**Dokumentvorlage, Version vom 21.02.2019**

# Dossier zur Nutzenbewertung gemäß § 35a SGB V

*Cabozantinib-L-malat (Cabometyx®)*

Ipsen Pharma GmbH

**Modul 4 D Anhang 4I2**

*Behandlung des fortgeschrittenen Nierenzellkarzinoms bei nicht vorbehandelten Erwachsenen in Kombination mit Nivolumab*

Medizinischer Nutzen und
medizinischer Zusatznutzen,
Patientengruppen mit therapeutisch
bedeutsamem Zusatznutzen

Stand: 23.04.2021

**Statistische Outputs der CheckMate 9ER Studie für die Subpopulation D1 zum Datenschnitt vom 10.09.2020**

TABLE 2.1.1: Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Overall Survival (months) | | | |
| Total number of subjects | N | 74 | 72 |
| Number of subjects with events | N | 15 (20.3%) | 15 (20.8%) |
| Number of censored cases | N | 59 (79.7%) | 57 (79.2%) |
| Time to first event (Months) | Mean (SE) | 21.66 (0.62) | 25.01 (0.88) |
| | Q1 [95% CI] | 23.80 [19.91;NYR] | 28.40 [18.66;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [28.35;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.9280 | |
| Stratified Cox PH model | HR (b) | 0.97 [0.47;1.98] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 2.1.2: Overall Survival (months) - by subgroups - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 15 (20.3%) | NYR [NYR;NYR] | 72 | 15 (20.8%) | NYR [28.35;NYR] | 0.97 [0.47;1.98] | 0.9280 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 4 (9.8%) | NYR [NYR;NYR] | 48 | 10 (20.8%) | NYR [NYR;NYR] | 0.39 [0.12;1.25] | 0.0996 | 0.0622 |
| >= 65 | 33 | 11 (33.3%) | NYR [19.91;NYR] | 24 | 5 (20.8%) | 28.35 [28.35;NYR] | 1.75 [0.61;5.03] | 0.2960 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 4 (9.8%) | NYR [NYR;NYR] | 48 | 10 (20.8%) | NYR [NYR;NYR] | 0.39 [0.12;1.25] | 0.0996 | 0.1582 |
| >= 65 AND < 75 | 25 | 8 (32.0%) | NYR [14.29;NYR] | 18 | 3 (16.7%) | NYR [NYR;NYR] | 2.15 [0.57;8.11] | 0.2467 | |
| >= 75 | 8 | 3 (37.5%) | NYR [13.08;NYR] | 6 | 2 (33.3%) | 28.35 [6.18;28.35] | 2.06 [0.21;19.87] | 0.5213 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 8 (20.5%) | NYR [NYR;NYR] | 37 | 6 (16.2%) | NYR [NYR;NYR] | 1.19 [0.41;3.45] | 0.7423 | 0.5185 |
| Rest of World (ROW) | 35 | 7 (20.0%) | NYR [NYR;NYR] | 35 | 9 (25.7%) | 28.35 [22.60;NYR] | 0.76 [0.28;2.04] | 0.5852 | |

a: Number of patients in the Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 2.1.2: Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 15 (23.1%) | NYR [NYR;NYR] | 61 | 13 (21.3%) | NYR [28.35;NYR] | 1.06 [0.50;2.23] | 0.8757 | 0.9910 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 2 (18.2%) | NYR [13.60;NYR] | <0.01 [<0.01;NE] | 0.1900 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 2 (28.6%) | NYR [5.49;NYR] | 13 | 5 (38.5%) | NYR [9.43;NYR] | 0.79 [0.15;4.08] | 0.7749 | 0.9802 |
| Not Hispanic or Latino | 43 | 10 (23.3%) | NYR [23.82;NYR] | 32 | 7 (21.9%) | 28.35 [NYR;NYR] | 0.98 [0.37;2.59] | 0.9719 | |
| Not Reported | 24 | 3 (12.5%) | NYR [NYR;NYR] | 27 | 3 (11.1%) | NYR [22.60;NYR] | 0.99 [0.20;4.91] | 0.9903 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 11 (19.6%) | NYR [NYR;NYR] | 49 | 9 (18.4%) | NYR [28.35;NYR] | 1.03 [0.43;2.50] | 0.9403 | 0.7588 |
| Female | 18 | 4 (22.2%) | NYR [19.91;NYR] | 23 | 6 (26.1%) | NYR [18.66;NYR] | 0.85 [0.24;3.01] | 0.8005 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 5 (35.7%) | NYR [13.08;NYR] | 19 | 6 (31.6%) | NYR [20.90;NYR] | 1.05 [0.32;3.44] | 0.9398 | 0.9820 |
| >= 1 Year | 60 | 10 (16.7%) | NYR [NYR;NYR] | 51 | 9 (17.6%) | NYR [28.35;NYR] | 0.95 [0.38;2.33] | 0.9042 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 2.1.2: Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 3 (27.3%) | NYR [22.28;NYR] | 13 | 4 (30.8%) | NYR [20.90;NYR] | 0.66 [0.15;2.98] | 0.5844 | 0.7645 |
| Yes | 63 | 12 (19.0%) | NYR [NYR;NYR] | 59 | 11 (18.6%) | NYR [28.35;NYR] | 1.01 [0.44;2.28] | 0.9902 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 12 (18.8%) | NYR [NYR;NYR] | 66 | 15 (22.7%) | NYR [28.35;NYR] | 0.78 [0.36;1.66] | 0.5115 | 0.9882 |
| Yes | 10 | 3 (30.0%) | NYR [4.37;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1559 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [NYR;NYR] | 10 | 3 (30.0%) | NYR [3.15;NYR] | 0.28 [0.03;2.67] | 0.2347 | 0.4985 |
| < 1% | 61 | 12 (19.7%) | NYR [NYR;NYR] | 61 | 12 (19.7%) | NYR [28.35;NYR] | 1.01 [0.45;2.25] | 0.9756 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 5 (27.8%) | NYR [22.28;NYR] | 21 | 6 (28.6%) | NYR [20.90;NYR] | 0.85 [0.26;2.81] | 0.7927 | 0.7069 |
| Non-Stage IV | 53 | 10 (18.9%) | NYR [NYR;NYR] | 51 | 9 (17.6%) | NYR [28.35;NYR] | 1.09 [0.44;2.67] | 0.8571 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 2.2.1: Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Progression Free Survival (BICR) Primary (months) | | | |
| Total number of subjects | N | 74 | 72 |
| Number of subjects with events | N | 31 (41.9%) | 37 (51.4%) |
| Number of censored cases | N | 43 (58.1%) | 35 (48.6%) |
| Time to first event (Months) | Mean (SE) | 17.90 (0.98) | 13.82 (0.99) |
| | Q1 [95% CI] | 11.00 [7.36;12.75] | 7.00 [5.49;9.43] |
| | Median [95% CI] | 24.71 [13.08;NYR] | 12.81 [9.56;18.46] |
| | Q3 [95% CI] | NYR [24.71;NYR] | 22.60 [18.46;NYR] |
| | p-value (a) | 0.0441 | |
| Stratified Cox PH model | HR (b) | 0.61 [0.38;0.99] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 2.2.2: Progression Free Survival (BICR) Primary (months) - by subgroups - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 31 (41.9%) | 24.71 [13.08;NYR] | 72 | 37 (51.4%) | 12.81 [9.56;18.46] | 0.61 [0.38;0.99] | 0.0441 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 15 (36.6%) | NYR [13.60;NYR] | 48 | 28 (58.3%) | 12.48 [8.28;16.26] | 0.38 [0.20;0.71] | 0.0018 | 0.0622 |
| >= 65 | 33 | 16 (48.5%) | 13.34 [11.10;NYR] | 24 | 9 (37.5%) | NYR [6.18;NYR] | 1.07 [0.47;2.42] | 0.8744 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 15 (36.6%) | NYR [13.60;NYR] | 48 | 28 (58.3%) | 12.48 [8.28;16.26] | 0.38 [0.20;0.71] | 0.0018 | 0.0836 |
| >= 65 AND < 75 | 25 | 12 (48.0%) | 13.34 [8.71;NYR] | 18 | 6 (33.3%) | NYR [6.93;NYR] | 1.33 [0.50;3.55] | 0.5648 | |
| >= 75 | 8 | 4 (50.0%) | 24.71 [2.04;24.71] | 6 | 3 (50.0%) | 8.69 [5.82;11.20] | 0.25 [0.04;1.61] | 0.1204 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 16 (41.0%) | 24.71 [12.78;NYR] | 37 | 19 (51.4%) | 12.81 [8.28;NYR] | 0.56 [0.29;1.10] | 0.0854 | 0.9459 |
| Rest of World (ROW) | 35 | 15 (42.9%) | 22.14 [11.10;NYR] | 35 | 18 (51.4%) | 12.48 [6.93;NYR] | 0.62 [0.31;1.22] | 0.1660 | |

a: Number of patients in the Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 2.2.2: Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 29 (44.6%) | 22.14 [12.75;NYR] | 61 | 32 (52.5%) | 12.48 [9.56;18.46] | 0.62 [0.37;1.02] | 0.0573 | 0.3805 |
| Non-White | 9 | 2 (22.2%) | NYR [11.10;NYR] | 11 | 5 (45.5%) | 16.26 [5.49;NYR] | 0.30 [0.06;1.56] | 0.1287 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 5 (71.4%) | 11.53 [2.83;NYR] | 13 | 8 (61.5%) | 7.85 [4.47;NYR] | 0.85 [0.28;2.61] | 0.7720 | 0.6544 |
| Not Hispanic or Latino | 43 | 17 (39.5%) | 22.14 [12.78;NYR] | 32 | 17 (53.1%) | 10.87 [8.28;18.46] | 0.50 [0.26;1.00] | 0.0444 | |
| Not Reported | 24 | 9 (37.5%) | 24.71 [12.45;NYR] | 27 | 12 (44.4%) | 16.10 [11.20;NYR] | 0.58 [0.24;1.40] | 0.2238 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 23 (41.1%) | 22.14 [13.08;NYR] | 49 | 24 (49.0%) | 13.86 [9.56;NYR] | 0.60 [0.34;1.06] | 0.0773 | 0.7820 |
| Female | 18 | 8 (44.4%) | NYR [6.93;NYR] | 23 | 13 (56.5%) | 11.20 [5.82;22.57] | 0.55 [0.22;1.33] | 0.1754 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 5 (35.7%) | NYR [8.71;NYR] | 19 | 13 (68.4%) | 12.48 [5.82;16.10] | 0.39 [0.14;1.10] | 0.0633 | 0.3144 |
| >= 1 Year | 60 | 26 (43.3%) | 22.14 [12.75;NYR] | 51 | 23 (45.1%) | 13.86 [9.43;NYR] | 0.68 [0.39;1.19] | 0.1732 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 2.2.2: Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 7 (63.6%) | 12.75 [6.77;NYR] | 13 | 7 (53.8%) | 12.81 [5.49;NYR] | 0.90 [0.31;2.57] | 0.8428 | 0.3539 |
| Yes | 63 | 24 (38.1%) | 24.71 [13.60;NYR] | 59 | 30 (50.8%) | 12.48 [8.31;22.57] | 0.53 [0.31;0.90] | 0.0173 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 24 (37.5%) | 24.71 [13.08;NYR] | 66 | 35 (53.0%) | 12.81 [9.43;18.46] | 0.50 [0.29;0.83] | 0.0070 | 0.2358 |
| Yes | 10 | 7 (70.0%) | 13.26 [2.04;NYR] | 6 | 2 (33.3%) | NYR [6.08;NYR] | 1.48 [0.29;7.58] | 0.6326 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 3 (27.3%) | NYR [11.53;NYR] | 10 | 7 (70.0%) | 13.86 [2.56;22.57] | 0.20 [0.05;0.78] | 0.0106 | 0.0465 |
| < 1% | 61 | 26 (42.6%) | 24.71 [12.75;NYR] | 61 | 29 (47.5%) | 12.48 [9.56;NYR] | 0.67 [0.40;1.14] | 0.1413 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 9 (50.0%) | 13.34 [7.36;NYR] | 21 | 14 (66.7%) | 12.48 [5.49;22.57] | 0.58 [0.25;1.35] | 0.1989 | 0.8386 |
| Non-Stage IV | 53 | 22 (41.5%) | 24.71 [13.08;NYR] | 51 | 23 (45.1%) | 13.86 [8.31;NYR] | 0.62 [0.35;1.12] | 0.1118 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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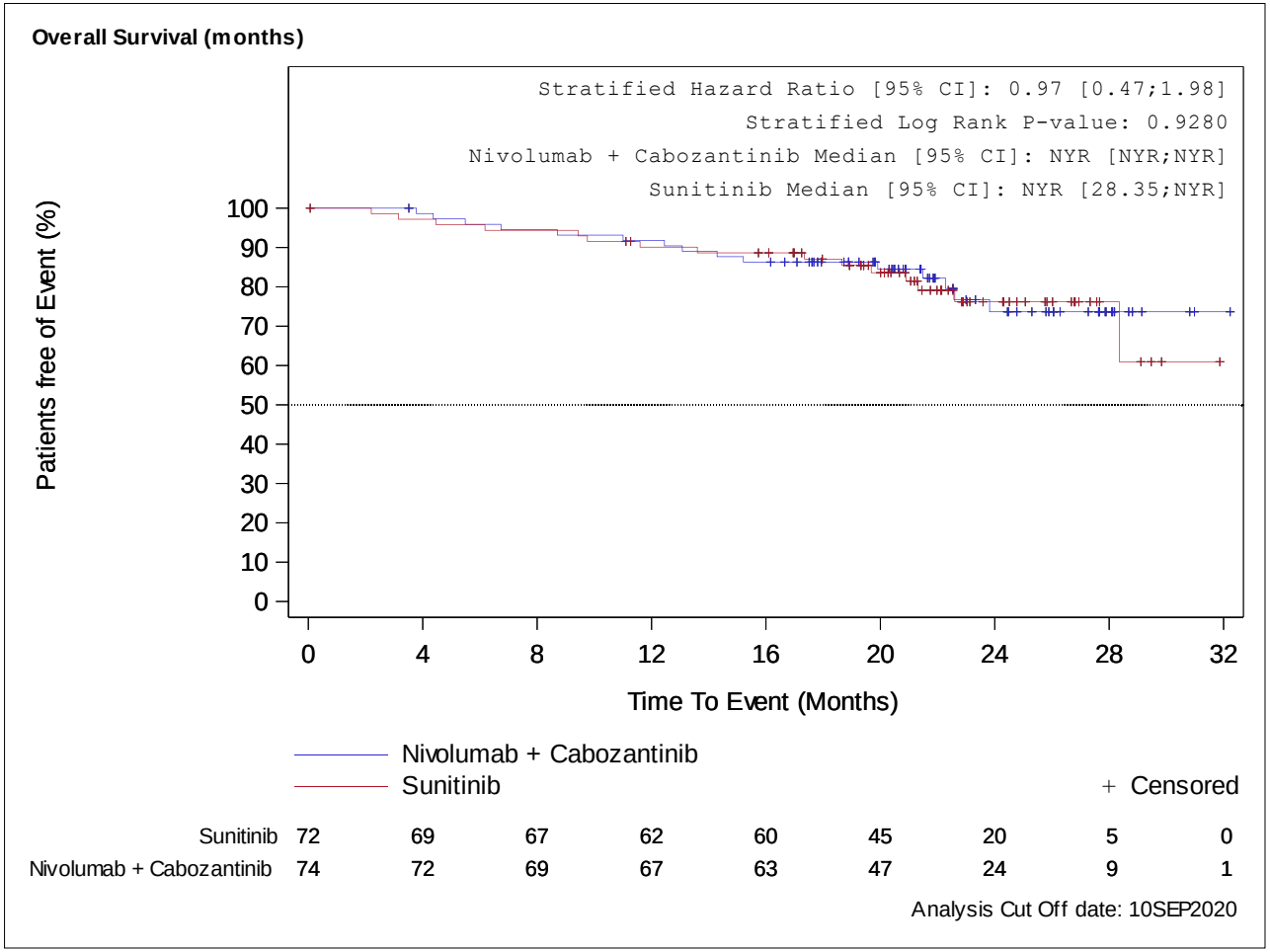
FIGURE 2.1.1: Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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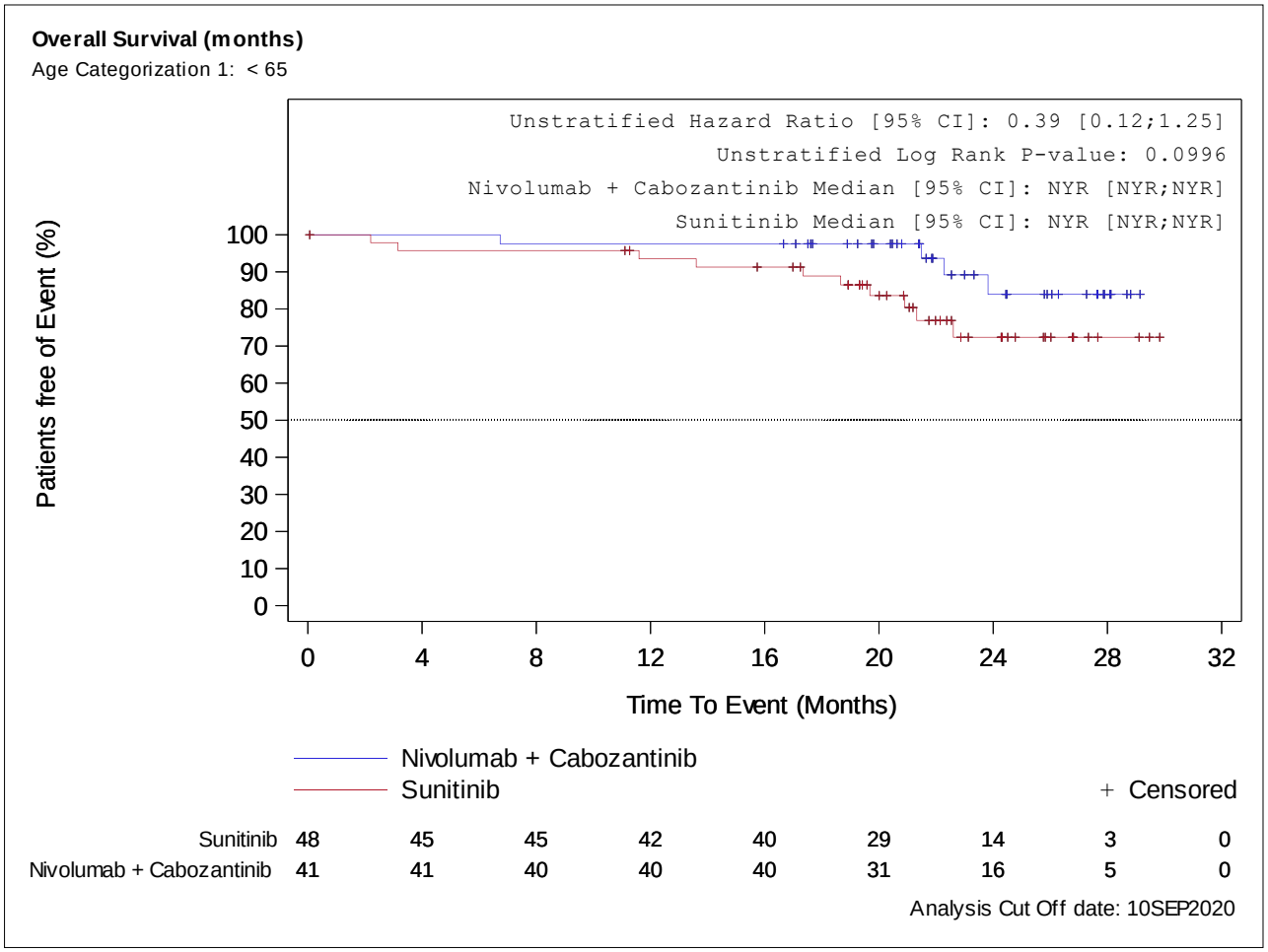
FIGURE 2.1.2.1: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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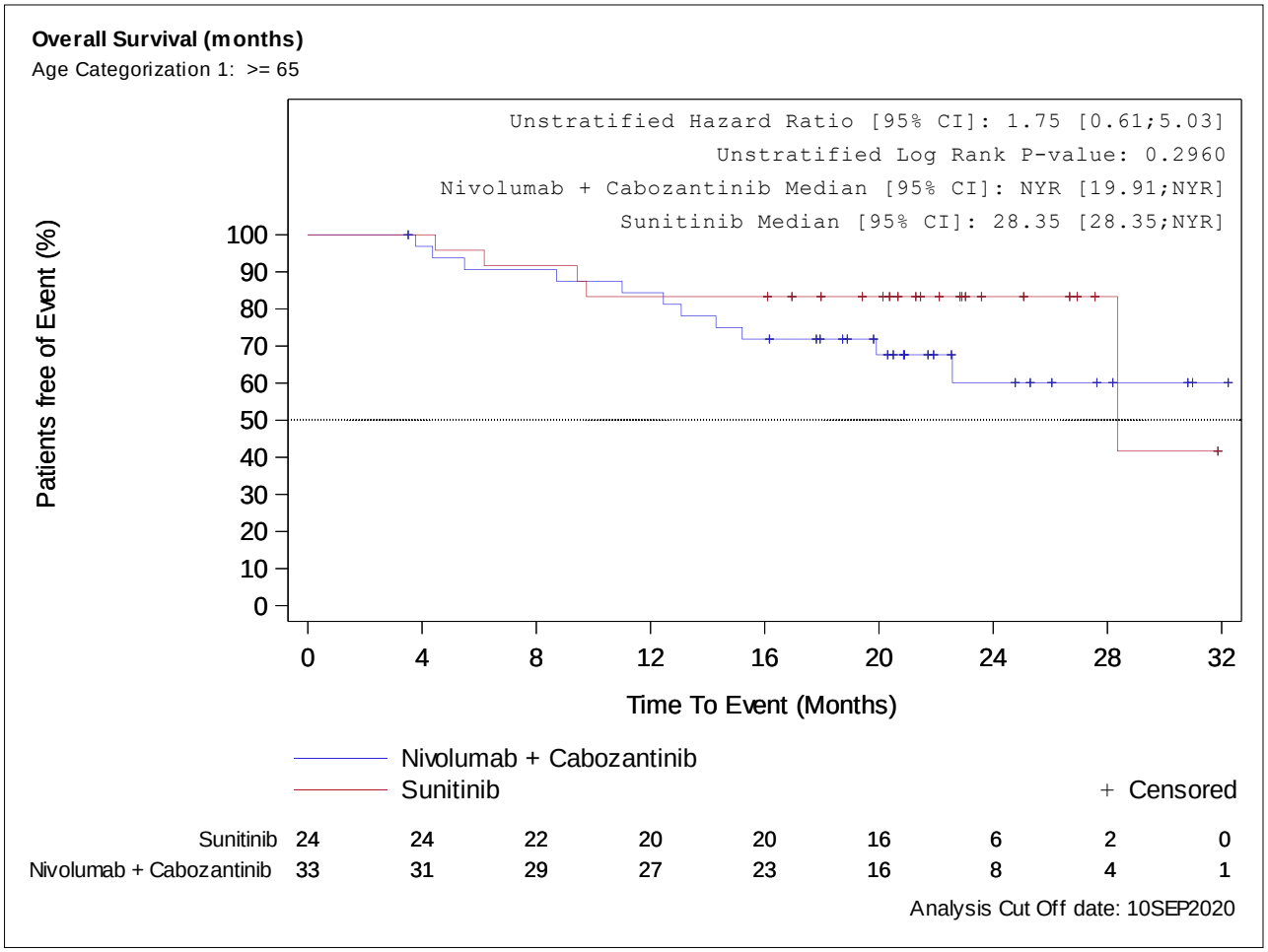
FIGURE 2.1.2.2: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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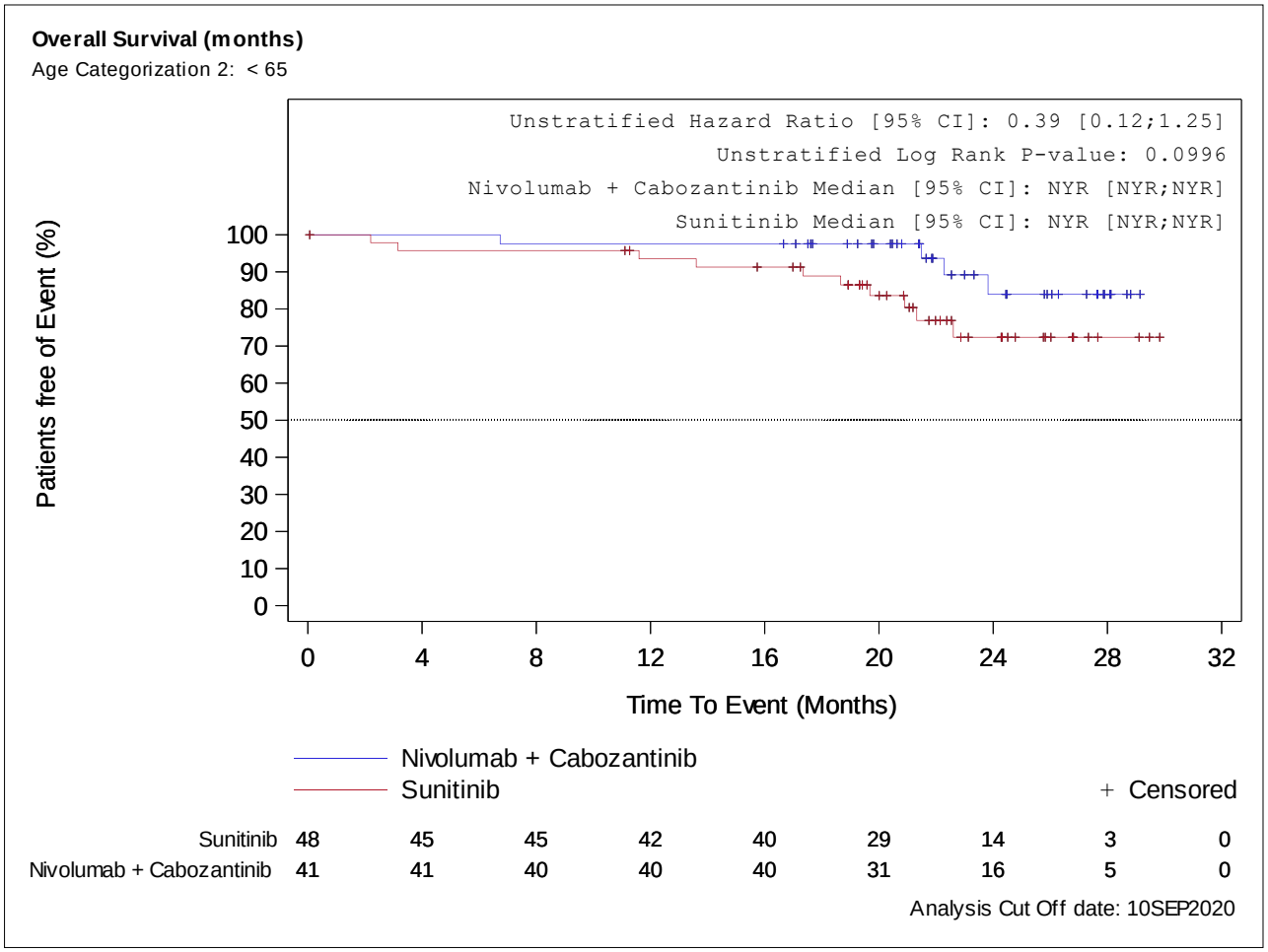
FIGURE 2.1.2.3: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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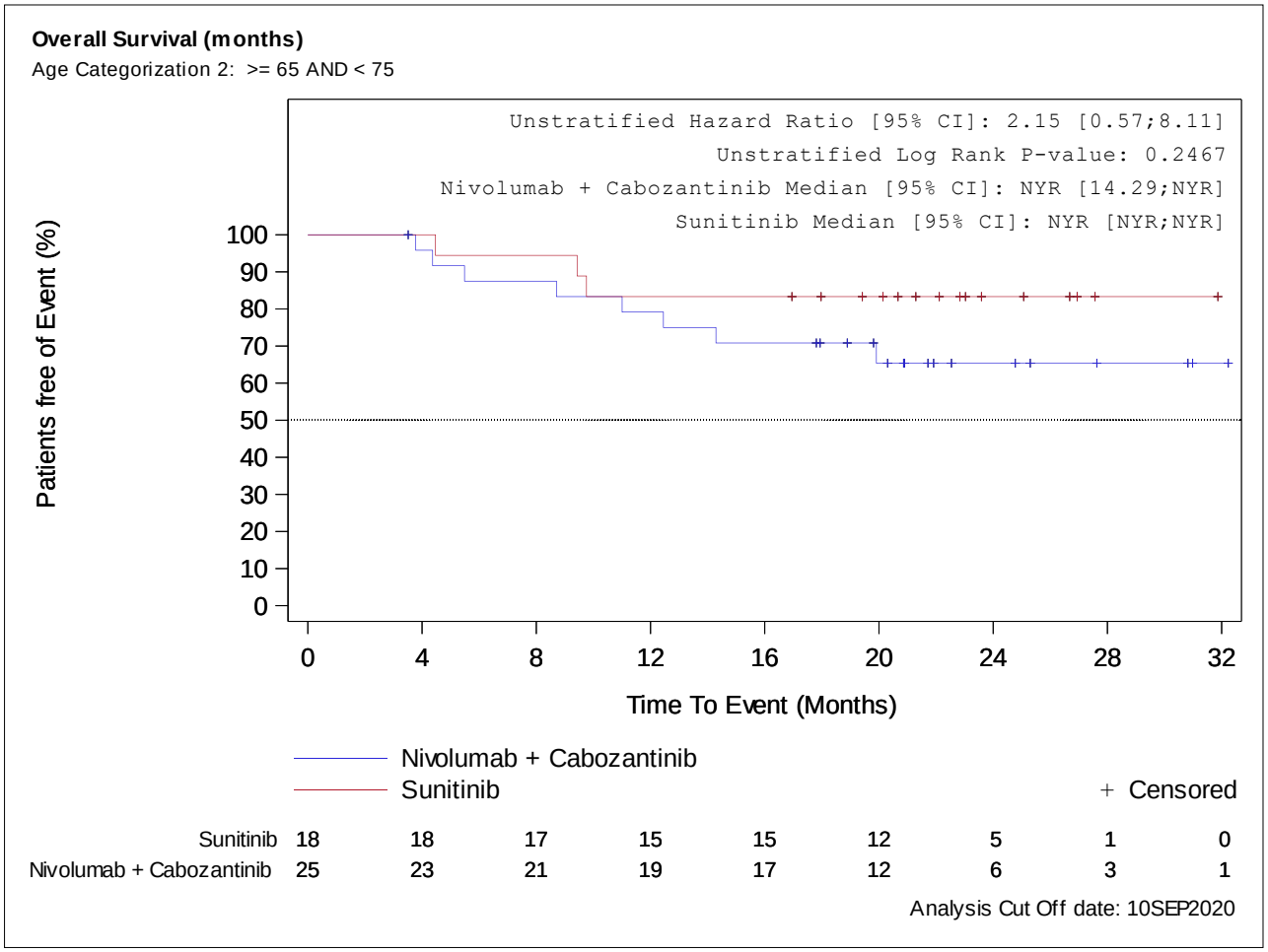
FIGURE 2.1.2.4: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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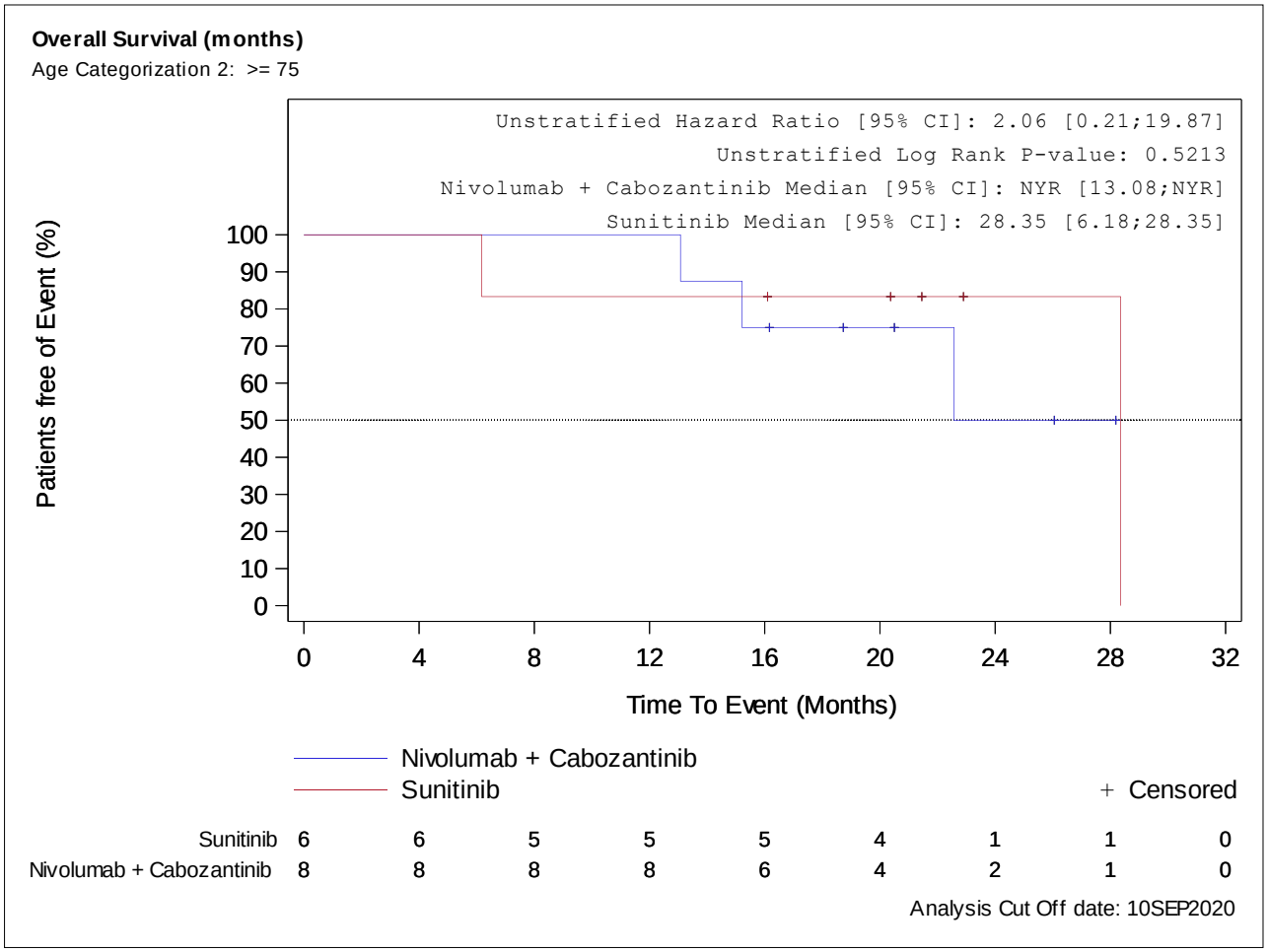
FIGURE 2.1.2.5: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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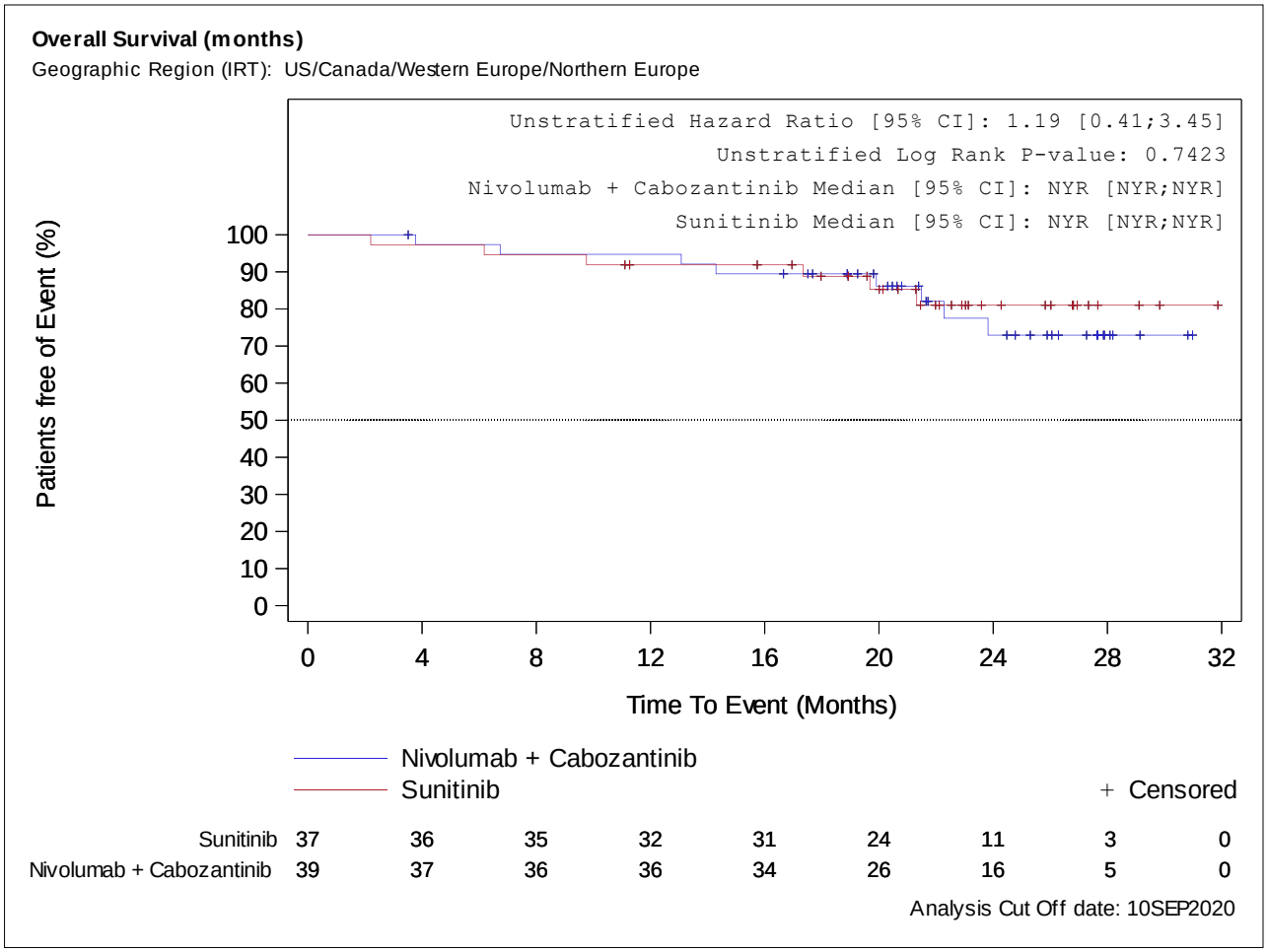
FIGURE 2.1.2.6: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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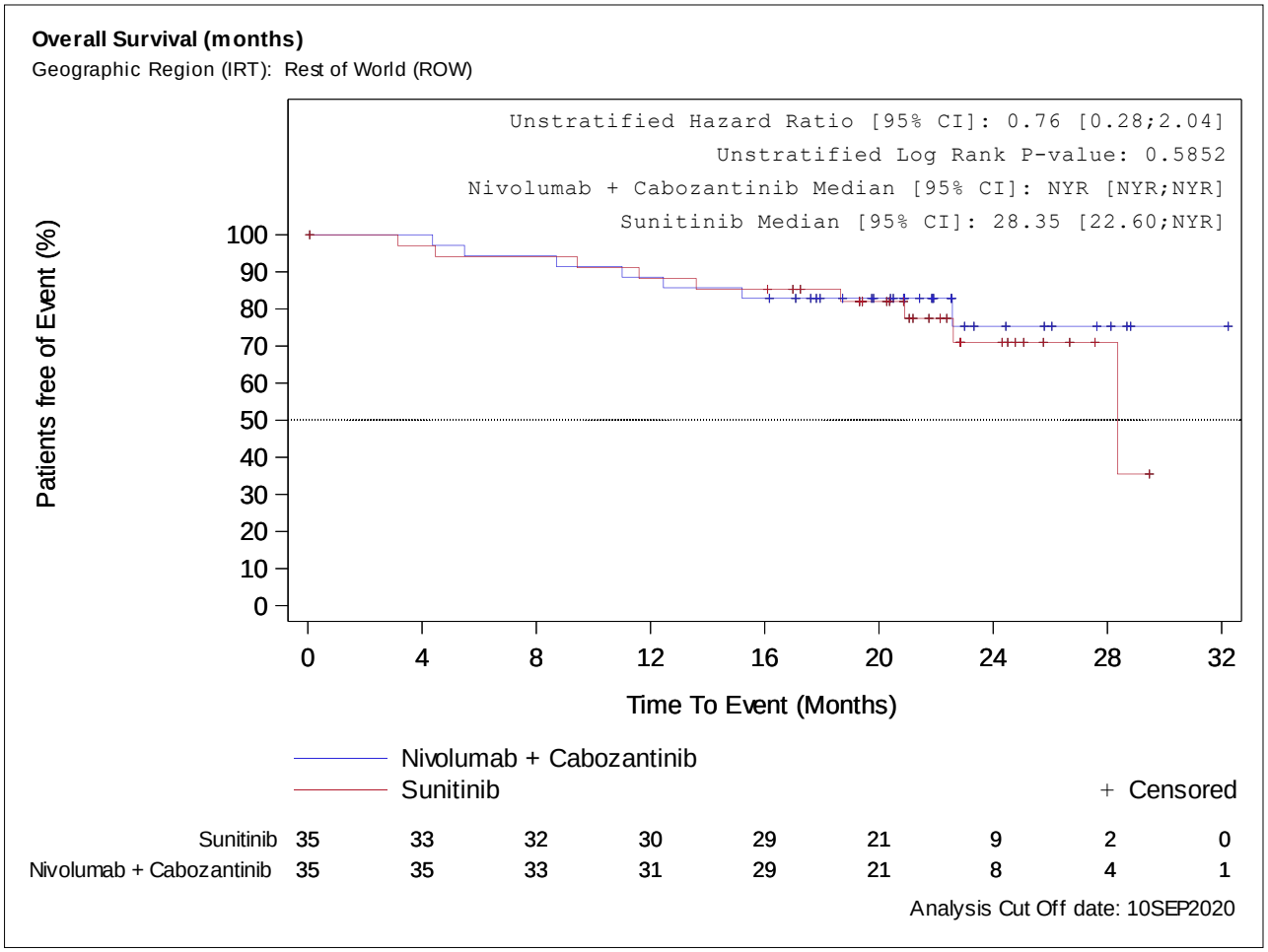
FIGURE 2.1.2.7: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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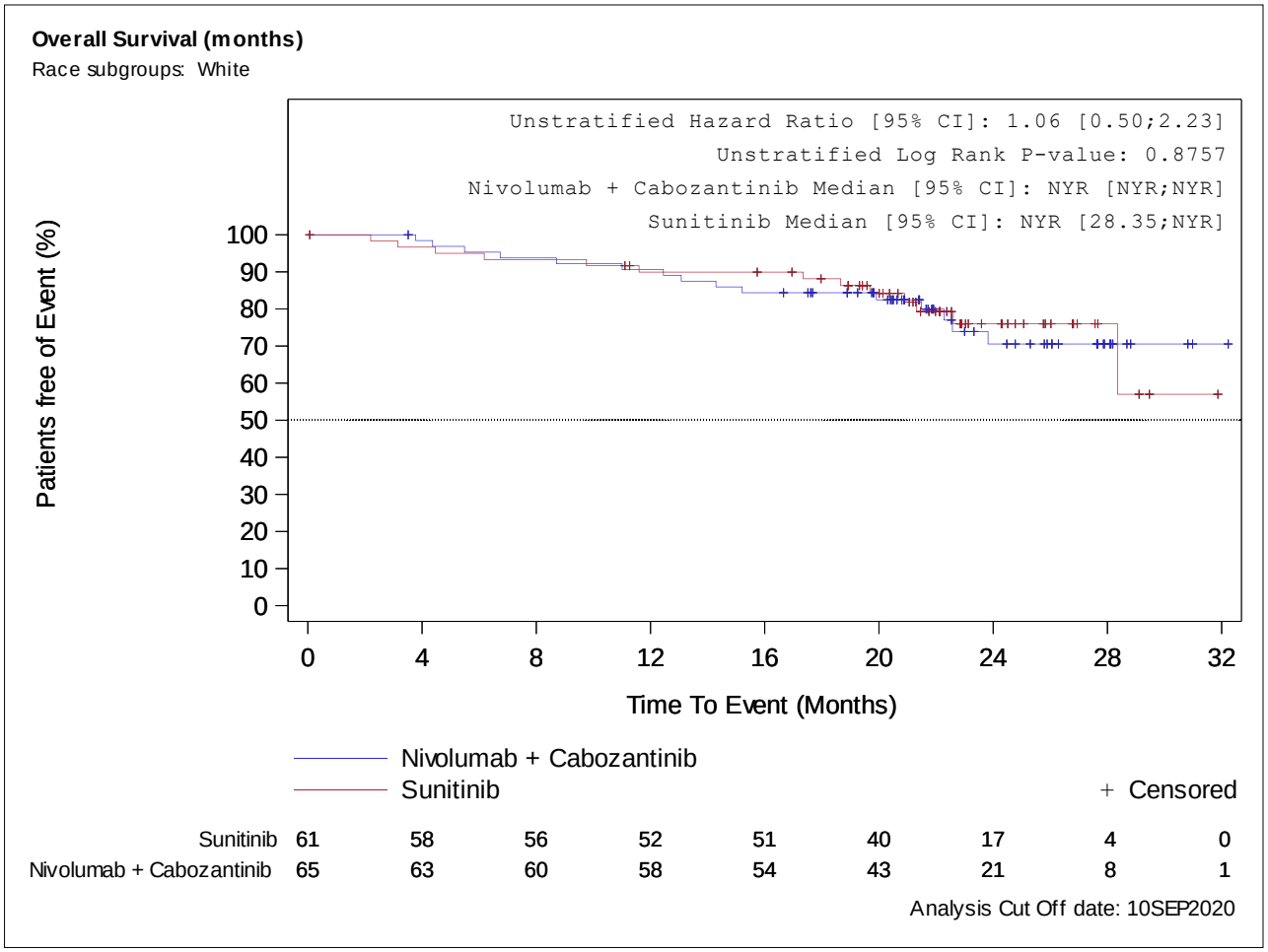
FIGURE 2.1.2.8: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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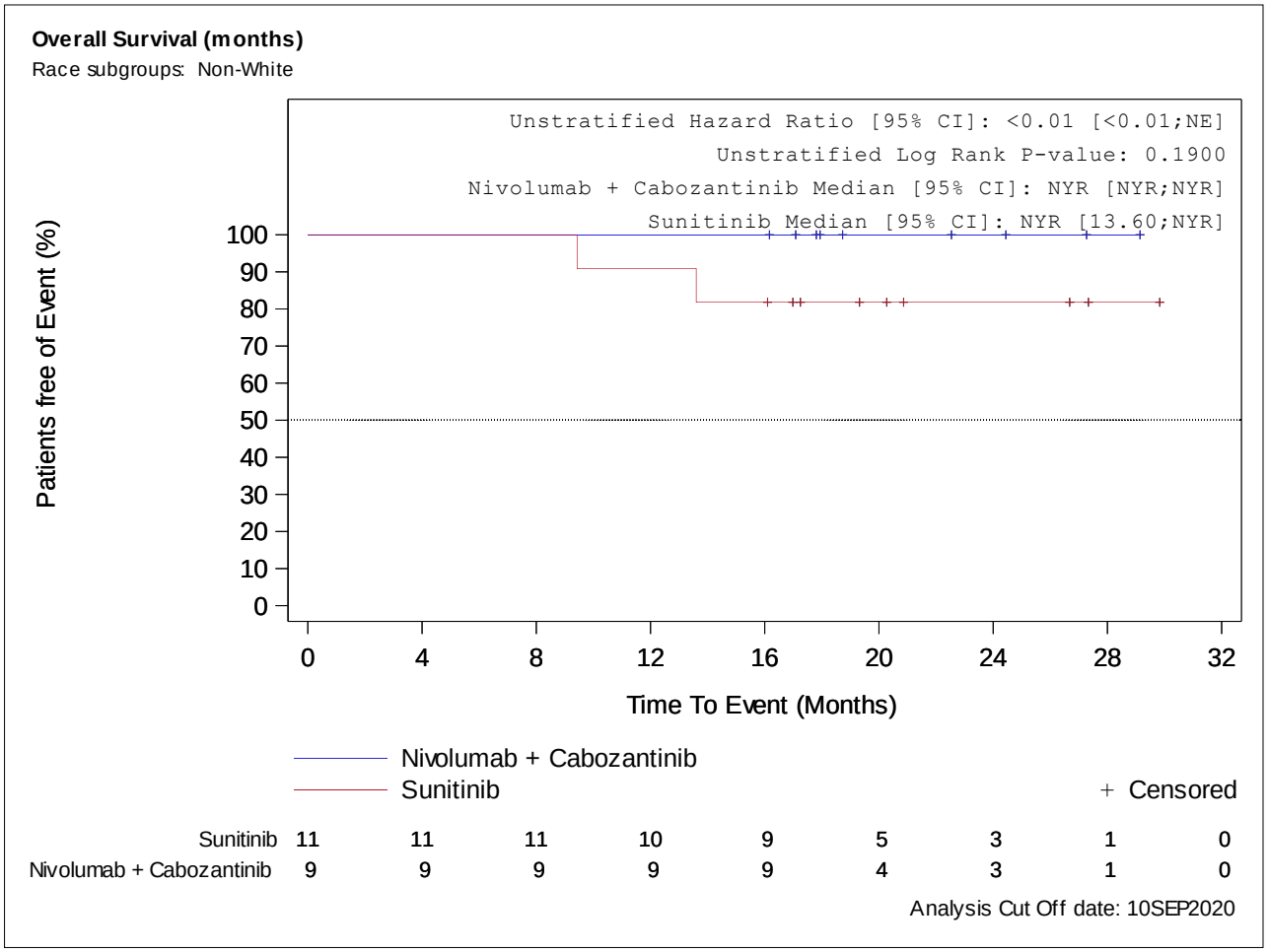
FIGURE 2.1.2.9: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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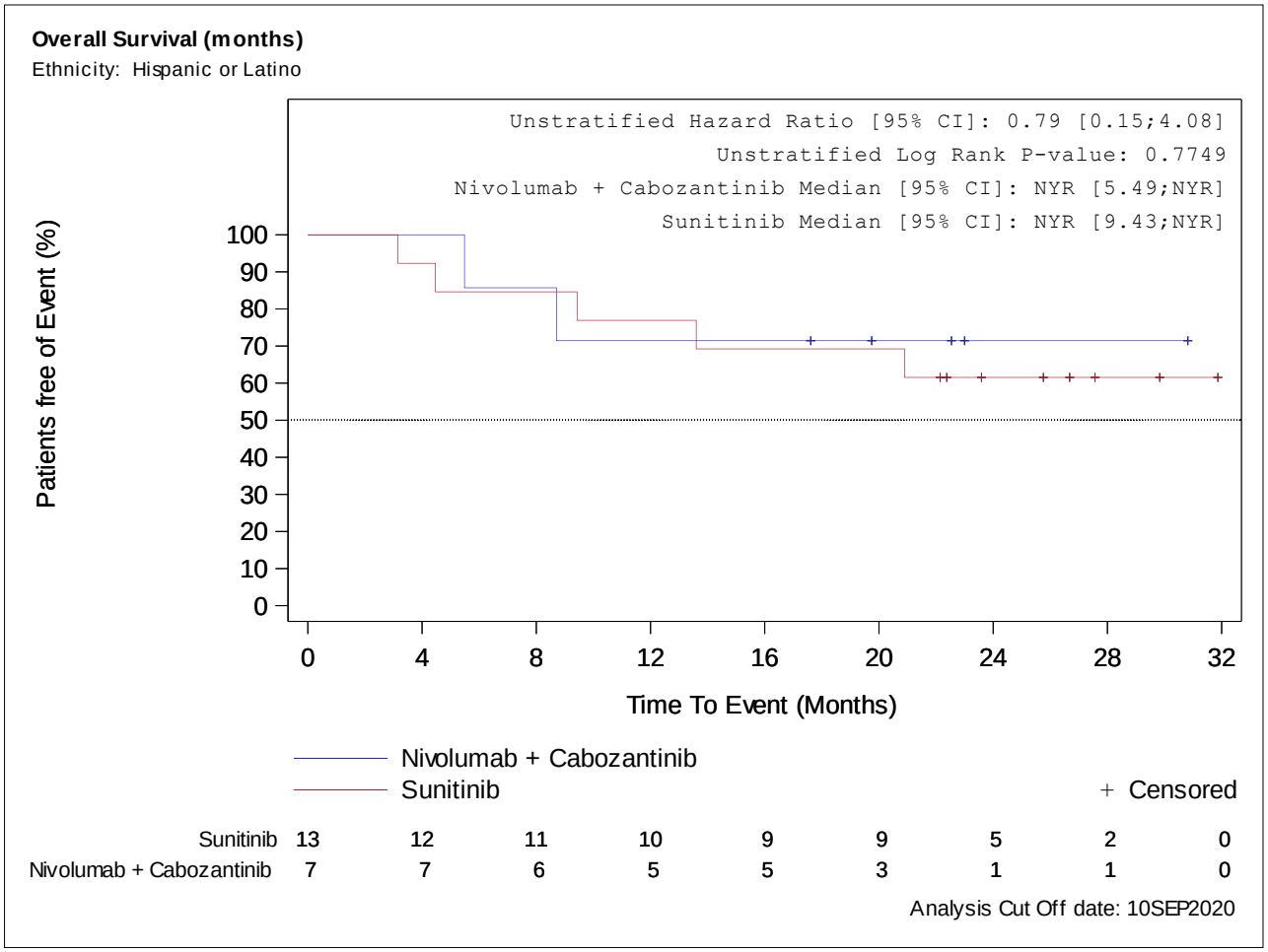
FIGURE 2.1.2.10: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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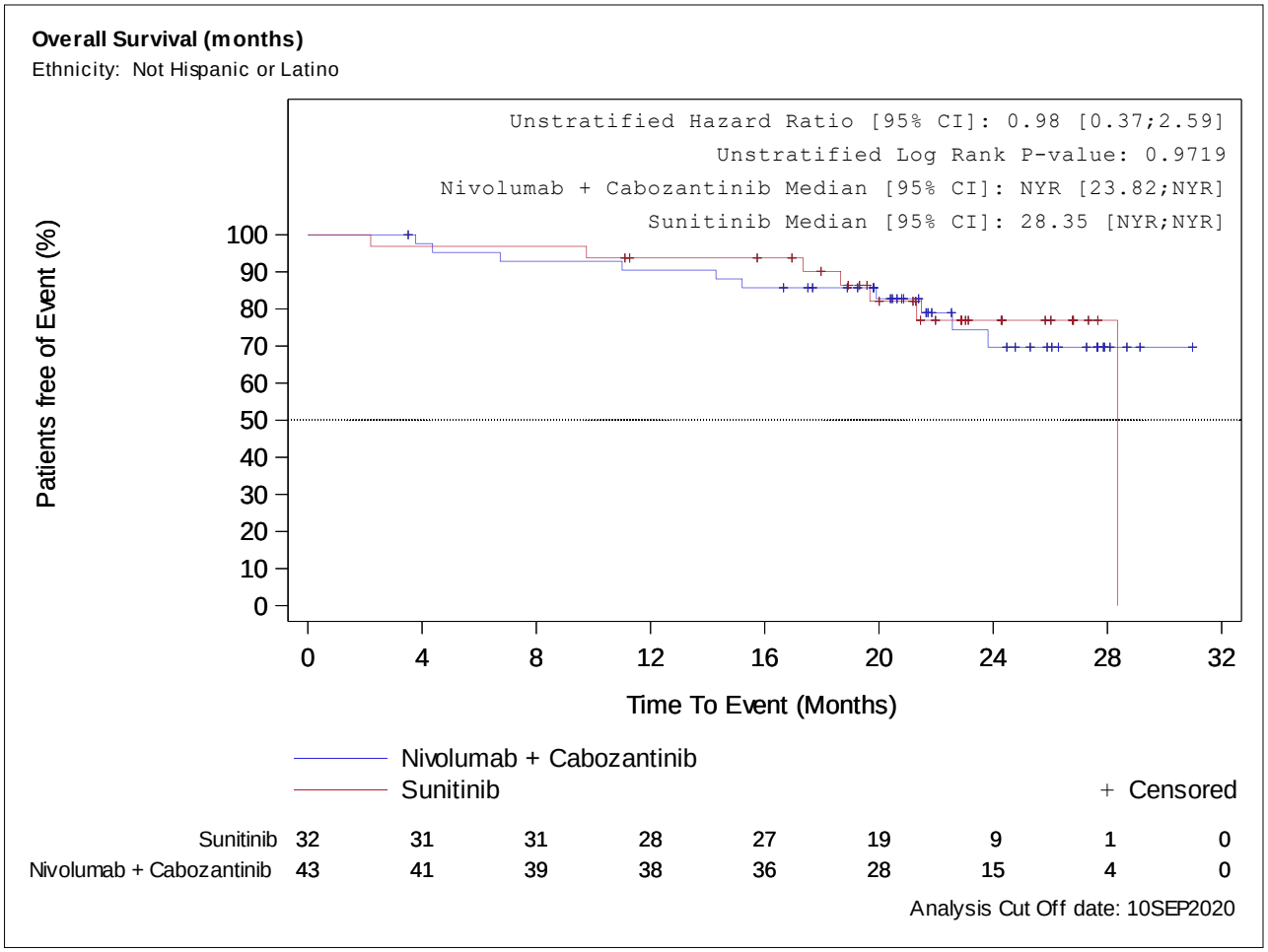
FIGURE 2.1.2.11: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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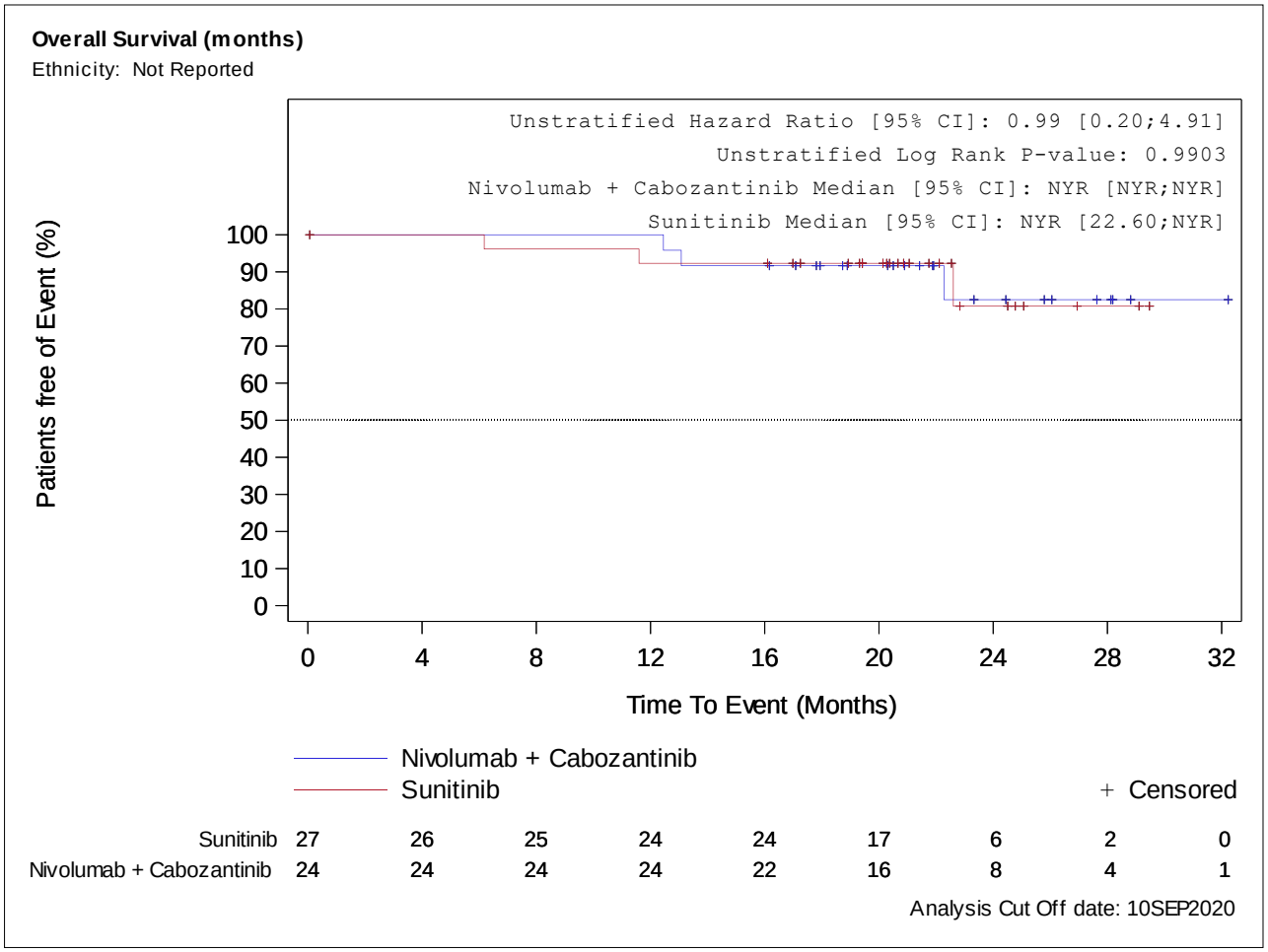
FIGURE 2.1.2.12: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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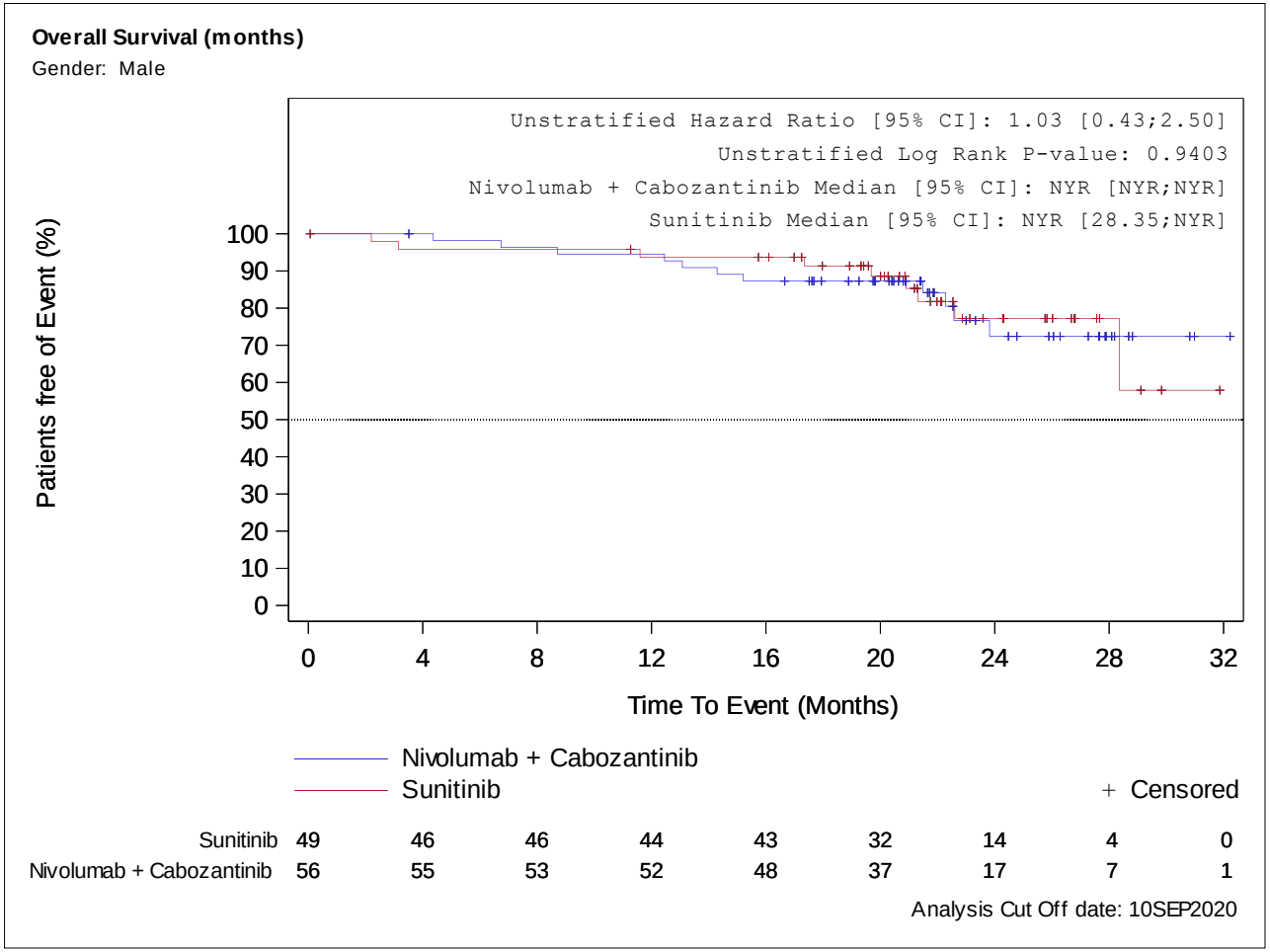
FIGURE 2.1.2.13: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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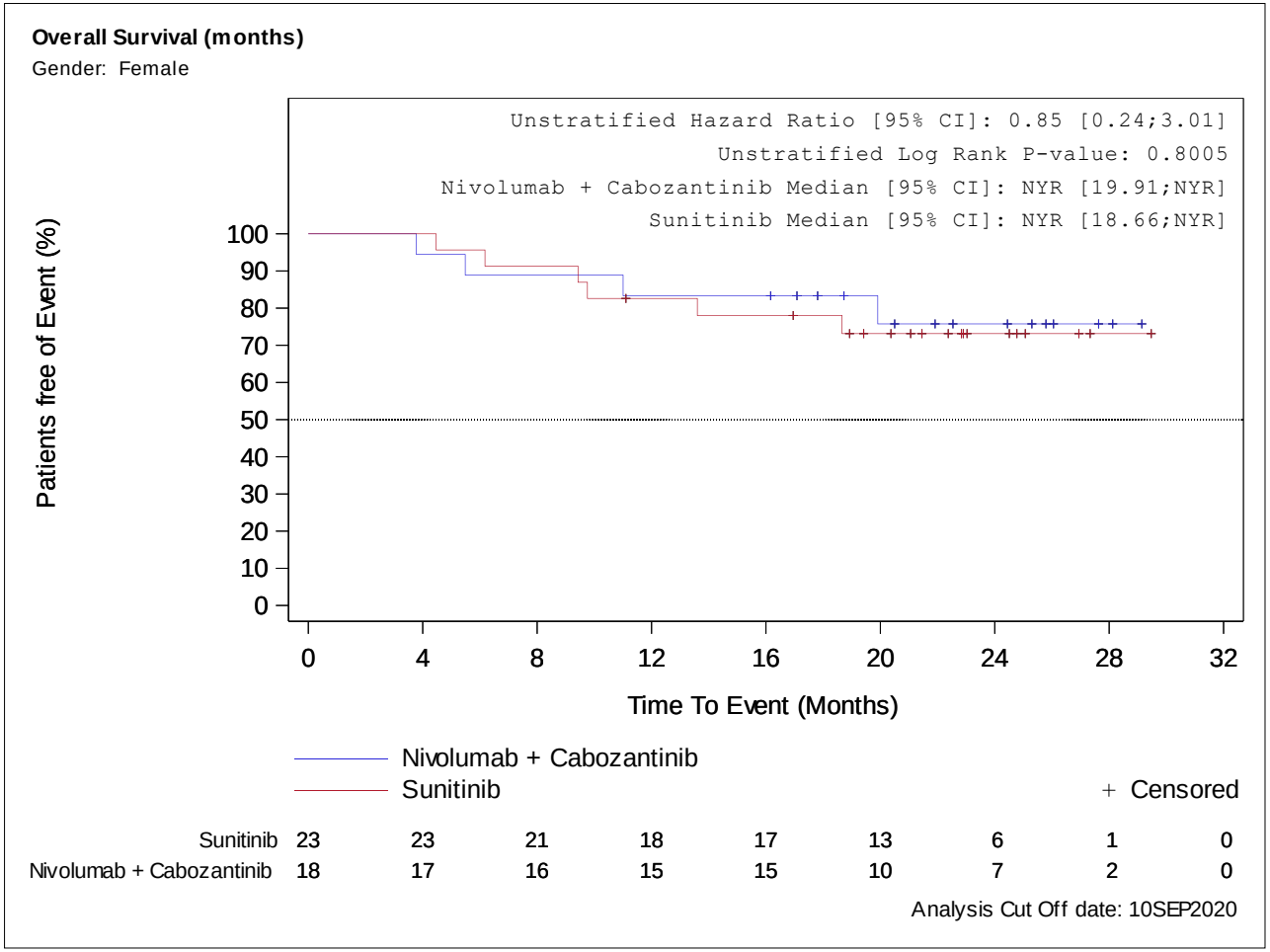
FIGURE 2.1.2.14: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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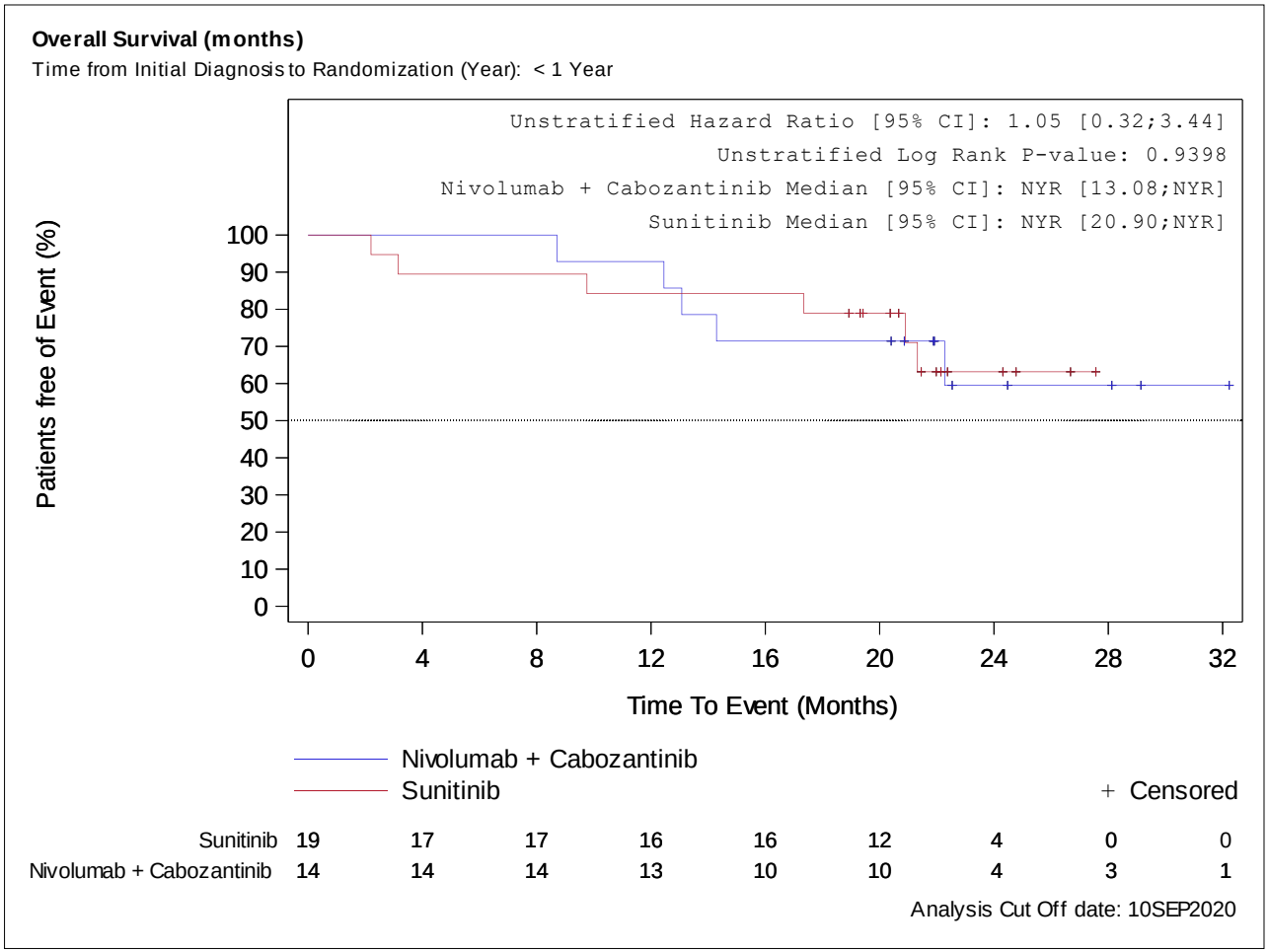
FIGURE 2.1.2.15: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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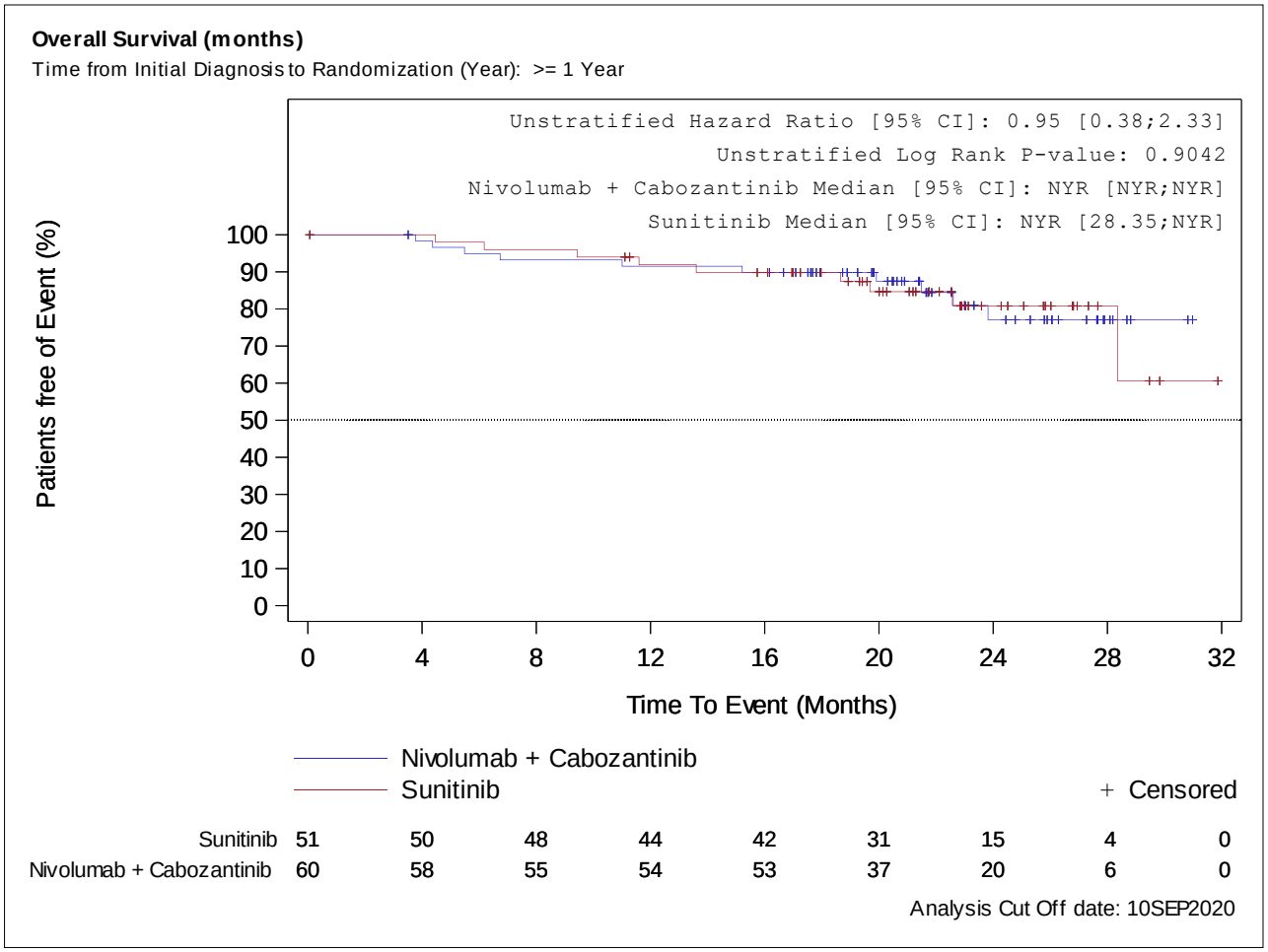
FIGURE 2.1.2.16: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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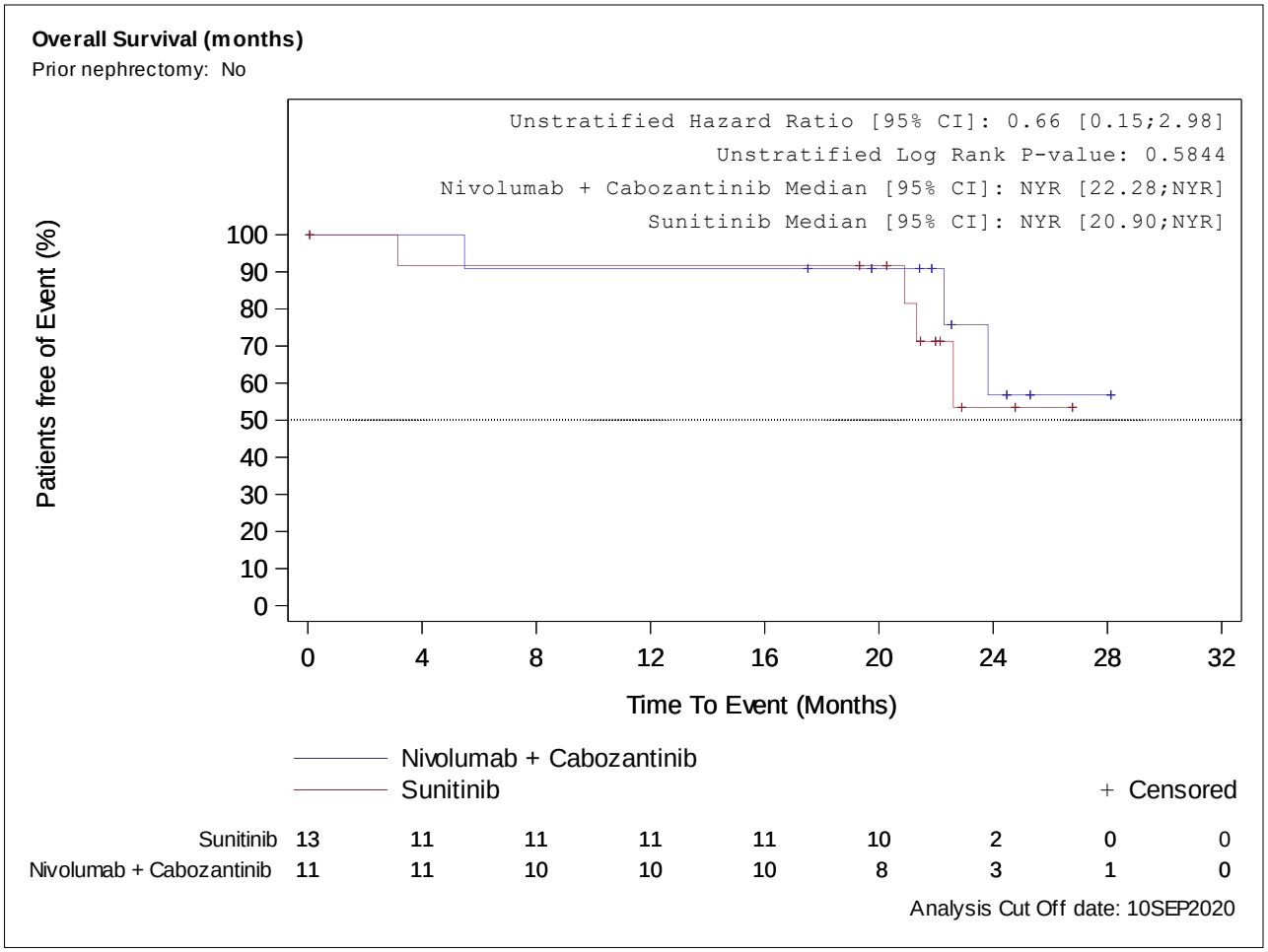
FIGURE 2.1.2.17: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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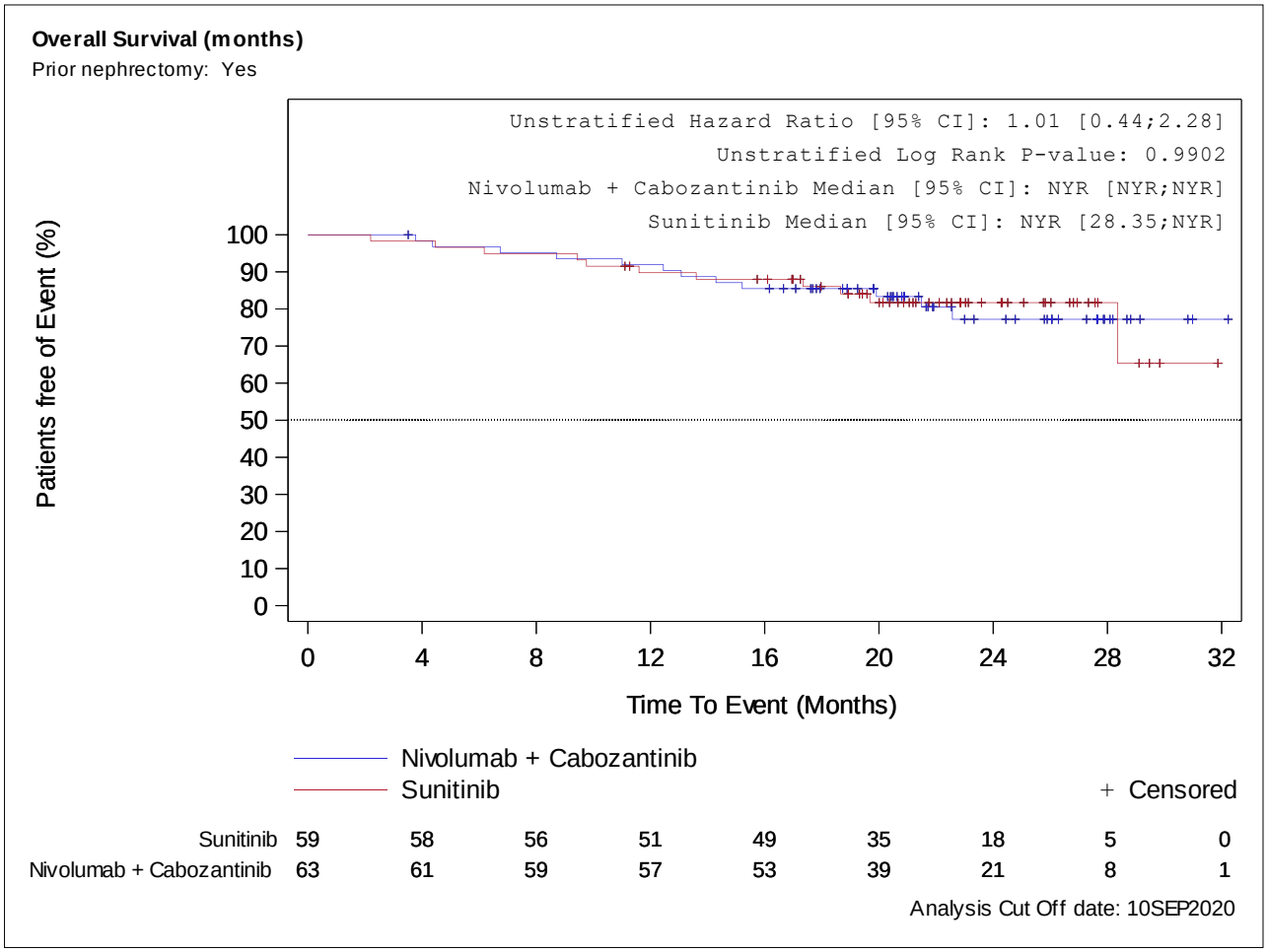
FIGURE 2.1.2.18: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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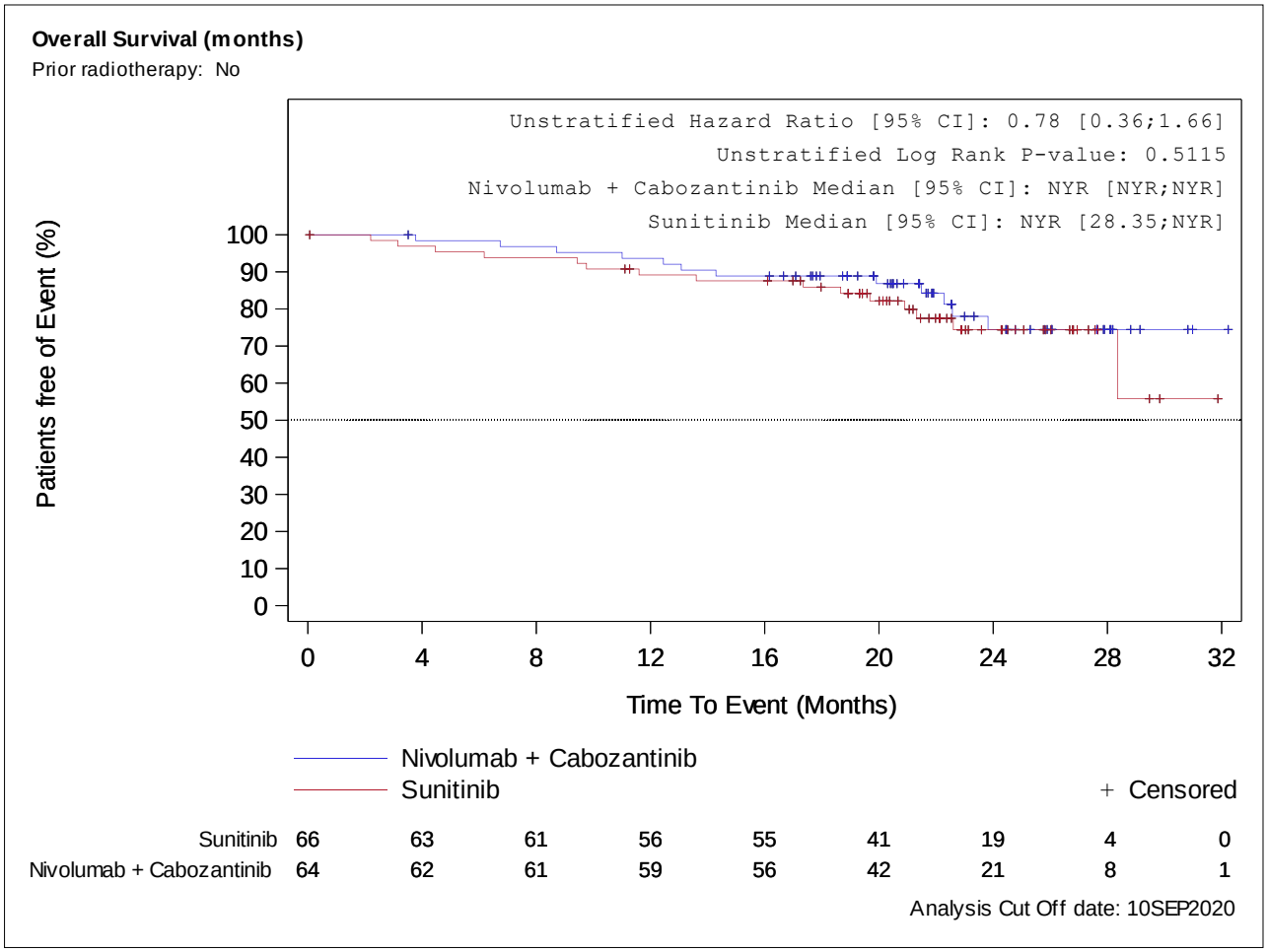
FIGURE 2.1.2.19: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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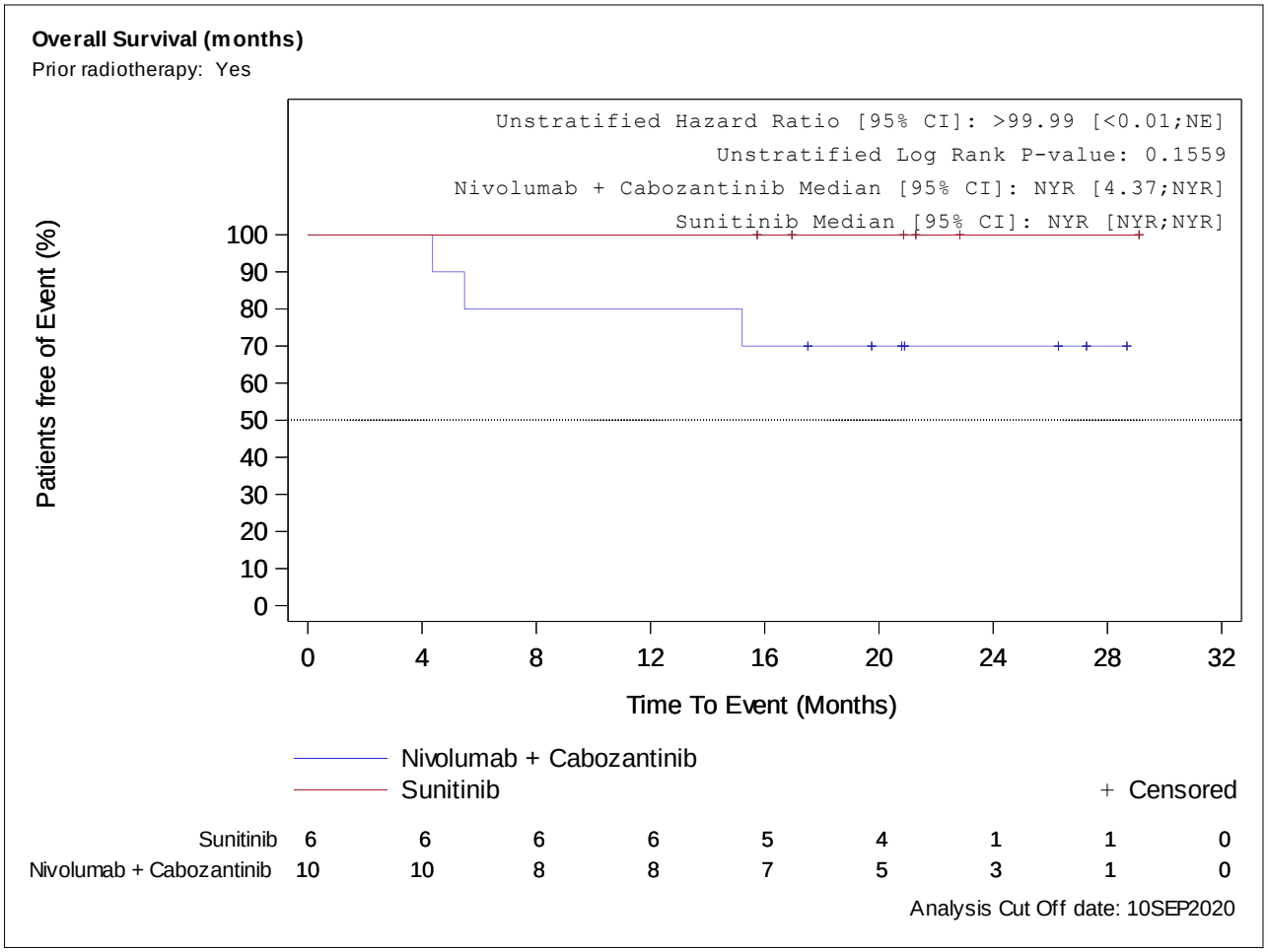
FIGURE 2.1.2.20: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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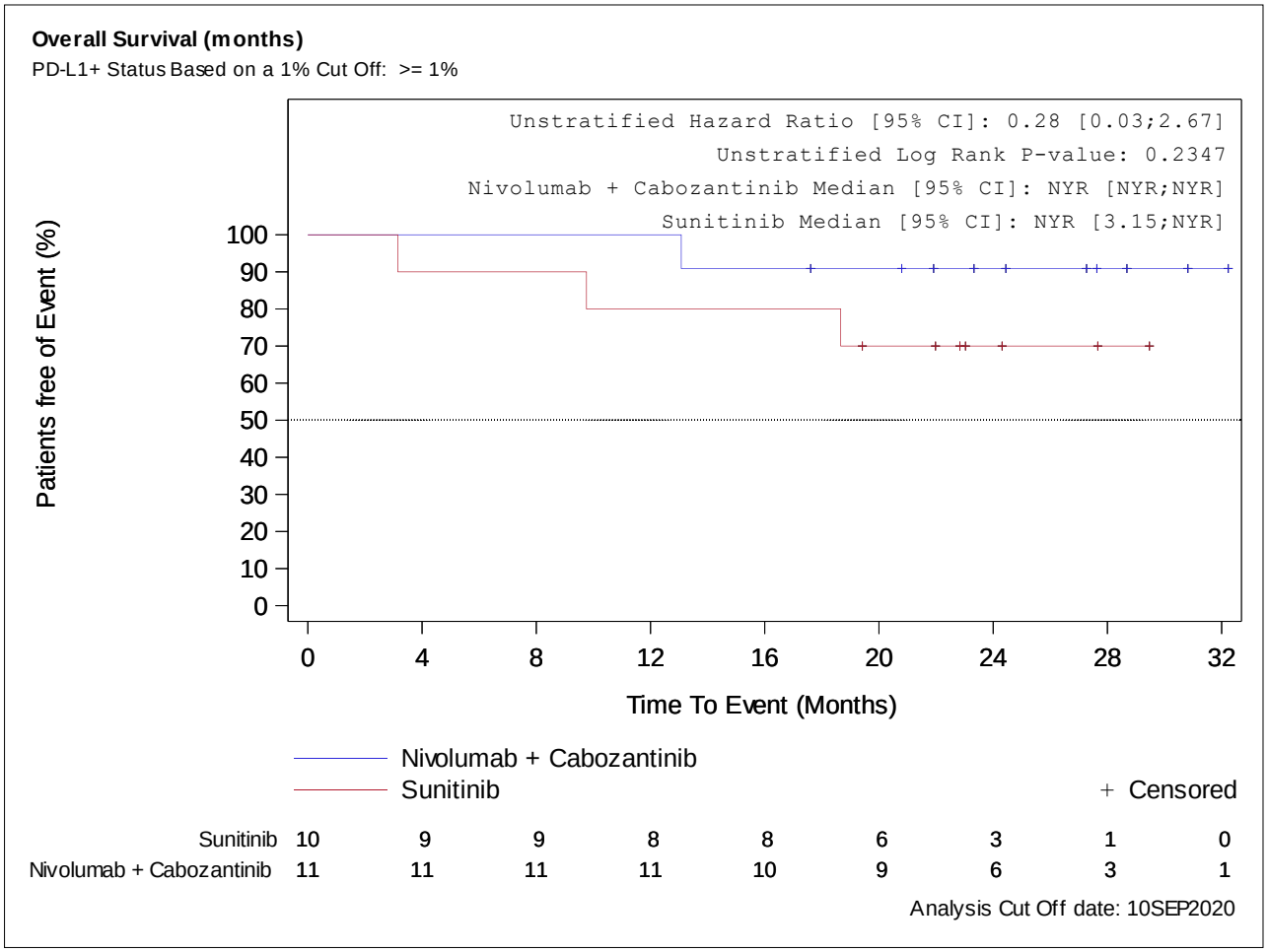
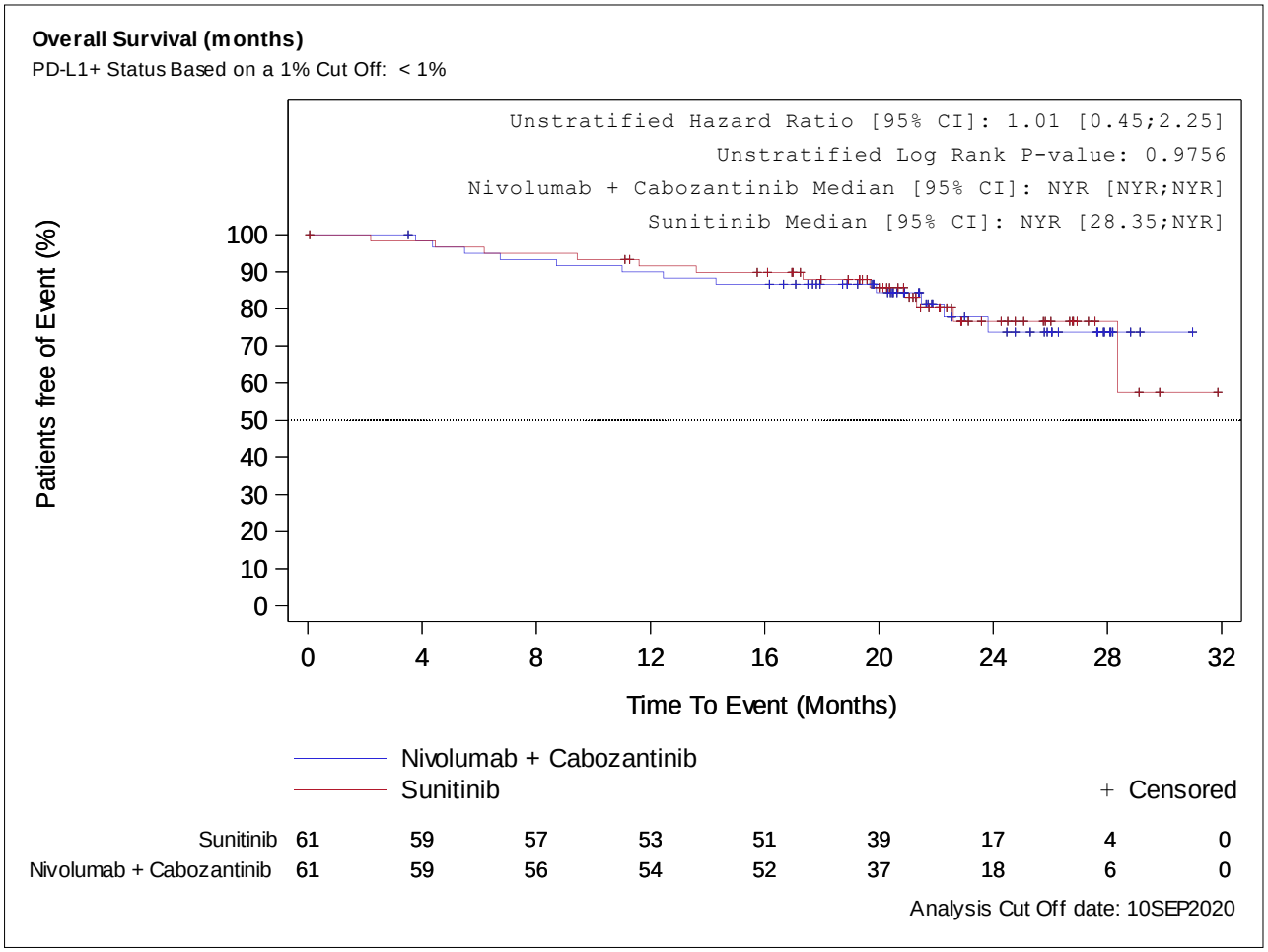
FIGURE 2.1.2.21: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.01 KM efficacy.sas] run Monday, March 22, 2021 at 12:48:18

FIGURE 2.1.2.22: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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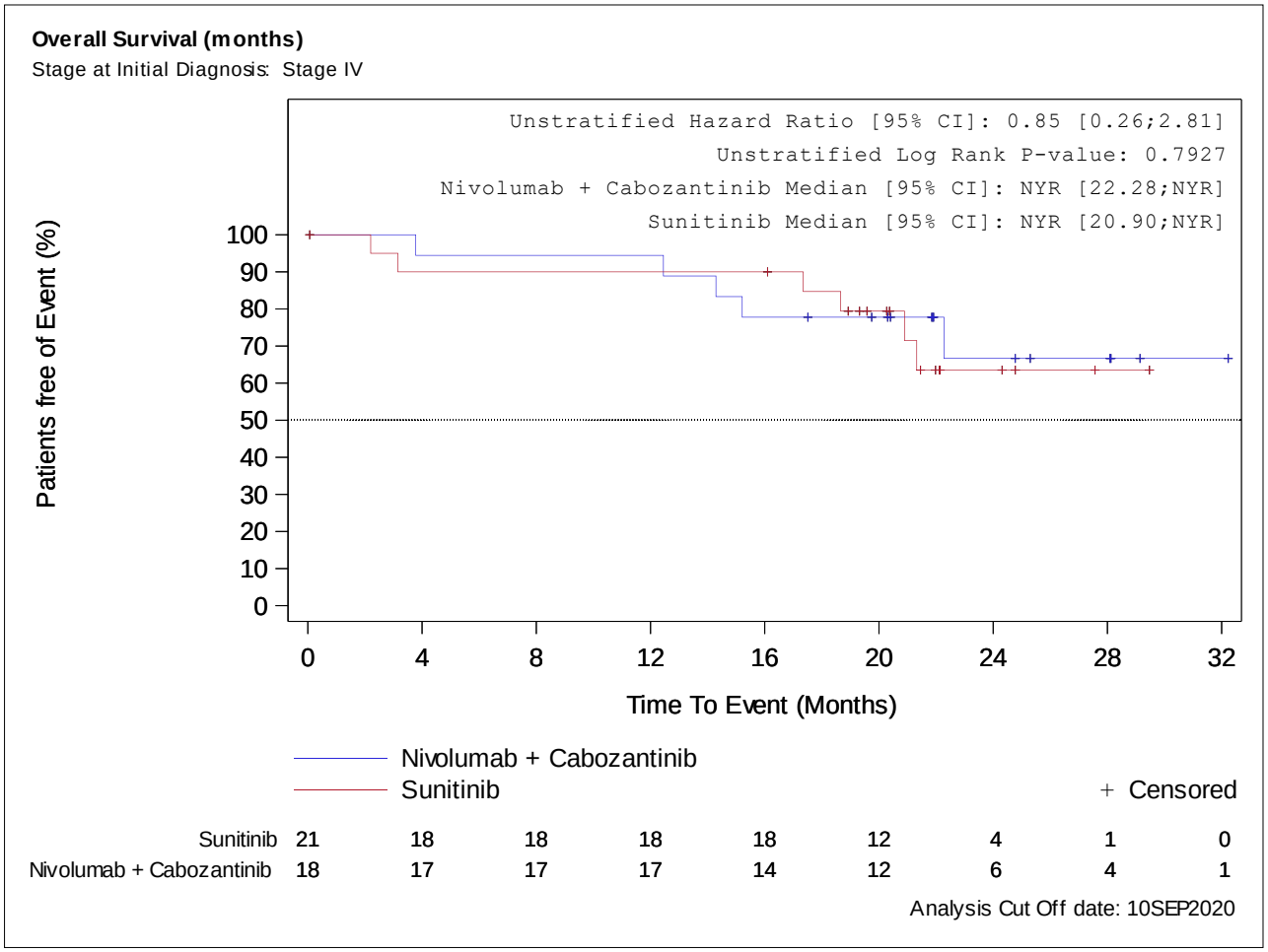
FIGURE 2.1.2.23: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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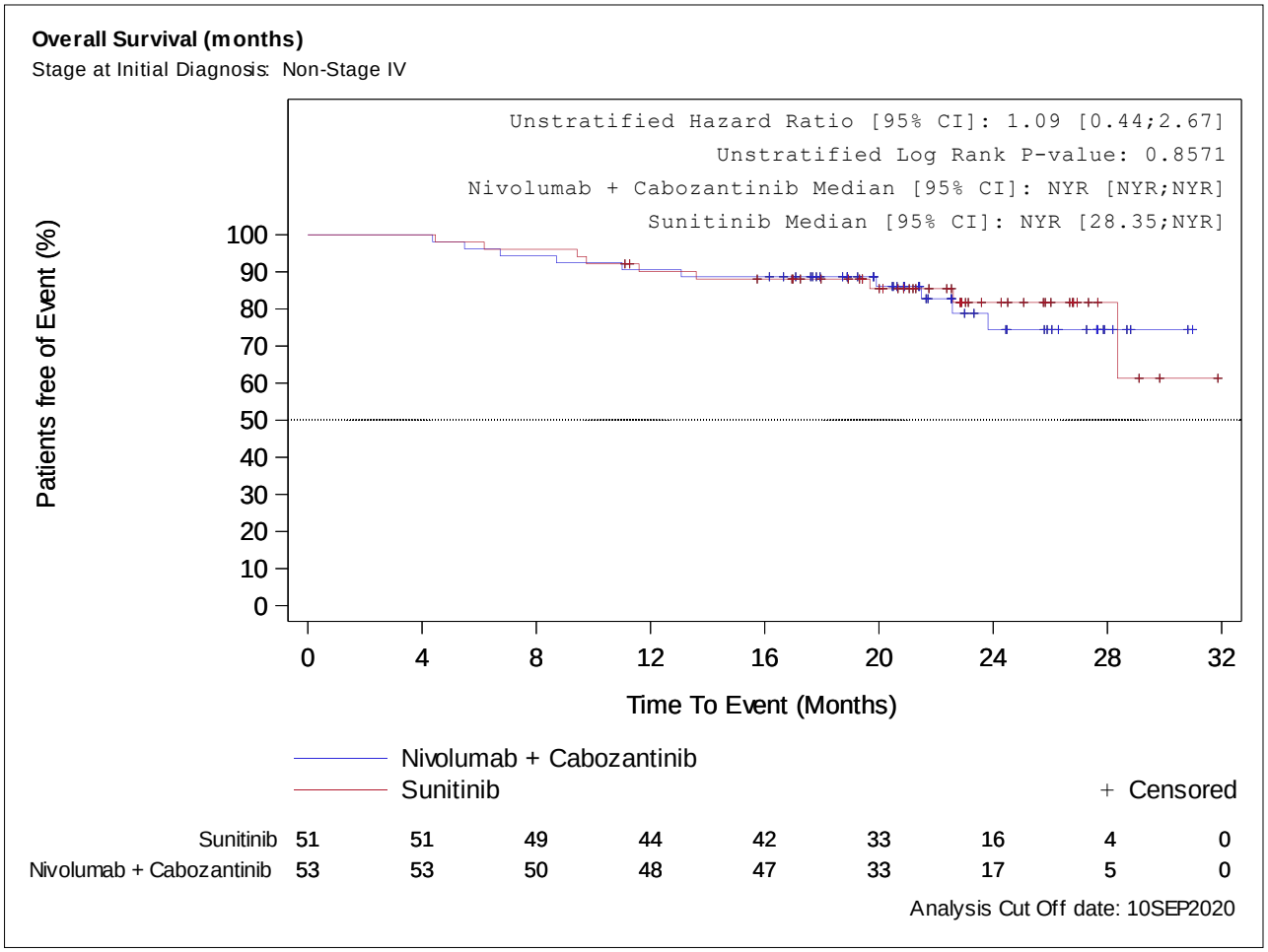
FIGURE 2.1.2.24: Kaplan-Meier curve - Overall Survival (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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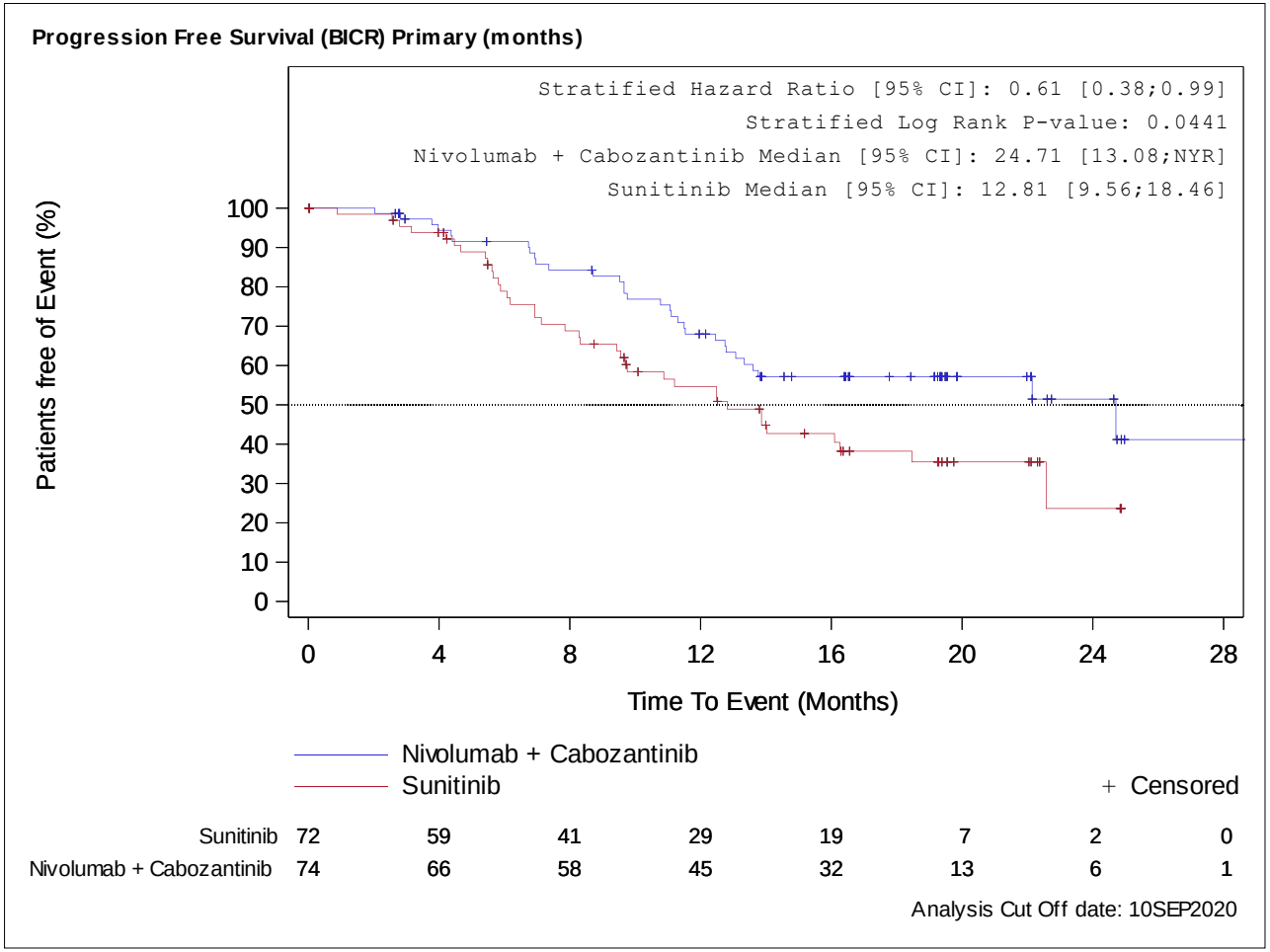
FIGURE 2.2.1: Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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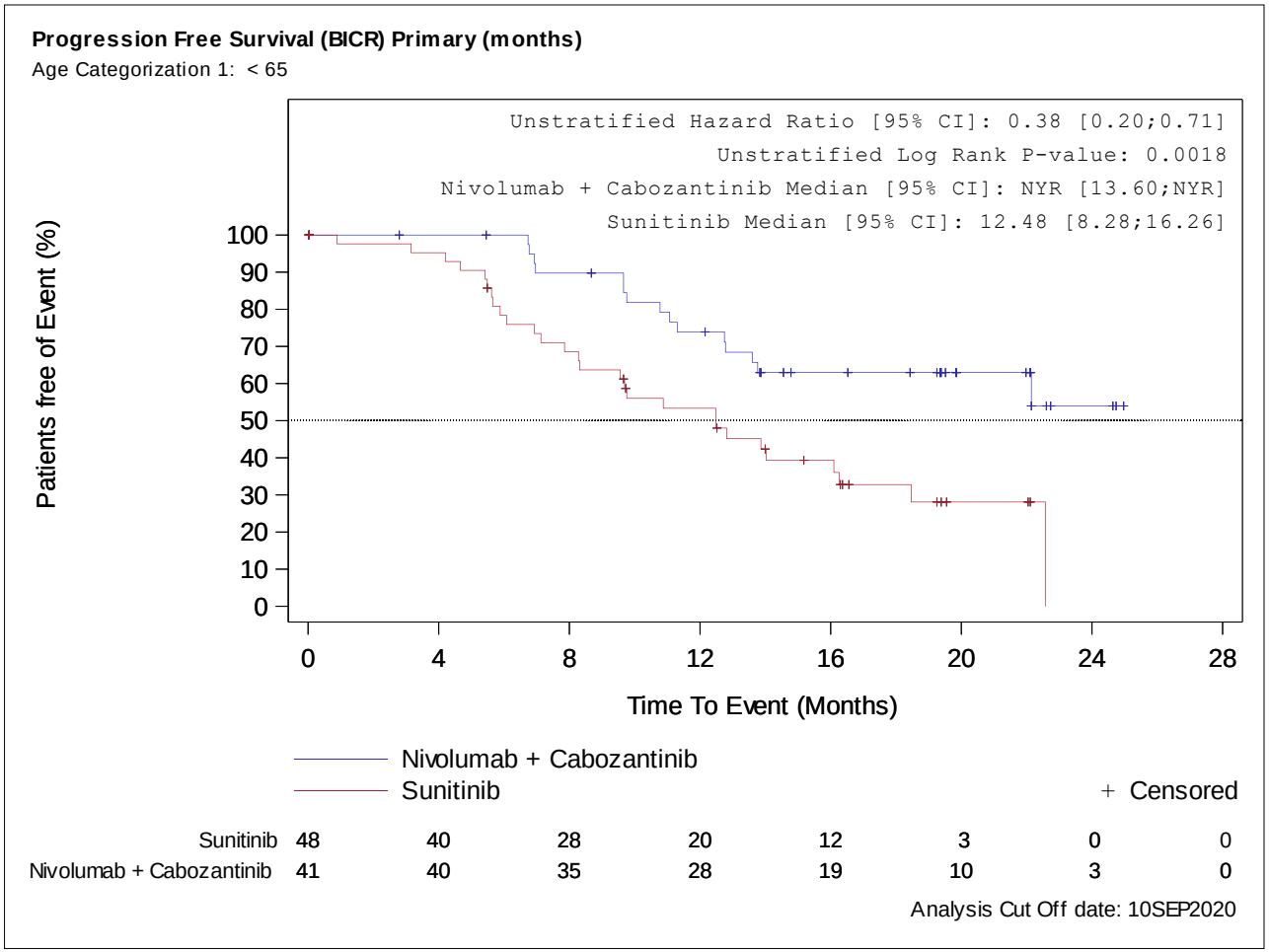
FIGURE 2.2.2.1: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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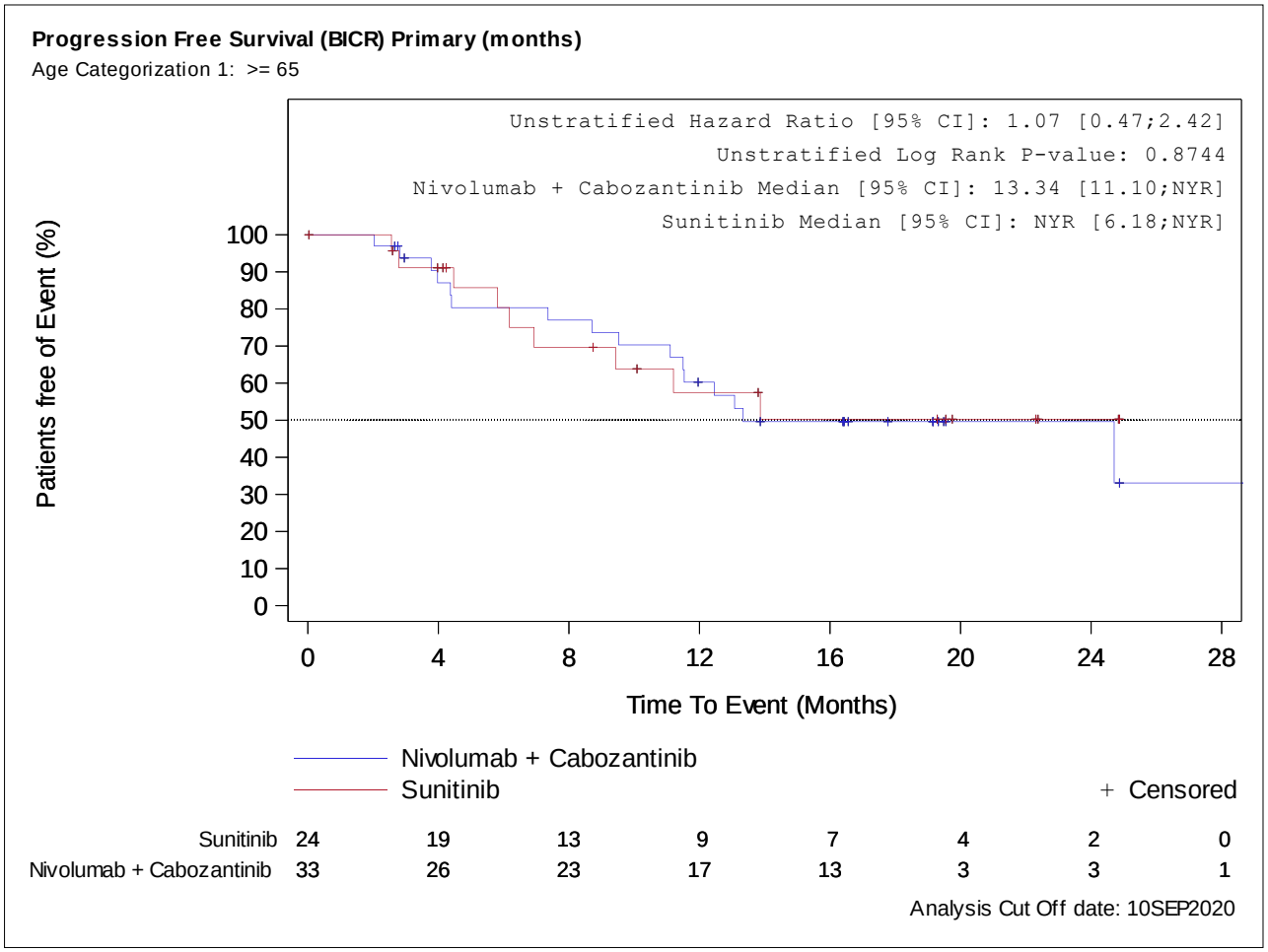
FIGURE 2.2.2.2: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
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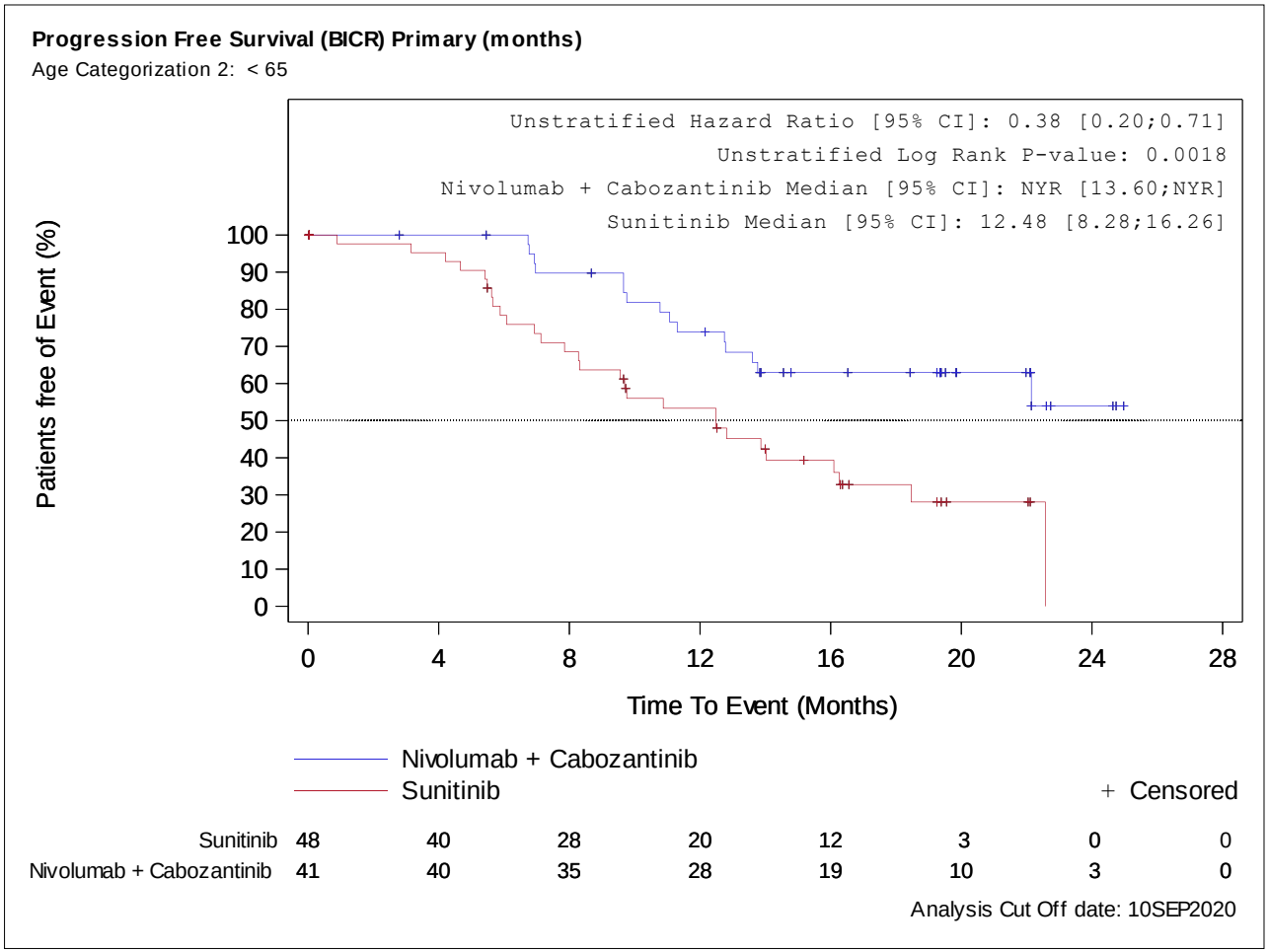
FIGURE 2.2.2.3: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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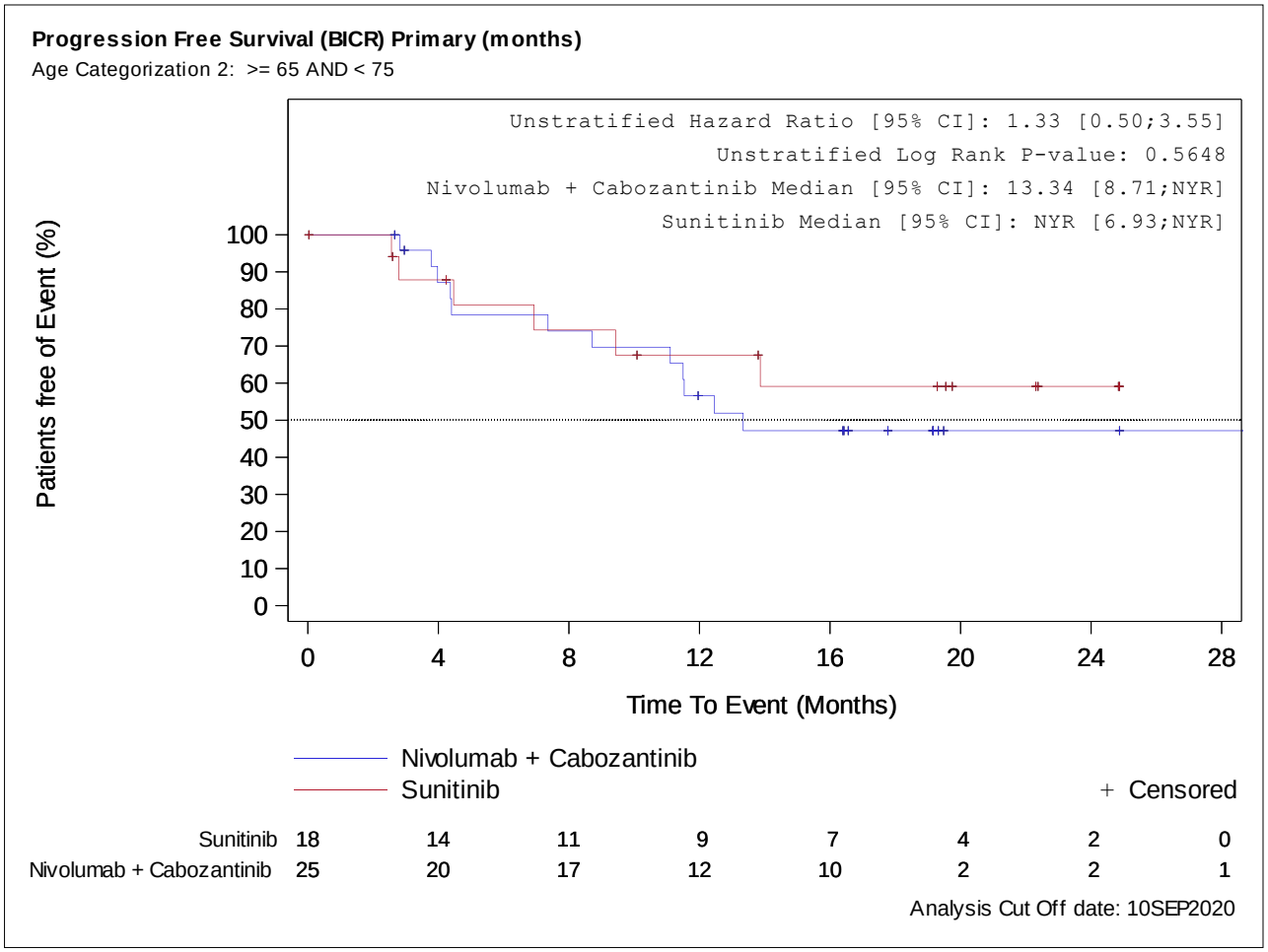
FIGURE 2.2.2.4: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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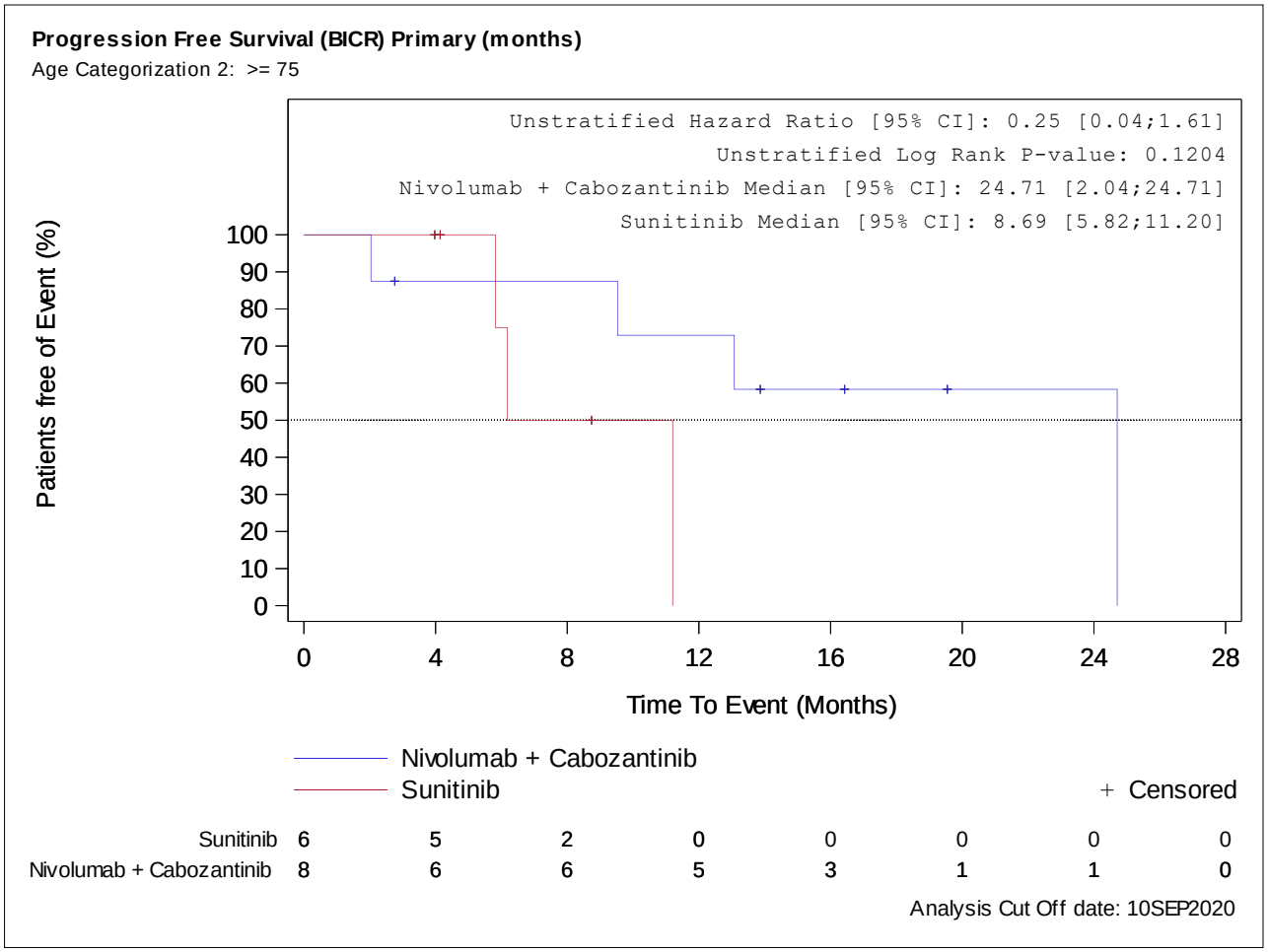
FIGURE 2.2.2.5: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75




Analysis Cut Off date: 10SEP2020
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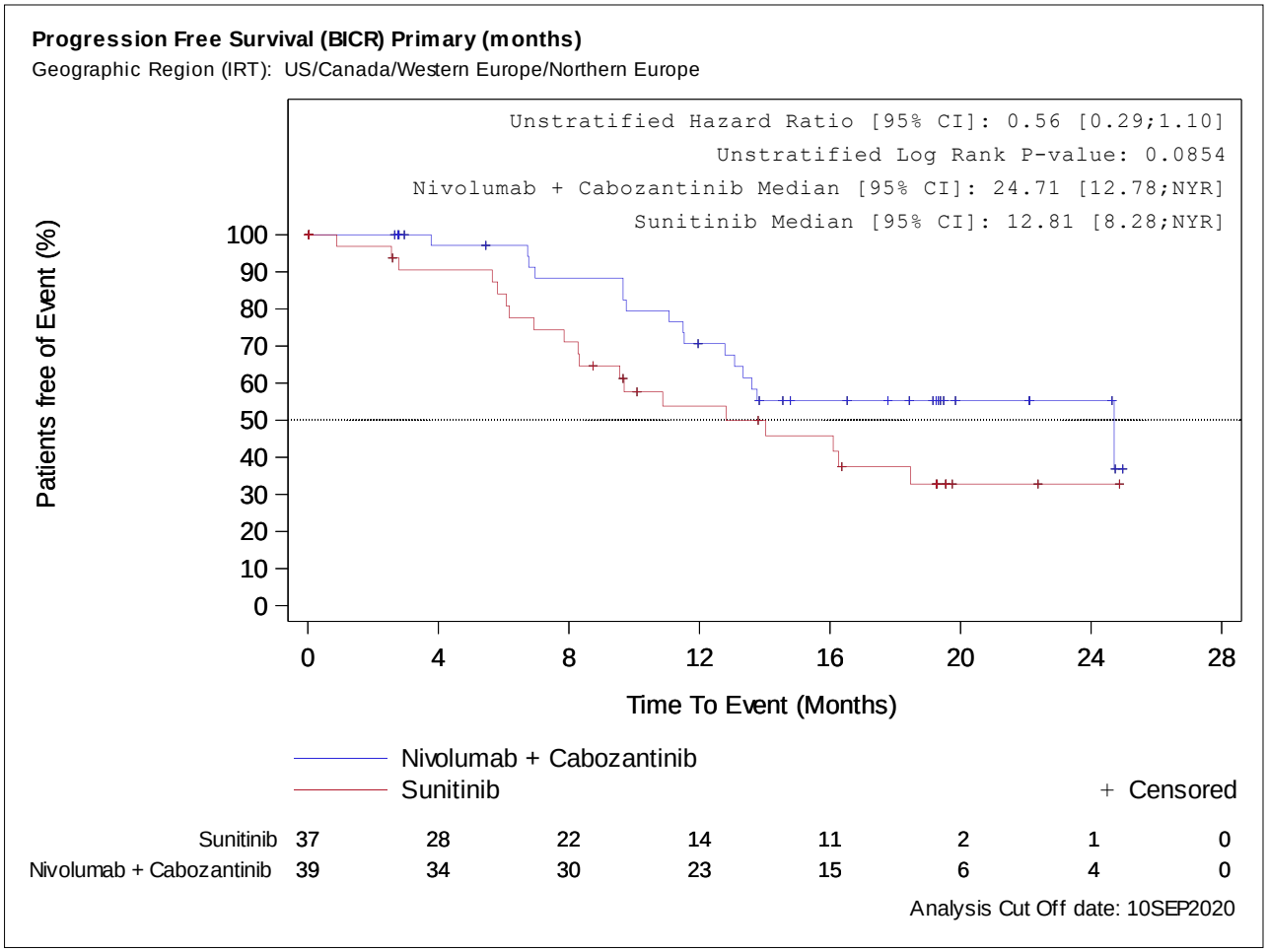
FIGURE 2.2.2.6: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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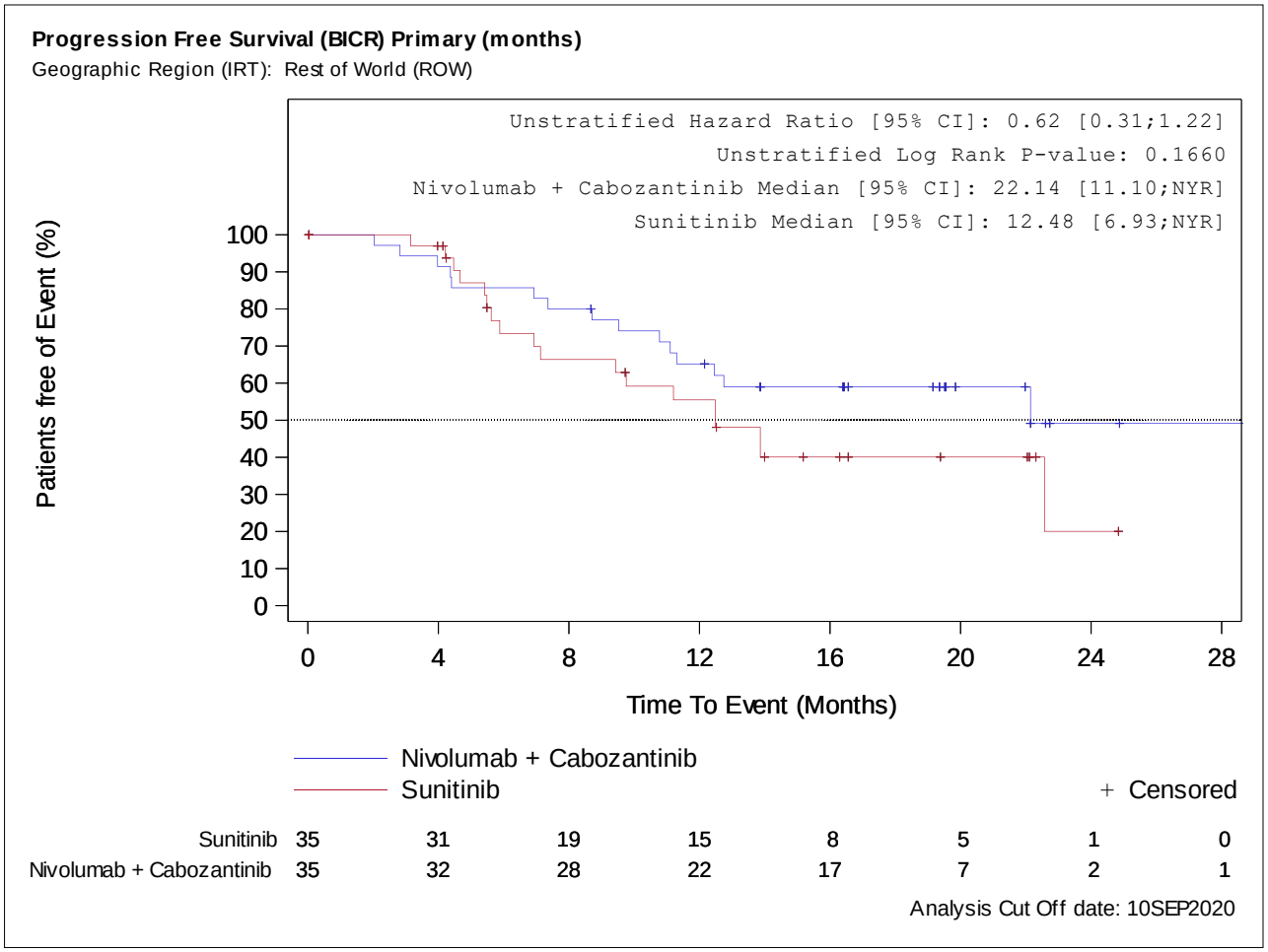
FIGURE 2.2.2.7: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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FIGURE 2.2.2.8: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White

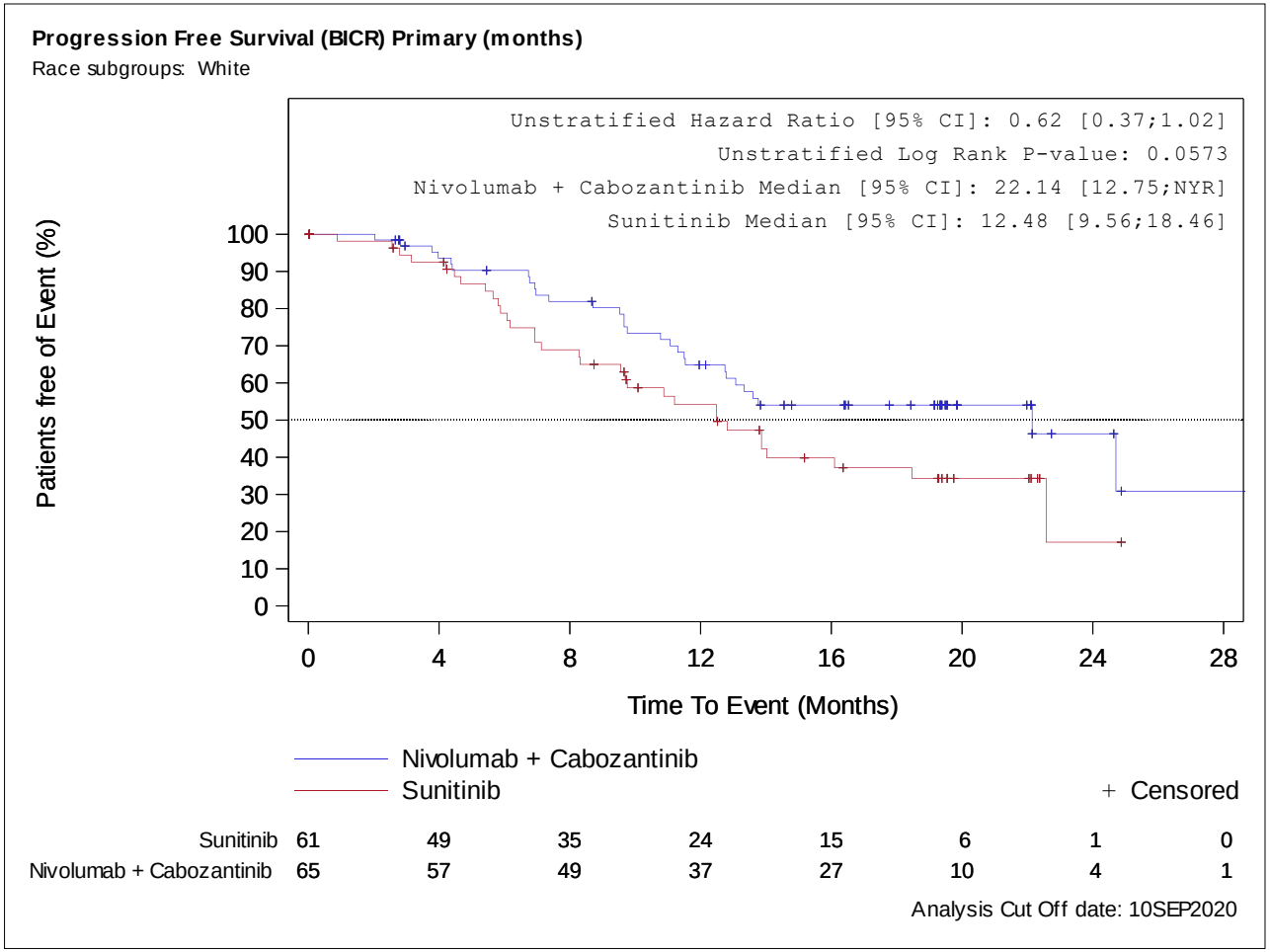


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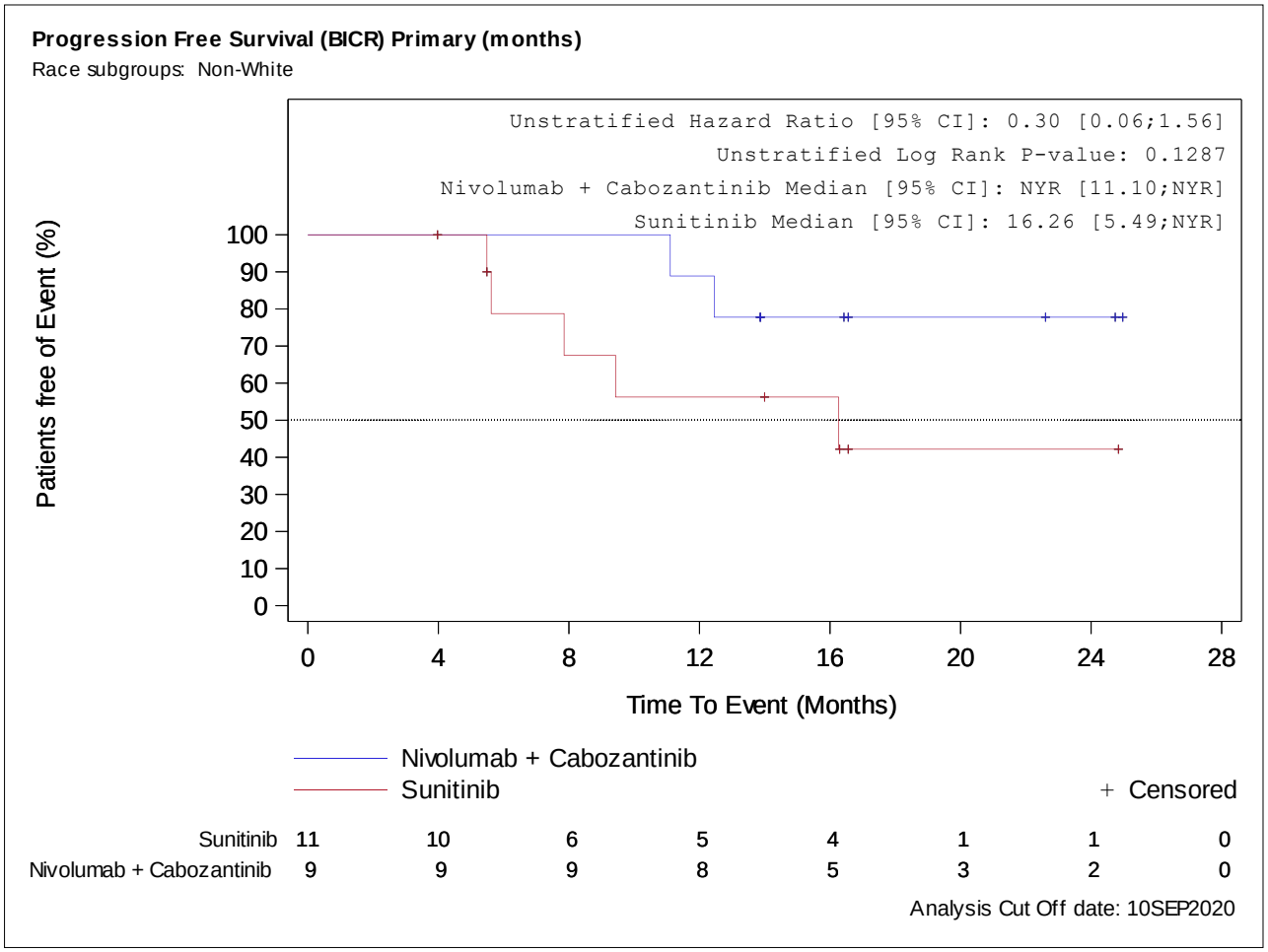
FIGURE 2.2.2.9: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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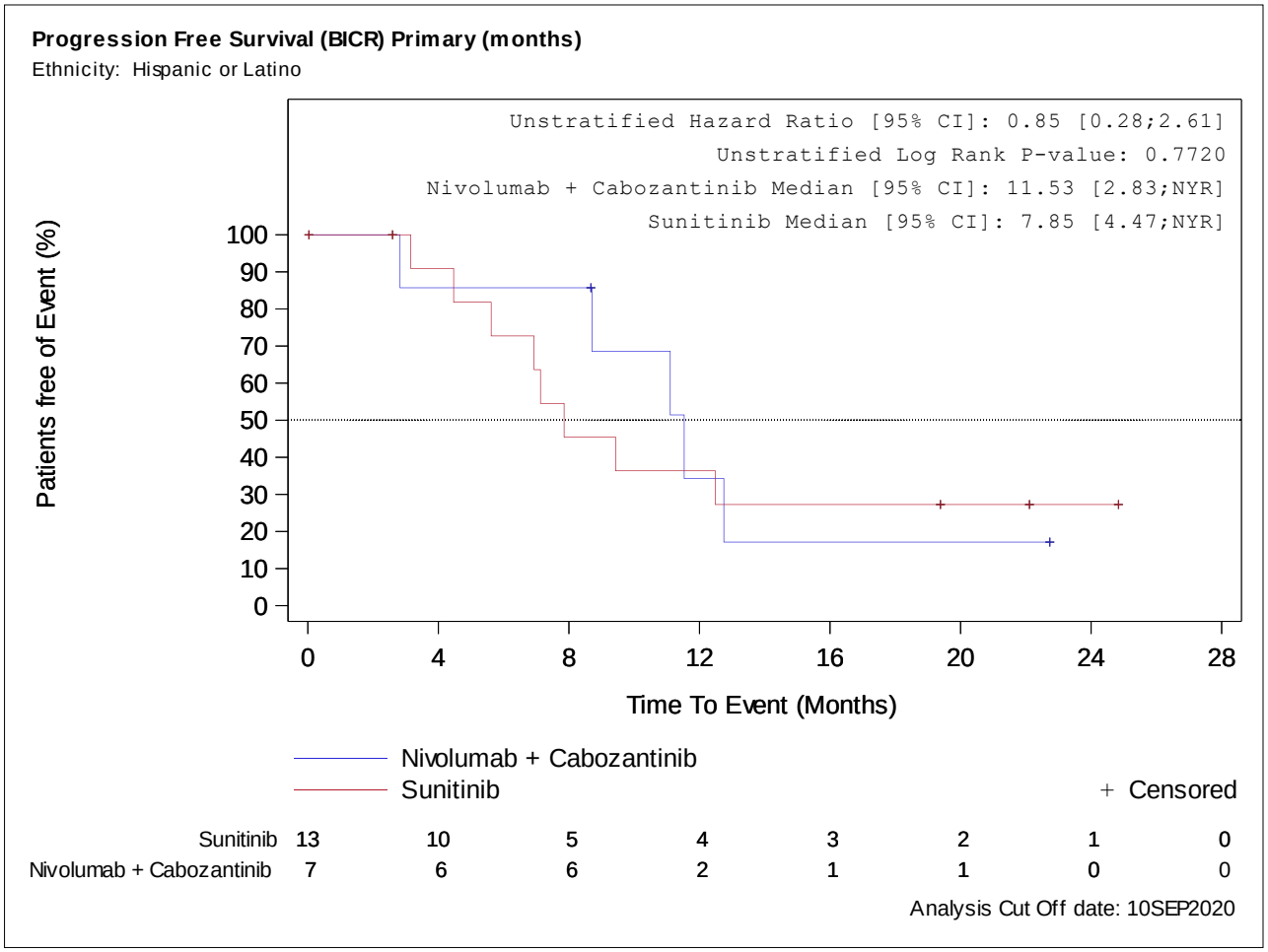
FIGURE 2.2.2.10: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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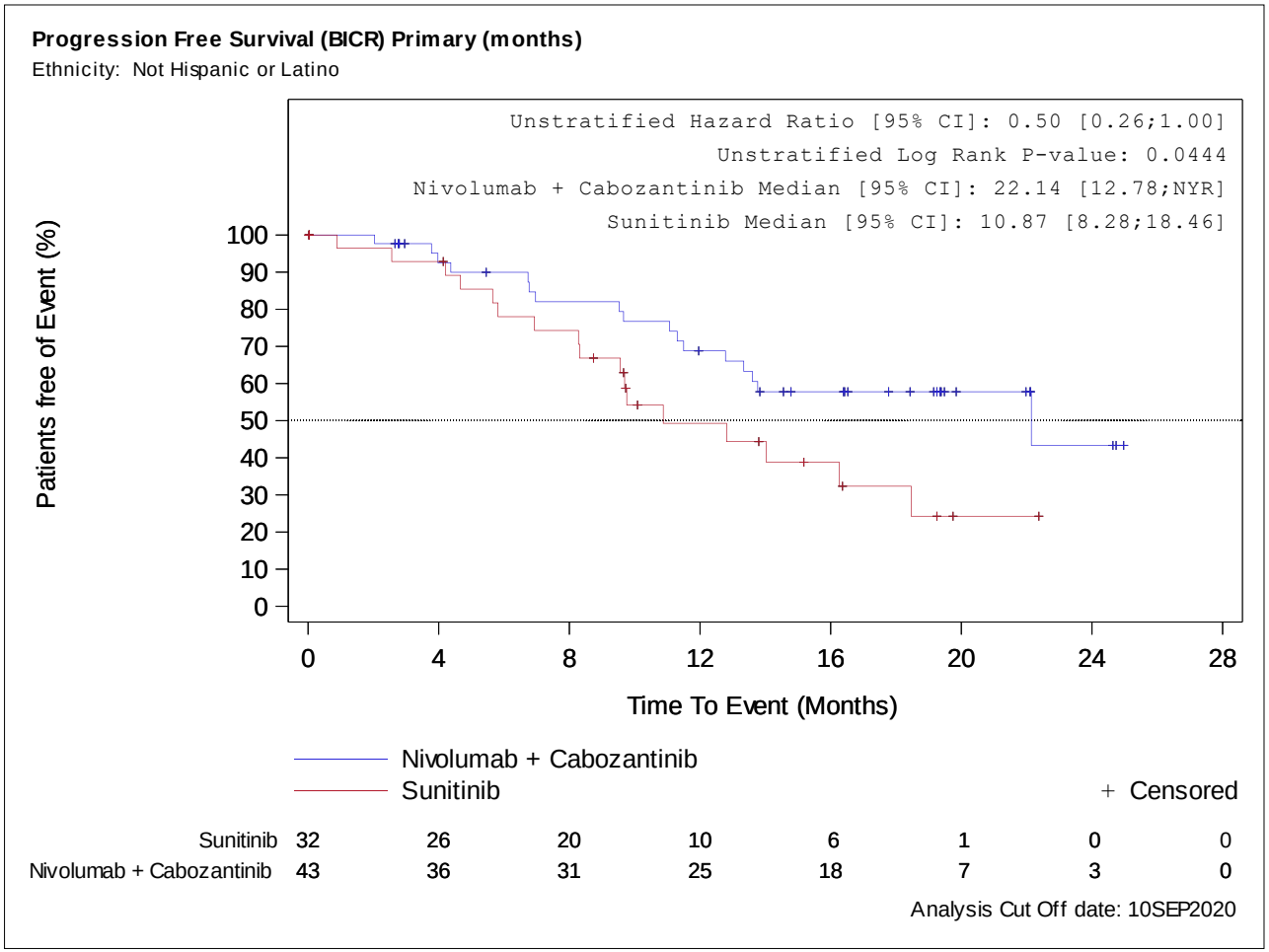
FIGURE 2.2.2.11: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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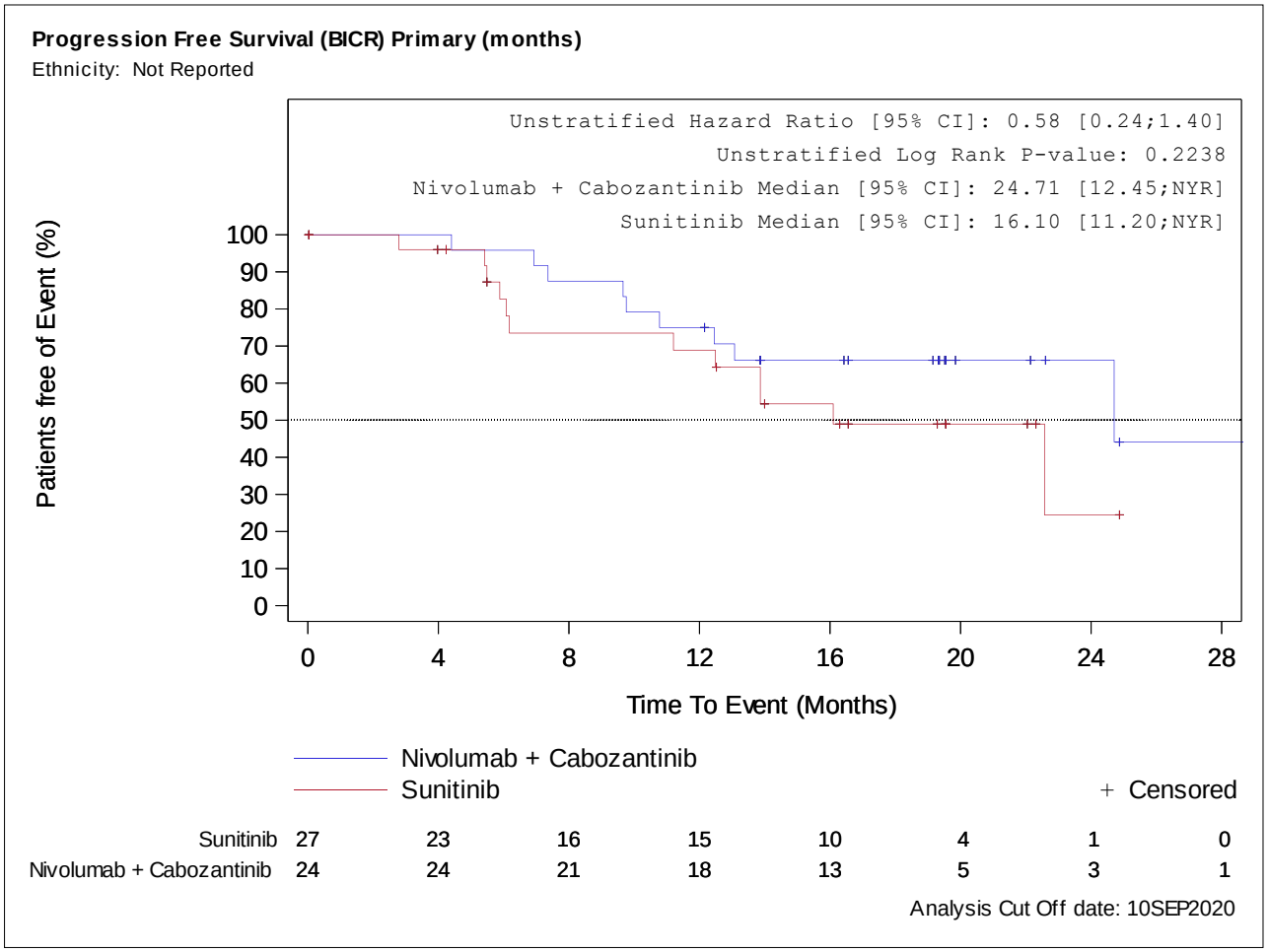
FIGURE 2.2.2.12: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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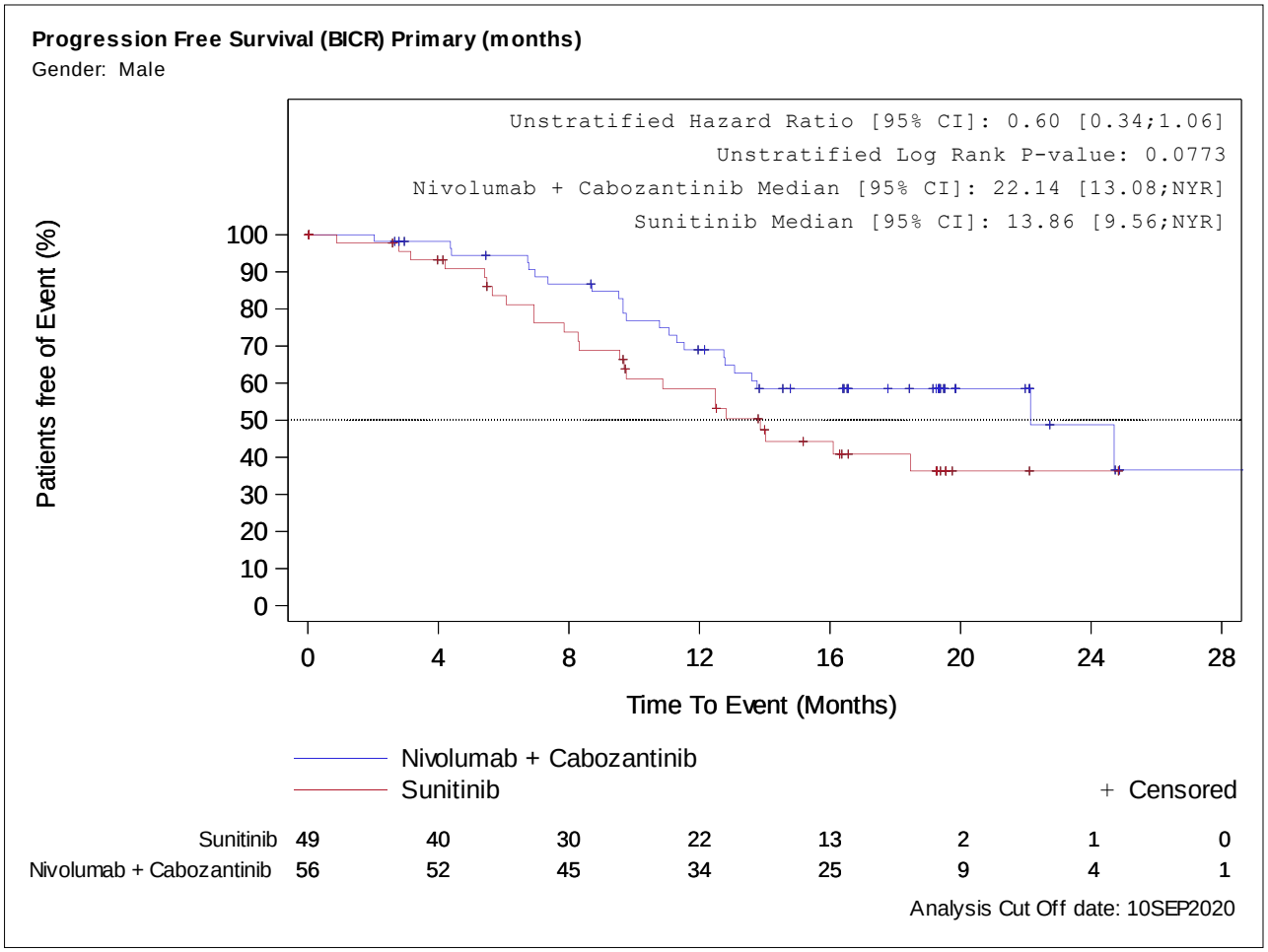
FIGURE 2.2.2.13: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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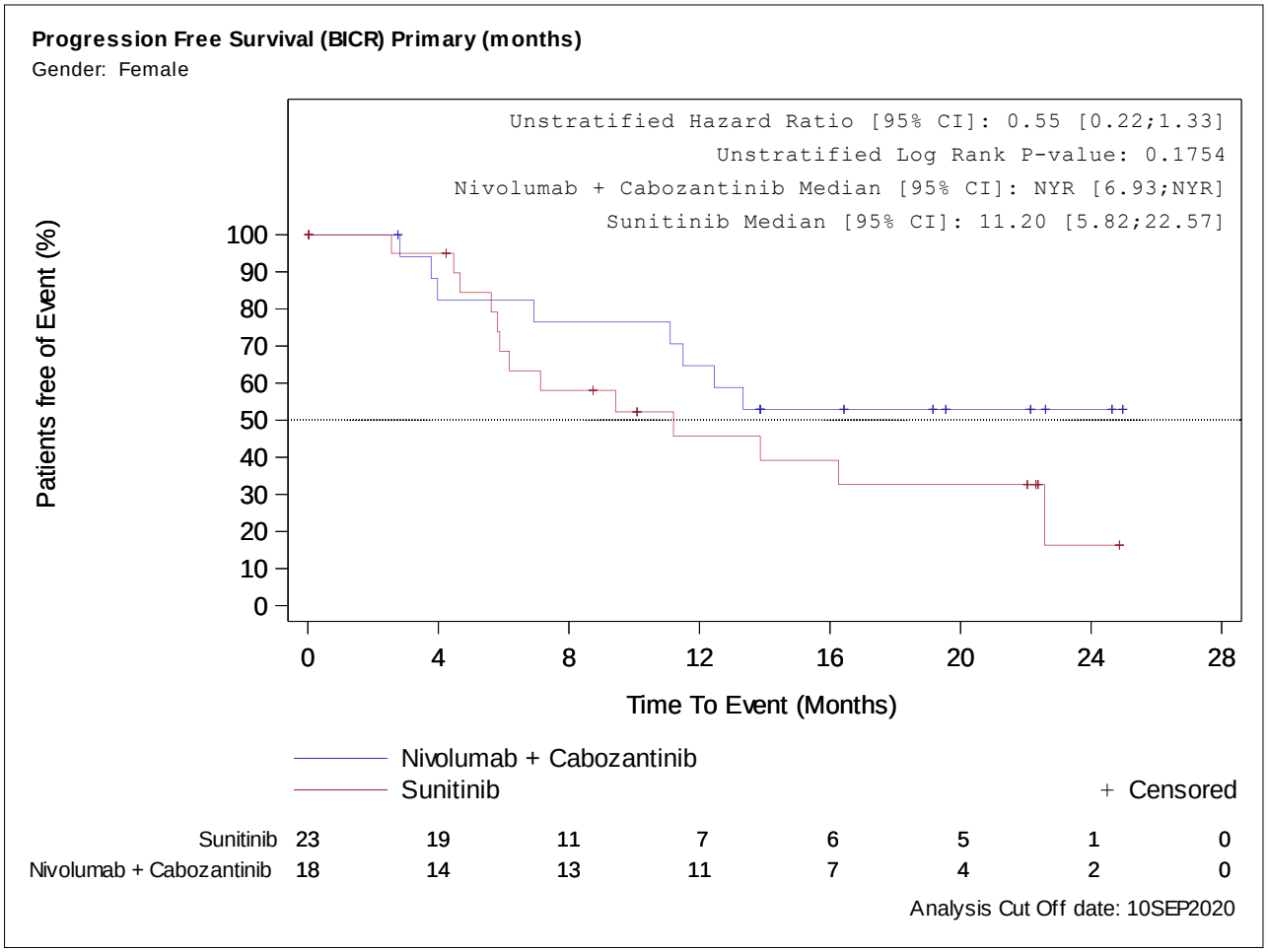
FIGURE 2.2.2.14: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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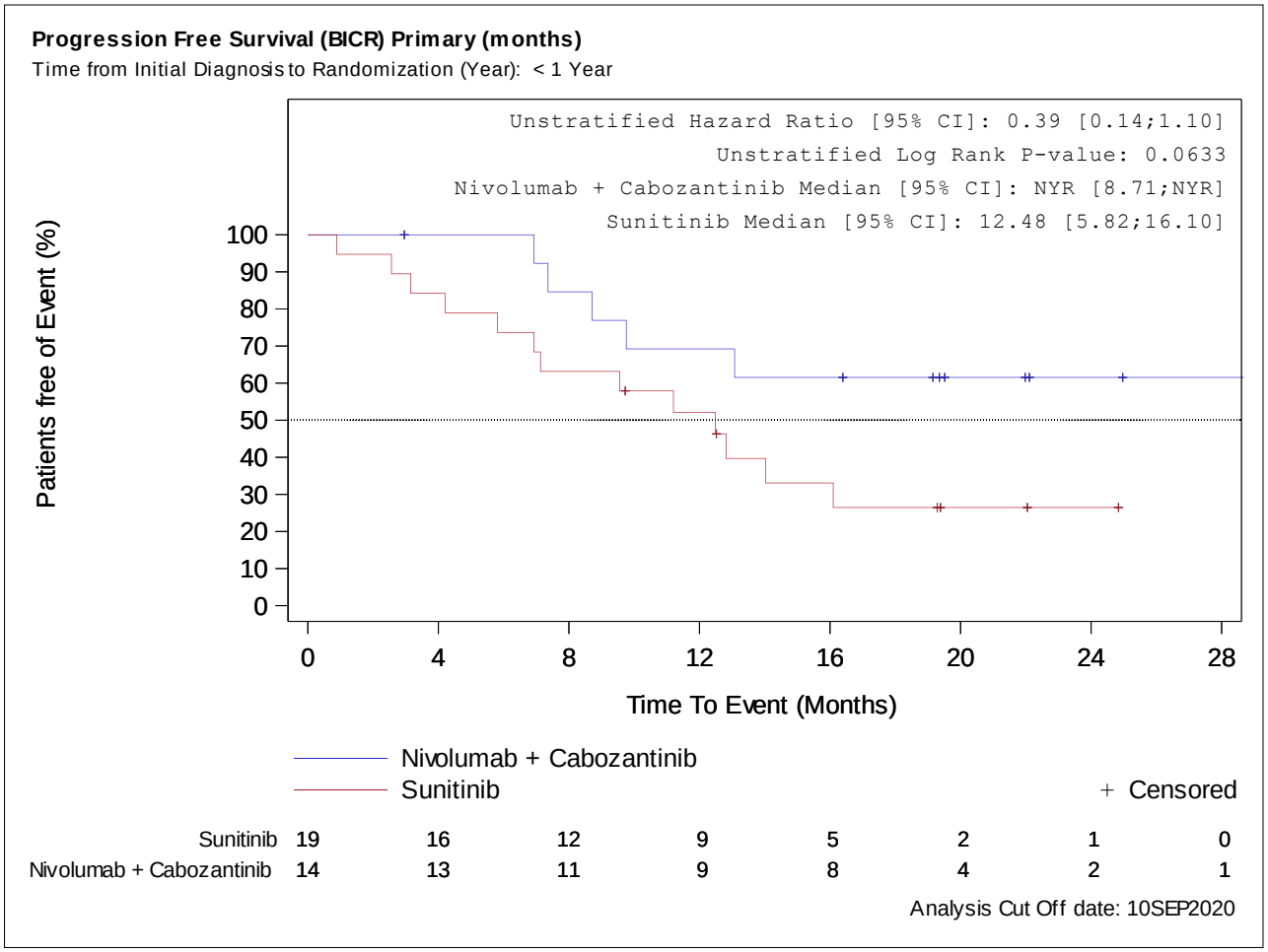
FIGURE 2.2.2.15: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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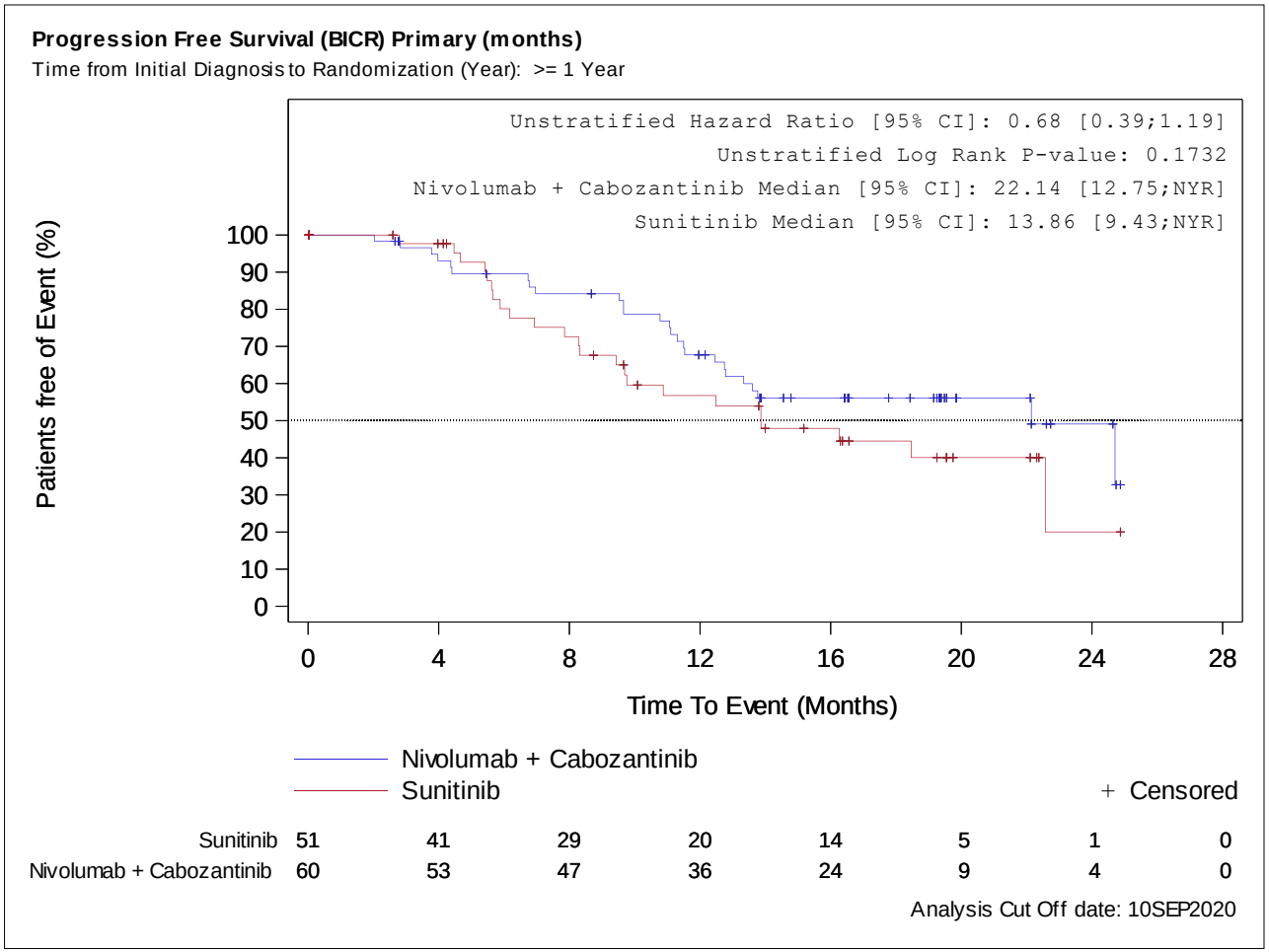
FIGURE 2.2.2.16: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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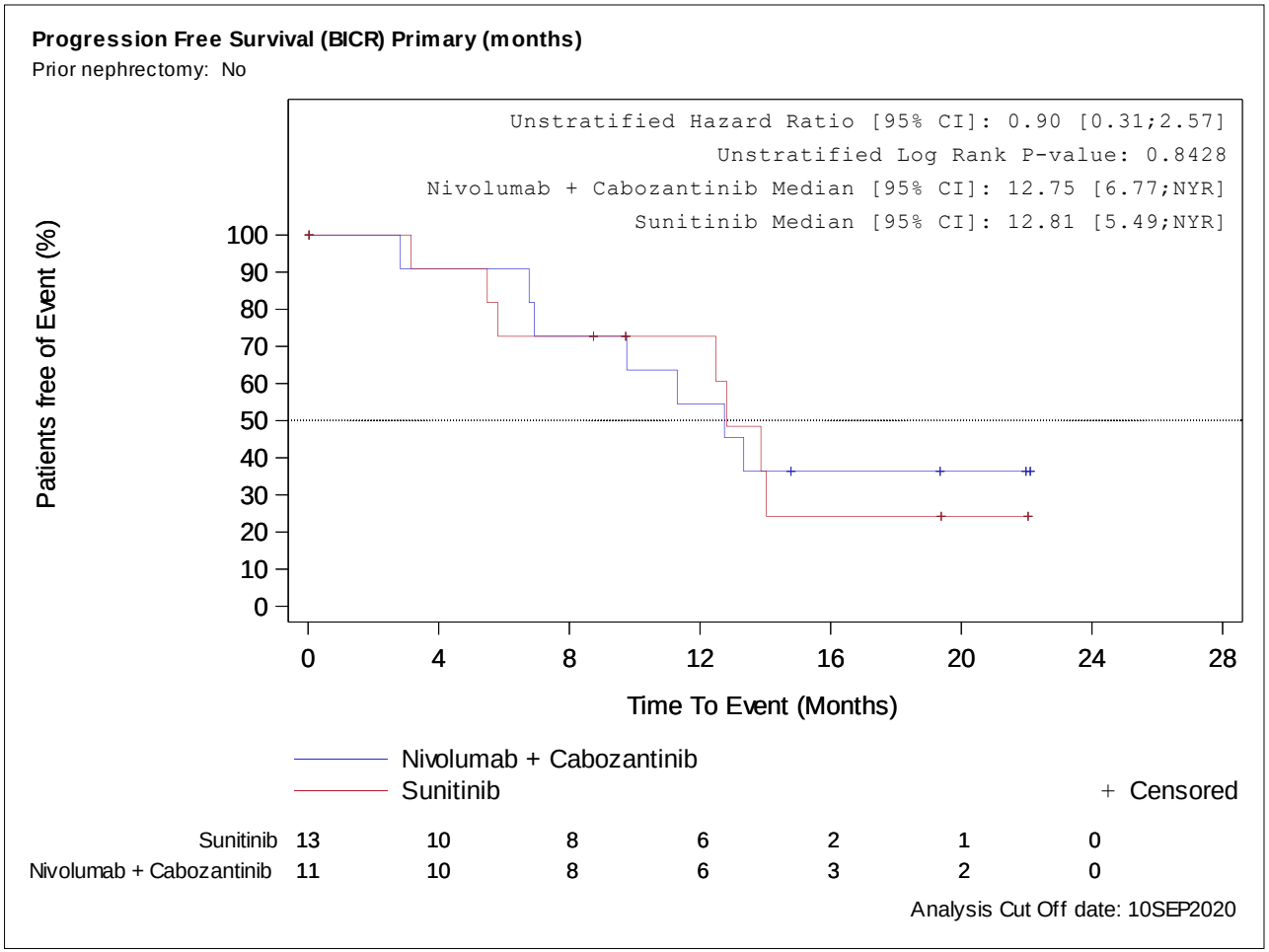
FIGURE 2.2.2.17: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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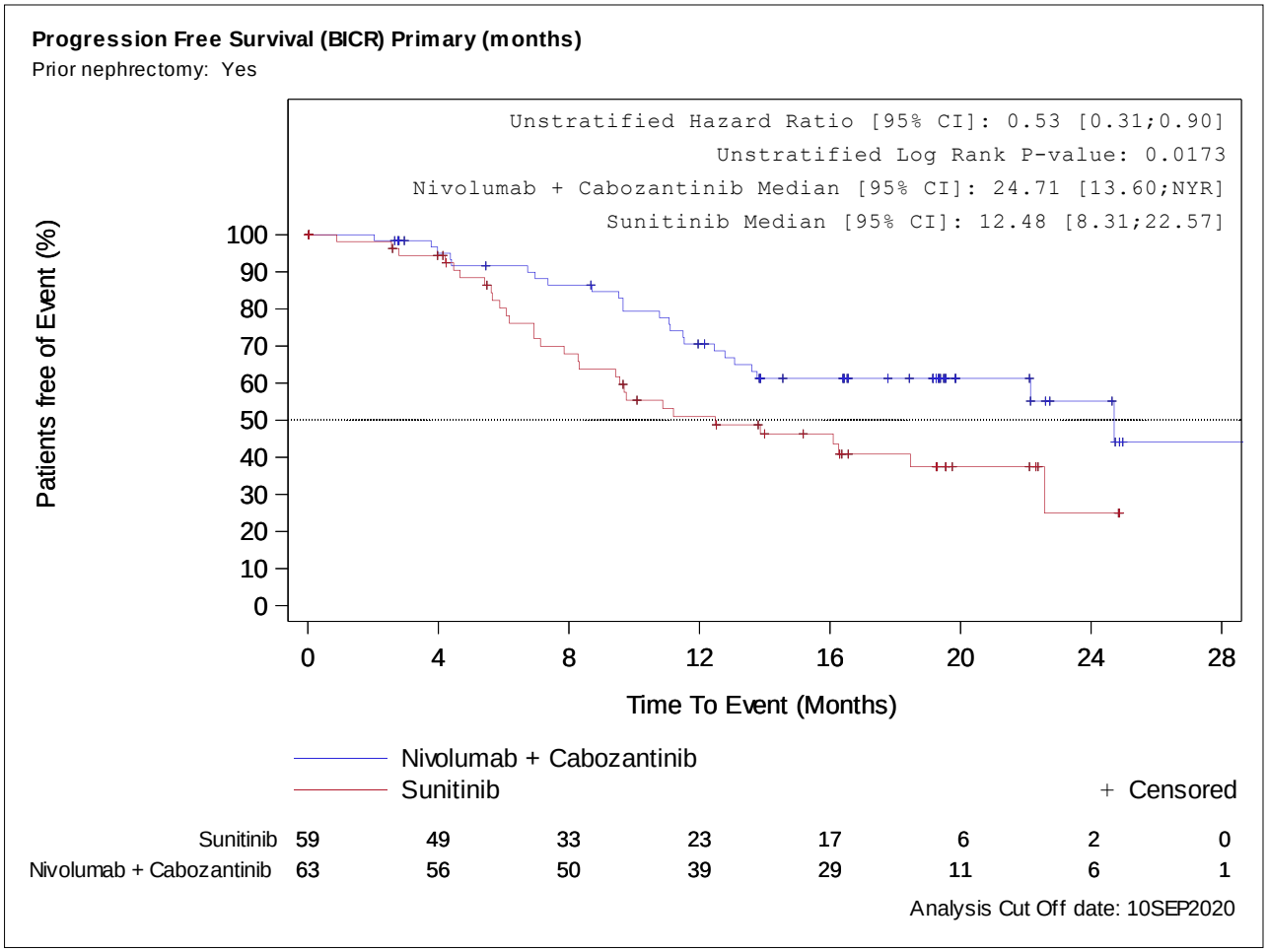
FIGURE 2.2.2.18: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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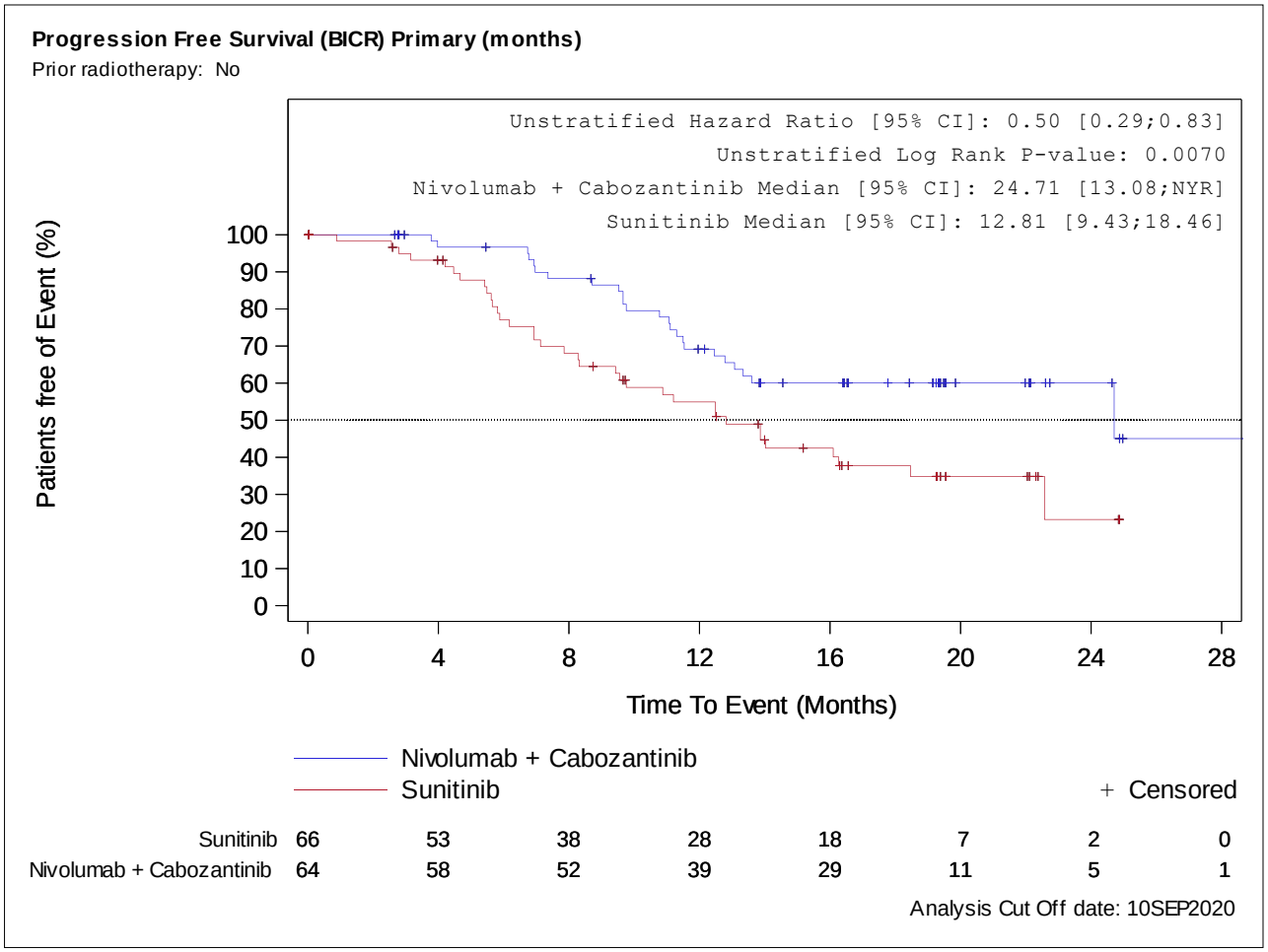
FIGURE 2.2.2.19: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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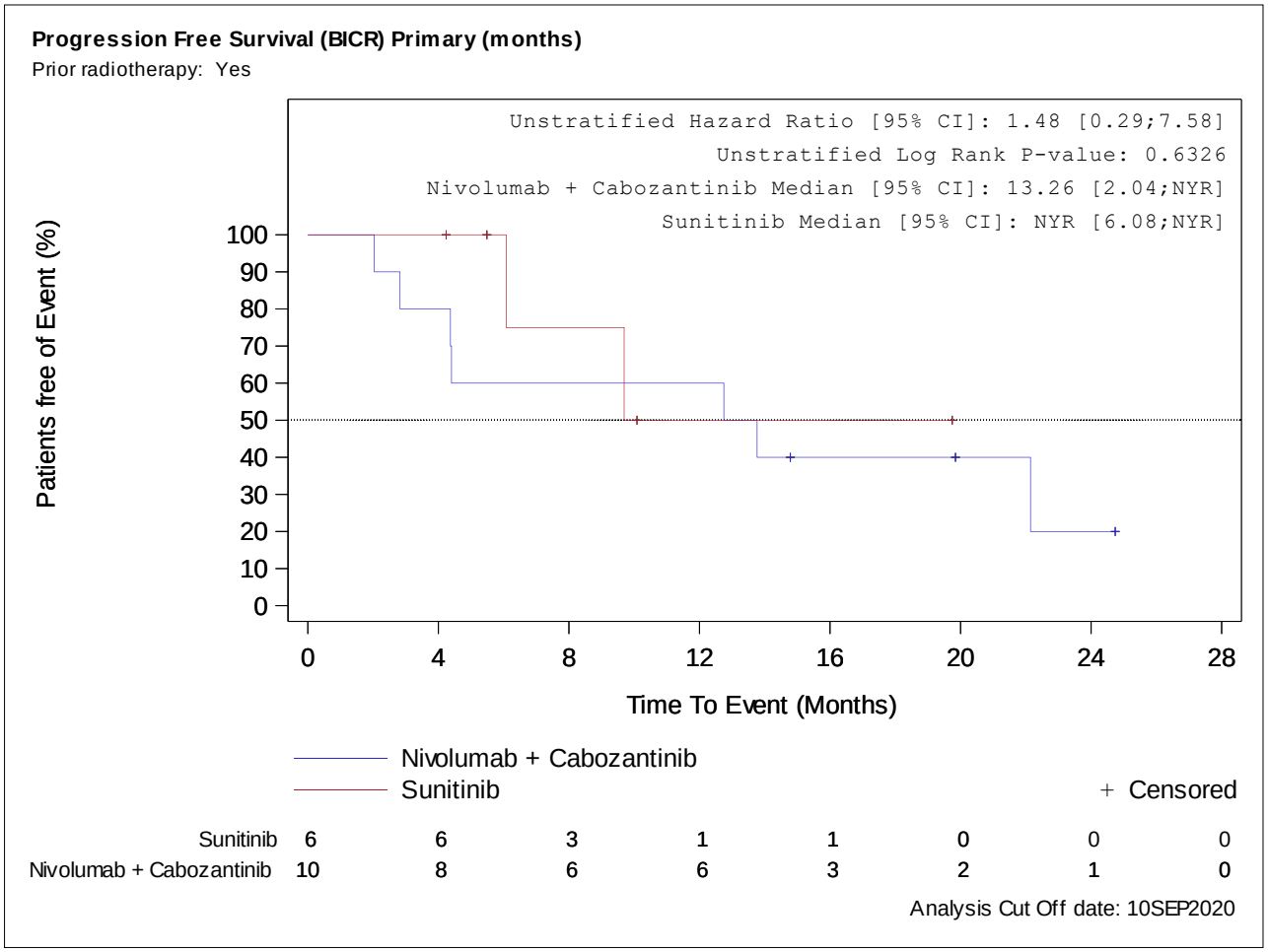
FIGURE 2.2.2.20: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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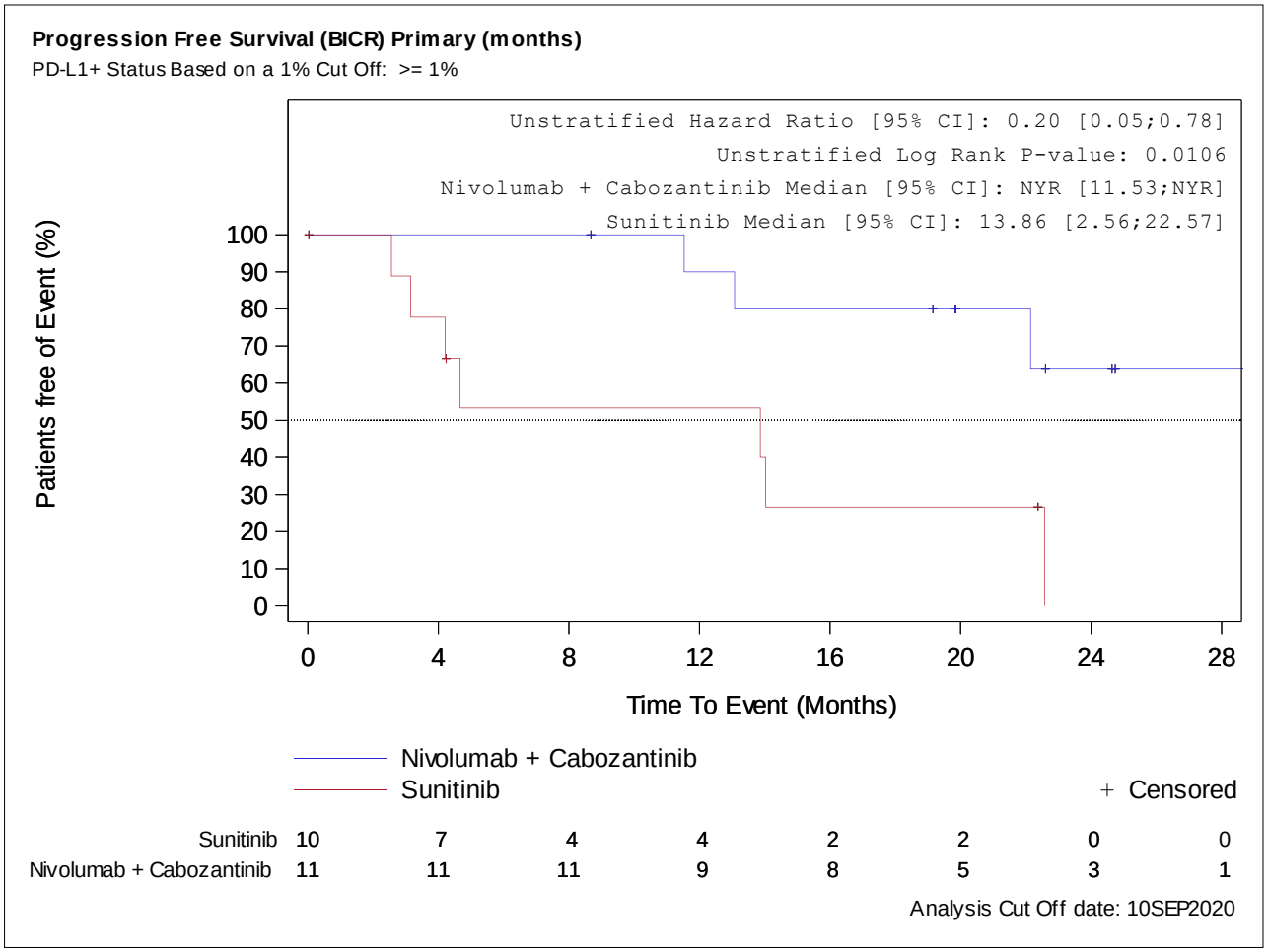
FIGURE 2.2.2.21: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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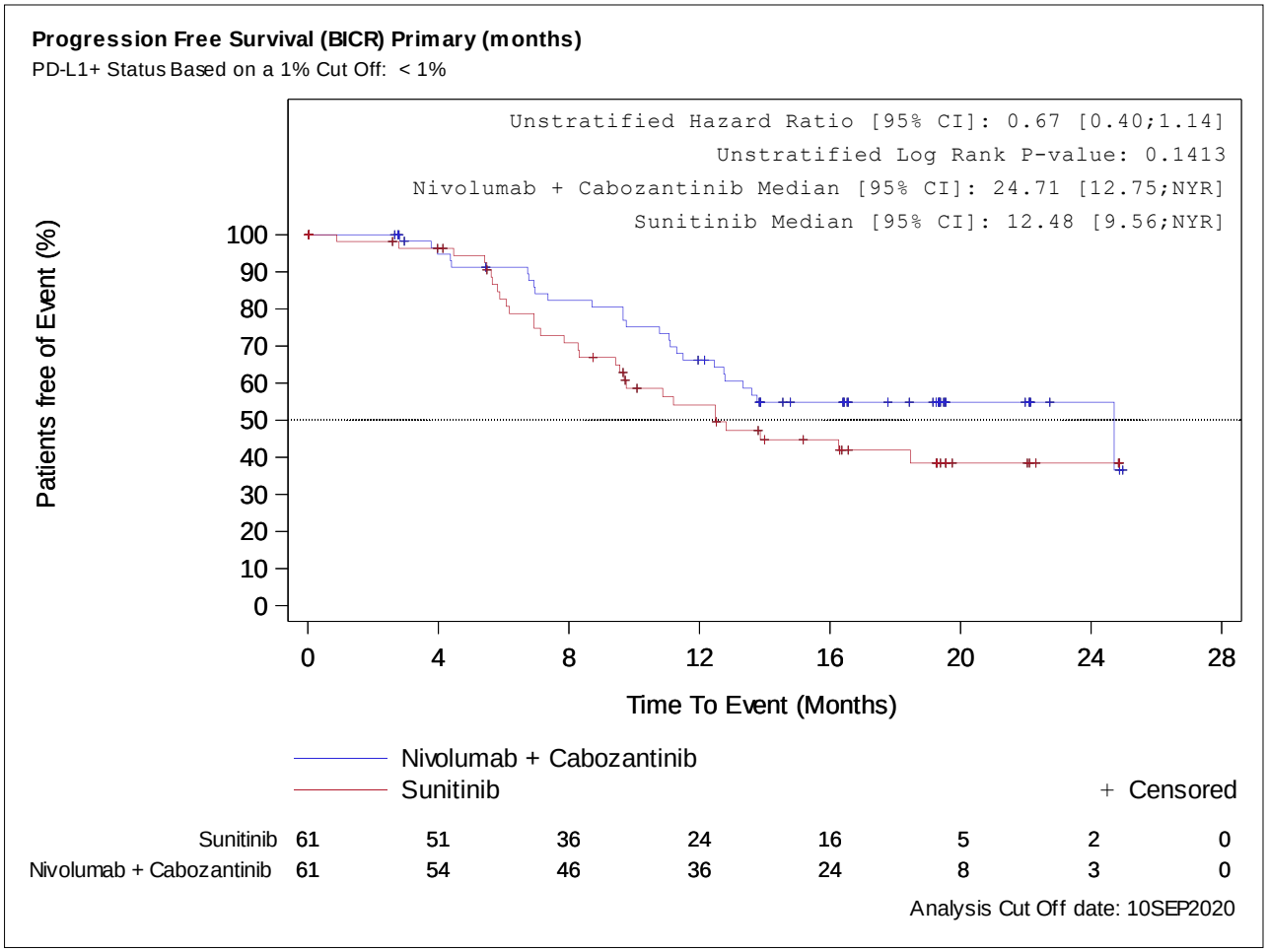
FIGURE 2.2.2.22: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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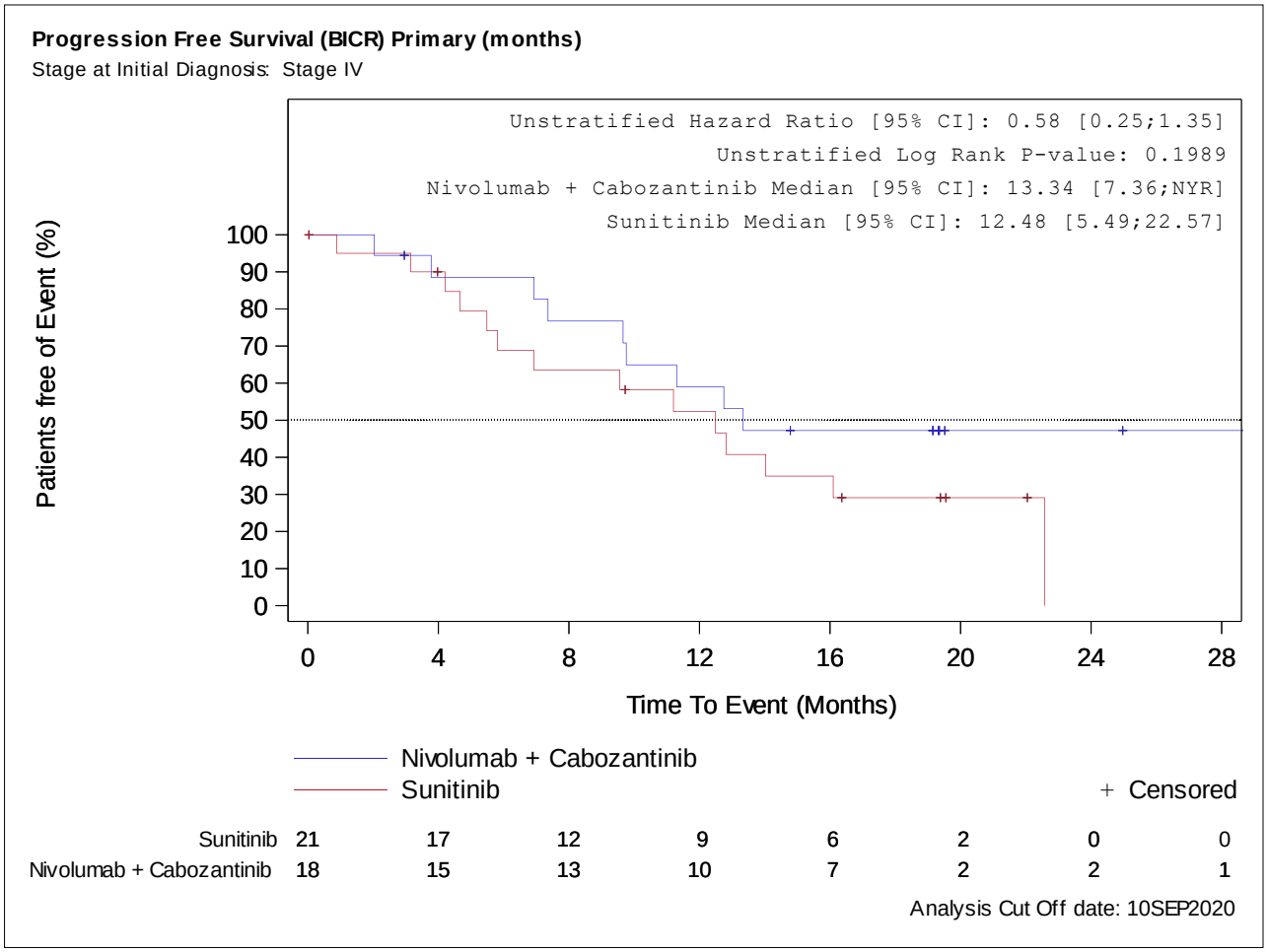
FIGURE 2.2.2.23: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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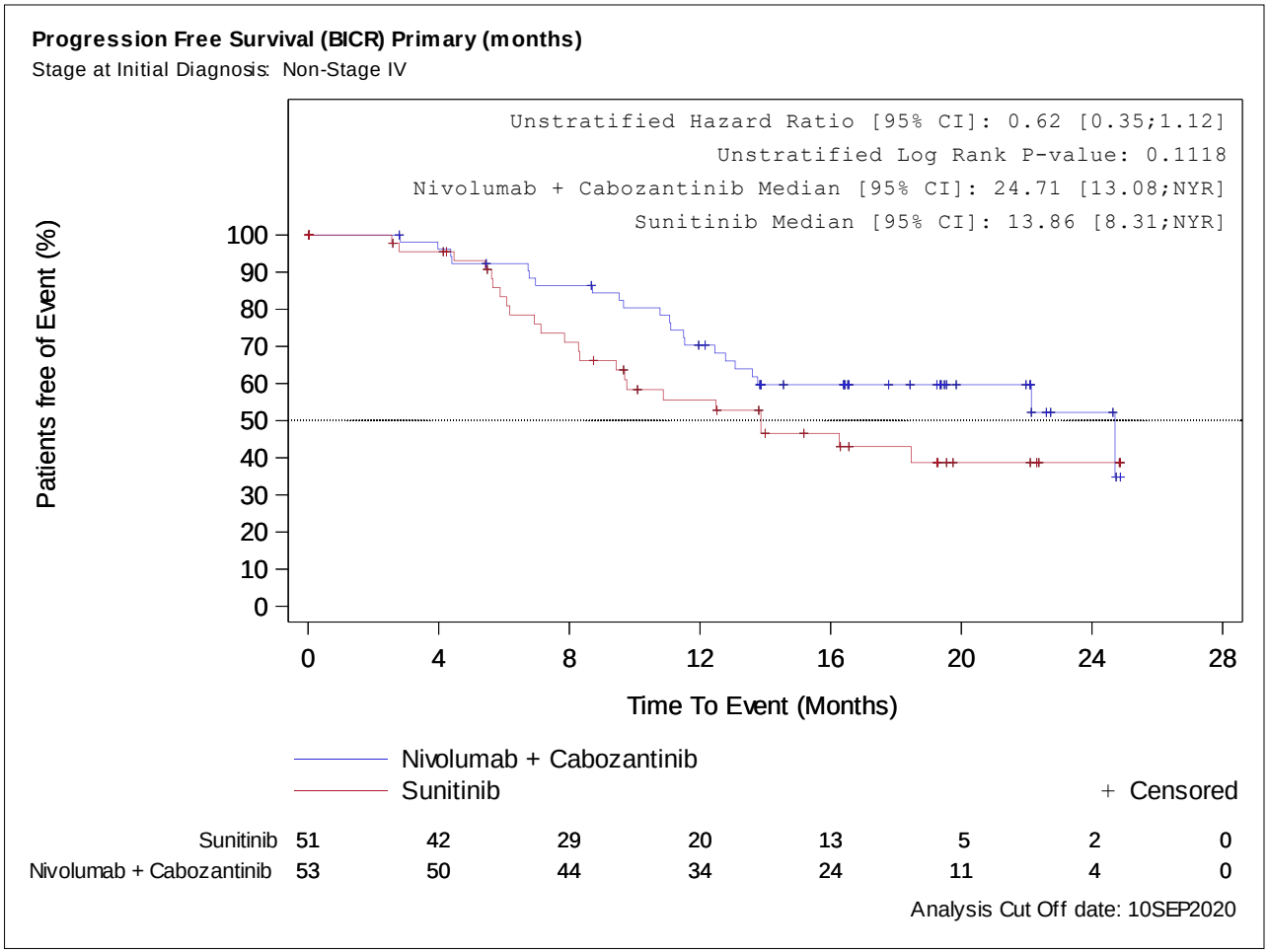
FIGURE 2.2.2.24: Kaplan-Meier curve - Progression Free Survival (BICR) Primary (months) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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TABLE 2.15: Binary Outcome Analysis: Objective response rate (ORR) per Independent Radiology Review Committee (IRC) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | Sunitinib | | Sunitinib vs. Nivolumab + Cabozantinib | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Population | n | Events (%) | n | Events (%) | OR (95% CI) | RR (95% CI) | RD (95% CI) | CMH or Logistic Regression p-value [1] | P-val [2] for trt*subgroup interaction |
| **Overall** | | | | | | | | | |
| Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) | 74 | 49 (66%) | 72 | 32 (44%) | 2.41 (1.24, 4.71) | 1.53 (1.12, 2.07) | 21.9% (6.2%, 37.6%) | 0.0093+* | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 30 (73%) | 48 | 22 (46%) | 3.22 (1.32, 7.88) | 1.60 (1.11, 2.29) | 27.3% (7.8%, 46.9%) | 0.0105* | 0.3238 |
| >= 65 | 33 | 19 (58%) | 24 | 10 (42%) | 1.90 (0.65, 5.51) | 1.38 (0.79, 2.41) | 15.9% (-10.0%, 41.9%) | 0.2889 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 30 (73%) | 48 | 22 (46%) | 3.22 (1.32, 7.88) | 1.60 (1.11, 2.29) | 27.3% (7.8%, 46.9%) | 0.0105* | 0.3307 |
| >= 65 AND < 75 | 25 | 14 (56%) | 18 | 9 (50%) | 1.27 (0.38, 4.29) | 1.12 (0.63, 2.00) | 6.0% (-24.2%, 36.2%) | 0.7631 | |
| >= 75 | 8 | 5 (63%) | 6 | 1 (17%) | 8.33 (0.63, 110.02) | 3.75 (0.58, 24.28) | 45.8% (0.9%, 90.7%) | 0.1375 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 29 (74%) | 37 | 15 (41%) | 4.25 (1.61, 11.26) | 1.83 (1.19, 2.82) | 33.8% (12.9%, 54.7%) | 0.0049* | 0.0915 |
| Rest of World (ROW) | 35 | 20 (57%) | 35 | 17 (49%) | 1.41 (0.55, 3.62) | 1.18 (0.75, 1.84) | 8.6% (-14.7%, 31.9%) | 0.6324 | |

Notes:
Analysis on overall population is calculated based on stratified Generalized Linear Models, for OR, RR, and RD, stratified by by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
Analysis on subgroups uses unstratified, unstandardized methods for calculating OR, RR, and RD.
[1] Unstratified Logistic Regression p-values are presented for all subgroups.
[2] Estimates from unstratified Logistic Regression for interaction effect are presented for all subgroups.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.
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TABLE 2.15: Binary Outcome Analysis: Objective response rate (ORR) per Independent Radiology Review Committee (IRC) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | Sunitinib | | Sunitinib vs. Nivolumab + Cabozantinib | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Population | n | Events (%) | n | Events (%) | OR (95% CI) | RR (95% CI) | RD (95% CI) | CMH or Logistic Regression p-value [1] | P-val [2] for trt*subgroup interaction |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 41 (63%) | 61 | 26 (43%) | 2.30 (1.12, 4.70) | 1.48 (1.05, 2.09) | 20.5% (3.4%, 37.5%) | 0.0317* | 0.2752 |
| Non-White | 9 | 8 (89%) | 11 | 6 (55%) | 6.67 (0.61, 73.03) | 1.63 (0.91, 2.93) | 34.3% (-1.5%, 70.2%) | 0.1571 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 5 (71%) | 13 | 5 (38%) | 4.00 (0.55, 29.10) | 1.86 (0.81, 4.27) | 33.0% (-9.7%, 75.6%) | 0.3498 | 0.6350 |
| Not Hispanic or Latino | 43 | 26 (60%) | 32 | 14 (44%) | 1.97 (0.78, 4.97) | 1.38 (0.87, 2.19) | 16.7% (-5.8%, 39.3%) | 0.1684 | |
| Not Reported | 24 | 18 (75%) | 27 | 13 (48%) | 3.23 (0.98, 10.65) | 1.56 (0.99, 2.45) | 26.9% (1.3%, 52.5%) | 0.0840 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 36 (64%) | 49 | 24 (49%) | 1.88 (0.86, 4.10) | 1.31 (0.93, 1.86) | 15.3% (-3.5%, 34.1%) | 0.1204 | 0.2641 |
| Female | 18 | 13 (72%) | 23 | 8 (35%) | 4.88 (1.27, 18.65) | 2.08 (1.11, 3.89) | 37.4% (9.0%, 65.8%) | 0.0278* | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 10 (71%) | 19 | 8 (42%) | 3.44 (0.79, 15.02) | 1.70 (0.91, 3.16) | 29.3% (-3.1%, 61.8%) | 0.1582 | 0.5573 |
| >= 1 Year | 60 | 39 (65%) | 51 | 24 (47%) | 2.09 (0.97, 4.49) | 1.38 (0.98, 1.95) | 17.9% (-0.3%, 36.2%) | 0.0832 | |
| Not Reported | 0 | 0 | 2 | 0 (0.0%) | NE | NE | NE | NE | |

Notes:
Analysis on overall population is calculated based on stratified Generalized Linear Models, for OR, RR, and RD, stratified by by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
Analysis on subgroups uses unstratified, unstandardized methods for calculating OR, RR, and RD.
[1] Unstratified Logistic Regression p-values are presented for all subgroups.
[2] Estimates from unstratified Logistic Regression for interaction effect are presented for all subgroups.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.
Analysis Cut Off date: 10SEP2020
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TABLE 2.15: Binary Outcome Analysis: Objective response rate (ORR) per Independent Radiology Review Committee (IRC) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | Sunitinib | | Sunitinib vs. Nivolumab + Cabozantinib | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Population | n | Events (%) | n | Events (%) | OR (95% CI) | RR (95% CI) | RD (95% CI) | CMH or Logistic Regression p-value [1] | P-val [2] for trt*subgroup interaction |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 7 (64%) | 13 | 6 (46%) | 2.04 (0.40, 10.55) | 1.38 (0.66, 2.88) | 17.5% (-21.8%, 56.8%) | 0.4442 | 0.8121 |
| Yes | 63 | 42 (67%) | 59 | 26 (44%) | 2.54 (1.22, 5.29) | 1.51 (1.08, 2.12) | 22.6% (5.4%, 39.8%) | 0.0175* | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 46 (72%) | 66 | 31 (47%) | 2.89 (1.39, 5.98) | 1.53 (1.14, 2.06) | 24.9% (8.6%, 41.2%) | 0.0045* | 0.2104 |
| Yes | 10 | 3 (30%) | 6 | 1 (17%) | 2.14 (0.17, 27.10) | 1.80 (0.24, 13.63) | 13.3% (-27.8%, 54.5%) | 1.0000 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 8 (73%) | 10 | 4 (40%) | 4.00 (0.64, 25.02) | 1.82 (0.78, 4.22) | 32.7% (-7.5%, 72.9%) | 0.1984 | 0.1298 |
| < 1% | 61 | 41 (67%) | 61 | 27 (44%) | 2.58 (1.24, 5.39) | 1.52 (1.09, 2.12) | 23.0% (5.8%, 40.1%) | 0.0174* | |
| Not Reported | 2 | 0 (0.0%) | 1 | 1 (100%) | 0.07 (0.00, 5.49) | 0.22 (0.02, 3.16) | -58.3% (-100.0%, 15.0%) | 0.3333 | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 11 (61%) | 21 | 9 (43%) | 2.10 (0.58, 7.56) | 1.43 (0.77, 2.64) | 18.3% (-12.7%, 49.2%) | 0.3406 | 0.6222 |
| Non-Stage IV | 53 | 37 (70%) | 51 | 23 (45%) | 2.82 (1.26, 6.30) | 1.55 (1.09, 2.20) | 24.7% (6.3%, 43.1%) | 0.0168* | |
| Not Reported | 3 | 1 (33%) | 0 | 0 | NE | NE | NE | NE | |

Notes:
Analysis on overall population is calculated based on stratified Generalized Linear Models, for OR, RR, and RD, stratified by by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
Analysis on subgroups uses unstratified, unstandardized methods for calculating OR, RR, and RD.
[1] Unstratified Logistic Regression p-values are presented for all subgroups.
[2] Estimates from unstratified Logistic Regression for interaction effect are presented for all subgroups.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.
Analysis Cut Off date: 10SEP2020
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TABLE 3.1.1: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 74 (100.0%) | 71 (100.0%) |
| Number of censored cases | N | 0 (0.0%) | 0 (0.0%) |
| Time to first event (Months) | Mean (SE) | 0.58 (0.08) | 0.71 (0.18) |
| | Q1 [95% CI] | 0.20 [0.07;0.26] | 0.20 [0.10;0.30] |
| | Median [95% CI] | 0.46 [0.26;0.49] | 0.39 [0.33;0.49] |
| | Q3 [95% CI] | 0.60 [0.49;0.95] | 0.60 [0.49;0.72] |
| | p-value (a) | 0.8761 | |
| Stratified Cox PH model | HR (b) | 0.98 [0.70;1.37] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:06:07

TABLE 3.1.2: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 74 (100.0%) | 0.46 [0.26;0.49] | 71 | 71 (100.0%) | 0.39 [0.33;0.49] | 0.98 [0.70;1.37] | 0.8761 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 41 (100.0%) | 0.30 [0.13;0.49] | 47 | 47 (100.0%) | 0.43 [0.36;0.53] | 1.18 [0.77;1.81] | 0.4225 | 0.1981 |
| >= 65 | 33 | 33 (100.0%) | 0.46 [0.33;0.49] | 24 | 24 (100.0%) | 0.36 [0.13;0.49] | 0.74 [0.43;1.27] | 0.2337 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 41 (100.0%) | 0.30 [0.13;0.49] | 47 | 47 (100.0%) | 0.43 [0.36;0.53] | 1.18 [0.77;1.81] | 0.4225 | 0.3487 |
| >= 65 AND < 75 | 25 | 25 (100.0%) | 0.46 [0.26;0.49] | 18 | 18 (100.0%) | 0.36 [0.13;0.49] | 0.81 [0.44;1.49] | 0.4634 | |
| >= 75 | 8 | 8 (100.0%) | 0.48 [0.03;0.99] | 6 | 6 (100.0%) | 0.38 [0.07;0.66] | 0.69 [0.22;2.15] | 0.4777 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 39 (100.0%) | 0.46 [0.13;0.56] | 37 | 37 (100.0%) | 0.43 [0.20;0.66] | 1.00 [0.63;1.59] | 0.9740 | 0.8612 |
| Rest of World (ROW) | 35 | 35 (100.0%) | 0.43 [0.26;0.46] | 34 | 34 (100.0%) | 0.38 [0.30;0.53] | 1.07 [0.66;1.73] | 0.8161 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.1.2: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 65 (100.0%) | 0.46 [0.30;0.49] | 60 | 60 (100.0%) | 0.39 [0.30;0.53] | 1.05 [0.73;1.50] | 0.8224 | 0.8909 |
| Non-White | 9 | 9 (100.0%) | 0.26 [0.07;0.49] | 11 | 11 (100.0%) | 0.43 [0.07;0.46] | 1.01 [0.40;2.52] | 0.9598 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 7 (100.0%) | 0.43 [0.03;1.31] | 13 | 13 (100.0%) | 0.33 [0.07;0.49] | 0.86 [0.34;2.22] | 0.7562 | 0.9071 |
| Not Hispanic or Latino | 43 | 43 (100.0%) | 0.46 [0.26;0.49] | 32 | 32 (100.0%) | 0.41 [0.20;0.49] | 0.96 [0.60;1.53] | 0.8339 | |
| Not Reported | 24 | 24 (100.0%) | 0.44 [0.10;0.49] | 26 | 26 (100.0%) | 0.43 [0.30;0.66] | 1.03 [0.58;1.82] | 0.9658 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 56 (100.0%) | 0.46 [0.26;0.49] | 48 | 48 (100.0%) | 0.43 [0.30;0.66] | 1.13 [0.76;1.67] | 0.5439 | 0.3573 |
| Female | 18 | 18 (100.0%) | 0.43 [0.26;0.49] | 23 | 23 (100.0%) | 0.36 [0.20;0.46] | 0.76 [0.40;1.45] | 0.3786 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 14 (100.0%) | 0.39 [0.13;0.95] | 19 | 19 (100.0%) | 0.33 [0.16;0.53] | 0.59 [0.28;1.24] | 0.1434 | 0.2264 |
| >= 1 Year | 60 | 60 (100.0%) | 0.46 [0.26;0.49] | 50 | 50 (100.0%) | 0.41 [0.36;0.49] | 1.13 [0.77;1.65] | 0.5442 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.1.2: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 11 (100.0%) | 0.43 [0.10;0.49] | 12 | 12 (100.0%) | 0.46 [0.10;0.72] | 1.58 [0.67;3.71] | 0.3309 | 0.3869 |
| Yes | 63 | 63 (100.0%) | 0.46 [0.26;0.49] | 59 | 59 (100.0%) | 0.39 [0.30;0.46] | 0.97 [0.68;1.39] | 0.8275 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 64 (100.0%) | 0.46 [0.26;0.49] | 65 | 65 (100.0%) | 0.39 [0.30;0.49] | 1.02 [0.72;1.44] | 0.9655 | 0.9639 |
| Yes | 10 | 10 (100.0%) | 0.43 [0.03;0.49] | 6 | 6 (100.0%) | 0.44 [0.13;0.99] | 0.96 [0.34;2.71] | 0.9790 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 11 (100.0%) | 0.26 [0.10;0.49] | 10 | 10 (100.0%) | 0.39 [0.03;1.25] | 1.49 [0.61;3.65] | 0.3554 | 0.0533 |
| < 1% | 61 | 61 (100.0%) | 0.46 [0.30;0.49] | 60 | 60 (100.0%) | 0.41 [0.33;0.49] | 0.95 [0.66;1.36] | 0.7357 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 18 (100.0%) | 0.48 [0.46;0.82] | 20 | 20 (100.0%) | 0.48 [0.10;0.69] | 0.69 [0.36;1.35] | 0.2604 | 0.4319 |
| Non-Stage IV | 53 | 53 (100.0%) | 0.33 [0.23;0.49] | 51 | 51 (100.0%) | 0.39 [0.26;0.46] | 1.09 [0.74;1.61] | 0.6772 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.2.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 74 (100.0%) | 71 (100.0%) |
| Number of censored cases | N | 0 (0.0%) | 0 (0.0%) |
| Time to first event (Months) | Mean (SE) | 0.58 (0.08) | 0.71 (0.18) |
| | Q1 [95% CI] | 0.20 [0.07;0.26] | 0.20 [0.10;0.30] |
| | Median [95% CI] | 0.46 [0.26;0.49] | 0.39 [0.33;0.49] |
| | Q3 [95% CI] | 0.60 [0.49;0.95] | 0.60 [0.49;0.72] |
| | p-value (a) | 0.8761 | |
| Stratified Cox PH model | HR (b) | 0.98 [0.70;1.37] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.2.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 74 (100.0%) | 0.46 [0.26;0.49] | 71 | 71 (100.0%) | 0.39 [0.33;0.49] | 0.98 [0.70;1.37] | 0.8761 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 41 (100.0%) | 0.30 [0.13;0.49] | 47 | 47 (100.0%) | 0.43 [0.36;0.53] | 1.18 [0.77;1.81] | 0.4225 | 0.1981 |
| >= 65 | 33 | 33 (100.0%) | 0.46 [0.33;0.49] | 24 | 24 (100.0%) | 0.36 [0.13;0.49] | 0.74 [0.43;1.27] | 0.2337 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 41 (100.0%) | 0.30 [0.13;0.49] | 47 | 47 (100.0%) | 0.43 [0.36;0.53] | 1.18 [0.77;1.81] | 0.4225 | 0.3487 |
| >= 65 AND < 75 | 25 | 25 (100.0%) | 0.46 [0.26;0.49] | 18 | 18 (100.0%) | 0.36 [0.13;0.49] | 0.81 [0.44;1.49] | 0.4634 | |
| >= 75 | 8 | 8 (100.0%) | 0.48 [0.03;0.99] | 6 | 6 (100.0%) | 0.38 [0.07;0.66] | 0.69 [0.22;2.15] | 0.4777 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 39 (100.0%) | 0.46 [0.13;0.56] | 37 | 37 (100.0%) | 0.43 [0.20;0.66] | 1.00 [0.63;1.59] | 0.9740 | 0.8612 |
| Rest of World (ROW) | 35 | 35 (100.0%) | 0.43 [0.26;0.46] | 34 | 34 (100.0%) | 0.38 [0.30;0.53] | 1.07 [0.66;1.73] | 0.8161 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.2.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 65 (100.0%) | 0.46 [0.30;0.49] | 60 | 60 (100.0%) | 0.39 [0.30;0.53] | 1.05 [0.73;1.50] | 0.8224 | 0.8909 |
| Non-White | 9 | 9 (100.0%) | 0.26 [0.07;0.49] | 11 | 11 (100.0%) | 0.43 [0.07;0.46] | 1.01 [0.40;2.52] | 0.9598 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 7 (100.0%) | 0.43 [0.03;1.31] | 13 | 13 (100.0%) | 0.33 [0.07;0.49] | 0.86 [0.34;2.22] | 0.7562 | 0.9071 |
| Not Hispanic or Latino | 43 | 43 (100.0%) | 0.46 [0.26;0.49] | 32 | 32 (100.0%) | 0.41 [0.20;0.49] | 0.96 [0.60;1.53] | 0.8339 | |
| Not Reported | 24 | 24 (100.0%) | 0.44 [0.10;0.49] | 26 | 26 (100.0%) | 0.43 [0.30;0.66] | 1.03 [0.58;1.82] | 0.9658 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 56 (100.0%) | 0.46 [0.26;0.49] | 48 | 48 (100.0%) | 0.43 [0.30;0.66] | 1.13 [0.76;1.67] | 0.5439 | 0.3573 |
| Female | 18 | 18 (100.0%) | 0.43 [0.26;0.49] | 23 | 23 (100.0%) | 0.36 [0.20;0.46] | 0.76 [0.40;1.45] | 0.3786 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 14 (100.0%) | 0.39 [0.13;0.95] | 19 | 19 (100.0%) | 0.33 [0.16;0.53] | 0.59 [0.28;1.24] | 0.1434 | 0.2264 |
| >= 1 Year | 60 | 60 (100.0%) | 0.46 [0.26;0.49] | 50 | 50 (100.0%) | 0.41 [0.36;0.49] | 1.13 [0.77;1.65] | 0.5442 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.2.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 11 (100.0%) | 0.43 [0.10;0.49] | 12 | 12 (100.0%) | 0.46 [0.10;0.72] | 1.58 [0.67;3.71] | 0.3309 | 0.3869 |
| Yes | 63 | 63 (100.0%) | 0.46 [0.26;0.49] | 59 | 59 (100.0%) | 0.39 [0.30;0.46] | 0.97 [0.68;1.39] | 0.8275 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 64 (100.0%) | 0.46 [0.26;0.49] | 65 | 65 (100.0%) | 0.39 [0.30;0.49] | 1.02 [0.72;1.44] | 0.9655 | 0.9639 |
| Yes | 10 | 10 (100.0%) | 0.43 [0.03;0.49] | 6 | 6 (100.0%) | 0.44 [0.13;0.99] | 0.96 [0.34;2.71] | 0.9790 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 11 (100.0%) | 0.26 [0.10;0.49] | 10 | 10 (100.0%) | 0.39 [0.03;1.25] | 1.49 [0.61;3.65] | 0.3554 | 0.0533 |
| < 1% | 61 | 61 (100.0%) | 0.46 [0.30;0.49] | 60 | 60 (100.0%) | 0.41 [0.33;0.49] | 0.95 [0.66;1.36] | 0.7357 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 18 (100.0%) | 0.48 [0.46;0.82] | 20 | 20 (100.0%) | 0.48 [0.10;0.69] | 0.69 [0.36;1.35] | 0.2604 | 0.4319 |
| Non-Stage IV | 53 | 53 (100.0%) | 0.33 [0.23;0.49] | 51 | 51 (100.0%) | 0.39 [0.26;0.46] | 1.09 [0.74;1.61] | 0.6772 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.3.1: Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 58 (78.4%) | 51 (71.8%) |
| Number of censored cases | N | 16 (21.6%) | 20 (28.2%) |
| Time to first event (Months) | Mean (SE) | 8.38 (1.00) | 9.24 (1.24) |
| | Q1 [95% CI] | 1.40 [0.92;1.77] | 1.00 [0.69;2.04] |
| | Median [95% CI] | 3.24 [2.40;8.08] | 3.68 [2.07;5.68] |
| | Q3 [95% CI] | 17.40 [9.17;NYR] | 24.40 [7.23;NYR] |
| | p-value (a) | 0.9044 | |
| Stratified Cox PH model | HR (b) | 0.98 [0.67;1.43] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 3.3.2: Treatment Emergent AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 58 (78.4%) | 3.24 [2.40;8.08] | 71 | 51 (71.8%) | 3.68 [2.07;5.68] | 0.98 [0.67;1.43] | 0.9044 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 29 (70.7%) | 9.03 [2.66;16.43] | 47 | 30 (63.8%) | 4.44 [2.10;24.41] | 1.00 [0.60;1.66] | 0.9934 | 0.7728 |
| >= 65 | 33 | 29 (87.9%) | 2.40 [1.38;3.22] | 24 | 21 (87.5%) | 2.09 [0.69;5.42] | 0.88 [0.50;1.55] | 0.6396 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 29 (70.7%) | 9.03 [2.66;16.43] | 47 | 30 (63.8%) | 4.44 [2.10;24.41] | 1.00 [0.60;1.66] | 0.9934 | 0.2816 |
| >= 65 AND < 75 | 25 | 23 (92.0%) | 2.40 [1.35;3.38] | 18 | 16 (88.9%) | 2.76 [0.95;7.23] | 1.13 [0.59;2.14] | 0.7108 | |
| >= 75 | 8 | 6 (75.0%) | 2.05 [0.46;22.18] | 6 | 5 (83.3%) | 0.77 [0.56;NYR] | 0.41 [0.12;1.48] | 0.1669 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 29 (74.4%) | 2.99 [1.45;9.95] | 37 | 22 (59.5%) | 5.68 [2.10;NYR] | 1.35 [0.77;2.35] | 0.2902 | 0.1448 |
| Rest of World (ROW) | 35 | 29 (82.9%) | 5.03 [1.64;8.08] | 34 | 29 (85.3%) | 2.14 [1.02;3.88] | 0.77 [0.46;1.28] | 0.3105 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.3.2: Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 51 (78.5%) | 3.09 [1.87;6.93] | 60 | 43 (71.7%) | 3.68 [2.07;7.23] | 1.08 [0.72;1.62] | 0.7087 | 0.5505 |
| Non-White | 9 | 7 (77.8%) | 13.31 [0.95;17.45] | 11 | 8 (72.7%) | 3.22 [0.66;NYR] | 0.72 [0.26;2.00] | 0.5323 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 6 (85.7%) | 7.85 [0.49;9.43] | 13 | 11 (84.6%) | 2.14 [0.49;5.78] | 0.80 [0.29;2.23] | 0.6695 | 0.0618 |
| Not Hispanic or Latino | 43 | 35 (81.4%) | 2.66 [1.58;5.03] | 32 | 18 (56.3%) | 4.12 [2.04;NYR] | 1.63 [0.92;2.89] | 0.0889 | |
| Not Reported | 24 | 17 (70.8%) | 7.98 [1.41;22.18] | 26 | 22 (84.6%) | 3.68 [0.99;7.23] | 0.58 [0.31;1.11] | 0.0964 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 44 (78.6%) | 3.15 [2.40;9.03] | 48 | 31 (64.6%) | 3.71 [2.07;24.61] | 1.20 [0.76;1.90] | 0.4360 | 0.2603 |
| Female | 18 | 14 (77.8%) | 4.47 [0.95;15.87] | 23 | 20 (87.0%) | 2.30 [0.85;5.78] | 0.74 [0.37;1.48] | 0.3915 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 13 (92.9%) | 5.29 [1.35;12.58] | 19 | 14 (73.7%) | 2.50 [1.25;7.56] | 1.07 [0.50;2.29] | 0.8618 | 0.9587 |
| >= 1 Year | 60 | 45 (75.0%) | 3.15 [1.77;9.17] | 50 | 35 (70.0%) | 4.37 [2.04;10.35] | 1.07 [0.69;1.66] | 0.7754 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.3.2: Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 9 (81.8%) | 3.38 [0.49;20.11] | 12 | 8 (66.7%) | 2.09 [1.02;NYR] | 1.05 [0.40;2.74] | 0.9321 | 0.9892 |
| Yes | 63 | 49 (77.8%) | 3.09 [2.17;8.08] | 59 | 43 (72.9%) | 3.88 [2.10;5.78] | 1.02 [0.68;1.54] | 0.9209 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 49 (76.6%) | 4.14 [1.87;9.03] | 65 | 45 (69.2%) | 3.71 [2.10;7.56] | 1.06 [0.70;1.58] | 0.7981 | 0.3472 |
| Yes | 10 | 9 (90.0%) | 2.71 [0.26;9.66] | 6 | 6 (100.0%) | 1.53 [0.62;5.49] | 0.56 [0.18;1.68] | 0.2917 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 10 (90.9%) | 9.03 [0.99;9.95] | 10 | 8 (80.0%) | 3.09 [0.36;10.35] | 1.04 [0.40;2.66] | 0.9405 | 0.9864 |
| < 1% | 61 | 46 (75.4%) | 3.22 [1.87;7.85] | 60 | 43 (71.7%) | 3.45 [2.07;5.78] | 0.98 [0.65;1.49] | 0.9283 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 17 (94.4%) | 2.48 [0.92;5.03] | 20 | 14 (70.0%) | 3.58 [1.35;10.35] | 1.75 [0.86;3.56] | 0.1195 | 0.0734 |
| Non-Stage IV | 53 | 38 (71.7%) | 6.93 [2.53;13.31] | 51 | 37 (72.5%) | 3.68 [1.77;5.78] | 0.83 [0.53;1.31] | 0.4156 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.4.1: Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 59 (79.7%) | 51 (71.8%) |
| Number of censored cases | N | 15 (20.3%) | 20 (28.2%) |
| Time to first event (Months) | Mean (SE) | 8.30 (0.99) | 9.39 (1.24) |
| | Q1 [95% CI] | 1.40 [0.92;1.77] | 1.00 [0.69;2.04] |
| | Median [95% CI] | 3.24 [2.40;8.08] | 3.68 [2.07;5.78] |
| | Q3 [95% CI] | 16.40 [9.17;NYR] | 24.40 [7.56;NYR] |
| | p-value (a) | 0.9263 | |
| Stratified Cox PH model | HR (b) | 1.02 [0.70;1.49] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 3.4.2: Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 59 (79.7%) | 3.24 [2.40;8.08] | 71 | 51 (71.8%) | 3.68 [2.07;5.78] | 1.02 [0.70;1.49] | 0.9263 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 29 (70.7%) | 9.03 [2.66;16.43] | 47 | 30 (63.8%) | 4.44 [2.10;24.41] | 1.02 [0.61;1.70] | 0.9345 | 0.8359 |
| >= 65 | 33 | 30 (90.9%) | 2.40 [1.38;3.22] | 24 | 21 (87.5%) | 2.09 [0.69;5.42] | 0.92 [0.52;1.62] | 0.7682 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 29 (70.7%) | 9.03 [2.66;16.43] | 47 | 30 (63.8%) | 4.44 [2.10;24.41] | 1.02 [0.61;1.70] | 0.9345 | 0.4258 |
| >= 65 AND < 75 | 25 | 23 (92.0%) | 2.40 [1.35;3.38] | 18 | 16 (88.9%) | 2.76 [0.95;7.23] | 1.13 [0.59;2.14] | 0.7153 | |
| >= 75 | 8 | 7 (87.5%) | 2.05 [0.46;22.18] | 6 | 5 (83.3%) | 0.77 [0.56;NYR] | 0.41 [0.12;1.48] | 0.1669 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 30 (76.9%) | 2.99 [1.45;9.95] | 37 | 22 (59.5%) | 5.68 [2.10;NYR] | 1.41 [0.81;2.44] | 0.2215 | 0.1190 |
| Rest of World (ROW) | 35 | 29 (82.9%) | 5.03 [1.64;8.08] | 34 | 29 (85.3%) | 2.32 [1.02;5.42] | 0.78 [0.46;1.31] | 0.3460 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.4.2: Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 52 (80.0%) | 3.09 [1.87;6.93] | 60 | 43 (71.7%) | 3.70 [2.07;7.23] | 1.13 [0.75;1.69] | 0.5681 | 0.4996 |
| Non-White | 9 | 7 (77.8%) | 13.31 [0.95;17.45] | 11 | 8 (72.7%) | 3.22 [0.66;NYR] | 0.67 [0.24;1.88] | 0.4520 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 6 (85.7%) | 7.85 [0.49;9.43] | 13 | 11 (84.6%) | 2.14 [0.49;5.78] | 0.82 [0.30;2.29] | 0.7069 | 0.0840 |
| Not Hispanic or Latino | 43 | 35 (81.4%) | 2.66 [1.58;5.03] | 32 | 18 (56.3%) | 4.12 [2.04;NYR] | 1.65 [0.93;2.92] | 0.0819 | |
| Not Reported | 24 | 18 (75.0%) | 7.98 [1.41;17.45] | 26 | 22 (84.6%) | 4.55 [0.99;7.56] | 0.63 [0.33;1.18] | 0.1469 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 45 (80.4%) | 3.15 [2.40;9.03] | 48 | 31 (64.6%) | 4.04 [2.07;24.61] | 1.25 [0.79;1.97] | 0.3448 | 0.2454 |
| Female | 18 | 14 (77.8%) | 4.47 [0.95;15.87] | 23 | 20 (87.0%) | 2.30 [0.85;5.78] | 0.74 [0.37;1.49] | 0.3997 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 14 (100.0%) | 5.29 [1.35;12.58] | 19 | 14 (73.7%) | 2.50 [1.25;7.56] | 1.17 [0.56;2.46] | 0.6819 | 0.8304 |
| >= 1 Year | 60 | 45 (75.0%) | 3.15 [1.77;9.17] | 50 | 35 (70.0%) | 4.37 [2.04;13.11] | 1.09 [0.70;1.69] | 0.7116 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.4.2: Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 9 (81.8%) | 3.38 [0.49;20.11] | 12 | 8 (66.7%) | 2.09 [1.02;NYR] | 1.05 [0.40;2.74] | 0.9321 | 0.9835 |
| Yes | 63 | 50 (79.4%) | 3.09 [2.17;8.08] | 59 | 43 (72.9%) | 3.88 [2.10;7.23] | 1.06 [0.71;1.60] | 0.7830 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 50 (78.1%) | 4.14 [1.87;9.03] | 65 | 45 (69.2%) | 3.71 [2.10;7.56] | 1.09 [0.73;1.64] | 0.6694 | 0.3146 |
| Yes | 10 | 9 (90.0%) | 2.71 [0.26;9.66] | 6 | 6 (100.0%) | 1.53 [0.62;5.49] | 0.56 [0.18;1.68] | 0.2917 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 11 (100.0%) | 9.03 [0.99;9.95] | 10 | 8 (80.0%) | 3.09 [0.36;10.35] | 1.15 [0.46;2.91] | 0.7587 | 0.9502 |
| < 1% | 61 | 46 (75.4%) | 3.22 [1.87;7.85] | 60 | 43 (71.7%) | 3.56 [2.07;5.78] | 1.00 [0.66;1.51] | 0.9881 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 17 (94.4%) | 2.48 [0.92;5.03] | 20 | 14 (70.0%) | 3.58 [1.35;10.35] | 1.77 [0.87;3.61] | 0.1108 | 0.0858 |
| Non-Stage IV | 53 | 39 (73.6%) | 6.93 [2.53;12.98] | 51 | 37 (72.5%) | 3.68 [1.77;5.78] | 0.87 [0.55;1.36] | 0.5281 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.5.1: Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Serious Treatment Emergent Adverse Events - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 35 (47.3%) | 21 (29.6%) |
| Number of censored cases | N | 39 (52.7%) | 50 (70.4%) |
| Time to first event (Months) | Mean (SE) | 13.63 (0.88) | 18.46 (1.20) |
| | Q1 [95% CI] | 5.40 [2.73;9.95] | 5.80 [2.30;NYR] |
| | Median [95% CI] | 19.58 [14.16;NYR] | NYR [24.61;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.1000 | |
| Stratified Cox PH model | HR (b) | 1.58 [0.91;2.74] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 3.5.2: Serious Treatment Emergent Adverse Events - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 35 (47.3%) | 19.58 [14.16;NYR] | 71 | 21 (29.6%) | NYR [24.61;NYR] | 1.58 [0.91;2.74] | 0.1000 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 17 (41.5%) | NYR [15.61;NYR] | 47 | 12 (25.5%) | NYR [24.61;NYR] | 1.55 [0.74;3.25] | 0.2423 | 0.8046 |
| >= 65 | 33 | 18 (54.5%) | 14.69 [5.36;NYR] | 24 | 9 (37.5%) | NYR [2.37;NYR] | 1.34 [0.60;2.99] | 0.4673 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 17 (41.5%) | NYR [15.61;NYR] | 47 | 12 (25.5%) | NYR [24.61;NYR] | 1.55 [0.74;3.25] | 0.2423 | 0.6857 |
| >= 65 AND < 75 | 25 | 14 (56.0%) | 14.69 [5.16;NYR] | 18 | 8 (44.4%) | NYR [2.30;NYR] | 1.14 [0.48;2.71] | 0.7745 | |
| >= 75 | 8 | 4 (50.0%) | NYR [1.51;NYR] | 6 | 1 (16.7%) | NYR [0.85;NYR] | 2.81 [0.31;25.20] | 0.3349 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 17 (43.6%) | 19.58 [14.16;NYR] | 37 | 14 (37.8%) | NYR [5.49;NYR] | 0.97 [0.48;1.98] | 0.9411 | 0.0624 |
| Rest of World (ROW) | 35 | 18 (51.4%) | 18.86 [5.78;NYR] | 34 | 7 (20.6%) | NYR [24.61;NYR] | 2.81 [1.17;6.73] | 0.0157 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.5.2: Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 32 (49.2%) | 18.89 [9.95;NYR] | 60 | 21 (35.0%) | NYR [24.61;NYR] | 1.36 [0.78;2.35] | 0.2778 | 0.9864 |
| Non-White | 9 | 3 (33.3%) | NYR [7.85;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0780 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 6 (85.7%) | 7.85 [3.22;18.89] | 13 | 5 (38.5%) | 24.61 [2.37;NYR] | 2.72 [0.76;9.72] | 0.1089 | 0.4878 |
| Not Hispanic or Latino | 43 | 20 (46.5%) | 19.58 [9.95;NYR] | 32 | 12 (37.5%) | NYR [4.17;NYR] | 1.20 [0.59;2.46] | 0.6200 | |
| Not Reported | 24 | 9 (37.5%) | NYR [14.69;NYR] | 26 | 4 (15.4%) | NYR [NYR;NYR] | 2.42 [0.75;7.88] | 0.1279 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 27 (48.2%) | 19.58 [9.95;NYR] | 48 | 12 (25.0%) | NYR [24.61;NYR] | 1.98 [1.00;3.90] | 0.0456 | 0.2262 |
| Female | 18 | 8 (44.4%) | NYR [5.78;NYR] | 23 | 9 (39.1%) | NYR [2.37;NYR] | 0.94 [0.36;2.45] | 0.9037 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 8 (57.1%) | 14.16 [5.03;NYR] | 19 | 7 (36.8%) | NYR [4.17;NYR] | 1.52 [0.55;4.21] | 0.4121 | 0.9330 |
| >= 1 Year | 60 | 27 (45.0%) | 19.58 [14.69;NYR] | 50 | 13 (26.0%) | NYR [24.61;NYR] | 1.65 [0.85;3.20] | 0.1337 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.5.2: Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 5 (45.5%) | NYR [3.22;NYR] | 12 | 3 (25.0%) | NYR [1.54;NYR] | 1.72 [0.41;7.20] | 0.4553 | 0.8716 |
| Yes | 63 | 30 (47.6%) | 19.58 [12.65;NYR] | 59 | 18 (30.5%) | NYR [24.61;NYR] | 1.52 [0.85;2.73] | 0.1578 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 27 (42.2%) | NYR [15.61;NYR] | 65 | 19 (29.2%) | NYR [24.61;NYR] | 1.36 [0.75;2.44] | 0.3091 | 0.3608 |
| Yes | 10 | 8 (80.0%) | 7.49 [0.26;18.86] | 6 | 2 (33.3%) | NYR [0.72;NYR] | 3.09 [0.65;14.63] | 0.1345 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 6 (54.5%) | 18.89 [9.82;NYR] | 10 | 5 (50.0%) | NYR [1.25;NYR] | 0.79 [0.24;2.61] | 0.6989 | 0.6241 |
| < 1% | 61 | 27 (44.3%) | NYR [14.16;NYR] | 60 | 16 (26.7%) | NYR [24.61;NYR] | 1.64 [0.88;3.04] | 0.1157 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 9 (50.0%) | 17.18 [5.03;NYR] | 20 | 7 (35.0%) | NYR [4.17;NYR] | 1.46 [0.54;3.93] | 0.4514 | 0.9491 |
| Non-Stage IV | 53 | 24 (45.3%) | NYR [14.69;NYR] | 51 | 14 (27.5%) | NYR [24.61;NYR] | 1.54 [0.79;2.97] | 0.1996 | |
| Not Reported | 3 | 2 (66.7%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.6.1: Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 37 (50.0%) | 23 (32.4%) |
| Number of censored cases | N | 37 (50.0%) | 48 (67.6%) |
| Time to first event (Months) | Mean (SE) | 13.47 (0.87) | 18.31 (1.18) |
| | Q1 [95% CI] | 5.40 [2.73;9.89] | 5.80 [2.30;24.61] |
| | Median [95% CI] | 18.89 [12.65;NYR] | NYR [21.29;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0862 | |
| Stratified Cox PH model | HR (b) | 1.58 [0.93;2.69] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.6.2: Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 37 (50.0%) | 18.89 [12.65;NYR] | 71 | 23 (32.4%) | NYR [21.29;NYR] | 1.58 [0.93;2.69] | 0.0862 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 17 (41.5%) | NYR [15.61;NYR] | 47 | 13 (27.7%) | NYR [24.61;NYR] | 1.46 [0.71;3.02] | 0.2980 | 0.9568 |
| >= 65 | 33 | 20 (60.6%) | 14.16 [5.36;NYR] | 24 | 10 (41.7%) | 21.29 [2.37;NYR] | 1.40 [0.65;2.99] | 0.3875 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 17 (41.5%) | NYR [15.61;NYR] | 47 | 13 (27.7%) | NYR [24.61;NYR] | 1.46 [0.71;3.02] | 0.2980 | 0.5587 |
| >= 65 AND < 75 | 25 | 15 (60.0%) | 14.69 [5.16;NYR] | 18 | 9 (50.0%) | 21.29 [2.30;NYR] | 1.13 [0.49;2.58] | 0.7780 | |
| >= 75 | 8 | 5 (62.5%) | 11.25 [1.51;NYR] | 6 | 1 (16.7%) | NYR [0.85;NYR] | 3.50 [0.41;30.10] | 0.2233 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 18 (46.2%) | 19.58 [12.98;NYR] | 37 | 15 (40.5%) | NYR [5.49;NYR] | 0.98 [0.50;1.96] | 0.9651 | 0.0701 |
| Rest of World (ROW) | 35 | 19 (54.3%) | 15.61 [5.78;NYR] | 34 | 8 (23.5%) | NYR [24.61;NYR] | 2.70 [1.18;6.19] | 0.0142 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.6.2: Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 34 (52.3%) | 18.86 [9.89;NYR] | 60 | 23 (38.3%) | 24.61 [20.86;NYR] | 1.35 [0.79;2.28] | 0.2715 | 0.9859 |
| Non-White | 9 | 3 (33.3%) | NYR [7.85;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0721 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 6 (85.7%) | 7.85 [3.22;18.89] | 13 | 6 (46.2%) | 24.61 [2.37;NYR] | 2.54 [0.76;8.45] | 0.1173 | 0.3892 |
| Not Hispanic or Latino | 43 | 21 (48.8%) | 19.58 [9.89;NYR] | 32 | 13 (40.6%) | NYR [4.17;NYR] | 1.17 [0.58;2.33] | 0.6631 | |
| Not Reported | 24 | 10 (41.7%) | NYR [12.98;NYR] | 26 | 4 (15.4%) | NYR [NYR;NYR] | 2.79 [0.87;8.90] | 0.0706 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 28 (50.0%) | 18.89 [9.95;NYR] | 48 | 14 (29.2%) | 24.61 [21.29;NYR] | 1.81 [0.95;3.44] | 0.0666 | 0.4047 |
| Female | 18 | 9 (50.0%) | 17.18 [5.78;NYR] | 23 | 9 (39.1%) | NYR [2.37;NYR] | 1.06 [0.42;2.68] | 0.8974 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 9 (64.3%) | 13.57 [5.03;NYR] | 19 | 8 (42.1%) | NYR [4.17;NYR] | 1.49 [0.58;3.88] | 0.4061 | 0.9143 |
| >= 1 Year | 60 | 28 (46.7%) | 19.58 [12.65;NYR] | 50 | 14 (28.0%) | NYR [21.29;NYR] | 1.65 [0.87;3.13] | 0.1245 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:43:21

TABLE 3.6.2: Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 5 (45.5%) | NYR [3.22;NYR] | 12 | 4 (33.3%) | NYR [1.54;NYR] | 1.36 [0.36;5.06] | 0.6492 | 0.8097 |
| Yes | 63 | 32 (50.8%) | 18.89 [9.95;NYR] | 59 | 19 (32.2%) | NYR [21.29;NYR] | 1.58 [0.89;2.78] | 0.1134 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 29 (45.3%) | NYR [14.69;NYR] | 65 | 20 (30.8%) | NYR [24.61;NYR] | 1.41 [0.80;2.50] | 0.2339 | 0.5998 |
| Yes | 10 | 8 (80.0%) | 7.49 [0.26;18.86] | 6 | 3 (50.0%) | 21.29 [0.72;21.29] | 2.20 [0.58;8.38] | 0.2368 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 7 (63.6%) | 15.61 [9.82;NYR] | 10 | 5 (50.0%) | NYR [1.25;NYR] | 0.95 [0.30;3.01] | 0.9282 | 0.8070 |
| < 1% | 61 | 28 (45.9%) | NYR [14.16;NYR] | 60 | 18 (30.0%) | NYR [21.29;NYR] | 1.55 [0.86;2.81] | 0.1420 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 9 (50.0%) | 17.18 [5.03;NYR] | 20 | 8 (40.0%) | NYR [4.17;NYR] | 1.31 [0.50;3.39] | 0.5853 | 0.7203 |
| Non-Stage IV | 53 | 26 (49.1%) | 19.58 [12.65;NYR] | 51 | 15 (29.4%) | NYR [21.29;NYR] | 1.59 [0.84;3.01] | 0.1479 | |
| Not Reported | 3 | 2 (66.7%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.7.1: Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 24 (32.4%) | 12 (16.9%) |
| Number of censored cases | N | 50 (67.6%) | 59 (83.1%) |
| Time to first event (Months) | Mean (SE) | 17.21 (0.91) | 13.16 (0.59) |
| | Q1 [95% CI] | 14.20 [5.49;21.95] | NYR [5.52;NYR] |
| | Median [95% CI] | NYR [21.95;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0948 | |
| Stratified Cox PH model | HR (b) | 1.79 [0.90;3.59] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 3.7.2: Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 24 (32.4%) | NYR [21.95;NYR] | 71 | 12 (16.9%) | NYR [NYR;NYR] | 1.79 [0.90;3.59] | 0.0948 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 9 (22.0%) | NYR [NYR;NYR] | 47 | 4 (8.5%) | NYR [NYR;NYR] | 2.03 [0.62;6.63] | 0.2330 | 0.5418 |
| >= 65 | 33 | 15 (45.5%) | NYR [7.82;NYR] | 24 | 8 (33.3%) | NYR [3.22;NYR] | 1.34 [0.57;3.16] | 0.5007 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 9 (22.0%) | NYR [NYR;NYR] | 47 | 4 (8.5%) | NYR [NYR;NYR] | 2.03 [0.62;6.63] | 0.2330 | 0.8161 |
| >= 65 AND < 75 | 25 | 12 (48.0%) | 14.16 [7.82;NYR] | 18 | 6 (33.3%) | NYR [2.37;NYR] | 1.37 [0.51;3.66] | 0.5260 | |
| >= 75 | 8 | 3 (37.5%) | NYR [0.95;NYR] | 6 | 2 (33.3%) | NYR [0.85;NYR] | 1.22 [0.20;7.40] | 0.8280 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 14 (35.9%) | NYR [18.37;NYR] | 37 | 8 (21.6%) | NYR [NYR;NYR] | 1.49 [0.62;3.55] | 0.3685 | 0.5038 |
| Rest of World (ROW) | 35 | 10 (28.6%) | NYR [NYR;NYR] | 34 | 4 (11.8%) | NYR [NYR;NYR] | 2.45 [0.77;7.83] | 0.1167 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.7.2: Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 18 (27.7%) | NYR [NYR;NYR] | 60 | 11 (18.3%) | NYR [NYR;NYR] | 1.39 [0.66;2.95] | 0.3844 | 0.1156 |
| Non-White | 9 | 6 (66.7%) | 18.37 [0.95;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 7.94 [0.95;66.07] | 0.0229 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 4 (57.1%) | 8.08 [5.13;NYR] | 13 | 4 (30.8%) | NYR [2.37;NYR] | 1.68 [0.42;6.77] | 0.4632 | 0.9887 |
| Not Hispanic or Latino | 43 | 16 (37.2%) | NYR [18.37;NYR] | 32 | 6 (18.8%) | NYR [NYR;NYR] | 1.91 [0.75;4.89] | 0.1683 | |
| Not Reported | 24 | 4 (16.7%) | NYR [NYR;NYR] | 26 | 2 (7.7%) | NYR [NYR;NYR] | 1.94 [0.35;10.63] | 0.4357 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 15 (26.8%) | NYR [NYR;NYR] | 48 | 5 (10.4%) | NYR [NYR;NYR] | 2.31 [0.84;6.37] | 0.0955 | 0.6602 |
| Female | 18 | 9 (50.0%) | 18.37 [2.30;NYR] | 23 | 7 (30.4%) | NYR [3.22;NYR] | 1.70 [0.63;4.56] | 0.2875 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 3 (21.4%) | NYR [18.37;NYR] | 19 | 3 (15.8%) | NYR [NYR;NYR] | 1.08 [0.22;5.39] | 0.9227 | 0.5764 |
| >= 1 Year | 60 | 21 (35.0%) | NYR [19.58;NYR] | 50 | 9 (18.0%) | NYR [NYR;NYR] | 1.89 [0.86;4.13] | 0.1044 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.7.2: Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 2 (16.7%) | NYR [15.18;NYR] | <0.01 [<0.01;NE] | 0.1362 | 0.9887 |
| Yes | 63 | 24 (38.1%) | NYR [18.37;NYR] | 59 | 10 (16.9%) | NYR [NYR;NYR] | 2.18 [1.04;4.56] | 0.0337 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 21 (32.8%) | NYR [NYR;NYR] | 65 | 11 (16.9%) | NYR [NYR;NYR] | 1.84 [0.89;3.82] | 0.0961 | 0.9364 |
| Yes | 10 | 3 (30.0%) | NYR [2.86;NYR] | 6 | 1 (16.7%) | NYR [1.58;NYR] | 1.01 [0.09;11.22] | 0.9919 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 5 (45.5%) | 21.95 [8.05;NYR] | 10 | 2 (20.0%) | NYR [2.30;NYR] | 1.84 [0.36;9.51] | 0.4603 | 0.9921 |
| < 1% | 61 | 19 (31.1%) | NYR [NYR;NYR] | 60 | 10 (16.7%) | NYR [NYR;NYR] | 1.79 [0.83;3.86] | 0.1292 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 3 (16.7%) | NYR [18.37;NYR] | 20 | 2 (10.0%) | NYR [NYR;NYR] | 1.47 [0.24;8.81] | 0.6745 | 0.9248 |
| Non-Stage IV | 53 | 19 (35.8%) | NYR [19.58;NYR] | 51 | 10 (19.6%) | NYR [NYR;NYR] | 1.71 [0.80;3.68] | 0.1641 | |
| Not Reported | 3 | 2 (66.7%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.8.1: Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 24 (32.4%) | 12 (16.9%) |
| Number of censored cases | N | 50 (67.6%) | 59 (83.1%) |
| Time to first event (Months) | Mean (SE) | 17.24 (0.91) | 13.18 (0.58) |
| | Q1 [95% CI] | 14.20 [5.49;21.95] | NYR [5.52;NYR] |
| | Median [95% CI] | NYR [21.95;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0734 | |
| Stratified Cox PH model | HR (b) | 1.87 [0.93;3.75] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 3.8.2: Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 24 (32.4%) | NYR [21.95;NYR] | 71 | 12 (16.9%) | NYR [NYR;NYR] | 1.87 [0.93;3.75] | 0.0734 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 9 (22.0%) | NYR [NYR;NYR] | 47 | 4 (8.5%) | NYR [NYR;NYR] | 2.10 [0.64;6.87] | 0.2075 | 0.4962 |
| >= 65 | 33 | 15 (45.5%) | NYR [7.82;NYR] | 24 | 8 (33.3%) | NYR [3.22;NYR] | 1.35 [0.57;3.19] | 0.4892 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 9 (22.0%) | NYR [NYR;NYR] | 47 | 4 (8.5%) | NYR [NYR;NYR] | 2.10 [0.64;6.87] | 0.2075 | 0.7804 |
| >= 65 AND < 75 | 25 | 12 (48.0%) | 14.16 [7.82;NYR] | 18 | 6 (33.3%) | NYR [2.37;NYR] | 1.35 [0.51;3.61] | 0.5436 | |
| >= 75 | 8 | 3 (37.5%) | NYR [0.95;NYR] | 6 | 2 (33.3%) | NYR [0.85;NYR] | 1.22 [0.20;7.40] | 0.8280 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 14 (35.9%) | NYR [18.37;NYR] | 37 | 8 (21.6%) | NYR [NYR;NYR] | 1.54 [0.64;3.67] | 0.3273 | 0.5175 |
| Rest of World (ROW) | 35 | 10 (28.6%) | NYR [NYR;NYR] | 34 | 4 (11.8%) | NYR [NYR;NYR] | 2.51 [0.79;8.01] | 0.1077 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.8.2: Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 18 (27.7%) | NYR [NYR;NYR] | 60 | 11 (18.3%) | NYR [NYR;NYR] | 1.43 [0.68;3.03] | 0.3474 | 0.1167 |
| Non-White | 9 | 6 (66.7%) | 18.37 [0.95;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 8.20 [0.98;68.27] | 0.0204 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 4 (57.1%) | 8.08 [5.13;NYR] | 13 | 4 (30.8%) | NYR [2.37;NYR] | 1.68 [0.42;6.77] | 0.4632 | 0.9847 |
| Not Hispanic or Latino | 43 | 16 (37.2%) | NYR [18.37;NYR] | 32 | 6 (18.8%) | NYR [NYR;NYR] | 1.95 [0.76;4.99] | 0.1549 | |
| Not Reported | 24 | 4 (16.7%) | NYR [NYR;NYR] | 26 | 2 (7.7%) | NYR [NYR;NYR] | 2.04 [0.37;11.17] | 0.4001 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 15 (26.8%) | NYR [NYR;NYR] | 48 | 5 (10.4%) | NYR [NYR;NYR] | 2.41 [0.87;6.64] | 0.0792 | 0.6630 |
| Female | 18 | 9 (50.0%) | 18.37 [2.30;NYR] | 23 | 7 (30.4%) | NYR [5.52;NYR] | 1.75 [0.65;4.70] | 0.2599 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 3 (21.4%) | NYR [18.37;NYR] | 19 | 3 (15.8%) | NYR [NYR;NYR] | 1.14 [0.23;5.64] | 0.8770 | 0.5800 |
| >= 1 Year | 60 | 21 (35.0%) | NYR [19.58;NYR] | 50 | 9 (18.0%) | NYR [NYR;NYR] | 1.94 [0.89;4.24] | 0.0899 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.8.2: Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 2 (16.7%) | NYR [15.18;NYR] | <0.01 [<0.01;NE] | 0.1240 | 0.9887 |
| Yes | 63 | 24 (38.1%) | NYR [18.37;NYR] | 59 | 10 (16.9%) | NYR [NYR;NYR] | 2.22 [1.06;4.65] | 0.0296 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 21 (32.8%) | NYR [NYR;NYR] | 65 | 11 (16.9%) | NYR [NYR;NYR] | 1.89 [0.91;3.93] | 0.0814 | 0.9306 |
| Yes | 10 | 3 (30.0%) | NYR [2.86;NYR] | 6 | 1 (16.7%) | NYR [1.58;NYR] | 1.01 [0.09;11.22] | 0.9919 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 5 (45.5%) | 21.95 [8.05;NYR] | 10 | 2 (20.0%) | NYR [2.30;NYR] | 1.91 [0.37;9.89] | 0.4303 | 0.9930 |
| < 1% | 61 | 19 (31.1%) | NYR [NYR;NYR] | 60 | 10 (16.7%) | NYR [NYR;NYR] | 1.85 [0.86;3.98] | 0.1102 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 3 (16.7%) | NYR [18.37;NYR] | 20 | 2 (10.0%) | NYR [NYR;NYR] | 1.52 [0.25;9.11] | 0.6443 | 0.9342 |
| Non-Stage IV | 53 | 19 (35.8%) | NYR [19.58;NYR] | 51 | 10 (19.6%) | NYR [NYR;NYR] | 1.77 [0.82;3.81] | 0.1391 | |
| Not Reported | 3 | 2 (66.7%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.9.1: Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 74 (100.0%) | 71 (100.0%) |
| Number of censored cases | N | 0 (0.0%) | 0 (0.0%) |
| Time to first event (Months) | Mean (SE) | 0.58 (0.08) | 0.71 (0.18) |
| | Q1 [95% CI] | 0.20 [0.07;0.26] | 0.20 [0.10;0.30] |
| | Median [95% CI] | 0.46 [0.26;0.49] | 0.39 [0.33;0.49] |
| | Q3 [95% CI] | 0.60 [0.49;0.95] | 0.60 [0.49;0.72] |
| | p-value (a) | 0.8761 | |
| Stratified Cox PH model | HR (b) | 0.98 [0.70;1.37] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 3.9.2: Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 74 (100.0%) | 0.46 [0.26;0.49] | 71 | 71 (100.0%) | 0.39 [0.33;0.49] | 0.98 [0.70;1.37] | 0.8761 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 41 (100.0%) | 0.30 [0.13;0.49] | 47 | 47 (100.0%) | 0.43 [0.36;0.53] | 1.18 [0.77;1.81] | 0.4225 | 0.1981 |
| >= 65 | 33 | 33 (100.0%) | 0.46 [0.33;0.49] | 24 | 24 (100.0%) | 0.36 [0.13;0.49] | 0.74 [0.43;1.27] | 0.2337 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 41 (100.0%) | 0.30 [0.13;0.49] | 47 | 47 (100.0%) | 0.43 [0.36;0.53] | 1.18 [0.77;1.81] | 0.4225 | 0.3487 |
| >= 65 AND < 75 | 25 | 25 (100.0%) | 0.46 [0.26;0.49] | 18 | 18 (100.0%) | 0.36 [0.13;0.49] | 0.81 [0.44;1.49] | 0.4634 | |
| >= 75 | 8 | 8 (100.0%) | 0.48 [0.03;0.99] | 6 | 6 (100.0%) | 0.38 [0.07;0.66] | 0.69 [0.22;2.15] | 0.4777 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 39 (100.0%) | 0.46 [0.13;0.56] | 37 | 37 (100.0%) | 0.43 [0.20;0.66] | 1.00 [0.63;1.59] | 0.9740 | 0.8612 |
| Rest of World (ROW) | 35 | 35 (100.0%) | 0.43 [0.26;0.46] | 34 | 34 (100.0%) | 0.38 [0.30;0.53] | 1.07 [0.66;1.73] | 0.8161 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.9.2: Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 65 (100.0%) | 0.46 [0.30;0.49] | 60 | 60 (100.0%) | 0.39 [0.30;0.53] | 1.05 [0.73;1.50] | 0.8224 | 0.8909 |
| Non-White | 9 | 9 (100.0%) | 0.26 [0.07;0.49] | 11 | 11 (100.0%) | 0.43 [0.07;0.46] | 1.01 [0.40;2.52] | 0.9598 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 7 (100.0%) | 0.43 [0.03;1.31] | 13 | 13 (100.0%) | 0.33 [0.07;0.49] | 0.86 [0.34;2.22] | 0.7562 | 0.9071 |
| Not Hispanic or Latino | 43 | 43 (100.0%) | 0.46 [0.26;0.49] | 32 | 32 (100.0%) | 0.41 [0.20;0.49] | 0.96 [0.60;1.53] | 0.8339 | |
| Not Reported | 24 | 24 (100.0%) | 0.44 [0.10;0.49] | 26 | 26 (100.0%) | 0.43 [0.30;0.66] | 1.03 [0.58;1.82] | 0.9658 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 56 (100.0%) | 0.46 [0.26;0.49] | 48 | 48 (100.0%) | 0.43 [0.30;0.66] | 1.13 [0.76;1.67] | 0.5439 | 0.3573 |
| Female | 18 | 18 (100.0%) | 0.43 [0.26;0.49] | 23 | 23 (100.0%) | 0.36 [0.20;0.46] | 0.76 [0.40;1.45] | 0.3786 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 14 (100.0%) | 0.39 [0.13;0.95] | 19 | 19 (100.0%) | 0.33 [0.16;0.53] | 0.59 [0.28;1.24] | 0.1434 | 0.2264 |
| >= 1 Year | 60 | 60 (100.0%) | 0.46 [0.26;0.49] | 50 | 50 (100.0%) | 0.41 [0.36;0.49] | 1.13 [0.77;1.65] | 0.5442 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.9.2: Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 11 (100.0%) | 0.43 [0.10;0.49] | 12 | 12 (100.0%) | 0.46 [0.10;0.72] | 1.58 [0.67;3.71] | 0.3309 | 0.3869 |
| Yes | 63 | 63 (100.0%) | 0.46 [0.26;0.49] | 59 | 59 (100.0%) | 0.39 [0.30;0.46] | 0.97 [0.68;1.39] | 0.8275 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 64 (100.0%) | 0.46 [0.26;0.49] | 65 | 65 (100.0%) | 0.39 [0.30;0.49] | 1.02 [0.72;1.44] | 0.9655 | 0.9639 |
| Yes | 10 | 10 (100.0%) | 0.43 [0.03;0.49] | 6 | 6 (100.0%) | 0.44 [0.13;0.99] | 0.96 [0.34;2.71] | 0.9790 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 11 (100.0%) | 0.26 [0.10;0.49] | 10 | 10 (100.0%) | 0.39 [0.03;1.25] | 1.49 [0.61;3.65] | 0.3554 | 0.0533 |
| < 1% | 61 | 61 (100.0%) | 0.46 [0.30;0.49] | 60 | 60 (100.0%) | 0.41 [0.33;0.49] | 0.95 [0.66;1.36] | 0.7357 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 18 (100.0%) | 0.48 [0.46;0.82] | 20 | 20 (100.0%) | 0.48 [0.10;0.69] | 0.69 [0.36;1.35] | 0.2604 | 0.4319 |
| Non-Stage IV | 53 | 53 (100.0%) | 0.33 [0.23;0.49] | 51 | 51 (100.0%) | 0.39 [0.26;0.46] | 1.09 [0.74;1.61] | 0.6772 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.10.1: Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 74 (100.0%) | 71 (100.0%) |
| Number of censored cases | N | 0 (0.0%) | 0 (0.0%) |
| Time to first event (Months) | Mean (SE) | 0.58 (0.08) | 0.71 (0.18) |
| | Q1 [95% CI] | 0.20 [0.07;0.26] | 0.20 [0.10;0.30] |
| | Median [95% CI] | 0.46 [0.26;0.49] | 0.39 [0.33;0.49] |
| | Q3 [95% CI] | 0.60 [0.49;0.95] | 0.60 [0.49;0.72] |
| | p-value (a) | 0.8761 | |
| Stratified Cox PH model | HR (b) | 0.98 [0.70;1.37] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 3.10.2: Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 74 (100.0%) | 0.46 [0.26;0.49] | 71 | 71 (100.0%) | 0.39 [0.33;0.49] | 0.98 [0.70;1.37] | 0.8761 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 41 (100.0%) | 0.30 [0.13;0.49] | 47 | 47 (100.0%) | 0.43 [0.36;0.53] | 1.18 [0.77;1.81] | 0.4225 | 0.1981 |
| >= 65 | 33 | 33 (100.0%) | 0.46 [0.33;0.49] | 24 | 24 (100.0%) | 0.36 [0.13;0.49] | 0.74 [0.43;1.27] | 0.2337 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 41 (100.0%) | 0.30 [0.13;0.49] | 47 | 47 (100.0%) | 0.43 [0.36;0.53] | 1.18 [0.77;1.81] | 0.4225 | 0.3487 |
| >= 65 AND < 75 | 25 | 25 (100.0%) | 0.46 [0.26;0.49] | 18 | 18 (100.0%) | 0.36 [0.13;0.49] | 0.81 [0.44;1.49] | 0.4634 | |
| >= 75 | 8 | 8 (100.0%) | 0.48 [0.03;0.99] | 6 | 6 (100.0%) | 0.38 [0.07;0.66] | 0.69 [0.22;2.15] | 0.4777 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 39 (100.0%) | 0.46 [0.13;0.56] | 37 | 37 (100.0%) | 0.43 [0.20;0.66] | 1.00 [0.63;1.59] | 0.9740 | 0.8612 |
| Rest of World (ROW) | 35 | 35 (100.0%) | 0.43 [0.26;0.46] | 34 | 34 (100.0%) | 0.38 [0.30;0.53] | 1.07 [0.66;1.73] | 0.8161 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.10.2: Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 65 (100.0%) | 0.46 [0.30;0.49] | 60 | 60 (100.0%) | 0.39 [0.30;0.53] | 1.05 [0.73;1.50] | 0.8224 | 0.8909 |
| Non-White | 9 | 9 (100.0%) | 0.26 [0.07;0.49] | 11 | 11 (100.0%) | 0.43 [0.07;0.46] | 1.01 [0.40;2.52] | 0.9598 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 7 (100.0%) | 0.43 [0.03;1.31] | 13 | 13 (100.0%) | 0.33 [0.07;0.49] | 0.86 [0.34;2.22] | 0.7562 | 0.9071 |
| Not Hispanic or Latino | 43 | 43 (100.0%) | 0.46 [0.26;0.49] | 32 | 32 (100.0%) | 0.41 [0.20;0.49] | 0.96 [0.60;1.53] | 0.8339 | |
| Not Reported | 24 | 24 (100.0%) | 0.44 [0.10;0.49] | 26 | 26 (100.0%) | 0.43 [0.30;0.66] | 1.03 [0.58;1.82] | 0.9658 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 56 (100.0%) | 0.46 [0.26;0.49] | 48 | 48 (100.0%) | 0.43 [0.30;0.66] | 1.13 [0.76;1.67] | 0.5439 | 0.3573 |
| Female | 18 | 18 (100.0%) | 0.43 [0.26;0.49] | 23 | 23 (100.0%) | 0.36 [0.20;0.46] | 0.76 [0.40;1.45] | 0.3786 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 14 (100.0%) | 0.39 [0.13;0.95] | 19 | 19 (100.0%) | 0.33 [0.16;0.53] | 0.59 [0.28;1.24] | 0.1434 | 0.2264 |
| >= 1 Year | 60 | 60 (100.0%) | 0.46 [0.26;0.49] | 50 | 50 (100.0%) | 0.41 [0.36;0.49] | 1.13 [0.77;1.65] | 0.5442 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.10.2: Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 11 (100.0%) | 0.43 [0.10;0.49] | 12 | 12 (100.0%) | 0.46 [0.10;0.72] | 1.58 [0.67;3.71] | 0.3309 | 0.3869 |
| Yes | 63 | 63 (100.0%) | 0.46 [0.26;0.49] | 59 | 59 (100.0%) | 0.39 [0.30;0.46] | 0.97 [0.68;1.39] | 0.8275 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 64 (100.0%) | 0.46 [0.26;0.49] | 65 | 65 (100.0%) | 0.39 [0.30;0.49] | 1.02 [0.72;1.44] | 0.9655 | 0.9639 |
| Yes | 10 | 10 (100.0%) | 0.43 [0.03;0.49] | 6 | 6 (100.0%) | 0.44 [0.13;0.99] | 0.96 [0.34;2.71] | 0.9790 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 11 (100.0%) | 0.26 [0.10;0.49] | 10 | 10 (100.0%) | 0.39 [0.03;1.25] | 1.49 [0.61;3.65] | 0.3554 | 0.0533 |
| < 1% | 61 | 61 (100.0%) | 0.46 [0.30;0.49] | 60 | 60 (100.0%) | 0.41 [0.33;0.49] | 0.95 [0.66;1.36] | 0.7357 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 18 (100.0%) | 0.48 [0.46;0.82] | 20 | 20 (100.0%) | 0.48 [0.10;0.69] | 0.69 [0.36;1.35] | 0.2604 | 0.4319 |
| Non-Stage IV | 53 | 53 (100.0%) | 0.33 [0.23;0.49] | 51 | 51 (100.0%) | 0.39 [0.26;0.46] | 1.09 [0.74;1.61] | 0.6772 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:13:18

TABLE 3.11.1: Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 58 (78.4%) | 51 (71.8%) |
| Number of censored cases | N | 16 (21.6%) | 20 (28.2%) |
| Time to first event (Months) | Mean (SE) | 8.38 (1.00) | 9.24 (1.24) |
| | Q1 [95% CI] | 1.40 [0.92;1.77] | 1.00 [0.69;2.04] |
| | Median [95% CI] | 3.24 [2.40;8.08] | 3.68 [2.07;5.68] |
| | Q3 [95% CI] | 17.40 [9.17;NYR] | 24.40 [7.23;NYR] |
| | p-value (a) | 0.9044 | |
| Stratified Cox PH model | HR (b) | 0.98 [0.67;1.43] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:20:40

TABLE 3.11.2: Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 58 (78.4%) | 3.24 [2.40;8.08] | 71 | 51 (71.8%) | 3.68 [2.07;5.68] | 0.98 [0.67;1.43] | 0.9044 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 29 (70.7%) | 9.03 [2.66;16.43] | 47 | 30 (63.8%) | 4.44 [2.10;24.41] | 1.00 [0.60;1.66] | 0.9934 | 0.7728 |
| >= 65 | 33 | 29 (87.9%) | 2.40 [1.38;3.22] | 24 | 21 (87.5%) | 2.09 [0.69;5.42] | 0.88 [0.50;1.55] | 0.6396 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 29 (70.7%) | 9.03 [2.66;16.43] | 47 | 30 (63.8%) | 4.44 [2.10;24.41] | 1.00 [0.60;1.66] | 0.9934 | 0.2816 |
| >= 65 AND < 75 | 25 | 23 (92.0%) | 2.40 [1.35;3.38] | 18 | 16 (88.9%) | 2.76 [0.95;7.23] | 1.13 [0.59;2.14] | 0.7108 | |
| >= 75 | 8 | 6 (75.0%) | 2.05 [0.46;22.18] | 6 | 5 (83.3%) | 0.77 [0.56;NYR] | 0.41 [0.12;1.48] | 0.1669 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 29 (74.4%) | 2.99 [1.45;9.95] | 37 | 22 (59.5%) | 5.68 [2.10;NYR] | 1.35 [0.77;2.35] | 0.2902 | 0.1448 |
| Rest of World (ROW) | 35 | 29 (82.9%) | 5.03 [1.64;8.08] | 34 | 29 (85.3%) | 2.14 [1.02;3.88] | 0.77 [0.46;1.28] | 0.3105 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:20:40

TABLE 3.11.2: Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 51 (78.5%) | 3.09 [1.87;6.93] | 60 | 43 (71.7%) | 3.68 [2.07;7.23] | 1.08 [0.72;1.62] | 0.7087 | 0.5505 |
| Non-White | 9 | 7 (77.8%) | 13.31 [0.95;17.45] | 11 | 8 (72.7%) | 3.22 [0.66;NYR] | 0.72 [0.26;2.00] | 0.5323 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 6 (85.7%) | 7.85 [0.49;9.43] | 13 | 11 (84.6%) | 2.14 [0.49;5.78] | 0.80 [0.29;2.23] | 0.6695 | 0.0618 |
| Not Hispanic or Latino | 43 | 35 (81.4%) | 2.66 [1.58;5.03] | 32 | 18 (56.3%) | 4.12 [2.04;NYR] | 1.63 [0.92;2.89] | 0.0889 | |
| Not Reported | 24 | 17 (70.8%) | 7.98 [1.41;22.18] | 26 | 22 (84.6%) | 3.68 [0.99;7.23] | 0.58 [0.31;1.11] | 0.0964 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 44 (78.6%) | 3.15 [2.40;9.03] | 48 | 31 (64.6%) | 3.71 [2.07;24.61] | 1.20 [0.76;1.90] | 0.4360 | 0.2603 |
| Female | 18 | 14 (77.8%) | 4.47 [0.95;15.87] | 23 | 20 (87.0%) | 2.30 [0.85;5.78] | 0.74 [0.37;1.48] | 0.3915 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 13 (92.9%) | 5.29 [1.35;12.58] | 19 | 14 (73.7%) | 2.50 [1.25;7.56] | 1.07 [0.50;2.29] | 0.8618 | 0.9587 |
| >= 1 Year | 60 | 45 (75.0%) | 3.15 [1.77;9.17] | 50 | 35 (70.0%) | 4.37 [2.04;10.35] | 1.07 [0.69;1.66] | 0.7754 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:20:40

TABLE 3.11.2: Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 9 (81.8%) | 3.38 [0.49;20.11] | 12 | 8 (66.7%) | 2.09 [1.02;NYR] | 1.05 [0.40;2.74] | 0.9321 | 0.9892 |
| Yes | 63 | 49 (77.8%) | 3.09 [2.17;8.08] | 59 | 43 (72.9%) | 3.88 [2.10;5.78] | 1.02 [0.68;1.54] | 0.9209 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 49 (76.6%) | 4.14 [1.87;9.03] | 65 | 45 (69.2%) | 3.71 [2.10;7.56] | 1.06 [0.70;1.58] | 0.7981 | 0.3472 |
| Yes | 10 | 9 (90.0%) | 2.71 [0.26;9.66] | 6 | 6 (100.0%) | 1.53 [0.62;5.49] | 0.56 [0.18;1.68] | 0.2917 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 10 (90.9%) | 9.03 [0.99;9.95] | 10 | 8 (80.0%) | 3.09 [0.36;10.35] | 1.04 [0.40;2.66] | 0.9405 | 0.9864 |
| < 1% | 61 | 46 (75.4%) | 3.22 [1.87;7.85] | 60 | 43 (71.7%) | 3.45 [2.07;5.78] | 0.98 [0.65;1.49] | 0.9283 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 17 (94.4%) | 2.48 [0.92;5.03] | 20 | 14 (70.0%) | 3.58 [1.35;10.35] | 1.75 [0.86;3.56] | 0.1195 | 0.0734 |
| Non-Stage IV | 53 | 38 (71.7%) | 6.93 [2.53;13.31] | 51 | 37 (72.5%) | 3.68 [1.77;5.78] | 0.83 [0.53;1.31] | 0.4156 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.12.1: Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 58 (78.4%) | 51 (71.8%) |
| Number of censored cases | N | 16 (21.6%) | 20 (28.2%) |
| Time to first event (Months) | Mean (SE) | 8.41 (1.00) | 9.39 (1.24) |
| | Q1 [95% CI] | 1.40 [0.92;1.77] | 1.00 [0.69;2.04] |
| | Median [95% CI] | 3.24 [2.40;8.08] | 3.68 [2.07;5.78] |
| | Q3 [95% CI] | 17.40 [9.17;NYR] | 24.40 [7.56;NYR] |
| | p-value (a) | 0.9703 | |
| Stratified Cox PH model | HR (b) | 0.99 [0.68;1.45] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:28:06

TABLE 3.12.2: Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 58 (78.4%) | 3.24 [2.40;8.08] | 71 | 51 (71.8%) | 3.68 [2.07;5.78] | 0.99 [0.68;1.45] | 0.9703 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 29 (70.7%) | 9.03 [2.66;16.43] | 47 | 30 (63.8%) | 4.44 [2.10;24.41] | 1.02 [0.61;1.70] | 0.9345 | 0.7692 |
| >= 65 | 33 | 29 (87.9%) | 2.40 [1.38;3.22] | 24 | 21 (87.5%) | 2.09 [0.69;5.42] | 0.89 [0.51;1.58] | 0.6925 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 29 (70.7%) | 9.03 [2.66;16.43] | 47 | 30 (63.8%) | 4.44 [2.10;24.41] | 1.02 [0.61;1.70] | 0.9345 | 0.3328 |
| >= 65 AND < 75 | 25 | 23 (92.0%) | 2.40 [1.35;3.38] | 18 | 16 (88.9%) | 2.76 [0.95;7.23] | 1.13 [0.59;2.14] | 0.7153 | |
| >= 75 | 8 | 6 (75.0%) | 2.05 [0.46;22.18] | 6 | 5 (83.3%) | 0.77 [0.56;NYR] | 0.41 [0.12;1.48] | 0.1669 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 29 (74.4%) | 2.99 [1.45;9.95] | 37 | 22 (59.5%) | 5.68 [2.10;NYR] | 1.37 [0.79;2.38] | 0.2689 | 0.1421 |
| Rest of World (ROW) | 35 | 29 (82.9%) | 5.03 [1.64;8.08] | 34 | 29 (85.3%) | 2.32 [1.02;5.42] | 0.78 [0.46;1.31] | 0.3460 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:28:06

TABLE 3.12.2: Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 51 (78.5%) | 3.09 [1.87;6.93] | 60 | 43 (71.7%) | 3.70 [2.07;7.23] | 1.11 [0.74;1.66] | 0.6335 | 0.5314 |
| Non-White | 9 | 7 (77.8%) | 13.31 [0.95;17.45] | 11 | 8 (72.7%) | 3.22 [0.66;NYR] | 0.67 [0.24;1.88] | 0.4520 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 6 (85.7%) | 7.85 [0.49;9.43] | 13 | 11 (84.6%) | 2.14 [0.49;5.78] | 0.82 [0.30;2.29] | 0.7069 | 0.0684 |
| Not Hispanic or Latino | 43 | 35 (81.4%) | 2.66 [1.58;5.03] | 32 | 18 (56.3%) | 4.12 [2.04;NYR] | 1.65 [0.93;2.92] | 0.0819 | |
| Not Reported | 24 | 17 (70.8%) | 7.98 [1.41;22.18] | 26 | 22 (84.6%) | 4.55 [0.99;7.56] | 0.60 [0.32;1.14] | 0.1149 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 44 (78.6%) | 3.15 [2.40;9.03] | 48 | 31 (64.6%) | 4.04 [2.07;24.61] | 1.22 [0.77;1.93] | 0.3971 | 0.2725 |
| Female | 18 | 14 (77.8%) | 4.47 [0.95;15.87] | 23 | 20 (87.0%) | 2.30 [0.85;5.78] | 0.74 [0.37;1.49] | 0.3997 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 13 (92.9%) | 5.29 [1.35;12.58] | 19 | 14 (73.7%) | 2.50 [1.25;7.56] | 1.09 [0.51;2.33] | 0.8233 | 0.9642 |
| >= 1 Year | 60 | 45 (75.0%) | 3.15 [1.77;9.17] | 50 | 35 (70.0%) | 4.37 [2.04;13.11] | 1.09 [0.70;1.69] | 0.7116 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:28:06

TABLE 3.12.2: Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 9 (81.8%) | 3.38 [0.49;20.11] | 12 | 8 (66.7%) | 2.09 [1.02;NYR] | 1.05 [0.40;2.74] | 0.9321 | 0.9805 |
| Yes | 63 | 49 (77.8%) | 3.09 [2.17;8.08] | 59 | 43 (72.9%) | 3.88 [2.10;7.23] | 1.04 [0.69;1.57] | 0.8558 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 49 (76.6%) | 4.14 [1.87;9.03] | 65 | 45 (69.2%) | 3.71 [2.10;7.56] | 1.07 [0.72;1.61] | 0.7364 | 0.3342 |
| Yes | 10 | 9 (90.0%) | 2.71 [0.26;9.66] | 6 | 6 (100.0%) | 1.53 [0.62;5.49] | 0.56 [0.18;1.68] | 0.2917 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 10 (90.9%) | 9.03 [0.99;9.95] | 10 | 8 (80.0%) | 3.09 [0.36;10.35] | 1.04 [0.40;2.66] | 0.9405 | 0.9924 |
| < 1% | 61 | 46 (75.4%) | 3.22 [1.87;7.85] | 60 | 43 (71.7%) | 3.56 [2.07;5.78] | 1.00 [0.66;1.51] | 0.9881 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 17 (94.4%) | 2.48 [0.92;5.03] | 20 | 14 (70.0%) | 3.58 [1.35;10.35] | 1.77 [0.87;3.61] | 0.1108 | 0.0774 |
| Non-Stage IV | 53 | 38 (71.7%) | 6.93 [2.53;13.31] | 51 | 37 (72.5%) | 3.68 [1.77;5.78] | 0.85 [0.54;1.33] | 0.4672 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.13.1: Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 35 (47.3%) | 19 (26.8%) |
| Number of censored cases | N | 39 (52.7%) | 52 (73.2%) |
| Time to first event (Months) | Mean (SE) | 13.63 (0.88) | 19.02 (1.18) |
| | Q1 [95% CI] | 5.40 [2.73;9.95] | 10.60 [2.37;NYR] |
| | Median [95% CI] | 19.58 [14.16;NYR] | NYR [24.61;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0424 | |
| Stratified Cox PH model | HR (b) | 1.78 [1.01;3.15] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:35:28

TABLE 3.13.2: Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 35 (47.3%) | 19.58 [14.16;NYR] | 71 | 19 (26.8%) | NYR [24.61;NYR] | 1.78 [1.01;3.15] | 0.0424 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 17 (41.5%) | NYR [15.61;NYR] | 47 | 11 (23.4%) | NYR [24.61;NYR] | 1.69 [0.79;3.61] | 0.1694 | 0.8579 |
| >= 65 | 33 | 18 (54.5%) | 14.69 [5.36;NYR] | 24 | 8 (33.3%) | NYR [10.55;NYR] | 1.52 [0.66;3.50] | 0.3197 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 17 (41.5%) | NYR [15.61;NYR] | 47 | 11 (23.4%) | NYR [24.61;NYR] | 1.69 [0.79;3.61] | 0.1694 | 0.7720 |
| >= 65 AND < 75 | 25 | 14 (56.0%) | 14.69 [5.16;NYR] | 18 | 7 (38.9%) | NYR [2.37;NYR] | 1.31 [0.53;3.25] | 0.5598 | |
| >= 75 | 8 | 4 (50.0%) | NYR [1.51;NYR] | 6 | 1 (16.7%) | NYR [0.85;NYR] | 2.81 [0.31;25.20] | 0.3349 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 17 (43.6%) | 19.58 [14.16;NYR] | 37 | 13 (35.1%) | NYR [5.72;NYR] | 1.05 [0.51;2.16] | 0.8989 | 0.0542 |
| Rest of World (ROW) | 35 | 18 (51.4%) | 18.86 [5.78;NYR] | 34 | 6 (17.6%) | NYR [24.61;NYR] | 3.29 [1.31;8.31] | 0.0075 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.13.2: Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 32 (49.2%) | 18.89 [9.95;NYR] | 60 | 19 (31.7%) | NYR [24.61;NYR] | 1.50 [0.85;2.65] | 0.1579 | 0.9868 |
| Non-White | 9 | 3 (33.3%) | NYR [7.85;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0780 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 6 (85.7%) | 7.85 [3.22;18.89] | 13 | 5 (38.5%) | 24.61 [2.37;NYR] | 2.72 [0.76;9.72] | 0.1089 | 0.6935 |
| Not Hispanic or Latino | 43 | 20 (46.5%) | 19.58 [9.95;NYR] | 32 | 10 (31.3%) | NYR [5.72;NYR] | 1.44 [0.67;3.09] | 0.3418 | |
| Not Reported | 24 | 9 (37.5%) | NYR [14.69;NYR] | 26 | 4 (15.4%) | NYR [NYR;NYR] | 2.42 [0.75;7.88] | 0.1279 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 27 (48.2%) | 19.58 [9.95;NYR] | 48 | 11 (22.9%) | NYR [24.61;NYR] | 2.16 [1.07;4.35] | 0.0278 | 0.2641 |
| Female | 18 | 8 (44.4%) | NYR [5.78;NYR] | 23 | 8 (34.8%) | NYR [3.88;NYR] | 1.07 [0.40;2.85] | 0.8938 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 8 (57.1%) | 14.16 [5.03;NYR] | 19 | 5 (26.3%) | NYR [10.55;NYR] | 2.15 [0.70;6.56] | 0.1700 | 0.6559 |
| >= 1 Year | 60 | 27 (45.0%) | 19.58 [14.69;NYR] | 50 | 13 (26.0%) | NYR [24.61;NYR] | 1.65 [0.85;3.20] | 0.1337 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.13.2: Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 5 (45.5%) | NYR [3.22;NYR] | 12 | 3 (25.0%) | NYR [1.54;NYR] | 1.72 [0.41;7.20] | 0.4553 | 0.9921 |
| Yes | 63 | 30 (47.6%) | 19.58 [12.65;NYR] | 59 | 16 (27.1%) | NYR [24.61;NYR] | 1.71 [0.93;3.14] | 0.0787 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 27 (42.2%) | NYR [15.61;NYR] | 65 | 17 (26.2%) | NYR [24.61;NYR] | 1.52 [0.83;2.78] | 0.1763 | 0.4366 |
| Yes | 10 | 8 (80.0%) | 7.49 [0.26;18.86] | 6 | 2 (33.3%) | NYR [0.72;NYR] | 3.09 [0.65;14.63] | 0.1345 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 6 (54.5%) | 18.89 [9.82;NYR] | 10 | 3 (30.0%) | NYR [1.25;NYR] | 1.36 [0.34;5.49] | 0.6612 | 0.9863 |
| < 1% | 61 | 27 (44.3%) | NYR [14.16;NYR] | 60 | 16 (26.7%) | NYR [24.61;NYR] | 1.64 [0.88;3.04] | 0.1157 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 9 (50.0%) | 17.18 [5.03;NYR] | 20 | 6 (30.0%) | NYR [5.72;NYR] | 1.71 [0.61;4.82] | 0.3037 | 0.9408 |
| Non-Stage IV | 53 | 24 (45.3%) | NYR [14.69;NYR] | 51 | 13 (25.5%) | NYR [24.61;NYR] | 1.65 [0.84;3.25] | 0.1408 | |
| Not Reported | 3 | 2 (66.7%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.14.1: Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 36 (48.6%) | 21 (29.6%) |
| Number of censored cases | N | 38 (51.4%) | 50 (70.4%) |
| Time to first event (Months) | Mean (SE) | 13.56 (0.87) | 18.74 (1.16) |
| | Q1 [95% CI] | 5.40 [2.73;9.89] | 10.60 [2.37;NYR] |
| | Median [95% CI] | 18.89 [12.65;NYR] | NYR [24.61;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0583 | |
| Stratified Cox PH model | HR (b) | 1.69 [0.98;2.91] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 3.14.2: Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 36 (48.6%) | 18.89 [12.65;NYR] | 71 | 21 (29.6%) | NYR [24.61;NYR] | 1.69 [0.98;2.91] | 0.0583 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 17 (41.5%) | NYR [15.61;NYR] | 47 | 11 (23.4%) | NYR [24.61;NYR] | 1.74 [0.81;3.71] | 0.1495 | 0.6559 |
| >= 65 | 33 | 19 (57.6%) | 14.69 [5.36;NYR] | 24 | 10 (41.7%) | 21.29 [4.40;NYR] | 1.35 [0.63;2.91] | 0.4376 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 17 (41.5%) | NYR [15.61;NYR] | 47 | 11 (23.4%) | NYR [24.61;NYR] | 1.74 [0.81;3.71] | 0.1495 | 0.6045 |
| >= 65 AND < 75 | 25 | 15 (60.0%) | 14.69 [5.16;NYR] | 18 | 9 (50.0%) | 21.29 [2.37;NYR] | 1.15 [0.50;2.63] | 0.7454 | |
| >= 75 | 8 | 4 (50.0%) | NYR [1.51;NYR] | 6 | 1 (16.7%) | NYR [0.85;NYR] | 2.97 [0.33;26.64] | 0.3067 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 17 (43.6%) | NYR [14.16;NYR] | 37 | 15 (40.5%) | NYR [5.49;NYR] | 0.95 [0.47;1.90] | 0.8794 | 0.0231 |
| Rest of World (ROW) | 35 | 19 (54.3%) | 15.61 [5.78;NYR] | 34 | 6 (17.6%) | NYR [24.61;NYR] | 3.63 [1.45;9.09] | 0.0033 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.14.2: Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 33 (50.8%) | 18.89 [9.89;NYR] | 60 | 21 (35.0%) | NYR [21.29;NYR] | 1.44 [0.83;2.49] | 0.1910 | 0.9863 |
| Non-White | 9 | 3 (33.3%) | NYR [7.85;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0721 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 6 (85.7%) | 7.85 [3.22;18.89] | 13 | 5 (38.5%) | 24.61 [2.37;NYR] | 2.98 [0.83;10.71] | 0.0790 | 0.5038 |
| Not Hispanic or Latino | 43 | 21 (48.8%) | 19.58 [9.89;NYR] | 32 | 12 (37.5%) | NYR [4.40;NYR] | 1.28 [0.63;2.61] | 0.4960 | |
| Not Reported | 24 | 9 (37.5%) | NYR [14.69;NYR] | 26 | 4 (15.4%) | NYR [NYR;NYR] | 2.52 [0.77;8.19] | 0.1116 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 27 (48.2%) | 19.58 [9.95;NYR] | 48 | 12 (25.0%) | NYR [24.61;NYR] | 2.04 [1.03;4.03] | 0.0361 | 0.3110 |
| Female | 18 | 9 (50.0%) | 17.18 [5.78;NYR] | 23 | 9 (39.1%) | NYR [3.88;NYR] | 1.08 [0.43;2.72] | 0.8745 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 8 (57.1%) | 14.16 [5.03;NYR] | 19 | 6 (31.6%) | NYR [5.72;NYR] | 1.87 [0.65;5.40] | 0.2376 | 0.8222 |
| >= 1 Year | 60 | 28 (46.7%) | 19.58 [12.65;NYR] | 50 | 14 (28.0%) | NYR [21.29;NYR] | 1.65 [0.87;3.13] | 0.1245 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.14.2: Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 5 (45.5%) | NYR [3.22;NYR] | 12 | 3 (25.0%) | NYR [1.54;NYR] | 1.76 [0.42;7.38] | 0.4322 | 0.9118 |
| Yes | 63 | 31 (49.2%) | 18.89 [9.95;NYR] | 59 | 18 (30.5%) | NYR [21.29;NYR] | 1.63 [0.91;2.91] | 0.0979 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 28 (43.8%) | NYR [15.61;NYR] | 65 | 18 (27.7%) | NYR [24.61;NYR] | 1.53 [0.84;2.76] | 0.1599 | 0.7012 |
| Yes | 10 | 8 (80.0%) | 7.49 [0.26;18.86] | 6 | 3 (50.0%) | 21.29 [0.72;21.29] | 2.20 [0.58;8.38] | 0.2368 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 6 (54.5%) | 18.89 [9.82;NYR] | 10 | 4 (40.0%) | NYR [1.25;NYR] | 1.05 [0.29;3.75] | 0.9388 | 0.8681 |
| < 1% | 61 | 28 (45.9%) | NYR [14.16;NYR] | 60 | 17 (28.3%) | NYR [24.61;NYR] | 1.64 [0.89;2.99] | 0.1066 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 9 (50.0%) | 17.18 [5.03;NYR] | 20 | 6 (30.0%) | NYR [5.72;NYR] | 1.75 [0.62;4.91] | 0.2869 | 0.8367 |
| Non-Stage IV | 53 | 25 (47.2%) | 19.58 [12.65;NYR] | 51 | 15 (29.4%) | NYR [21.29;NYR] | 1.54 [0.81;2.92] | 0.1826 | |
| Not Reported | 3 | 2 (66.7%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.15.1: Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 24 (32.4%) | 9 (12.7%) |
| Number of censored cases | N | 50 (67.6%) | 62 (87.3%) |
| Time to first event (Months) | Mean (SE) | 17.21 (0.91) | 5.09 (0.15) |
| | Q1 [95% CI] | 14.20 [5.49;21.95] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [21.95;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0199 | |
| Stratified Cox PH model | HR (b) | 2.42 [1.12;5.22] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:50:25

TABLE 3.15.2: Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 24 (32.4%) | NYR [21.95;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 2.42 [1.12;5.22] | 0.0199 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 9 (22.0%) | NYR [NYR;NYR] | 47 | 2 (4.3%) | NYR [NYR;NYR] | 4.11 [0.88;19.14] | 0.0515 | 0.2641 |
| >= 65 | 33 | 15 (45.5%) | NYR [7.82;NYR] | 24 | 7 (29.2%) | NYR [5.52;NYR] | 1.55 [0.63;3.79] | 0.3370 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 9 (22.0%) | NYR [NYR;NYR] | 47 | 2 (4.3%) | NYR [NYR;NYR] | 4.11 [0.88;19.14] | 0.0515 | 0.5002 |
| >= 65 AND < 75 | 25 | 12 (48.0%) | 14.16 [7.82;NYR] | 18 | 5 (27.8%) | NYR [3.22;NYR] | 1.67 [0.59;4.76] | 0.3269 | |
| >= 75 | 8 | 3 (37.5%) | NYR [0.95;NYR] | 6 | 2 (33.3%) | NYR [0.85;NYR] | 1.22 [0.20;7.40] | 0.8280 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 14 (35.9%) | NYR [18.37;NYR] | 37 | 7 (18.9%) | NYR [NYR;NYR] | 1.70 [0.69;4.22] | 0.2464 | 0.2457 |
| Rest of World (ROW) | 35 | 10 (28.6%) | NYR [NYR;NYR] | 34 | 2 (5.9%) | NYR [NYR;NYR] | 4.97 [1.09;22.68] | 0.0216 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.15.2: Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 18 (27.7%) | NYR [NYR;NYR] | 60 | 8 (13.3%) | NYR [NYR;NYR] | 1.93 [0.84;4.44] | 0.1148 | 0.2025 |
| Non-White | 9 | 6 (66.7%) | 18.37 [0.95;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 7.94 [0.95;66.07] | 0.0229 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 4 (57.1%) | 8.08 [5.13;NYR] | 13 | 4 (30.8%) | NYR [2.37;NYR] | 1.68 [0.42;6.77] | 0.4632 | 0.7774 |
| Not Hispanic or Latino | 43 | 16 (37.2%) | NYR [18.37;NYR] | 32 | 4 (12.5%) | NYR [NYR;NYR] | 2.86 [0.95;8.55] | 0.0496 | |
| Not Reported | 24 | 4 (16.7%) | NYR [NYR;NYR] | 26 | 1 (3.8%) | NYR [NYR;NYR] | 3.91 [0.44;35.07] | 0.1887 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 15 (26.8%) | NYR [NYR;NYR] | 48 | 3 (6.3%) | NYR [NYR;NYR] | 3.88 [1.12;13.41] | 0.0211 | 0.4153 |
| Female | 18 | 9 (50.0%) | 18.37 [2.30;NYR] | 23 | 6 (26.1%) | NYR [5.52;NYR] | 1.99 [0.71;5.60] | 0.1825 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 3 (21.4%) | NYR [18.37;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | 3.09 [0.32;29.92] | 0.3048 | 0.6971 |
| >= 1 Year | 60 | 21 (35.0%) | NYR [19.58;NYR] | 50 | 8 (16.0%) | NYR [NYR;NYR] | 2.14 [0.95;4.83] | 0.0608 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.15.2: Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3404 | 0.9897 |
| Yes | 63 | 24 (38.1%) | NYR [18.37;NYR] | 59 | 8 (13.6%) | NYR [NYR;NYR] | 2.73 [1.23;6.08] | 0.0103 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 21 (32.8%) | NYR [NYR;NYR] | 65 | 8 (12.3%) | NYR [NYR;NYR] | 2.54 [1.13;5.75] | 0.0199 | 0.7370 |
| Yes | 10 | 3 (30.0%) | NYR [2.86;NYR] | 6 | 1 (16.7%) | NYR [1.58;NYR] | 1.01 [0.09;11.22] | 0.9919 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 5 (45.5%) | 21.95 [8.05;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0569 | 0.9999 |
| < 1% | 61 | 19 (31.1%) | NYR [NYR;NYR] | 60 | 9 (15.0%) | NYR [NYR;NYR] | 2.01 [0.91;4.44] | 0.0785 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 3 (16.7%) | NYR [18.37;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | 2.84 [0.29;27.38] | 0.3464 | 0.7633 |
| Non-Stage IV | 53 | 19 (35.8%) | NYR [19.58;NYR] | 51 | 8 (15.7%) | NYR [NYR;NYR] | 2.16 [0.94;4.93] | 0.0615 | |
| Not Reported | 3 | 2 (66.7%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.16.1: Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 24 (32.4%) | 9 (12.7%) |
| Number of censored cases | N | 50 (67.6%) | 62 (87.3%) |
| Time to first event (Months) | Mean (SE) | 17.24 (0.91) | 5.10 (0.15) |
| | Q1 [95% CI] | 14.20 [5.49;21.95] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [21.95;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0143 | |
| Stratified Cox PH model | HR (b) | 2.53 [1.17;5.45] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.16.2: Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 24 (32.4%) | NYR [21.95;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 2.53 [1.17;5.45] | 0.0143 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 9 (22.0%) | NYR [NYR;NYR] | 47 | 2 (4.3%) | NYR [NYR;NYR] | 4.29 [0.92;19.95] | 0.0432 | 0.2393 |
| >= 65 | 33 | 15 (45.5%) | NYR [7.82;NYR] | 24 | 7 (29.2%) | NYR [5.52;NYR] | 1.56 [0.64;3.83] | 0.3251 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 9 (22.0%) | NYR [NYR;NYR] | 47 | 2 (4.3%) | NYR [NYR;NYR] | 4.29 [0.92;19.95] | 0.0432 | 0.4679 |
| >= 65 AND < 75 | 25 | 12 (48.0%) | 14.16 [7.82;NYR] | 18 | 5 (27.8%) | NYR [3.22;NYR] | 1.66 [0.58;4.71] | 0.3364 | |
| >= 75 | 8 | 3 (37.5%) | NYR [0.95;NYR] | 6 | 2 (33.3%) | NYR [0.85;NYR] | 1.22 [0.20;7.40] | 0.8280 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 14 (35.9%) | NYR [18.37;NYR] | 37 | 7 (18.9%) | NYR [NYR;NYR] | 1.76 [0.71;4.37] | 0.2147 | 0.2508 |
| Rest of World (ROW) | 35 | 10 (28.6%) | NYR [NYR;NYR] | 34 | 2 (5.9%) | NYR [NYR;NYR] | 5.13 [1.12;23.42] | 0.0187 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.16.2: Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 18 (27.7%) | NYR [NYR;NYR] | 60 | 8 (13.3%) | NYR [NYR;NYR] | 1.99 [0.87;4.59] | 0.0974 | 0.2054 |
| Non-White | 9 | 6 (66.7%) | 18.37 [0.95;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 8.20 [0.98;68.27] | 0.0204 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 4 (57.1%) | 8.08 [5.13;NYR] | 13 | 4 (30.8%) | NYR [2.37;NYR] | 1.68 [0.42;6.77] | 0.4632 | 0.7622 |
| Not Hispanic or Latino | 43 | 16 (37.2%) | NYR [18.37;NYR] | 32 | 4 (12.5%) | NYR [NYR;NYR] | 2.94 [0.98;8.81] | 0.0430 | |
| Not Reported | 24 | 4 (16.7%) | NYR [NYR;NYR] | 26 | 1 (3.8%) | NYR [NYR;NYR] | 4.11 [0.46;36.83] | 0.1701 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 15 (26.8%) | NYR [NYR;NYR] | 48 | 3 (6.3%) | NYR [NYR;NYR] | 4.07 [1.18;14.06] | 0.0164 | 0.4190 |
| Female | 18 | 9 (50.0%) | 18.37 [2.30;NYR] | 23 | 6 (26.1%) | NYR [5.52;NYR] | 2.06 [0.73;5.78] | 0.1620 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 3 (21.4%) | NYR [18.37;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | 3.31 [0.34;31.91] | 0.2729 | 0.6882 |
| >= 1 Year | 60 | 21 (35.0%) | NYR [19.58;NYR] | 50 | 8 (16.0%) | NYR [NYR;NYR] | 2.21 [0.98;4.98] | 0.0507 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.16.2: Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3404 | 0.9898 |
| Yes | 63 | 24 (38.1%) | NYR [18.37;NYR] | 59 | 8 (13.6%) | NYR [NYR;NYR] | 2.79 [1.25;6.22] | 0.0086 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 21 (32.8%) | NYR [NYR;NYR] | 65 | 8 (12.3%) | NYR [NYR;NYR] | 2.63 [1.17;5.95] | 0.0155 | 0.7252 |
| Yes | 10 | 3 (30.0%) | NYR [2.86;NYR] | 6 | 1 (16.7%) | NYR [1.58;NYR] | 1.01 [0.09;11.22] | 0.9919 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 5 (45.5%) | 21.95 [8.05;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0477 | 0.9999 |
| < 1% | 61 | 19 (31.1%) | NYR [NYR;NYR] | 60 | 9 (15.0%) | NYR [NYR;NYR] | 2.07 [0.94;4.58] | 0.0663 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 3 (16.7%) | NYR [18.37;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | 3.01 [0.31;29.00] | 0.3161 | 0.7484 |
| Non-Stage IV | 53 | 19 (35.8%) | NYR [19.58;NYR] | 51 | 8 (15.7%) | NYR [NYR;NYR] | 2.23 [0.98;5.11] | 0.0501 | |
| Not Reported | 3 | 2 (66.7%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:57:48

TABLE 3.17.1: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 35 (47.3%) | 29 (40.8%) |
| Number of censored cases | N | 39 (52.7%) | 42 (59.2%) |
| Time to first event (Months) | Mean (SE) | 12.66 (1.00) | 11.86 (0.85) |
| | Q1 [95% CI] | 2.80 [1.81;5.55] | 5.40 [1.38;11.30] |
| | Median [95% CI] | 19.48 [8.57;NYR] | 15.18 [11.30;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.7323 | |
| Stratified Cox PH model | HR (b) | 1.09 [0.66;1.79] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:32:49

TABLE 3.17.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 35 (47.3%) | 19.48 [8.57;NYR] | 71 | 29 (40.8%) | 15.18 [11.30;NYR] | 1.09 [0.66;1.79] | 0.7323 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 23 (56.1%) | 11.73 [4.34;NYR] | 47 | 17 (36.2%) | 17.45 [12.45;NYR] | 1.49 [0.80;2.81] | 0.2102 | 0.0321 |
| >= 65 | 33 | 12 (36.4%) | NYR [4.21;NYR] | 24 | 12 (50.0%) | 7.89 [2.14;NYR] | 0.55 [0.24;1.24] | 0.1456 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 23 (56.1%) | 11.73 [4.34;NYR] | 47 | 17 (36.2%) | 17.45 [12.45;NYR] | 1.49 [0.80;2.81] | 0.2102 | 0.0324 |
| >= 65 AND < 75 | 25 | 9 (36.0%) | NYR [4.17;NYR] | 18 | 11 (61.1%) | 4.80 [0.72;NYR] | 0.44 [0.18;1.07] | 0.0624 | |
| >= 75 | 8 | 3 (37.5%) | 19.91 [0.95;NYR] | 6 | 1 (16.7%) | NYR [5.32;NYR] | 1.78 [0.18;17.93] | 0.6219 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 13 (33.3%) | NYR [16.76;NYR] | 37 | 9 (24.3%) | NYR [13.80;NYR] | 1.20 [0.51;2.83] | 0.6887 | 0.6249 |
| Rest of World (ROW) | 35 | 22 (62.9%) | 8.28 [2.92;19.91] | 34 | 20 (58.8%) | 11.30 [1.38;15.18] | 0.93 [0.51;1.70] | 0.8196 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:32:49

TABLE 3.17.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 30 (46.2%) | 19.91 [8.57;NYR] | 60 | 23 (38.3%) | 15.18 [11.30;NYR] | 1.05 [0.61;1.82] | 0.8512 | 0.7532 |
| Non-White | 9 | 5 (55.6%) | 16.76 [0.53;NYR] | 11 | 6 (54.5%) | 13.37 [0.69;NYR] | 0.93 [0.28;3.08] | 0.9099 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 4 (57.1%) | 8.28 [1.38;NYR] | 13 | 7 (53.8%) | 15.18 [0.72;15.18] | 0.79 [0.23;2.72] | 0.6844 | 0.7682 |
| Not Hispanic or Latino | 43 | 17 (39.5%) | NYR [5.55;NYR] | 32 | 9 (28.1%) | NYR [13.80;NYR] | 1.34 [0.59;3.01] | 0.4861 | |
| Not Reported | 24 | 14 (58.3%) | 15.61 [4.17;NYR] | 26 | 13 (50.0%) | 13.37 [7.89;NYR] | 1.05 [0.49;2.23] | 0.9071 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 23 (41.1%) | NYR [8.77;NYR] | 48 | 18 (37.5%) | 17.45 [12.45;NYR] | 1.01 [0.54;1.87] | 0.9995 | 0.8680 |
| Female | 18 | 12 (66.7%) | 8.57 [2.30;19.91] | 23 | 11 (47.8%) | 11.30 [1.38;NYR] | 1.12 [0.49;2.55] | 0.7534 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 8 (57.1%) | 12.67 [1.81;NYR] | 19 | 8 (42.1%) | NYR [2.30;NYR] | 1.31 [0.49;3.49] | 0.5871 | 0.5440 |
| >= 1 Year | 60 | 27 (45.0%) | 19.91 [8.28;NYR] | 50 | 21 (42.0%) | 14.00 [11.30;NYR] | 0.89 [0.50;1.59] | 0.6983 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.17.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 10 (90.9%) | 2.79 [1.38;5.55] | 12 | 4 (33.3%) | NYR [1.38;NYR] | 3.74 [1.16;12.03] | 0.0189 | 0.0154 |
| Yes | 63 | 25 (39.7%) | NYR [16.76;NYR] | 59 | 25 (42.4%) | 14.00 [11.30;NYR] | 0.76 [0.43;1.32] | 0.3251 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 30 (46.9%) | 19.48 [8.57;NYR] | 65 | 27 (41.5%) | 14.00 [11.30;NYR] | 0.95 [0.56;1.60] | 0.8382 | 0.5668 |
| Yes | 10 | 5 (50.0%) | 4.17 [0.49;NYR] | 6 | 2 (33.3%) | NYR [0.69;NYR] | 1.54 [0.30;7.96] | 0.6155 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [4.21;NYR] | 10 | 7 (70.0%) | 1.76 [0.69;NYR] | 0.15 [0.03;0.74] | 0.0078 | 0.0141 |
| < 1% | 61 | 32 (52.5%) | 16.76 [5.55;NYR] | 60 | 22 (36.7%) | 15.18 [12.45;NYR] | 1.39 [0.80;2.39] | 0.2428 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 10 (55.6%) | 8.57 [2.79;NYR] | 20 | 8 (40.0%) | NYR [2.30;NYR] | 1.34 [0.53;3.39] | 0.5357 | 0.5636 |
| Non-Stage IV | 53 | 24 (45.3%) | 19.91 [8.77;NYR] | 51 | 21 (41.2%) | 14.00 [11.30;NYR] | 0.91 [0.51;1.65] | 0.7642 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.18.1: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 35 (47.3%) | 29 (40.8%) |
| Number of censored cases | N | 39 (52.7%) | 42 (59.2%) |
| Time to first event (Months) | Mean (SE) | 12.74 (0.99) | 12.08 (0.84) |
| | Q1 [95% CI] | 2.80 [1.81;5.55] | 5.40 [1.38;11.30] |
| | Median [95% CI] | 19.91 [8.57;NYR] | 17.45 [12.45;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.6218 | |
| Stratified Cox PH model | HR (b) | 1.13 [0.69;1.86] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:40:03

TABLE 3.18.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 35 (47.3%) | 19.91 [8.57;NYR] | 71 | 29 (40.8%) | 17.45 [12.45;NYR] | 1.13 [0.69;1.86] | 0.6218 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 23 (56.1%) | 11.73 [4.34;NYR] | 47 | 17 (36.2%) | NYR [13.37;NYR] | 1.57 [0.84;2.95] | 0.1560 | 0.0364 |
| >= 65 | 33 | 12 (36.4%) | NYR [14.26;NYR] | 24 | 12 (50.0%) | 13.80 [2.14;NYR] | 0.59 [0.26;1.34] | 0.2060 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 23 (56.1%) | 11.73 [4.34;NYR] | 47 | 17 (36.2%) | NYR [13.37;NYR] | 1.57 [0.84;2.95] | 0.1560 | 0.0341 |
| >= 65 AND < 75 | 25 | 9 (36.0%) | NYR [4.17;NYR] | 18 | 11 (61.1%) | 6.34 [0.72;NYR] | 0.49 [0.20;1.19] | 0.1095 | |
| >= 75 | 8 | 3 (37.5%) | 19.91 [0.95;NYR] | 6 | 1 (16.7%) | NYR [5.32;NYR] | 1.68 [0.17;16.77] | 0.6562 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 13 (33.3%) | NYR [16.76;NYR] | 37 | 9 (24.3%) | NYR [14.00;NYR] | 1.29 [0.55;3.03] | 0.5764 | 0.5741 |
| Rest of World (ROW) | 35 | 22 (62.9%) | 8.57 [2.92;19.91] | 34 | 20 (58.8%) | 11.30 [1.38;NYR] | 0.95 [0.52;1.73] | 0.8660 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:40:03

TABLE 3.18.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 30 (46.2%) | 19.91 [8.57;NYR] | 60 | 23 (38.3%) | 17.45 [12.45;NYR] | 1.11 [0.65;1.92] | 0.6991 | 0.7352 |
| Non-White | 9 | 5 (55.6%) | 16.76 [0.53;NYR] | 11 | 6 (54.5%) | 13.37 [0.69;NYR] | 0.93 [0.28;3.08] | 0.9099 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 4 (57.1%) | 8.28 [1.38;NYR] | 13 | 7 (53.8%) | 15.18 [0.72;15.18] | 0.82 [0.24;2.81] | 0.7234 | 0.7937 |
| Not Hispanic or Latino | 43 | 17 (39.5%) | NYR [14.26;NYR] | 32 | 9 (28.1%) | NYR [13.80;NYR] | 1.35 [0.60;3.05] | 0.4651 | |
| Not Reported | 24 | 14 (58.3%) | 15.61 [4.17;NYR] | 26 | 13 (50.0%) | 13.37 [7.89;NYR] | 1.08 [0.50;2.30] | 0.8454 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 23 (41.1%) | NYR [8.77;NYR] | 48 | 18 (37.5%) | 17.45 [13.37;NYR] | 1.05 [0.57;1.96] | 0.8792 | 0.8256 |
| Female | 18 | 12 (66.7%) | 8.57 [2.30;19.91] | 23 | 11 (47.8%) | 11.30 [1.38;NYR] | 1.20 [0.53;2.72] | 0.6345 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 8 (57.1%) | 12.67 [1.81;NYR] | 19 | 8 (42.1%) | NYR [2.30;NYR] | 1.32 [0.50;3.53] | 0.5685 | 0.5490 |
| >= 1 Year | 60 | 27 (45.0%) | NYR [8.77;NYR] | 50 | 21 (42.0%) | 15.18 [12.45;NYR] | 0.93 [0.52;1.66] | 0.8094 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:40:03

TABLE 3.18.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 10 (90.9%) | 2.79 [1.38;5.55] | 12 | 4 (33.3%) | NYR [1.38;NYR] | 4.06 [1.25;13.18] | 0.0128 | 0.0145 |
| Yes | 63 | 25 (39.7%) | NYR [16.76;NYR] | 59 | 25 (42.4%) | 15.18 [11.30;NYR] | 0.79 [0.45;1.38] | 0.4059 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 30 (46.9%) | 19.91 [8.77;NYR] | 65 | 27 (41.5%) | 15.18 [11.30;NYR] | 0.99 [0.59;1.67] | 0.9756 | 0.5546 |
| Yes | 10 | 5 (50.0%) | NYR [0.49;NYR] | 6 | 2 (33.3%) | NYR [0.69;NYR] | 1.57 [0.30;8.09] | 0.5980 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [4.21;NYR] | 10 | 7 (70.0%) | 1.76 [0.69;NYR] | 0.15 [0.03;0.74] | 0.0078 | 0.0125 |
| < 1% | 61 | 32 (52.5%) | 17.31 [5.55;NYR] | 60 | 22 (36.7%) | NYR [12.45;NYR] | 1.46 [0.85;2.52] | 0.1714 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 10 (55.6%) | 8.57 [2.79;NYR] | 20 | 8 (40.0%) | NYR [2.30;NYR] | 1.38 [0.54;3.50] | 0.4938 | 0.5704 |
| Non-Stage IV | 53 | 24 (45.3%) | 19.91 [8.77;NYR] | 51 | 21 (41.2%) | 15.18 [12.45;NYR] | 0.96 [0.53;1.73] | 0.8919 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:40:03

TABLE 3.19.1: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 1 (1.4%) | 0 (0.0%) |
| Number of censored cases | N | 73 (98.6%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 1.84 (.) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.3320 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.19.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3320 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2948 | 0.9993 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2948 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3367 | 0.9993 |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.19.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 1 (1.5%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3449 | 0.9994 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3074 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 1 (1.8%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3545 | 0.9992 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2440 | 0.9994 |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.19.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2963 | 0.9996 |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3211 | 0.9995 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 1 (1.6%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3295 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2918 | 0.9994 |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.20.1: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 1 (1.4%) | 0 (0.0%) |
| Number of censored cases | N | 73 (98.6%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 1.84 (.) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.3245 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.20.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3245 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2843 | 0.9993 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2843 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3300 | 0.9993 |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.20.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 1 (1.5%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3367 | 0.9994 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2980 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 1 (1.8%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3545 | 0.9992 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2440 | 0.9994 |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.20.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2963 | 0.9994 |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3136 | 0.9995 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 1 (1.6%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3213 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2918 | 0.9994 |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:53:53

TABLE 3.21.1: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:00:47

TABLE 3.21.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:00:47

TABLE 3.21.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:00:47

TABLE 3.21.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.22.1: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:07:46

TABLE 3.22.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:07:46

TABLE 3.22.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:07:46

TABLE 3.22.2: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.23.1: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 56 (75.7%) | 37 (52.1%) |
| Number of censored cases | N | 18 (24.3%) | 34 (47.9%) |
| Time to first event (Months) | Mean (SE) | 9.27 (1.14) | 8.72 (0.83) |
| | Q1 [95% CI] | 1.60 [0.95;1.91] | 2.20 [1.61;3.45] |
| | Median [95% CI] | 4.37 [2.10;10.61] | 8.71 [3.48;NYR] |
| | Q3 [95% CI] | 16.60 [12.94;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0405 | |
| Stratified Cox PH model | HR (b) | 1.55 [1.02;2.36] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:14:40

TABLE 3.23.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 56 (75.7%) | 4.37 [2.10;10.61] | 71 | 37 (52.1%) | 8.71 [3.48;NYR] | 1.55 [1.02;2.36] | 0.0405 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 36 (87.8%) | 2.33 [1.71;6.60] | 47 | 27 (57.4%) | 8.71 [3.48;15.70] | 1.79 [1.09;2.95] | 0.0208 | 0.5329 |
| >= 65 | 33 | 20 (60.6%) | 6.77 [2.27;16.59] | 24 | 10 (41.7%) | NYR [2.14;NYR] | 1.34 [0.63;2.88] | 0.4461 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 36 (87.8%) | 2.33 [1.71;6.60] | 47 | 27 (57.4%) | 8.71 [3.48;15.70] | 1.79 [1.09;2.95] | 0.0208 | 0.2090 |
| >= 65 AND < 75 | 25 | 17 (68.0%) | 6.77 [1.91;12.94] | 18 | 7 (38.9%) | NYR [2.14;NYR] | 1.85 [0.76;4.48] | 0.1691 | |
| >= 75 | 8 | 3 (37.5%) | NYR [1.51;NYR] | 6 | 3 (50.0%) | 2.83 [0.56;NYR] | 0.55 [0.11;2.73] | 0.4555 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 33 (84.6%) | 2.27 [1.61;6.18] | 37 | 17 (45.9%) | 9.36 [3.48;NYR] | 2.28 [1.27;4.10] | 0.0045 | 0.0572 |
| Rest of World (ROW) | 35 | 23 (65.7%) | 8.54 [2.66;17.41] | 34 | 20 (58.8%) | 5.13 [2.99;NYR] | 1.00 [0.55;1.83] | 0.9924 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.23.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 50 (76.9%) | 4.17 [1.94;8.54] | 60 | 30 (50.0%) | 9.36 [3.71;NYR] | 1.71 [1.09;2.69] | 0.0187 | 0.2544 |
| Non-White | 9 | 6 (66.7%) | 13.01 [0.26;NYR] | 11 | 7 (63.6%) | 3.45 [0.43;NYR] | 0.86 [0.29;2.59] | 0.7900 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 4 (57.1%) | 4.93 [0.26;NYR] | 13 | 8 (61.5%) | 4.86 [1.61;15.70] | 0.69 [0.20;2.32] | 0.5385 | 0.2448 |
| Not Hispanic or Latino | 43 | 35 (81.4%) | 2.33 [1.71;6.77] | 32 | 15 (46.9%) | 4.73 [3.25;NYR] | 2.12 [1.16;3.89] | 0.0128 | |
| Not Reported | 24 | 17 (70.8%) | 9.58 [1.71;16.59] | 26 | 14 (53.8%) | 9.36 [2.14;NYR] | 1.28 [0.63;2.60] | 0.4921 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 44 (78.6%) | 2.50 [1.84;8.54] | 48 | 26 (54.2%) | 9.36 [3.88;NYR] | 1.76 [1.08;2.86] | 0.0208 | 0.2828 |
| Female | 18 | 12 (66.7%) | 6.11 [2.10;17.41] | 23 | 11 (47.8%) | 3.71 [2.10;NYR] | 0.98 [0.43;2.25] | 0.9554 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 11 (78.6%) | 11.78 [1.71;14.16] | 19 | 10 (52.6%) | 15.24 [3.48;NYR] | 1.64 [0.69;3.92] | 0.2608 | 0.9077 |
| >= 1 Year | 60 | 45 (75.0%) | 3.22 [1.84;6.77] | 50 | 25 (50.0%) | 4.73 [2.83;NYR] | 1.61 [0.99;2.62] | 0.0546 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.23.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 10 (90.9%) | 2.66 [1.61;4.93] | 12 | 7 (58.3%) | 4.86 [2.83;NYR] | 2.34 [0.88;6.18] | 0.0787 | 0.4520 |
| Yes | 63 | 46 (73.0%) | 6.18 [2.10;12.94] | 59 | 30 (50.8%) | 8.71 [3.71;NYR] | 1.46 [0.92;2.31] | 0.1068 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 49 (76.6%) | 2.94 [1.91;6.77] | 65 | 33 (50.8%) | 8.71 [3.48;NYR] | 1.66 [1.07;2.58] | 0.0231 | 0.3364 |
| Yes | 10 | 7 (70.0%) | 16.59 [0.16;25.49] | 6 | 4 (66.7%) | 3.88 [2.14;NYR] | 0.65 [0.18;2.36] | 0.5084 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 8 (72.7%) | 10.71 [1.71;25.49] | 10 | 6 (60.0%) | 2.81 [0.26;NYR] | 0.79 [0.27;2.33] | 0.6703 | 0.4407 |
| < 1% | 61 | 47 (77.0%) | 3.22 [1.91;6.77] | 60 | 30 (50.0%) | 8.71 [3.88;NYR] | 1.74 [1.10;2.75] | 0.0166 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 12 (66.7%) | 12.94 [1.84;15.67] | 20 | 13 (65.0%) | 3.48 [0.82;15.70] | 0.88 [0.40;1.93] | 0.7446 | 0.1129 |
| Non-Stage IV | 53 | 41 (77.4%) | 4.37 [2.10;6.77] | 51 | 24 (47.1%) | 11.37 [3.88;NYR] | 1.84 [1.11;3.04] | 0.0166 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.24.1: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 56 (75.7%) | 38 (53.5%) |
| Number of censored cases | N | 18 (24.3%) | 33 (46.5%) |
| Time to first event (Months) | Mean (SE) | 9.44 (1.15) | 8.93 (0.81) |
| | Q1 [95% CI] | 1.60 [0.95;1.91] | 2.20 [1.61;3.48] |
| | Median [95% CI] | 4.37 [2.10;10.61] | 8.71 [3.88;NYR] |
| | Q3 [95% CI] | 17.40 [12.94;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0328 | |
| Stratified Cox PH model | HR (b) | 1.57 [1.03;2.39] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 3.24.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 56 (75.7%) | 4.37 [2.10;10.61] | 71 | 38 (53.5%) | 8.71 [3.88;NYR] | 1.57 [1.03;2.39] | 0.0328 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 36 (87.8%) | 2.33 [1.71;6.60] | 47 | 27 (57.4%) | 8.71 [3.48;NYR] | 1.85 [1.12;3.05] | 0.0144 | 0.4461 |
| >= 65 | 33 | 20 (60.6%) | 6.77 [2.27;NYR] | 24 | 11 (45.8%) | NYR [2.14;NYR] | 1.29 [0.62;2.70] | 0.4985 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 36 (87.8%) | 2.33 [1.71;6.60] | 47 | 27 (57.4%) | 8.71 [3.48;NYR] | 1.85 [1.12;3.05] | 0.0144 | 0.2582 |
| >= 65 AND < 75 | 25 | 17 (68.0%) | 6.77 [1.91;16.59] | 18 | 8 (44.4%) | NYR [2.14;NYR] | 1.69 [0.73;3.92] | 0.2192 | |
| >= 75 | 8 | 3 (37.5%) | NYR [1.51;NYR] | 6 | 3 (50.0%) | NYR [0.56;NYR] | 0.57 [0.11;2.87] | 0.4935 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 33 (84.6%) | 2.27 [1.61;6.18] | 37 | 18 (48.6%) | 11.37 [3.71;NYR] | 2.30 [1.29;4.09] | 0.0036 | 0.0605 |
| Rest of World (ROW) | 35 | 23 (65.7%) | 10.61 [2.66;17.41] | 34 | 20 (58.8%) | 5.13 [2.99;NYR] | 1.02 [0.56;1.86] | 0.9494 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.24.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 50 (76.9%) | 4.17 [1.94;8.54] | 60 | 31 (51.7%) | 11.37 [4.27;NYR] | 1.73 [1.11;2.71] | 0.0151 | 0.2502 |
| Non-White | 9 | 6 (66.7%) | 13.01 [0.26;NYR] | 11 | 7 (63.6%) | 3.45 [0.43;NYR] | 0.88 [0.29;2.63] | 0.8140 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 4 (57.1%) | 4.93 [0.26;NYR] | 13 | 8 (61.5%) | 4.86 [1.61;NYR] | 0.79 [0.24;2.64] | 0.6954 | 0.3217 |
| Not Hispanic or Latino | 43 | 35 (81.4%) | 2.33 [1.71;6.77] | 32 | 16 (50.0%) | 4.73 [3.25;NYR] | 2.07 [1.14;3.74] | 0.0140 | |
| Not Reported | 24 | 17 (70.8%) | 9.58 [1.71;17.41] | 26 | 14 (53.8%) | 11.37 [2.99;NYR] | 1.32 [0.65;2.69] | 0.4372 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 44 (78.6%) | 2.50 [1.84;8.54] | 48 | 26 (54.2%) | 9.36 [3.88;NYR] | 1.79 [1.10;2.91] | 0.0174 | 0.2799 |
| Female | 18 | 12 (66.7%) | 6.11 [2.10;17.41] | 23 | 12 (52.2%) | 4.50 [2.14;NYR] | 1.02 [0.46;2.29] | 0.9649 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 11 (78.6%) | 11.78 [1.71;14.16] | 19 | 11 (57.9%) | 9.36 [3.48;NYR] | 1.52 [0.65;3.54] | 0.3330 | 0.6937 |
| >= 1 Year | 60 | 45 (75.0%) | 3.70 [1.84;6.77] | 50 | 25 (50.0%) | 8.71 [3.06;NYR] | 1.69 [1.04;2.76] | 0.0334 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.24.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 10 (90.9%) | 2.66 [1.61;4.93] | 12 | 7 (58.3%) | 4.86 [2.83;NYR] | 2.34 [0.88;6.18] | 0.0787 | 0.4627 |
| Yes | 63 | 46 (73.0%) | 6.18 [2.10;12.94] | 59 | 31 (52.5%) | 9.36 [3.88;NYR] | 1.46 [0.93;2.31] | 0.0985 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 49 (76.6%) | 2.94 [1.91;6.77] | 65 | 34 (52.3%) | 8.71 [3.71;NYR] | 1.69 [1.09;2.62] | 0.0177 | 0.3452 |
| Yes | 10 | 7 (70.0%) | 16.59 [0.16;25.49] | 6 | 4 (66.7%) | 7.62 [2.14;NYR] | 0.65 [0.18;2.35] | 0.5044 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 8 (72.7%) | 10.71 [1.71;25.49] | 10 | 7 (70.0%) | 2.81 [0.26;NYR] | 0.69 [0.25;1.93] | 0.4751 | 0.2367 |
| < 1% | 61 | 47 (77.0%) | 3.22 [1.91;6.77] | 60 | 30 (50.0%) | 15.24 [4.27;NYR] | 1.83 [1.16;2.90] | 0.0086 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 12 (66.7%) | 12.94 [1.84;15.67] | 20 | 13 (65.0%) | 3.48 [0.82;15.70] | 0.88 [0.40;1.93] | 0.7462 | 0.0977 |
| Non-Stage IV | 53 | 41 (77.4%) | 4.37 [2.10;8.54] | 51 | 25 (49.0%) | 11.37 [4.27;NYR] | 1.87 [1.13;3.07] | 0.0126 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.25.1: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 8 (10.8%) | 4 (5.6%) |
| Number of censored cases | N | 66 (89.2%) | 67 (94.4%) |
| Time to first event (Months) | Mean (SE) | 19.01 (0.45) | 6.10 (0.12) |
| | Q1 [95% CI] | NYR [20.11;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.4146 | |
| Stratified Cox PH model | HR (b) | 1.64 [0.49;5.47] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.25.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.64 [0.49;5.47] | 0.4146 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [NYR;NYR] | 2.16 [0.56;8.37] | 0.2531 | 0.4004 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 0.59 [0.04;9.60] | 0.7090 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [NYR;NYR] | 2.16 [0.56;8.37] | 0.2531 | 1.0000 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4692 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 1 (16.7%) | NYR [0.66;NYR] | <0.01 [<0.01;NE] | 0.2482 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NYR [NYR;NYR] | 37 | 2 (5.4%) | NYR [NYR;NYR] | 1.88 [0.36;9.69] | 0.4452 | 0.7039 |
| Rest of World (ROW) | 35 | 3 (8.6%) | NYR [NYR;NYR] | 34 | 2 (5.9%) | NYR [NYR;NYR] | 1.26 [0.21;7.55] | 0.8020 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.25.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 7 (10.8%) | NYR [NYR;NYR] | 60 | 3 (5.0%) | NYR [NYR;NYR] | 1.80 [0.46;6.96] | 0.3880 | 0.6651 |
| Non-White | 9 | 1 (11.1%) | NYR [7.85;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 1.04 [0.06;16.81] | 0.9767 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [7.85;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2059 | 0.5768 |
| Not Hispanic or Latino | 43 | 6 (14.0%) | NYR [NYR;NYR] | 32 | 2 (6.3%) | NYR [NYR;NYR] | 1.94 [0.39;9.64] | 0.4087 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 2 (7.7%) | NYR [NYR;NYR] | 0.47 [0.04;5.17] | 0.5252 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 6 (10.7%) | NYR [NYR;NYR] | 48 | 4 (8.3%) | NYR [NYR;NYR] | 1.10 [0.31;3.91] | 0.8822 | 0.9919 |
| Female | 18 | 2 (11.1%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1924 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [20.11;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1822 | 0.9920 |
| >= 1 Year | 60 | 6 (10.0%) | NYR [NYR;NYR] | 50 | 4 (8.0%) | NYR [NYR;NYR] | 1.04 [0.29;3.70] | 0.9478 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.25.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NYR [11.04;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | 1.67 [0.15;18.97] | 0.6760 | 0.9971 |
| Yes | 63 | 6 (9.5%) | NYR [NYR;NYR] | 59 | 3 (5.1%) | NYR [NYR;NYR] | 1.61 [0.40;6.45] | 0.4958 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 7 (10.9%) | NYR [NYR;NYR] | 65 | 3 (4.6%) | NYR [NYR;NYR] | 1.93 [0.50;7.49] | 0.3309 | 0.4320 |
| Yes | 10 | 1 (10.0%) | NYR [19.29;NYR] | 6 | 1 (16.7%) | NYR [6.28;NYR] | 0.49 [0.03;8.21] | 0.6115 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [12.65;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2684 | 1.0000 |
| < 1% | 61 | 6 (9.8%) | NYR [NYR;NYR] | 60 | 4 (6.7%) | NYR [NYR;NYR] | 1.24 [0.35;4.41] | 0.7350 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3428 | 0.9927 |
| Non-Stage IV | 53 | 7 (13.2%) | NYR [NYR;NYR] | 51 | 3 (5.9%) | NYR [NYR;NYR] | 1.78 [0.46;6.88] | 0.3977 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.26.1: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 8 (10.8%) | 5 (7.0%) |
| Number of censored cases | N | 66 (89.2%) | 66 (93.0%) |
| Time to first event (Months) | Mean (SE) | 19.04 (0.44) | 6.08 (0.12) |
| | Q1 [95% CI] | NYR [20.11;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.5793 | |
| Stratified Cox PH model | HR (b) | 1.37 [0.45;4.20] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.26.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 1.37 [0.45;4.20] | 0.5793 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [NYR;NYR] | 2.26 [0.58;8.74] | 0.2264 | 0.1636 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 2 (8.3%) | NYR [NYR;NYR] | 0.33 [0.03;3.68] | 0.3457 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [NYR;NYR] | 2.26 [0.58;8.74] | 0.2264 | 0.7458 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 1 (5.6%) | NYR [NYR;NYR] | 0.65 [0.04;10.65] | 0.7643 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 1 (16.7%) | NYR [0.66;NYR] | <0.01 [<0.01;NE] | 0.2482 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NYR [NYR;NYR] | 37 | 3 (8.1%) | NYR [NYR;NYR] | 1.32 [0.31;5.53] | 0.7051 | 0.9759 |
| Rest of World (ROW) | 35 | 3 (8.6%) | NYR [NYR;NYR] | 34 | 2 (5.9%) | NYR [NYR;NYR] | 1.34 [0.22;8.02] | 0.7480 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.26.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 7 (10.8%) | NYR [NYR;NYR] | 60 | 4 (6.7%) | NYR [NYR;NYR] | 1.43 [0.42;4.89] | 0.5658 | 0.8241 |
| Non-White | 9 | 1 (11.1%) | NYR [7.85;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 1.11 [0.07;17.74] | 0.9435 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [7.85;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2482 | 0.7145 |
| Not Hispanic or Latino | 43 | 6 (14.0%) | NYR [NYR;NYR] | 32 | 3 (9.4%) | NYR [NYR;NYR] | 1.39 [0.35;5.55] | 0.6423 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 2 (7.7%) | NYR [NYR;NYR] | 0.50 [0.04;5.50] | 0.5608 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 6 (10.7%) | NYR [NYR;NYR] | 48 | 4 (8.3%) | NYR [NYR;NYR] | 1.15 [0.32;4.08] | 0.8299 | 0.6217 |
| Female | 18 | 2 (11.1%) | NYR [NYR;NYR] | 23 | 1 (4.3%) | NYR [NYR;NYR] | 2.05 [0.18;22.68] | 0.5511 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [20.11;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | 2.05 [0.18;22.68] | 0.5511 | 0.6067 |
| >= 1 Year | 60 | 6 (10.0%) | NYR [NYR;NYR] | 50 | 4 (8.0%) | NYR [NYR;NYR] | 1.10 [0.31;3.91] | 0.8798 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.26.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NYR [11.04;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | 1.76 [0.16;19.72] | 0.6433 | 0.8075 |
| Yes | 63 | 6 (9.5%) | NYR [NYR;NYR] | 59 | 4 (6.8%) | NYR [NYR;NYR] | 1.27 [0.36;4.49] | 0.7150 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 7 (10.9%) | NYR [NYR;NYR] | 65 | 4 (6.2%) | NYR [NYR;NYR] | 1.55 [0.45;5.29] | 0.4825 | 0.5518 |
| Yes | 10 | 1 (10.0%) | NYR [19.29;NYR] | 6 | 1 (16.7%) | NYR [6.28;NYR] | 0.60 [0.04;9.66] | 0.7140 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [12.65;NYR] | 10 | 1 (10.0%) | NYR [4.40;NYR] | 1.51 [0.14;16.67] | 0.7348 | 0.9960 |
| < 1% | 61 | 6 (9.8%) | NYR [NYR;NYR] | 60 | 4 (6.7%) | NYR [NYR;NYR] | 1.33 [0.37;4.71] | 0.6599 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3428 | 0.9922 |
| Non-Stage IV | 53 | 7 (13.2%) | NYR [NYR;NYR] | 51 | 4 (7.8%) | NYR [NYR;NYR] | 1.45 [0.42;4.95] | 0.5538 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.27.1: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 6 (8.1%) | 0 (0.0%) |
| Number of censored cases | N | 68 (91.9%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 16.69 (0.39) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0274 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.27.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0274 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 4 (9.8%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0561 | 1.0000 |
| >= 65 | 33 | 2 (6.1%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2966 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 4 (9.8%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0561 | 1.0000 |
| >= 65 AND < 75 | 25 | 2 (8.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3116 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 3 (7.7%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1414 | 1.0000 |
| Rest of World (ROW) | 35 | 3 (8.6%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1016 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.27.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 5 (7.7%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0472 | 1.0000 |
| Non-White | 9 | 1 (11.1%) | NYR [7.85;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3173 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 2 (28.6%) | NYR [5.16;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0993 | 1.0000 |
| Not Hispanic or Latino | 43 | 3 (7.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1825 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3496 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 3 (5.4%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1357 | 0.9999 |
| Female | 18 | 3 (16.7%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1006 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9982 |
| >= 1 Year | 60 | 6 (10.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0389 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.27.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3173 | 1.0000 |
| Yes | 63 | 5 (7.9%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0447 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 4 (6.3%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0654 | 0.9999 |
| Yes | 10 | 2 (20.0%) | NYR [5.16;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3057 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [12.65;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 | 1.0000 |
| < 1% | 61 | 5 (8.2%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0382 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9981 |
| Non-Stage IV | 53 | 6 (11.3%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0294 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.28.1: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 6 (8.1%) | 1 (1.4%) |
| Number of censored cases | N | 68 (91.9%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 16.71 (0.38) | 4.40 (.) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0998 | |
| Stratified Cox PH model | HR (b) | 4.99 [0.60;41.61] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.28.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 4.99 [0.60;41.61] | 0.0998 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 4 (9.8%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0526 | 0.9943 |
| >= 65 | 33 | 2 (6.1%) | NYR [NYR;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 1.30 [0.12;14.39] | 0.8303 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 4 (9.8%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0526 | 1.0000 |
| >= 65 AND < 75 | 25 | 2 (8.0%) | NYR [NYR;NYR] | 18 | 1 (5.6%) | NYR [NYR;NYR] | 1.27 [0.11;14.17] | 0.8442 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 3 (7.7%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 2.32 [0.24;22.51] | 0.4556 | 0.9952 |
| Rest of World (ROW) | 35 | 3 (8.6%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0952 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.28.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 5 (7.7%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 4.07 [0.48;34.93] | 0.1648 | 0.9959 |
| Non-White | 9 | 1 (11.1%) | NYR [7.85;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2918 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 2 (28.6%) | NYR [5.16;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1056 | 1.0000 |
| Not Hispanic or Latino | 43 | 3 (7.0%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 1.88 [0.19;18.21] | 0.5806 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3276 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 3 (5.4%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1311 | 0.9941 |
| Female | 18 | 3 (16.7%) | NYR [NYR;NYR] | 23 | 1 (4.3%) | NYR [NYR;NYR] | 3.06 [0.32;29.47] | 0.3092 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3642 | 0.9946 |
| >= 1 Year | 60 | 6 (10.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0365 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.28.2: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3173 | 0.9957 |
| Yes | 63 | 5 (7.9%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 4.17 [0.49;35.73] | 0.1572 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 4 (6.3%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 3.66 [0.41;32.76] | 0.2146 | 0.9954 |
| Yes | 10 | 2 (20.0%) | NYR [5.16;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3216 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [12.65;NYR] | 10 | 1 (10.0%) | NYR [4.40;NYR] | 0.76 [0.05;12.12] | 0.8434 | 1.0000 |
| < 1% | 61 | 5 (8.2%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0359 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9998 |
| Non-Stage IV | 53 | 6 (11.3%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 4.93 [0.59;41.01] | 0.1020 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.29.1: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 34 (45.9%) | 27 (38.0%) |
| Number of censored cases | N | 40 (54.1%) | 44 (62.0%) |
| Time to first event (Months) | Mean (SE) | 14.88 (1.32) | 11.78 (0.89) |
| | Q1 [95% CI] | 2.40 [1.45;3.94] | 2.40 [0.72;8.25] |
| | Median [95% CI] | 24.80 [4.63;NYR] | NYR [15.21;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.5320 | |
| Stratified Cox PH model | HR (b) | 1.17 [0.70;1.95] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:56:21

TABLE 3.29.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 34 (45.9%) | 24.80 [4.63;NYR] | 71 | 27 (38.0%) | NYR [15.21;NYR] | 1.17 [0.70;1.95] | 0.5320 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 20 (48.8%) | 21.62 [3.94;NYR] | 47 | 17 (36.2%) | NYR [15.21;NYR] | 1.33 [0.70;2.55] | 0.3800 | 0.5752 |
| >= 65 | 33 | 14 (42.4%) | 24.80 [2.40;NYR] | 24 | 10 (41.7%) | NYR [2.37;NYR] | 0.98 [0.44;2.21] | 0.9702 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 20 (48.8%) | 21.62 [3.94;NYR] | 47 | 17 (36.2%) | NYR [15.21;NYR] | 1.33 [0.70;2.55] | 0.3800 | 0.8221 |
| >= 65 AND < 75 | 25 | 13 (52.0%) | 24.80 [1.87;NYR] | 18 | 9 (50.0%) | 7.56 [1.77;NYR] | 1.06 [0.45;2.48] | 0.8831 | |
| >= 75 | 8 | 1 (12.5%) | NYR [2.33;NYR] | 6 | 1 (16.7%) | NYR [0.72;NYR] | 0.61 [0.04;9.93] | 0.7276 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 18 (46.2%) | NYR [4.24;NYR] | 37 | 12 (32.4%) | NYR [8.25;NYR] | 1.40 [0.67;2.91] | 0.3654 | 0.6082 |
| Rest of World (ROW) | 35 | 16 (45.7%) | 24.80 [2.96;NYR] | 34 | 15 (44.1%) | NYR [2.37;NYR] | 1.03 [0.51;2.09] | 0.9194 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.29.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 33 (50.8%) | 9.69 [3.15;NYR] | 60 | 23 (38.3%) | NYR [8.25;NYR] | 1.36 [0.80;2.33] | 0.2520 | 0.1266 |
| Non-White | 9 | 1 (11.1%) | NYR [21.62;NYR] | 11 | 4 (36.4%) | NYR [0.72;NYR] | 0.24 [0.03;2.13] | 0.1624 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [2.76;NYR] | 13 | 8 (61.5%) | 4.80 [1.77;NYR] | 0.18 [0.02;1.41] | 0.0647 | 0.0688 |
| Not Hispanic or Latino | 43 | 21 (48.8%) | 9.69 [2.40;NYR] | 32 | 8 (25.0%) | NYR [NYR;NYR] | 2.18 [0.96;4.92] | 0.0564 | |
| Not Reported | 24 | 12 (50.0%) | 23.21 [2.96;NYR] | 26 | 11 (42.3%) | NYR [2.07;NYR] | 1.00 [0.44;2.28] | 0.9971 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 27 (48.2%) | 24.80 [3.22;NYR] | 48 | 16 (33.3%) | NYR [15.21;NYR] | 1.55 [0.84;2.89] | 0.1612 | 0.1478 |
| Female | 18 | 7 (38.9%) | 21.62 [1.94;NYR] | 23 | 11 (47.8%) | NYR [0.76;NYR] | 0.71 [0.28;1.84] | 0.4867 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 10 (71.4%) | 2.68 [1.22;NYR] | 19 | 6 (31.6%) | NYR [8.25;NYR] | 3.46 [1.25;9.59] | 0.0112 | 0.0368 |
| >= 1 Year | 60 | 24 (40.0%) | NYR [9.69;NYR] | 50 | 20 (40.0%) | NYR [2.99;NYR] | 0.91 [0.50;1.64] | 0.7454 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.29.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 5 (45.5%) | NYR [0.53;NYR] | 12 | 3 (25.0%) | NYR [8.25;NYR] | 1.97 [0.47;8.27] | 0.3472 | 0.3509 |
| Yes | 63 | 29 (46.0%) | 24.80 [4.24;NYR] | 59 | 24 (40.7%) | NYR [4.80;NYR] | 1.07 [0.62;1.83] | 0.8105 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 32 (50.0%) | 21.62 [3.94;NYR] | 65 | 24 (36.9%) | NYR [15.21;NYR] | 1.36 [0.80;2.31] | 0.2519 | 0.1199 |
| Yes | 10 | 2 (20.0%) | NYR [0.49;NYR] | 6 | 3 (50.0%) | NYR [0.62;NYR] | 0.36 [0.06;2.19] | 0.2504 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 5 (45.5%) | NYR [1.94;NYR] | 10 | 4 (40.0%) | NYR [0.69;NYR] | 0.87 [0.23;3.25] | 0.8482 | 0.8504 |
| < 1% | 61 | 29 (47.5%) | 24.80 [3.94;NYR] | 60 | 22 (36.7%) | NYR [8.25;NYR] | 1.34 [0.77;2.33] | 0.3039 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 10 (55.6%) | 3.22 [1.84;NYR] | 20 | 9 (45.0%) | 17.28 [3.71;NYR] | 1.41 [0.57;3.49] | 0.4488 | 0.6989 |
| Non-Stage IV | 53 | 23 (43.4%) | 24.80 [5.09;NYR] | 51 | 18 (35.3%) | NYR [7.56;NYR] | 1.14 [0.62;2.12] | 0.6761 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.30.1: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 34 (45.9%) | 27 (38.0%) |
| Number of censored cases | N | 40 (54.1%) | 44 (62.0%) |
| Time to first event (Months) | Mean (SE) | 14.98 (1.31) | 11.87 (0.89) |
| | Q1 [95% CI] | 2.40 [1.45;3.94] | 2.40 [0.72;8.25] |
| | Median [95% CI] | 24.80 [5.09;NYR] | NYR [15.21;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.5059 | |
| Stratified Cox PH model | HR (b) | 1.19 [0.71;1.97] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.30.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 34 (45.9%) | 24.80 [5.09;NYR] | 71 | 27 (38.0%) | NYR [15.21;NYR] | 1.19 [0.71;1.97] | 0.5059 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 20 (48.8%) | 21.62 [3.94;NYR] | 47 | 17 (36.2%) | NYR [15.21;NYR] | 1.33 [0.70;2.55] | 0.3792 | 0.6093 |
| >= 65 | 33 | 14 (42.4%) | 24.80 [2.40;NYR] | 24 | 10 (41.7%) | NYR [2.37;NYR] | 1.01 [0.45;2.29] | 0.9668 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 20 (48.8%) | 21.62 [3.94;NYR] | 47 | 17 (36.2%) | NYR [15.21;NYR] | 1.33 [0.70;2.55] | 0.3792 | 0.8466 |
| >= 65 AND < 75 | 25 | 13 (52.0%) | 24.80 [1.87;NYR] | 18 | 9 (50.0%) | 7.56 [1.77;NYR] | 1.07 [0.46;2.52] | 0.8606 | |
| >= 75 | 8 | 1 (12.5%) | NYR [2.33;NYR] | 6 | 1 (16.7%) | NYR [0.72;NYR] | 0.68 [0.04;10.98] | 0.7878 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 18 (46.2%) | NYR [4.24;NYR] | 37 | 12 (32.4%) | NYR [15.21;NYR] | 1.45 [0.70;3.01] | 0.3212 | 0.5721 |
| Rest of World (ROW) | 35 | 16 (45.7%) | 24.80 [2.96;NYR] | 34 | 15 (44.1%) | NYR [2.37;NYR] | 1.02 [0.50;2.06] | 0.9518 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.30.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 33 (50.8%) | 9.69 [3.22;NYR] | 60 | 23 (38.3%) | NYR [15.21;NYR] | 1.38 [0.81;2.35] | 0.2394 | 0.1255 |
| Non-White | 9 | 1 (11.1%) | NYR [21.62;NYR] | 11 | 4 (36.4%) | NYR [0.72;NYR] | 0.24 [0.03;2.13] | 0.1624 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [2.76;NYR] | 13 | 8 (61.5%) | 4.80 [1.77;NYR] | 0.18 [0.02;1.41] | 0.0647 | 0.0722 |
| Not Hispanic or Latino | 43 | 21 (48.8%) | NYR [2.40;NYR] | 32 | 8 (25.0%) | NYR [NYR;NYR] | 2.17 [0.96;4.91] | 0.0568 | |
| Not Reported | 24 | 12 (50.0%) | 23.21 [2.96;NYR] | 26 | 11 (42.3%) | NYR [2.07;NYR] | 1.04 [0.46;2.38] | 0.9138 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 27 (48.2%) | 24.80 [3.94;NYR] | 48 | 16 (33.3%) | NYR [17.28;NYR] | 1.55 [0.83;2.88] | 0.1641 | 0.1677 |
| Female | 18 | 7 (38.9%) | 21.62 [1.94;NYR] | 23 | 11 (47.8%) | NYR [0.76;NYR] | 0.73 [0.28;1.88] | 0.5146 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 10 (71.4%) | 2.68 [1.22;NYR] | 19 | 6 (31.6%) | NYR [8.25;NYR] | 3.55 [1.28;9.86] | 0.0095 | 0.0363 |
| >= 1 Year | 60 | 24 (40.0%) | NYR [9.69;NYR] | 50 | 20 (40.0%) | NYR [2.99;NYR] | 0.91 [0.50;1.65] | 0.7622 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.30.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 5 (45.5%) | NYR [0.53;NYR] | 12 | 3 (25.0%) | NYR [8.25;NYR] | 2.07 [0.49;8.70] | 0.3112 | 0.3430 |
| Yes | 63 | 29 (46.0%) | 24.80 [4.63;NYR] | 59 | 24 (40.7%) | NYR [7.23;NYR] | 1.08 [0.63;1.85] | 0.7869 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 32 (50.0%) | 21.62 [3.94;NYR] | 65 | 24 (36.9%) | NYR [15.21;NYR] | 1.38 [0.81;2.34] | 0.2306 | 0.1097 |
| Yes | 10 | 2 (20.0%) | NYR [0.49;NYR] | 6 | 3 (50.0%) | NYR [0.62;NYR] | 0.36 [0.06;2.19] | 0.2504 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 5 (45.5%) | NYR [1.94;NYR] | 10 | 4 (40.0%) | NYR [0.69;NYR] | 0.89 [0.24;3.32] | 0.8761 | 0.8447 |
| < 1% | 61 | 29 (47.5%) | 24.80 [3.94;NYR] | 60 | 22 (36.7%) | NYR [17.28;NYR] | 1.35 [0.78;2.36] | 0.2834 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 10 (55.6%) | 5.98 [1.84;NYR] | 20 | 9 (45.0%) | 17.28 [3.71;NYR] | 1.41 [0.57;3.48] | 0.4493 | 0.7311 |
| Non-Stage IV | 53 | 23 (43.4%) | NYR [5.09;NYR] | 51 | 18 (35.3%) | NYR [7.56;NYR] | 1.16 [0.63;2.15] | 0.6395 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.31.1: TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 9 (12.2%) | 6 (8.5%) |
| Number of censored cases | N | 65 (87.8%) | 65 (91.5%) |
| Time to first event (Months) | Mean (SE) | 9.36 (0.29) | 22.83 (0.75) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [24.41;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.5846 | |
| Stratified Cox PH model | HR (b) | 1.33 [0.47;3.76] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:10:10

TABLE 3.31.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 6 (8.5%) | NYR [NYR;NYR] | 1.33 [0.47;3.76] | 0.5846 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [24.41;NYR] | 1.61 [0.38;6.80] | 0.5099 | 0.5456 |
| >= 65 | 33 | 4 (12.1%) | NYR [NYR;NYR] | 24 | 3 (12.5%) | NYR [NYR;NYR] | 0.94 [0.21;4.21] | 0.9372 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [24.41;NYR] | 1.61 [0.38;6.80] | 0.5099 | 0.8371 |
| >= 65 AND < 75 | 25 | 4 (16.0%) | NYR [NYR;NYR] | 18 | 3 (16.7%) | NYR [NYR;NYR] | 0.93 [0.21;4.18] | 0.9309 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NYR [NYR;NYR] | 37 | 5 (13.5%) | NYR [NYR;NYR] | 0.80 [0.23;2.79] | 0.7307 | 0.2092 |
| Rest of World (ROW) | 35 | 4 (11.4%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | NYR [24.41;NYR] | 3.95 [0.44;35.39] | 0.1839 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:10:10

TABLE 3.31.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 9 (13.8%) | NYR [NYR;NYR] | 60 | 6 (10.0%) | NYR [24.41;NYR] | 1.27 [0.45;3.59] | 0.6465 | 0.9999 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 1 (7.7%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.4631 | 0.9951 |
| Not Hispanic or Latino | 43 | 6 (14.0%) | NYR [NYR;NYR] | 32 | 3 (9.4%) | NYR [NYR;NYR] | 1.43 [0.36;5.71] | 0.6128 | |
| Not Reported | 24 | 3 (12.5%) | NYR [NYR;NYR] | 26 | 2 (7.7%) | NYR [24.41;NYR] | 1.44 [0.24;8.65] | 0.6868 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 7 (12.5%) | NYR [NYR;NYR] | 48 | 3 (6.3%) | NYR [NYR;NYR] | 1.95 [0.50;7.55] | 0.3234 | 0.4279 |
| Female | 18 | 2 (11.1%) | NYR [NYR;NYR] | 23 | 3 (13.0%) | NYR [24.41;NYR] | 0.83 [0.14;4.95] | 0.8320 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 2 (10.5%) | NYR [NYR;NYR] | 0.50 [0.05;5.50] | 0.5614 | 0.4643 |
| >= 1 Year | 60 | 8 (13.3%) | NYR [NYR;NYR] | 50 | 4 (8.0%) | NYR [24.41;NYR] | 1.59 [0.48;5.28] | 0.4450 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.31.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [8.97;NYR] | 12 | 1 (8.3%) | NYR [10.02;NYR] | 0.74 [0.05;11.81] | 0.8292 | 0.8029 |
| Yes | 63 | 8 (12.7%) | NYR [NYR;NYR] | 59 | 5 (8.5%) | NYR [NYR;NYR] | 1.41 [0.46;4.33] | 0.5410 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 8 (12.5%) | NYR [NYR;NYR] | 65 | 5 (7.7%) | NYR [NYR;NYR] | 1.46 [0.48;4.47] | 0.5060 | 0.5528 |
| Yes | 10 | 1 (10.0%) | NYR [1.64;NYR] | 6 | 1 (16.7%) | NYR [1.58;NYR] | 0.55 [0.03;8.78] | 0.6660 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 9 (14.8%) | NYR [NYR;NYR] | 60 | 6 (10.0%) | NYR [24.41;NYR] | 1.36 [0.48;3.84] | 0.5545 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 3 (16.7%) | NYR [NYR;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | 2.94 [0.31;28.31] | 0.3268 | 0.4114 |
| Non-Stage IV | 53 | 6 (11.3%) | NYR [NYR;NYR] | 51 | 5 (9.8%) | NYR [24.41;NYR] | 1.08 [0.33;3.56] | 0.8938 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.32.1: TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 9 (12.2%) | 6 (8.5%) |
| Number of censored cases | N | 65 (87.8%) | 65 (91.5%) |
| Time to first event (Months) | Mean (SE) | 9.36 (0.29) | 22.90 (0.72) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [24.41;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.5125 | |
| Stratified Cox PH model | HR (b) | 1.41 [0.50;3.97] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.32.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 6 (8.5%) | NYR [NYR;NYR] | 1.41 [0.50;3.97] | 0.5125 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [24.41;NYR] | 1.71 [0.40;7.20] | 0.4620 | 0.5256 |
| >= 65 | 33 | 4 (12.1%) | NYR [NYR;NYR] | 24 | 3 (12.5%) | NYR [NYR;NYR] | 0.96 [0.21;4.27] | 0.9537 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [24.41;NYR] | 1.71 [0.40;7.20] | 0.4620 | 0.8173 |
| >= 65 AND < 75 | 25 | 4 (16.0%) | NYR [NYR;NYR] | 18 | 3 (16.7%) | NYR [NYR;NYR] | 0.93 [0.21;4.18] | 0.9309 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NYR [NYR;NYR] | 37 | 5 (13.5%) | NYR [NYR;NYR] | 0.86 [0.25;2.96] | 0.8065 | 0.2097 |
| Rest of World (ROW) | 35 | 4 (11.4%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | NYR [24.41;NYR] | 4.05 [0.45;36.24] | 0.1752 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.32.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 9 (13.8%) | NYR [NYR;NYR] | 60 | 6 (10.0%) | NYR [24.41;NYR] | 1.32 [0.47;3.71] | 0.5993 | 0.9999 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 1 (7.7%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.4631 | 0.9948 |
| Not Hispanic or Latino | 43 | 6 (14.0%) | NYR [NYR;NYR] | 32 | 3 (9.4%) | NYR [NYR;NYR] | 1.46 [0.36;5.82] | 0.5918 | |
| Not Reported | 24 | 3 (12.5%) | NYR [NYR;NYR] | 26 | 2 (7.7%) | NYR [24.41;NYR] | 1.49 [0.25;8.96] | 0.6591 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 7 (12.5%) | NYR [NYR;NYR] | 48 | 3 (6.3%) | NYR [NYR;NYR] | 2.04 [0.53;7.87] | 0.2923 | 0.4409 |
| Female | 18 | 2 (11.1%) | NYR [NYR;NYR] | 23 | 3 (13.0%) | NYR [24.41;NYR] | 0.86 [0.14;5.15] | 0.8658 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 2 (10.5%) | NYR [NYR;NYR] | 0.55 [0.05;6.07] | 0.6206 | 0.4620 |
| >= 1 Year | 60 | 8 (13.3%) | NYR [NYR;NYR] | 50 | 4 (8.0%) | NYR [24.41;NYR] | 1.62 [0.49;5.38] | 0.4264 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:17:07

TABLE 3.32.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [8.97;NYR] | 12 | 1 (8.3%) | NYR [10.02;NYR] | 0.79 [0.05;12.61] | 0.8665 | 0.8025 |
| Yes | 63 | 8 (12.7%) | NYR [NYR;NYR] | 59 | 5 (8.5%) | NYR [NYR;NYR] | 1.44 [0.47;4.43] | 0.5164 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 8 (12.5%) | NYR [NYR;NYR] | 65 | 5 (7.7%) | NYR [NYR;NYR] | 1.53 [0.50;4.67] | 0.4563 | 0.5185 |
| Yes | 10 | 1 (10.0%) | NYR [1.64;NYR] | 6 | 1 (16.7%) | NYR [1.58;NYR] | 0.55 [0.03;8.78] | 0.6660 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 9 (14.8%) | NYR [NYR;NYR] | 60 | 6 (10.0%) | NYR [24.41;NYR] | 1.42 [0.51;4.01] | 0.5009 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 3 (16.7%) | NYR [NYR;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | 2.99 [0.31;28.76] | 0.3190 | 0.4217 |
| Non-Stage IV | 53 | 6 (11.3%) | NYR [NYR;NYR] | 51 | 5 (9.8%) | NYR [24.41;NYR] | 1.10 [0.34;3.62] | 0.8721 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.33.1: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 2 (2.8%) |
| Number of censored cases | N | 72 (97.3%) | 69 (97.2%) |
| Time to first event (Months) | Mean (SE) | 1.84 (0.01) | 2.34 (0.04) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.9605 | |
| Stratified Cox PH model | HR (b) | 0.95 [0.13;6.76] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.33.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.95 [0.13;6.76] | 0.9605 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.12 [0.07;17.94] | 0.9353 | 0.8289 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 0.72 [0.05;11.56] | 0.8178 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.12 [0.07;17.94] | 0.9353 | 0.9773 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 1 (5.6%) | NYR [NYR;NYR] | 0.73 [0.05;11.75] | 0.8269 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 0.94 [0.06;14.96] | 0.9626 | 0.9879 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | NYR [NYR;NYR] | 0.96 [0.06;15.29] | 0.9750 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.33.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 0.90 [0.13;6.41] | 0.9183 | 1.0000 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 1 (7.7%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.4631 | 1.0000 |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 1.47 [0.13;16.20] | 0.7522 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1884 | 0.9967 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 2 (8.7%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.1948 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 2 (4.0%) | NYR [NYR;NYR] | 0.81 [0.11;5.78] | 0.8369 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.33.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 2 (3.4%) | NYR [NYR;NYR] | 0.92 [0.13;6.50] | 0.9296 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 2 (3.1%) | NYR [NYR;NYR] | 1.00 [0.14;7.07] | 0.9967 | 1.0000 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 2 (3.3%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 0.96 [0.14;6.83] | 0.9695 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Non-Stage IV | 53 | 2 (3.8%) | NYR [NYR;NYR] | 51 | 2 (3.9%) | NYR [NYR;NYR] | 0.94 [0.13;6.69] | 0.9528 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.34.1: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 2 (2.8%) |
| Number of censored cases | N | 72 (97.3%) | 69 (97.2%) |
| Time to first event (Months) | Mean (SE) | 1.84 (0.01) | 2.34 (0.04) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.9750 | |
| Stratified Cox PH model | HR (b) | 0.97 [0.14;6.88] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.34.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.97 [0.14;6.88] | 0.9750 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.13 [0.07;18.14] | 0.9291 | 0.8266 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 0.74 [0.05;11.81] | 0.8297 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.13 [0.07;18.14] | 0.9291 | 0.9755 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 1 (5.6%) | NYR [NYR;NYR] | 0.73 [0.05;11.75] | 0.8269 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 0.94 [0.06;14.96] | 0.9626 | 0.9818 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | NYR [NYR;NYR] | 0.99 [0.06;15.76] | 0.9918 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.34.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 0.92 [0.13;6.52] | 0.9321 | 1.0000 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 1 (7.7%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.4631 | 1.0000 |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 1.47 [0.13;16.20] | 0.7522 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1884 | 0.9965 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 2 (8.7%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.2058 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 2 (4.0%) | NYR [NYR;NYR] | 0.83 [0.12;5.90] | 0.8532 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:31:05

TABLE 3.34.2: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 2 (3.4%) | NYR [NYR;NYR] | 0.93 [0.13;6.61] | 0.9436 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 2 (3.1%) | NYR [NYR;NYR] | 1.01 [0.14;7.18] | 0.9906 | 1.0000 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 2 (3.3%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 0.98 [0.14;6.95] | 0.9833 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Non-Stage IV | 53 | 2 (3.8%) | NYR [NYR;NYR] | 51 | 2 (3.9%) | NYR [NYR;NYR] | 0.96 [0.14;6.83] | 0.9689 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.35.1: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 3 (4.1%) | 1 (1.4%) |
| Number of censored cases | N | 71 (95.9%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 1.80 (0.04) | 0.46 (.) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.3627 | |
| Stratified Cox PH model | HR (b) | 2.74 [0.28;26.40] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:38:03

TABLE 3.35.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 2.74 [0.28;26.40] | 0.3627 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 2.28 [0.21;25.15] | 0.4888 | 0.9953 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3938 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 2.28 [0.21;25.15] | 0.4888 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 1 (12.5%) | NYR [0.49;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3865 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3300 | 0.9964 |
| Rest of World (ROW) | 35 | 2 (5.7%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | NYR [NYR;NYR] | 1.94 [0.18;21.41] | 0.5812 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.35.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 3 (4.6%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0954 | 0.9970 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3657 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 2 (28.6%) | NYR [0.03;NYR] | 13 | 1 (7.7%) | NYR [NYR;NYR] | 4.01 [0.36;44.28] | 0.2200 | 1.0000 |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2980 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 3 (5.4%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1056 | 0.9956 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 1 (4.3%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3763 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2440 | 0.9957 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 1.65 [0.15;18.21] | 0.6790 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.35.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2963 | 0.9952 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 1.88 [0.17;20.76] | 0.5995 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 2.04 [0.19;22.52] | 0.5516 | 0.9951 |
| Yes | 10 | 1 (10.0%) | NYR [1.84;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [0.49;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1672 | 1.0000 |
| < 1% | 61 | 1 (1.6%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 0.96 [0.06;15.33] | 0.9762 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2918 | 0.9955 |
| Non-Stage IV | 53 | 2 (3.8%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 1.94 [0.18;21.35] | 0.5827 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.36.1: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 3 (4.1%) | 1 (1.4%) |
| Number of censored cases | N | 71 (95.9%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 1.80 (0.04) | 0.46 (.) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.3579 | |
| Stratified Cox PH model | HR (b) | 2.77 [0.29;26.65] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.36.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 2.77 [0.29;26.65] | 0.3579 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 2.31 [0.21;25.52] | 0.4806 | 0.9953 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3938 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 2.31 [0.21;25.52] | 0.4806 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 1 (12.5%) | NYR [0.49;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3865 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3300 | 0.9964 |
| Rest of World (ROW) | 35 | 2 (5.7%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | NYR [NYR;NYR] | 1.96 [0.18;21.63] | 0.5752 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.36.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 3 (4.6%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0935 | 0.9970 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3657 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 2 (28.6%) | NYR [0.03;NYR] | 13 | 1 (7.7%) | NYR [NYR;NYR] | 4.01 [0.36;44.28] | 0.2200 | 1.0000 |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2980 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 3 (5.4%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1056 | 0.9956 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 1 (4.3%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3763 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2440 | 0.9957 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 1.67 [0.15;18.46] | 0.6705 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:45:00

TABLE 3.36.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2963 | 0.9952 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 1.88 [0.17;20.76] | 0.5995 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 2.04 [0.19;22.52] | 0.5516 | 0.9951 |
| Yes | 10 | 1 (10.0%) | NYR [1.84;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [0.49;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1672 | 1.0000 |
| < 1% | 61 | 1 (1.6%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 0.98 [0.06;15.59] | 0.9859 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2918 | 0.9955 |
| Non-Stage IV | 53 | 2 (3.8%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 1.94 [0.18;21.35] | 0.5827 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.37.1: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:51:56

TABLE 3.37.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.37.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.37.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.38.1: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.38.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.38.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:58:54

TABLE 3.38.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.39.1: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:05:30

TABLE 3.39.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.39.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:05:30

TABLE 3.39.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.40.1: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:11:43

TABLE 3.40.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.40.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:11:44

TABLE 3.40.2: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.41.1: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 0 (0.0%) |
| Number of censored cases | N | 72 (97.3%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 13.90 (0.05) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.2733 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:17:56

TABLE 3.41.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2733 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2102 | 0.9989 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2102 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4337 | 1.0000 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3805 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:17:56

TABLE 3.41.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2446 | 0.9991 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4795 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3527 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2565 | 0.9989 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9989 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2750 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:17:56

TABLE 3.41.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9991 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2397 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4000 | 0.9999 |
| Yes | 10 | 1 (10.0%) | NYR [12.02;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4497 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [12.02;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2286 | 1.0000 |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9993 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4227 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:17:56

TABLE 3.42.1: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 0 (0.0%) |
| Number of censored cases | N | 72 (97.3%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 13.90 (0.04) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.2375 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:24:09

TABLE 3.42.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2375 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1967 | 0.9989 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1967 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4363 | 1.0000 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3778 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:24:09

TABLE 3.42.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2325 | 0.9991 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4547 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3404 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2397 | 0.9989 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9989 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2709 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:24:09

TABLE 3.42.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9991 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2254 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3961 | 0.9999 |
| Yes | 10 | 1 (10.0%) | NYR [12.02;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3980 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [12.02;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2100 | 1.0000 |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9993 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4142 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:24:09

TABLE 3.43.1: TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 1 (1.4%) | 0 (0.0%) |
| Number of censored cases | N | 73 (98.6%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 17.08 (.) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.3865 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.43.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3865 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4179 | 0.9992 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4179 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 | 0.9992 |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.43.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 1 (1.5%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4171 | 0.9994 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4617 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 1 (1.8%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4467 | 0.9992 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9992 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4406 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.43.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9993 |
| Yes | 63 | 1 (1.6%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3993 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9996 |
| Yes | 10 | 1 (10.0%) | NYR [17.08;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.5127 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [17.08;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4142 | 0.9996 |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.44.1: TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 1 (1.4%) | 0 (0.0%) |
| Number of censored cases | N | 73 (98.6%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 17.08 (.) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.3865 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.44.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3865 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4038 | 0.9992 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4038 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4414 | 0.9992 |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.44.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 1 (1.5%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4221 | 0.9994 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4956 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 1 (1.8%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4442 | 0.9992 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9992 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4539 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.44.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9993 |
| Yes | 63 | 1 (1.6%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4197 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9997 |
| Yes | 10 | 1 (10.0%) | NYR [17.08;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.5127 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [17.08;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4142 | 1.0000 |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.45.1: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 0 (0.0%) |
| Number of censored cases | N | 72 (97.3%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 17.47 (0.01) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.2457 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:42:49

TABLE 3.45.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2457 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2501 | 0.9989 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2501 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 | 1.0000 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3827 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:42:49

TABLE 3.45.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2452 | 0.9991 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4617 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3907 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2810 | 0.9989 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9989 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2744 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:42:50

TABLE 3.45.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9991 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2345 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3907 | 0.9999 |
| Yes | 10 | 1 (10.0%) | NYR [17.08;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.5127 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [17.08;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2341 | 0.9993 |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9993 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4142 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:42:50

TABLE 3.46.1: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 0 (0.0%) |
| Number of censored cases | N | 72 (97.3%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 17.47 (0.01) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.2457 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:49:04

TABLE 3.46.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2457 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2356 | 0.9989 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2356 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4414 | 1.0000 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4000 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.46.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2508 | 0.9991 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4956 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3711 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2784 | 0.9989 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9989 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2888 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:49:04

TABLE 3.46.2: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9990 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2525 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4036 | 0.9999 |
| Yes | 10 | 1 (10.0%) | NYR [17.08;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.5127 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [17.08;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2341 | 1.0000 |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9993 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4366 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.47.1: TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 16 (21.6%) | 14 (19.7%) |
| Number of censored cases | N | 58 (78.4%) | 57 (80.3%) |
| Time to first event (Months) | Mean (SE) | 15.90 (0.72) | 20.56 (0.99) |
| | Q1 [95% CI] | 18.80 [5.55;NYR] | 21.20 [10.38;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [24.41;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.9673 | |
| Stratified Cox PH model | HR (b) | 1.02 [0.49;2.09] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:55:19

TABLE 3.47.2: TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 16 (21.6%) | NYR [NYR;NYR] | 71 | 14 (19.7%) | NYR [24.41;NYR] | 1.02 [0.49;2.09] | 0.9673 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 11 (26.8%) | NYR [NYR;NYR] | 47 | 7 (14.9%) | NYR [24.41;NYR] | 1.72 [0.66;4.45] | 0.2589 | 0.0766 |
| >= 65 | 33 | 5 (15.2%) | NYR [18.76;NYR] | 24 | 7 (29.2%) | 21.16 [7.23;NYR] | 0.44 [0.14;1.40] | 0.1551 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 11 (26.8%) | NYR [NYR;NYR] | 47 | 7 (14.9%) | NYR [24.41;NYR] | 1.72 [0.66;4.45] | 0.2589 | 0.4824 |
| >= 65 AND < 75 | 25 | 5 (20.0%) | NYR [17.45;NYR] | 18 | 5 (27.8%) | NYR [7.23;NYR] | 0.69 [0.20;2.42] | 0.5609 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 2 (33.3%) | NYR [4.80;NYR] | <0.01 [<0.01;NE] | 0.1010 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 10 (25.6%) | NYR [NYR;NYR] | 37 | 7 (18.9%) | NYR [NYR;NYR] | 1.25 [0.47;3.28] | 0.6558 | 0.5204 |
| Rest of World (ROW) | 35 | 6 (17.1%) | NYR [NYR;NYR] | 34 | 7 (20.6%) | 24.41 [21.16;NYR] | 0.69 [0.23;2.06] | 0.5039 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:55:19

TABLE 3.47.2: TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 16 (24.6%) | NYR [NYR;NYR] | 60 | 12 (20.0%) | NYR [24.41;NYR] | 1.13 [0.54;2.40] | 0.7432 | 0.9902 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 2 (18.2%) | 21.16 [17.38;NYR] | <0.01 [<0.01;NE] | 0.0977 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 3 (42.9%) | NYR [1.38;NYR] | 13 | 3 (23.1%) | 21.16 [6.44;21.16] | 6.79 [0.70;65.50] | 0.0552 | 0.1838 |
| Not Hispanic or Latino | 43 | 10 (23.3%) | NYR [NYR;NYR] | 32 | 5 (15.6%) | NYR [NYR;NYR] | 1.48 [0.50;4.33] | 0.4746 | |
| Not Reported | 24 | 3 (12.5%) | NYR [NYR;NYR] | 26 | 6 (23.1%) | NYR [17.38;NYR] | 0.40 [0.10;1.61] | 0.1824 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 15 (26.8%) | NYR [NYR;NYR] | 48 | 10 (20.8%) | NYR [21.16;NYR] | 1.22 [0.54;2.72] | 0.6315 | 0.1992 |
| Female | 18 | 1 (5.6%) | NYR [NYR;NYR] | 23 | 4 (17.4%) | NYR [24.41;NYR] | 0.24 [0.03;2.22] | 0.1766 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [NYR;NYR] | 19 | 4 (21.1%) | NYR [14.52;NYR] | 0.46 [0.08;2.58] | 0.3697 | 0.3934 |
| >= 1 Year | 60 | 14 (23.3%) | NYR [NYR;NYR] | 50 | 9 (18.0%) | NYR [24.41;NYR] | 1.23 [0.53;2.84] | 0.6289 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:55:19

TABLE 3.47.2: TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 5 (45.5%) | NYR [1.41;NYR] | 12 | 3 (25.0%) | NYR [4.83;NYR] | 2.26 [0.54;9.46] | 0.2531 | 0.2587 |
| Yes | 63 | 11 (17.5%) | NYR [NYR;NYR] | 59 | 11 (18.6%) | NYR [24.41;NYR] | 0.79 [0.34;1.84] | 0.5869 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 13 (20.3%) | NYR [NYR;NYR] | 65 | 13 (20.0%) | NYR [24.41;NYR] | 0.88 [0.41;1.89] | 0.7378 | 0.4523 |
| Yes | 10 | 3 (30.0%) | NYR [0.49;NYR] | 6 | 1 (16.7%) | NYR [17.38;NYR] | 2.24 [0.23;21.71] | 0.4748 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 3 (27.3%) | NYR [9.95;NYR] | 10 | 1 (10.0%) | NYR [3.48;NYR] | 2.31 [0.24;22.27] | 0.4563 | 0.7262 |
| < 1% | 61 | 13 (21.3%) | NYR [NYR;NYR] | 60 | 13 (21.7%) | NYR [21.16;NYR] | 0.88 [0.40;1.90] | 0.7362 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 4 (22.2%) | NYR [18.76;NYR] | 20 | 3 (15.0%) | NYR [14.52;NYR] | 1.31 [0.29;5.91] | 0.7224 | 0.5886 |
| Non-Stage IV | 53 | 11 (20.8%) | NYR [NYR;NYR] | 51 | 11 (21.6%) | NYR [21.16;NYR] | 0.84 [0.37;1.95] | 0.6900 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:55:19

TABLE 3.48.1: TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 16 (21.6%) | 14 (19.7%) |
| Number of censored cases | N | 58 (78.4%) | 57 (80.3%) |
| Time to first event (Months) | Mean (SE) | 15.96 (0.71) | 20.87 (0.92) |
| | Q1 [95% CI] | NYR [5.55;NYR] | 21.20 [10.38;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [24.41;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.8892 | |
| Stratified Cox PH model | HR (b) | 1.05 [0.51;2.16] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.48.2: TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 16 (21.6%) | NYR [NYR;NYR] | 71 | 14 (19.7%) | NYR [24.41;NYR] | 1.05 [0.51;2.16] | 0.8892 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 11 (26.8%) | NYR [NYR;NYR] | 47 | 7 (14.9%) | NYR [24.41;NYR] | 1.78 [0.69;4.61] | 0.2295 | 0.0850 |
| >= 65 | 33 | 5 (15.2%) | NYR [18.76;NYR] | 24 | 7 (29.2%) | NYR [14.49;NYR] | 0.48 [0.15;1.52] | 0.2002 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 11 (26.8%) | NYR [NYR;NYR] | 47 | 7 (14.9%) | NYR [24.41;NYR] | 1.78 [0.69;4.61] | 0.2295 | 0.5231 |
| >= 65 AND < 75 | 25 | 5 (20.0%) | NYR [18.76;NYR] | 18 | 5 (27.8%) | NYR [7.23;NYR] | 0.71 [0.20;2.50] | 0.5957 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 2 (33.3%) | NYR [4.80;NYR] | <0.01 [<0.01;NE] | 0.0584 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 10 (25.6%) | NYR [NYR;NYR] | 37 | 7 (18.9%) | NYR [NYR;NYR] | 1.33 [0.51;3.50] | 0.5645 | 0.4918 |
| Rest of World (ROW) | 35 | 6 (17.1%) | NYR [NYR;NYR] | 34 | 7 (20.6%) | 24.41 [21.16;NYR] | 0.71 [0.24;2.12] | 0.5343 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.48.2: TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 16 (24.6%) | NYR [NYR;NYR] | 60 | 12 (20.0%) | NYR [24.41;NYR] | 1.19 [0.56;2.52] | 0.6484 | 0.9902 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 2 (18.2%) | 21.16 [17.38;NYR] | <0.01 [<0.01;NE] | 0.0833 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 3 (42.9%) | NYR [1.38;NYR] | 13 | 3 (23.1%) | 21.16 [6.44;21.16] | 7.16 [0.74;69.30] | 0.0476 | 0.1758 |
| Not Hispanic or Latino | 43 | 10 (23.3%) | NYR [NYR;NYR] | 32 | 5 (15.6%) | NYR [NYR;NYR] | 1.52 [0.52;4.44] | 0.4446 | |
| Not Reported | 24 | 3 (12.5%) | NYR [NYR;NYR] | 26 | 6 (23.1%) | NYR [24.41;NYR] | 0.42 [0.11;1.71] | 0.2138 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 15 (26.8%) | NYR [NYR;NYR] | 48 | 10 (20.8%) | NYR [21.16;NYR] | 1.27 [0.57;2.84] | 0.5547 | 0.2029 |
| Female | 18 | 1 (5.6%) | NYR [NYR;NYR] | 23 | 4 (17.4%) | NYR [24.41;NYR] | 0.28 [0.03;2.55] | 0.2298 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [NYR;NYR] | 19 | 4 (21.1%) | NYR [14.52;NYR] | 0.48 [0.09;2.71] | 0.3971 | 0.4014 |
| >= 1 Year | 60 | 14 (23.3%) | NYR [NYR;NYR] | 50 | 9 (18.0%) | NYR [24.41;NYR] | 1.27 [0.55;2.95] | 0.5710 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.48.2: TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 5 (45.5%) | NYR [1.41;NYR] | 12 | 3 (25.0%) | NYR [4.83;NYR] | 2.19 [0.52;9.20] | 0.2706 | 0.2742 |
| Yes | 63 | 11 (17.5%) | NYR [NYR;NYR] | 59 | 11 (18.6%) | NYR [24.41;NYR] | 0.83 [0.36;1.92] | 0.6617 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 13 (20.3%) | NYR [NYR;NYR] | 65 | 13 (20.0%) | NYR [24.41;NYR] | 0.92 [0.43;1.99] | 0.8357 | 0.4558 |
| Yes | 10 | 3 (30.0%) | NYR [0.49;NYR] | 6 | 1 (16.7%) | NYR [17.38;NYR] | 2.24 [0.23;21.71] | 0.4748 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 3 (27.3%) | NYR [9.95;NYR] | 10 | 1 (10.0%) | NYR [3.48;NYR] | 2.49 [0.26;24.02] | 0.4141 | 0.7333 |
| < 1% | 61 | 13 (21.3%) | NYR [NYR;NYR] | 60 | 13 (21.7%) | NYR [21.16;NYR] | 0.92 [0.42;1.98] | 0.8241 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 4 (22.2%) | NYR [18.76;NYR] | 20 | 3 (15.0%) | NYR [14.52;NYR] | 1.38 [0.31;6.18] | 0.6740 | 0.6231 |
| Non-Stage IV | 53 | 11 (20.8%) | NYR [NYR;NYR] | 51 | 11 (21.6%) | NYR [24.41;NYR] | 0.89 [0.39;2.07] | 0.7899 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.49.1: TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 1 (1.4%) |
| Number of censored cases | N | 72 (97.3%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 4.94 (0.03) | 4.37 (.) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.6558 | |
| Stratified Cox PH model | HR (b) | 1.71 [0.16;18.91] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.49.2: TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.71 [0.16;18.91] | 0.6558 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.06 [0.07;16.99] | 0.9658 | 0.9960 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4461 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.06 [0.07;16.99] | 0.9658 | 1.0000 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4617 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 2 (5.1%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 1.64 [0.15;18.11] | 0.6825 | 0.9999 |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.49.2: TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.64 [0.15;18.12] | 0.6821 | 0.9999 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 1.47 [0.13;16.22] | 0.7514 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 1 (2.1%) | NYR [NYR;NYR] | 1.66 [0.15;18.36] | 0.6741 | 0.9999 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 1.51 [0.14;16.68] | 0.7338 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:07:44

TABLE 3.49.2: TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9999 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 1.68 [0.15;18.49] | 0.6697 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 1.80 [0.16;19.86] | 0.6260 | 0.9999 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 2 (3.3%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.78 [0.16;19.59] | 0.6342 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9999 |
| Non-Stage IV | 53 | 2 (3.8%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 1.63 [0.15;17.99] | 0.6866 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.50.1: TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 1 (1.4%) |
| Number of censored cases | N | 72 (97.3%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 4.94 (0.03) | 4.37 (.) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.6028 | |
| Stratified Cox PH model | HR (b) | 1.87 [0.17;20.65] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:13:56

TABLE 3.50.2: TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.87 [0.17;20.65] | 0.6028 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.05 [0.07;16.78] | 0.9728 | 0.9955 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3938 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.05 [0.07;16.78] | 0.9728 | 1.0000 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3961 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 2 (5.1%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 1.83 [0.17;20.24] | 0.6148 | 0.9999 |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.50.2: TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.76 [0.16;19.44] | 0.6392 | 0.9999 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 1.48 [0.13;16.37] | 0.7455 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 1 (2.1%) | NYR [NYR;NYR] | 1.69 [0.15;18.64] | 0.6647 | 0.9999 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 1.64 [0.15;18.04] | 0.6849 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.50.2: TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9999 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 1.82 [0.17;20.08] | 0.6194 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 1.94 [0.18;21.45] | 0.5801 | 0.9999 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 2 (3.3%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.92 [0.17;21.16] | 0.5882 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9999 |
| Non-Stage IV | 53 | 2 (3.8%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 1.85 [0.17;20.46] | 0.6084 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.51.1: TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 1 (1.4%) |
| Number of censored cases | N | 72 (97.3%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 11.56 (0.14) | 4.37 (.) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.6964 | |
| Stratified Cox PH model | HR (b) | 1.61 [0.15;17.72] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:20:04

TABLE 3.51.2: TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.61 [0.15;17.72] | 0.6964 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.06 [0.07;16.99] | 0.9658 | 0.9961 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4892 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.06 [0.07;16.99] | 0.9658 | 1.0000 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4431 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 0.80 [0.05;12.83] | 0.8763 | 0.9966 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3865 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:20:05

TABLE 3.51.2: TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.53 [0.14;16.88] | 0.7280 | 0.9999 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 0.73 [0.05;11.72] | 0.8257 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3613 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 1 (2.1%) | NYR [NYR;NYR] | 1.50 [0.14;16.64] | 0.7381 | 1.0000 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3576 | 0.9965 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 0.74 [0.05;11.88] | 0.8331 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:20:05

TABLE 3.51.2: TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9999 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 1.56 [0.14;17.24] | 0.7143 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 1.63 [0.15;18.08] | 0.6861 | 0.9999 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 2 (3.3%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.60 [0.14;17.77] | 0.6974 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3711 | 0.9961 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 0.79 [0.05;12.70] | 0.8702 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.52.1: TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 1 (1.4%) |
| Number of censored cases | N | 72 (97.3%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 11.57 (0.13) | 4.37 (.) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.6303 | |
| Stratified Cox PH model | HR (b) | 1.79 [0.16;19.72] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.52.2: TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.79 [0.16;19.72] | 0.6303 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.05 [0.07;16.78] | 0.9728 | 0.9957 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4543 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.05 [0.07;16.78] | 0.9728 | 1.0000 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4467 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 0.89 [0.06;14.22] | 0.9340 | 0.9966 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3532 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.52.2: TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.62 [0.15;17.93] | 0.6901 | 0.9999 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 0.73 [0.05;11.73] | 0.8261 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3496 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 1 (2.1%) | NYR [NYR;NYR] | 1.59 [0.14;17.57] | 0.7026 | 1.0000 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3173 | 0.9966 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 0.80 [0.05;12.73] | 0.8714 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.52.2: TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9999 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 1.67 [0.15;18.46] | 0.6725 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 1.74 [0.16;19.31] | 0.6461 | 0.9999 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 2 (3.3%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.73 [0.16;19.12] | 0.6520 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3329 | 0.9961 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 0.89 [0.06;14.27] | 0.9358 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.53.1: TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 55 (74.3%) | 46 (64.8%) |
| Number of censored cases | N | 19 (25.7%) | 25 (35.2%) |
| Time to first event (Months) | Mean (SE) | 4.95 (0.56) | 9.14 (1.23) |
| | Q1 [95% CI] | 1.00 [0.56;1.74] | 1.80 [0.62;2.27] |
| | Median [95% CI] | 2.38 [1.87;4.44] | 4.40 [2.79;7.66] |
| | Q3 [95% CI] | 10.60 [5.13;NYR] | 23.80 [7.66;NYR] |
| | p-value (a) | 0.1946 | |
| Stratified Cox PH model | HR (b) | 1.31 [0.88;1.95] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.53.2: TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 55 (74.3%) | 2.38 [1.87;4.44] | 71 | 46 (64.8%) | 4.40 [2.79;7.66] | 1.31 [0.88;1.95] | 0.1946 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 33 (80.5%) | 2.33 [1.41;4.80] | 47 | 31 (66.0%) | 4.40 [2.33;11.10] | 1.45 [0.88;2.36] | 0.1401 | 0.4222 |
| >= 65 | 33 | 22 (66.7%) | 2.43 [1.77;10.28] | 24 | 15 (62.5%) | 4.73 [1.02;23.72] | 1.03 [0.53;2.00] | 0.9262 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 33 (80.5%) | 2.33 [1.41;4.80] | 47 | 31 (66.0%) | 4.40 [2.33;11.10] | 1.45 [0.88;2.36] | 0.1401 | 0.3996 |
| >= 65 AND < 75 | 25 | 19 (76.0%) | 2.17 [1.74;3.25] | 18 | 12 (66.7%) | 4.73 [1.02;23.72] | 1.35 [0.64;2.84] | 0.4314 | |
| >= 75 | 8 | 3 (37.5%) | NYR [0.53;NYR] | 6 | 3 (50.0%) | NYR [0.56;NYR] | 0.66 [0.13;3.37] | 0.6091 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 28 (71.8%) | 3.78 [1.97;6.90] | 37 | 23 (62.2%) | 7.10 [2.10;15.54] | 1.24 [0.71;2.15] | 0.4428 | 0.9055 |
| Rest of World (ROW) | 35 | 27 (77.1%) | 1.91 [1.41;2.43] | 34 | 23 (67.6%) | 3.48 [1.77;7.36] | 1.30 [0.75;2.28] | 0.3589 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.53.2: TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 48 (73.8%) | 2.43 [1.91;4.80] | 60 | 36 (60.0%) | 6.21 [3.22;12.81] | 1.41 [0.92;2.18] | 0.1140 | 0.1787 |
| Non-White | 9 | 7 (77.8%) | 1.41 [0.07;NYR] | 11 | 10 (90.9%) | 1.81 [0.49;5.78] | 0.67 [0.24;1.89] | 0.4480 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 5 (71.4%) | 2.60 [0.82;NYR] | 13 | 8 (61.5%) | 4.73 [0.53;9.66] | 0.73 [0.21;2.46] | 0.6057 | 0.6698 |
| Not Hispanic or Latino | 43 | 31 (72.1%) | 2.50 [1.77;6.18] | 32 | 22 (68.8%) | 3.25 [1.74;12.81] | 1.16 [0.67;2.01] | 0.5886 | |
| Not Reported | 24 | 19 (79.2%) | 2.07 [0.79;4.80] | 26 | 16 (61.5%) | 6.21 [2.27;23.72] | 1.54 [0.79;3.00] | 0.1992 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 40 (71.4%) | 2.50 [1.77;4.80] | 48 | 32 (66.7%) | 3.48 [2.27;7.66] | 1.19 [0.74;1.89] | 0.4759 | 0.5598 |
| Female | 18 | 15 (83.3%) | 2.10 [0.82;7.00] | 23 | 14 (60.9%) | 6.21 [1.74;23.72] | 1.45 [0.70;3.02] | 0.3203 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 8 (57.1%) | 3.30 [0.33;NYR] | 19 | 14 (73.7%) | 2.27 [0.56;7.66] | 0.77 [0.32;1.85] | 0.5669 | 0.1068 |
| >= 1 Year | 60 | 47 (78.3%) | 2.38 [1.77;3.78] | 50 | 31 (62.0%) | 5.78 [3.22;11.10] | 1.51 [0.96;2.37] | 0.0766 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.53.2: TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 9 (81.8%) | 2.33 [0.43;7.56] | 12 | 6 (50.0%) | 7.66 [0.36;NYR] | 1.76 [0.63;4.97] | 0.2769 | 0.5132 |
| Yes | 63 | 46 (73.0%) | 2.43 [1.74;5.13] | 59 | 40 (67.8%) | 3.48 [2.27;7.10] | 1.19 [0.78;1.82] | 0.4287 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 49 (76.6%) | 2.17 [1.41;4.44] | 65 | 41 (63.1%) | 5.78 [3.22;9.66] | 1.43 [0.95;2.17] | 0.0889 | 0.0376 |
| Yes | 10 | 6 (60.0%) | 3.78 [1.41;NYR] | 6 | 5 (83.3%) | 0.79 [0.30;NYR] | 0.37 [0.11;1.23] | 0.0931 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 10 (90.9%) | 2.53 [0.82;6.18] | 10 | 8 (80.0%) | 4.16 [0.30;15.54] | 1.44 [0.54;3.81] | 0.4651 | 0.8718 |
| < 1% | 61 | 44 (72.1%) | 2.33 [1.87;4.80] | 60 | 37 (61.7%) | 4.73 [3.22;9.66] | 1.27 [0.82;1.97] | 0.2838 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 12 (66.7%) | 3.15 [0.92;NYR] | 20 | 14 (70.0%) | 2.69 [1.71;7.66] | 0.98 [0.45;2.13] | 0.9700 | 0.2893 |
| Non-Stage IV | 53 | 42 (79.2%) | 2.17 [1.41;3.25] | 51 | 32 (62.7%) | 5.78 [3.22;11.10] | 1.47 [0.93;2.34] | 0.0991 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:32:28

TABLE 3.54.1: TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 55 (74.3%) | 47 (66.2%) |
| Number of censored cases | N | 19 (25.7%) | 24 (33.8%) |
| Time to first event (Months) | Mean (SE) | 5.00 (0.57) | 9.58 (1.21) |
| | Q1 [95% CI] | 1.00 [0.56;1.74] | 1.80 [0.62;2.27] |
| | Median [95% CI] | 2.38 [1.87;4.44] | 5.78 [2.79;8.05] |
| | Q3 [95% CI] | 12.20 [5.36;NYR] | 23.80 [9.66;NYR] |
| | p-value (a) | 0.1732 | |
| Stratified Cox PH model | HR (b) | 1.32 [0.89;1.96] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 3.54.2: TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 55 (74.3%) | 2.38 [1.87;4.44] | 71 | 47 (66.2%) | 5.78 [2.79;8.05] | 1.32 [0.89;1.96] | 0.1732 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 33 (80.5%) | 2.33 [1.41;4.80] | 47 | 32 (68.1%) | 5.78 [2.79;9.66] | 1.46 [0.90;2.38] | 0.1245 | 0.4852 |
| >= 65 | 33 | 22 (66.7%) | 2.43 [1.77;10.28] | 24 | 15 (62.5%) | 4.73 [1.02;23.72] | 1.08 [0.56;2.08] | 0.8252 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 33 (80.5%) | 2.33 [1.41;4.80] | 47 | 32 (68.1%) | 5.78 [2.79;9.66] | 1.46 [0.90;2.38] | 0.1245 | 0.4829 |
| >= 65 AND < 75 | 25 | 19 (76.0%) | 2.17 [1.74;7.56] | 18 | 12 (66.7%) | 4.73 [1.02;23.72] | 1.38 [0.65;2.91] | 0.3994 | |
| >= 75 | 8 | 3 (37.5%) | NYR [0.53;NYR] | 6 | 3 (50.0%) | NYR [0.56;NYR] | 0.70 [0.14;3.54] | 0.6668 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 28 (71.8%) | 3.78 [1.97;6.90] | 37 | 23 (62.2%) | 7.10 [2.79;15.54] | 1.30 [0.75;2.25] | 0.3506 | 0.9939 |
| Rest of World (ROW) | 35 | 27 (77.1%) | 1.91 [1.41;2.43] | 34 | 24 (70.6%) | 3.48 [1.77;7.36] | 1.28 [0.74;2.23] | 0.3823 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.54.2: TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 48 (73.8%) | 2.43 [1.91;4.80] | 60 | 36 (60.0%) | 6.24 [3.25;15.54] | 1.48 [0.96;2.28] | 0.0761 | 0.1225 |
| Non-White | 9 | 7 (77.8%) | 1.41 [0.07;NYR] | 11 | 11 (100.0%) | 1.81 [0.49;5.78] | 0.59 [0.22;1.63] | 0.3016 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 5 (71.4%) | 2.60 [0.82;NYR] | 13 | 8 (61.5%) | 5.78 [0.53;NYR] | 0.95 [0.30;2.96] | 0.9239 | 0.7136 |
| Not Hispanic or Latino | 43 | 31 (72.1%) | 2.50 [1.77;6.18] | 32 | 22 (68.8%) | 3.37 [1.74;12.81] | 1.18 [0.68;2.04] | 0.5534 | |
| Not Reported | 24 | 19 (79.2%) | 2.07 [0.79;4.80] | 26 | 17 (65.4%) | 6.21 [2.27;23.72] | 1.55 [0.80;2.98] | 0.1894 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 40 (71.4%) | 2.51 [1.77;4.80] | 48 | 33 (68.8%) | 3.48 [2.27;8.05] | 1.17 [0.74;1.86] | 0.5050 | 0.4166 |
| Female | 18 | 15 (83.3%) | 2.10 [0.82;7.00] | 23 | 14 (60.9%) | 6.21 [1.77;23.72] | 1.54 [0.74;3.20] | 0.2534 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 8 (57.1%) | 3.30 [0.33;NYR] | 19 | 14 (73.7%) | 2.27 [0.56;7.66] | 0.78 [0.33;1.87] | 0.5834 | 0.1083 |
| >= 1 Year | 60 | 47 (78.3%) | 2.38 [1.77;4.80] | 50 | 32 (64.0%) | 6.24 [3.25;12.81] | 1.53 [0.98;2.40] | 0.0632 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.54.2: TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 9 (81.8%) | 2.33 [0.43;7.56] | 12 | 7 (58.3%) | 7.66 [0.36;NYR] | 1.70 [0.62;4.62] | 0.2945 | 0.6481 |
| Yes | 63 | 46 (73.0%) | 2.43 [1.74;5.13] | 59 | 40 (67.8%) | 4.73 [2.33;9.66] | 1.23 [0.80;1.88] | 0.3484 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 49 (76.6%) | 2.17 [1.41;4.44] | 65 | 42 (64.6%) | 6.21 [3.25;9.66] | 1.46 [0.97;2.21] | 0.0707 | 0.0343 |
| Yes | 10 | 6 (60.0%) | 4.98 [1.41;NYR] | 6 | 5 (83.3%) | 0.79 [0.30;NYR] | 0.36 [0.11;1.20] | 0.0825 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 10 (90.9%) | 2.53 [0.82;6.18] | 10 | 8 (80.0%) | 4.16 [0.30;15.54] | 1.44 [0.54;3.81] | 0.4651 | 0.7829 |
| < 1% | 61 | 44 (72.1%) | 2.33 [1.87;4.80] | 60 | 38 (63.3%) | 5.78 [3.22;11.10] | 1.30 [0.84;2.02] | 0.2315 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 12 (66.7%) | 3.15 [0.92;NYR] | 20 | 15 (75.0%) | 2.69 [1.71;7.66] | 0.92 [0.43;1.97] | 0.8339 | 0.1838 |
| Non-Stage IV | 53 | 42 (79.2%) | 2.17 [1.41;3.25] | 51 | 32 (62.7%) | 6.24 [3.22;12.81] | 1.56 [0.99;2.48] | 0.0573 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.55.1: TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 9 (12.2%) | 10 (14.1%) |
| Number of censored cases | N | 65 (87.8%) | 61 (85.9%) |
| Time to first event (Months) | Mean (SE) | 10.58 (0.31) | 13.48 (0.55) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [7.66;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.5298 | |
| Stratified Cox PH model | HR (b) | 0.75 [0.30;1.85] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:44:54

TABLE 3.55.2: TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 10 (14.1%) | NYR [NYR;NYR] | 0.75 [0.30;1.85] | 0.5298 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 3 (7.3%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [NYR;NYR] | 1.03 [0.21;5.14] | 0.9697 | 0.4111 |
| >= 65 | 33 | 6 (18.2%) | NYR [NYR;NYR] | 24 | 7 (29.2%) | NYR [3.35;NYR] | 0.46 [0.15;1.37] | 0.1487 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 3 (7.3%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [NYR;NYR] | 1.03 [0.21;5.14] | 0.9697 | 0.9111 |
| >= 65 AND < 75 | 25 | 6 (24.0%) | NYR [11.43;NYR] | 18 | 5 (27.8%) | NYR [5.09;NYR] | 0.67 [0.20;2.21] | 0.5043 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 2 (33.3%) | NYR [1.81;NYR] | <0.01 [<0.01;NE] | 0.0801 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NYR [NYR;NYR] | 37 | 2 (5.4%) | NYR [NYR;NYR] | 2.07 [0.40;10.71] | 0.3758 | 0.1220 |
| Rest of World (ROW) | 35 | 4 (11.4%) | NYR [NYR;NYR] | 34 | 8 (23.5%) | NYR [NYR;NYR] | 0.43 [0.13;1.41] | 0.1502 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.55.2: TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 8 (12.3%) | NYR [NYR;NYR] | 60 | 5 (8.3%) | NYR [NYR;NYR] | 1.31 [0.43;4.02] | 0.6336 | 0.1219 |
| Non-White | 9 | 1 (11.1%) | NYR [2.53;NYR] | 11 | 5 (45.5%) | NYR [1.81;NYR] | 0.20 [0.02;1.73] | 0.1051 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [5.13;NYR] | 13 | 5 (38.5%) | 5.78 [3.22;NYR] | 0.21 [0.02;1.87] | 0.1267 | 0.1728 |
| Not Hispanic or Latino | 43 | 8 (18.6%) | NYR [NYR;NYR] | 32 | 2 (6.3%) | NYR [NYR;NYR] | 2.87 [0.61;13.52] | 0.1638 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 3 (11.5%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.0637 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 5 (8.9%) | NYR [NYR;NYR] | 48 | 8 (16.7%) | NYR [NYR;NYR] | 0.46 [0.15;1.42] | 0.1681 | 0.1226 |
| Female | 18 | 4 (22.2%) | NYR [8.02;NYR] | 23 | 2 (8.7%) | NYR [NYR;NYR] | 2.35 [0.43;12.85] | 0.3132 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 4 (21.1%) | NYR [7.66;NYR] | 0.27 [0.03;2.45] | 0.2133 | 0.2725 |
| >= 1 Year | 60 | 8 (13.3%) | NYR [NYR;NYR] | 50 | 6 (12.0%) | NYR [NYR;NYR] | 1.00 [0.35;2.88] | 0.9962 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:44:54

TABLE 3.55.2: TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [8.02;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | 0.81 [0.05;13.34] | 0.8820 | 0.9014 |
| Yes | 63 | 8 (12.7%) | NYR [NYR;NYR] | 59 | 9 (15.3%) | NYR [NYR;NYR] | 0.74 [0.28;1.92] | 0.5297 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 8 (12.5%) | NYR [NYR;NYR] | 65 | 9 (13.8%) | NYR [NYR;NYR] | 0.77 [0.30;2.01] | 0.5955 | 0.8050 |
| Yes | 10 | 1 (10.0%) | NYR [2.53;NYR] | 6 | 1 (16.7%) | NYR [0.95;NYR] | 0.55 [0.03;8.78] | 0.6660 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [5.13;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1913 | 1.0000 |
| < 1% | 61 | 7 (11.5%) | NYR [NYR;NYR] | 60 | 10 (16.7%) | NYR [NYR;NYR] | 0.59 [0.22;1.55] | 0.2733 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 4 (22.2%) | NYR [11.43;NYR] | 20 | 3 (15.0%) | NYR [NYR;NYR] | 1.33 [0.30;5.98] | 0.7073 | 0.3956 |
| Non-Stage IV | 53 | 5 (9.4%) | NYR [NYR;NYR] | 51 | 7 (13.7%) | NYR [NYR;NYR] | 0.59 [0.19;1.87] | 0.3631 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.56.1: TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 9 (12.2%) | 10 (14.1%) |
| Number of censored cases | N | 65 (87.8%) | 61 (85.9%) |
| Time to first event (Months) | Mean (SE) | 10.59 (0.31) | 13.56 (0.53) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [15.15;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.5690 | |
| Stratified Cox PH model | HR (b) | 0.77 [0.31;1.90] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:51:09

TABLE 3.56.2: TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 10 (14.1%) | NYR [NYR;NYR] | 0.77 [0.31;1.90] | 0.5690 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 3 (7.3%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [NYR;NYR] | 1.05 [0.21;5.22] | 0.9522 | 0.4508 |
| >= 65 | 33 | 6 (18.2%) | NYR [NYR;NYR] | 24 | 7 (29.2%) | NYR [7.66;NYR] | 0.51 [0.17;1.54] | 0.2212 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 3 (7.3%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [NYR;NYR] | 1.05 [0.21;5.22] | 0.9522 | 0.9382 |
| >= 65 AND < 75 | 25 | 6 (24.0%) | NYR [NYR;NYR] | 18 | 5 (27.8%) | NYR [5.09;NYR] | 0.73 [0.22;2.41] | 0.5995 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 2 (33.3%) | NYR [1.81;NYR] | <0.01 [<0.01;NE] | 0.0872 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NYR [NYR;NYR] | 37 | 2 (5.4%) | NYR [NYR;NYR] | 2.17 [0.42;11.22] | 0.3439 | 0.1135 |
| Rest of World (ROW) | 35 | 4 (11.4%) | NYR [NYR;NYR] | 34 | 8 (23.5%) | NYR [NYR;NYR] | 0.43 [0.13;1.43] | 0.1551 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.56.2: TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 8 (12.3%) | NYR [NYR;NYR] | 60 | 5 (8.3%) | NYR [NYR;NYR] | 1.38 [0.45;4.22] | 0.5735 | 0.1149 |
| Non-White | 9 | 1 (11.1%) | NYR [2.53;NYR] | 11 | 5 (45.5%) | NYR [1.81;NYR] | 0.20 [0.02;1.73] | 0.1051 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [5.13;NYR] | 13 | 5 (38.5%) | NYR [3.22;NYR] | 0.24 [0.03;2.11] | 0.1660 | 0.1846 |
| Not Hispanic or Latino | 43 | 8 (18.6%) | NYR [NYR;NYR] | 32 | 2 (6.3%) | NYR [NYR;NYR] | 2.95 [0.63;13.92] | 0.1512 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 3 (11.5%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.0753 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 5 (8.9%) | NYR [NYR;NYR] | 48 | 8 (16.7%) | NYR [NYR;NYR] | 0.48 [0.16;1.46] | 0.1853 | 0.1116 |
| Female | 18 | 4 (22.2%) | NYR [8.02;NYR] | 23 | 2 (8.7%) | NYR [NYR;NYR] | 2.62 [0.48;14.35] | 0.2514 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 4 (21.1%) | NYR [7.66;NYR] | 0.29 [0.03;2.56] | 0.2325 | 0.2731 |
| >= 1 Year | 60 | 8 (13.3%) | NYR [NYR;NYR] | 50 | 6 (12.0%) | NYR [NYR;NYR] | 1.05 [0.36;3.02] | 0.9362 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.56.2: TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [8.02;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | 1.04 [0.07;16.71] | 0.9755 | 0.8888 |
| Yes | 63 | 8 (12.7%) | NYR [NYR;NYR] | 59 | 9 (15.3%) | NYR [NYR;NYR] | 0.77 [0.30;1.99] | 0.5832 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 8 (12.5%) | NYR [NYR;NYR] | 65 | 9 (13.8%) | NYR [NYR;NYR] | 0.81 [0.31;2.10] | 0.6627 | 0.7983 |
| Yes | 10 | 1 (10.0%) | NYR [2.53;NYR] | 6 | 1 (16.7%) | NYR [0.95;NYR] | 0.55 [0.03;8.78] | 0.6660 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [5.13;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1786 | 1.0000 |
| < 1% | 61 | 7 (11.5%) | NYR [NYR;NYR] | 60 | 10 (16.7%) | NYR [NYR;NYR] | 0.62 [0.23;1.62] | 0.3209 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 4 (22.2%) | NYR [11.43;NYR] | 20 | 3 (15.0%) | NYR [NYR;NYR] | 1.35 [0.30;6.06] | 0.6917 | 0.4282 |
| Non-Stage IV | 53 | 5 (9.4%) | NYR [NYR;NYR] | 51 | 7 (13.7%) | NYR [NYR;NYR] | 0.64 [0.20;2.01] | 0.4338 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.57.1: TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 4 (5.4%) | 0 (0.0%) |
| Number of censored cases | N | 70 (94.6%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 5.07 (0.05) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0577 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:57:23

TABLE 3.57.2: TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0577 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1400 | 1.0000 |
| >= 65 | 33 | 2 (6.1%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2604 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1400 | 1.0000 |
| >= 65 AND < 75 | 25 | 2 (8.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2656 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3505 | 0.9999 |
| Rest of World (ROW) | 35 | 3 (8.6%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0935 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:57:23

TABLE 3.57.2: TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 4 (6.2%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0642 | 0.9987 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [5.13;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2850 | 1.0000 |
| Not Hispanic or Latino | 43 | 3 (7.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1333 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 3 (5.4%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1117 | 1.0000 |
| Female | 18 | 1 (5.6%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2918 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2850 | 1.0000 |
| >= 1 Year | 60 | 3 (5.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1268 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:57:23

TABLE 3.57.2: TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9987 |
| Yes | 63 | 4 (6.3%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0622 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 4 (6.3%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0534 | 0.9989 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3938 | 1.0000 |
| < 1% | 61 | 3 (4.9%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0981 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2888 | 1.0000 |
| Non-Stage IV | 53 | 3 (5.7%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1095 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.58.1: TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 4 (5.4%) | 0 (0.0%) |
| Number of censored cases | N | 70 (94.6%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 5.08 (0.05) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0556 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:03:37

TABLE 3.58.2: TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0556 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1400 | 1.0000 |
| >= 65 | 33 | 2 (6.1%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2229 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1400 | 1.0000 |
| >= 65 AND < 75 | 25 | 2 (8.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2163 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3367 | 0.9999 |
| Rest of World (ROW) | 35 | 3 (8.6%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0931 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.58.2: TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 4 (6.2%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0588 | 0.9987 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [5.13;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2320 | 1.0000 |
| Not Hispanic or Latino | 43 | 3 (7.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1316 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 3 (5.4%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1069 | 1.0000 |
| Female | 18 | 1 (5.6%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2583 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2705 | 1.0000 |
| >= 1 Year | 60 | 3 (5.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1161 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:03:37

TABLE 3.58.2: TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9987 |
| Yes | 63 | 4 (6.3%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0552 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 4 (6.3%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0469 | 0.9989 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3657 | 1.0000 |
| < 1% | 61 | 3 (4.9%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0888 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3035 | 1.0000 |
| Non-Stage IV | 53 | 3 (5.7%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0942 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.59.1: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 3 (4.1%) | 0 (0.0%) |
| Number of censored cases | N | 71 (95.9%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 17.14 (0.26) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.1273 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.59.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1273 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2020 | 1.0000 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4561 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2020 | 1.0000 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4692 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 2 (5.1%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2304 | 0.9999 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3519 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:09:50

TABLE 3.59.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2044 | 0.9999 |
| Non-White | 9 | 1 (11.1%) | NYR [17.45;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3711 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2585 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3496 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 1 (1.8%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3723 | 0.9998 |
| Female | 18 | 2 (11.1%) | NYR [17.45;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1272 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [17.45;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1523 | 0.9998 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3897 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.59.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [8.57;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4028 | 0.9999 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2157 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 3 (4.7%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1188 | 0.9990 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 3 (4.9%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1211 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 2 (11.1%) | NYR [17.45;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1753 | 0.9999 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3686 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:09:50

TABLE 3.60.1: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 3 (4.1%) | 0 (0.0%) |
| Number of censored cases | N | 71 (95.9%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 17.15 (0.25) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.1270 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.60.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1270 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1892 | 1.0000 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4497 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1892 | 1.0000 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4692 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 2 (5.1%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2304 | 0.9999 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3583 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.60.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1972 | 0.9999 |
| Non-White | 9 | 1 (11.1%) | NYR [17.45;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4142 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2675 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3496 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 1 (1.8%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3585 | 0.9998 |
| Female | 18 | 2 (11.1%) | NYR [17.45;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1464 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [17.45;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1396 | 0.9998 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3791 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.60.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [8.57;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3711 | 0.9999 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2238 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 3 (4.7%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1161 | 0.9991 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 3 (4.9%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1174 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 2 (11.1%) | NYR [17.45;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1573 | 0.9998 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3603 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.61.1: TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.61.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.61.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.61.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.62.1: TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:28:26

TABLE 3.62.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.62.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:28:26

TABLE 3.62.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.63.1: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.63.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.63.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.63.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.64.1: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:40:55

TABLE 3.64.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.64.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.64.2: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.65.1: TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.65.2: TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.65.2: TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.65.2: TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.66.1: TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:42:02

TABLE 3.66.2: TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:42:02

TABLE 3.66.2: TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:42:02

TABLE 3.66.2: TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.67.1: TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:48:54

TABLE 3.67.2: TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.67.2: TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.67.2: TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.68.1: TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.68.2: TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.68.2: TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.68.2: TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.69.1: TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - DIABETES MELLITUS - Serious AE - | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.69.2: TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.69.2: TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.69.2: TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.70.1: TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) -- Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.70.2: TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.70.2: TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) -- Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.70.2: TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) -- Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.71.1: TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 56 (75.7%) | 37 (52.1%) |
| Number of censored cases | N | 18 (24.3%) | 34 (47.9%) |
| Time to first event (Months) | Mean (SE) | 9.30 (1.14) | 8.72 (0.83) |
| | Q1 [95% CI] | 1.60 [1.08;1.94] | 2.20 [1.61;3.45] |
| | Median [95% CI] | 4.37 [2.27;10.61] | 8.71 [3.48;NYR] |
| | Q3 [95% CI] | 16.60 [12.94;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0434 | |
| Stratified Cox PH model | HR (b) | 1.54 [1.01;2.34] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.71.2: TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 56 (75.7%) | 4.37 [2.27;10.61] | 71 | 37 (52.1%) | 8.71 [3.48;NYR] | 1.54 [1.01;2.34] | 0.0434 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 36 (87.8%) | 2.33 [1.71;6.60] | 47 | 27 (57.4%) | 8.71 [3.48;15.70] | 1.79 [1.09;2.95] | 0.0208 | 0.5013 |
| >= 65 | 33 | 20 (60.6%) | 6.77 [2.30;16.59] | 24 | 10 (41.7%) | NYR [2.14;NYR] | 1.31 [0.61;2.82] | 0.4827 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 36 (87.8%) | 2.33 [1.71;6.60] | 47 | 27 (57.4%) | 8.71 [3.48;15.70] | 1.79 [1.09;2.95] | 0.0208 | 0.2087 |
| >= 65 AND < 75 | 25 | 17 (68.0%) | 6.77 [2.27;12.94] | 18 | 7 (38.9%) | NYR [2.14;NYR] | 1.80 [0.74;4.37] | 0.1883 | |
| >= 75 | 8 | 3 (37.5%) | NYR [1.51;NYR] | 6 | 3 (50.0%) | 2.83 [0.56;NYR] | 0.55 [0.11;2.73] | 0.4555 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 33 (84.6%) | 2.27 [1.61;6.18] | 37 | 17 (45.9%) | 9.36 [3.48;NYR] | 2.28 [1.27;4.10] | 0.0045 | 0.0509 |
| Rest of World (ROW) | 35 | 23 (65.7%) | 8.54 [2.66;17.41] | 34 | 20 (58.8%) | 5.13 [2.99;NYR] | 0.99 [0.54;1.80] | 0.9651 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.71.2: TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)


| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 50 (76.9%) | 4.17 [1.94;8.54] | 60 | 30 (50.0%) | 9.36 [3.71;NYR] | 1.71 [1.09;2.69] | 0.0187 | 0.2117 |
| Non-White | 9 | 6 (66.7%) | 13.01 [0.33;NYR] | 11 | 7 (63.6%) | 3.45 [0.43;NYR] | 0.81 [0.27;2.42] | 0.7018 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 4 (57.1%) | 4.93 [2.27;NYR] | 13 | 8 (61.5%) | 4.86 [1.61;15.70] | 0.64 [0.19;2.15] | 0.4701 | 0.2047 |
| Not Hispanic or Latino | 43 | 35 (81.4%) | 2.33 [1.71;6.77] | 32 | 15 (46.9%) | 4.73 [3.25;NYR] | 2.12 [1.16;3.89] | 0.0128 | |
| Not Reported | 24 | 17 (70.8%) | 9.58 [1.71;16.59] | 26 | 14 (53.8%) | 9.36 [2.14;NYR] | 1.28 [0.63;2.60] | 0.4921 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 44 (78.6%) | 2.50 [1.84;8.54] | 48 | 26 (54.2%) | 9.36 [3.88;NYR] | 1.76 [1.08;2.86] | 0.0208 | 0.2474 |
| Female | 18 | 12 (66.7%) | 6.11 [2.37;17.41] | 23 | 11 (47.8%) | 3.71 [2.10;NYR] | 0.94 [0.41;2.15] | 0.8718 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 11 (78.6%) | 11.78 [1.71;14.16] | 19 | 10 (52.6%) | 15.24 [3.48;NYR] | 1.64 [0.69;3.92] | 0.2608 | 0.9259 |
| >= 1 Year | 60 | 45 (75.0%) | 3.22 [1.91;6.77] | 50 | 25 (50.0%) | 4.73 [2.83;NYR] | 1.59 [0.97;2.59] | 0.0608 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.71.2: TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)


| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 10 (90.9%) | 2.66 [1.61;4.93] | 12 | 7 (58.3%) | 4.86 [2.83;NYR] | 2.34 [0.88;6.18] | 0.0787 | 0.4347 |
| Yes | 63 | 46 (73.0%) | 6.18 [2.27;12.94] | 59 | 30 (50.8%) | 8.71 [3.71;NYR] | 1.44 [0.91;2.28] | 0.1167 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 49 (76.6%) | 2.94 [1.94;6.77] | 65 | 33 (50.8%) | 8.71 [3.48;NYR] | 1.65 [1.06;2.56] | 0.0256 | 0.3415 |
| Yes | 10 | 7 (70.0%) | 16.59 [0.16;25.49] | 6 | 4 (66.7%) | 3.88 [2.14;NYR] | 0.65 [0.18;2.36] | 0.5084 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 8 (72.7%) | 10.71 [1.71;25.49] | 10 | 6 (60.0%) | 2.81 [0.26;NYR] | 0.79 [0.27;2.33] | 0.6703 | 0.4446 |
| < 1% | 61 | 47 (77.0%) | 3.22 [1.94;6.77] | 60 | 30 (50.0%) | 8.71 [3.88;NYR] | 1.73 [1.09;2.73] | 0.0183 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 12 (66.7%) | 12.94 [1.84;15.67] | 20 | 13 (65.0%) | 3.48 [0.82;15.70] | 0.88 [0.40;1.93] | 0.7446 | 0.1172 |
| Non-Stage IV | 53 | 41 (77.4%) | 4.37 [2.10;6.77] | 51 | 24 (47.1%) | 11.37 [3.88;NYR] | 1.82 [1.10;3.01] | 0.0183 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.72.1: TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 56 (75.7%) | 38 (53.5%) |
| Number of censored cases | N | 18 (24.3%) | 33 (46.5%) |
| Time to first event (Months) | Mean (SE) | 9.46 (1.15) | 8.93 (0.81) |
| | Q1 [95% CI] | 1.60 [1.08;1.94] | 2.20 [1.61;3.48] |
| | Median [95% CI] | 4.37 [2.27;10.61] | 8.71 [3.88;NYR] |
| | Q3 [95% CI] | 17.40 [12.94;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0350 | |
| Stratified Cox PH model | HR (b) | 1.56 [1.03;2.37] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:23:40

TABLE 3.72.2: TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 56 (75.7%) | 4.37 [2.27;10.61] | 71 | 38 (53.5%) | 8.71 [3.88;NYR] | 1.56 [1.03;2.37] | 0.0350 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 36 (87.8%) | 2.33 [1.71;6.60] | 47 | 27 (57.4%) | 8.71 [3.48;NYR] | 1.85 [1.12;3.05] | 0.0144 | 0.4176 |
| >= 65 | 33 | 20 (60.6%) | 6.77 [2.30;NYR] | 24 | 11 (45.8%) | NYR [2.14;NYR] | 1.26 [0.60;2.64] | 0.5331 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 36 (87.8%) | 2.33 [1.71;6.60] | 47 | 27 (57.4%) | 8.71 [3.48;NYR] | 1.85 [1.12;3.05] | 0.0144 | 0.2570 |
| >= 65 AND < 75 | 25 | 17 (68.0%) | 6.77 [2.27;16.59] | 18 | 8 (44.4%) | NYR [2.14;NYR] | 1.65 [0.71;3.82] | 0.2418 | |
| >= 75 | 8 | 3 (37.5%) | NYR [1.51;NYR] | 6 | 3 (50.0%) | NYR [0.56;NYR] | 0.57 [0.11;2.87] | 0.4935 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 33 (84.6%) | 2.27 [1.61;6.18] | 37 | 18 (48.6%) | 11.37 [3.71;NYR] | 2.30 [1.29;4.09] | 0.0036 | 0.0537 |
| Rest of World (ROW) | 35 | 23 (65.7%) | 10.61 [2.66;17.41] | 34 | 20 (58.8%) | 5.13 [2.99;NYR] | 1.00 [0.55;1.83] | 0.9892 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.72.2: TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 50 (76.9%) | 4.17 [1.94;8.54] | 60 | 31 (51.7%) | 11.37 [4.27;NYR] | 1.73 [1.11;2.71] | 0.0151 | 0.2077 |
| Non-White | 9 | 6 (66.7%) | 13.01 [0.33;NYR] | 11 | 7 (63.6%) | 3.45 [0.43;NYR] | 0.82 [0.27;2.46] | 0.7249 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 4 (57.1%) | 4.93 [2.27;NYR] | 13 | 8 (61.5%) | 4.86 [1.61;NYR] | 0.74 [0.22;2.45] | 0.6156 | 0.2724 |
| Not Hispanic or Latino | 43 | 35 (81.4%) | 2.33 [1.71;6.77] | 32 | 16 (50.0%) | 4.73 [3.25;NYR] | 2.07 [1.14;3.74] | 0.0140 | |
| Not Reported | 24 | 17 (70.8%) | 9.58 [1.71;17.41] | 26 | 14 (53.8%) | 11.37 [2.99;NYR] | 1.32 [0.65;2.69] | 0.4372 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 44 (78.6%) | 2.50 [1.84;8.54] | 48 | 26 (54.2%) | 9.36 [3.88;NYR] | 1.79 [1.10;2.91] | 0.0174 | 0.2468 |
| Female | 18 | 12 (66.7%) | 6.11 [2.37;17.41] | 23 | 12 (52.2%) | 4.50 [2.14;NYR] | 0.99 [0.44;2.21] | 0.9708 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 11 (78.6%) | 11.78 [1.71;14.16] | 19 | 11 (57.9%) | 9.36 [3.48;NYR] | 1.52 [0.65;3.54] | 0.3330 | 0.7094 |
| >= 1 Year | 60 | 45 (75.0%) | 3.70 [1.91;6.77] | 50 | 25 (50.0%) | 8.71 [3.06;NYR] | 1.67 [1.03;2.73] | 0.0370 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.72.2: TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 10 (90.9%) | 2.66 [1.61;4.93] | 12 | 7 (58.3%) | 4.86 [2.83;NYR] | 2.34 [0.88;6.18] | 0.0787 | 0.4460 |
| Yes | 63 | 46 (73.0%) | 6.18 [2.27;12.94] | 59 | 31 (52.5%) | 9.36 [3.88;NYR] | 1.45 [0.92;2.29] | 0.1068 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 49 (76.6%) | 2.94 [1.94;6.77] | 65 | 34 (52.3%) | 8.71 [3.71;NYR] | 1.68 [1.08;2.60] | 0.0195 | 0.3497 |
| Yes | 10 | 7 (70.0%) | 16.59 [0.16;25.49] | 6 | 4 (66.7%) | 7.62 [2.14;NYR] | 0.65 [0.18;2.35] | 0.5044 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 8 (72.7%) | 10.71 [1.71;25.49] | 10 | 7 (70.0%) | 2.81 [0.26;NYR] | 0.69 [0.25;1.93] | 0.4751 | 0.2393 |
| < 1% | 61 | 47 (77.0%) | 3.22 [1.94;6.77] | 60 | 30 (50.0%) | 15.24 [4.27;NYR] | 1.82 [1.15;2.88] | 0.0094 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 12 (66.7%) | 12.94 [1.84;15.67] | 20 | 13 (65.0%) | 3.48 [0.82;15.70] | 0.88 [0.40;1.93] | 0.7462 | 0.1010 |
| Non-Stage IV | 53 | 41 (77.4%) | 4.37 [2.10;8.54] | 51 | 25 (49.0%) | 11.37 [4.27;NYR] | 1.85 [1.13;3.05] | 0.0138 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.73.1: TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 8 (10.8%) | 4 (5.6%) |
| Number of censored cases | N | 66 (89.2%) | 67 (94.4%) |
| Time to first event (Months) | Mean (SE) | 19.01 (0.45) | 6.10 (0.12) |
| | Q1 [95% CI] | NYR [20.11;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.4146 | |
| Stratified Cox PH model | HR (b) | 1.64 [0.49;5.47] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.73.2: TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.64 [0.49;5.47] | 0.4146 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [NYR;NYR] | 2.16 [0.56;8.37] | 0.2531 | 0.4004 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 0.59 [0.04;9.60] | 0.7090 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [NYR;NYR] | 2.16 [0.56;8.37] | 0.2531 | 1.0000 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4692 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 1 (16.7%) | NYR [0.66;NYR] | <0.01 [<0.01;NE] | 0.2482 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NYR [NYR;NYR] | 37 | 2 (5.4%) | NYR [NYR;NYR] | 1.88 [0.36;9.69] | 0.4452 | 0.7039 |
| Rest of World (ROW) | 35 | 3 (8.6%) | NYR [NYR;NYR] | 34 | 2 (5.9%) | NYR [NYR;NYR] | 1.26 [0.21;7.55] | 0.8020 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.73.2: TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 7 (10.8%) | NYR [NYR;NYR] | 60 | 3 (5.0%) | NYR [NYR;NYR] | 1.80 [0.46;6.96] | 0.3880 | 0.6651 |
| Non-White | 9 | 1 (11.1%) | NYR [7.85;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 1.04 [0.06;16.81] | 0.9767 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [7.85;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2059 | 0.5768 |
| Not Hispanic or Latino | 43 | 6 (14.0%) | NYR [NYR;NYR] | 32 | 2 (6.3%) | NYR [NYR;NYR] | 1.94 [0.39;9.64] | 0.4087 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 2 (7.7%) | NYR [NYR;NYR] | 0.47 [0.04;5.17] | 0.5252 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 6 (10.7%) | NYR [NYR;NYR] | 48 | 4 (8.3%) | NYR [NYR;NYR] | 1.10 [0.31;3.91] | 0.8822 | 0.9919 |
| Female | 18 | 2 (11.1%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1924 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [20.11;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1822 | 0.9920 |
| >= 1 Year | 60 | 6 (10.0%) | NYR [NYR;NYR] | 50 | 4 (8.0%) | NYR [NYR;NYR] | 1.04 [0.29;3.70] | 0.9478 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.73.2: TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NYR [11.04;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | 1.67 [0.15;18.97] | 0.6760 | 0.9971 |
| Yes | 63 | 6 (9.5%) | NYR [NYR;NYR] | 59 | 3 (5.1%) | NYR [NYR;NYR] | 1.61 [0.40;6.45] | 0.4958 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 7 (10.9%) | NYR [NYR;NYR] | 65 | 3 (4.6%) | NYR [NYR;NYR] | 1.93 [0.50;7.49] | 0.3309 | 0.4320 |
| Yes | 10 | 1 (10.0%) | NYR [19.29;NYR] | 6 | 1 (16.7%) | NYR [6.28;NYR] | 0.49 [0.03;8.21] | 0.6115 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [12.65;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2684 | 1.0000 |
| < 1% | 61 | 6 (9.8%) | NYR [NYR;NYR] | 60 | 4 (6.7%) | NYR [NYR;NYR] | 1.24 [0.35;4.41] | 0.7350 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3428 | 0.9927 |
| Non-Stage IV | 53 | 7 (13.2%) | NYR [NYR;NYR] | 51 | 3 (5.9%) | NYR [NYR;NYR] | 1.78 [0.46;6.88] | 0.3977 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.74.1: TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 8 (10.8%) | 5 (7.0%) |
| Number of censored cases | N | 66 (89.2%) | 66 (93.0%) |
| Time to first event (Months) | Mean (SE) | 19.04 (0.44) | 6.08 (0.12) |
| | Q1 [95% CI] | NYR [20.11;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.5793 | |
| Stratified Cox PH model | HR (b) | 1.37 [0.45;4.20] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.74.2: TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 1.37 [0.45;4.20] | 0.5793 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [NYR;NYR] | 2.26 [0.58;8.74] | 0.2264 | 0.1636 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 2 (8.3%) | NYR [NYR;NYR] | 0.33 [0.03;3.68] | 0.3457 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [NYR;NYR] | 2.26 [0.58;8.74] | 0.2264 | 0.7458 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 1 (5.6%) | NYR [NYR;NYR] | 0.65 [0.04;10.65] | 0.7643 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 1 (16.7%) | NYR [0.66;NYR] | <0.01 [<0.01;NE] | 0.2482 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NYR [NYR;NYR] | 37 | 3 (8.1%) | NYR [NYR;NYR] | 1.32 [0.31;5.53] | 0.7051 | 0.9759 |
| Rest of World (ROW) | 35 | 3 (8.6%) | NYR [NYR;NYR] | 34 | 2 (5.9%) | NYR [NYR;NYR] | 1.34 [0.22;8.02] | 0.7480 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.74.2: TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 7 (10.8%) | NYR [NYR;NYR] | 60 | 4 (6.7%) | NYR [NYR;NYR] | 1.43 [0.42;4.89] | 0.5658 | 0.8241 |
| Non-White | 9 | 1 (11.1%) | NYR [7.85;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 1.11 [0.07;17.74] | 0.9435 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [7.85;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2482 | 0.7145 |
| Not Hispanic or Latino | 43 | 6 (14.0%) | NYR [NYR;NYR] | 32 | 3 (9.4%) | NYR [NYR;NYR] | 1.39 [0.35;5.55] | 0.6423 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 2 (7.7%) | NYR [NYR;NYR] | 0.50 [0.04;5.50] | 0.5608 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 6 (10.7%) | NYR [NYR;NYR] | 48 | 4 (8.3%) | NYR [NYR;NYR] | 1.15 [0.32;4.08] | 0.8299 | 0.6217 |
| Female | 18 | 2 (11.1%) | NYR [NYR;NYR] | 23 | 1 (4.3%) | NYR [NYR;NYR] | 2.05 [0.18;22.68] | 0.5511 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [20.11;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | 2.05 [0.18;22.68] | 0.5511 | 0.6067 |
| >= 1 Year | 60 | 6 (10.0%) | NYR [NYR;NYR] | 50 | 4 (8.0%) | NYR [NYR;NYR] | 1.10 [0.31;3.91] | 0.8798 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.74.2: TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NYR [11.04;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | 1.76 [0.16;19.72] | 0.6433 | 0.8075 |
| Yes | 63 | 6 (9.5%) | NYR [NYR;NYR] | 59 | 4 (6.8%) | NYR [NYR;NYR] | 1.27 [0.36;4.49] | 0.7150 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 7 (10.9%) | NYR [NYR;NYR] | 65 | 4 (6.2%) | NYR [NYR;NYR] | 1.55 [0.45;5.29] | 0.4825 | 0.5518 |
| Yes | 10 | 1 (10.0%) | NYR [19.29;NYR] | 6 | 1 (16.7%) | NYR [6.28;NYR] | 0.60 [0.04;9.66] | 0.7140 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [12.65;NYR] | 10 | 1 (10.0%) | NYR [4.40;NYR] | 1.51 [0.14;16.67] | 0.7348 | 0.9960 |
| < 1% | 61 | 6 (9.8%) | NYR [NYR;NYR] | 60 | 4 (6.7%) | NYR [NYR;NYR] | 1.33 [0.37;4.71] | 0.6599 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3428 | 0.9922 |
| Non-Stage IV | 53 | 7 (13.2%) | NYR [NYR;NYR] | 51 | 4 (7.8%) | NYR [NYR;NYR] | 1.45 [0.42;4.95] | 0.5538 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.75.1: TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 6 (8.1%) | 0 (0.0%) |
| Number of censored cases | N | 68 (91.9%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 16.69 (0.39) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0274 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 3.75.2: TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0274 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 4 (9.8%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0561 | 1.0000 |
| >= 65 | 33 | 2 (6.1%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2966 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 4 (9.8%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0561 | 1.0000 |
| >= 65 AND < 75 | 25 | 2 (8.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3116 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 3 (7.7%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1414 | 1.0000 |
| Rest of World (ROW) | 35 | 3 (8.6%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1016 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.75.2: TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 5 (7.7%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0472 | 1.0000 |
| Non-White | 9 | 1 (11.1%) | NYR [7.85;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3173 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 2 (28.6%) | NYR [5.16;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0993 | 1.0000 |
| Not Hispanic or Latino | 43 | 3 (7.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1825 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3496 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 3 (5.4%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1357 | 0.9999 |
| Female | 18 | 3 (16.7%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1006 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9982 |
| >= 1 Year | 60 | 6 (10.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0389 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.75.2: TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3173 | 1.0000 |
| Yes | 63 | 5 (7.9%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0447 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 4 (6.3%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0654 | 0.9999 |
| Yes | 10 | 2 (20.0%) | NYR [5.16;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3057 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [12.65;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 | 1.0000 |
| < 1% | 61 | 5 (8.2%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0382 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9981 |
| Non-Stage IV | 53 | 6 (11.3%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0294 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:44:27

TABLE 3.76.1: TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 6 (8.1%) | 1 (1.4%) |
| Number of censored cases | N | 68 (91.9%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 16.71 (0.38) | 4.40 (.) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0998 | |
| Stratified Cox PH model | HR (b) | 4.99 [0.60;41.61] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:51:24

TABLE 3.76.2: TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 4.99 [0.60;41.61] | 0.0998 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 4 (9.8%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0526 | 0.9943 |
| >= 65 | 33 | 2 (6.1%) | NYR [NYR;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 1.30 [0.12;14.39] | 0.8303 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 4 (9.8%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0526 | 1.0000 |
| >= 65 AND < 75 | 25 | 2 (8.0%) | NYR [NYR;NYR] | 18 | 1 (5.6%) | NYR [NYR;NYR] | 1.27 [0.11;14.17] | 0.8442 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 3 (7.7%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 2.32 [0.24;22.51] | 0.4556 | 0.9952 |
| Rest of World (ROW) | 35 | 3 (8.6%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0952 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.76.2: TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 5 (7.7%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 4.07 [0.48;34.93] | 0.1648 | 0.9959 |
| Non-White | 9 | 1 (11.1%) | NYR [7.85;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2918 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 2 (28.6%) | NYR [5.16;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1056 | 1.0000 |
| Not Hispanic or Latino | 43 | 3 (7.0%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 1.88 [0.19;18.21] | 0.5806 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3276 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 3 (5.4%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1311 | 0.9941 |
| Female | 18 | 3 (16.7%) | NYR [NYR;NYR] | 23 | 1 (4.3%) | NYR [NYR;NYR] | 3.06 [0.32;29.47] | 0.3092 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3642 | 0.9946 |
| >= 1 Year | 60 | 6 (10.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0365 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.76.2: TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3173 | 0.9957 |
| Yes | 63 | 5 (7.9%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 4.17 [0.49;35.73] | 0.1572 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 4 (6.3%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 3.66 [0.41;32.76] | 0.2146 | 0.9954 |
| Yes | 10 | 2 (20.0%) | NYR [5.16;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3216 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [12.65;NYR] | 10 | 1 (10.0%) | NYR [4.40;NYR] | 0.76 [0.05;12.12] | 0.8434 | 1.0000 |
| < 1% | 61 | 5 (8.2%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0359 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9998 |
| Non-Stage IV | 53 | 6 (11.3%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 4.93 [0.59;41.01] | 0.1020 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.77.1: TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 33 (44.6%) | 24 (33.8%) |
| Number of censored cases | N | 41 (55.4%) | 47 (66.2%) |
| Time to first event (Months) | Mean (SE) | 15.38 (1.30) | 10.90 (0.76) |
| | Q1 [95% CI] | 2.40 [1.58;4.63] | 2.80 [0.76;15.21] |
| | Median [95% CI] | 24.80 [6.01;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.4245 | |
| Stratified Cox PH model | HR (b) | 1.24 [0.73;2.11] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.77.2: TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 33 (44.6%) | 24.80 [6.01;NYR] | 71 | 24 (33.8%) | NYR [NYR;NYR] | 1.24 [0.73;2.11] | 0.4245 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 20 (48.8%) | 21.62 [4.24;NYR] | 47 | 14 (29.8%) | NYR [NYR;NYR] | 1.60 [0.81;3.17] | 0.1734 | 0.2806 |
| >= 65 | 33 | 13 (39.4%) | 24.80 [3.22;NYR] | 24 | 10 (41.7%) | NYR [2.37;NYR] | 0.89 [0.39;2.03] | 0.7879 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 20 (48.8%) | 21.62 [4.24;NYR] | 47 | 14 (29.8%) | NYR [NYR;NYR] | 1.60 [0.81;3.17] | 0.1734 | 0.5627 |
| >= 65 AND < 75 | 25 | 12 (48.0%) | 24.80 [1.87;NYR] | 18 | 9 (50.0%) | 7.56 [1.77;NYR] | 0.95 [0.40;2.26] | 0.9126 | |
| >= 75 | 8 | 1 (12.5%) | NYR [2.33;NYR] | 6 | 1 (16.7%) | NYR [0.72;NYR] | 0.61 [0.04;9.93] | 0.7276 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 18 (46.2%) | NYR [4.63;NYR] | 37 | 12 (32.4%) | NYR [9.63;NYR] | 1.36 [0.65;2.82] | 0.4145 | 0.8525 |
| Rest of World (ROW) | 35 | 15 (42.9%) | 24.80 [3.22;NYR] | 34 | 12 (35.3%) | NYR [2.99;NYR] | 1.17 [0.55;2.50] | 0.6753 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.77.2: TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 32 (49.2%) | 24.80 [3.94;NYR] | 60 | 22 (36.7%) | NYR [9.63;NYR] | 1.33 [0.77;2.30] | 0.2970 | 0.4383 |
| Non-White | 9 | 1 (11.1%) | NYR [21.62;NYR] | 11 | 2 (18.2%) | NYR [0.72;NYR] | 0.48 [0.04;5.38] | 0.5418 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [2.76;NYR] | 13 | 6 (46.2%) | NYR [1.77;NYR] | 0.25 [0.03;2.05] | 0.1600 | 0.1258 |
| Not Hispanic or Latino | 43 | 21 (48.8%) | 9.69 [2.40;NYR] | 32 | 8 (25.0%) | NYR [NYR;NYR] | 2.14 [0.95;4.84] | 0.0623 | |
| Not Reported | 24 | 11 (45.8%) | 24.80 [3.94;NYR] | 26 | 10 (38.5%) | NYR [7.23;NYR] | 0.95 [0.40;2.26] | 0.9148 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 27 (48.2%) | 24.80 [3.94;NYR] | 48 | 14 (29.2%) | NYR [NYR;NYR] | 1.77 [0.93;3.39] | 0.0794 | 0.0765 |
| Female | 18 | 6 (33.3%) | NYR [4.63;NYR] | 23 | 10 (43.5%) | NYR [0.76;NYR] | 0.64 [0.23;1.76] | 0.3839 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 9 (64.3%) | 3.09 [1.22;NYR] | 19 | 5 (26.3%) | NYR [9.63;NYR] | 3.47 [1.16;10.42] | 0.0181 | 0.0502 |
| >= 1 Year | 60 | 24 (40.0%) | NYR [16.13;NYR] | 50 | 19 (38.0%) | NYR [2.99;NYR] | 0.93 [0.51;1.69] | 0.8070 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.77.2: TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 5 (45.5%) | NYR [1.38;NYR] | 12 | 2 (16.7%) | NYR [9.63;NYR] | 3.05 [0.59;15.76] | 0.1616 | 0.2230 |
| Yes | 63 | 28 (44.4%) | 24.80 [5.09;NYR] | 59 | 22 (37.3%) | NYR [7.56;NYR] | 1.10 [0.63;1.93] | 0.7295 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 31 (48.4%) | 24.80 [4.63;NYR] | 65 | 22 (33.8%) | NYR [15.21;NYR] | 1.39 [0.80;2.40] | 0.2367 | 0.3525 |
| Yes | 10 | 2 (20.0%) | NYR [0.49;NYR] | 6 | 2 (33.3%) | NYR [0.62;NYR] | 0.56 [0.08;4.00] | 0.5586 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 4 (36.4%) | NYR [2.33;NYR] | 10 | 4 (40.0%) | NYR [0.69;NYR] | 0.65 [0.16;2.62] | 0.5431 | 0.5546 |
| < 1% | 61 | 29 (47.5%) | 24.80 [4.24;NYR] | 60 | 19 (31.7%) | NYR [NYR;NYR] | 1.53 [0.86;2.73] | 0.1469 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 9 (50.0%) | 8.74 [1.84;NYR] | 20 | 8 (40.0%) | NYR [3.71;NYR] | 1.36 [0.52;3.52] | 0.5235 | 0.9258 |
| Non-Stage IV | 53 | 23 (43.4%) | 24.80 [6.01;NYR] | 51 | 16 (31.4%) | NYR [NYR;NYR] | 1.27 [0.67;2.41] | 0.4574 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:58:24

TABLE 3.78.1: TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 33 (44.6%) | 24 (33.8%) |
| Number of censored cases | N | 41 (55.4%) | 47 (66.2%) |
| Time to first event (Months) | Mean (SE) | 15.49 (1.29) | 10.96 (0.76) |
| | Q1 [95% CI] | 2.40 [1.58;4.63] | 2.80 [0.76;15.21] |
| | Median [95% CI] | 24.80 [6.01;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.3889 | |
| Stratified Cox PH model | HR (b) | 1.26 [0.74;2.15] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:05:19

TABLE 3.78.2: TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 33 (44.6%) | 24.80 [6.01;NYR] | 71 | 24 (33.8%) | NYR [NYR;NYR] | 1.26 [0.74;2.15] | 0.3889 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 20 (48.8%) | 21.62 [4.24;NYR] | 47 | 14 (29.8%) | NYR [NYR;NYR] | 1.61 [0.81;3.19] | 0.1671 | 0.2980 |
| >= 65 | 33 | 13 (39.4%) | 24.80 [3.22;NYR] | 24 | 10 (41.7%) | NYR [2.37;NYR] | 0.92 [0.40;2.10] | 0.8464 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 20 (48.8%) | 21.62 [4.24;NYR] | 47 | 14 (29.8%) | NYR [NYR;NYR] | 1.61 [0.81;3.19] | 0.1671 | 0.5819 |
| >= 65 AND < 75 | 25 | 12 (48.0%) | 24.80 [1.87;NYR] | 18 | 9 (50.0%) | 7.56 [1.77;NYR] | 0.96 [0.40;2.29] | 0.9358 | |
| >= 75 | 8 | 1 (12.5%) | NYR [2.33;NYR] | 6 | 1 (16.7%) | NYR [0.72;NYR] | 0.68 [0.04;10.98] | 0.7878 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 18 (46.2%) | NYR [4.63;NYR] | 37 | 12 (32.4%) | NYR [15.21;NYR] | 1.40 [0.67;2.91] | 0.3659 | 0.8212 |
| Rest of World (ROW) | 35 | 15 (42.9%) | 24.80 [3.22;NYR] | 34 | 12 (35.3%) | NYR [2.99;NYR] | 1.16 [0.54;2.48] | 0.6909 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.78.2: TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 32 (49.2%) | 24.80 [4.24;NYR] | 60 | 22 (36.7%) | NYR [15.21;NYR] | 1.35 [0.78;2.33] | 0.2772 | 0.4357 |
| Non-White | 9 | 1 (11.1%) | NYR [21.62;NYR] | 11 | 2 (18.2%) | NYR [0.72;NYR] | 0.48 [0.04;5.38] | 0.5418 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [2.76;NYR] | 13 | 6 (46.2%) | NYR [1.77;NYR] | 0.25 [0.03;2.05] | 0.1600 | 0.1343 |
| Not Hispanic or Latino | 43 | 21 (48.8%) | NYR [2.40;NYR] | 32 | 8 (25.0%) | NYR [NYR;NYR] | 2.13 [0.94;4.83] | 0.0633 | |
| Not Reported | 24 | 11 (45.8%) | 24.80 [3.94;NYR] | 26 | 10 (38.5%) | NYR [7.23;NYR] | 0.99 [0.42;2.35] | 0.9873 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 27 (48.2%) | 24.80 [4.24;NYR] | 48 | 14 (29.2%) | NYR [NYR;NYR] | 1.78 [0.93;3.39] | 0.0788 | 0.0880 |
| Female | 18 | 6 (33.3%) | NYR [4.63;NYR] | 23 | 10 (43.5%) | NYR [0.76;NYR] | 0.65 [0.24;1.79] | 0.4049 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 9 (64.3%) | 3.09 [1.22;NYR] | 19 | 5 (26.3%) | NYR [9.63;NYR] | 3.60 [1.20;10.82] | 0.0150 | 0.0497 |
| >= 1 Year | 60 | 24 (40.0%) | NYR [16.13;NYR] | 50 | 19 (38.0%) | NYR [2.99;NYR] | 0.93 [0.51;1.71] | 0.8290 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.78.2: TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 5 (45.5%) | NYR [1.38;NYR] | 12 | 2 (16.7%) | NYR [9.63;NYR] | 3.18 [0.62;16.44] | 0.1441 | 0.2205 |
| Yes | 63 | 28 (44.4%) | NYR [6.01;NYR] | 59 | 22 (37.3%) | NYR [15.21;NYR] | 1.11 [0.64;1.95] | 0.7069 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 31 (48.4%) | 24.80 [4.63;NYR] | 65 | 22 (33.8%) | NYR [NYR;NYR] | 1.41 [0.82;2.44] | 0.2111 | 0.3282 |
| Yes | 10 | 2 (20.0%) | NYR [0.49;NYR] | 6 | 2 (33.3%) | NYR [0.62;NYR] | 0.56 [0.08;4.00] | 0.5586 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 4 (36.4%) | NYR [2.33;NYR] | 10 | 4 (40.0%) | NYR [0.69;NYR] | 0.67 [0.17;2.69] | 0.5689 | 0.5474 |
| < 1% | 61 | 29 (47.5%) | 24.80 [4.24;NYR] | 60 | 19 (31.7%) | NYR [NYR;NYR] | 1.55 [0.87;2.77] | 0.1326 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 9 (50.0%) | 8.74 [1.84;NYR] | 20 | 8 (40.0%) | NYR [3.71;NYR] | 1.35 [0.52;3.51] | 0.5284 | 0.9610 |
| Non-Stage IV | 53 | 23 (43.4%) | NYR [6.01;NYR] | 51 | 16 (31.4%) | NYR [NYR;NYR] | 1.29 [0.68;2.45] | 0.4302 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.79.1: TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 9 (12.2%) | 5 (7.0%) |
| Number of censored cases | N | 65 (87.8%) | 66 (93.0%) |
| Time to first event (Months) | Mean (SE) | 9.91 (0.31) | 23.13 (0.69) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [24.41;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.3794 | |
| Stratified Cox PH model | HR (b) | 1.63 [0.54;4.87] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:12:15

TABLE 3.79.2: TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 1.63 [0.54;4.87] | 0.3794 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [24.41;NYR] | 1.60 [0.38;6.75] | 0.5172 | 0.8530 |
| >= 65 | 33 | 4 (12.1%) | NYR [NYR;NYR] | 24 | 2 (8.3%) | NYR [NYR;NYR] | 1.44 [0.26;7.86] | 0.6702 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [24.41;NYR] | 1.60 [0.38;6.75] | 0.5172 | 0.9862 |
| >= 65 AND < 75 | 25 | 4 (16.0%) | NYR [NYR;NYR] | 18 | 2 (11.1%) | NYR [NYR;NYR] | 1.43 [0.26;7.83] | 0.6728 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NYR [NYR;NYR] | 37 | 4 (10.8%) | NYR [NYR;NYR] | 1.02 [0.27;3.82] | 0.9733 | 0.2924 |
| Rest of World (ROW) | 35 | 4 (11.4%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | NYR [24.41;NYR] | 3.95 [0.44;35.39] | 0.1839 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:12:15

TABLE 3.79.2: TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)


| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 9 (13.8%) | NYR [NYR;NYR] | 60 | 5 (8.3%) | NYR [24.41;NYR] | 1.53 [0.51;4.58] | 0.4414 | 0.9999 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 1 (7.7%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.4631 | 0.8292 |
| Not Hispanic or Latino | 43 | 6 (14.0%) | NYR [NYR;NYR] | 32 | 3 (9.4%) | NYR [NYR;NYR] | 1.42 [0.35;5.67] | 0.6208 | |
| Not Reported | 24 | 3 (12.5%) | NYR [NYR;NYR] | 26 | 1 (3.8%) | NYR [24.41;NYR] | 2.93 [0.30;28.23] | 0.3294 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 7 (12.5%) | NYR [NYR;NYR] | 48 | 2 (4.2%) | NYR [NYR;NYR] | 2.94 [0.61;14.15] | 0.1582 | 0.2806 |
| Female | 18 | 2 (11.1%) | NYR [NYR;NYR] | 23 | 3 (13.0%) | NYR [24.41;NYR] | 0.83 [0.14;4.95] | 0.8320 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | 1.04 [0.07;16.65] | 0.9774 | 0.8513 |
| >= 1 Year | 60 | 8 (13.3%) | NYR [NYR;NYR] | 50 | 4 (8.0%) | NYR [24.41;NYR] | 1.58 [0.48;5.26] | 0.4484 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:12:15

TABLE 3.79.2: TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)


| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [8.97;NYR] | 12 | 1 (8.3%) | NYR [10.02;NYR] | 0.74 [0.05;11.81] | 0.8292 | 0.6963 |
| Yes | 63 | 8 (12.7%) | NYR [NYR;NYR] | 59 | 4 (6.8%) | NYR [NYR;NYR] | 1.77 [0.53;5.87] | 0.3466 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 8 (12.5%) | NYR [NYR;NYR] | 65 | 4 (6.2%) | NYR [NYR;NYR] | 1.83 [0.55;6.11] | 0.3148 | 0.4456 |
| Yes | 10 | 1 (10.0%) | NYR [1.64;NYR] | 6 | 1 (16.7%) | NYR [1.58;NYR] | 0.55 [0.03;8.78] | 0.6660 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 9 (14.8%) | NYR [NYR;NYR] | 60 | 5 (8.3%) | NYR [24.41;NYR] | 1.64 [0.55;4.90] | 0.3712 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 3 (16.7%) | NYR [NYR;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | 2.84 [0.29;27.34] | 0.3454 | 0.5293 |
| Non-Stage IV | 53 | 6 (11.3%) | NYR [NYR;NYR] | 51 | 4 (7.8%) | NYR [24.41;NYR] | 1.36 [0.38;4.84] | 0.6299 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.80.1: TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 9 (12.2%) | 5 (7.0%) |
| Number of censored cases | N | 65 (87.8%) | 66 (93.0%) |
| Time to first event (Months) | Mean (SE) | 9.91 (0.31) | 23.17 (0.68) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [24.41;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.3333 | |
| Stratified Cox PH model | HR (b) | 1.71 [0.57;5.10] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:19:15

TABLE 3.80.2: TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 1.71 [0.57;5.10] | 0.3333 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [24.41;NYR] | 1.70 [0.40;7.17] | 0.4650 | 0.8301 |
| >= 65 | 33 | 4 (12.1%) | NYR [NYR;NYR] | 24 | 2 (8.3%) | NYR [NYR;NYR] | 1.45 [0.27;7.92] | 0.6636 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 3 (6.4%) | NYR [24.41;NYR] | 1.70 [0.40;7.17] | 0.4650 | 0.9790 |
| >= 65 AND < 75 | 25 | 4 (16.0%) | NYR [NYR;NYR] | 18 | 2 (11.1%) | NYR [NYR;NYR] | 1.43 [0.26;7.83] | 0.6728 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NYR [NYR;NYR] | 37 | 4 (10.8%) | NYR [NYR;NYR] | 1.08 [0.29;4.02] | 0.9116 | 0.2889 |
| Rest of World (ROW) | 35 | 4 (11.4%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | NYR [24.41;NYR] | 4.05 [0.45;36.24] | 0.1752 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.80.2: TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 9 (13.8%) | NYR [NYR;NYR] | 60 | 5 (8.3%) | NYR [24.41;NYR] | 1.58 [0.53;4.74] | 0.4064 | 0.9999 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 1 (7.7%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.4631 | 0.8271 |
| Not Hispanic or Latino | 43 | 6 (14.0%) | NYR [NYR;NYR] | 32 | 3 (9.4%) | NYR [NYR;NYR] | 1.46 [0.36;5.82] | 0.5918 | |
| Not Reported | 24 | 3 (12.5%) | NYR [NYR;NYR] | 26 | 1 (3.8%) | NYR [24.41;NYR] | 2.99 [0.31;28.84] | 0.3196 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 7 (12.5%) | NYR [NYR;NYR] | 48 | 2 (4.2%) | NYR [NYR;NYR] | 3.06 [0.63;14.71] | 0.1420 | 0.2910 |
| Female | 18 | 2 (11.1%) | NYR [NYR;NYR] | 23 | 3 (13.0%) | NYR [24.41;NYR] | 0.86 [0.14;5.15] | 0.8658 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | 1.16 [0.07;18.55] | 0.9162 | 0.8519 |
| >= 1 Year | 60 | 8 (13.3%) | NYR [NYR;NYR] | 50 | 4 (8.0%) | NYR [24.41;NYR] | 1.62 [0.49;5.37] | 0.4287 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.80.2: TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [8.97;NYR] | 12 | 1 (8.3%) | NYR [10.02;NYR] | 0.79 [0.05;12.61] | 0.8665 | 0.6906 |
| Yes | 63 | 8 (12.7%) | NYR [NYR;NYR] | 59 | 4 (6.8%) | NYR [NYR;NYR] | 1.80 [0.54;6.00] | 0.3298 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 8 (12.5%) | NYR [NYR;NYR] | 65 | 4 (6.2%) | NYR [NYR;NYR] | 1.91 [0.57;6.35] | 0.2829 | 0.4238 |
| Yes | 10 | 1 (10.0%) | NYR [1.64;NYR] | 6 | 1 (16.7%) | NYR [1.58;NYR] | 0.55 [0.03;8.78] | 0.6660 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 9 (14.8%) | NYR [NYR;NYR] | 60 | 5 (8.3%) | NYR [24.41;NYR] | 1.71 [0.57;5.10] | 0.3328 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 3 (16.7%) | NYR [NYR;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | 2.99 [0.31;28.76] | 0.3190 | 0.5371 |
| Non-Stage IV | 53 | 6 (11.3%) | NYR [NYR;NYR] | 51 | 4 (7.8%) | NYR [24.41;NYR] | 1.38 [0.39;4.90] | 0.6183 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.81.1: TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 2 (2.8%) |
| Number of censored cases | N | 72 (97.3%) | 69 (97.2%) |
| Time to first event (Months) | Mean (SE) | 1.84 (0.01) | 2.34 (0.04) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.9605 | |
| Stratified Cox PH model | HR (b) | 0.95 [0.13;6.76] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.81.2: TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.95 [0.13;6.76] | 0.9605 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.12 [0.07;17.94] | 0.9353 | 0.8289 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 0.72 [0.05;11.56] | 0.8178 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.12 [0.07;17.94] | 0.9353 | 0.9773 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 1 (5.6%) | NYR [NYR;NYR] | 0.73 [0.05;11.75] | 0.8269 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 0.94 [0.06;14.96] | 0.9626 | 0.9879 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | NYR [NYR;NYR] | 0.96 [0.06;15.29] | 0.9750 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.81.2: TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 0.90 [0.13;6.41] | 0.9183 | 1.0000 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 1 (7.7%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.4631 | 1.0000 |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 1.47 [0.13;16.20] | 0.7522 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1884 | 0.9967 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 2 (8.7%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.1948 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 2 (4.0%) | NYR [NYR;NYR] | 0.81 [0.11;5.78] | 0.8369 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:26:14

TABLE 3.81.2: TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 2 (3.4%) | NYR [NYR;NYR] | 0.92 [0.13;6.50] | 0.9296 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 2 (3.1%) | NYR [NYR;NYR] | 1.00 [0.14;7.07] | 0.9967 | 1.0000 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 2 (3.3%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 0.96 [0.14;6.83] | 0.9695 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Non-Stage IV | 53 | 2 (3.8%) | NYR [NYR;NYR] | 51 | 2 (3.9%) | NYR [NYR;NYR] | 0.94 [0.13;6.69] | 0.9528 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:26:14

TABLE 3.82.1: TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 2 (2.8%) |
| Number of censored cases | N | 72 (97.3%) | 69 (97.2%) |
| Time to first event (Months) | Mean (SE) | 1.84 (0.01) | 2.34 (0.04) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.9750 | |
| Stratified Cox PH model | HR (b) | 0.97 [0.14;6.88] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:33:11

TABLE 3.82.2: TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.97 [0.14;6.88] | 0.9750 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.13 [0.07;18.14] | 0.9291 | 0.8266 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 0.74 [0.05;11.81] | 0.8297 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.13 [0.07;18.14] | 0.9291 | 0.9755 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 1 (5.6%) | NYR [NYR;NYR] | 0.73 [0.05;11.75] | 0.8269 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 0.94 [0.06;14.96] | 0.9626 | 0.9818 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | NYR [NYR;NYR] | 0.99 [0.06;15.76] | 0.9918 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.82.2: TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 0.92 [0.13;6.52] | 0.9321 | 1.0000 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 1 (7.7%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.4631 | 1.0000 |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 1.47 [0.13;16.20] | 0.7522 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1884 | 0.9965 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 2 (8.7%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.2058 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 2 (4.0%) | NYR [NYR;NYR] | 0.83 [0.12;5.90] | 0.8532 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:33:12

TABLE 3.82.2: TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 2 (3.4%) | NYR [NYR;NYR] | 0.93 [0.13;6.61] | 0.9436 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 2 (3.1%) | NYR [NYR;NYR] | 1.01 [0.14;7.18] | 0.9906 | 1.0000 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 2 (3.3%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 0.98 [0.14;6.95] | 0.9833 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Non-Stage IV | 53 | 2 (3.8%) | NYR [NYR;NYR] | 51 | 2 (3.9%) | NYR [NYR;NYR] | 0.96 [0.14;6.83] | 0.9689 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.83.1: TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 1 (1.4%) |
| Number of censored cases | N | 72 (97.3%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 1.82 (0.03) | 0.46 (.) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.6363 | |
| Stratified Cox PH model | HR (b) | 1.77 [0.16;19.56] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:40:05

TABLE 3.83.2: TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.77 [0.16;19.56] | 0.6363 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.11 [0.07;17.74] | 0.9416 | 0.9955 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3938 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.11 [0.07;17.74] | 0.9416 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 1 (12.5%) | NYR [0.49;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3865 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3300 | 0.9965 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | NYR [NYR;NYR] | 0.94 [0.06;15.07] | 0.9666 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.83.2: TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)


| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1762 | 0.9968 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3657 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [1.84;NYR] | 13 | 1 (7.7%) | NYR [NYR;NYR] | 1.78 [0.11;28.54] | 0.6781 | 1.0000 |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2980 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1884 | 0.9962 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 1 (4.3%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3763 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2440 | 0.9969 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 0.81 [0.05;12.92] | 0.8799 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.83.2: TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2963 | 0.9961 |
| Yes | 63 | 1 (1.6%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 0.93 [0.06;14.84] | 0.9582 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 1.01 [0.06;16.11] | 0.9956 | 0.9966 |
| Yes | 10 | 1 (10.0%) | NYR [1.84;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3404 | 1.0000 |
| < 1% | 61 | 1 (1.6%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 0.96 [0.06;15.33] | 0.9762 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2918 | 0.9962 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 0.95 [0.06;15.23] | 0.9727 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.84.1: TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 1 (1.4%) |
| Number of censored cases | N | 72 (97.3%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 1.82 (0.03) | 0.46 (.) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.6287 | |
| Stratified Cox PH model | HR (b) | 1.79 [0.16;19.81] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:47:03

TABLE 3.84.2: TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.79 [0.16;19.81] | 0.6287 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.13 [0.07;18.14] | 0.9291 | 0.9955 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3938 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.13 [0.07;18.14] | 0.9291 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 1 (12.5%) | NYR [0.49;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3865 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3300 | 0.9965 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | NYR [NYR;NYR] | 0.96 [0.06;15.30] | 0.9752 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.84.2: TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1726 | 0.9969 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3657 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [1.84;NYR] | 13 | 1 (7.7%) | NYR [NYR;NYR] | 1.78 [0.11;28.54] | 0.6781 | 1.0000 |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2980 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1884 | 0.9962 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 1 (4.3%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3763 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2440 | 0.9969 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 0.82 [0.05;13.19] | 0.8916 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.84.2: TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2963 | 0.9961 |
| Yes | 63 | 1 (1.6%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 0.93 [0.06;14.84] | 0.9582 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 1.01 [0.06;16.11] | 0.9956 | 0.9966 |
| Yes | 10 | 1 (10.0%) | NYR [1.84;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3404 | 1.0000 |
| < 1% | 61 | 1 (1.6%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 0.98 [0.06;15.59] | 0.9859 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2918 | 0.9962 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 0.95 [0.06;15.23] | 0.9727 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.85.1: TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:53:57

TABLE 3.85.2: TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.85.2: TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:53:57

TABLE 3.85.2: TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.86.1: TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:00:52

TABLE 3.86.2: TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.86.2: TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.86.2: TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.87.1: TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:07:12

TABLE 3.87.2: TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.87.2: TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:07:12

TABLE 3.87.2: TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.88.1: TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 3.88.2: TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.88.2: TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.88.2: TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.89.1: TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 10 (13.5%) | 7 (9.9%) |
| Number of censored cases | N | 64 (86.5%) | 64 (90.1%) |
| Time to first event (Months) | Mean (SE) | 16.06 (0.62) | 7.41 (0.21) |
| | Q1 [95% CI] | NYR [17.91;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.6026 | |
| Stratified Cox PH model | HR (b) | 1.29 [0.49;3.39] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 3.89.2: TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 1.29 [0.49;3.39] | 0.6026 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 8 (19.5%) | NYR [NYR;NYR] | 47 | 4 (8.5%) | NYR [NYR;NYR] | 2.14 [0.64;7.12] | 0.2049 | 0.1483 |
| >= 65 | 33 | 2 (6.1%) | NYR [NYR;NYR] | 24 | 3 (12.5%) | NYR [NYR;NYR] | 0.42 [0.07;2.55] | 0.3335 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 8 (19.5%) | NYR [NYR;NYR] | 47 | 4 (8.5%) | NYR [NYR;NYR] | 2.14 [0.64;7.12] | 0.2049 | 0.3492 |
| >= 65 AND < 75 | 25 | 2 (8.0%) | NYR [NYR;NYR] | 18 | 3 (16.7%) | NYR [7.89;NYR] | 0.41 [0.07;2.46] | 0.3135 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 3 (7.7%) | NYR [NYR;NYR] | 37 | 2 (5.4%) | NYR [NYR;NYR] | 1.24 [0.21;7.46] | 0.8145 | 0.9824 |
| Rest of World (ROW) | 35 | 7 (20.0%) | NYR [NYR;NYR] | 34 | 5 (14.7%) | NYR [NYR;NYR] | 1.30 [0.41;4.09] | 0.6523 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.89.2: TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)


| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 8 (12.3%) | NYR [NYR;NYR] | 60 | 5 (8.3%) | NYR [NYR;NYR] | 1.42 [0.46;4.34] | 0.5368 | 0.8225 |
| Non-White | 9 | 2 (22.2%) | NYR [3.22;NYR] | 11 | 2 (18.2%) | NYR [4.17;NYR] | 1.08 [0.15;7.73] | 0.9389 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [1.84;NYR] | 13 | 3 (23.1%) | NYR [4.17;NYR] | 0.53 [0.06;5.15] | 0.5882 | 0.5519 |
| Not Hispanic or Latino | 43 | 4 (9.3%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 2.92 [0.33;26.13] | 0.3160 | |
| Not Reported | 24 | 5 (20.8%) | NYR [NYR;NYR] | 26 | 3 (11.5%) | NYR [NYR;NYR] | 1.69 [0.40;7.07] | 0.4682 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 7 (12.5%) | NYR [NYR;NYR] | 48 | 5 (10.4%) | NYR [NYR;NYR] | 1.15 [0.37;3.64] | 0.8088 | 0.6899 |
| Female | 18 | 3 (16.7%) | NYR [17.91;NYR] | 23 | 2 (8.7%) | NYR [NYR;NYR] | 1.80 [0.30;10.78] | 0.5157 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 4 (28.6%) | NYR [11.17;NYR] | 19 | 3 (15.8%) | NYR [NYR;NYR] | 1.60 [0.36;7.19] | 0.5357 | 0.7518 |
| >= 1 Year | 60 | 6 (10.0%) | NYR [NYR;NYR] | 50 | 4 (8.0%) | NYR [NYR;NYR] | 1.21 [0.34;4.29] | 0.7671 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.89.2: TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 5 (45.5%) | NYR [1.84;NYR] | 12 | 2 (16.7%) | NYR [1.38;NYR] | 2.93 [0.57;15.16] | 0.1814 | 0.2495 |
| Yes | 63 | 5 (7.9%) | NYR [NYR;NYR] | 59 | 5 (8.5%) | NYR [NYR;NYR] | 0.84 [0.24;2.91] | 0.7842 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 9 (14.1%) | NYR [NYR;NYR] | 65 | 7 (10.8%) | NYR [NYR;NYR] | 1.20 [0.45;3.23] | 0.7128 | 0.9916 |
| Yes | 10 | 1 (10.0%) | NYR [1.84;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 10 (16.4%) | NYR [NYR;NYR] | 60 | 7 (11.7%) | NYR [NYR;NYR] | 1.32 [0.50;3.48] | 0.5680 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 5 (27.8%) | NYR [11.17;NYR] | 20 | 3 (15.0%) | NYR [NYR;NYR] | 1.66 [0.40;6.96] | 0.4877 | 0.6618 |
| Non-Stage IV | 53 | 5 (9.4%) | NYR [NYR;NYR] | 51 | 4 (7.8%) | NYR [NYR;NYR] | 1.16 [0.31;4.33] | 0.8223 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.90.1: TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 10 (13.5%) | 7 (9.9%) |
| Number of censored cases | N | 64 (86.5%) | 64 (90.1%) |
| Time to first event (Months) | Mean (SE) | 16.08 (0.61) | 7.41 (0.21) |
| | Q1 [95% CI] | NYR [17.91;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.5694 | |
| Stratified Cox PH model | HR (b) | 1.32 [0.50;3.47] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.90.2: TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 1.32 [0.50;3.47] | 0.5694 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 8 (19.5%) | NYR [NYR;NYR] | 47 | 4 (8.5%) | NYR [NYR;NYR] | 2.19 [0.66;7.27] | 0.1911 | 0.1519 |
| >= 65 | 33 | 2 (6.1%) | NYR [NYR;NYR] | 24 | 3 (12.5%) | NYR [NYR;NYR] | 0.46 [0.08;2.76] | 0.3835 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 8 (19.5%) | NYR [NYR;NYR] | 47 | 4 (8.5%) | NYR [NYR;NYR] | 2.19 [0.66;7.27] | 0.1911 | 0.3556 |
| >= 65 AND < 75 | 25 | 2 (8.0%) | NYR [NYR;NYR] | 18 | 3 (16.7%) | NYR [7.89;NYR] | 0.44 [0.07;2.66] | 0.3607 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 3 (7.7%) | NYR [NYR;NYR] | 37 | 2 (5.4%) | NYR [NYR;NYR] | 1.28 [0.21;7.72] | 0.7841 | 0.9695 |
| Rest of World (ROW) | 35 | 7 (20.0%) | NYR [NYR;NYR] | 34 | 5 (14.7%) | NYR [NYR;NYR] | 1.32 [0.42;4.16] | 0.6320 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.90.2: TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 8 (12.3%) | NYR [NYR;NYR] | 60 | 5 (8.3%) | NYR [NYR;NYR] | 1.45 [0.47;4.44] | 0.5115 | 0.8226 |
| Non-White | 9 | 2 (22.2%) | NYR [3.22;NYR] | 11 | 2 (18.2%) | NYR [4.17;NYR] | 1.08 [0.15;7.73] | 0.9389 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [1.84;NYR] | 13 | 3 (23.1%) | NYR [4.17;NYR] | 0.57 [0.06;5.44] | 0.6254 | 0.5493 |
| Not Hispanic or Latino | 43 | 4 (9.3%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 2.85 [0.32;25.60] | 0.3272 | |
| Not Reported | 24 | 5 (20.8%) | NYR [NYR;NYR] | 26 | 3 (11.5%) | NYR [NYR;NYR] | 1.80 [0.43;7.52] | 0.4166 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 7 (12.5%) | NYR [NYR;NYR] | 48 | 5 (10.4%) | NYR [NYR;NYR] | 1.17 [0.37;3.70] | 0.7864 | 0.6667 |
| Female | 18 | 3 (16.7%) | NYR [17.91;NYR] | 23 | 2 (8.7%) | NYR [NYR;NYR] | 1.89 [0.32;11.31] | 0.4794 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 4 (28.6%) | NYR [11.17;NYR] | 19 | 3 (15.8%) | NYR [NYR;NYR] | 1.65 [0.37;7.39] | 0.5098 | 0.7480 |
| >= 1 Year | 60 | 6 (10.0%) | NYR [NYR;NYR] | 50 | 4 (8.0%) | NYR [NYR;NYR] | 1.26 [0.35;4.46] | 0.7219 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.90.2: TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 5 (45.5%) | NYR [1.84;NYR] | 12 | 2 (16.7%) | NYR [1.38;NYR] | 2.93 [0.57;15.16] | 0.1814 | 0.2481 |
| Yes | 63 | 5 (7.9%) | NYR [NYR;NYR] | 59 | 5 (8.5%) | NYR [NYR;NYR] | 0.86 [0.25;2.98] | 0.8115 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 9 (14.1%) | NYR [NYR;NYR] | 65 | 7 (10.8%) | NYR [NYR;NYR] | 1.23 [0.46;3.31] | 0.6777 | 0.9915 |
| Yes | 10 | 1 (10.0%) | NYR [1.84;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 10 (16.4%) | NYR [NYR;NYR] | 60 | 7 (11.7%) | NYR [NYR;NYR] | 1.36 [0.52;3.57] | 0.5341 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 5 (27.8%) | NYR [11.17;NYR] | 20 | 3 (15.0%) | NYR [NYR;NYR] | 1.79 [0.43;7.48] | 0.4253 | 0.6600 |
| Non-Stage IV | 53 | 5 (9.4%) | NYR [NYR;NYR] | 51 | 4 (7.8%) | NYR [NYR;NYR] | 1.21 [0.32;4.51] | 0.7763 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.91.1: TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 1 (1.4%) | 0 (0.0%) |
| Number of censored cases | N | 73 (98.6%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 1.84 (.) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.3320 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:32:07

TABLE 3.91.2: TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3320 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2948 | 0.9993 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2948 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3367 | 0.9993 |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.91.2: TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 1 (1.5%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3449 | 0.9994 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3074 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 1 (1.8%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3545 | 0.9992 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2440 | 0.9994 |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.91.2: TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2963 | 0.9996 |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3211 | 0.9995 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 1 (1.6%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3295 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2918 | 0.9994 |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.92.1: TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 1 (1.4%) | 0 (0.0%) |
| Number of censored cases | N | 73 (98.6%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 1.84 (.) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.3245 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.92.2: TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3245 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2843 | 0.9993 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2843 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3300 | 0.9993 |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.92.2: TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 1 (1.5%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3367 | 0.9994 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2980 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 1 (1.8%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3545 | 0.9992 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2440 | 0.9994 |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.92.2: TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2963 | 0.9994 |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3136 | 0.9995 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 1 (1.6%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3213 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2918 | 0.9994 |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.93.1: TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.93.2: TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.93.2: TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:44:38

TABLE 3.93.2: TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.94.1: TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:50:54

TABLE 3.94.2: TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:50:54

TABLE 3.94.2: TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.94.2: TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.95.1: TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:57:06

TABLE 3.95.2: TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.95.2: TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.95.2: TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.96.1: TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.96.2: TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.96.2: TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.96.2: TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.97.1: TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.97.2: TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.97.2: TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.97.2: TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.98.1: TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 3.98.2: TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.98.2: TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.98.2: TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.99.1: TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOPHYSITIS - Serious AE - | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.99.2: TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.99.2: TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.99.2: TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.100.1: TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:11

TABLE 3.100.2: TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.100.2: TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:11

TABLE 3.100.2: TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:11

TABLE 3.101.1: TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 22 (29.7%) | 25 (35.2%) |
| Number of censored cases | N | 52 (70.3%) | 46 (64.8%) |
| Time to first event (Months) | Mean (SE) | 18.40 (1.03) | 12.94 (0.79) |
| | Q1 [95% CI] | 14.20 [4.34;23.72] | 9.00 [2.56;13.80] |
| | Median [95% CI] | NYR [23.72;NYR] | 17.45 [13.37;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.1381 | |
| Stratified Cox PH model | HR (b) | 0.65 [0.36;1.16] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:34:20

TABLE 3.101.2: TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 22 (29.7%) | NYR [23.72;NYR] | 71 | 25 (35.2%) | 17.45 [13.37;NYR] | 0.65 [0.36;1.16] | 0.1381 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 16 (39.0%) | NYR [11.73;NYR] | 47 | 16 (34.0%) | 17.45 [13.37;NYR] | 0.91 [0.45;1.84] | 0.7925 | 0.0614 |
| >= 65 | 33 | 6 (18.2%) | NYR [19.91;NYR] | 24 | 9 (37.5%) | 13.80 [4.80;NYR] | 0.32 [0.11;0.91] | 0.0245 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 16 (39.0%) | NYR [11.73;NYR] | 47 | 16 (34.0%) | 17.45 [13.37;NYR] | 0.91 [0.45;1.84] | 0.7925 | 0.0341 |
| >= 65 AND < 75 | 25 | 3 (12.0%) | NYR [NYR;NYR] | 18 | 8 (44.4%) | 13.80 [2.14;NYR] | 0.16 [0.04;0.63] | 0.0029 | |
| >= 75 | 8 | 3 (37.5%) | 19.91 [0.95;NYR] | 6 | 1 (16.7%) | NYR [5.32;NYR] | 1.78 [0.18;17.93] | 0.6219 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 7 (17.9%) | NYR [NYR;NYR] | 37 | 8 (21.6%) | NYR [14.00;NYR] | 0.60 [0.21;1.67] | 0.3225 | 0.8833 |
| Rest of World (ROW) | 35 | 15 (42.9%) | 23.72 [10.64;NYR] | 34 | 17 (50.0%) | 12.45 [6.14;NYR] | 0.65 [0.32;1.30] | 0.2172 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:34:20

TABLE 3.101.2: TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 20 (30.8%) | NYR [23.72;NYR] | 60 | 20 (33.3%) | 17.45 [13.80;NYR] | 0.70 [0.37;1.30] | 0.2537 | 0.3648 |
| Non-White | 9 | 2 (22.2%) | NYR [0.95;NYR] | 11 | 5 (45.5%) | 13.37 [0.72;NYR] | 0.35 [0.07;1.84] | 0.1966 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 3 (42.9%) | NYR [1.38;NYR] | 13 | 5 (38.5%) | 16.56 [2.30;16.56] | 0.80 [0.19;3.41] | 0.7643 | 0.7485 |
| Not Hispanic or Latino | 43 | 11 (25.6%) | NYR [17.31;NYR] | 32 | 8 (25.0%) | NYR [13.80;NYR] | 0.88 [0.35;2.19] | 0.7785 | |
| Not Reported | 24 | 8 (33.3%) | NYR [19.91;NYR] | 26 | 12 (46.2%) | 14.00 [9.69;NYR] | 0.51 [0.21;1.26] | 0.1382 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 15 (26.8%) | NYR [23.72;NYR] | 48 | 16 (33.3%) | 17.45 [13.37;NYR] | 0.63 [0.31;1.29] | 0.1989 | 0.8808 |
| Female | 18 | 7 (38.9%) | 19.91 [10.64;NYR] | 23 | 9 (39.1%) | 14.03 [6.14;NYR] | 0.68 [0.25;1.83] | 0.4483 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 6 (42.9%) | 16.76 [4.21;NYR] | 19 | 7 (36.8%) | NYR [4.80;NYR] | 0.94 [0.31;2.80] | 0.9080 | 0.4610 |
| >= 1 Year | 60 | 16 (26.7%) | NYR [23.72;NYR] | 50 | 18 (36.0%) | 16.56 [13.37;NYR] | 0.53 [0.27;1.04] | 0.0606 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.101.2: TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 6 (54.5%) | 10.64 [1.81;NYR] | 12 | 3 (25.0%) | NYR [4.17;NYR] | 2.14 [0.53;8.66] | 0.2738 | 0.0695 |
| Yes | 63 | 16 (25.4%) | NYR [23.72;NYR] | 59 | 22 (37.3%) | 16.56 [13.37;NYR] | 0.47 [0.25;0.91] | 0.0219 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 19 (29.7%) | NYR [19.91;NYR] | 65 | 23 (35.4%) | 17.45 [13.37;NYR] | 0.60 [0.33;1.11] | 0.1004 | 0.9622 |
| Yes | 10 | 3 (30.0%) | NYR [1.38;NYR] | 6 | 2 (33.3%) | NYR [0.69;NYR] | 0.79 [0.13;4.74] | 0.7723 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [4.21;NYR] | 10 | 7 (70.0%) | 6.14 [0.69;17.45] | 0.16 [0.03;0.77] | 0.0100 | 0.1056 |
| < 1% | 61 | 19 (31.1%) | NYR [19.91;NYR] | 60 | 18 (30.0%) | NYR [13.37;NYR] | 0.81 [0.42;1.54] | 0.5129 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 7 (38.9%) | NYR [4.21;NYR] | 20 | 6 (30.0%) | NYR [6.14;NYR] | 1.33 [0.45;3.96] | 0.6096 | 0.1687 |
| Non-Stage IV | 53 | 15 (28.3%) | NYR [23.72;NYR] | 51 | 19 (37.3%) | 16.56 [12.45;NYR] | 0.50 [0.25;0.99] | 0.0439 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.102.1: TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 22 (29.7%) | 25 (35.2%) |
| Number of censored cases | N | 52 (70.3%) | 46 (64.8%) |
| Time to first event (Months) | Mean (SE) | 18.54 (1.01) | 13.18 (0.76) |
| | Q1 [95% CI] | 14.20 [4.34;23.72] | 9.60 [4.17;13.80] |
| | Median [95% CI] | NYR [23.72;NYR] | NYR [13.80;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.1835 | |
| Stratified Cox PH model | HR (b) | 0.68 [0.38;1.21] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:40:33

TABLE 3.102.2: TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 22 (29.7%) | NYR [23.72;NYR] | 71 | 25 (35.2%) | NYR [13.80;NYR] | 0.68 [0.38;1.21] | 0.1835 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 16 (39.0%) | NYR [16.76;NYR] | 47 | 16 (34.0%) | NYR [13.37;NYR] | 0.96 [0.48;1.94] | 0.9134 | 0.0704 |
| >= 65 | 33 | 6 (18.2%) | NYR [19.91;NYR] | 24 | 9 (37.5%) | NYR [4.80;NYR] | 0.35 [0.12;0.99] | 0.0395 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 16 (39.0%) | NYR [16.76;NYR] | 47 | 16 (34.0%) | NYR [13.37;NYR] | 0.96 [0.48;1.94] | 0.9134 | 0.0380 |
| >= 65 AND < 75 | 25 | 3 (12.0%) | NYR [NYR;NYR] | 18 | 8 (44.4%) | 13.80 [2.14;NYR] | 0.20 [0.05;0.75] | 0.0087 | |
| >= 75 | 8 | 3 (37.5%) | 19.91 [0.95;NYR] | 6 | 1 (16.7%) | NYR [5.32;NYR] | 1.68 [0.17;16.77] | 0.6562 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 7 (17.9%) | NYR [NYR;NYR] | 37 | 8 (21.6%) | NYR [17.45;NYR] | 0.64 [0.23;1.78] | 0.3863 | 0.9331 |
| Rest of World (ROW) | 35 | 15 (42.9%) | 23.72 [10.64;NYR] | 34 | 17 (50.0%) | 13.37 [8.28;NYR] | 0.66 [0.33;1.34] | 0.2482 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:40:33

TABLE 3.102.2: TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 20 (30.8%) | NYR [23.72;NYR] | 60 | 20 (33.3%) | NYR [14.00;NYR] | 0.74 [0.39;1.38] | 0.3394 | 0.3394 |
| Non-White | 9 | 2 (22.2%) | NYR [0.95;NYR] | 11 | 5 (45.5%) | 13.37 [0.72;NYR] | 0.35 [0.07;1.83] | 0.1929 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 3 (42.9%) | NYR [1.38;NYR] | 13 | 5 (38.5%) | 16.56 [2.30;16.56] | 0.88 [0.21;3.72] | 0.8568 | 0.7499 |
| Not Hispanic or Latino | 43 | 11 (25.6%) | NYR [NYR;NYR] | 32 | 8 (25.0%) | NYR [13.80;NYR] | 0.88 [0.35;2.19] | 0.7758 | |
| Not Reported | 24 | 8 (33.3%) | NYR [19.91;NYR] | 26 | 12 (46.2%) | 14.03 [9.69;NYR] | 0.52 [0.21;1.29] | 0.1523 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 15 (26.8%) | NYR [23.72;NYR] | 48 | 16 (33.3%) | NYR [13.80;NYR] | 0.66 [0.32;1.35] | 0.2508 | 0.8991 |
| Female | 18 | 7 (38.9%) | 19.91 [10.64;NYR] | 23 | 9 (39.1%) | 14.03 [6.14;NYR] | 0.68 [0.25;1.86] | 0.4635 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 6 (42.9%) | NYR [4.21;NYR] | 19 | 7 (36.8%) | NYR [4.80;NYR] | 0.97 [0.32;2.88] | 0.9500 | 0.4560 |
| >= 1 Year | 60 | 16 (26.7%) | NYR [23.72;NYR] | 50 | 18 (36.0%) | 16.56 [13.37;NYR] | 0.54 [0.27;1.08] | 0.0756 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.102.2: TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 6 (54.5%) | 10.64 [1.81;NYR] | 12 | 3 (25.0%) | NYR [4.17;NYR] | 2.34 [0.58;9.43] | 0.2170 | 0.0734 |
| Yes | 63 | 16 (25.4%) | NYR [23.72;NYR] | 59 | 22 (37.3%) | 17.45 [13.37;NYR] | 0.50 [0.26;0.95] | 0.0315 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 19 (29.7%) | NYR [23.72;NYR] | 65 | 23 (35.4%) | 17.45 [13.80;NYR] | 0.63 [0.34;1.16] | 0.1361 | 0.9249 |
| Yes | 10 | 3 (30.0%) | NYR [1.38;NYR] | 6 | 2 (33.3%) | NYR [0.69;NYR] | 0.83 [0.14;4.98] | 0.8192 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [4.21;NYR] | 10 | 7 (70.0%) | 6.14 [0.69;17.45] | 0.16 [0.03;0.80] | 0.0113 | 0.0941 |
| < 1% | 61 | 19 (31.1%) | NYR [19.91;NYR] | 60 | 18 (30.0%) | NYR [13.80;NYR] | 0.85 [0.45;1.64] | 0.6360 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 7 (38.9%) | NYR [4.21;NYR] | 20 | 6 (30.0%) | NYR [8.28;NYR] | 1.33 [0.45;3.98] | 0.6034 | 0.1917 |
| Non-Stage IV | 53 | 15 (28.3%) | NYR [23.72;NYR] | 51 | 19 (37.3%) | 16.56 [12.45;NYR] | 0.53 [0.26;1.05] | 0.0640 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:40:33

TABLE 3.103.1: TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.103.2: TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.103.2: TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.103.2: TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.104.1: TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.104.2: TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.104.2: TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:52:59

TABLE 3.104.2: TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.105.1: TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:59:11

TABLE 3.105.2: TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.105.2: TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:59:11

TABLE 3.105.2: TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.106.1: TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:05:23

TABLE 3.106.2: TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.106.2: TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:05:23

TABLE 3.106.2: TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.107.1: TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 0 (0.0%) |
| Number of censored cases | N | 72 (97.3%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 2.74 (0.03) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.1609 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:11:39

TABLE 3.107.2: TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1609 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1315 | 0.9990 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1315 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9991 |
| Rest of World (ROW) | 35 | 2 (5.7%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1634 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:11:39

TABLE 3.107.2: TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1805 | 0.9991 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2255 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1890 | 0.9989 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2440 | 0.9999 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3784 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:11:39

TABLE 3.107.2: TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9991 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1774 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3136 | 0.9999 |
| Yes | 10 | 1 (10.0%) | NYR [2.76;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4795 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3404 | 1.0000 |
| < 1% | 61 | 1 (1.6%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3213 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2918 | 0.9999 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3469 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.108.1: TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 0 (0.0%) |
| Number of censored cases | N | 72 (97.3%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 2.74 (0.03) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.1609 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:17:50

TABLE 3.108.2: TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1609 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1297 | 0.9990 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1297 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9991 |
| Rest of World (ROW) | 35 | 2 (5.7%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1603 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.108.2: TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1744 | 0.9991 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2234 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1908 | 0.9989 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2440 | 0.9999 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3613 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:17:50

TABLE 3.108.2: TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9991 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1712 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3136 | 0.9999 |
| Yes | 10 | 1 (10.0%) | NYR [2.76;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3404 | 1.0000 |
| < 1% | 61 | 1 (1.6%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3213 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2918 | 0.9999 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3266 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.109.1: TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:04

TABLE 3.109.2: TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.109.2: TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:04

TABLE 3.109.2: TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)


| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.110.1: TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:30:14

TABLE 3.110.2: TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.110.2: TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:30:15

TABLE 3.110.2: TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:30:15

TABLE 3.111.1: TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:36:31

TABLE 3.111.2: TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:36:31

TABLE 3.111.2: TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)


| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:36:31

TABLE 3.111.2: TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:36:31

TABLE 3.112.1: TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:42:45

TABLE 3.112.2: TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:42:45

TABLE 3.112.2: TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:42:45

TABLE 3.112.2: TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:42:45

TABLE 3.113.1: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 22 (29.7%) | 25 (35.2%) |
| Number of censored cases | N | 52 (70.3%) | 46 (64.8%) |
| Time to first event (Months) | Mean (SE) | 18.38 (1.04) | 12.94 (0.79) |
| | Q1 [95% CI] | 14.20 [4.34;23.72] | 9.00 [2.56;13.80] |
| | Median [95% CI] | NYR [23.72;NYR] | 17.45 [13.37;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.1406 | |
| Stratified Cox PH model | HR (b) | 0.65 [0.36;1.16] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:46:18

TABLE 3.113.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 22 (29.7%) | NYR [23.72;NYR] | 71 | 25 (35.2%) | 17.45 [13.37;NYR] | 0.65 [0.36;1.16] | 0.1406 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 16 (39.0%) | NYR [11.73;NYR] | 47 | 16 (34.0%) | 17.45 [13.37;NYR] | 0.92 [0.45;1.85] | 0.8007 | 0.0623 |
| >= 65 | 33 | 6 (18.2%) | NYR [19.91;NYR] | 24 | 9 (37.5%) | 13.80 [4.80;NYR] | 0.32 [0.11;0.91] | 0.0245 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 16 (39.0%) | NYR [11.73;NYR] | 47 | 16 (34.0%) | 17.45 [13.37;NYR] | 0.92 [0.45;1.85] | 0.8007 | 0.0351 |
| >= 65 AND < 75 | 25 | 3 (12.0%) | NYR [NYR;NYR] | 18 | 8 (44.4%) | 13.80 [2.14;NYR] | 0.16 [0.04;0.63] | 0.0029 | |
| >= 75 | 8 | 3 (37.5%) | 19.91 [0.95;NYR] | 6 | 1 (16.7%) | NYR [5.32;NYR] | 1.78 [0.18;17.93] | 0.6219 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 7 (17.9%) | NYR [NYR;NYR] | 37 | 8 (21.6%) | NYR [14.00;NYR] | 0.60 [0.21;1.67] | 0.3225 | 0.8777 |
| Rest of World (ROW) | 35 | 15 (42.9%) | 23.72 [10.64;NYR] | 34 | 17 (50.0%) | 12.45 [6.14;NYR] | 0.65 [0.32;1.31] | 0.2210 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.113.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 20 (30.8%) | NYR [23.72;NYR] | 60 | 20 (33.3%) | 17.45 [13.80;NYR] | 0.70 [0.37;1.31] | 0.2602 | 0.3629 |
| Non-White | 9 | 2 (22.2%) | NYR [0.95;NYR] | 11 | 5 (45.5%) | 13.37 [0.72;NYR] | 0.35 [0.07;1.84] | 0.1966 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 3 (42.9%) | NYR [1.38;NYR] | 13 | 5 (38.5%) | 16.56 [2.30;16.56] | 0.80 [0.19;3.41] | 0.7643 | 0.7474 |
| Not Hispanic or Latino | 43 | 11 (25.6%) | NYR [17.31;NYR] | 32 | 8 (25.0%) | NYR [13.80;NYR] | 0.88 [0.35;2.21] | 0.7847 | |
| Not Reported | 24 | 8 (33.3%) | NYR [19.91;NYR] | 26 | 12 (46.2%) | 14.00 [9.69;NYR] | 0.51 [0.21;1.26] | 0.1382 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 15 (26.8%) | NYR [23.72;NYR] | 48 | 16 (33.3%) | 17.45 [13.37;NYR] | 0.63 [0.31;1.29] | 0.2030 | 0.8785 |
| Female | 18 | 7 (38.9%) | 19.91 [10.64;NYR] | 23 | 9 (39.1%) | 14.03 [6.14;NYR] | 0.68 [0.25;1.83] | 0.4483 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 6 (42.9%) | 16.76 [4.21;NYR] | 19 | 7 (36.8%) | NYR [4.80;NYR] | 0.96 [0.32;2.86] | 0.9380 | 0.4452 |
| >= 1 Year | 60 | 16 (26.7%) | NYR [23.72;NYR] | 50 | 18 (36.0%) | 16.56 [13.37;NYR] | 0.53 [0.27;1.04] | 0.0606 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.113.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 6 (54.5%) | 10.64 [1.81;NYR] | 12 | 3 (25.0%) | NYR [4.17;NYR] | 2.14 [0.53;8.66] | 0.2738 | 0.0710 |
| Yes | 63 | 16 (25.4%) | NYR [23.72;NYR] | 59 | 22 (37.3%) | 16.56 [13.37;NYR] | 0.48 [0.25;0.91] | 0.0229 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 19 (29.7%) | NYR [19.91;NYR] | 65 | 23 (35.4%) | 17.45 [13.37;NYR] | 0.60 [0.33;1.12] | 0.1041 | 0.9660 |
| Yes | 10 | 3 (30.0%) | NYR [1.38;NYR] | 6 | 2 (33.3%) | NYR [0.69;NYR] | 0.79 [0.13;4.74] | 0.7723 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [4.21;NYR] | 10 | 7 (70.0%) | 6.14 [0.69;17.45] | 0.16 [0.03;0.77] | 0.0100 | 0.1059 |
| < 1% | 61 | 19 (31.1%) | NYR [19.91;NYR] | 60 | 18 (30.0%) | NYR [13.37;NYR] | 0.81 [0.42;1.55] | 0.5236 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 7 (38.9%) | NYR [4.21;NYR] | 20 | 6 (30.0%) | NYR [6.14;NYR] | 1.34 [0.45;3.99] | 0.6053 | 0.1646 |
| Non-Stage IV | 53 | 15 (28.3%) | NYR [23.72;NYR] | 51 | 19 (37.3%) | 16.56 [12.45;NYR] | 0.50 [0.25;0.99] | 0.0439 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:46:18

TABLE 3.114.1: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 22 (29.7%) | 25 (35.2%) |
| Number of censored cases | N | 52 (70.3%) | 46 (64.8%) |
| Time to first event (Months) | Mean (SE) | 18.51 (1.02) | 13.18 (0.76) |
| | Q1 [95% CI] | 14.20 [4.34;23.72] | 9.60 [4.17;13.80] |
| | Median [95% CI] | NYR [23.72;NYR] | NYR [13.80;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.1875 | |
| Stratified Cox PH model | HR (b) | 0.68 [0.38;1.21] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:53:36

TABLE 3.114.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 22 (29.7%) | NYR [23.72;NYR] | 71 | 25 (35.2%) | NYR [13.80;NYR] | 0.68 [0.38;1.21] | 0.1875 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 16 (39.0%) | NYR [16.76;NYR] | 47 | 16 (34.0%) | NYR [13.37;NYR] | 0.97 [0.48;1.95] | 0.9238 | 0.0691 |
| >= 65 | 33 | 6 (18.2%) | NYR [19.91;NYR] | 24 | 9 (37.5%) | NYR [4.80;NYR] | 0.35 [0.12;0.99] | 0.0395 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 16 (39.0%) | NYR [16.76;NYR] | 47 | 16 (34.0%) | NYR [13.37;NYR] | 0.97 [0.48;1.95] | 0.9238 | 0.0376 |
| >= 65 AND < 75 | 25 | 3 (12.0%) | NYR [NYR;NYR] | 18 | 8 (44.4%) | 13.80 [2.14;NYR] | 0.20 [0.05;0.75] | 0.0087 | |
| >= 75 | 8 | 3 (37.5%) | 19.91 [0.95;NYR] | 6 | 1 (16.7%) | NYR [5.32;NYR] | 1.68 [0.17;16.77] | 0.6562 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 7 (17.9%) | NYR [NYR;NYR] | 37 | 8 (21.6%) | NYR [17.45;NYR] | 0.64 [0.23;1.78] | 0.3863 | 0.9232 |
| Rest of World (ROW) | 35 | 15 (42.9%) | 23.72 [10.64;NYR] | 34 | 17 (50.0%) | 13.37 [8.28;NYR] | 0.67 [0.33;1.35] | 0.2535 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.114.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 20 (30.8%) | NYR [23.72;NYR] | 60 | 20 (33.3%) | NYR [14.00;NYR] | 0.74 [0.40;1.39] | 0.3440 | 0.3388 |
| Non-White | 9 | 2 (22.2%) | NYR [0.95;NYR] | 11 | 5 (45.5%) | 13.37 [0.72;NYR] | 0.35 [0.07;1.83] | 0.1929 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 3 (42.9%) | NYR [1.38;NYR] | 13 | 5 (38.5%) | 16.56 [2.30;16.56] | 0.88 [0.21;3.72] | 0.8568 | 0.7484 |
| Not Hispanic or Latino | 43 | 11 (25.6%) | NYR [NYR;NYR] | 32 | 8 (25.0%) | NYR [13.80;NYR] | 0.88 [0.35;2.21] | 0.7862 | |
| Not Reported | 24 | 8 (33.3%) | NYR [19.91;NYR] | 26 | 12 (46.2%) | 14.03 [9.69;NYR] | 0.52 [0.21;1.29] | 0.1523 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 15 (26.8%) | NYR [23.72;NYR] | 48 | 16 (33.3%) | NYR [13.80;NYR] | 0.66 [0.32;1.36] | 0.2550 | 0.9021 |
| Female | 18 | 7 (38.9%) | 19.91 [10.64;NYR] | 23 | 9 (39.1%) | 14.03 [6.14;NYR] | 0.68 [0.25;1.86] | 0.4635 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 6 (42.9%) | NYR [4.21;NYR] | 19 | 7 (36.8%) | NYR [4.80;NYR] | 0.99 [0.33;2.94] | 0.9801 | 0.4386 |
| >= 1 Year | 60 | 16 (26.7%) | NYR [23.72;NYR] | 50 | 18 (36.0%) | 16.56 [13.37;NYR] | 0.54 [0.27;1.08] | 0.0756 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.114.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 6 (54.5%) | 10.64 [1.81;NYR] | 12 | 3 (25.0%) | NYR [4.17;NYR] | 2.34 [0.58;9.43] | 0.2170 | 0.0745 |
| Yes | 63 | 16 (25.4%) | NYR [23.72;NYR] | 59 | 22 (37.3%) | 17.45 [13.37;NYR] | 0.50 [0.26;0.95] | 0.0322 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 19 (29.7%) | NYR [23.72;NYR] | 65 | 23 (35.4%) | 17.45 [13.80;NYR] | 0.63 [0.34;1.17] | 0.1390 | 0.9280 |
| Yes | 10 | 3 (30.0%) | NYR [1.38;NYR] | 6 | 2 (33.3%) | NYR [0.69;NYR] | 0.83 [0.14;4.98] | 0.8192 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [4.21;NYR] | 10 | 7 (70.0%) | 6.14 [0.69;17.45] | 0.16 [0.03;0.80] | 0.0113 | 0.0949 |
| < 1% | 61 | 19 (31.1%) | NYR [19.91;NYR] | 60 | 18 (30.0%) | NYR [13.80;NYR] | 0.86 [0.45;1.64] | 0.6425 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 7 (38.9%) | NYR [4.34;NYR] | 20 | 6 (30.0%) | NYR [8.28;NYR] | 1.35 [0.45;4.03] | 0.5924 | 0.1852 |
| Non-Stage IV | 53 | 15 (28.3%) | NYR [23.72;NYR] | 51 | 19 (37.3%) | 16.56 [12.45;NYR] | 0.53 [0.26;1.05] | 0.0640 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.115.1: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:00:57

TABLE 3.115.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:00:57

TABLE 3.115.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:00:57

TABLE 3.115.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:00:58

TABLE 3.116.1: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:08:17

TABLE 3.116.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:08:17

TABLE 3.116.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:08:17

TABLE 3.116.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.117.1: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:15:44

TABLE 3.117.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:15:44

TABLE 3.117.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:15:45

TABLE 3.117.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.118.1: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 0 (0.0%) | 0 (0.0%) |
| Number of censored cases | N | 74 (100.0%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | . | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | | |
| Stratified Cox PH model | HR (b) | NE [NE;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:23:07

TABLE 3.118.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 0 (0.0%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 0 (0.0%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:23:08

TABLE 3.118.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Not Hispanic or Latino | 43 | 0 (0.0%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 0 (0.0%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| >= 1 Year | 60 | 0 (0.0%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.118.2: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 63 | 0 (0.0%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.119.1: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 15 (20.3%) | 14 (19.7%) |
| Number of censored cases | N | 59 (79.7%) | 57 (80.3%) |
| Time to first event (Months) | Mean (SE) | 16.12 (0.70) | 20.56 (0.99) |
| | Q1 [95% CI] | NYR [9.95;NYR] | 21.20 [10.38;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [24.41;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.8557 | |
| Stratified Cox PH model | HR (b) | 0.94 [0.45;1.94] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:30:31

TABLE 3.119.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 15 (20.3%) | NYR [NYR;NYR] | 71 | 14 (19.7%) | NYR [24.41;NYR] | 0.94 [0.45;1.94] | 0.8557 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 11 (26.8%) | NYR [NYR;NYR] | 47 | 7 (14.9%) | NYR [24.41;NYR] | 1.72 [0.66;4.45] | 0.2589 | 0.0413 |
| >= 65 | 33 | 4 (12.1%) | NYR [18.76;NYR] | 24 | 7 (29.2%) | 21.16 [7.23;NYR] | 0.33 [0.10;1.14] | 0.0664 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 11 (26.8%) | NYR [NYR;NYR] | 47 | 7 (14.9%) | NYR [24.41;NYR] | 1.72 [0.66;4.45] | 0.2589 | 0.3209 |
| >= 65 AND < 75 | 25 | 4 (16.0%) | NYR [18.76;NYR] | 18 | 5 (27.8%) | NYR [7.23;NYR] | 0.51 [0.14;1.93] | 0.3136 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 2 (33.3%) | NYR [4.80;NYR] | <0.01 [<0.01;NE] | 0.1010 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 9 (23.1%) | NYR [NYR;NYR] | 37 | 7 (18.9%) | NYR [NYR;NYR] | 1.09 [0.40;2.93] | 0.8691 | 0.6543 |
| Rest of World (ROW) | 35 | 6 (17.1%) | NYR [NYR;NYR] | 34 | 7 (20.6%) | 24.41 [21.16;NYR] | 0.69 [0.23;2.06] | 0.5039 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:30:32

TABLE 3.119.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 15 (23.1%) | NYR [NYR;NYR] | 60 | 12 (20.0%) | NYR [24.41;NYR] | 1.04 [0.49;2.22] | 0.9220 | 0.9904 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 2 (18.2%) | 21.16 [17.38;NYR] | <0.01 [<0.01;NE] | 0.0977 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 2 (28.6%) | NYR [1.38;NYR] | 13 | 3 (23.1%) | 21.16 [6.44;21.16] | 1.25 [0.20;7.68] | 0.8112 | 0.3744 |
| Not Hispanic or Latino | 43 | 10 (23.3%) | NYR [NYR;NYR] | 32 | 5 (15.6%) | NYR [NYR;NYR] | 1.48 [0.50;4.33] | 0.4746 | |
| Not Reported | 24 | 3 (12.5%) | NYR [NYR;NYR] | 26 | 6 (23.1%) | NYR [17.38;NYR] | 0.40 [0.10;1.61] | 0.1824 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 14 (25.0%) | NYR [NYR;NYR] | 48 | 10 (20.8%) | NYR [21.16;NYR] | 1.11 [0.49;2.50] | 0.8094 | 0.2299 |
| Female | 18 | 1 (5.6%) | NYR [NYR;NYR] | 23 | 4 (17.4%) | NYR [24.41;NYR] | 0.24 [0.03;2.22] | 0.1766 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [NYR;NYR] | 19 | 4 (21.1%) | NYR [14.52;NYR] | 0.46 [0.08;2.58] | 0.3697 | 0.4508 |
| >= 1 Year | 60 | 13 (21.7%) | NYR [NYR;NYR] | 50 | 9 (18.0%) | NYR [24.41;NYR] | 1.12 [0.48;2.61] | 0.8032 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.119.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 5 (45.5%) | NYR [1.41;NYR] | 12 | 3 (25.0%) | NYR [4.83;NYR] | 2.26 [0.54;9.46] | 0.2531 | 0.2070 |
| Yes | 63 | 10 (15.9%) | NYR [NYR;NYR] | 59 | 11 (18.6%) | NYR [24.41;NYR] | 0.70 [0.30;1.65] | 0.4134 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 12 (18.8%) | NYR [NYR;NYR] | 65 | 13 (20.0%) | NYR [24.41;NYR] | 0.79 [0.36;1.73] | 0.5505 | 0.3996 |
| Yes | 10 | 3 (30.0%) | NYR [0.49;NYR] | 6 | 1 (16.7%) | NYR [17.38;NYR] | 2.24 [0.23;21.71] | 0.4748 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [9.95;NYR] | 10 | 1 (10.0%) | NYR [3.48;NYR] | 1.30 [0.12;14.35] | 0.8308 | 0.9389 |
| < 1% | 61 | 13 (21.3%) | NYR [NYR;NYR] | 60 | 13 (21.7%) | NYR [21.16;NYR] | 0.88 [0.40;1.90] | 0.7362 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 4 (22.2%) | NYR [18.76;NYR] | 20 | 3 (15.0%) | NYR [14.52;NYR] | 1.31 [0.29;5.91] | 0.7224 | 0.4984 |
| Non-Stage IV | 53 | 10 (18.9%) | NYR [NYR;NYR] | 51 | 11 (21.6%) | NYR [21.16;NYR] | 0.74 [0.32;1.76] | 0.4971 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.120.1: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 15 (20.3%) | 14 (19.7%) |
| Number of censored cases | N | 59 (79.7%) | 57 (80.3%) |
| Time to first event (Months) | Mean (SE) | 16.17 (0.69) | 20.87 (0.92) |
| | Q1 [95% CI] | NYR [9.95;NYR] | 21.20 [10.38;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [24.41;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.9350 | |
| Stratified Cox PH model | HR (b) | 0.97 [0.47;2.02] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.120.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 15 (20.3%) | NYR [NYR;NYR] | 71 | 14 (19.7%) | NYR [24.41;NYR] | 0.97 [0.47;2.02] | 0.9350 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 11 (26.8%) | NYR [NYR;NYR] | 47 | 7 (14.9%) | NYR [24.41;NYR] | 1.78 [0.69;4.61] | 0.2295 | 0.0464 |
| >= 65 | 33 | 4 (12.1%) | NYR [NYR;NYR] | 24 | 7 (29.2%) | NYR [14.49;NYR] | 0.36 [0.10;1.23] | 0.0900 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 11 (26.8%) | NYR [NYR;NYR] | 47 | 7 (14.9%) | NYR [24.41;NYR] | 1.78 [0.69;4.61] | 0.2295 | 0.3559 |
| >= 65 AND < 75 | 25 | 4 (16.0%) | NYR [18.76;NYR] | 18 | 5 (27.8%) | NYR [7.23;NYR] | 0.53 [0.14;1.99] | 0.3369 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 2 (33.3%) | NYR [4.80;NYR] | <0.01 [<0.01;NE] | 0.0584 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 9 (23.1%) | NYR [NYR;NYR] | 37 | 7 (18.9%) | NYR [NYR;NYR] | 1.16 [0.43;3.12] | 0.7696 | 0.6211 |
| Rest of World (ROW) | 35 | 6 (17.1%) | NYR [NYR;NYR] | 34 | 7 (20.6%) | 24.41 [21.16;NYR] | 0.71 [0.24;2.12] | 0.5343 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.120.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 15 (23.1%) | NYR [NYR;NYR] | 60 | 12 (20.0%) | NYR [24.41;NYR] | 1.09 [0.51;2.34] | 0.8219 | 0.9904 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 2 (18.2%) | 21.16 [17.38;NYR] | <0.01 [<0.01;NE] | 0.0833 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 2 (28.6%) | NYR [1.38;NYR] | 13 | 3 (23.1%) | 21.16 [6.44;21.16] | 1.28 [0.21;7.87] | 0.7915 | 0.3734 |
| Not Hispanic or Latino | 43 | 10 (23.3%) | NYR [NYR;NYR] | 32 | 5 (15.6%) | NYR [NYR;NYR] | 1.52 [0.52;4.44] | 0.4446 | |
| Not Reported | 24 | 3 (12.5%) | NYR [NYR;NYR] | 26 | 6 (23.1%) | NYR [24.41;NYR] | 0.42 [0.11;1.71] | 0.2138 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 14 (25.0%) | NYR [NYR;NYR] | 48 | 10 (20.8%) | NYR [21.16;NYR] | 1.16 [0.51;2.62] | 0.7201 | 0.2315 |
| Female | 18 | 1 (5.6%) | NYR [NYR;NYR] | 23 | 4 (17.4%) | NYR [24.41;NYR] | 0.28 [0.03;2.55] | 0.2298 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [NYR;NYR] | 19 | 4 (21.1%) | NYR [14.52;NYR] | 0.48 [0.09;2.71] | 0.3971 | 0.4606 |
| >= 1 Year | 60 | 13 (21.7%) | NYR [NYR;NYR] | 50 | 9 (18.0%) | NYR [24.41;NYR] | 1.15 [0.49;2.71] | 0.7413 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.120.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 5 (45.5%) | NYR [1.41;NYR] | 12 | 3 (25.0%) | NYR [4.83;NYR] | 2.19 [0.52;9.20] | 0.2706 | 0.2201 |
| Yes | 63 | 10 (15.9%) | NYR [NYR;NYR] | 59 | 11 (18.6%) | NYR [24.41;NYR] | 0.73 [0.31;1.73] | 0.4759 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 12 (18.8%) | NYR [NYR;NYR] | 65 | 13 (20.0%) | NYR [24.41;NYR] | 0.83 [0.38;1.82] | 0.6395 | 0.4057 |
| Yes | 10 | 3 (30.0%) | NYR [0.49;NYR] | 6 | 1 (16.7%) | NYR [17.38;NYR] | 2.24 [0.23;21.71] | 0.4748 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [9.95;NYR] | 10 | 1 (10.0%) | NYR [3.48;NYR] | 1.44 [0.13;15.92] | 0.7661 | 0.9415 |
| < 1% | 61 | 13 (21.3%) | NYR [NYR;NYR] | 60 | 13 (21.7%) | NYR [21.16;NYR] | 0.92 [0.42;1.98] | 0.8241 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 4 (22.2%) | NYR [18.76;NYR] | 20 | 3 (15.0%) | NYR [14.52;NYR] | 1.38 [0.31;6.18] | 0.6740 | 0.5297 |
| Non-Stage IV | 53 | 10 (18.9%) | NYR [NYR;NYR] | 51 | 11 (21.6%) | NYR [24.41;NYR] | 0.79 [0.33;1.86] | 0.5825 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.121.1: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 1 (1.4%) |
| Number of censored cases | N | 72 (97.3%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 4.94 (0.03) | 4.37 (.) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.6558 | |
| Stratified Cox PH model | HR (b) | 1.71 [0.16;18.91] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.121.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.71 [0.16;18.91] | 0.6558 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.06 [0.07;16.99] | 0.9658 | 0.9960 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4461 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.06 [0.07;16.99] | 0.9658 | 1.0000 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4617 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 2 (5.1%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 1.64 [0.15;18.11] | 0.6825 | 0.9999 |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:45:39

TABLE 3.121.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.64 [0.15;18.12] | 0.6821 | 0.9999 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 1.47 [0.13;16.22] | 0.7514 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 1 (2.1%) | NYR [NYR;NYR] | 1.66 [0.15;18.36] | 0.6741 | 0.9999 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 1.51 [0.14;16.68] | 0.7338 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.121.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9999 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 1.68 [0.15;18.49] | 0.6697 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 1.80 [0.16;19.86] | 0.6260 | 0.9999 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 2 (3.3%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.78 [0.16;19.59] | 0.6342 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9999 |
| Non-Stage IV | 53 | 2 (3.8%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 1.63 [0.15;17.99] | 0.6866 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:45:39

TABLE 3.122.1: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 1 (1.4%) |
| Number of censored cases | N | 72 (97.3%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 4.94 (0.03) | 4.37 (.) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.6028 | |
| Stratified Cox PH model | HR (b) | 1.87 [0.17;20.65] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:53:03

TABLE 3.122.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.87 [0.17;20.65] | 0.6028 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.05 [0.07;16.78] | 0.9728 | 0.9955 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3938 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.05 [0.07;16.78] | 0.9728 | 1.0000 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3961 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 2 (5.1%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 1.83 [0.17;20.24] | 0.6148 | 0.9999 |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.122.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.76 [0.16;19.44] | 0.6392 | 0.9999 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 1.48 [0.13;16.37] | 0.7455 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 1 (2.1%) | NYR [NYR;NYR] | 1.69 [0.15;18.64] | 0.6647 | 0.9999 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 1.64 [0.15;18.04] | 0.6849 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.122.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9999 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 1.82 [0.17;20.08] | 0.6194 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 1.94 [0.18;21.45] | 0.5801 | 0.9999 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 2 (3.3%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.92 [0.17;21.16] | 0.5882 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9999 |
| Non-Stage IV | 53 | 2 (3.8%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 1.85 [0.17;20.46] | 0.6084 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.123.1: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 1 (1.4%) |
| Number of censored cases | N | 72 (97.3%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 11.56 (0.14) | 4.37 (.) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.6964 | |
| Stratified Cox PH model | HR (b) | 1.61 [0.15;17.72] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.123.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.61 [0.15;17.72] | 0.6964 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.06 [0.07;16.99] | 0.9658 | 0.9961 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4892 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.06 [0.07;16.99] | 0.9658 | 1.0000 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4431 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 0.80 [0.05;12.83] | 0.8763 | 0.9966 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3865 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.123.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.53 [0.14;16.88] | 0.7280 | 0.9999 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 0.73 [0.05;11.72] | 0.8257 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3613 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 1 (2.1%) | NYR [NYR;NYR] | 1.50 [0.14;16.64] | 0.7381 | 1.0000 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3576 | 0.9965 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 0.74 [0.05;11.88] | 0.8331 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.123.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9999 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 1.56 [0.14;17.24] | 0.7143 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 1.63 [0.15;18.08] | 0.6861 | 0.9999 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 2 (3.3%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.60 [0.14;17.77] | 0.6974 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3711 | 0.9961 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 0.79 [0.05;12.70] | 0.8702 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.124.1: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 1 (1.4%) |
| Number of censored cases | N | 72 (97.3%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 11.57 (0.13) | 4.37 (.) |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.6303 | |
| Stratified Cox PH model | HR (b) | 1.79 [0.16;19.72] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.124.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.79 [0.16;19.72] | 0.6303 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.05 [0.07;16.78] | 0.9728 | 0.9957 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4543 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 1.05 [0.07;16.78] | 0.9728 | 1.0000 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4467 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 0.89 [0.06;14.22] | 0.9340 | 0.9966 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3532 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.124.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.62 [0.15;17.93] | 0.6901 | 0.9999 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 0.73 [0.05;11.73] | 0.8261 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3496 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 1 (2.1%) | NYR [NYR;NYR] | 1.59 [0.14;17.57] | 0.7026 | 1.0000 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3173 | 0.9966 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 0.80 [0.05;12.73] | 0.8714 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.124.2: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9999 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 1.67 [0.15;18.46] | 0.6725 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 1.74 [0.16;19.31] | 0.6461 | 0.9999 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 2 (3.3%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 1.73 [0.16;19.12] | 0.6520 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3329 | 0.9961 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 0.89 [0.06;14.27] | 0.9358 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.125.1: TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 0 (0.0%) |
| Number of censored cases | N | 72 (97.3%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 13.90 (0.05) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.2733 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 3.125.2: TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2733 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2102 | 0.9989 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2102 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4337 | 1.0000 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3805 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.125.2: TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2446 | 0.9991 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4795 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3527 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2565 | 0.9989 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9989 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2750 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:13:09

TABLE 3.125.2: TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)


| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9991 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2397 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4000 | 0.9999 |
| Yes | 10 | 1 (10.0%) | NYR [12.02;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4497 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [12.02;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2286 | 1.0000 |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9993 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4227 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.126.1: TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 0 (0.0%) |
| Number of censored cases | N | 72 (97.3%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 13.90 (0.04) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.2375 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.126.2: TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2375 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1967 | 0.9989 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1967 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4363 | 1.0000 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3778 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.126.2: TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2325 | 0.9991 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4547 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3404 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2397 | 0.9989 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9989 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2709 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.126.2: TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9991 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2254 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3961 | 0.9999 |
| Yes | 10 | 1 (10.0%) | NYR [12.02;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3980 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [12.02;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2100 | 1.0000 |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9993 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4142 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.127.1: TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 1 (1.4%) | 0 (0.0%) |
| Number of censored cases | N | 73 (98.6%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 17.08 (.) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.3865 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:26:22

TABLE 3.127.2: TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3865 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4179 | 0.9992 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4179 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 | 0.9992 |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.127.2: TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)


| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 1 (1.5%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4171 | 0.9994 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4617 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 1 (1.8%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4467 | 0.9992 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9992 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4406 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.127.2: TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9993 |
| Yes | 63 | 1 (1.6%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3993 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9996 |
| Yes | 10 | 1 (10.0%) | NYR [17.08;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.5127 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [17.08;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4142 | 0.9996 |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:26:23

TABLE 3.128.1: TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 1 (1.4%) | 0 (0.0%) |
| Number of censored cases | N | 73 (98.6%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 17.08 (.) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.3865 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:33:02

TABLE 3.128.2: TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3865 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4038 | 0.9992 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4038 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4414 | 0.9992 |
| Rest of World (ROW) | 35 | 0 (0.0%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:33:02

TABLE 3.128.2: TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 1 (1.5%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4221 | 0.9994 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4956 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 1 (1.8%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4442 | 0.9992 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9992 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4539 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.128.2: TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9993 |
| Yes | 63 | 1 (1.6%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4197 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 0 (0.0%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9997 |
| Yes | 10 | 1 (10.0%) | NYR [17.08;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.5127 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [17.08;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4142 | 1.0000 |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | NC |
| Non-Stage IV | 53 | 0 (0.0%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.129.1: TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 0 (0.0%) |
| Number of censored cases | N | 72 (97.3%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 17.47 (0.01) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.2457 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:39:29

TABLE 3.129.2: TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2457 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2501 | 0.9989 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2501 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 | 1.0000 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3827 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.129.2: TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)


| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2452 | 0.9991 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4617 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3907 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2810 | 0.9989 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9989 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2744 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:39:30

TABLE 3.129.2: TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9991 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2345 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3907 | 0.9999 |
| Yes | 10 | 1 (10.0%) | NYR [17.08;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.5127 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [17.08;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2341 | 0.9993 |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9993 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4142 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:39:30

TABLE 3.130.1: TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 0 (0.0%) |
| Number of censored cases | N | 72 (97.3%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 17.47 (0.01) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.2457 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:45:52

TABLE 3.130.2: TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2457 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2356 | 0.9989 |
| >= 65 | 33 | 0 (0.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 2 (4.9%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2356 | 1.0000 |
| >= 65 AND < 75 | 25 | 0 (0.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4414 | 1.0000 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4000 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:45:52

TABLE 3.130.2: TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2508 | 0.9991 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 1 (2.3%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4956 | |
| Not Reported | 24 | 1 (4.2%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3711 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2784 | 0.9989 |
| Female | 18 | 0 (0.0%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9989 |
| >= 1 Year | 60 | 2 (3.3%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2888 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.130.2: TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9990 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2525 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 1 (1.6%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4036 | 0.9999 |
| Yes | 10 | 1 (10.0%) | NYR [17.08;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.5127 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [17.08;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2341 | 1.0000 |
| < 1% | 61 | 0 (0.0%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9993 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4366 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.131.1: TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 32 (43.2%) | 8 (11.3%) |
| Number of censored cases | N | 42 (56.8%) | 63 (88.7%) |
| Time to first event (Months) | Mean (SE) | 13.96 (1.08) | 8.80 (0.33) |
| | Q1 [95% CI] | 3.80 [1.77;7.72] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [9.26;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0001 | |
| Stratified Cox PH model | HR (b) | 4.09 [1.88;8.88] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:52:09

TABLE 3.131.2: TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 32 (43.2%) | NYR [9.26;NYR] | 71 | 8 (11.3%) | NYR [NYR;NYR] | 4.09 [1.88;8.88] | 0.0001 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 16 (39.0%) | NYR [9.92;NYR] | 47 | 7 (14.9%) | NYR [NYR;NYR] | 2.61 [1.07;6.34] | 0.0278 | 0.1501 |
| >= 65 | 33 | 16 (48.5%) | 10.28 [3.58;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 12.88 [1.71;97.15] | 0.0013 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 16 (39.0%) | NYR [9.92;NYR] | 47 | 7 (14.9%) | NYR [NYR;NYR] | 2.61 [1.07;6.34] | 0.0278 | 0.6149 |
| >= 65 AND < 75 | 25 | 15 (60.0%) | 7.72 [1.97;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0002 | |
| >= 75 | 8 | 1 (12.5%) | NYR [0.72;NYR] | 6 | 1 (16.7%) | NYR [0.66;NYR] | 0.68 [0.04;10.98] | 0.7878 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 16 (41.0%) | NYR [8.05;NYR] | 37 | 3 (8.1%) | NYR [NYR;NYR] | 5.20 [1.51;17.86] | 0.0034 | 0.6219 |
| Rest of World (ROW) | 35 | 16 (45.7%) | NYR [4.80;NYR] | 34 | 5 (14.7%) | NYR [NYR;NYR] | 3.41 [1.25;9.31] | 0.0111 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.131.2: TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 28 (43.1%) | NYR [8.05;NYR] | 60 | 6 (10.0%) | NYR [NYR;NYR] | 4.63 [1.92;11.19] | 0.0002 | 0.4718 |
| Non-White | 9 | 4 (44.4%) | 21.62 [0.72;NYR] | 11 | 2 (18.2%) | NYR [2.33;NYR] | 2.24 [0.41;12.34] | 0.3422 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 5 (71.4%) | 3.75 [1.74;NYR] | 13 | 3 (23.1%) | NYR [9.66;NYR] | 2.99 [0.71;12.54] | 0.1213 | 0.5529 |
| Not Hispanic or Latino | 43 | 17 (39.5%) | NYR [6.18;NYR] | 32 | 4 (12.5%) | NYR [NYR;NYR] | 3.42 [1.15;10.18] | 0.0186 | |
| Not Reported | 24 | 10 (41.7%) | NYR [8.05;NYR] | 26 | 1 (3.8%) | NYR [NYR;NYR] | 11.57 [1.48;90.45] | 0.0031 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 24 (42.9%) | 21.62 [9.26;NYR] | 48 | 8 (16.7%) | NYR [NYR;NYR] | 2.70 [1.21;6.02] | 0.0113 | 0.9851 |
| Female | 18 | 8 (44.4%) | NYR [1.91;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0009 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 7 (50.0%) | 13.08 [0.43;NYR] | 19 | 2 (10.5%) | NYR [NYR;NYR] | 5.42 [1.12;26.11] | 0.0181 | 0.6200 |
| >= 1 Year | 60 | 25 (41.7%) | NYR [8.05;NYR] | 50 | 6 (12.0%) | NYR [NYR;NYR] | 3.60 [1.48;8.79] | 0.0026 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.131.2: TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 6 (54.5%) | 7.56 [0.43;NYR] | 12 | 2 (16.7%) | NYR [2.79;NYR] | 3.67 [0.74;18.20] | 0.0881 | 0.9258 |
| Yes | 63 | 26 (41.3%) | NYR [9.92;NYR] | 59 | 6 (10.2%) | NYR [NYR;NYR] | 4.27 [1.76;10.38] | 0.0005 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 27 (42.2%) | NYR [9.26;NYR] | 65 | 8 (12.3%) | NYR [NYR;NYR] | 3.59 [1.63;7.89] | 0.0007 | 0.9878 |
| Yes | 10 | 5 (50.0%) | 21.62 [1.87;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0938 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 6 (54.5%) | 21.62 [3.75;NYR] | 10 | 1 (10.0%) | NYR [0.46;NYR] | 5.18 [0.62;43.15] | 0.0894 | 0.9669 |
| < 1% | 61 | 26 (42.6%) | NYR [7.56;NYR] | 60 | 7 (11.7%) | NYR [NYR;NYR] | 3.90 [1.69;9.00] | 0.0006 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 10 (55.6%) | 8.05 [1.77;NYR] | 20 | 2 (10.0%) | NYR [NYR;NYR] | 6.62 [1.45;30.25] | 0.0049 | 0.4224 |
| Non-Stage IV | 53 | 21 (39.6%) | NYR [9.92;NYR] | 51 | 6 (11.8%) | NYR [NYR;NYR] | 3.36 [1.36;8.33] | 0.0054 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.132.1: TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 32 (43.2%) | 9 (12.7%) |
| Number of censored cases | N | 42 (56.8%) | 62 (87.3%) |
| Time to first event (Months) | Mean (SE) | 14.04 (1.07) | 8.79 (0.32) |
| | Q1 [95% CI] | 3.80 [1.77;7.72] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [9.26;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0002 | |
| Stratified Cox PH model | HR (b) | 3.77 [1.80;7.90] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.132.2: TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 32 (43.2%) | NYR [9.26;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 3.77 [1.80;7.90] | 0.0002 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 16 (39.0%) | NYR [9.92;NYR] | 47 | 8 (17.0%) | NYR [NYR;NYR] | 2.36 [1.01;5.52] | 0.0406 | 0.1116 |
| >= 65 | 33 | 16 (48.5%) | 10.28 [3.58;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 13.74 [1.82;>99.99] | 0.0009 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 16 (39.0%) | NYR [9.92;NYR] | 47 | 8 (17.0%) | NYR [NYR;NYR] | 2.36 [1.01;5.52] | 0.0406 | 0.6874 |
| >= 65 AND < 75 | 25 | 15 (60.0%) | 7.72 [1.97;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0002 | |
| >= 75 | 8 | 1 (12.5%) | NYR [0.72;NYR] | 6 | 1 (16.7%) | NYR [0.66;NYR] | 0.68 [0.04;10.98] | 0.7878 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 16 (41.0%) | NYR [8.05;NYR] | 37 | 3 (8.1%) | NYR [NYR;NYR] | 5.52 [1.61;18.96] | 0.0023 | 0.4346 |
| Rest of World (ROW) | 35 | 16 (45.7%) | NYR [4.80;NYR] | 34 | 6 (17.6%) | NYR [NYR;NYR] | 2.92 [1.14;7.46] | 0.0194 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.132.2: TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 28 (43.1%) | NYR [8.05;NYR] | 60 | 6 (10.0%) | NYR [NYR;NYR] | 4.84 [2.00;11.68] | 0.0001 | 0.2119 |
| Non-White | 9 | 4 (44.4%) | 21.62 [0.72;NYR] | 11 | 3 (27.3%) | NYR [2.33;NYR] | 1.55 [0.34;7.00] | 0.5650 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 5 (71.4%) | 3.75 [1.74;NYR] | 13 | 3 (23.1%) | NYR [9.66;NYR] | 3.52 [0.83;14.83] | 0.0714 | 0.8439 |
| Not Hispanic or Latino | 43 | 17 (39.5%) | NYR [6.18;NYR] | 32 | 4 (12.5%) | NYR [NYR;NYR] | 3.50 [1.18;10.40] | 0.0165 | |
| Not Reported | 24 | 10 (41.7%) | NYR [8.05;NYR] | 26 | 2 (7.7%) | NYR [NYR;NYR] | 5.98 [1.31;27.32] | 0.0085 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 24 (42.9%) | NYR [9.26;NYR] | 48 | 9 (18.8%) | NYR [NYR;NYR] | 2.47 [1.15;5.32] | 0.0167 | 0.9843 |
| Female | 18 | 8 (44.4%) | NYR [1.91;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0005 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 7 (50.0%) | 13.08 [0.43;NYR] | 19 | 2 (10.5%) | NYR [NYR;NYR] | 5.64 [1.17;27.22] | 0.0151 | 0.5154 |
| >= 1 Year | 60 | 25 (41.7%) | NYR [9.26;NYR] | 50 | 7 (14.0%) | NYR [NYR;NYR] | 3.29 [1.42;7.61] | 0.0032 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.132.2: TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 6 (54.5%) | 7.56 [0.43;NYR] | 12 | 3 (25.0%) | NYR [2.79;NYR] | 2.63 [0.66;10.56] | 0.1562 | 0.5516 |
| Yes | 63 | 26 (41.3%) | NYR [9.92;NYR] | 59 | 6 (10.2%) | NYR [NYR;NYR] | 4.46 [1.83;10.84] | 0.0003 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 27 (42.2%) | NYR [9.26;NYR] | 65 | 9 (13.8%) | NYR [NYR;NYR] | 3.34 [1.57;7.09] | 0.0009 | 0.9875 |
| Yes | 10 | 5 (50.0%) | 21.62 [1.87;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0918 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 6 (54.5%) | 21.62 [3.75;NYR] | 10 | 1 (10.0%) | NYR [0.46;NYR] | 5.27 [0.63;43.86] | 0.0852 | 0.9393 |
| < 1% | 61 | 26 (42.6%) | NYR [8.05;NYR] | 60 | 8 (13.3%) | NYR [NYR;NYR] | 3.59 [1.62;7.93] | 0.0007 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 10 (55.6%) | 8.05 [1.77;NYR] | 20 | 3 (15.0%) | NYR [NYR;NYR] | 4.60 [1.26;16.78] | 0.0110 | 0.7430 |
| Non-Stage IV | 53 | 21 (39.6%) | NYR [9.92;NYR] | 51 | 6 (11.8%) | NYR [NYR;NYR] | 3.62 [1.46;8.98] | 0.0030 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.133.1: TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 5 (6.8%) | 0 (0.0%) |
| Number of censored cases | N | 69 (93.2%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 7.77 (0.15) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0332 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.133.2: TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0332 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2998 | 0.9998 |
| >= 65 | 33 | 4 (12.1%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1084 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2998 | 1.0000 |
| >= 65 AND < 75 | 25 | 4 (16.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1074 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 3 (7.7%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1055 | 0.9999 |
| Rest of World (ROW) | 35 | 2 (5.7%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1786 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.133.2: TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 5 (7.7%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0377 | 0.9986 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 5 (11.6%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0540 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2004 | 0.9997 |
| Female | 18 | 3 (16.7%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0635 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2850 | 1.0000 |
| >= 1 Year | 60 | 4 (6.7%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0767 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.133.2: TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [8.02;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4028 | 1.0000 |
| Yes | 63 | 4 (6.3%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0590 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 5 (7.8%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0309 | 0.9988 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 5 (8.2%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0319 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 3 (16.7%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0721 | 0.9998 |
| Non-Stage IV | 53 | 2 (3.8%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1883 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.134.1: TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 5 (6.8%) | 0 (0.0%) |
| Number of censored cases | N | 69 (93.2%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 7.77 (0.15) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0285 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:11:07

TABLE 3.134.2: TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0285 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2998 | 0.9998 |
| >= 65 | 33 | 4 (12.1%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1000 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2998 | 1.0000 |
| >= 65 AND < 75 | 25 | 4 (16.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1074 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 3 (7.7%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0958 | 0.9999 |
| Rest of World (ROW) | 35 | 2 (5.7%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1704 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.134.2: TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 5 (7.7%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0347 | 0.9986 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 5 (11.6%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0500 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 2 (3.6%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1933 | 0.9997 |
| Female | 18 | 3 (16.7%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0522 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2705 | 1.0000 |
| >= 1 Year | 60 | 4 (6.7%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0704 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.134.2: TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [8.02;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2943 | 1.0000 |
| Yes | 63 | 4 (6.3%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0569 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 5 (7.8%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0275 | 0.9988 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 5 (8.2%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0281 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 3 (16.7%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0692 | 0.9998 |
| Non-Stage IV | 53 | 2 (3.8%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1801 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 3.135.1: TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - RASH - Serious AE - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 0 (0.0%) |
| Number of censored cases | N | 72 (97.3%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 4.99 (0.05) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.1787 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.135.2: TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1787 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2998 | 1.0000 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4038 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2998 | 1.0000 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3961 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3505 | 1.0000 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3404 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.135.2: TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1915 | 0.9991 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2246 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 1 (1.8%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3632 | 0.9999 |
| Female | 18 | 1 (5.6%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2918 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2850 | 1.0000 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3761 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.135.2: TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9991 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1884 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1717 | 0.9992 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 2 (3.3%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1765 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2888 | 0.9999 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3413 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.136.1: TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 2 (2.7%) | 0 (0.0%) |
| Number of censored cases | N | 72 (97.3%) | 71 (100.0%) |
| Time to first event (Months) | Mean (SE) | 4.99 (0.05) | . |
| | Q1 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.1715 | |
| Stratified Cox PH model | HR (b) | >99.99 [<0.01;NE] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 3.136.2: TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1715 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2998 | 1.0000 |
| >= 65 | 33 | 1 (3.0%) | NYR [NYR;NYR] | 24 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3938 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 1 (2.4%) | NYR [NYR;NYR] | 47 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2998 | 1.0000 |
| >= 65 AND < 75 | 25 | 1 (4.0%) | NYR [NYR;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3961 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 1 (2.6%) | NYR [NYR;NYR] | 37 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3367 | 1.0000 |
| Rest of World (ROW) | 35 | 1 (2.9%) | NYR [NYR;NYR] | 34 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3396 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.136.2: TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 2 (3.1%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1829 | 0.9991 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2232 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Gender** | | | | | | | | | |
| Male | 56 | 1 (1.8%) | NYR [NYR;NYR] | 48 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3568 | 0.9999 |
| Female | 18 | 1 (5.6%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2583 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2705 | 0.9999 |
| >= 1 Year | 60 | 1 (1.7%) | NYR [NYR;NYR] | 50 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3613 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 3.136.2: TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9991 |
| Yes | 63 | 2 (3.2%) | NYR [NYR;NYR] | 59 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1777 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 2 (3.1%) | NYR [NYR;NYR] | 65 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1608 | 0.9993 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 1.0000 |
| < 1% | 61 | 2 (3.3%) | NYR [NYR;NYR] | 60 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1666 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3035 | 0.9999 |
| Non-Stage IV | 53 | 1 (1.9%) | NYR [NYR;NYR] | 51 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3266 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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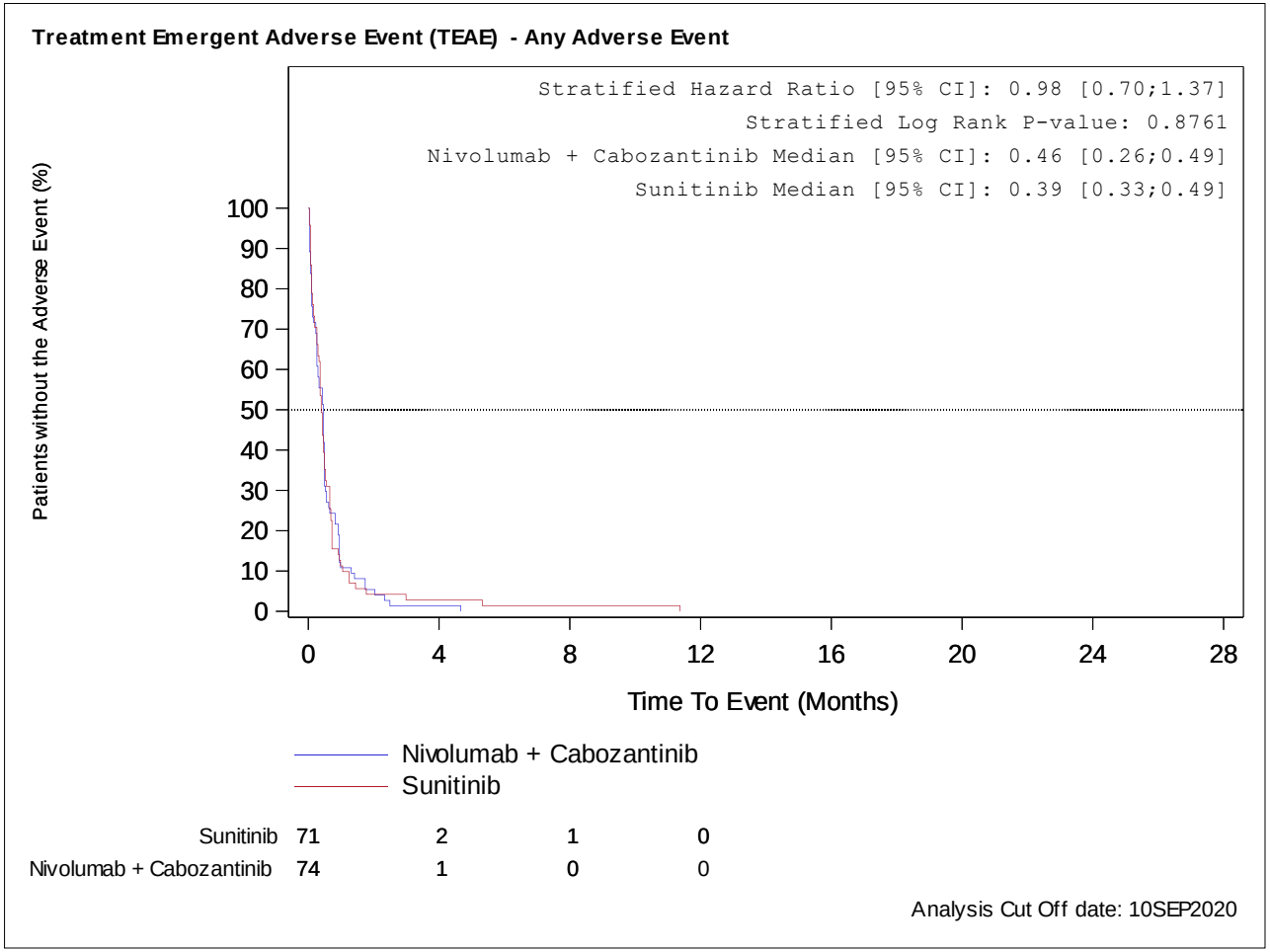
FIGURE 3.1.1: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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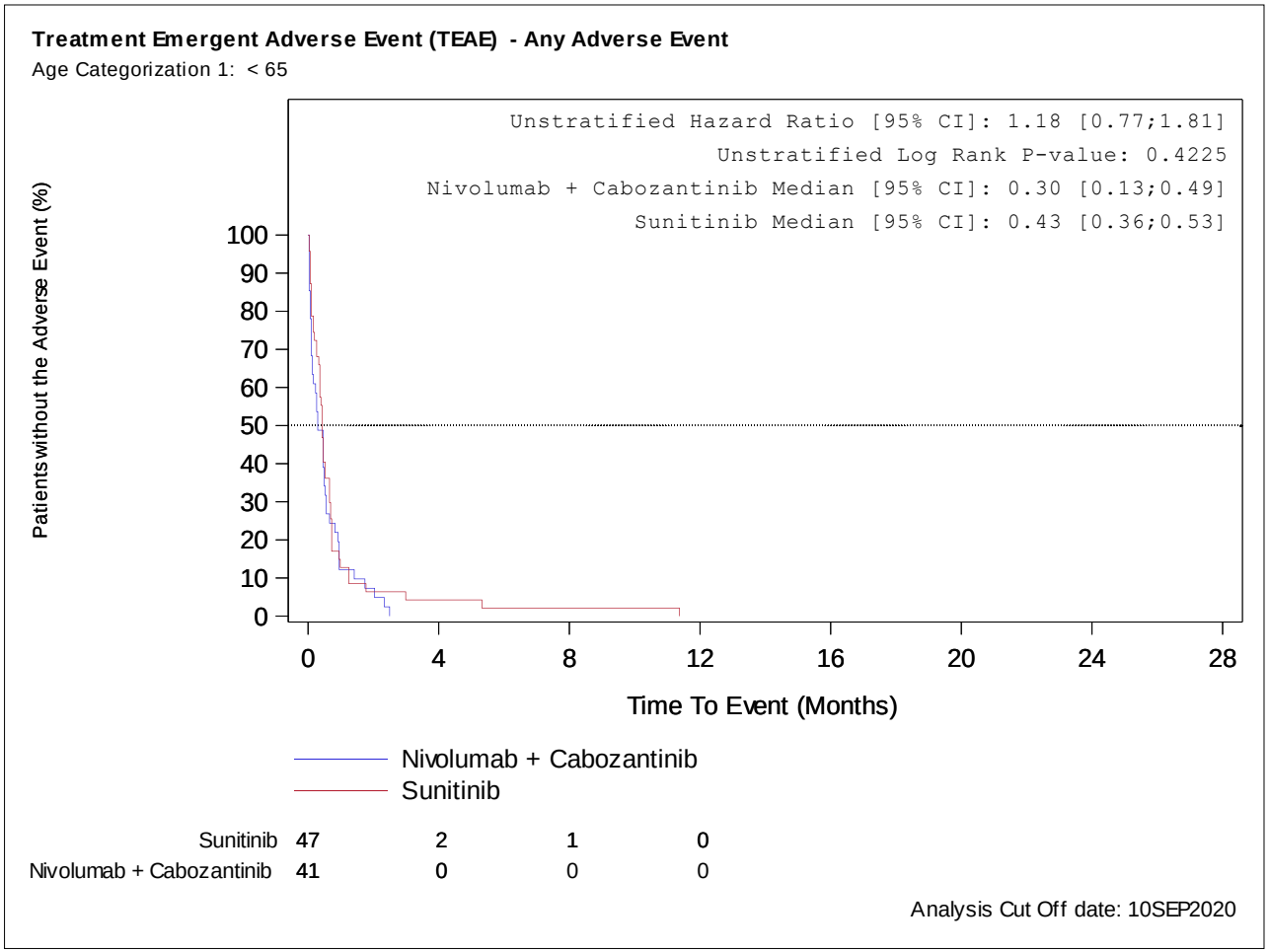
FIGURE 3.1.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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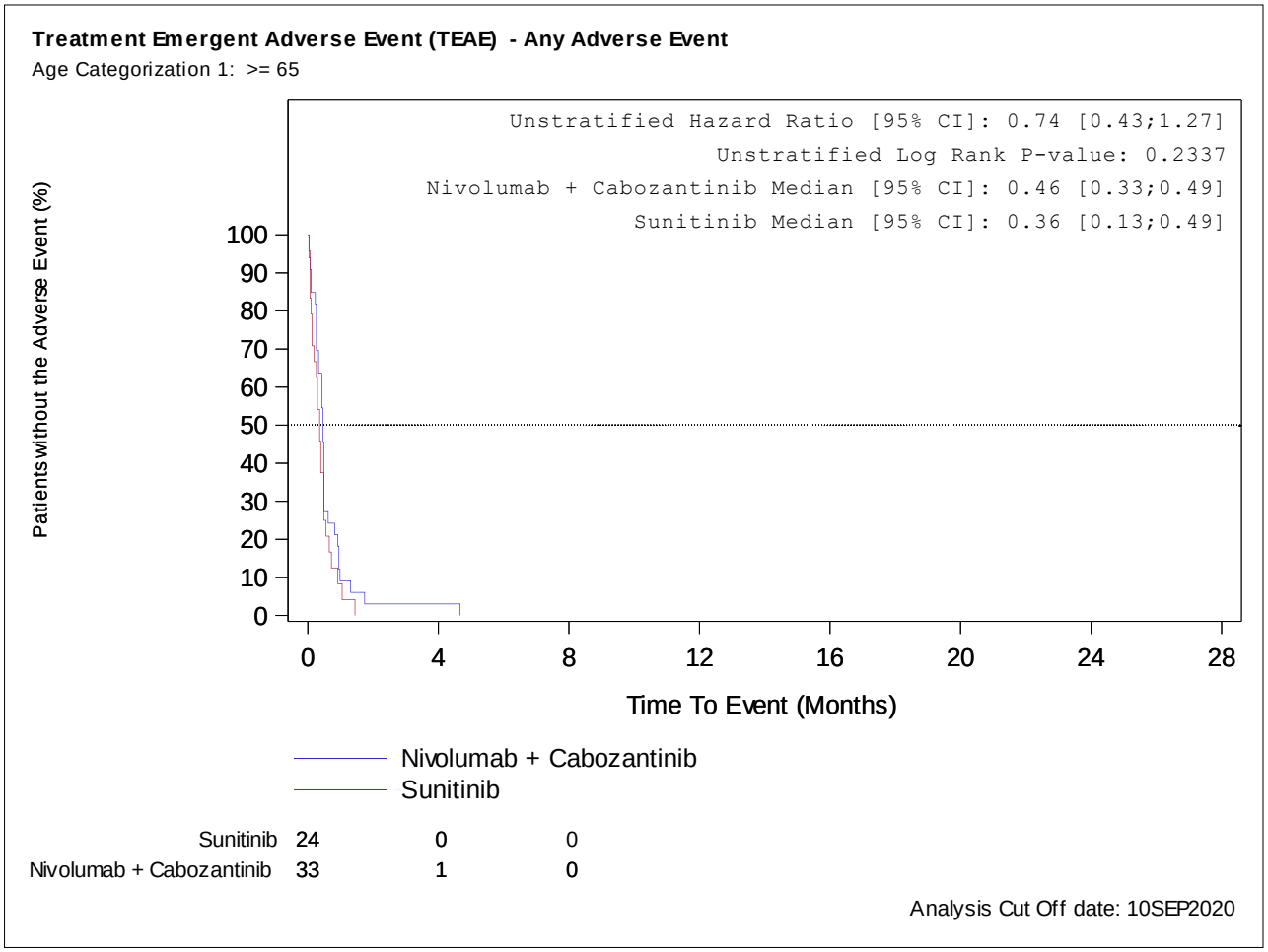
FIGURE 3.1.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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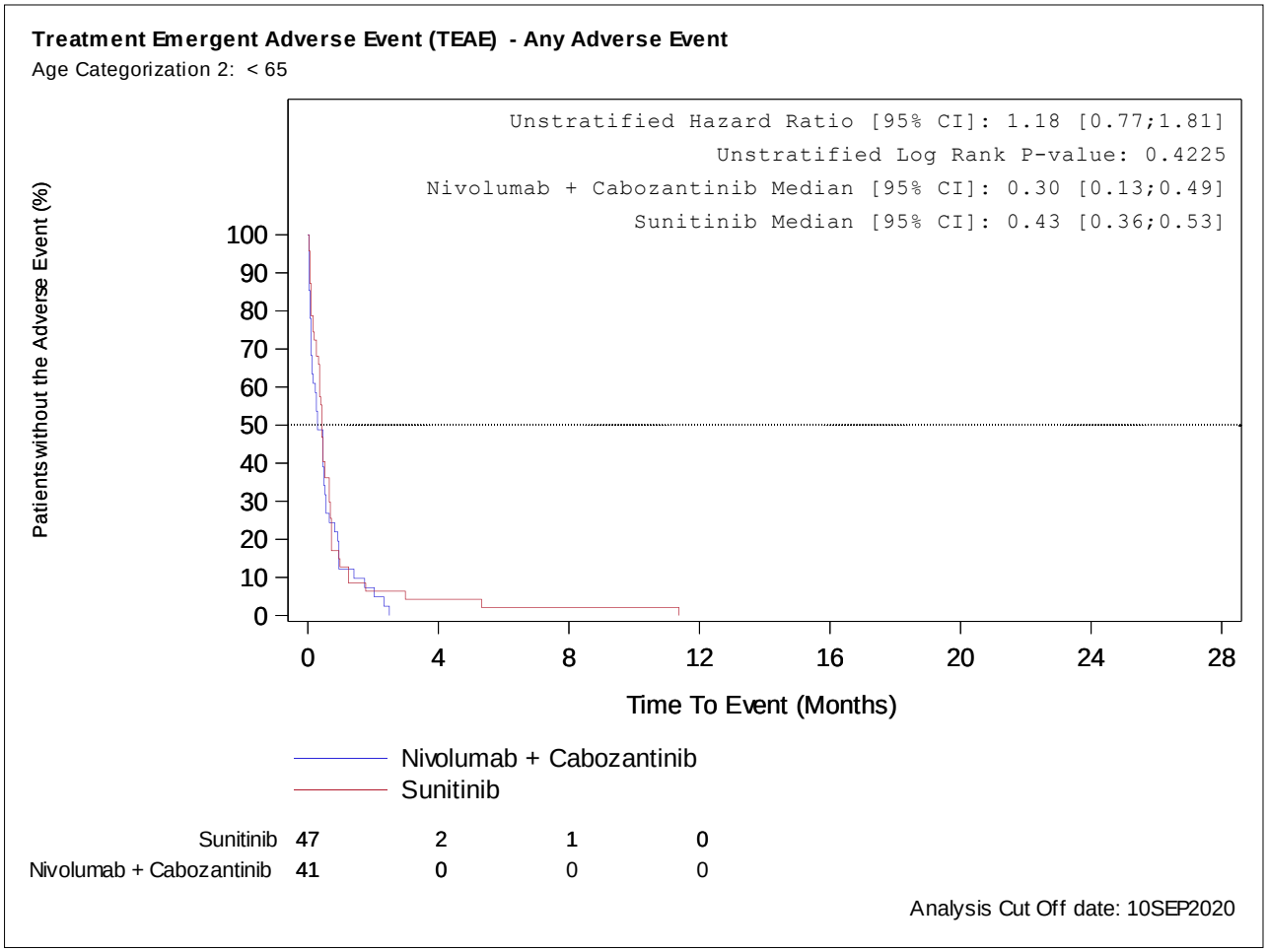
FIGURE 3.1.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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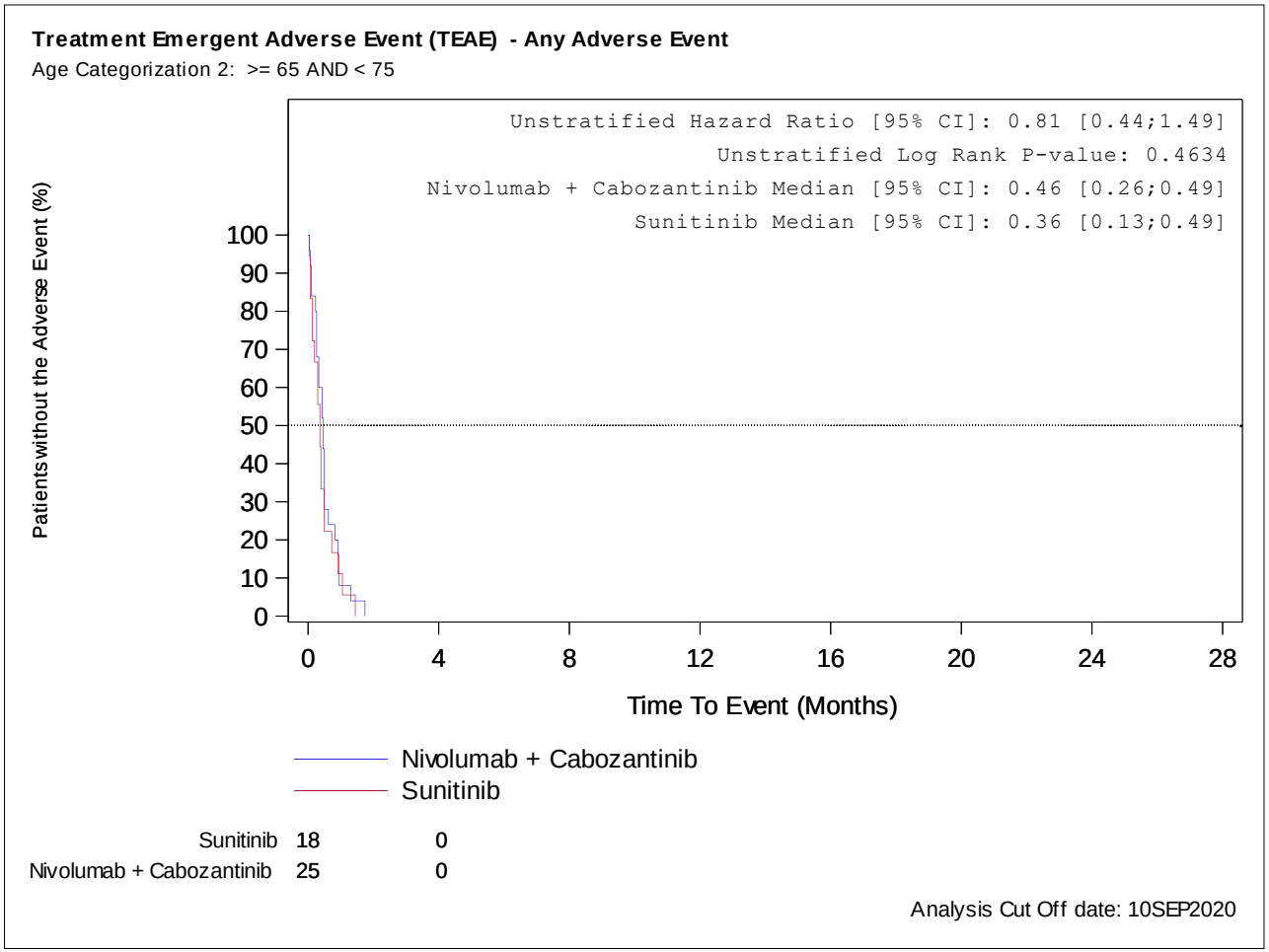
FIGURE 3.1.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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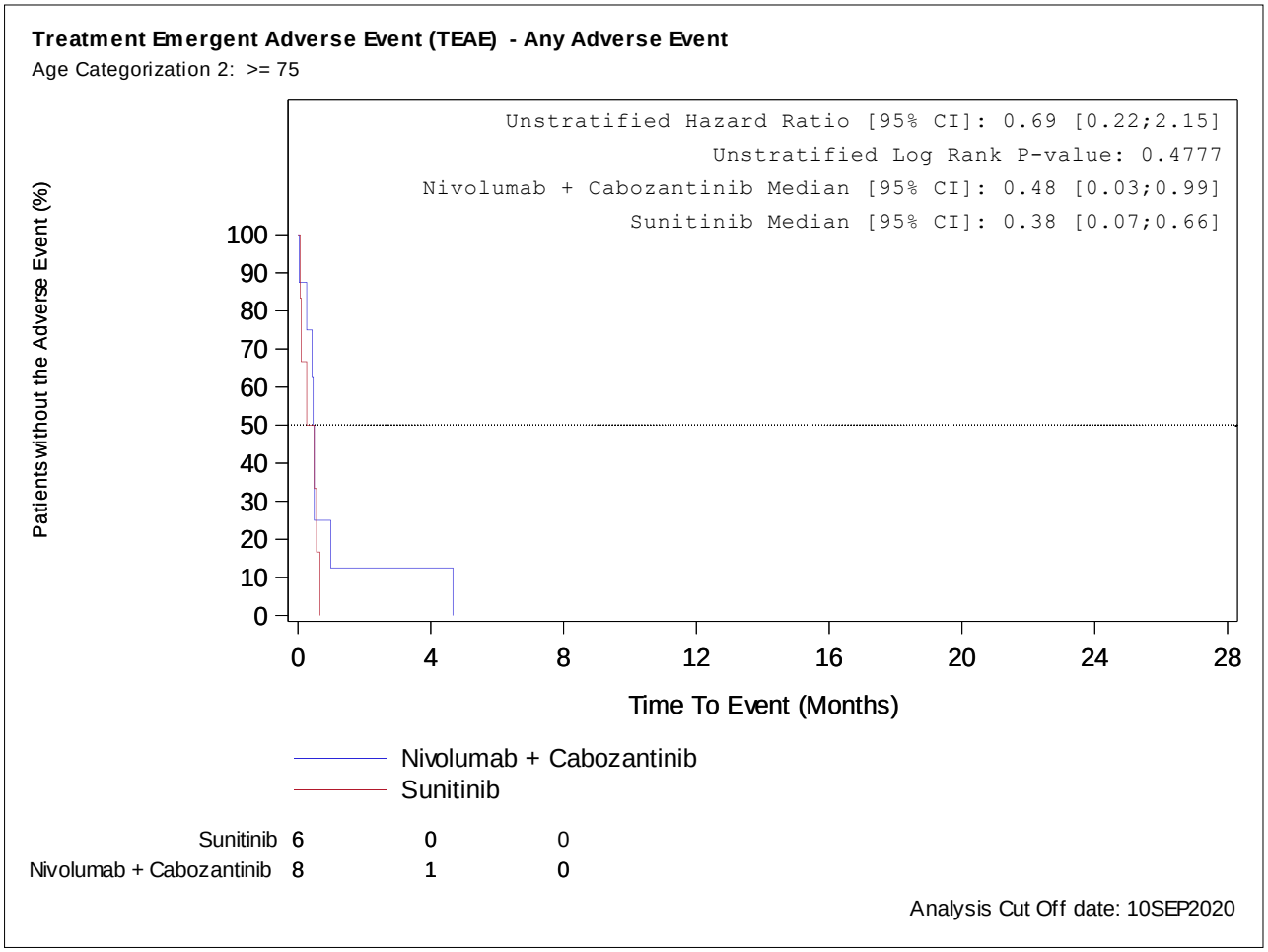
FIGURE 3.1.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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FIGURE 3.1.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe

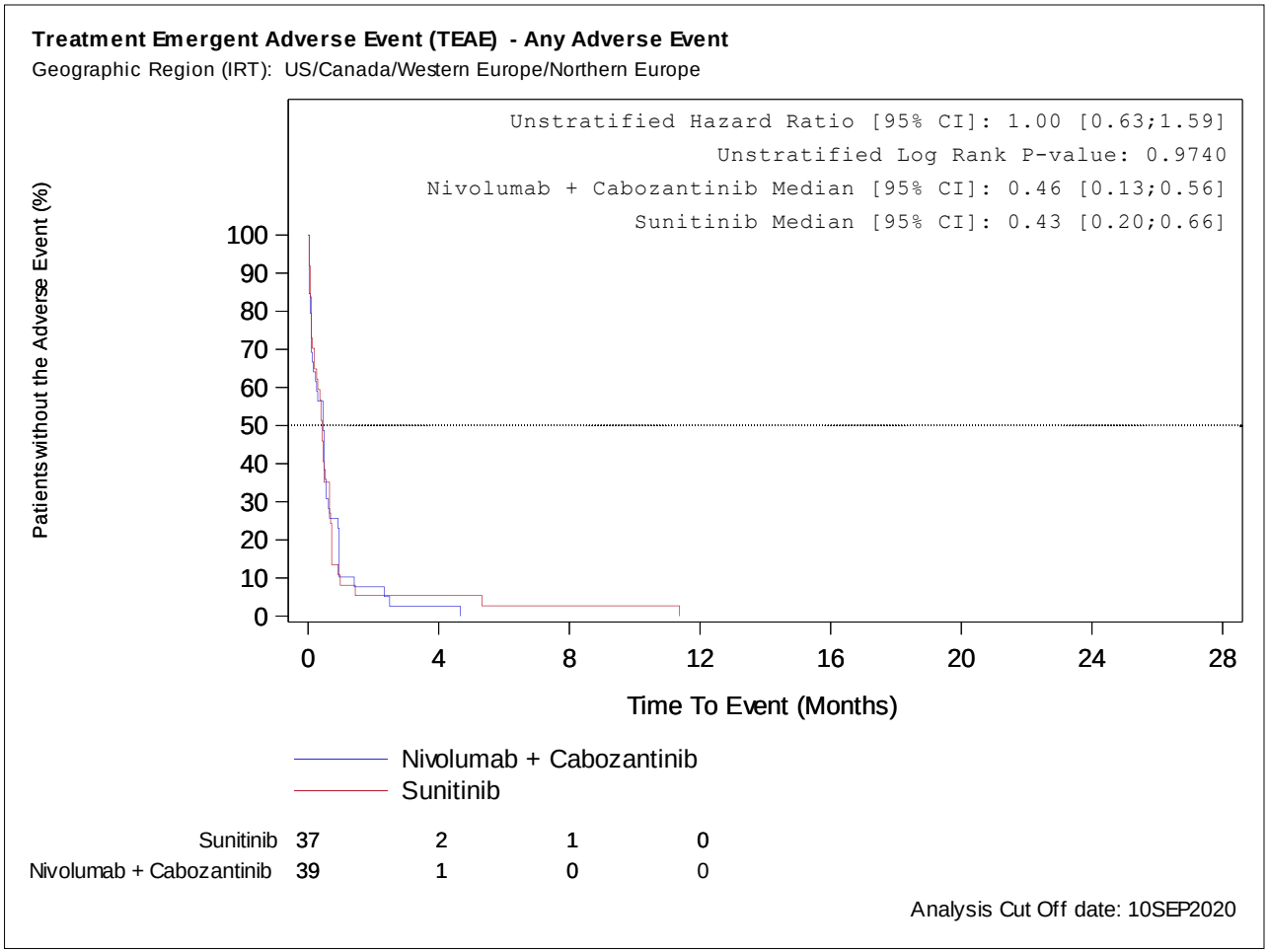


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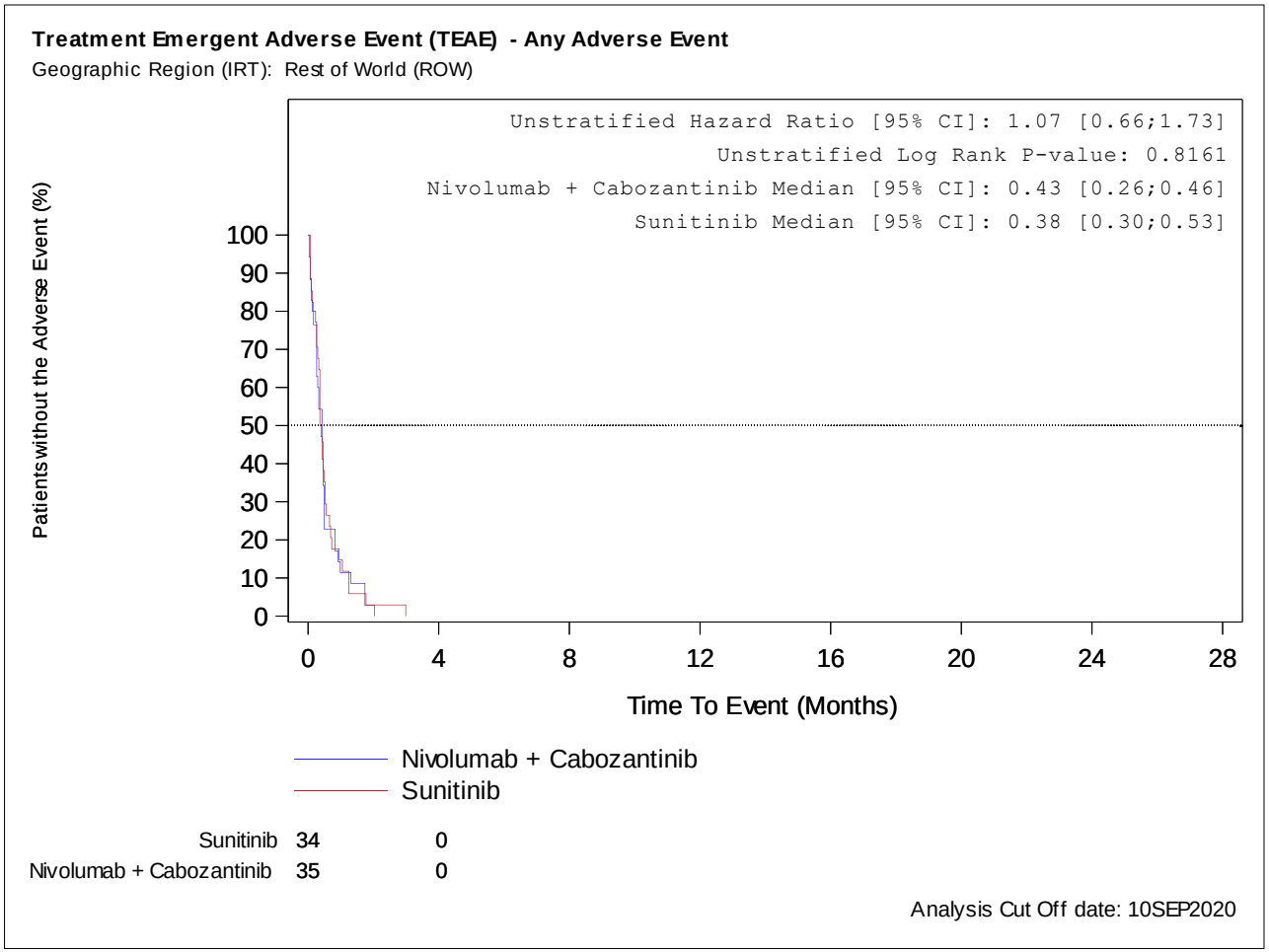
FIGURE 3.1.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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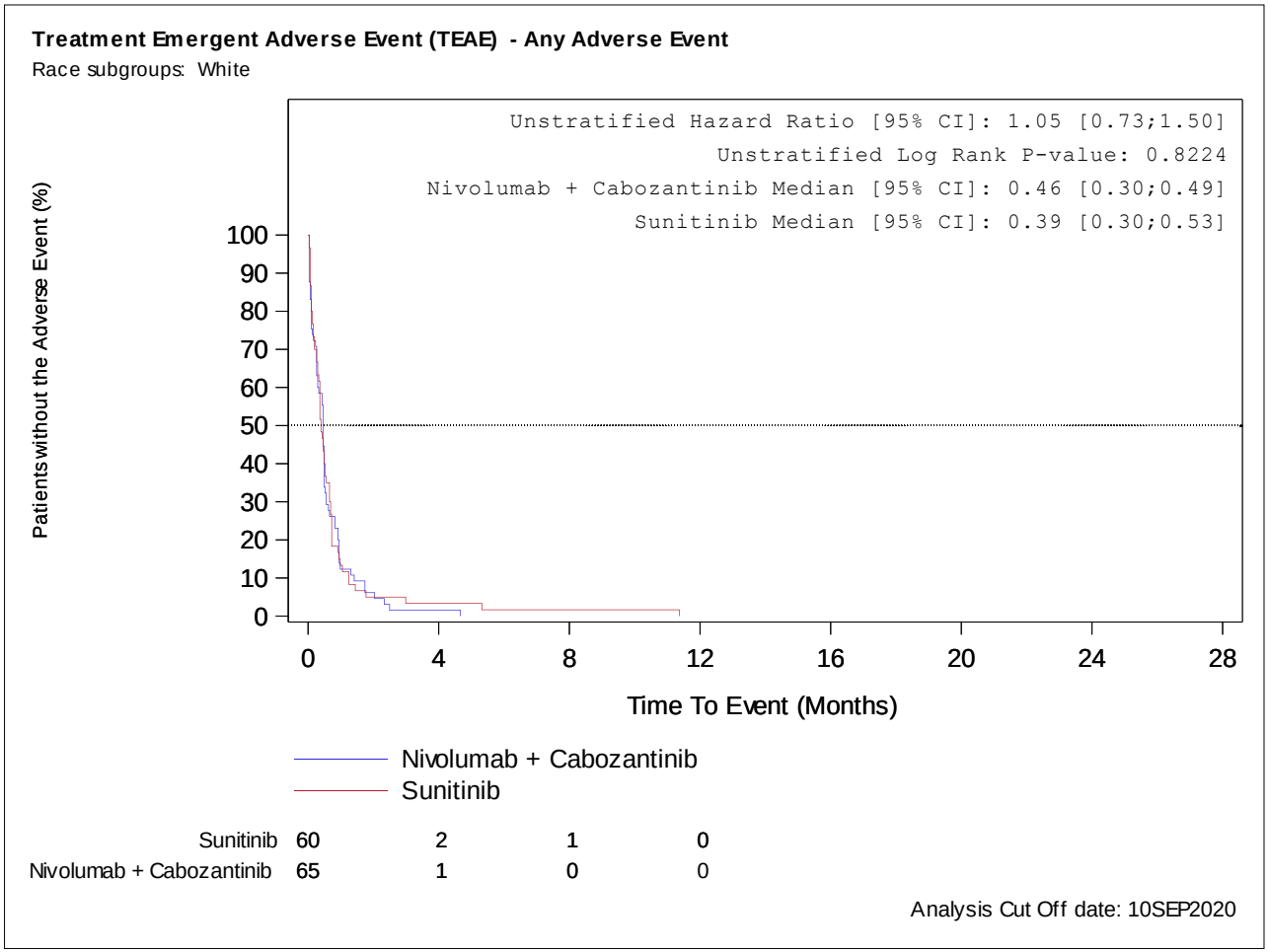
FIGURE 3.1.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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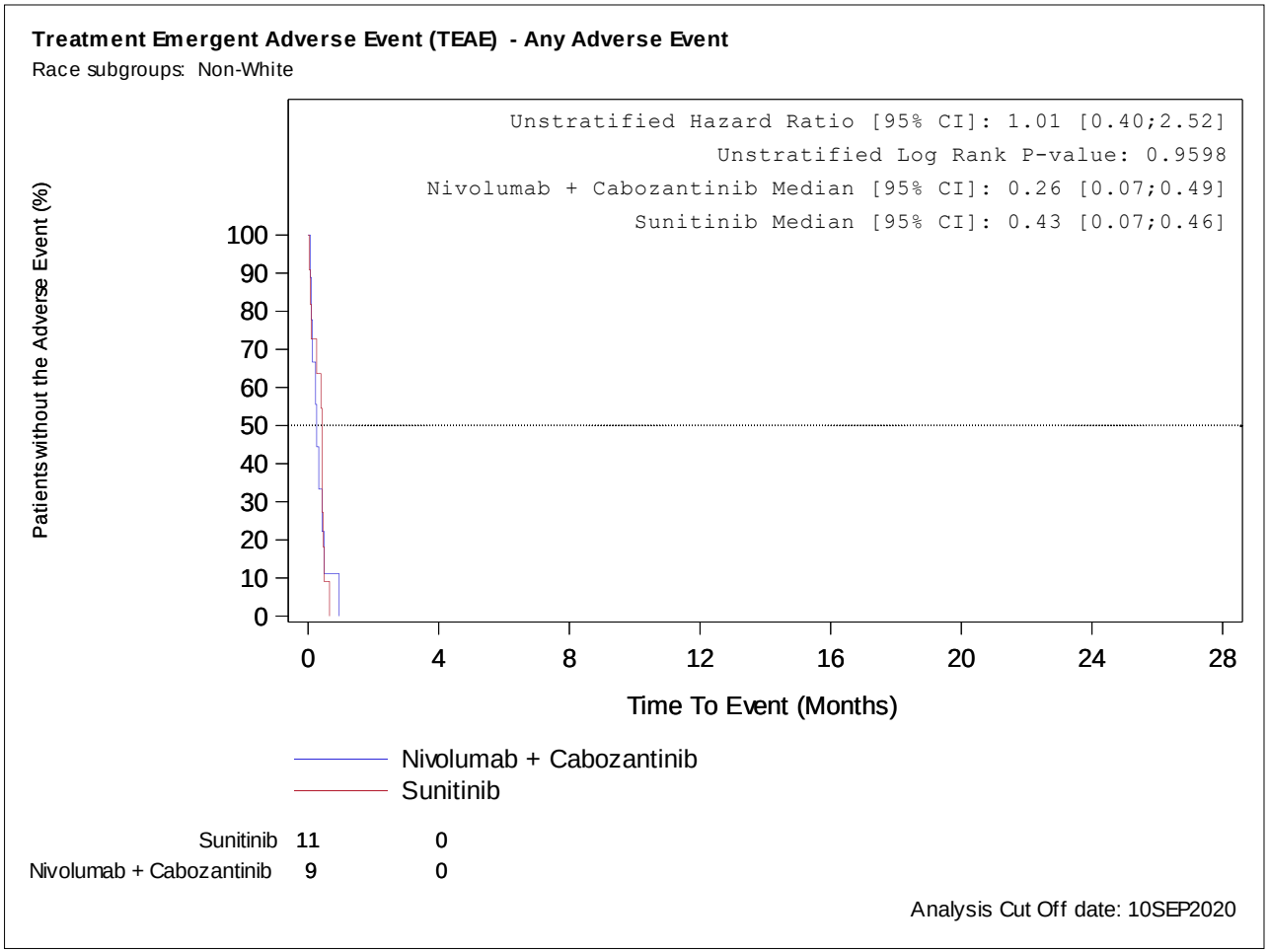
FIGURE 3.1.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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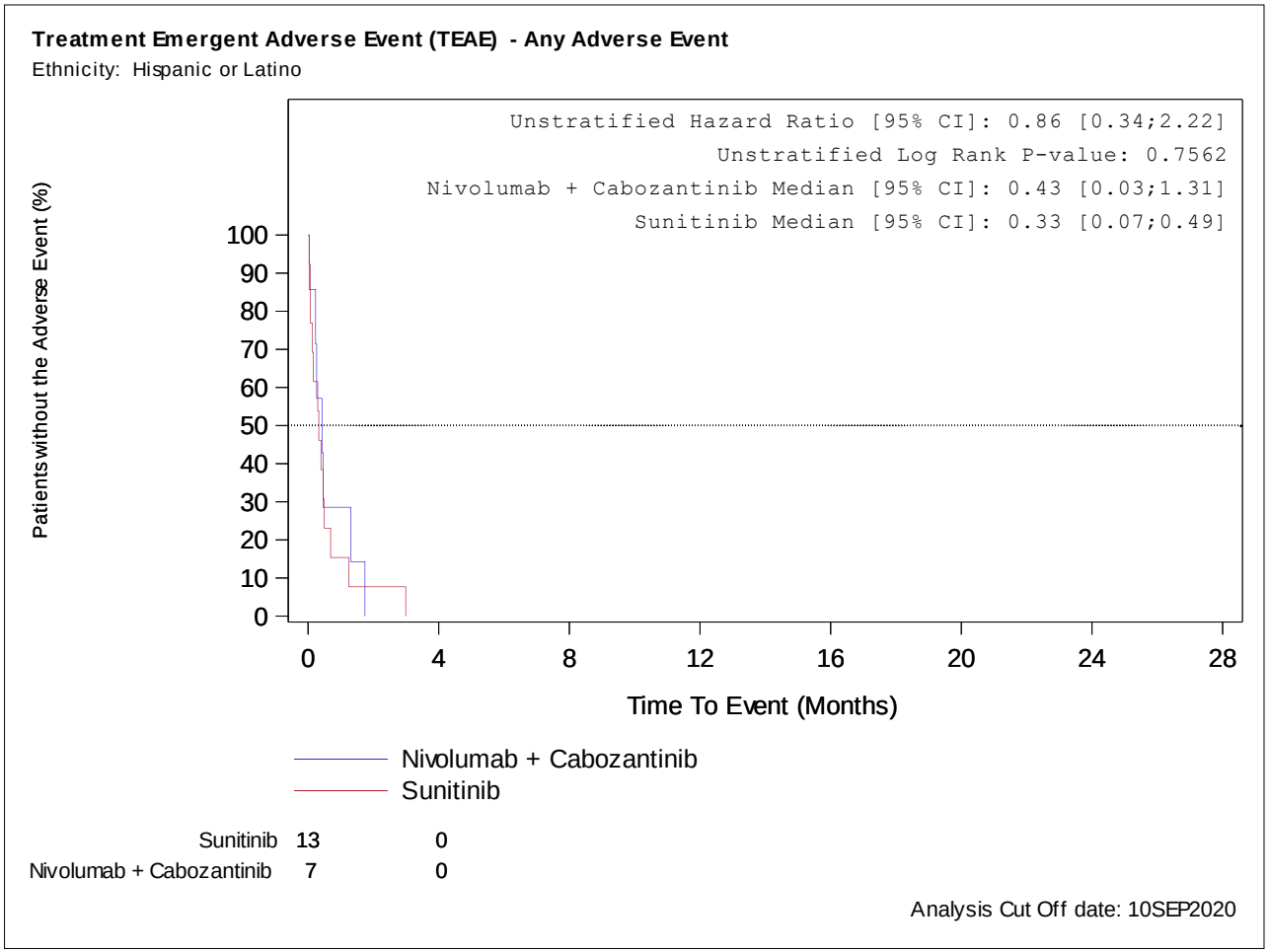
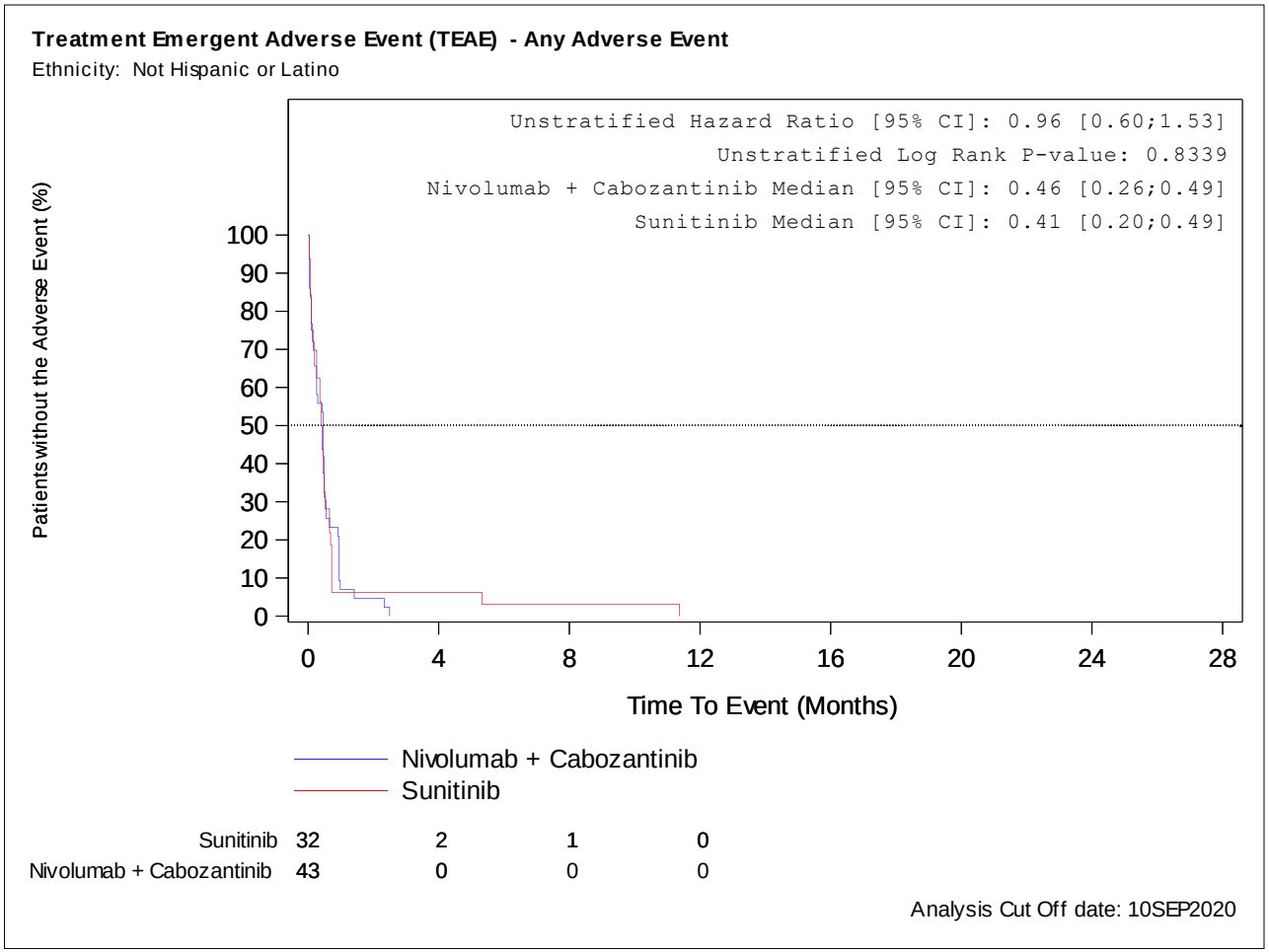
FIGURE 3.1.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



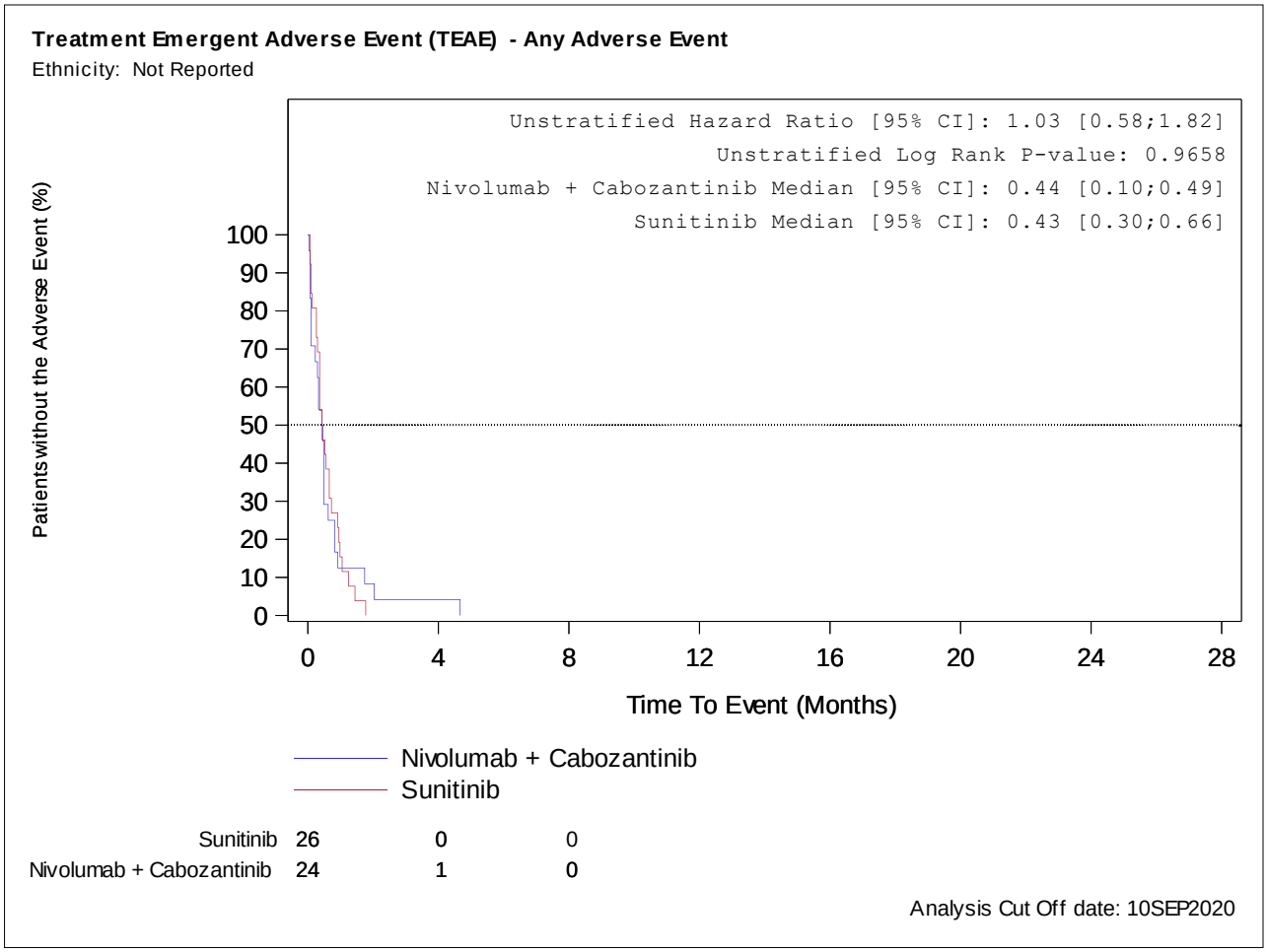

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:07:10

FIGURE 3.1.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



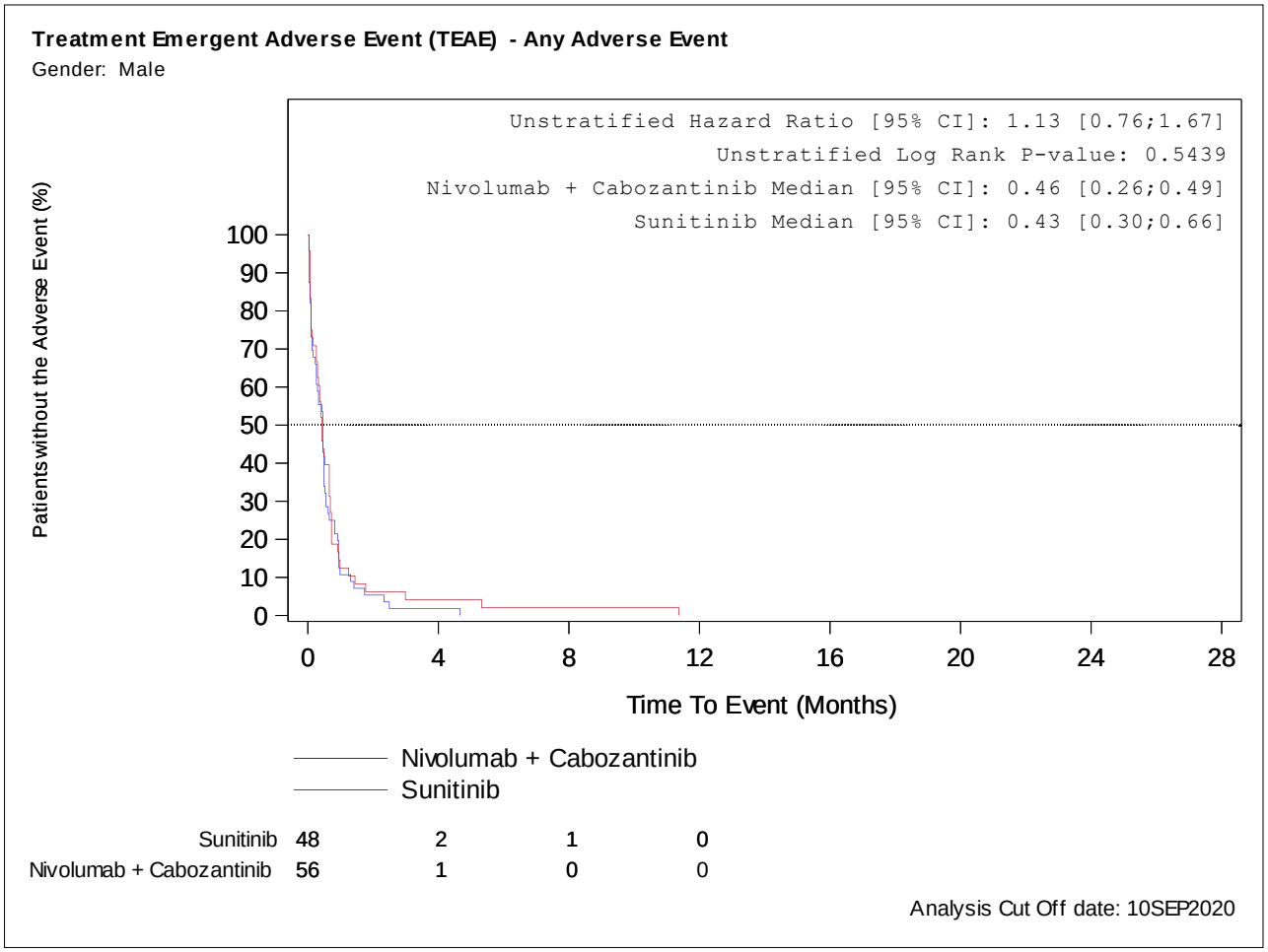

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:07:17

FIGURE 3.1.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



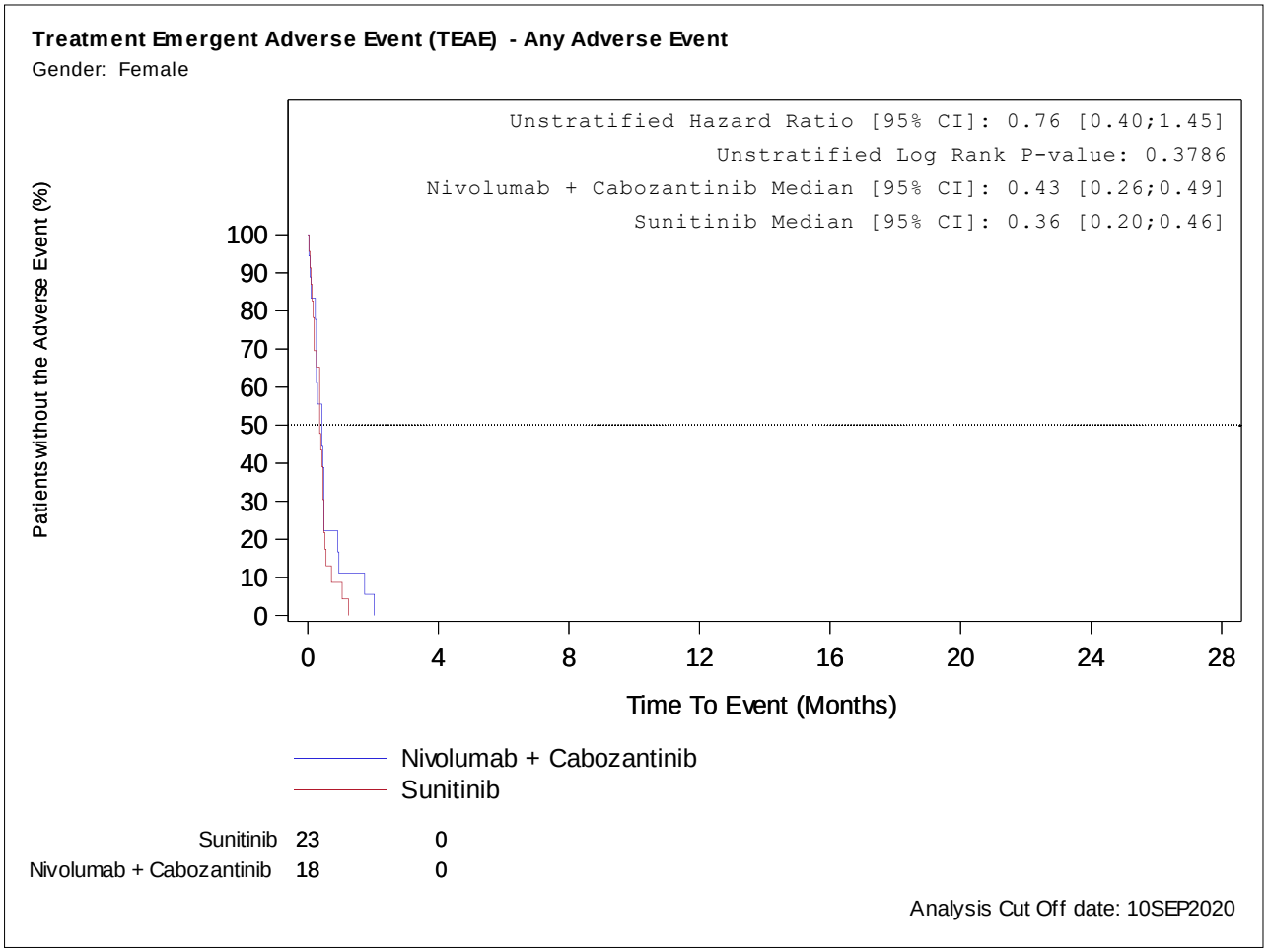

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:07:23

FIGURE 3.1.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



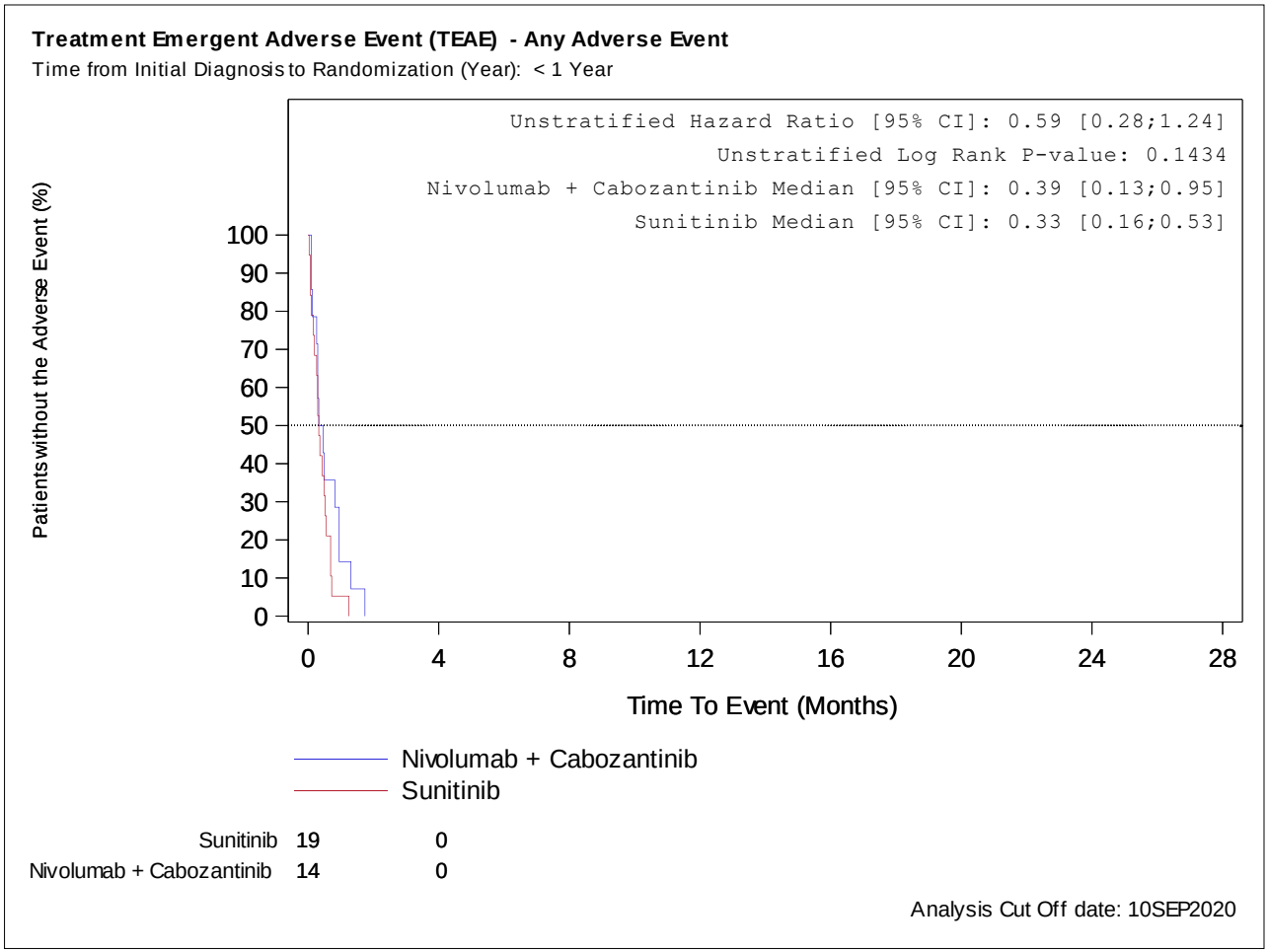

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:07:29

FIGURE 3.1.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:07:35

FIGURE 3.1.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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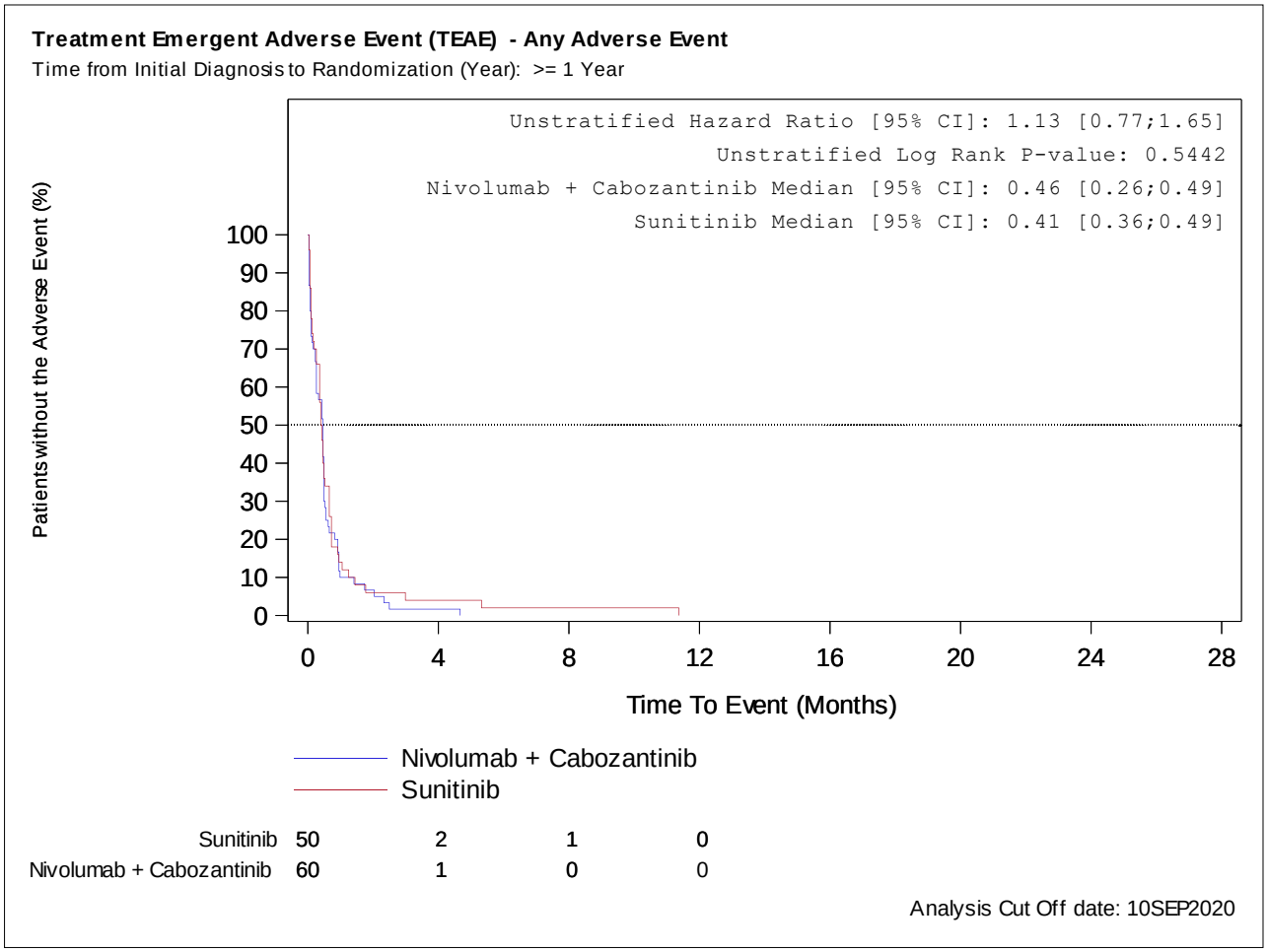
FIGURE 3.1.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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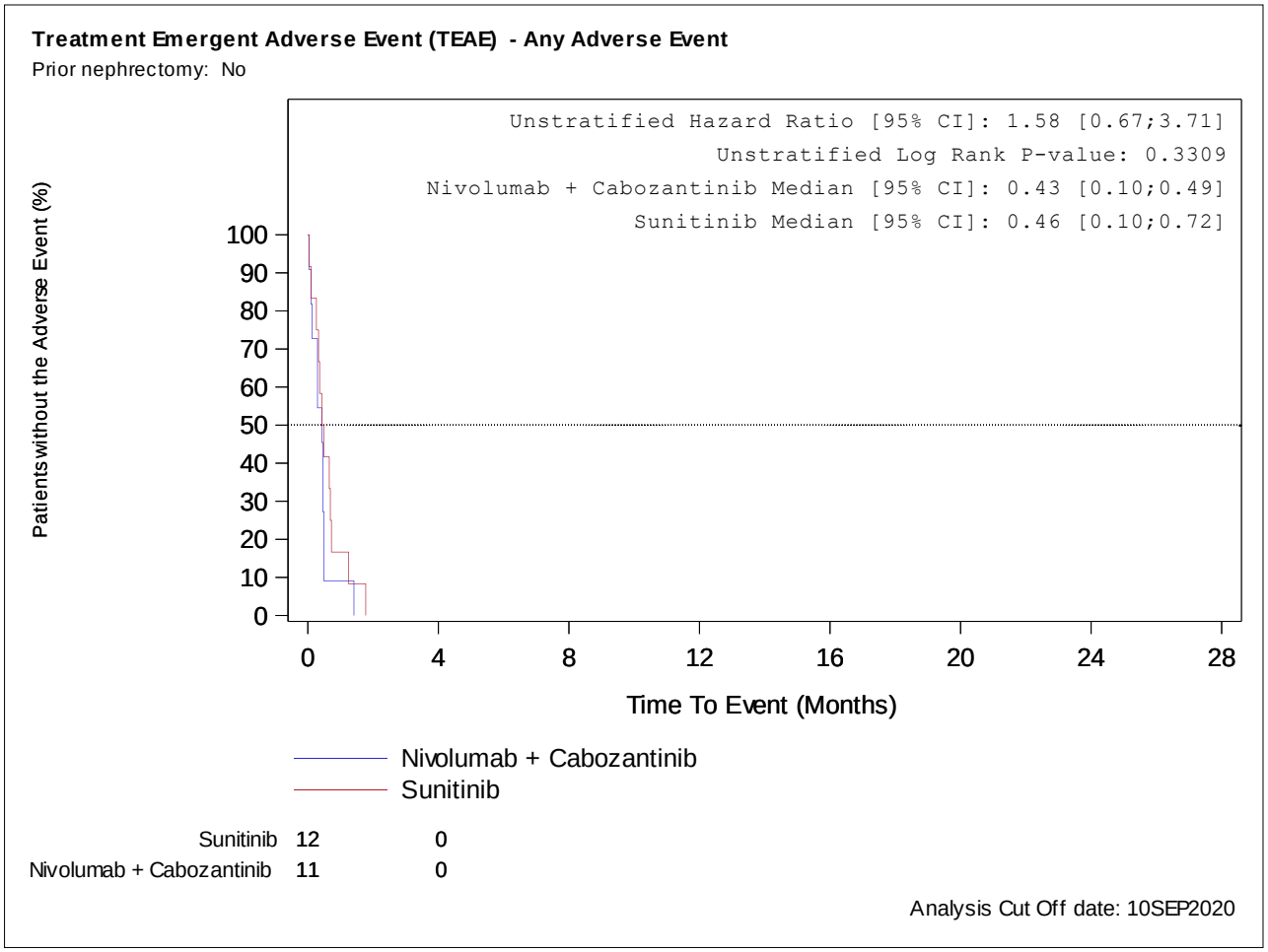
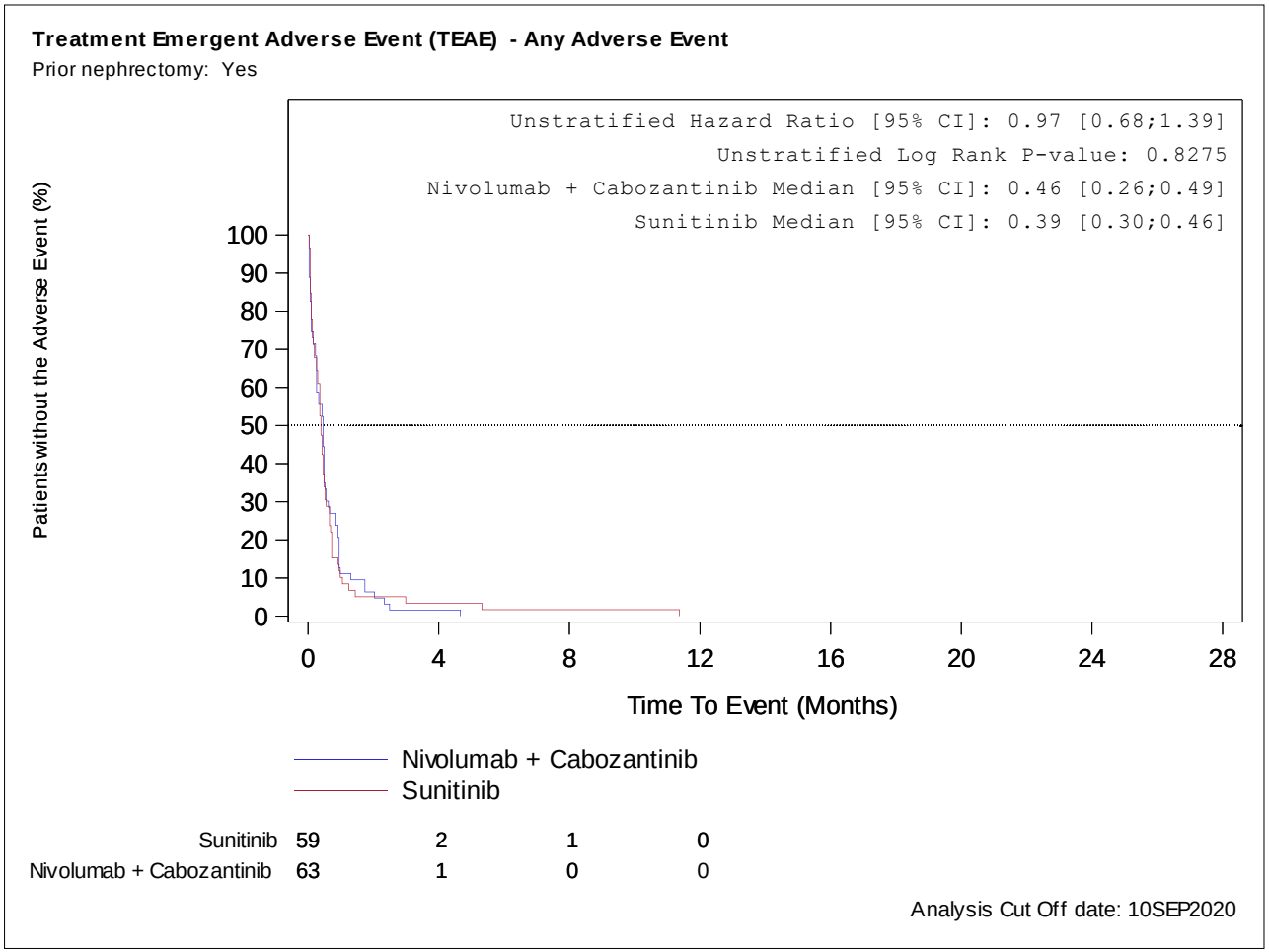
FIGURE 3.1.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



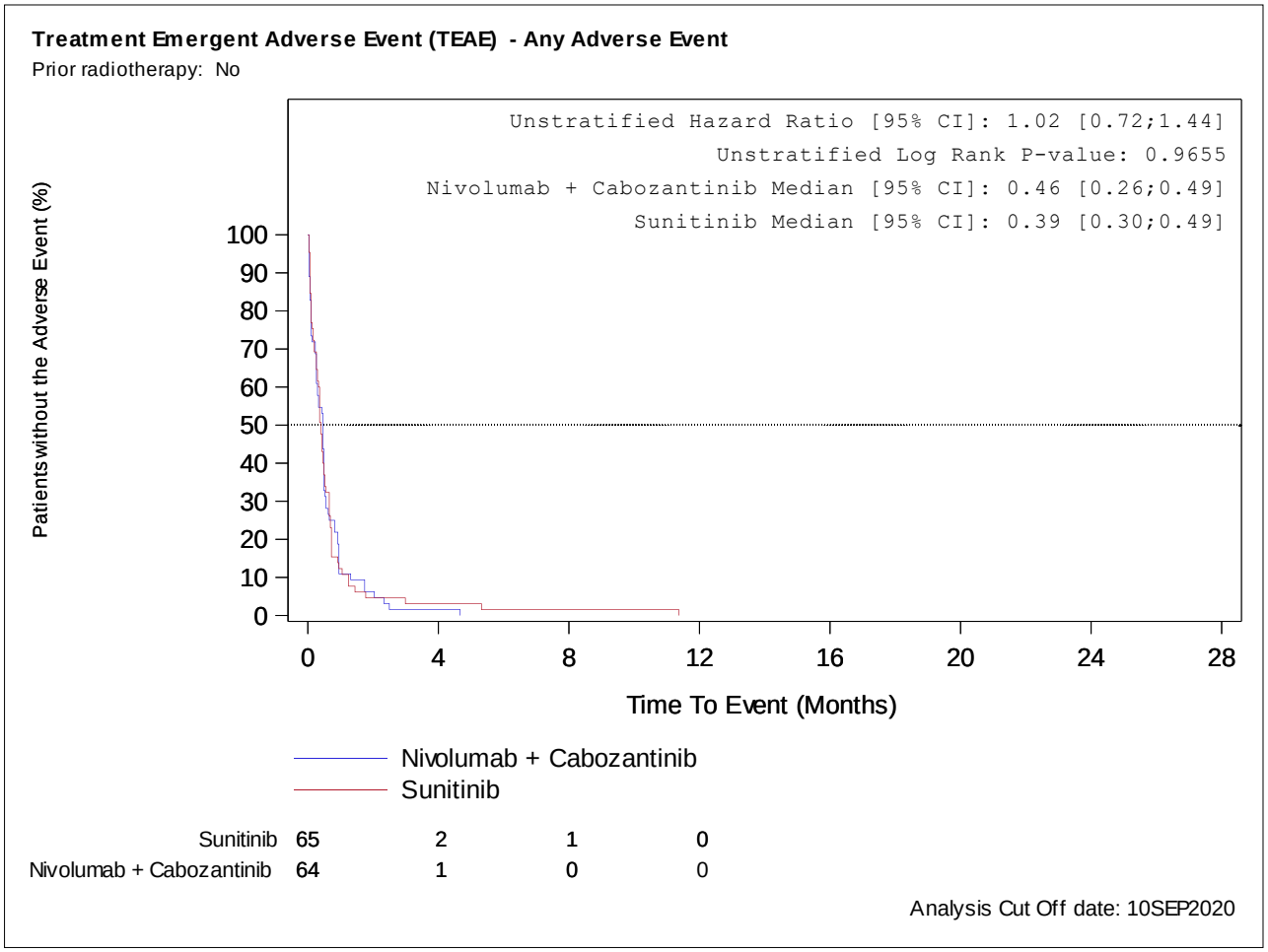

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:08:58

FIGURE 3.1.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



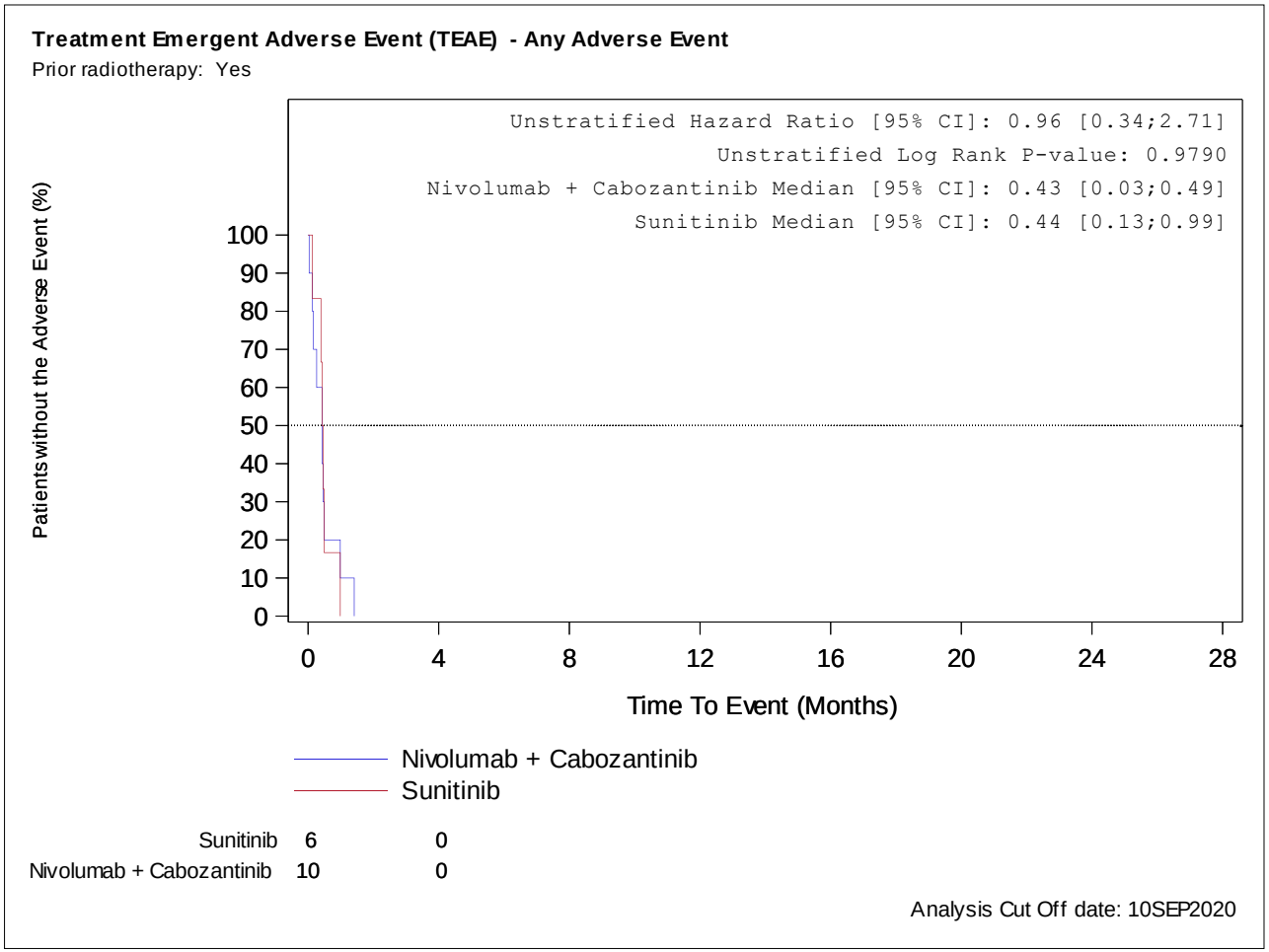

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:09:04

FIGURE 3.1.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



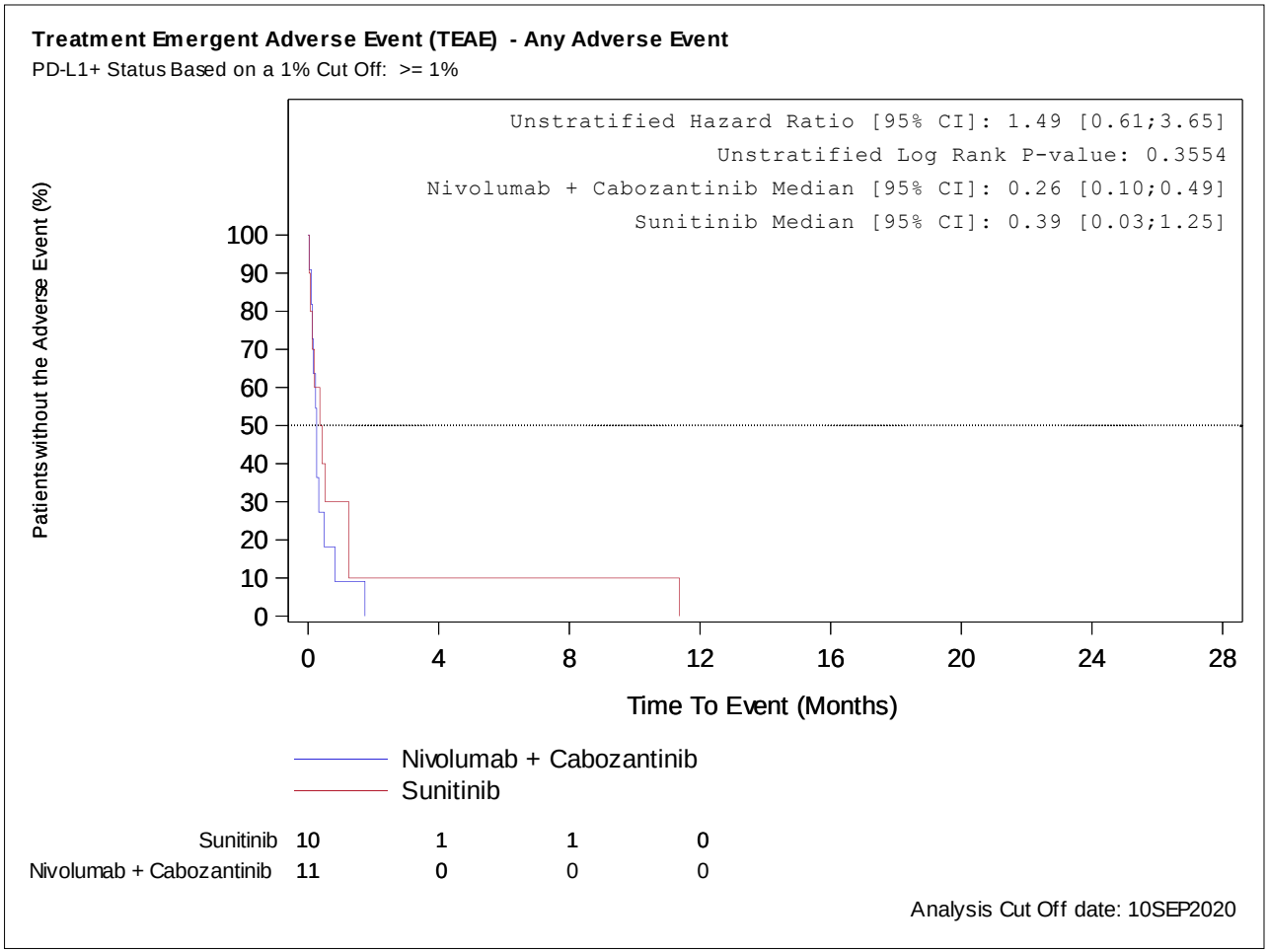

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:09:10

FIGURE 3.1.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



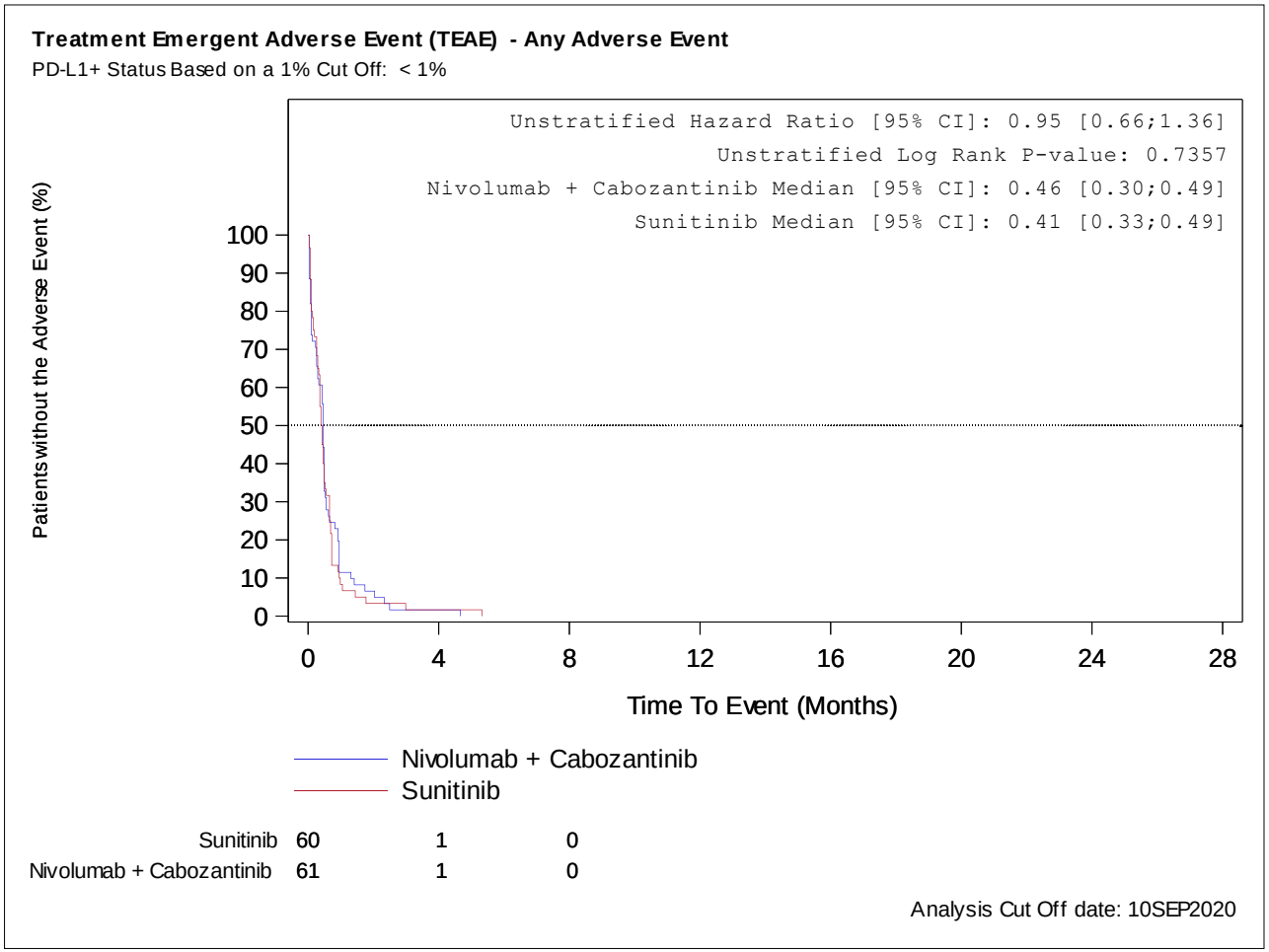

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:09:17

FIGURE 3.1.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



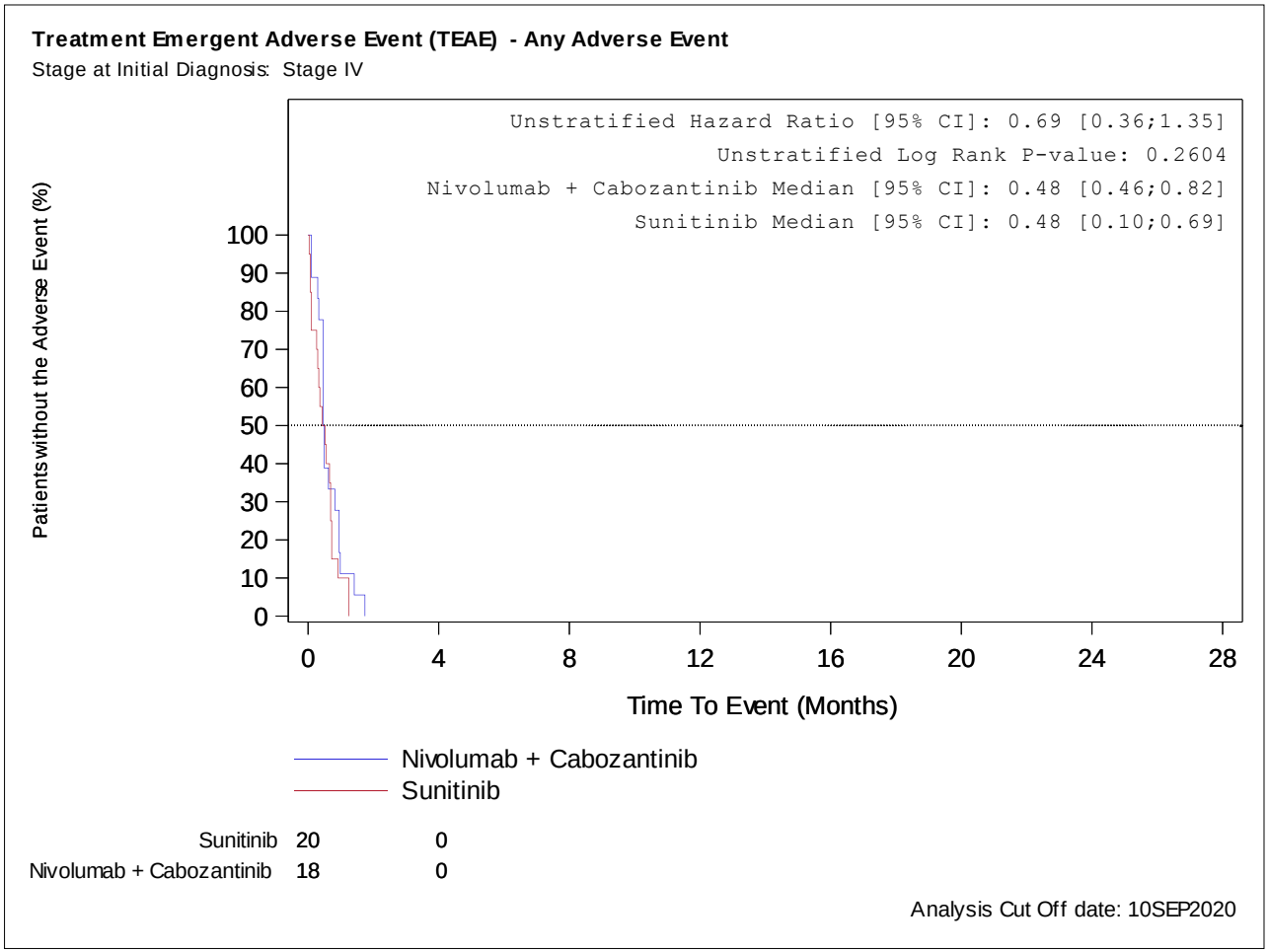

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:09:23

FIGURE 3.1.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



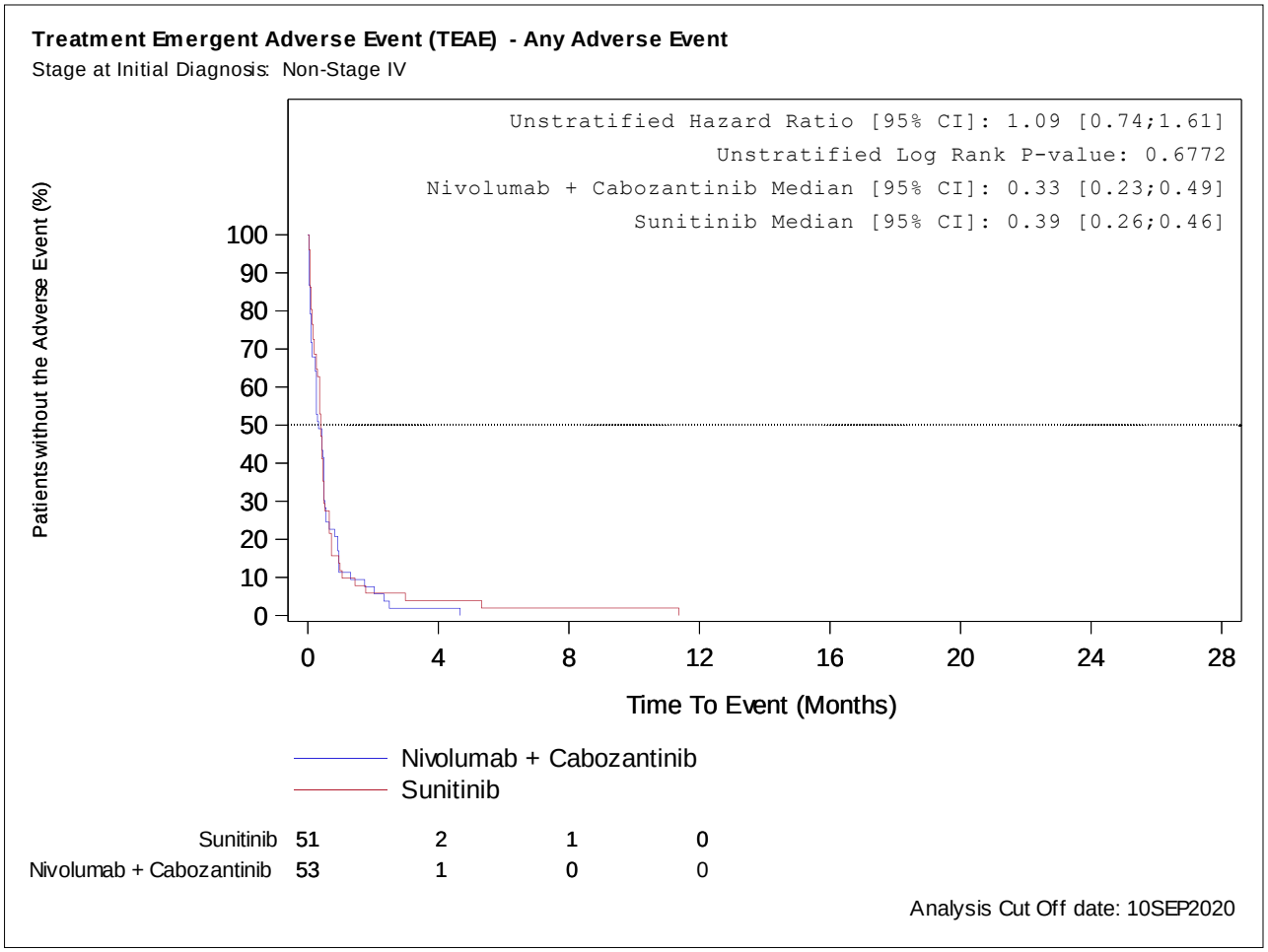

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:09:29

FIGURE 3.1.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



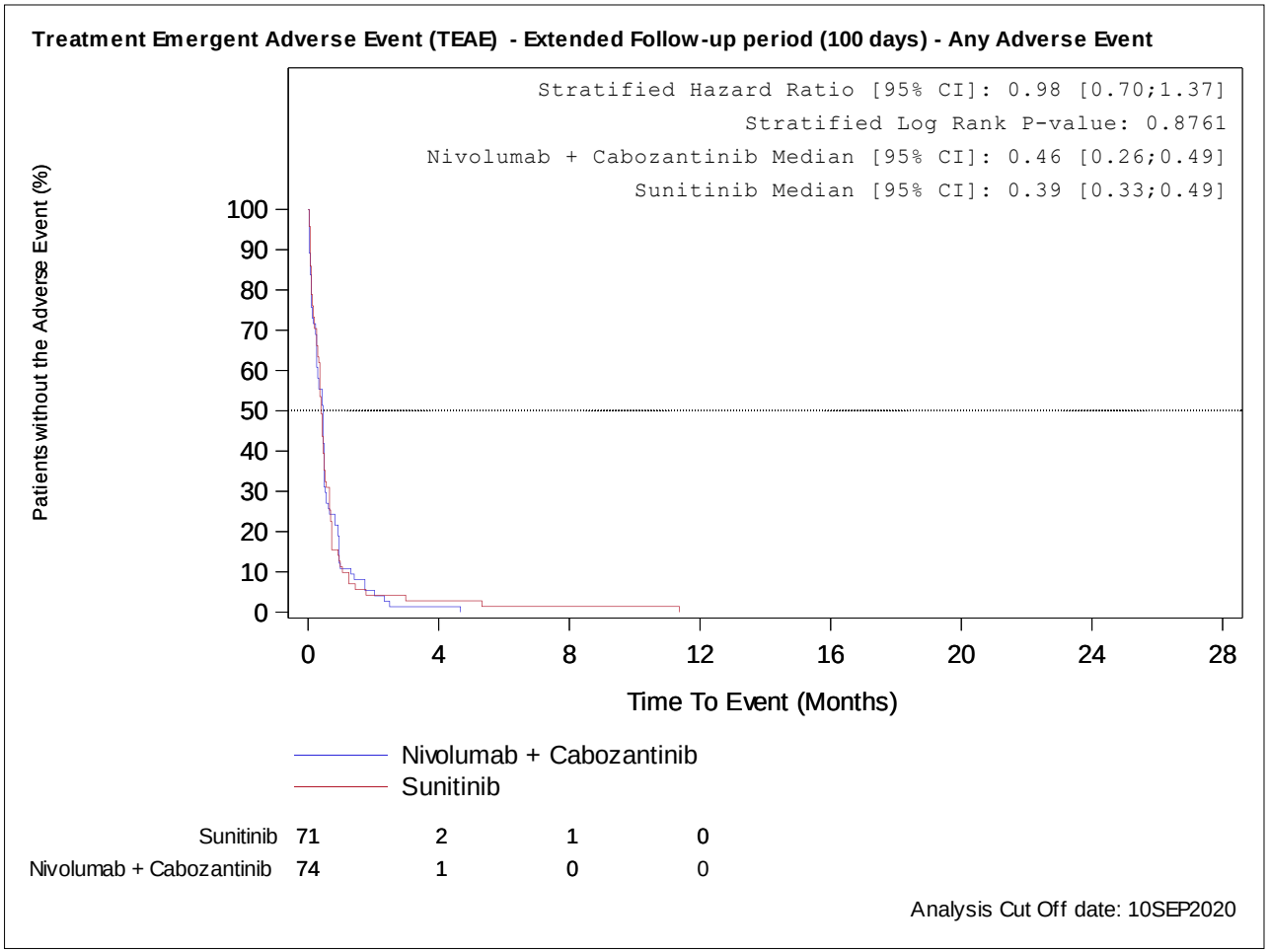

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:10:00

FIGURE 3.1.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



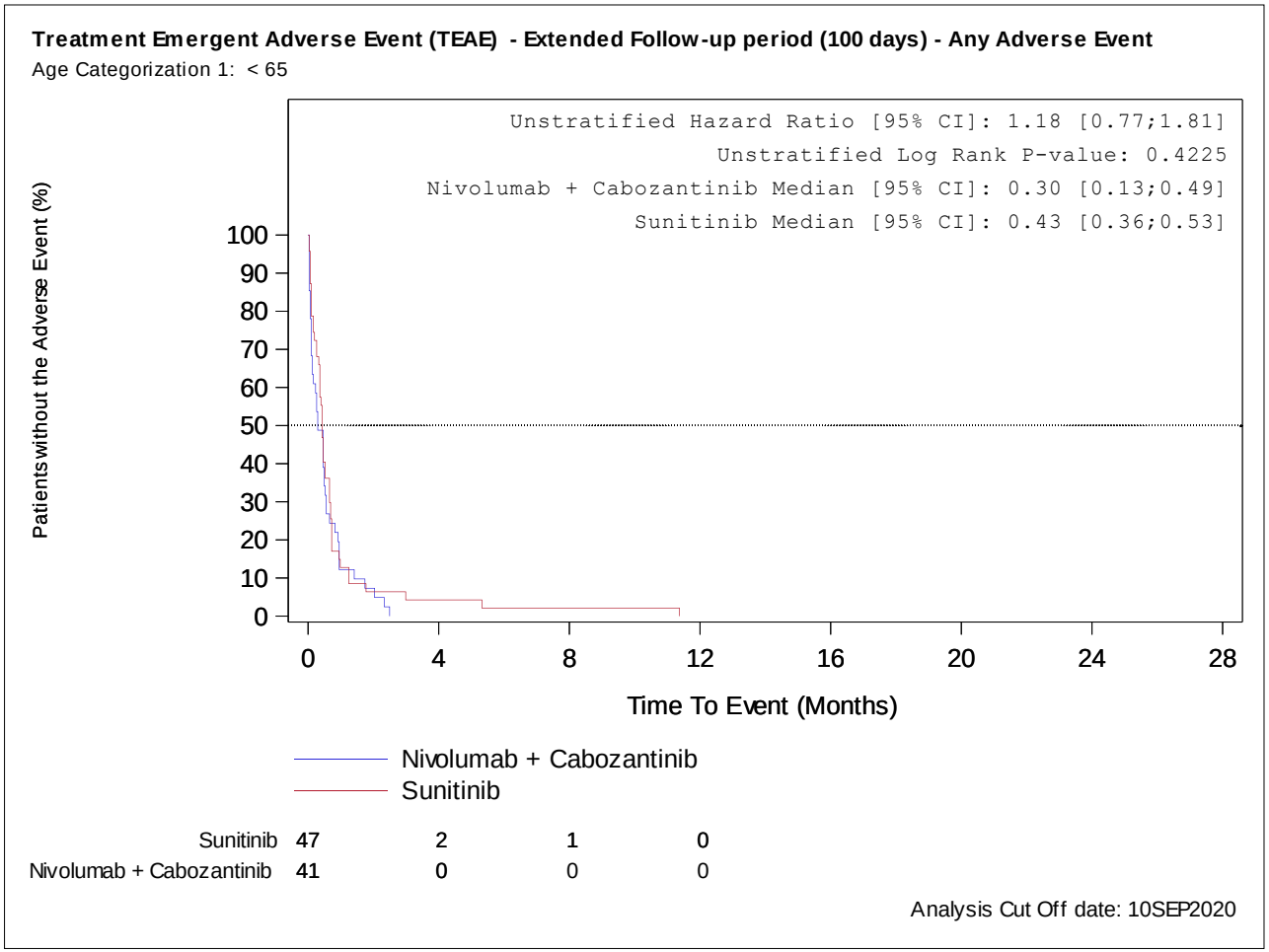

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:10:07

FIGURE 3.2.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:13:40

FIGURE 3.2.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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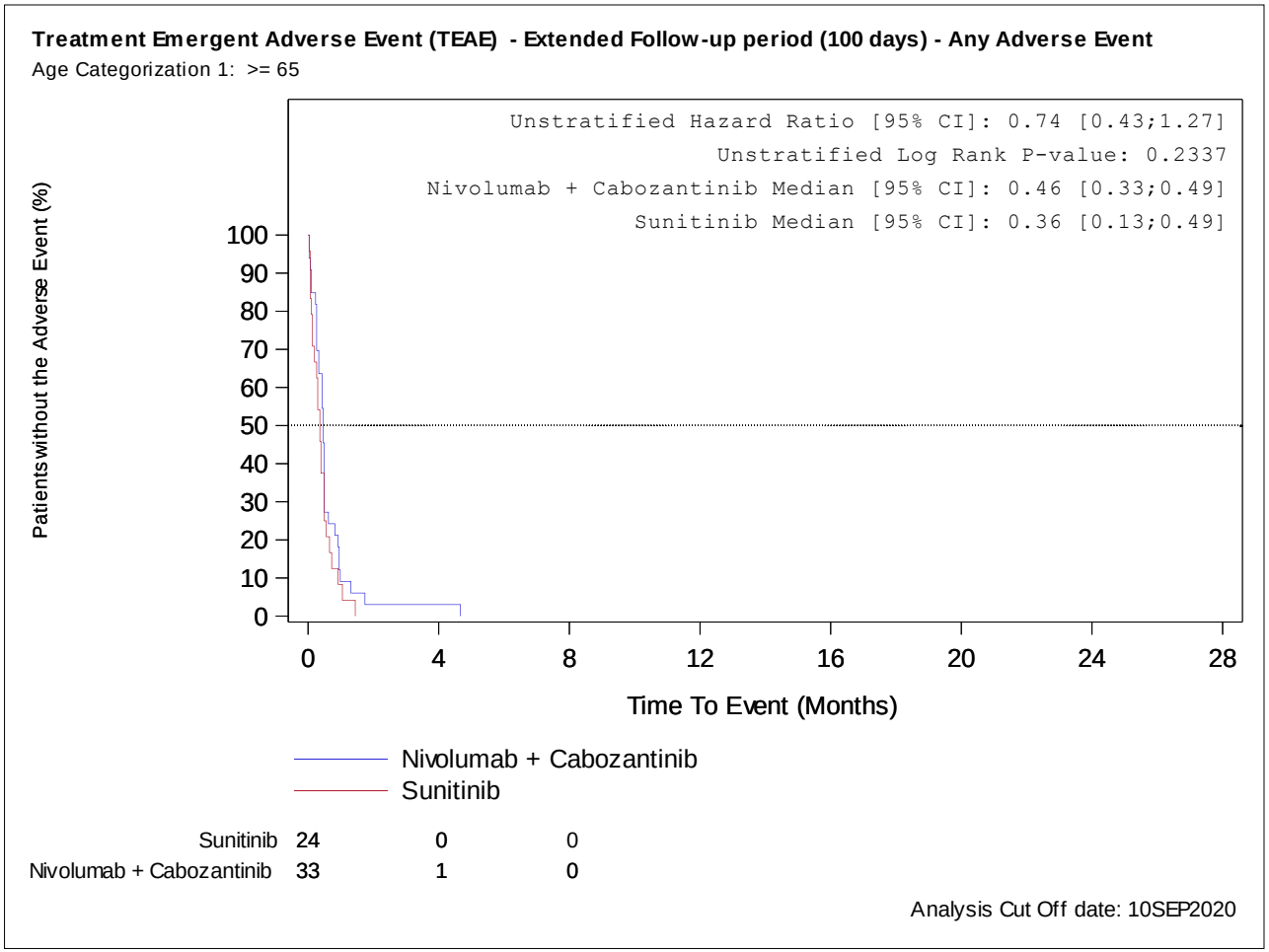
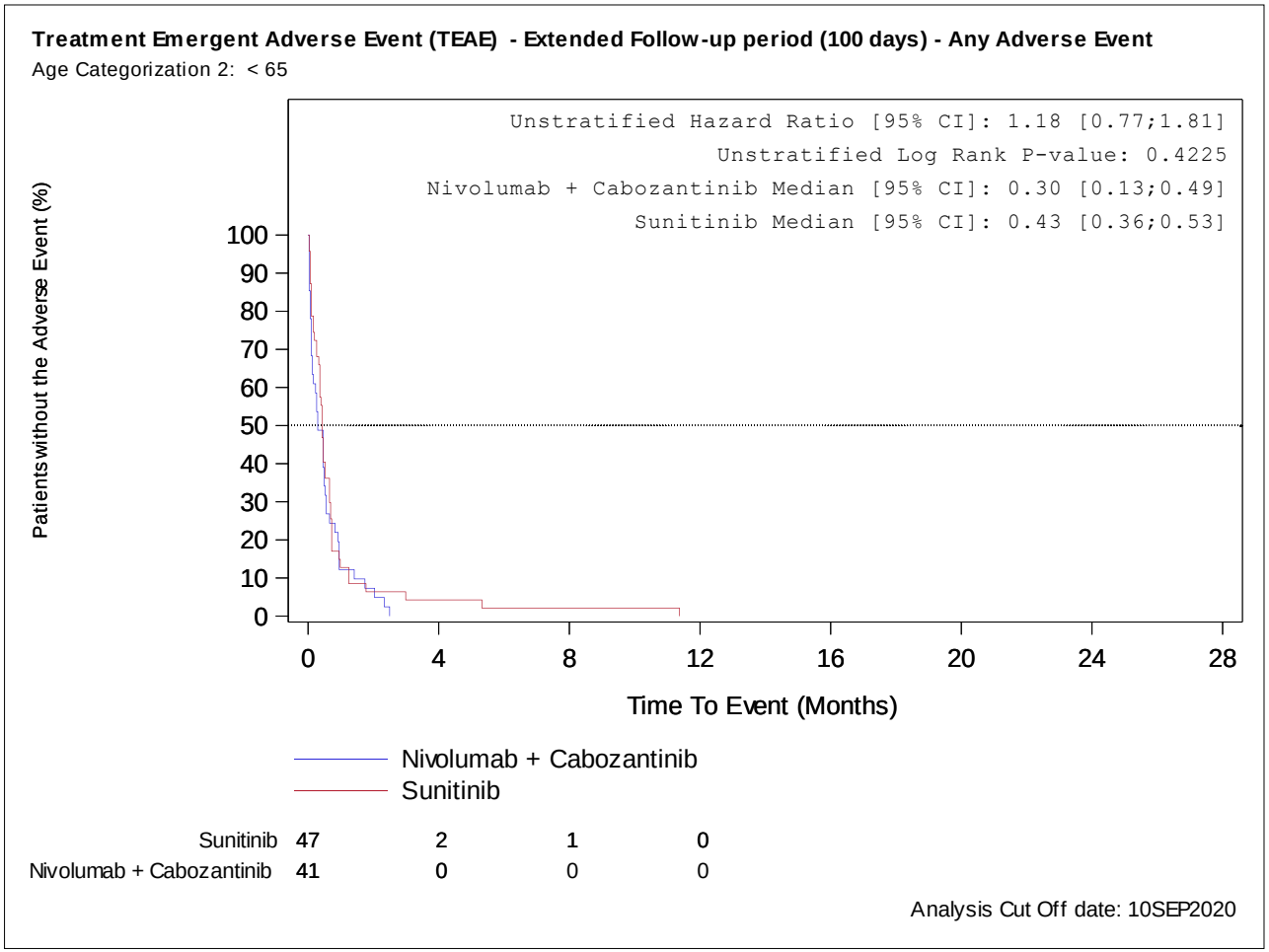
FIGURE 3.2.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



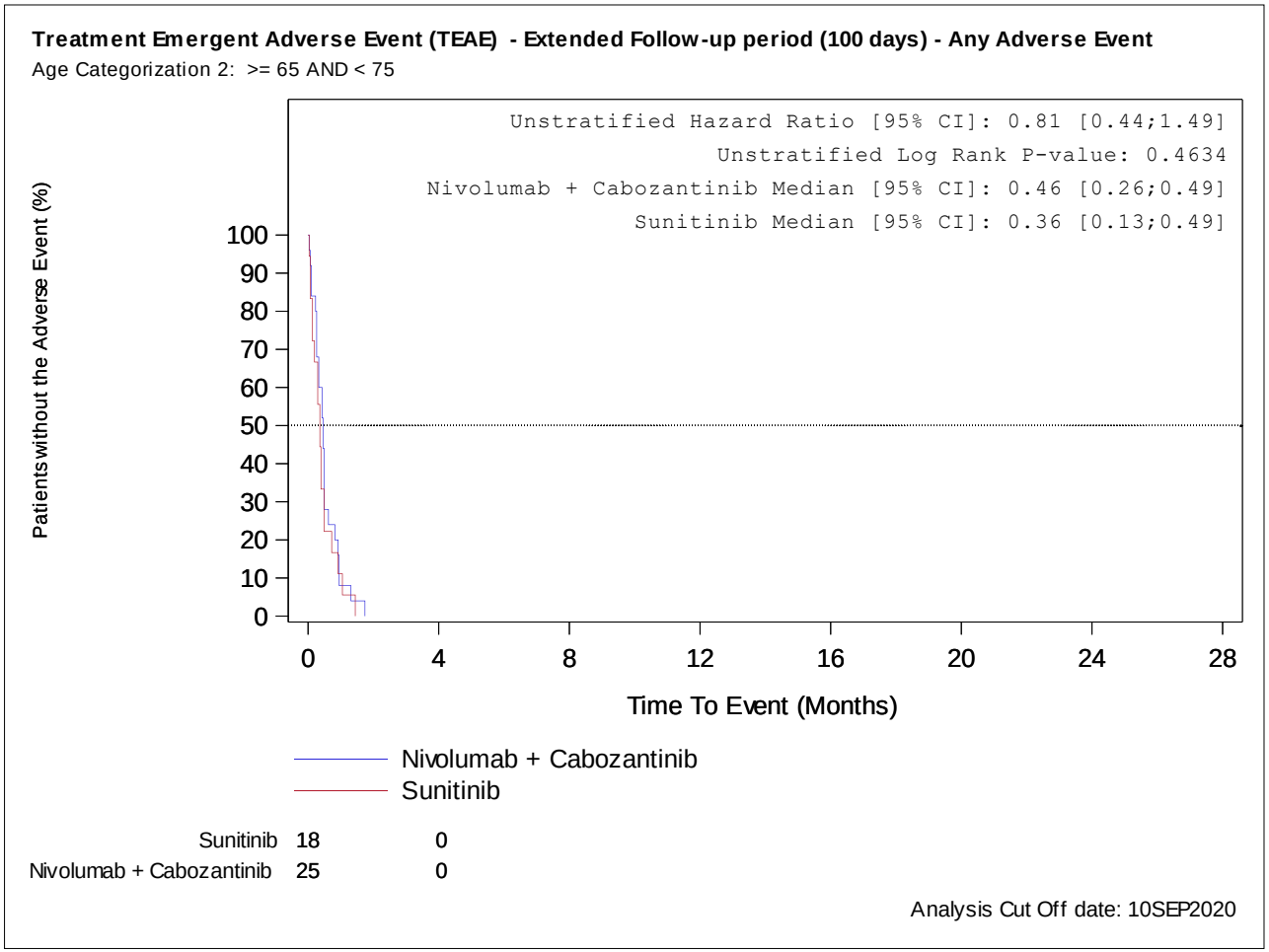

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:13:50

FIGURE 3.2.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



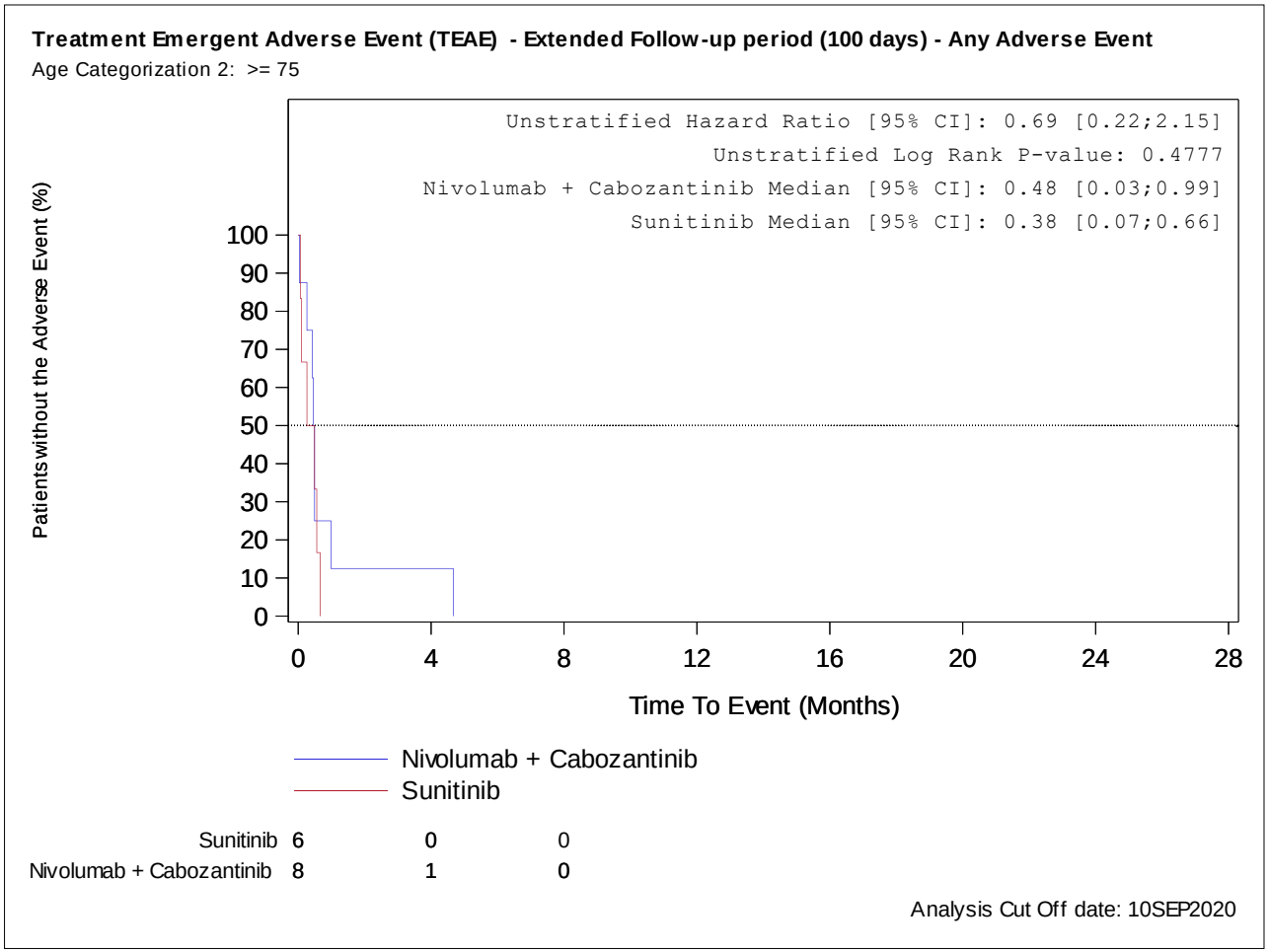

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:13:57

FIGURE 3.2.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



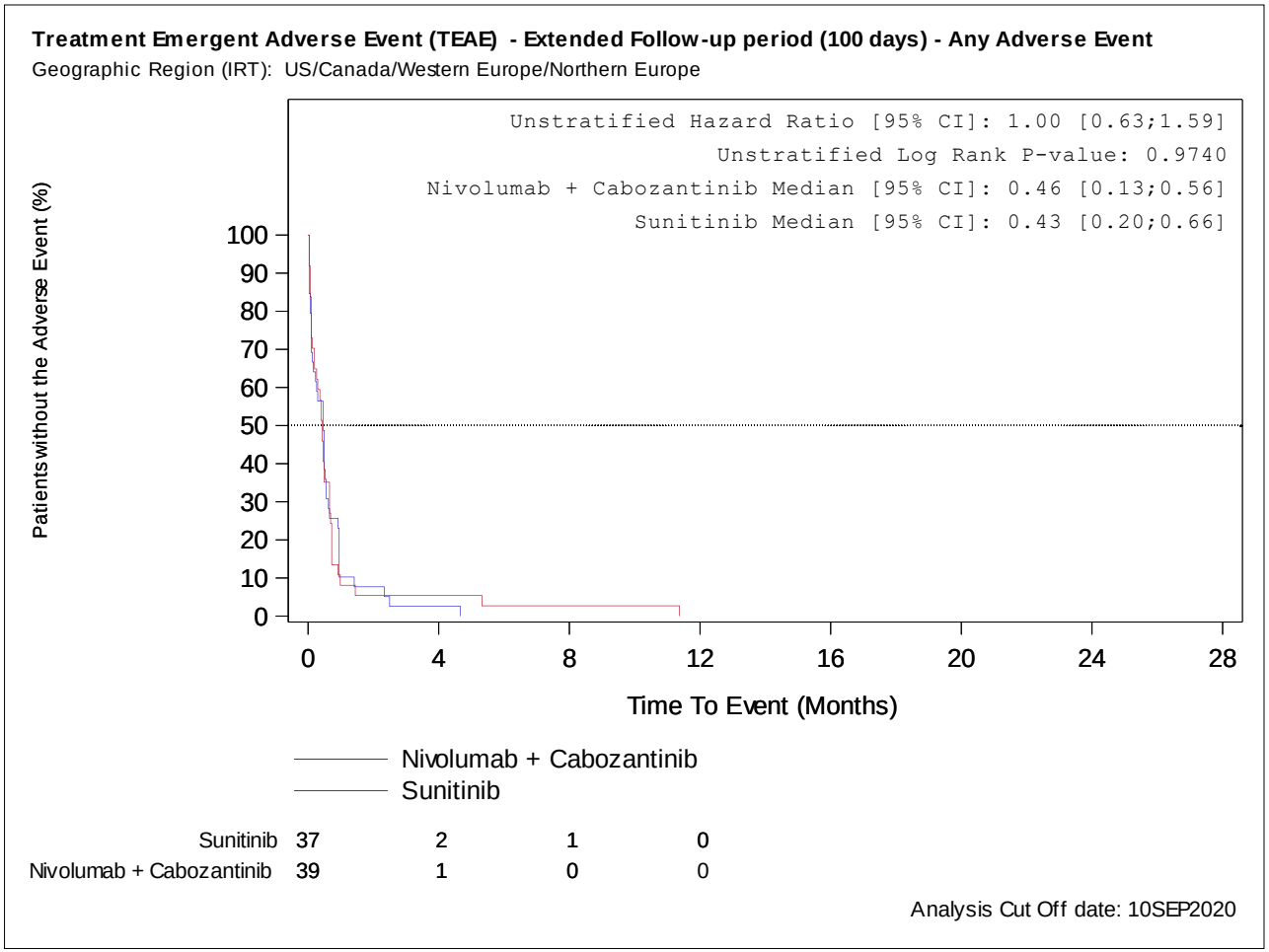

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:14:03

FIGURE 3.2.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



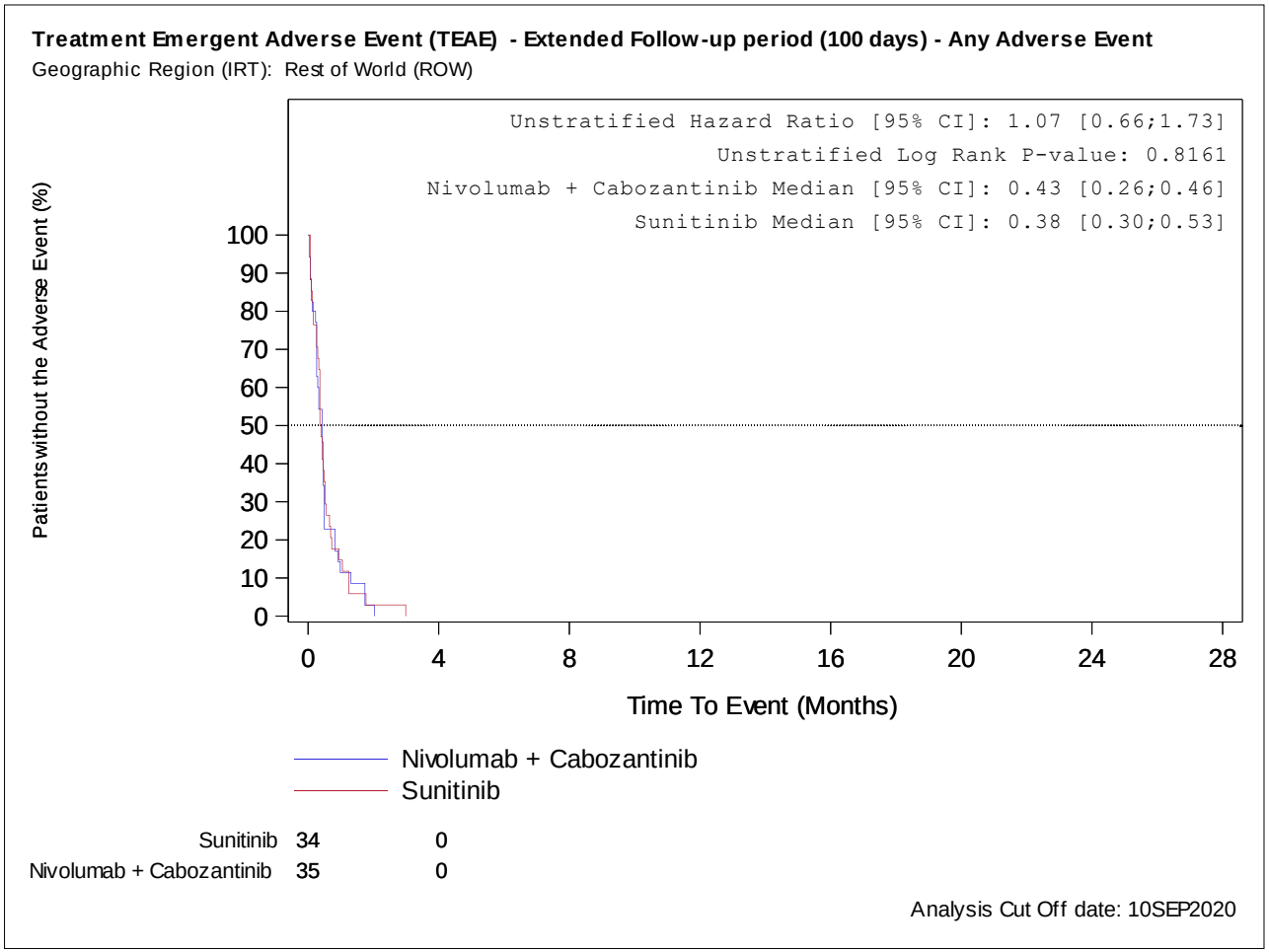

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:14:09

FIGURE 3.2.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



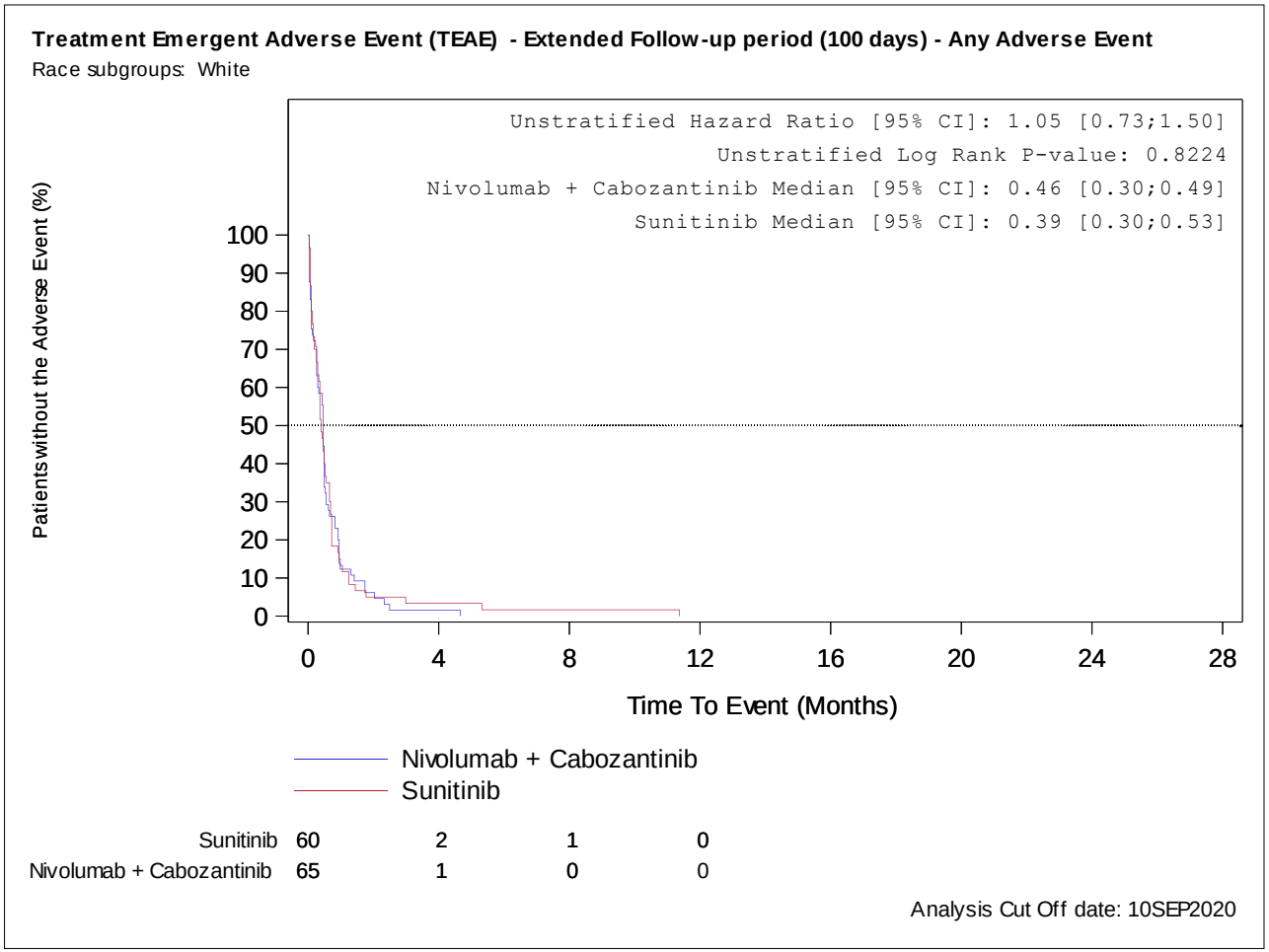

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:14:14

FIGURE 3.2.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



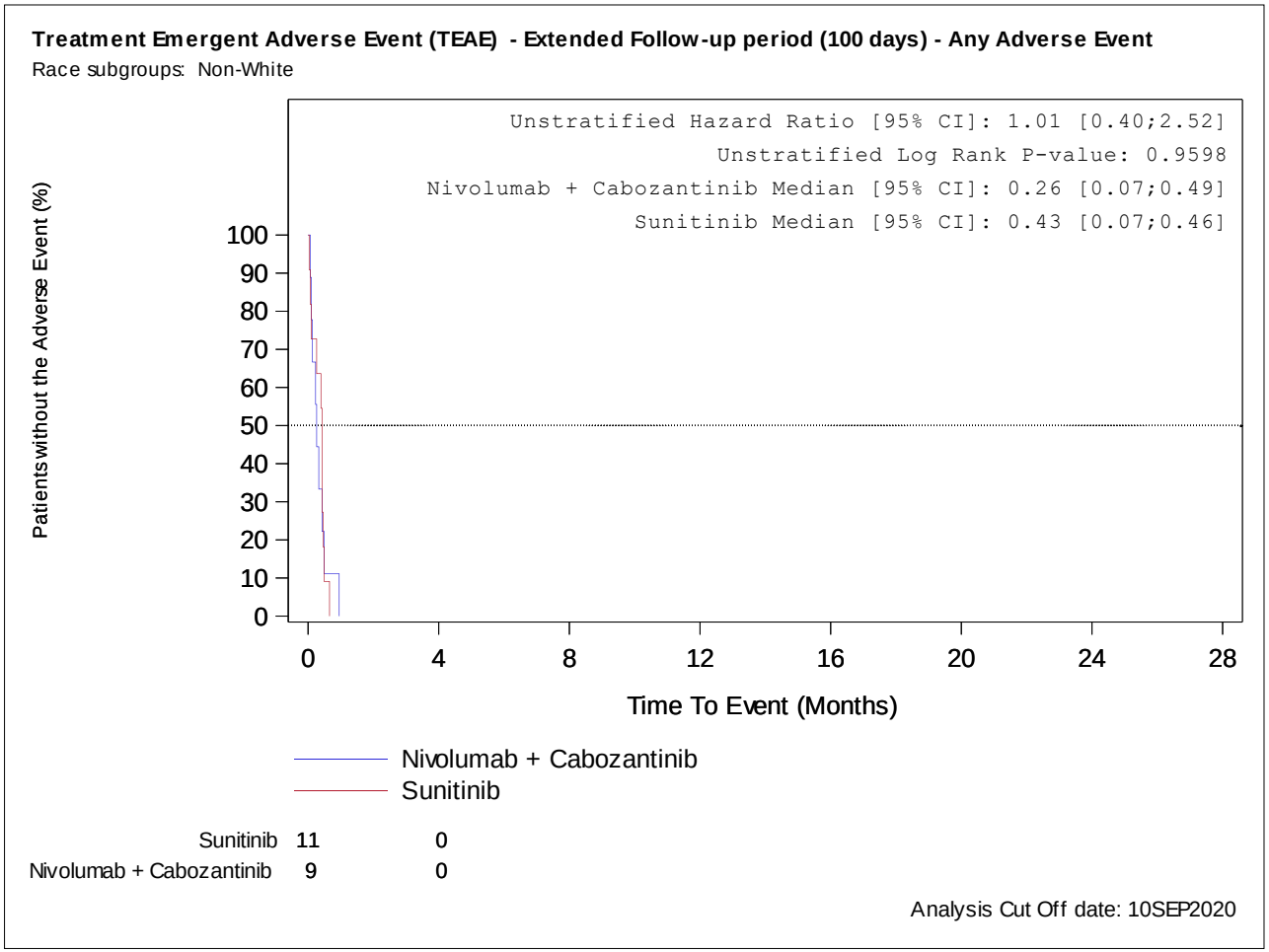

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:14:21

FIGURE 3.2.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



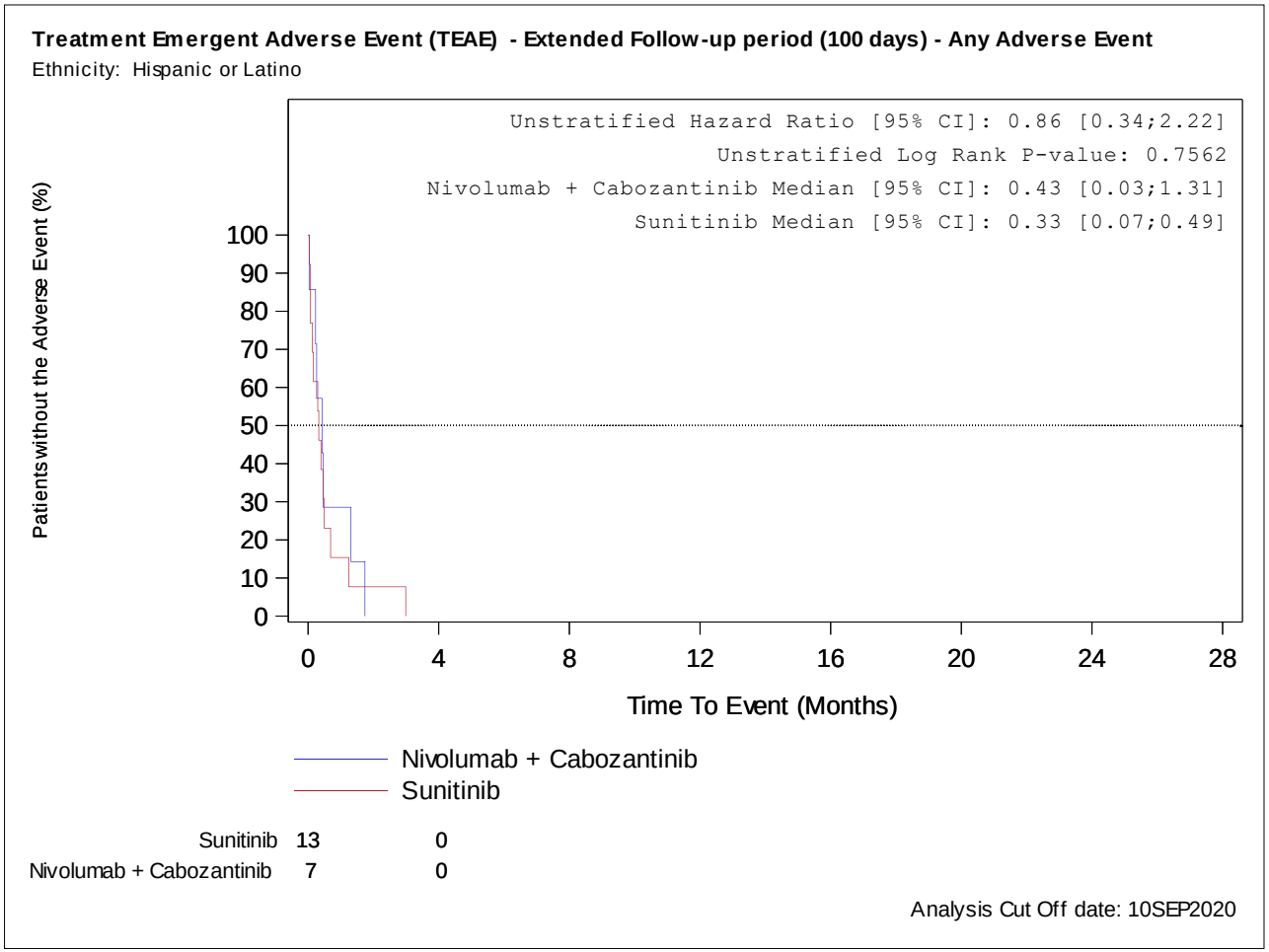

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:14:27

FIGURE 3.2.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



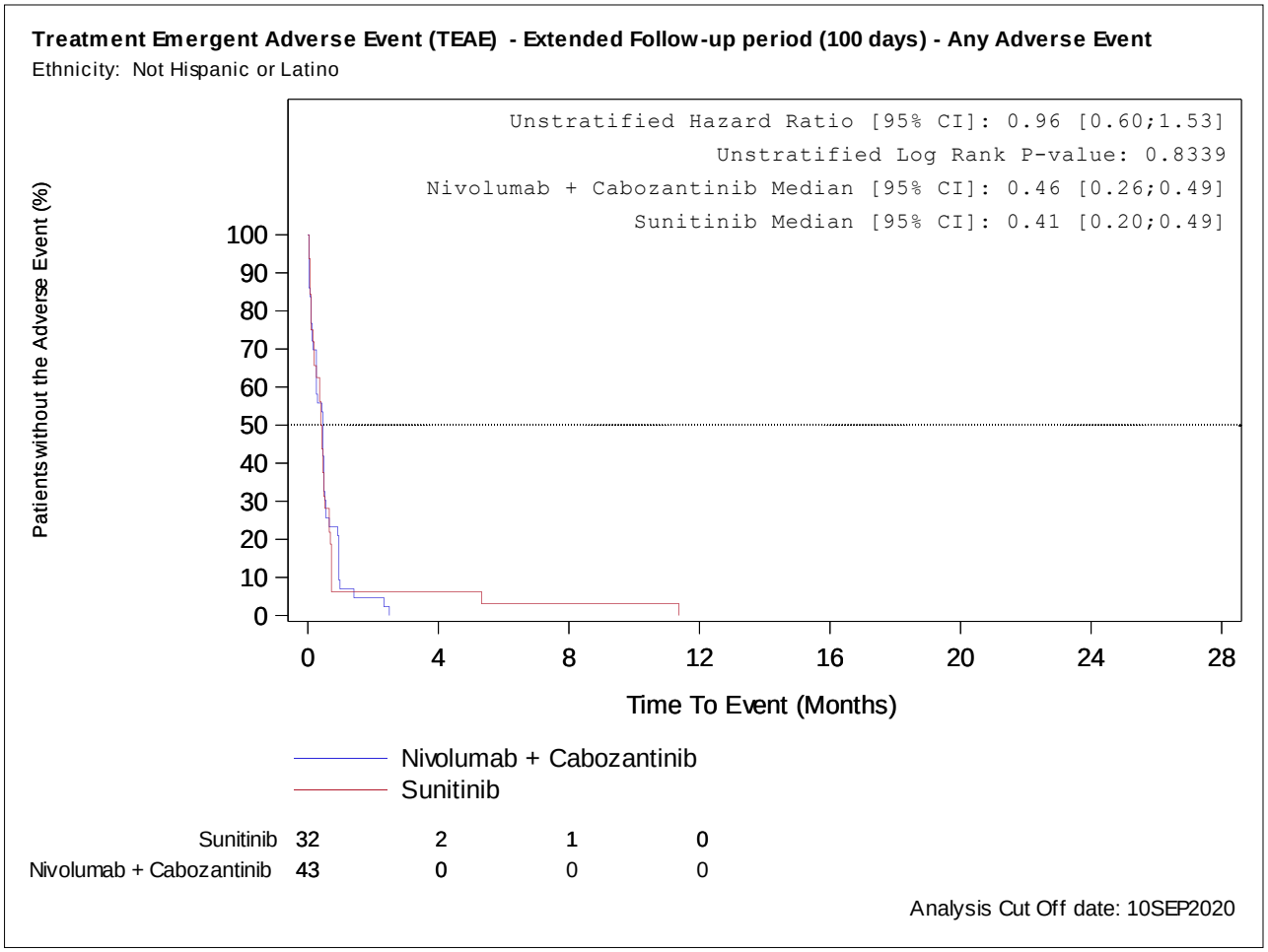

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:14:32

FIGURE 3.2.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



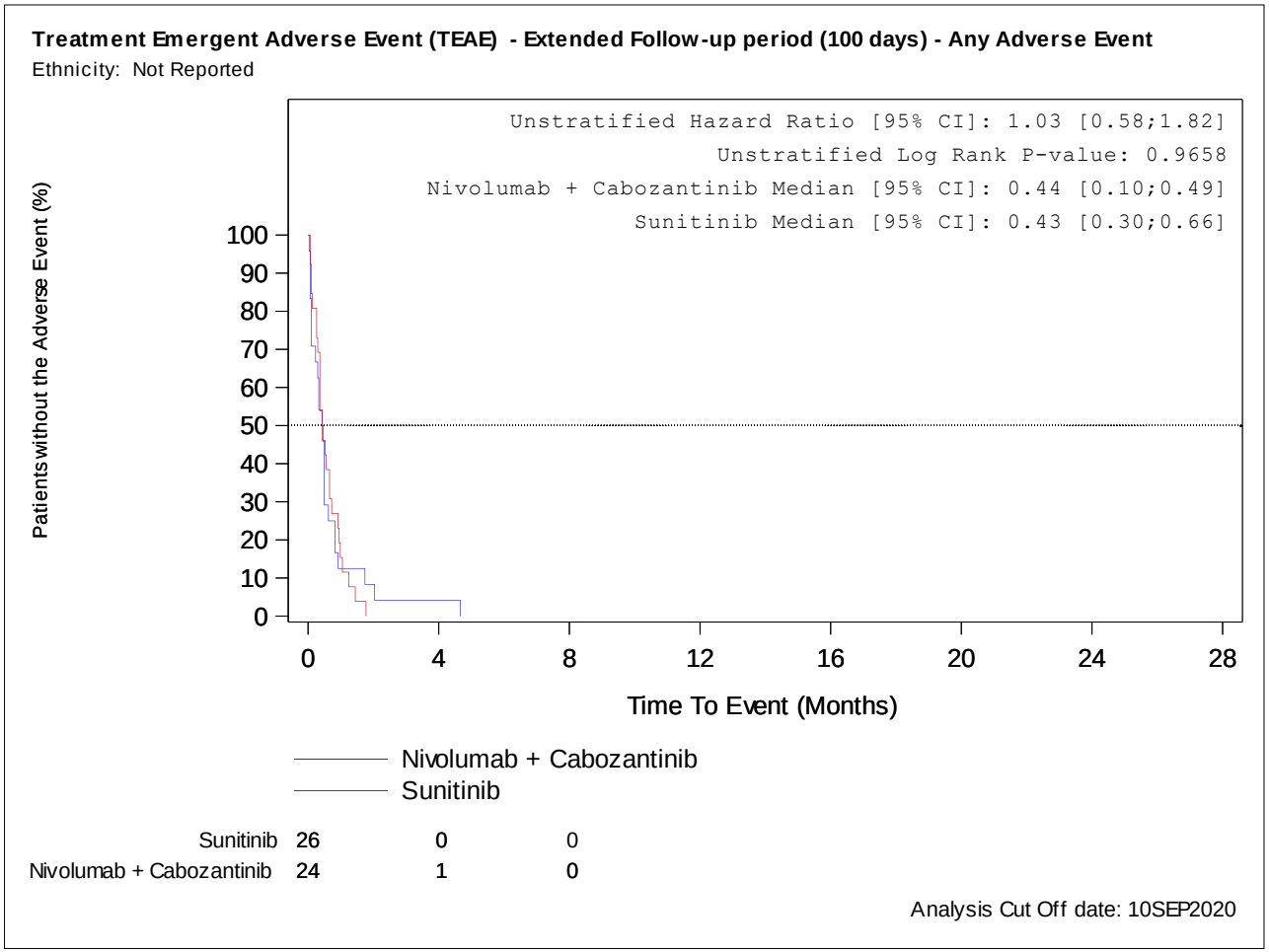

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:14:39

FIGURE 3.2.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



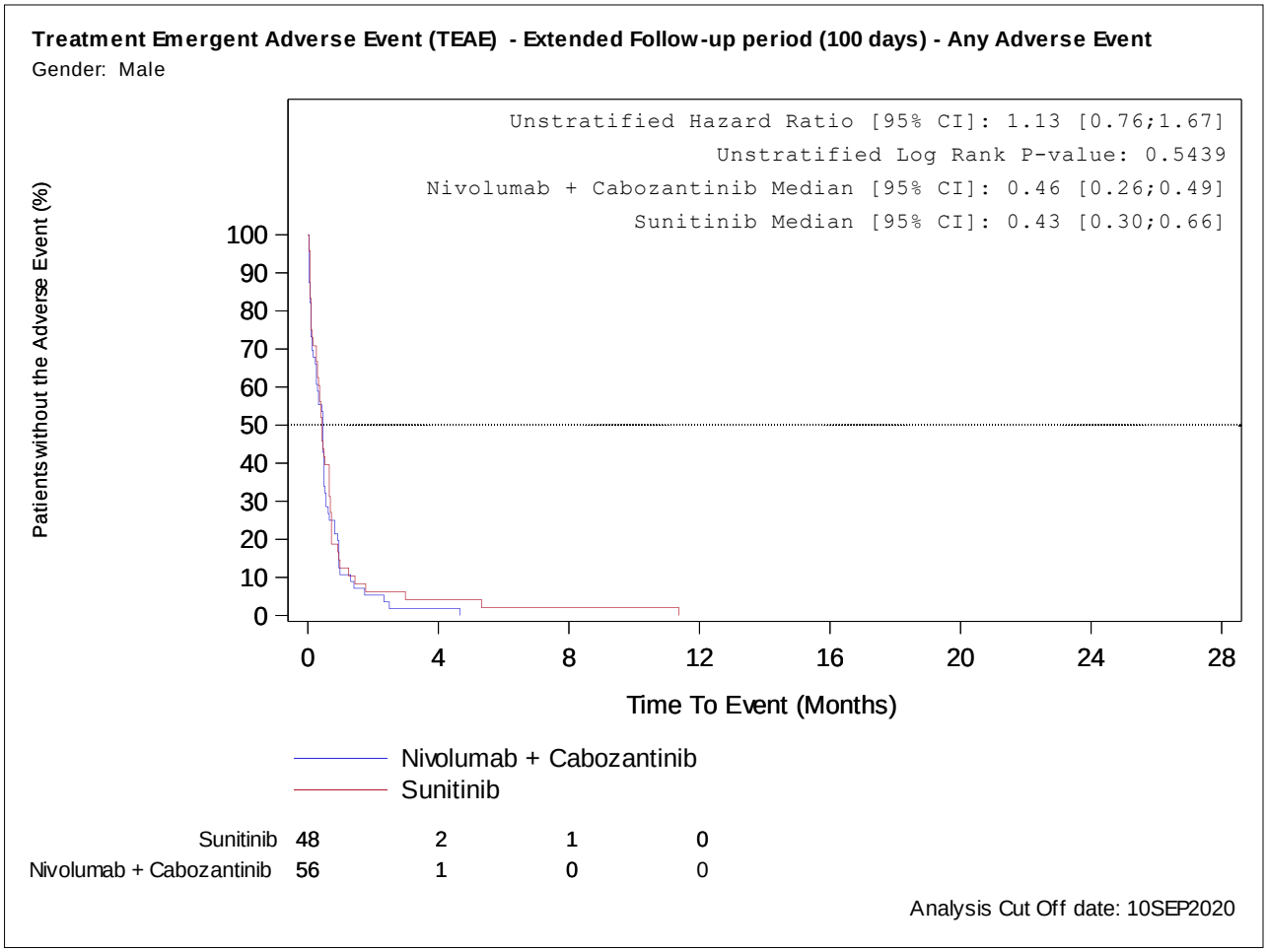

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:14:44

FIGURE 3.2.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:14:50

FIGURE 3.2.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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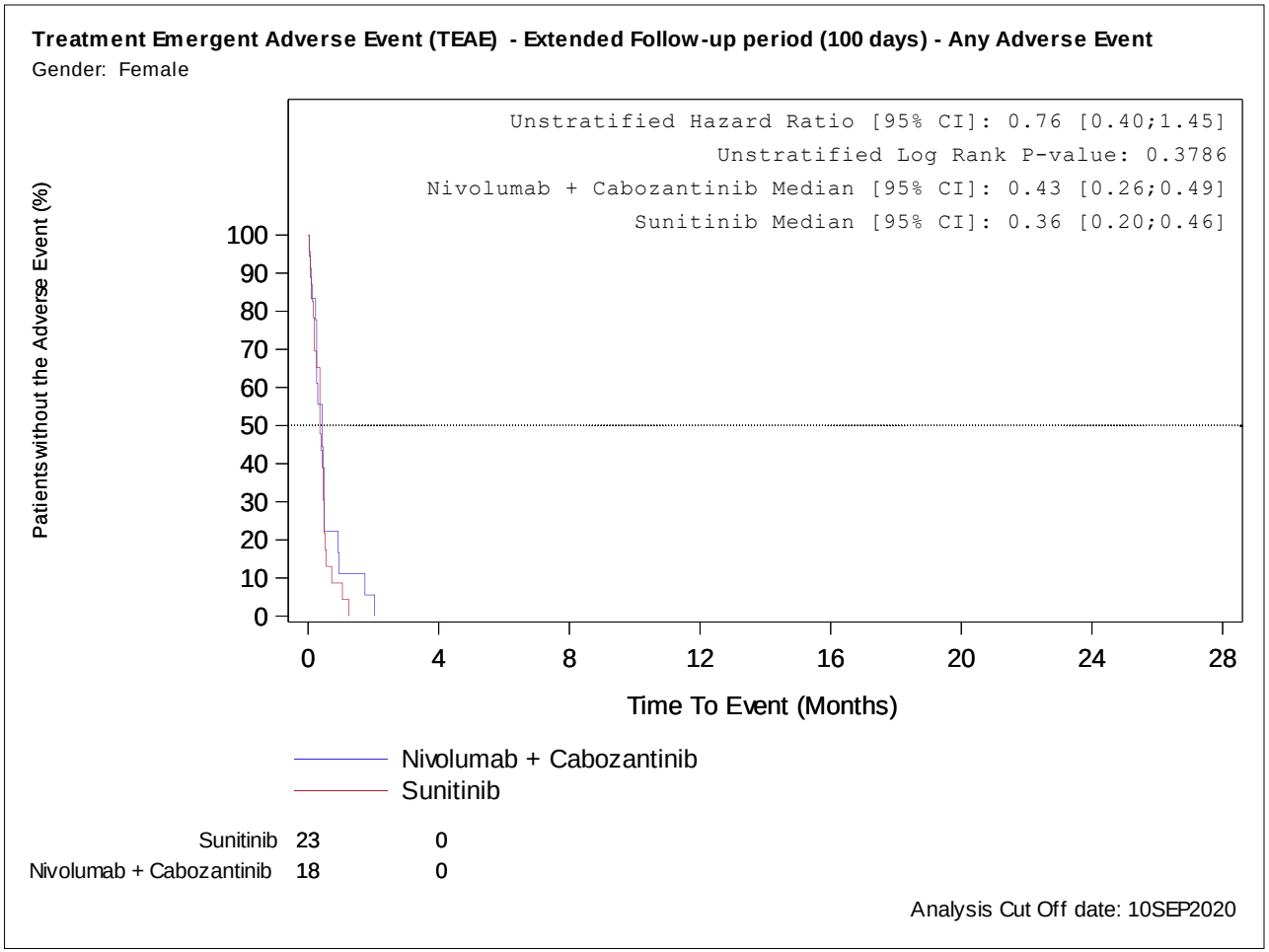
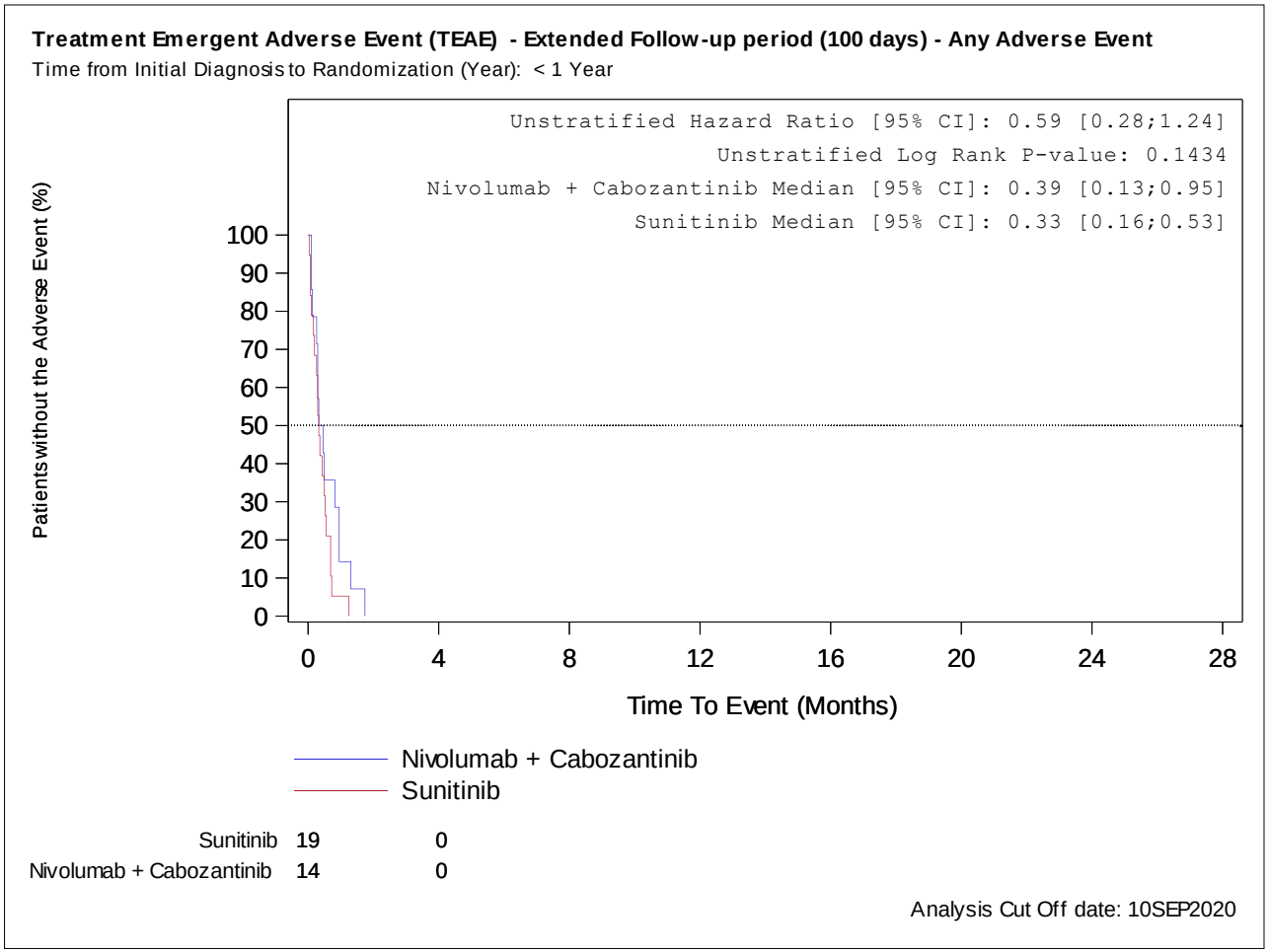
FIGURE 3.2.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



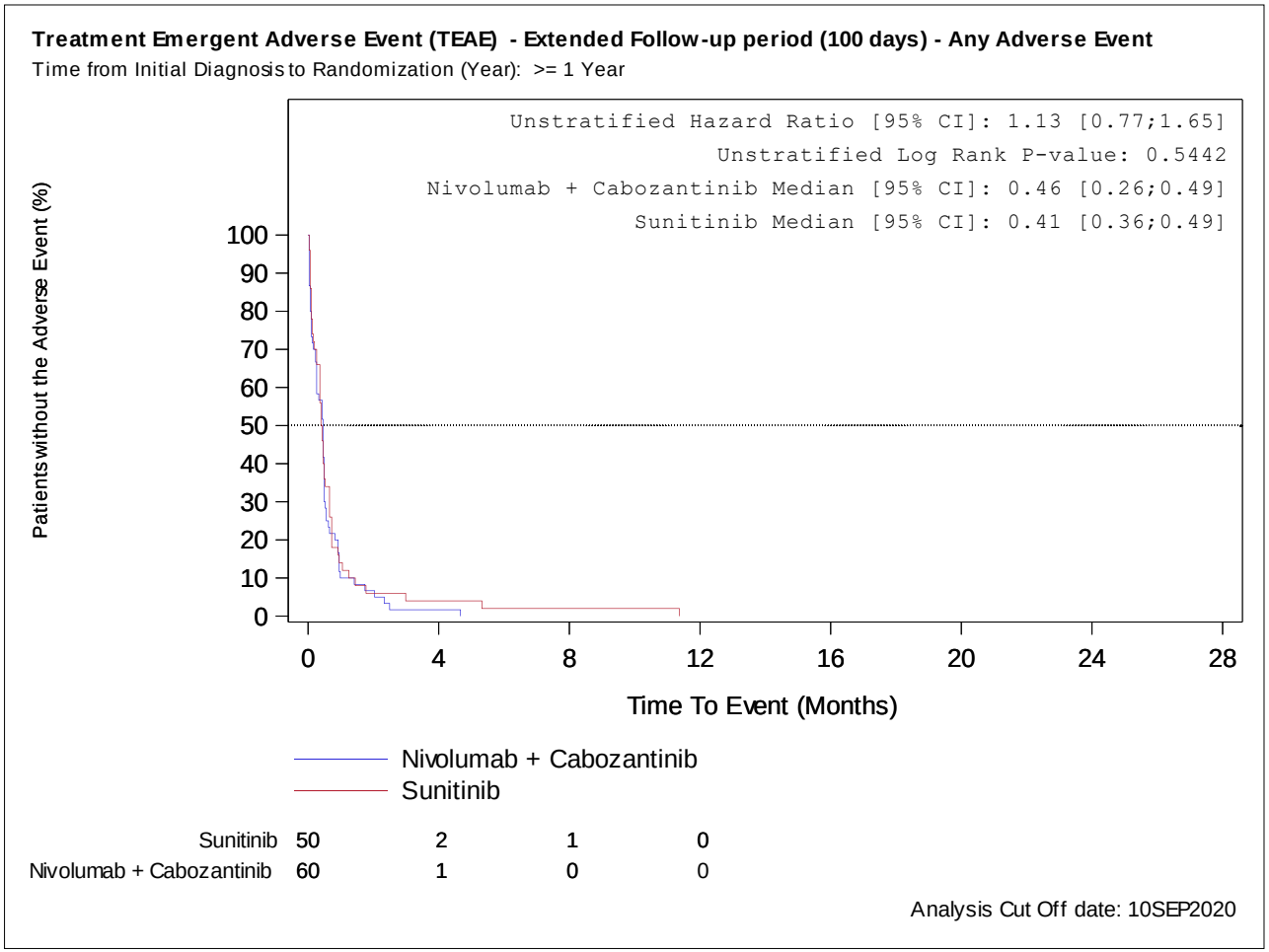

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:15:03

FIGURE 3.2.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



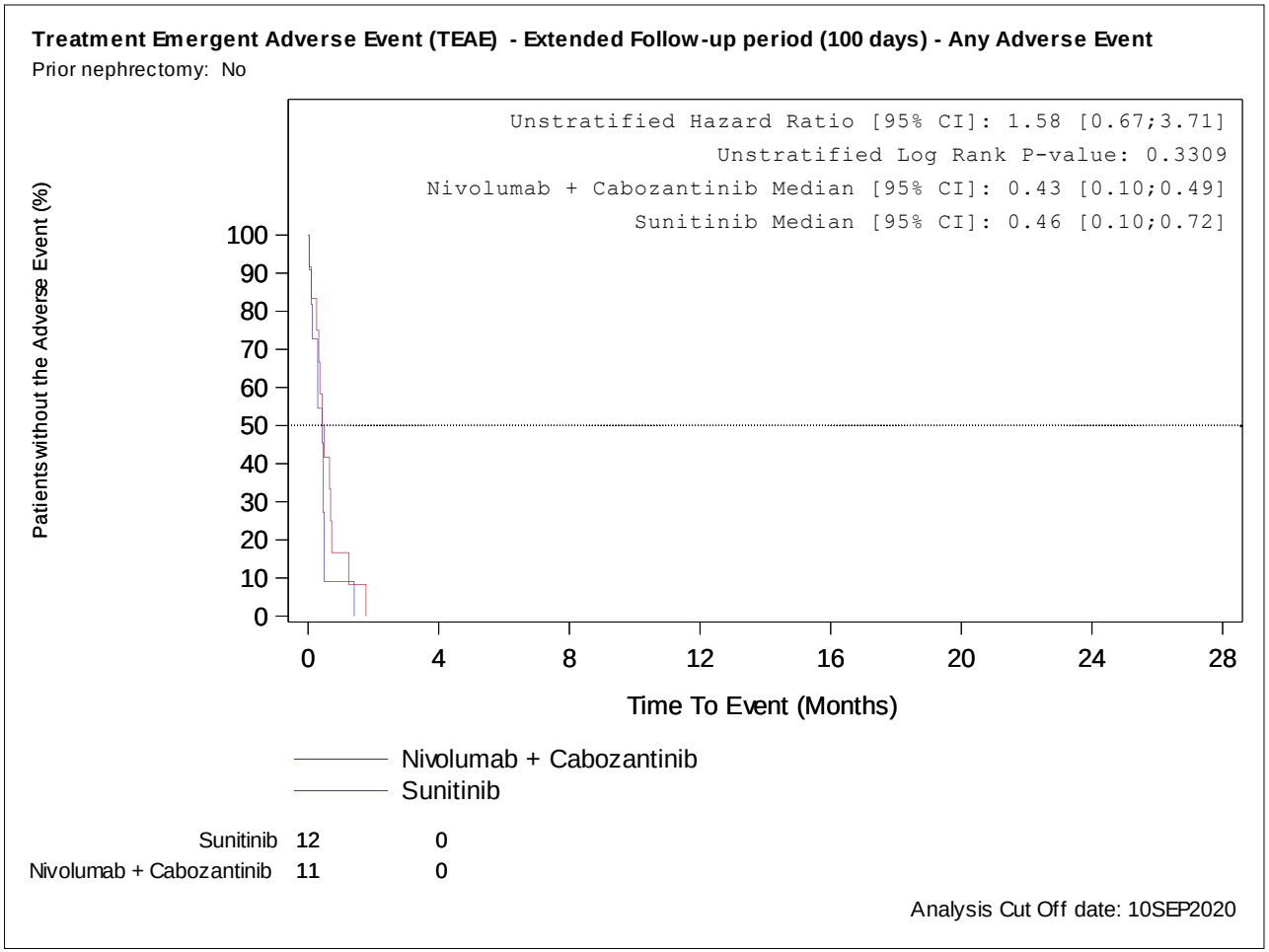

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:15:21

FIGURE 3.2.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:15:27

FIGURE 3.2.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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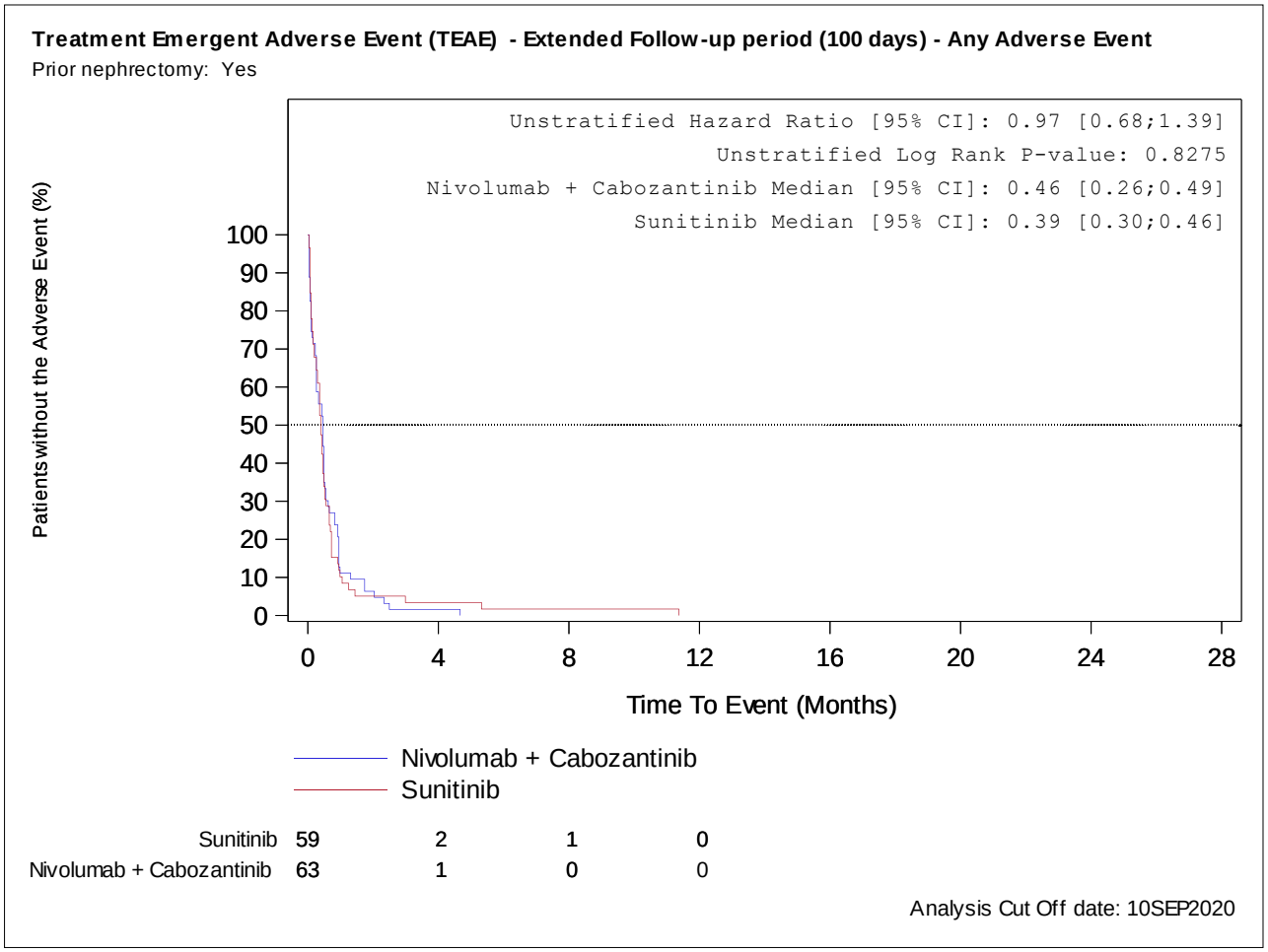
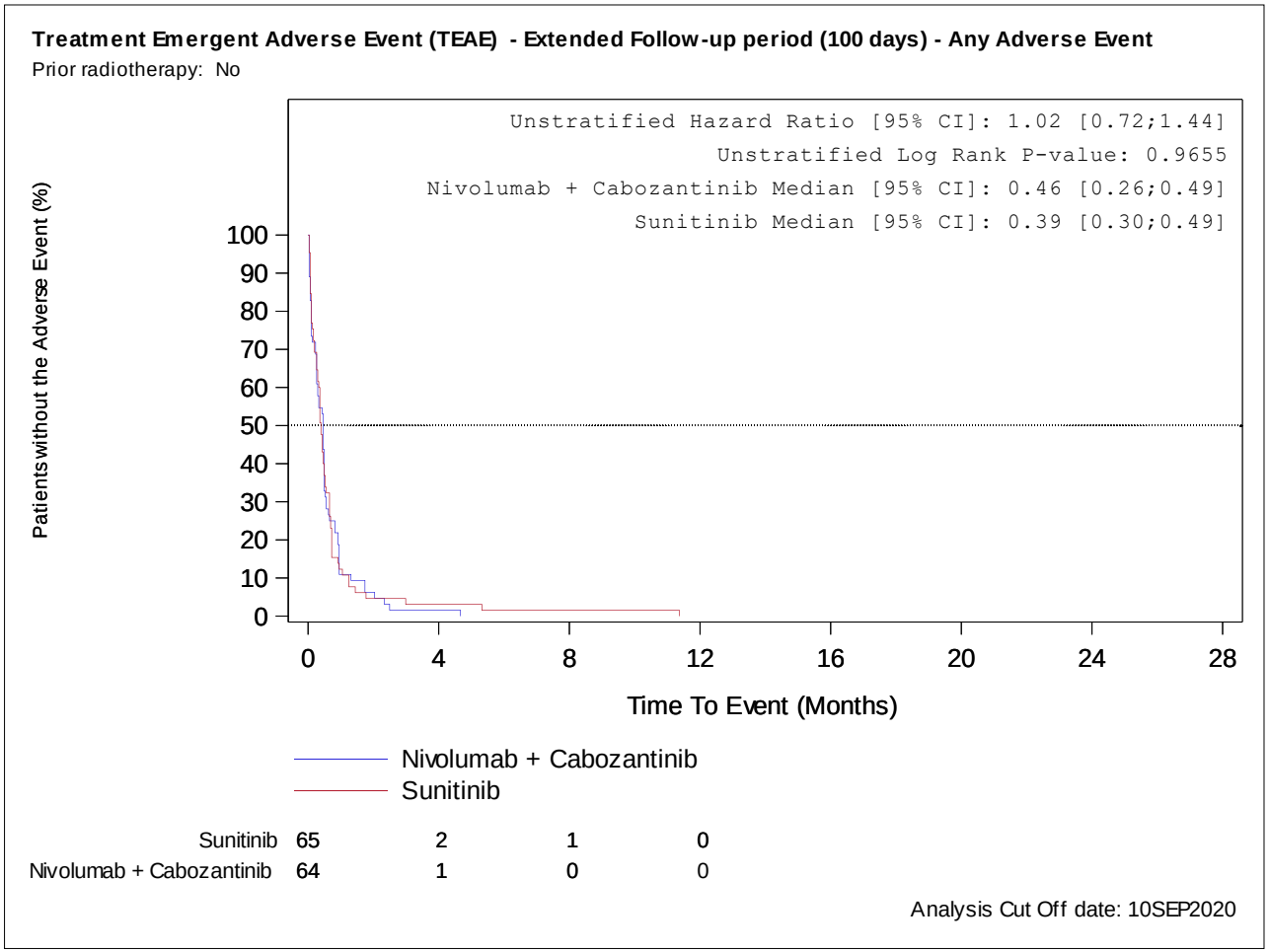
FIGURE 3.2.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



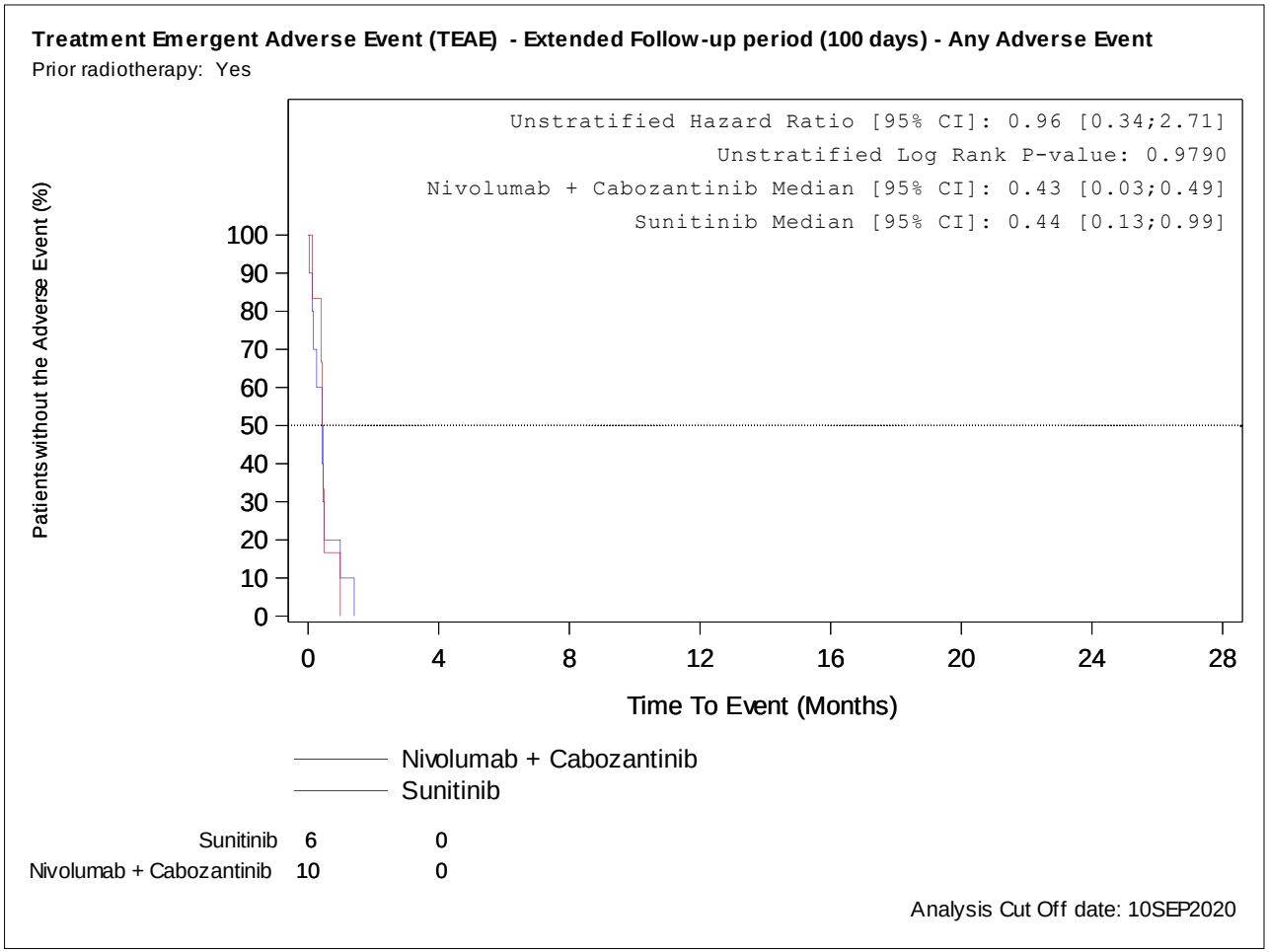

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:16:30

FIGURE 3.2.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



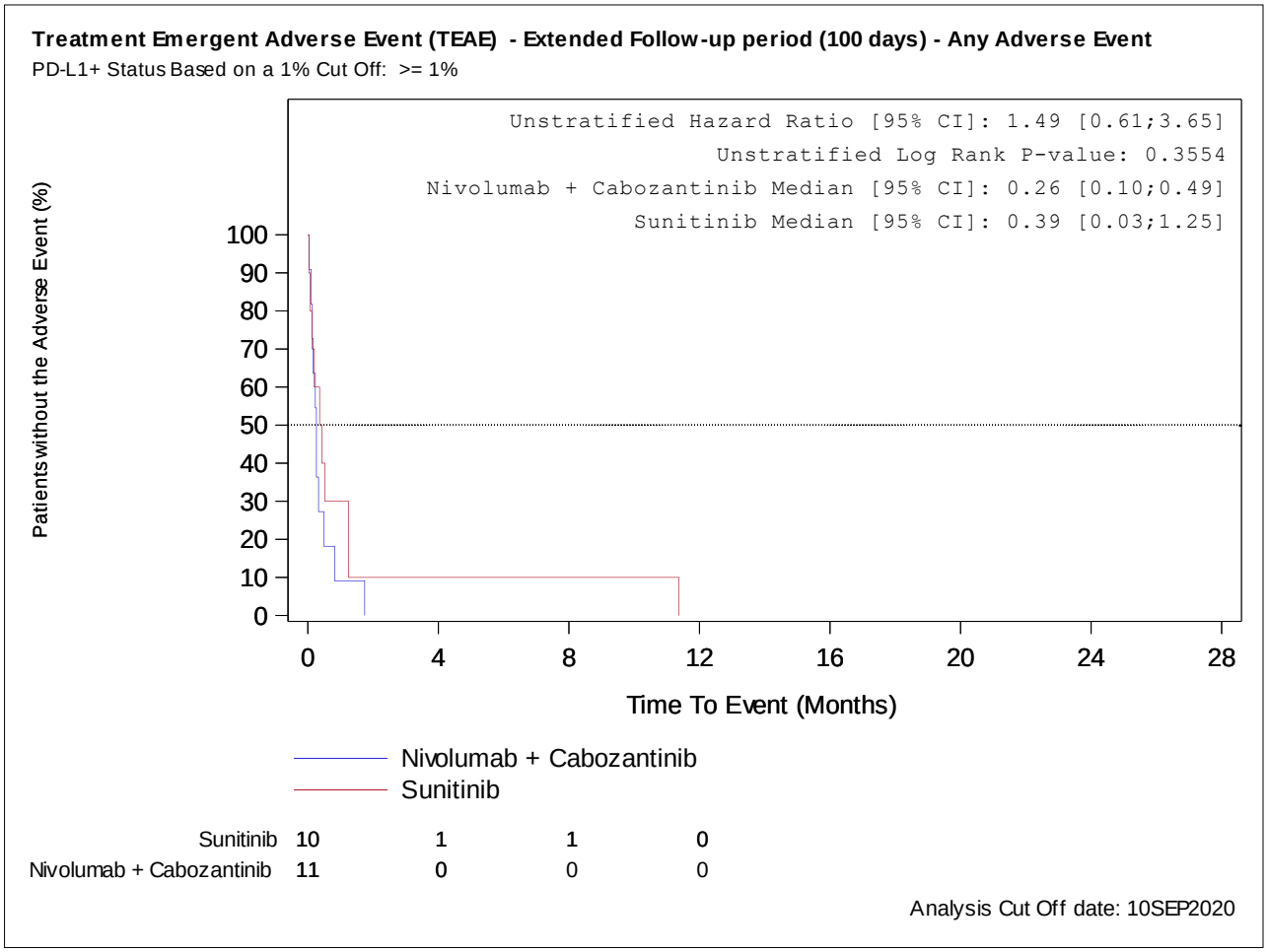

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:16:36

FIGURE 3.2.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



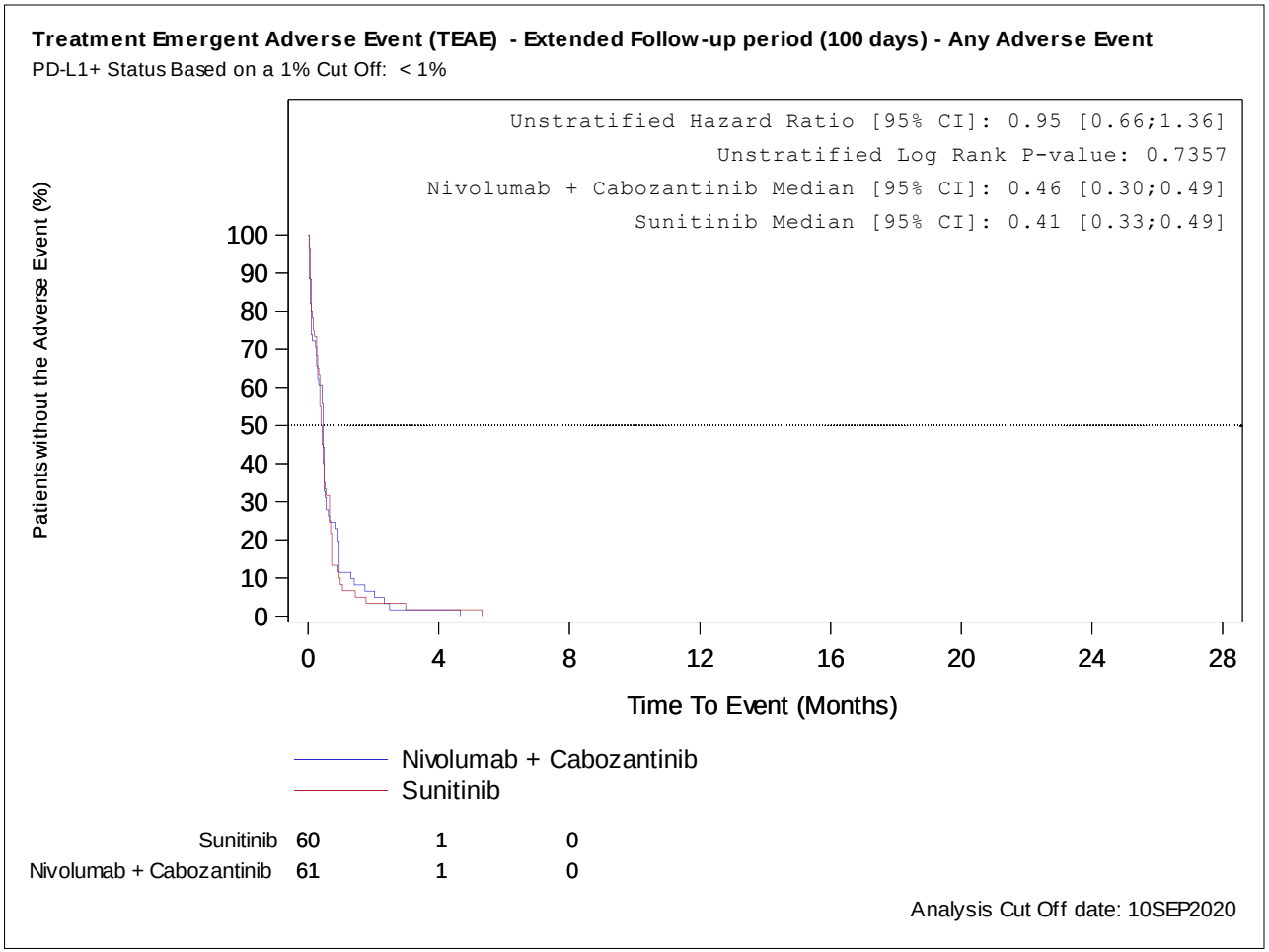

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:16:42

FIGURE 3.2.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



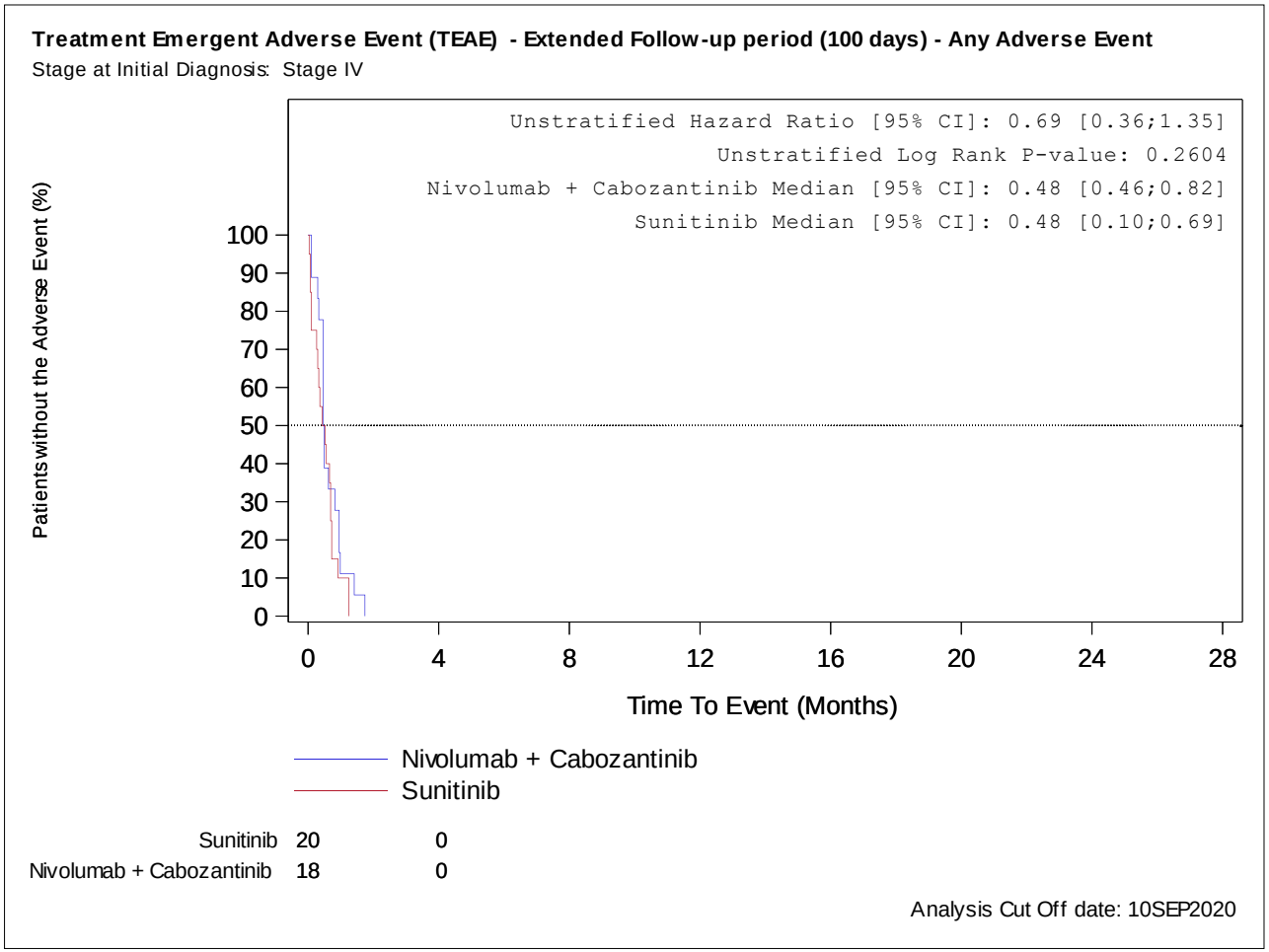

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:16:48

FIGURE 3.2.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



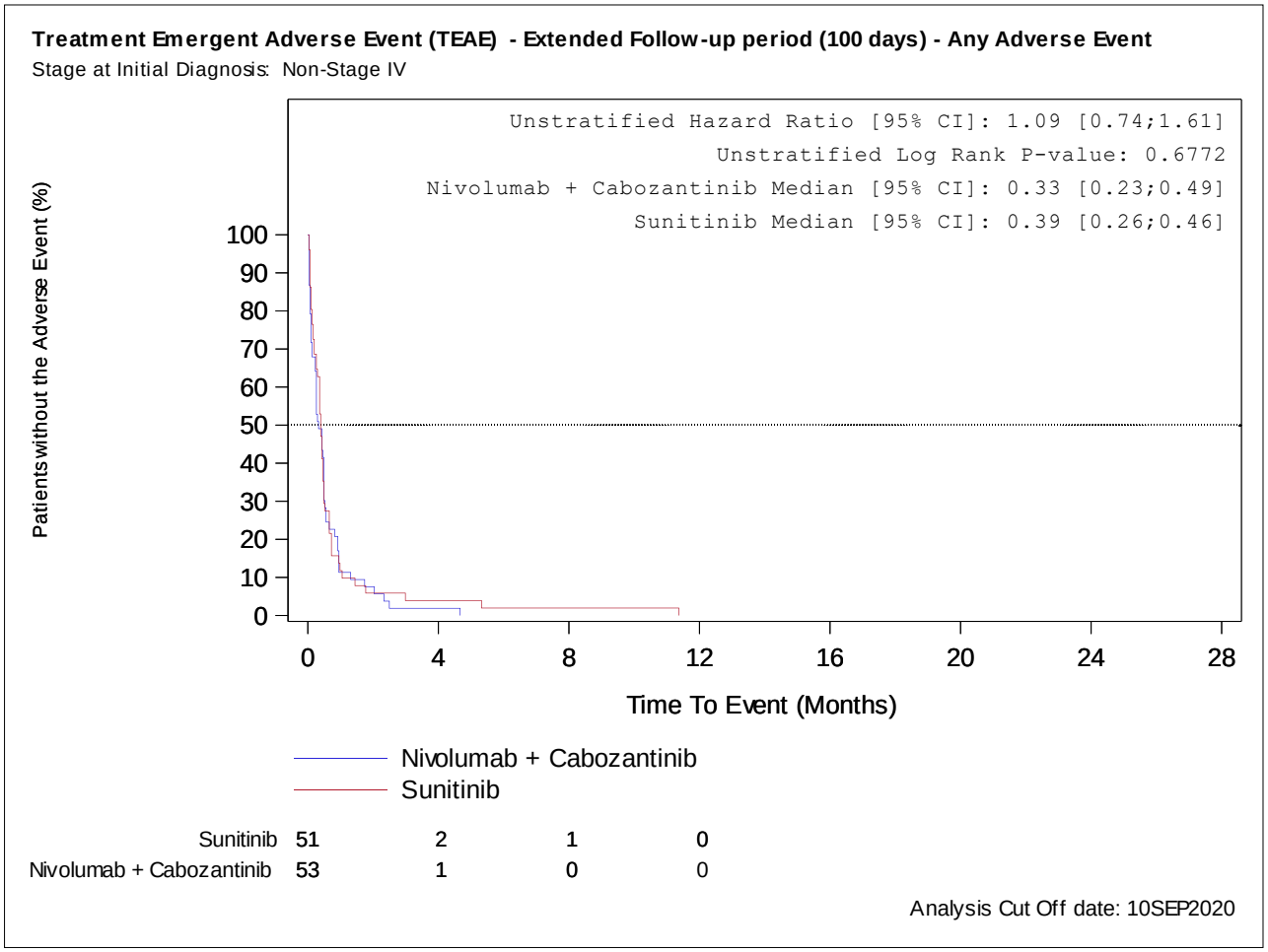

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:16:54

FIGURE 3.2.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



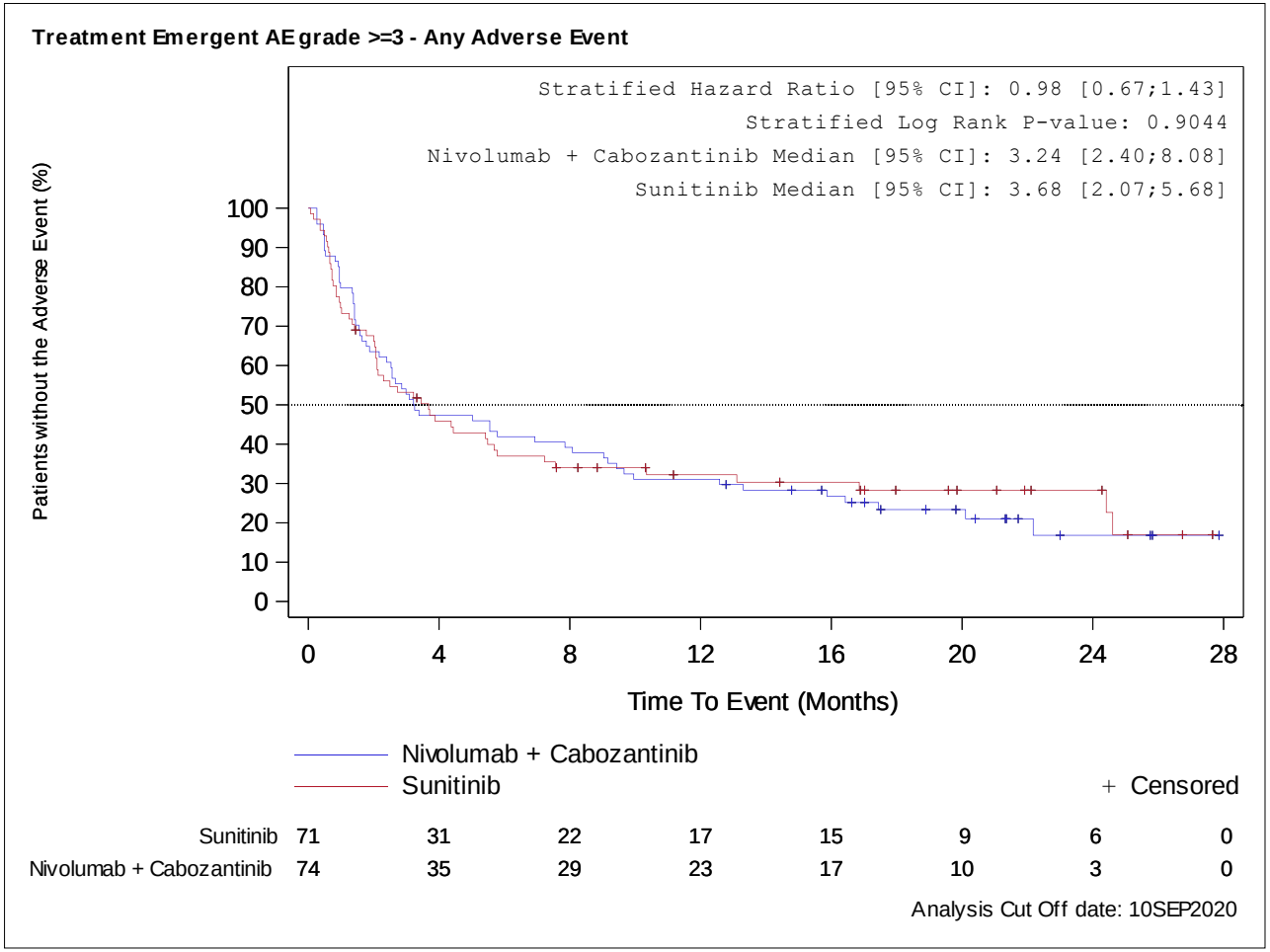

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:17:27

FIGURE 3.2.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



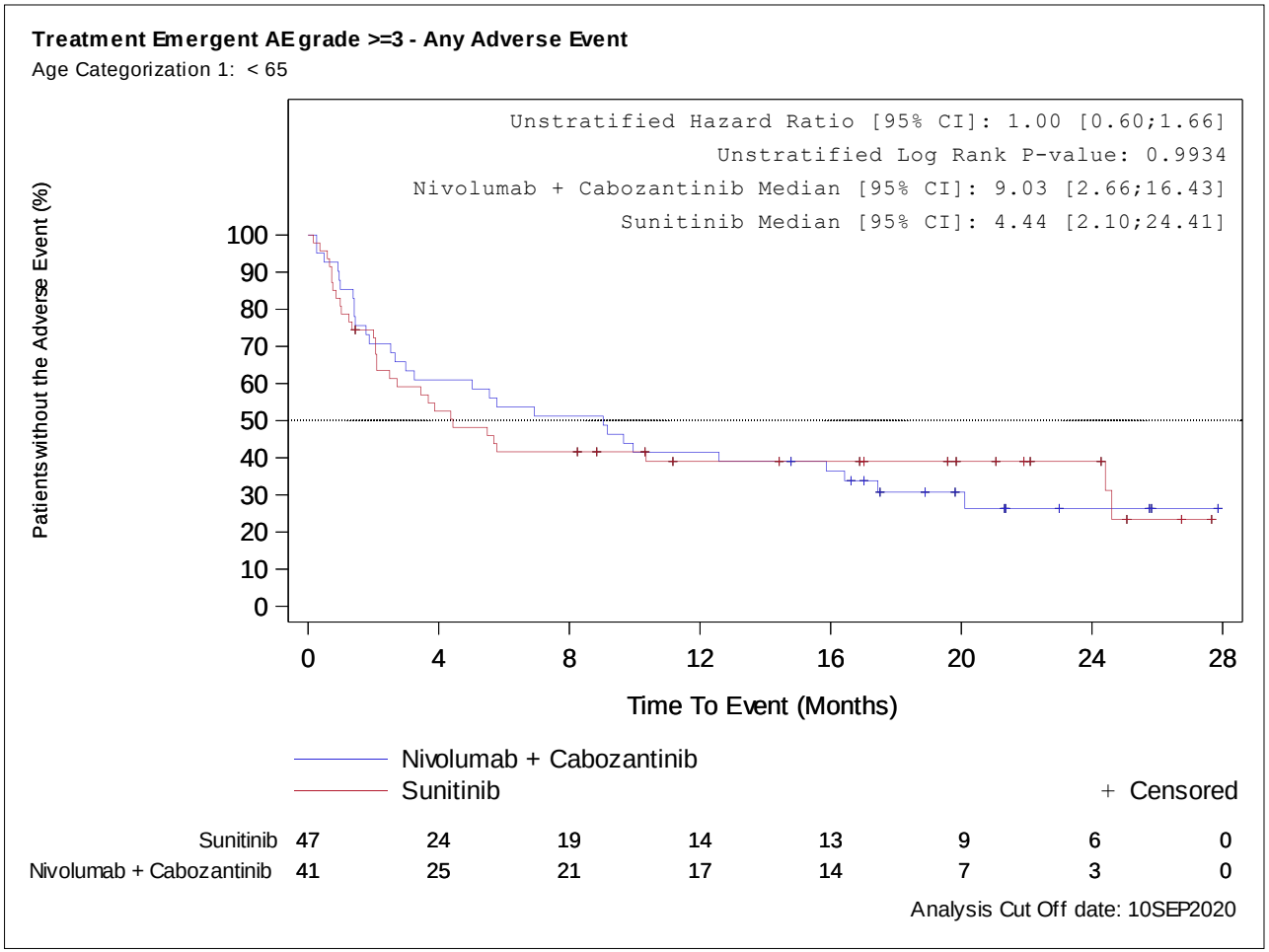

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:17:33

FIGURE 3.3.1: Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



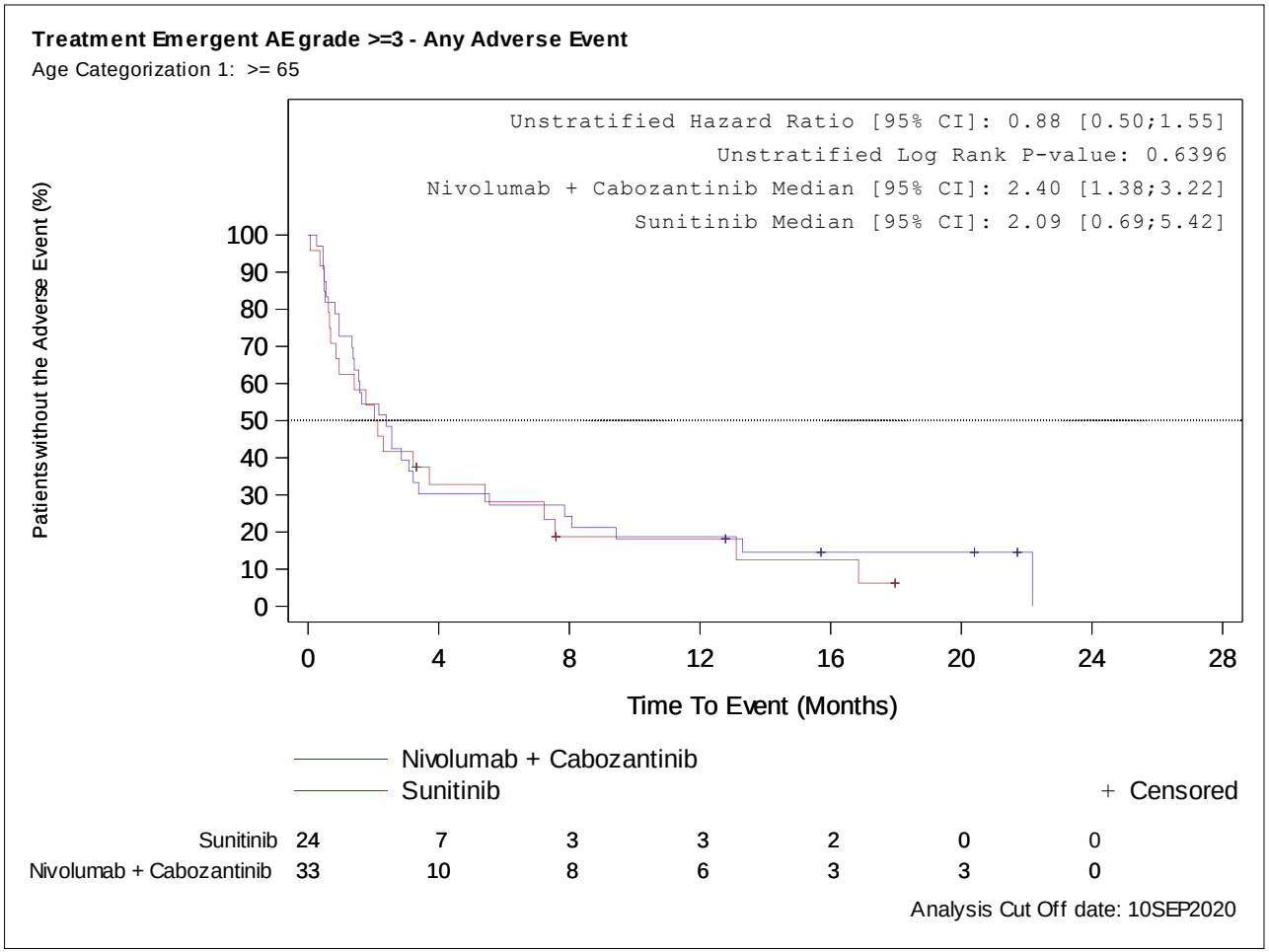

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:21:00

FIGURE 3.3.2.1: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



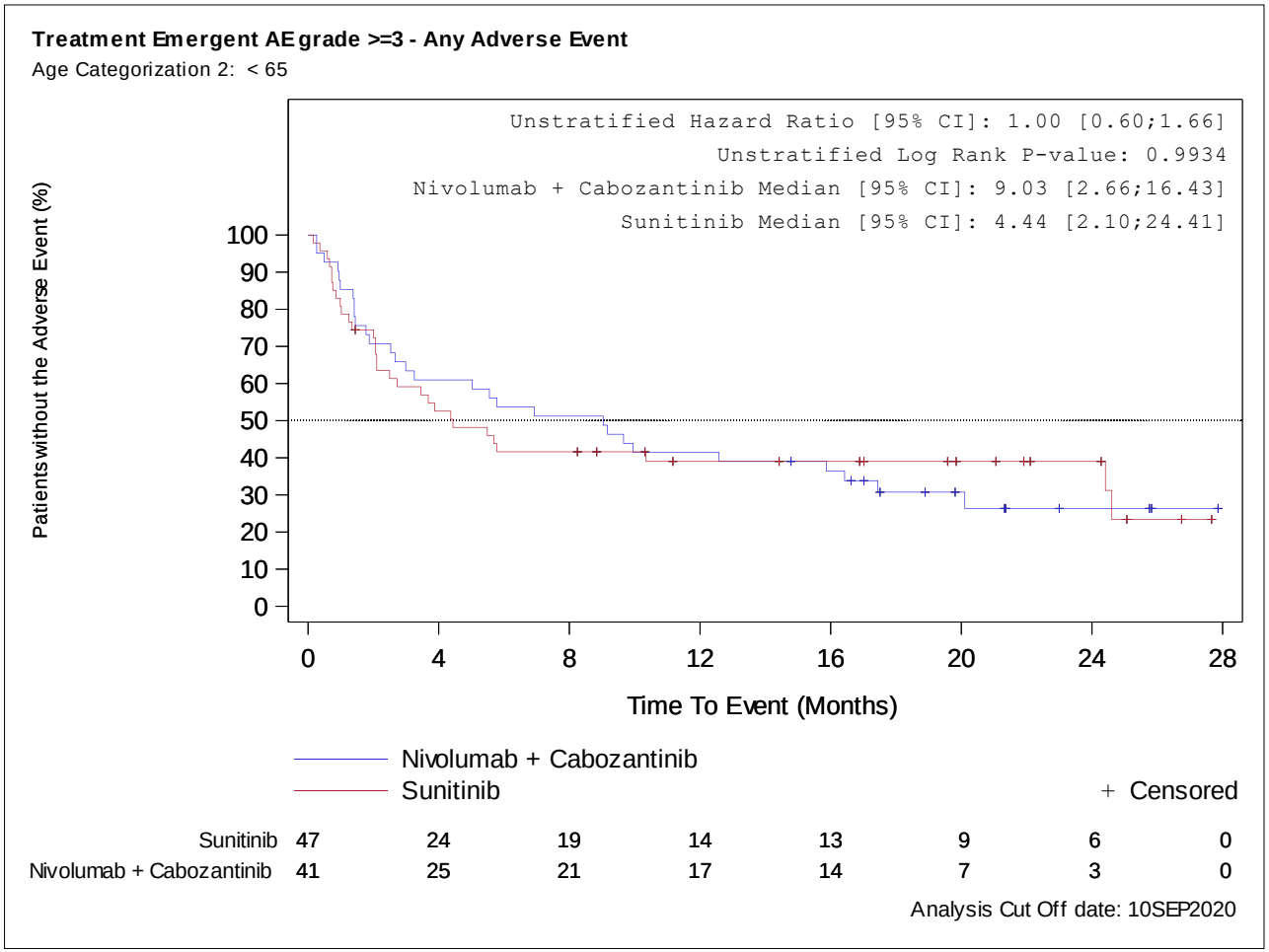

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:21:03

FIGURE 3.3.2.2: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



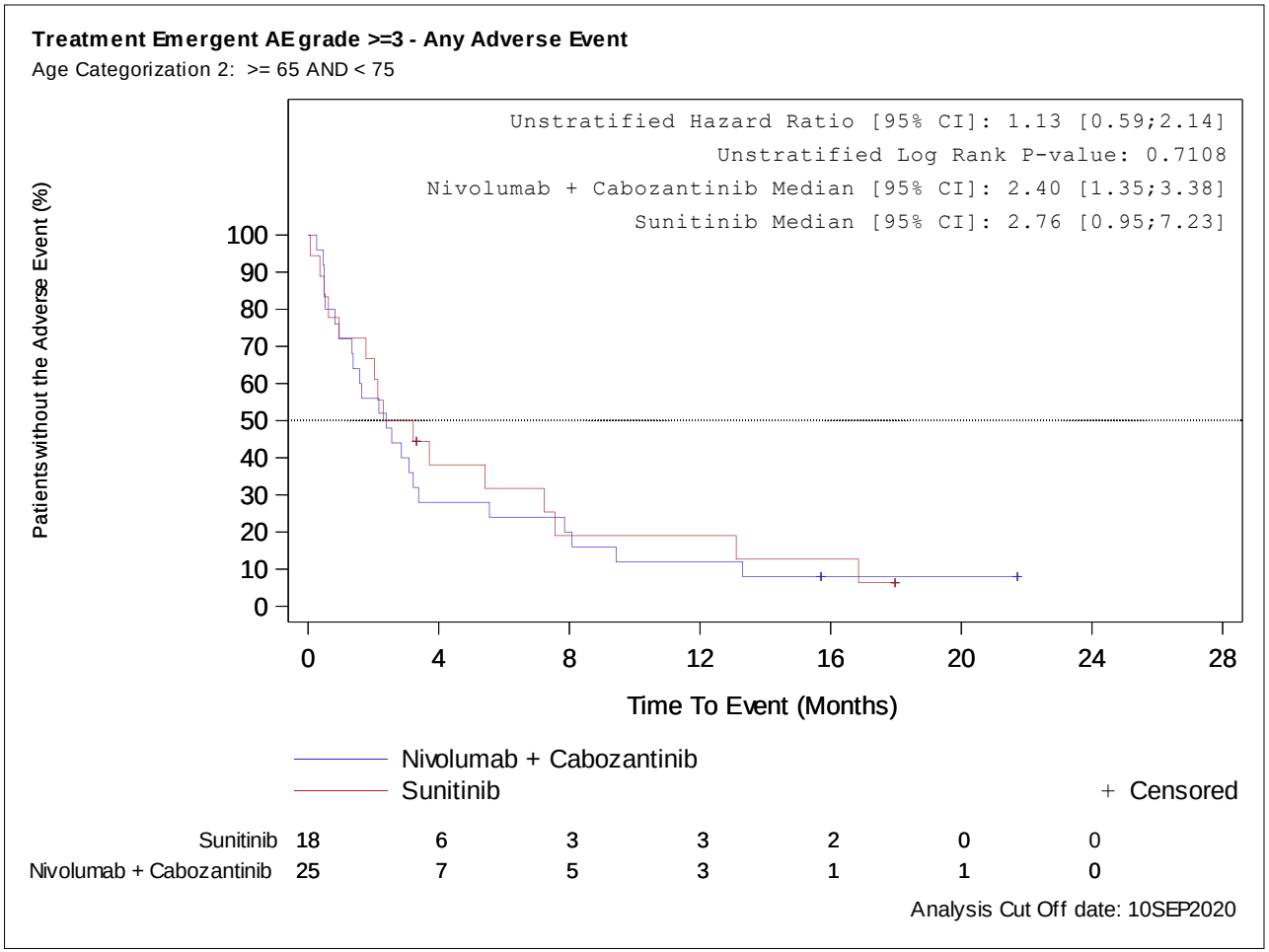

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:21:10

FIGURE 3.3.2.3: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  < 65



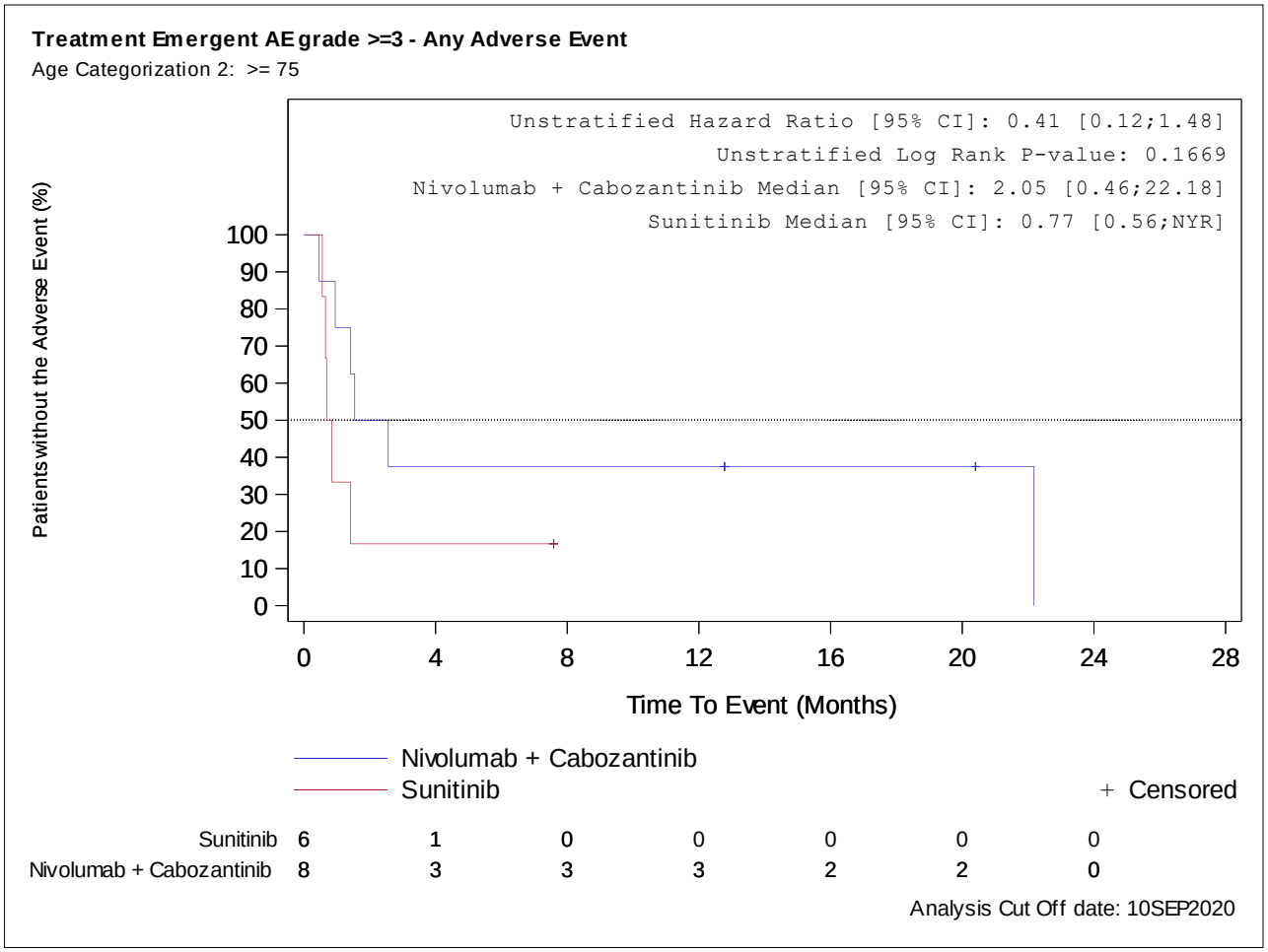

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:21:15

FIGURE 3.3.2.4: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



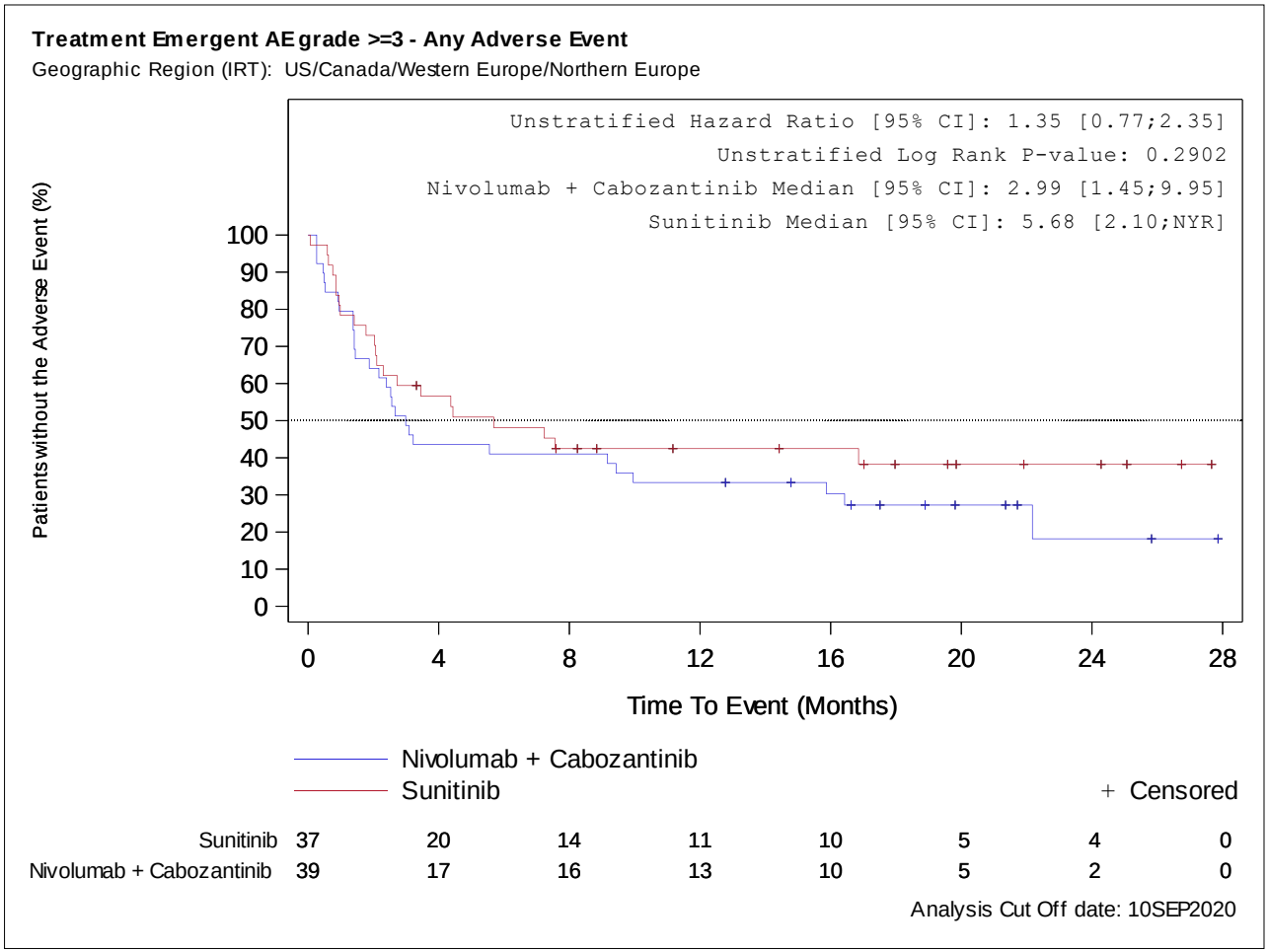

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:21:22

FIGURE 3.3.2.5: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



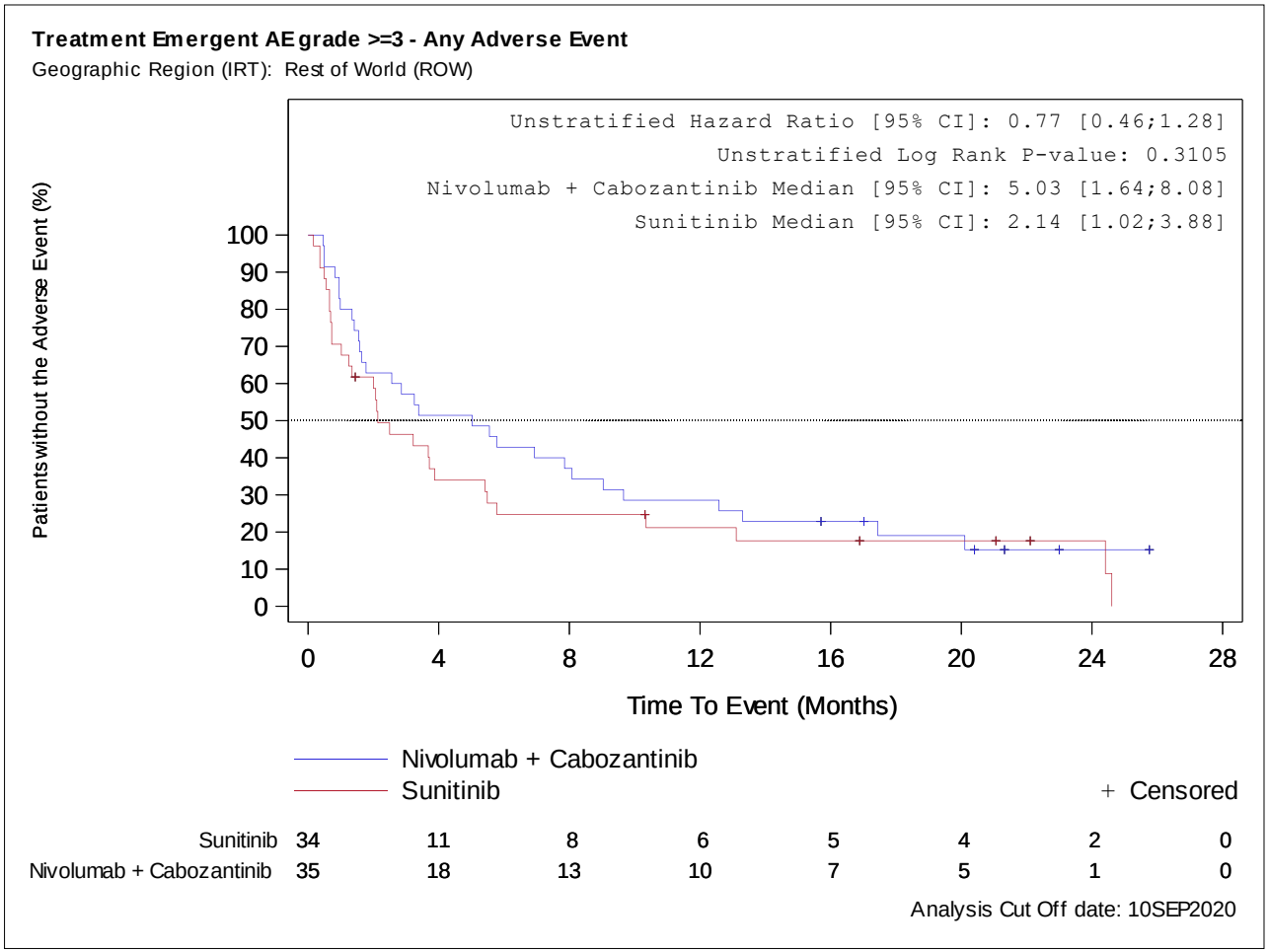

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:21:28

FIGURE 3.3.2.6: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



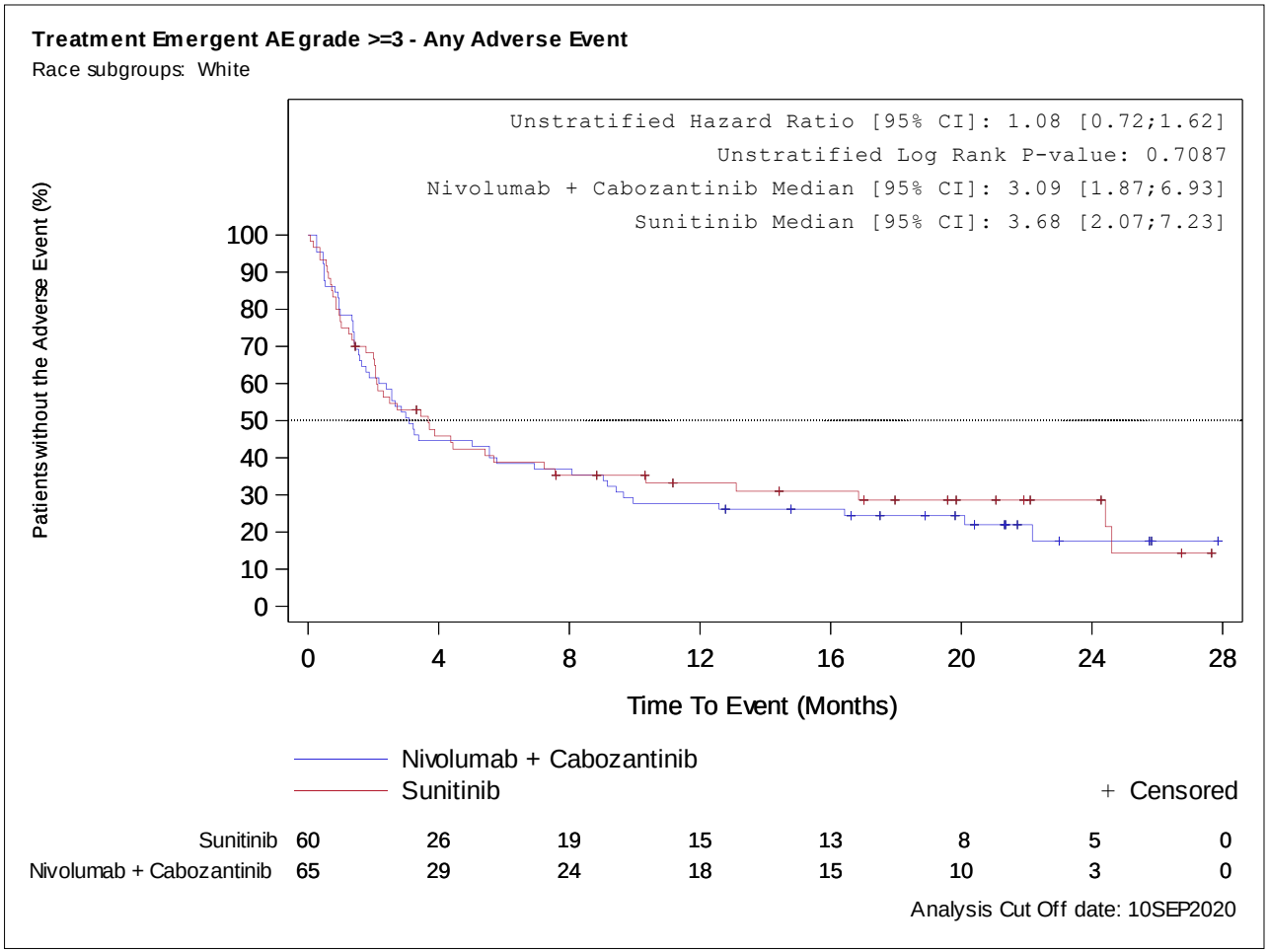

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:21:35

FIGURE 3.3.2.7: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



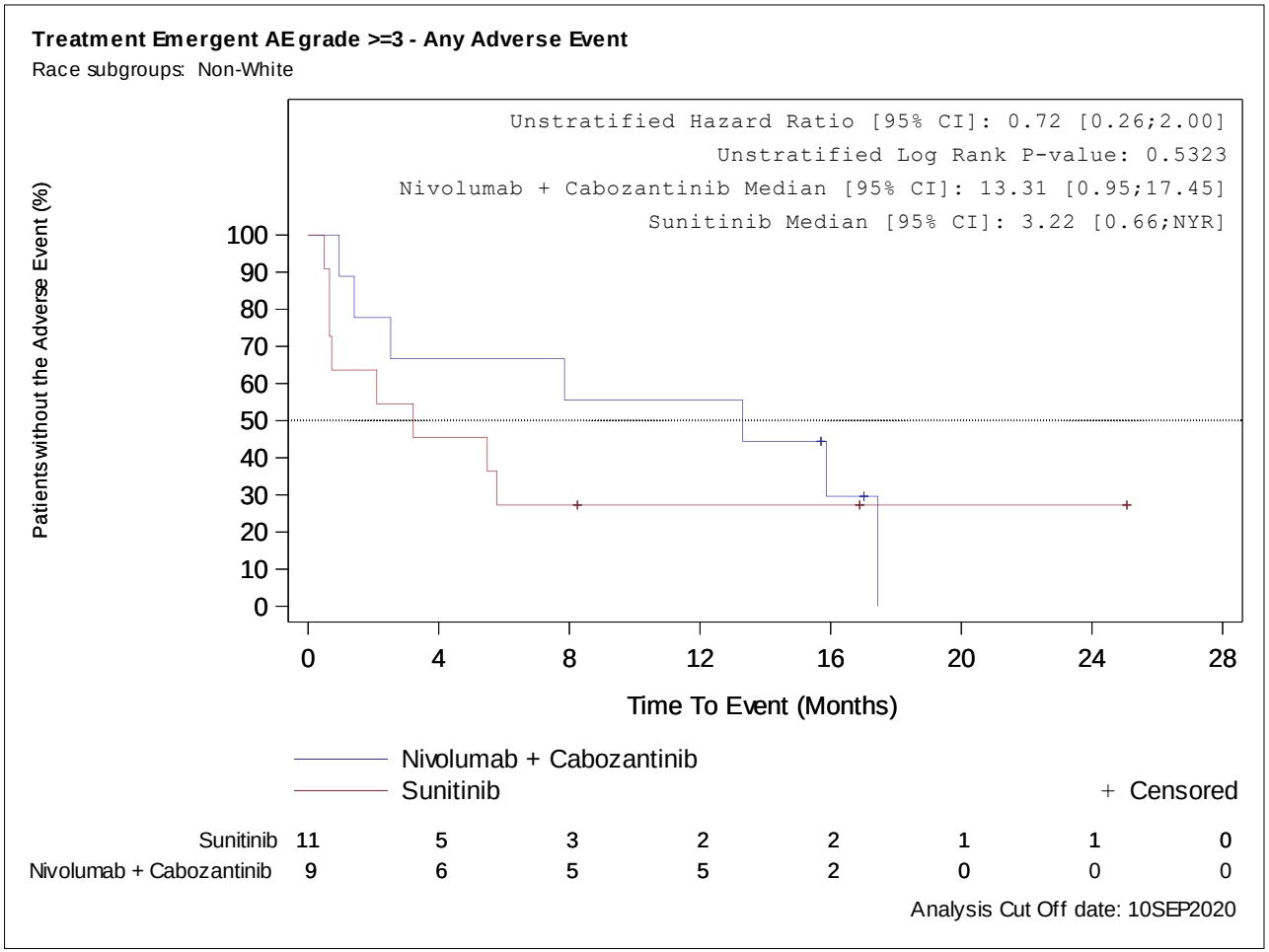

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:21:41

FIGURE 3.3.2.8: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



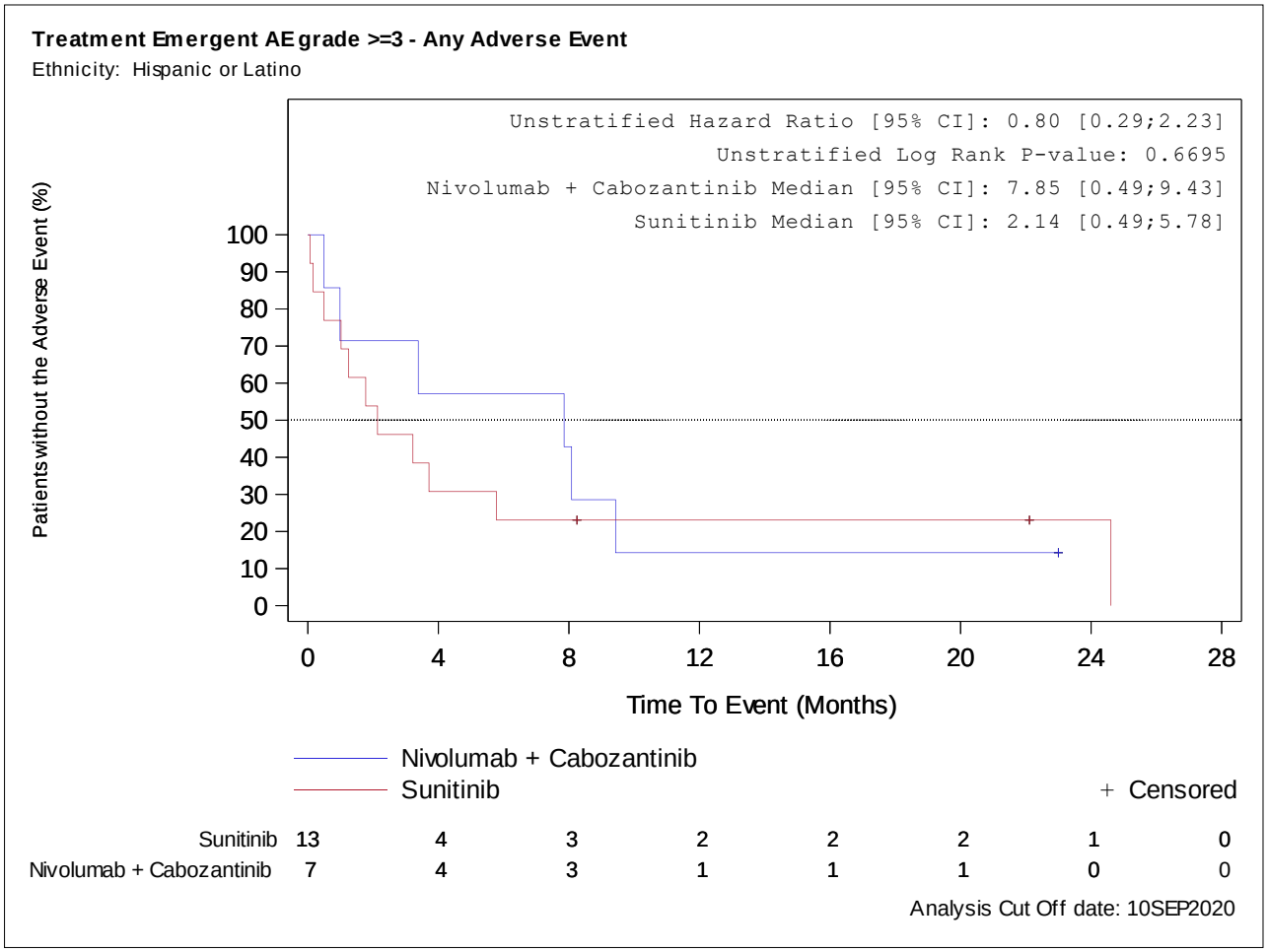

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:21:47

FIGURE 3.3.2.9: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



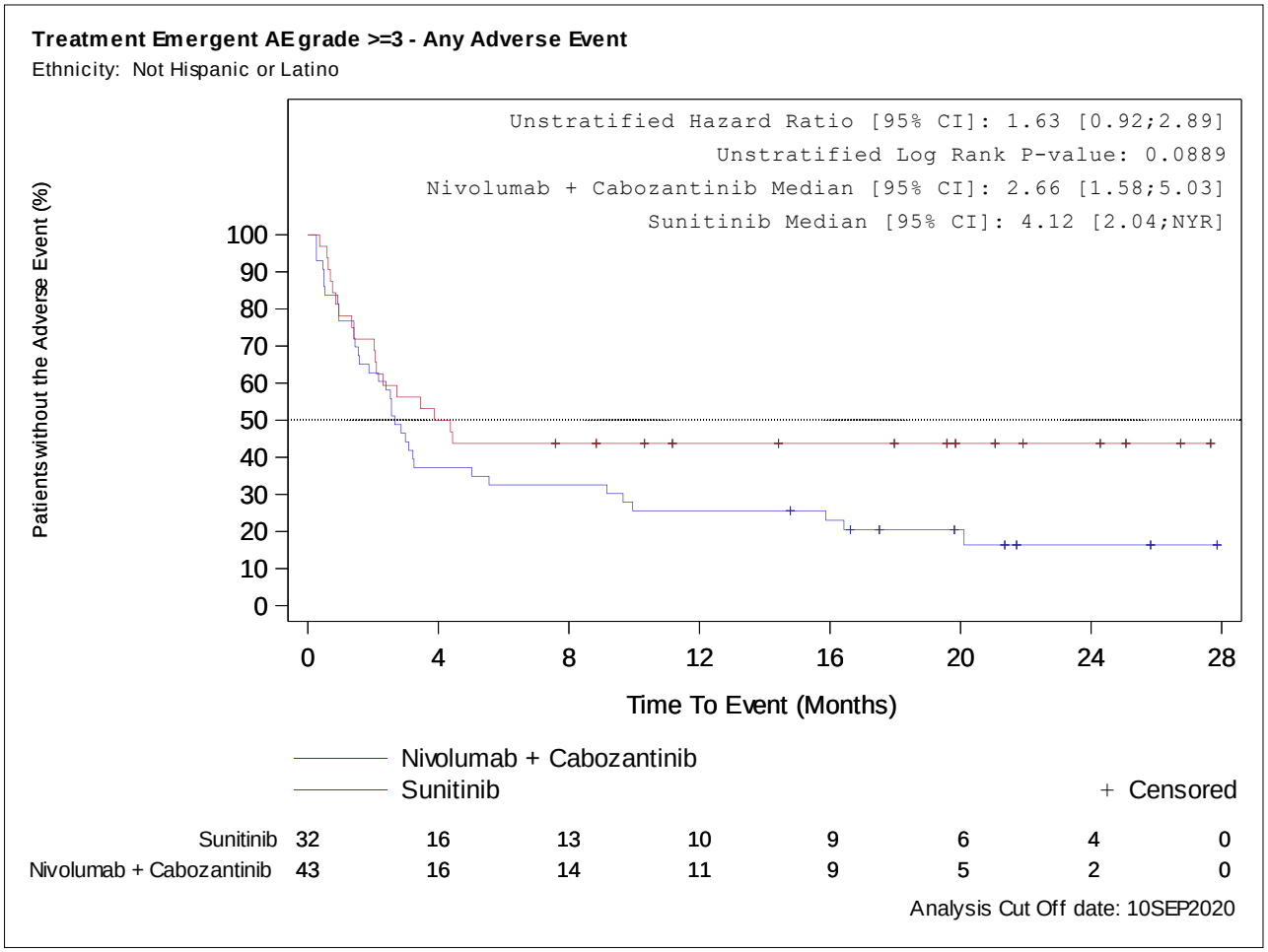

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:21:54

FIGURE 3.3.2.10: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



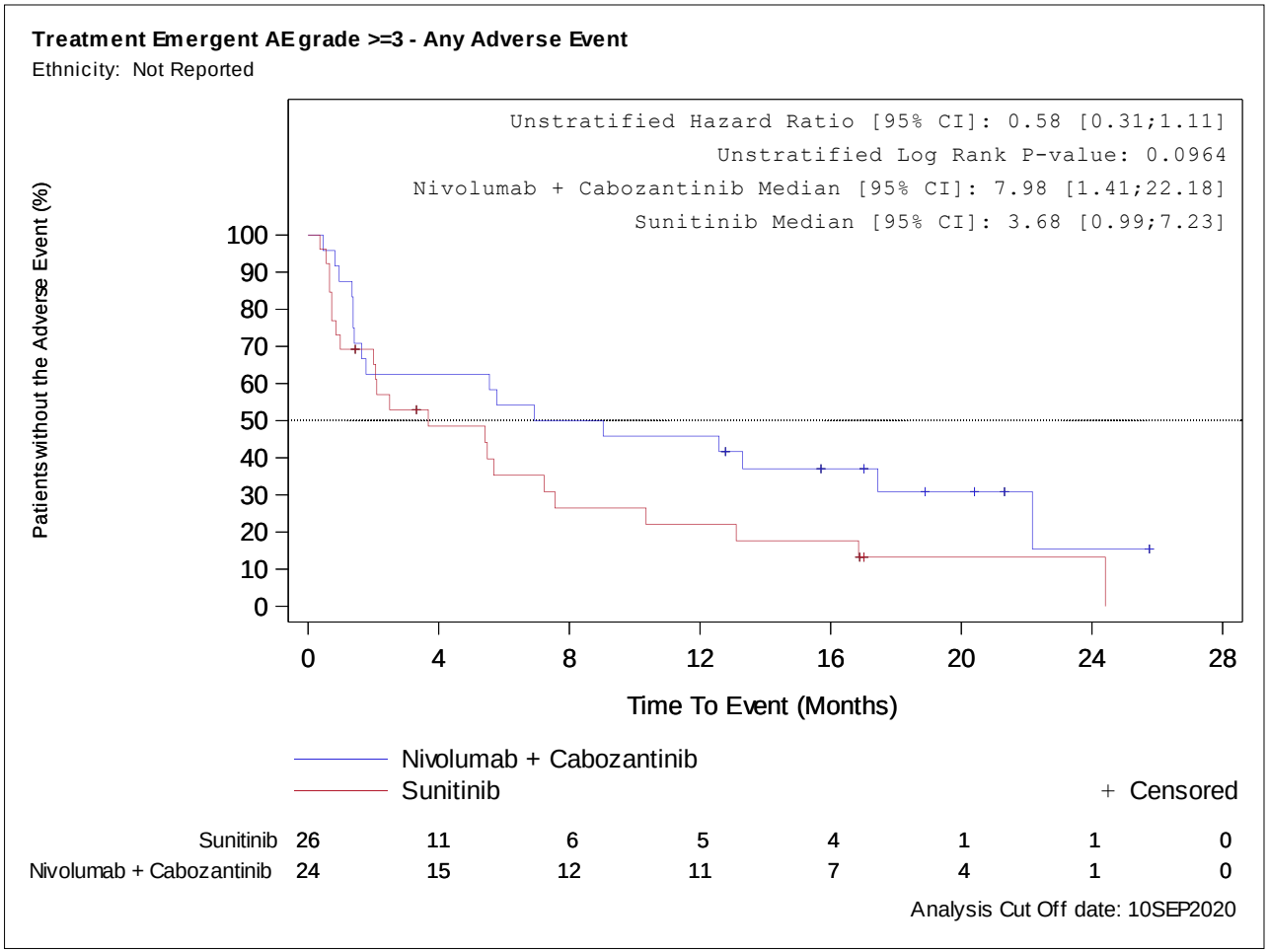

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:22:00

FIGURE 3.3.2.11: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity:  Not Hispanic or Latino



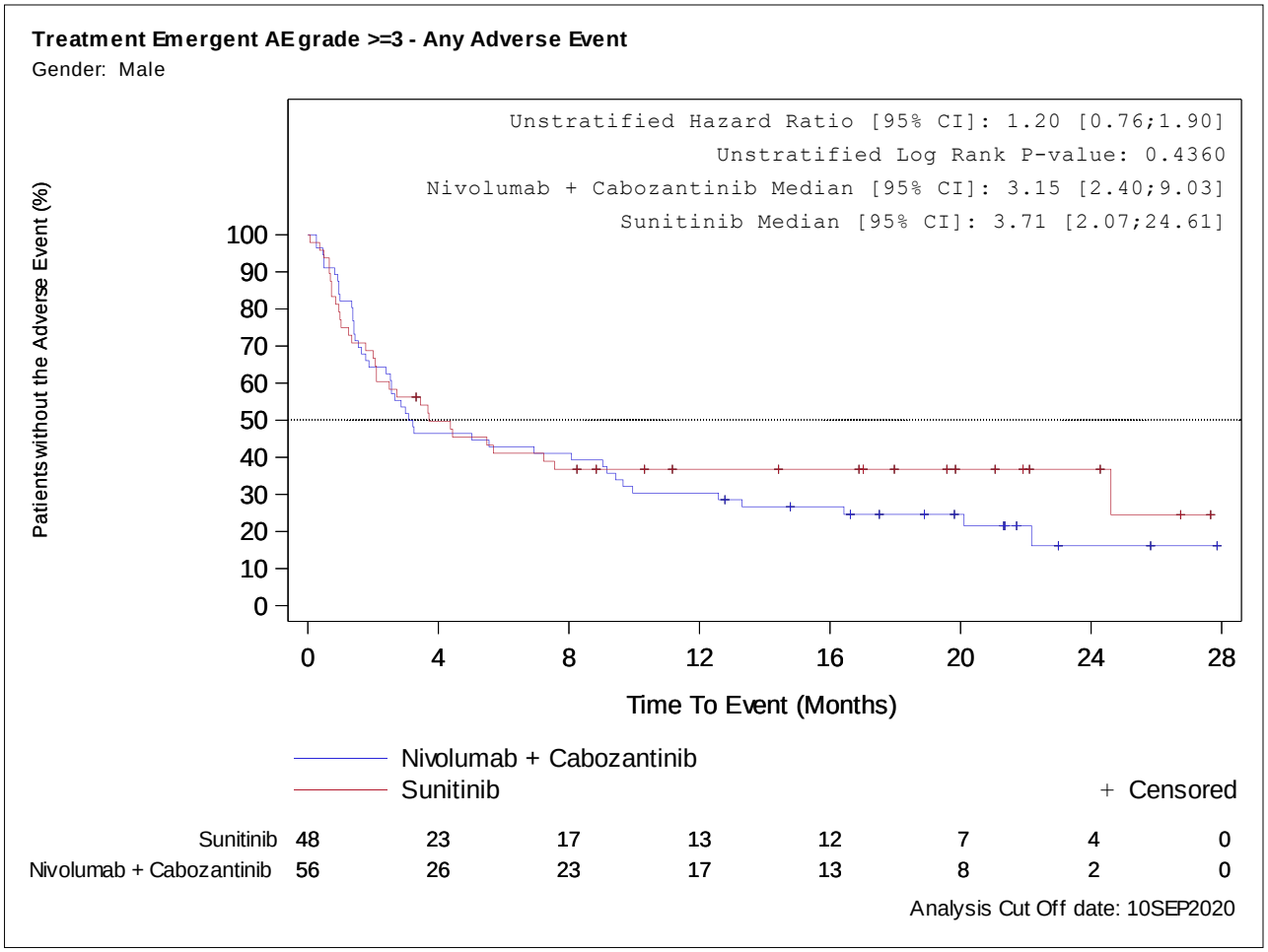

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:22:07

FIGURE 3.3.2.12: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



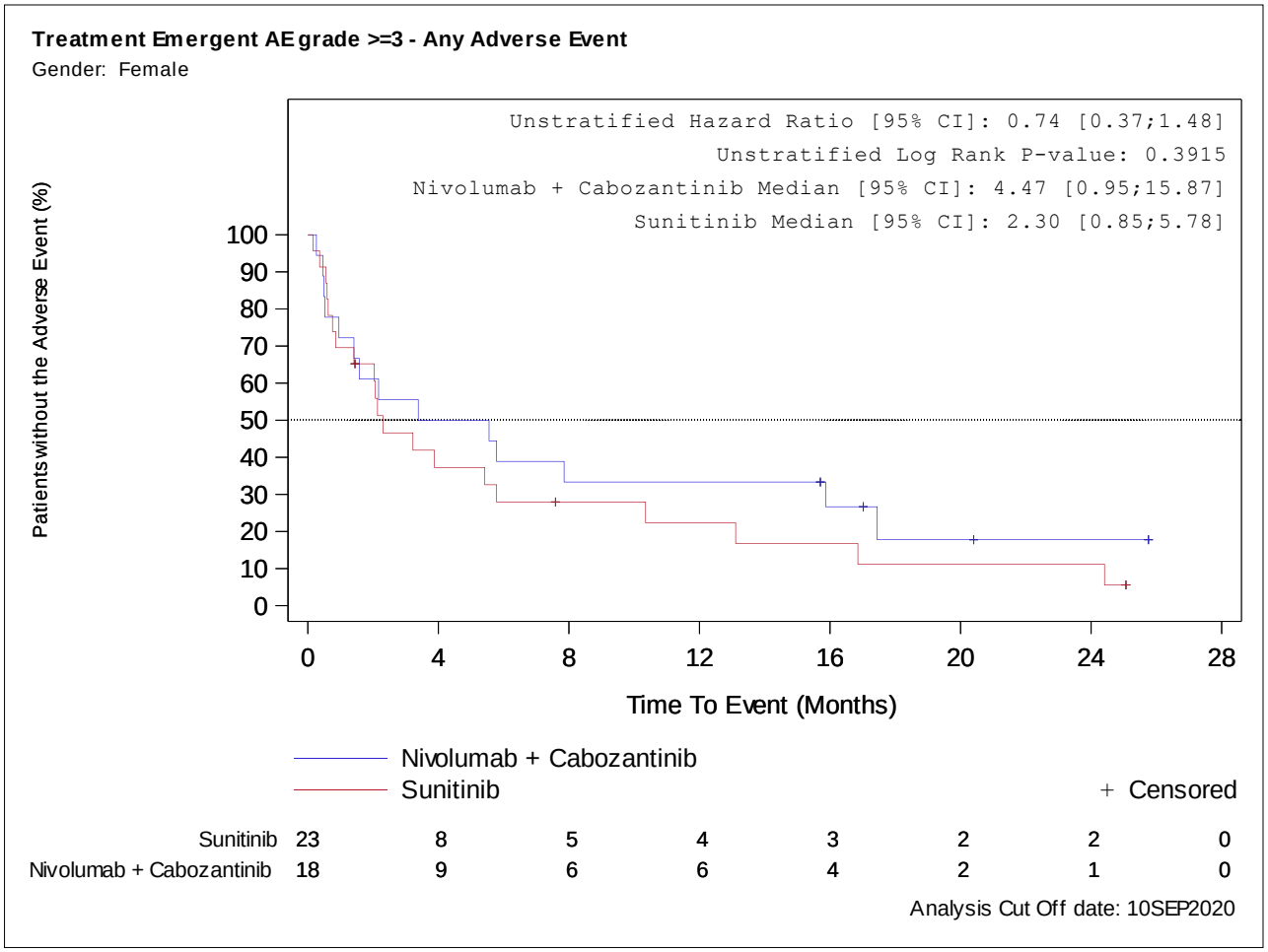

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:22:14

FIGURE 3.3.2.13: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



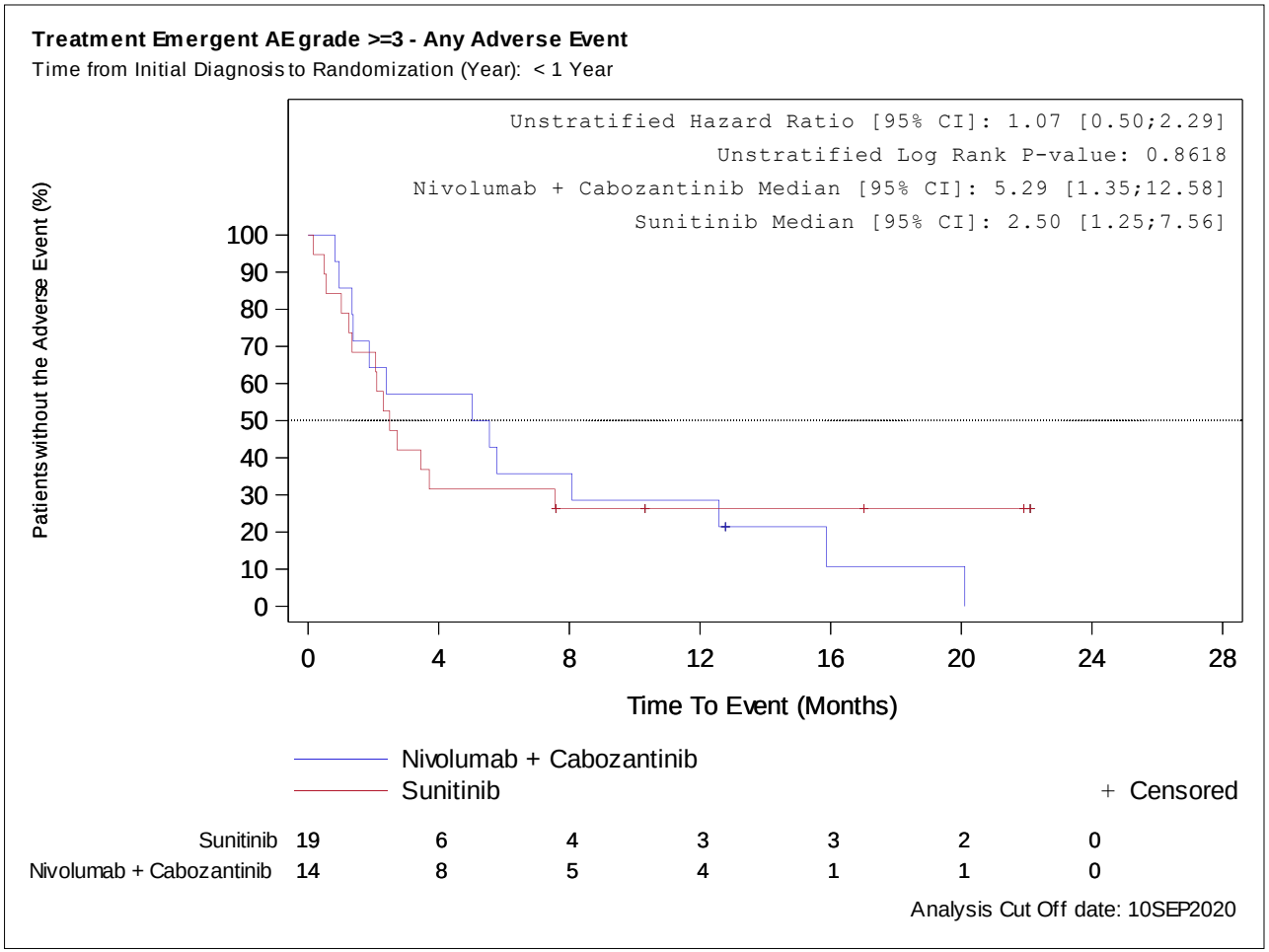

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:22:20

FIGURE 3.3.2.14: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:22:26

FIGURE 3.3.2.15: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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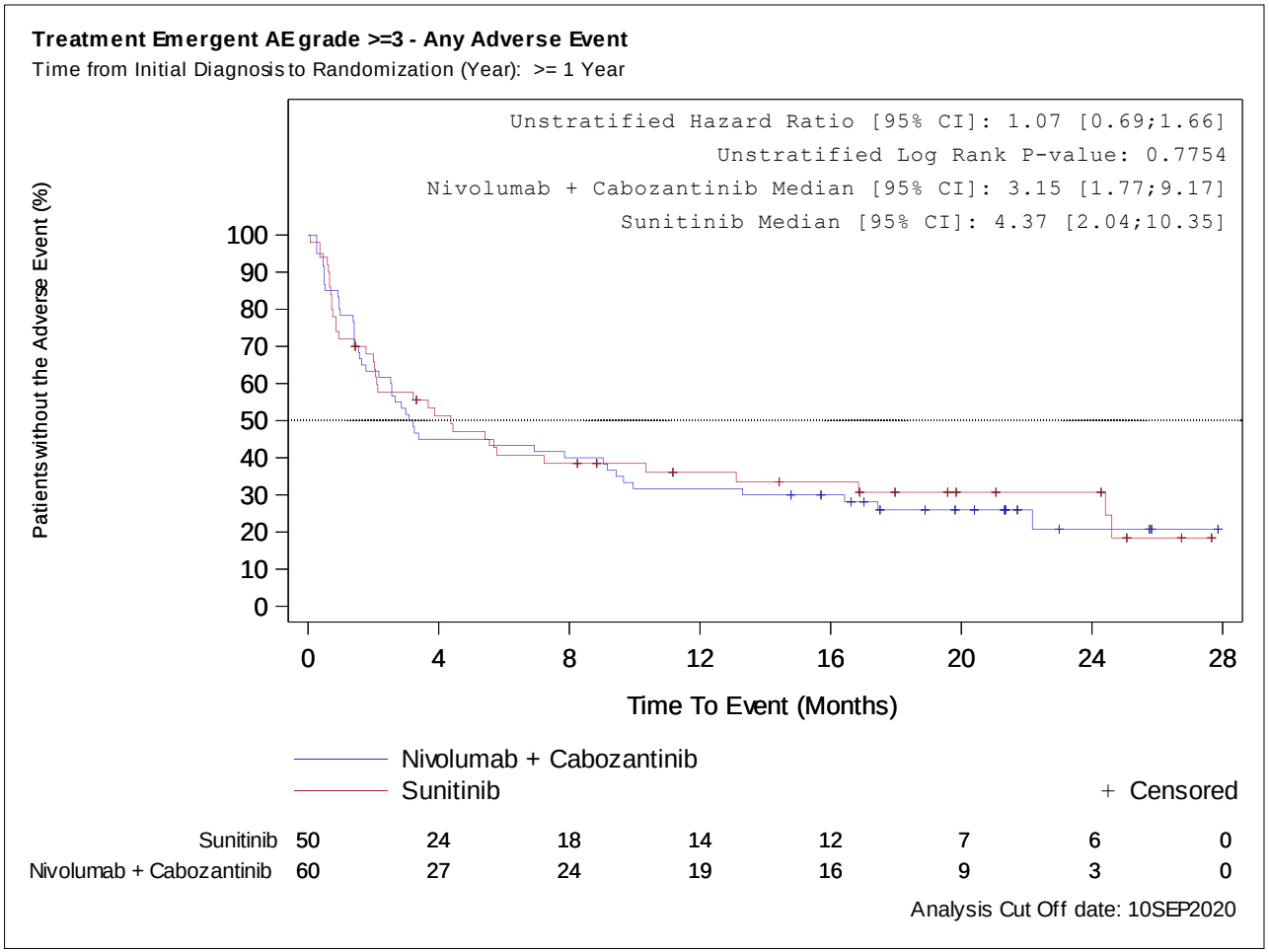
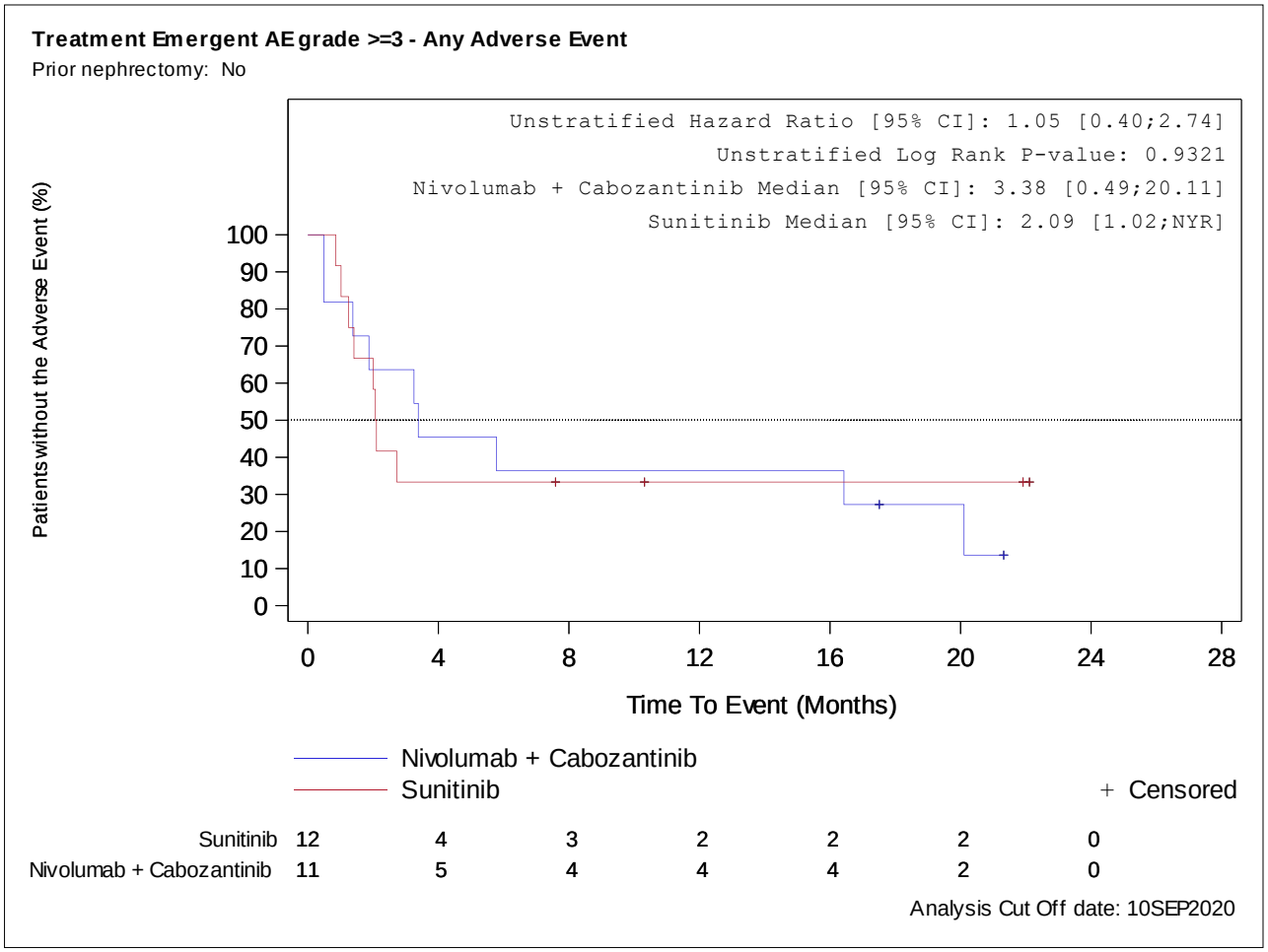
FIGURE 3.3.2.16: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



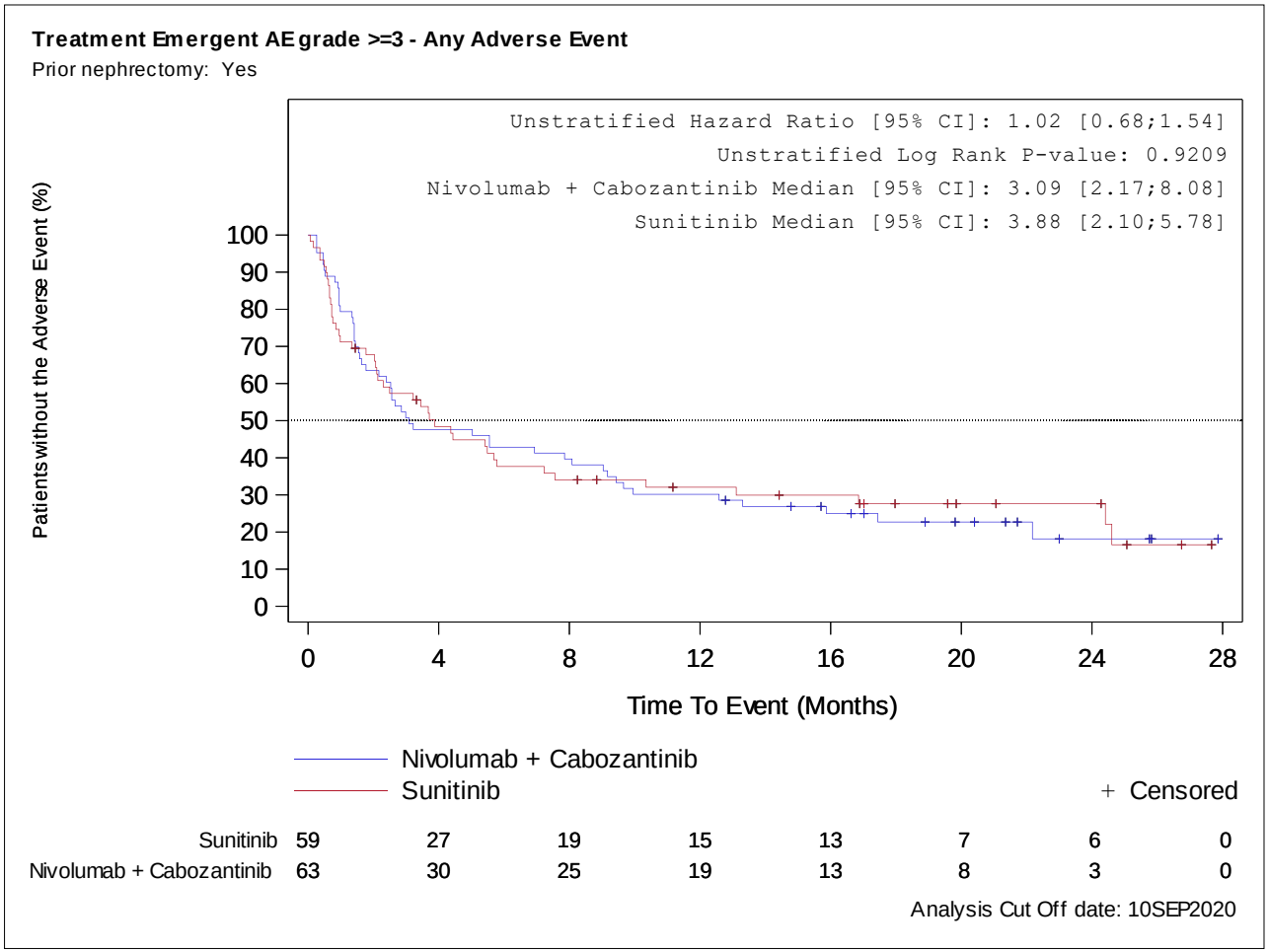

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:22:52

FIGURE 3.3.2.17: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



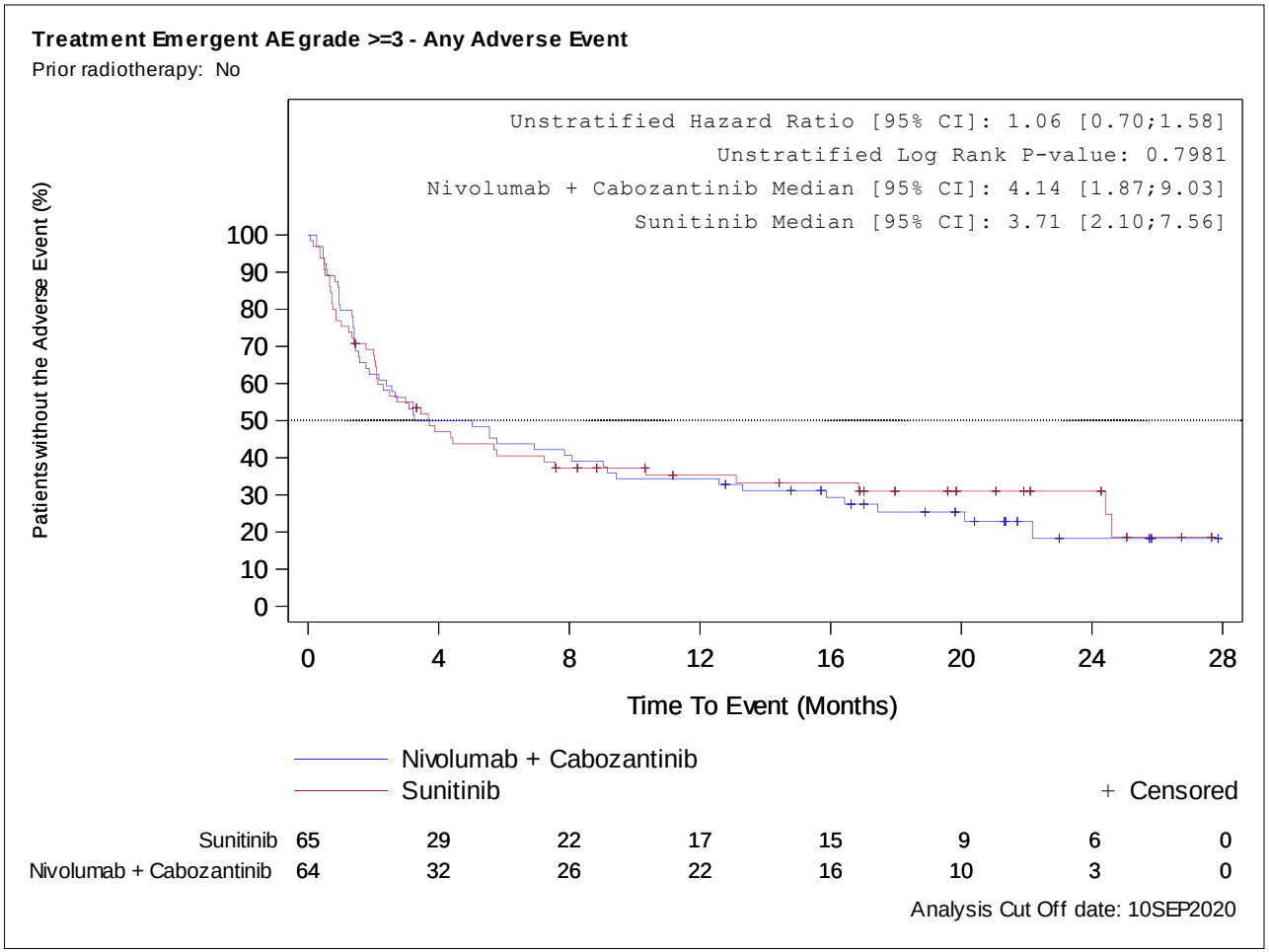

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:23:50

FIGURE 3.3.2.18: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy:  Yes



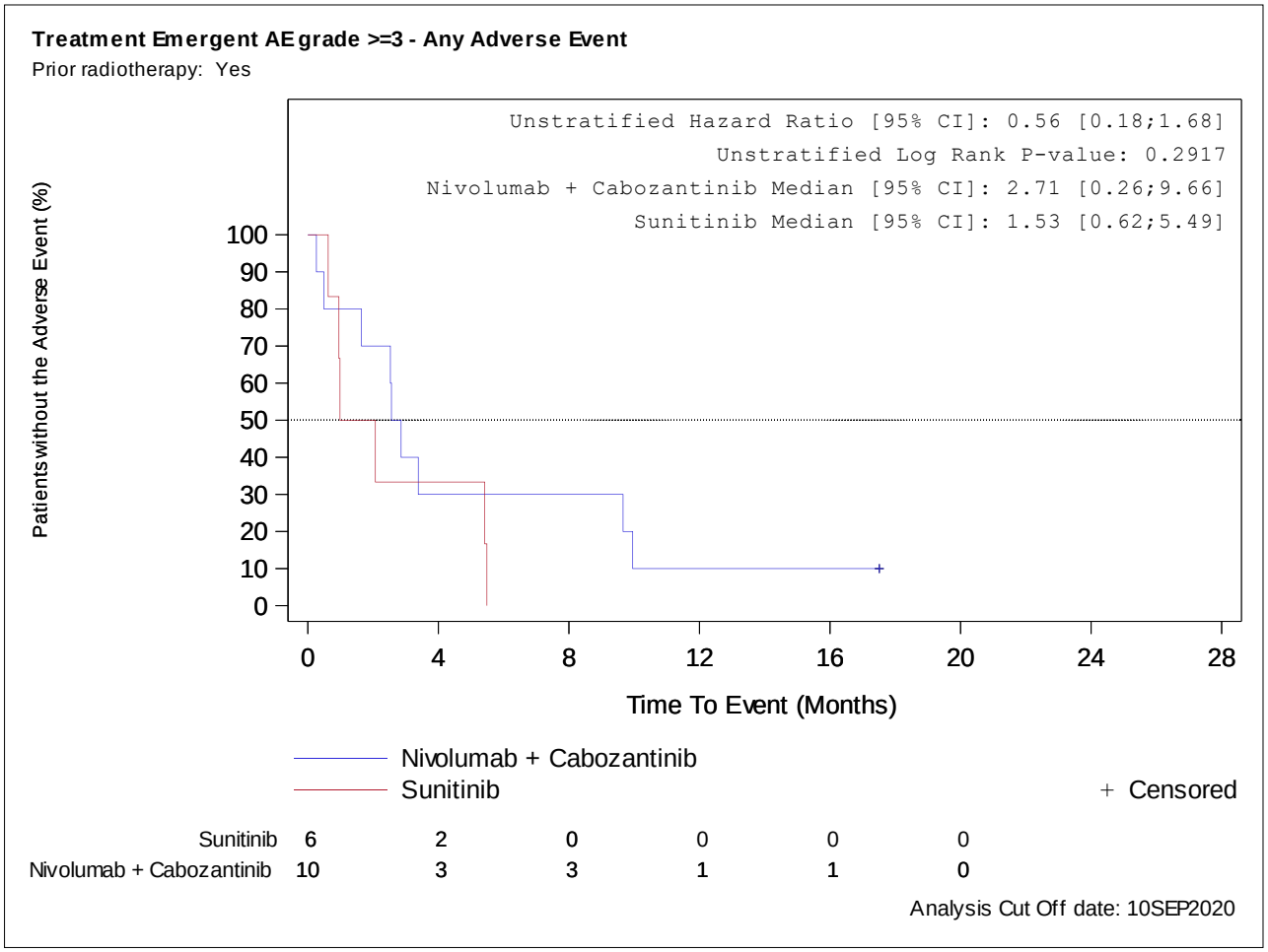

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:23:56

FIGURE 3.3.2.19: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:24:03

FIGURE 3.3.2.20: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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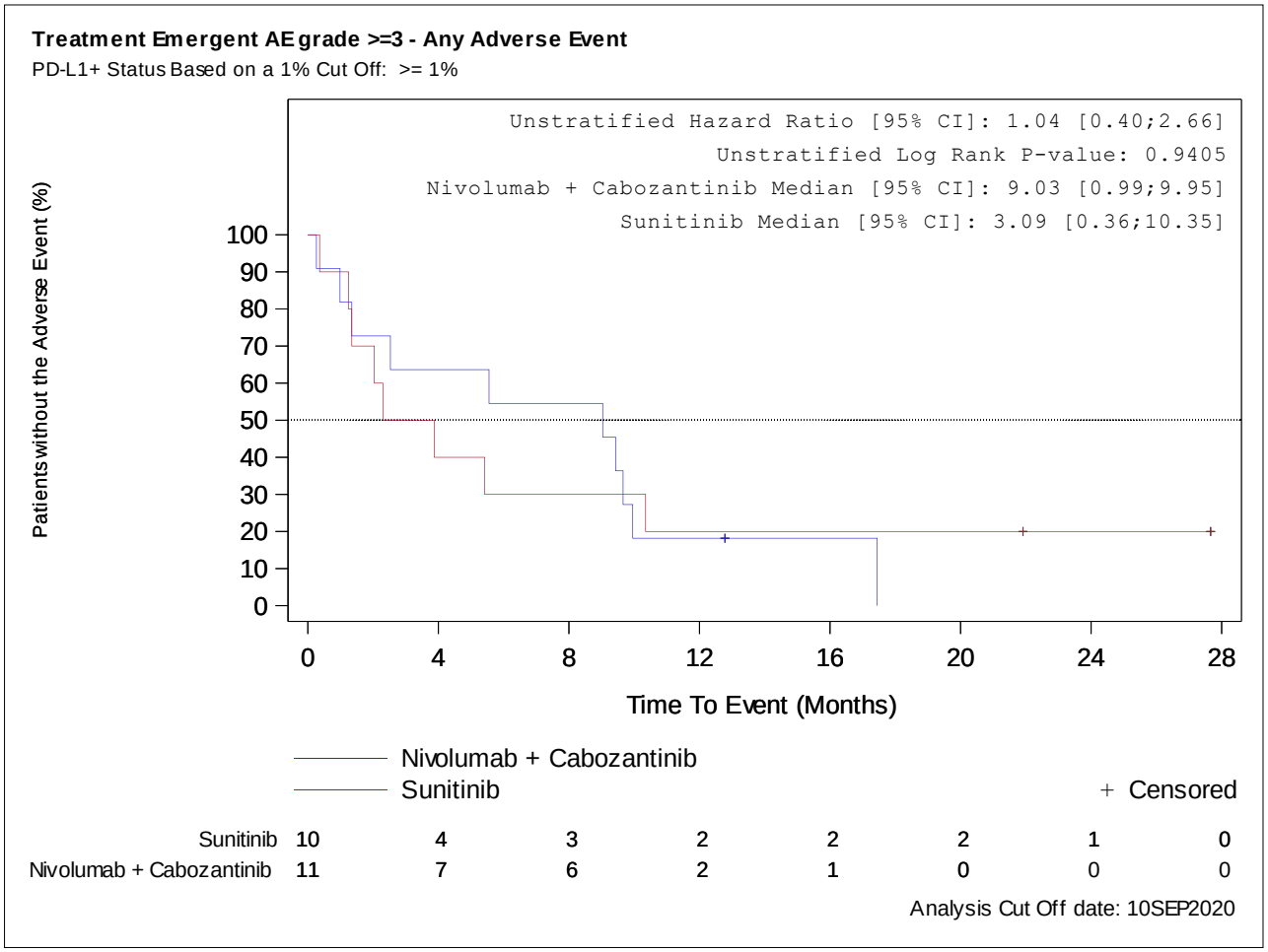
FIGURE 3.3.2.21: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off:  >= 1%




Analysis Cut Off date: 10SEP2020
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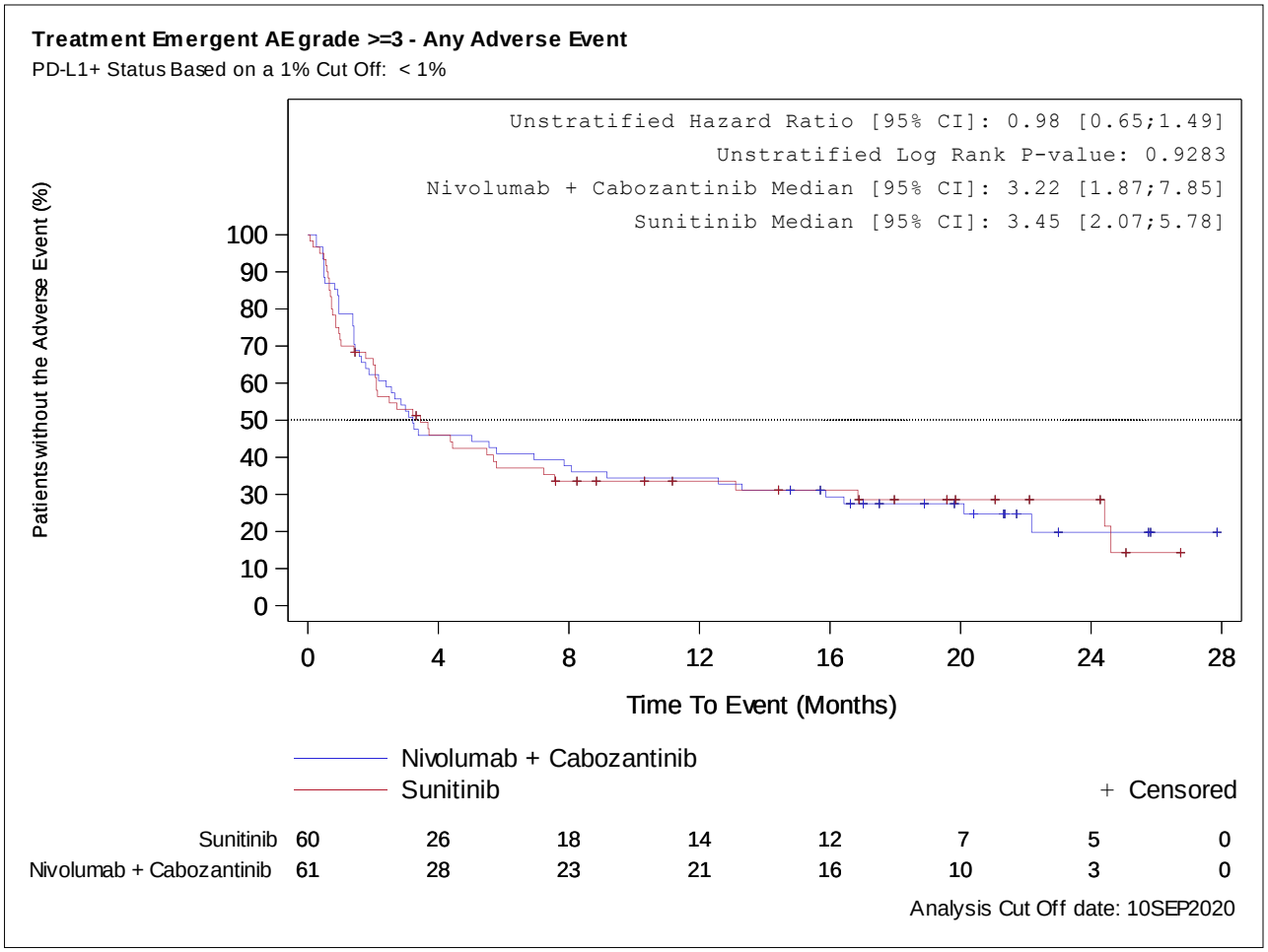
FIGURE 3.3.2.22: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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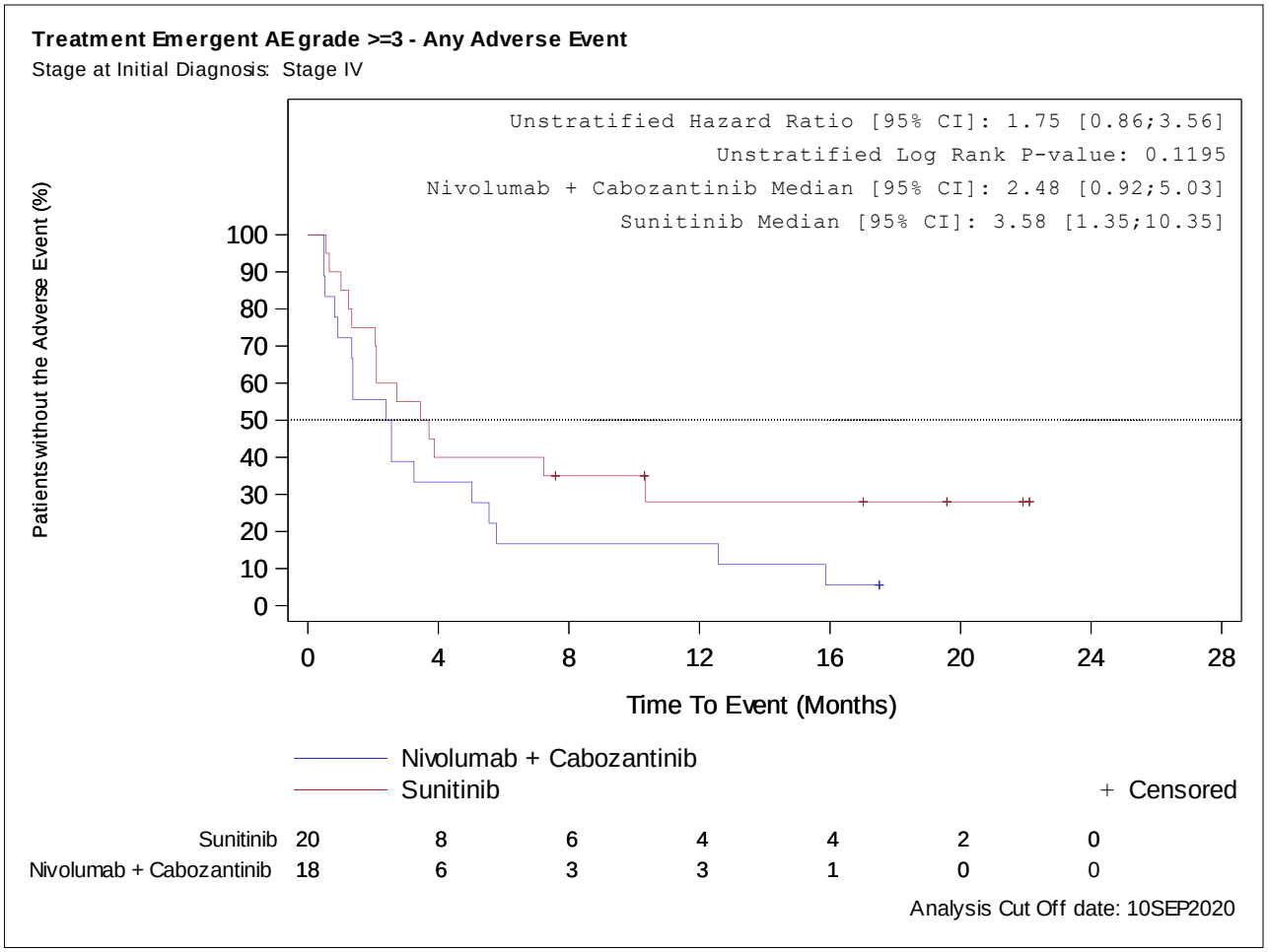
FIGURE 3.3.2.23: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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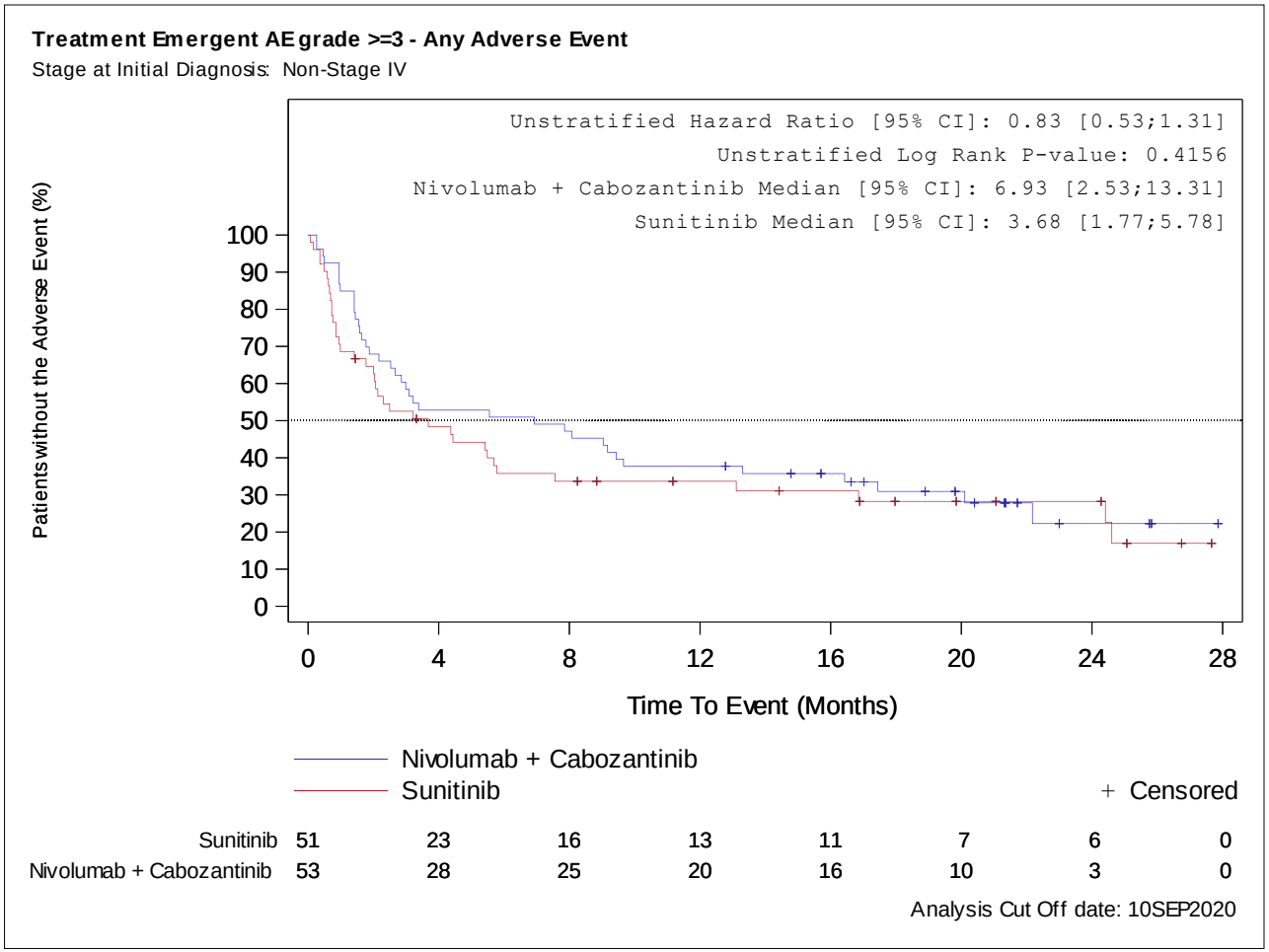
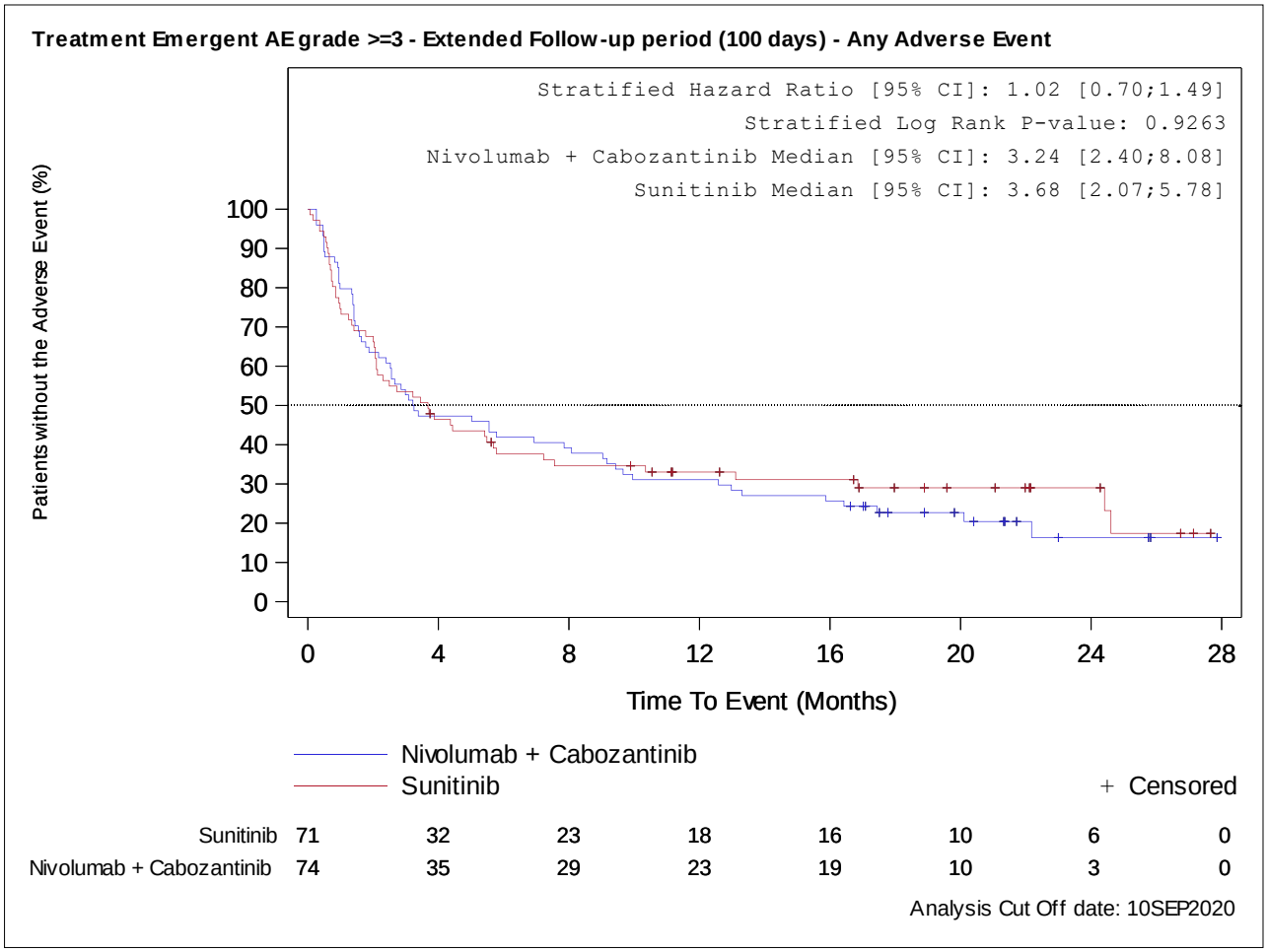
FIGURE 3.3.2.24: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



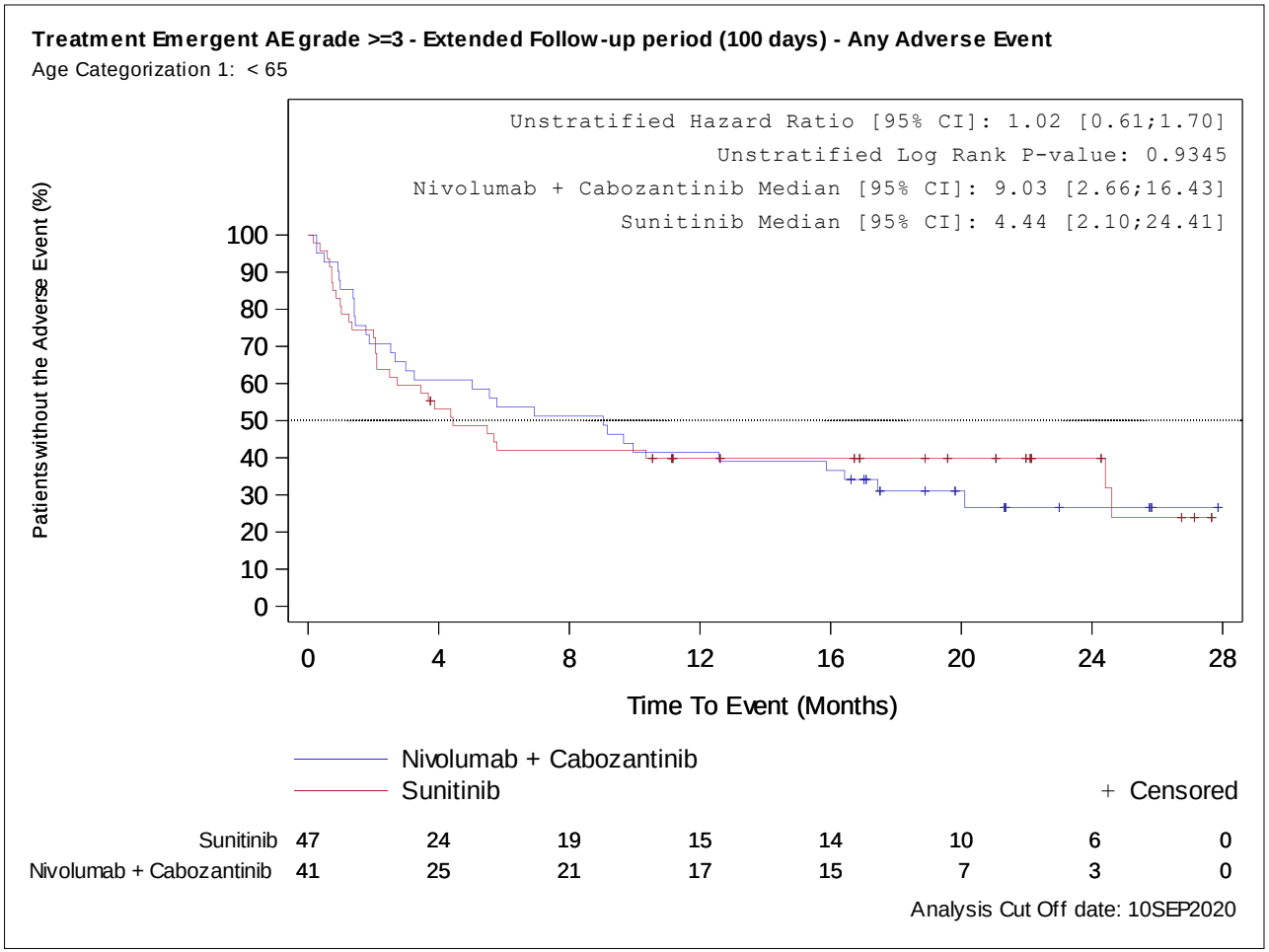

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:25:00

FIGURE 3.4.1: Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



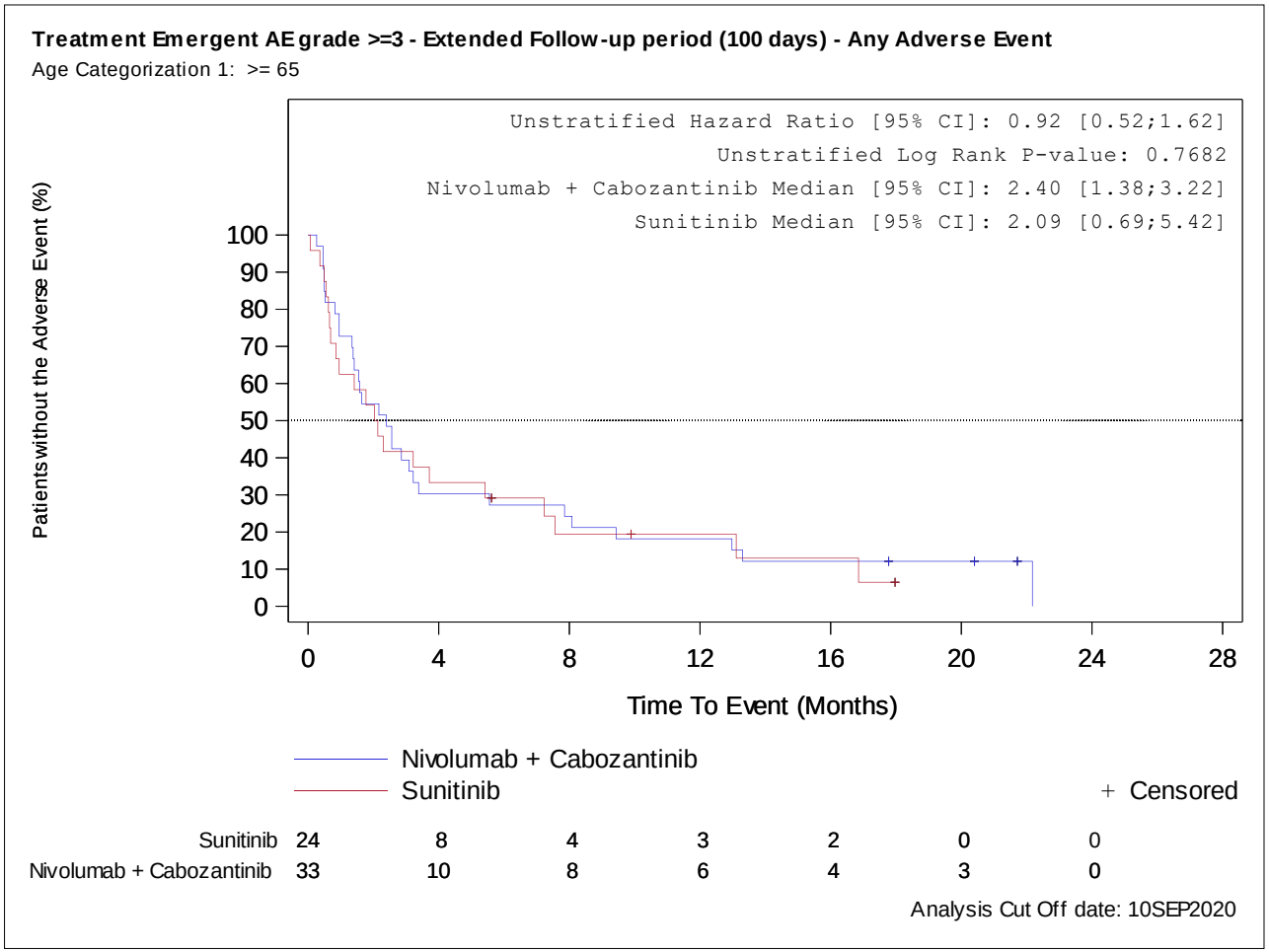

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:28:28

FIGURE 3.4.2.1: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



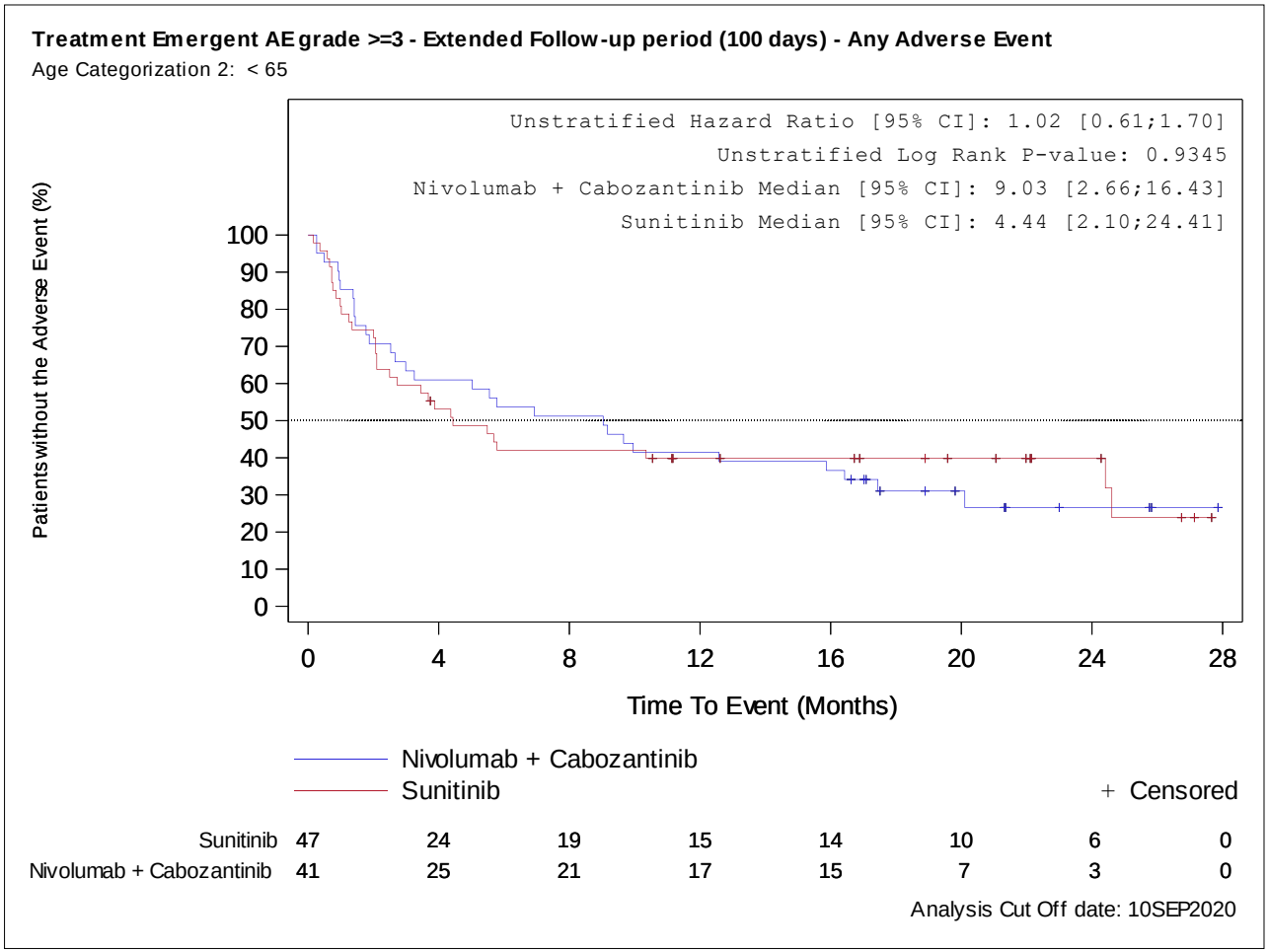

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:28:32

FIGURE 3.4.2.2: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:28:38

FIGURE 3.4.2.3: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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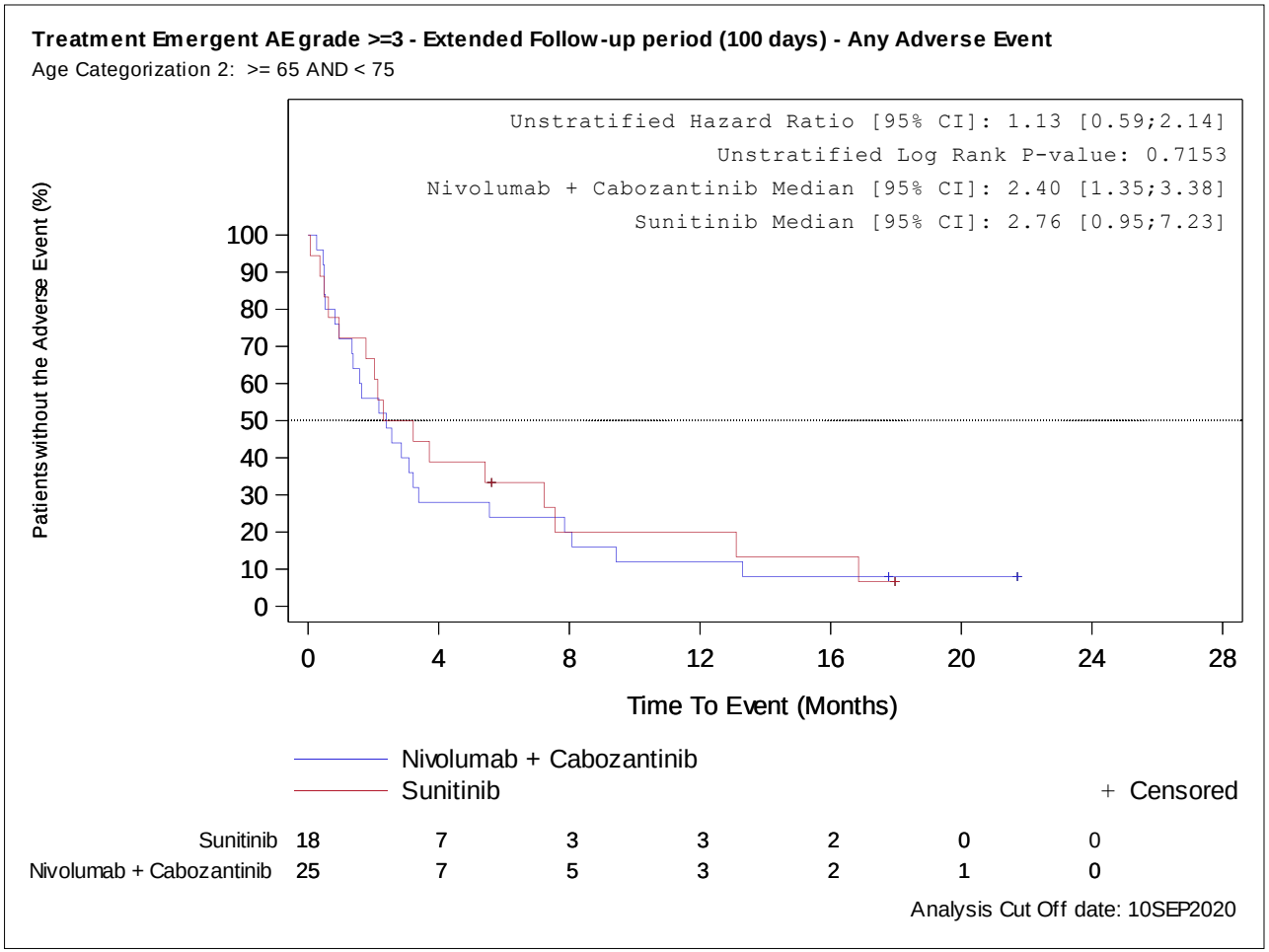
FIGURE 3.4.2.4: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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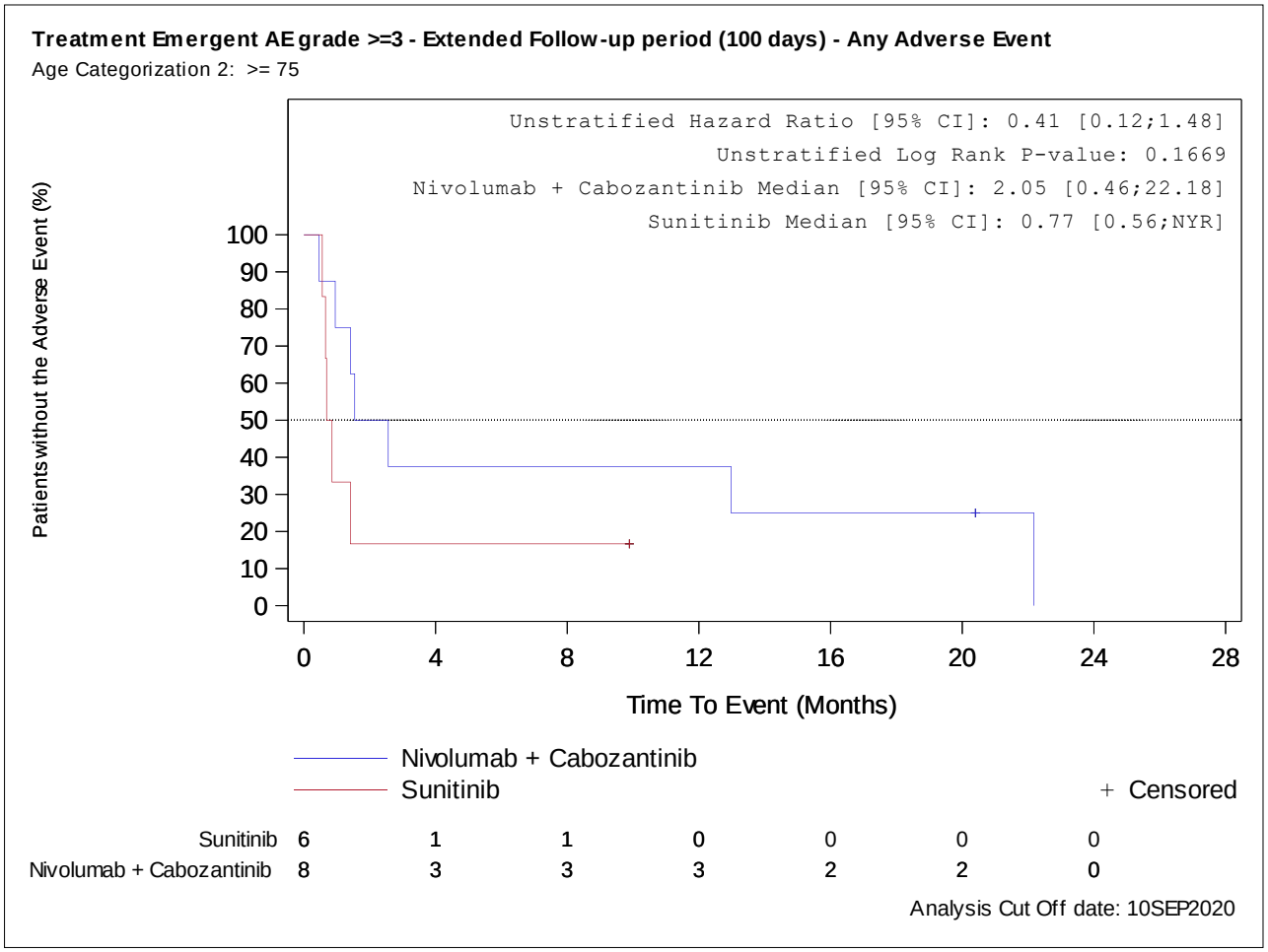
FIGURE 3.4.2.5: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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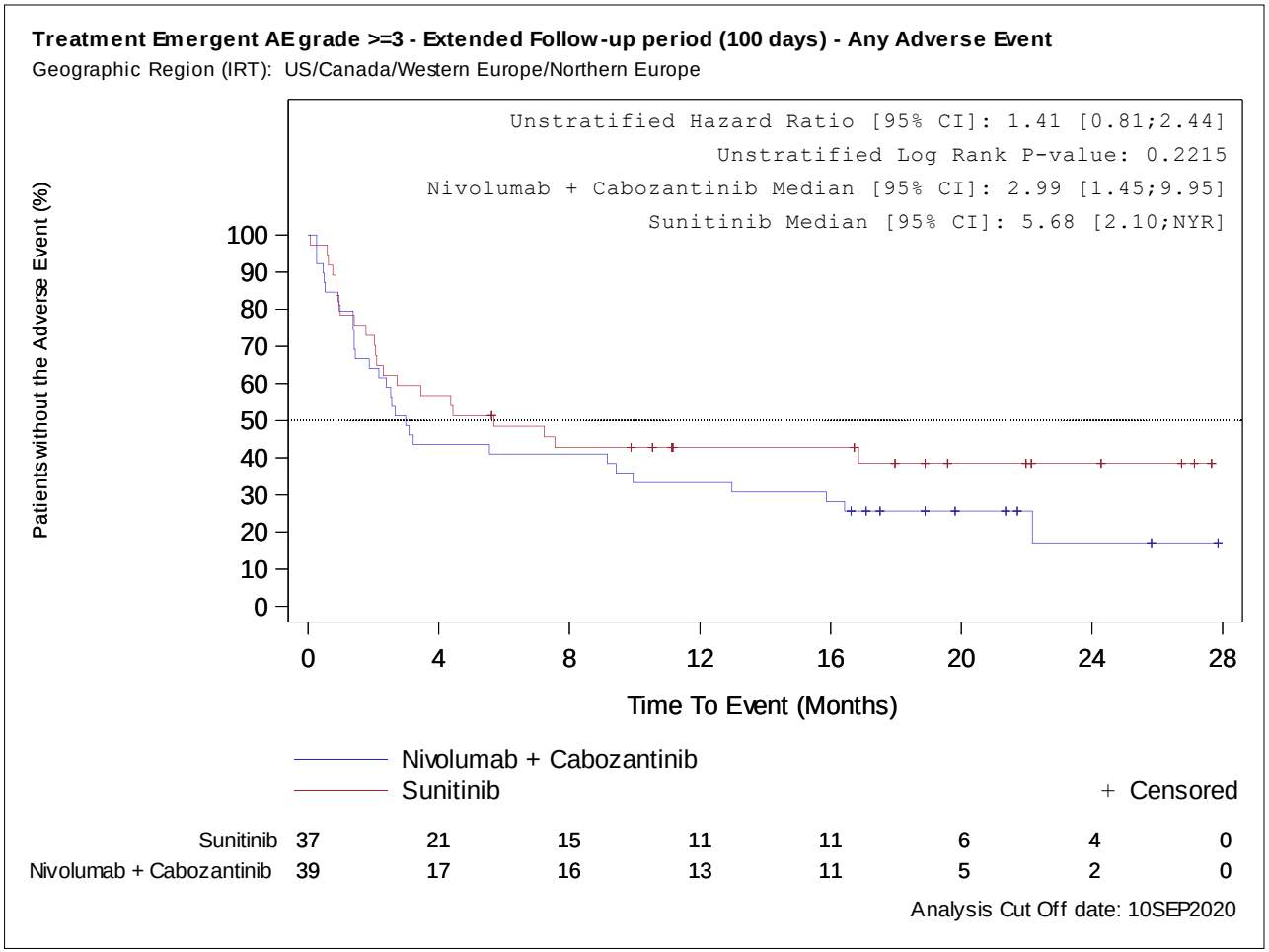
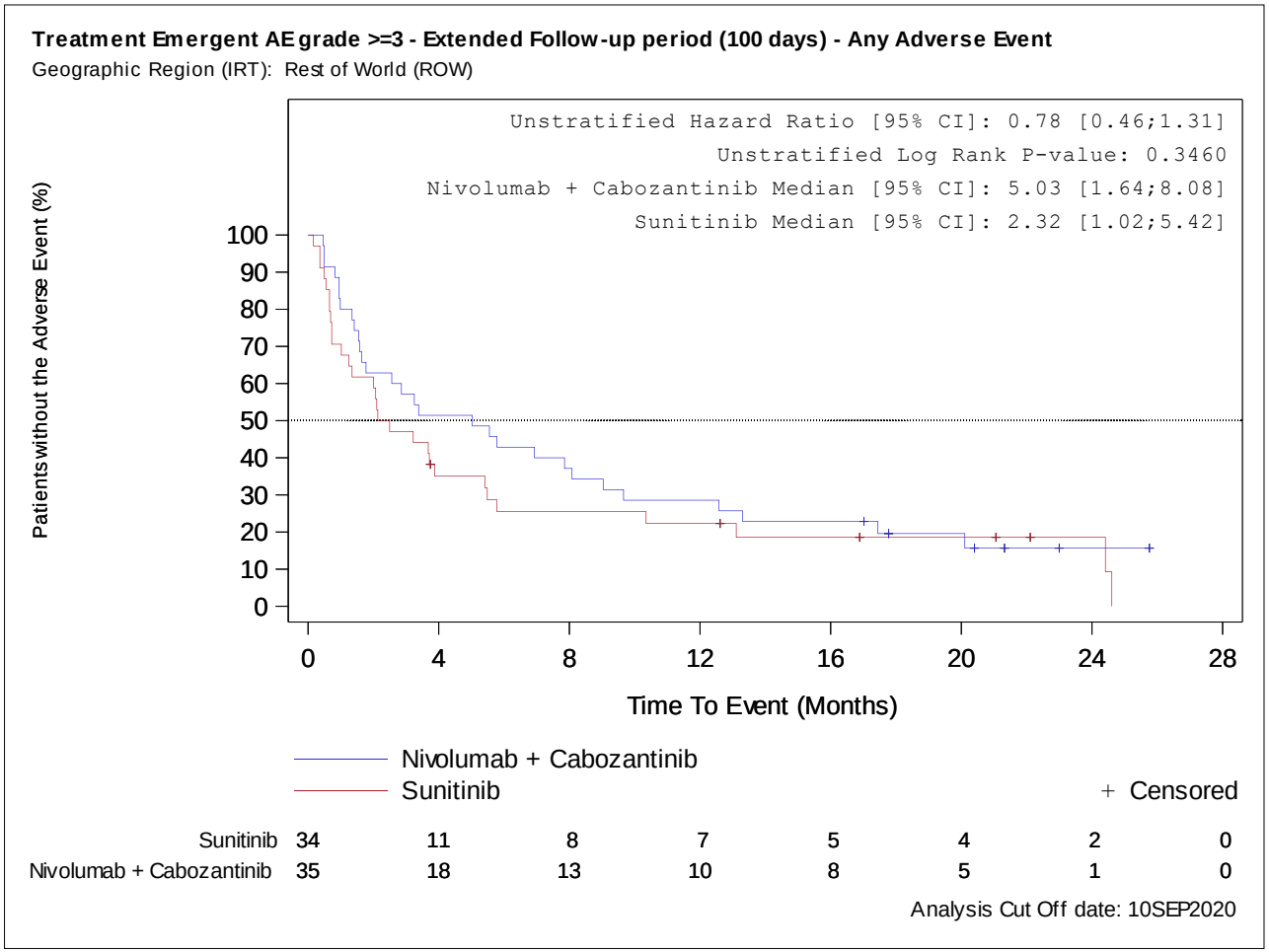
FIGURE 3.4.2.6: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



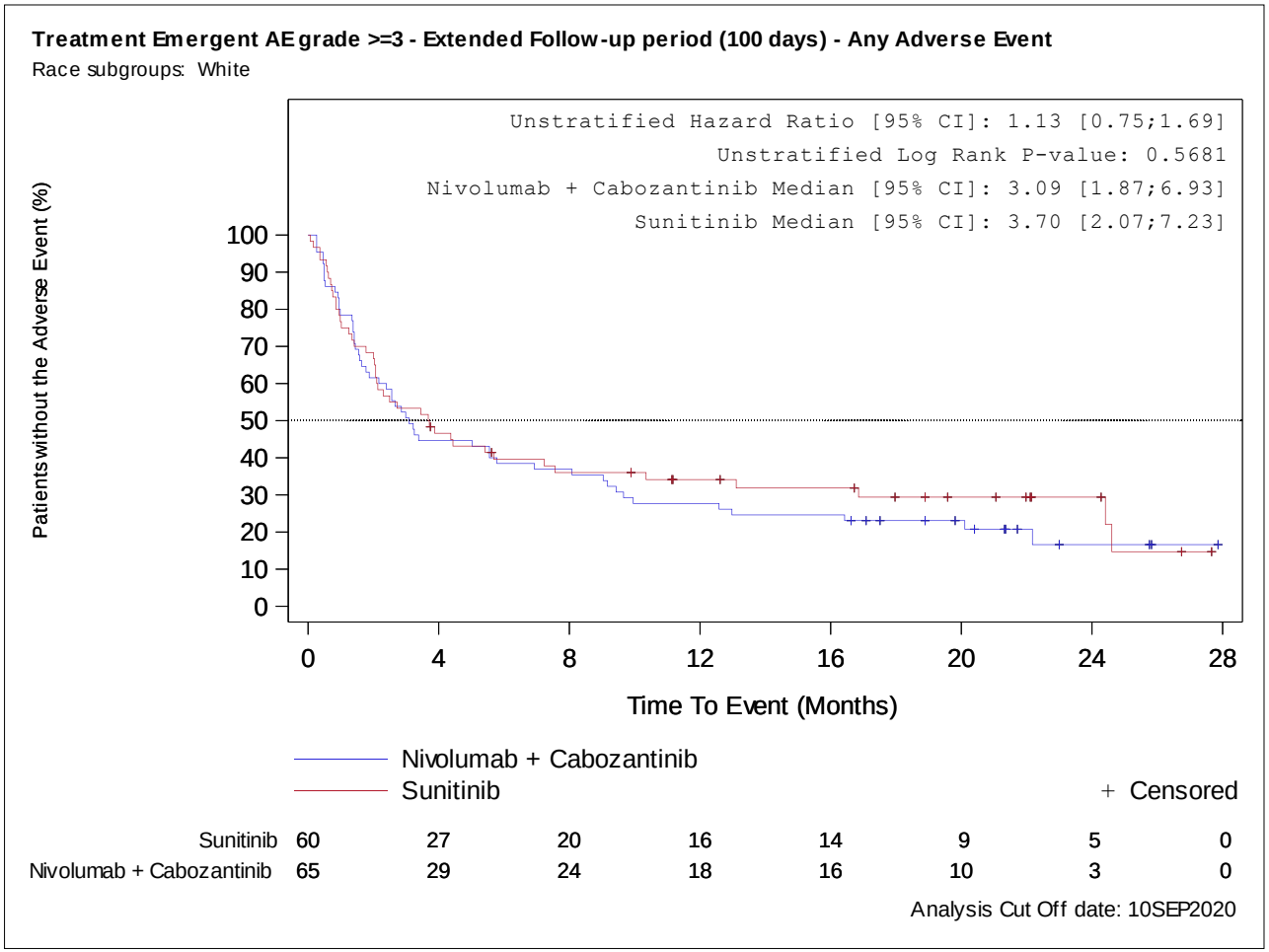

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:29:03

FIGURE 3.4.2.7: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:29:09

FIGURE 3.4.2.8: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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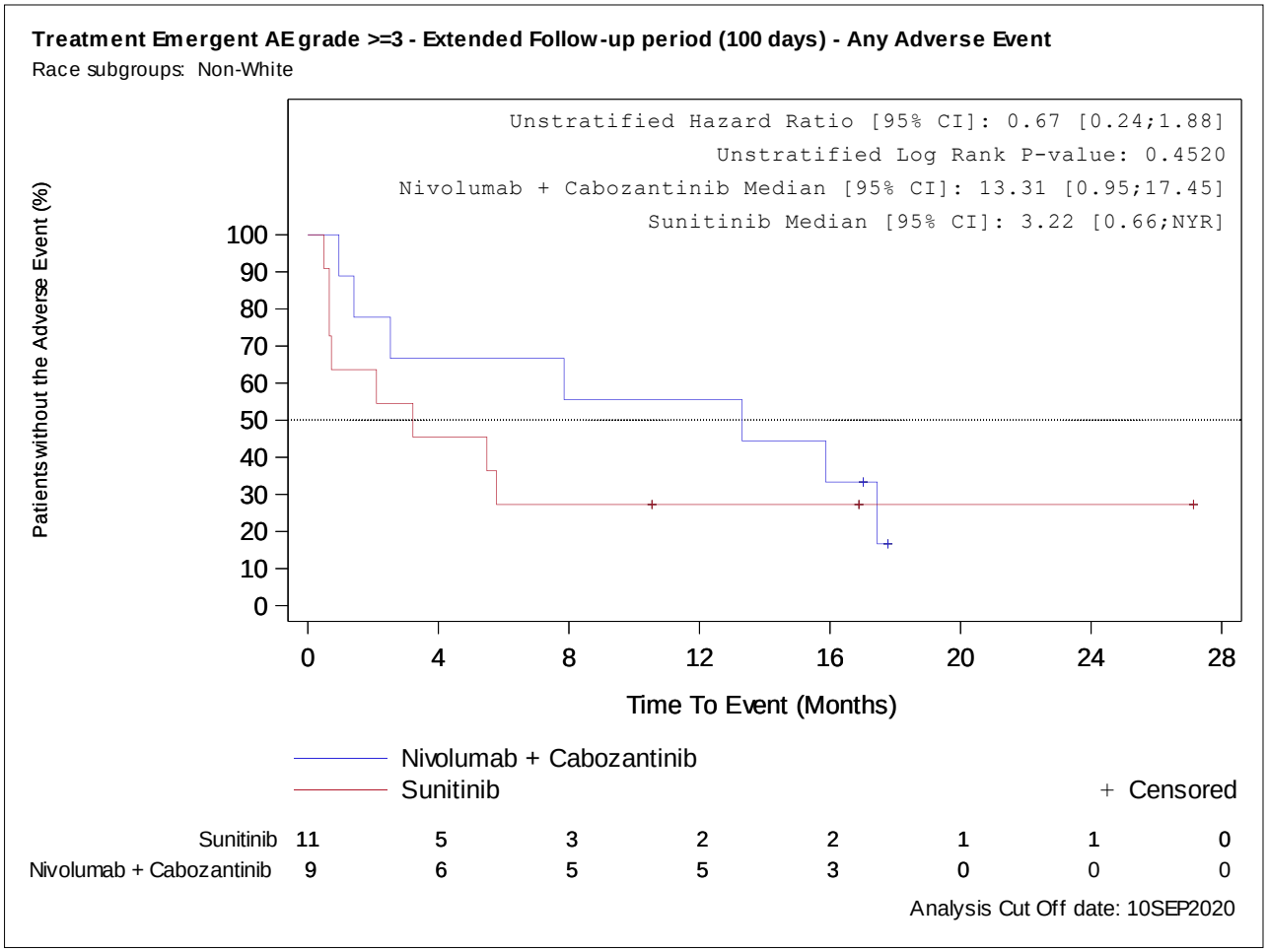
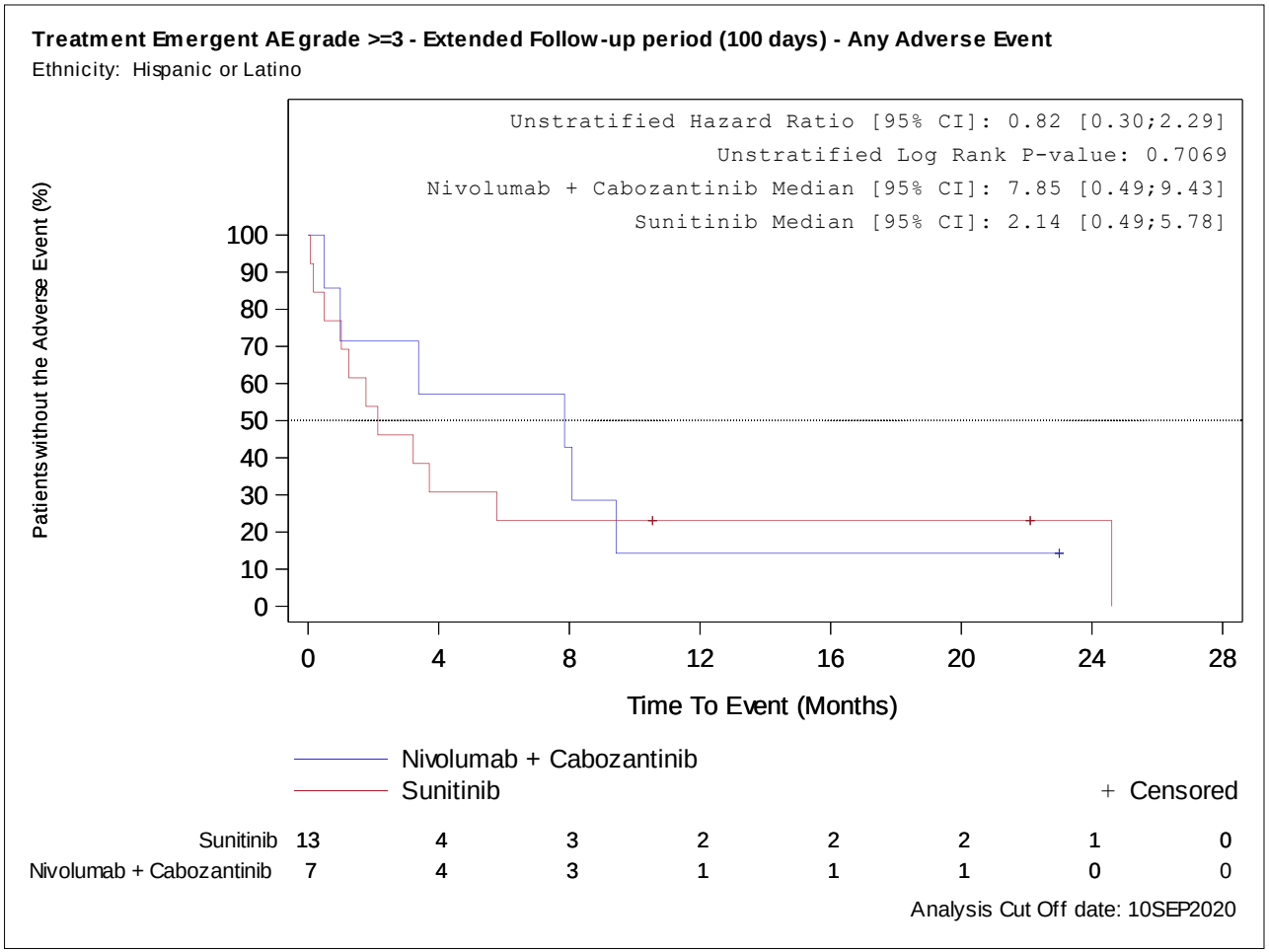
FIGURE 3.4.2.9: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:29:21

FIGURE 3.4.2.10: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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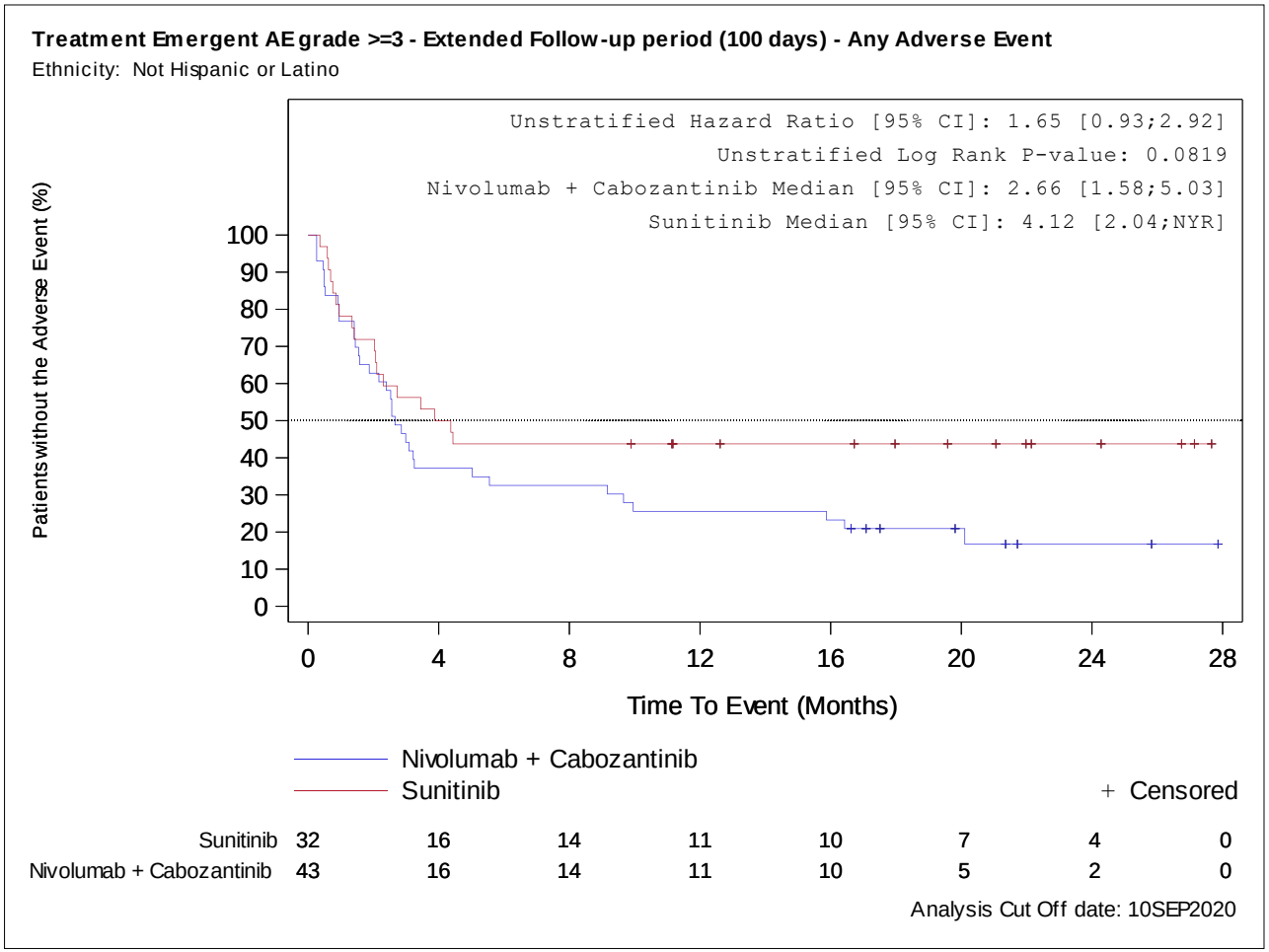
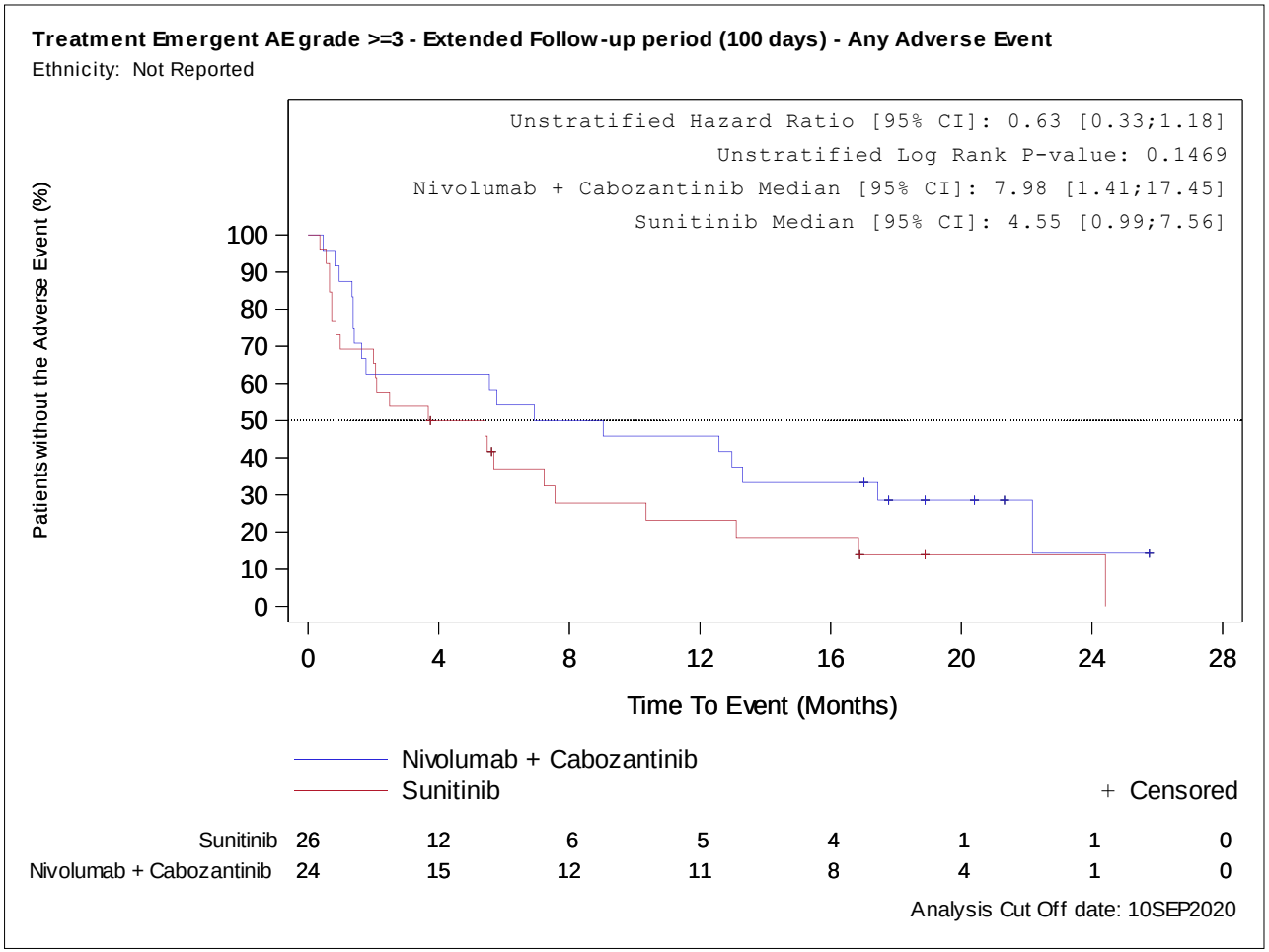
FIGURE 3.4.2.11: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



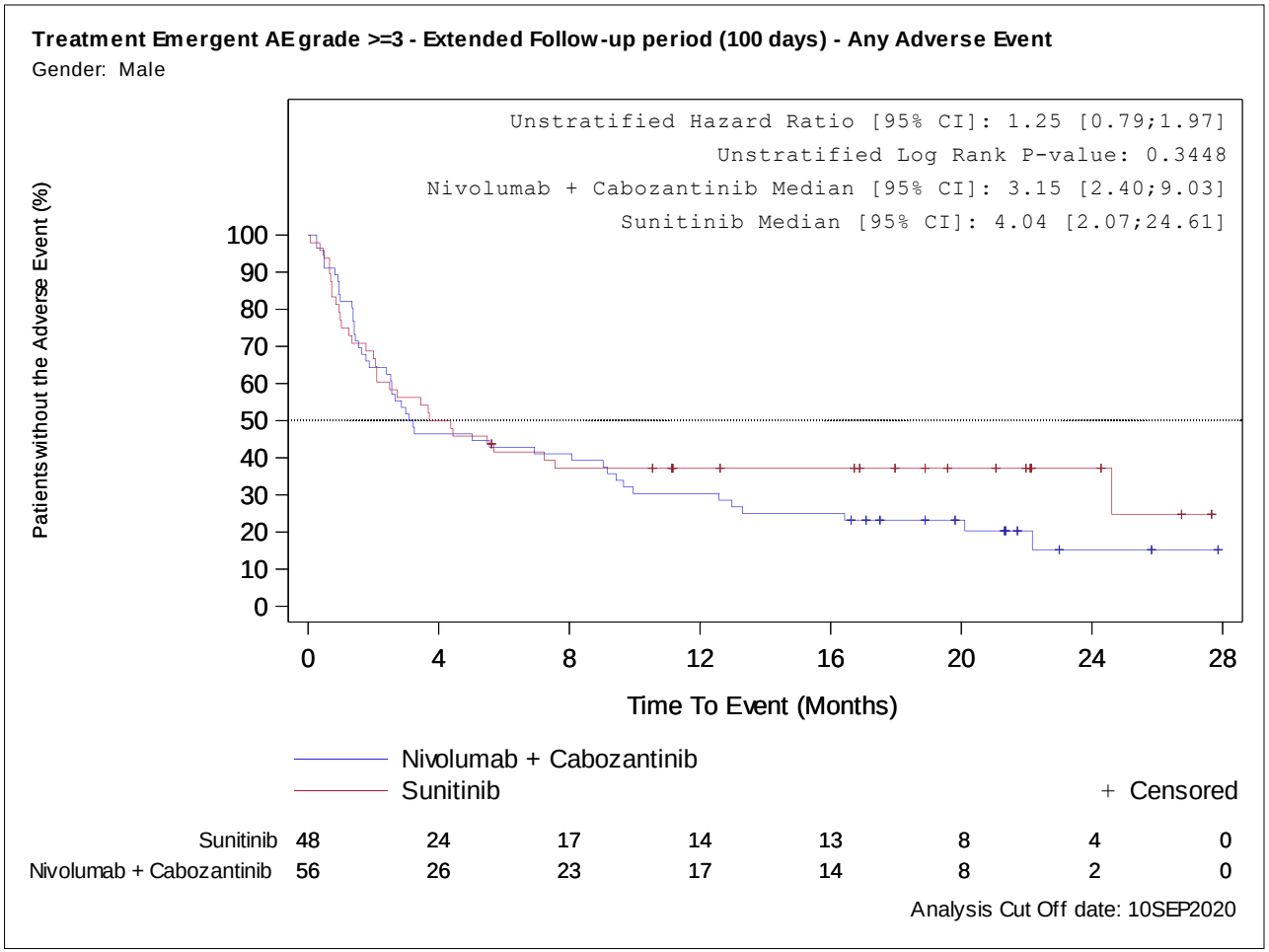

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:29:33

FIGURE 3.4.2.12: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:29:39

FIGURE 3.4.2.13: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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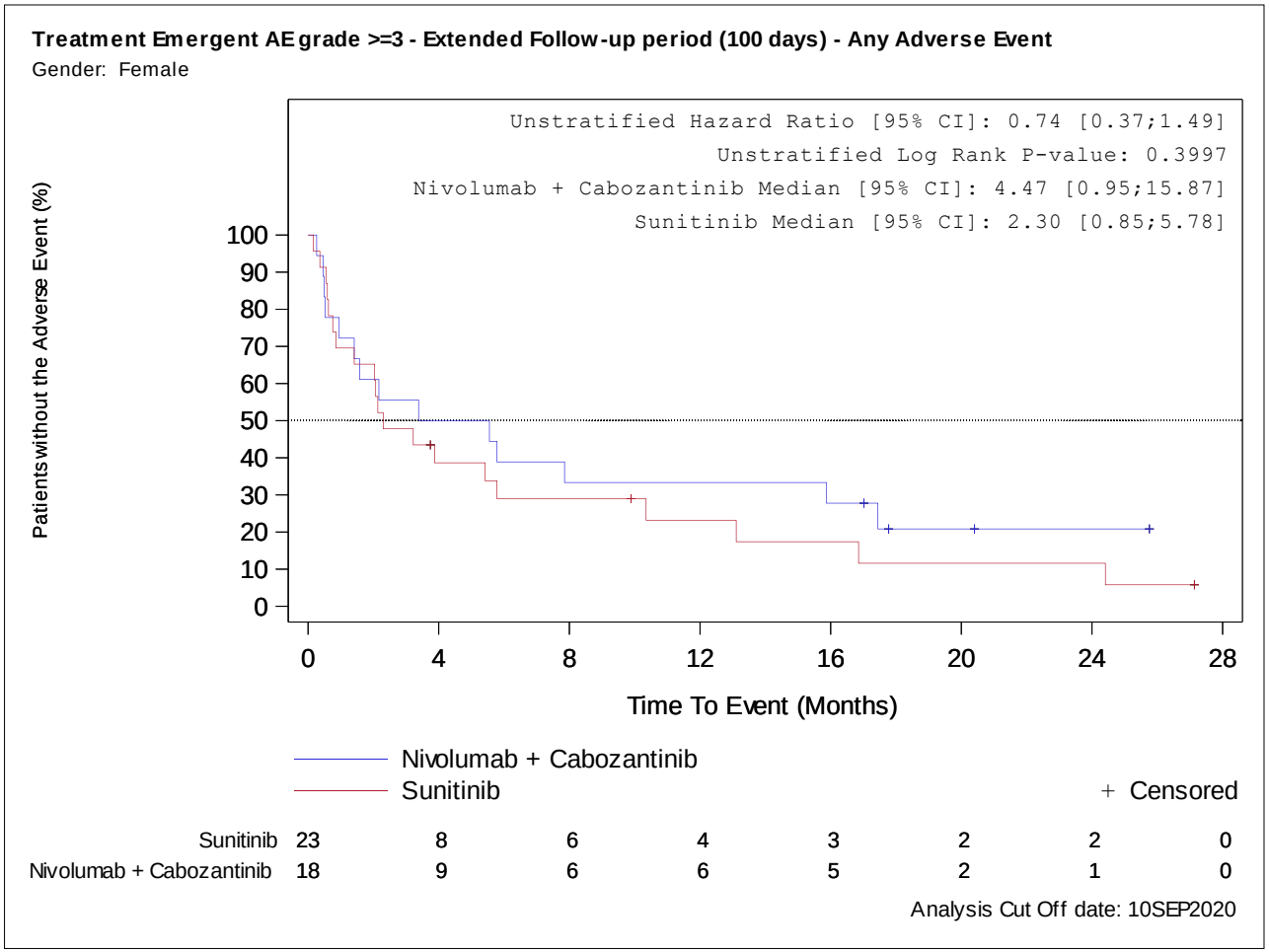
FIGURE 3.4.2.14: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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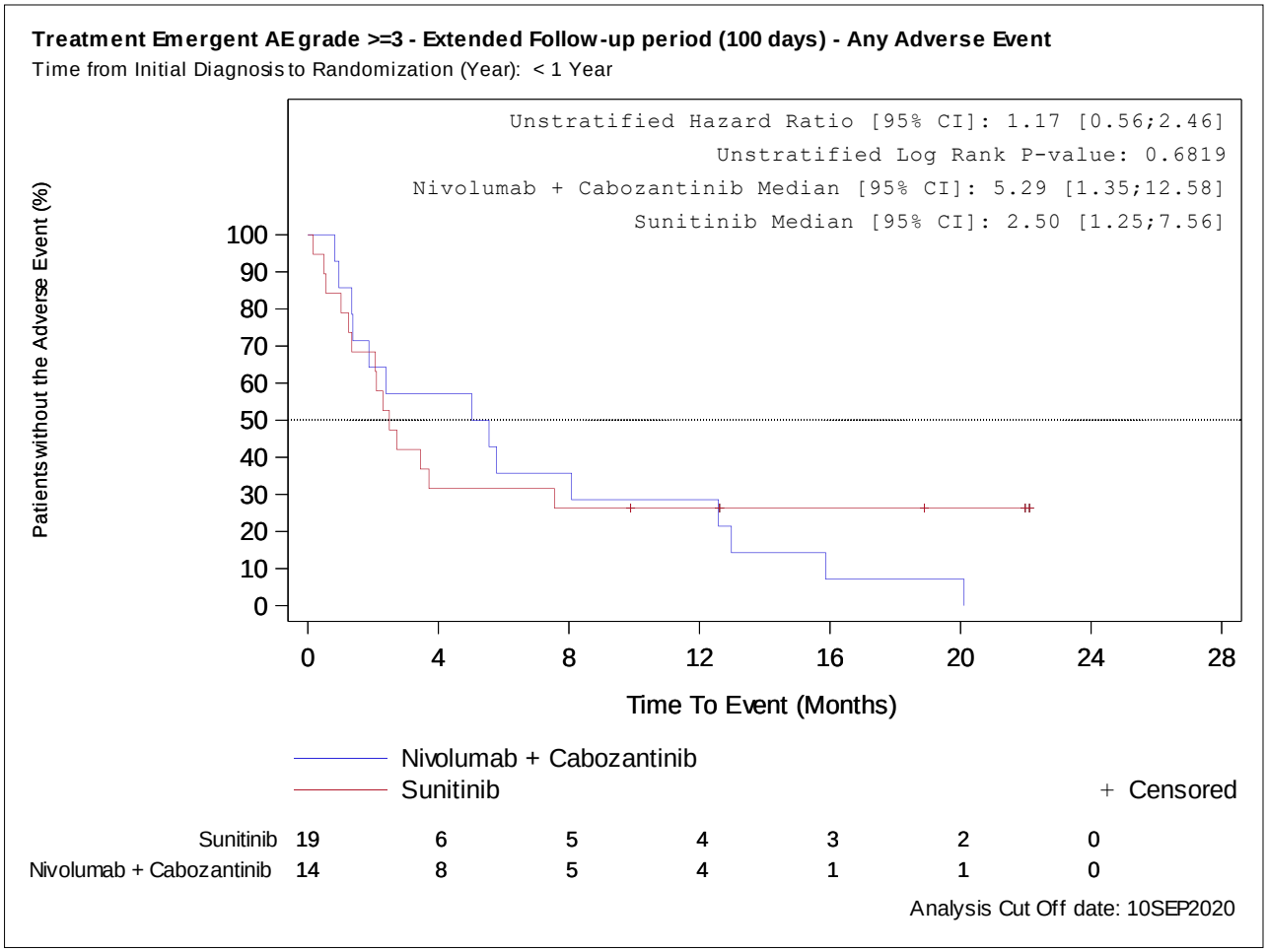
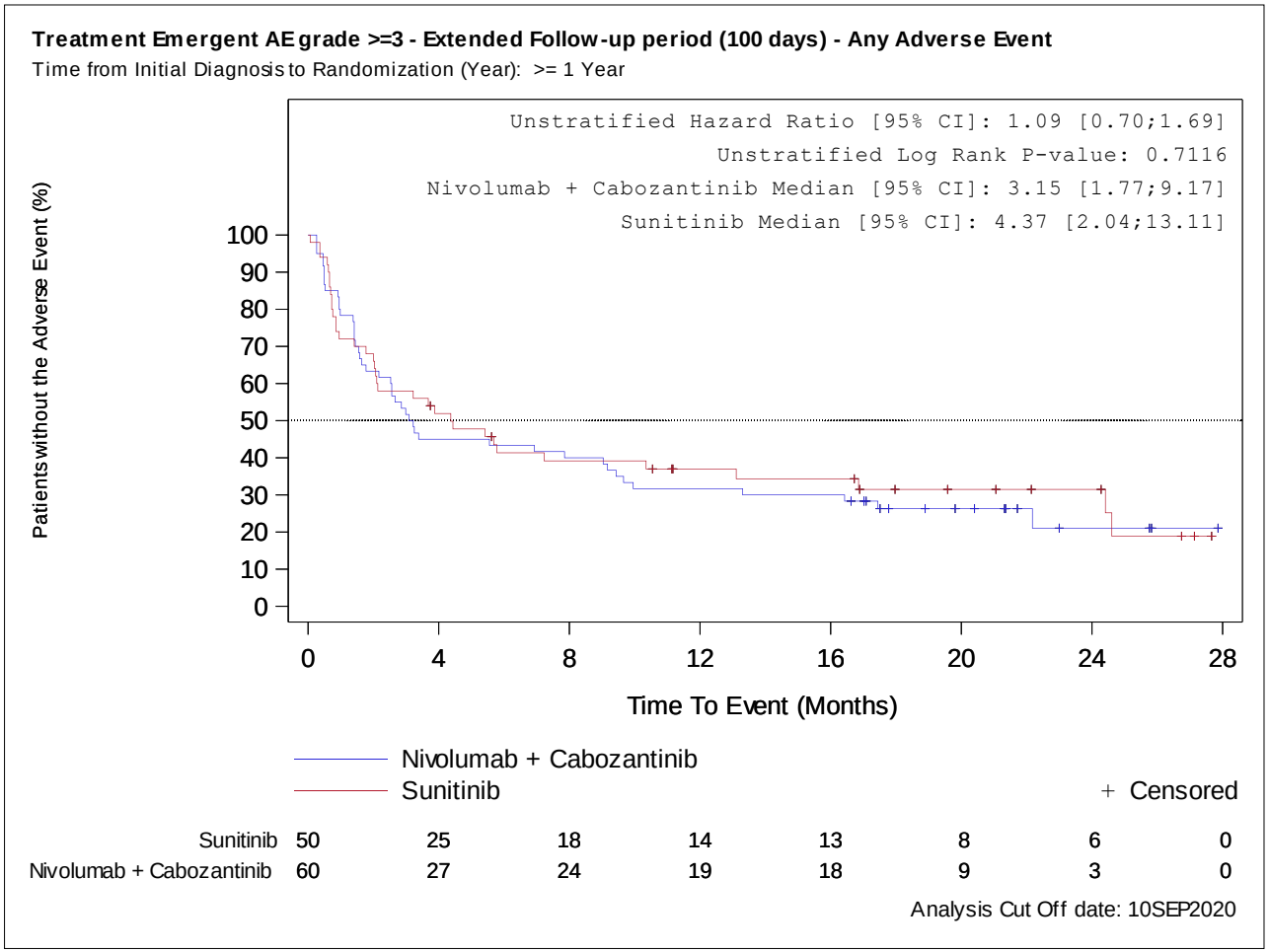
FIGURE 3.4.2.15: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



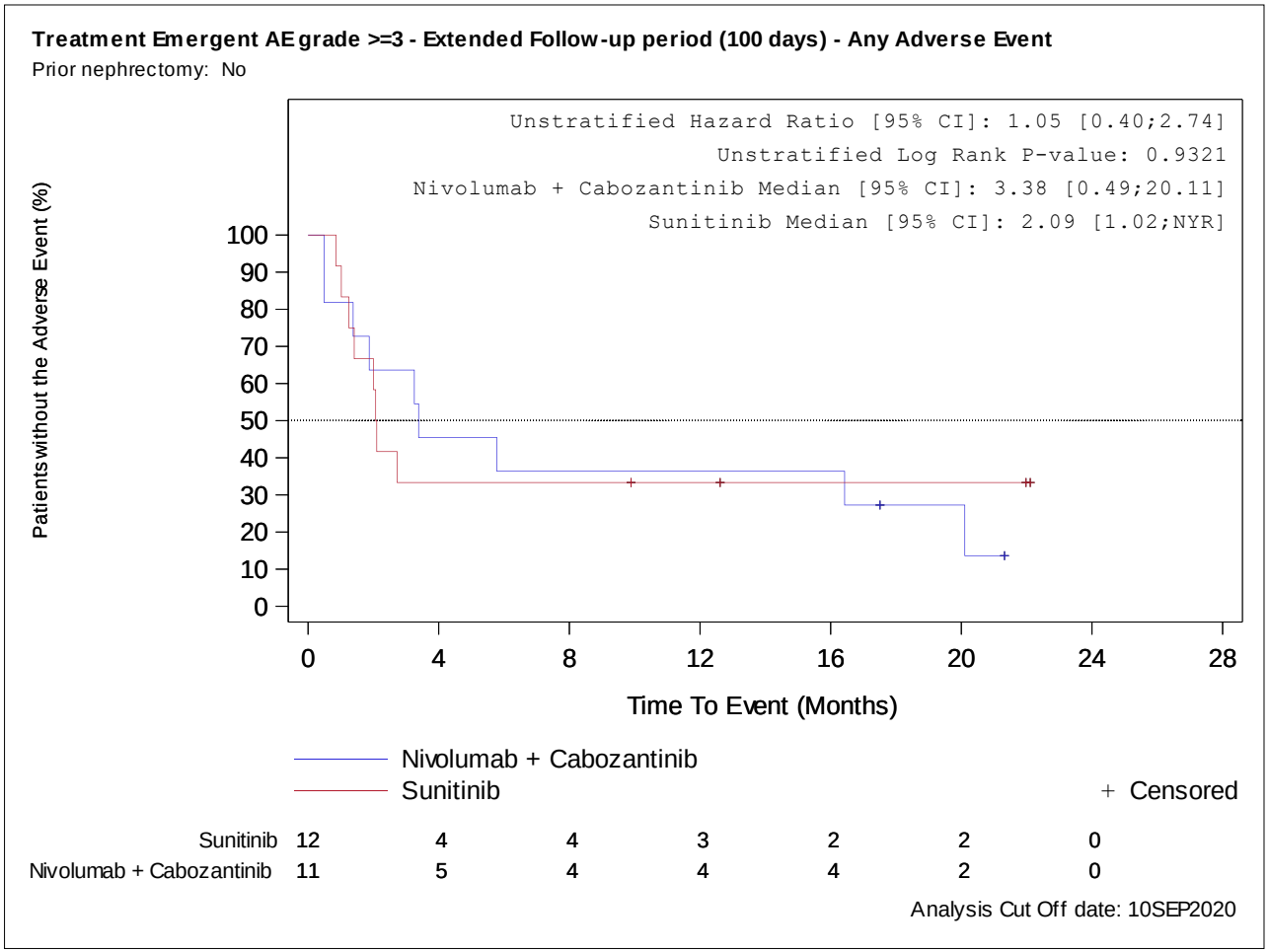

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:30:10

FIGURE 3.4.2.16: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



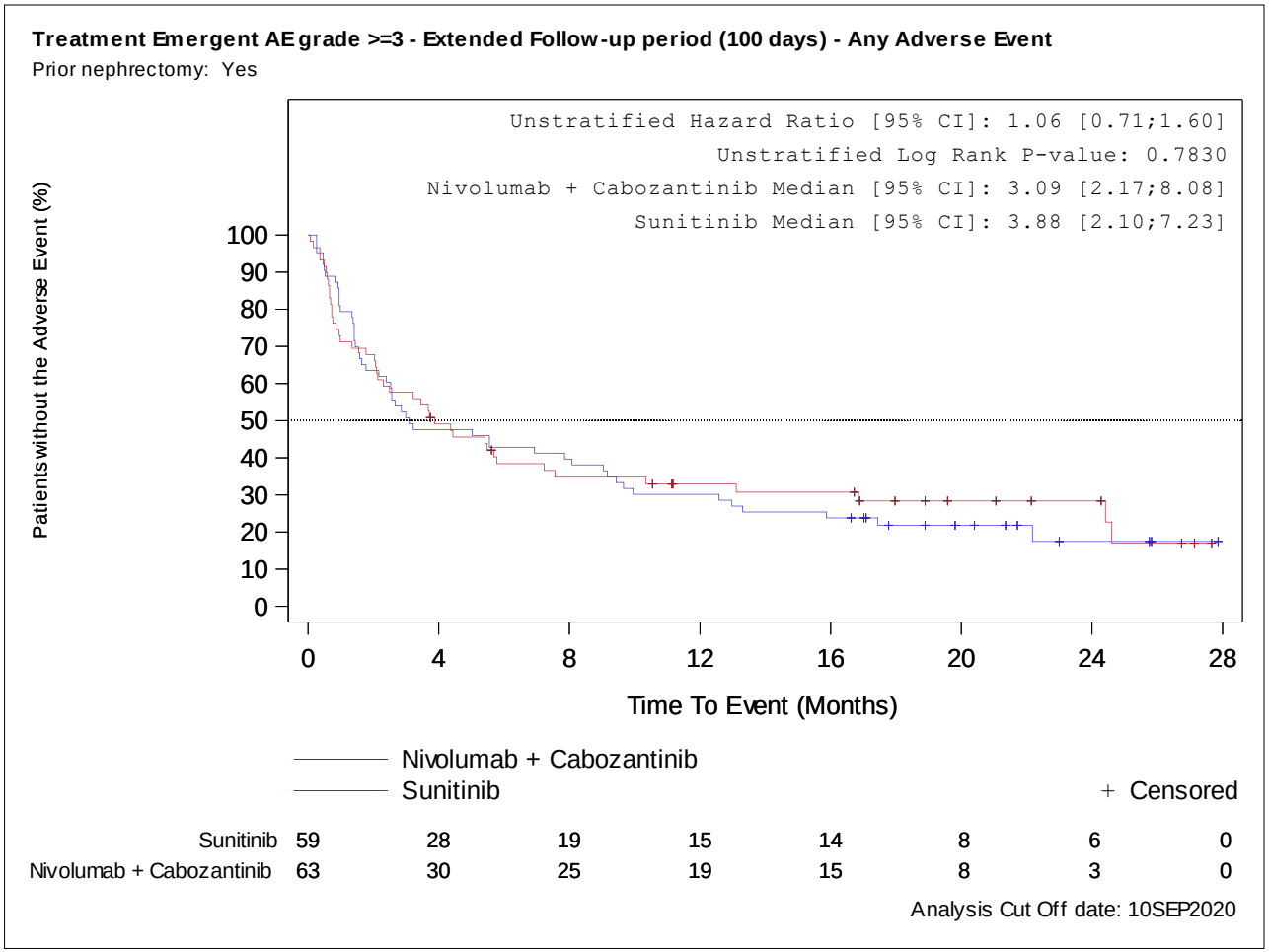

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:30:15

FIGURE 3.4.2.17: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:31:14

FIGURE 3.4.2.18: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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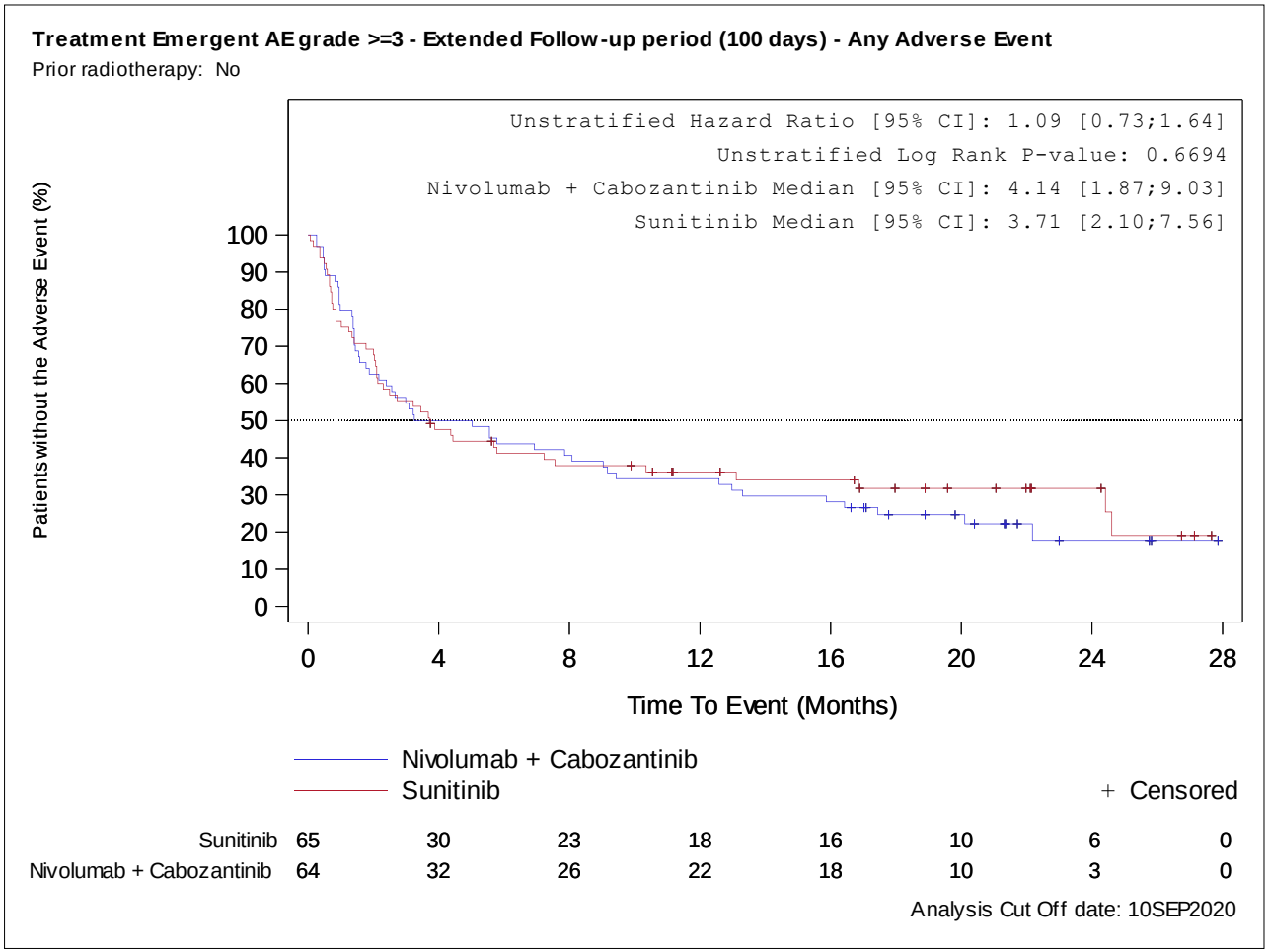
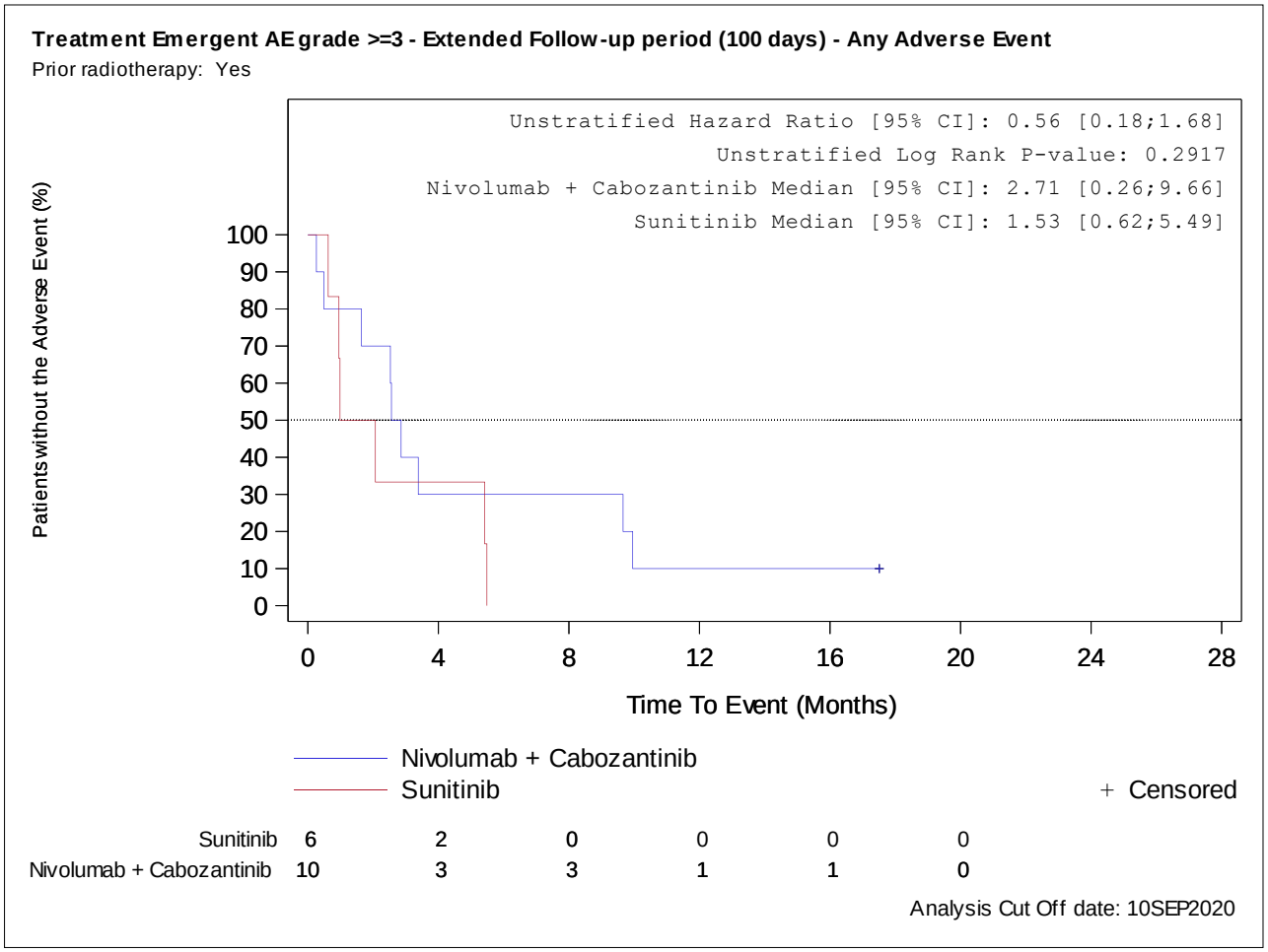
FIGURE 3.4.2.19: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



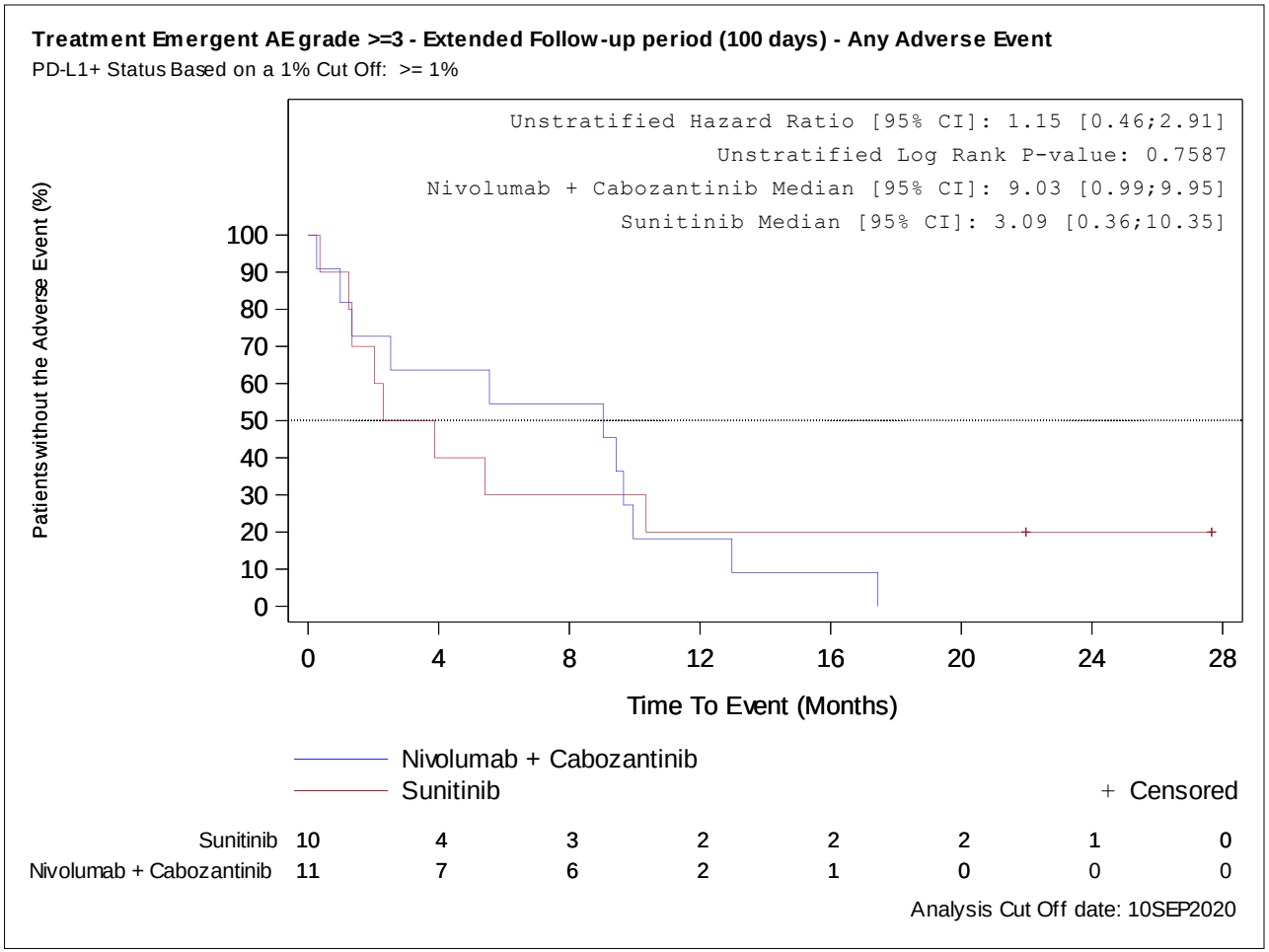

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:31:26

FIGURE 3.4.2.20: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



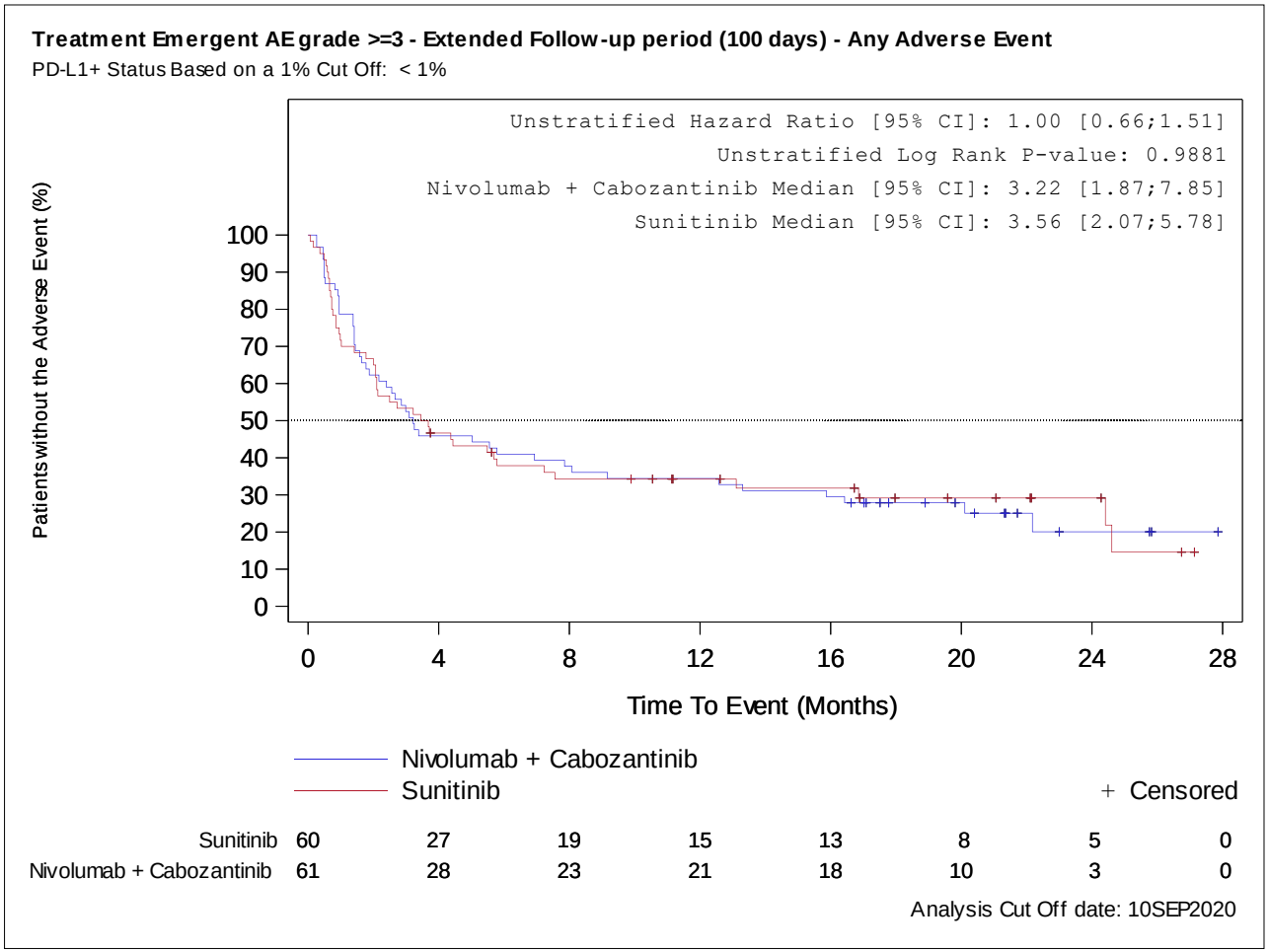

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:31:32

FIGURE 3.4.2.21: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



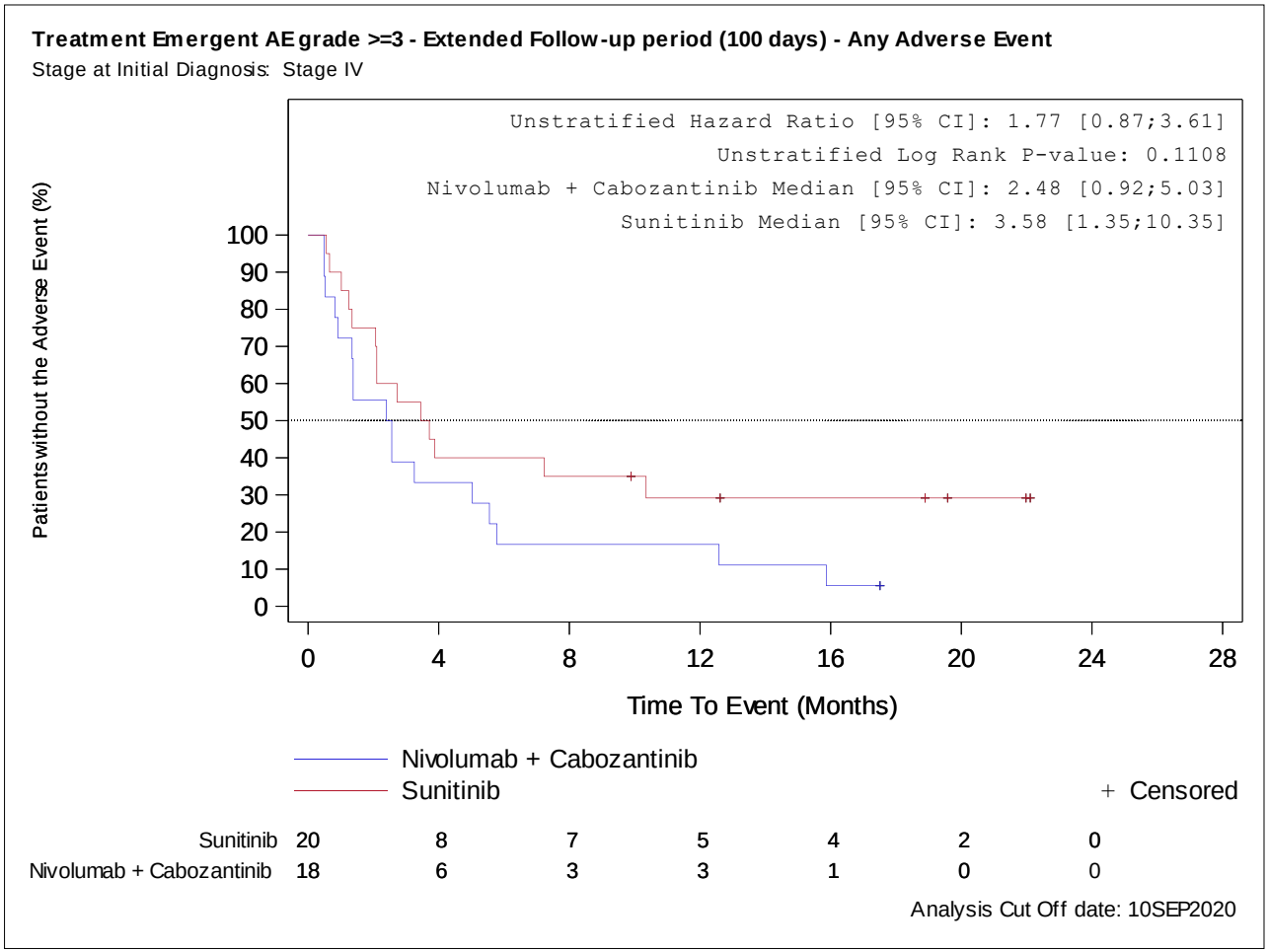

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:31:40

FIGURE 3.4.2.22: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:31:47

FIGURE 3.4.2.23: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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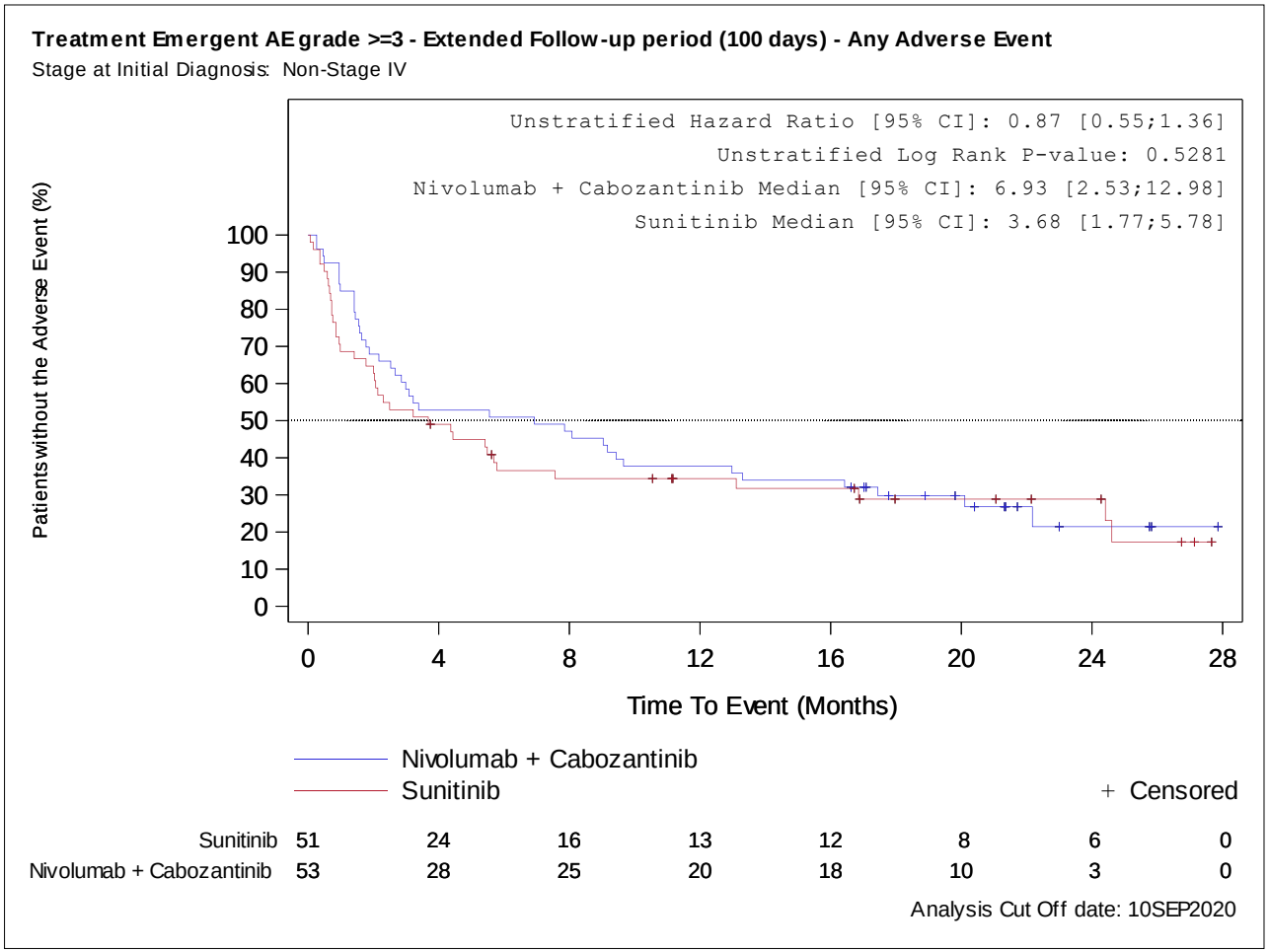
FIGURE 3.4.2.24: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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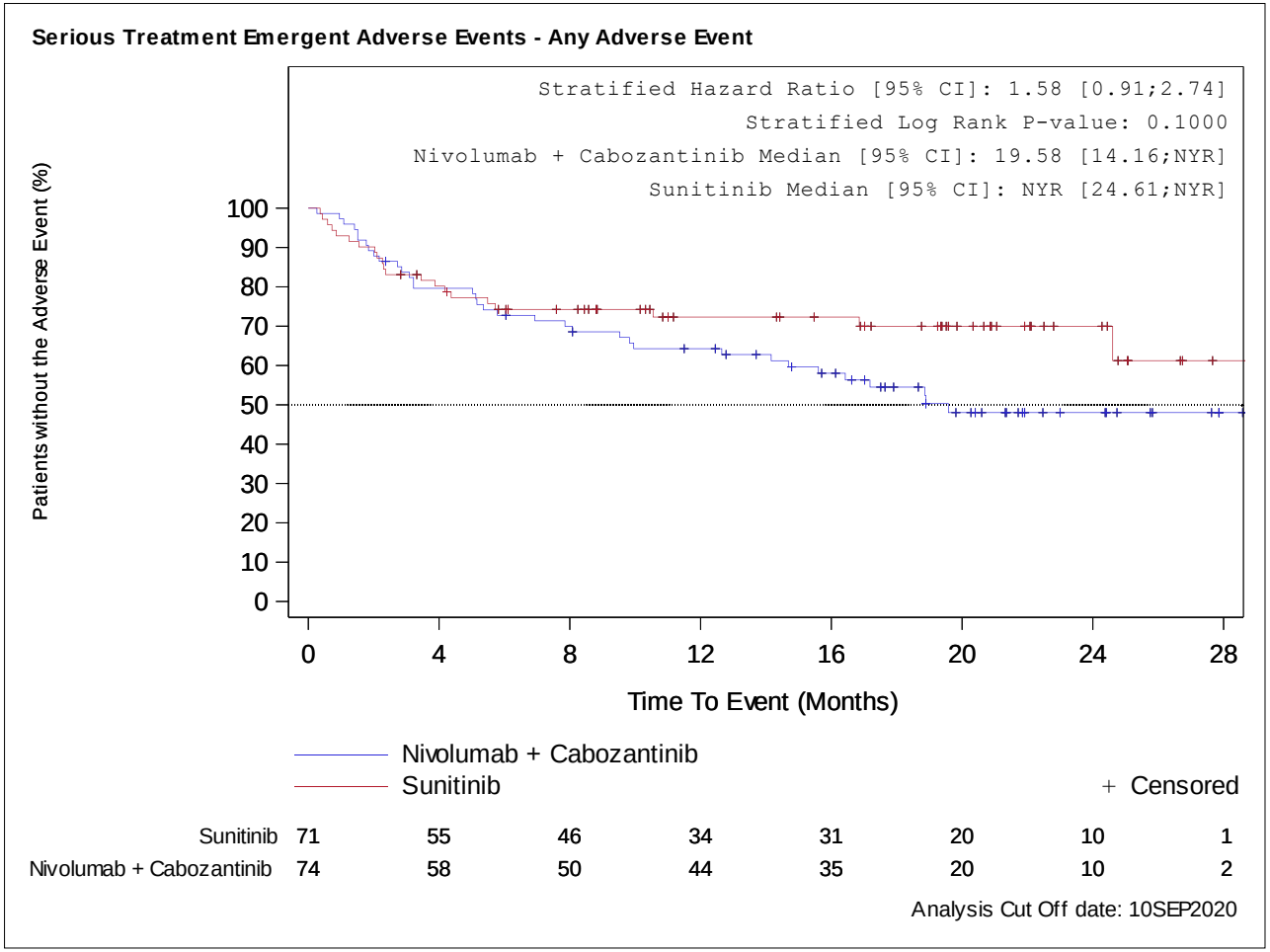
FIGURE 3.5.1: Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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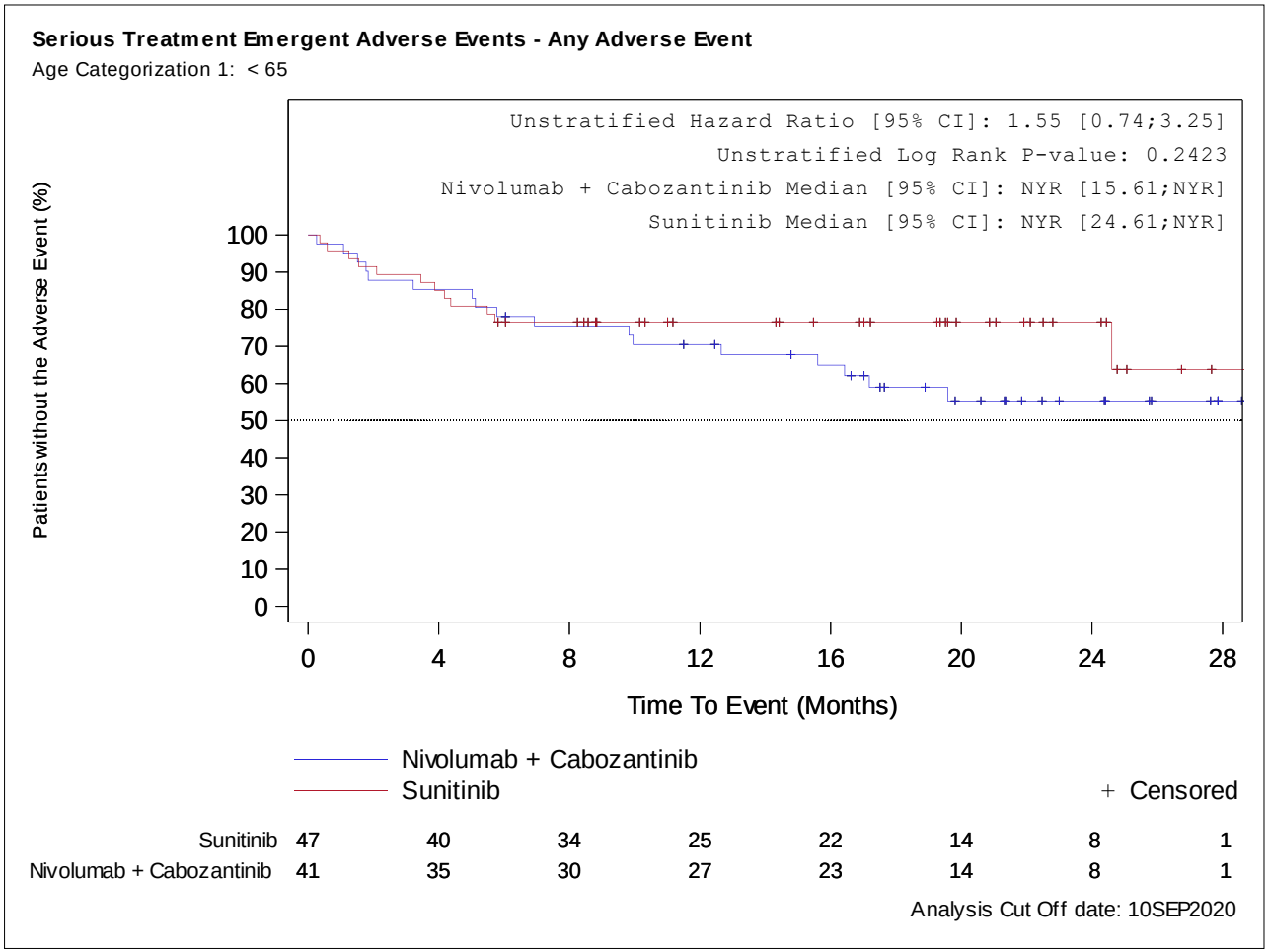
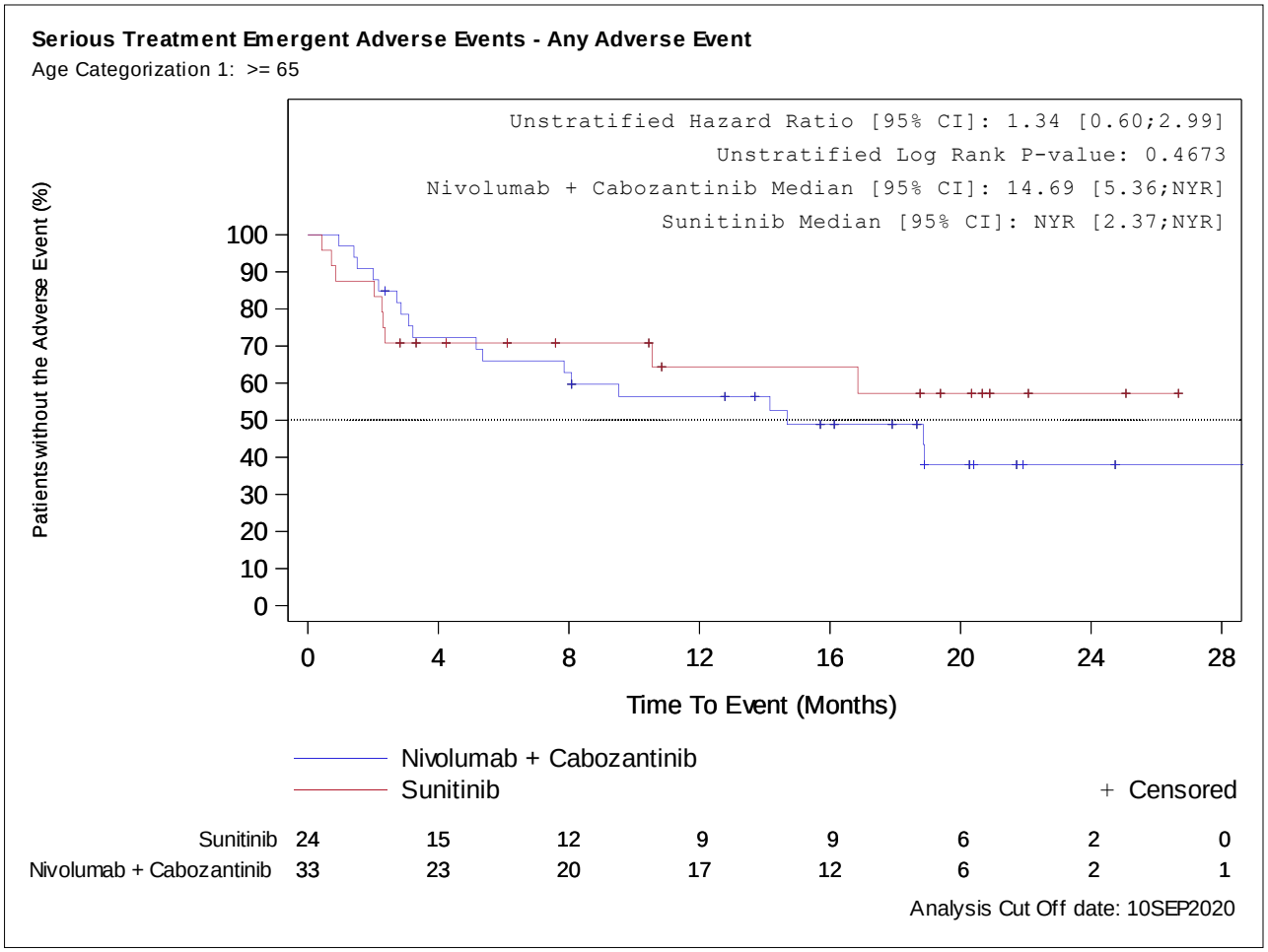
FIGURE 3.5.2.1: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



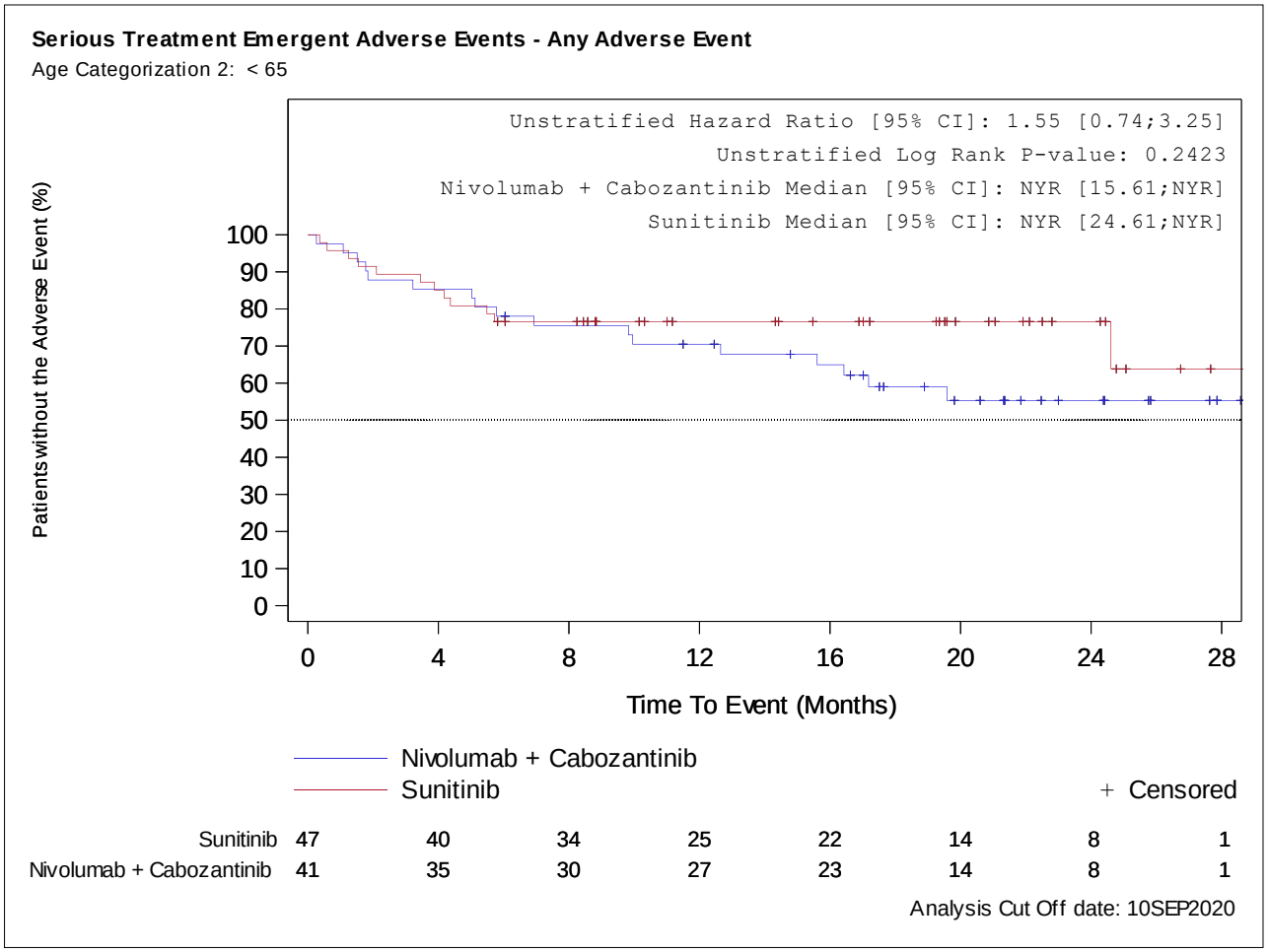

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:36:02

FIGURE 3.5.2.2: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:36:09

FIGURE 3.5.2.3: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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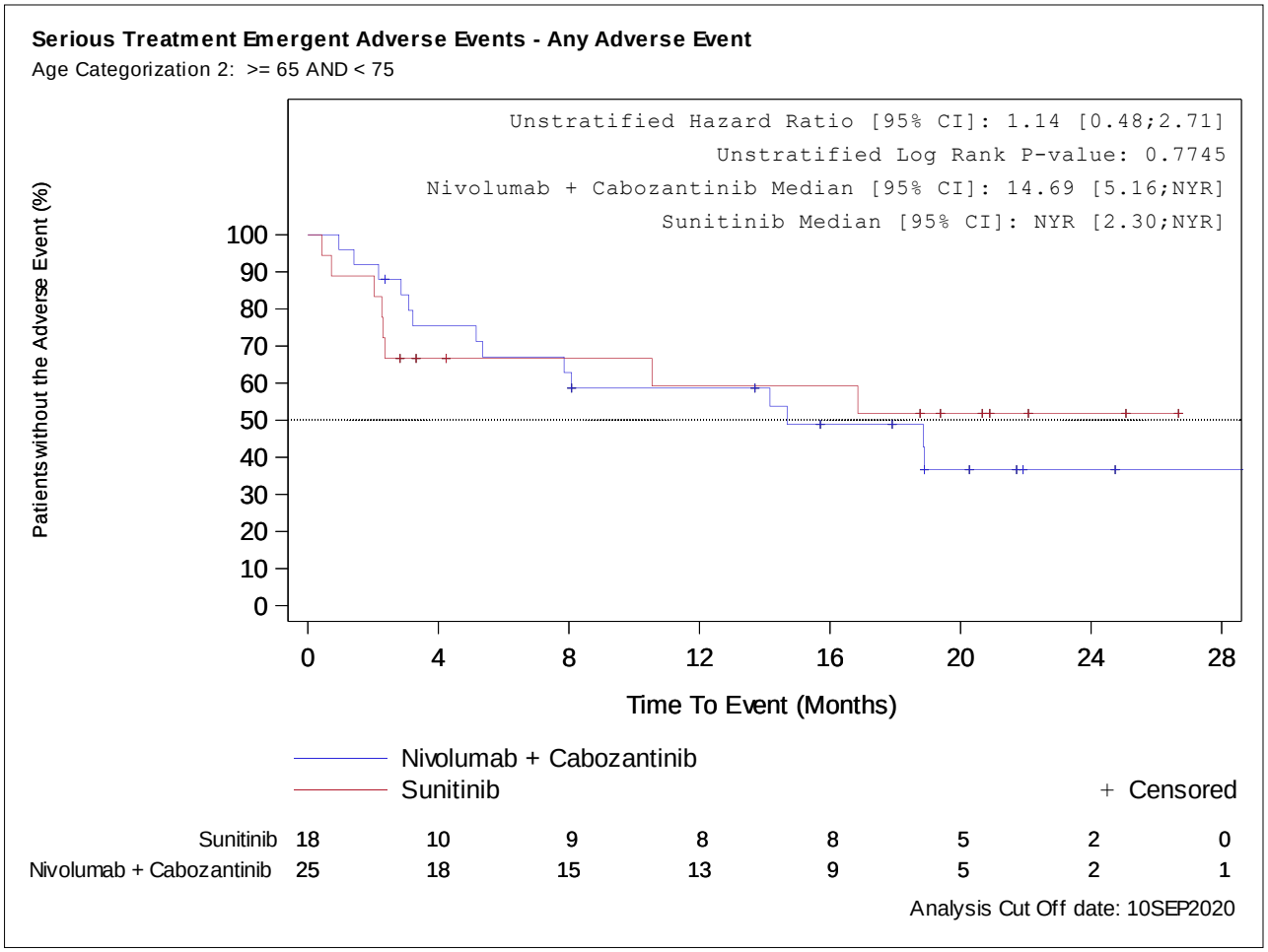
FIGURE 3.5.2.4: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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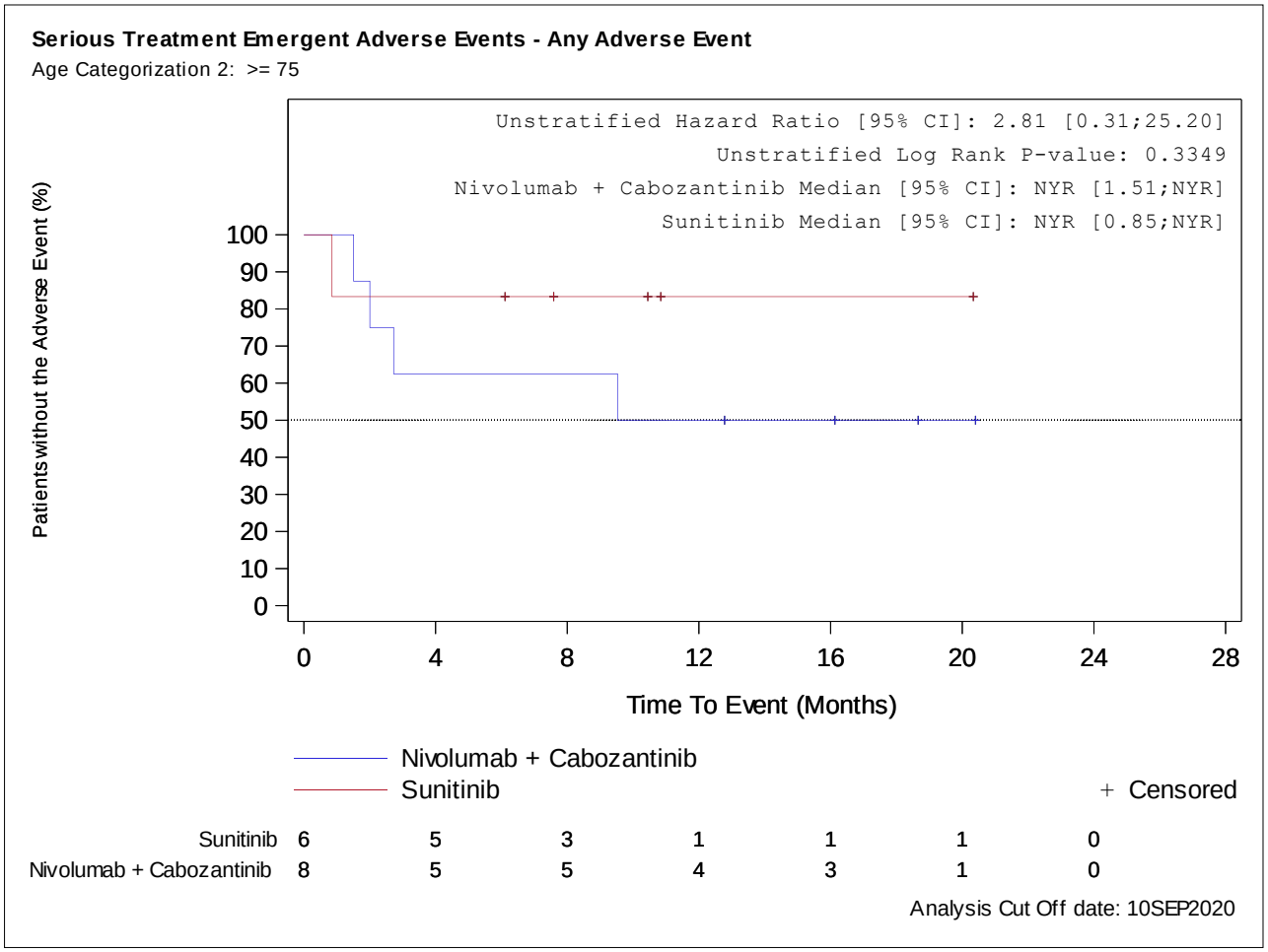
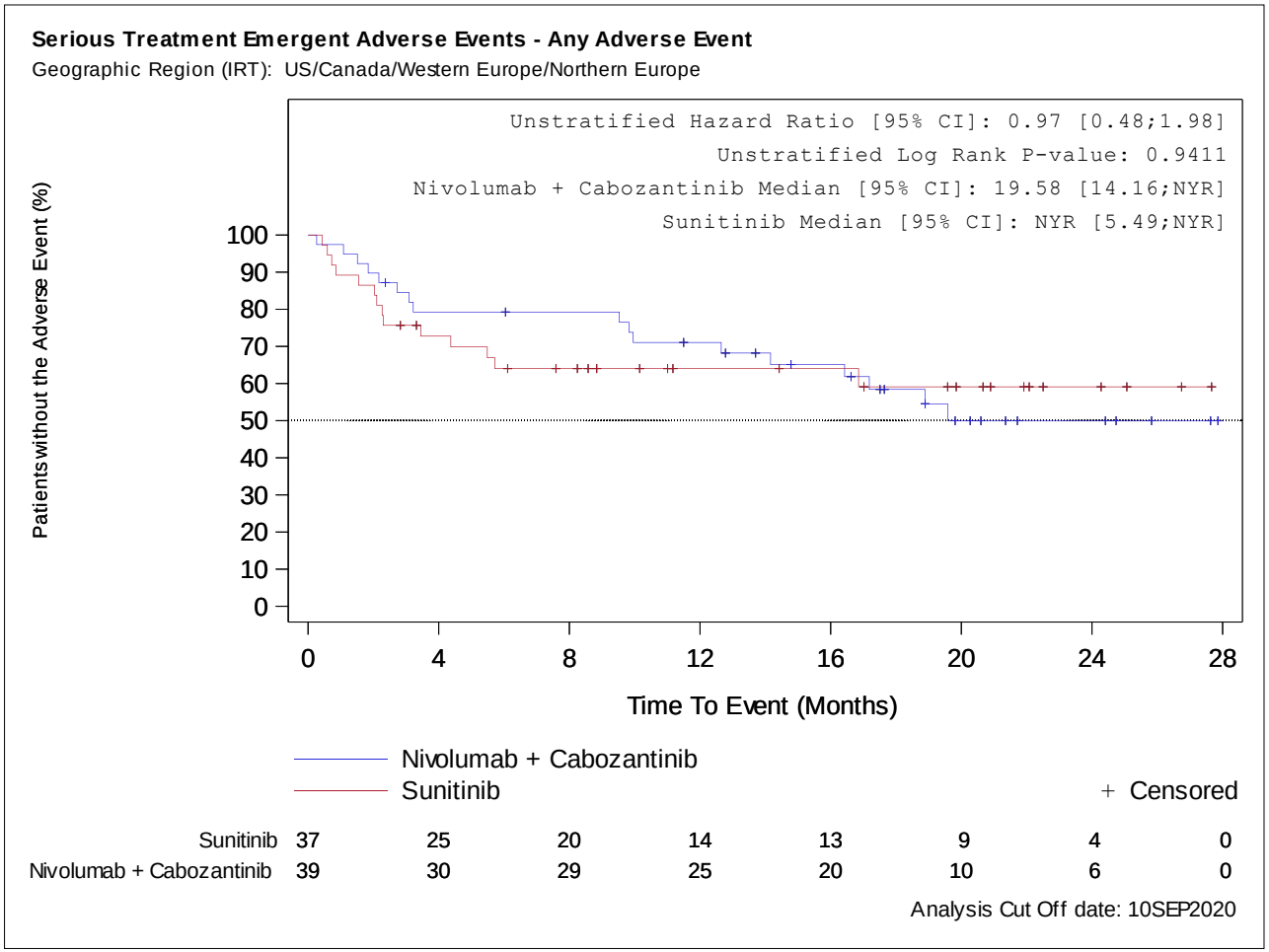
FIGURE 3.5.2.5: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



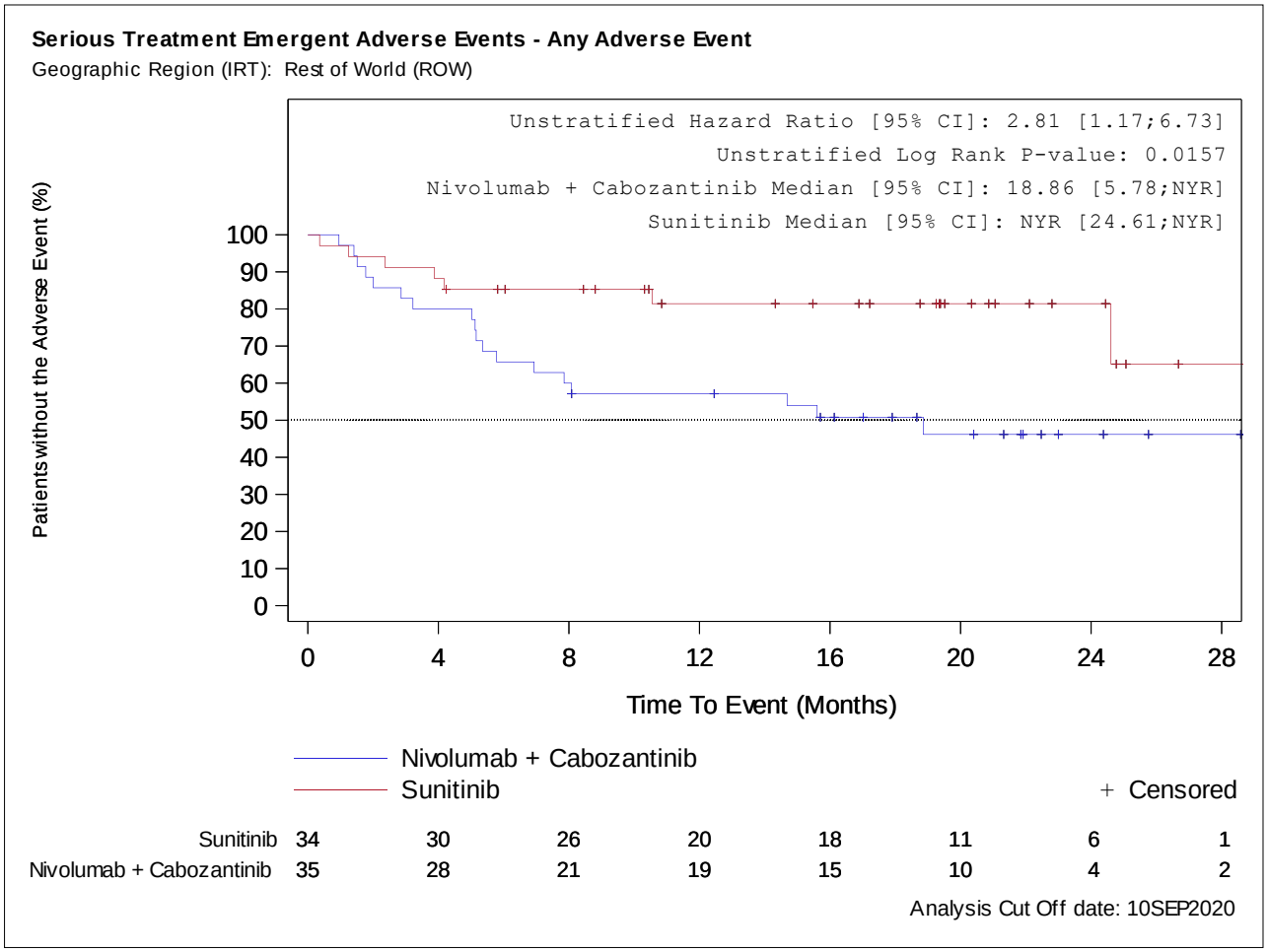

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:36:28

FIGURE 3.5.2.6: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



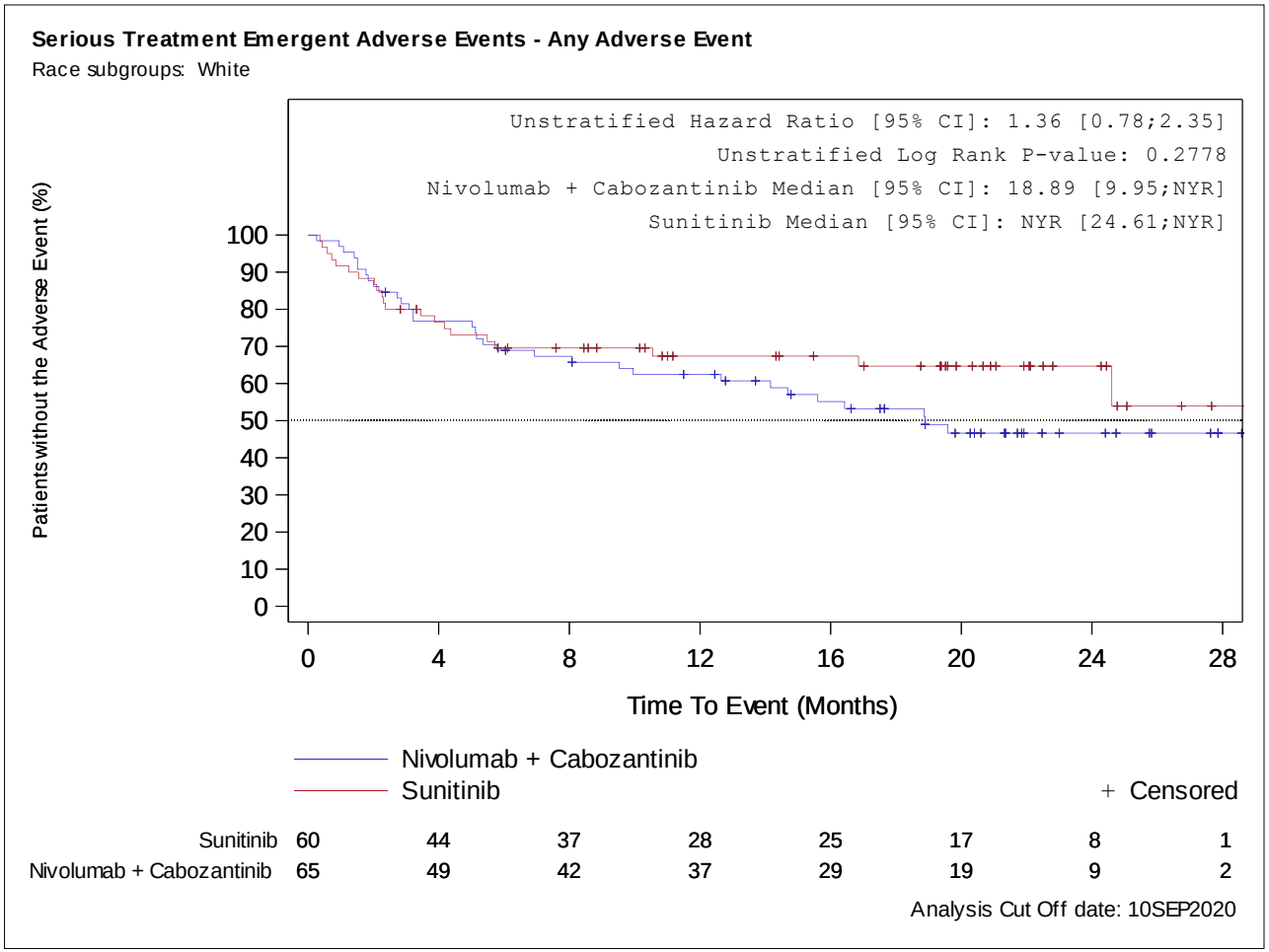

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:36:34

FIGURE 3.5.2.7: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



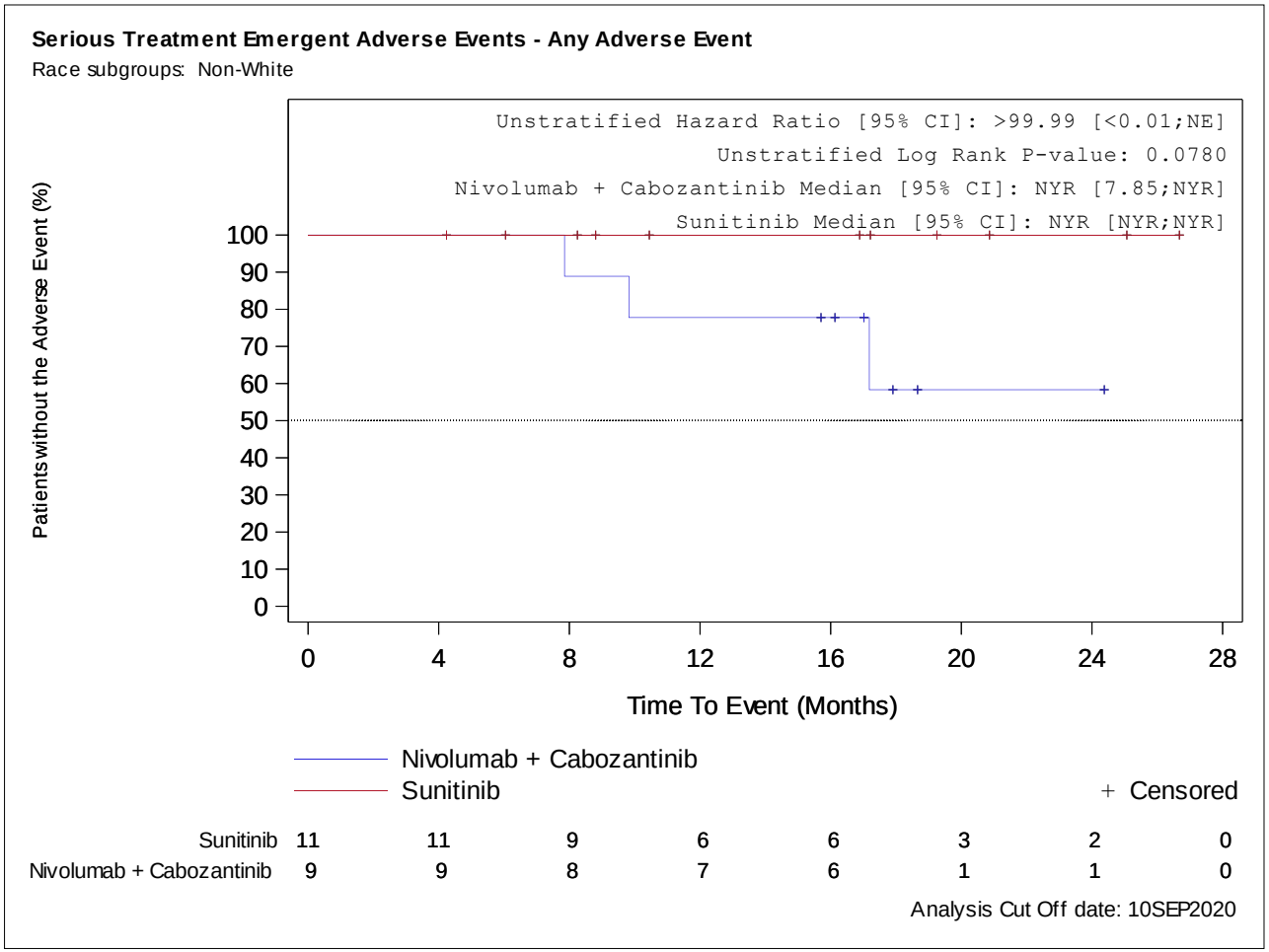

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:36:40

FIGURE 3.5.2.8: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



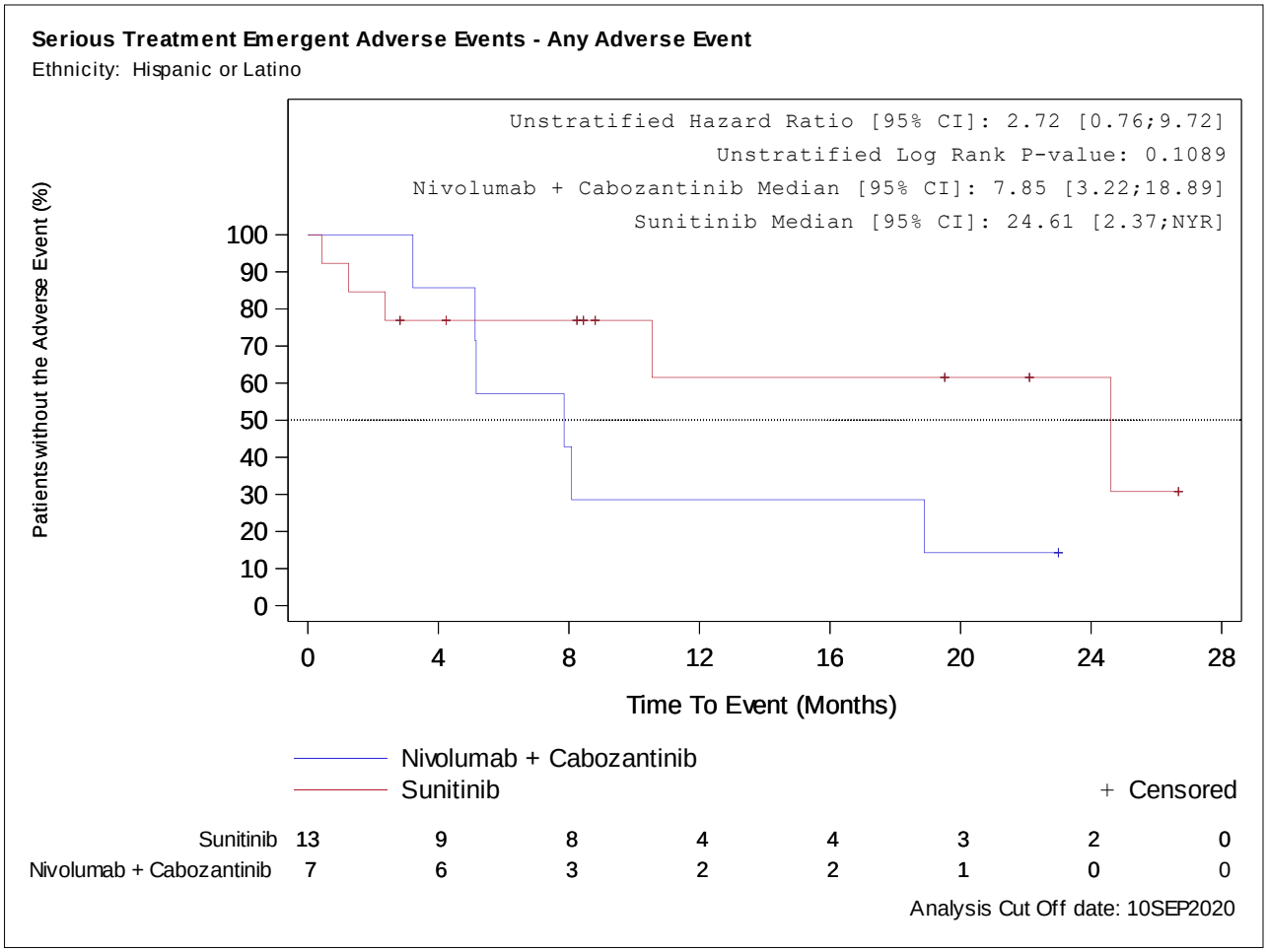

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:36:47

FIGURE 3.5.2.9: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



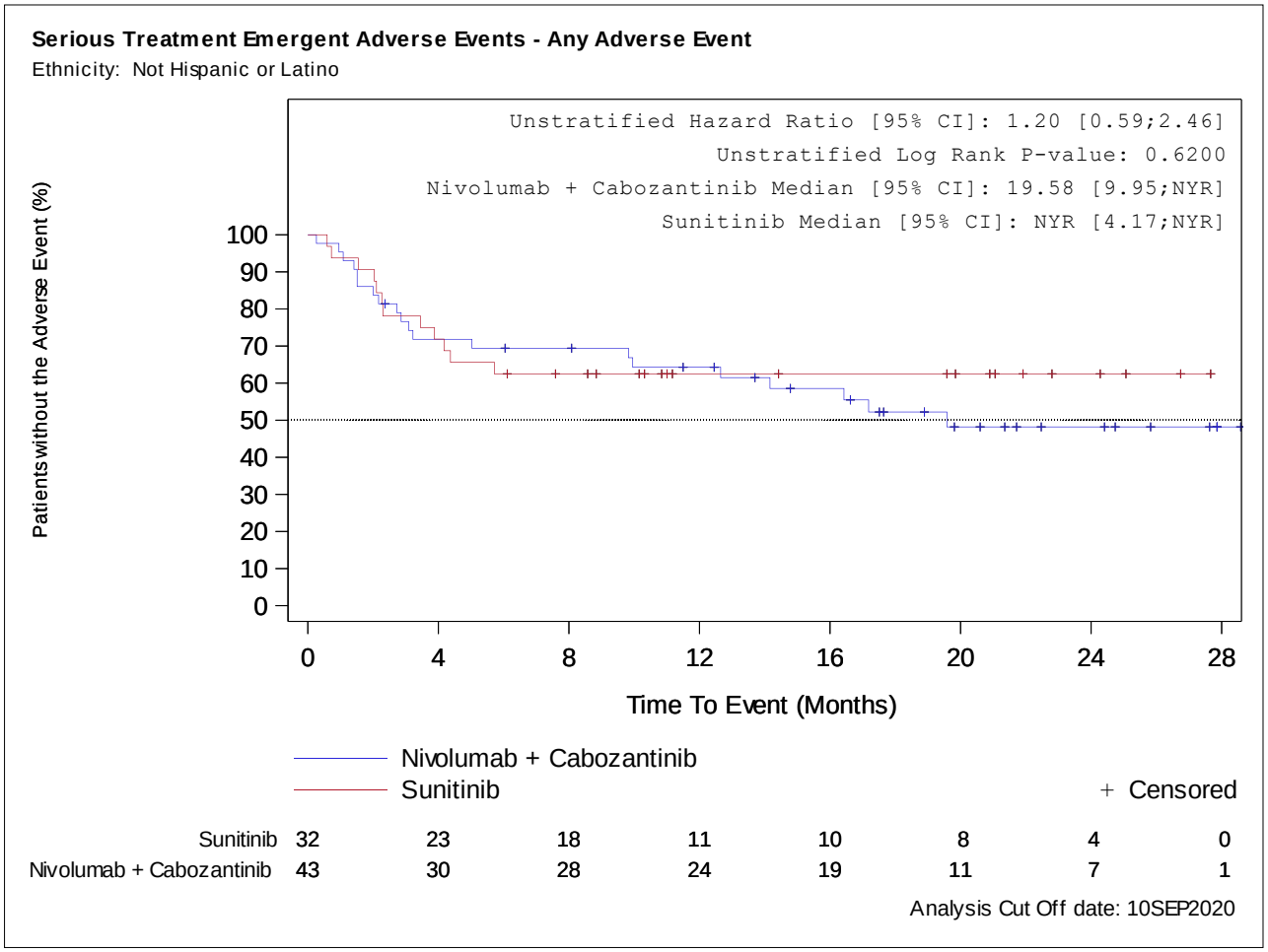

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:36:53

FIGURE 3.5.2.10: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



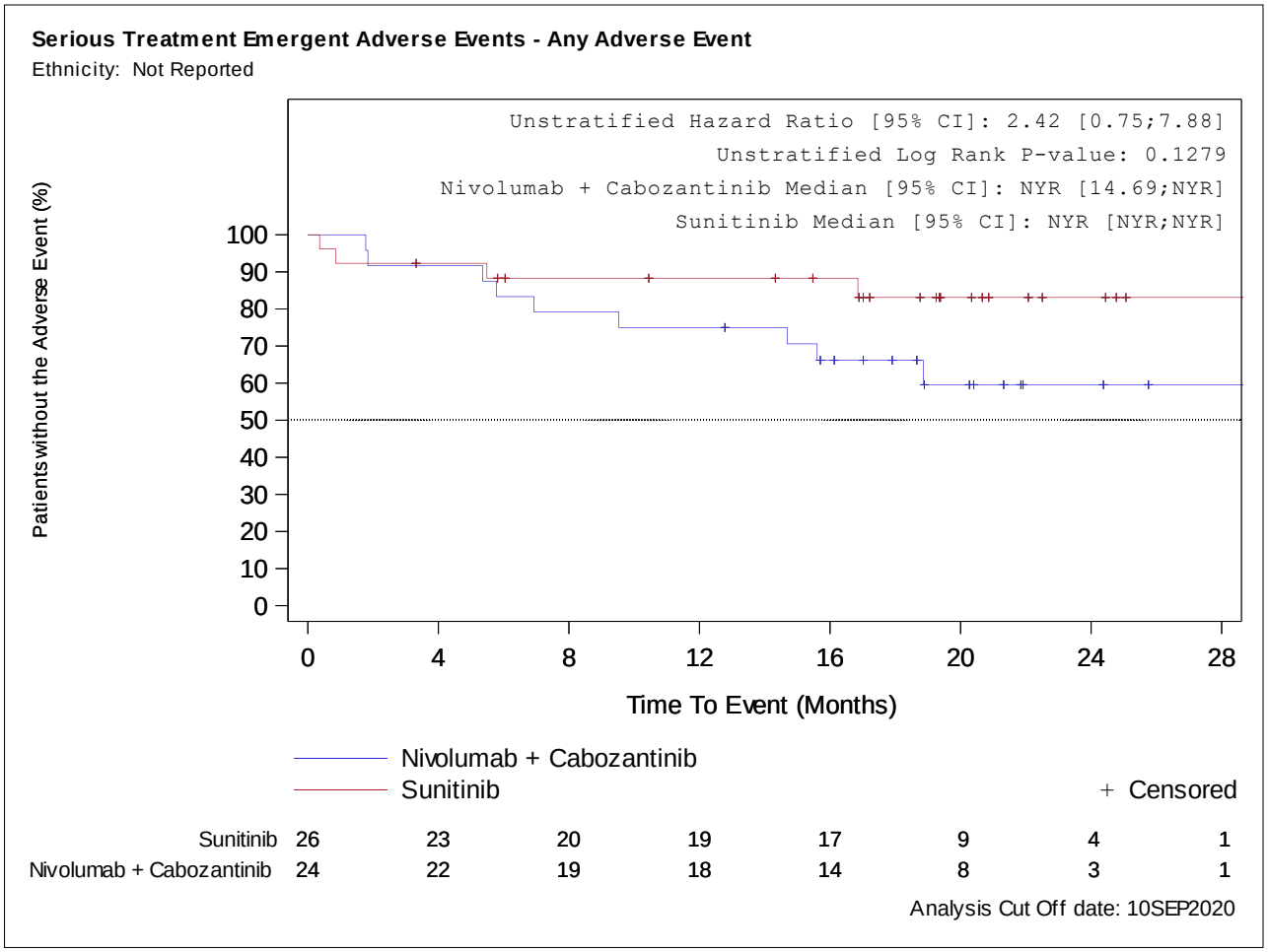

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:37:00

FIGURE 3.5.2.11: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:37:07

FIGURE 3.5.2.12: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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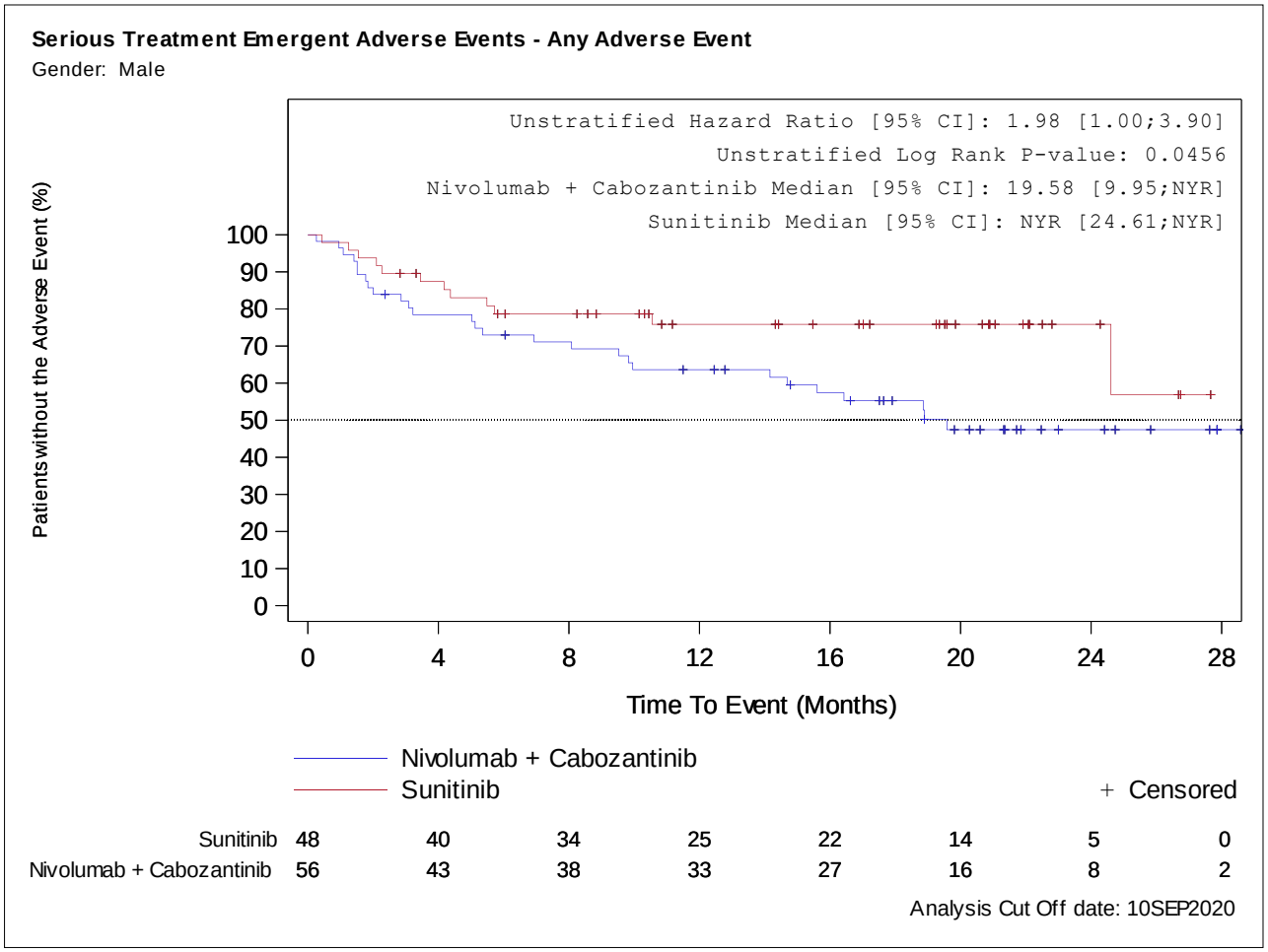
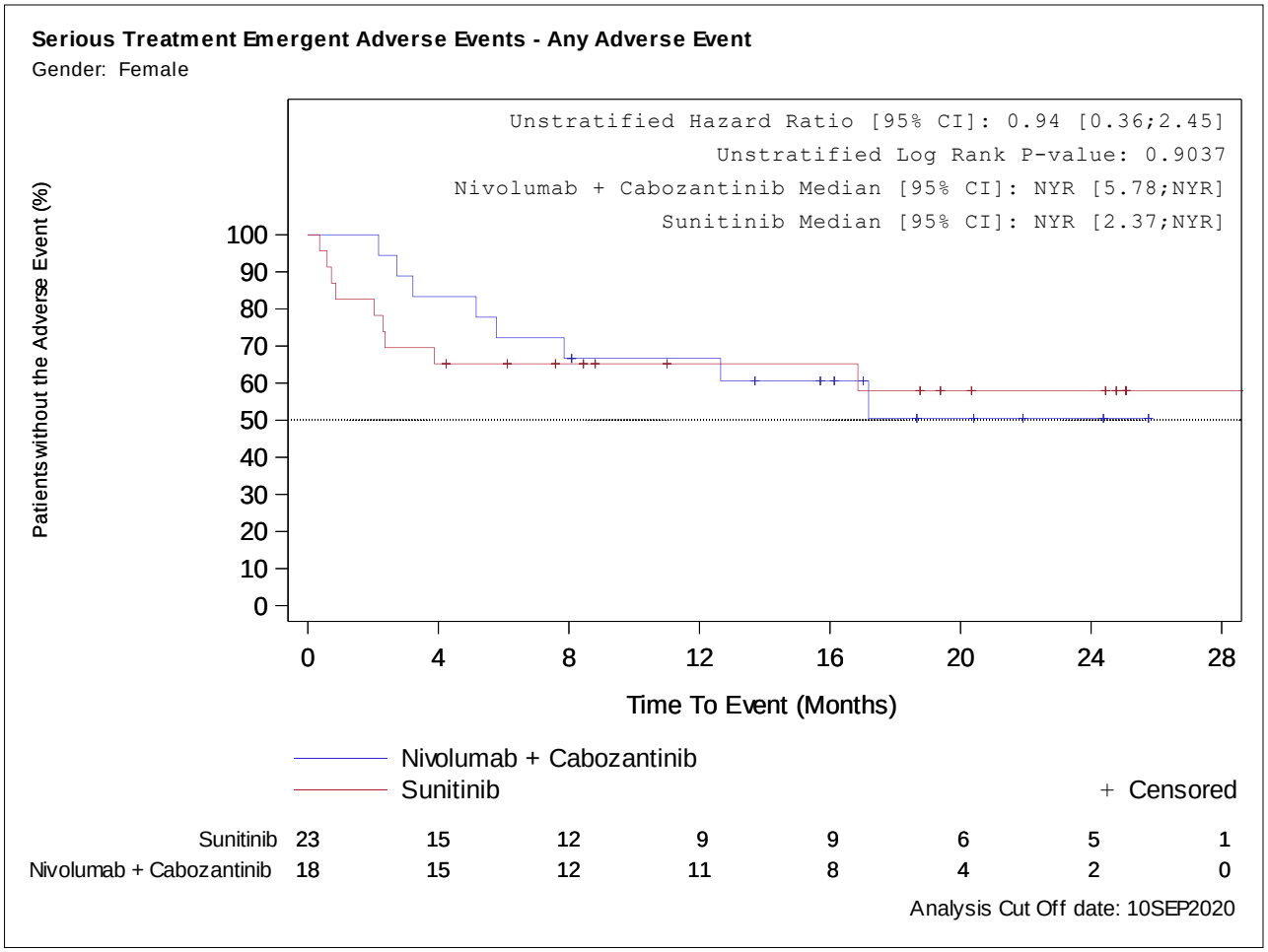
FIGURE 3.5.2.13: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



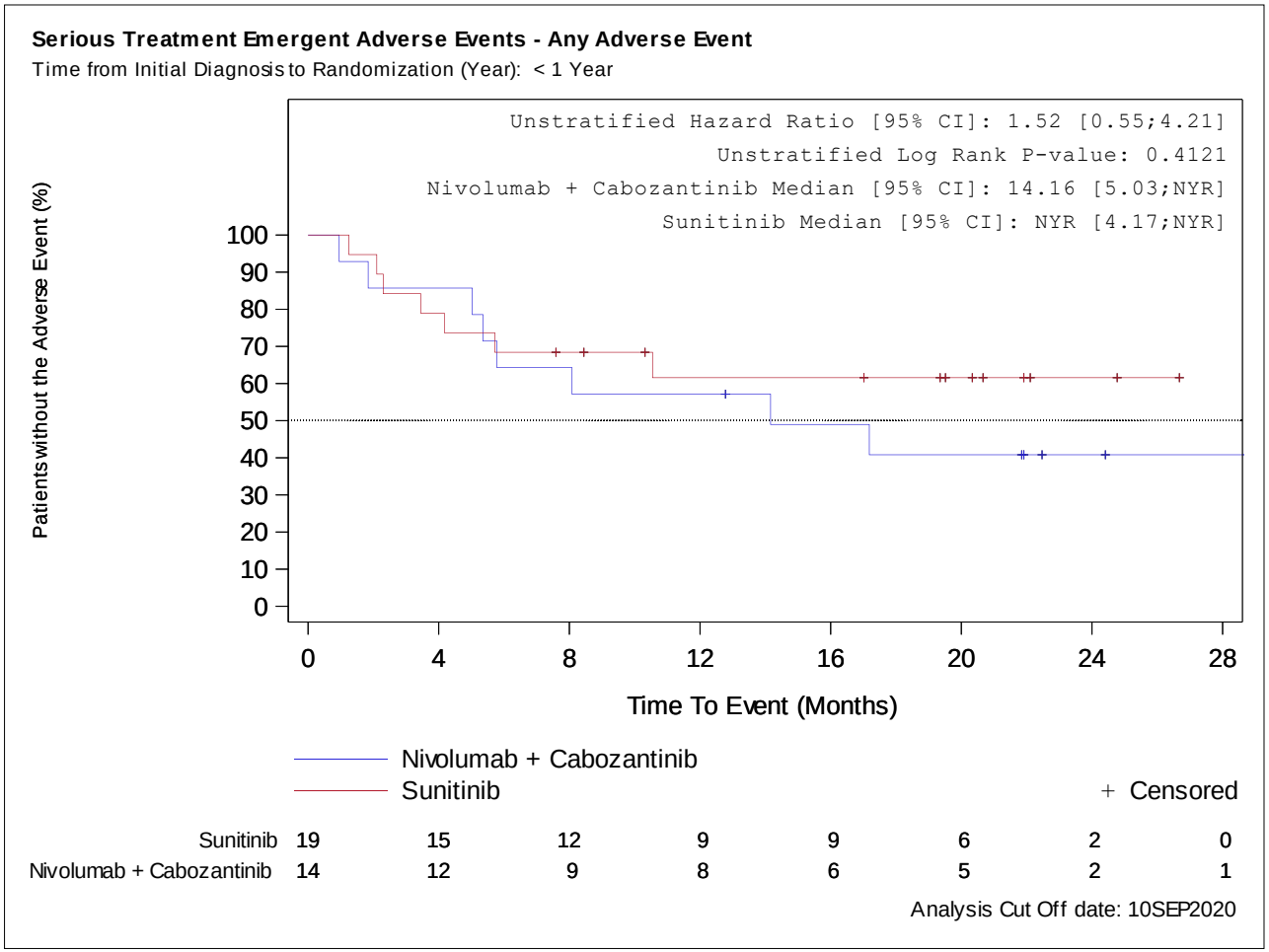

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:37:18

FIGURE 3.5.2.14: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



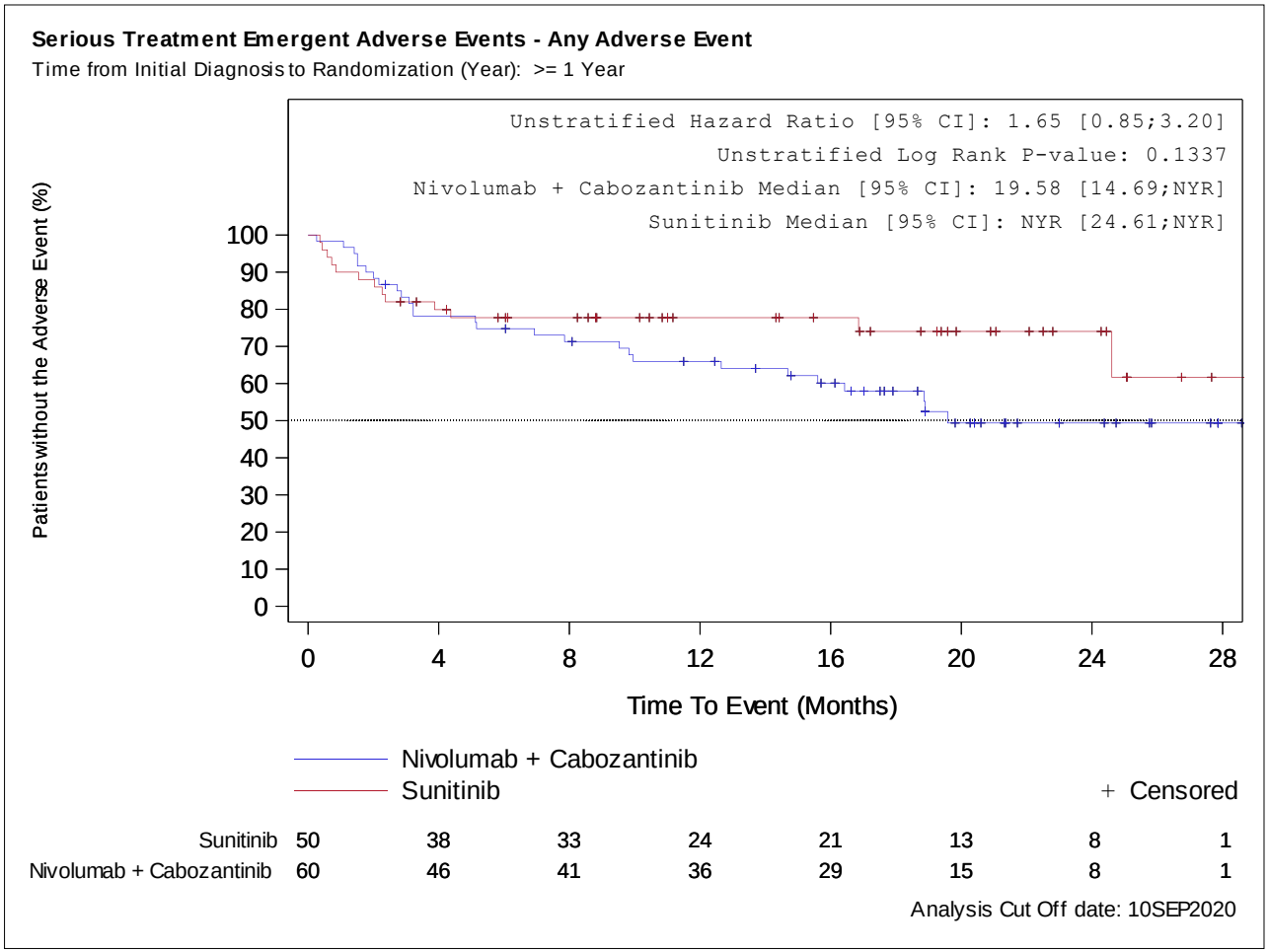

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:37:25

FIGURE 3.5.2.15: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:37:44

FIGURE 3.5.2.16: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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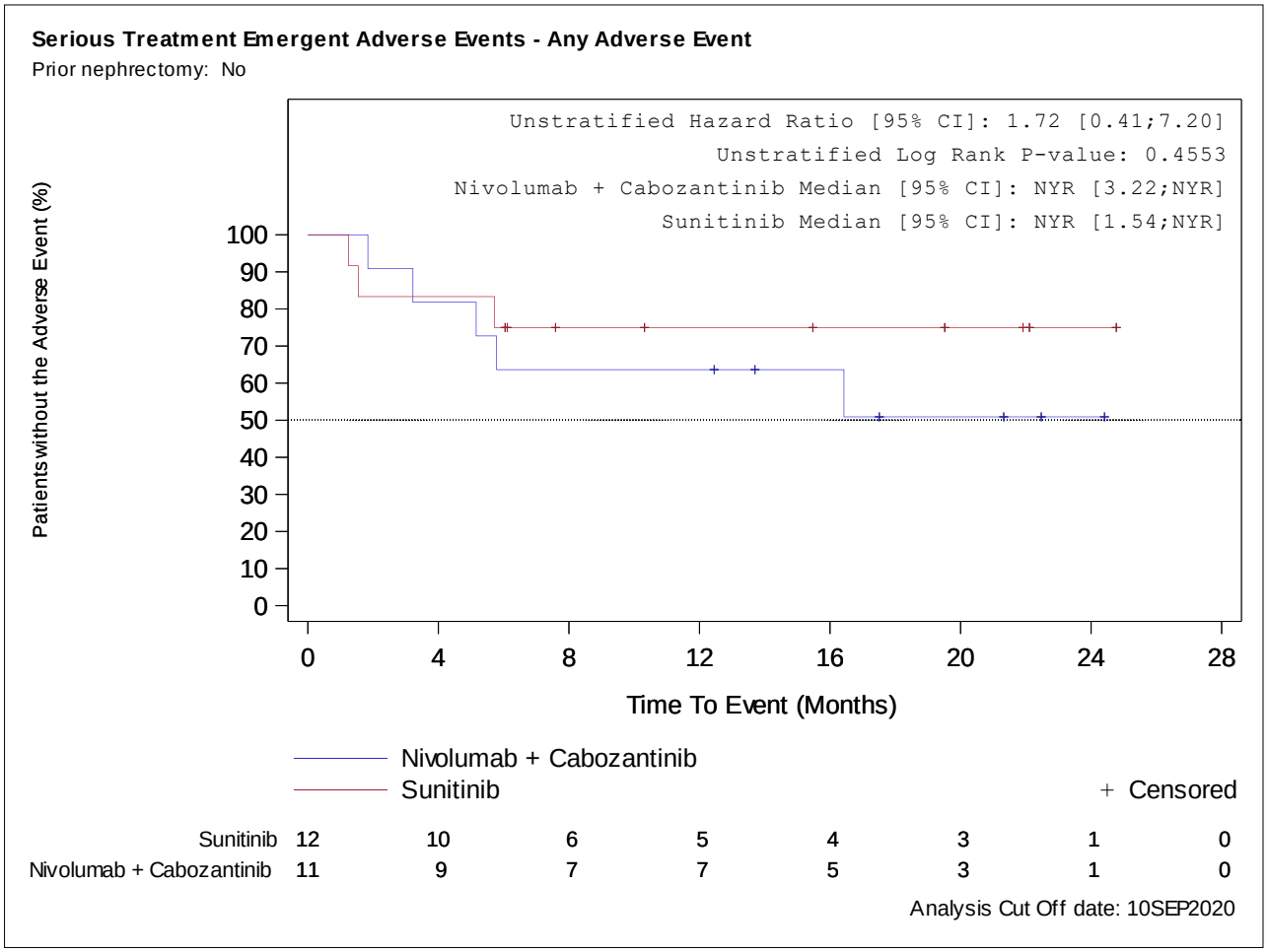
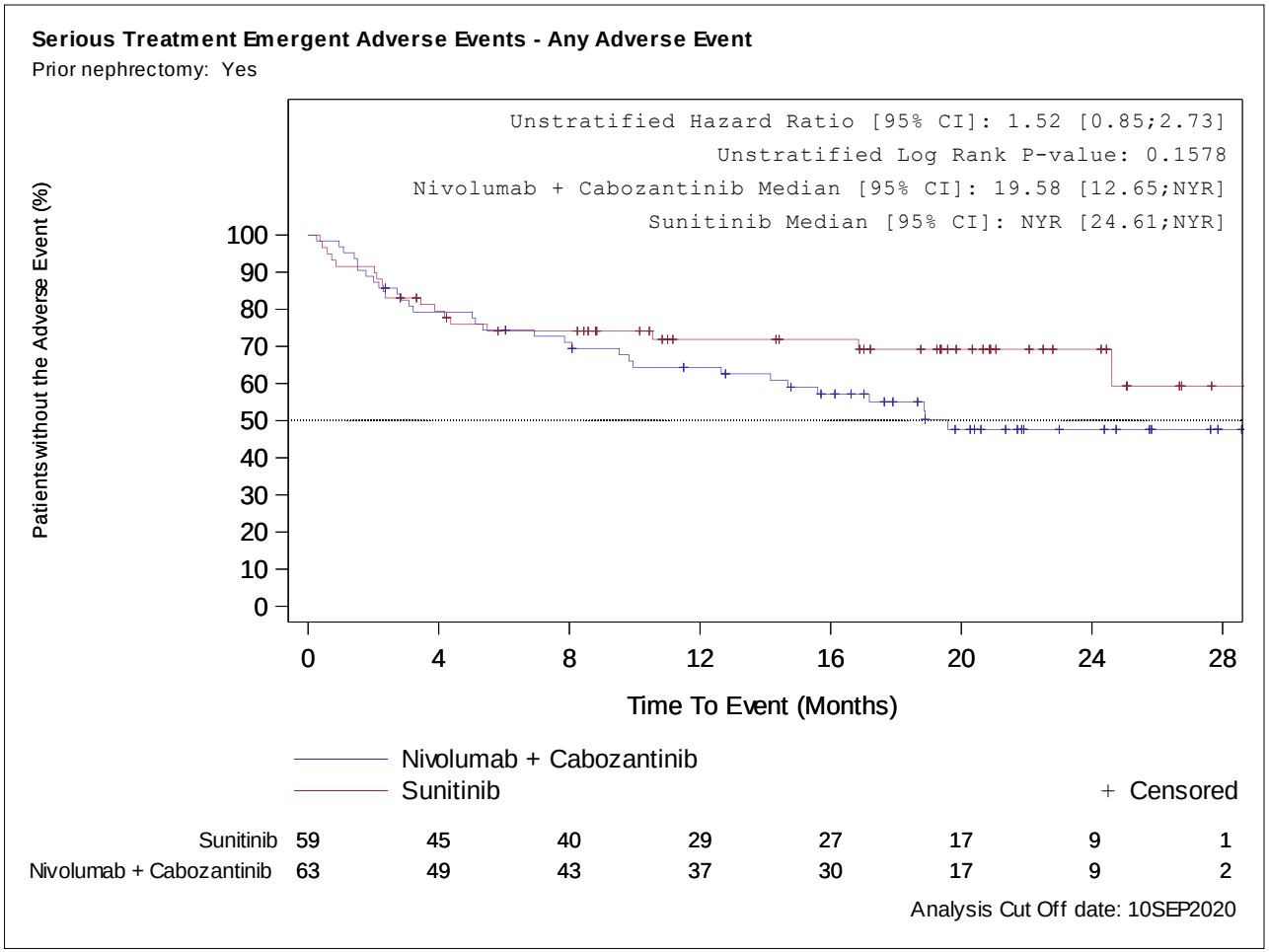
FIGURE 3.5.2.17: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



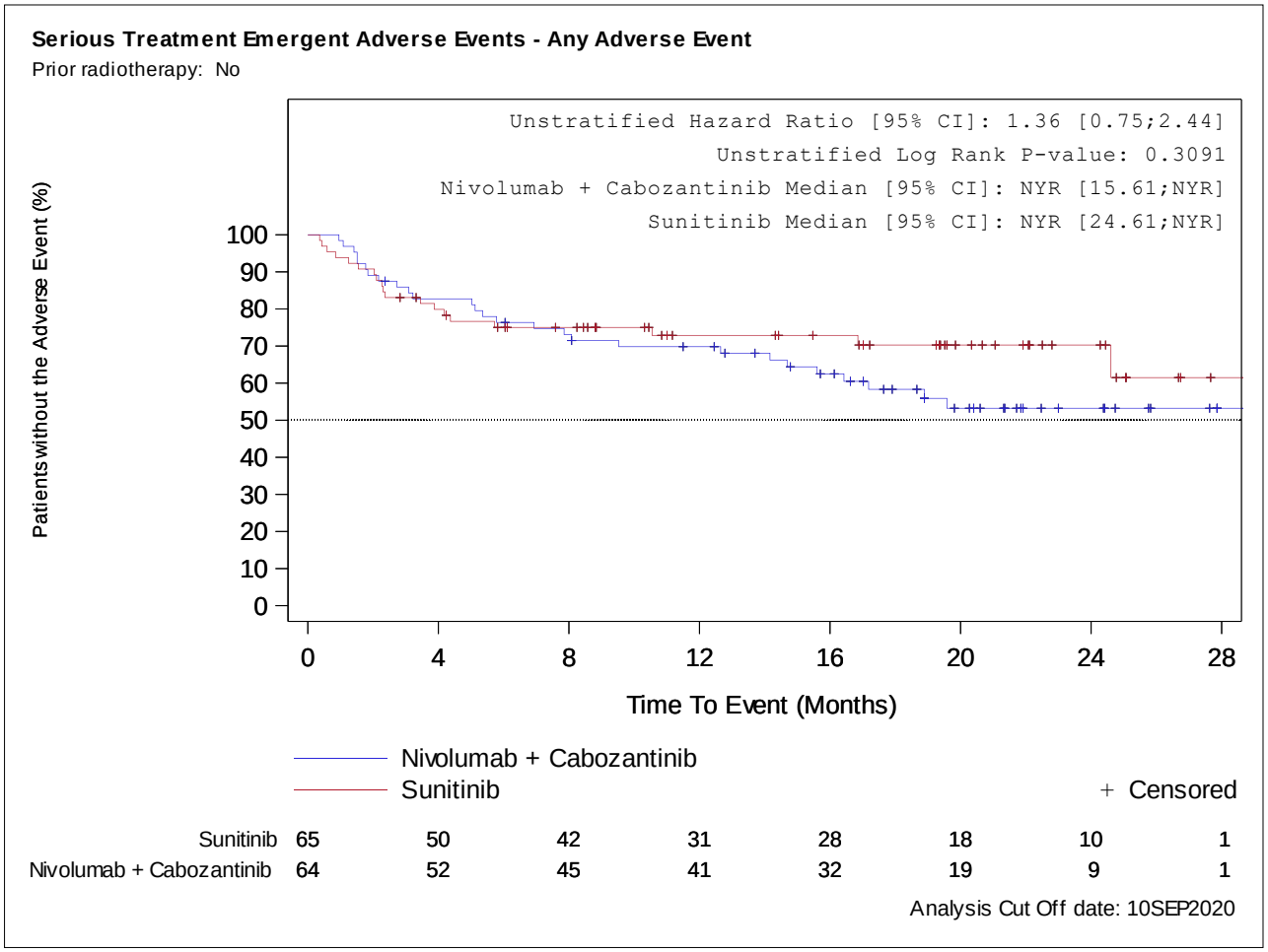

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:38:46

FIGURE 3.5.2.18: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



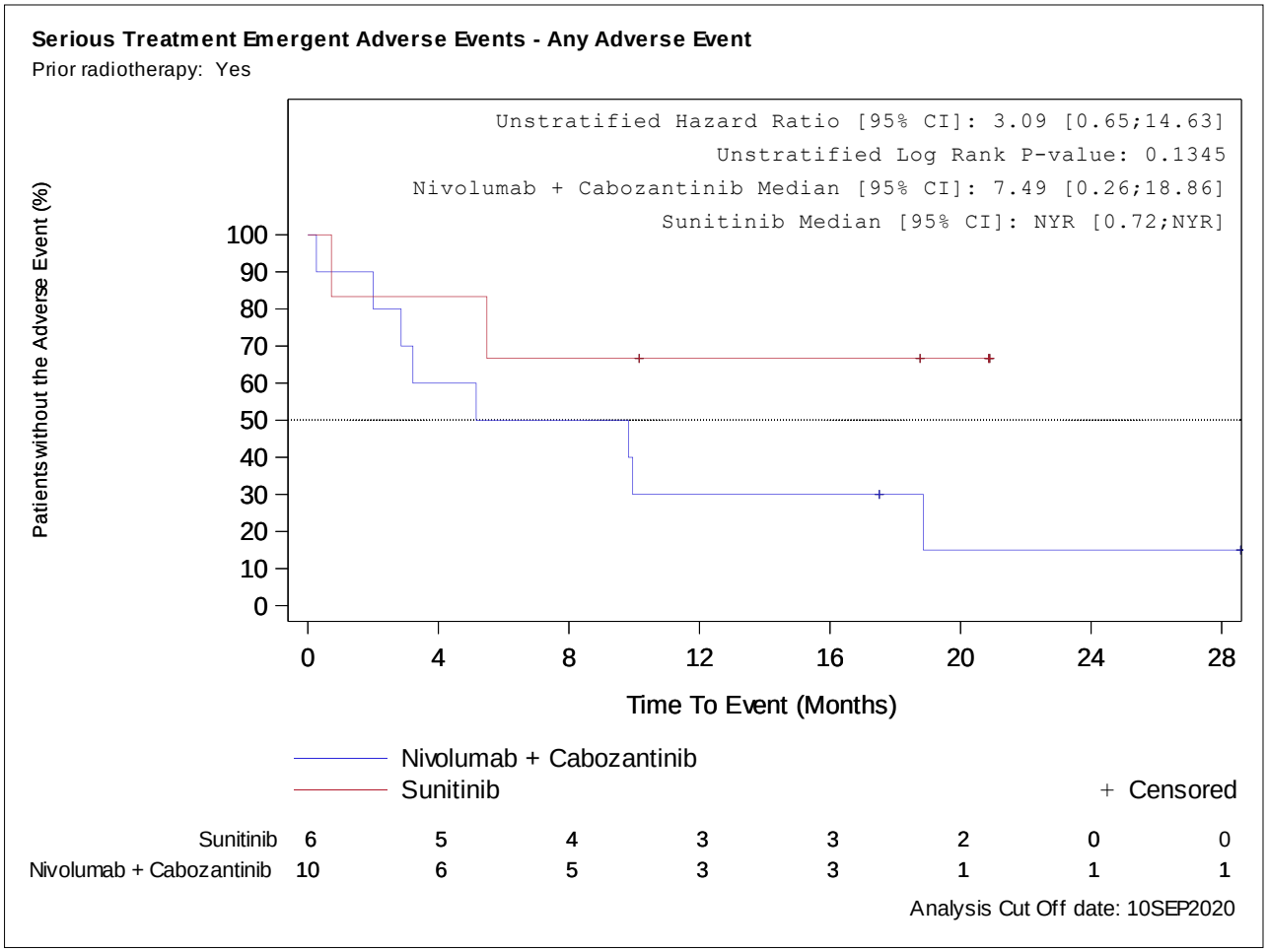

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:38:52

FIGURE 3.5.2.19: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



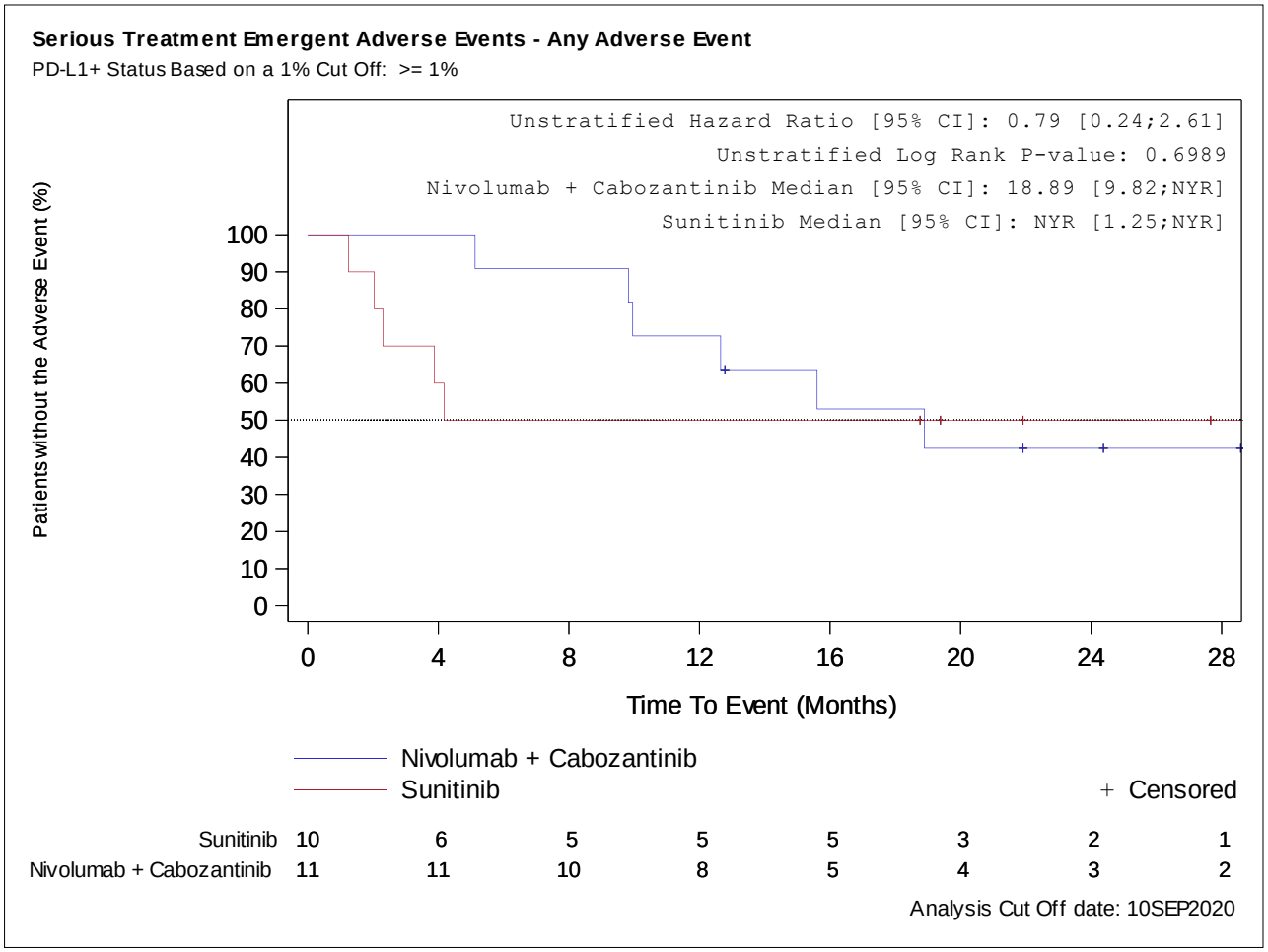

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:38:58

FIGURE 3.5.2.20: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



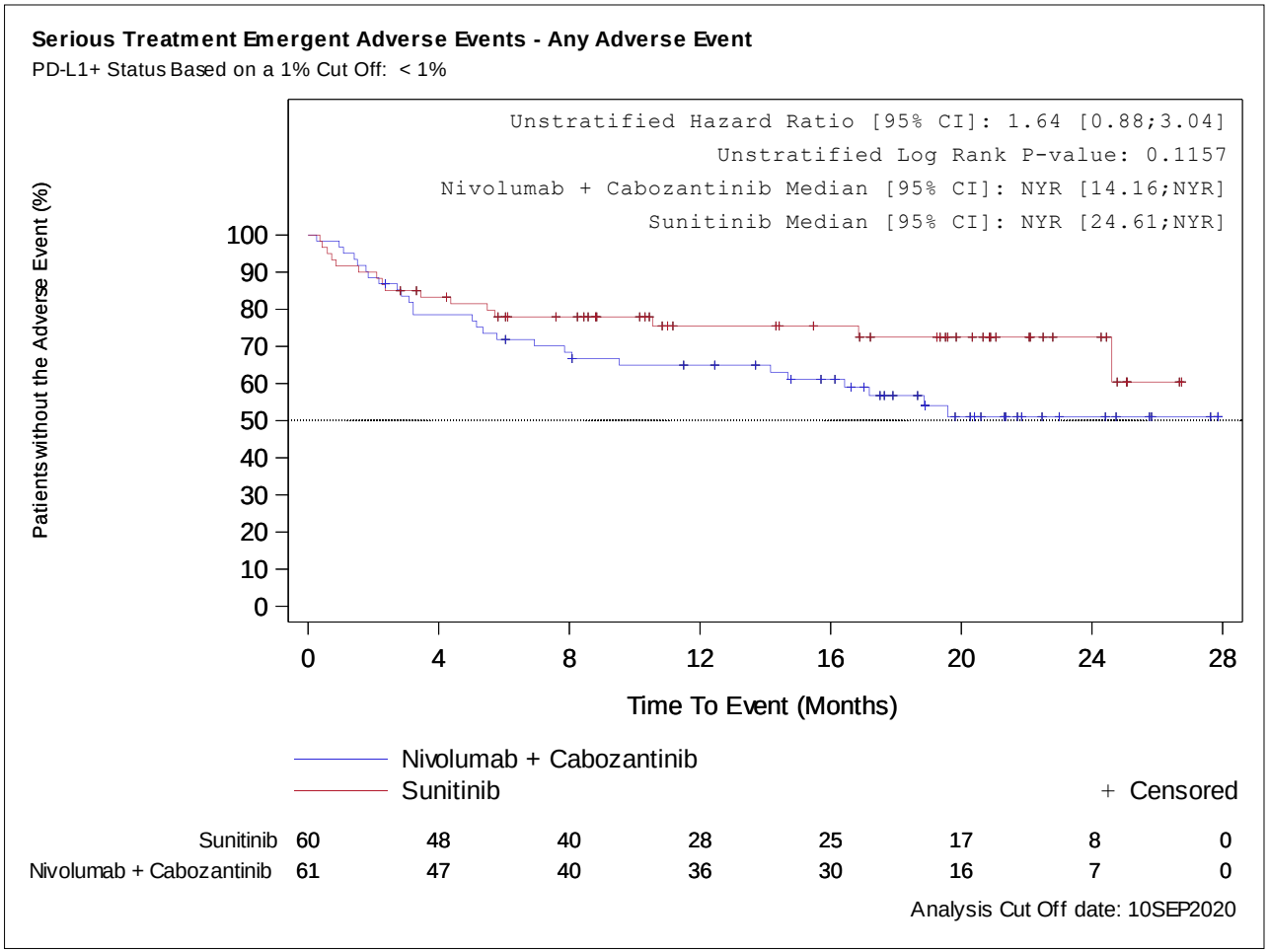

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:39:04

FIGURE 3.5.2.21: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:39:10

FIGURE 3.5.2.22: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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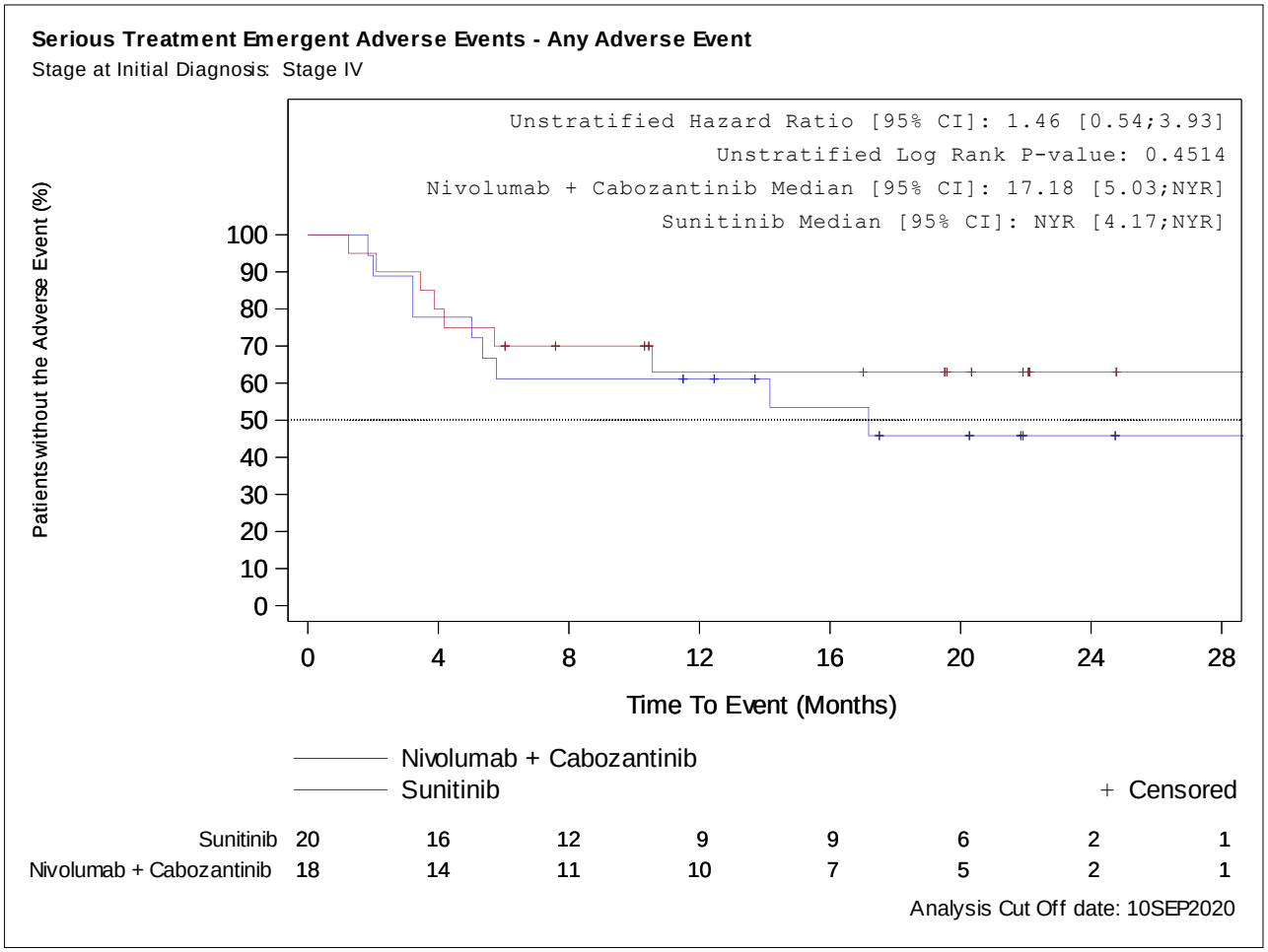
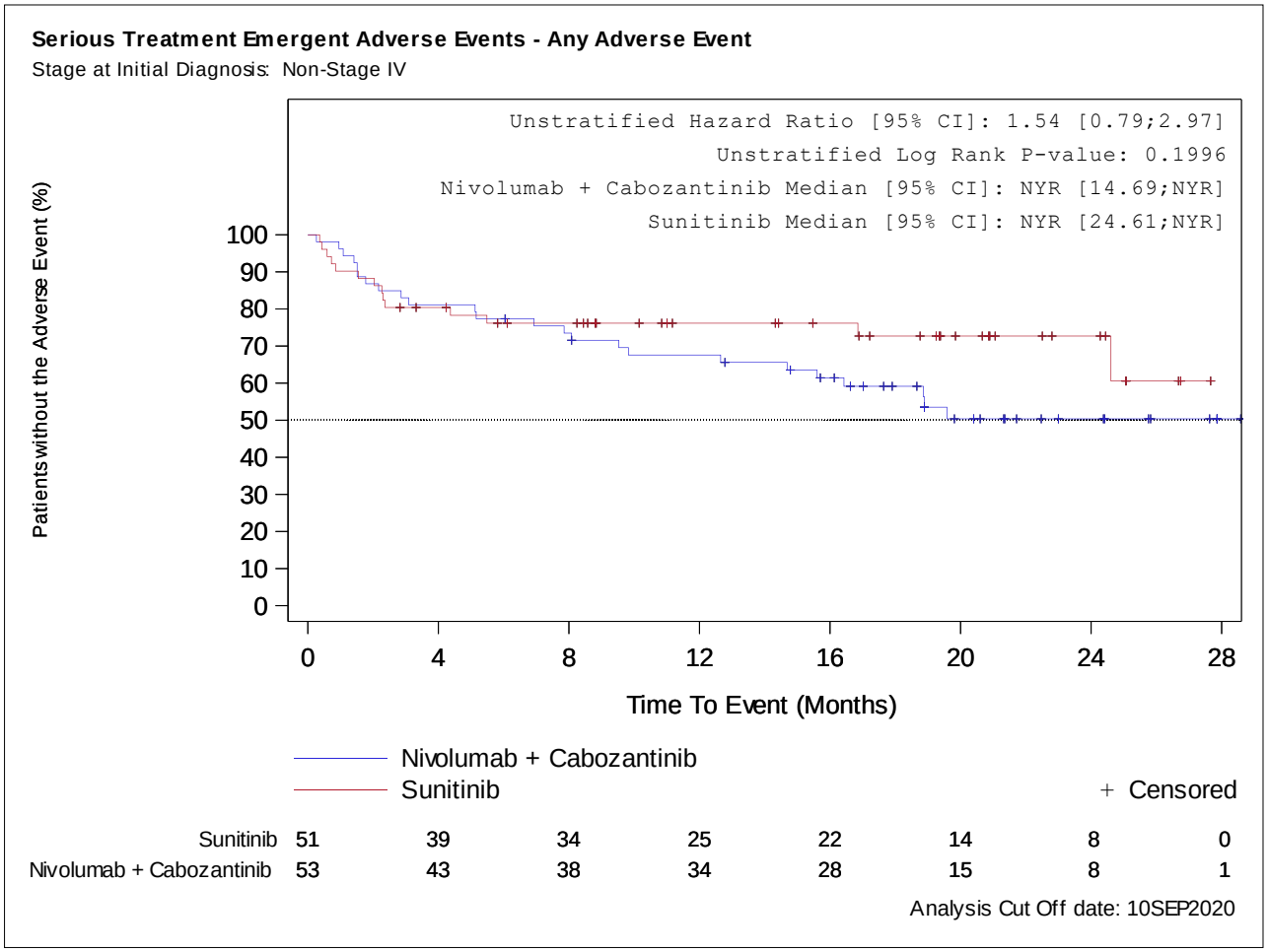
FIGURE 3.5.2.23: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



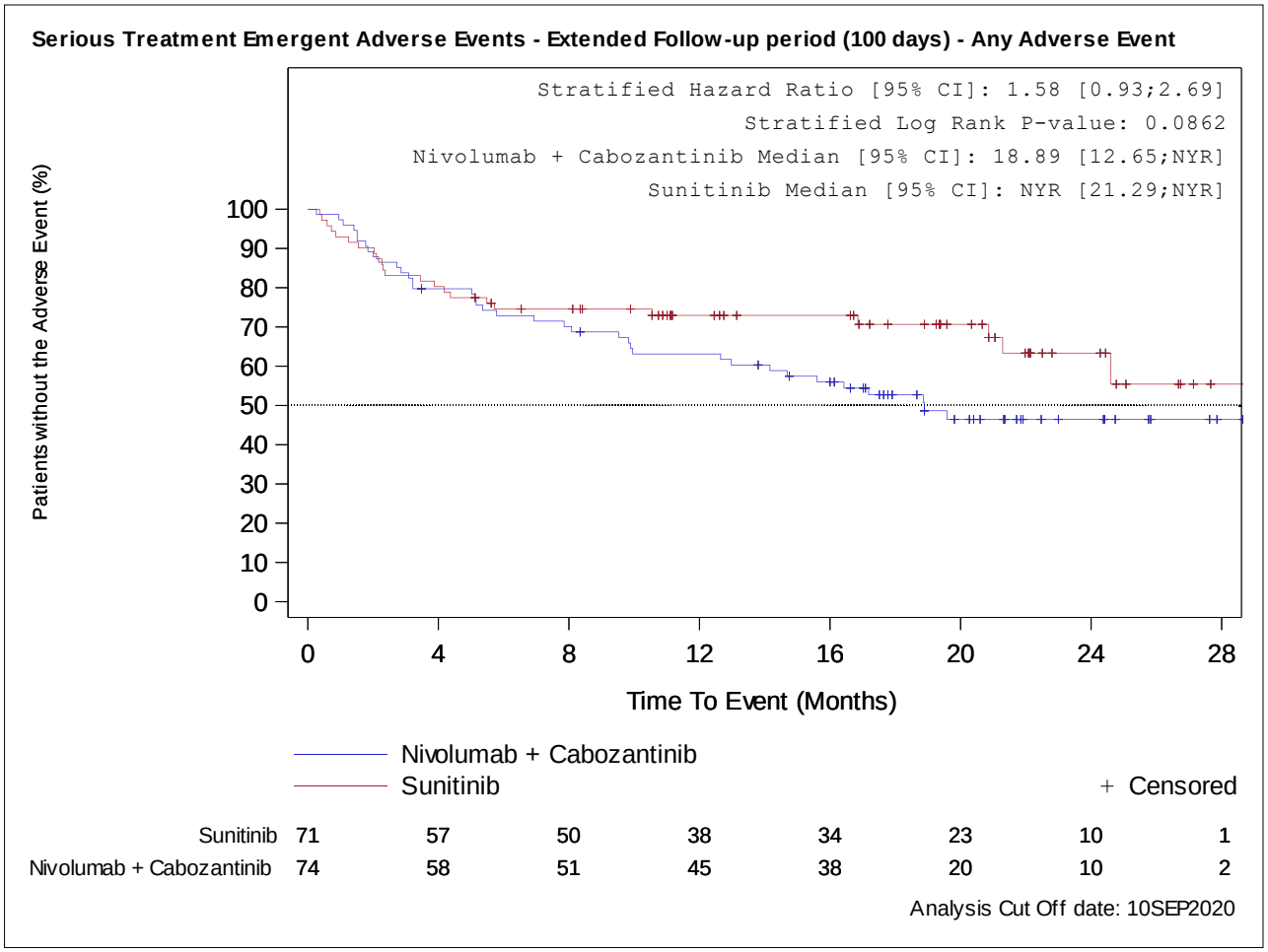

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:39:47

FIGURE 3.5.2.24: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



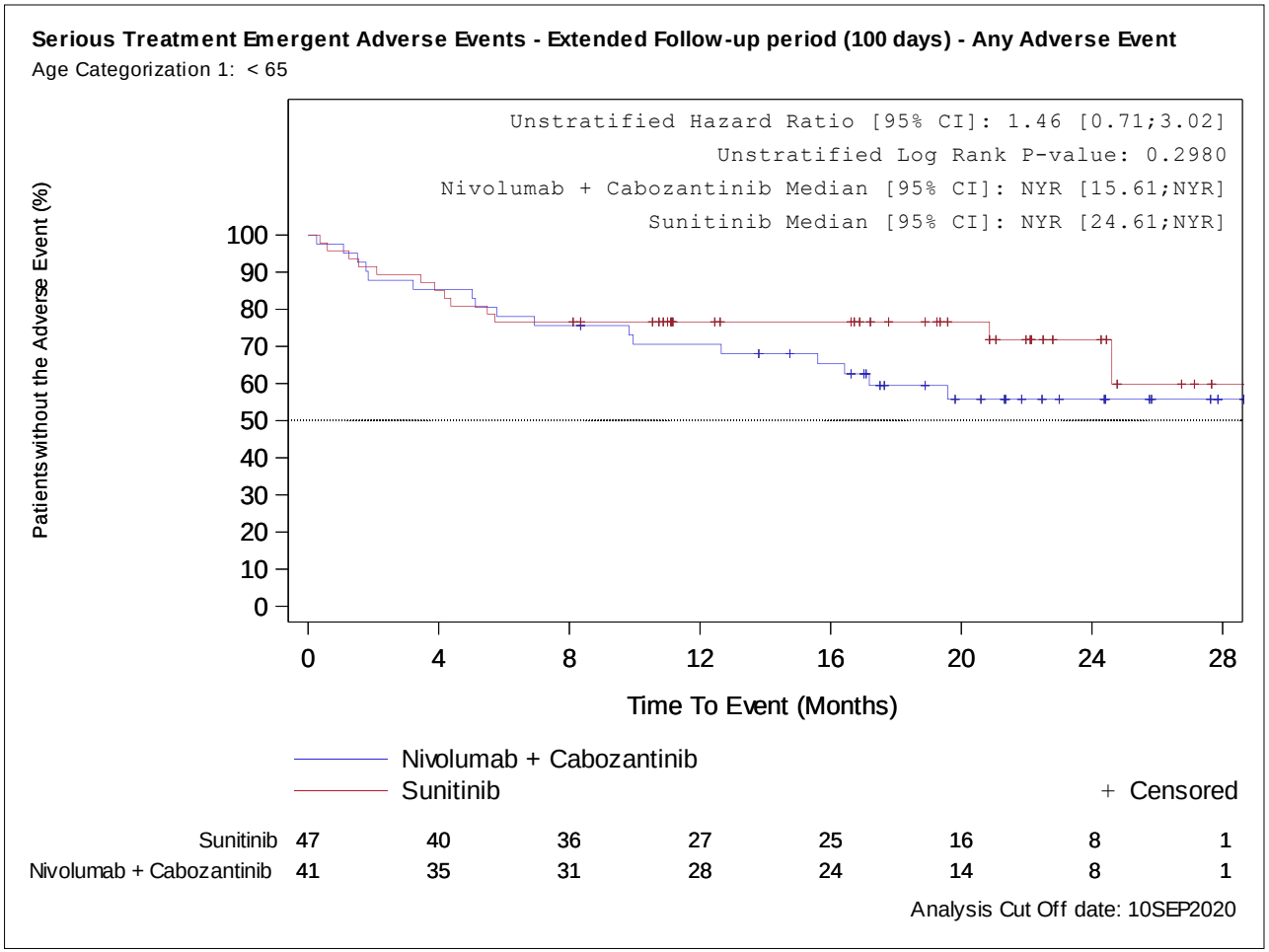

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:39:53

FIGURE 3.6.1: Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



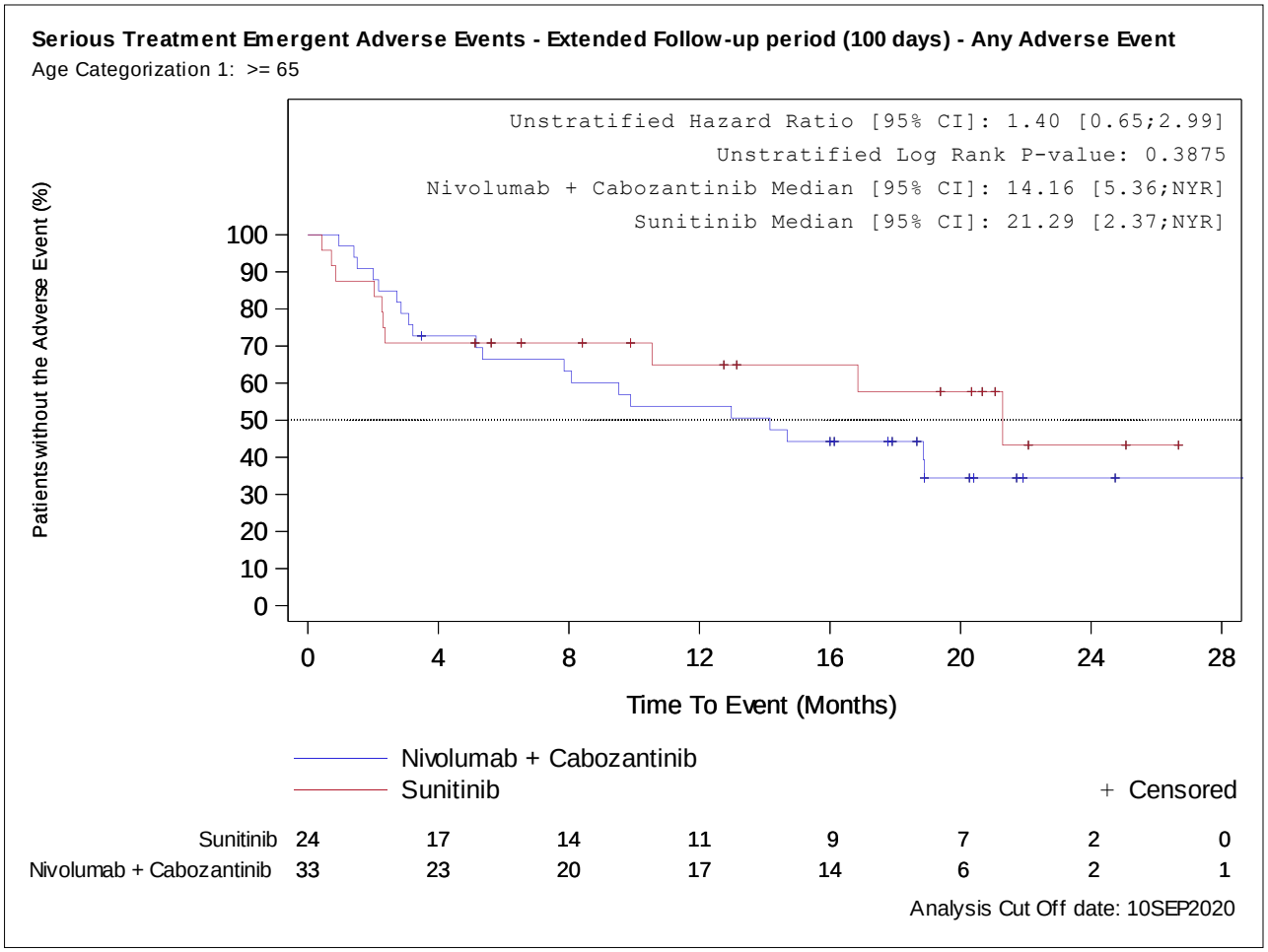

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:43:25

FIGURE 3.6.2.1: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



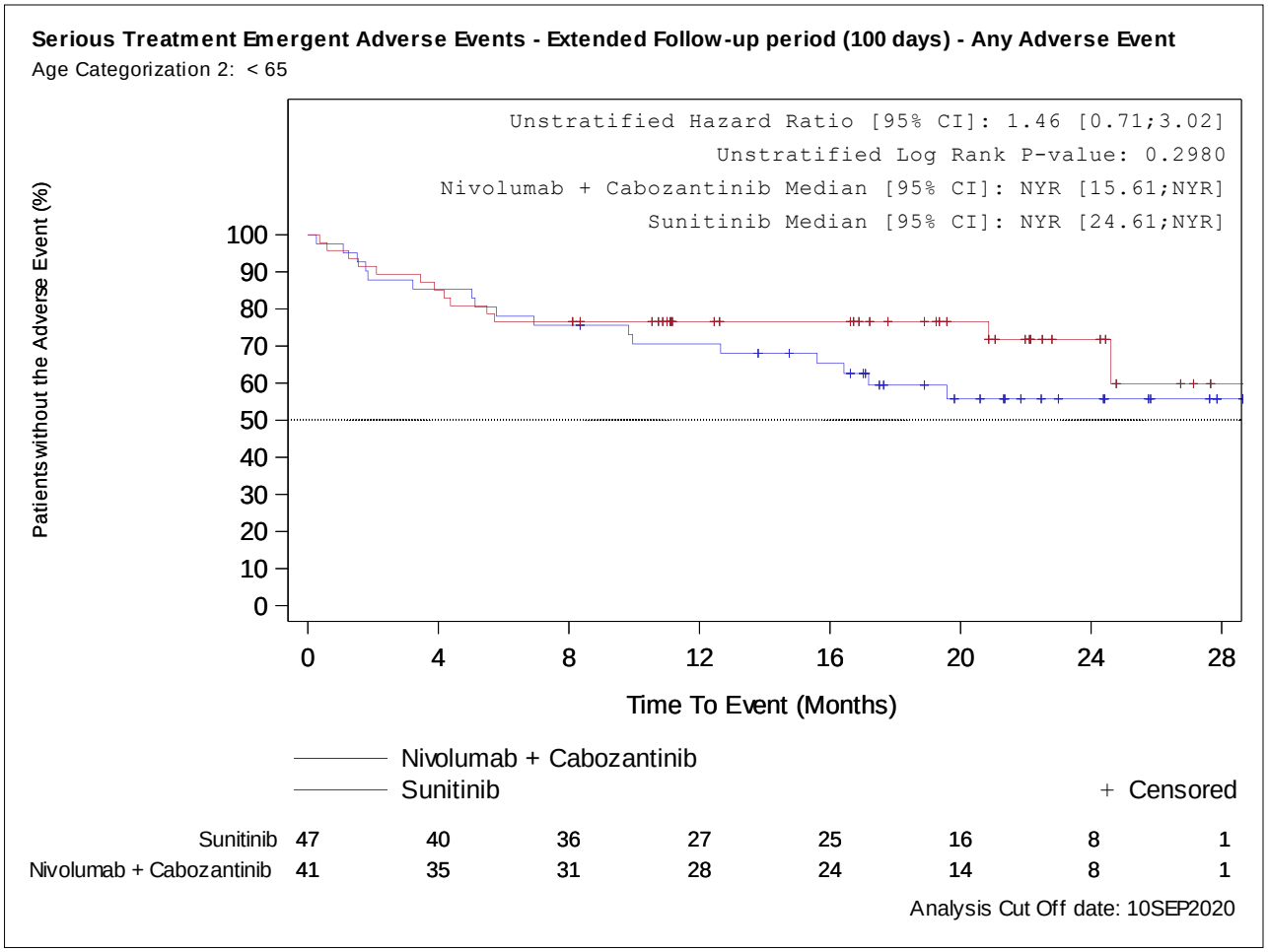

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:43:29

FIGURE 3.6.2.2: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



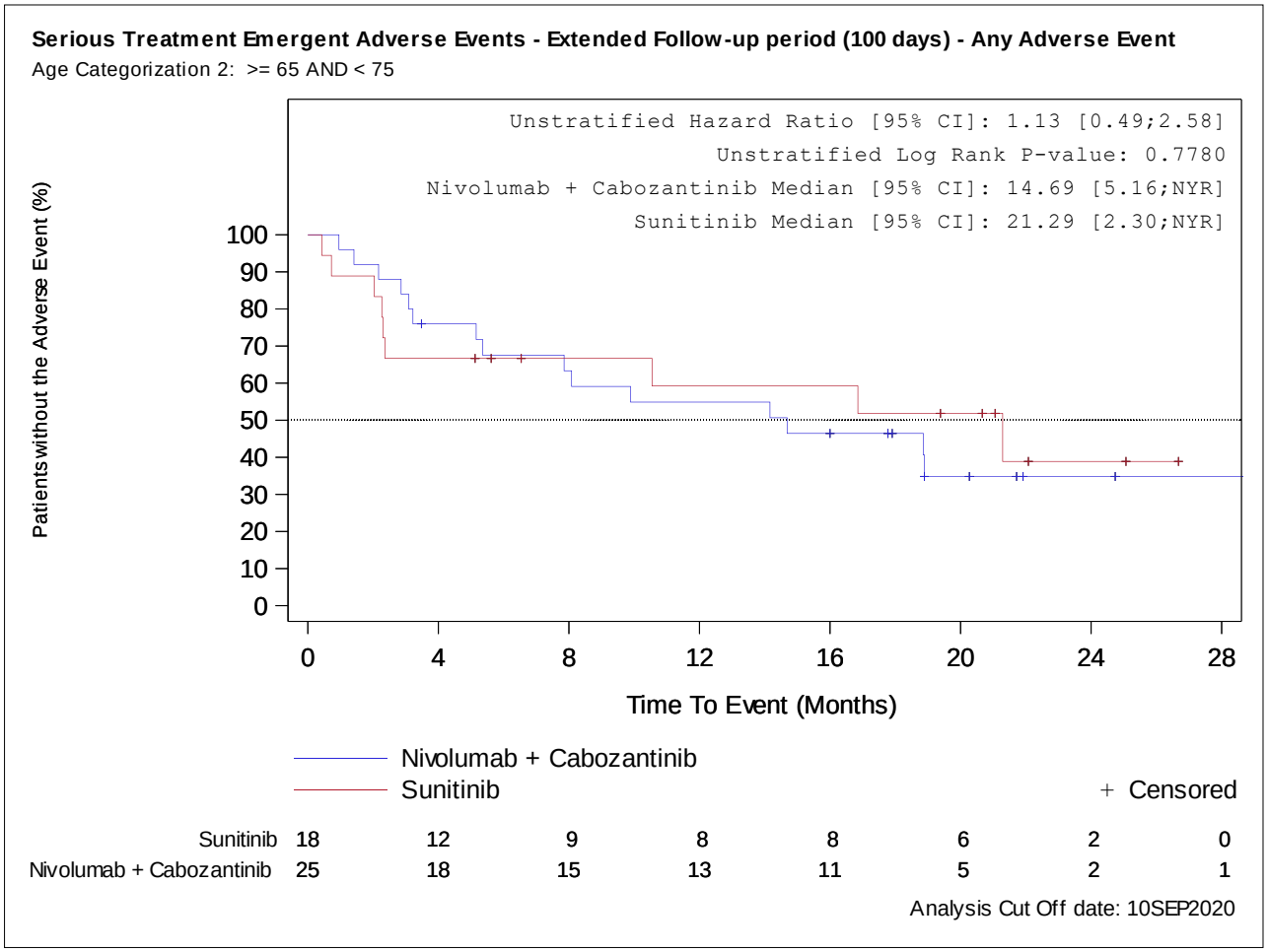

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:43:36

FIGURE 3.6.2.3: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



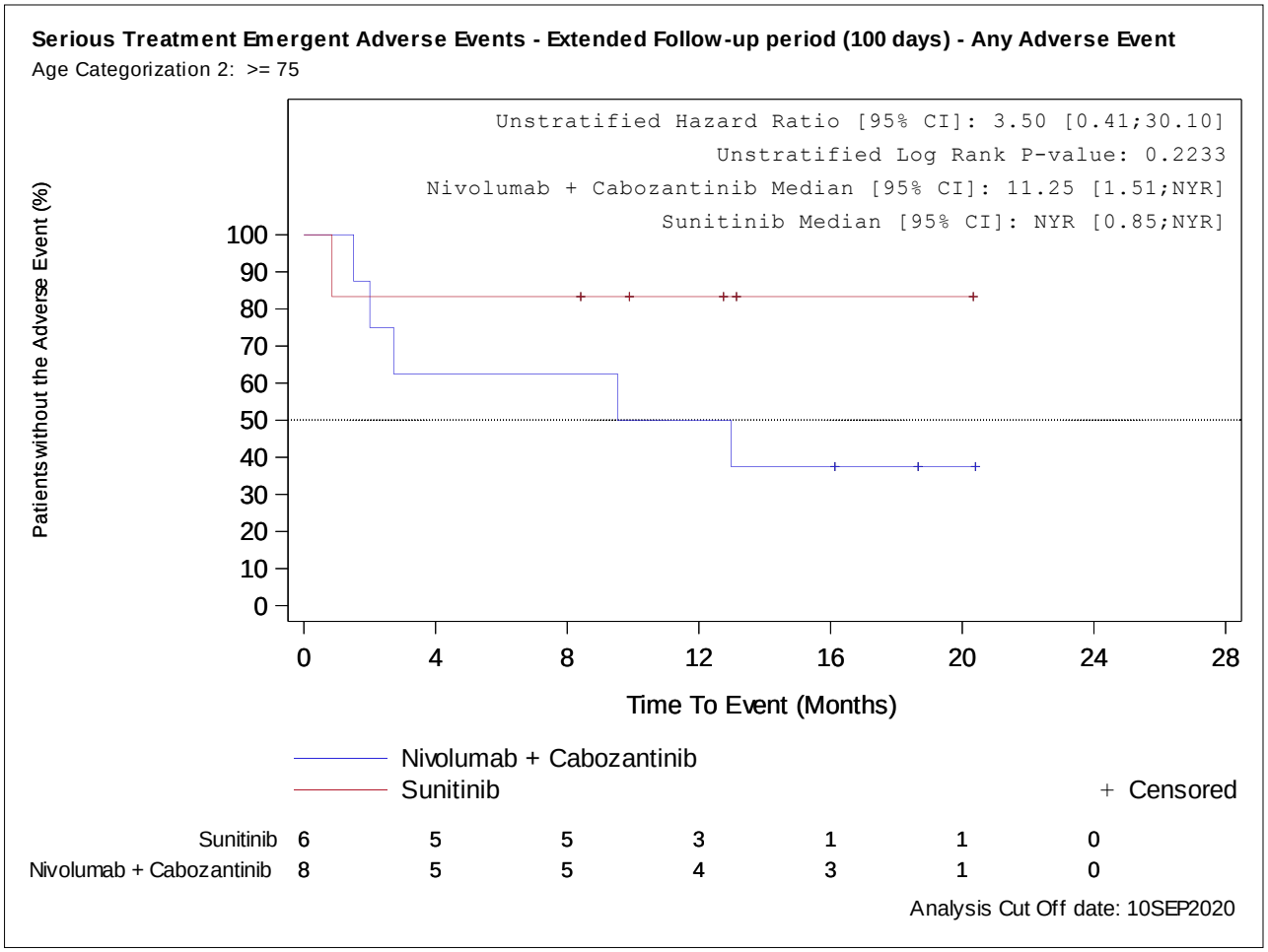

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:43:44

FIGURE 3.6.2.4: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



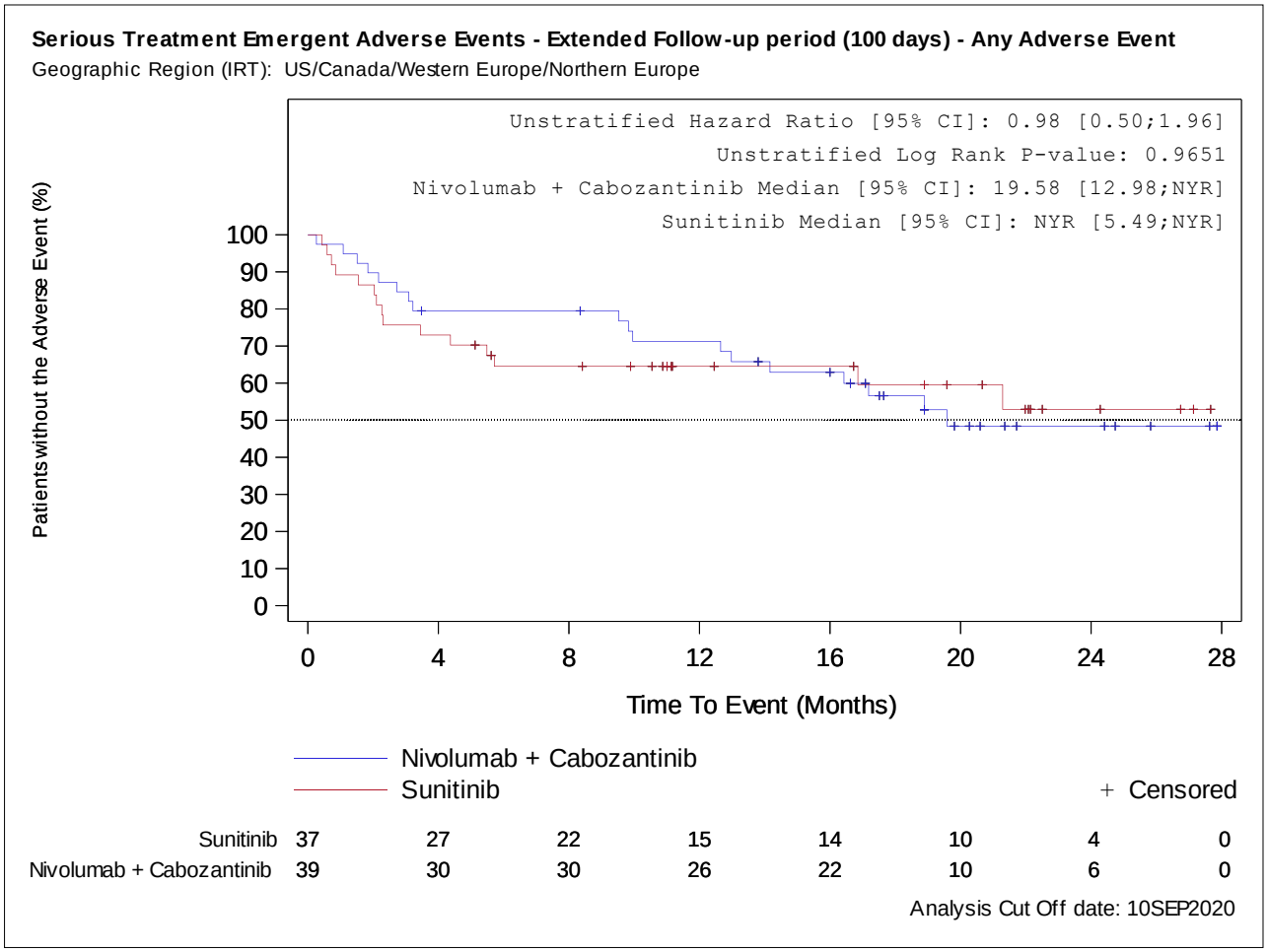

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:43:50

FIGURE 3.6.2.5: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



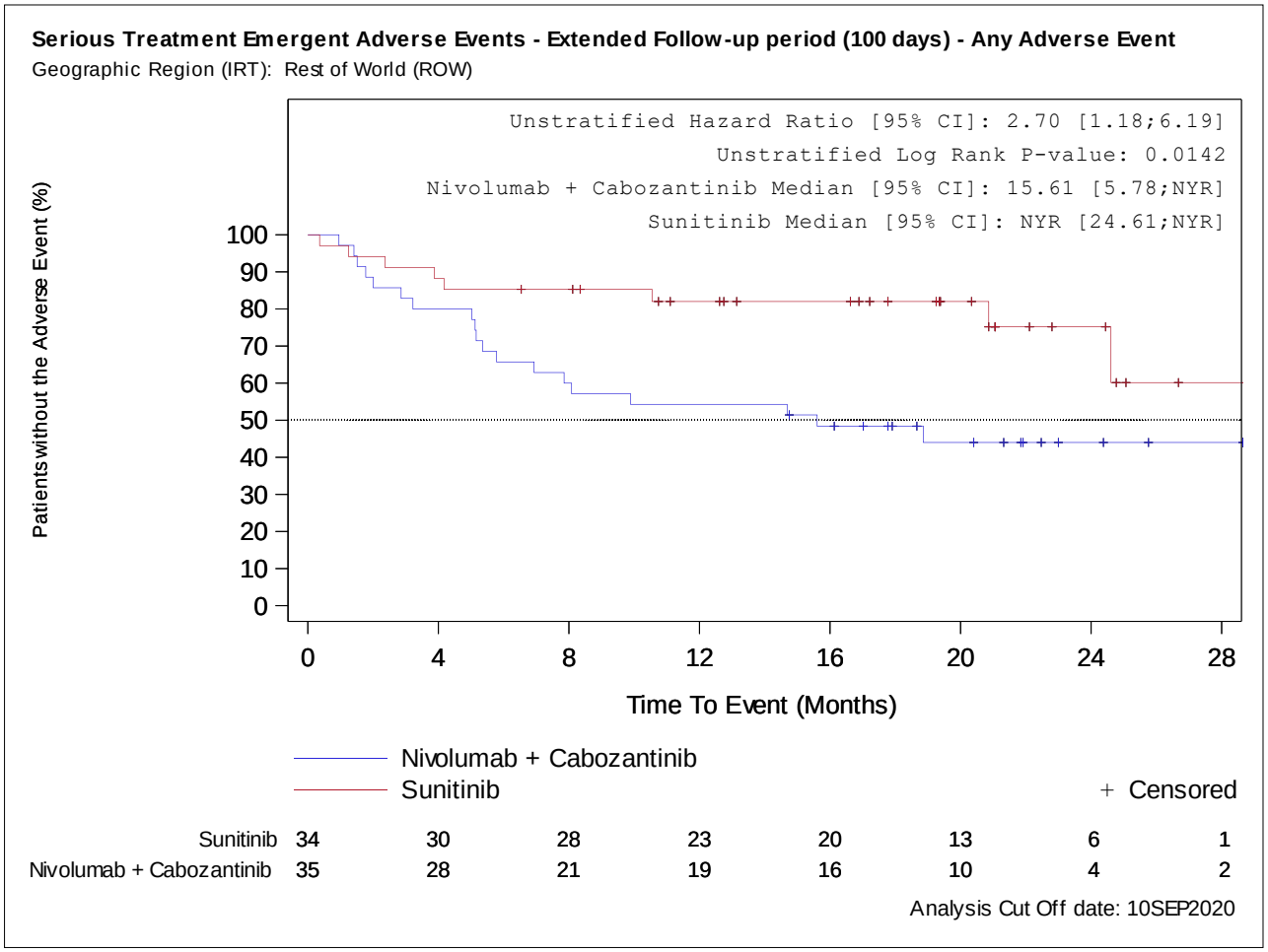

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:43:57

FIGURE 3.6.2.6: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



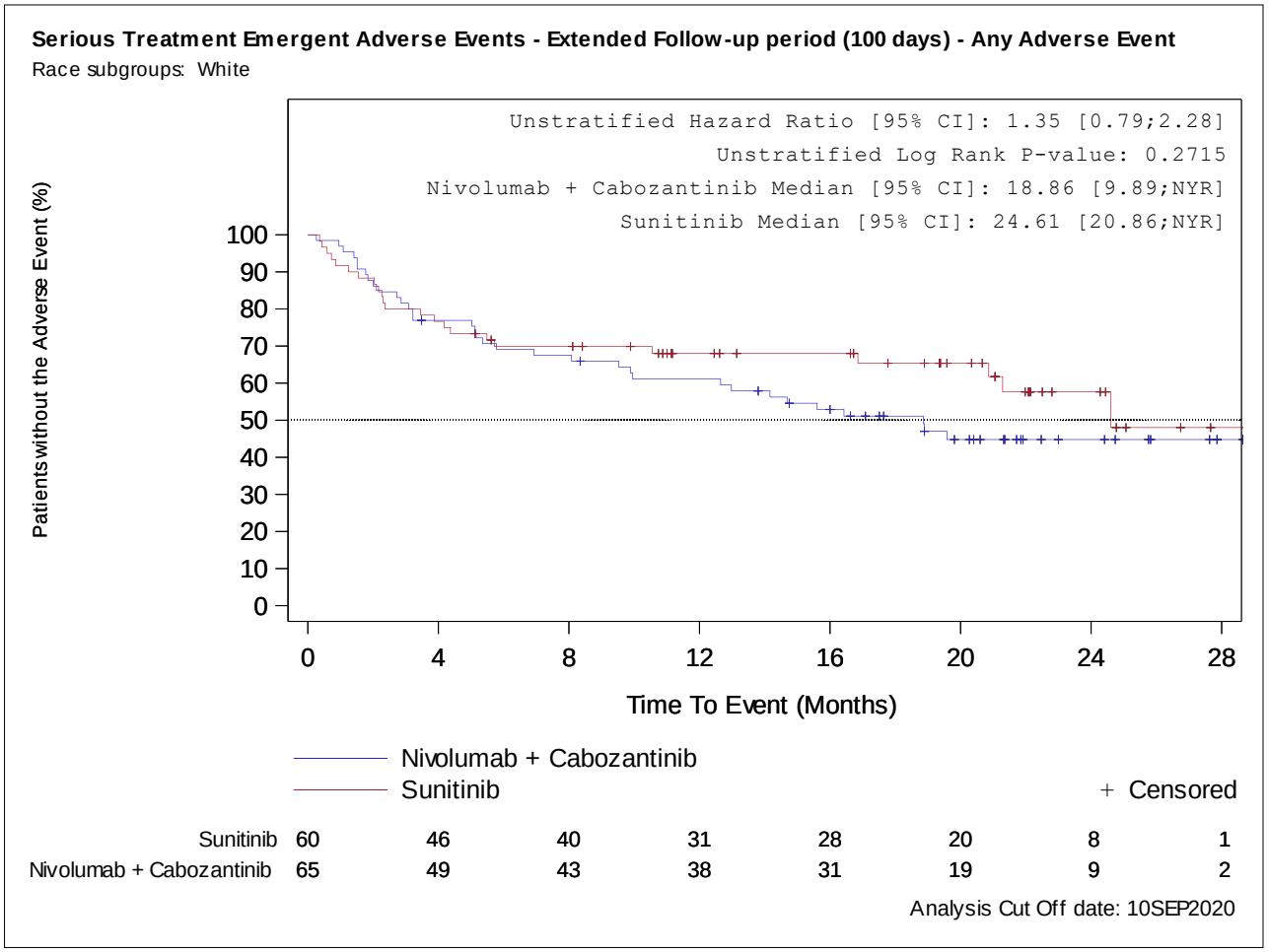

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:44:03

FIGURE 3.6.2.7: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



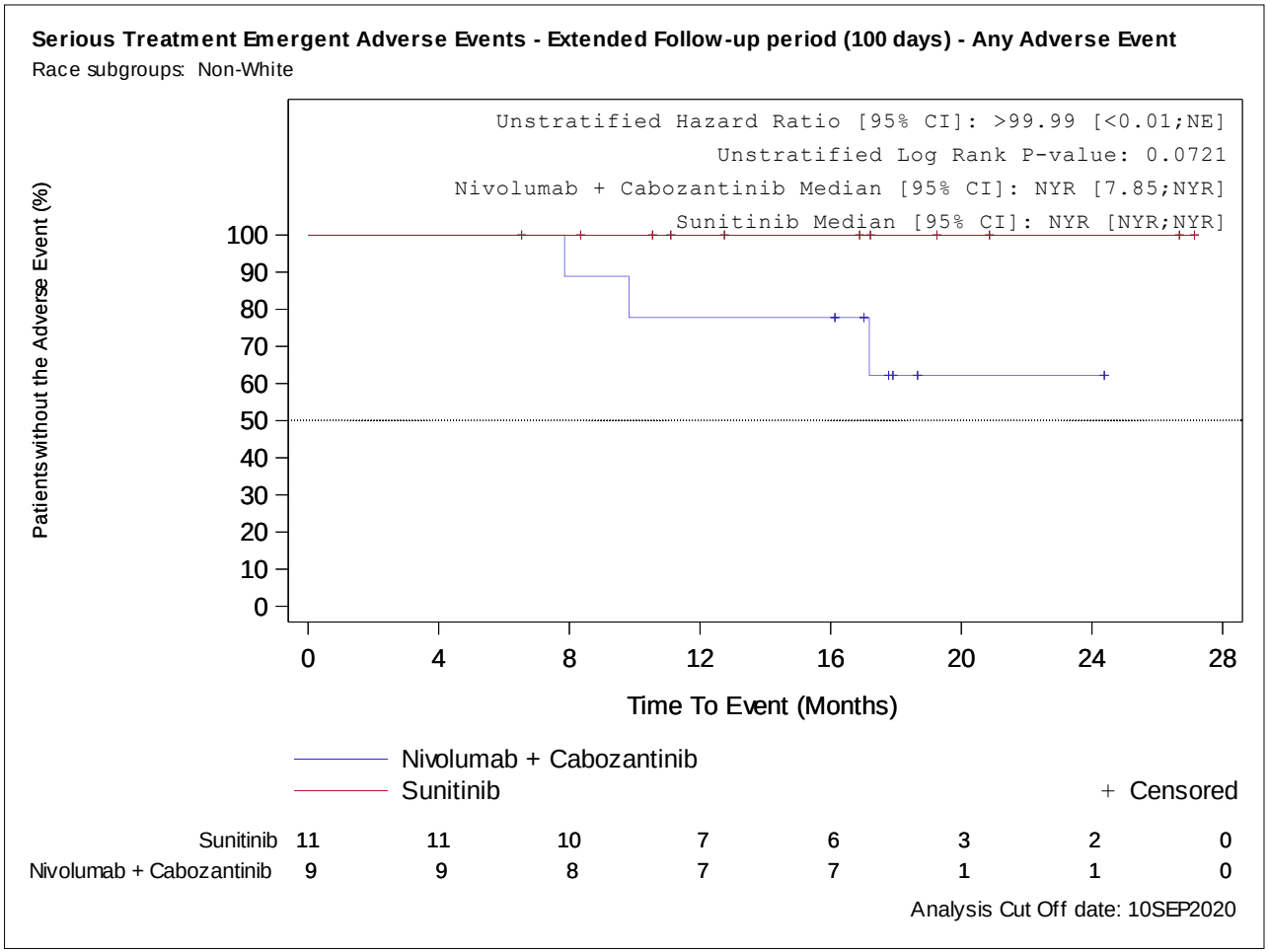

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:44:10

FIGURE 3.6.2.8: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:44:17

FIGURE 3.6.2.9: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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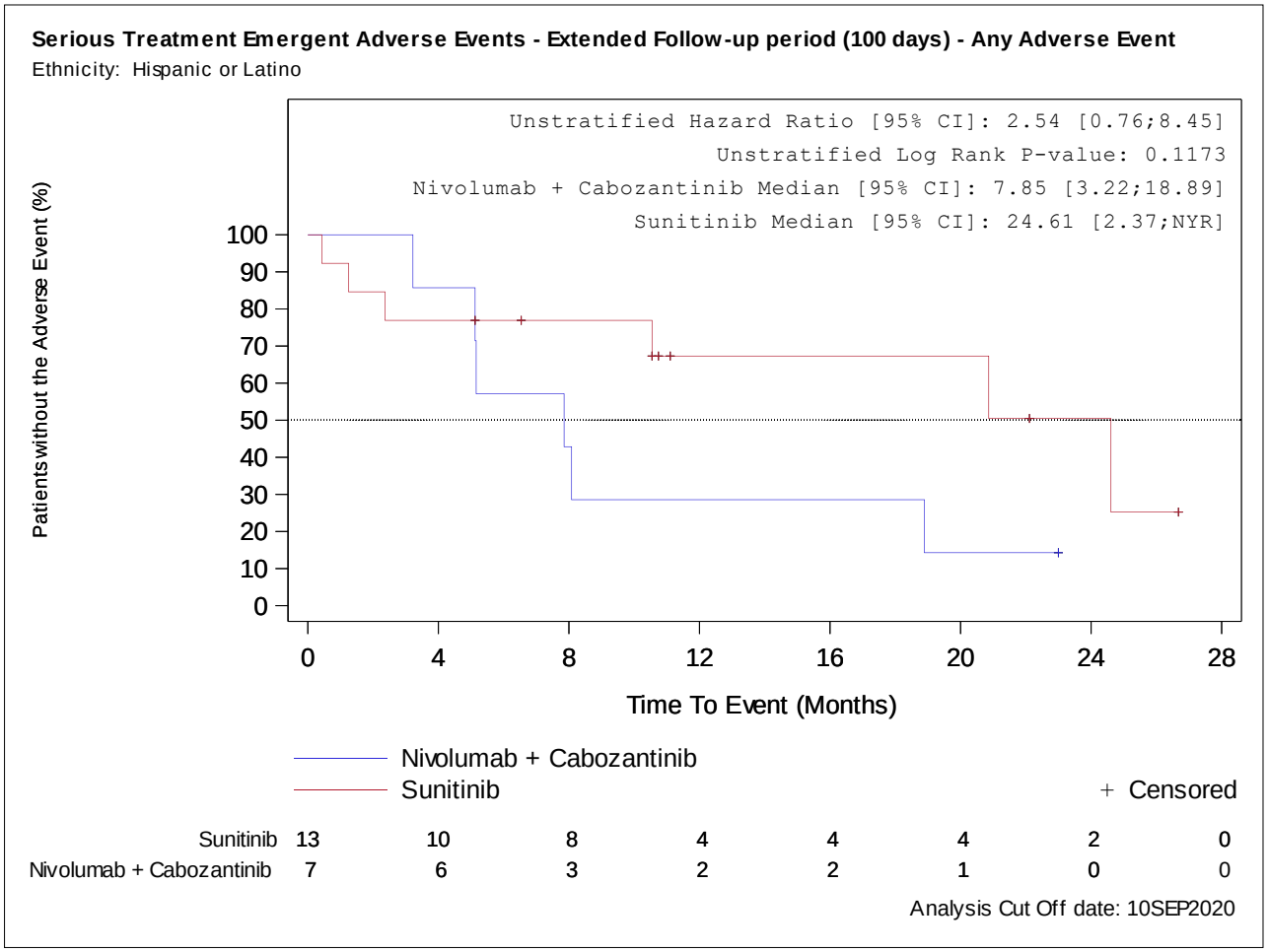
FIGURE 3.6.2.10: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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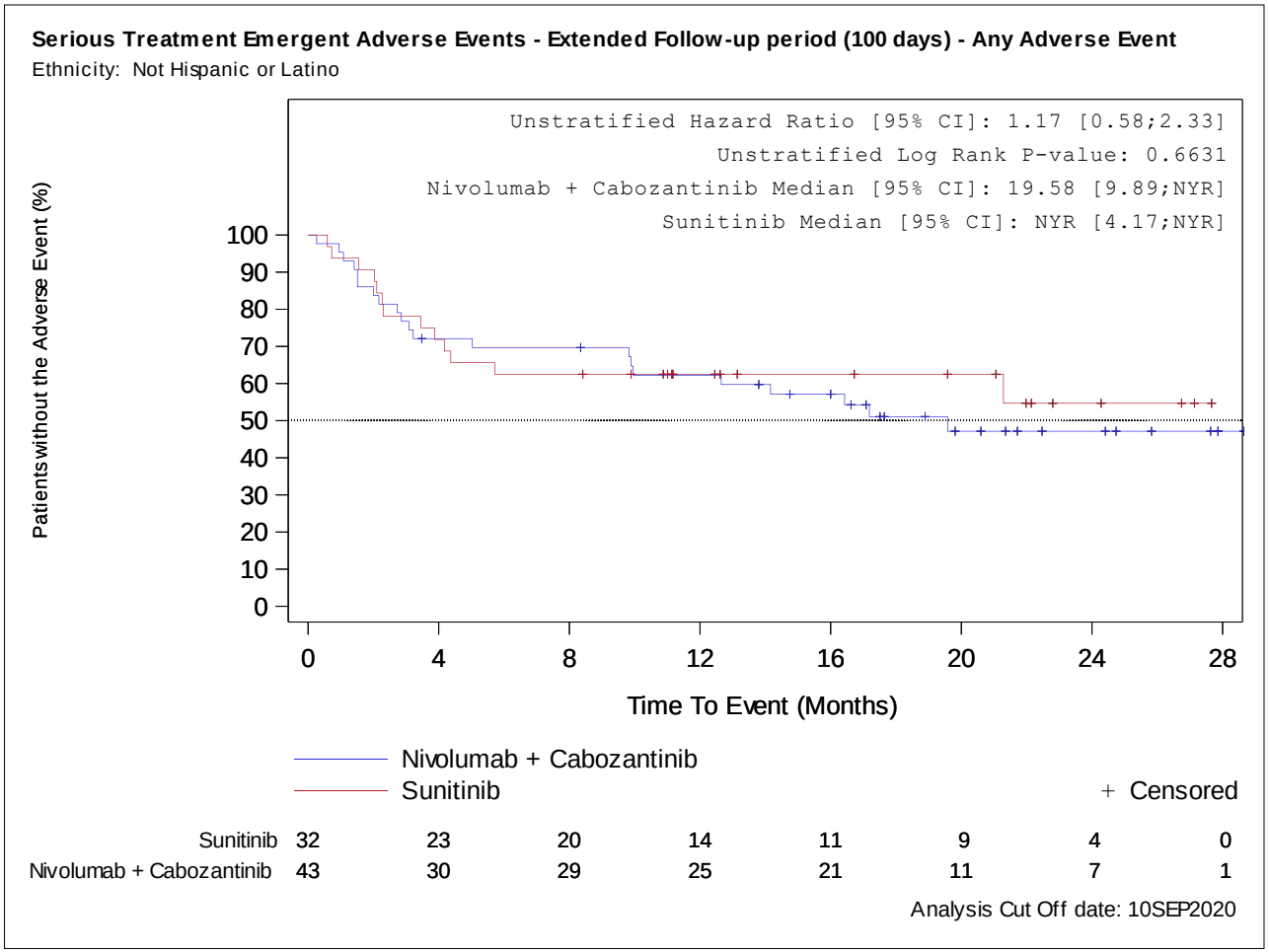
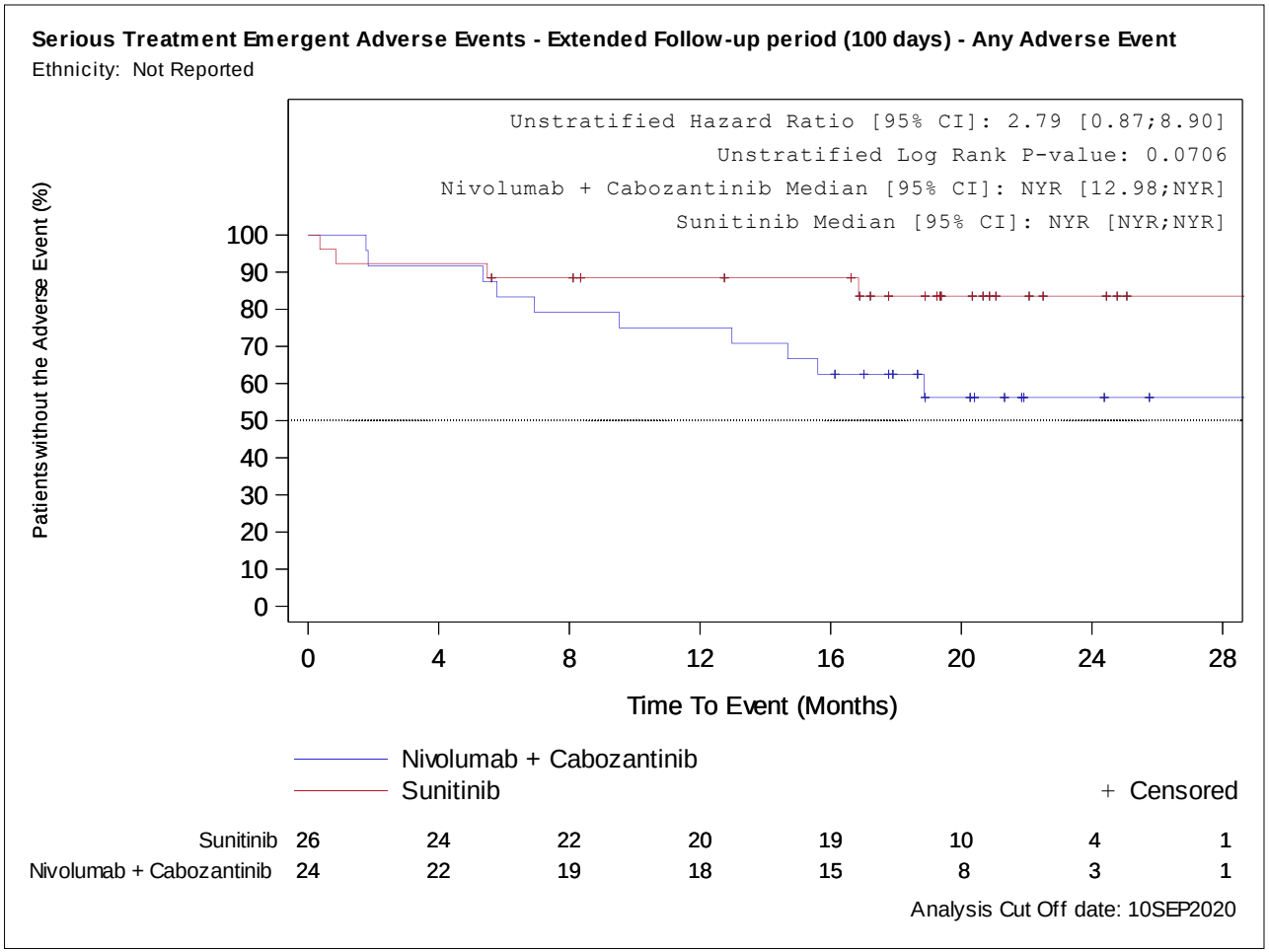
FIGURE 3.6.2.11: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:44:36

FIGURE 3.6.2.12: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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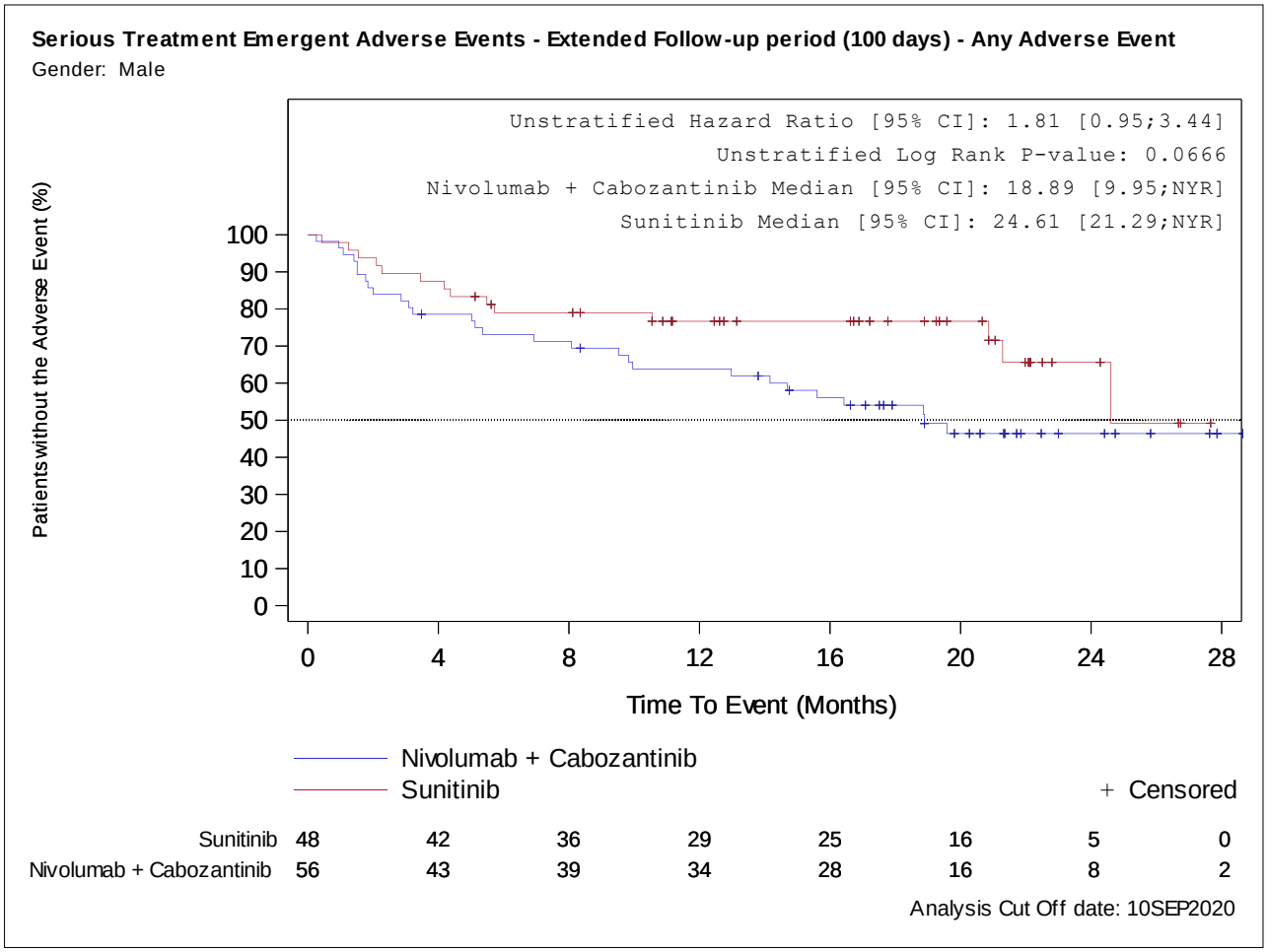
FIGURE 3.6.2.13: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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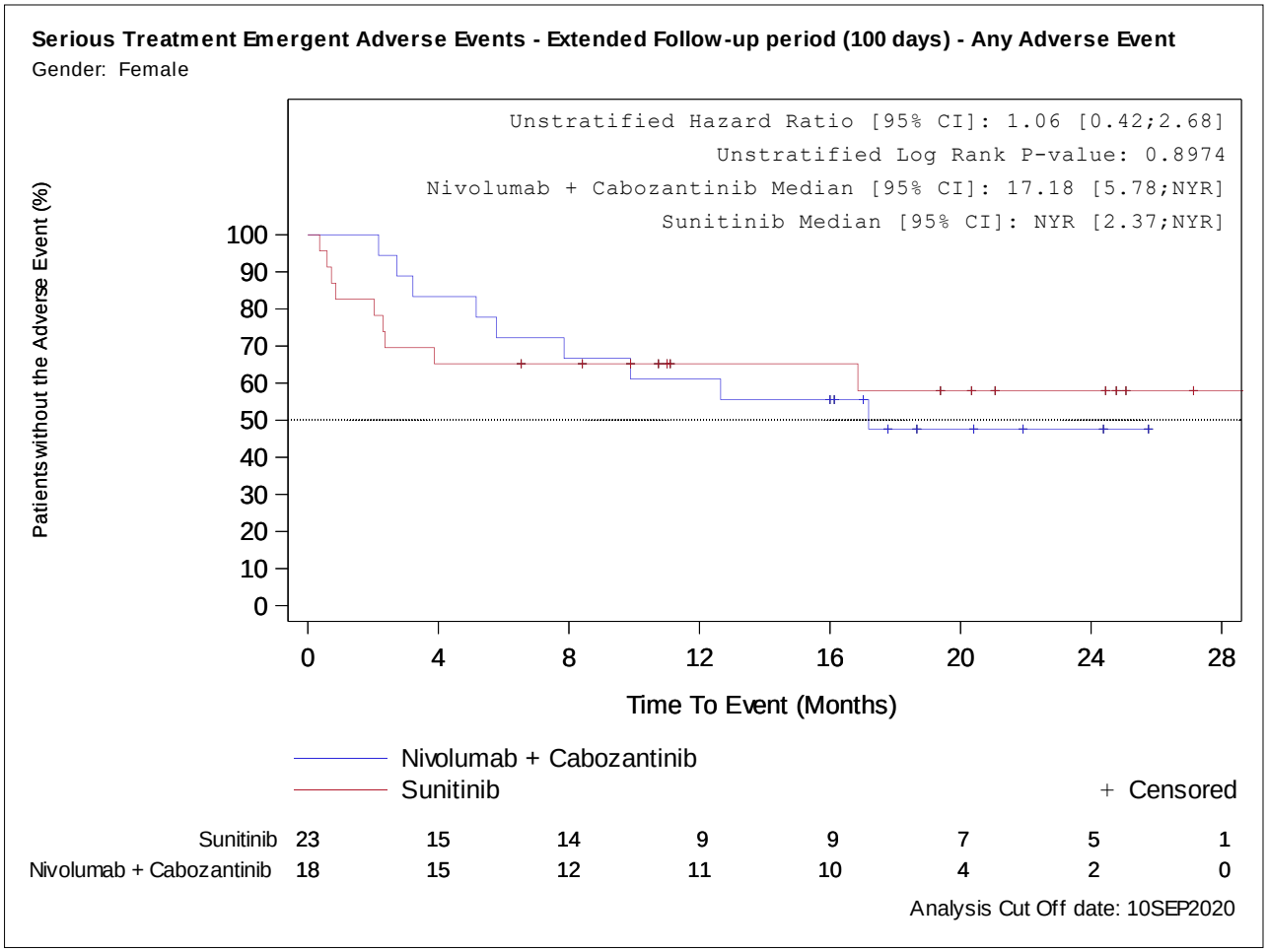
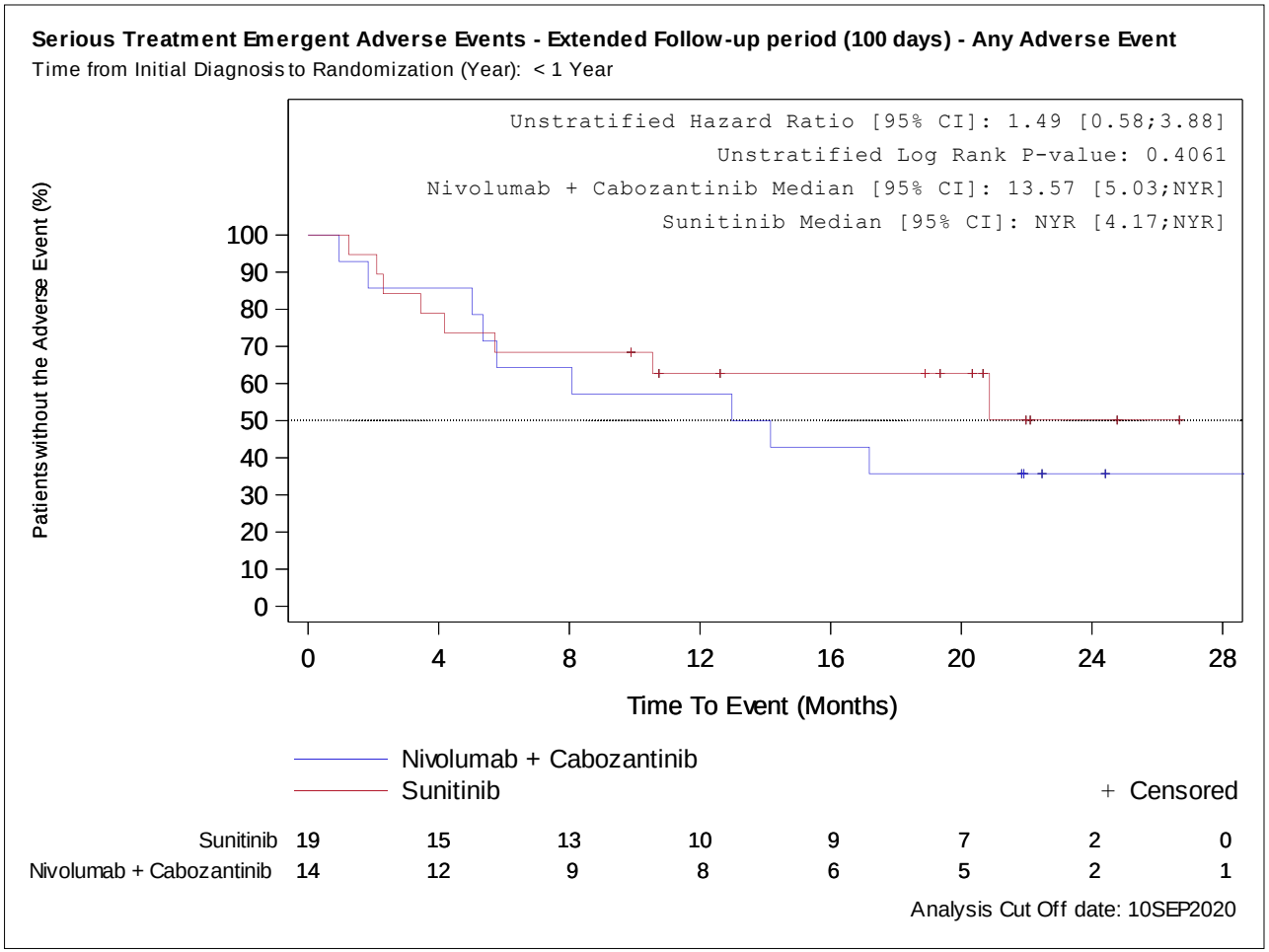
FIGURE 3.6.2.14: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



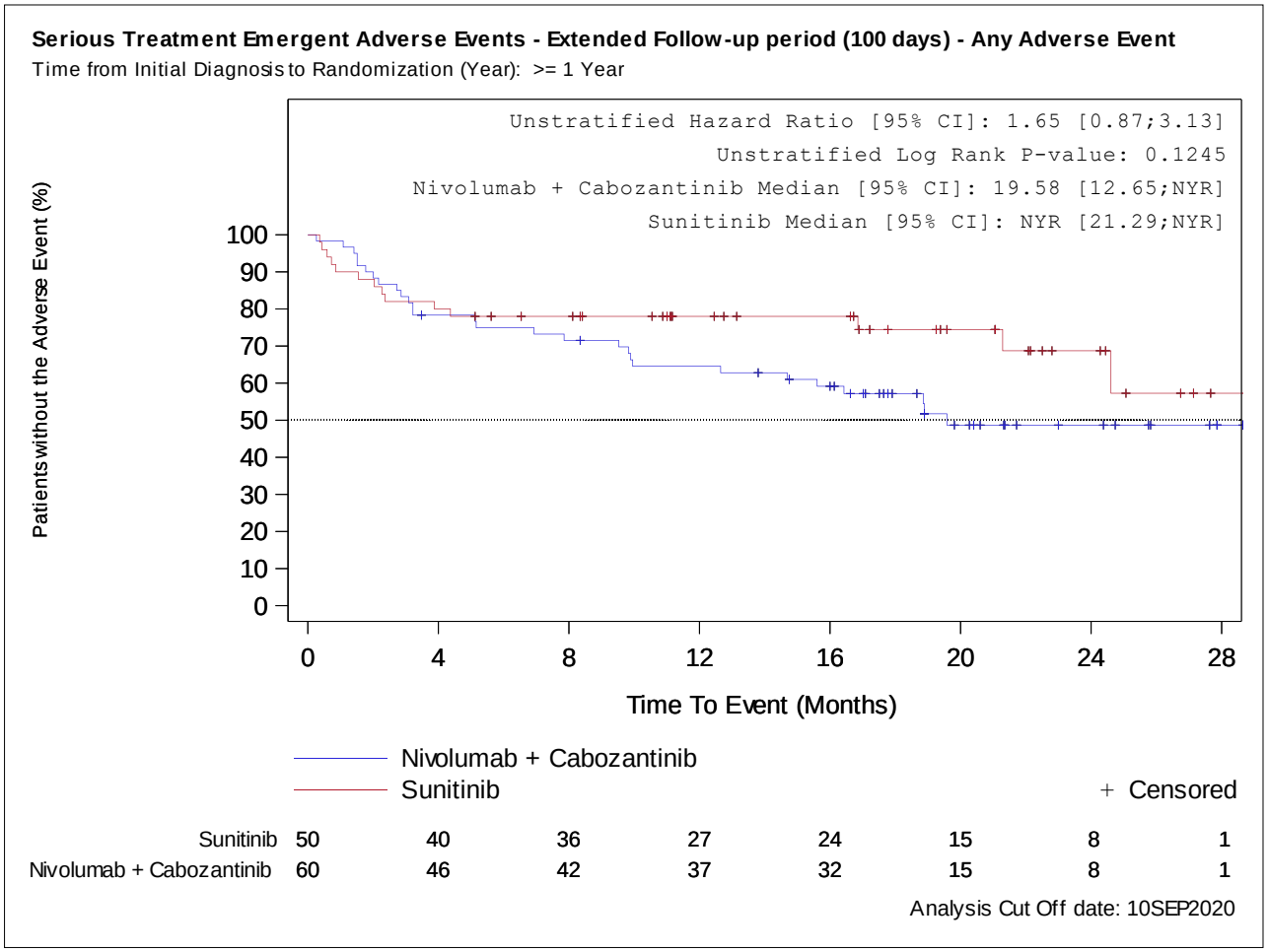

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:44:55

FIGURE 3.6.2.15: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:45:14

FIGURE 3.6.2.16: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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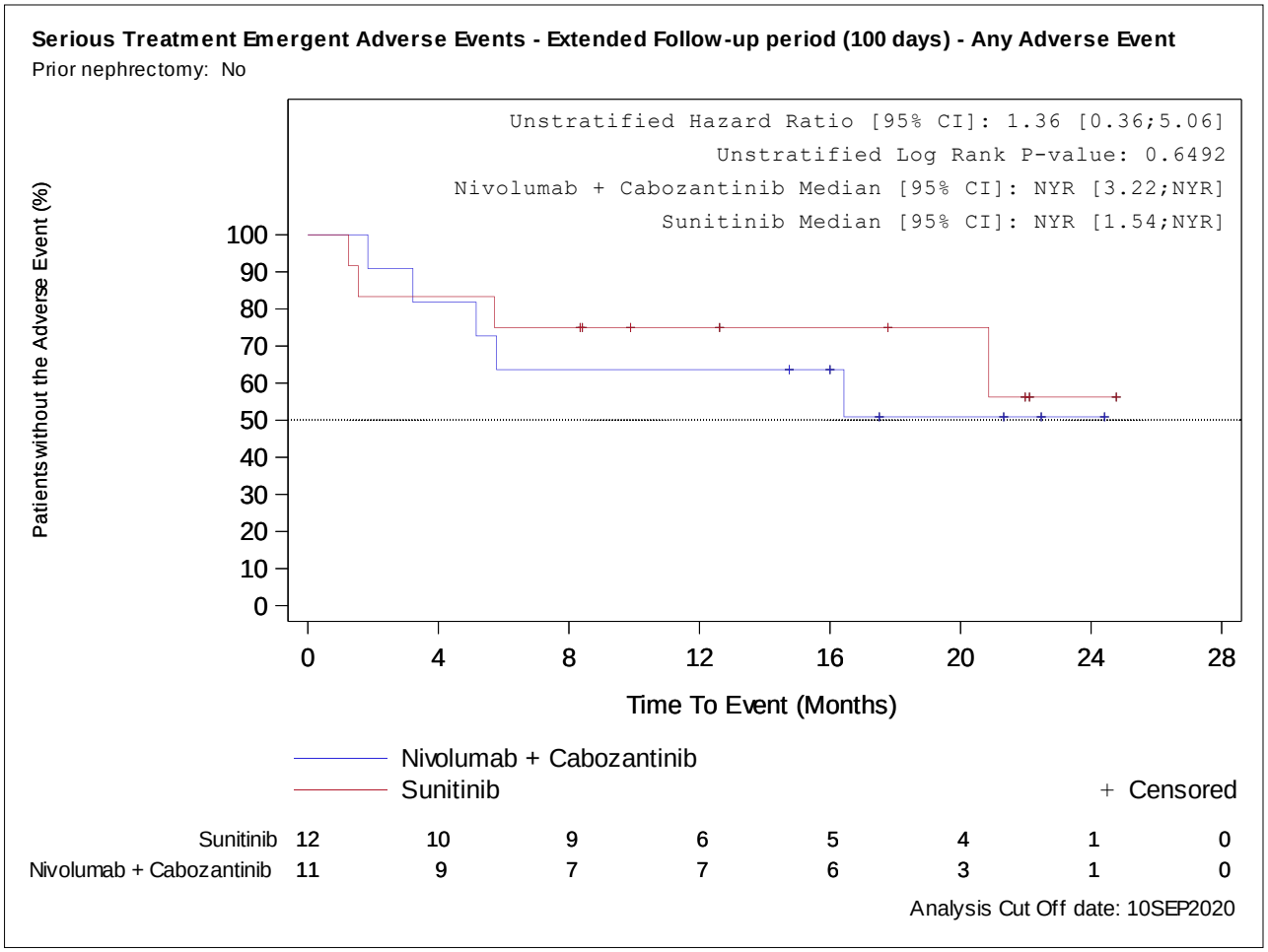
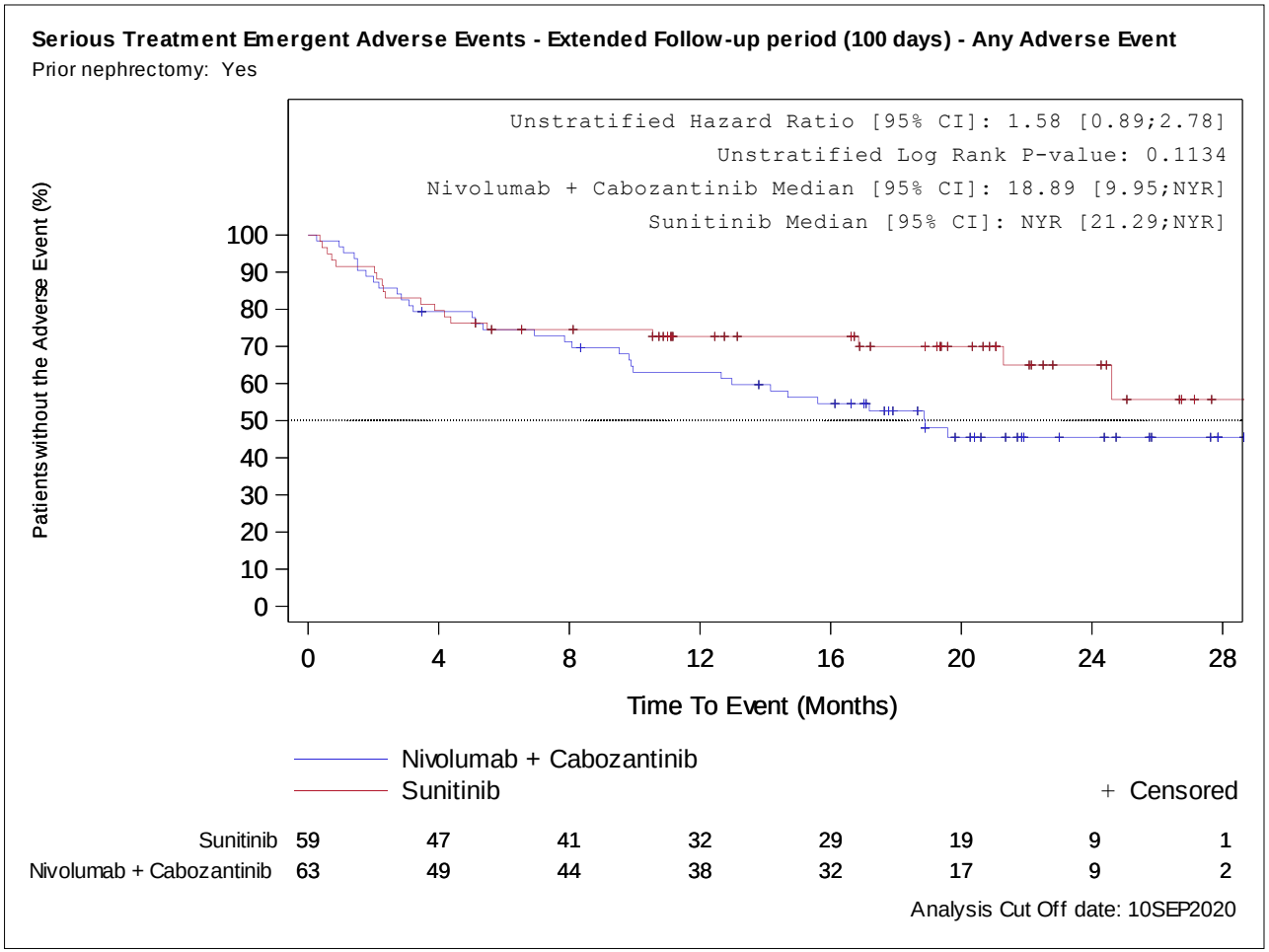
FIGURE 3.6.2.17: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



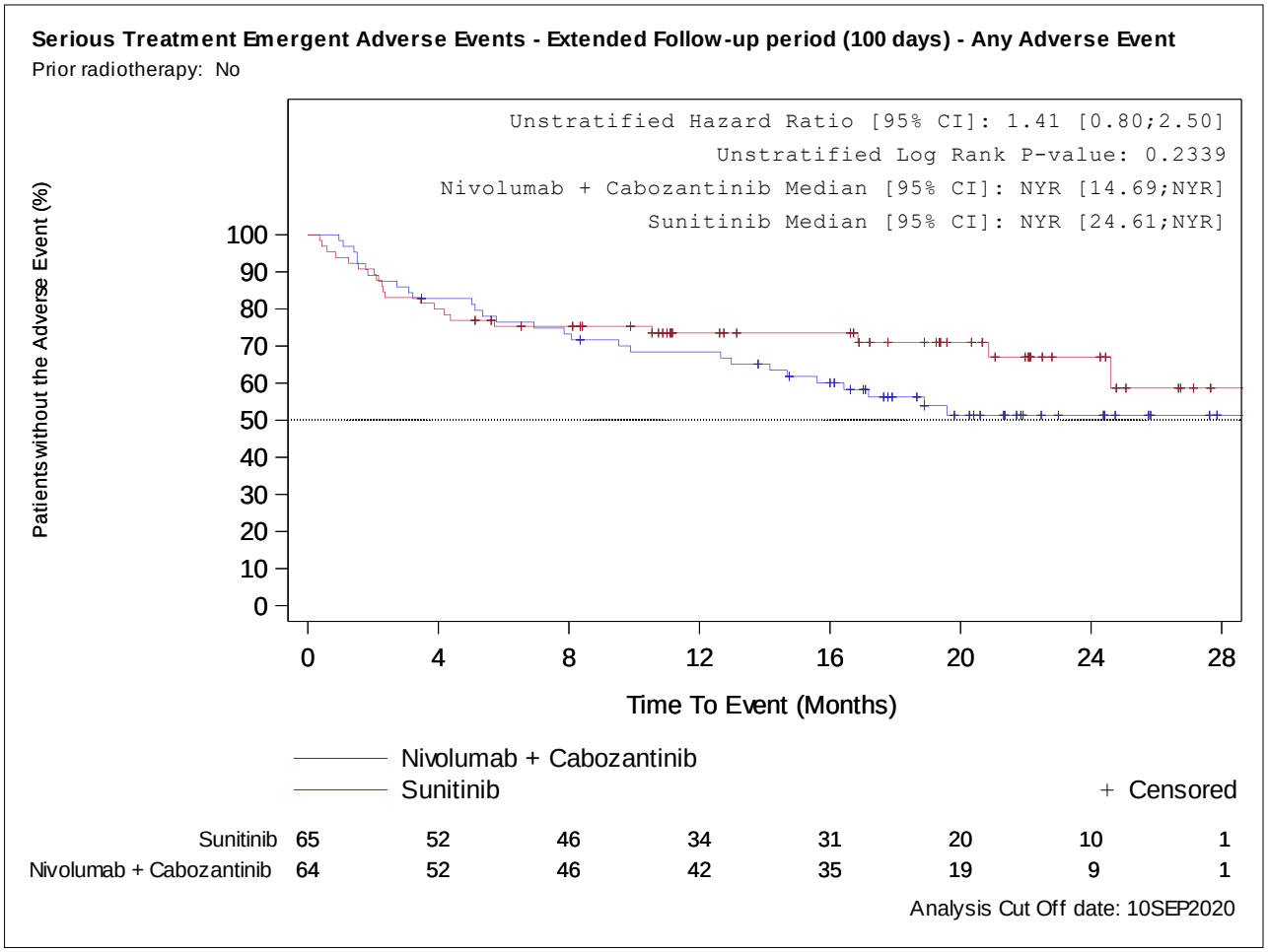

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:46:17

FIGURE 3.6.2.18: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



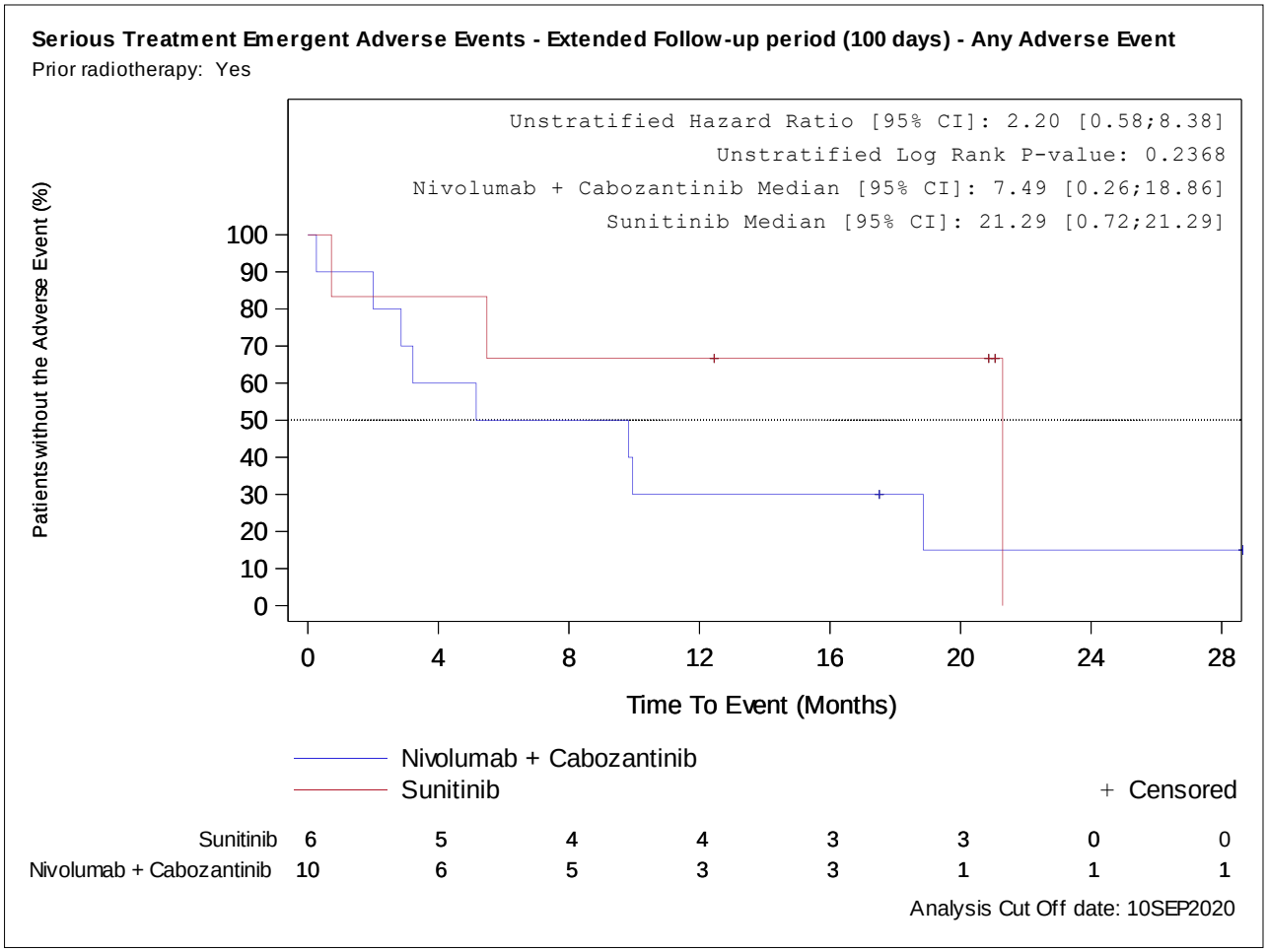

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:46:23

FIGURE 3.6.2.19: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



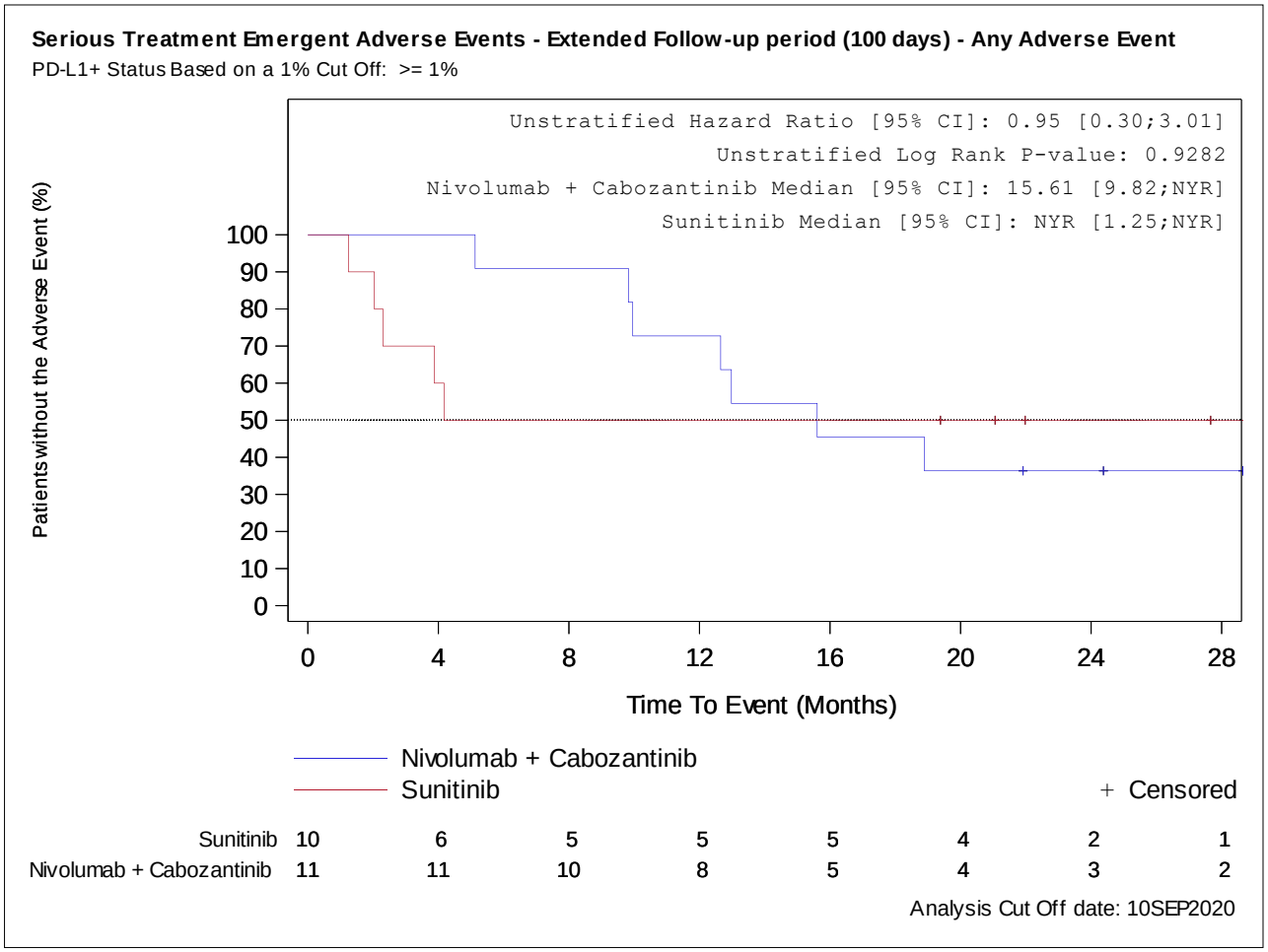

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:46:29

FIGURE 3.6.2.20: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:46:35

FIGURE 3.6.2.21: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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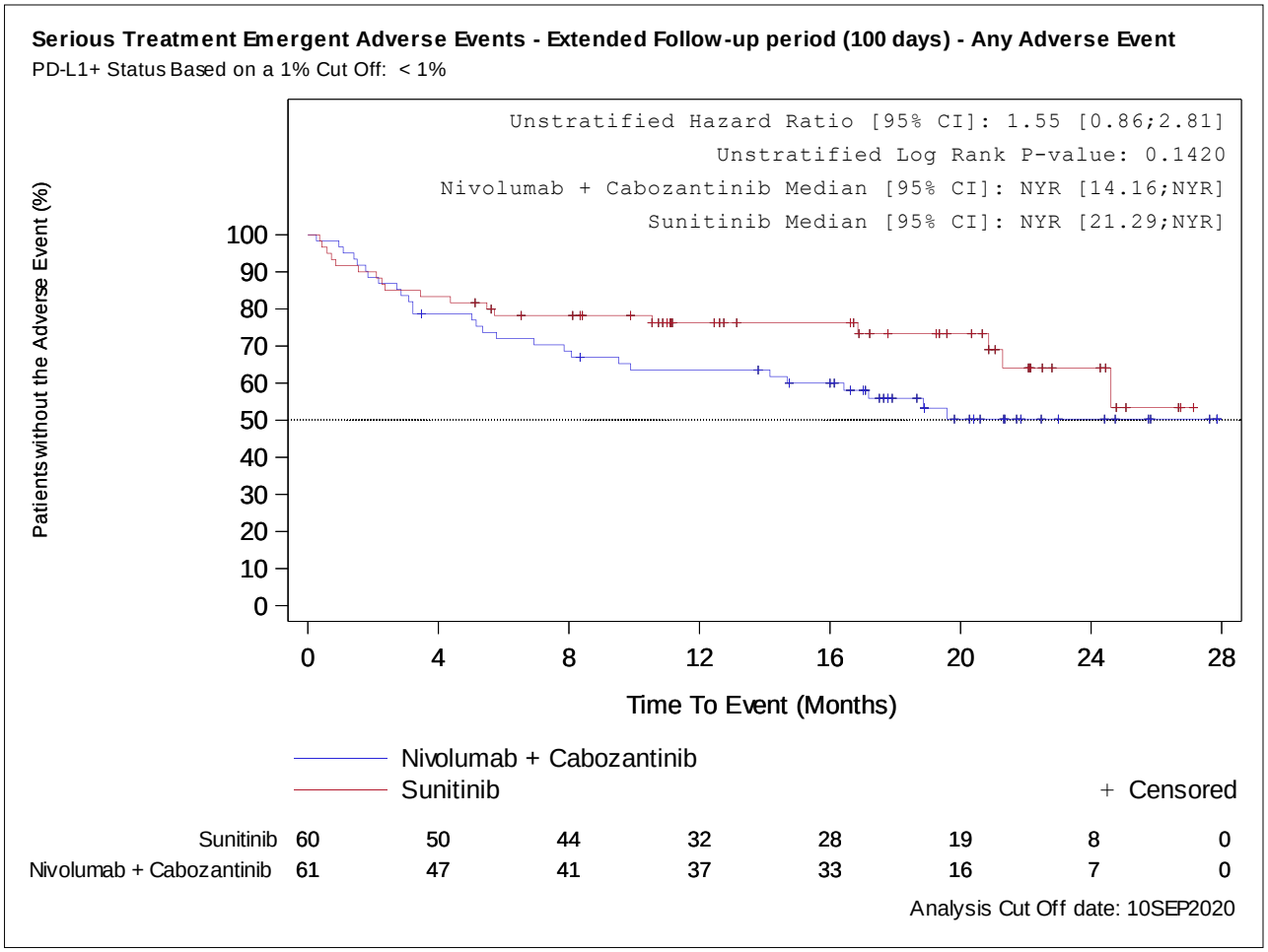
FIGURE 3.6.2.22: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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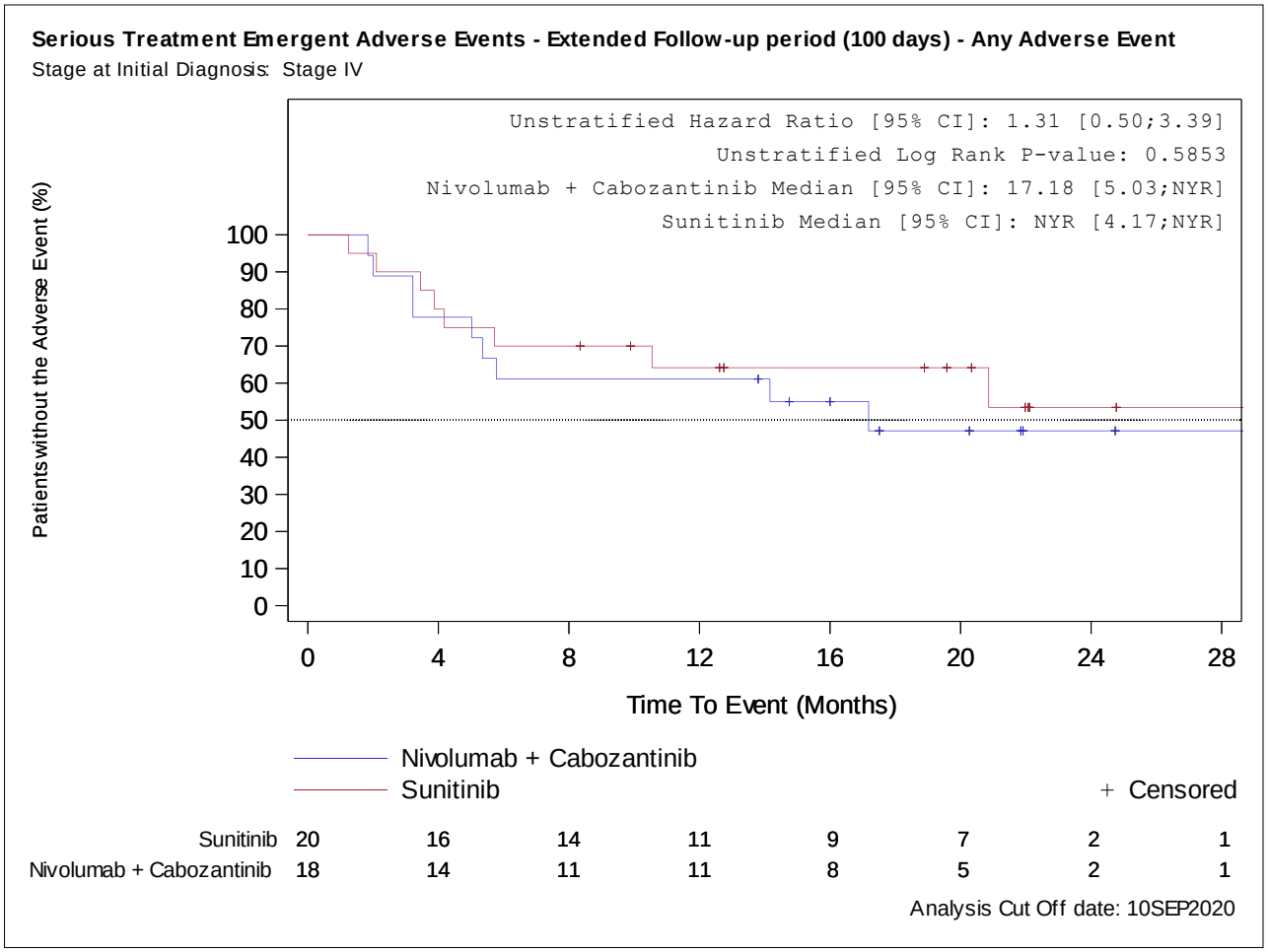
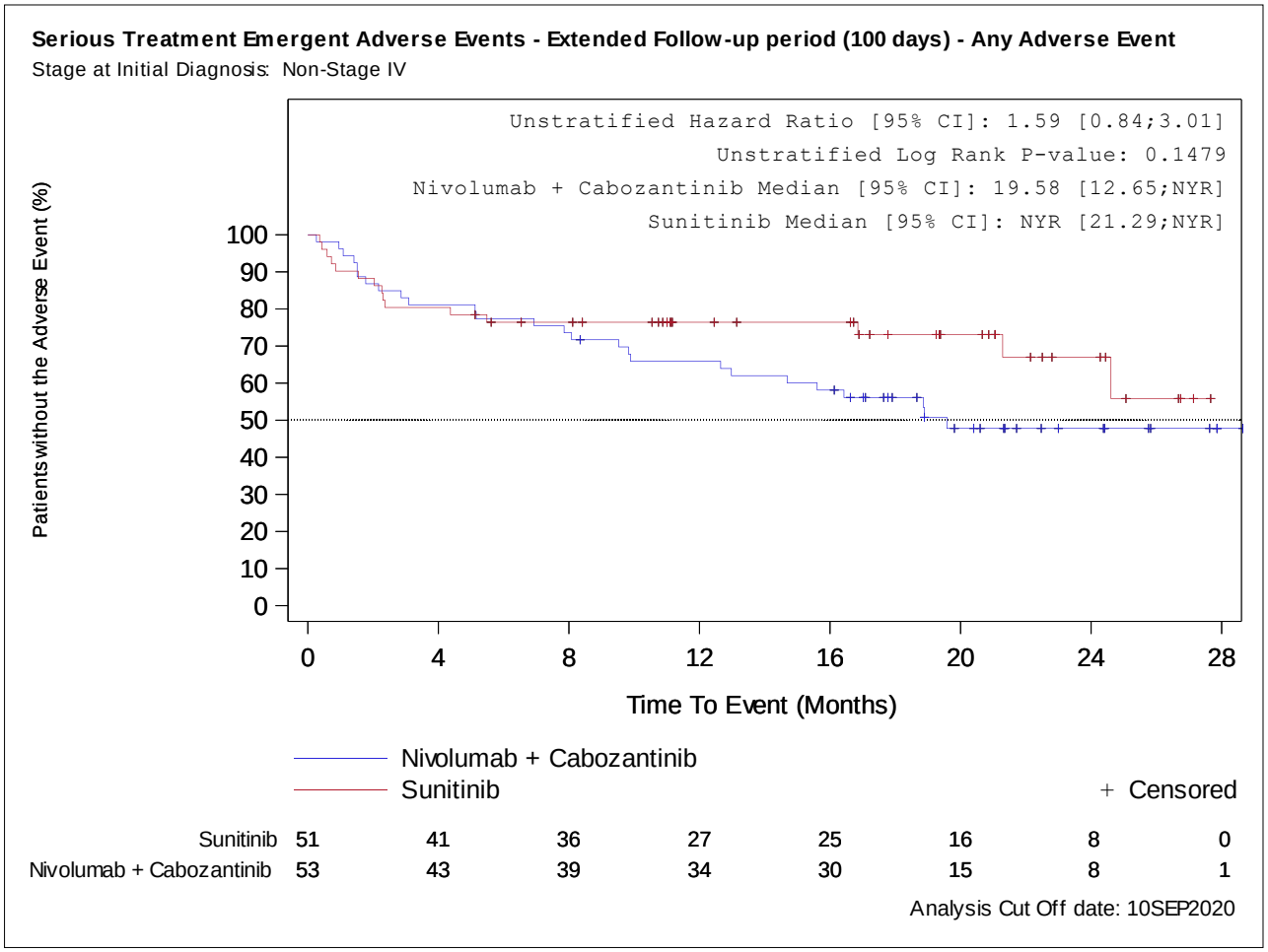
FIGURE 3.6.2.23: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



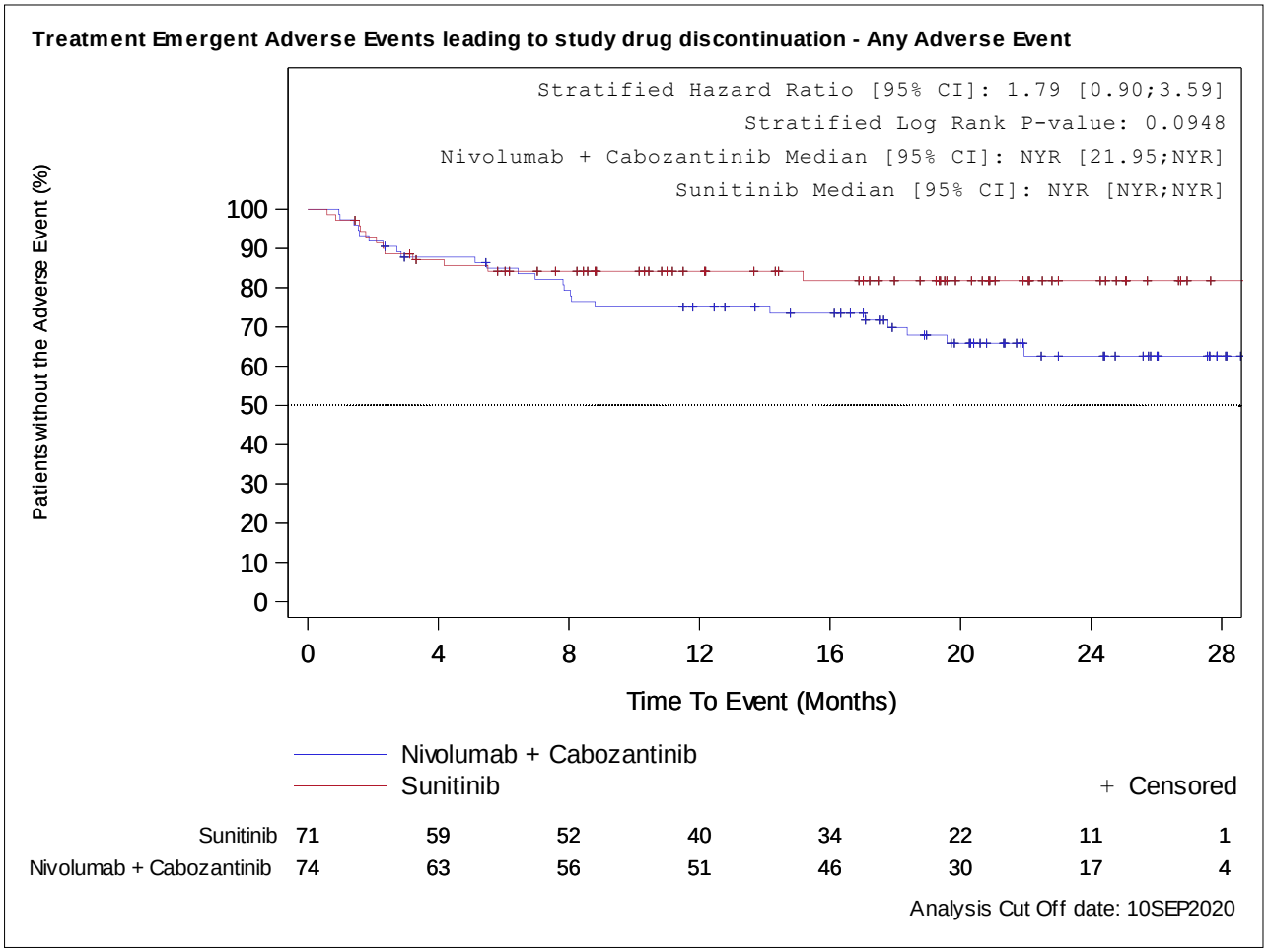

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:47:19

FIGURE 3.6.2.24: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



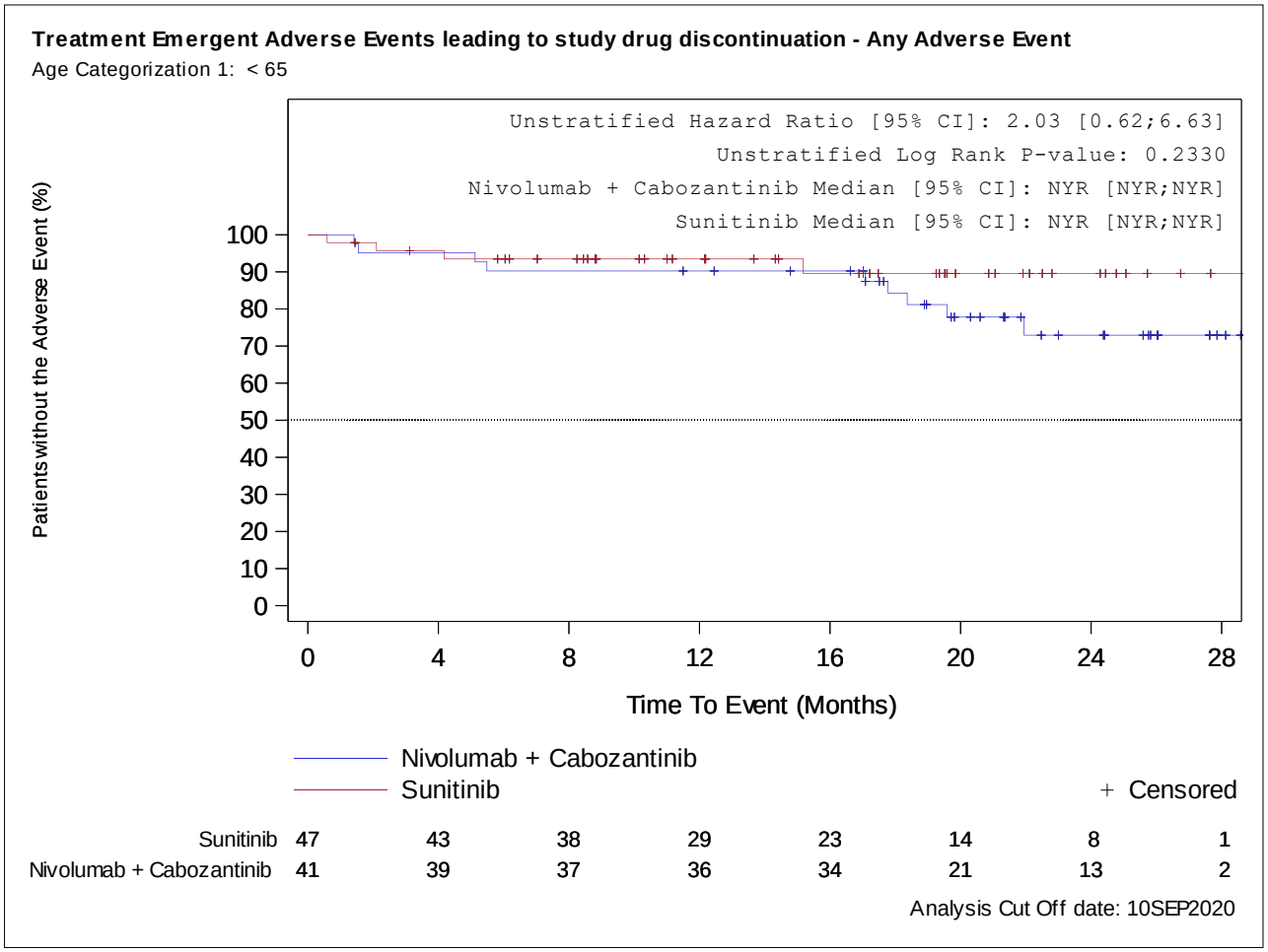

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:47:25

FIGURE 3.7.1: Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



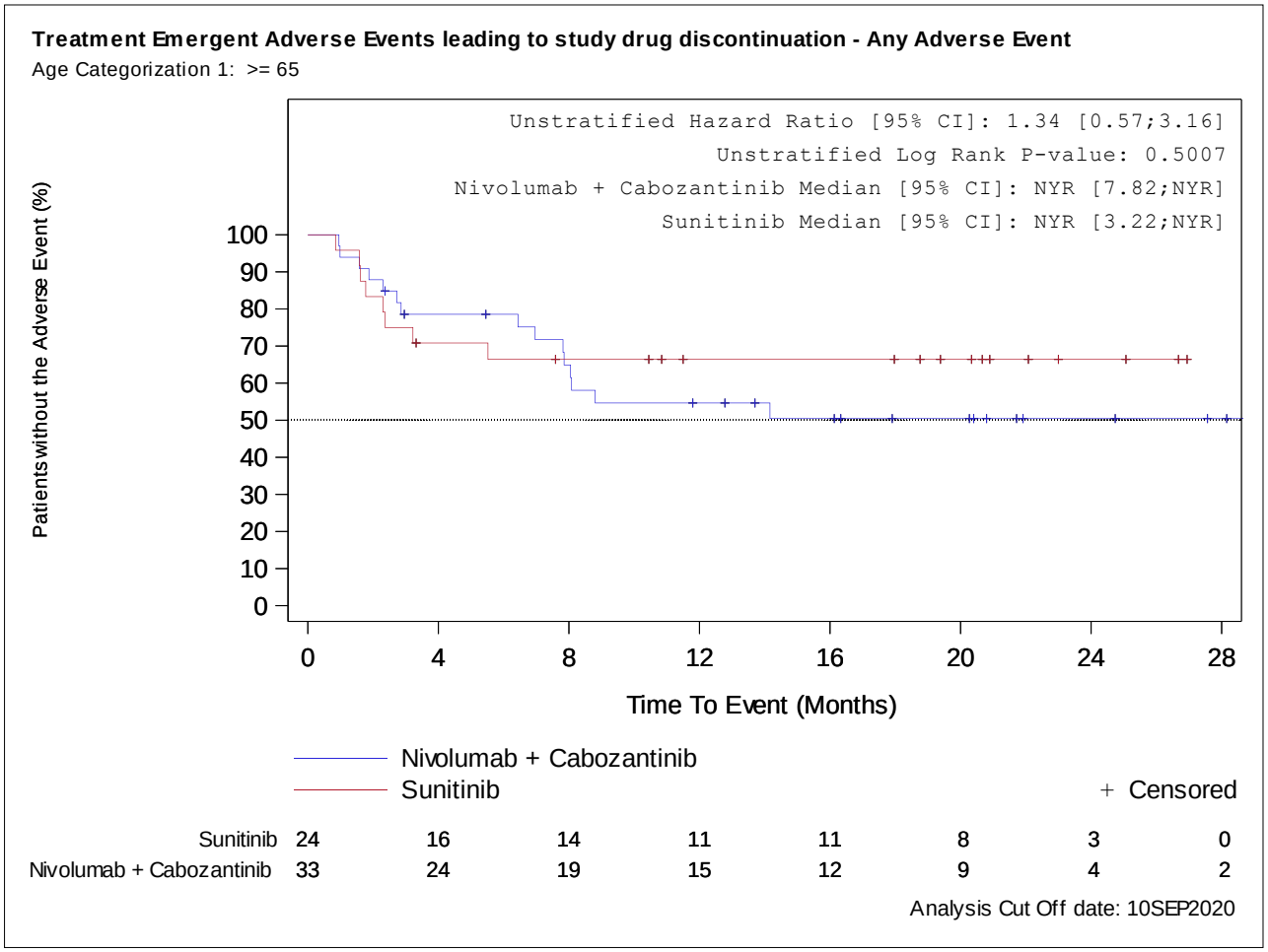

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:50:54

FIGURE 3.7.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



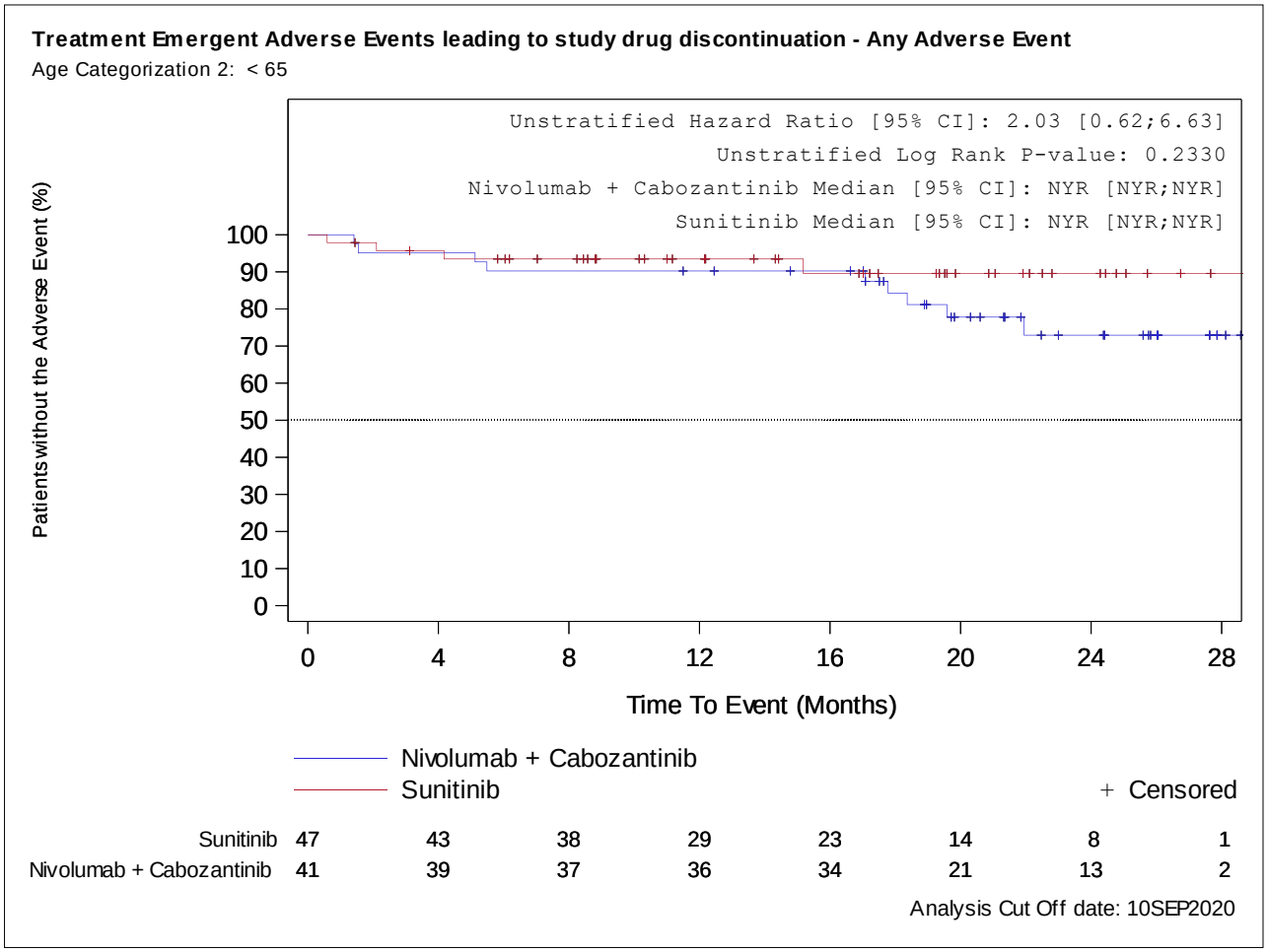

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:50:57

FIGURE 3.7.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



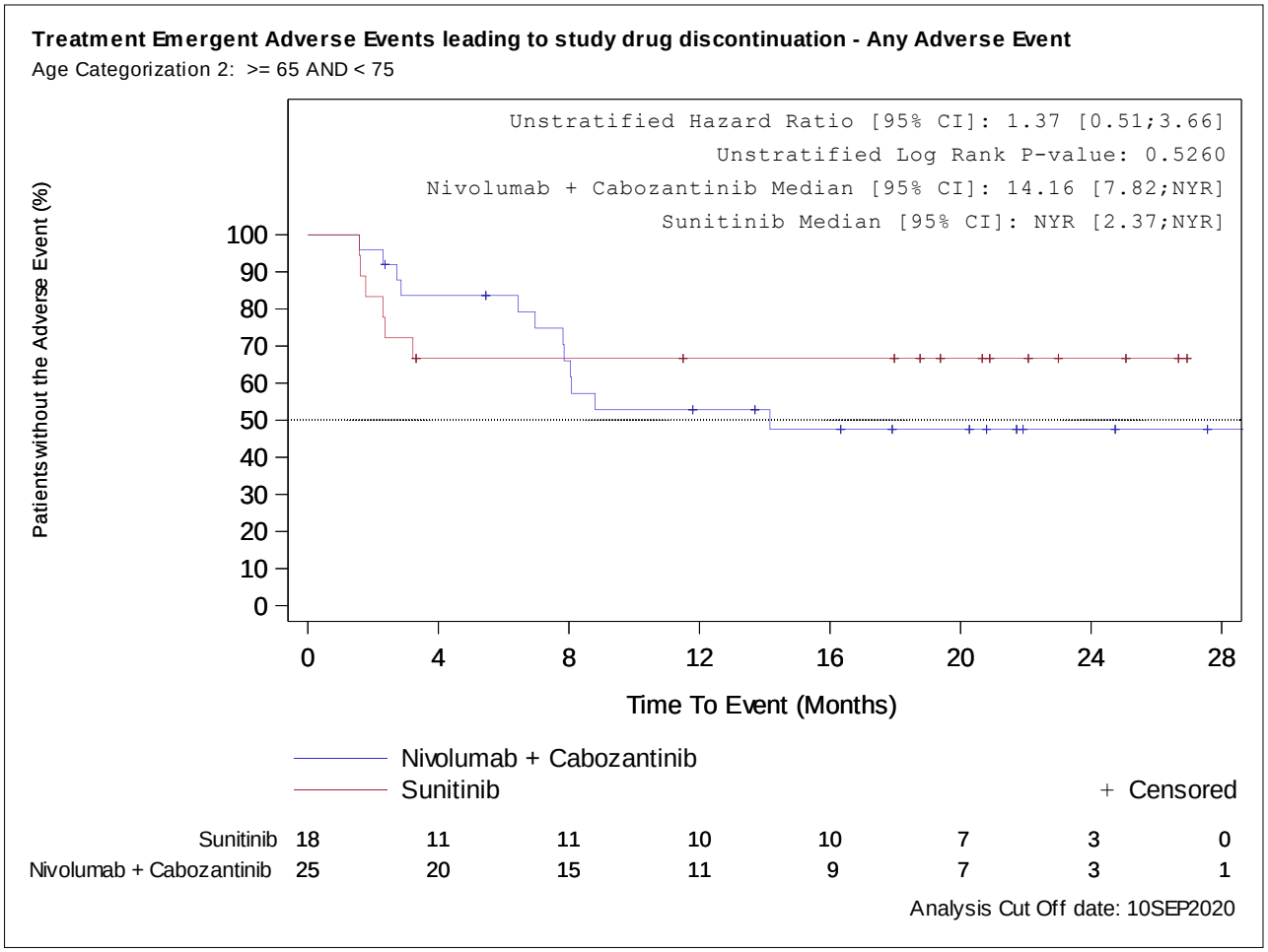

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:51:04

FIGURE 3.7.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



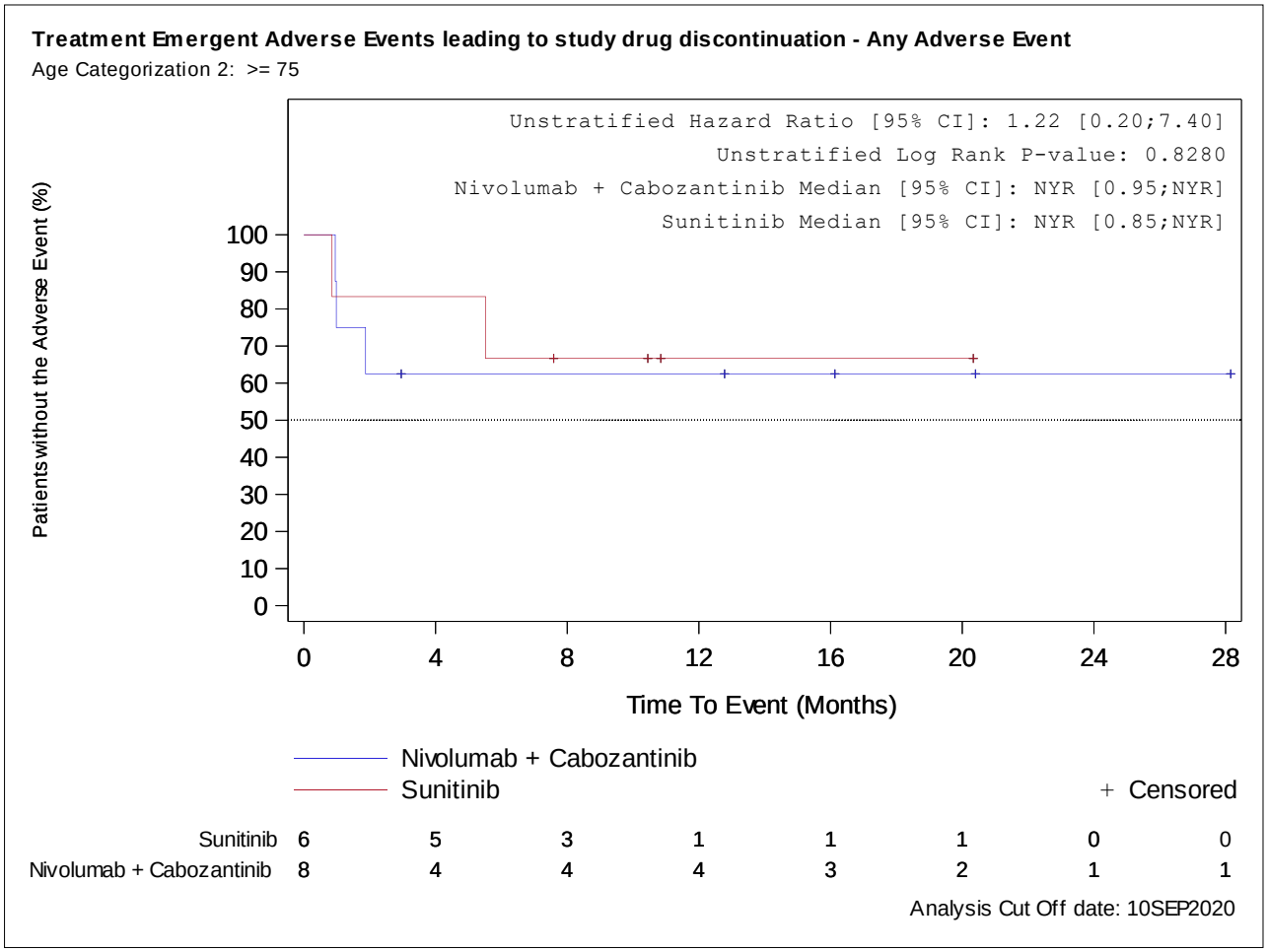

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:51:10

FIGURE 3.7.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



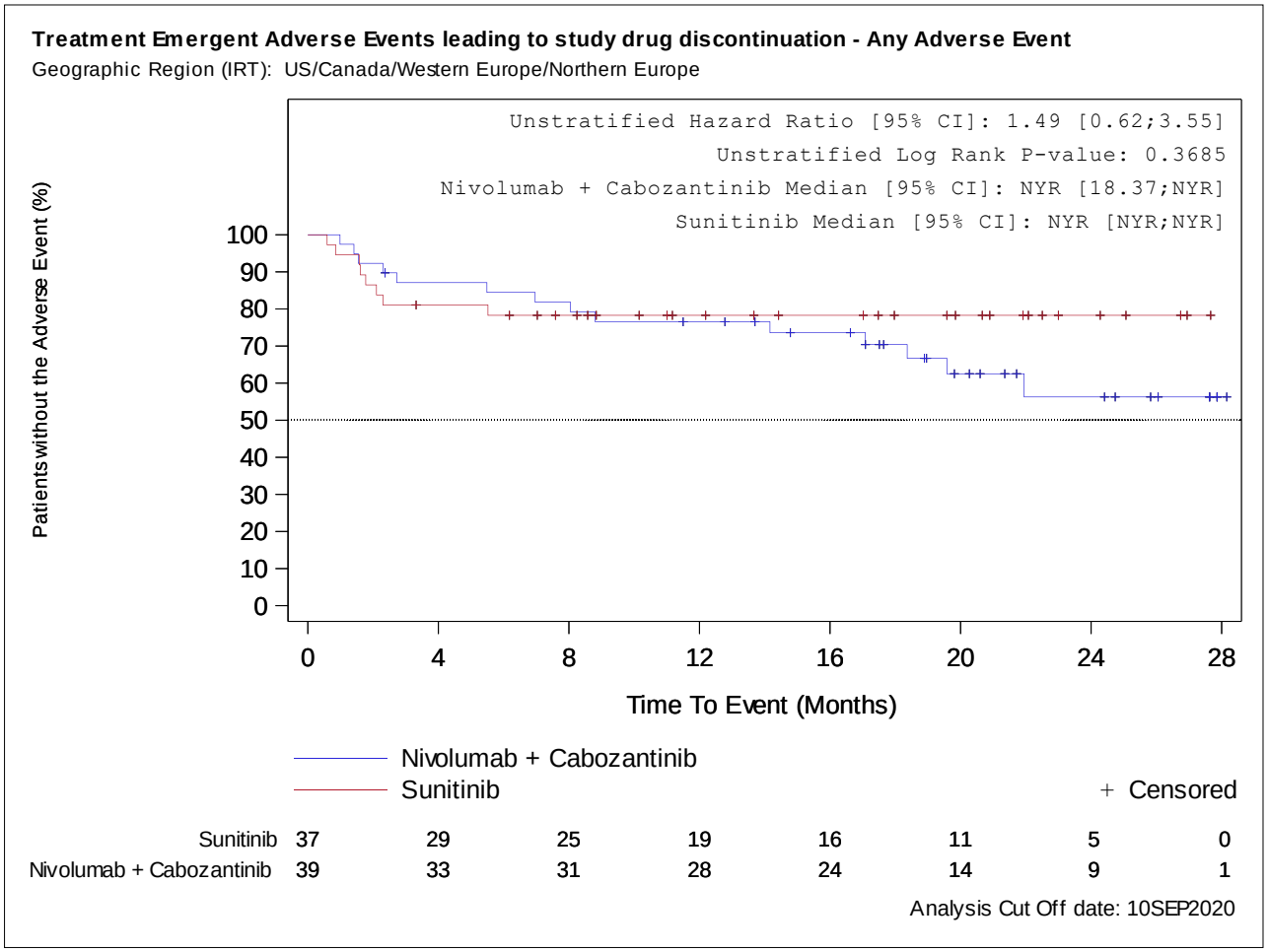

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:51:16

FIGURE 3.7.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



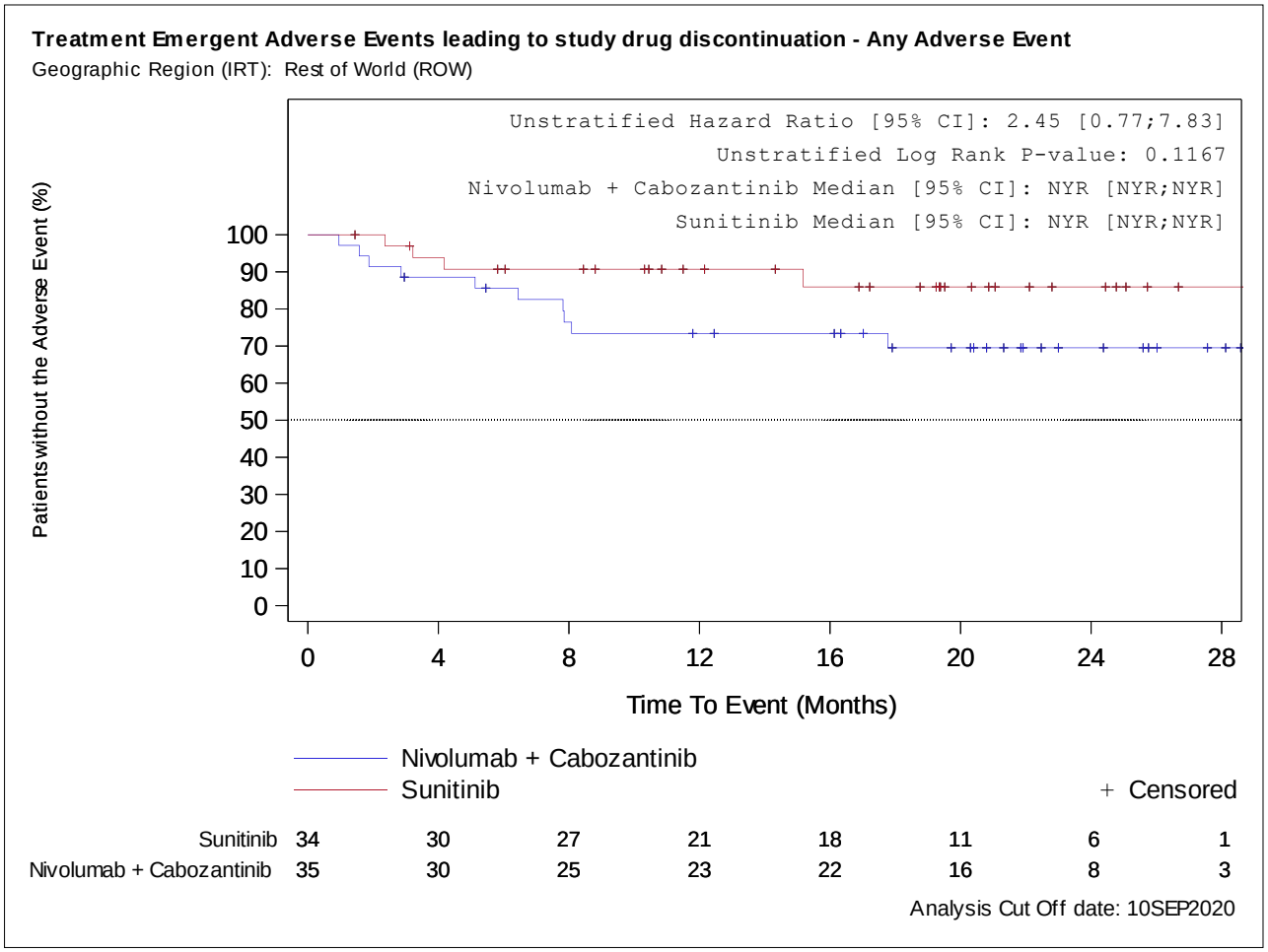

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:51:23

FIGURE 3.7.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



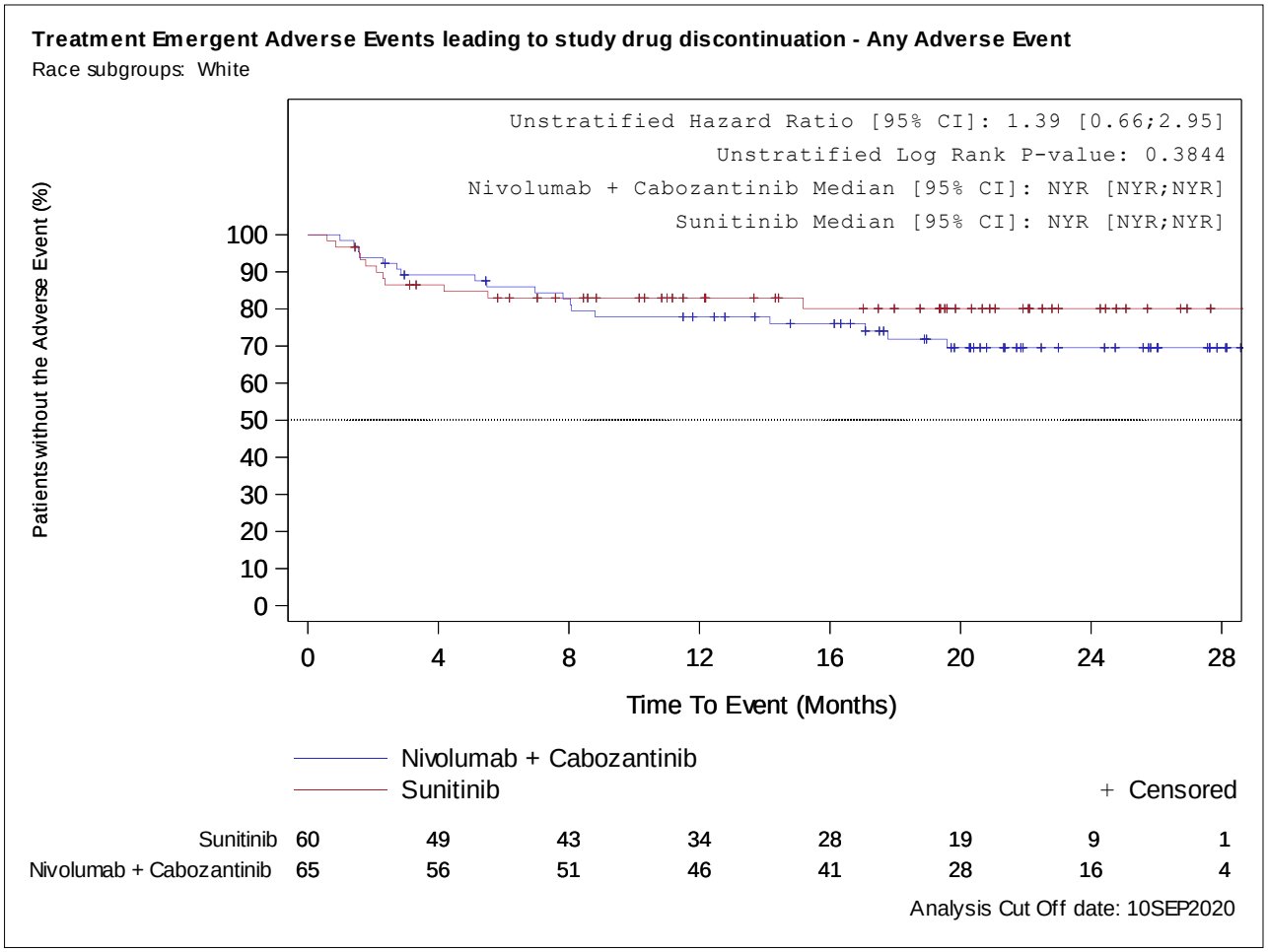

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:51:28

FIGURE 3.7.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



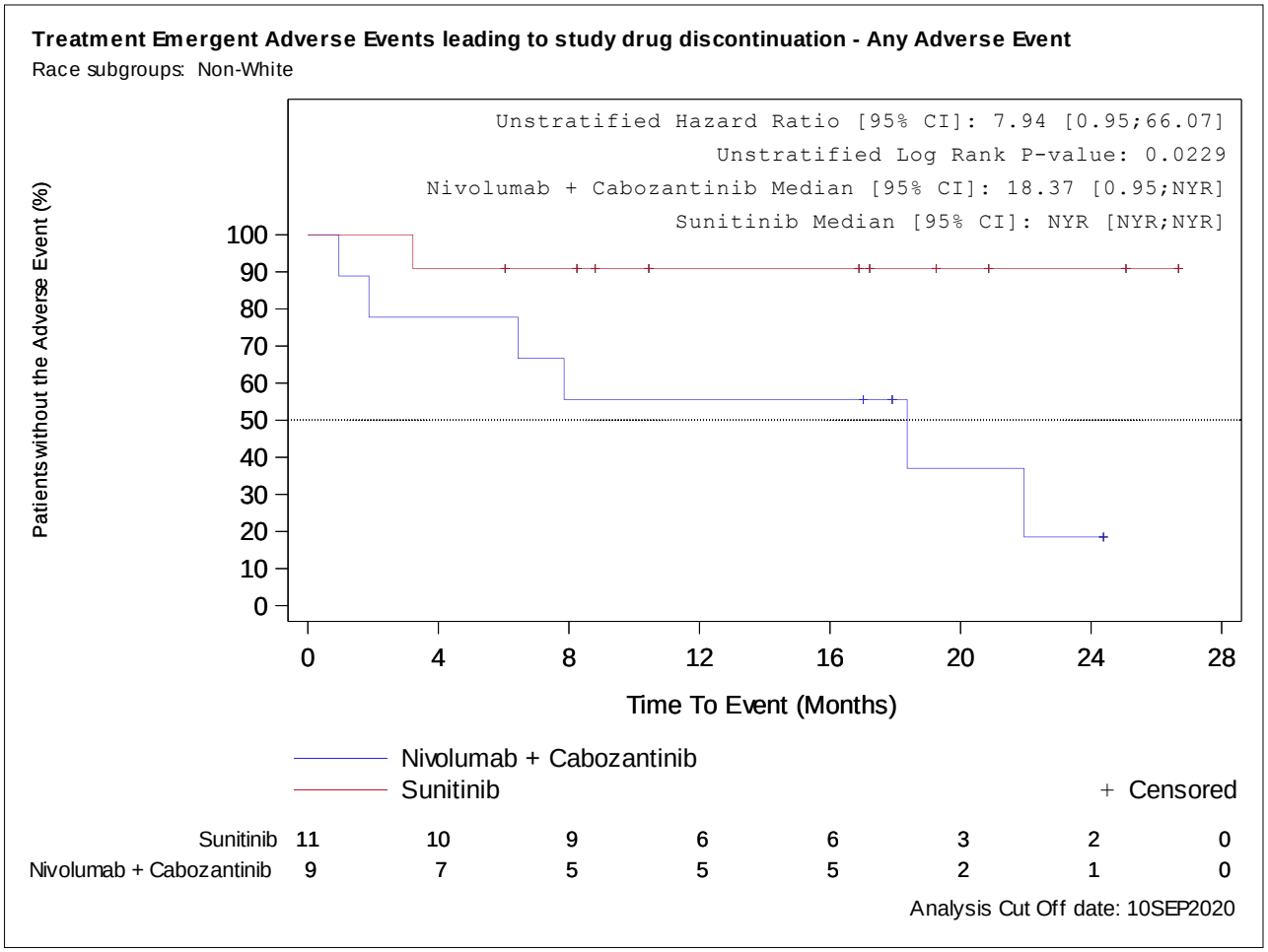

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:51:35

FIGURE 3.7.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



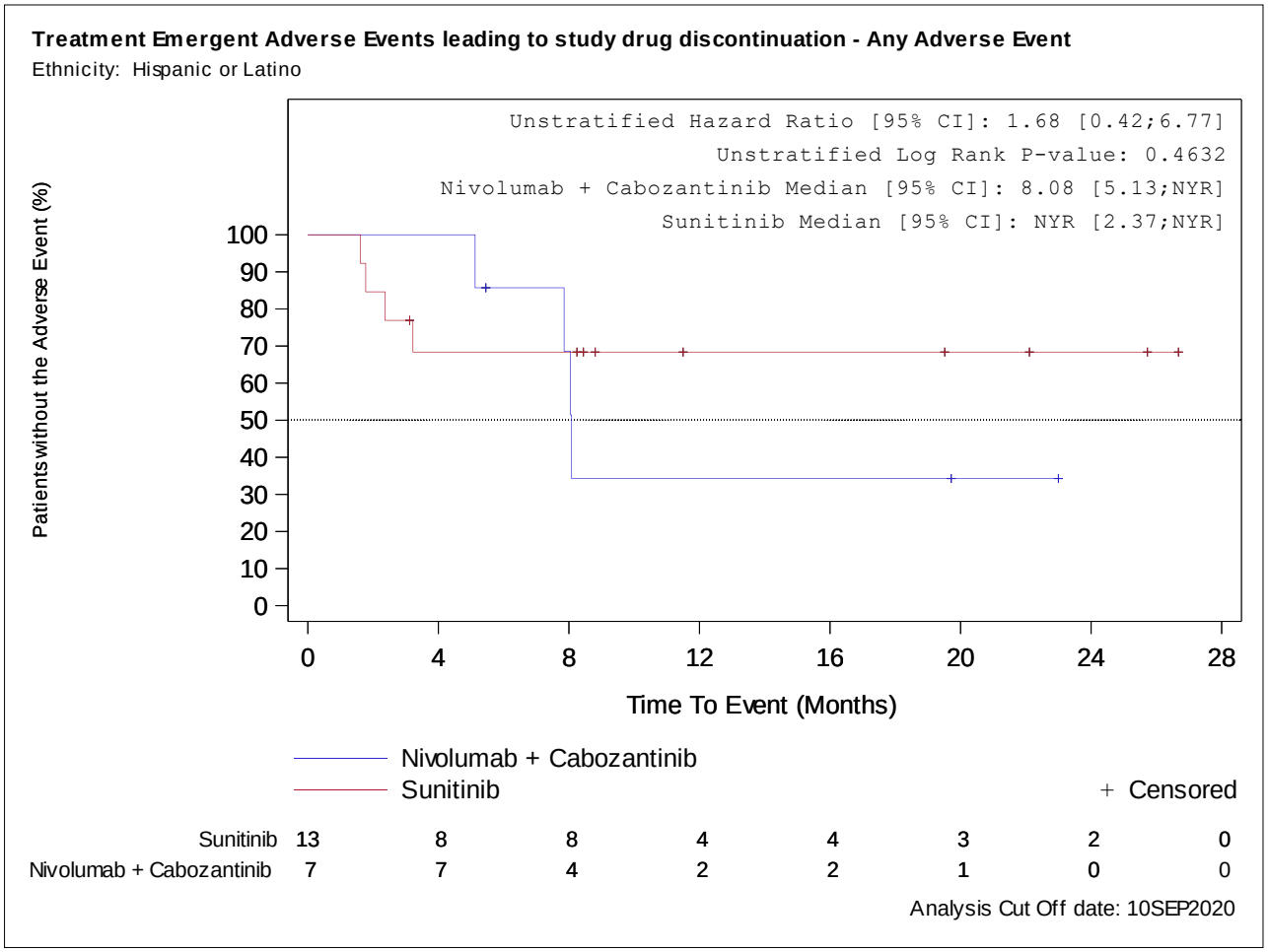

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:51:41

FIGURE 3.7.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



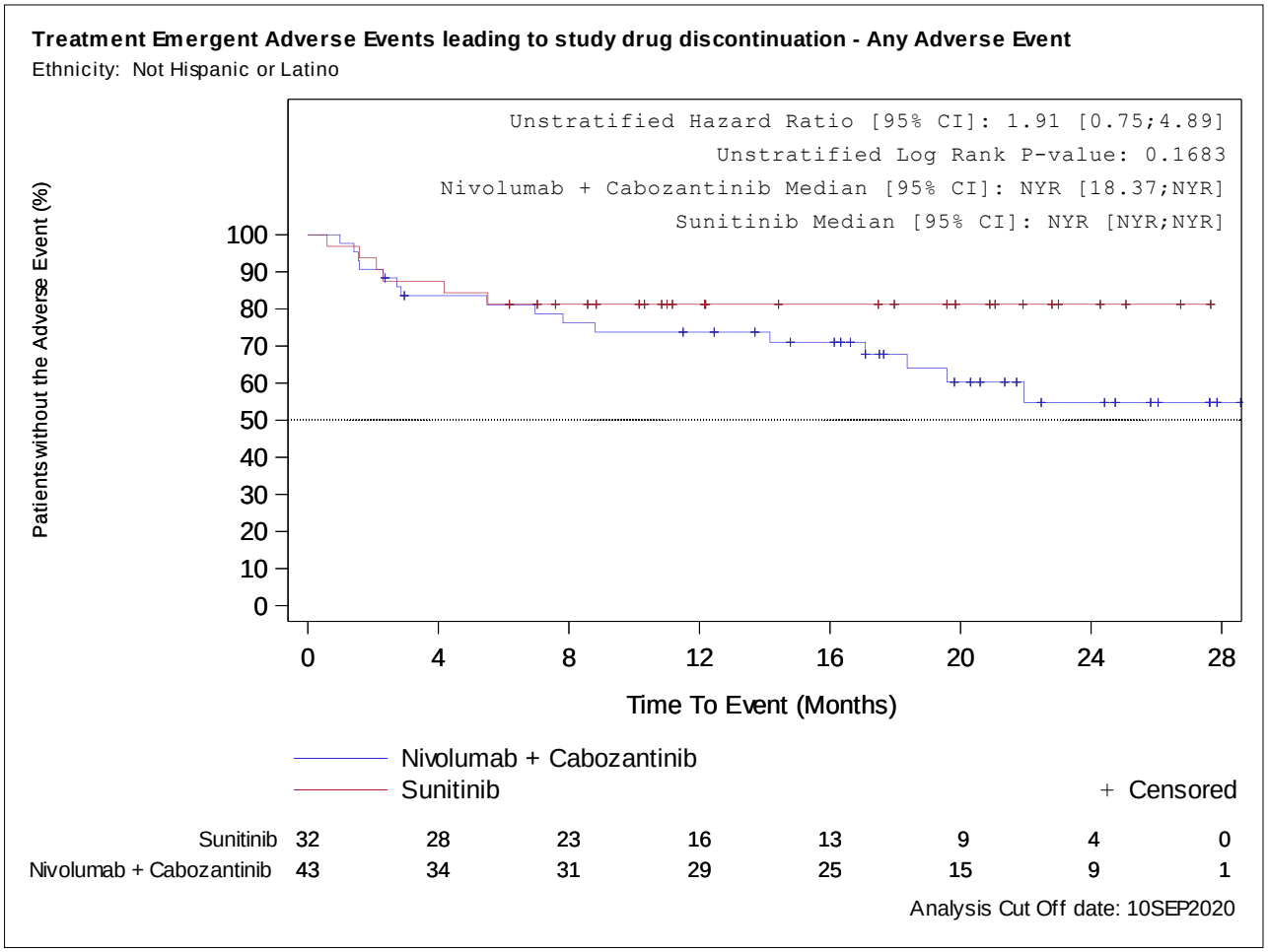

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:51:47

FIGURE 3.7.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



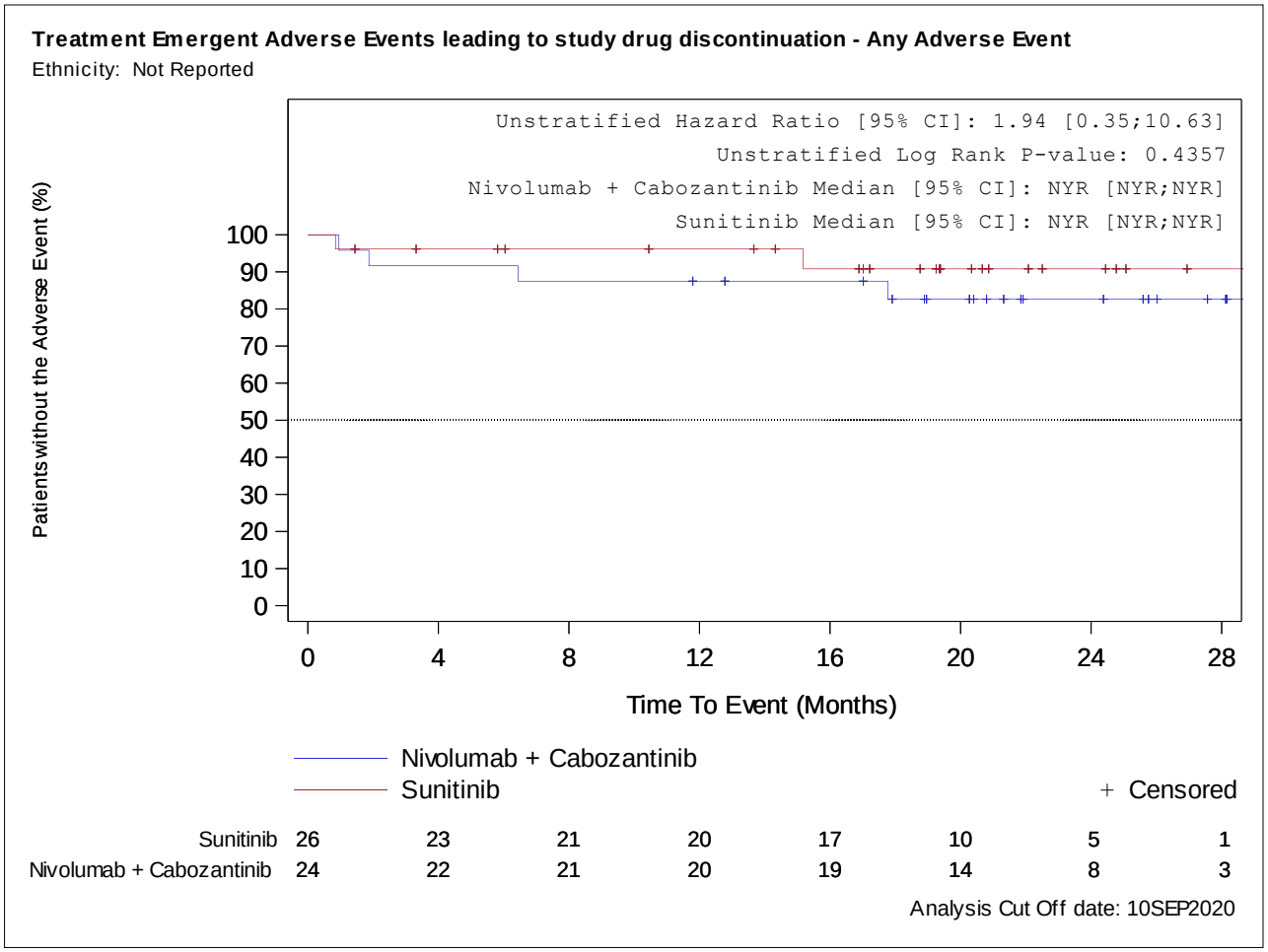

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:51:53

FIGURE 3.7.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:52:00

FIGURE 3.7.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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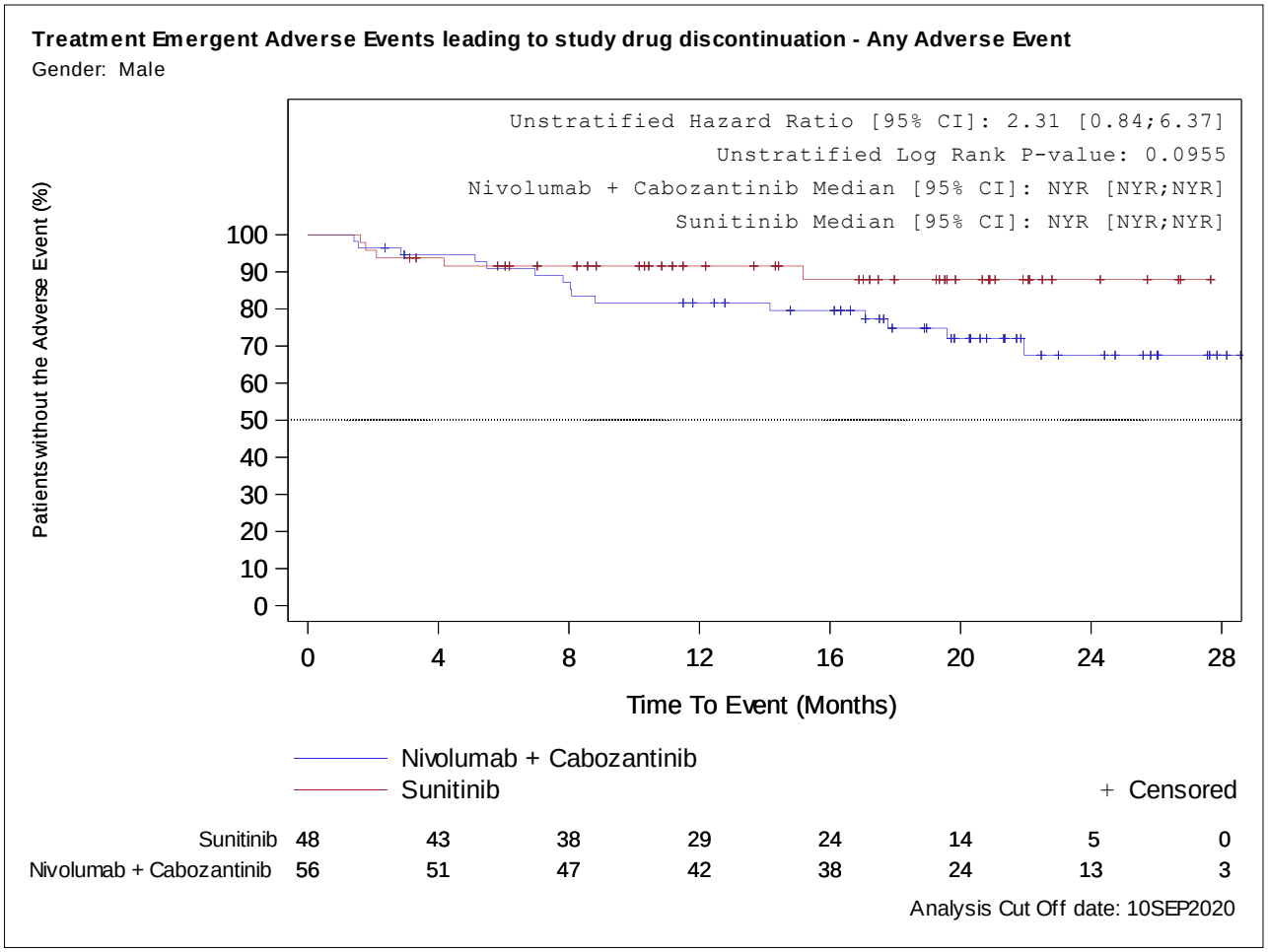
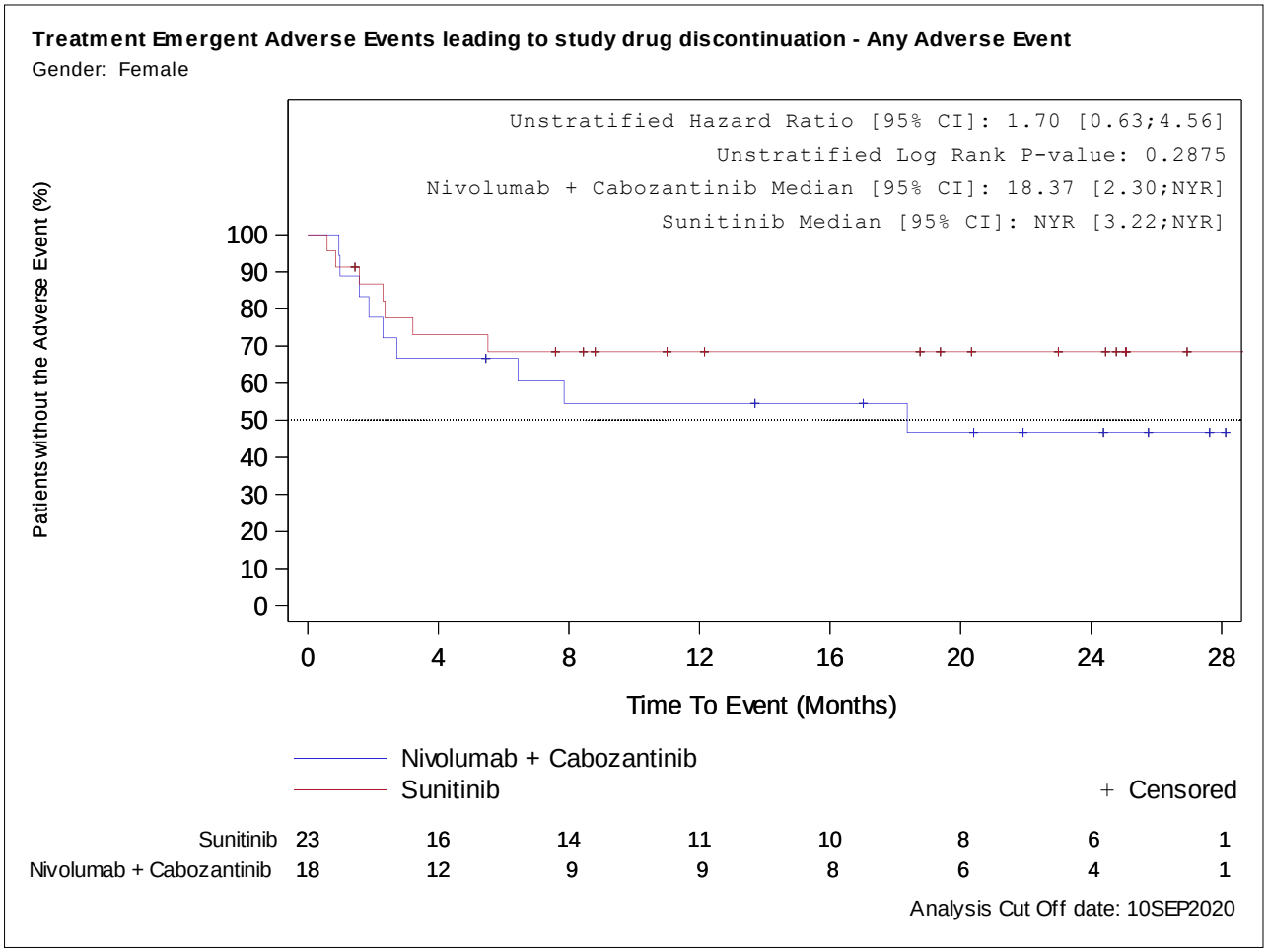
FIGURE 3.7.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



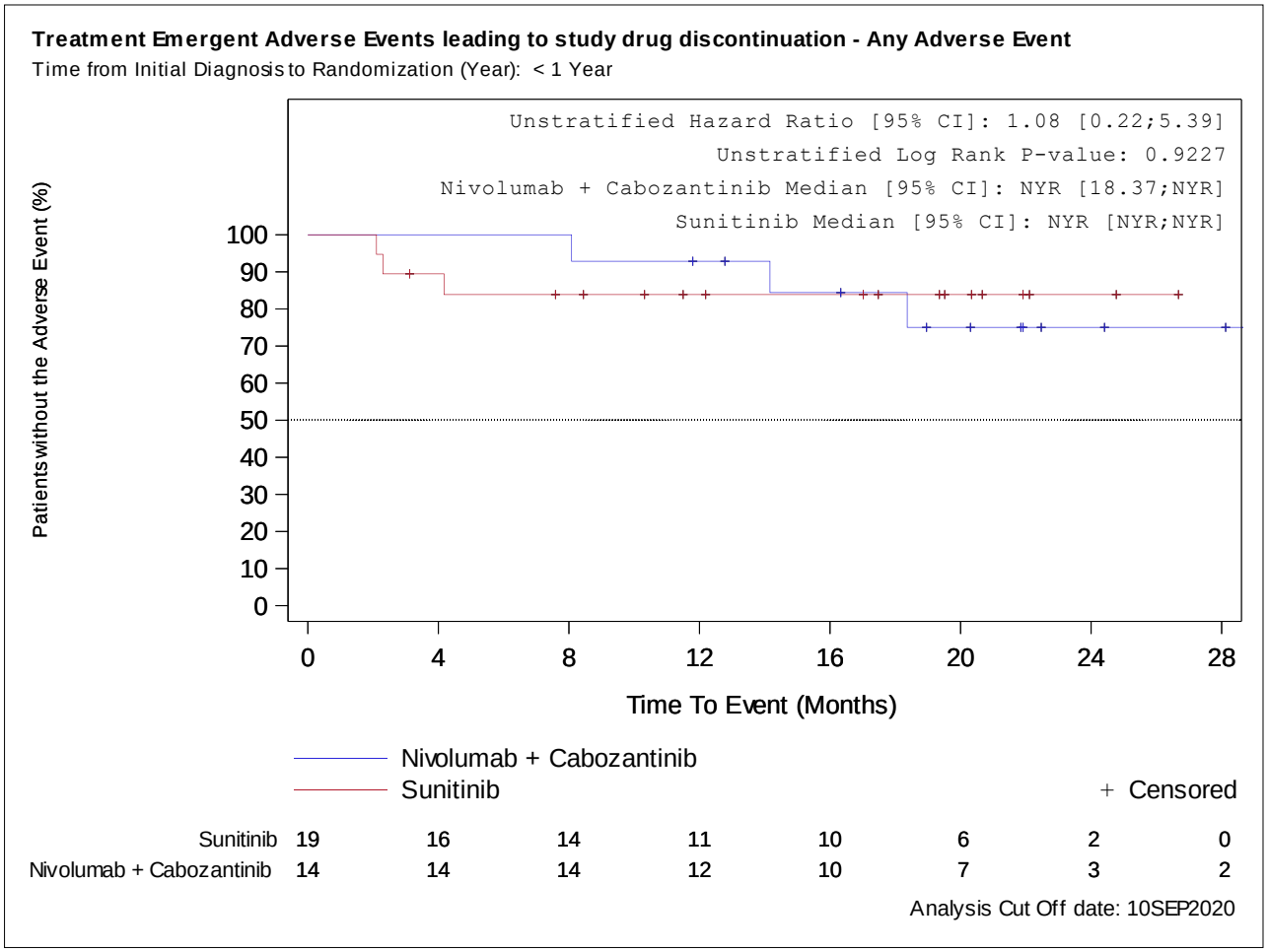

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:52:13

FIGURE 3.7.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



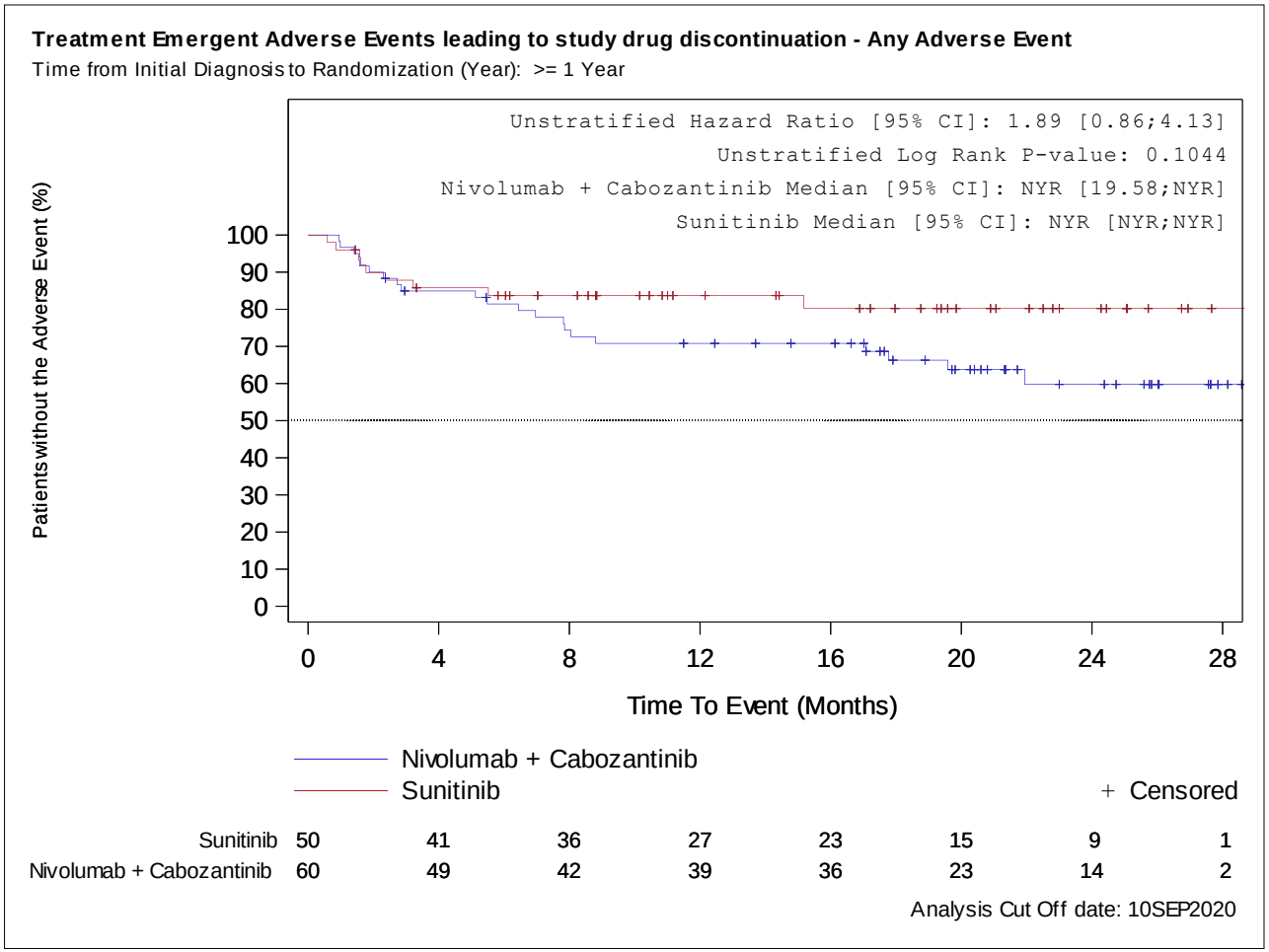

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:52:20

FIGURE 3.7.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



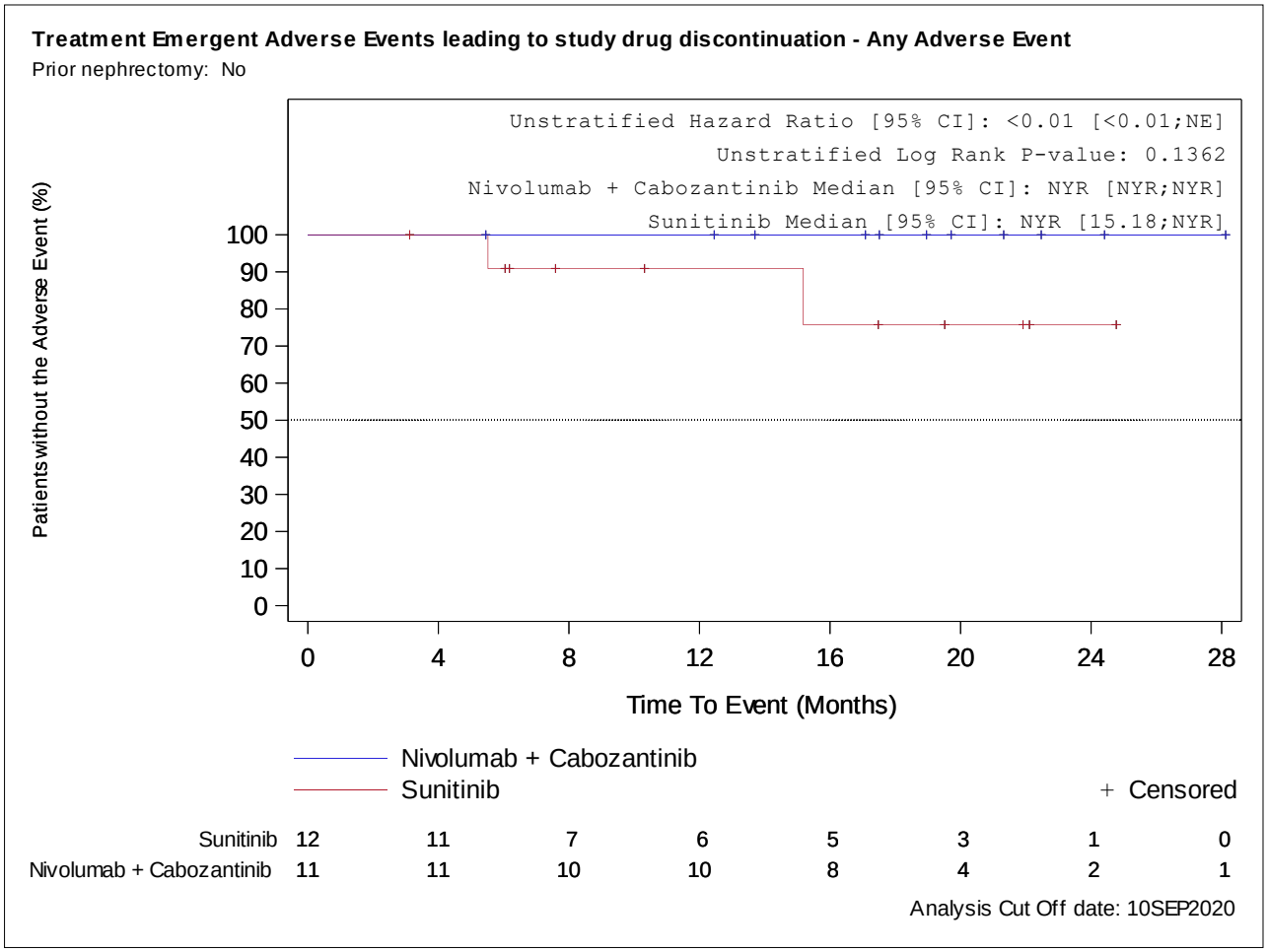

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:52:38

FIGURE 3.7.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:52:44

FIGURE 3.7.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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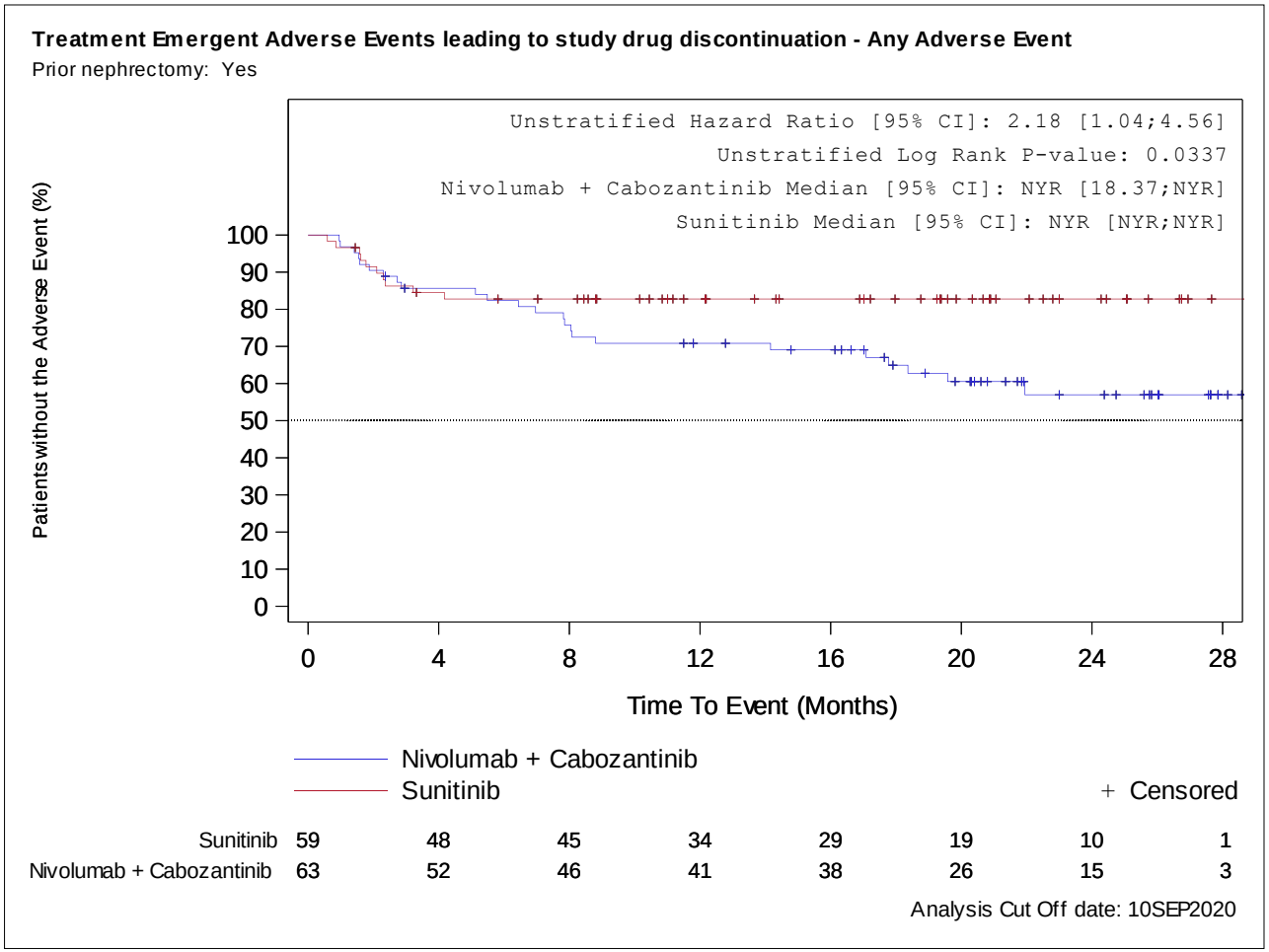
FIGURE 3.7.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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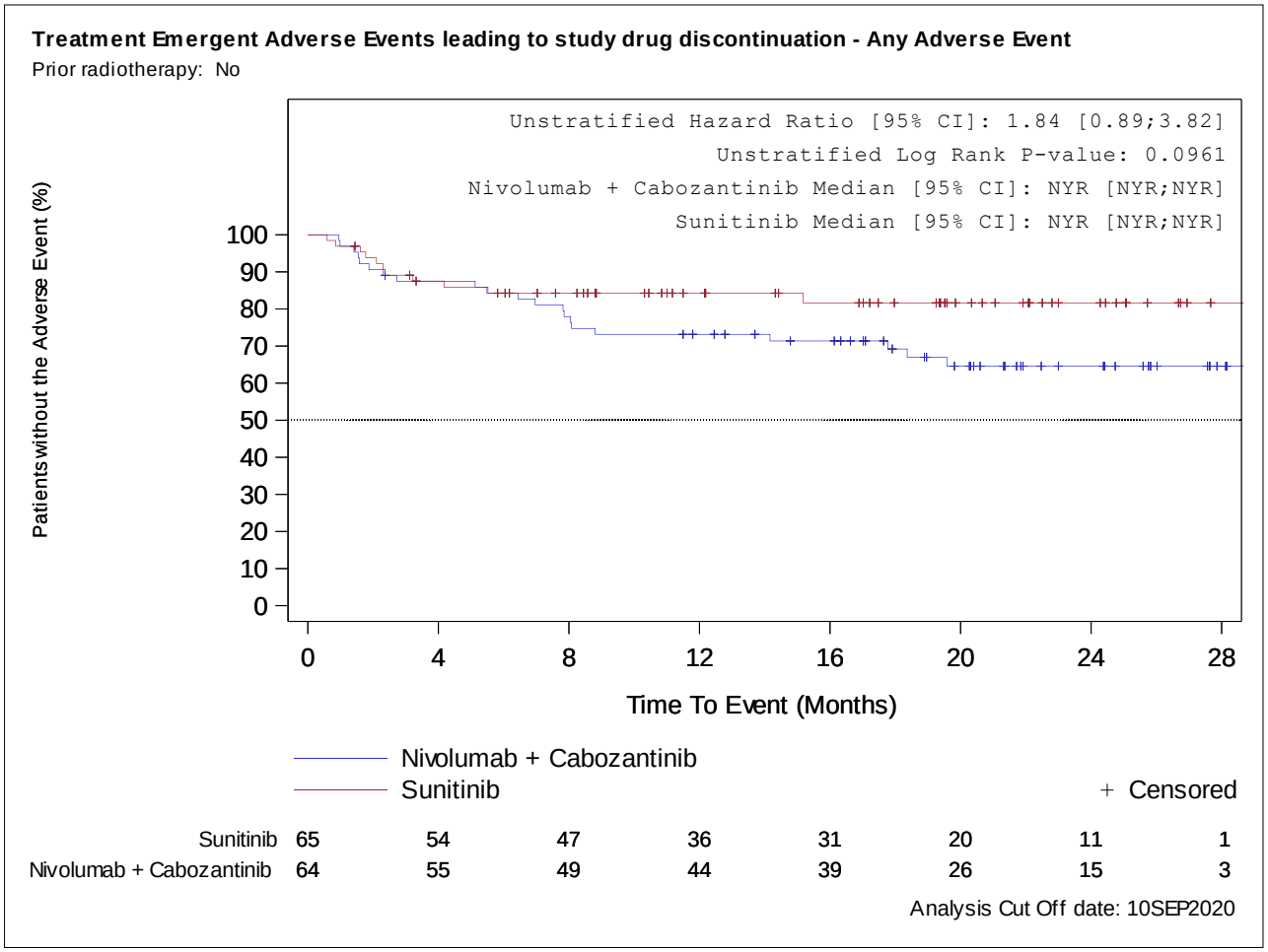
FIGURE 3.7.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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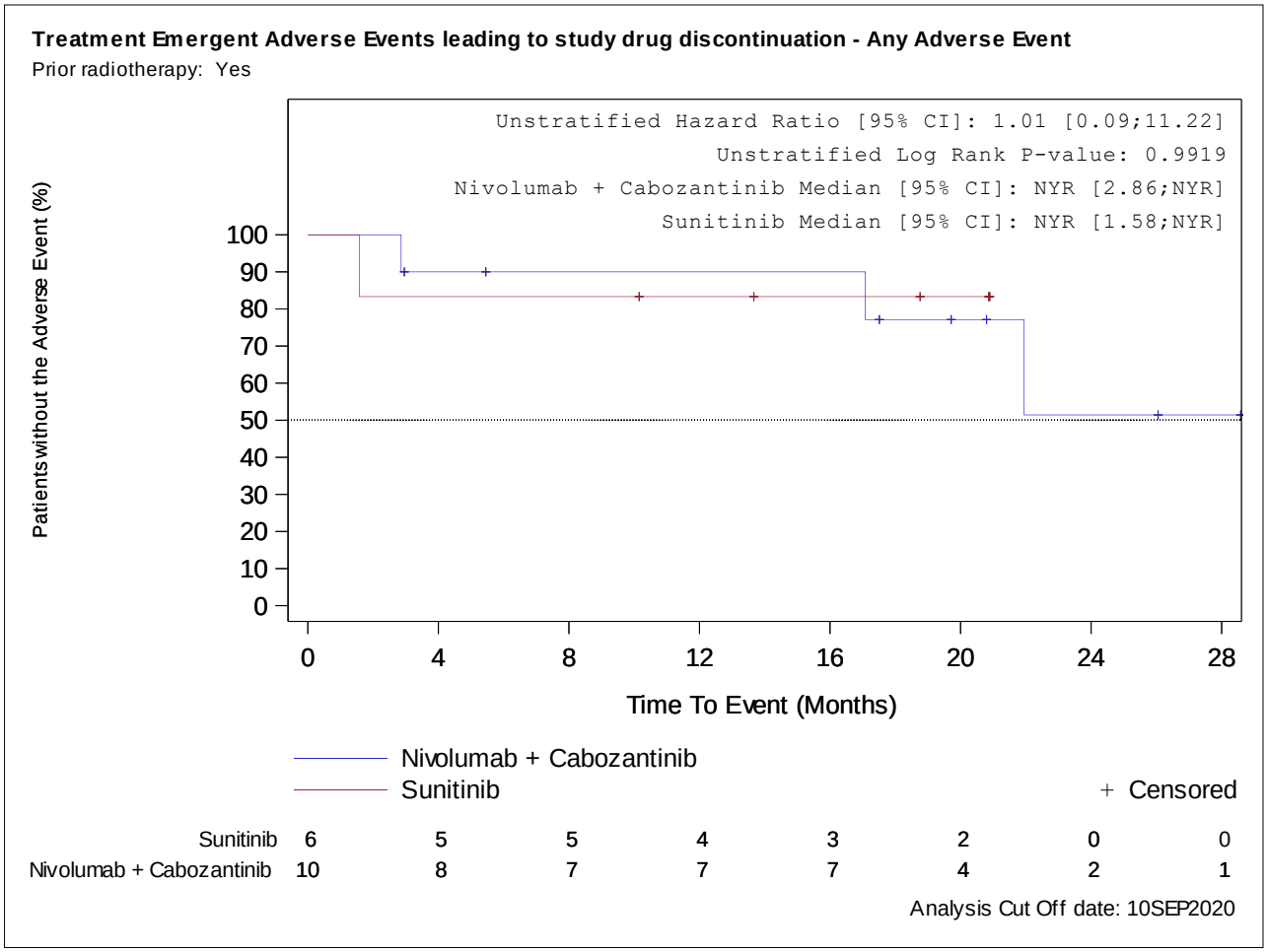
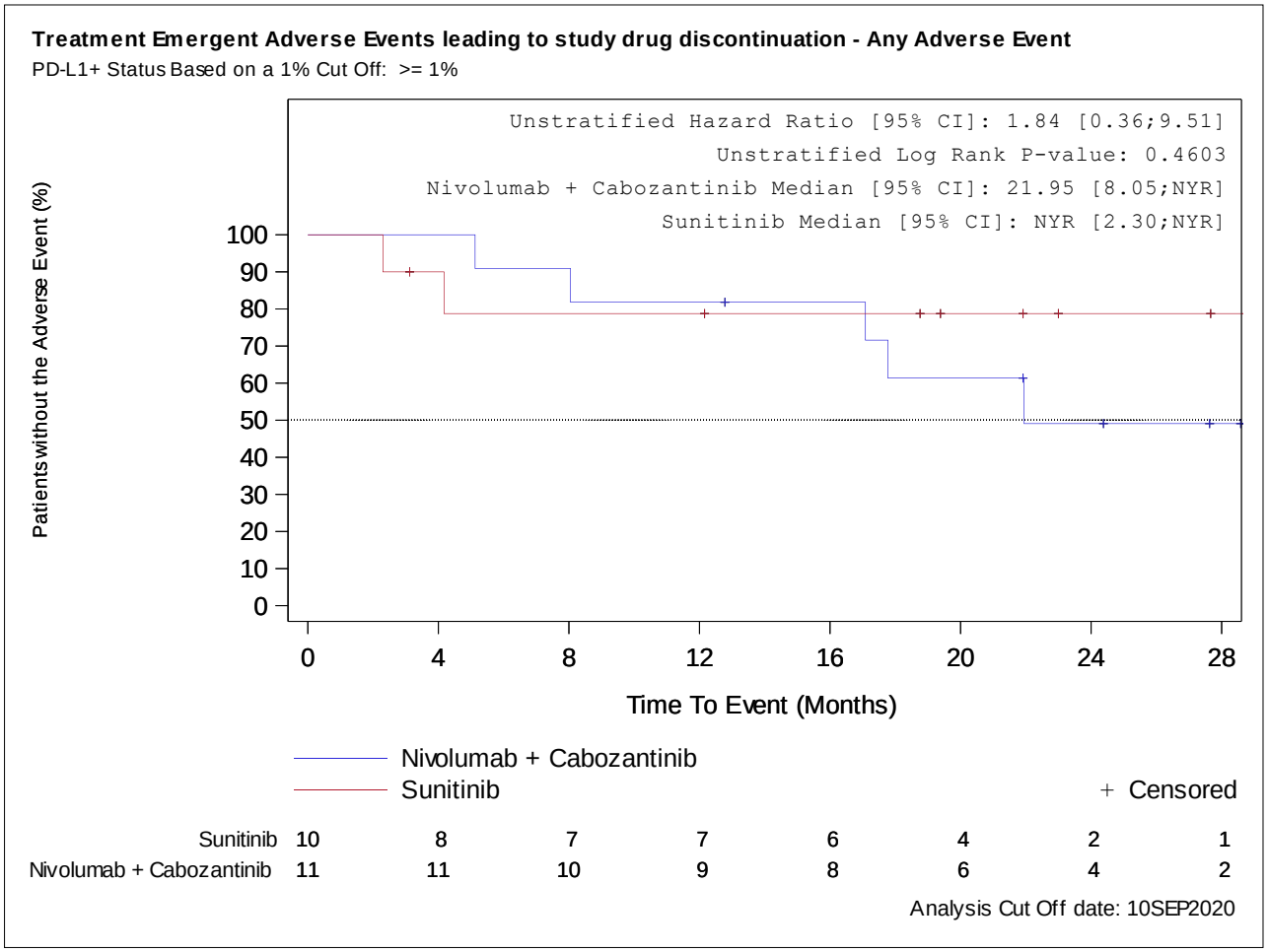
FIGURE 3.7.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



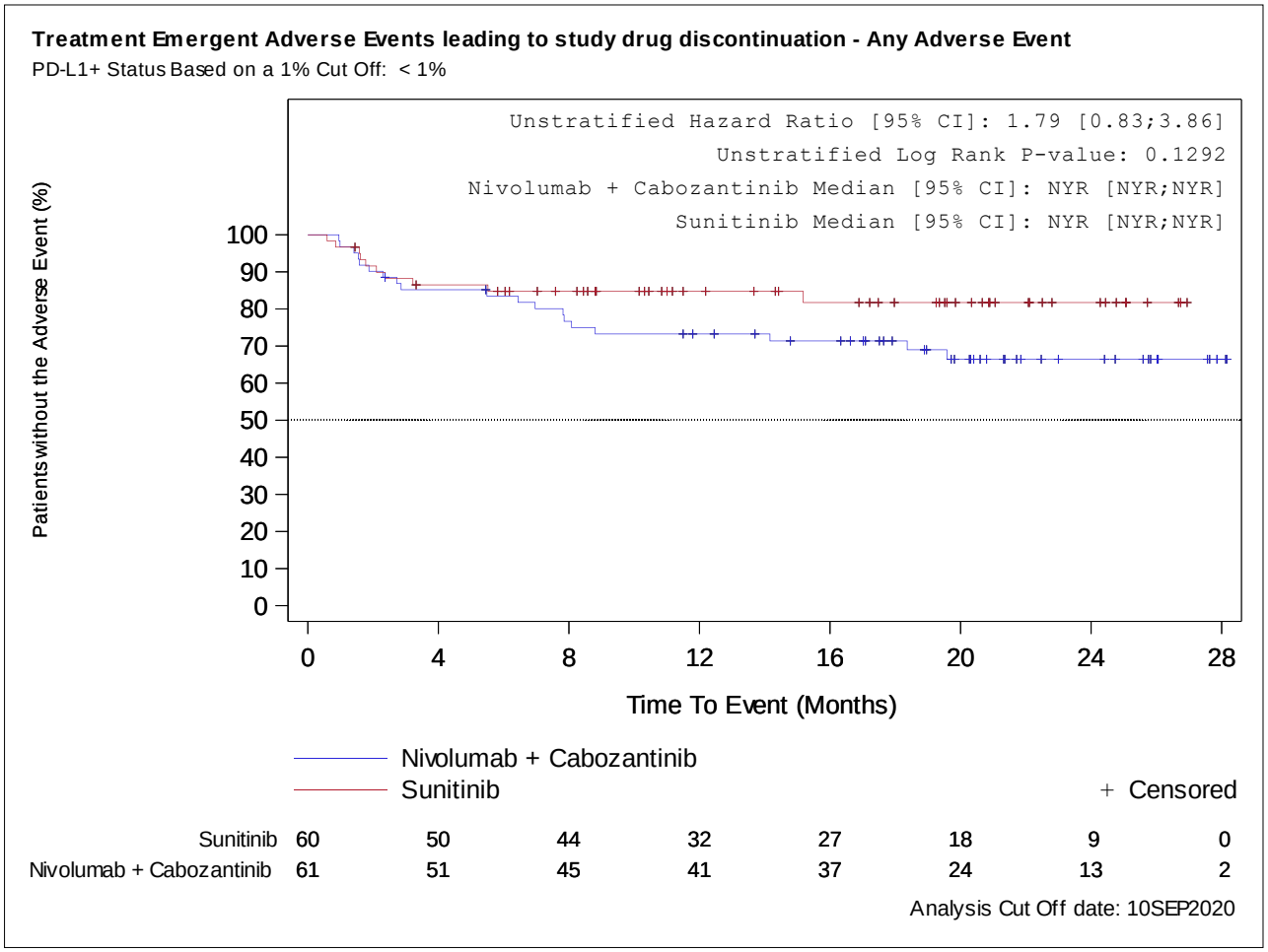

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:54:04

FIGURE 3.7.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



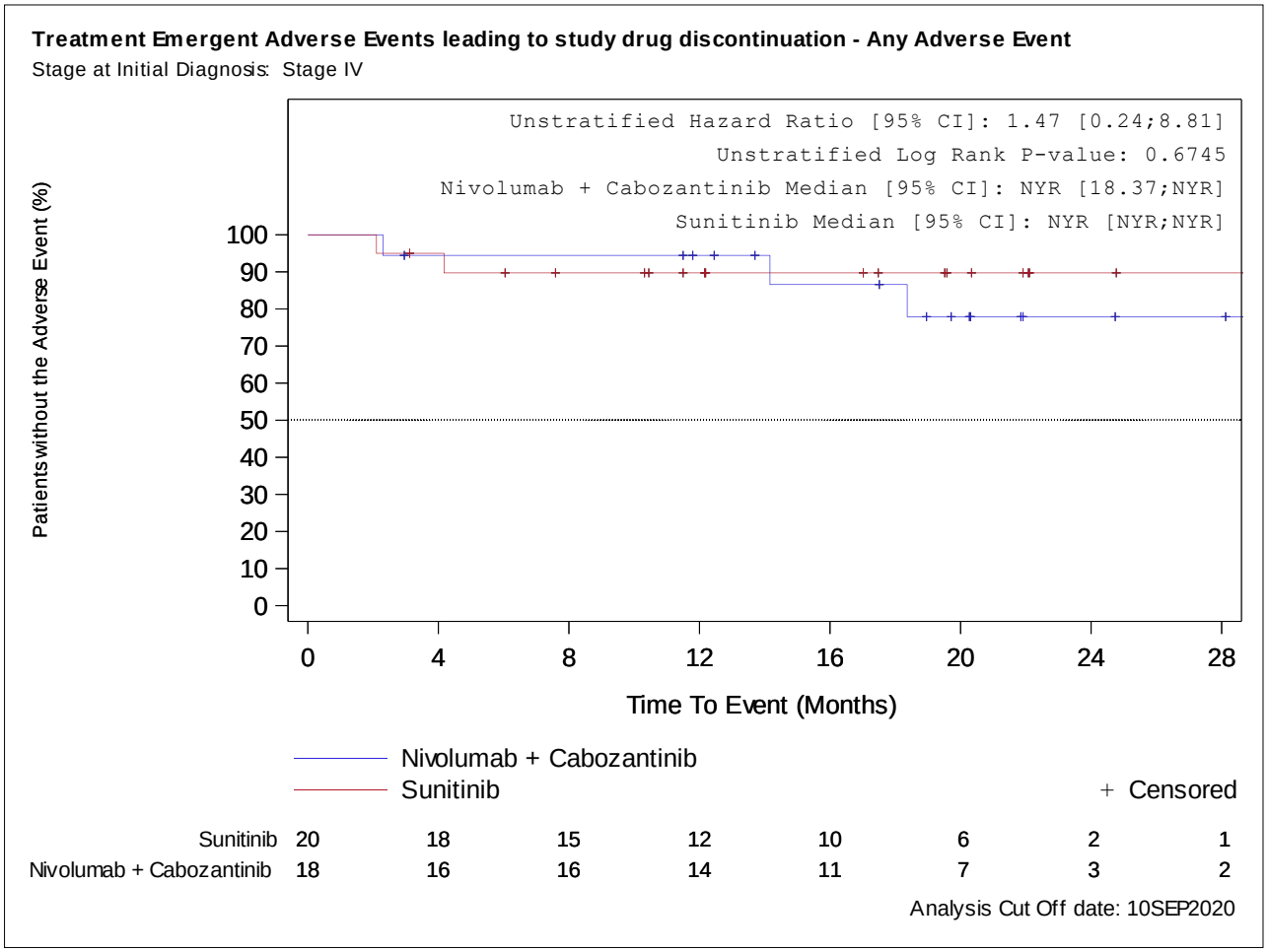

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:54:11

FIGURE 3.7.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:54:18

FIGURE 3.7.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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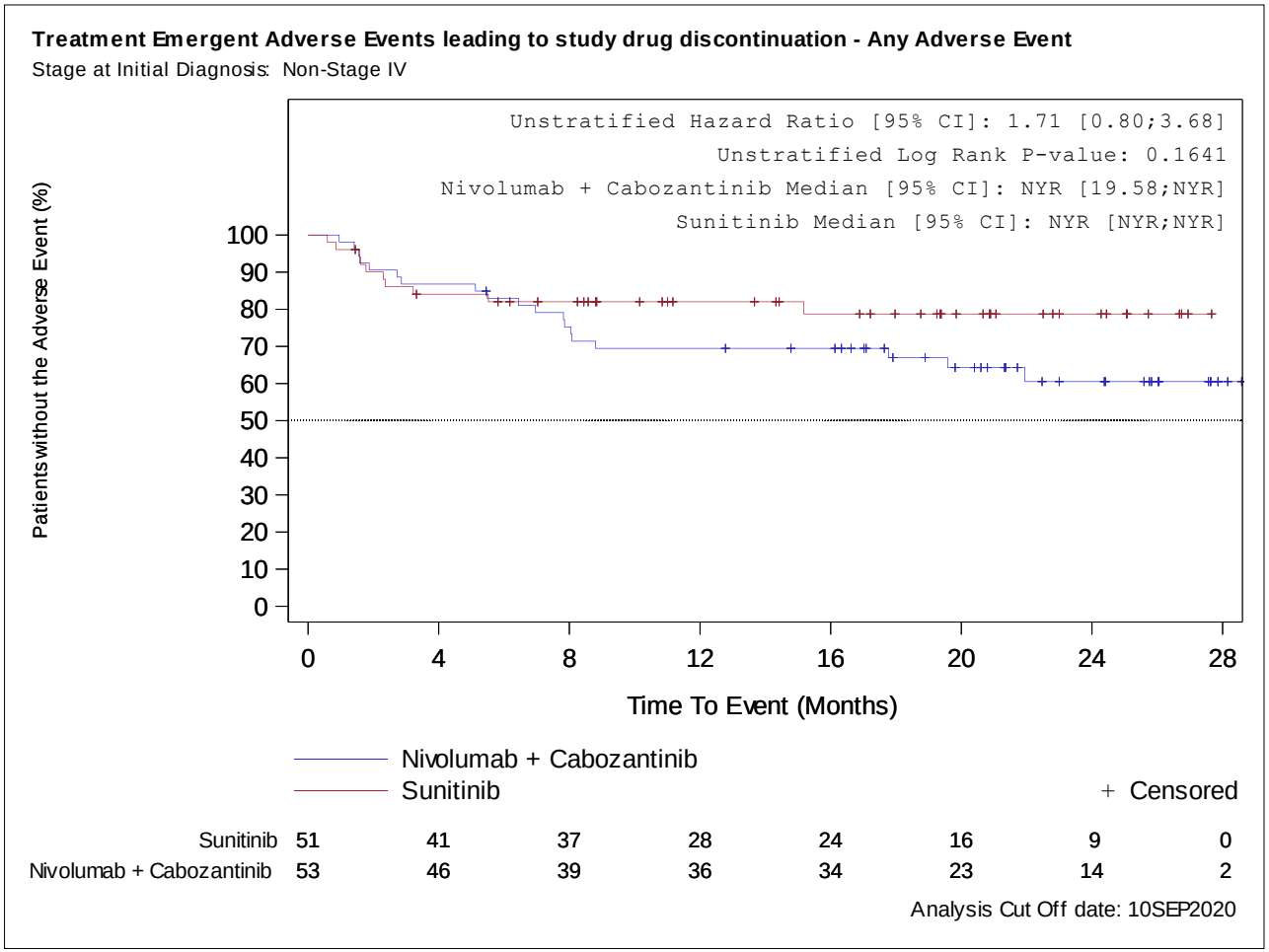
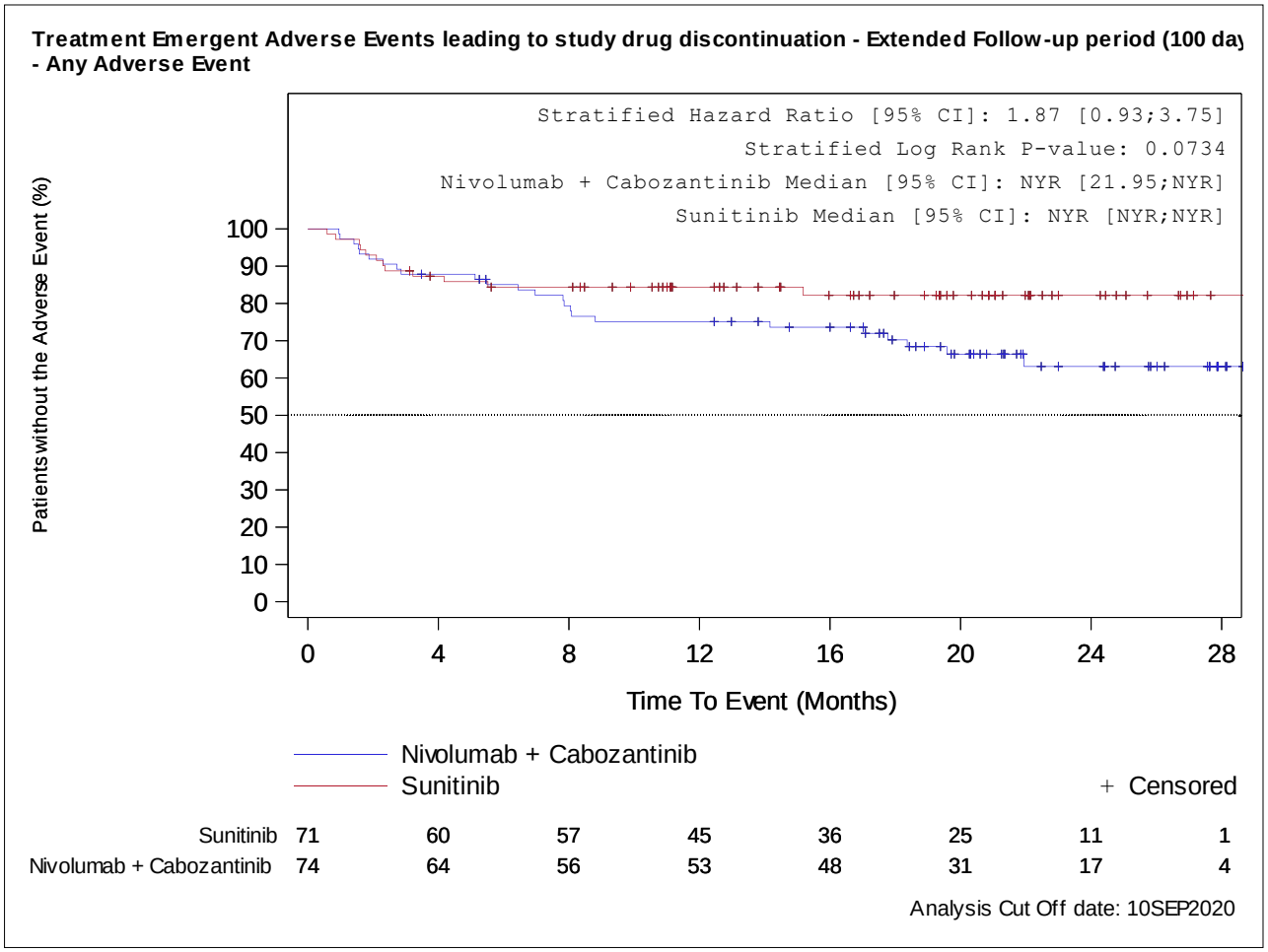
FIGURE 3.7.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



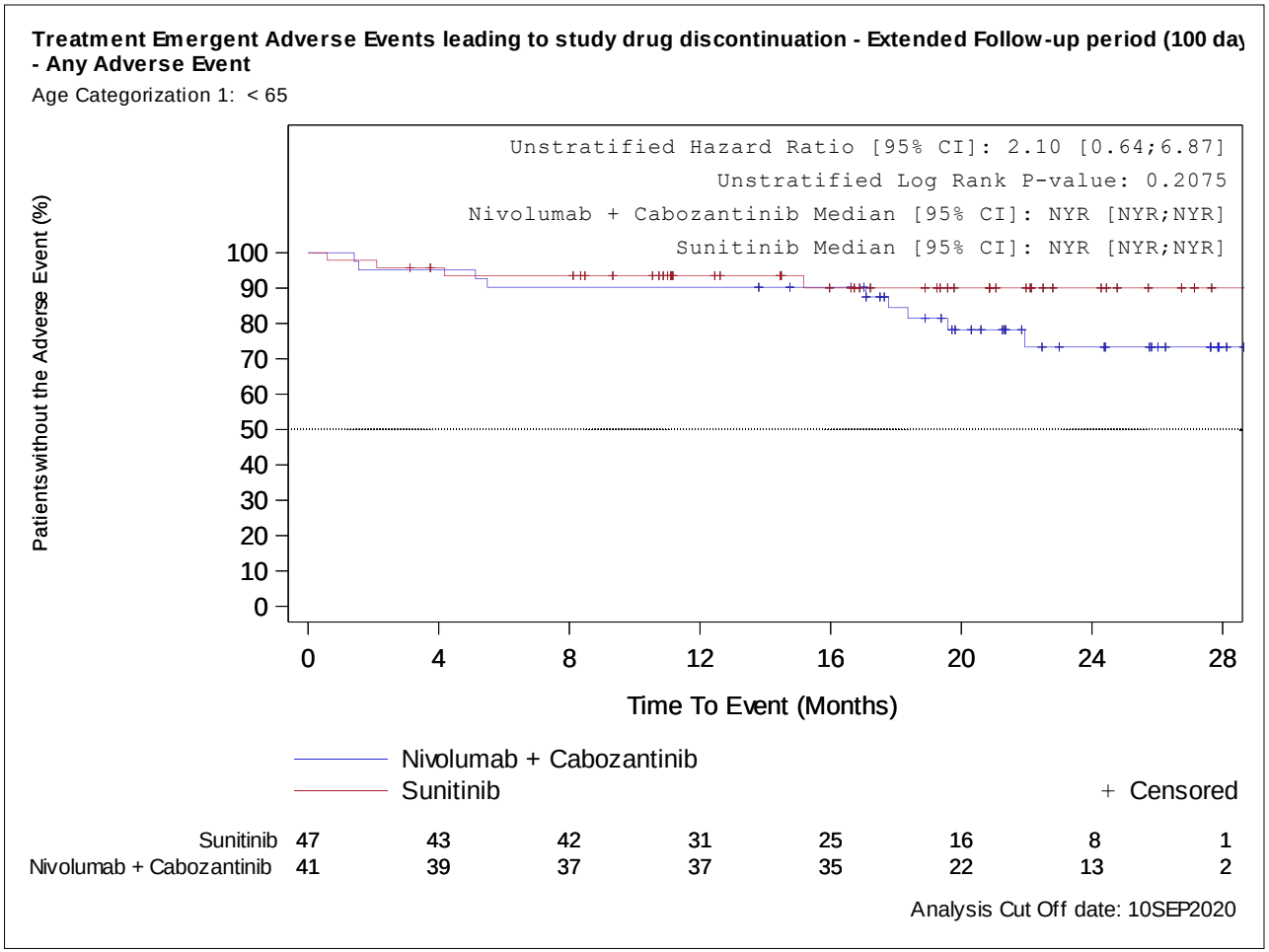

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:54:57

FIGURE 3.8.1: Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



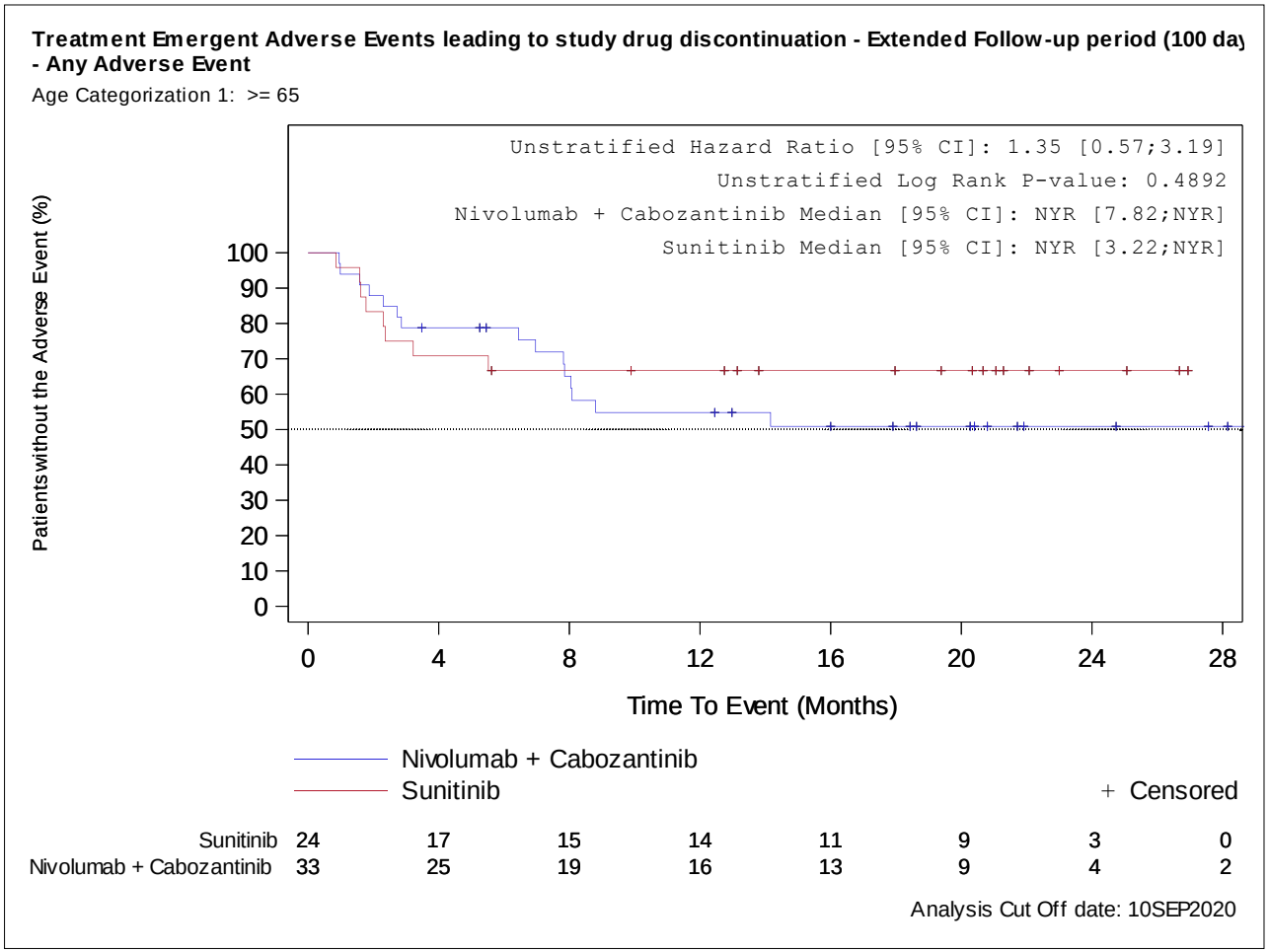

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:58:26

FIGURE 3.8.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



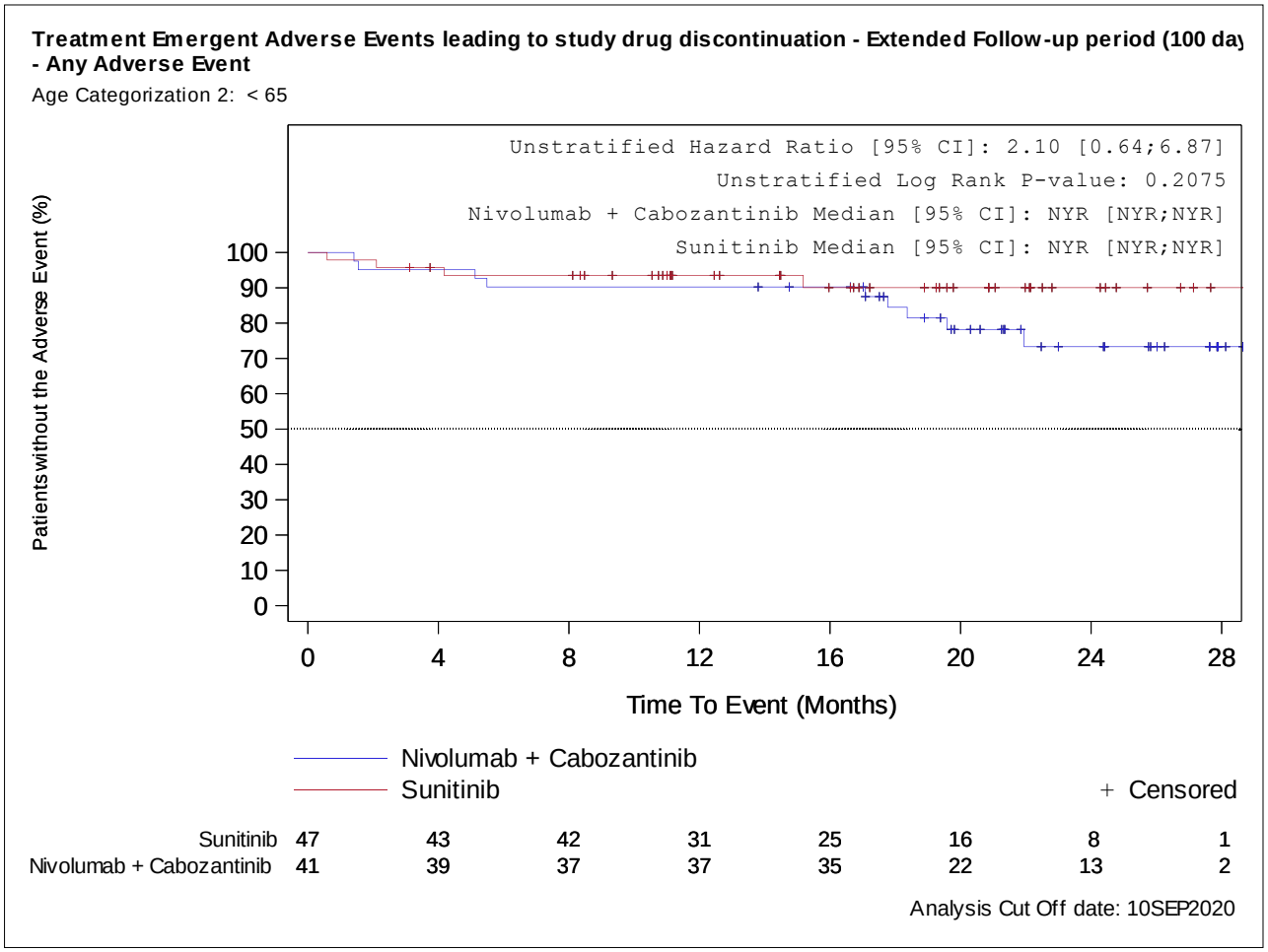

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:58:30

FIGURE 3.8.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:58:36

FIGURE 3.8.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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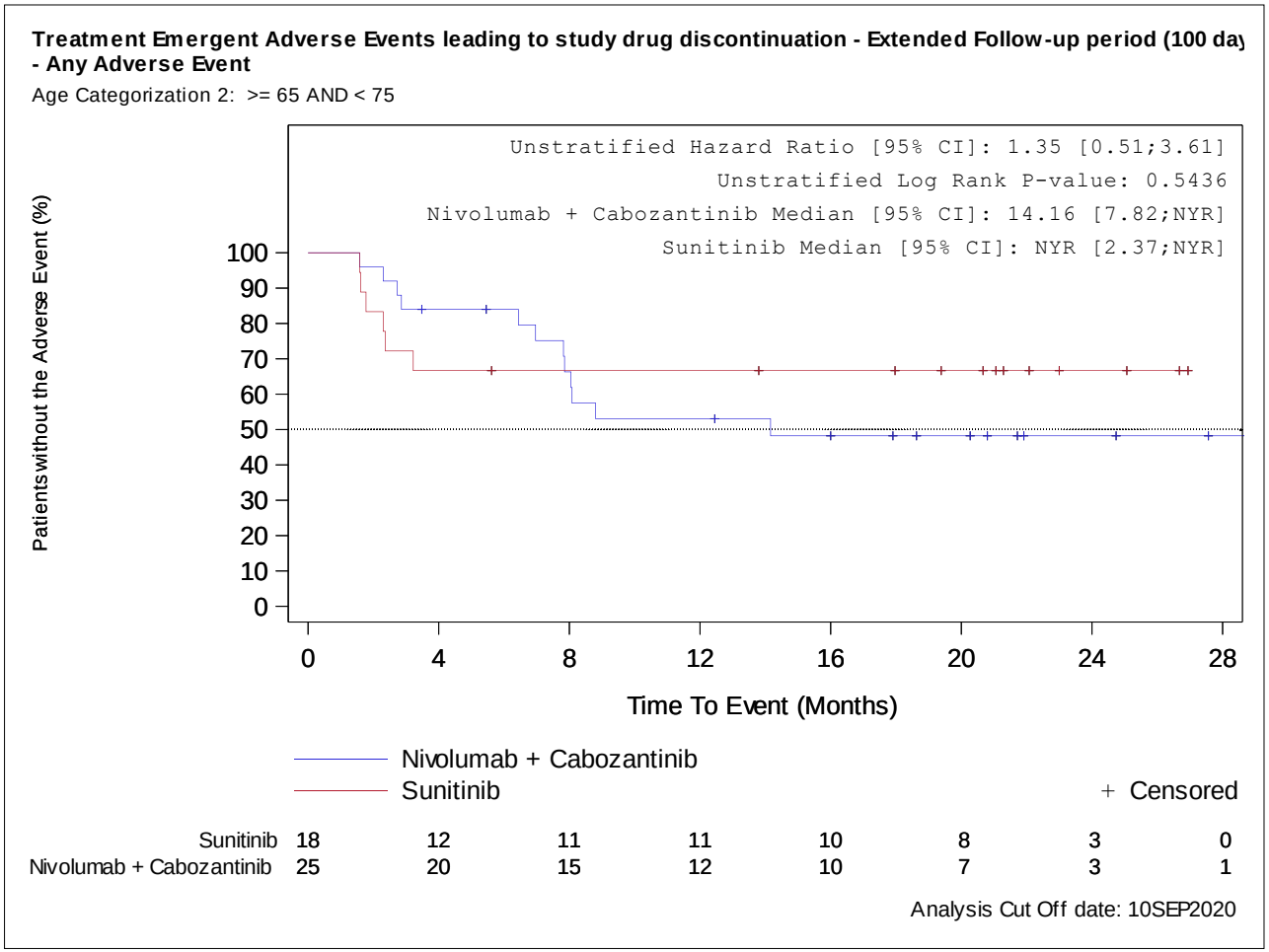
FIGURE 3.8.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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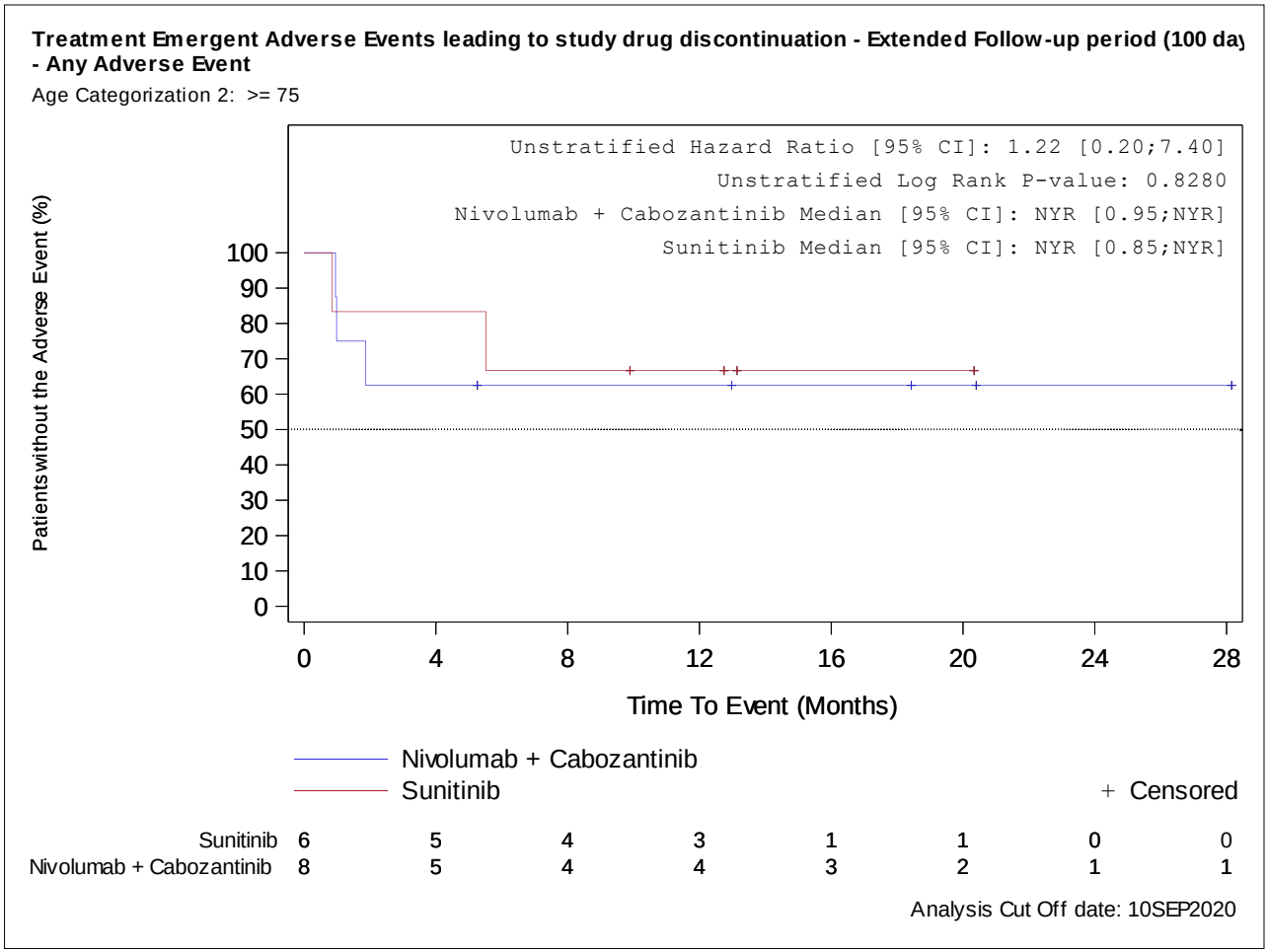
FIGURE 3.8.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75




Analysis Cut Off date: 10SEP2020
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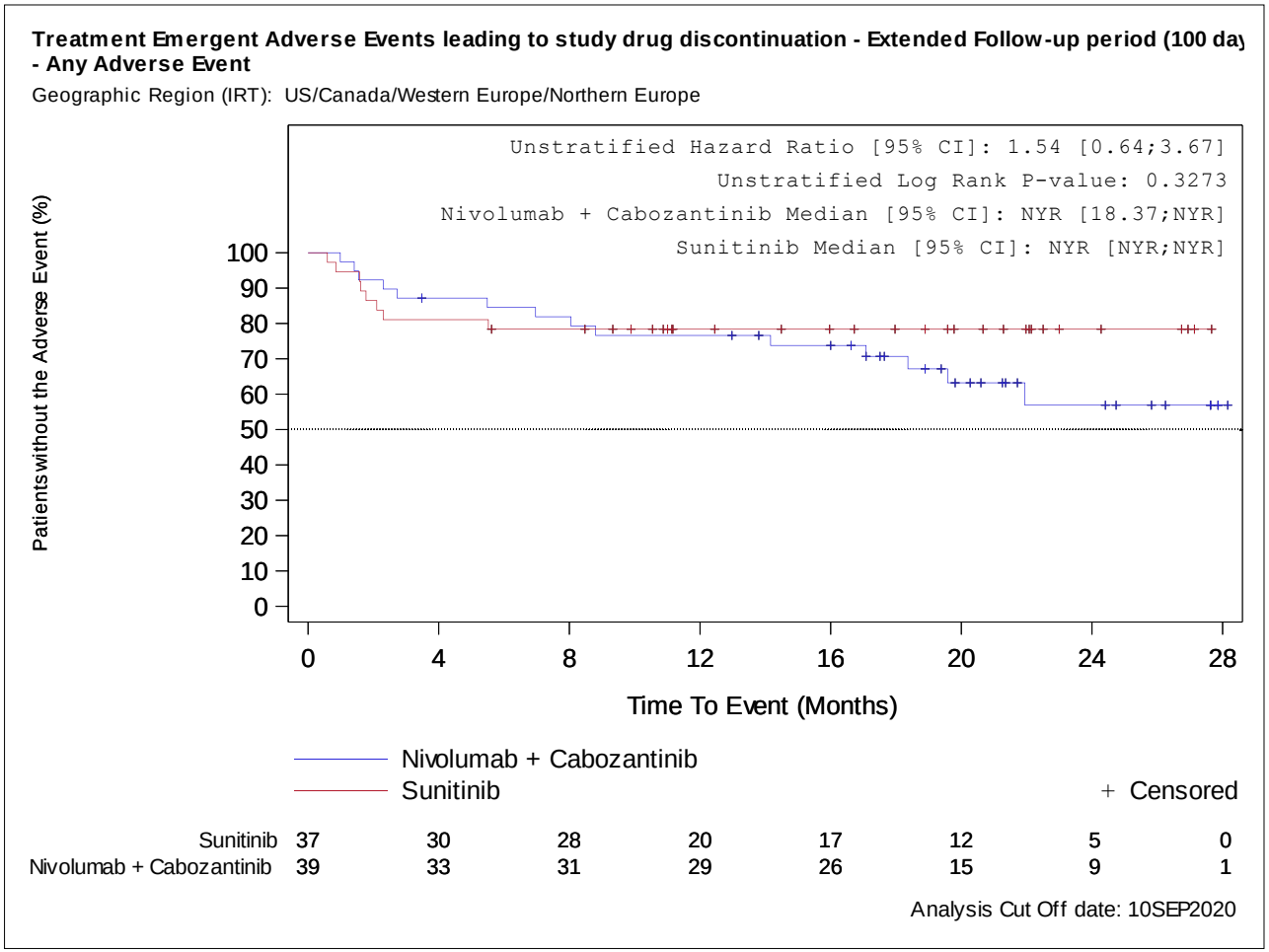
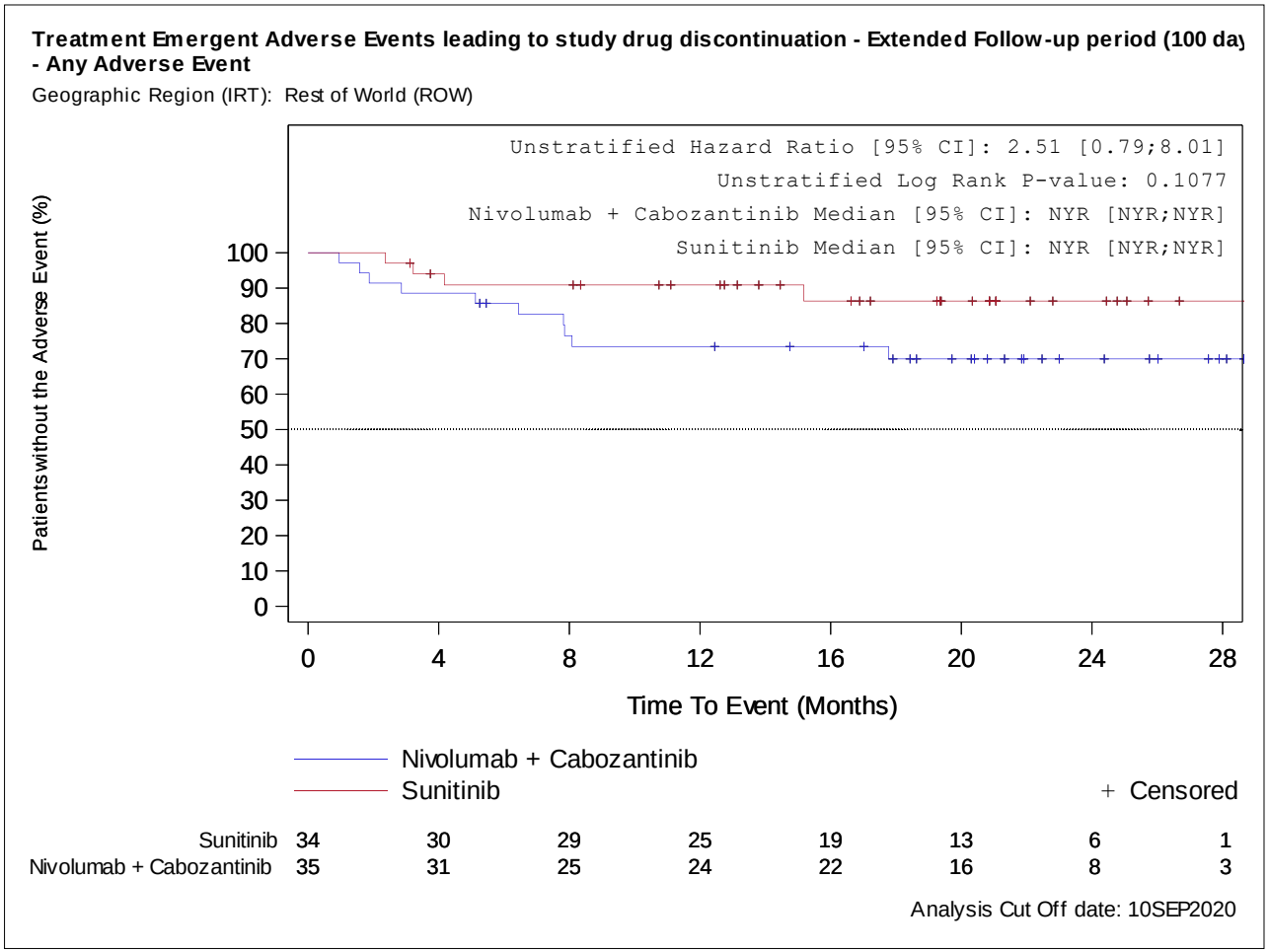
FIGURE 3.8.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



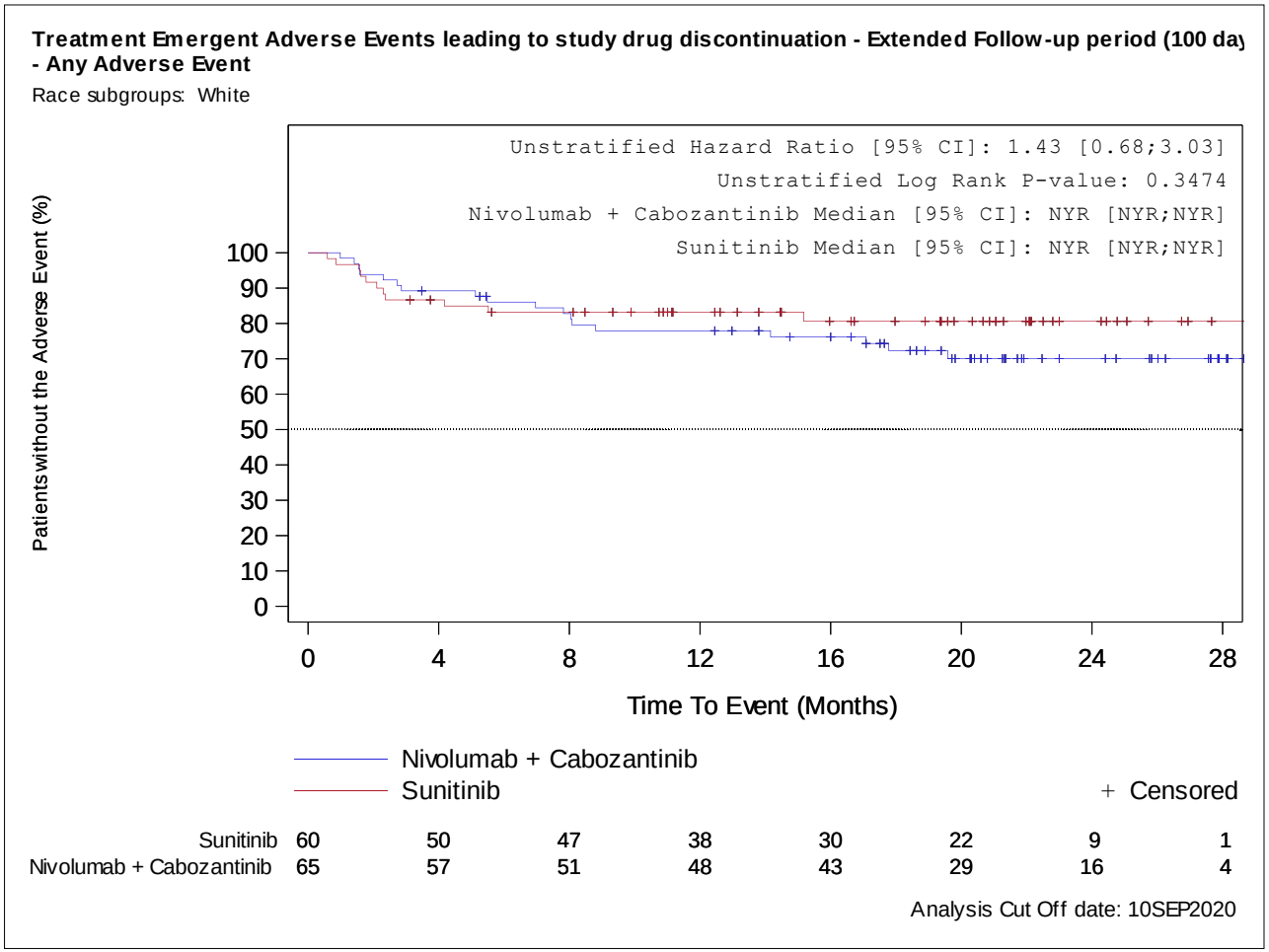

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:59:01

FIGURE 3.8.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



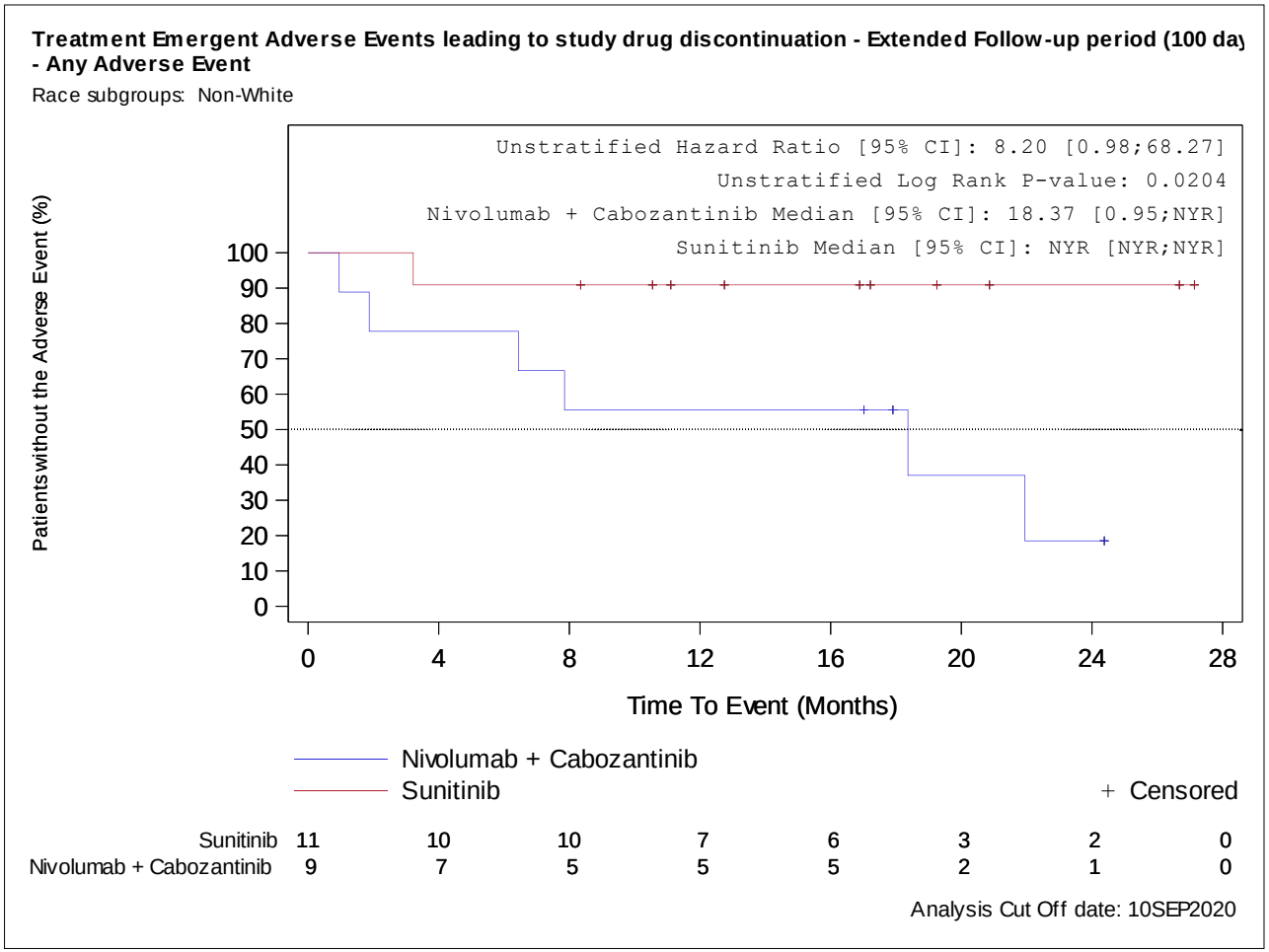

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:59:07

FIGURE 3.8.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



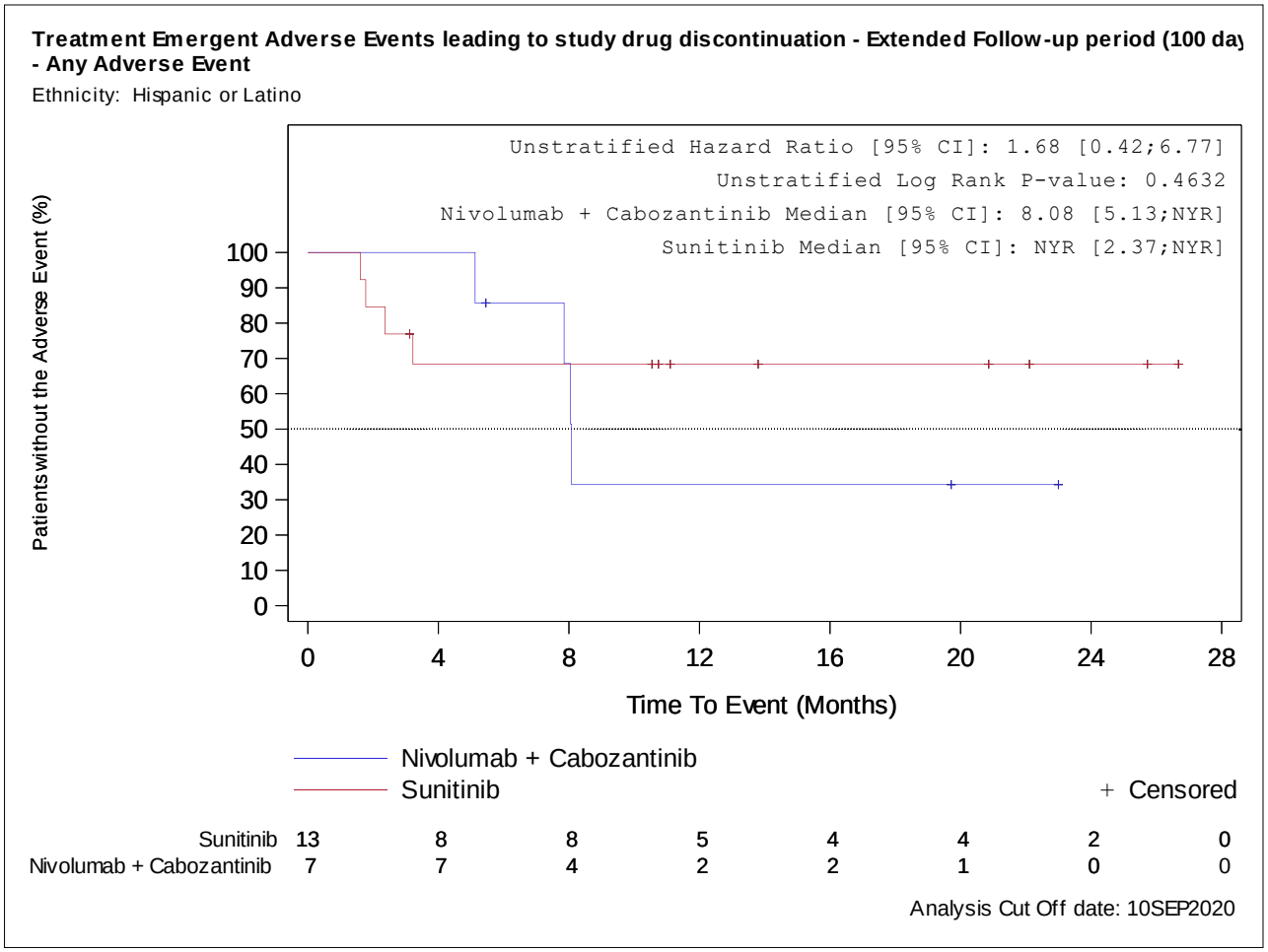

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:59:13

FIGURE 3.8.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



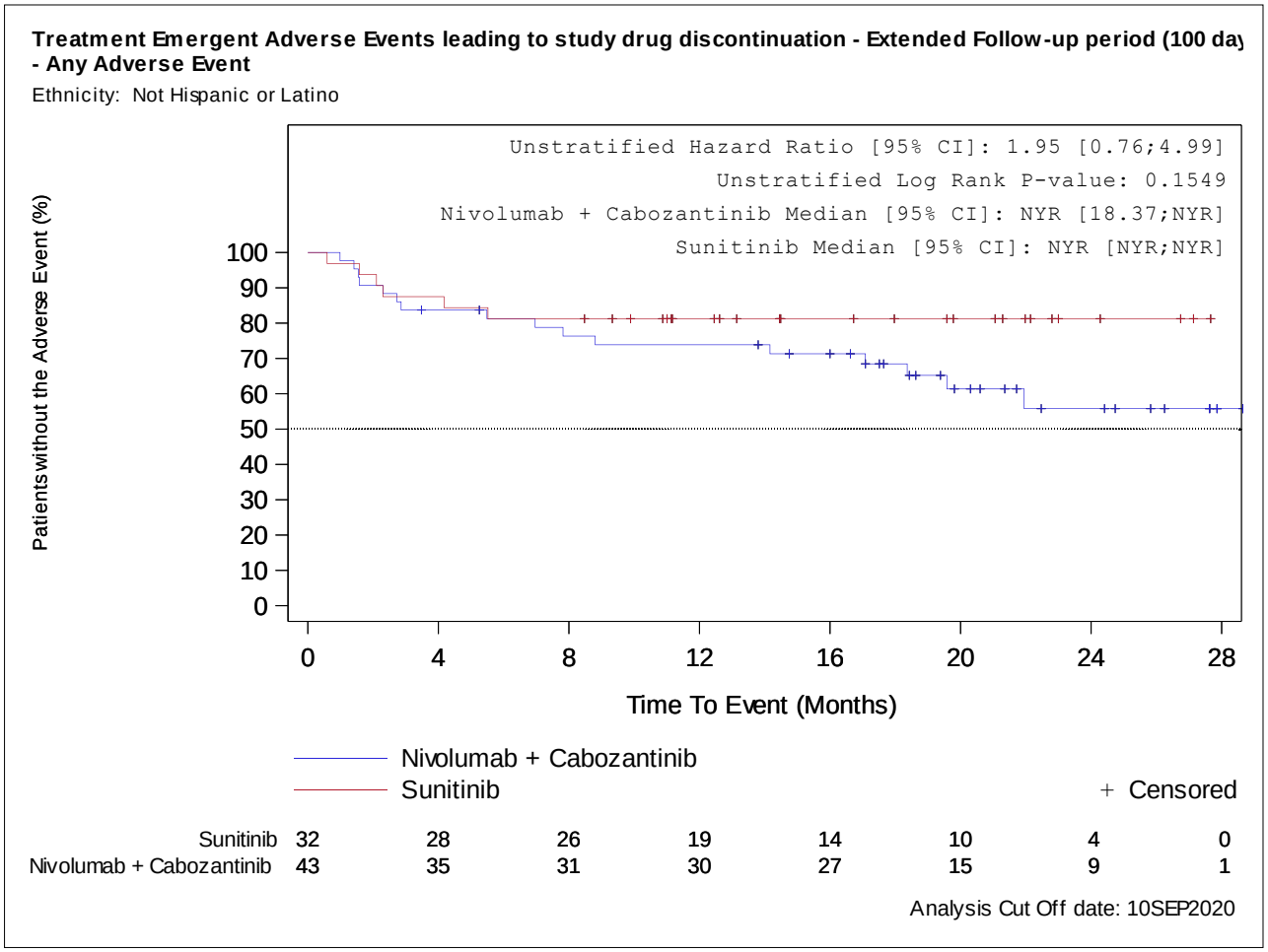

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:59:19

FIGURE 3.8.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



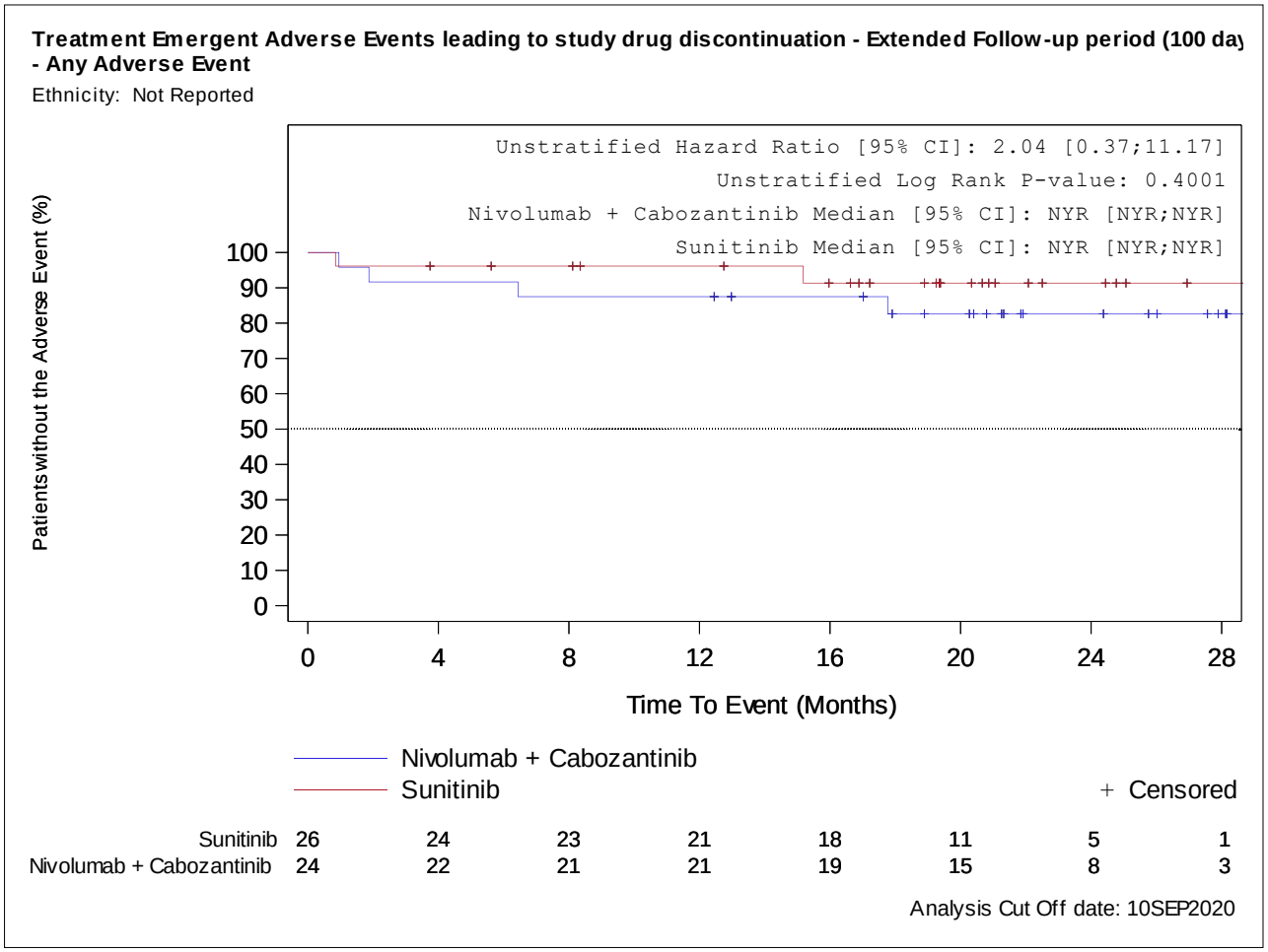

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:59:26

FIGURE 3.8.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:59:32

FIGURE 3.8.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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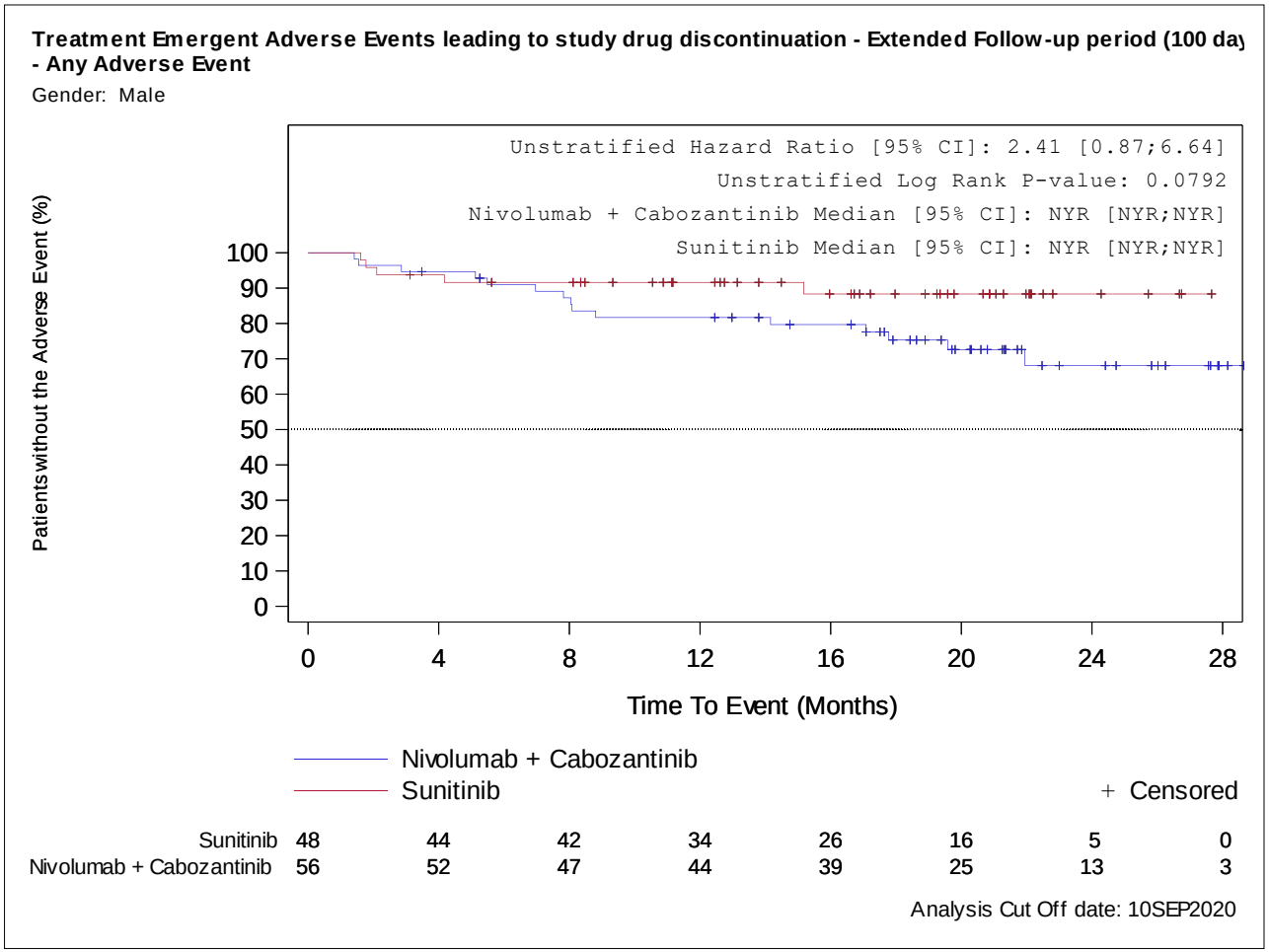
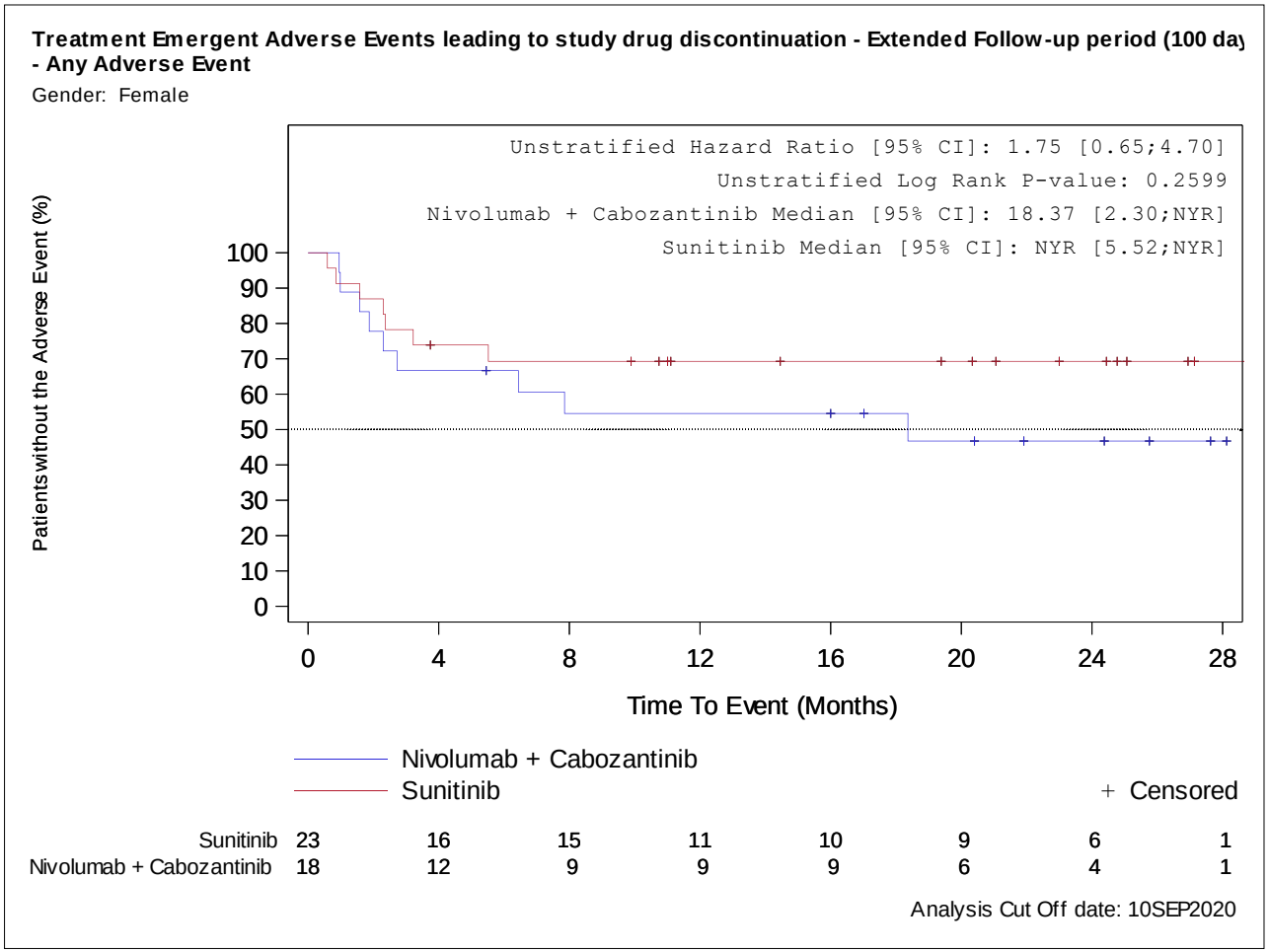
FIGURE 3.8.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



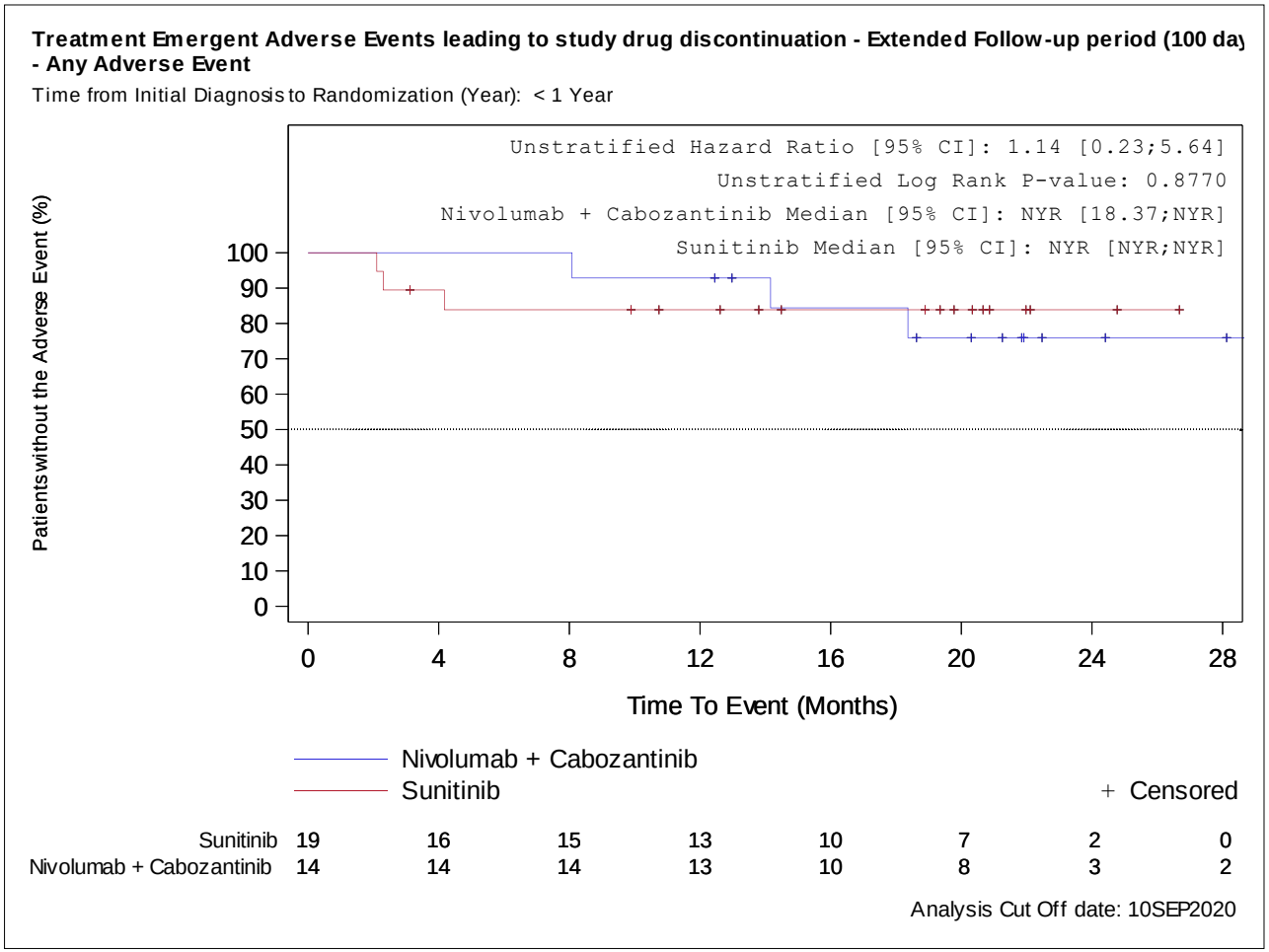

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:59:45

FIGURE 3.8.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



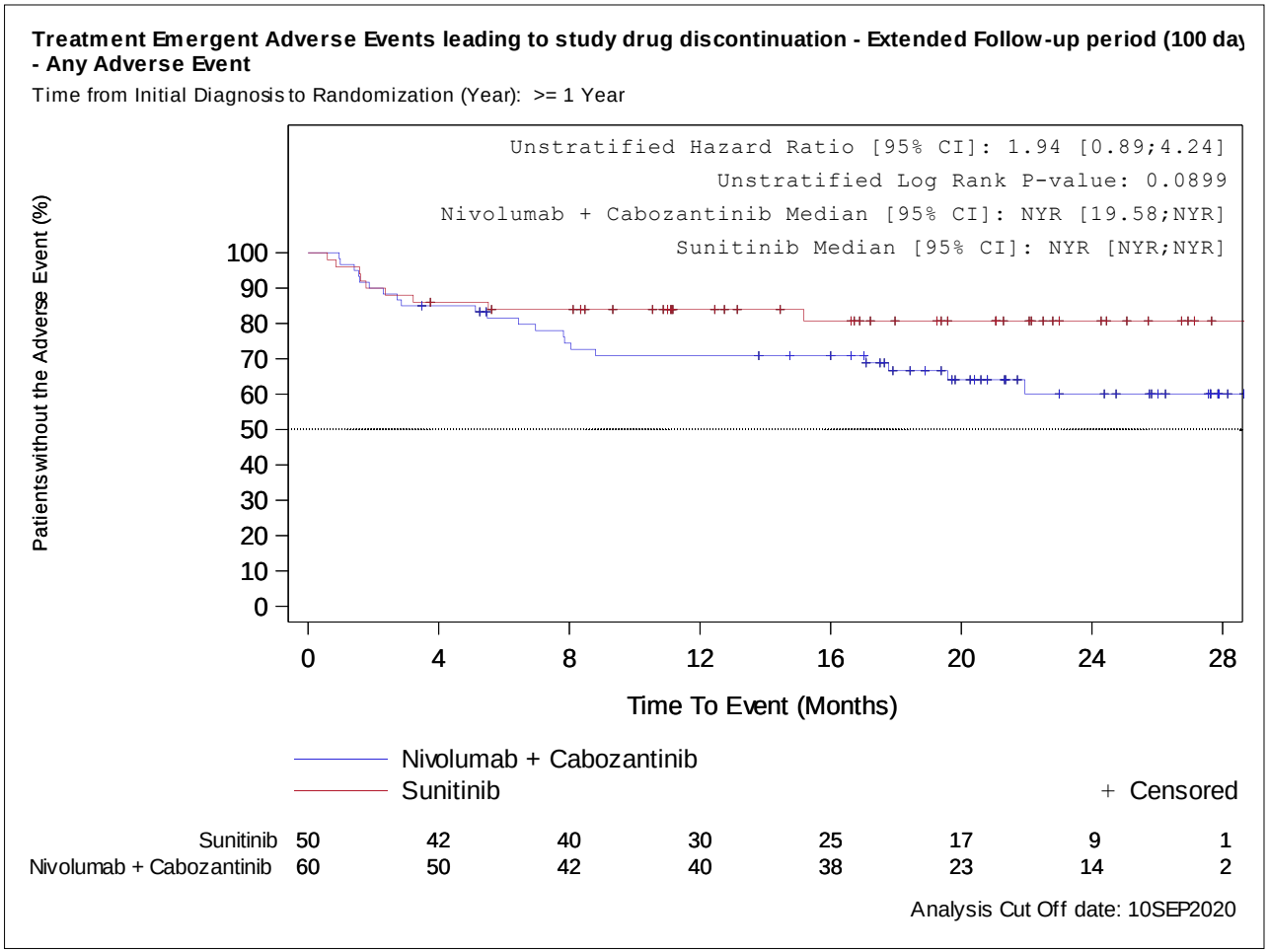

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 13:59:51

FIGURE 3.8.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



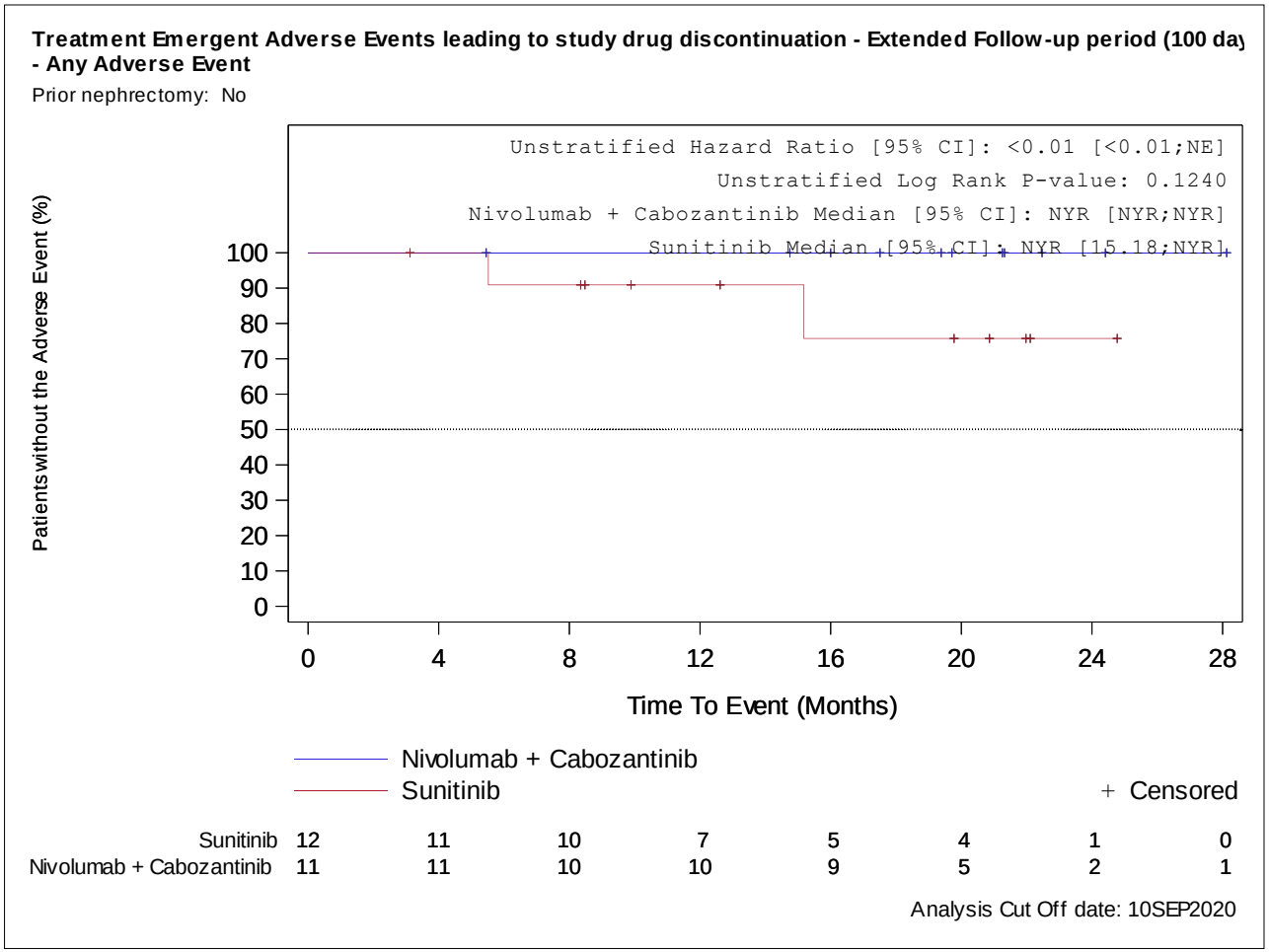

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:00:10

FIGURE 3.8.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



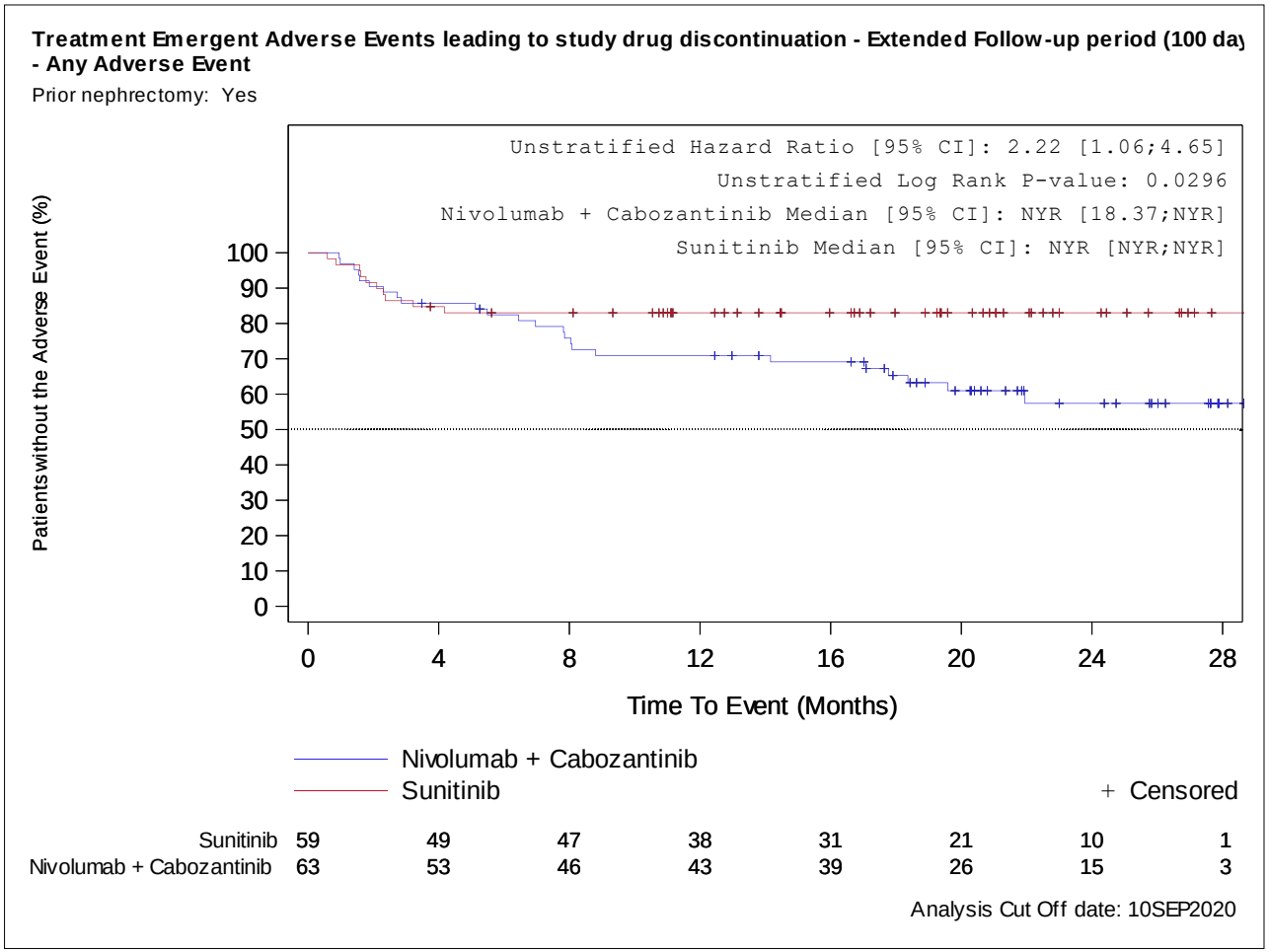

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:00:16

FIGURE 3.8.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



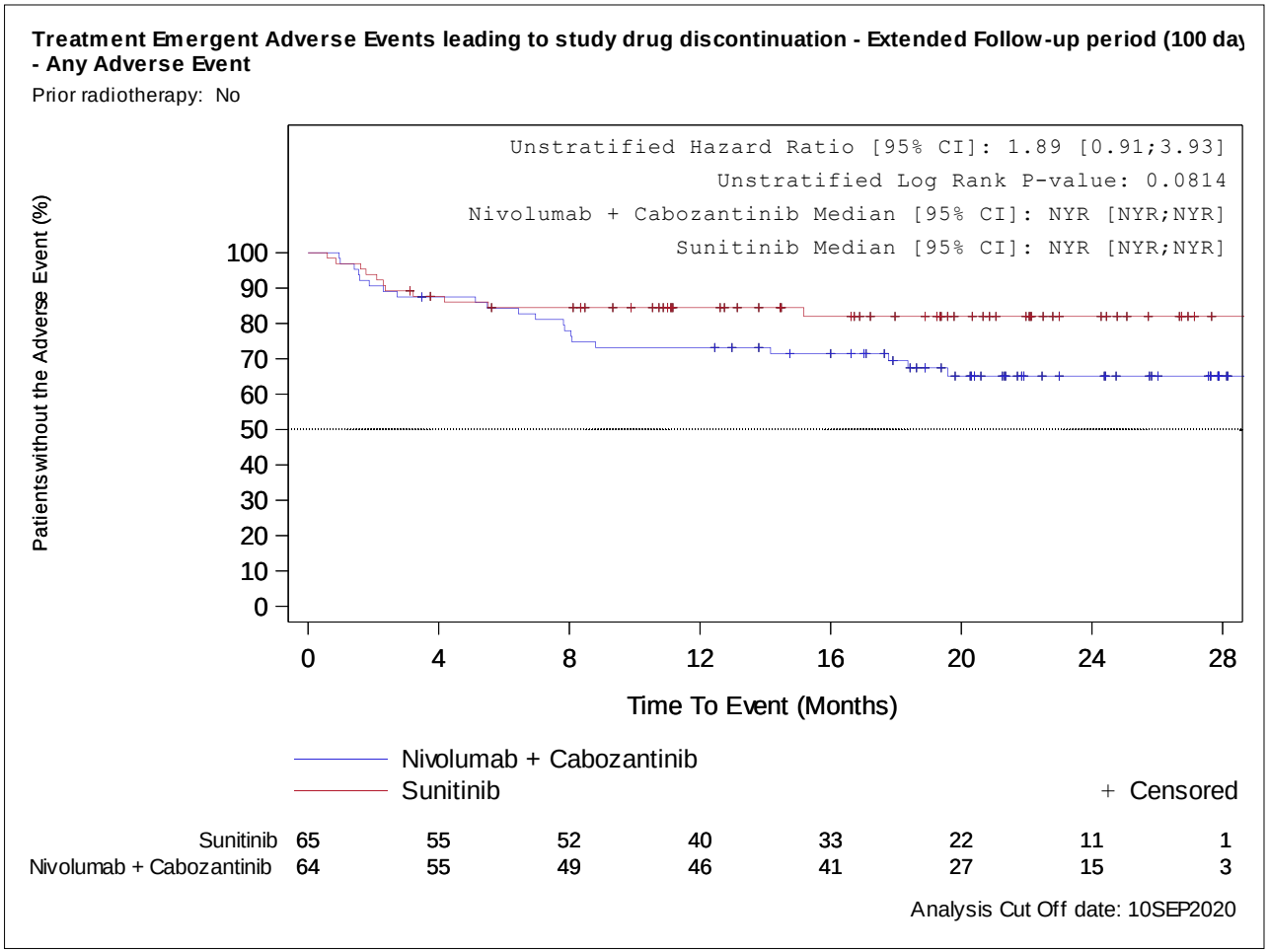

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:01:13

FIGURE 3.8.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



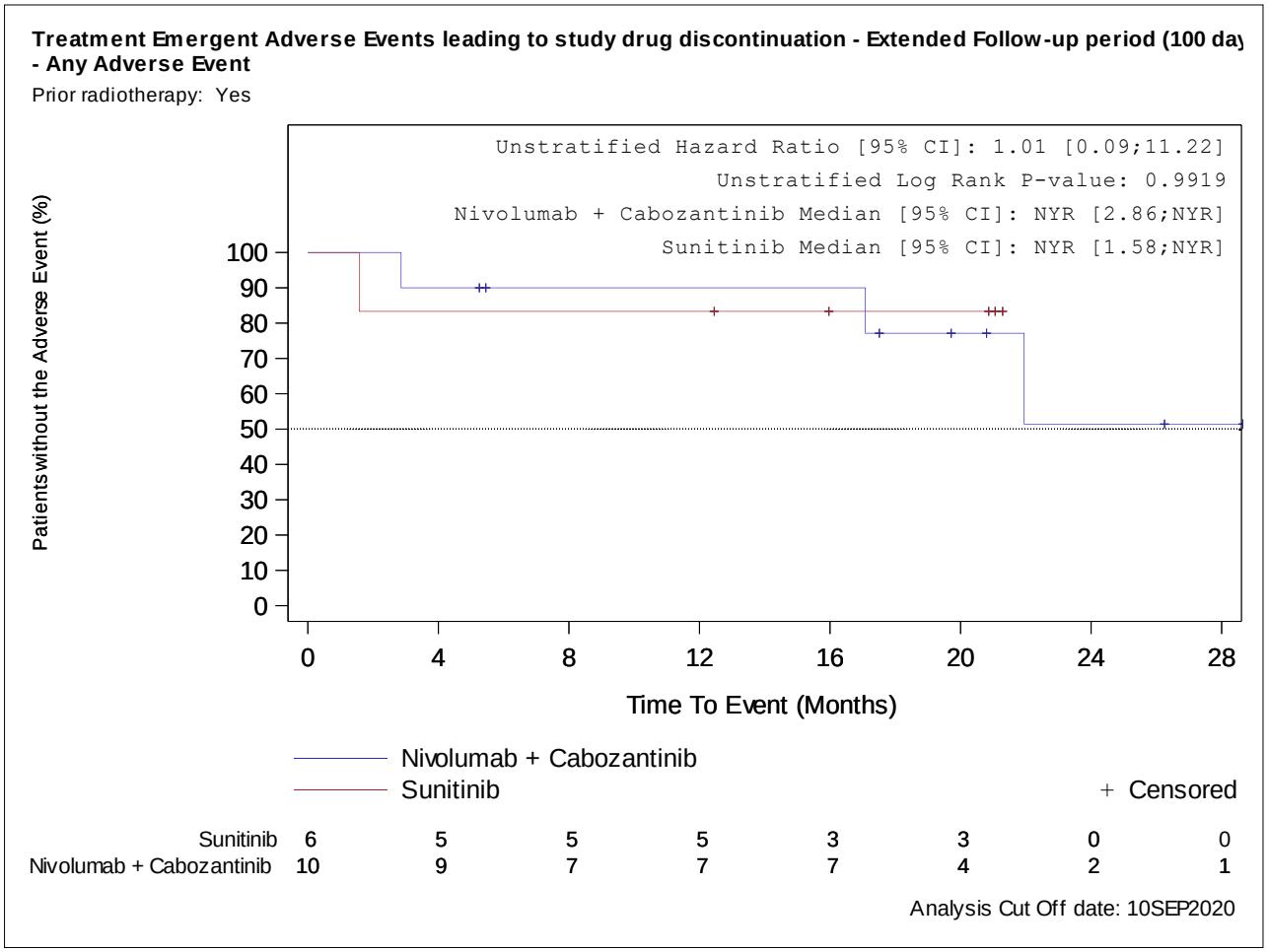

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:01:20

FIGURE 3.8.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



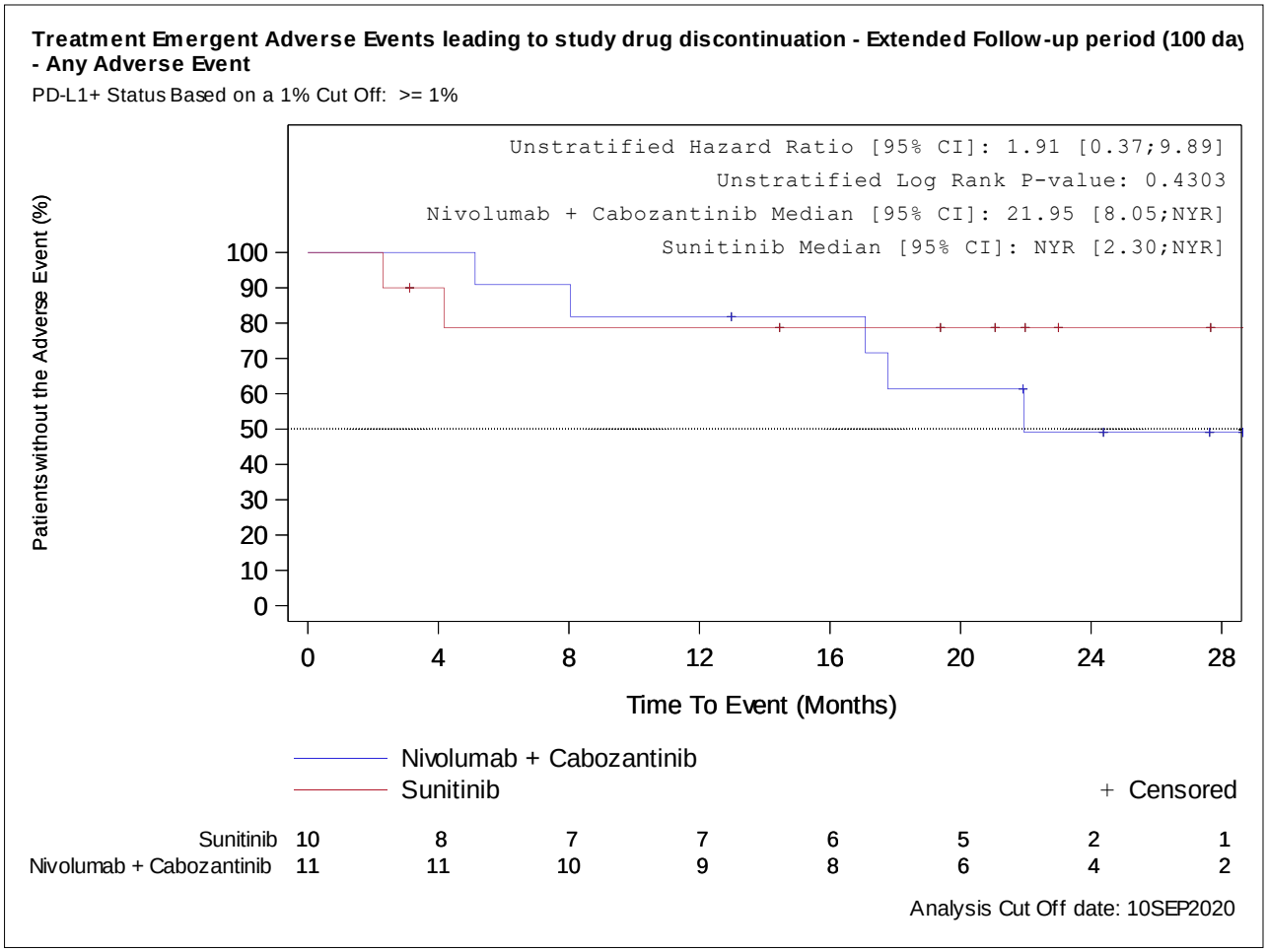

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:01:26

FIGURE 3.8.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:01:33

FIGURE 3.8.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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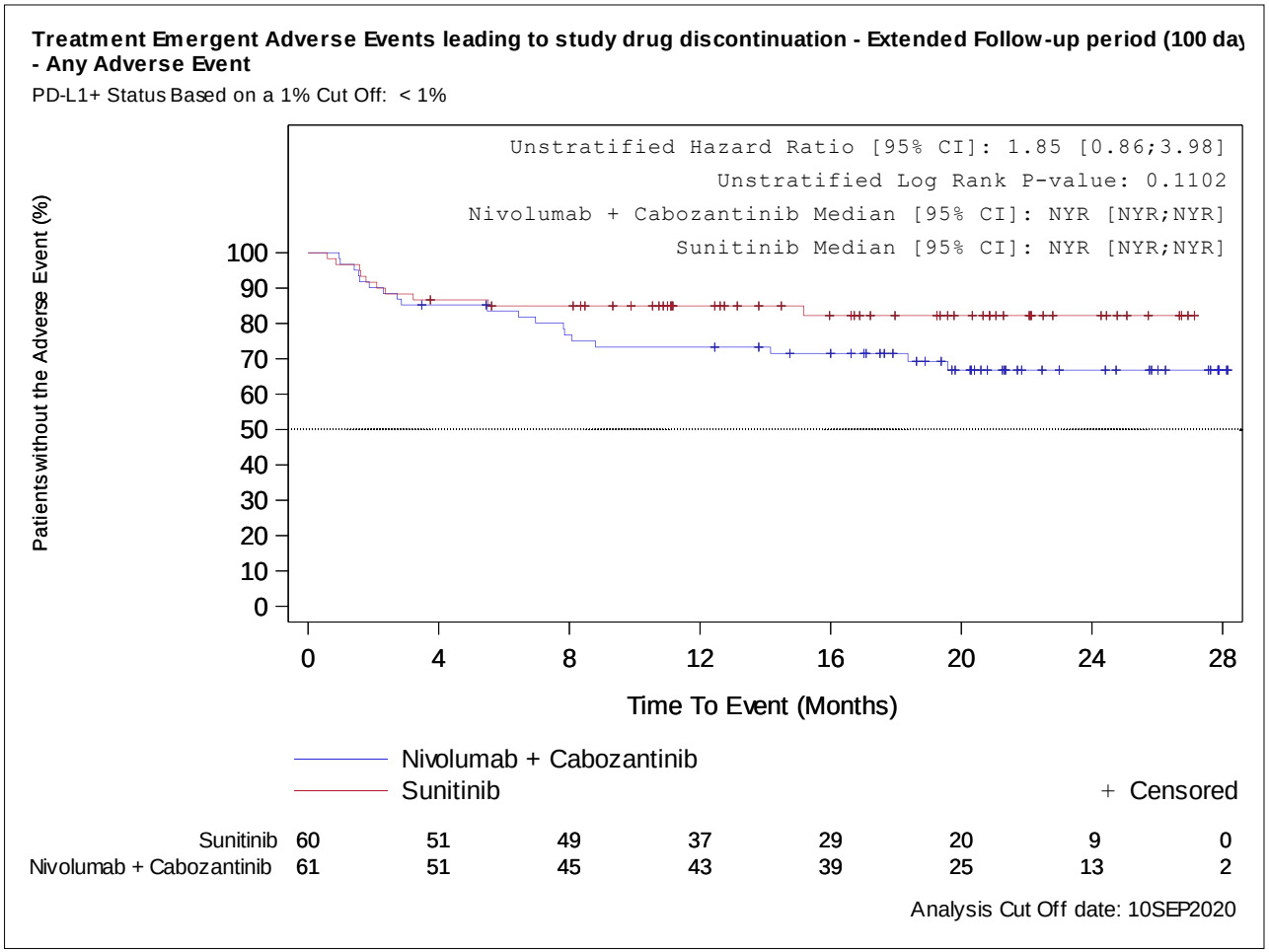
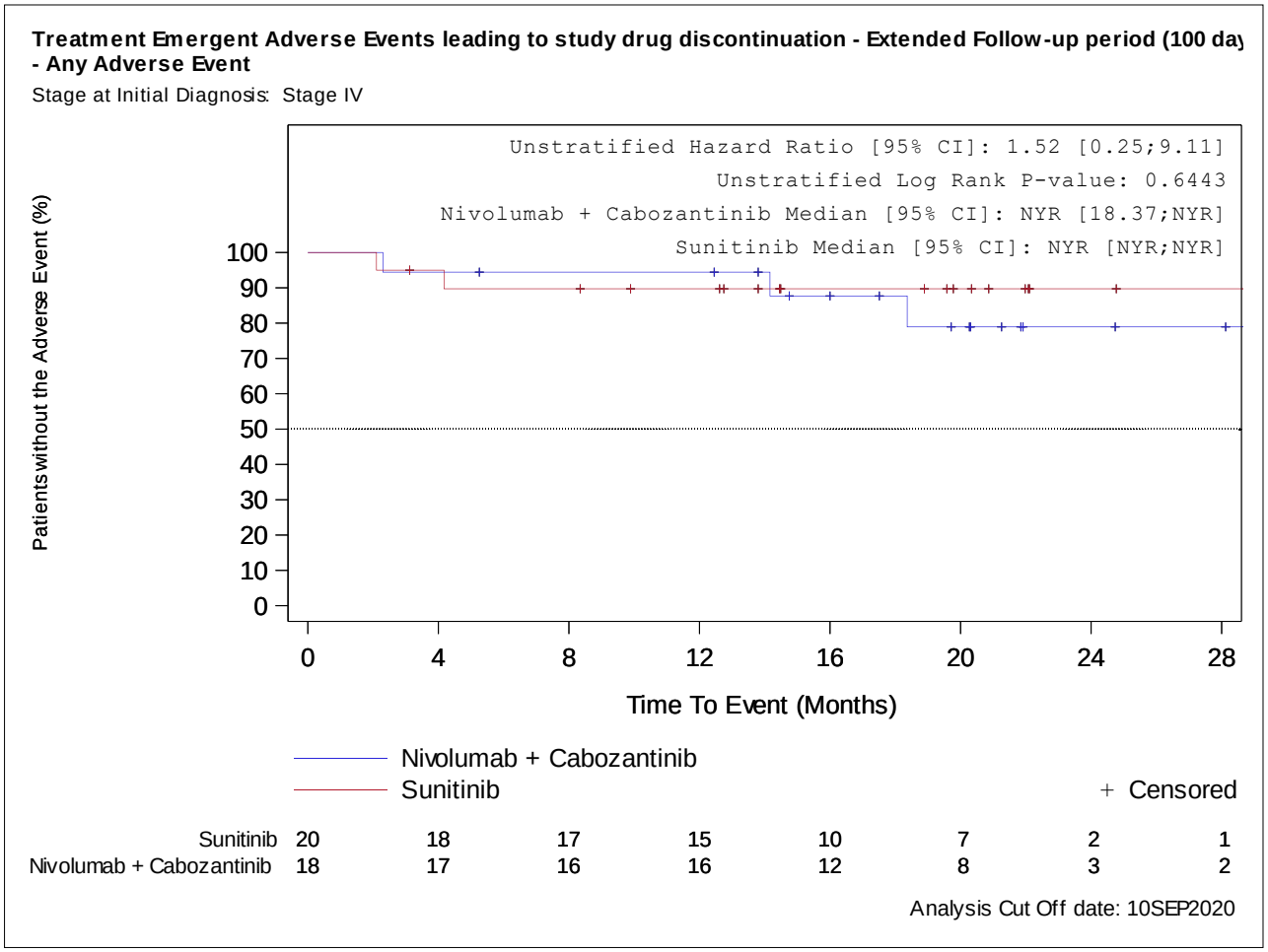
FIGURE 3.8.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



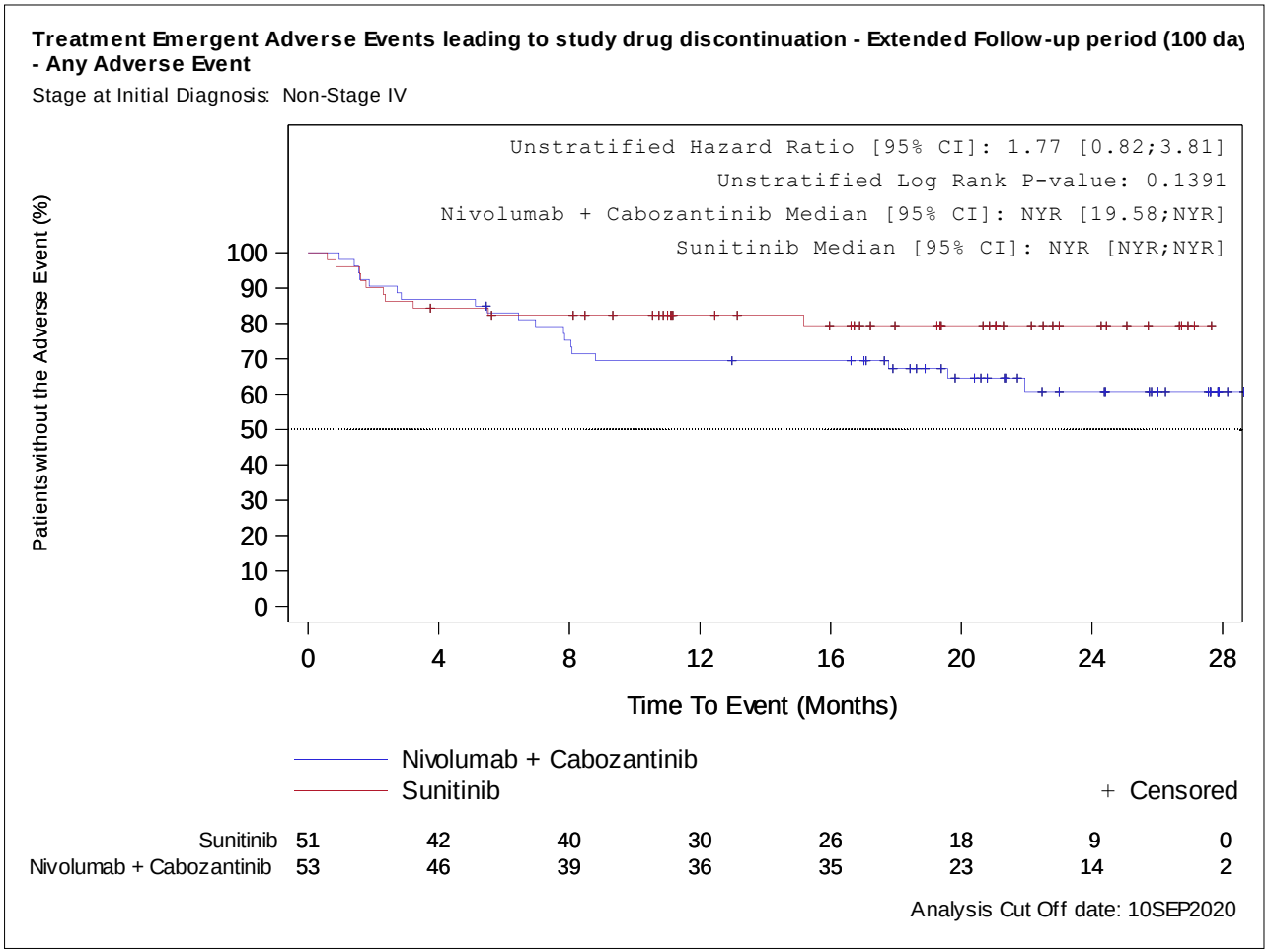

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:01:45

FIGURE 3.8.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



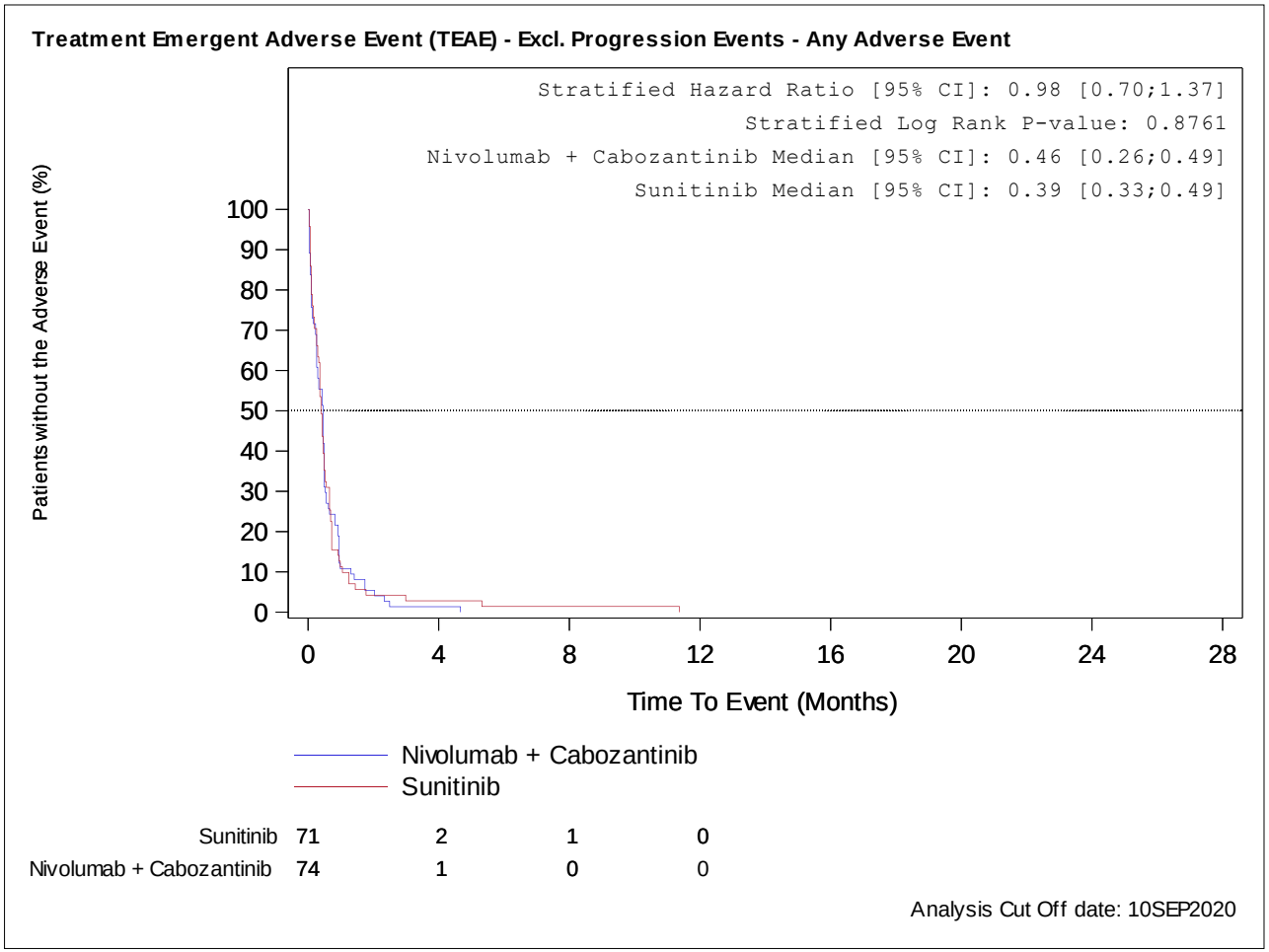

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:02:18

FIGURE 3.8.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:02:25

FIGURE 3.9.1: Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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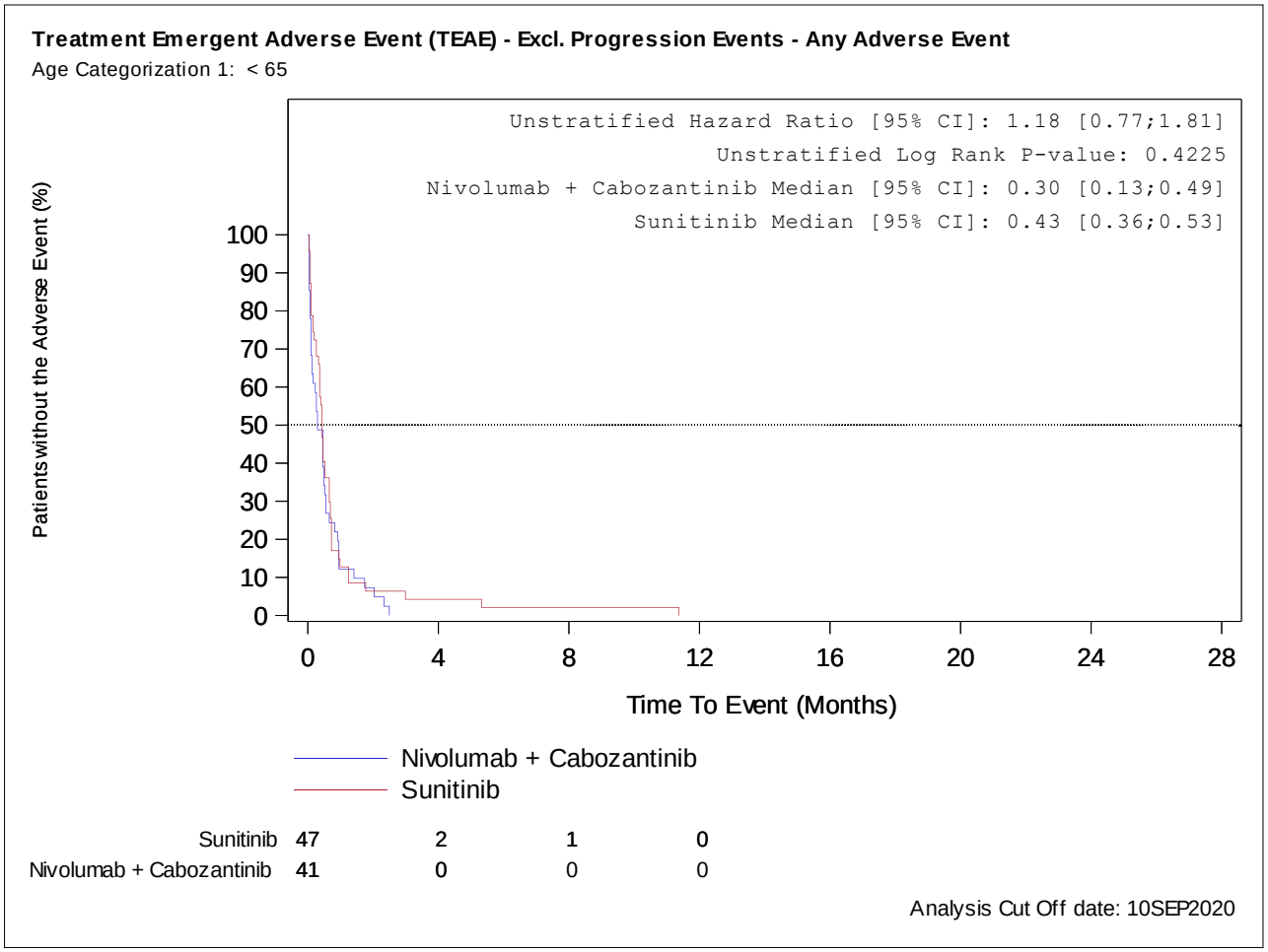
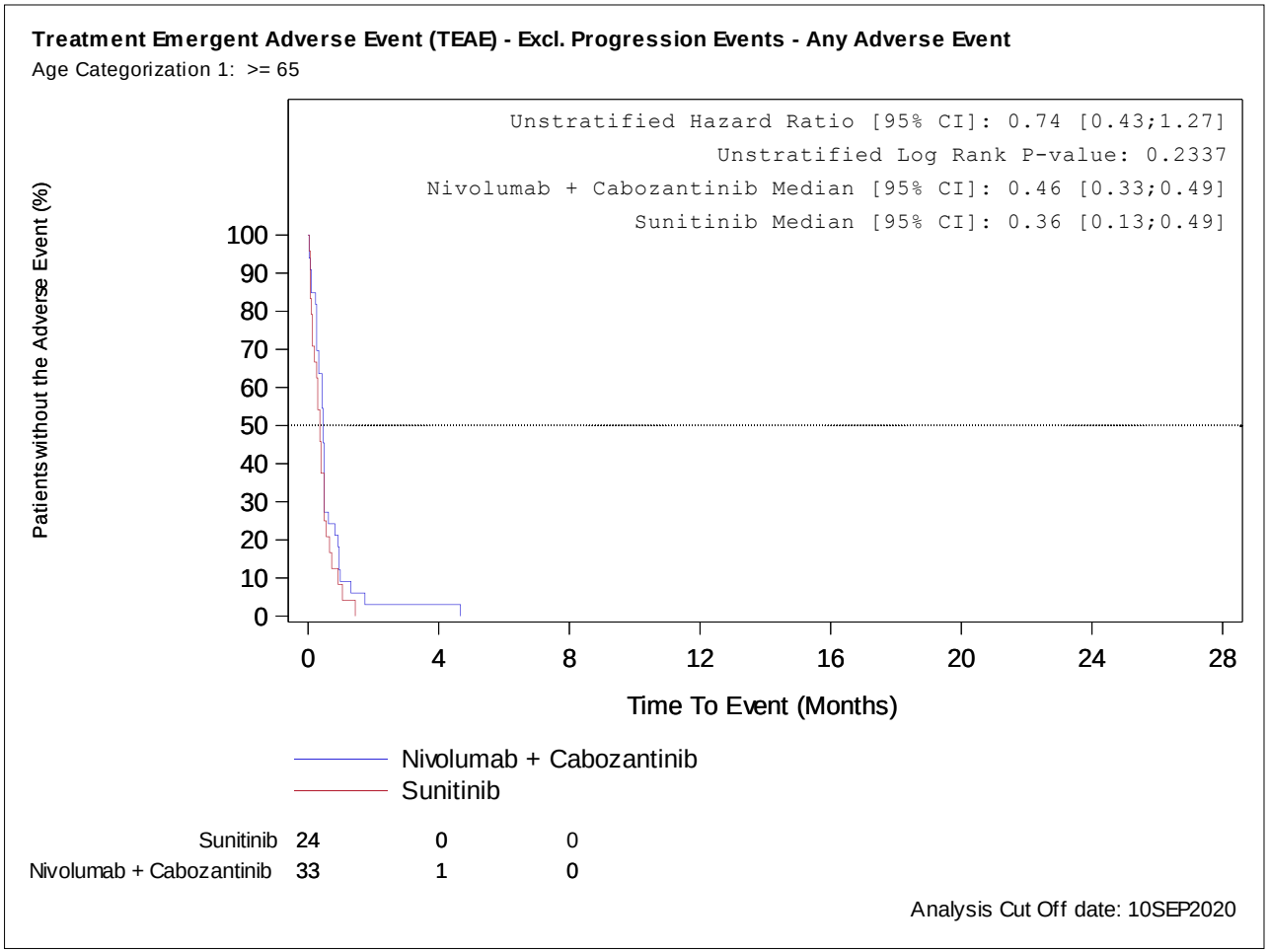
FIGURE 3.9.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



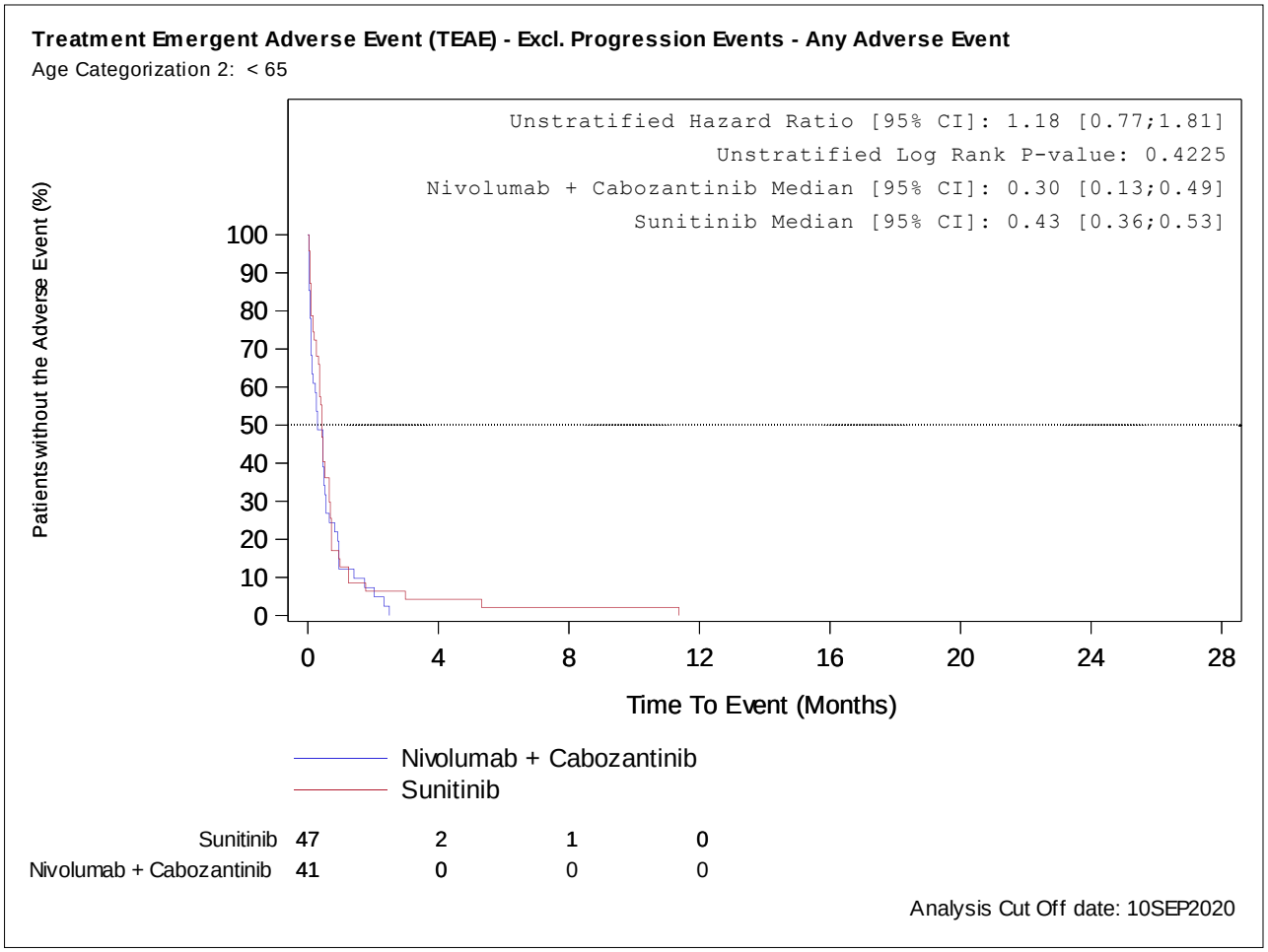

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:06:00

FIGURE 3.9.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:06:06

FIGURE 3.9.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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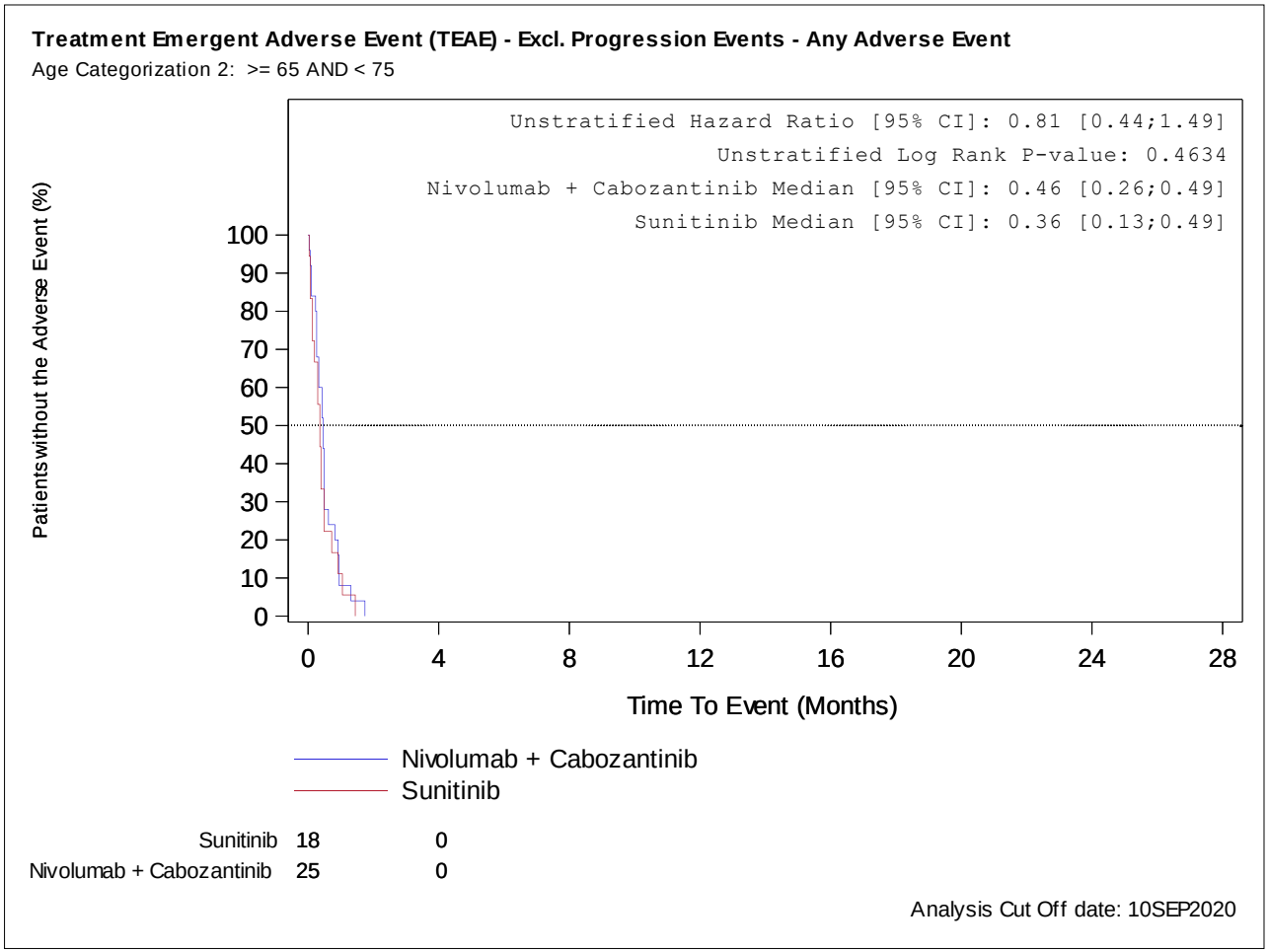
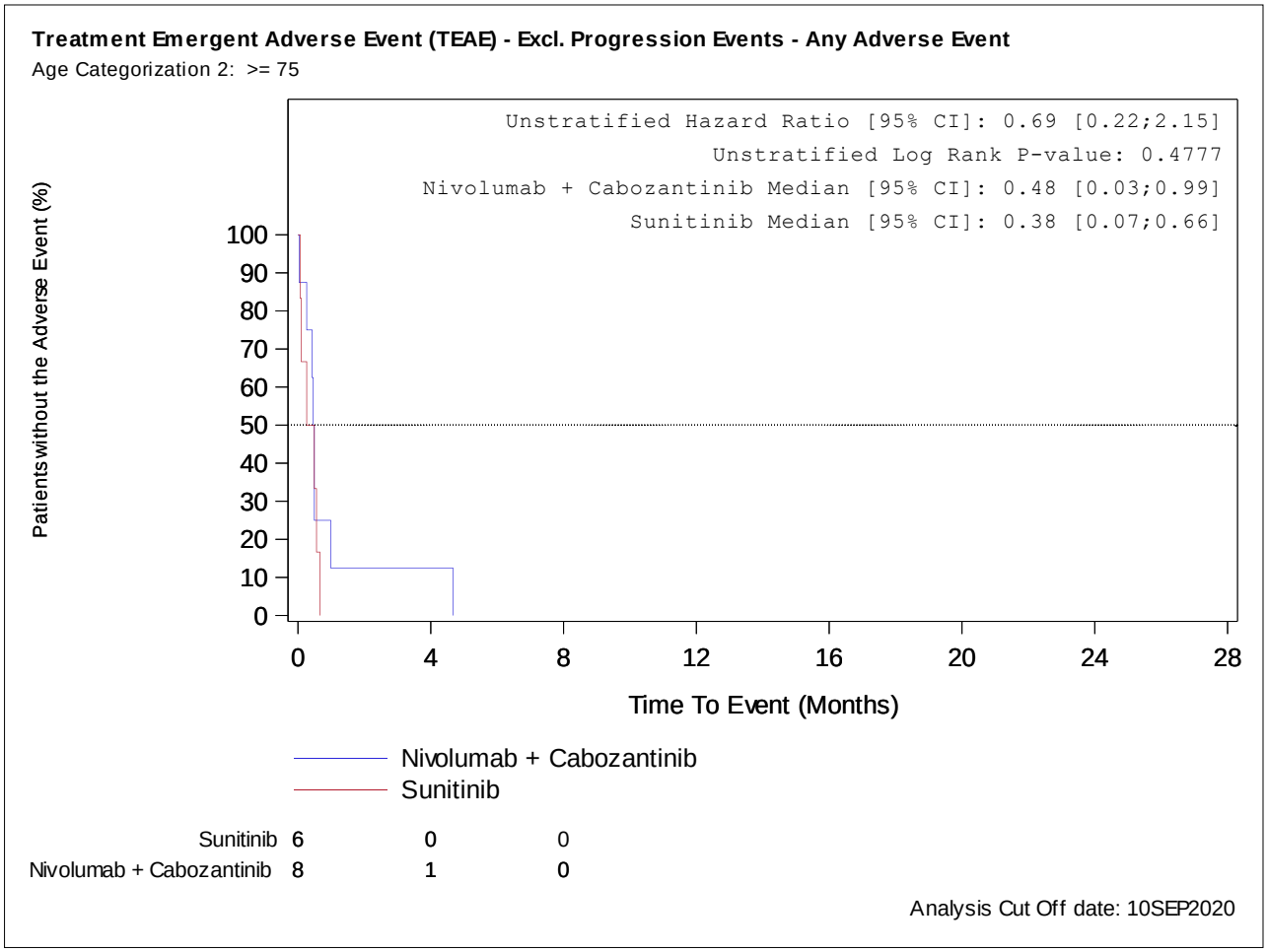
FIGURE 3.9.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



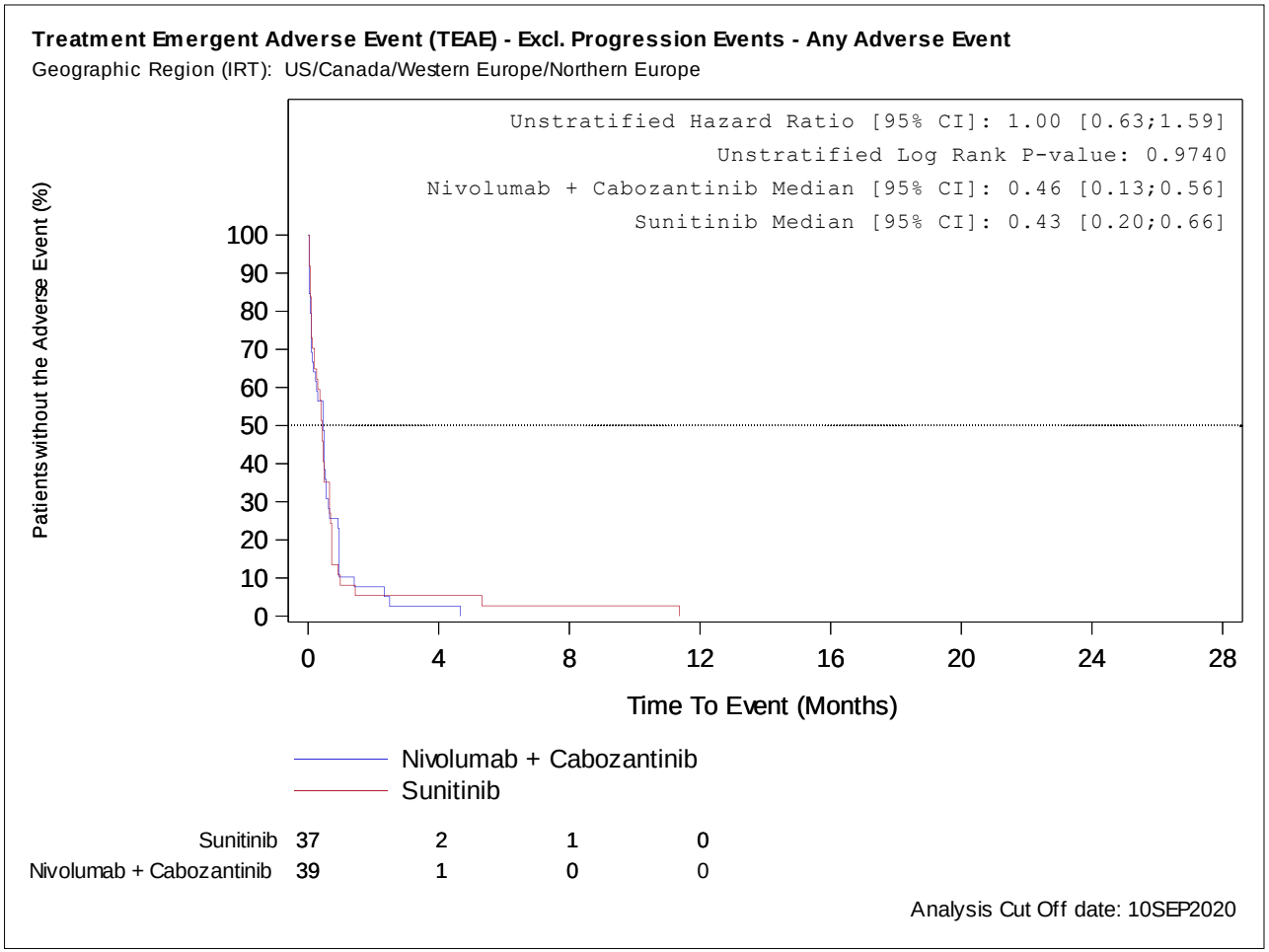

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:06:19

FIGURE 3.9.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



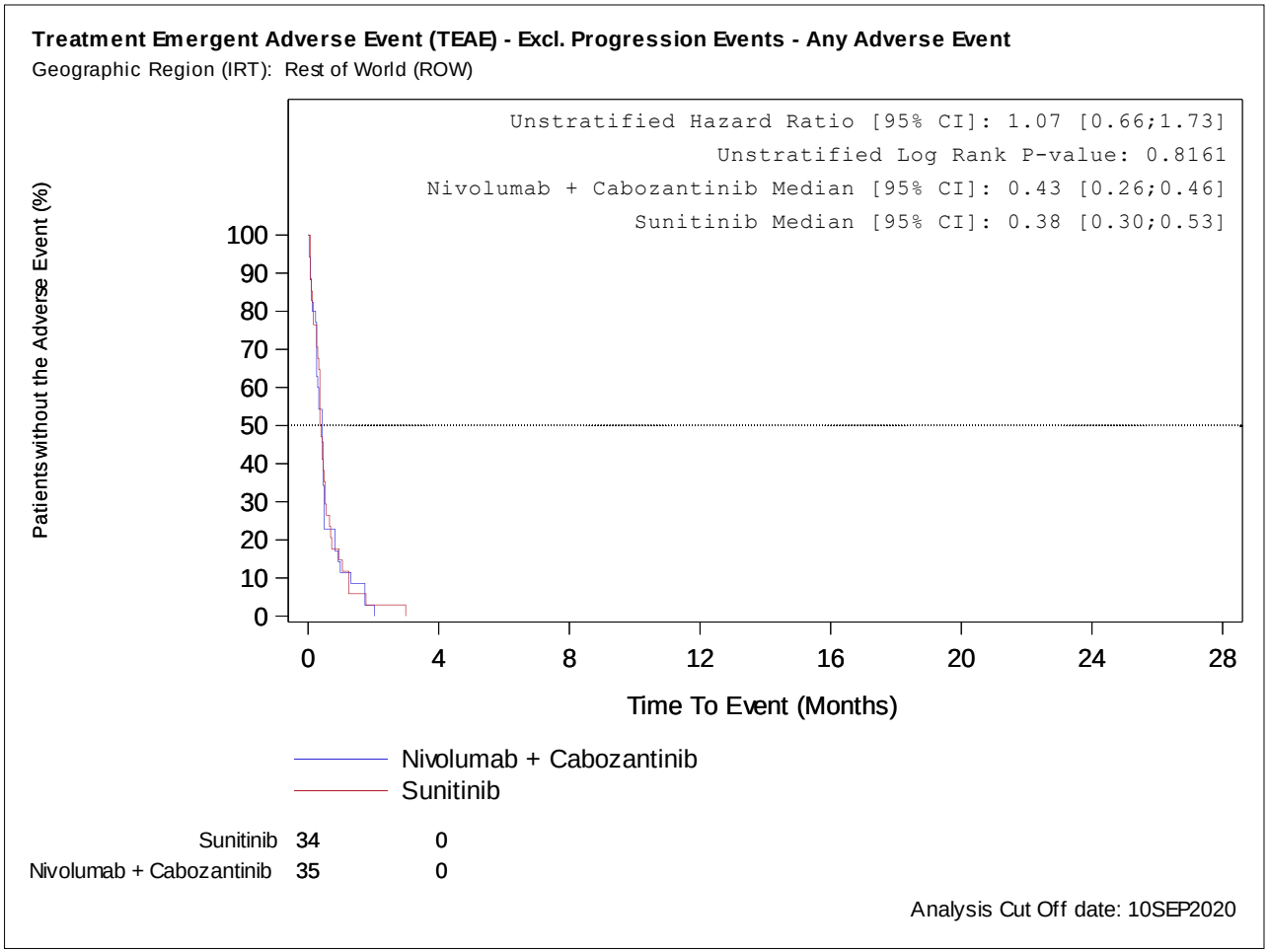

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:06:25

FIGURE 3.9.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



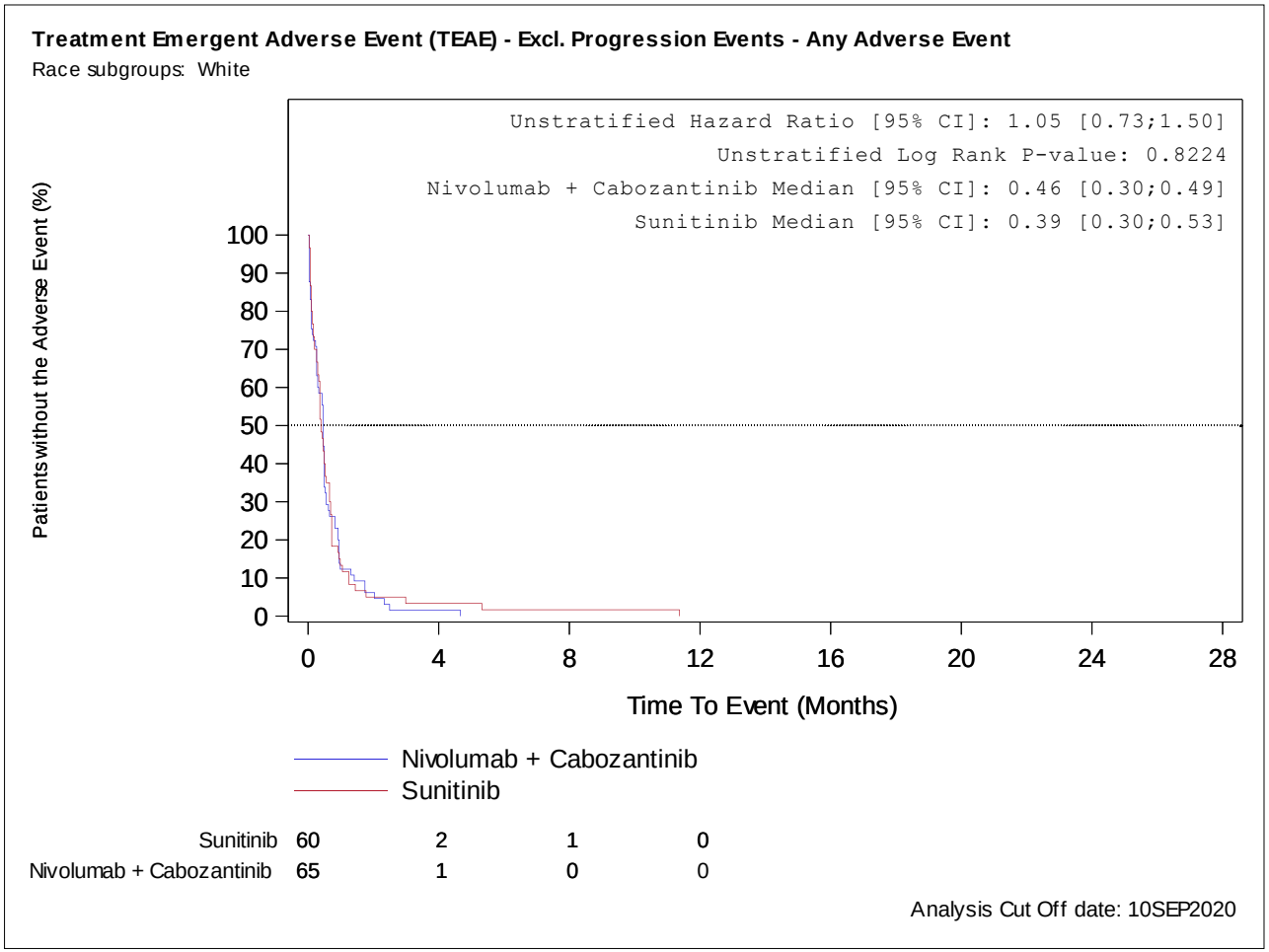

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:06:31

FIGURE 3.9.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



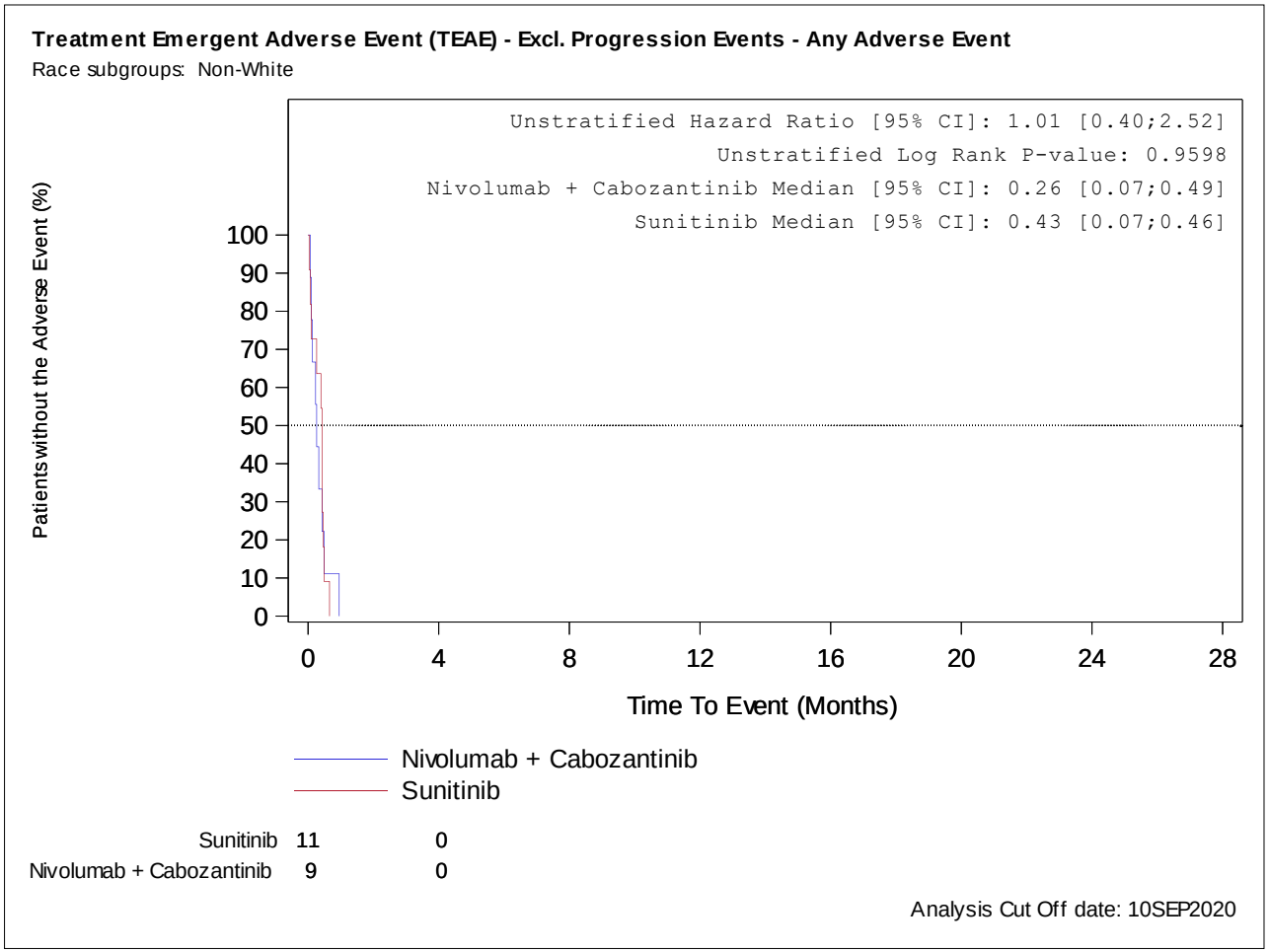

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:06:36

FIGURE 3.9.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



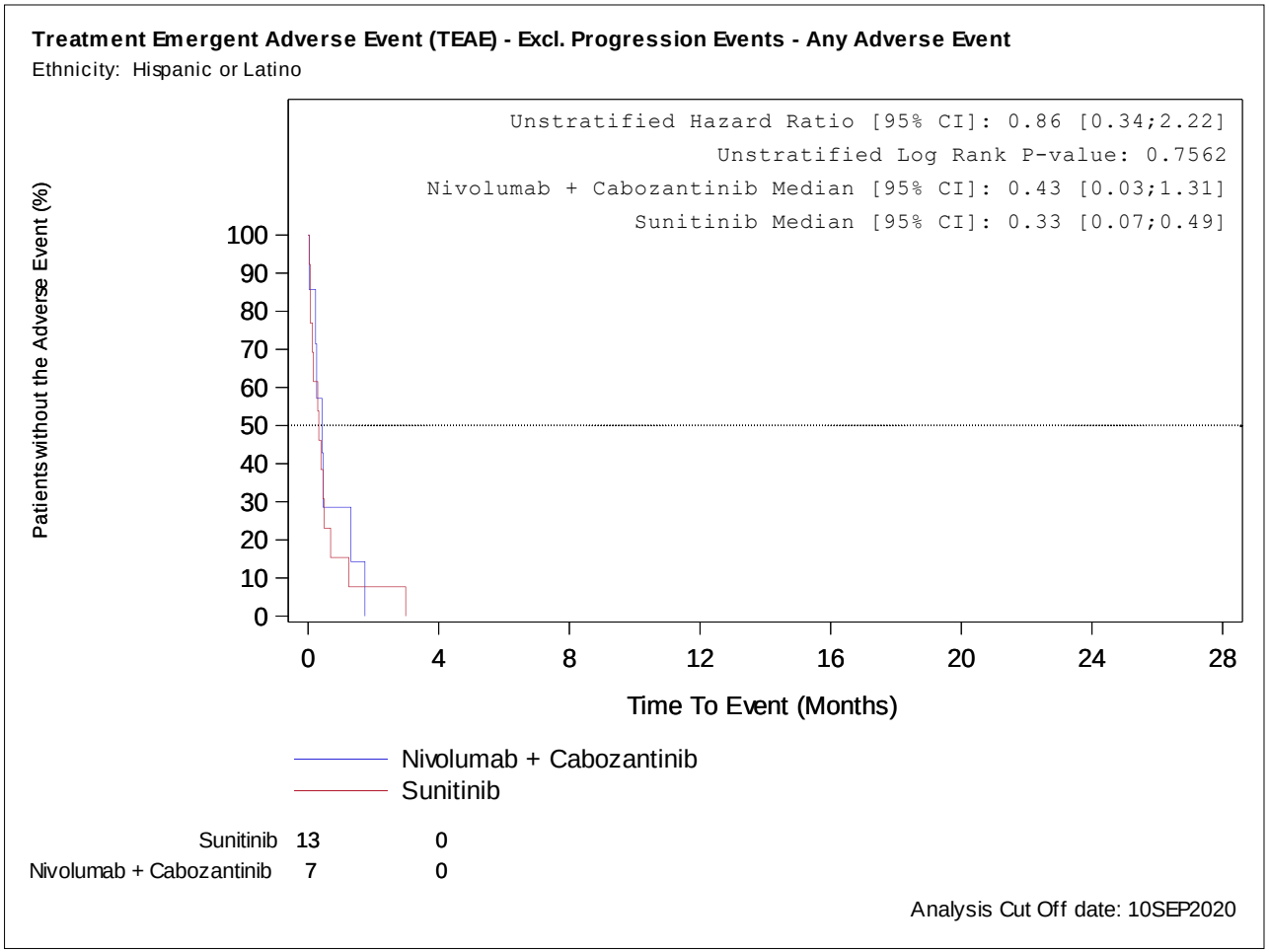

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:06:42

FIGURE 3.9.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



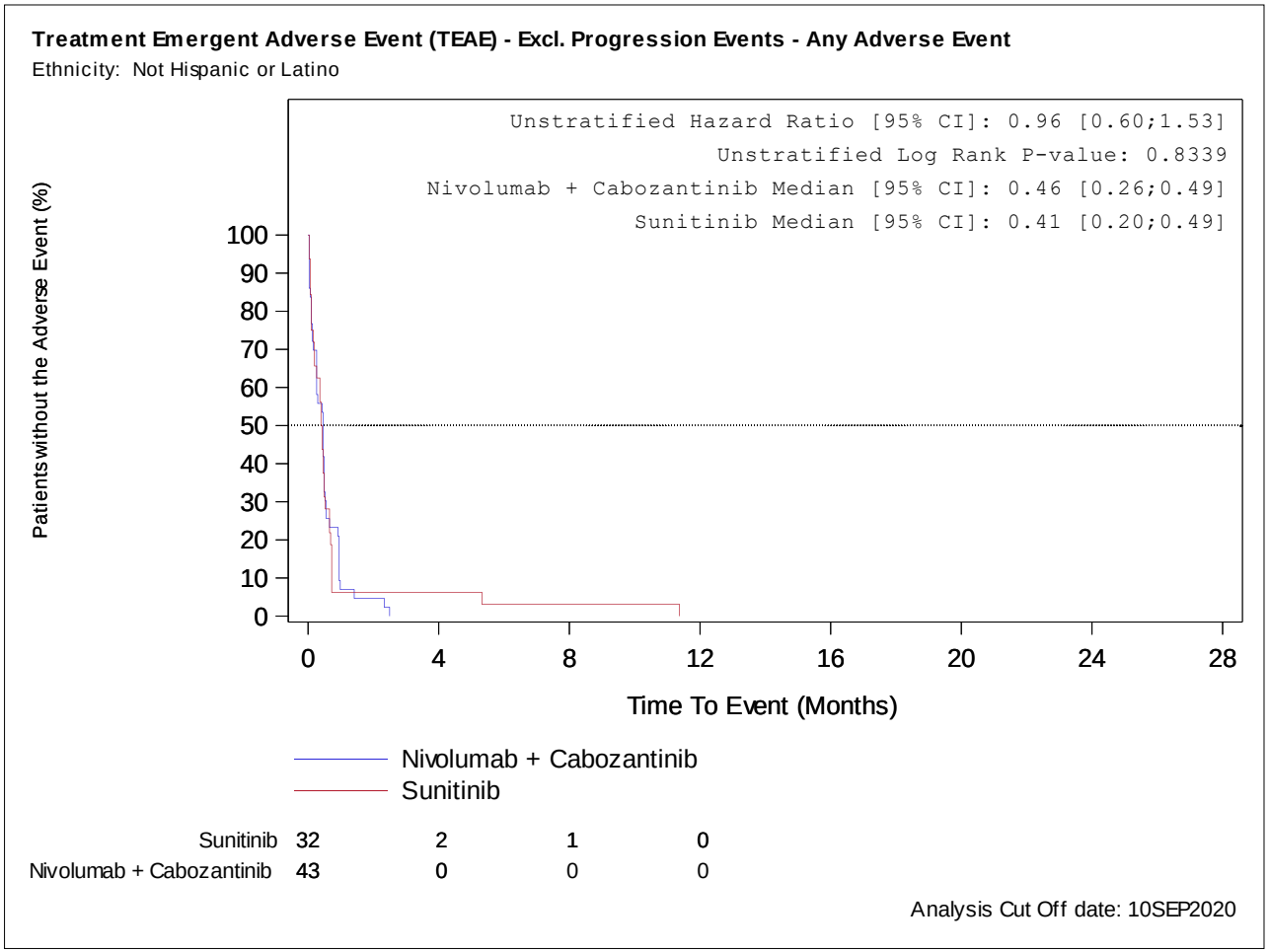

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:06:48

FIGURE 3.9.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



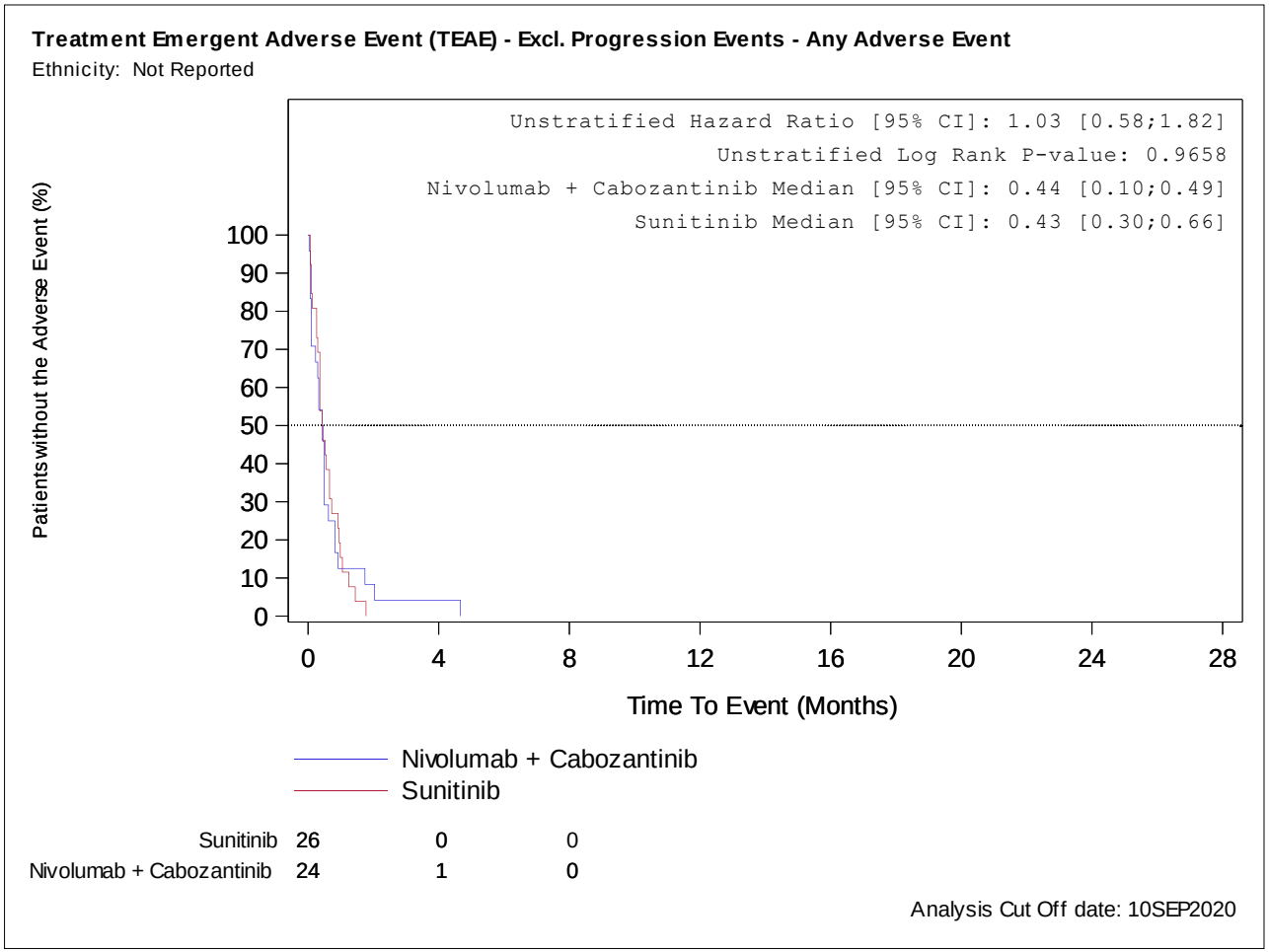

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:06:54

FIGURE 3.9.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



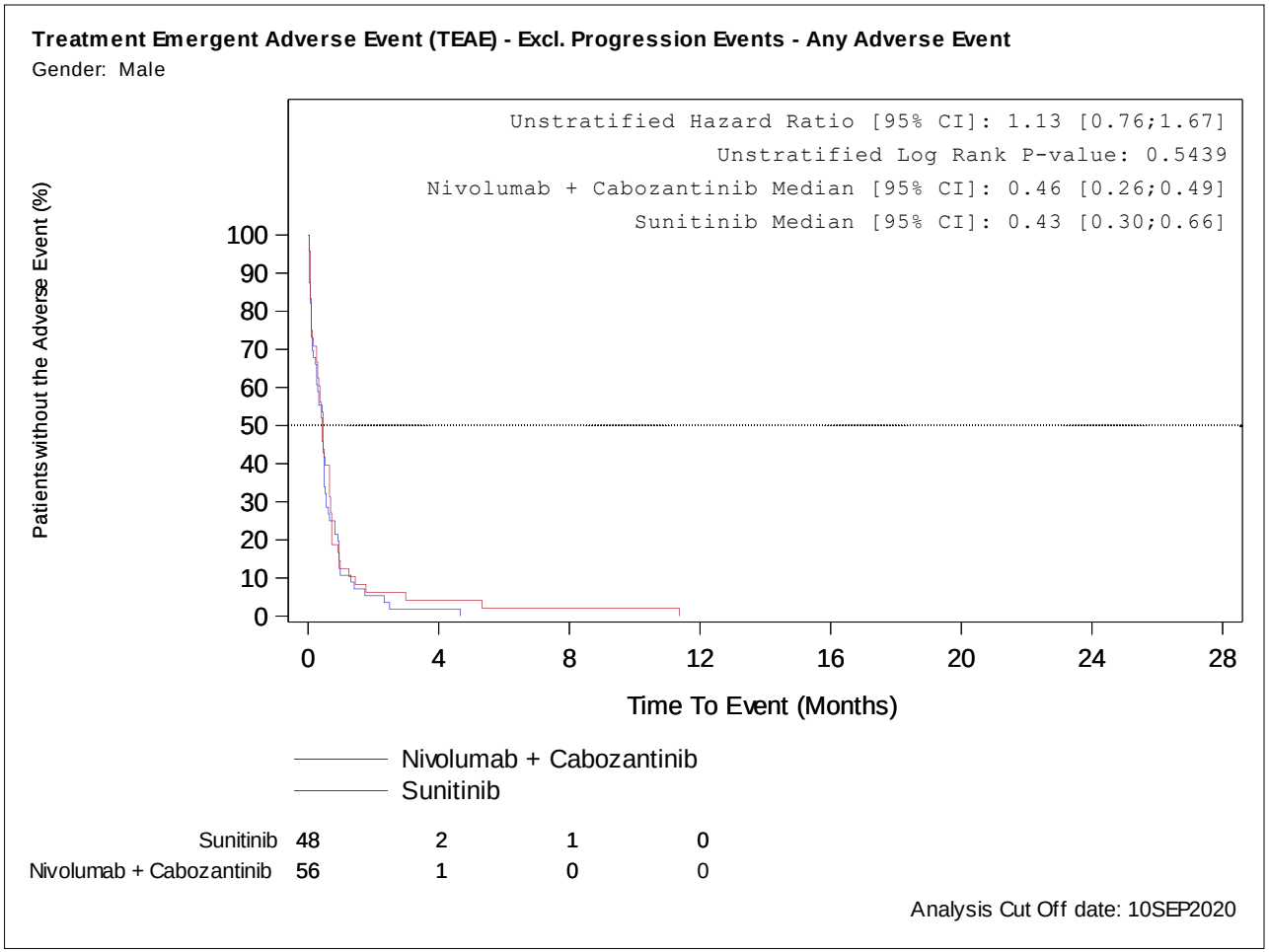

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:07:00

FIGURE 3.9.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



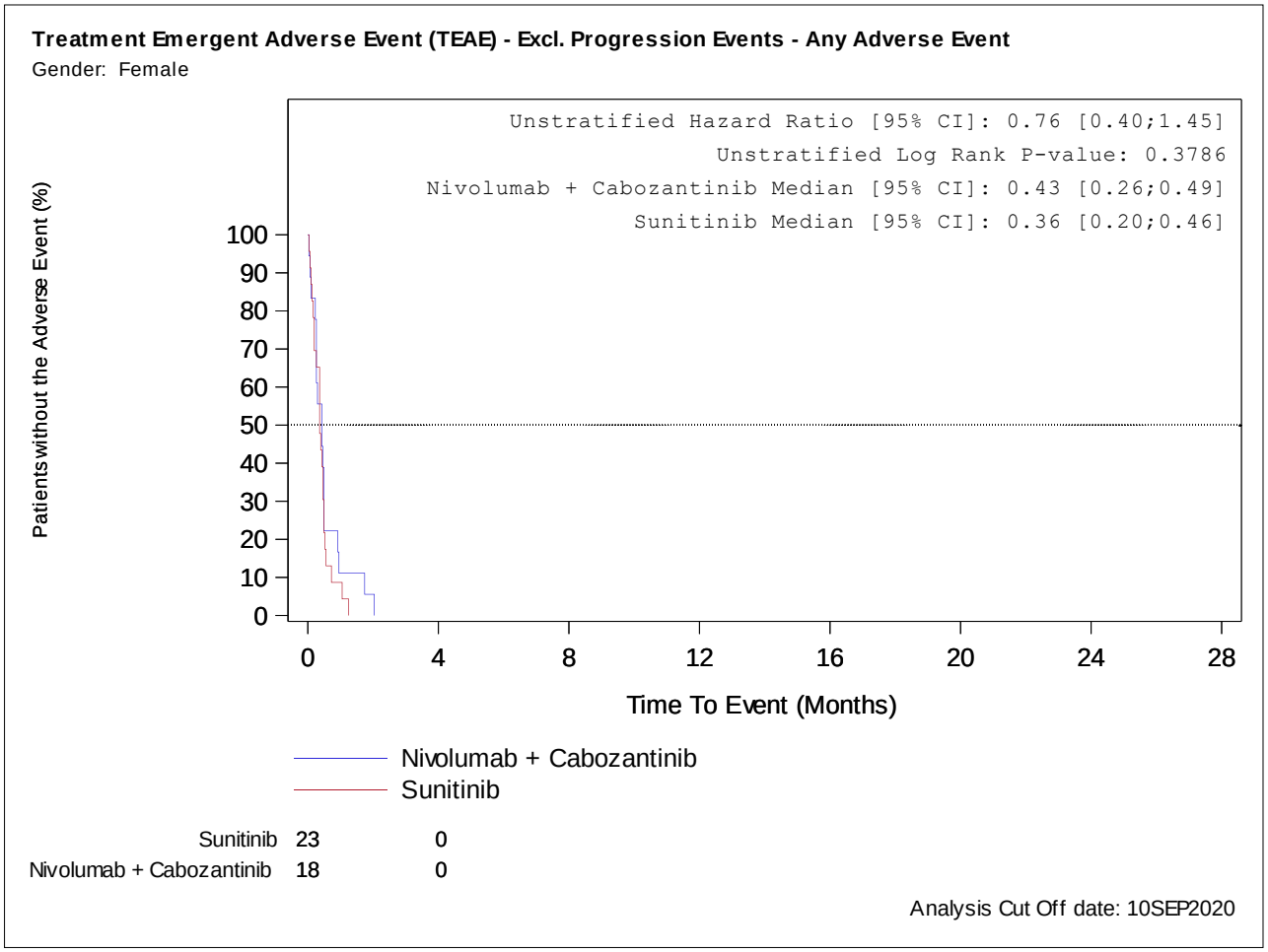

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:07:06

FIGURE 3.9.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



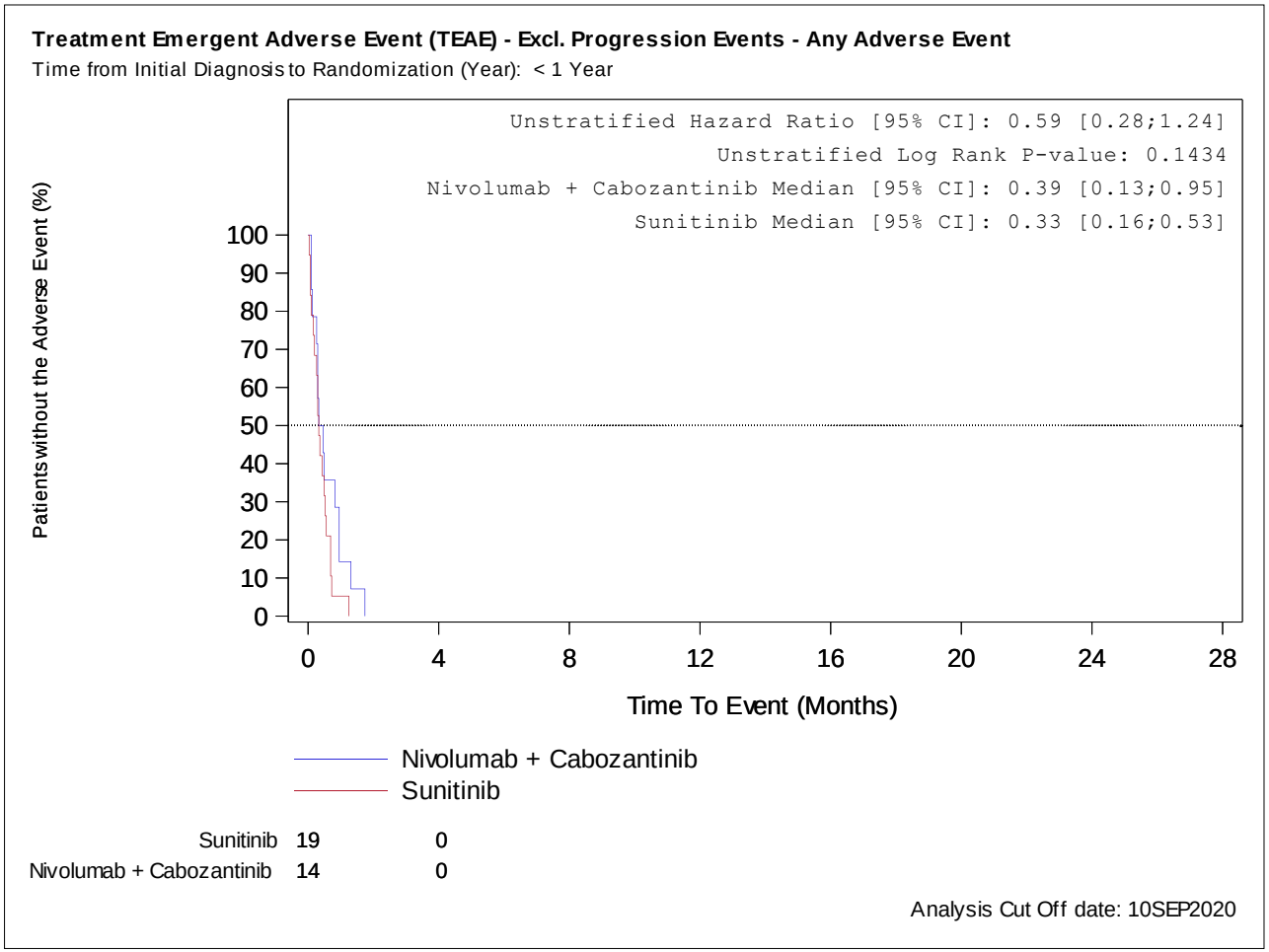

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:07:12

FIGURE 3.9.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



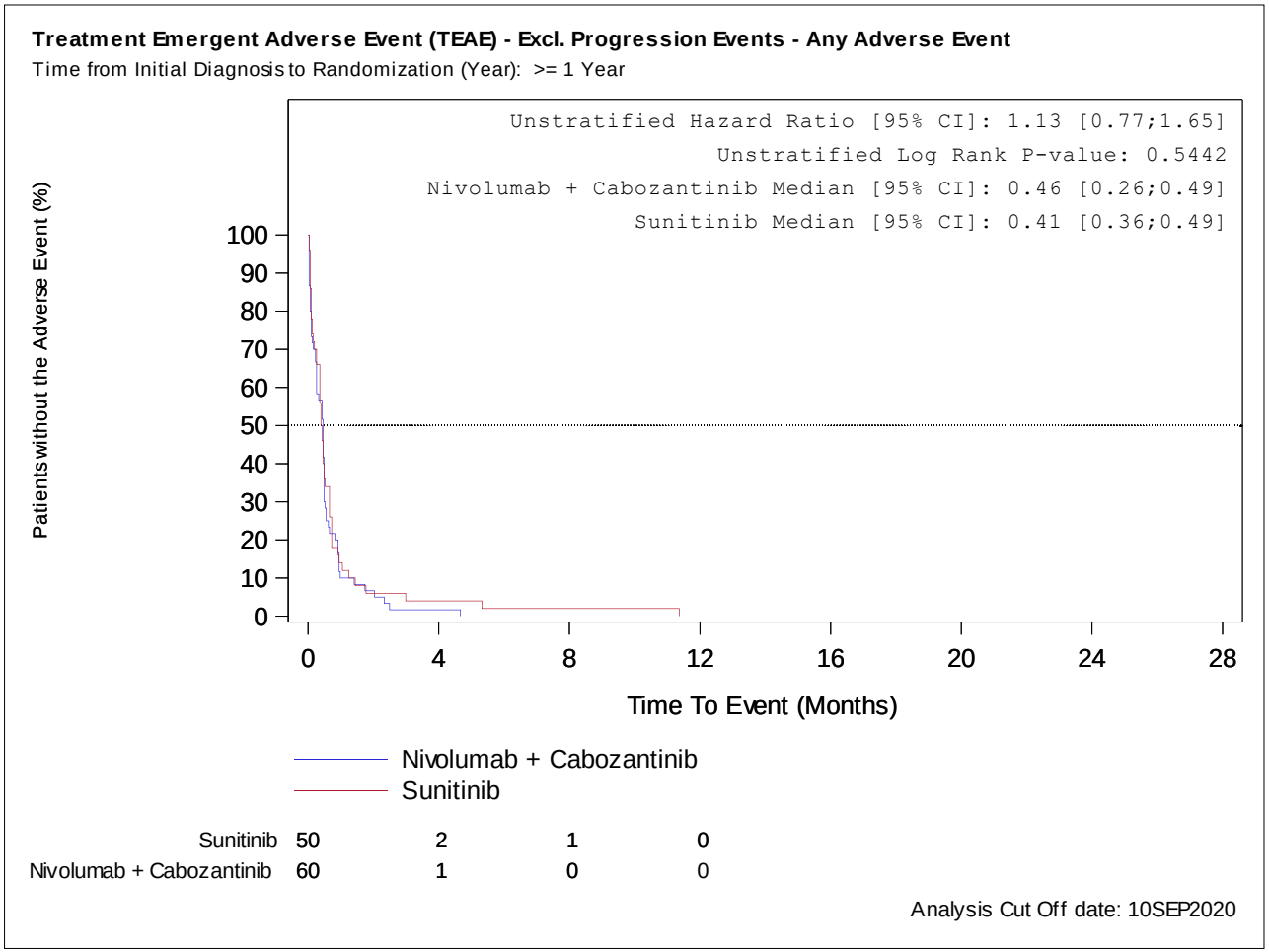

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:07:18

FIGURE 3.9.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



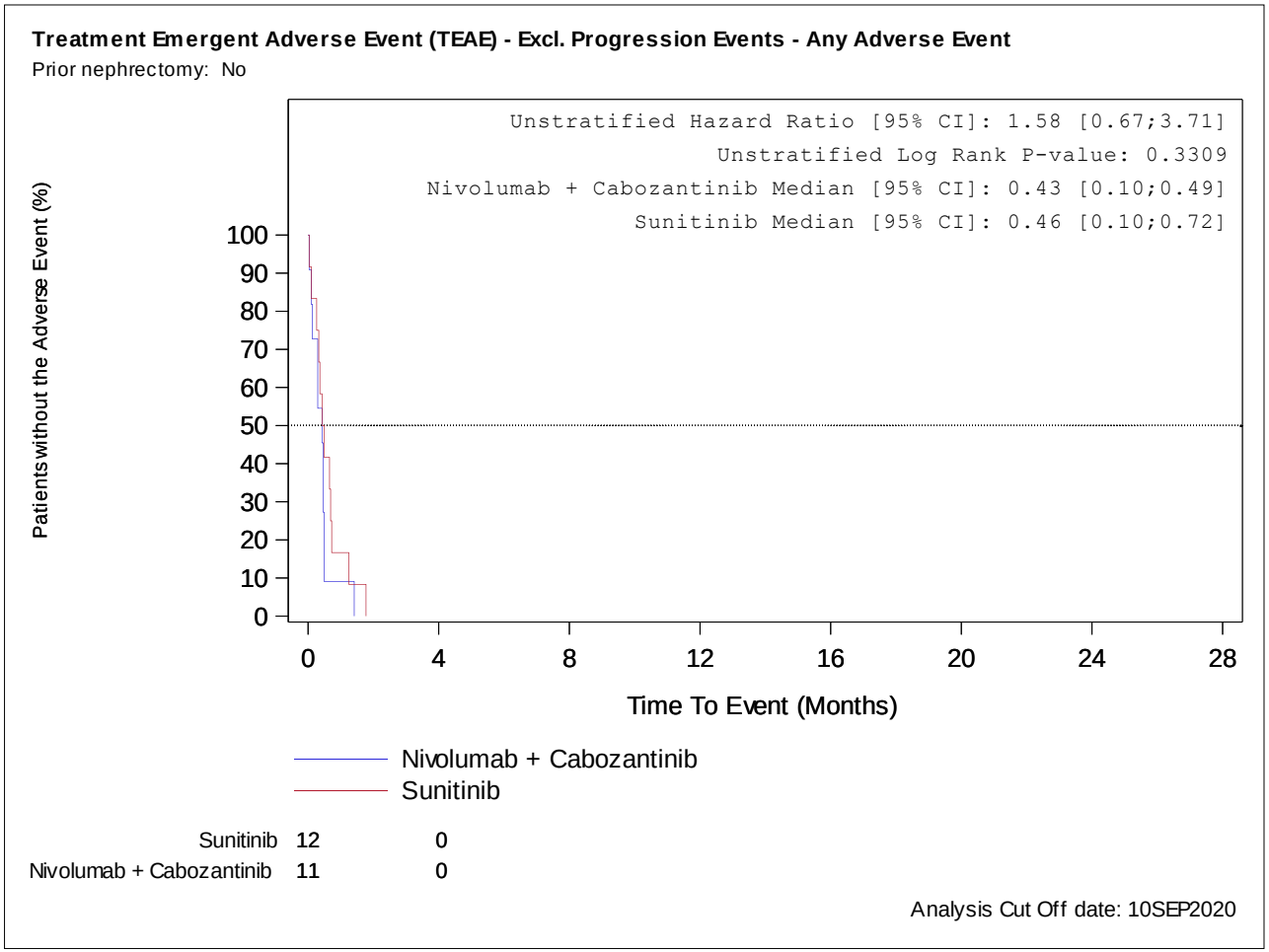

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:07:37

FIGURE 3.9.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



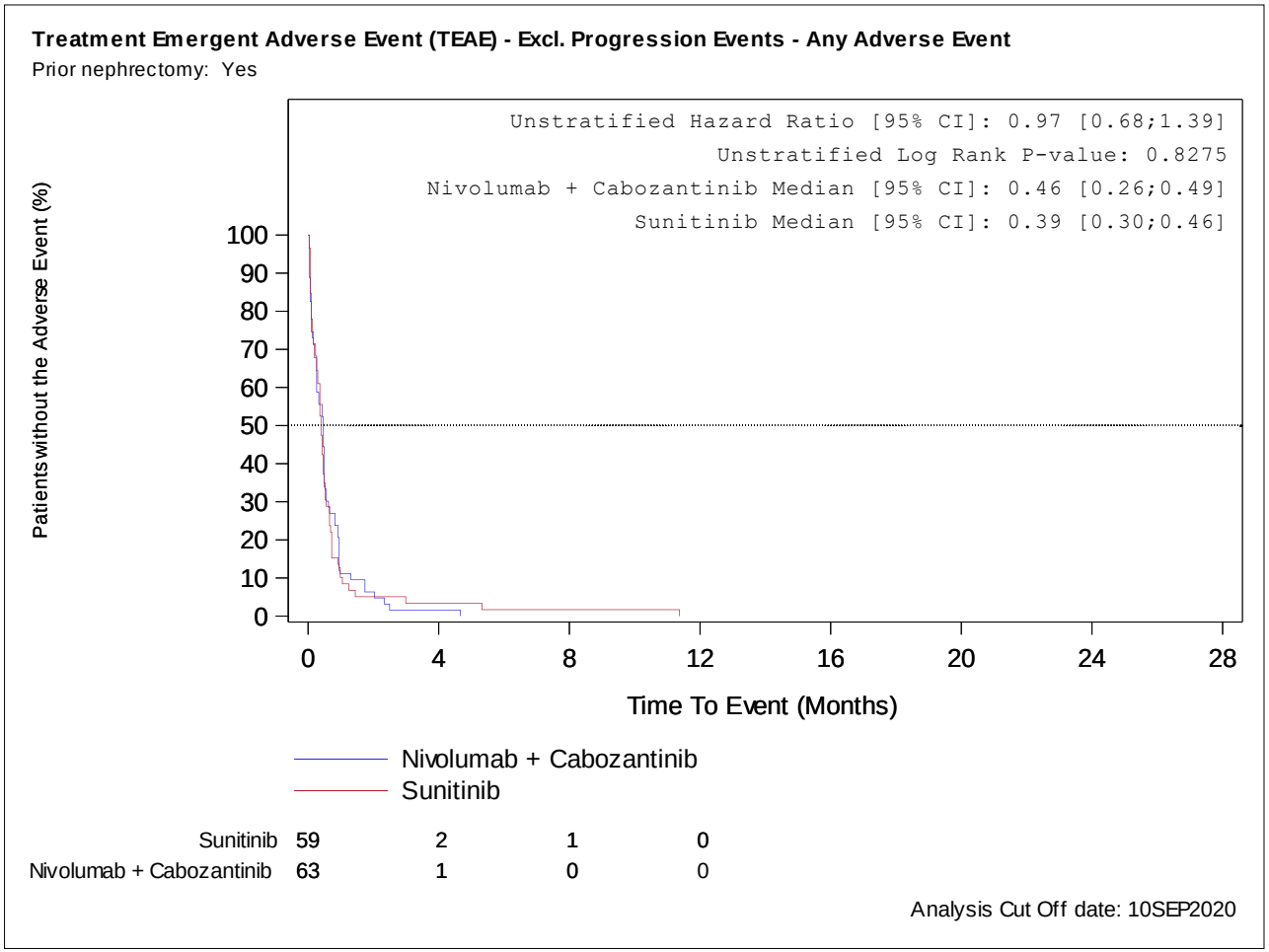

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:07:43

FIGURE 3.9.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



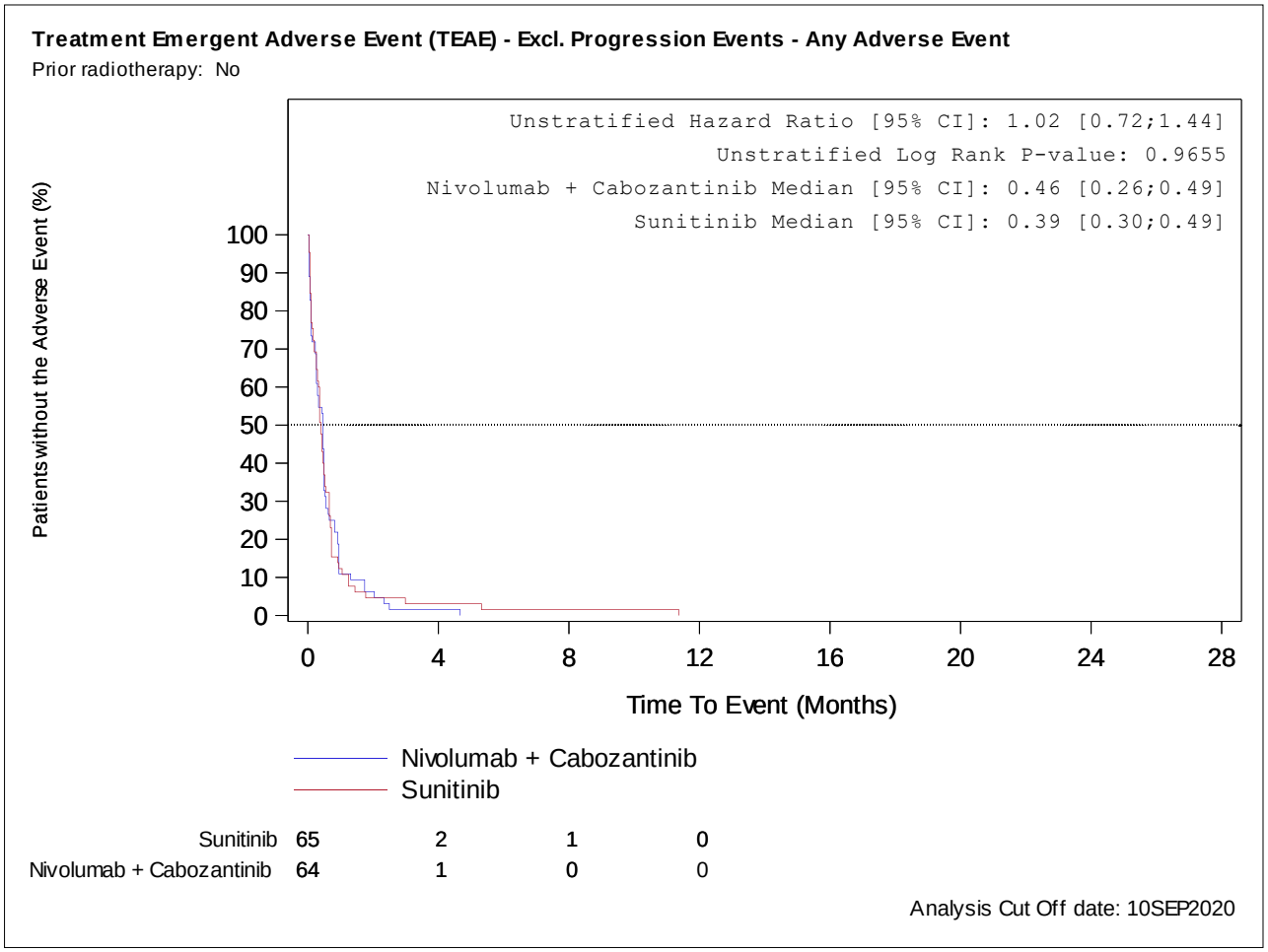

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:08:42

FIGURE 3.9.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



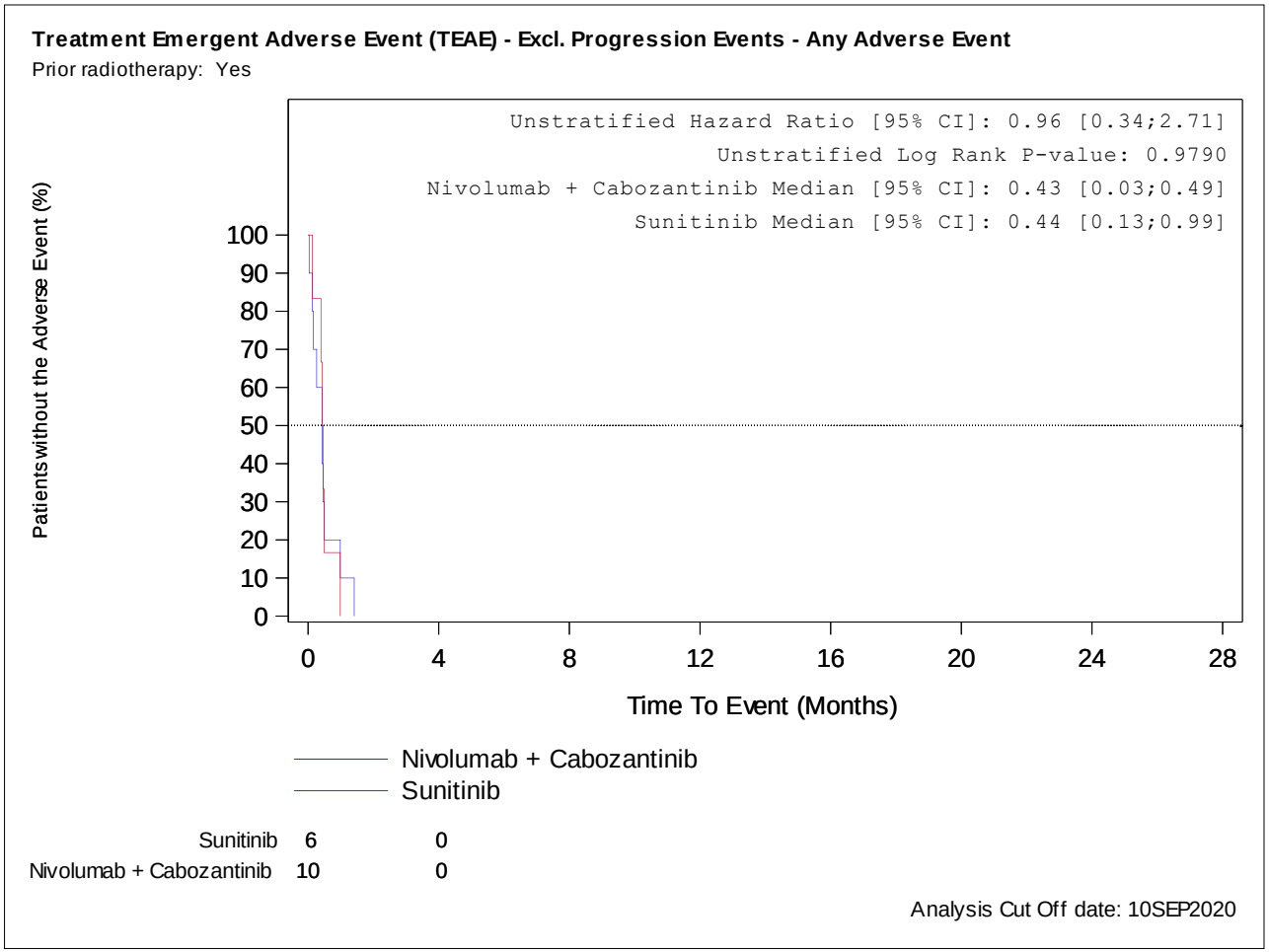

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:08:49

FIGURE 3.9.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



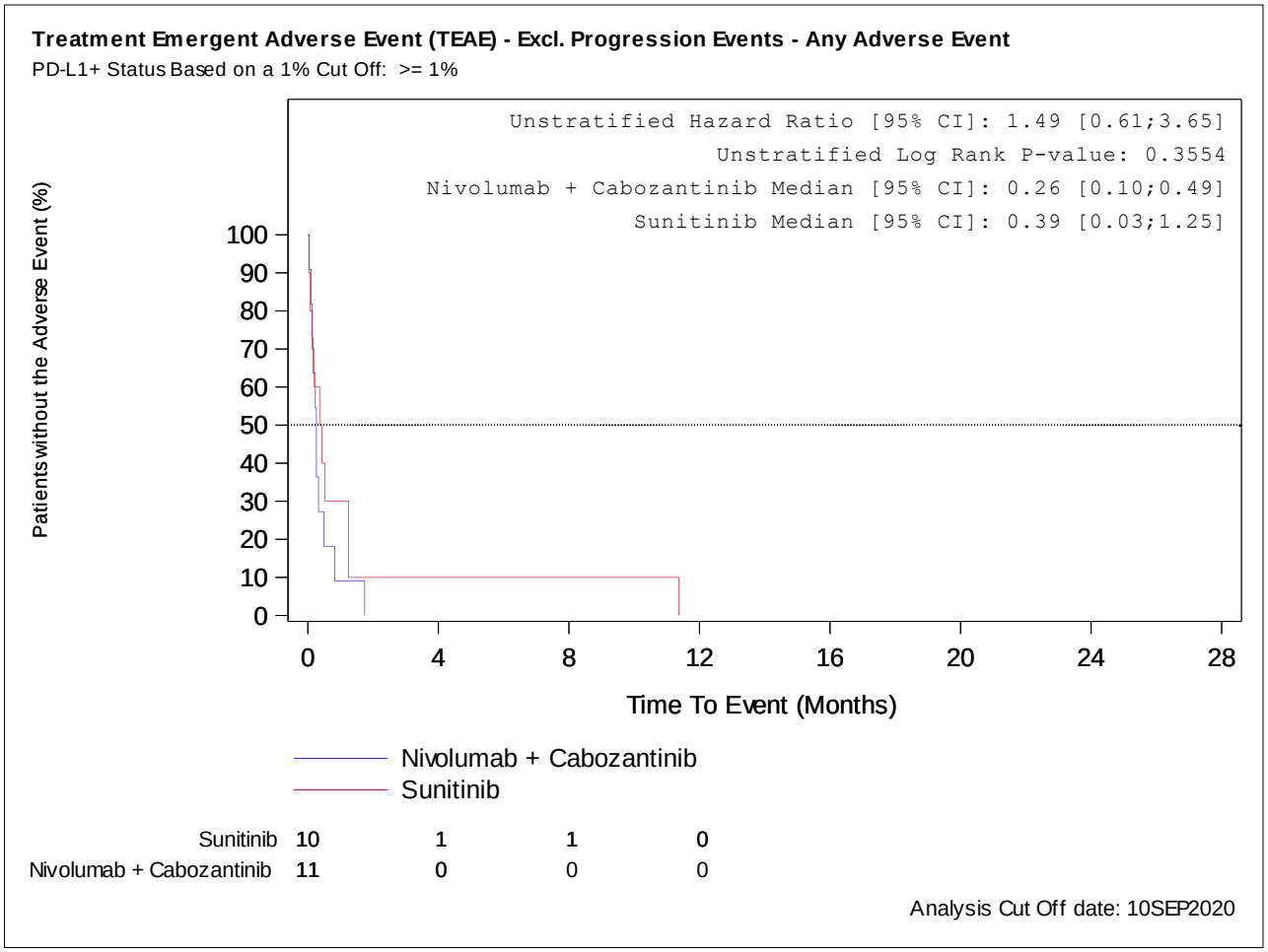

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:08:55

FIGURE 3.9.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



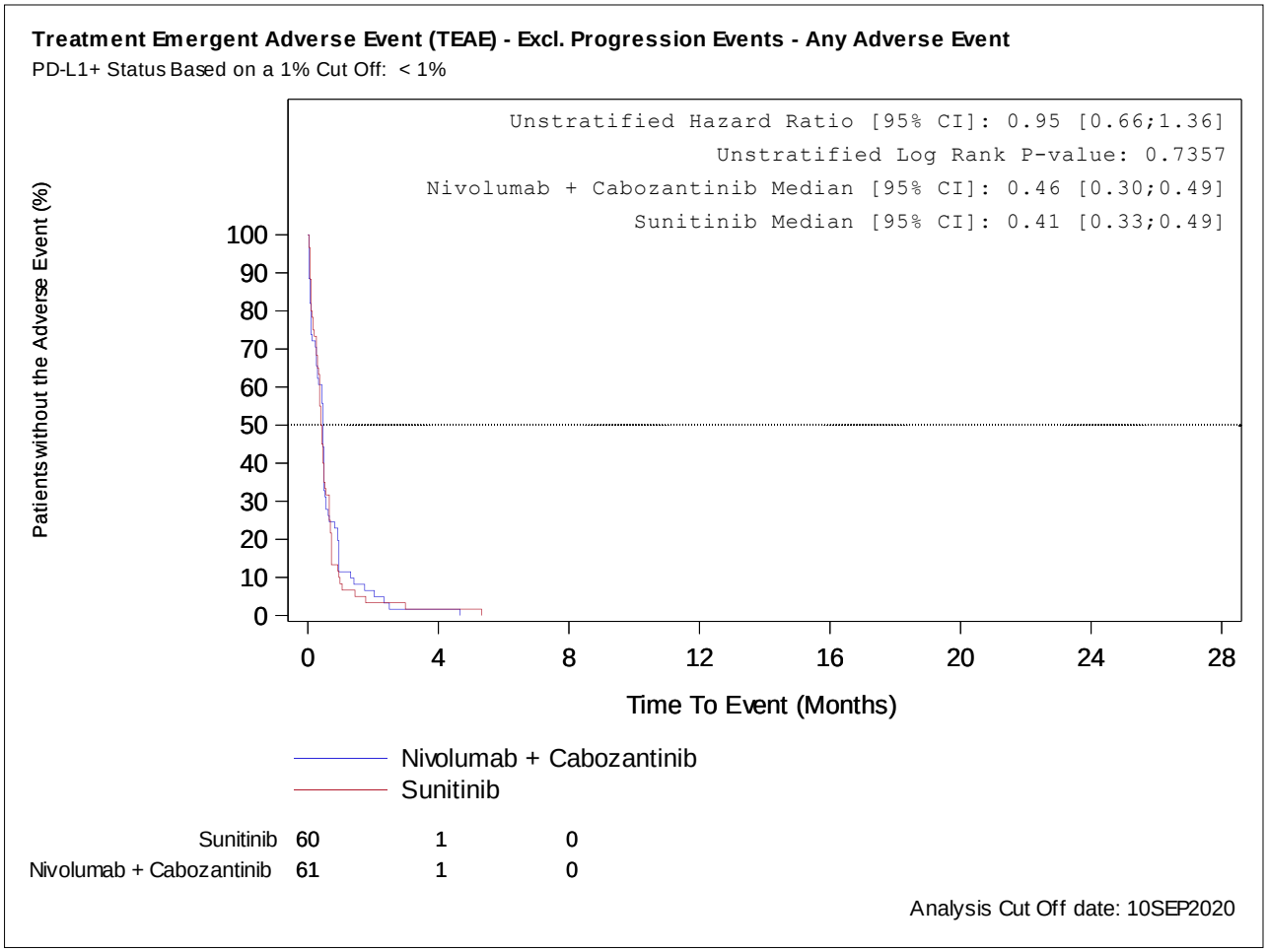

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:09:01

FIGURE 3.9.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



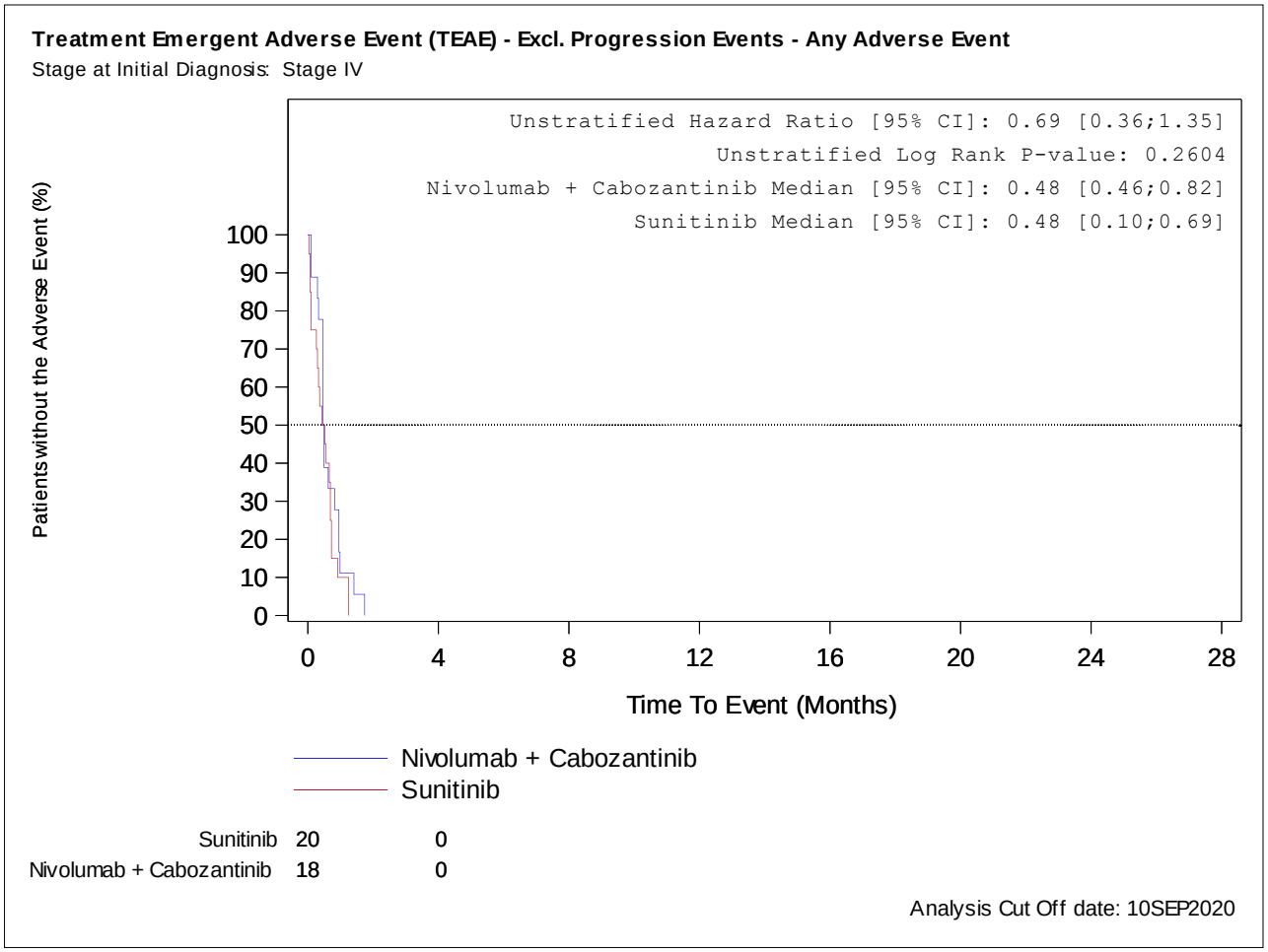

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:09:07

FIGURE 3.9.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



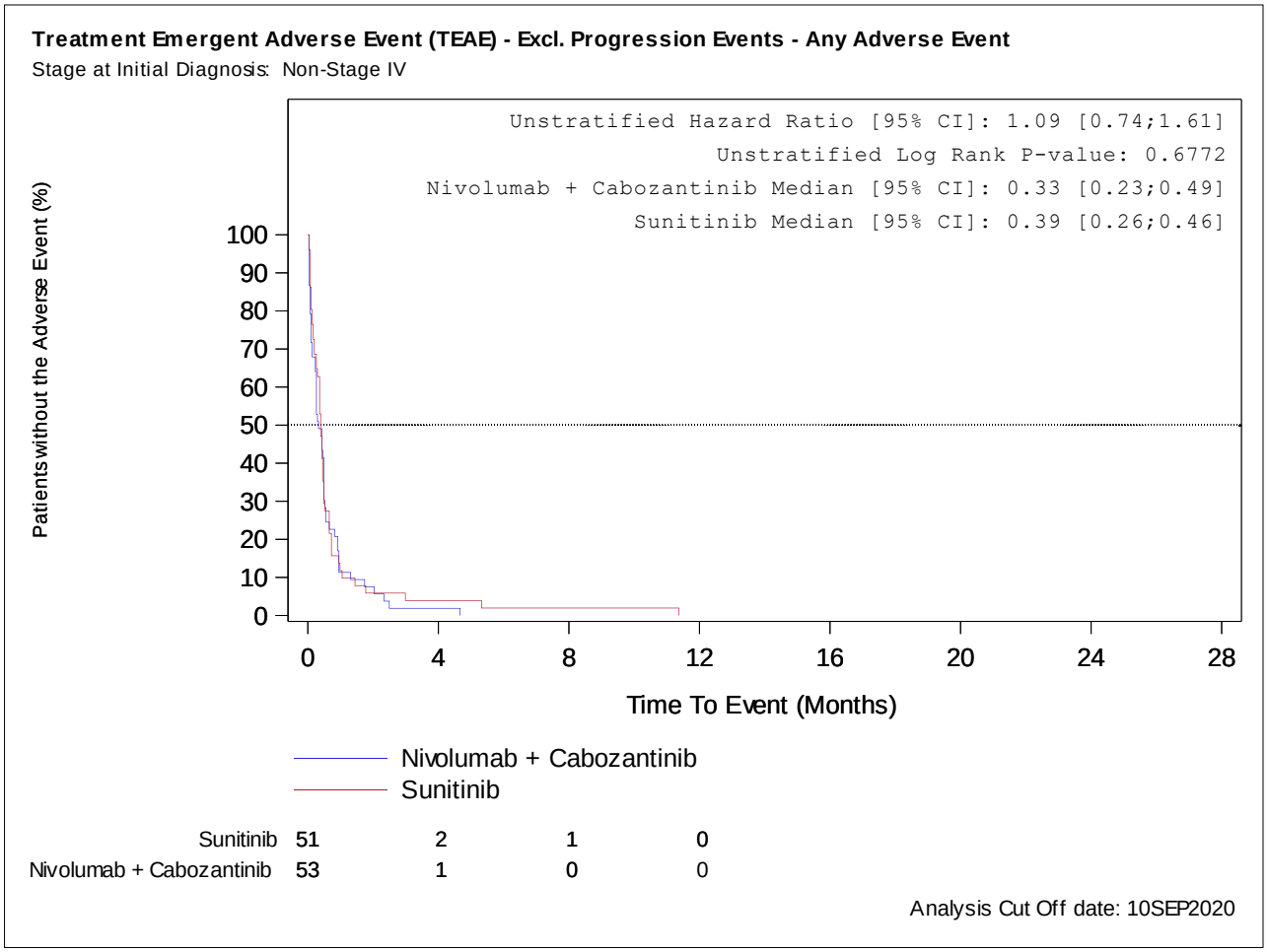

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:09:14

FIGURE 3.9.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



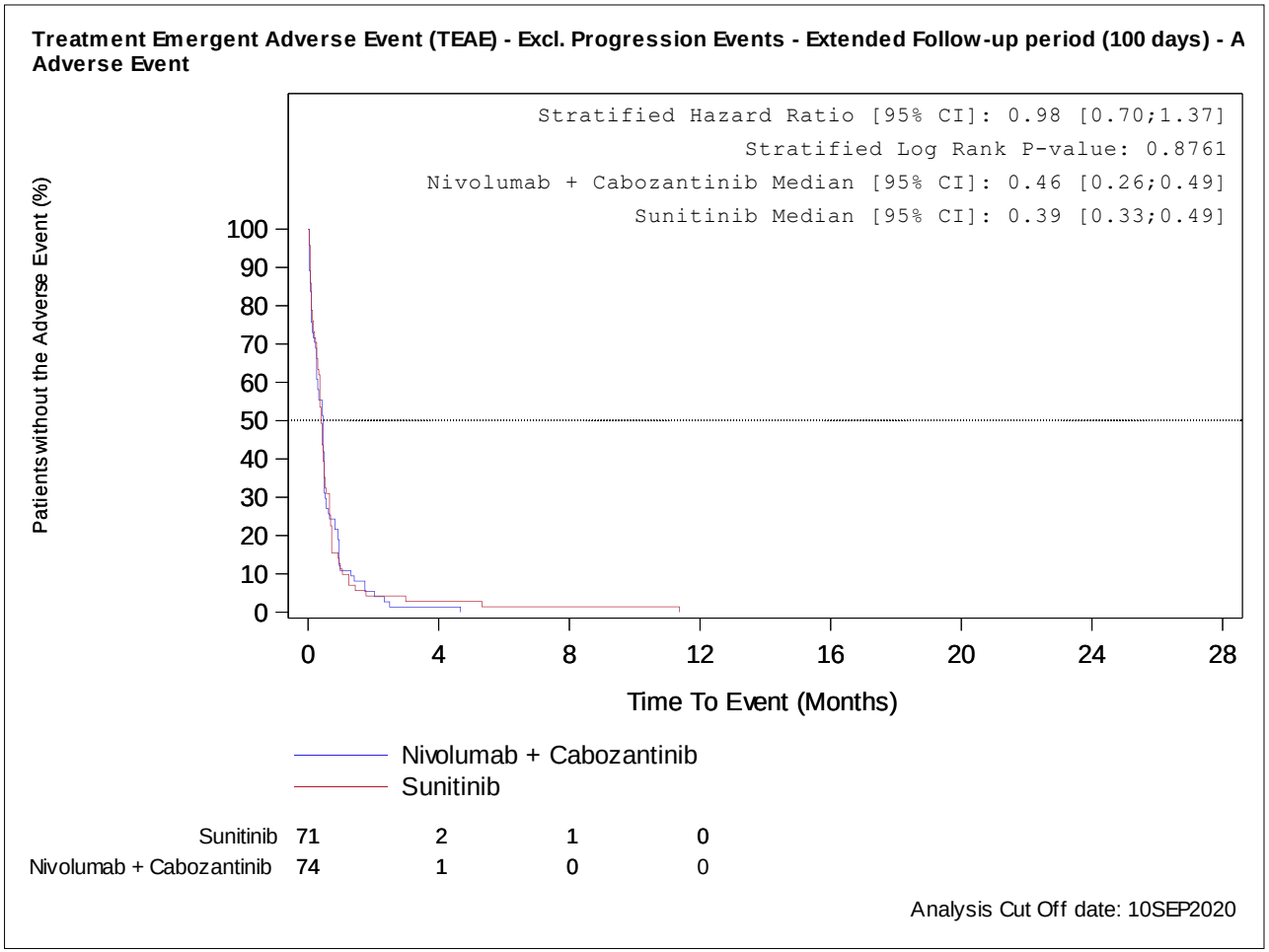

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:09:45

FIGURE 3.9.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



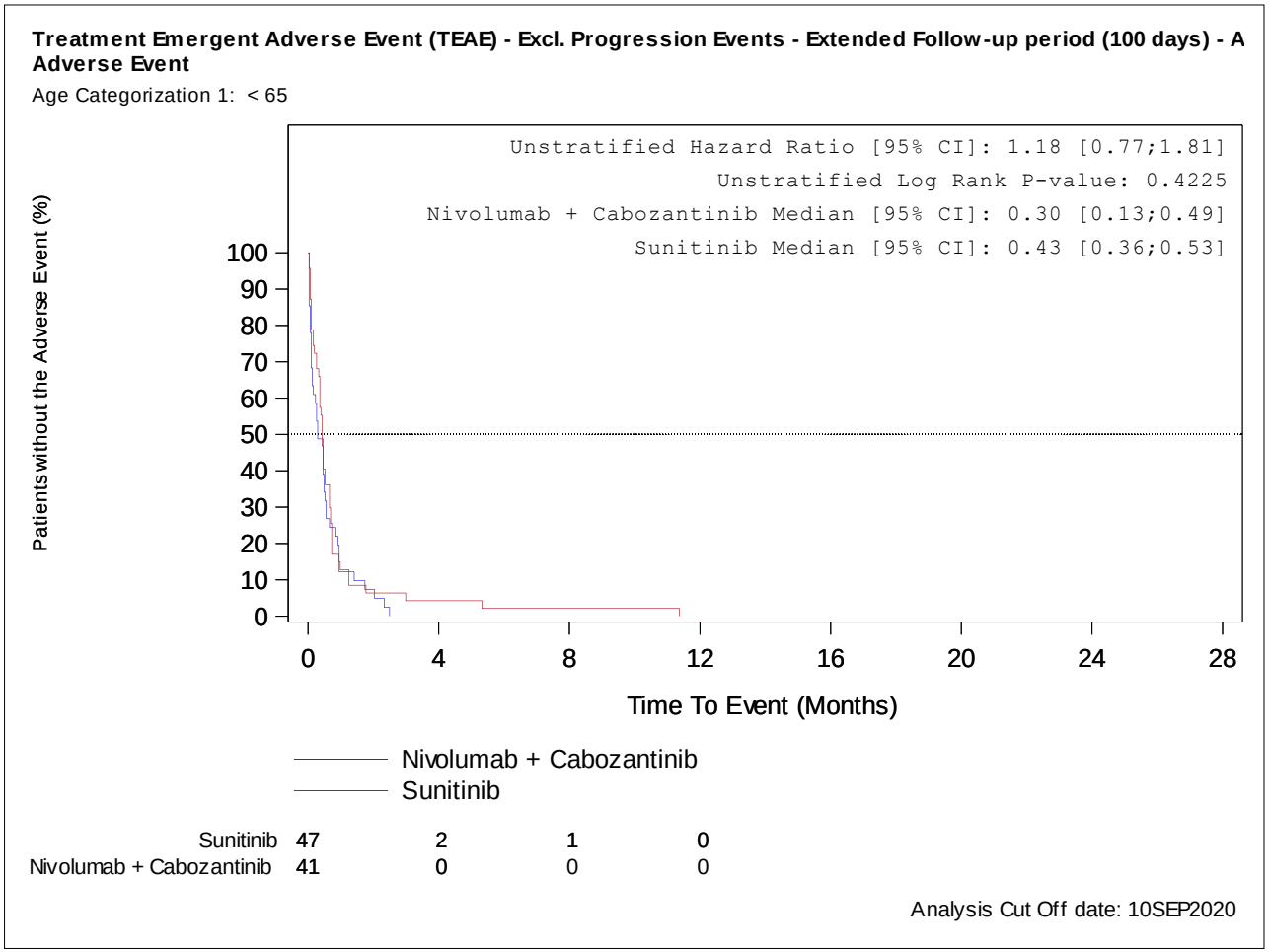

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:09:51

FIGURE 3.10.1: Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



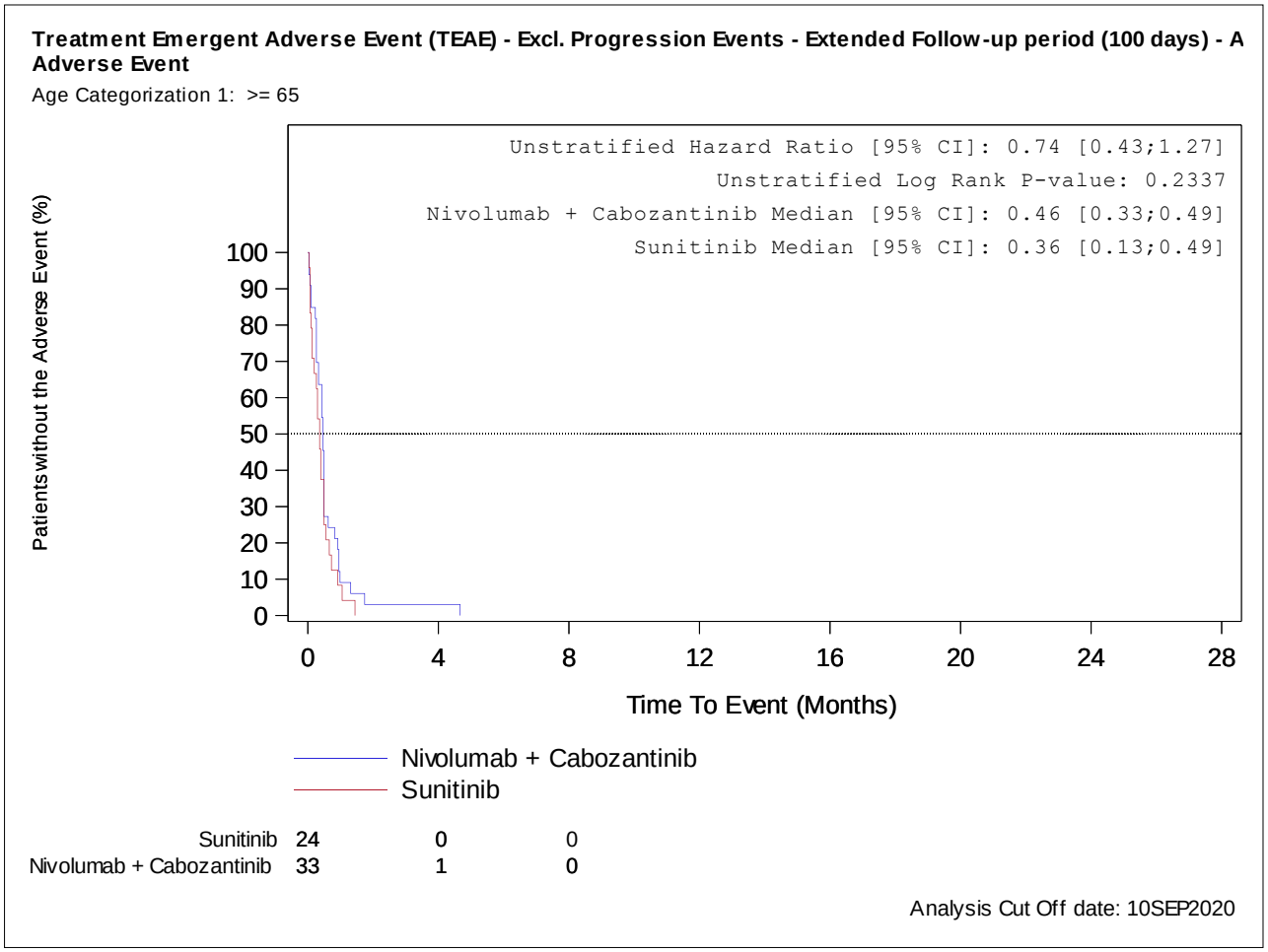

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:13:22

FIGURE 3.10.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



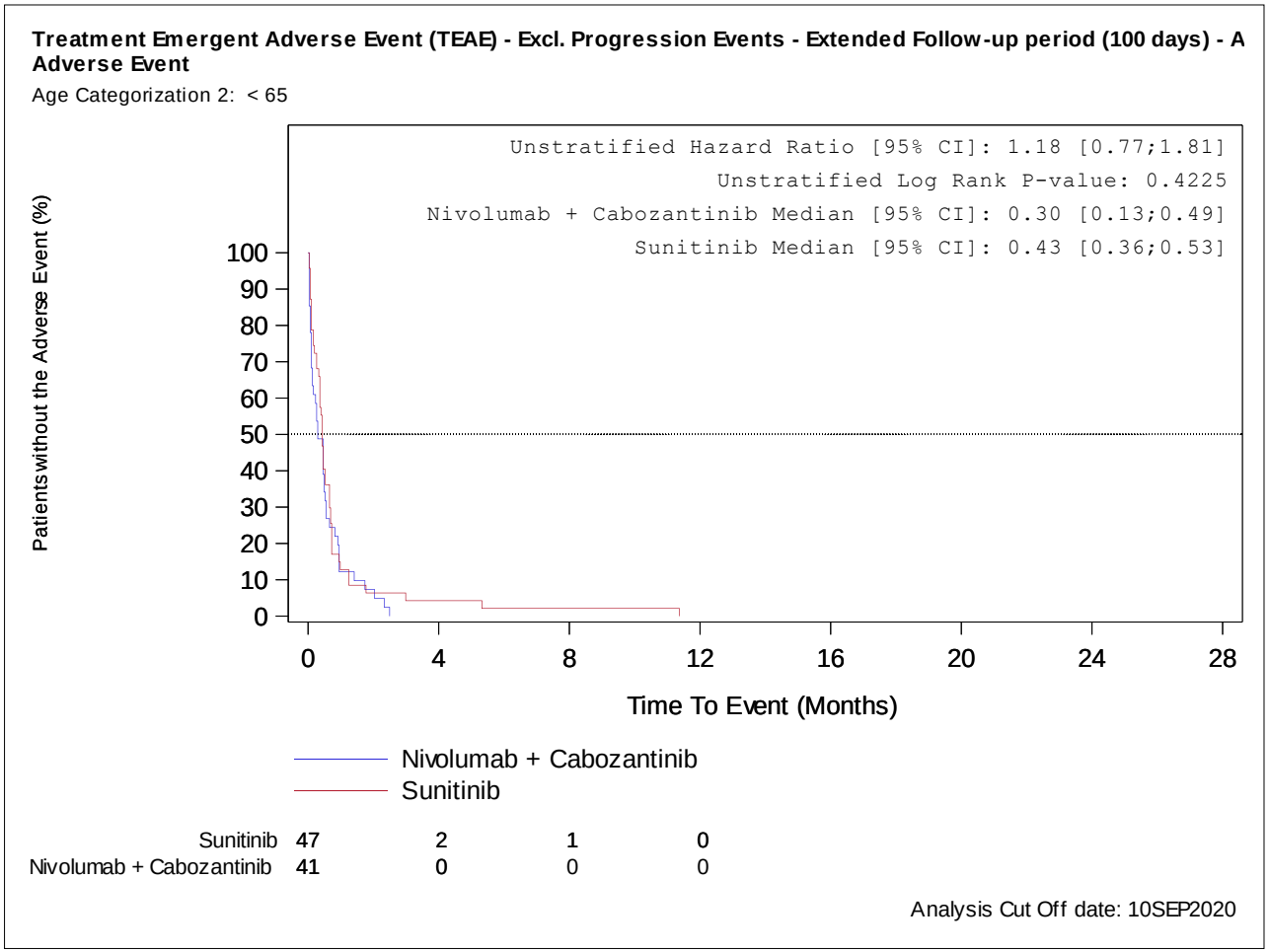

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:13:25

FIGURE 3.10.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



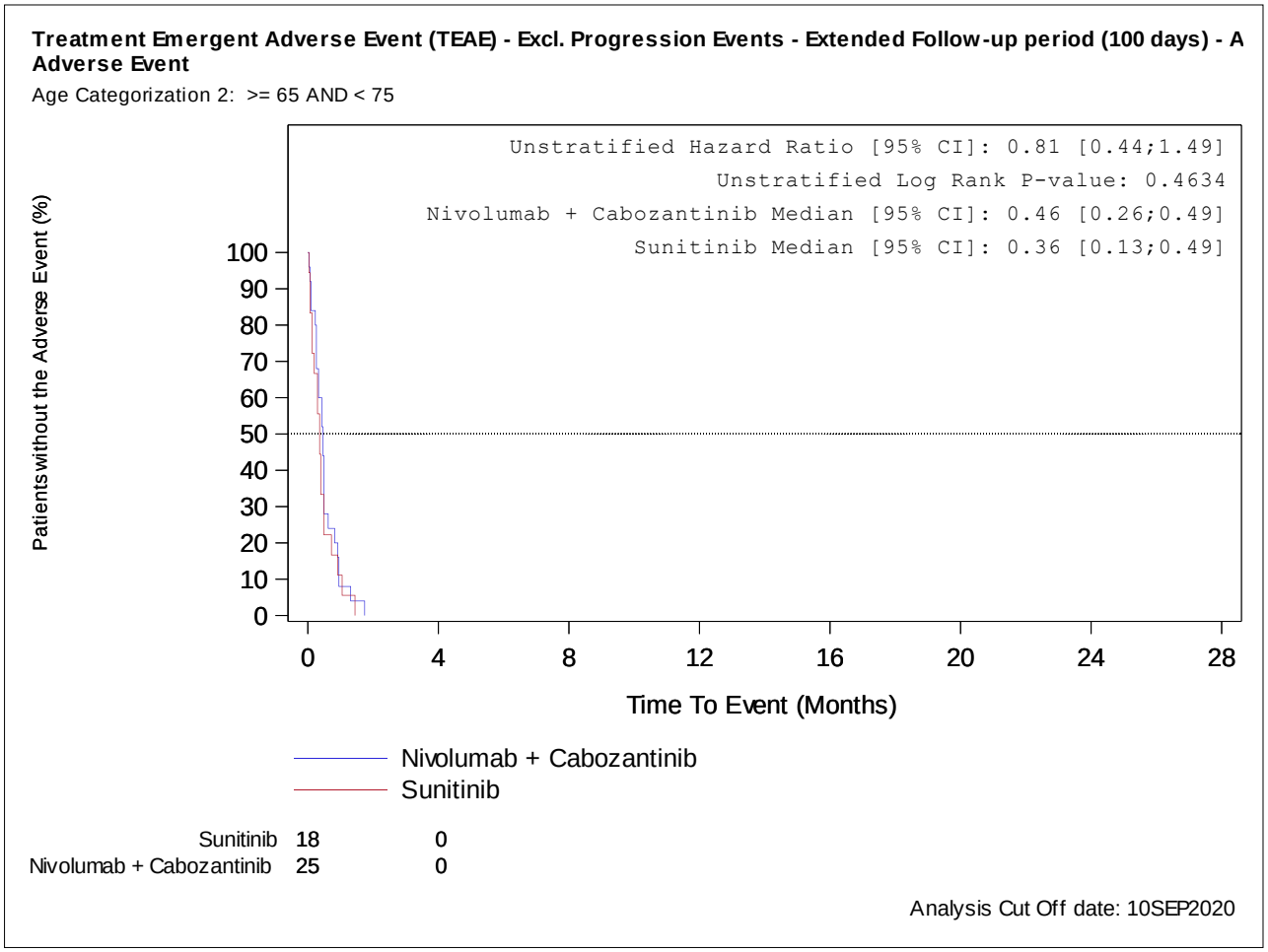

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:13:31

FIGURE 3.10.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



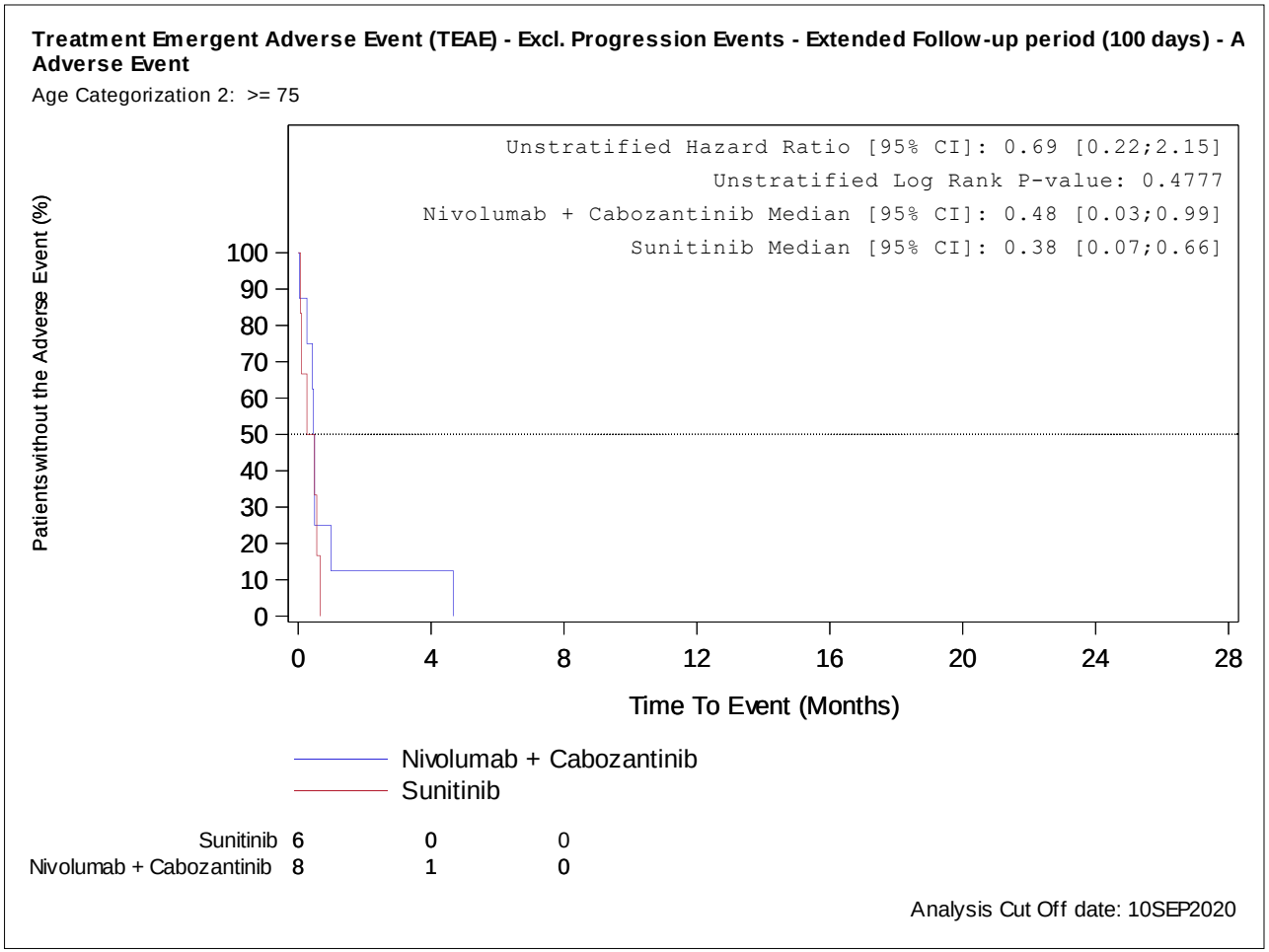

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:13:37

FIGURE 3.10.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



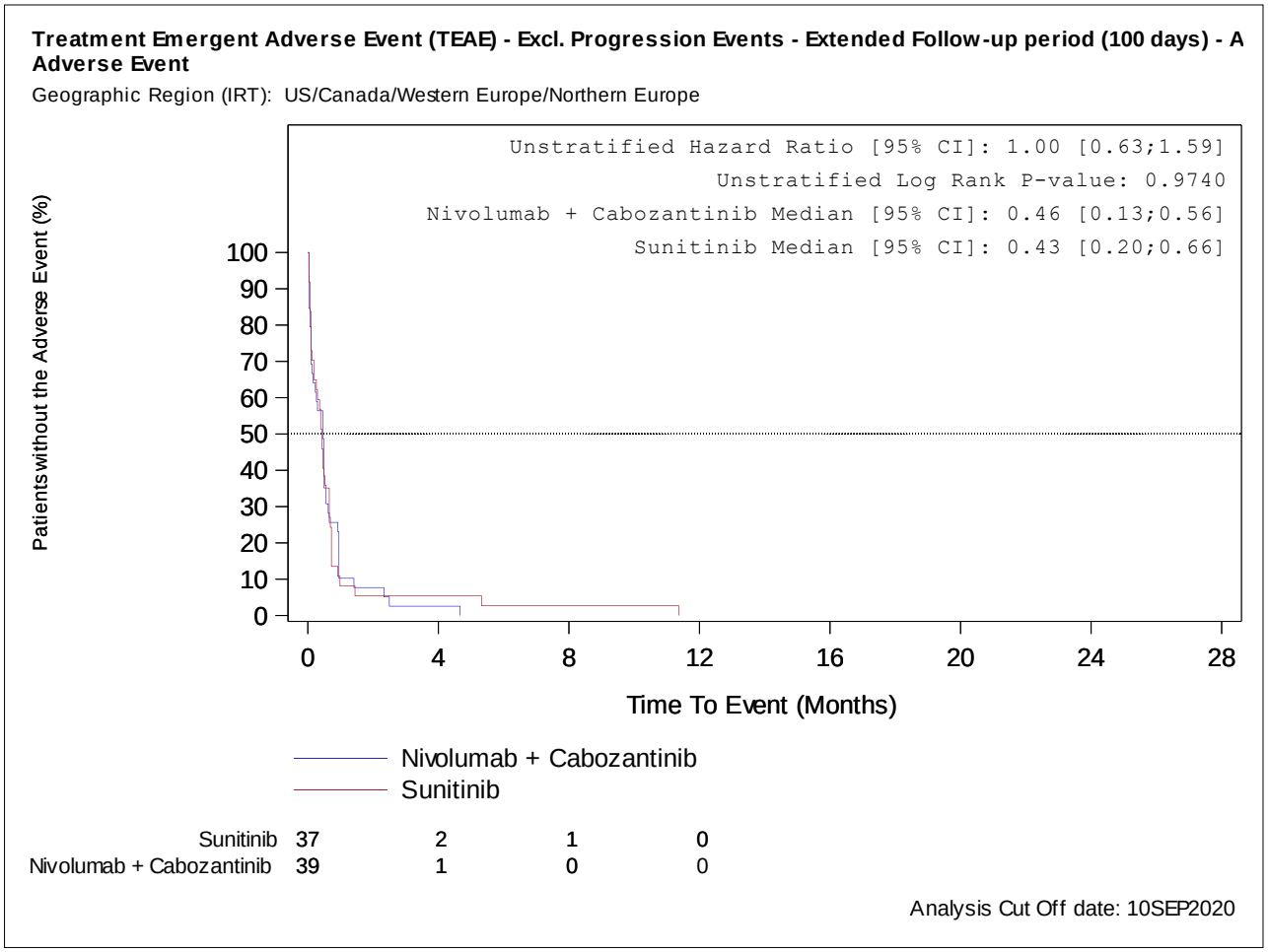

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:13:43

FIGURE 3.10.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



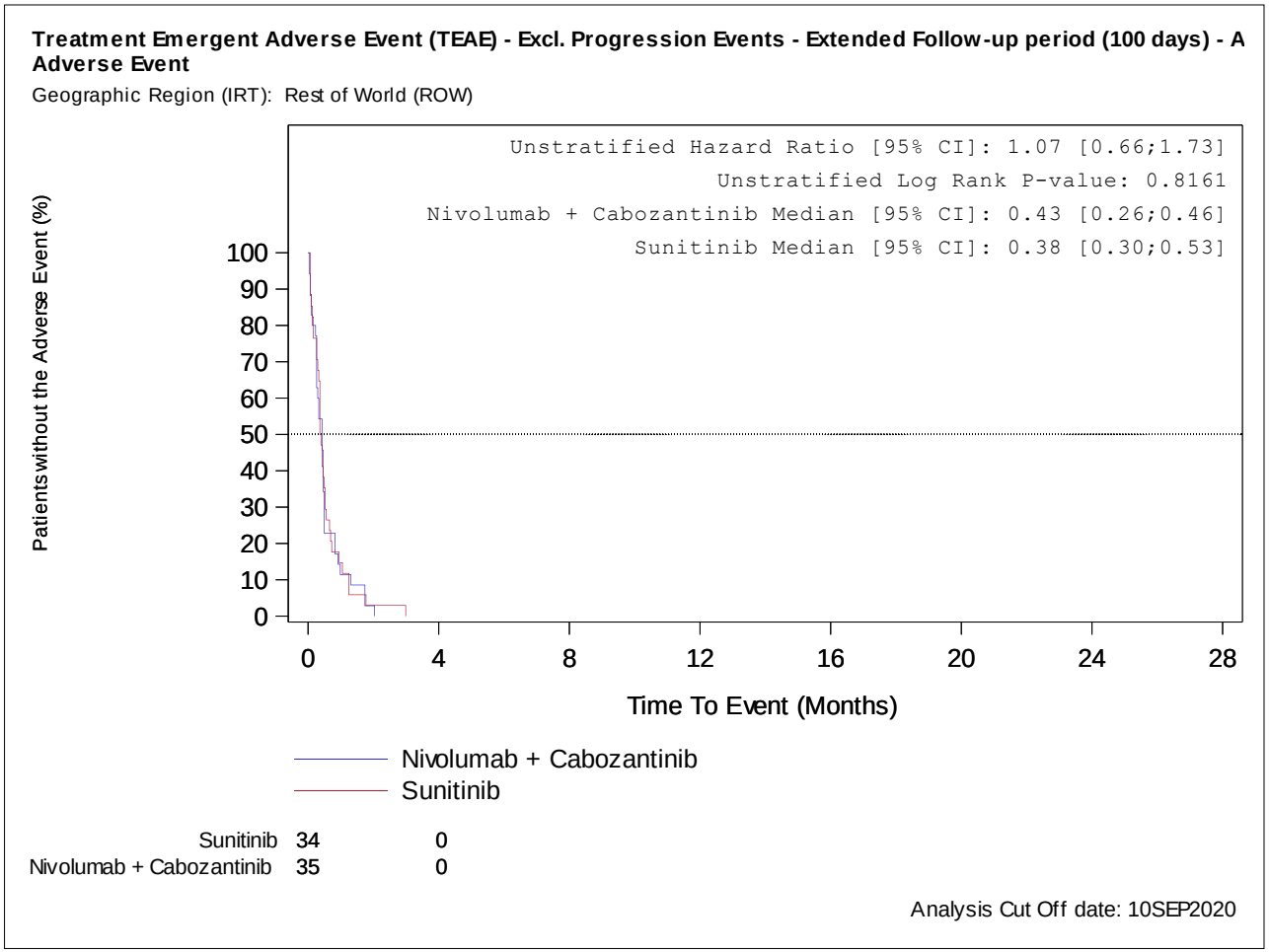

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:13:48

FIGURE 3.10.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



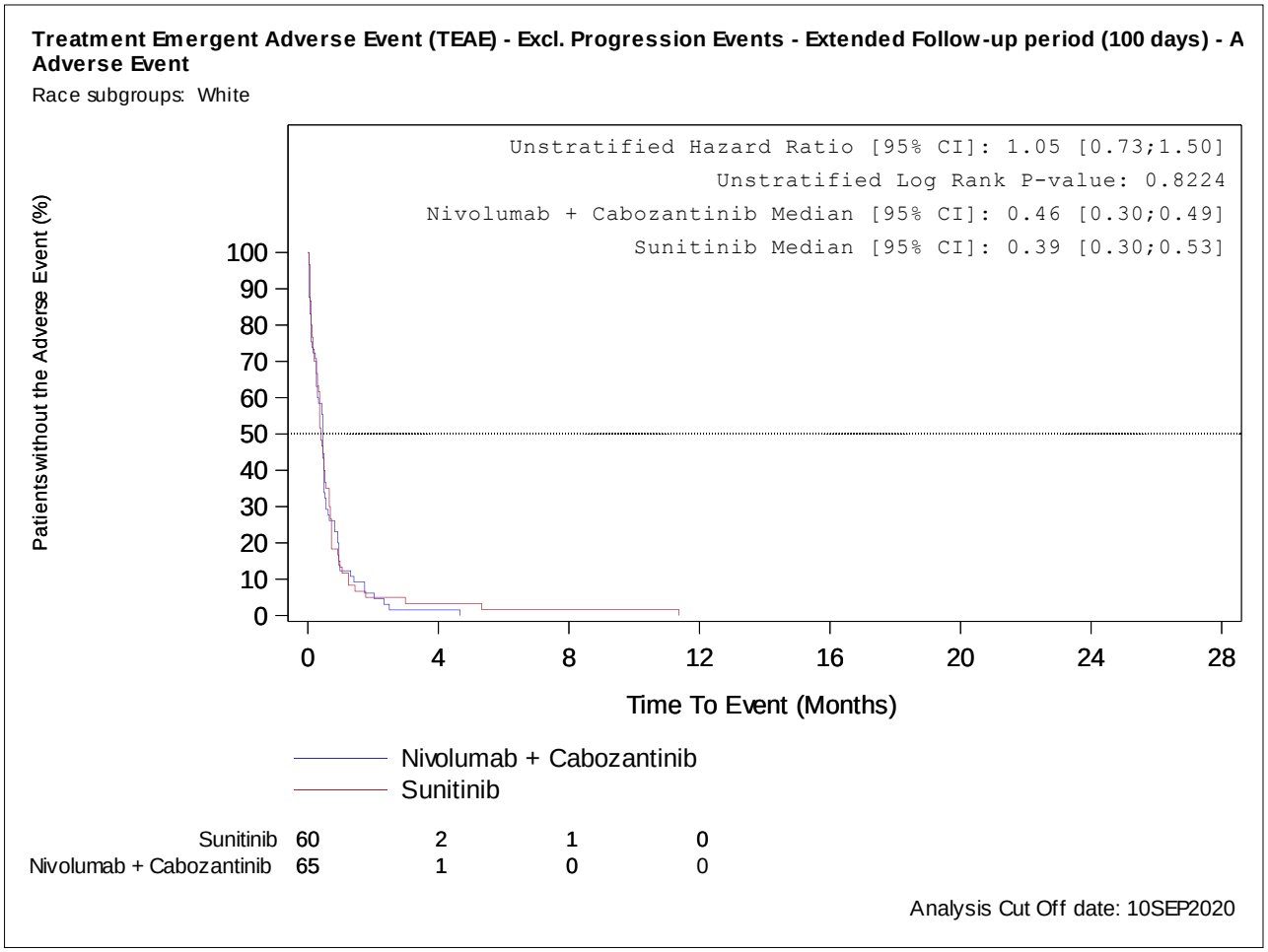

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:13:54

FIGURE 3.10.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



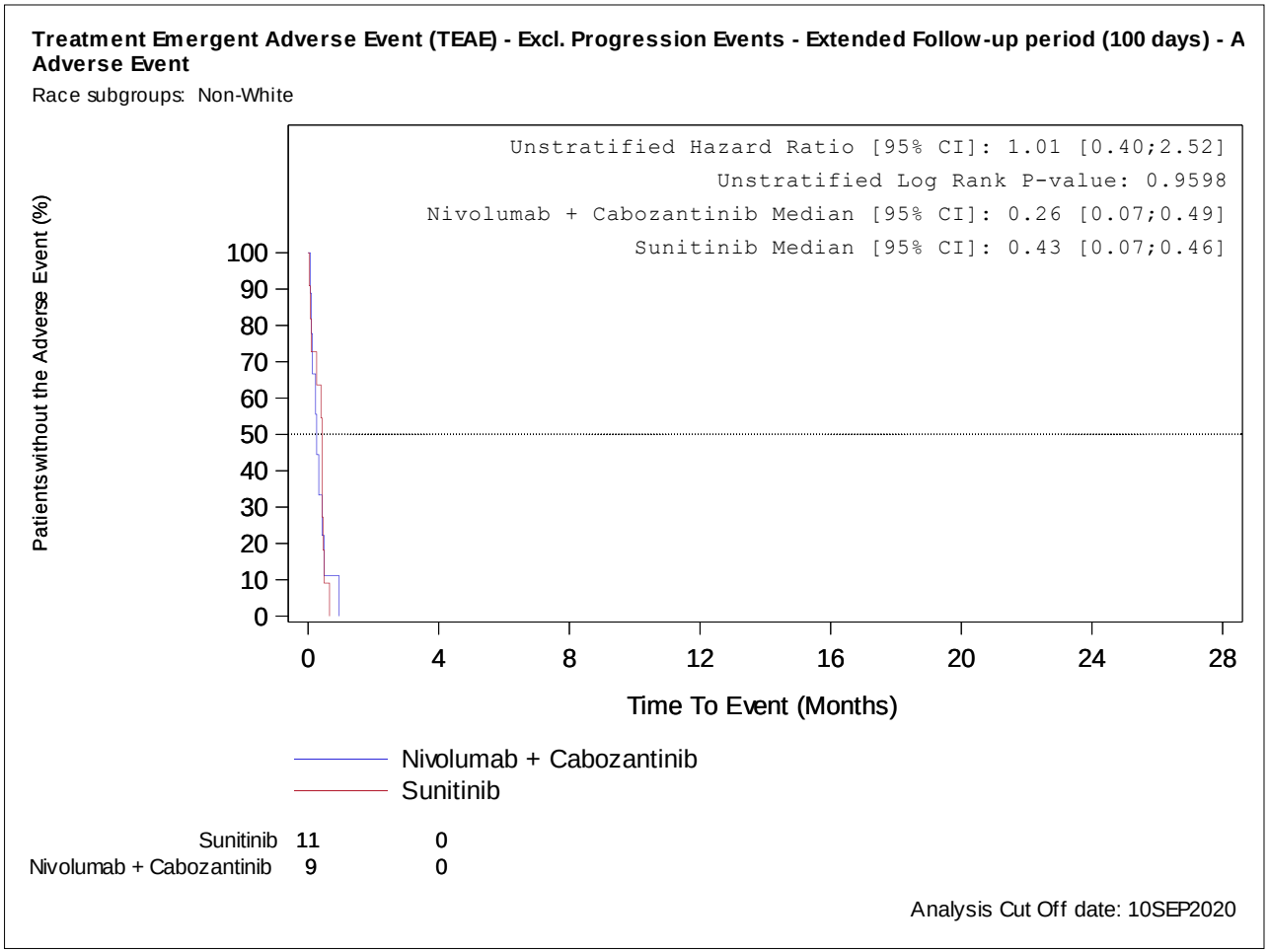

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:14:01

FIGURE 3.10.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



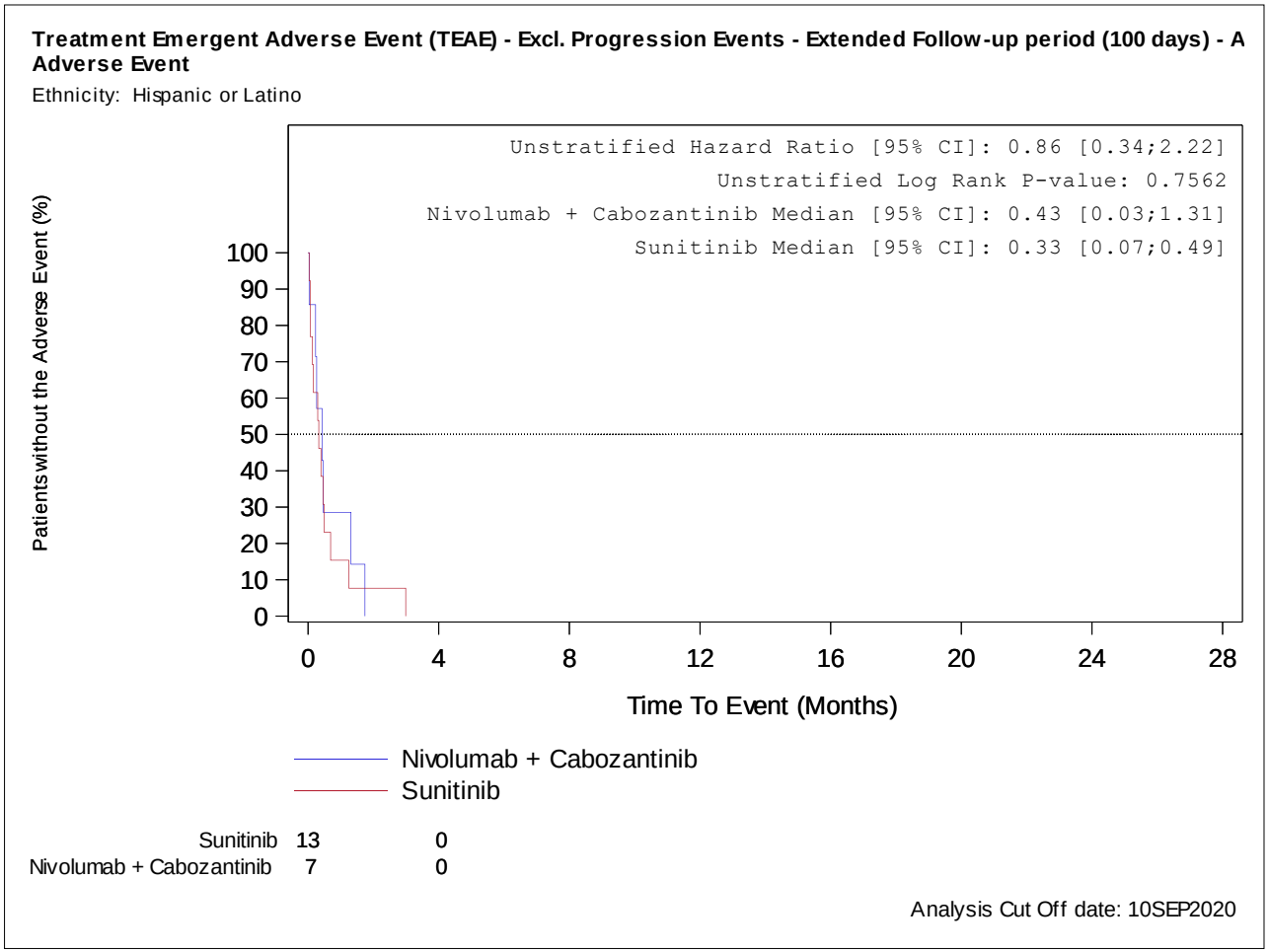

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:14:07

FIGURE 3.10.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



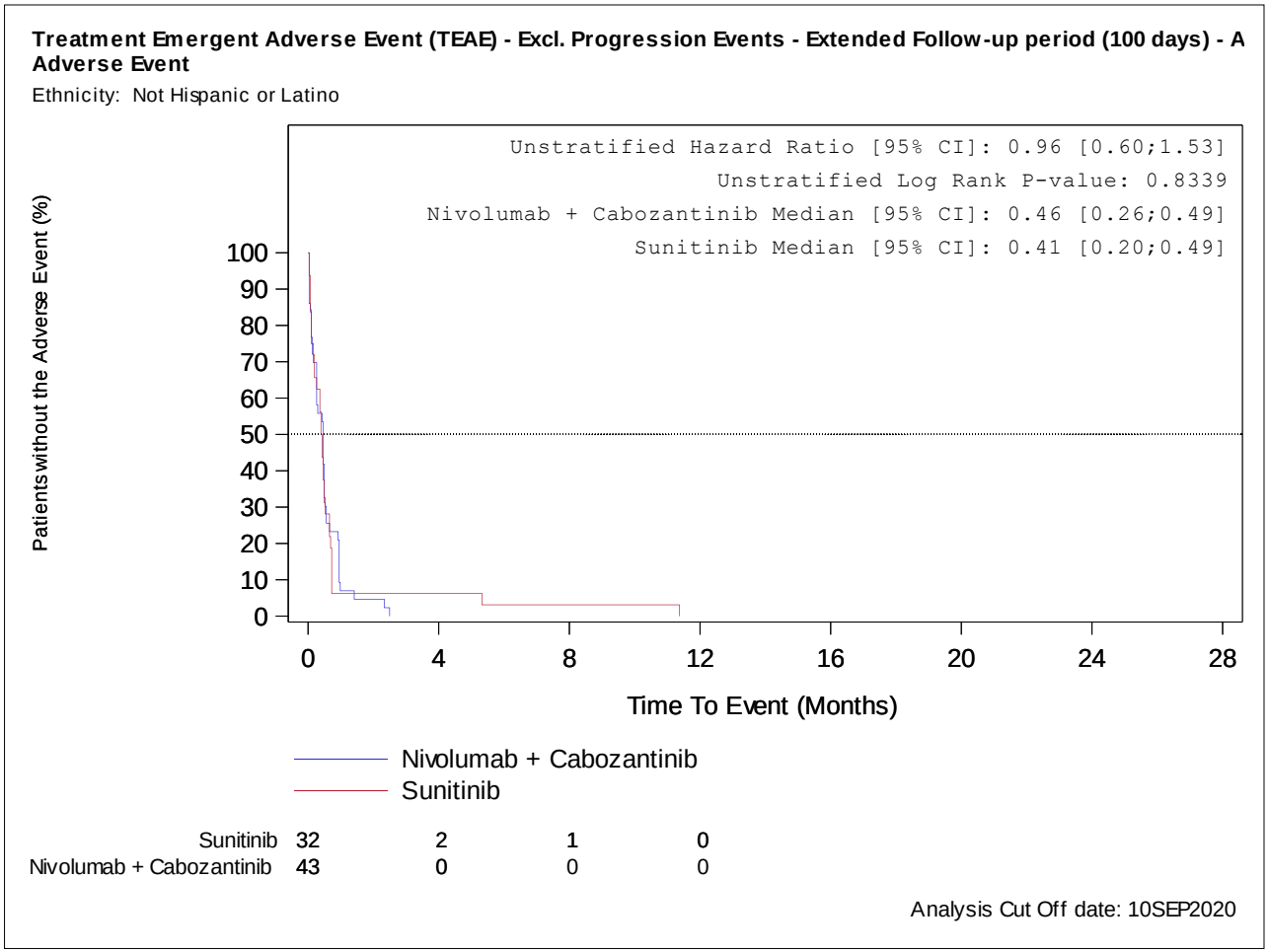

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:14:13

FIGURE 3.10.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



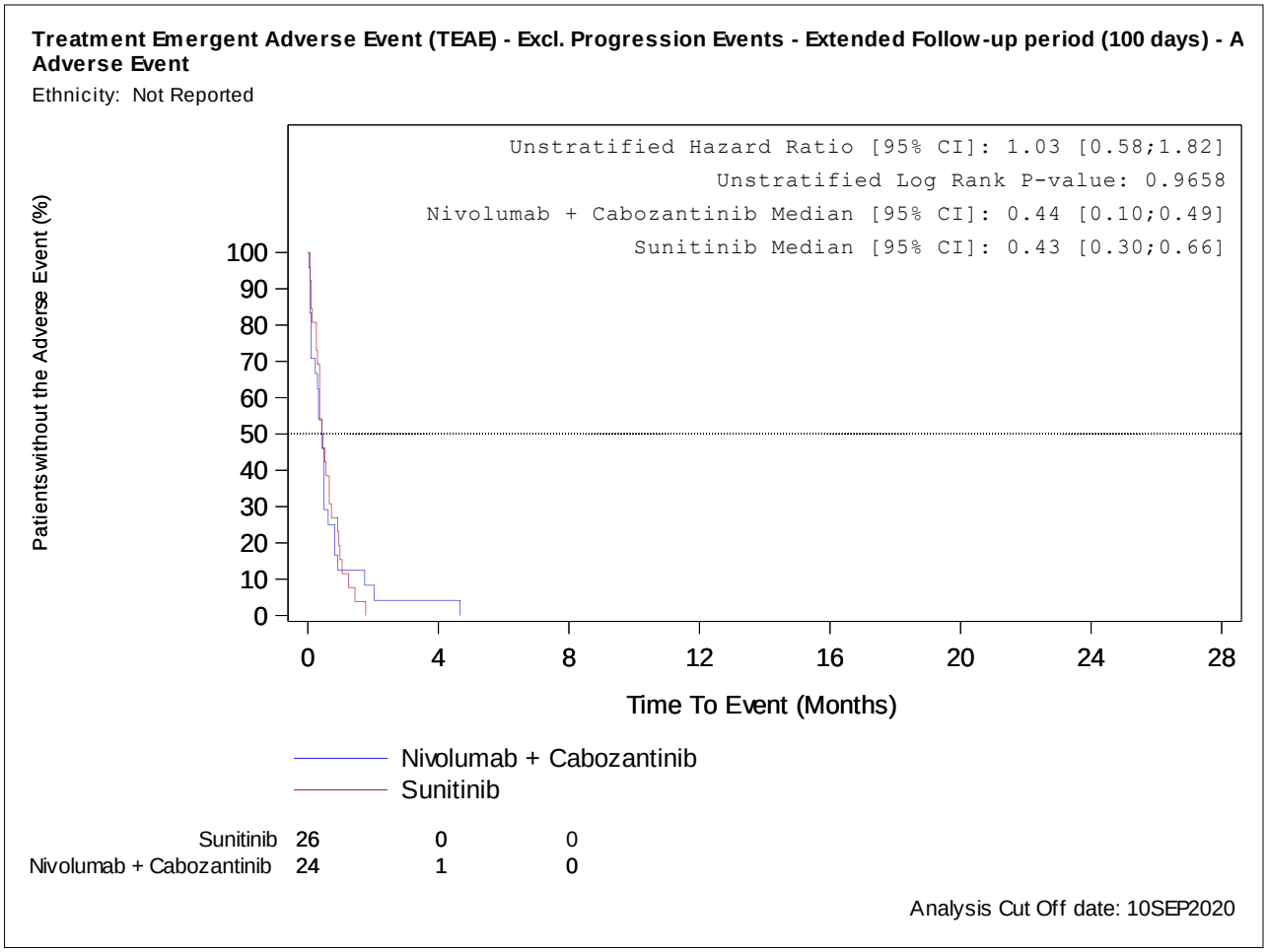

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:14:19

FIGURE 3.10.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



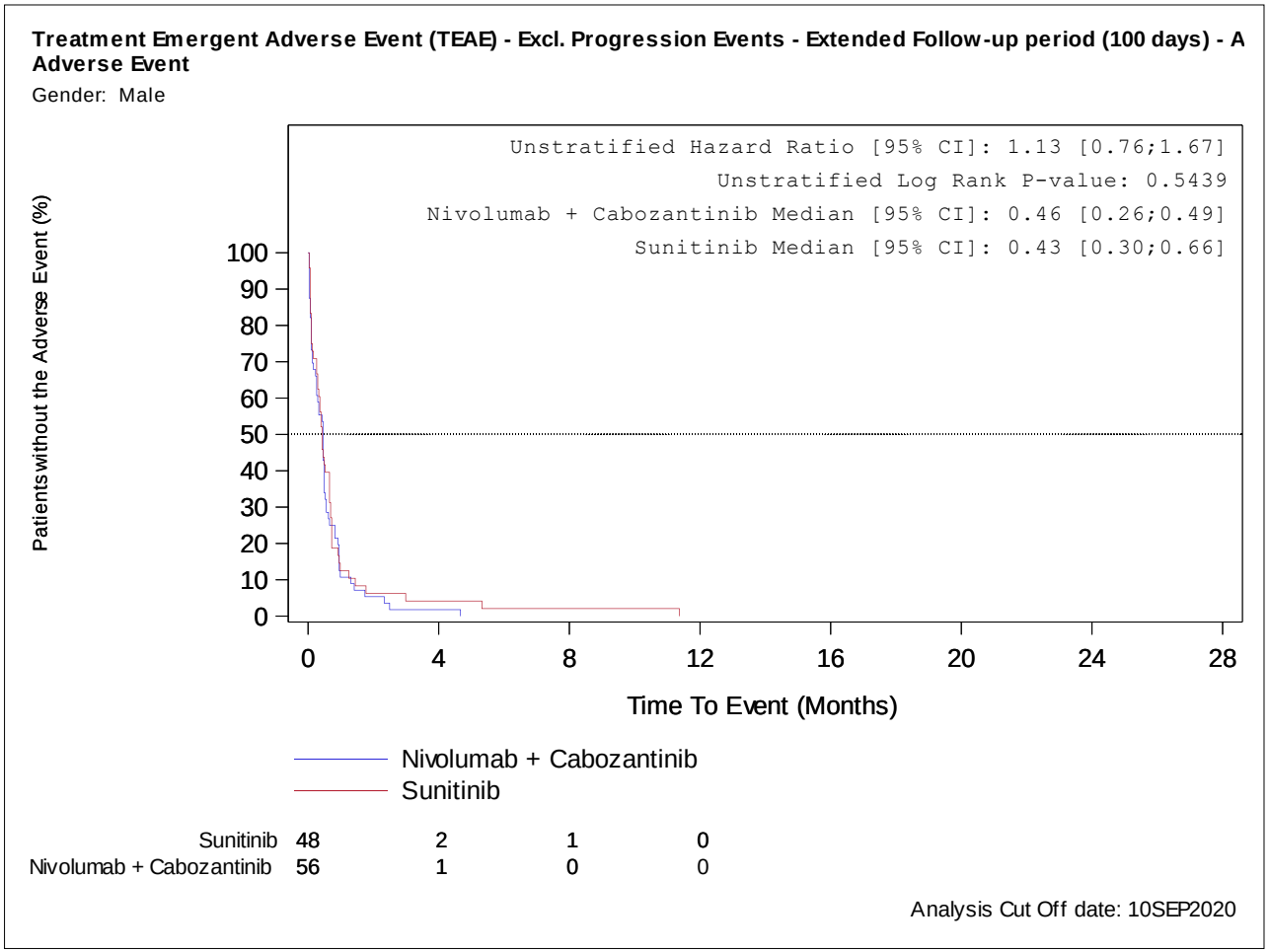

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:14:25

FIGURE 3.10.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



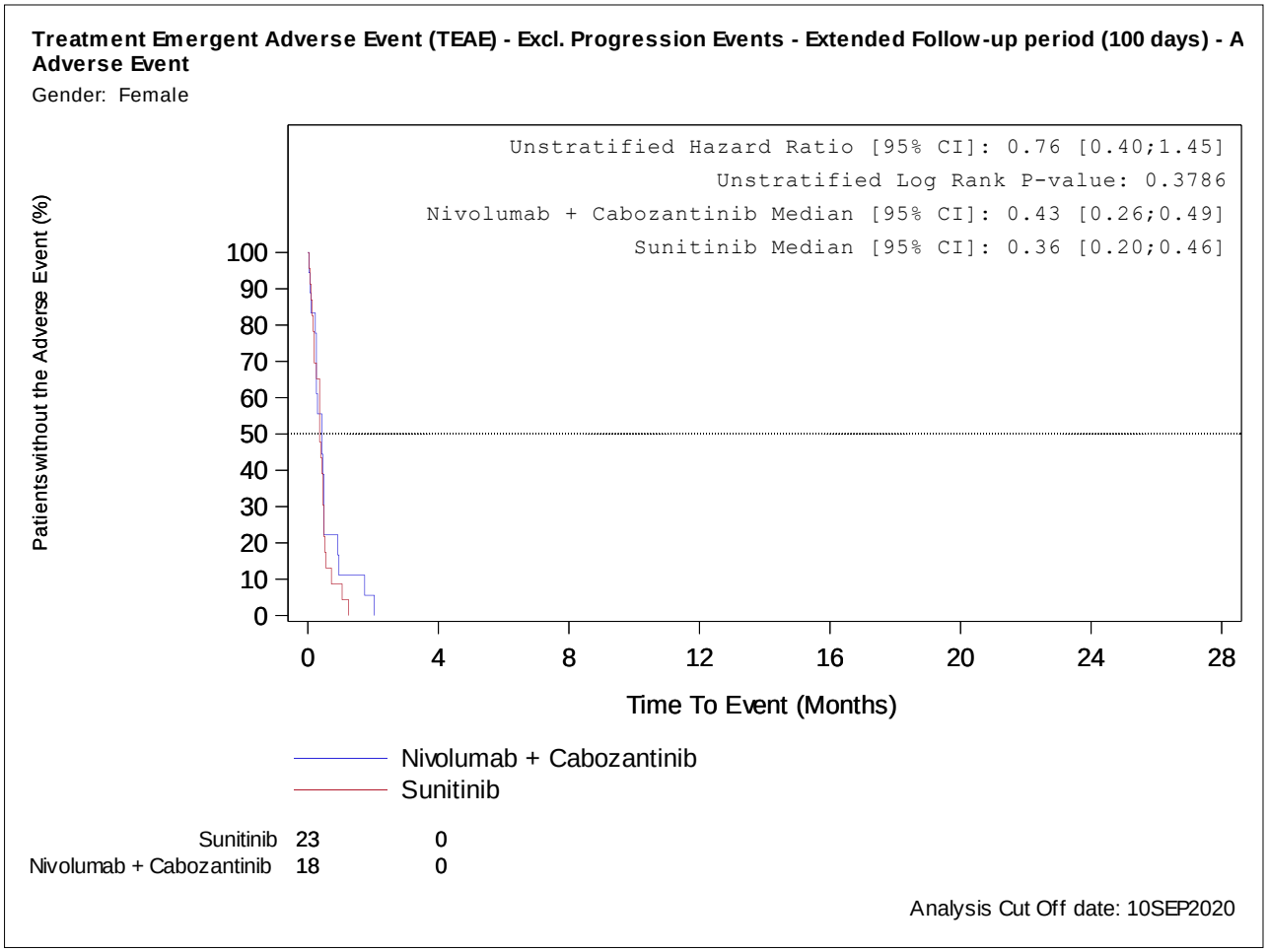

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:14:31

FIGURE 3.10.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



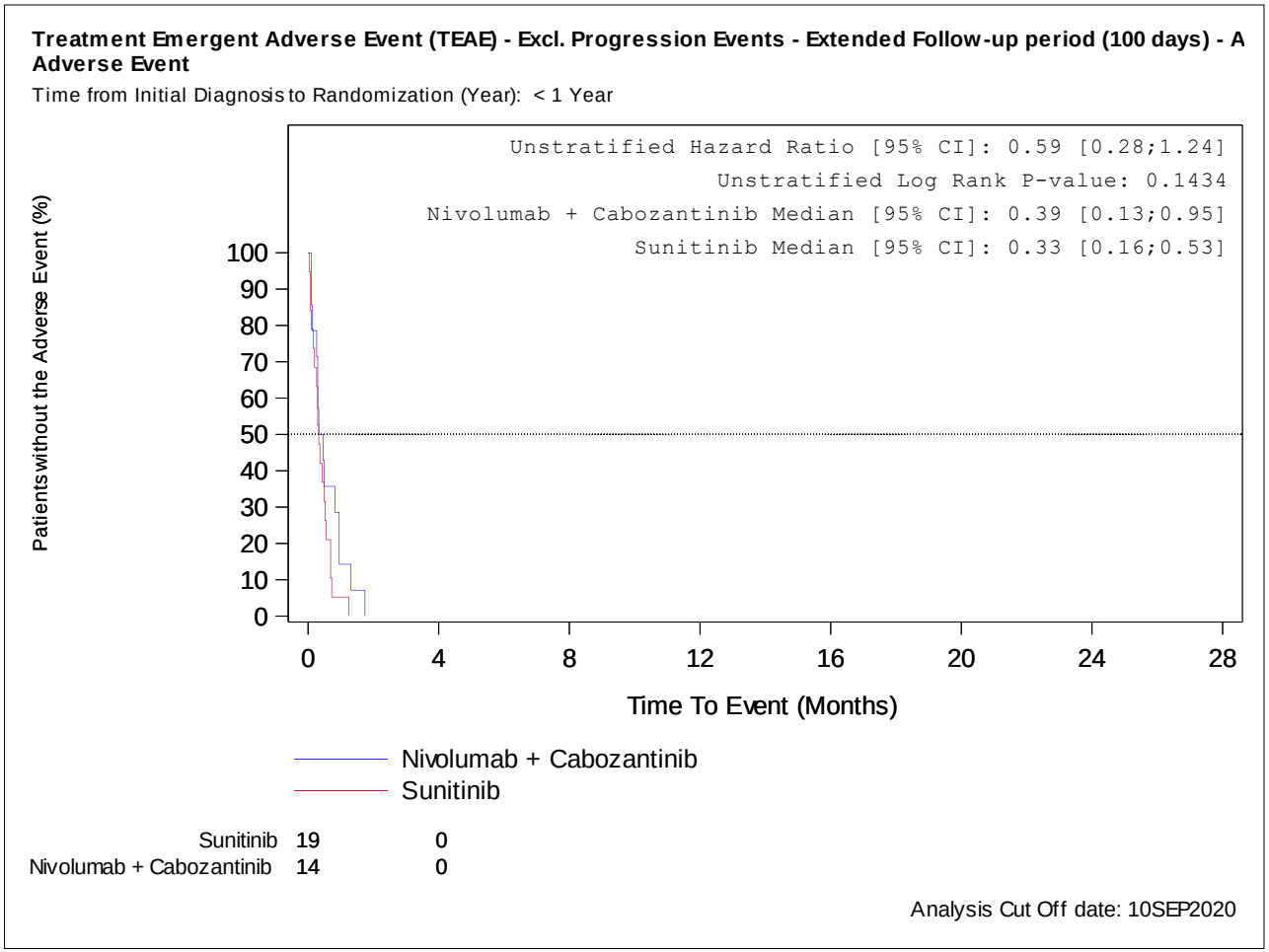

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:14:37

FIGURE 3.10.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



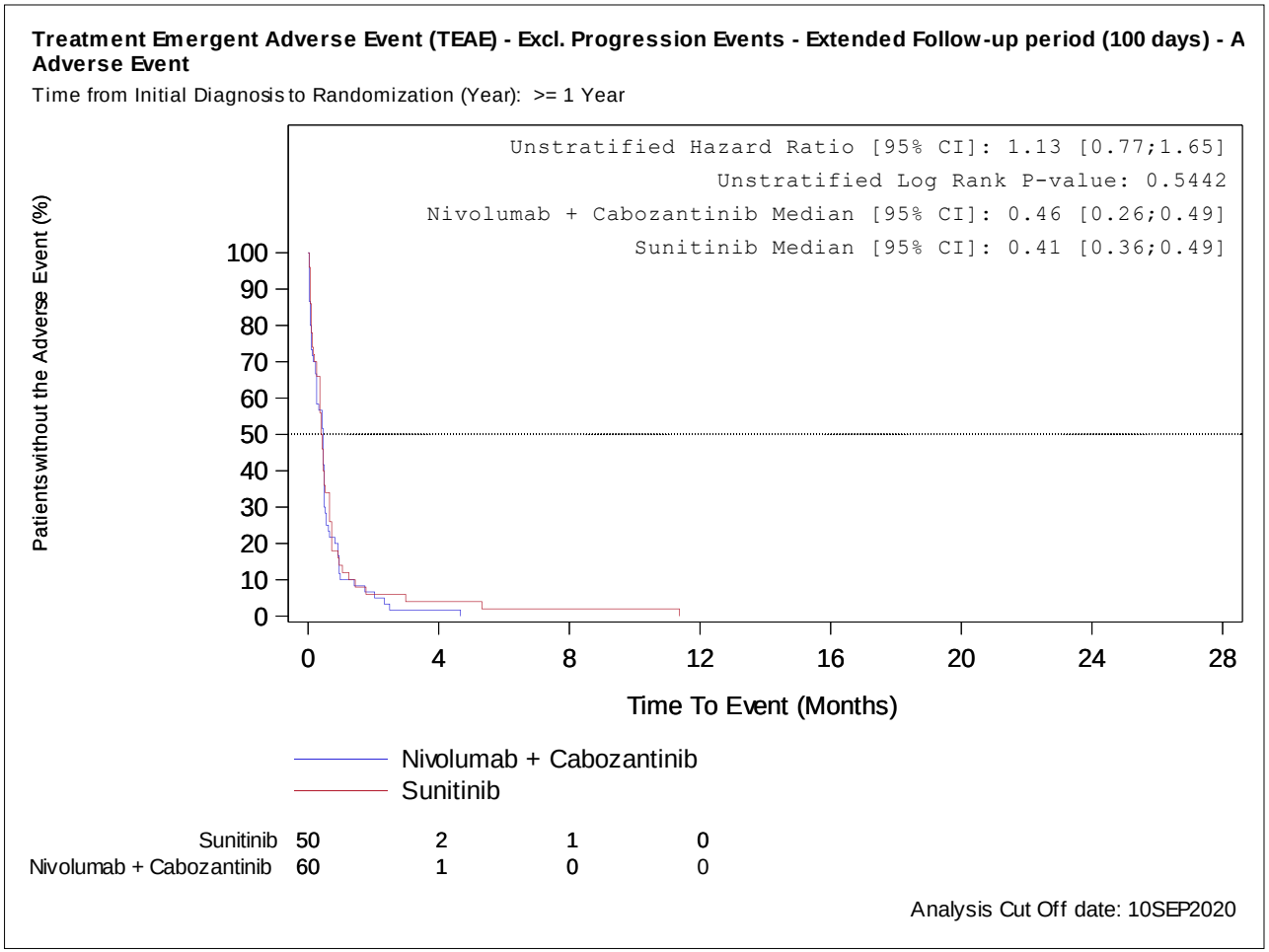

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:14:44

FIGURE 3.10.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



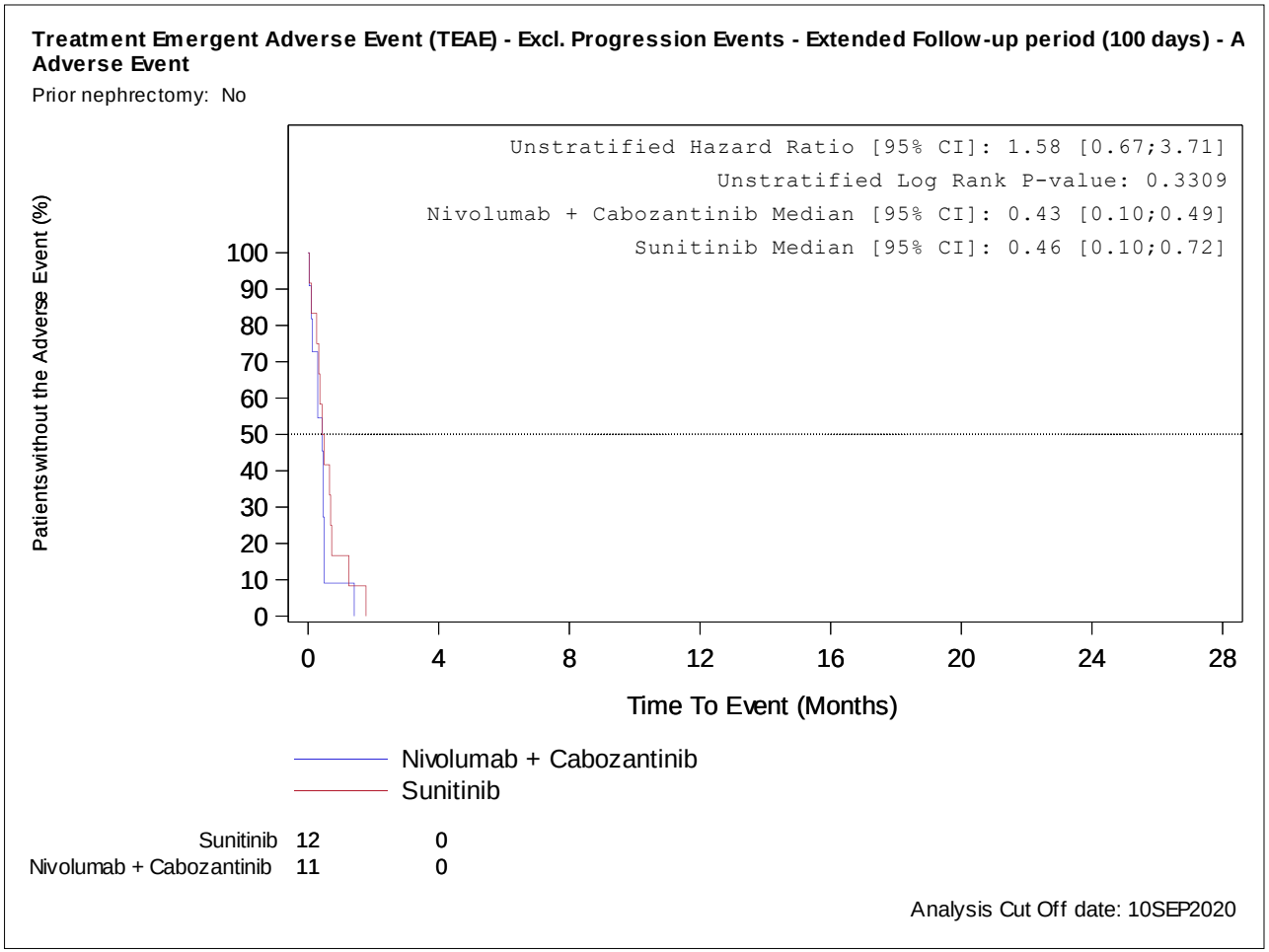

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:15:04

FIGURE 3.10.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



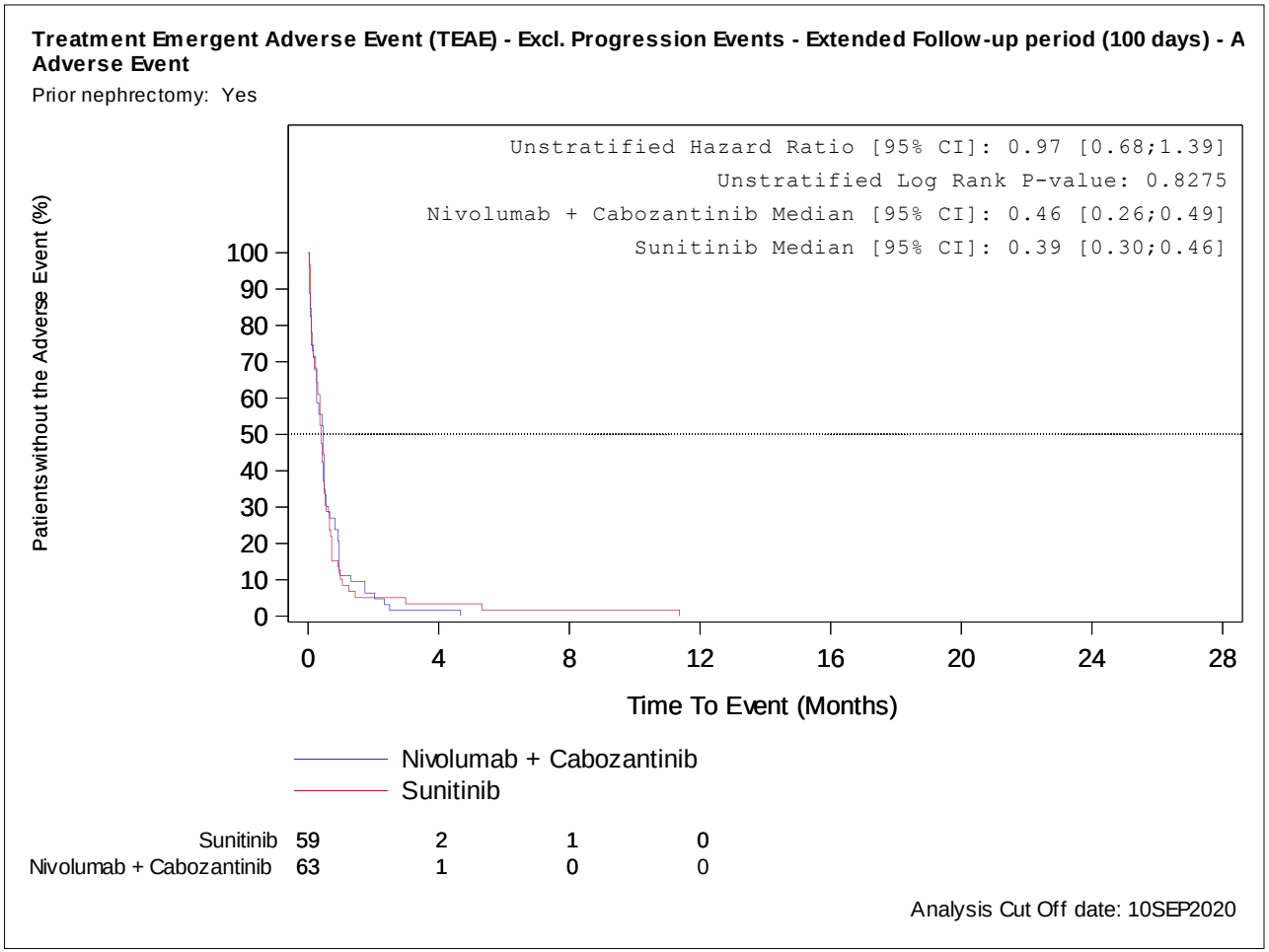

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:15:11

FIGURE 3.10.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



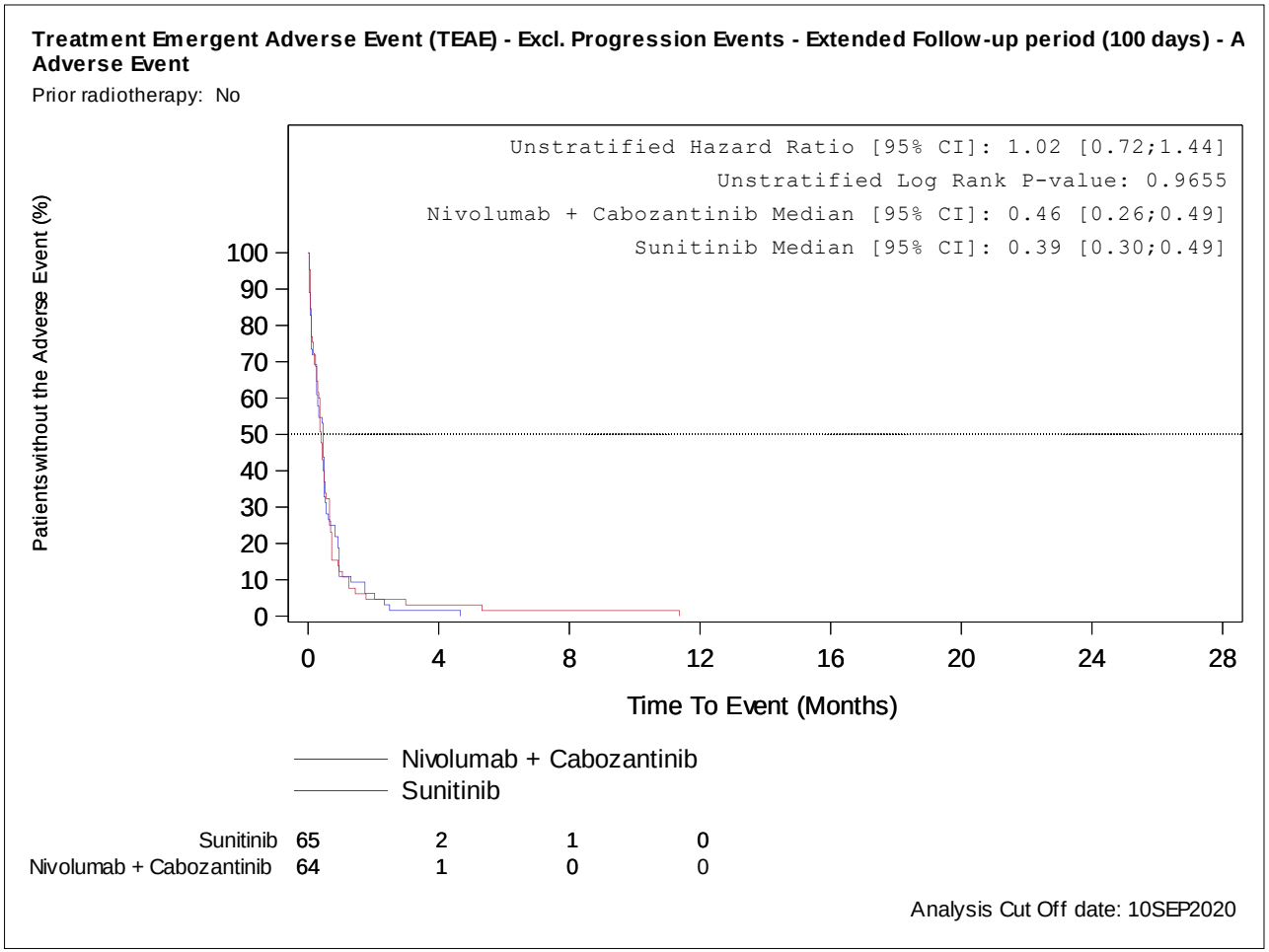

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:16:06

FIGURE 3.10.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



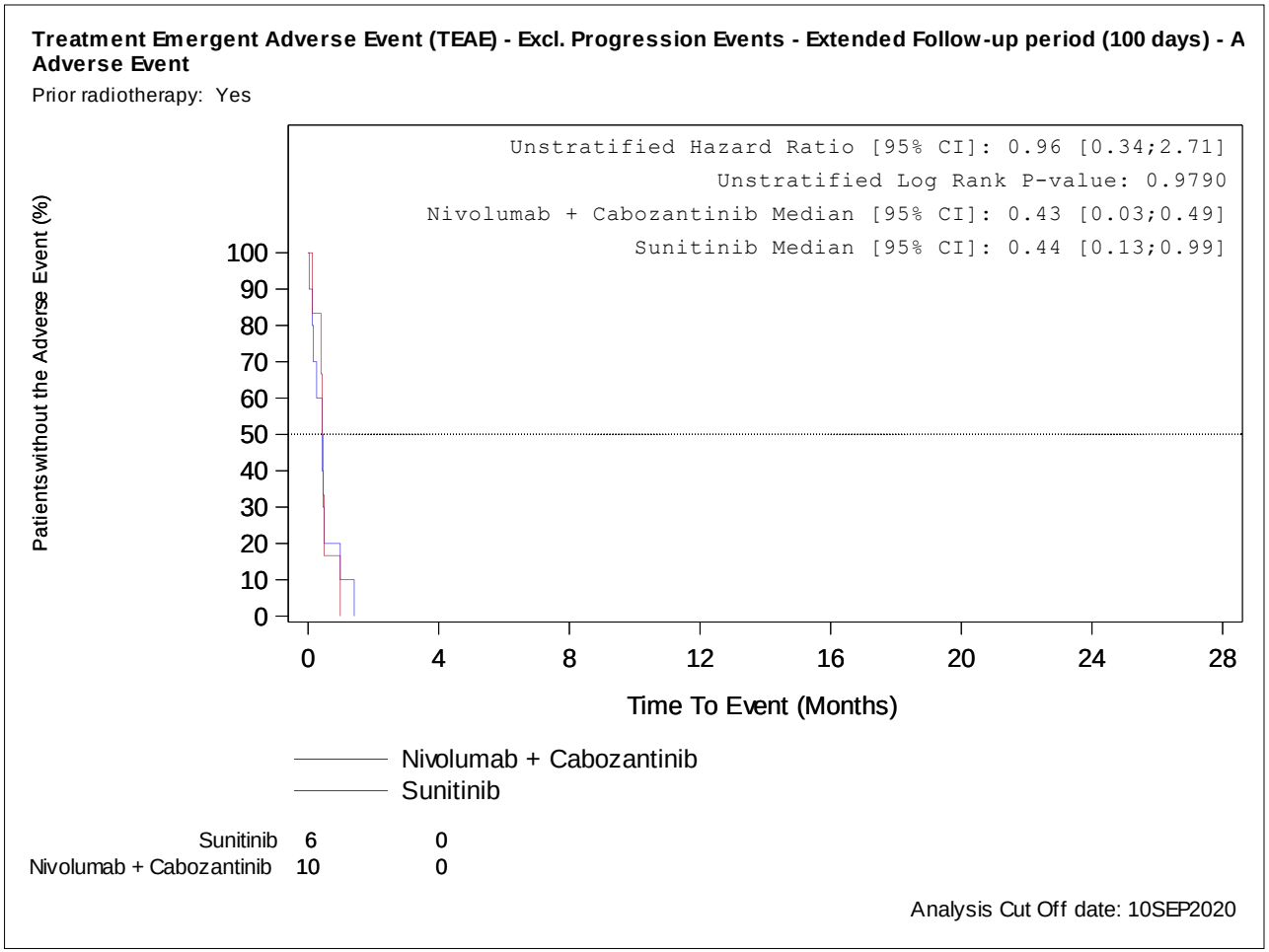

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:16:12

FIGURE 3.10.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



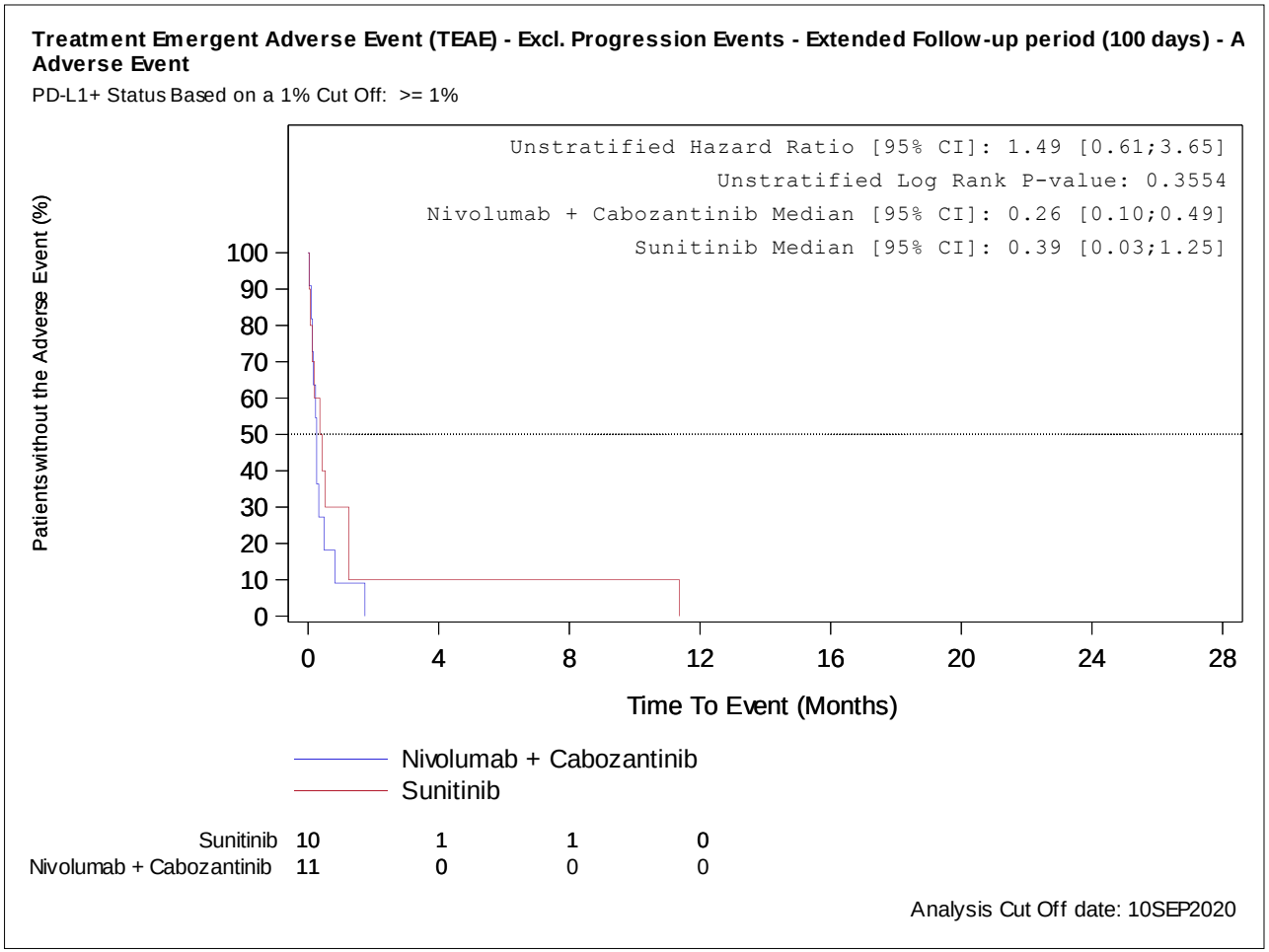

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:16:18

FIGURE 3.10.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



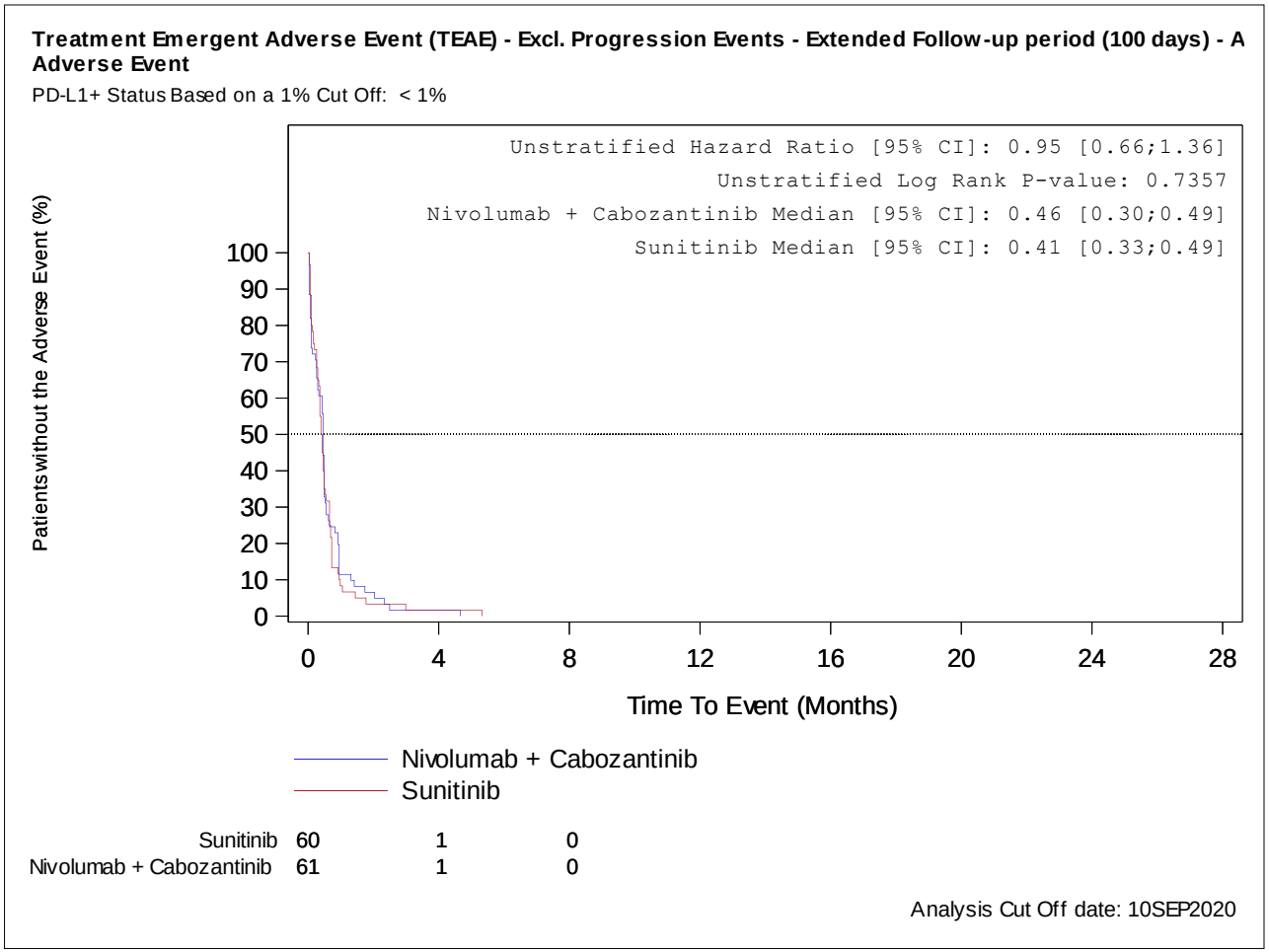

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:16:24

FIGURE 3.10.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



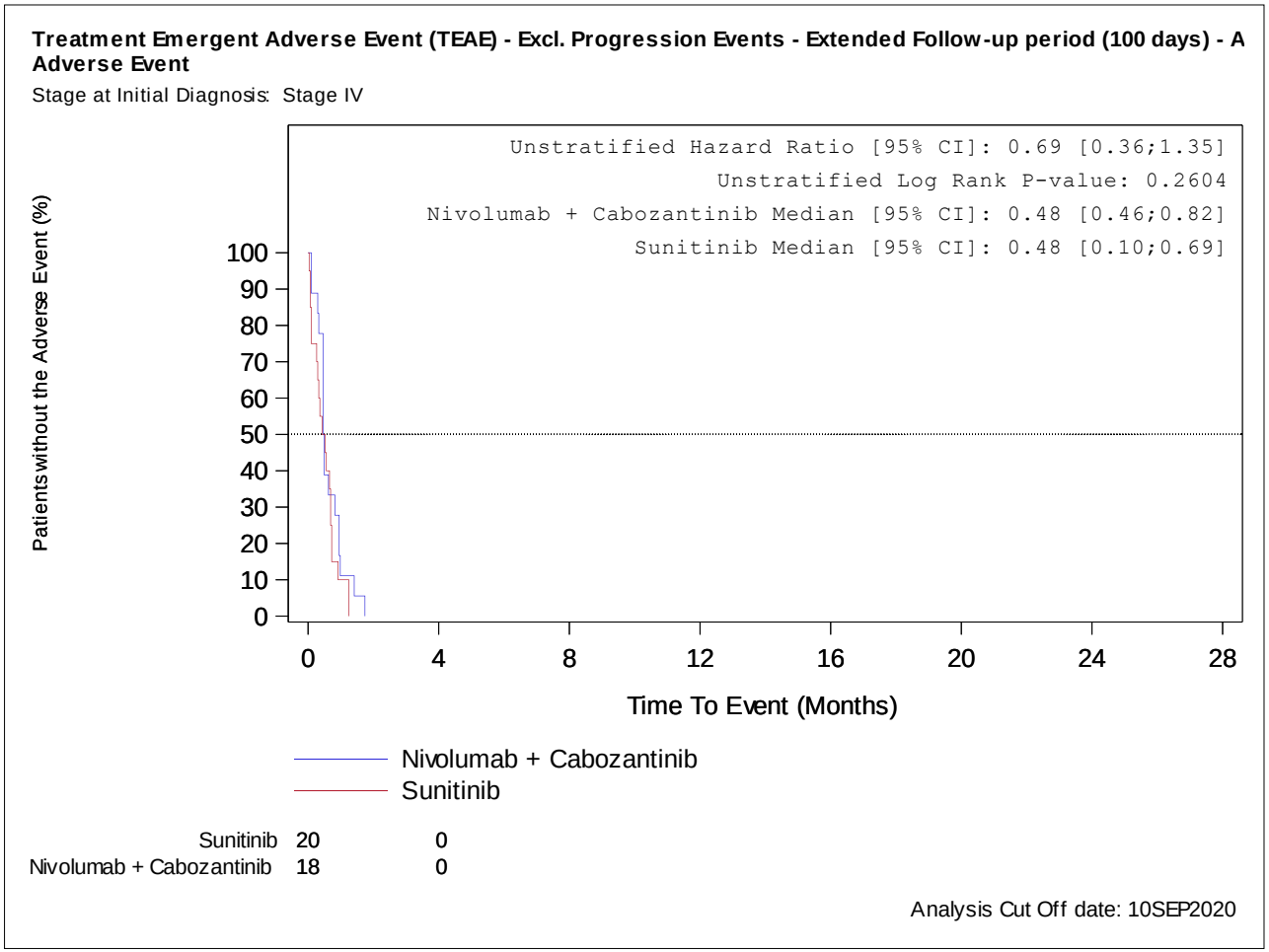

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:16:31

FIGURE 3.10.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



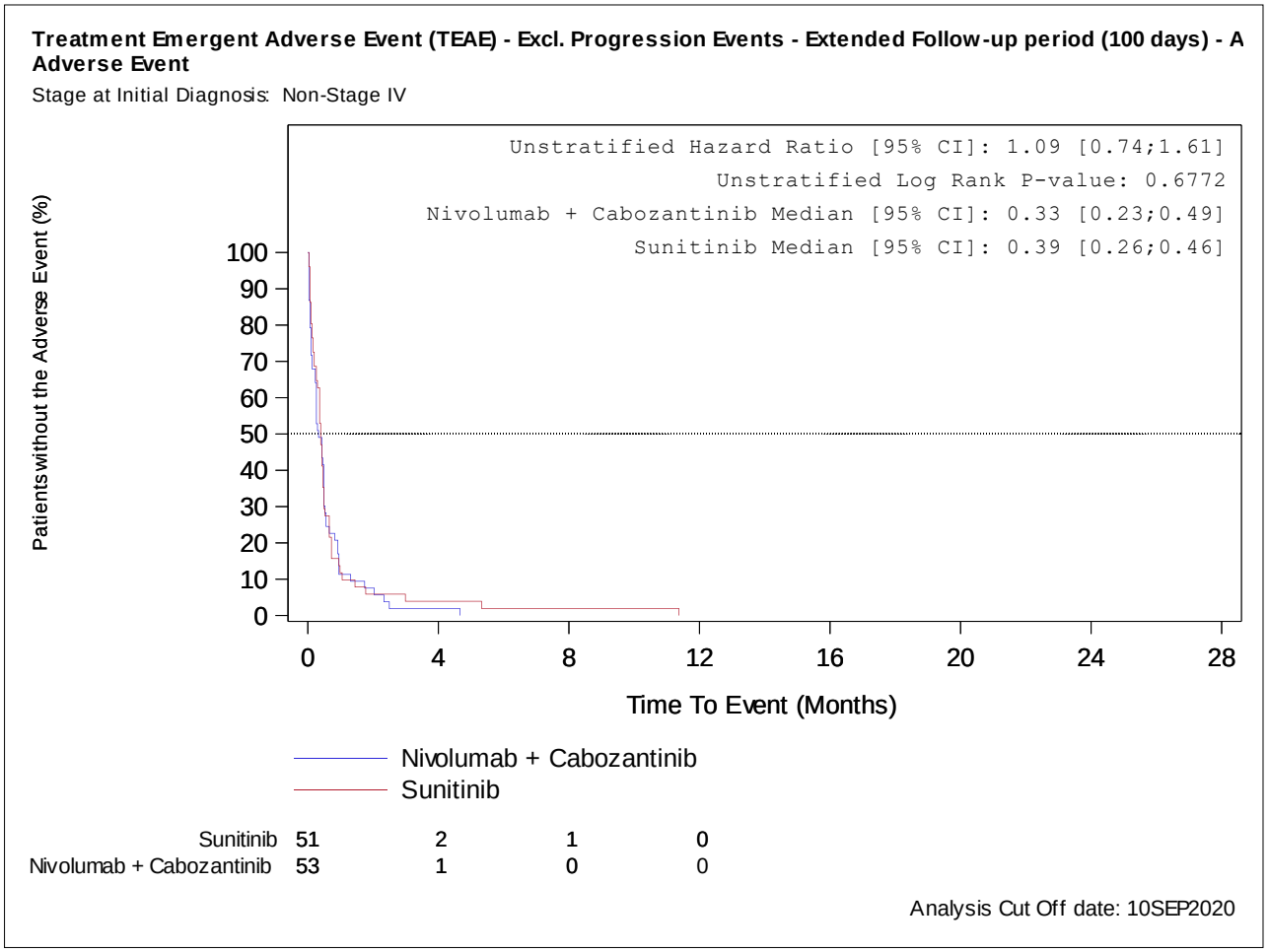

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:16:36

FIGURE 3.10.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis:  Stage IV



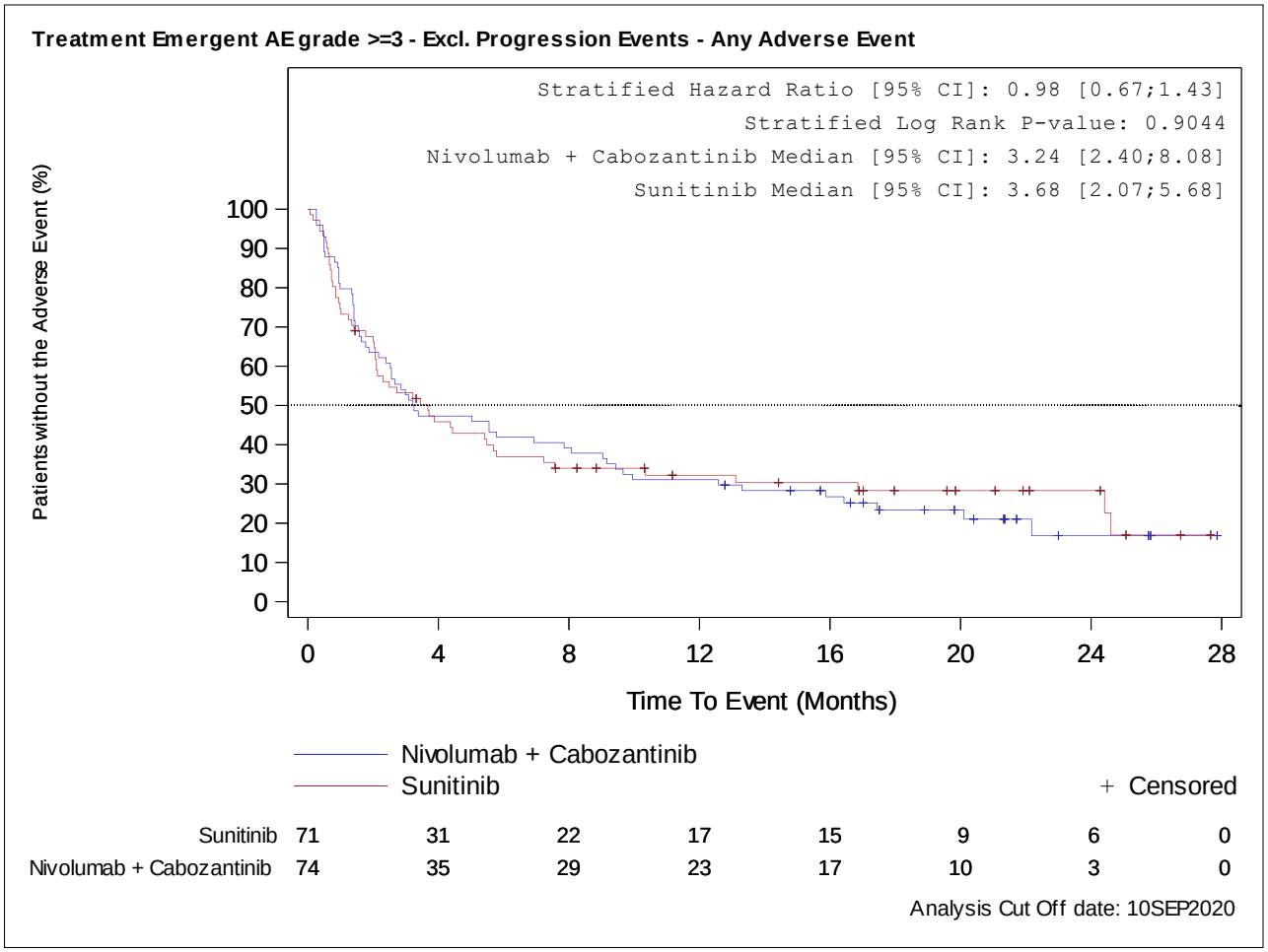

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:17:06

FIGURE 3.10.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



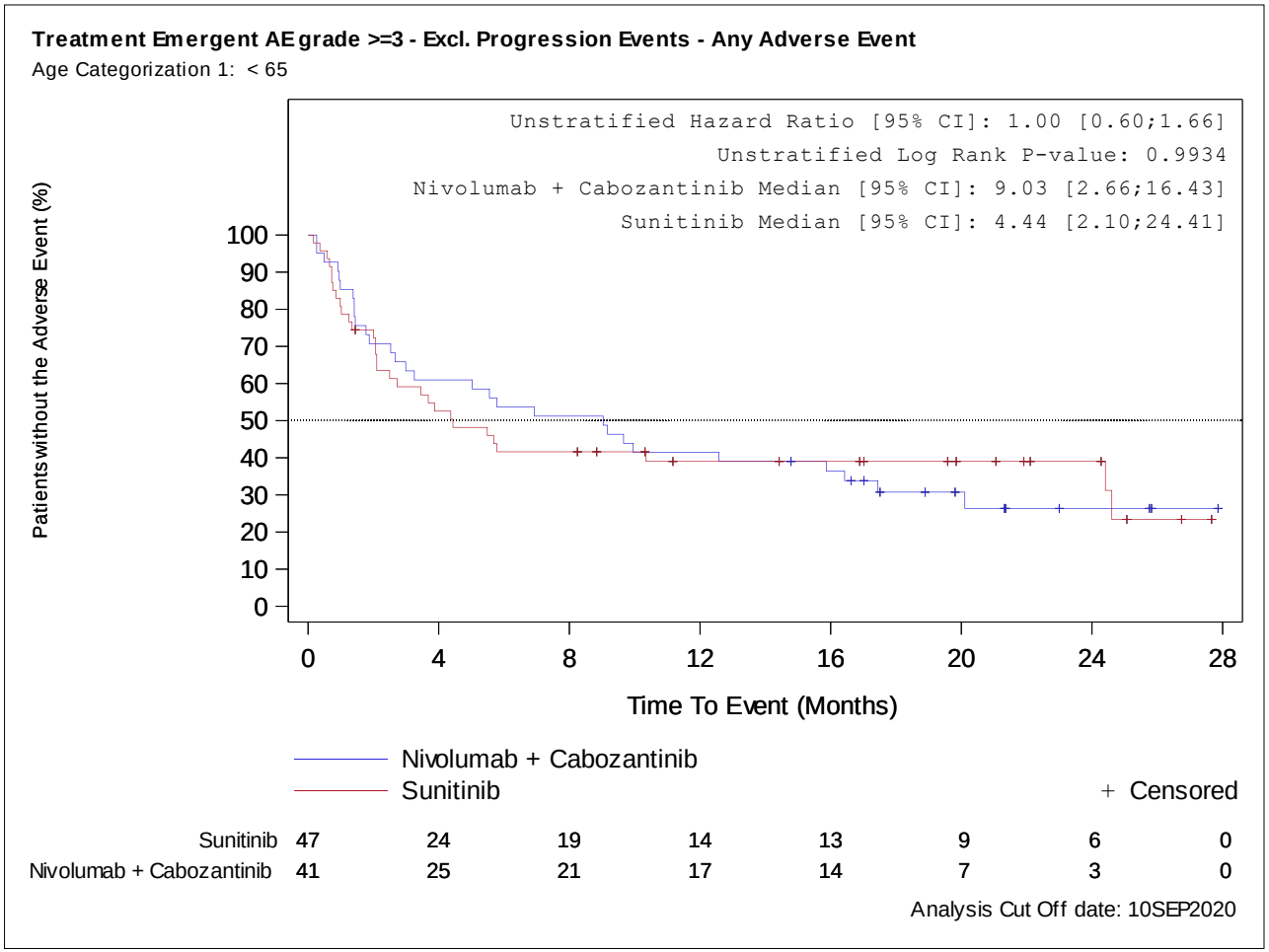

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:17:13

FIGURE 3.11.1: Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



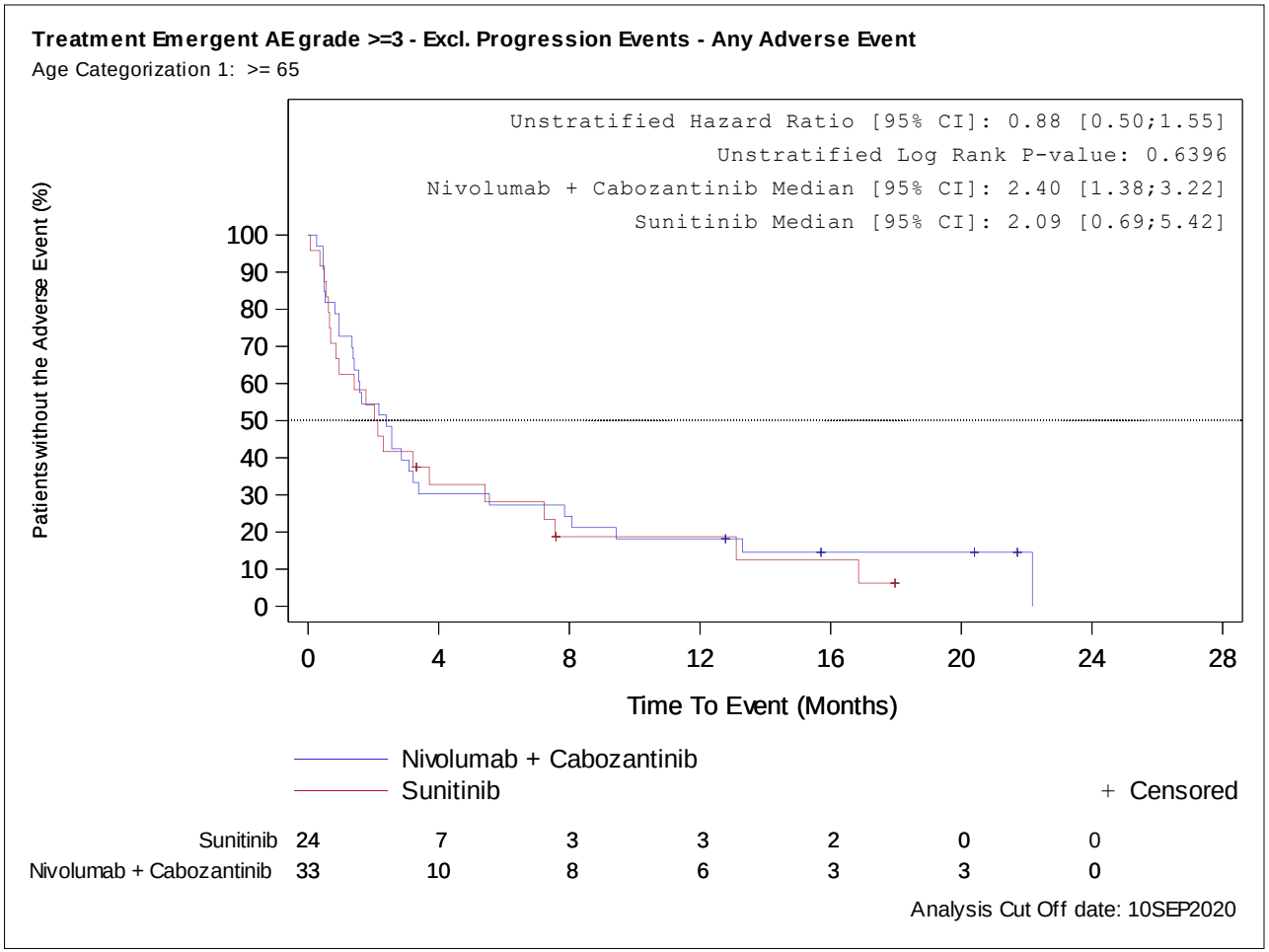

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:20:44

FIGURE 3.11.2.1: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



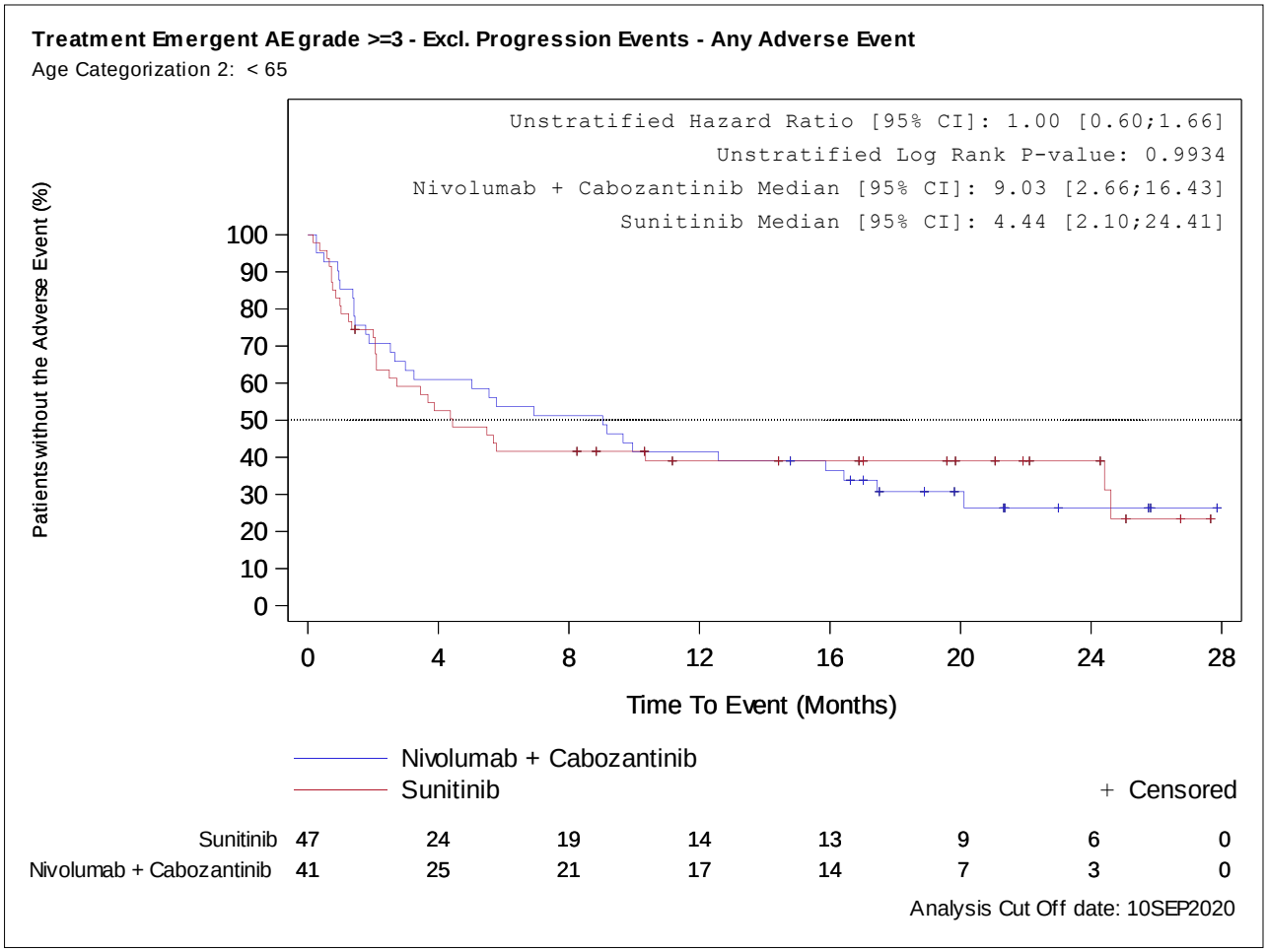

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:20:47

FIGURE 3.11.2.2: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:20:54

FIGURE 3.11.2.3: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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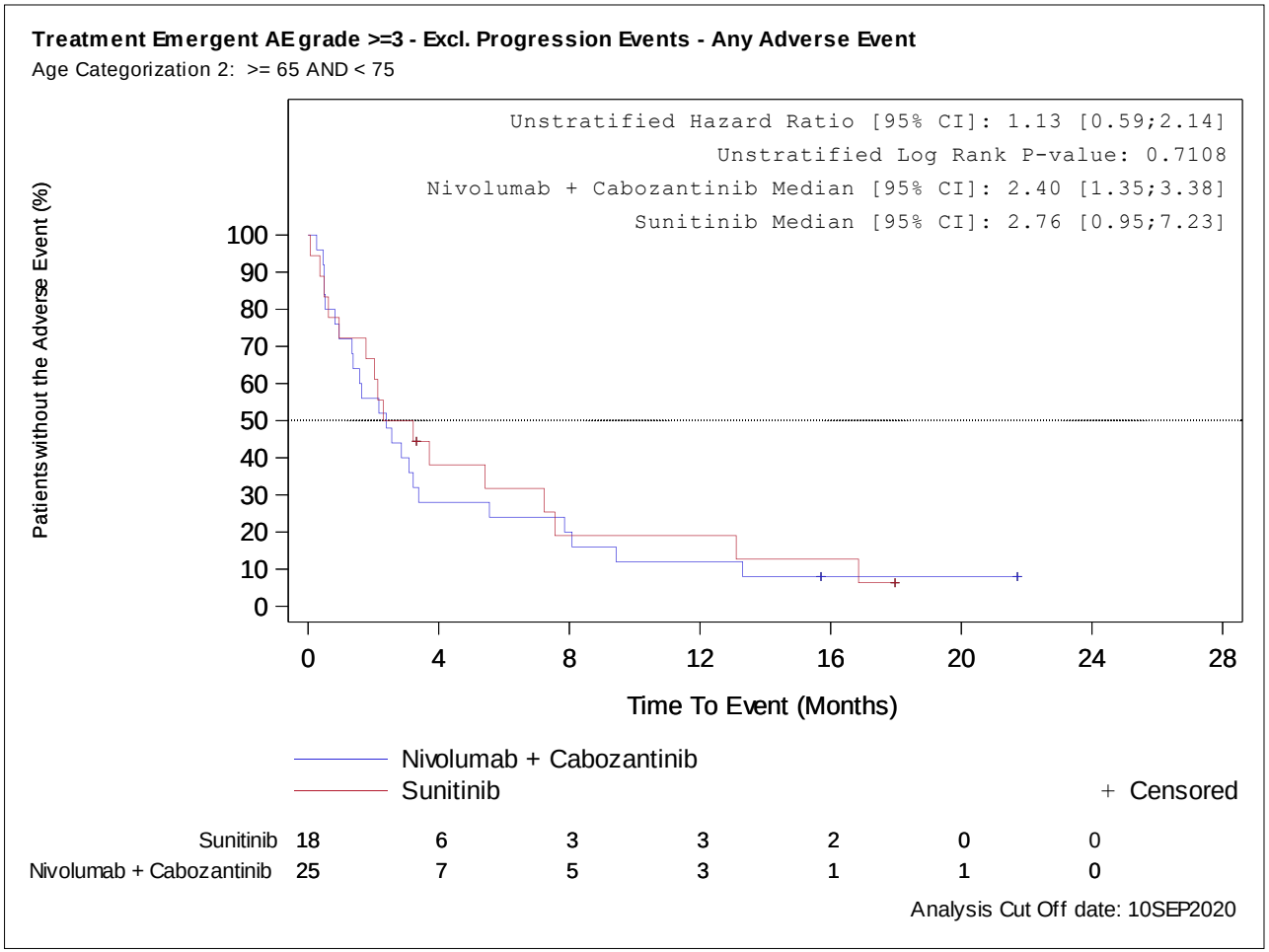
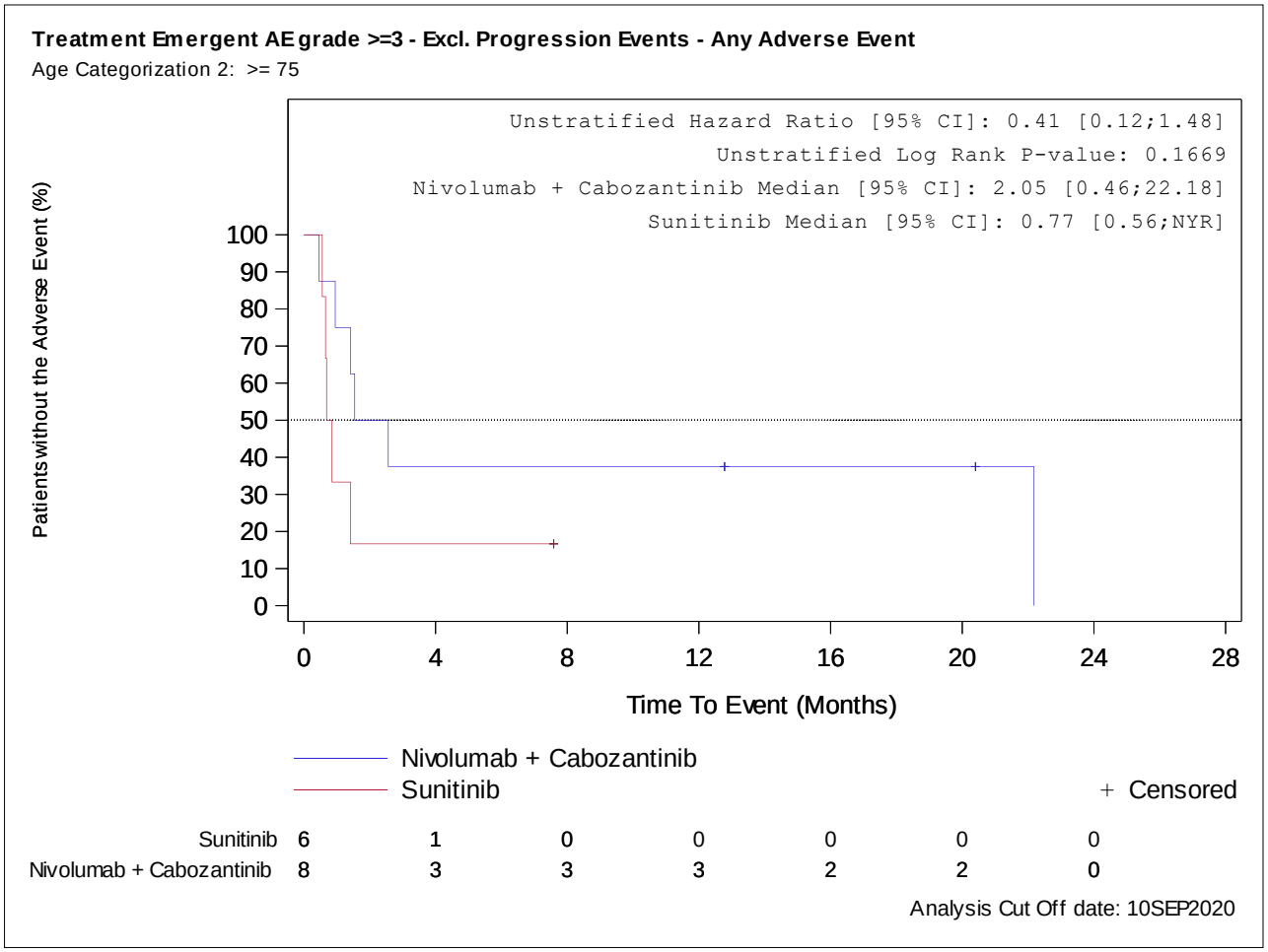
FIGURE 3.11.2.4: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



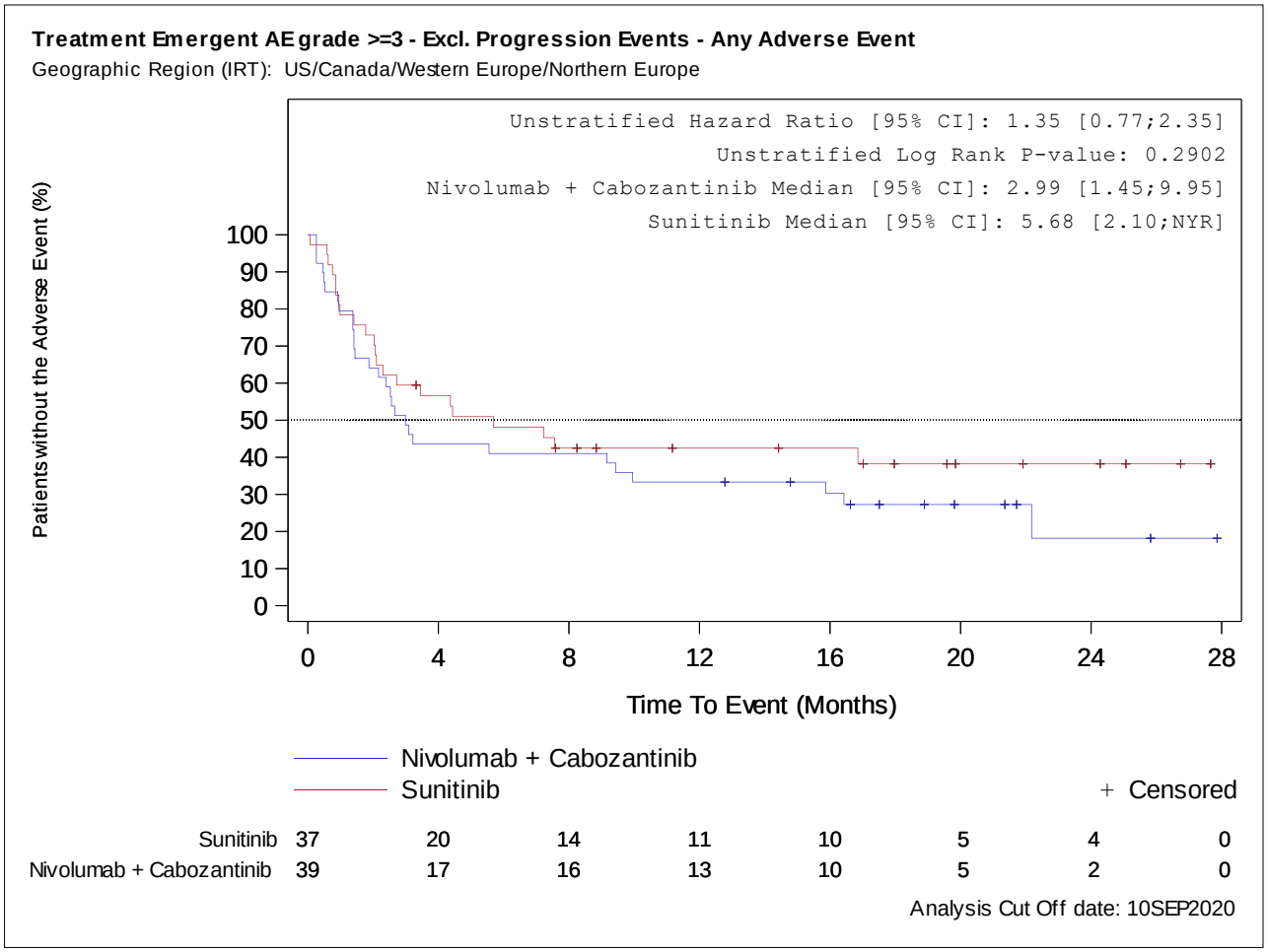

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:21:06

FIGURE 3.11.2.5: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



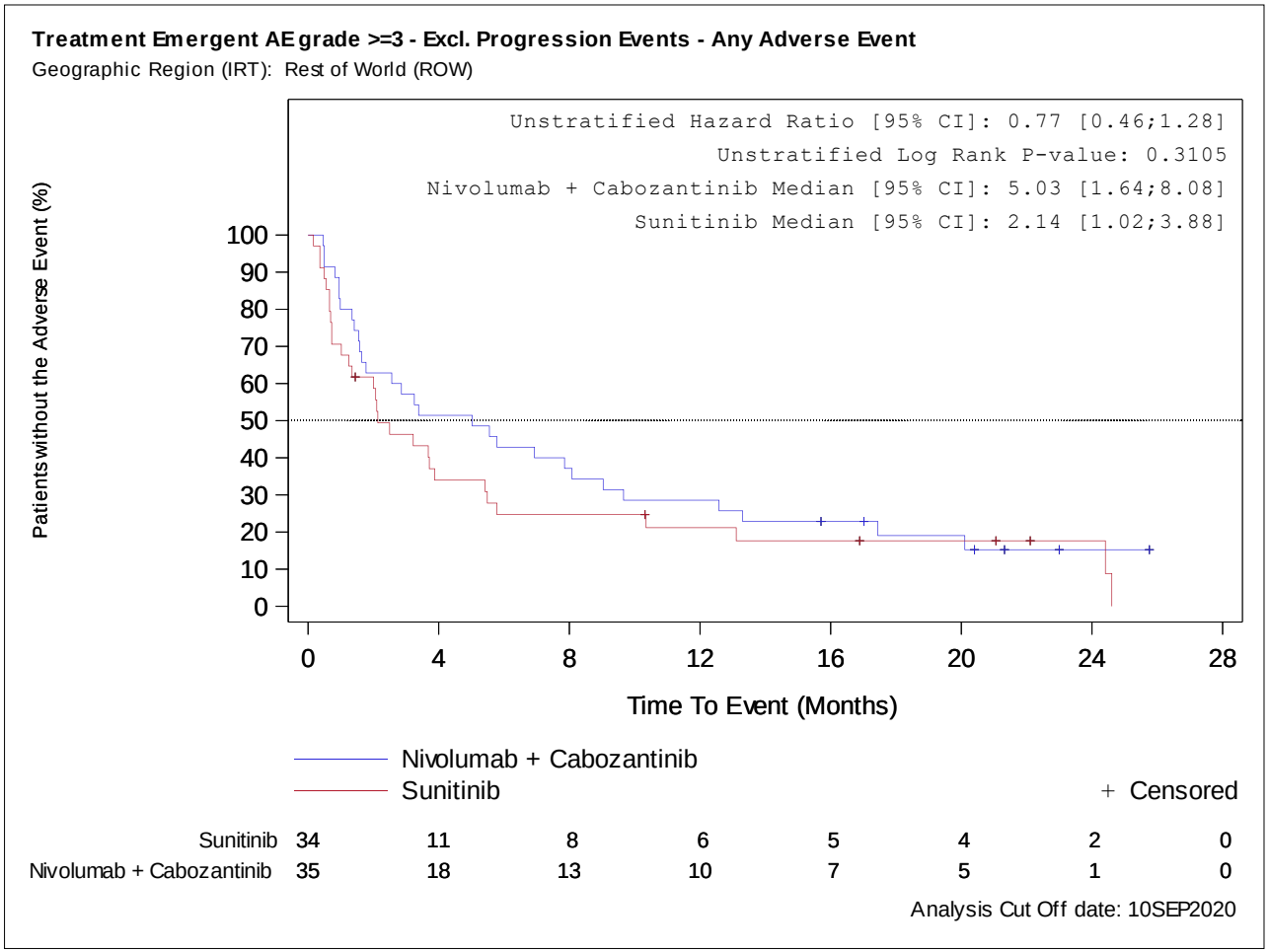

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:21:13

FIGURE 3.11.2.6: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



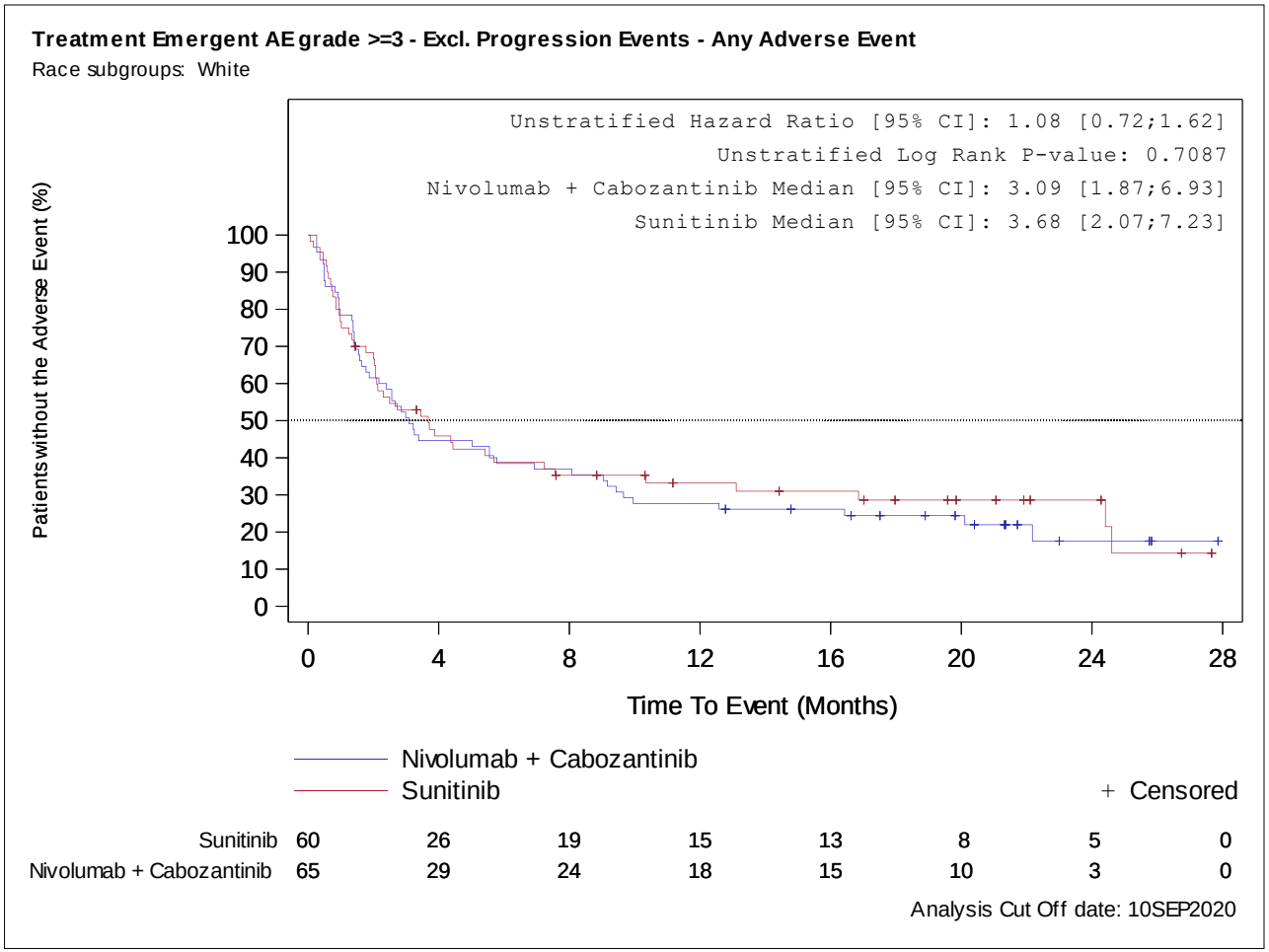

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:21:19

FIGURE 3.11.2.7: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



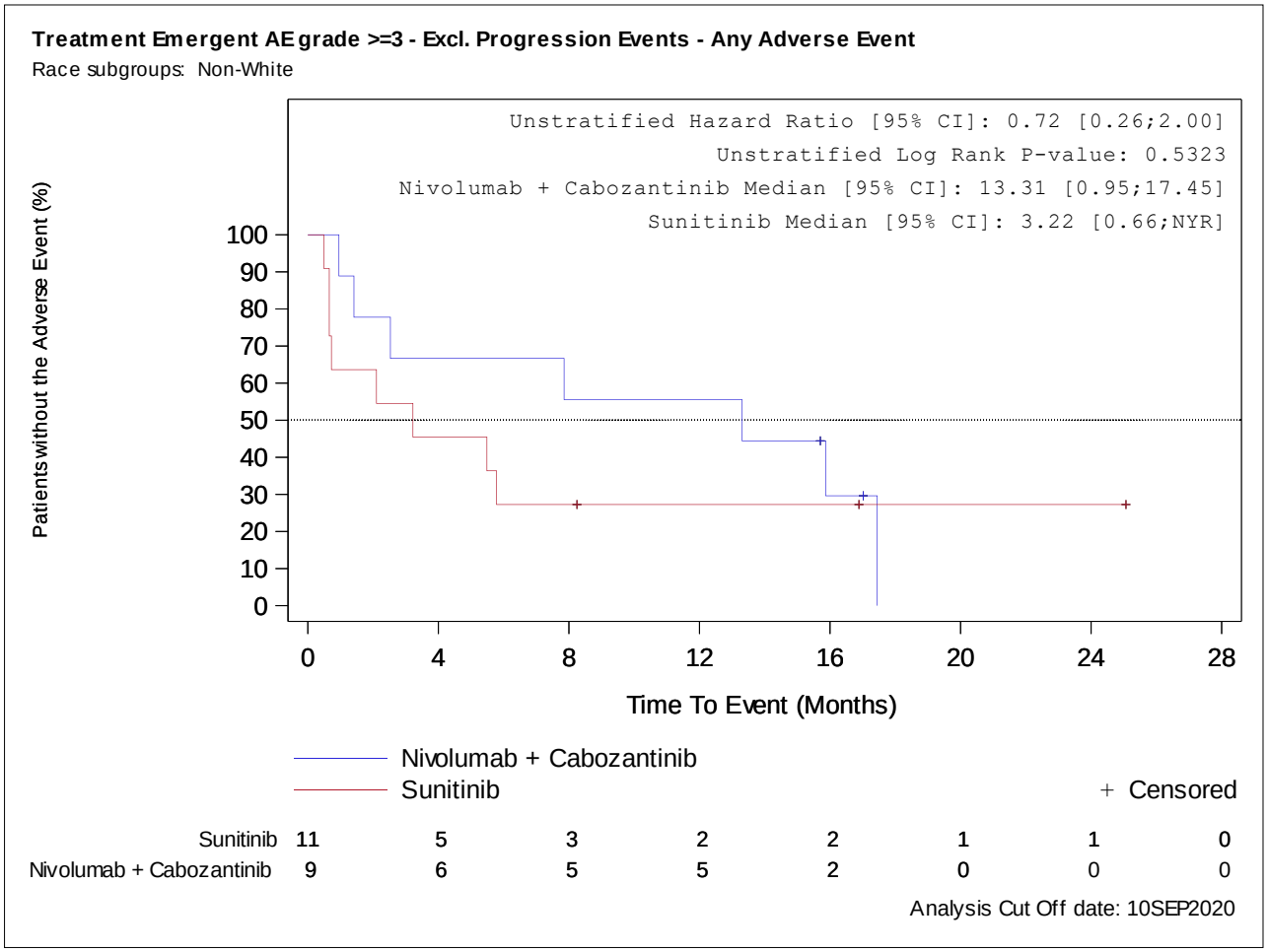

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:21:25

FIGURE 3.11.2.8: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



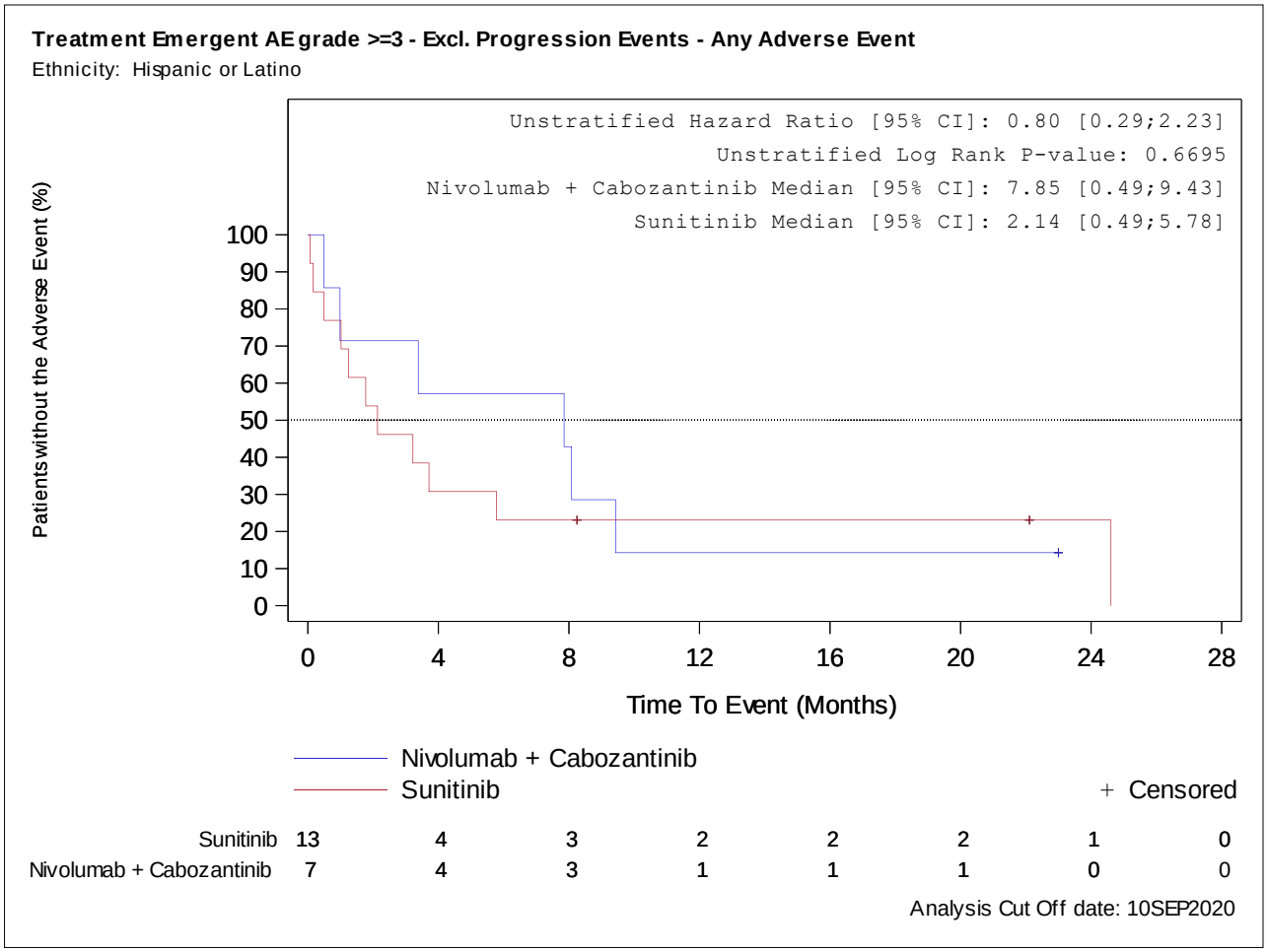

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:21:31

FIGURE 3.11.2.9: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



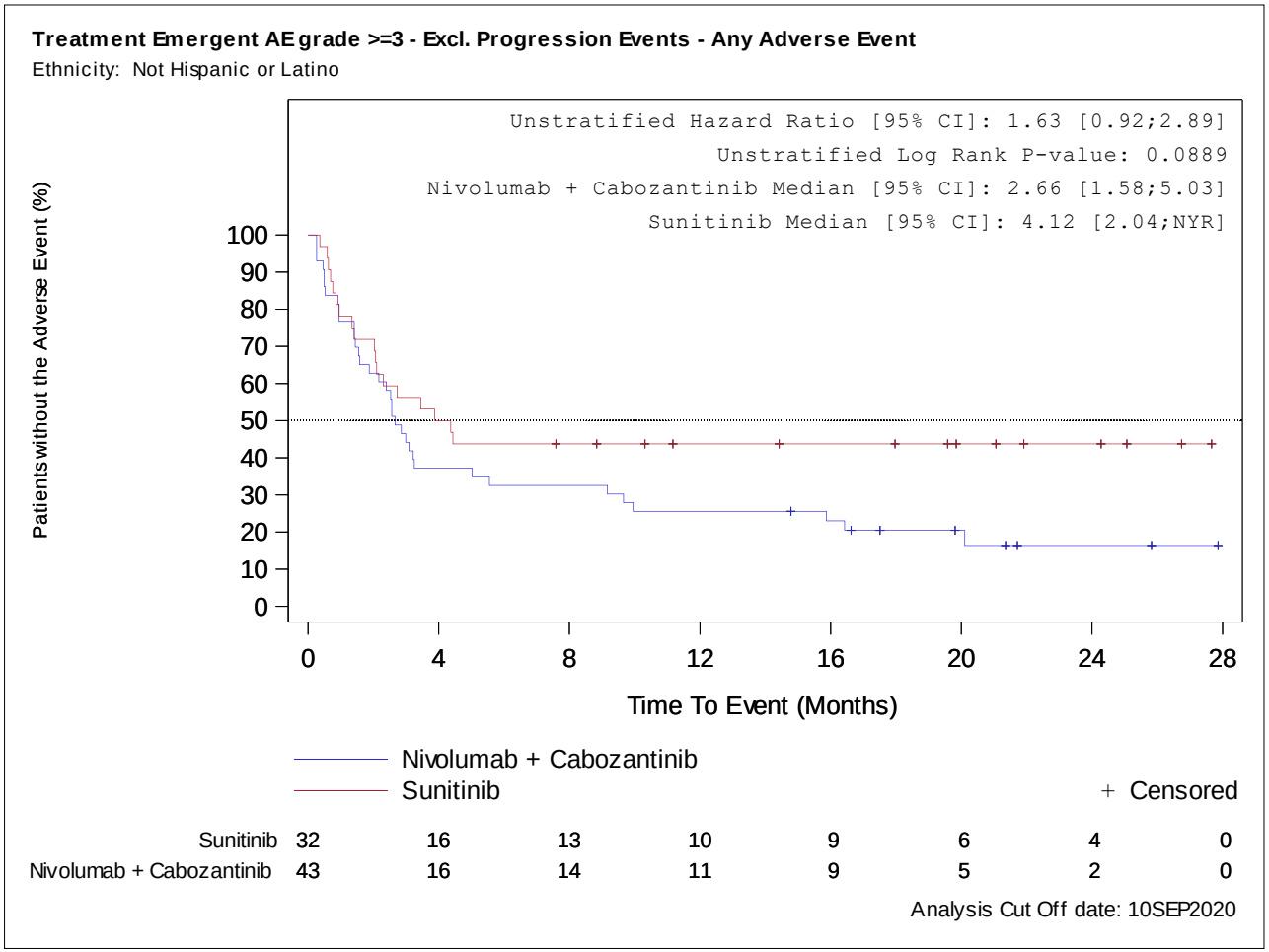

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:21:37

FIGURE 3.11.2.10: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



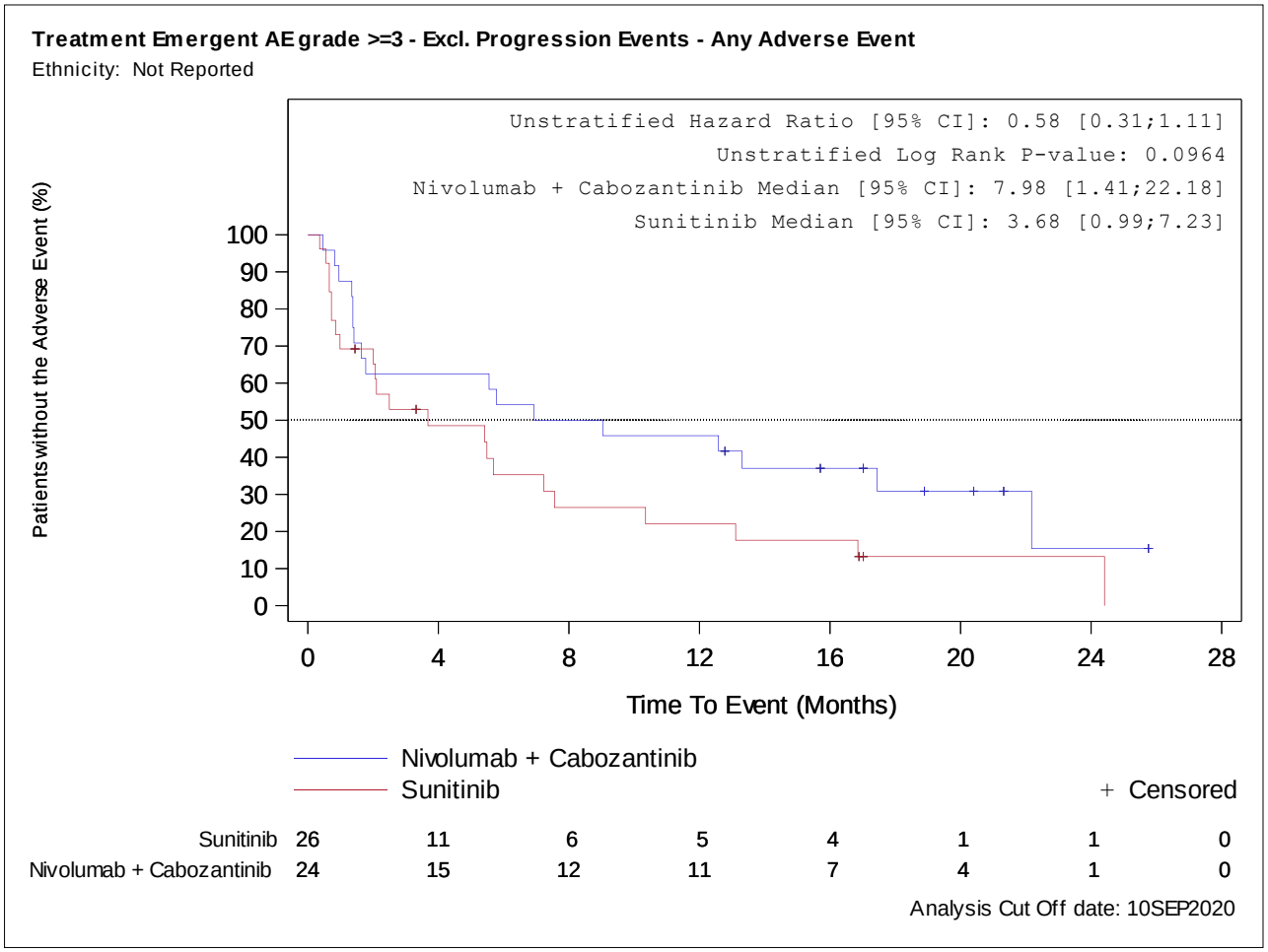

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:21:43

FIGURE 3.11.2.11: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



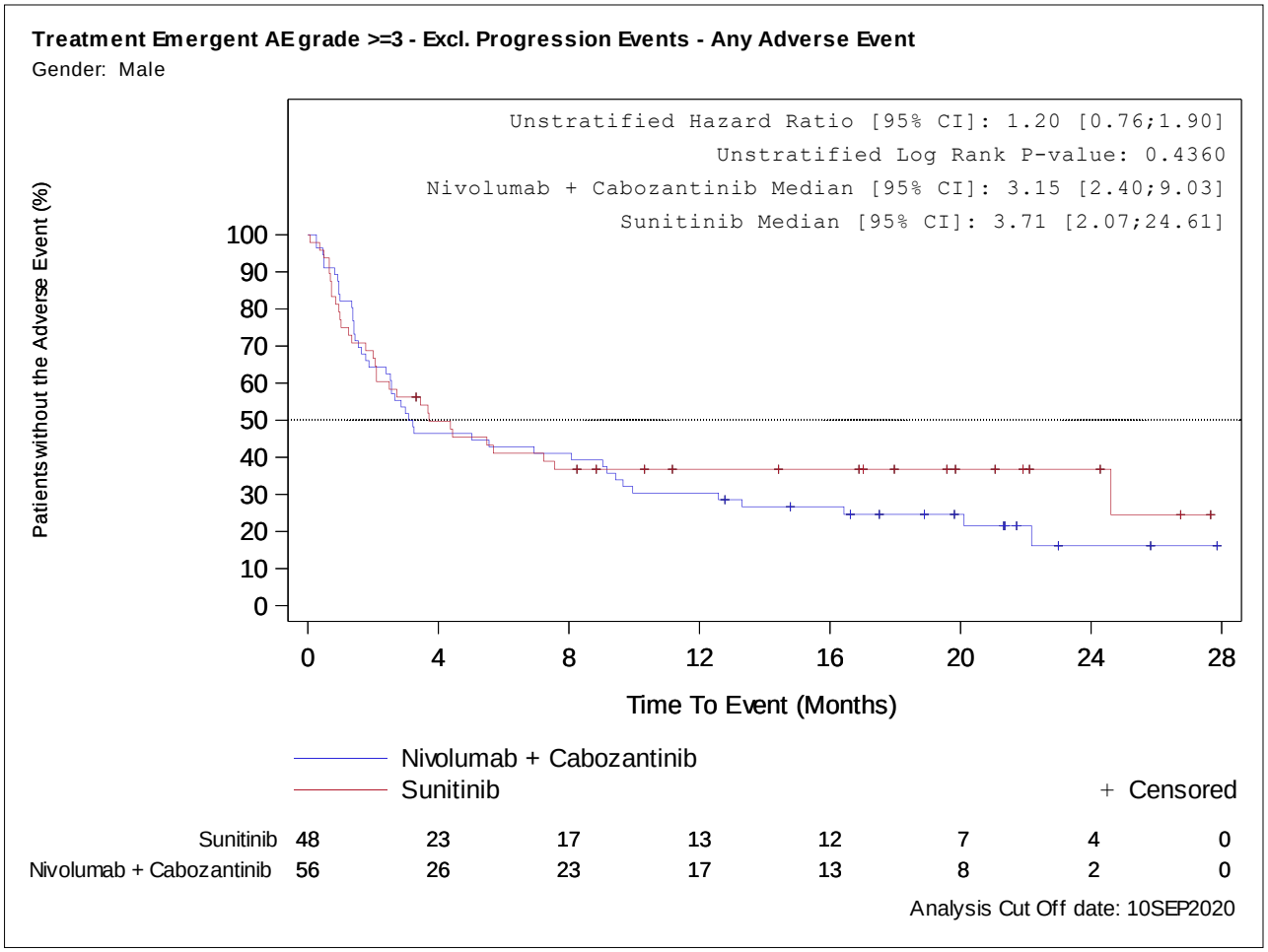

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:21:49

FIGURE 3.11.2.12: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



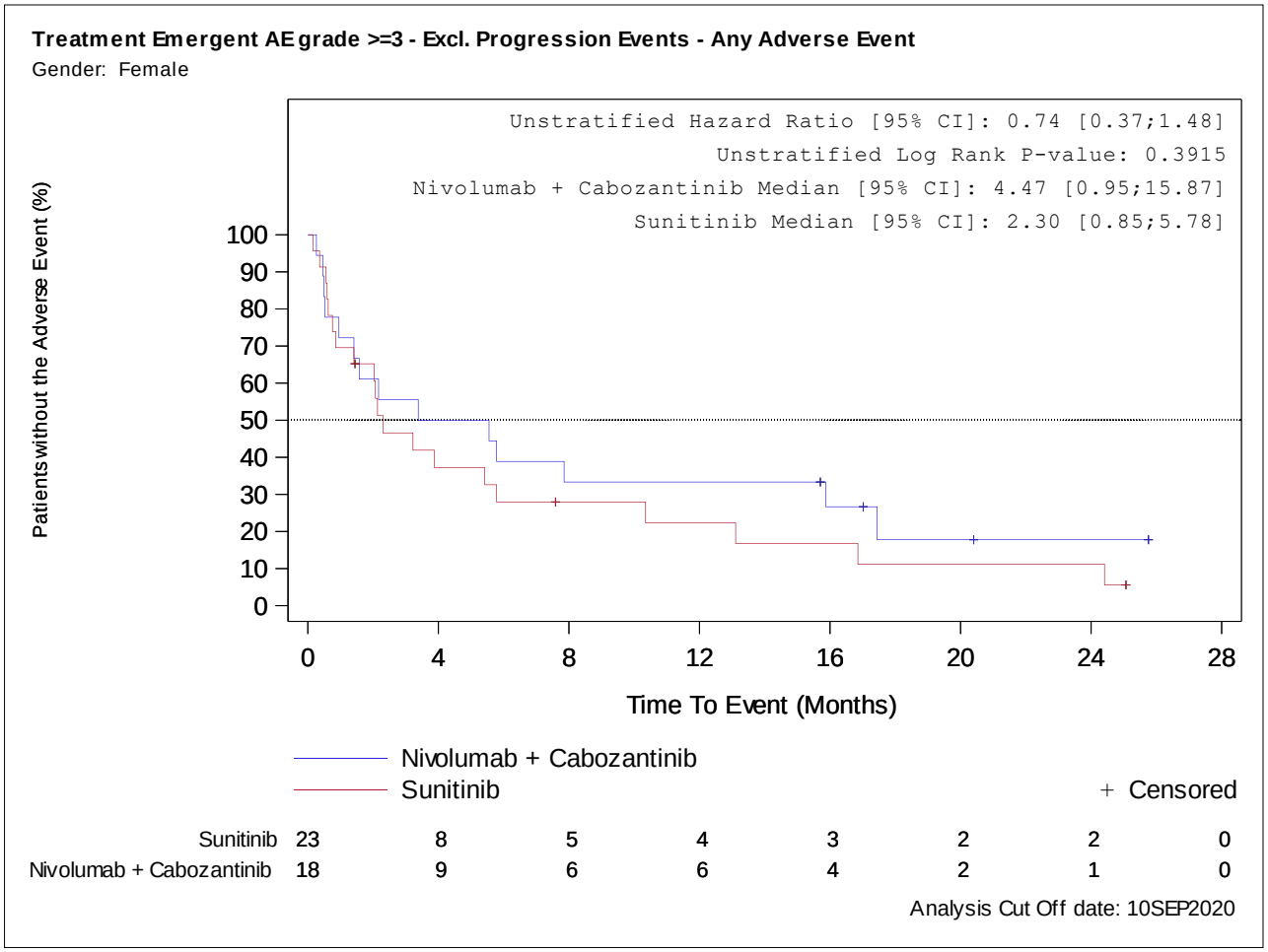

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:21:56

FIGURE 3.11.2.13: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:22:02

FIGURE 3.11.2.14: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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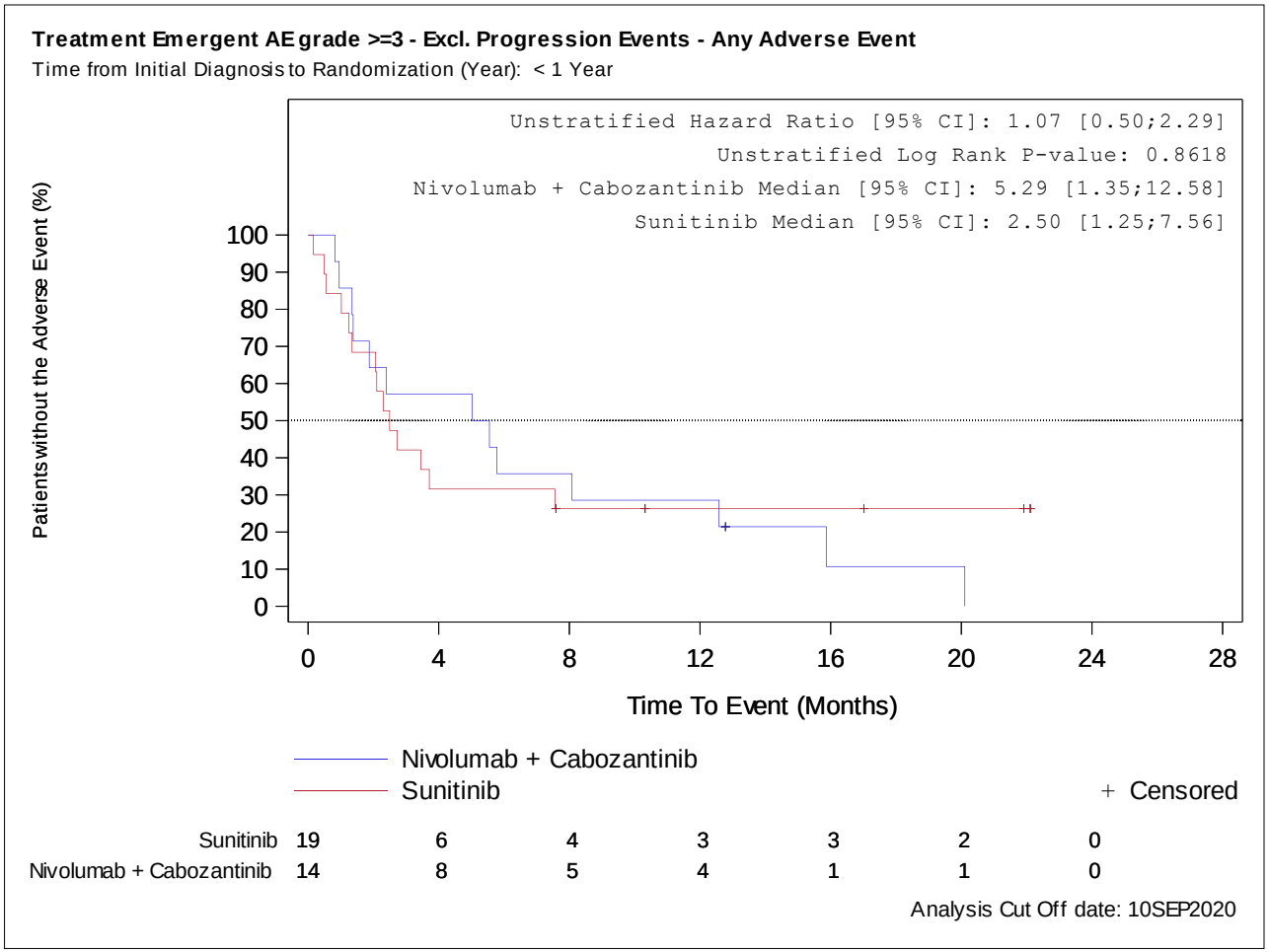
FIGURE 3.11.2.15: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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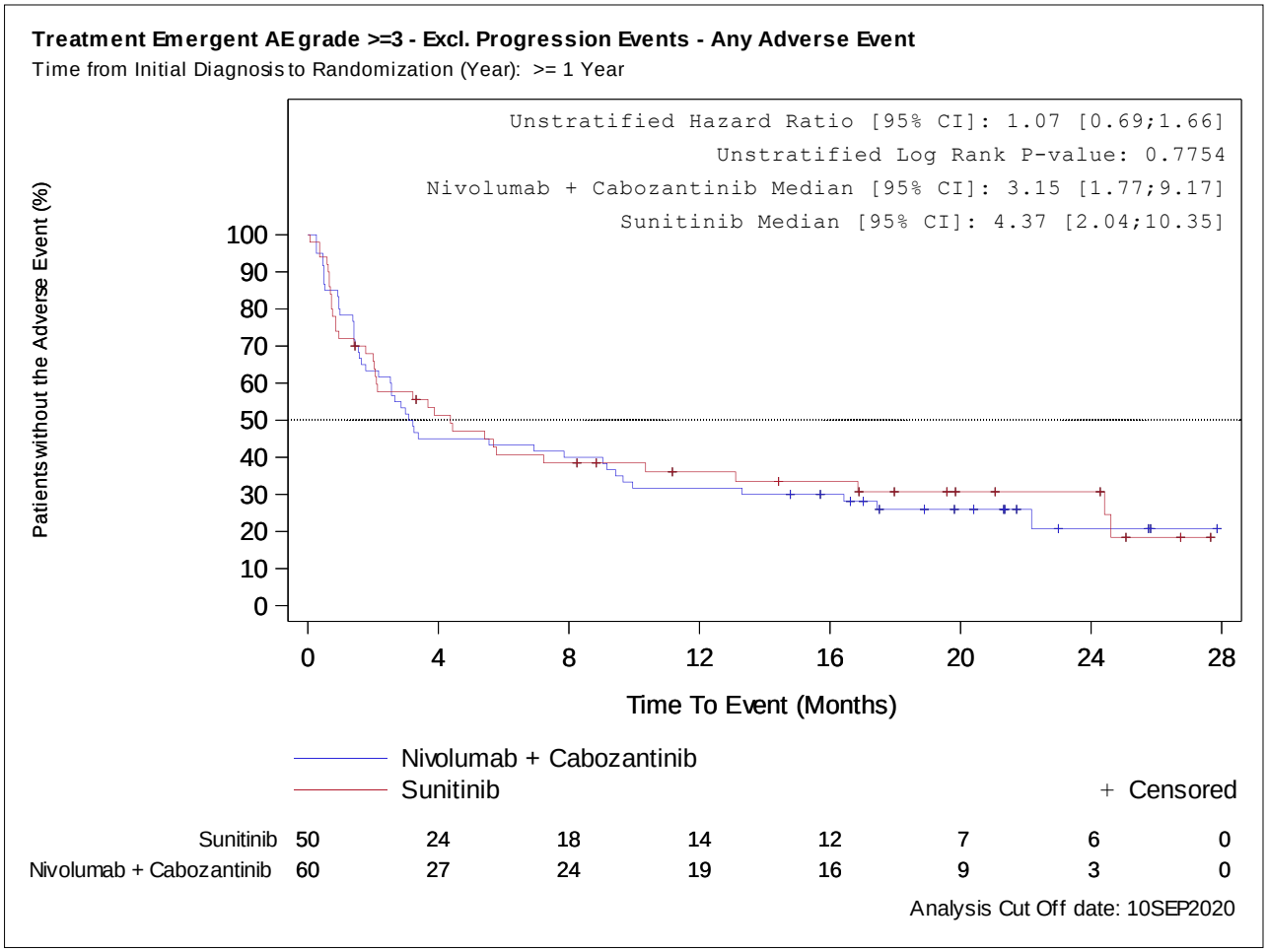
FIGURE 3.11.2.16: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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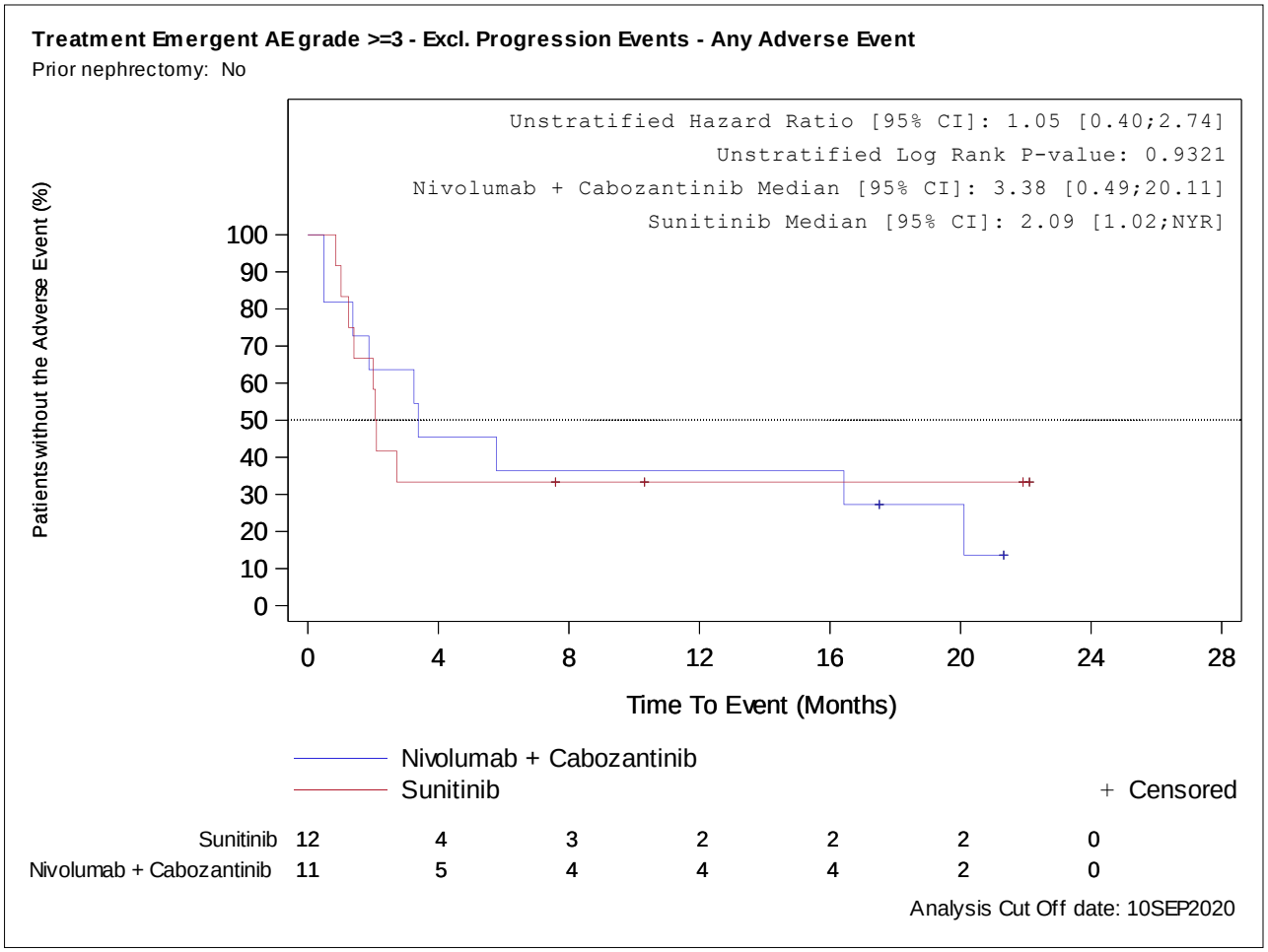
FIGURE 3.11.2.17: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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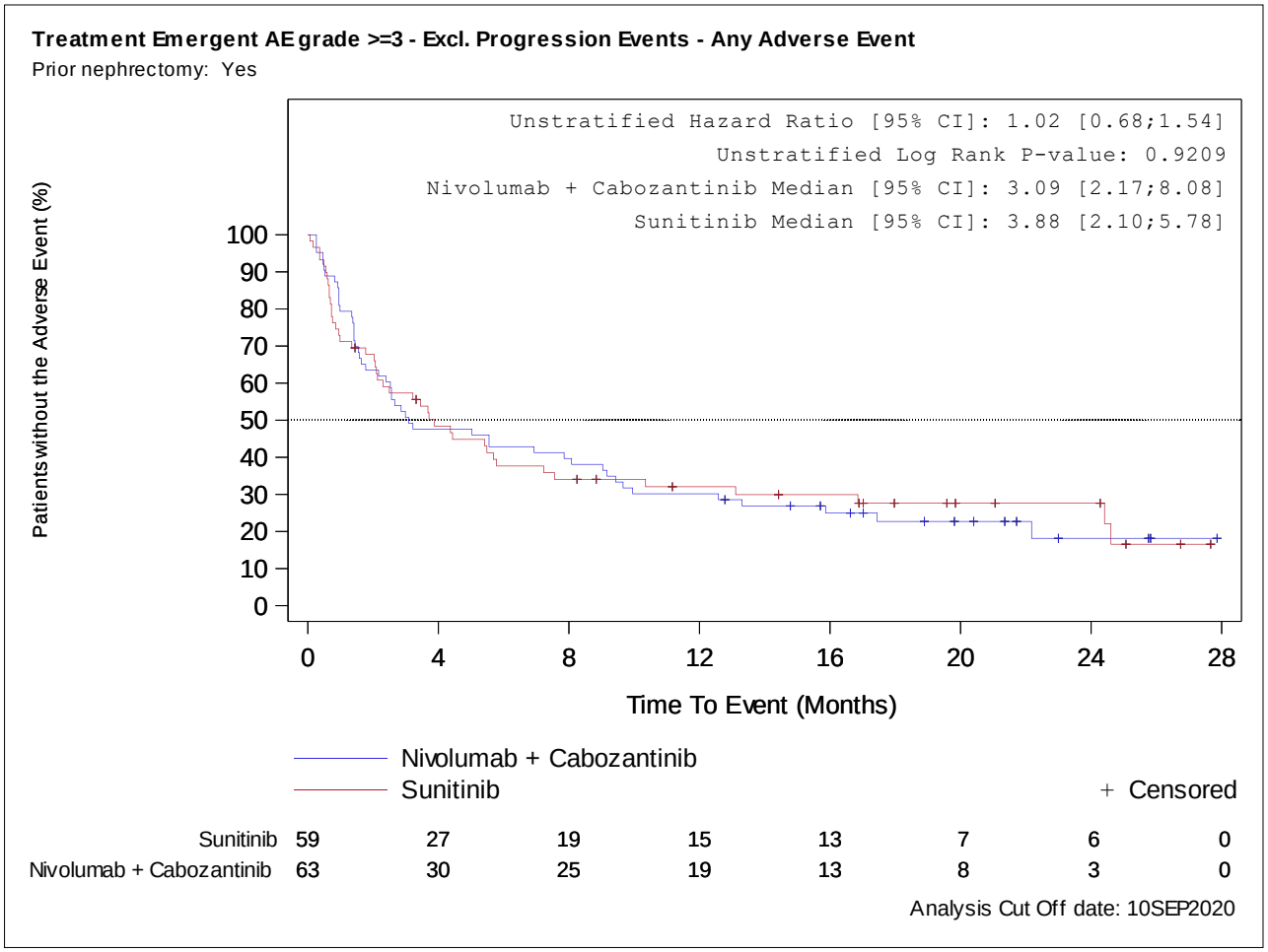
FIGURE 3.11.2.18: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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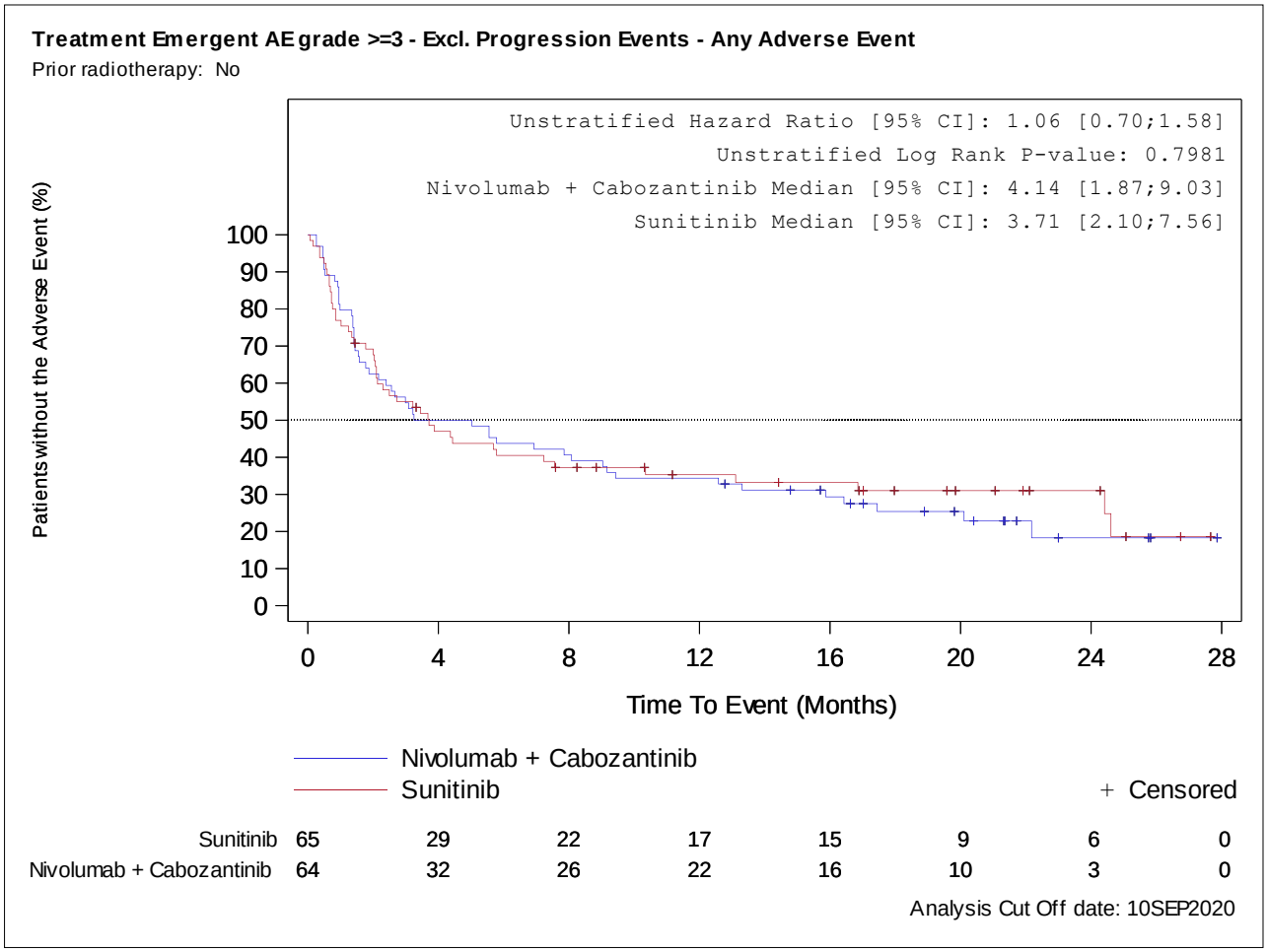
FIGURE 3.11.2.19: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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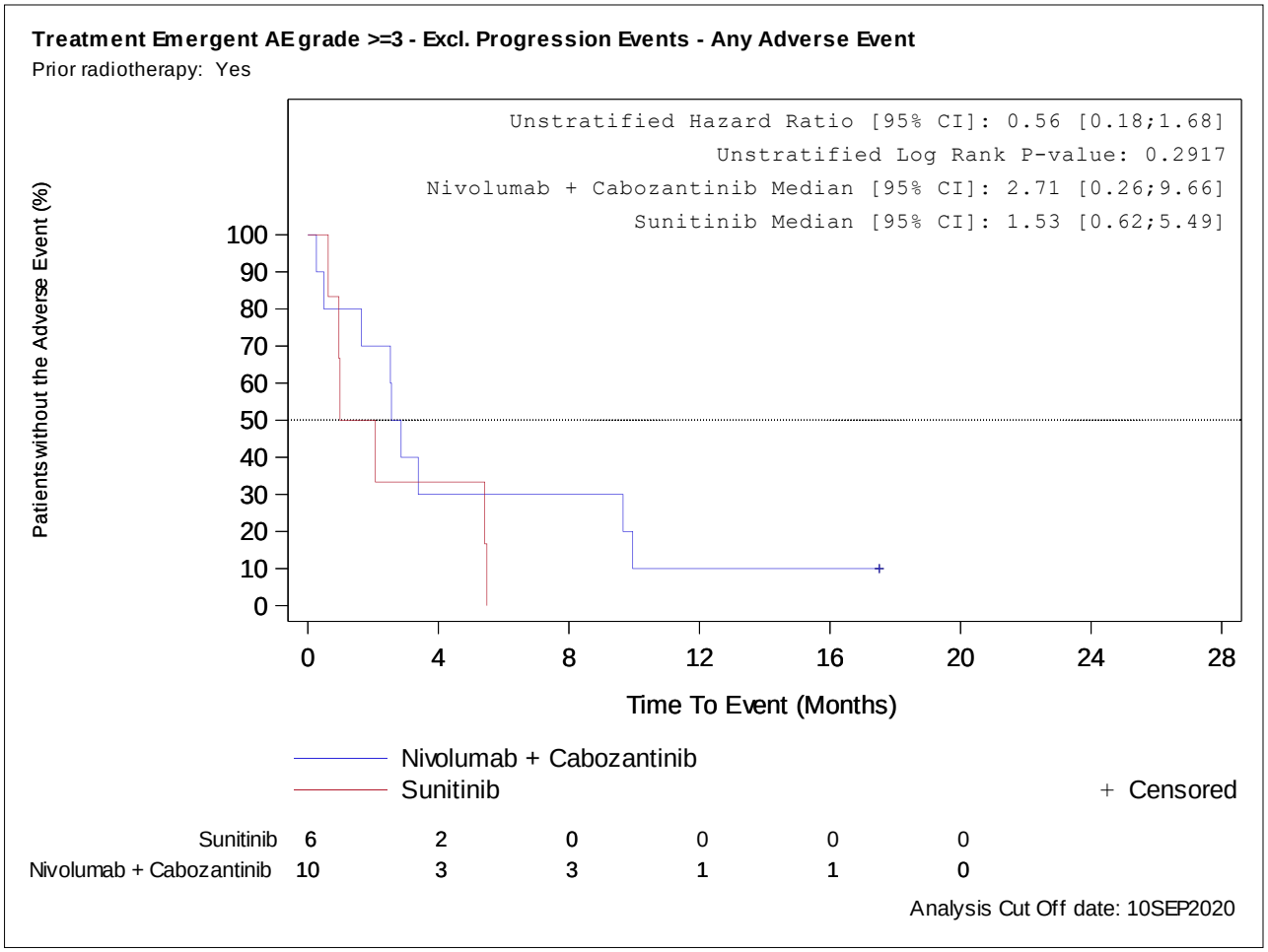
FIGURE 3.11.2.20: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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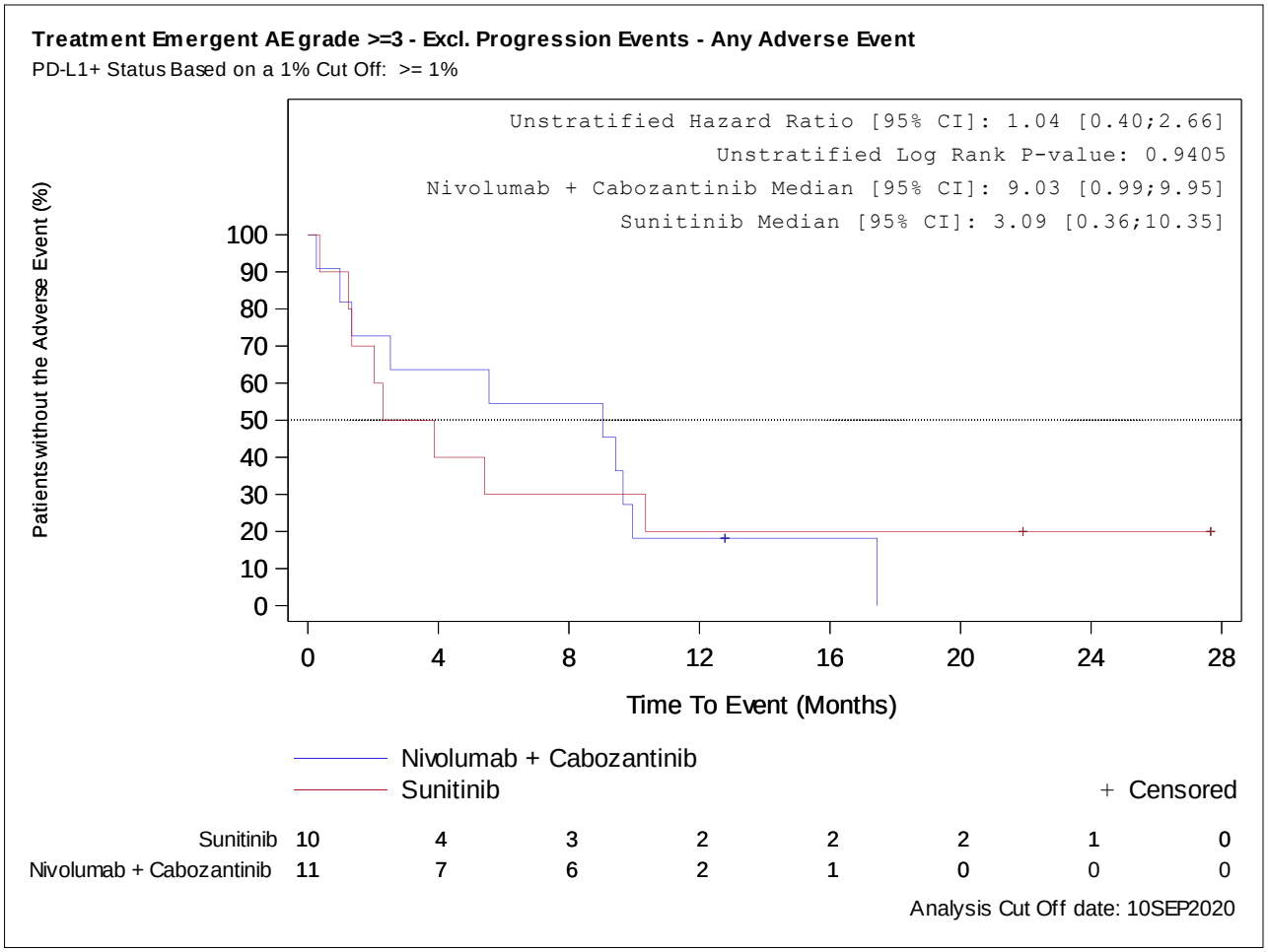
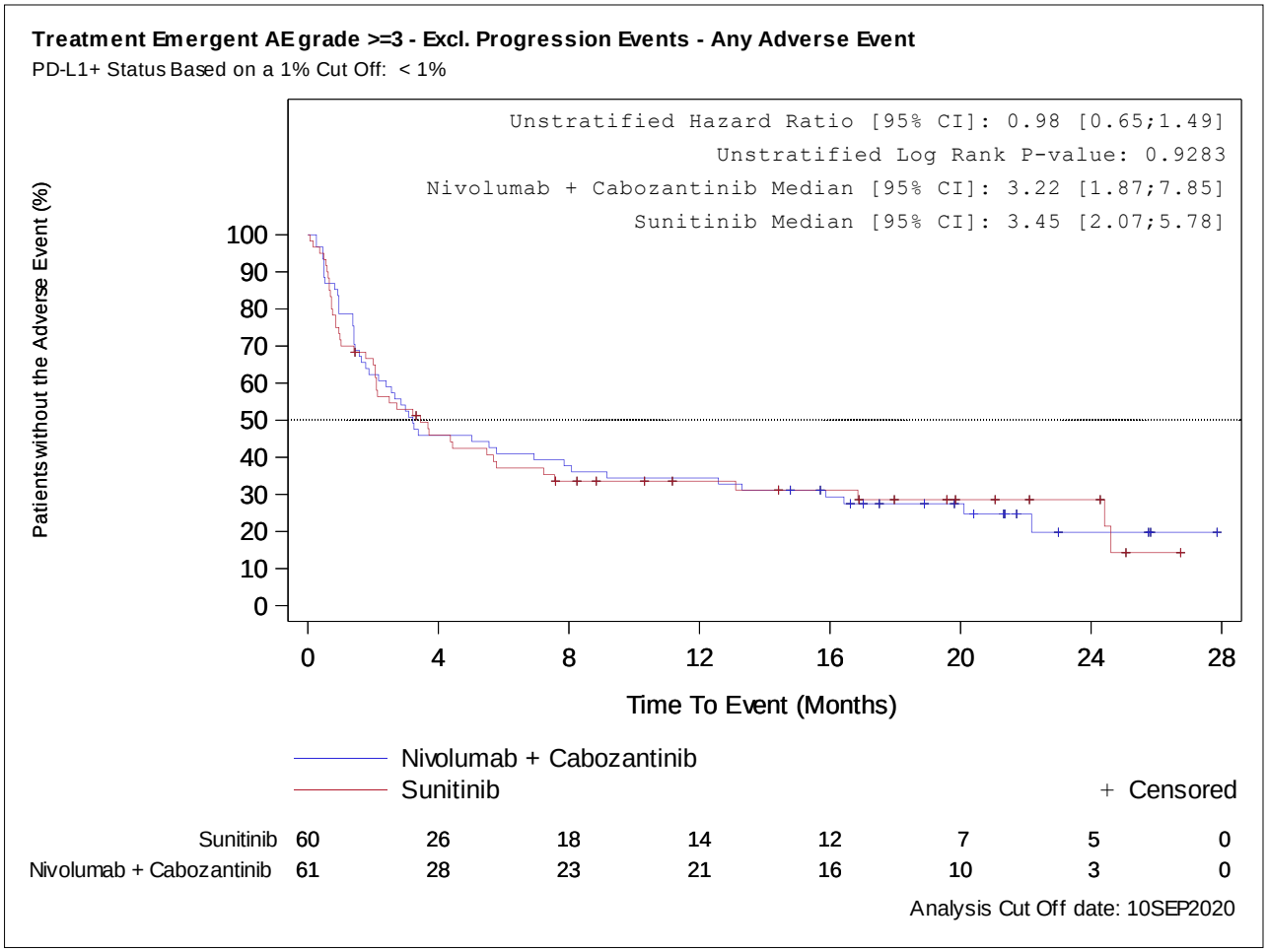
FIGURE 3.11.2.21: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off:  >= 1%



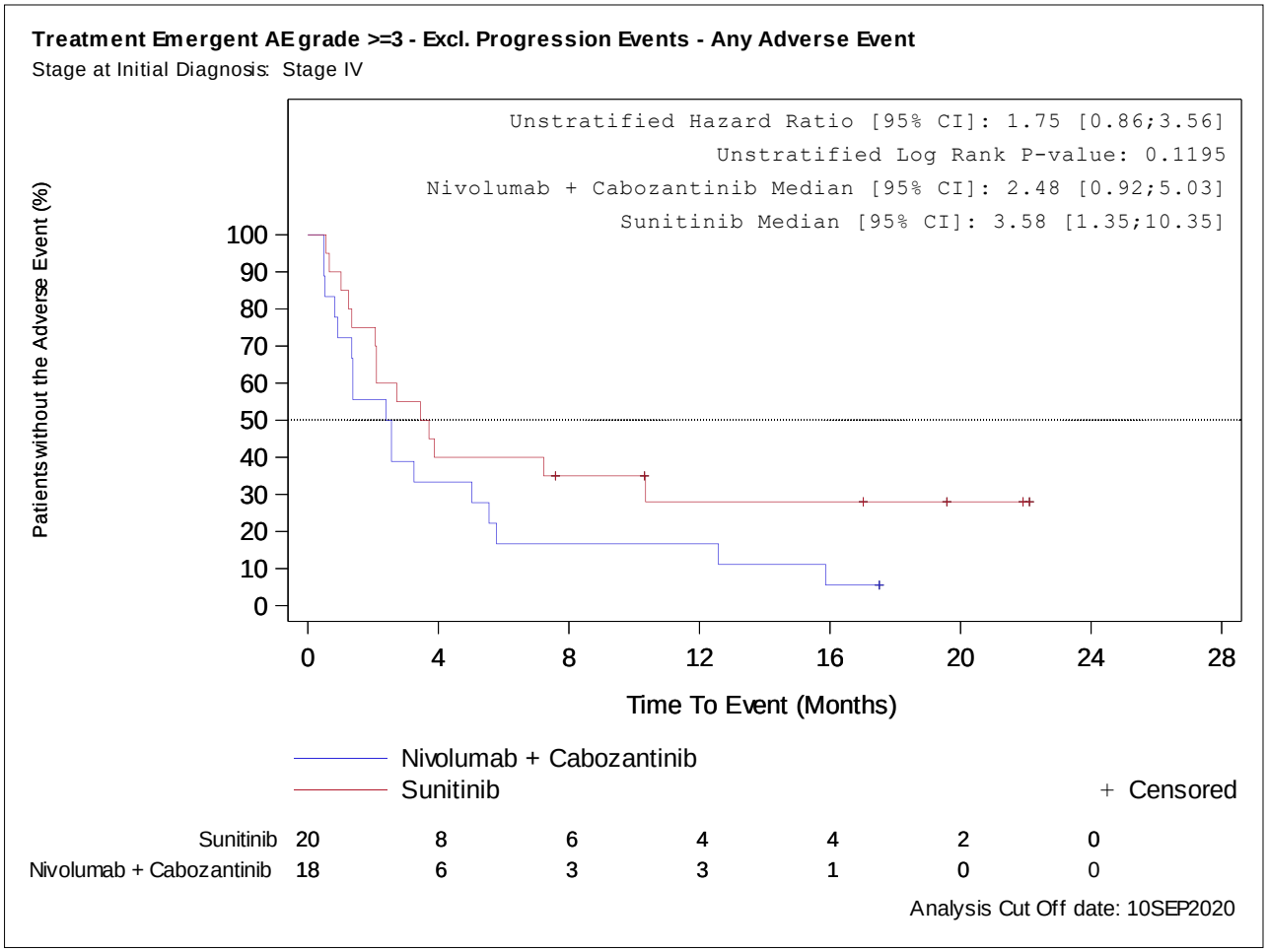

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:23:54

FIGURE 3.11.2.22: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



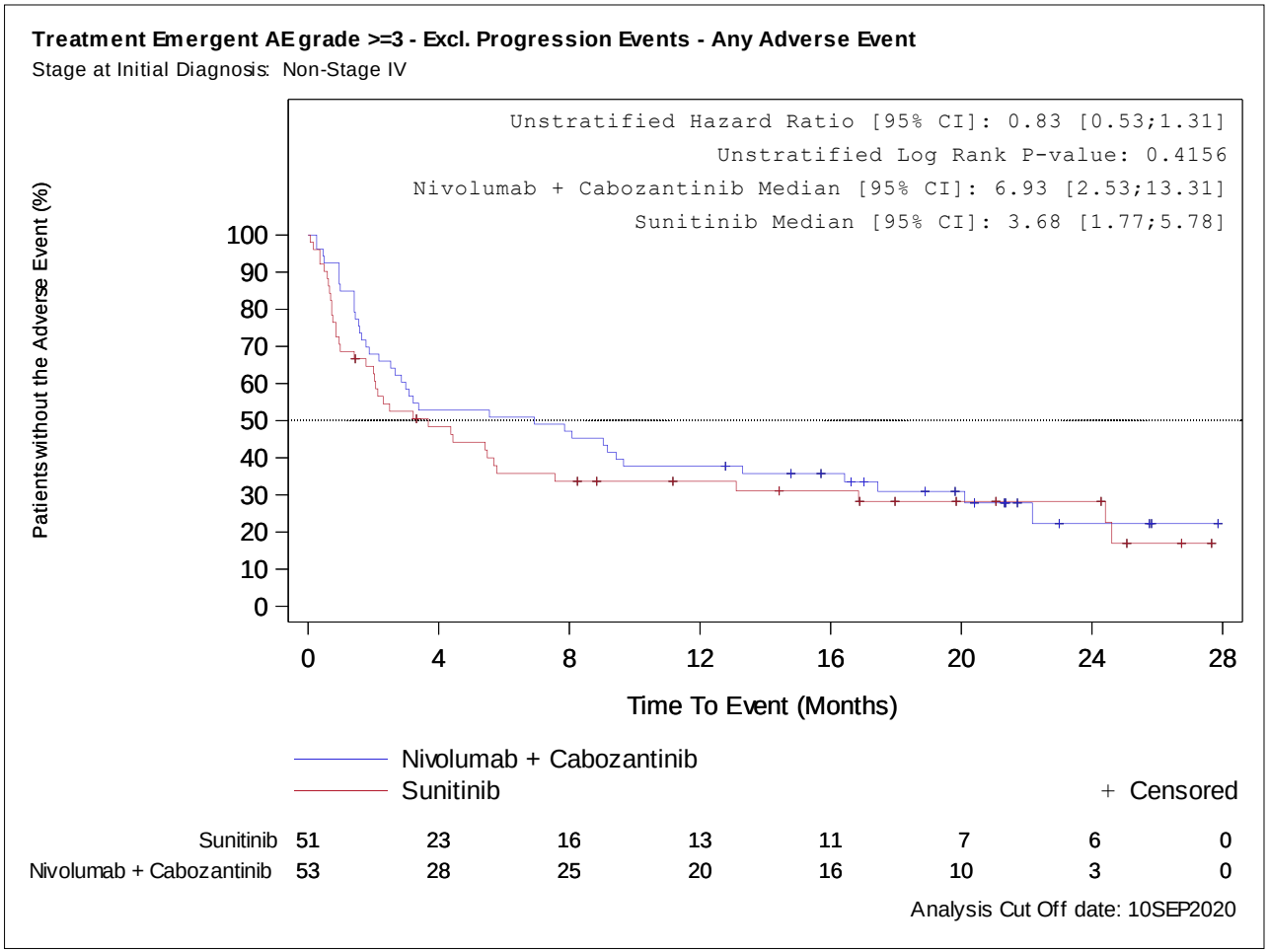

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:24:00

FIGURE 3.11.2.23: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis:  Stage IV



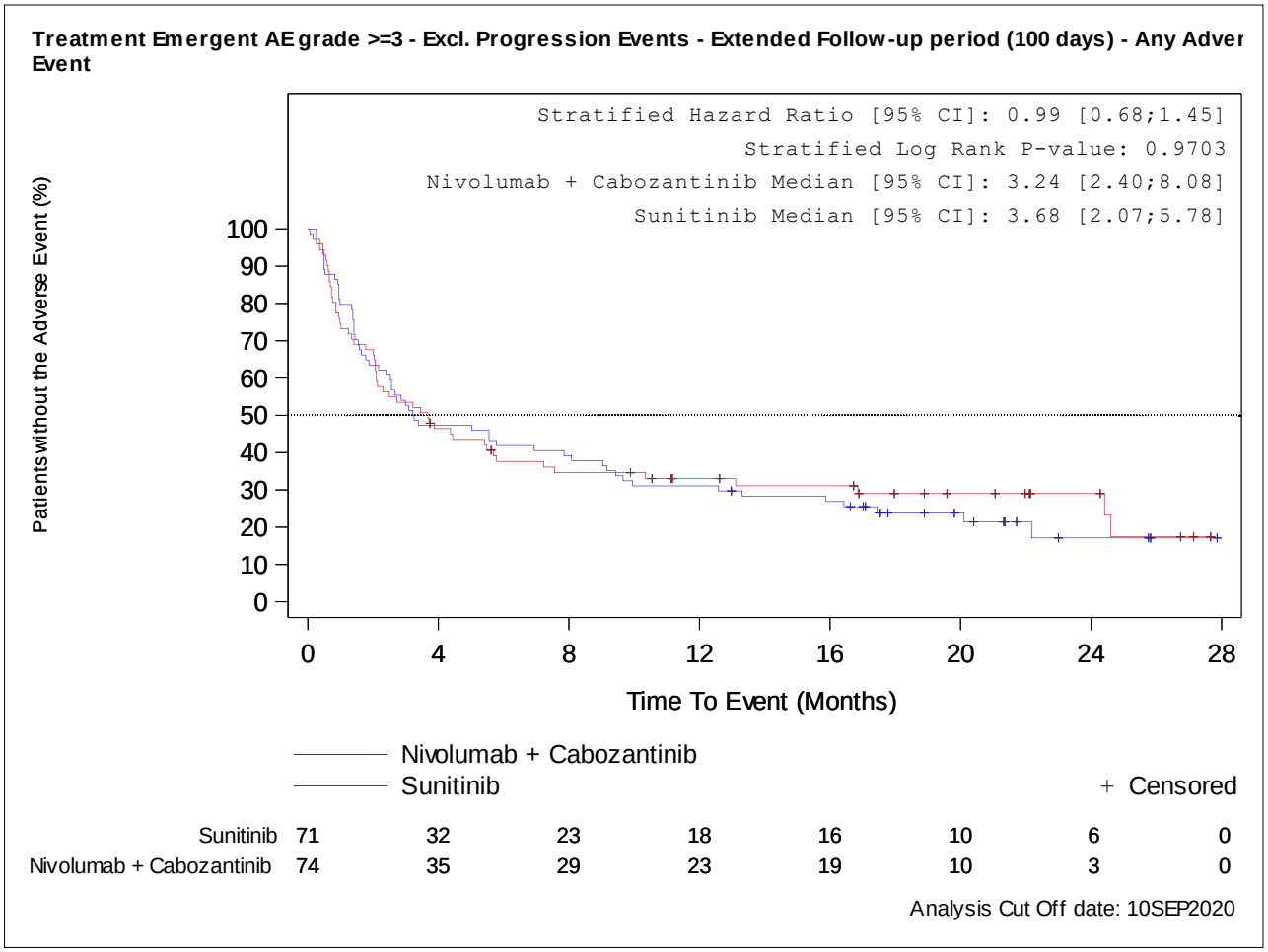

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:24:33

FIGURE 3.11.2.24: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



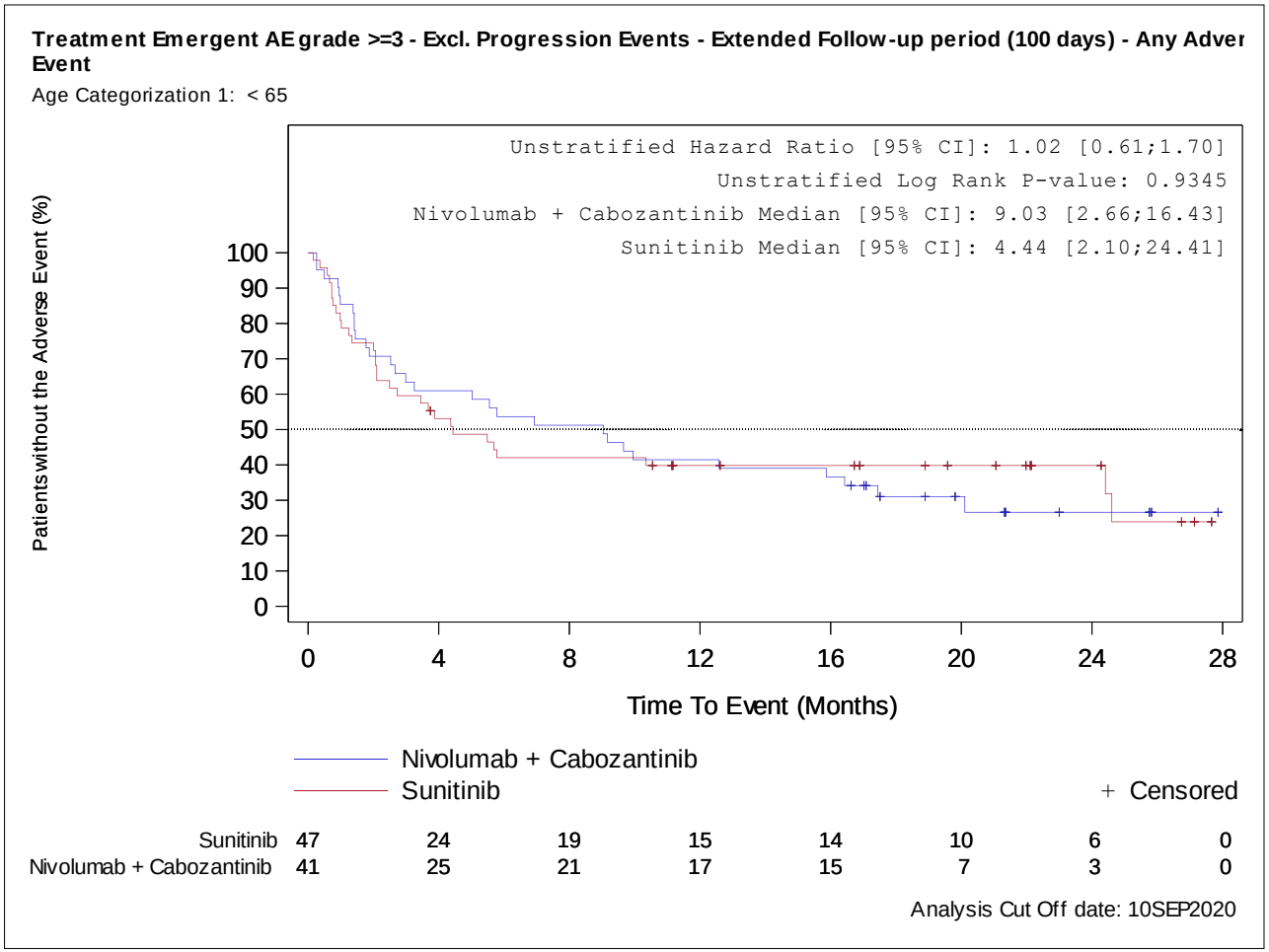

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:24:39

FIGURE 3.12.1: Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



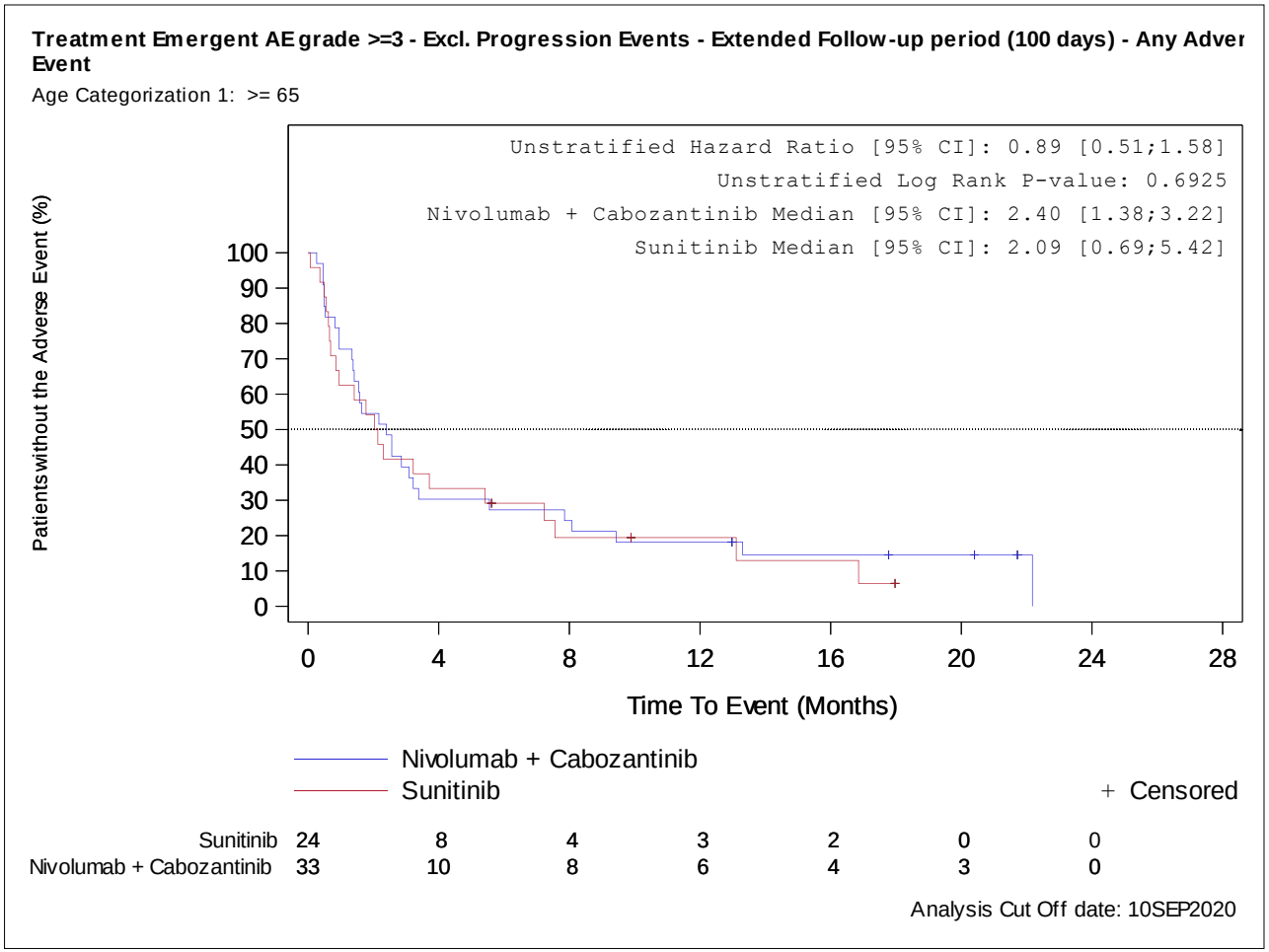

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:28:09

FIGURE 3.12.2.1: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



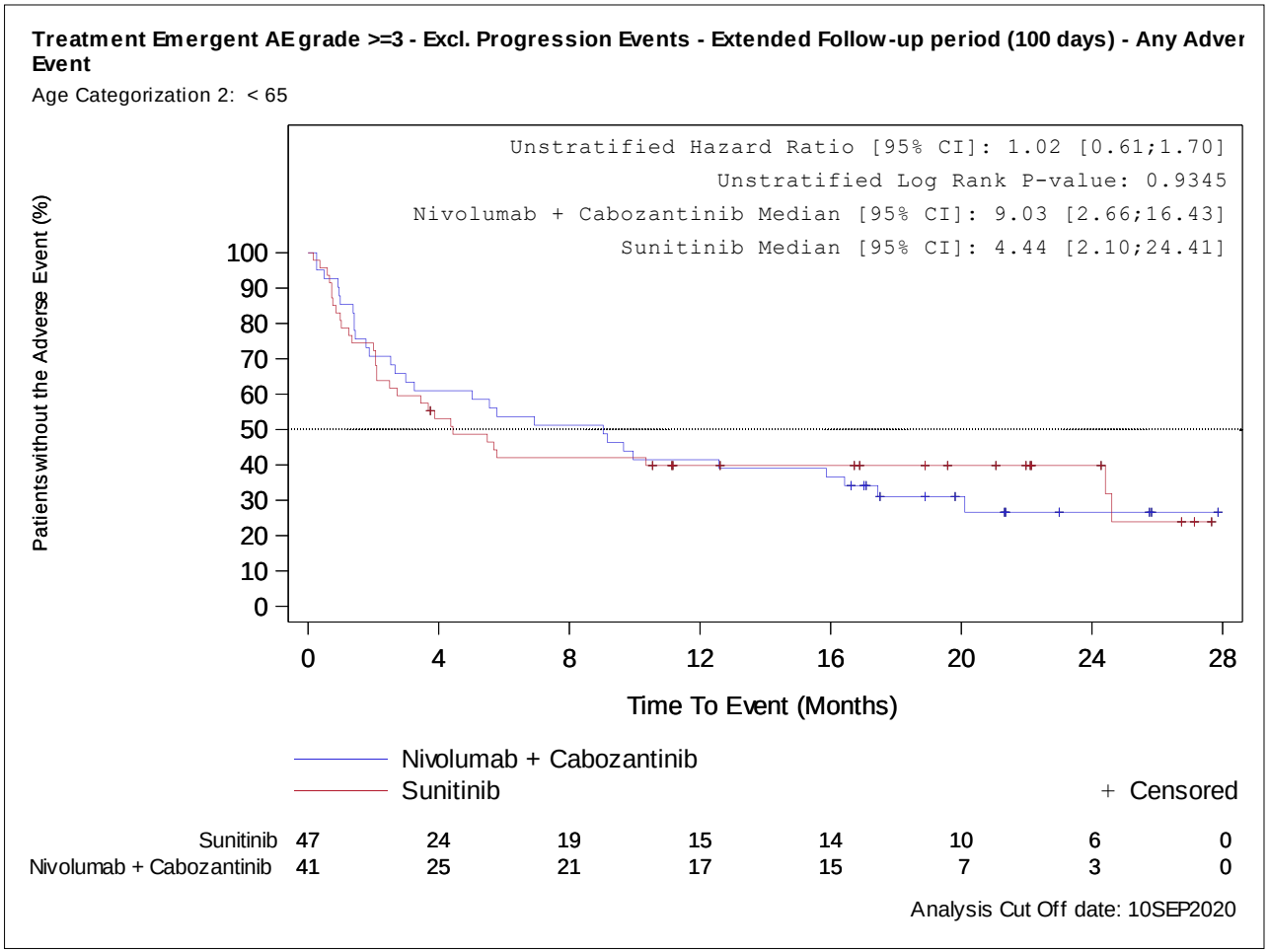

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:28:13

FIGURE 3.12.2.2: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



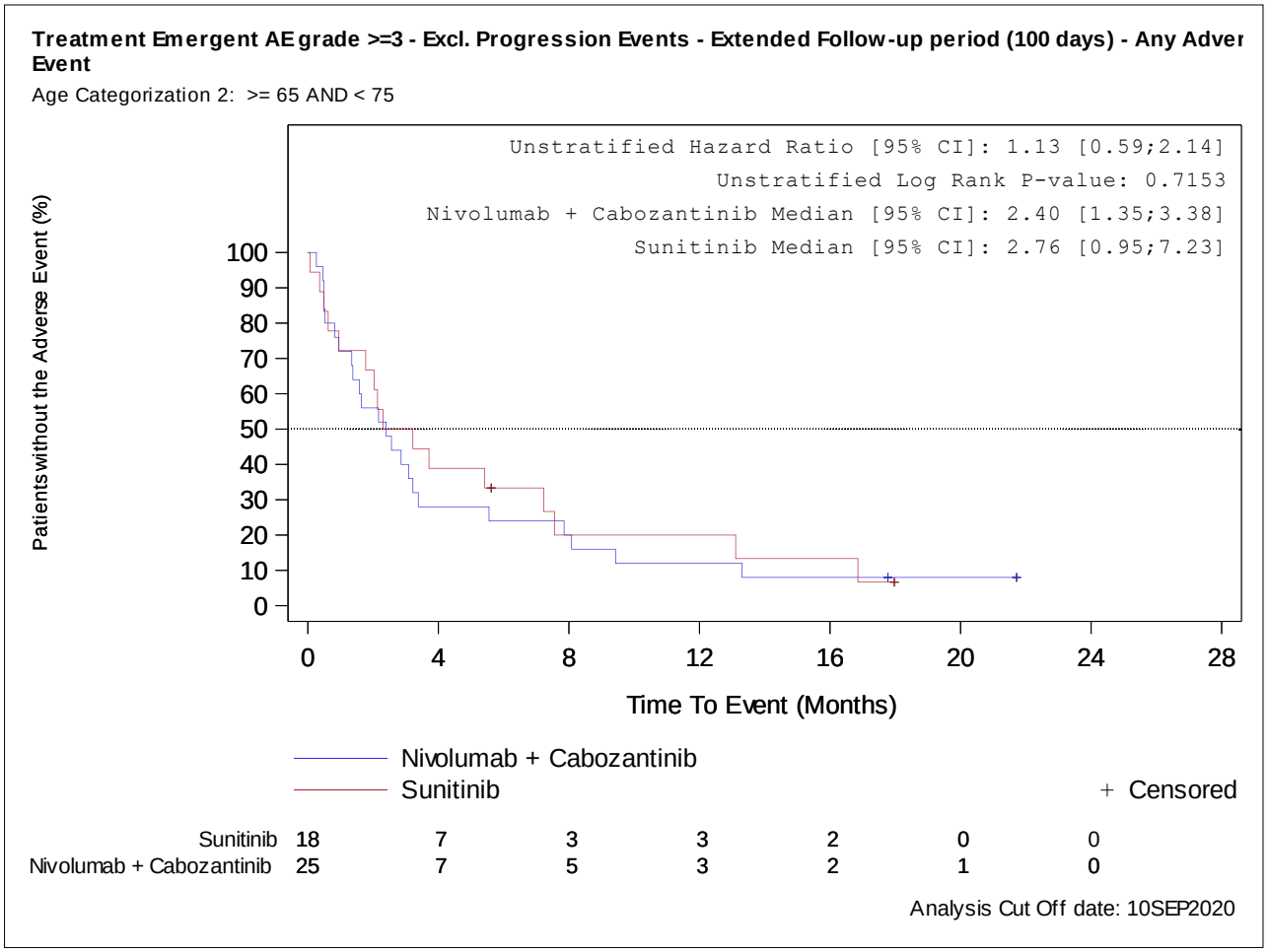

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:28:19

FIGURE 3.12.2.3: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



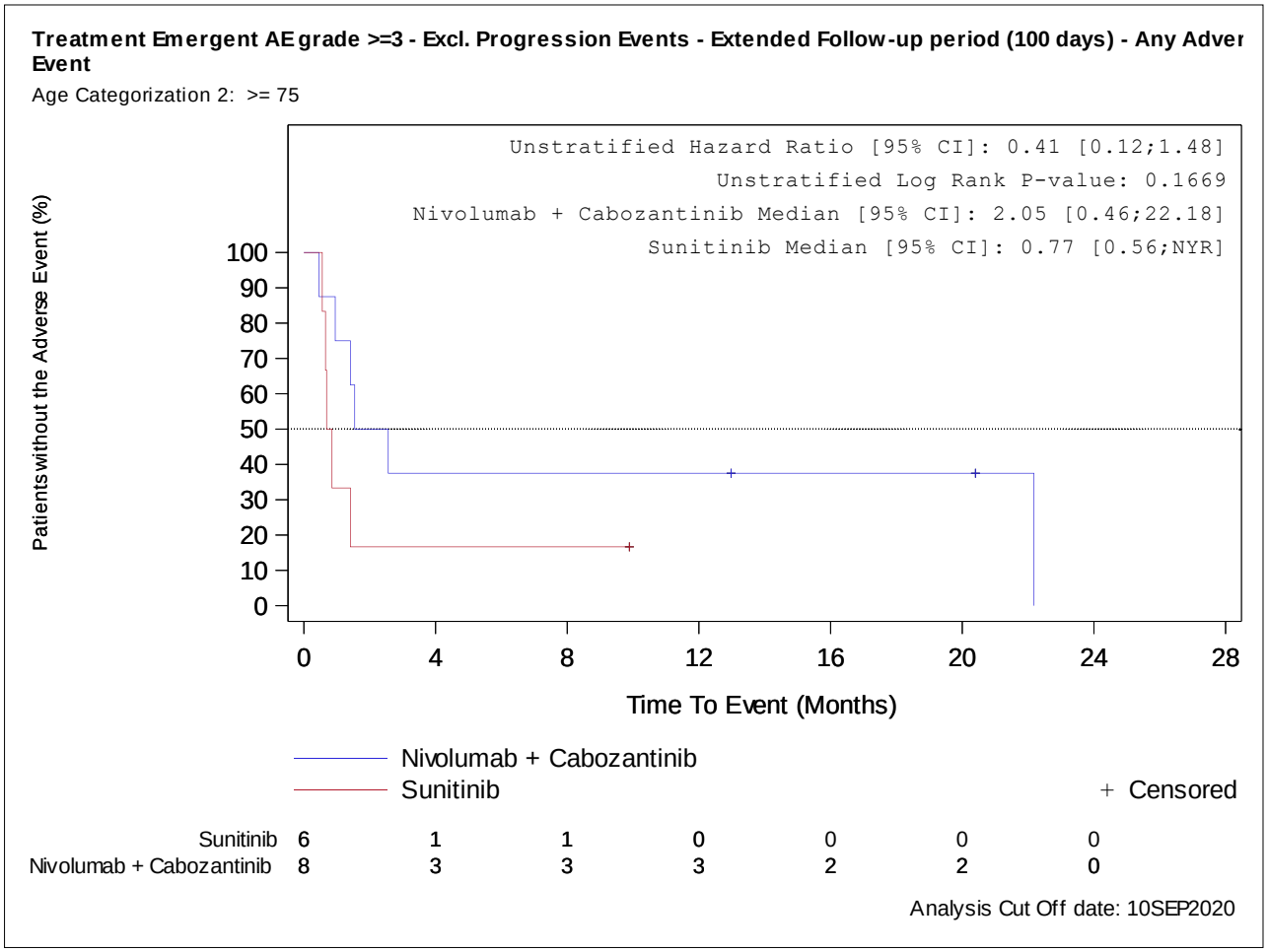

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:28:26

FIGURE 3.12.2.4: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



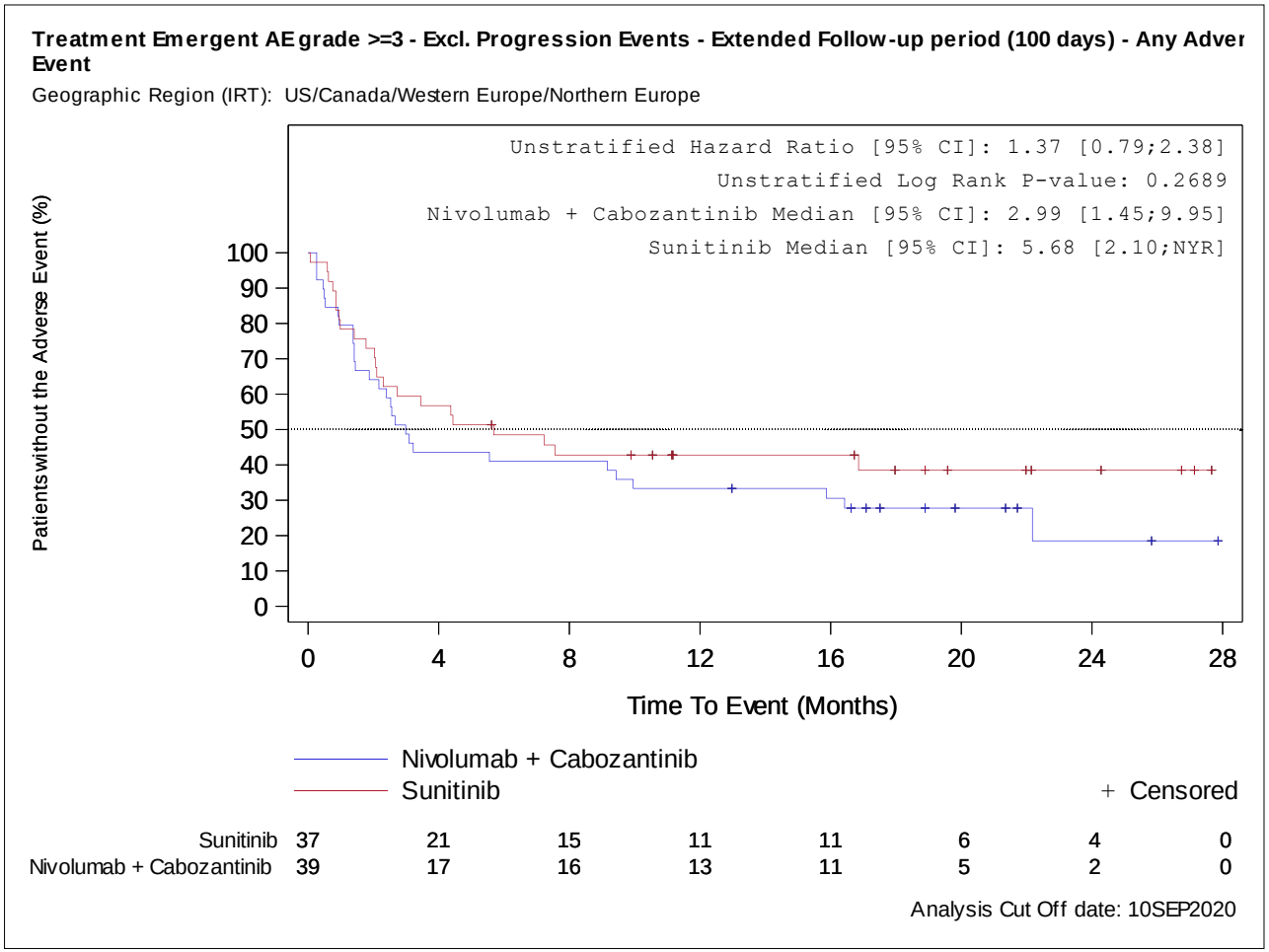

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:28:32

FIGURE 3.12.2.5: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



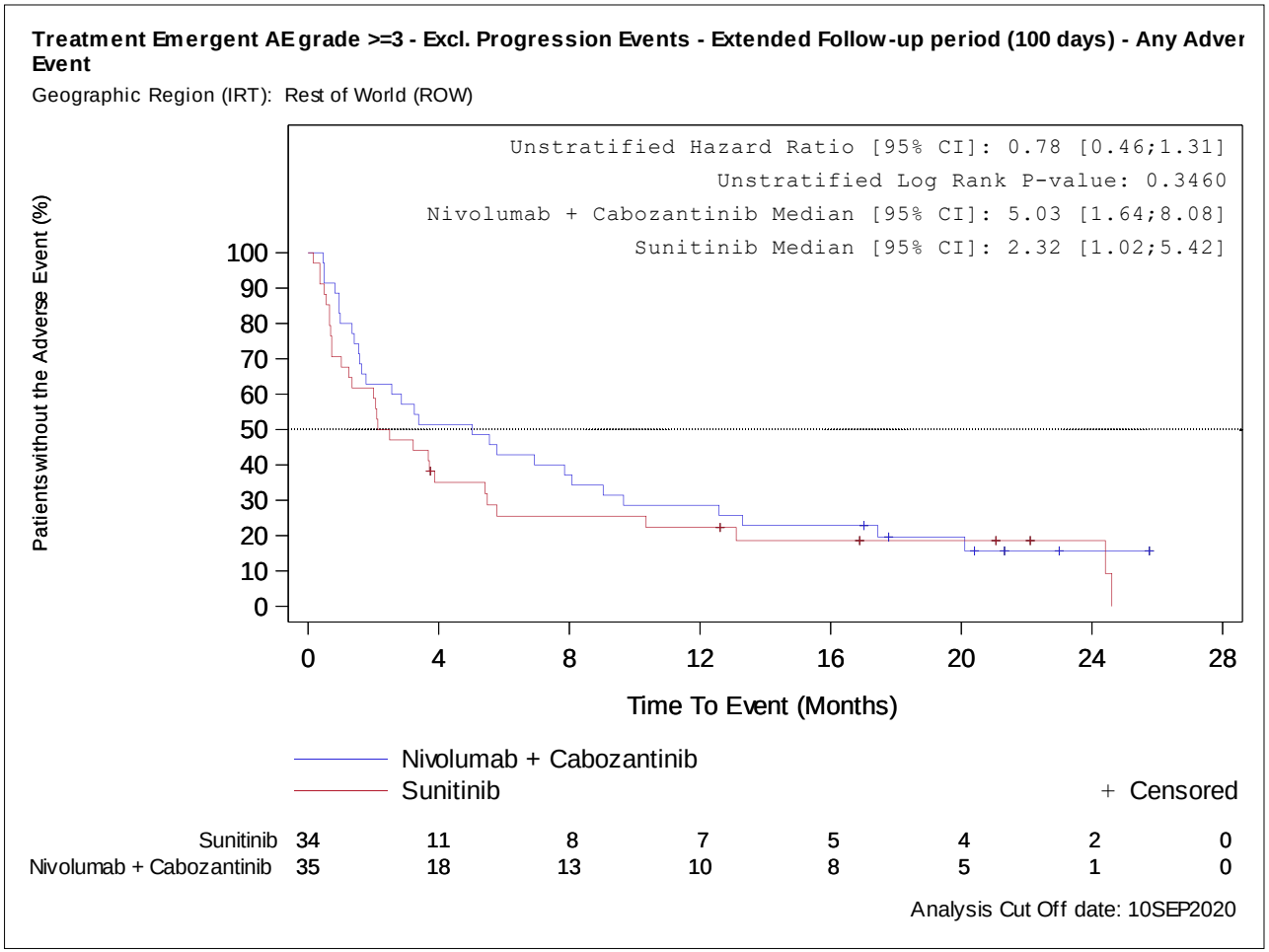

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:28:38

FIGURE 3.12.2.6: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



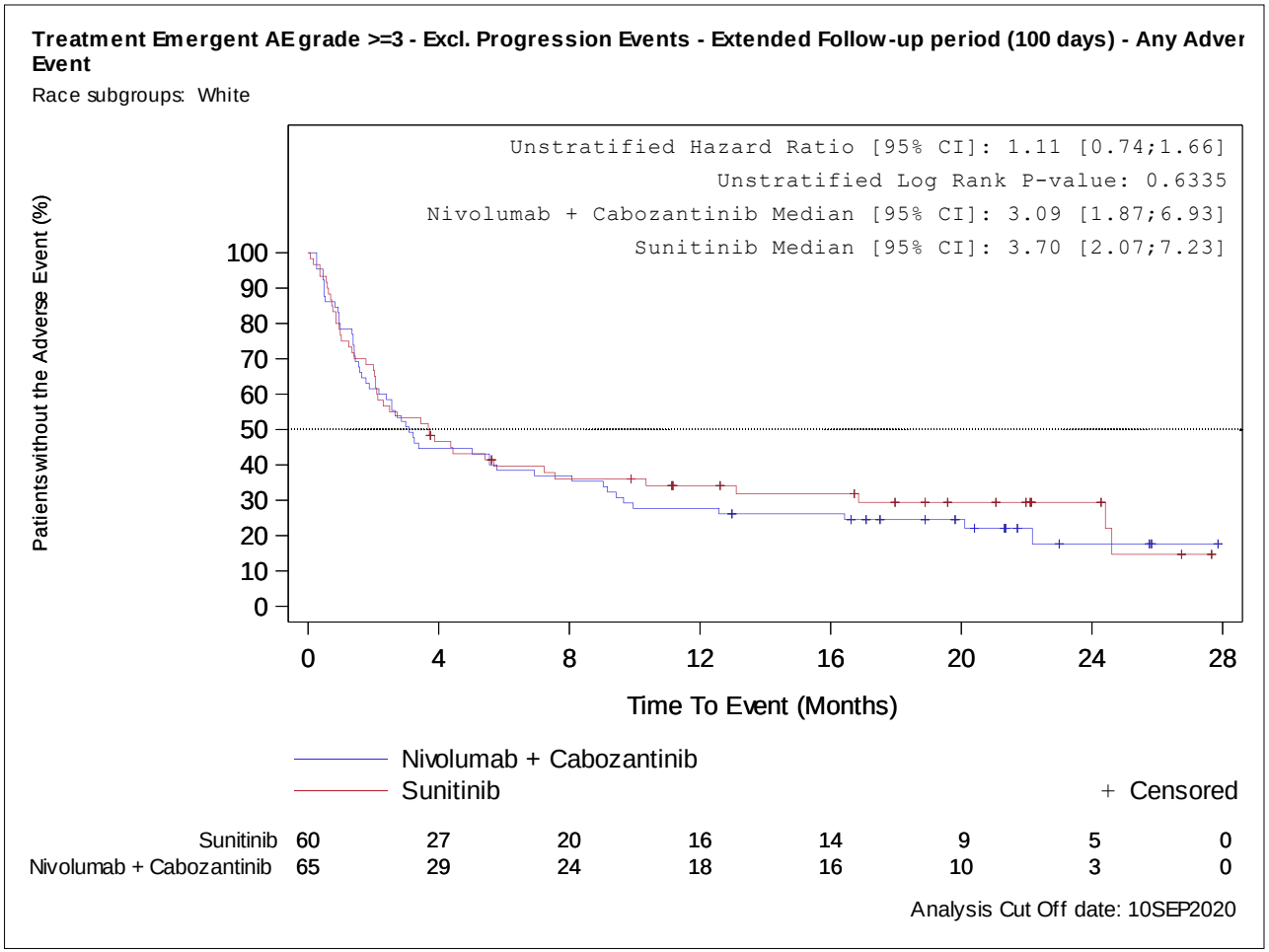

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:28:44

FIGURE 3.12.2.7: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:28:50

FIGURE 3.12.2.8: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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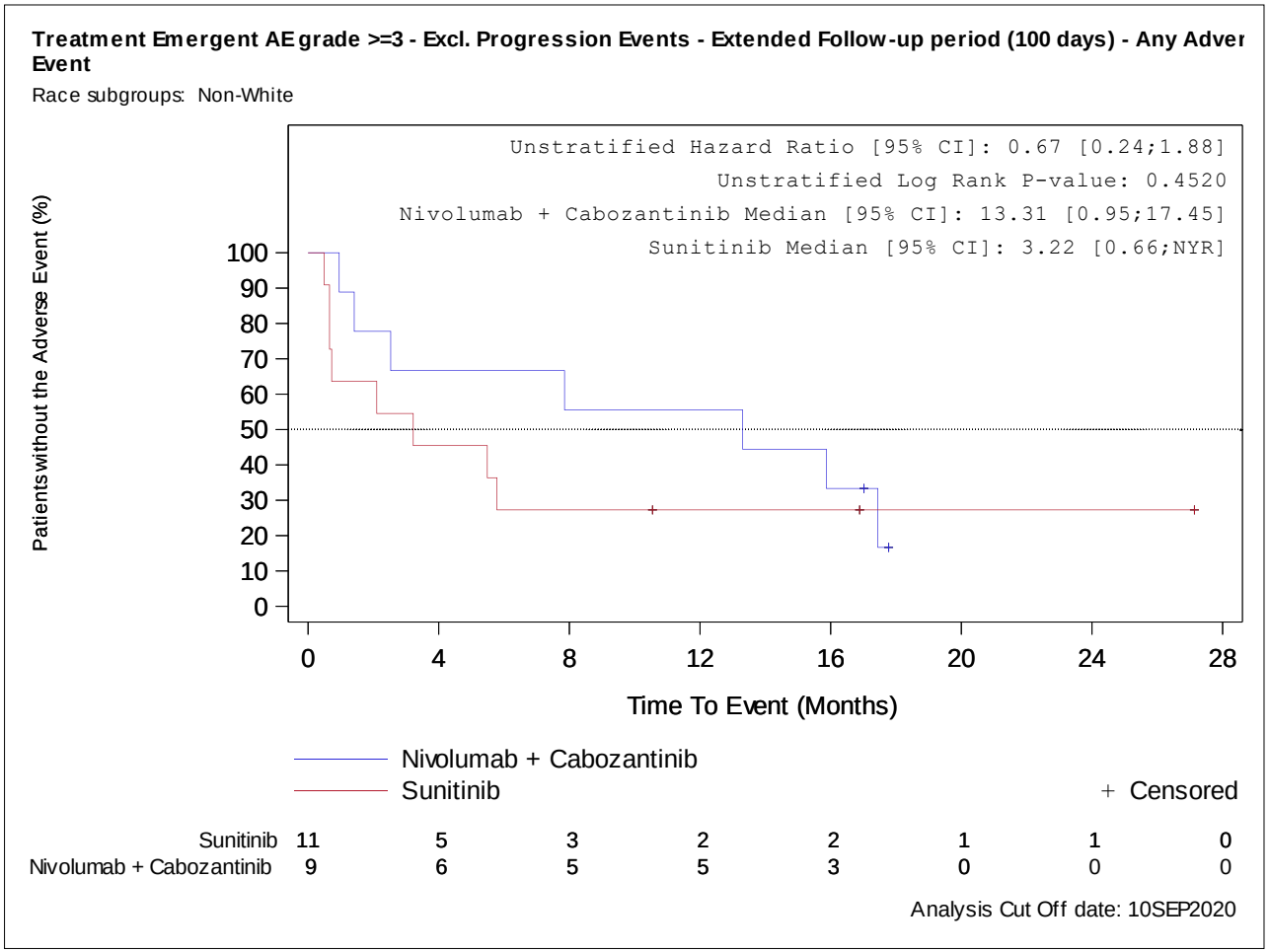
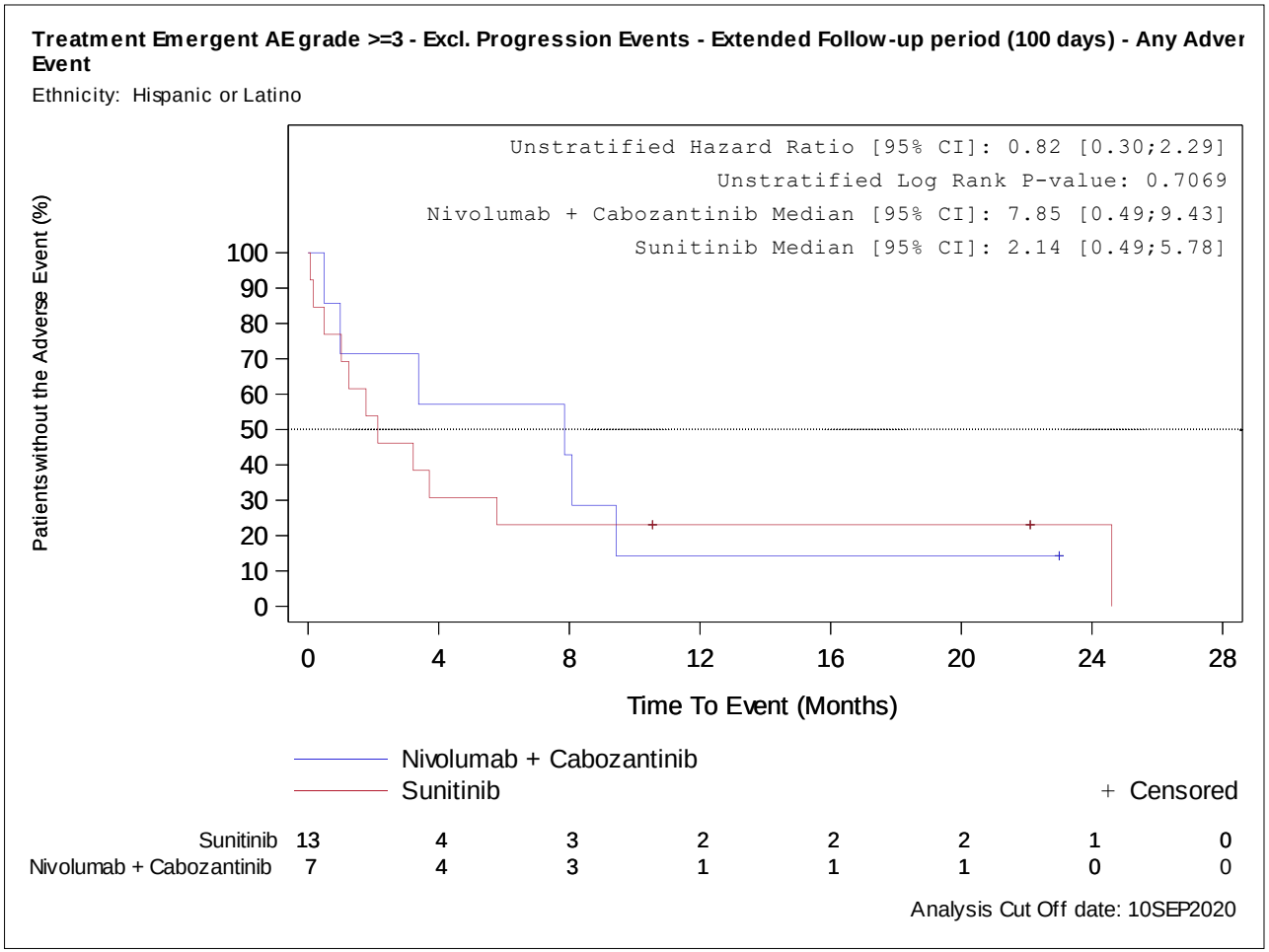
FIGURE 3.12.2.9: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



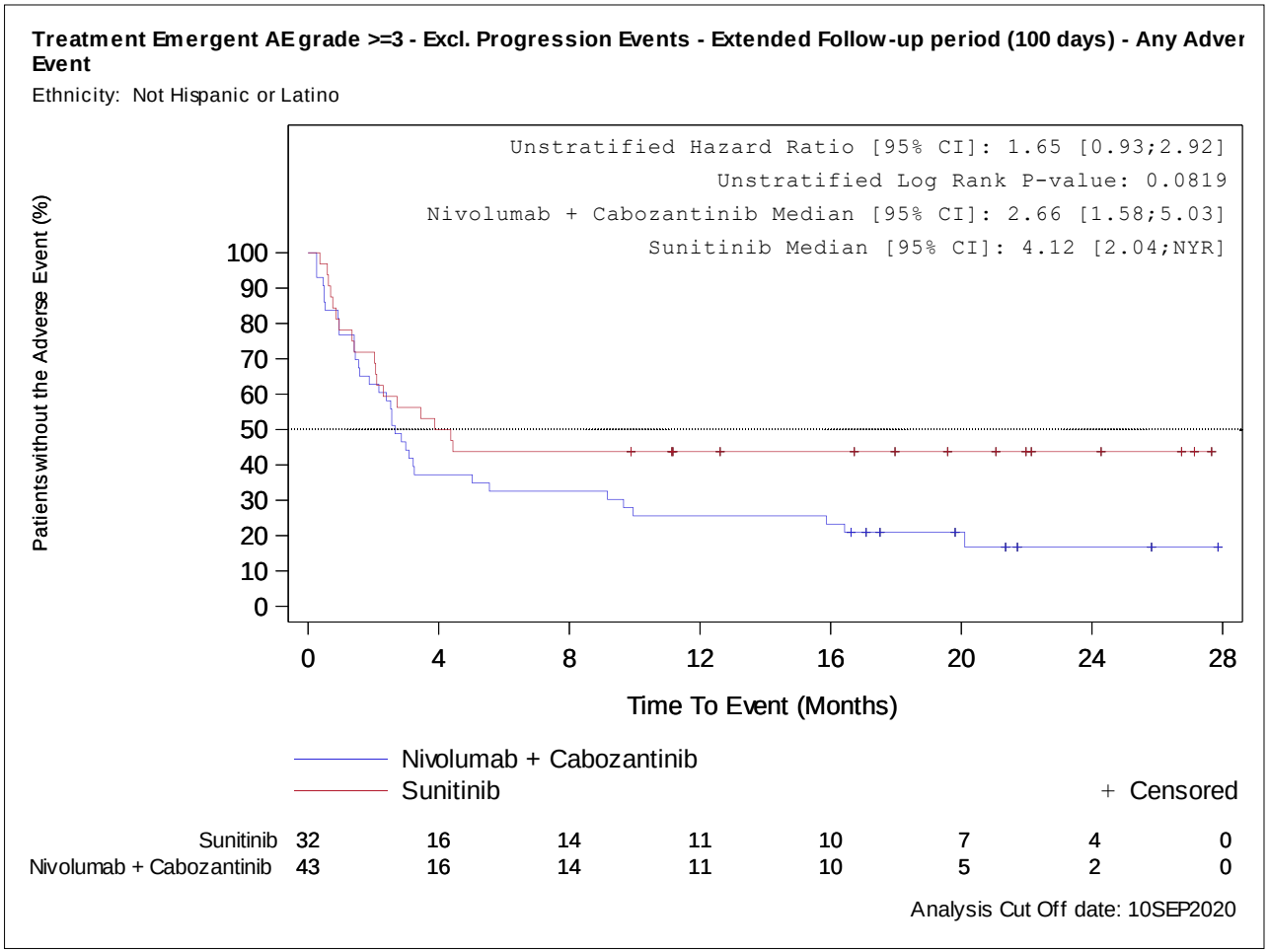

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:29:02

FIGURE 3.12.2.10: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:29:08

FIGURE 3.12.2.11: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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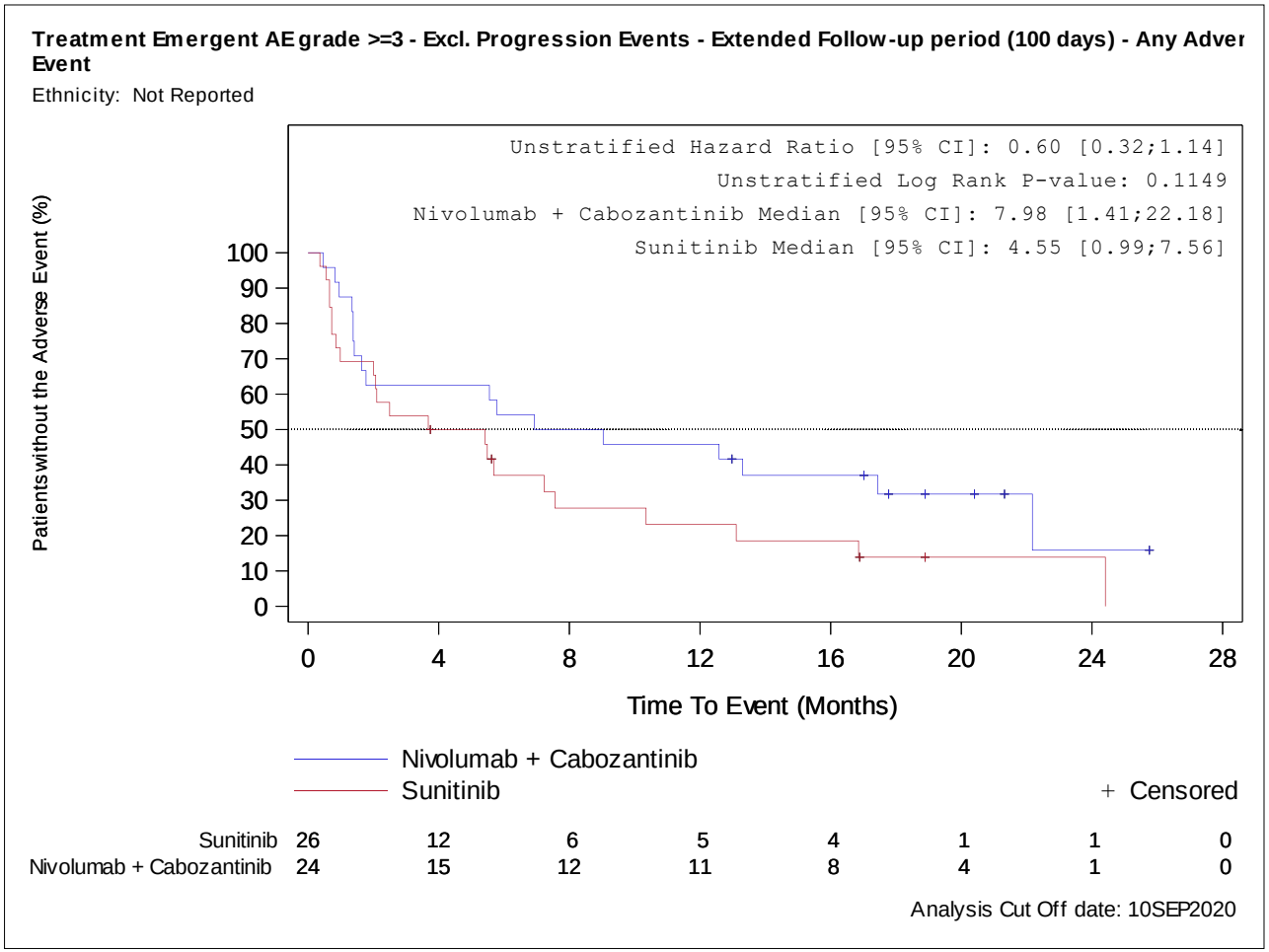
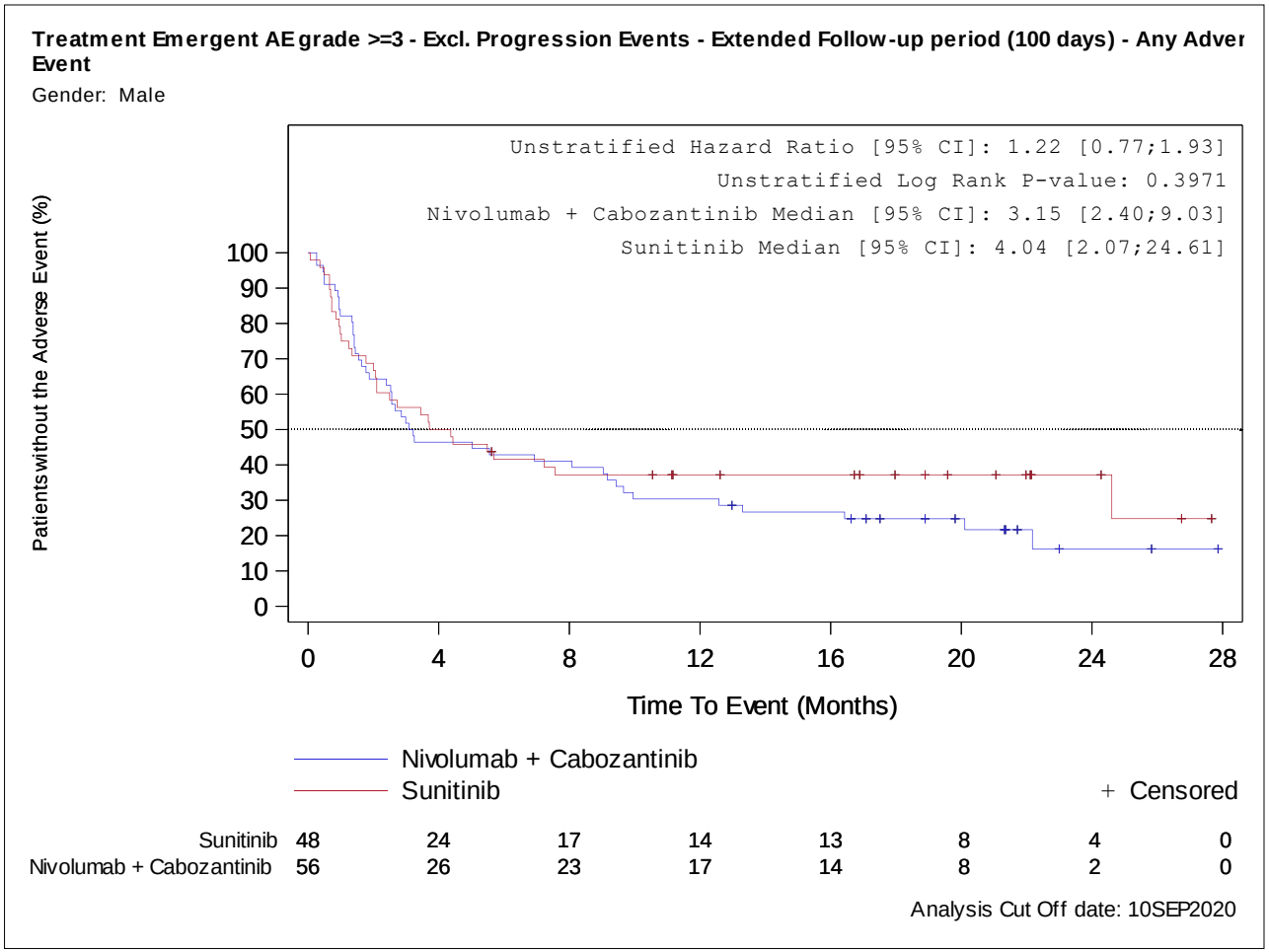
FIGURE 3.12.2.12: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



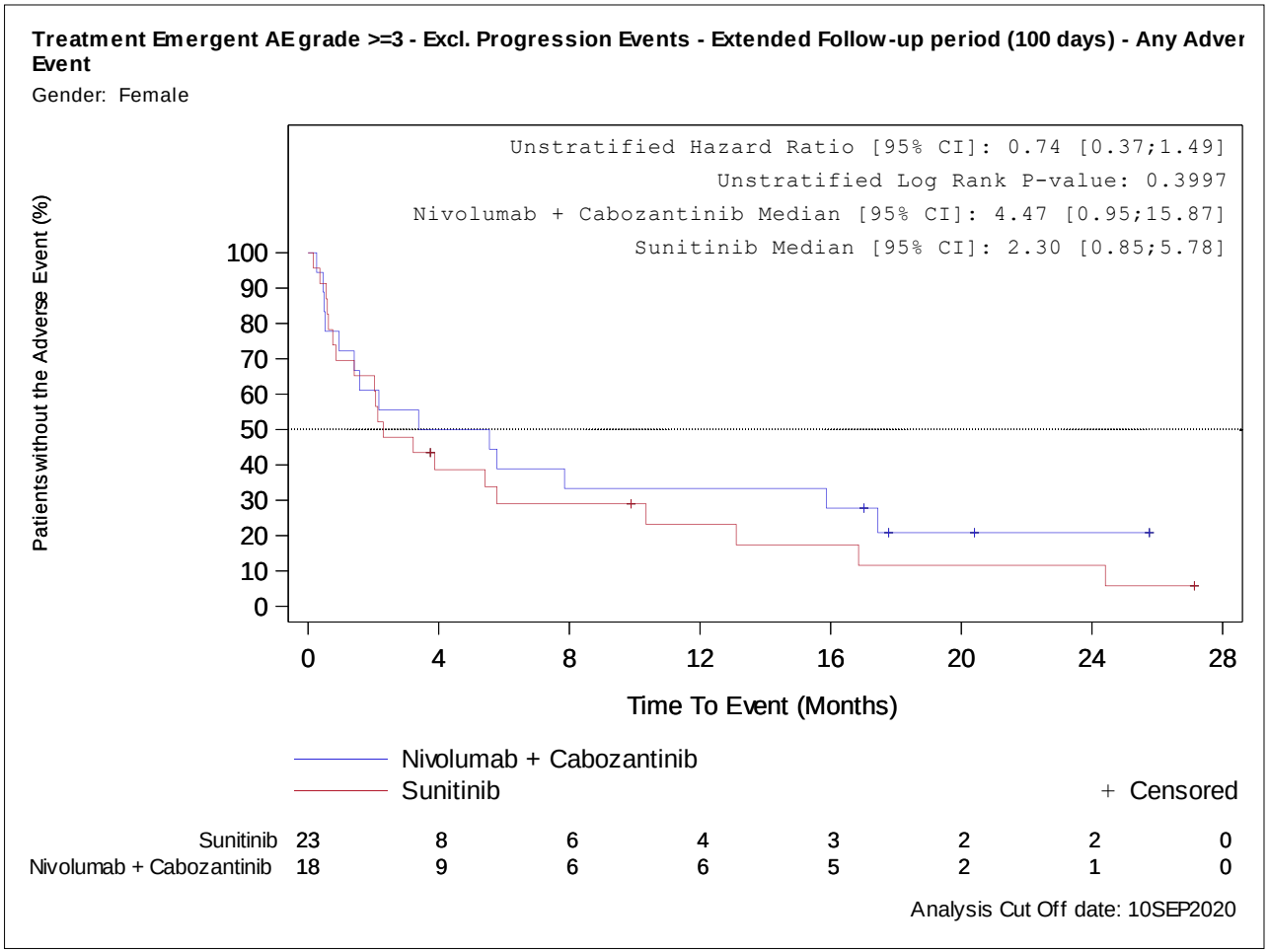

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:29:21

FIGURE 3.12.2.13: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



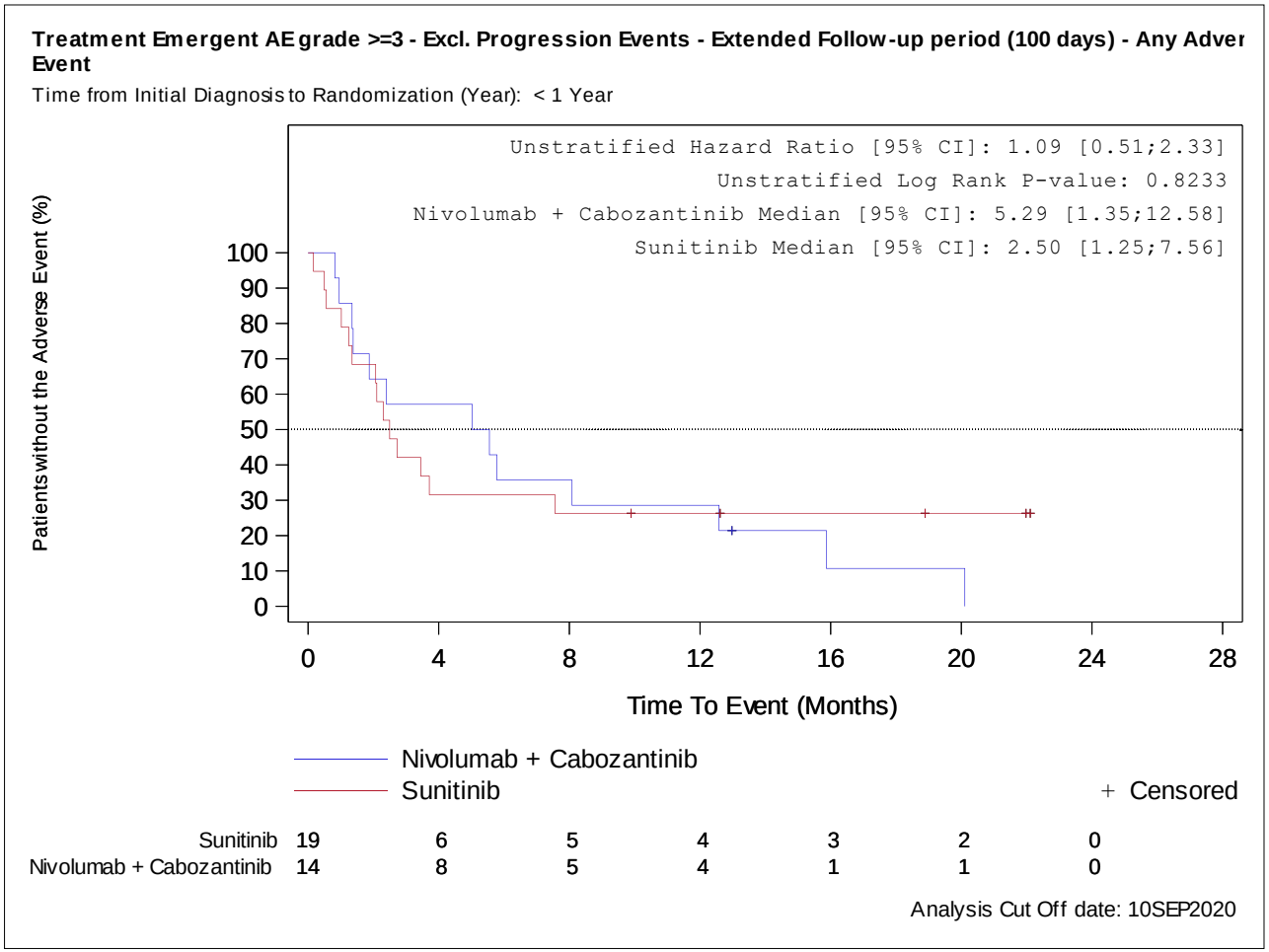

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:29:27

FIGURE 3.12.2.14: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



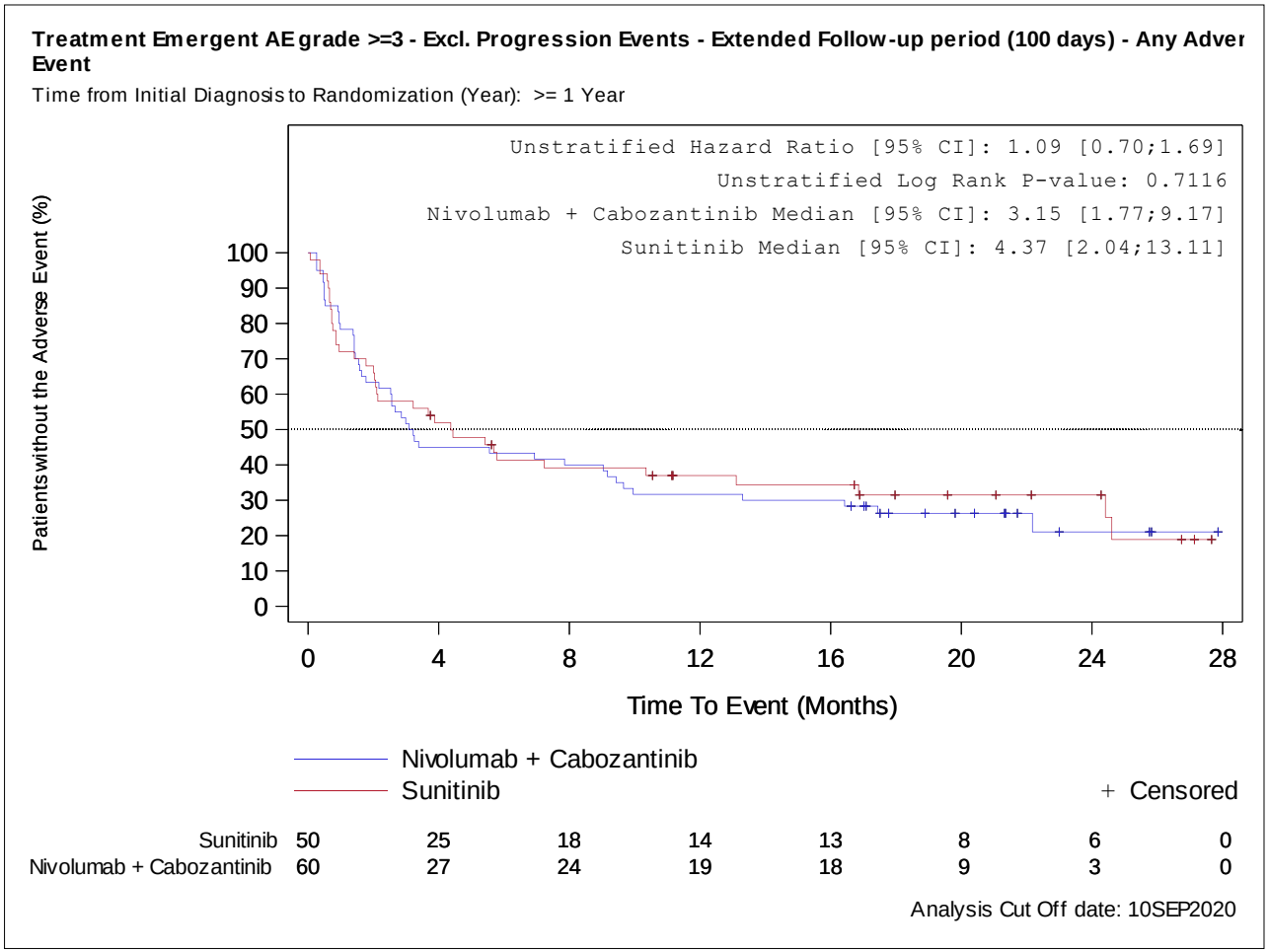

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:29:33

FIGURE 3.12.2.15: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



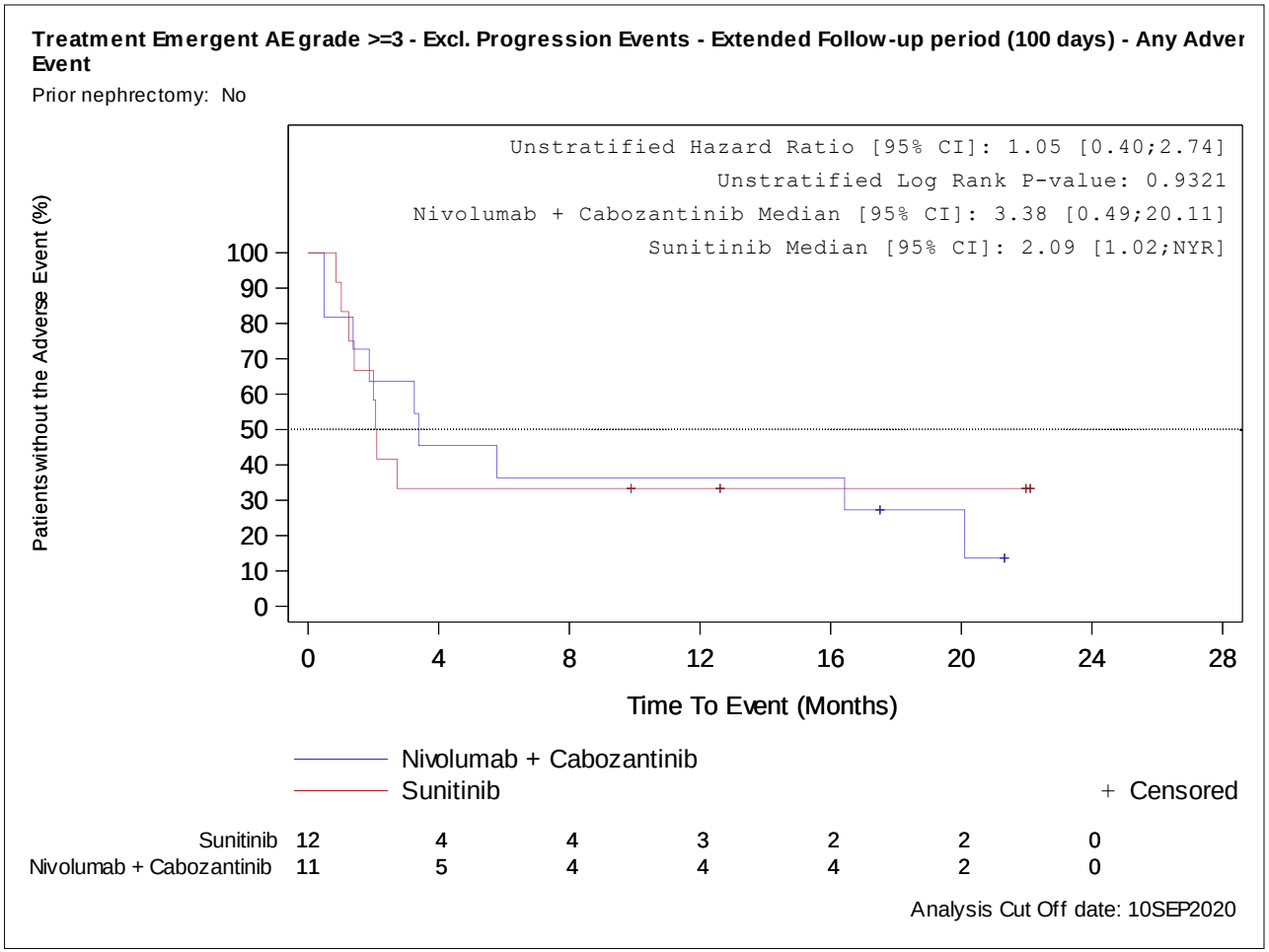

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:29:52

FIGURE 3.12.2.16: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:29:58

FIGURE 3.12.2.17: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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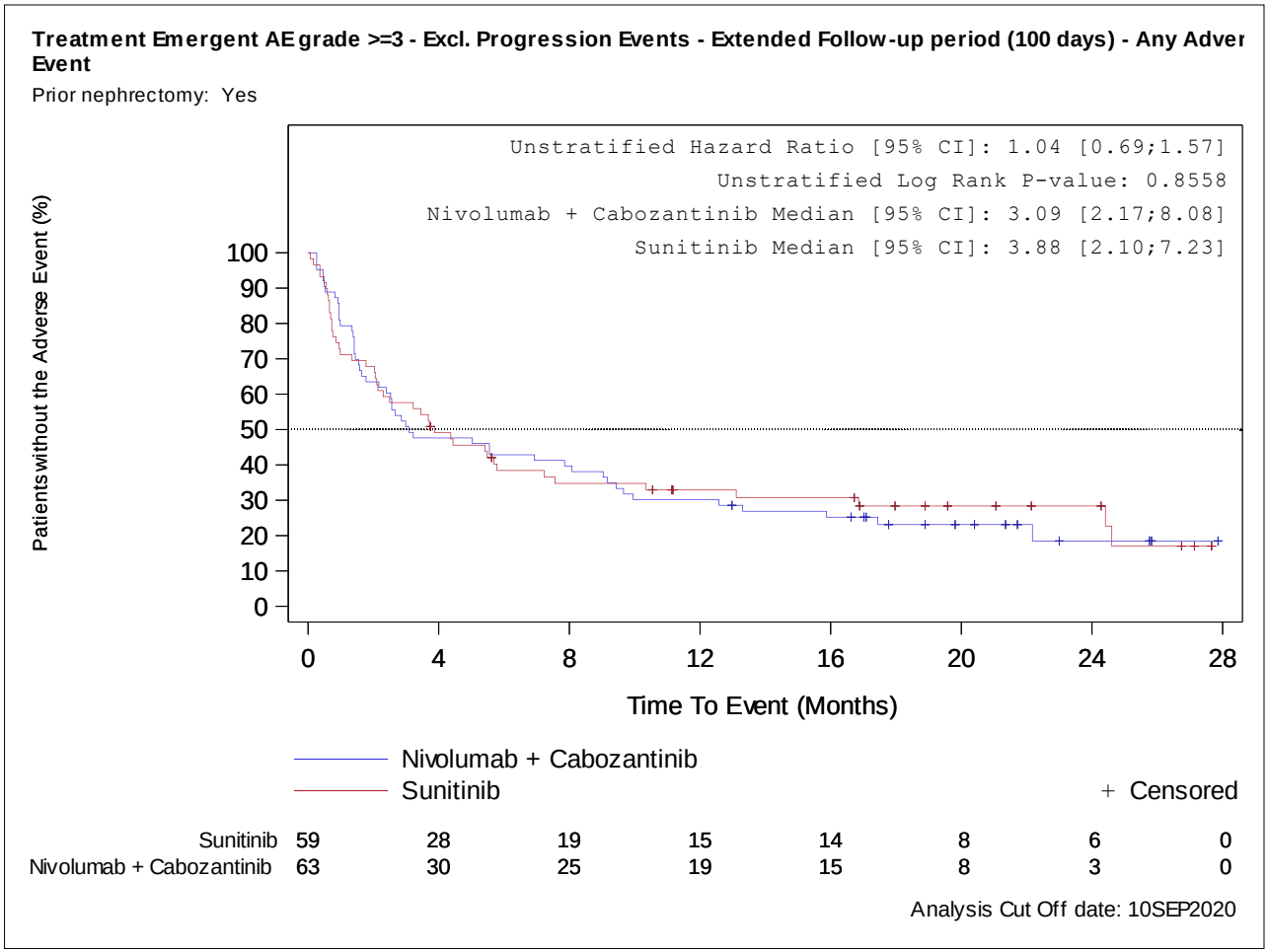
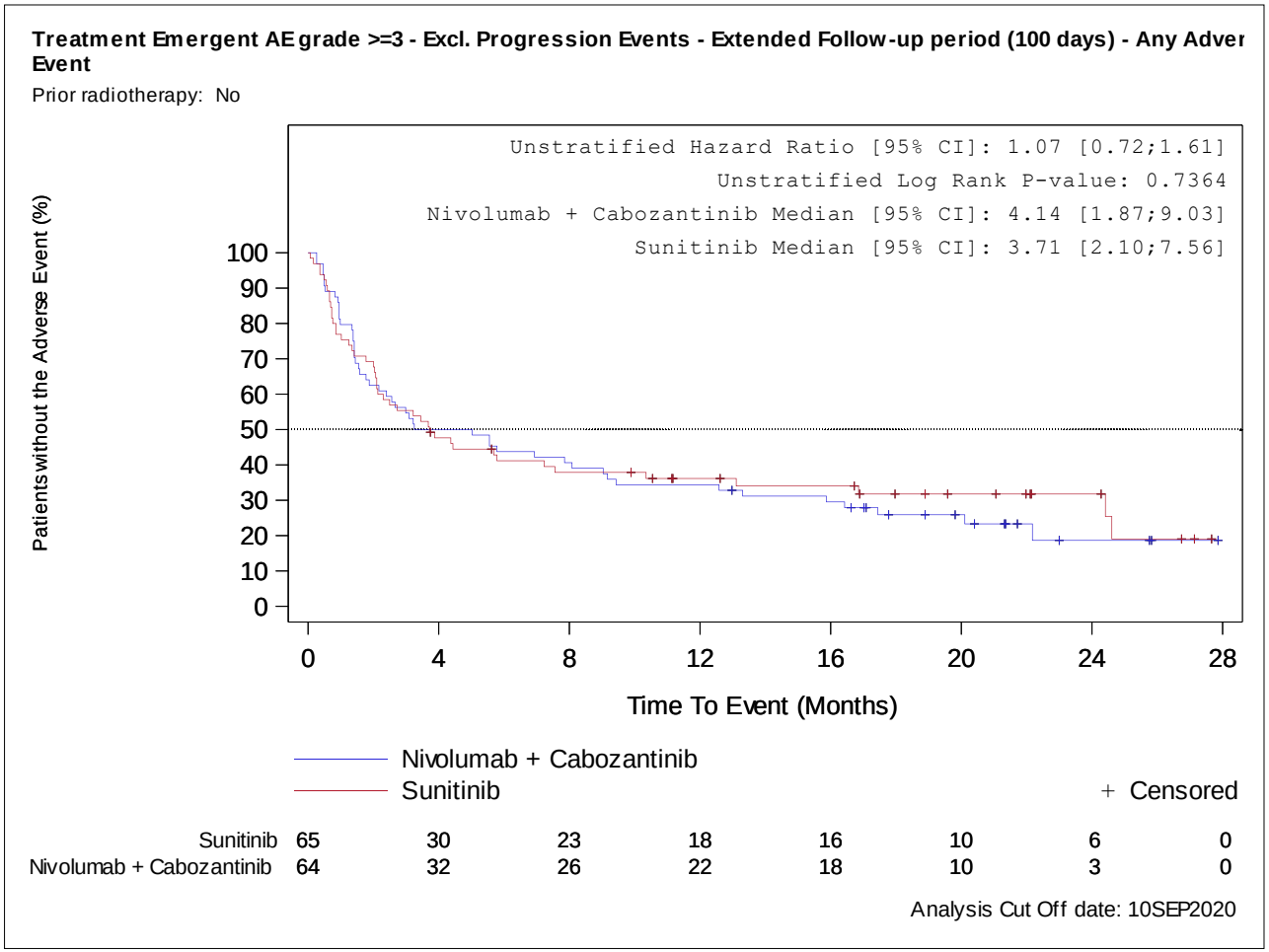
FIGURE 3.12.2.18: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:31:00

FIGURE 3.12.2.19: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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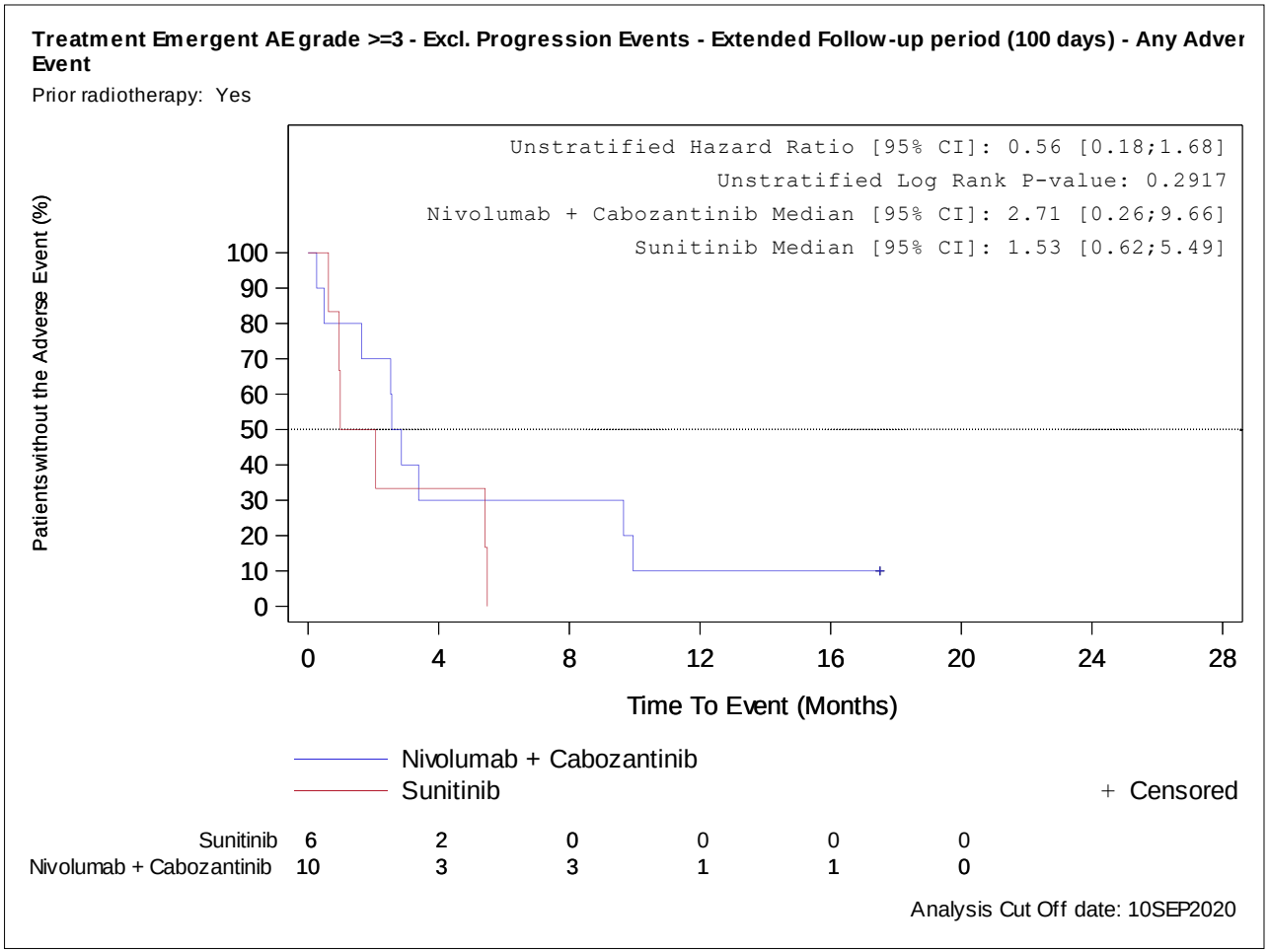
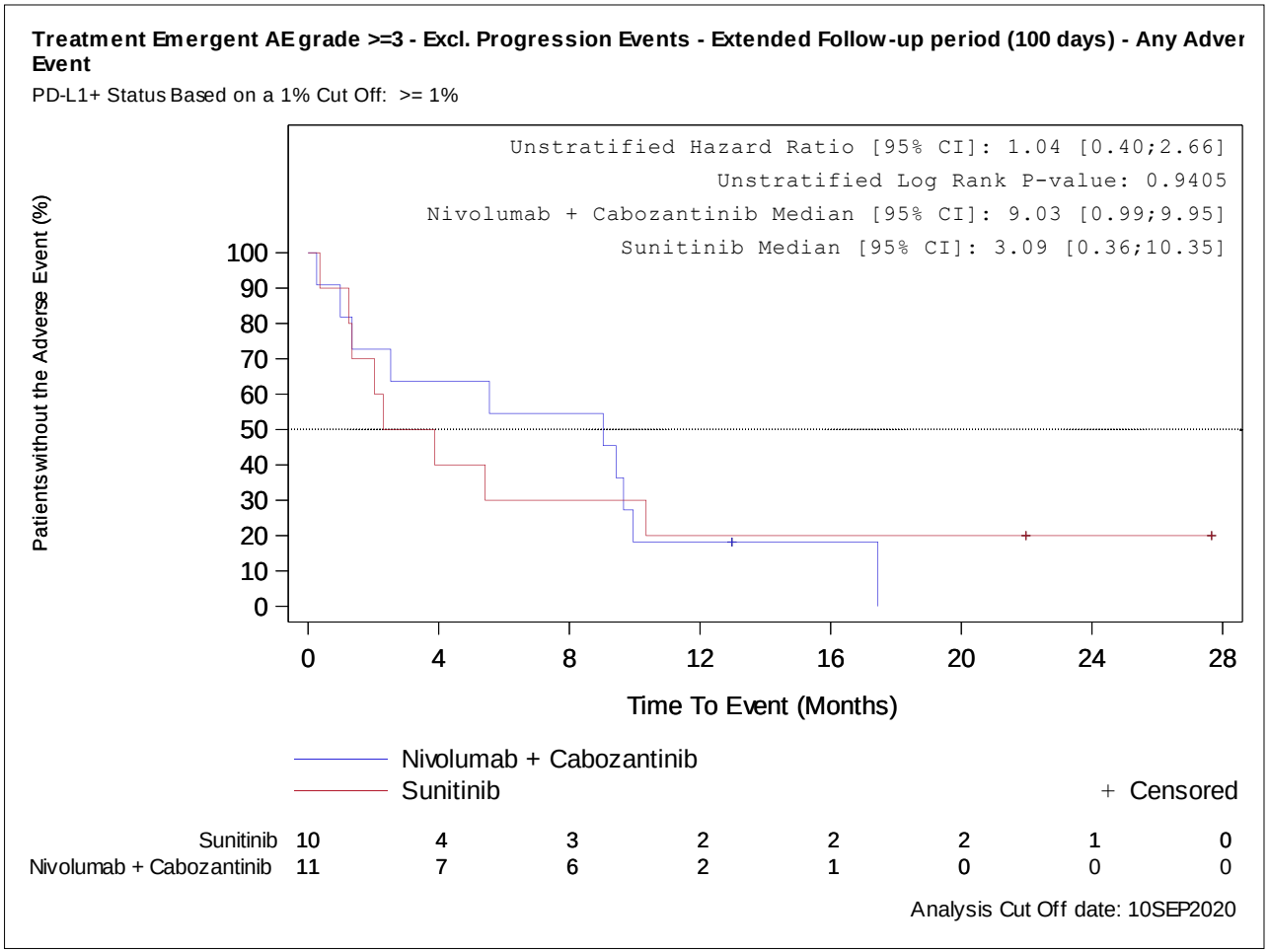
FIGURE 3.12.2.20: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:31:13

FIGURE 3.12.2.21: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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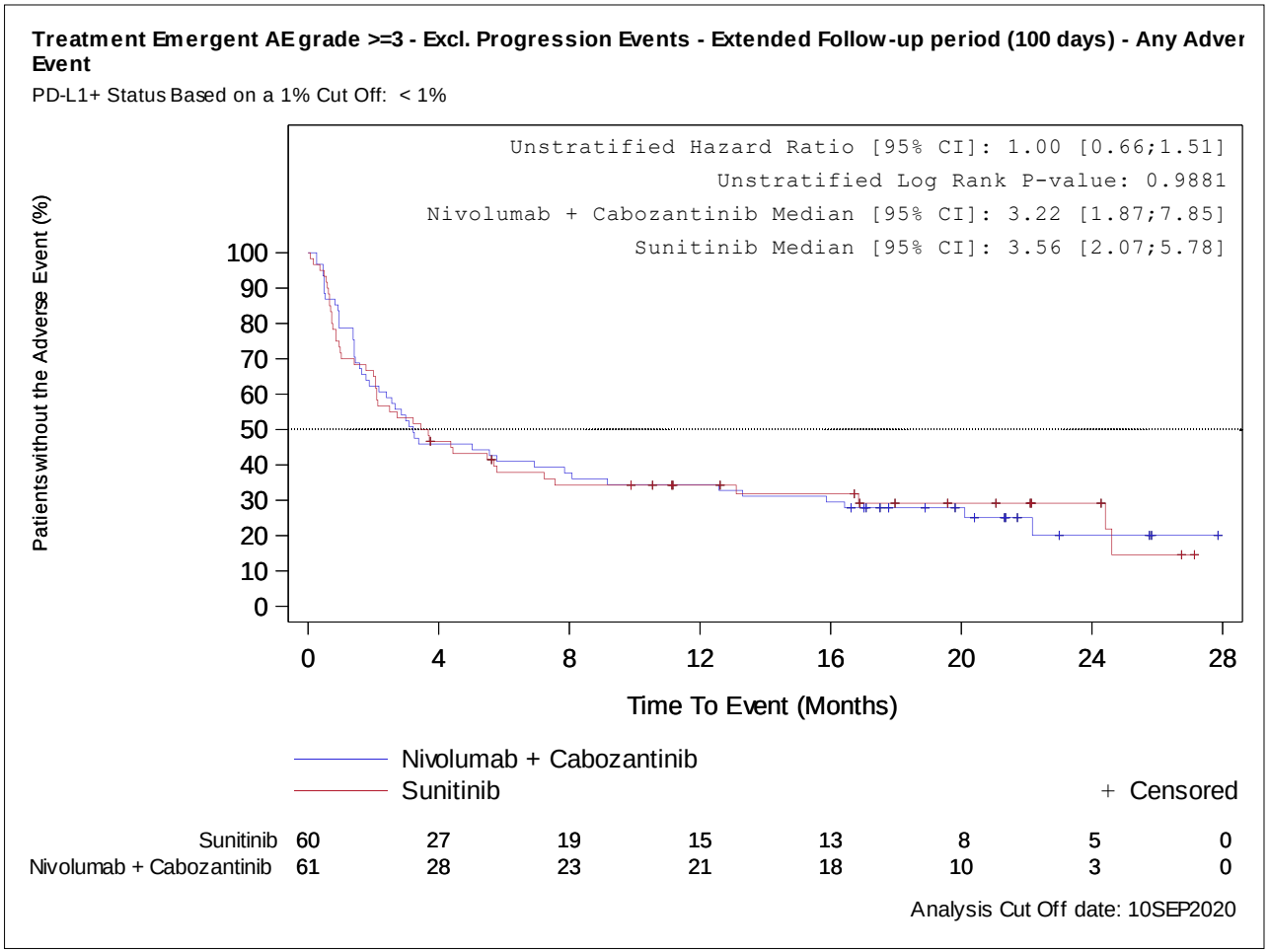
FIGURE 3.12.2.22: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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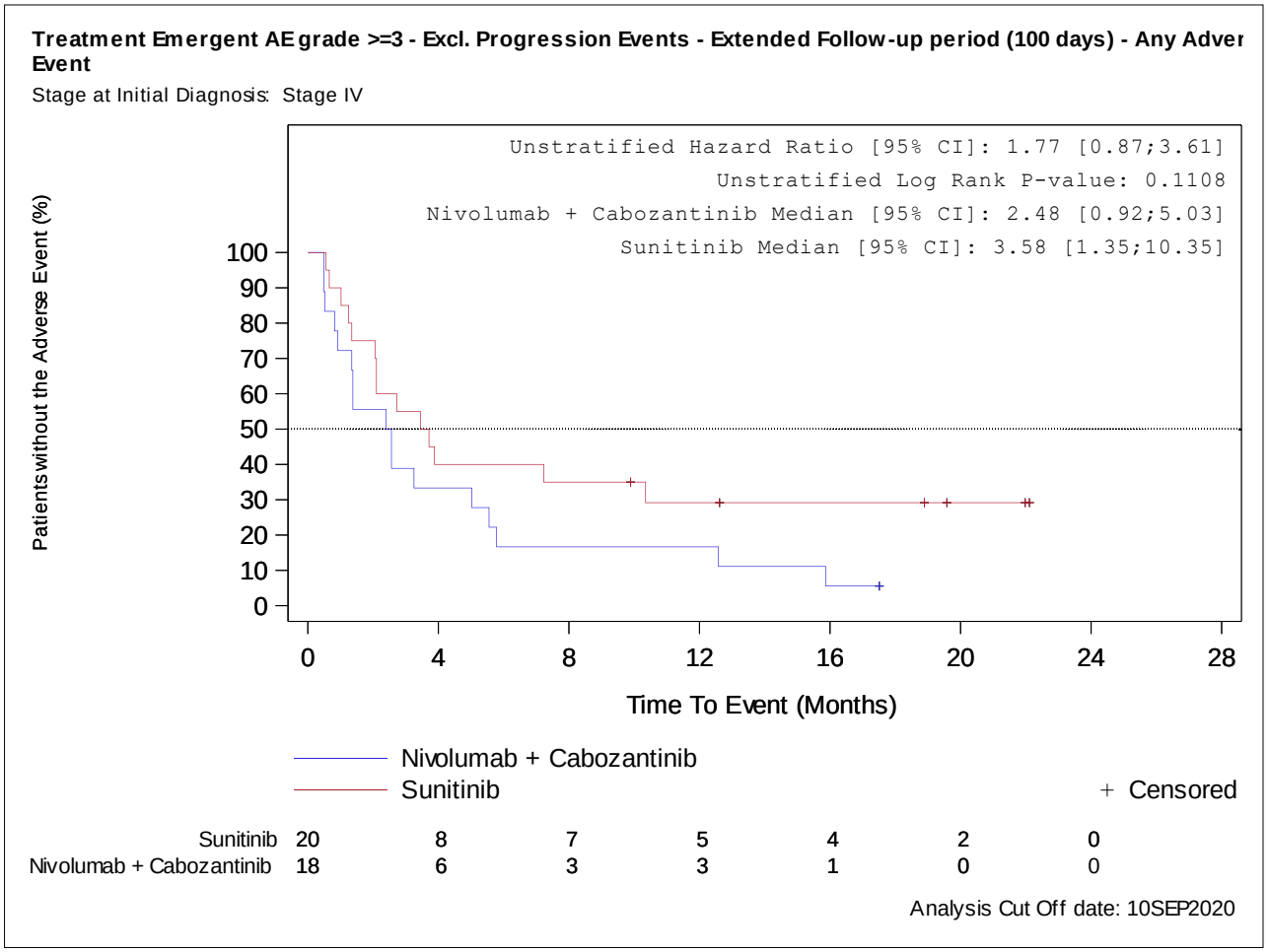
FIGURE 3.12.2.23: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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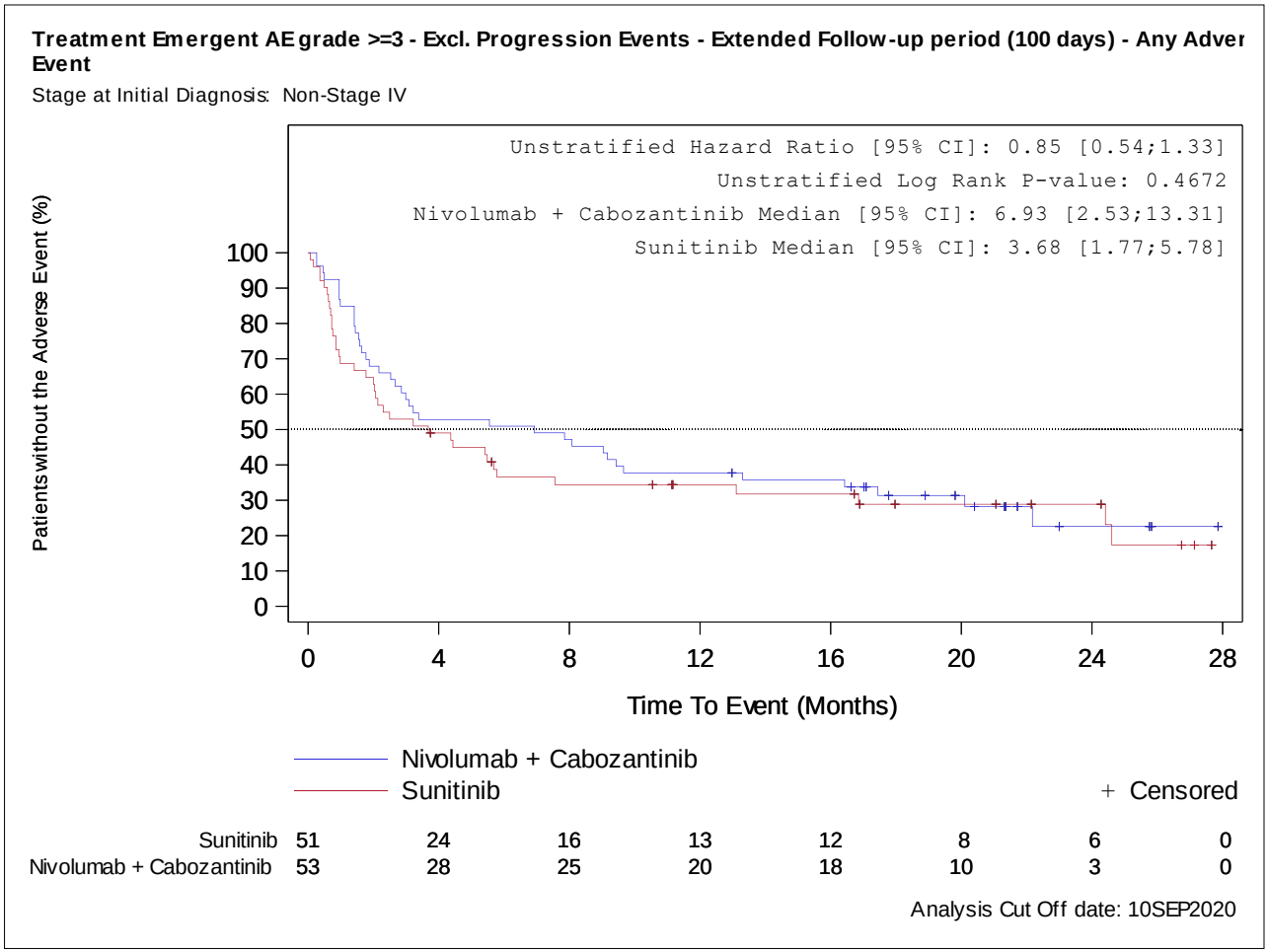
FIGURE 3.12.2.24: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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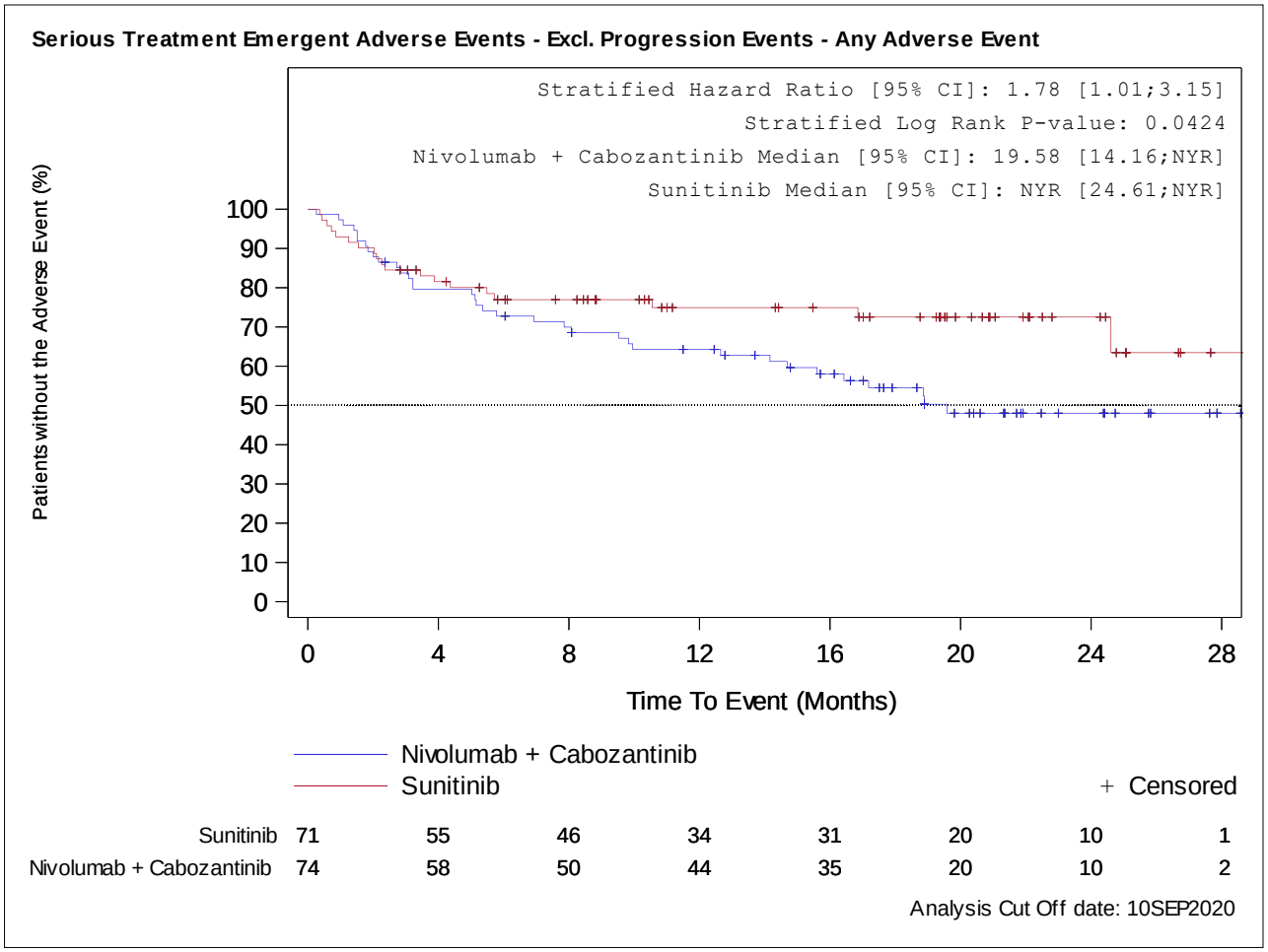
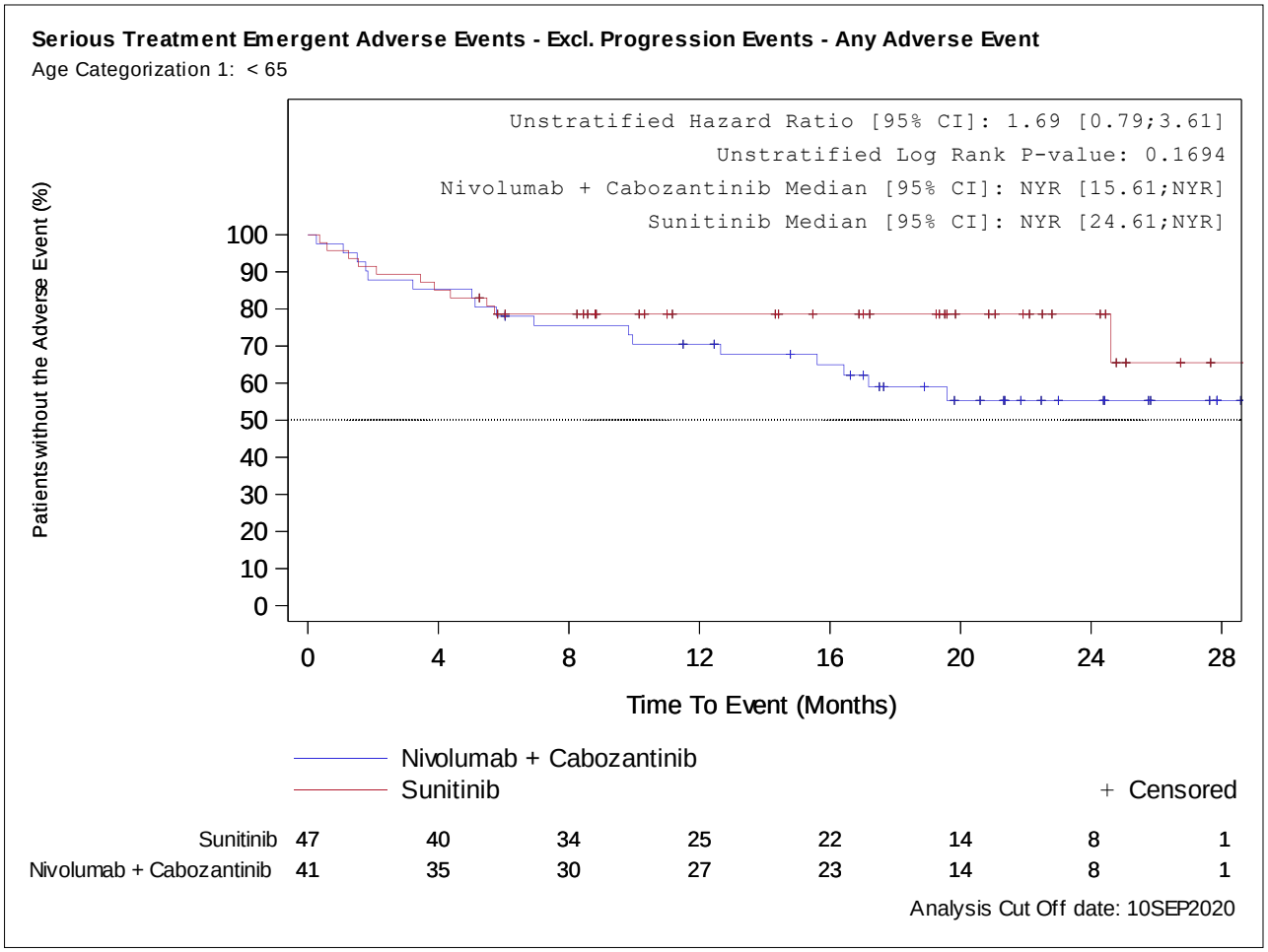
FIGURE 3.13.1: Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



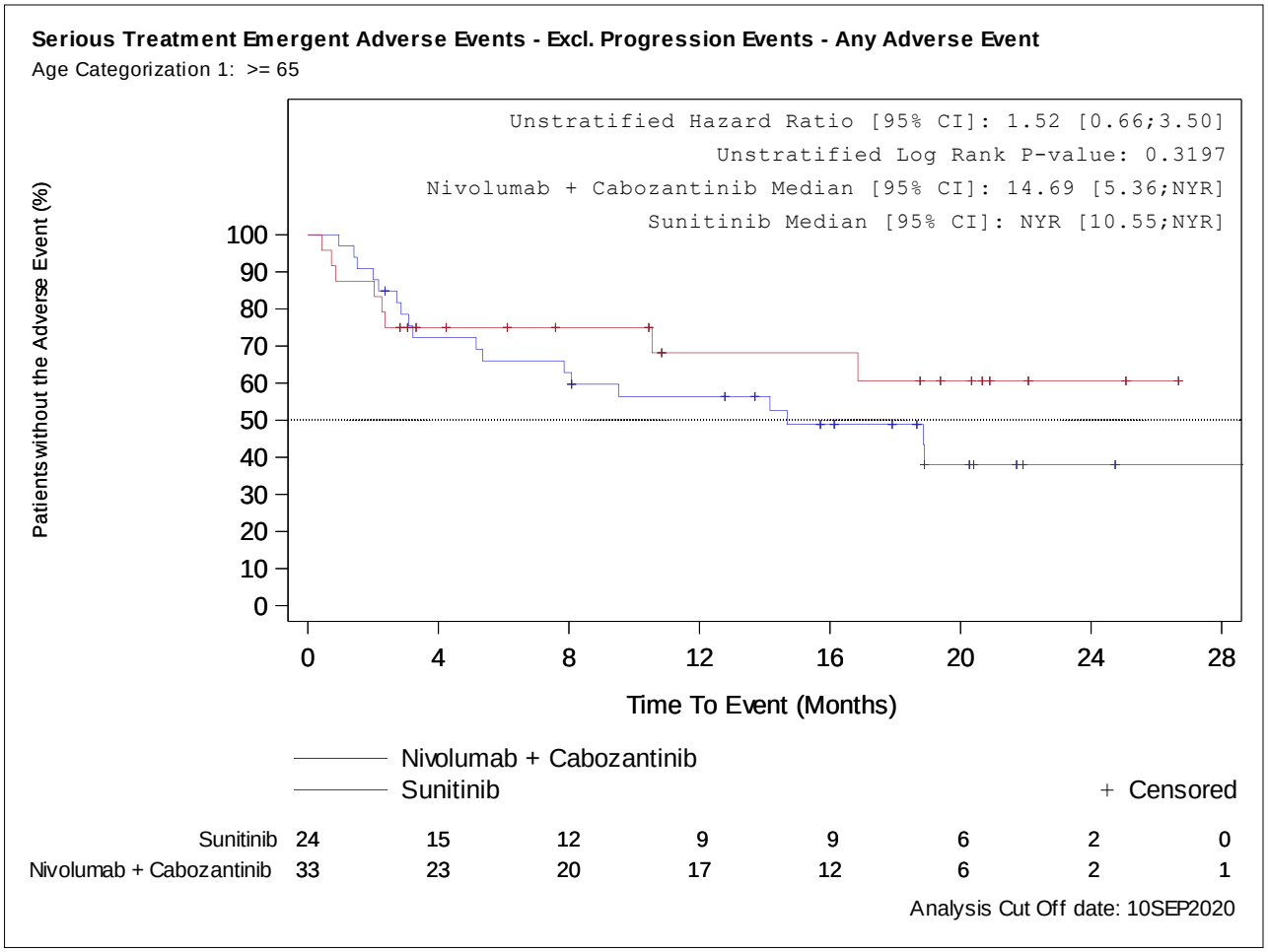

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:35:32

FIGURE 3.13.2.1: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



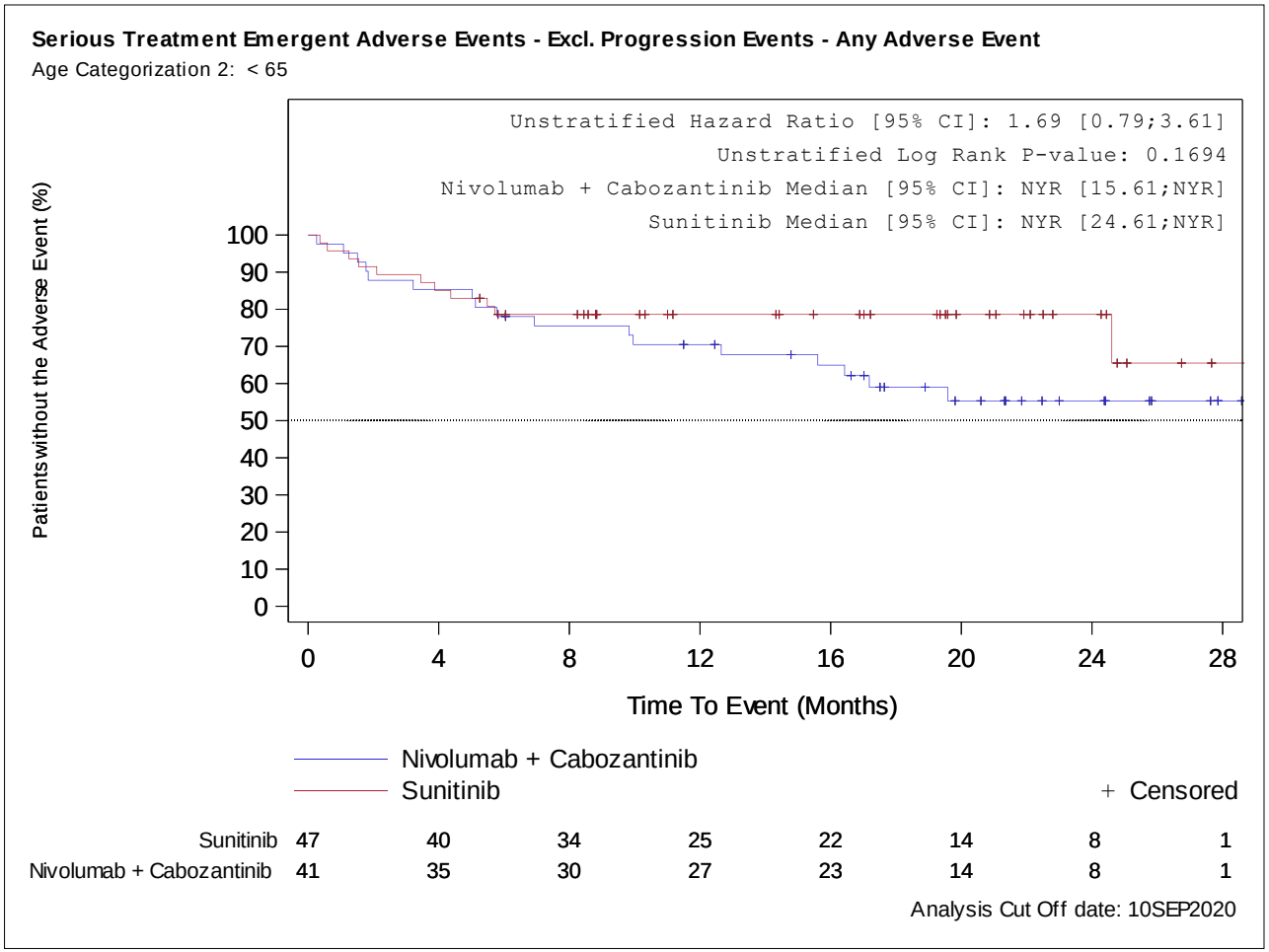

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:35:35

FIGURE 3.13.2.2: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



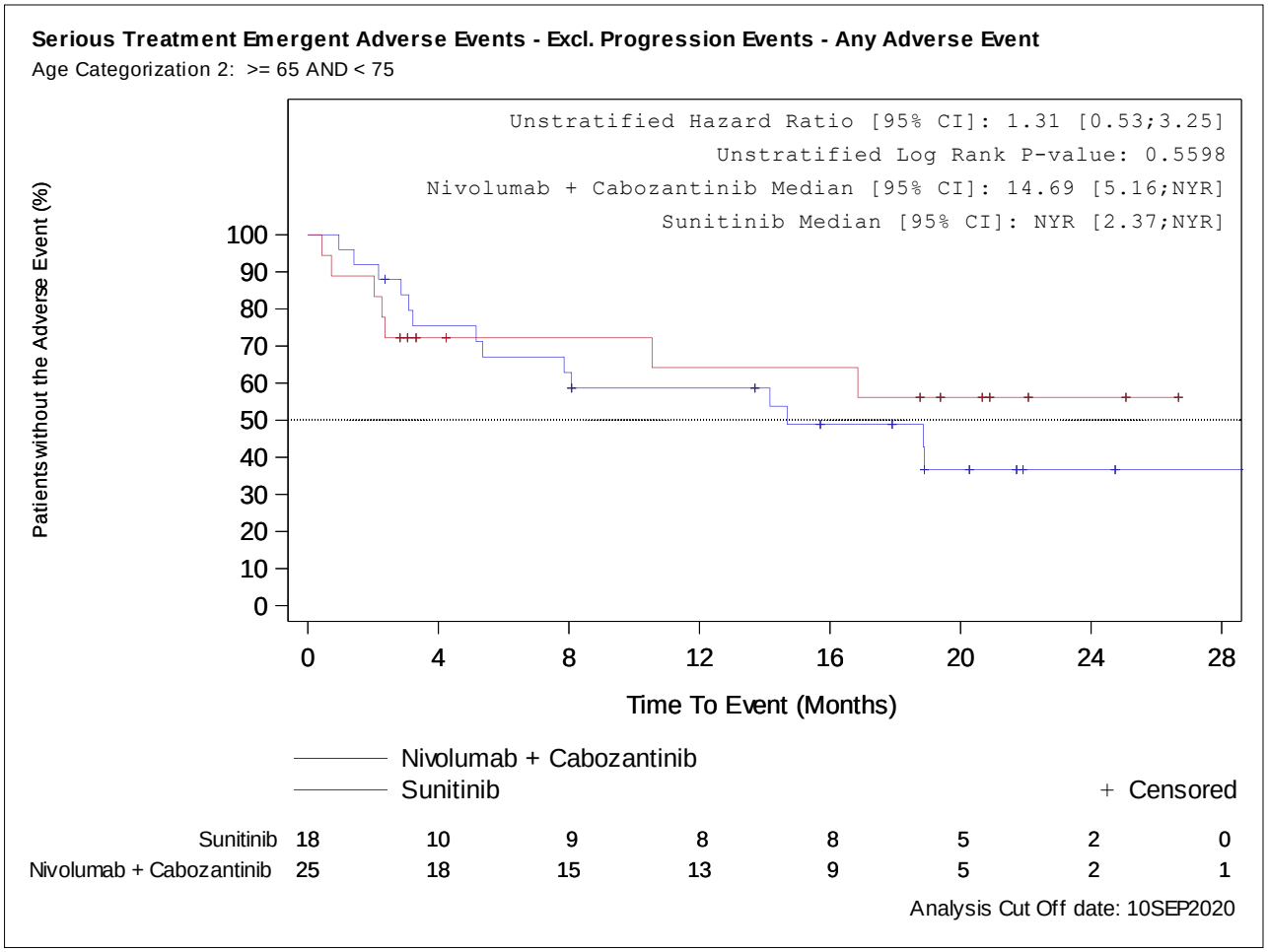

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:35:42

FIGURE 3.13.2.3: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



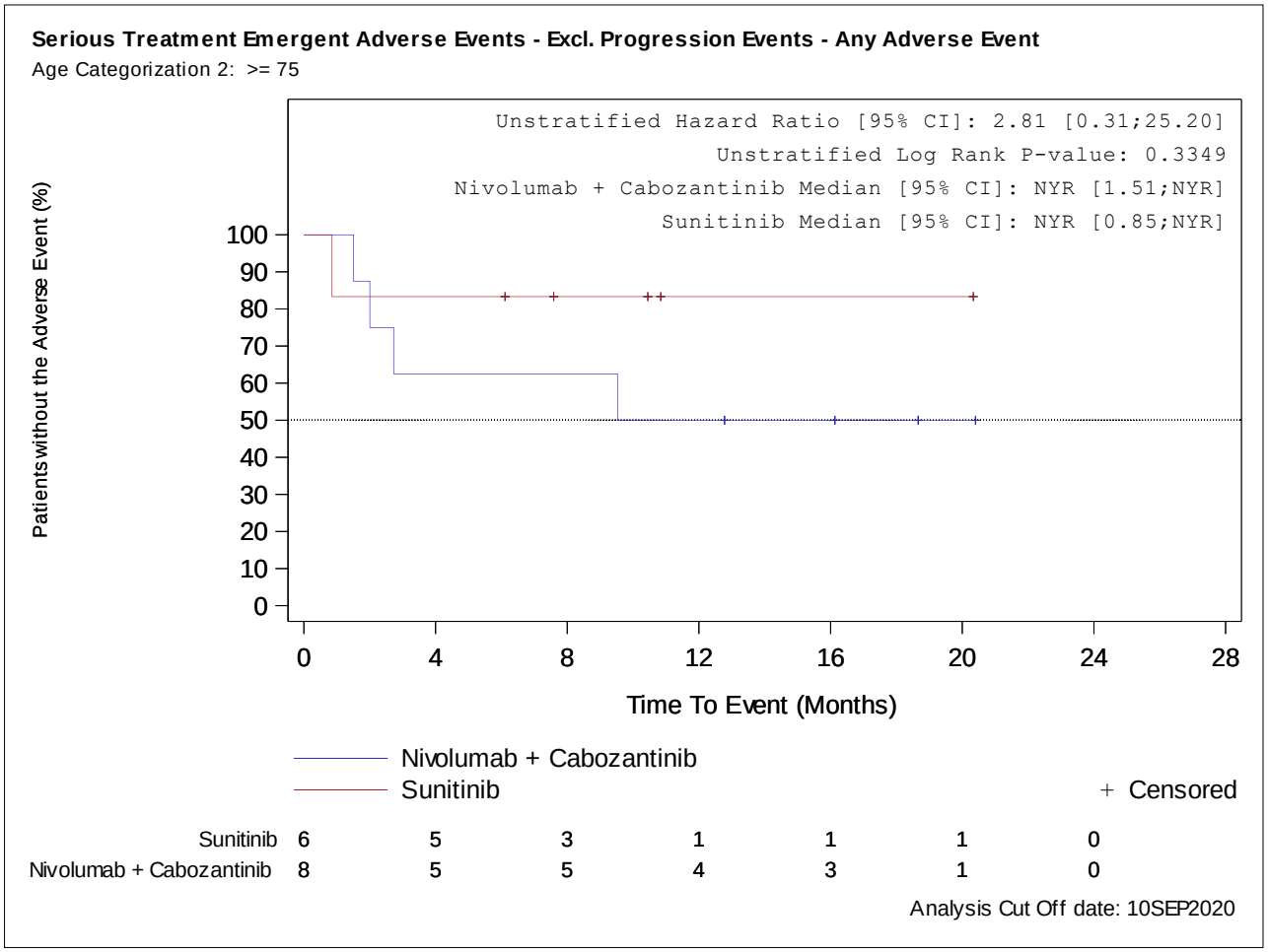

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:35:48

FIGURE 3.13.2.4: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



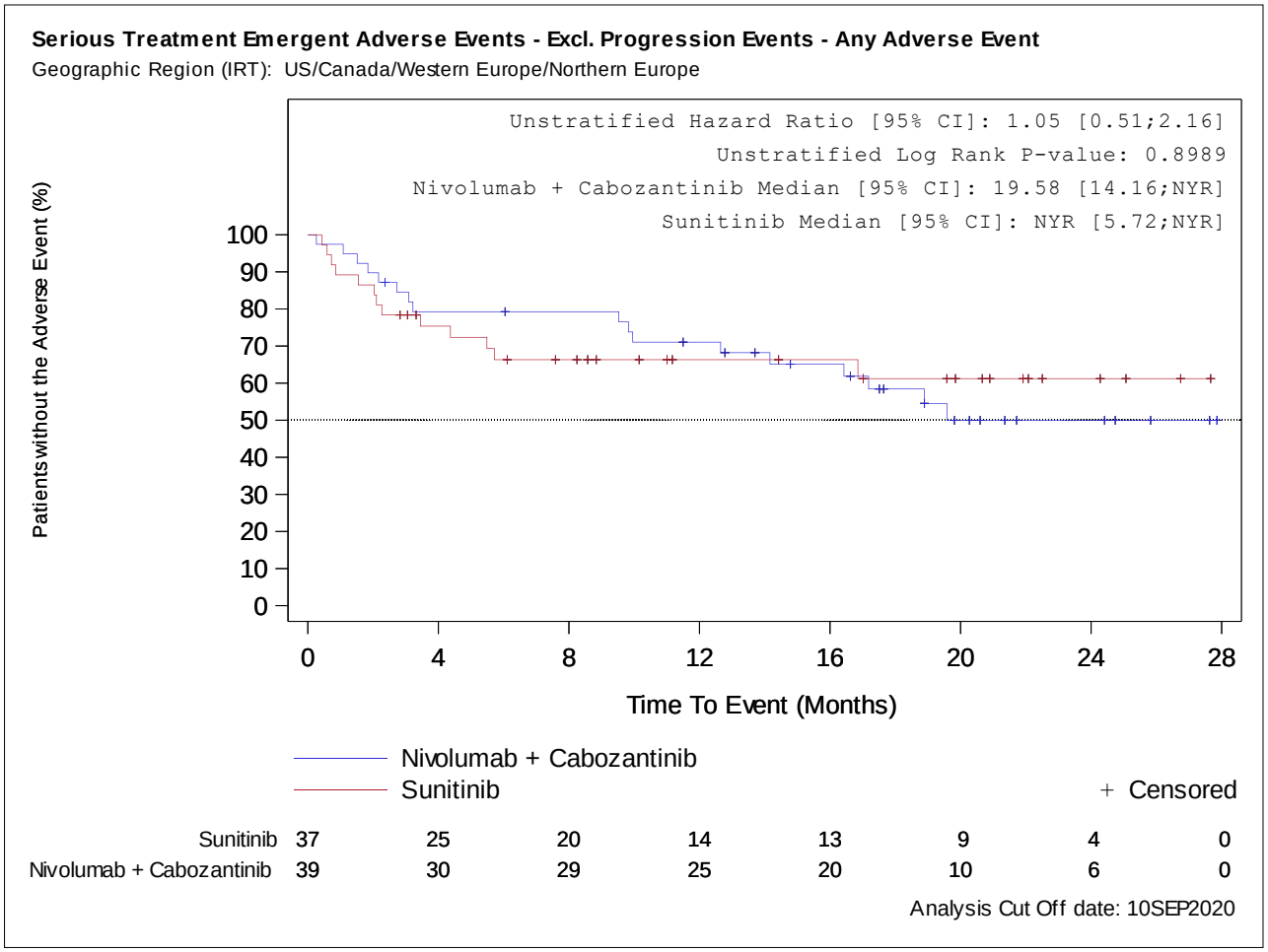

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:35:54

FIGURE 3.13.2.5: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



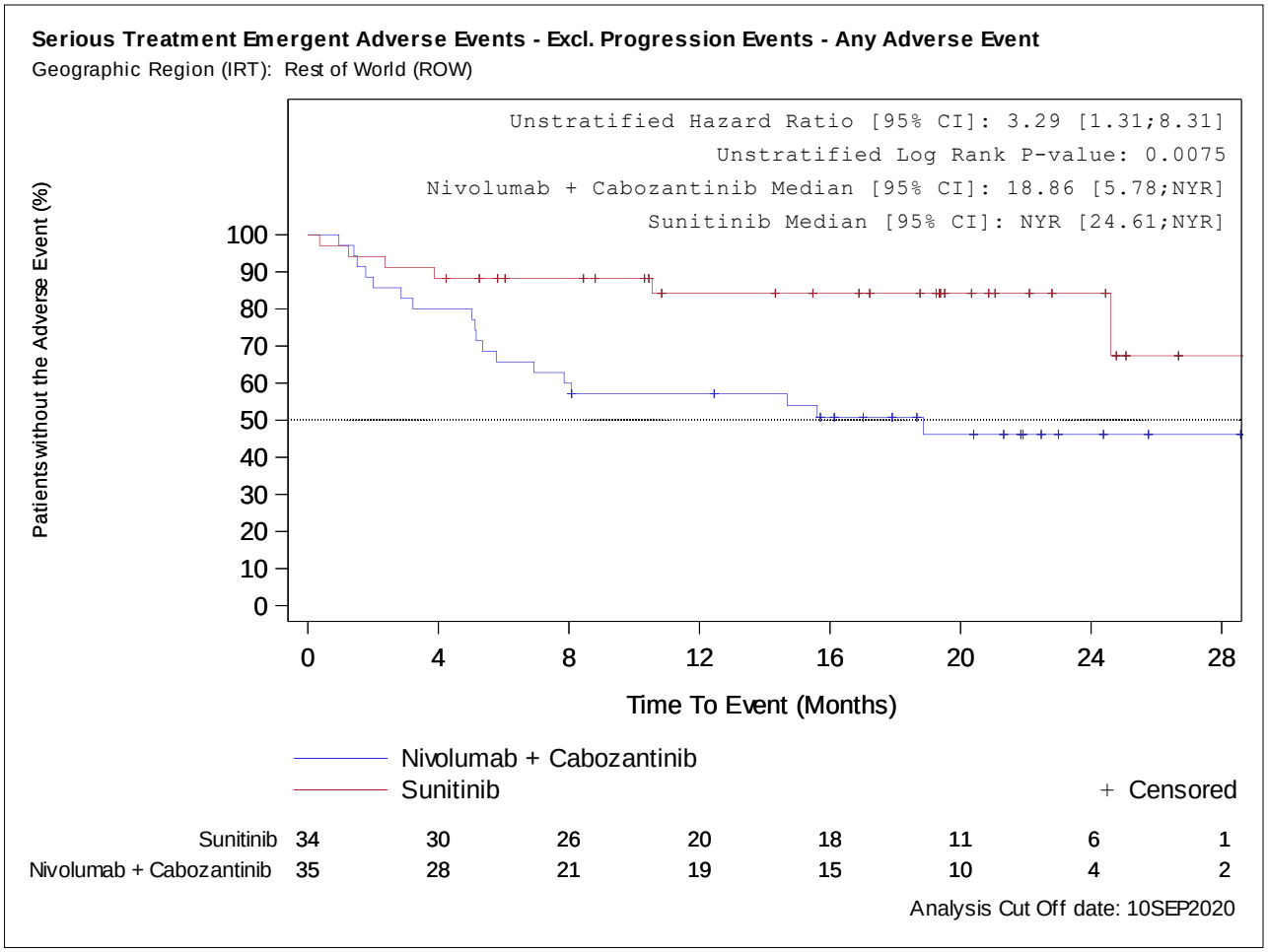

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:36:02

FIGURE 3.13.2.6: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



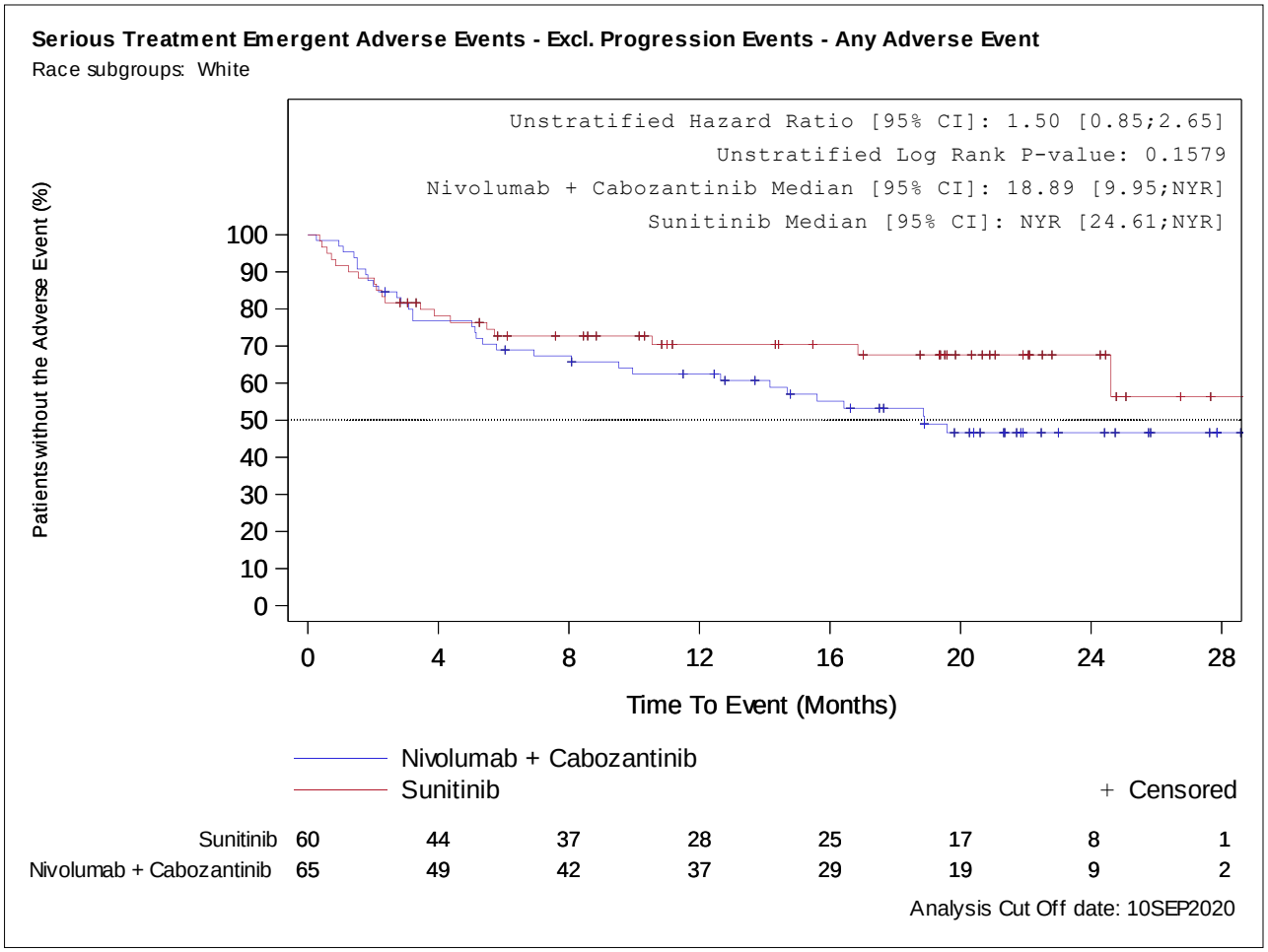

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:36:08

FIGURE 3.13.2.7: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



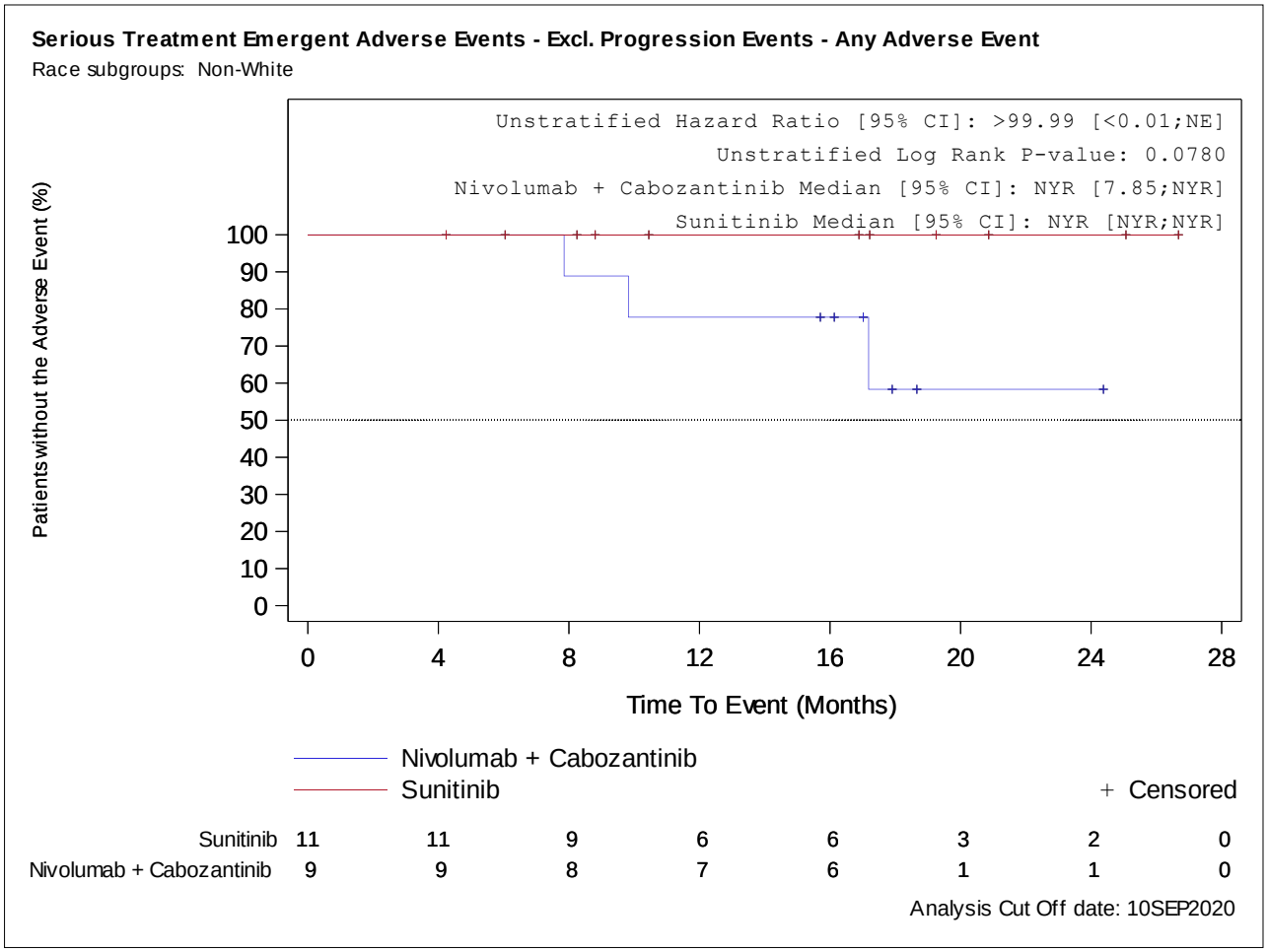

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:36:14

FIGURE 3.13.2.8: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:36:20

FIGURE 3.13.2.9: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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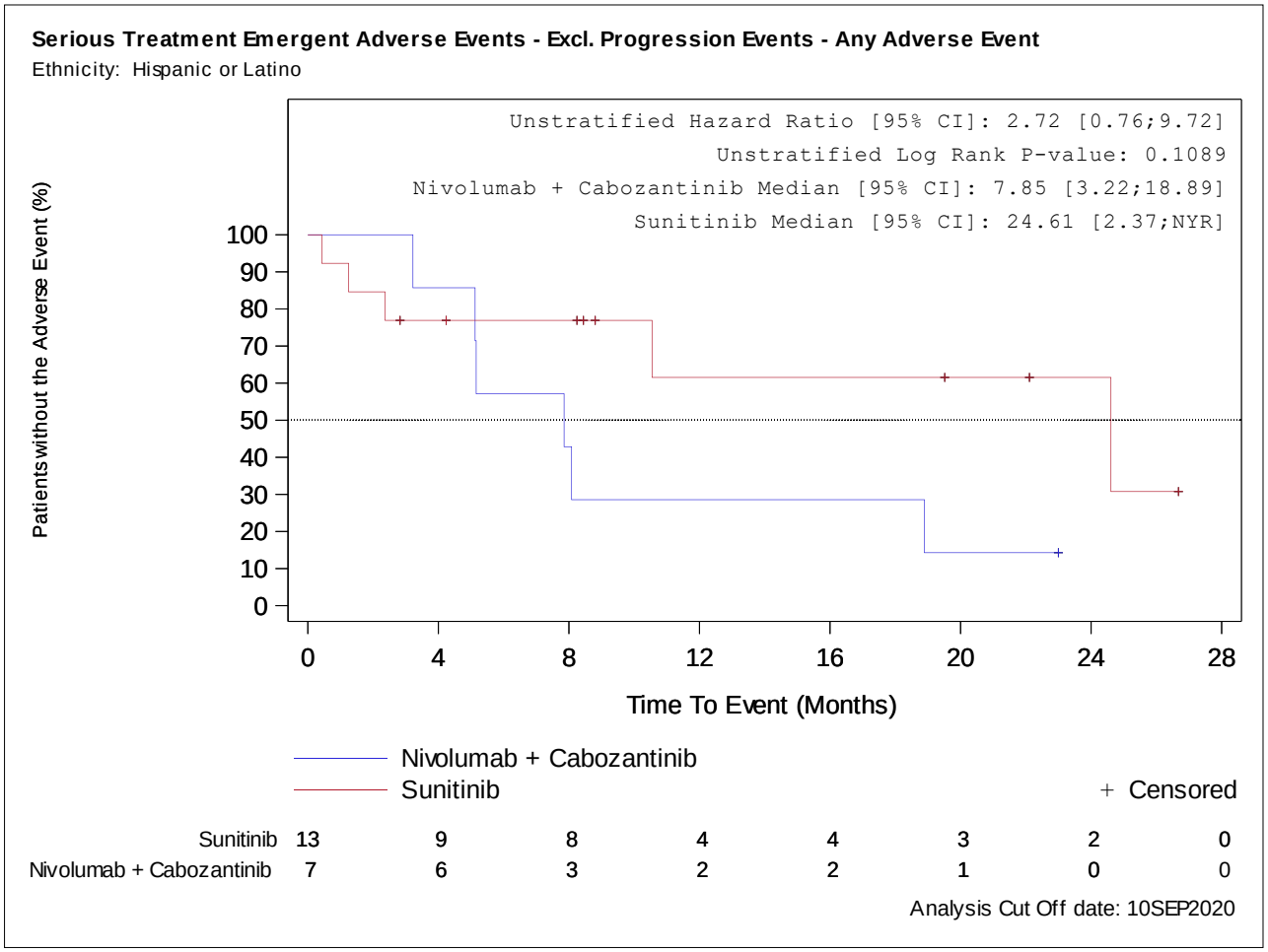
FIGURE 3.13.2.10: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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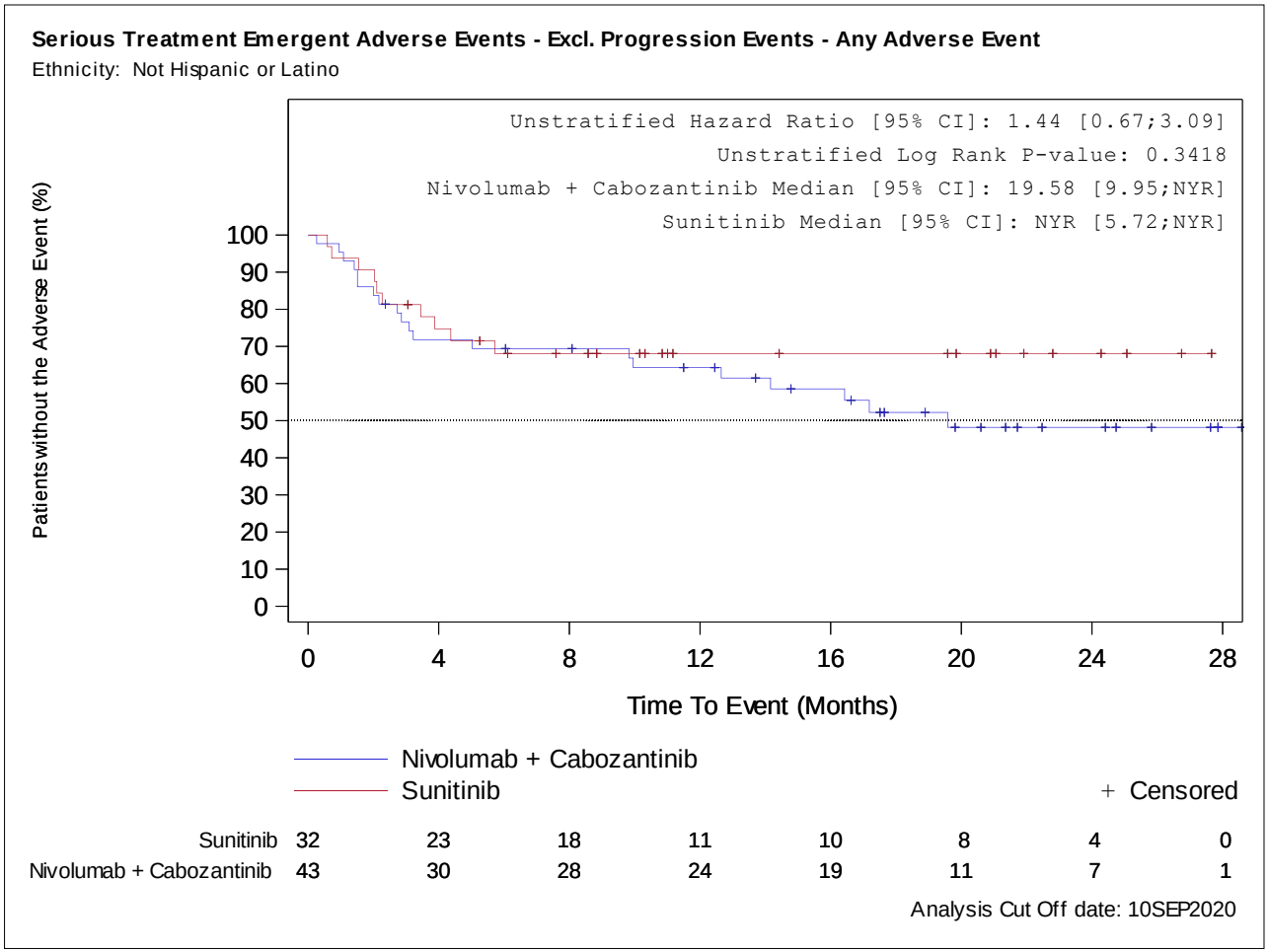
FIGURE 3.13.2.11: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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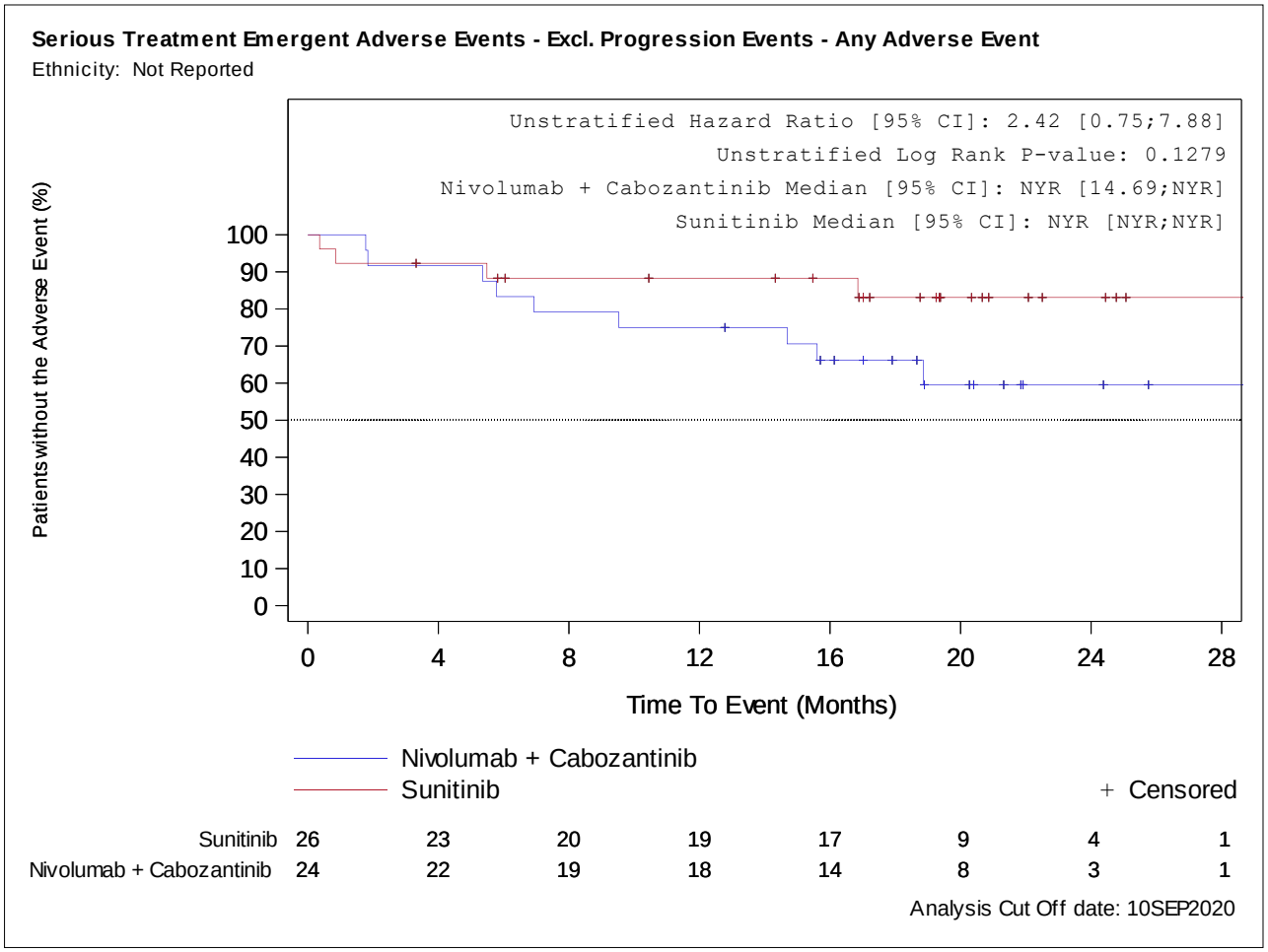
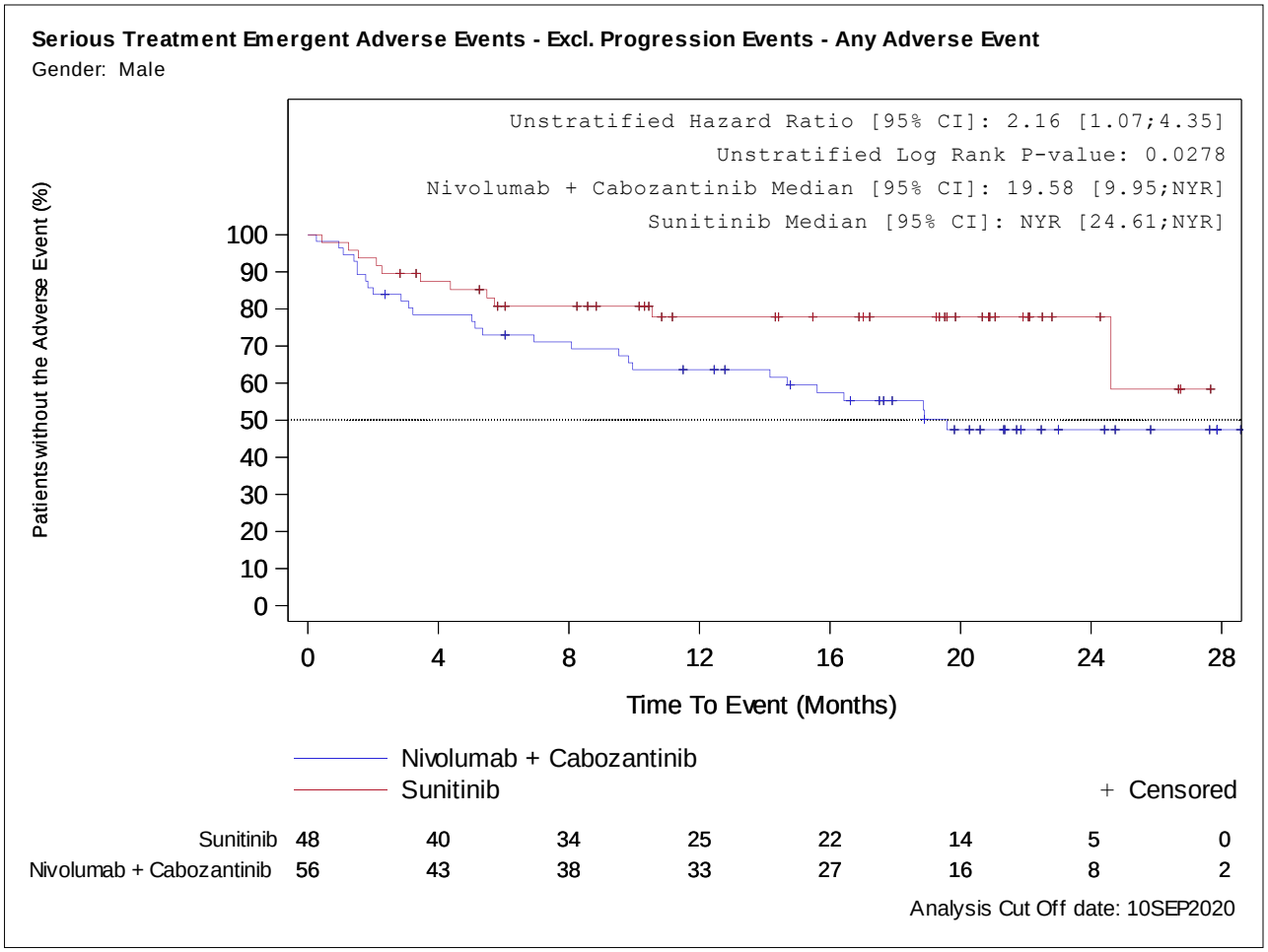
FIGURE 3.13.2.12: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:36:47

FIGURE 3.13.2.13: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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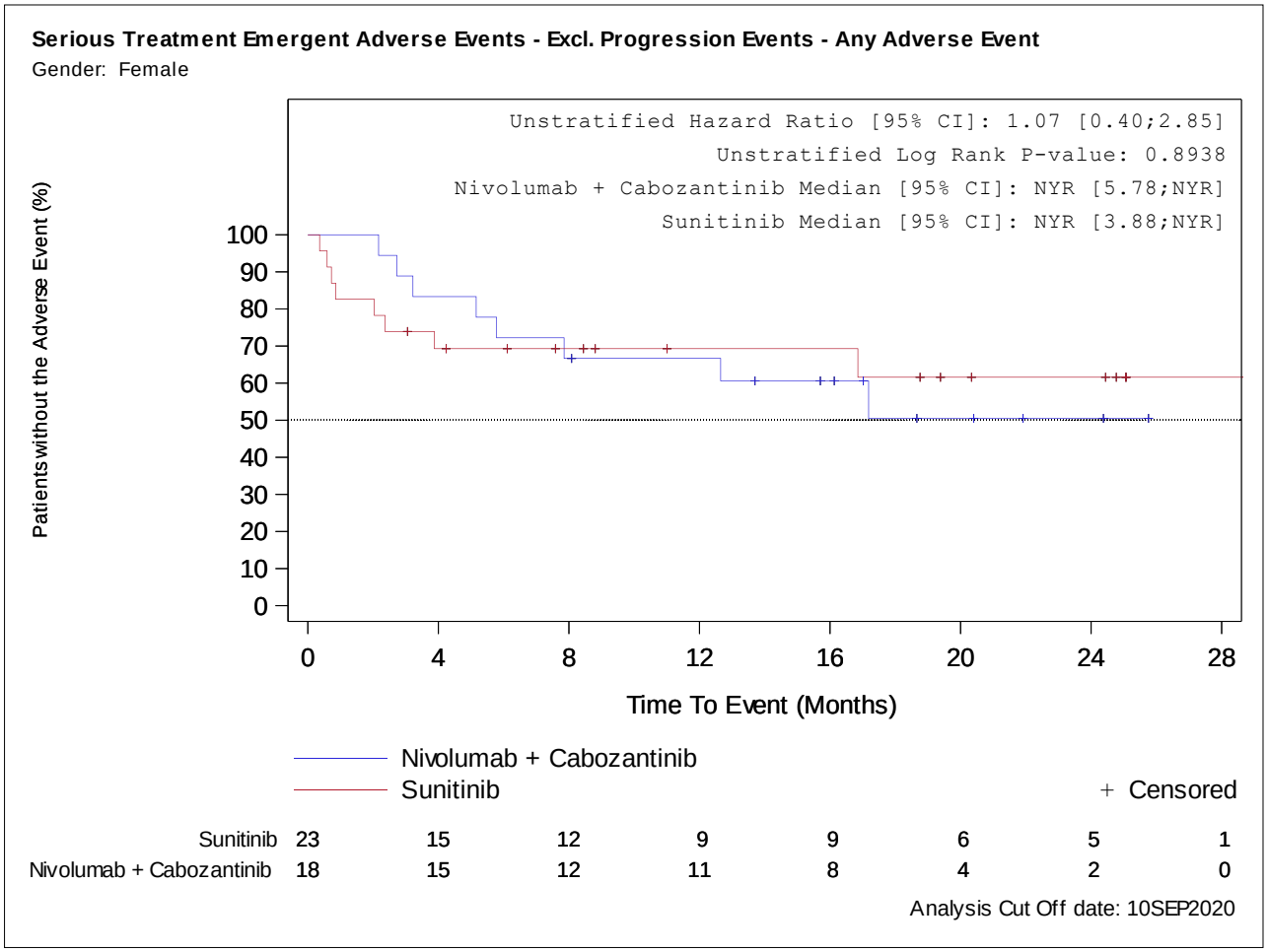
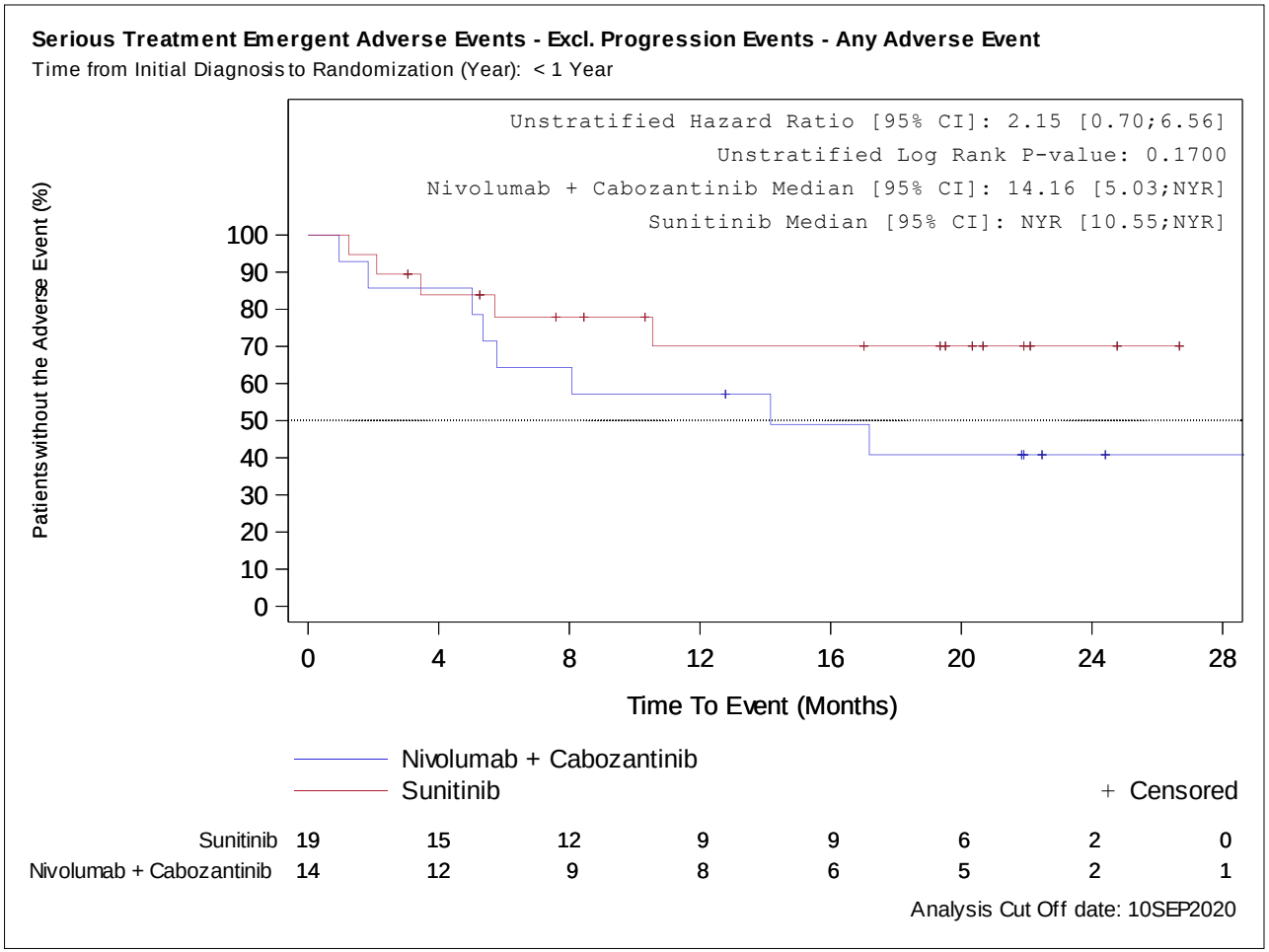
FIGURE 3.13.2.14: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:37:01

FIGURE 3.13.2.15: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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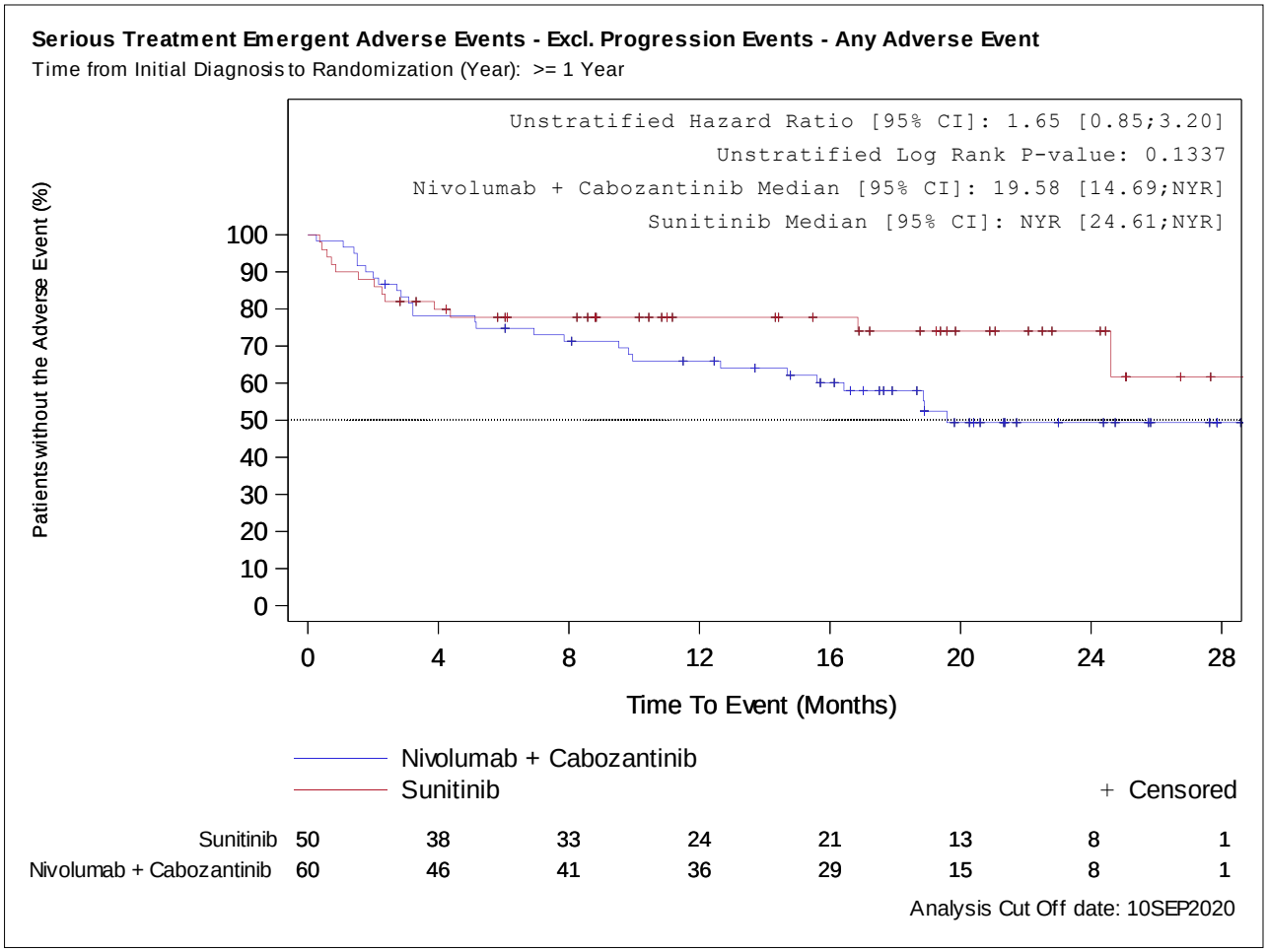
FIGURE 3.13.2.16: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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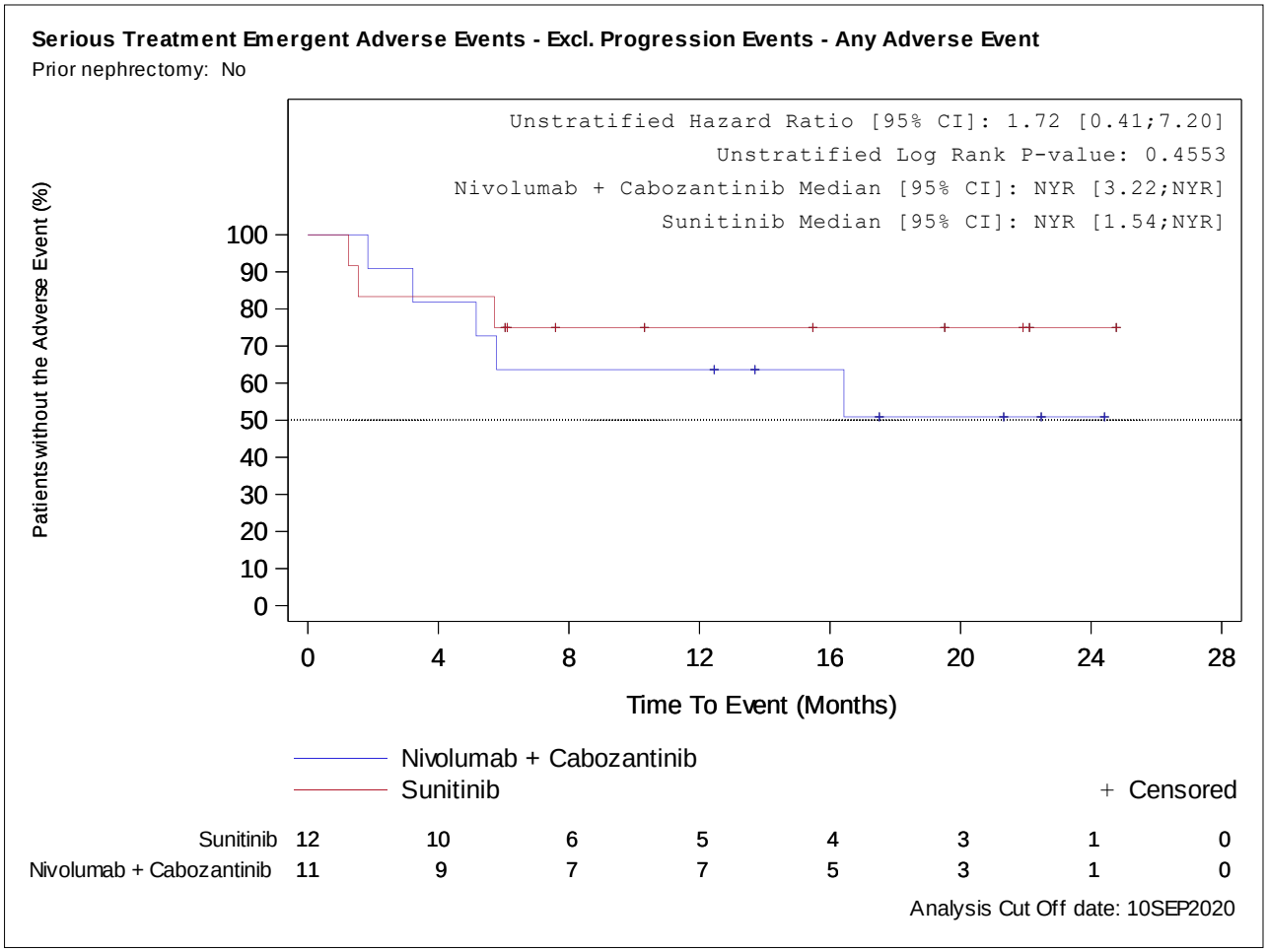
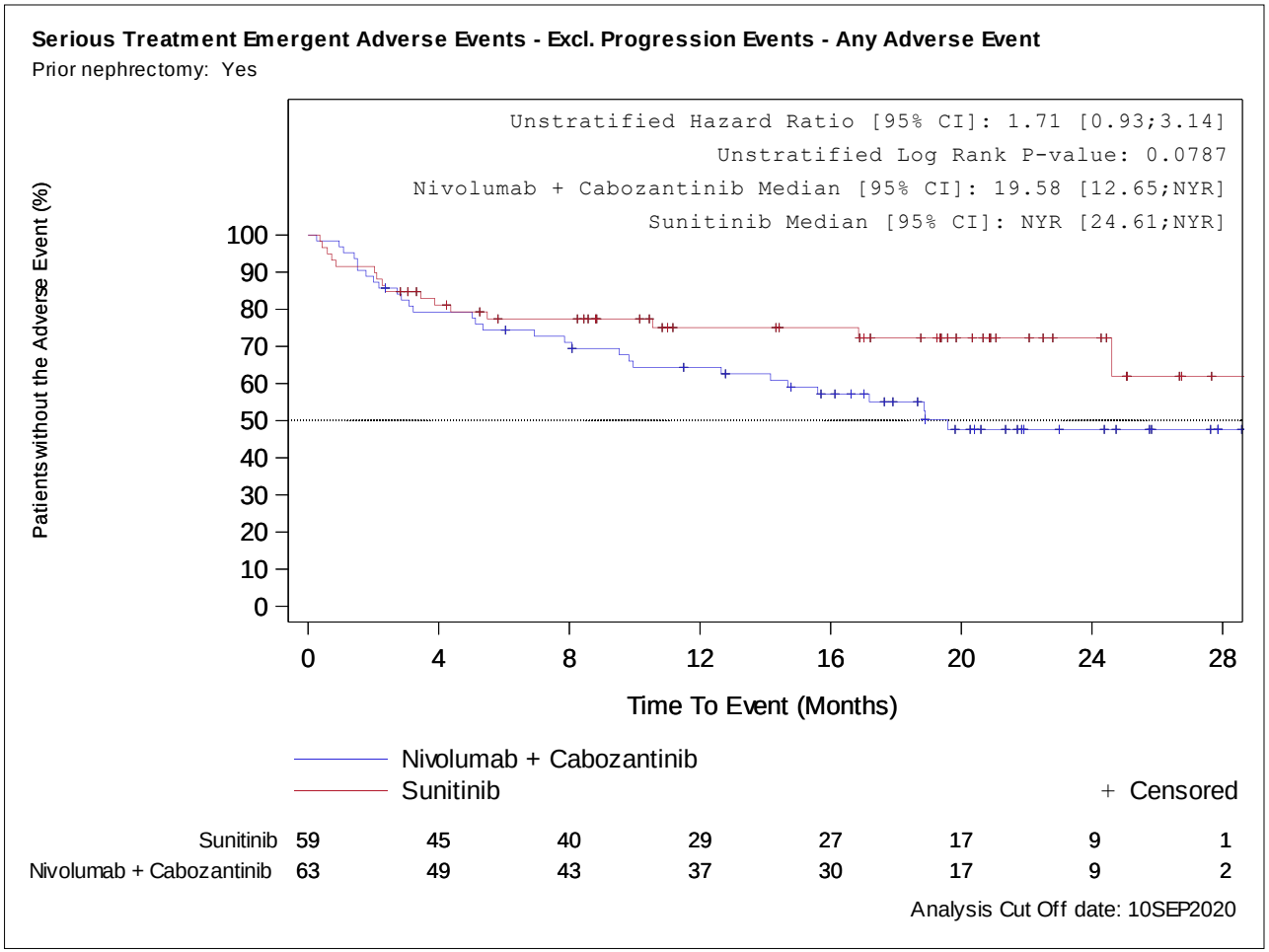
FIGURE 3.13.2.17: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:38:23

FIGURE 3.13.2.18: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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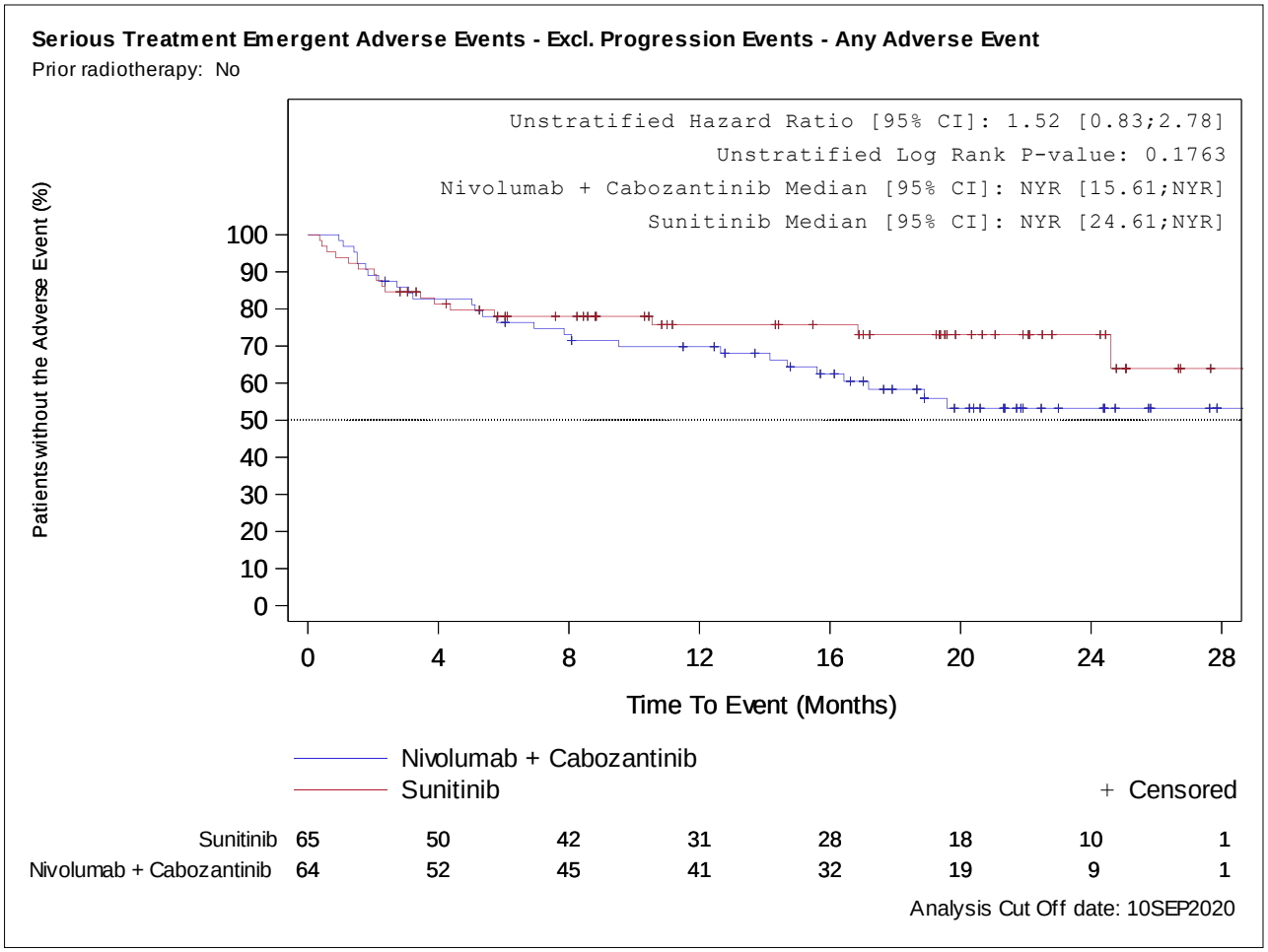
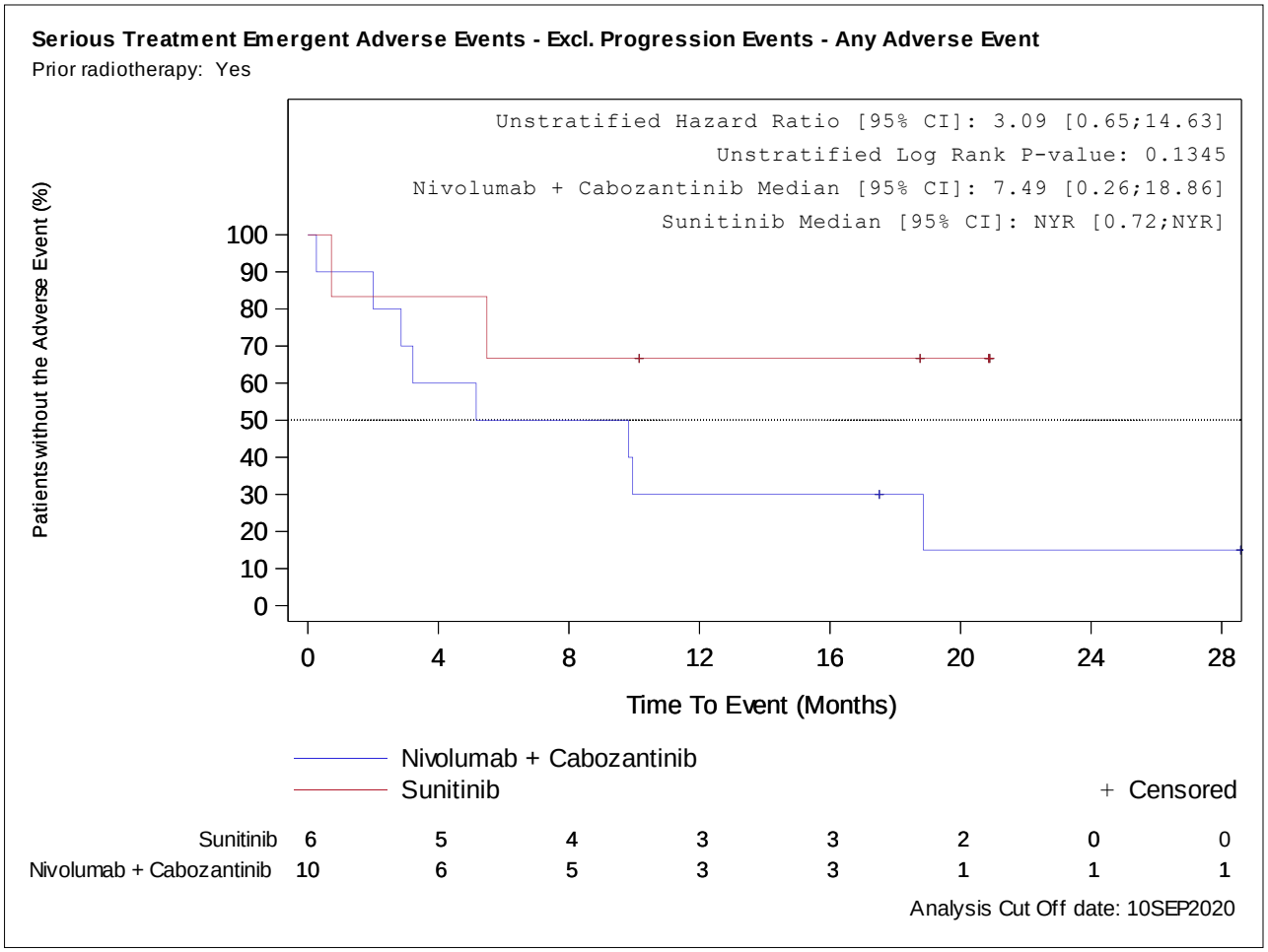
FIGURE 3.13.2.19: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:38:36

FIGURE 3.13.2.20: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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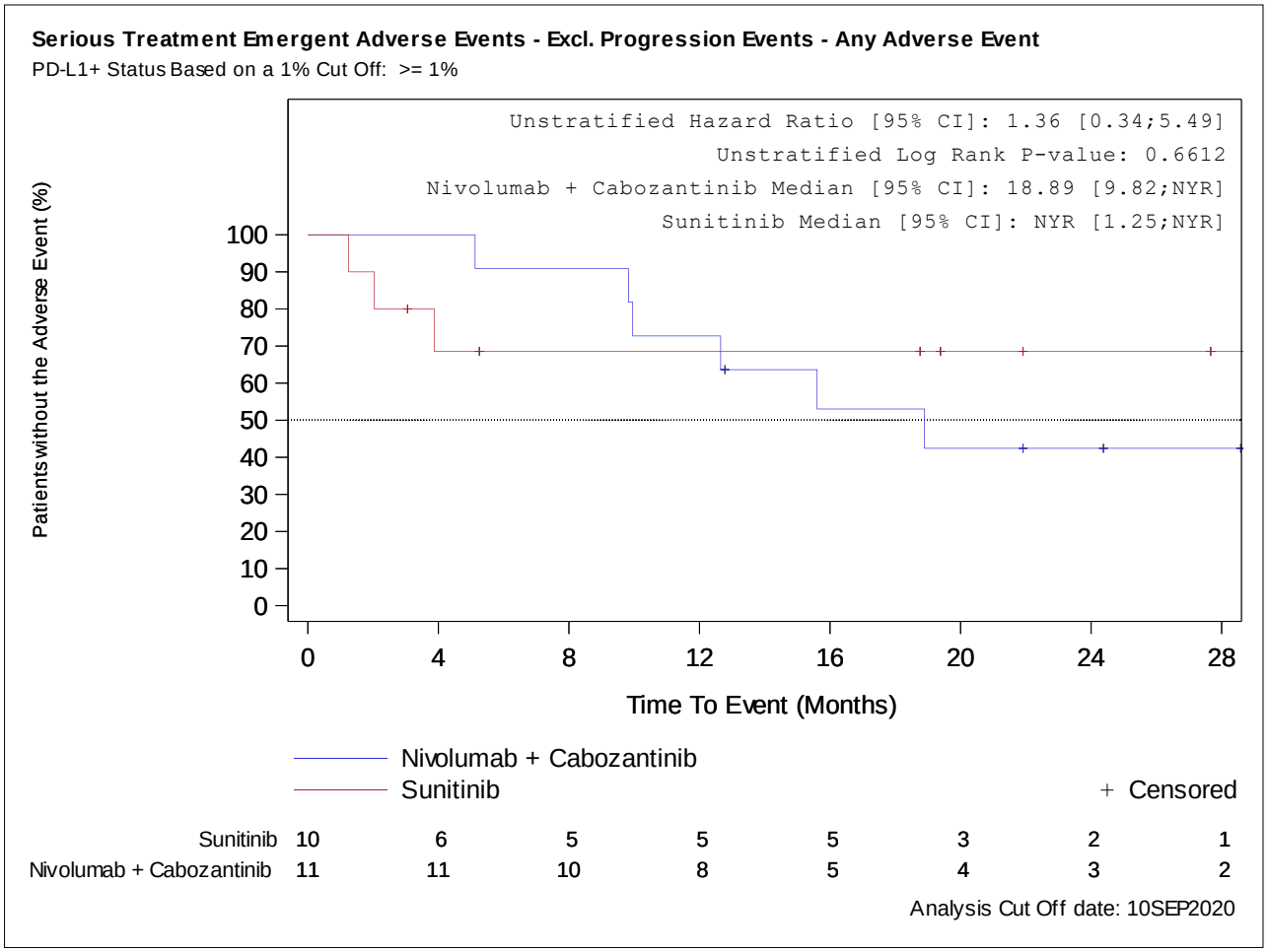
FIGURE 3.13.2.21: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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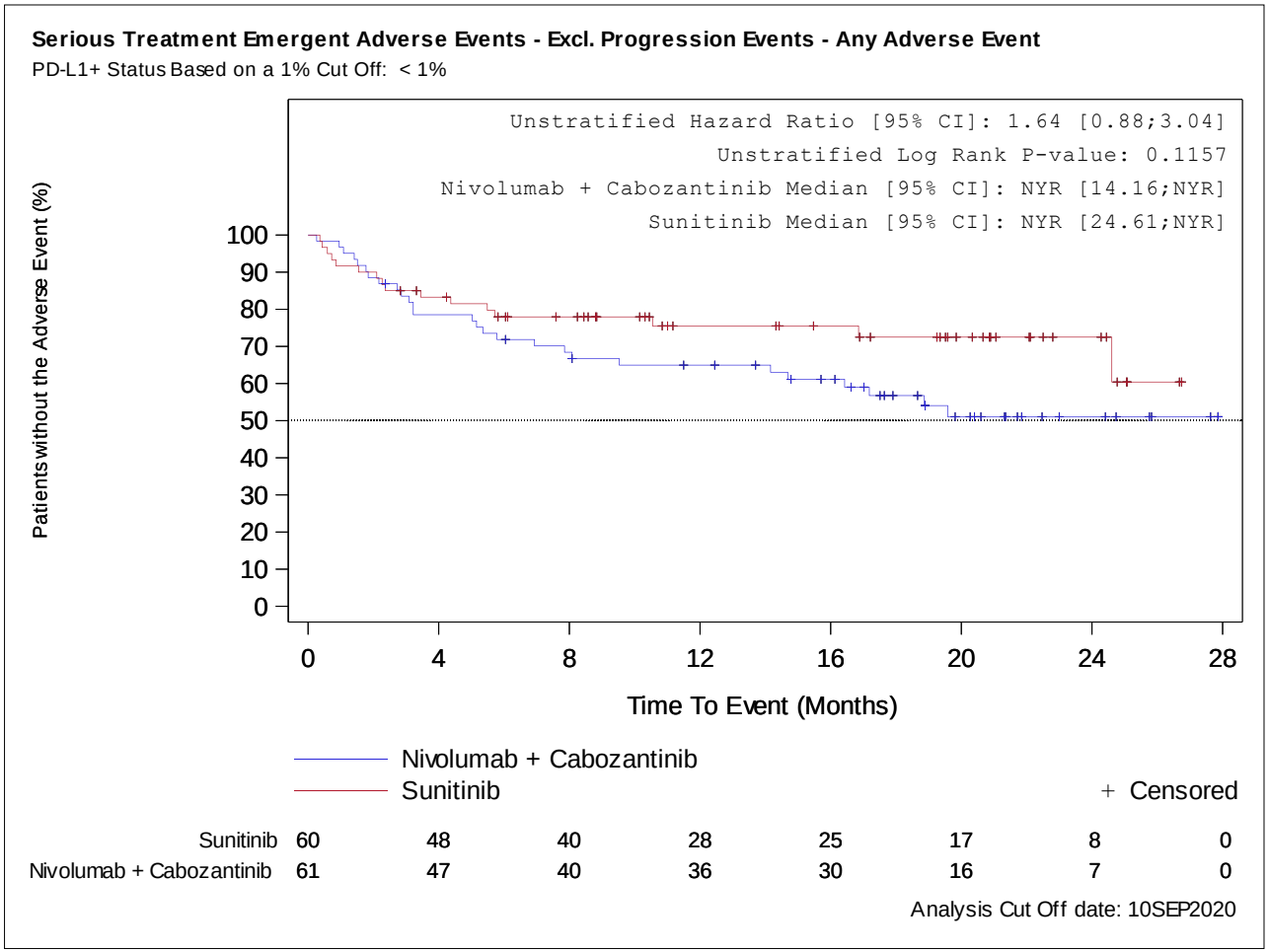
FIGURE 3.13.2.22: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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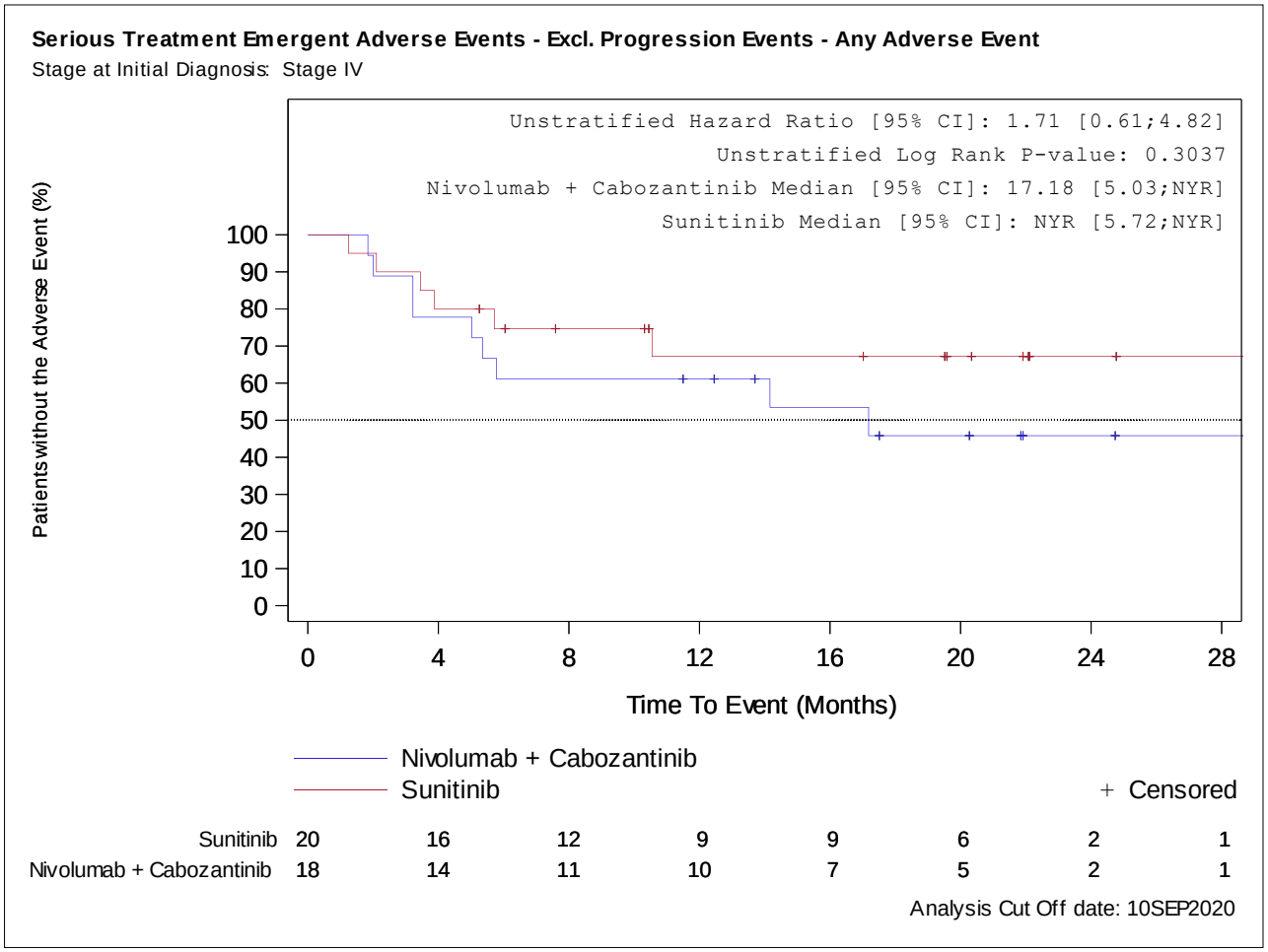
FIGURE 3.13.2.23: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis:  Stage IV




Analysis Cut Off date: 10SEP2020
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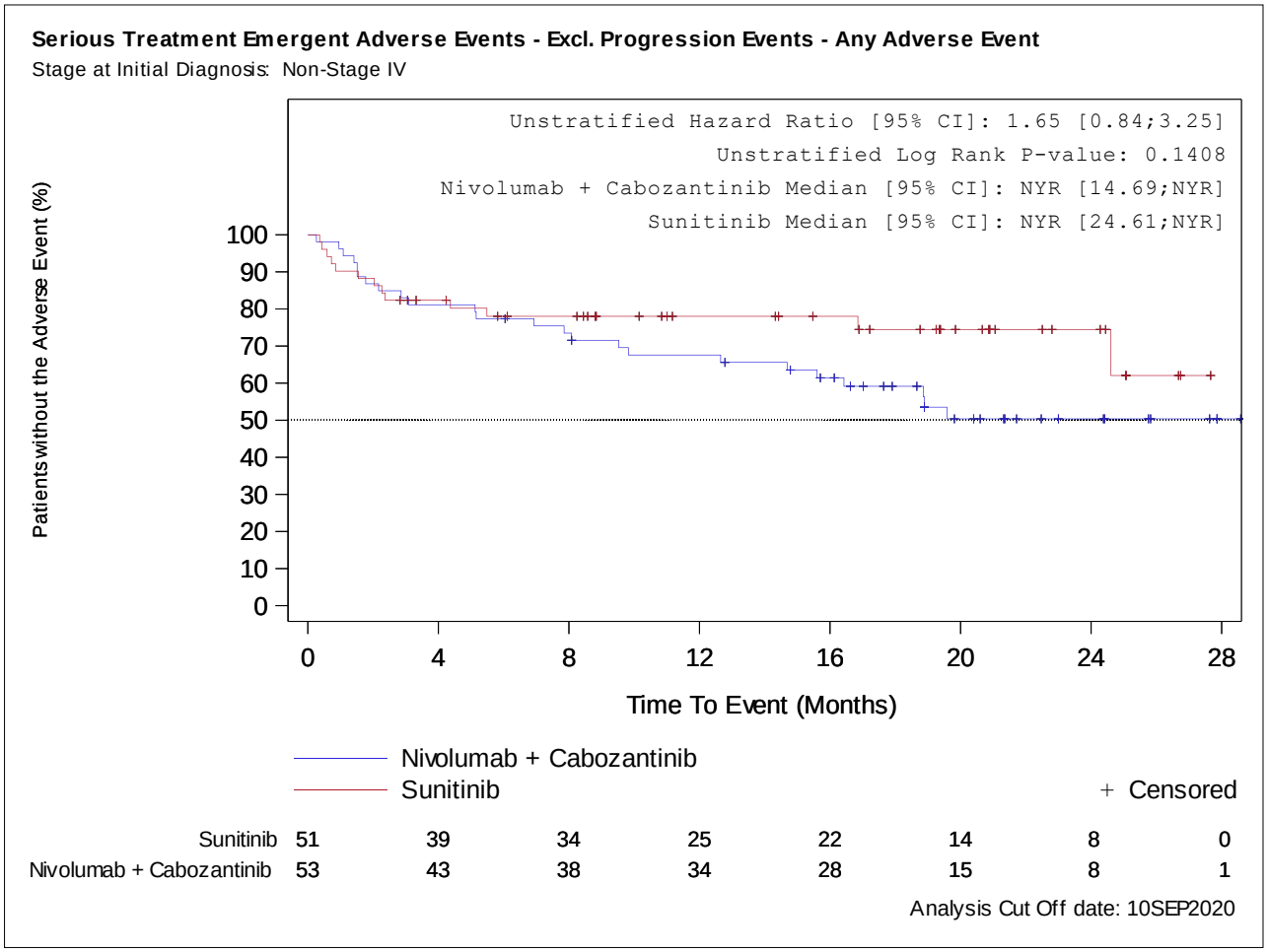
FIGURE 3.13.2.24: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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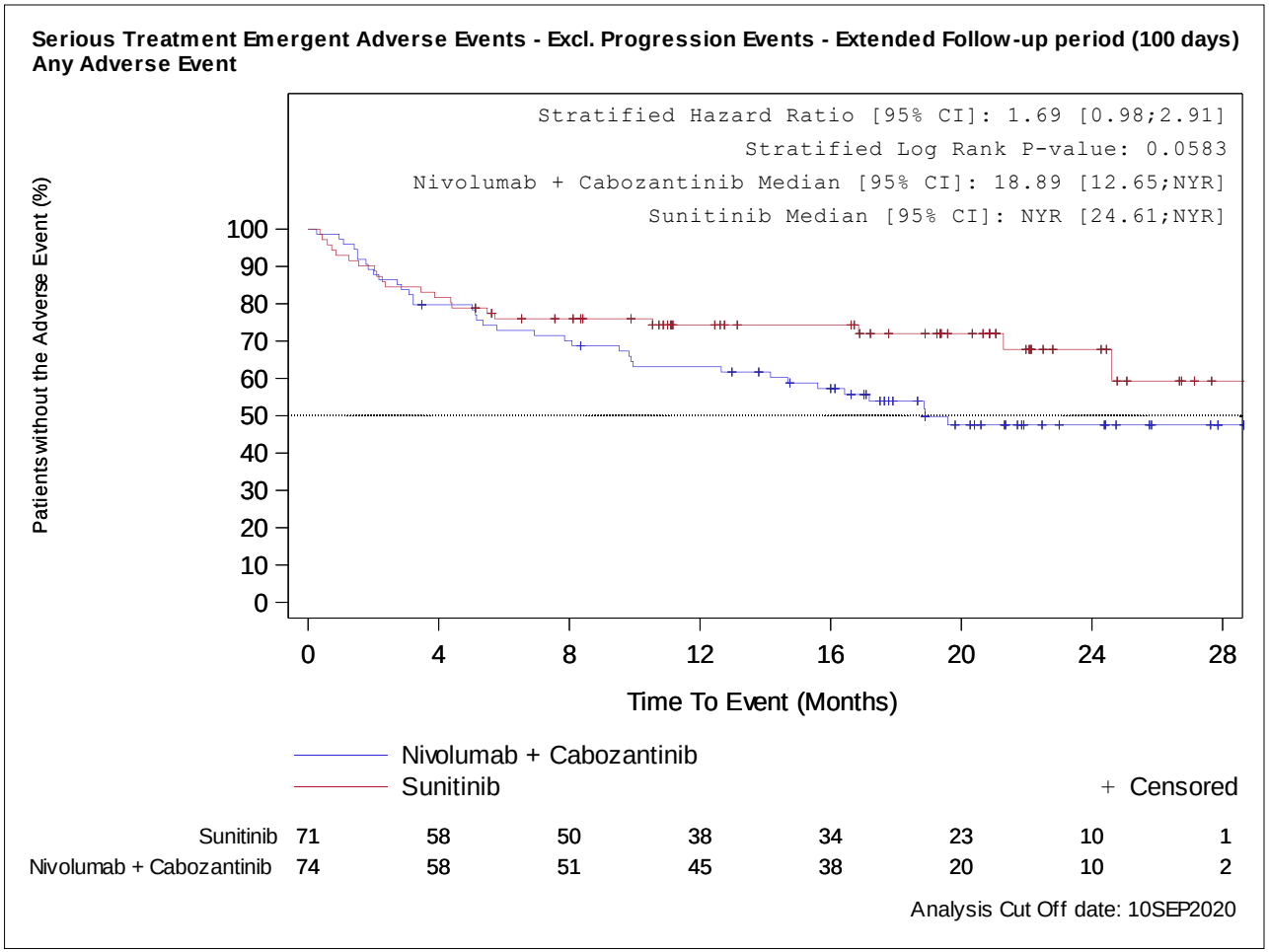
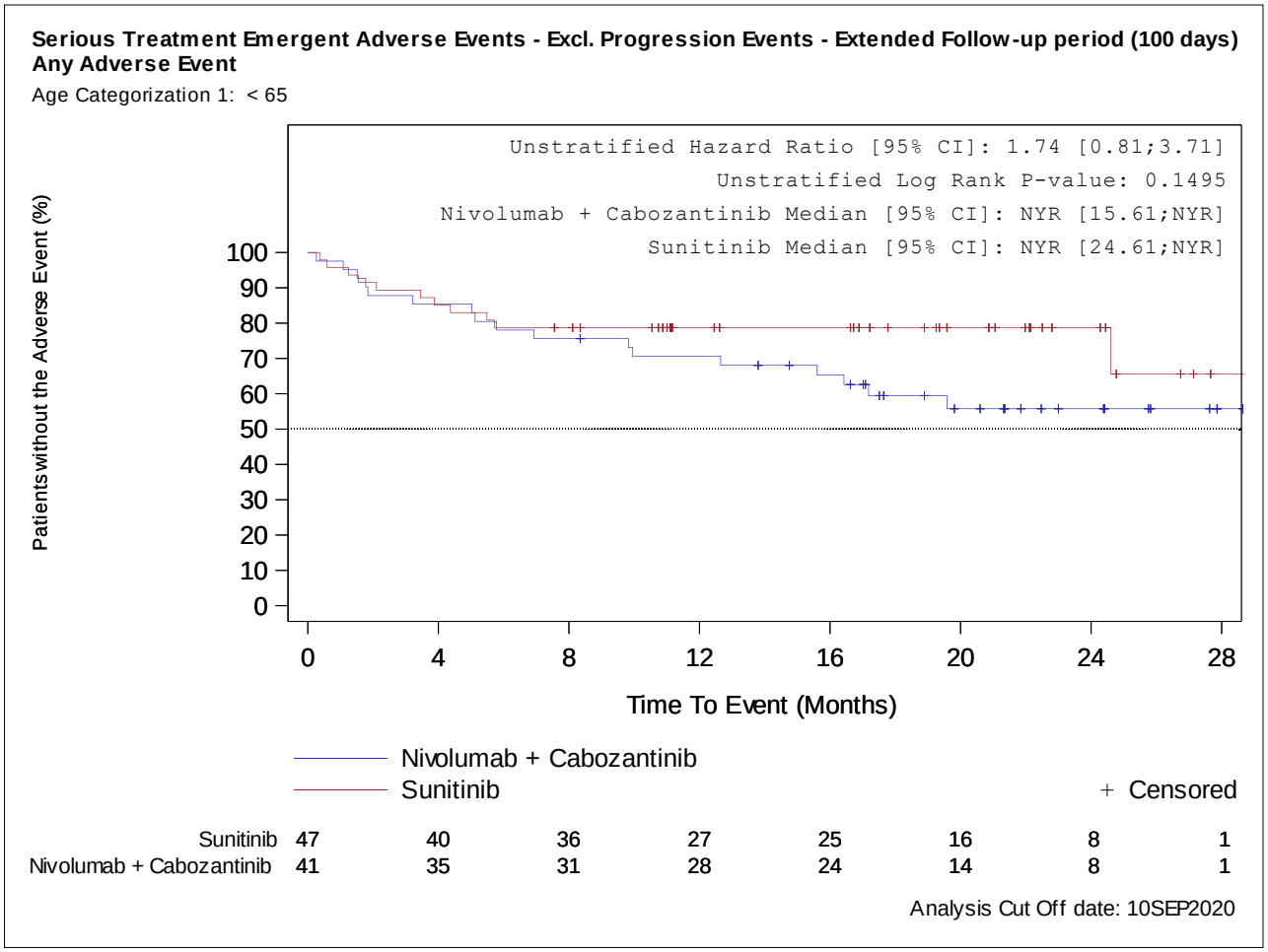
FIGURE 3.14.1: Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



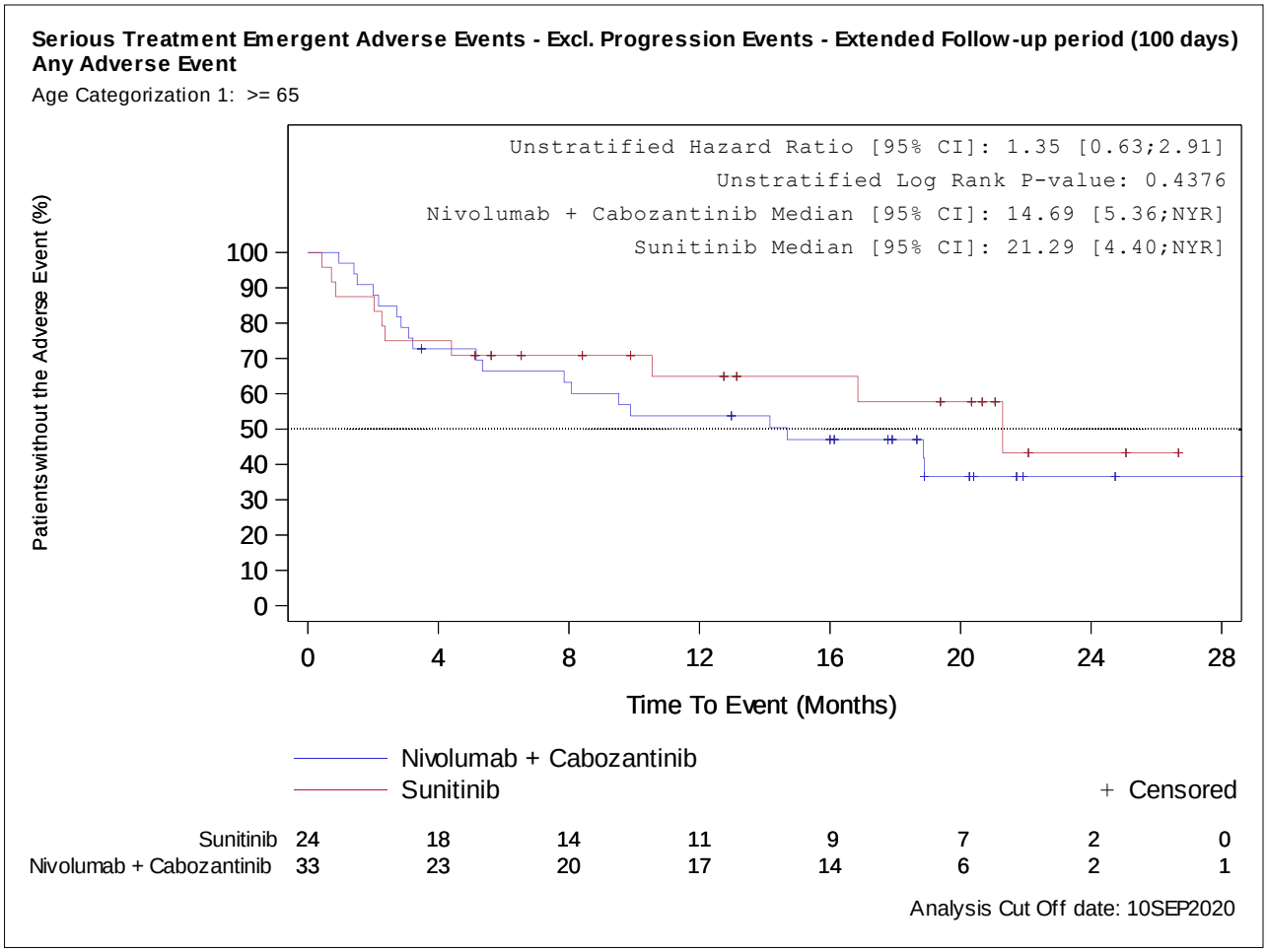

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:43:06

FIGURE 3.14.2.1: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:43:09

FIGURE 3.14.2.2: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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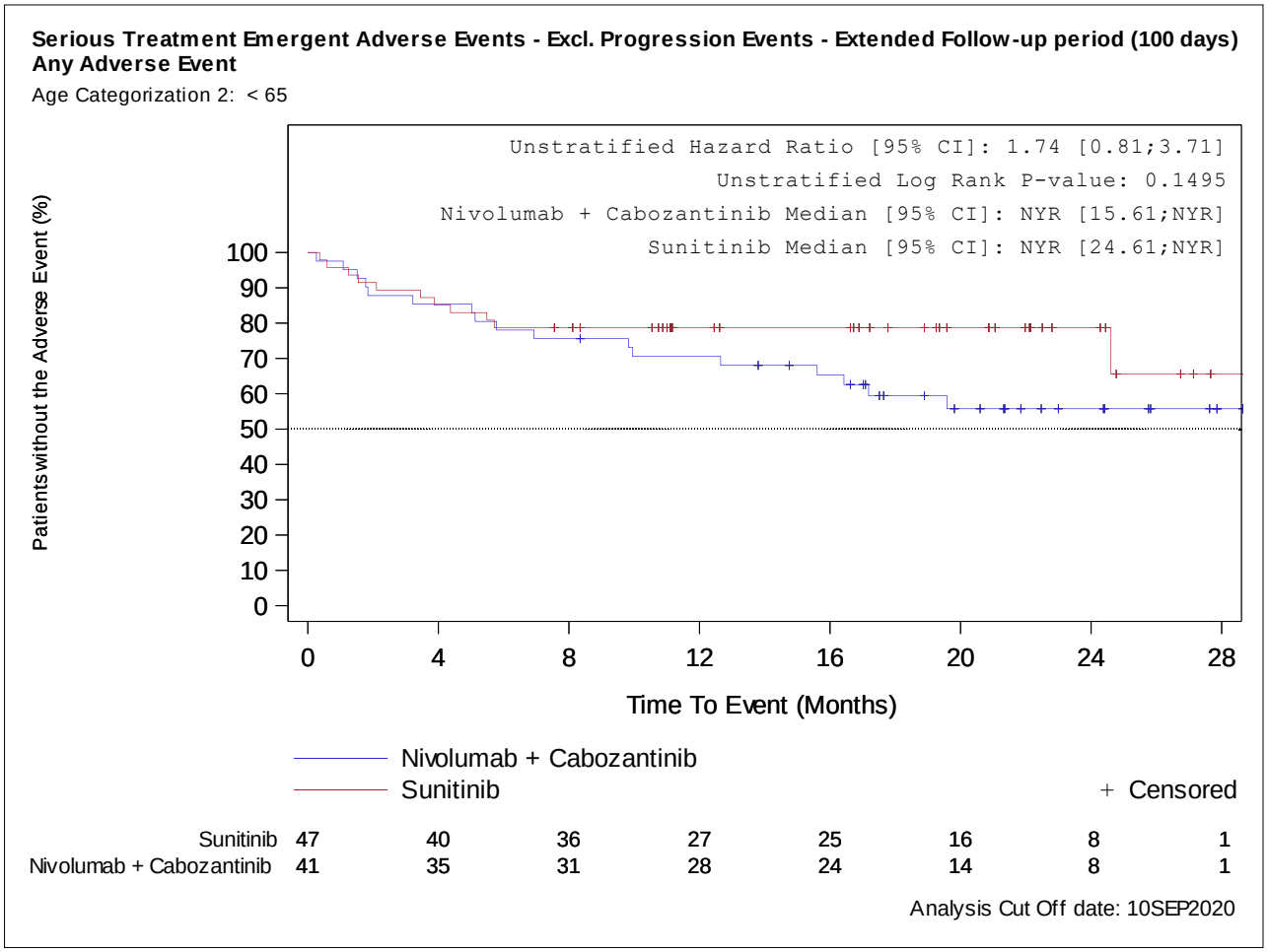
FIGURE 3.14.2.3: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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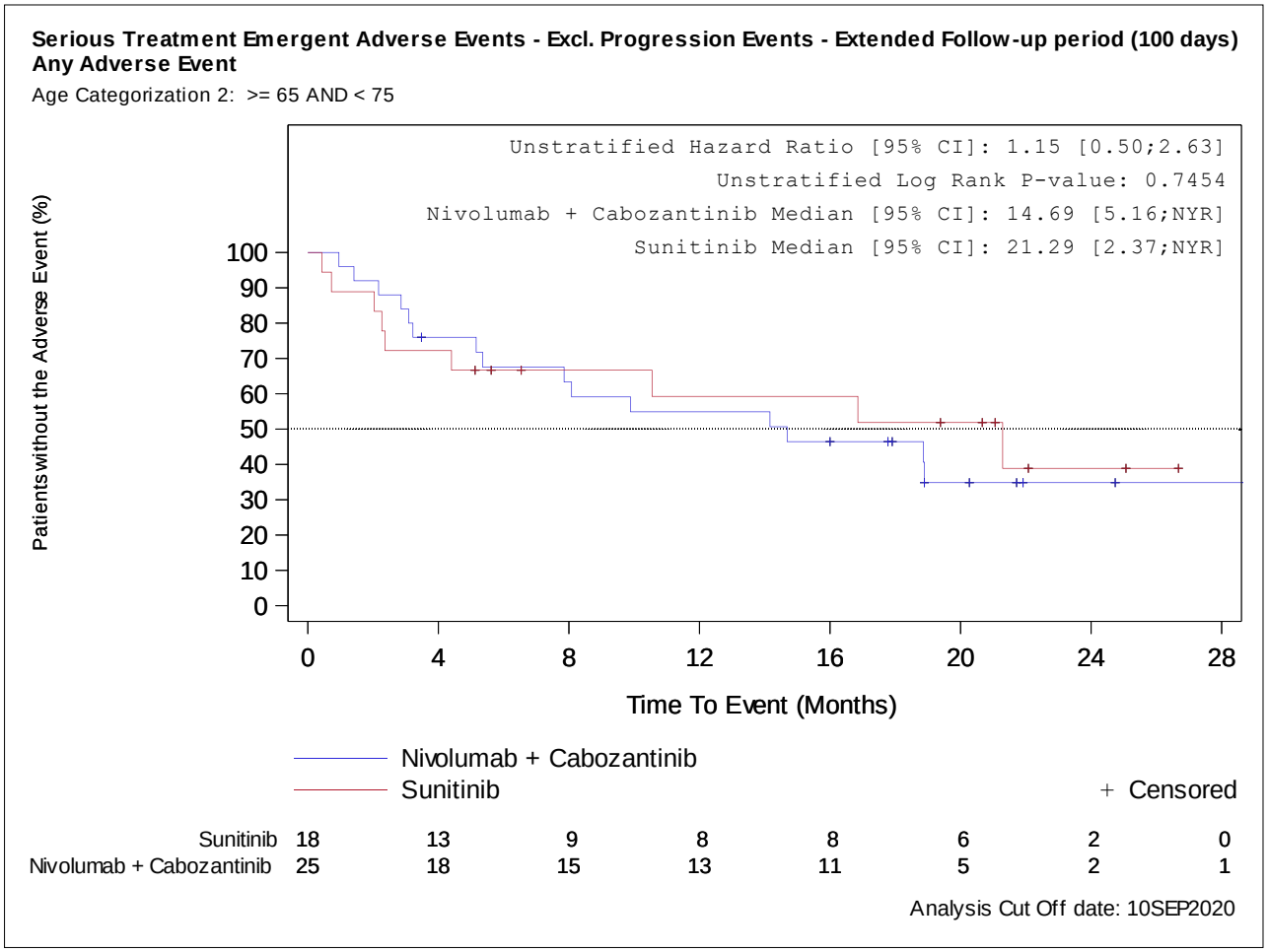
FIGURE 3.14.2.4: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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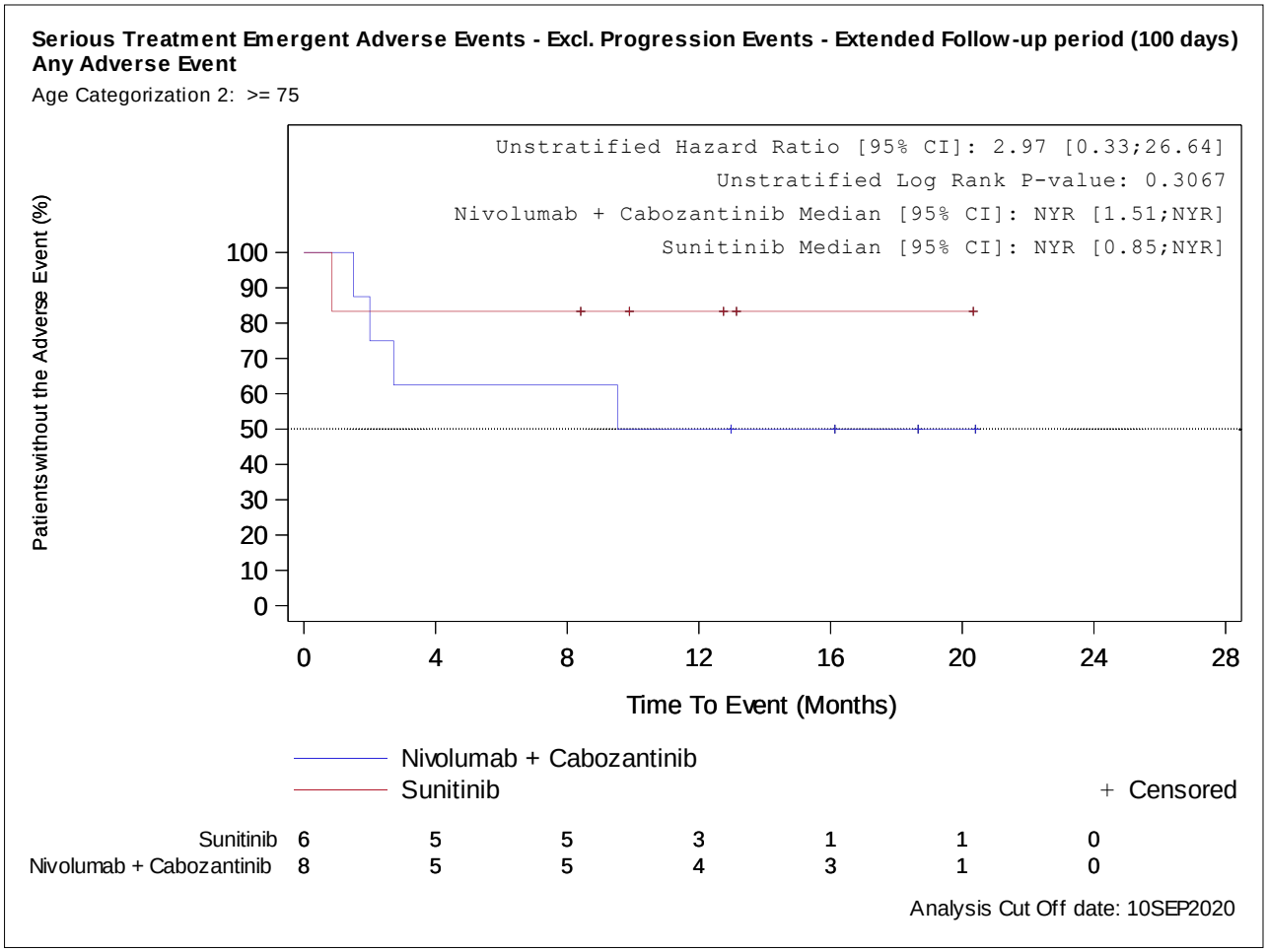
FIGURE 3.14.2.5: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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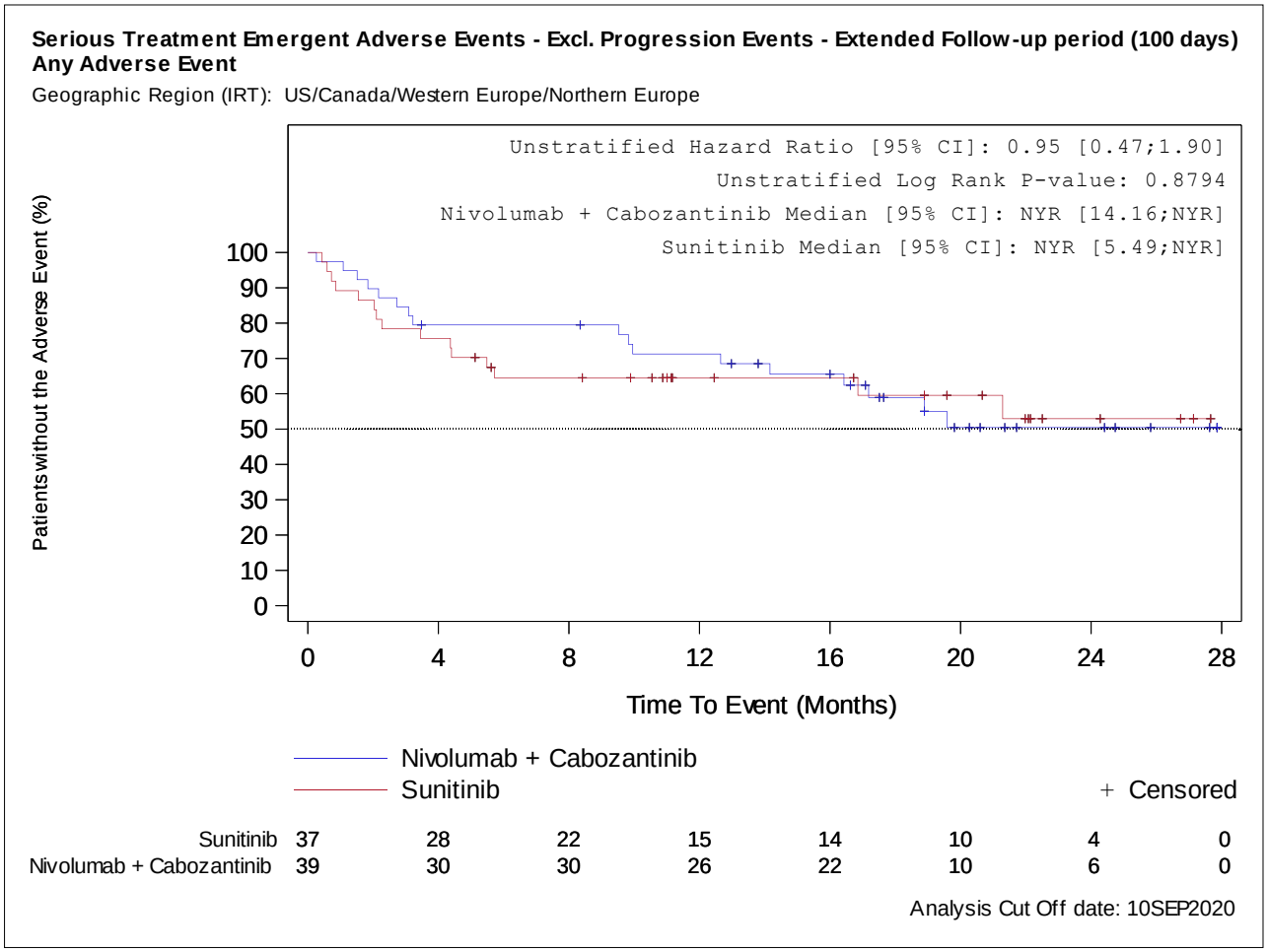
FIGURE 3.14.2.6: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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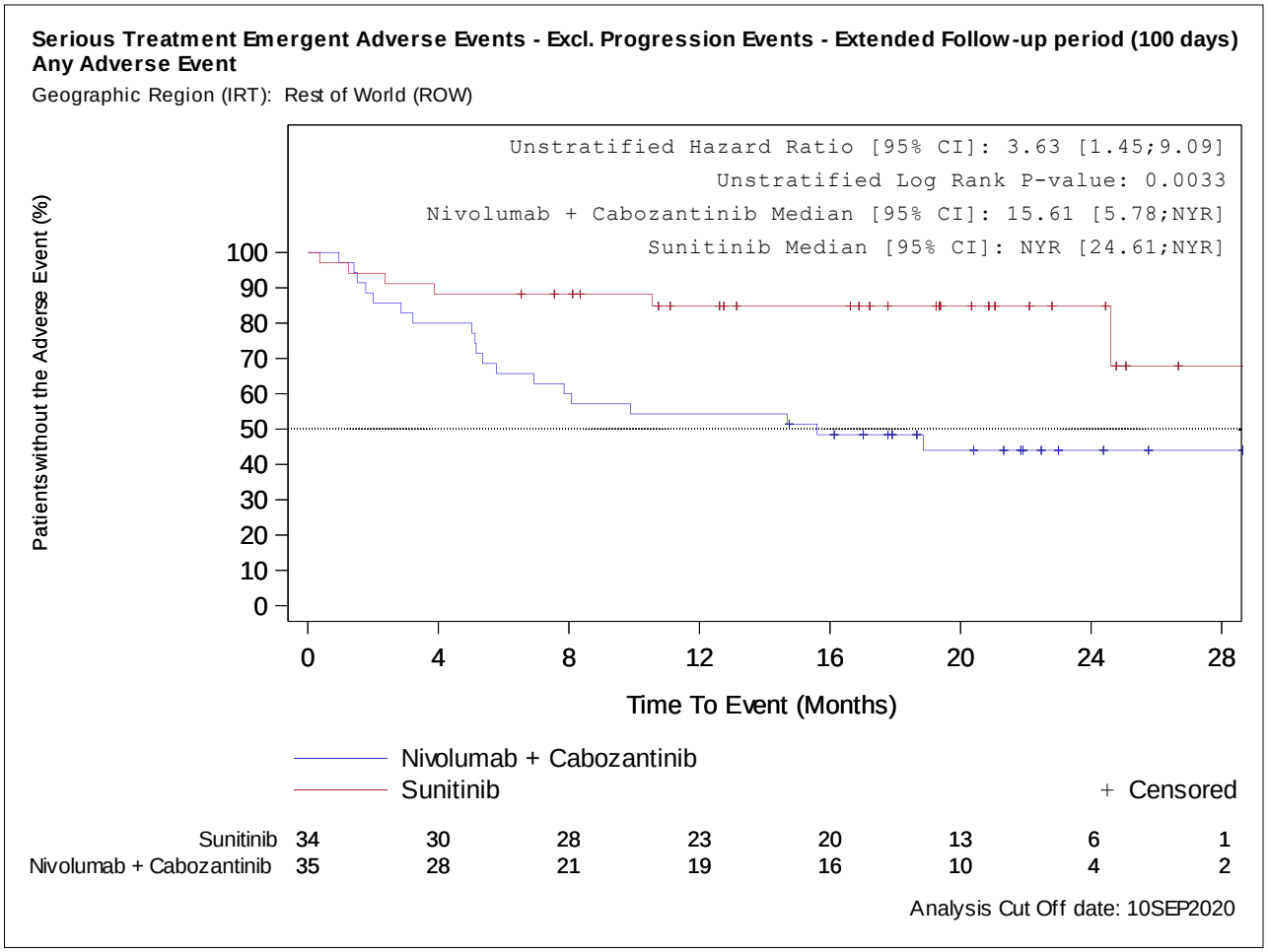
FIGURE 3.14.2.7: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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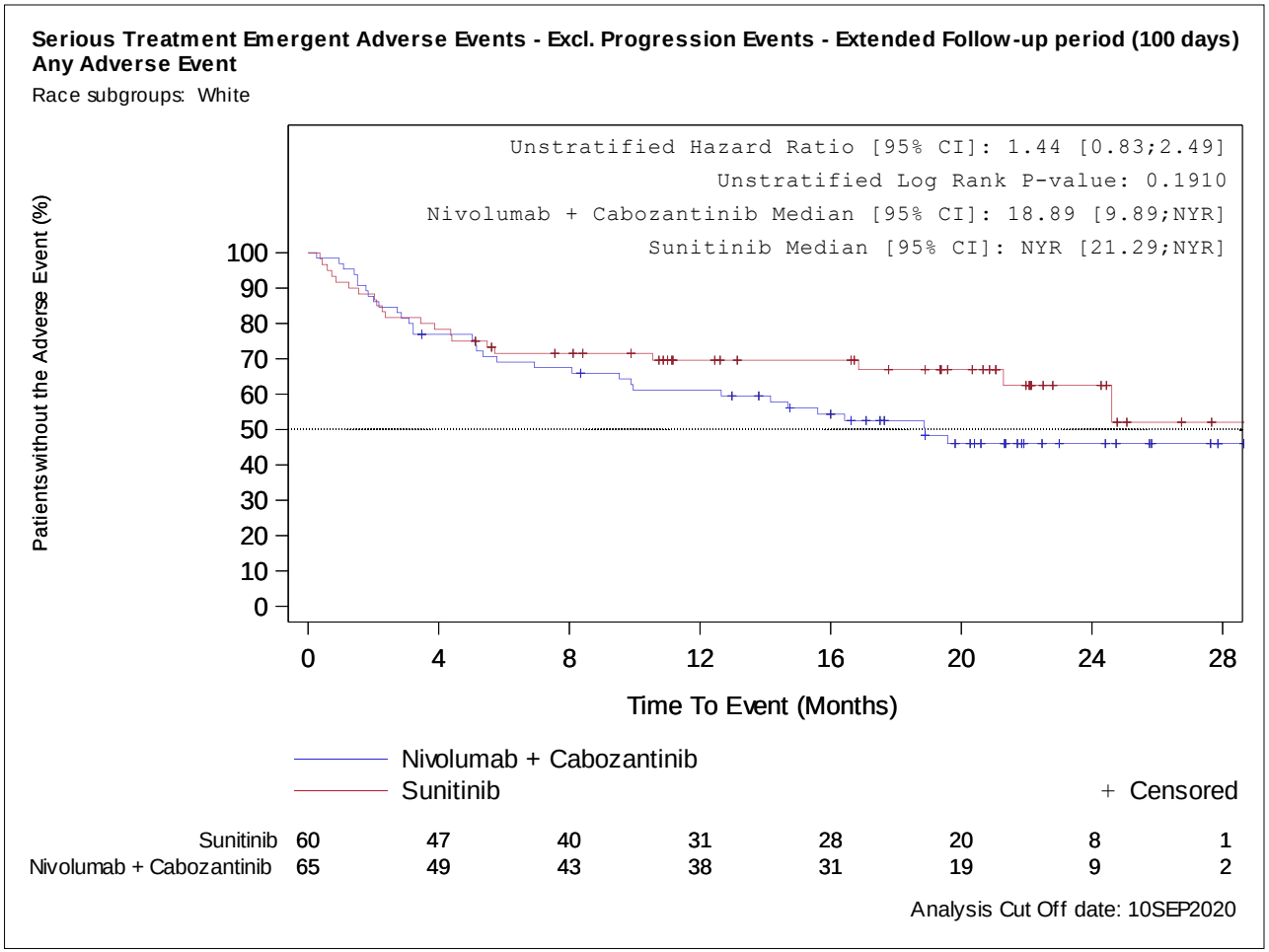
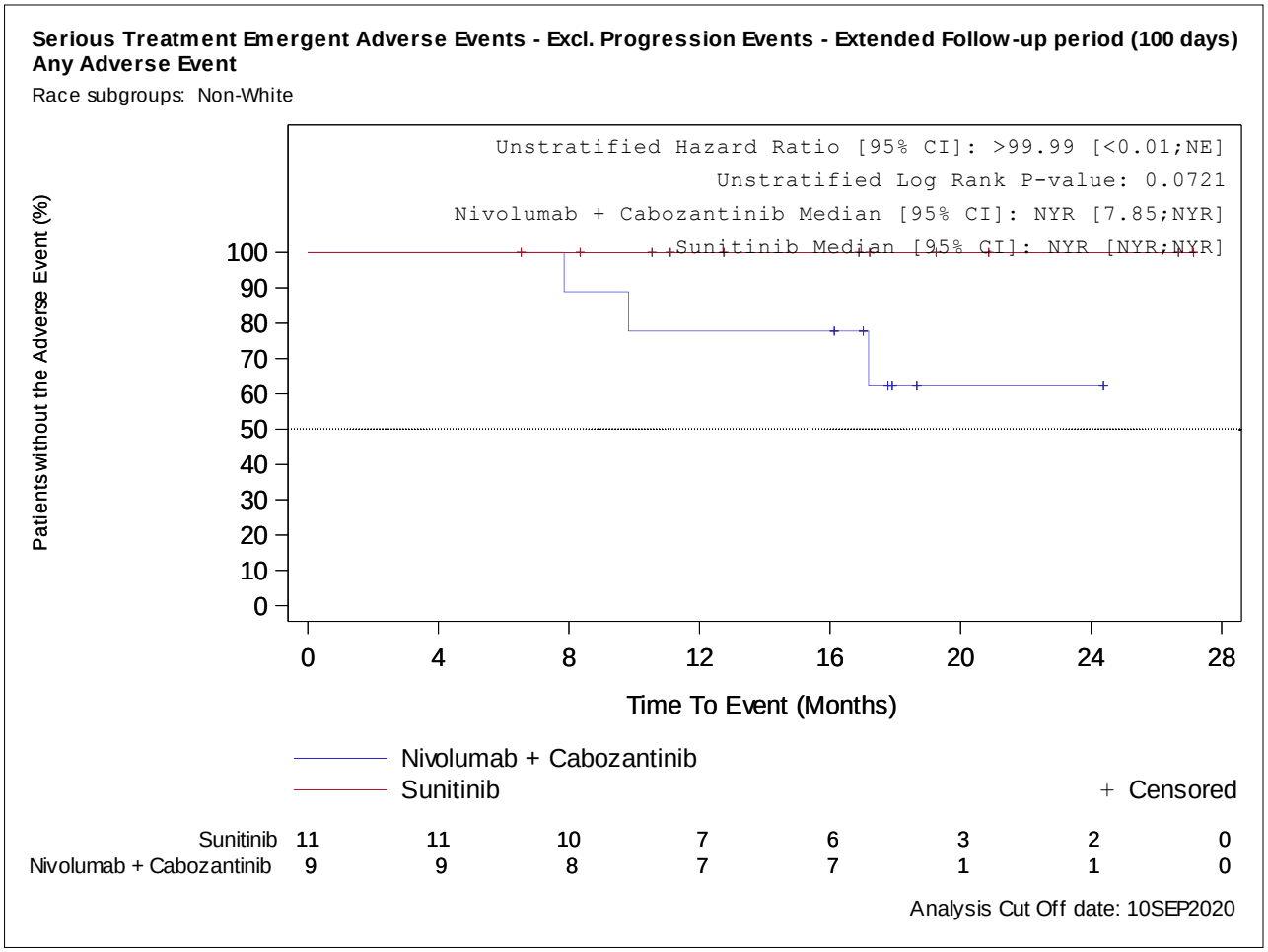
FIGURE 3.14.2.8: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:43:53

FIGURE 3.14.2.9: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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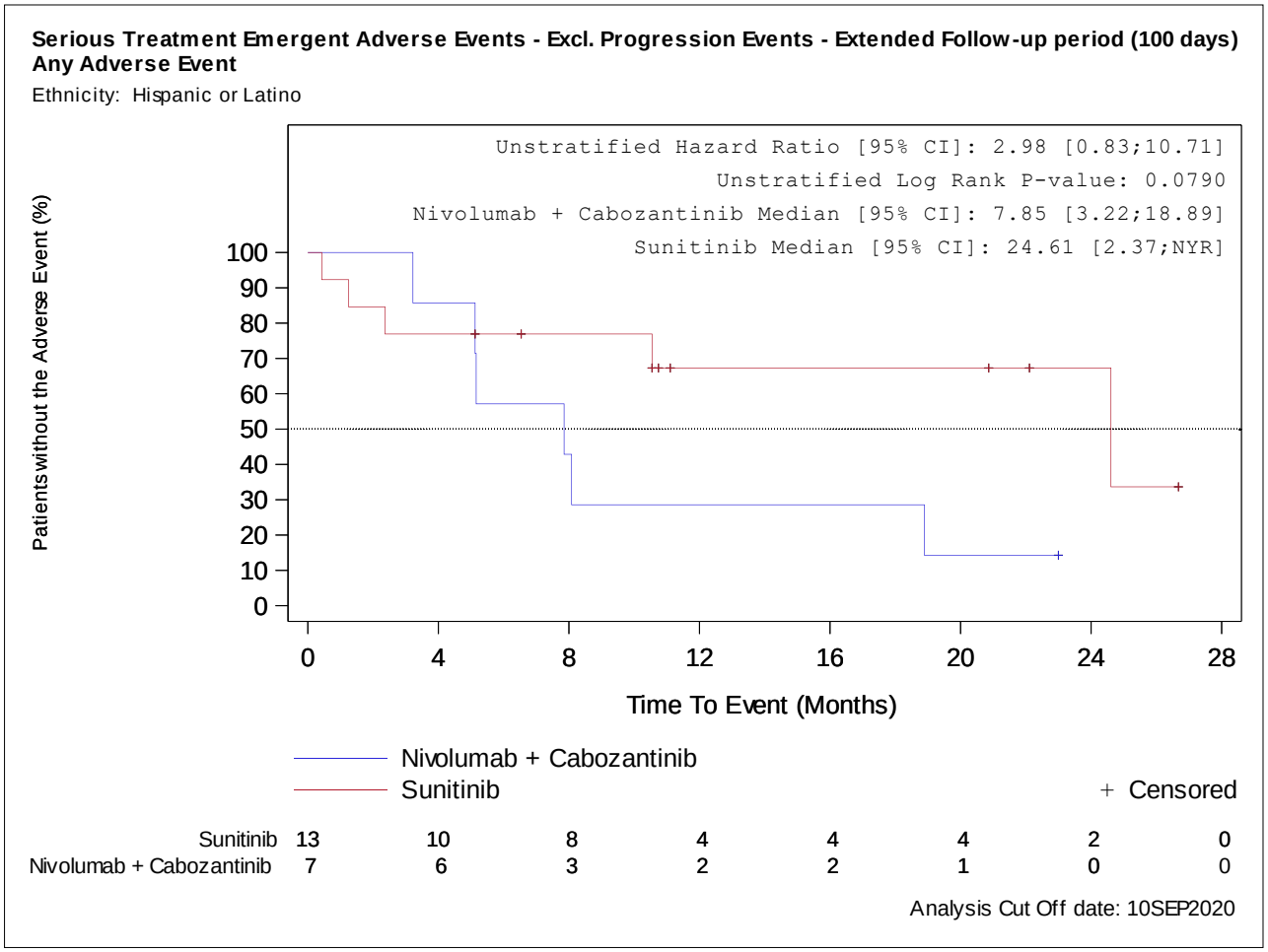
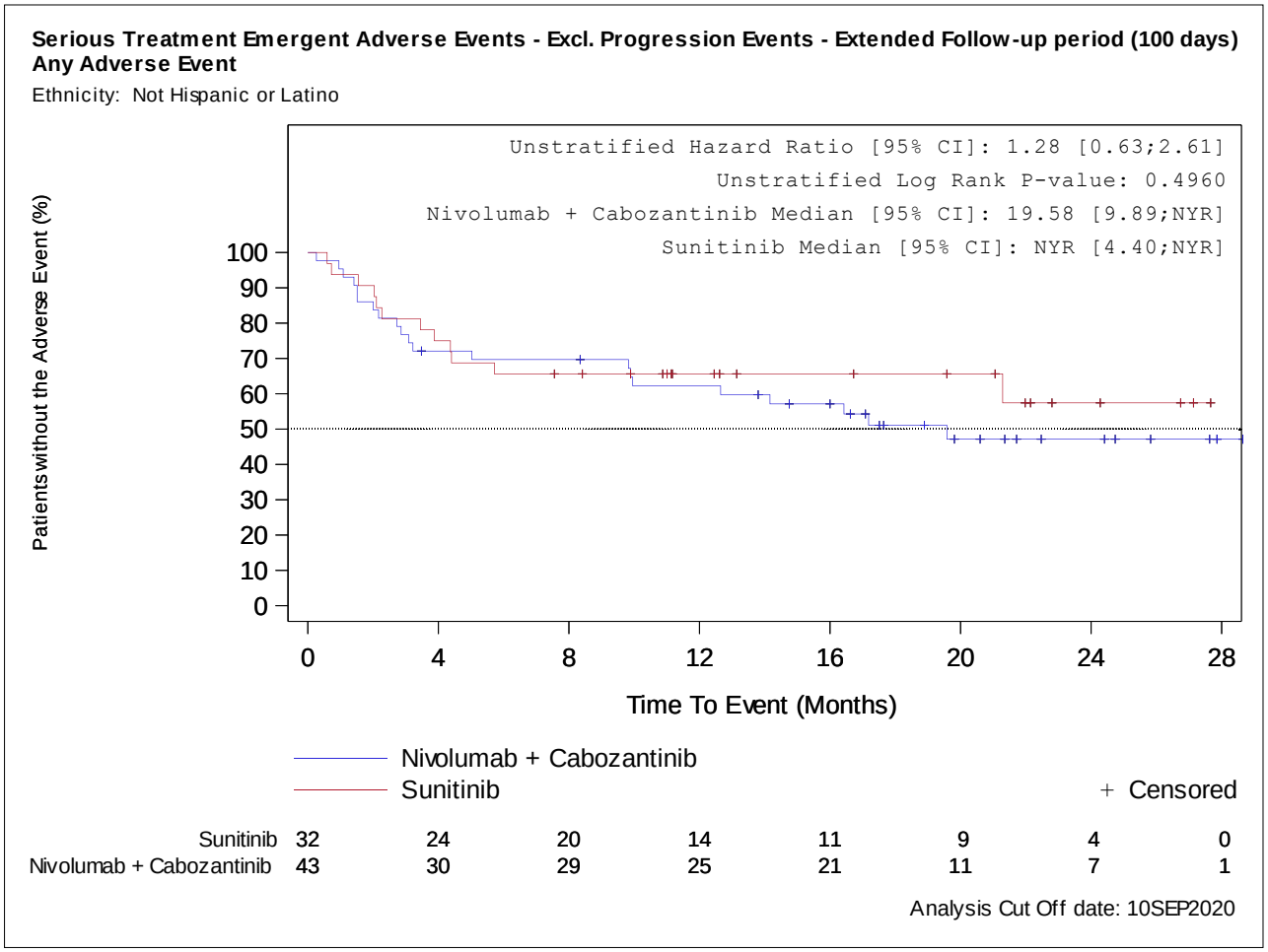
FIGURE 3.14.2.10: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



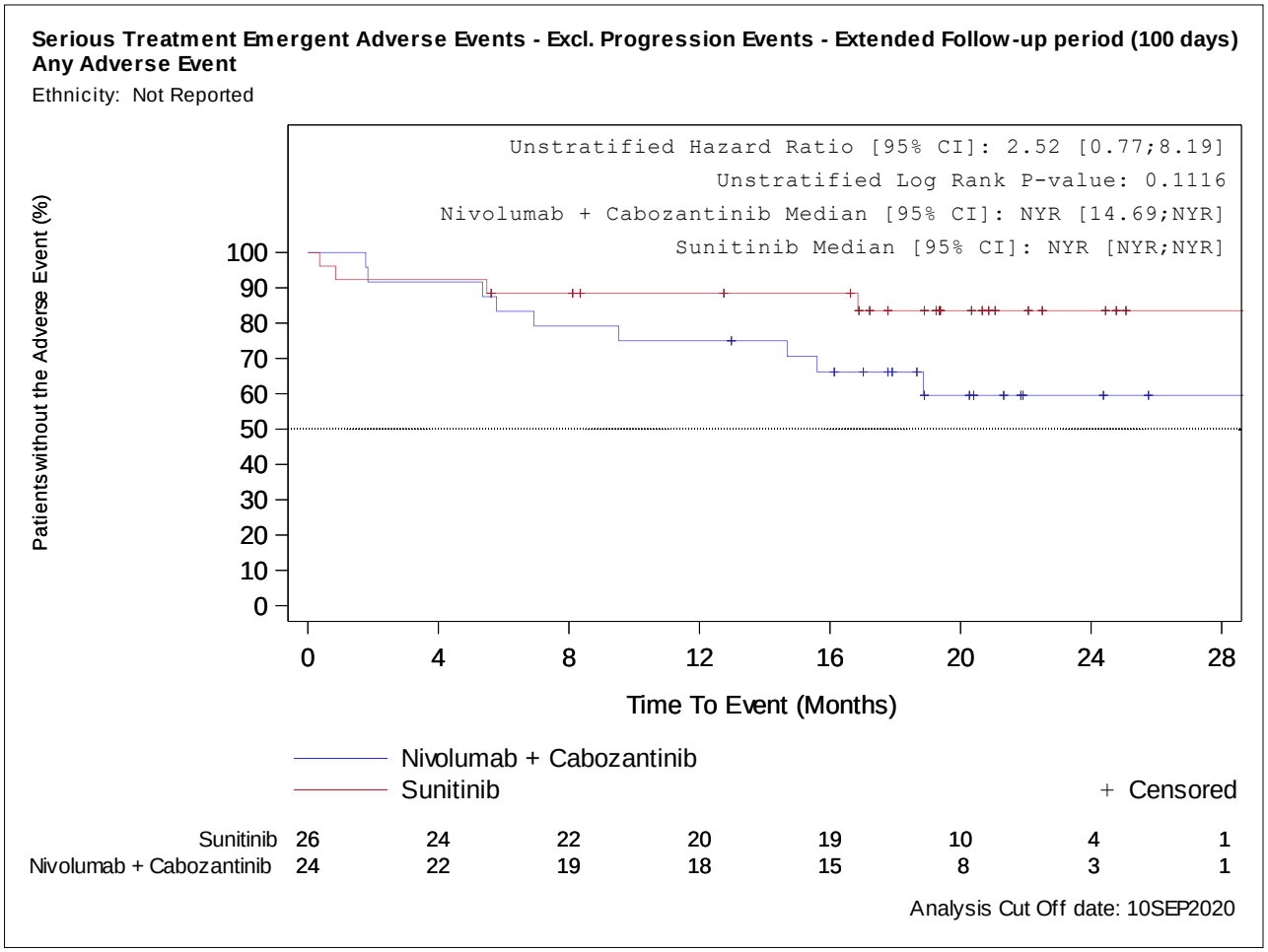

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:44:06

FIGURE 3.14.2.11: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



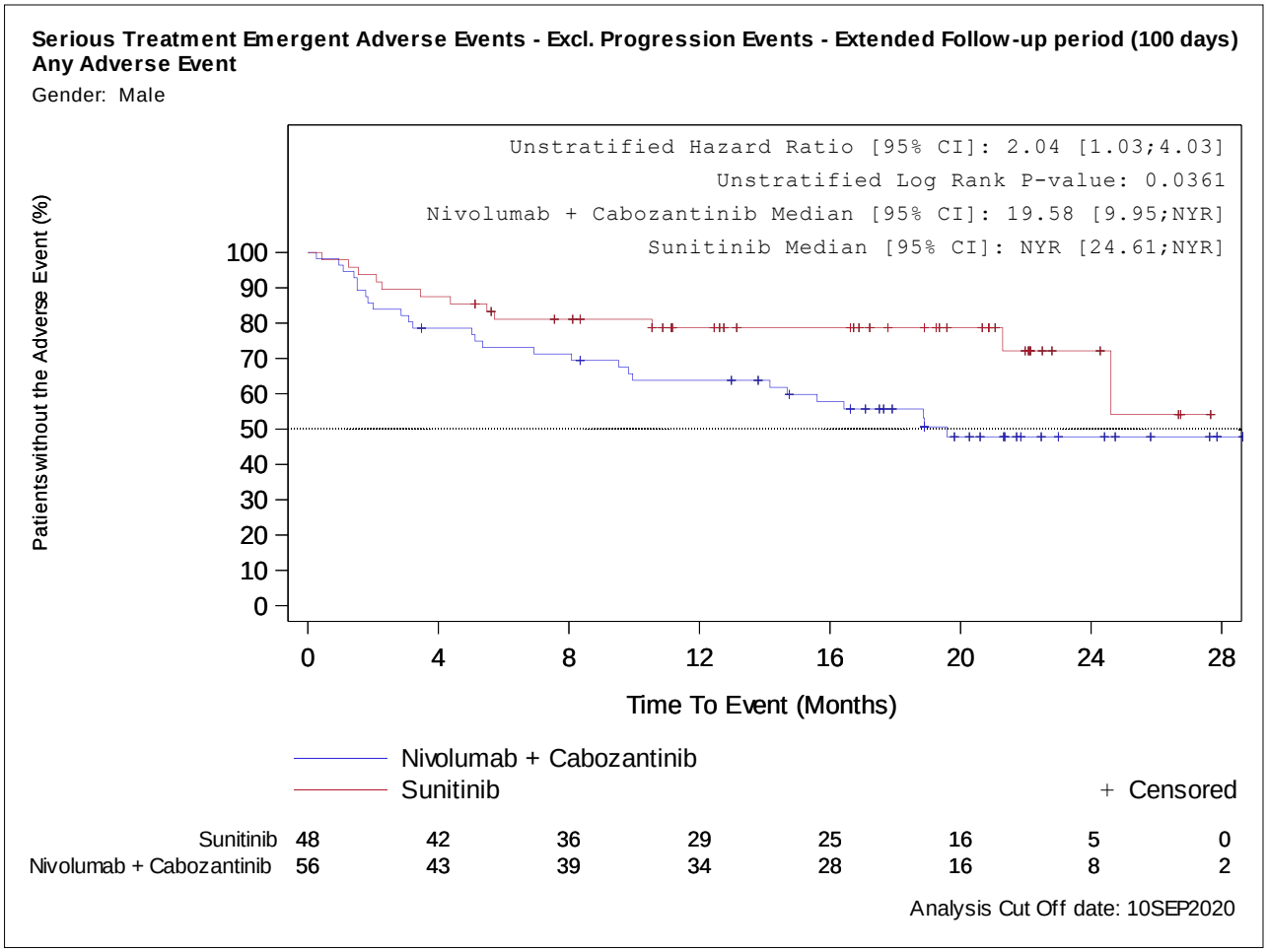

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:44:12

FIGURE 3.14.2.12: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



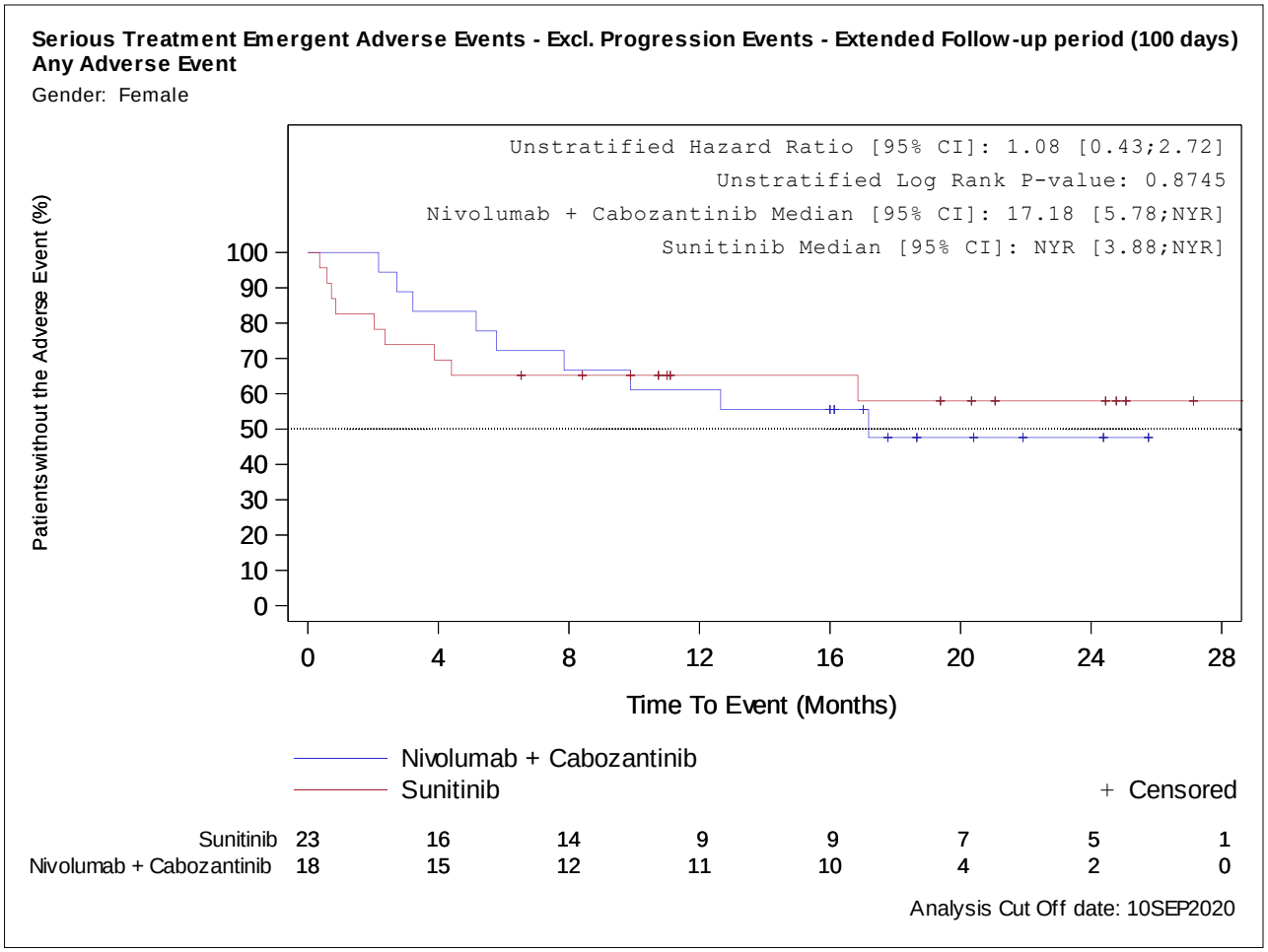

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:44:18

FIGURE 3.14.2.13: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:44:24

FIGURE 3.14.2.14: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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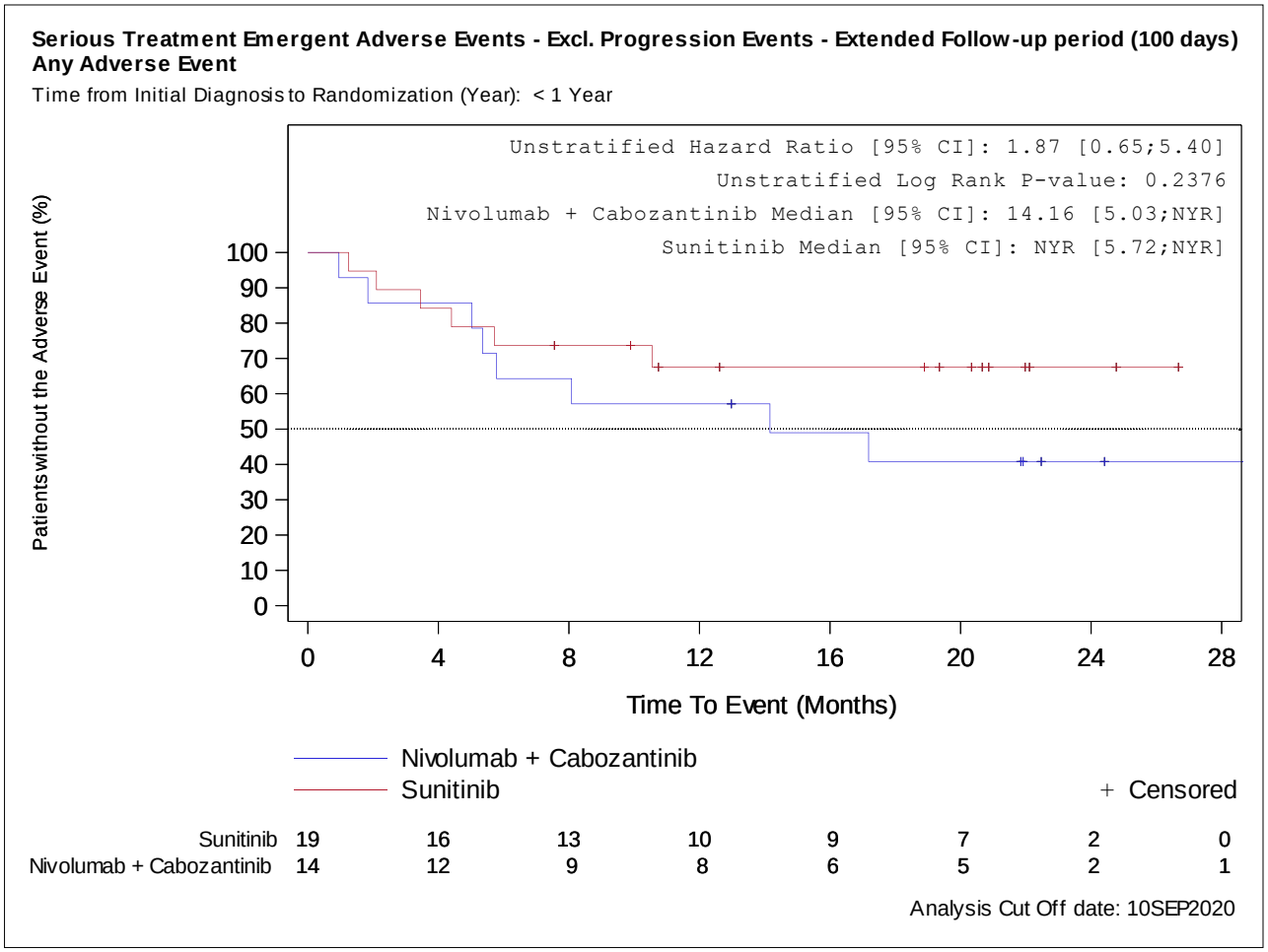
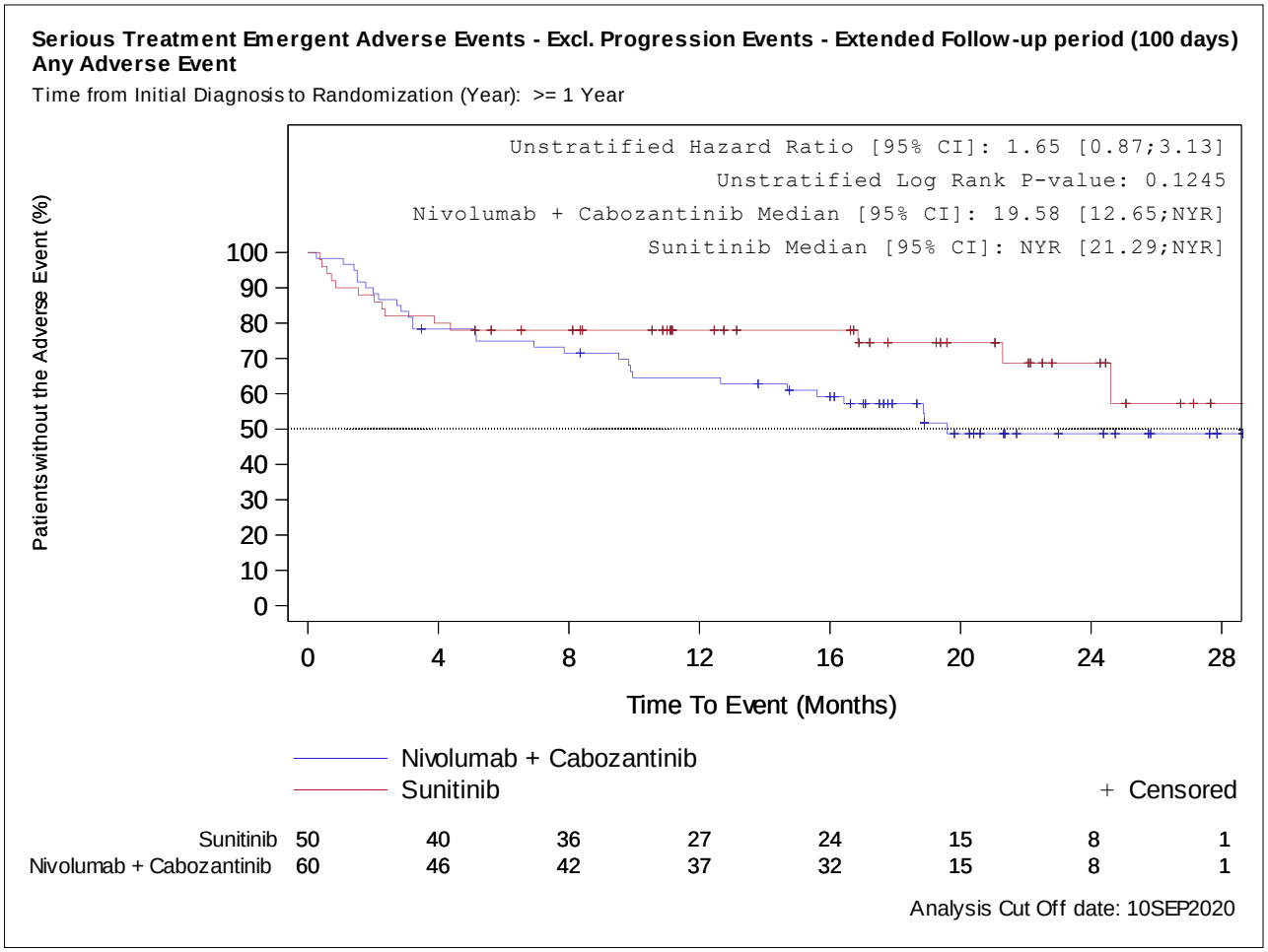
FIGURE 3.14.2.15: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



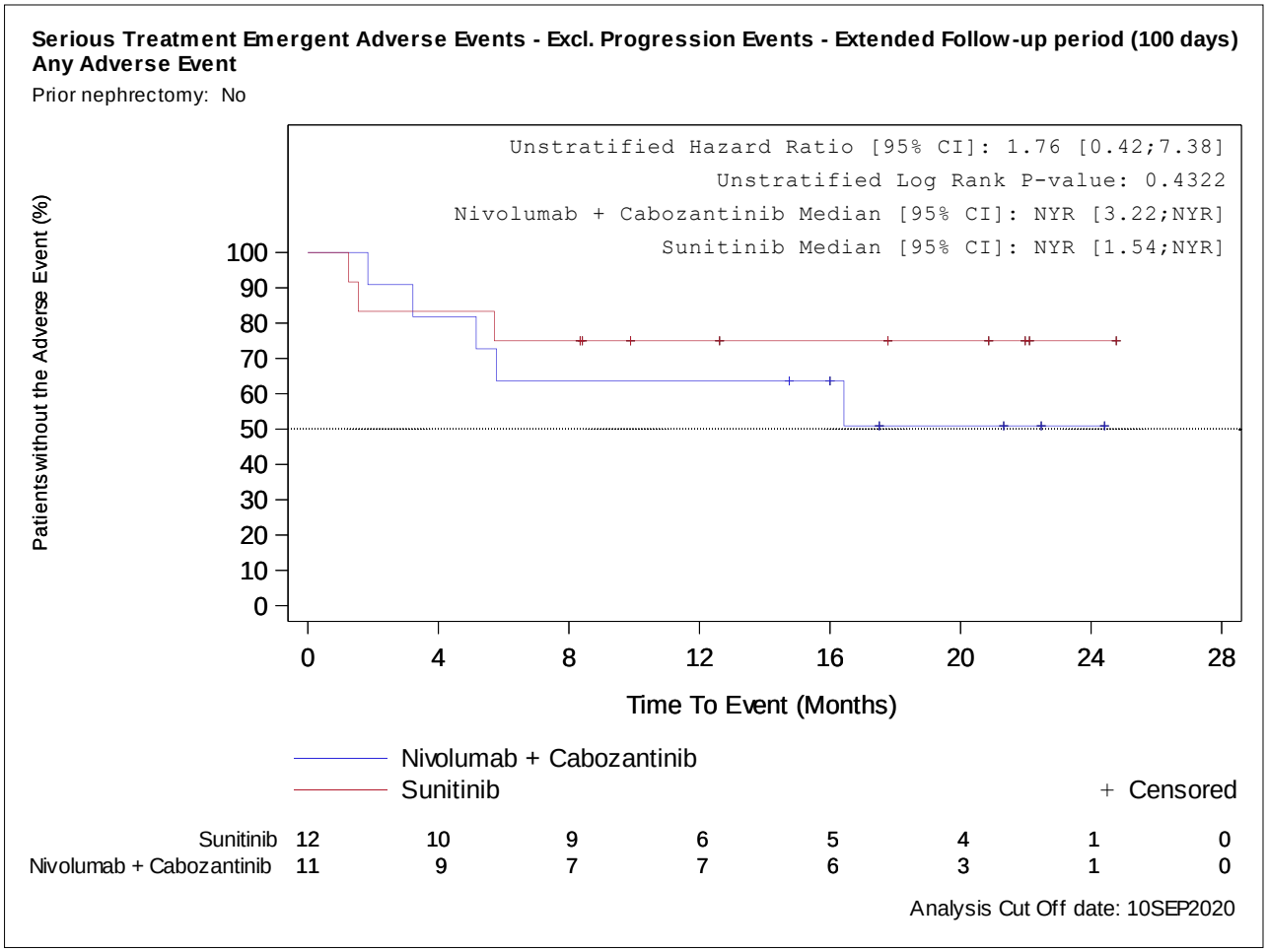

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:44:47

FIGURE 3.14.2.16: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



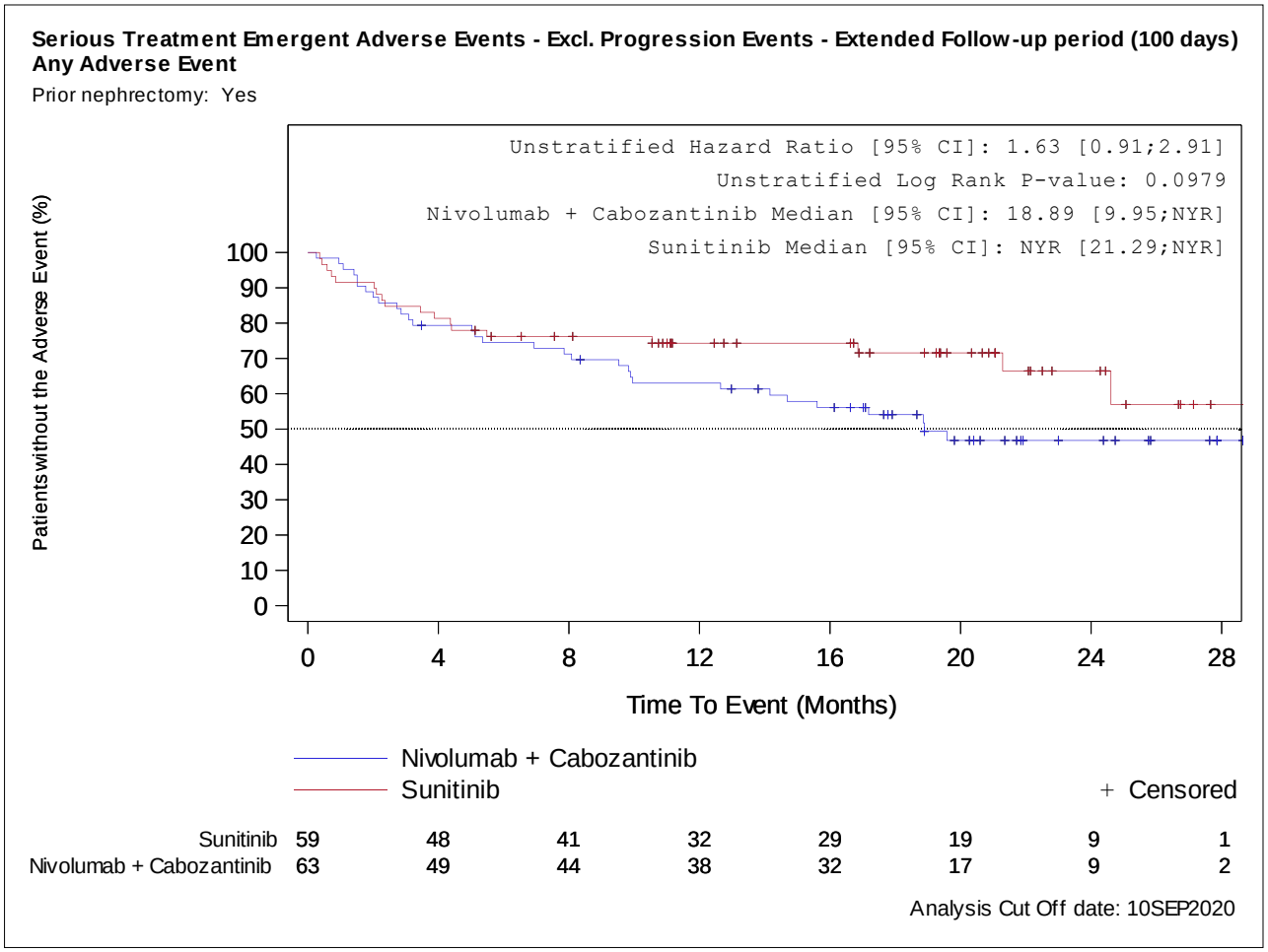

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:44:53

FIGURE 3.14.2.17: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:45:46

FIGURE 3.14.2.18: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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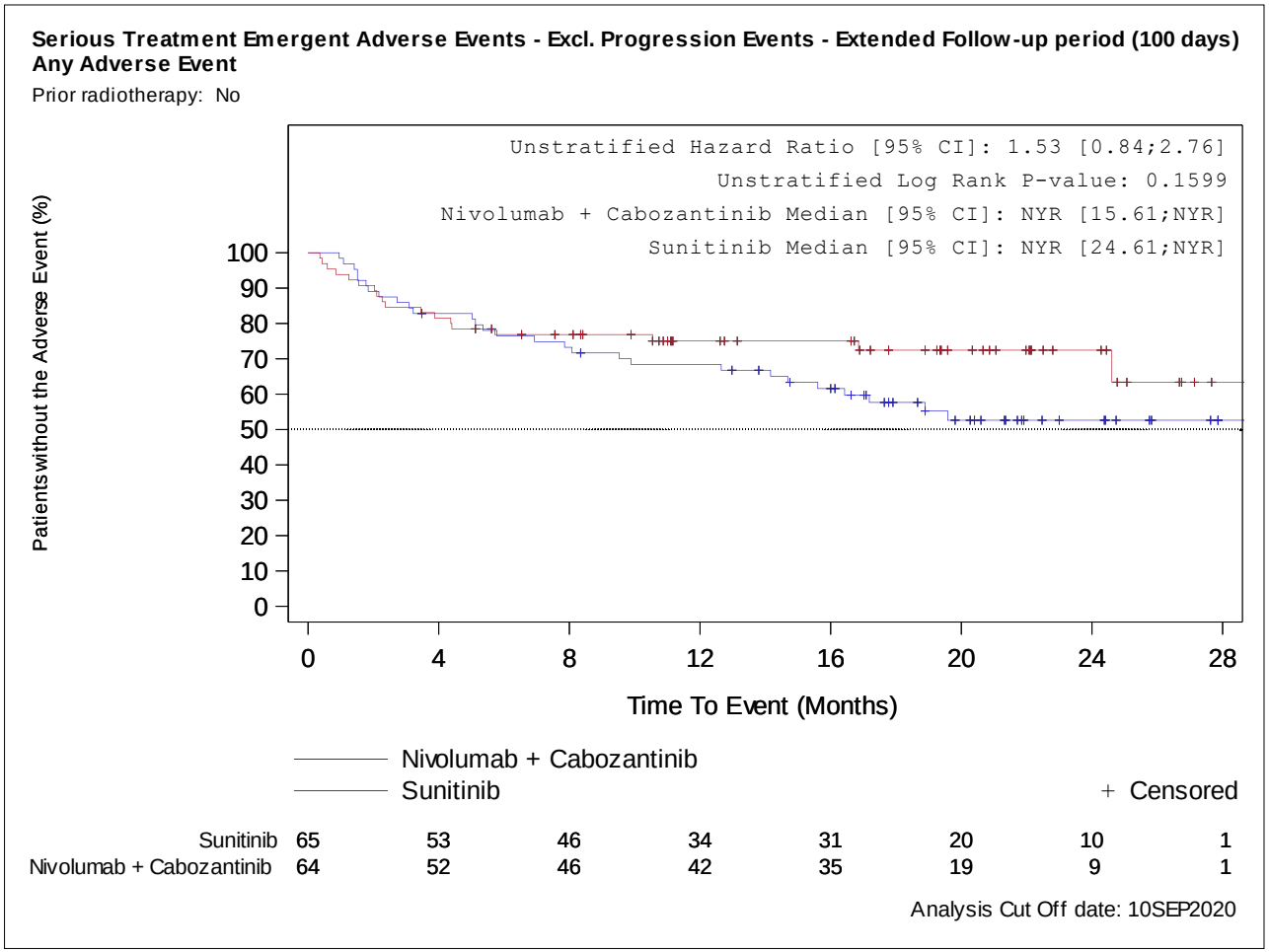
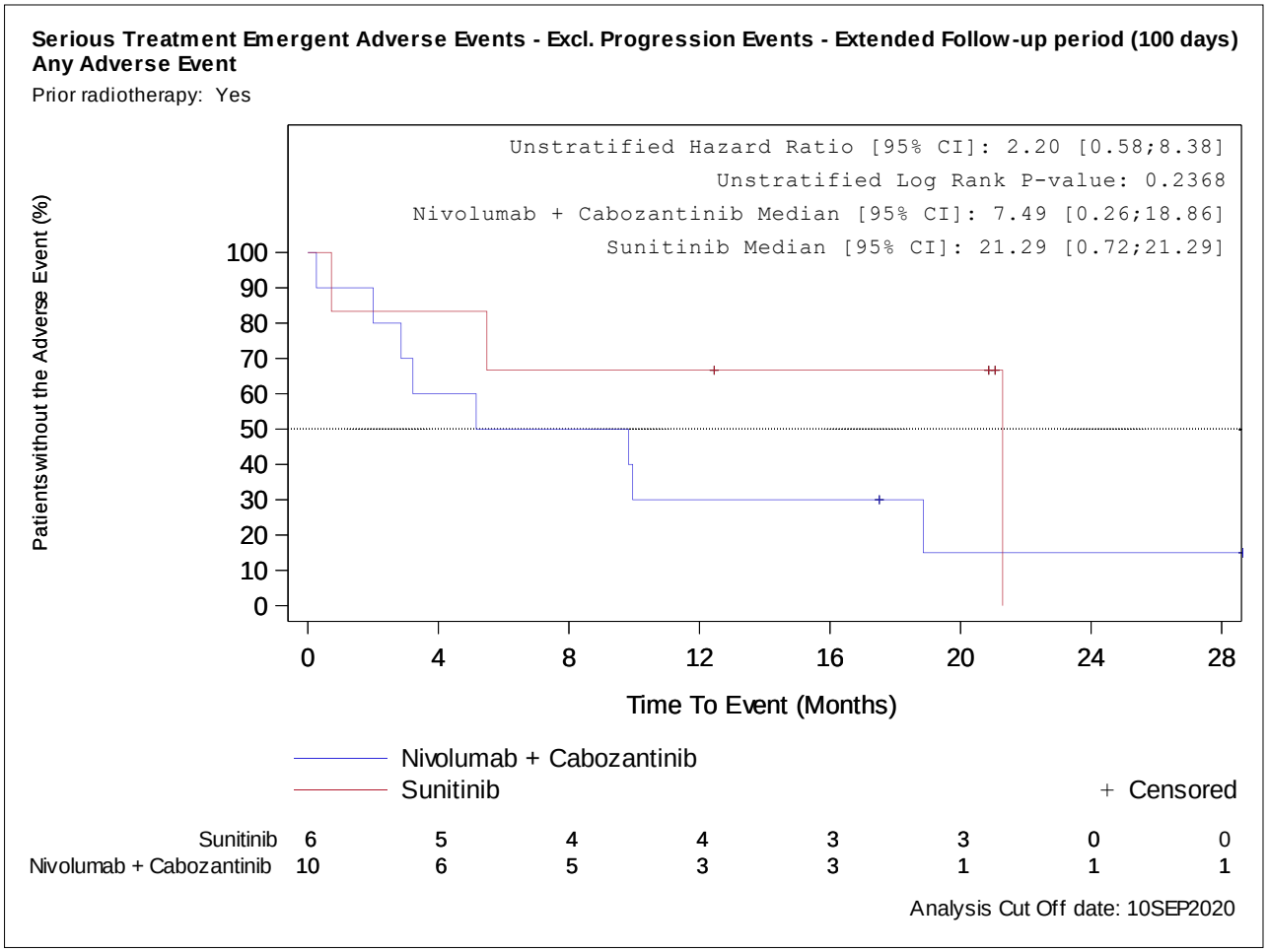
FIGURE 3.14.2.19: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



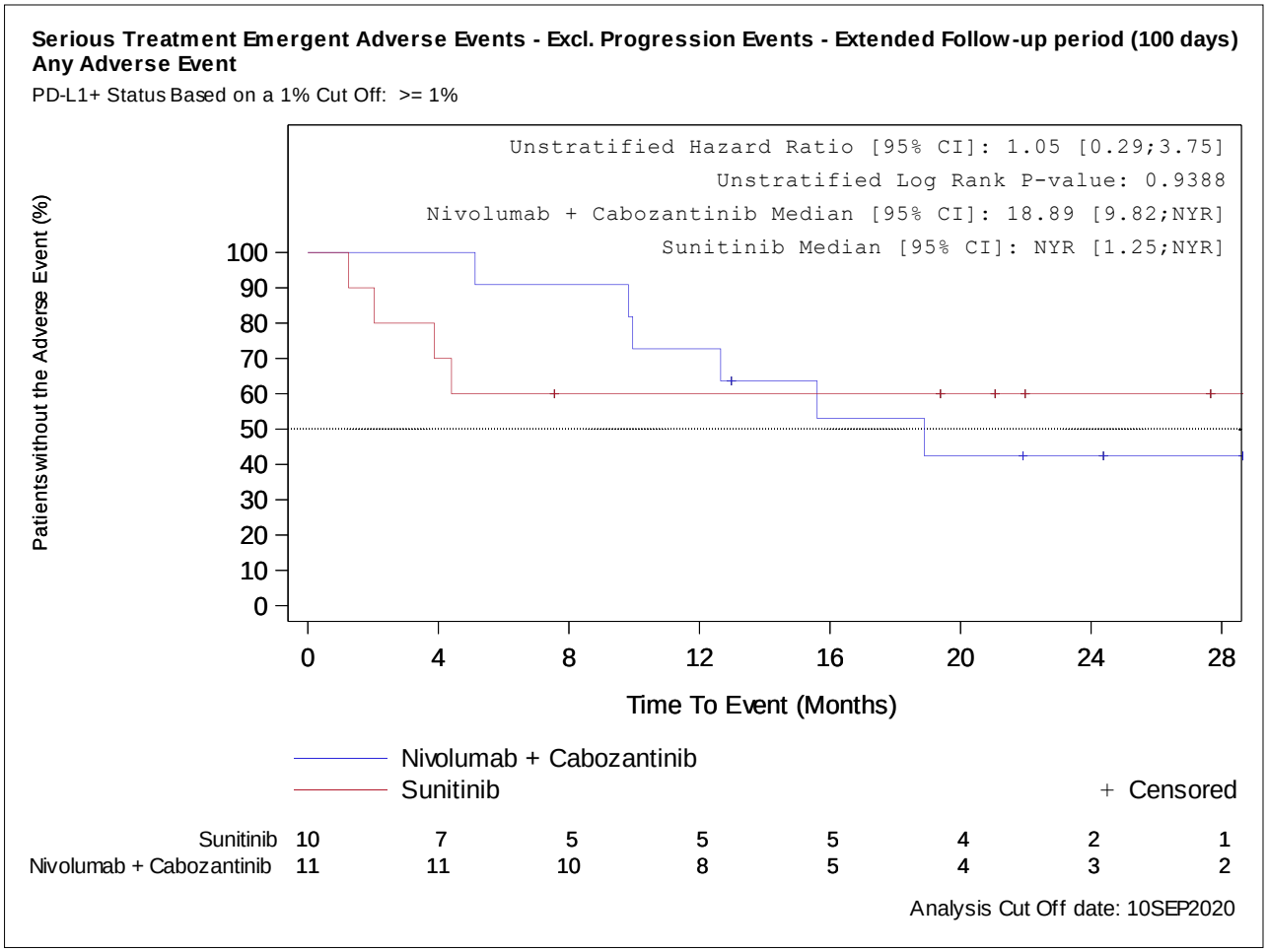

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:45:59

FIGURE 3.14.2.20: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



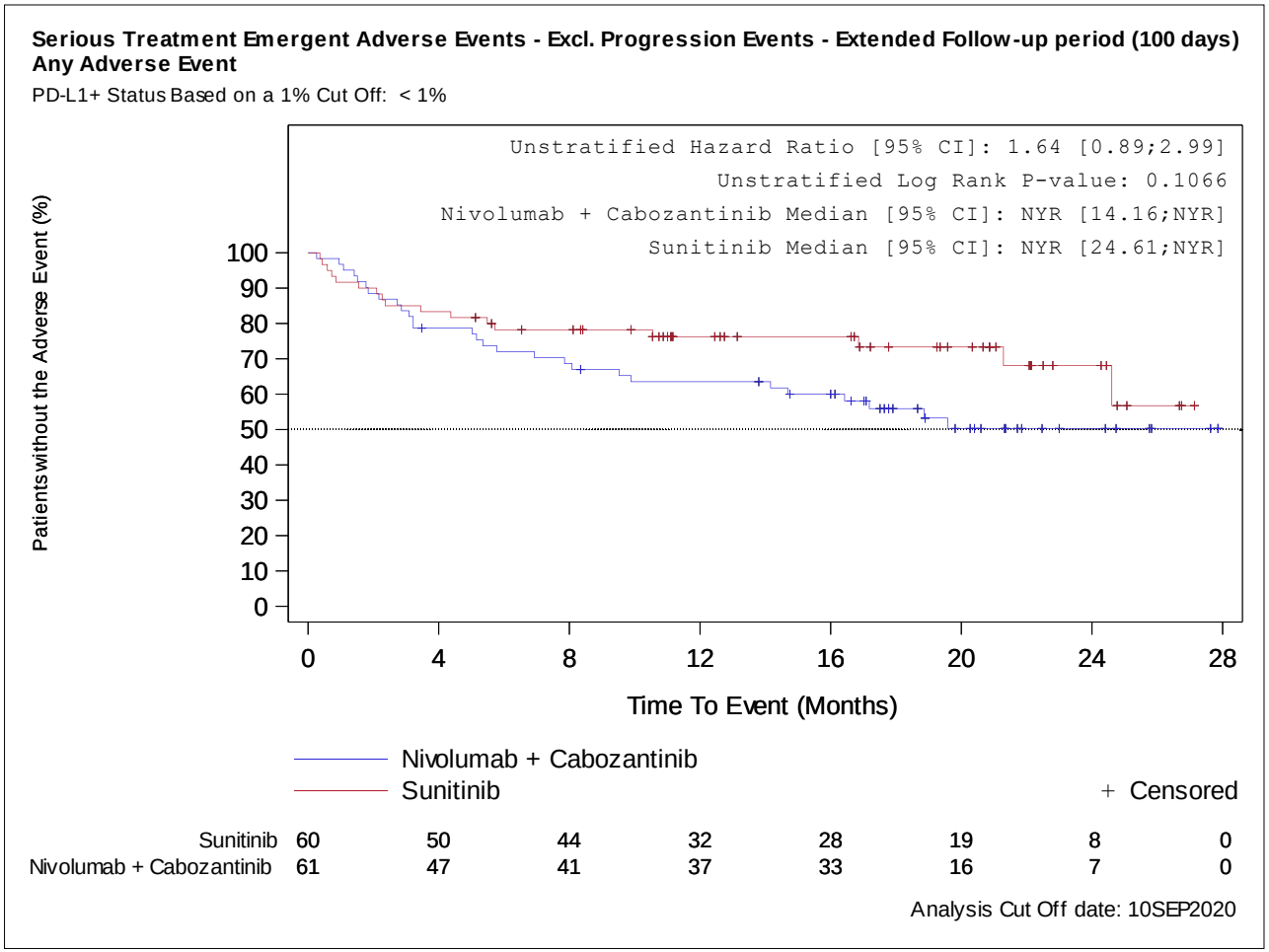

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:46:05

FIGURE 3.14.2.21: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:46:11

FIGURE 3.14.2.22: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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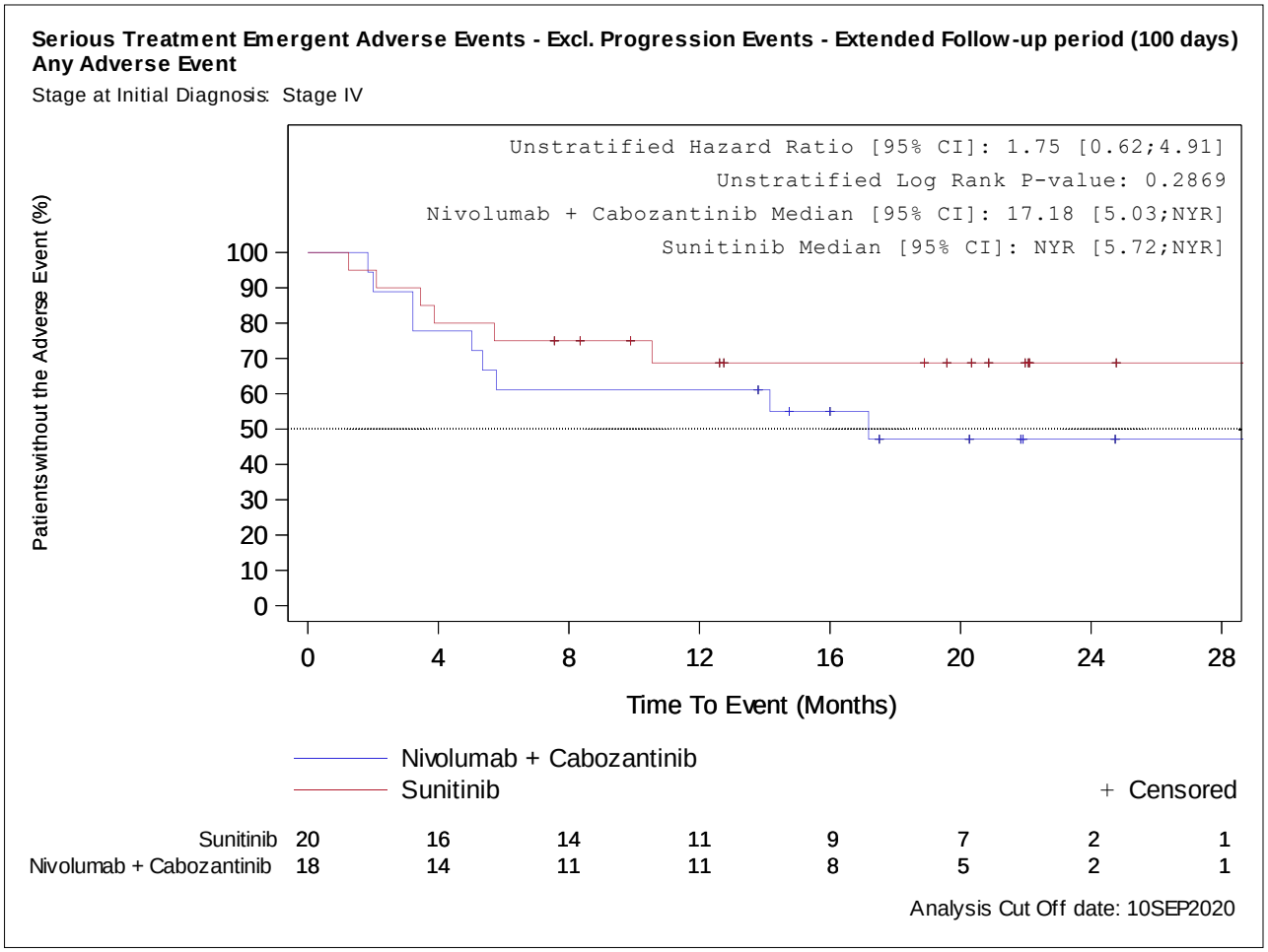
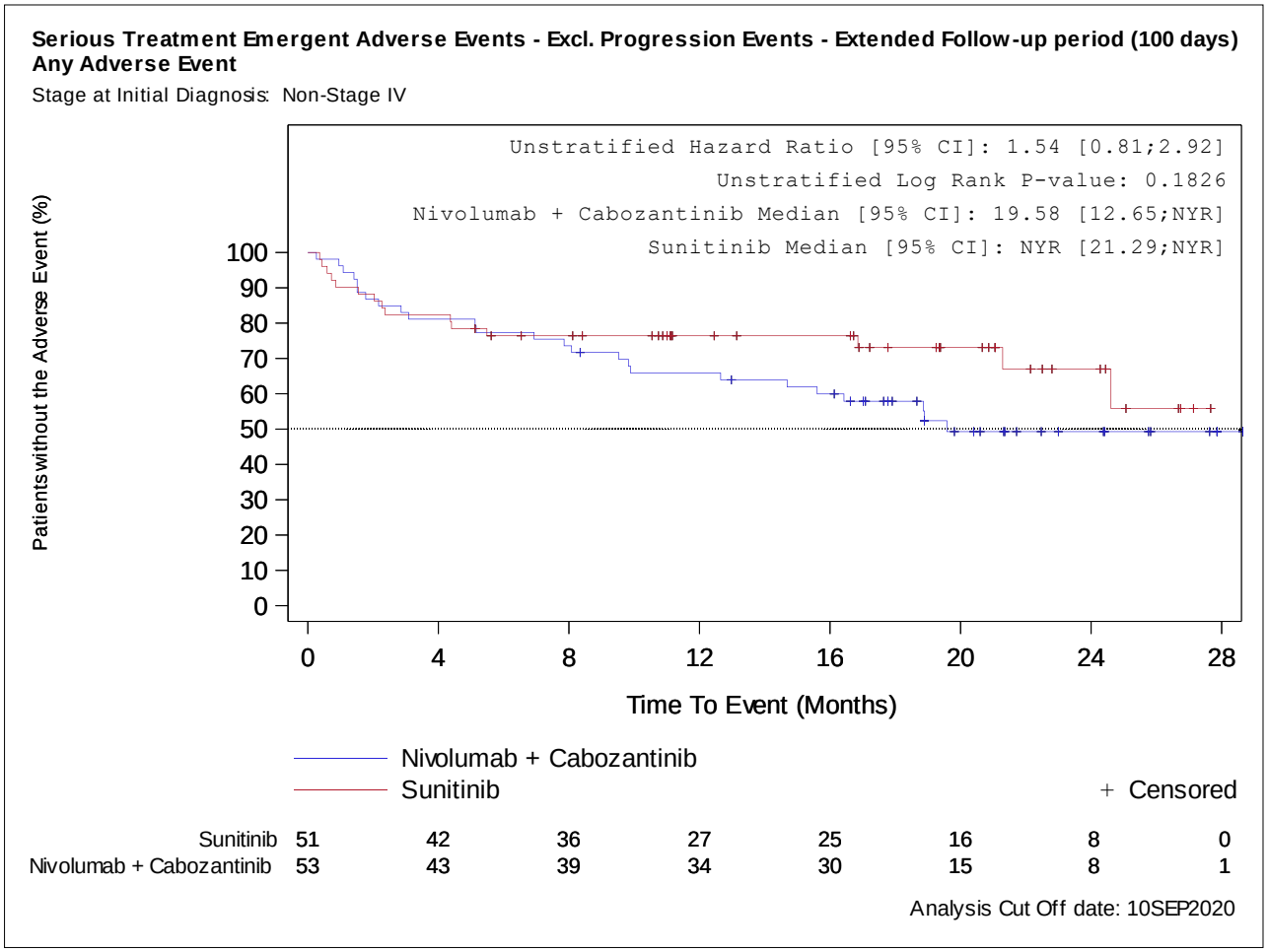
FIGURE 3.14.2.23: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:46:51

FIGURE 3.14.2.24: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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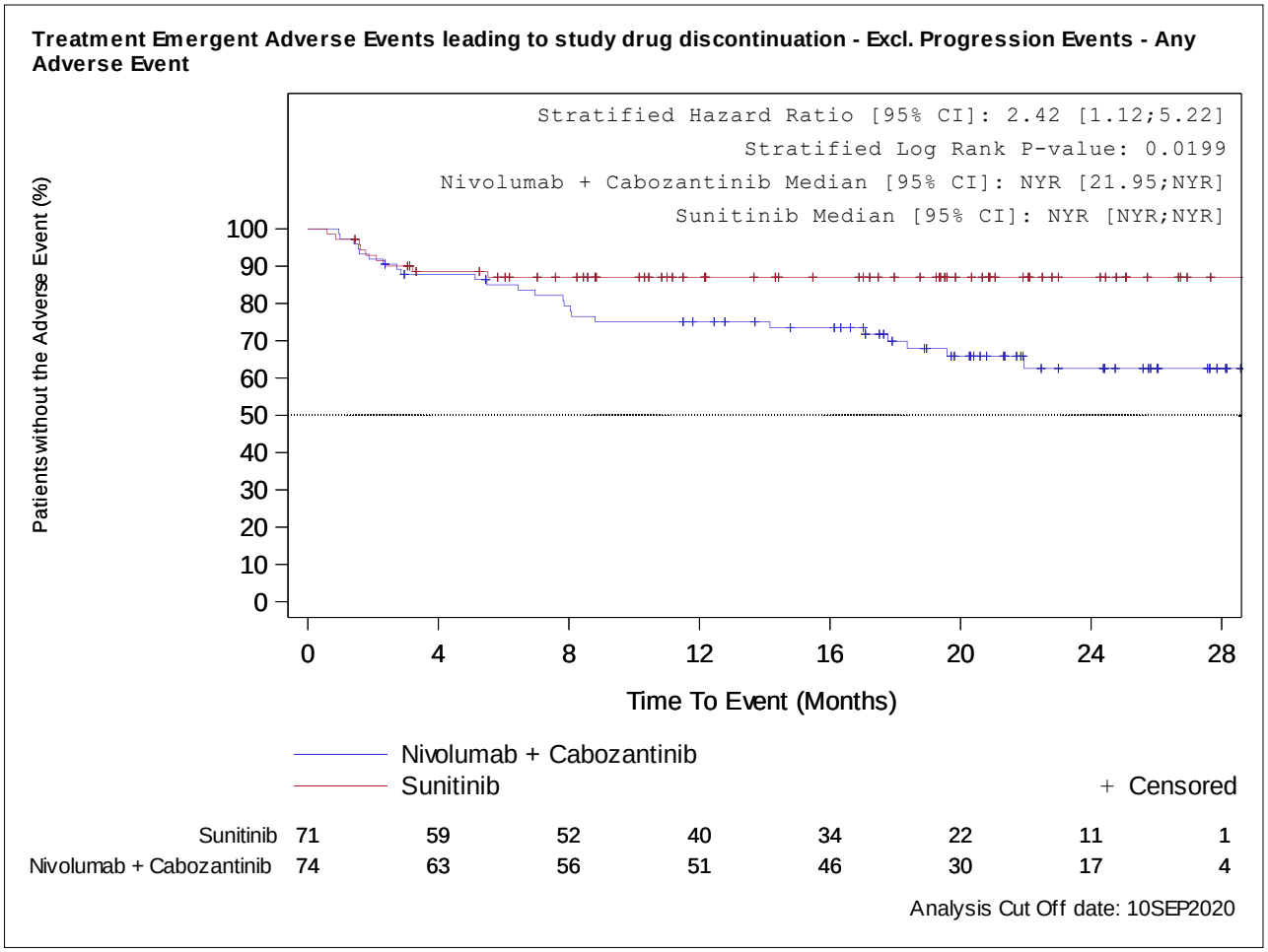
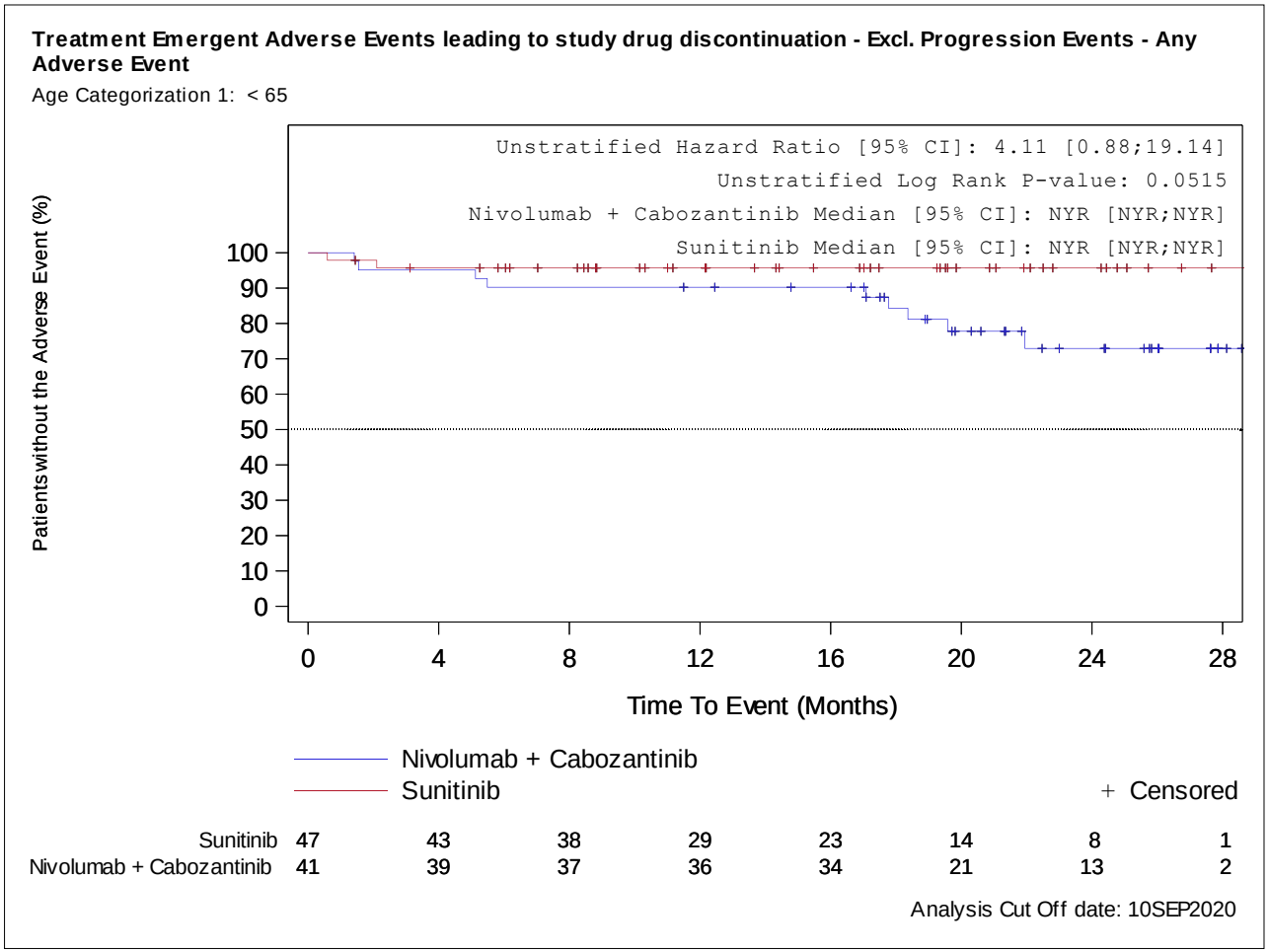
FIGURE 3.15.1: Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



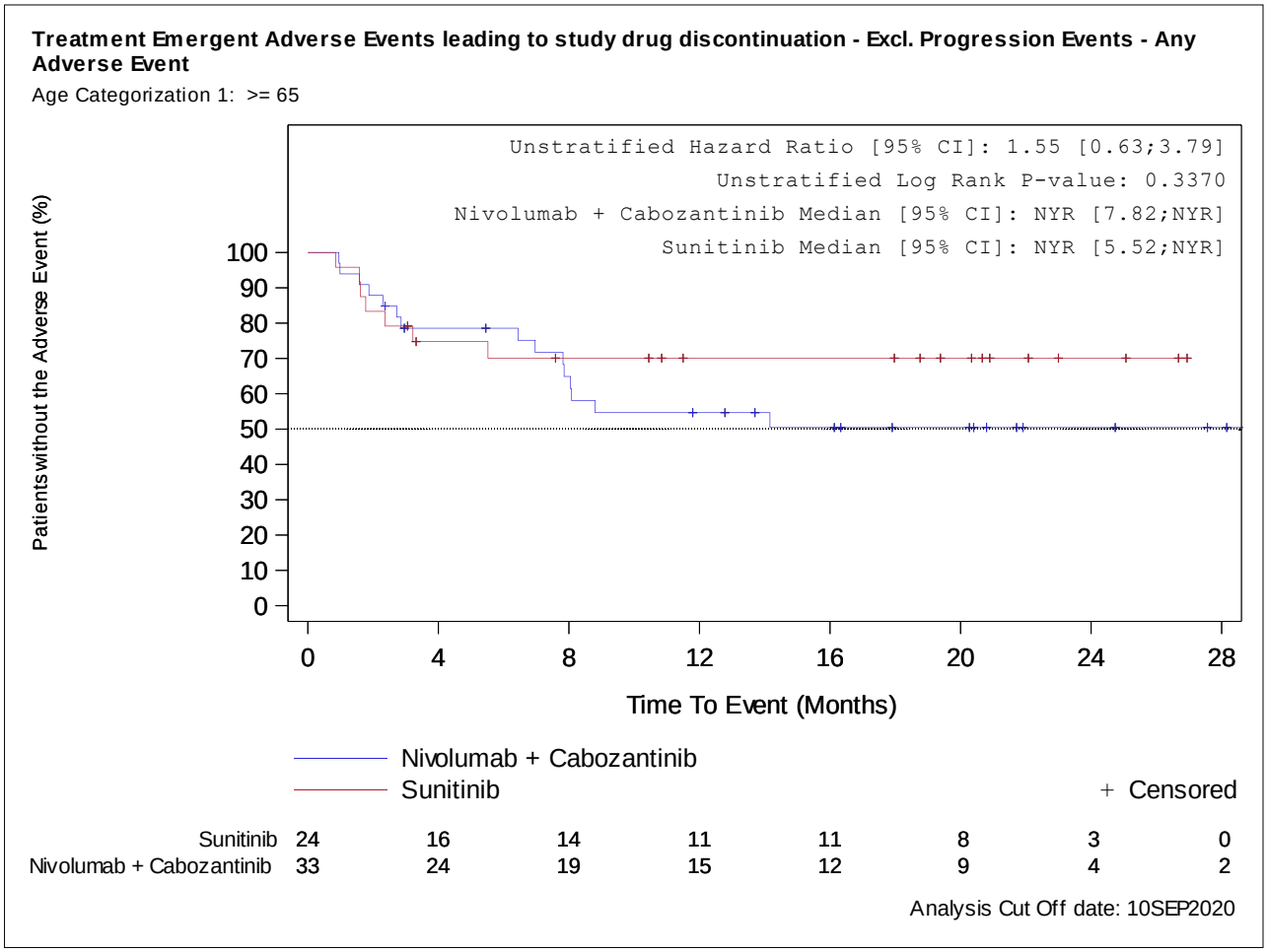

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:50:28

FIGURE 3.15.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



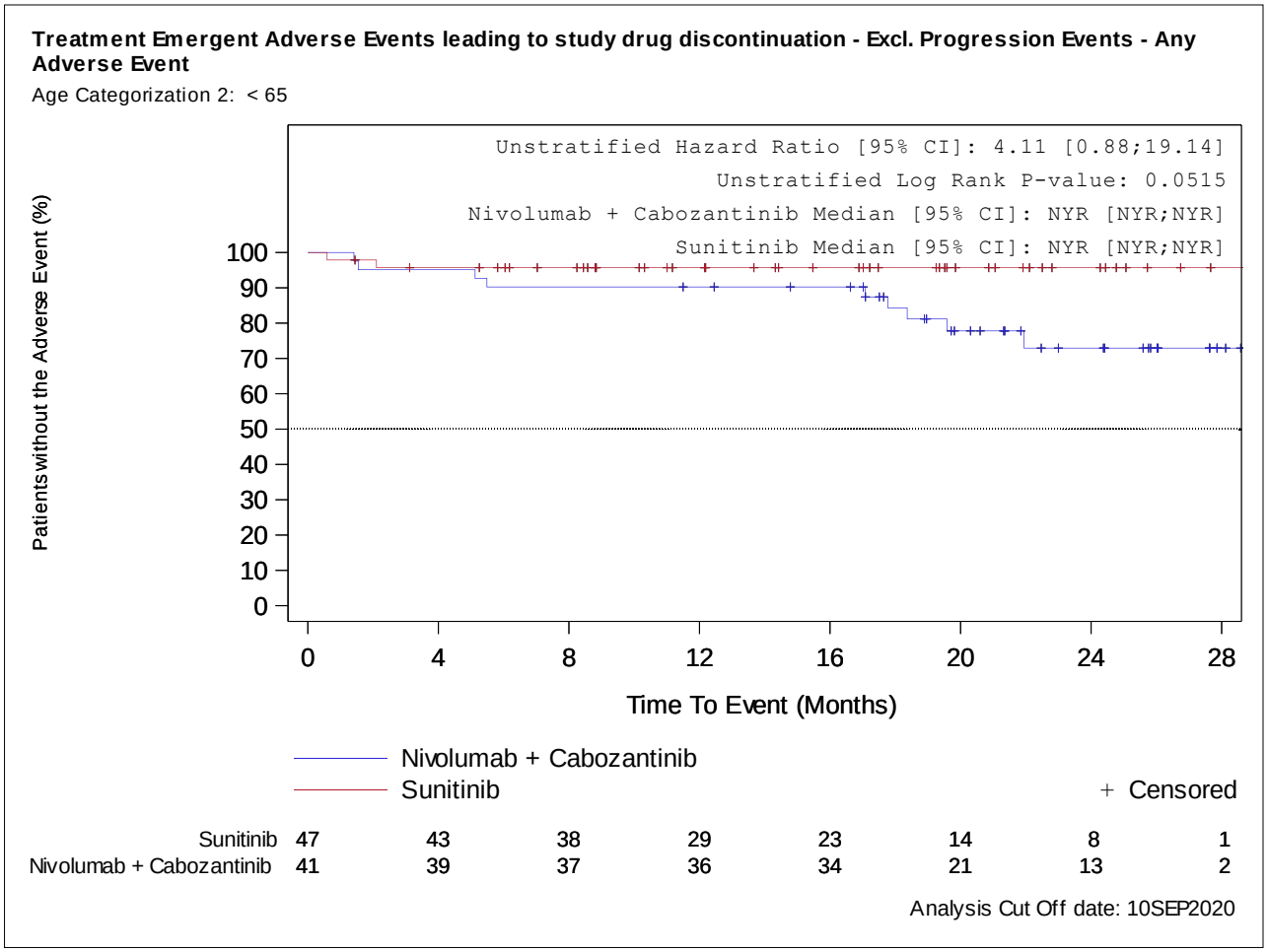

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:50:31

FIGURE 3.15.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



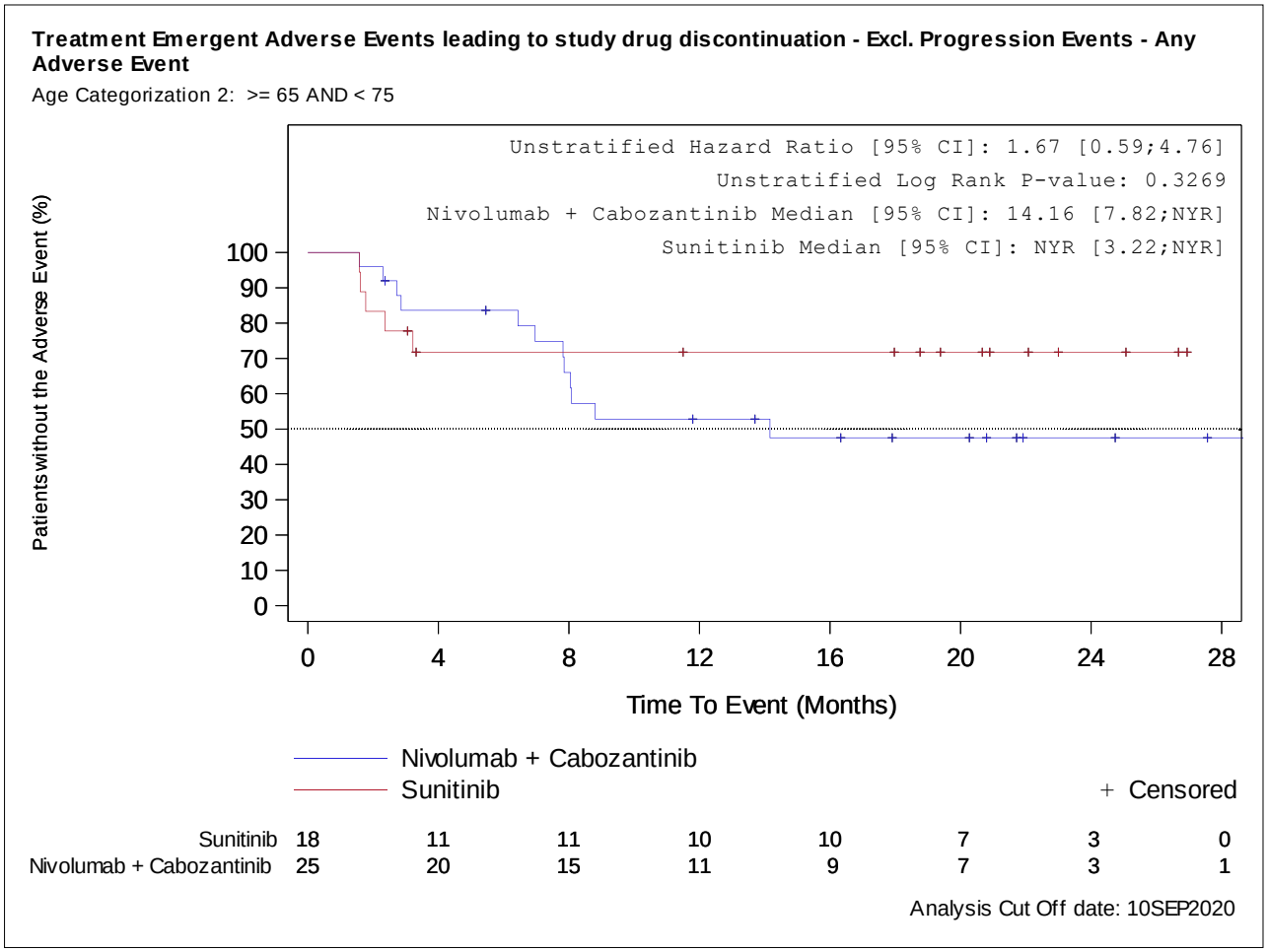

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:50:37

FIGURE 3.15.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



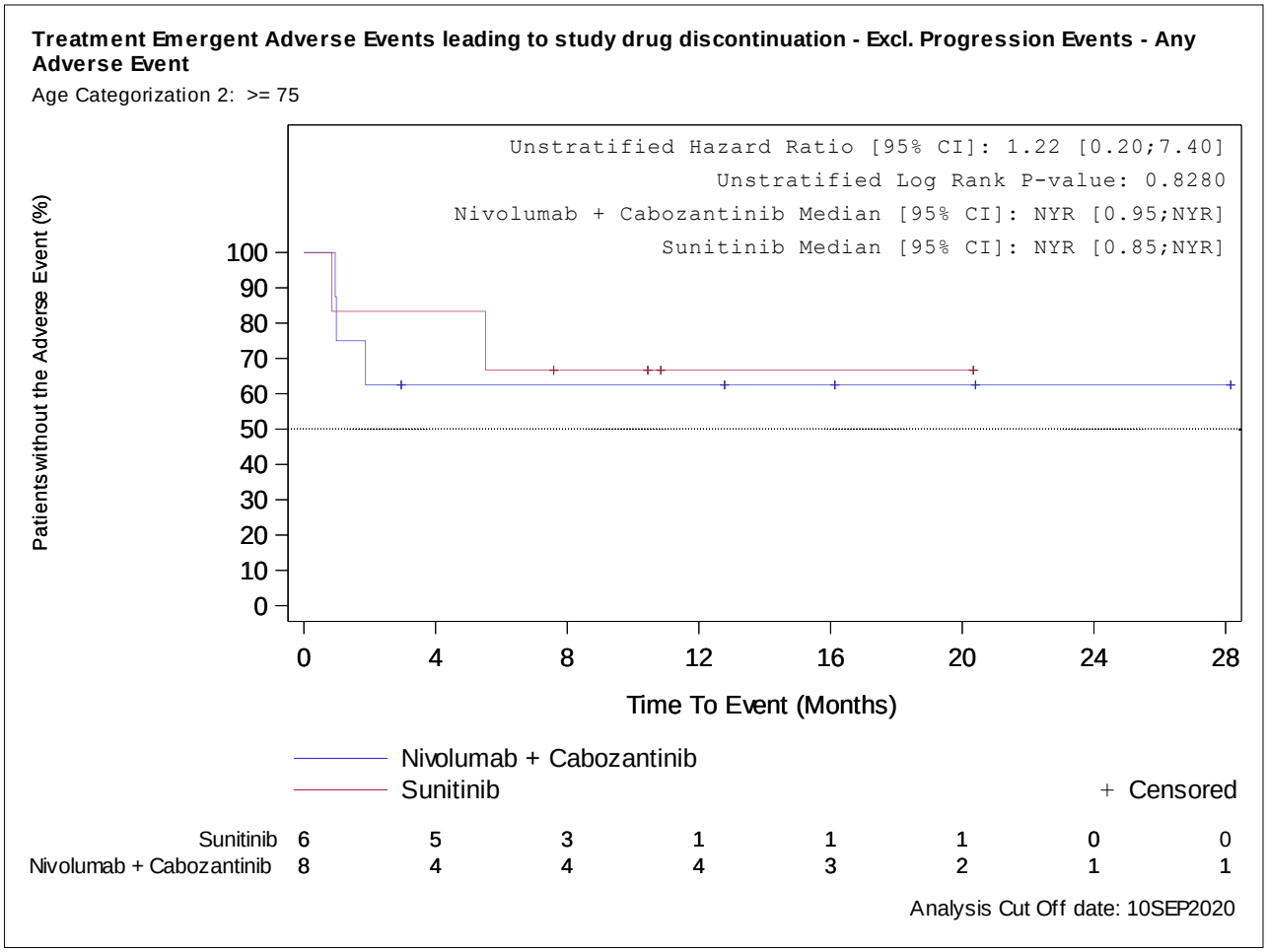

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:50:43

FIGURE 3.15.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



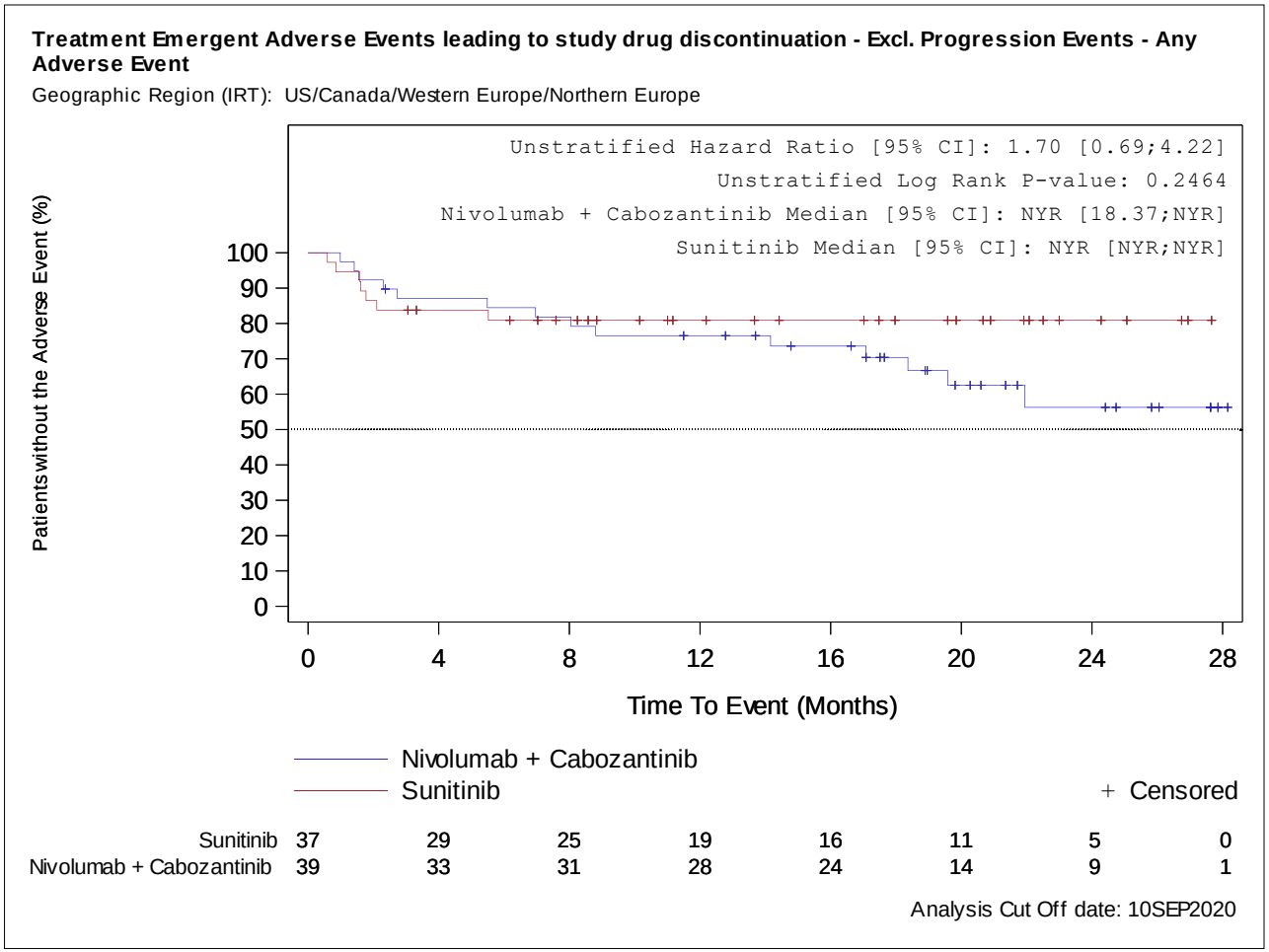

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:50:50

FIGURE 3.15.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



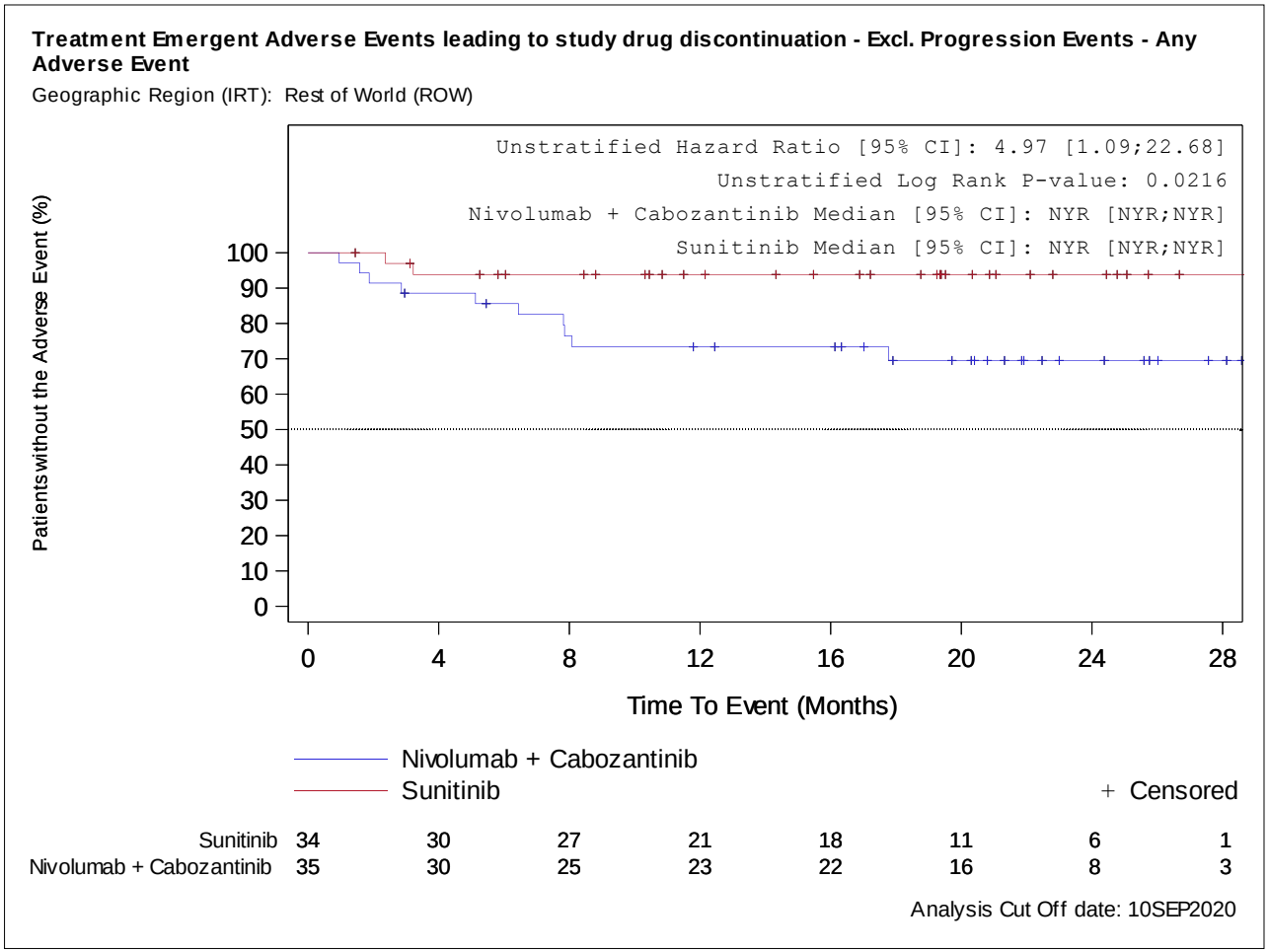

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:50:55

FIGURE 3.15.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



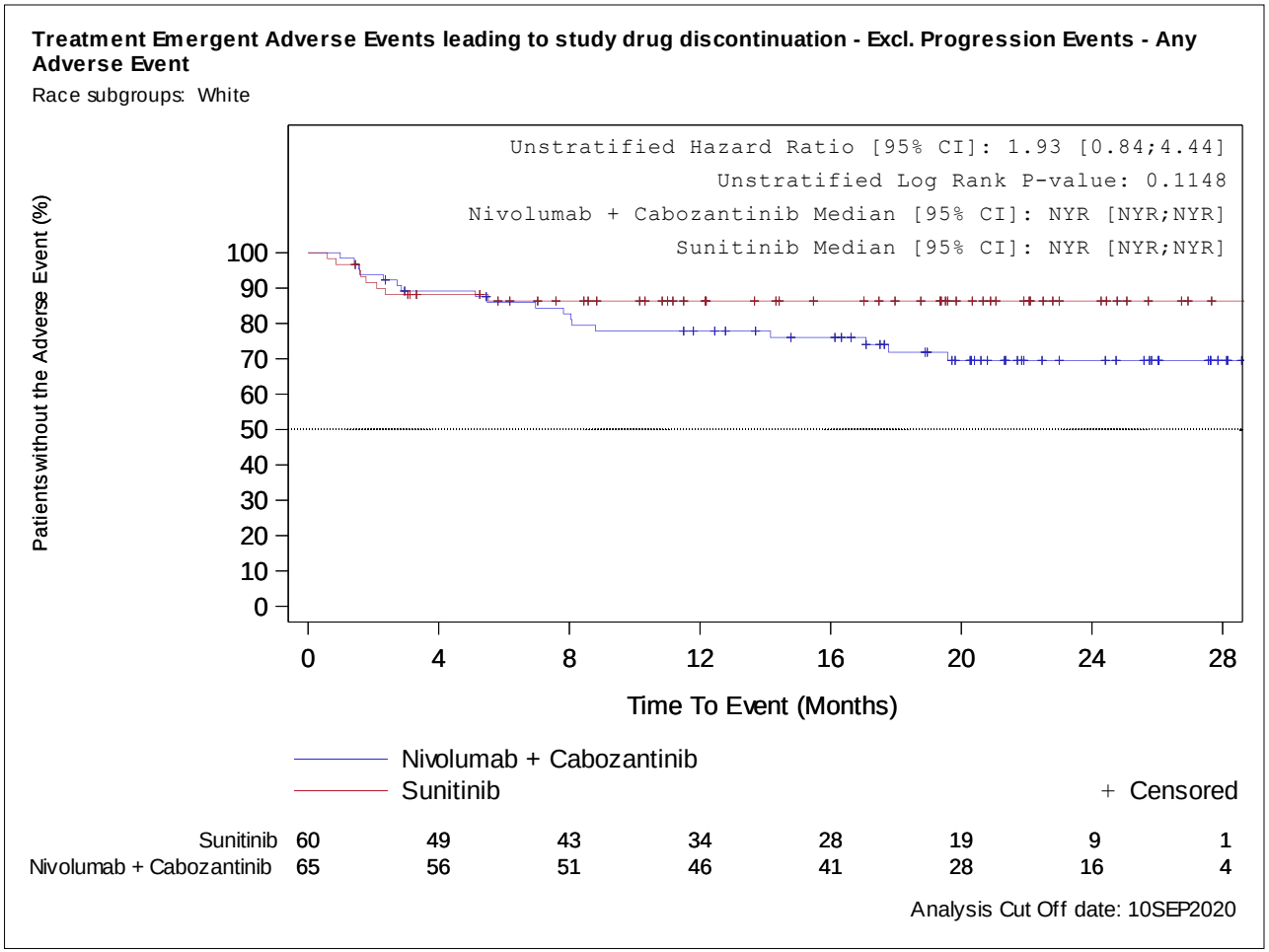

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:51:02

FIGURE 3.15.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



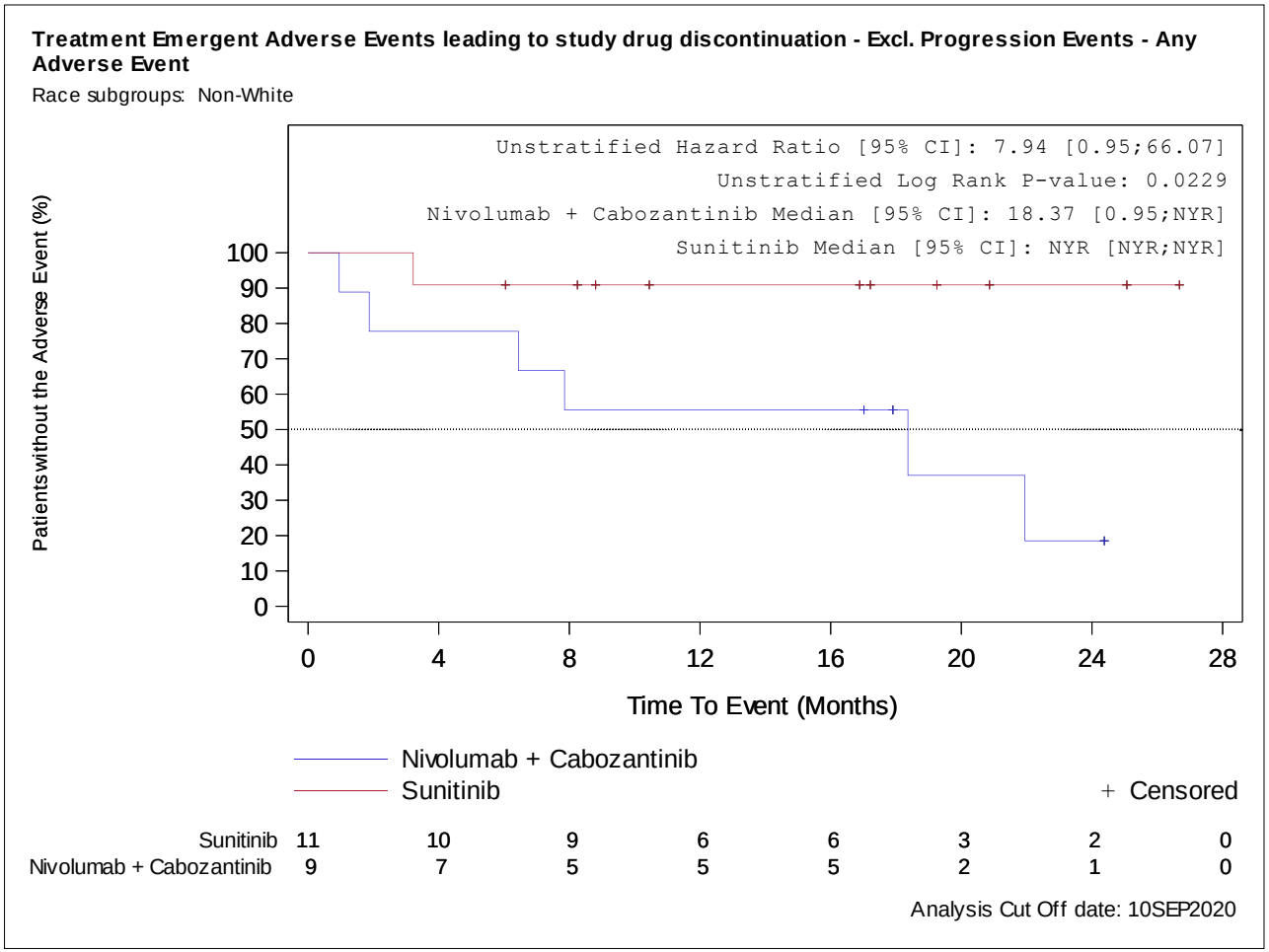

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:51:08

FIGURE 3.15.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



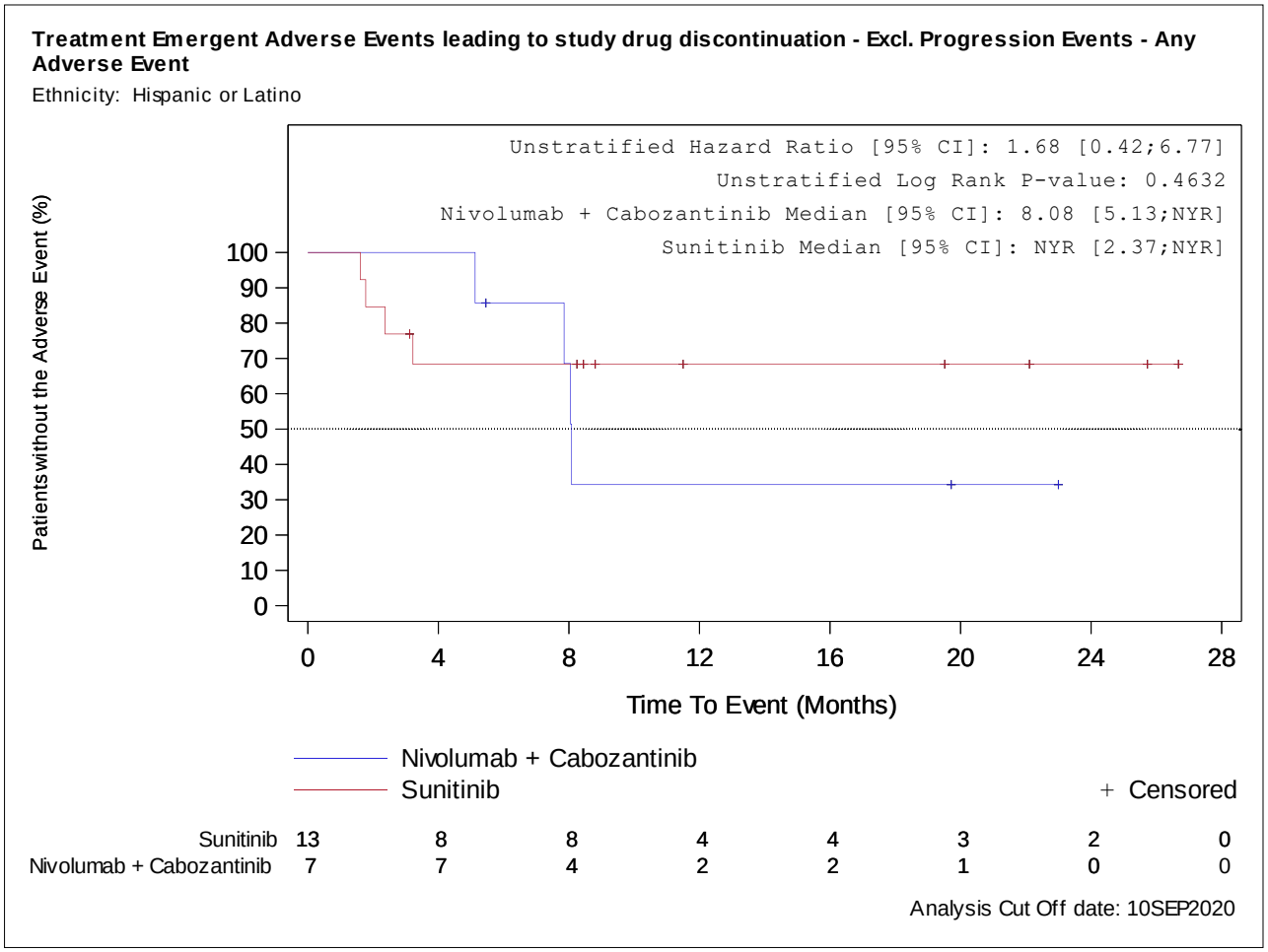

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:51:14

FIGURE 3.15.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



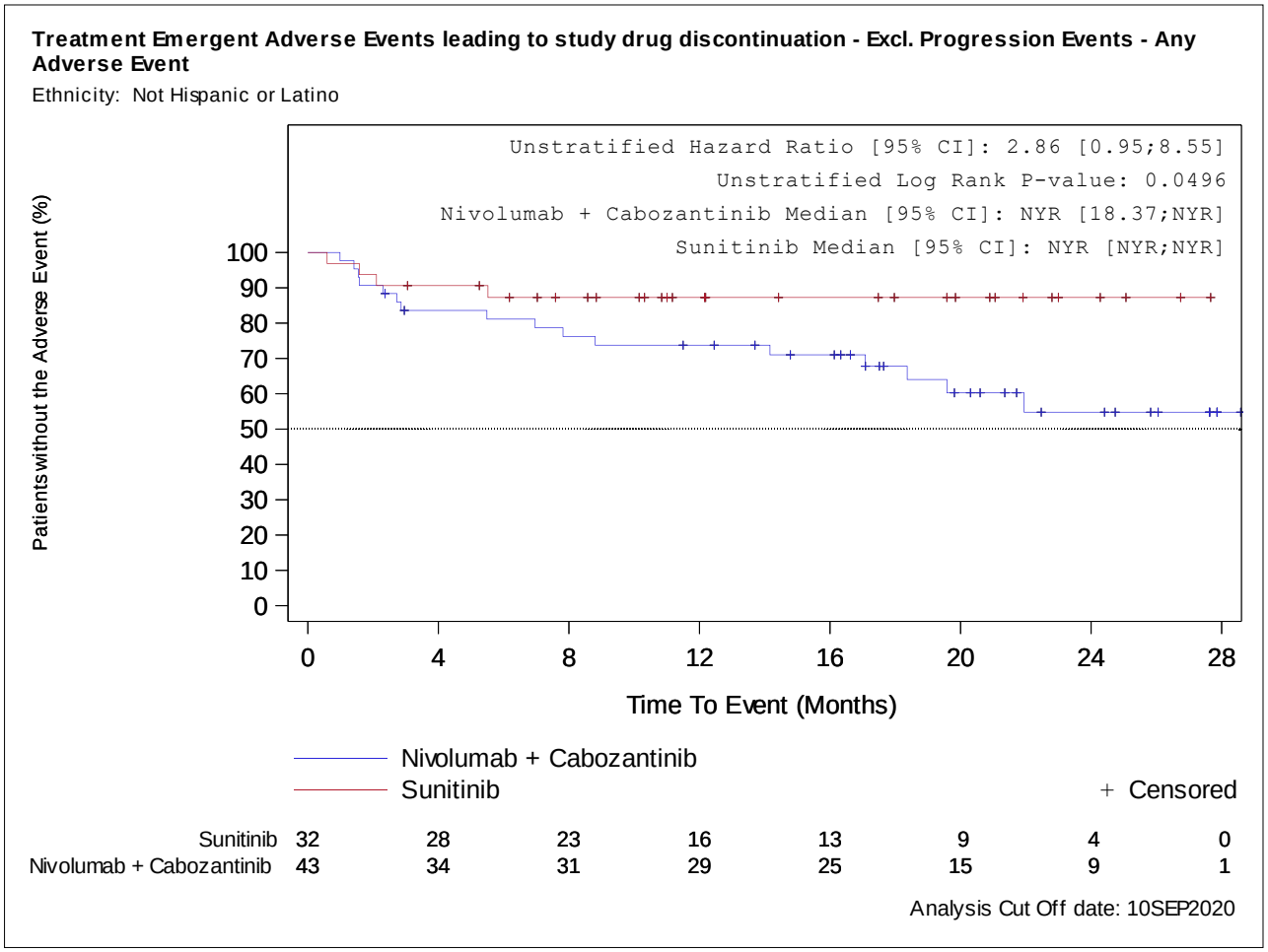

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:51:20

FIGURE 3.15.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



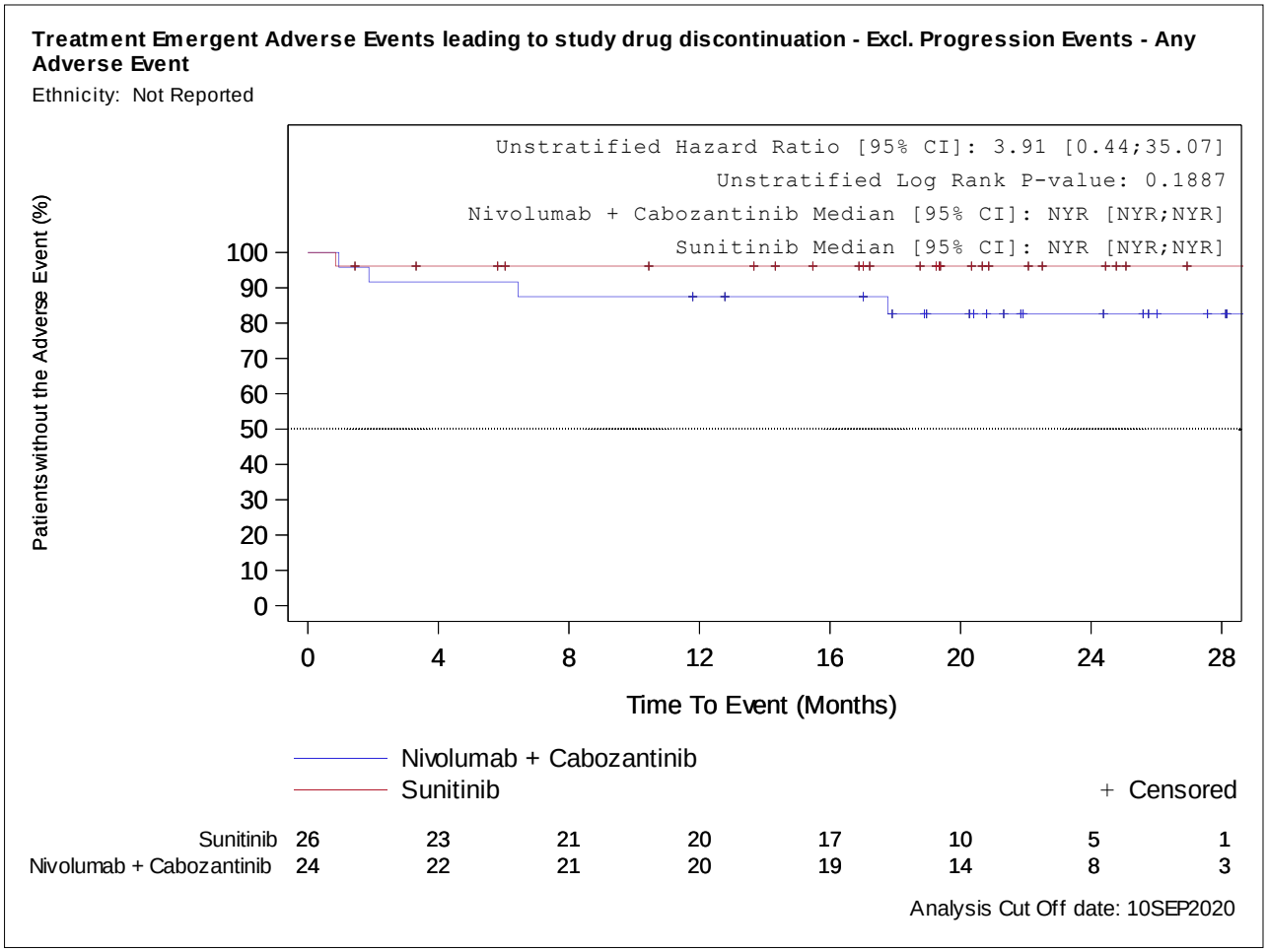

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:51:26

FIGURE 3.15.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



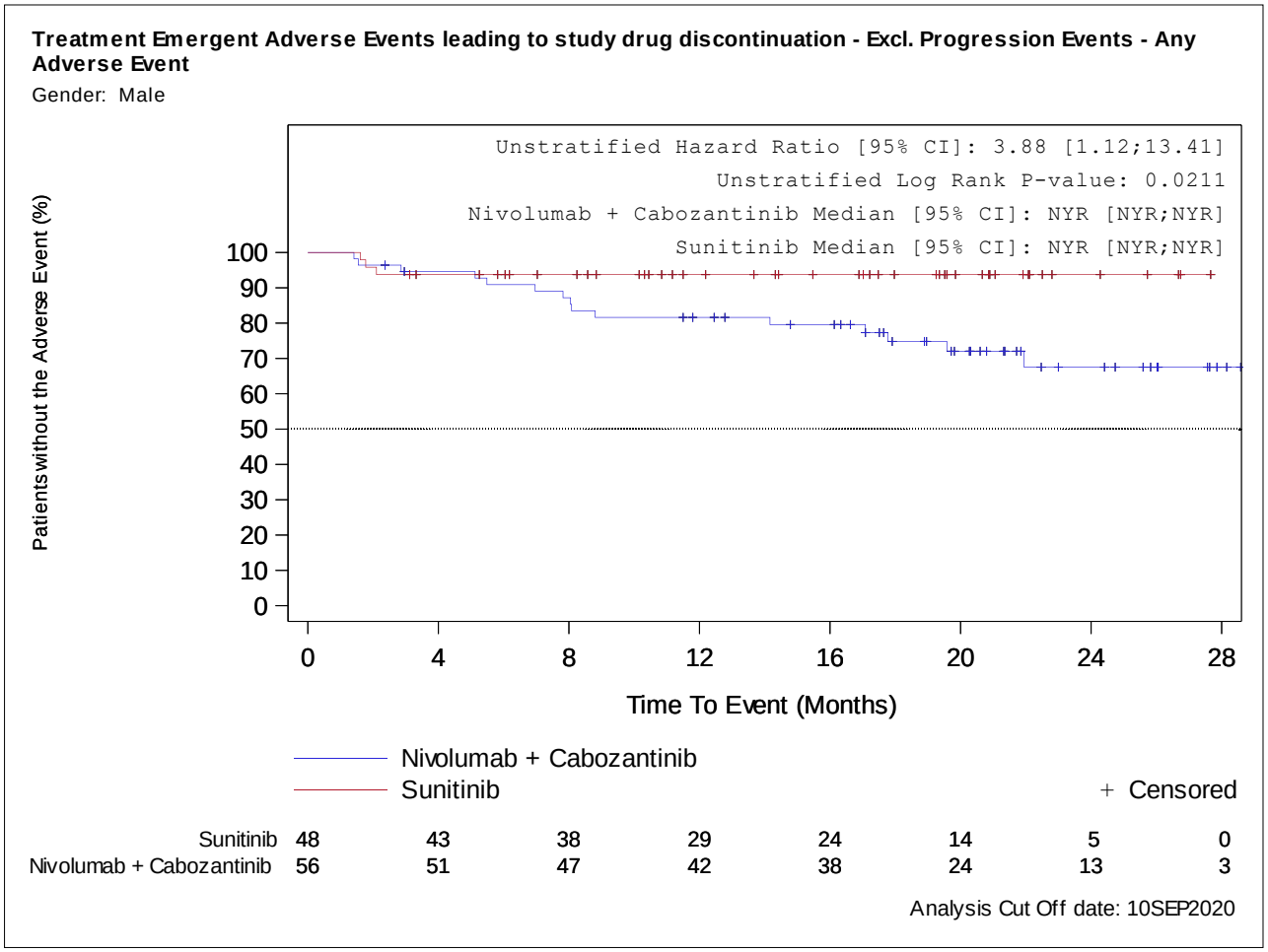

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:51:32

FIGURE 3.15.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



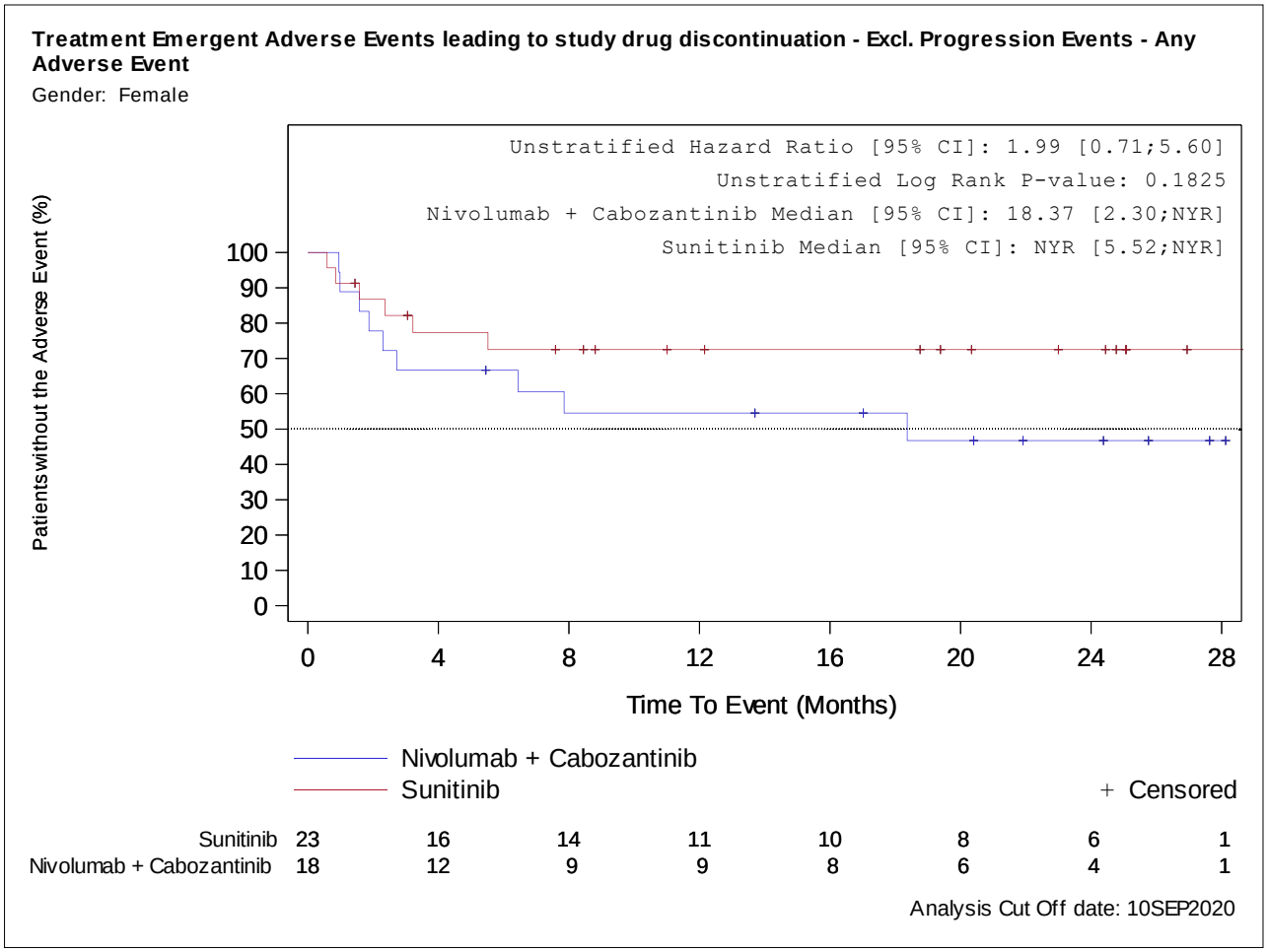

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:51:38

FIGURE 3.15.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



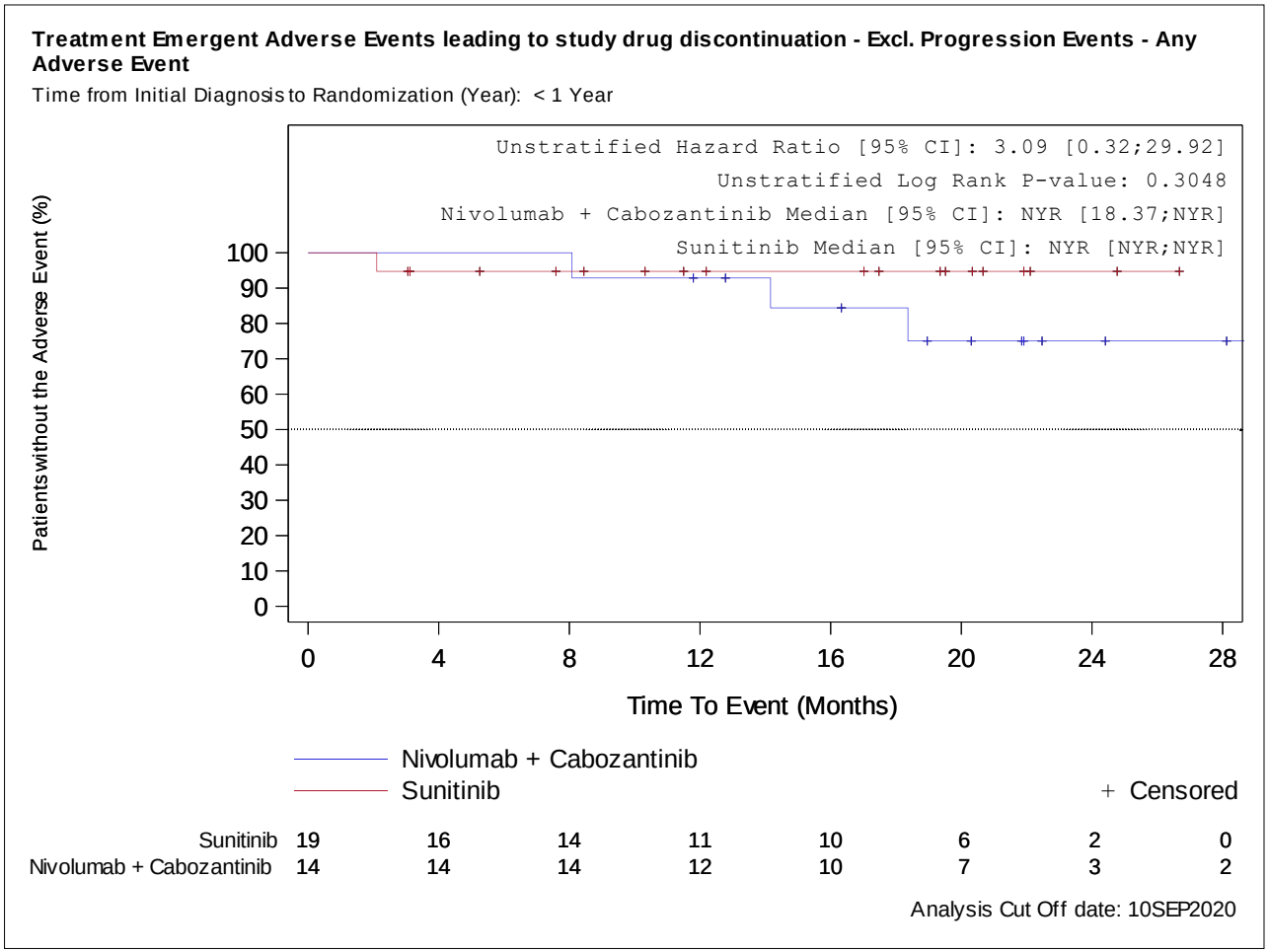

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:51:44

FIGURE 3.15.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



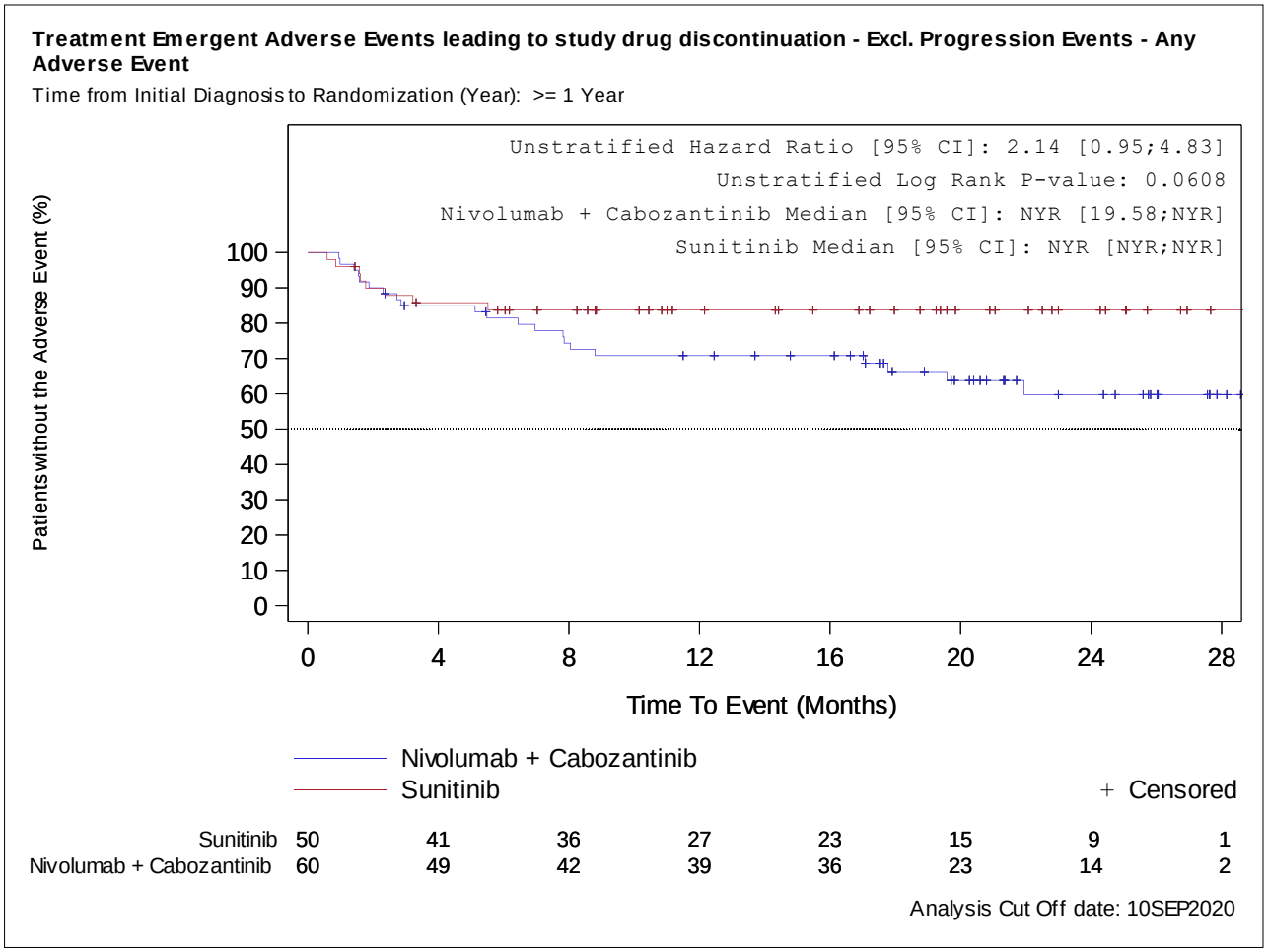

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:51:50

FIGURE 3.15.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



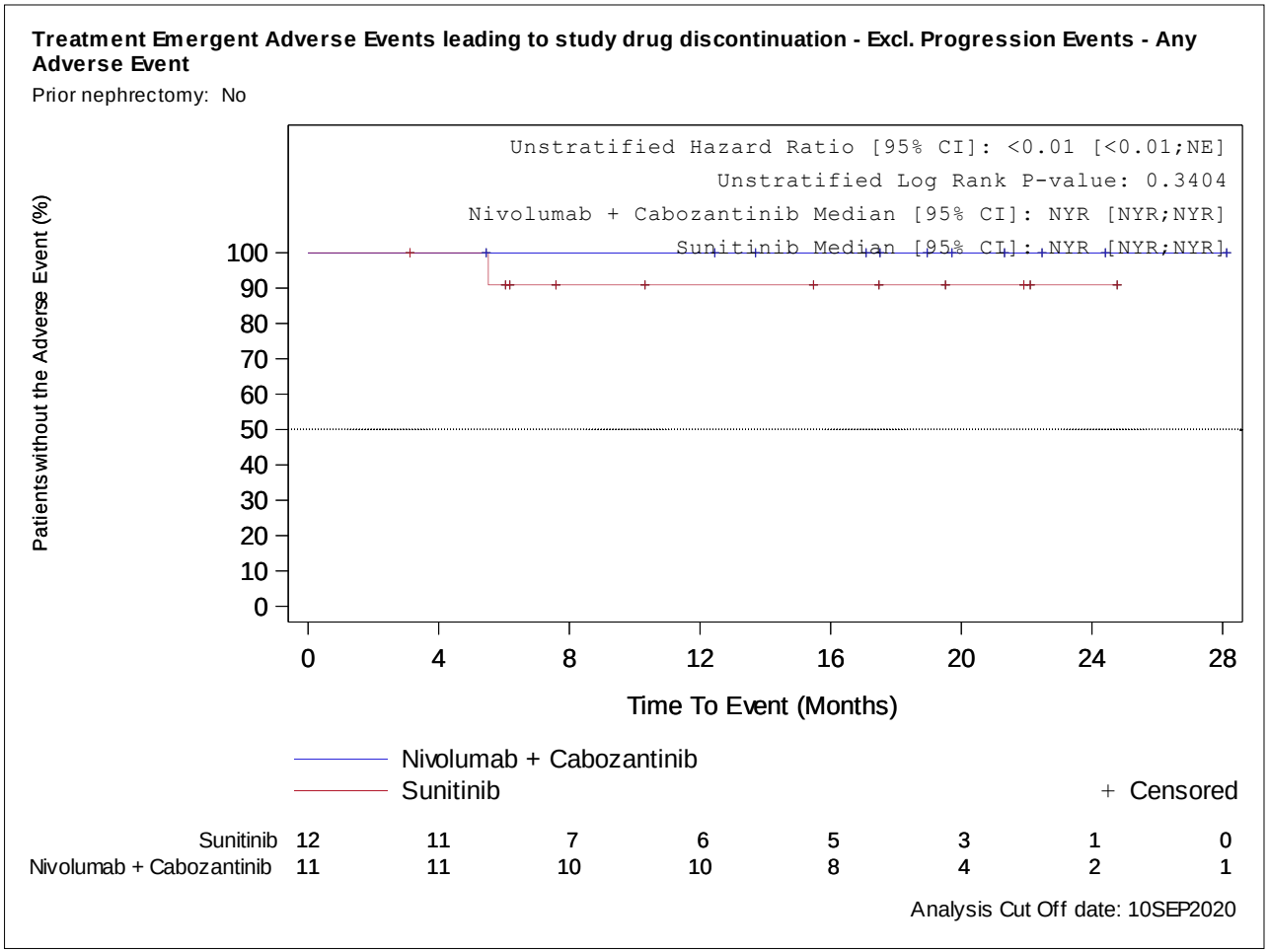

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:52:09

FIGURE 3.15.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



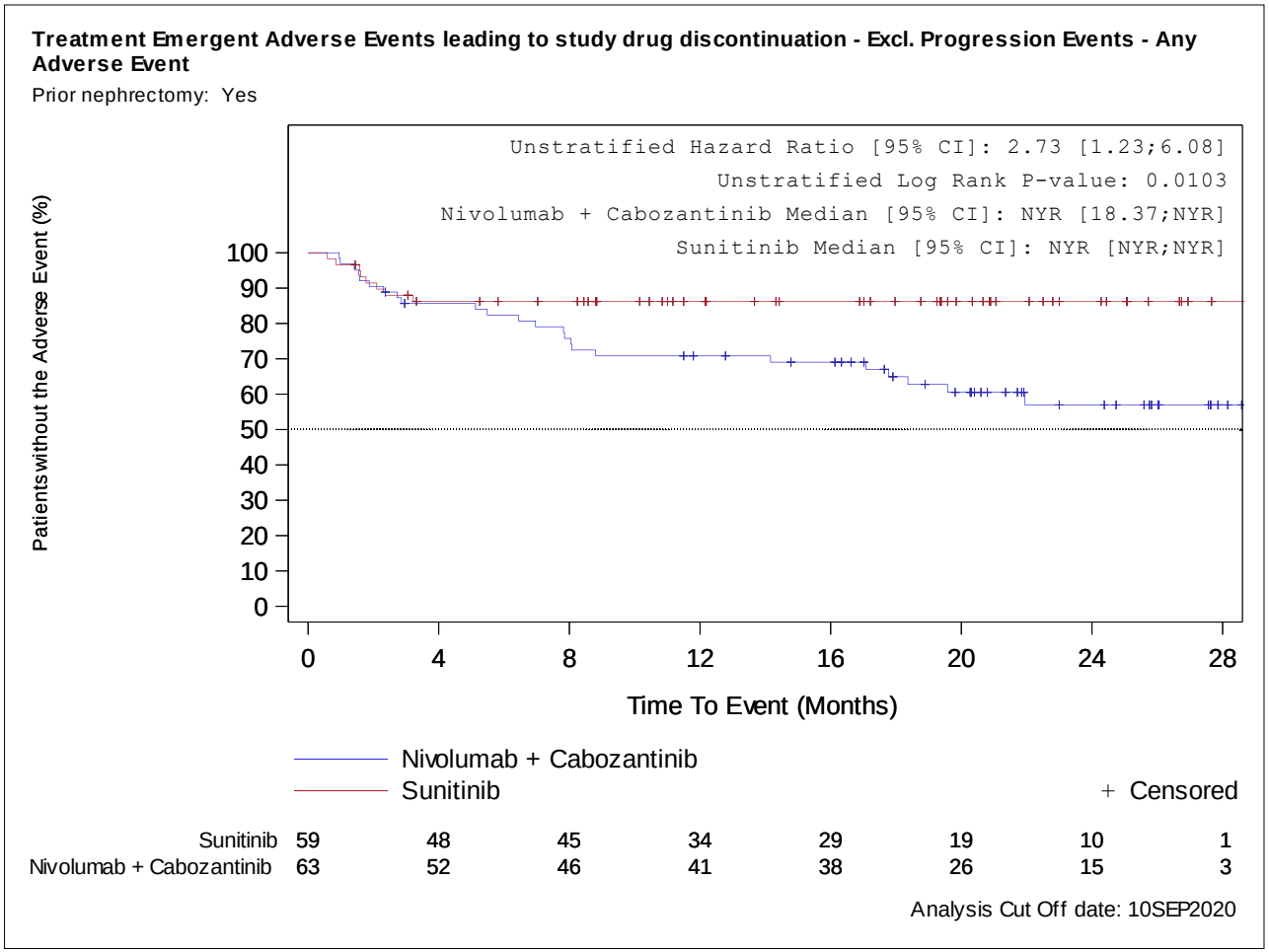

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:52:15

FIGURE 3.15.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



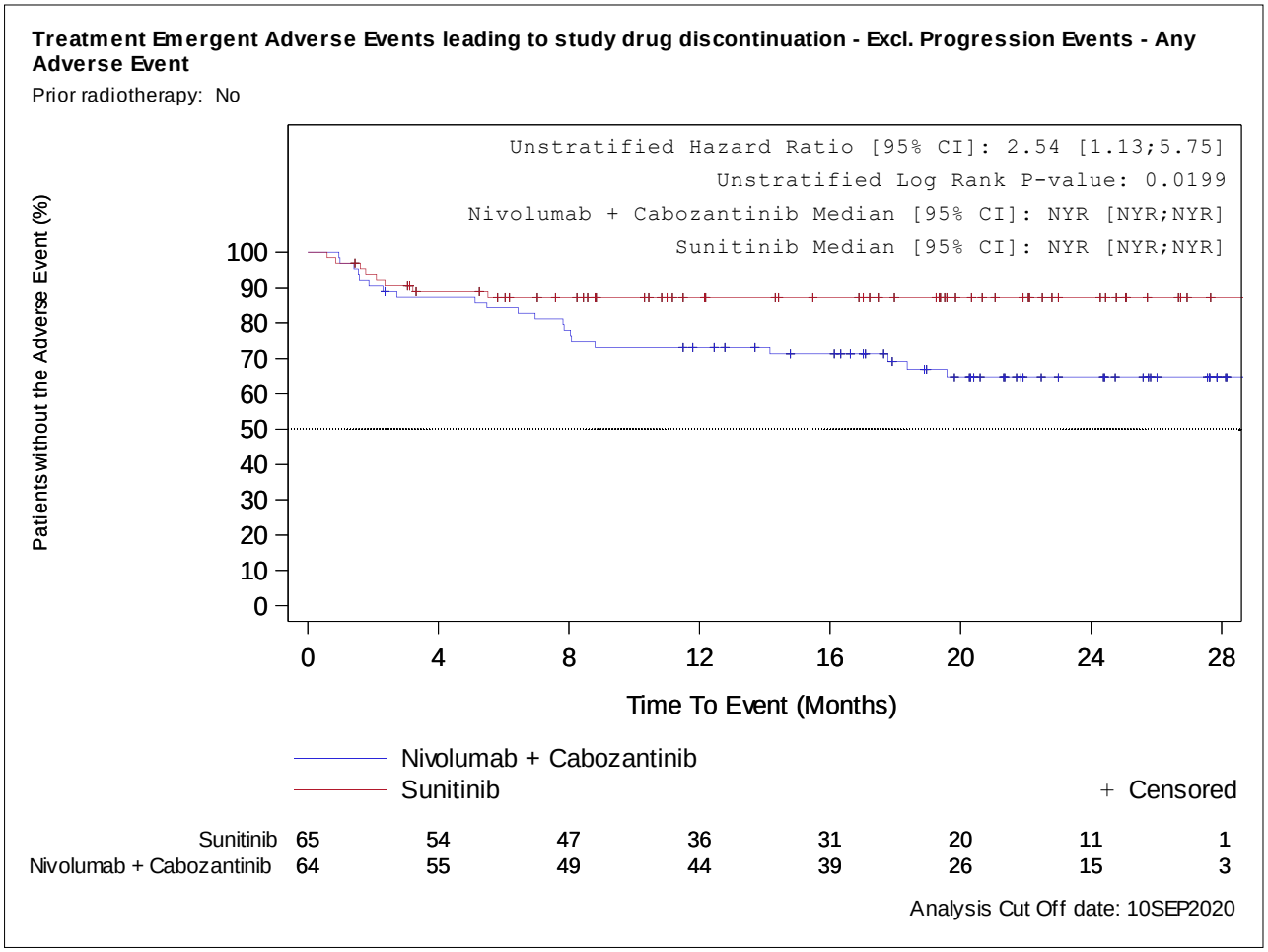

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:53:10

FIGURE 3.15.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



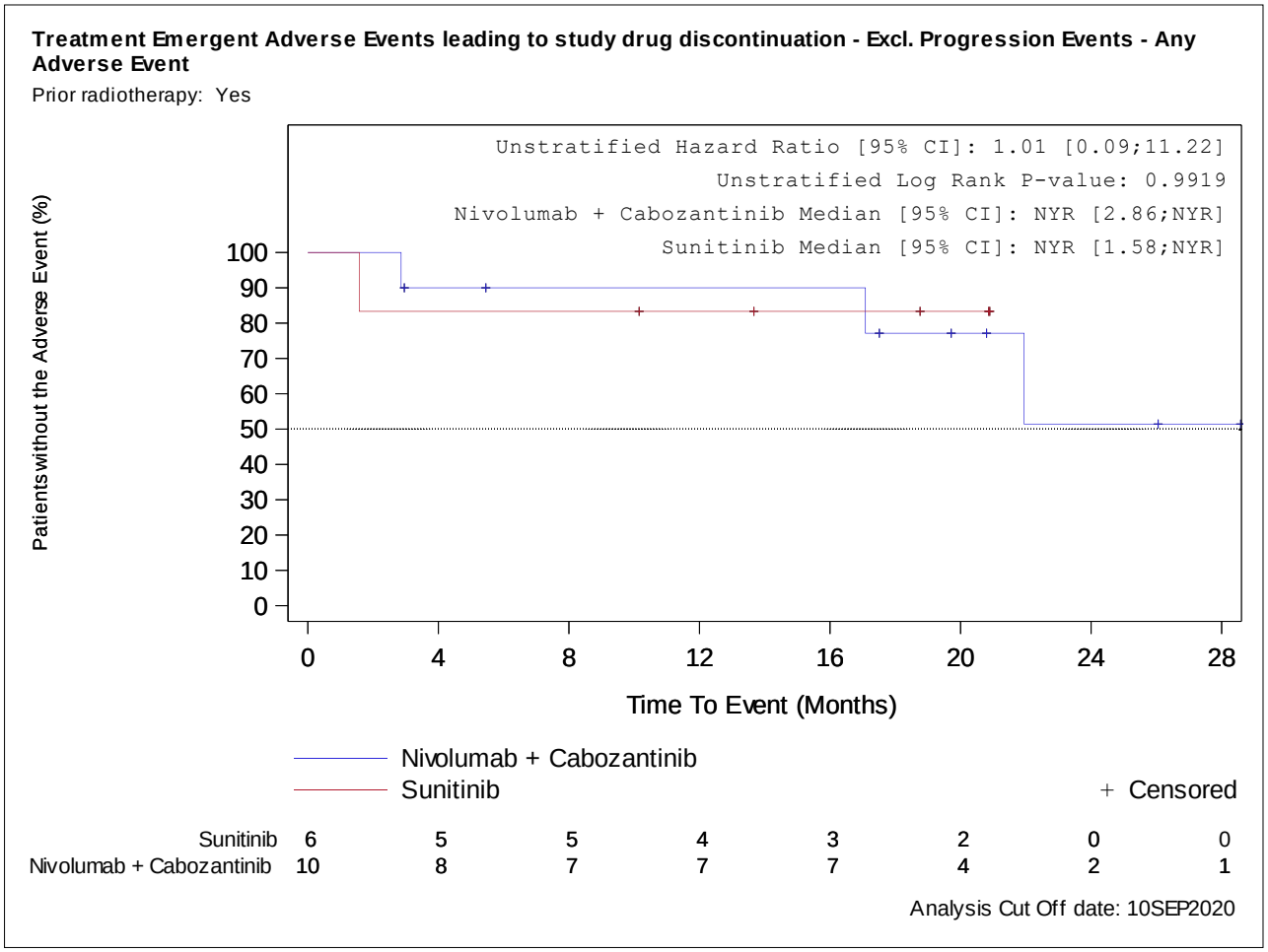

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:53:16

FIGURE 3.15.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:53:23

FIGURE 3.15.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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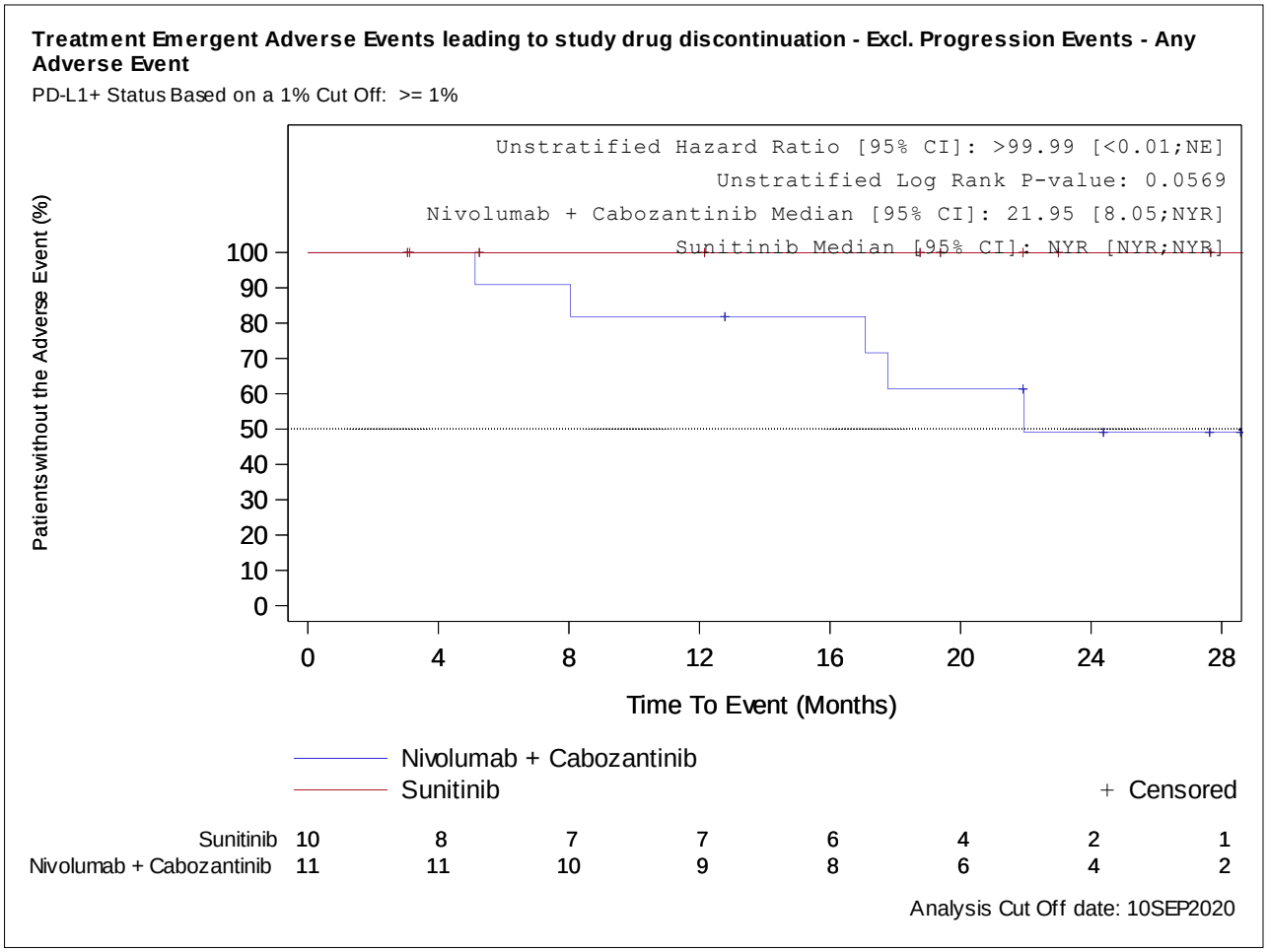
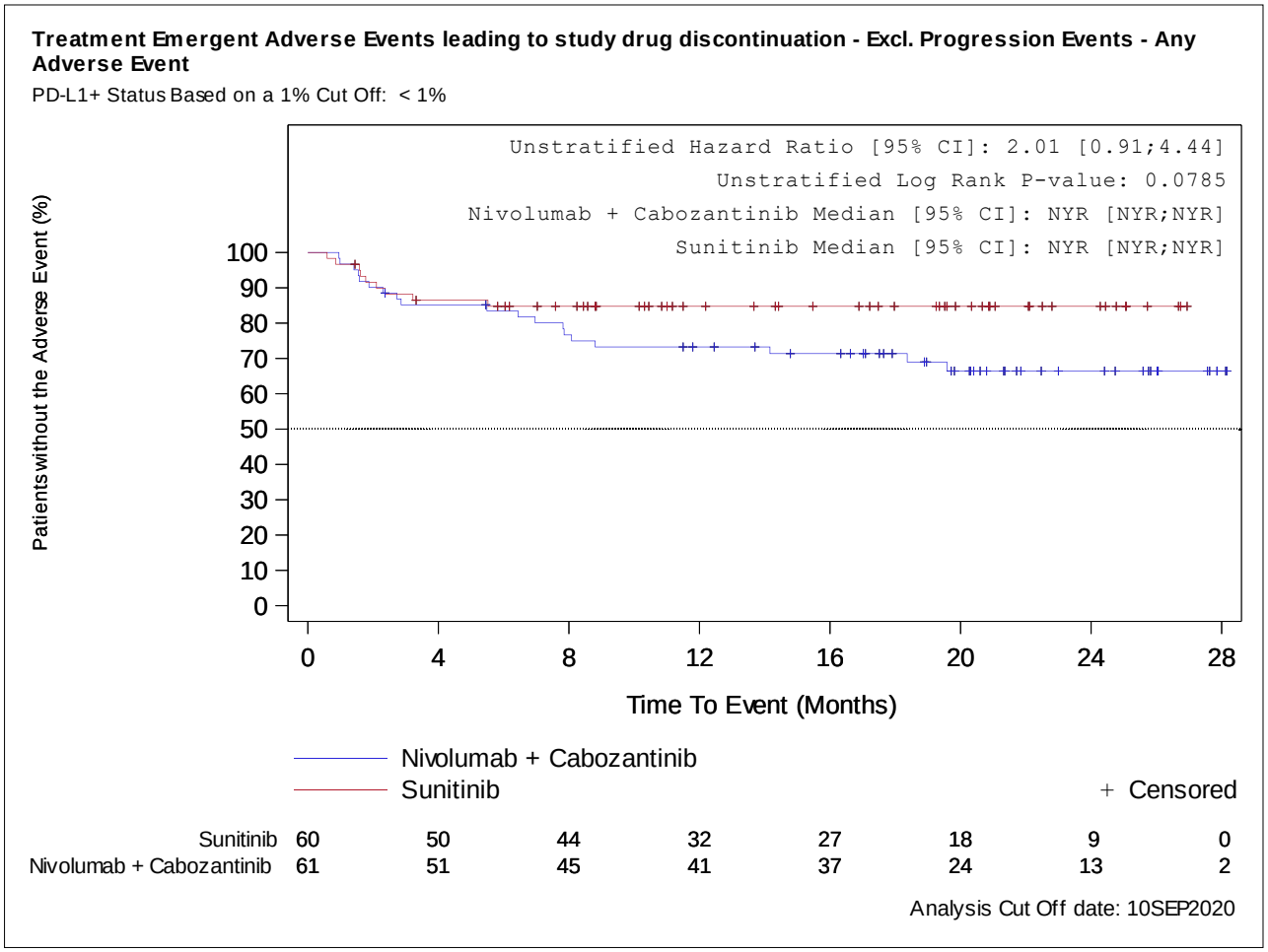
FIGURE 3.15.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



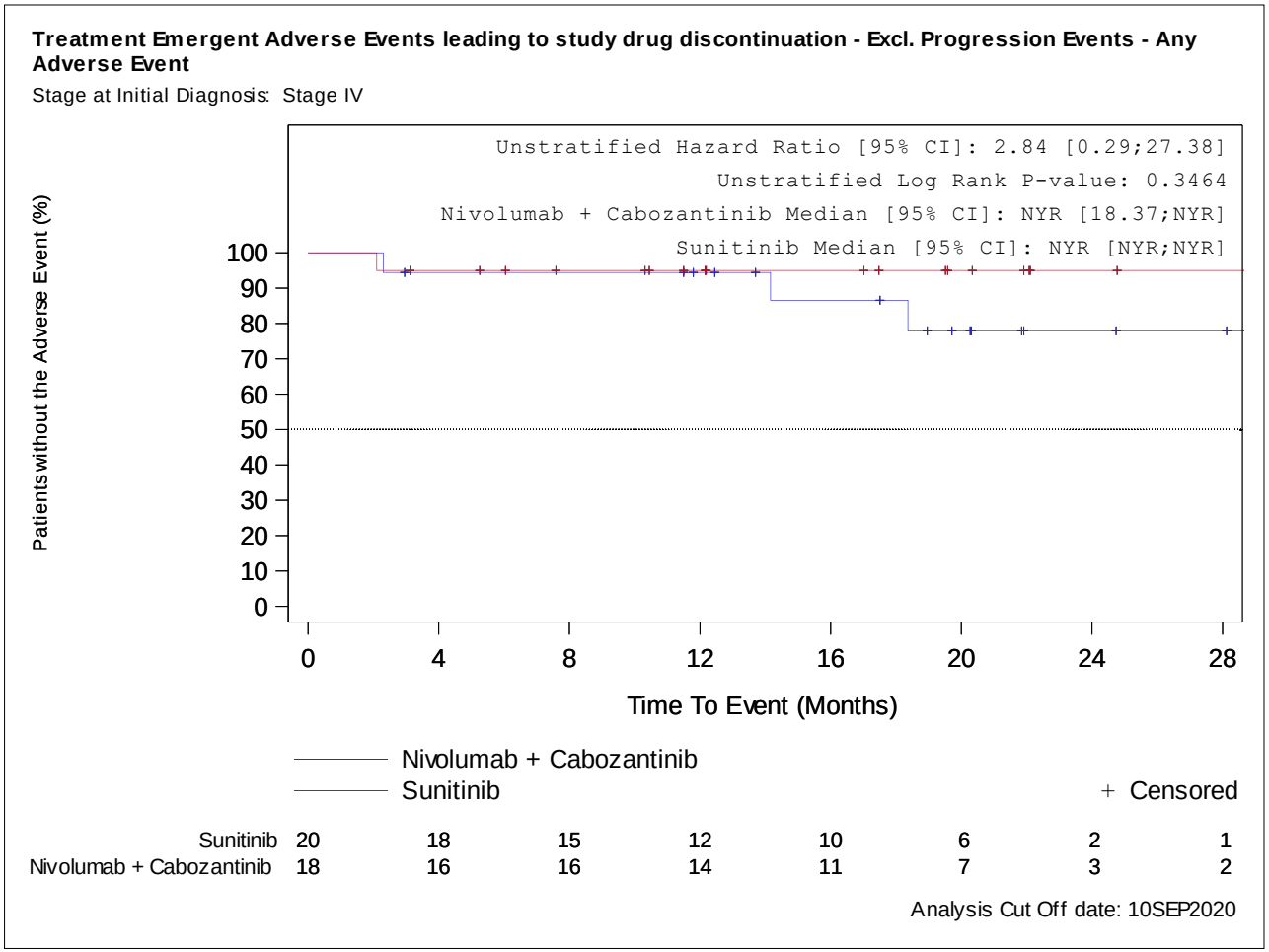

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:53:35

FIGURE 3.15.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



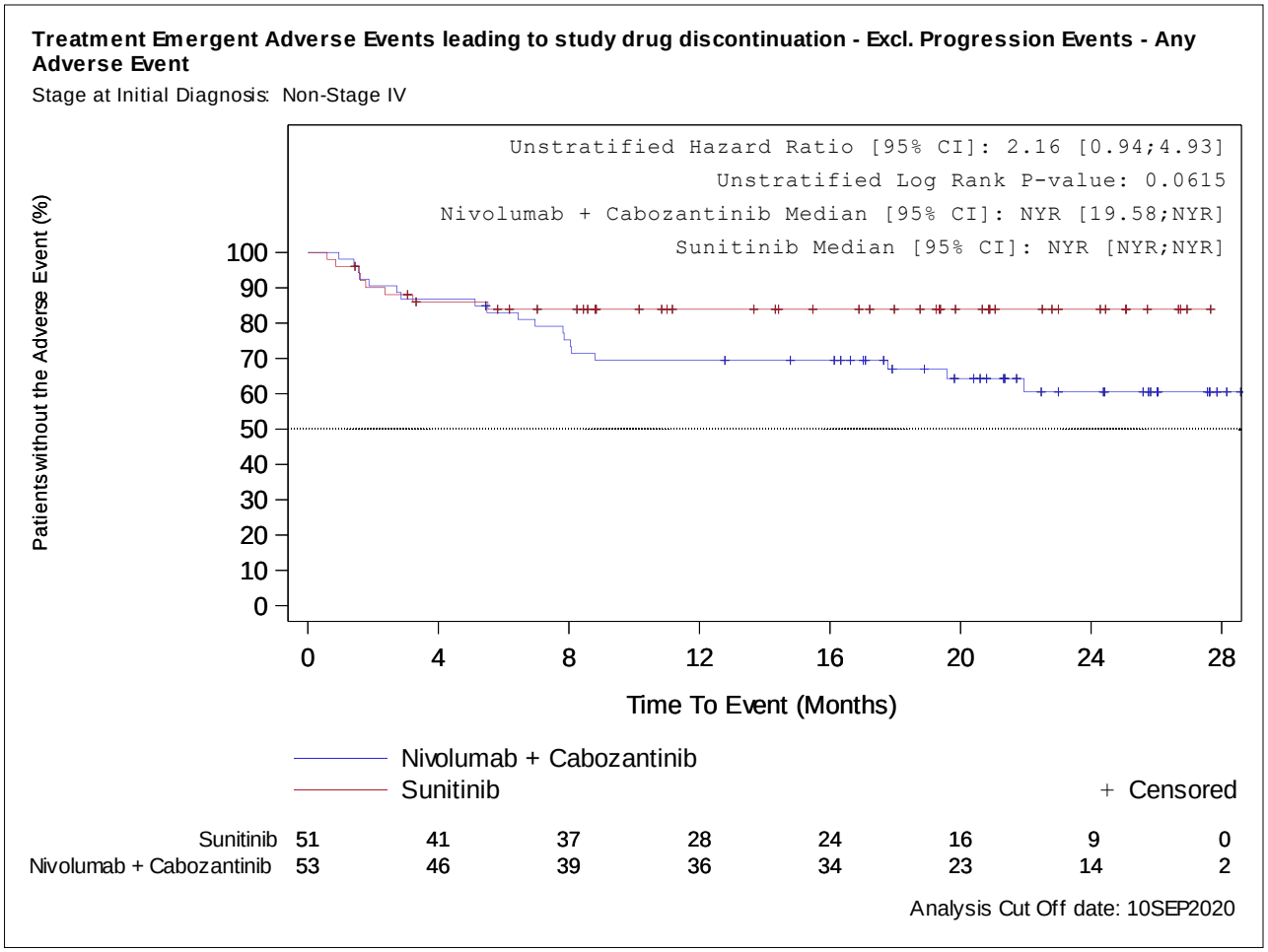

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:53:41

FIGURE 3.15.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



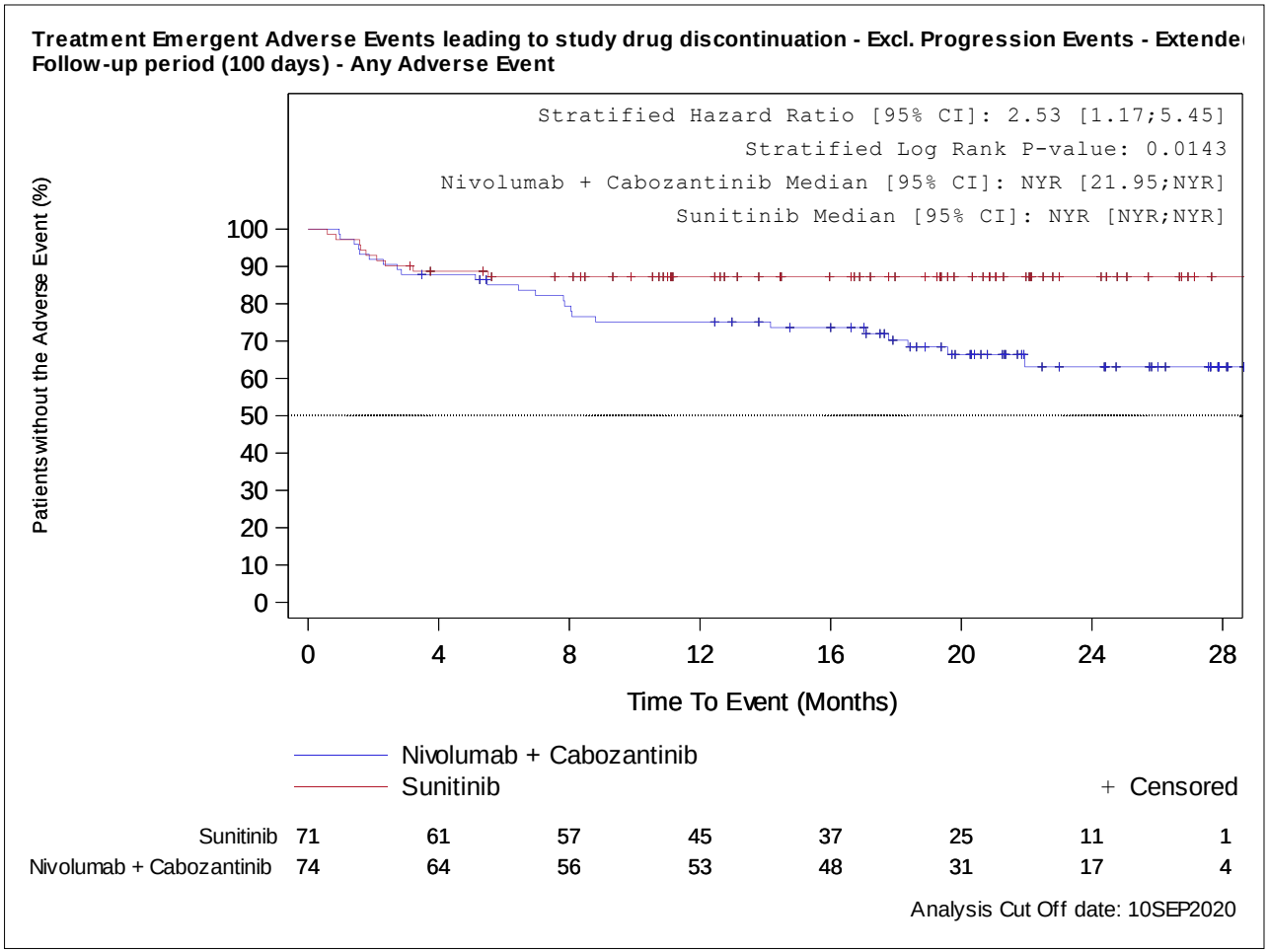

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:54:12

FIGURE 3.15.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



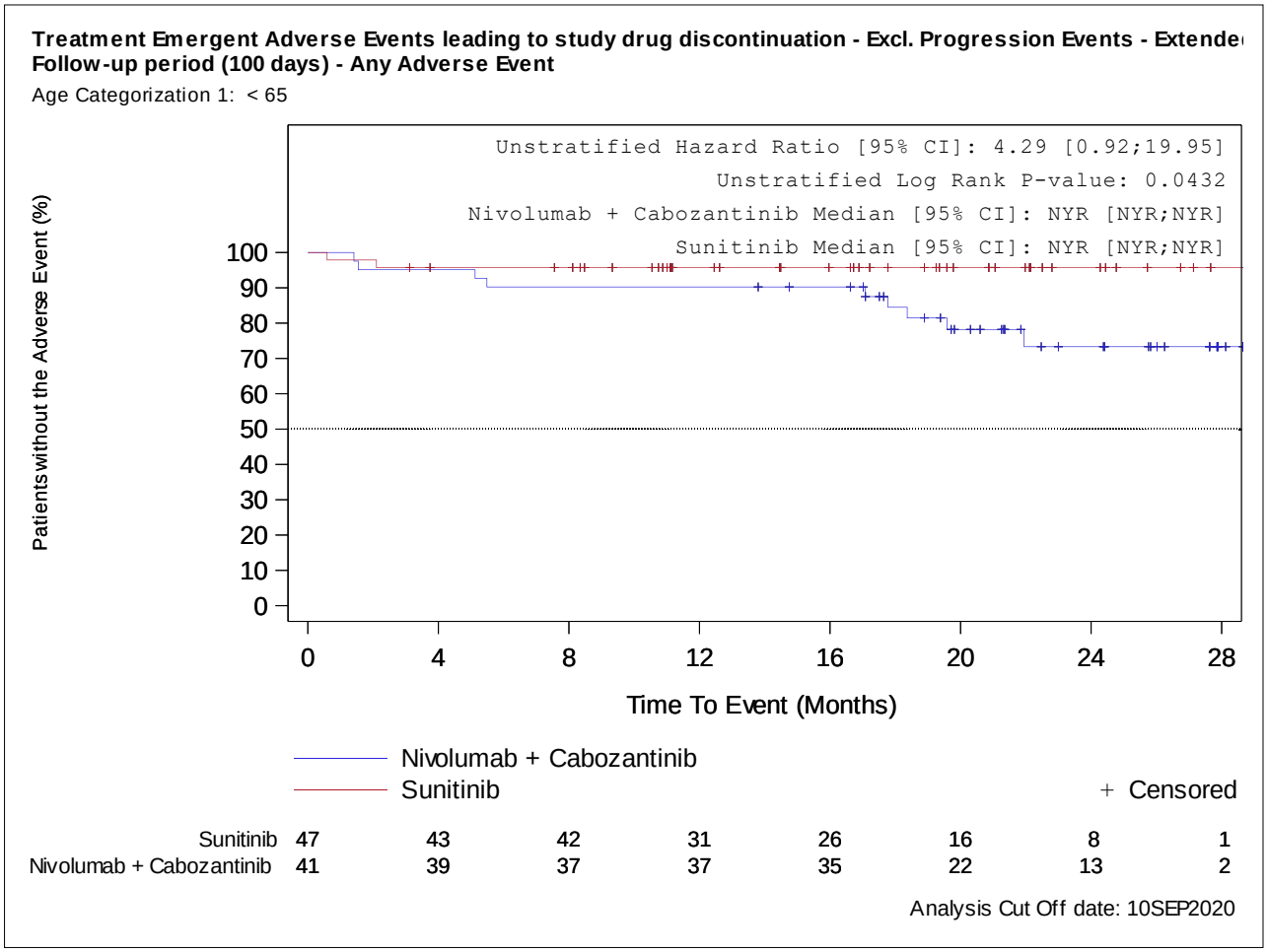

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:54:18

FIGURE 3.16.1: Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



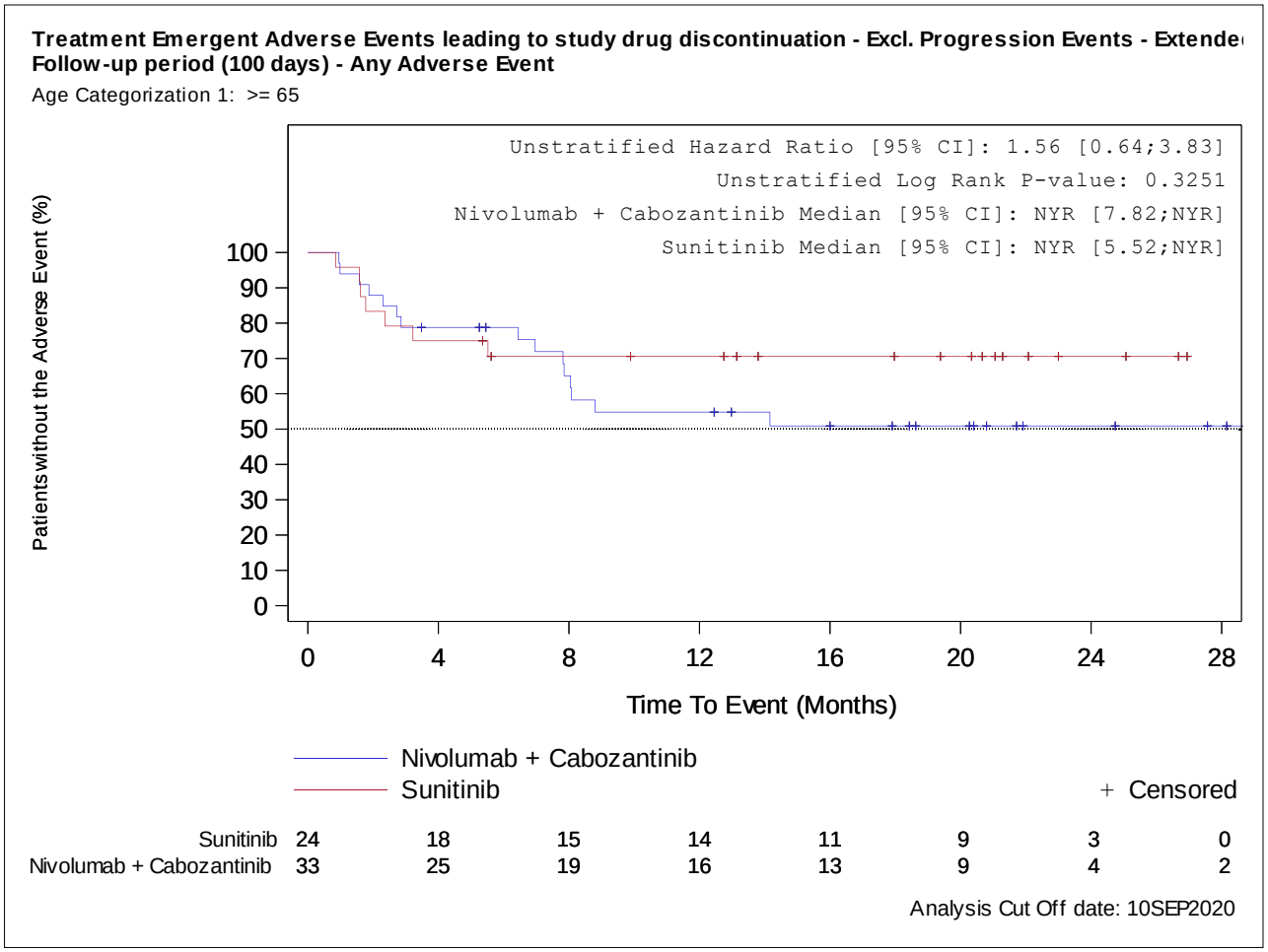

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:57:52

FIGURE 3.16.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



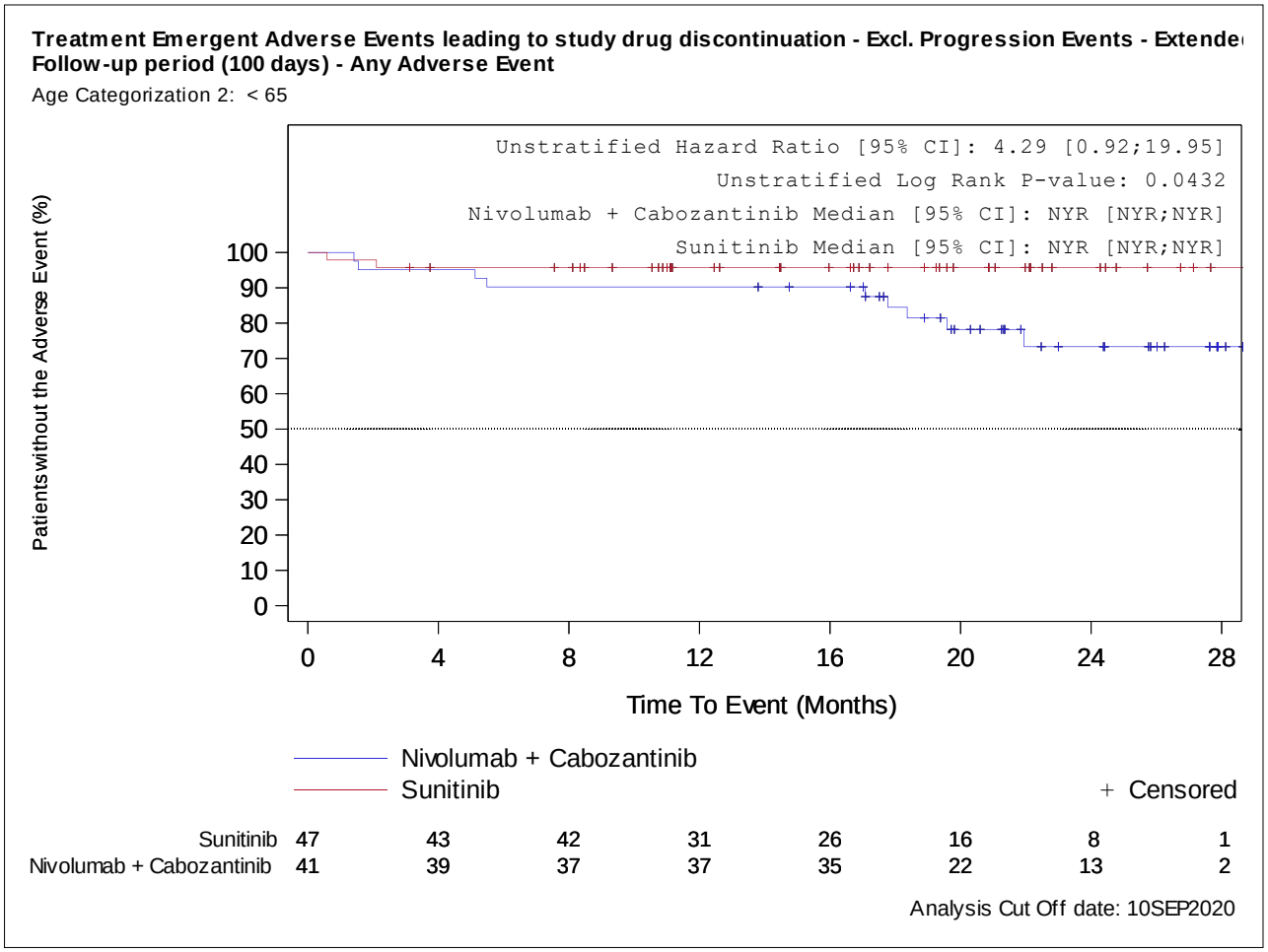

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:57:55

FIGURE 3.16.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



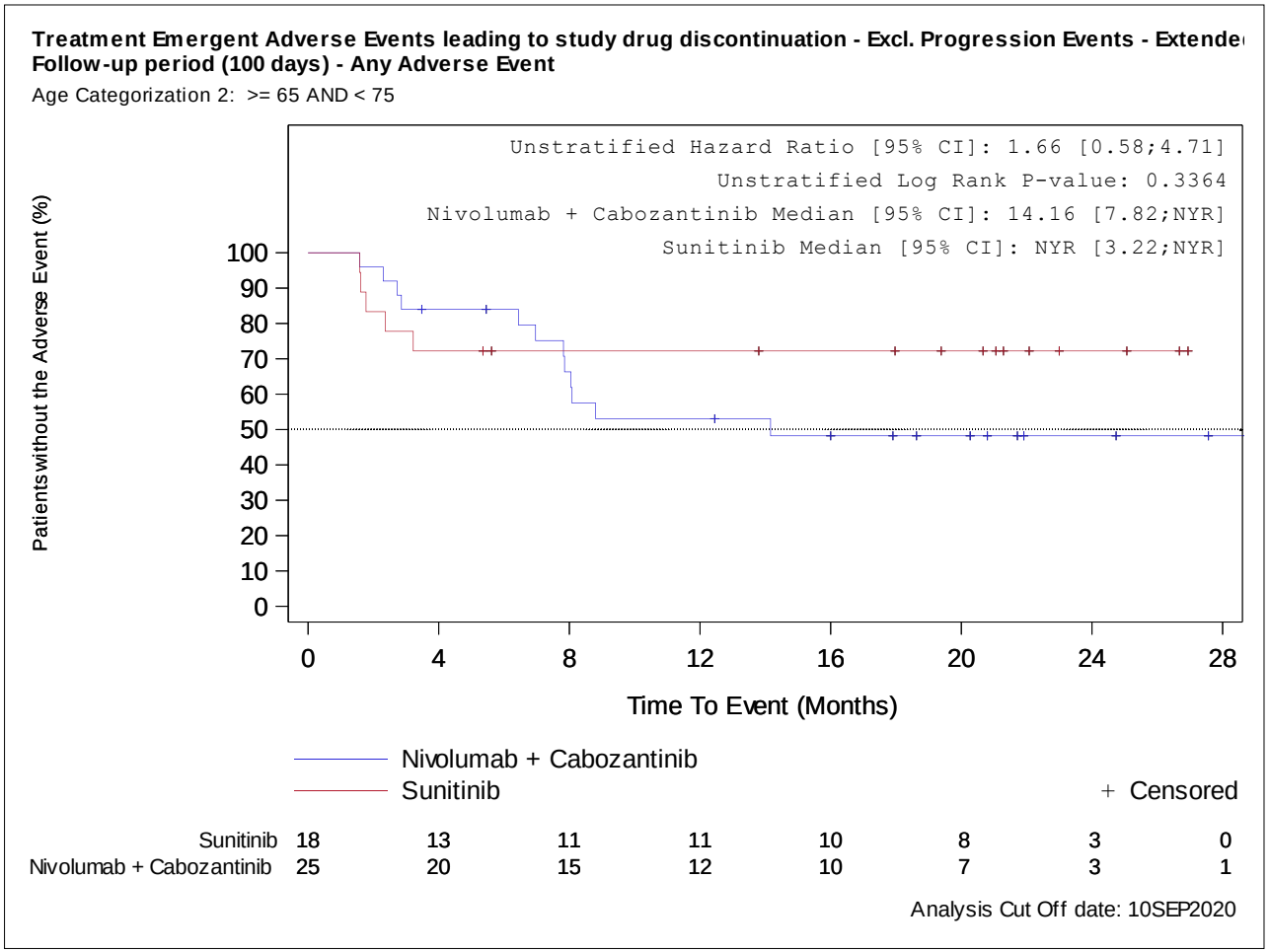

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:58:01

FIGURE 3.16.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



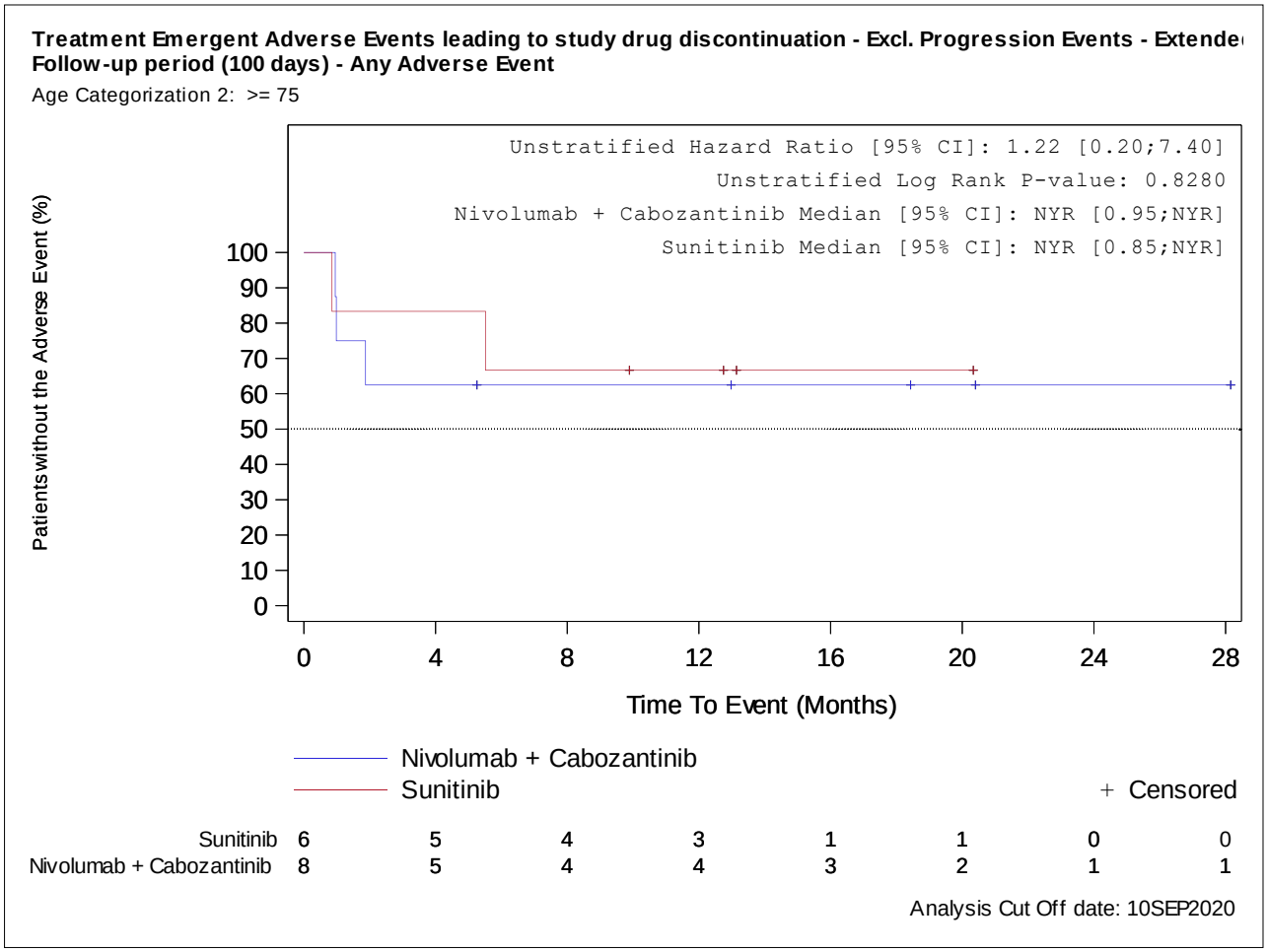

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:58:07

FIGURE 3.16.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



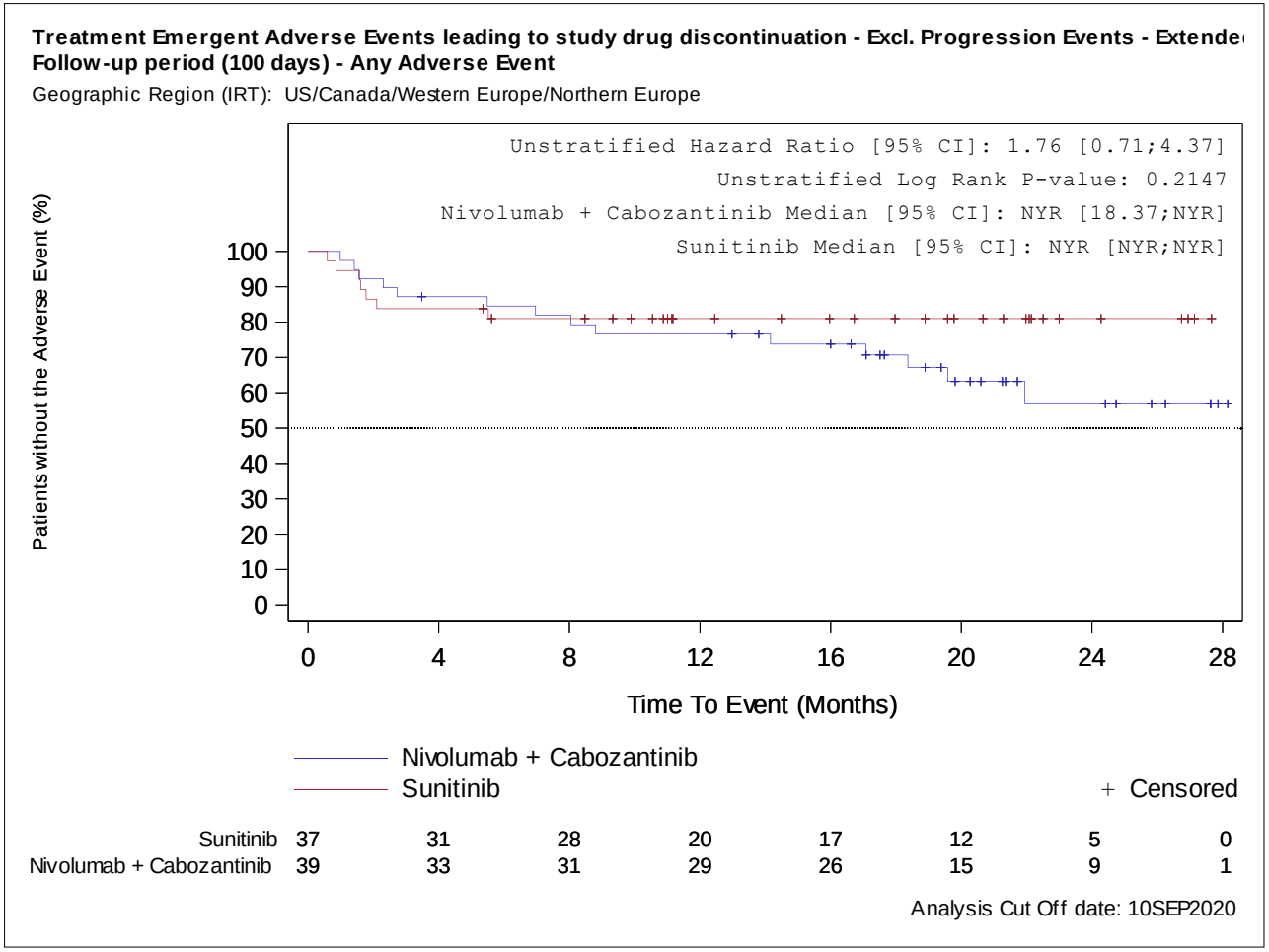

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:58:13

FIGURE 3.16.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



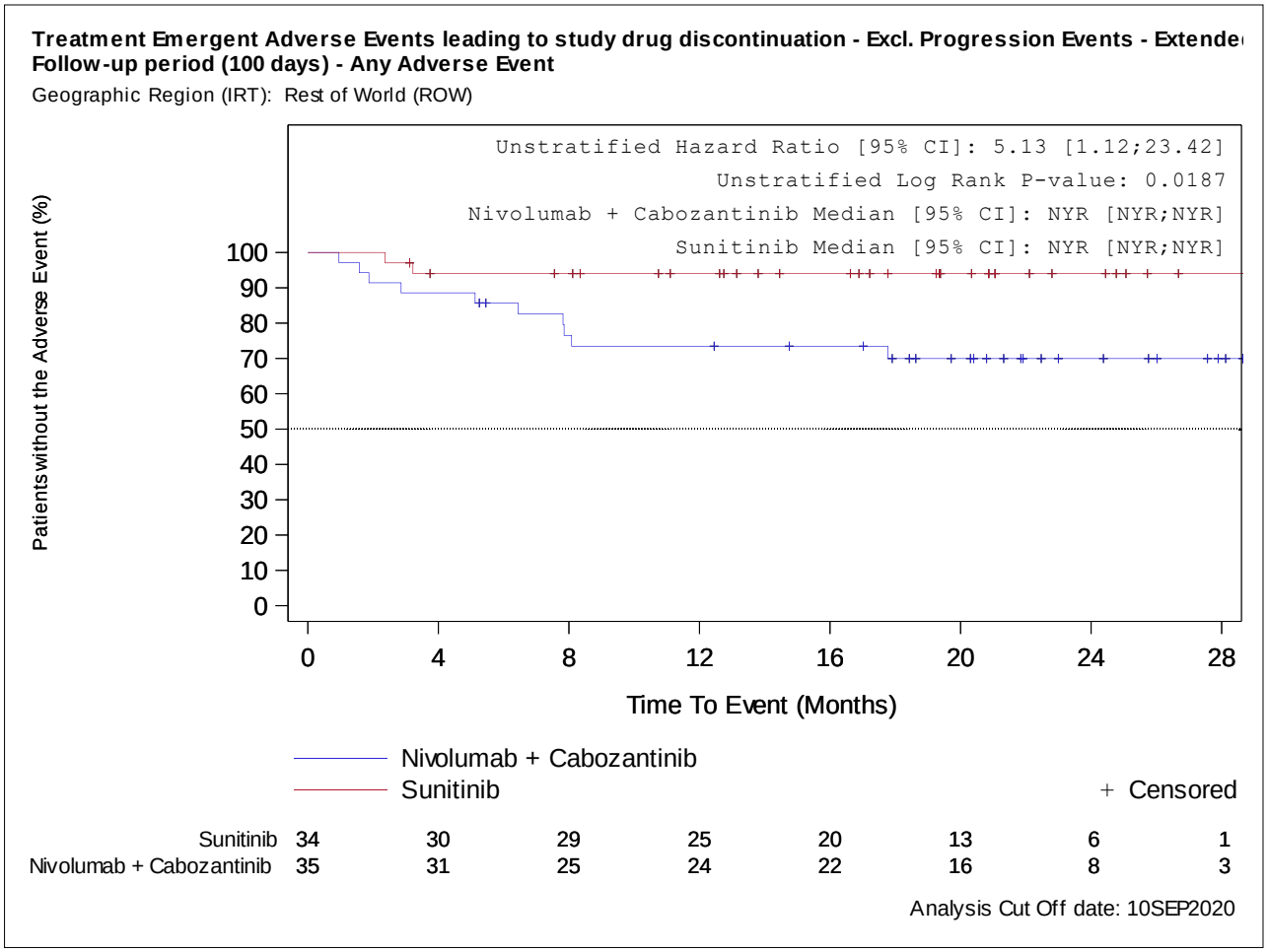

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:58:20

FIGURE 3.16.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



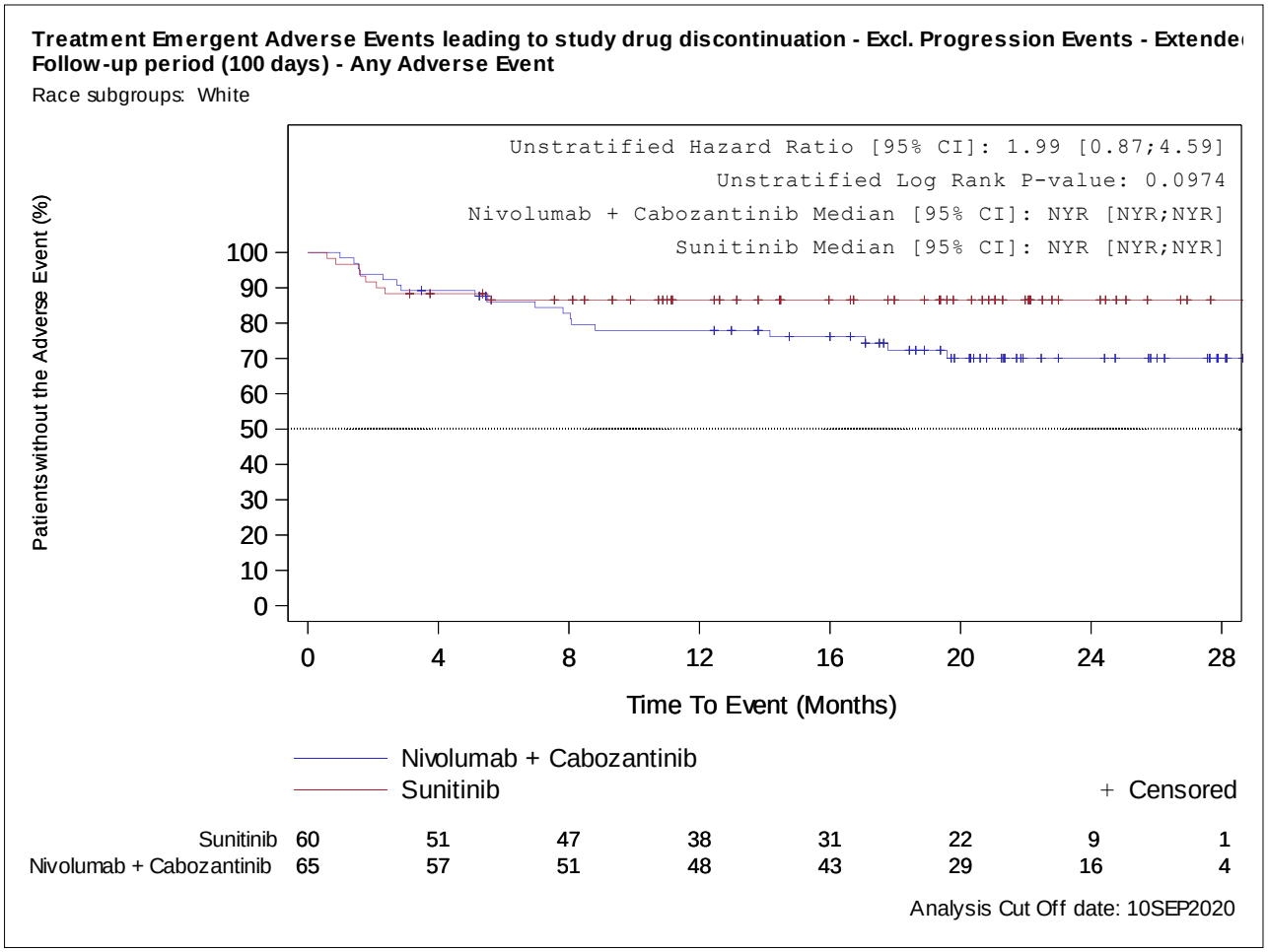

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:58:27

FIGURE 3.16.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



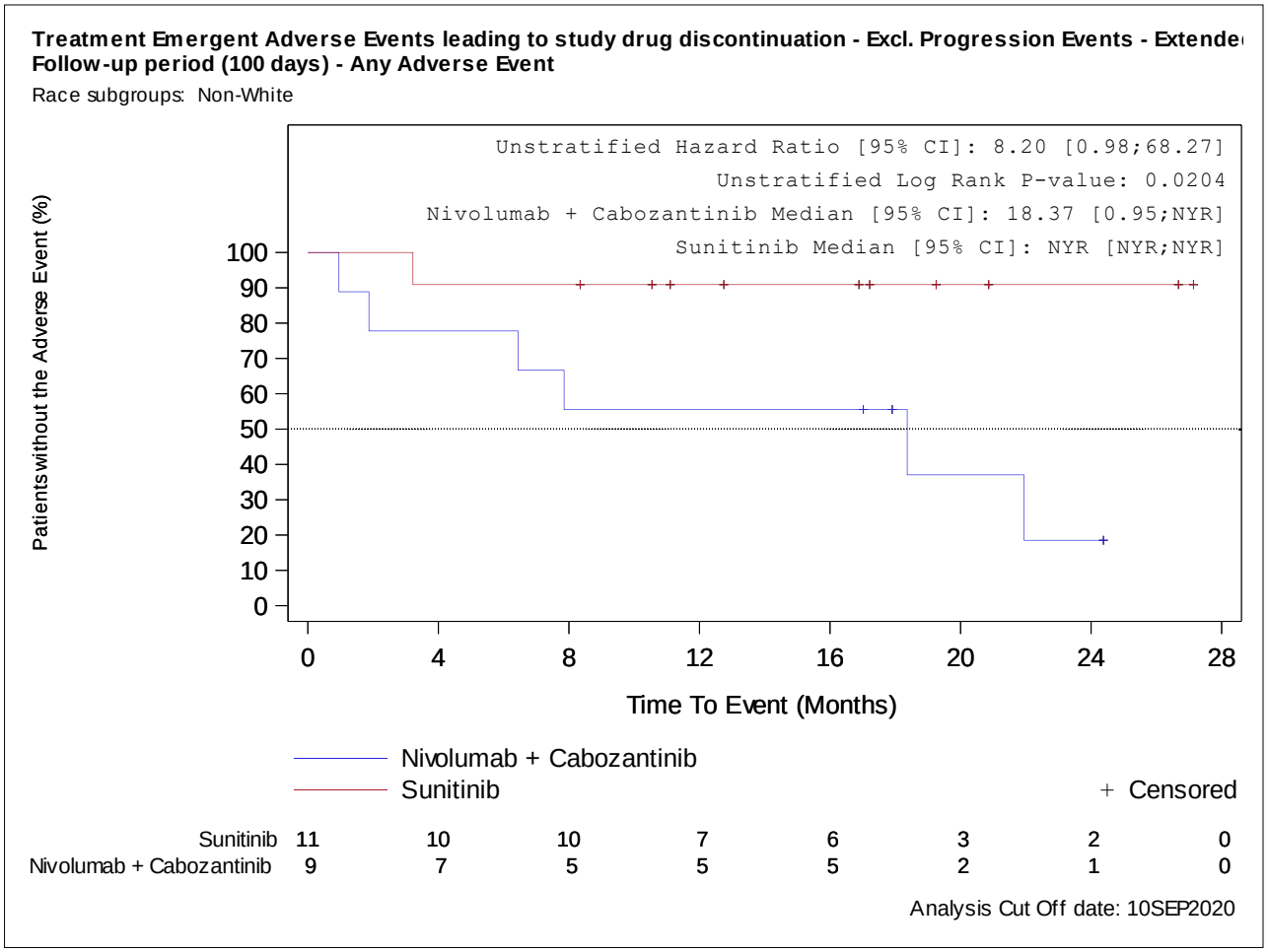

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:58:33

FIGURE 3.16.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



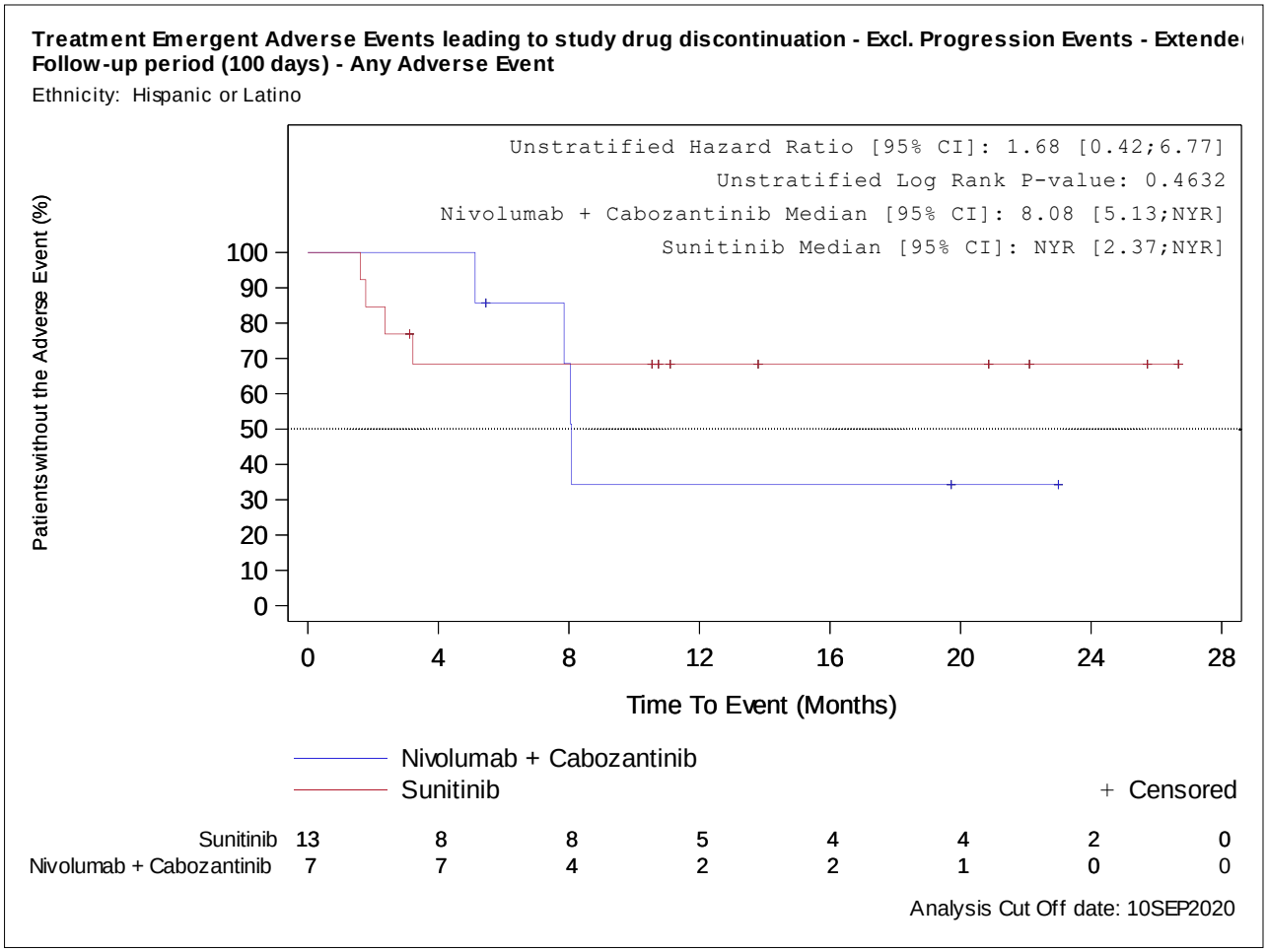

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:58:40

FIGURE 3.16.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



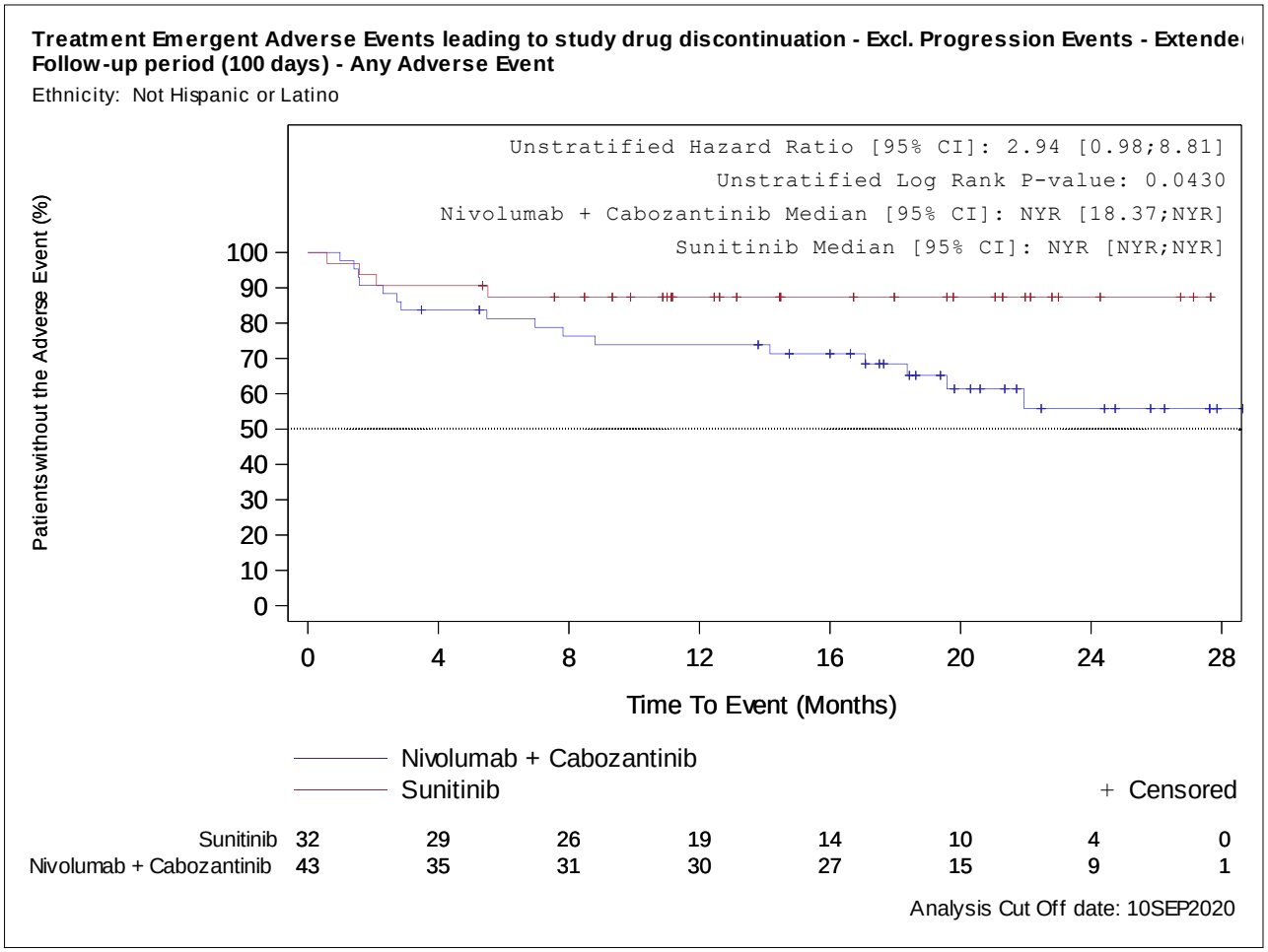

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:58:47

FIGURE 3.16.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



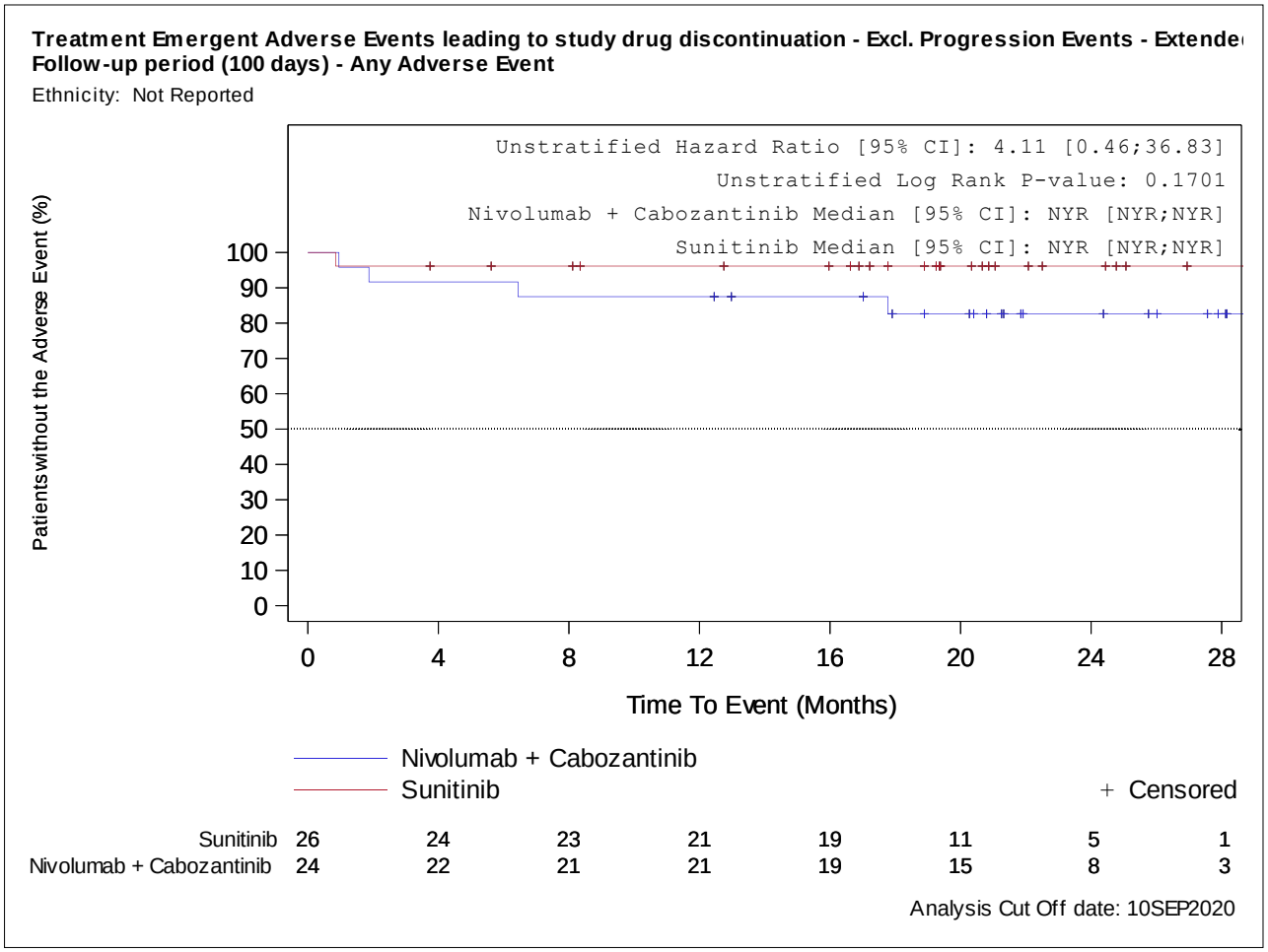

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:58:53

FIGURE 3.16.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



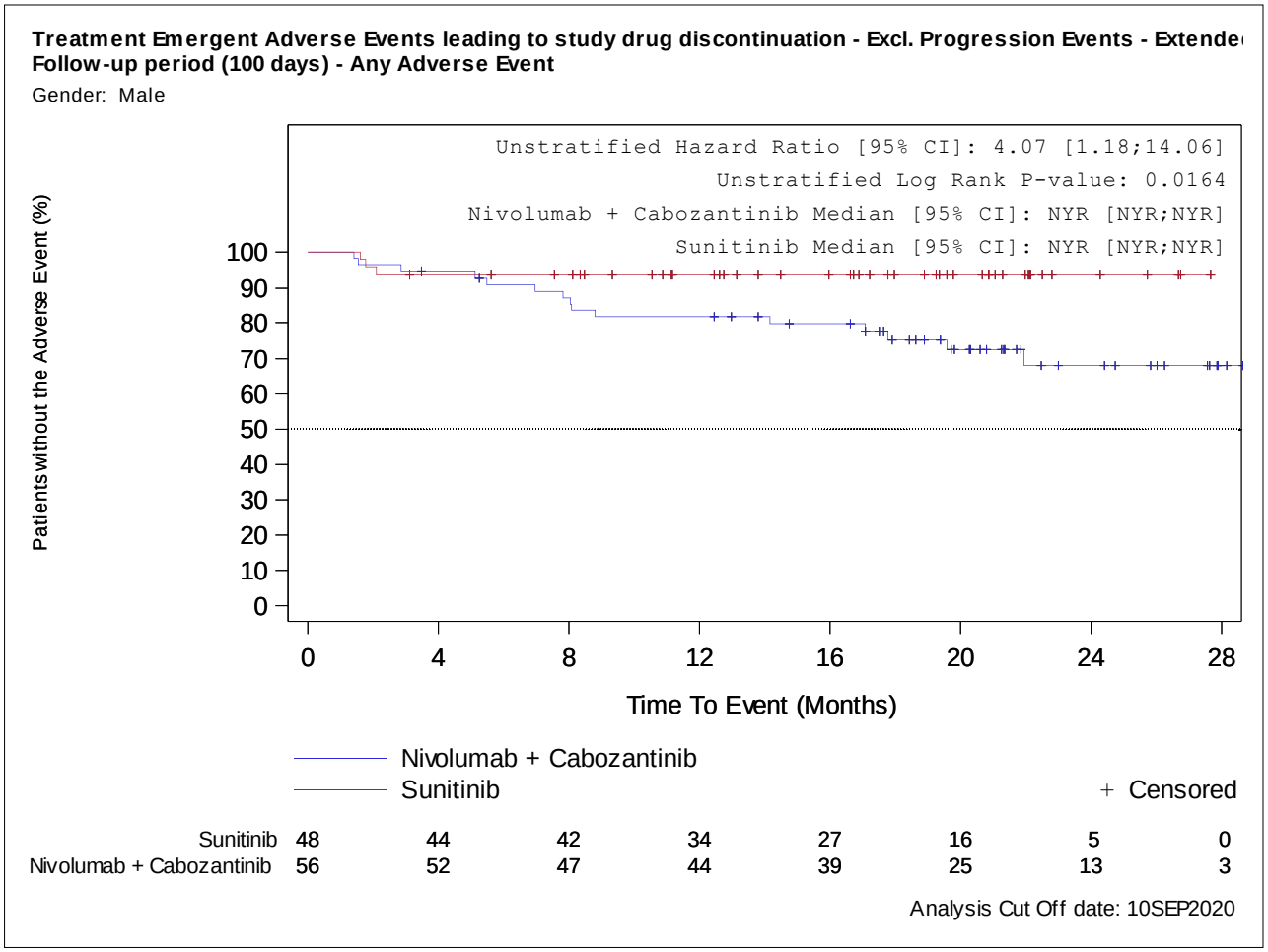

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:58:59

FIGURE 3.16.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



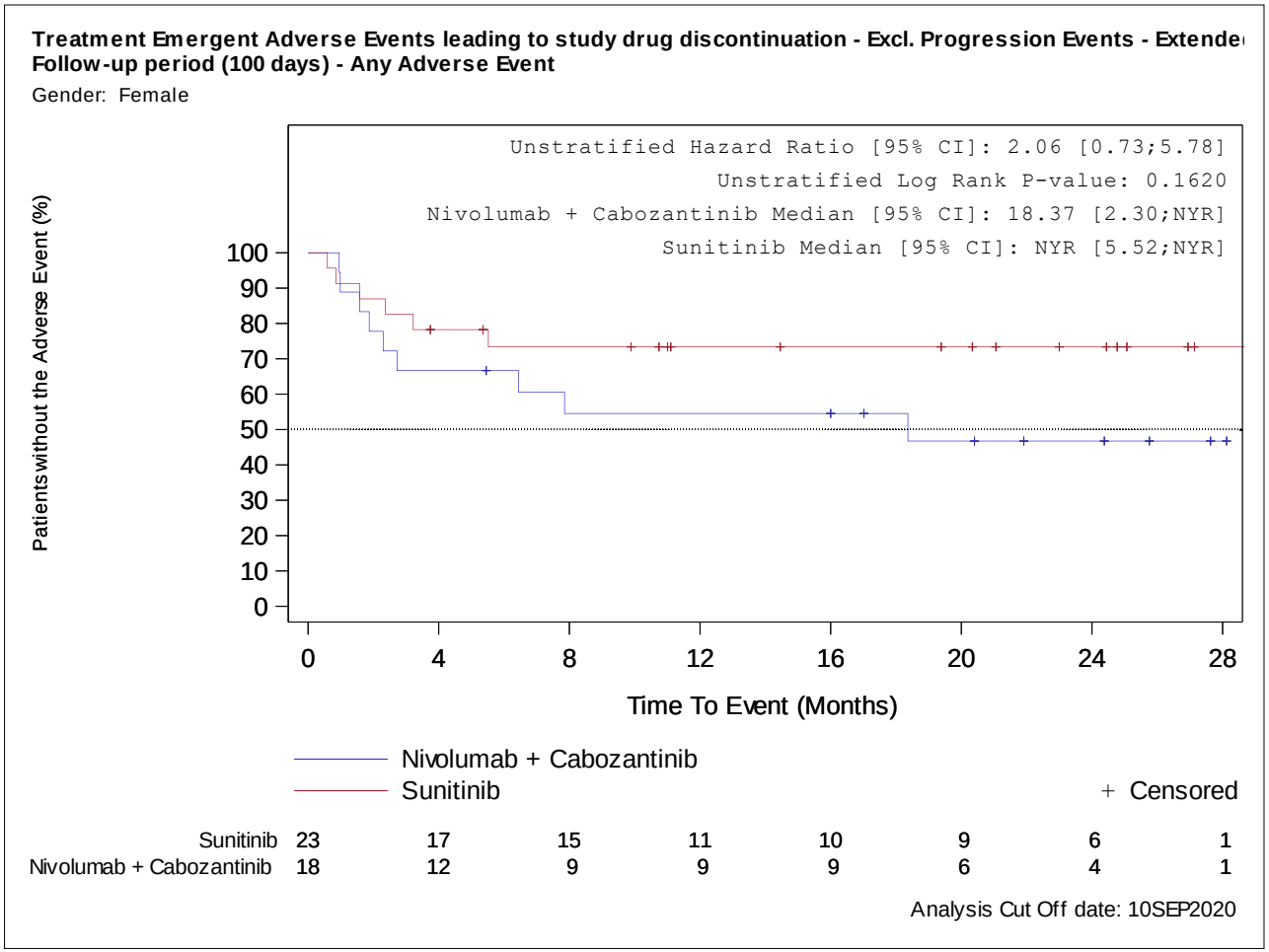

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:59:05

FIGURE 3.16.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



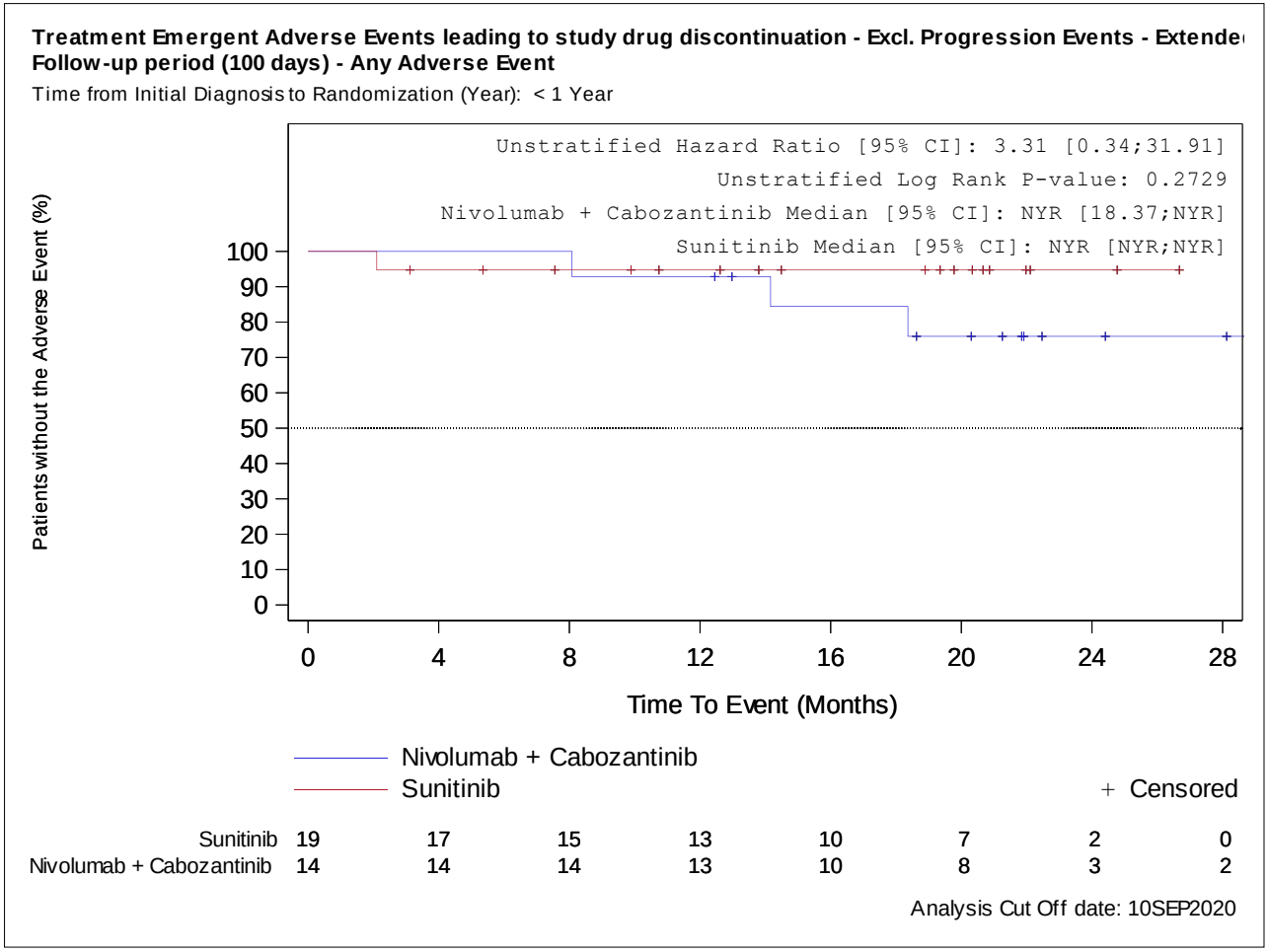

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:59:12

FIGURE 3.16.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:59:18

FIGURE 3.16.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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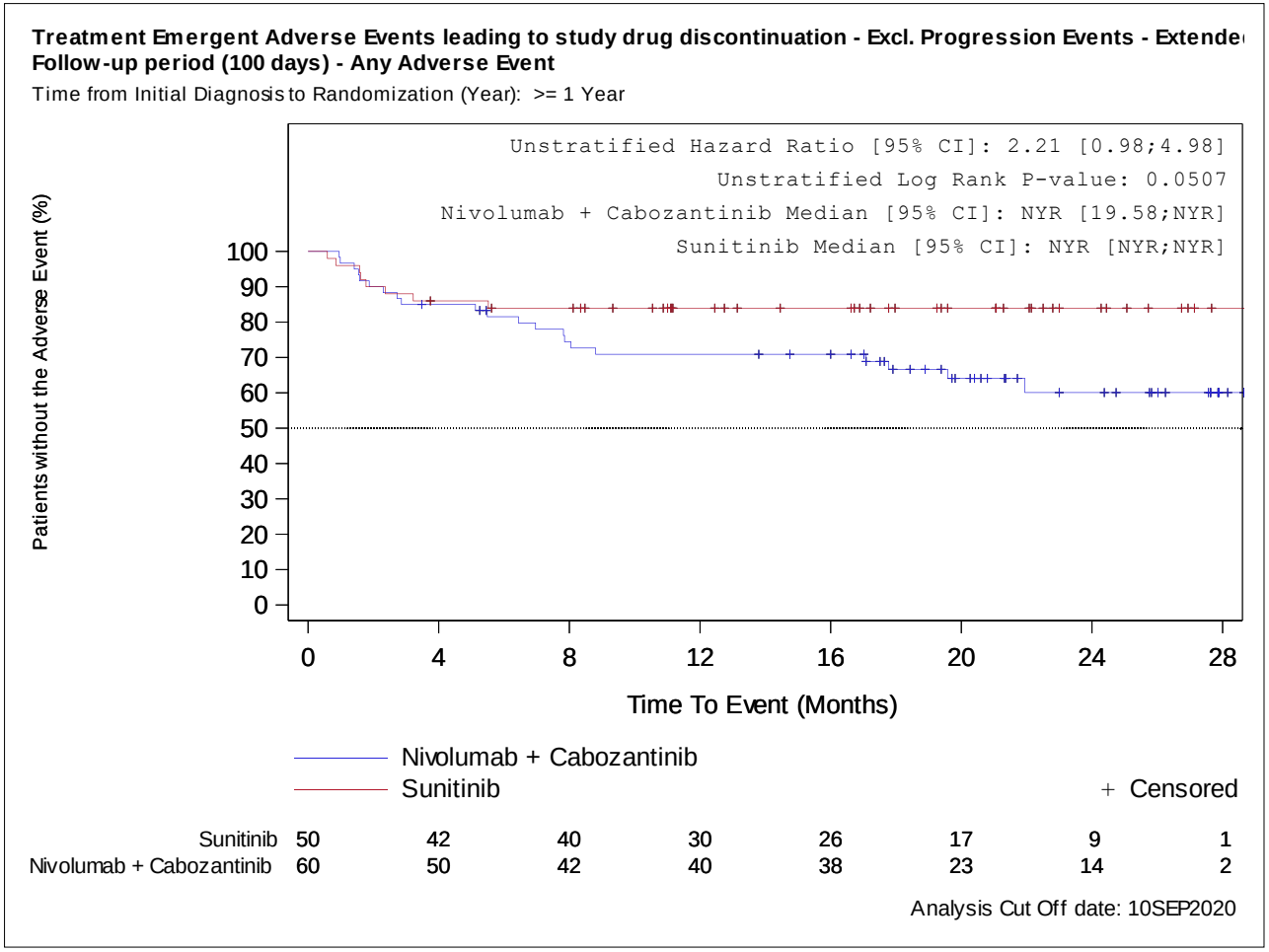
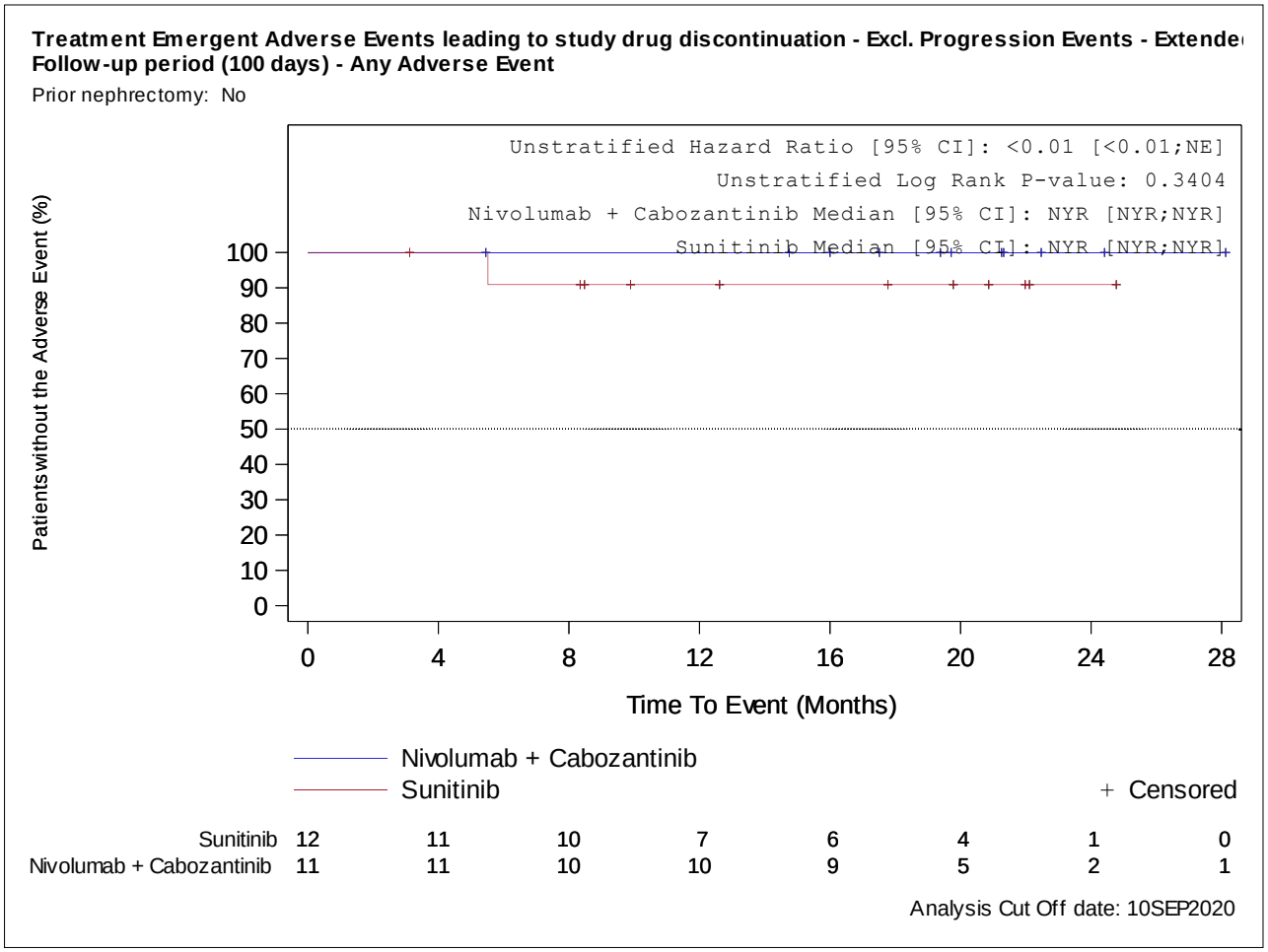
FIGURE 3.16.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



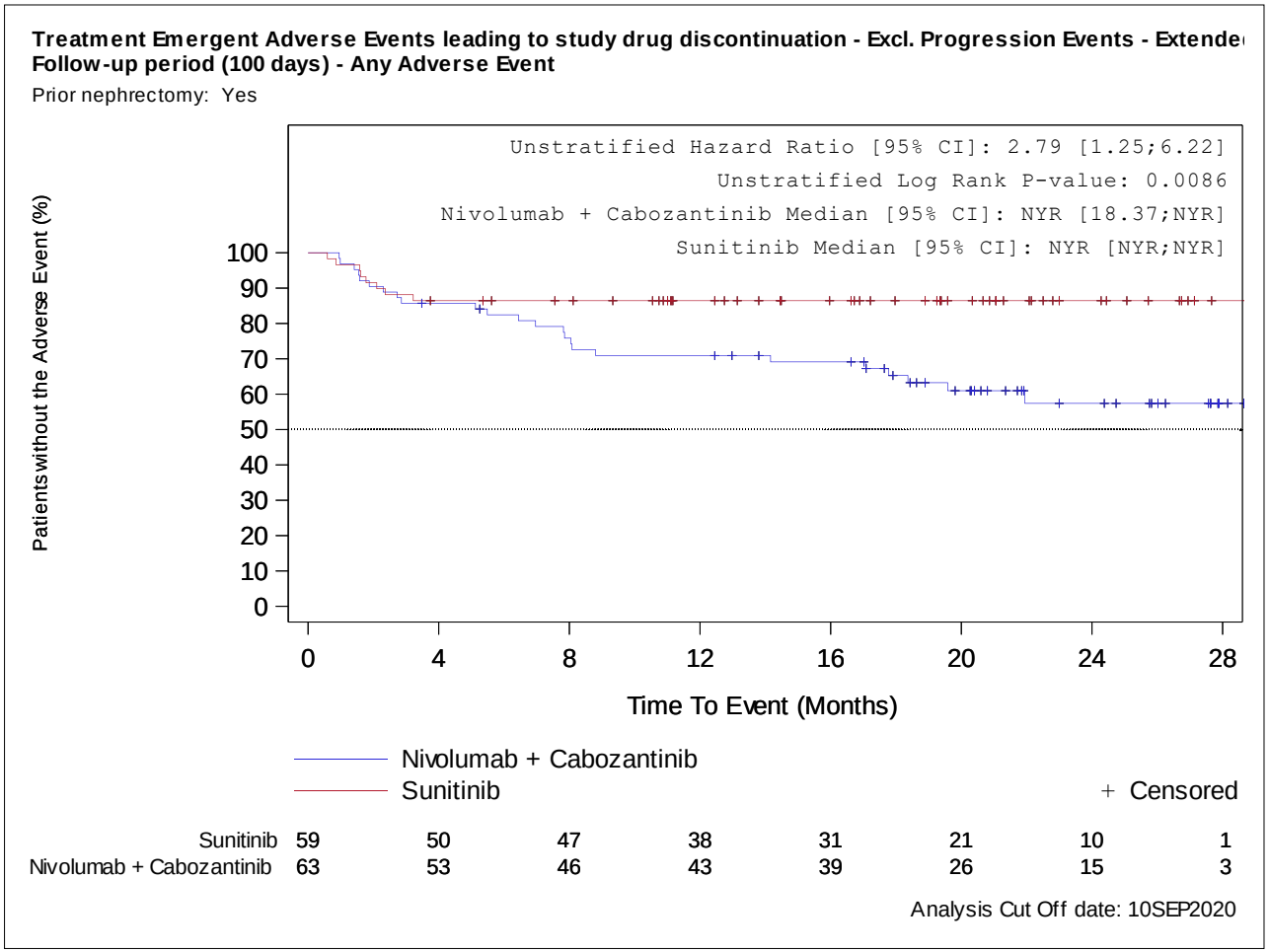

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 14:59:43

FIGURE 3.16.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:00:42

FIGURE 3.16.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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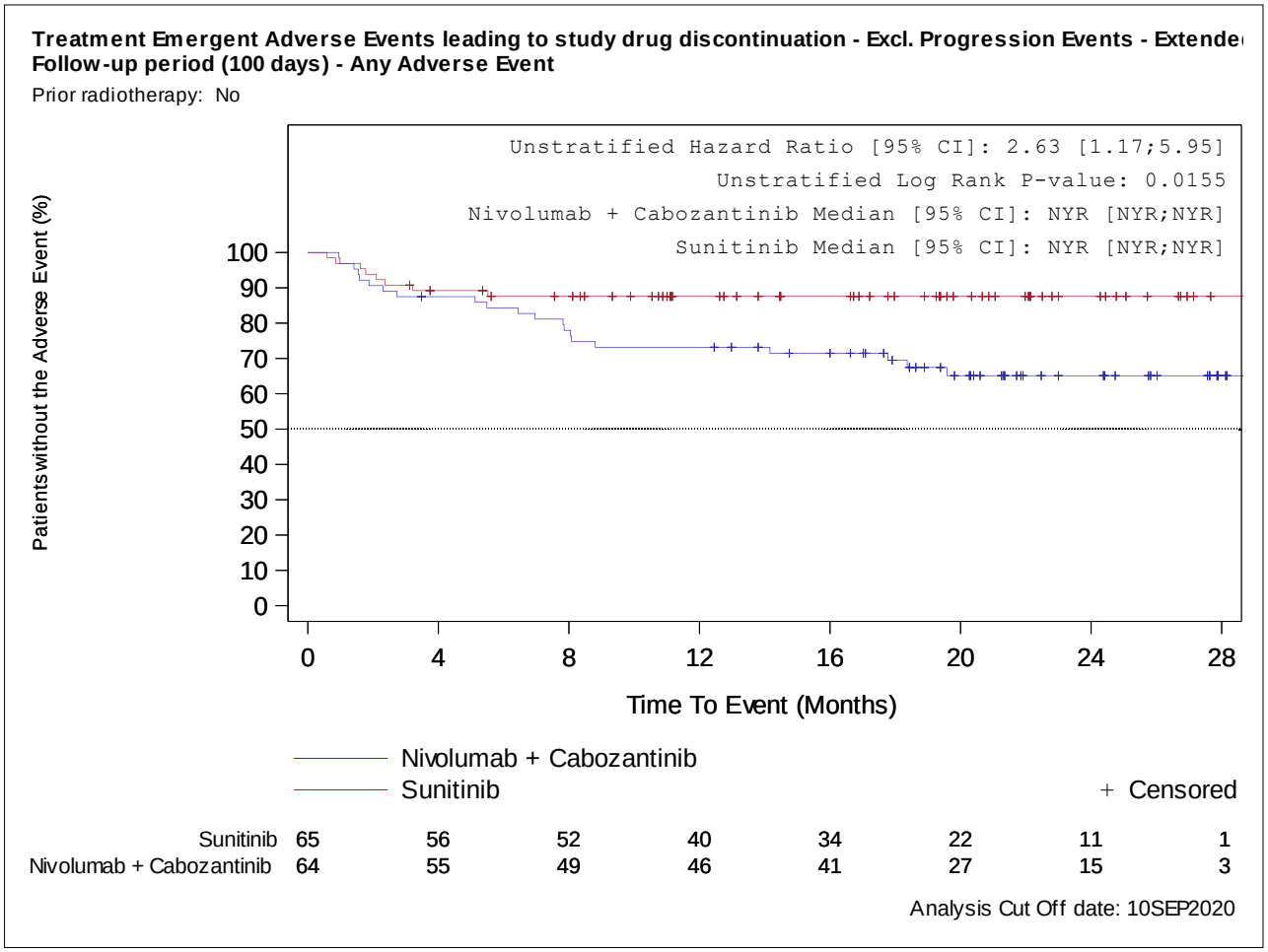
FIGURE 3.16.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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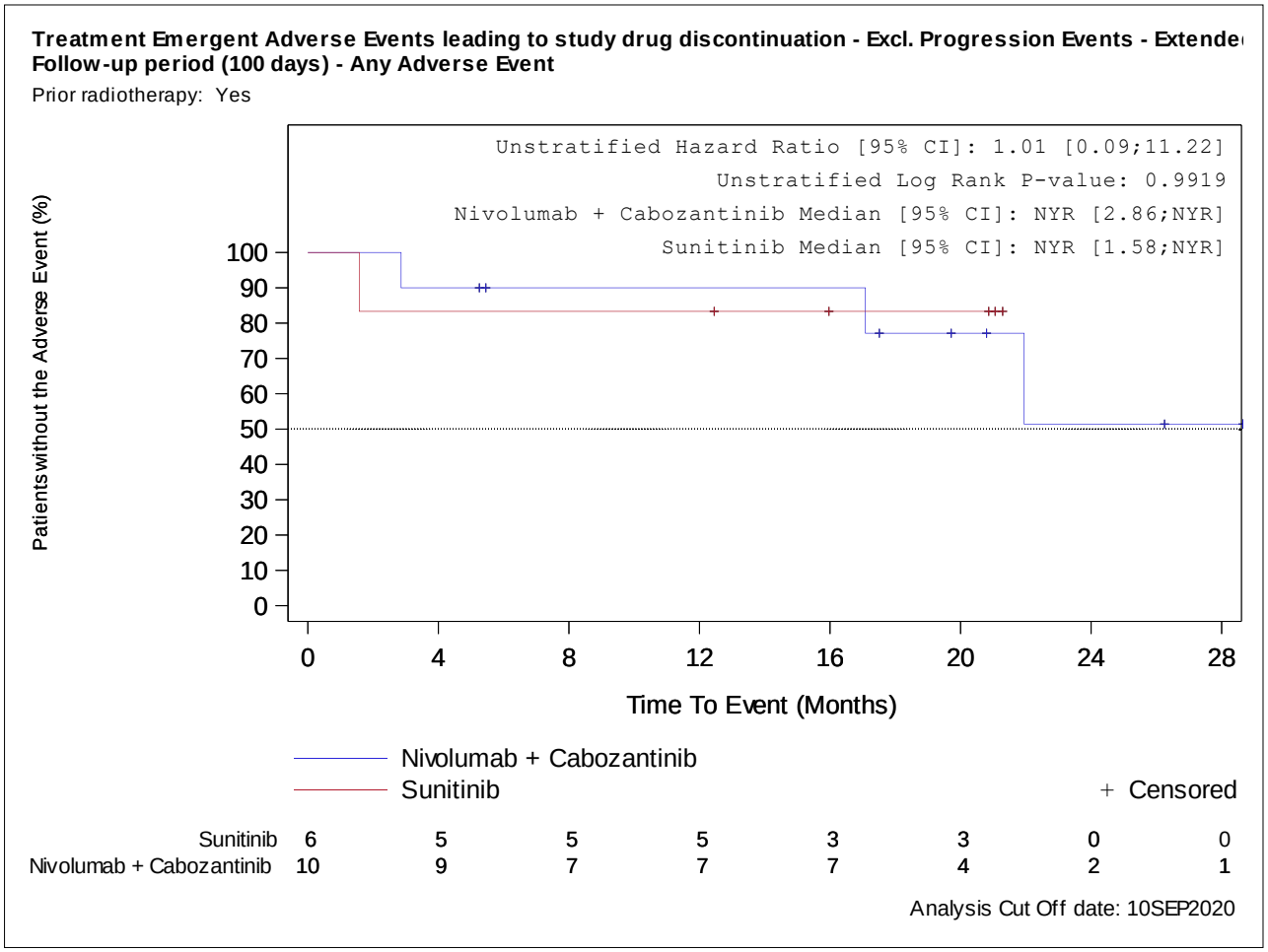
FIGURE 3.16.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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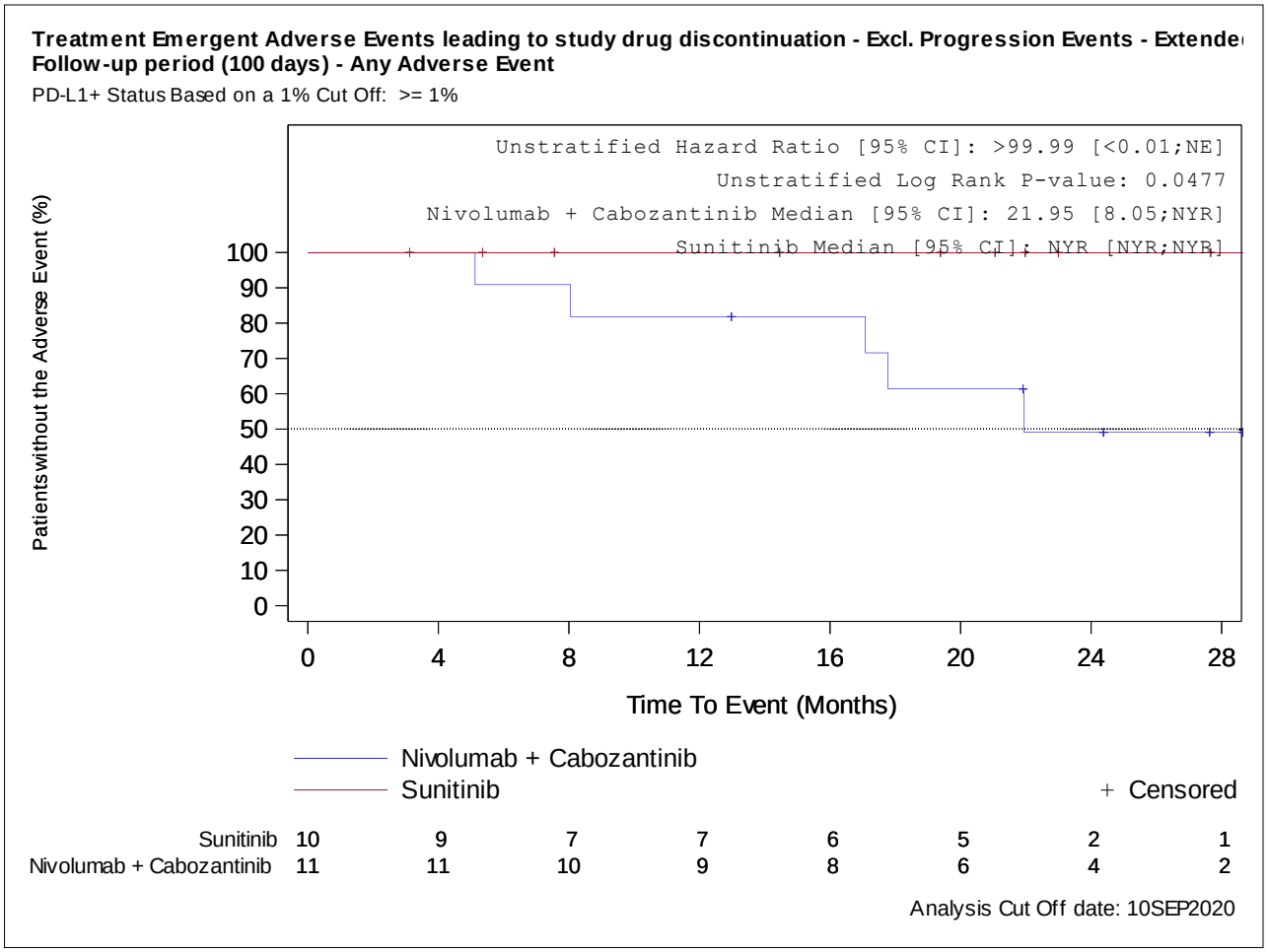
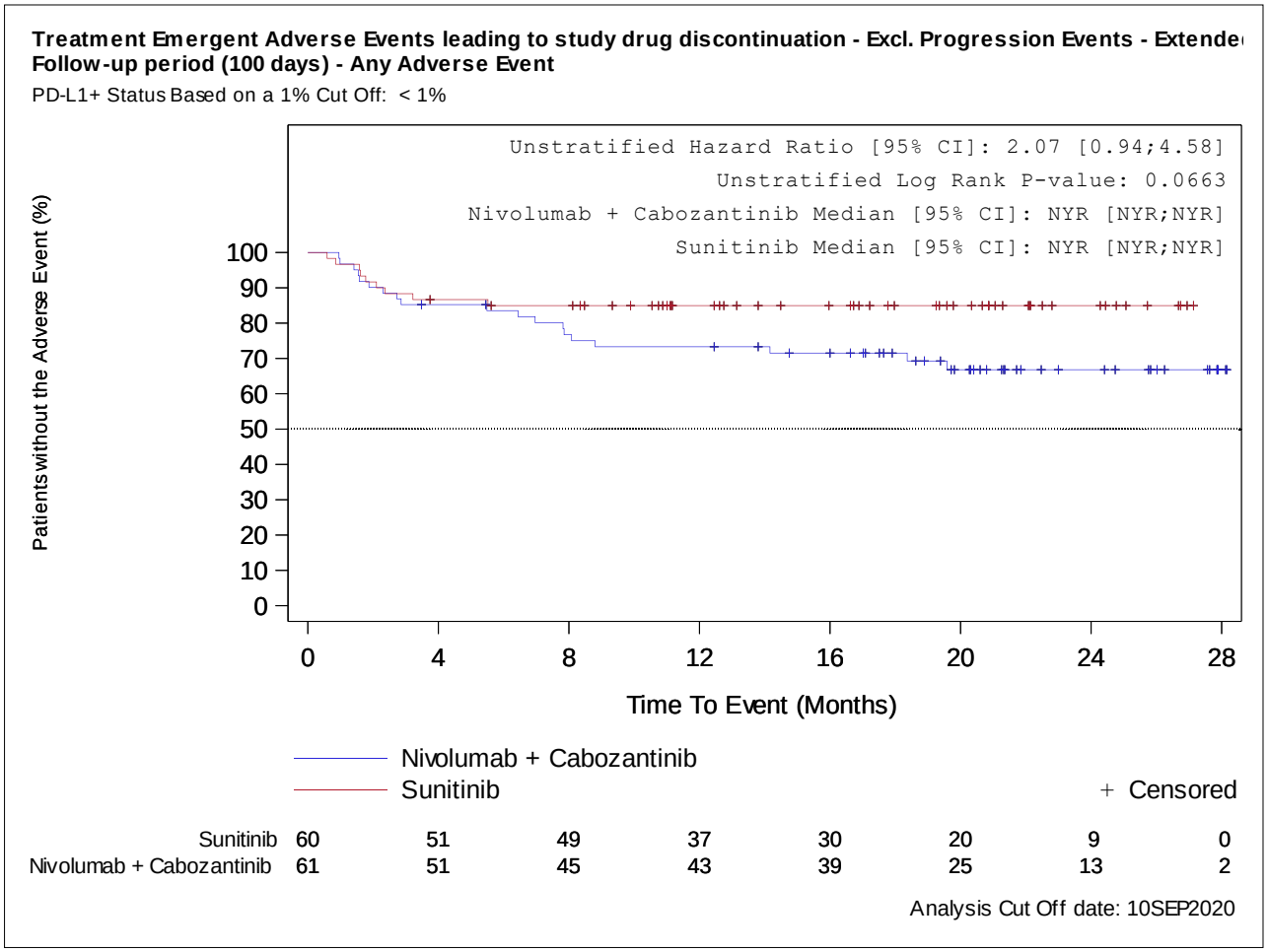
FIGURE 3.16.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



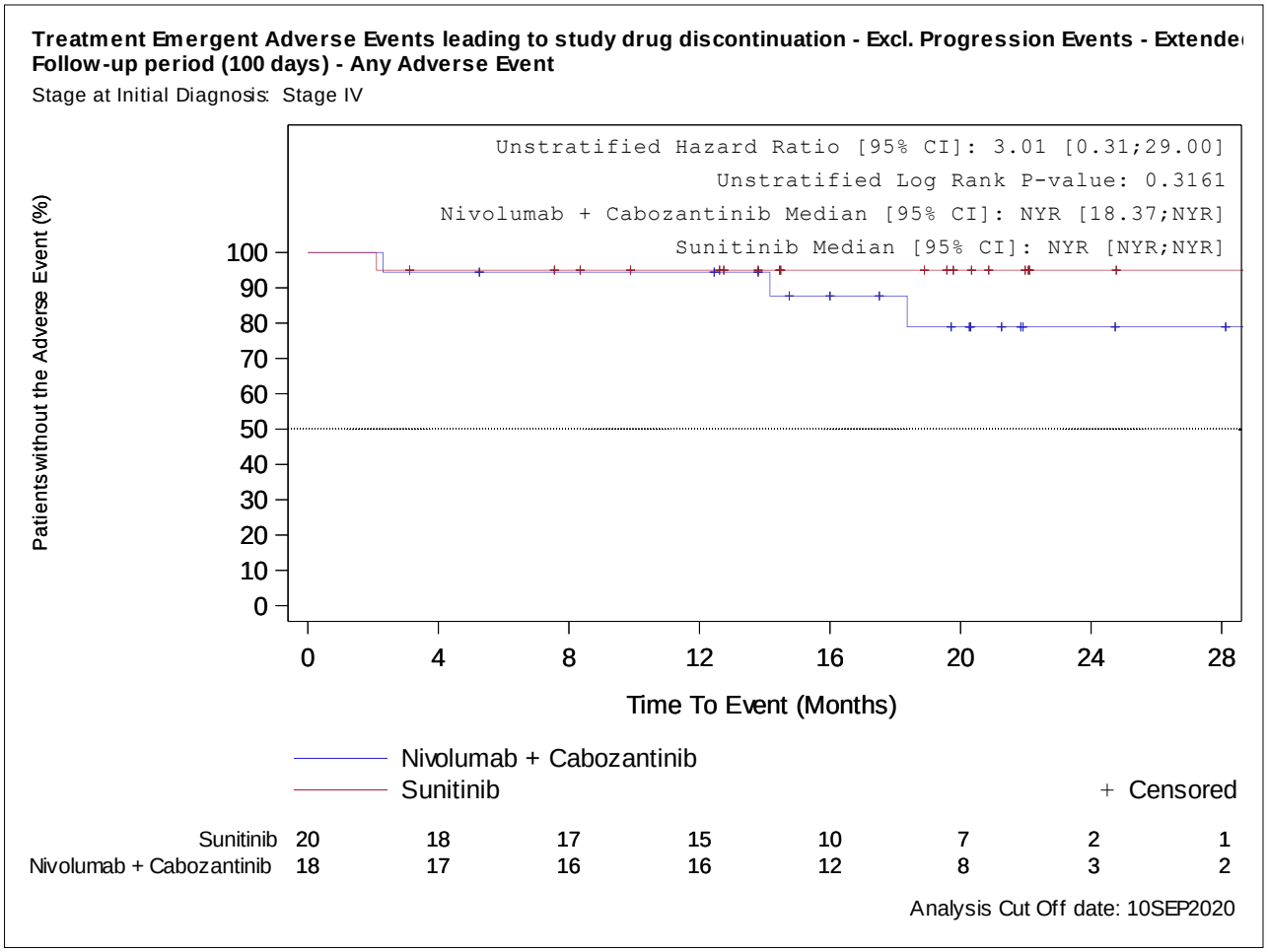

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:01:09

FIGURE 3.16.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



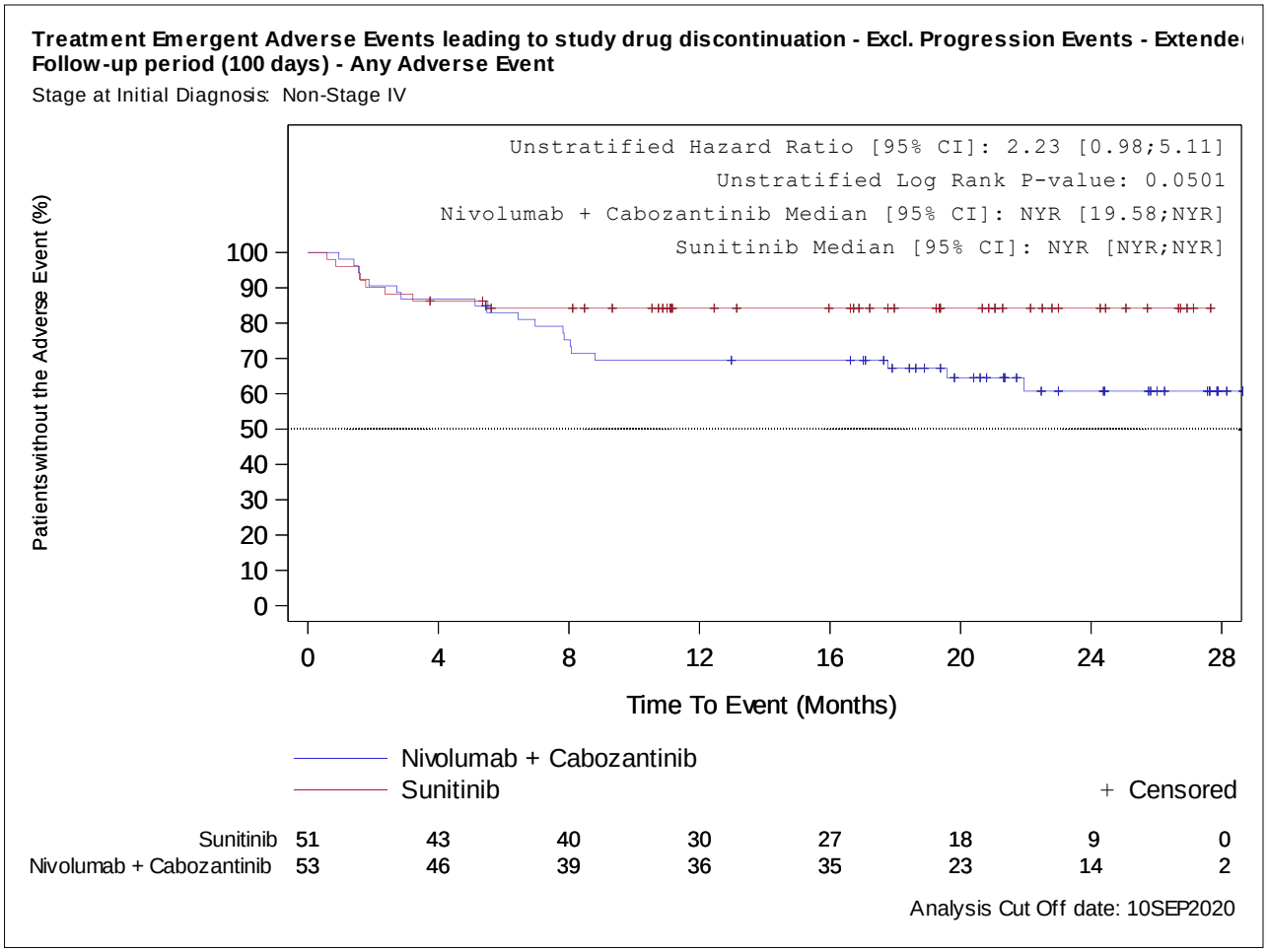

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:01:15

FIGURE 3.16.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



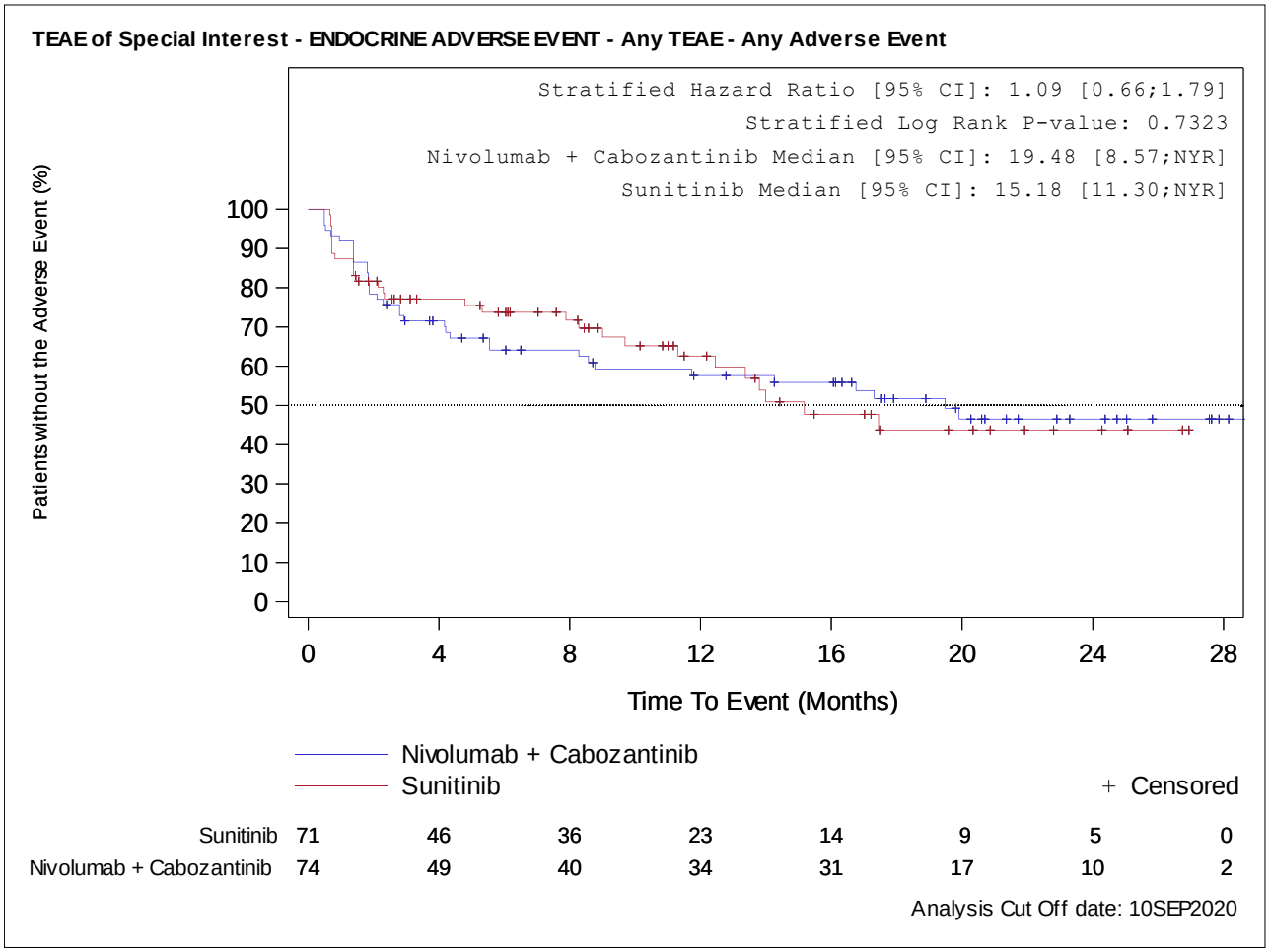

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:01:46

FIGURE 3.16.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Events leading to study drug discontinuation - Excl. Progression Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



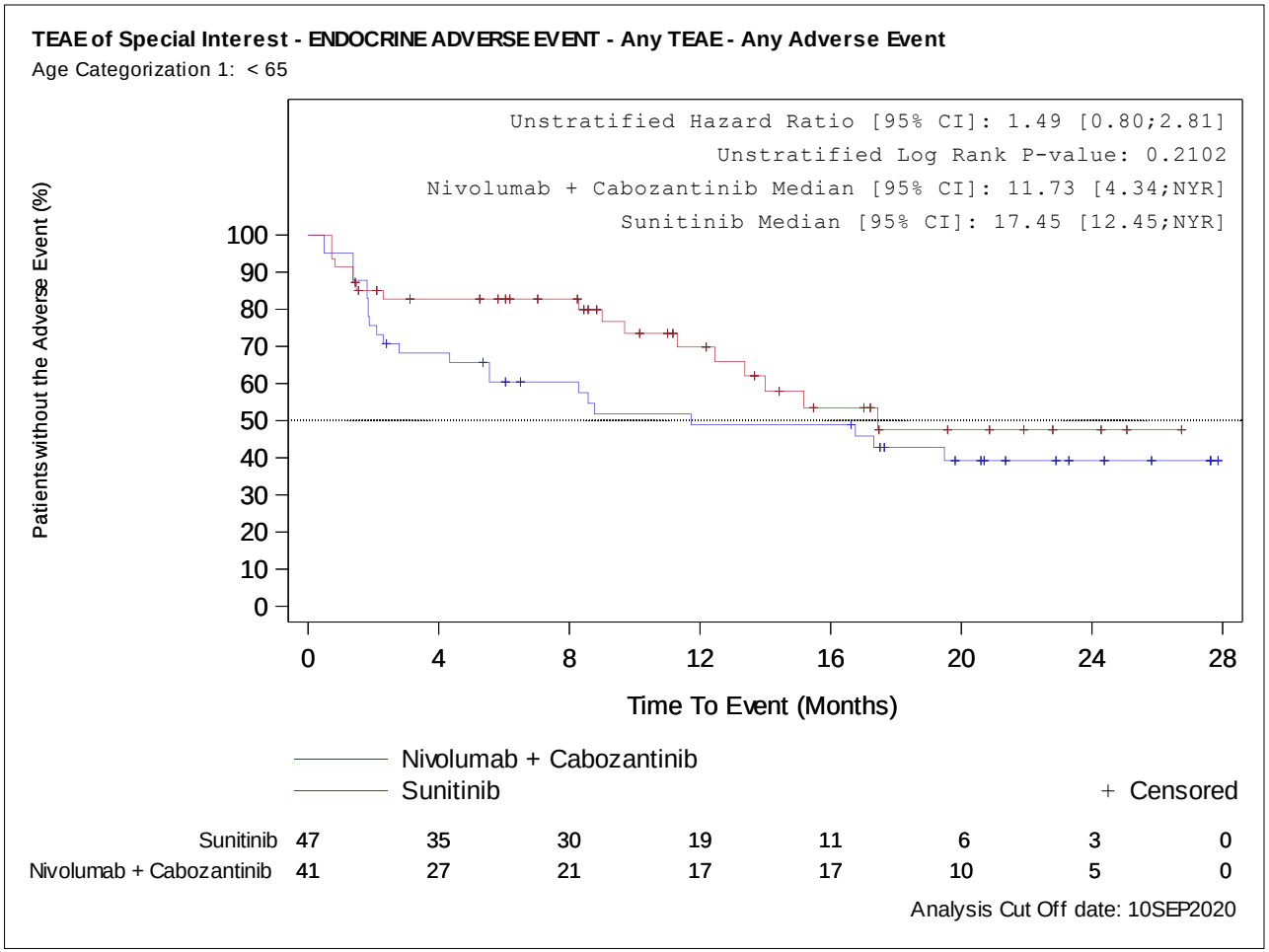

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:01:52

FIGURE 3.17.1: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



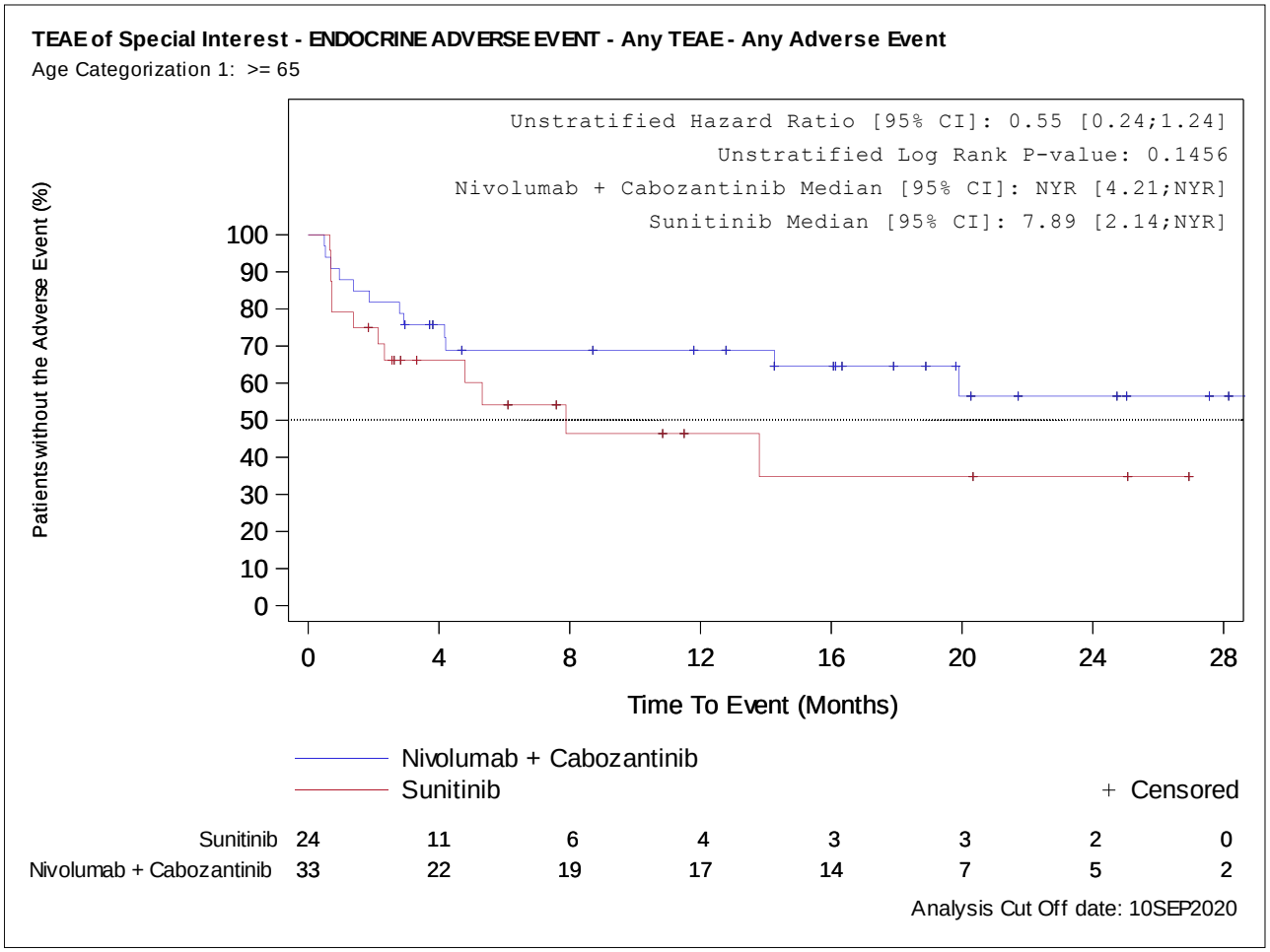

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:32:52

FIGURE 3.17.2.1: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



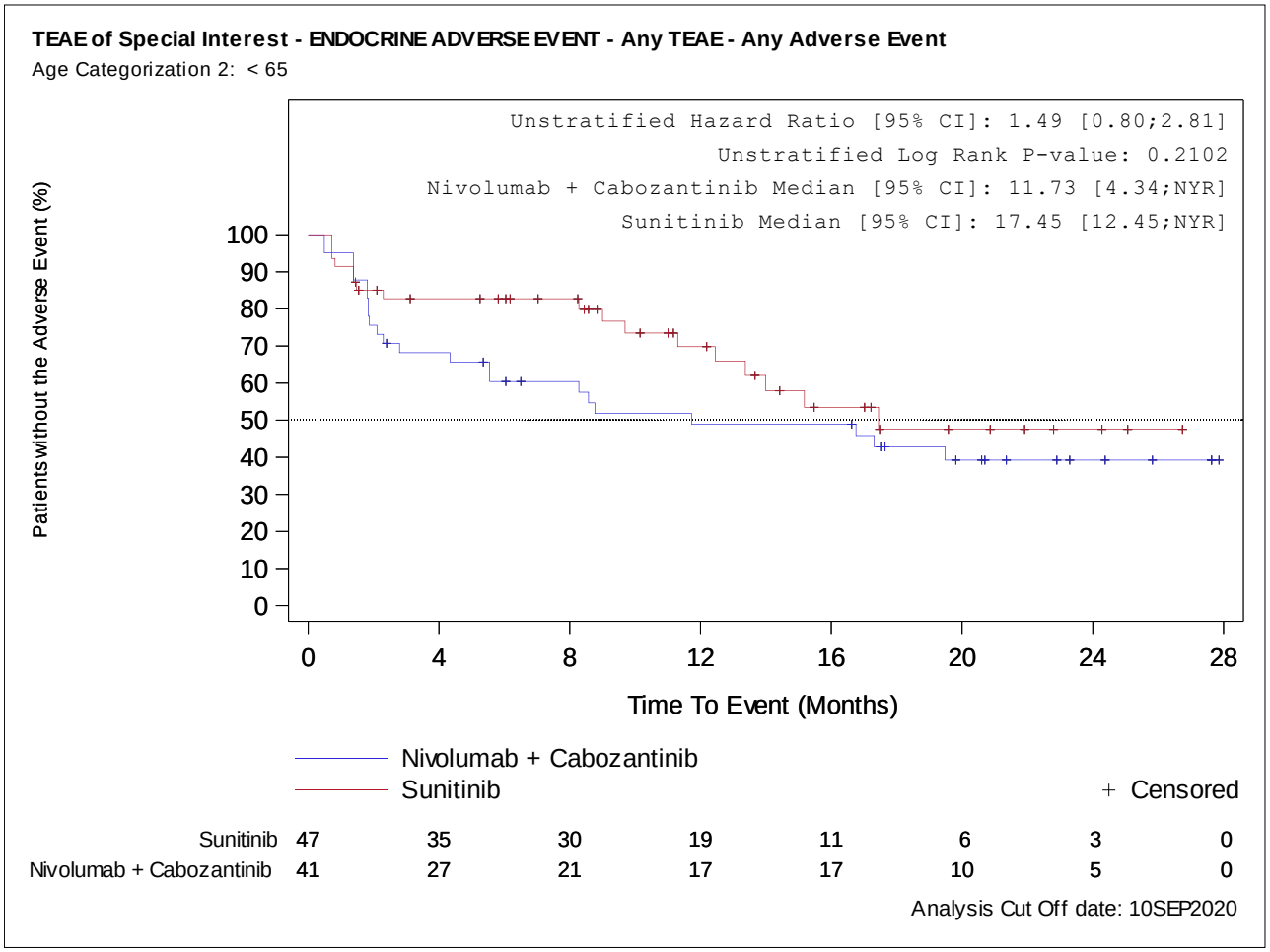

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:32:56

FIGURE 3.17.2.2: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



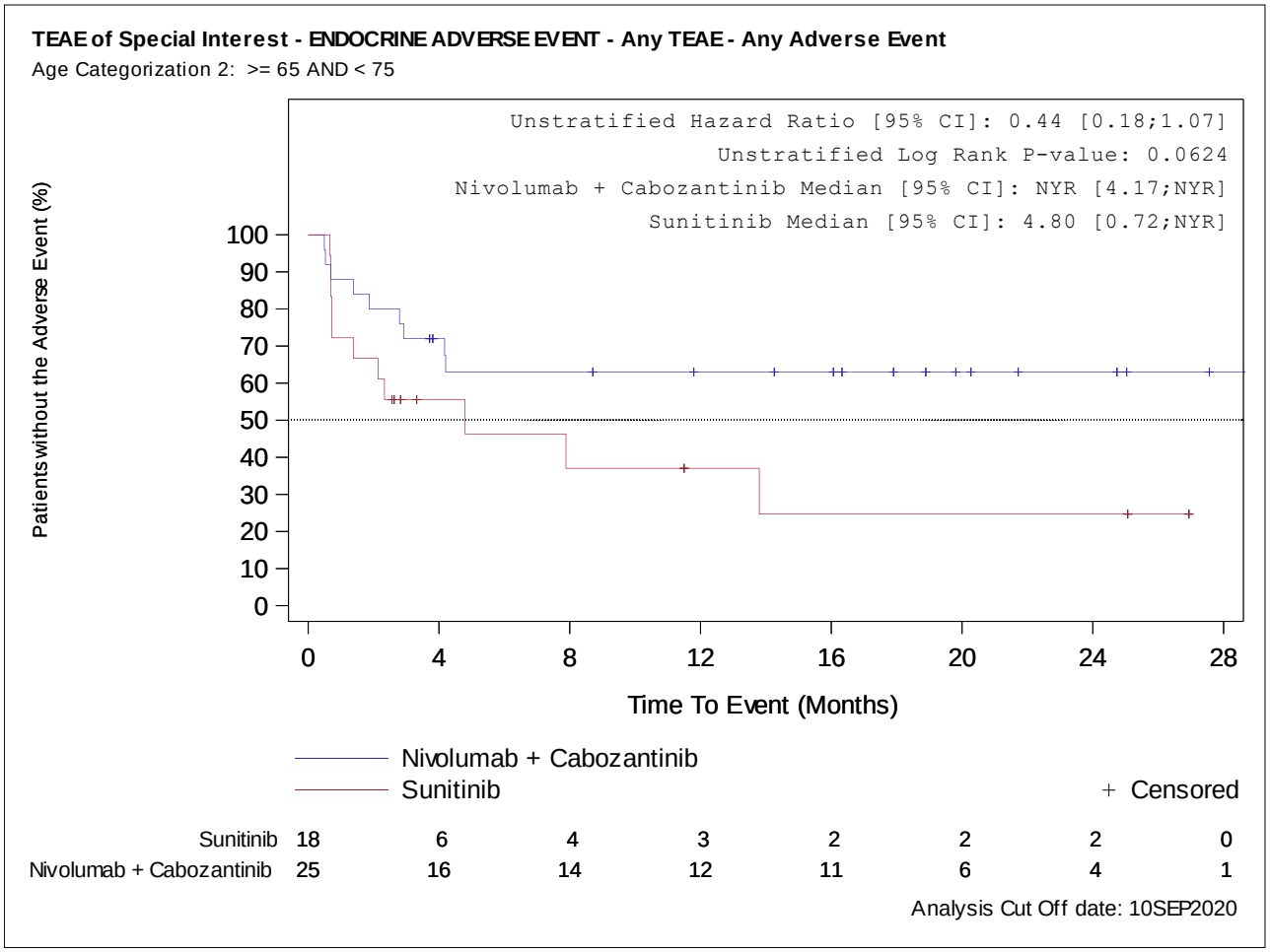

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:33:02

FIGURE 3.17.2.3: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



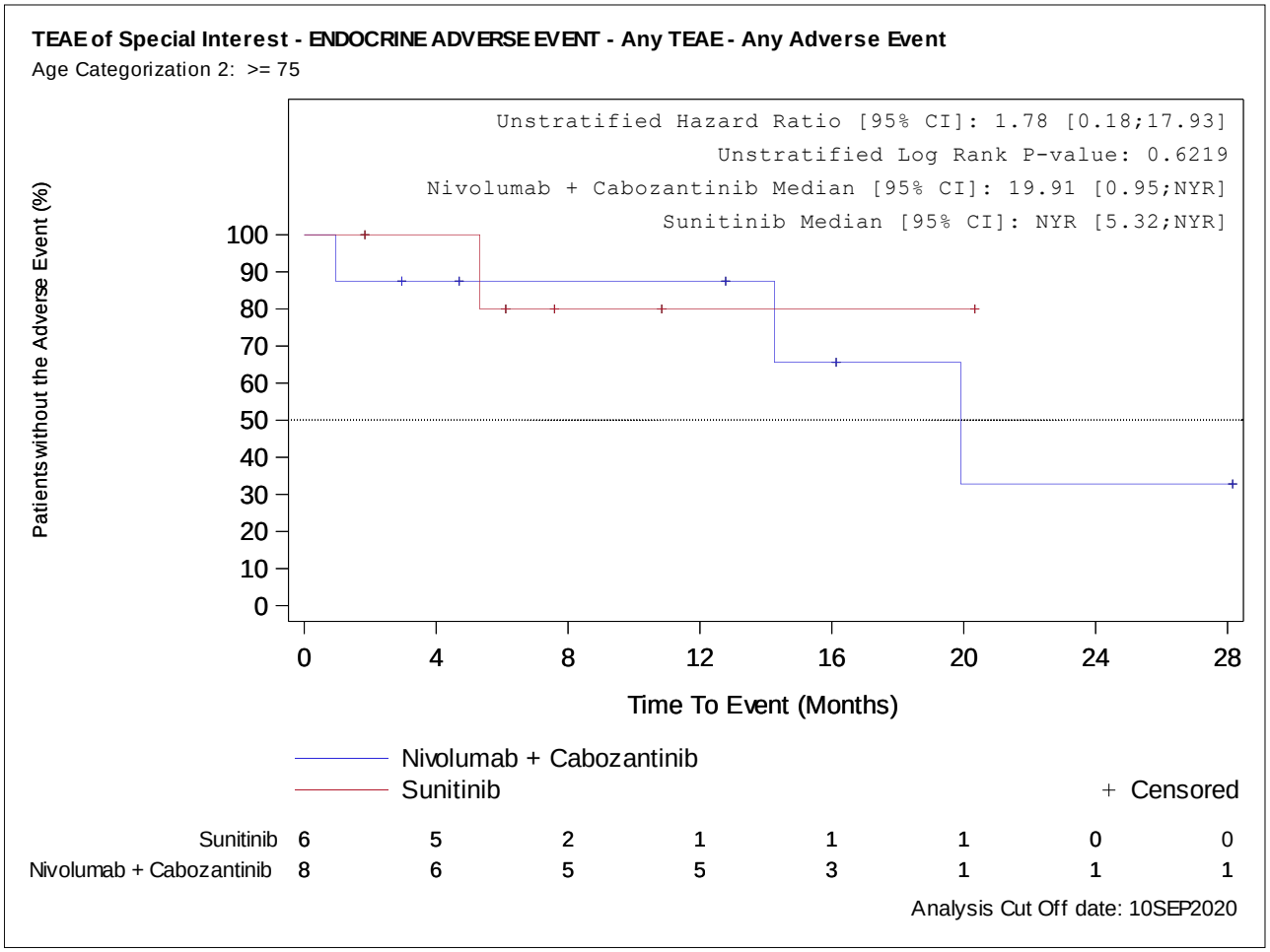

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:33:09

FIGURE 3.17.2.4: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



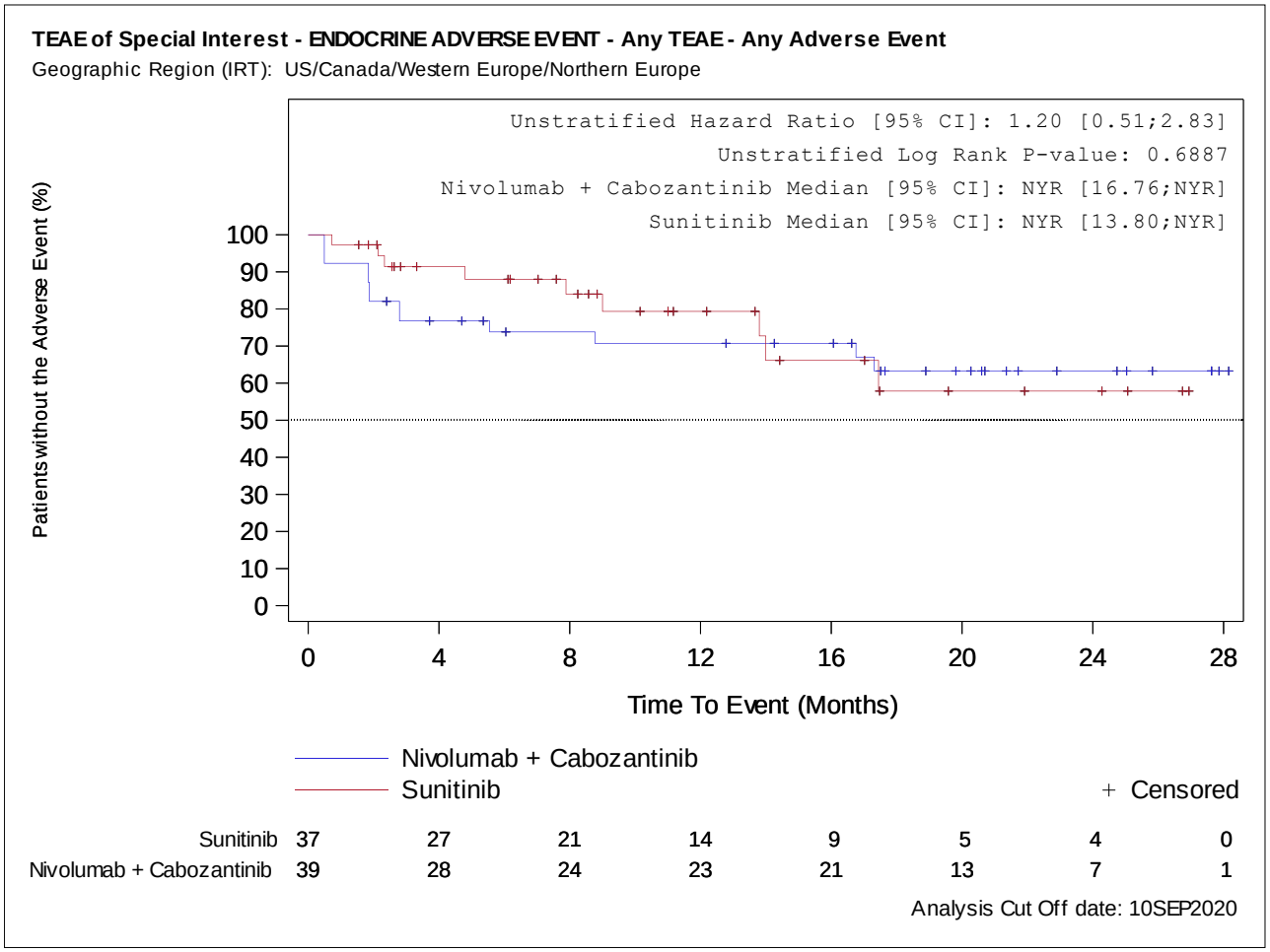

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:33:15

FIGURE 3.17.2.5: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



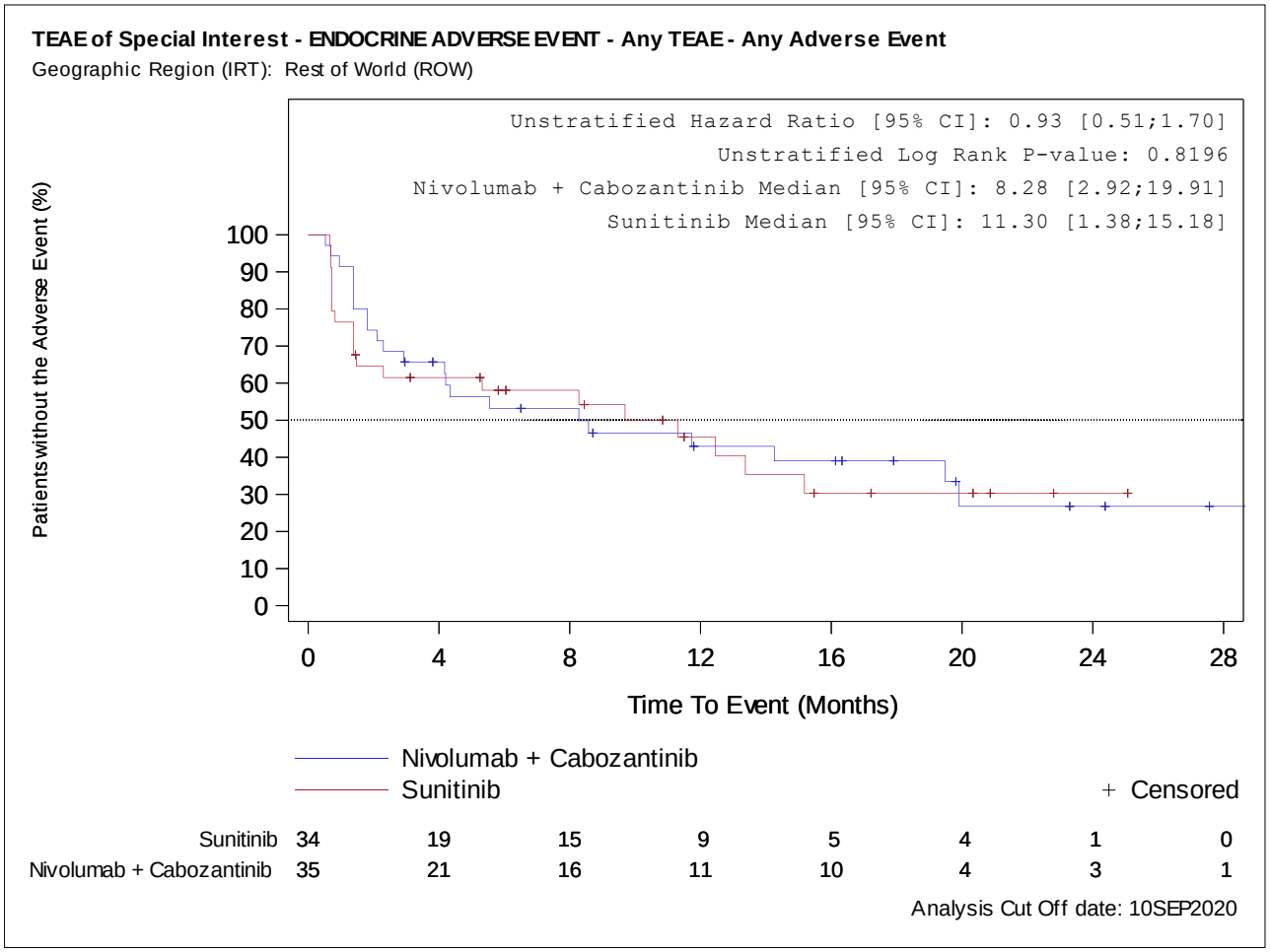

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:33:20

FIGURE 3.17.2.6: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



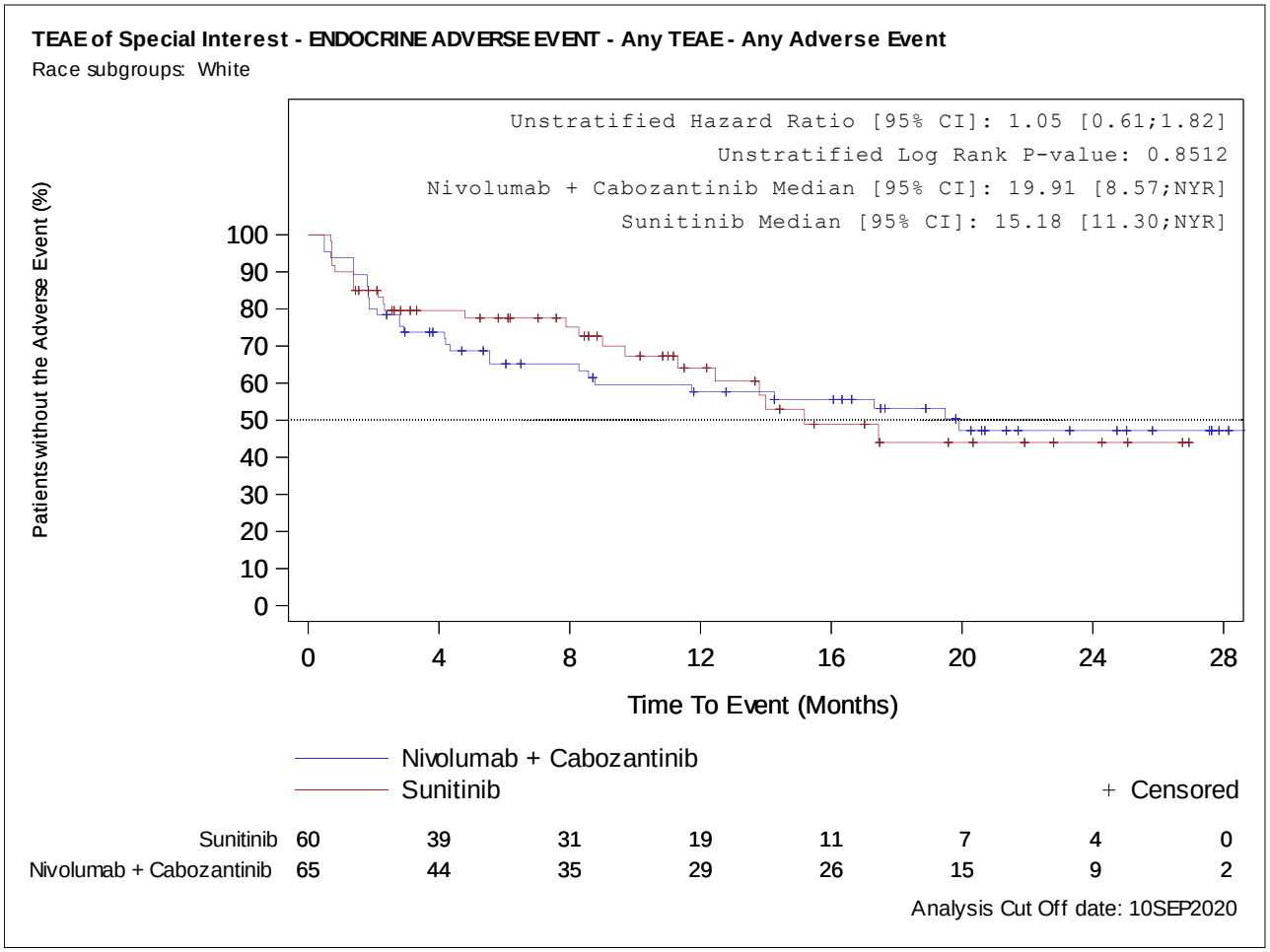

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:33:27

FIGURE 3.17.2.7: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



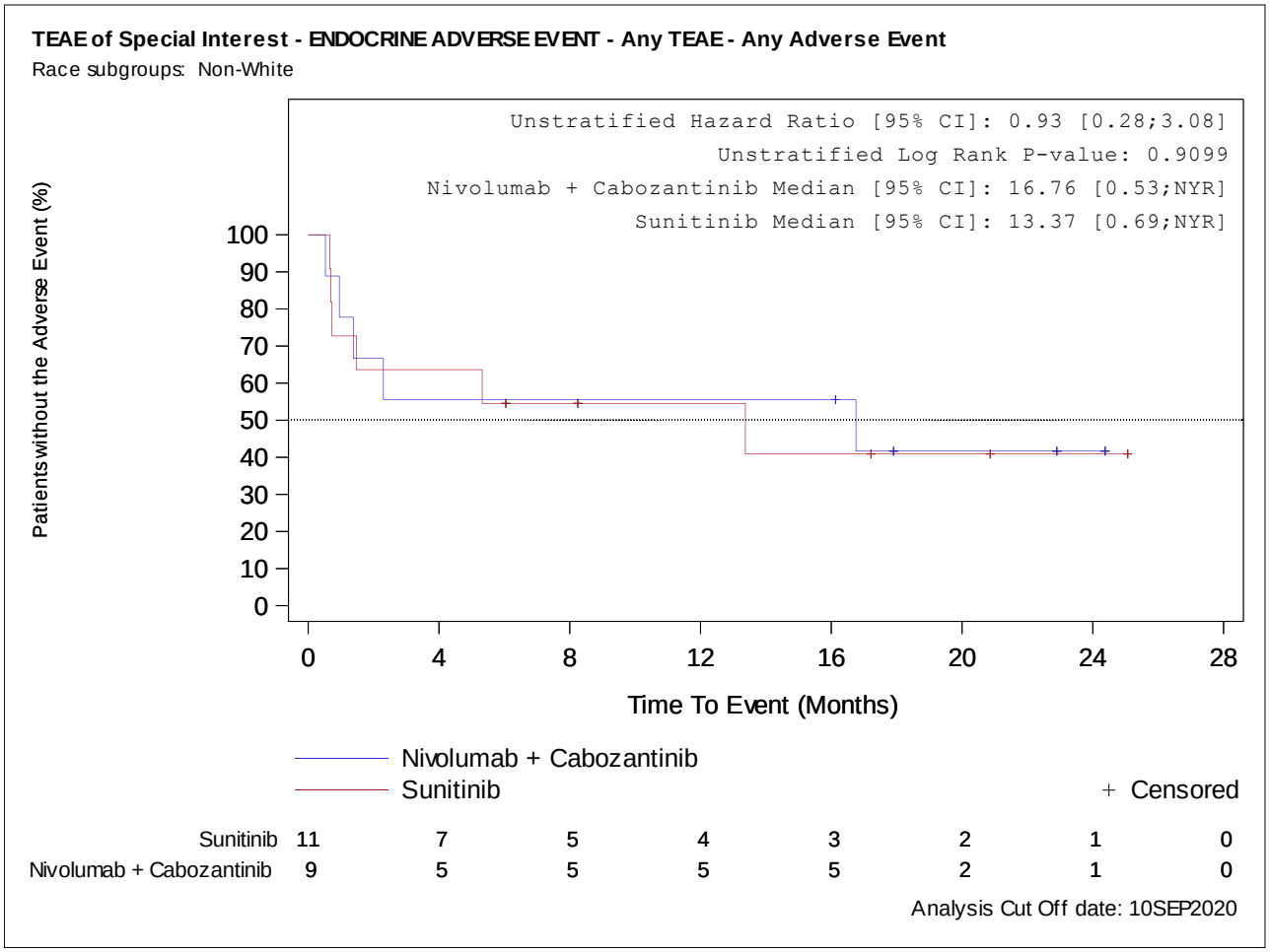

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:33:33

FIGURE 3.17.2.8: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



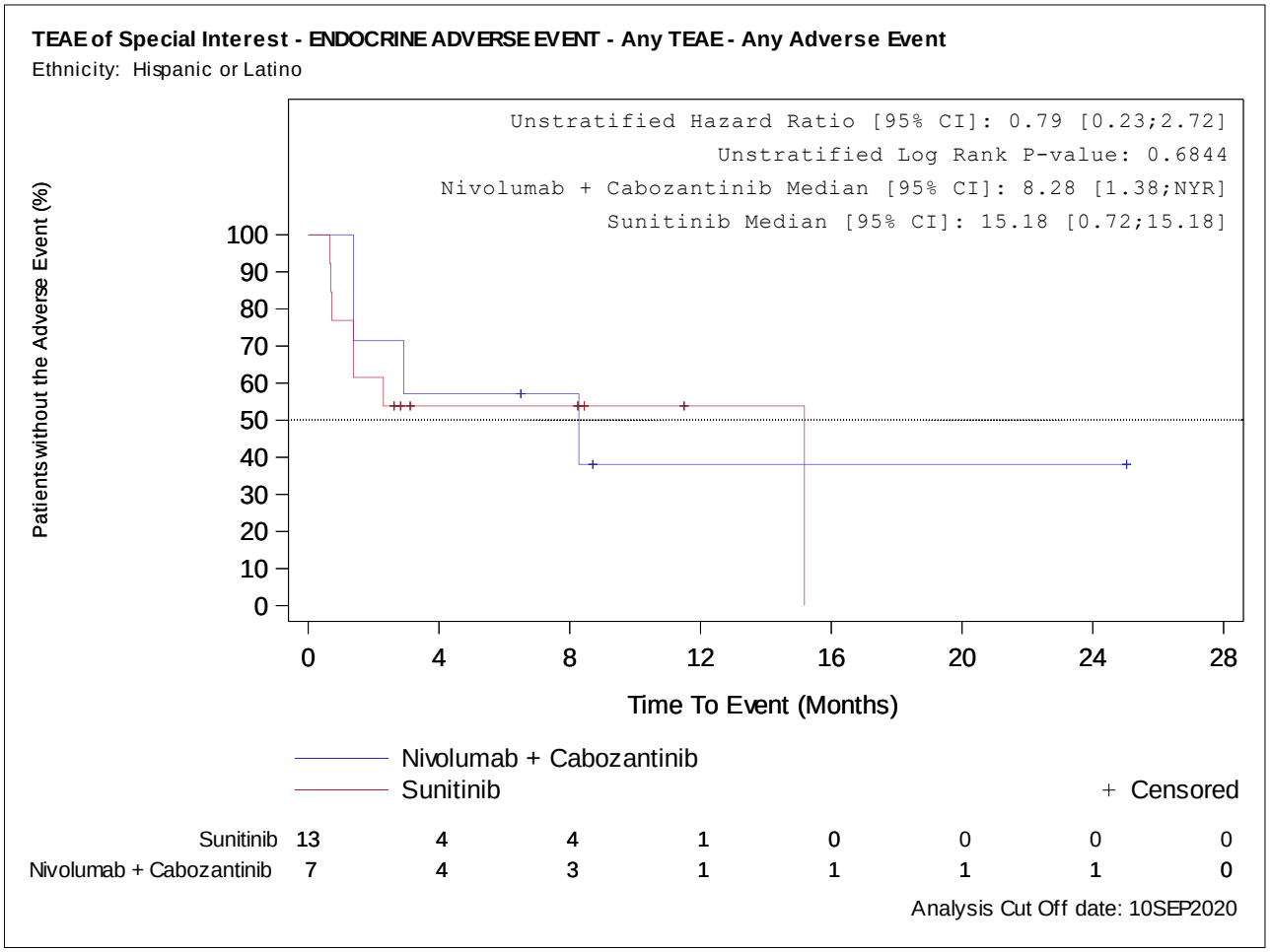

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:33:38

FIGURE 3.17.2.9: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



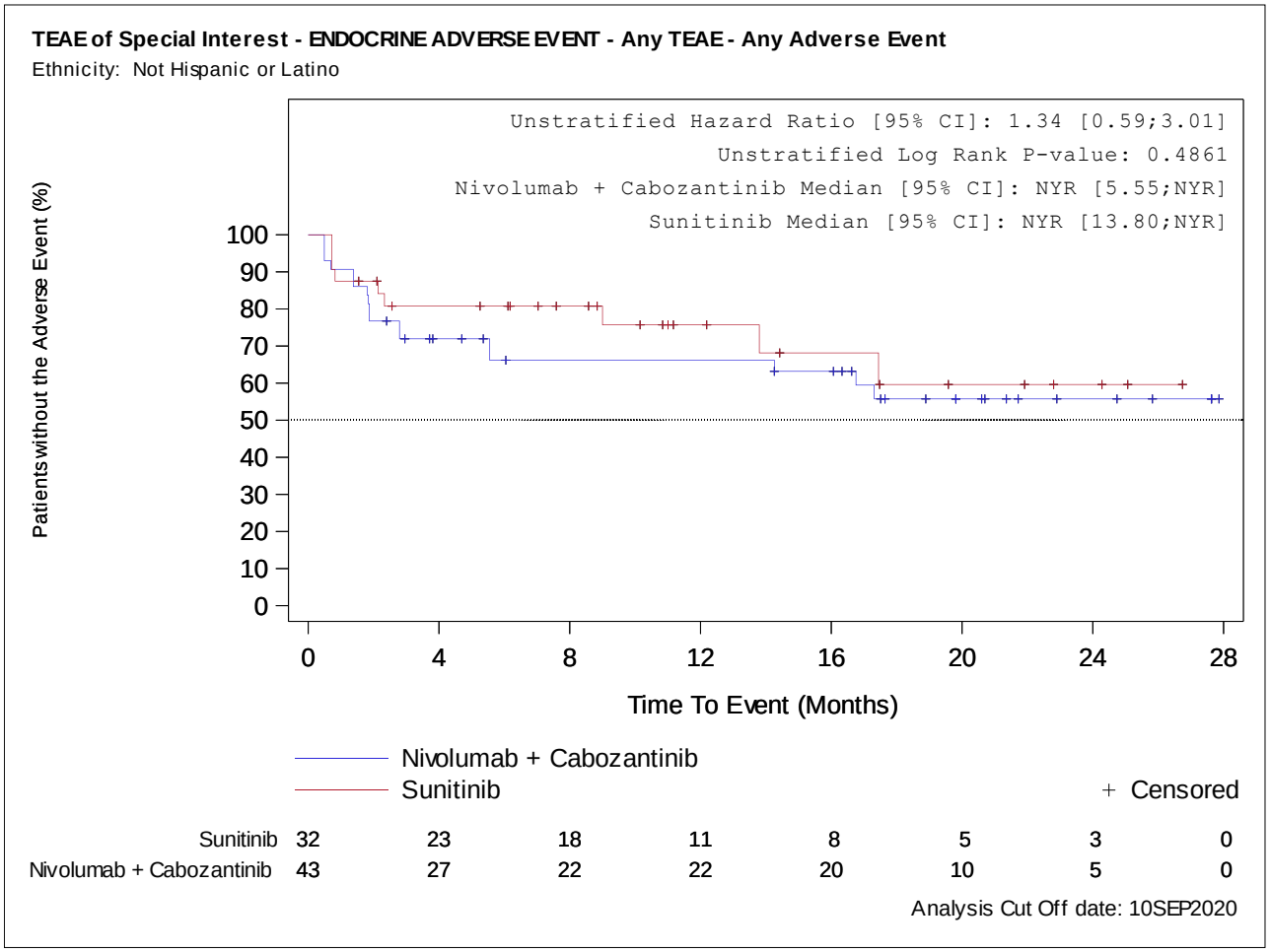

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:33:44

FIGURE 3.17.2.10: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



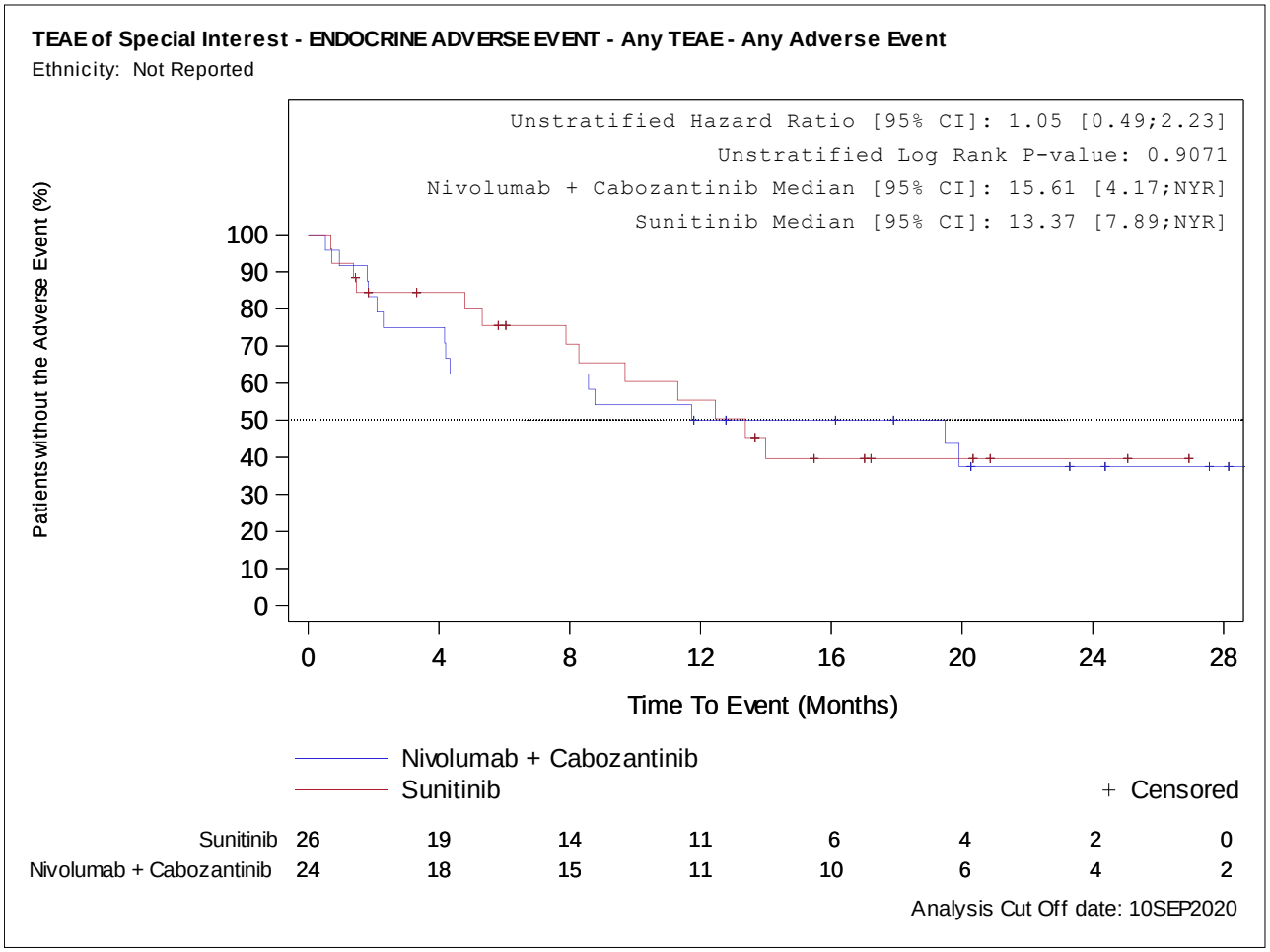

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:33:50

FIGURE 3.17.2.11: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



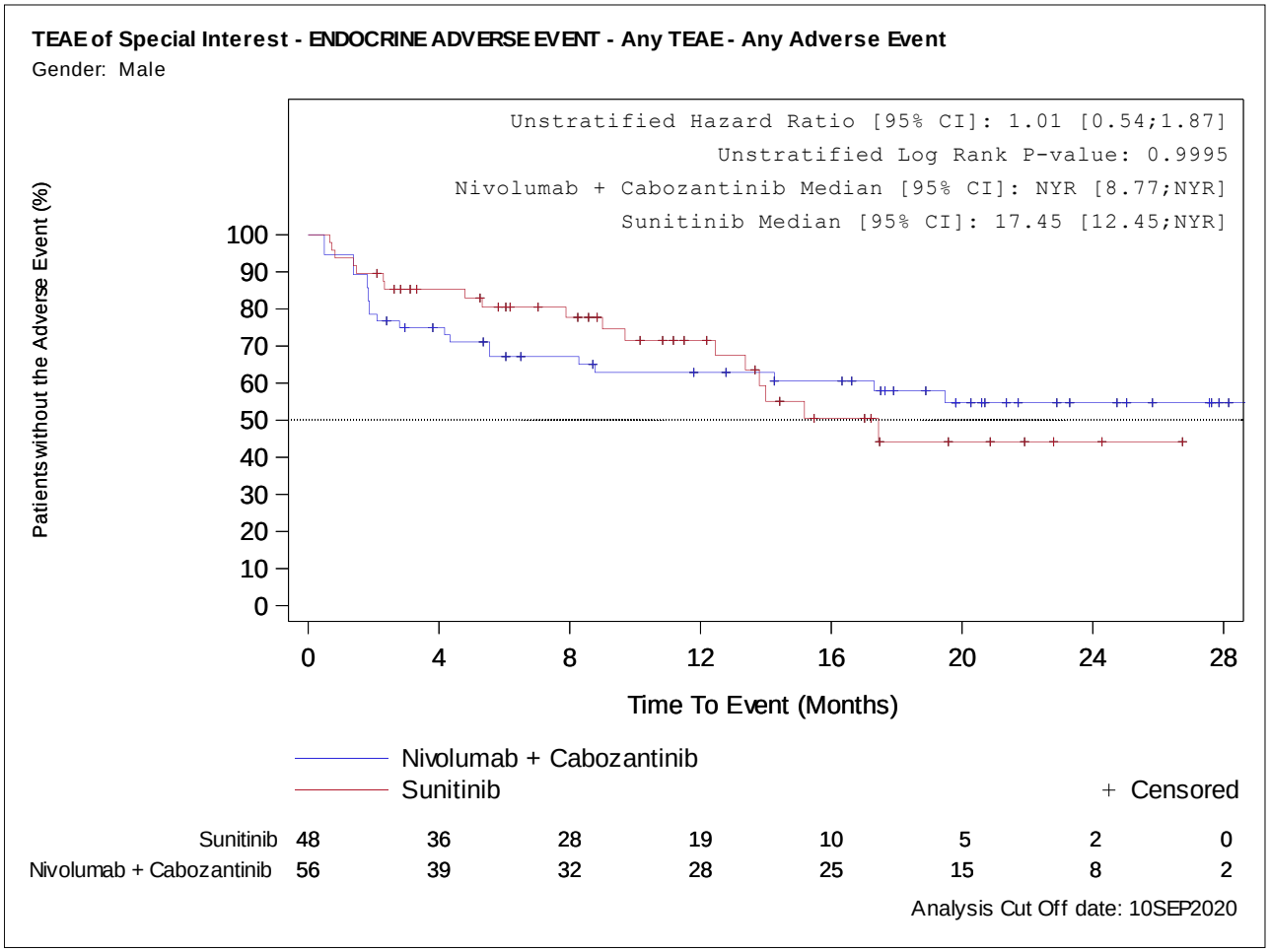

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:33:56

FIGURE 3.17.2.12: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



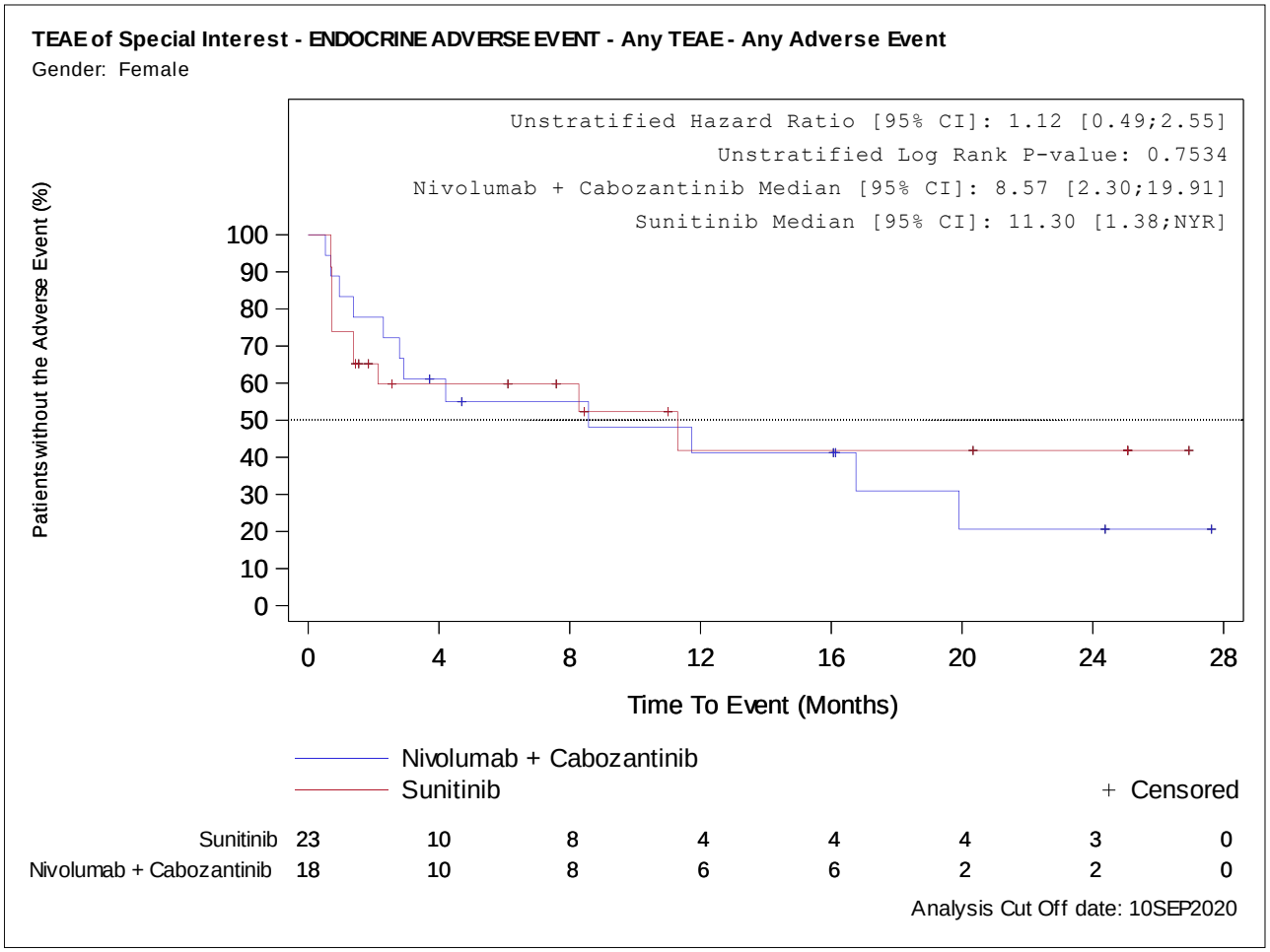

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:34:01

FIGURE 3.17.2.13: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



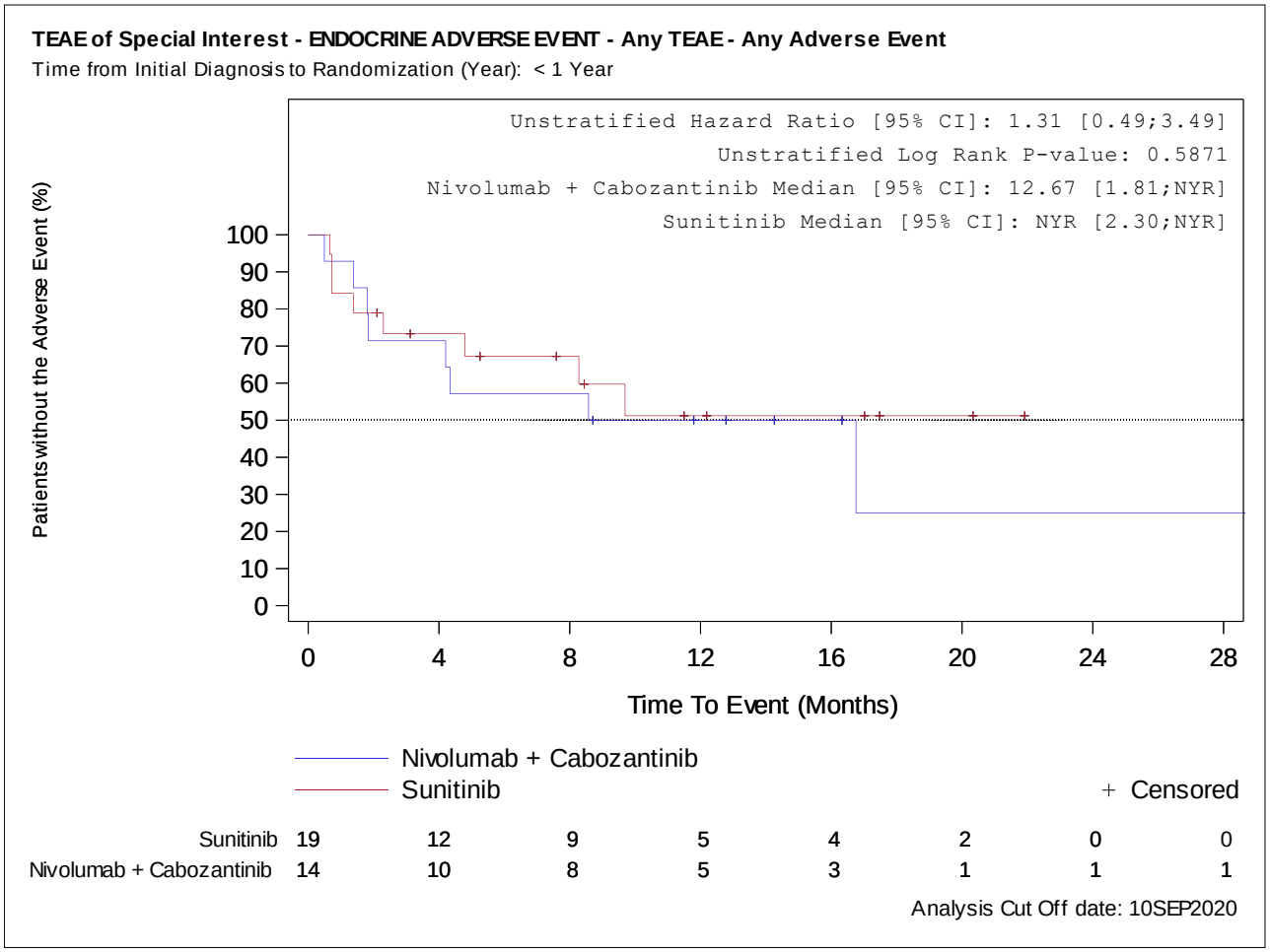

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:34:07

FIGURE 3.17.2.14: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



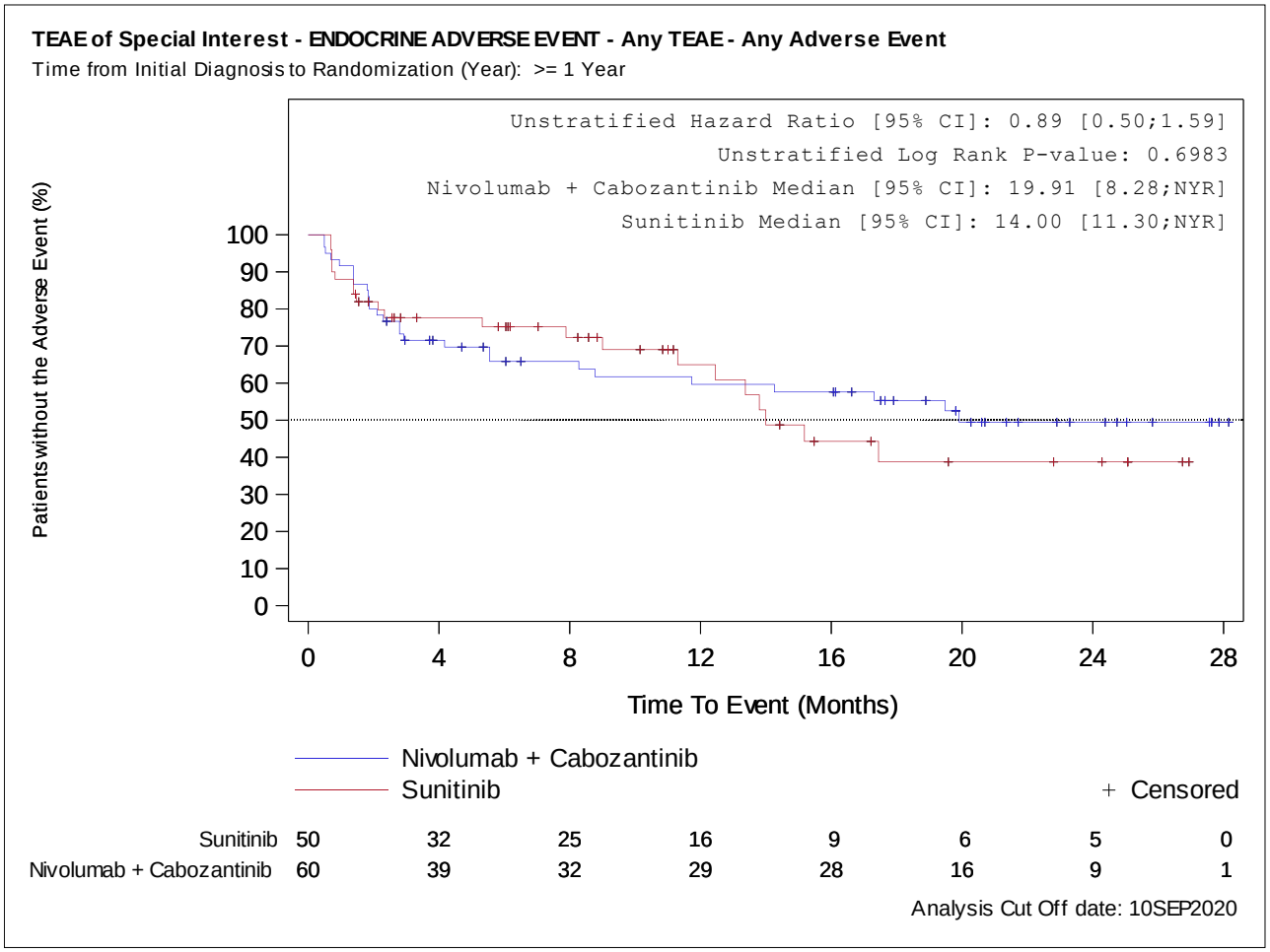

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:34:13

FIGURE 3.17.2.15: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



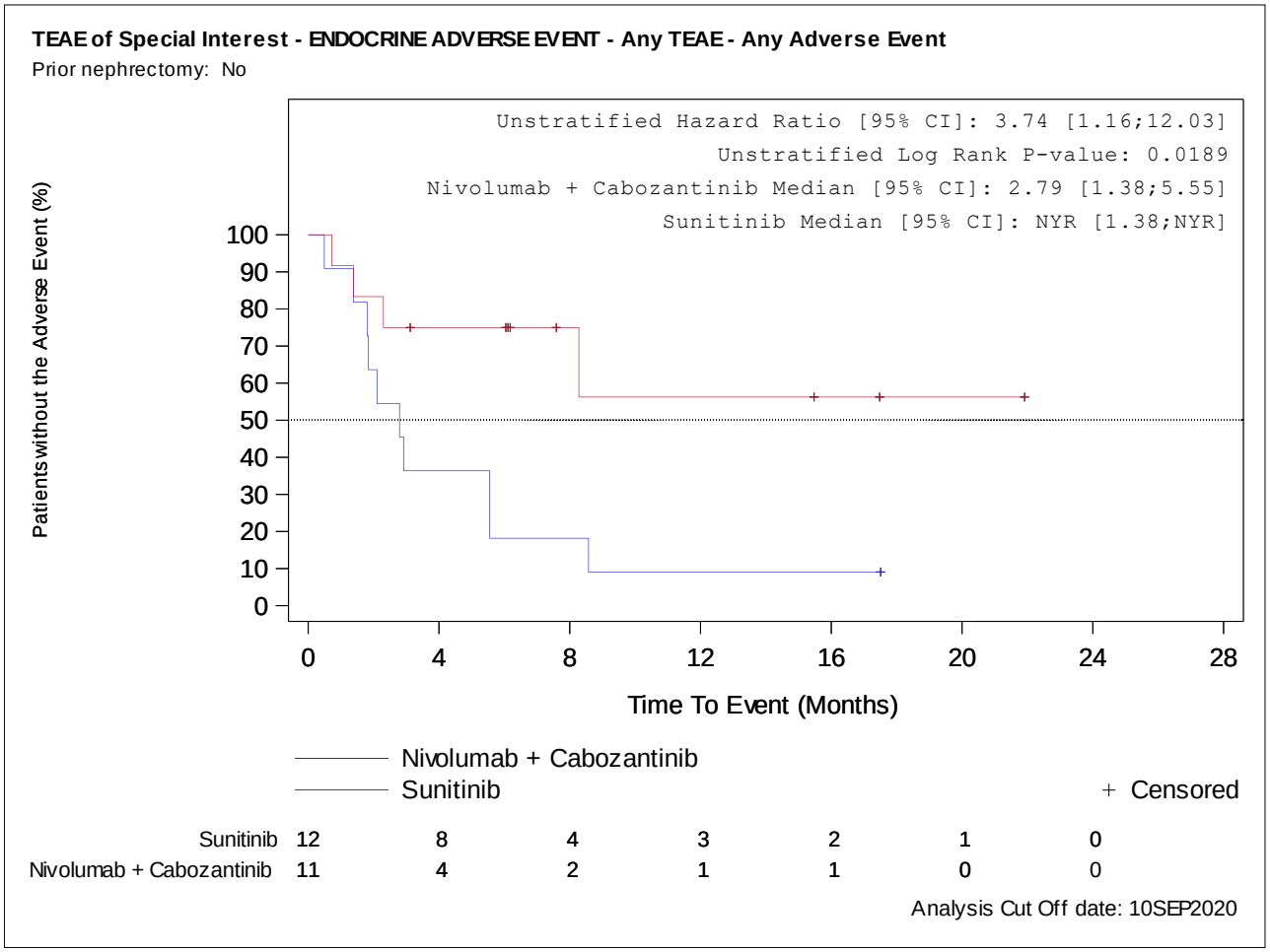

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:34:30

FIGURE 3.17.2.16: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



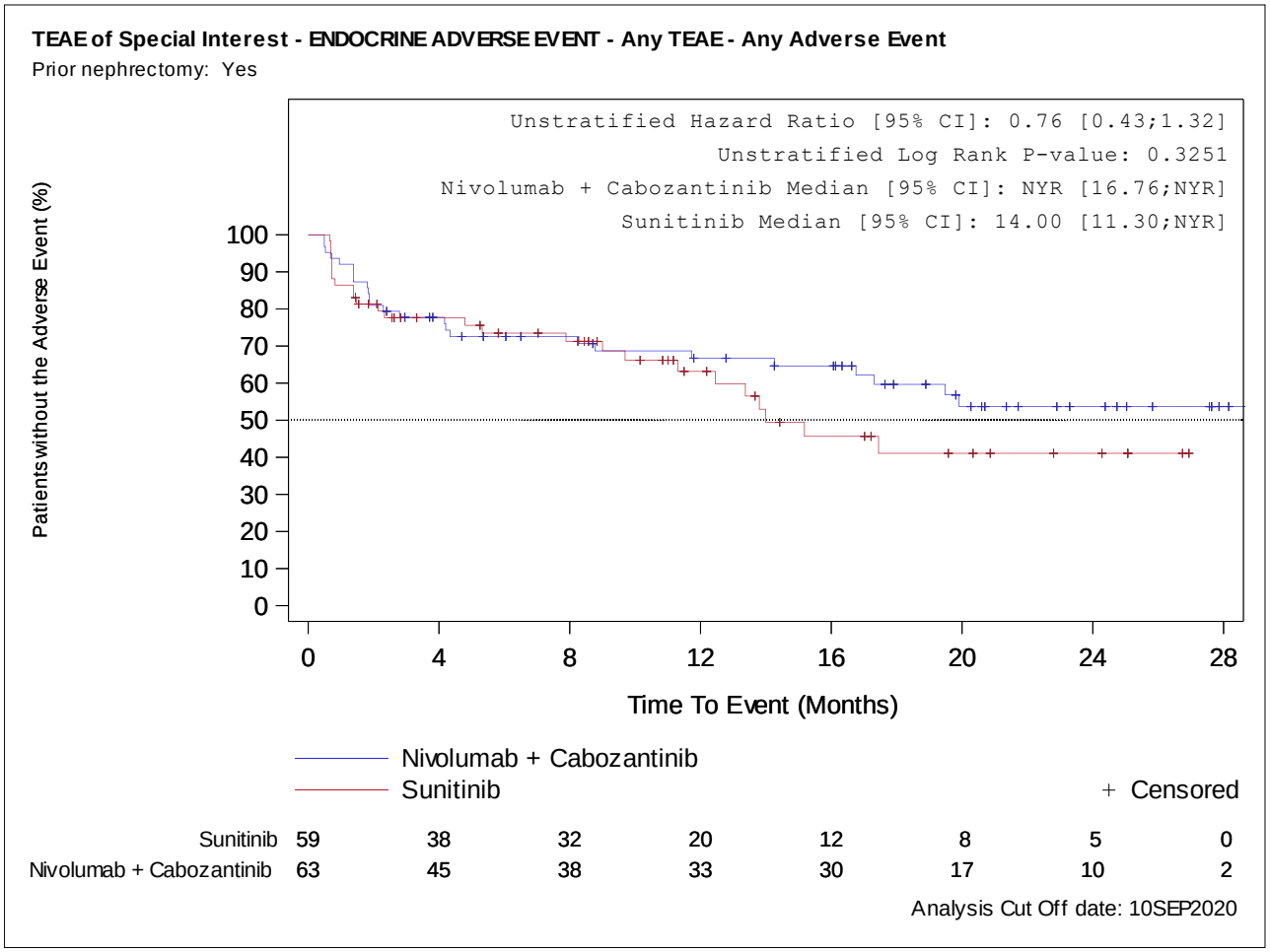

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:34:36

FIGURE 3.17.2.17: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



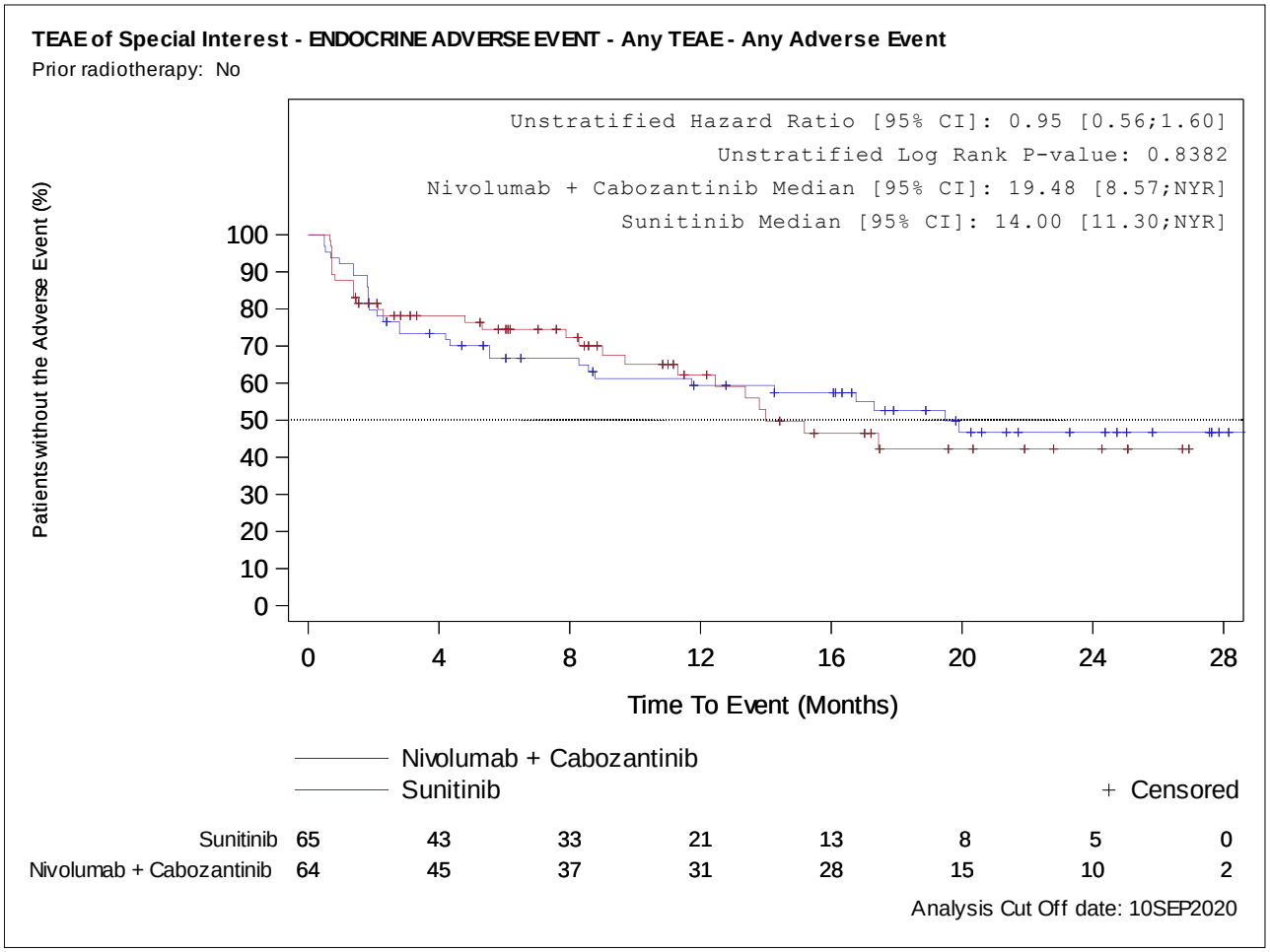

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:35:28

FIGURE 3.17.2.18: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



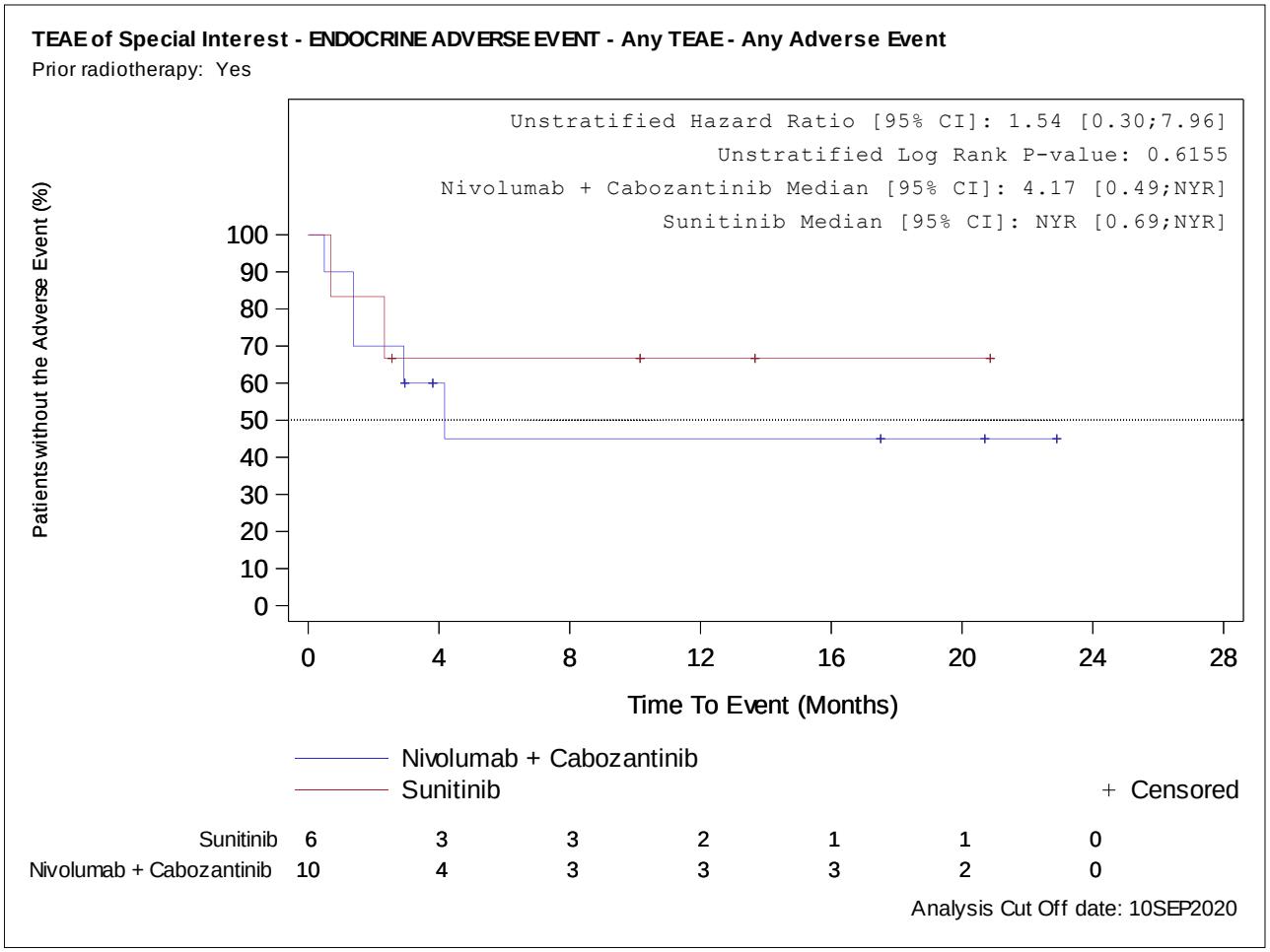

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:35:34

FIGURE 3.17.2.19: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



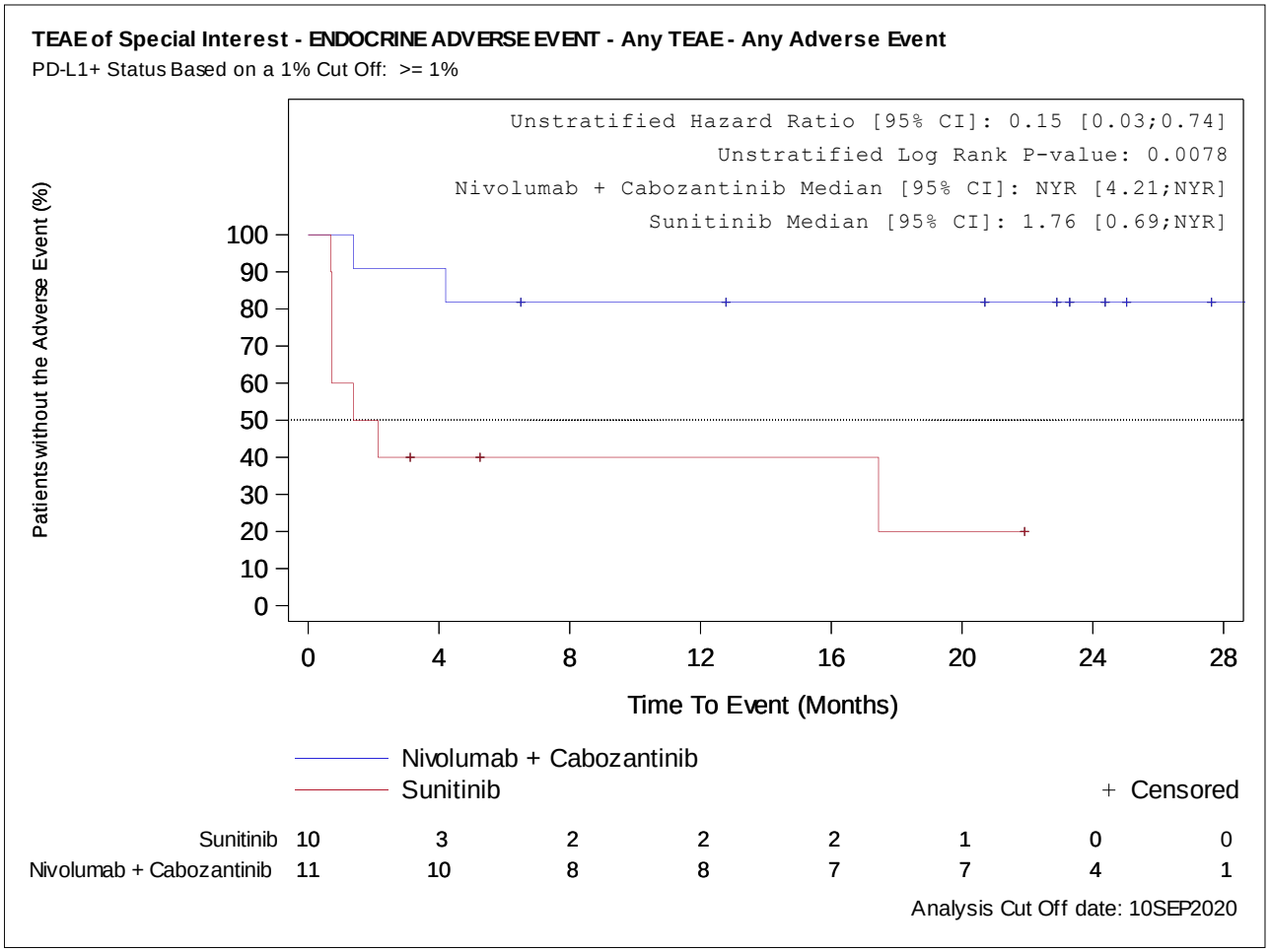

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:35:40

FIGURE 3.17.2.20: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



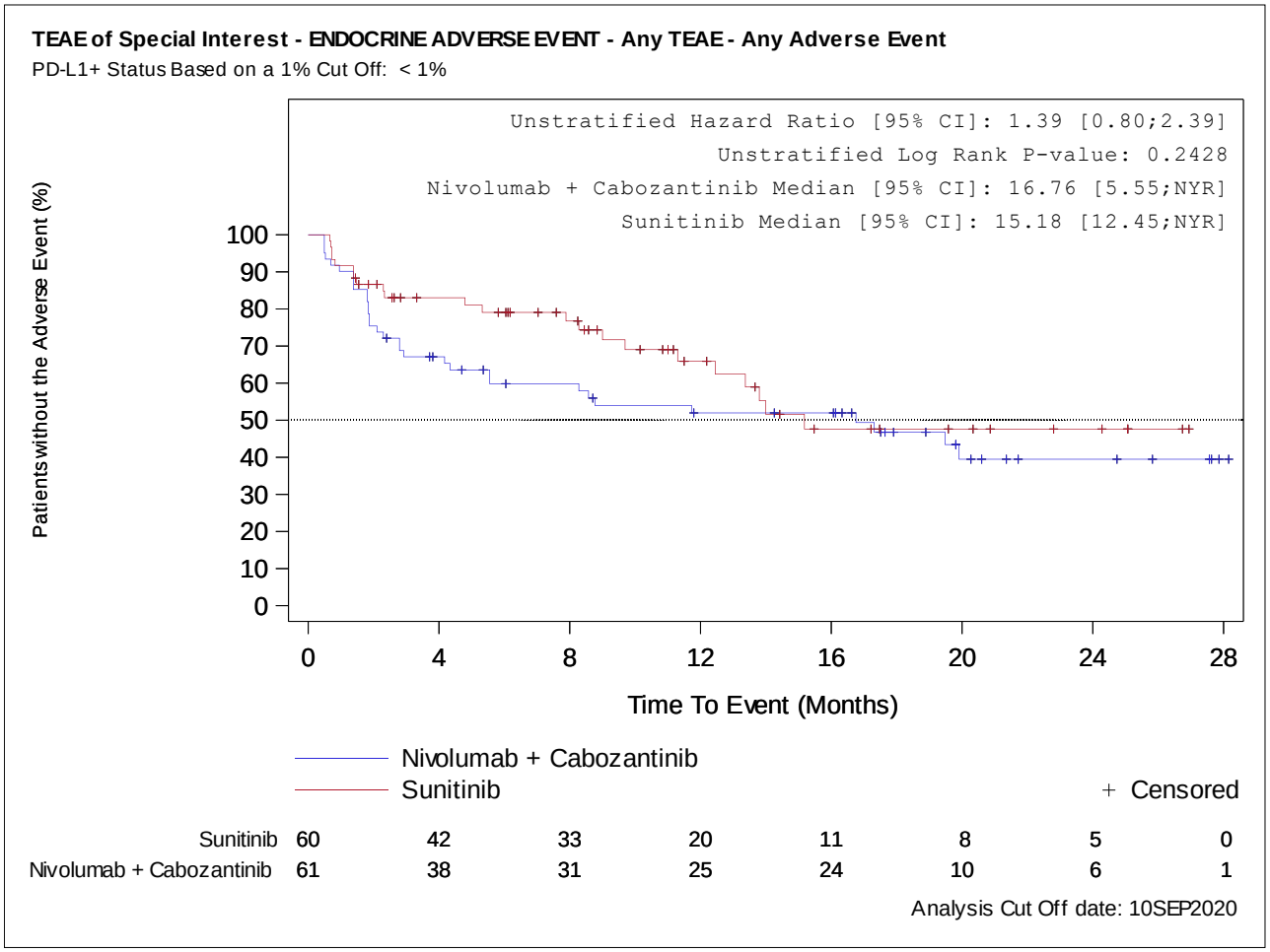

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:35:46

FIGURE 3.17.2.21: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:35:53

FIGURE 3.17.2.22: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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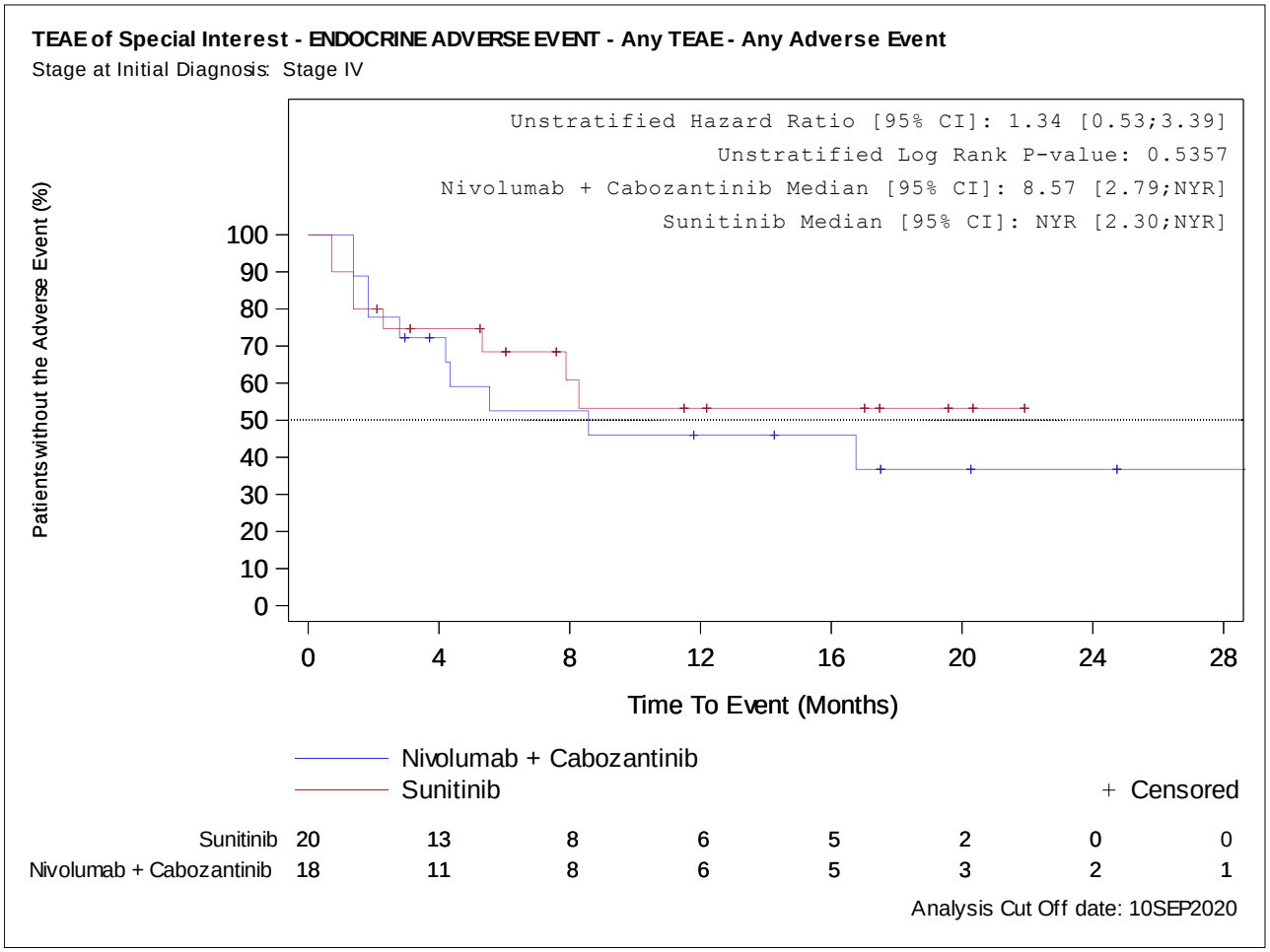
FIGURE 3.17.2.23: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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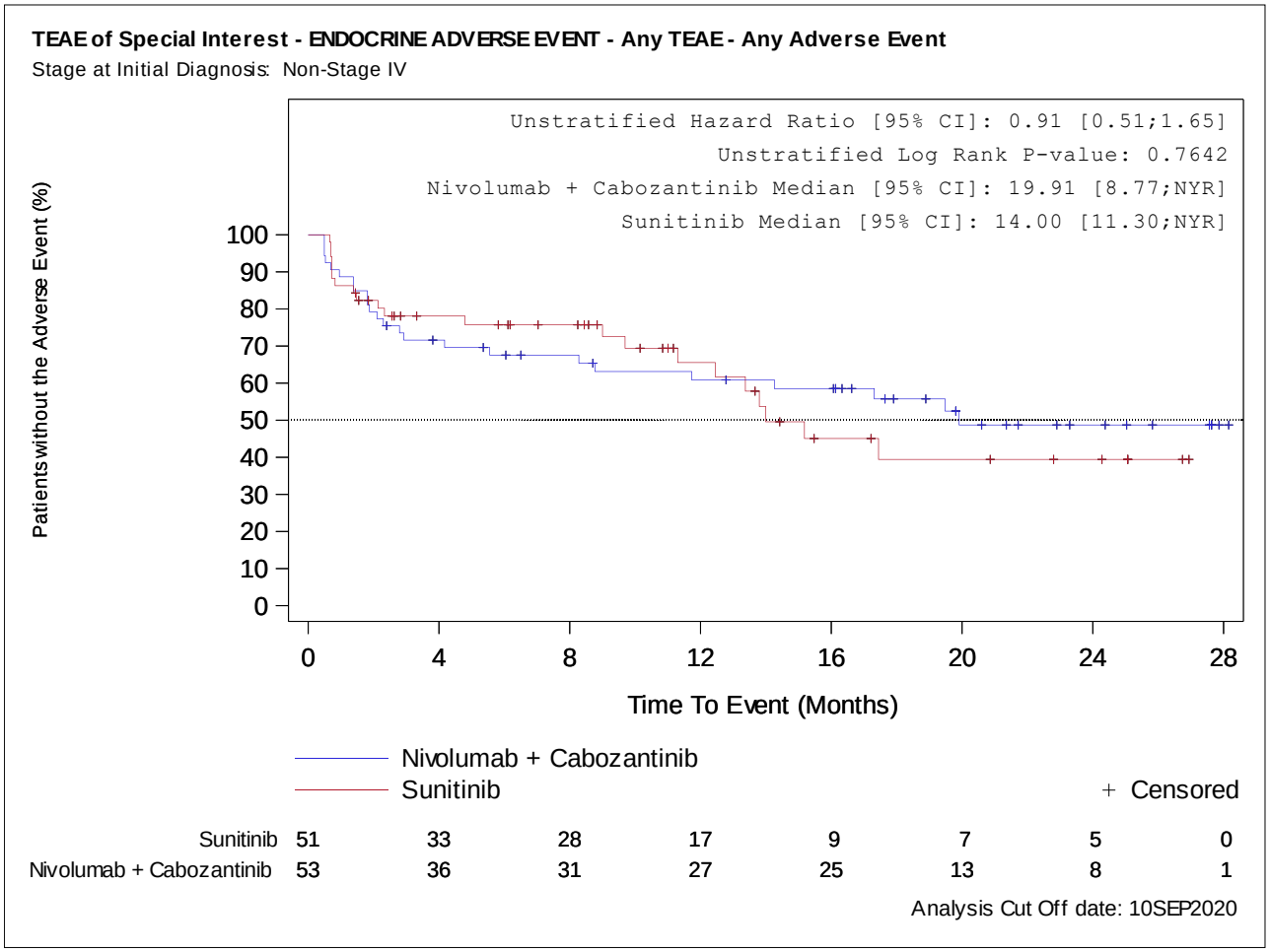
FIGURE 3.17.2.24: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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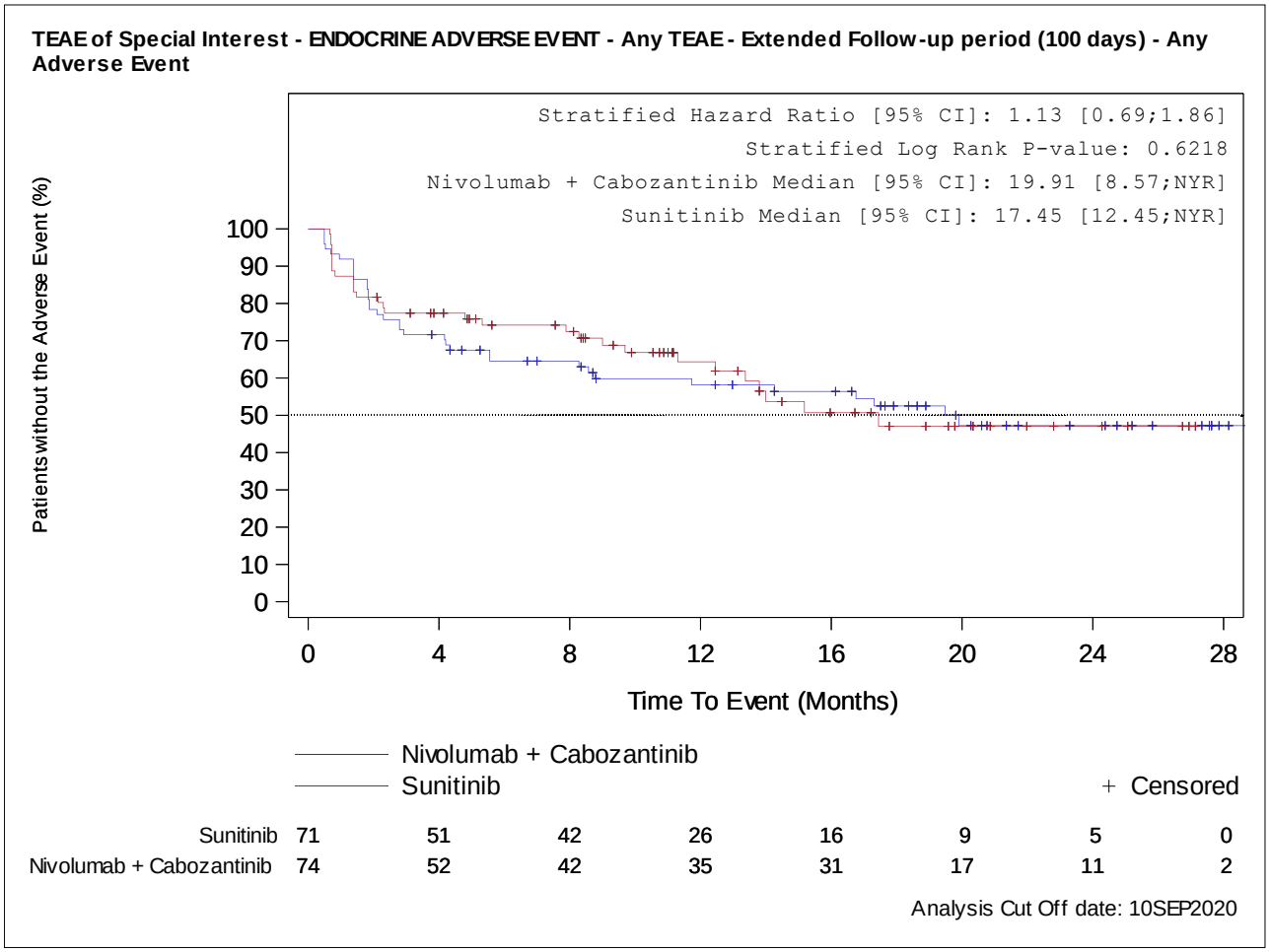
FIGURE 3.18.1: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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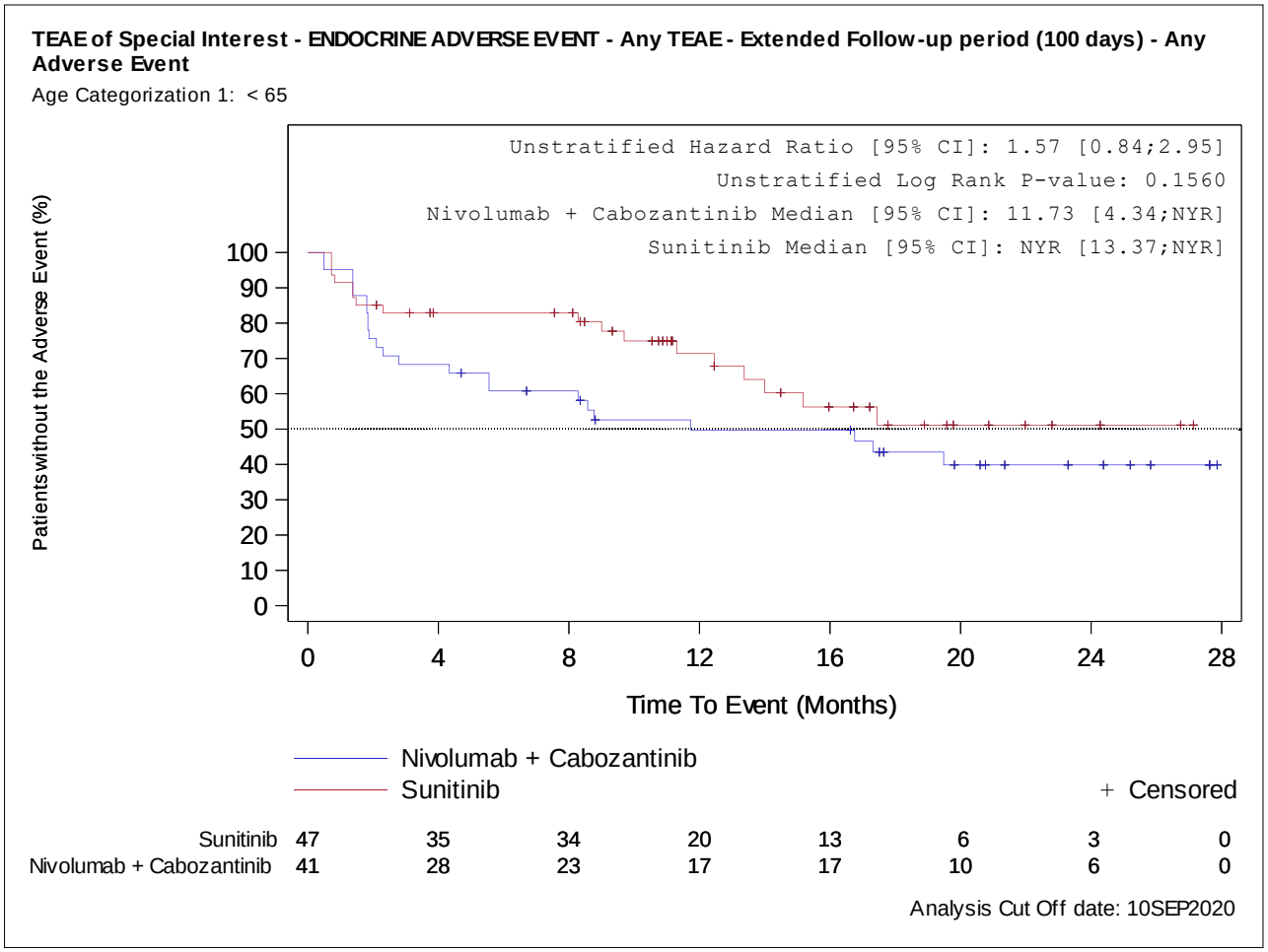
FIGURE 3.18.2.1: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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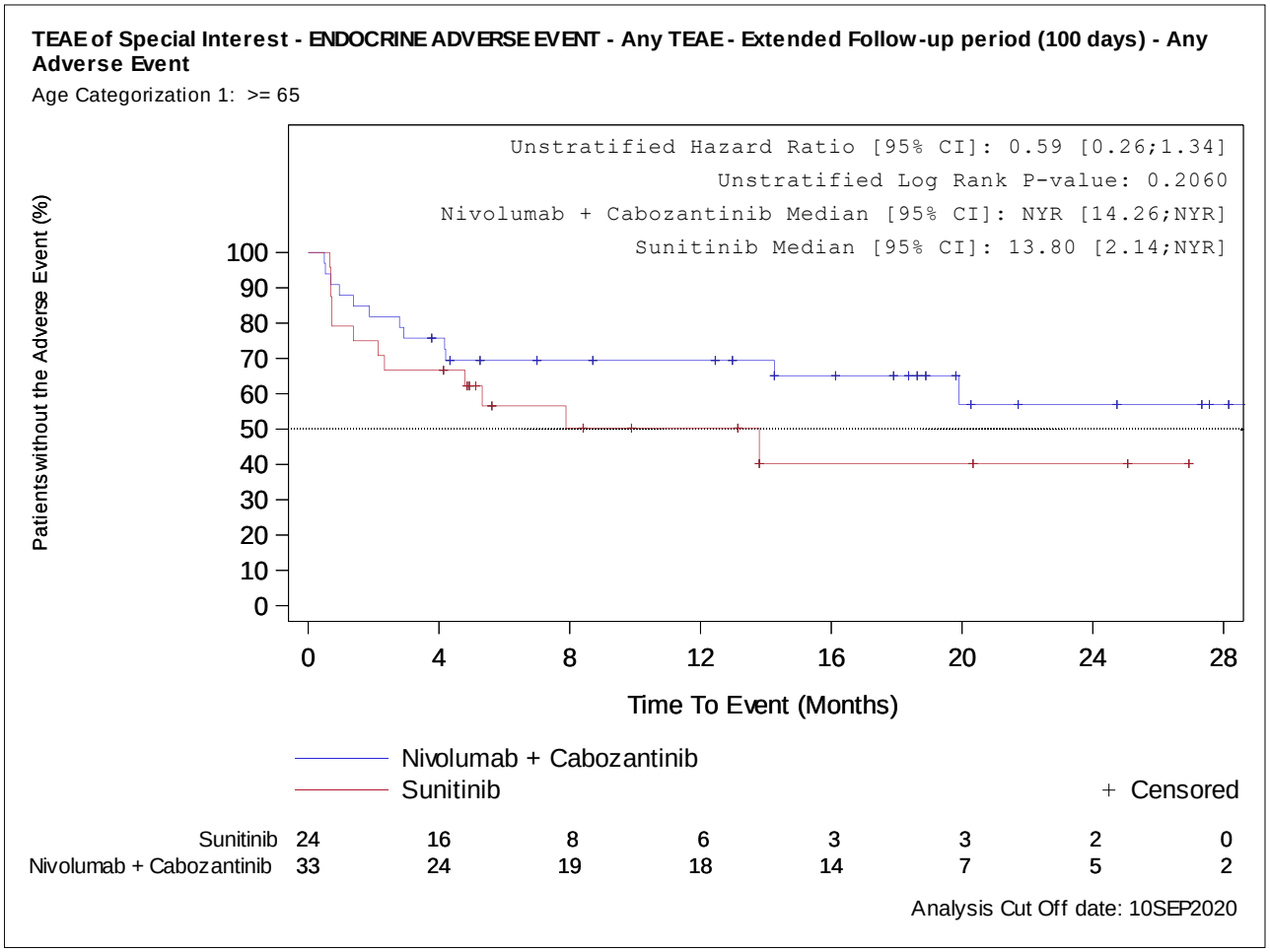
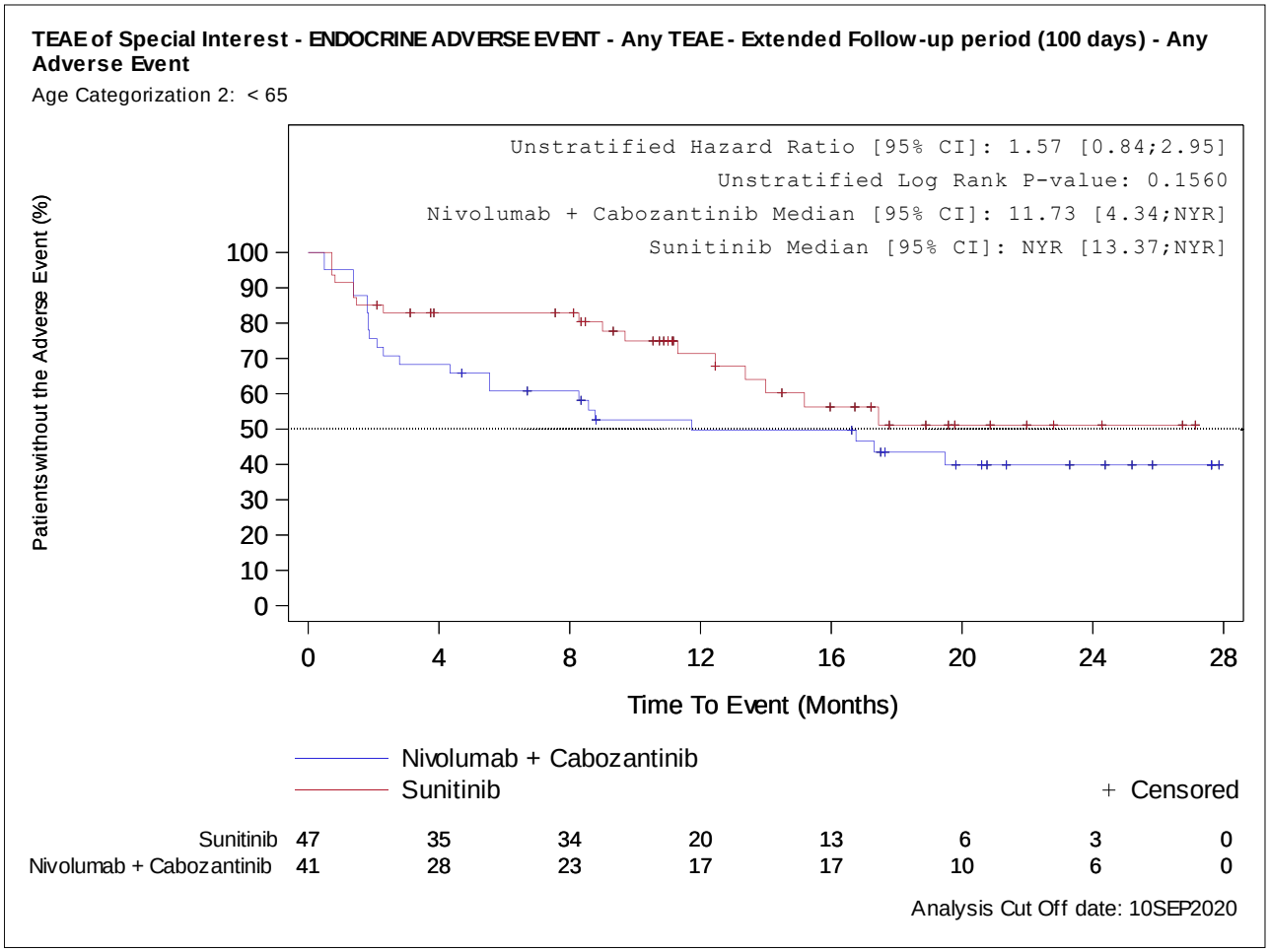
FIGURE 3.18.2.2: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



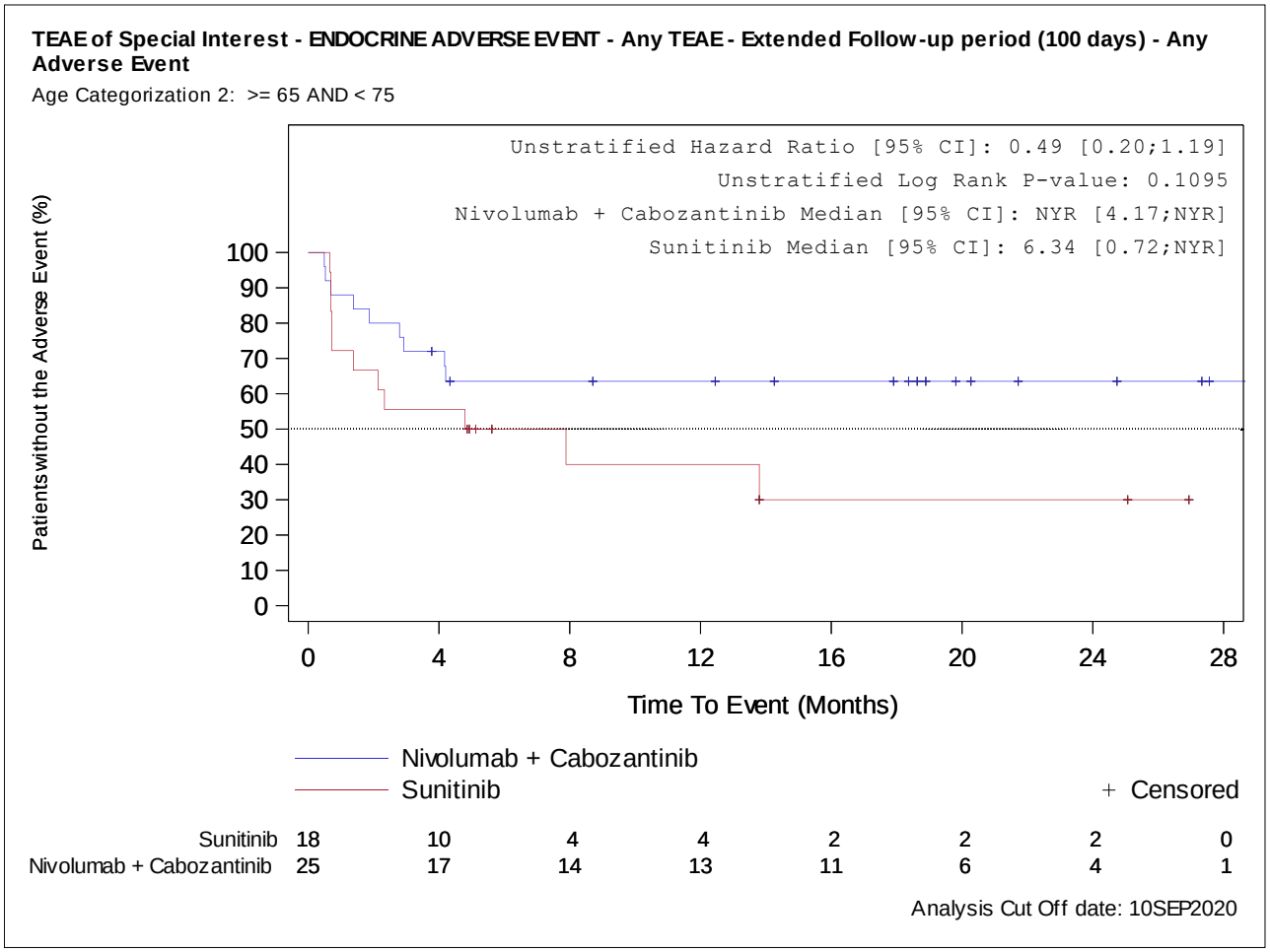

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:40:16

FIGURE 3.18.2.3: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



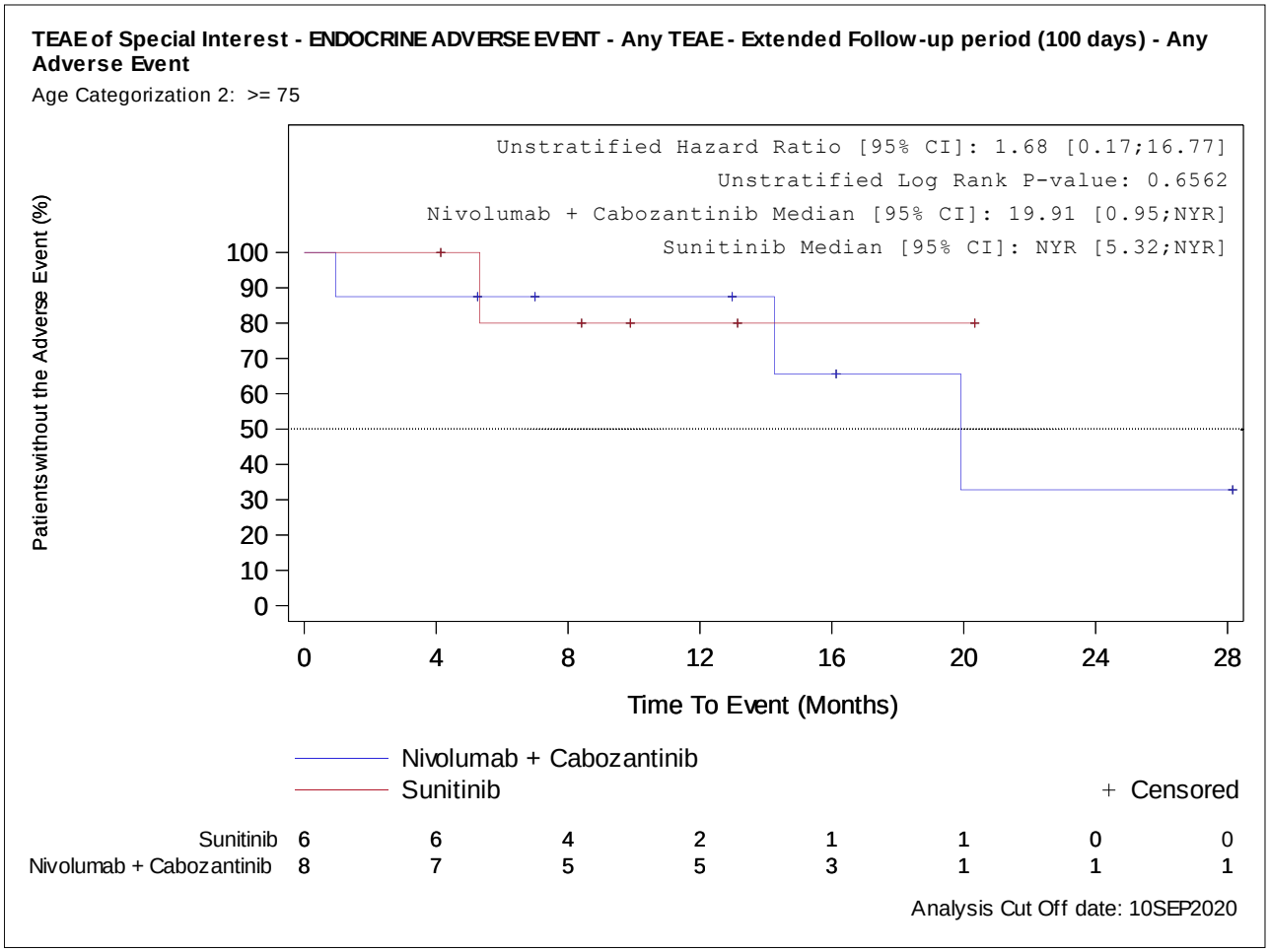

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:40:21

FIGURE 3.18.2.4: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



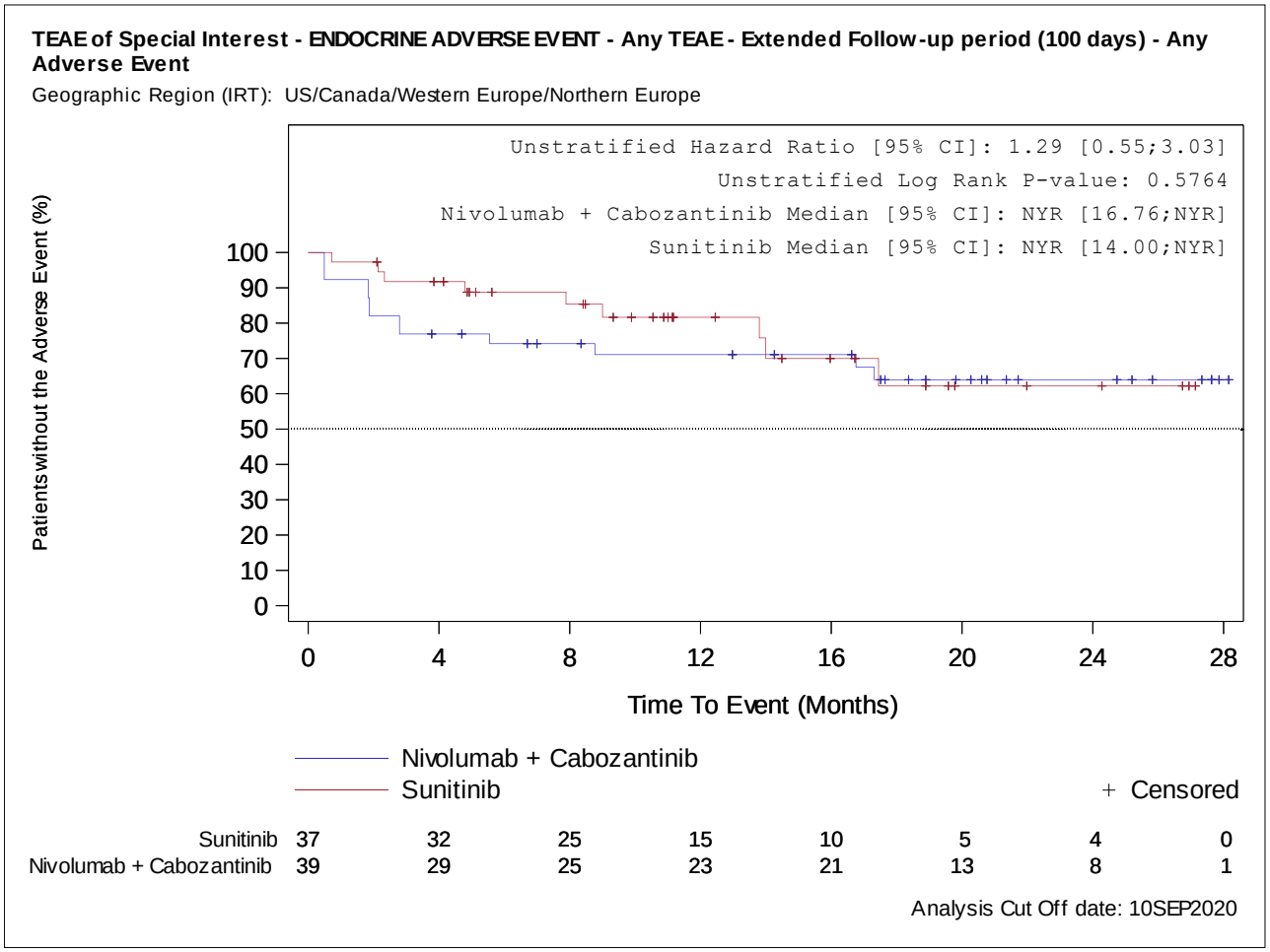

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:40:27

FIGURE 3.18.2.5: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



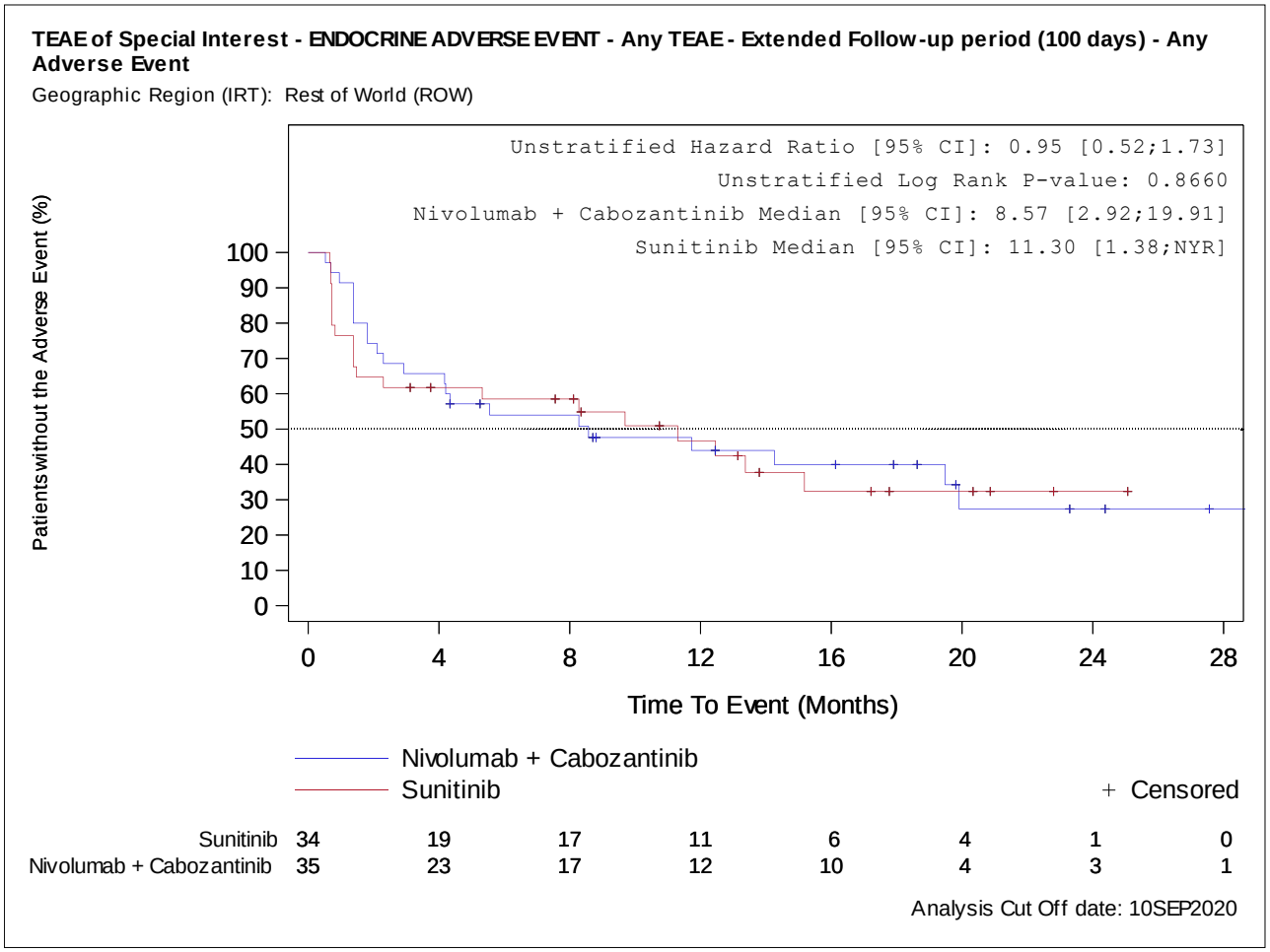

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:40:32

FIGURE 3.18.2.6: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



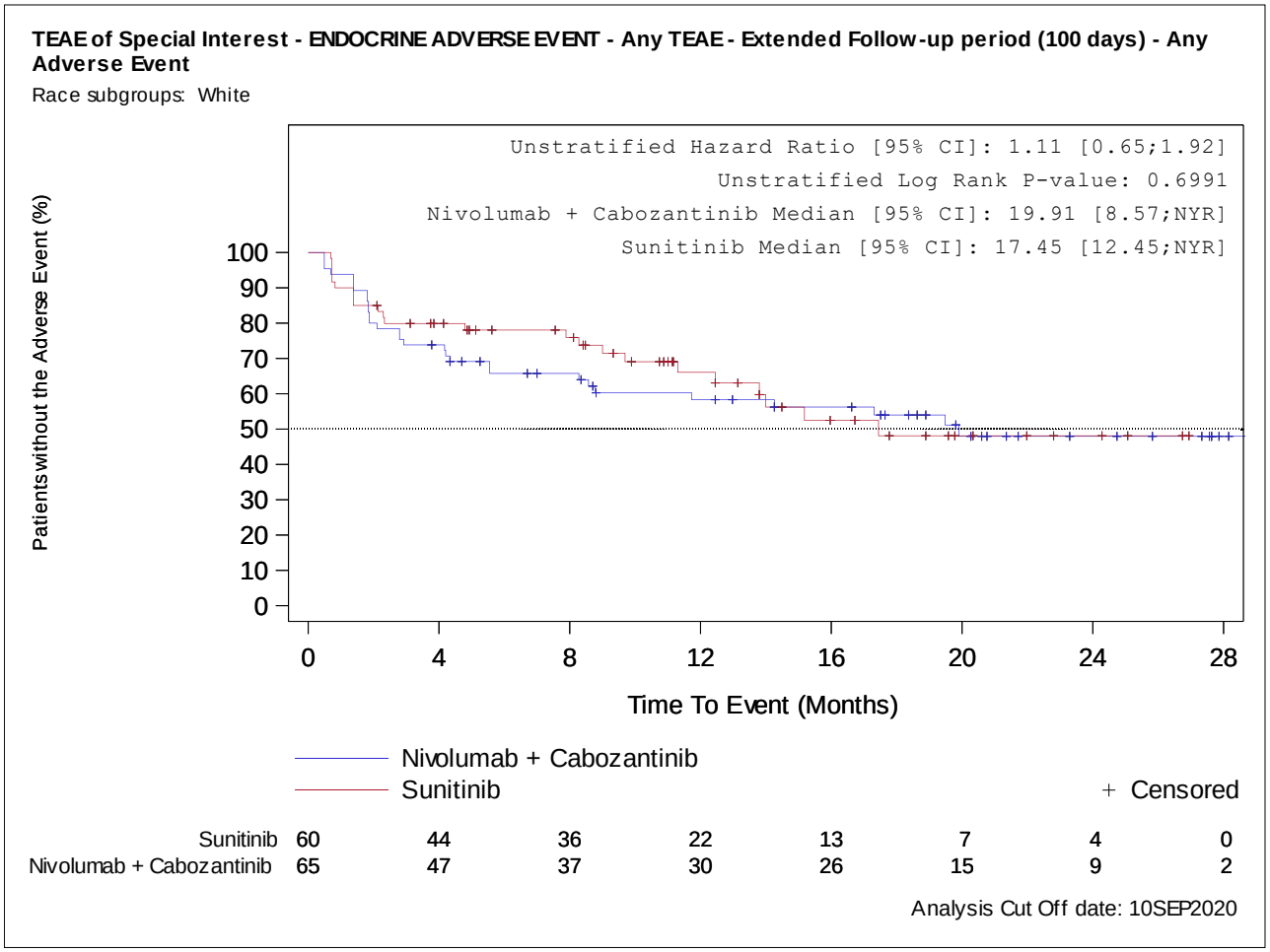

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:40:38

FIGURE 3.18.2.7: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



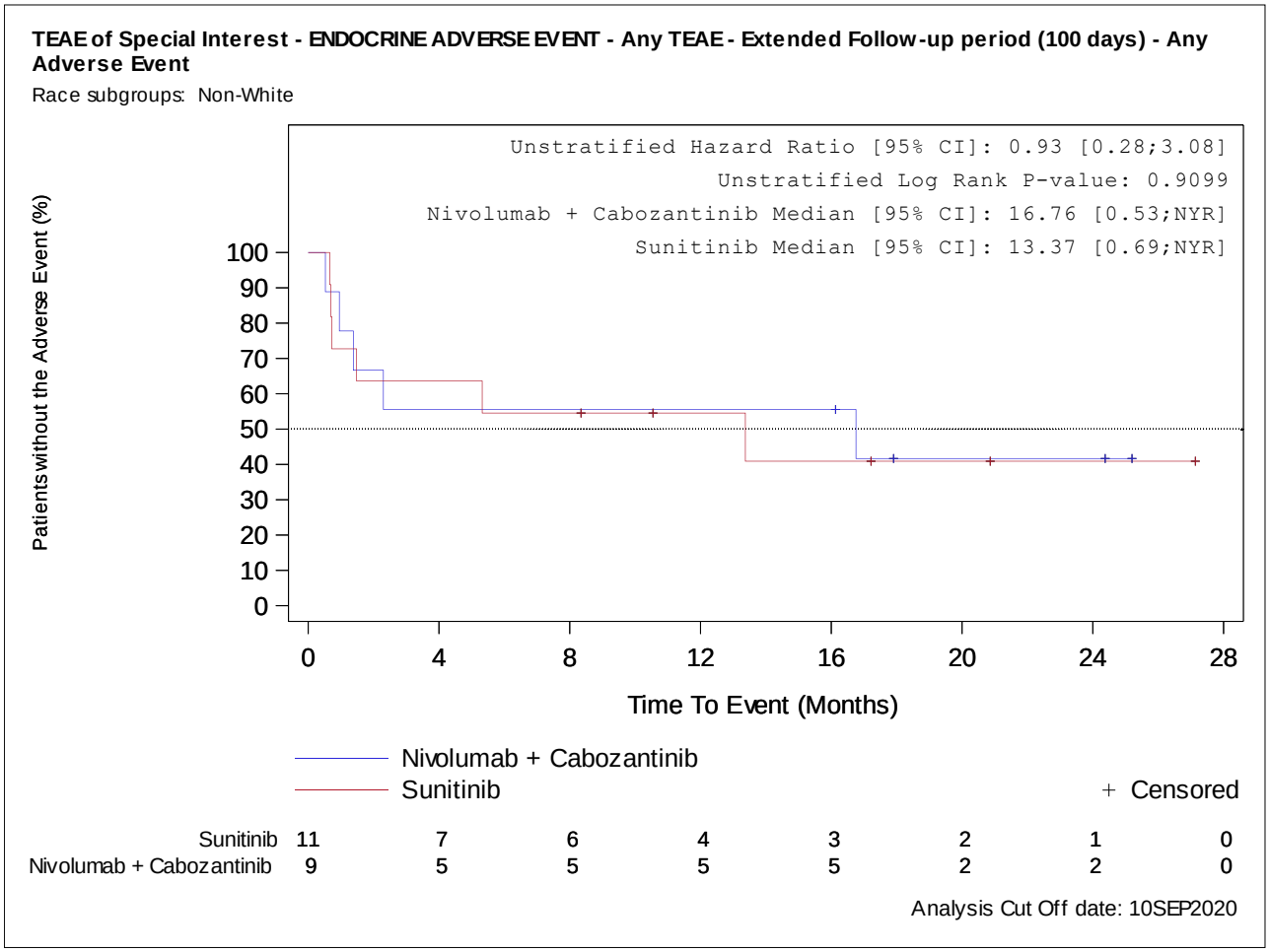

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:40:44

FIGURE 3.18.2.8: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



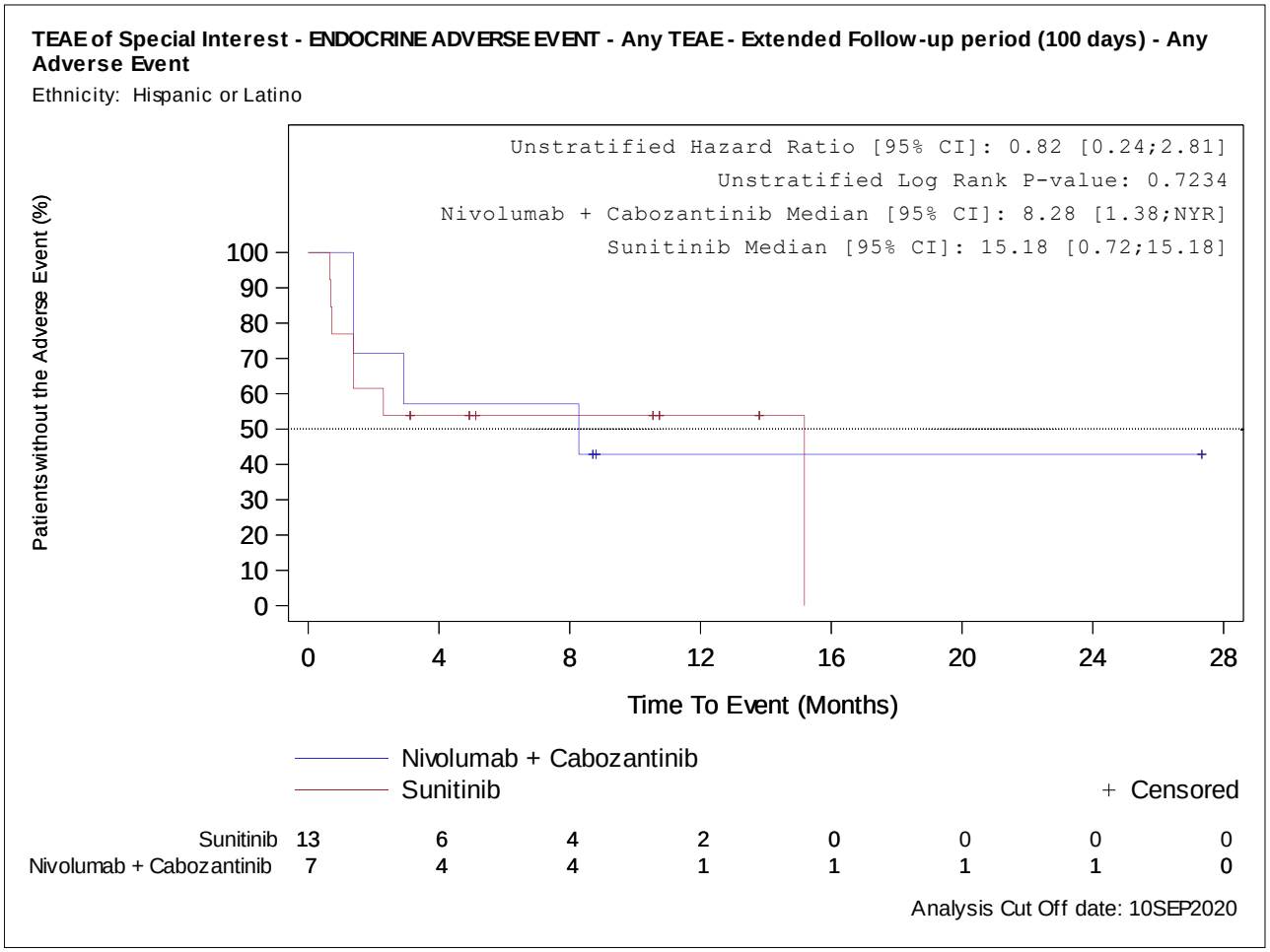

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:40:50

FIGURE 3.18.2.9: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



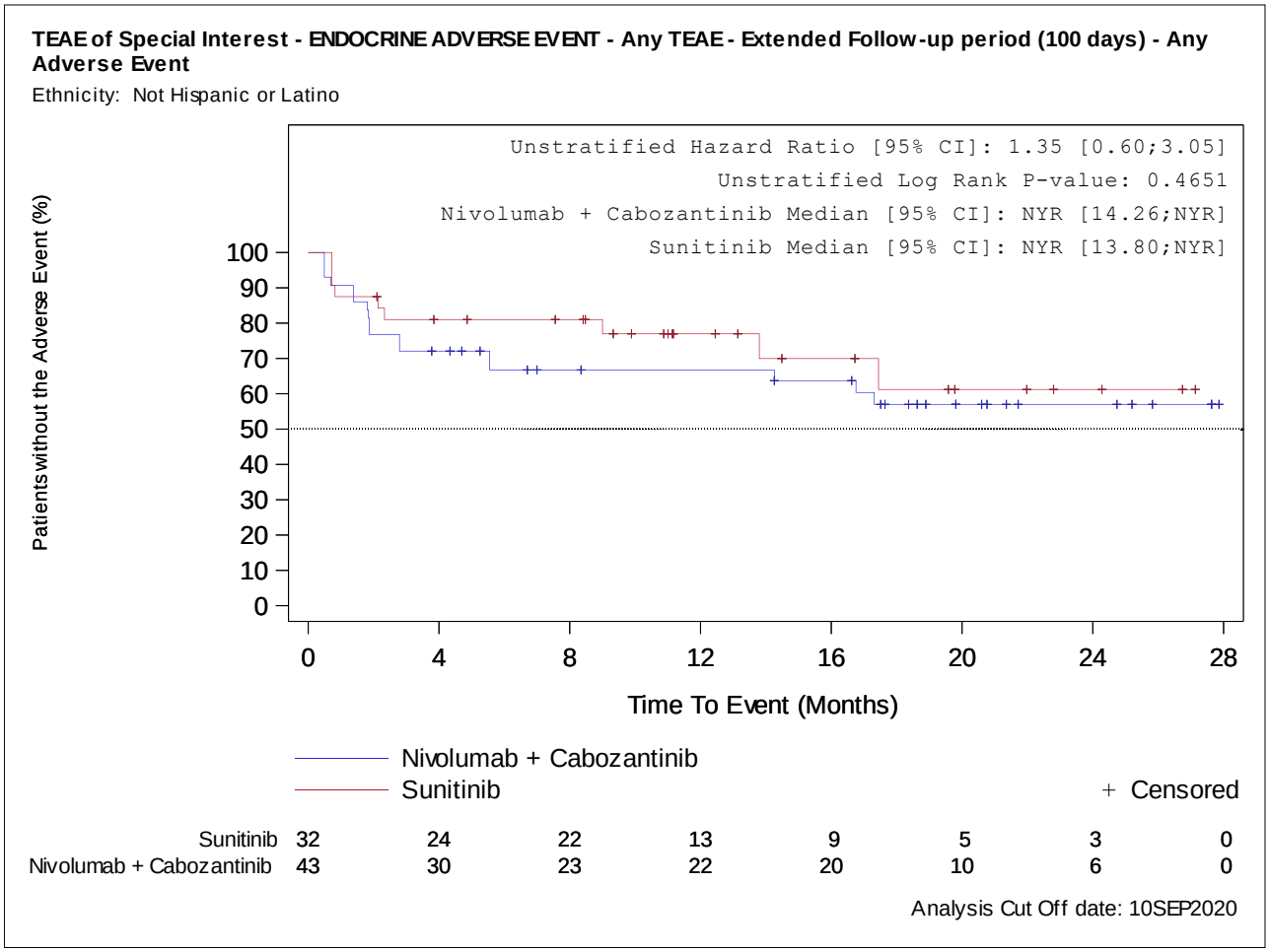

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:40:55

FIGURE 3.18.2.10: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:41:02

FIGURE 3.18.2.11: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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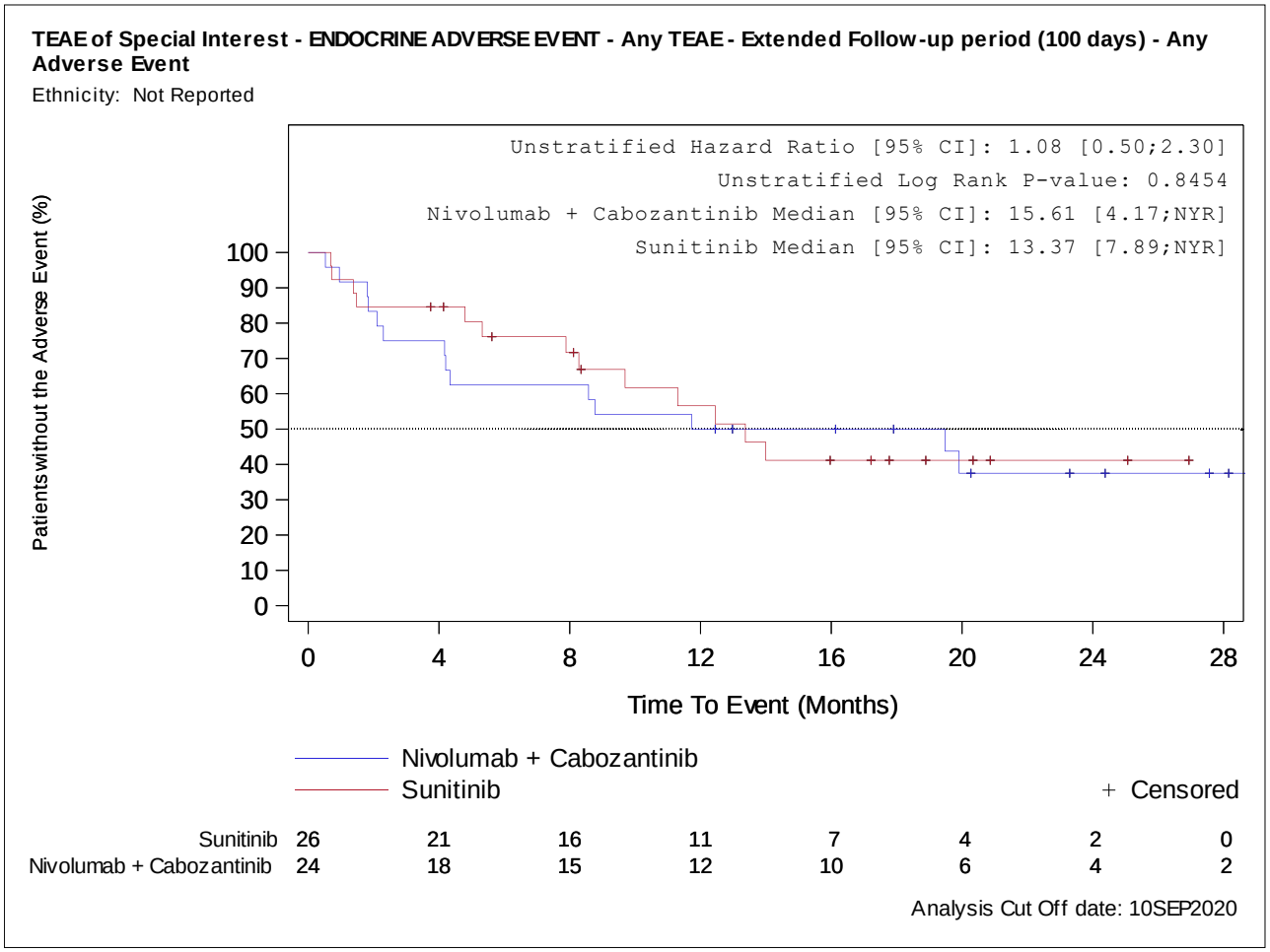
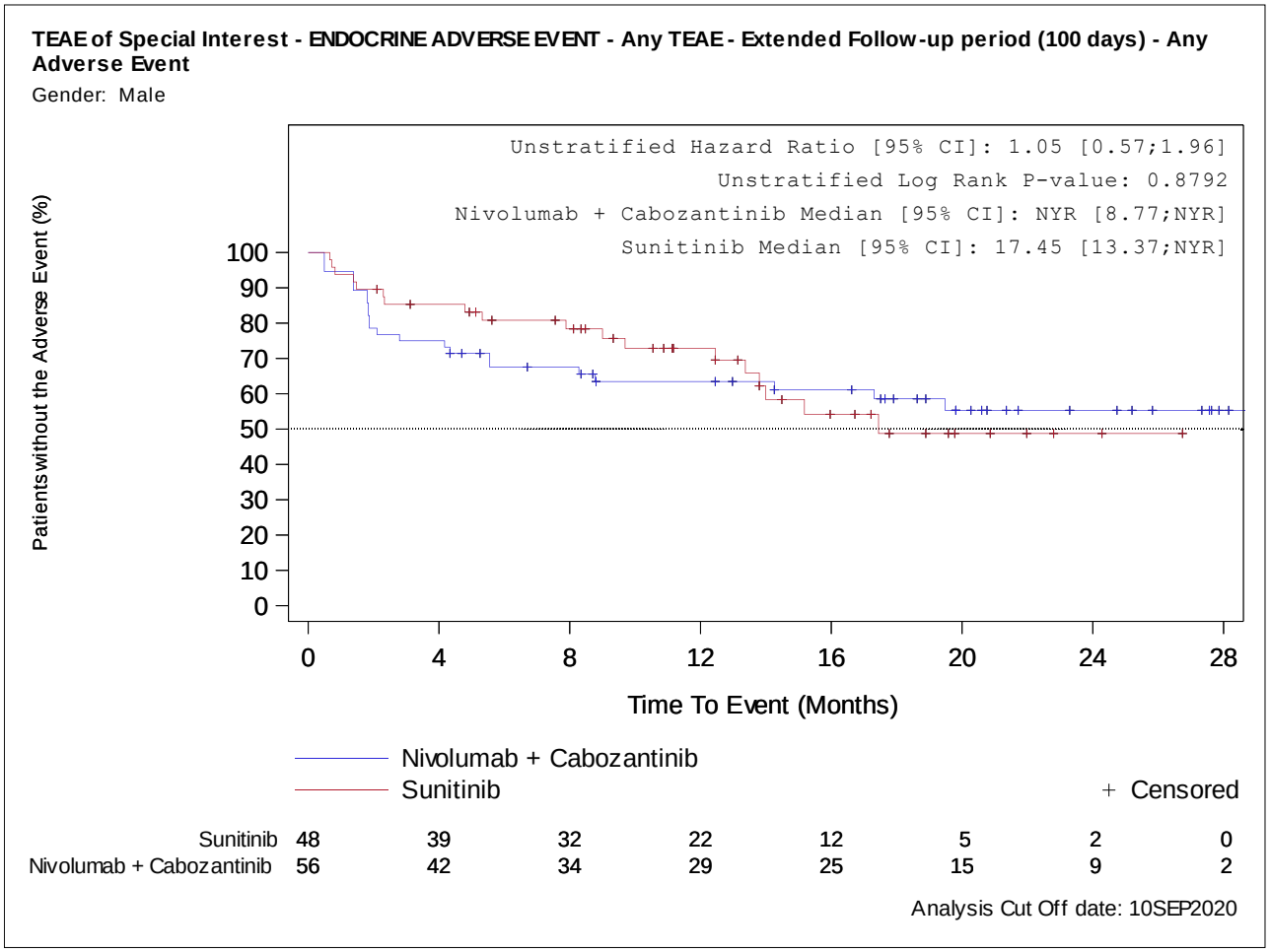
FIGURE 3.18.2.12: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



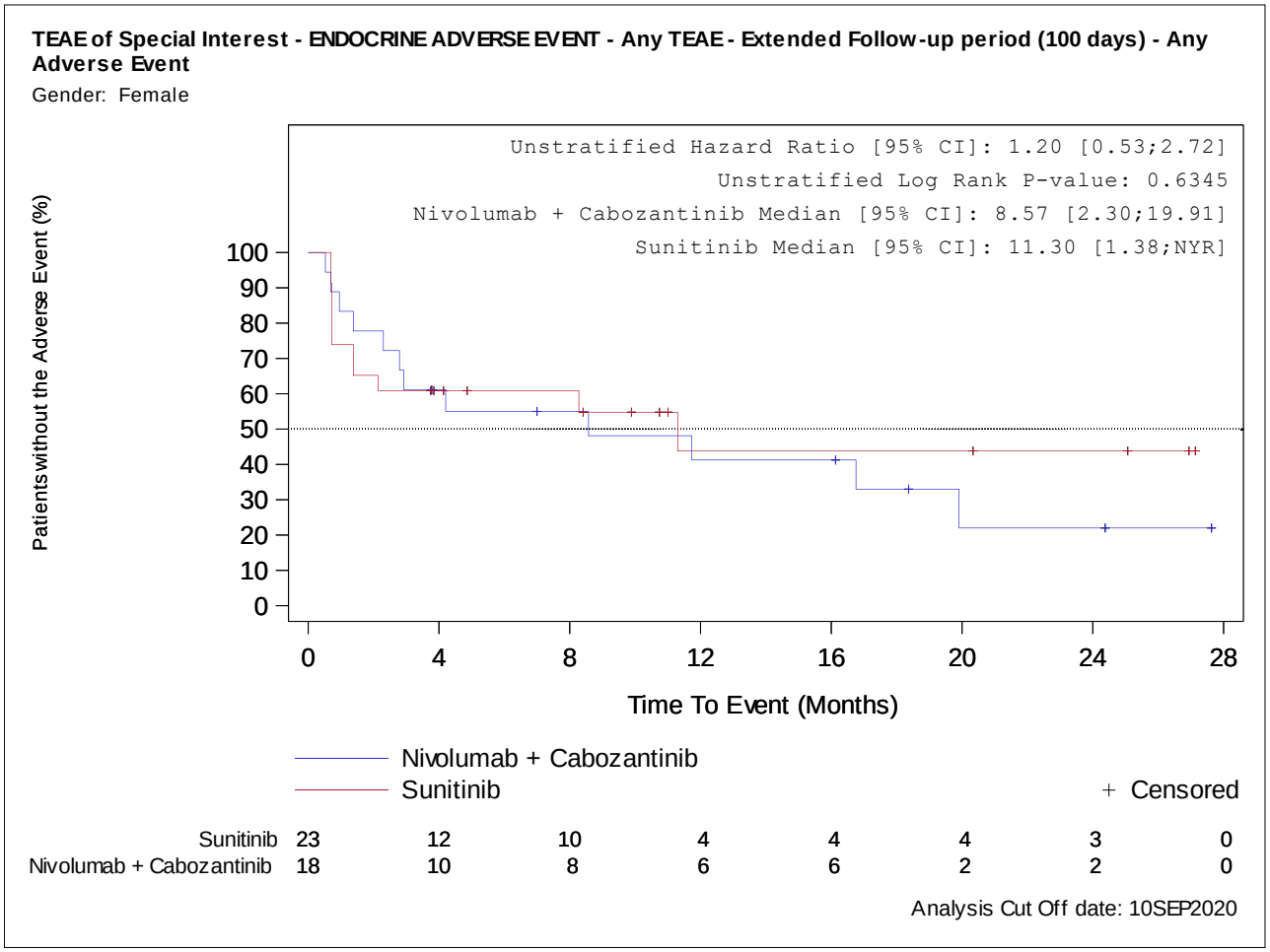

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:41:14

FIGURE 3.18.2.13: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



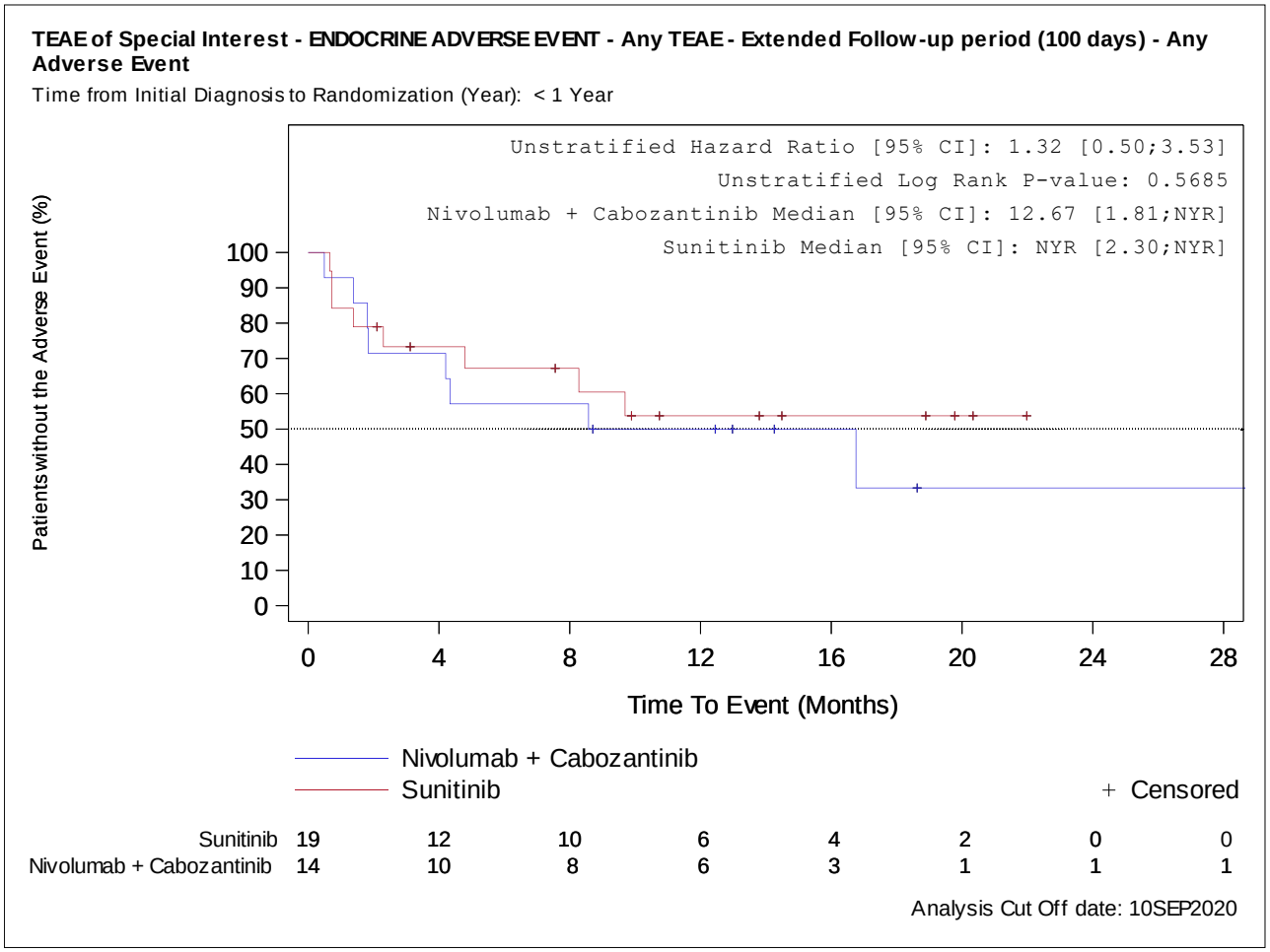

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:41:20

FIGURE 3.18.2.14: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:41:26

FIGURE 3.18.2.15: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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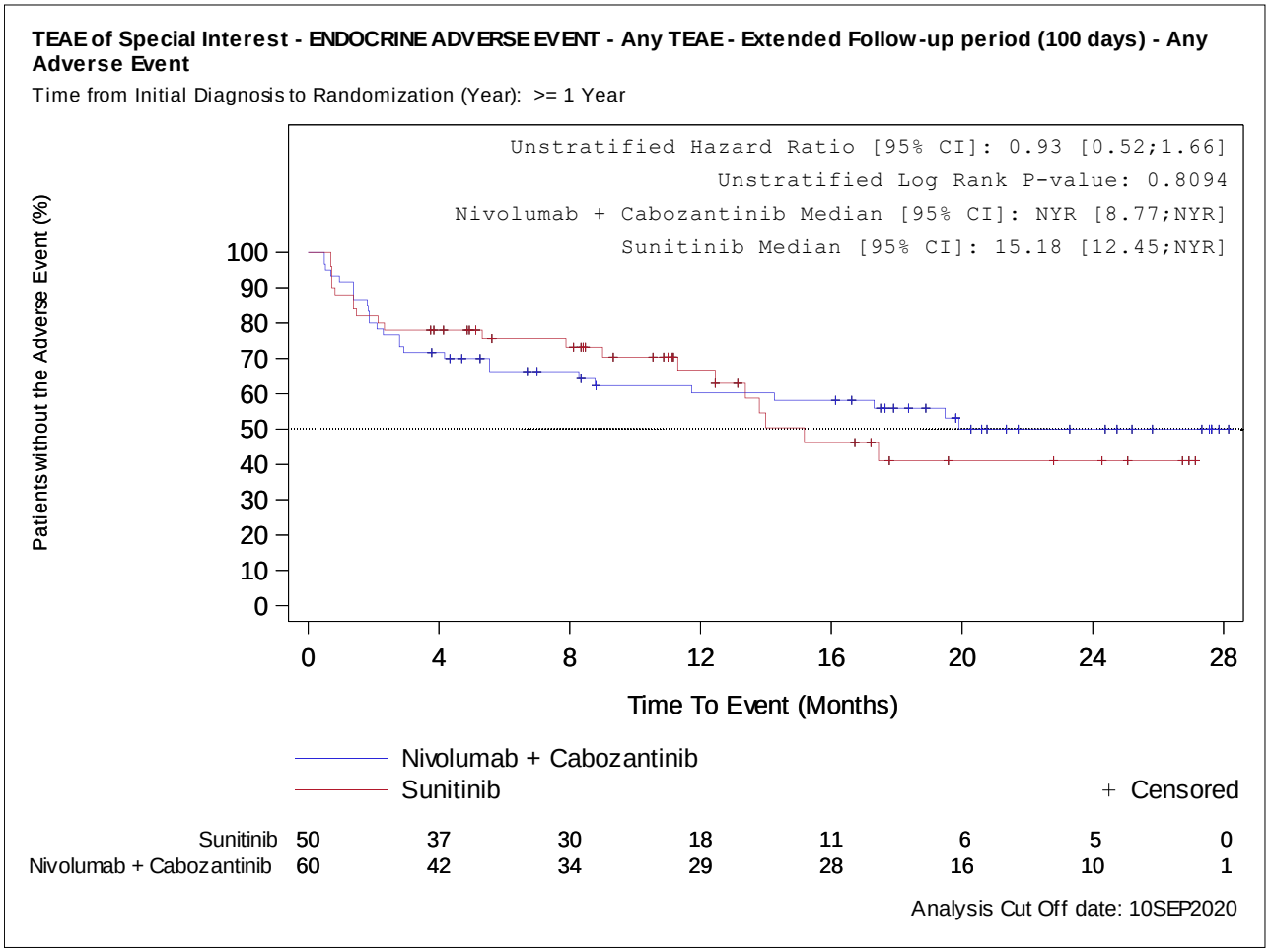
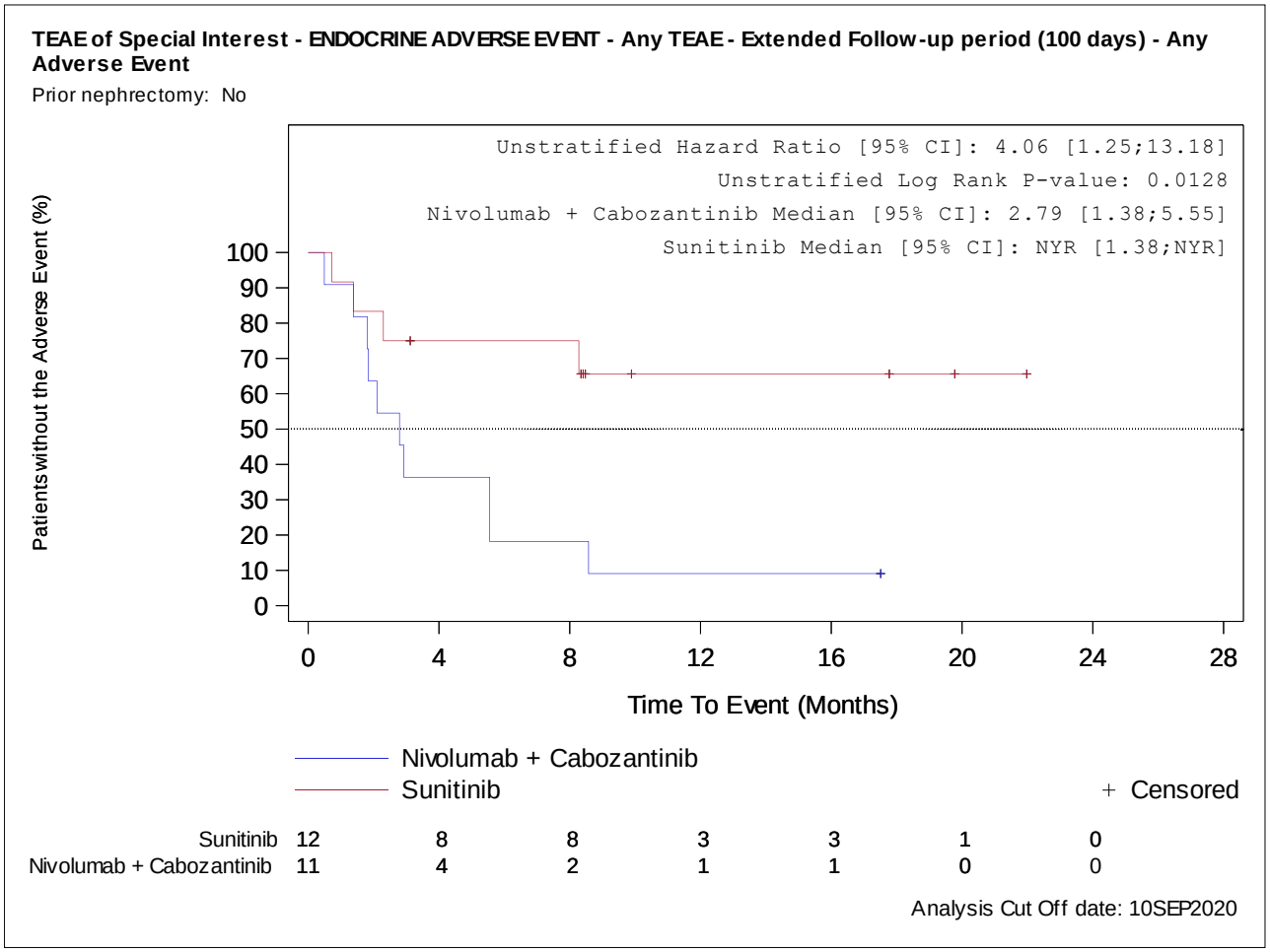
FIGURE 3.18.2.16: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



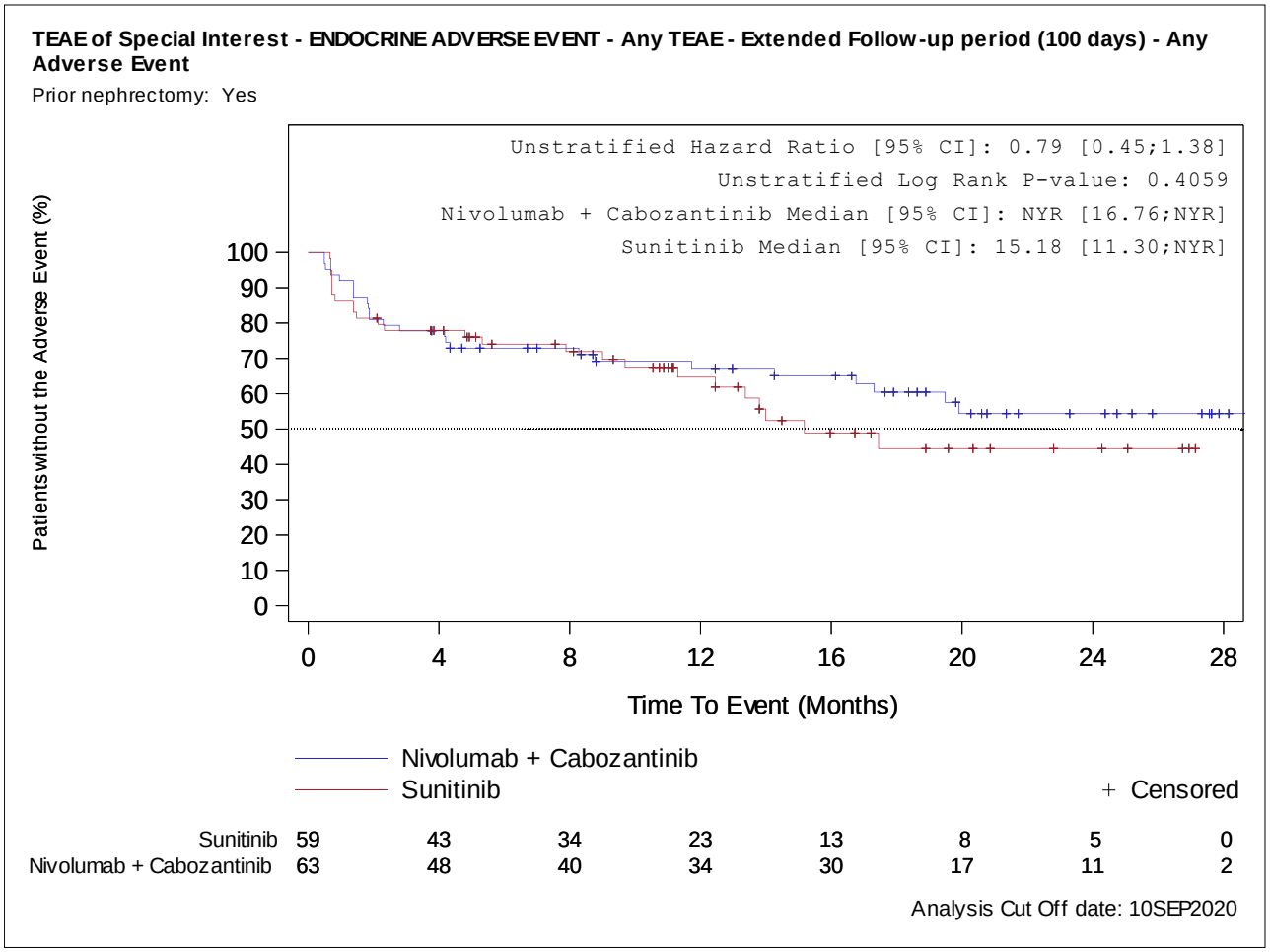

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:41:49

FIGURE 3.18.2.17: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:42:41

FIGURE 3.18.2.18: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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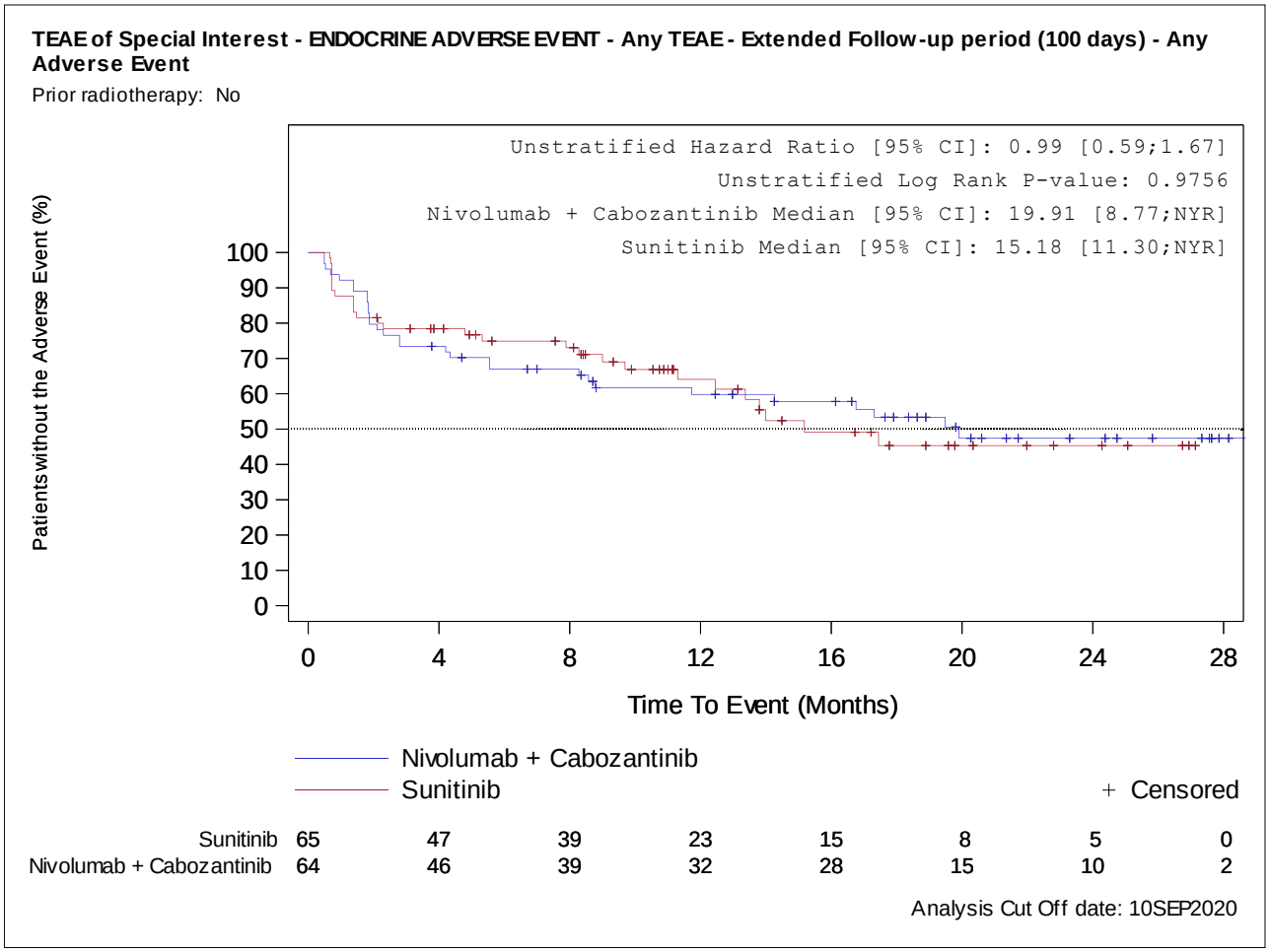
FIGURE 3.18.2.19: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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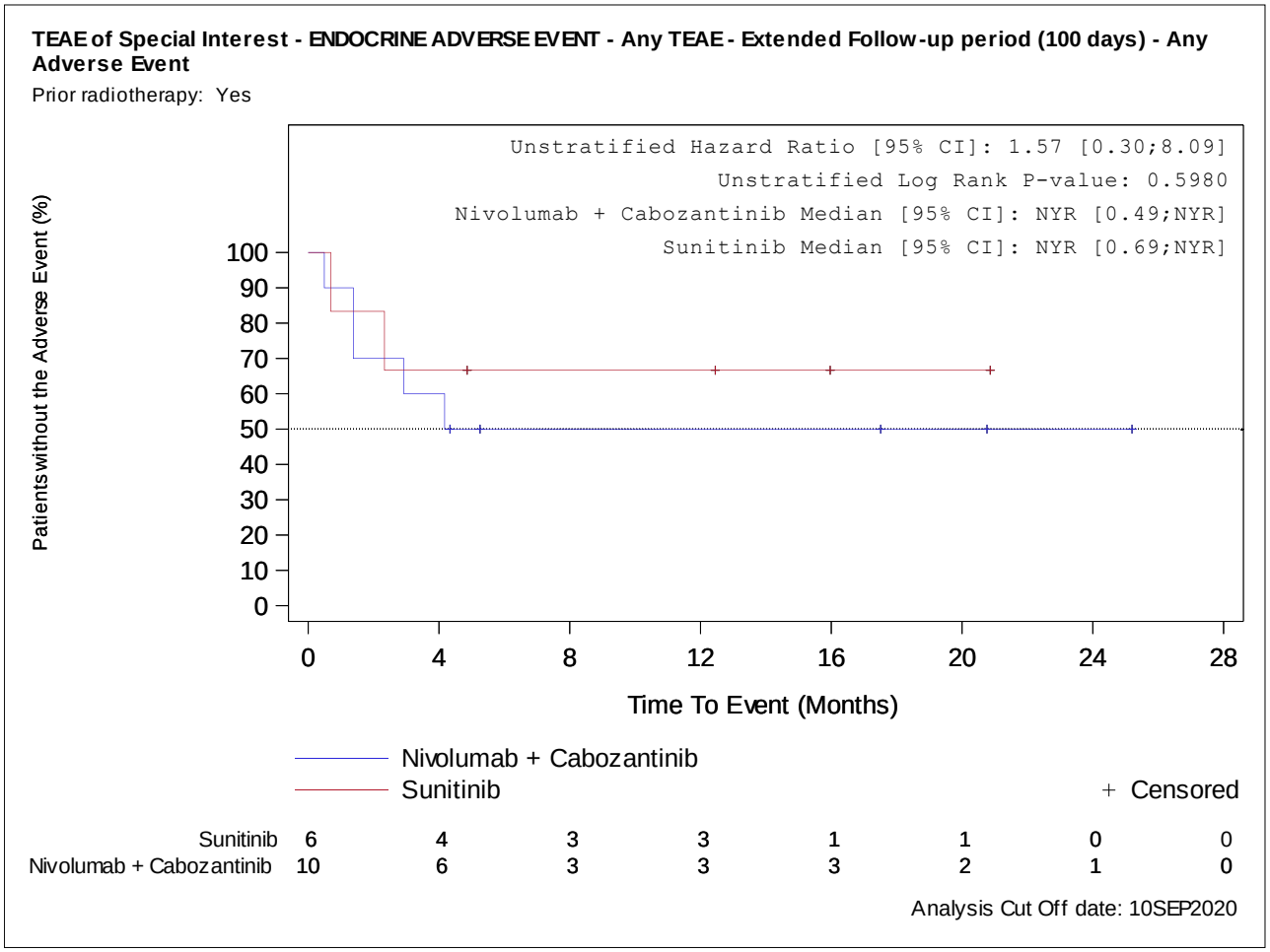
FIGURE 3.18.2.20: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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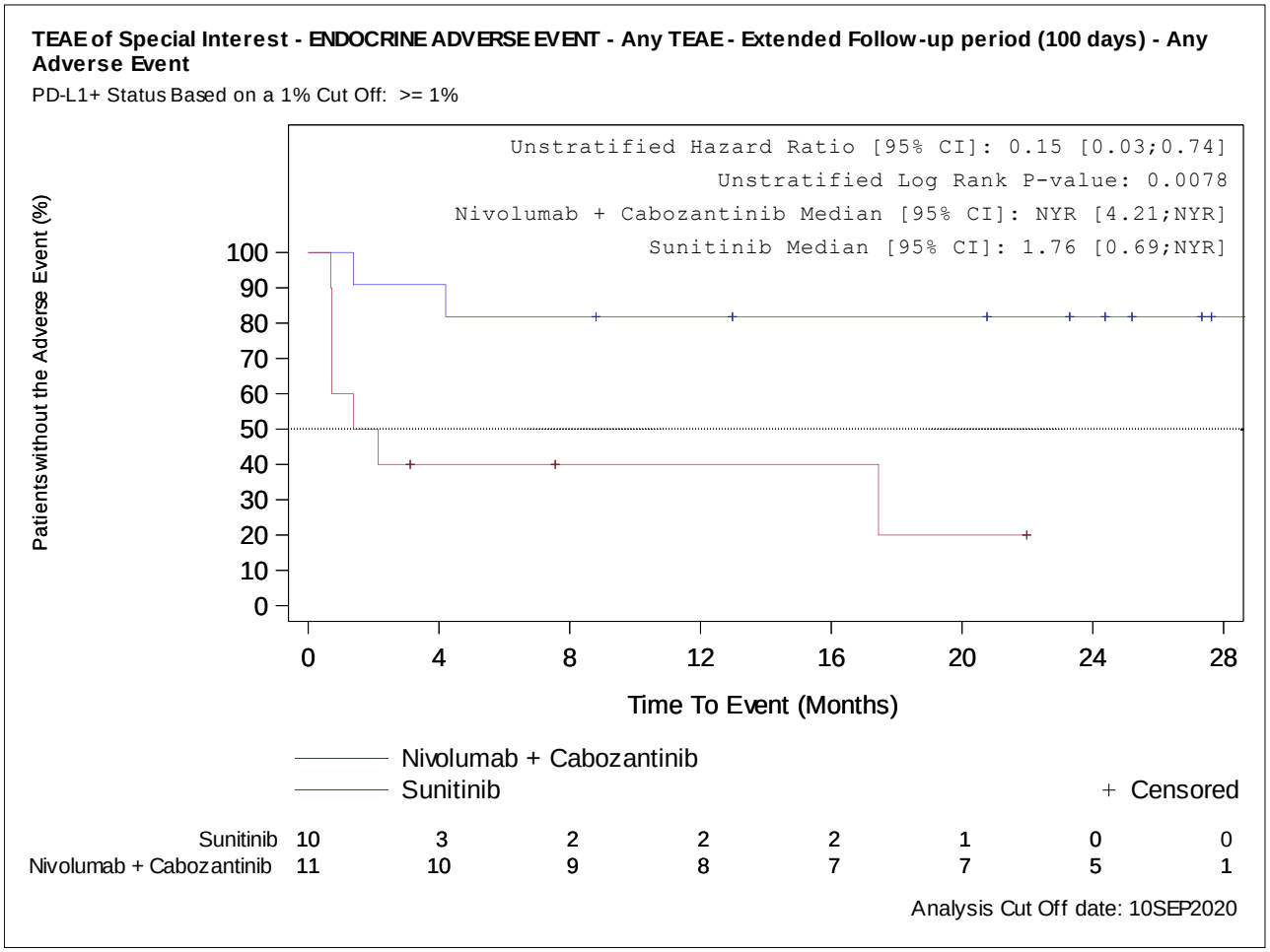
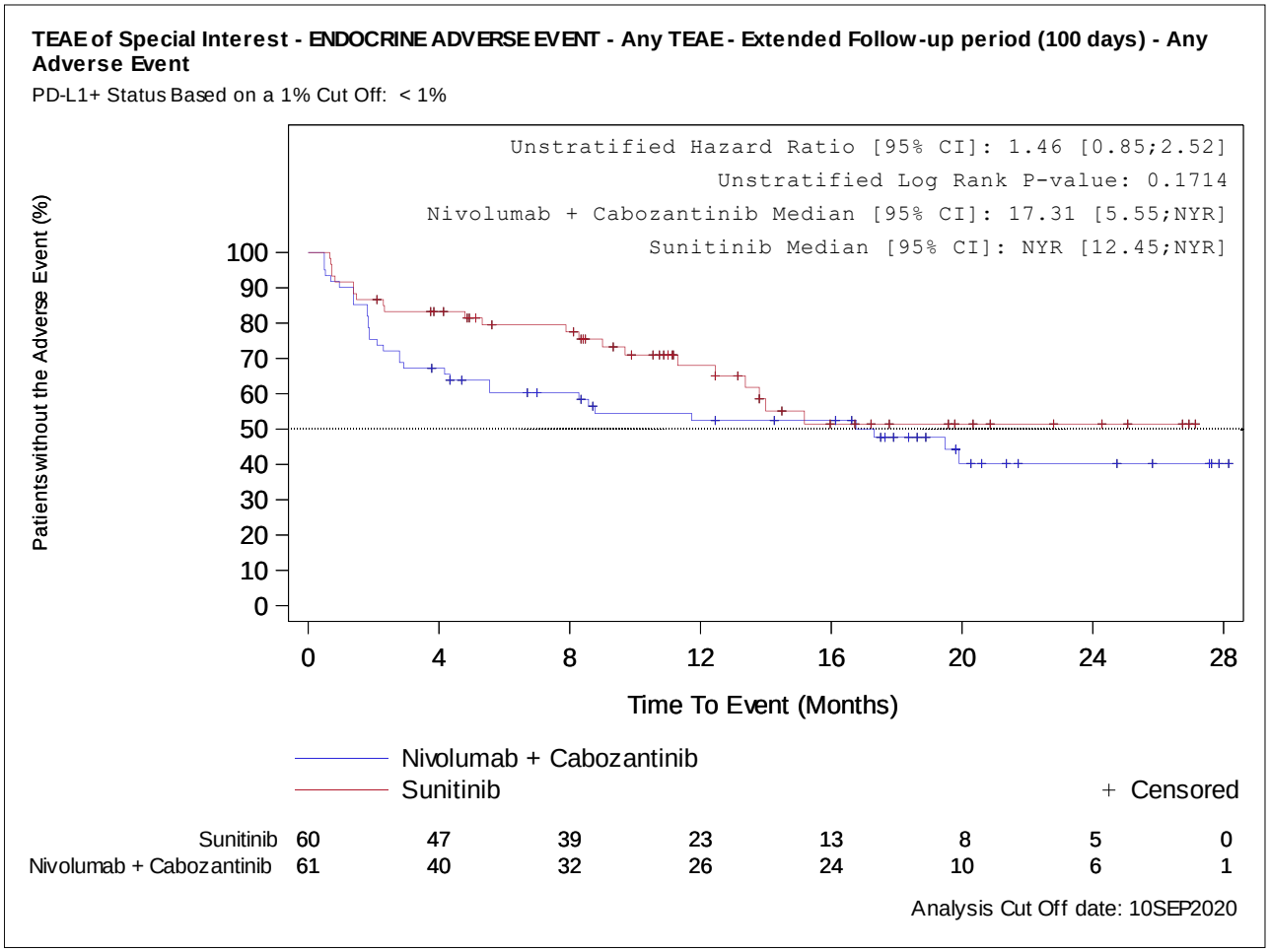
FIGURE 3.18.2.21: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



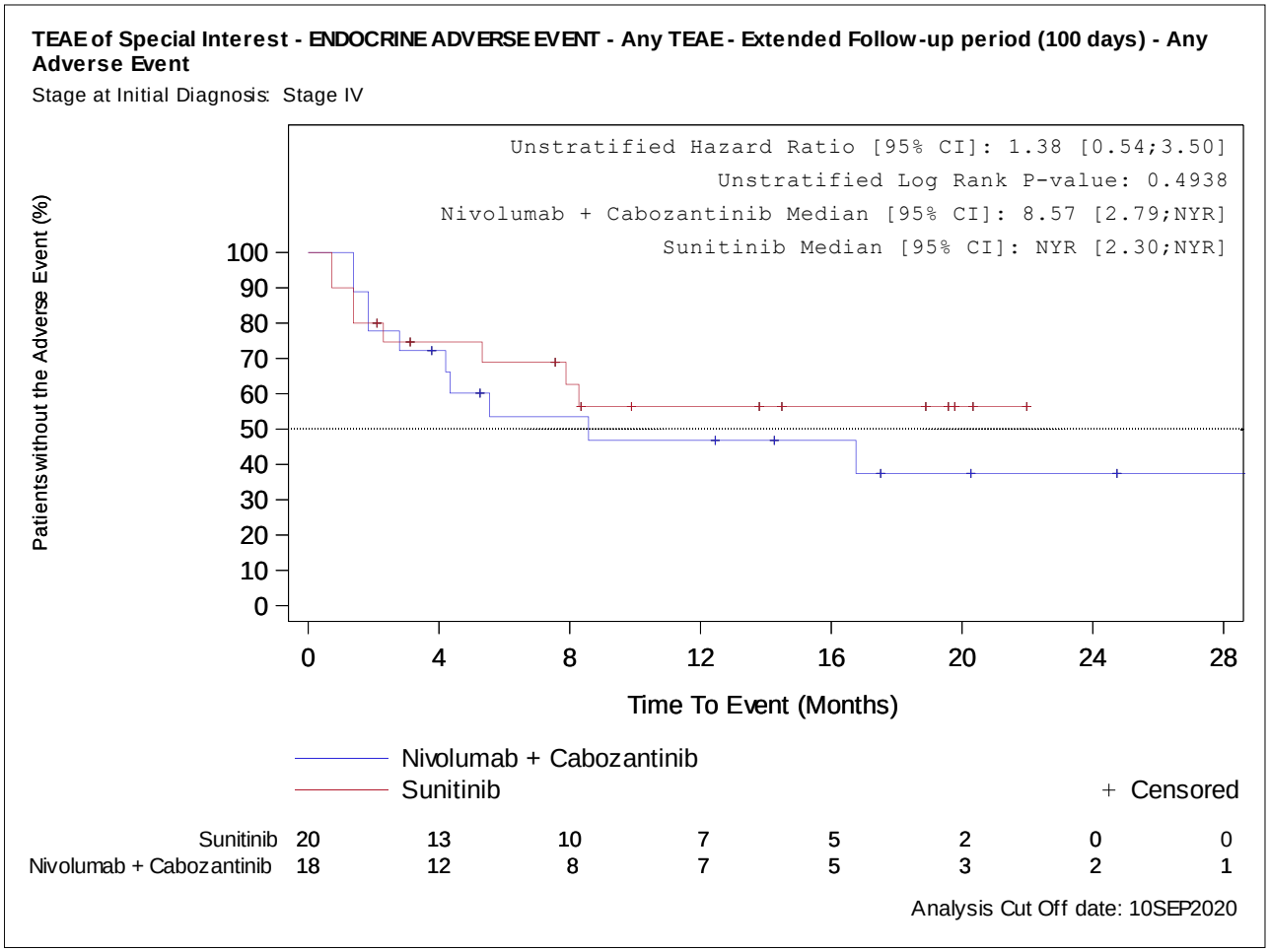

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:43:04

FIGURE 3.18.2.22: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:43:10

FIGURE 3.18.2.23: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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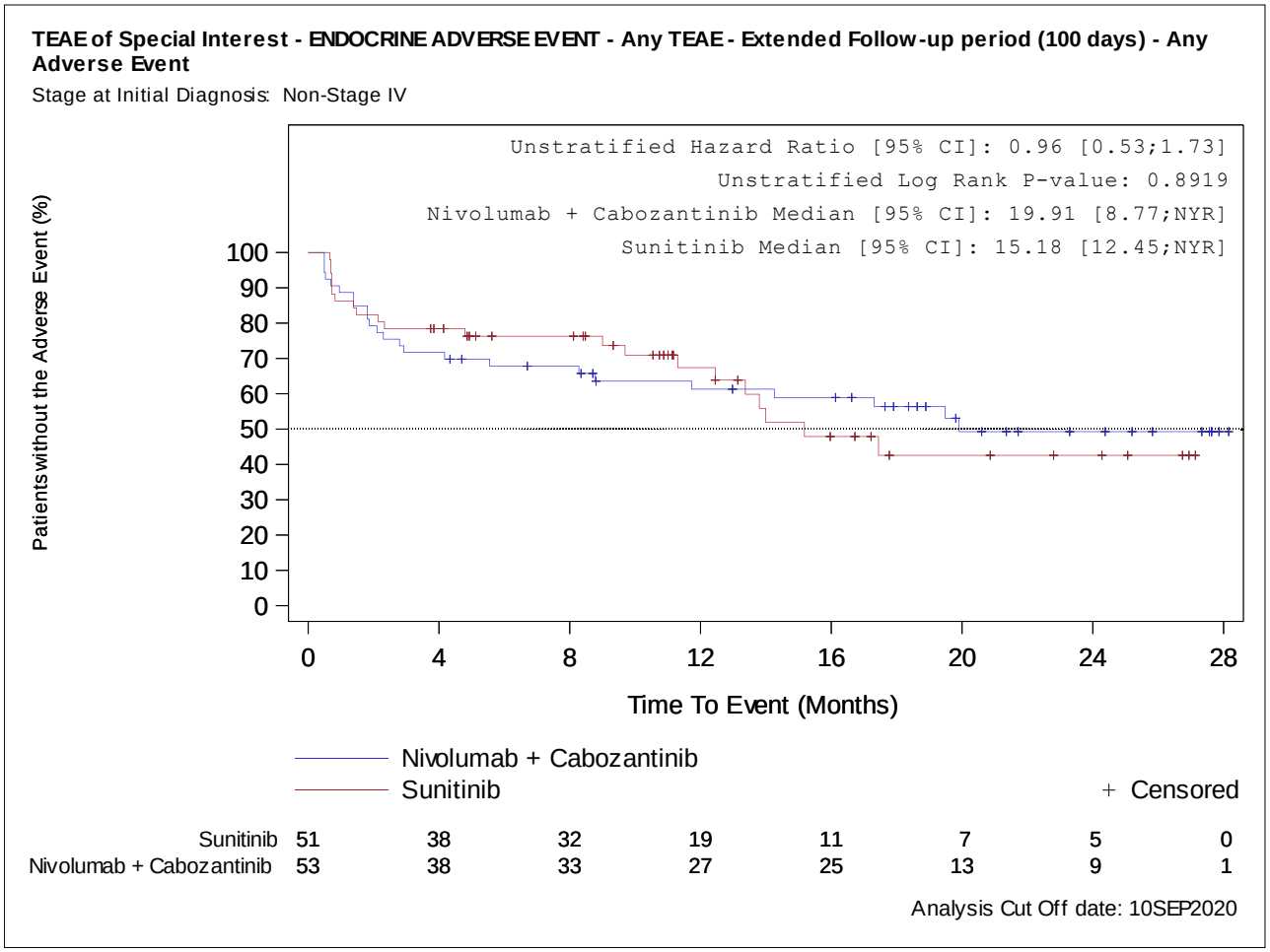
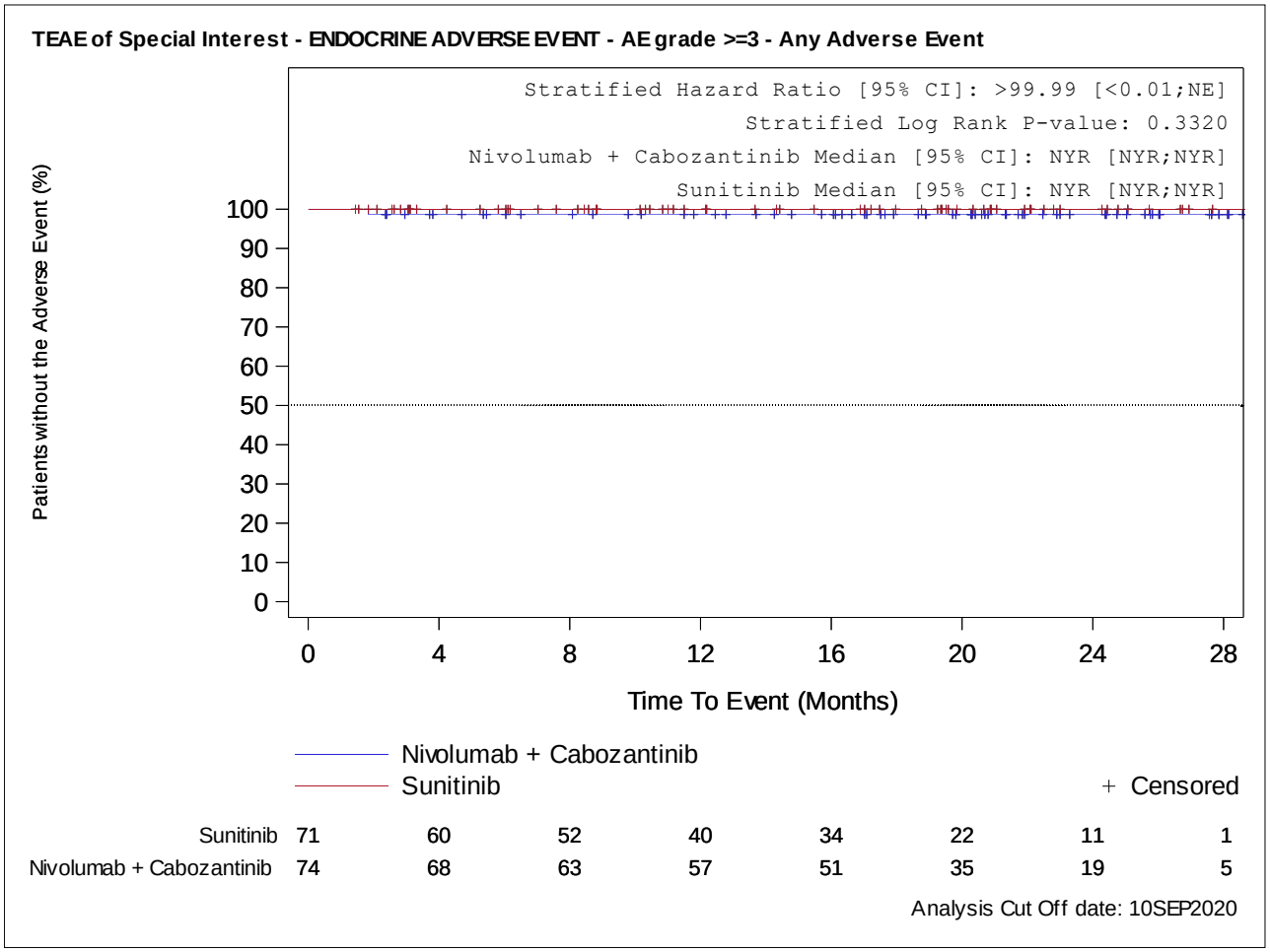
FIGURE 3.18.2.24: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



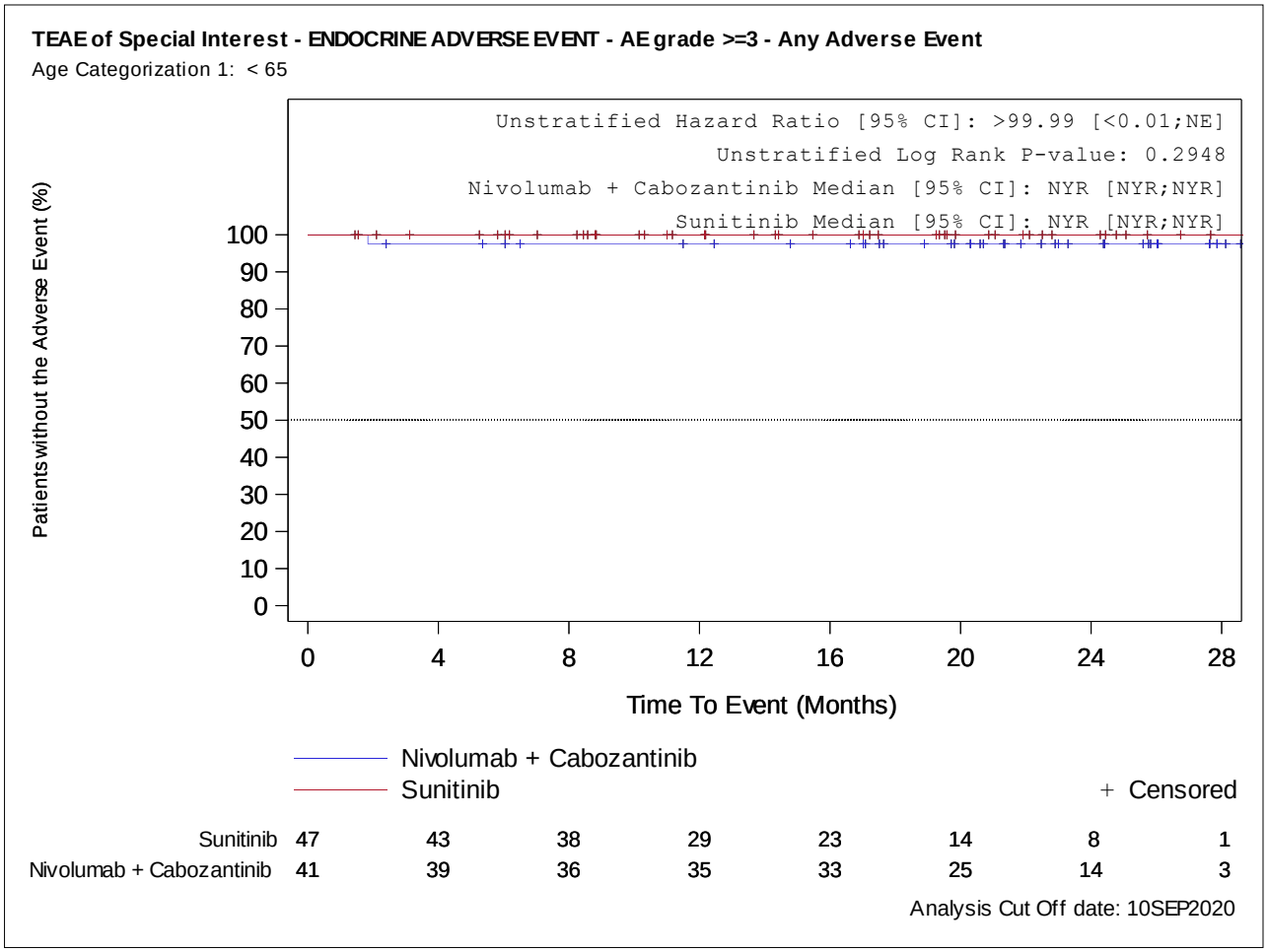

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:43:44

FIGURE 3.19.1: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:47:00

FIGURE 3.19.2.1: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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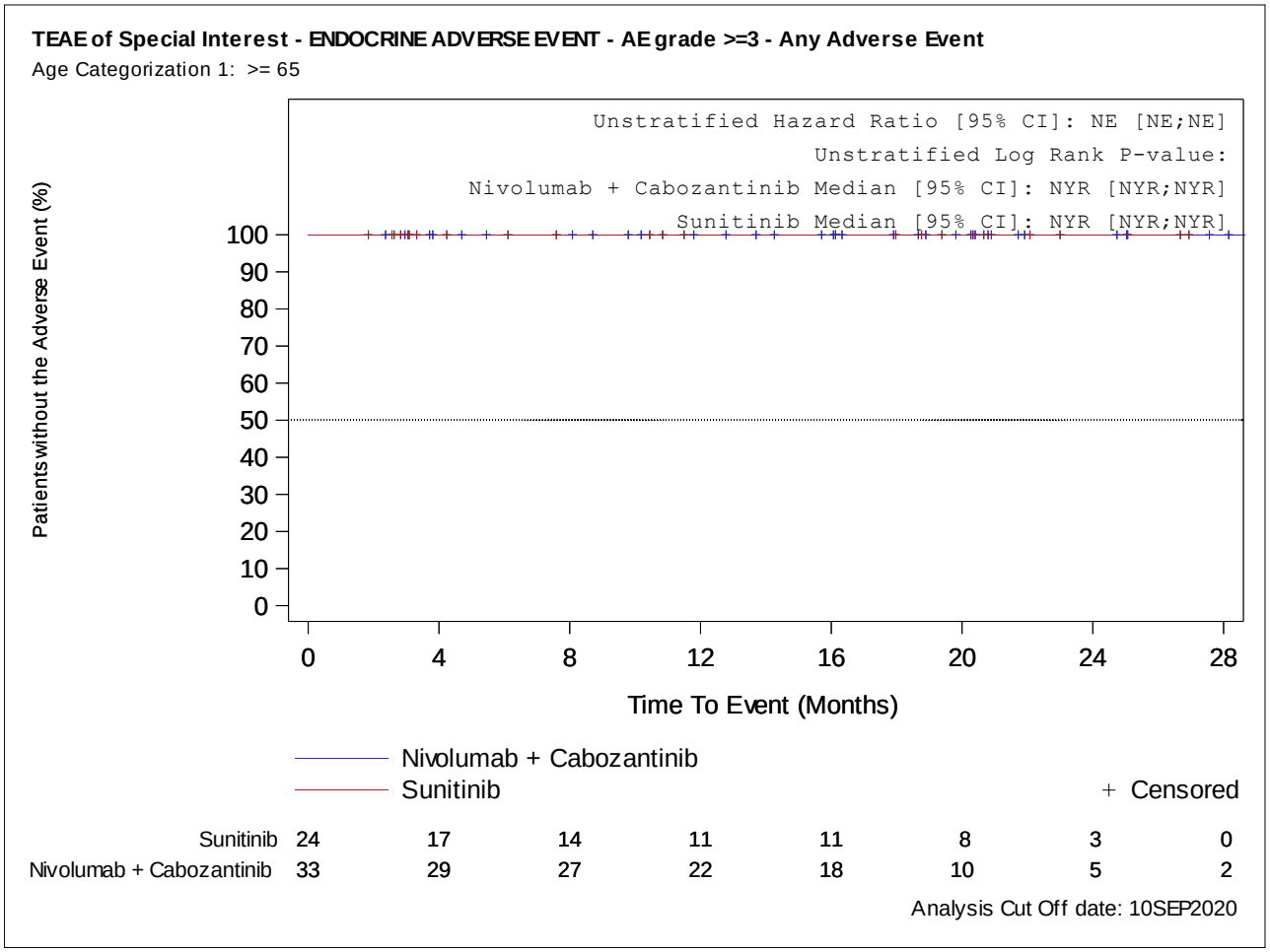
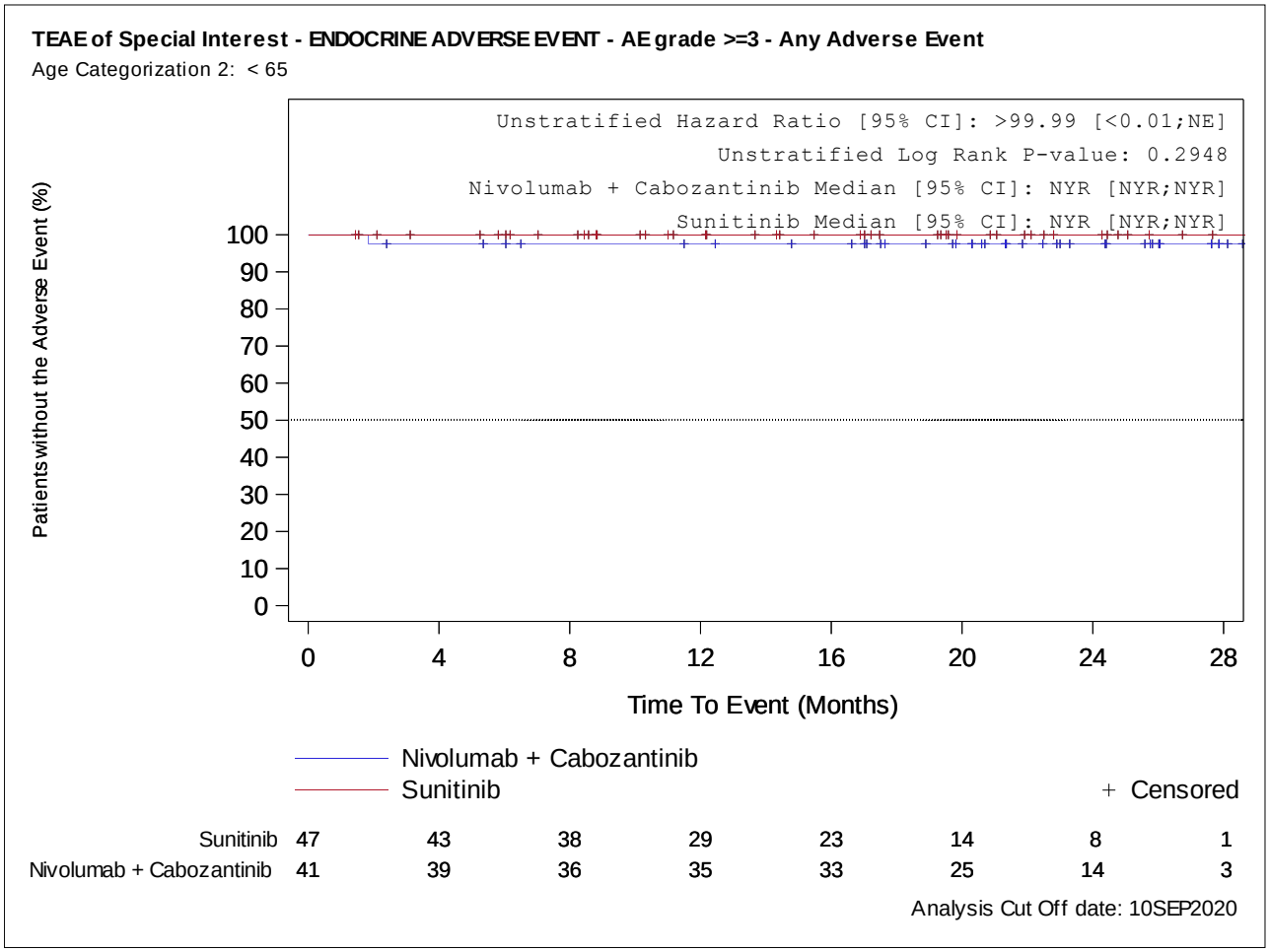
FIGURE 3.19.2.2: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



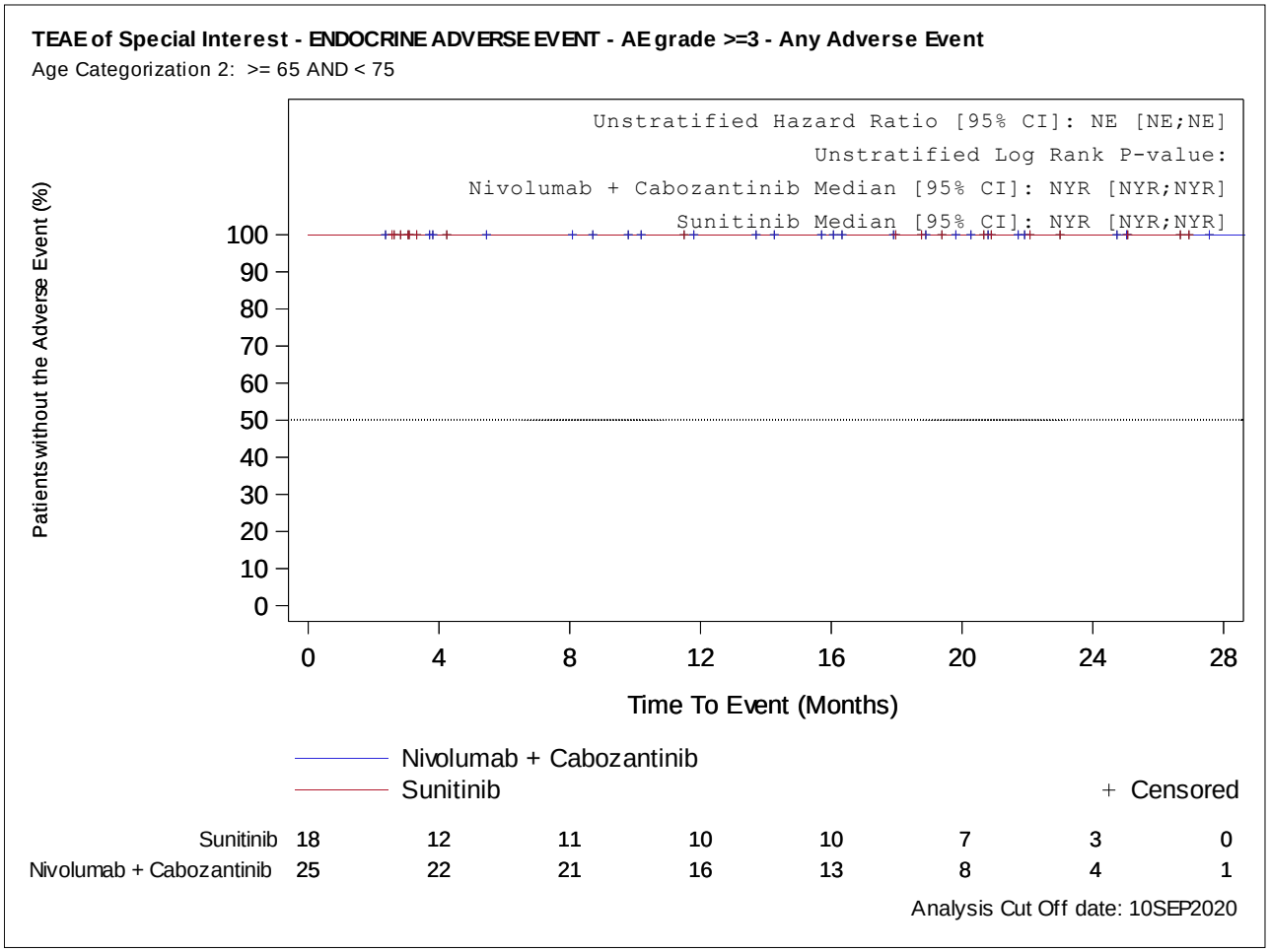

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:47:10

FIGURE 3.19.2.3: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



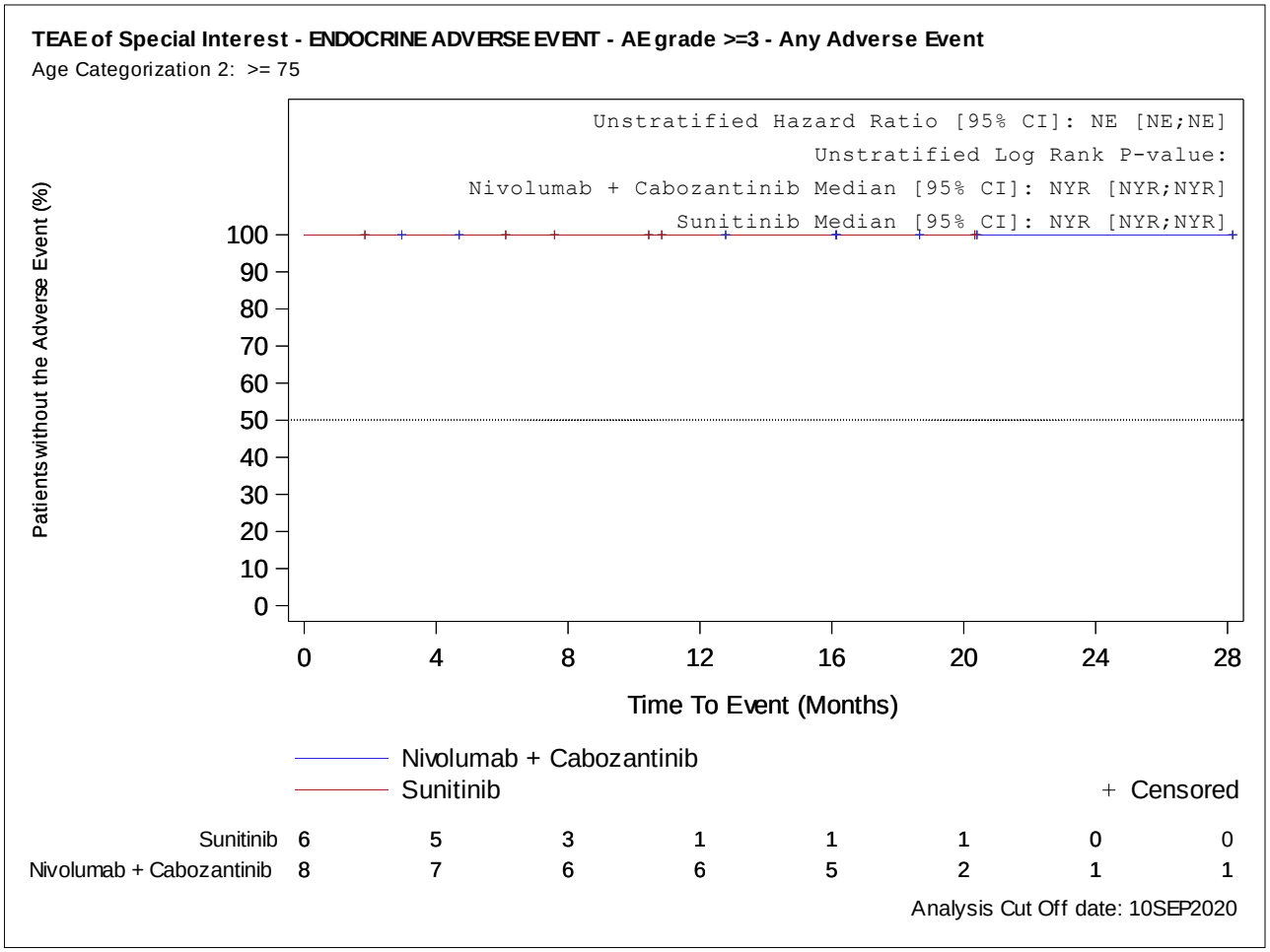

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:47:16

FIGURE 3.19.2.4: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



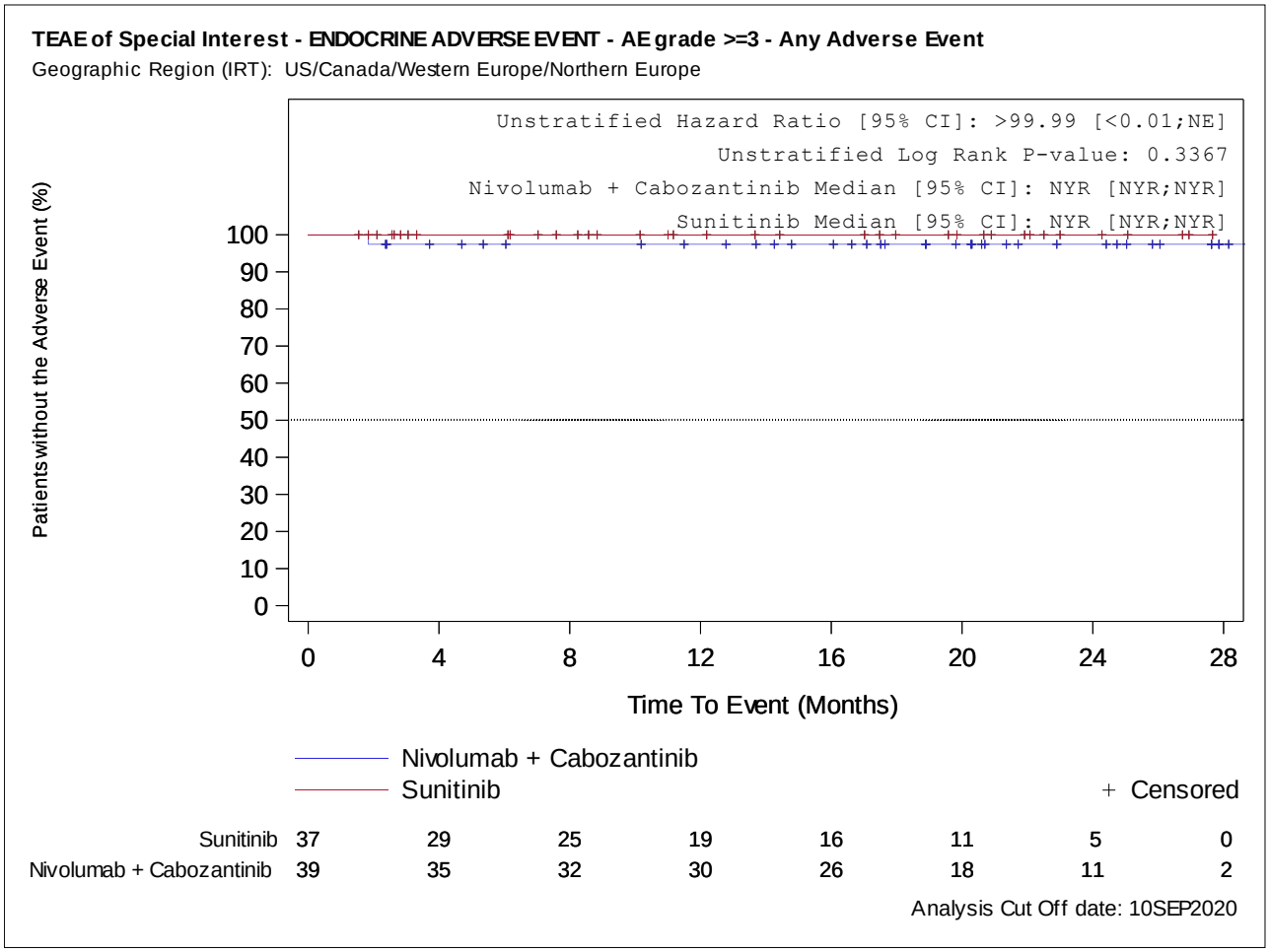

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:47:21

FIGURE 3.19.2.5: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



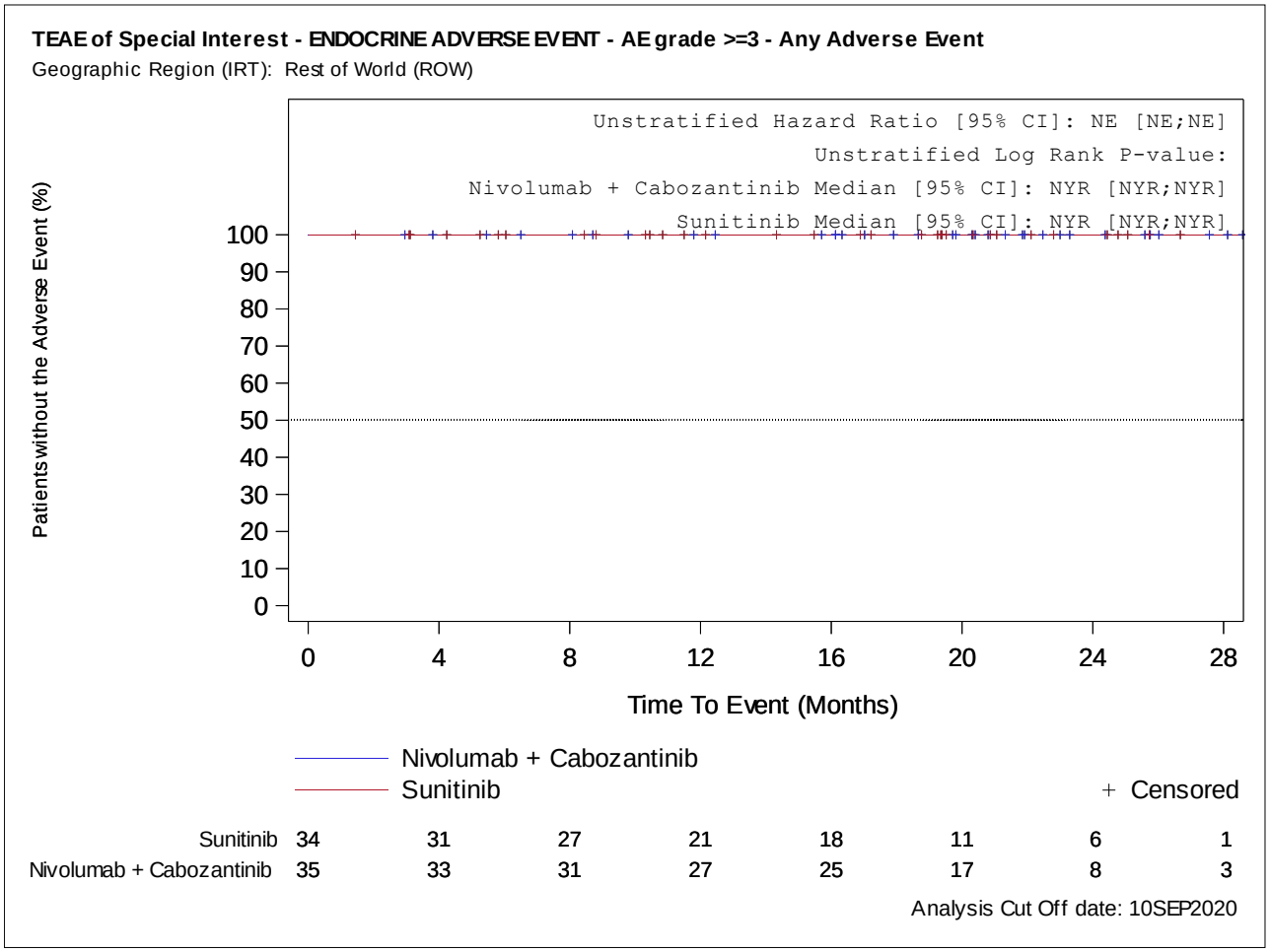

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:47:27

FIGURE 3.19.2.6: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



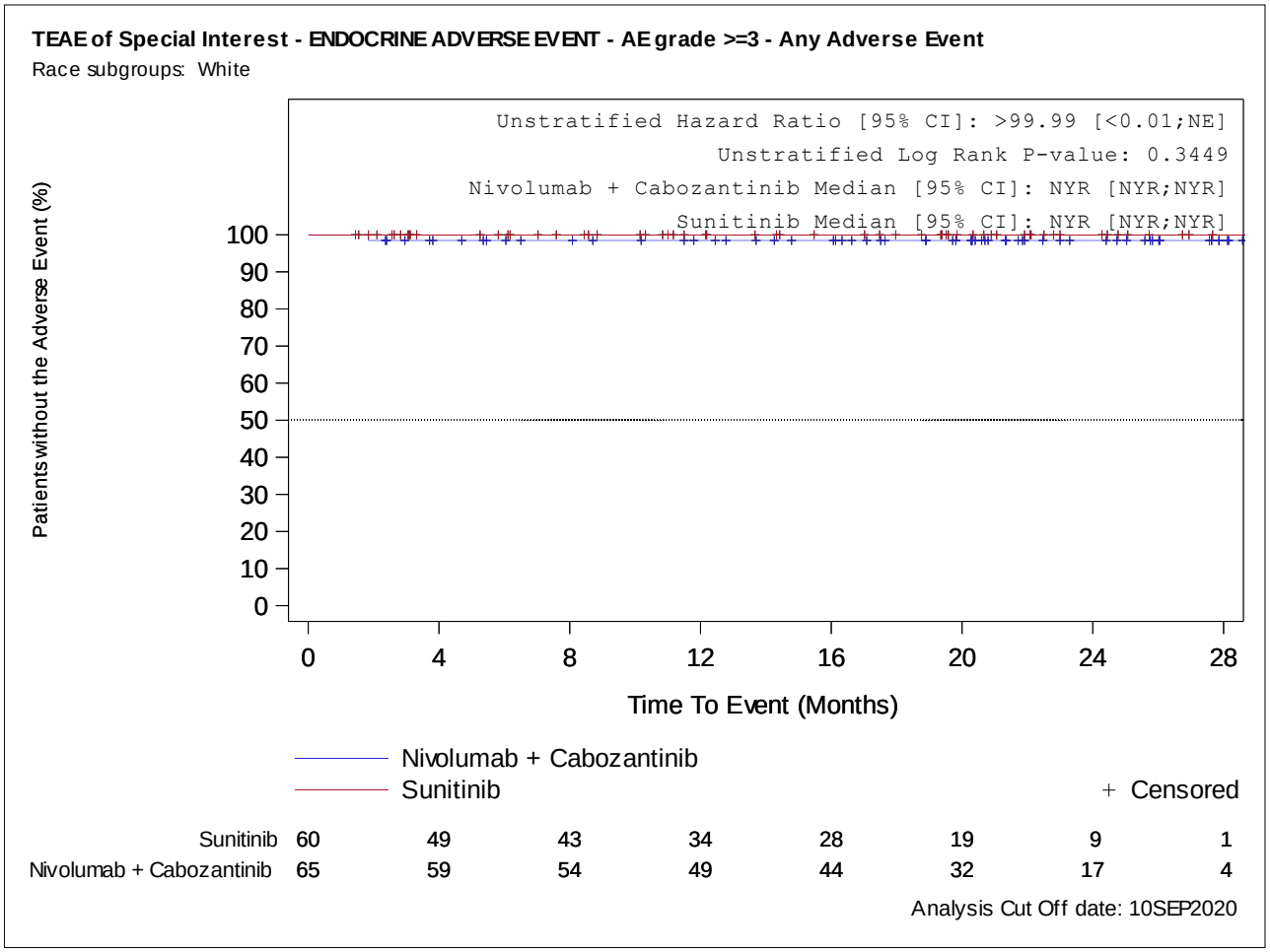

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:47:32

FIGURE 3.19.2.7: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



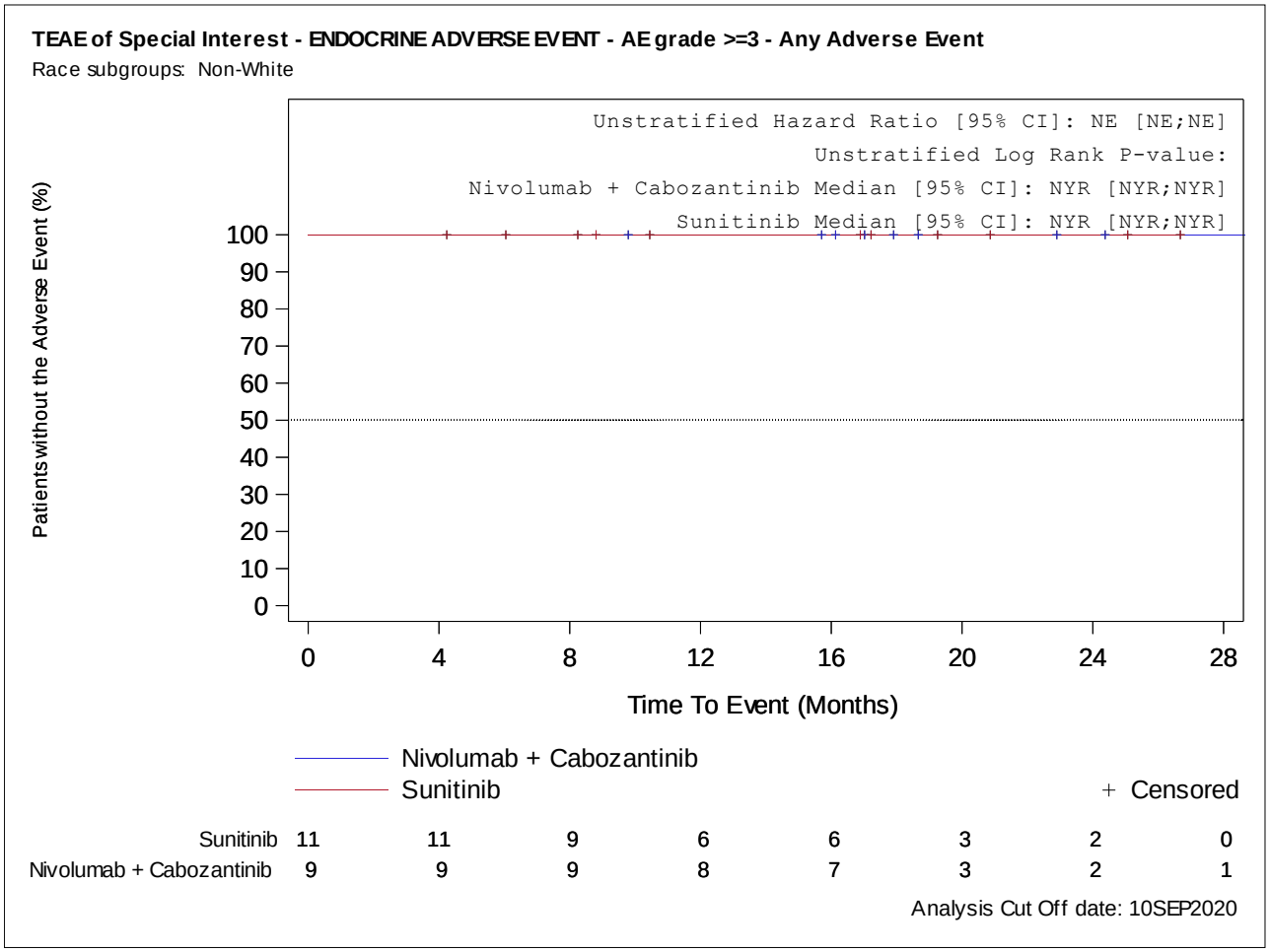

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:47:38

FIGURE 3.19.2.8: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



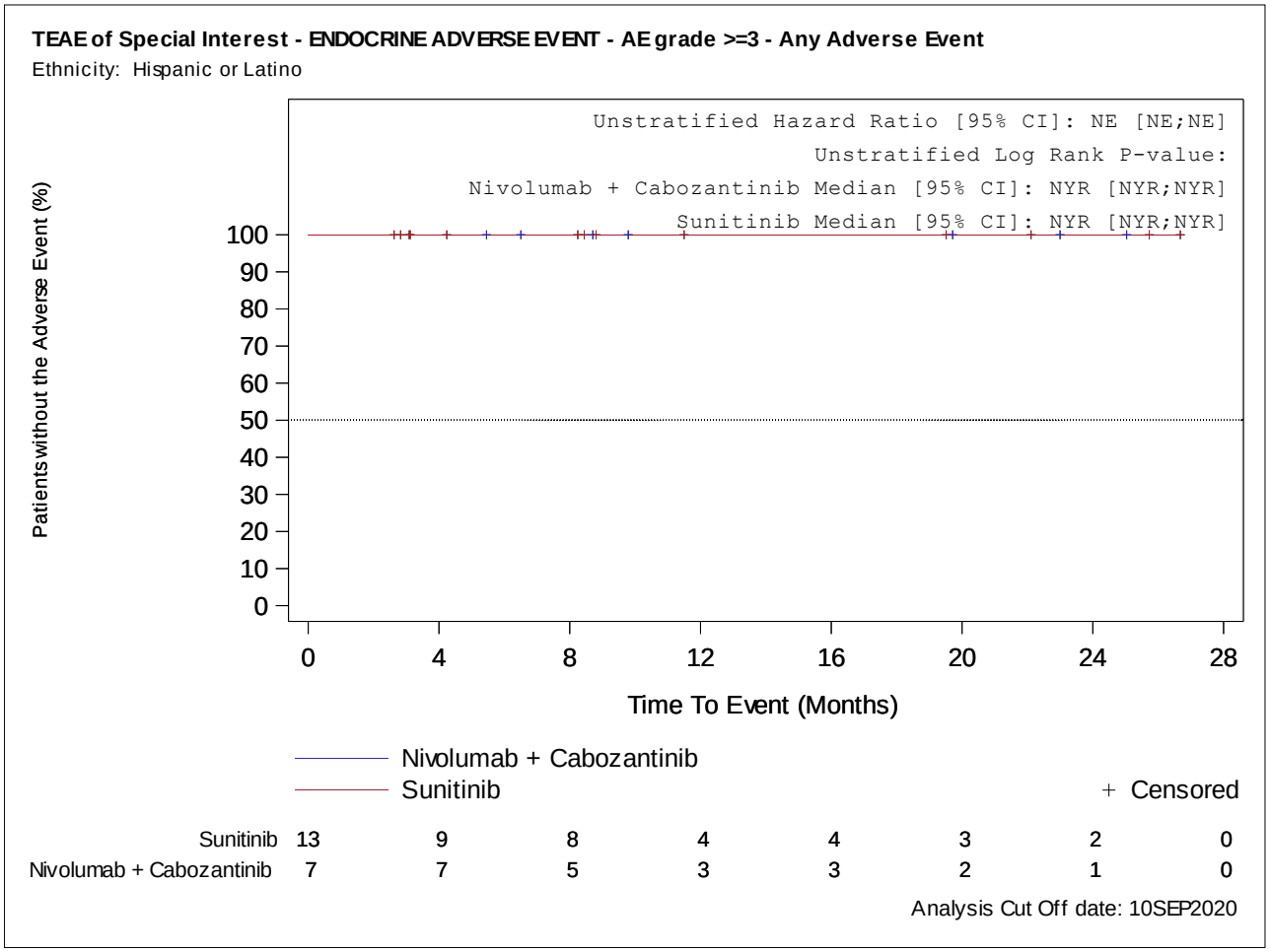

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:47:44

FIGURE 3.19.2.9: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:47:50

FIGURE 3.19.2.10: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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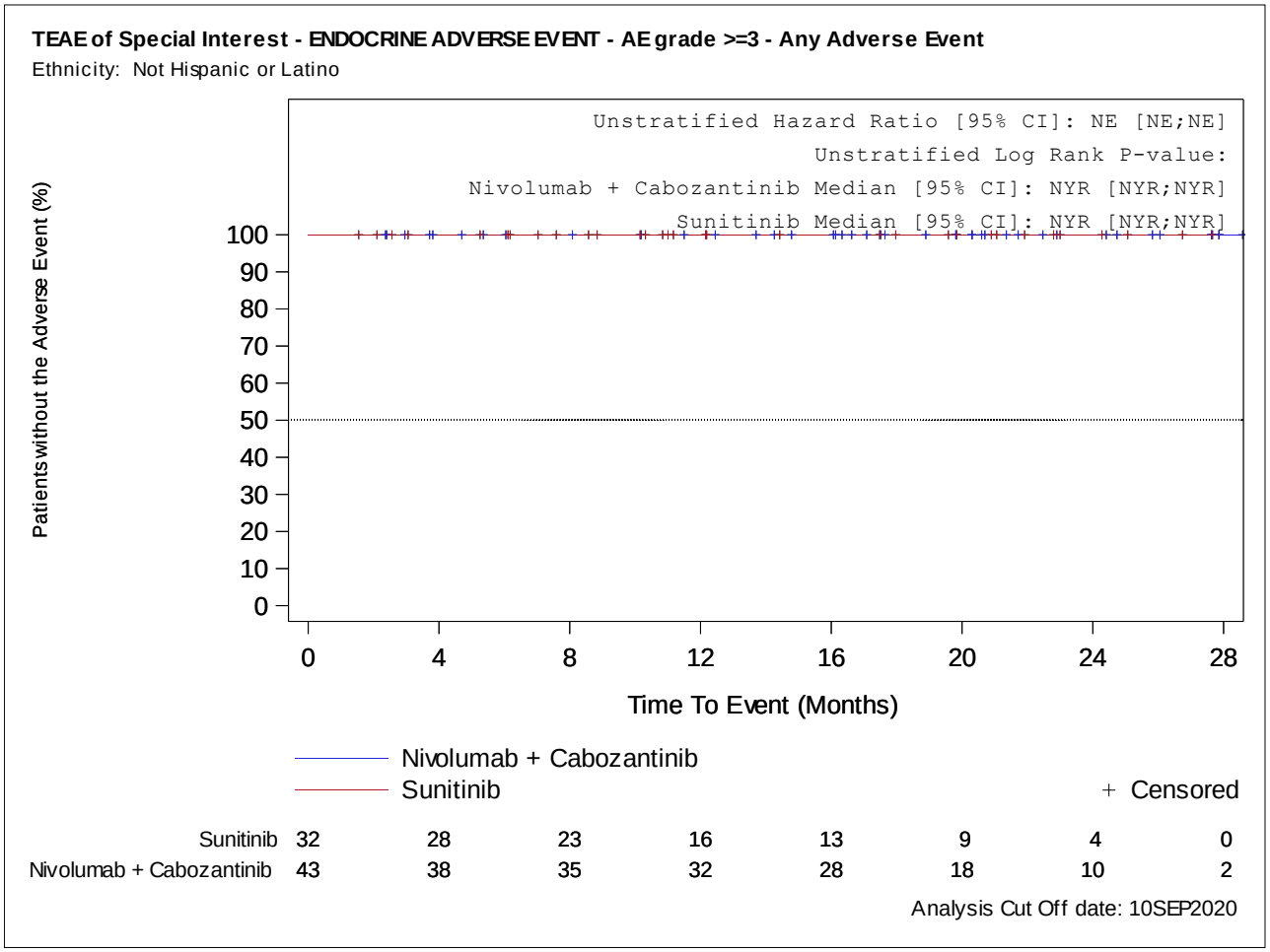
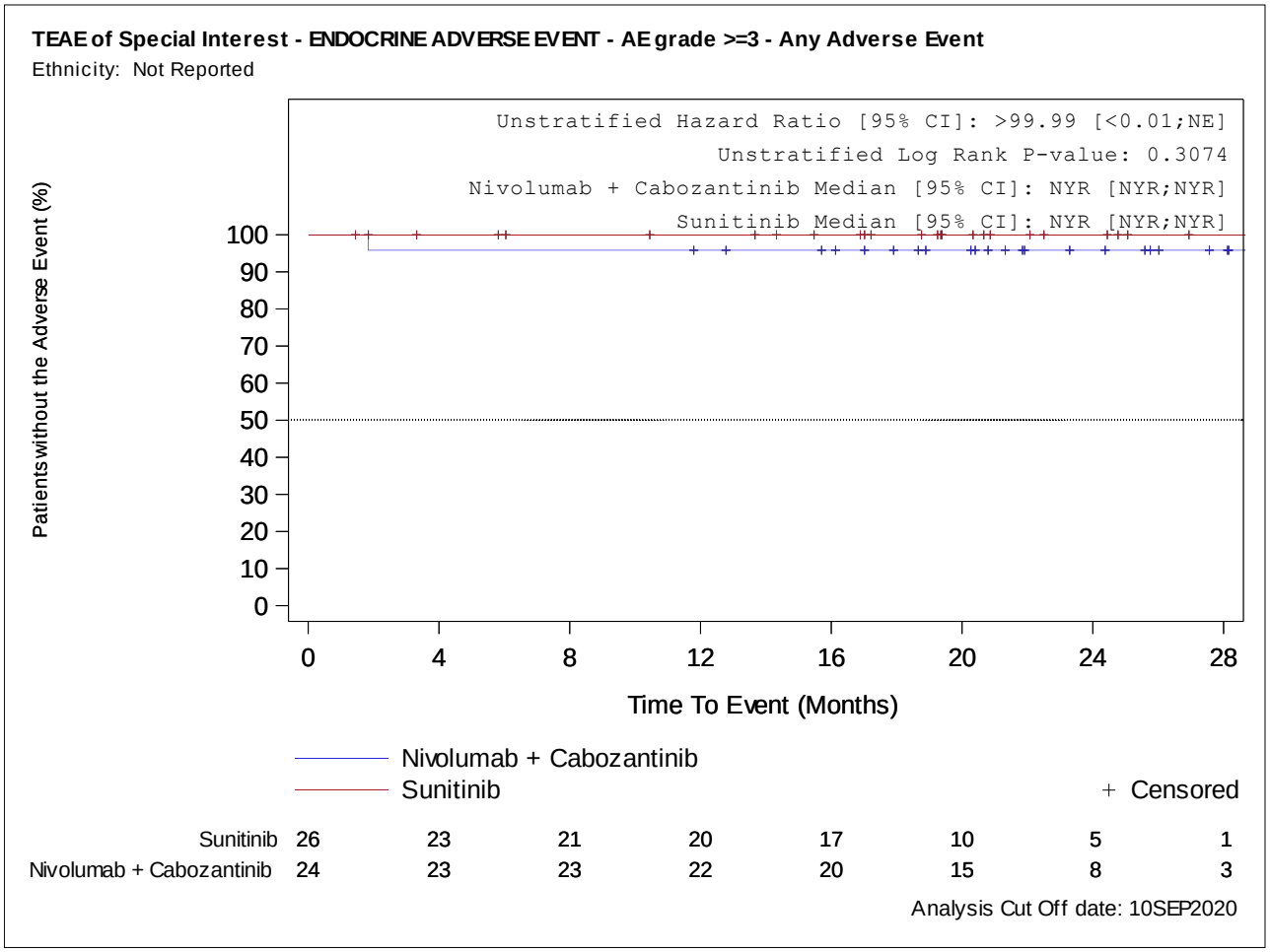
FIGURE 3.19.2.11: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



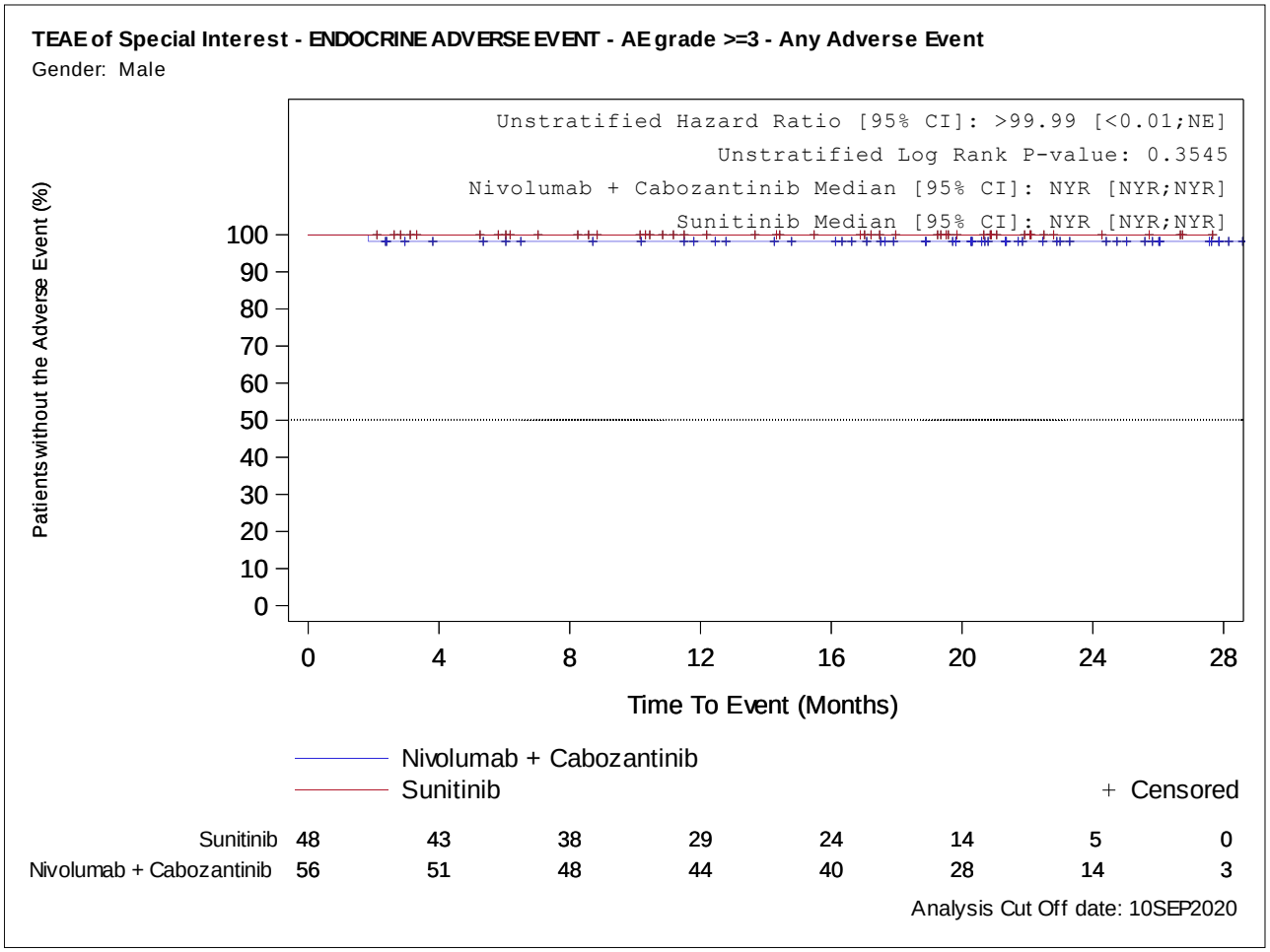

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:48:01

FIGURE 3.19.2.12: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



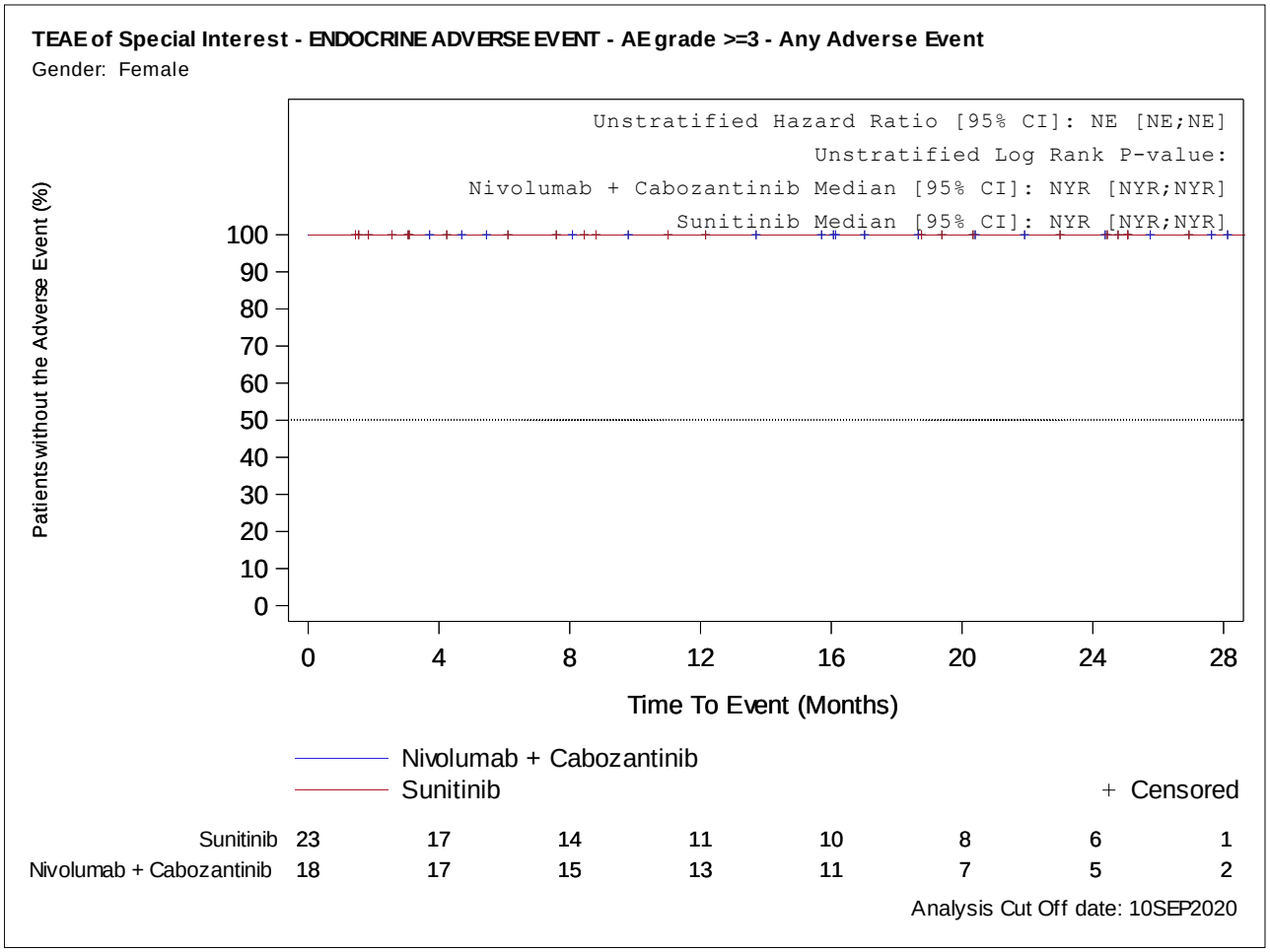

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:48:07

FIGURE 3.19.2.13: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



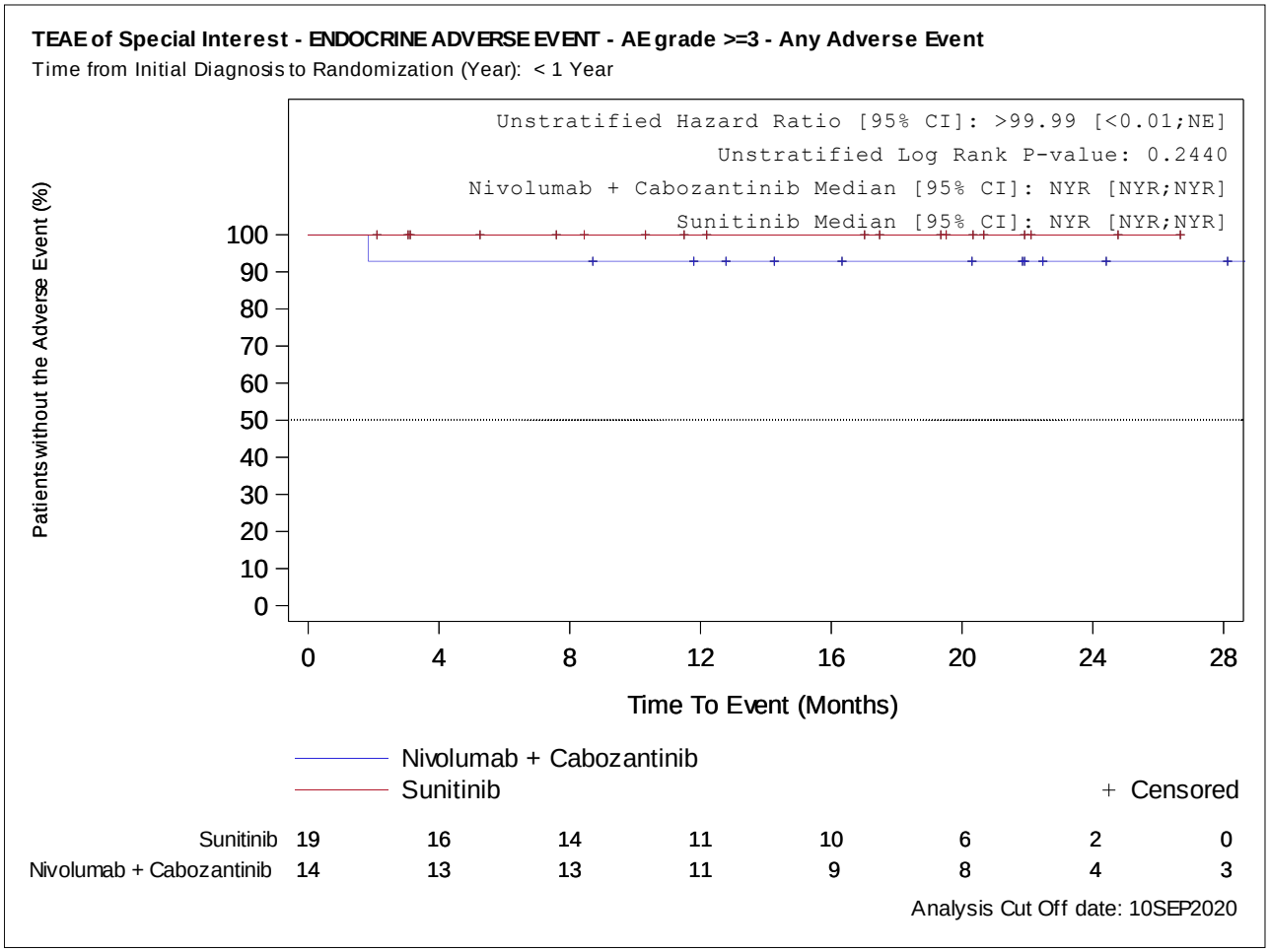

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:48:12

FIGURE 3.19.2.14: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



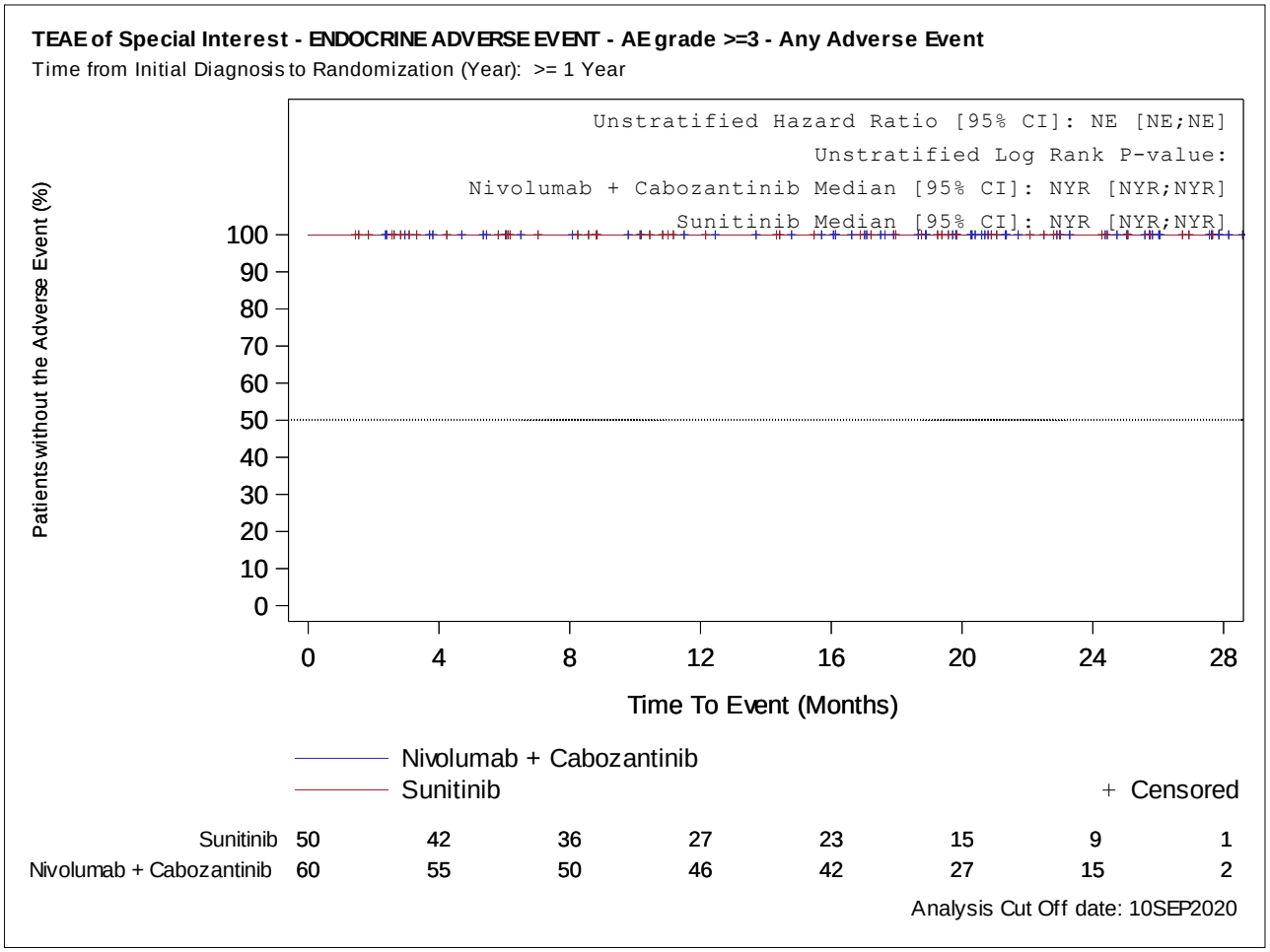

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:48:18

FIGURE 3.19.2.15: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:48:36

FIGURE 3.19.2.16: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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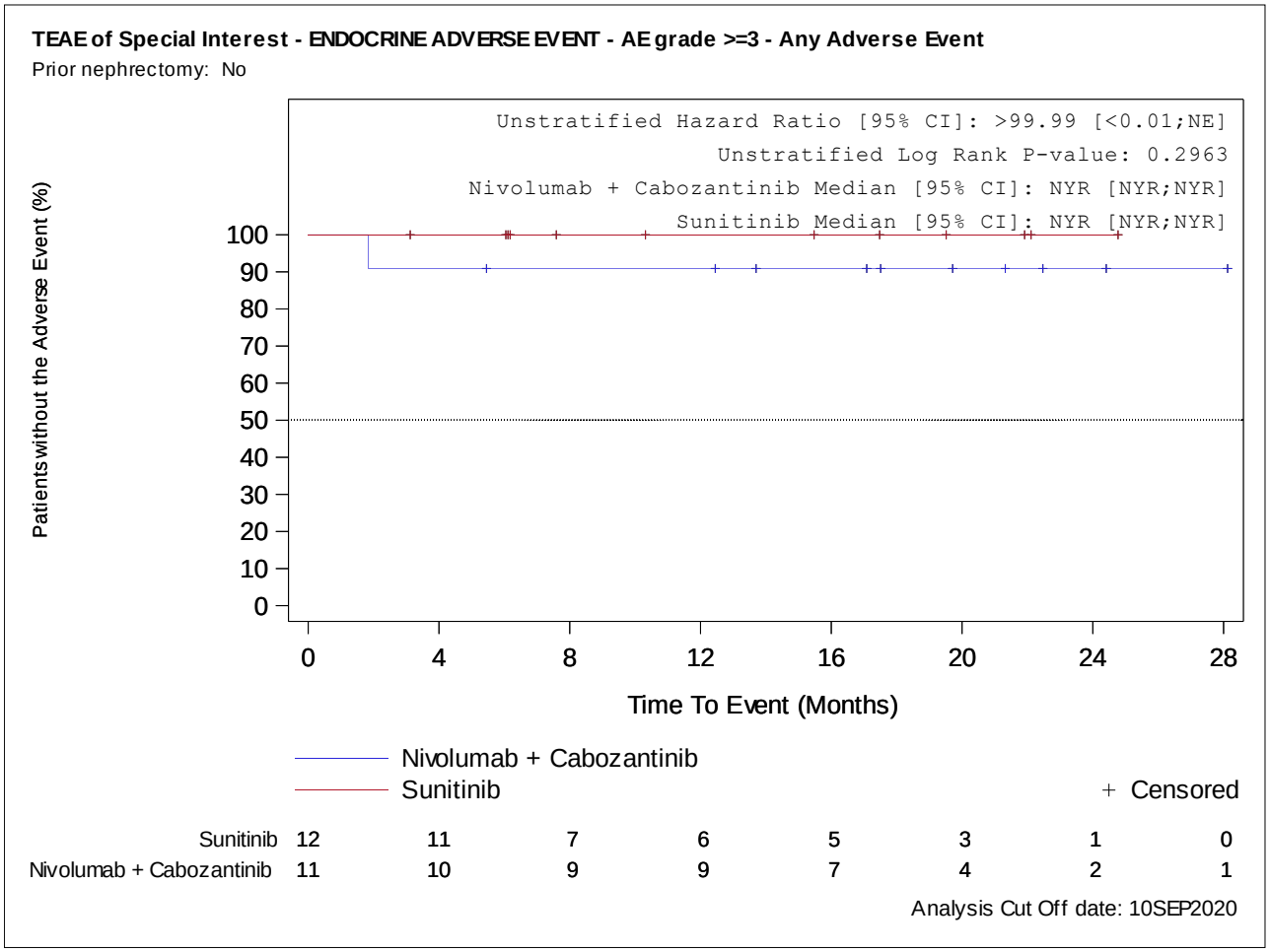
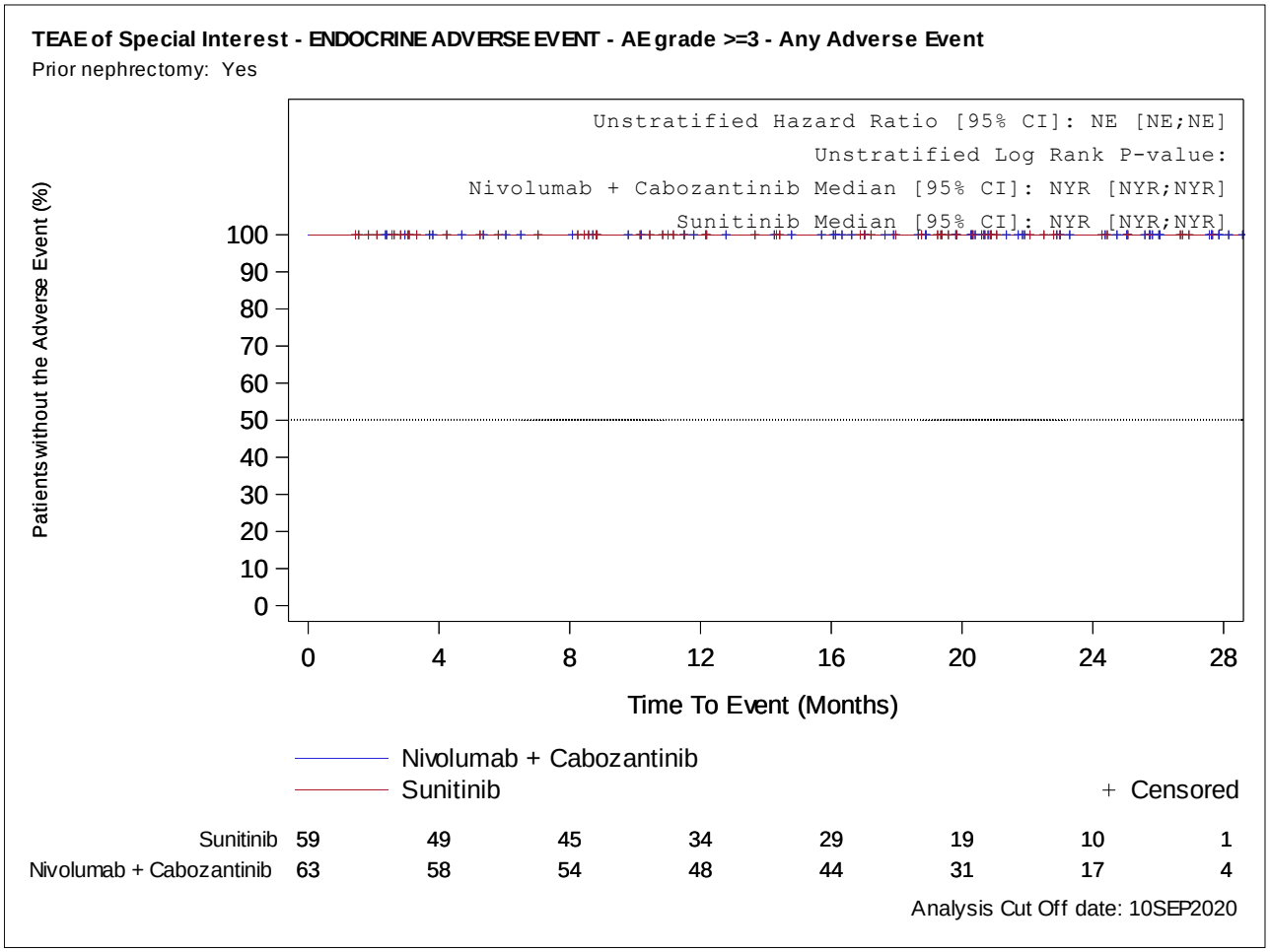
FIGURE 3.19.2.17: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



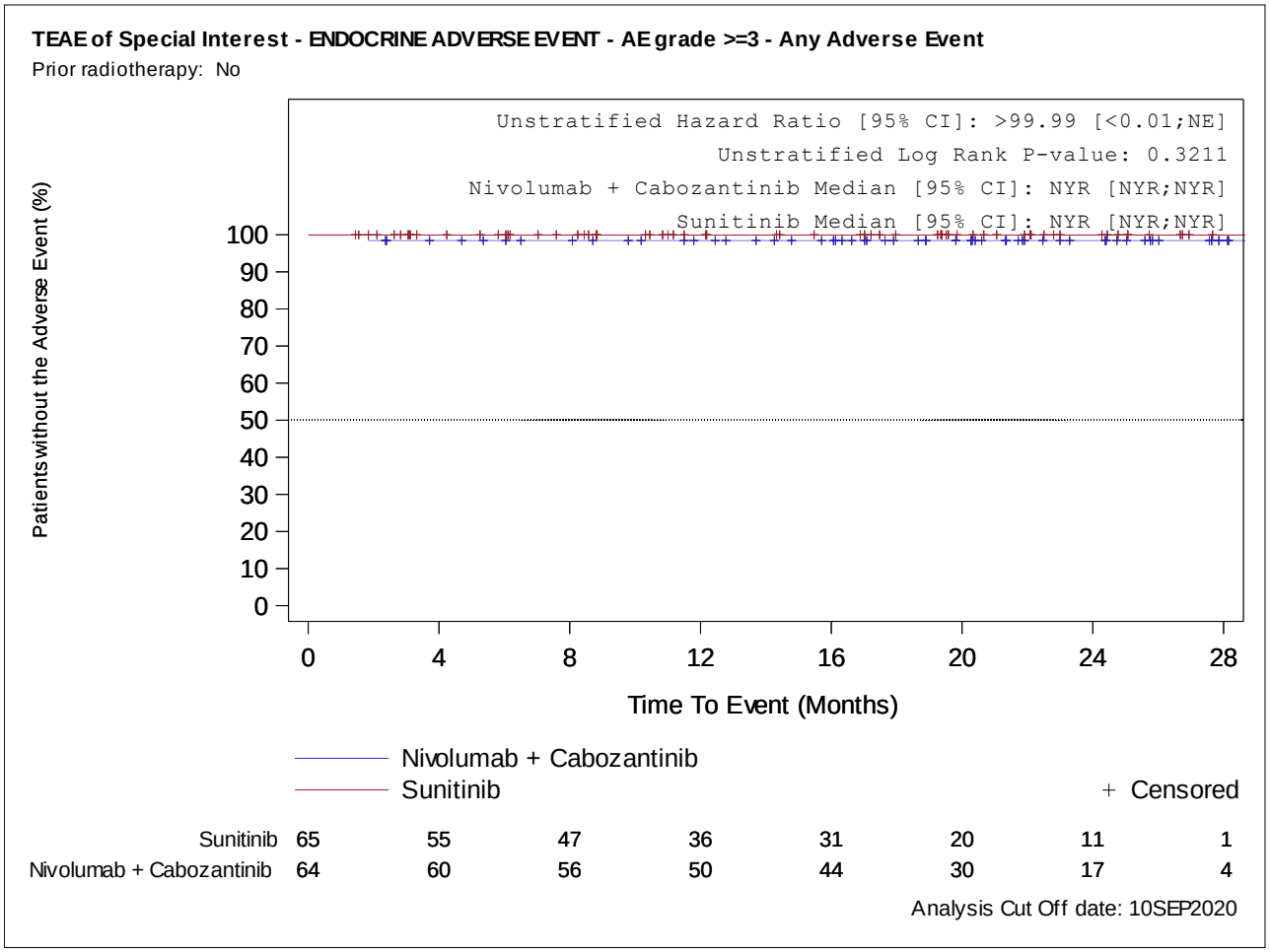

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:49:34

FIGURE 3.19.2.18: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:49:39

FIGURE 3.19.2.19: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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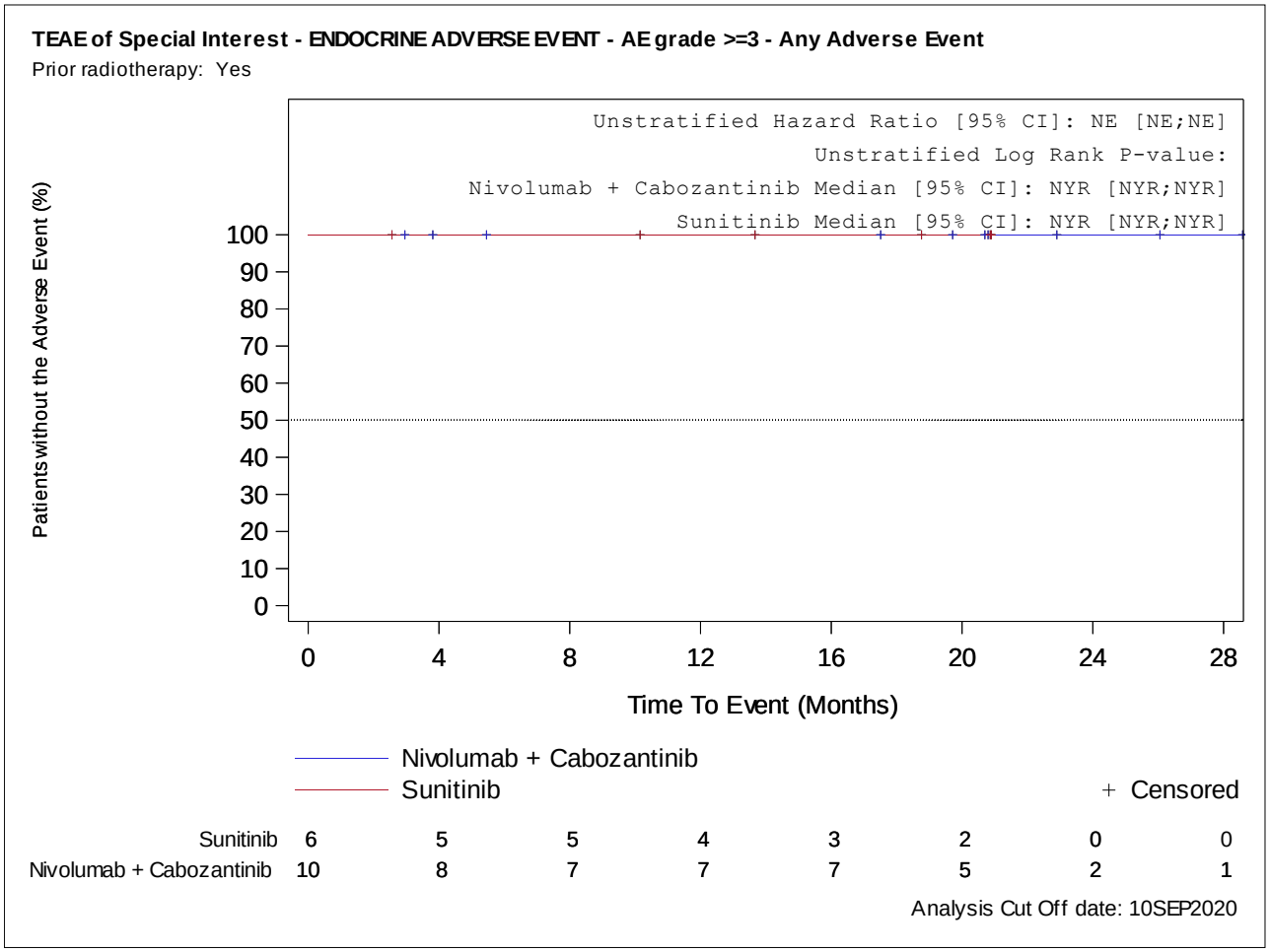
FIGURE 3.19.2.20: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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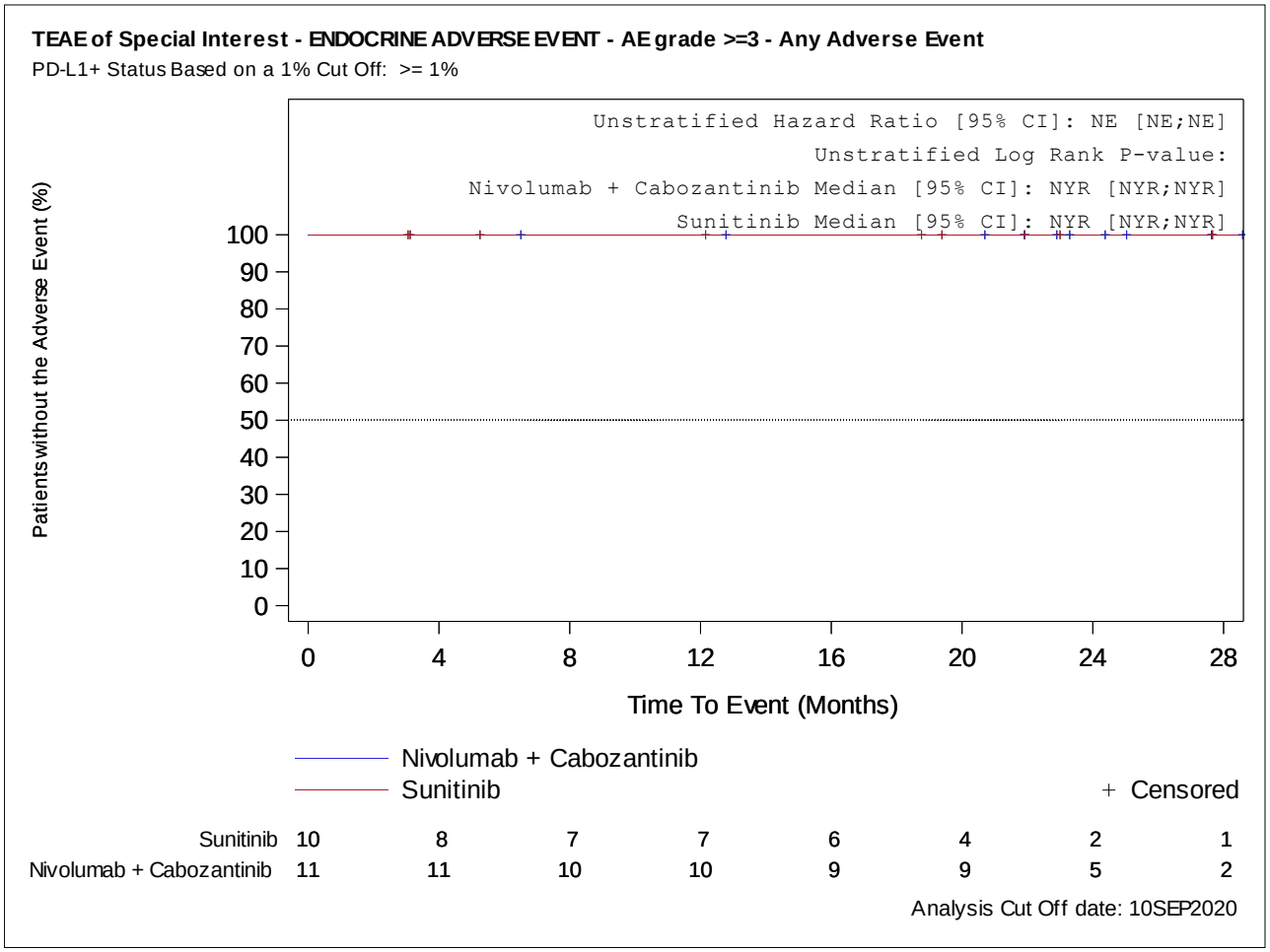
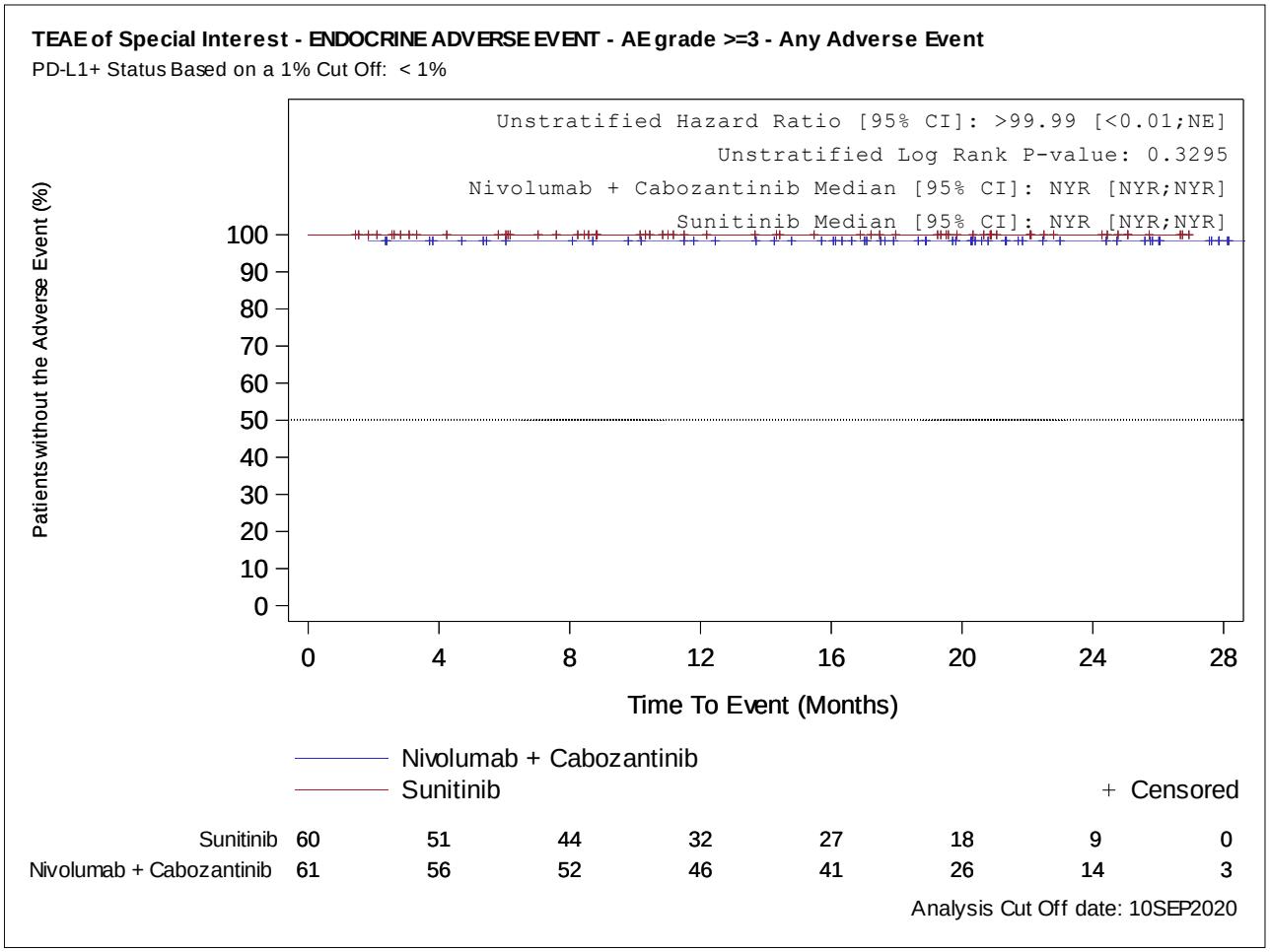
FIGURE 3.19.2.21: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



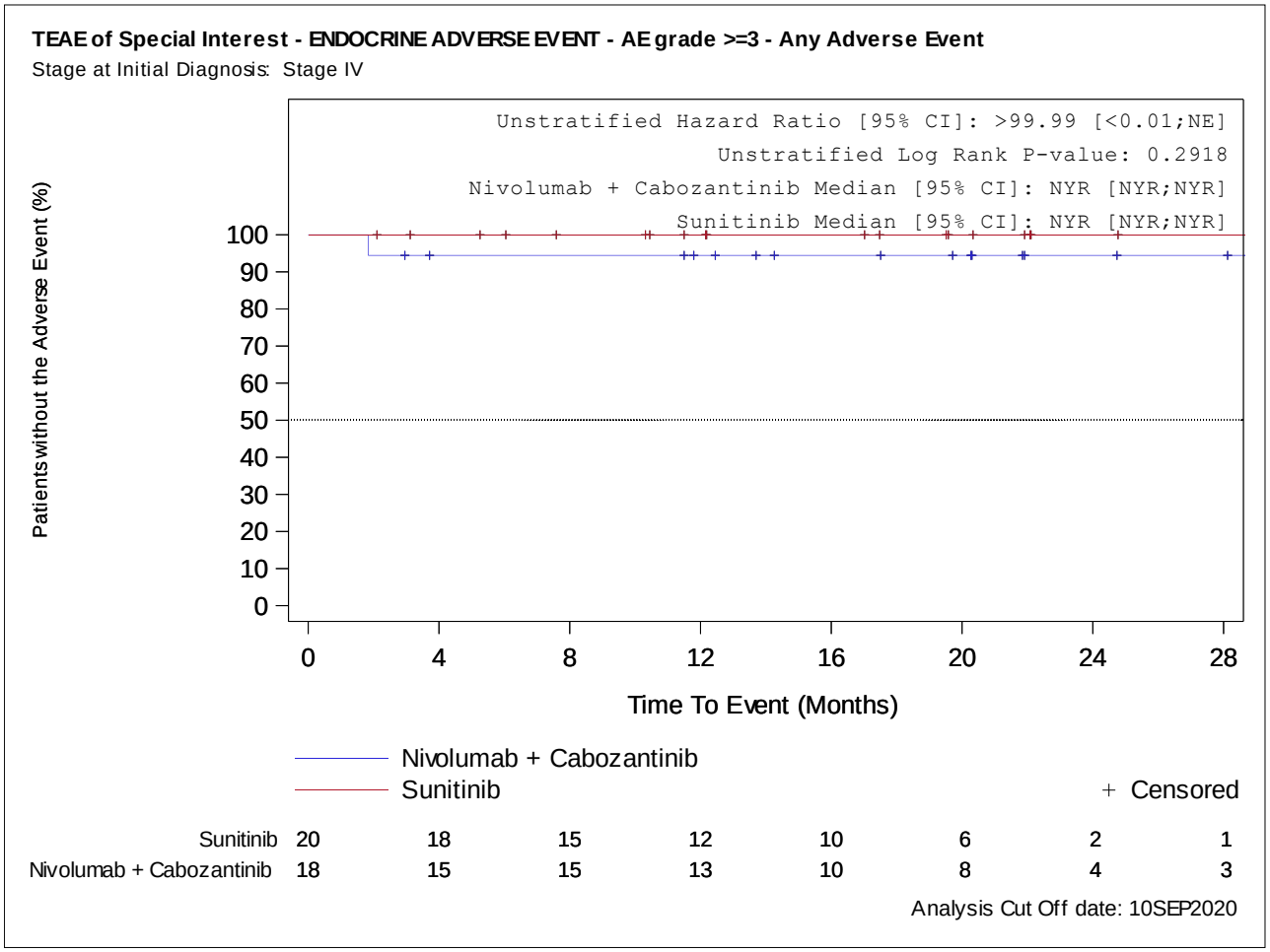

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:49:56

FIGURE 3.19.2.22: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



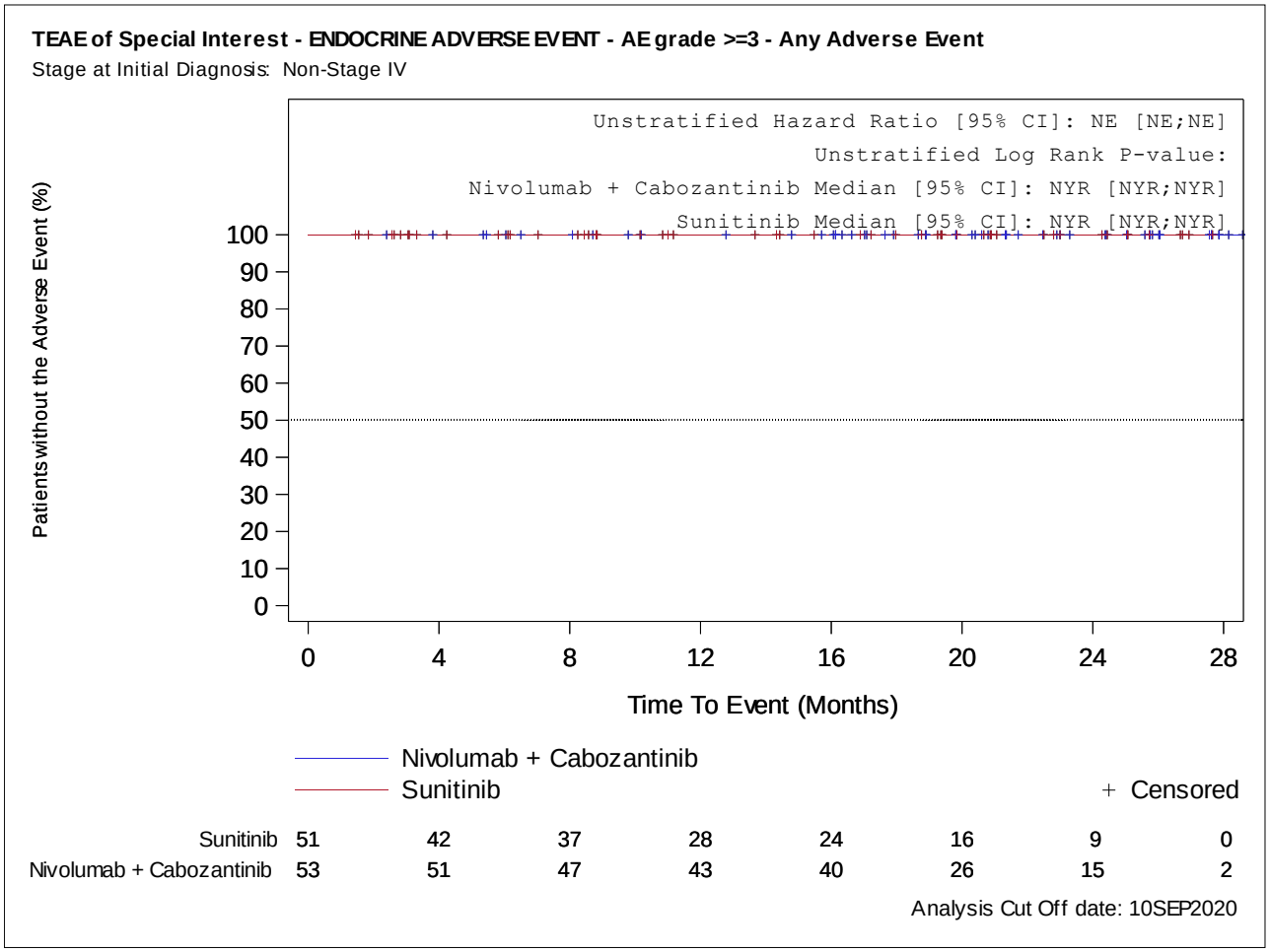

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:50:02

FIGURE 3.19.2.23: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:50:31

FIGURE 3.19.2.24: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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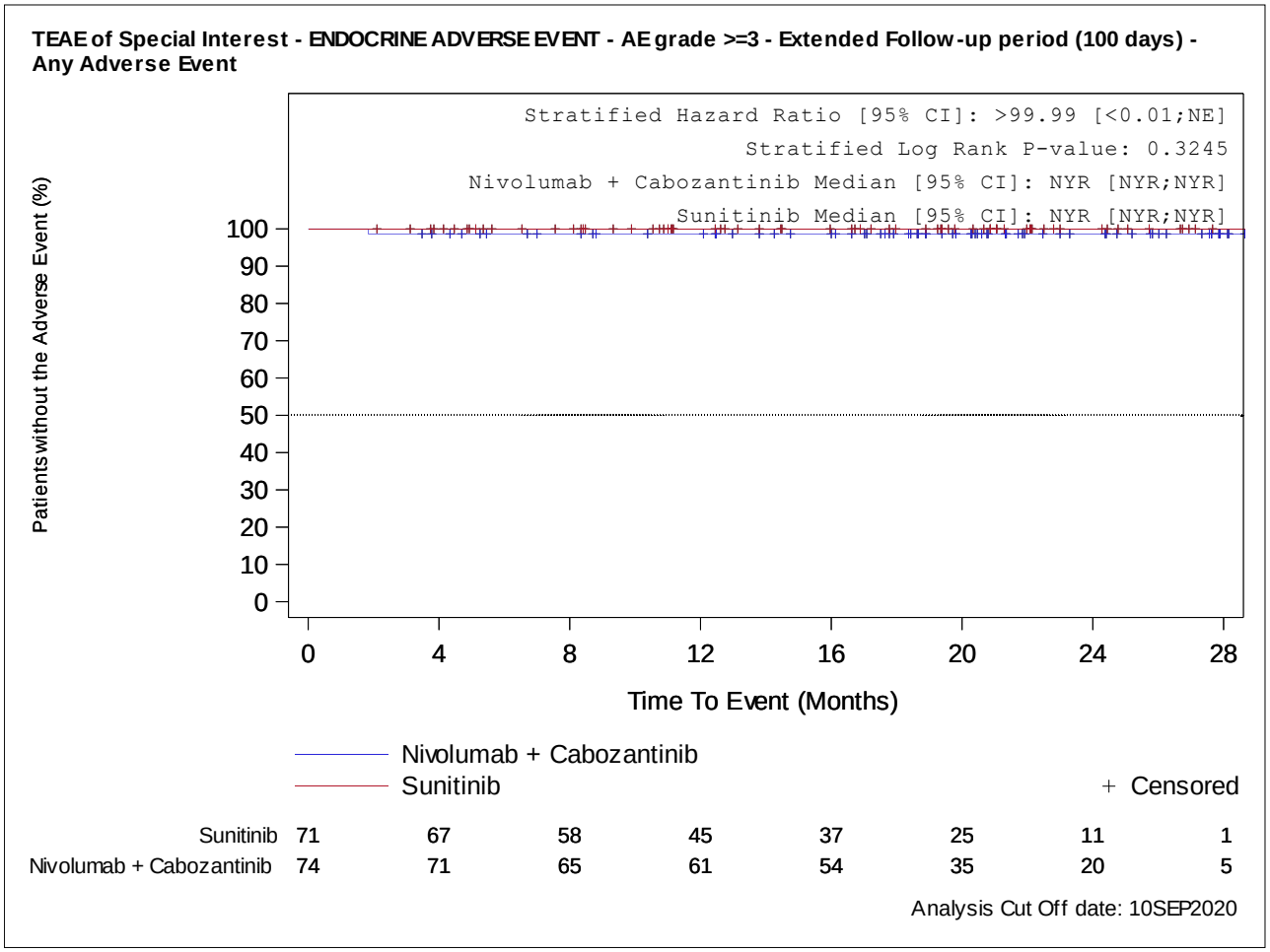
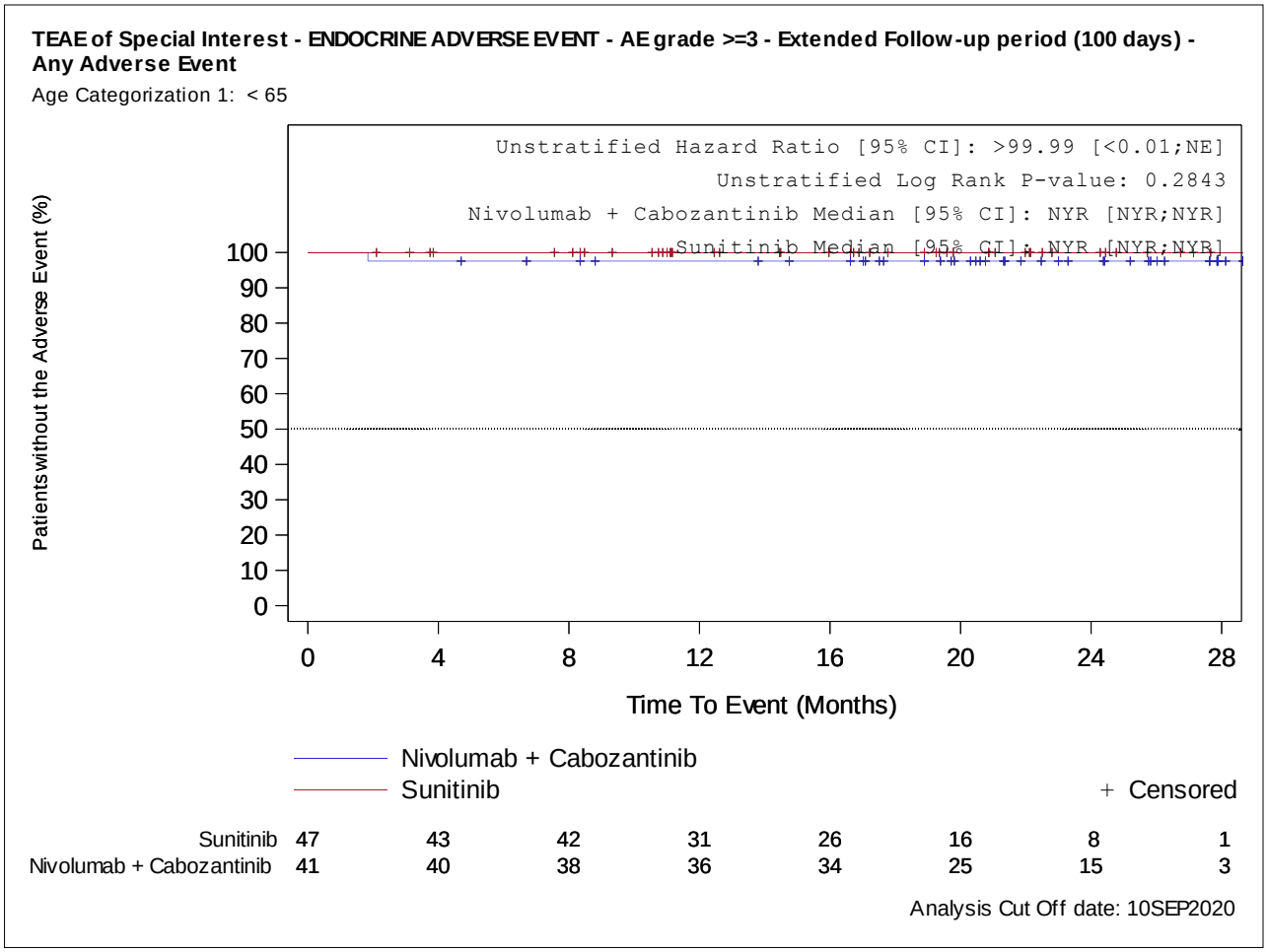
FIGURE 3.20.1: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



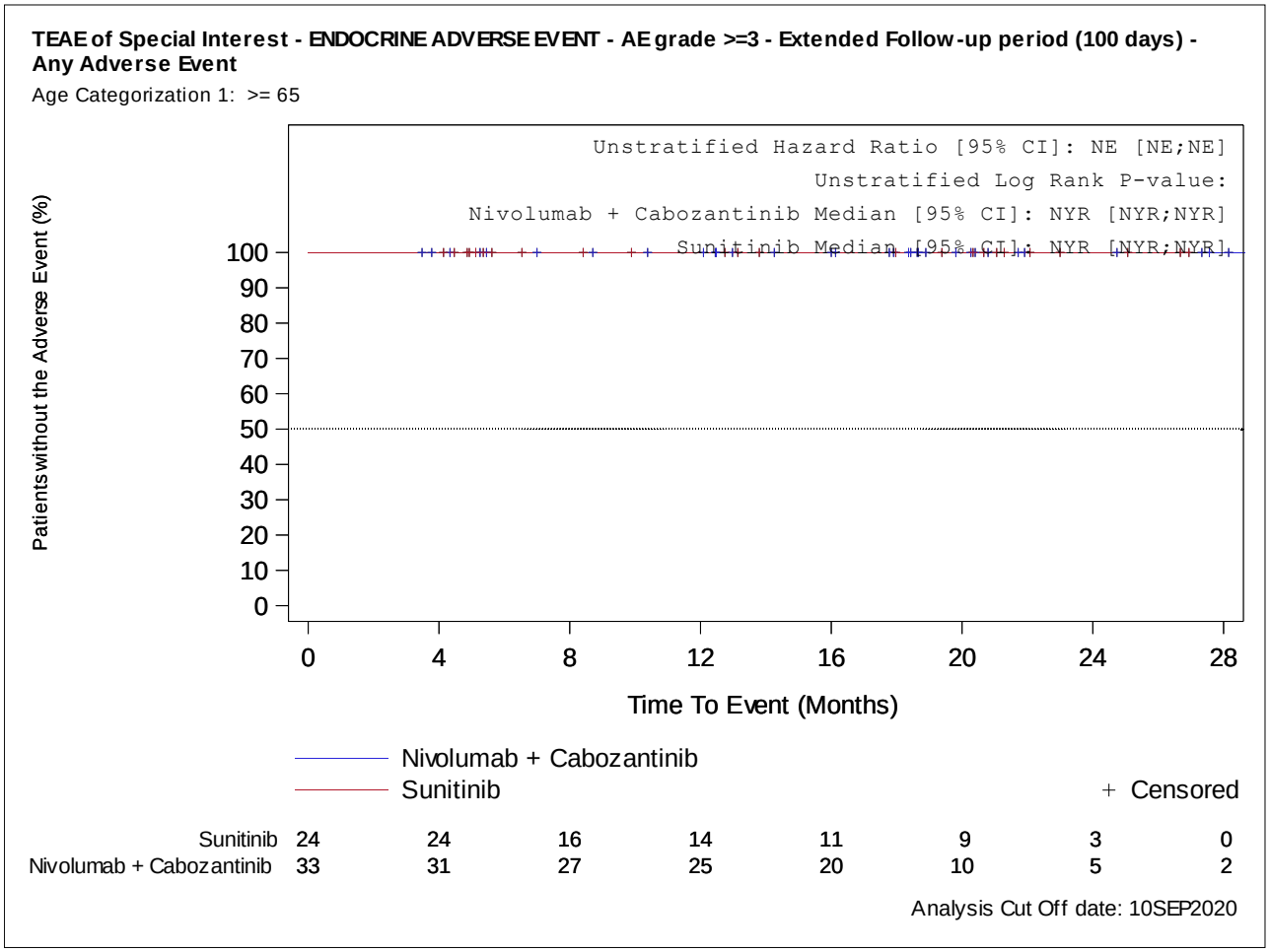

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:53:57

FIGURE 3.20.2.1: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  < 65



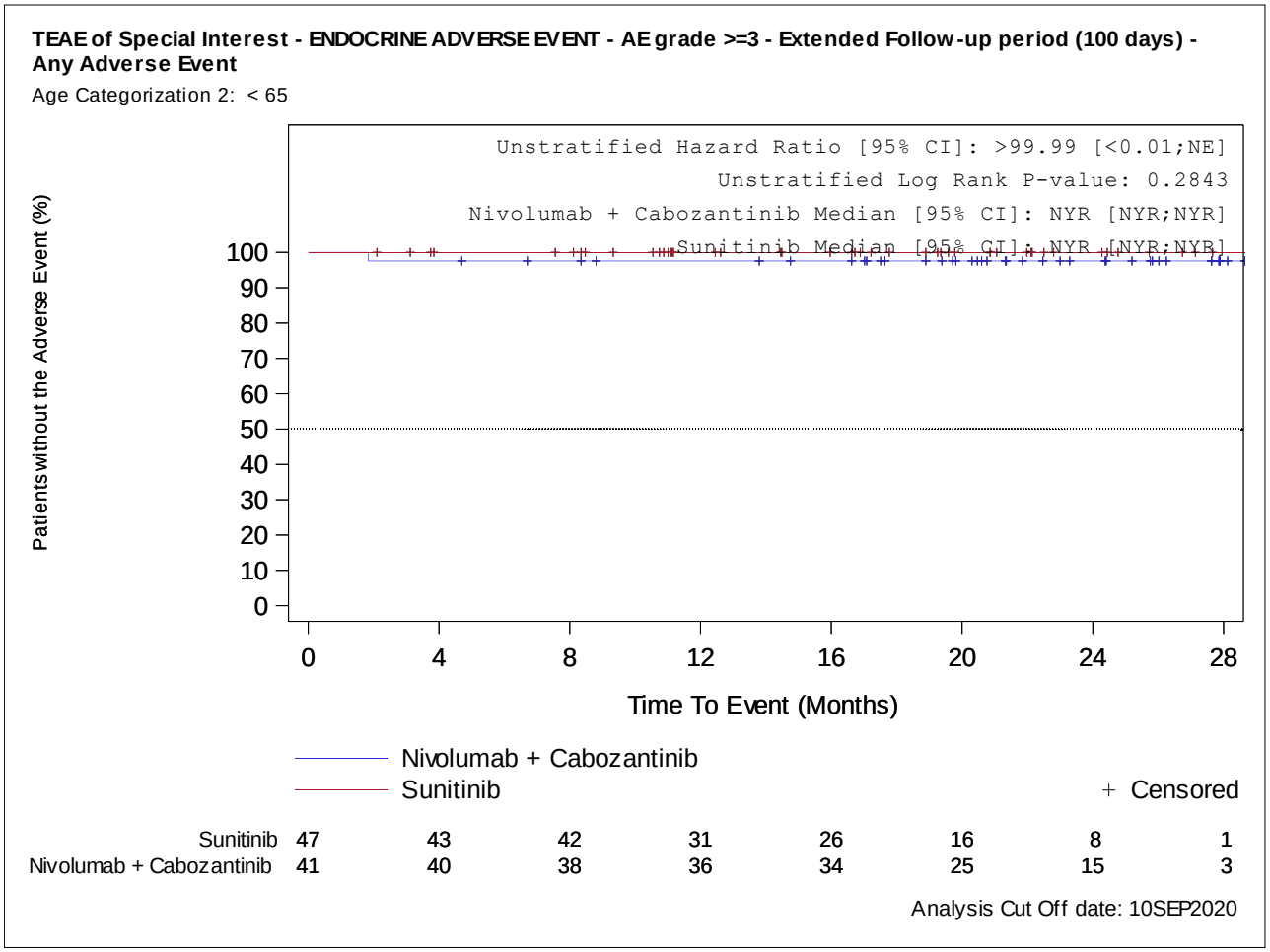

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:54:00

FIGURE 3.20.2.2: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



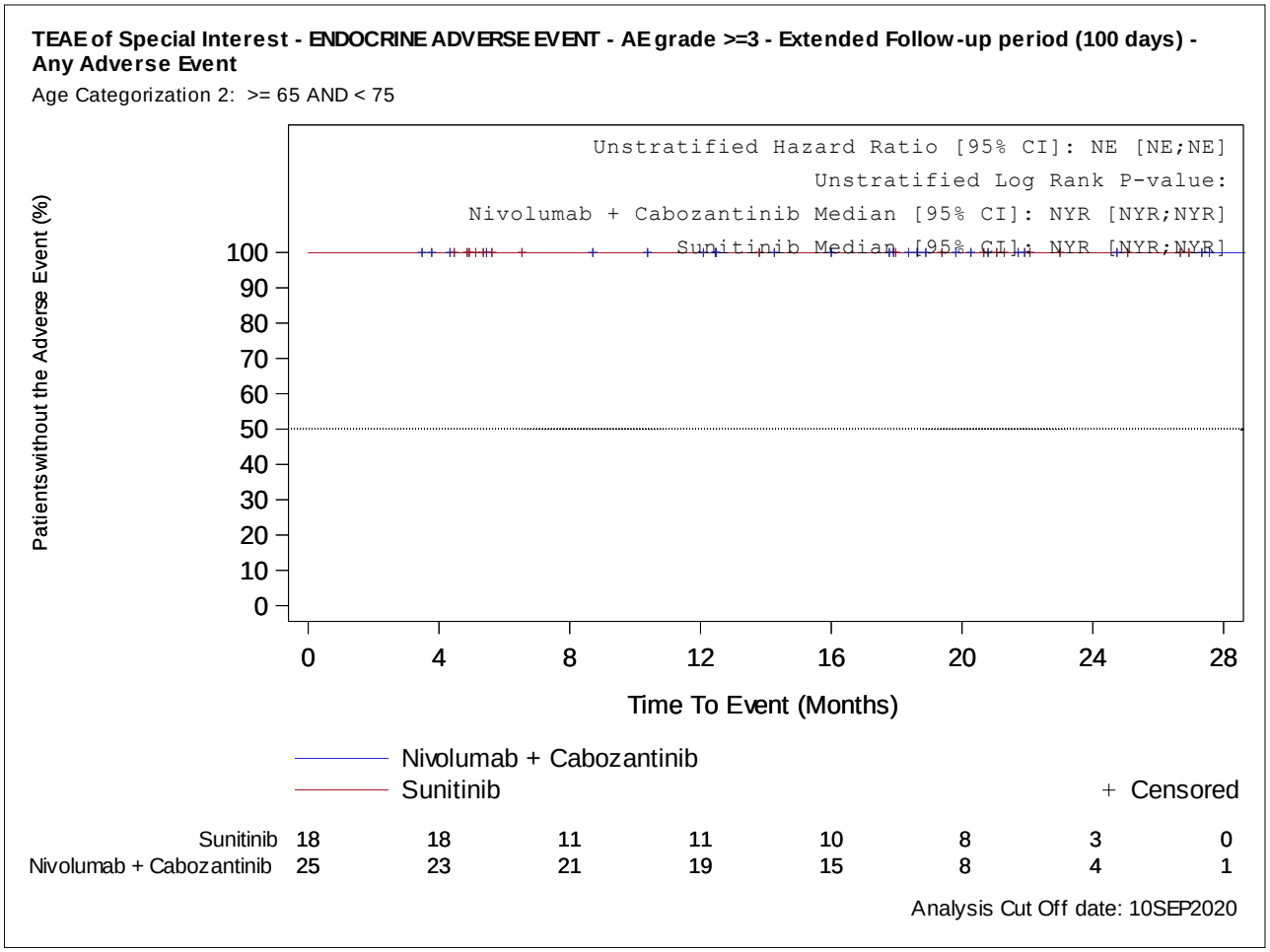

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:54:06

FIGURE 3.20.2.3: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



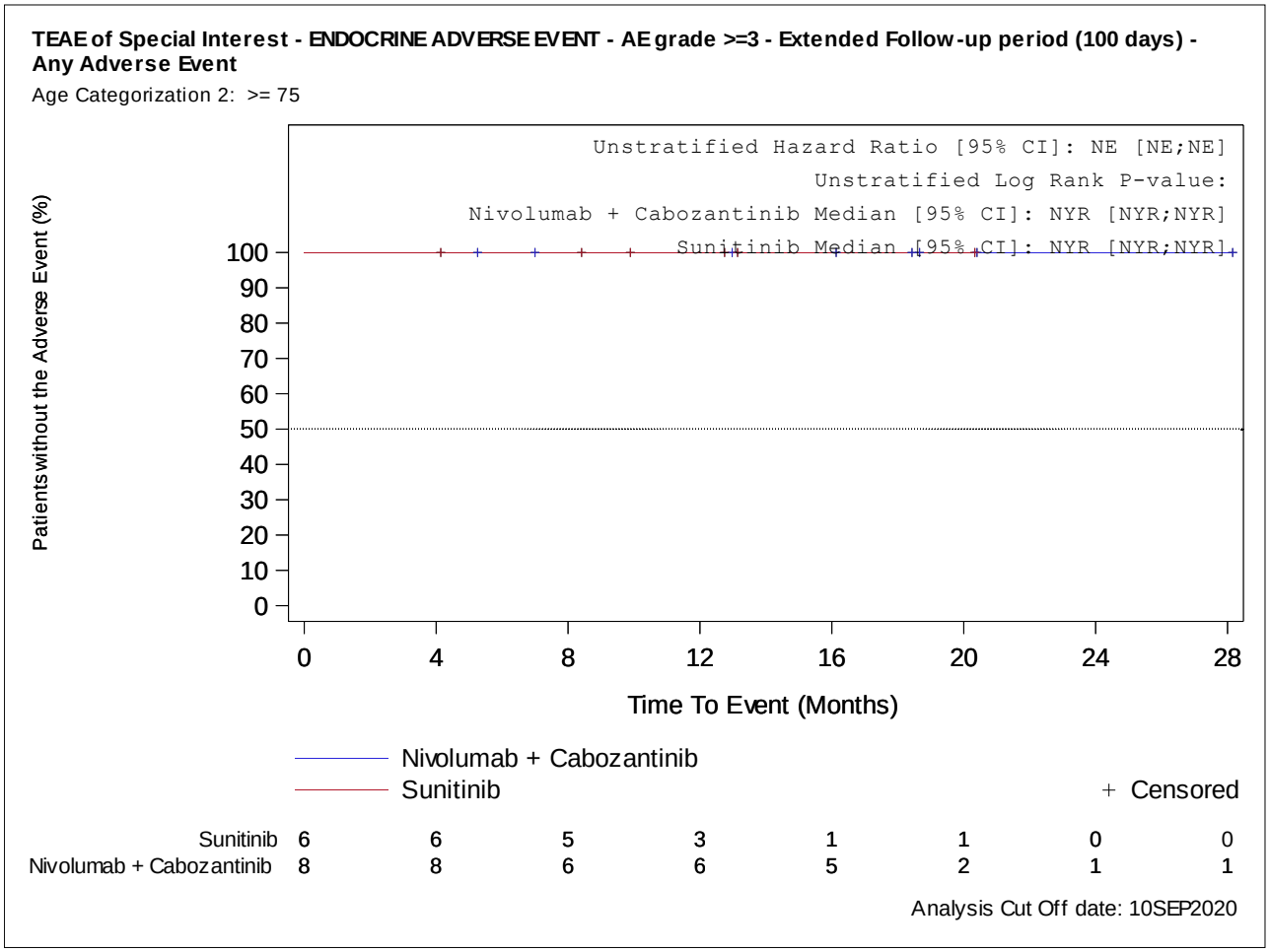

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:54:11

FIGURE 3.20.2.4: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



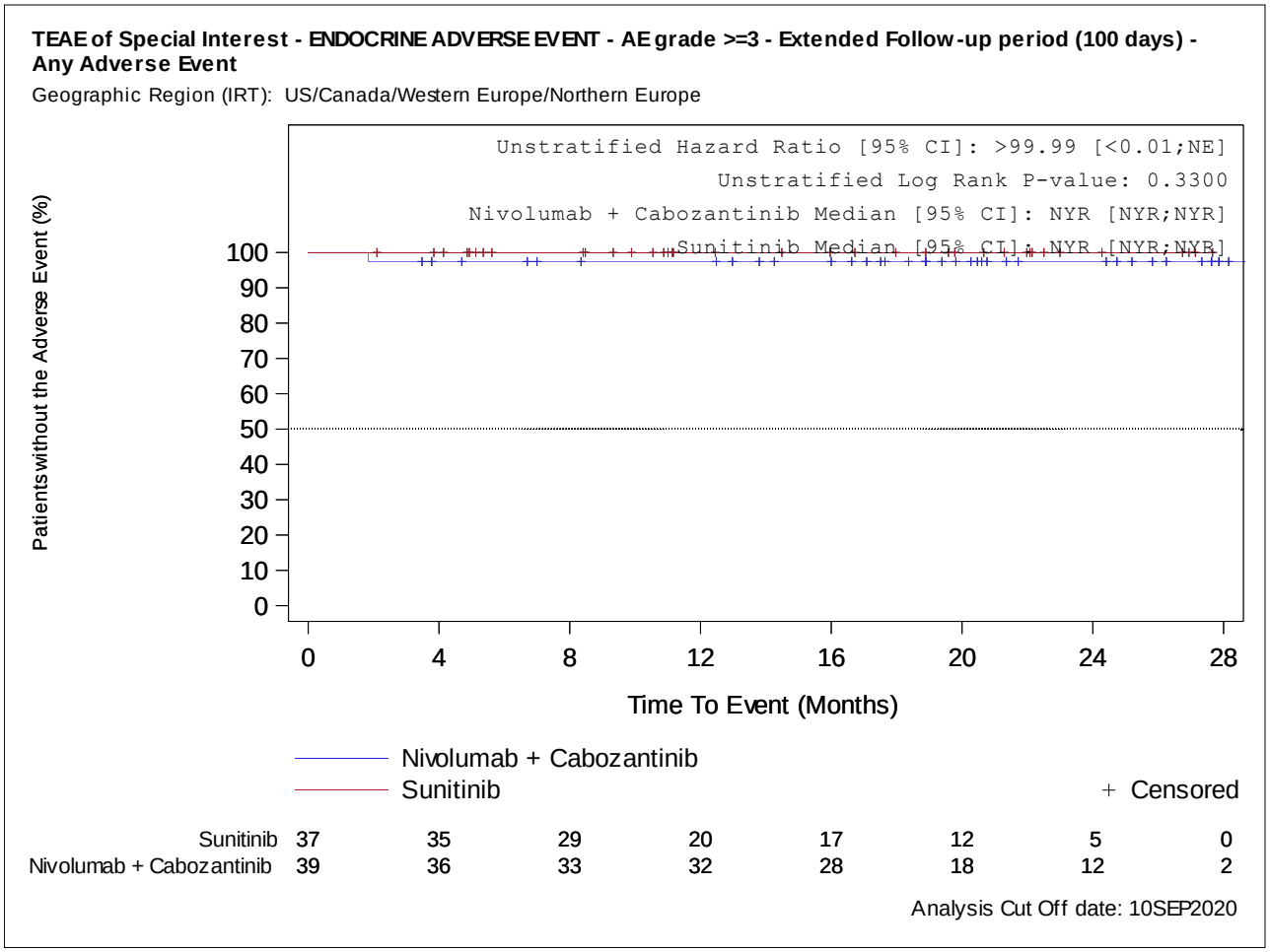

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:54:18

FIGURE 3.20.2.5: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



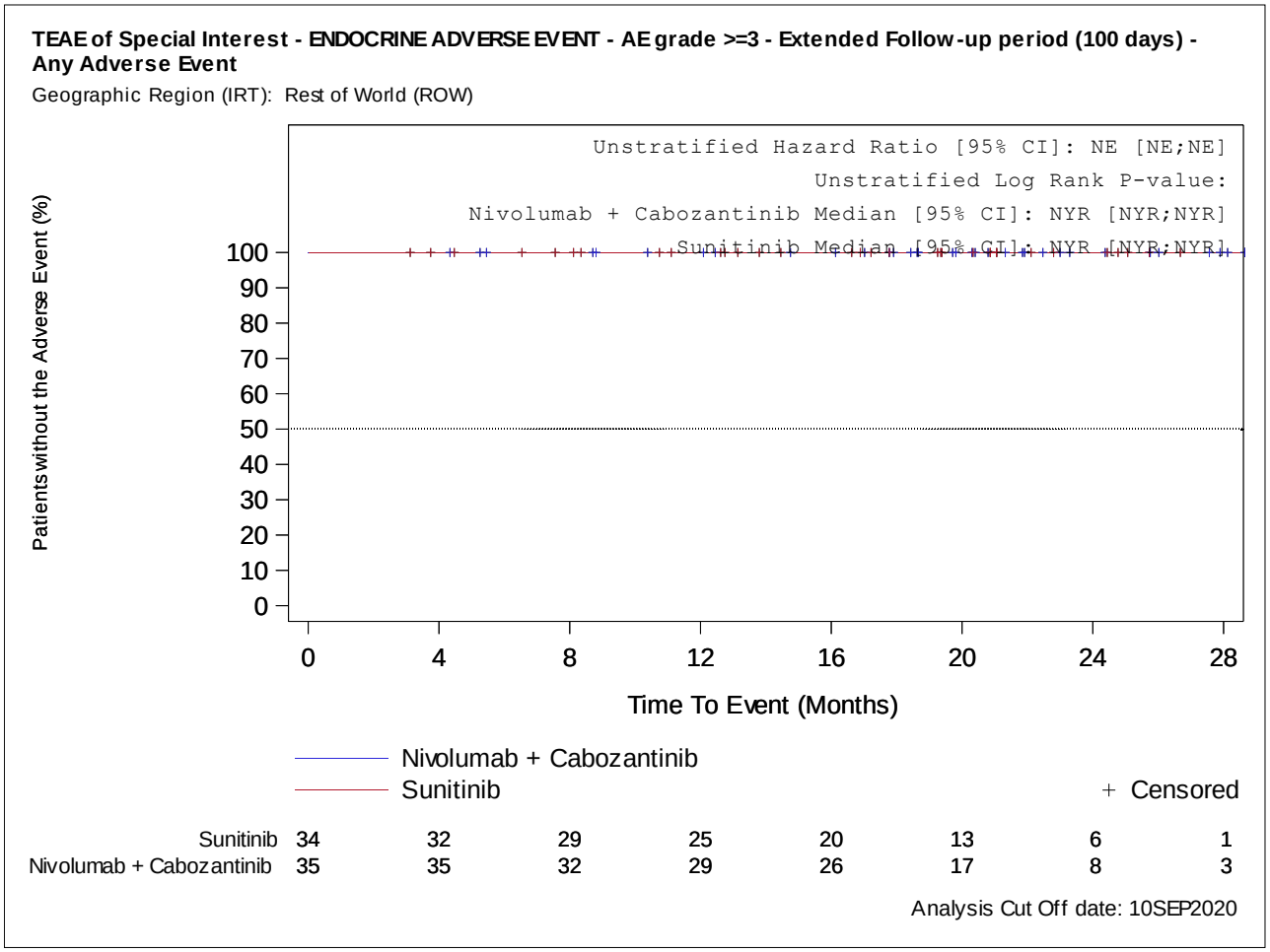

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:54:24

FIGURE 3.20.2.6: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



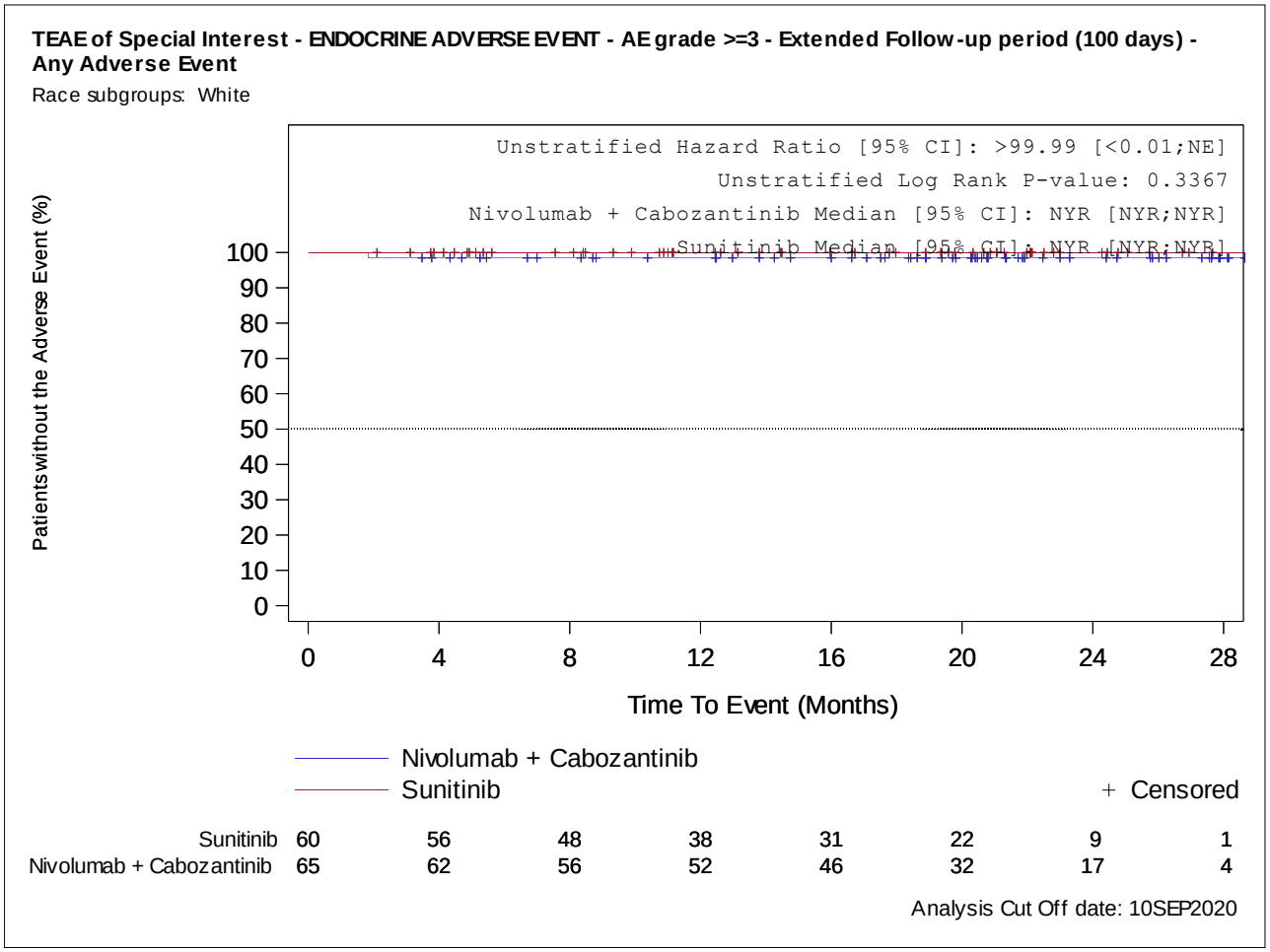

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:54:30

FIGURE 3.20.2.7: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



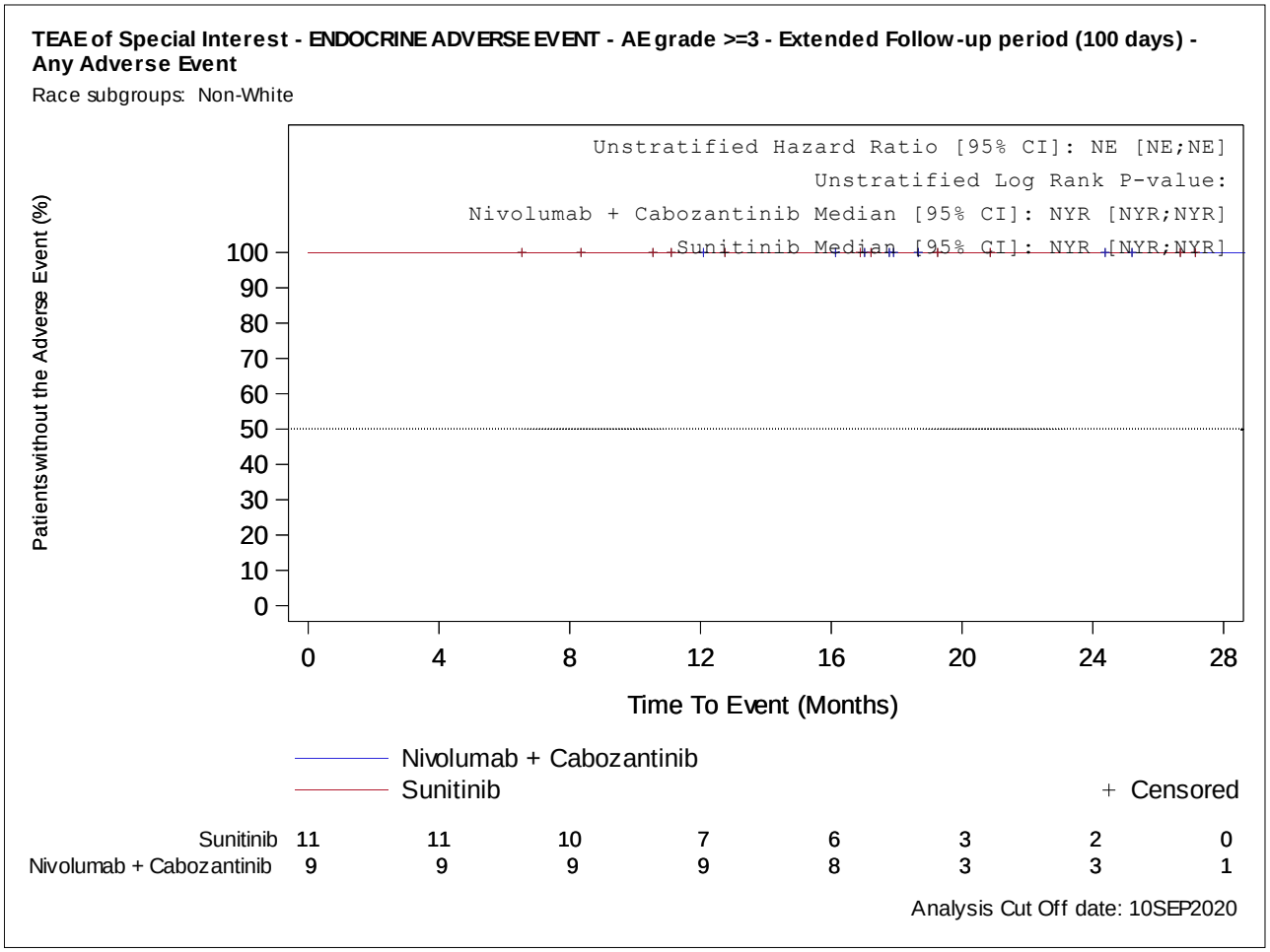

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:54:35

FIGURE 3.20.2.8: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



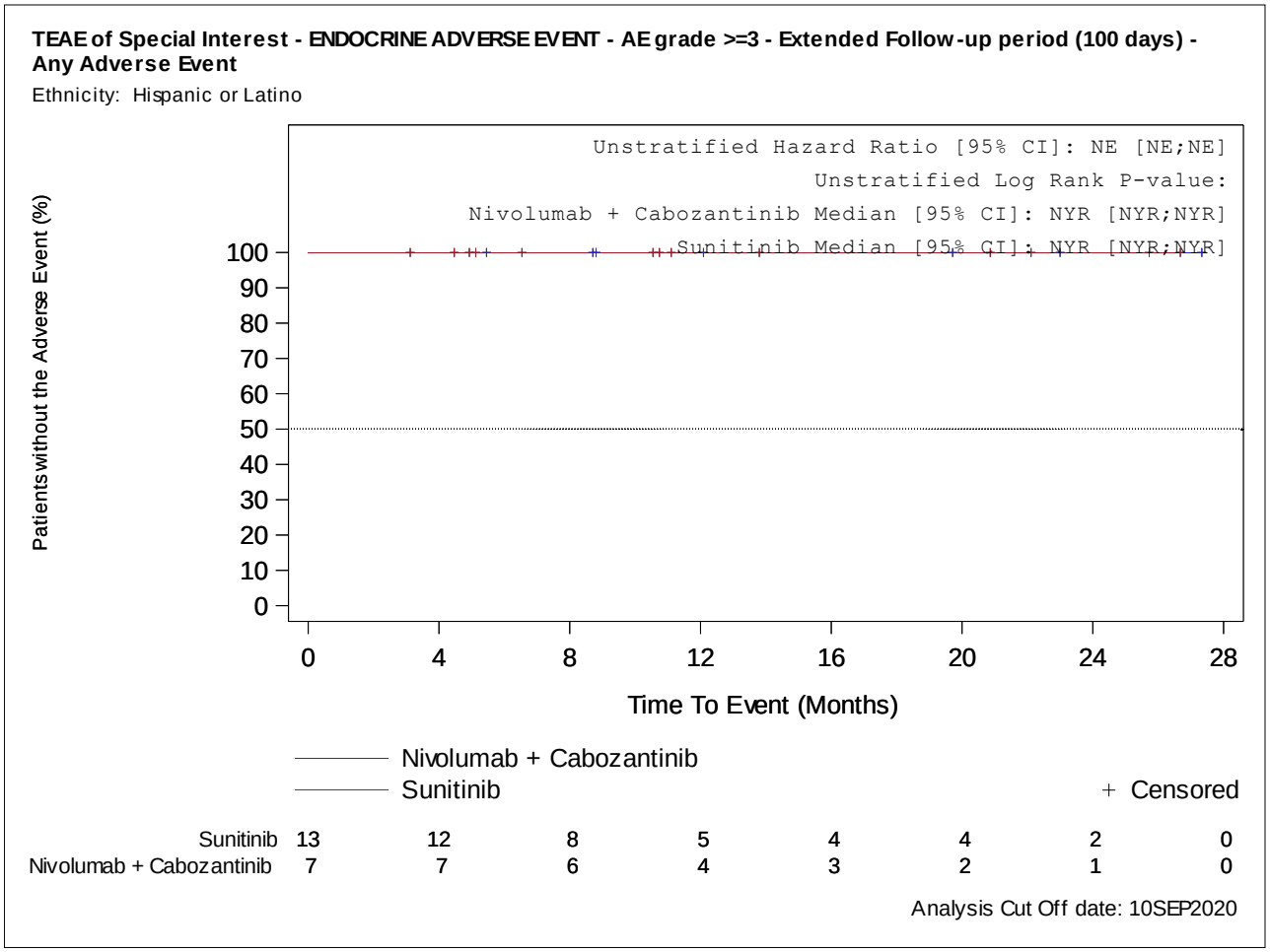

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:54:41

FIGURE 3.20.2.9: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



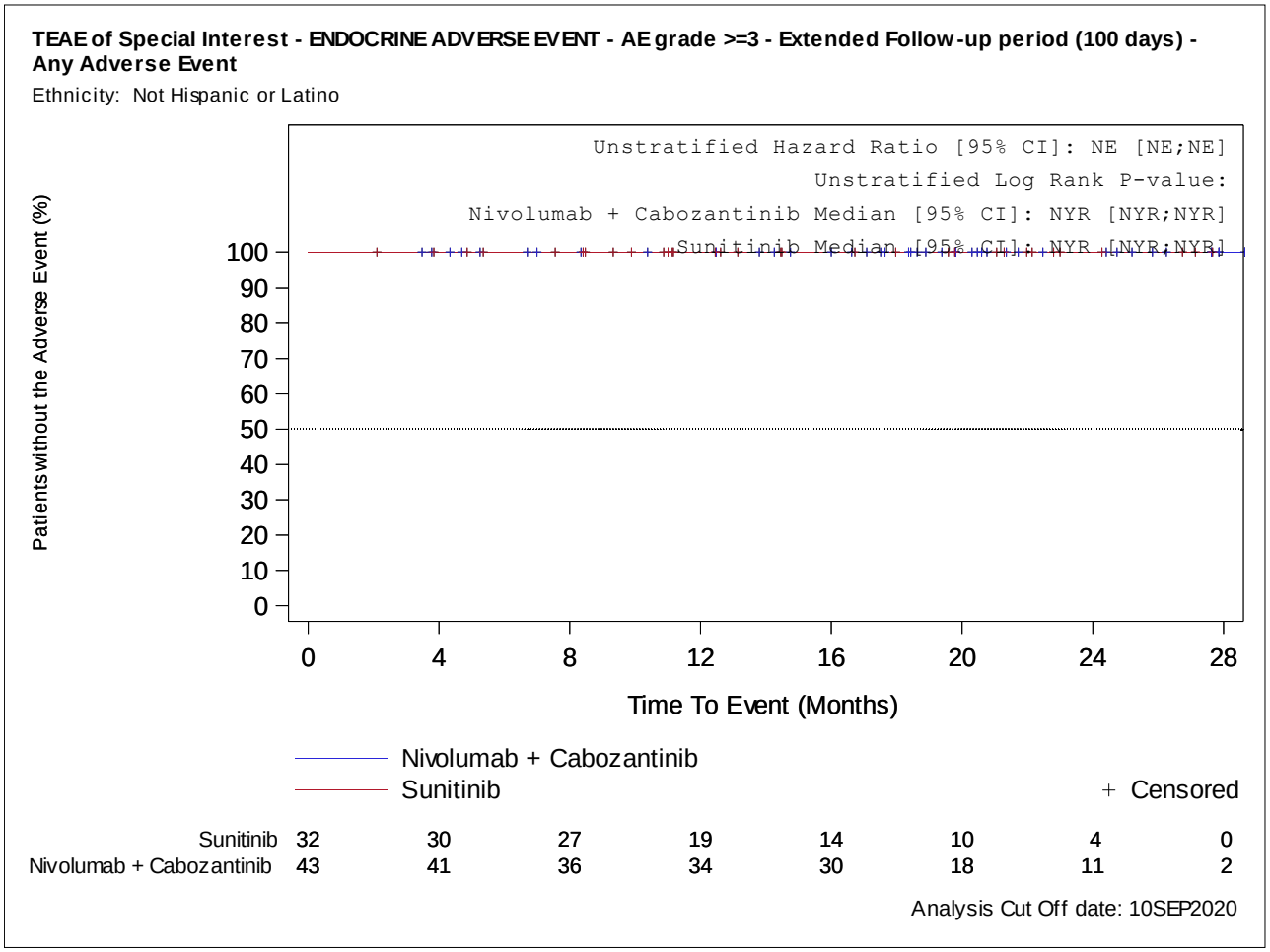

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:54:47

FIGURE 3.20.2.10: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



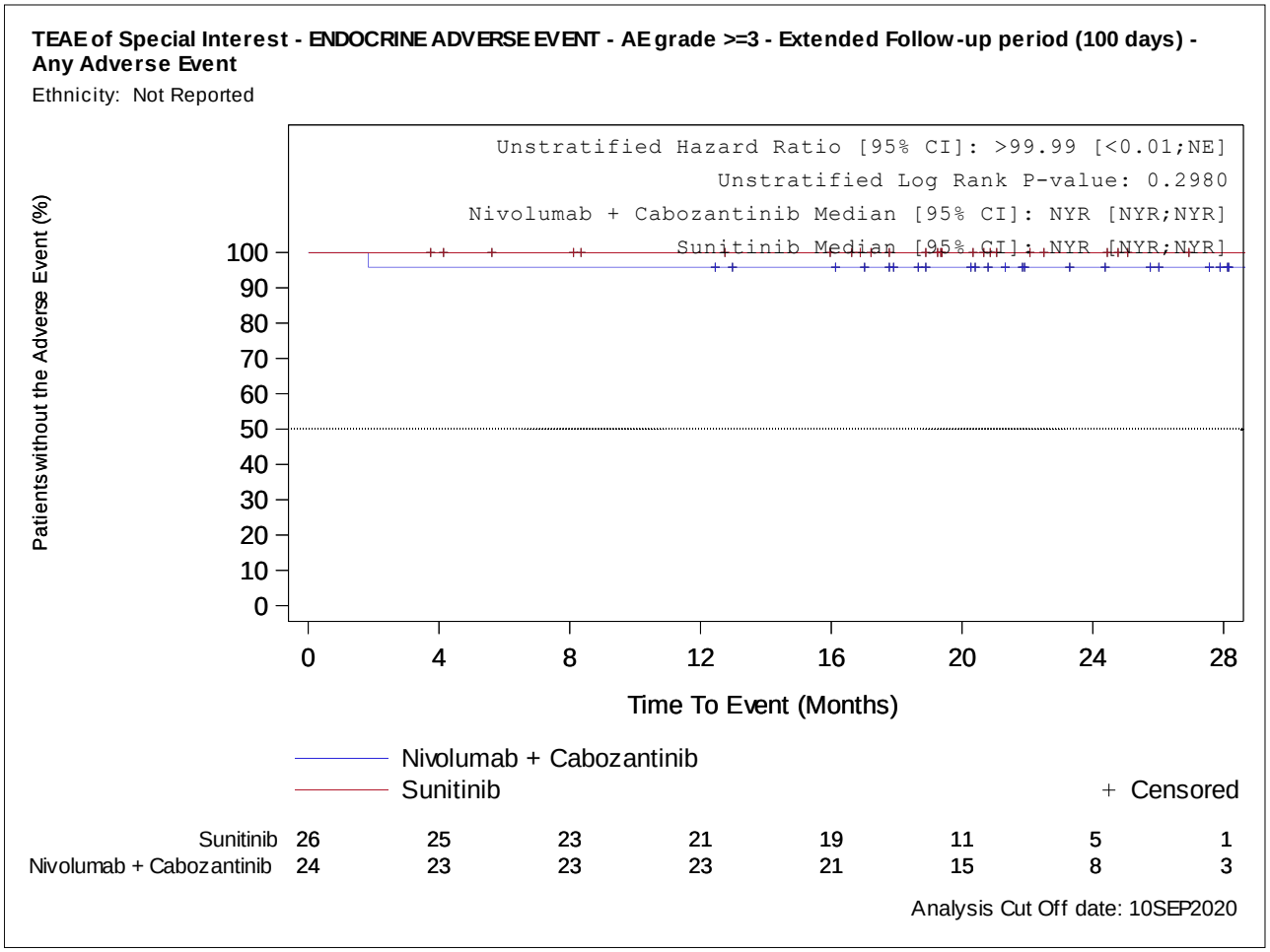

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:54:53

FIGURE 3.20.2.11: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity:  Not Hispanic or Latino



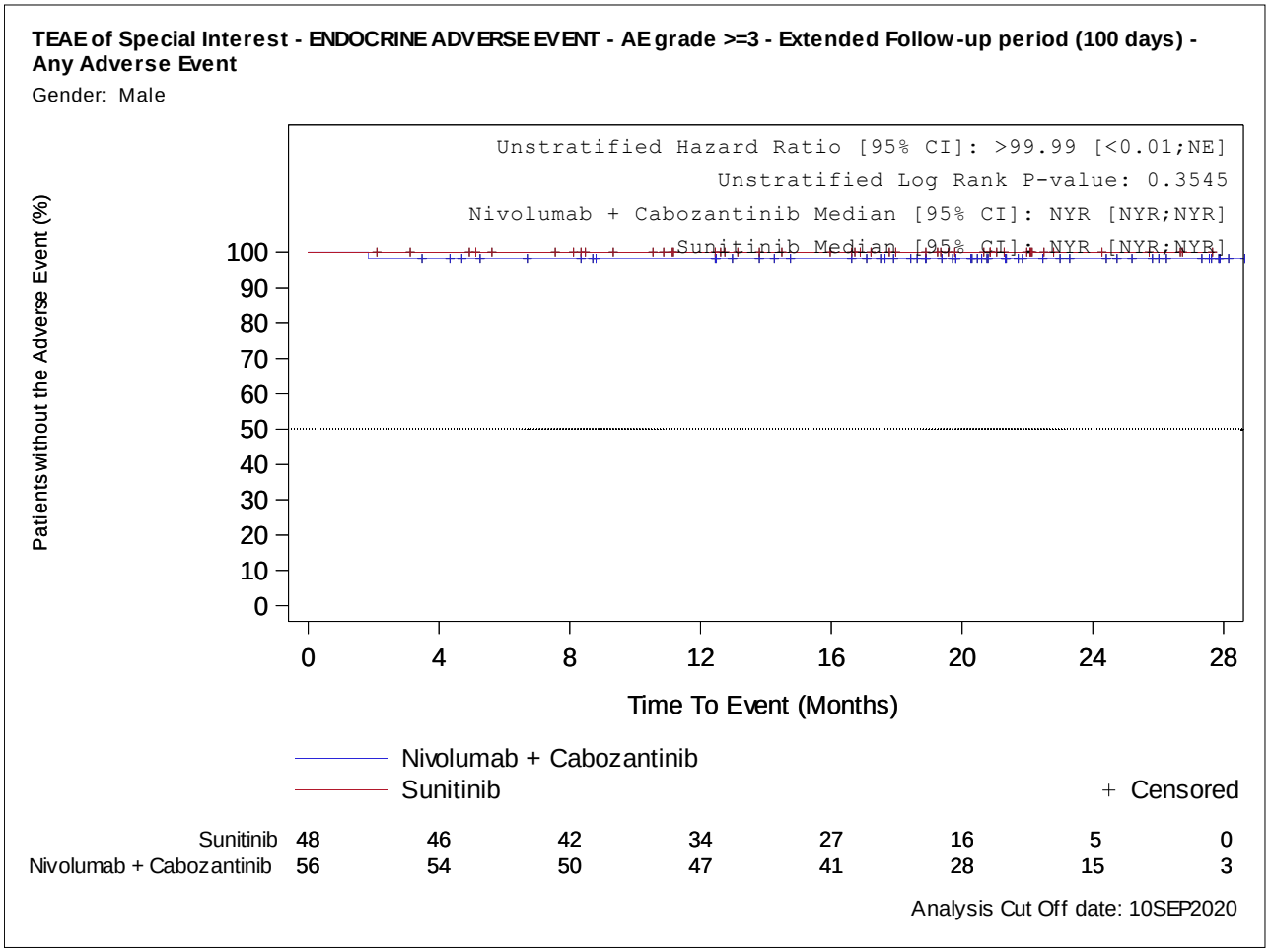

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:54:58

FIGURE 3.20.2.12: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



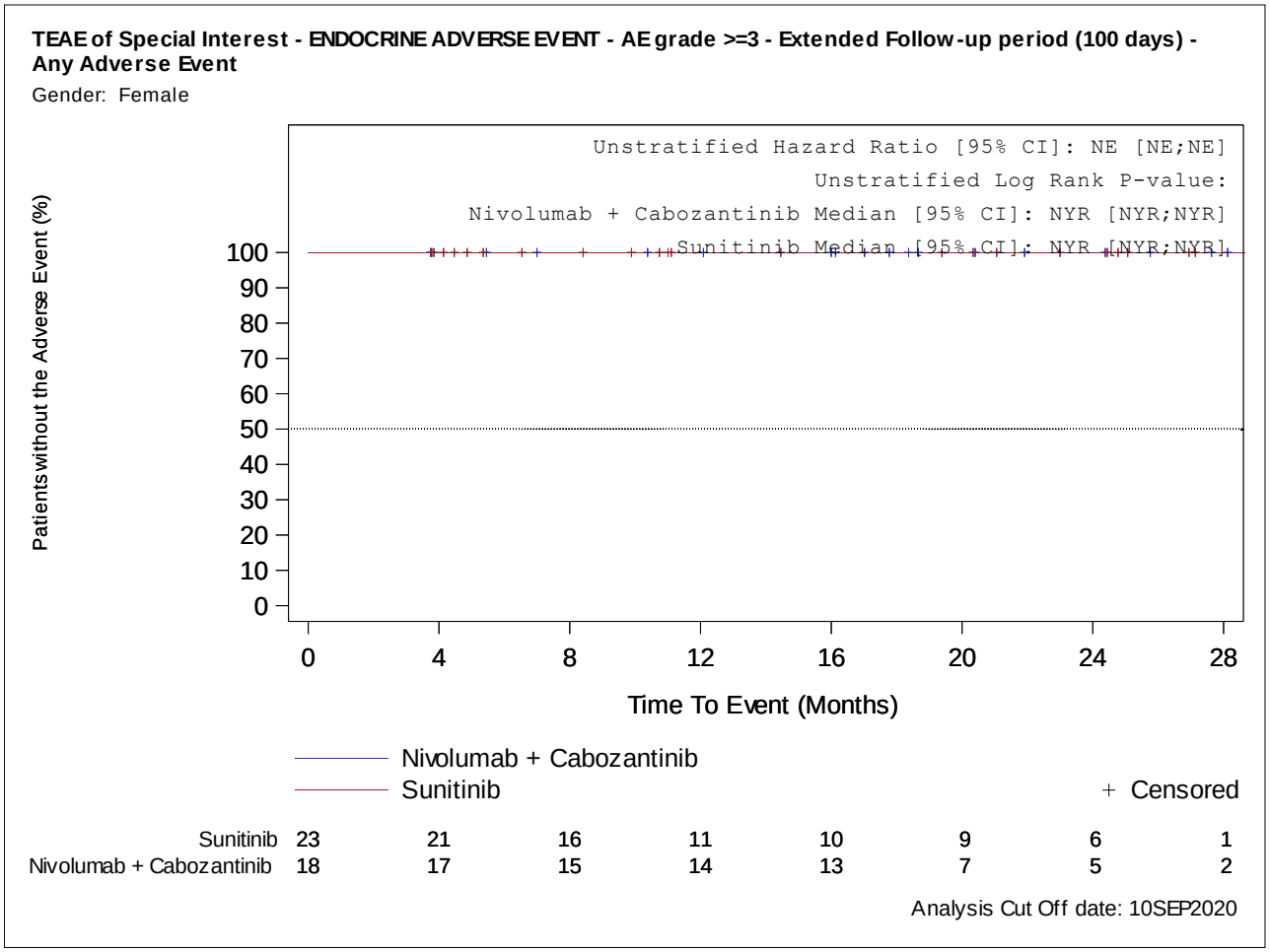

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:55:04

FIGURE 3.20.2.13: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



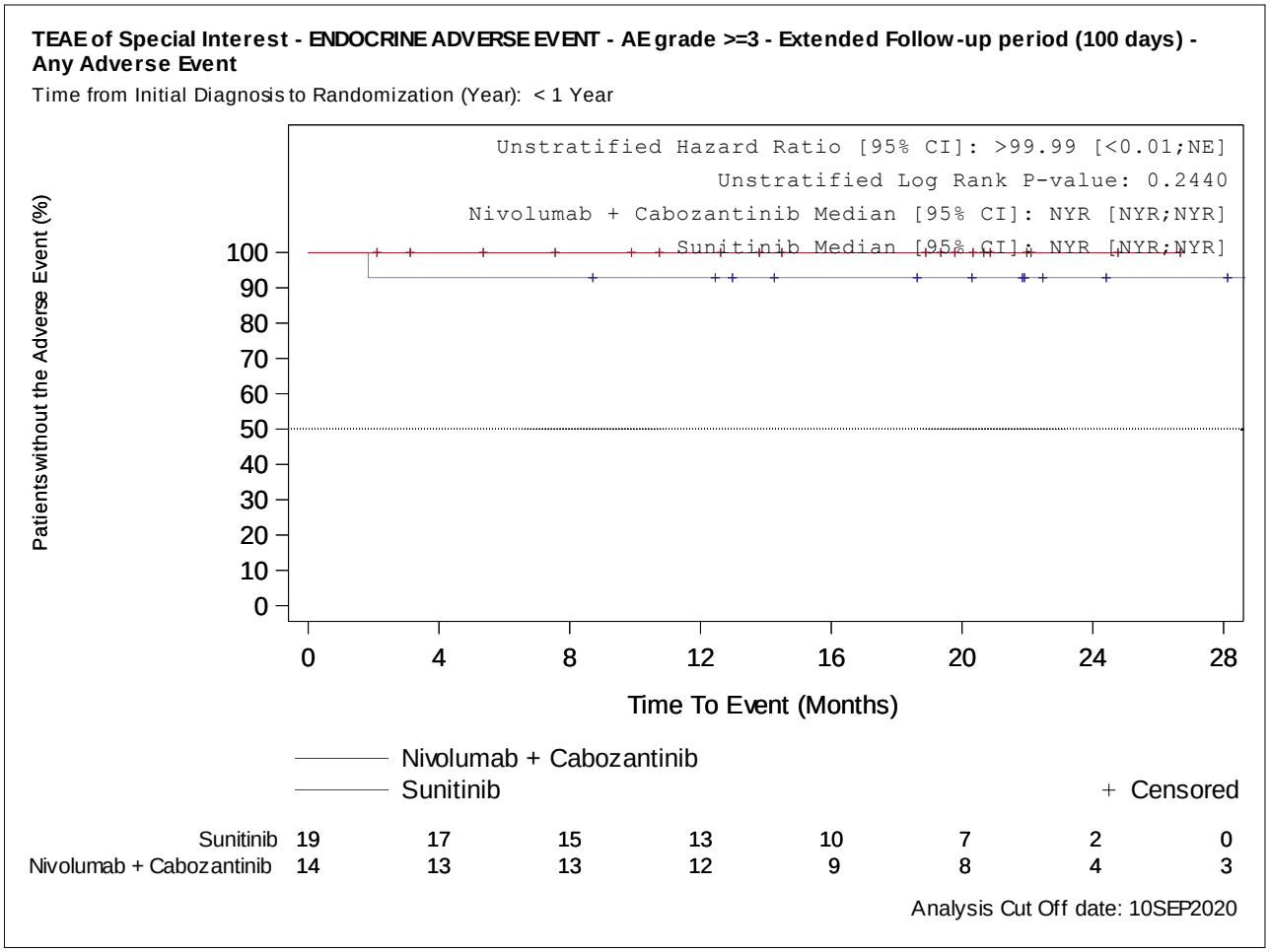

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:55:10

FIGURE 3.20.2.14: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



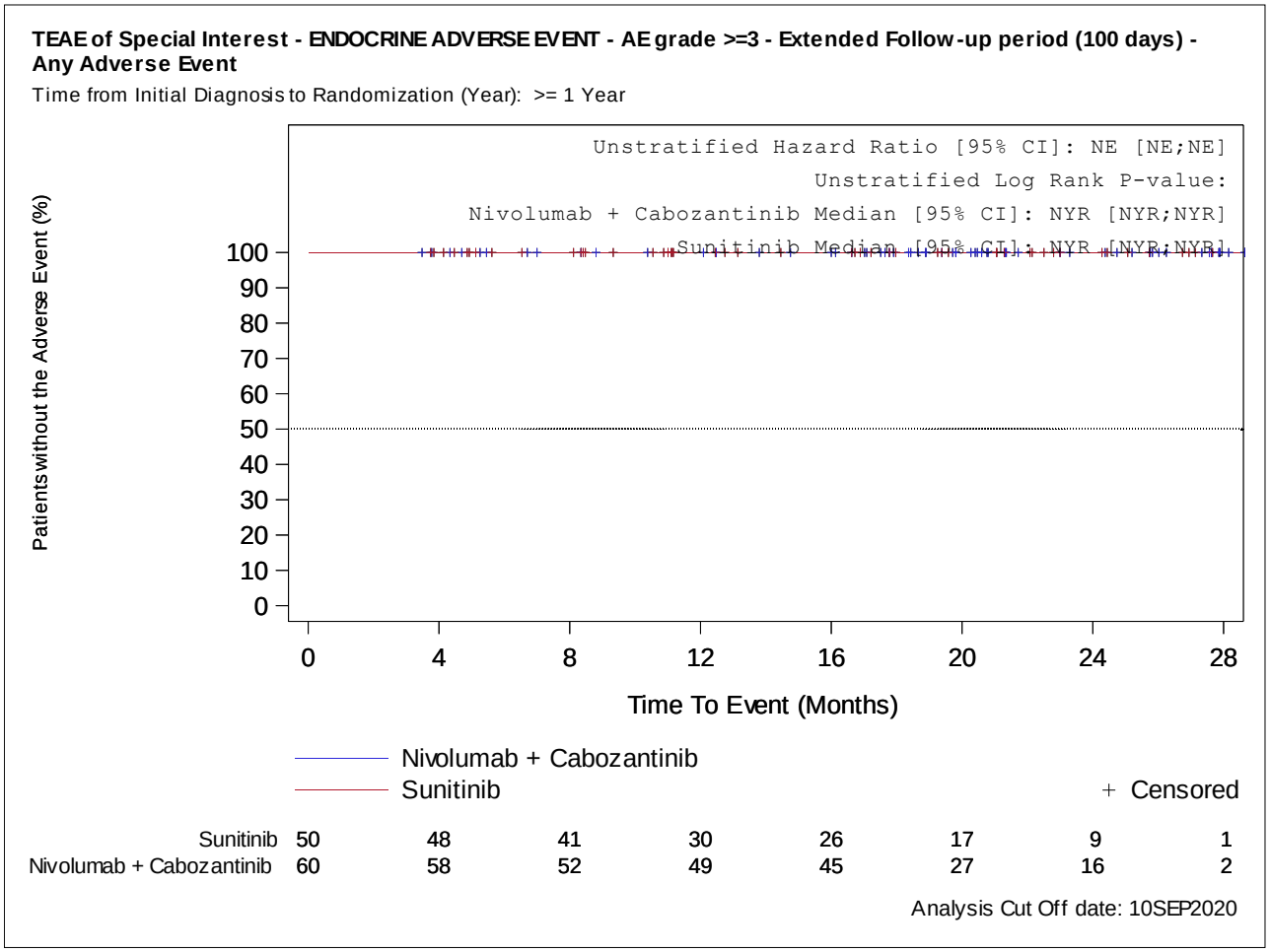

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:55:16

FIGURE 3.20.2.15: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:55:33

FIGURE 3.20.2.16: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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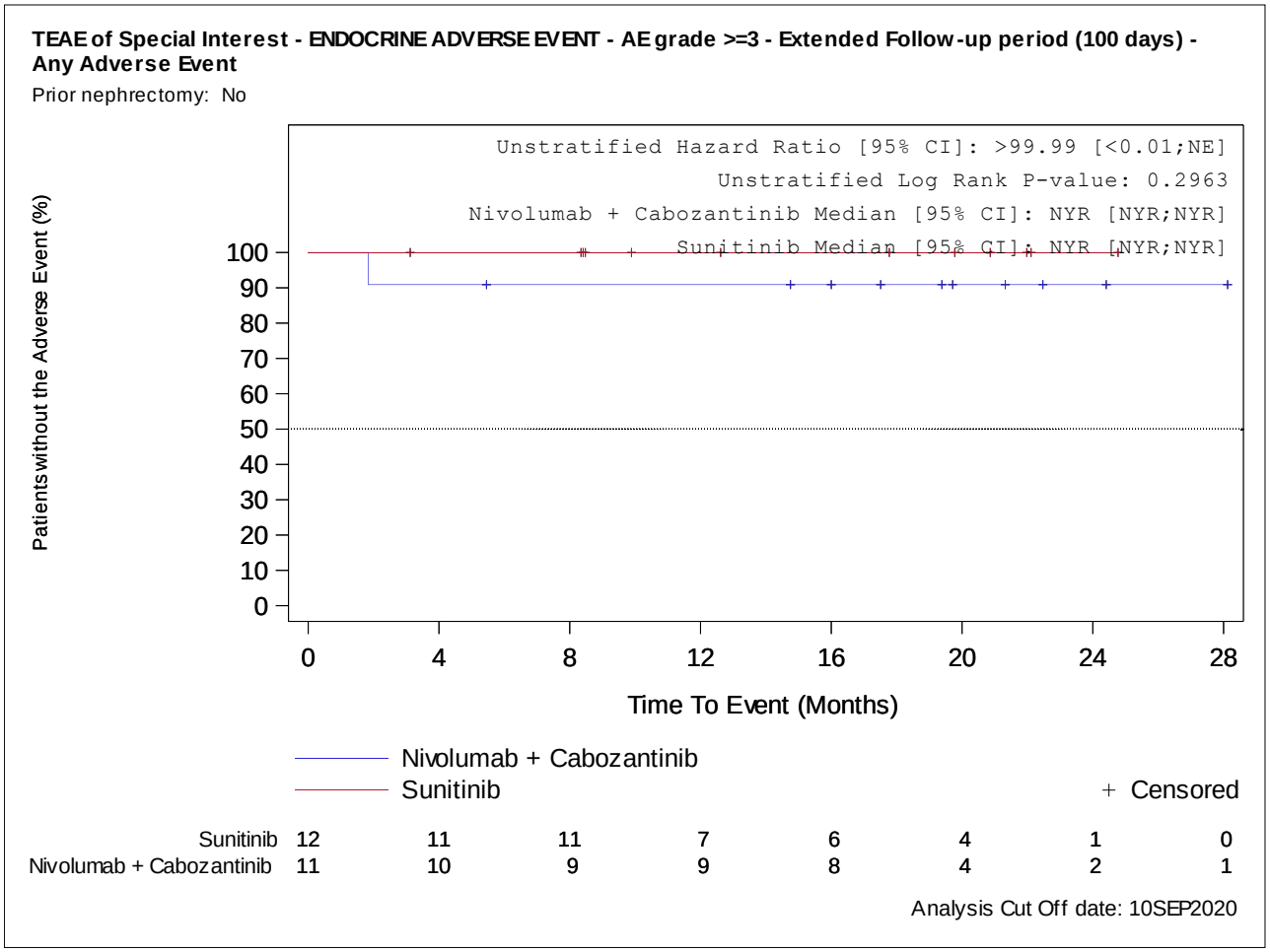
FIGURE 3.20.2.17: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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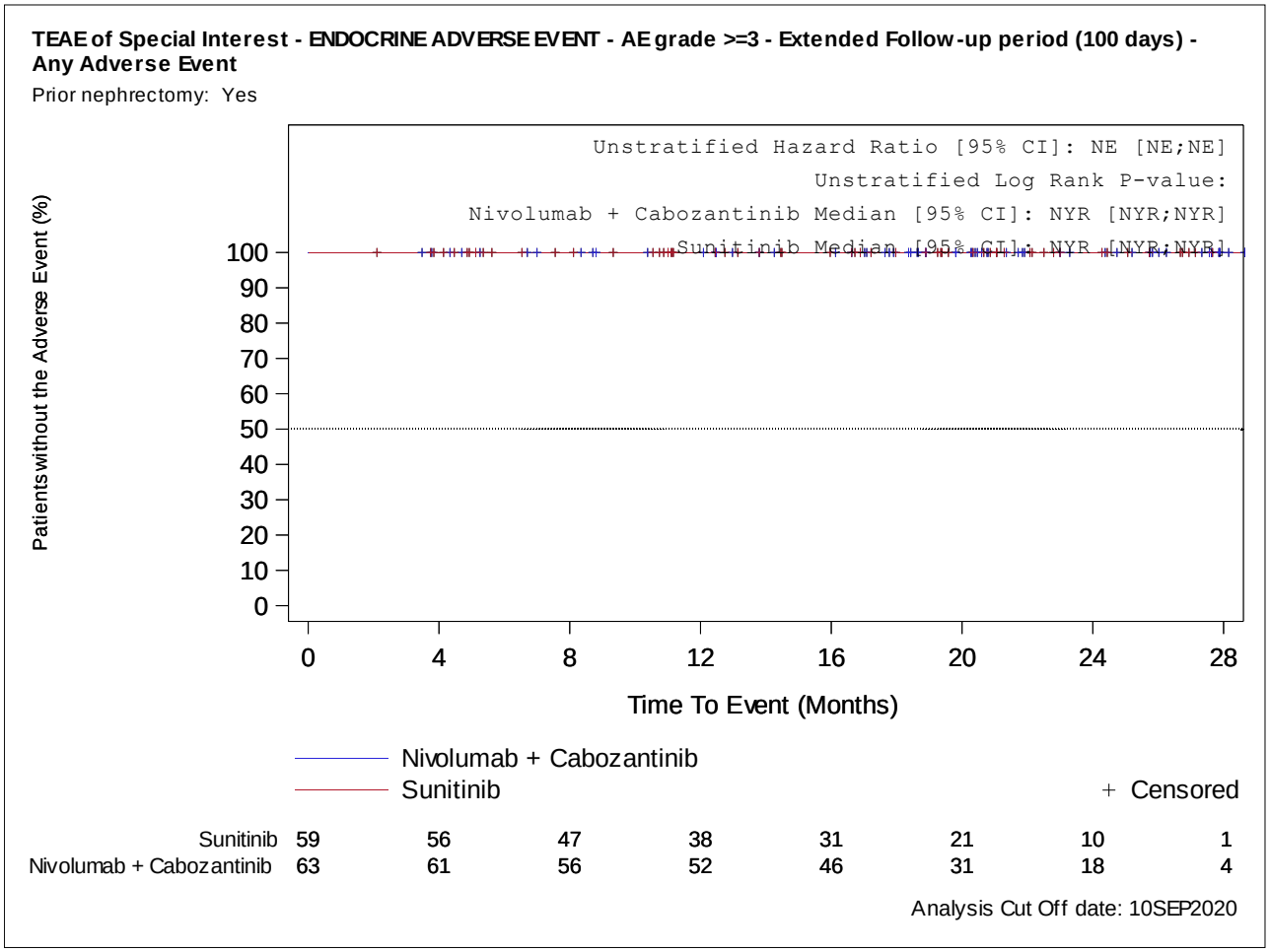
FIGURE 3.20.2.18: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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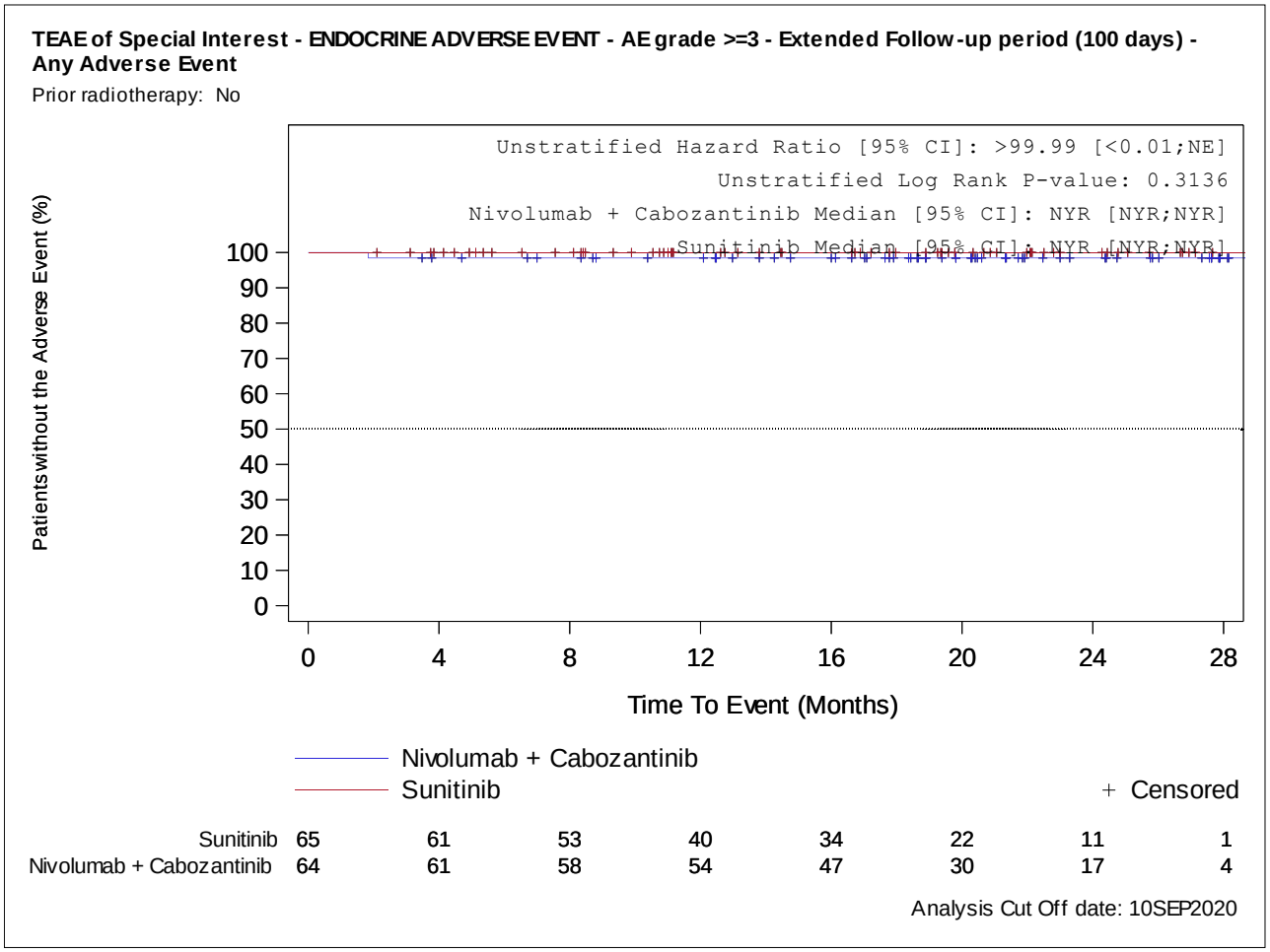
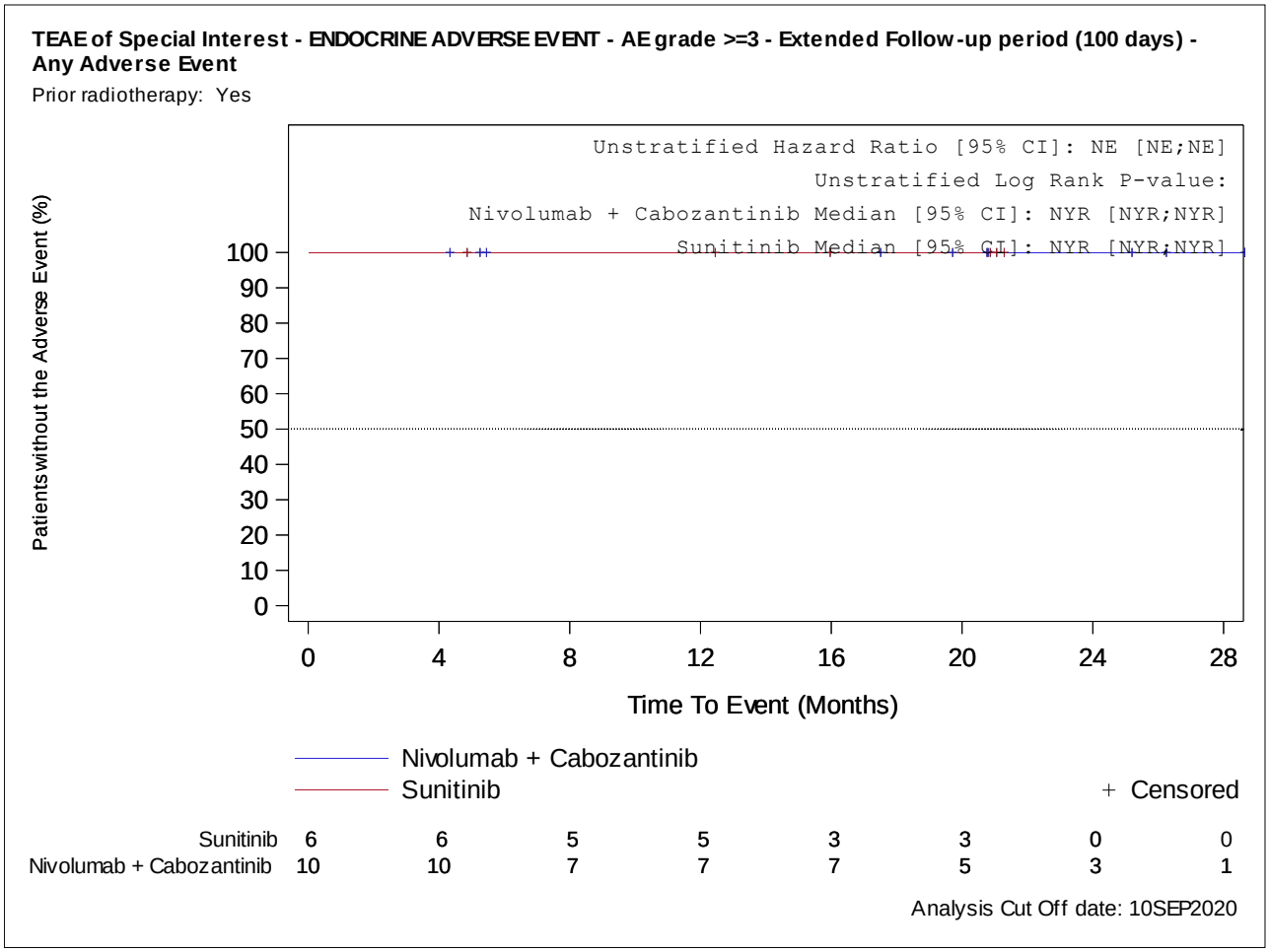
FIGURE 3.20.2.19: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



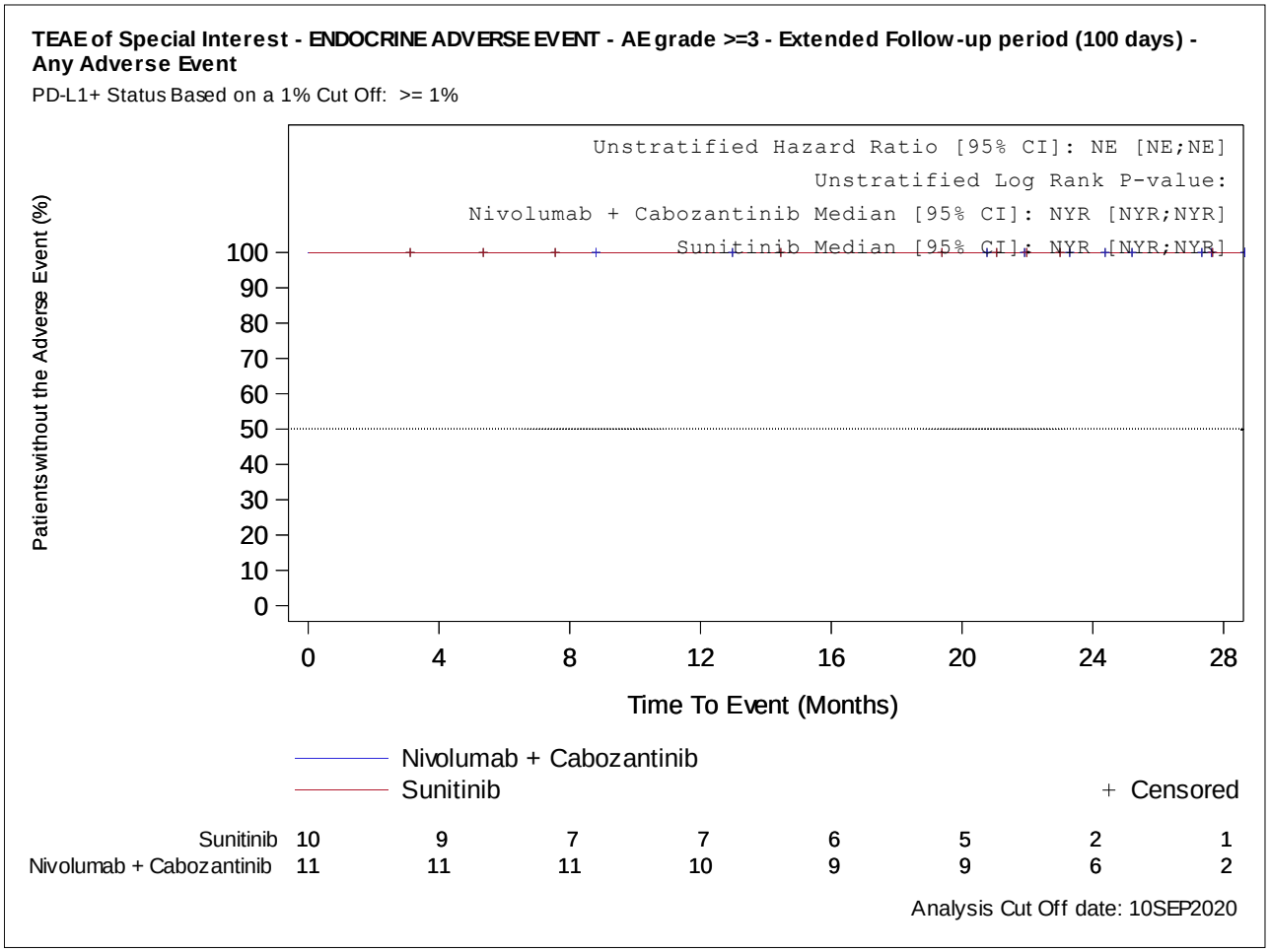

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:56:43

FIGURE 3.20.2.20: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



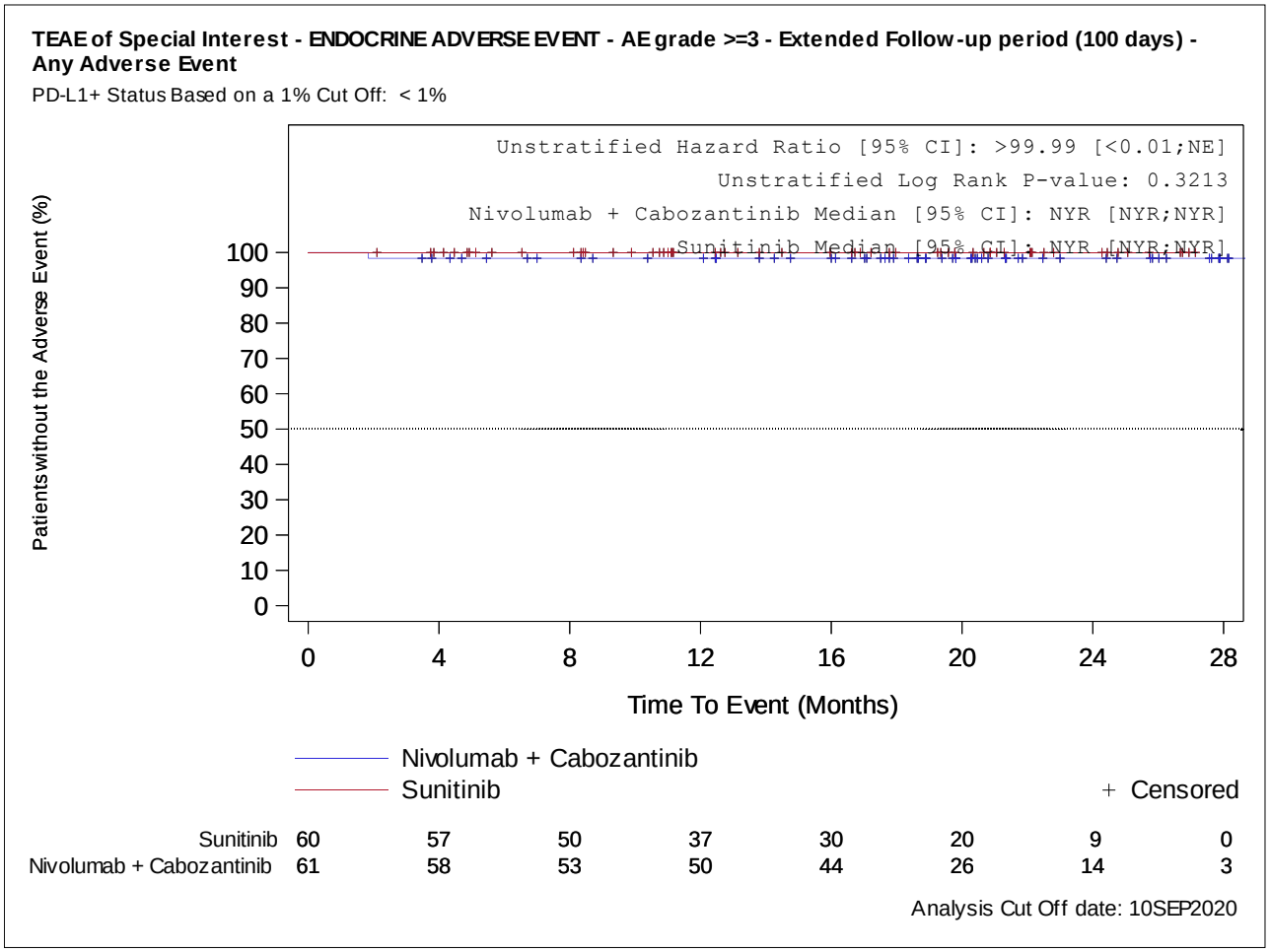

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:56:48

FIGURE 3.20.2.21: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



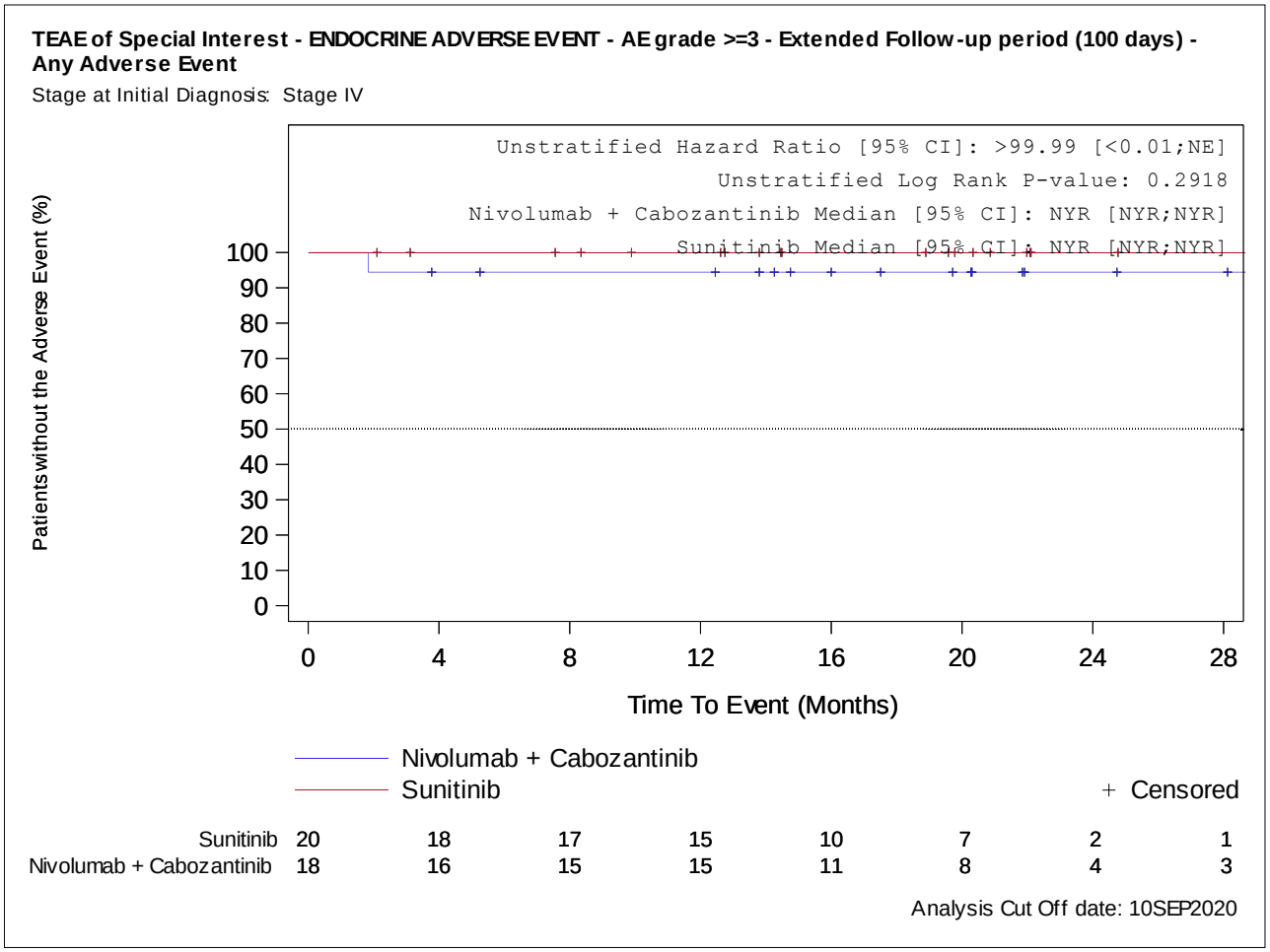

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:56:54

FIGURE 3.20.2.22: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



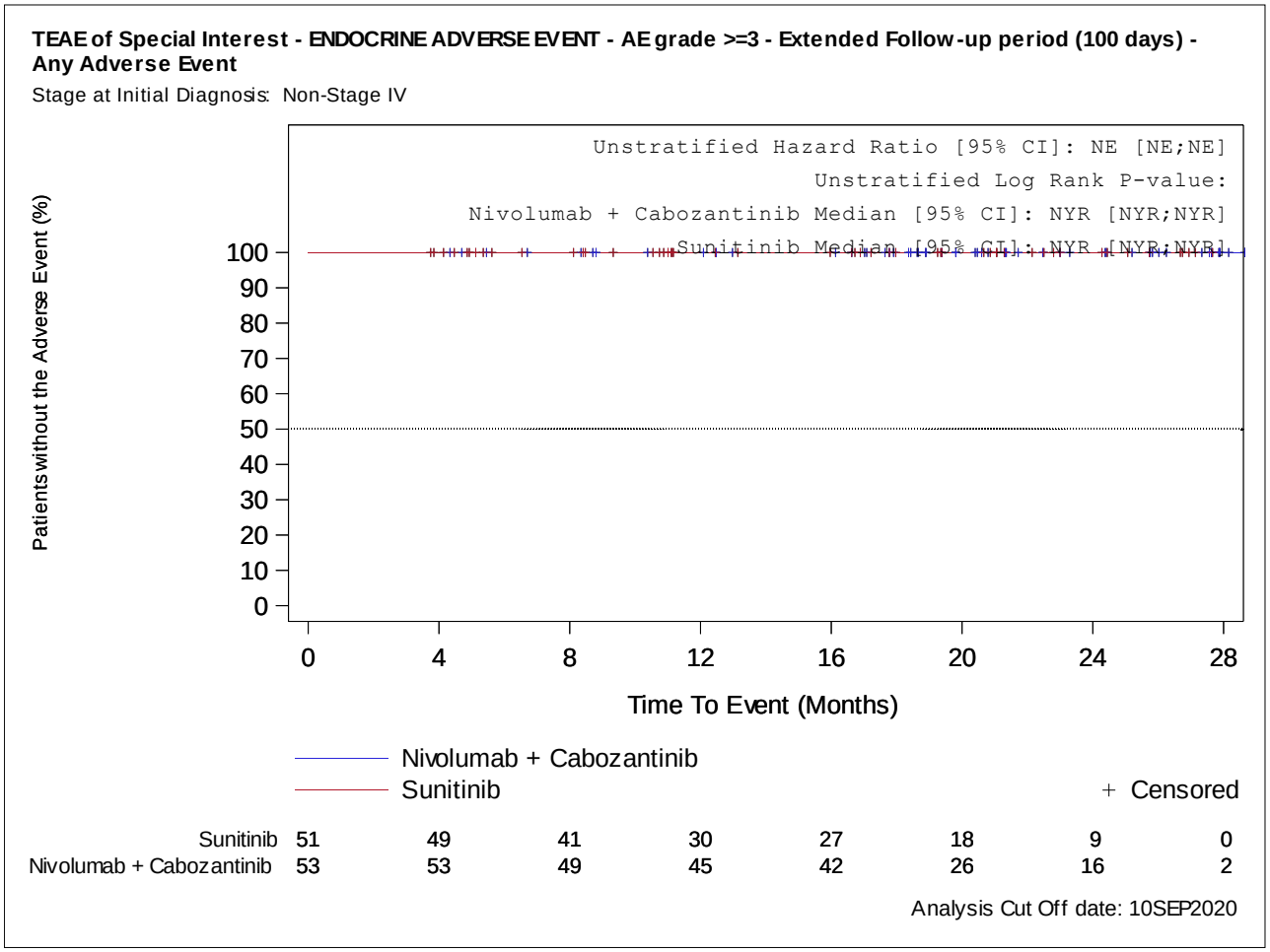

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:56:59

FIGURE 3.20.2.23: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



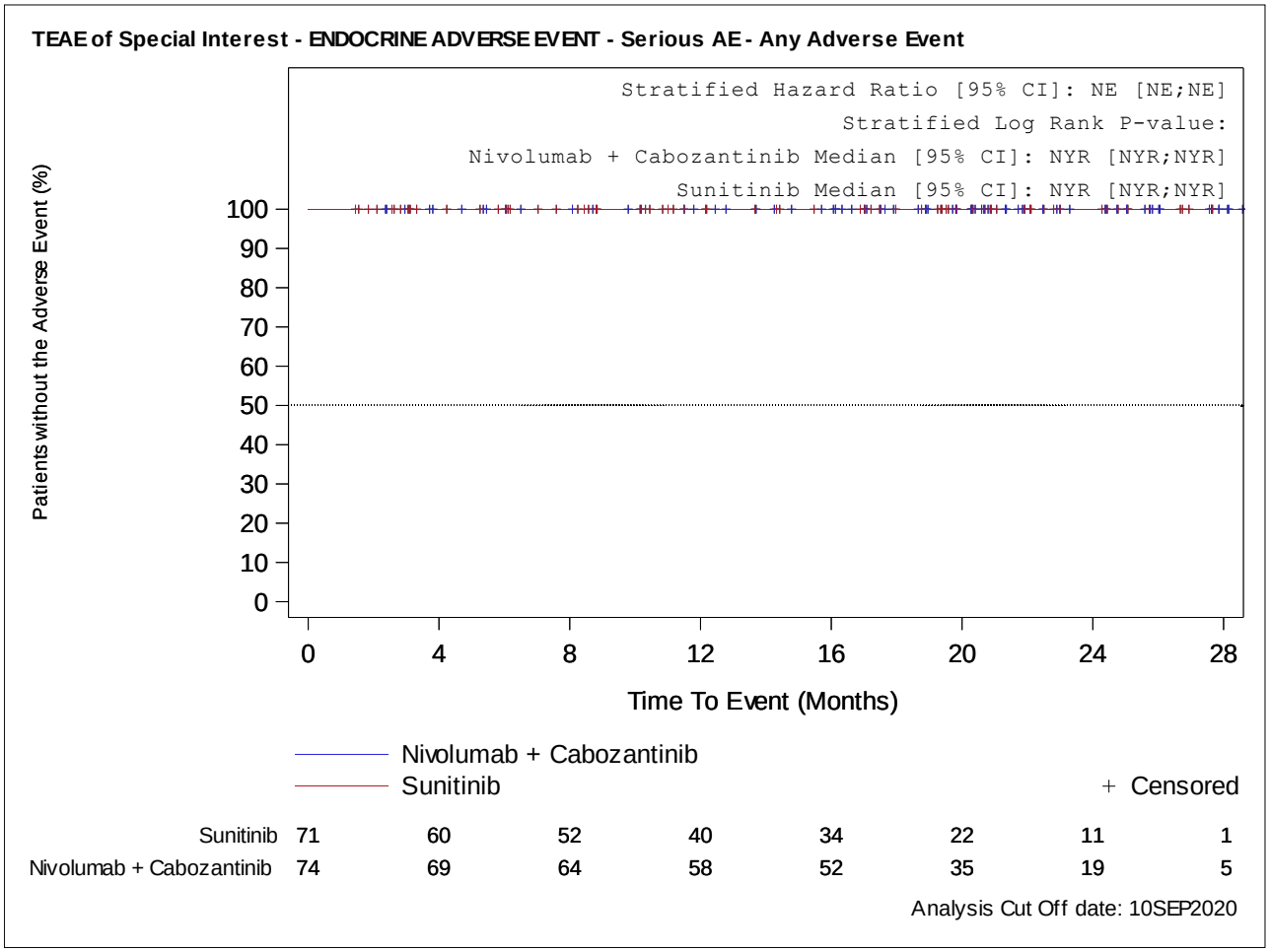

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:57:29

FIGURE 3.20.2.24: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



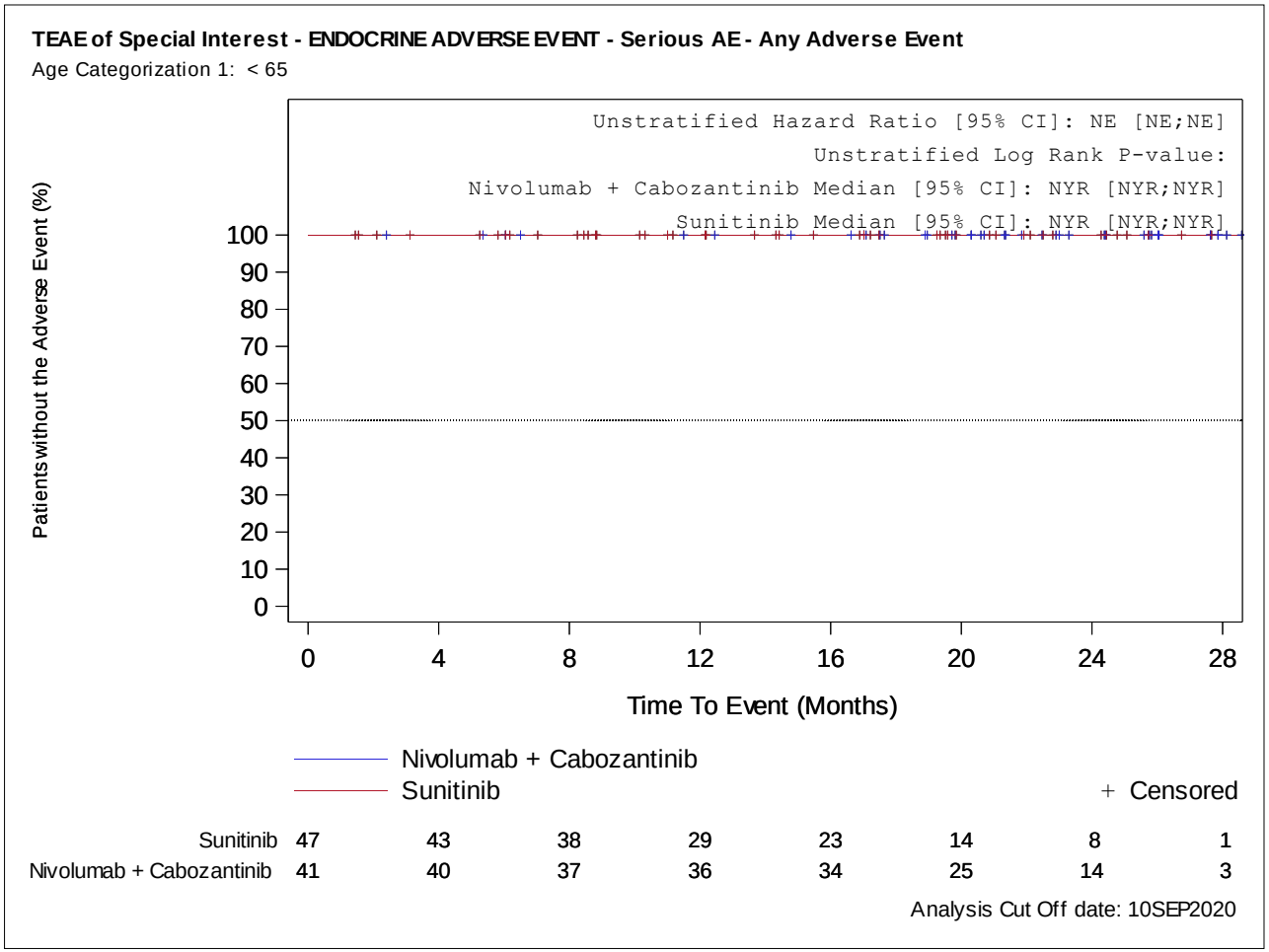

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:57:34

FIGURE 3.21.1: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



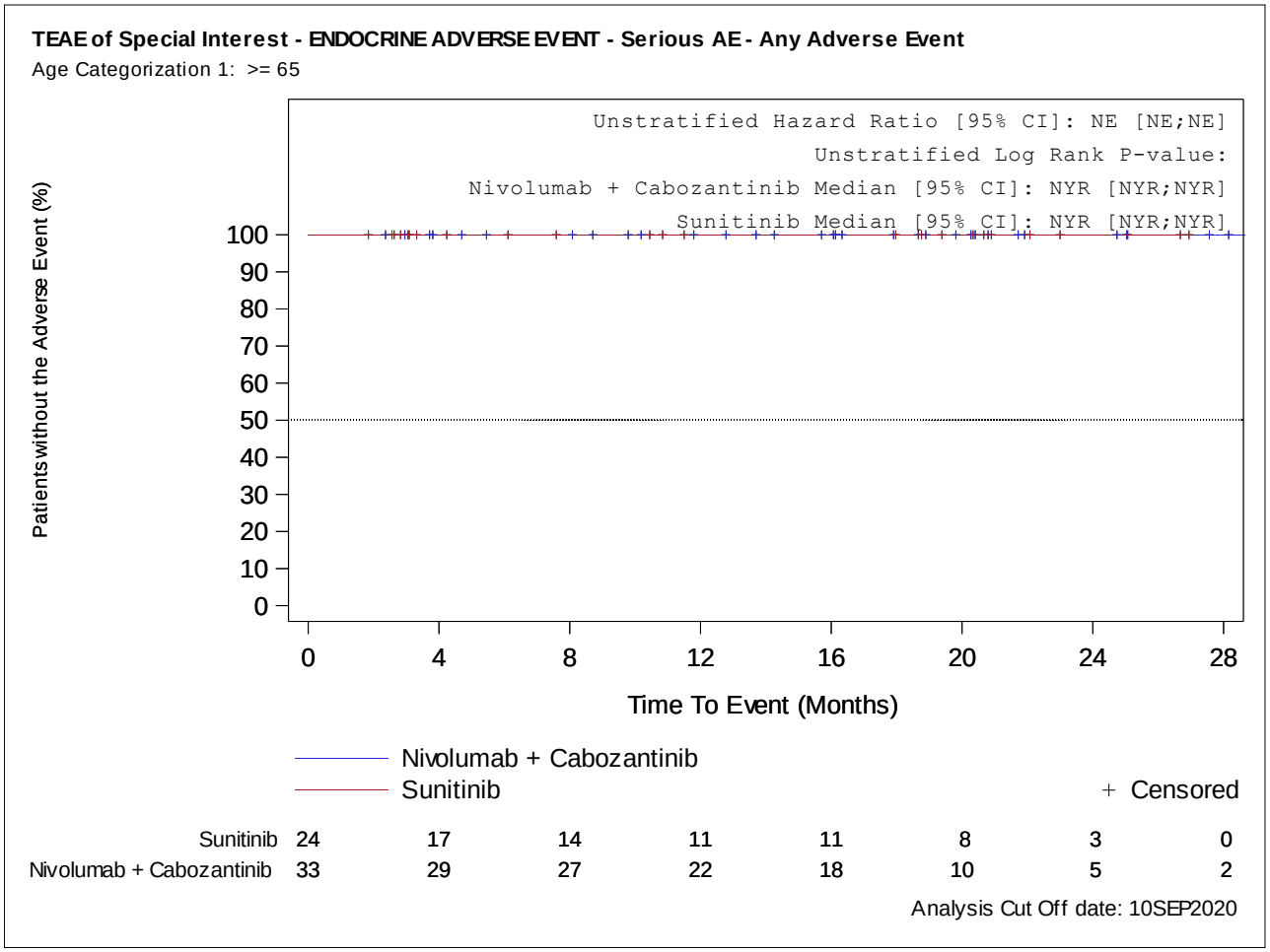

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:00:50

FIGURE 3.21.2.1: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



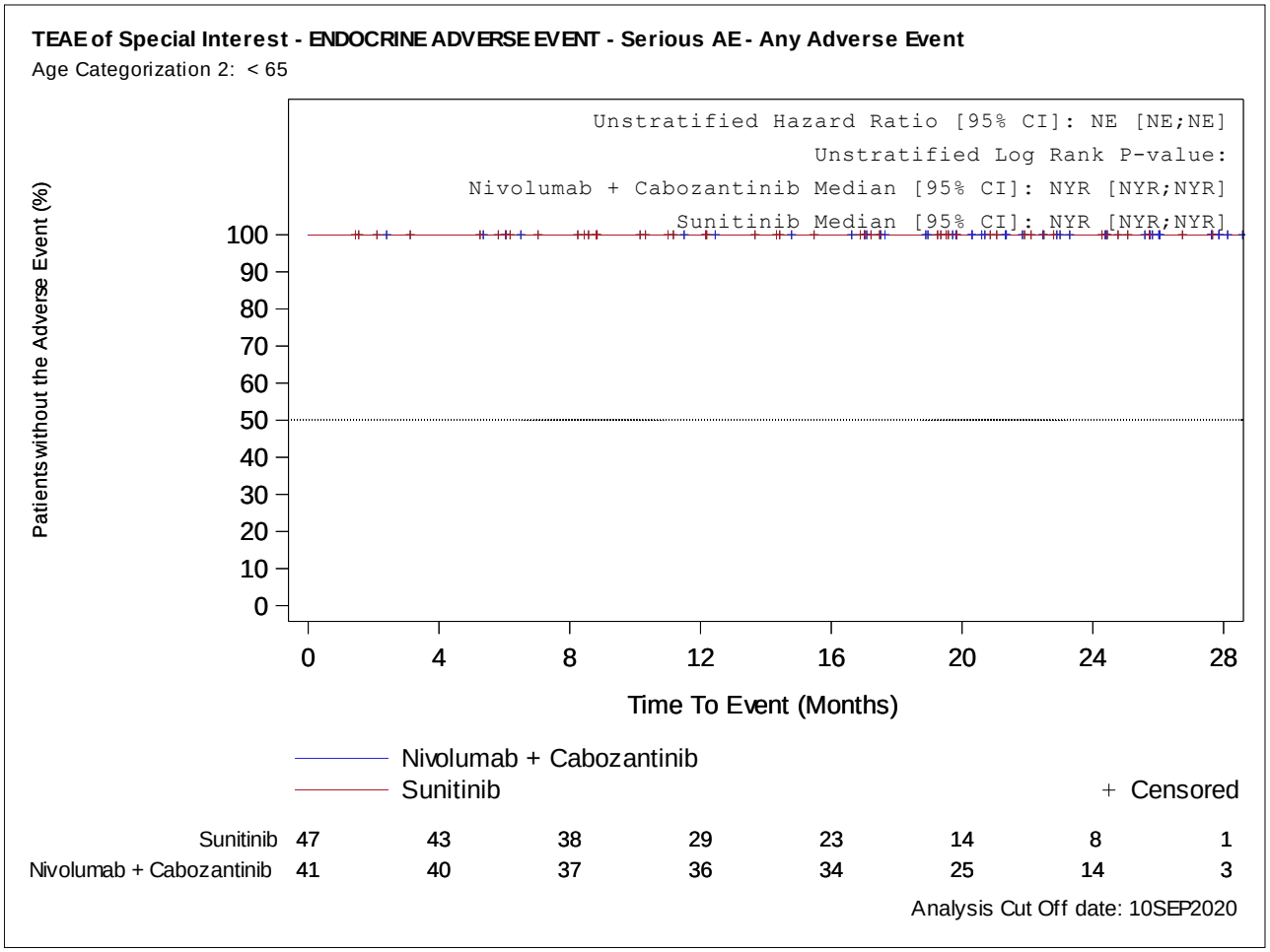

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:00:53

FIGURE 3.21.2.2: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



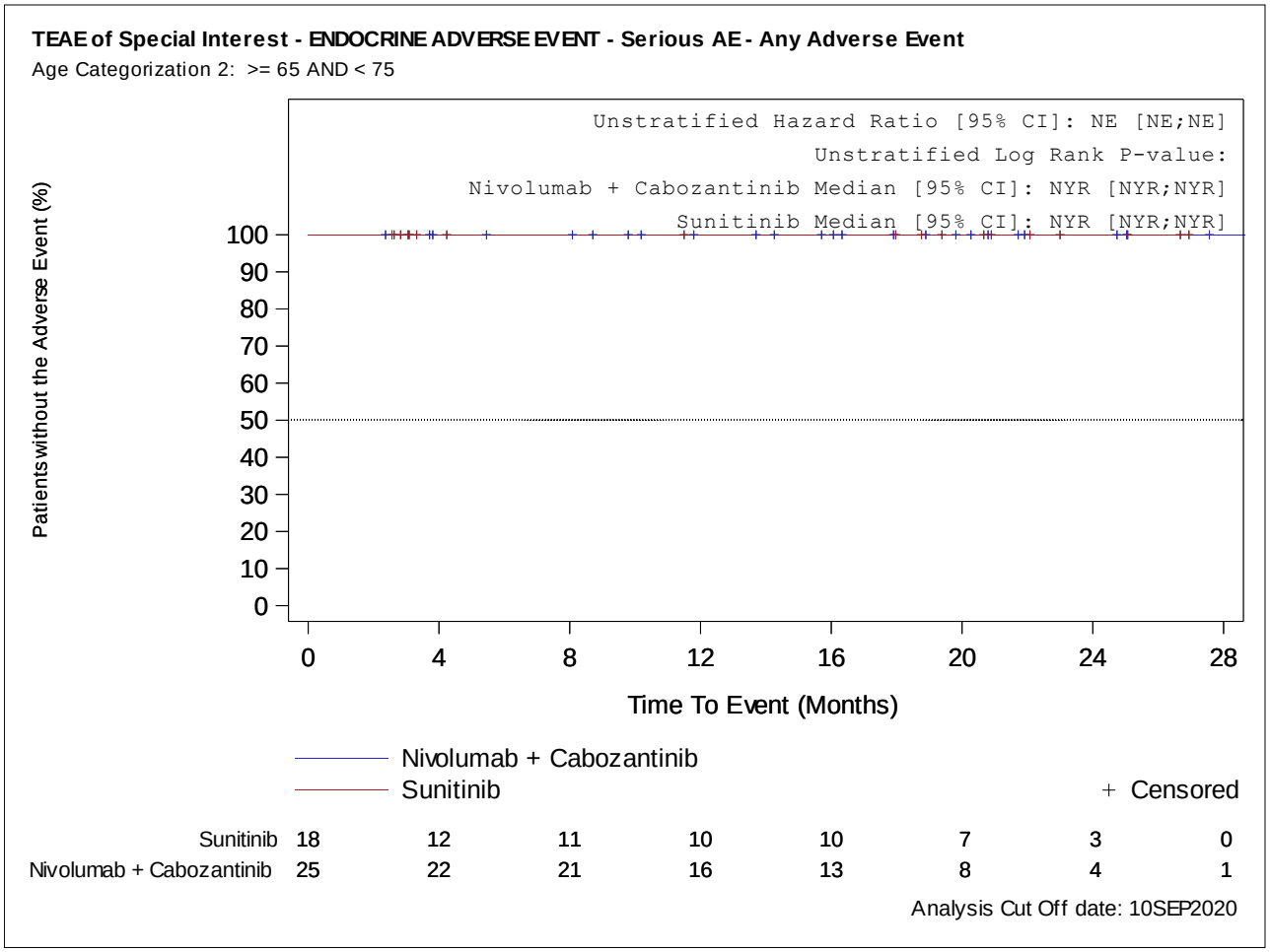

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:00:59

FIGURE 3.21.2.3: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



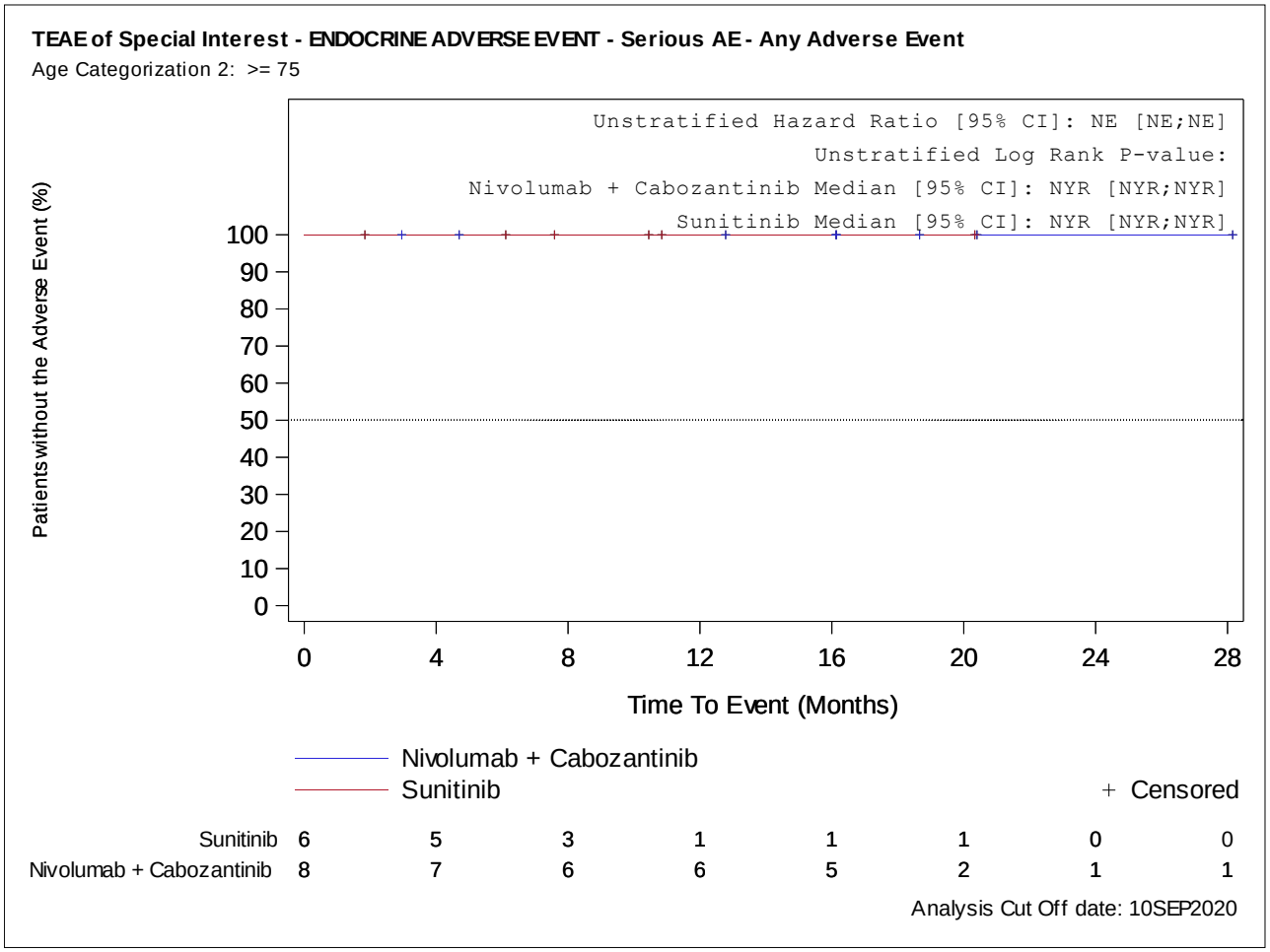

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:01:05

FIGURE 3.21.2.4: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



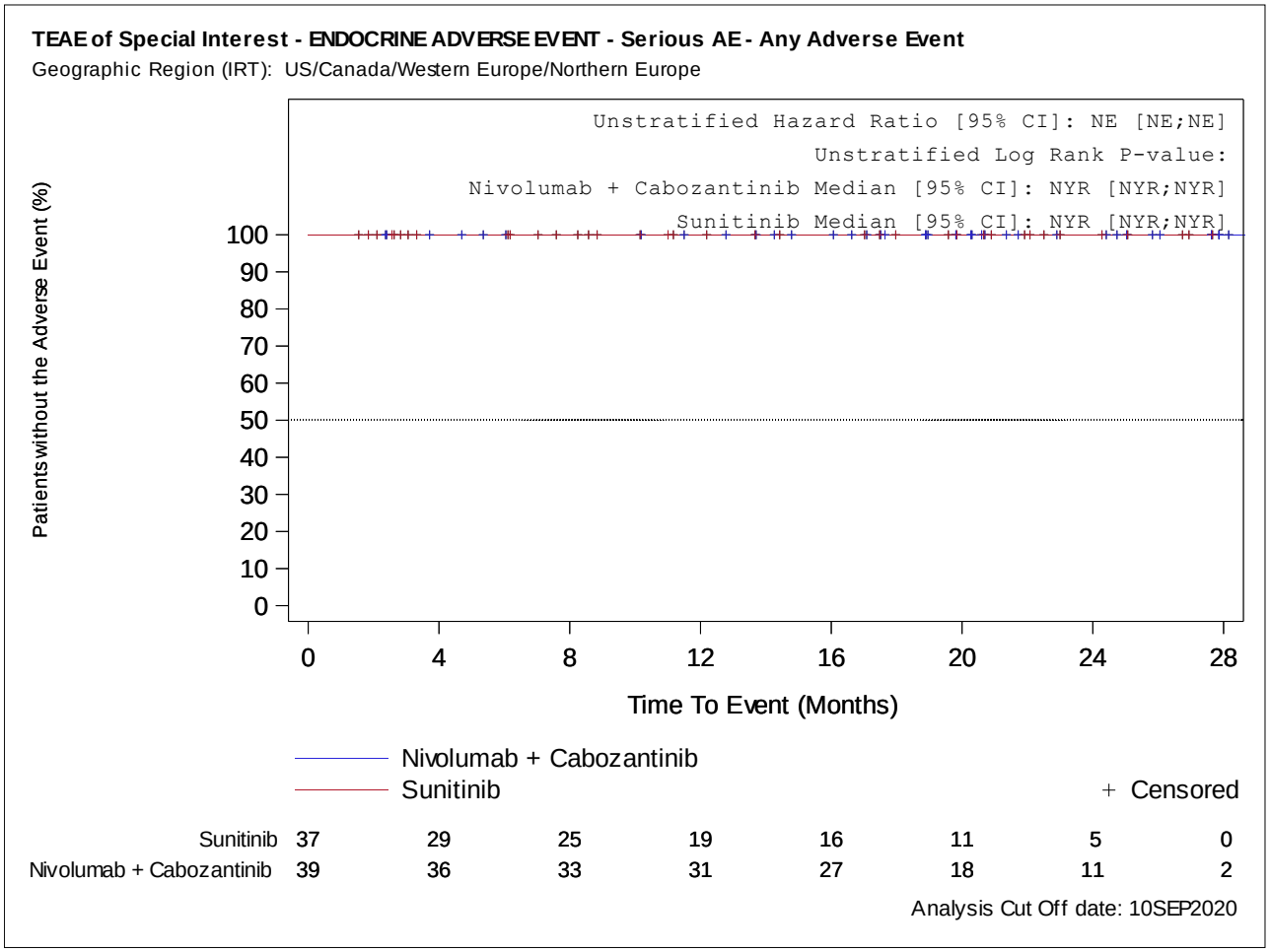

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:01:11

FIGURE 3.21.2.5: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



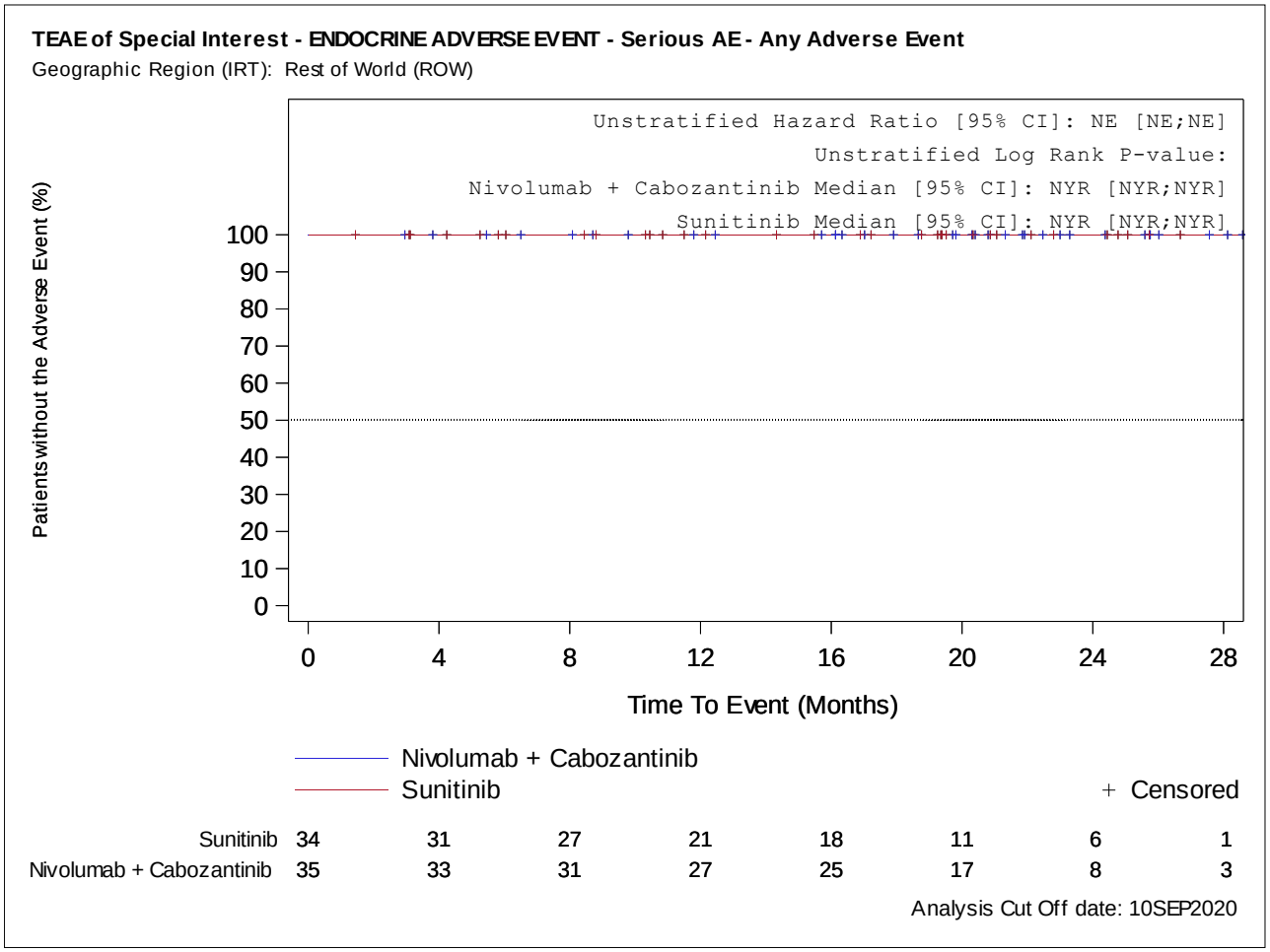

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:01:17

FIGURE 3.21.2.6: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



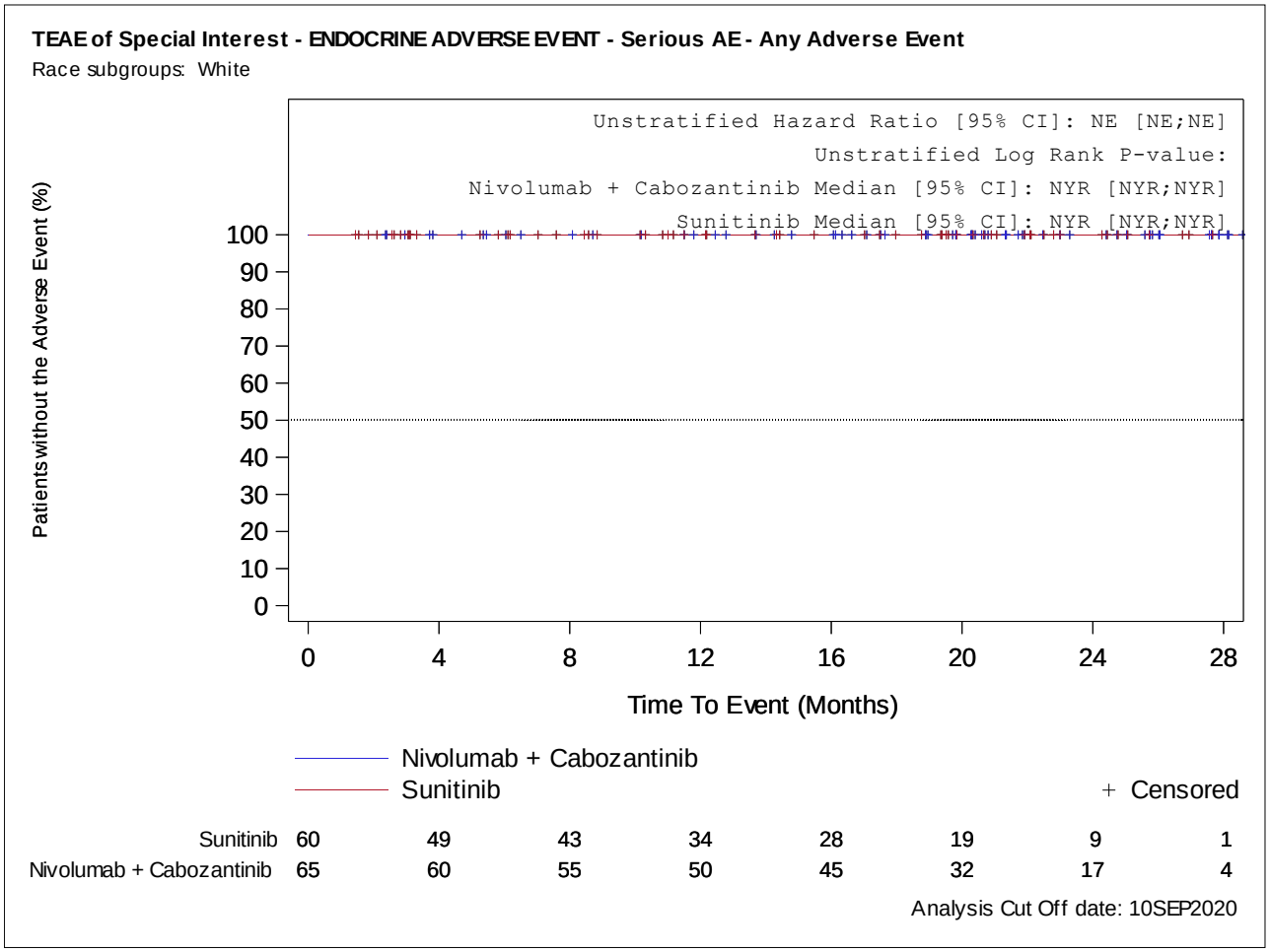

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:01:23

FIGURE 3.21.2.7: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



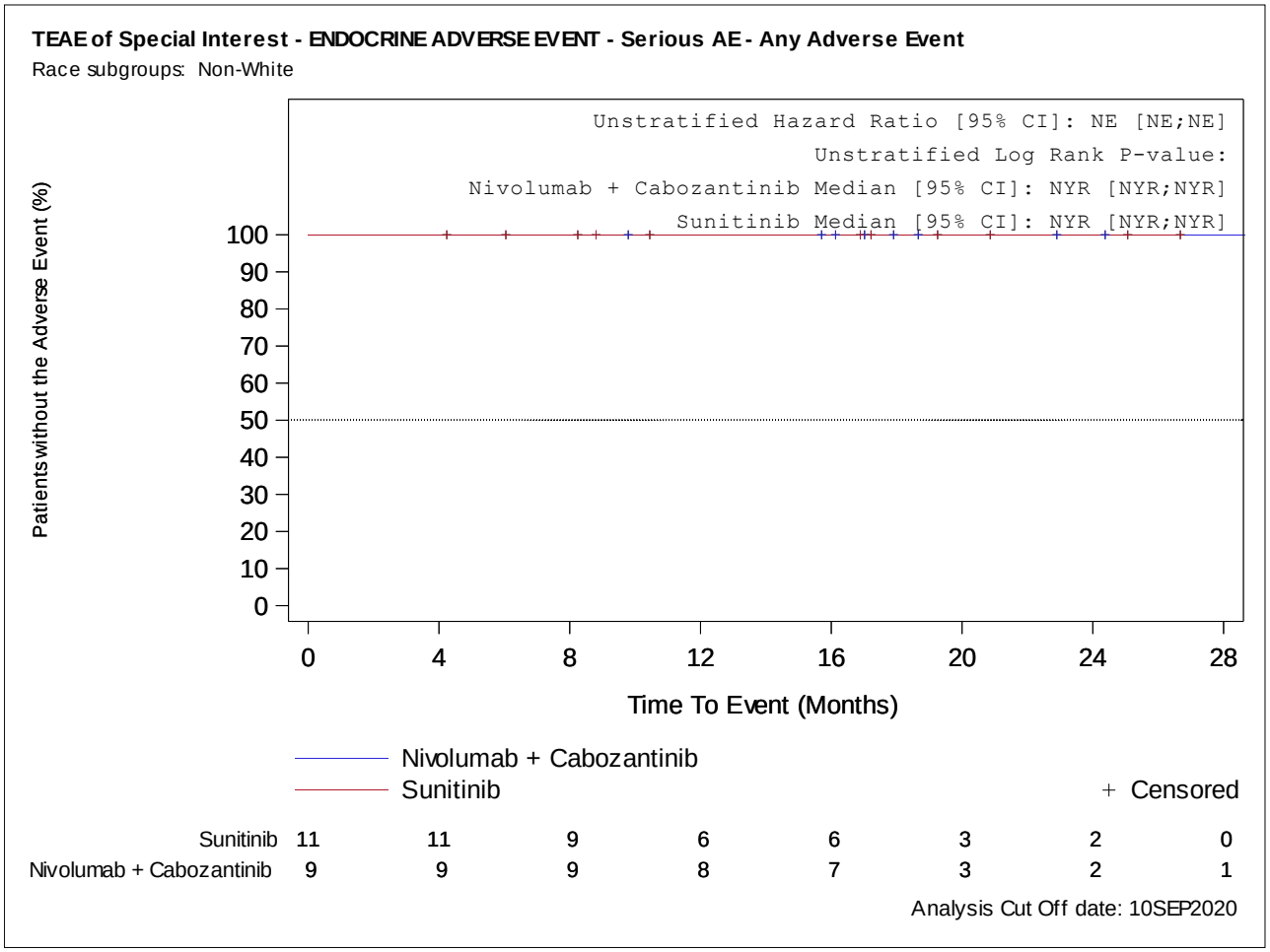

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:01:29

FIGURE 3.21.2.8: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



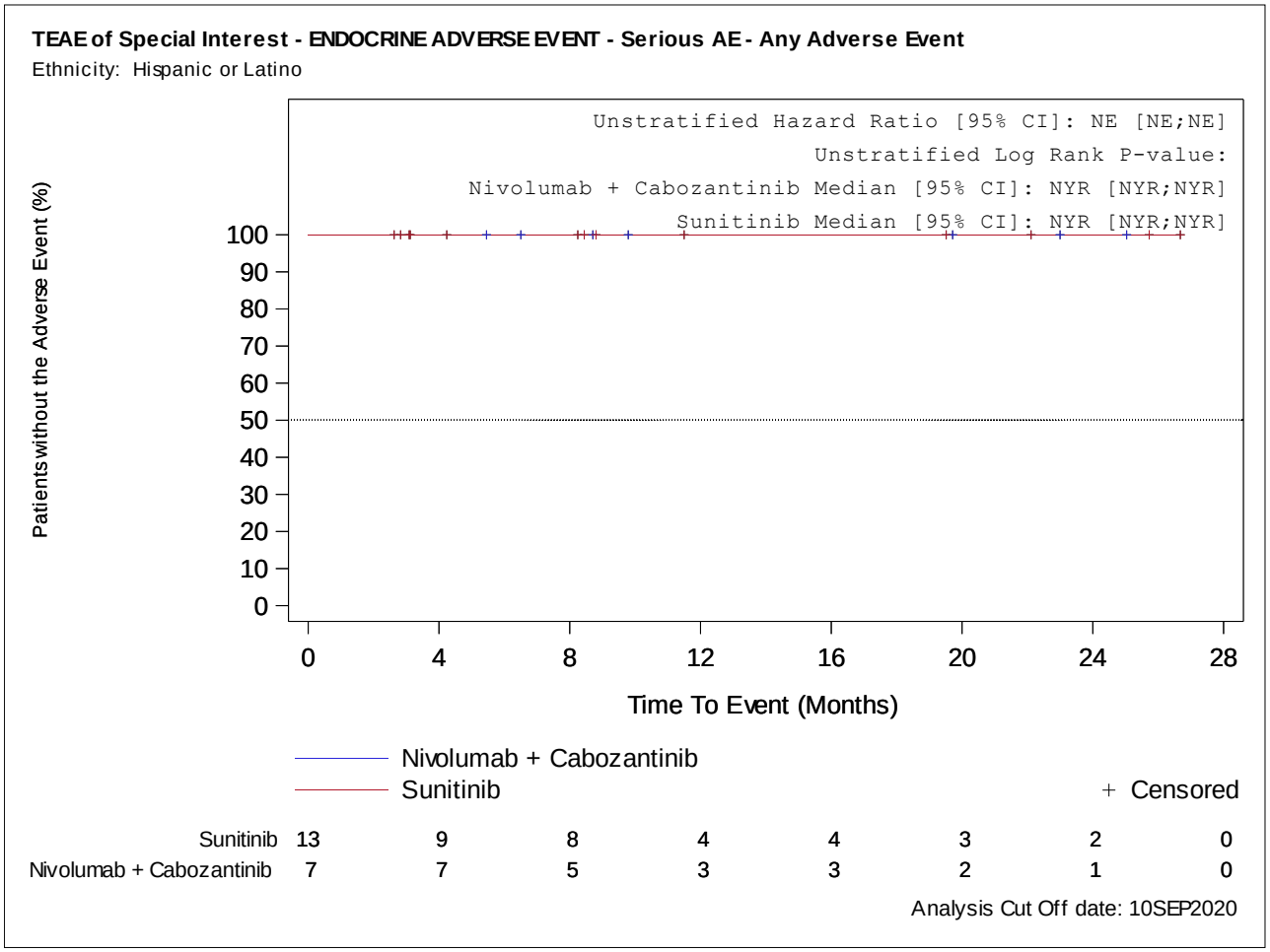

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:01:35

FIGURE 3.21.2.9: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



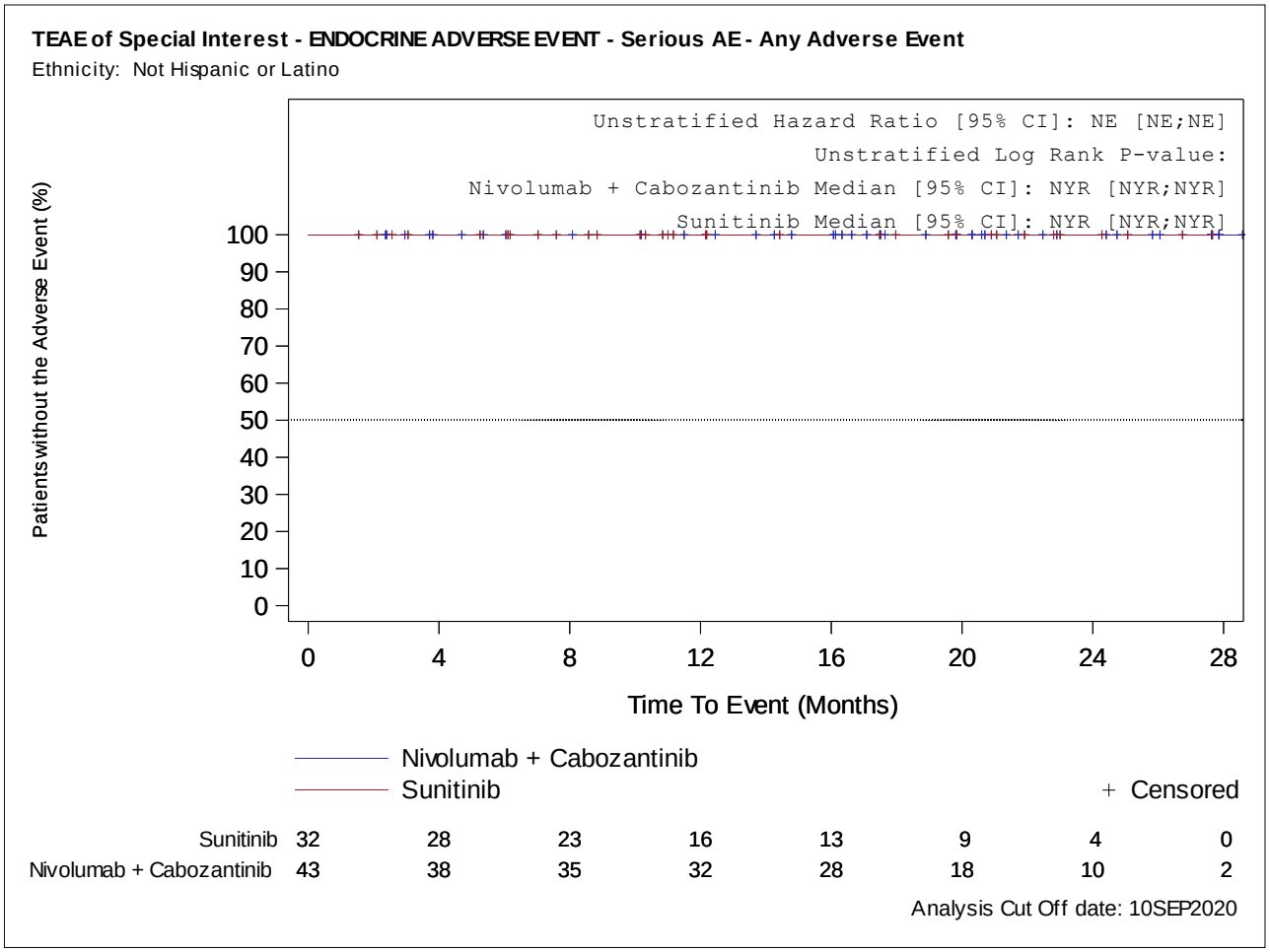

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:01:41

FIGURE 3.21.2.10: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



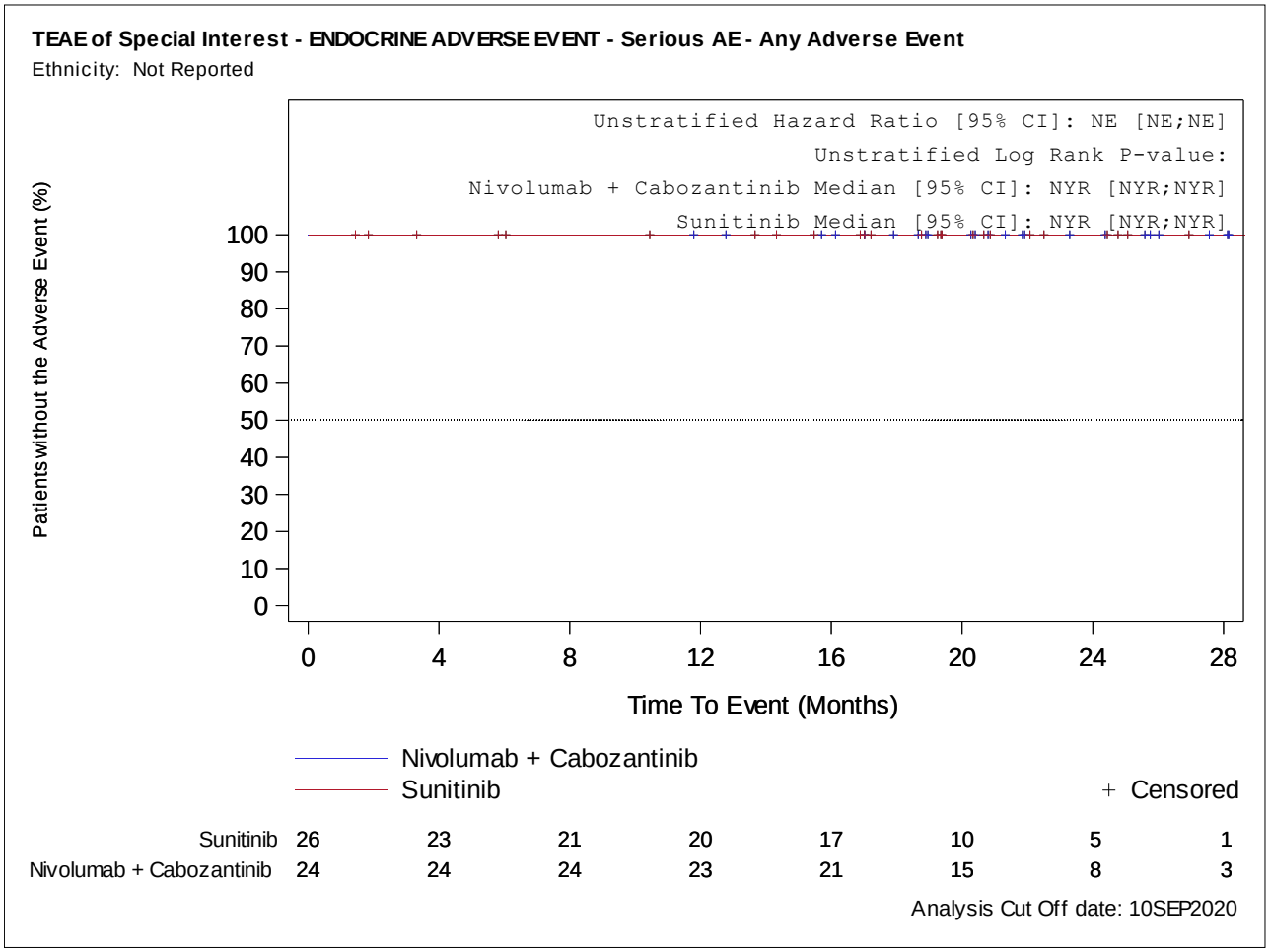

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:01:47

FIGURE 3.21.2.11: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



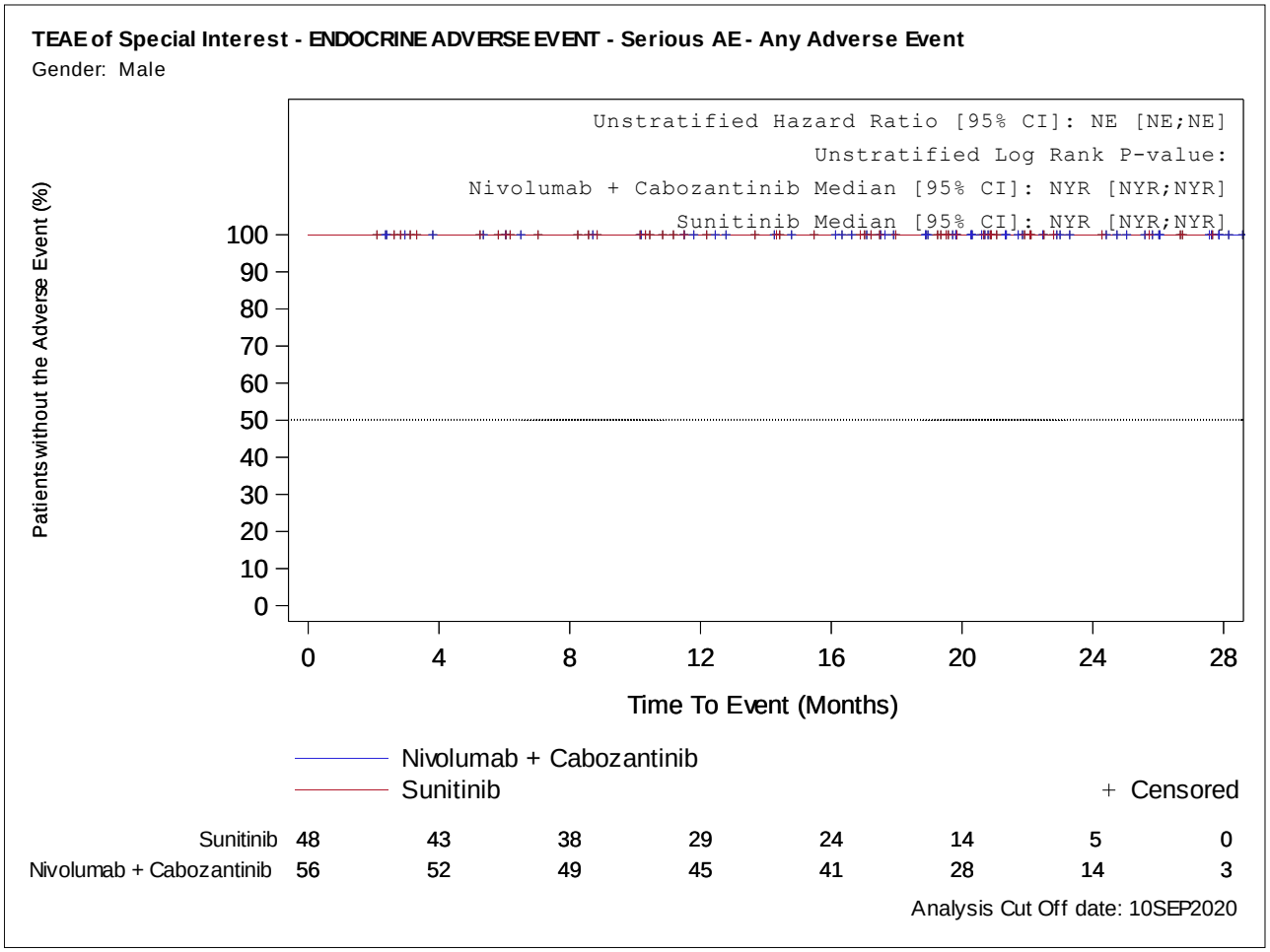

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:01:52

FIGURE 3.21.2.12: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



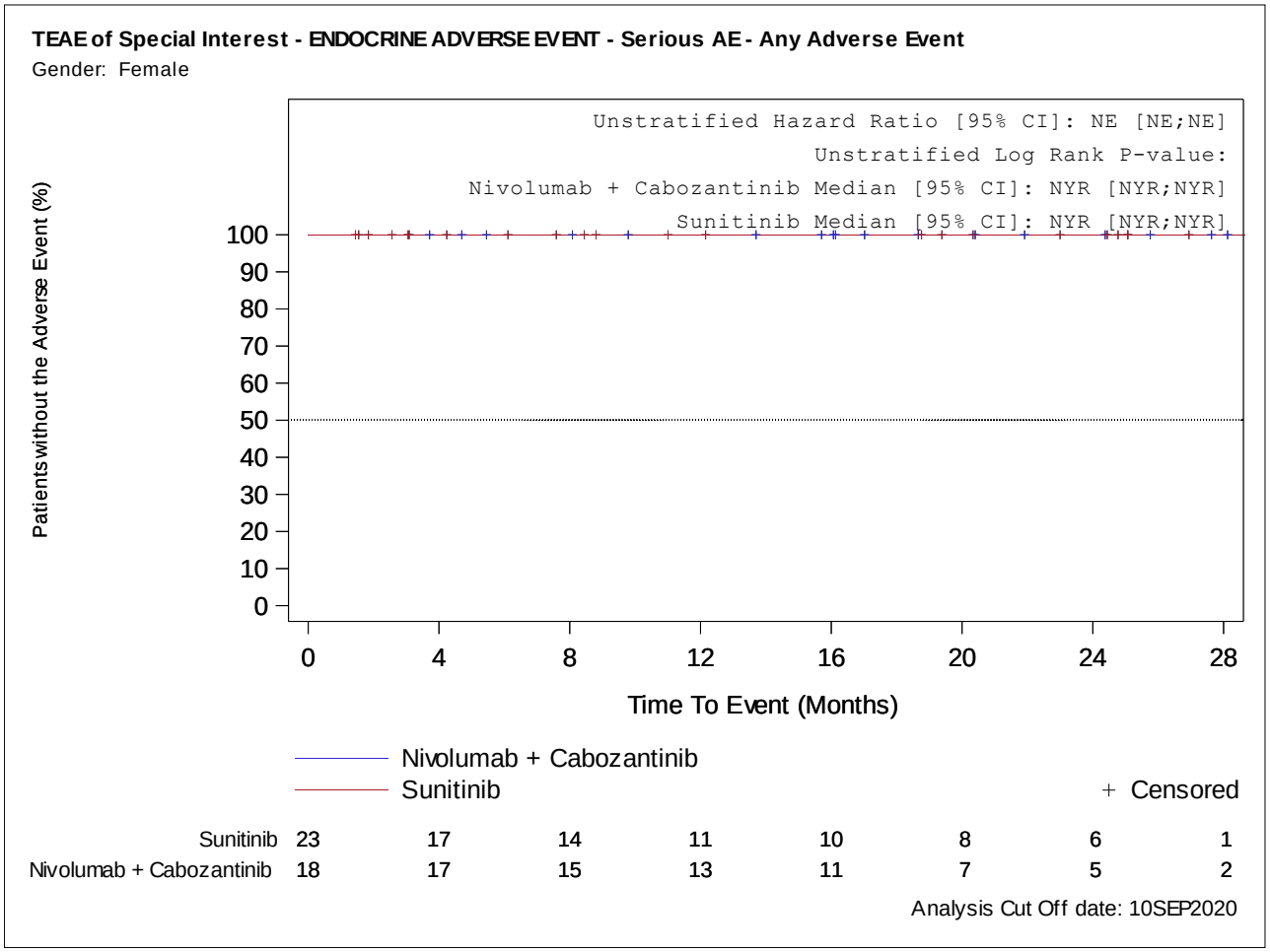

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:01:58

FIGURE 3.21.2.13: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



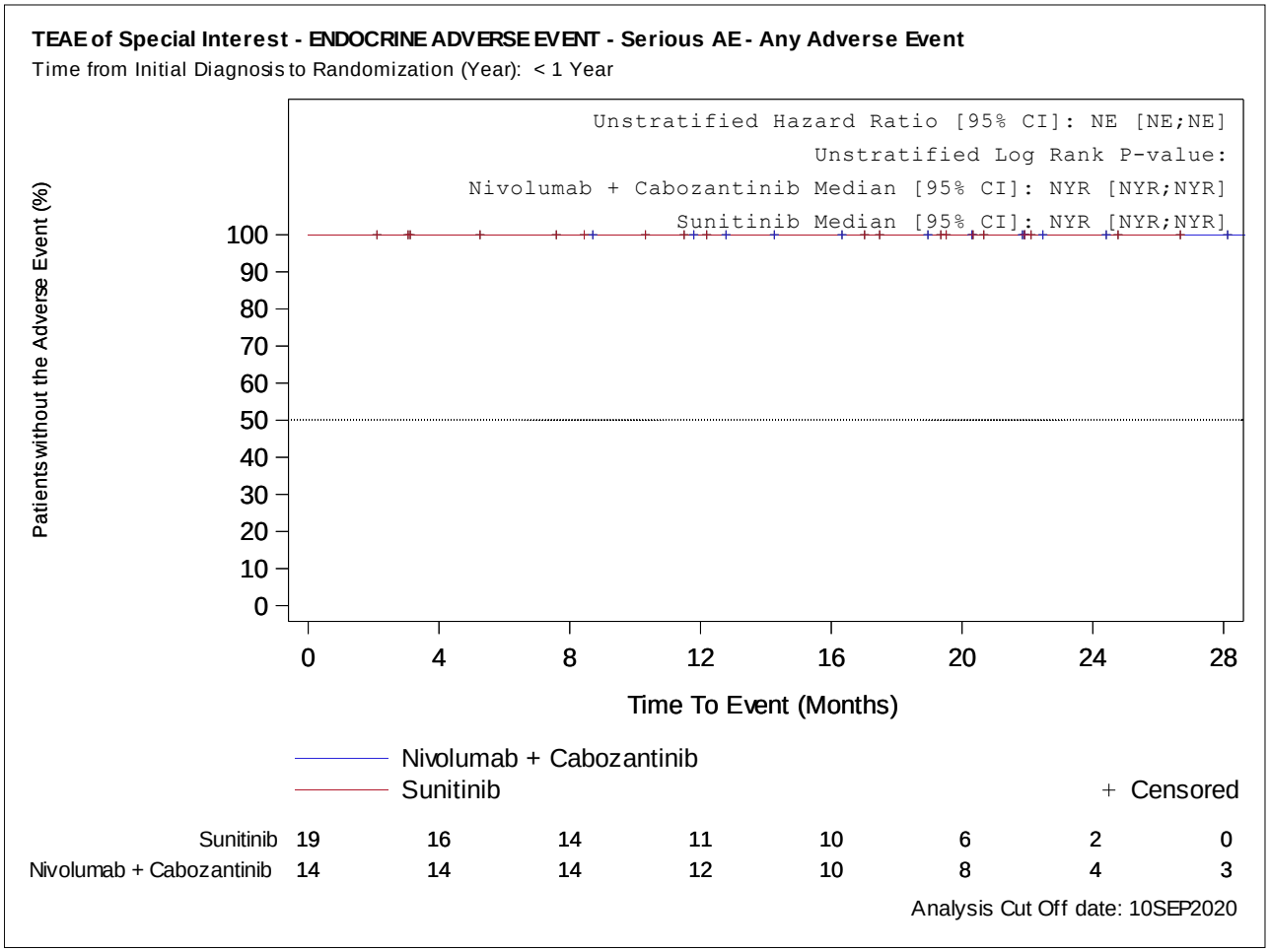

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:02:04

FIGURE 3.21.2.14: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



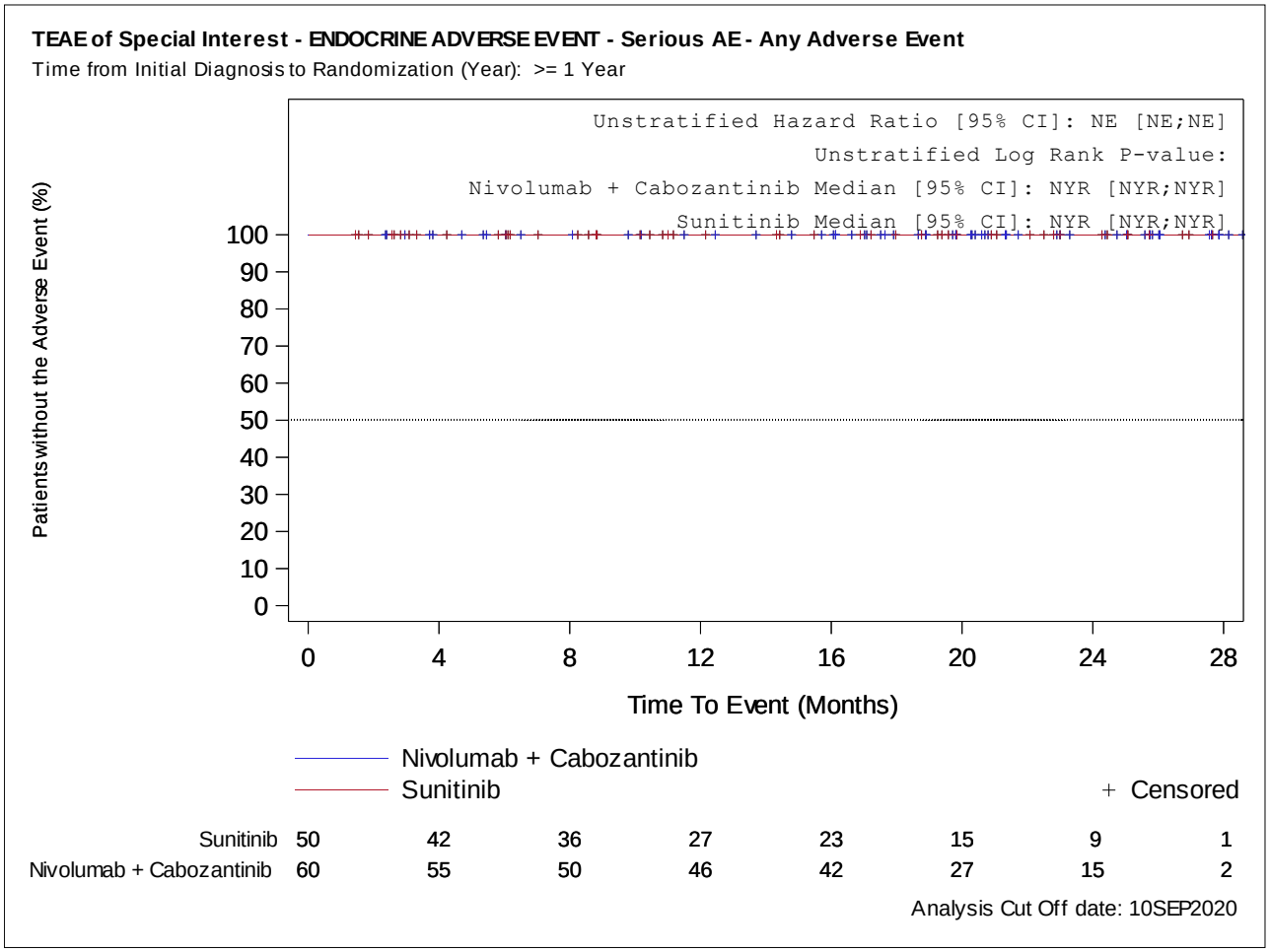

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:02:10

FIGURE 3.21.2.15: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



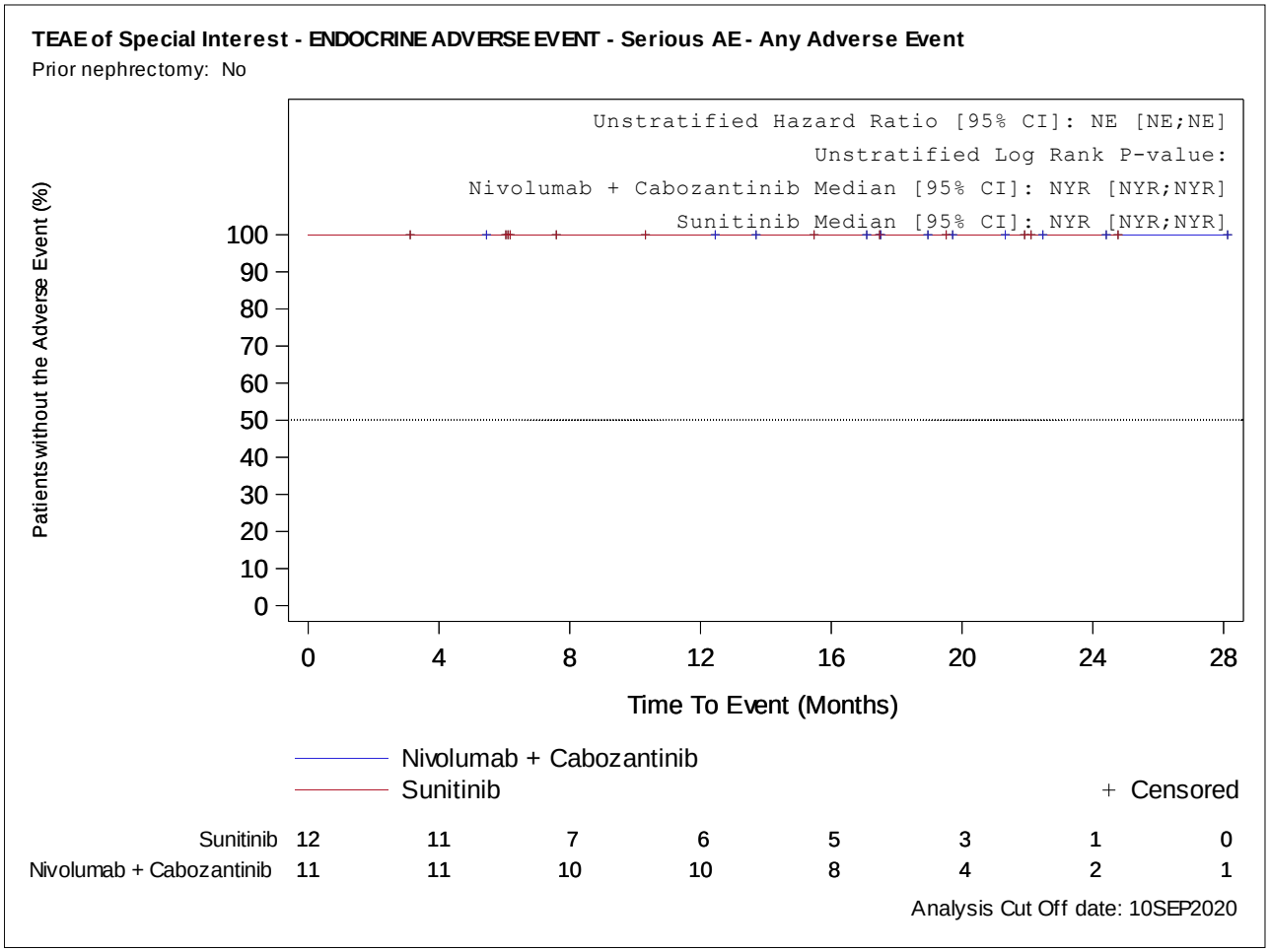

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:02:27

FIGURE 3.21.2.16: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



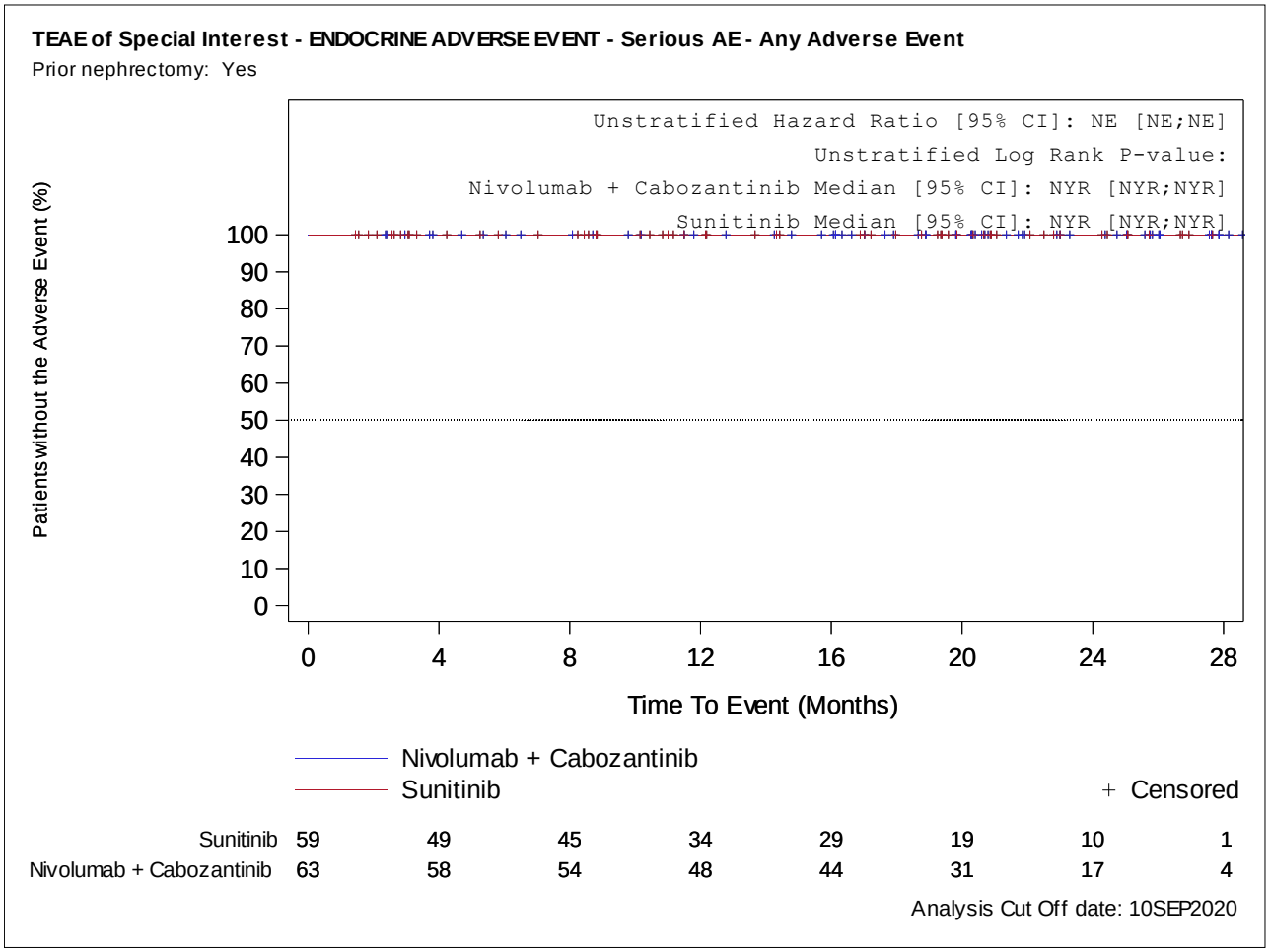

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:02:33

FIGURE 3.21.2.17: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



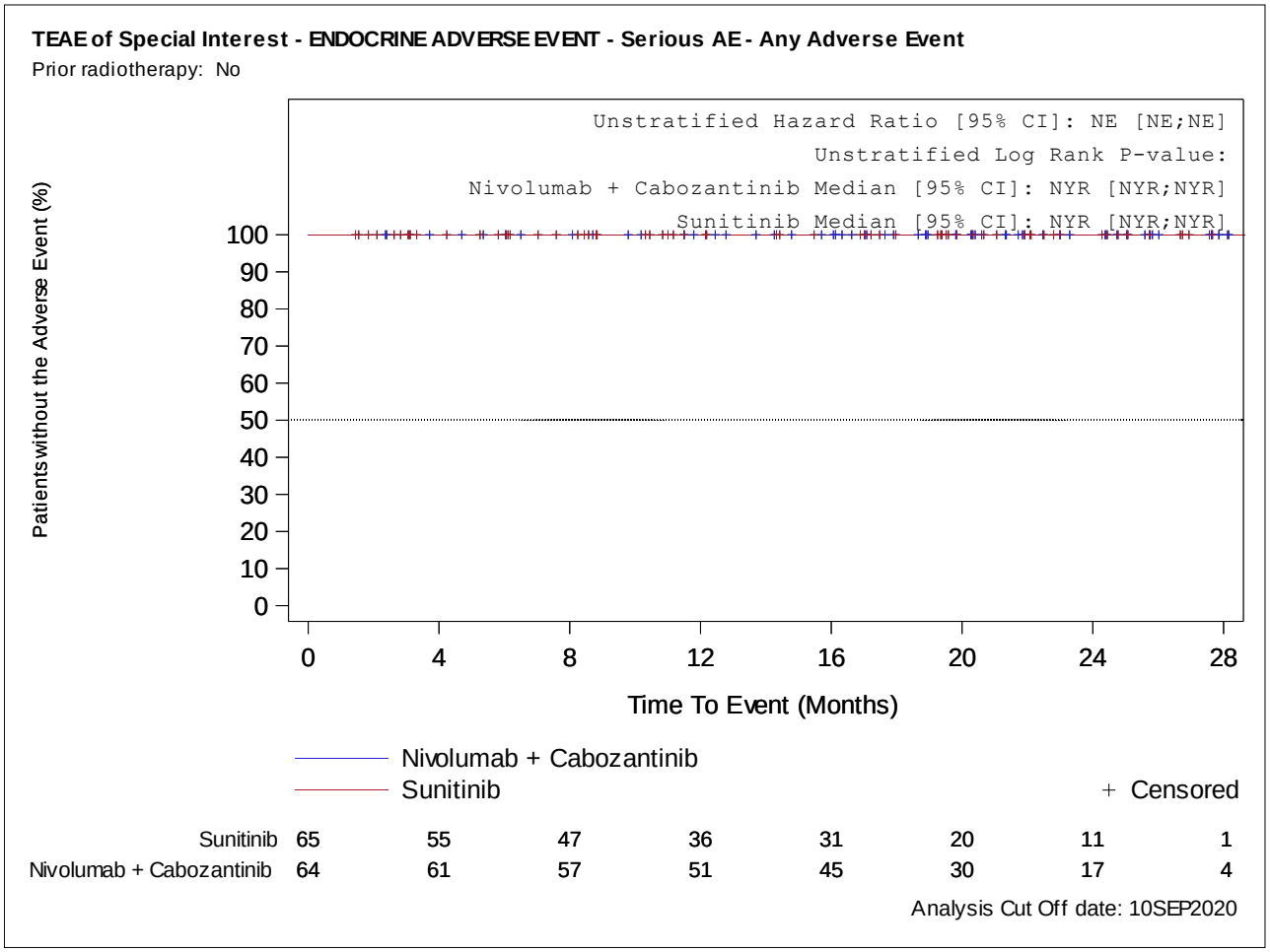

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:26

FIGURE 3.21.2.18: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



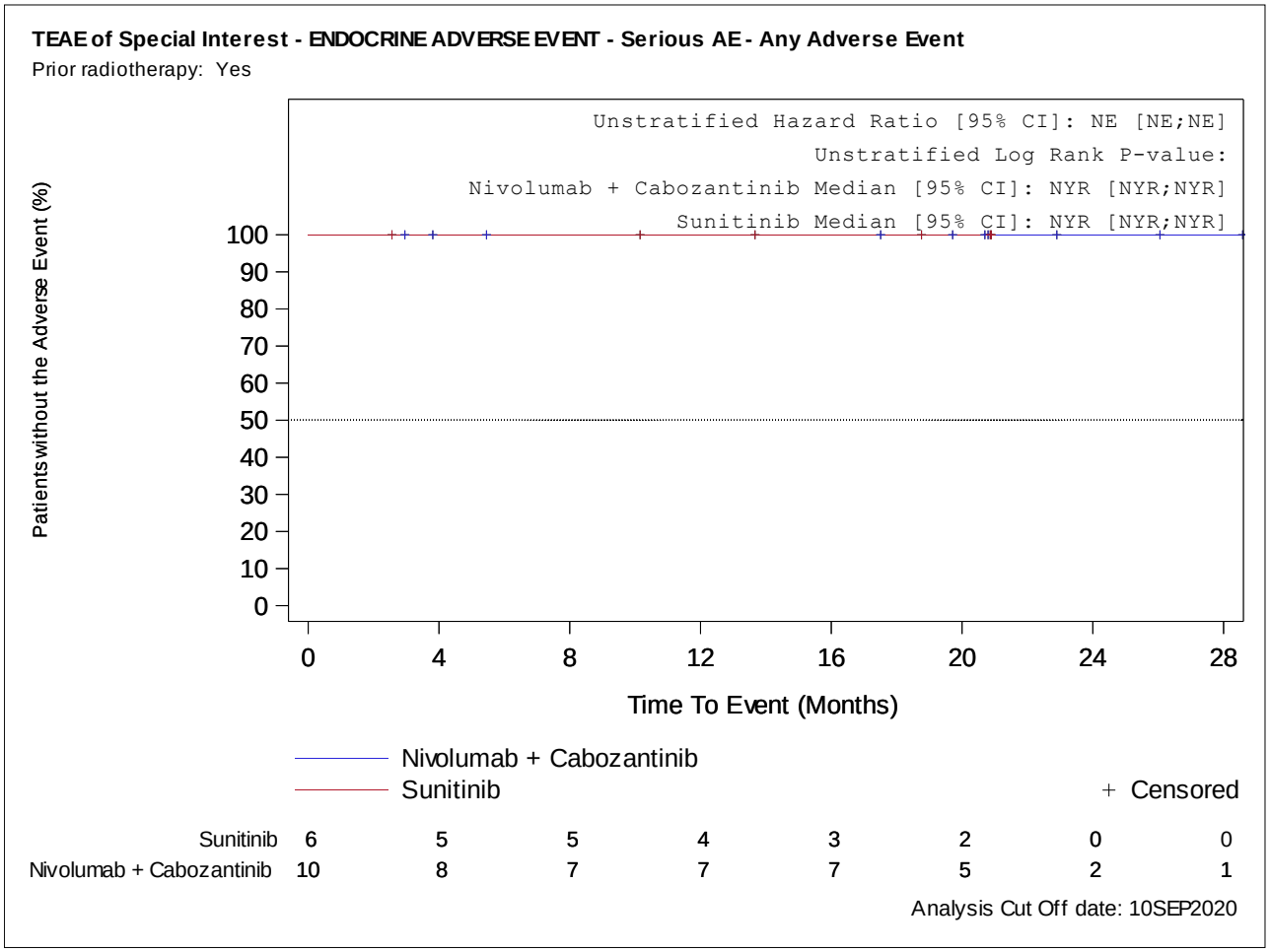

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:32

FIGURE 3.21.2.19: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



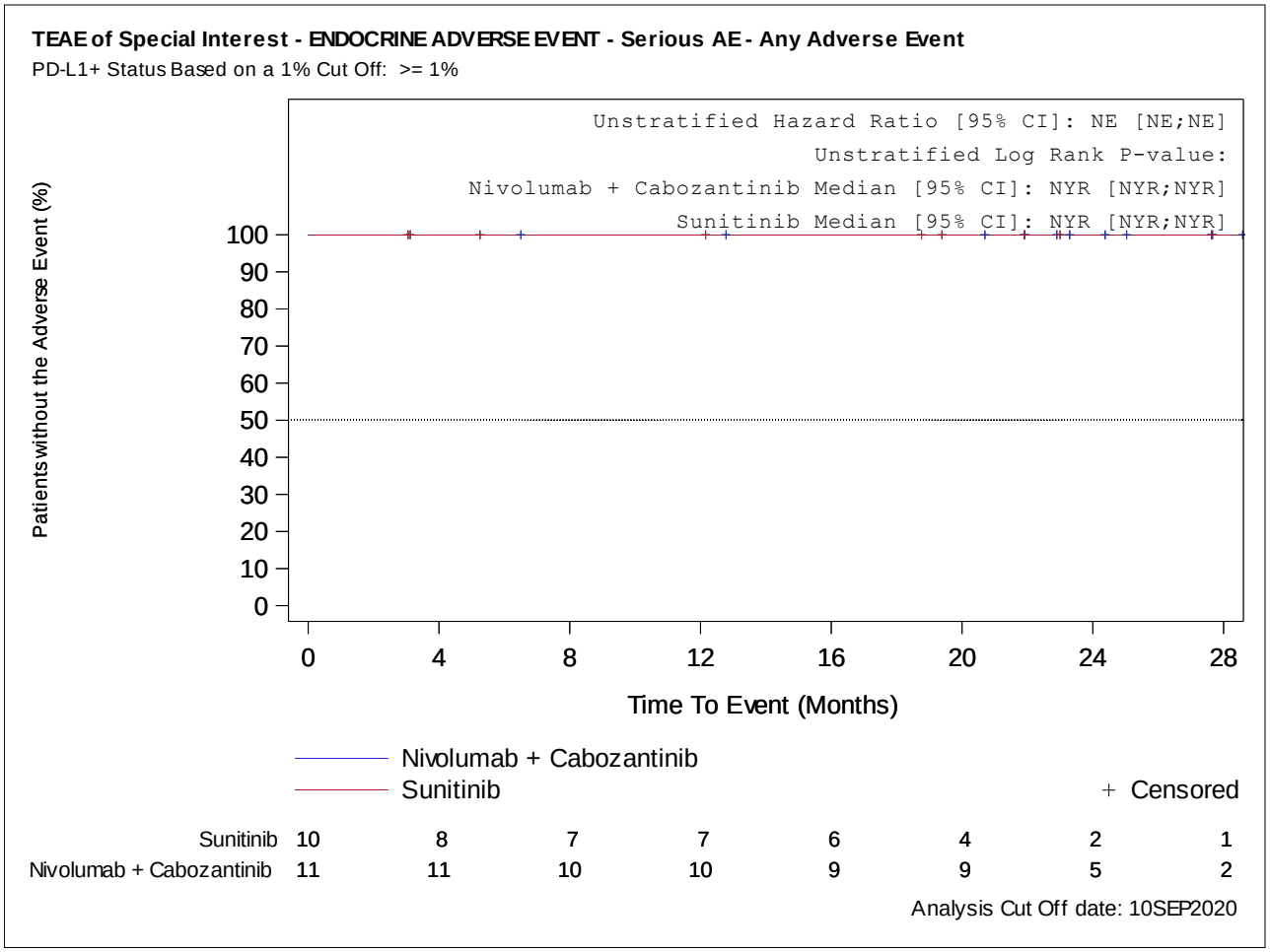

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:37

FIGURE 3.21.2.20: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



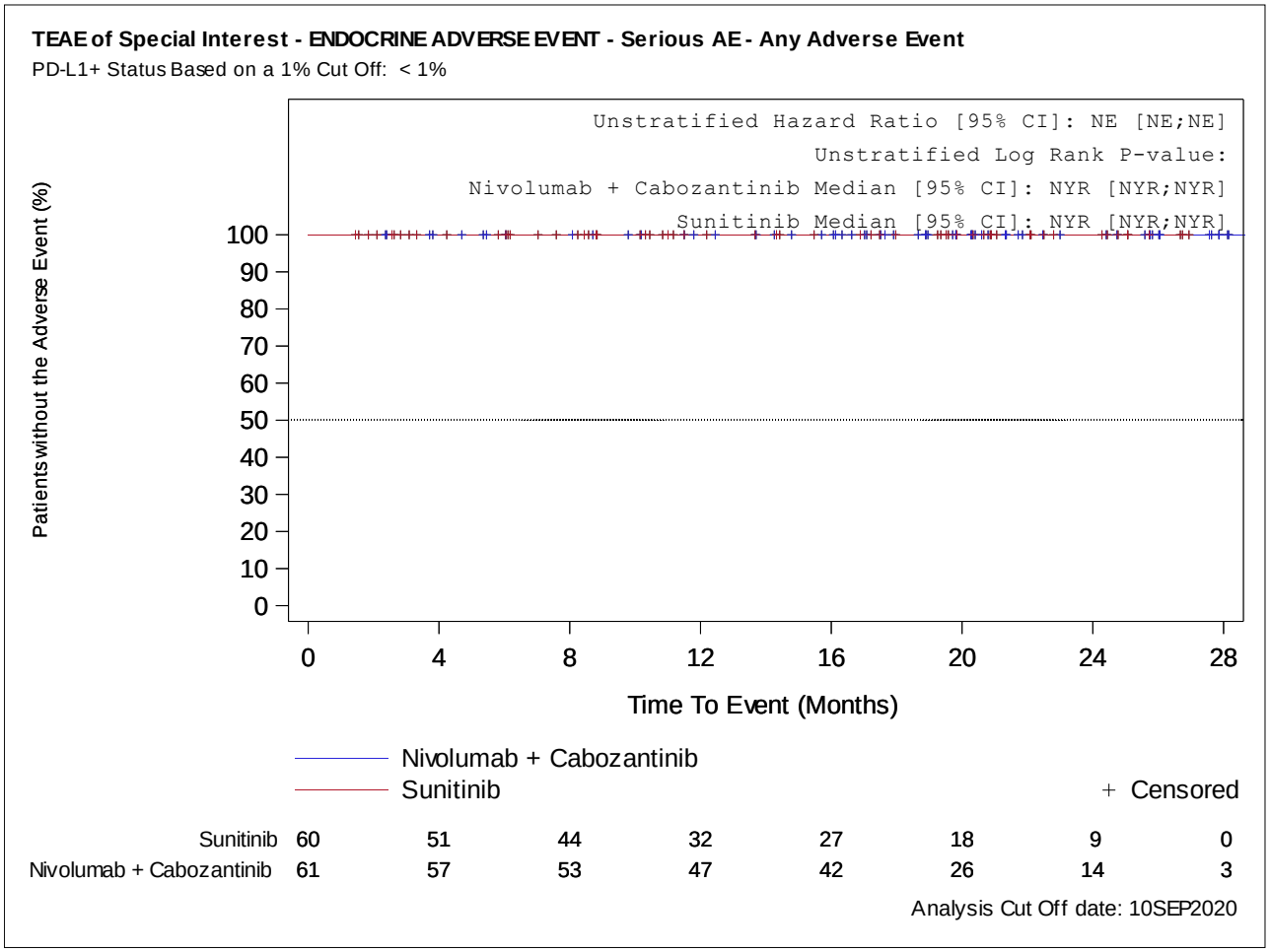

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:43

FIGURE 3.21.2.21: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



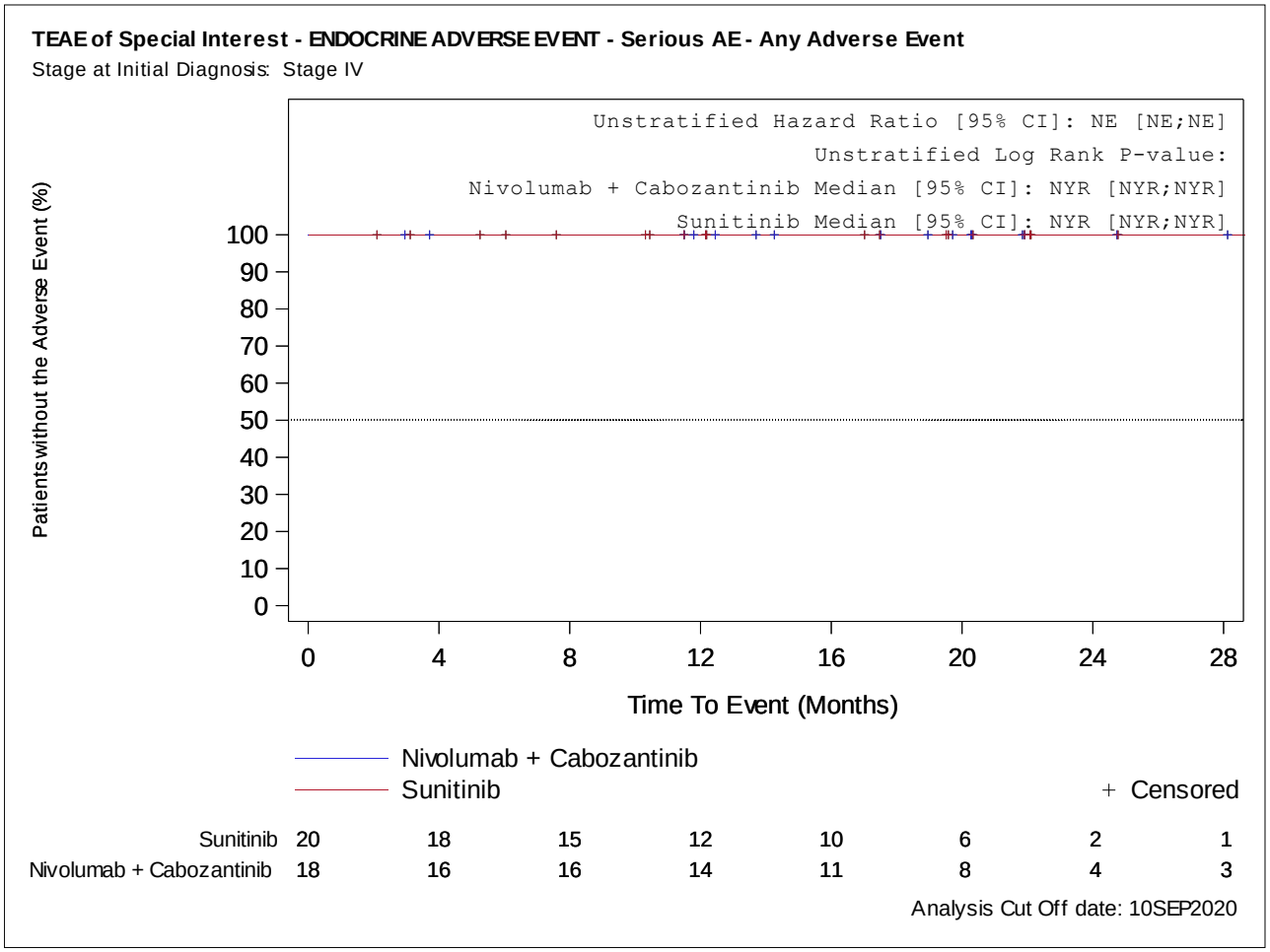

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:49

FIGURE 3.21.2.22: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



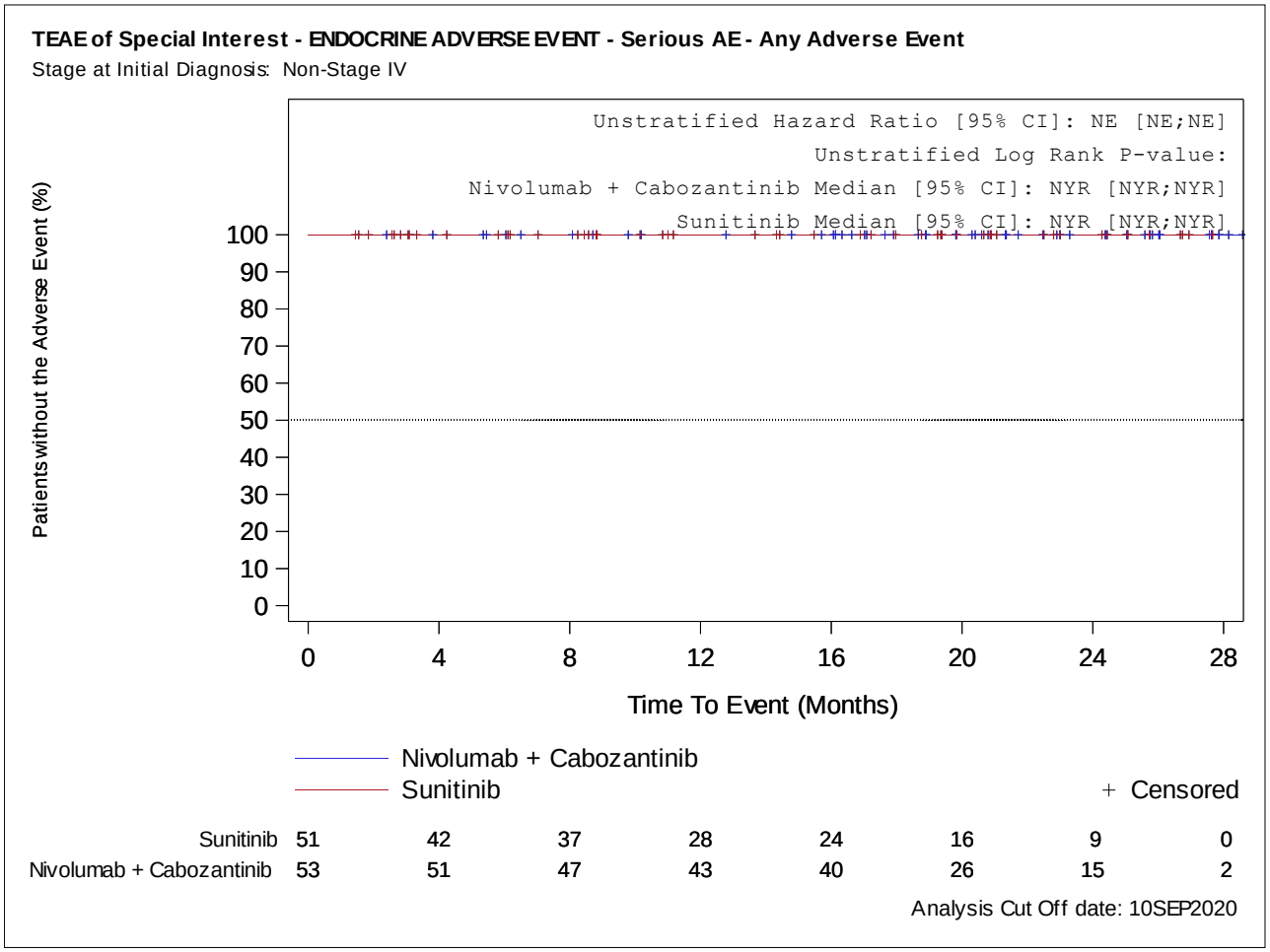

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:55

FIGURE 3.21.2.23: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



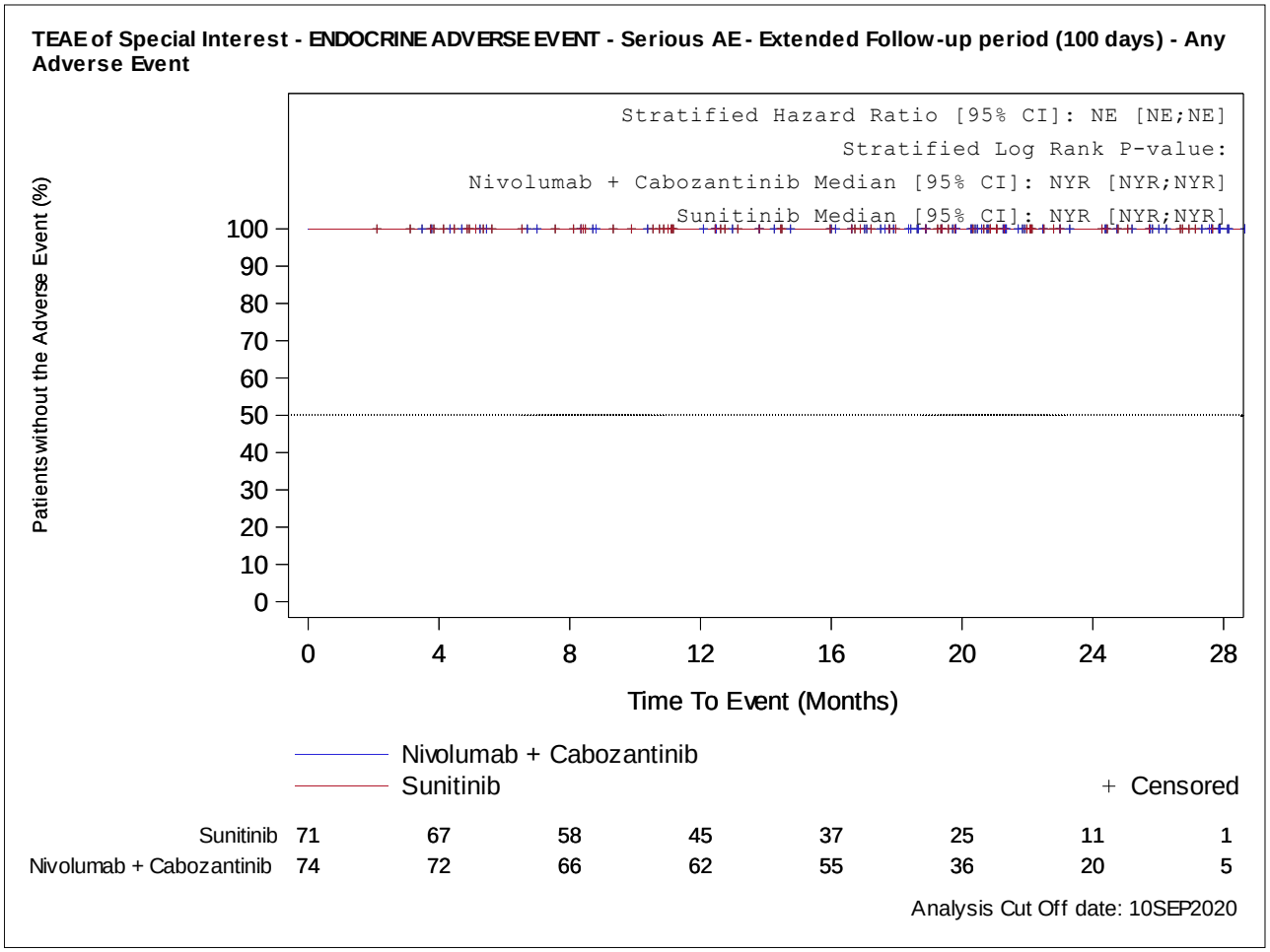

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:04:26

FIGURE 3.21.2.24: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



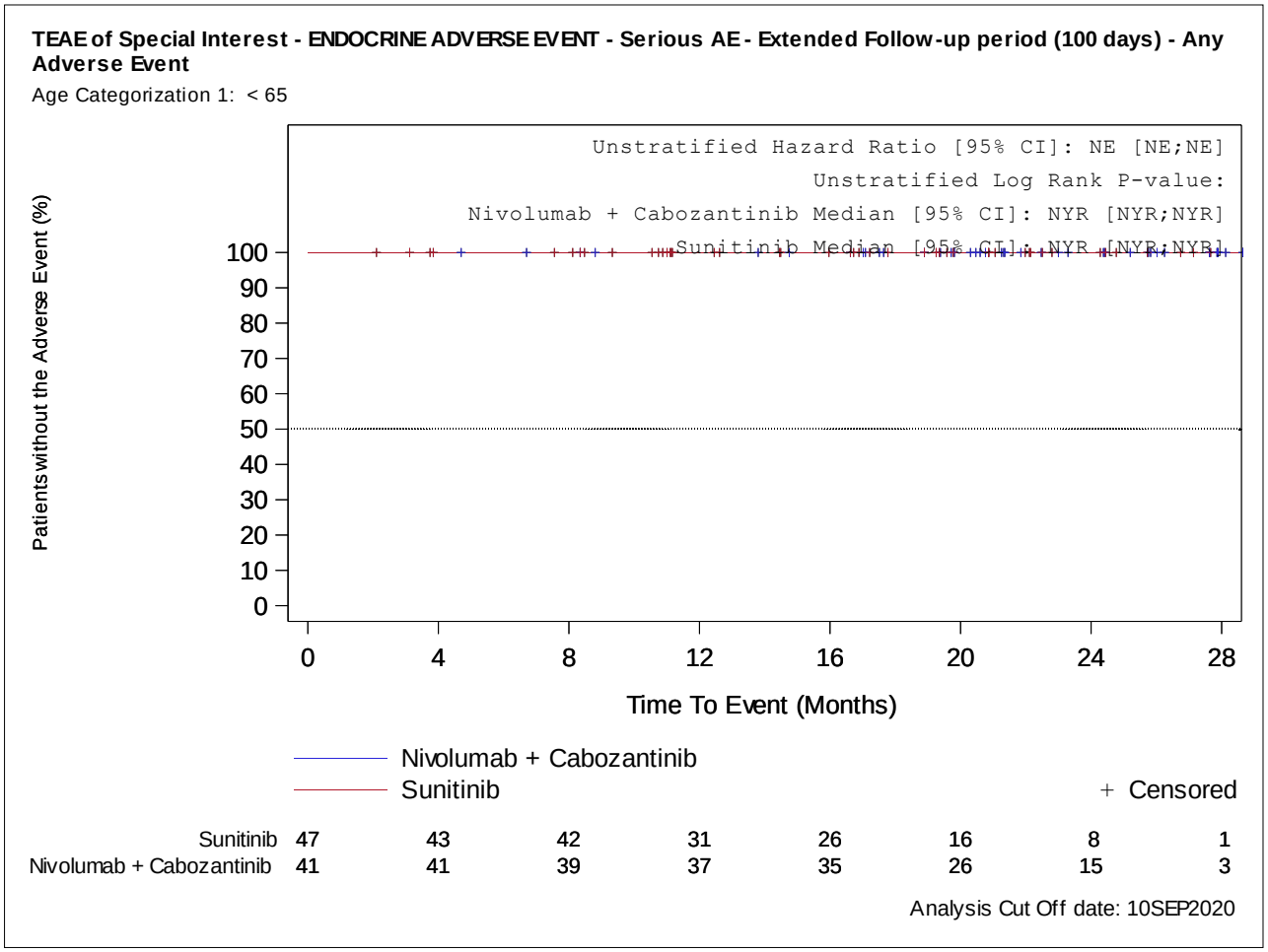

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:04:32

FIGURE 3.22.1: TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



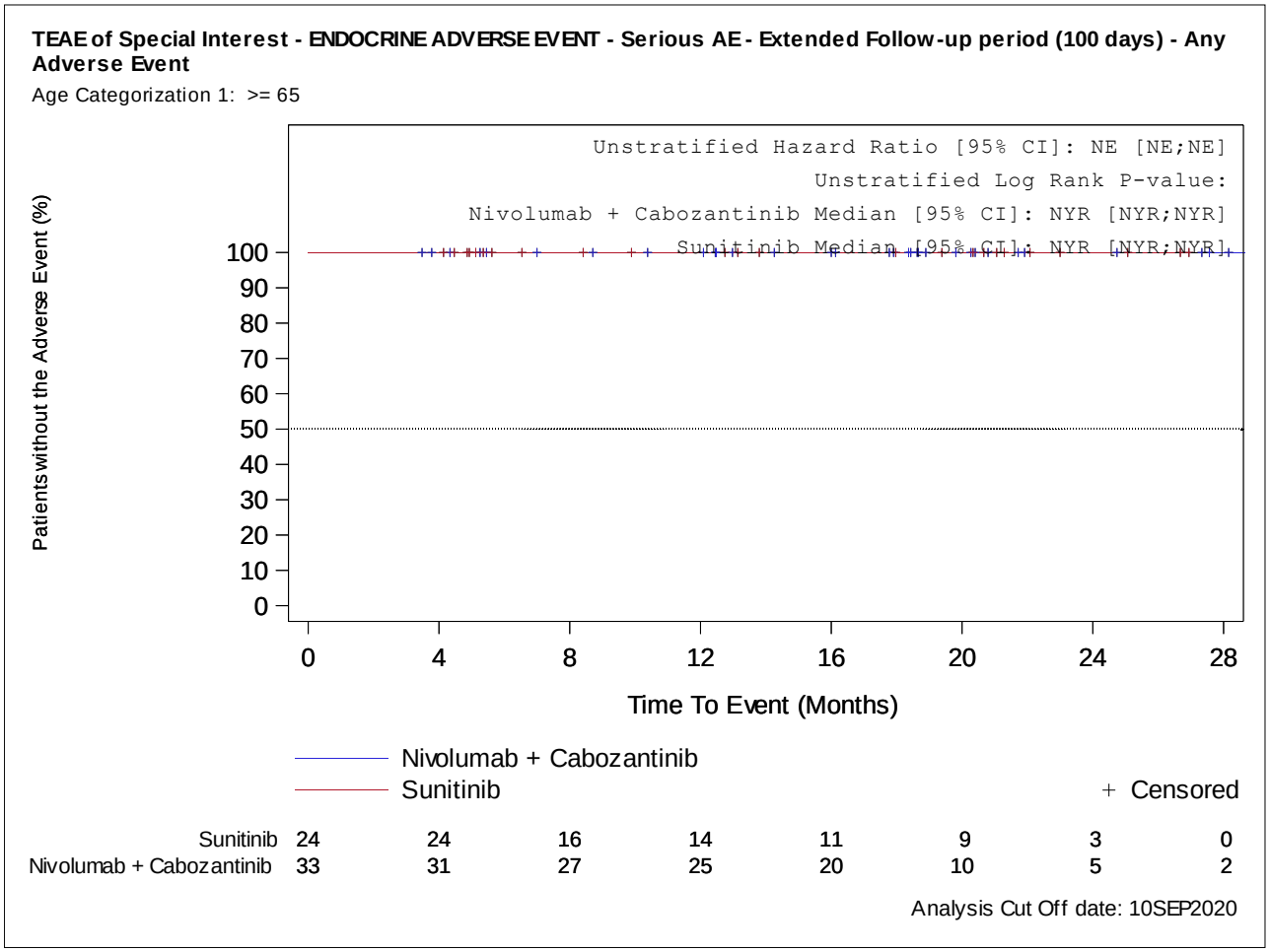

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:07:49

FIGURE 3.22.2.1: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



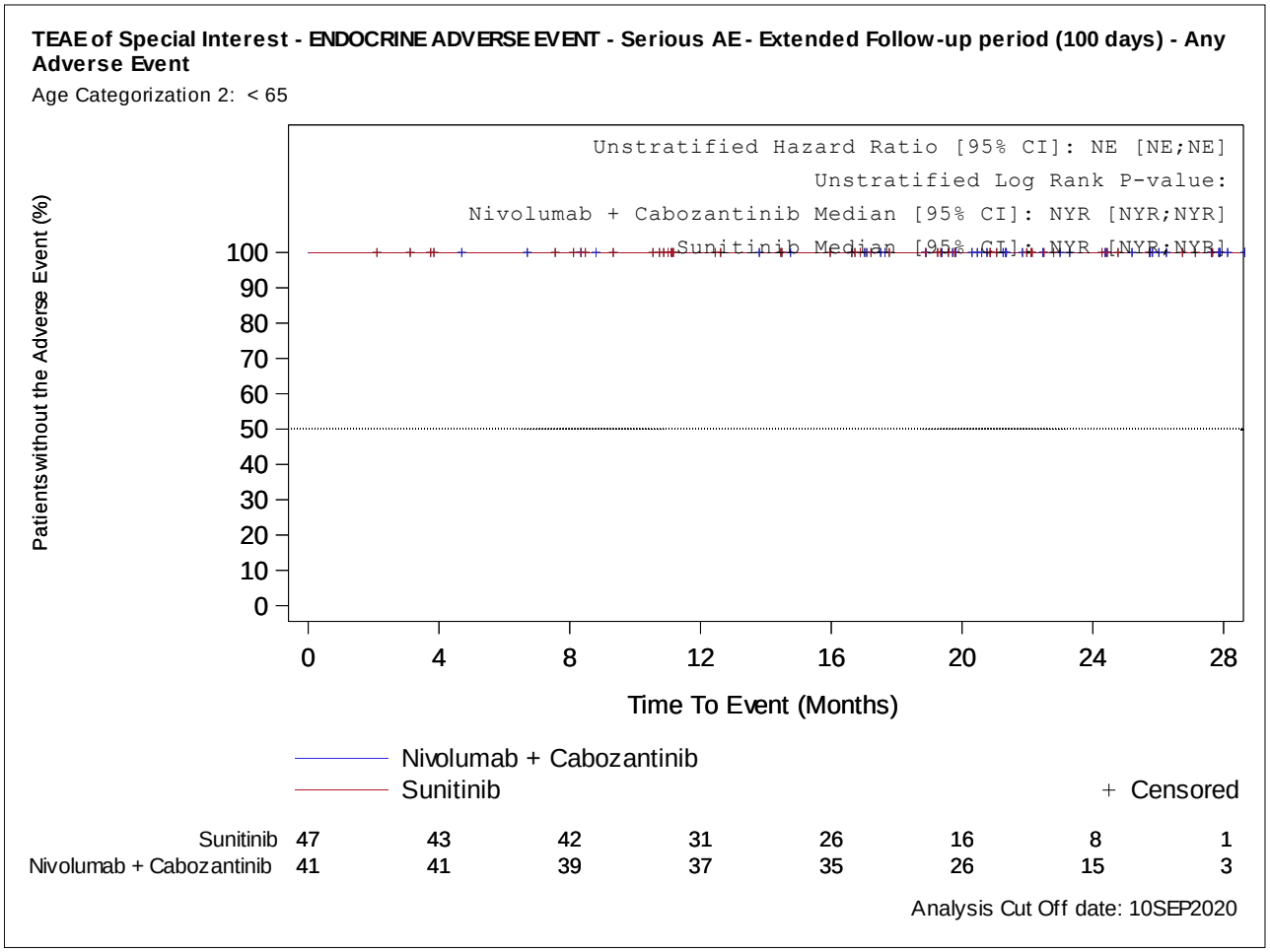

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:07:53

FIGURE 3.22.2.2: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:07:59

FIGURE 3.22.2.3: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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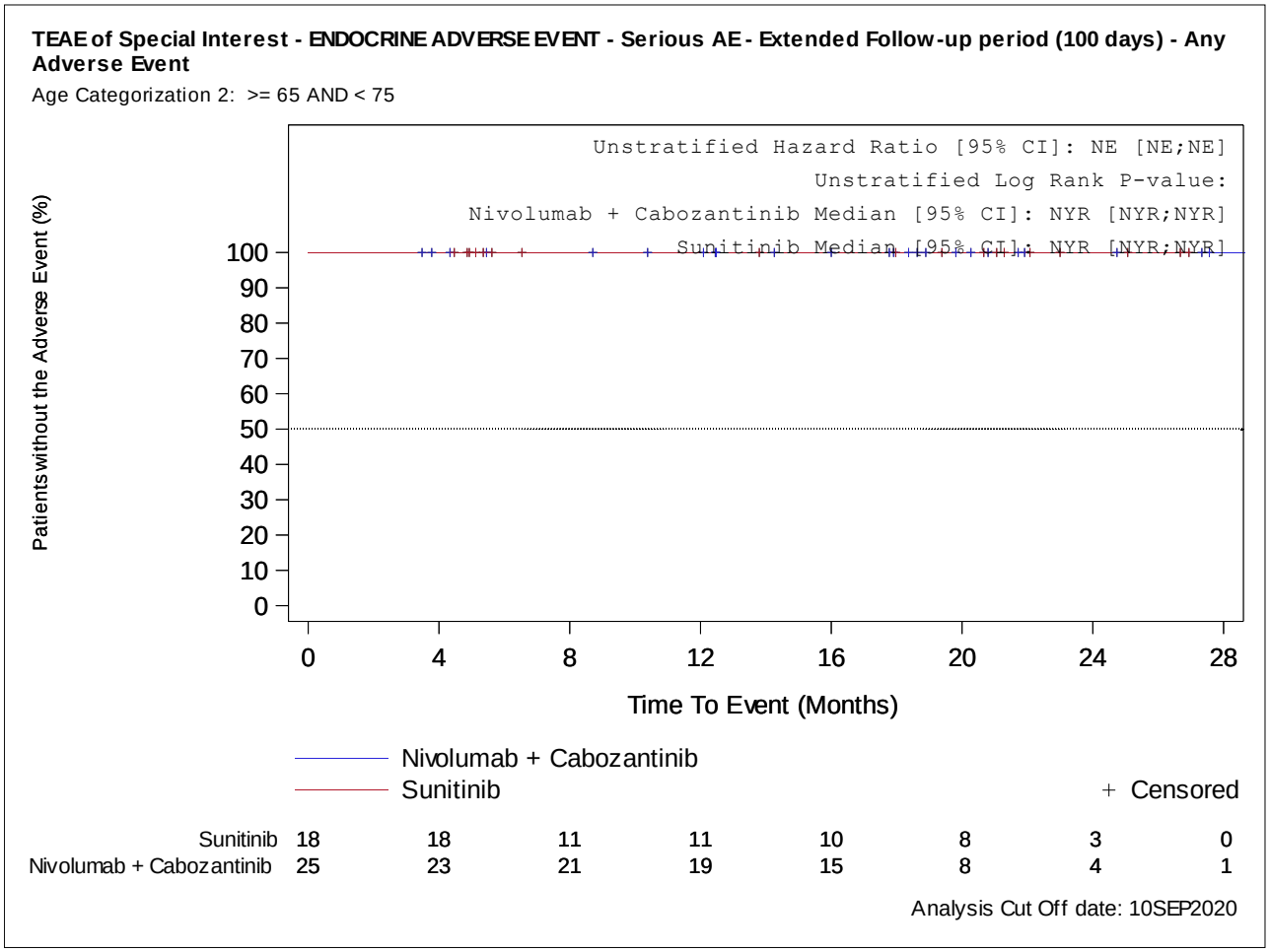
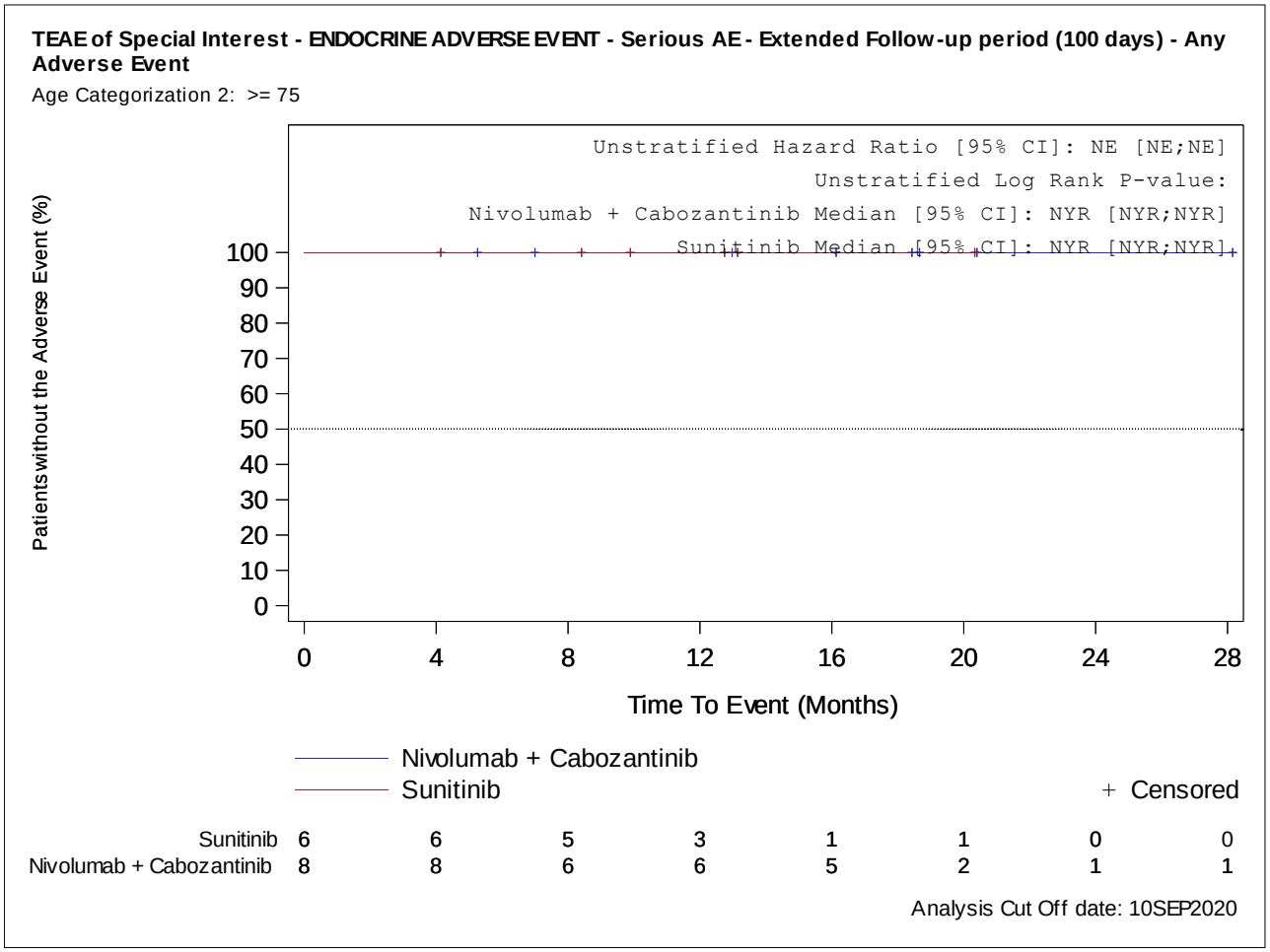
FIGURE 3.22.2.4: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



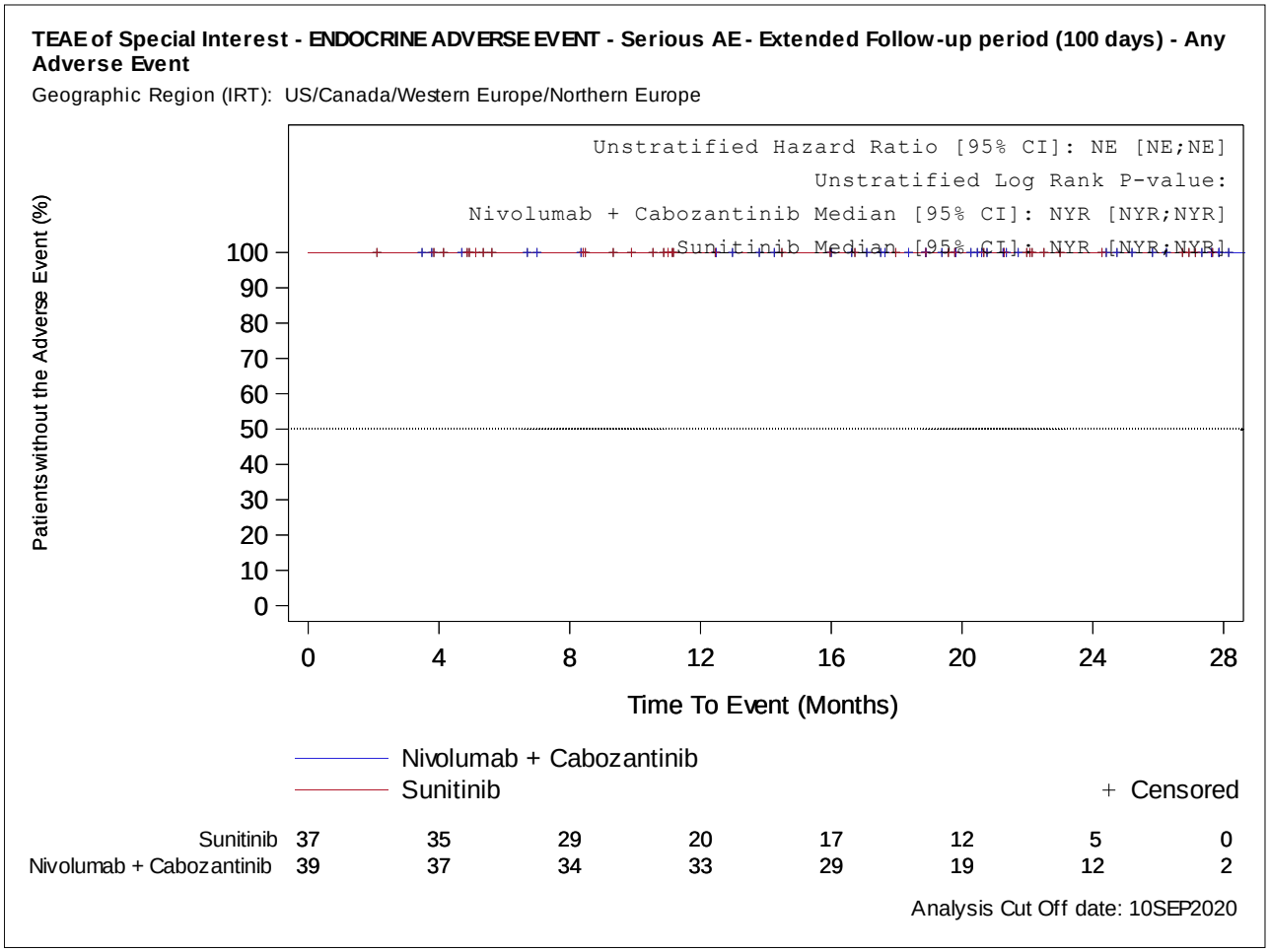

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:08:11

FIGURE 3.22.2.5: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



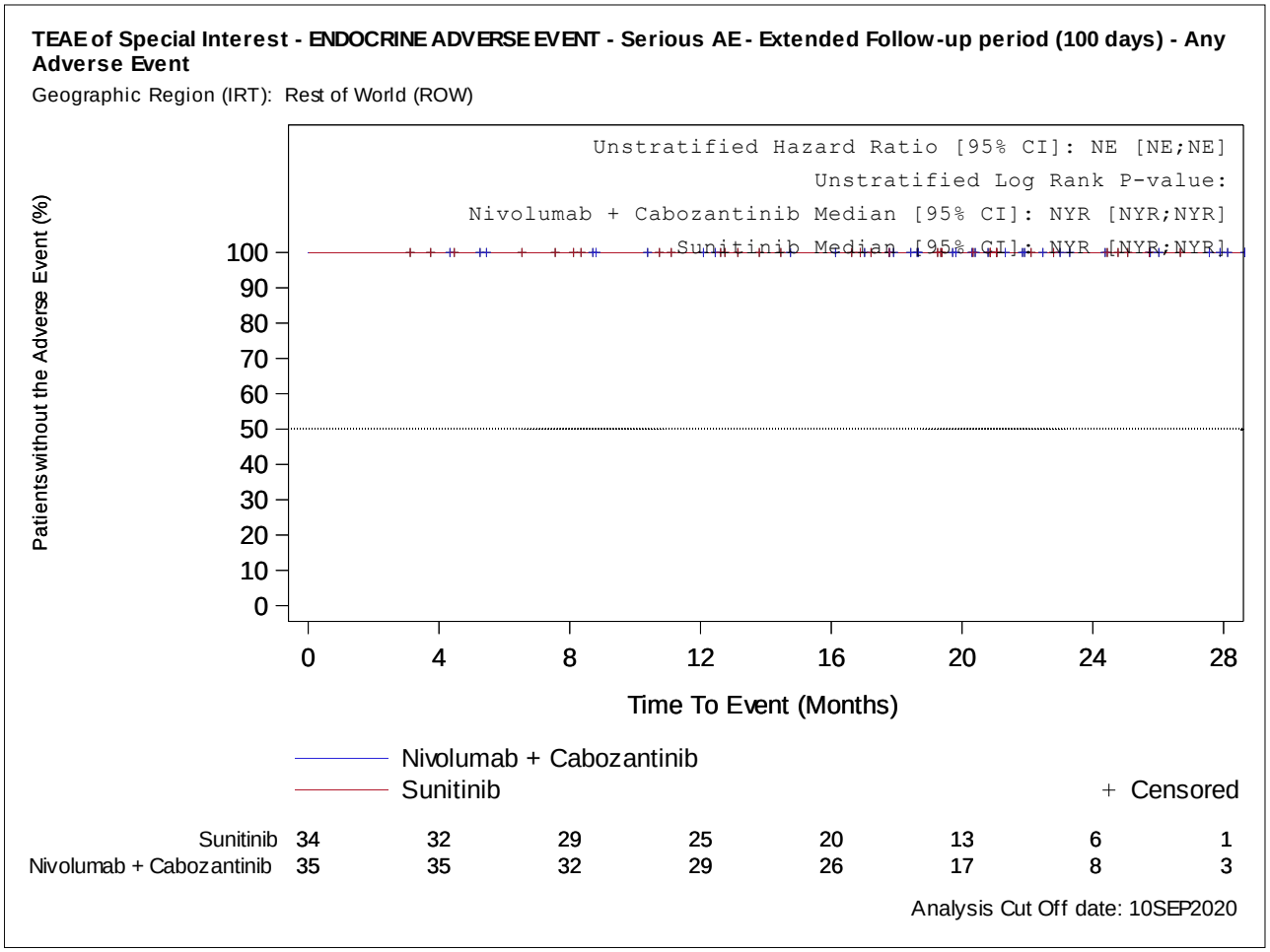

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:08:17

FIGURE 3.22.2.6: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



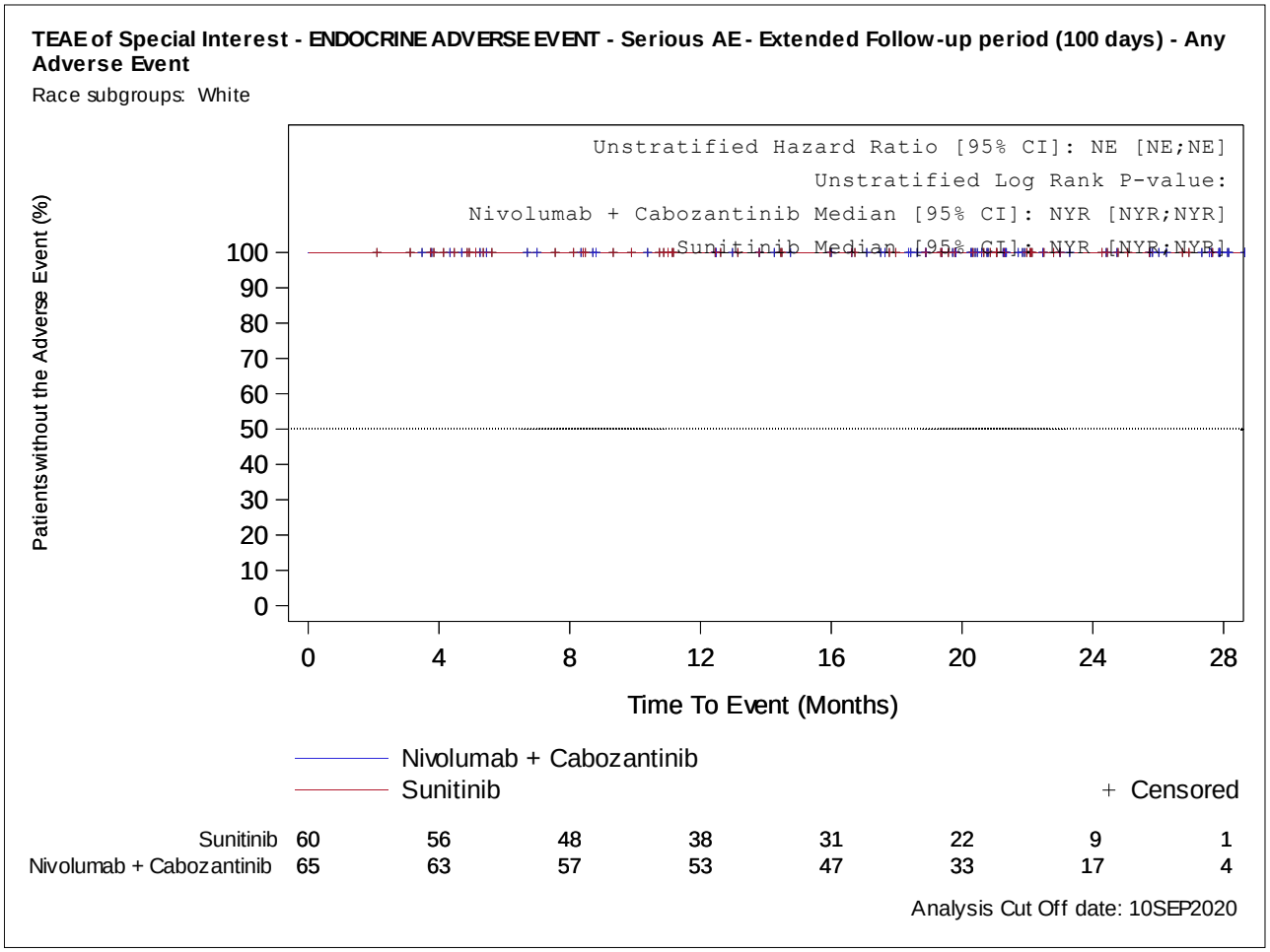

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:08:22

FIGURE 3.22.2.7: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



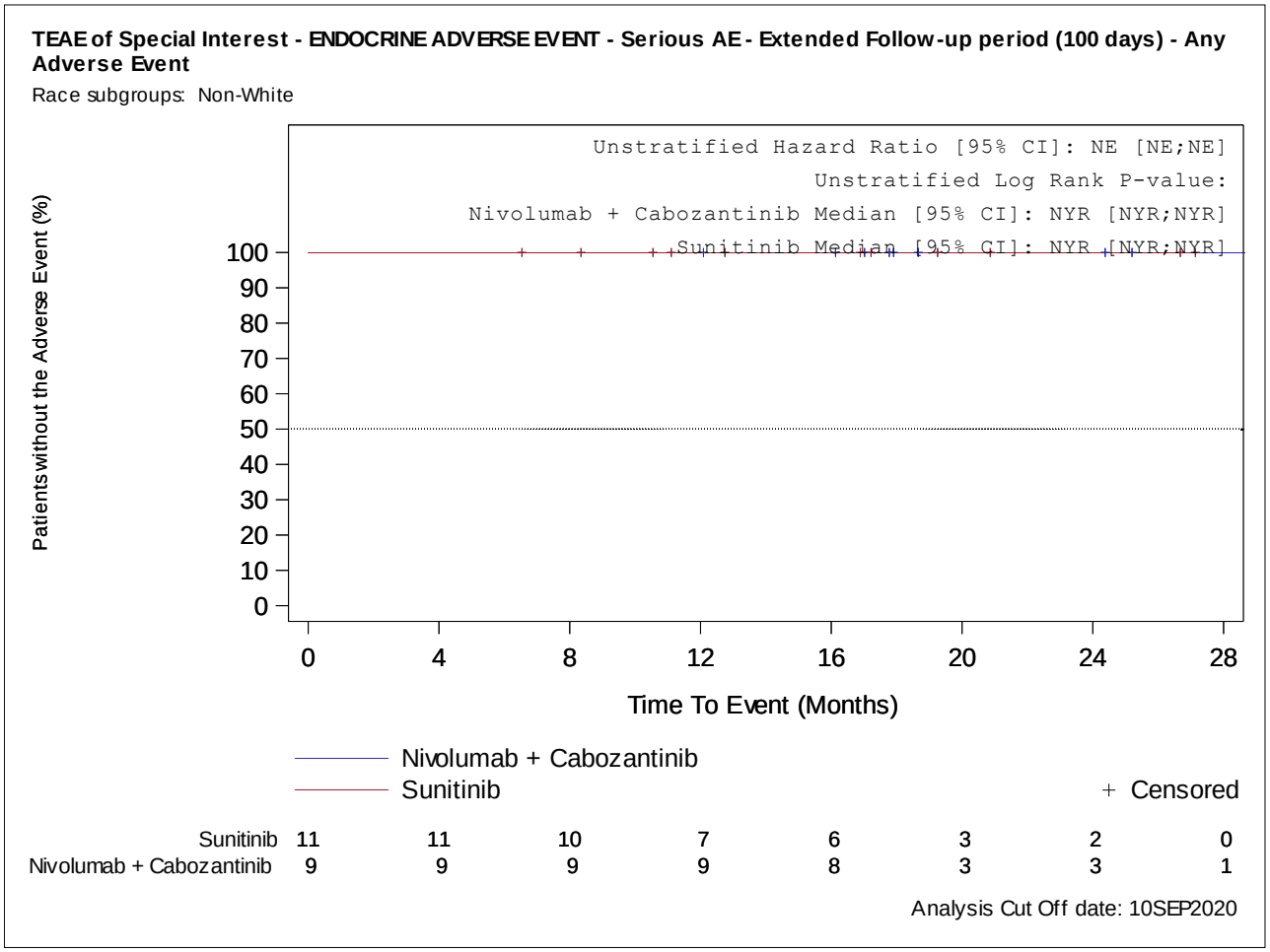

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:08:28

FIGURE 3.22.2.8: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



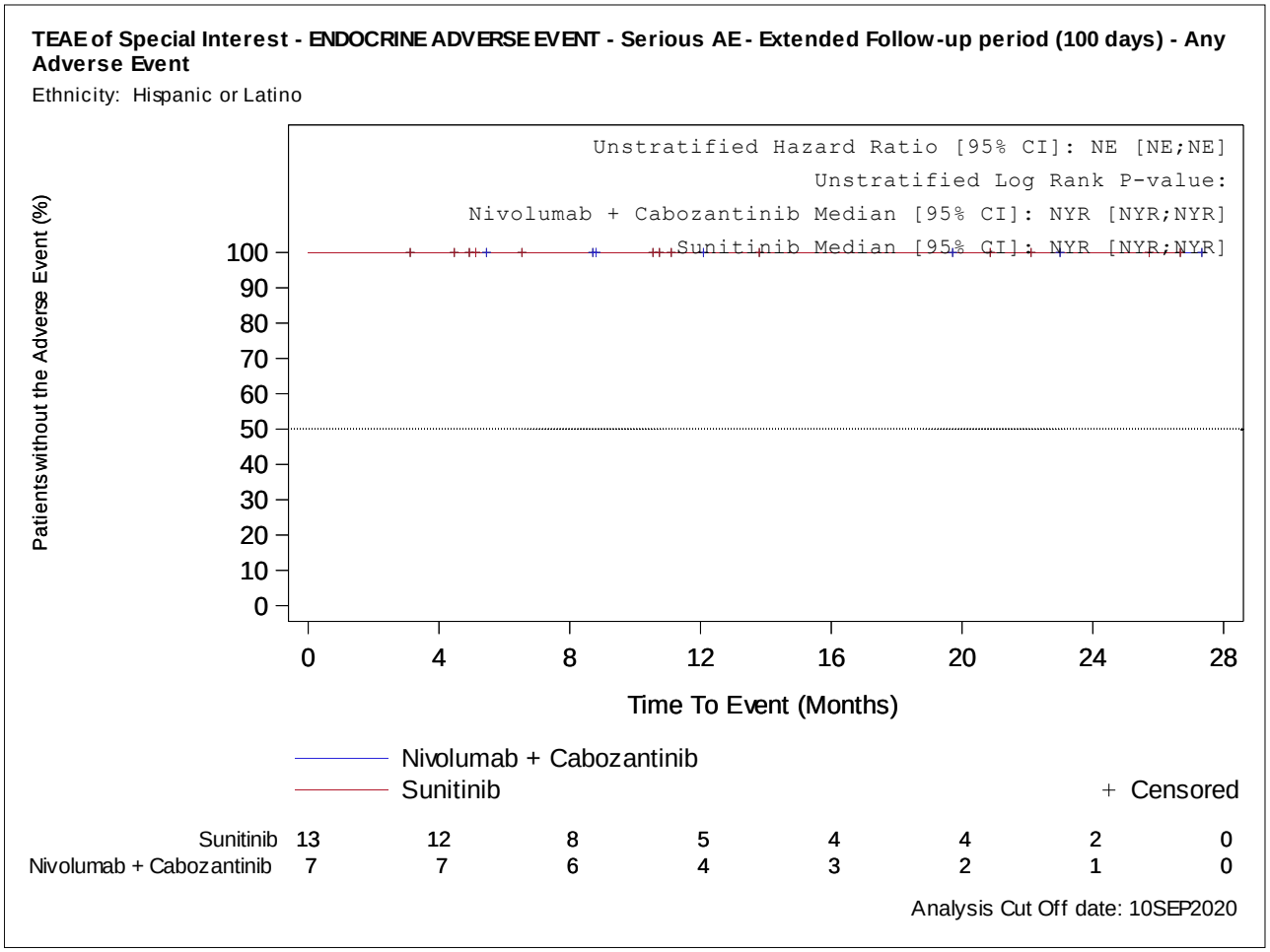

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:08:34

FIGURE 3.22.2.9: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



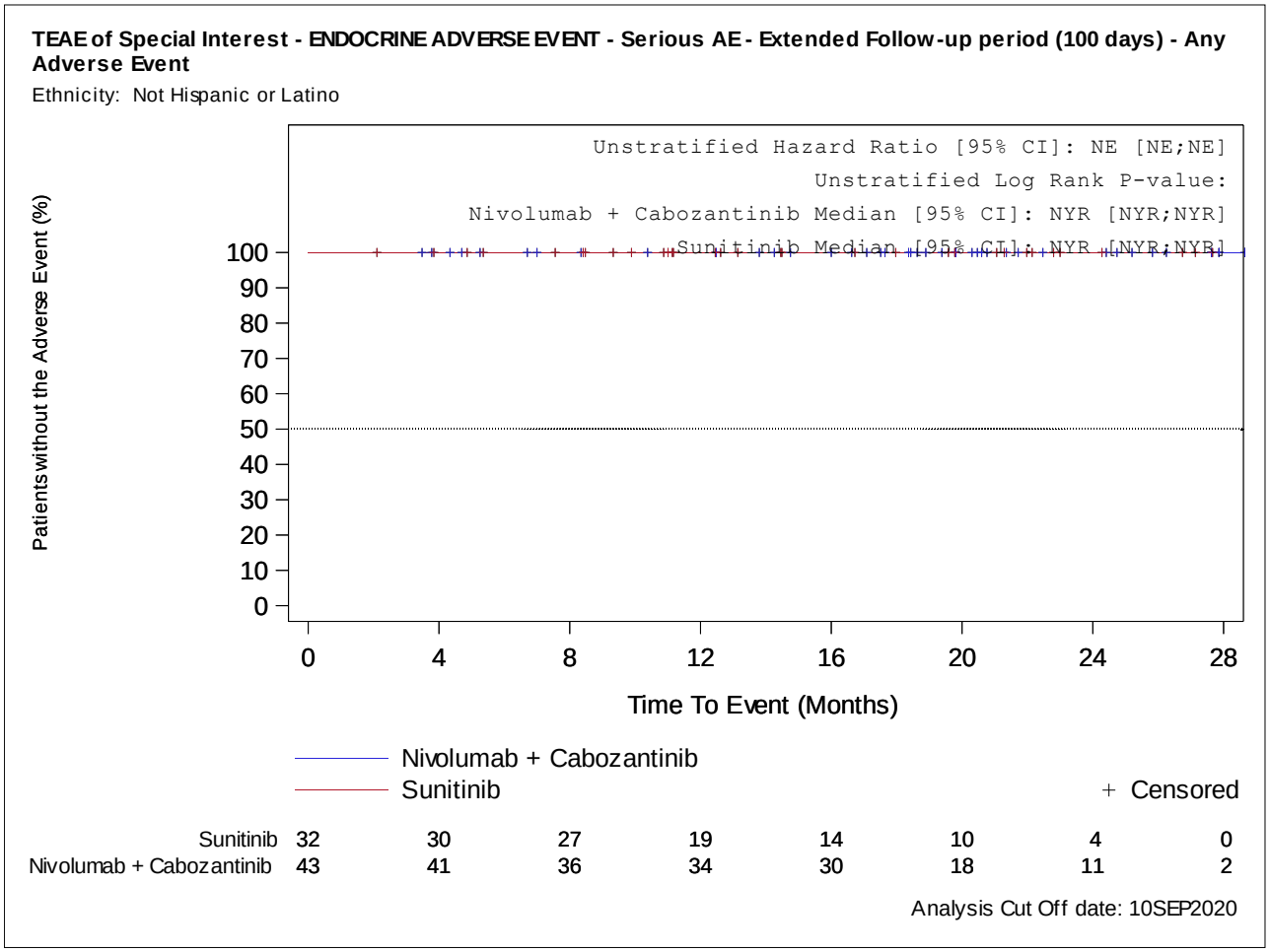

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:08:40

FIGURE 3.22.2.10: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



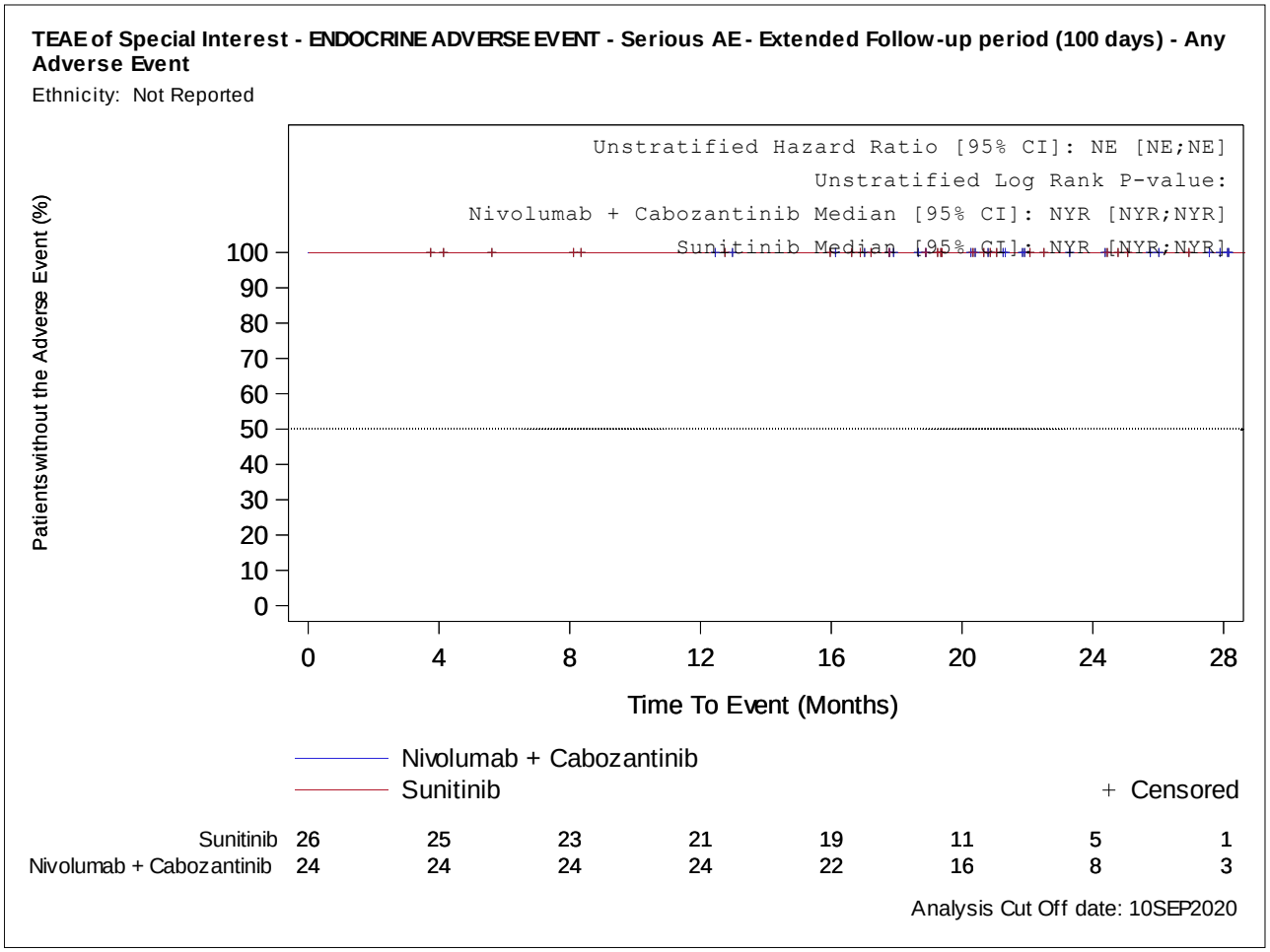

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:08:46

FIGURE 3.22.2.11: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



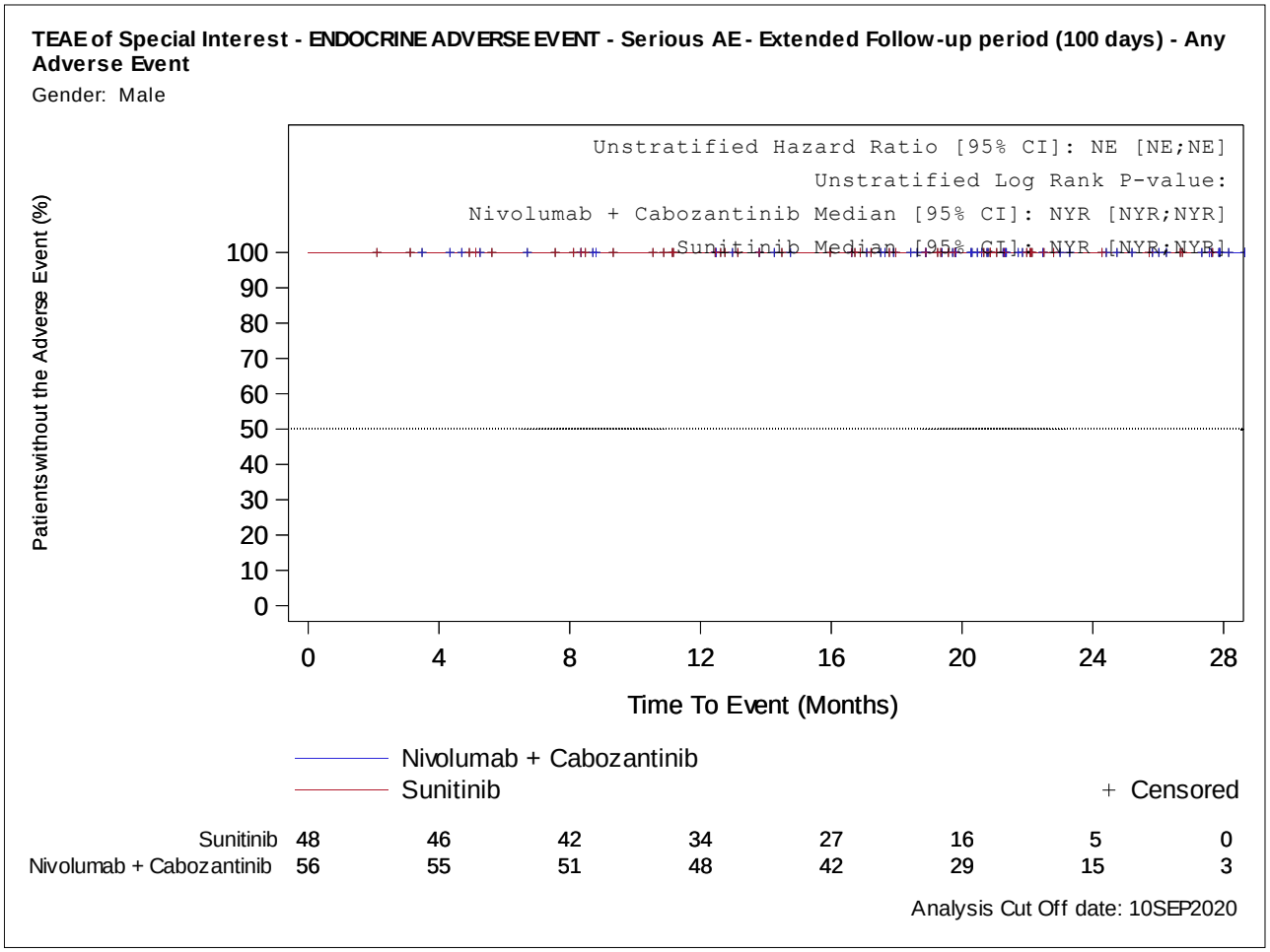

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:08:51

FIGURE 3.22.2.12: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



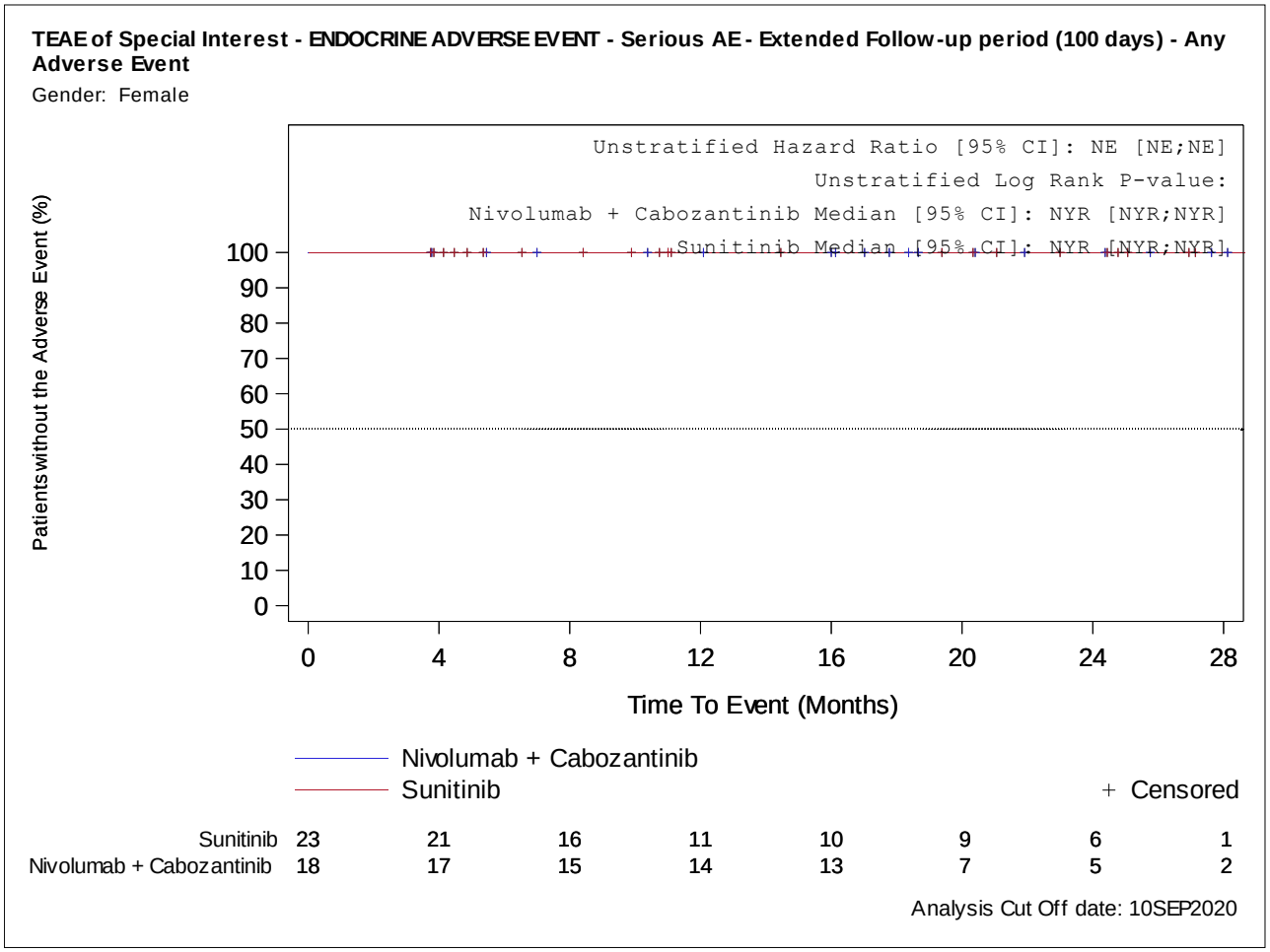

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:08:57

FIGURE 3.22.2.13: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



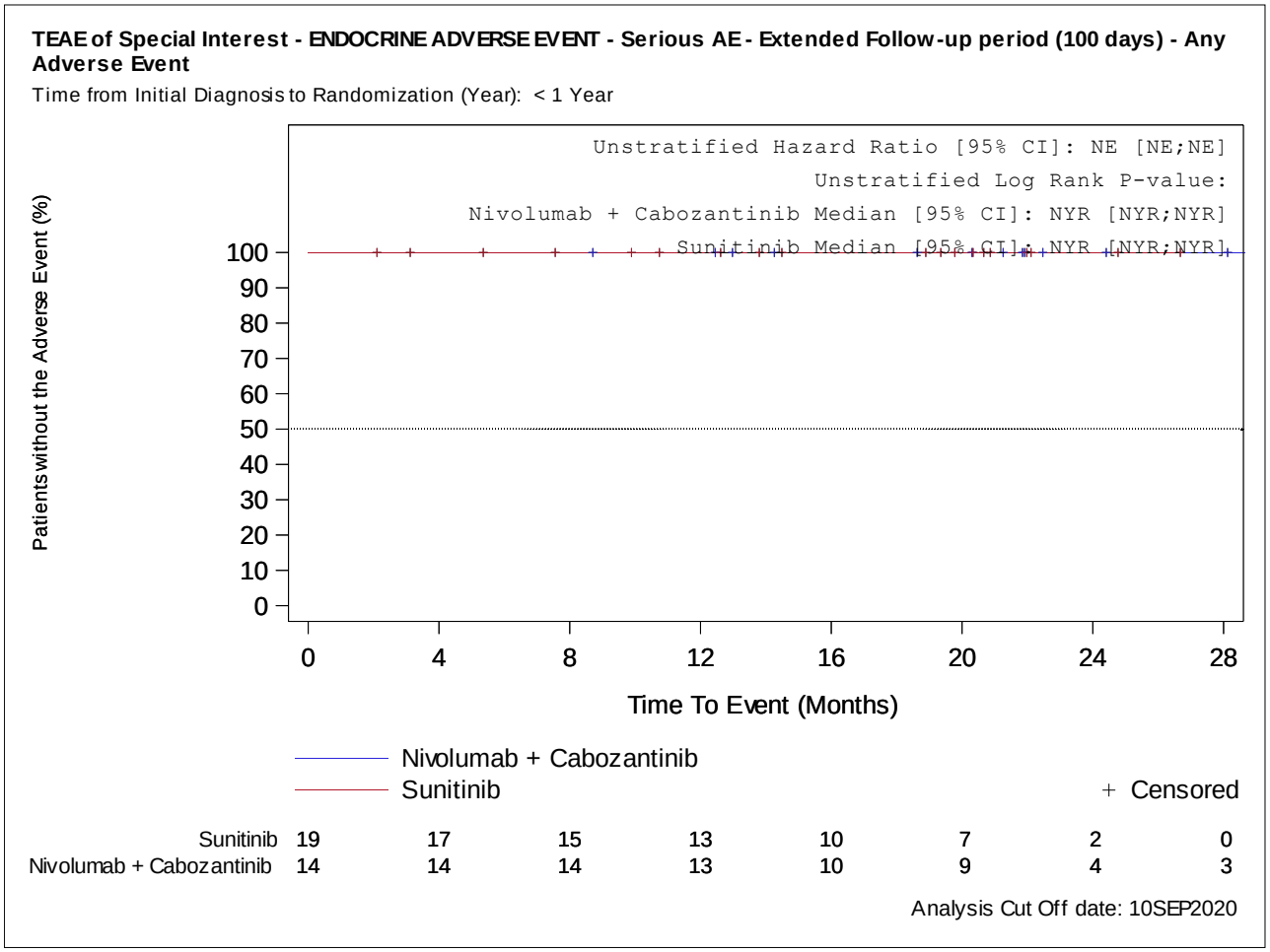

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:09:03

FIGURE 3.22.2.14: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



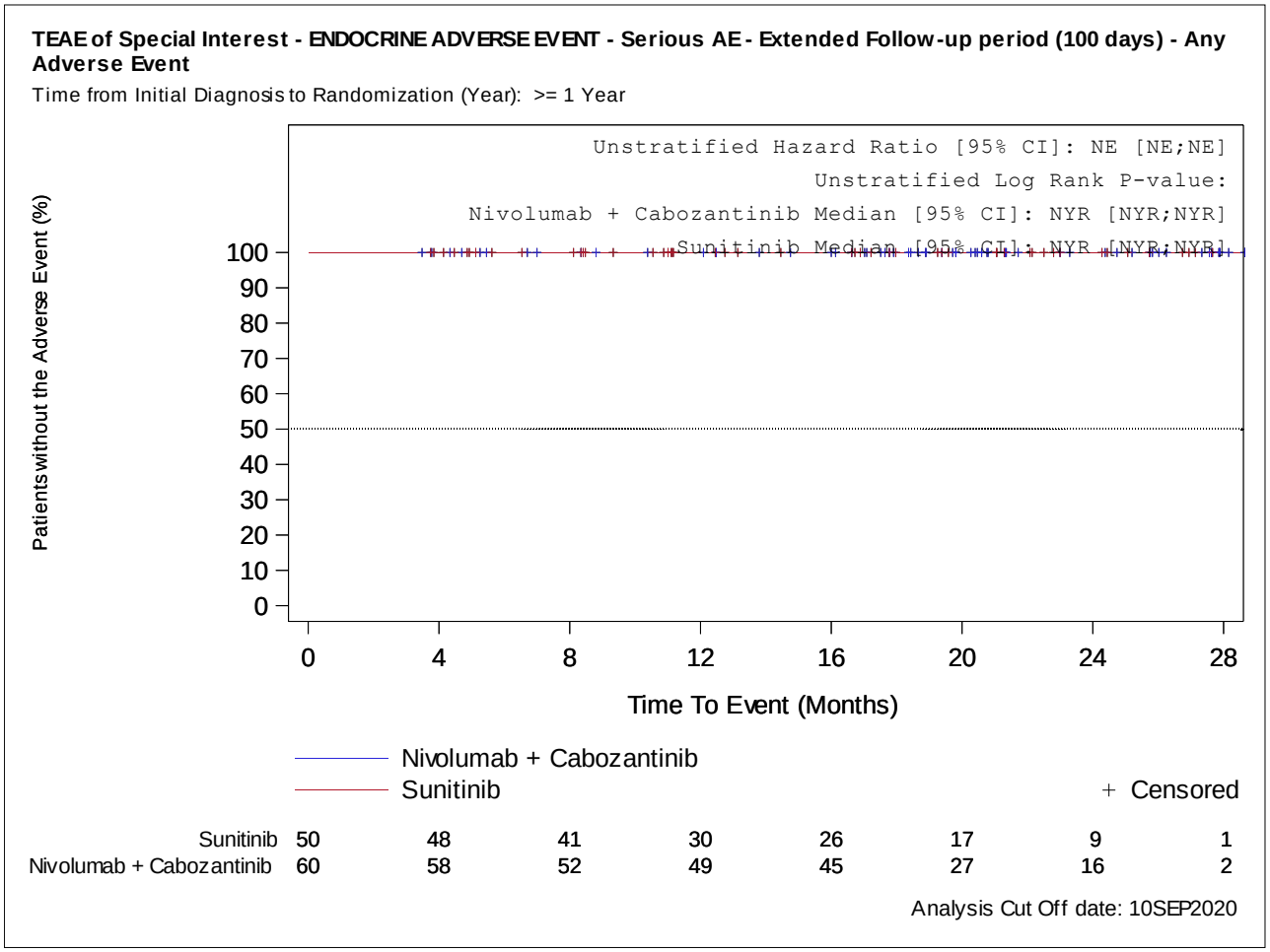

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:09:09

FIGURE 3.22.2.15: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



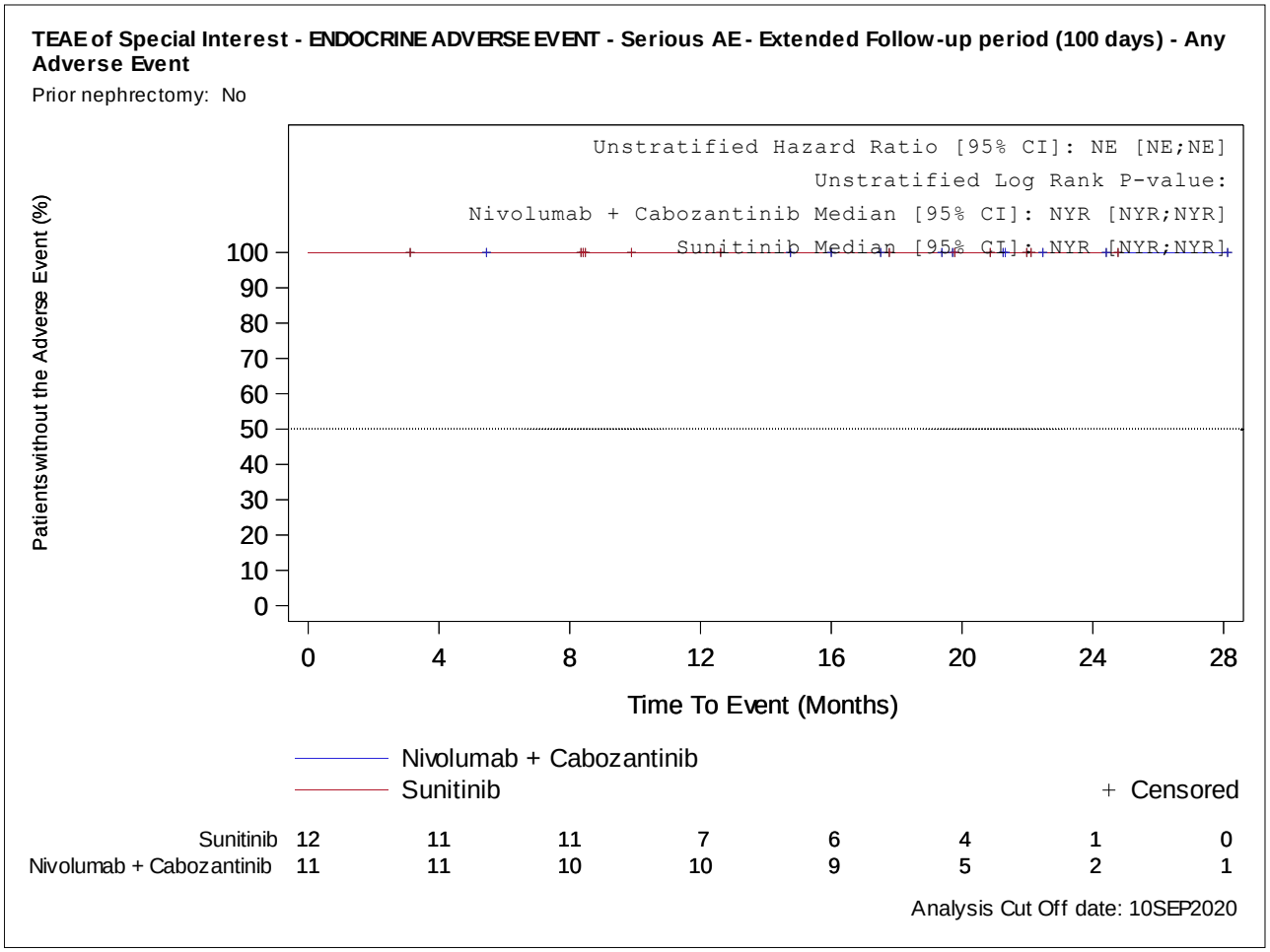

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:09:27

FIGURE 3.22.2.16: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



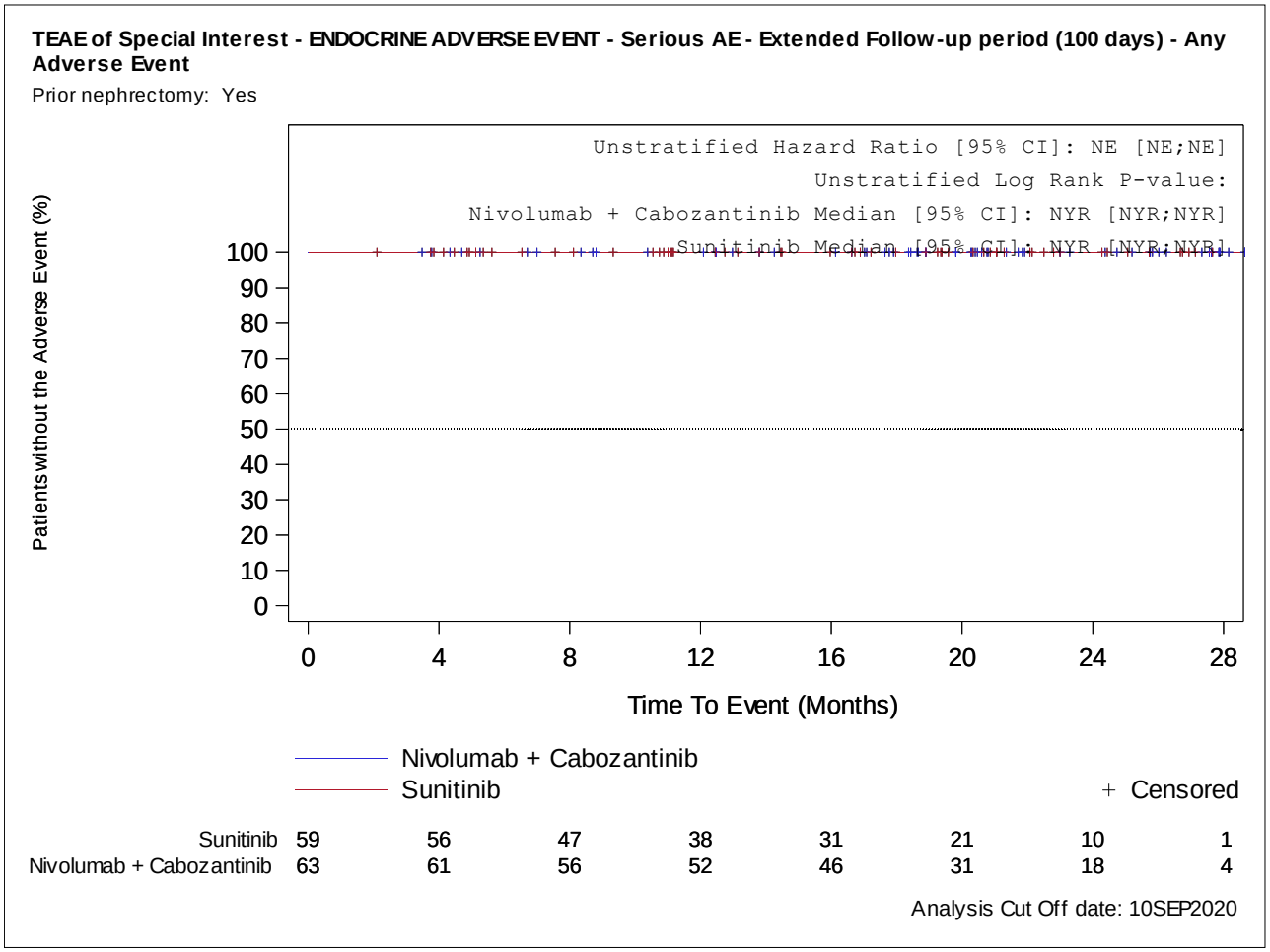

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:09:32

FIGURE 3.22.2.17: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



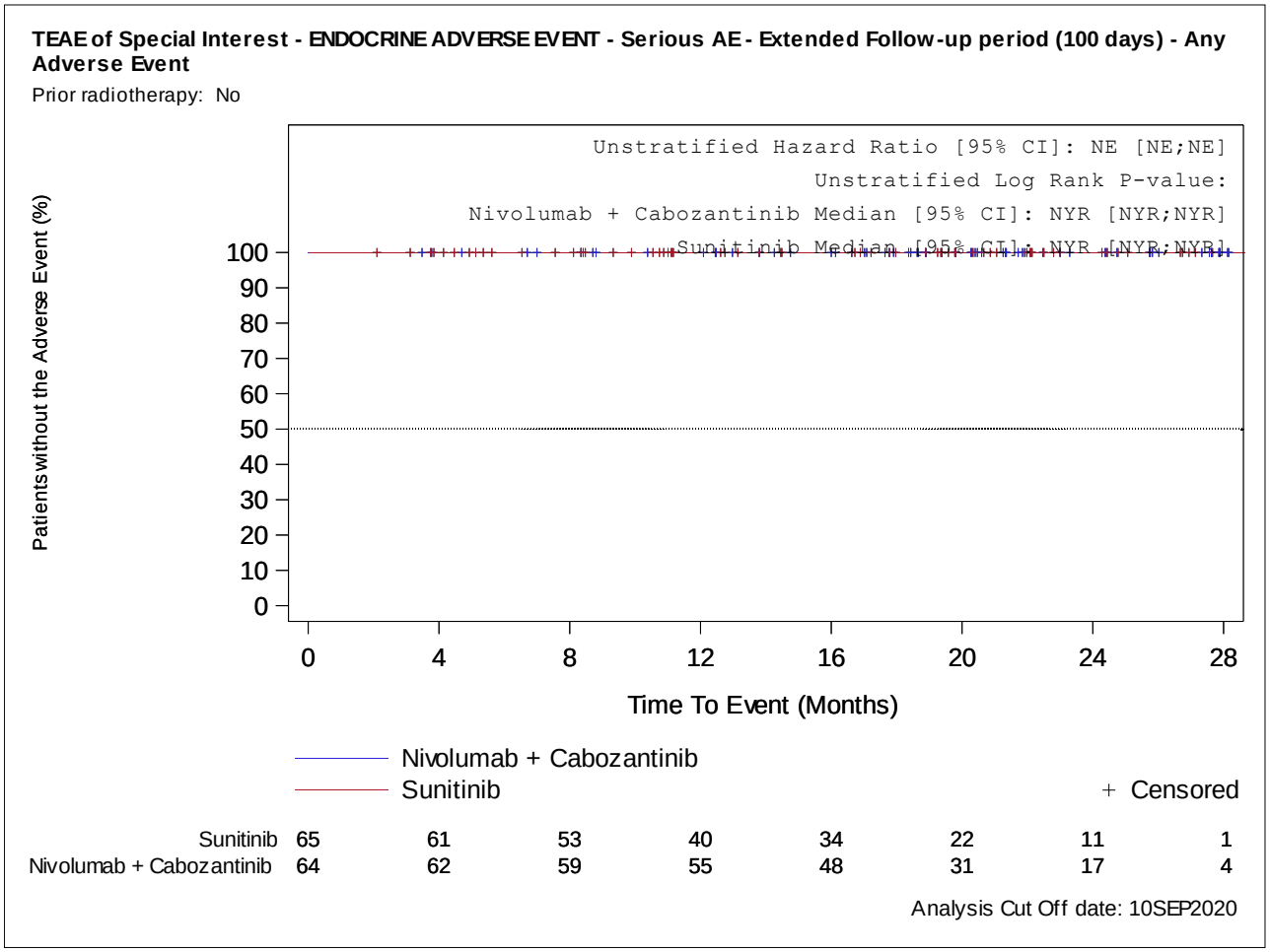

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:10:25

FIGURE 3.22.2.18: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:10:30

FIGURE 3.22.2.19: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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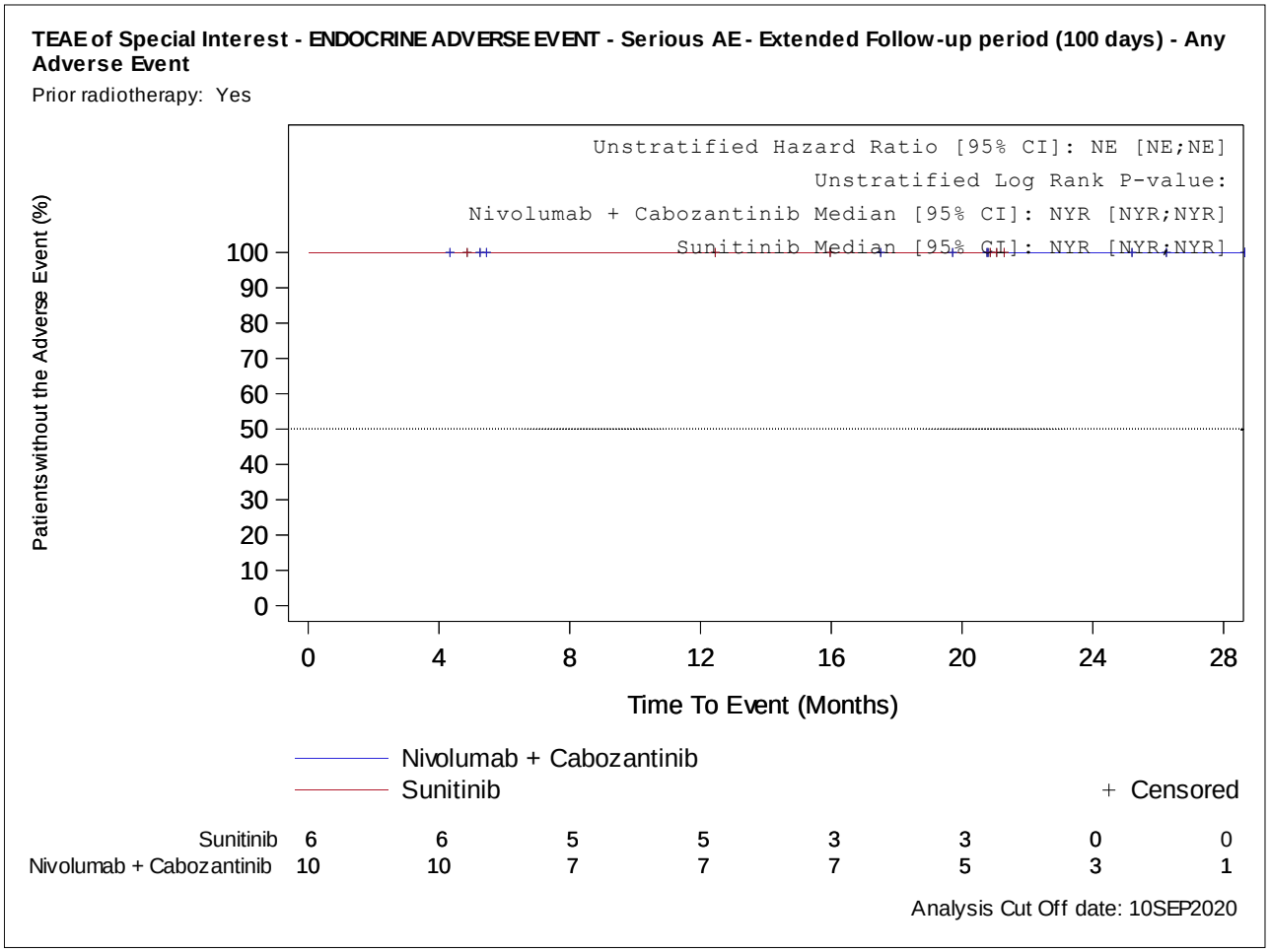
FIGURE 3.22.2.20: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy:  Yes




Analysis Cut Off date: 10SEP2020
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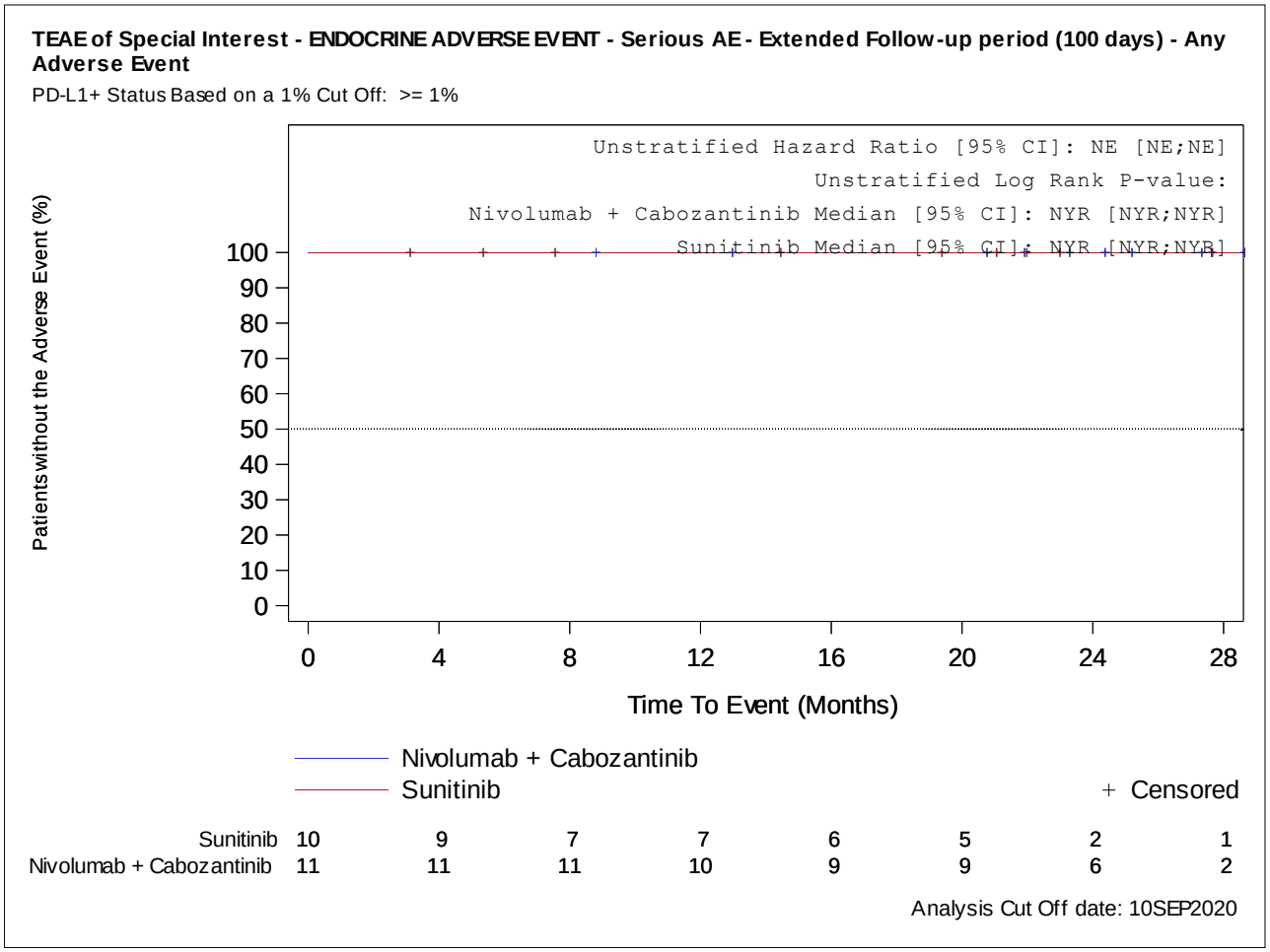
FIGURE 3.22.2.21: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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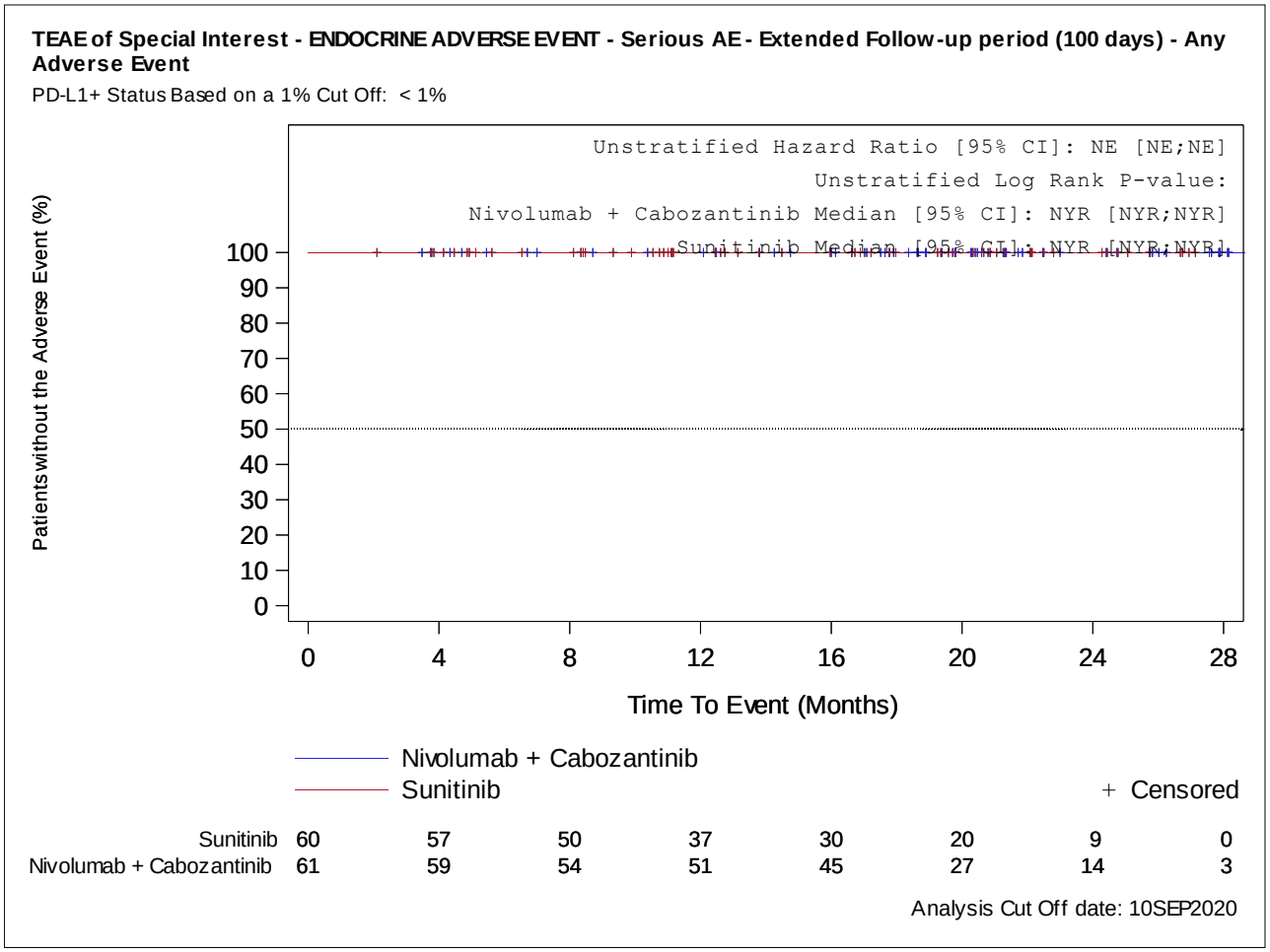
FIGURE 3.22.2.22: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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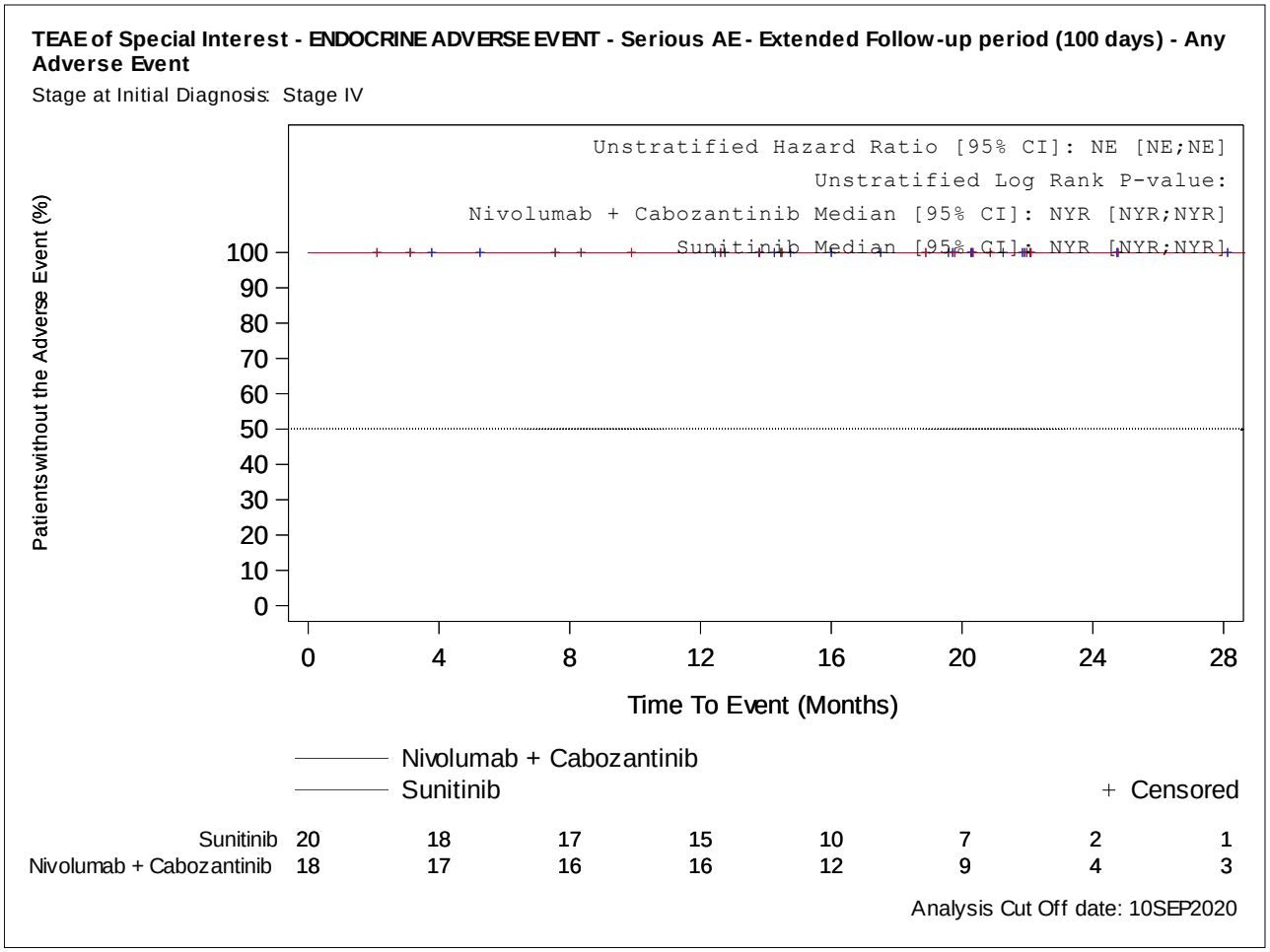
FIGURE 3.22.2.23: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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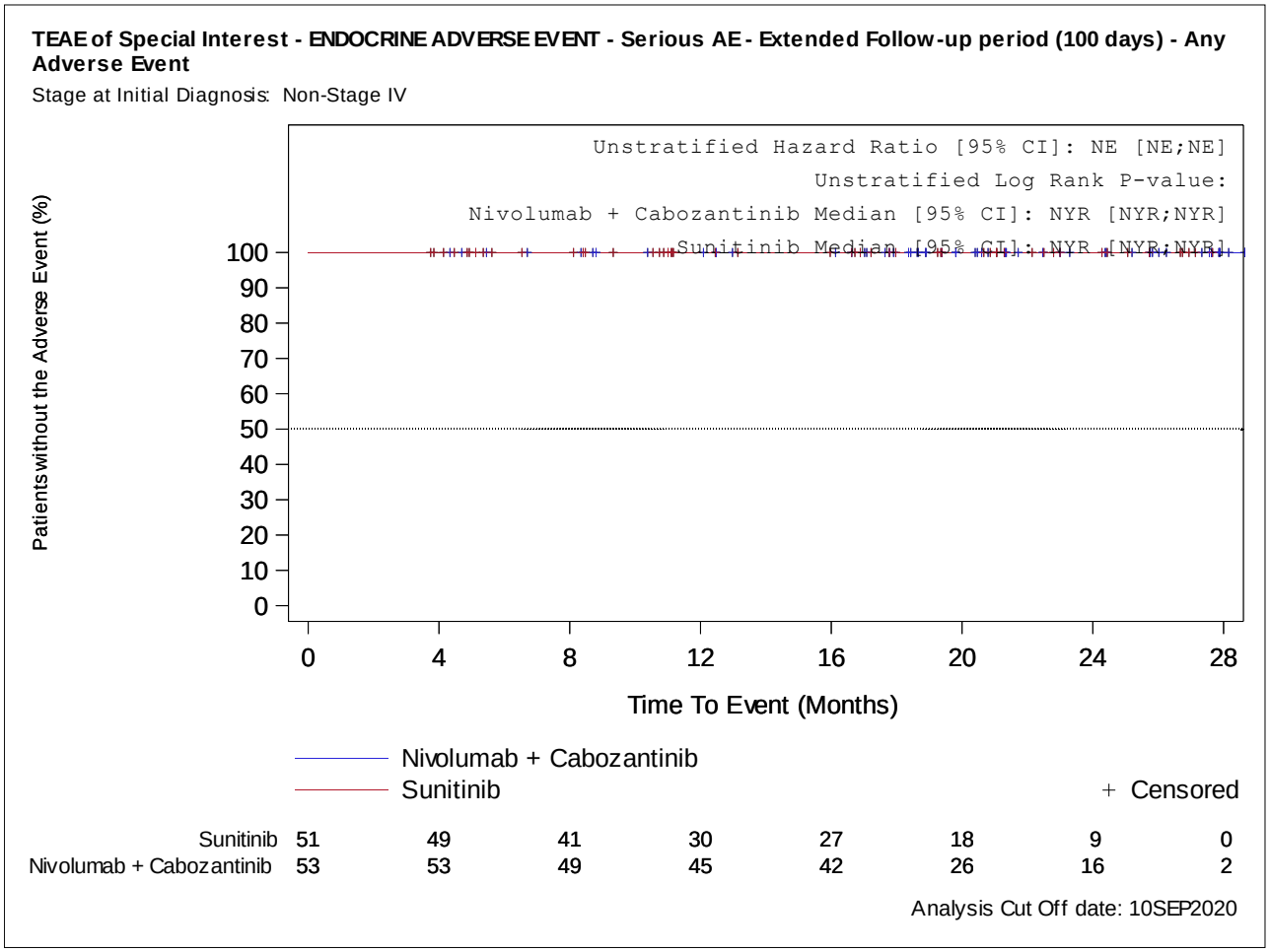
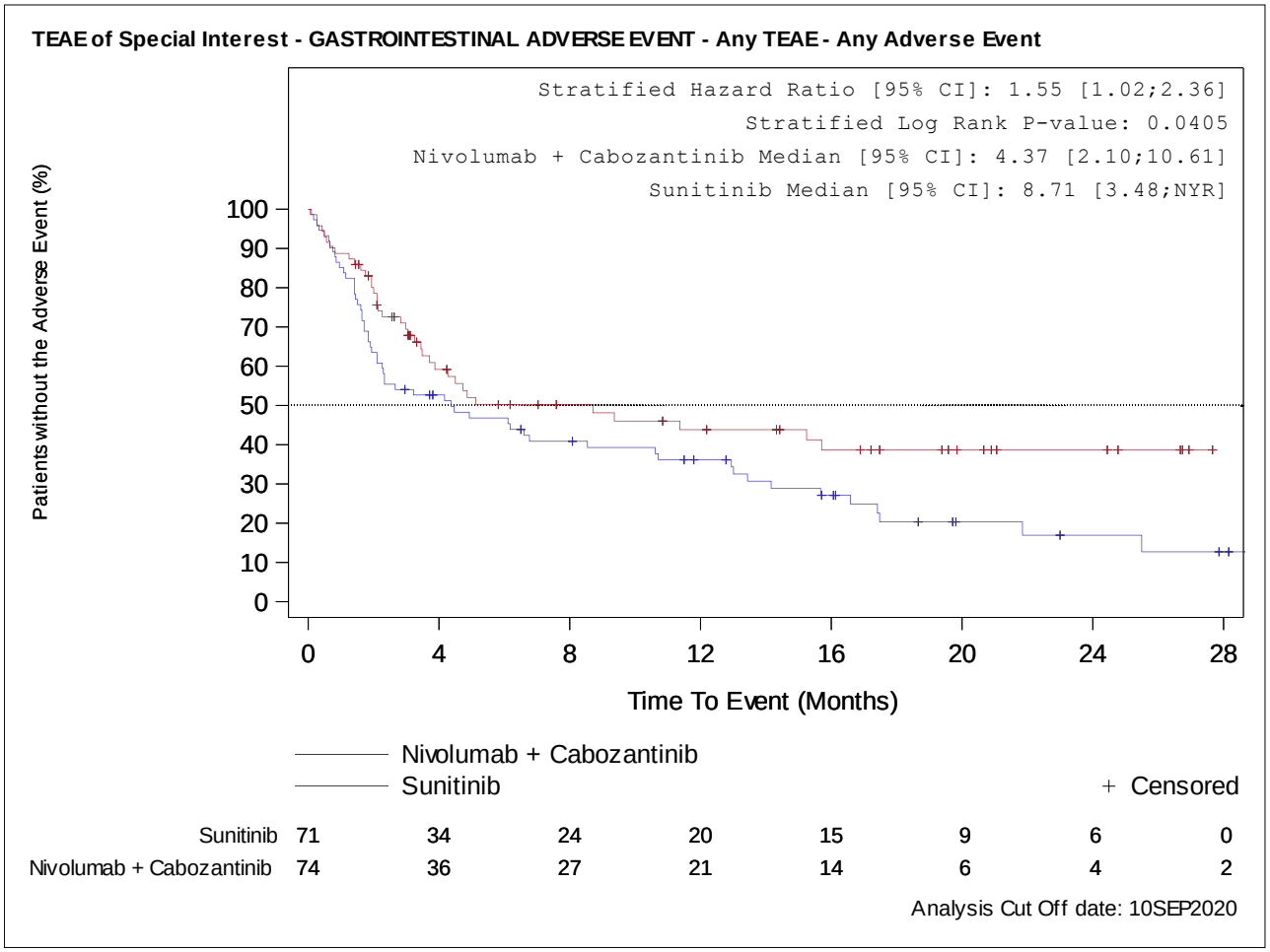
FIGURE 3.22.2.24: Kaplan-Meier curve - TEAE of Special Interest - ENDOCRINE ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



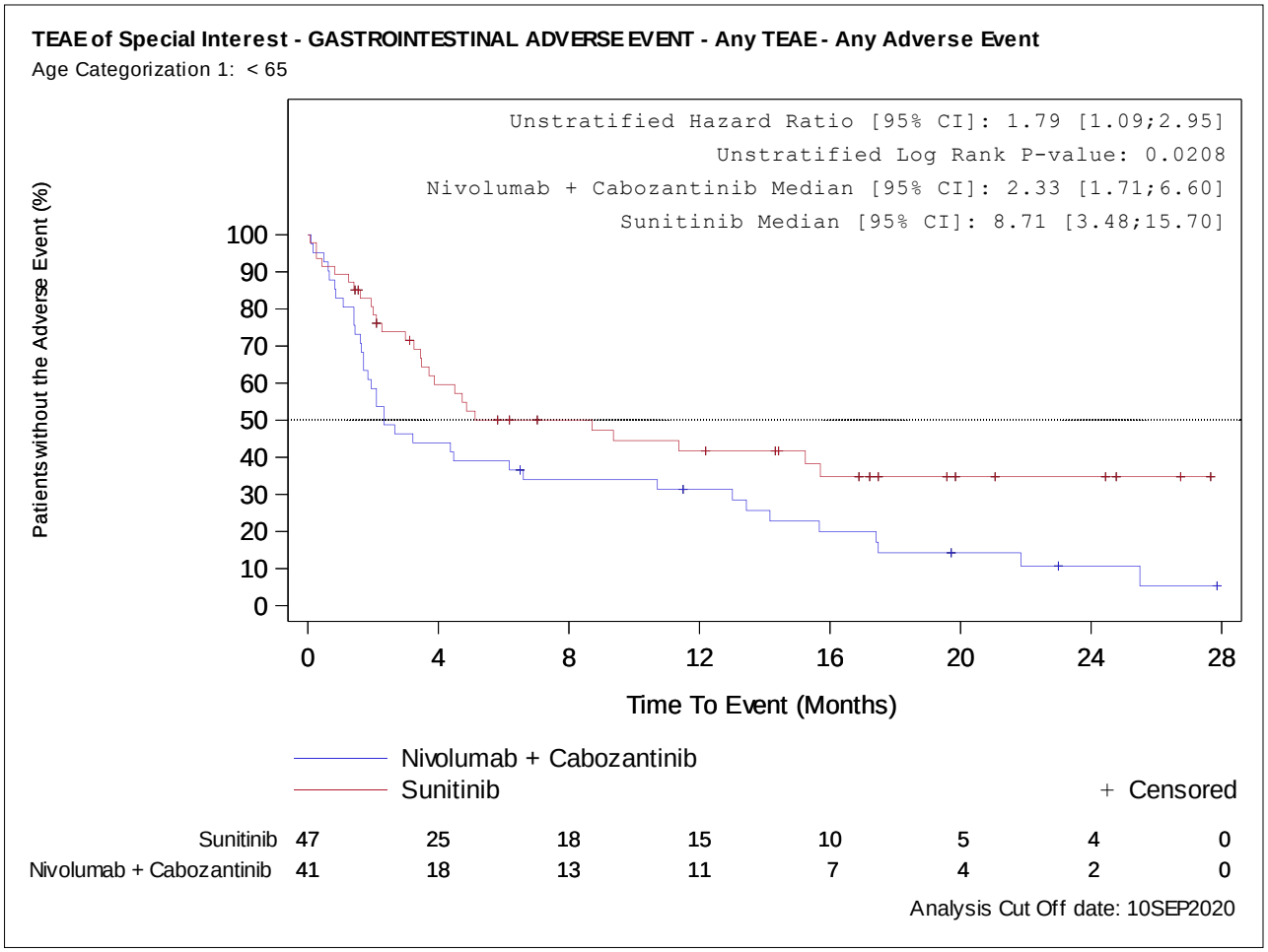

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:11:29

FIGURE 3.23.1: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:14:43

FIGURE 3.23.2.1: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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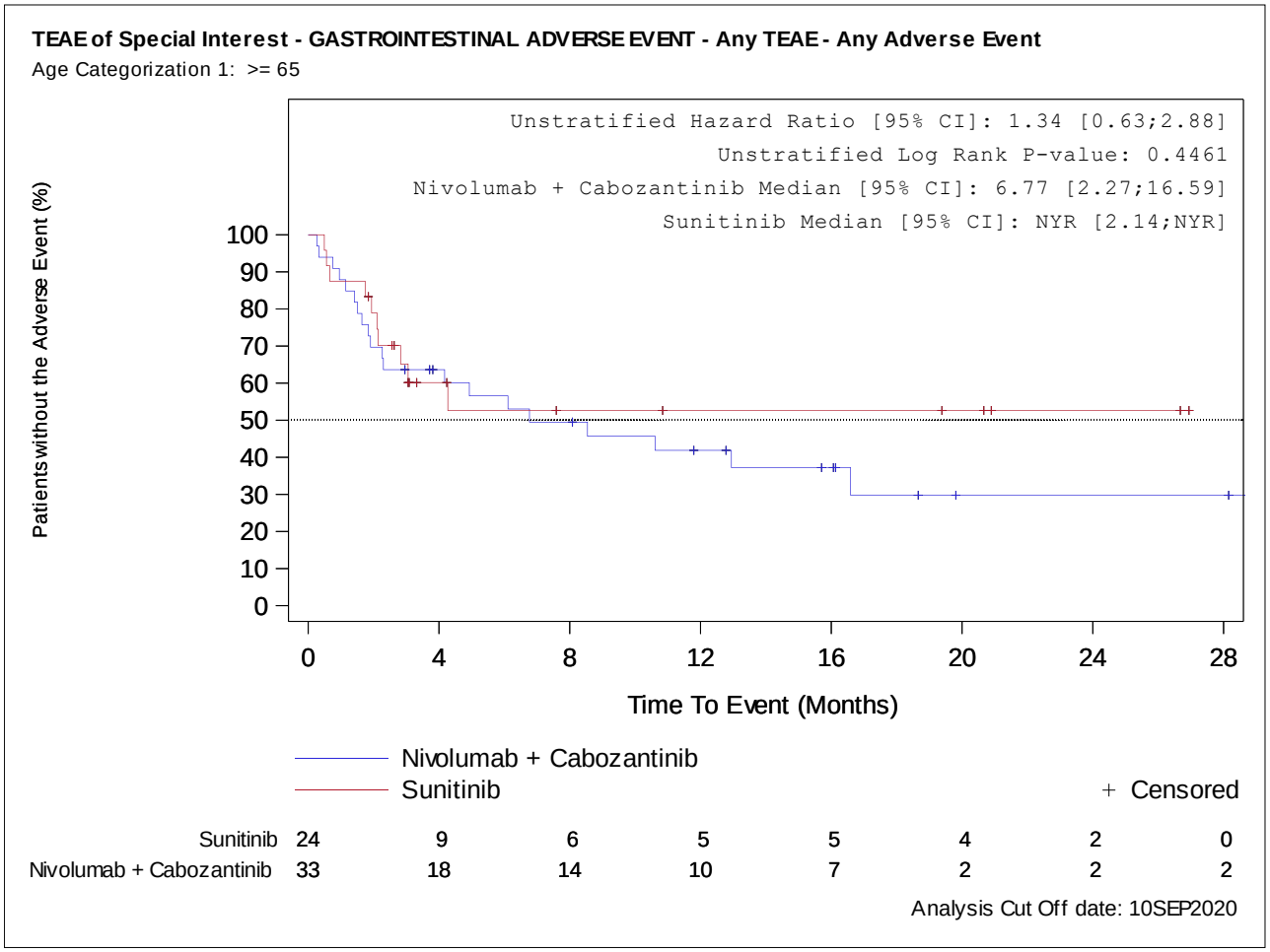
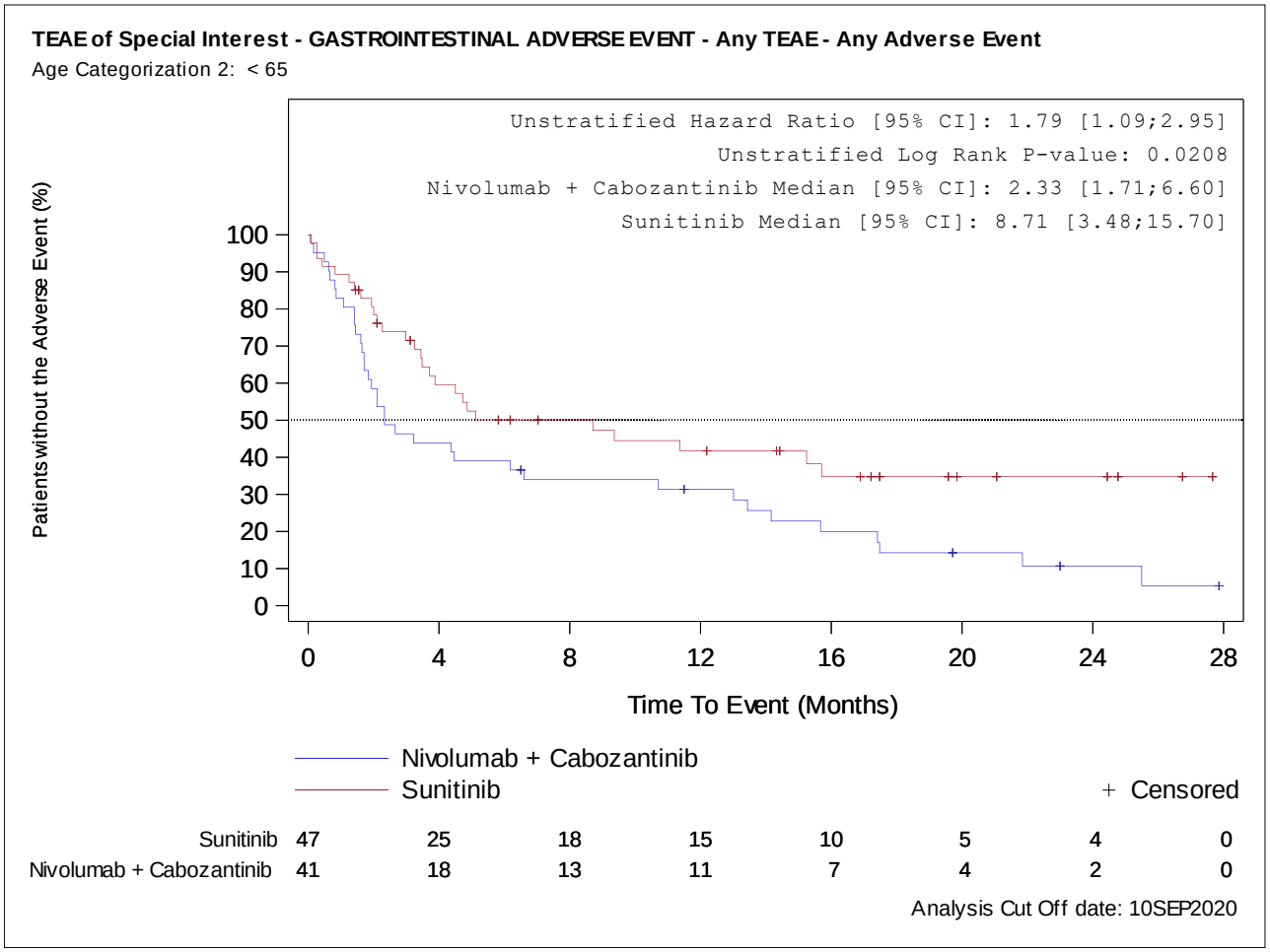
FIGURE 3.23.2.2: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



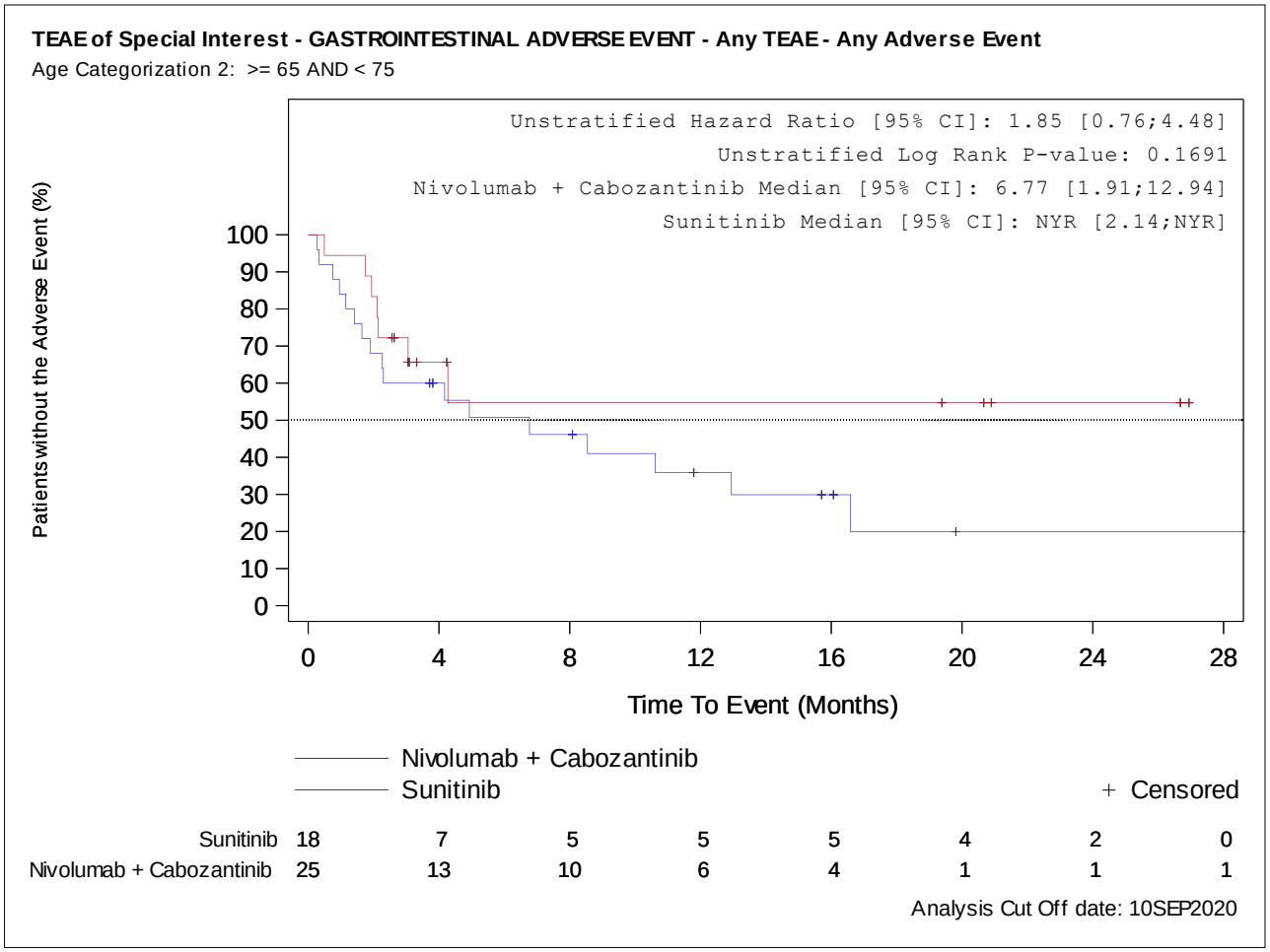

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:14:52

FIGURE 3.23.2.3: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



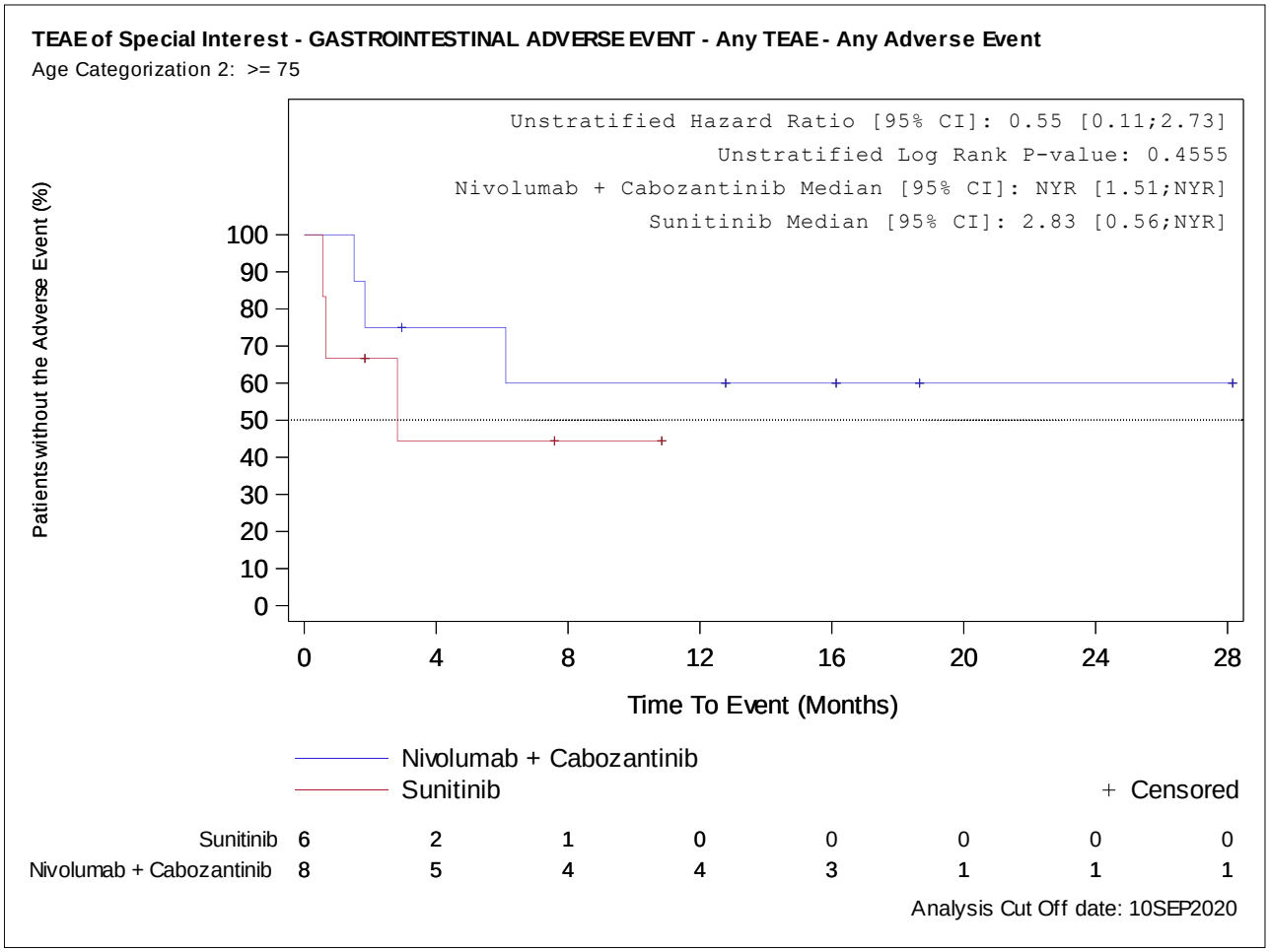

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:14:58

FIGURE 3.23.2.4: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



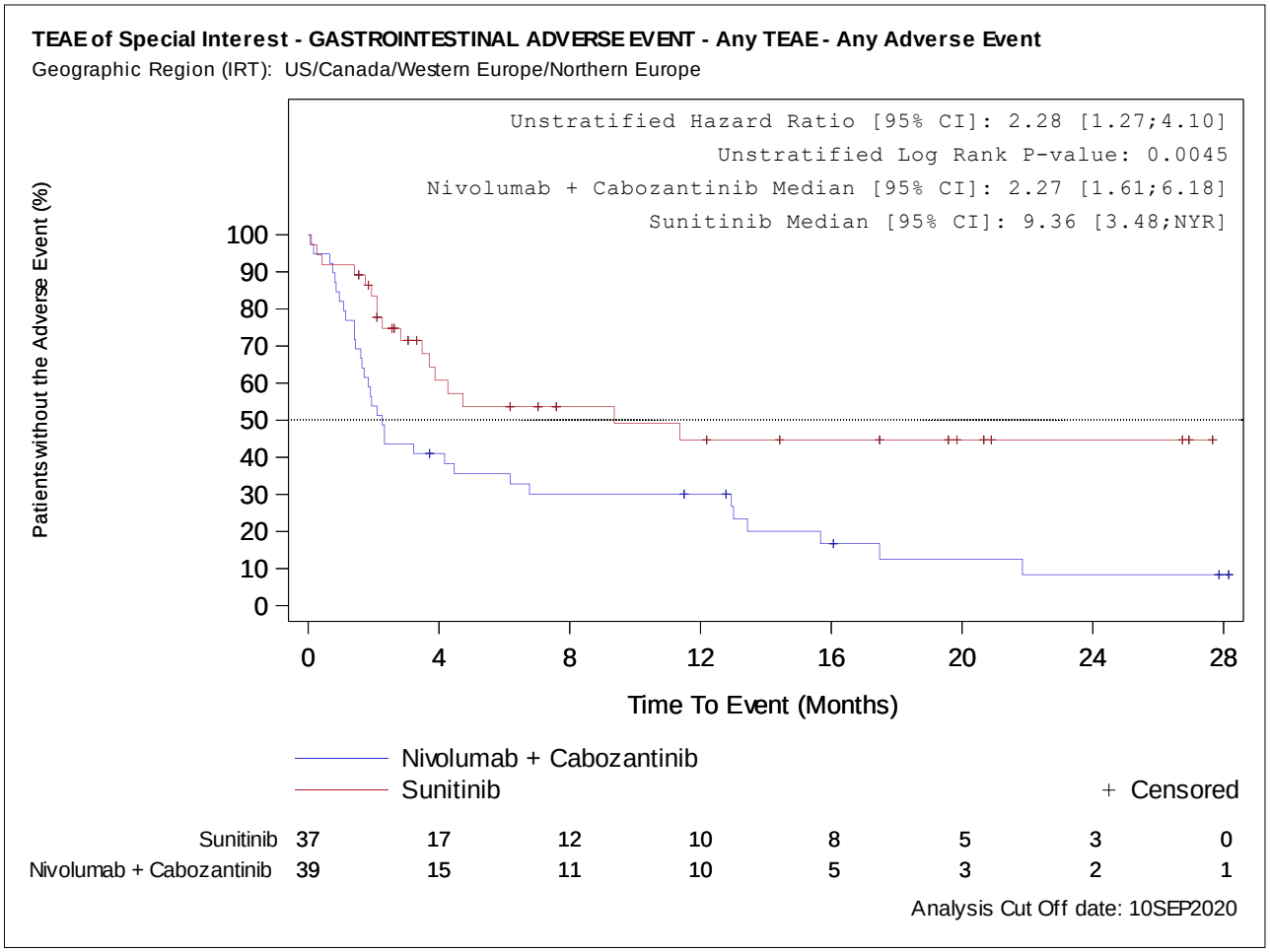

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:15:04

FIGURE 3.23.2.5: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



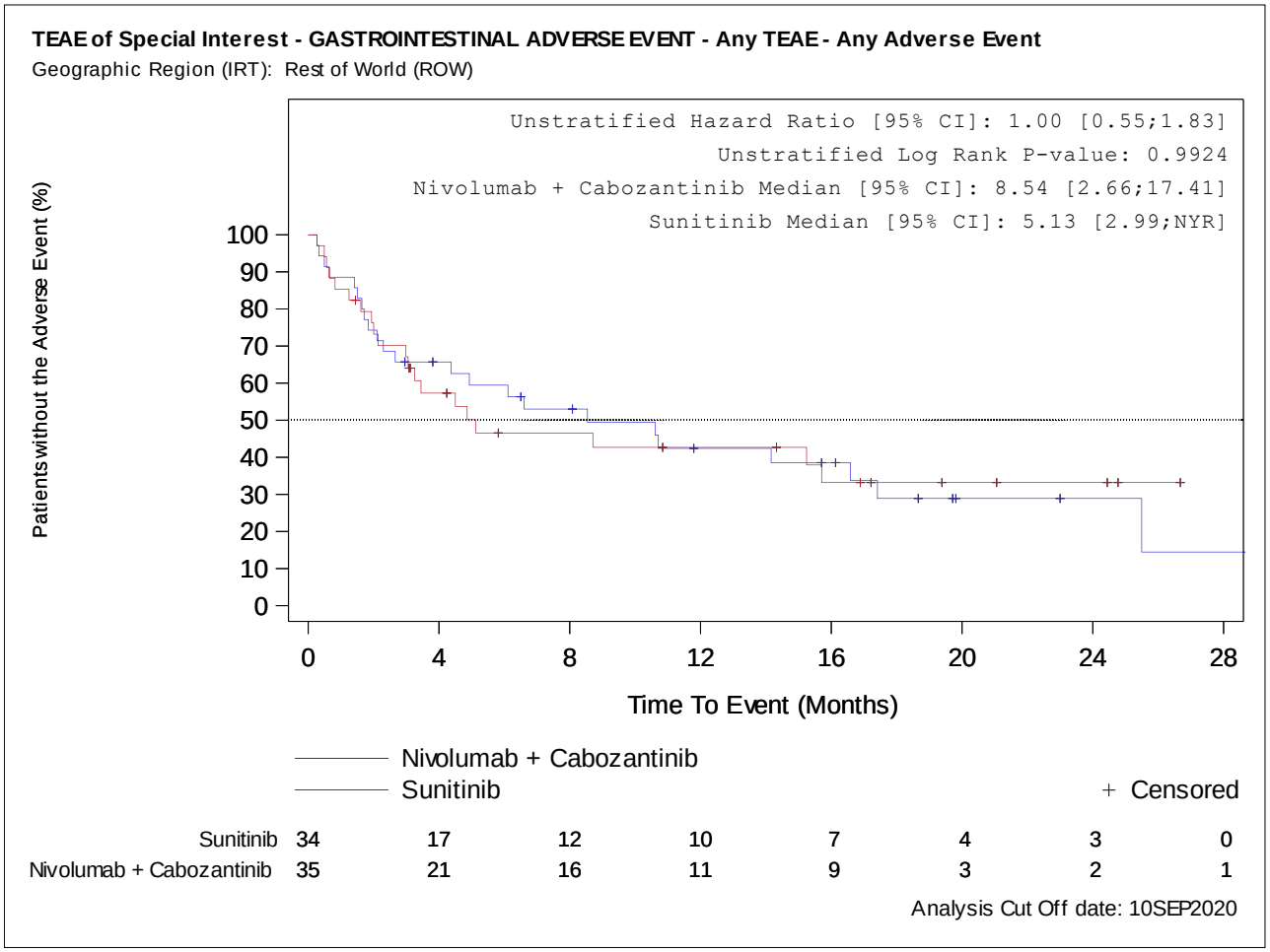

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:15:10

FIGURE 3.23.2.6: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



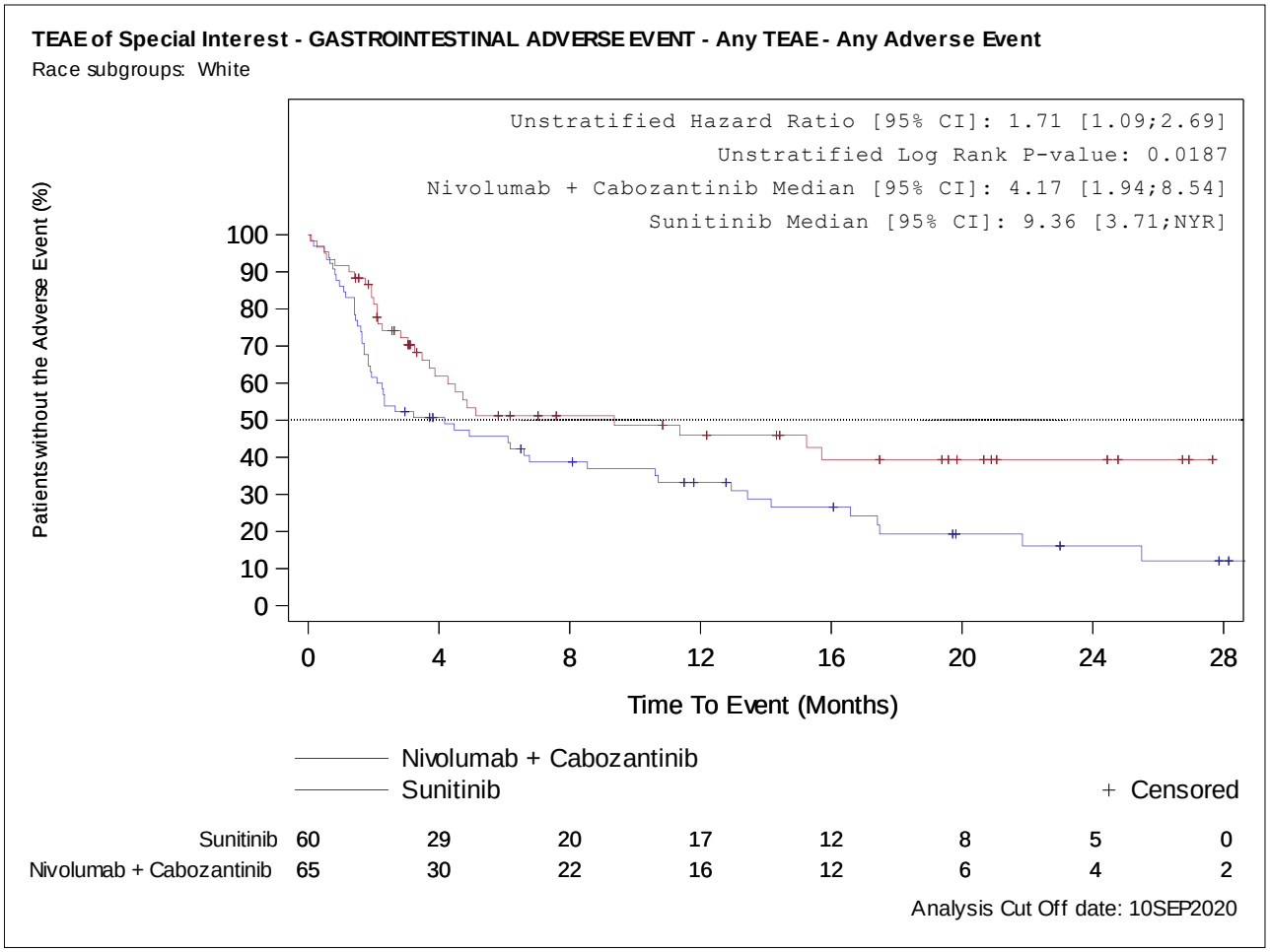

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:15:15

FIGURE 3.23.2.7: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



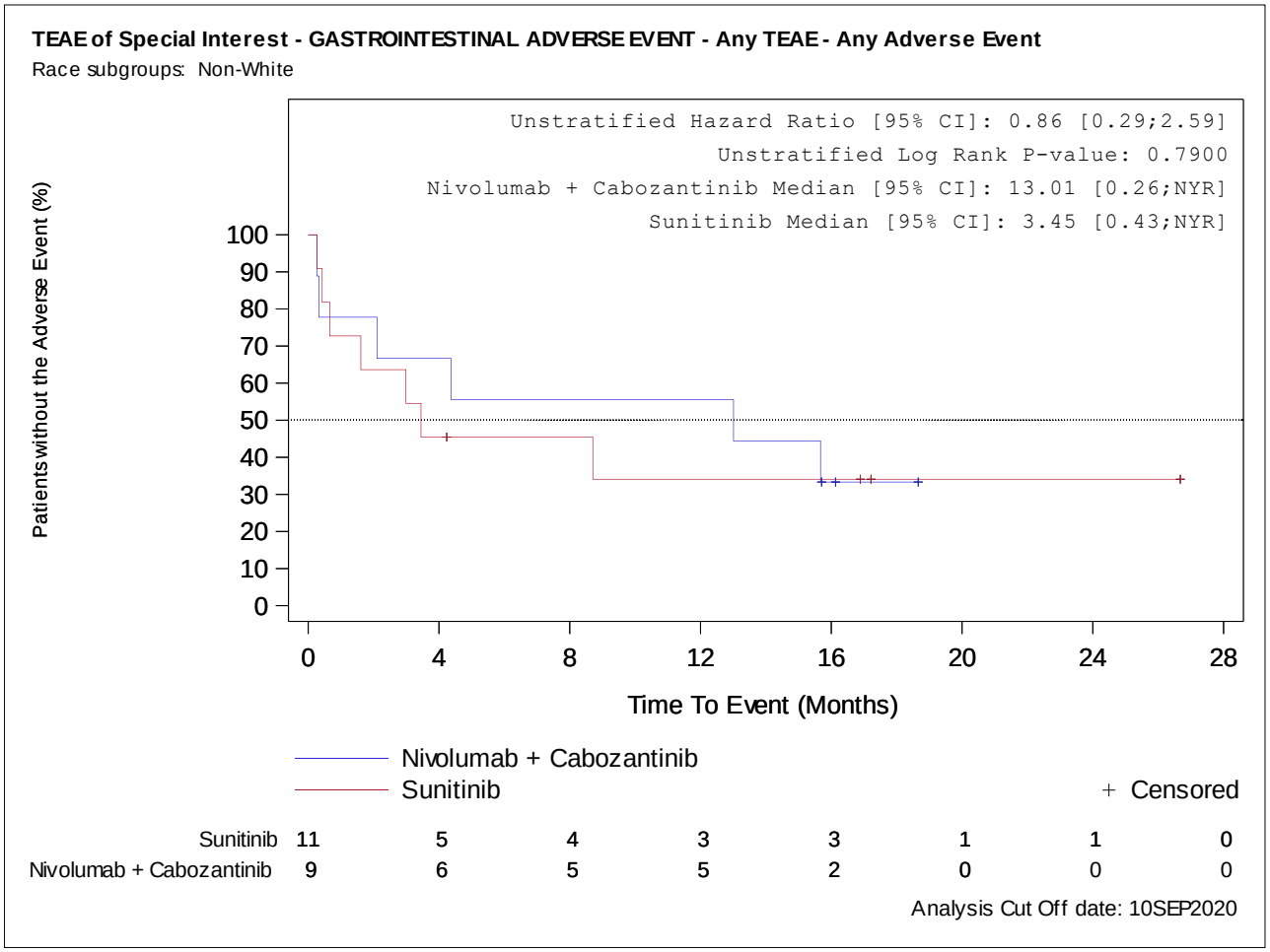

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:15:21

FIGURE 3.23.2.8: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



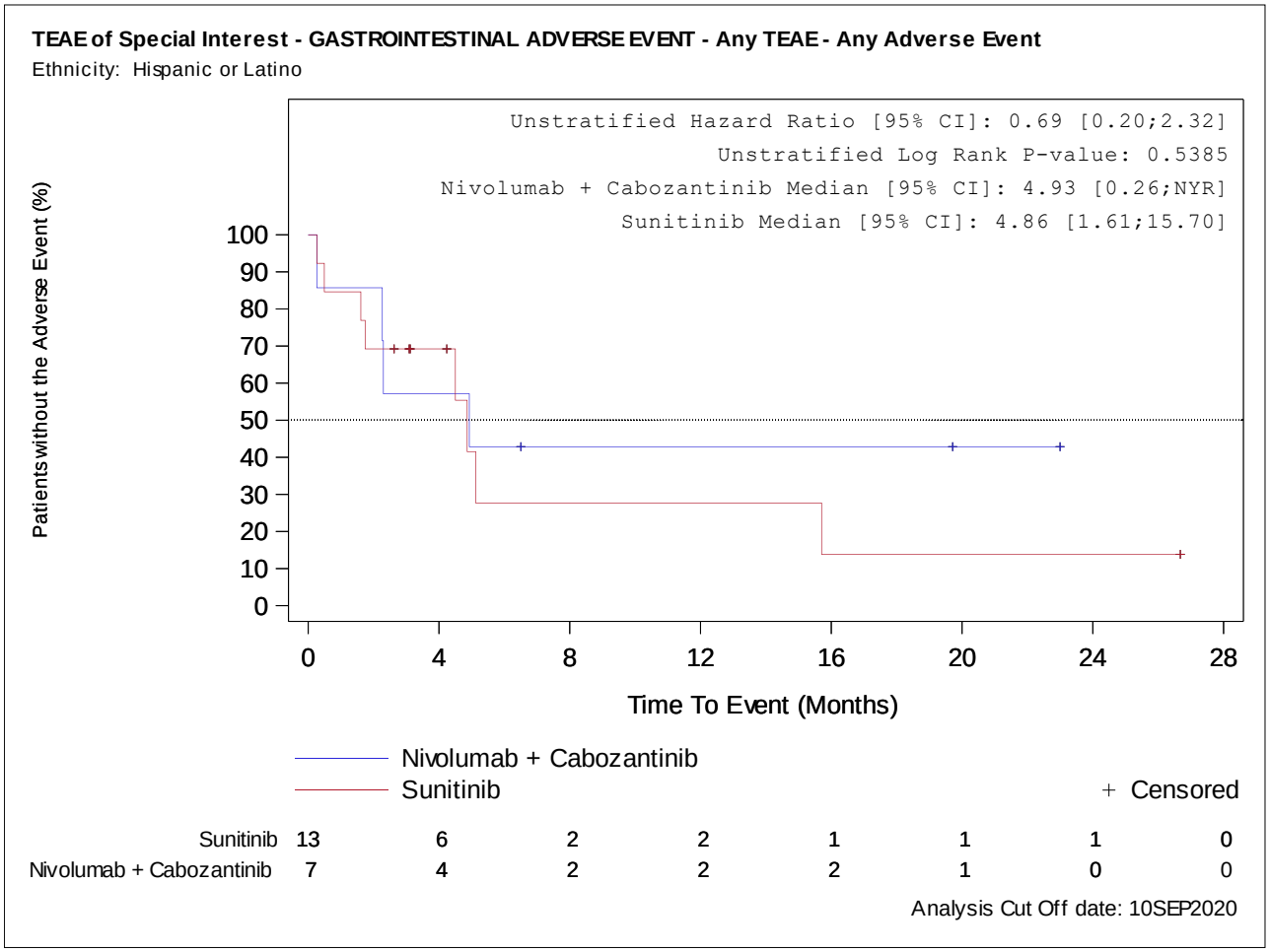

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:15:26

FIGURE 3.23.2.9: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



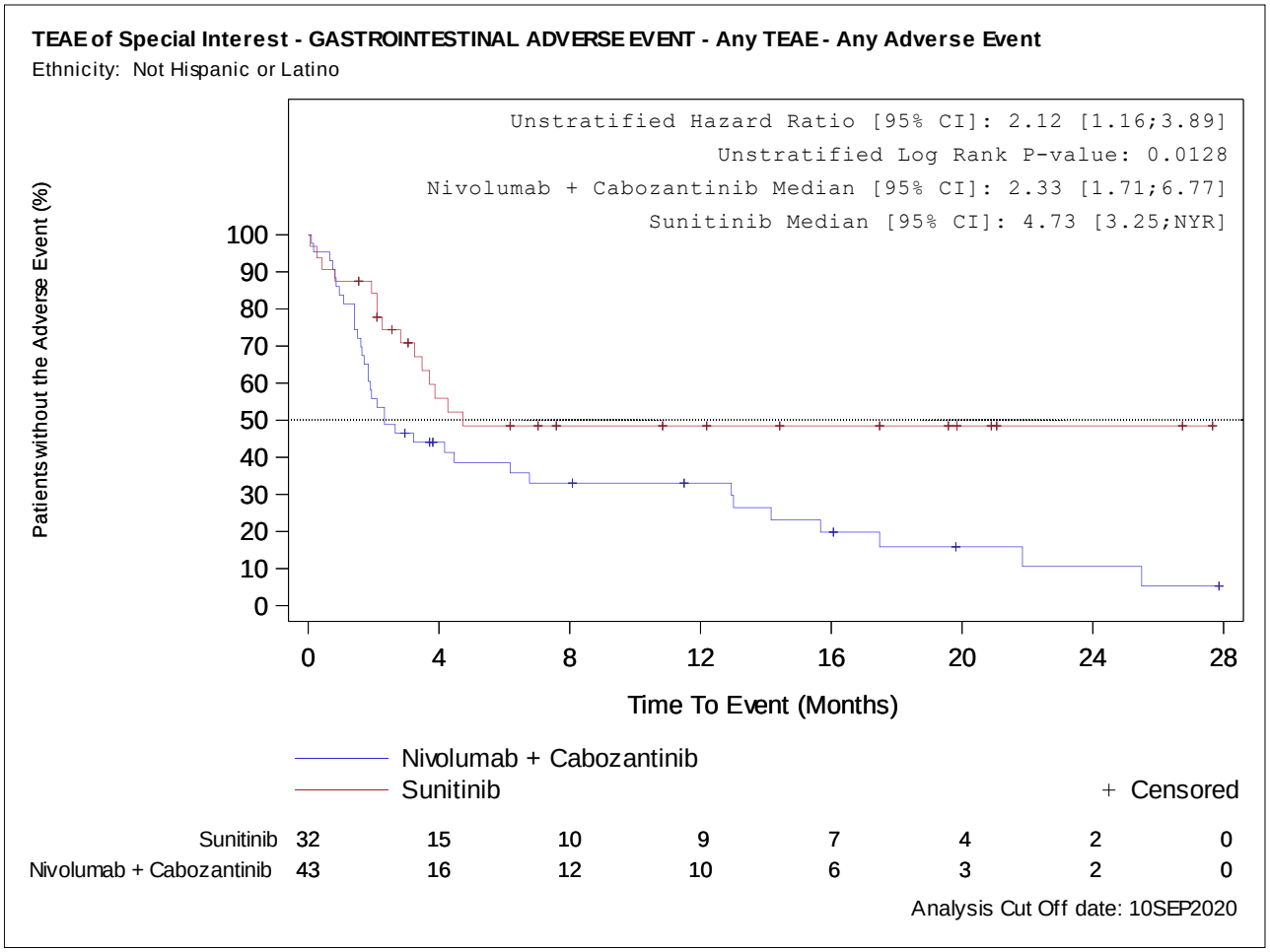

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:15:33

FIGURE 3.23.2.10: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



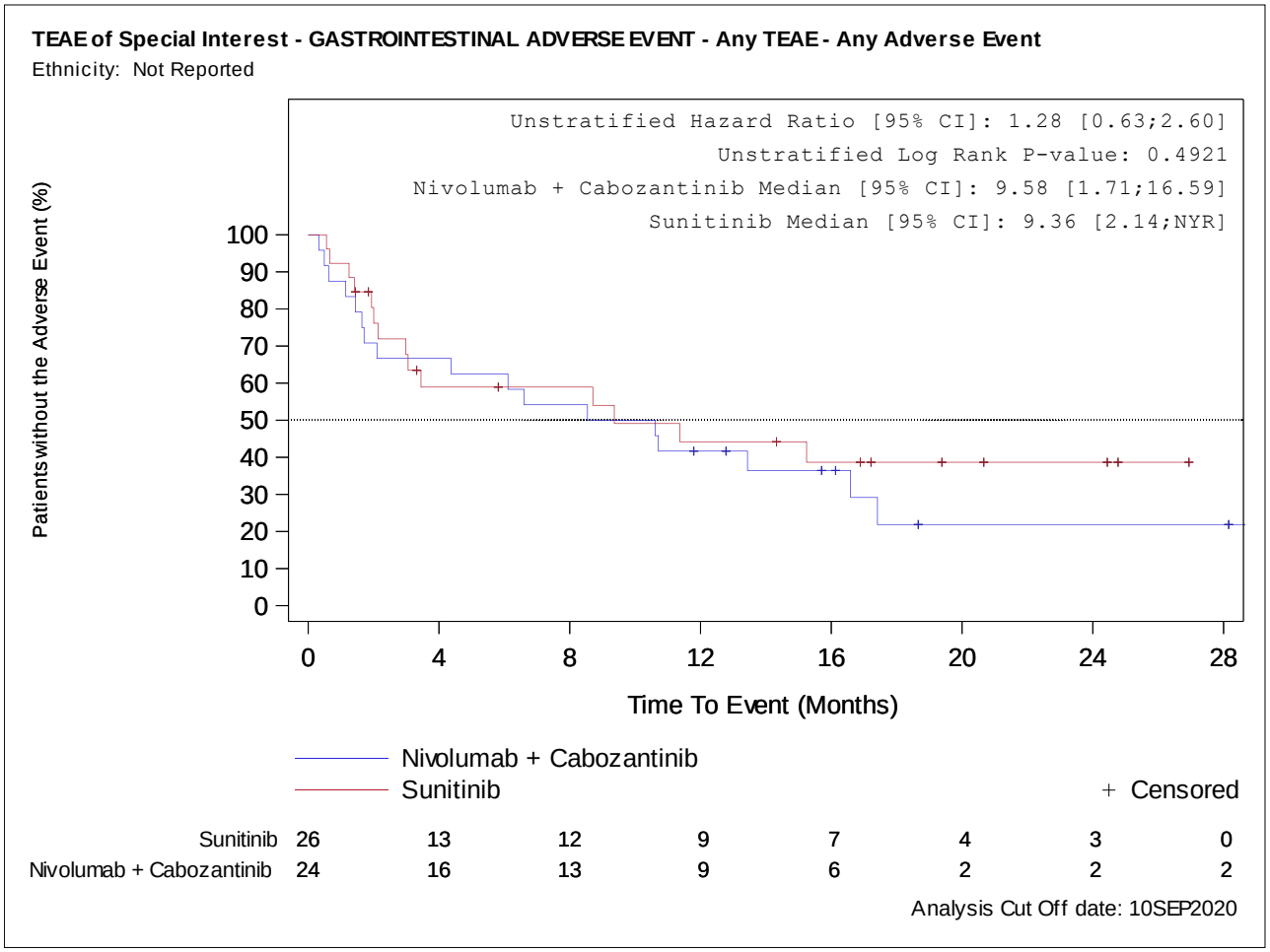

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:15:39

FIGURE 3.23.2.11: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



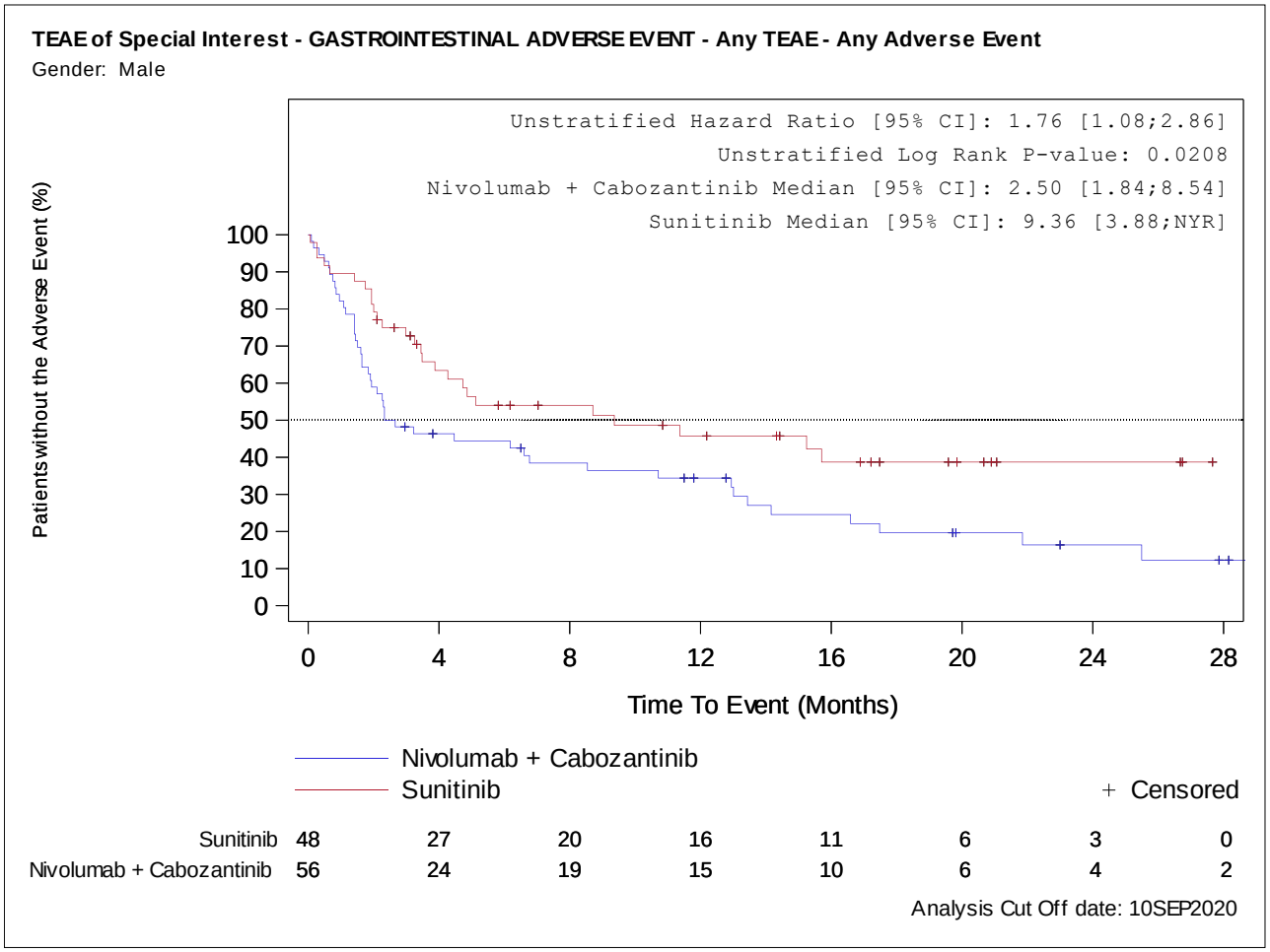

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:15:45

FIGURE 3.23.2.12: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



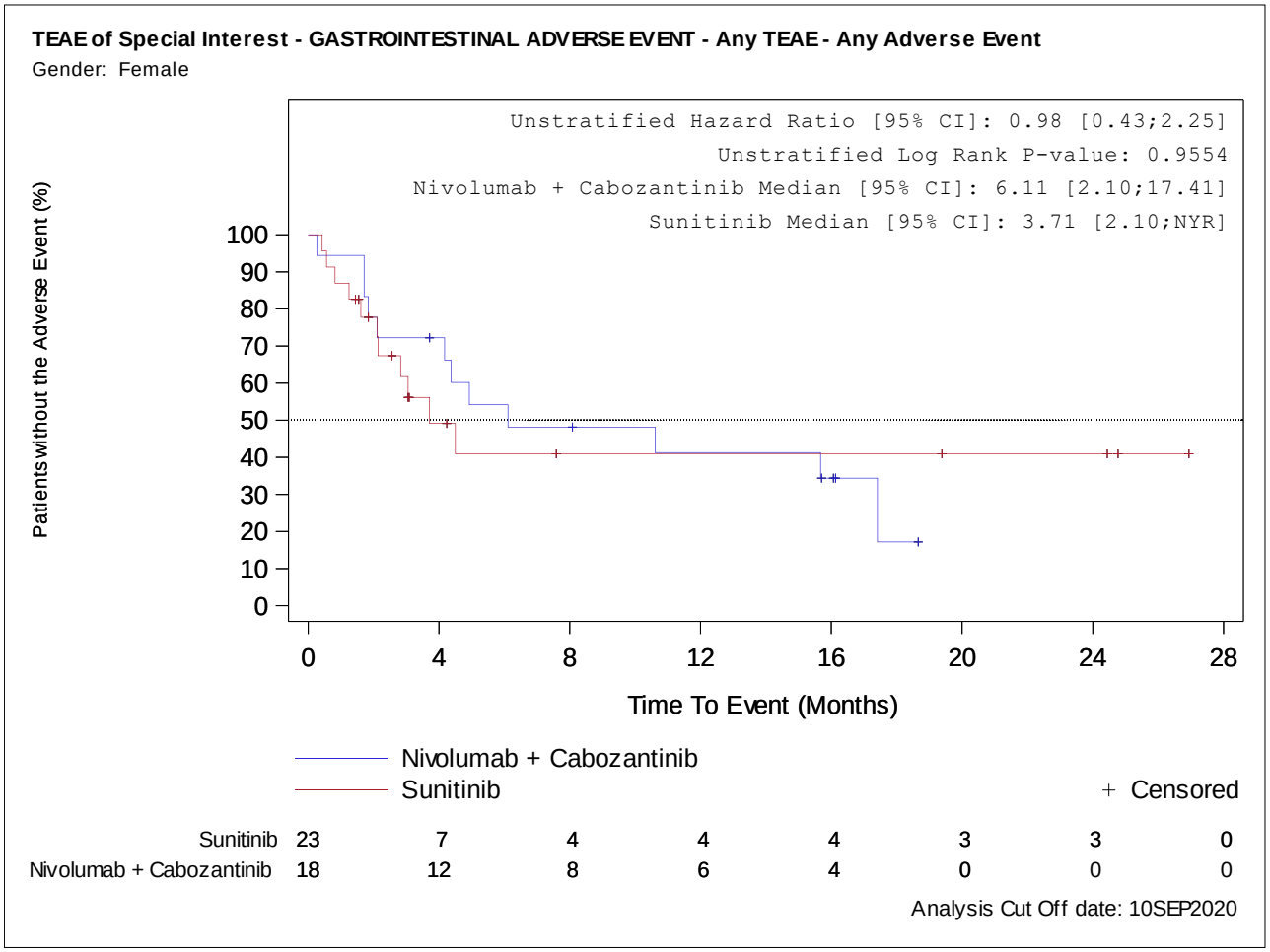

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:15:51

FIGURE 3.23.2.13: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



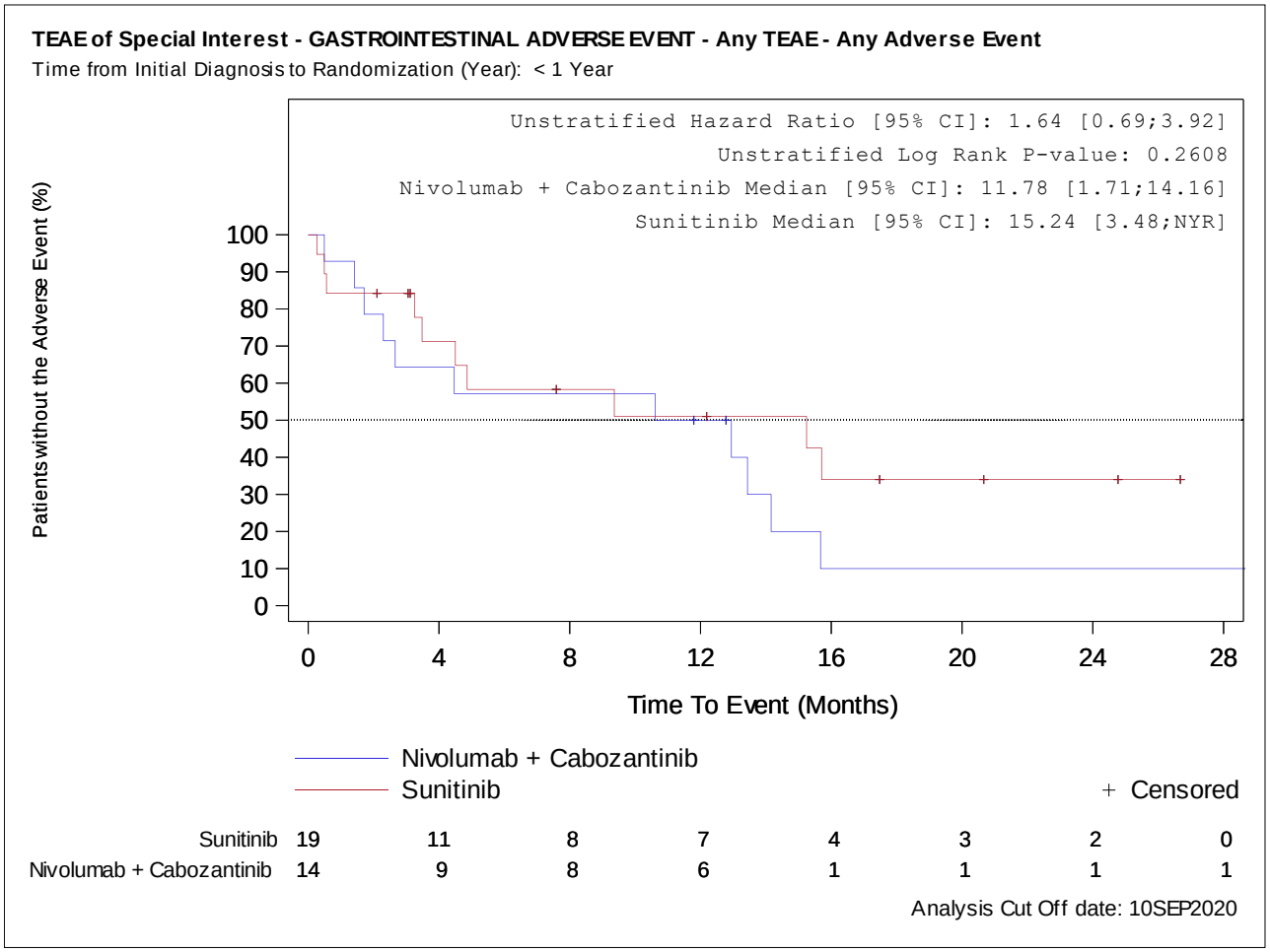

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:15:57

FIGURE 3.23.2.14: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



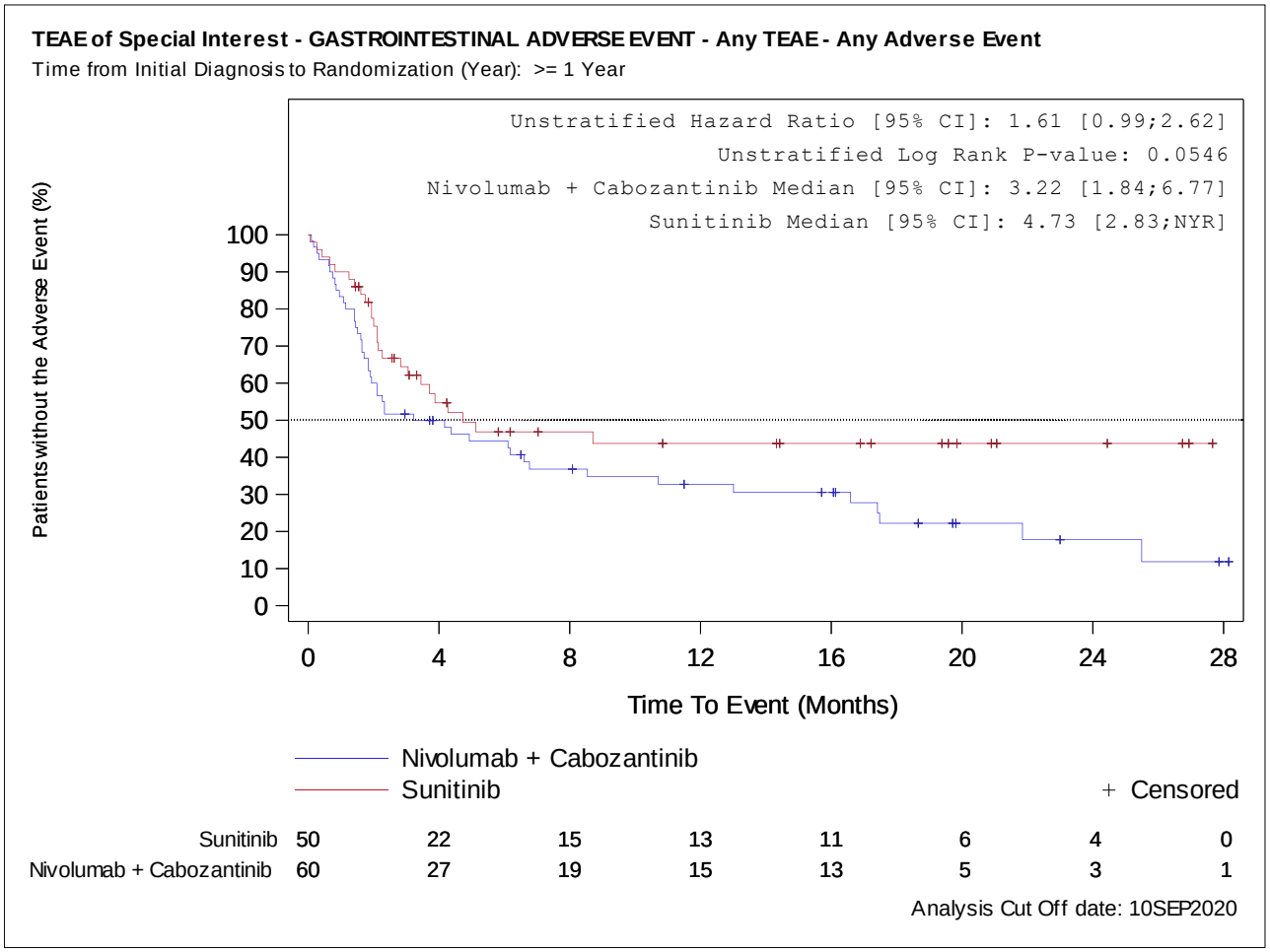

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:16:03

FIGURE 3.23.2.15: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



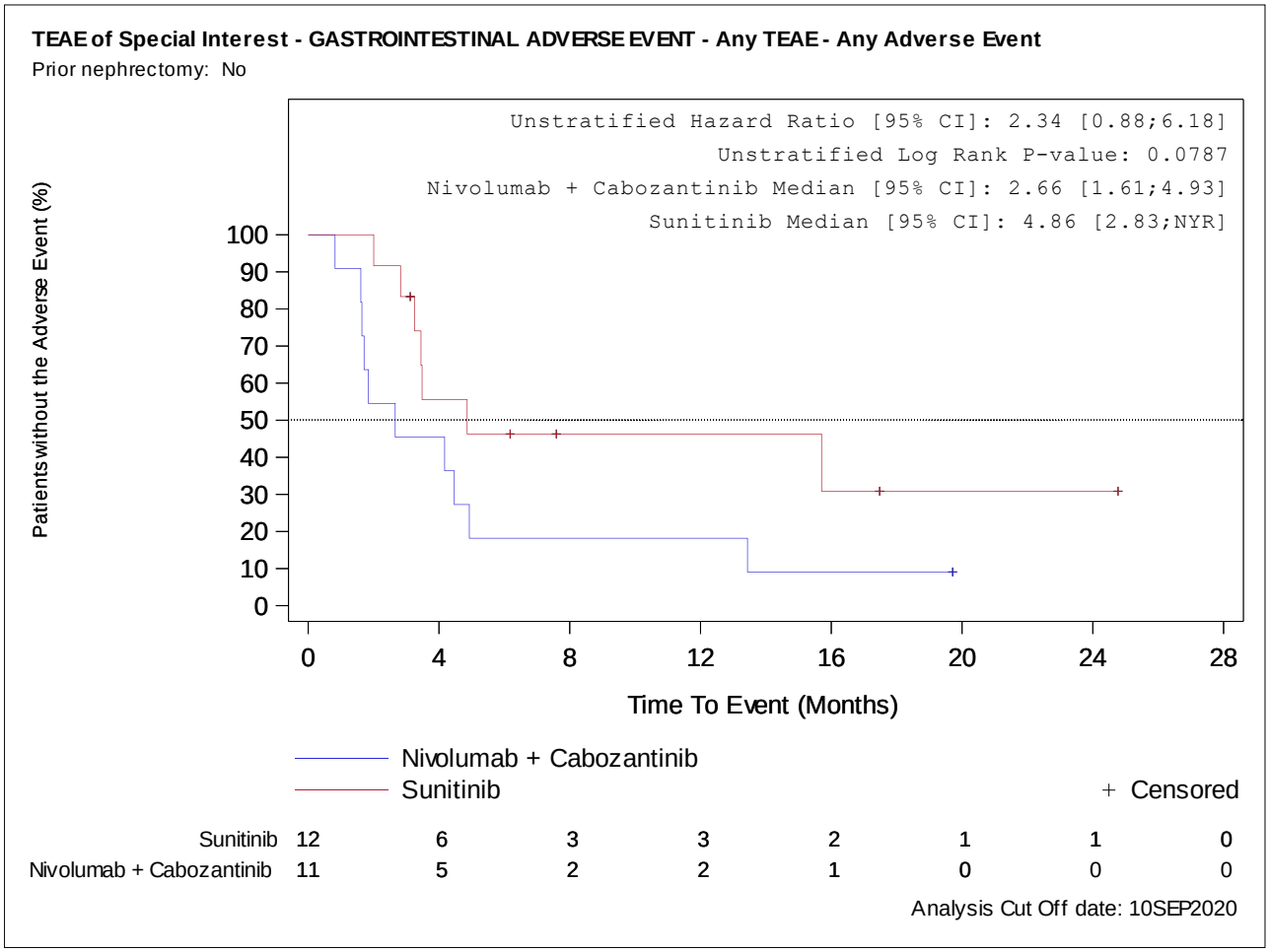

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:16:19

FIGURE 3.23.2.16: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



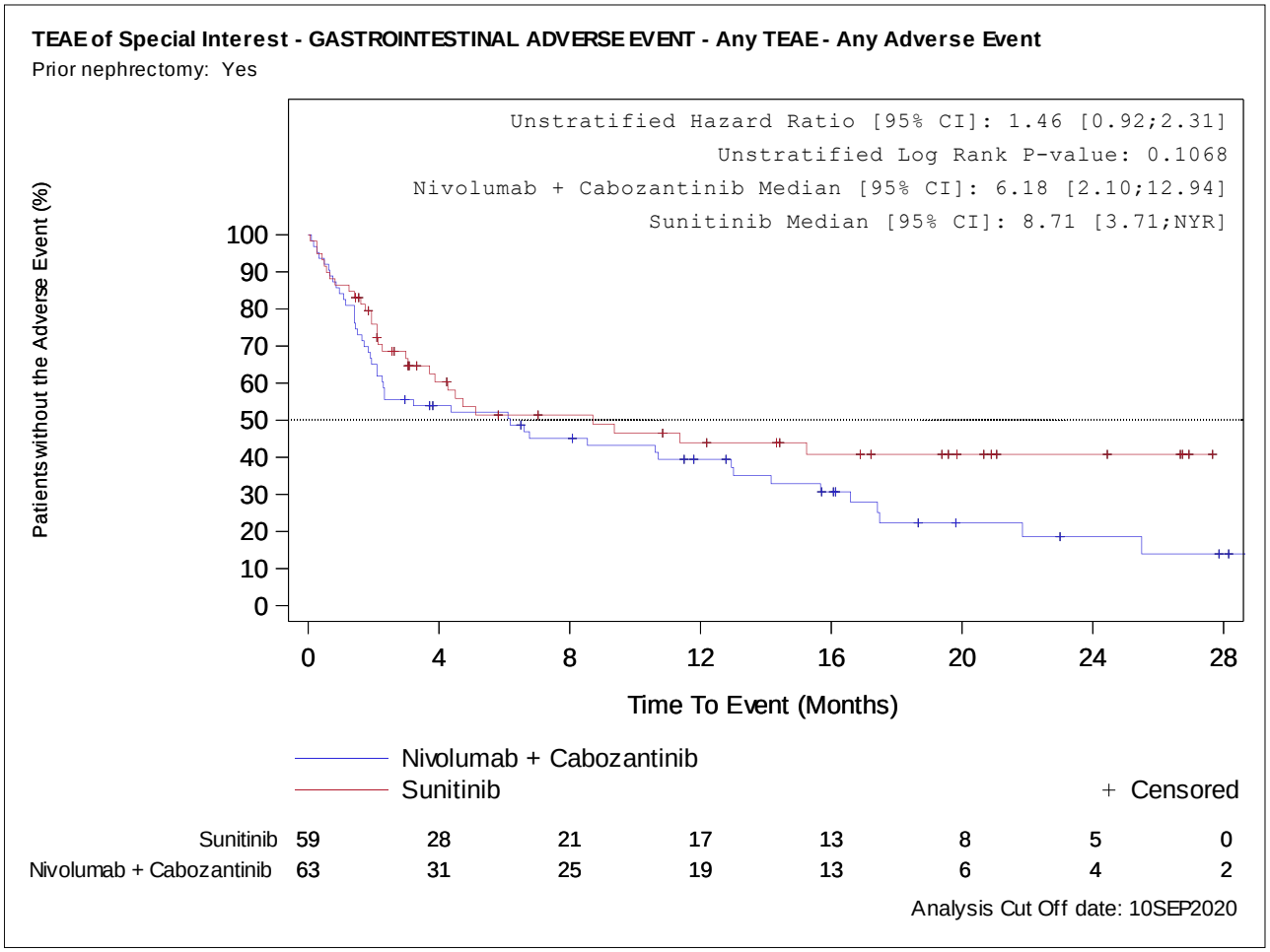

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:16:25

FIGURE 3.23.2.17: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



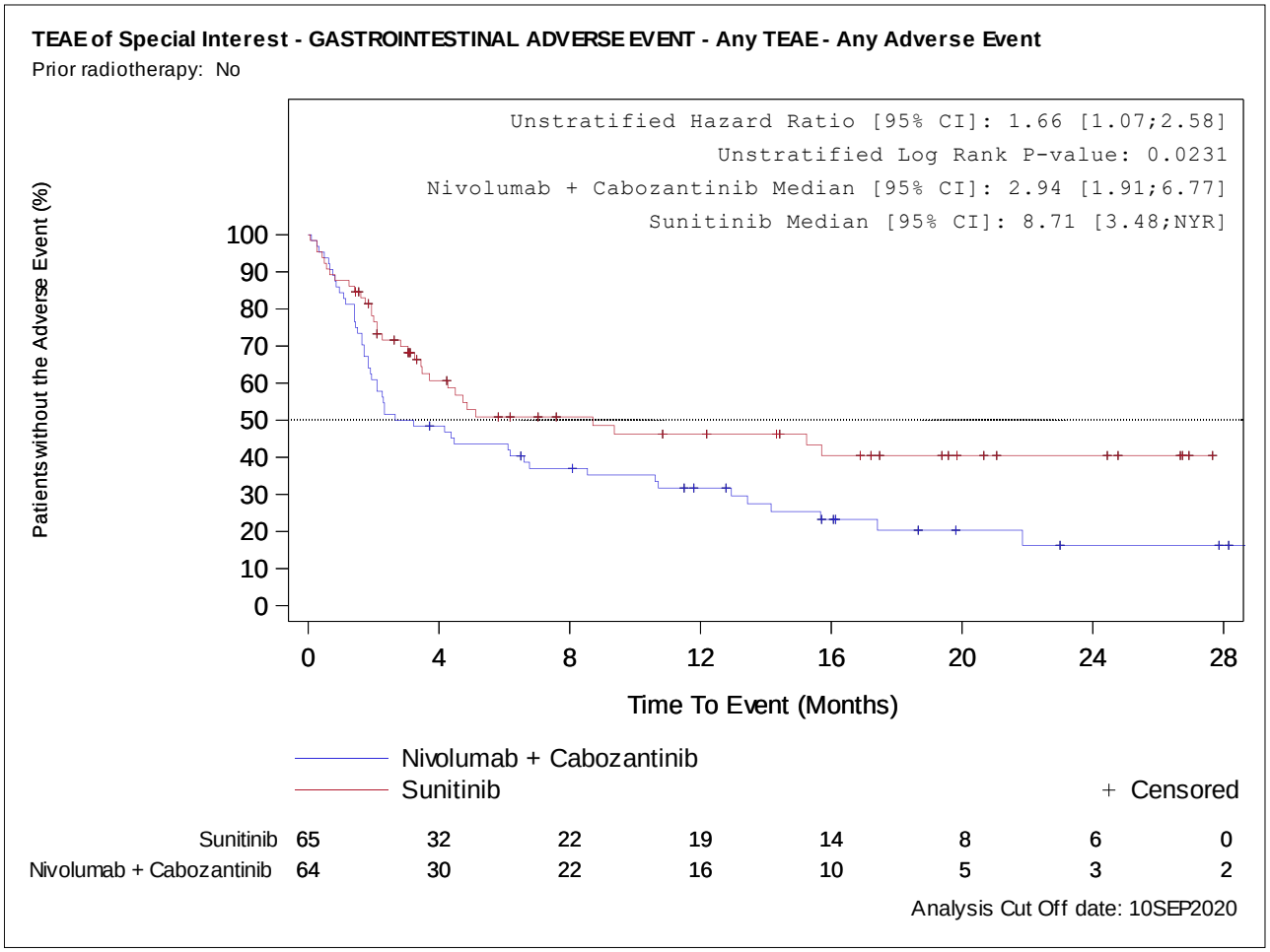

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:19

FIGURE 3.23.2.18: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



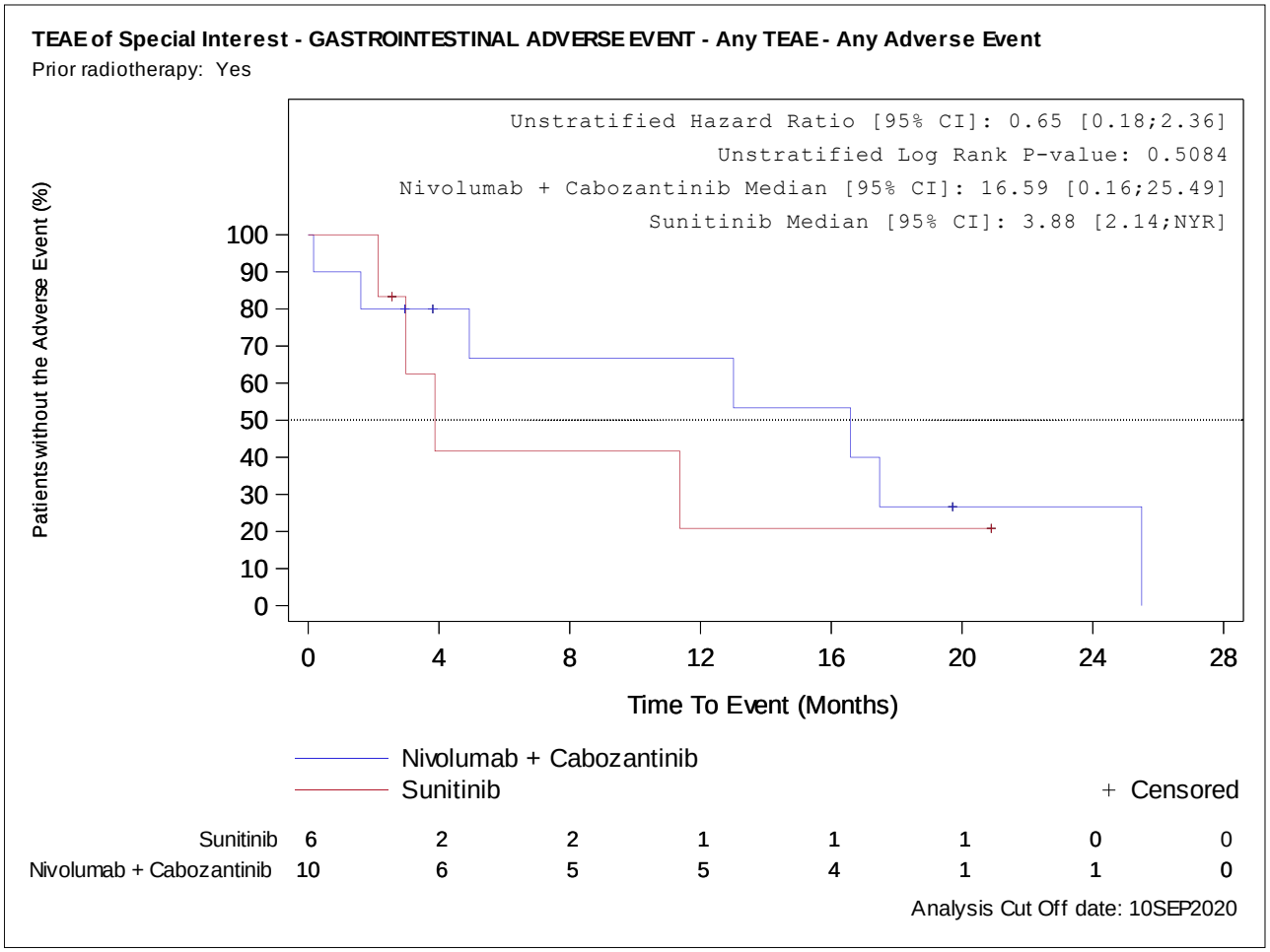

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:25

FIGURE 3.23.2.19: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



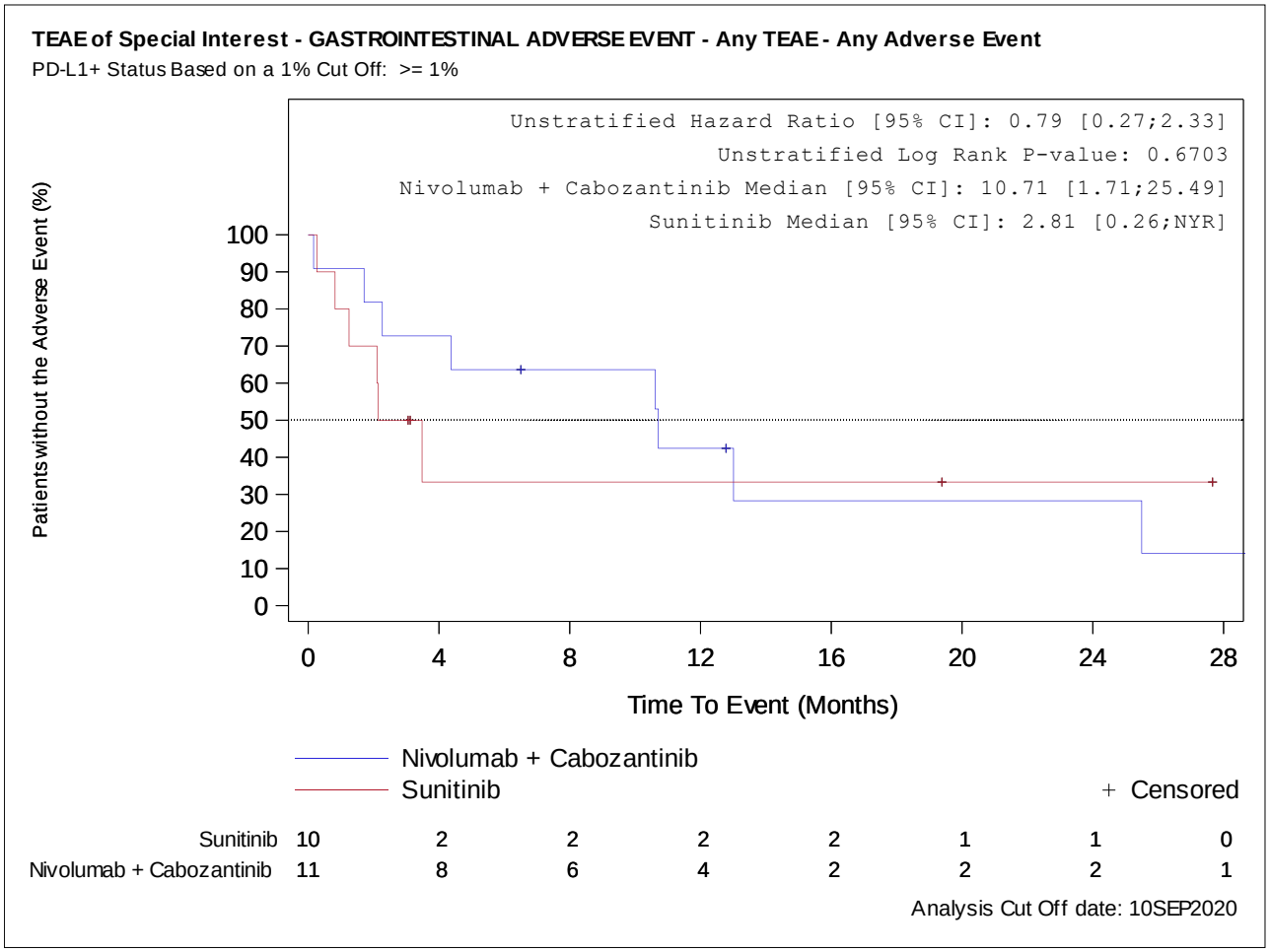

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:31

FIGURE 3.23.2.20: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



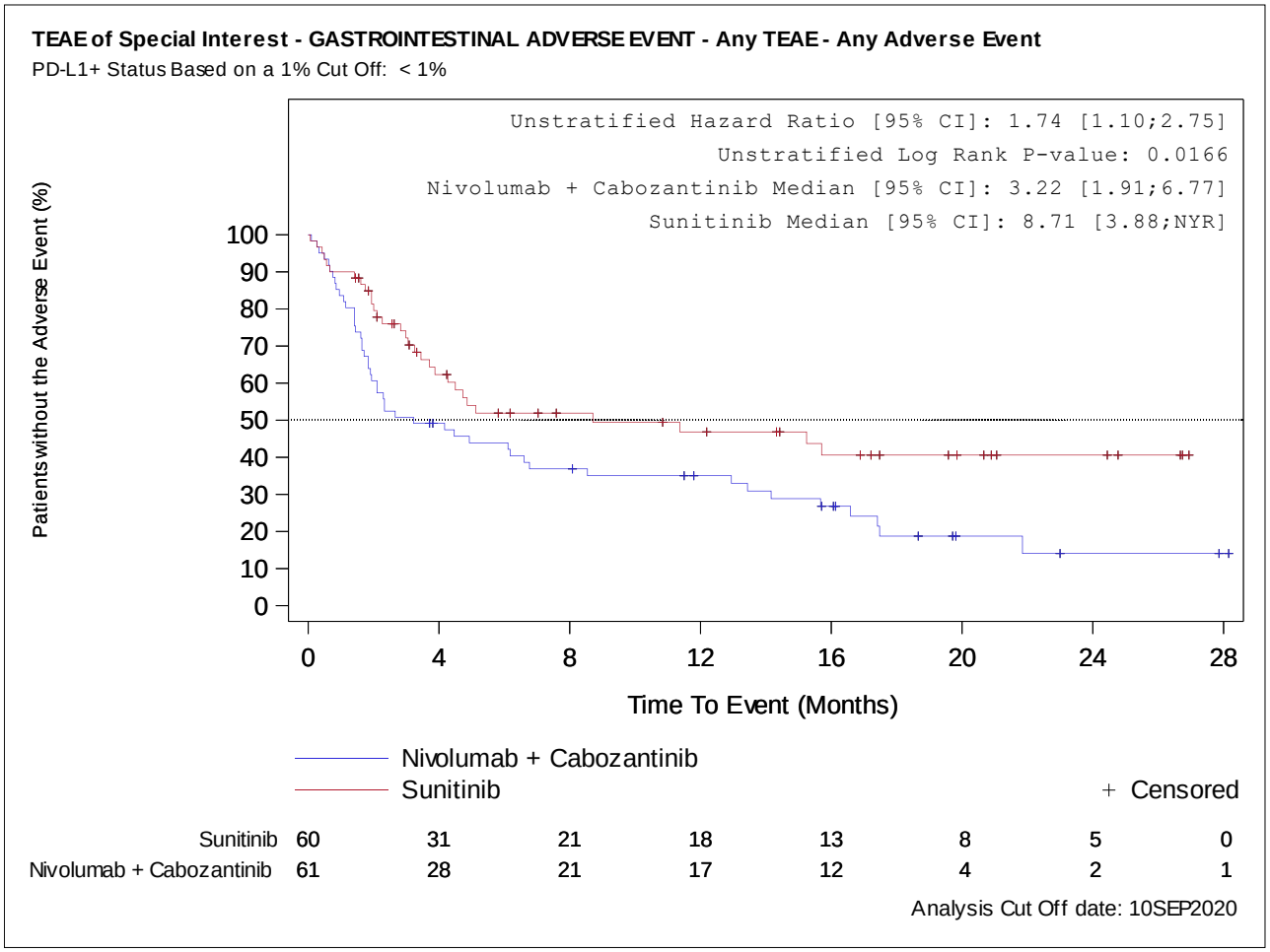

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:37

FIGURE 3.23.2.21: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



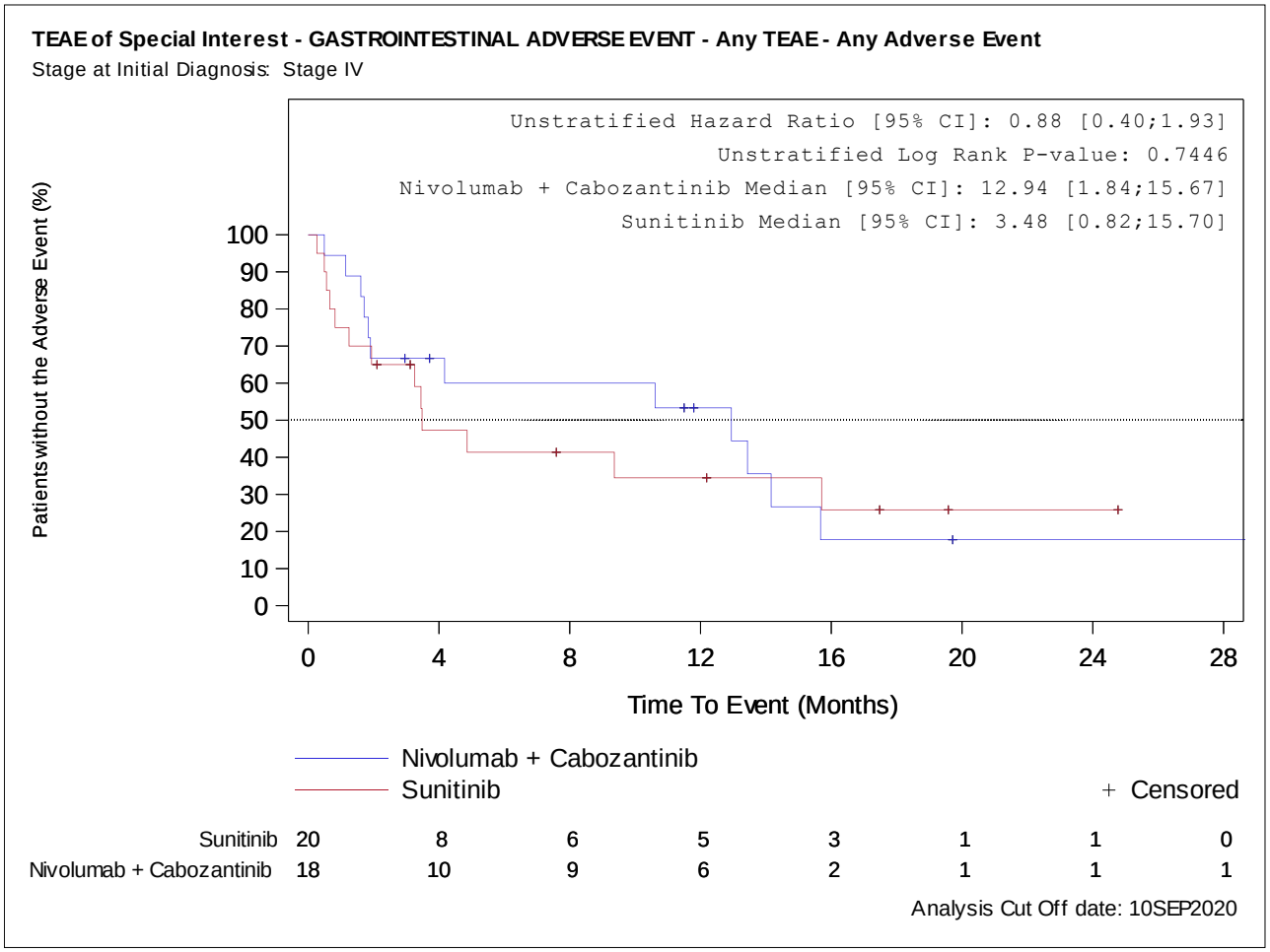

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:43

FIGURE 3.23.2.22: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



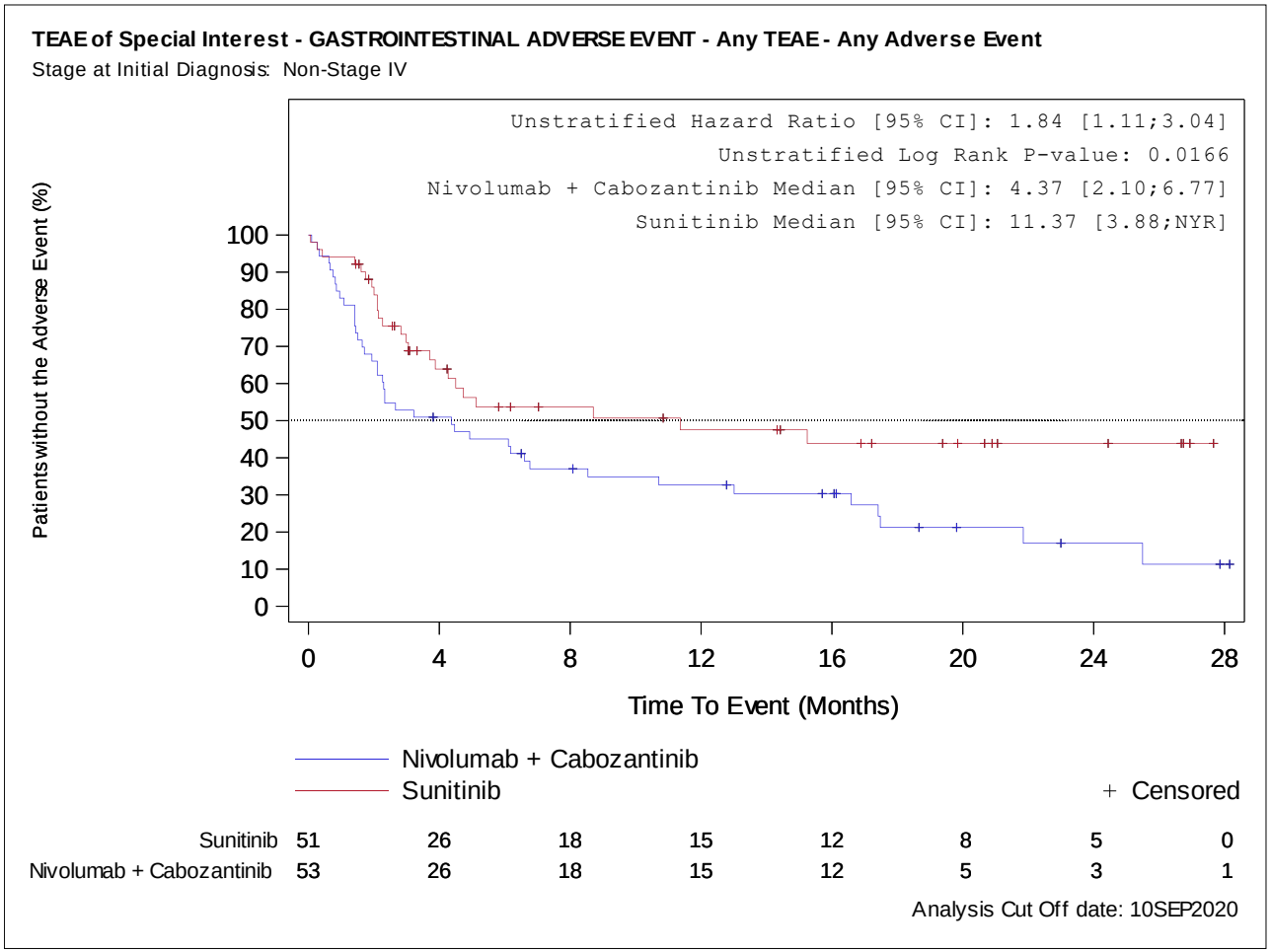

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:49

FIGURE 3.23.2.23: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



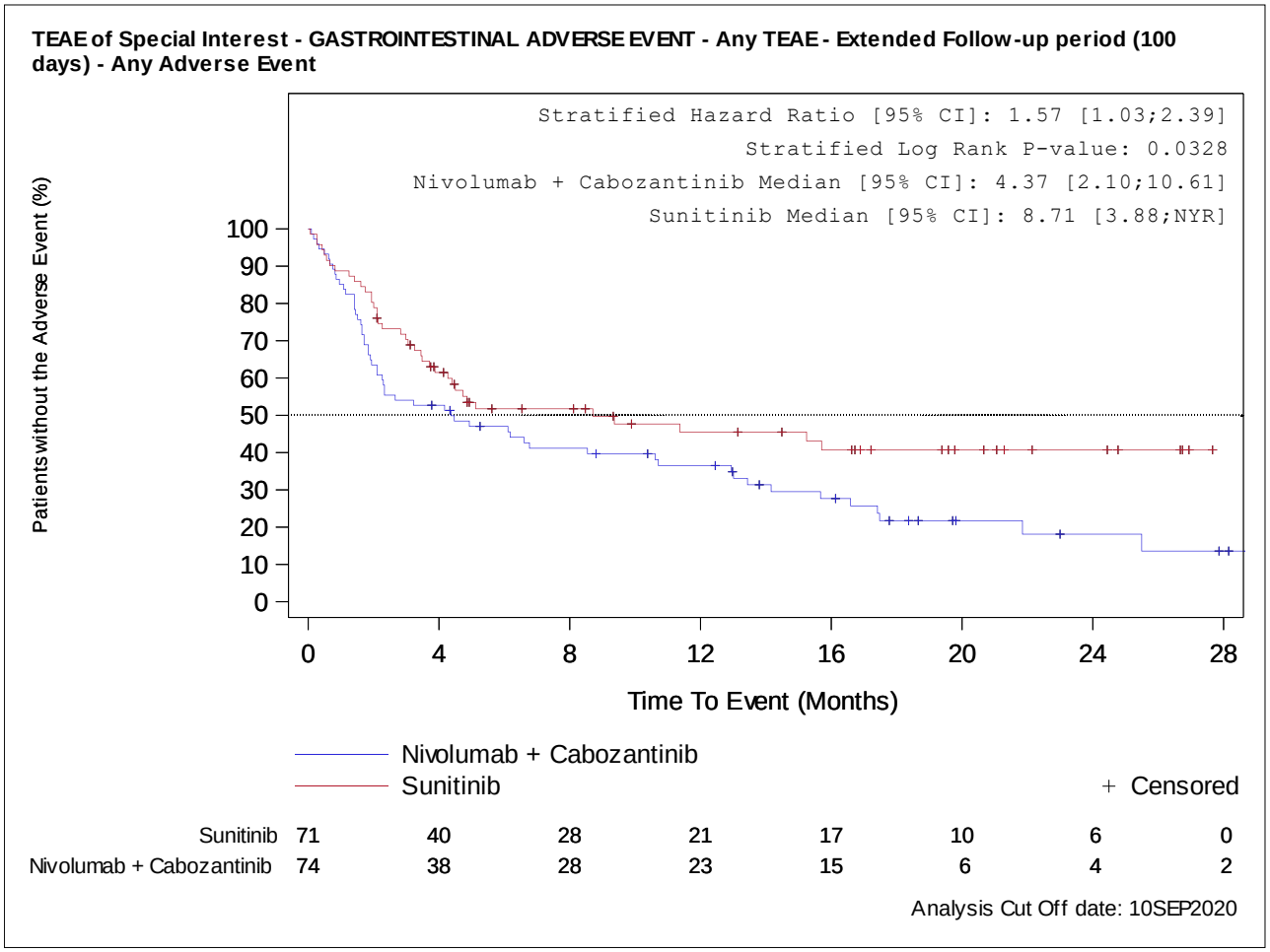

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:18:19

FIGURE 3.23.2.24: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



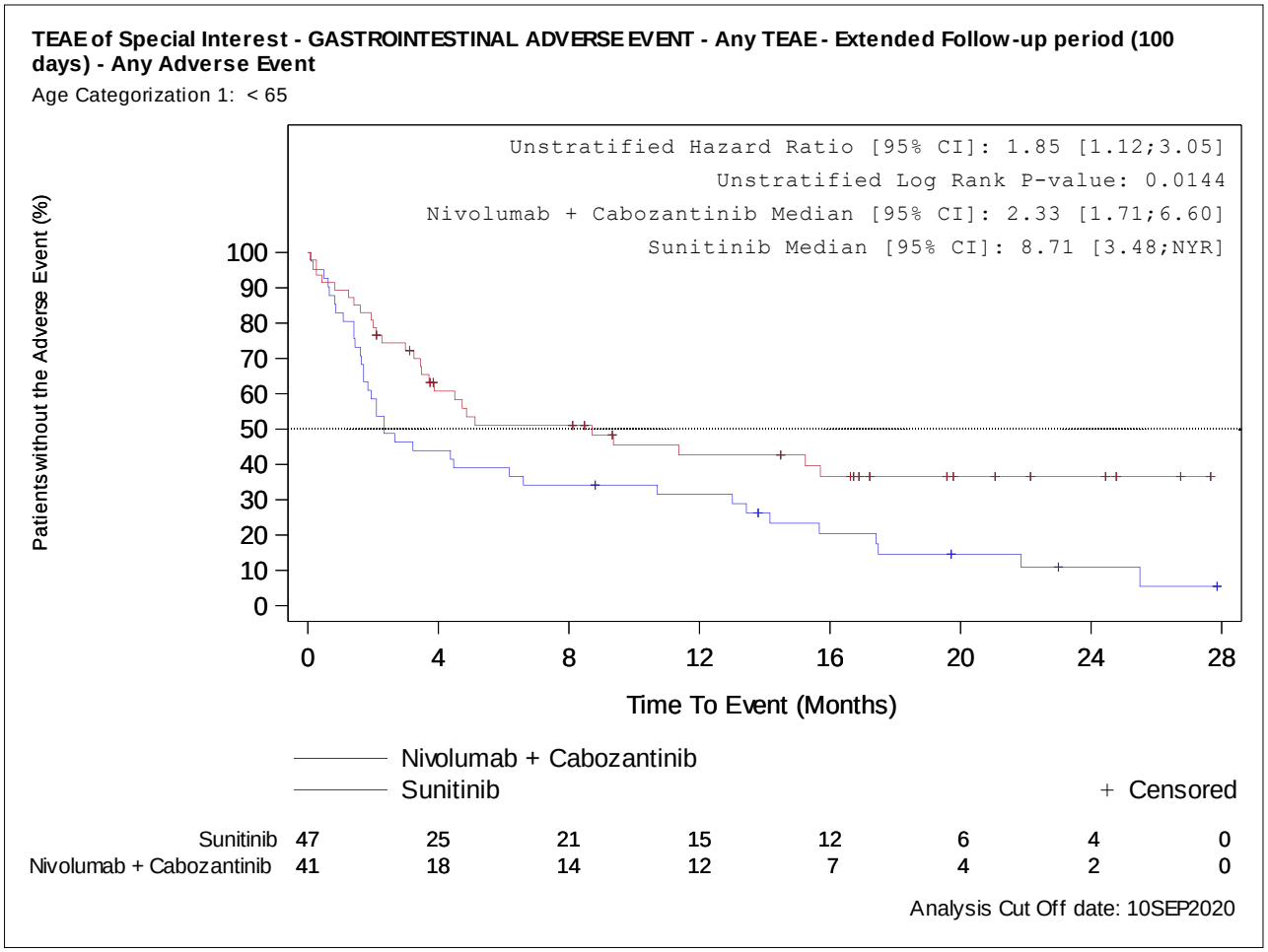

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:18:25

FIGURE 3.24.1: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



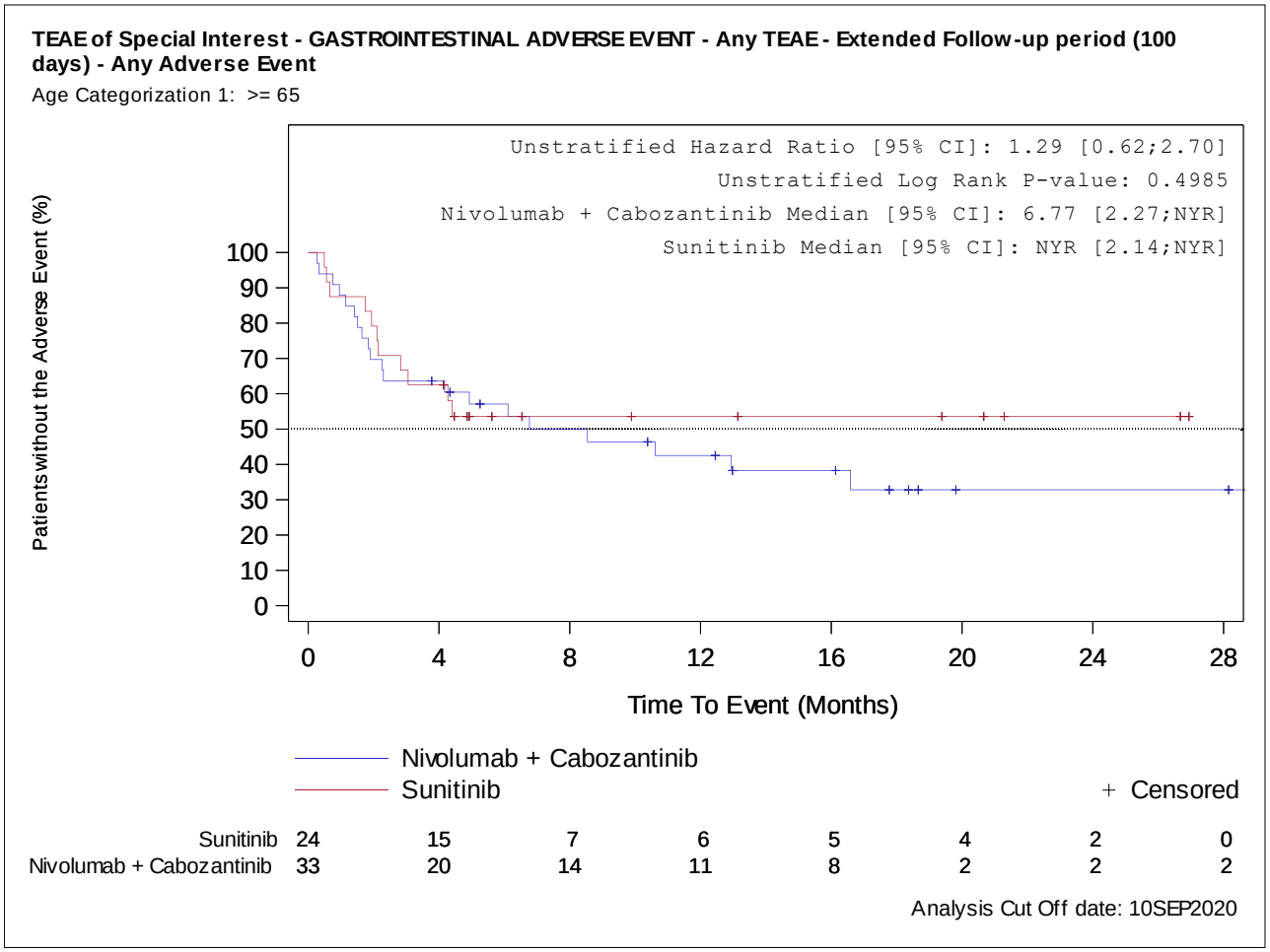

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:21:40

FIGURE 3.24.2.1: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



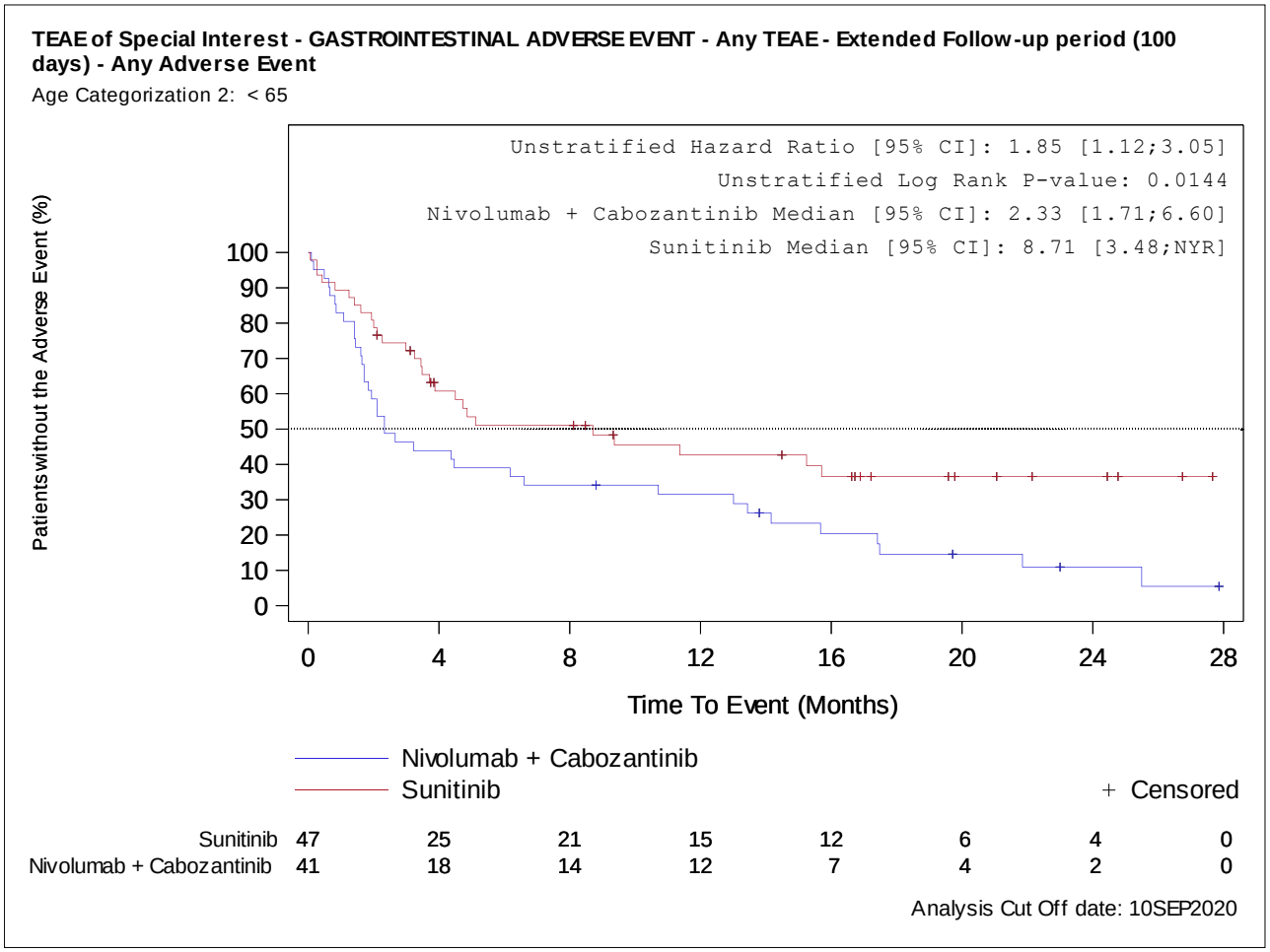

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:21:43

FIGURE 3.24.2.2: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



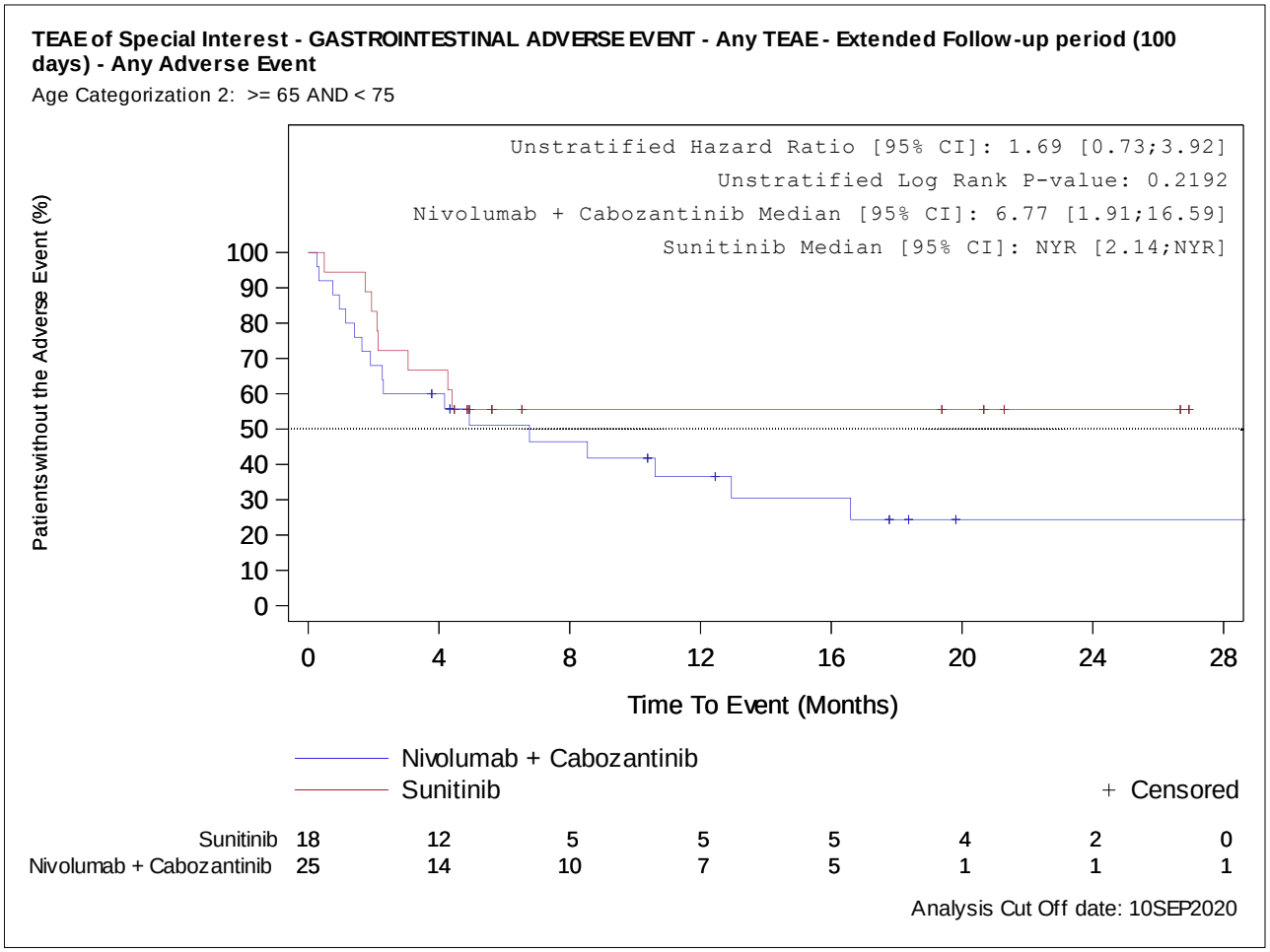

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:21:49

FIGURE 3.24.2.3: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



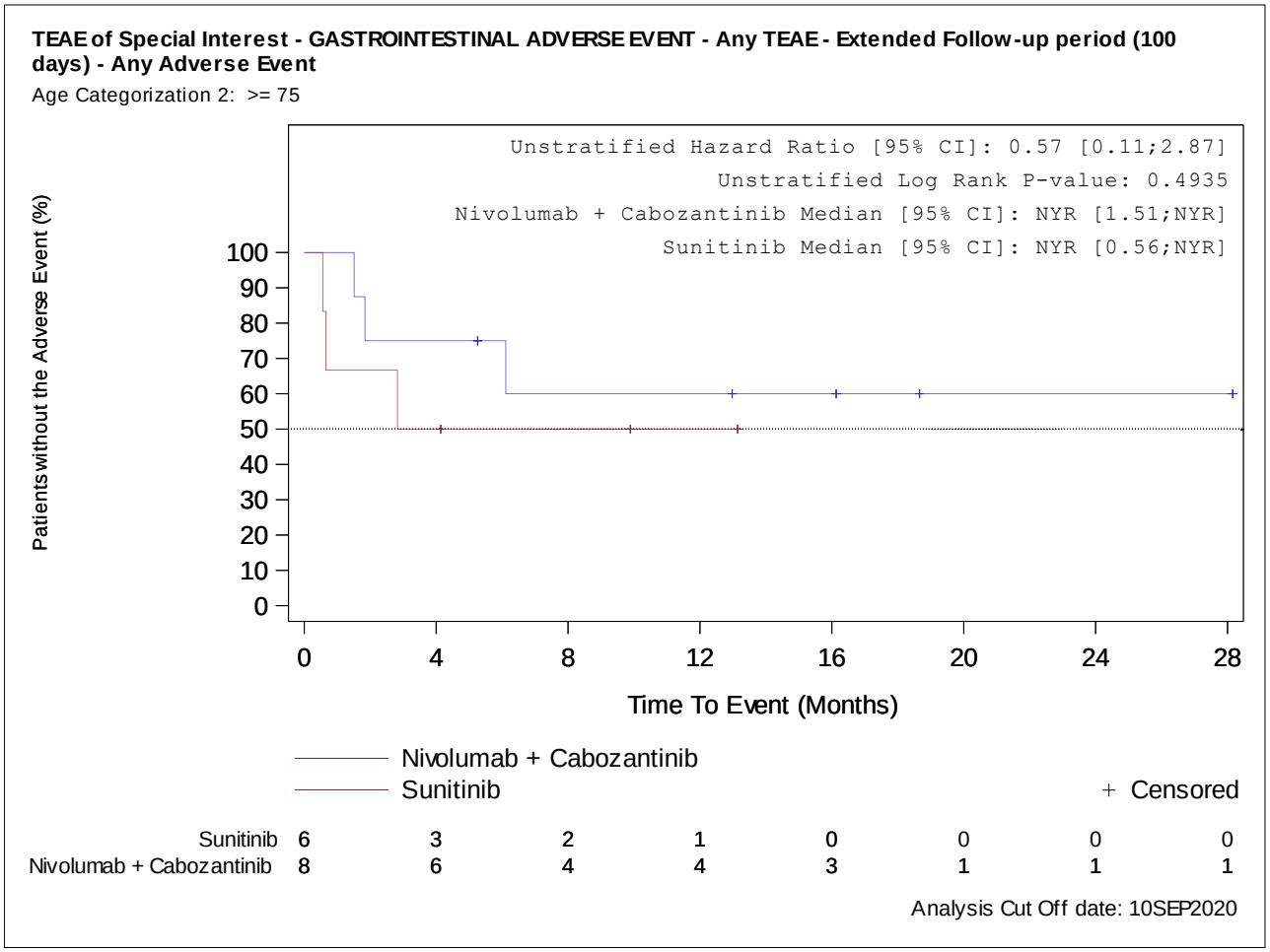

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:21:55

FIGURE 3.24.2.4: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



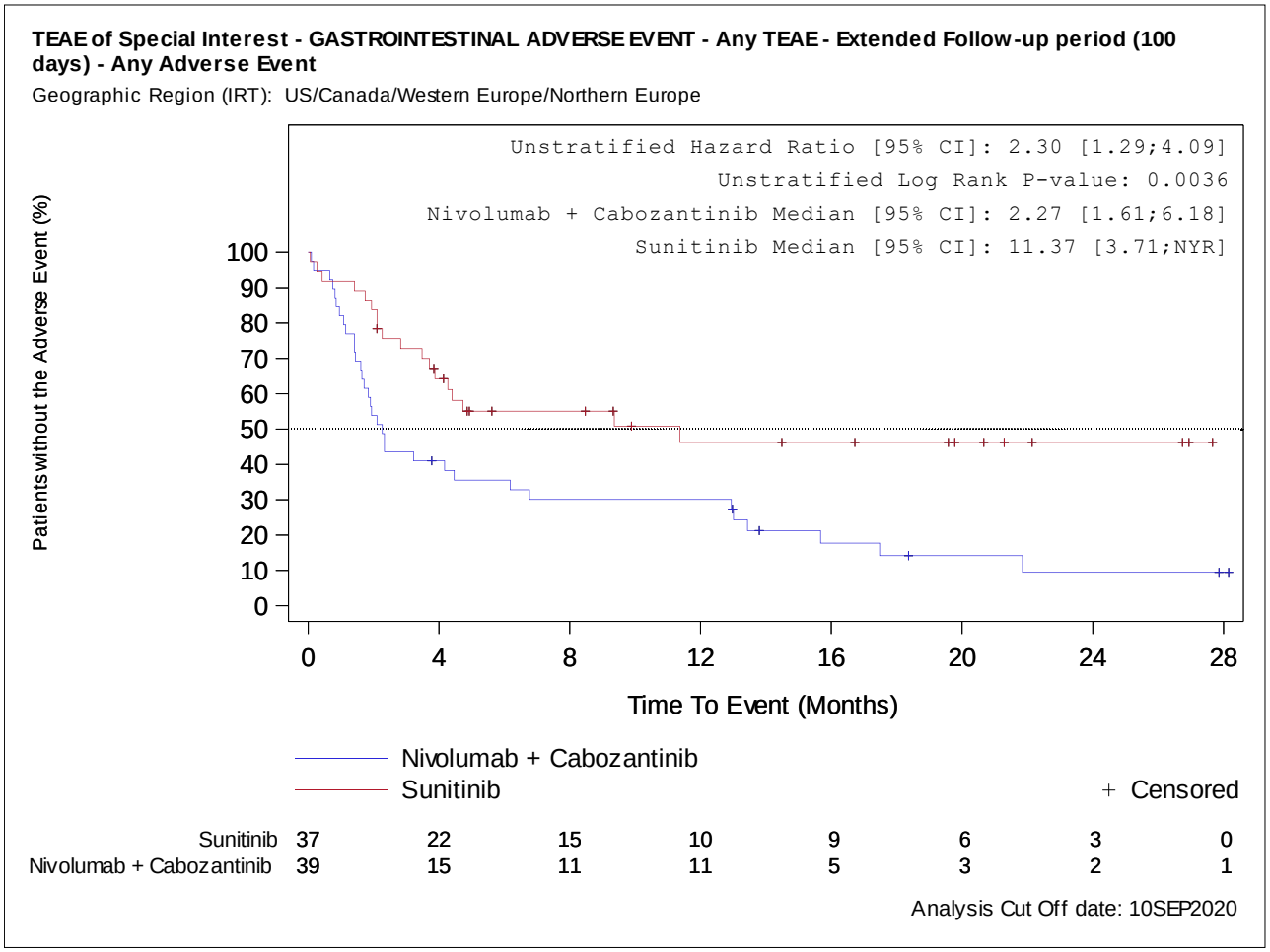

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:22:01

FIGURE 3.24.2.5: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



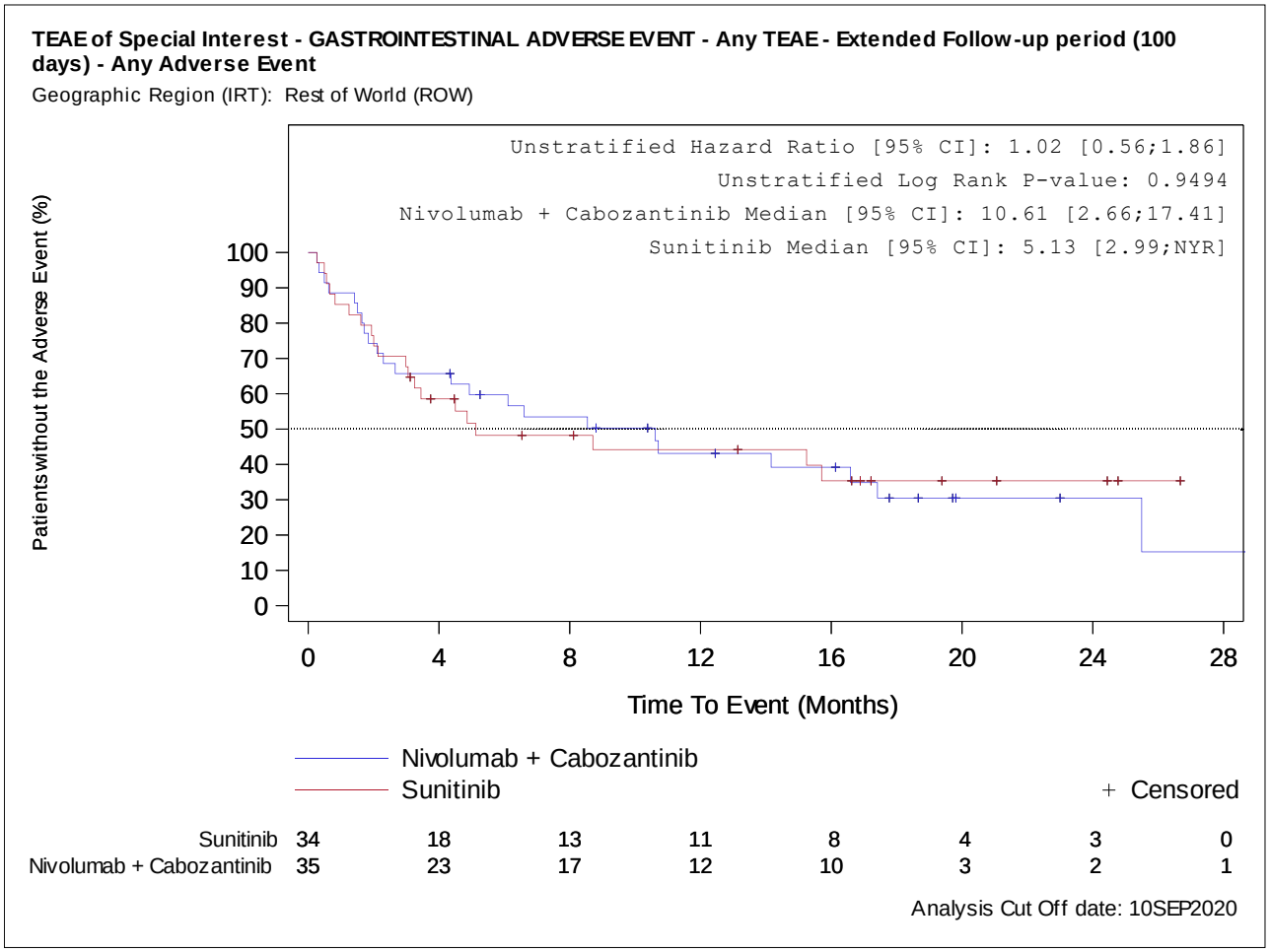

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:22:07

FIGURE 3.24.2.6: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



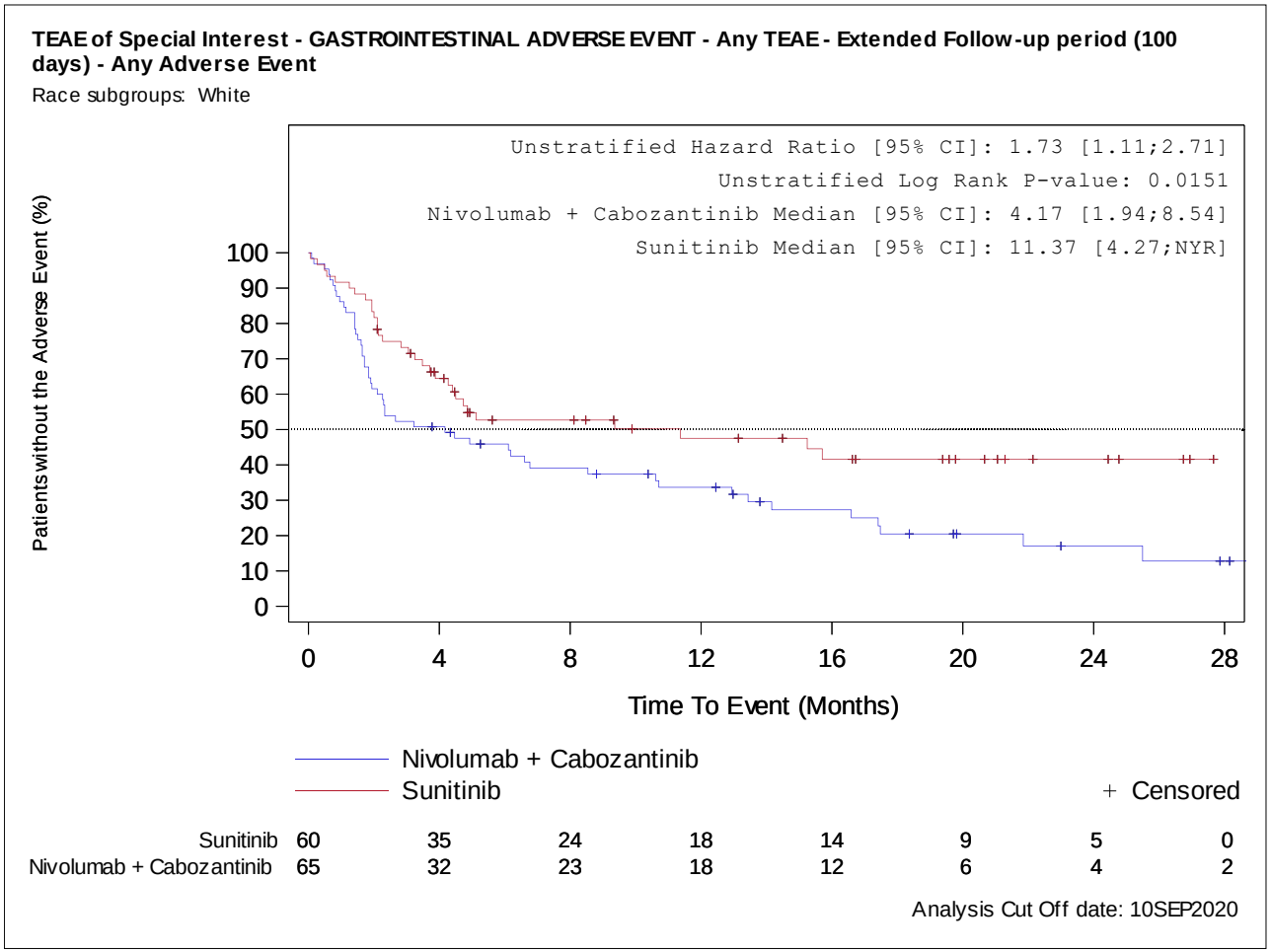

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:22:13

FIGURE 3.24.2.7: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



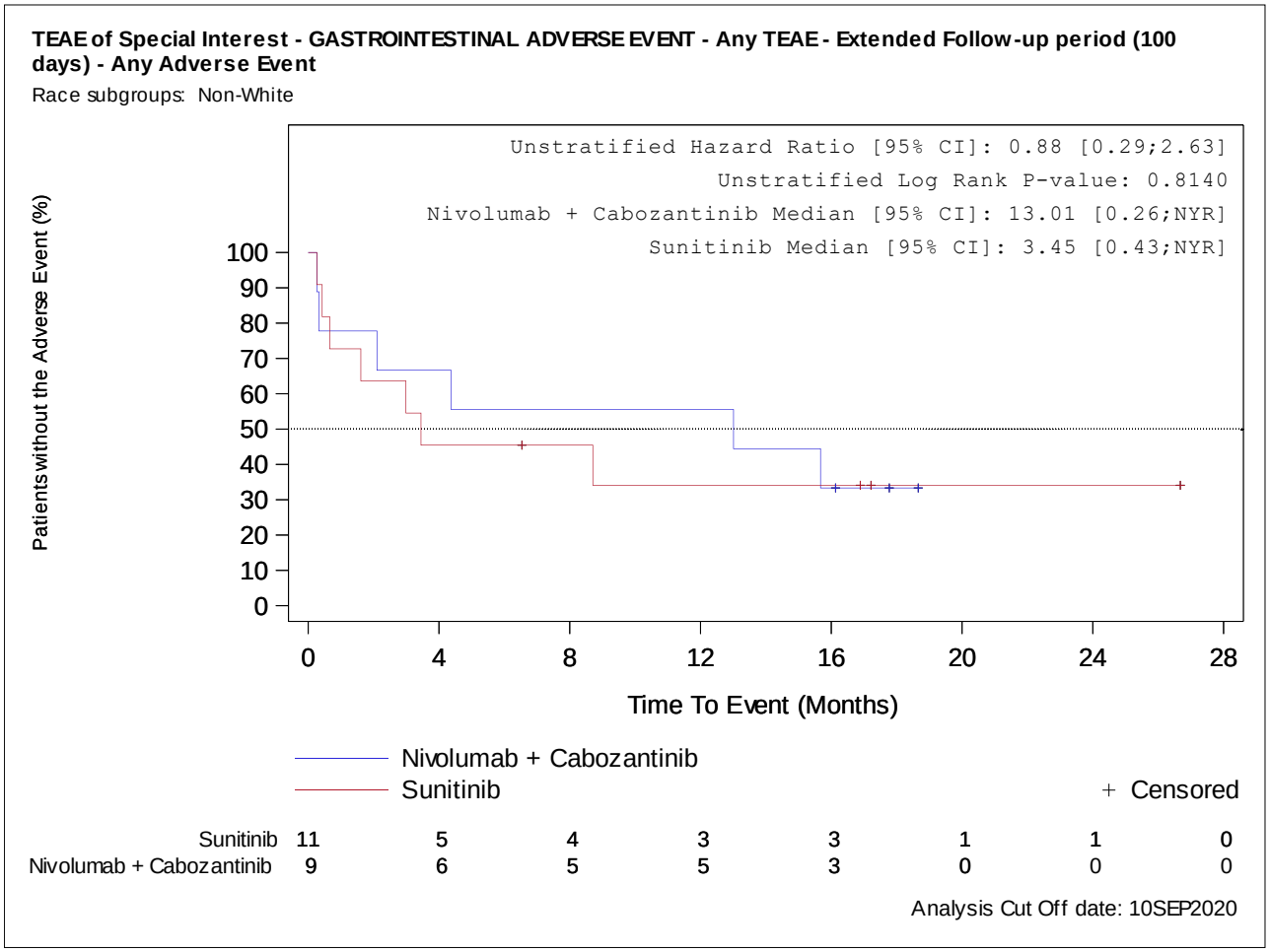

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:22:18

FIGURE 3.24.2.8: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



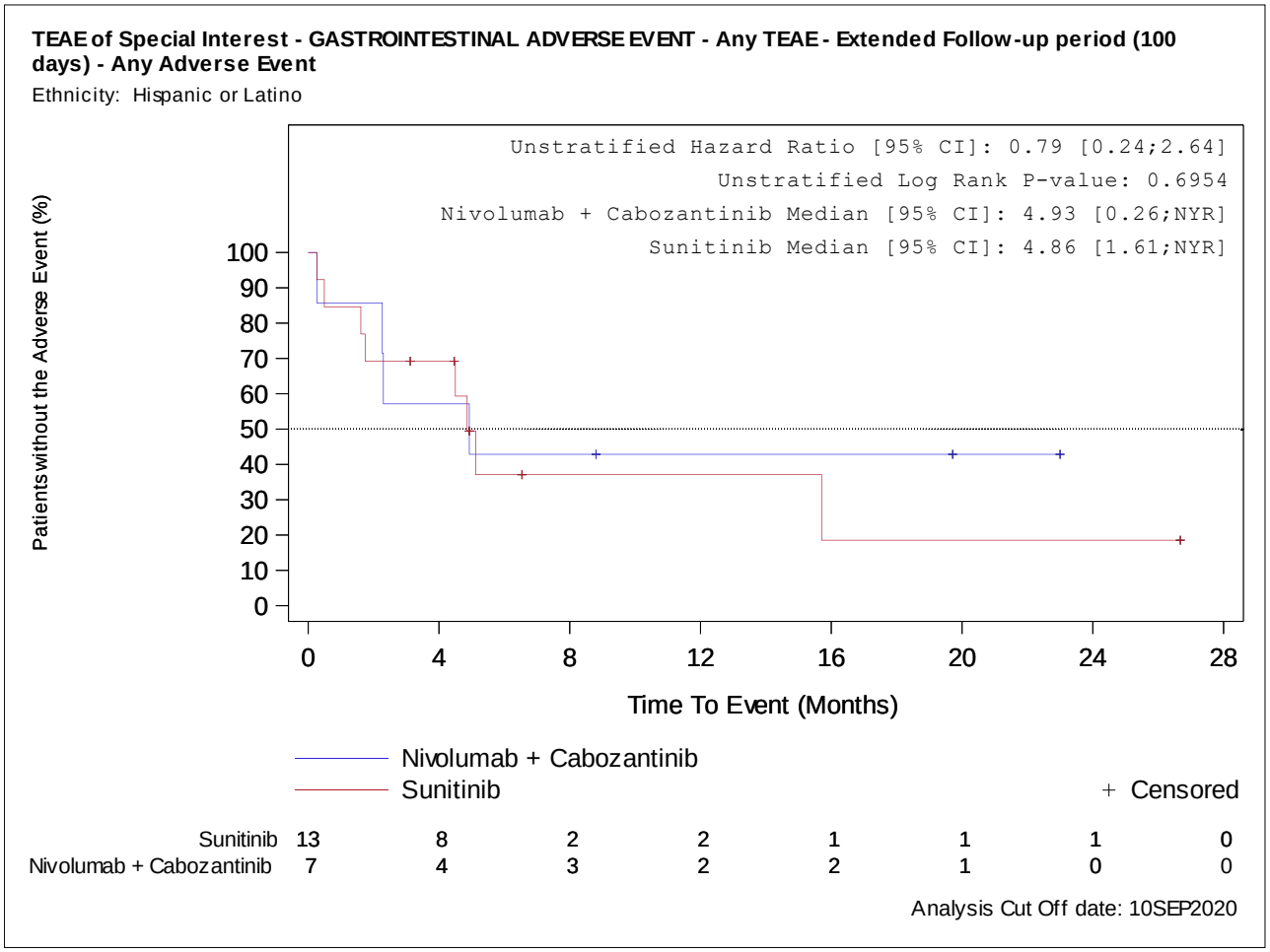

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:22:24

FIGURE 3.24.2.9: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



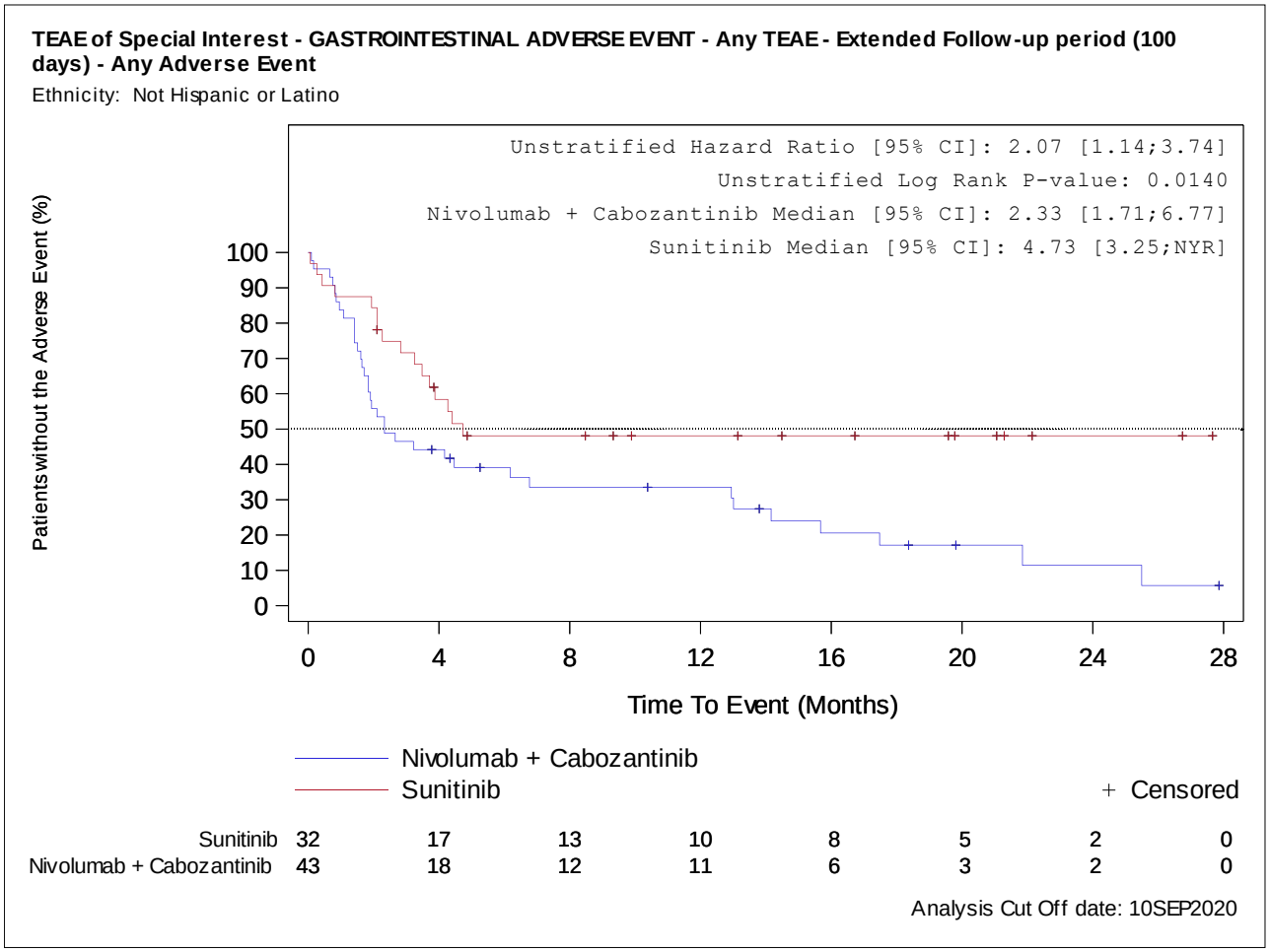

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:22:30

FIGURE 3.24.2.10: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



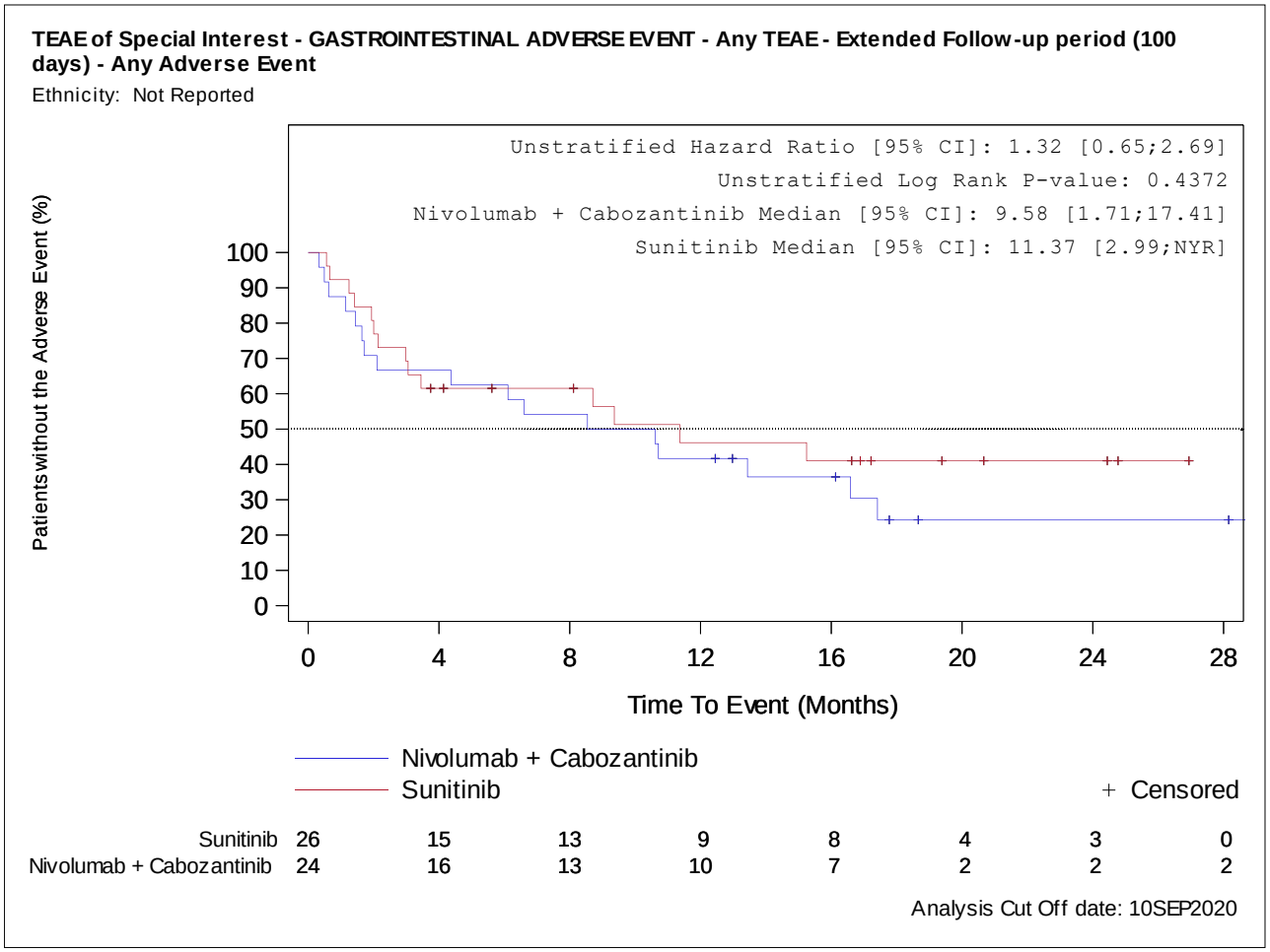

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:22:37

FIGURE 3.24.2.11: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



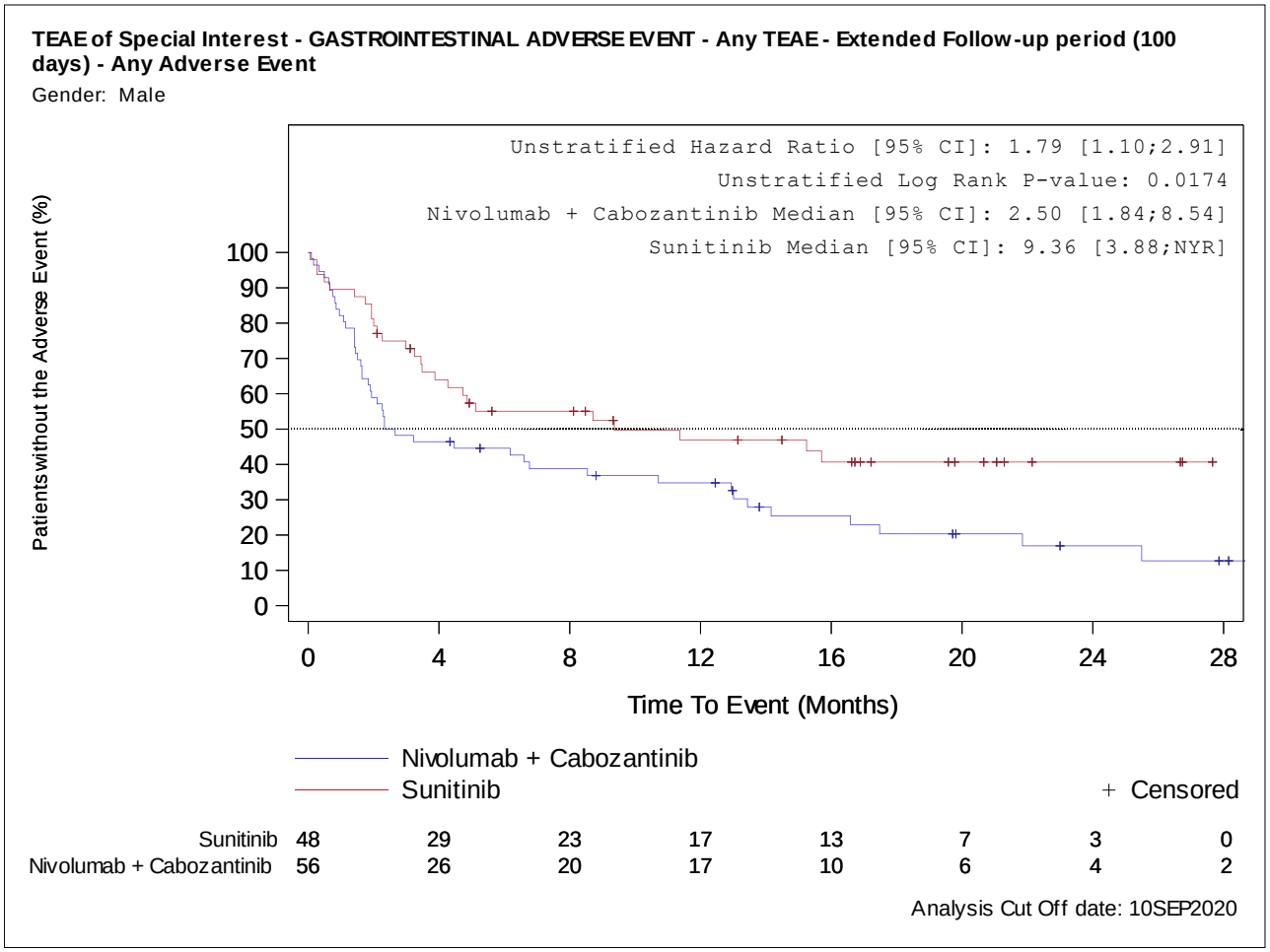

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:22:42

FIGURE 3.24.2.12: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



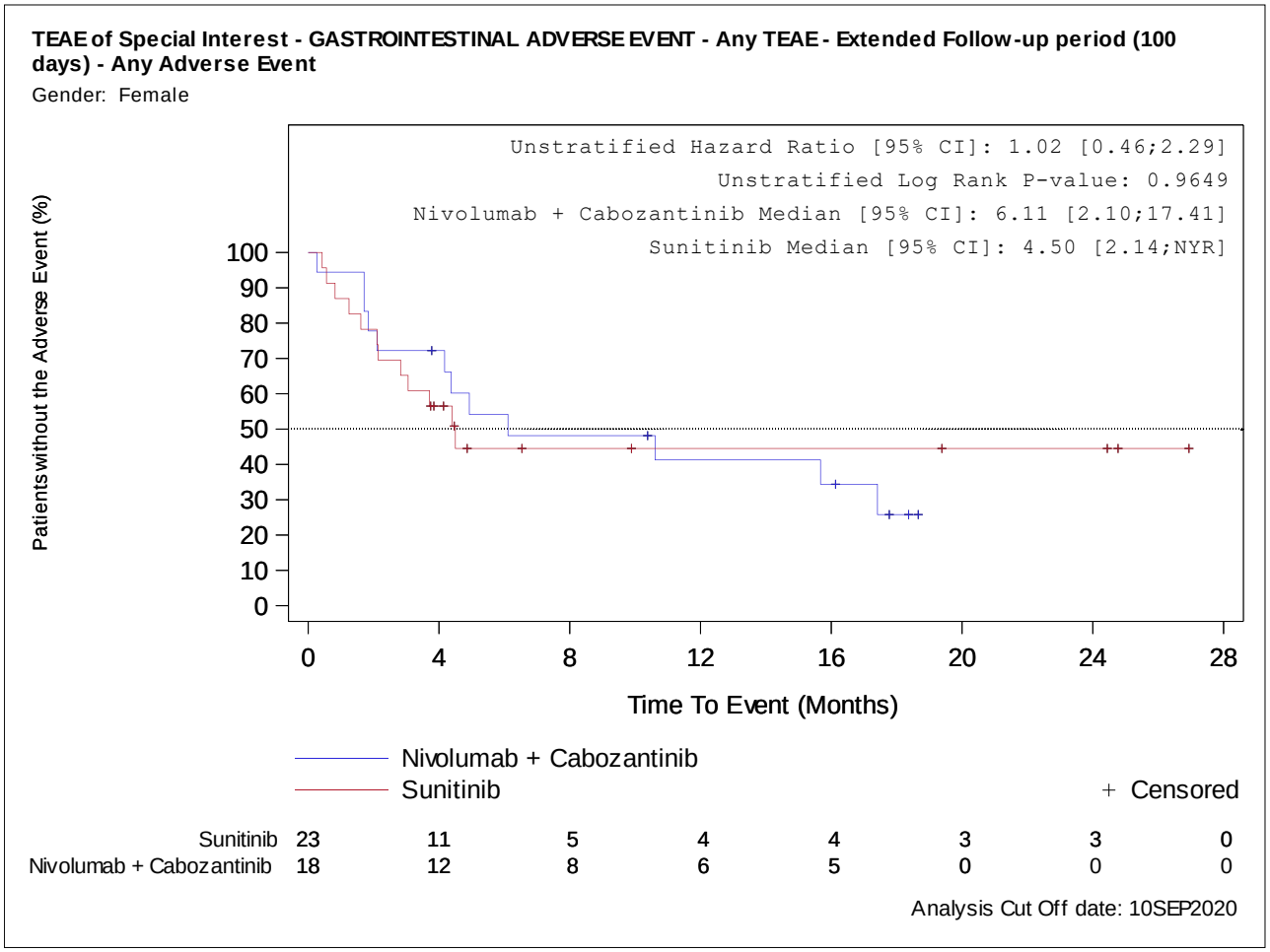

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:22:48

FIGURE 3.24.2.13: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



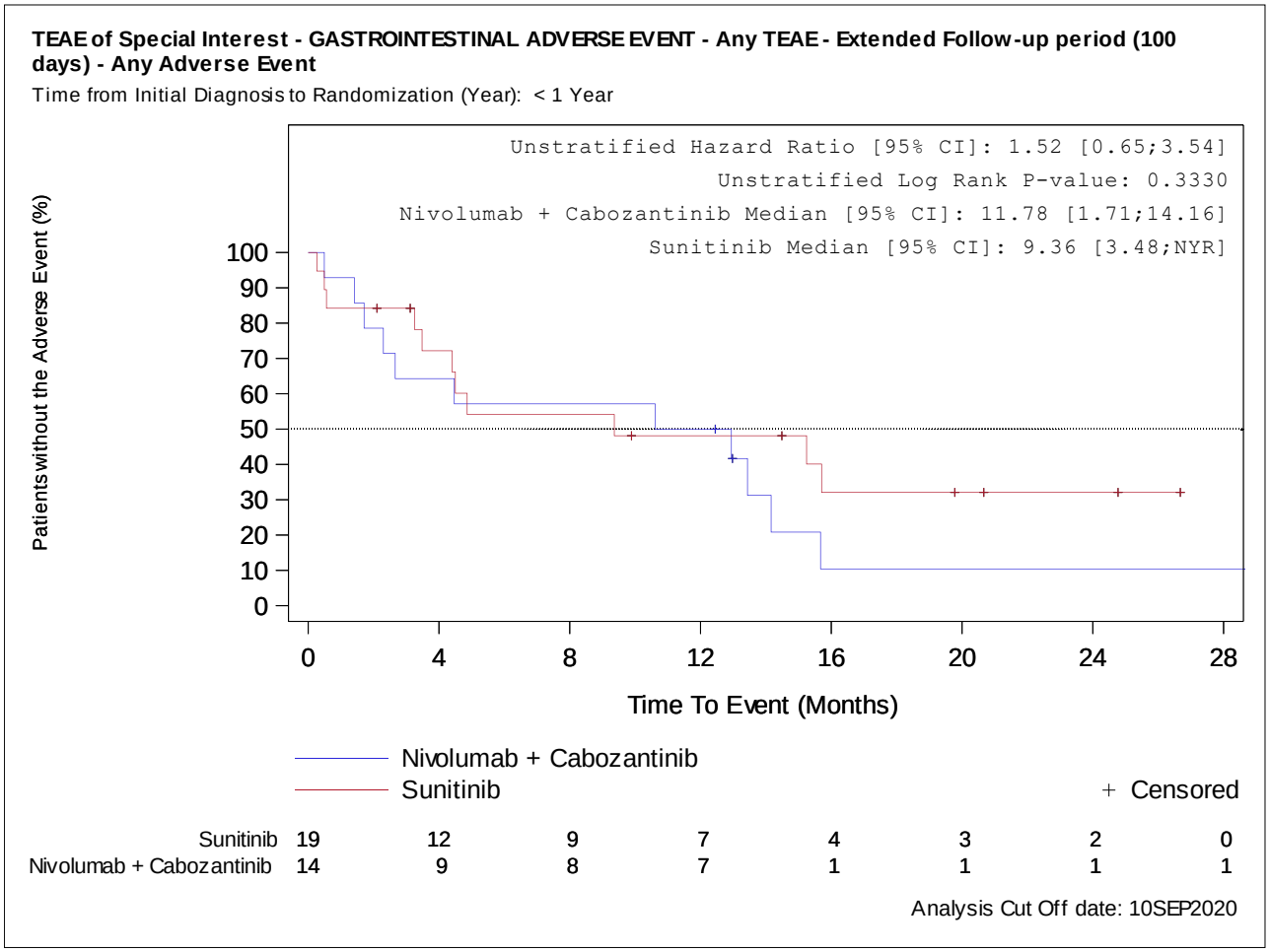

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:22:55

FIGURE 3.24.2.14: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:23:00

FIGURE 3.24.2.15: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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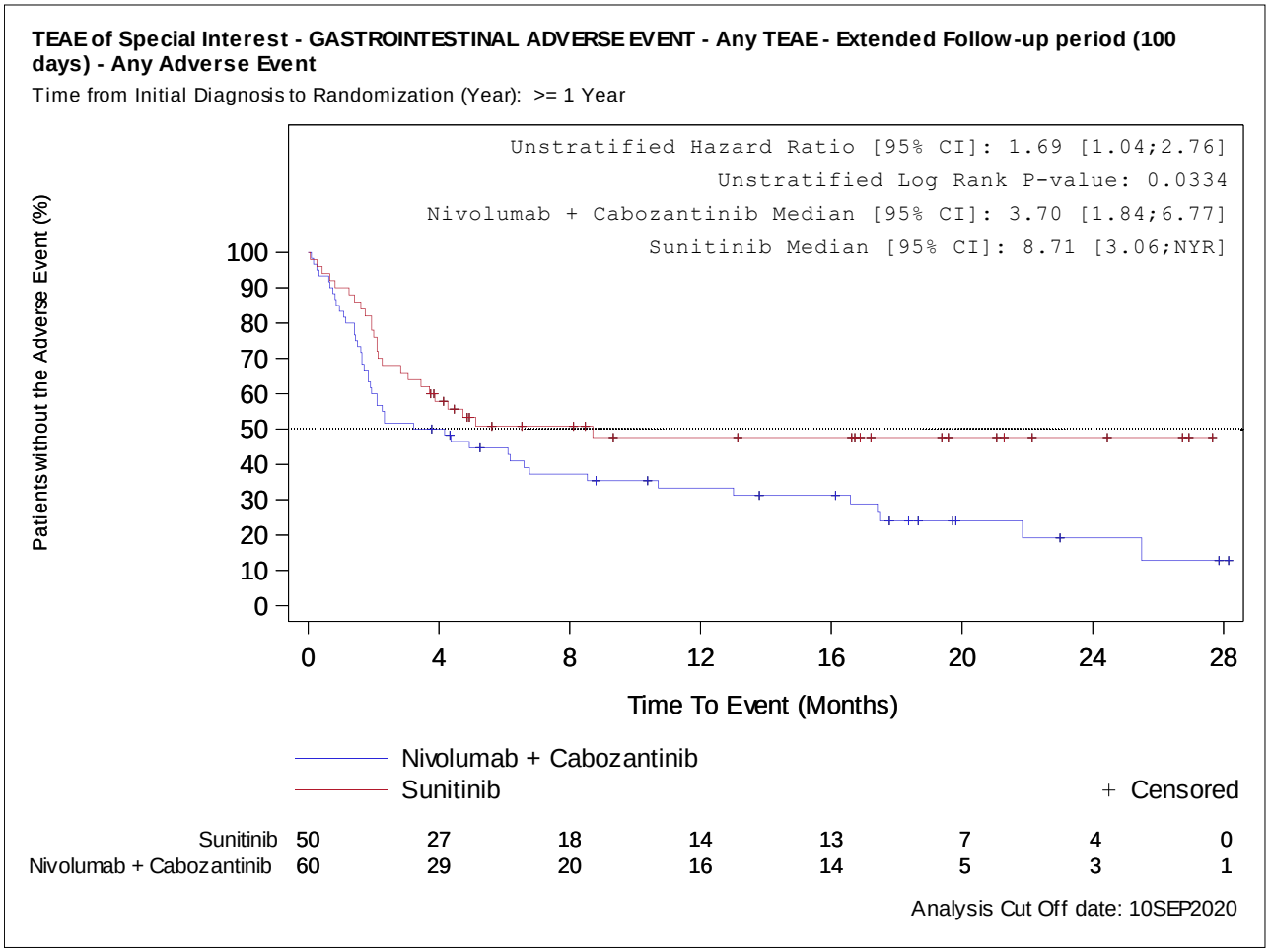
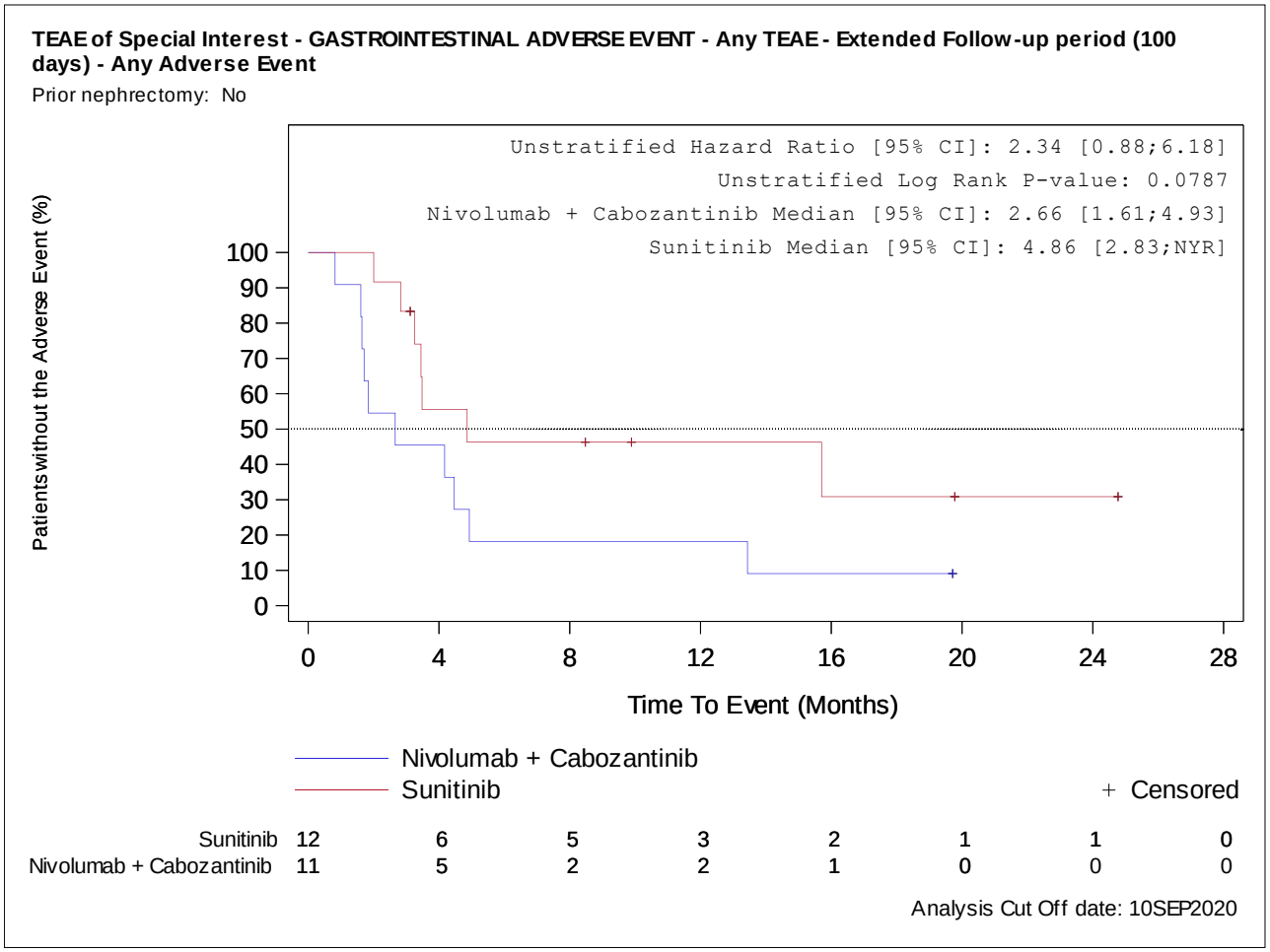
FIGURE 3.24.2.16: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:23:23

FIGURE 3.24.2.17: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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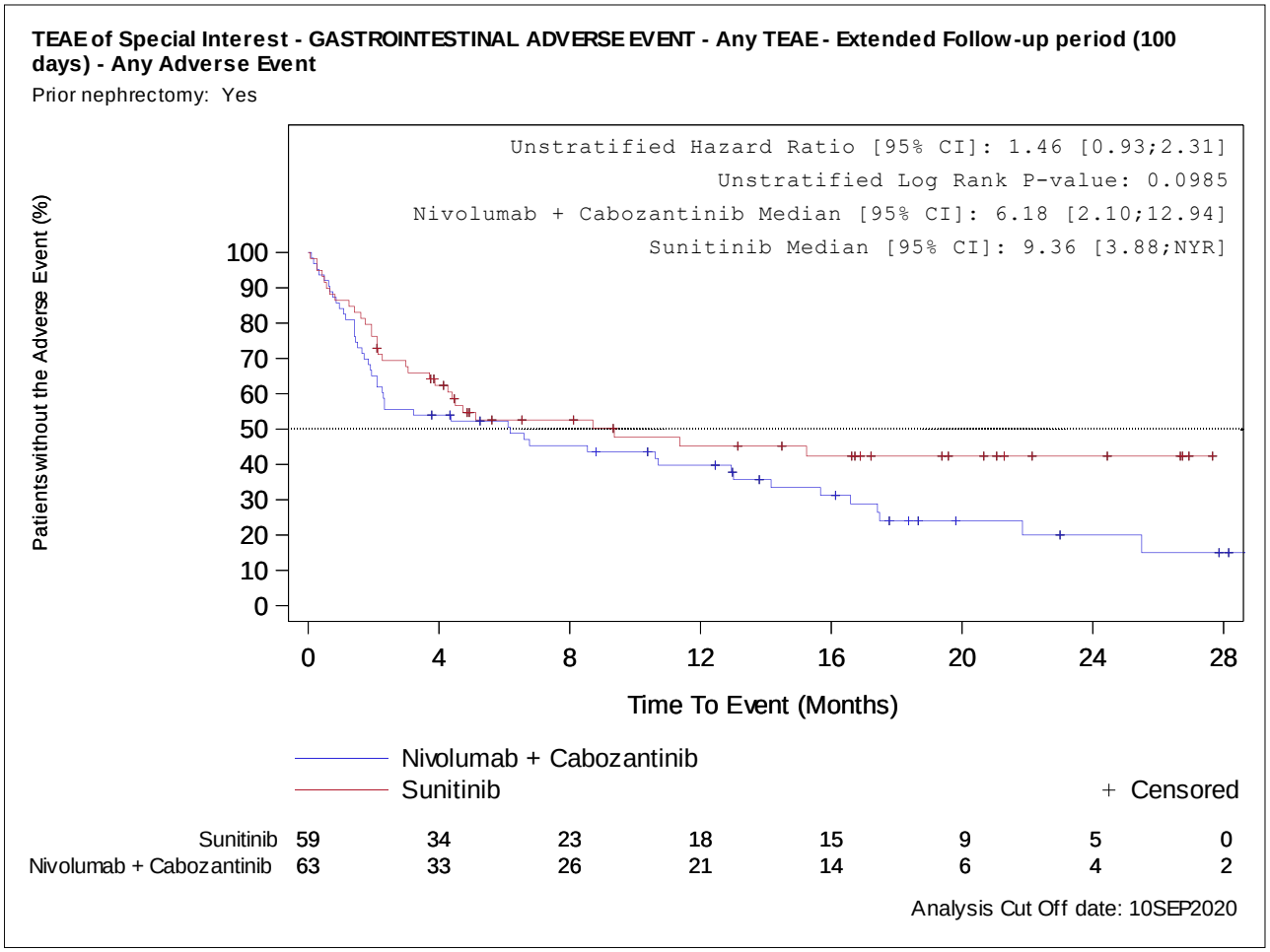
FIGURE 3.24.2.18: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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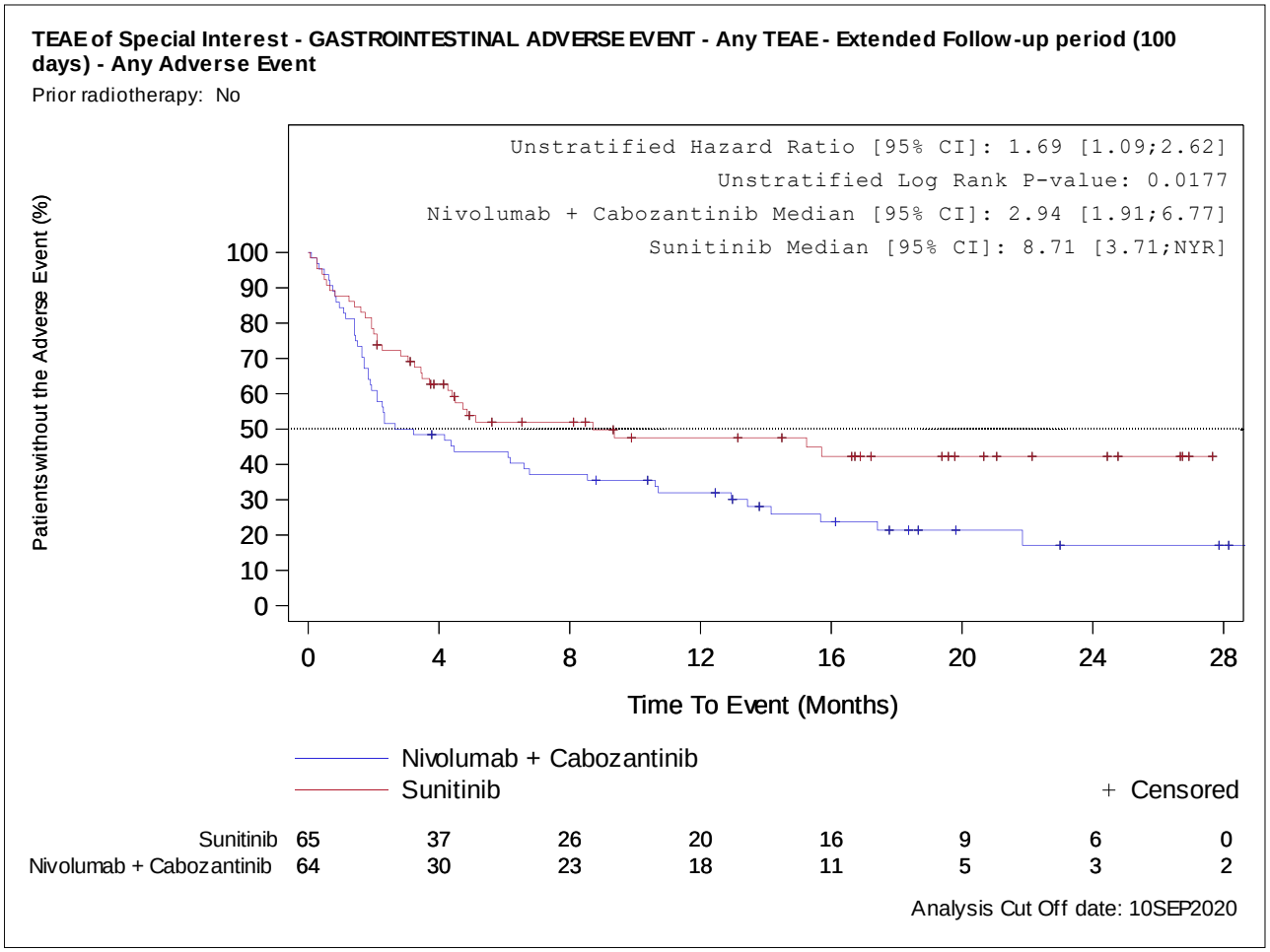
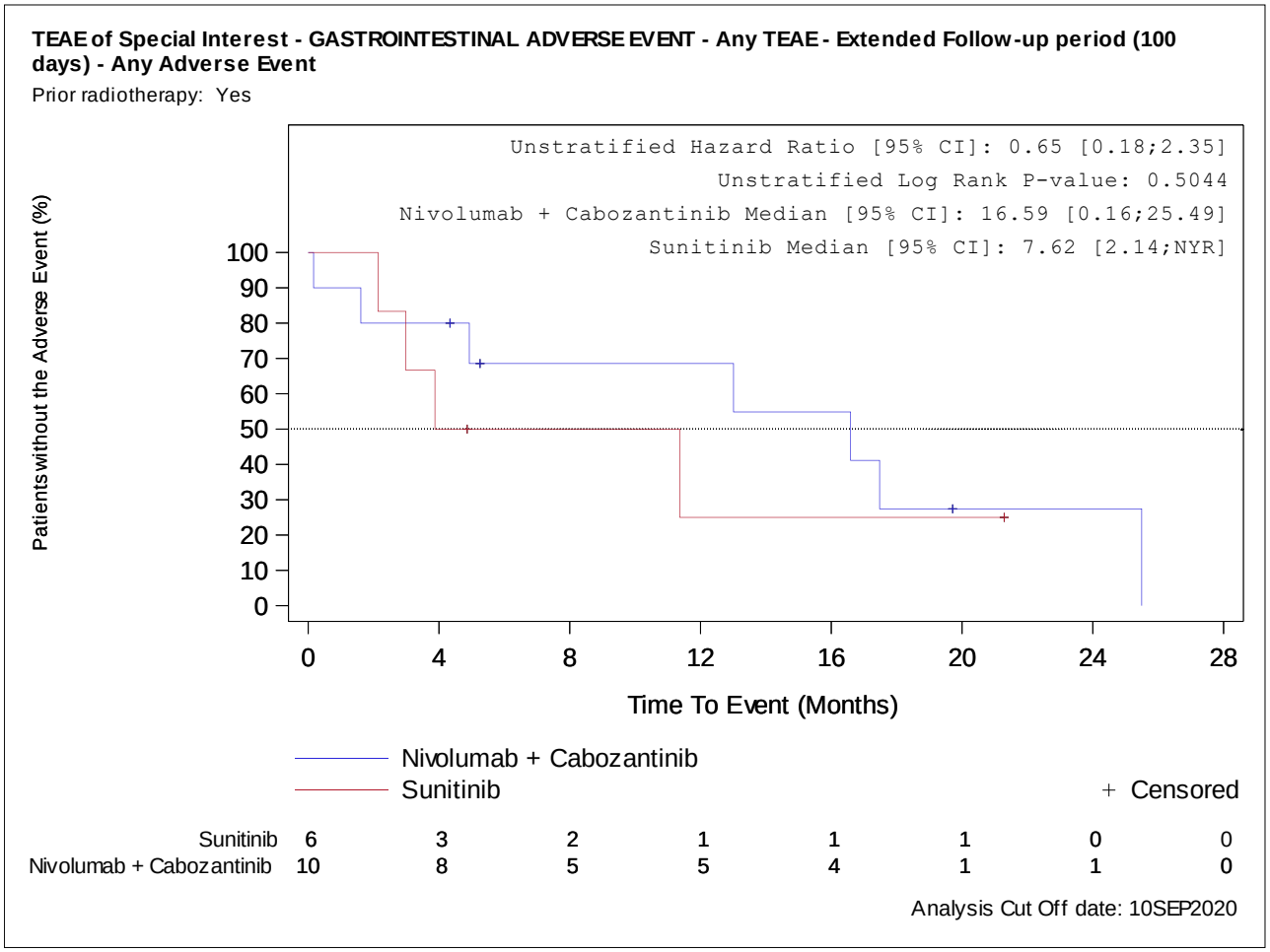
FIGURE 3.24.2.19: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:24:28

FIGURE 3.24.2.20: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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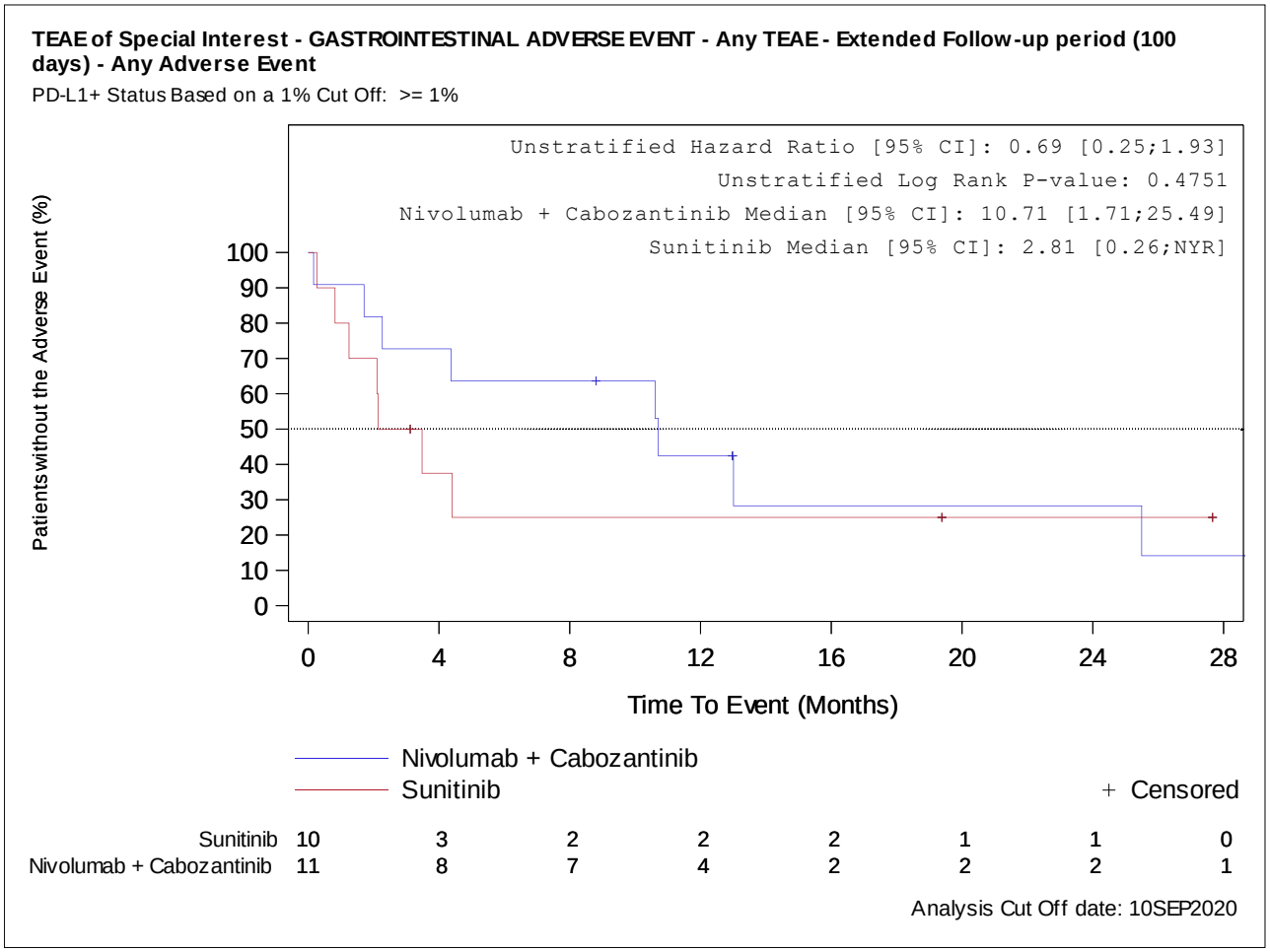
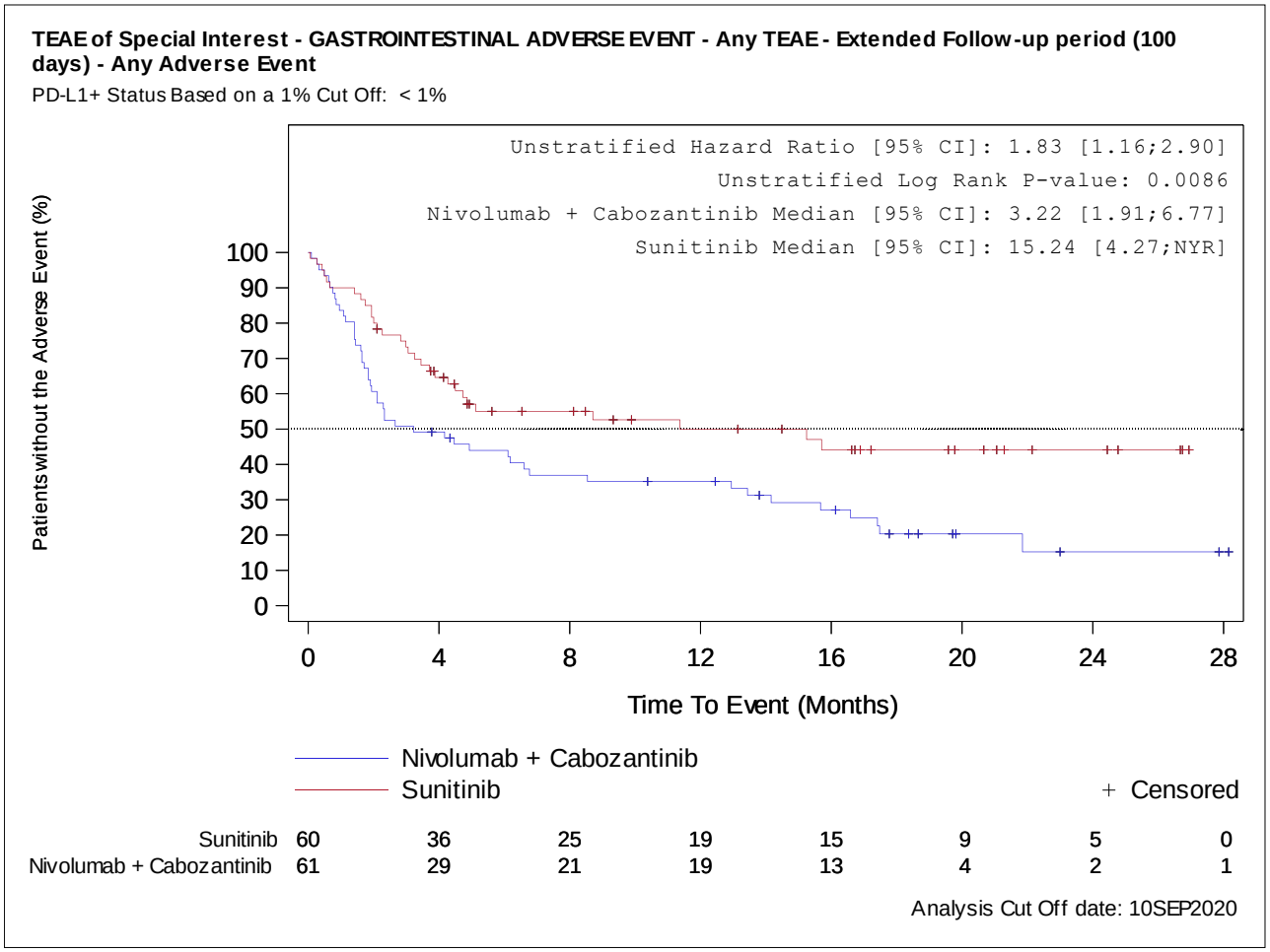
FIGURE 3.24.2.21: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:24:40

FIGURE 3.24.2.22: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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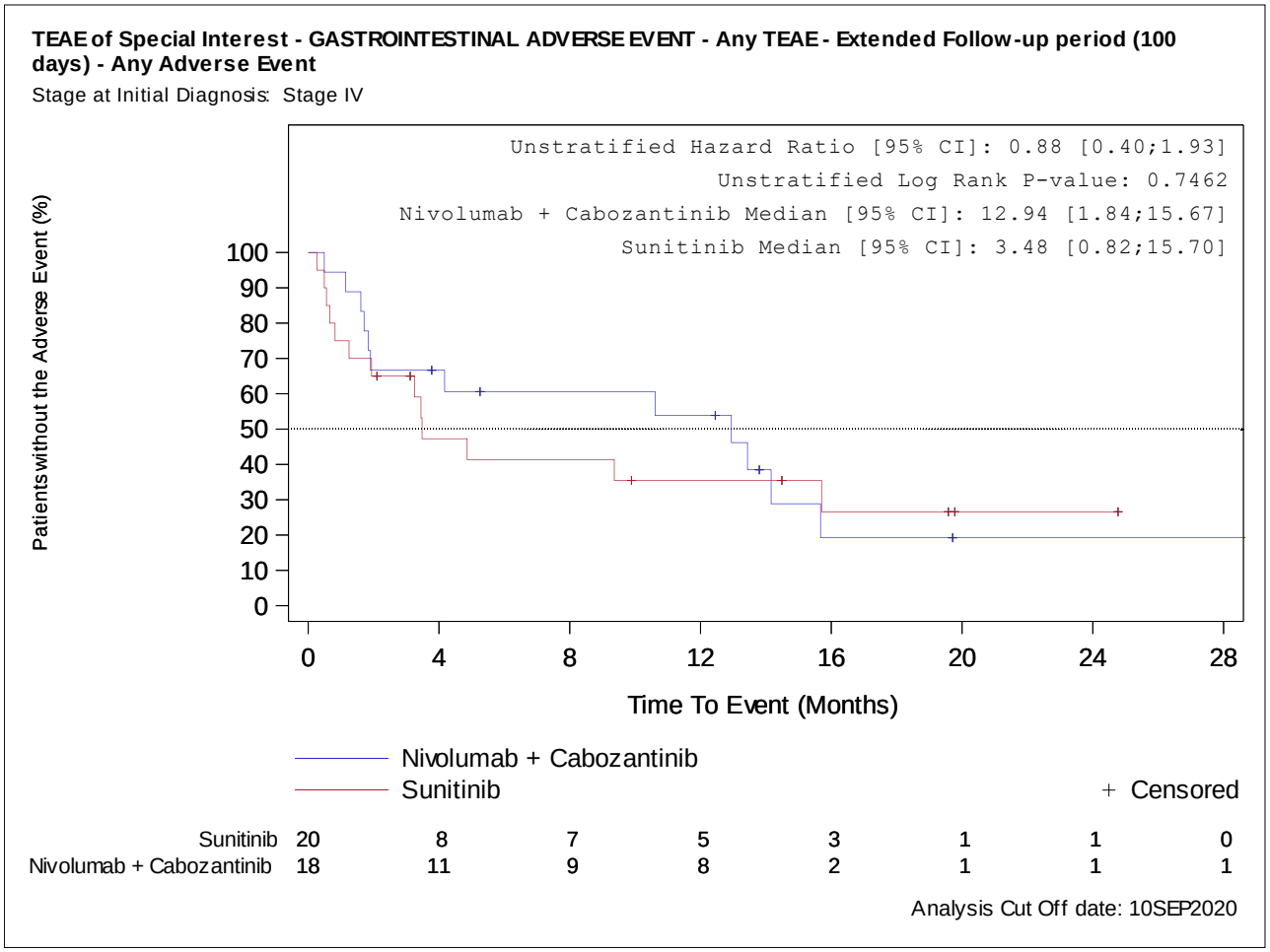
FIGURE 3.24.2.23: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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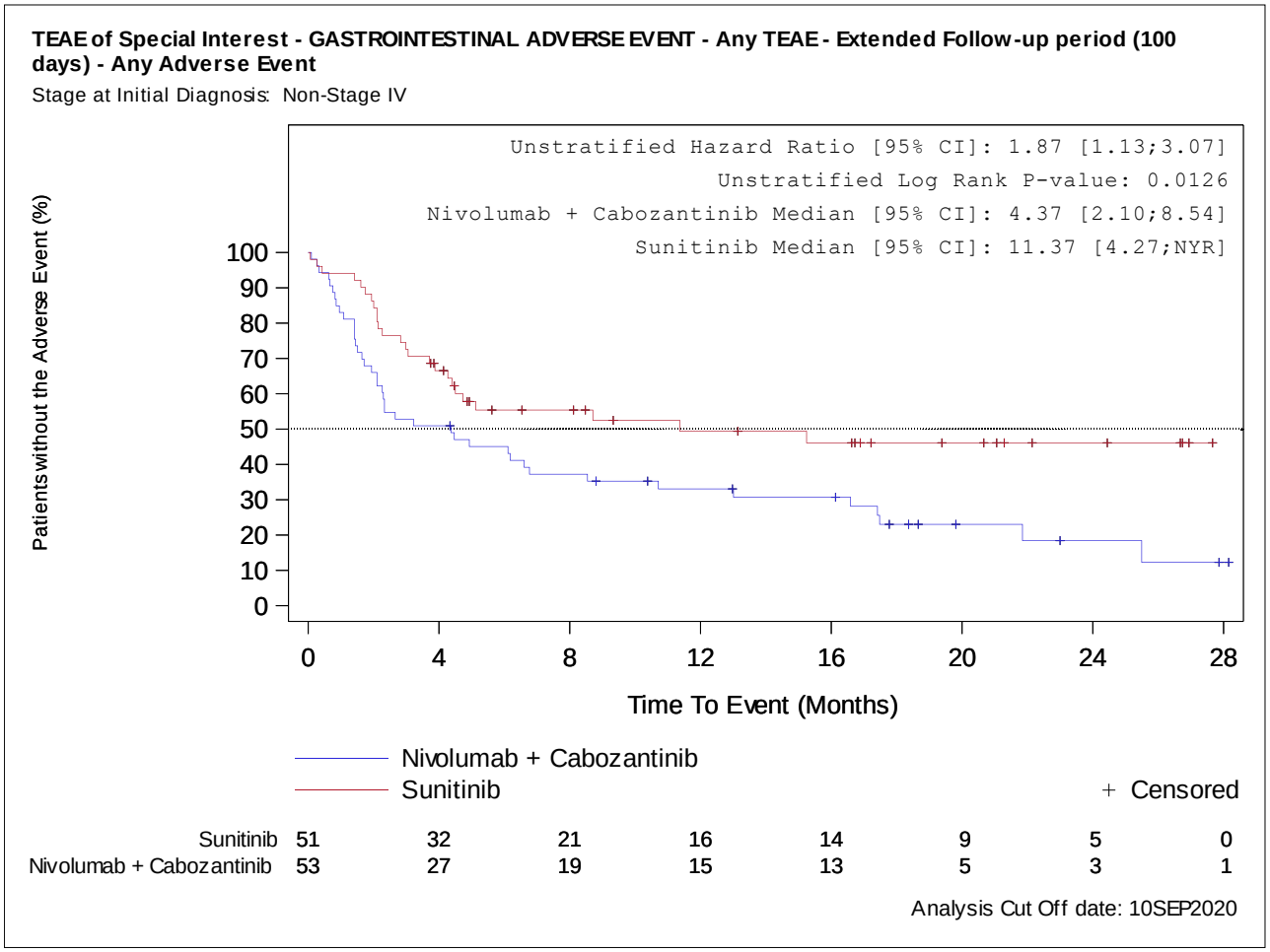
FIGURE 3.24.2.24: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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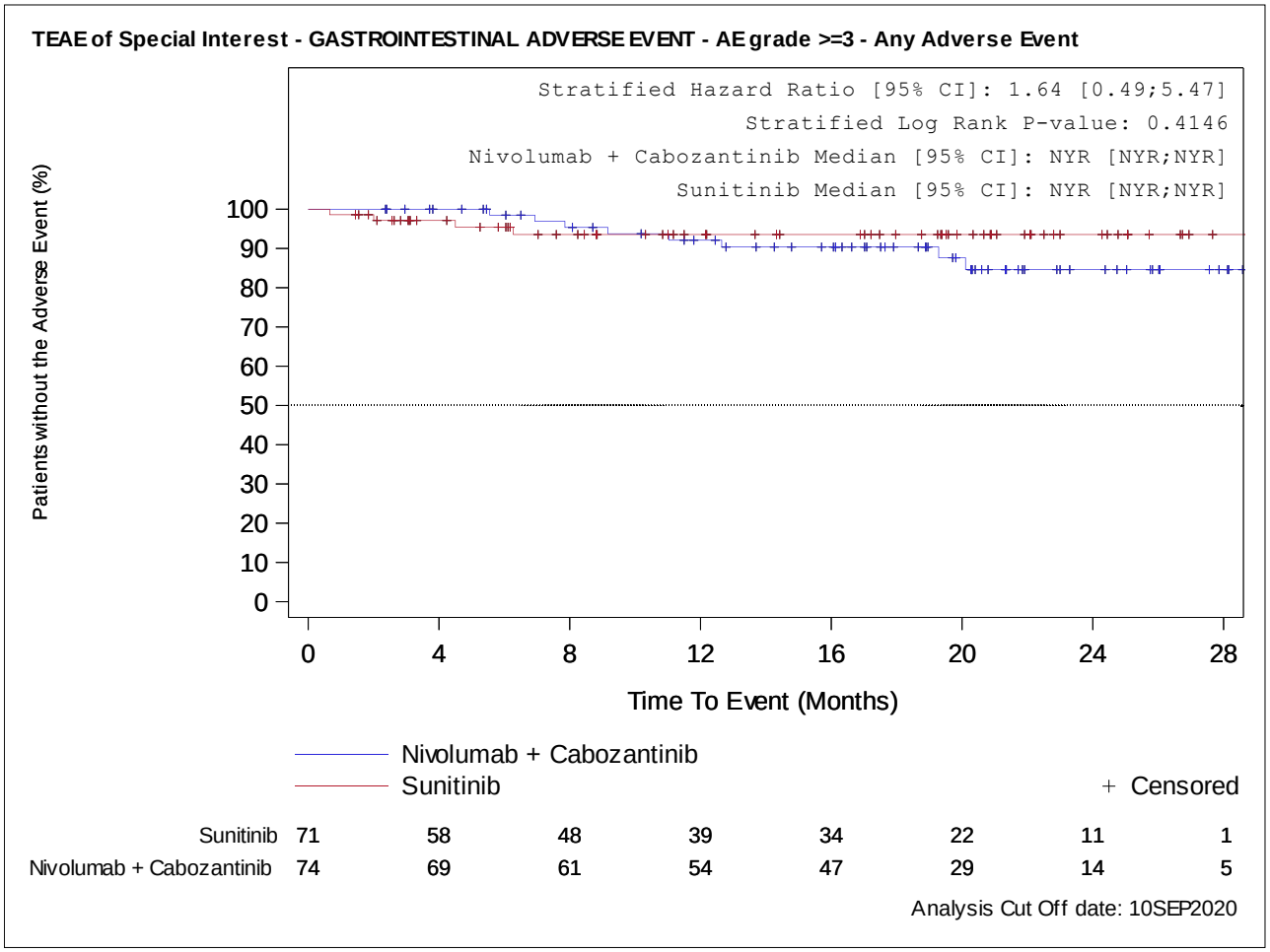
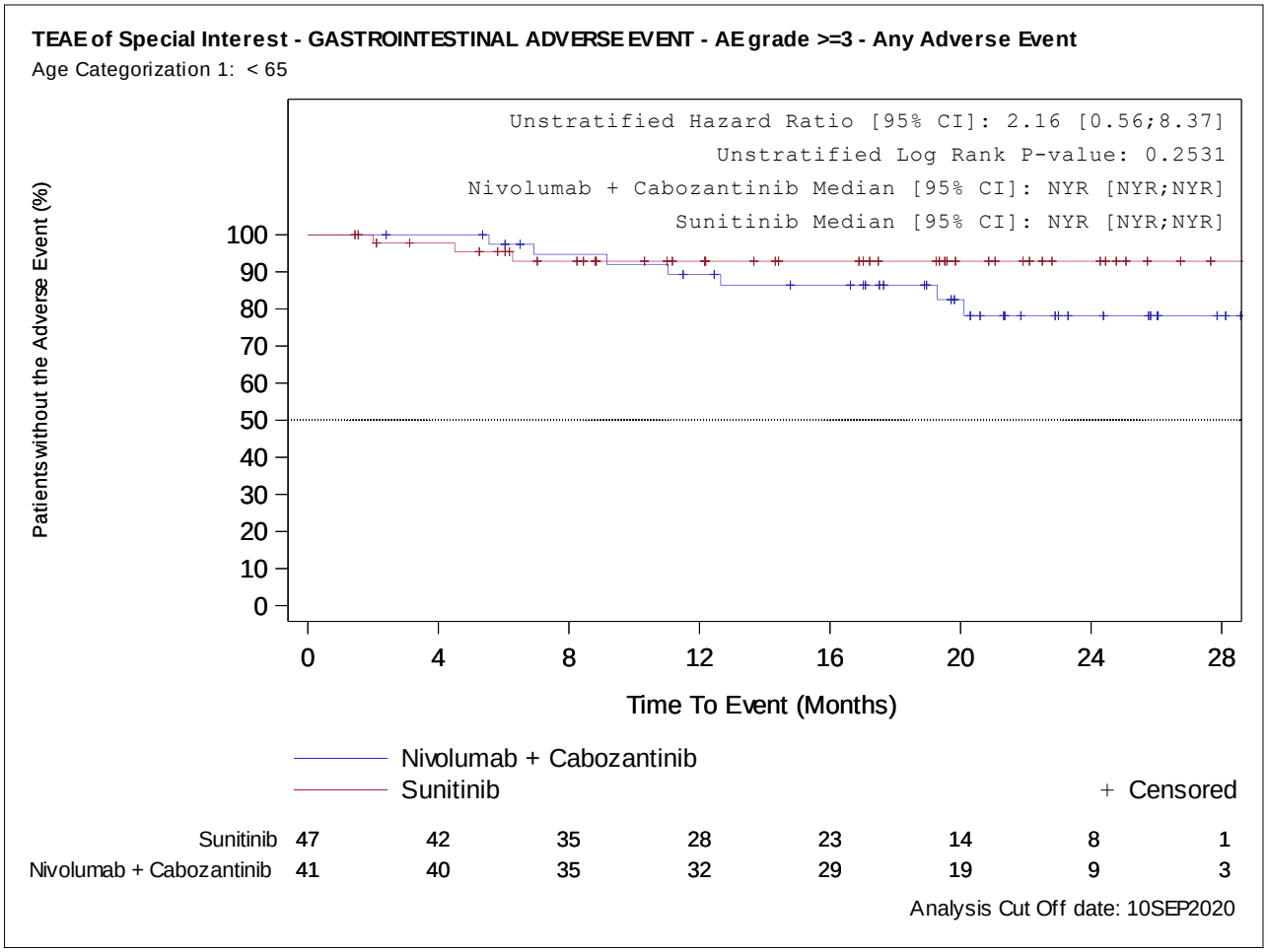
FIGURE 3.25.1: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:28:37

FIGURE 3.25.2.1: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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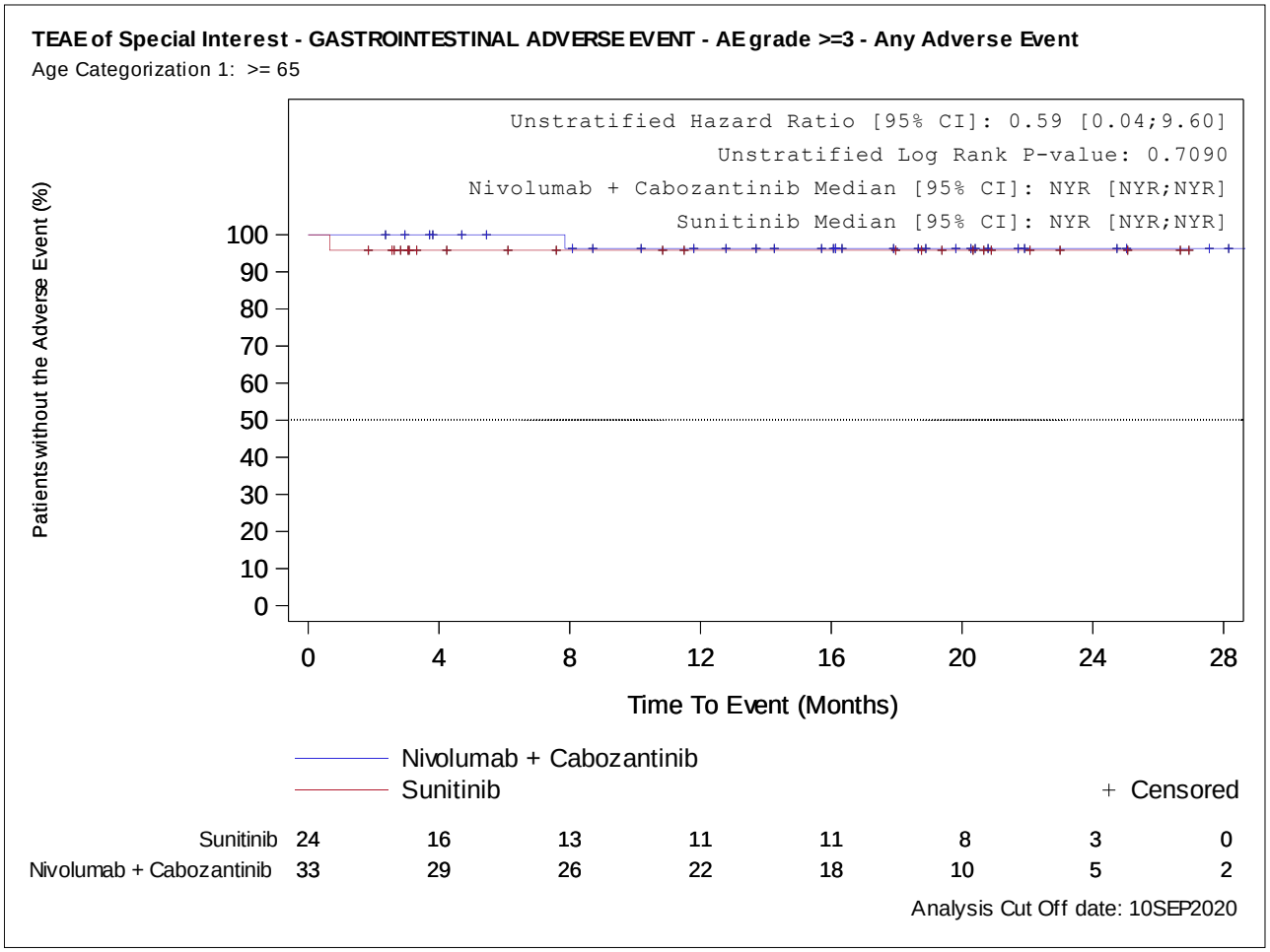
FIGURE 3.25.2.2: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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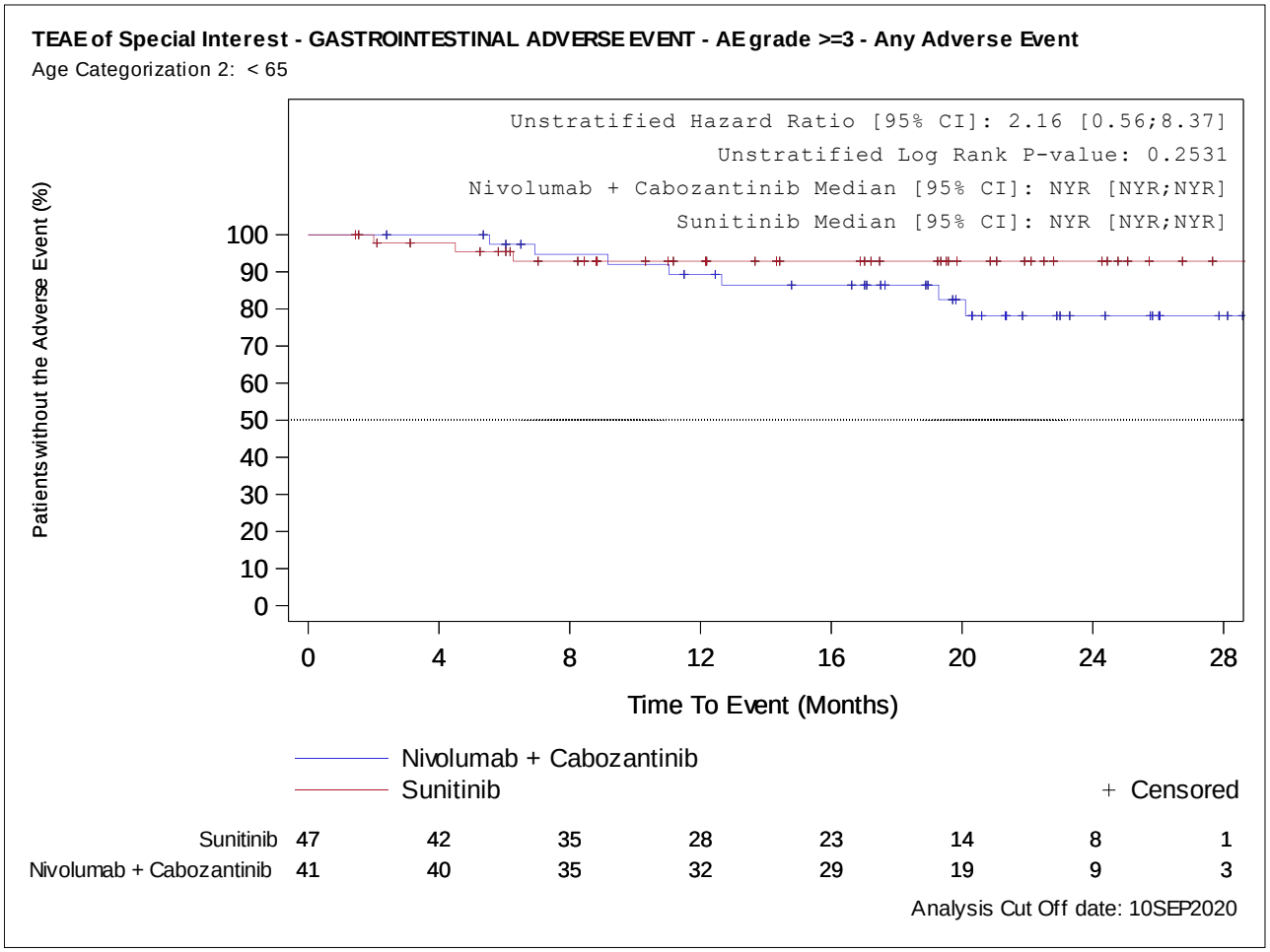
FIGURE 3.25.2.3: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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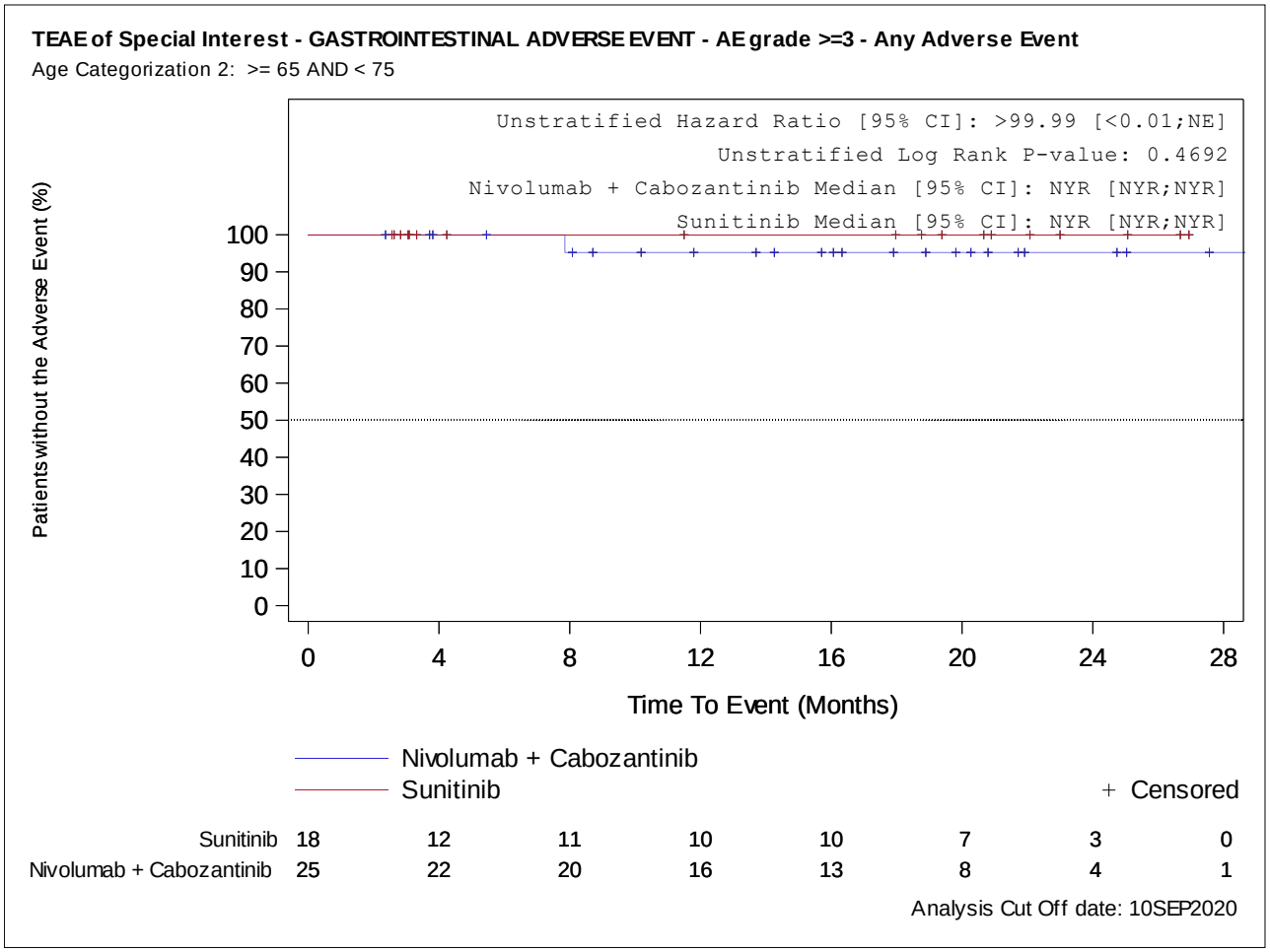
FIGURE 3.25.2.4: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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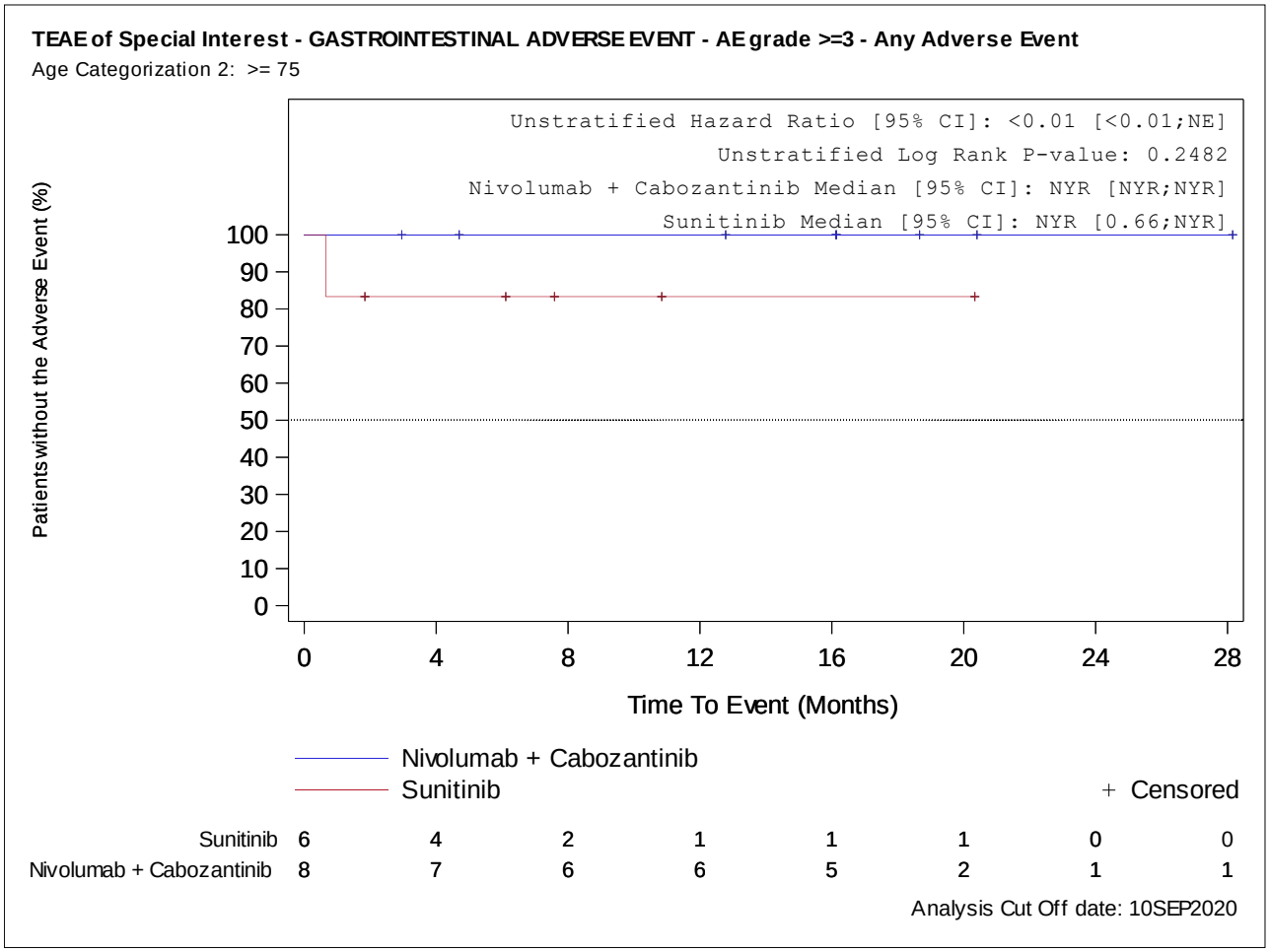
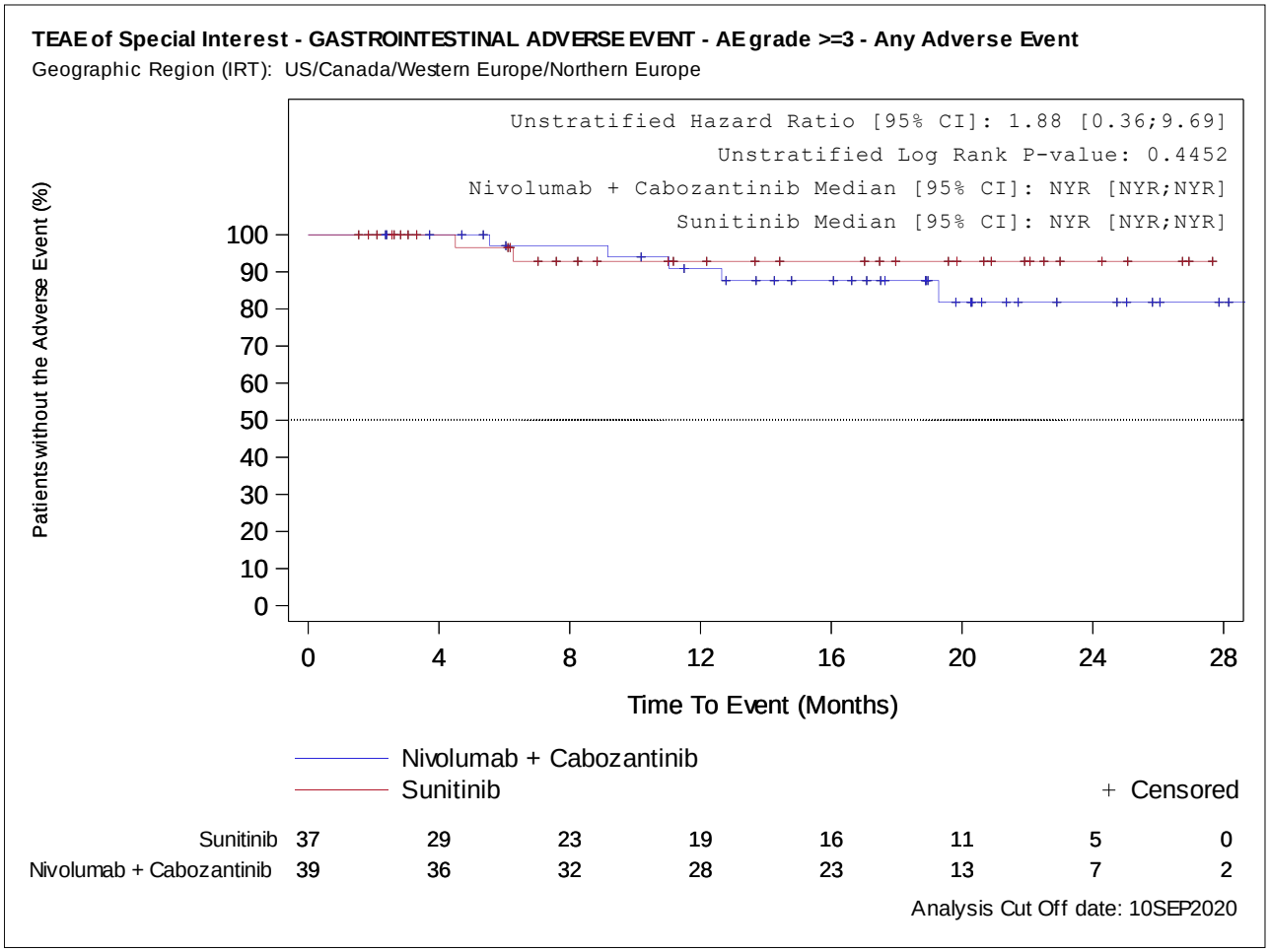
FIGURE 3.25.2.5: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



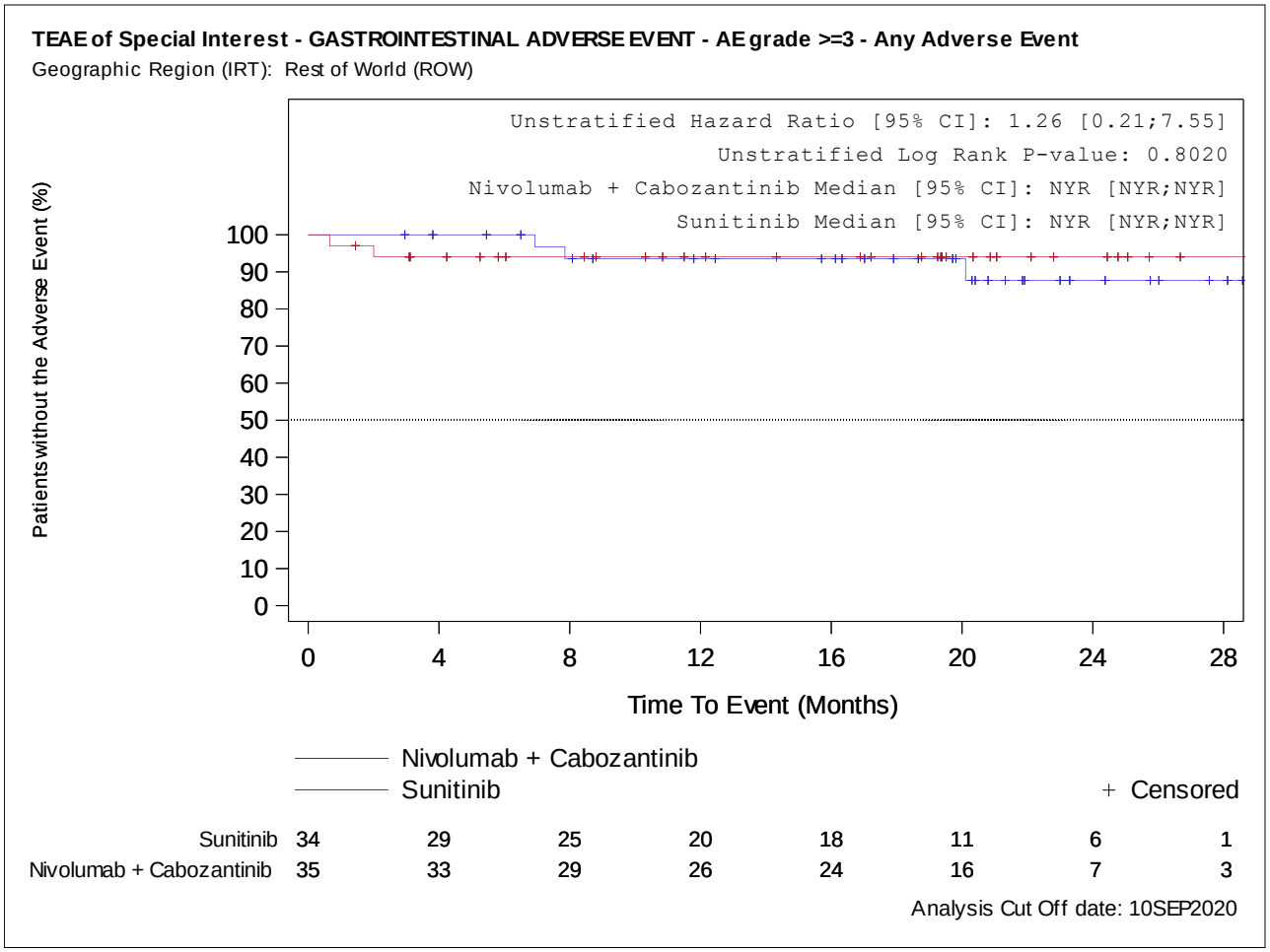

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:29:03

FIGURE 3.25.2.6: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



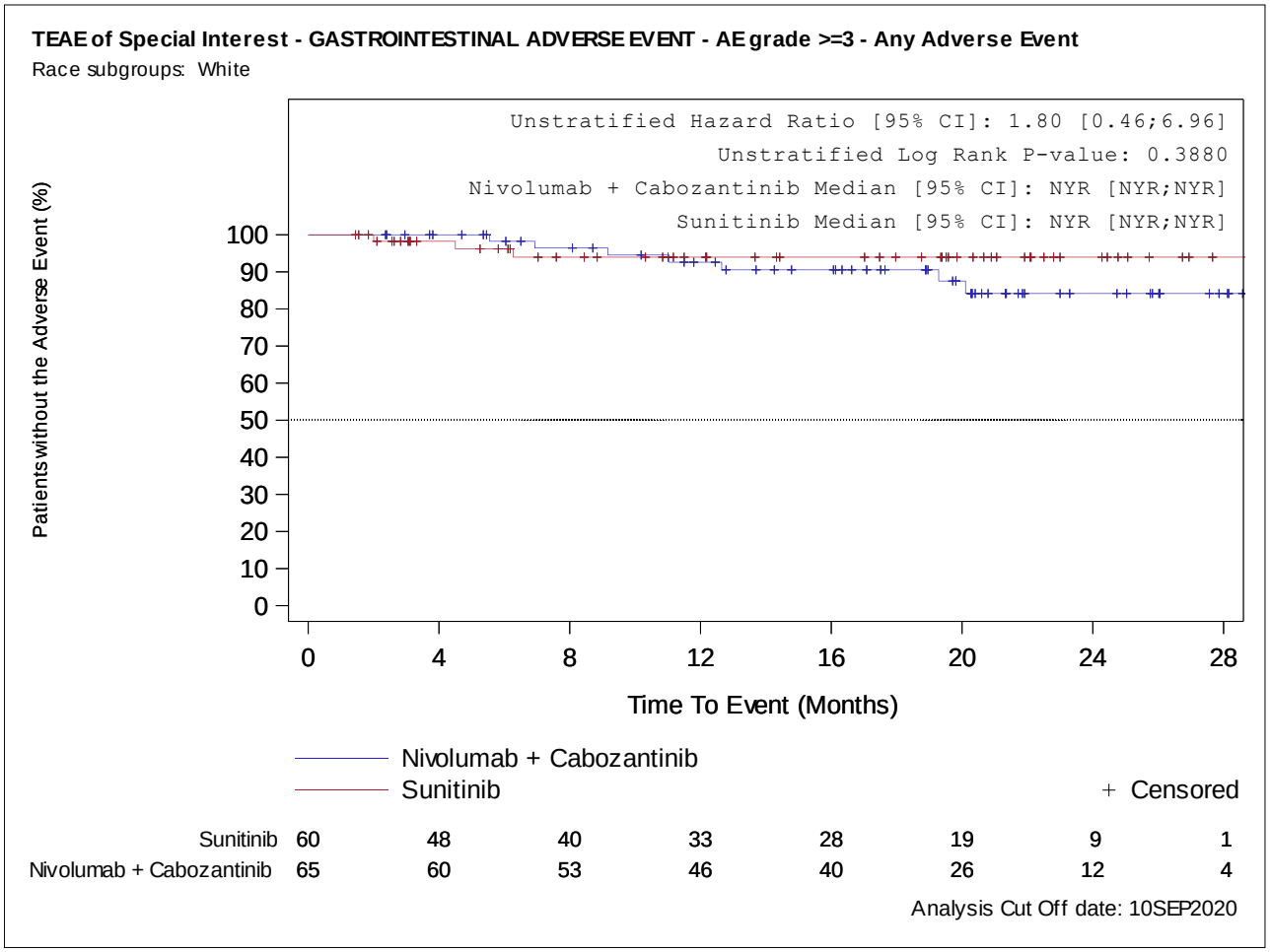

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:29:08

FIGURE 3.25.2.7: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



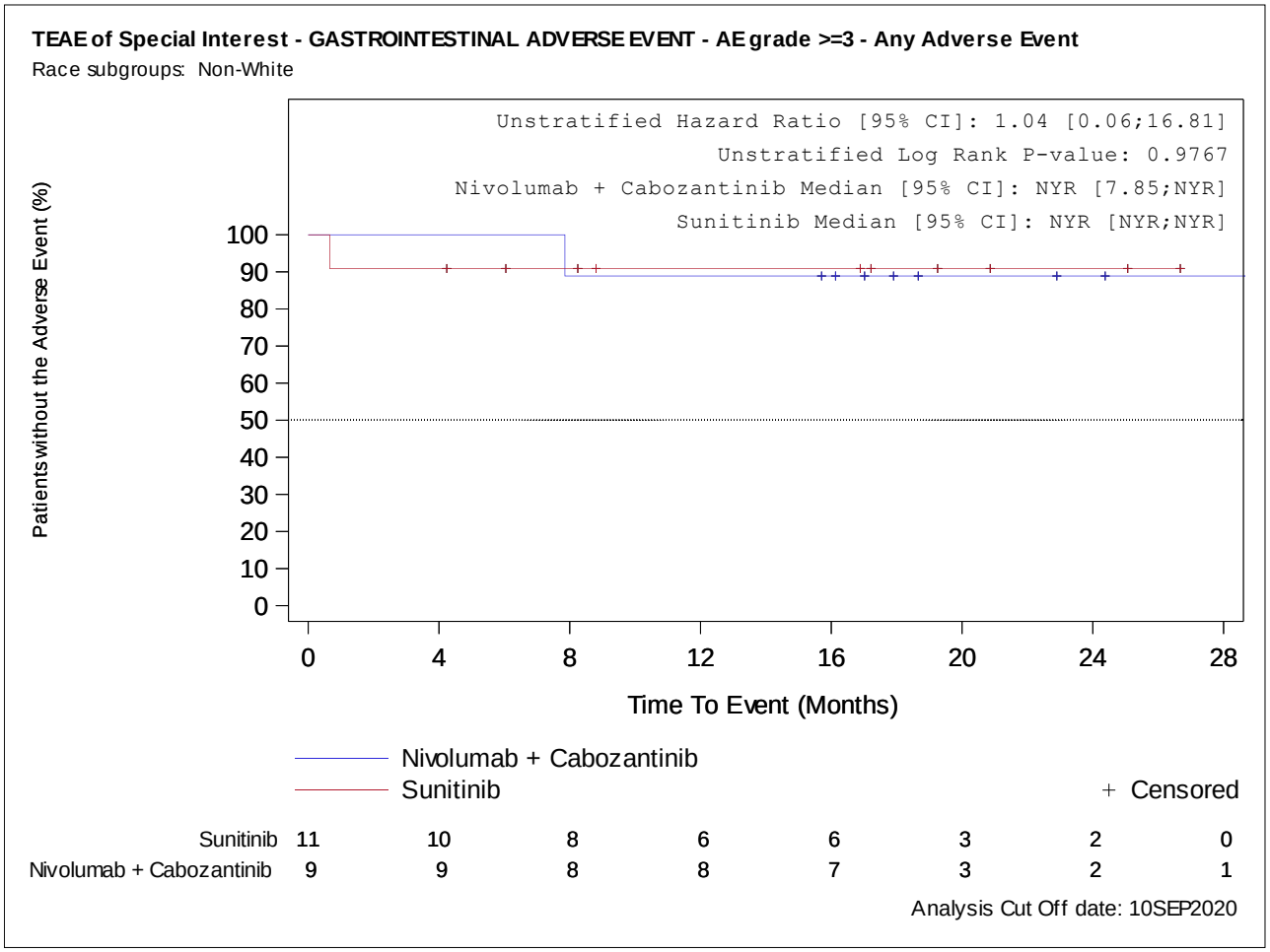

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:29:14

FIGURE 3.25.2.8: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



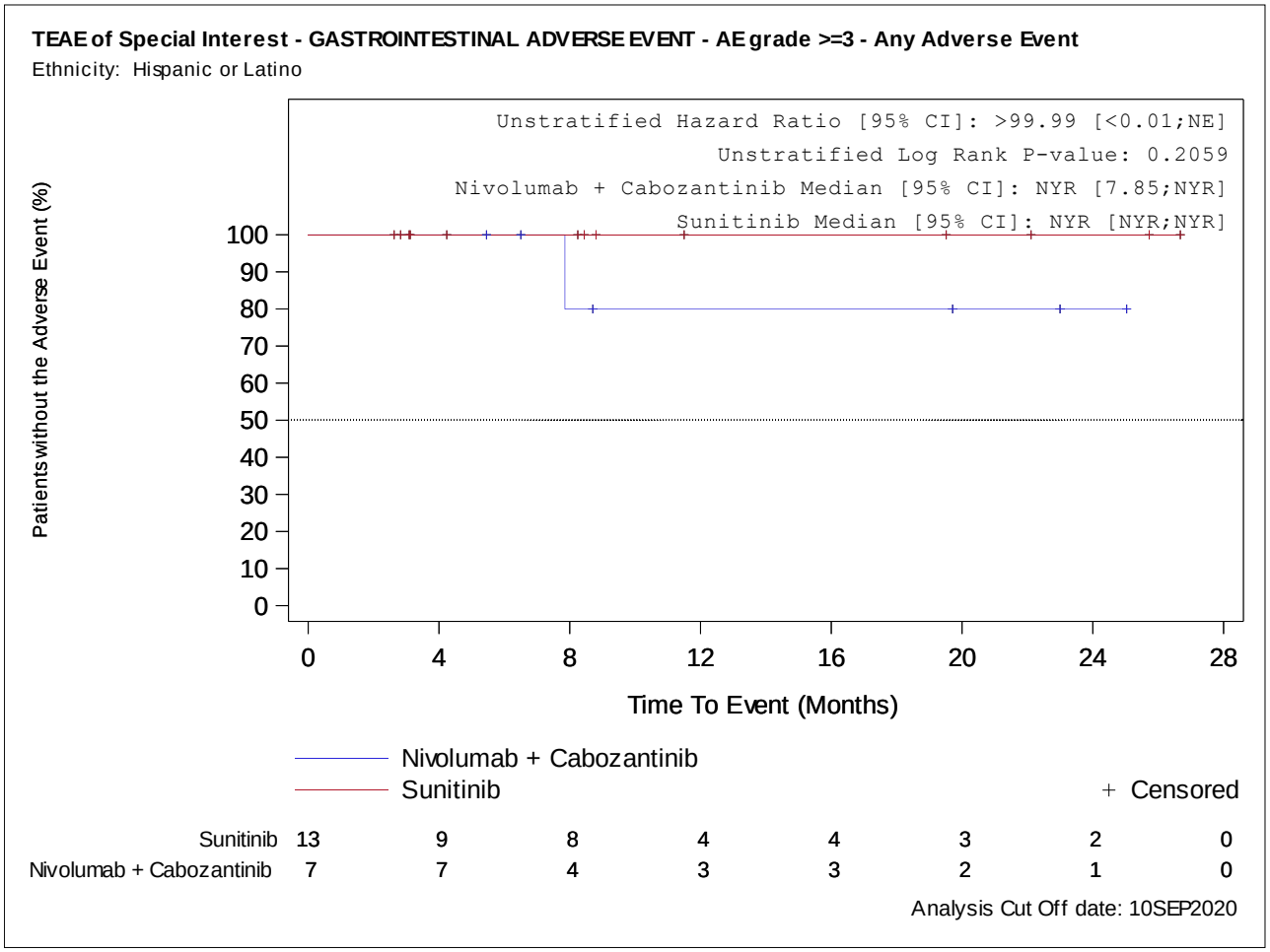

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:29:19

FIGURE 3.25.2.9: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



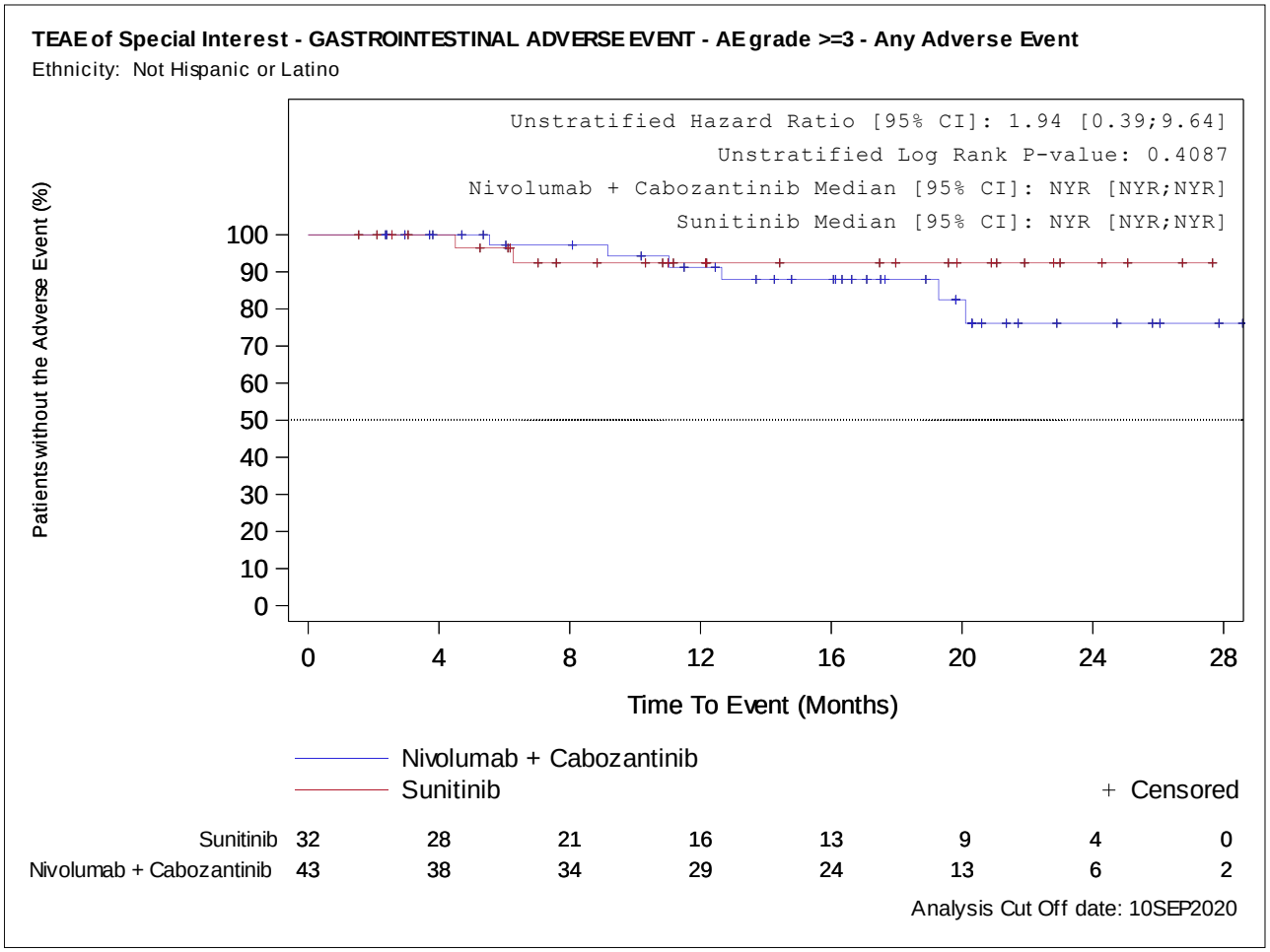

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:29:25

FIGURE 3.25.2.10: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



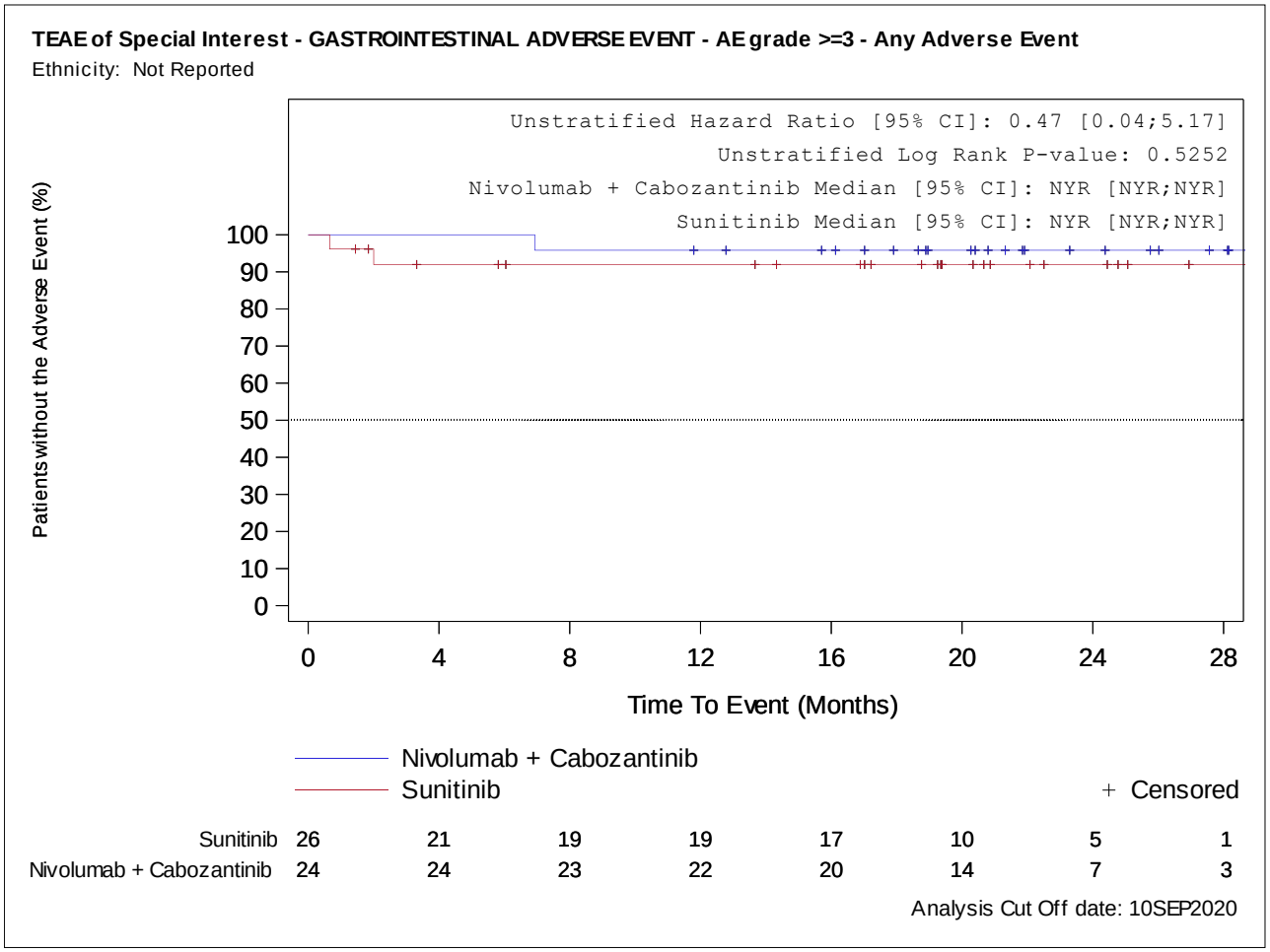

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:29:31

FIGURE 3.25.2.11: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:29:37

FIGURE 3.25.2.12: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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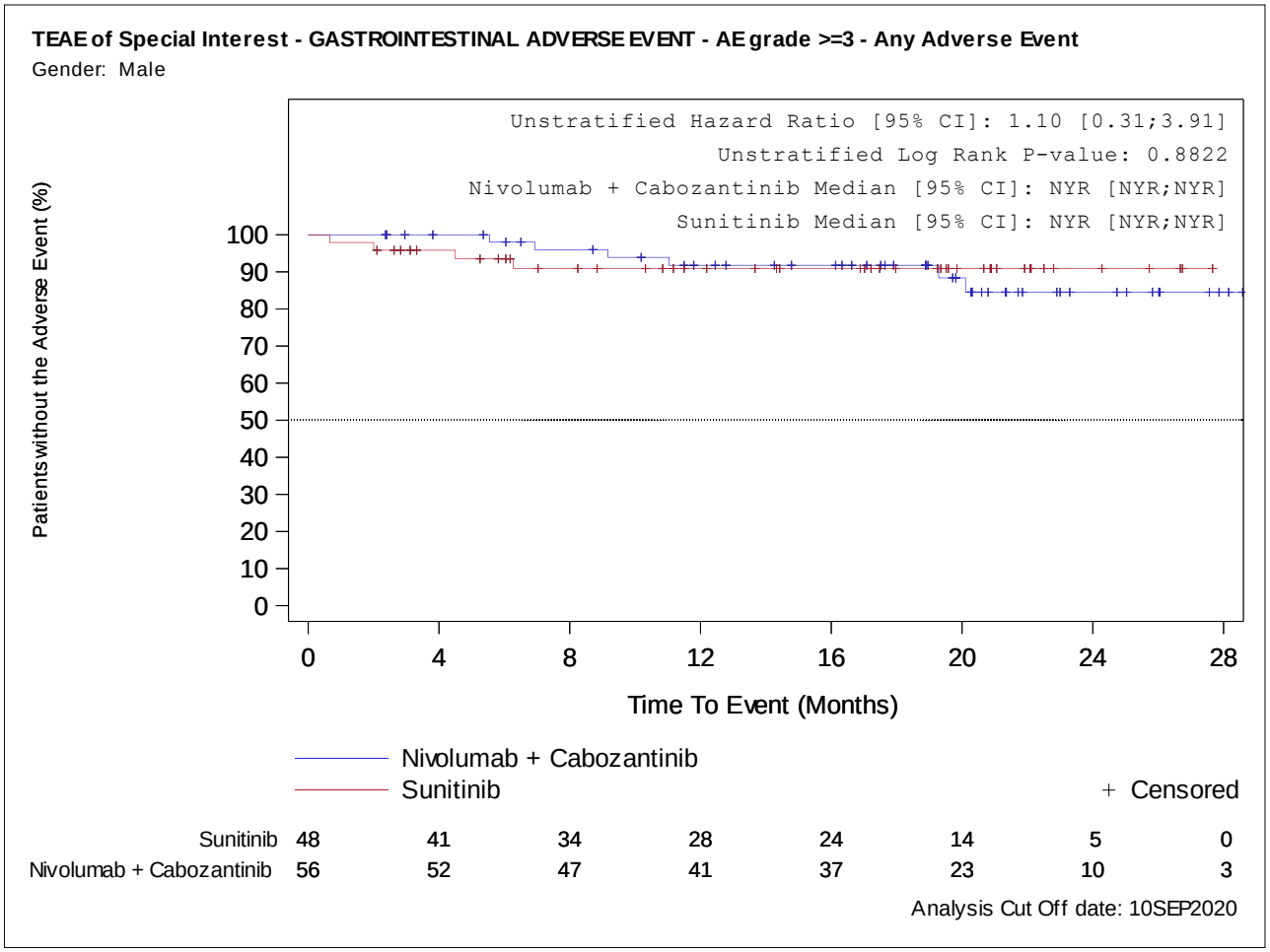
FIGURE 3.25.2.13: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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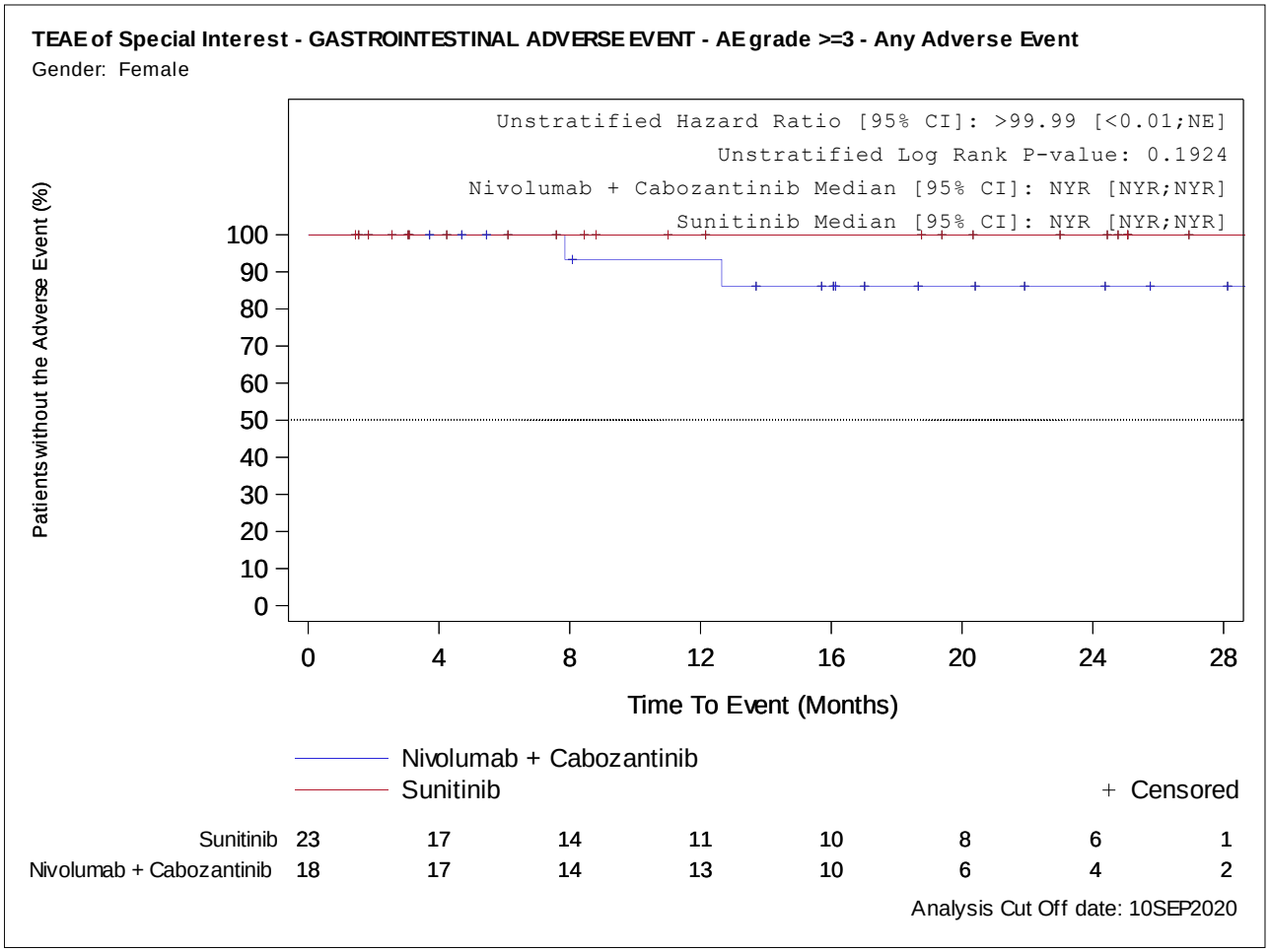
FIGURE 3.25.2.14: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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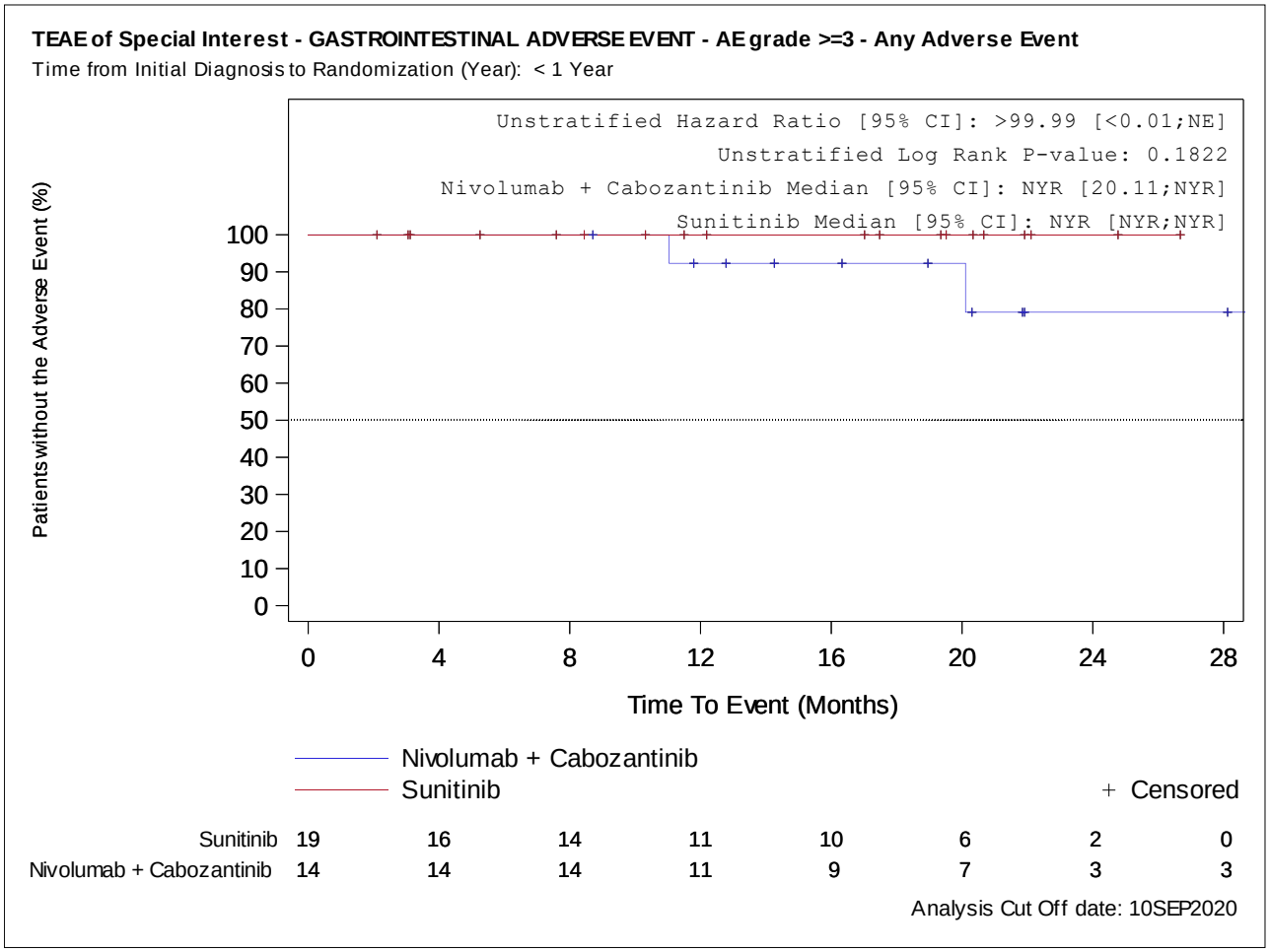
FIGURE 3.25.2.15: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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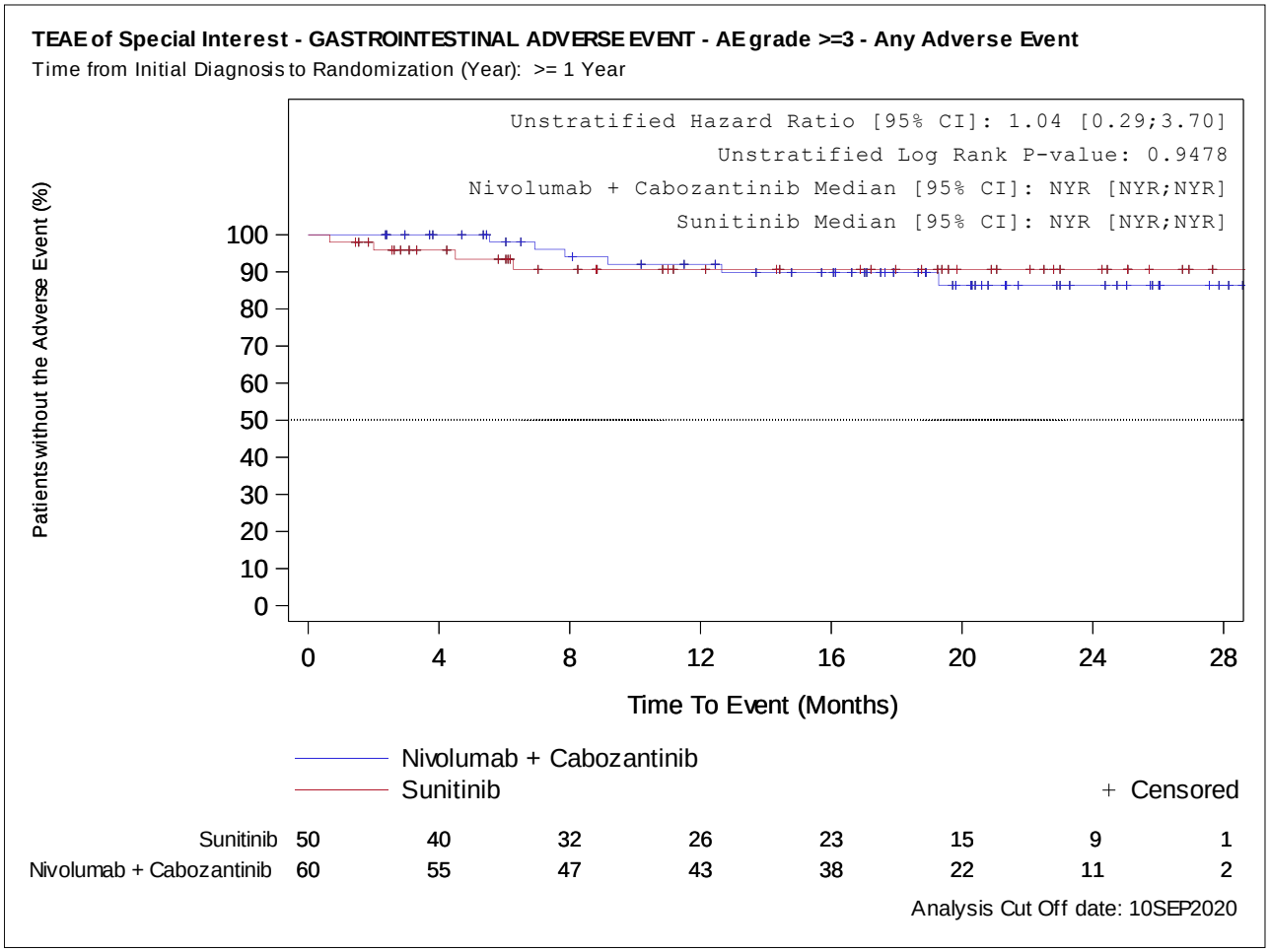
FIGURE 3.25.2.16: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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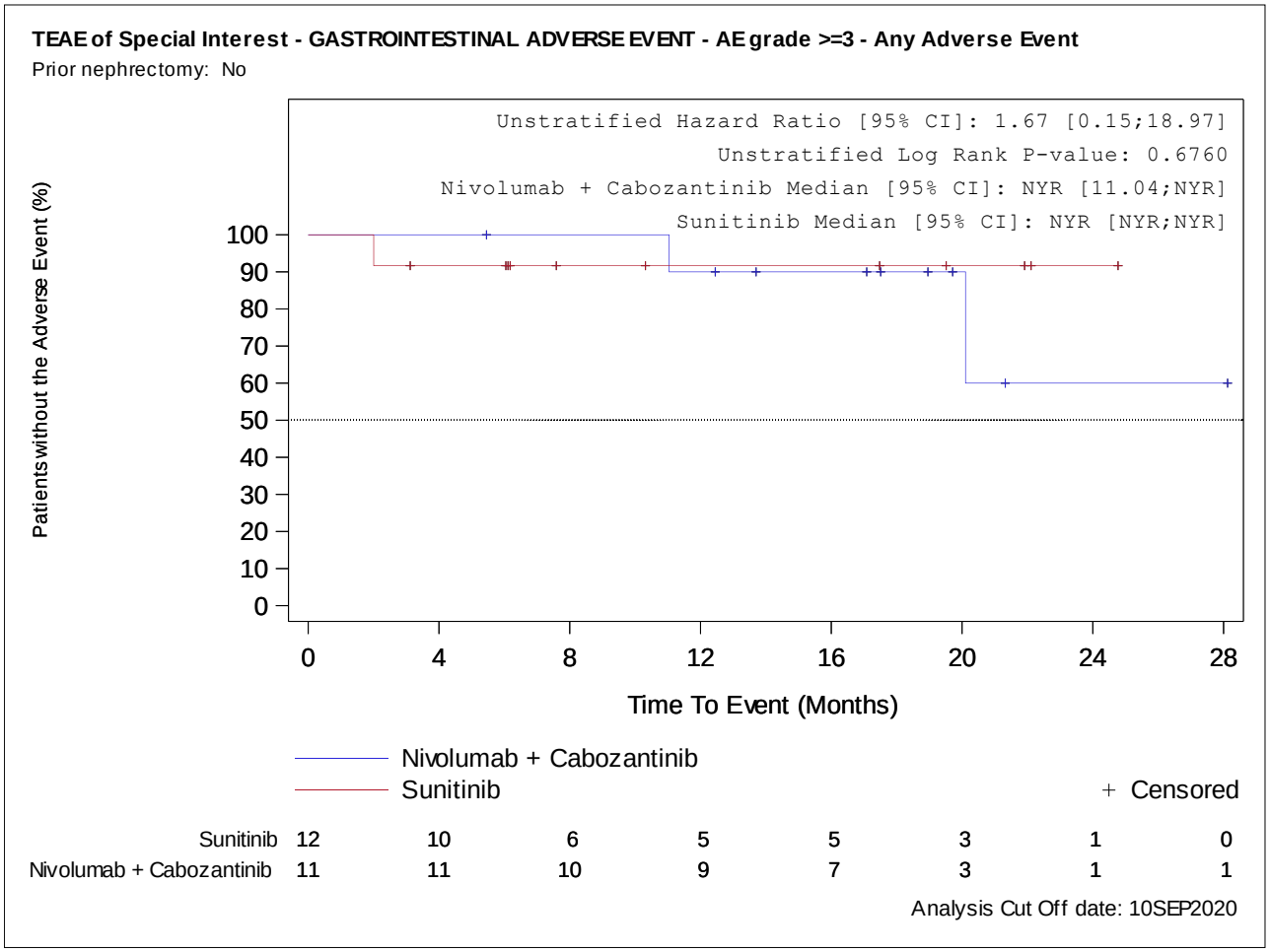
FIGURE 3.25.2.17: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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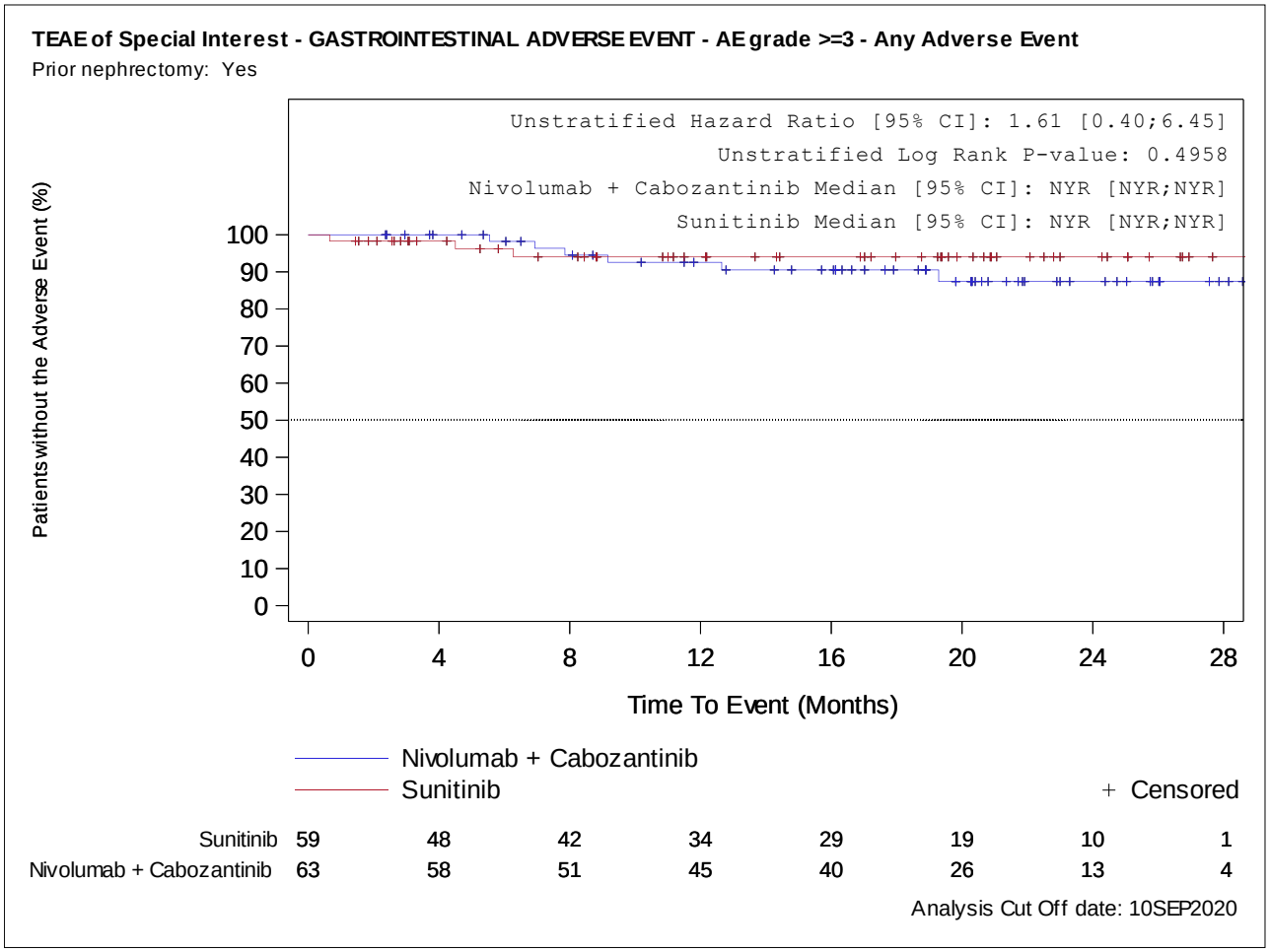
FIGURE 3.25.2.18: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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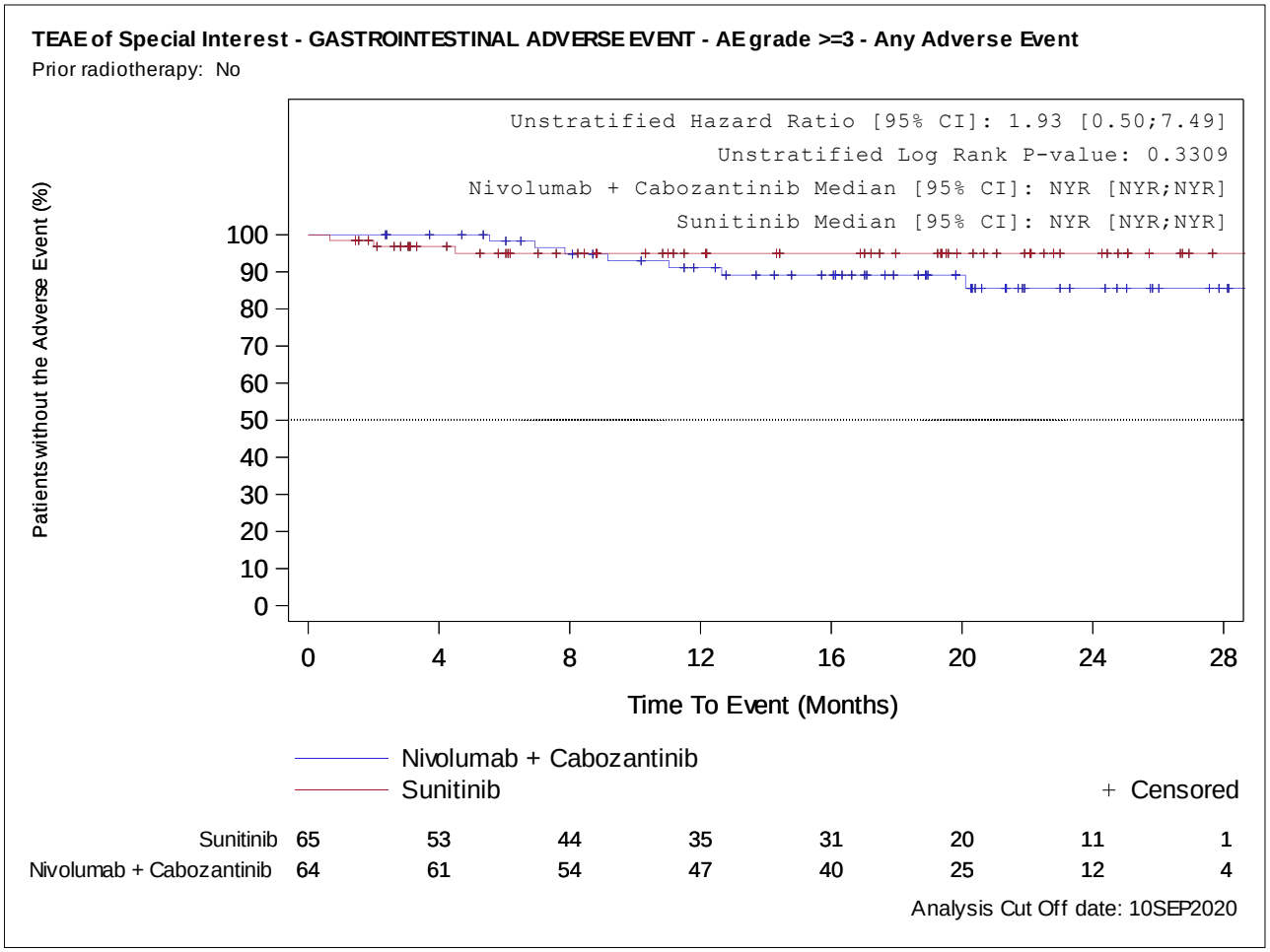
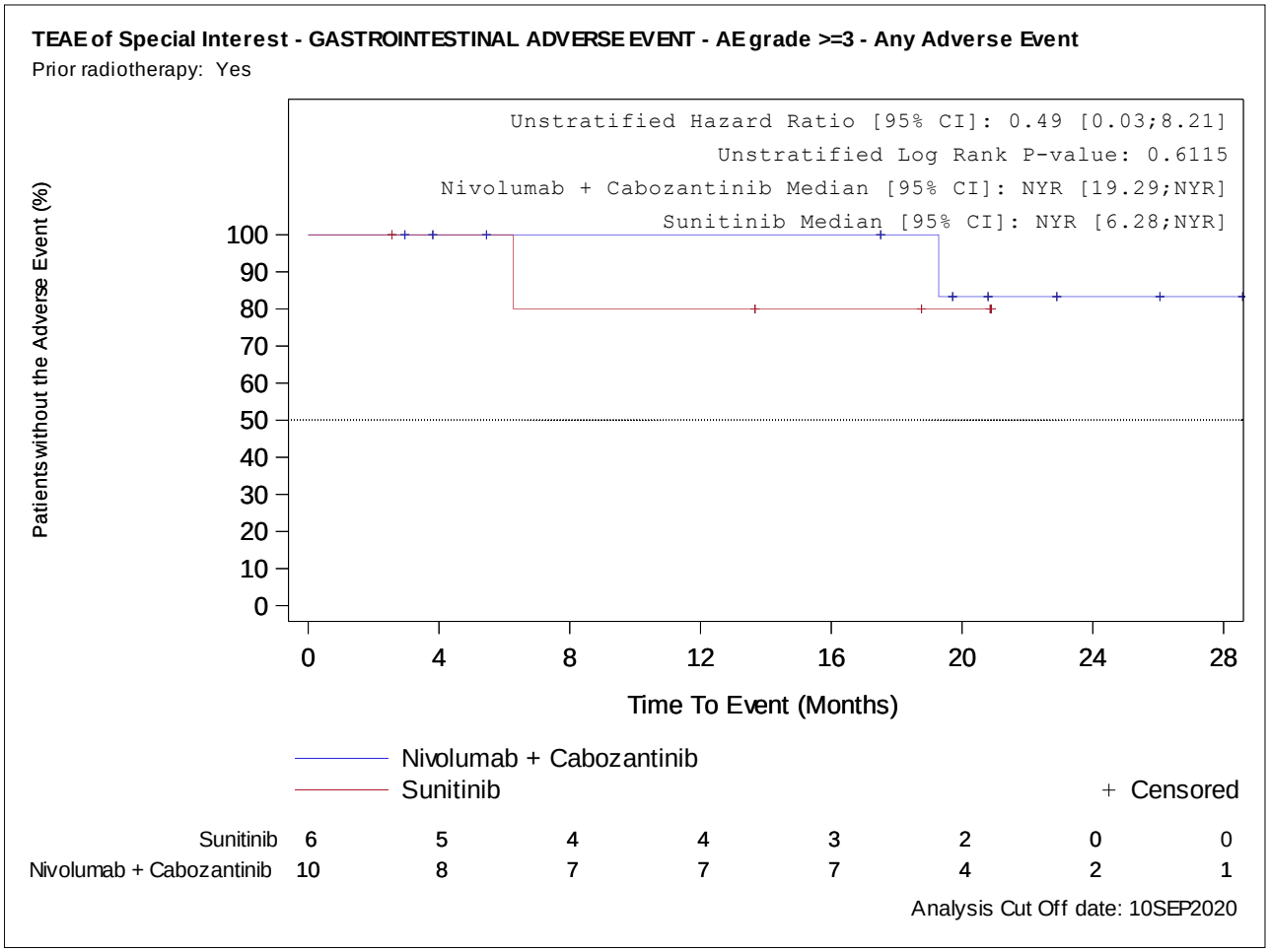
FIGURE 3.25.2.19: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



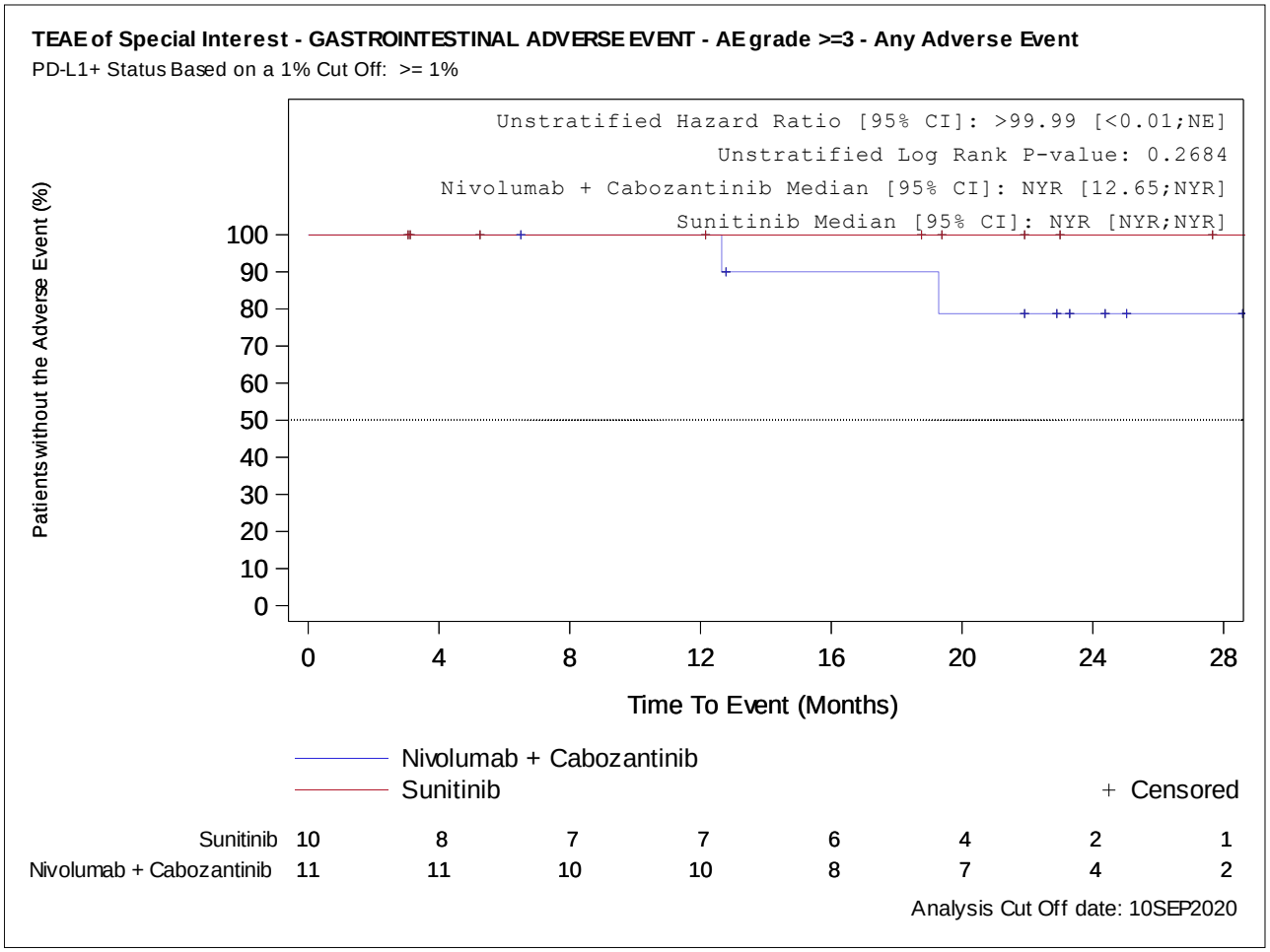

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:31:22

FIGURE 3.25.2.20: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



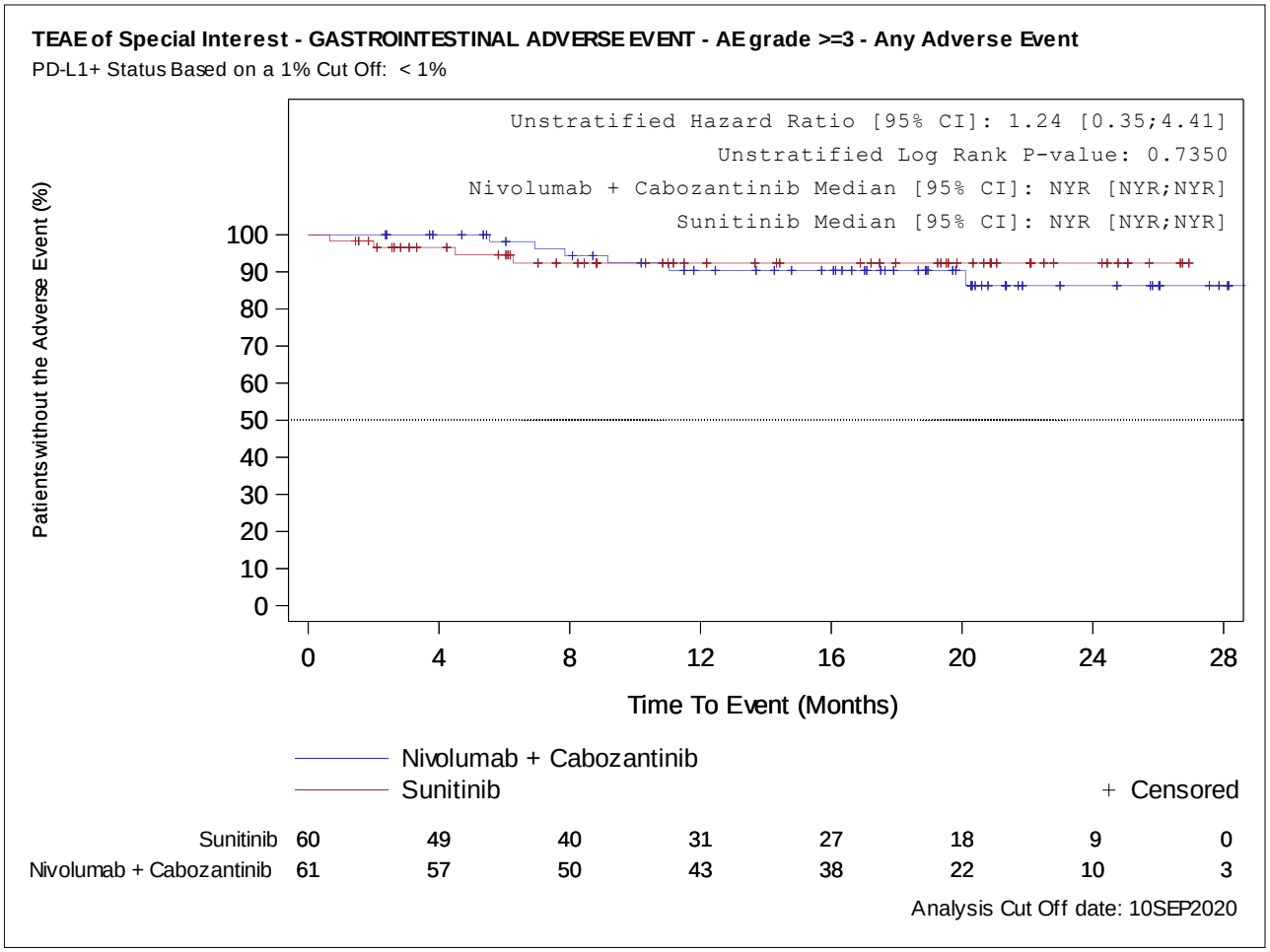

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:31:28

FIGURE 3.25.2.21: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



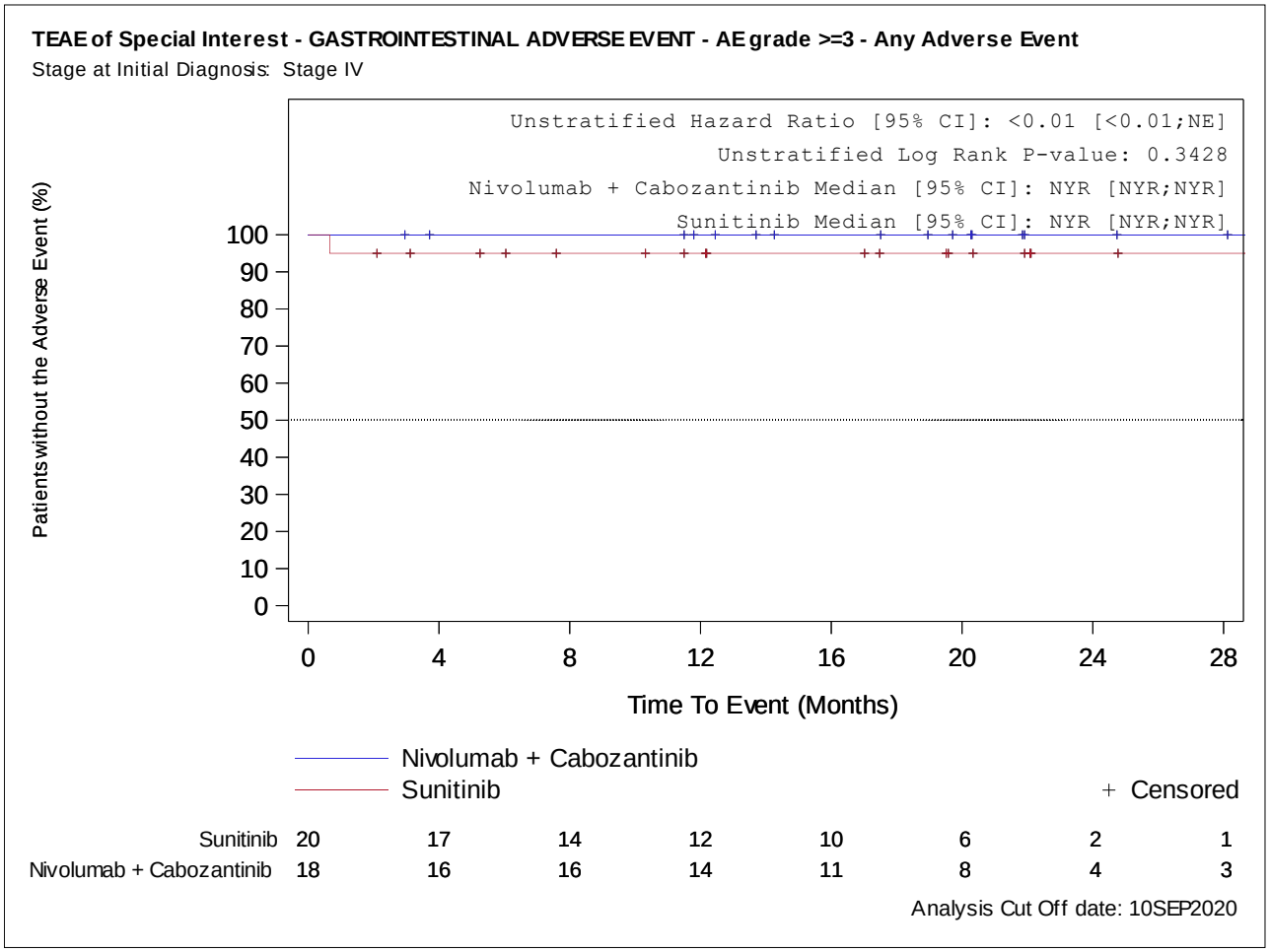

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:31:34

FIGURE 3.25.2.22: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



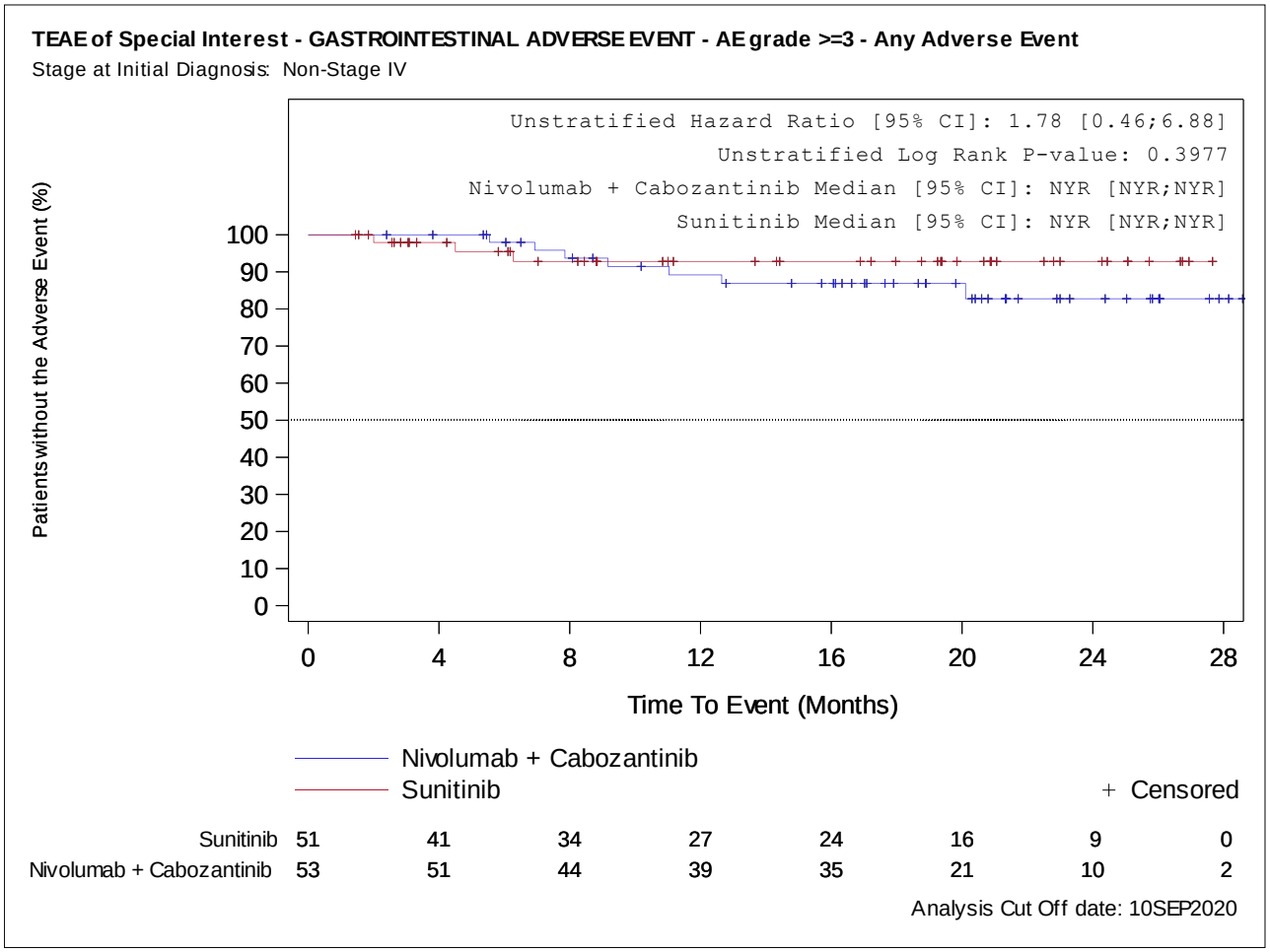

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:31:41

FIGURE 3.25.2.23: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



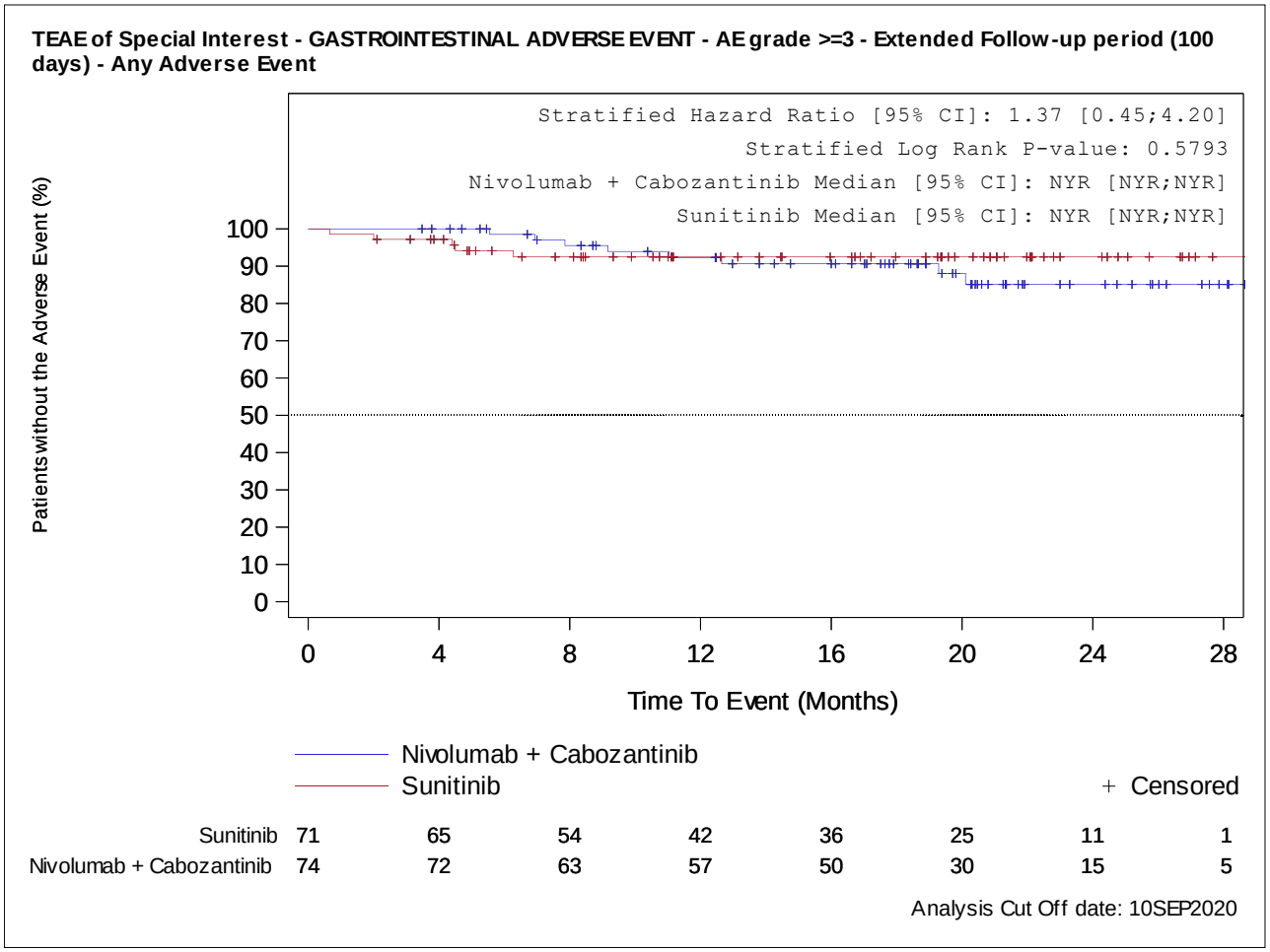

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:32:11

FIGURE 3.25.2.24: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



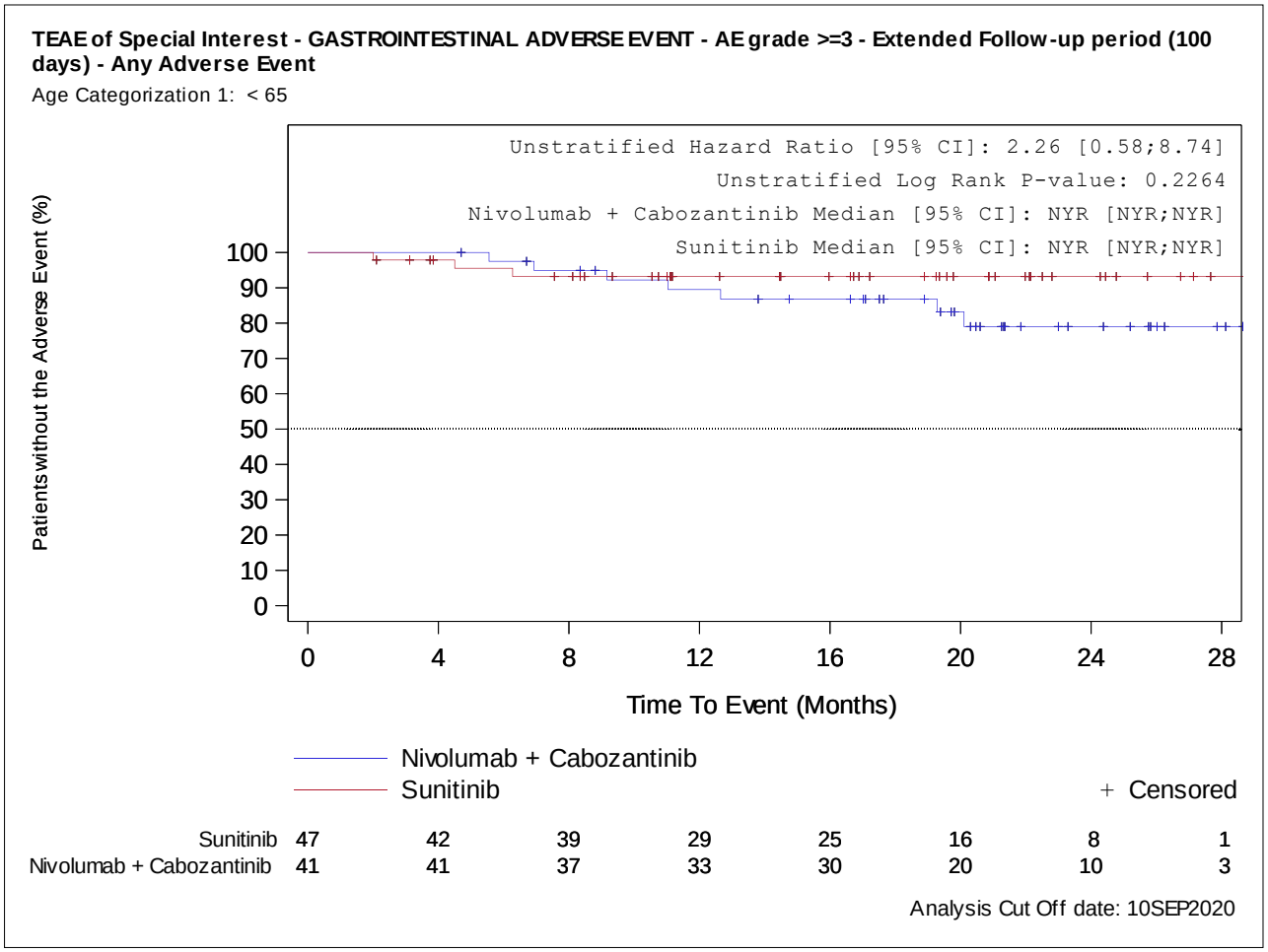

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:32:17

FIGURE 3.26.1: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



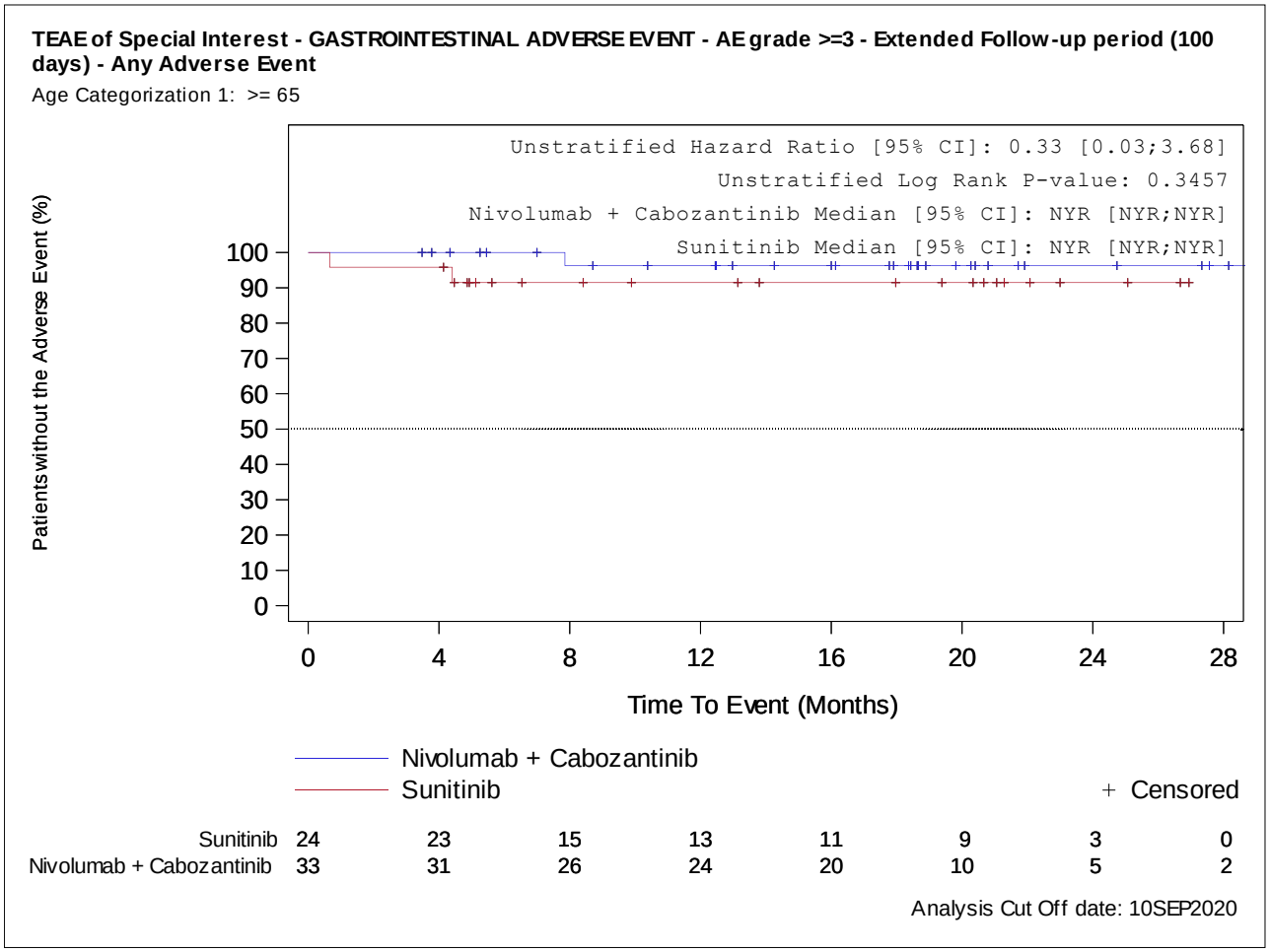

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:35:30

FIGURE 3.26.2.1: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



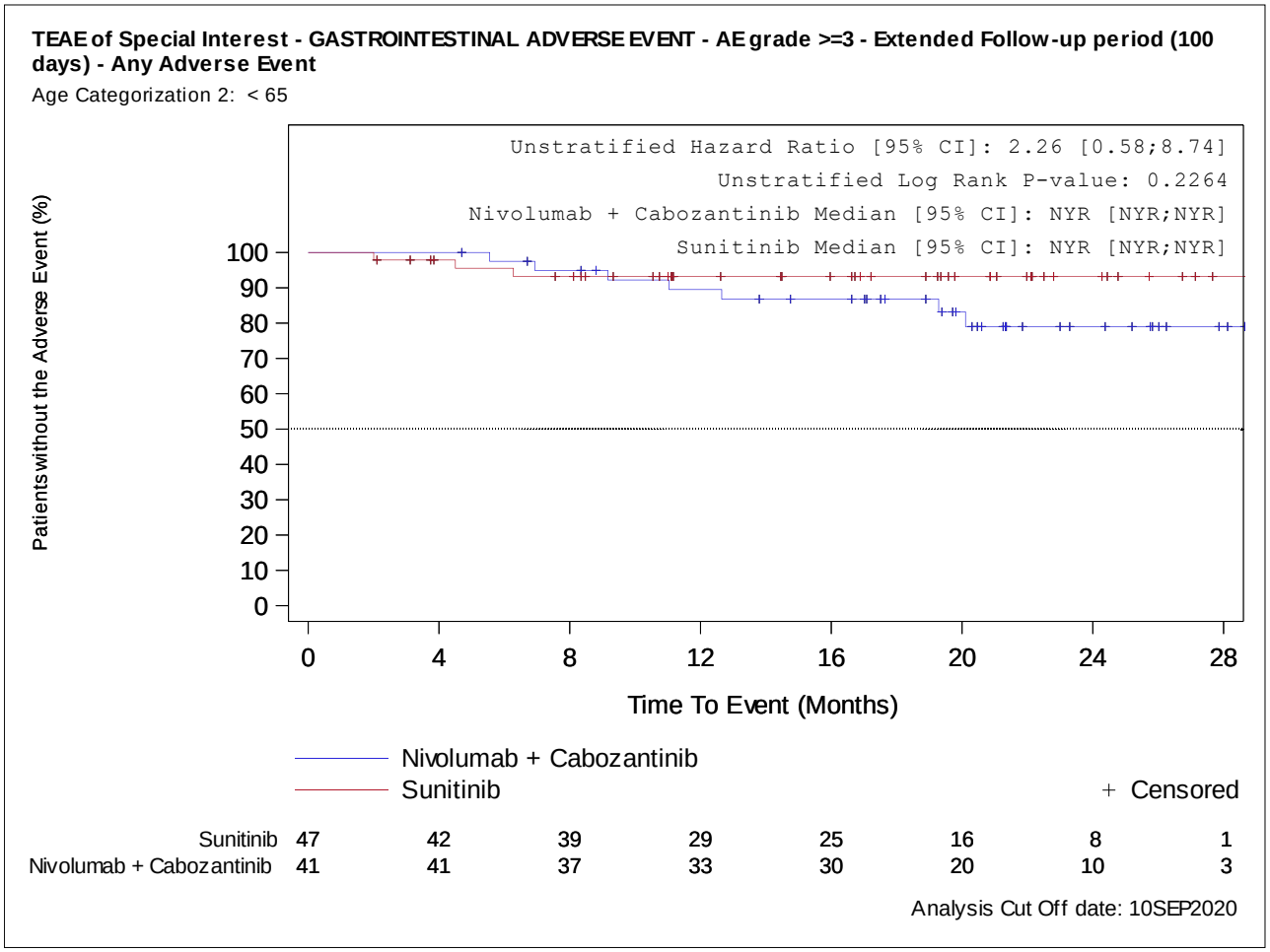

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:35:33

FIGURE 3.26.2.2: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



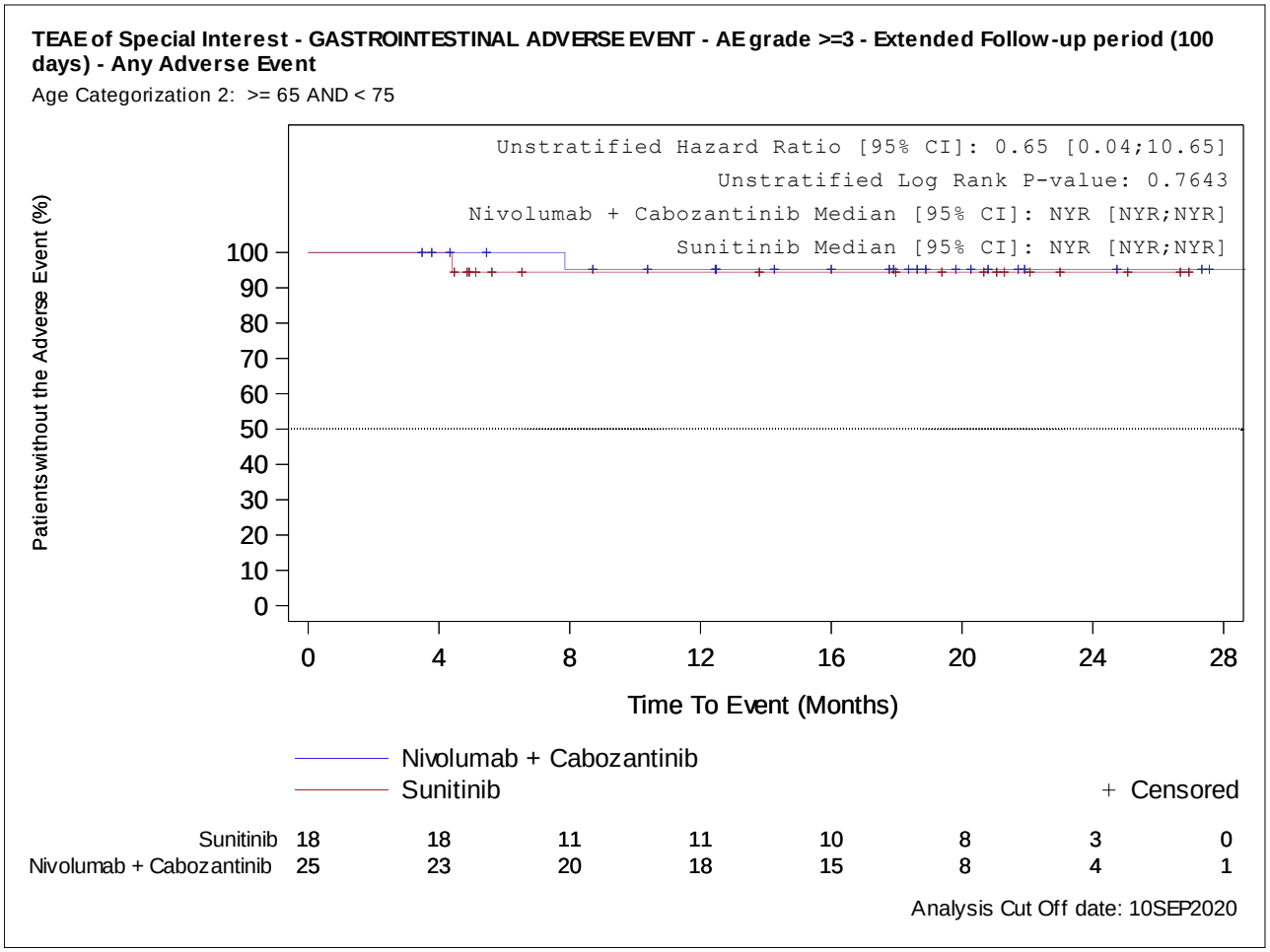

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:35:39

FIGURE 3.26.2.3: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



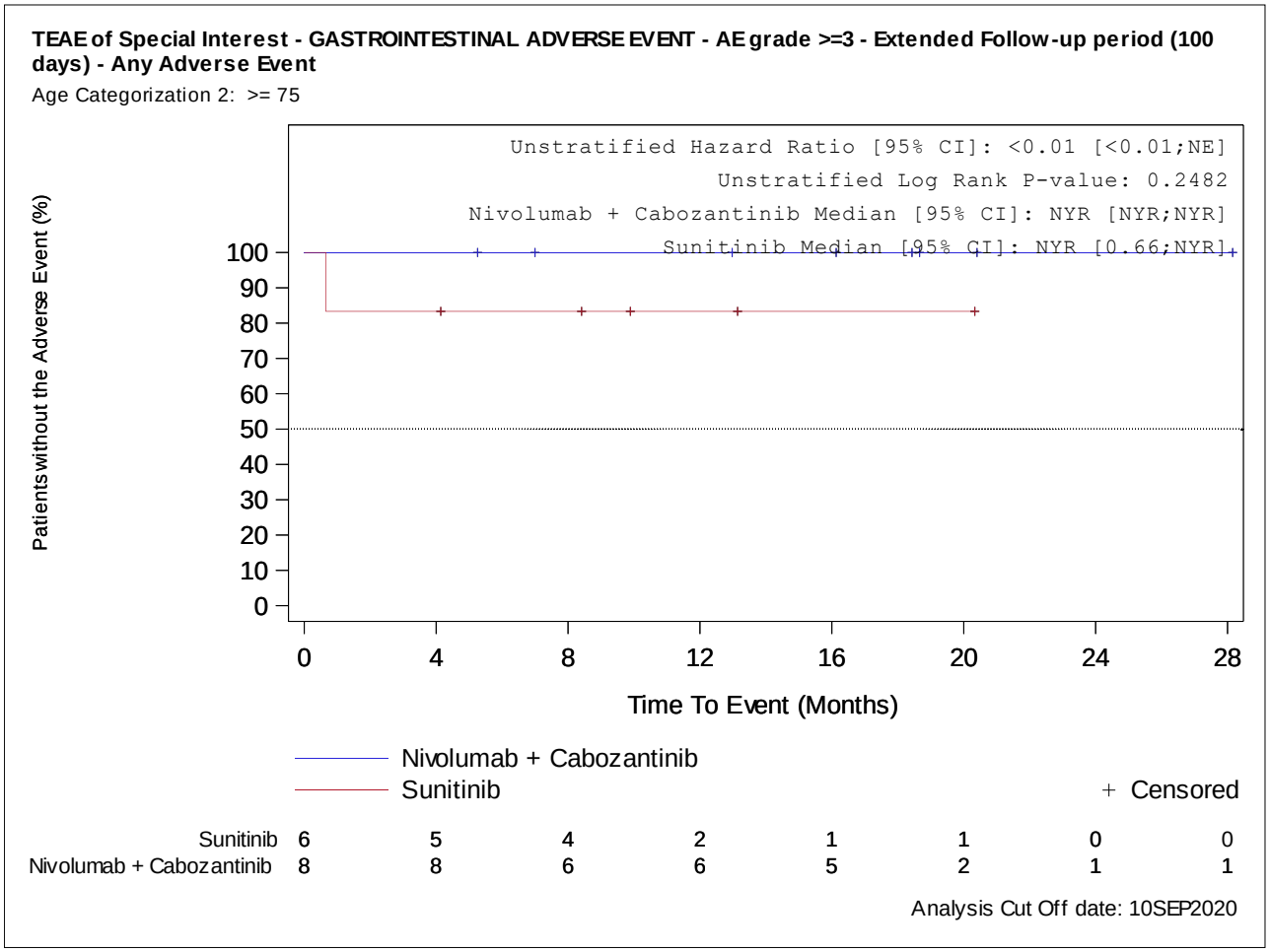

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:35:45

FIGURE 3.26.2.4: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



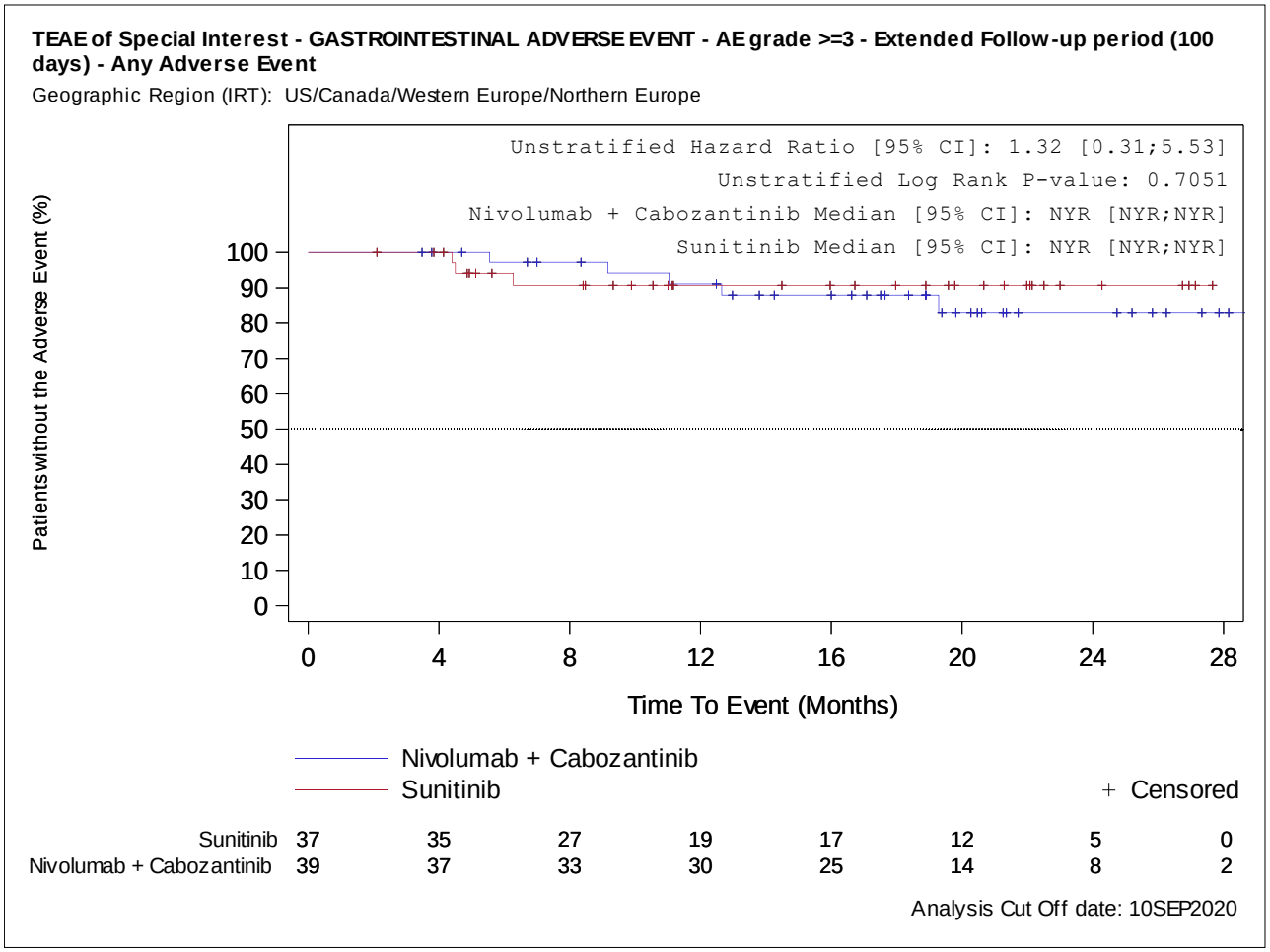

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:35:51

FIGURE 3.26.2.5: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



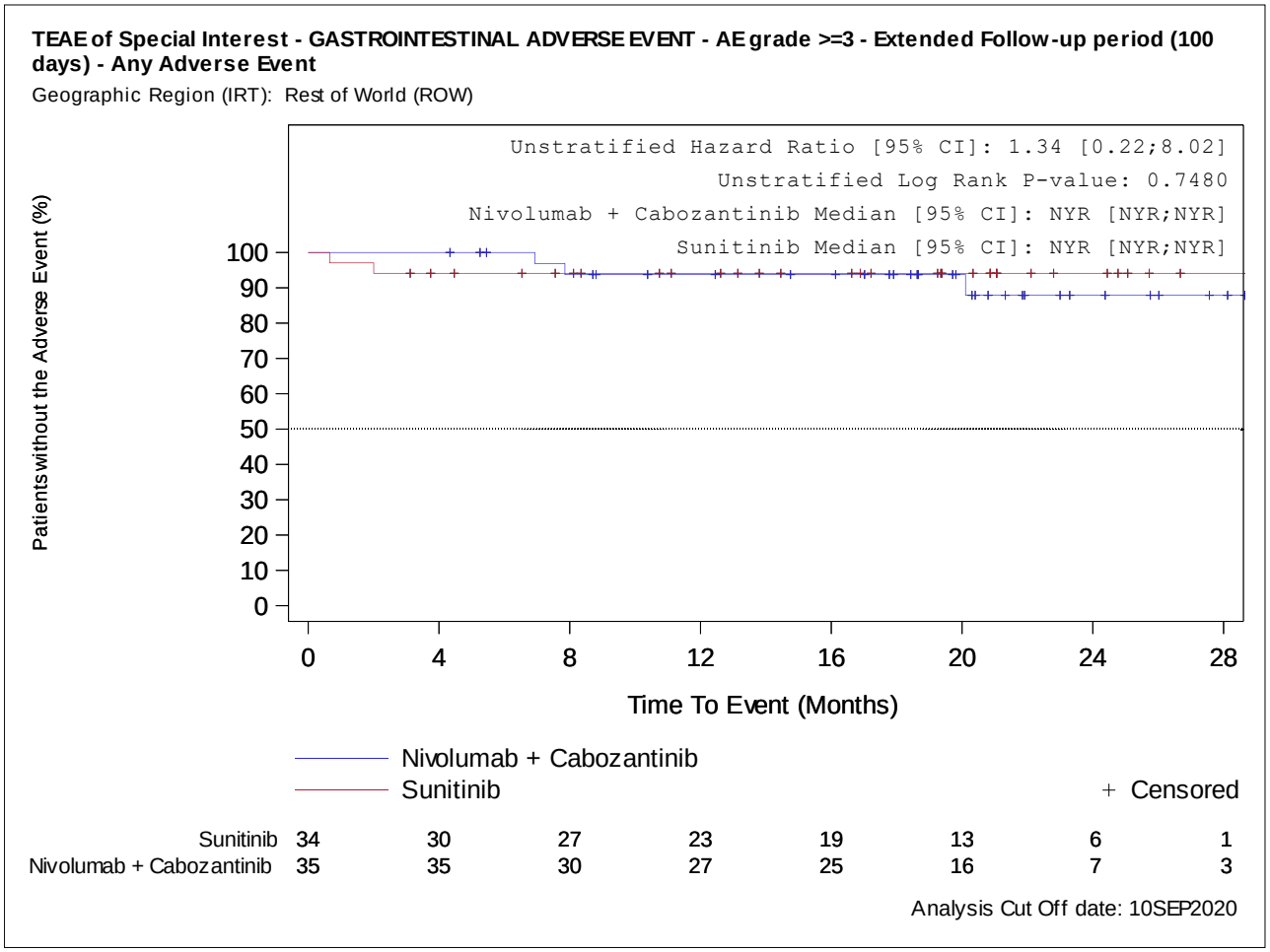

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:35:57

FIGURE 3.26.2.6: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



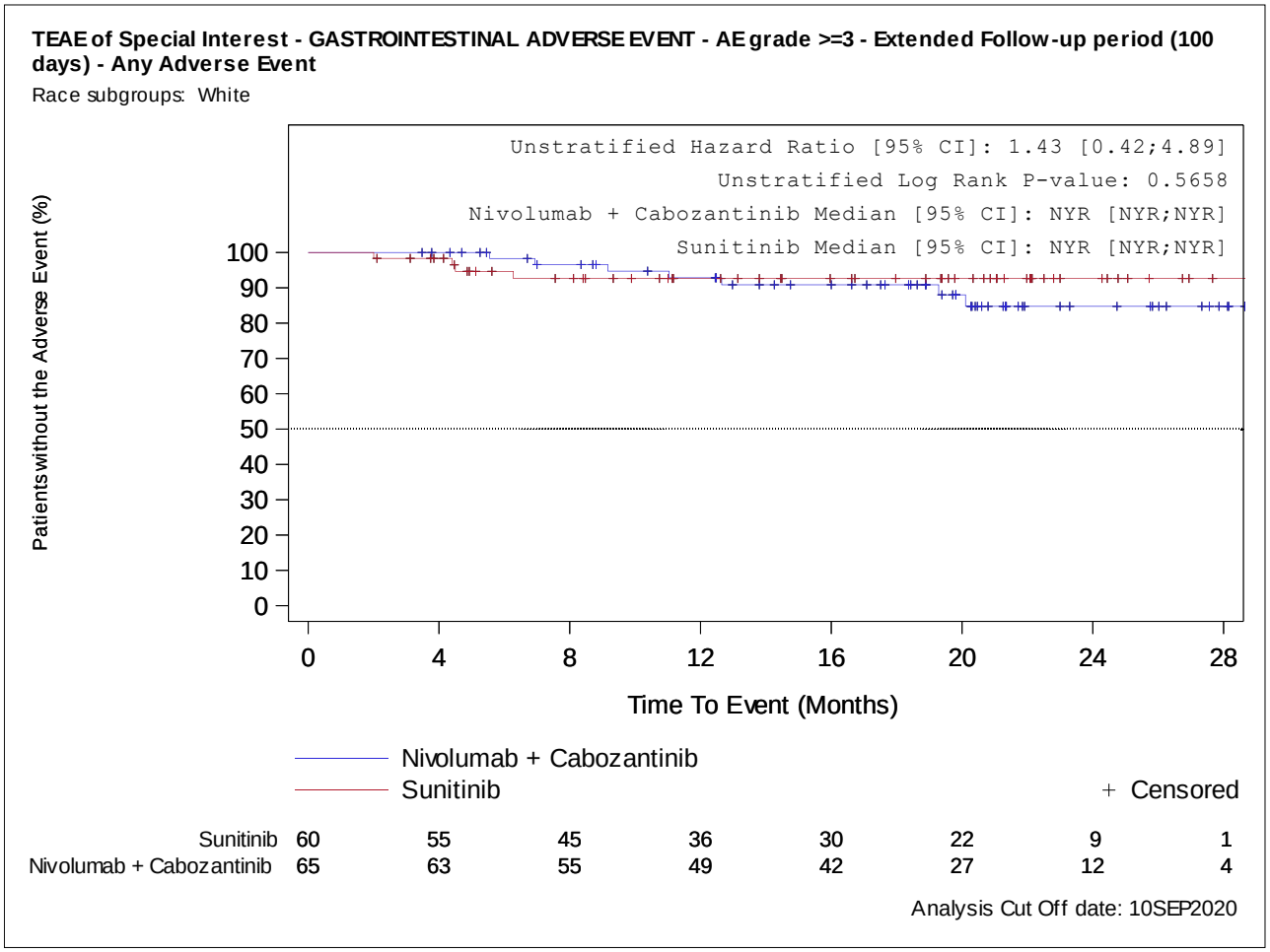

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:36:03

FIGURE 3.26.2.7: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



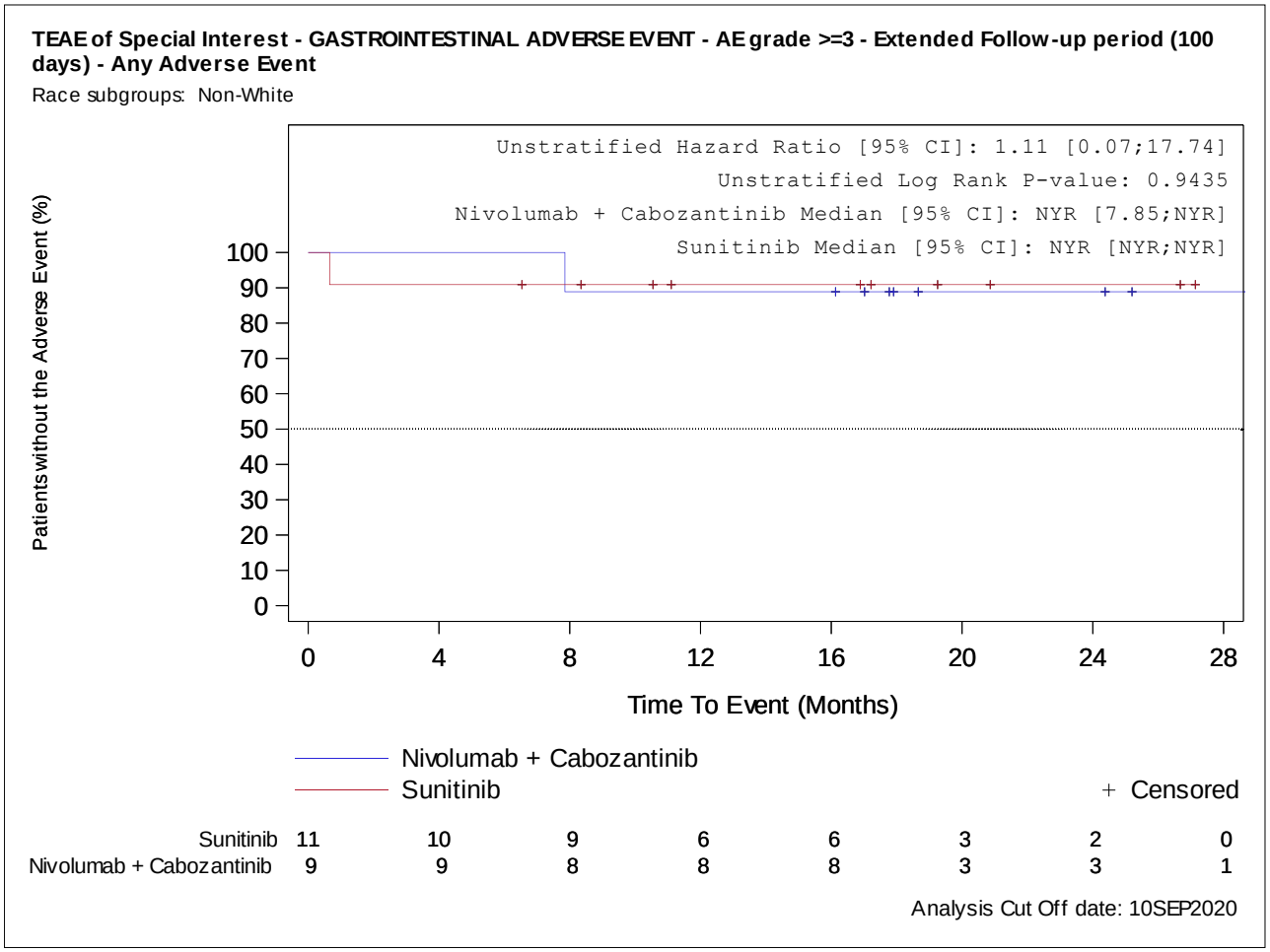

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:36:09

FIGURE 3.26.2.8: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



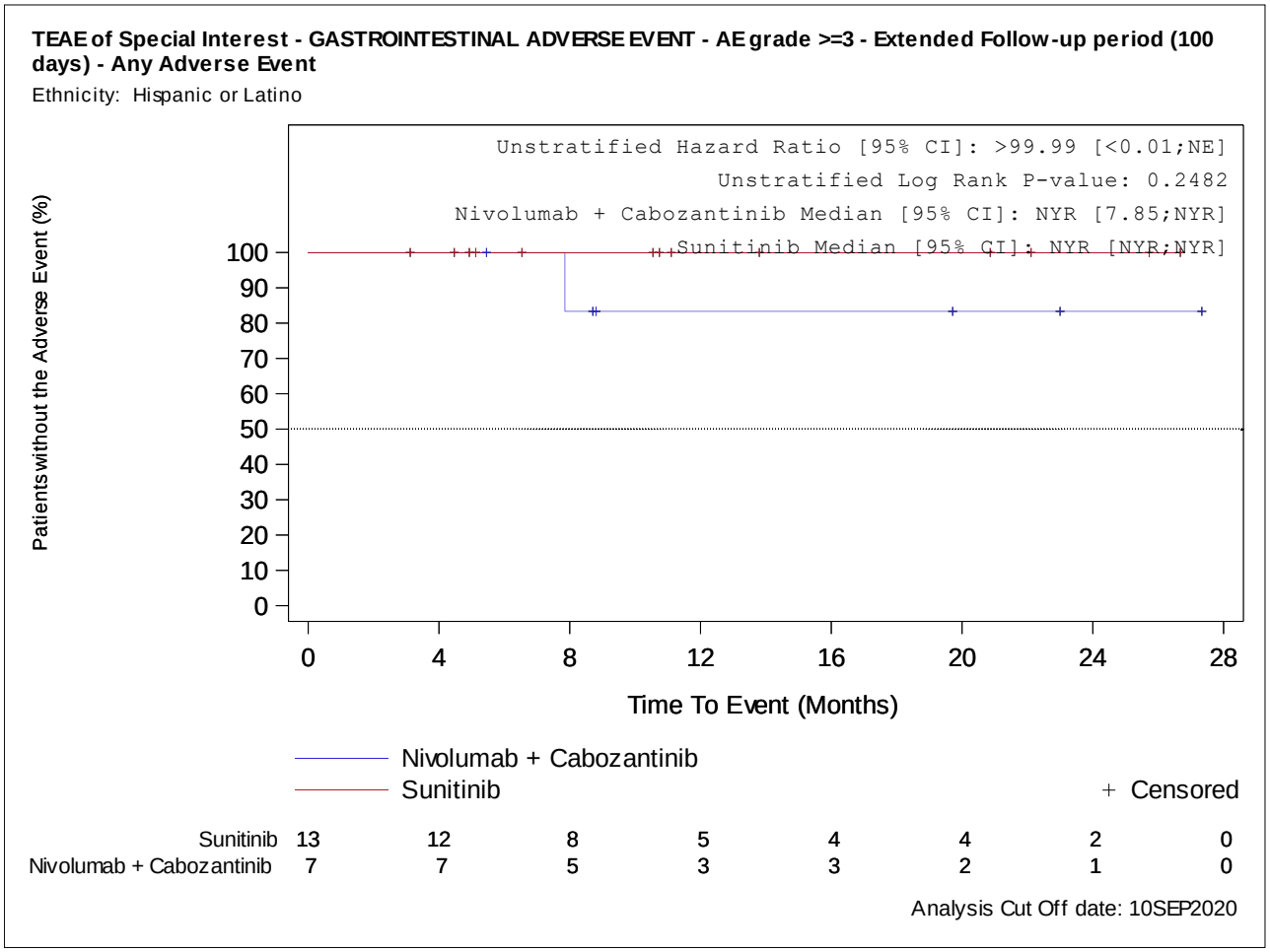

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:36:15

FIGURE 3.26.2.9: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



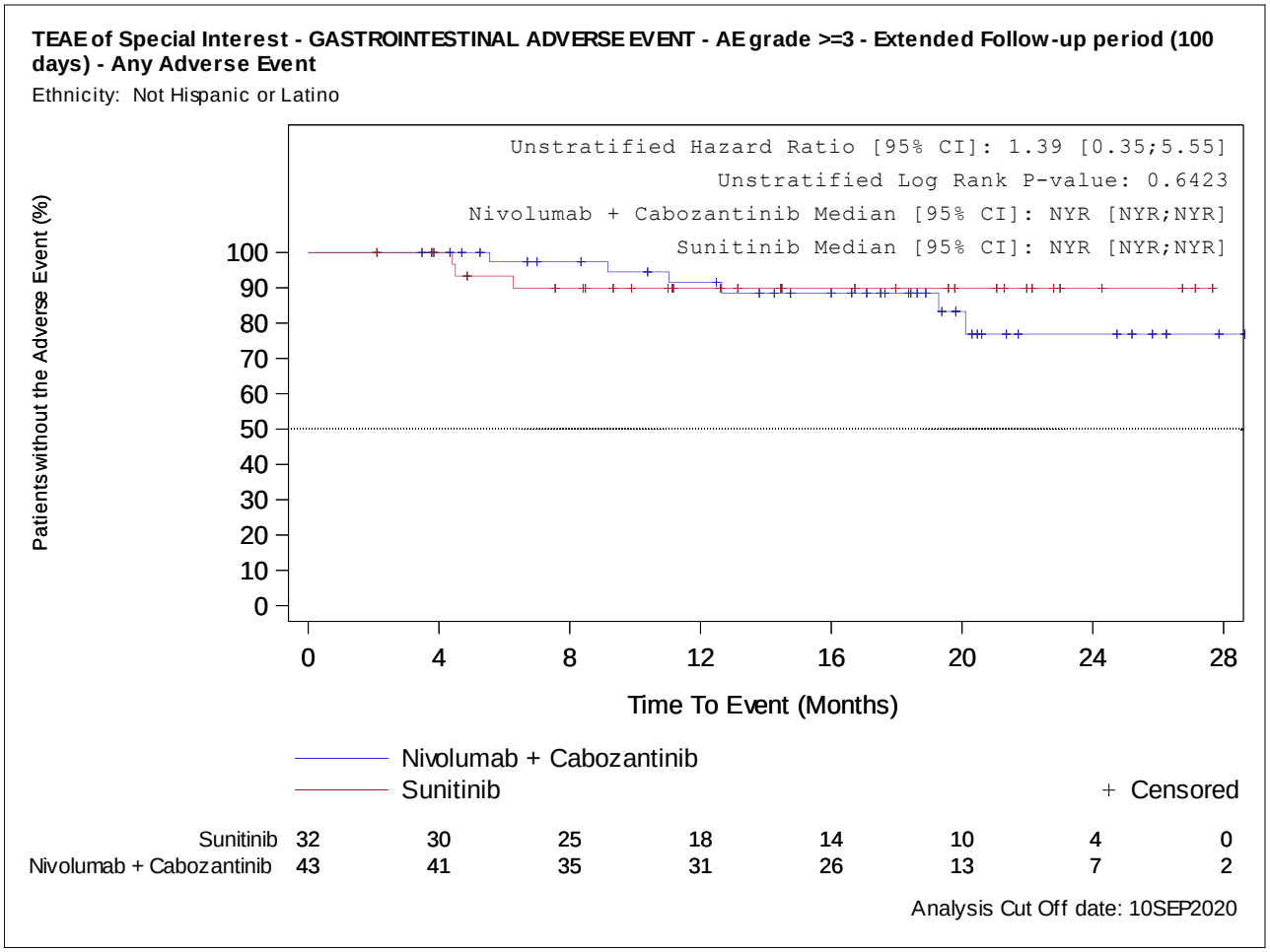

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:36:20

FIGURE 3.26.2.10: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



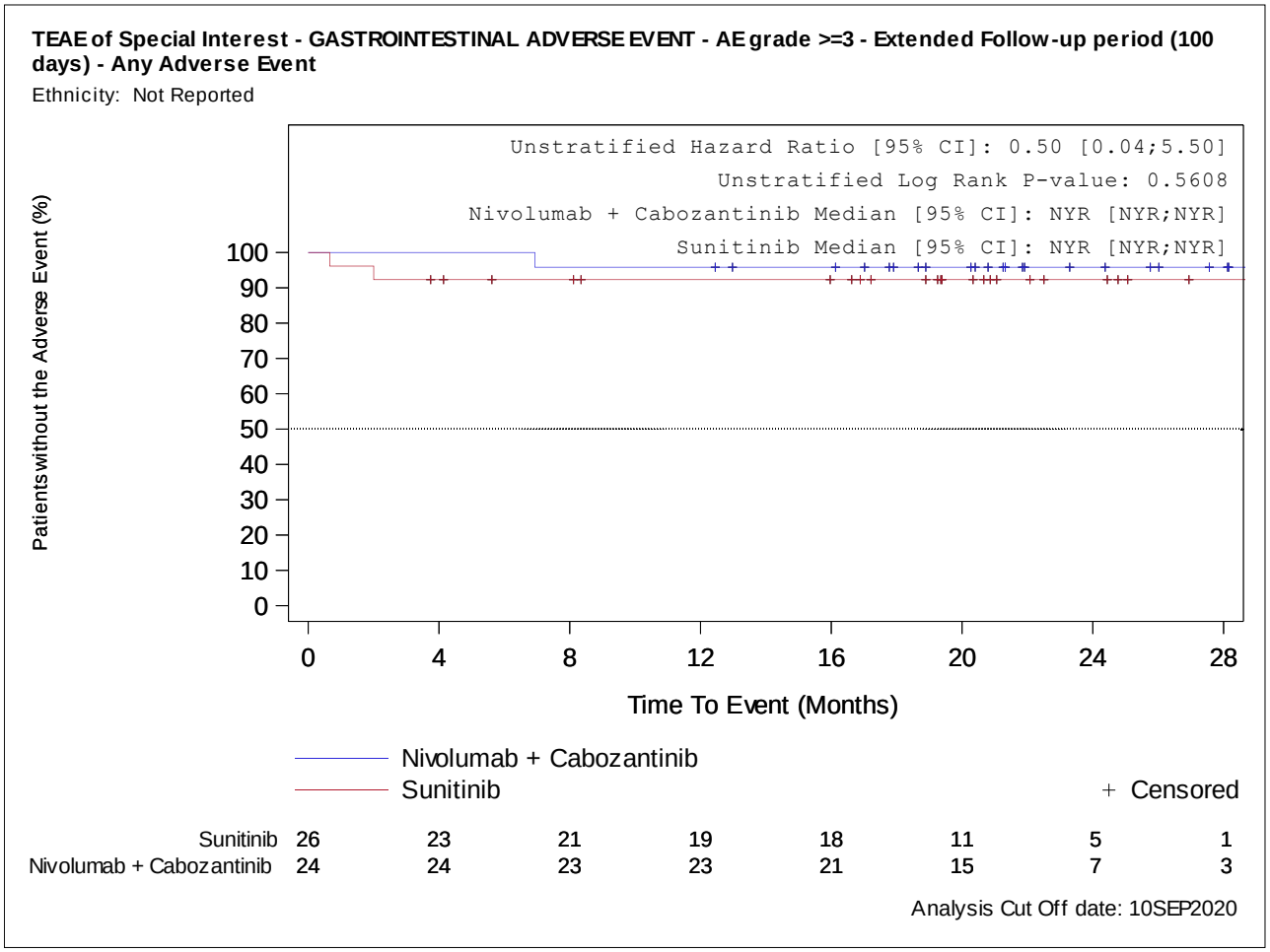

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:36:27

FIGURE 3.26.2.11: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



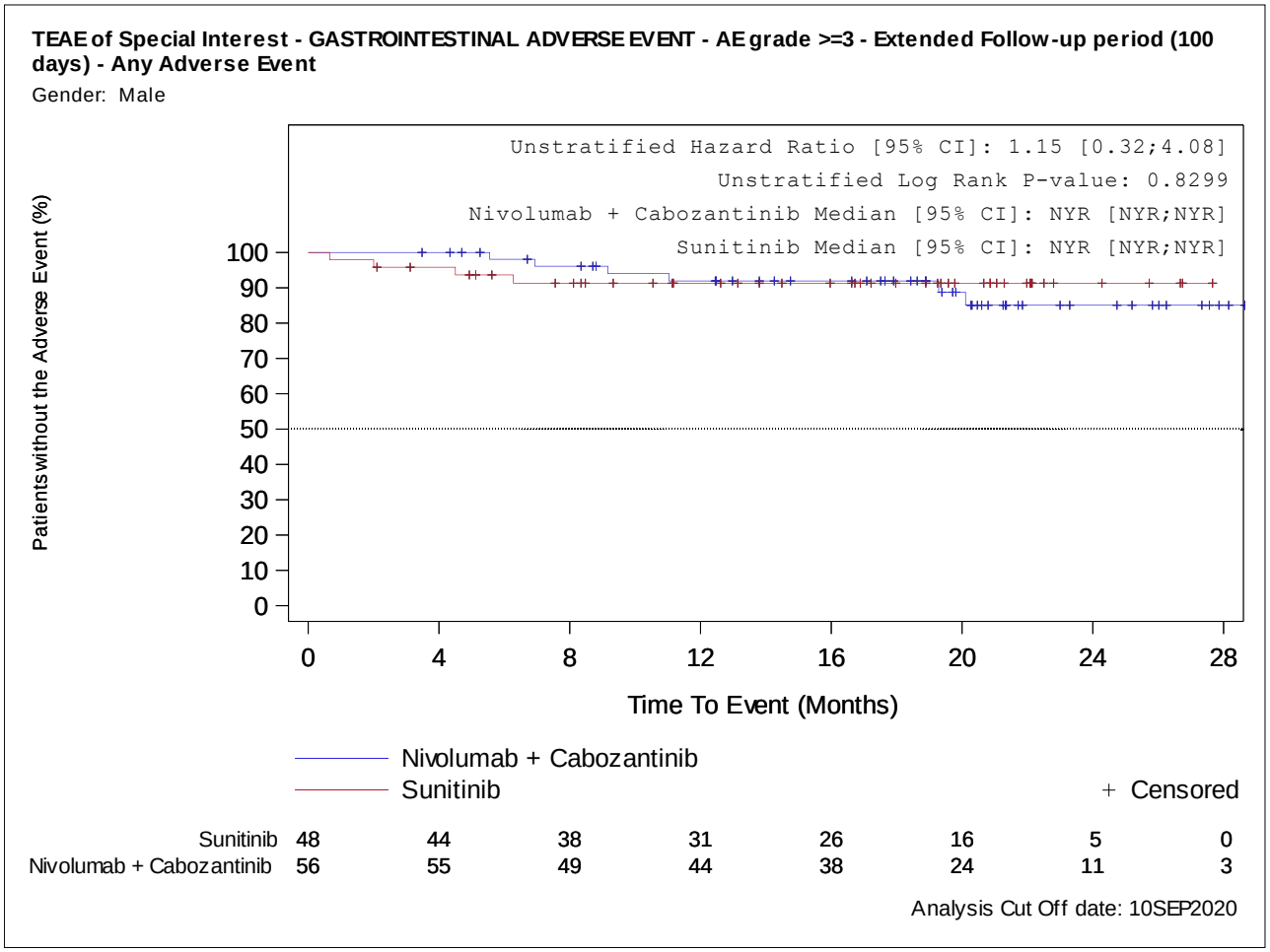

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:36:32

FIGURE 3.26.2.12: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



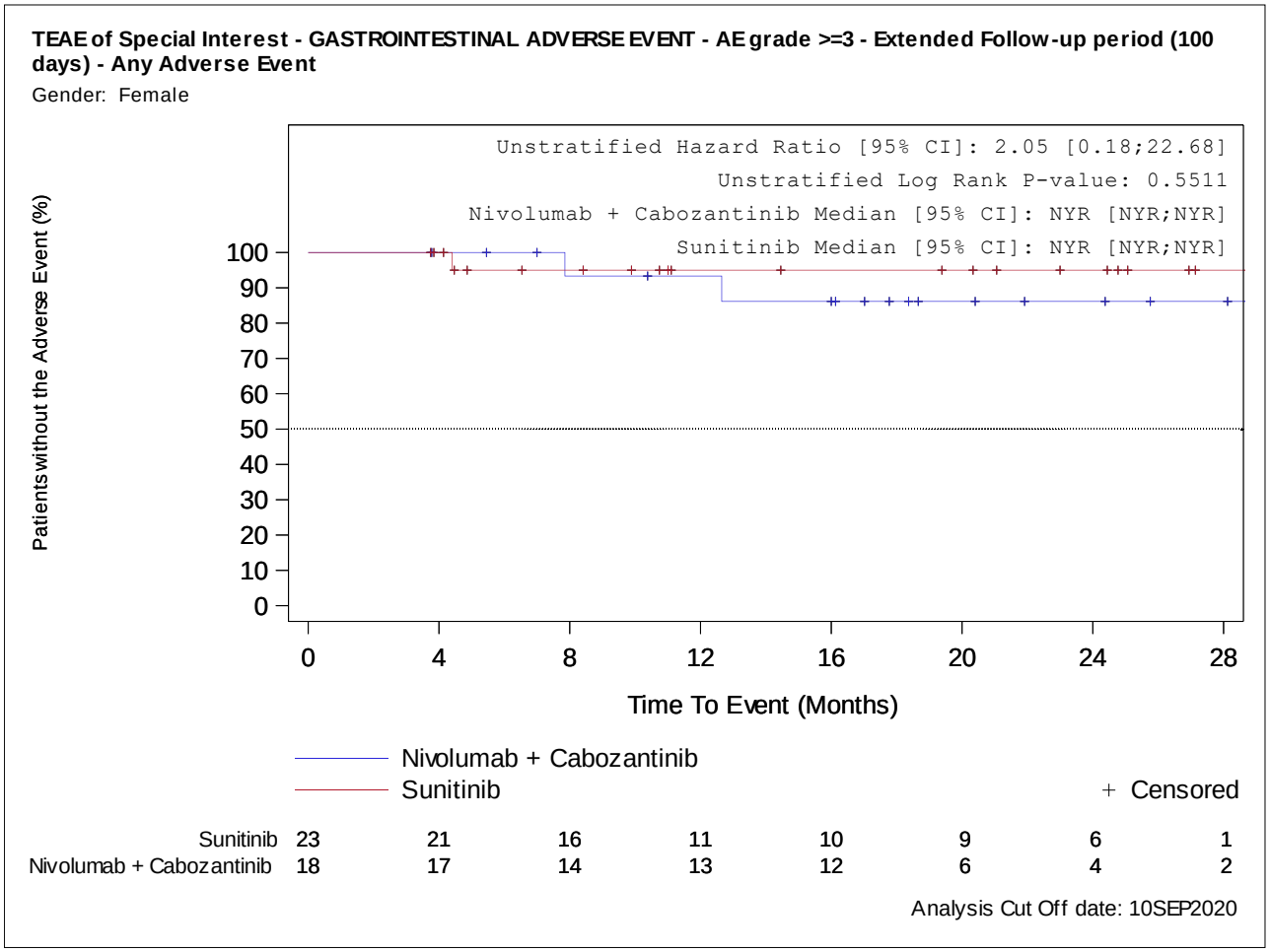

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:36:38

FIGURE 3.26.2.13: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



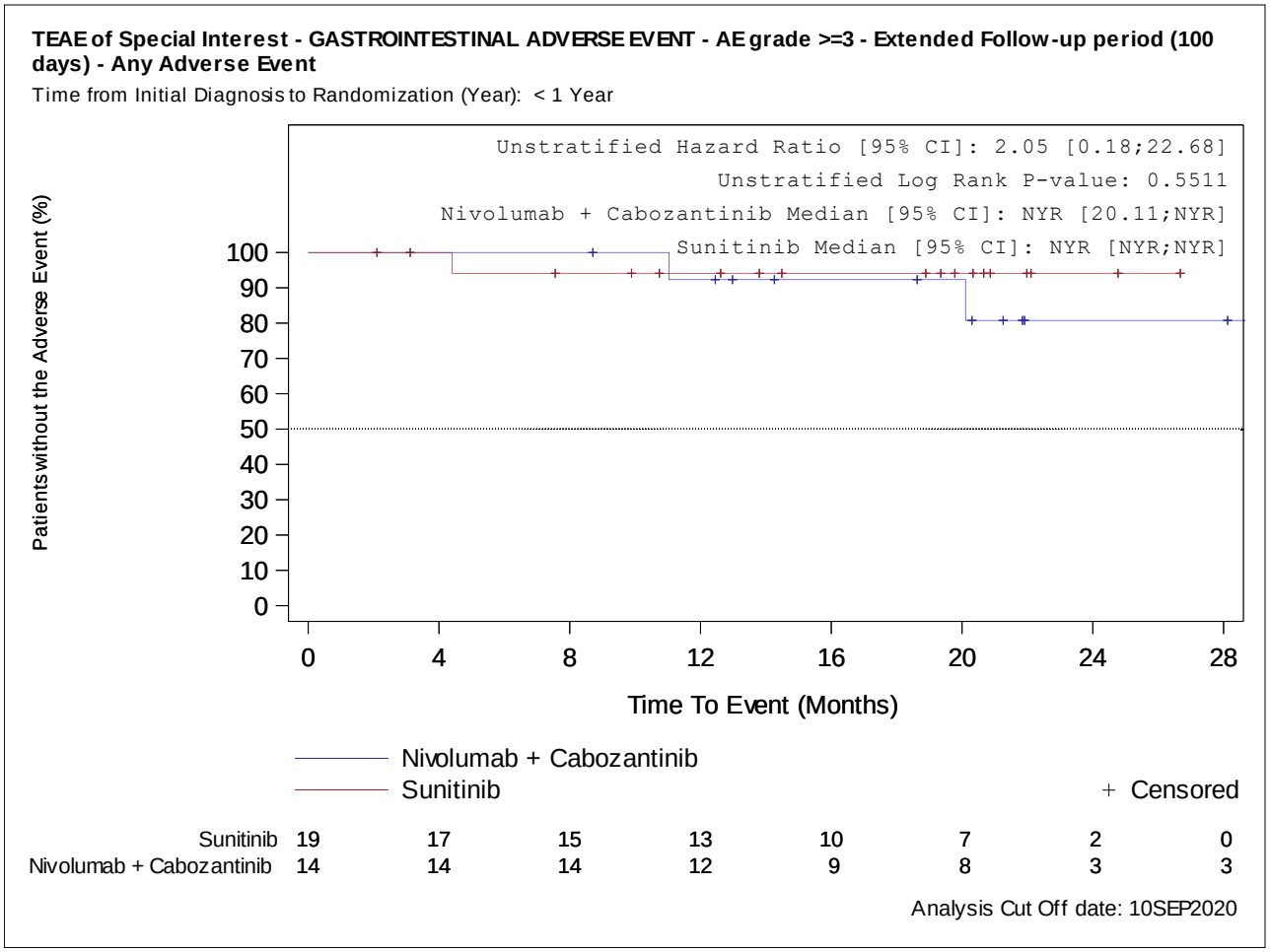

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:36:43

FIGURE 3.26.2.14: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



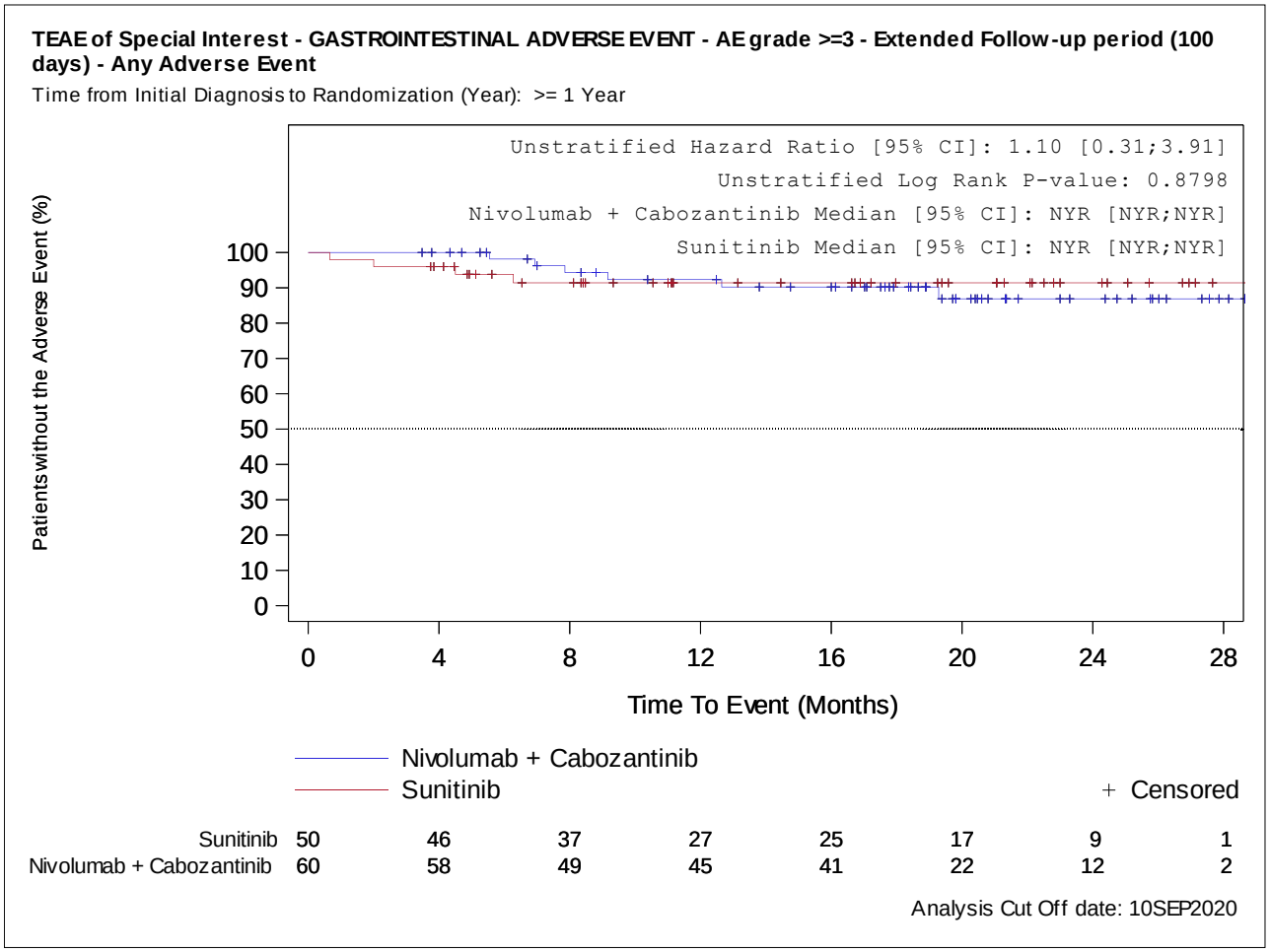

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:36:49

FIGURE 3.26.2.15: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



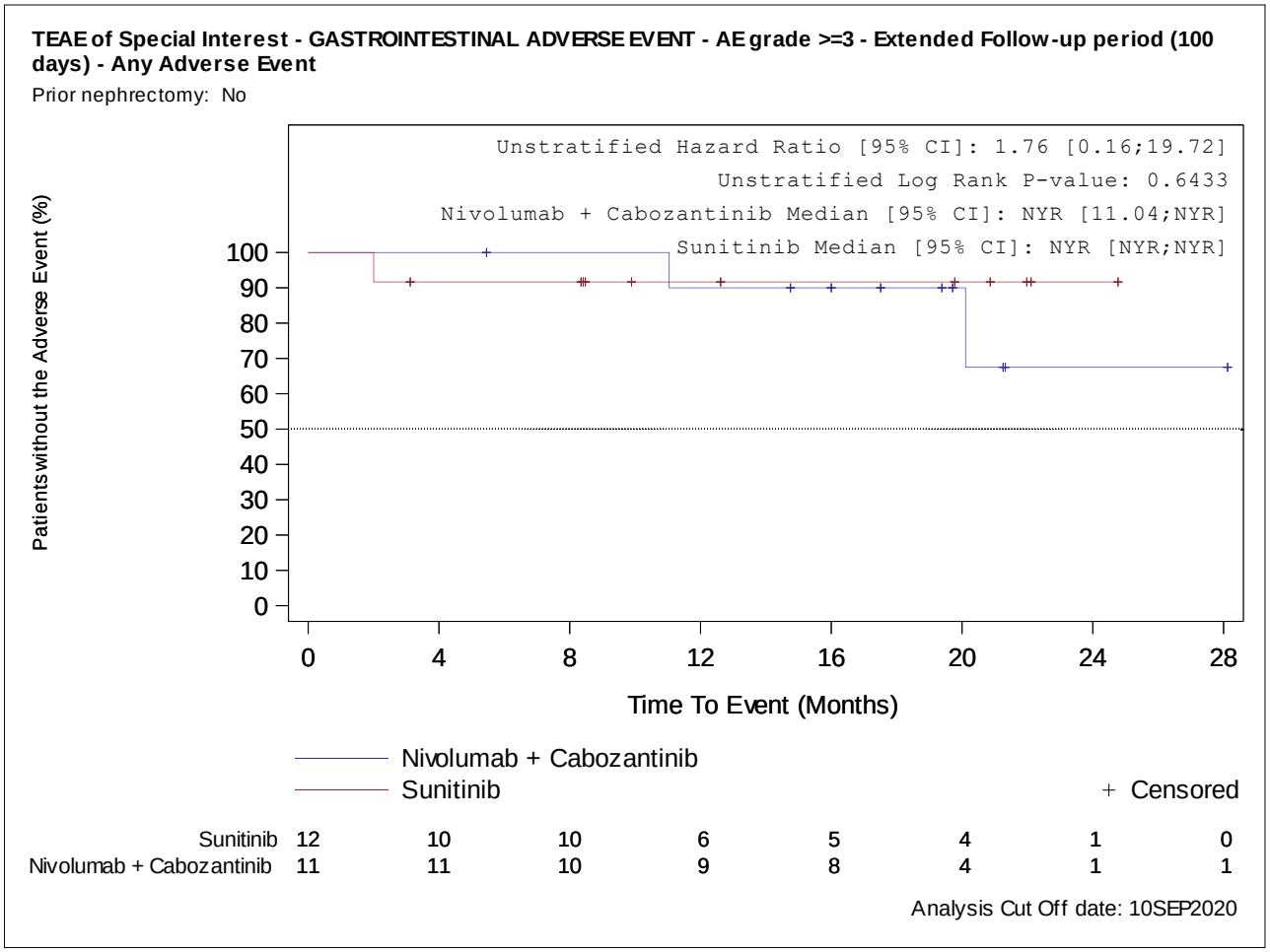

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:37:07

FIGURE 3.26.2.16: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



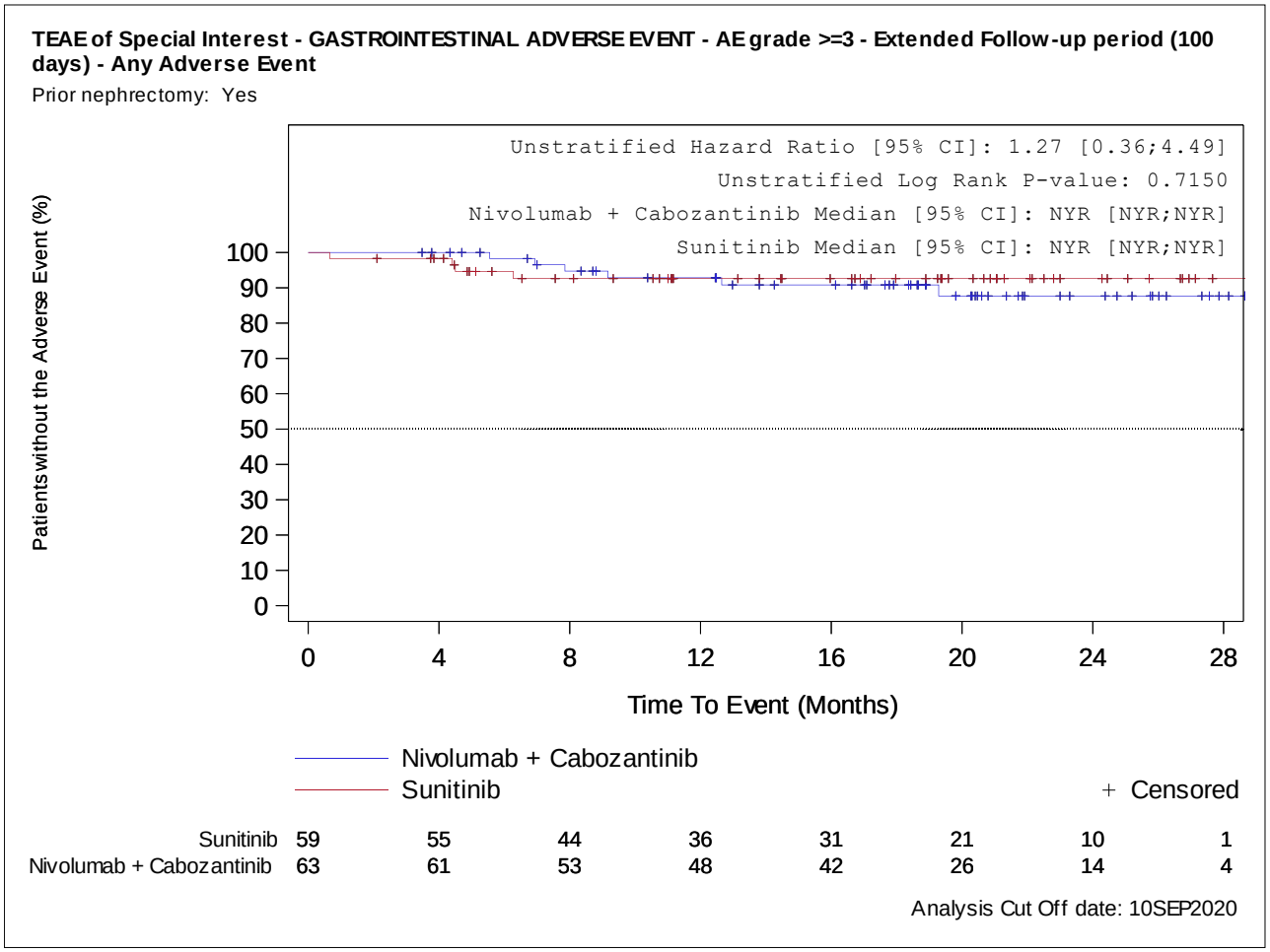

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:37:12

FIGURE 3.26.2.17: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



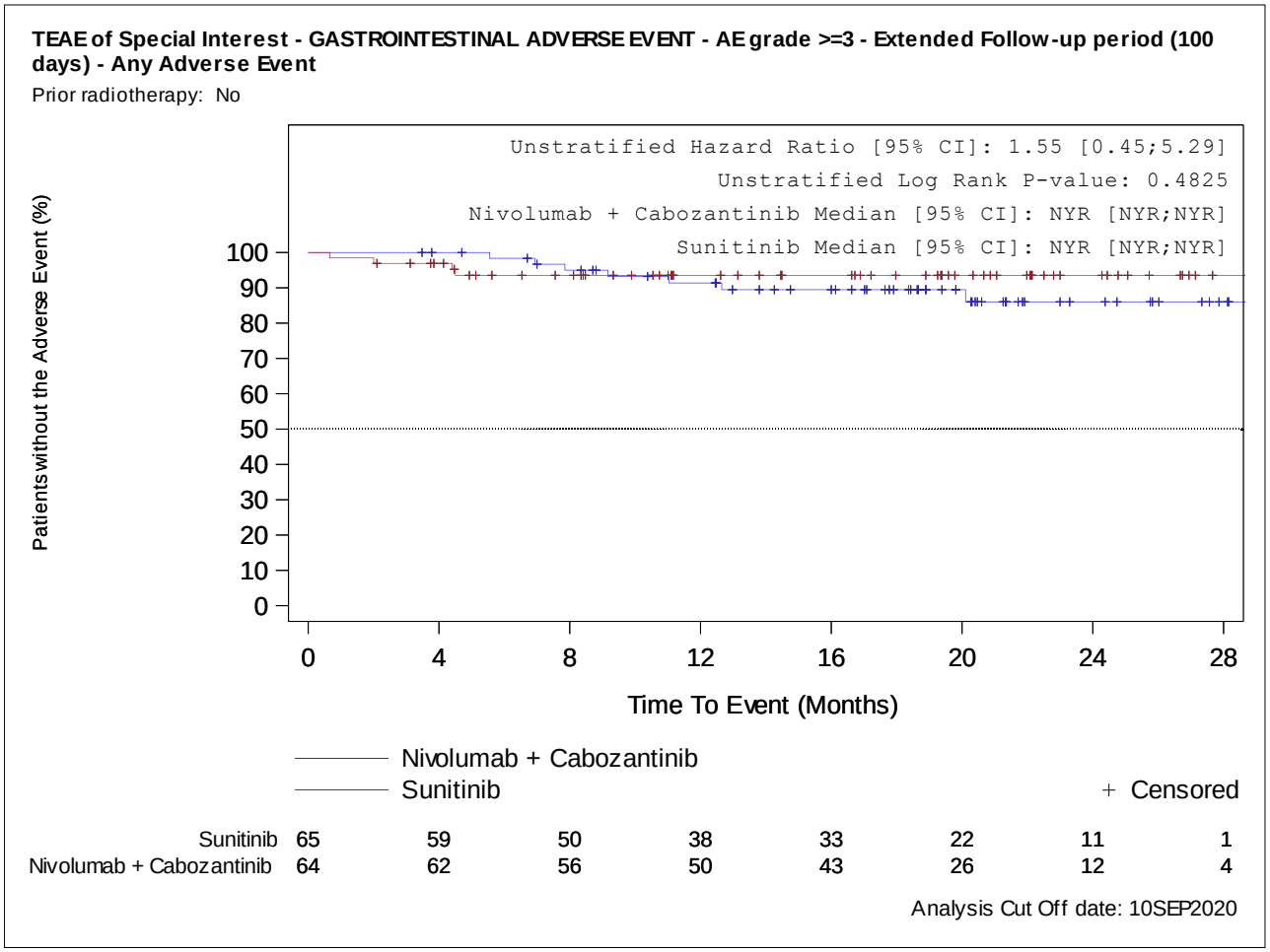

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:38:06

FIGURE 3.26.2.18: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



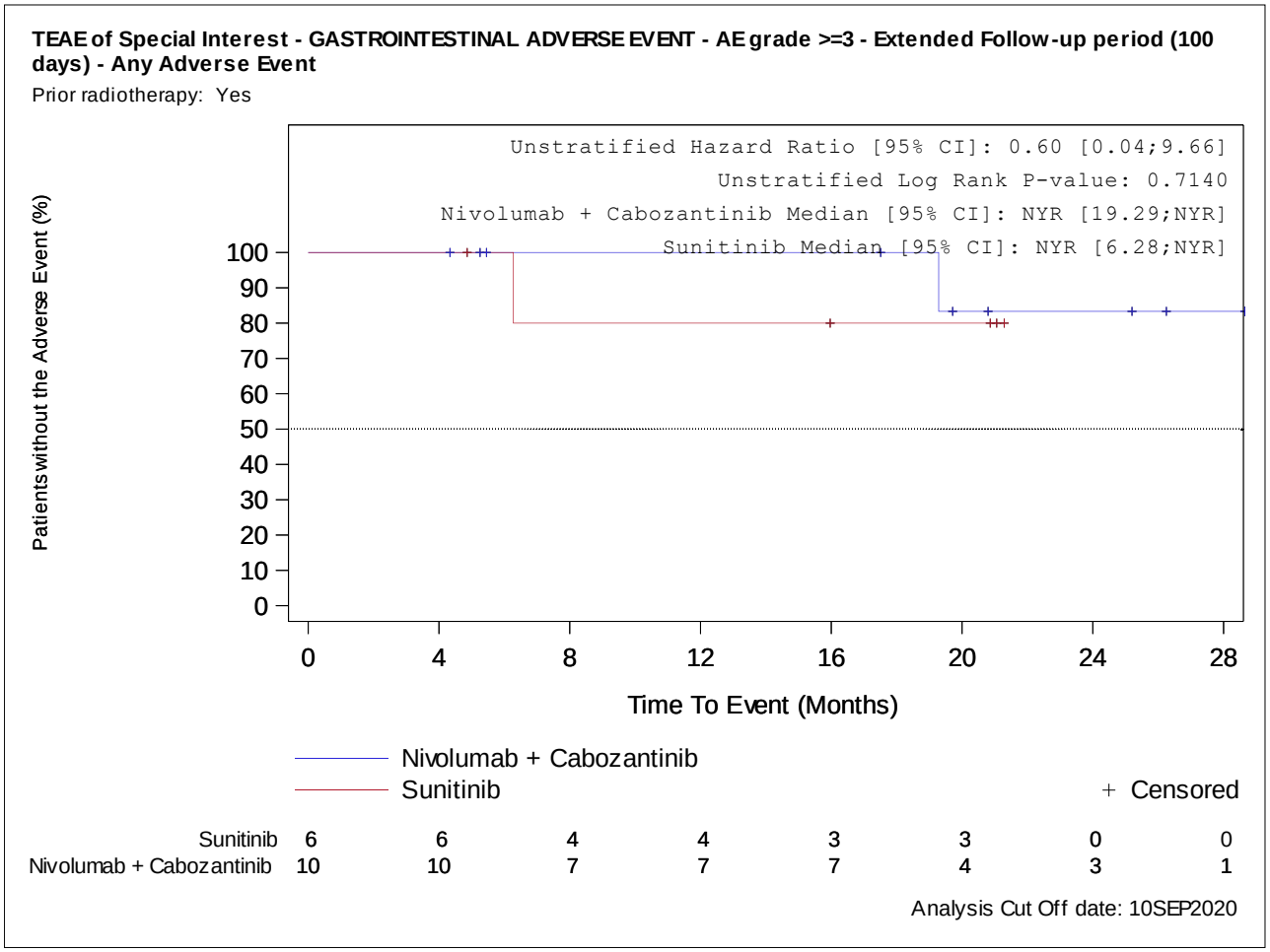

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:38:12

FIGURE 3.26.2.19: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



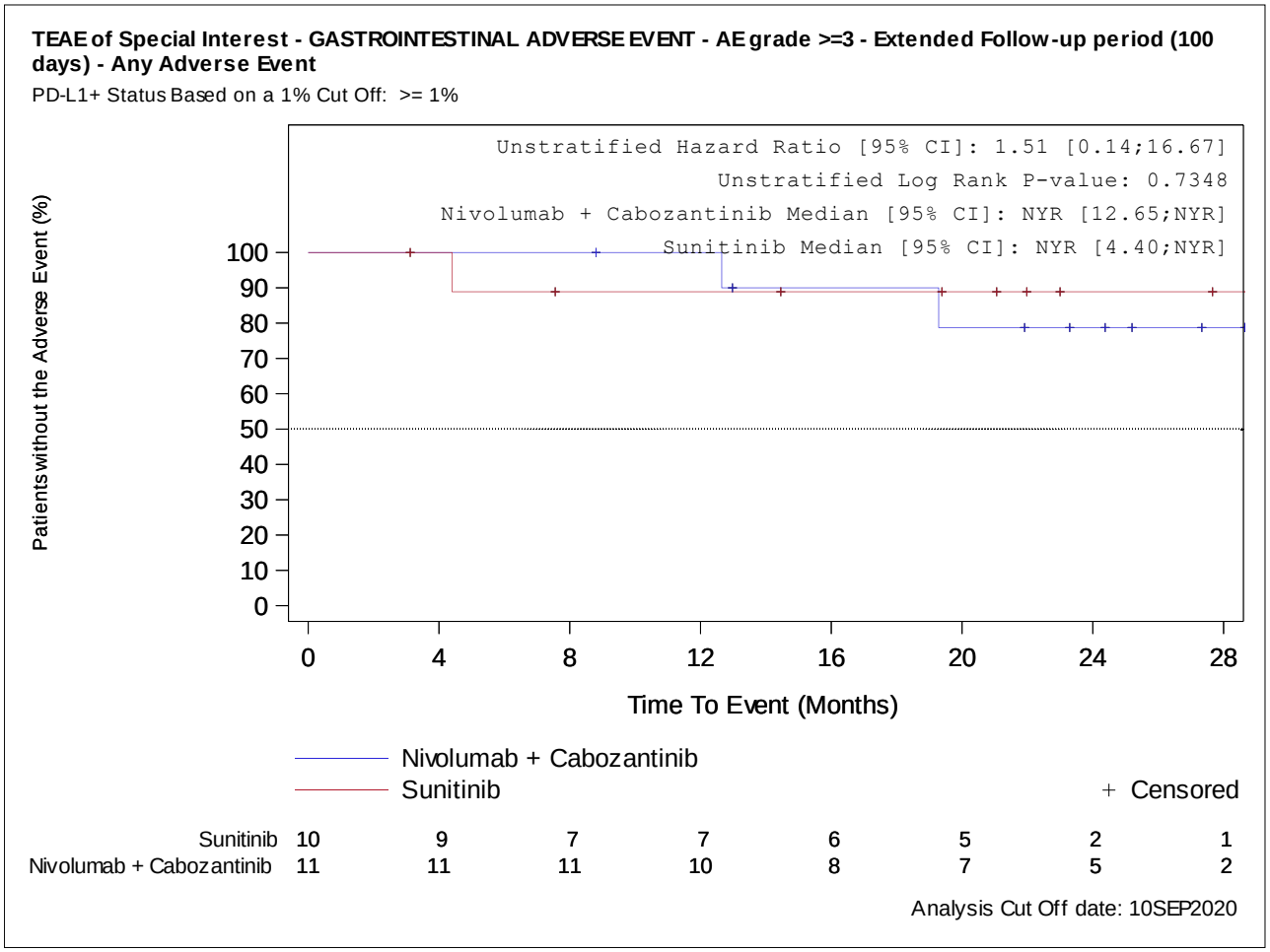

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:38:18

FIGURE 3.26.2.20: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



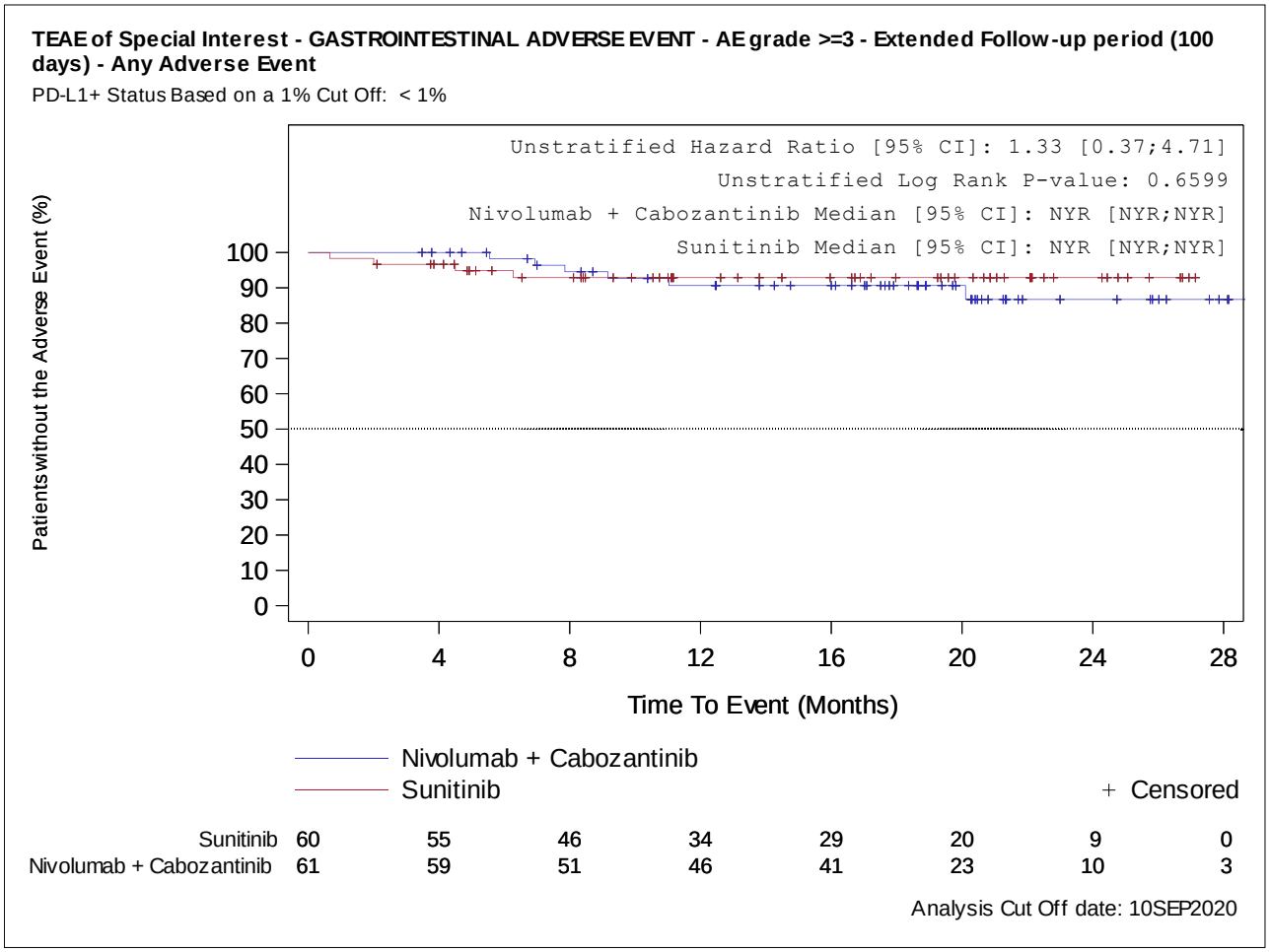

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:38:24

FIGURE 3.26.2.21: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



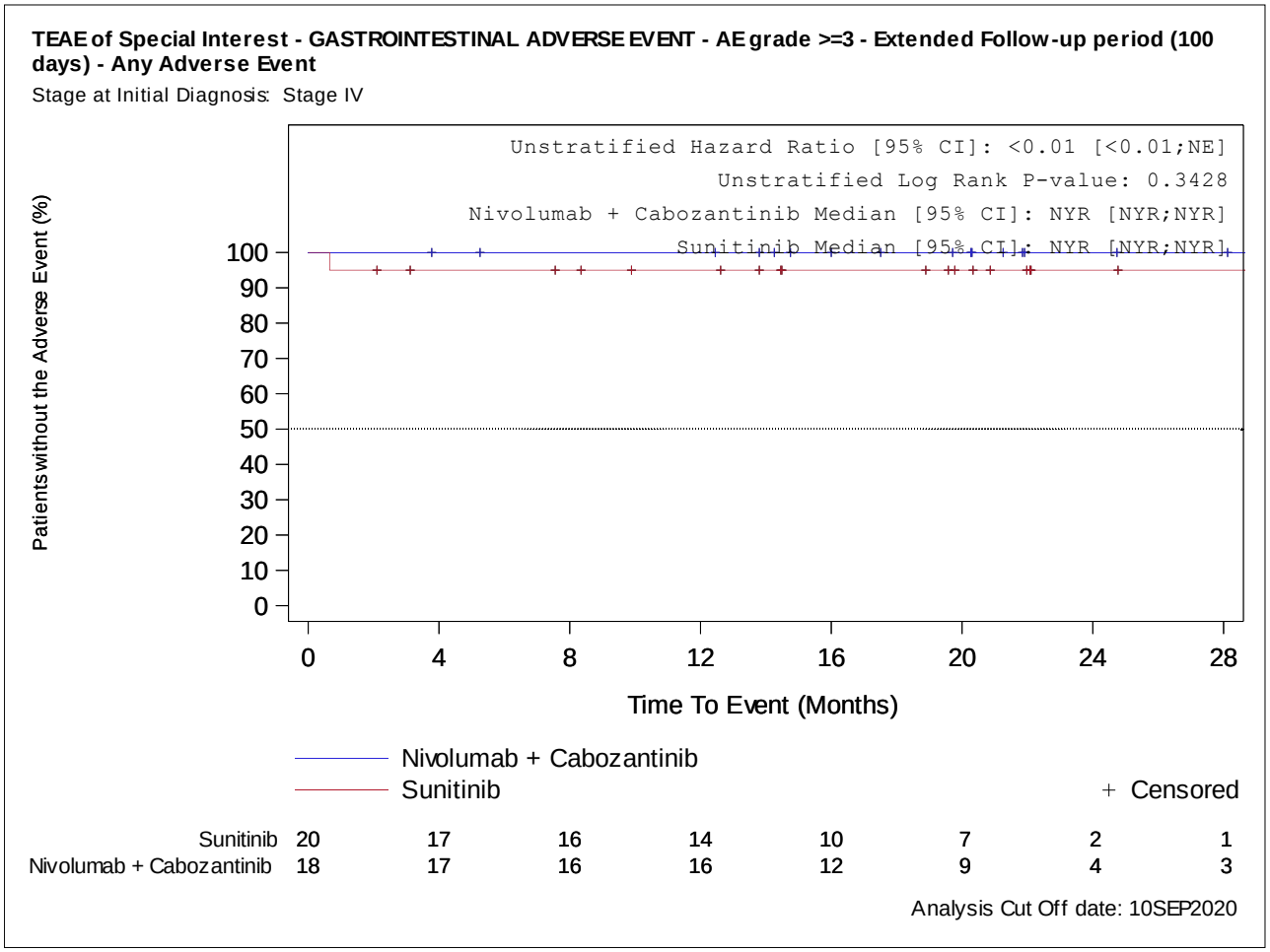

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:38:30

FIGURE 3.26.2.22: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



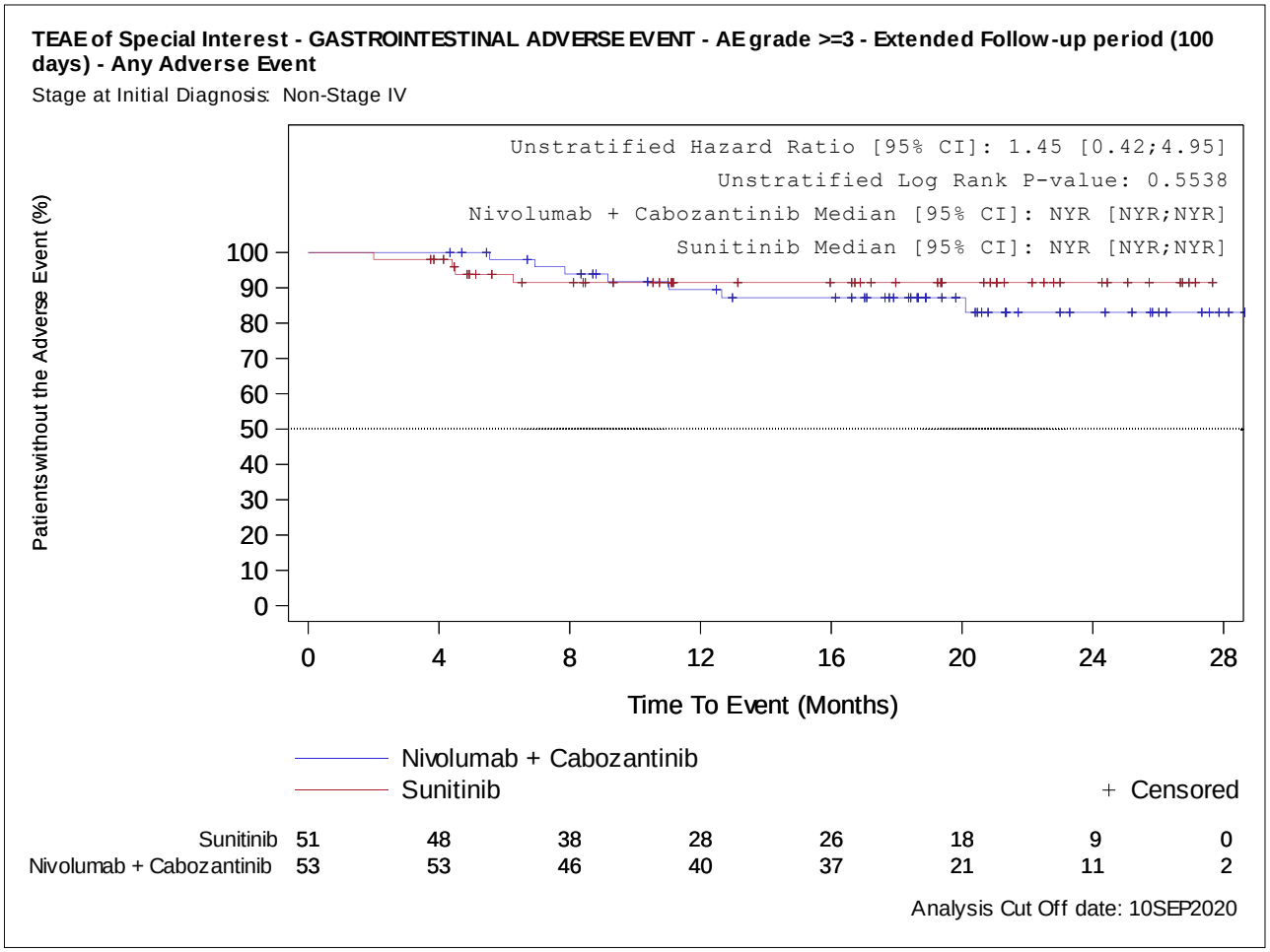

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:38:36

FIGURE 3.26.2.23: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



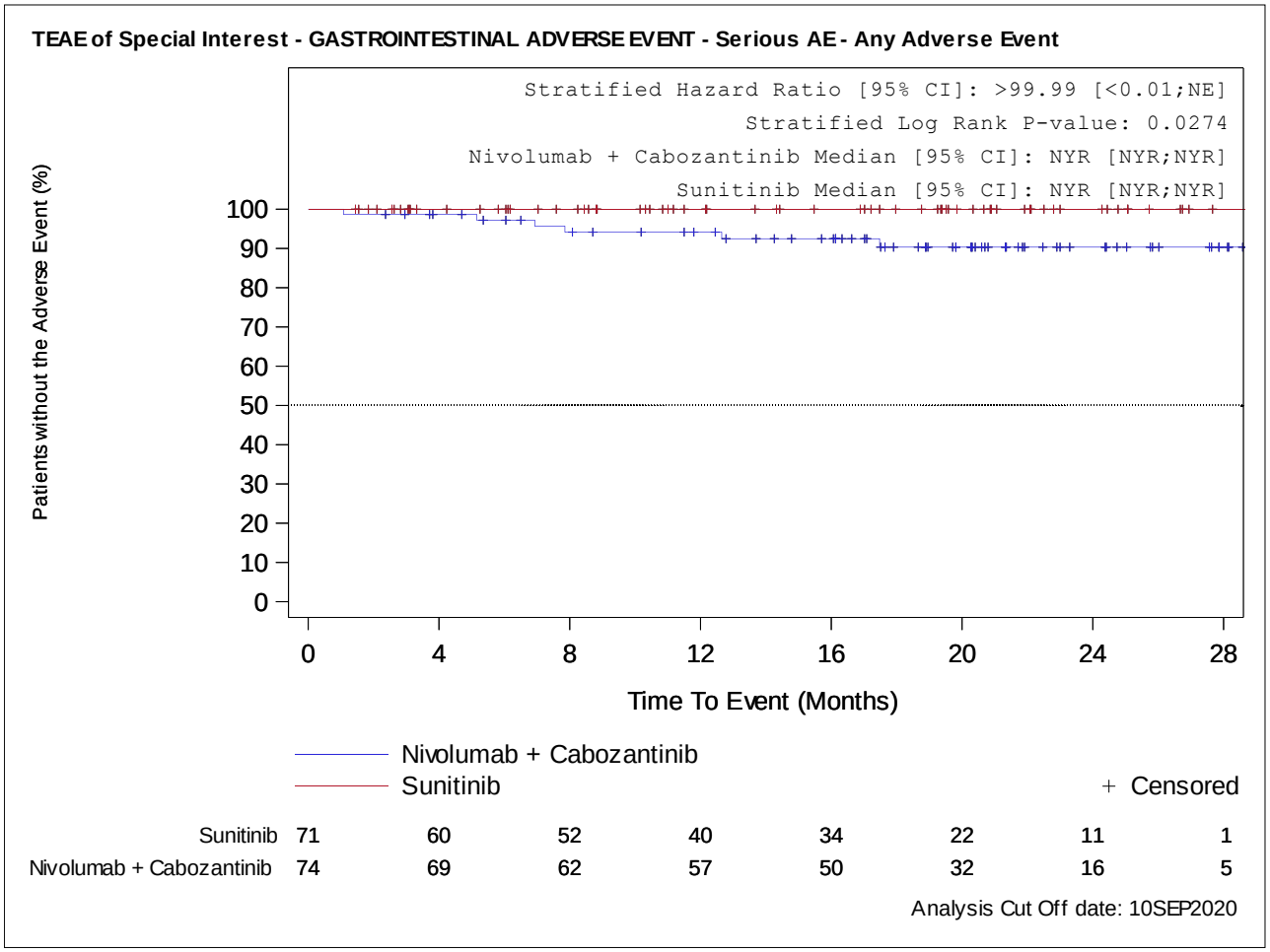

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:39:05

FIGURE 3.26.2.24: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



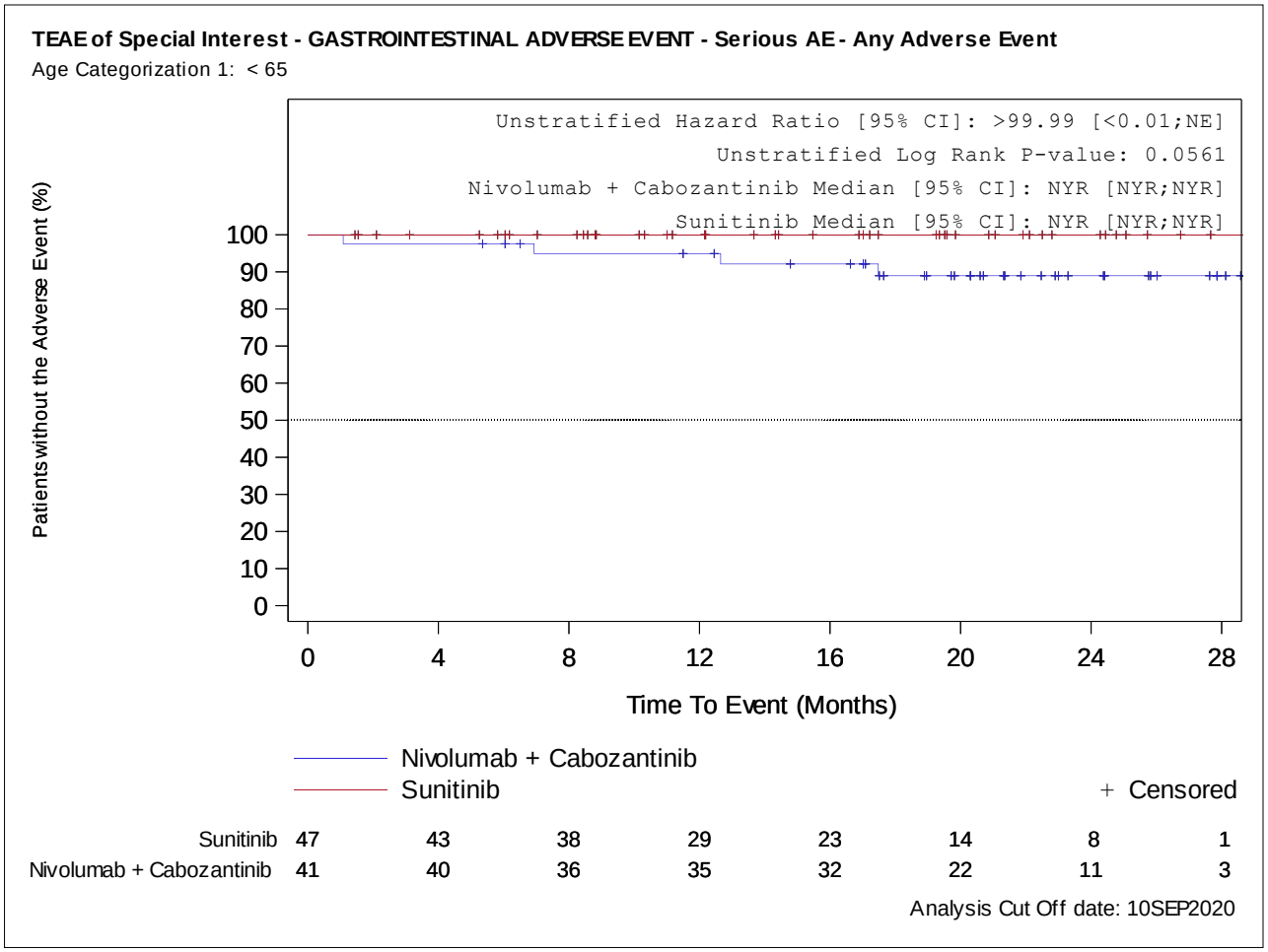

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:39:10

FIGURE 3.27.1: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



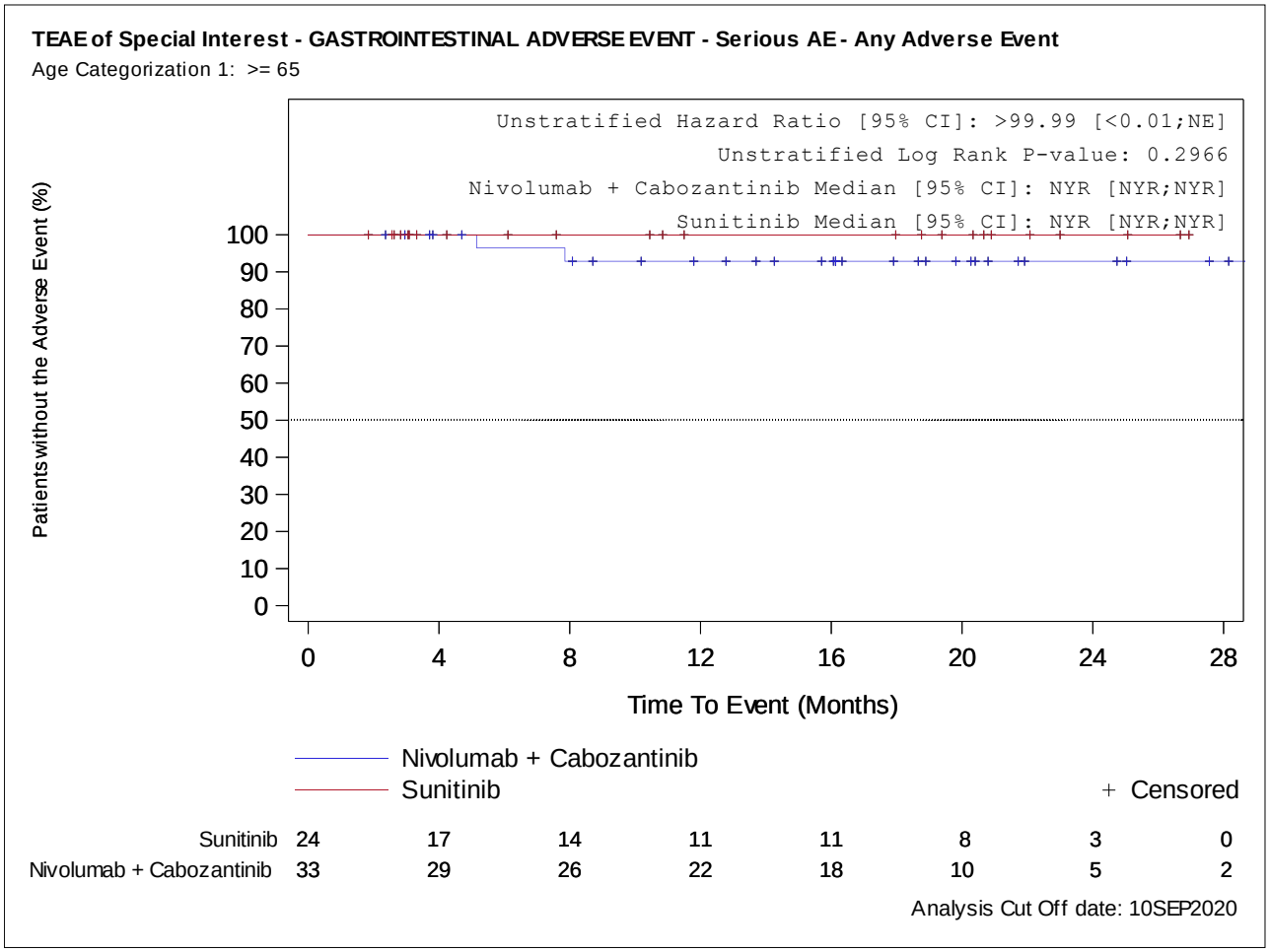

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:42:27

FIGURE 3.27.2.1: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



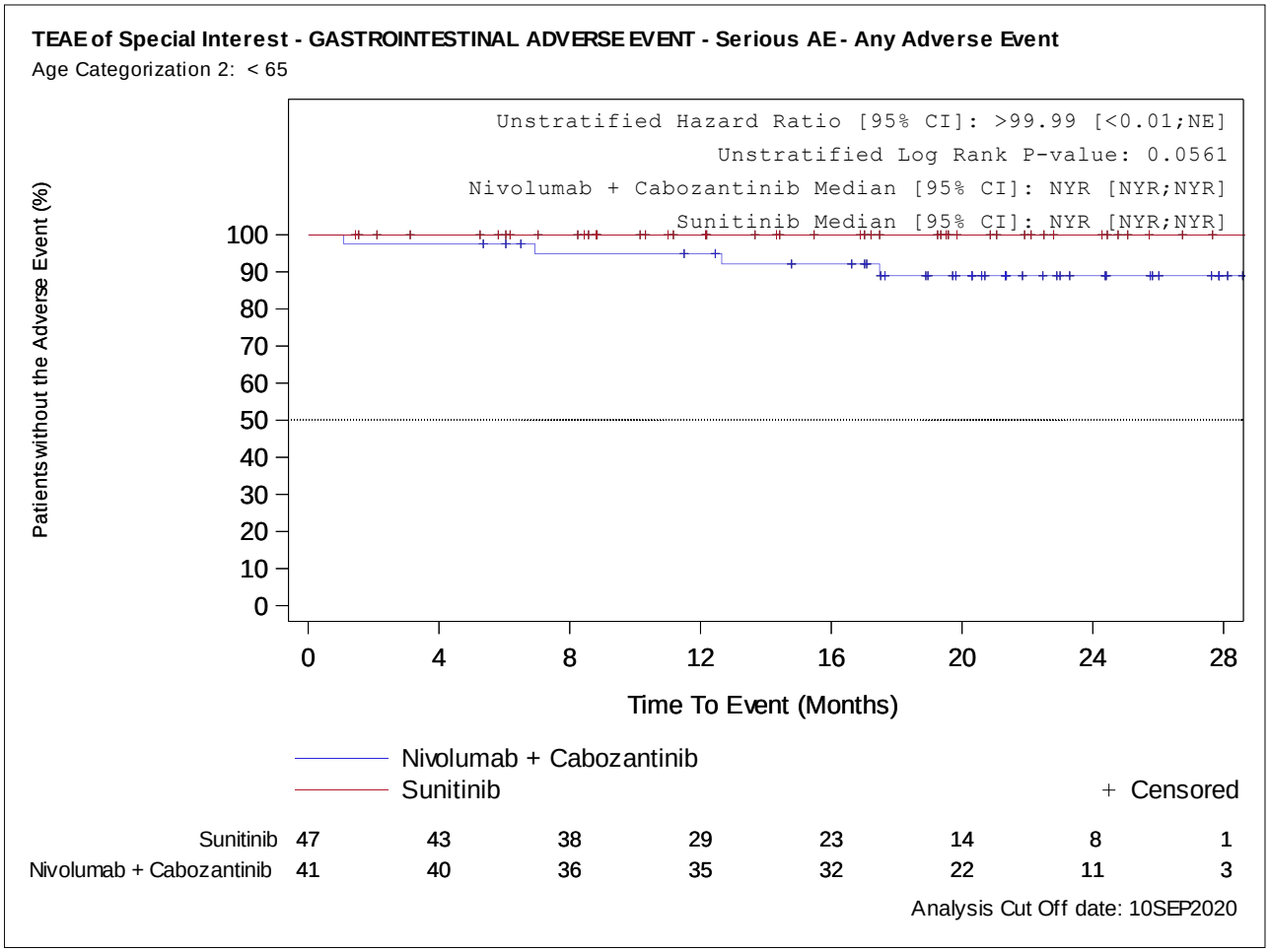

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:42:31

FIGURE 3.27.2.2: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



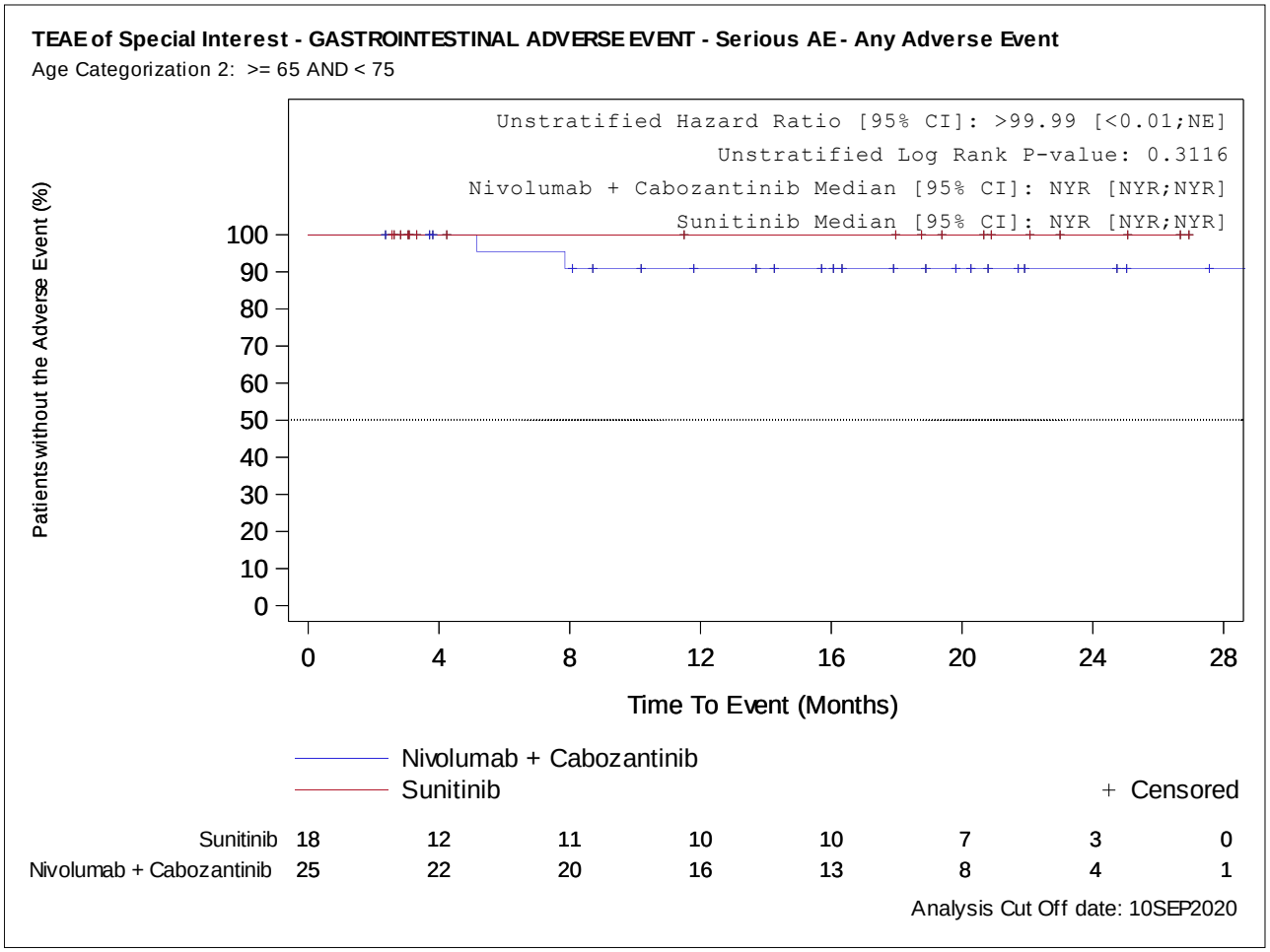

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:42:37

FIGURE 3.27.2.3: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



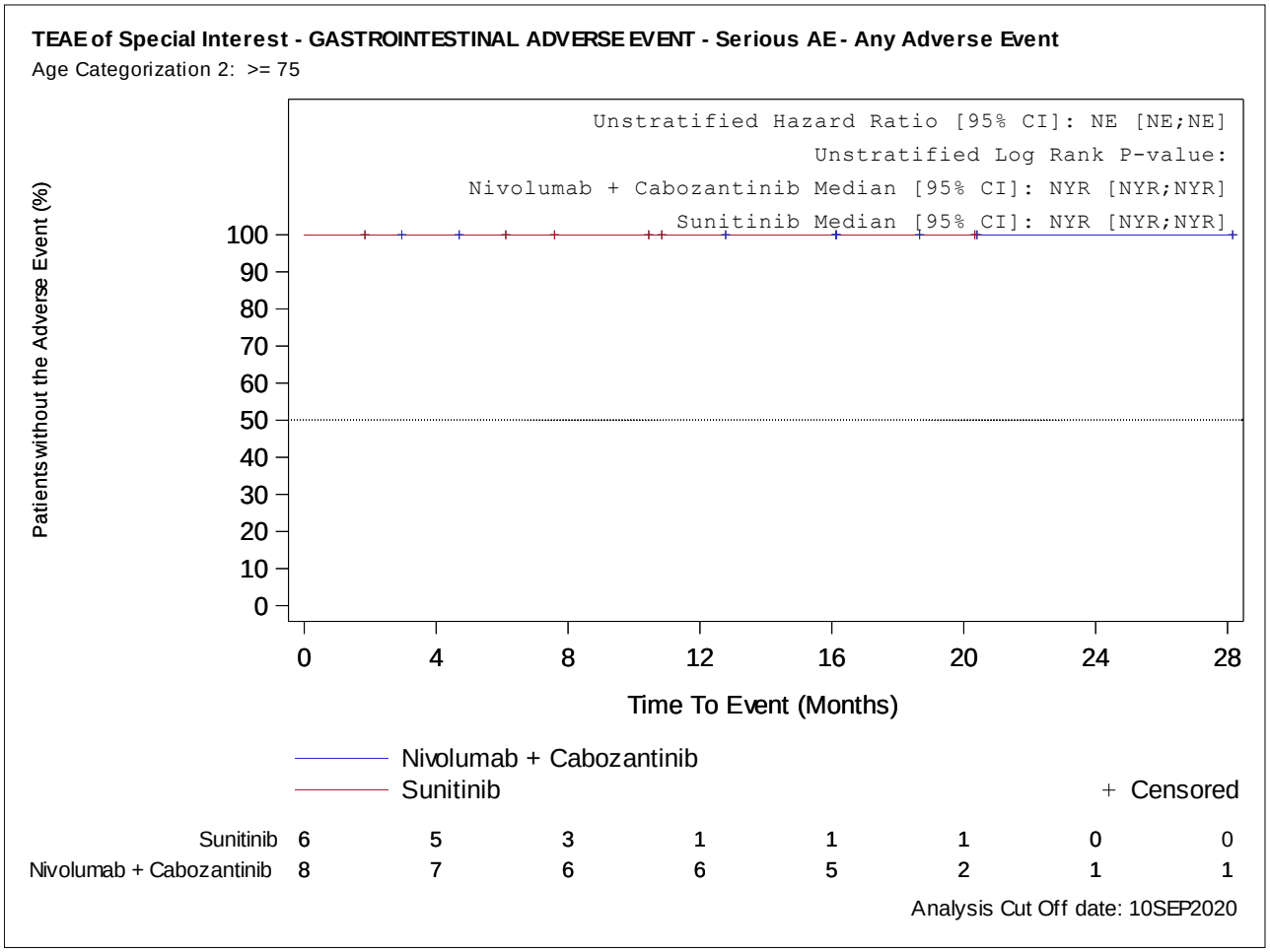

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:42:42

FIGURE 3.27.2.4: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



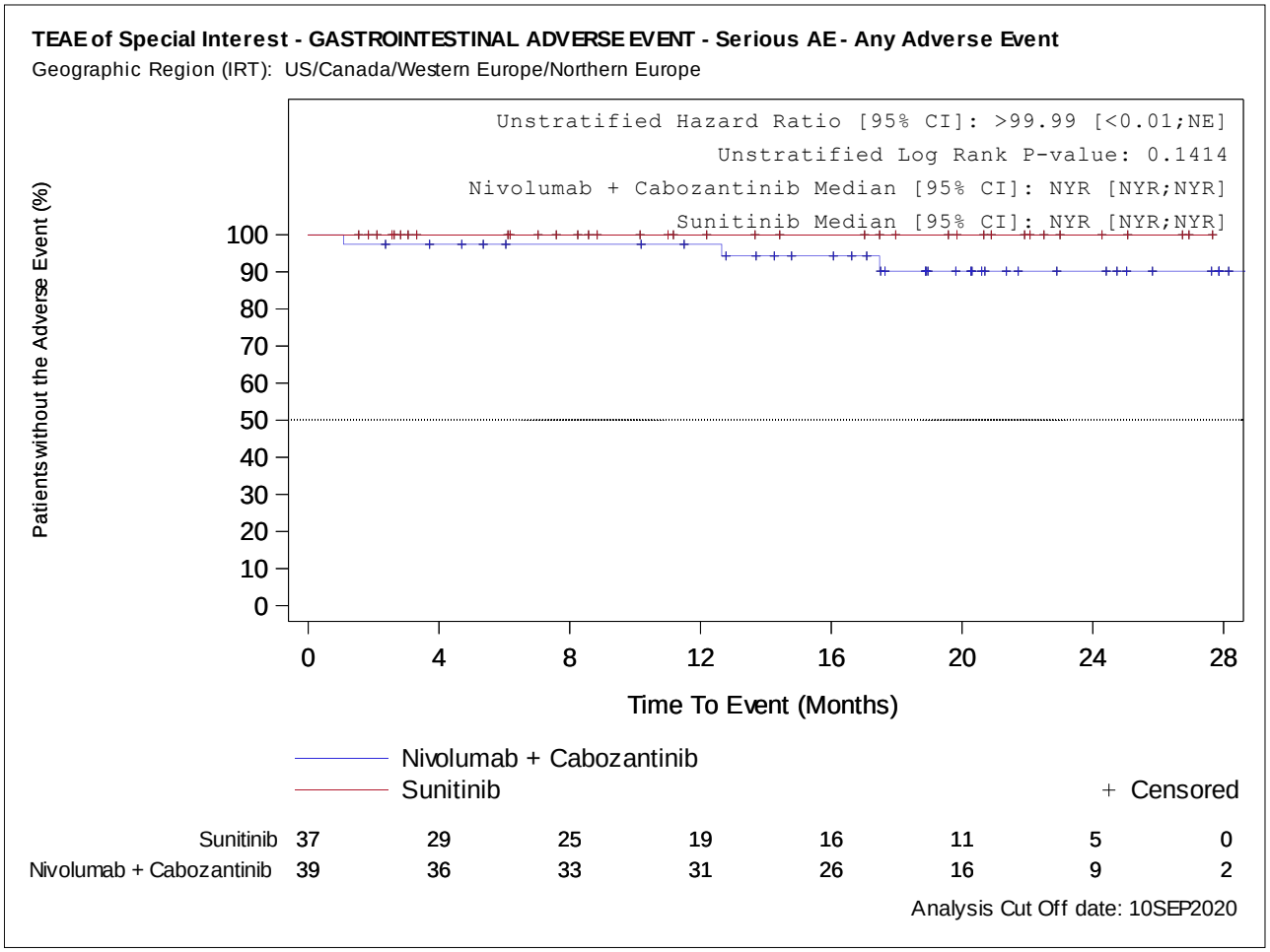

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:42:48

FIGURE 3.27.2.5: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



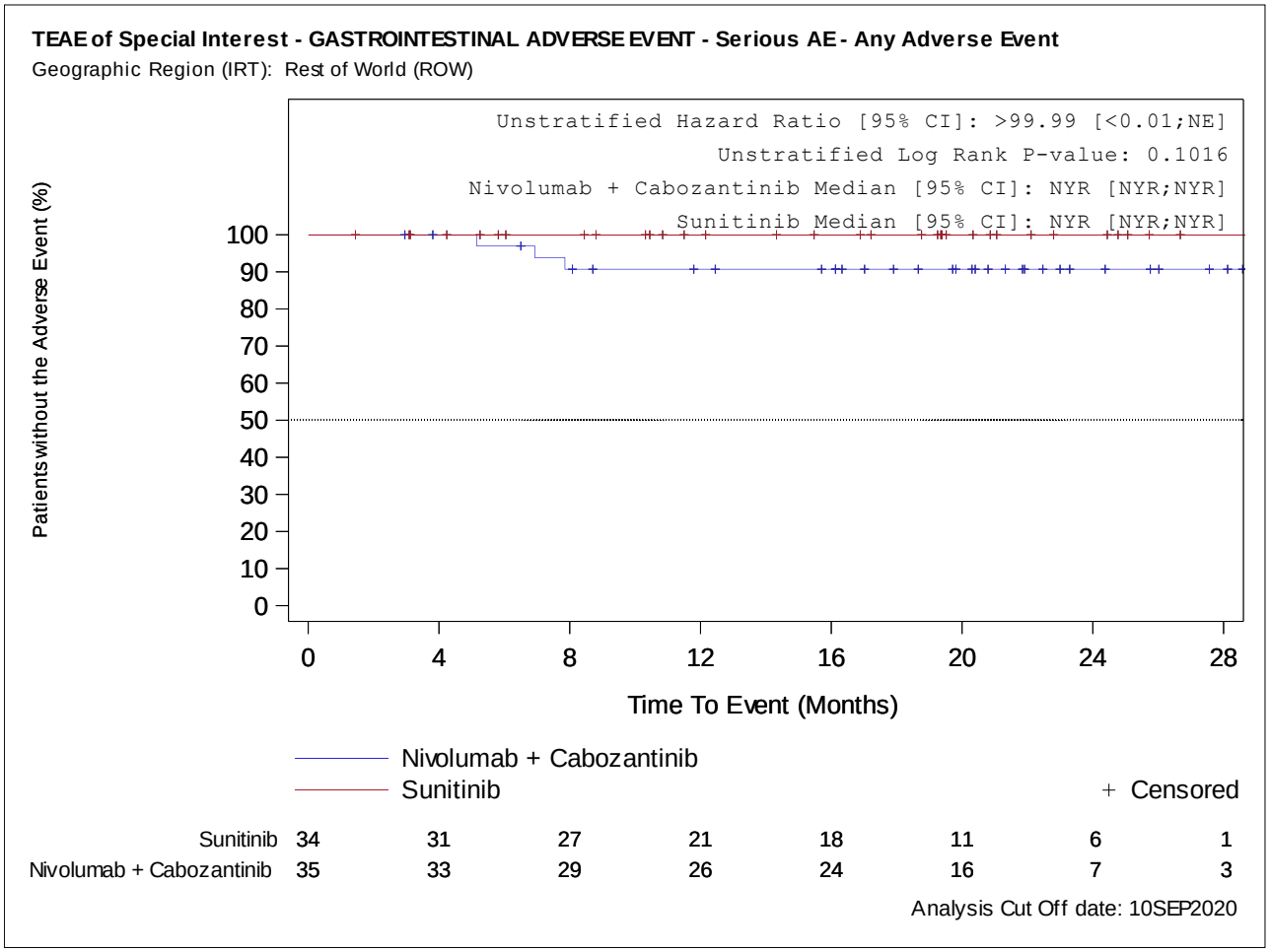

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:42:54

FIGURE 3.27.2.6: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



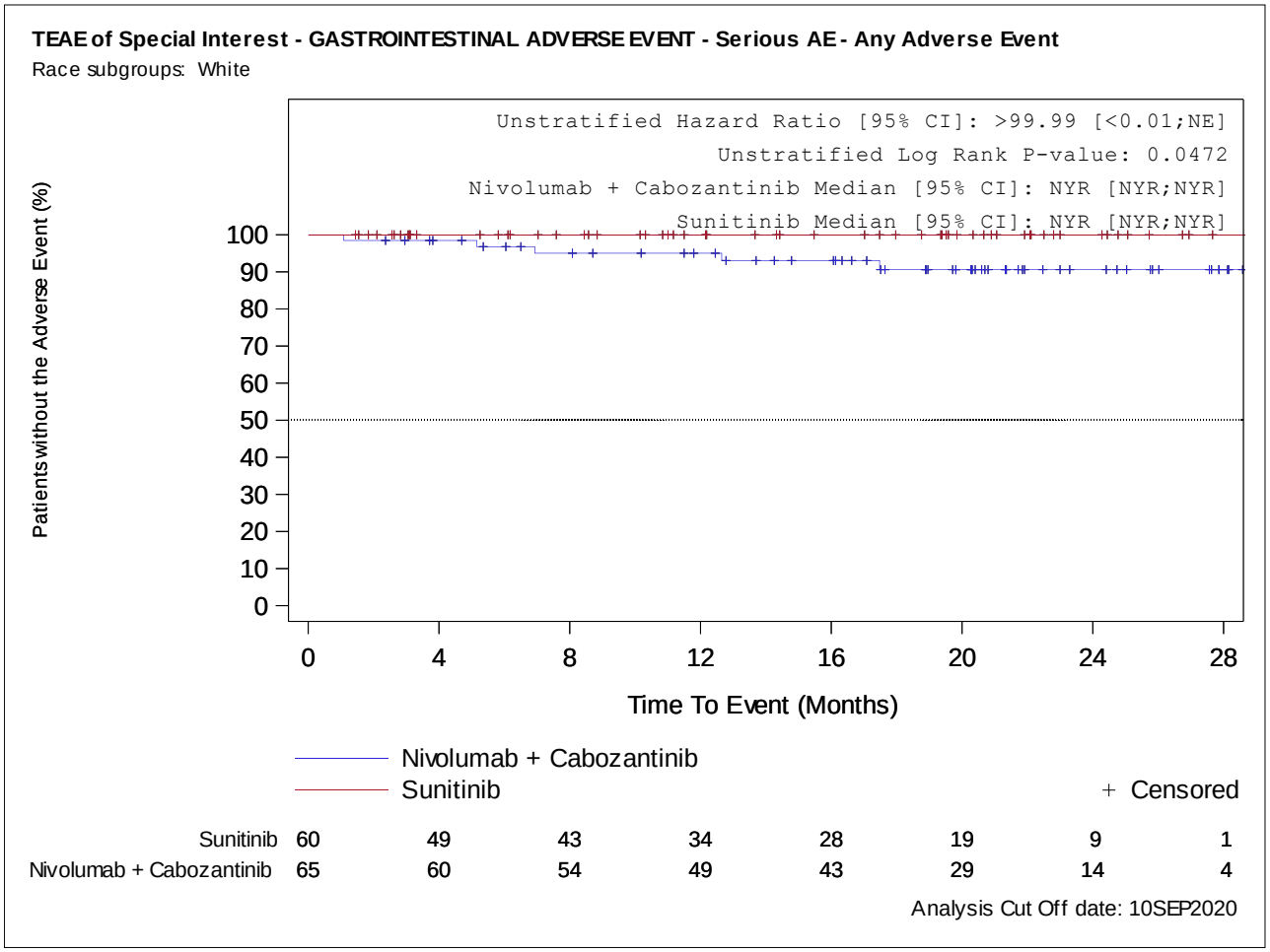

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:43:00

FIGURE 3.27.2.7: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



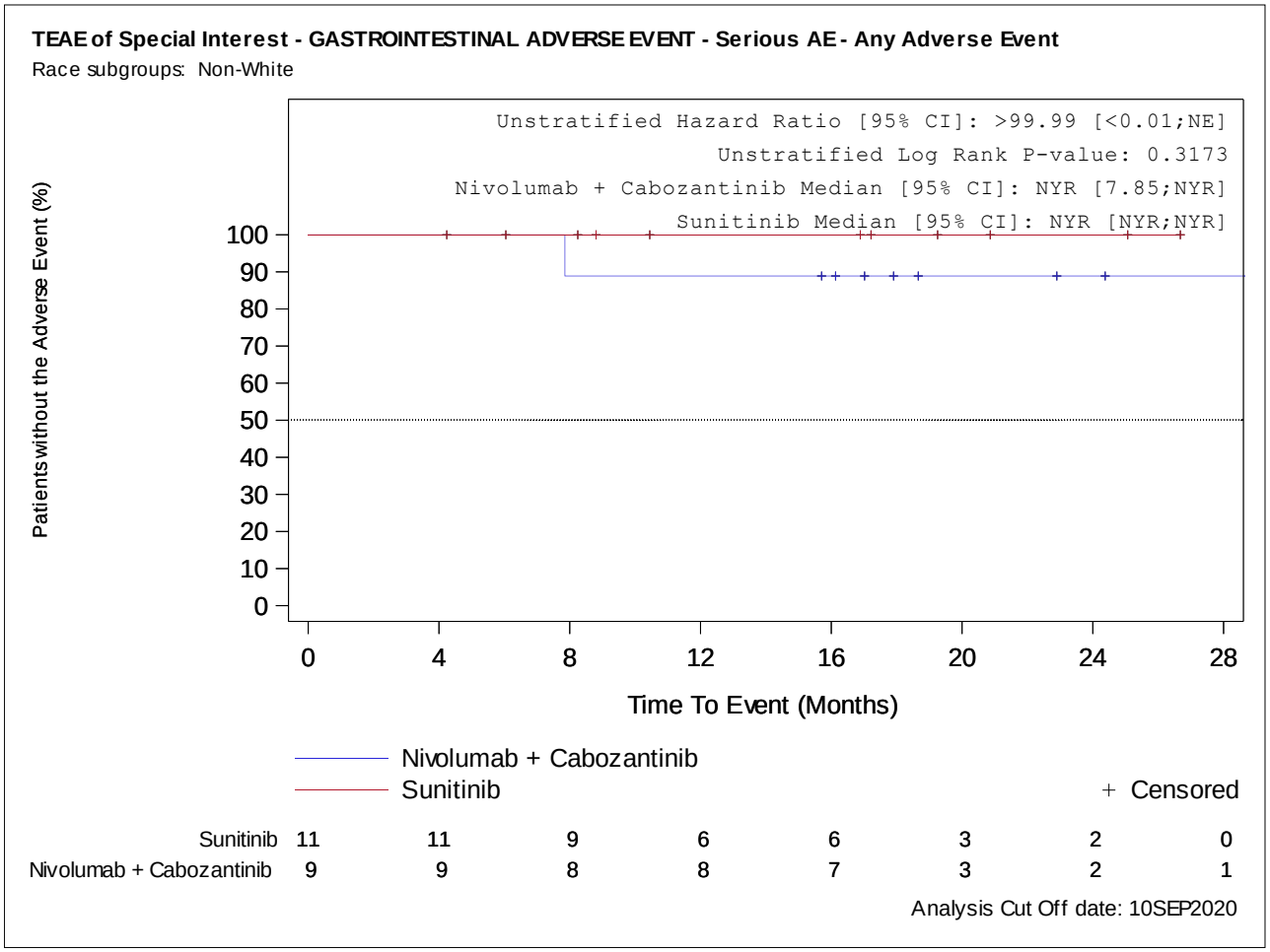

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:43:06

FIGURE 3.27.2.8: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



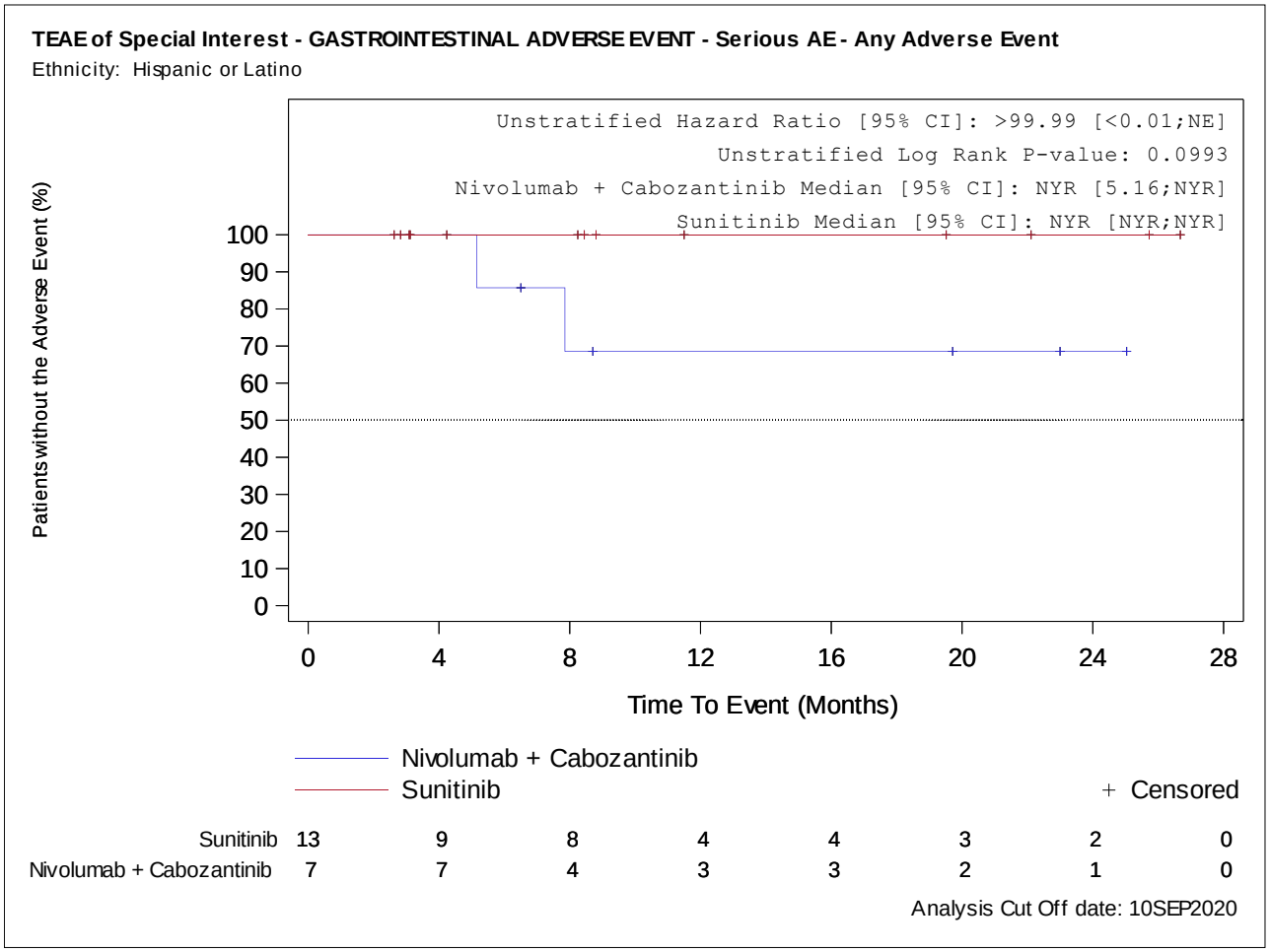

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:43:12

FIGURE 3.27.2.9: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



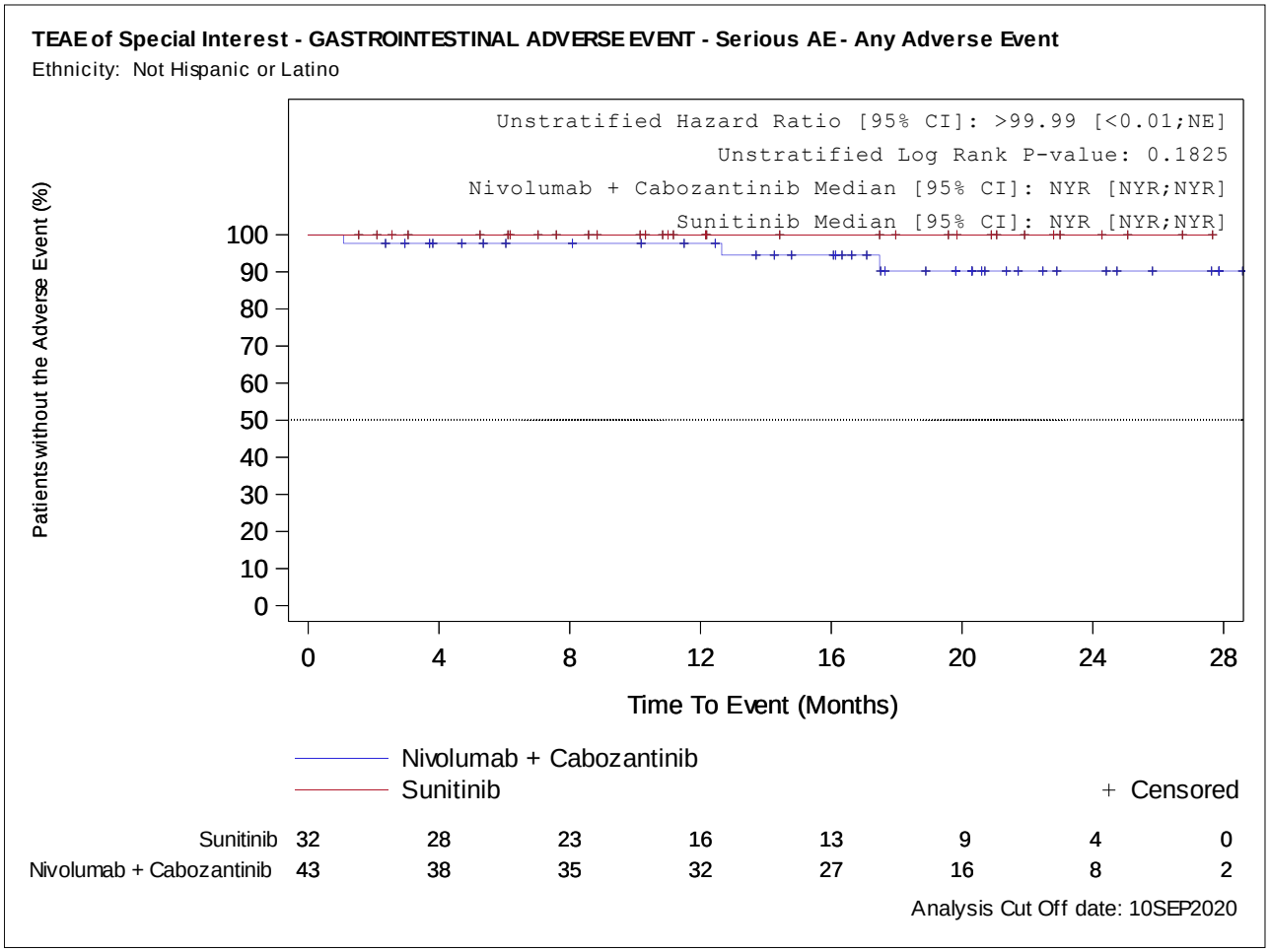

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:43:18

FIGURE 3.27.2.10: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



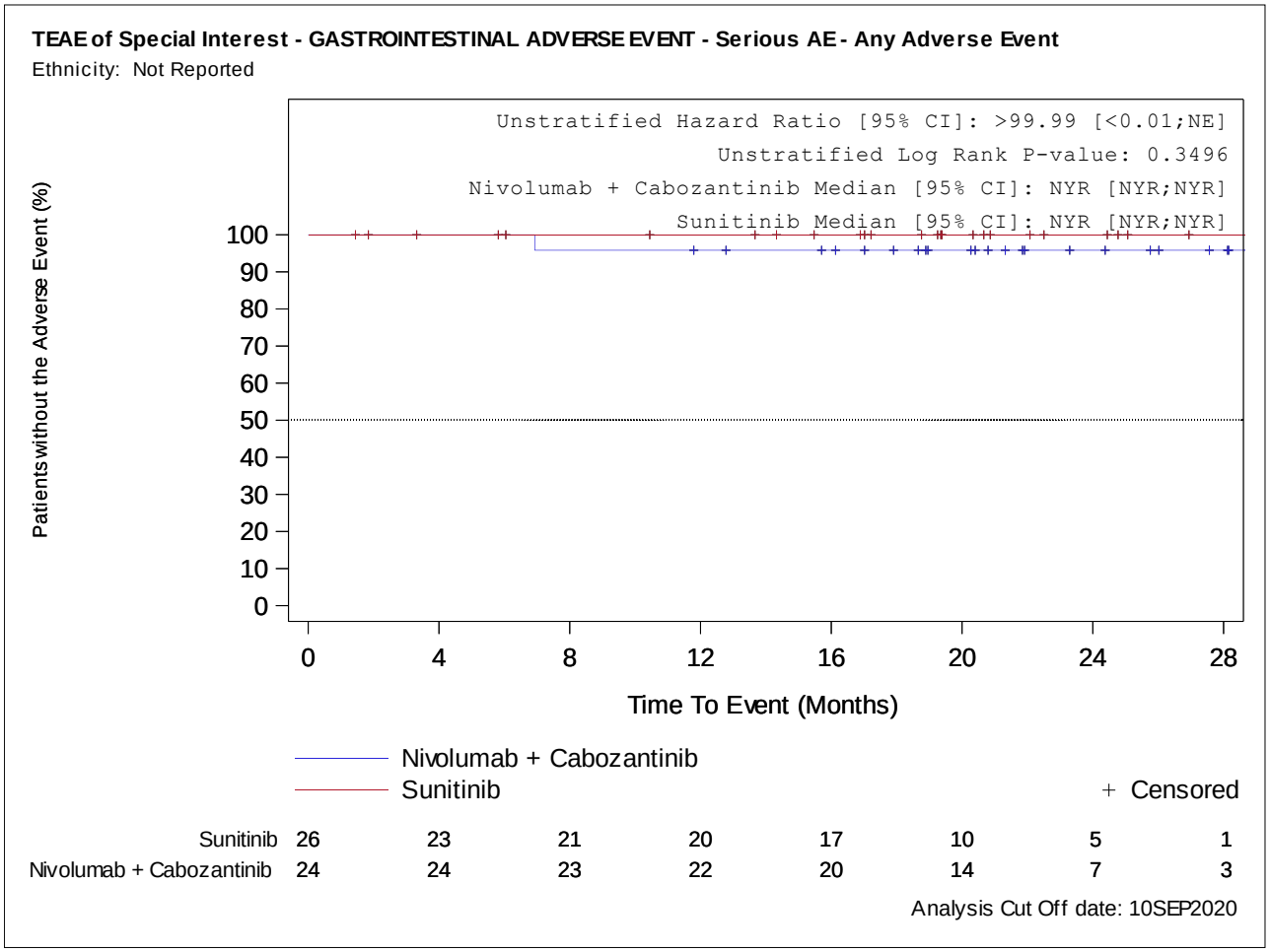

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:43:24

FIGURE 3.27.2.11: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



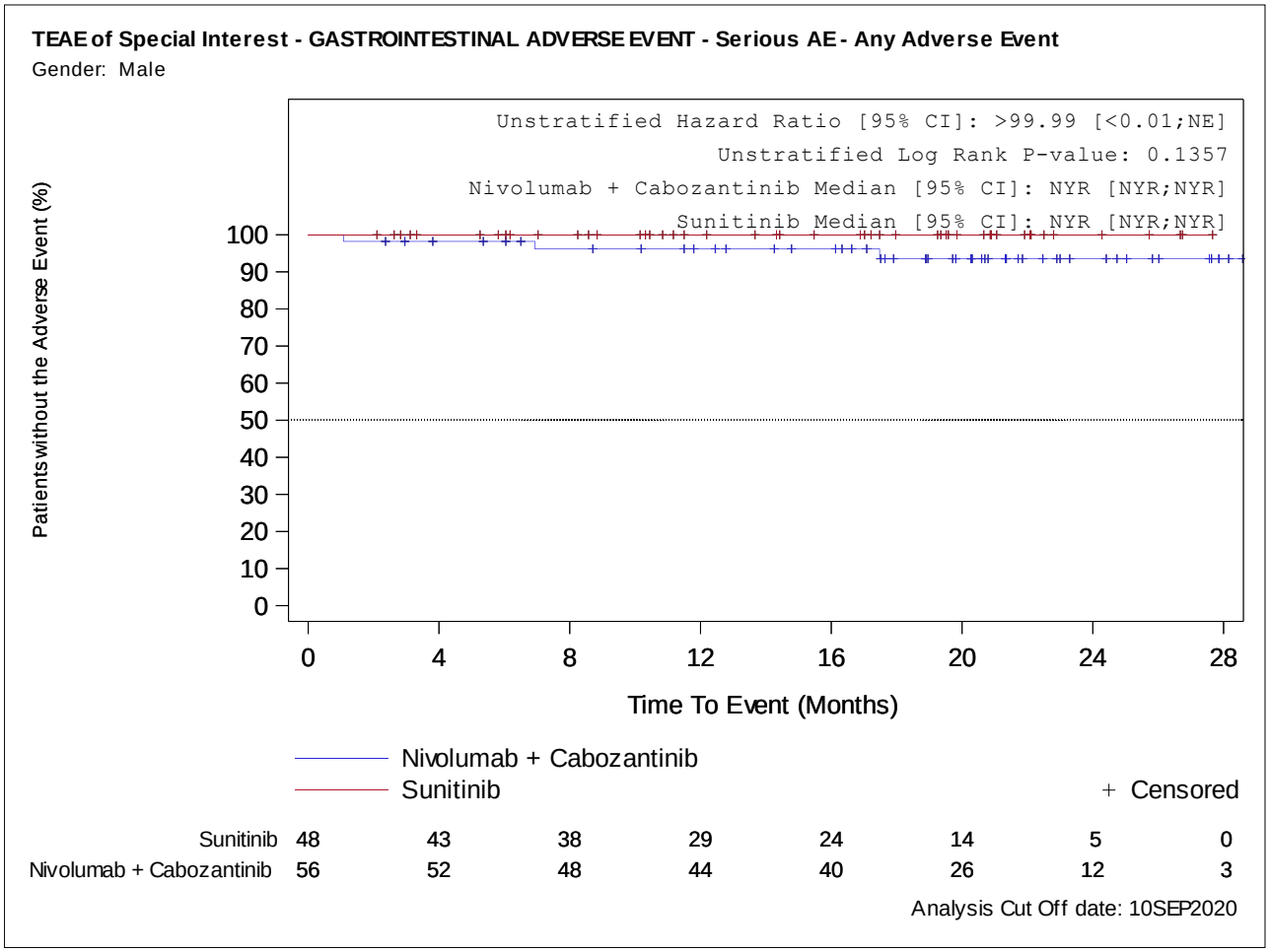

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:43:30

FIGURE 3.27.2.12: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



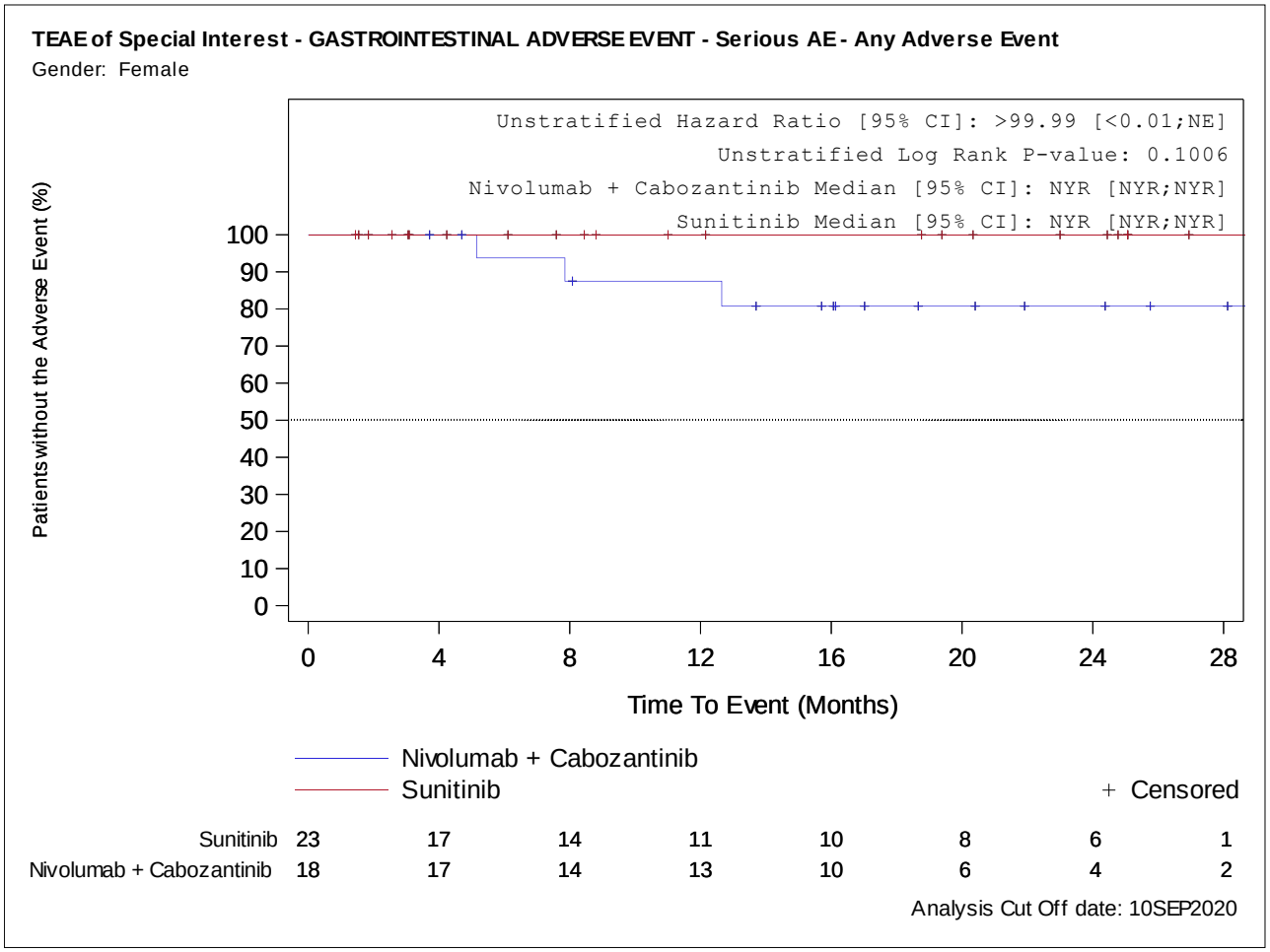

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:43:36

FIGURE 3.27.2.13: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



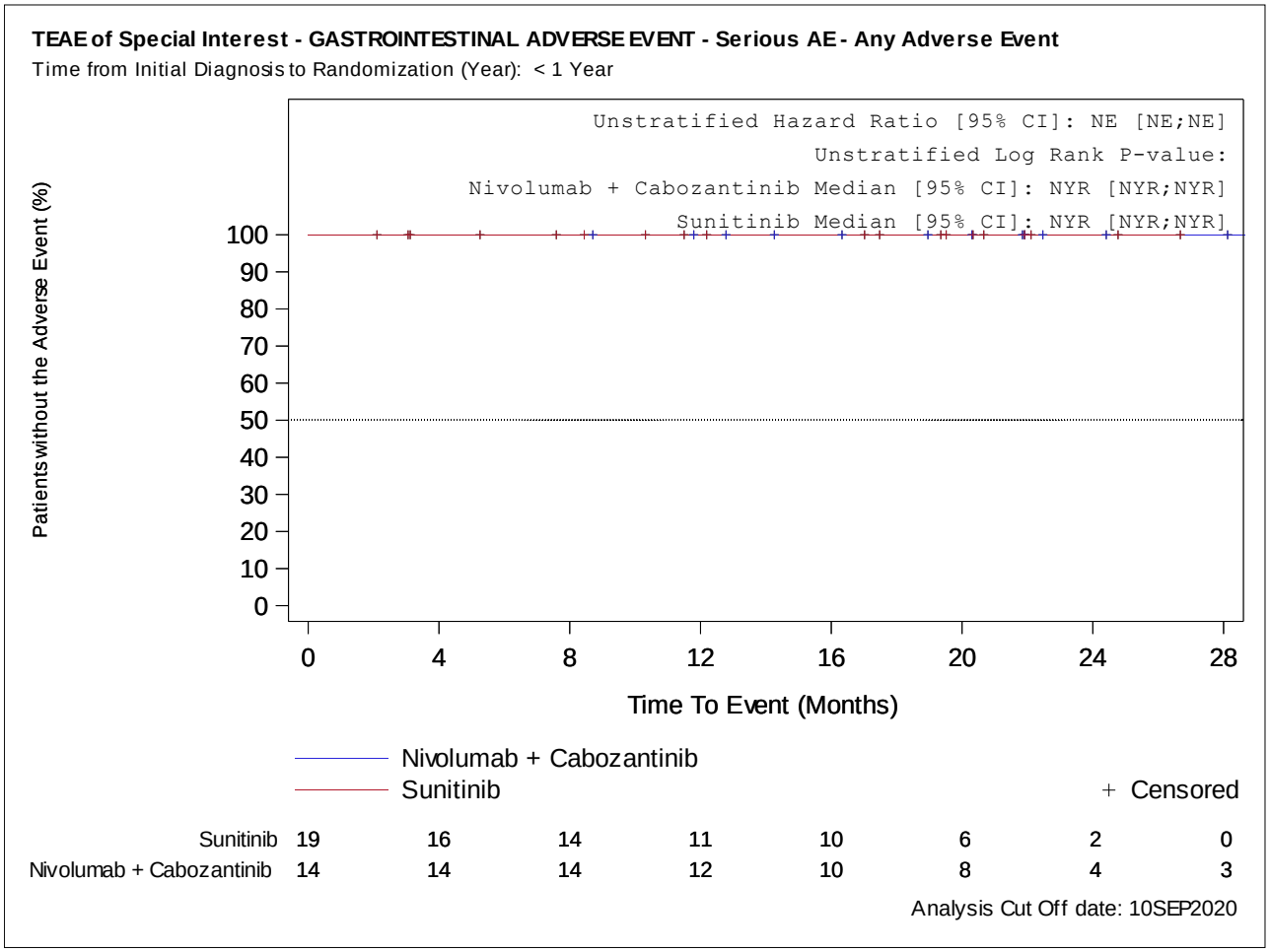

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:43:42

FIGURE 3.27.2.14: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



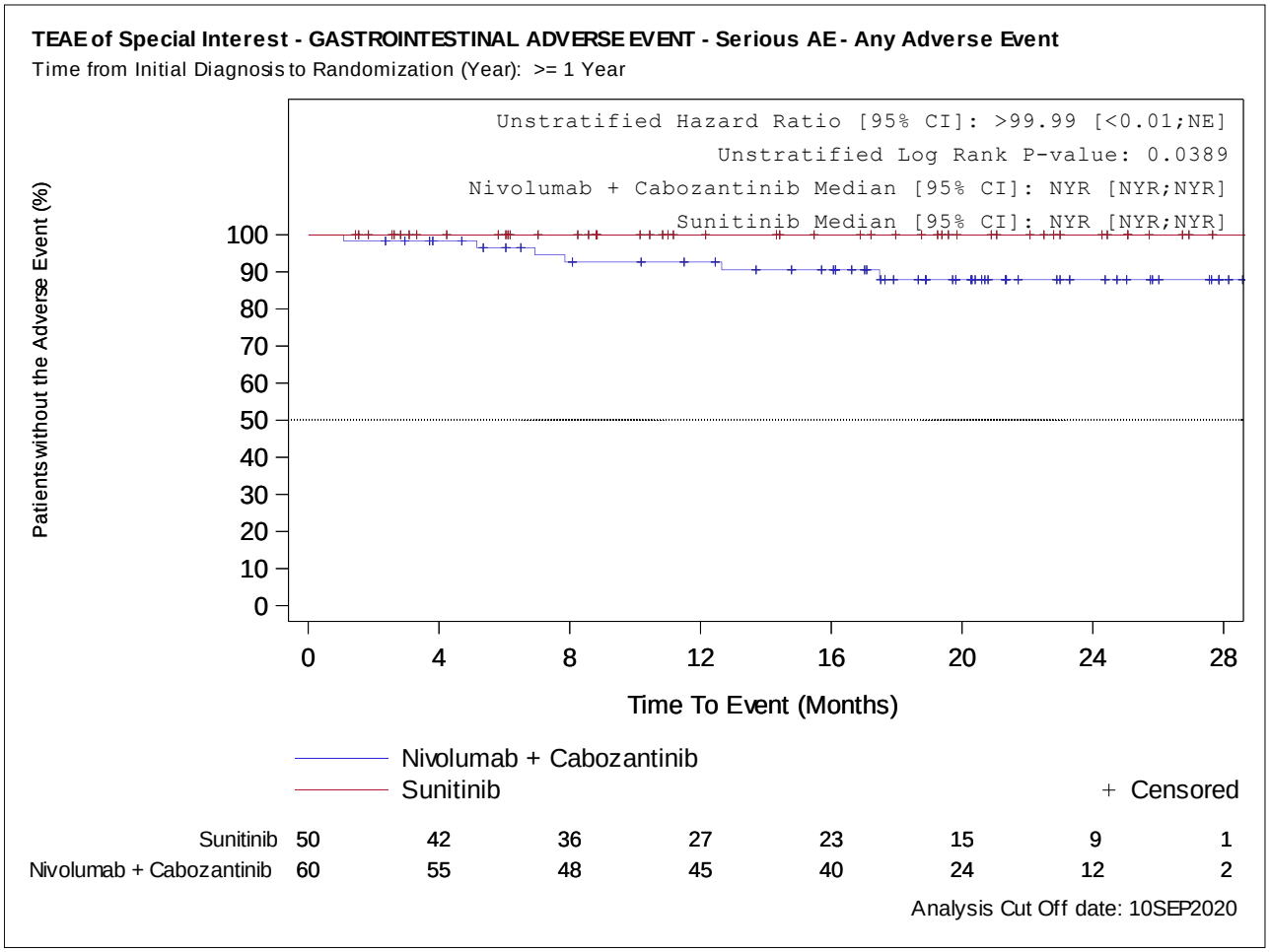

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:43:48

FIGURE 3.27.2.15: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



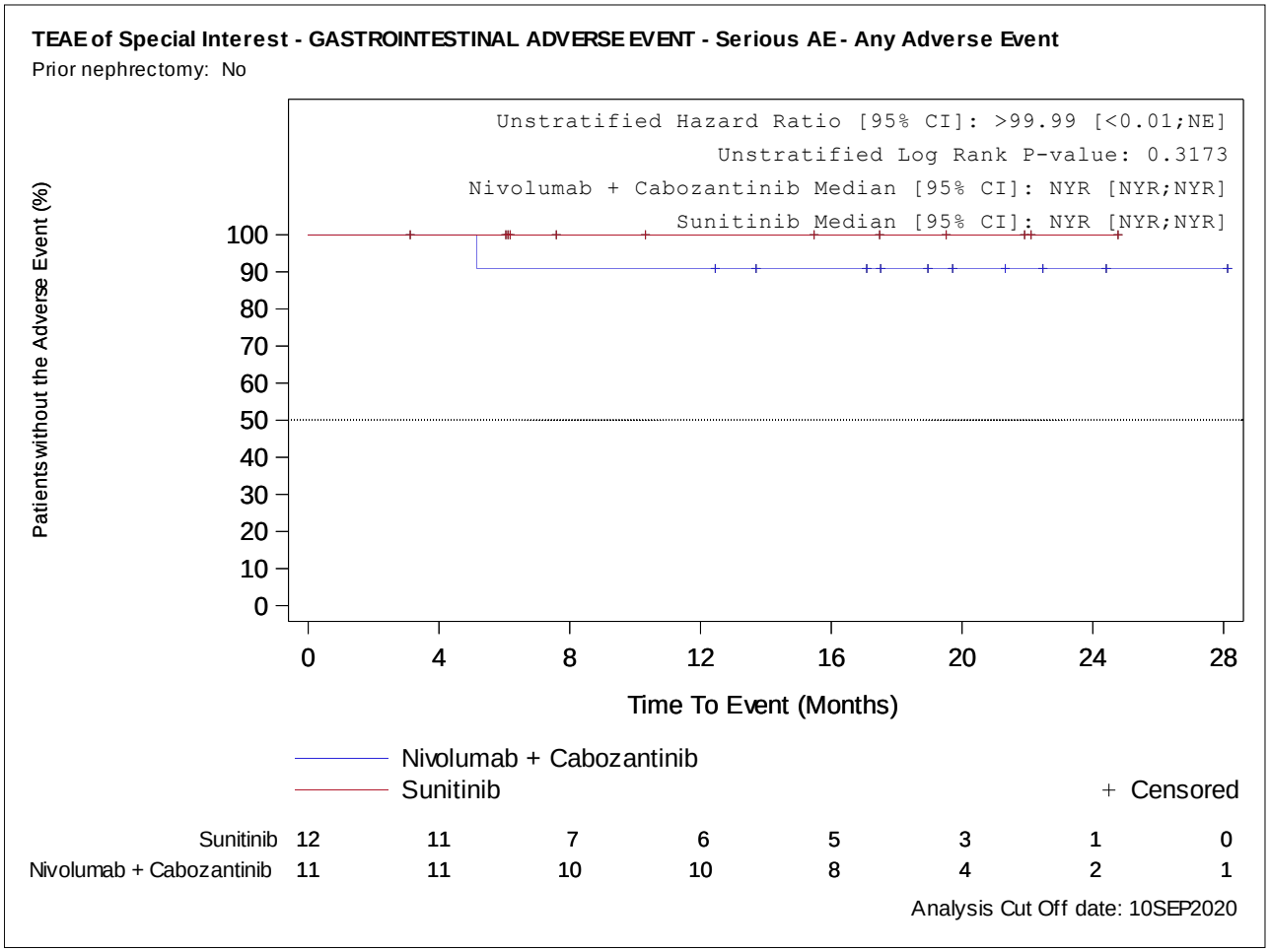

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:44:04

FIGURE 3.27.2.16: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



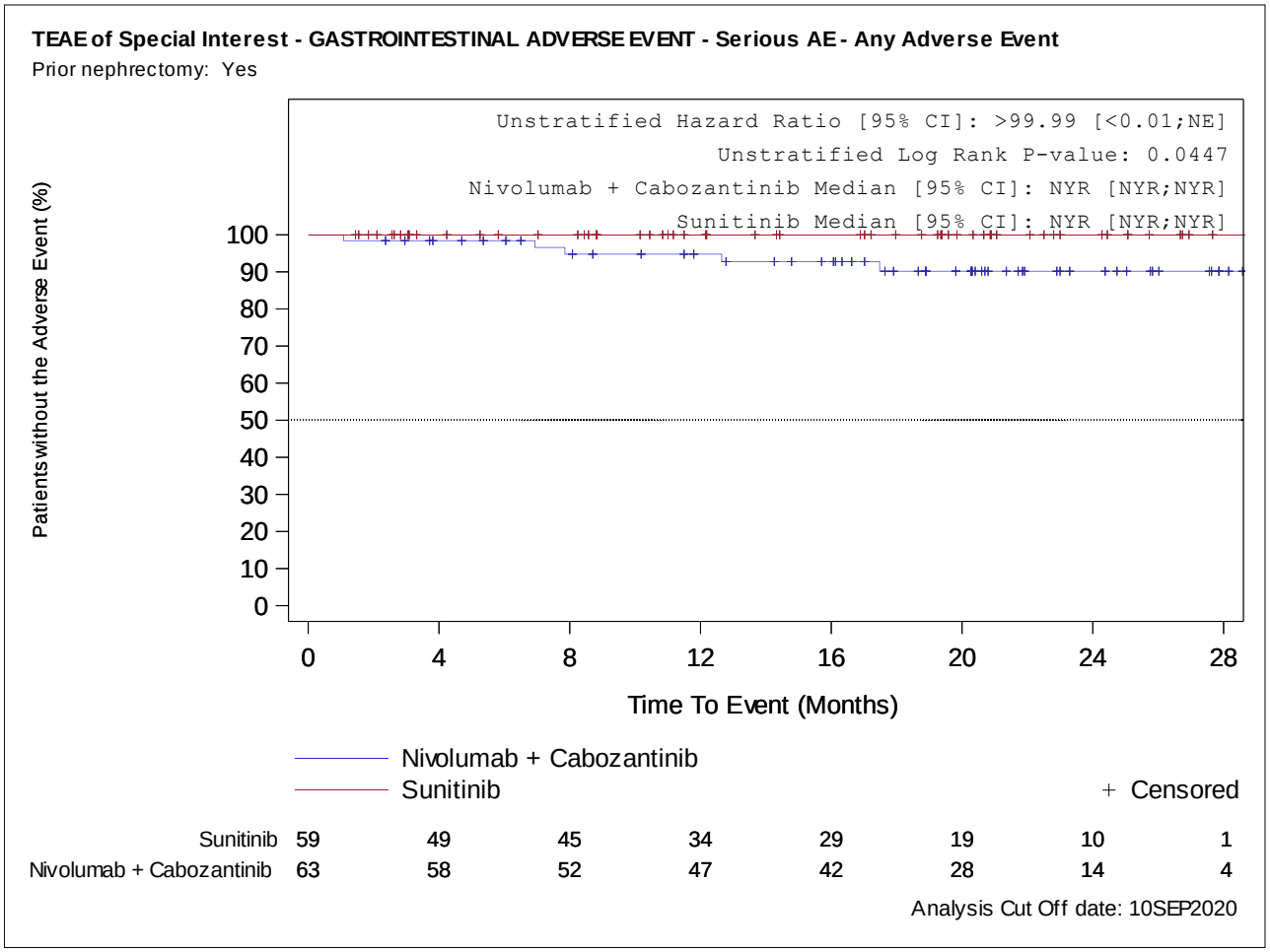

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:44:10

FIGURE 3.27.2.17: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



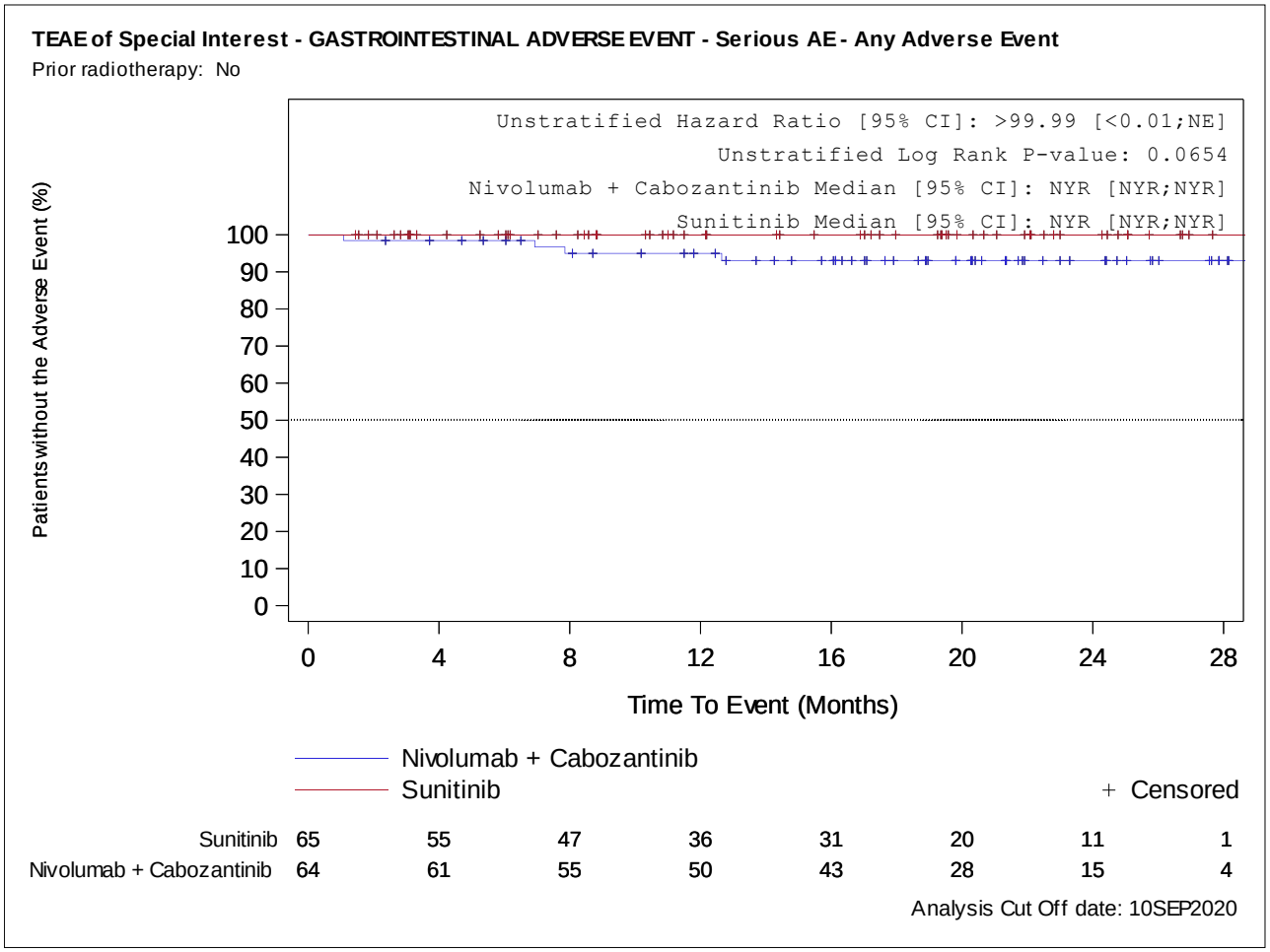

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:45:03

FIGURE 3.27.2.18: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



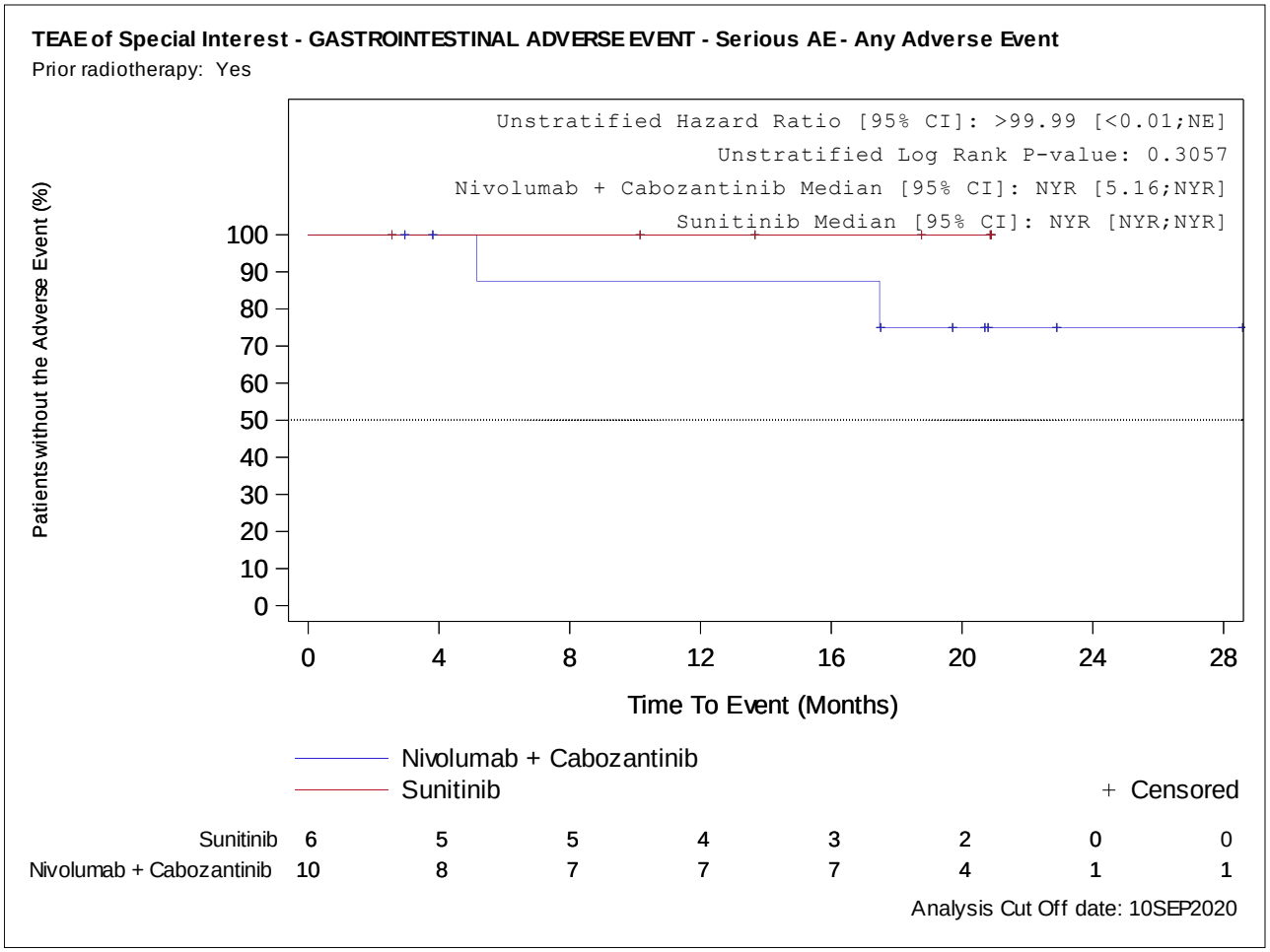

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:45:08

FIGURE 3.27.2.19: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



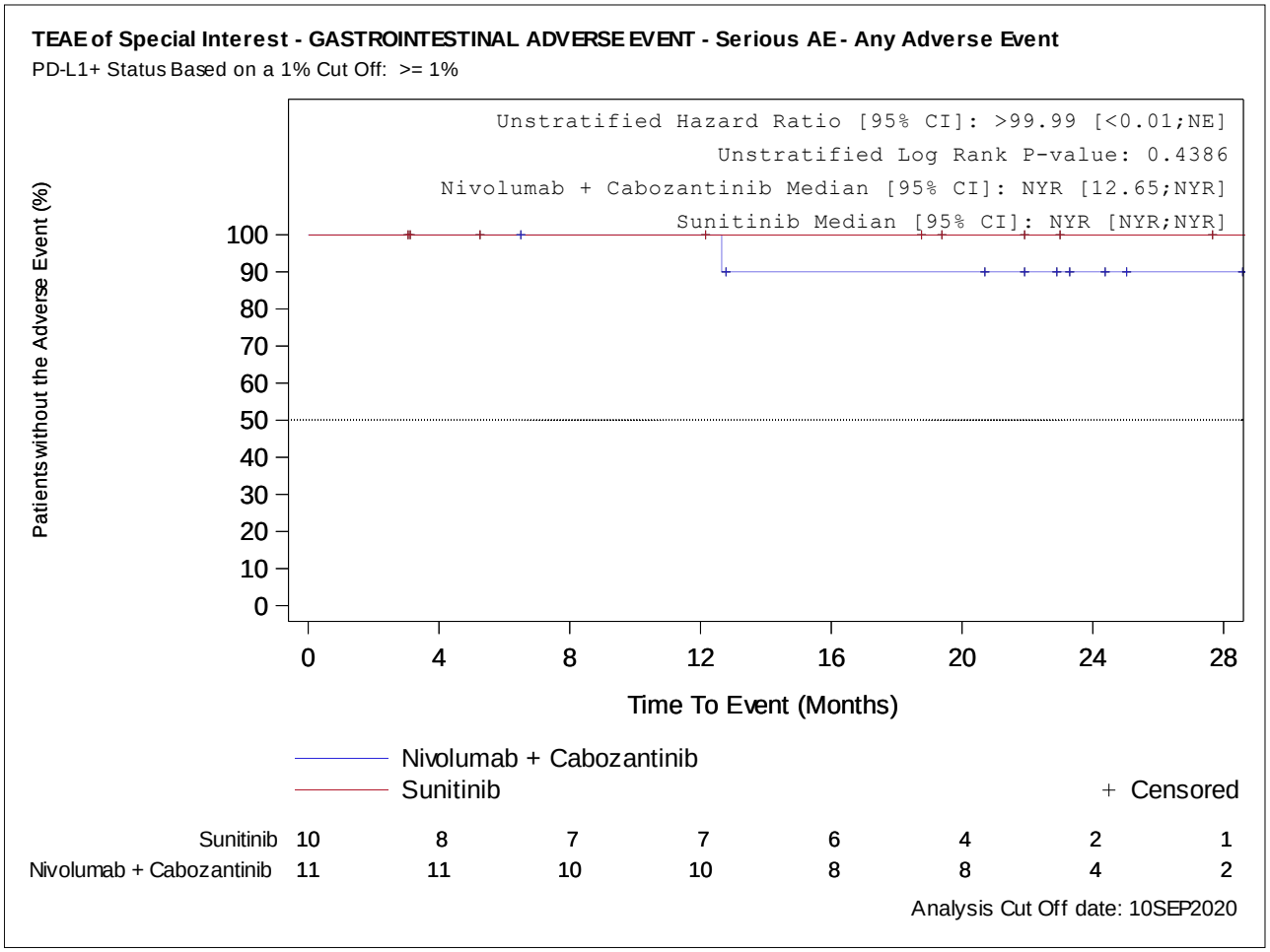

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:45:14

FIGURE 3.27.2.20: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



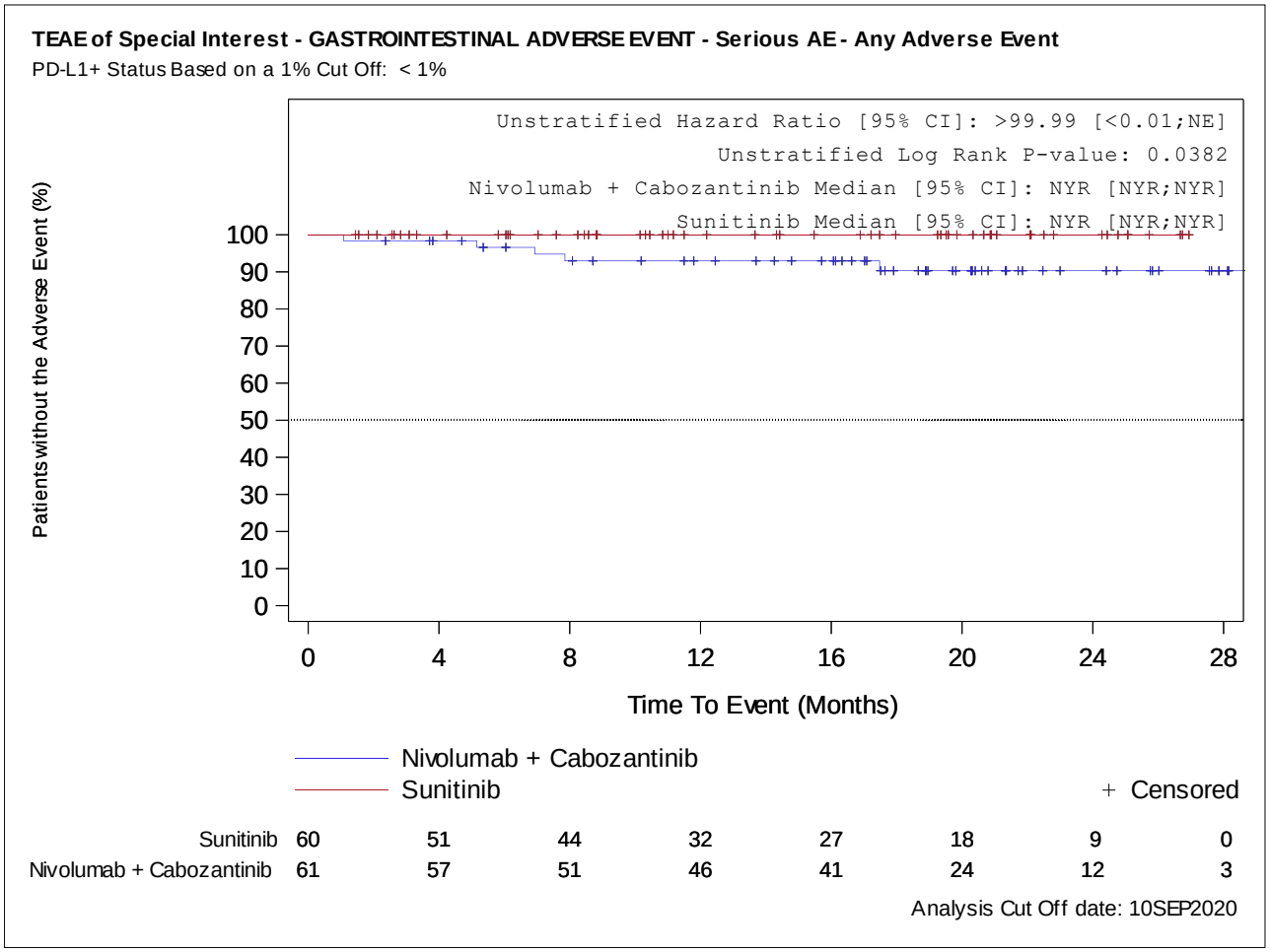

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:45:20

FIGURE 3.27.2.21: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



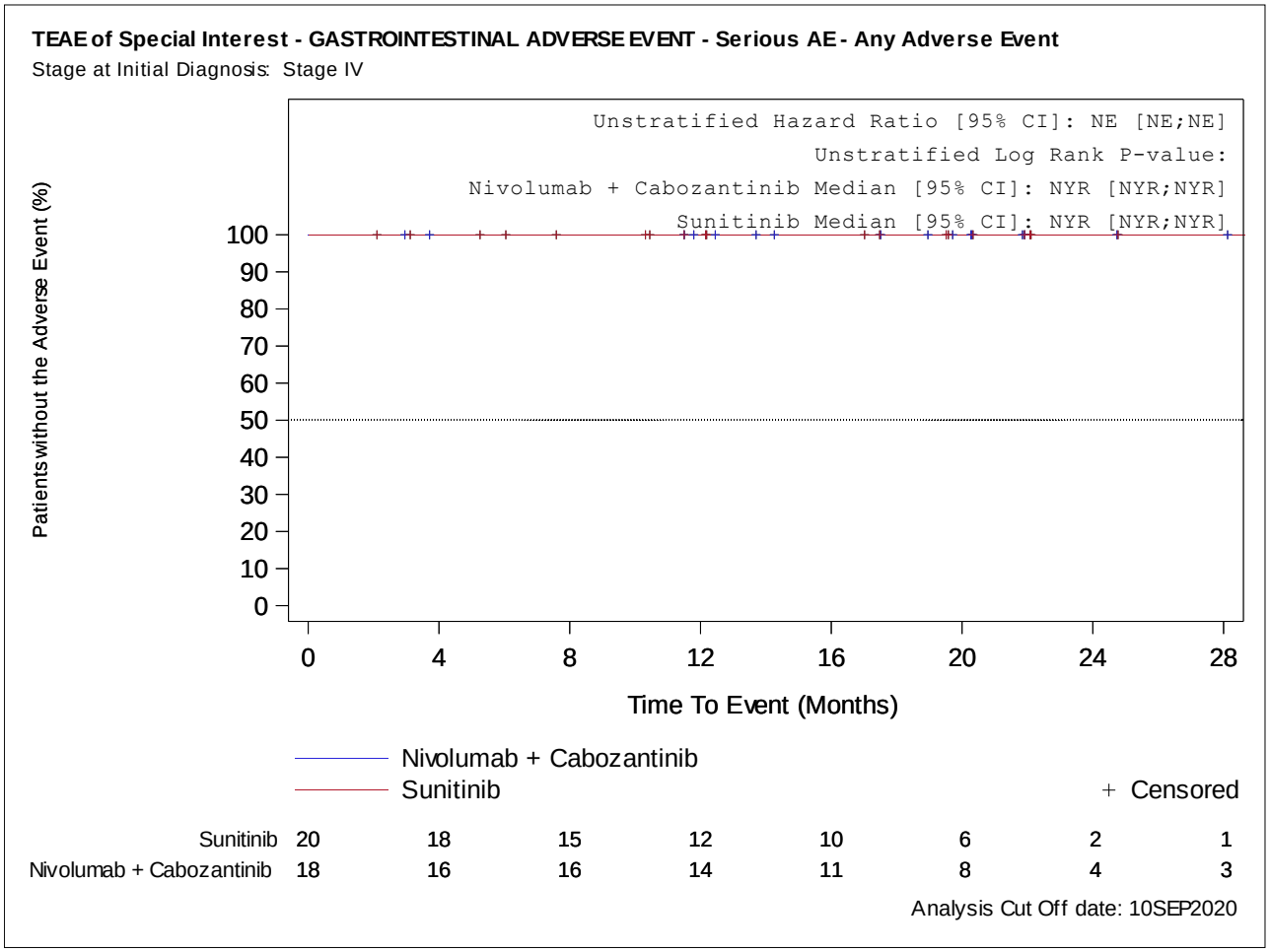

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:45:26

FIGURE 3.27.2.22: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



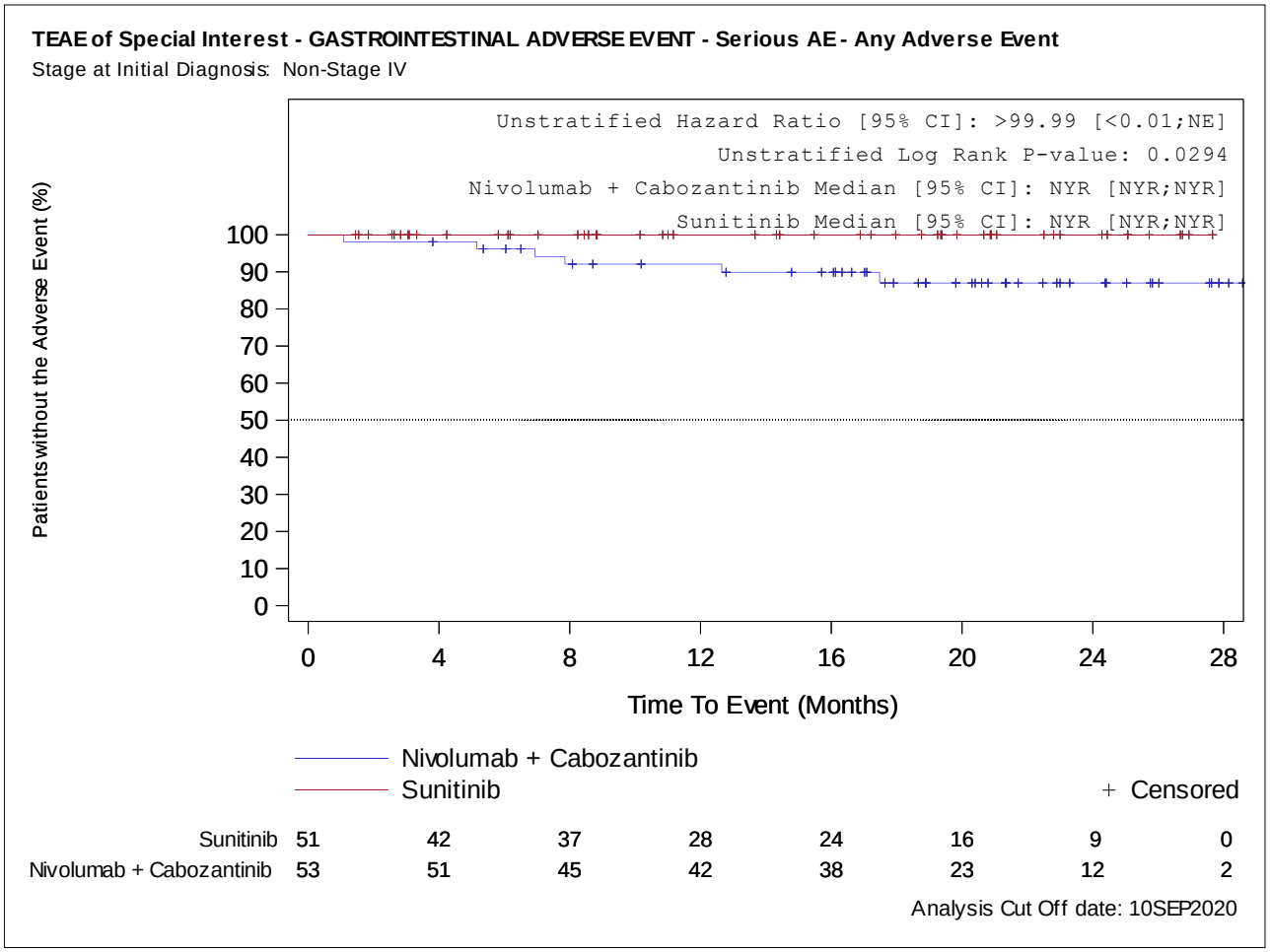

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:45:32

FIGURE 3.27.2.23: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



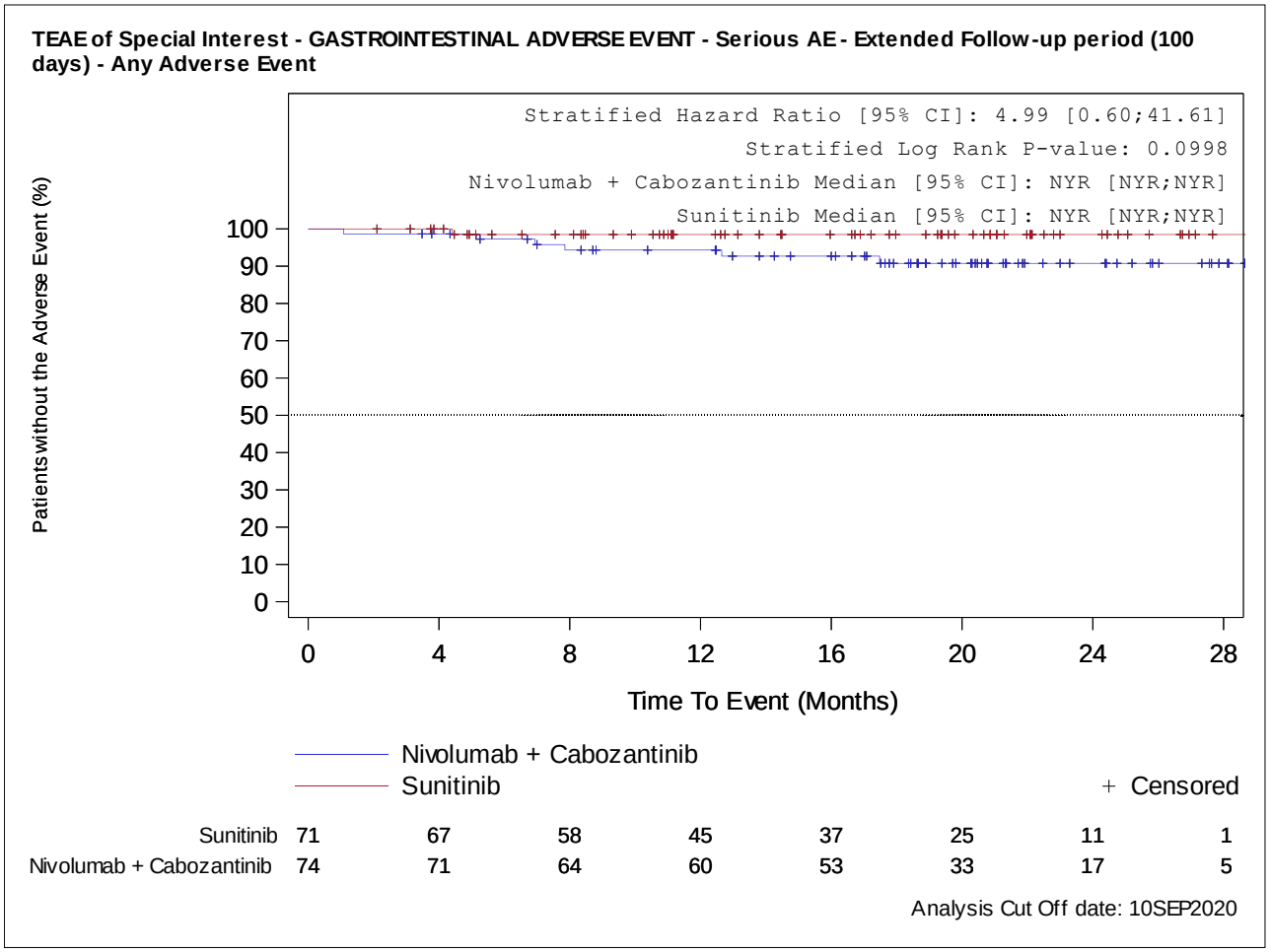

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:46:00

FIGURE 3.27.2.24: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



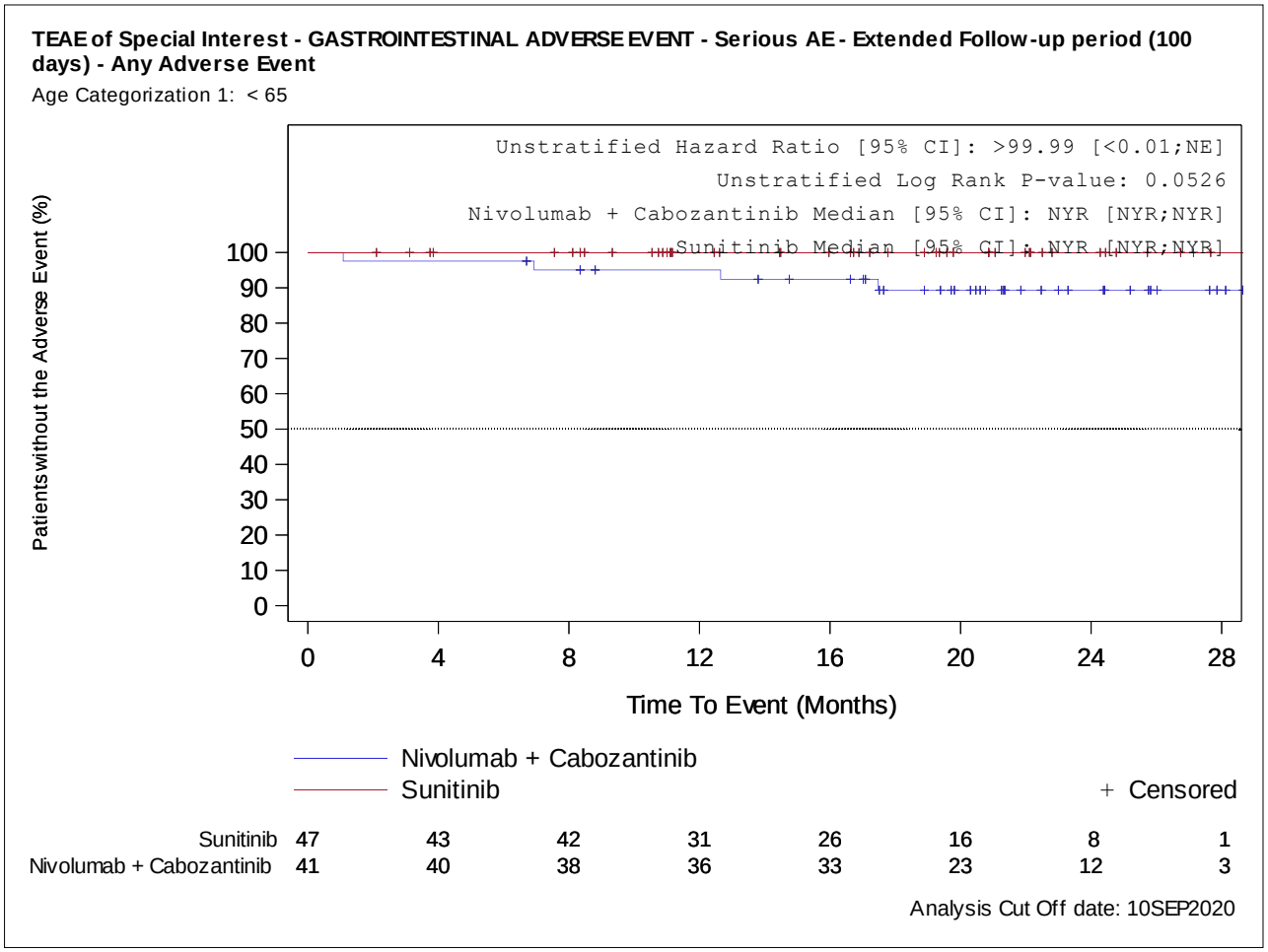

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:46:06

FIGURE 3.28.1: TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



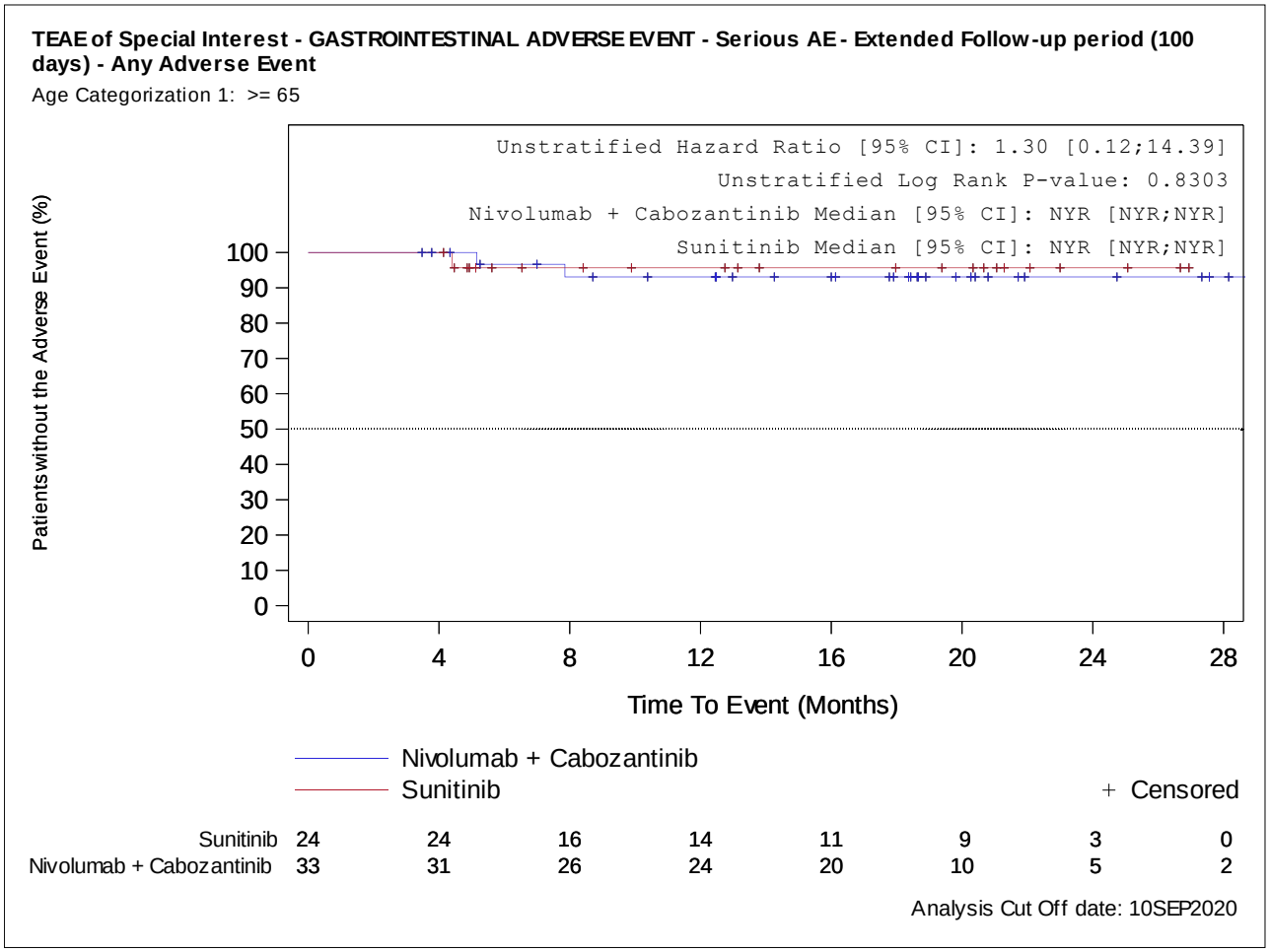

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:49:23

FIGURE 3.28.2.1: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



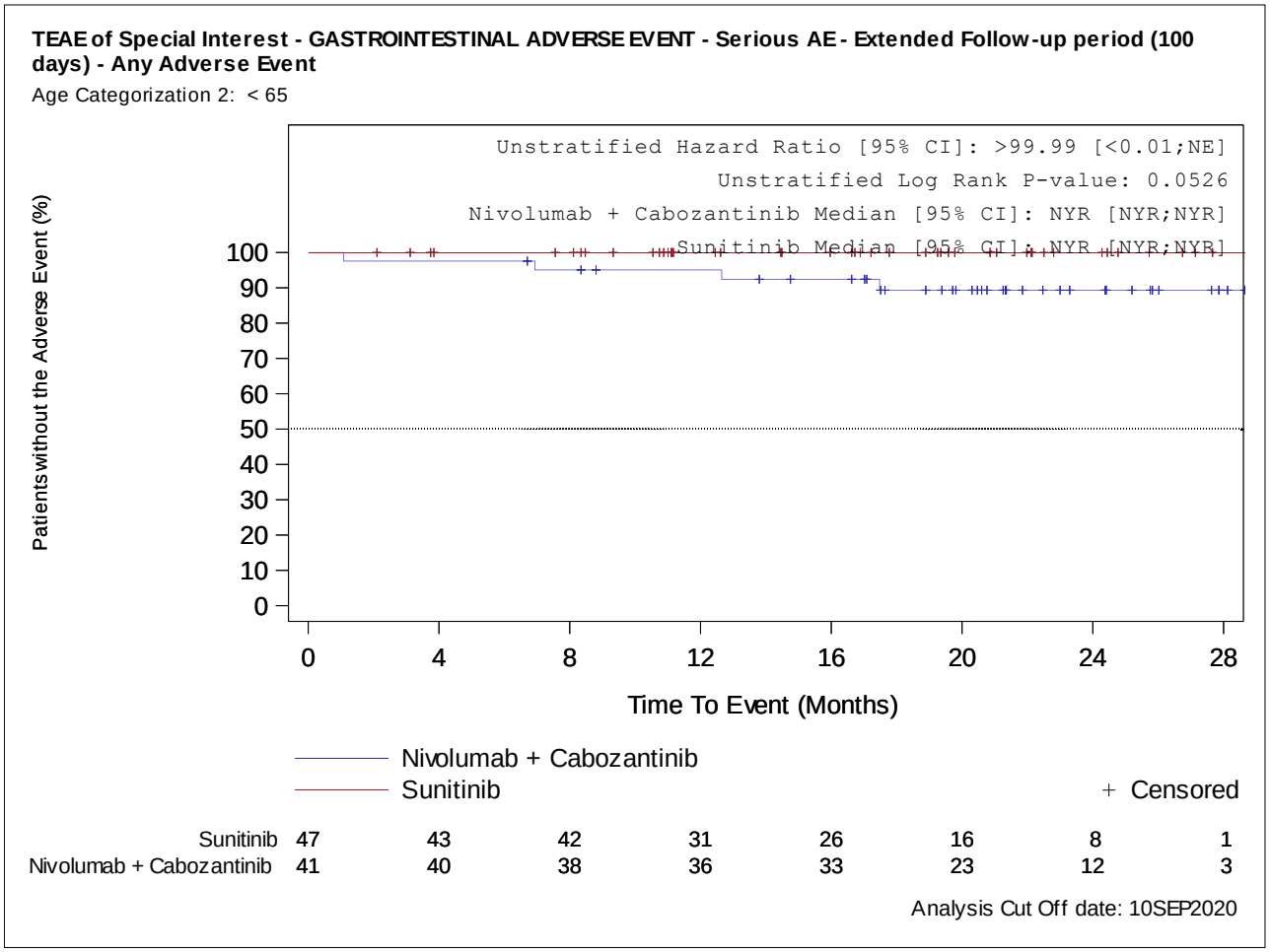

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:49:26

FIGURE 3.28.2.2: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



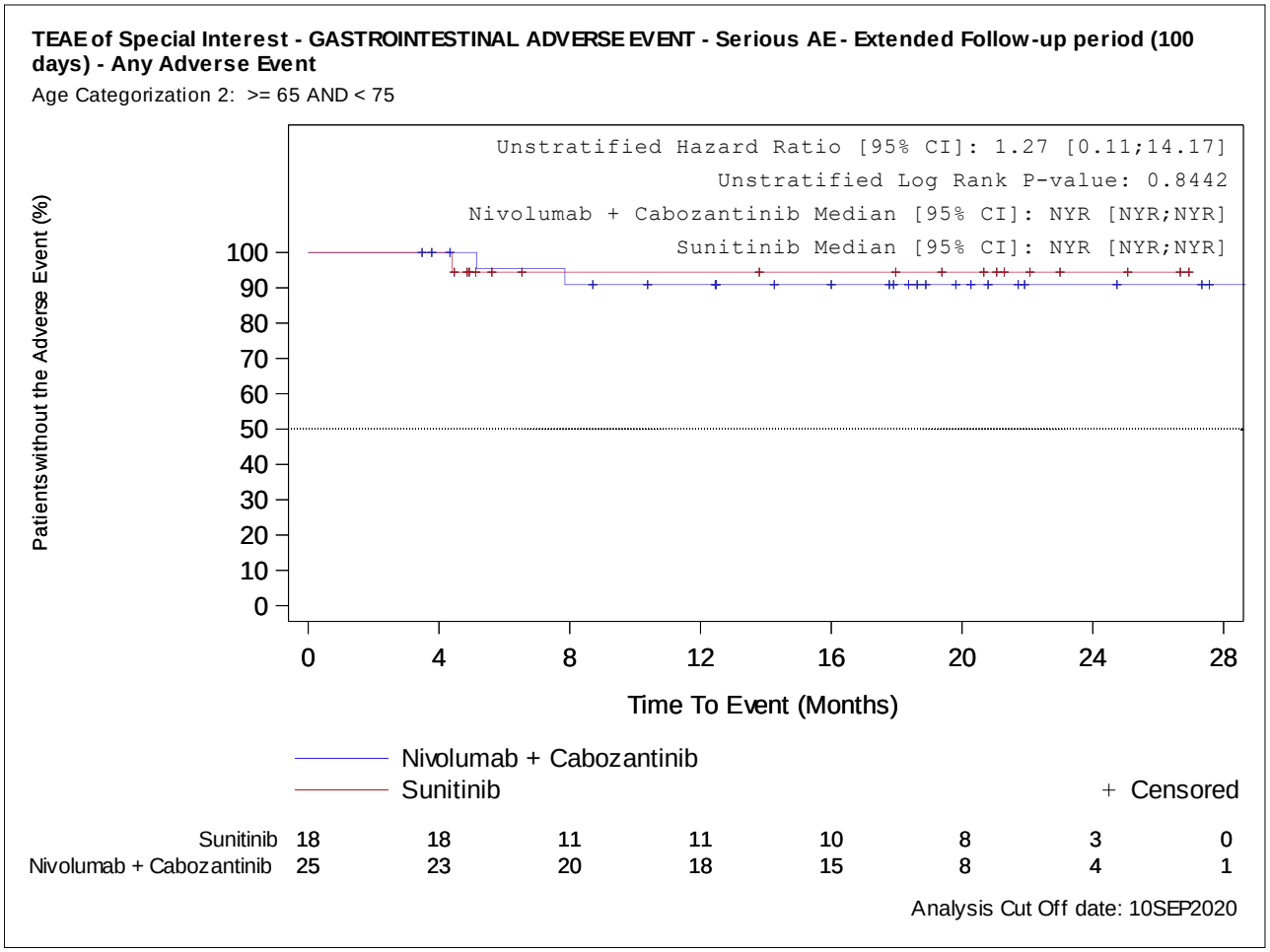

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:49:32

FIGURE 3.28.2.3: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



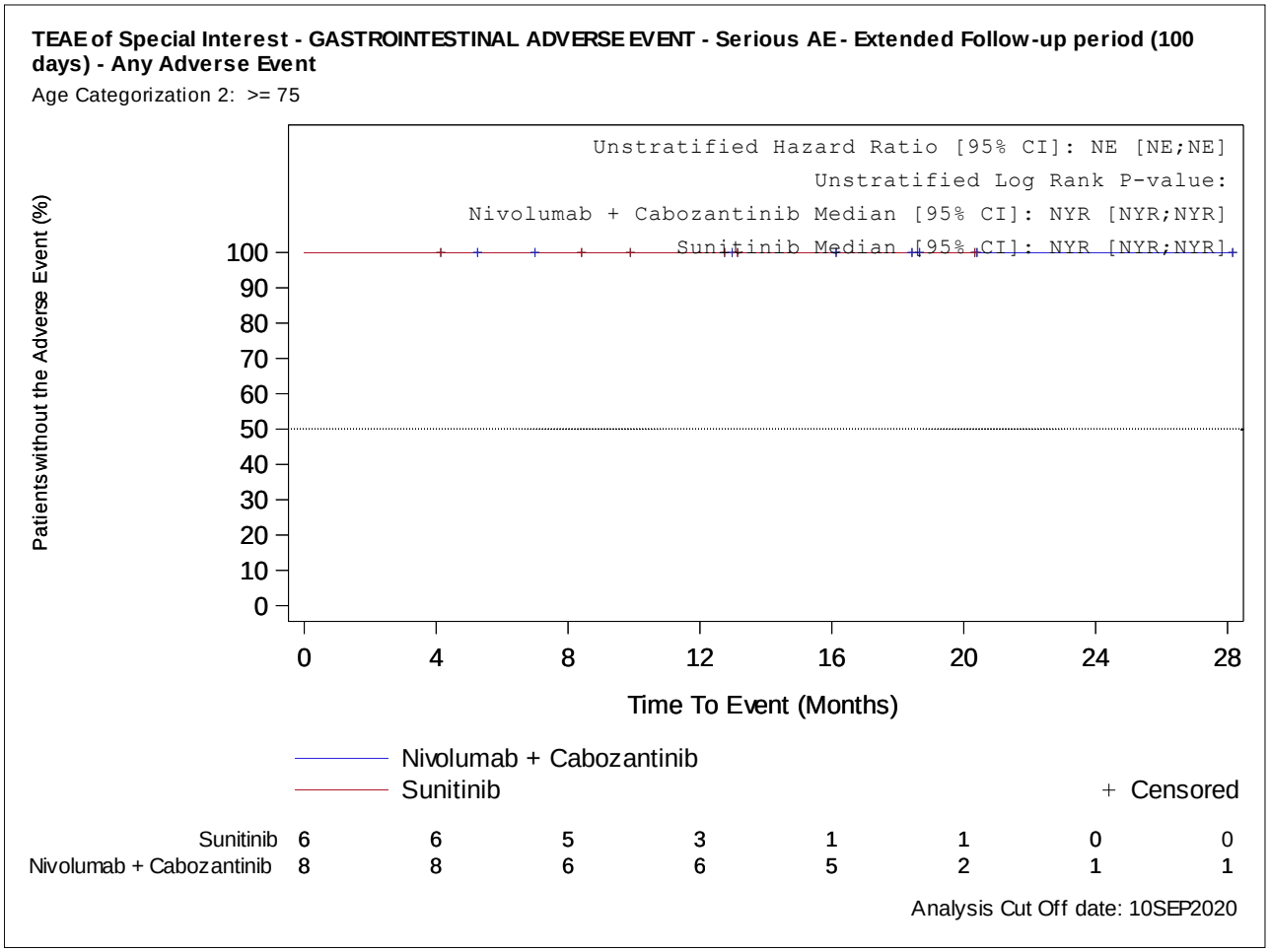

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:49:38

FIGURE 3.28.2.4: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



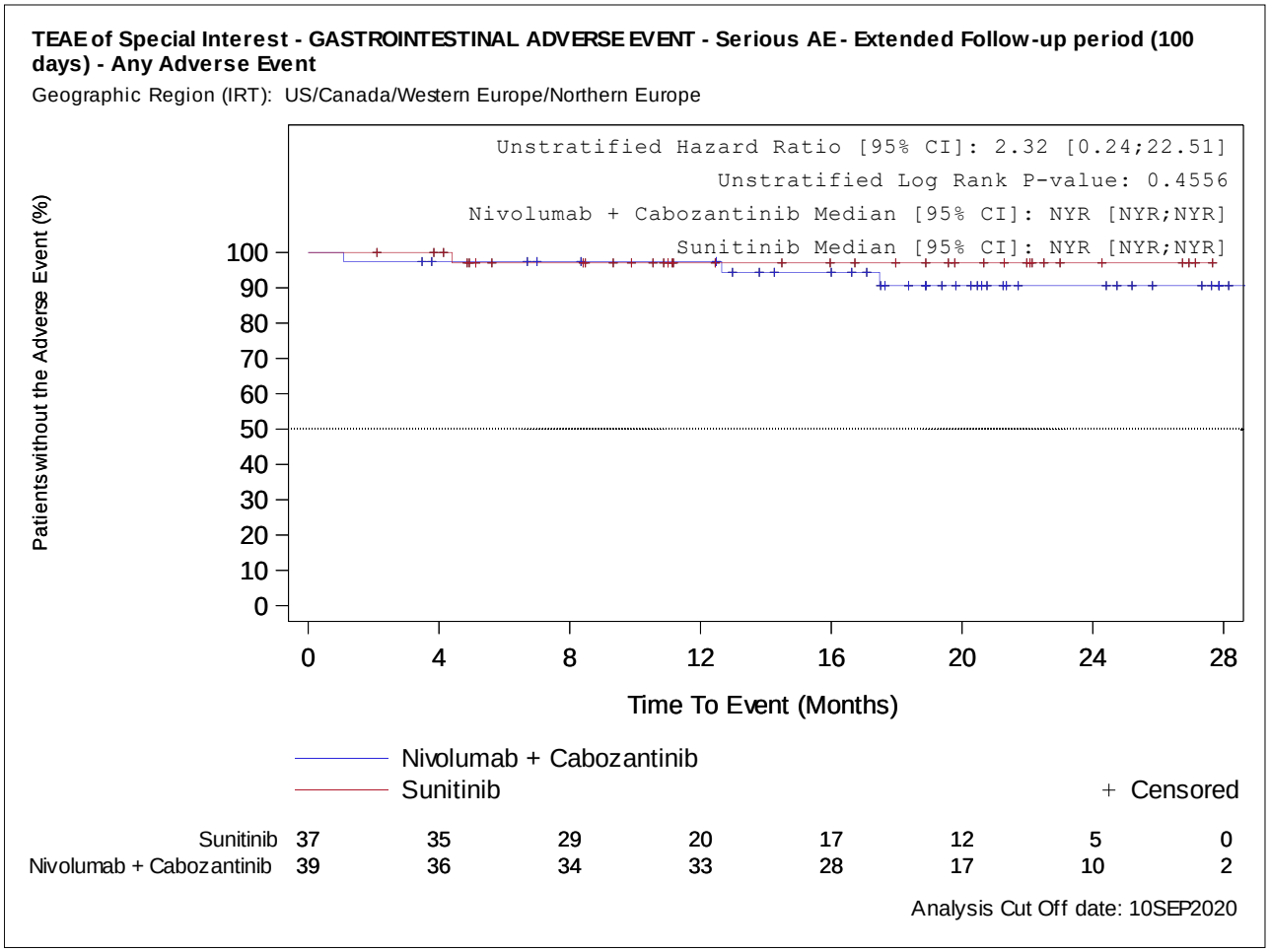

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:49:43

FIGURE 3.28.2.5: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



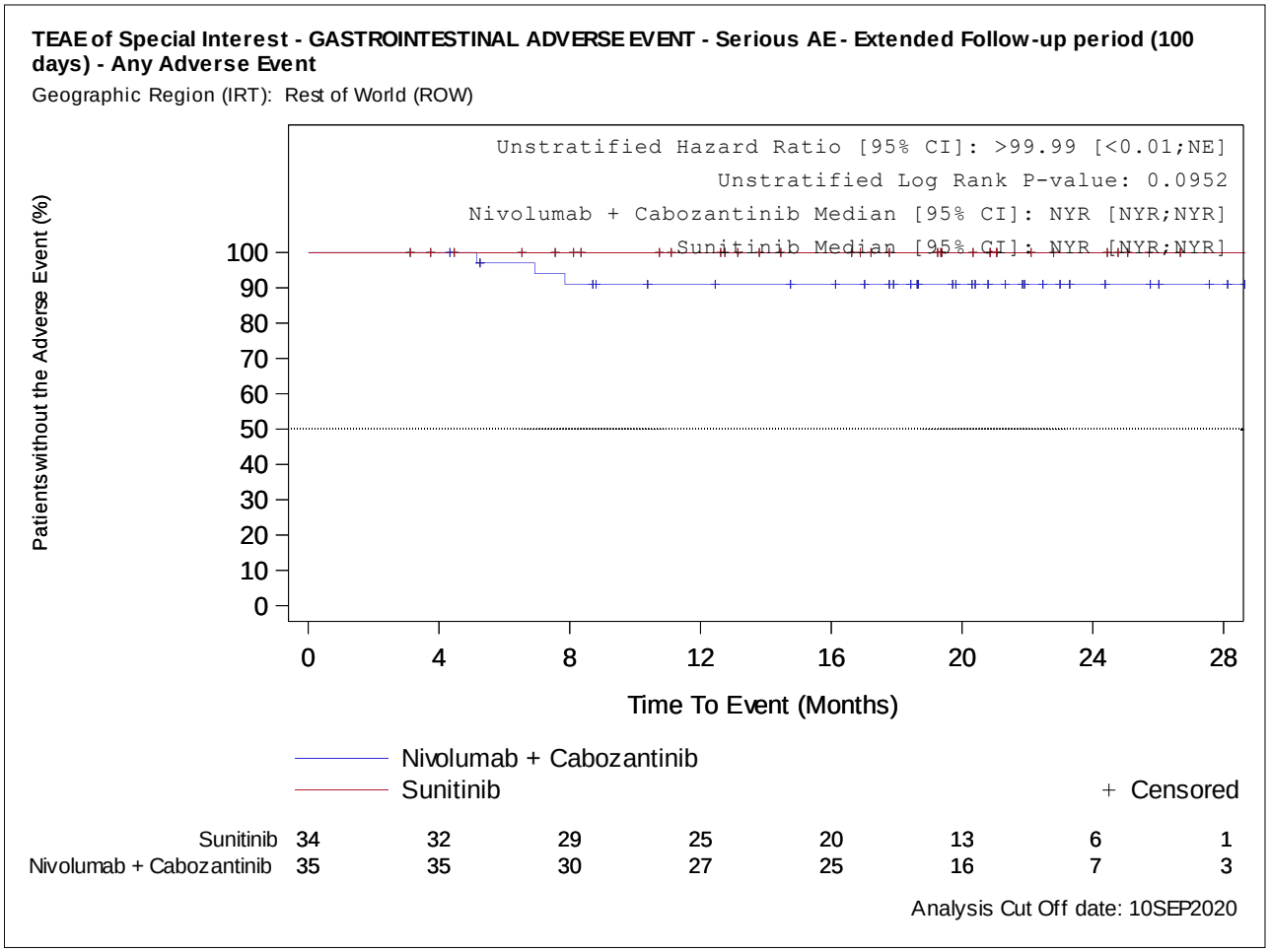

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:49:49

FIGURE 3.28.2.6: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



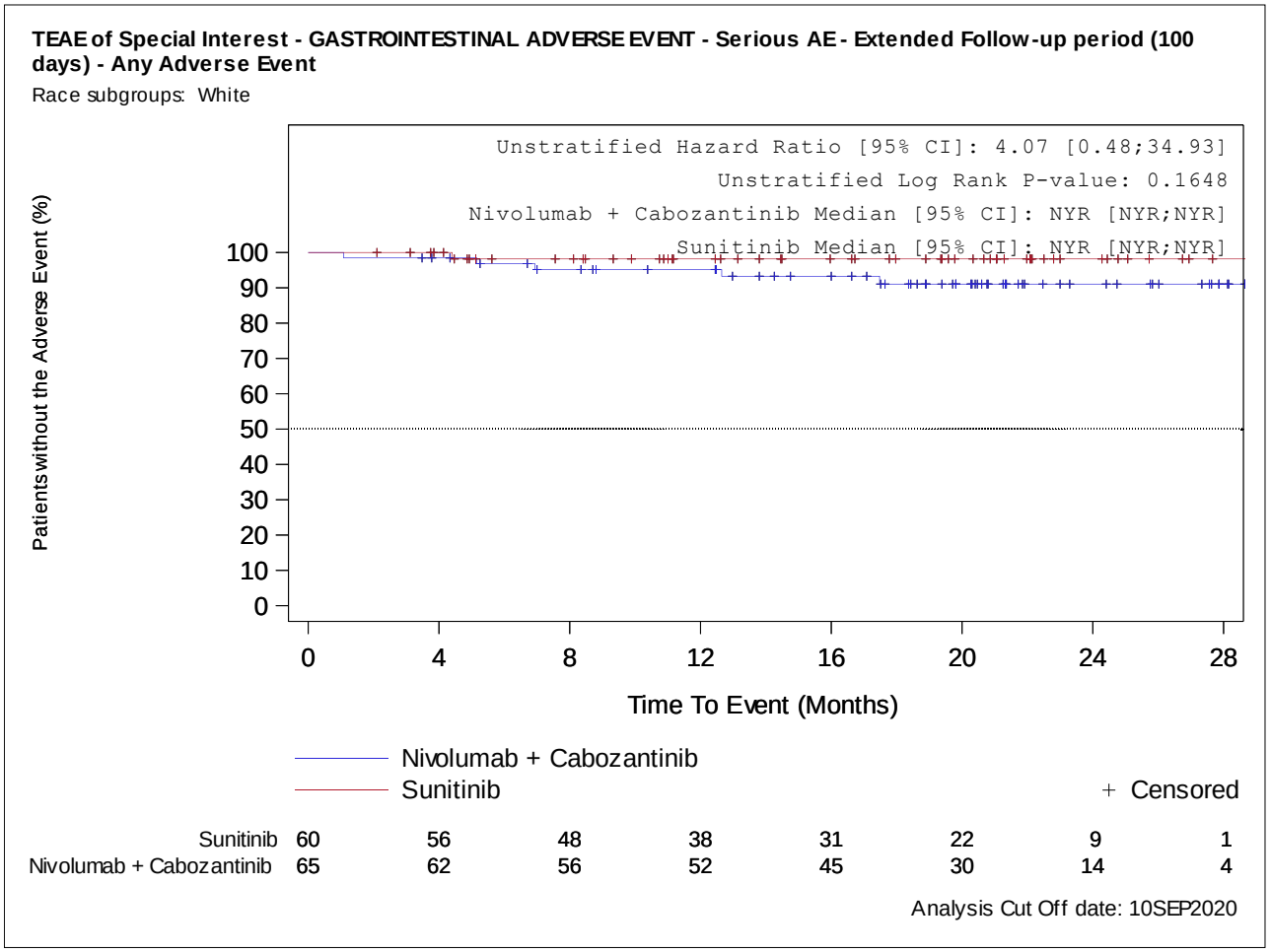

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:49:56

FIGURE 3.28.2.7: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



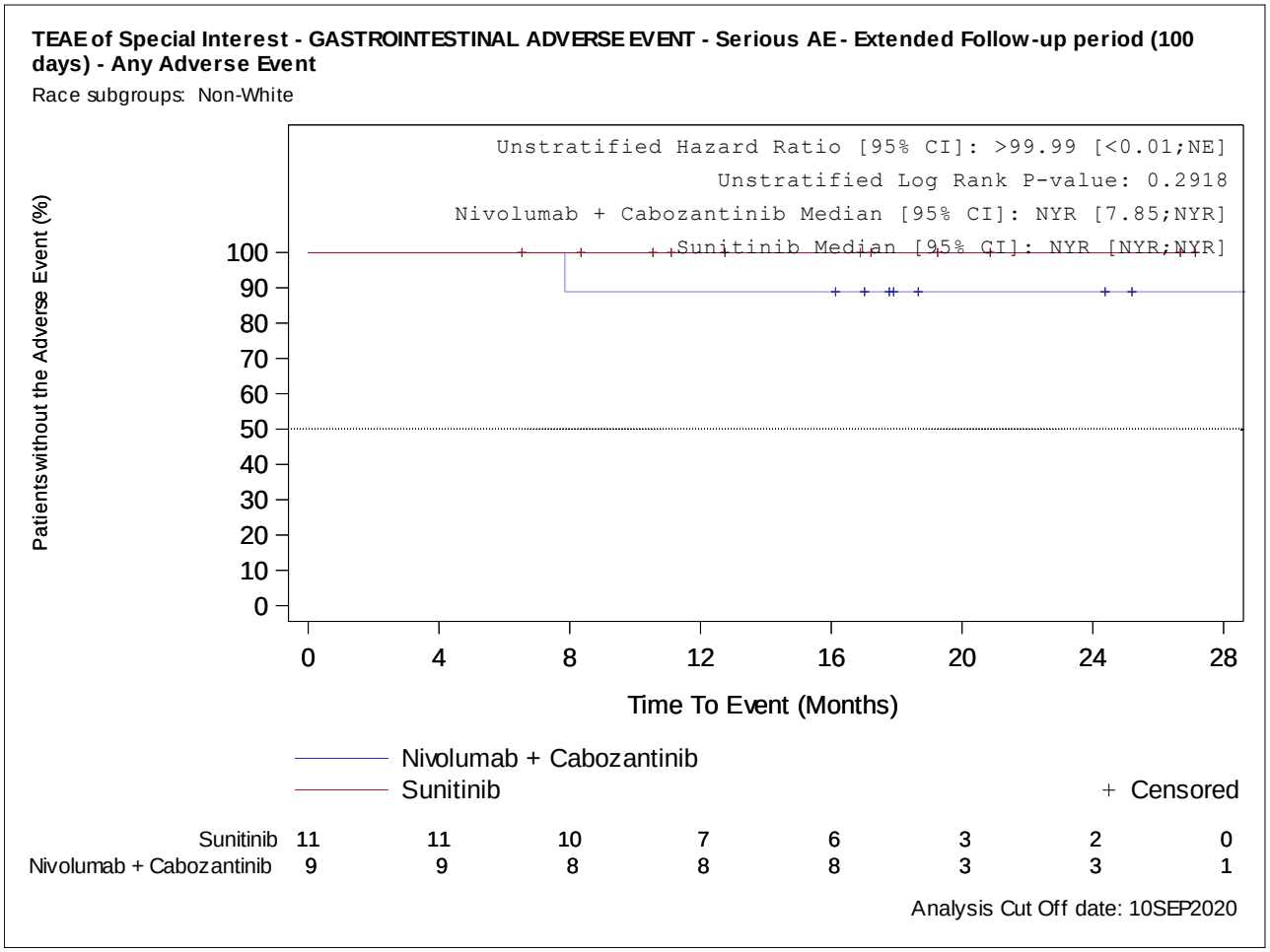

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:50:01

FIGURE 3.28.2.8: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



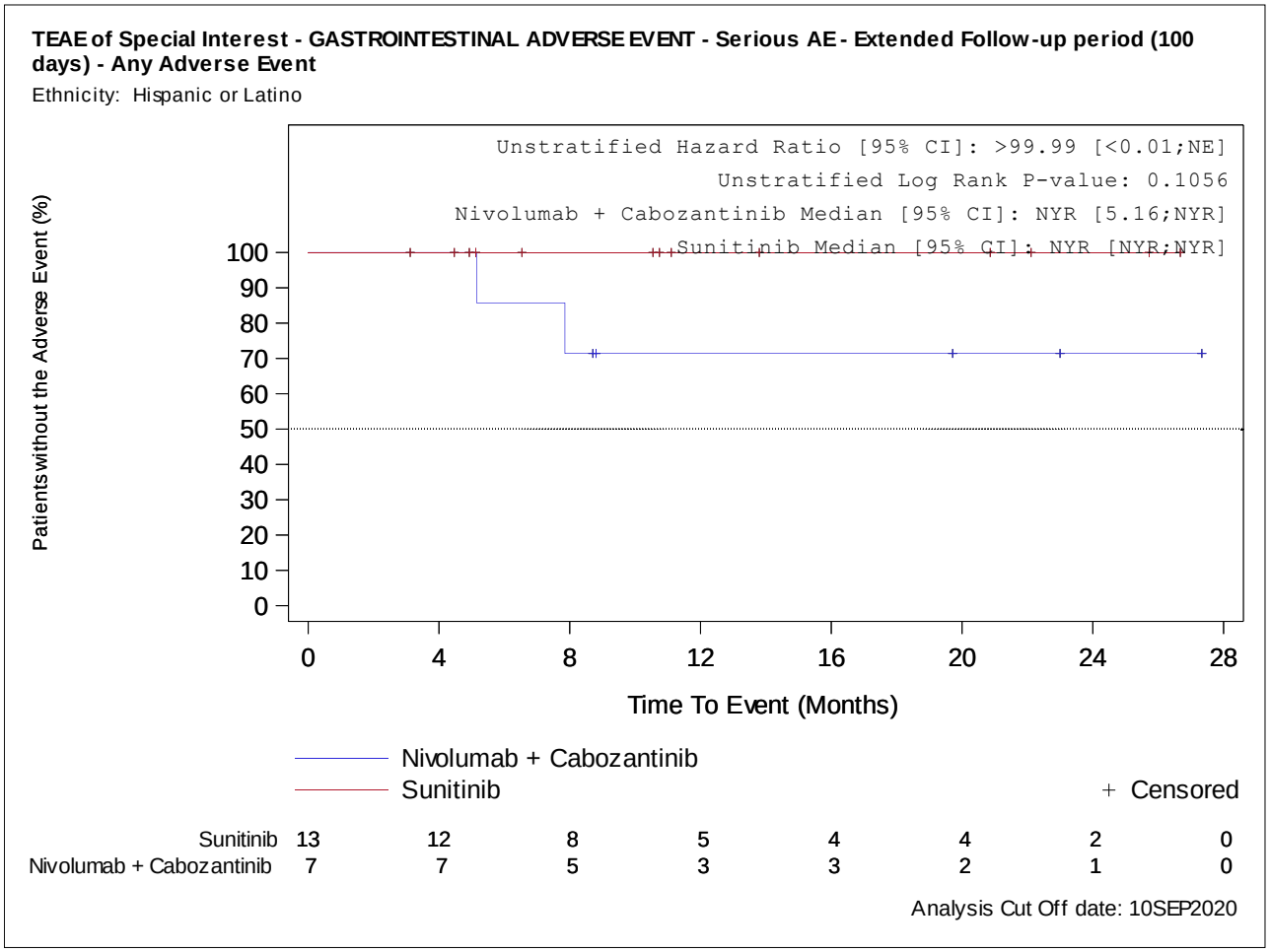

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:50:08

FIGURE 3.28.2.9: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



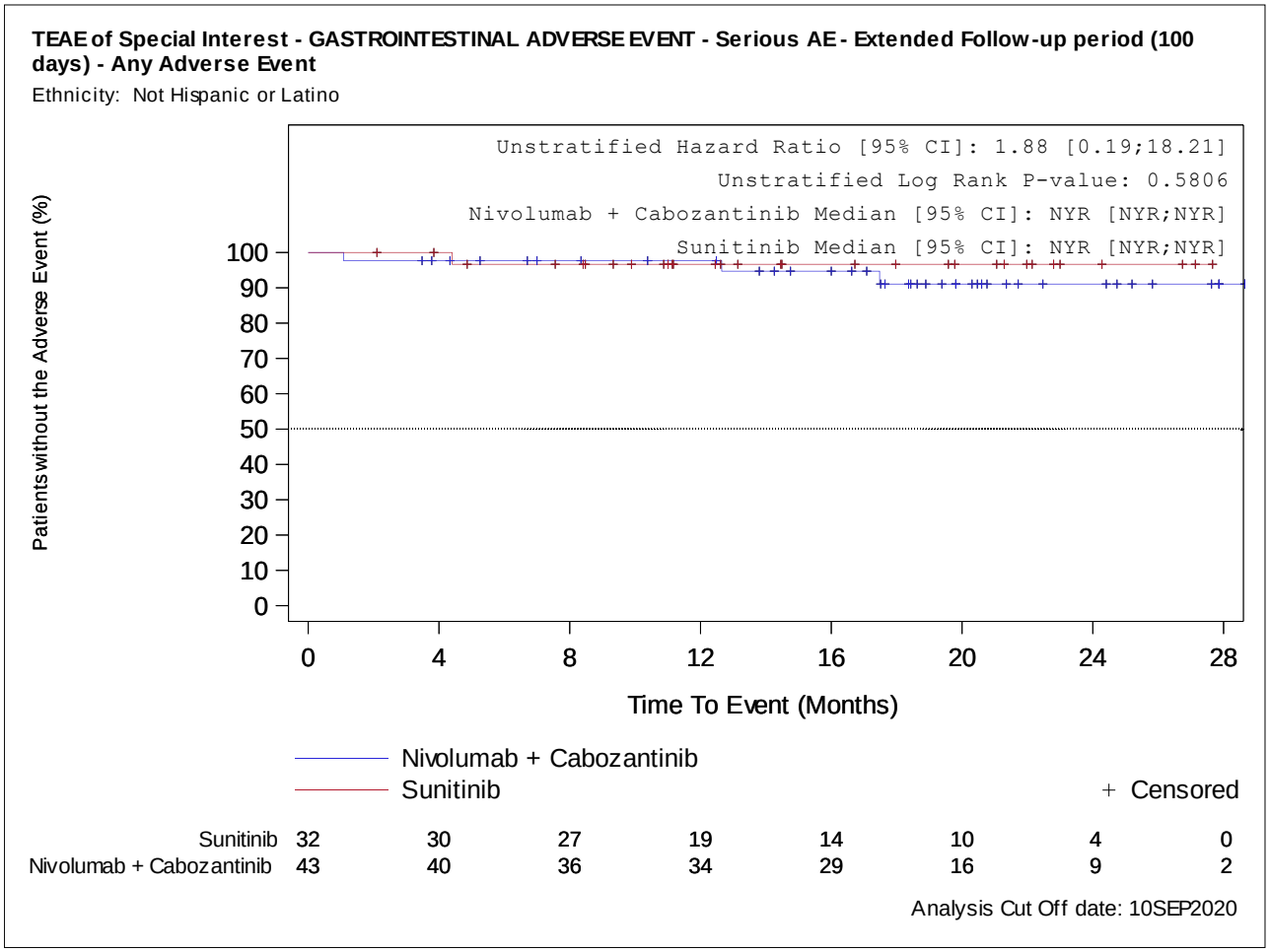

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:50:14

FIGURE 3.28.2.10: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



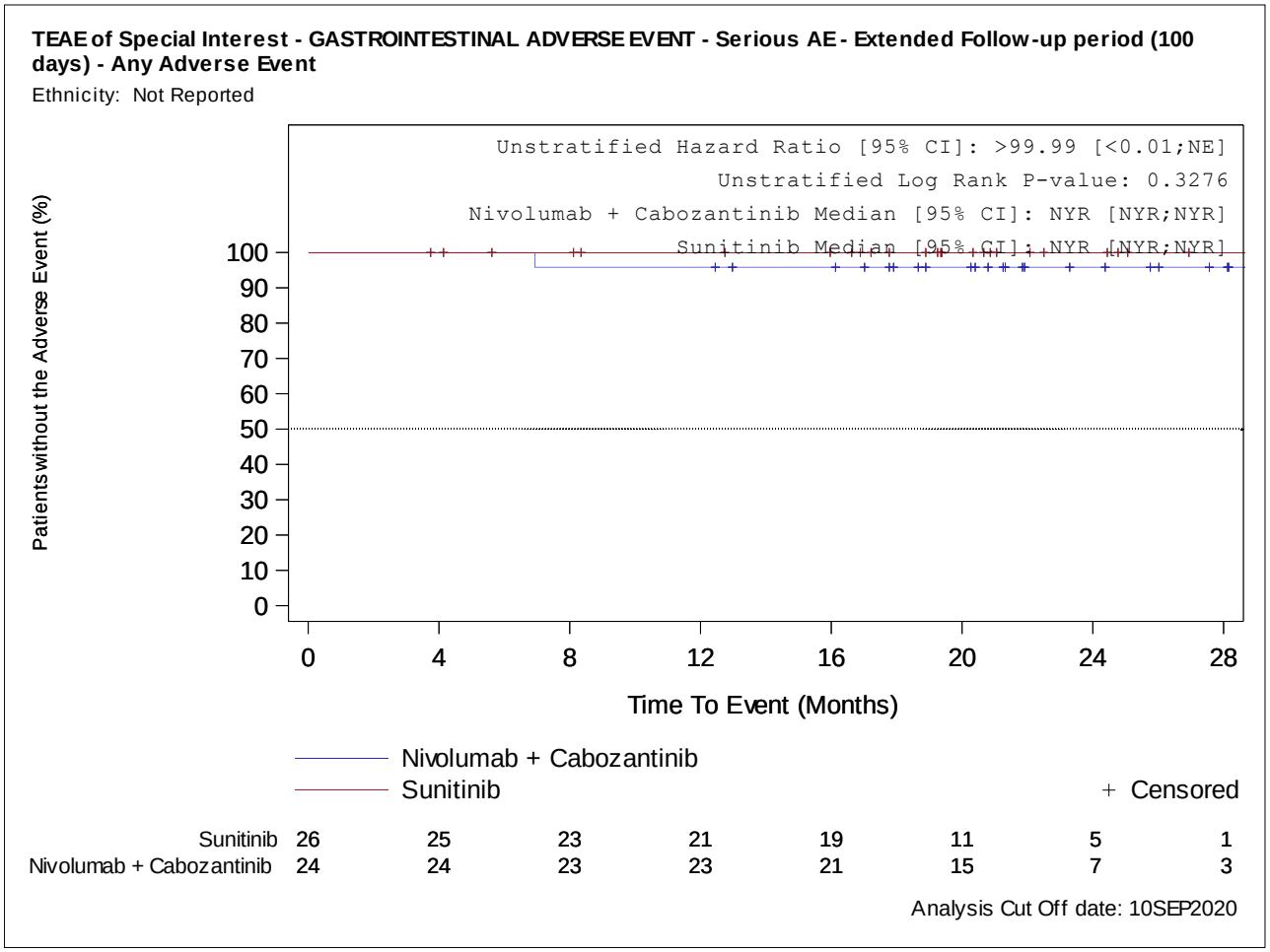

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:50:20

FIGURE 3.28.2.11: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



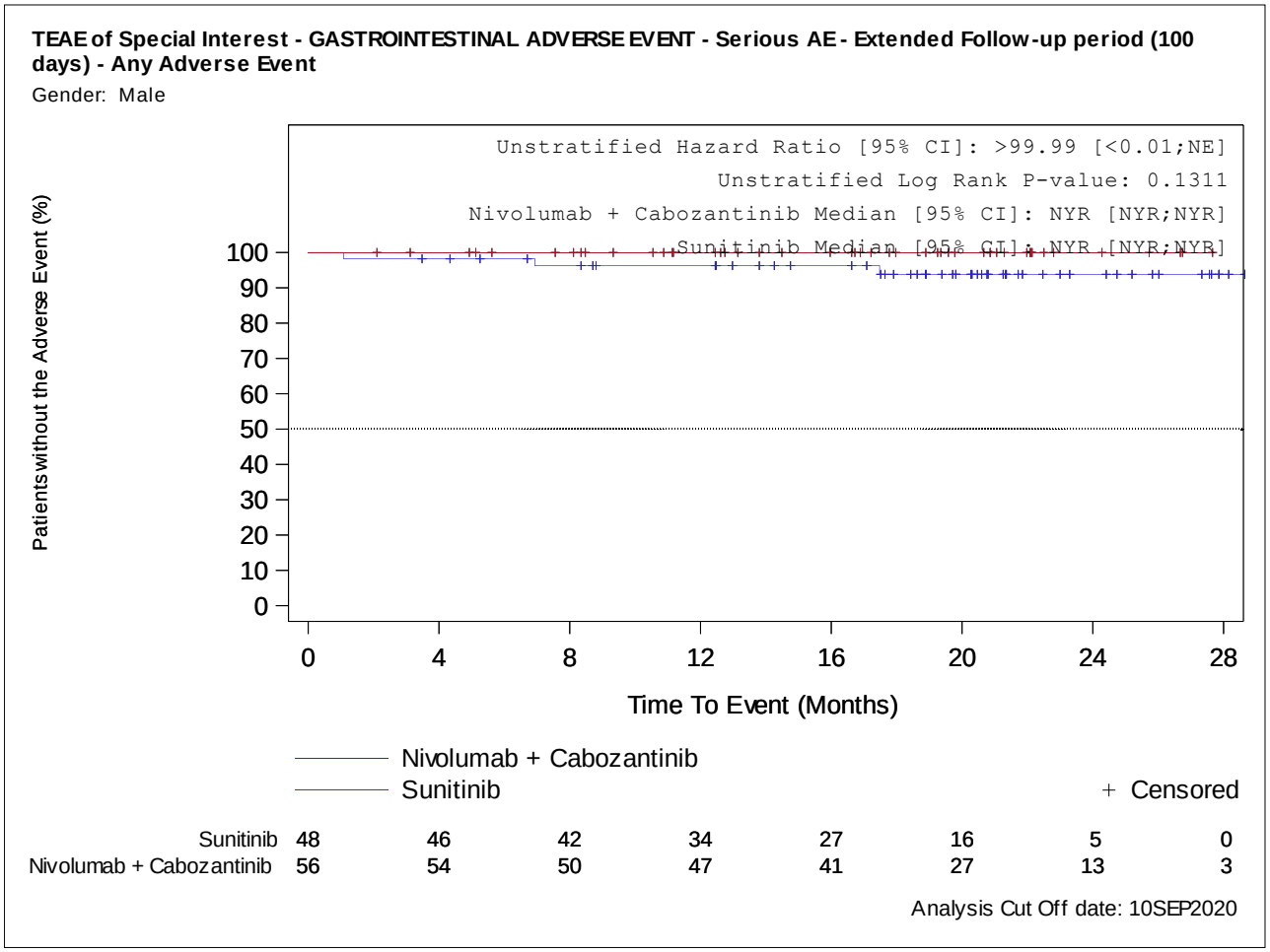

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:50:26

FIGURE 3.28.2.12: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



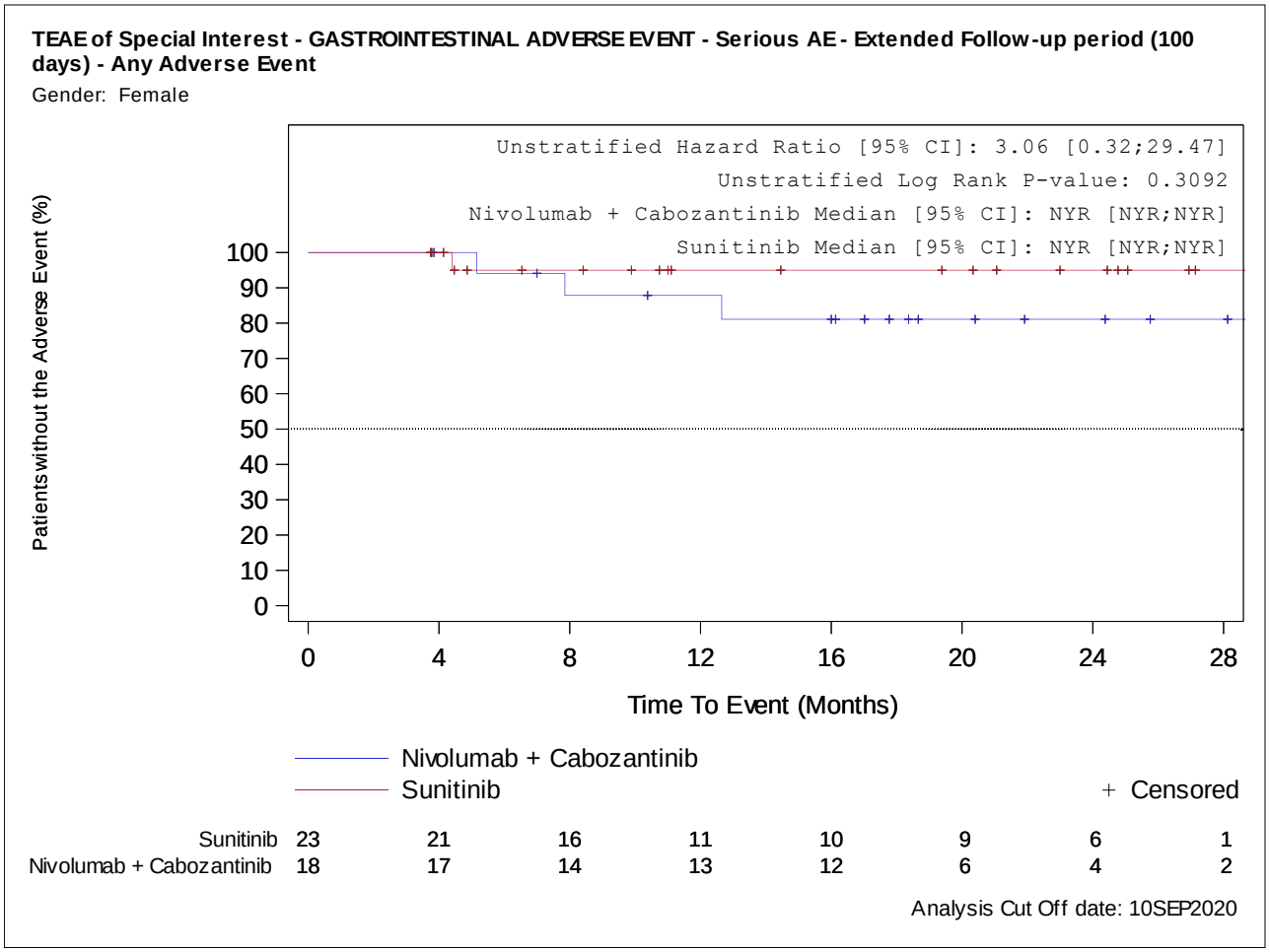

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:50:32

FIGURE 3.28.2.13: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



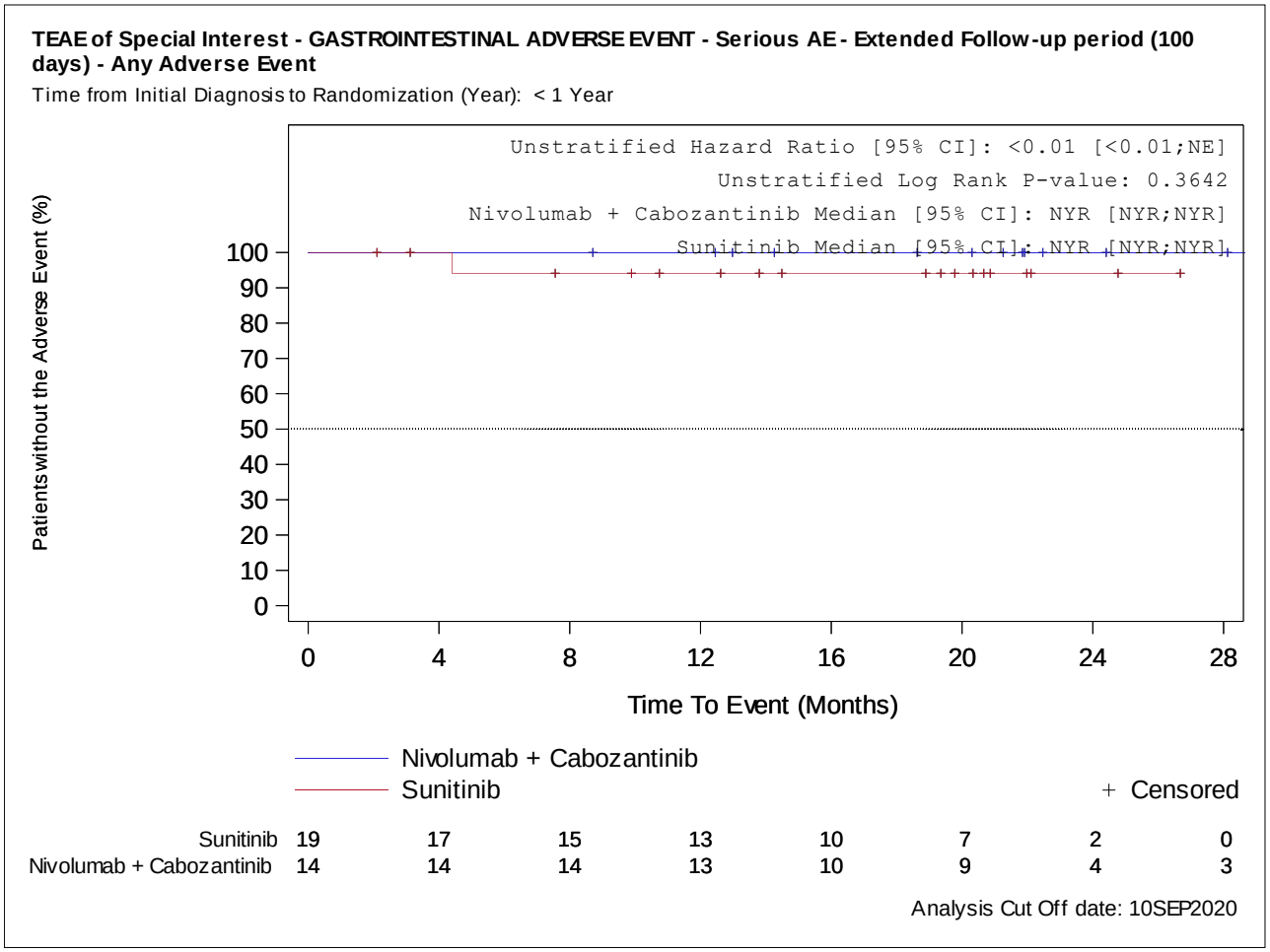

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:50:38

FIGURE 3.28.2.14: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



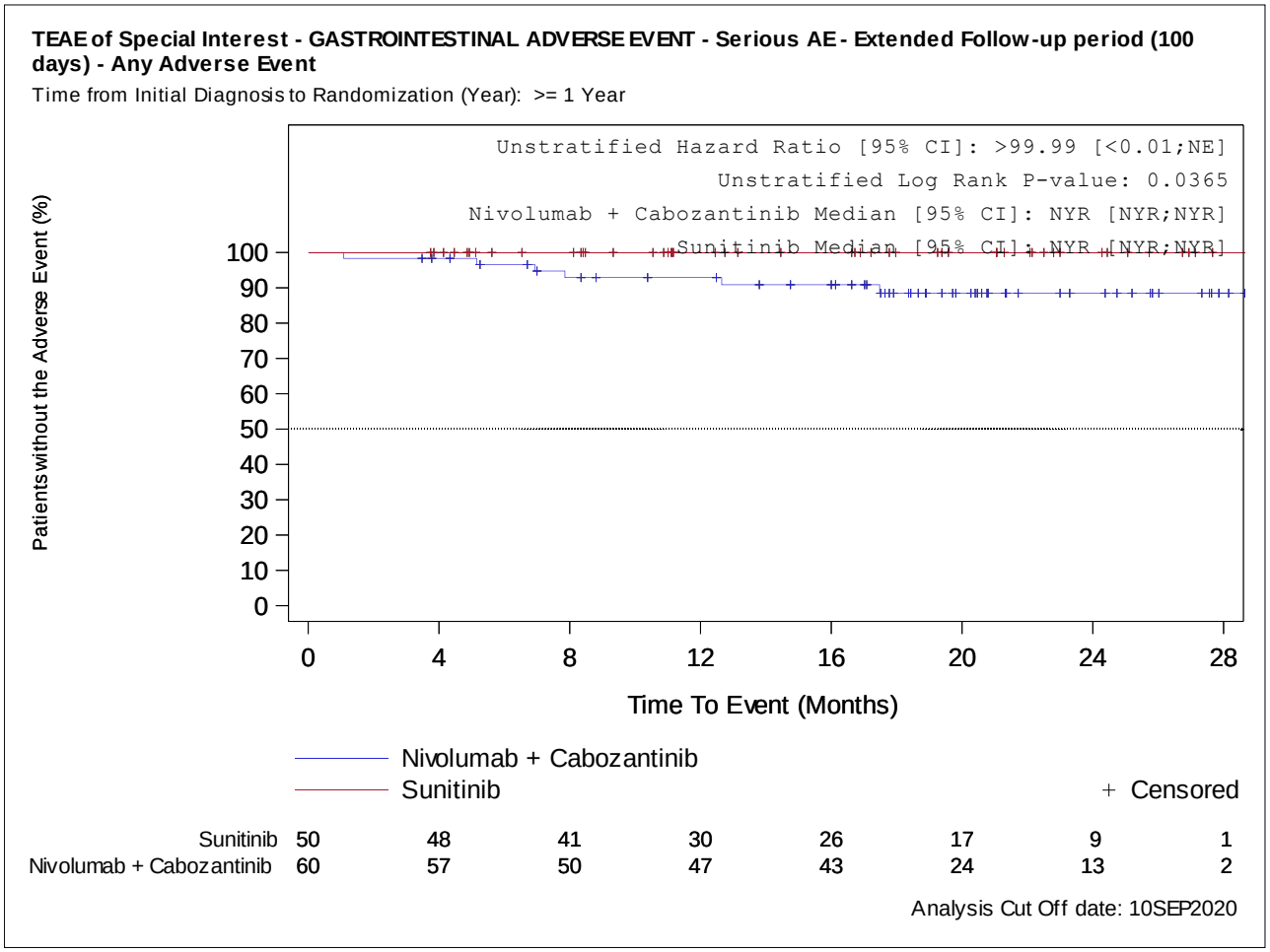

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:50:44

FIGURE 3.28.2.15: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



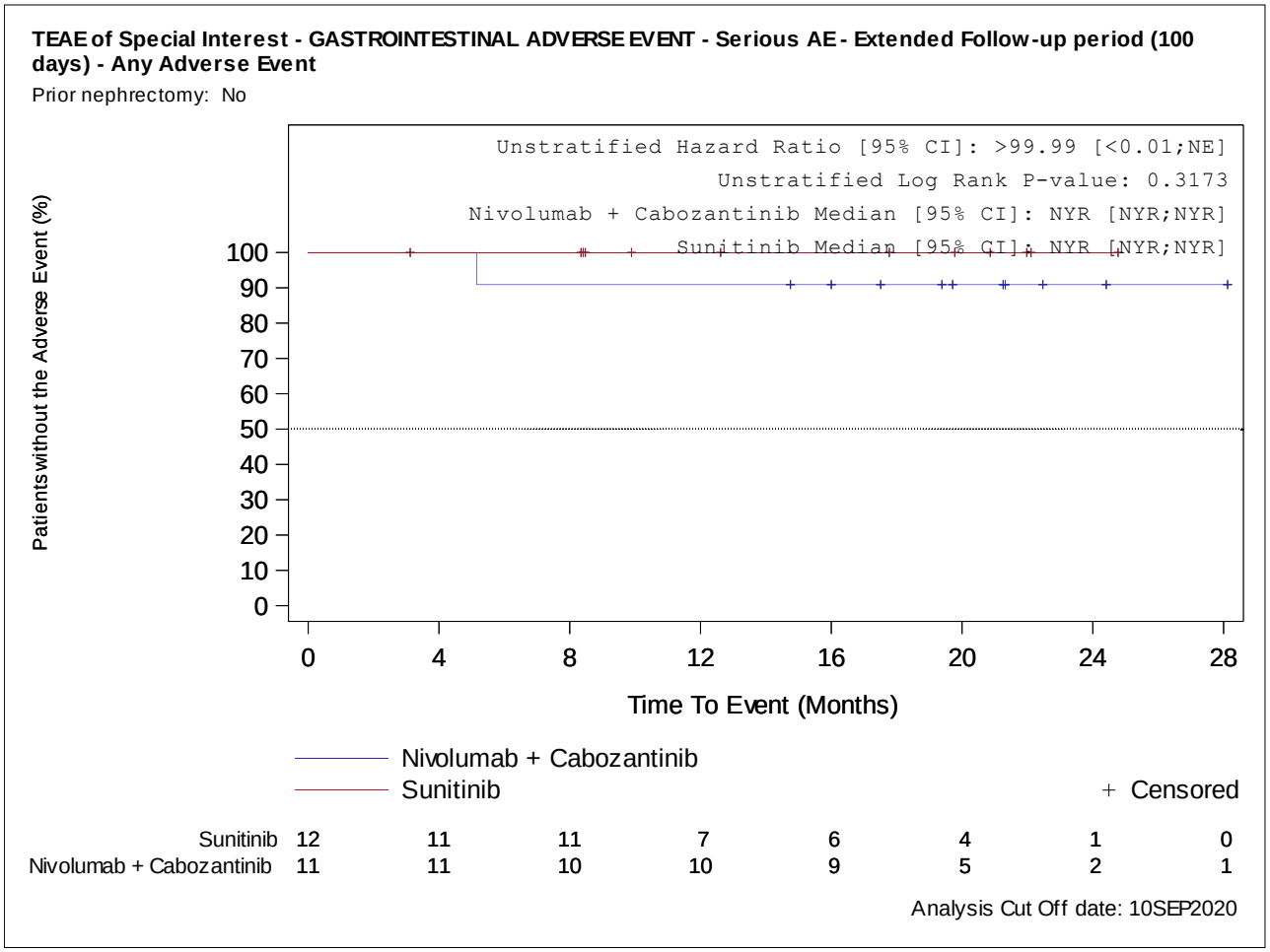

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:51:02

FIGURE 3.28.2.16: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



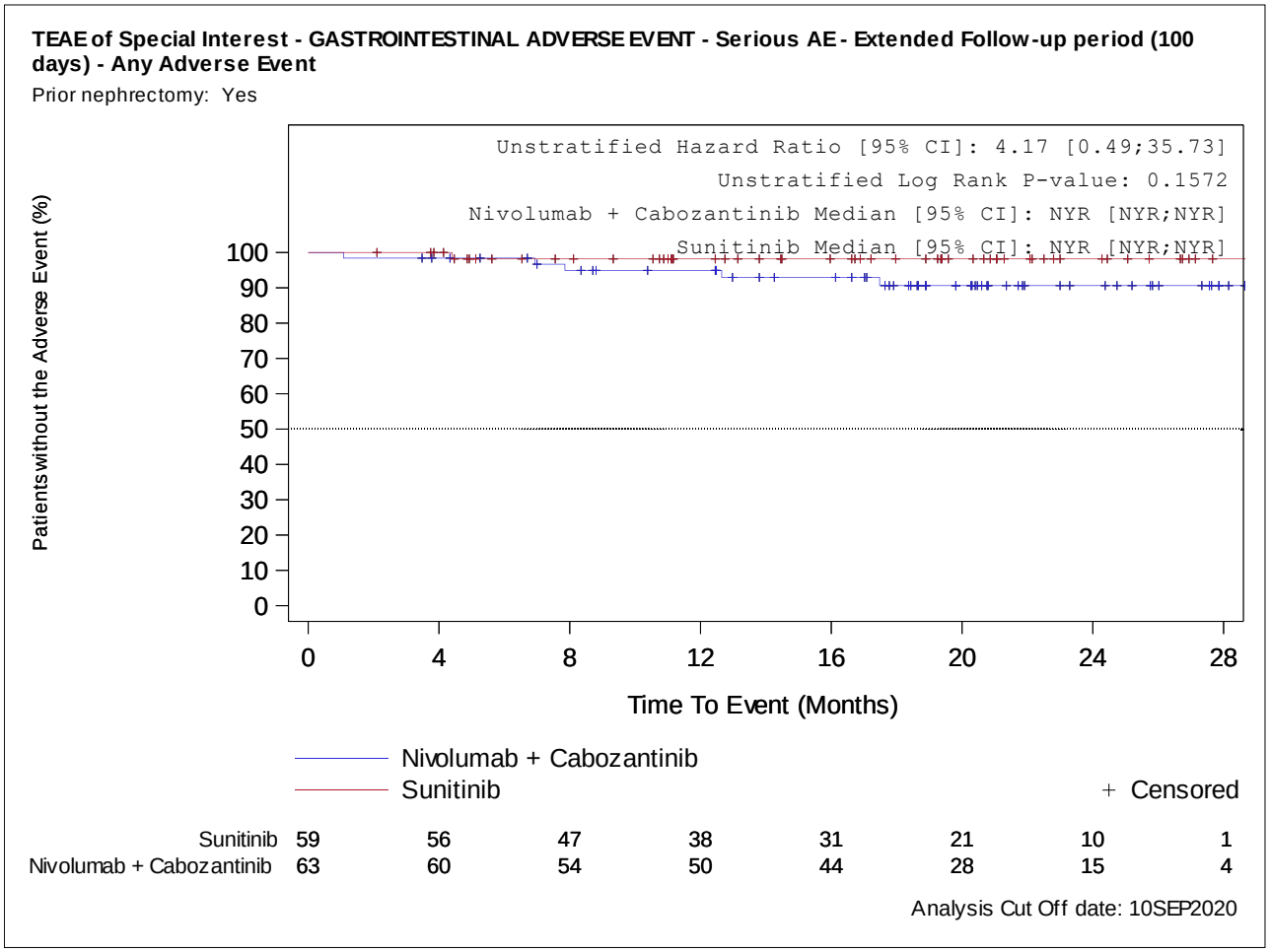

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:51:08

FIGURE 3.28.2.17: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



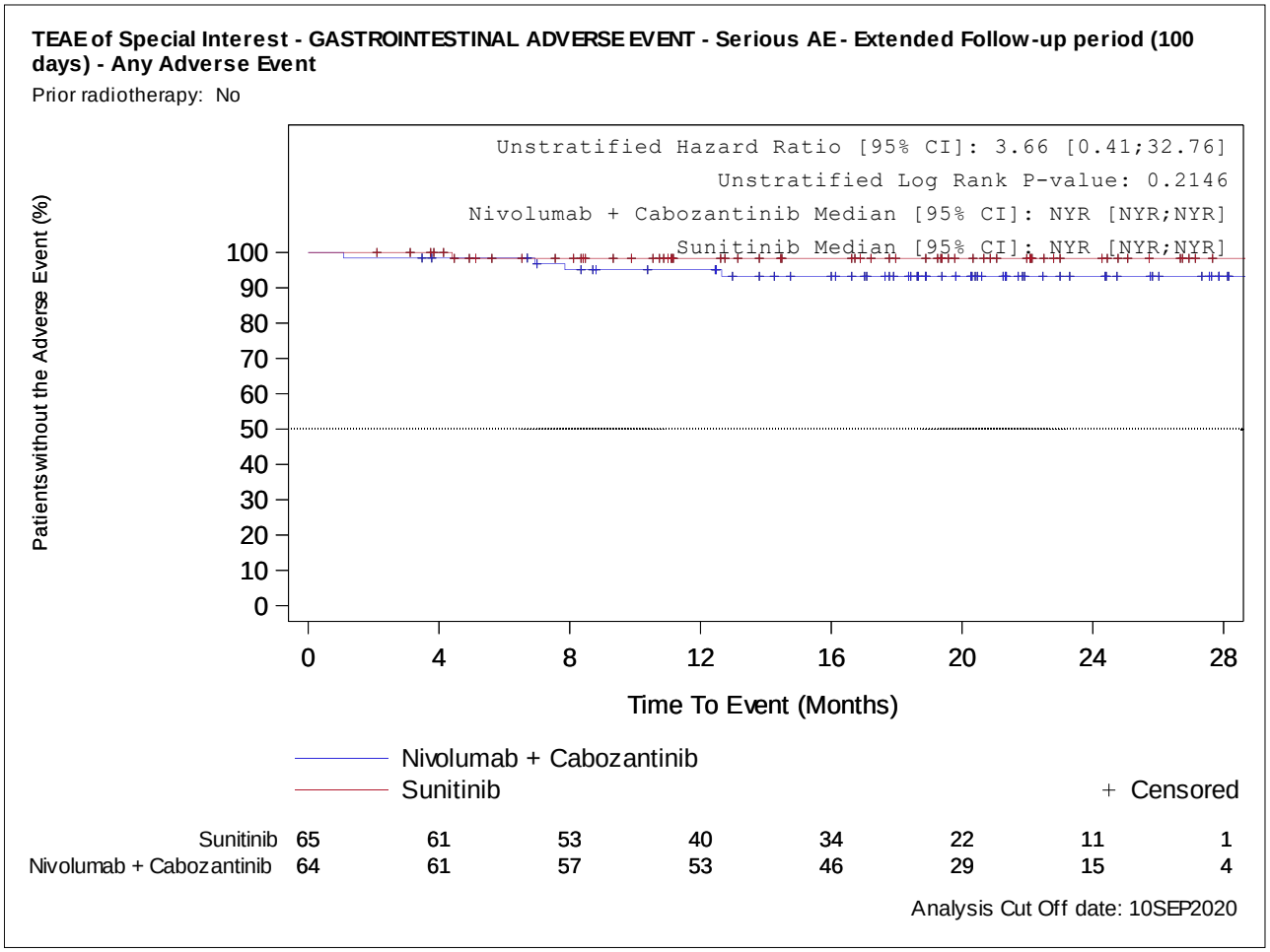

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:52:01

FIGURE 3.28.2.18: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



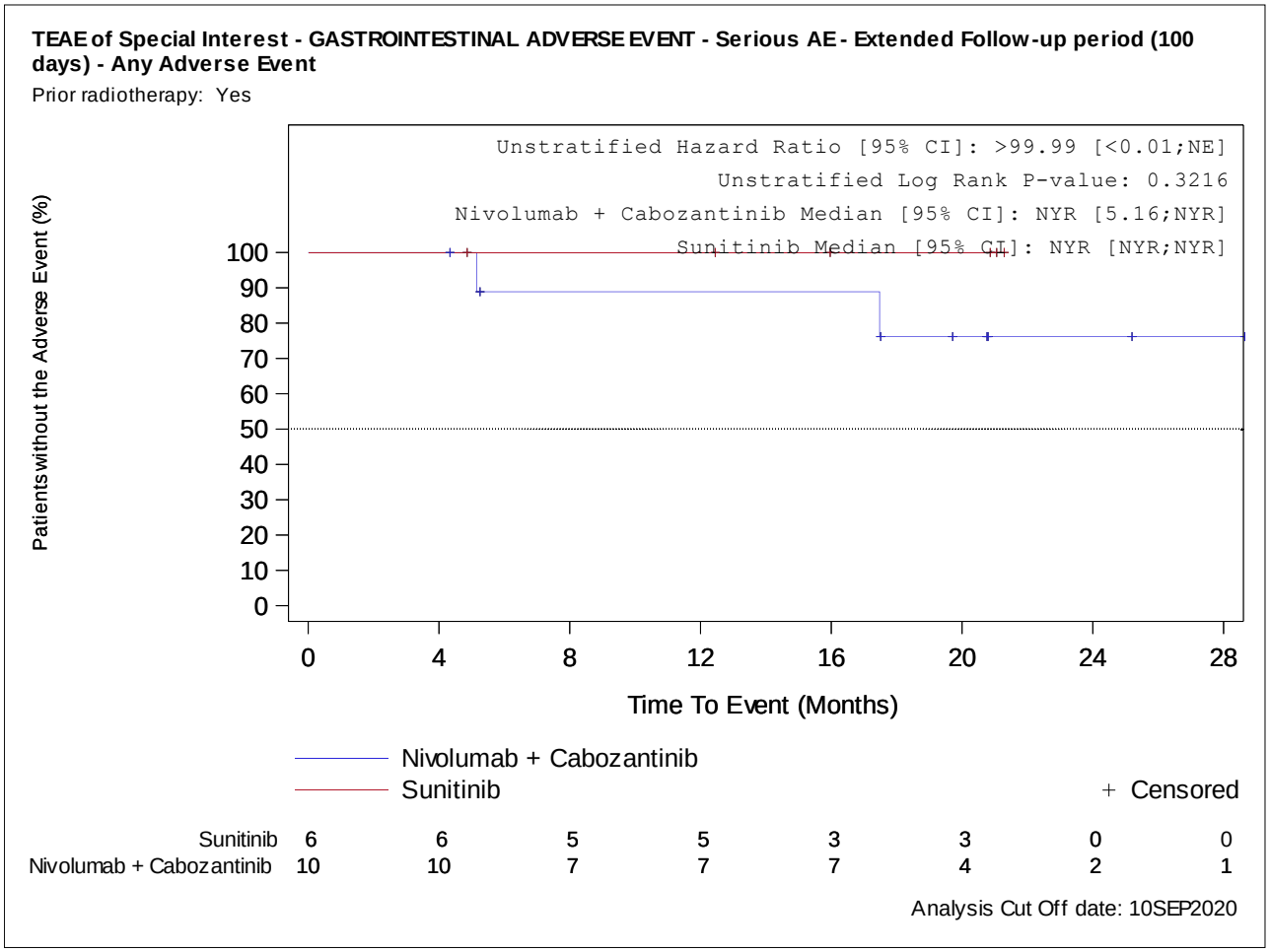

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:52:08

FIGURE 3.28.2.19: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



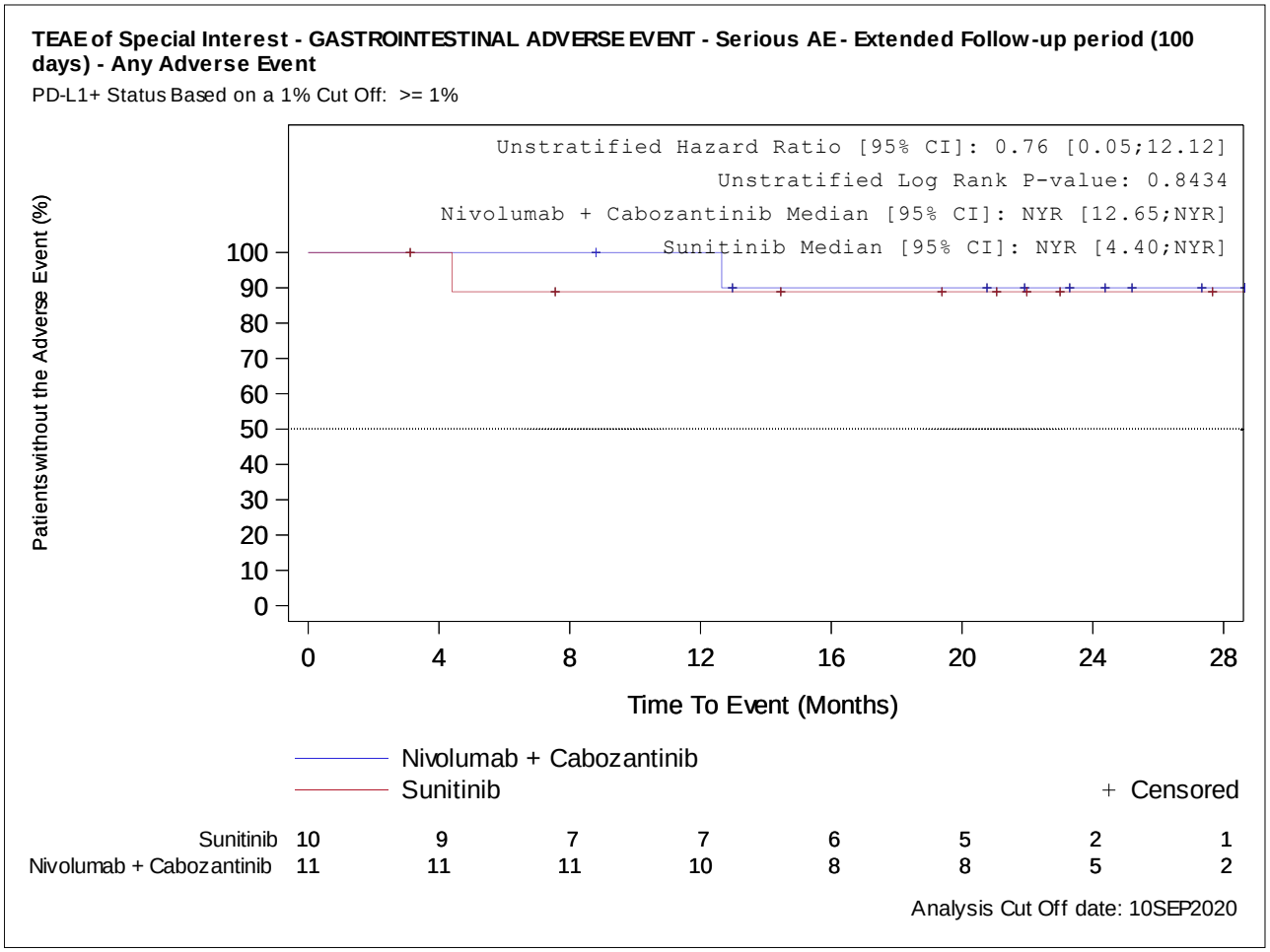

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:52:13

FIGURE 3.28.2.20: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



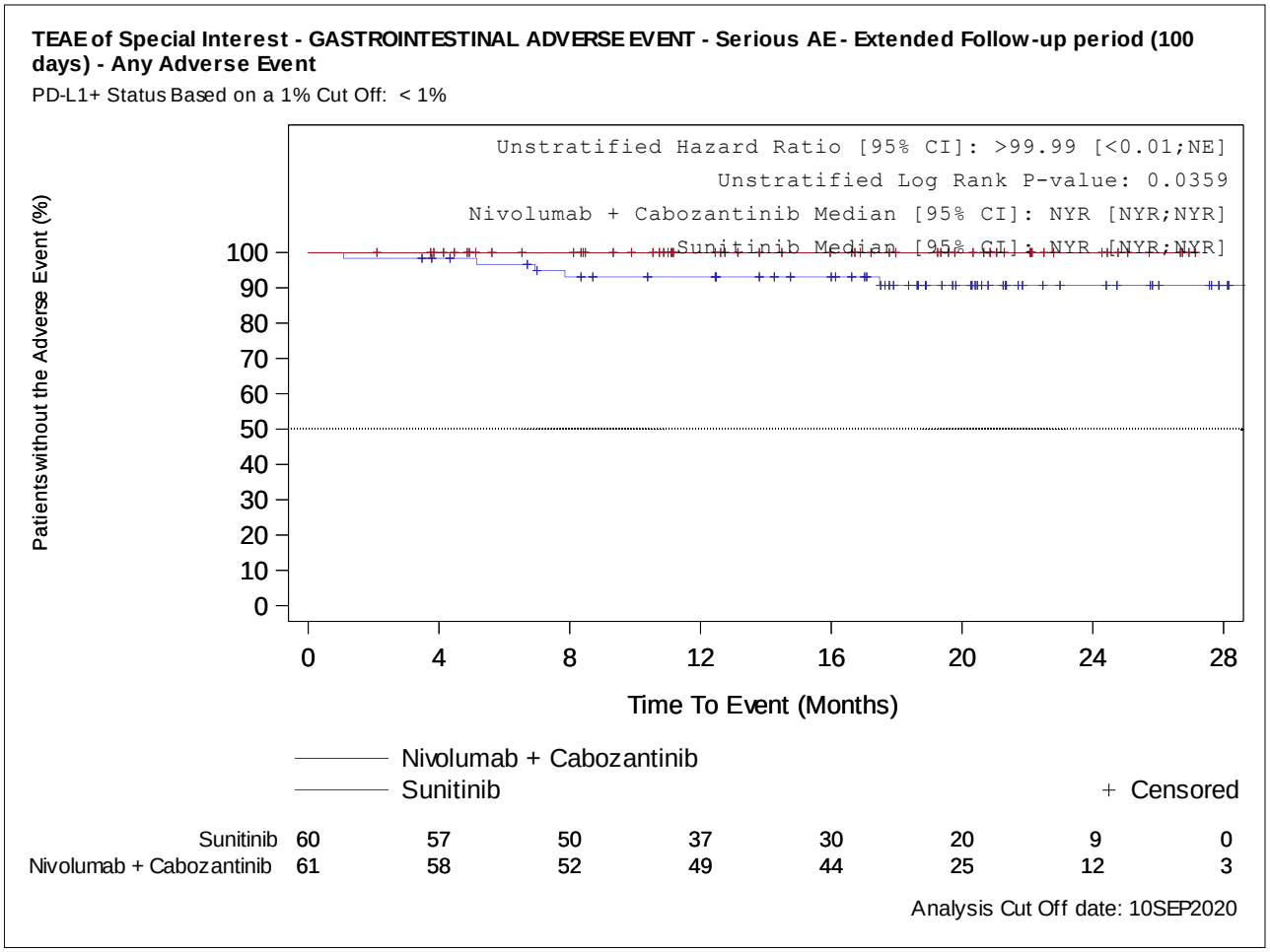

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:52:19

FIGURE 3.28.2.21: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



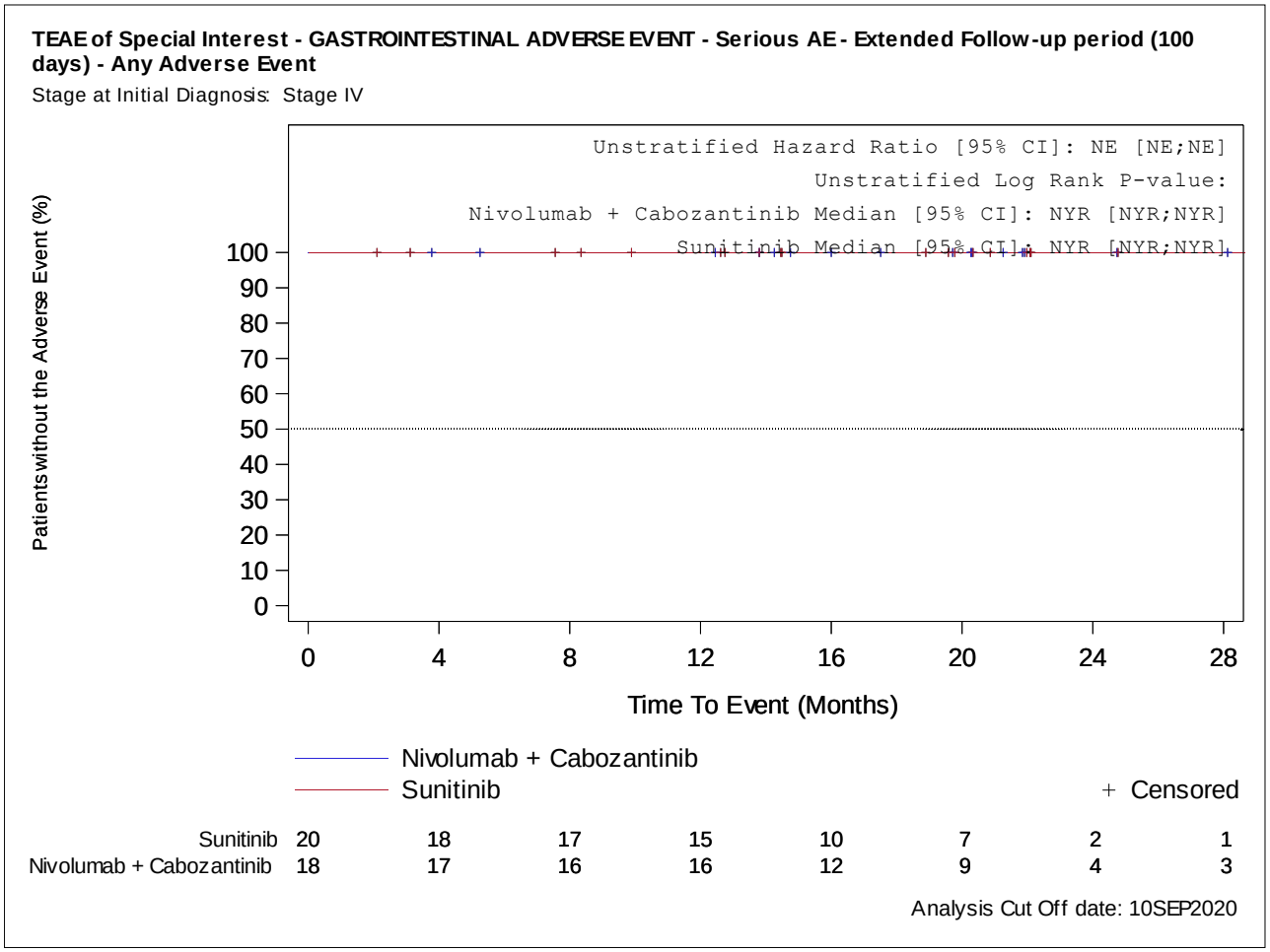

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:52:26

FIGURE 3.28.2.22: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:52:31

FIGURE 3.28.2.23: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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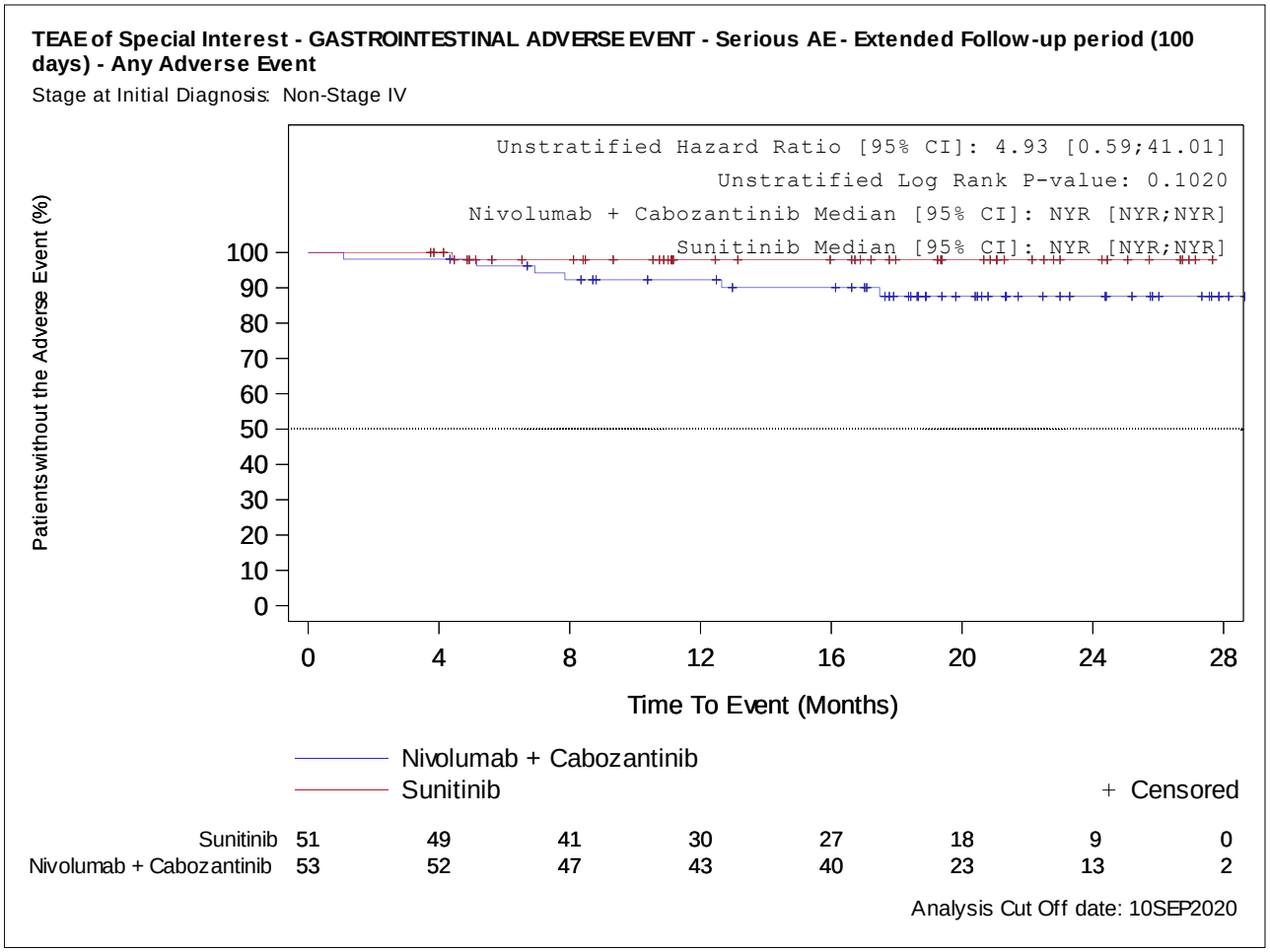
FIGURE 3.28.2.24: Kaplan-Meier curve - TEAE of Special Interest - GASTROINTESTINAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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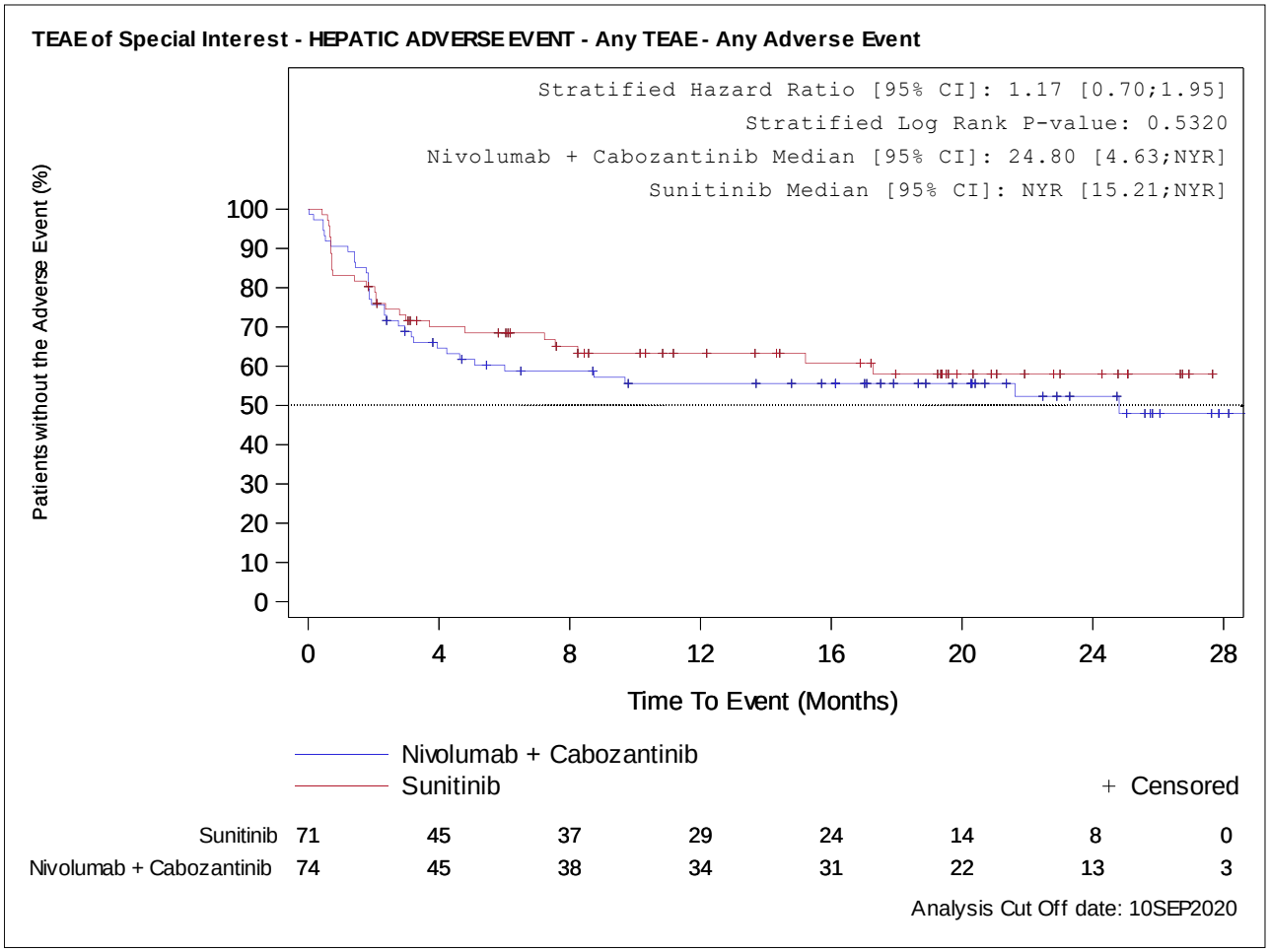
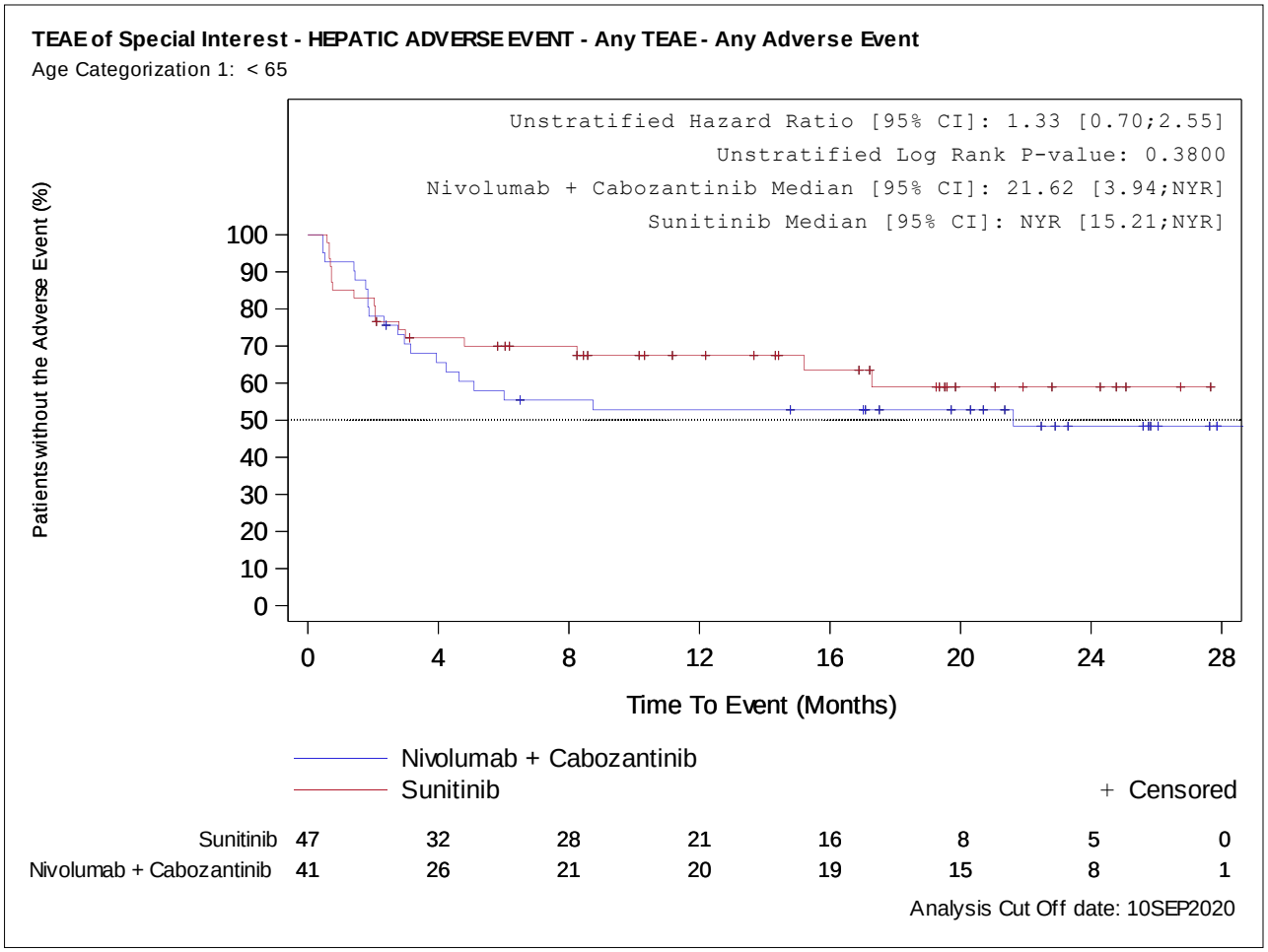
FIGURE 3.29.1: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:56:24

FIGURE 3.29.2.1: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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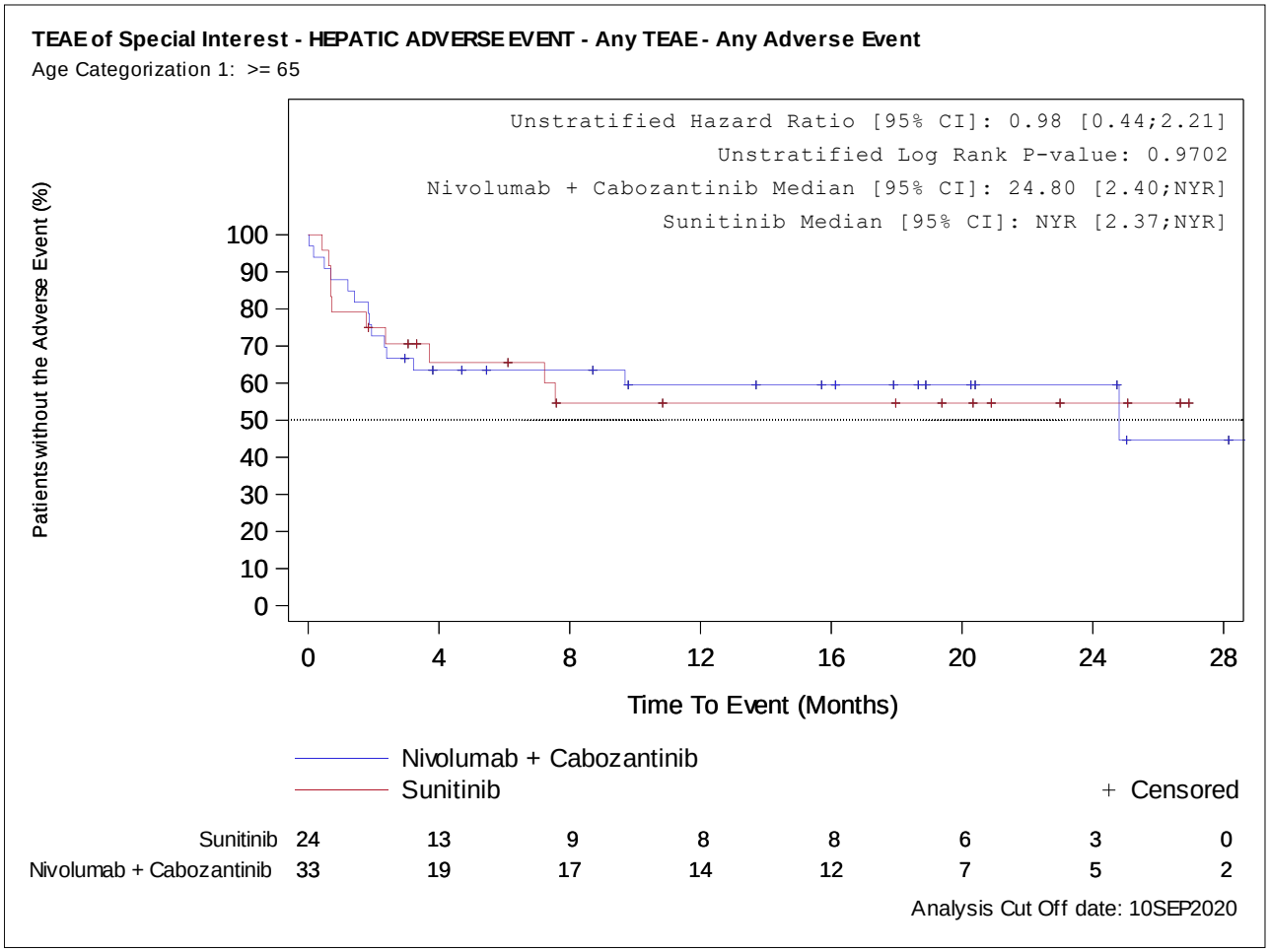
FIGURE 3.29.2.2: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
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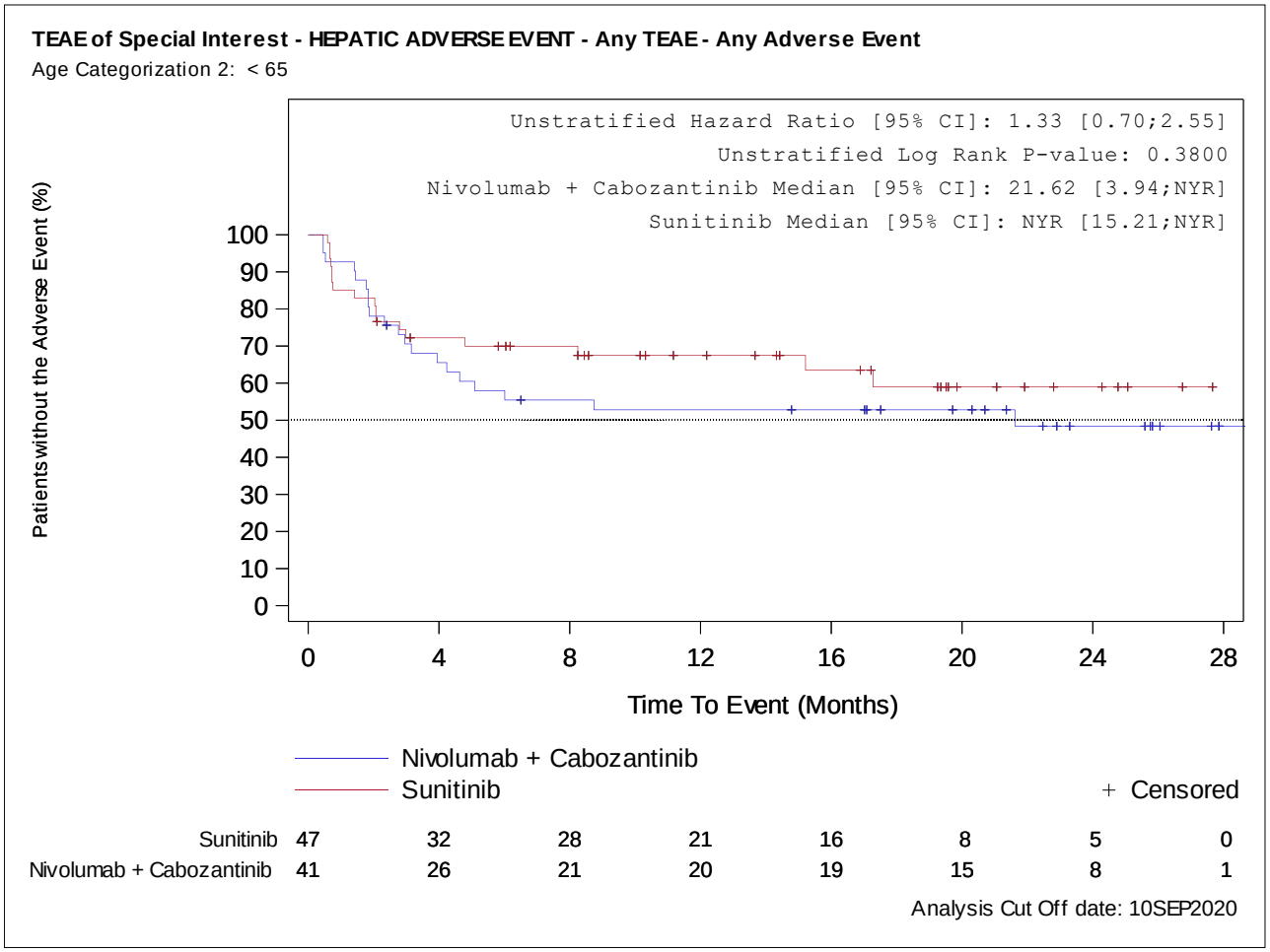
FIGURE 3.29.2.3: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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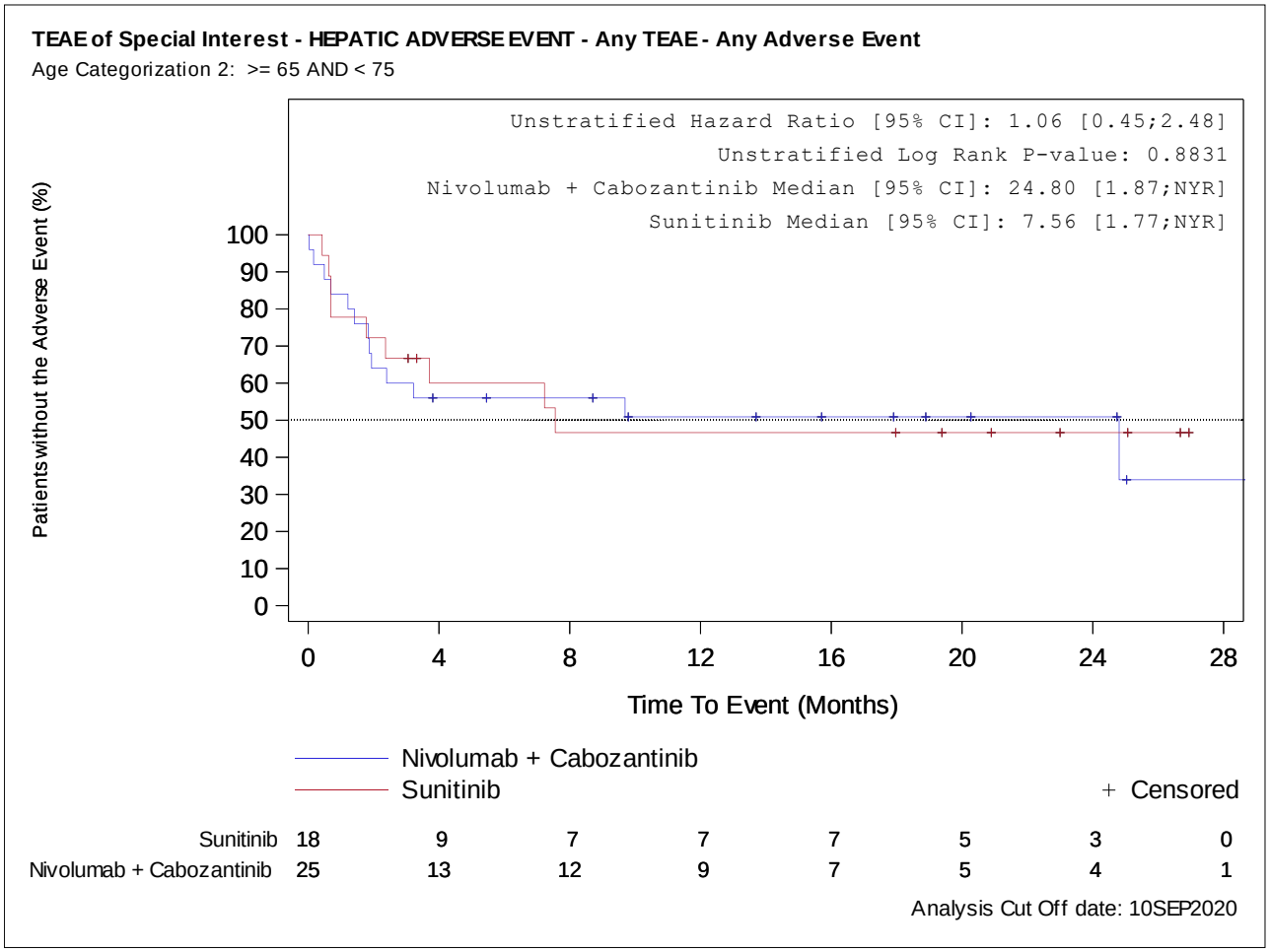
FIGURE 3.29.2.4: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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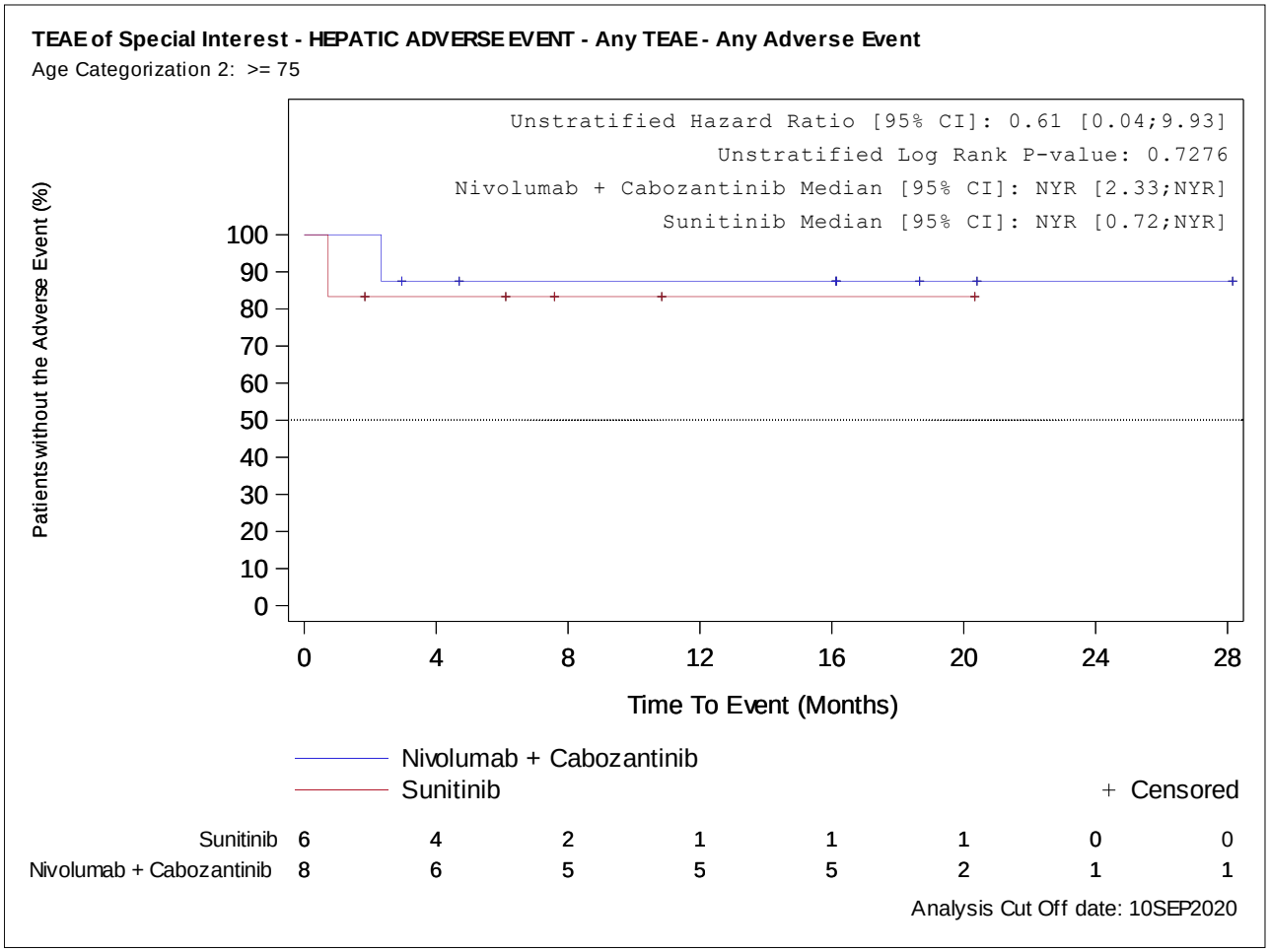
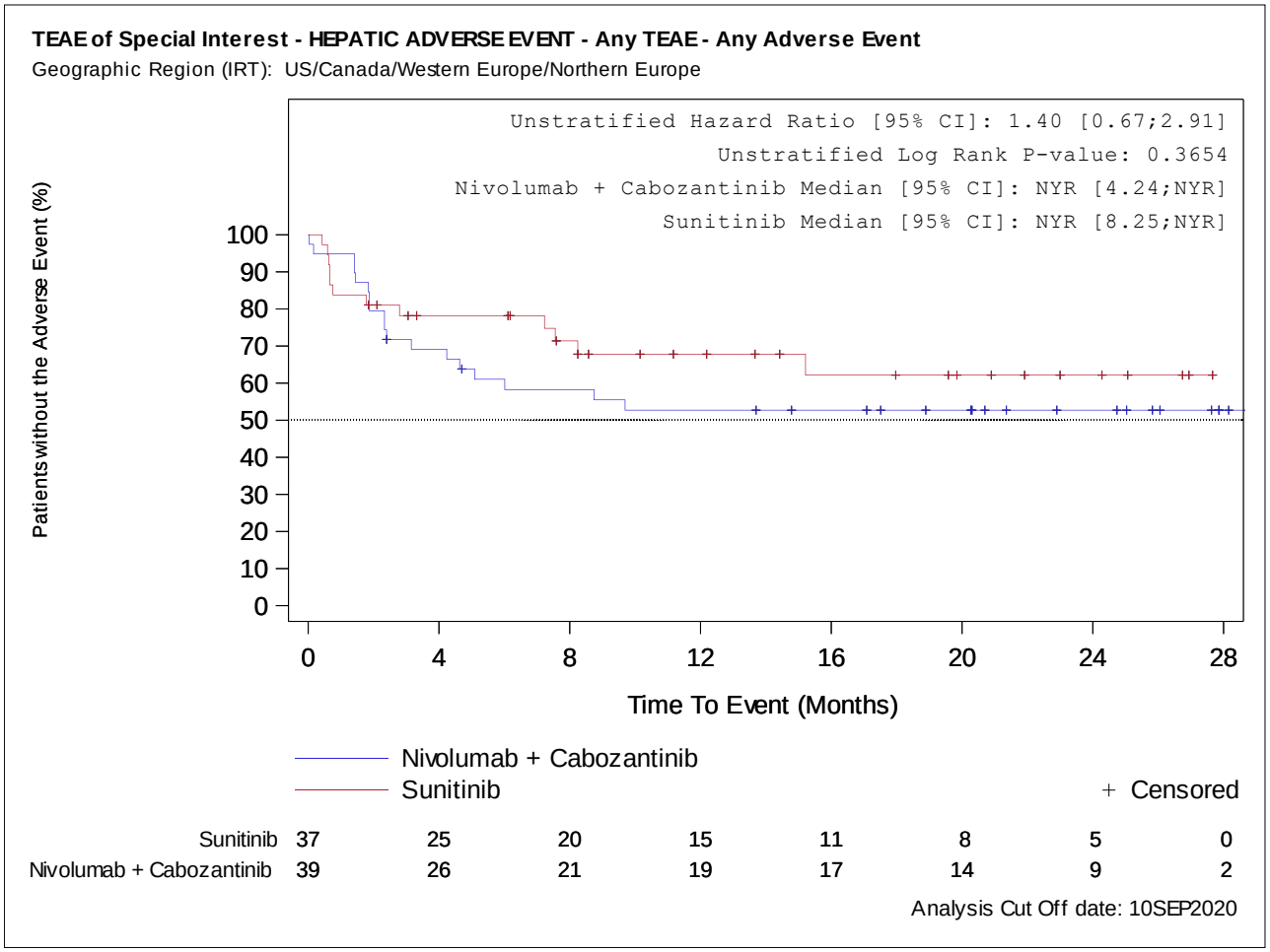
FIGURE 3.29.2.5: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



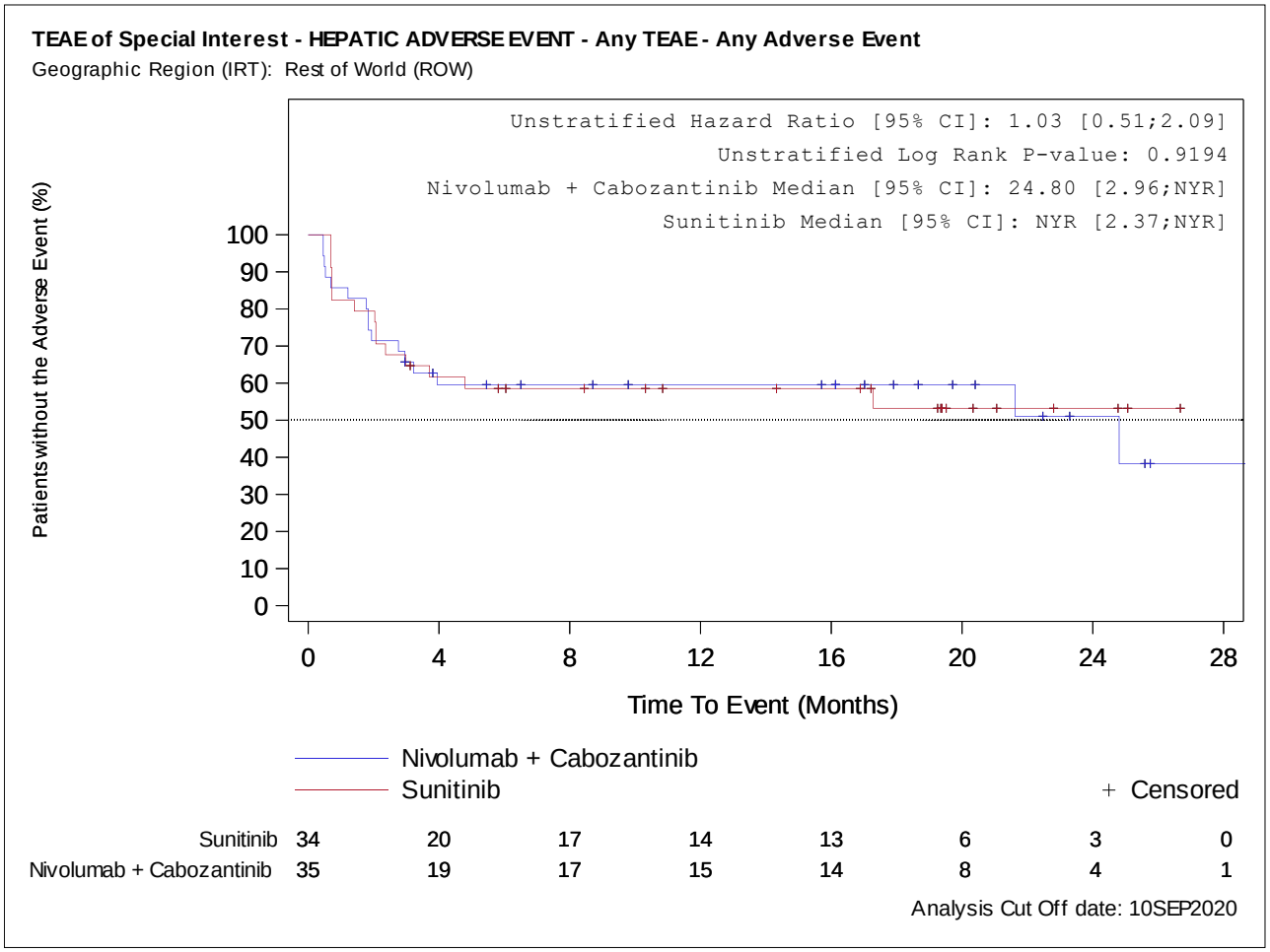

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:56:51

FIGURE 3.29.2.6: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



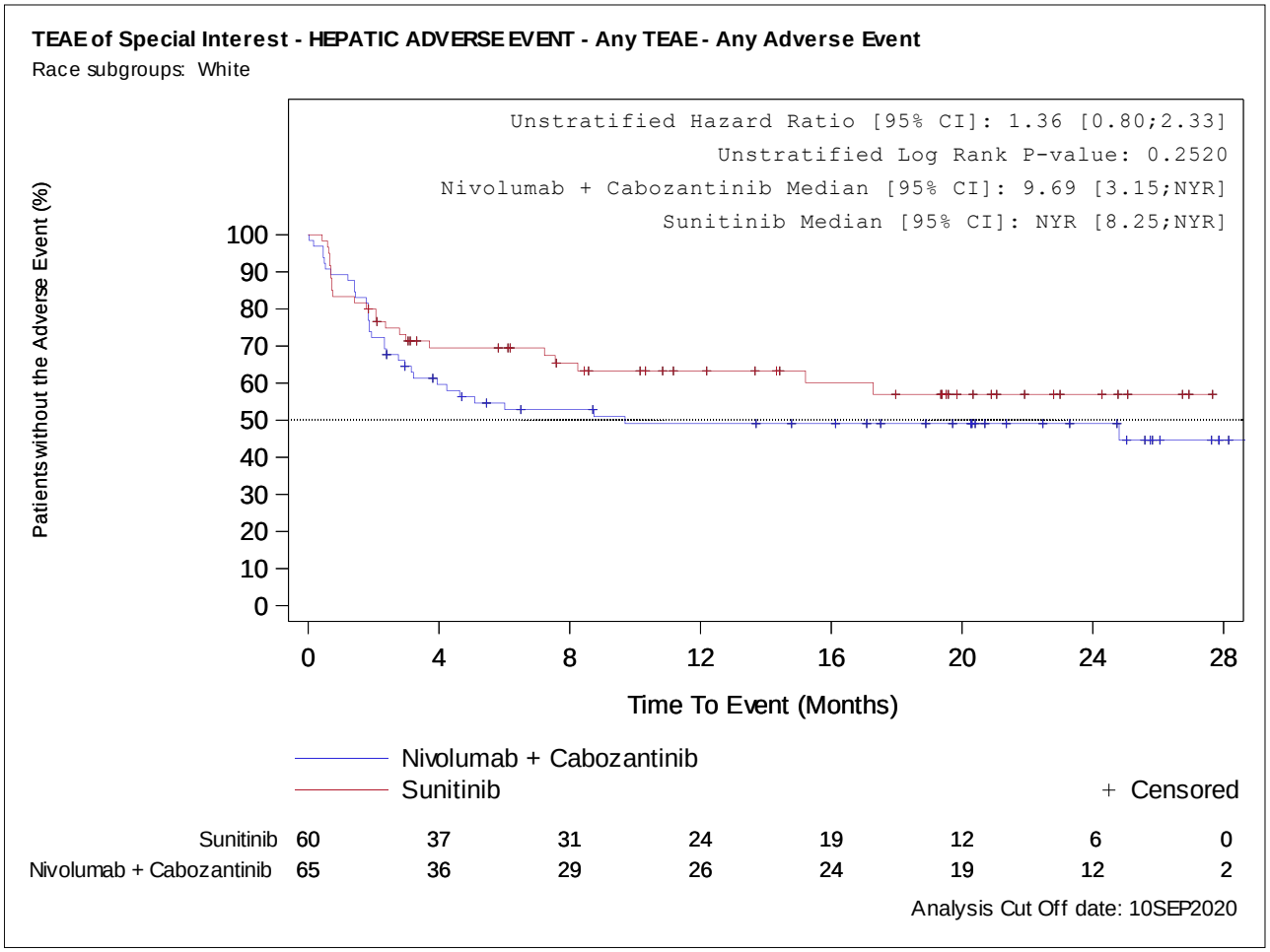

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:56:56

FIGURE 3.29.2.7: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



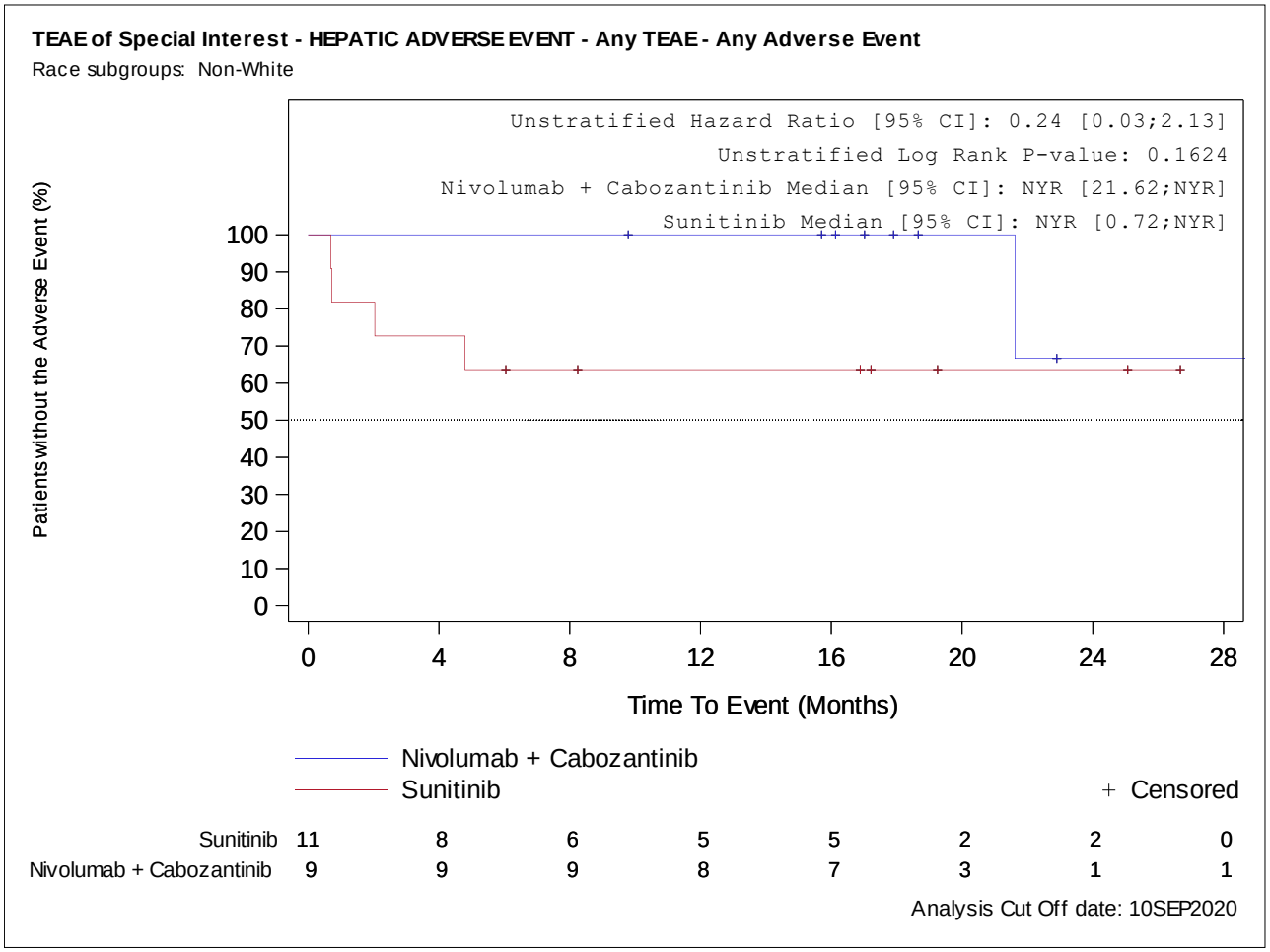

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:57:02

FIGURE 3.29.2.8: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



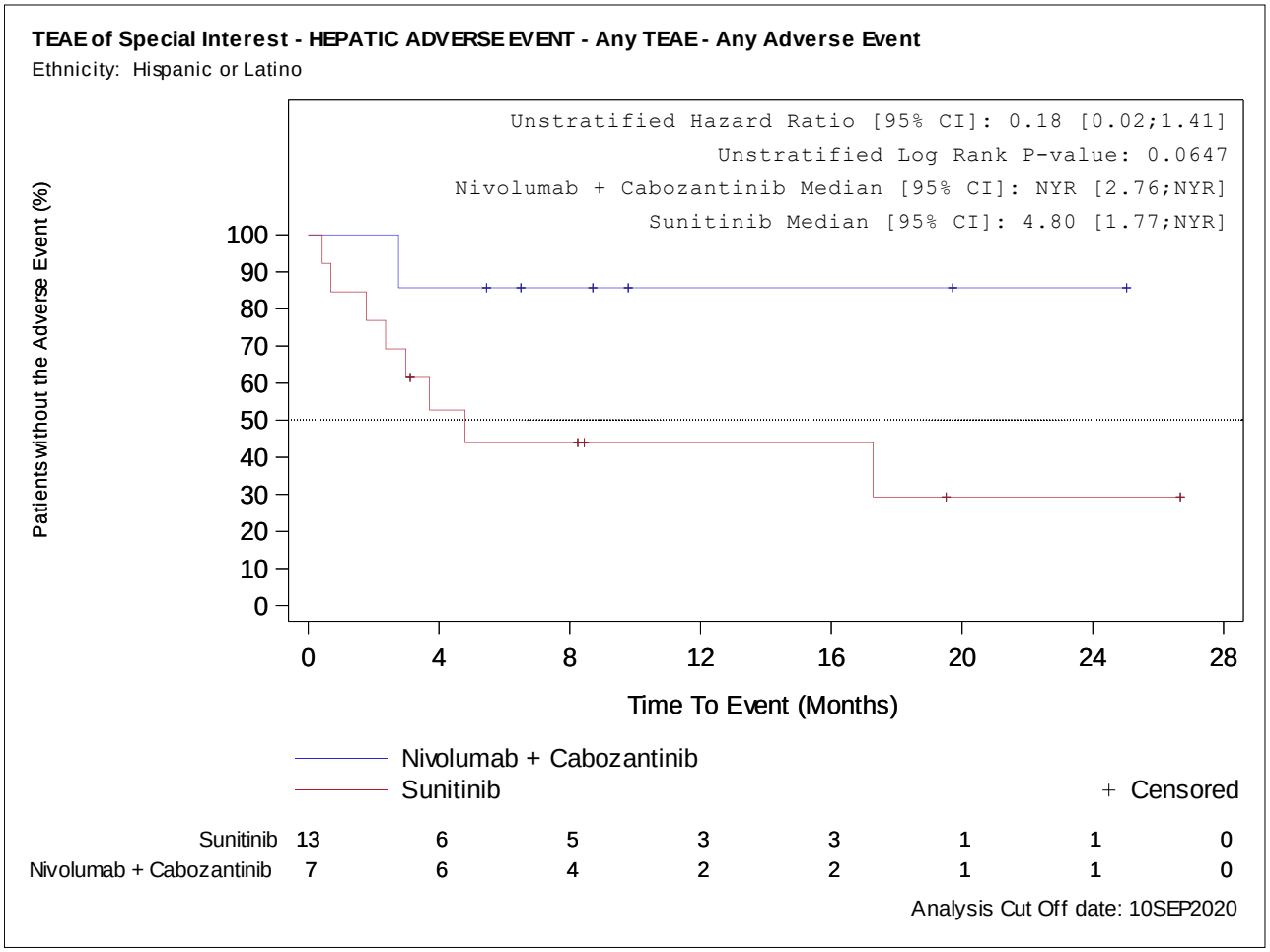

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:57:08

FIGURE 3.29.2.9: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



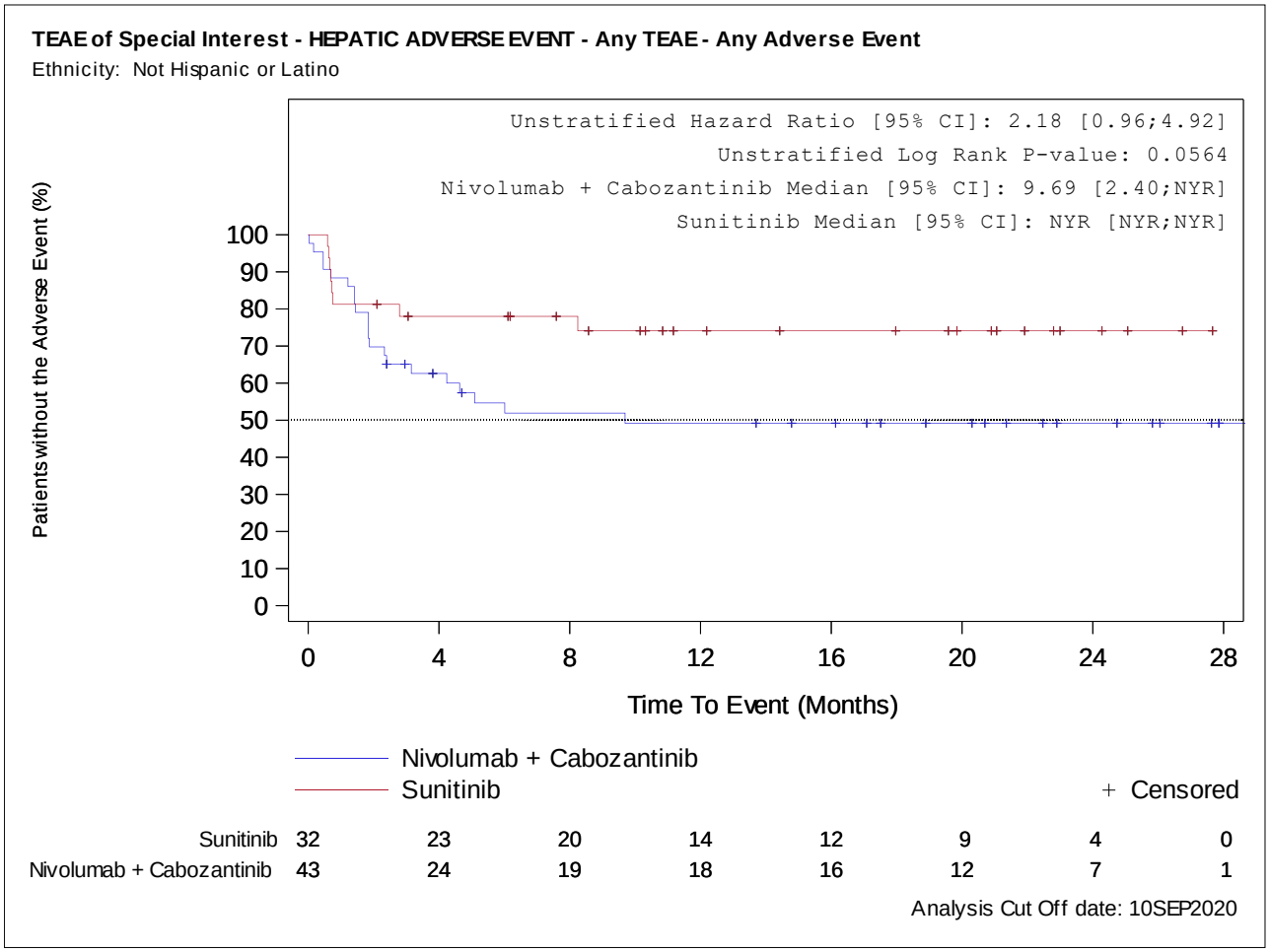

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:57:13

FIGURE 3.29.2.10: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:57:19

FIGURE 3.29.2.11: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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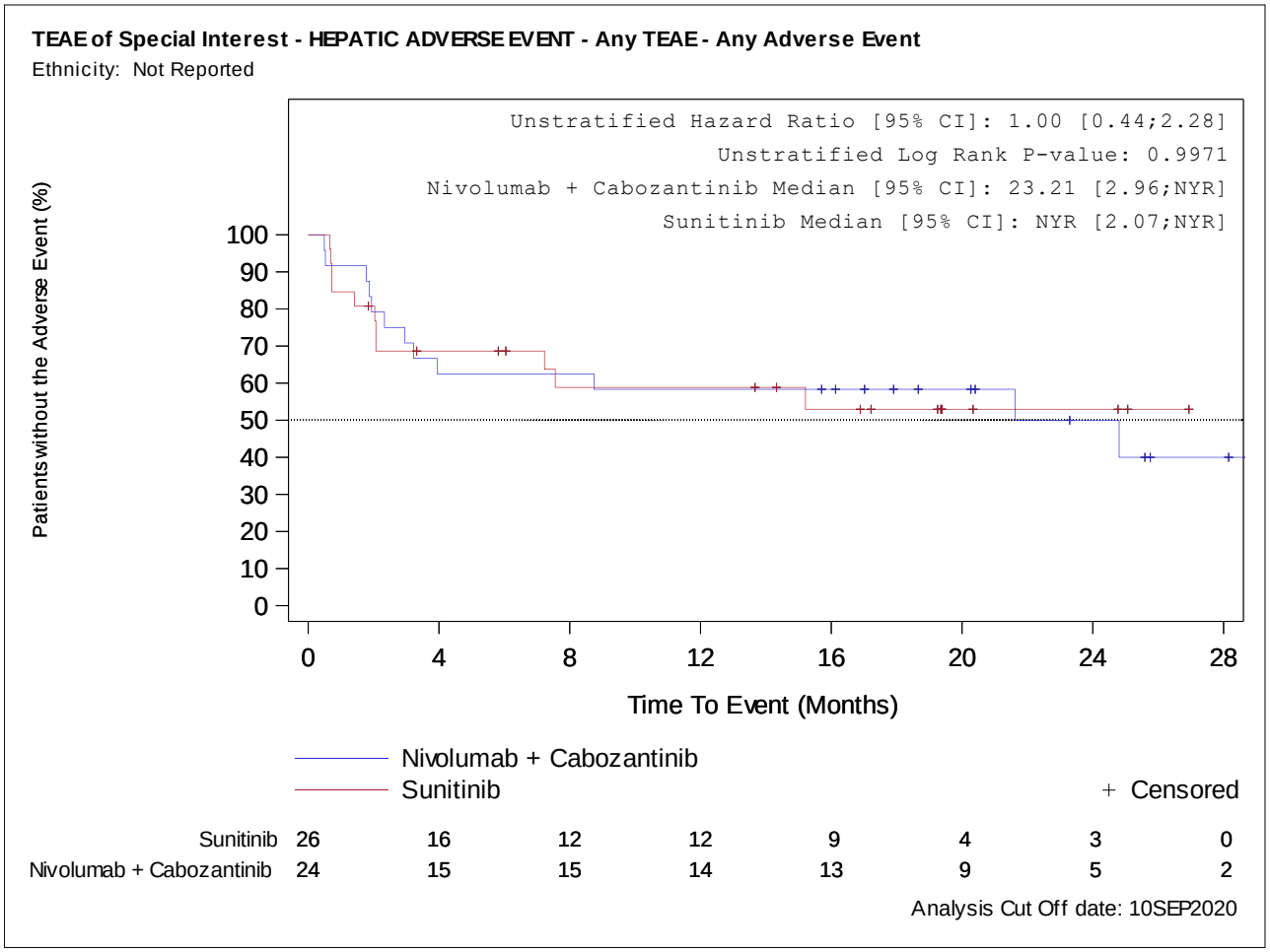
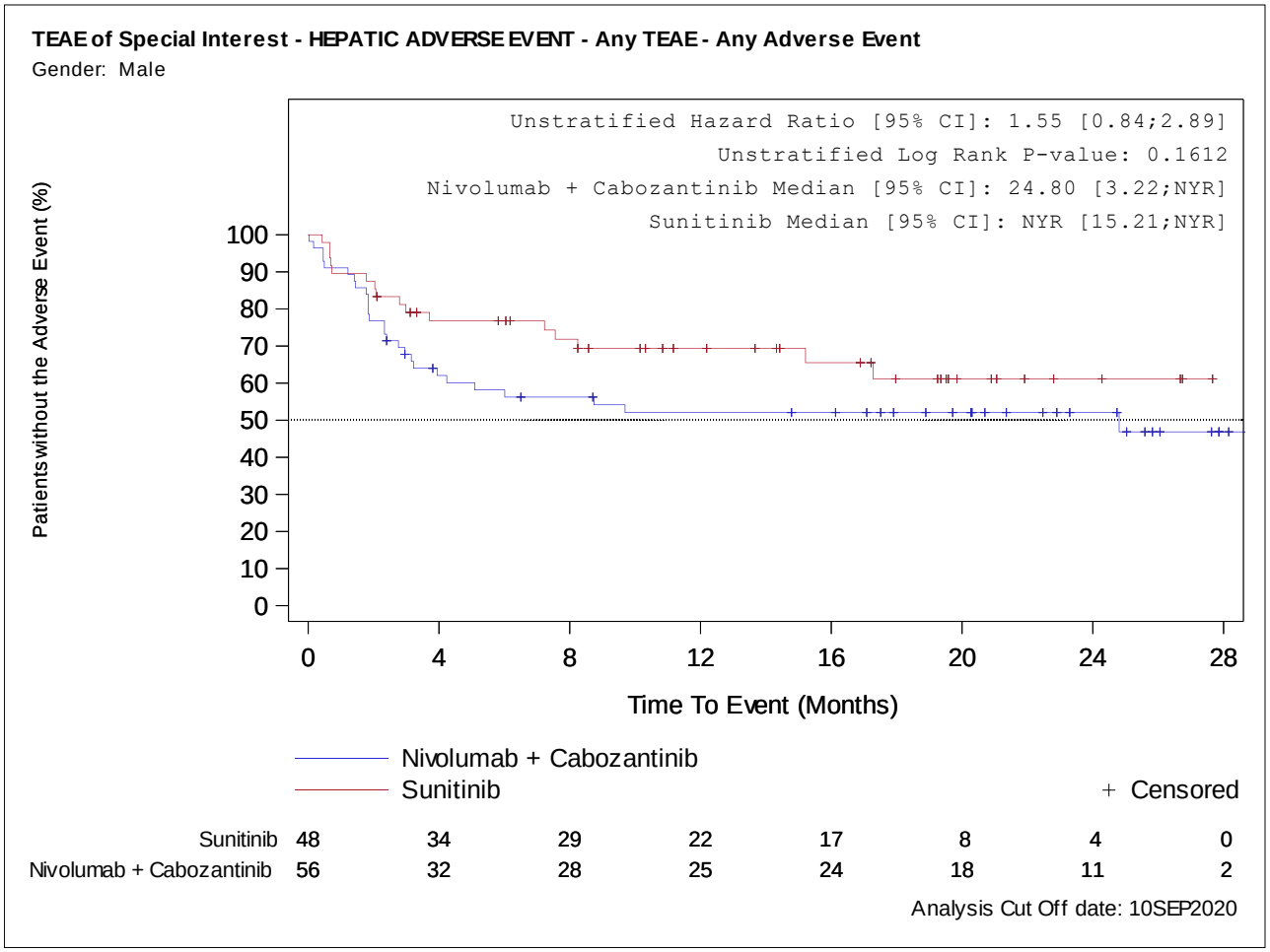
FIGURE 3.29.2.12: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



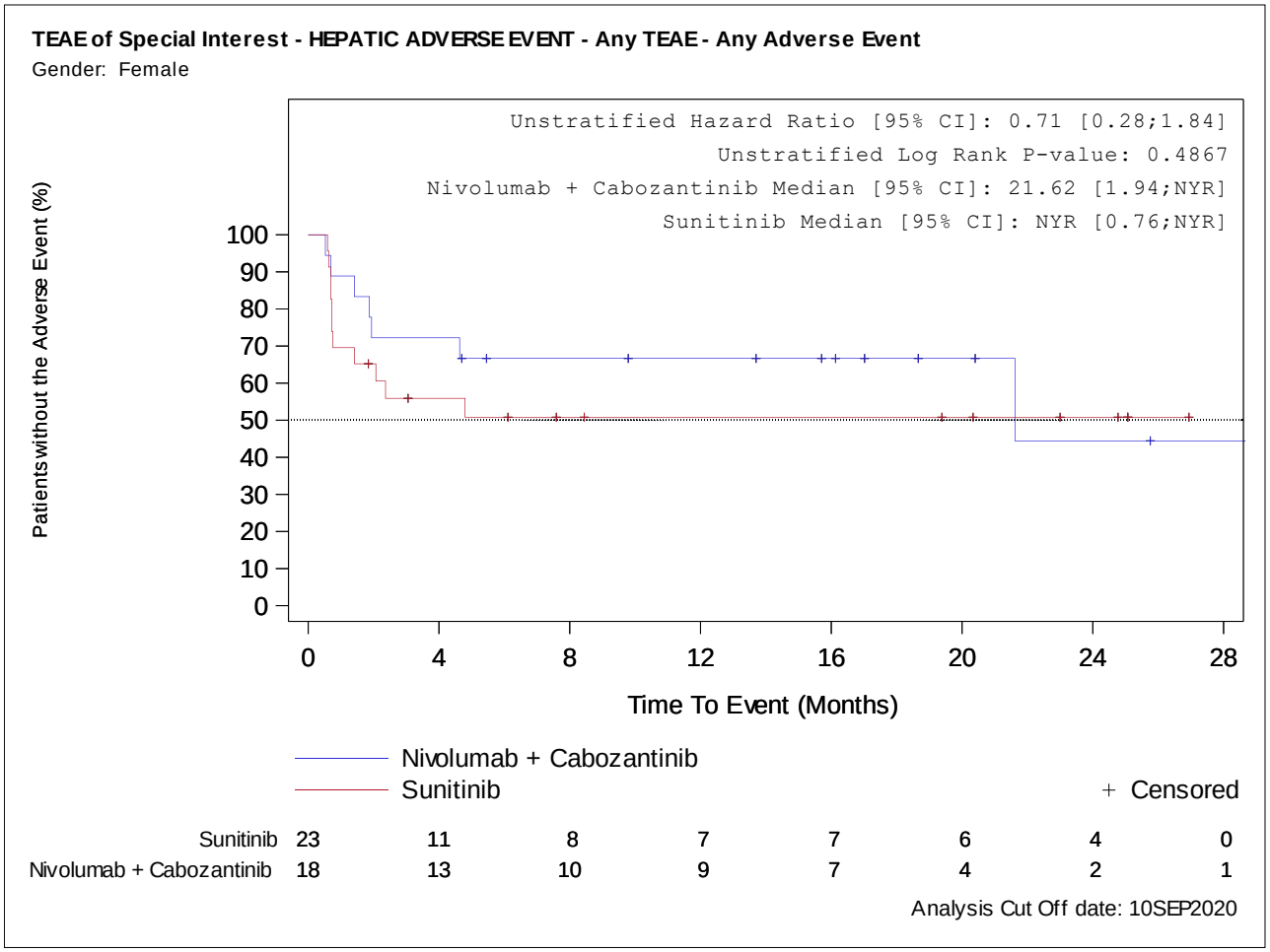

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:57:31

FIGURE 3.29.2.13: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



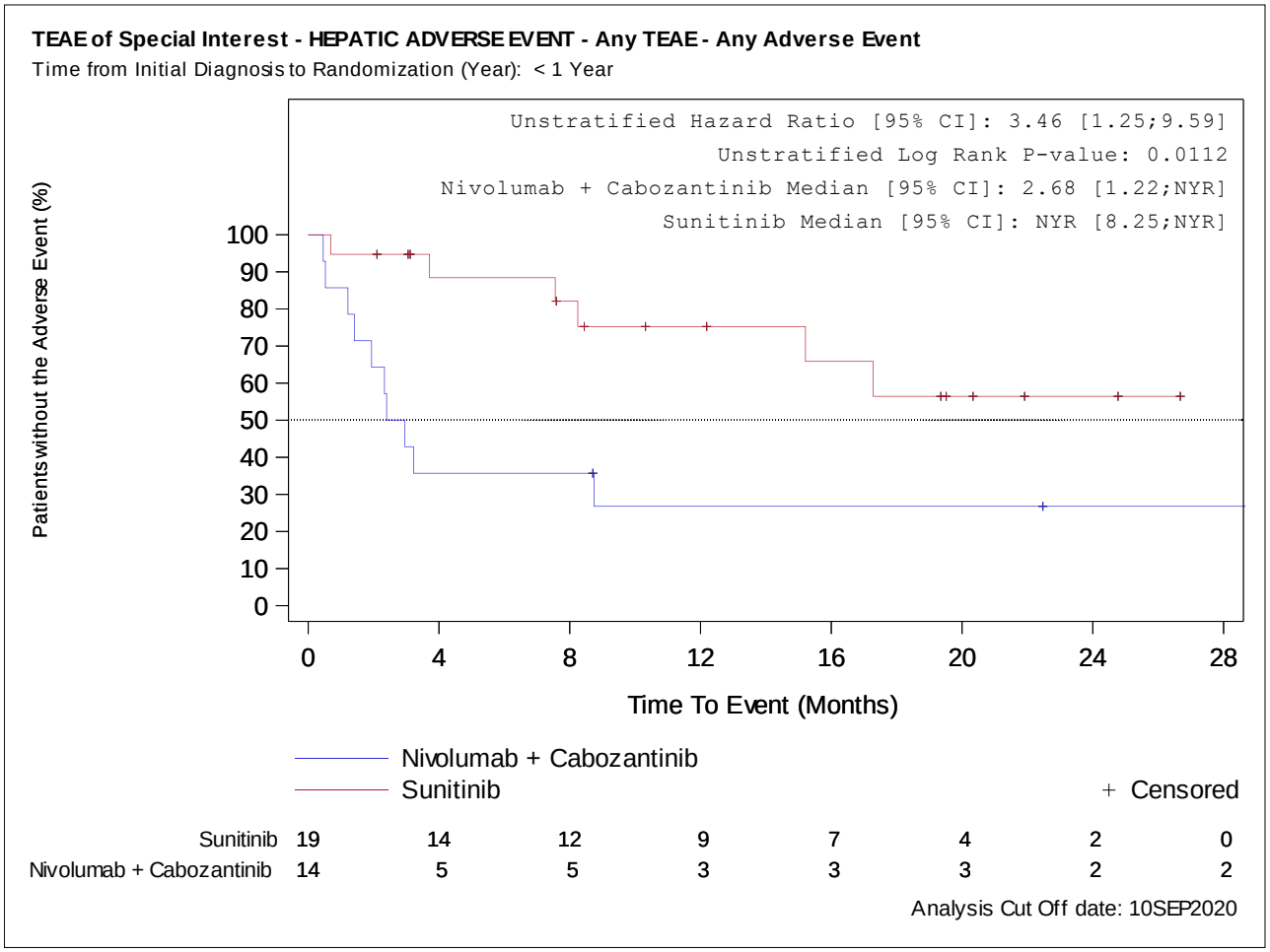

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:57:37

FIGURE 3.29.2.14: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



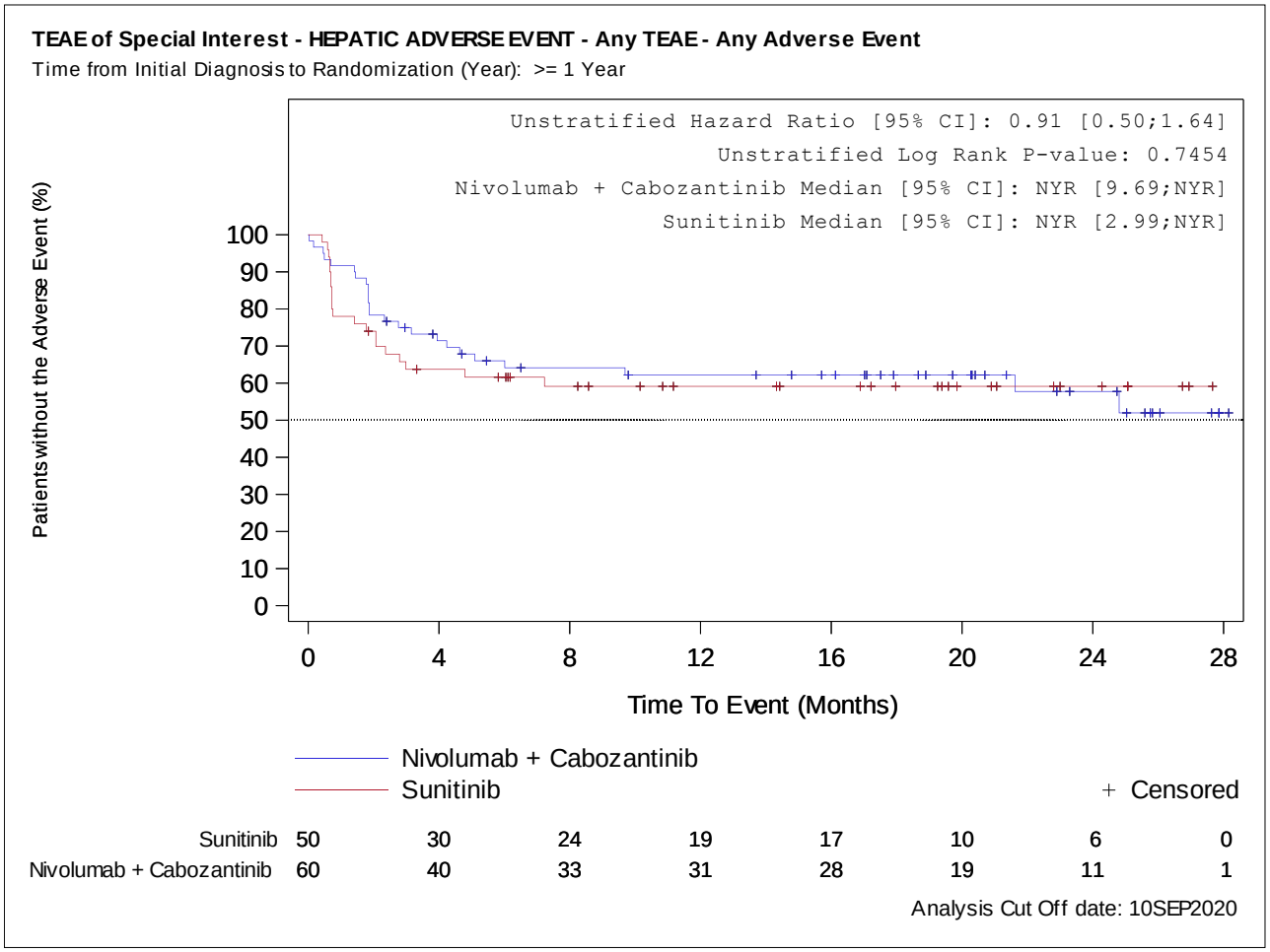

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:57:43

FIGURE 3.29.2.15: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



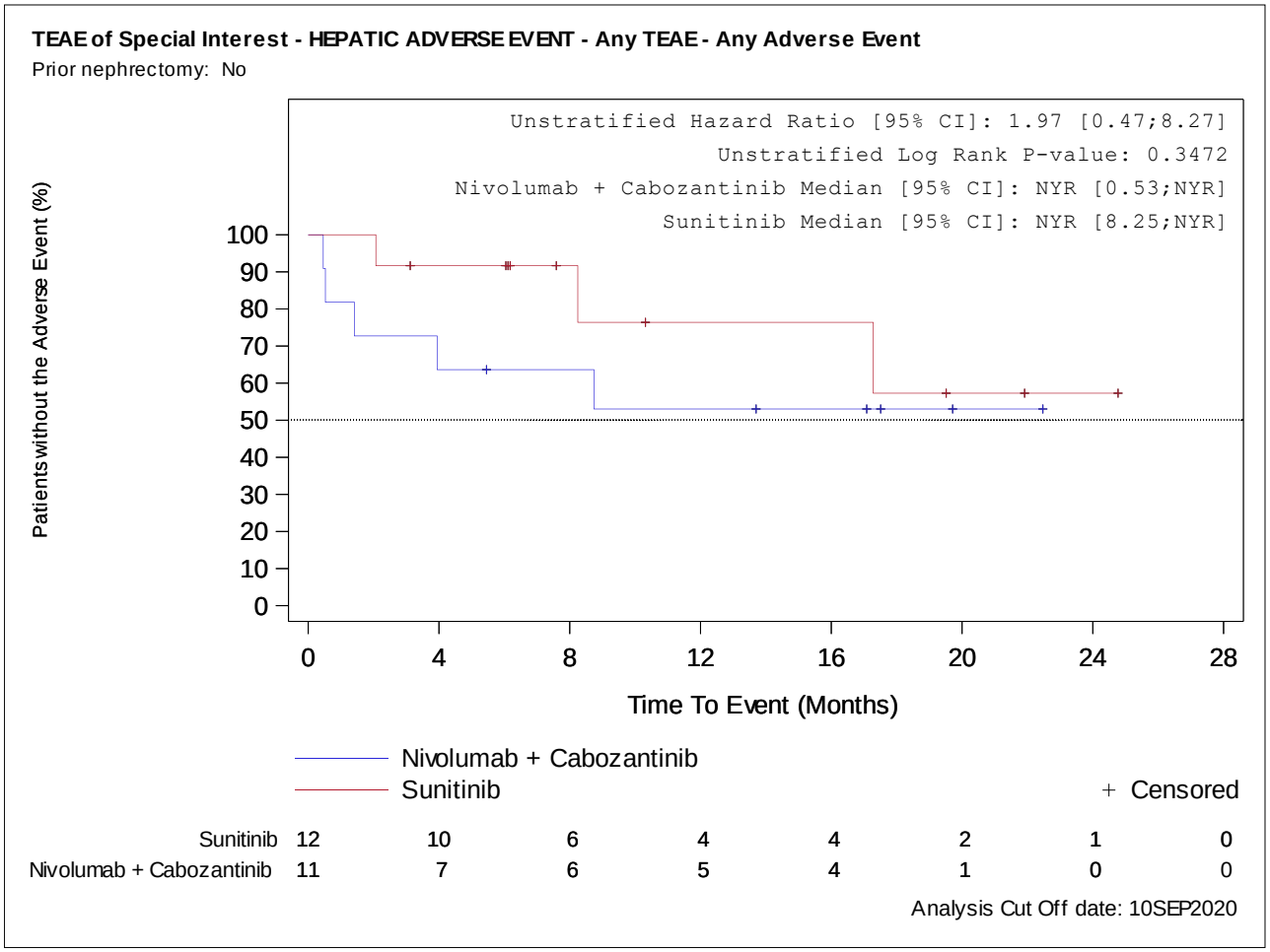

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:57:59

FIGURE 3.29.2.16: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



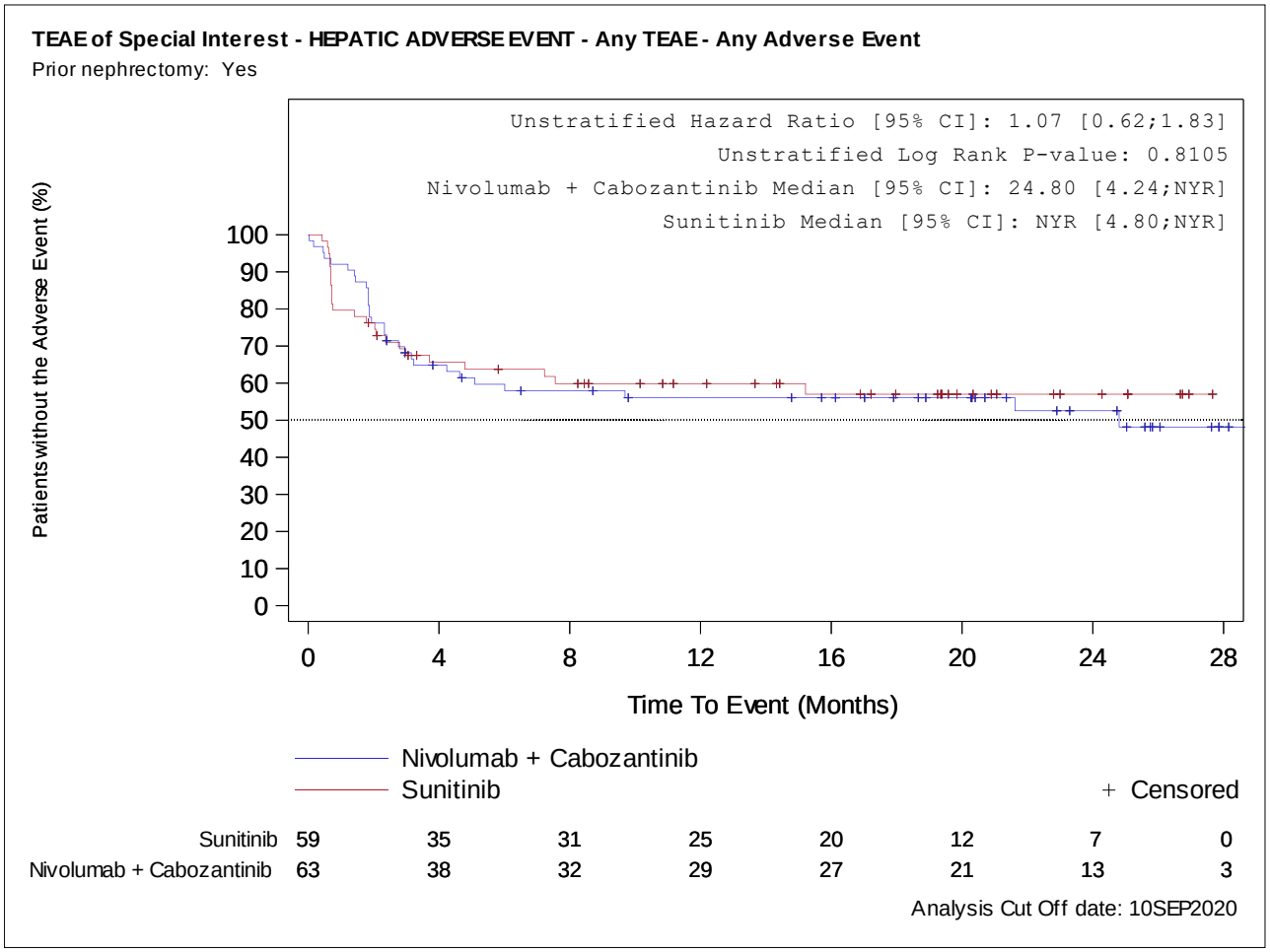

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:58:05

FIGURE 3.29.2.17: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



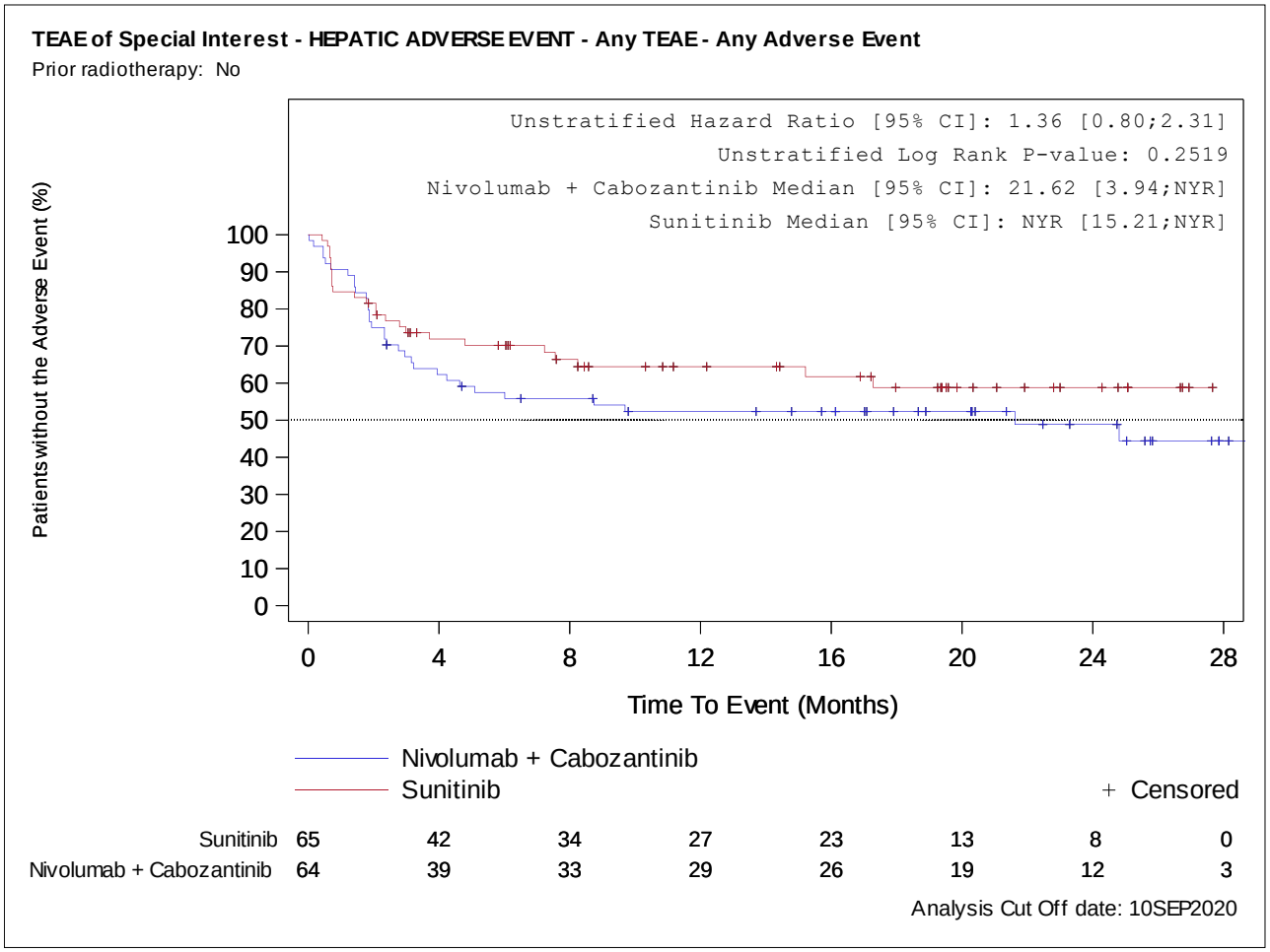

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:58:58

FIGURE 3.29.2.18: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



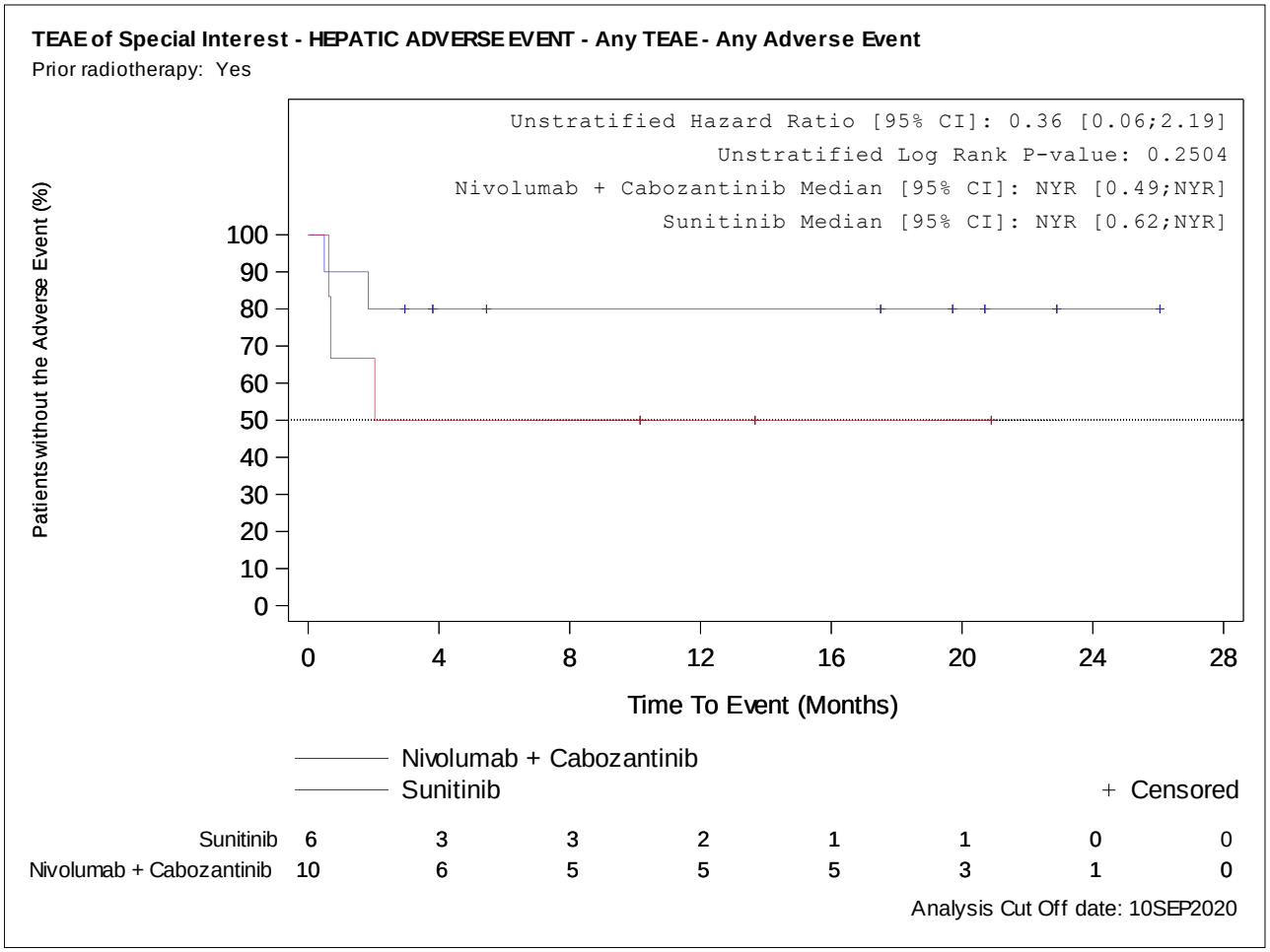

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:59:04

FIGURE 3.29.2.19: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



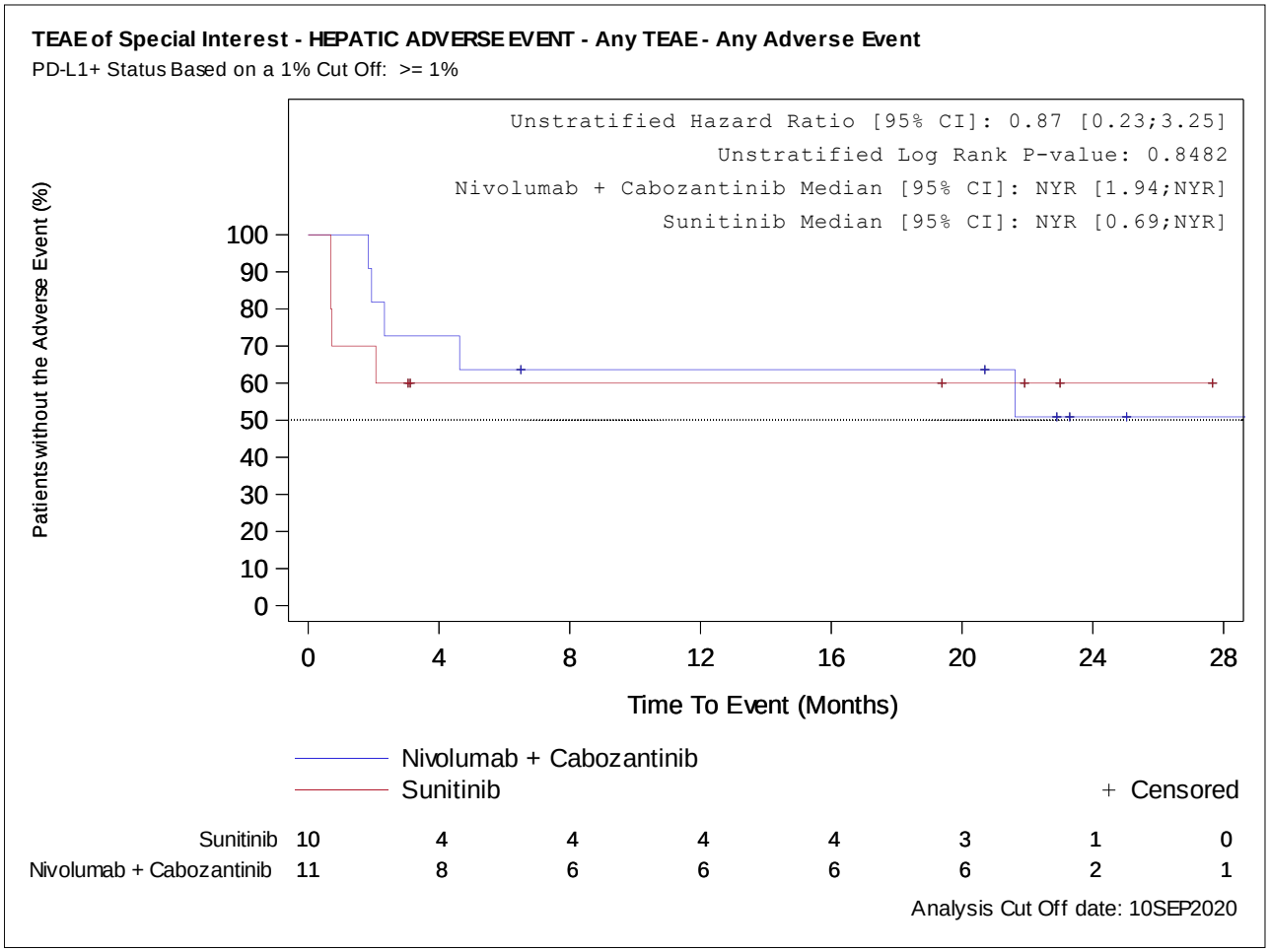

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:59:10

FIGURE 3.29.2.20: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



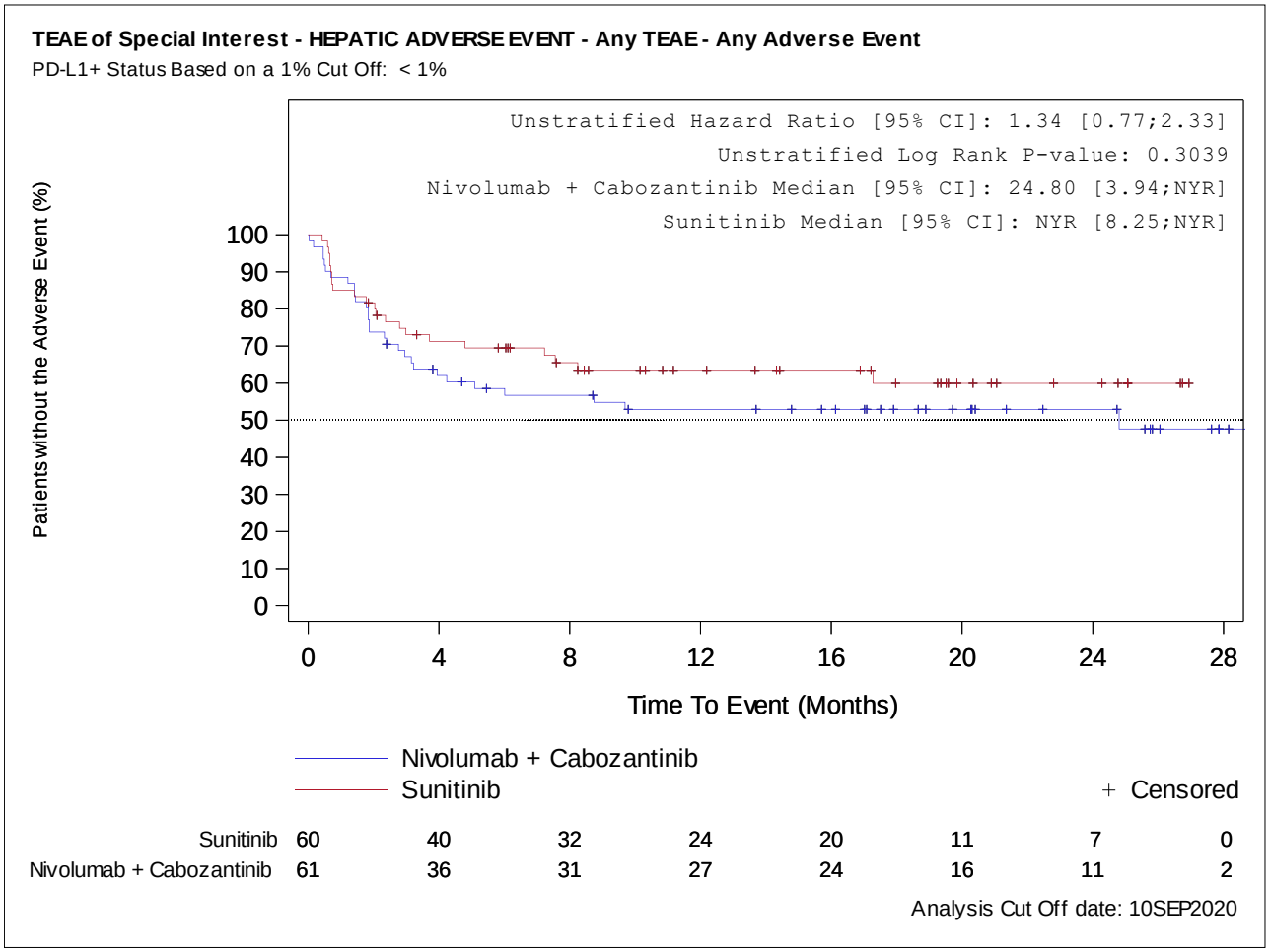

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:59:16

FIGURE 3.29.2.21: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



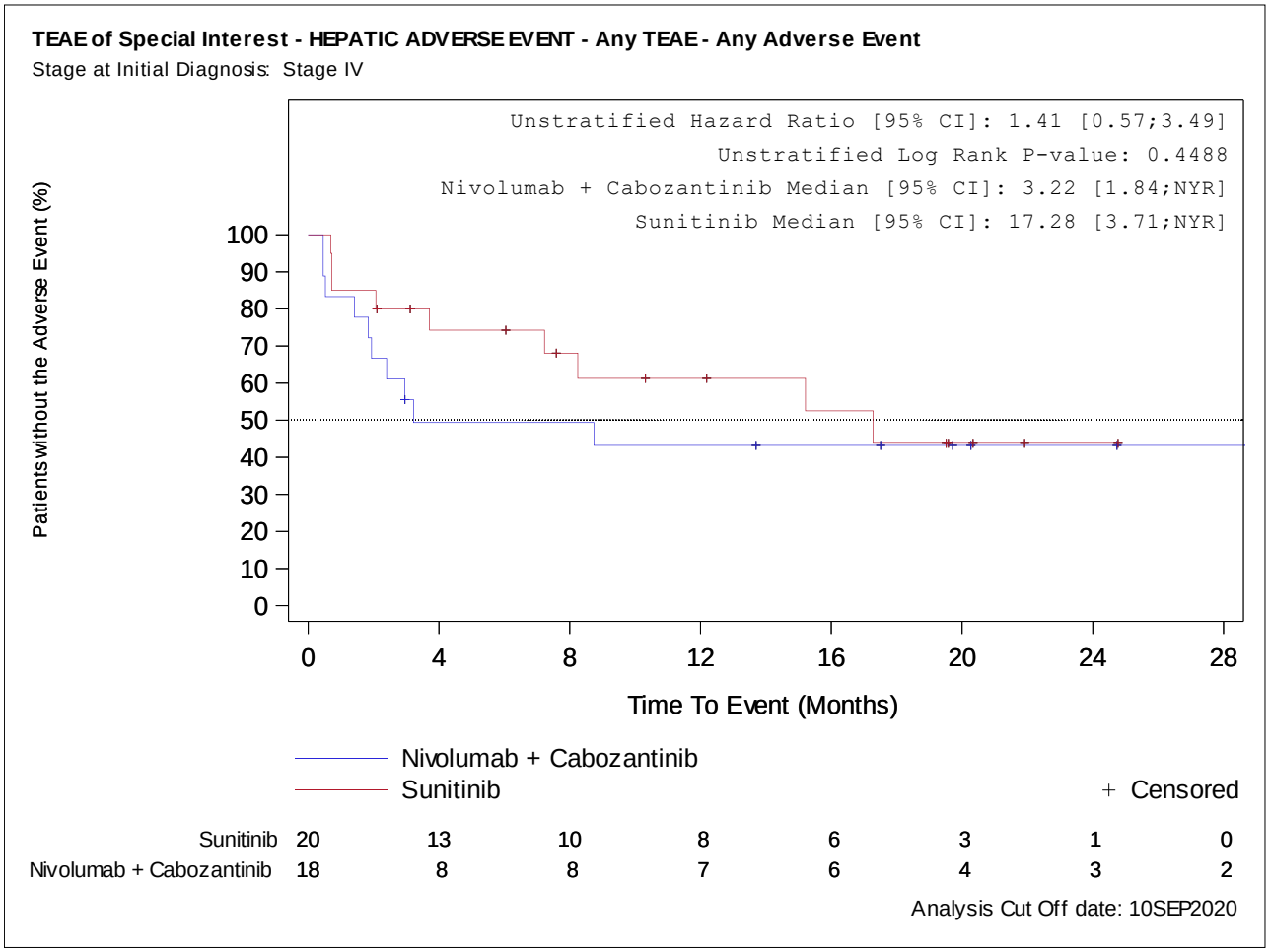

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:59:21

FIGURE 3.29.2.22: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



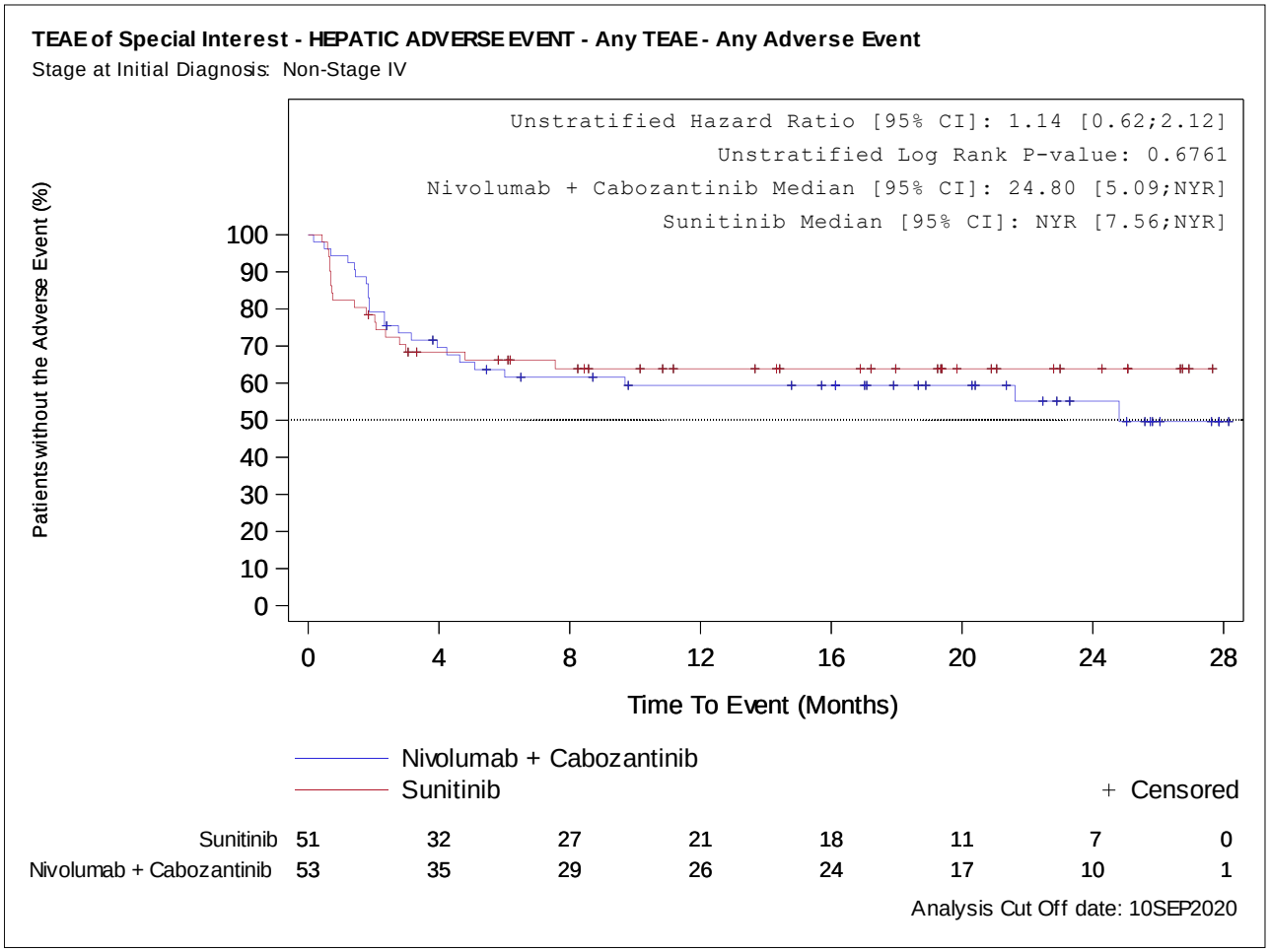

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:59:27

FIGURE 3.29.2.23: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



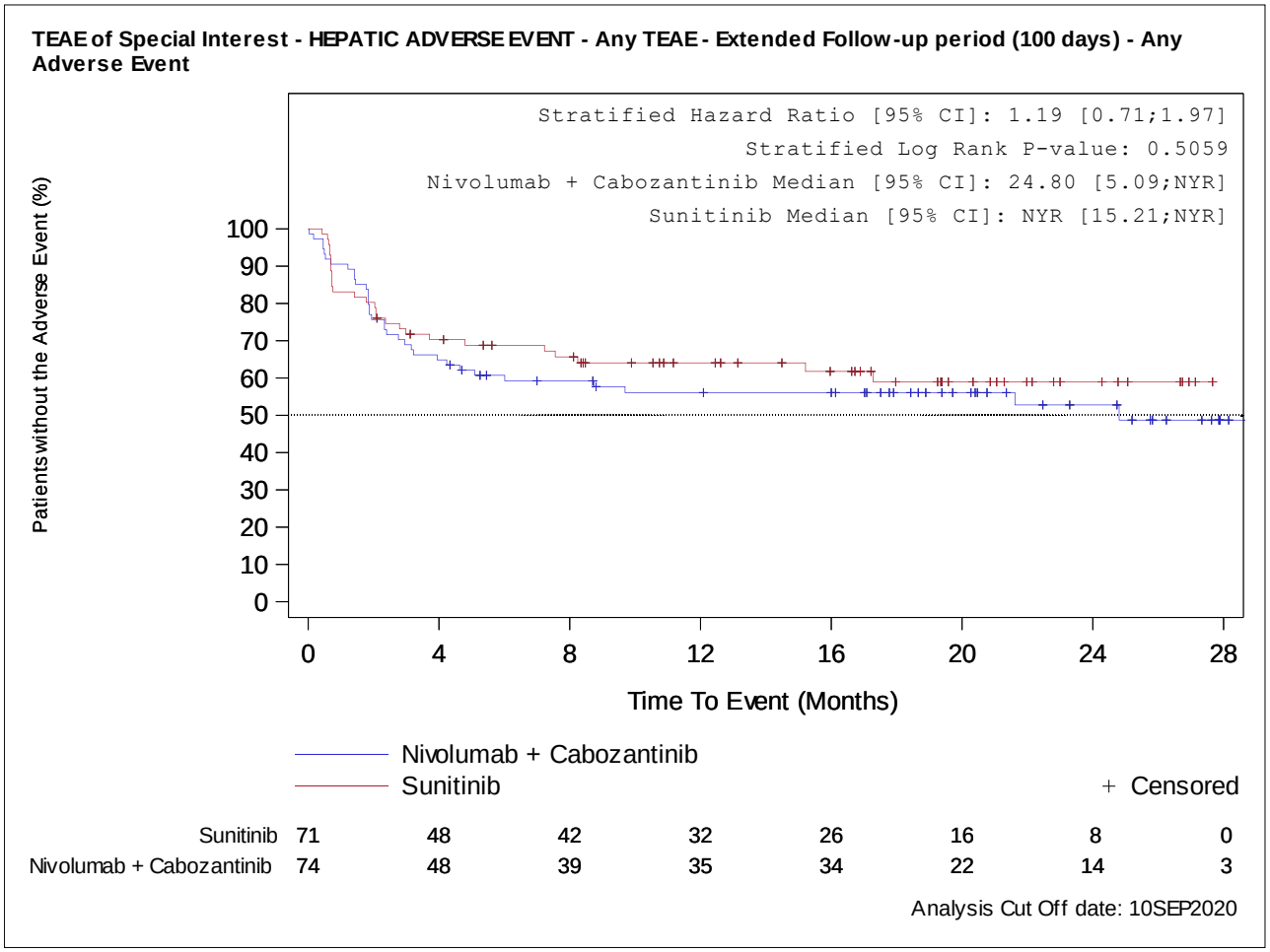

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:59:56

FIGURE 3.29.2.24: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



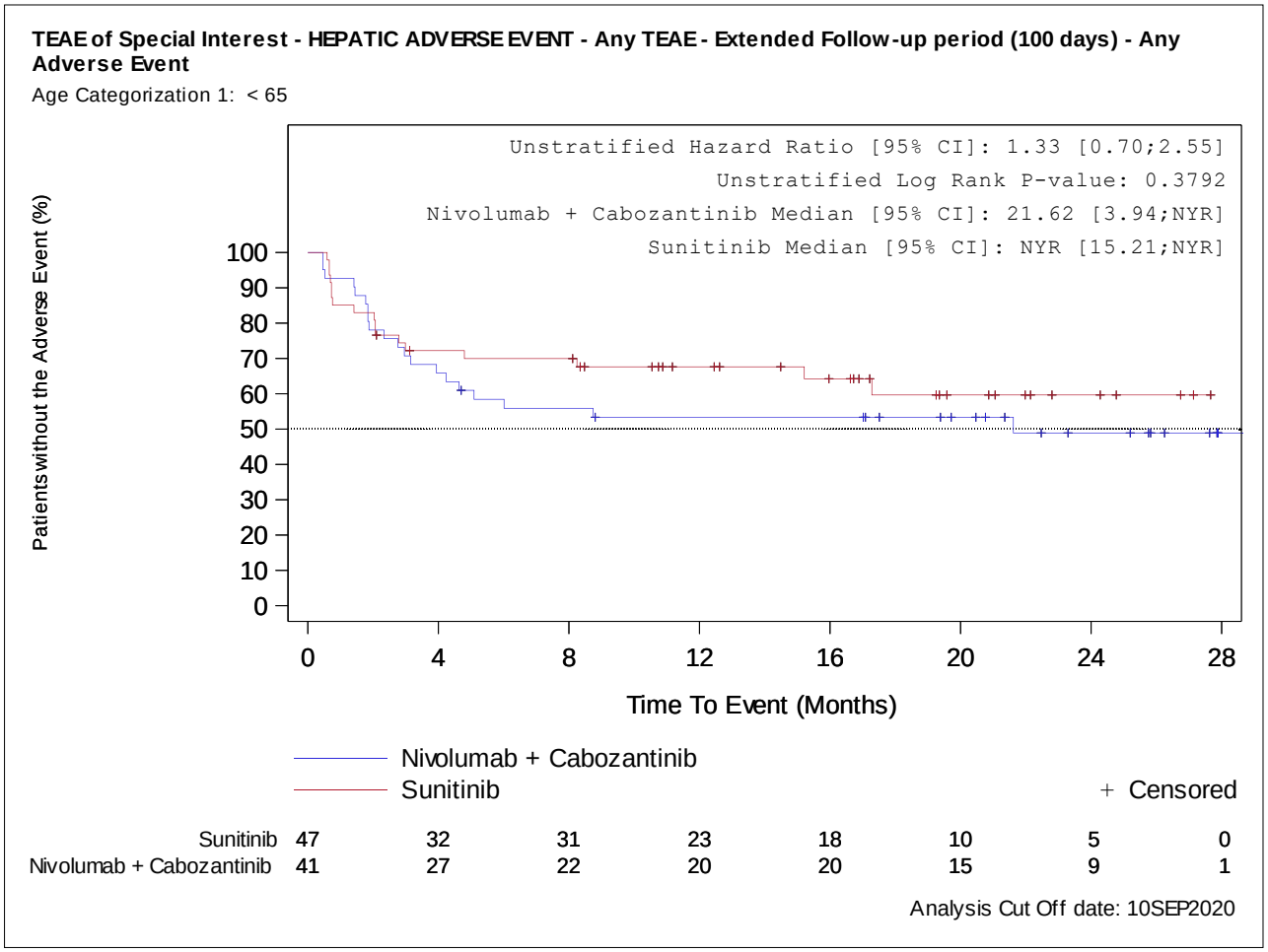

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:00:01

FIGURE 3.30.1: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



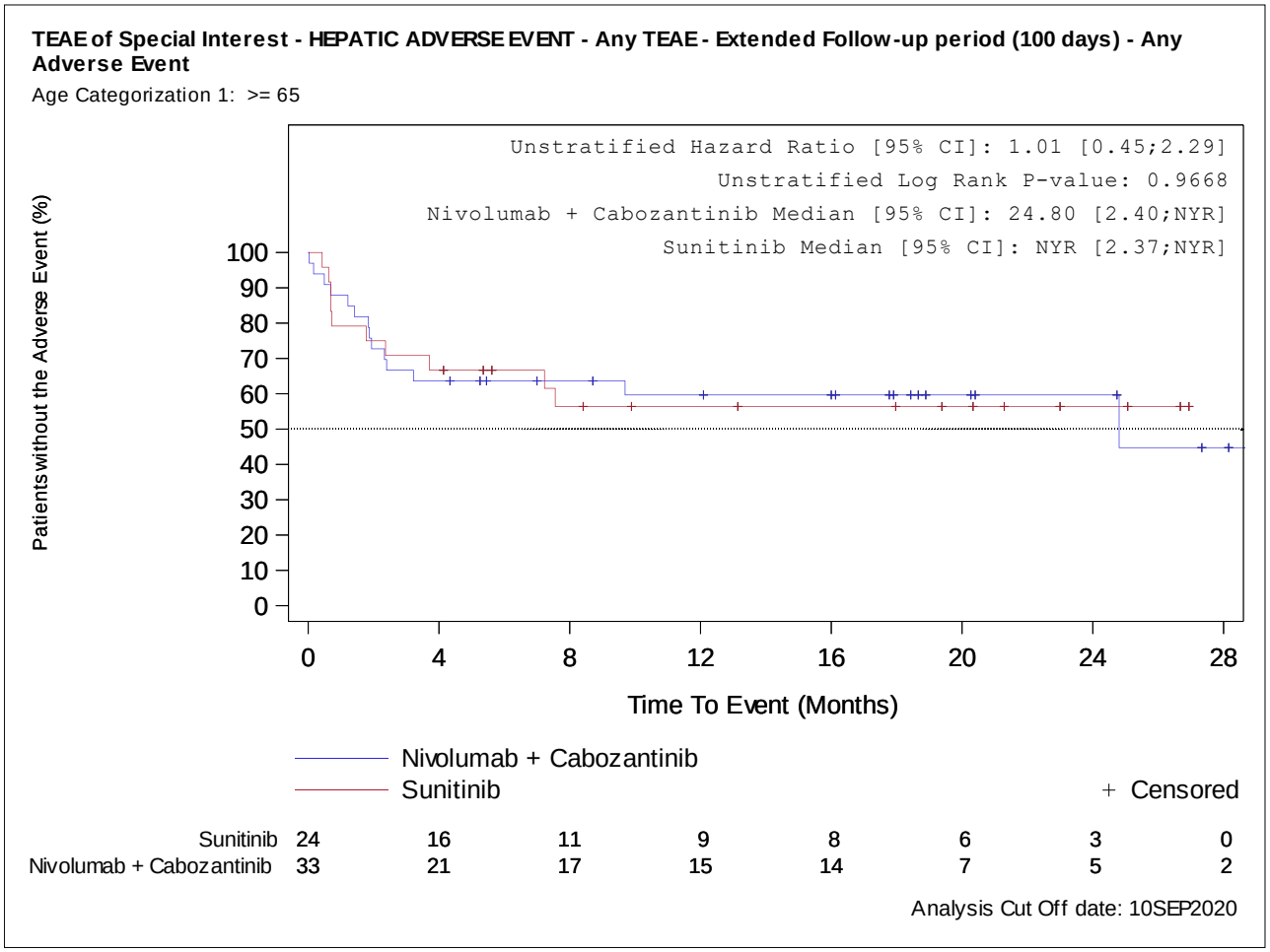

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:03:19

FIGURE 3.30.2.1: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



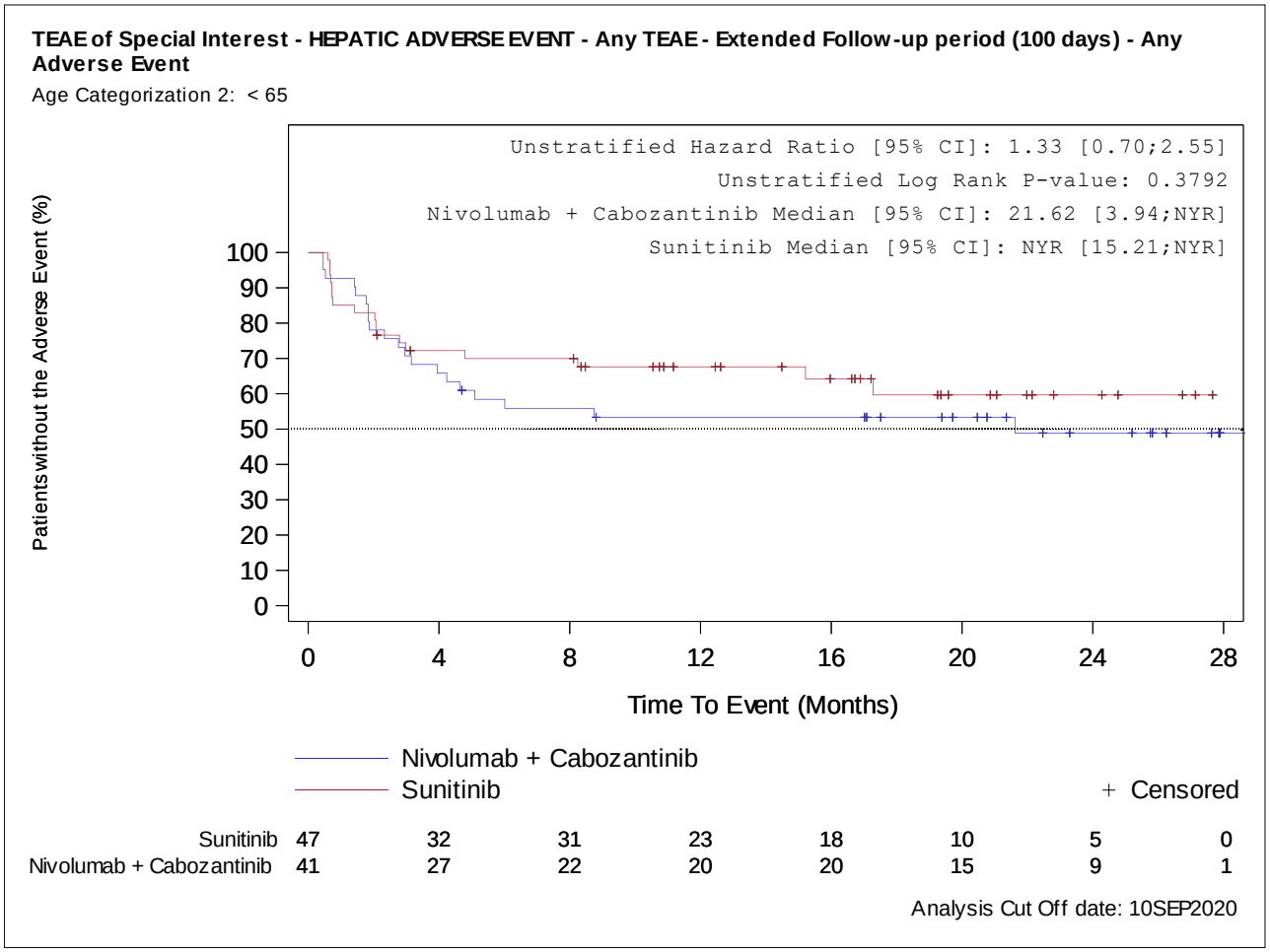

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:03:22

FIGURE 3.30.2.2: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



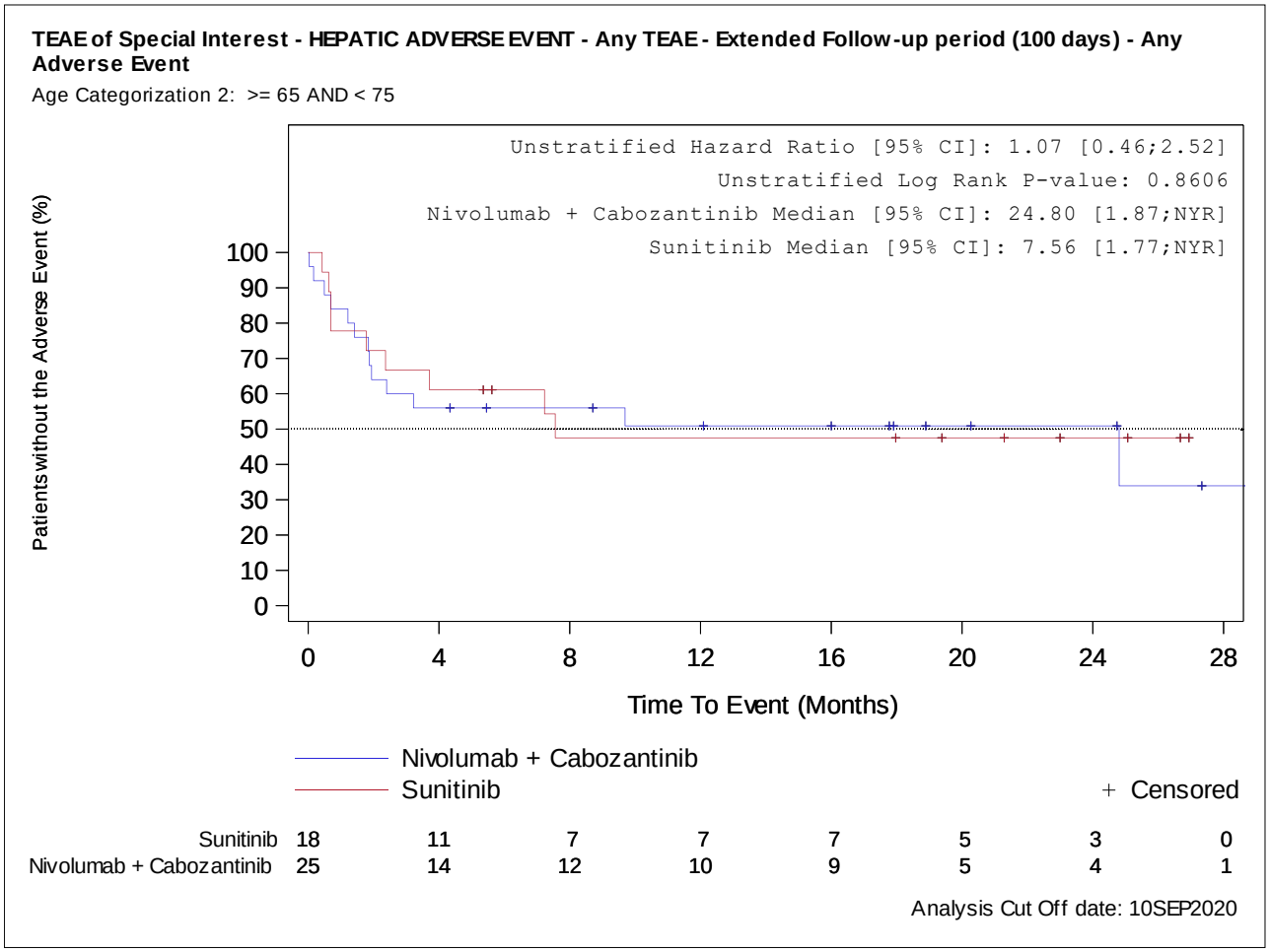

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:03:28

FIGURE 3.30.2.3: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



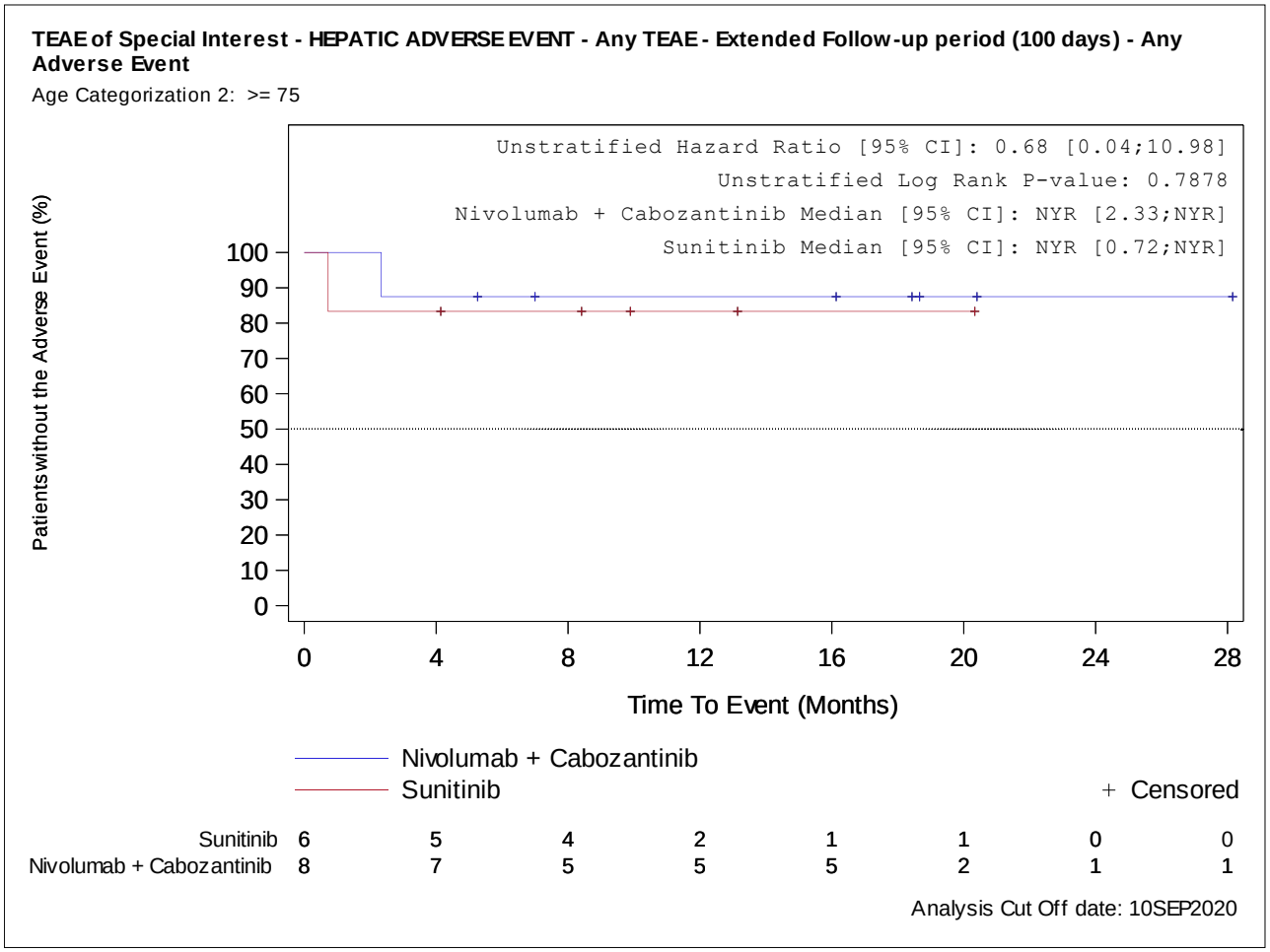

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:03:34

FIGURE 3.30.2.4: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



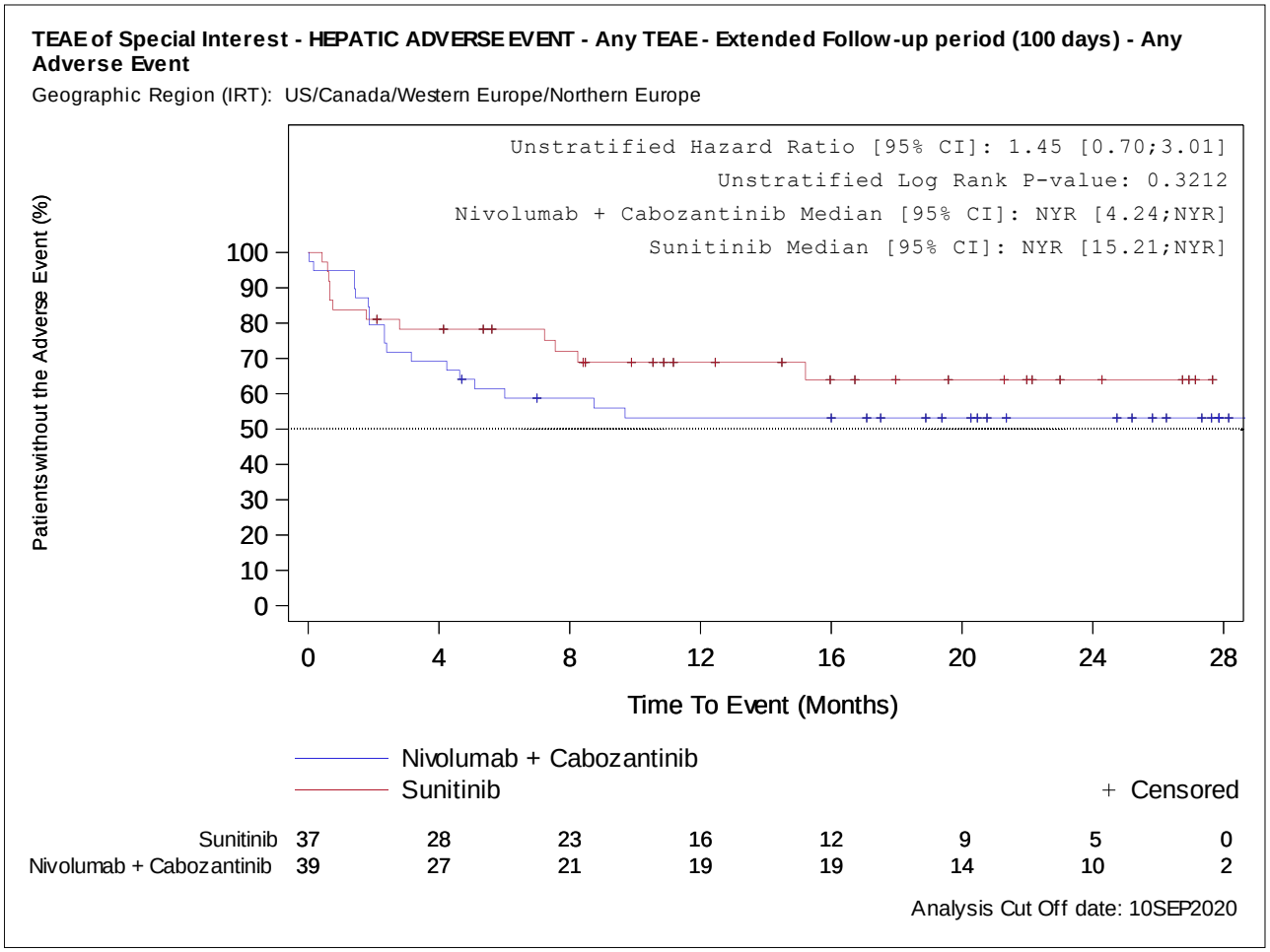

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:03:39

FIGURE 3.30.2.5: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



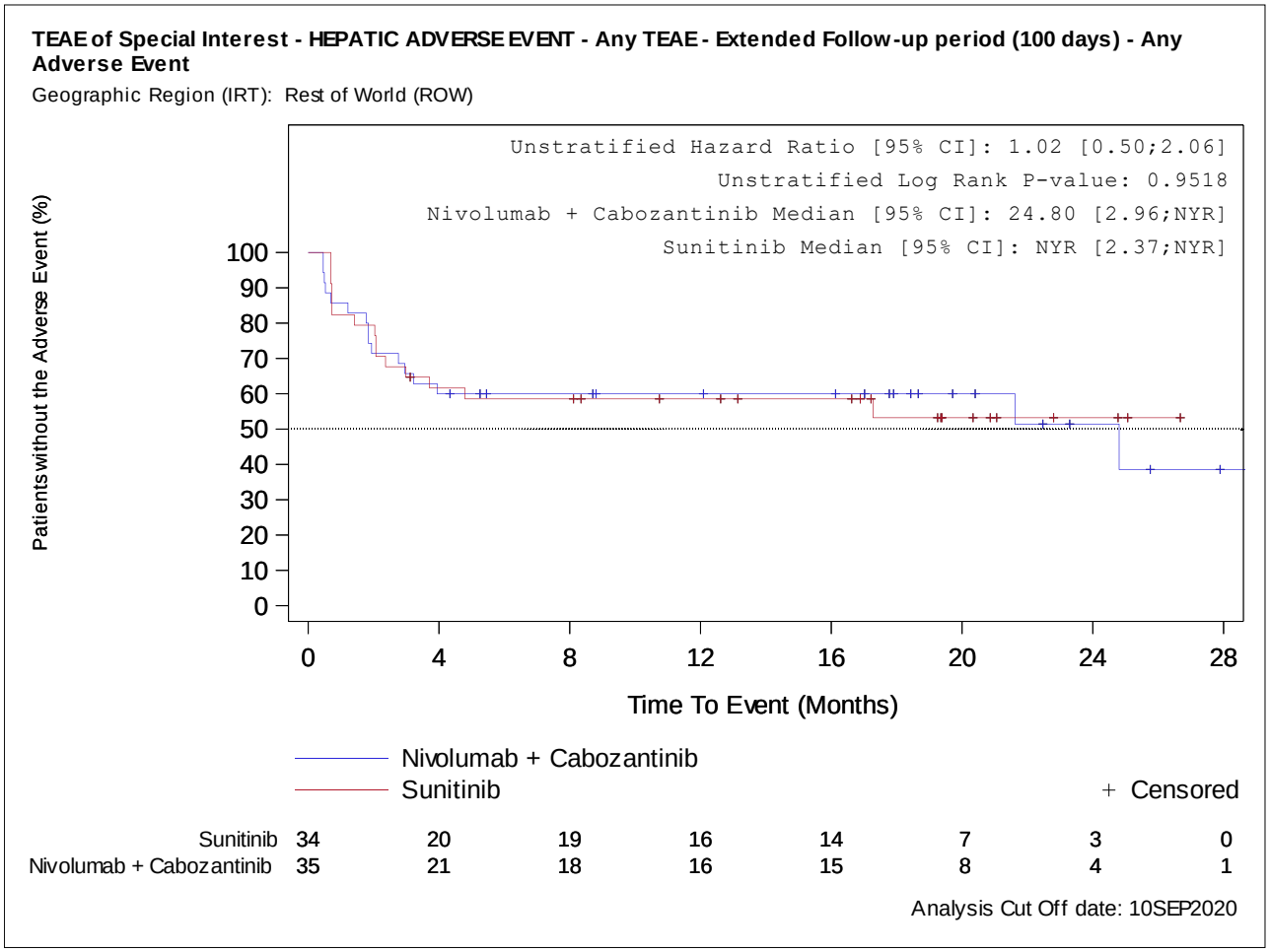

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:03:45

FIGURE 3.30.2.6: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



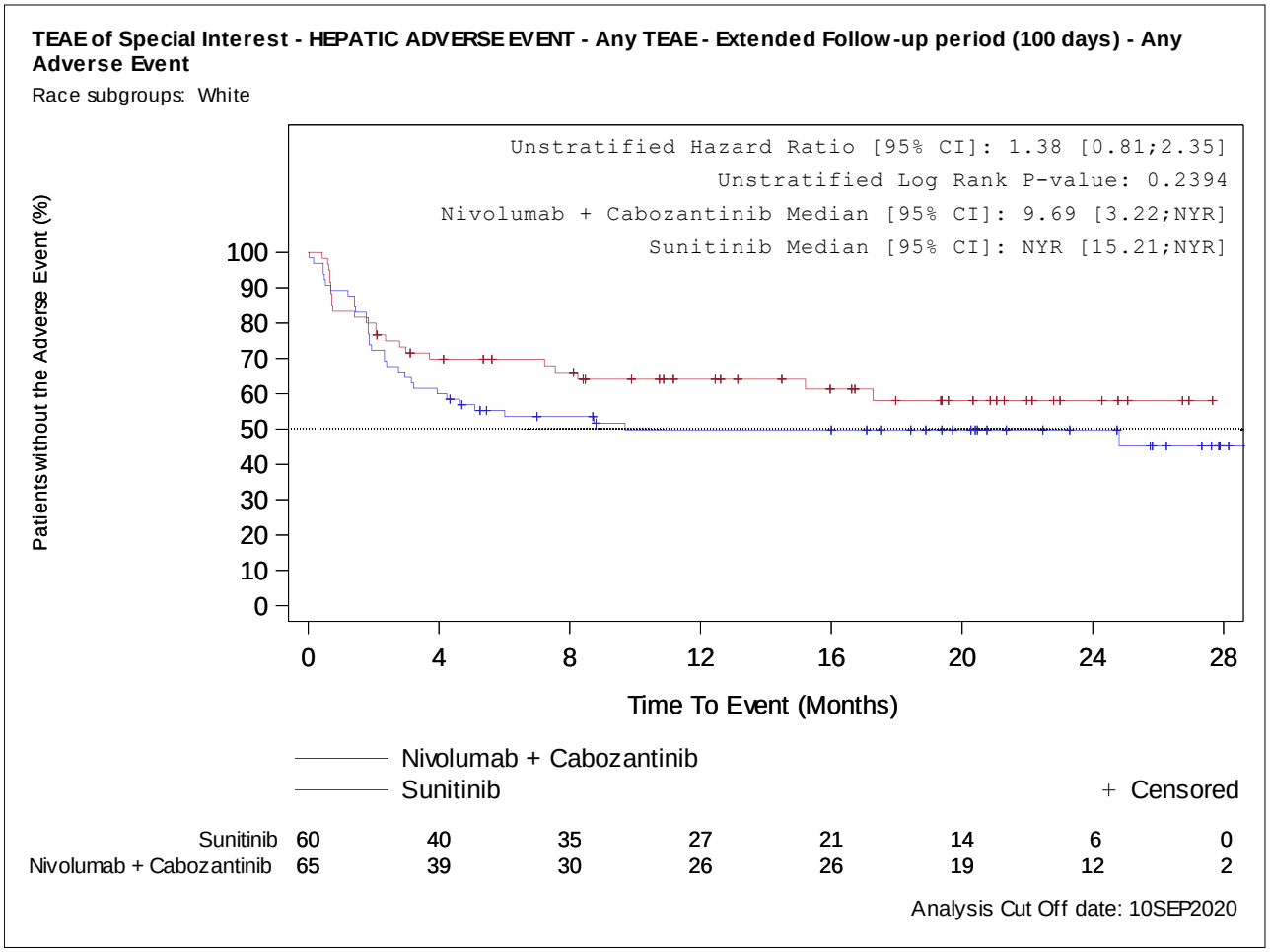

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:03:50

FIGURE 3.30.2.7: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



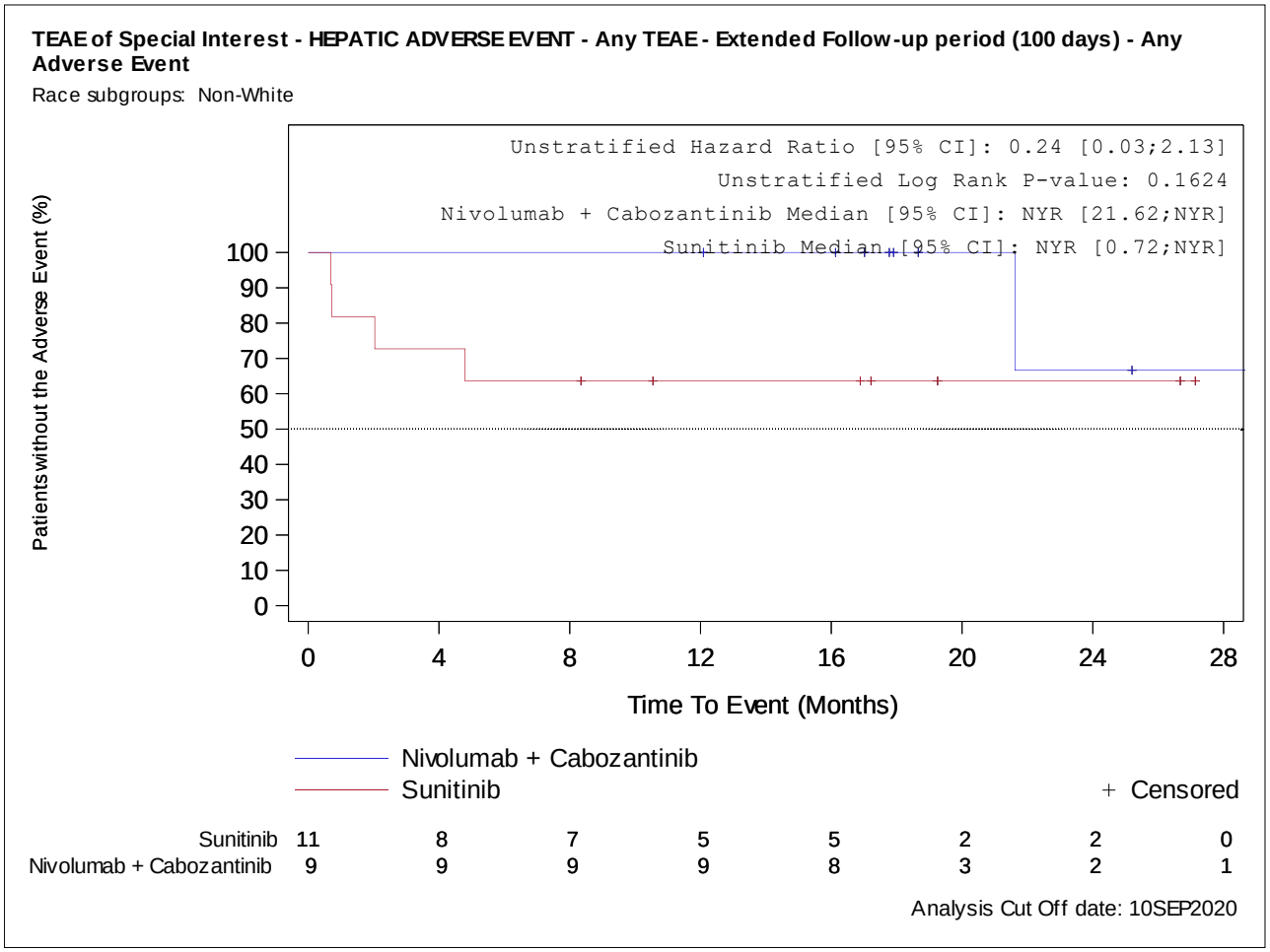

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:03:56

FIGURE 3.30.2.8: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



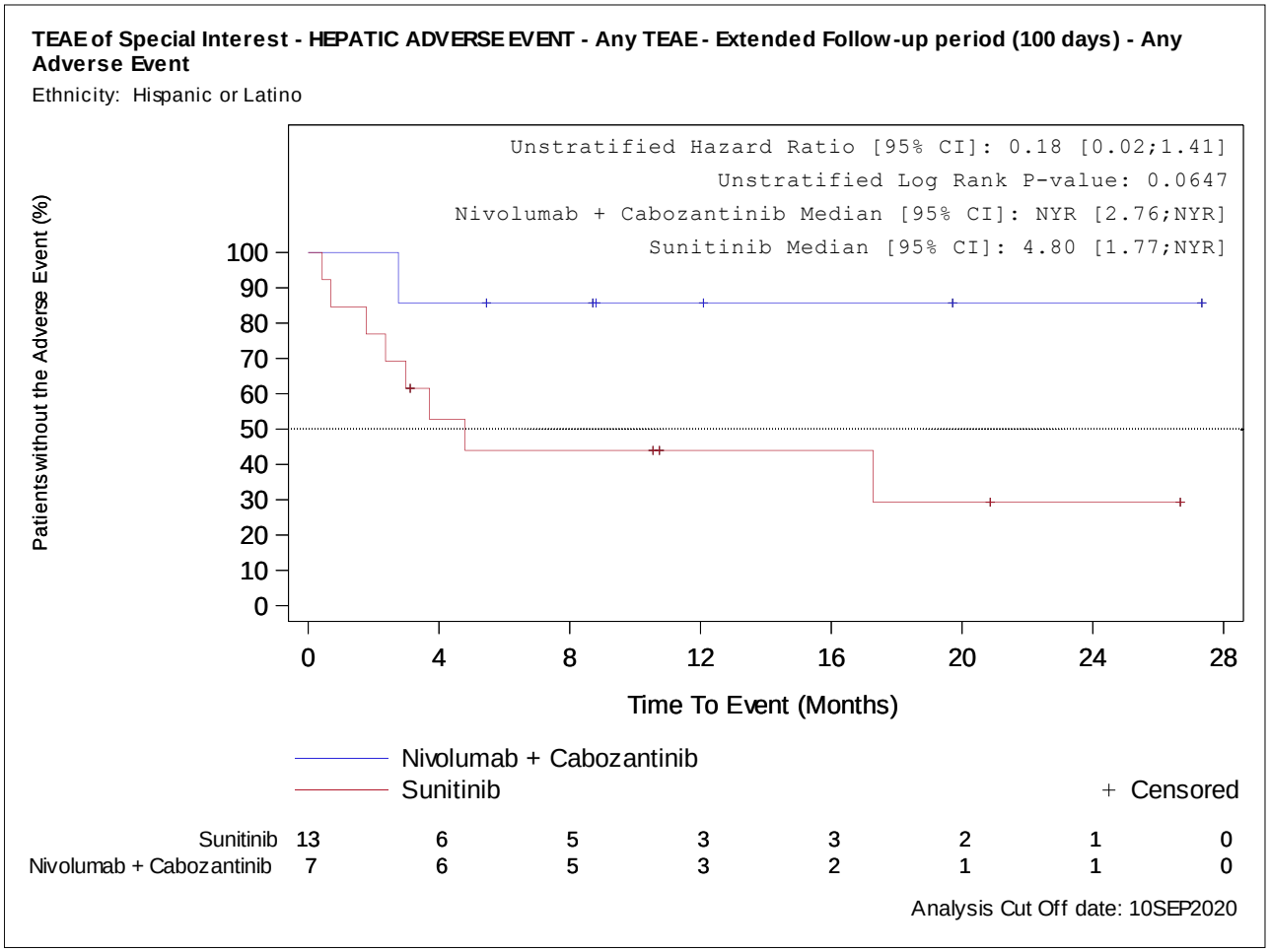

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:04:02

FIGURE 3.30.2.9: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



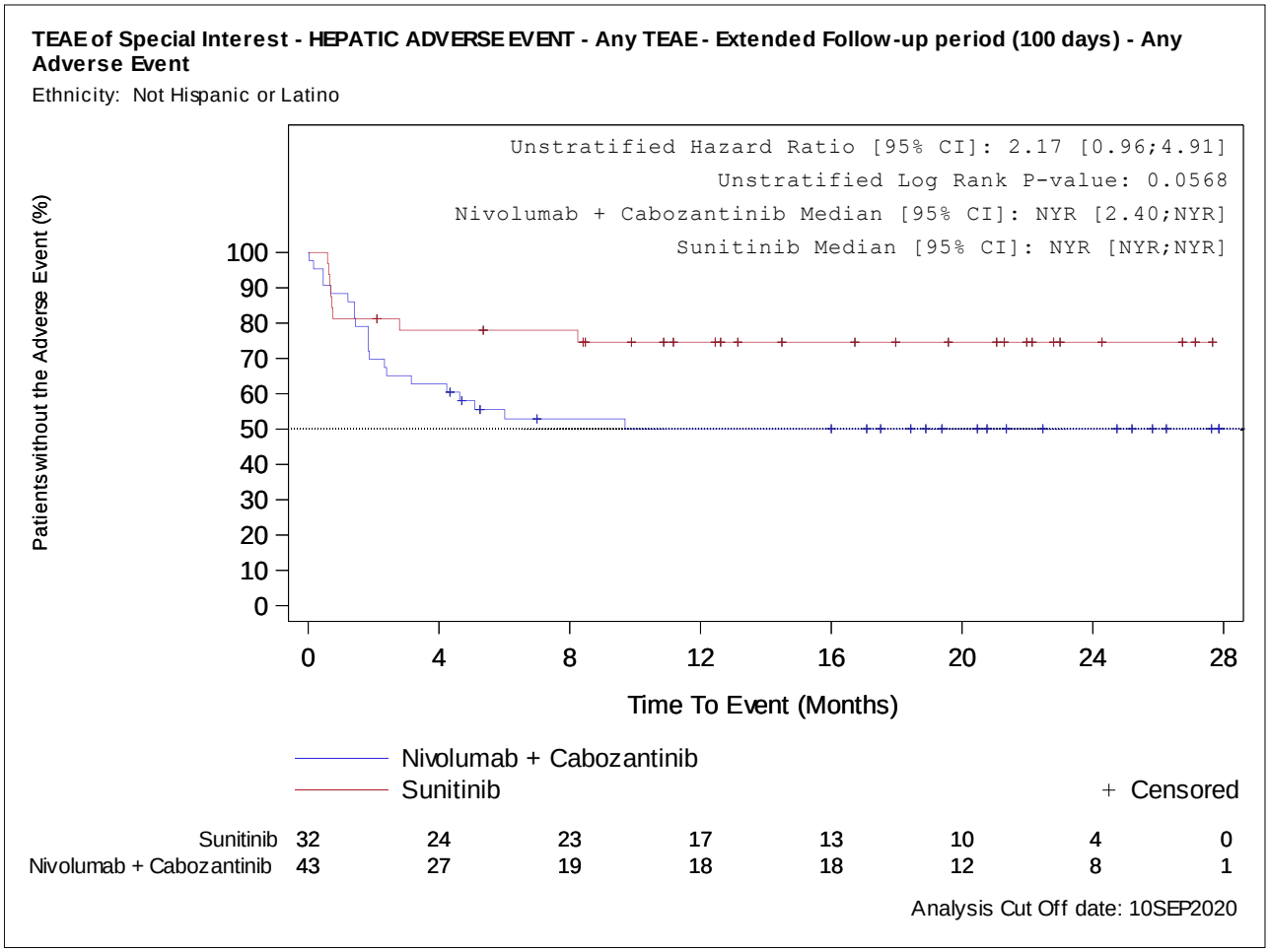

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:04:08

FIGURE 3.30.2.10: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



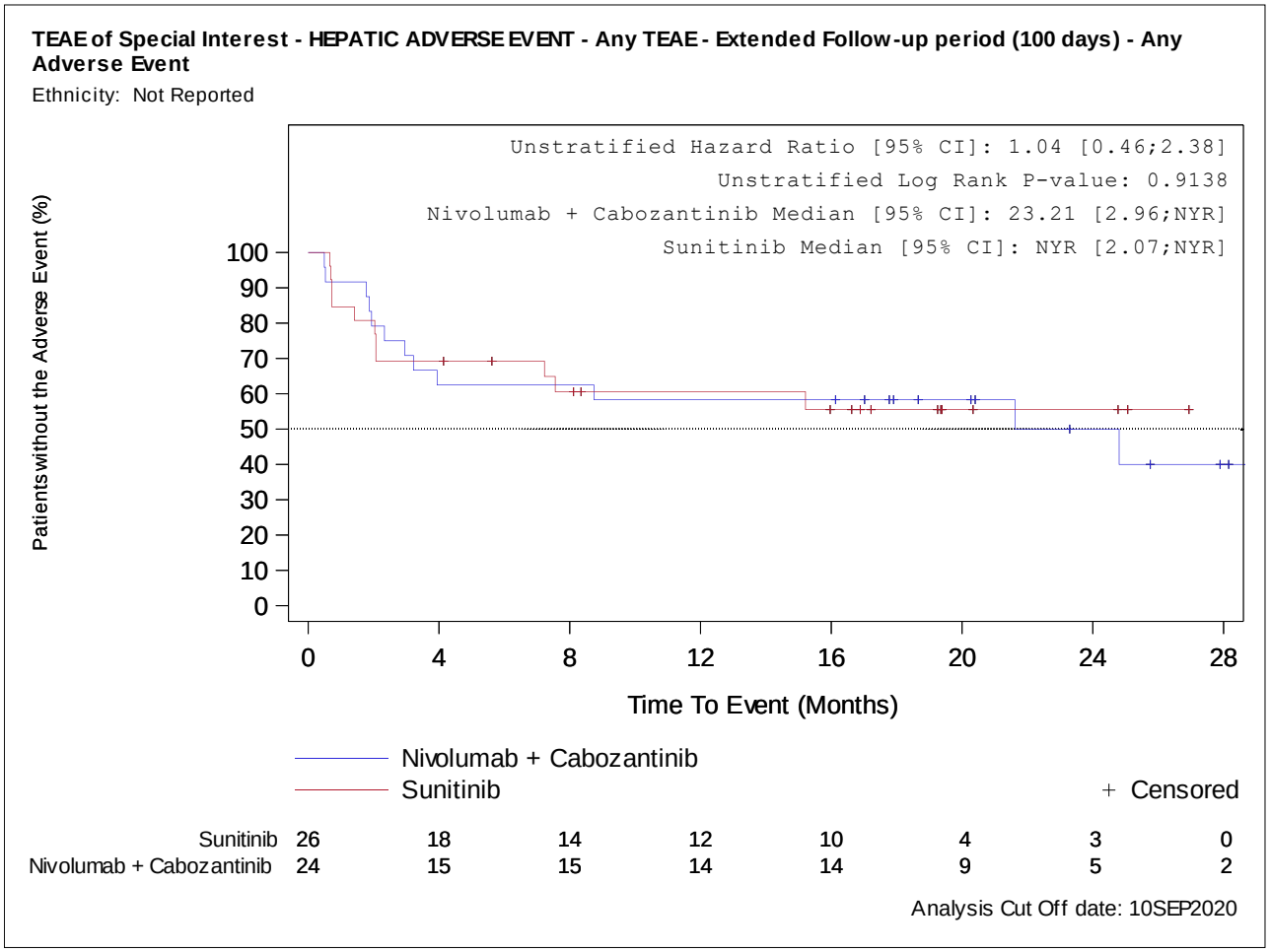

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:04:14

FIGURE 3.30.2.11: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



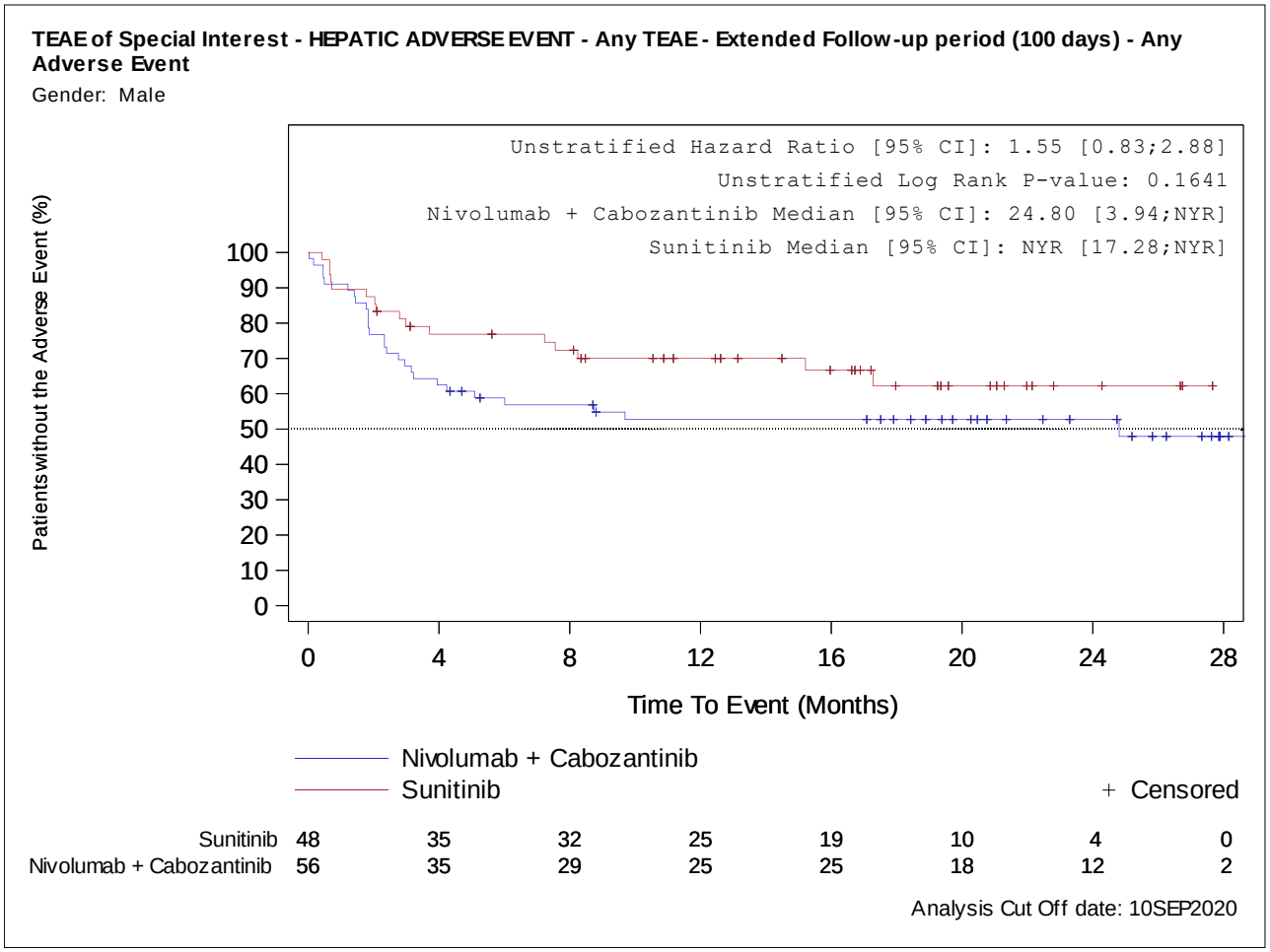

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:04:20

FIGURE 3.30.2.12: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



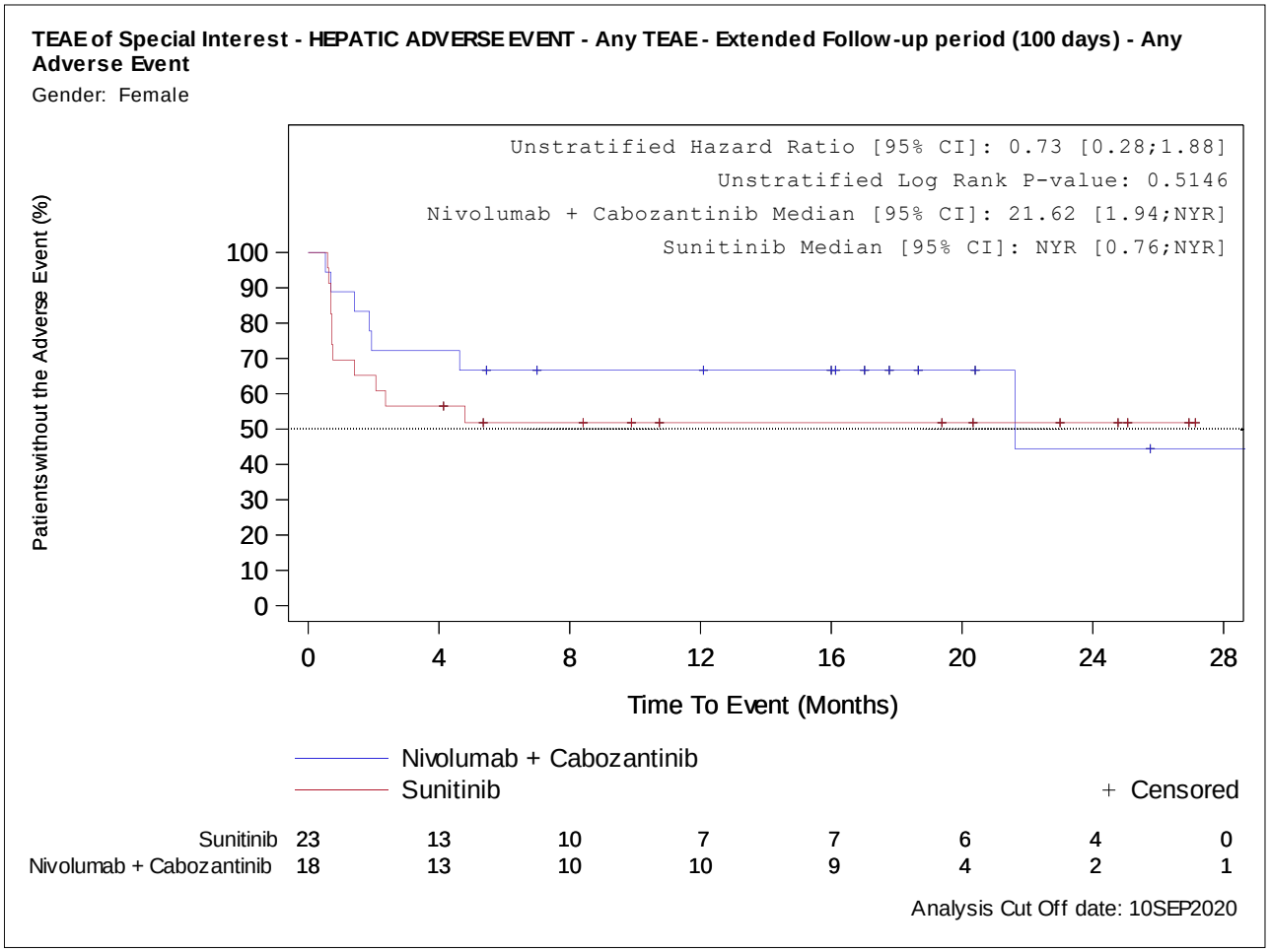

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:04:26

FIGURE 3.30.2.13: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



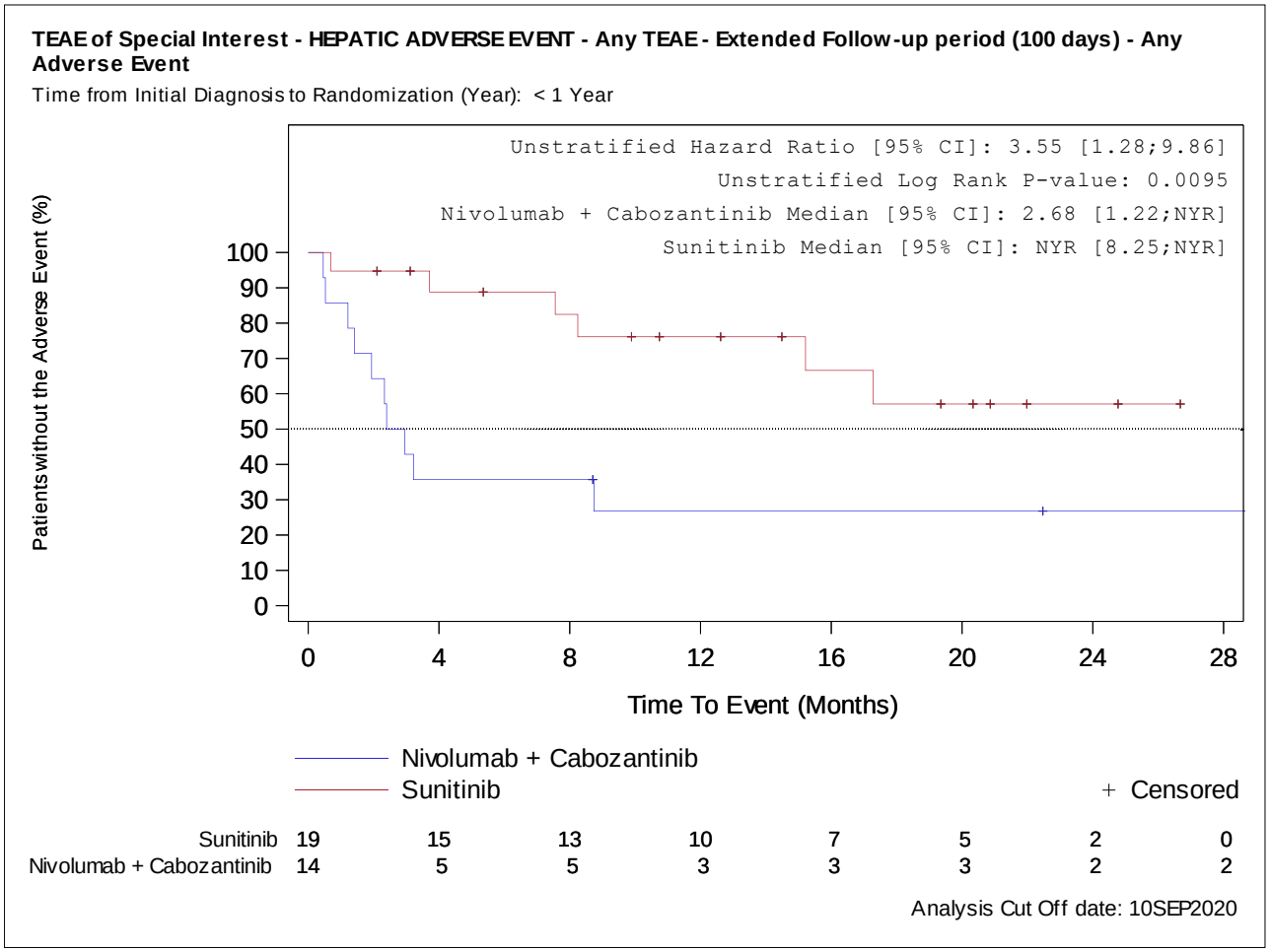

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:04:32

FIGURE 3.30.2.14: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



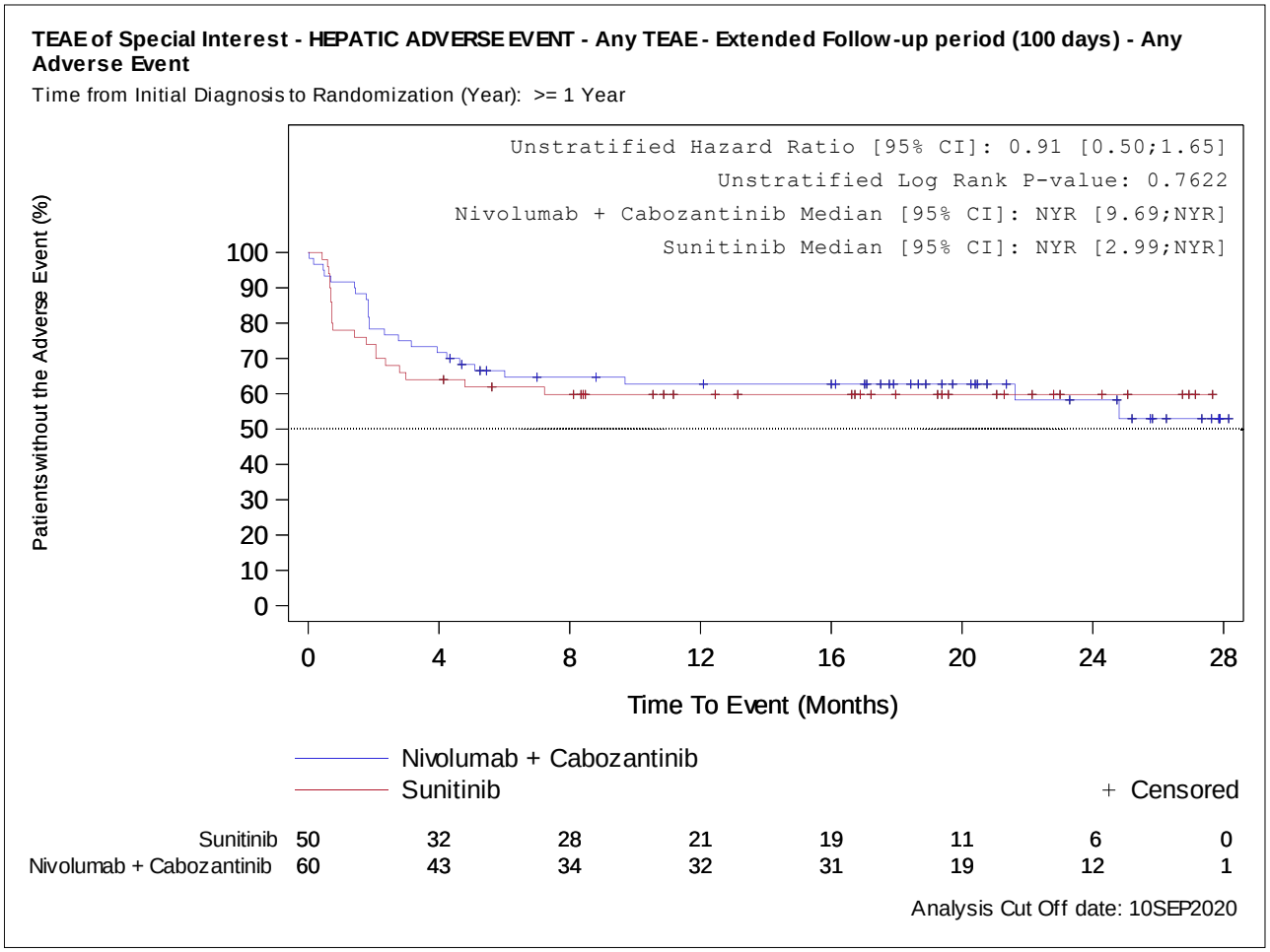

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:04:38

FIGURE 3.30.2.15: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



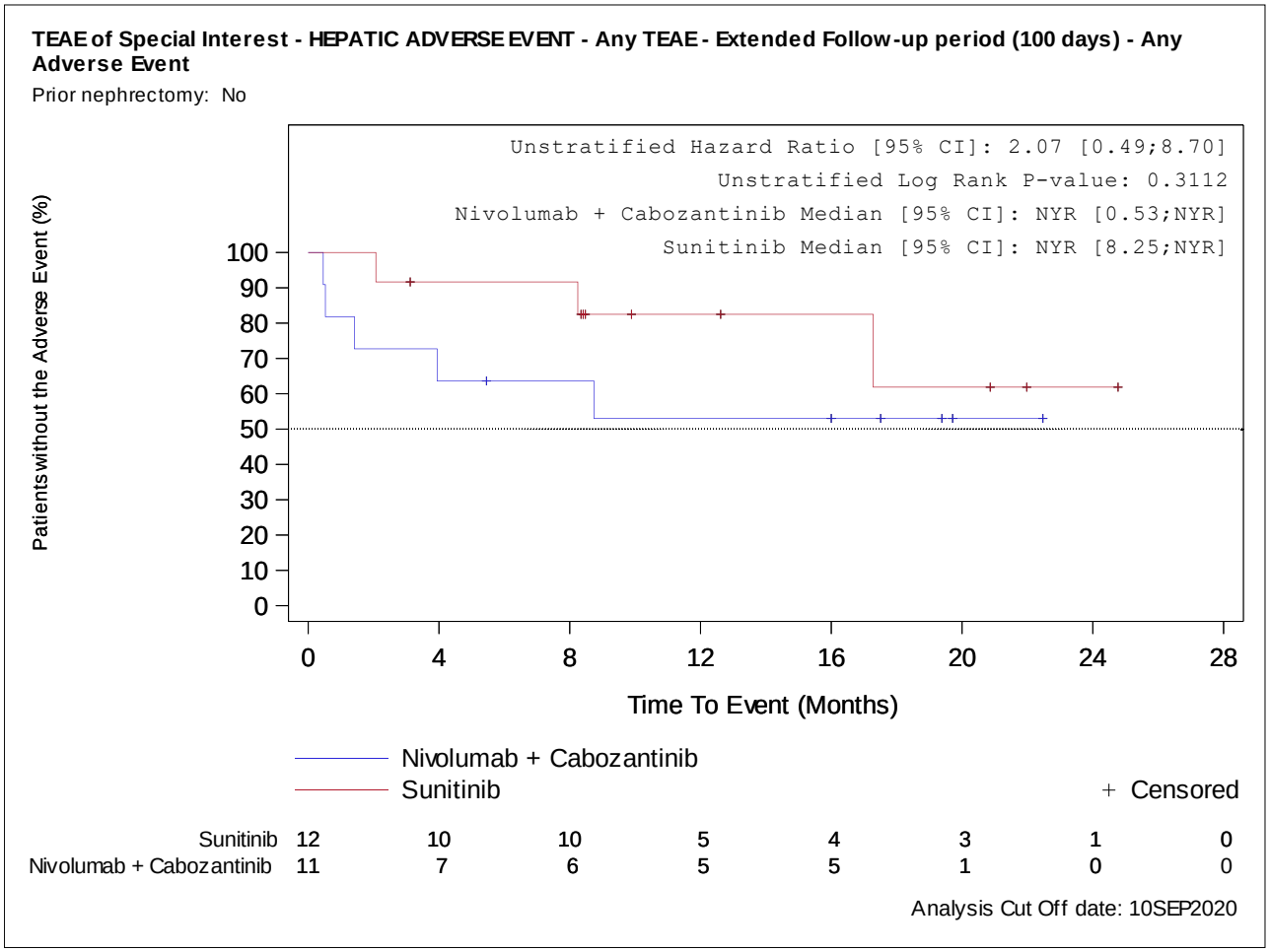

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:04:56

FIGURE 3.30.2.16: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



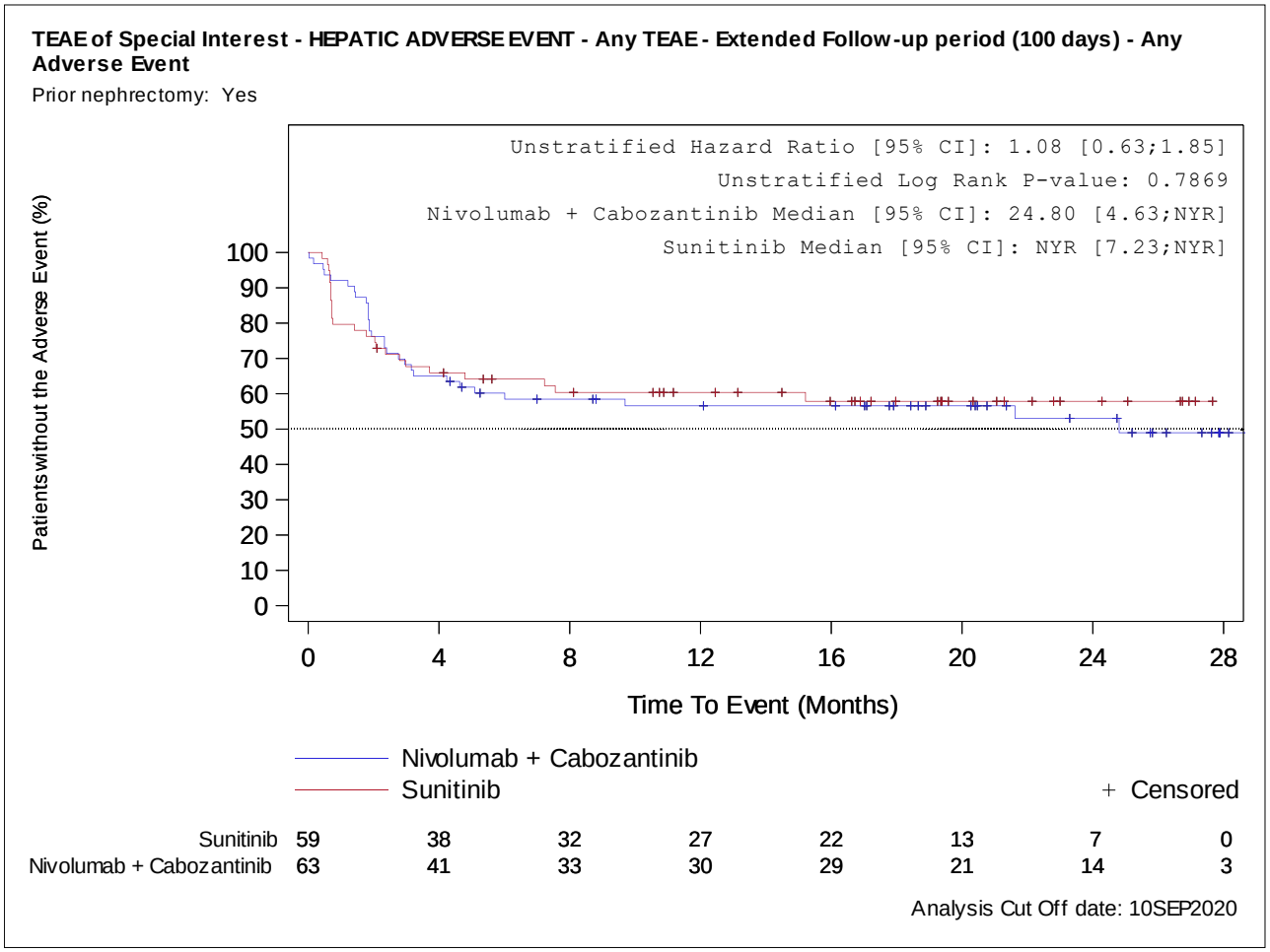

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:05:01

FIGURE 3.30.2.17: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



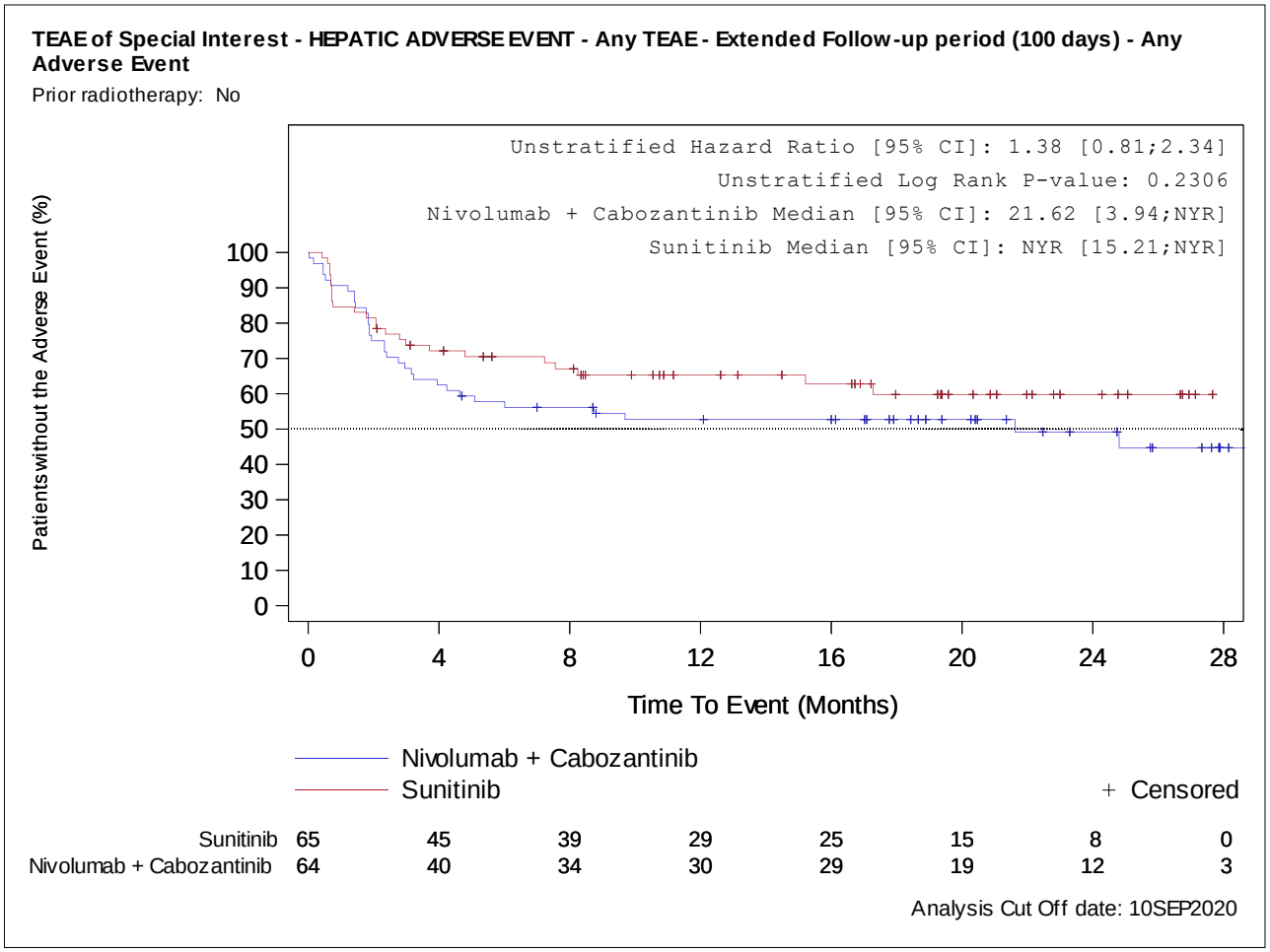

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:05:55

FIGURE 3.30.2.18: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



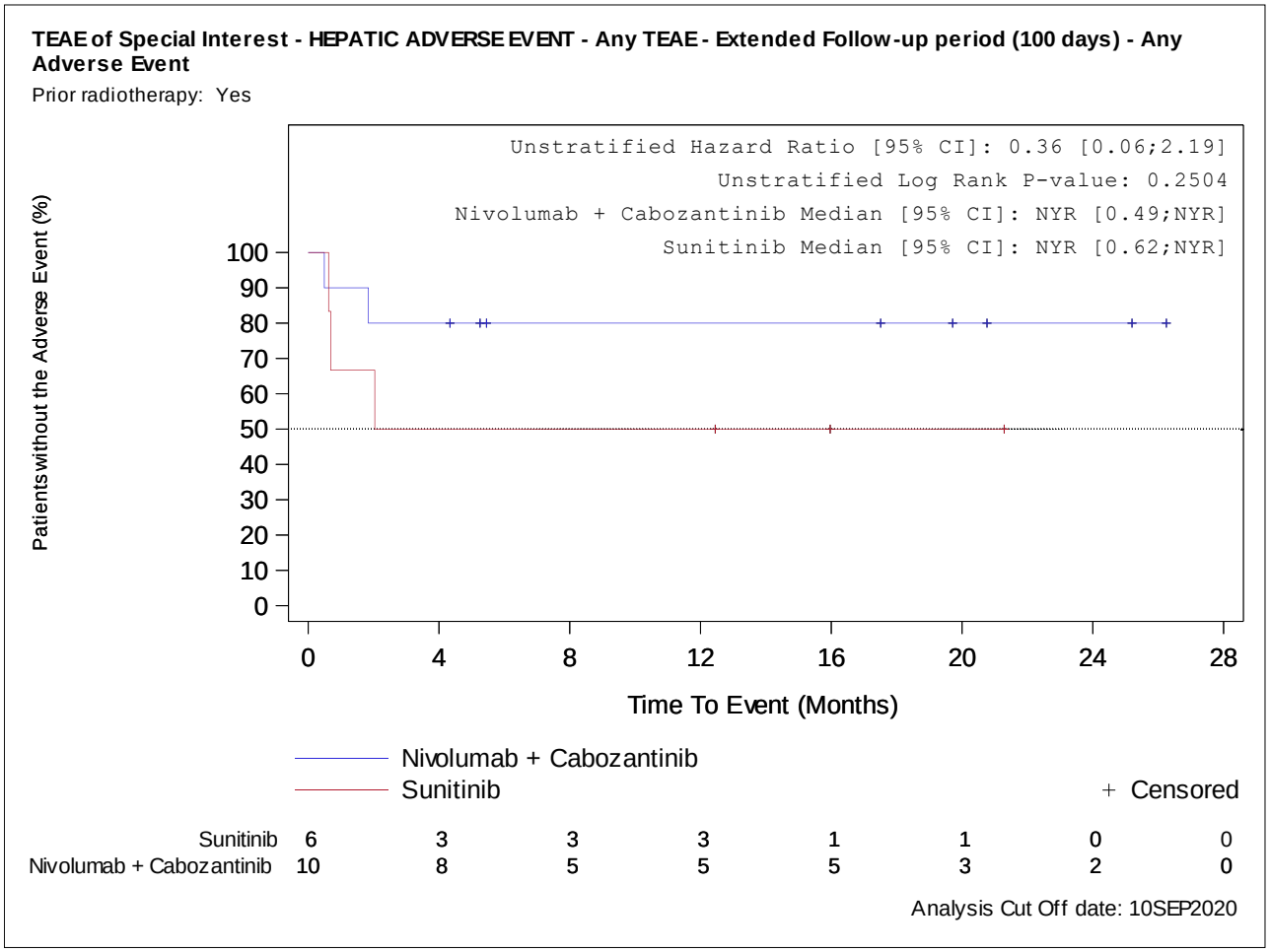

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:06:01

FIGURE 3.30.2.19: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



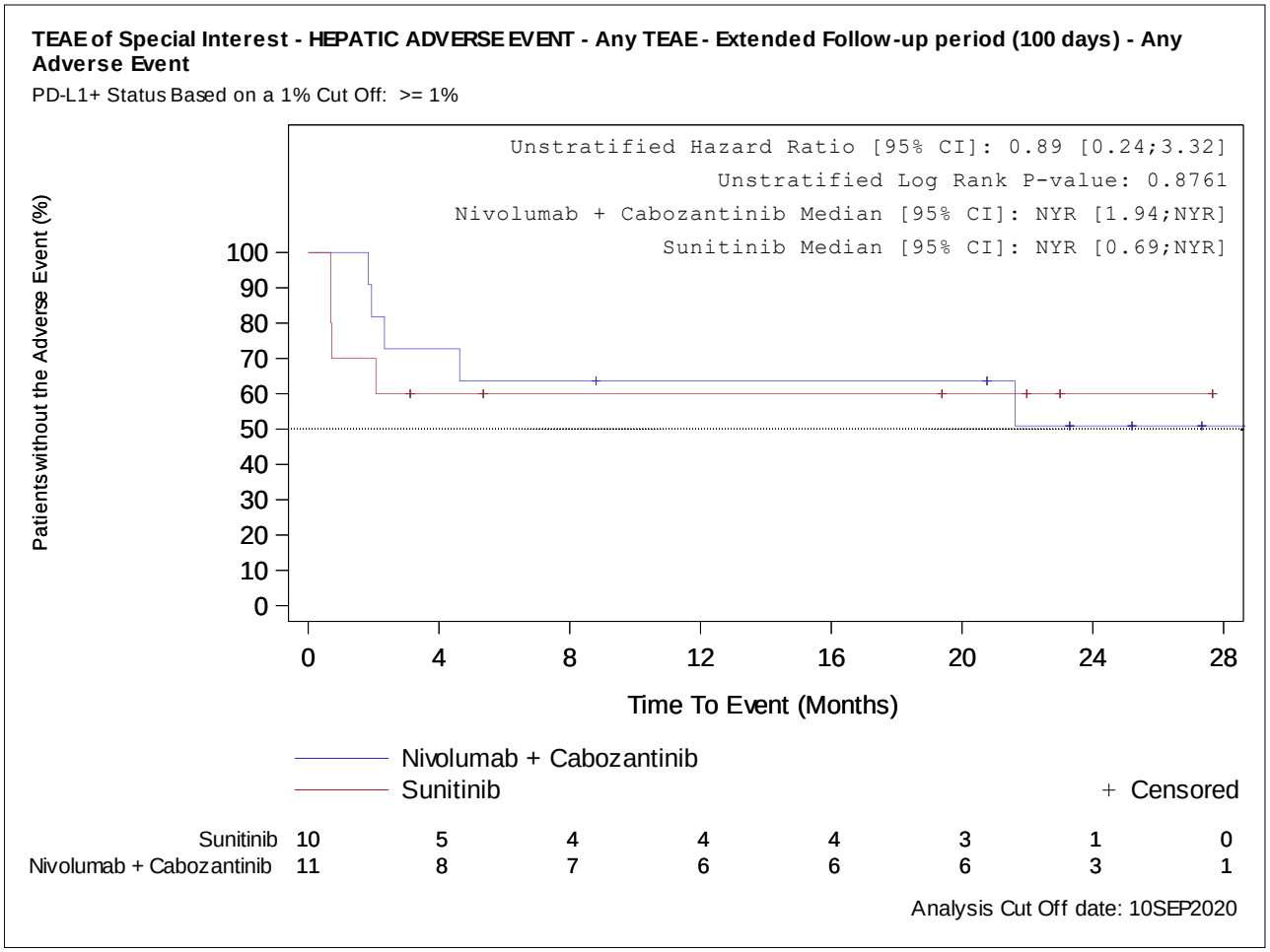

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:06:06

FIGURE 3.30.2.20: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



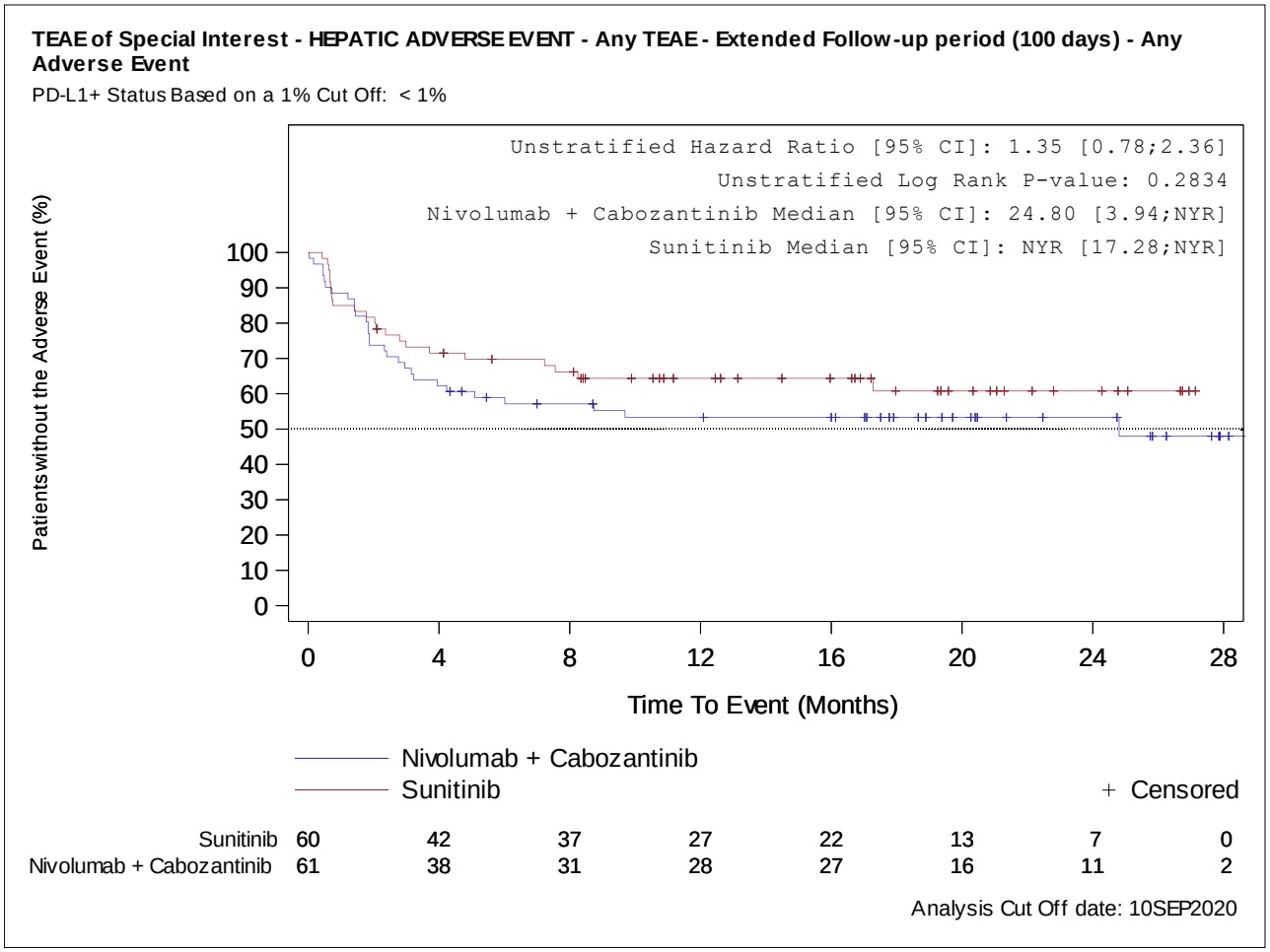

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:06:12

FIGURE 3.30.2.21: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



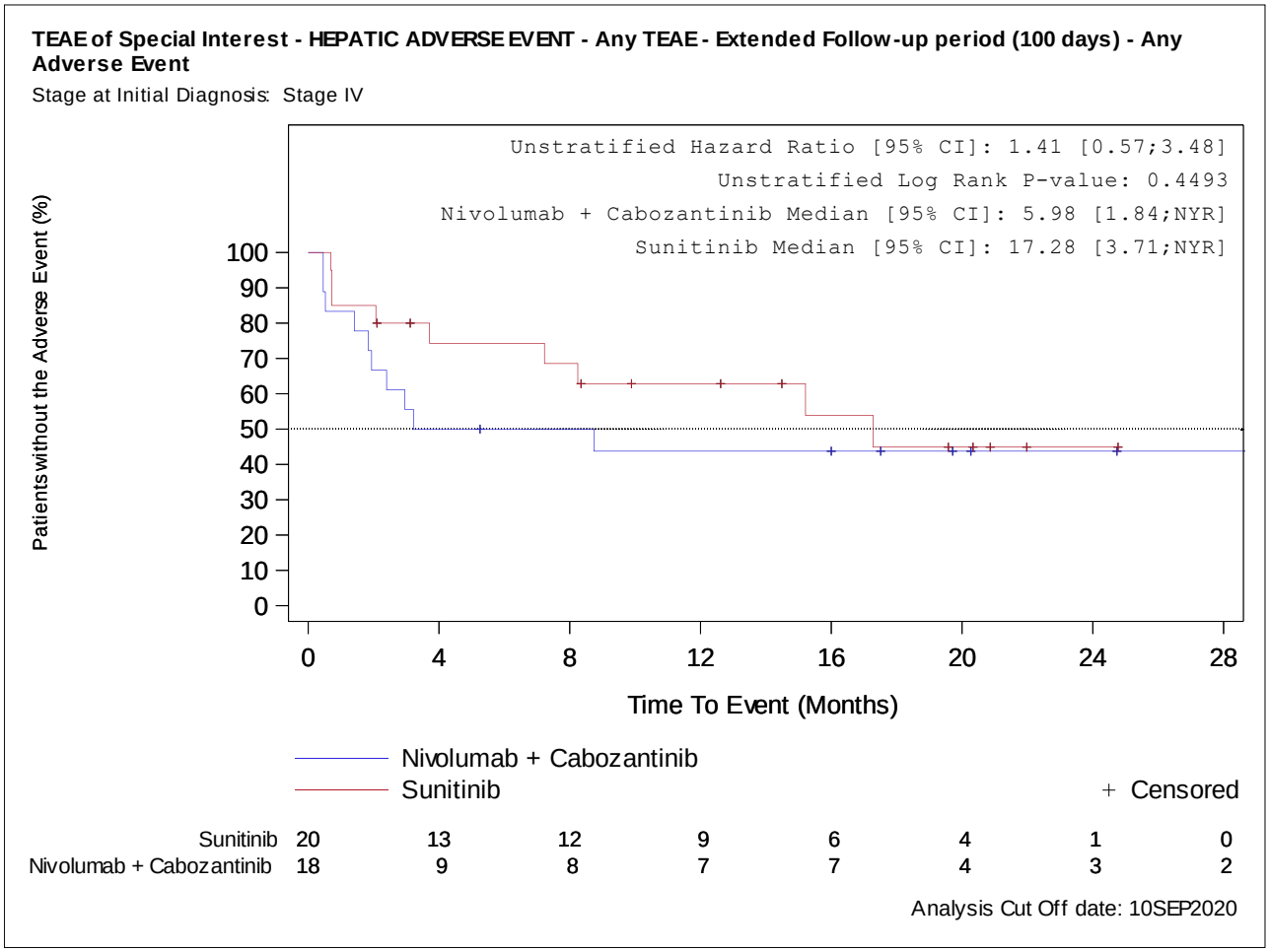

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:06:18

FIGURE 3.30.2.22: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



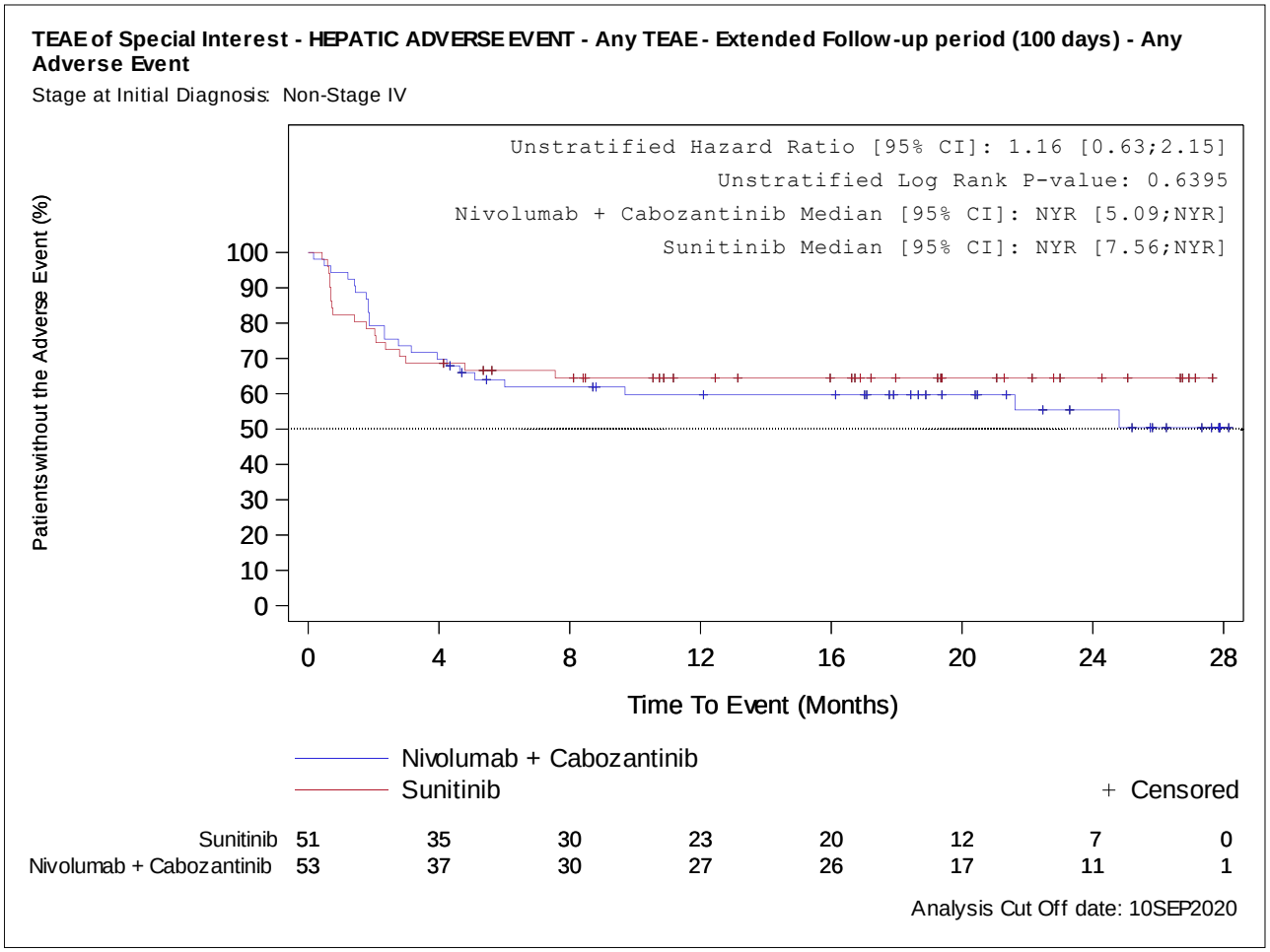

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:06:24

FIGURE 3.30.2.23: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



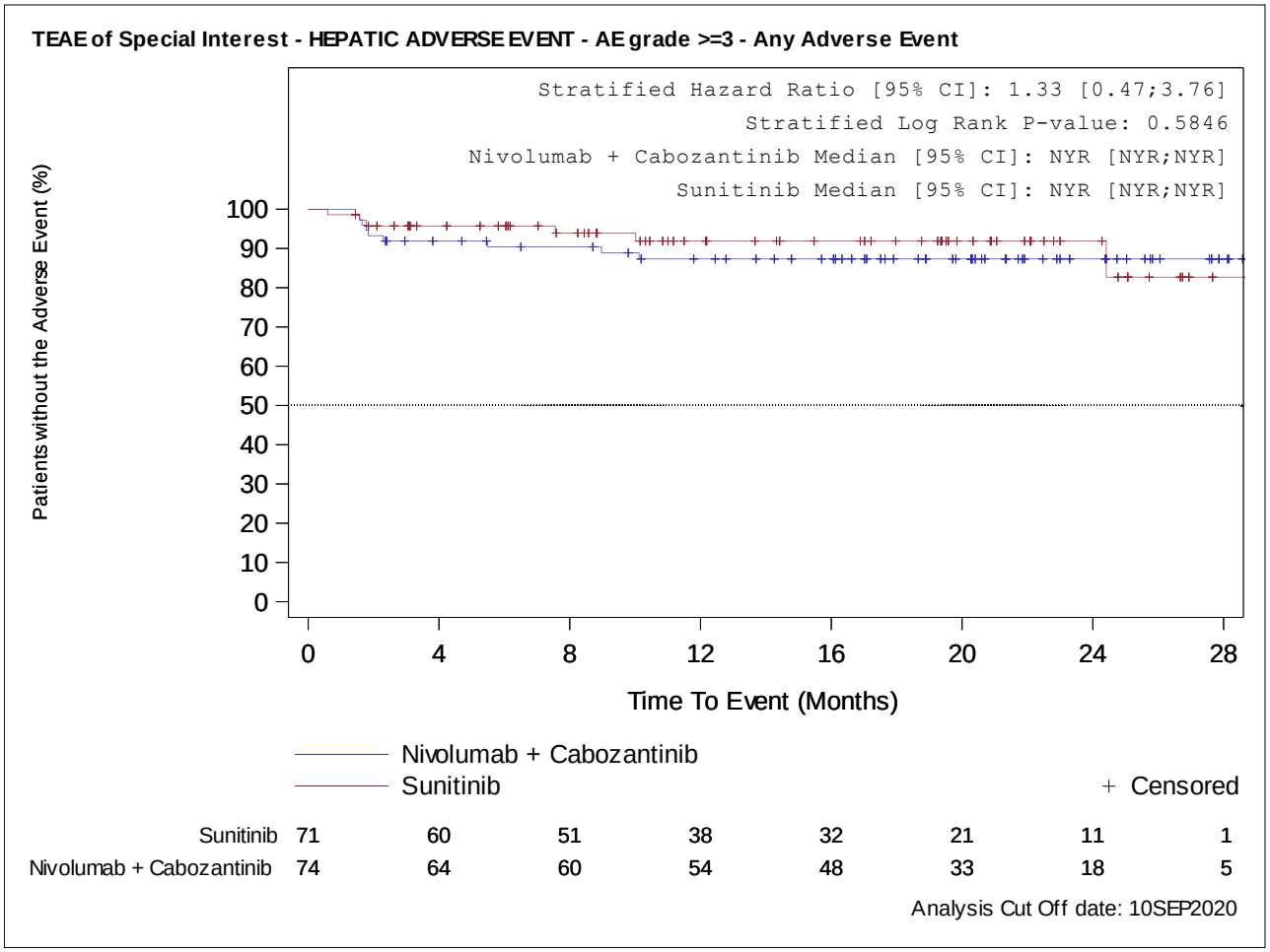

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:06:54

FIGURE 3.30.2.24: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



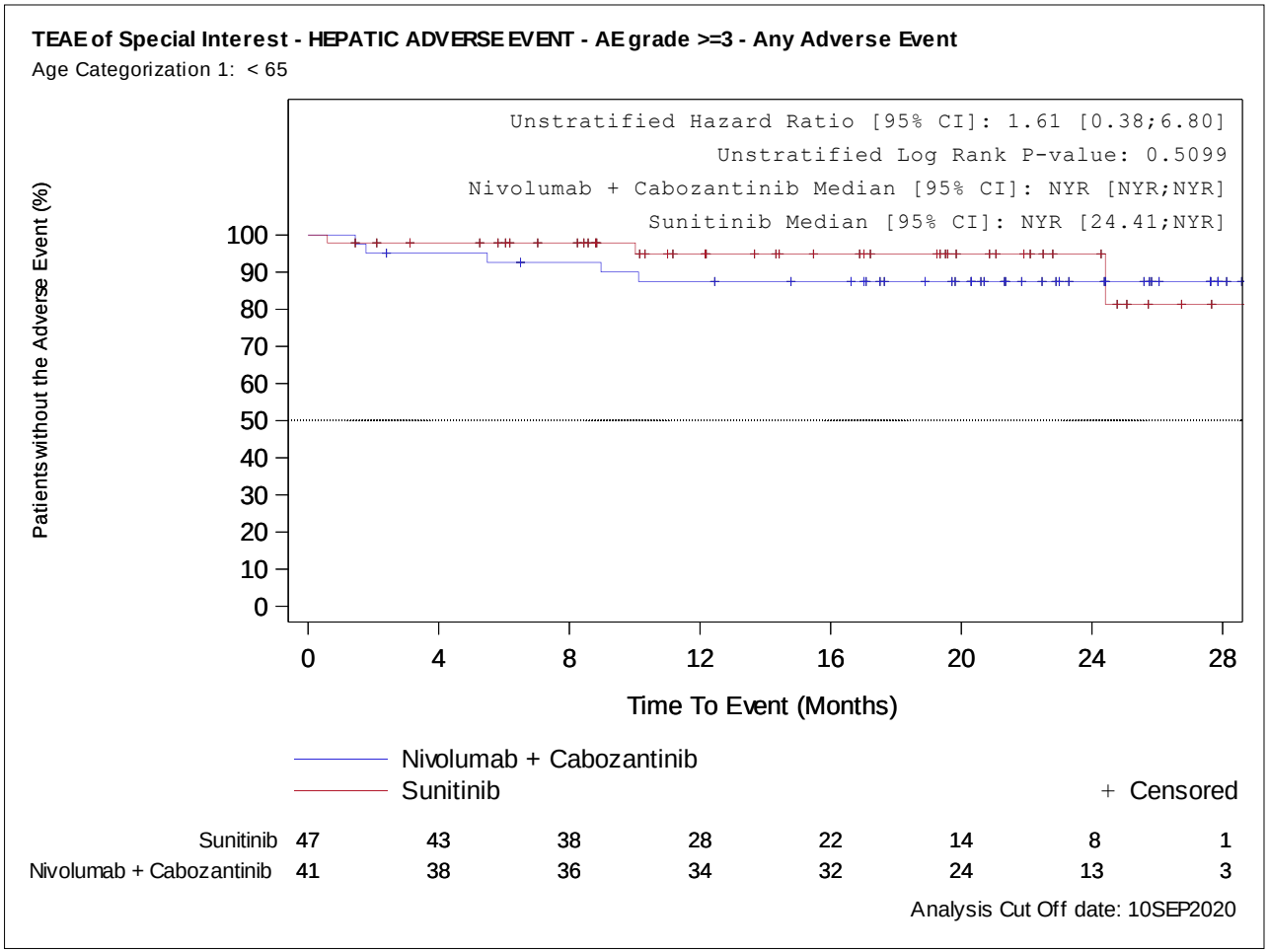

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:07:00

FIGURE 3.31.1: TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



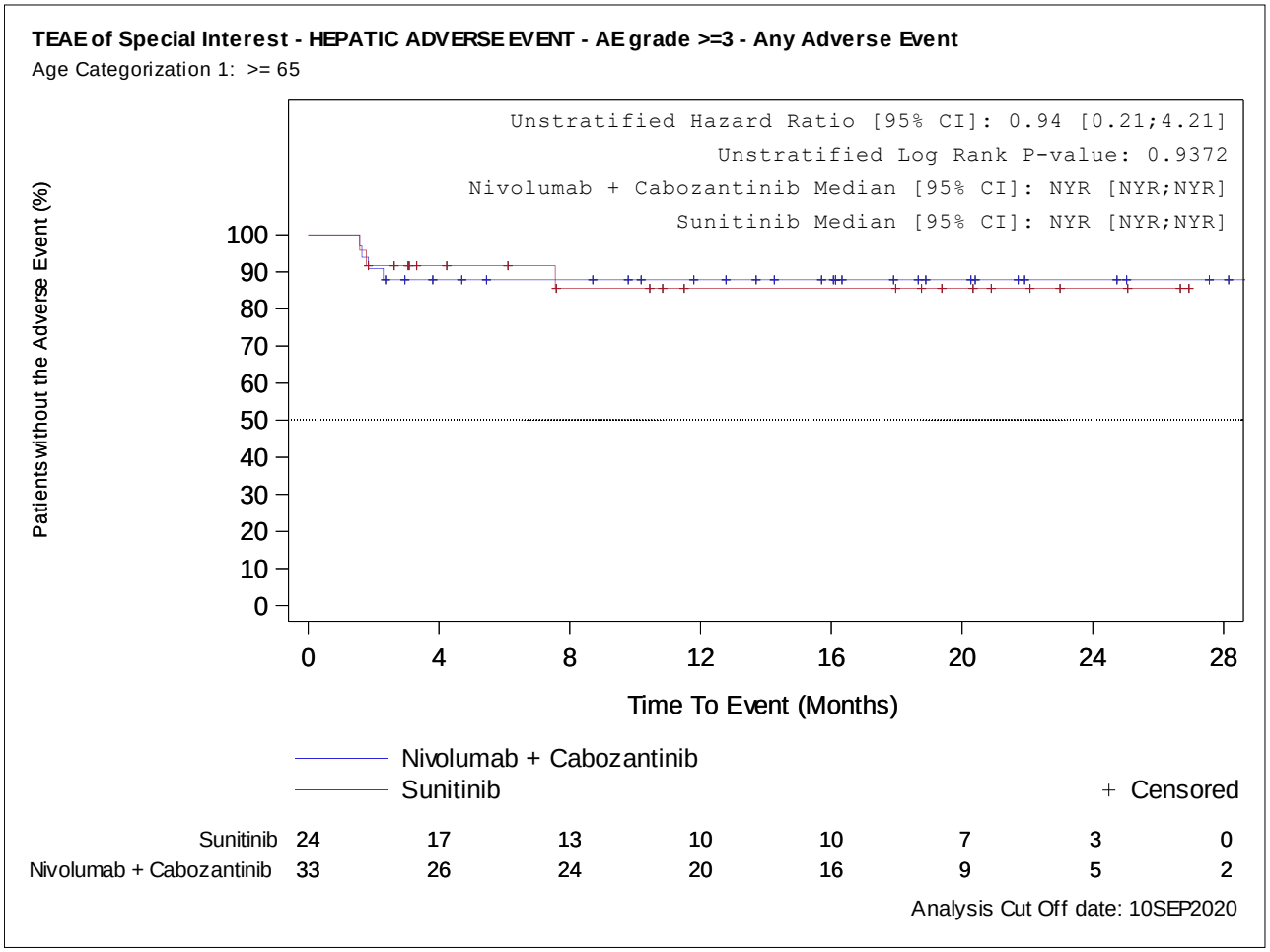

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:10:14

FIGURE 3.31.2.1: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



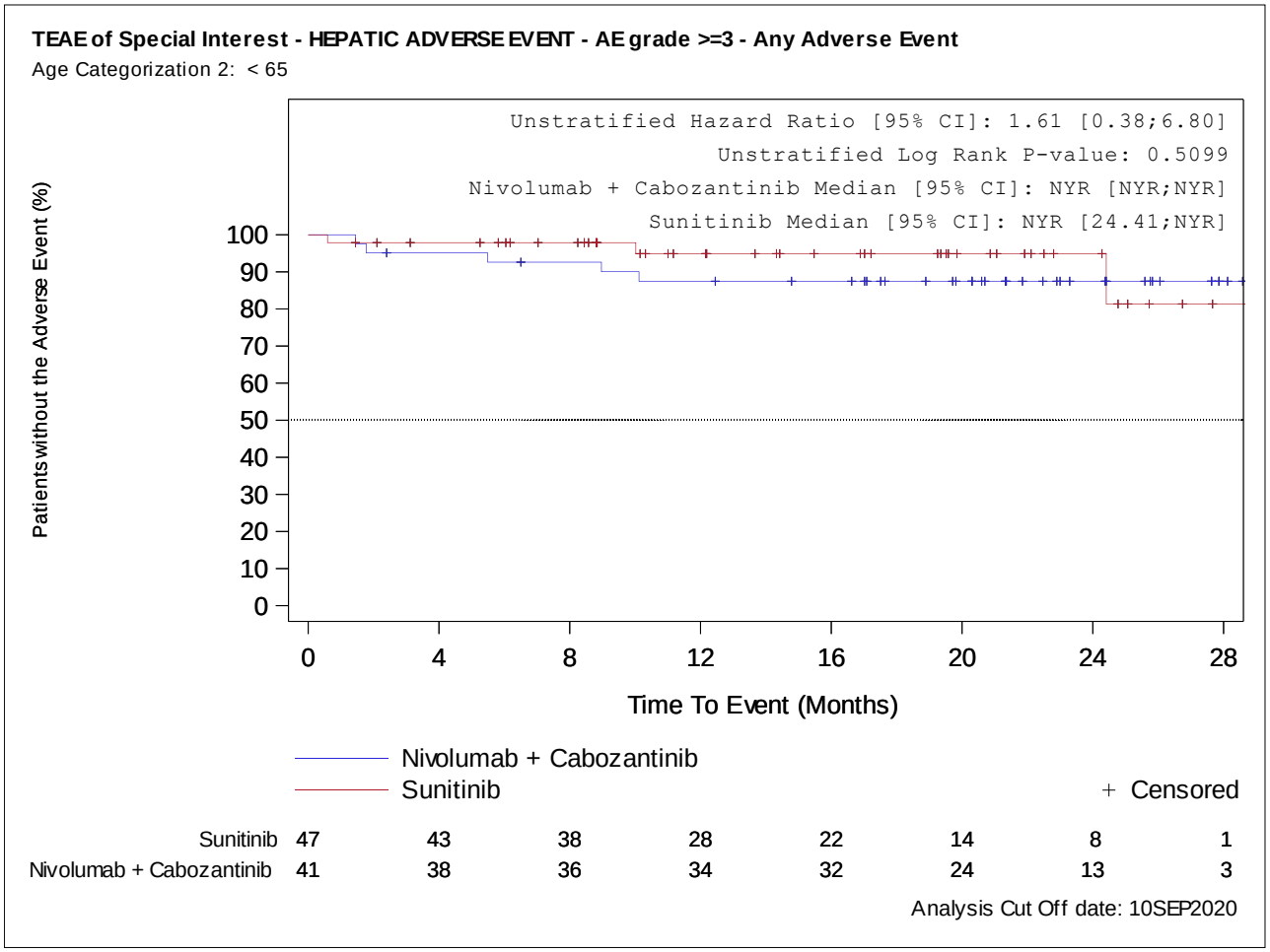

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:10:17

FIGURE 3.31.2.2: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



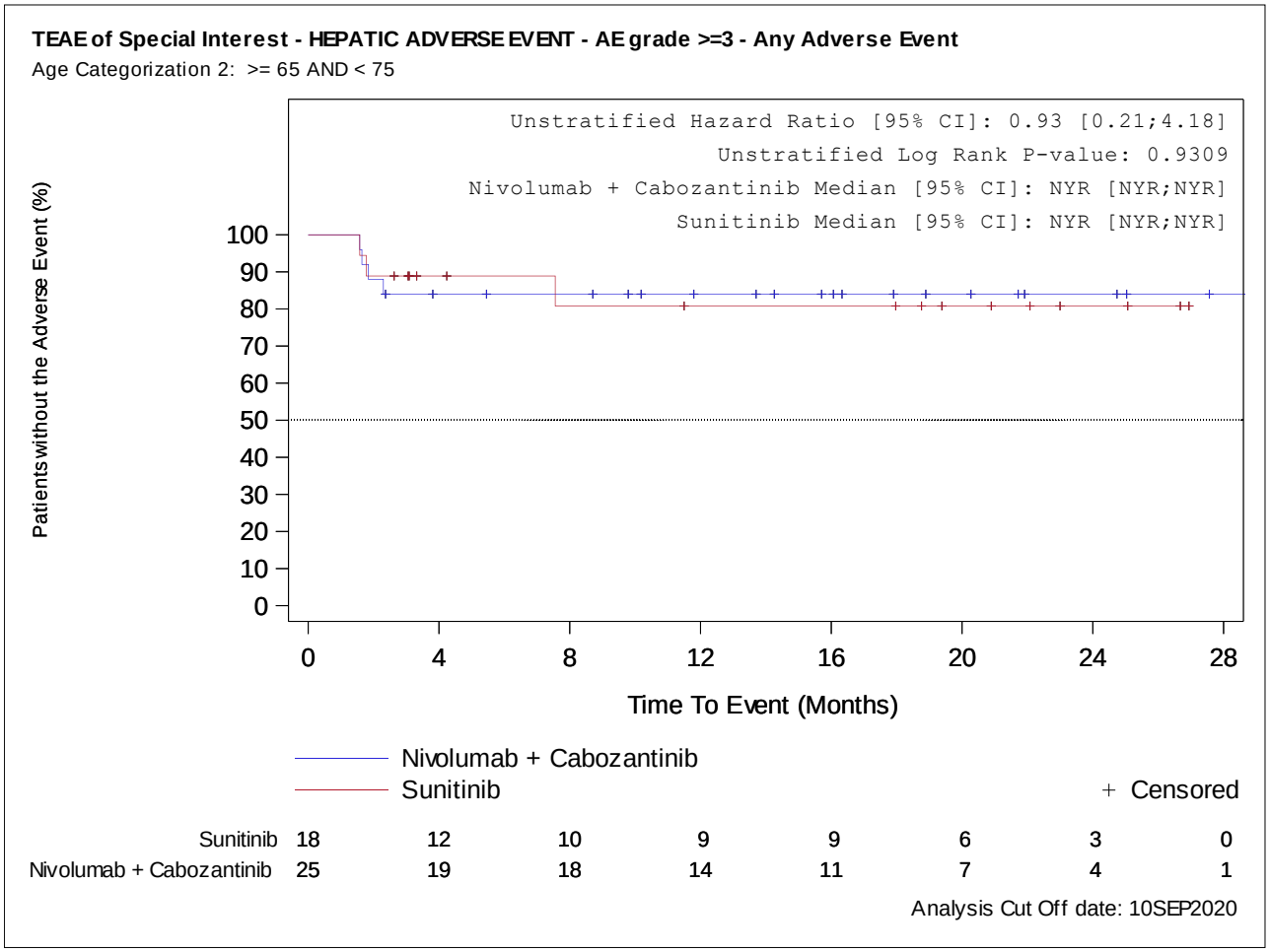

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:10:22

FIGURE 3.31.2.3: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



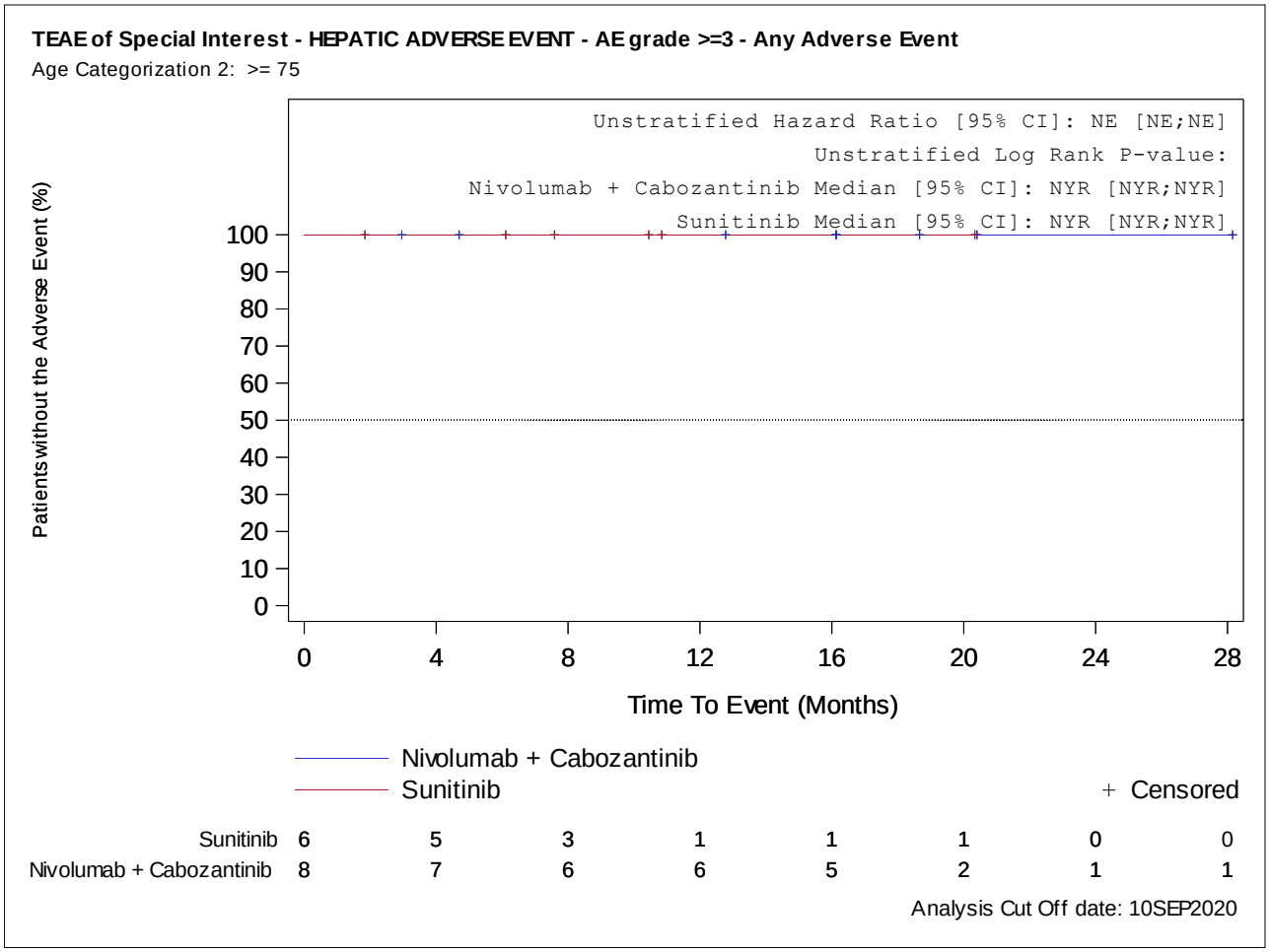

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:10:29

FIGURE 3.31.2.4: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



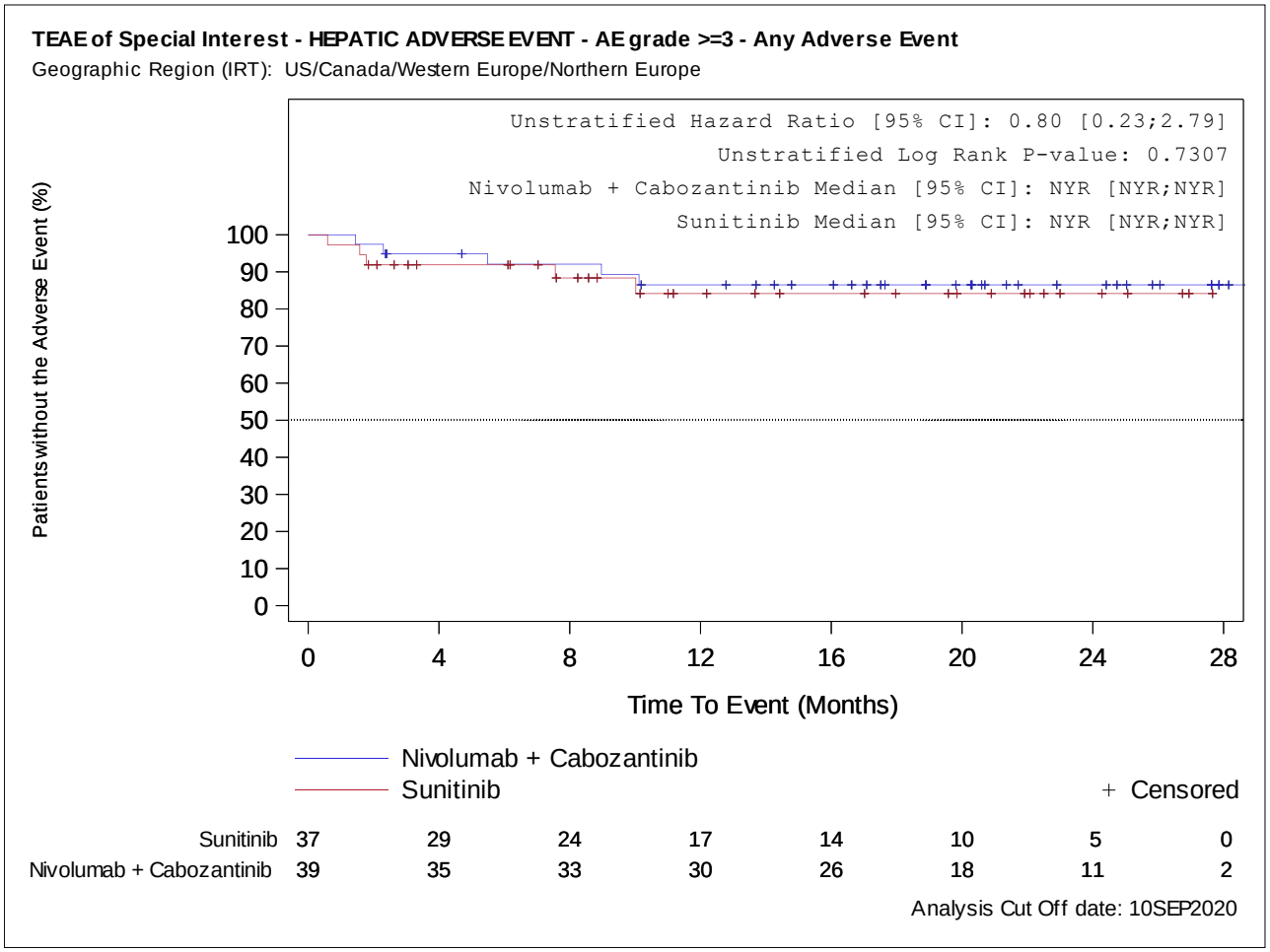

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:10:34

FIGURE 3.31.2.5: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



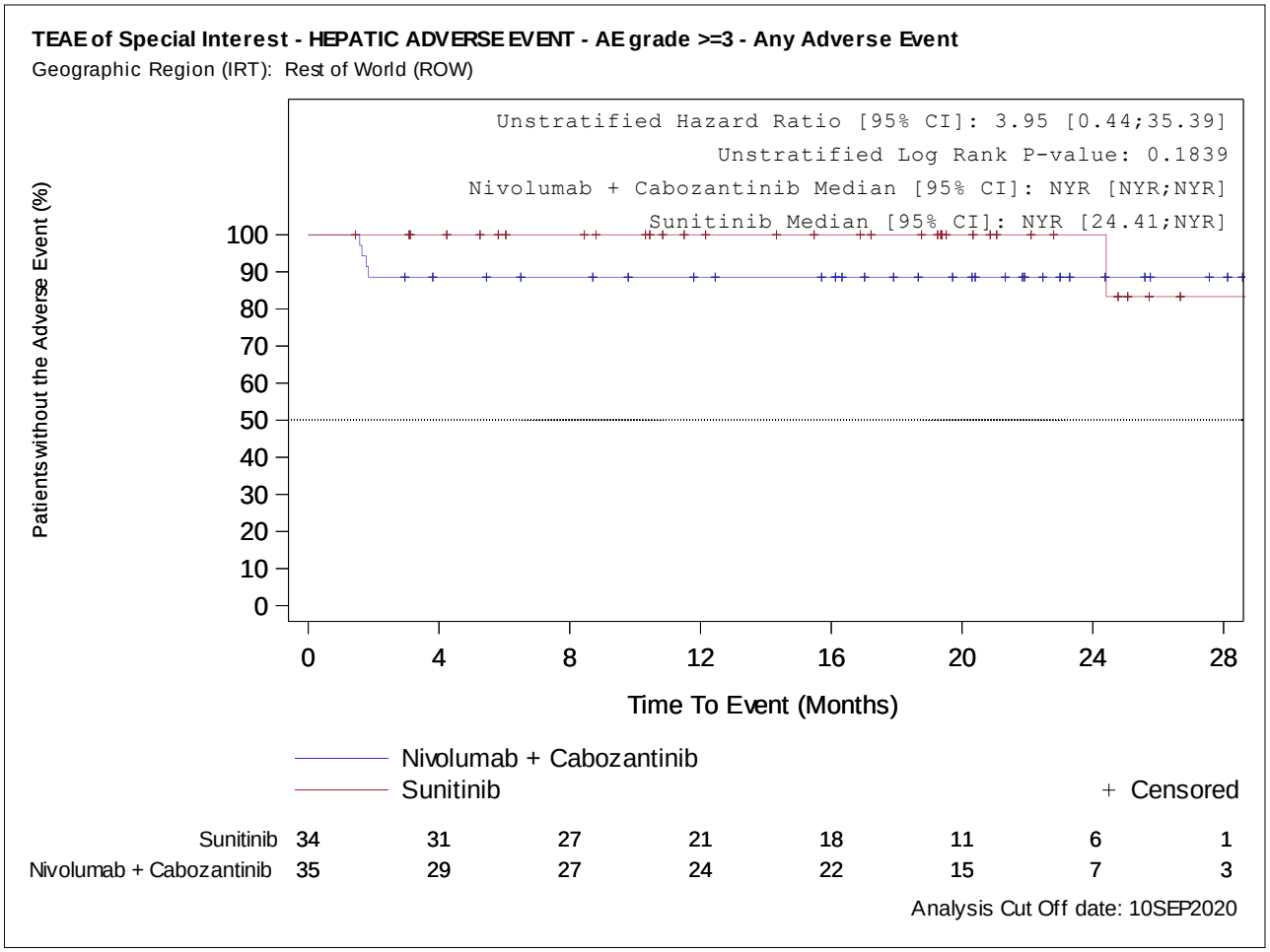

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:10:40

FIGURE 3.31.2.6: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



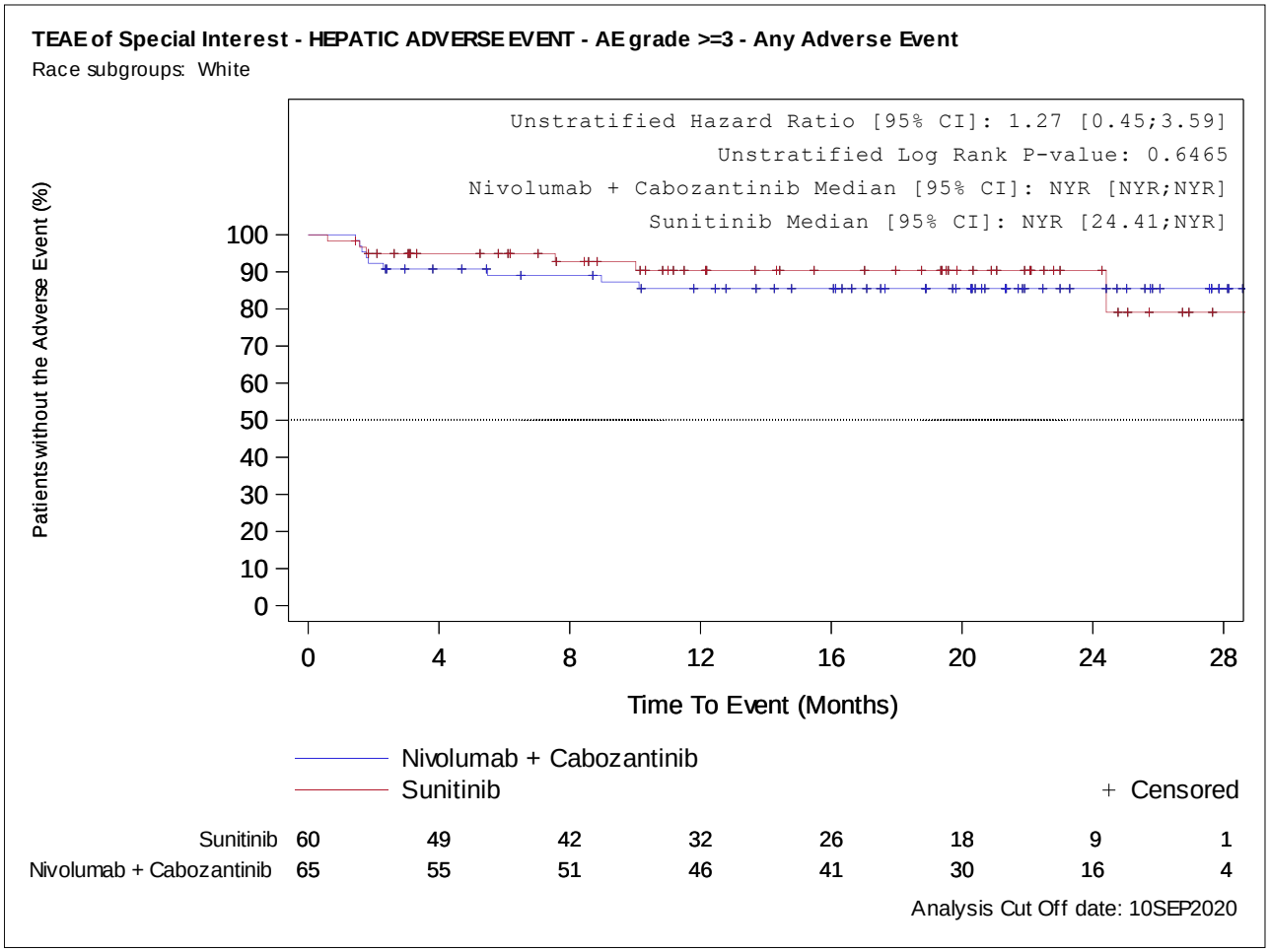

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:10:45

FIGURE 3.31.2.7: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



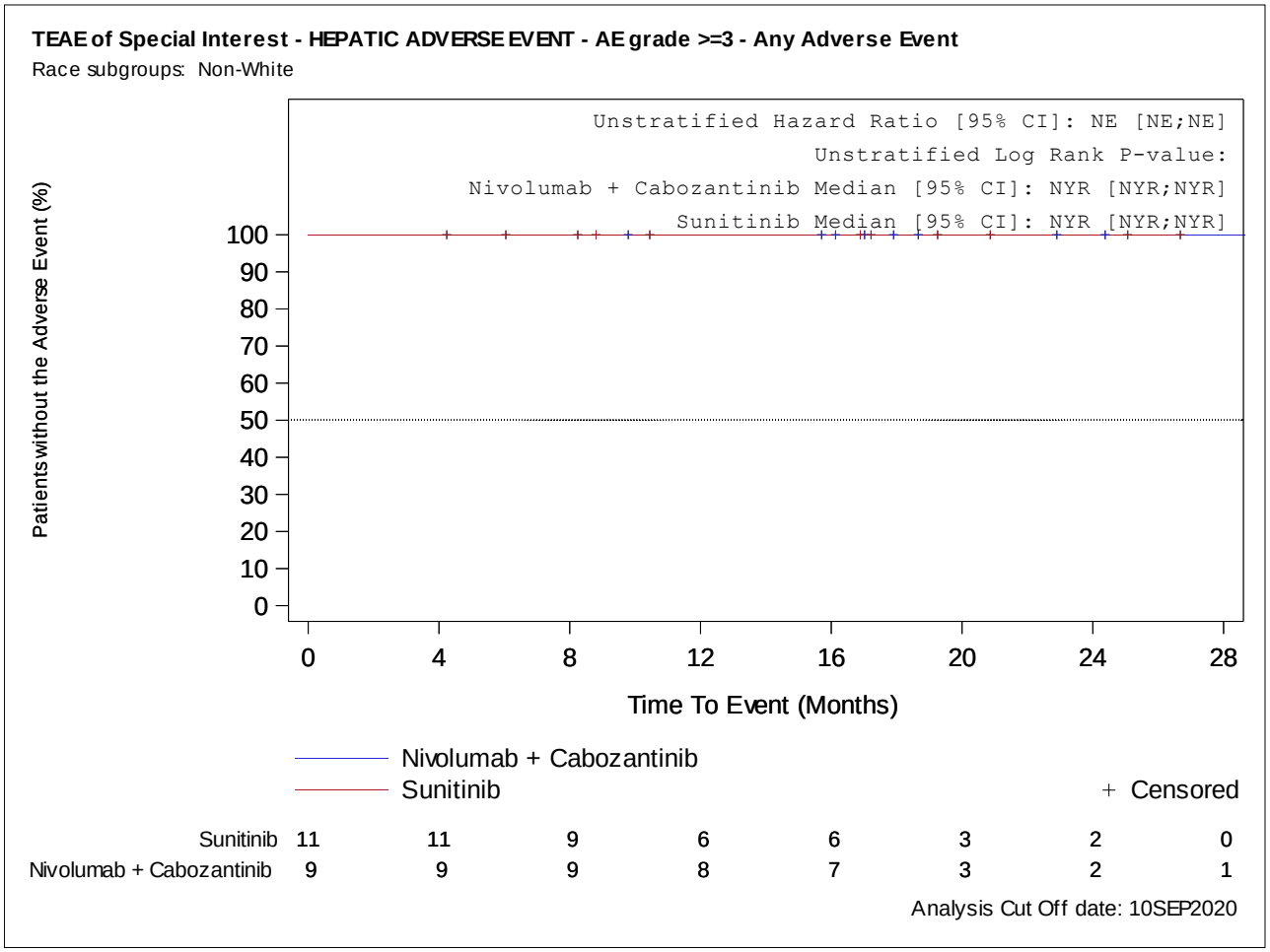

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:10:51

FIGURE 3.31.2.8: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



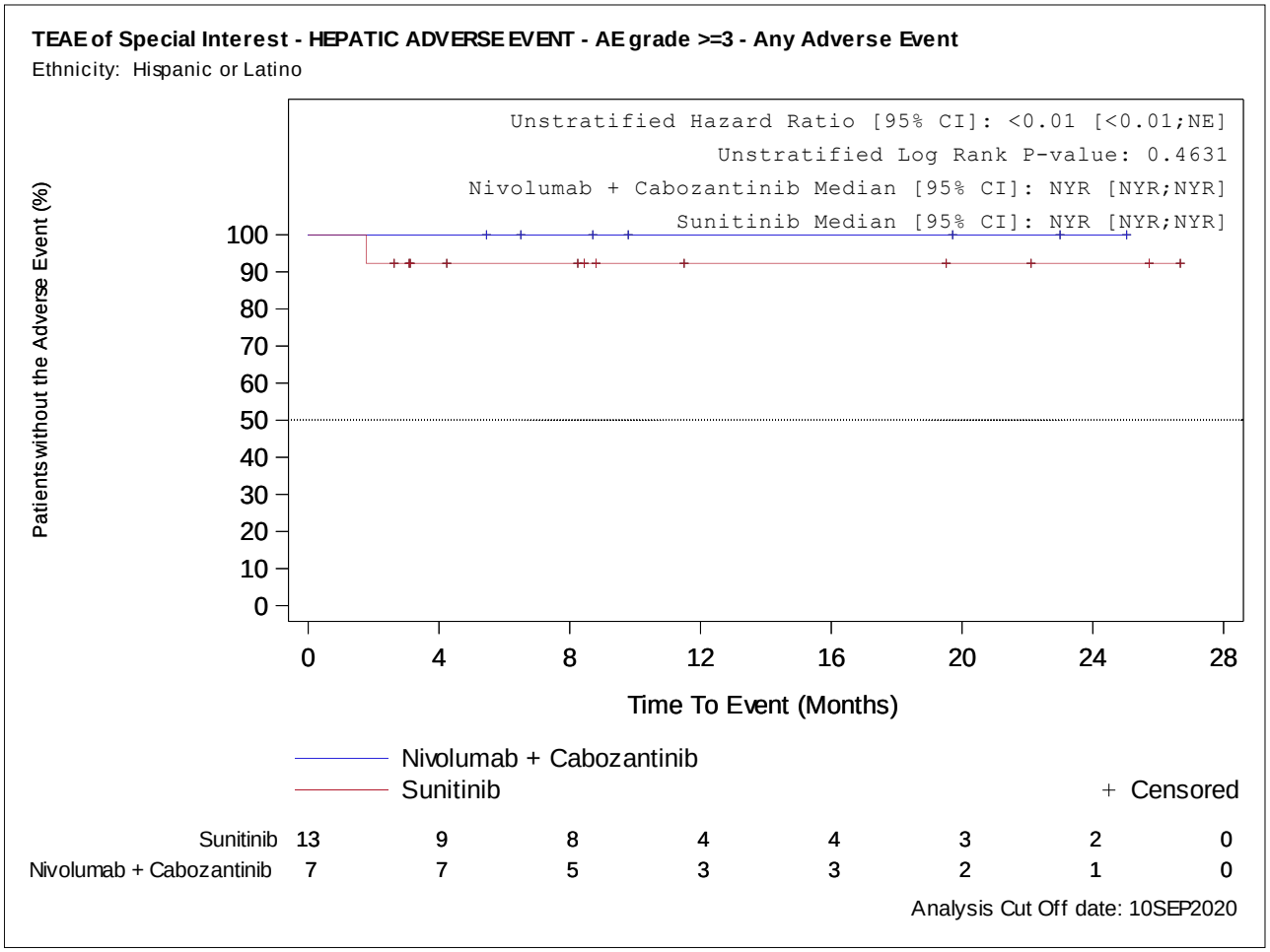

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:10:57

FIGURE 3.31.2.9: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



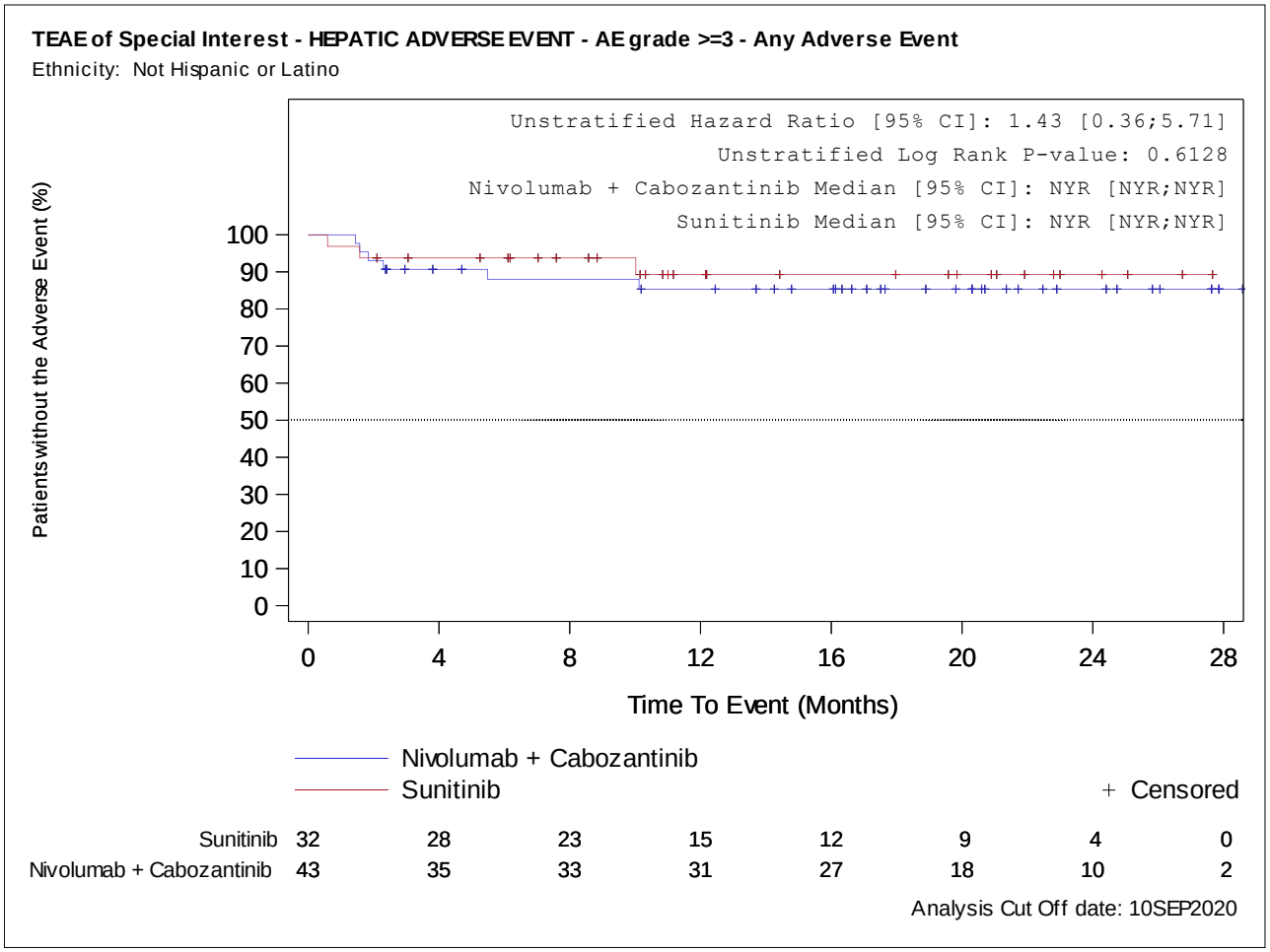

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:11:03

FIGURE 3.31.2.10: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



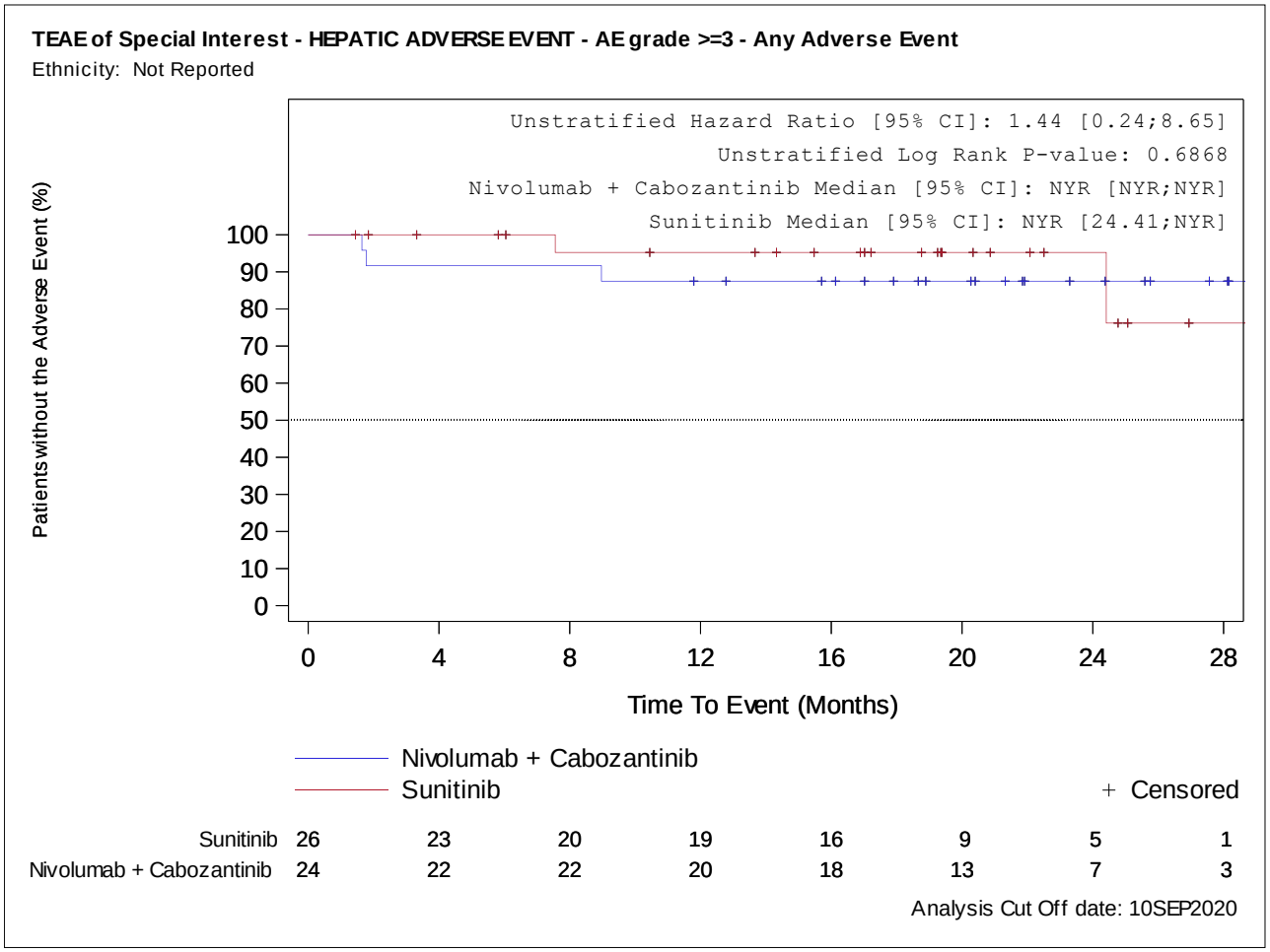

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:11:09

FIGURE 3.31.2.11: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



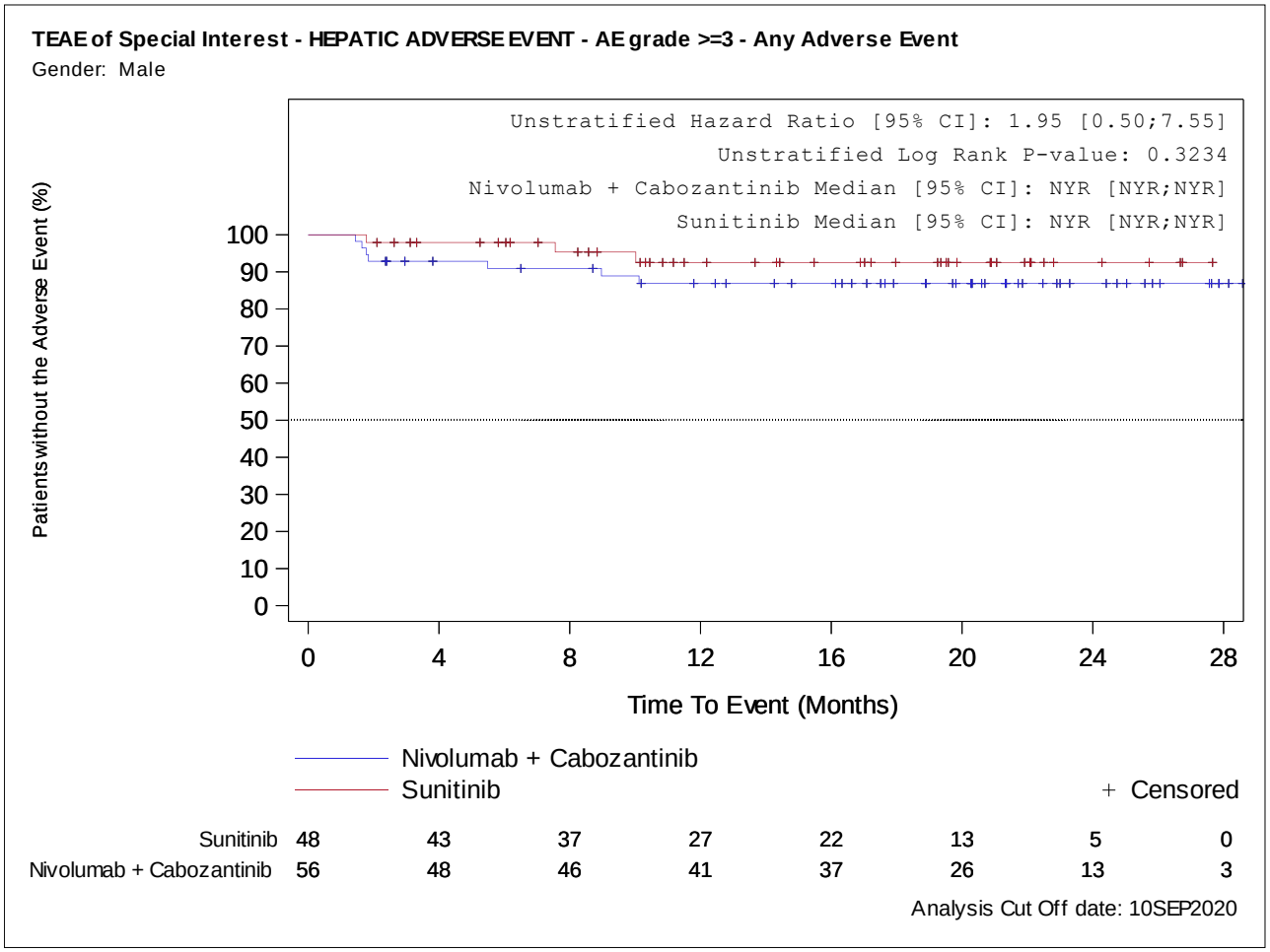

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:11:15

FIGURE 3.31.2.12: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



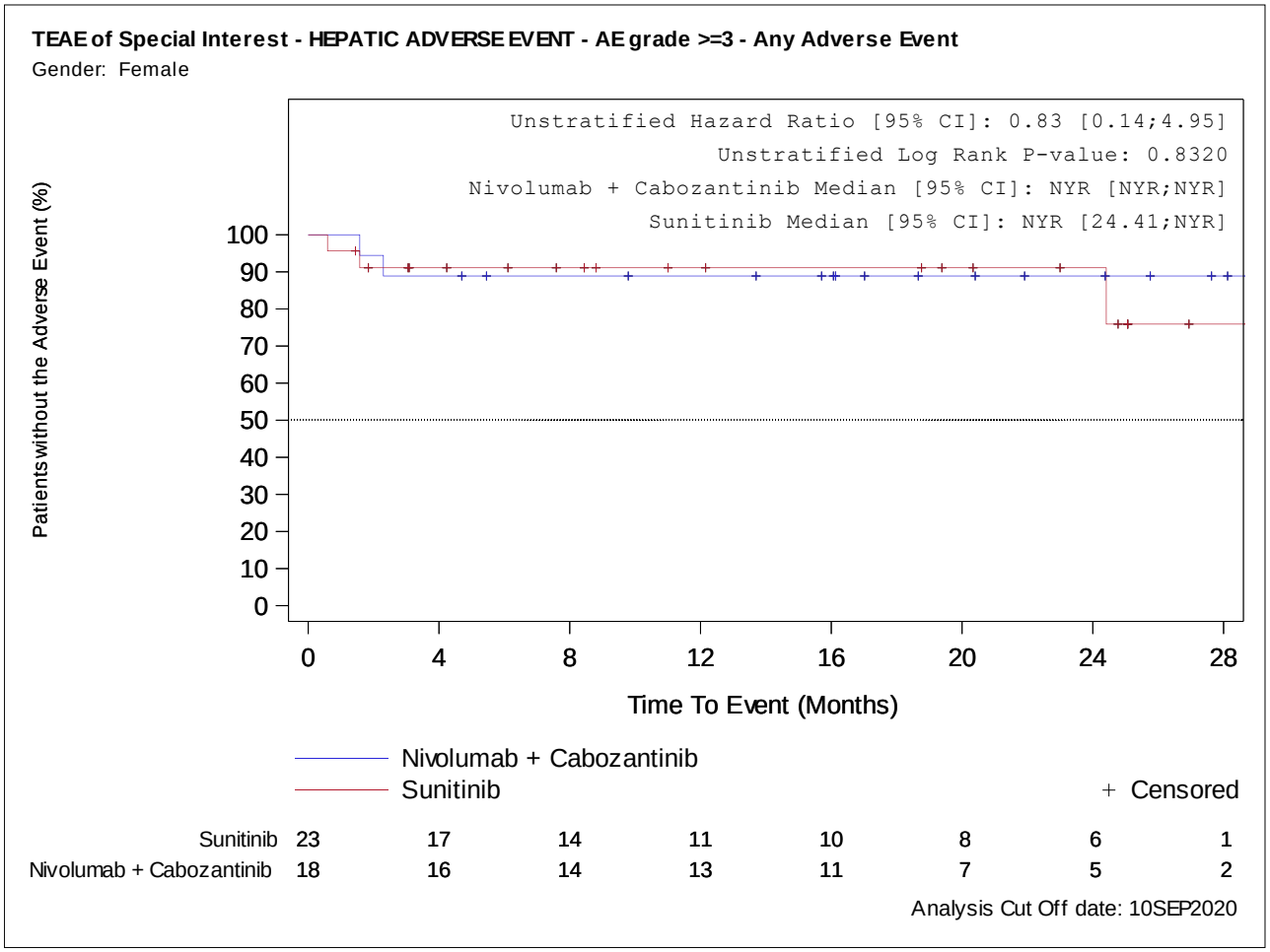

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:11:20

FIGURE 3.31.2.13: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



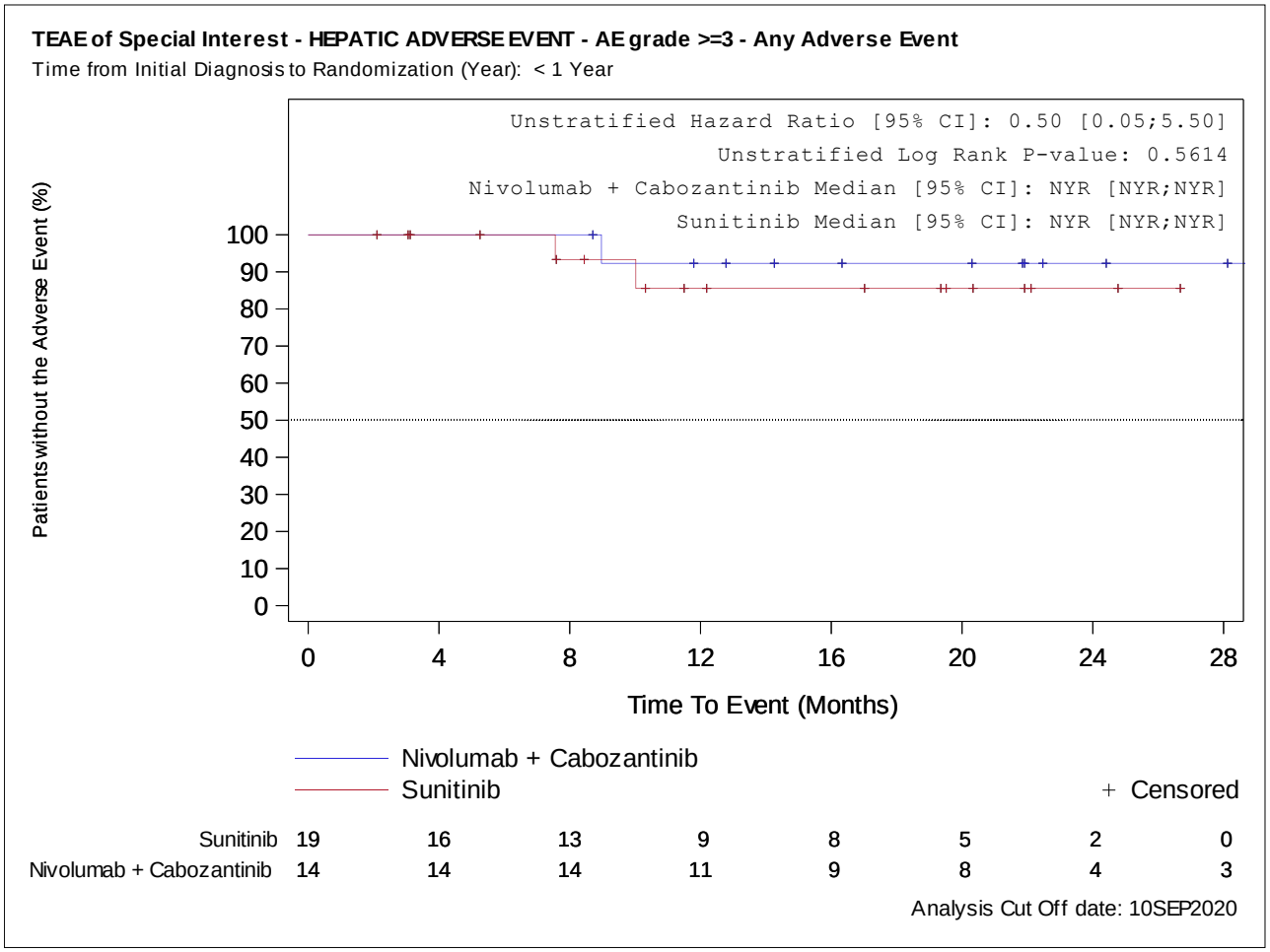

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:11:26

FIGURE 3.31.2.14: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



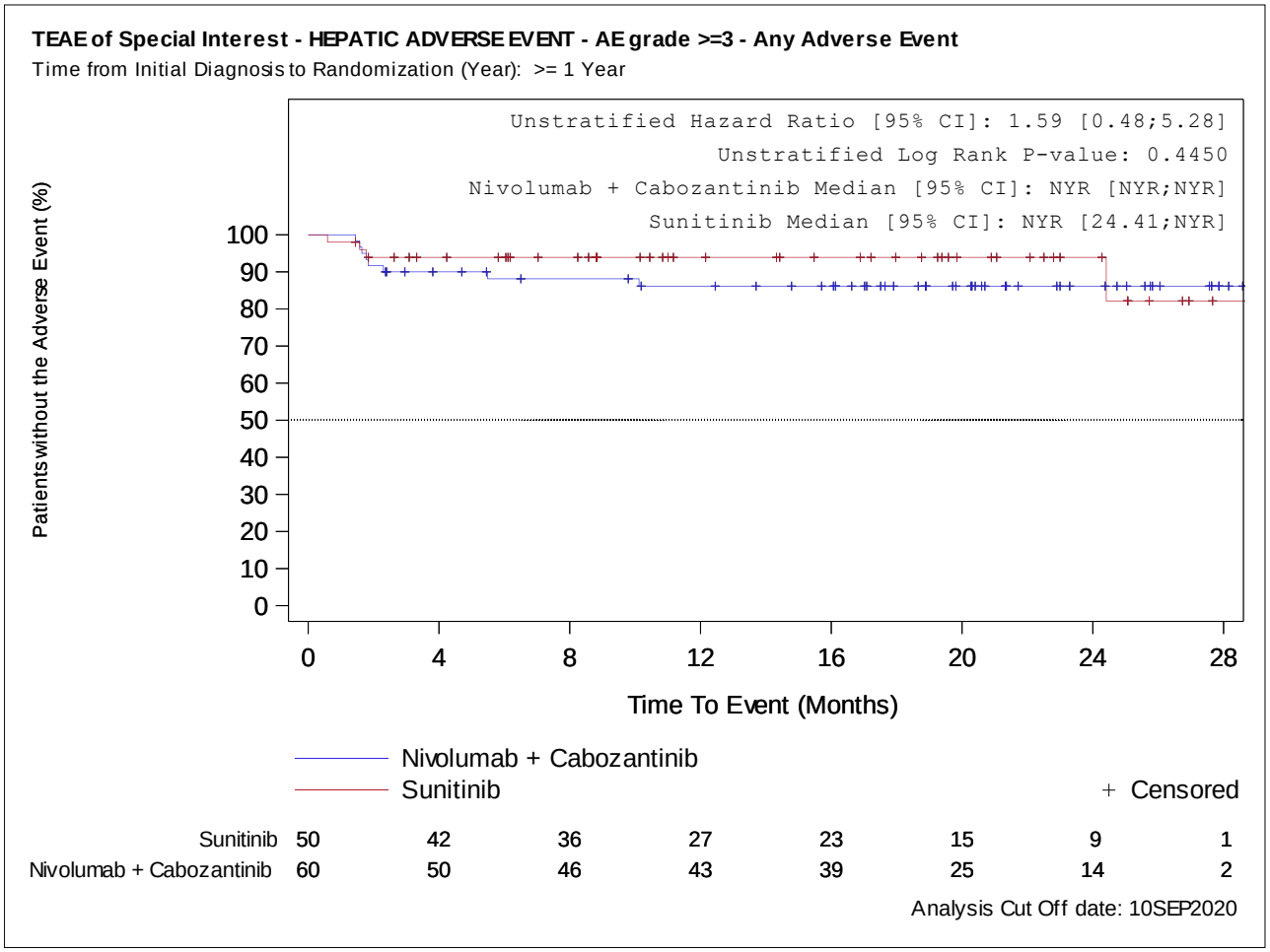

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:11:32

FIGURE 3.31.2.15: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



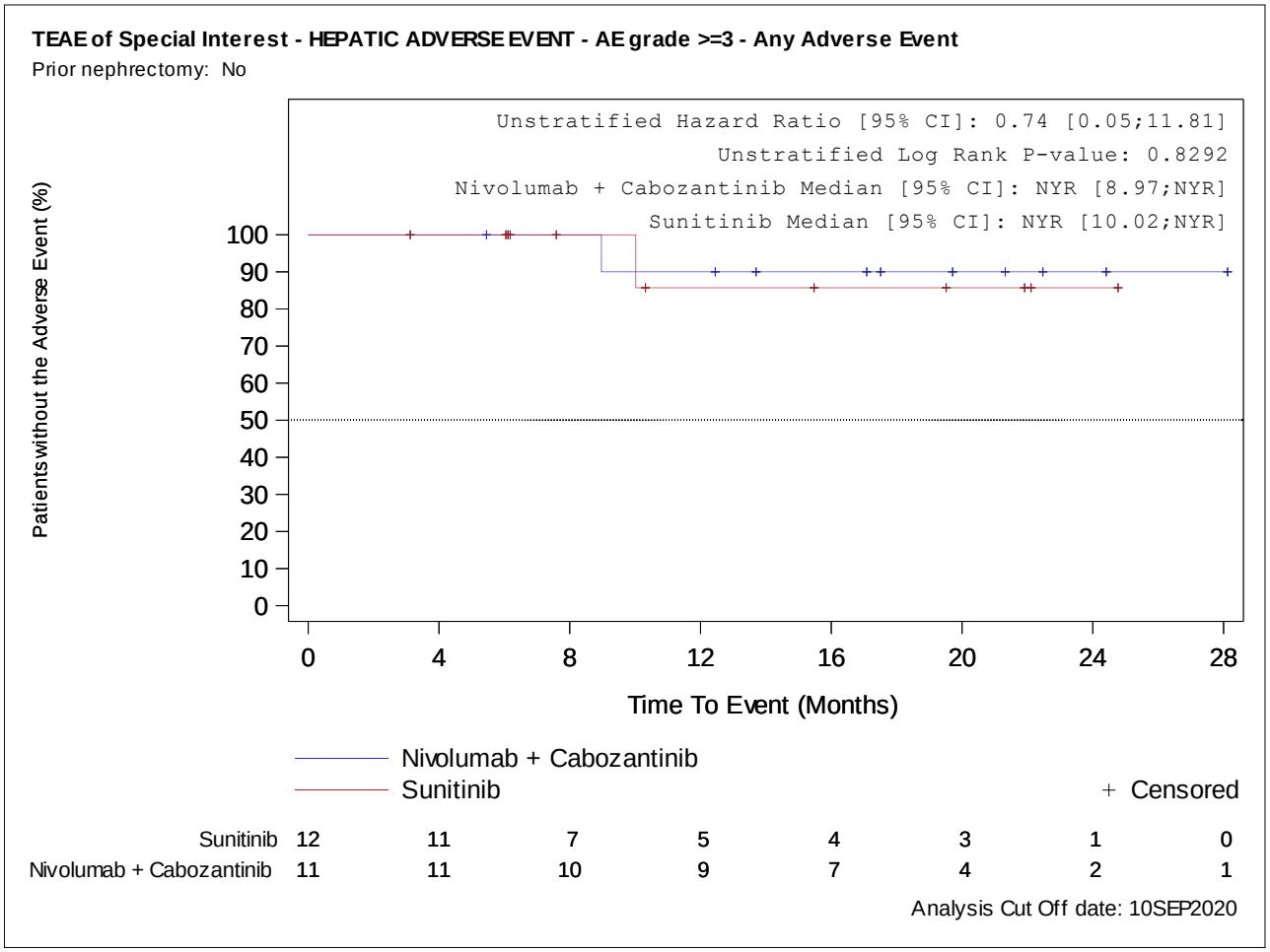

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:11:49

FIGURE 3.31.2.16: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



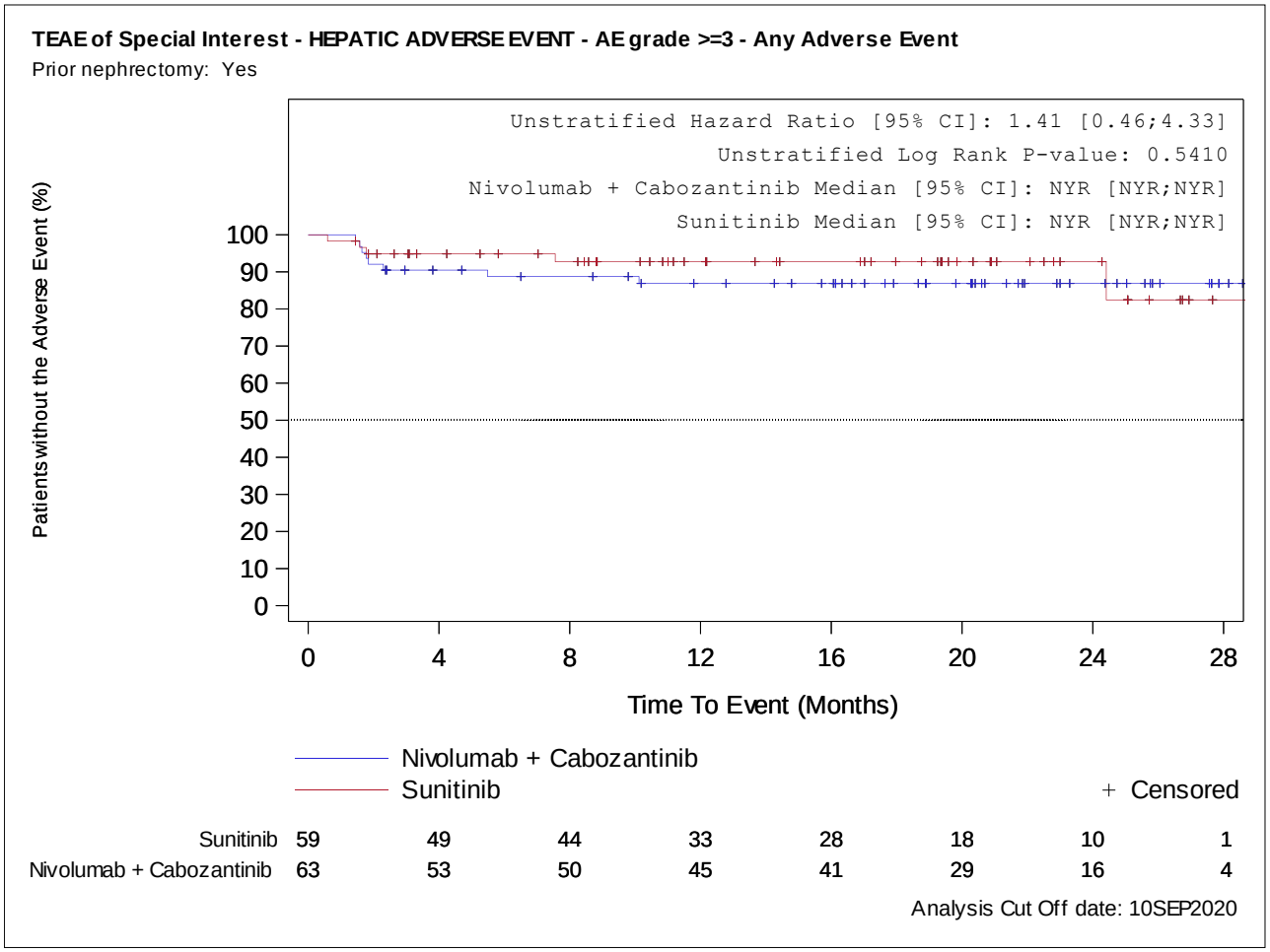

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:11:55

FIGURE 3.31.2.17: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



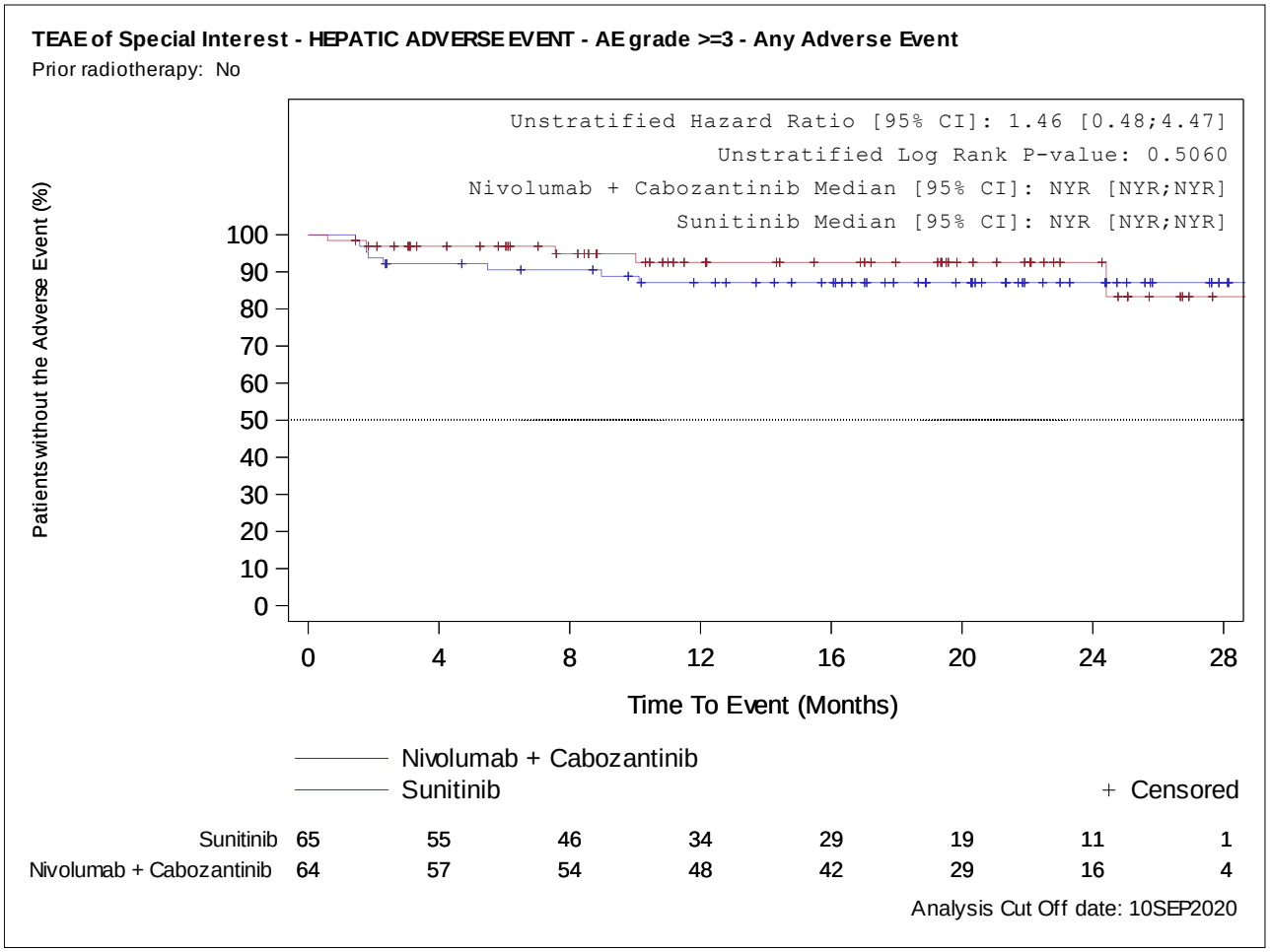

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:12:48

FIGURE 3.31.2.18: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



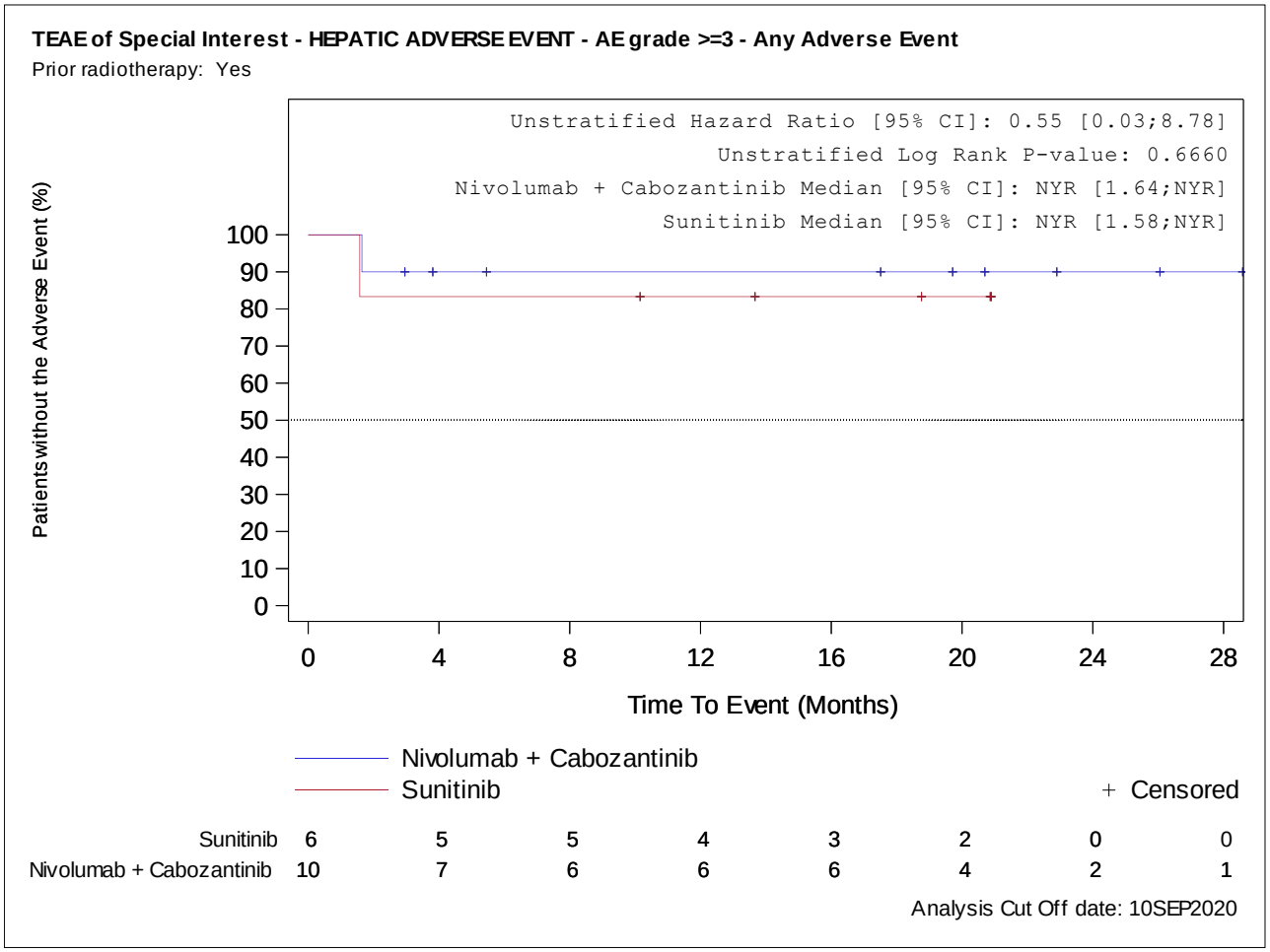

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:12:54

FIGURE 3.31.2.19: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



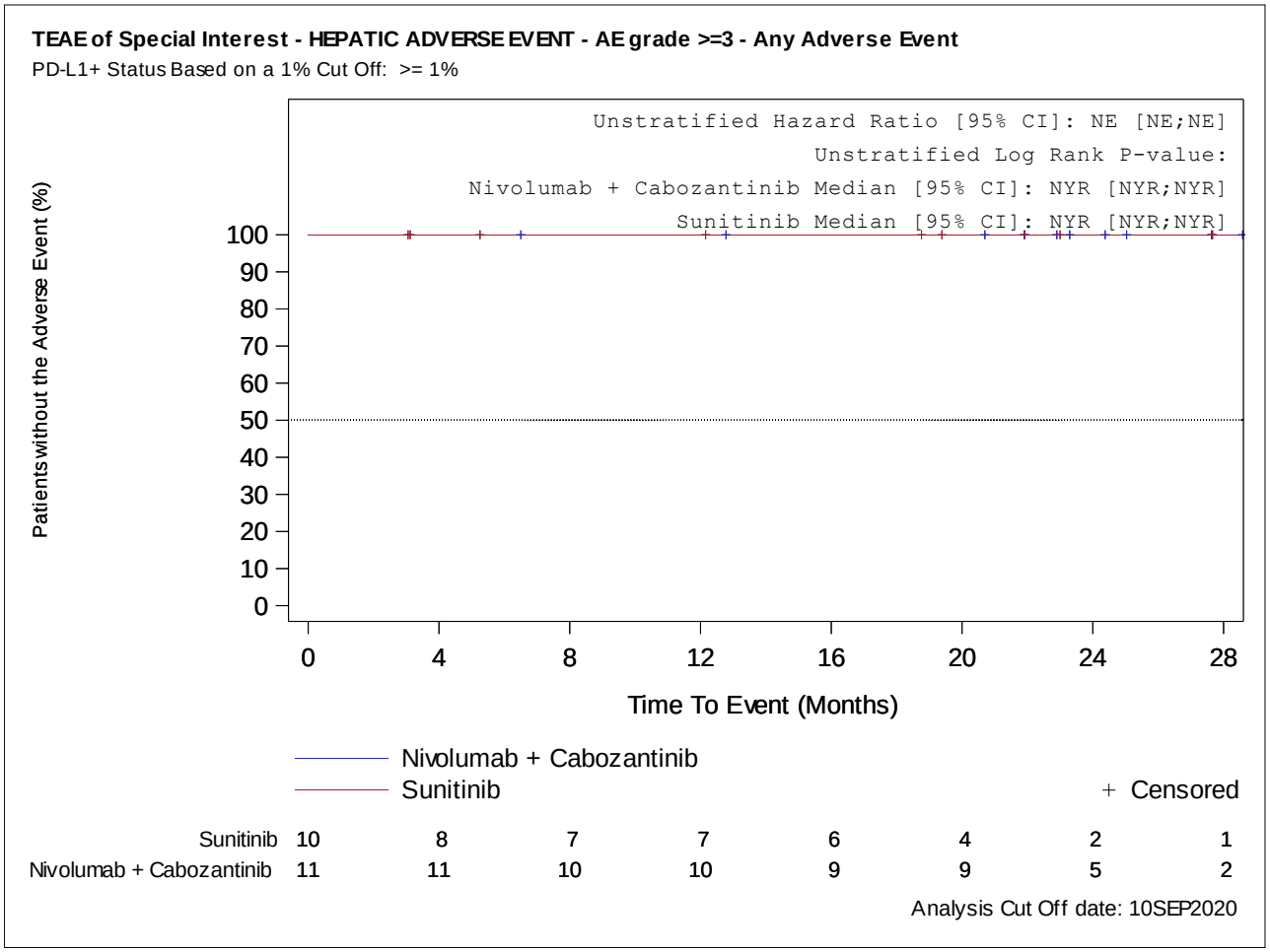

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:13:00

FIGURE 3.31.2.20: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



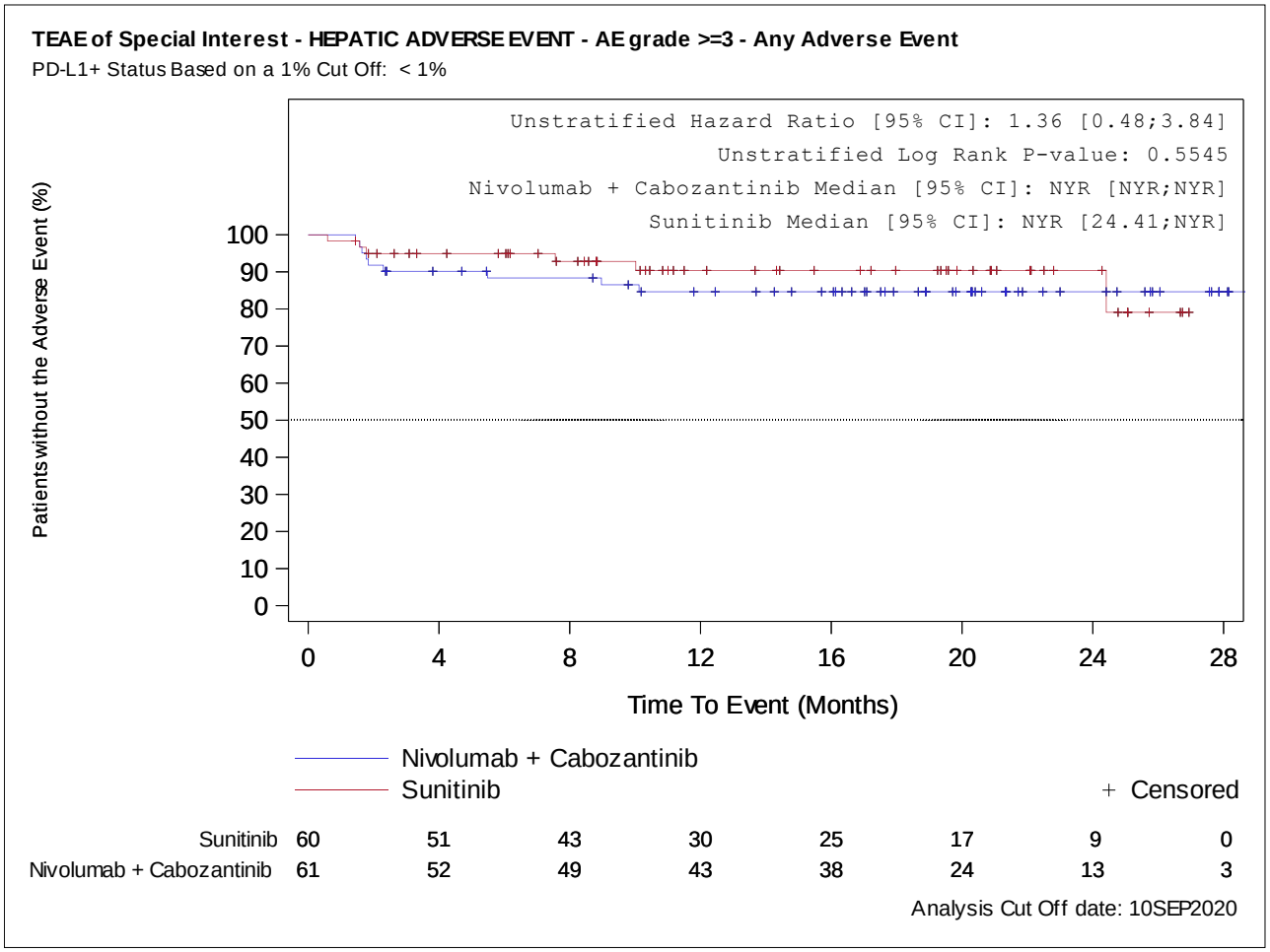

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:13:06

FIGURE 3.31.2.21: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



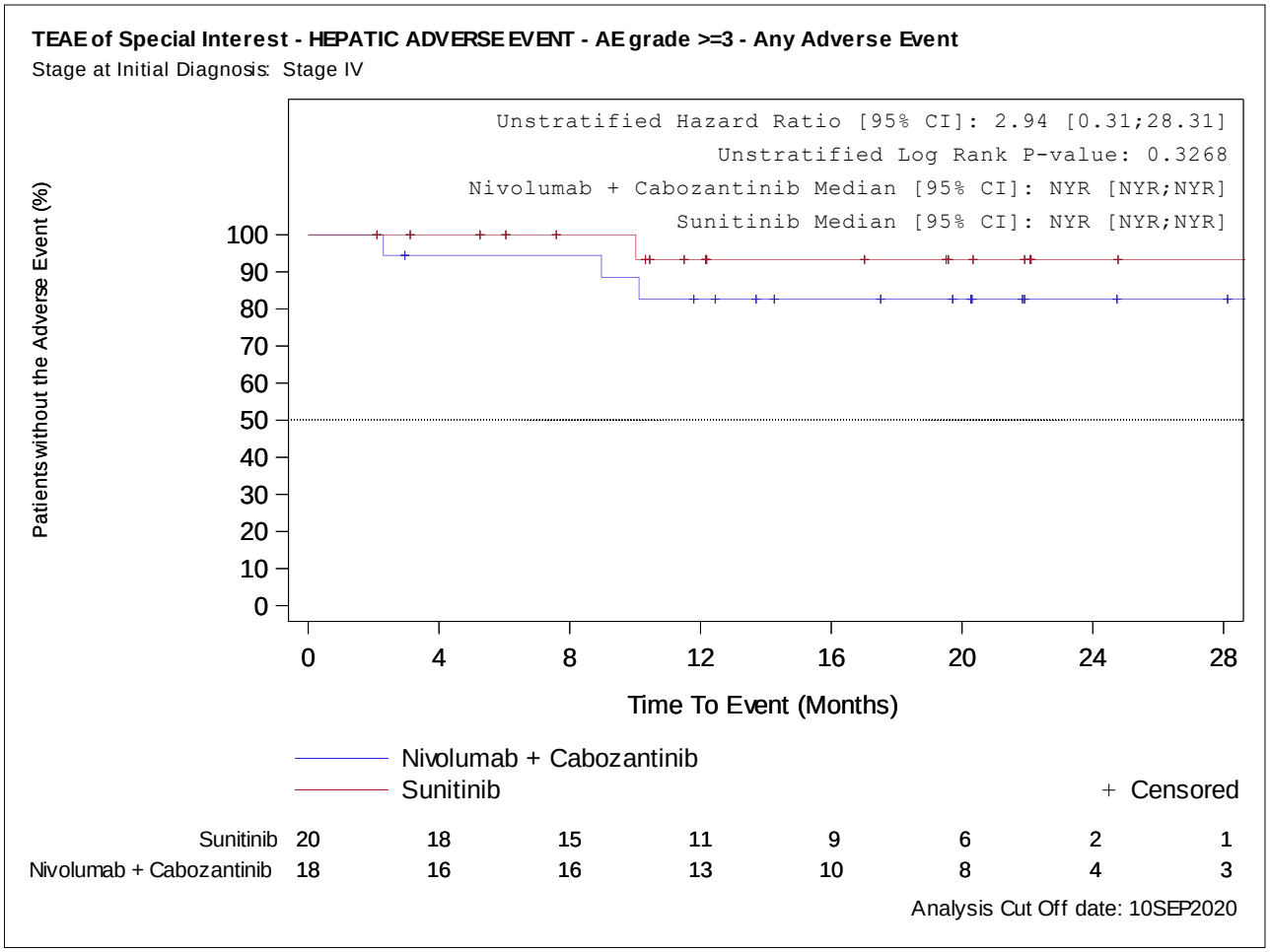

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:13:12

FIGURE 3.31.2.22: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



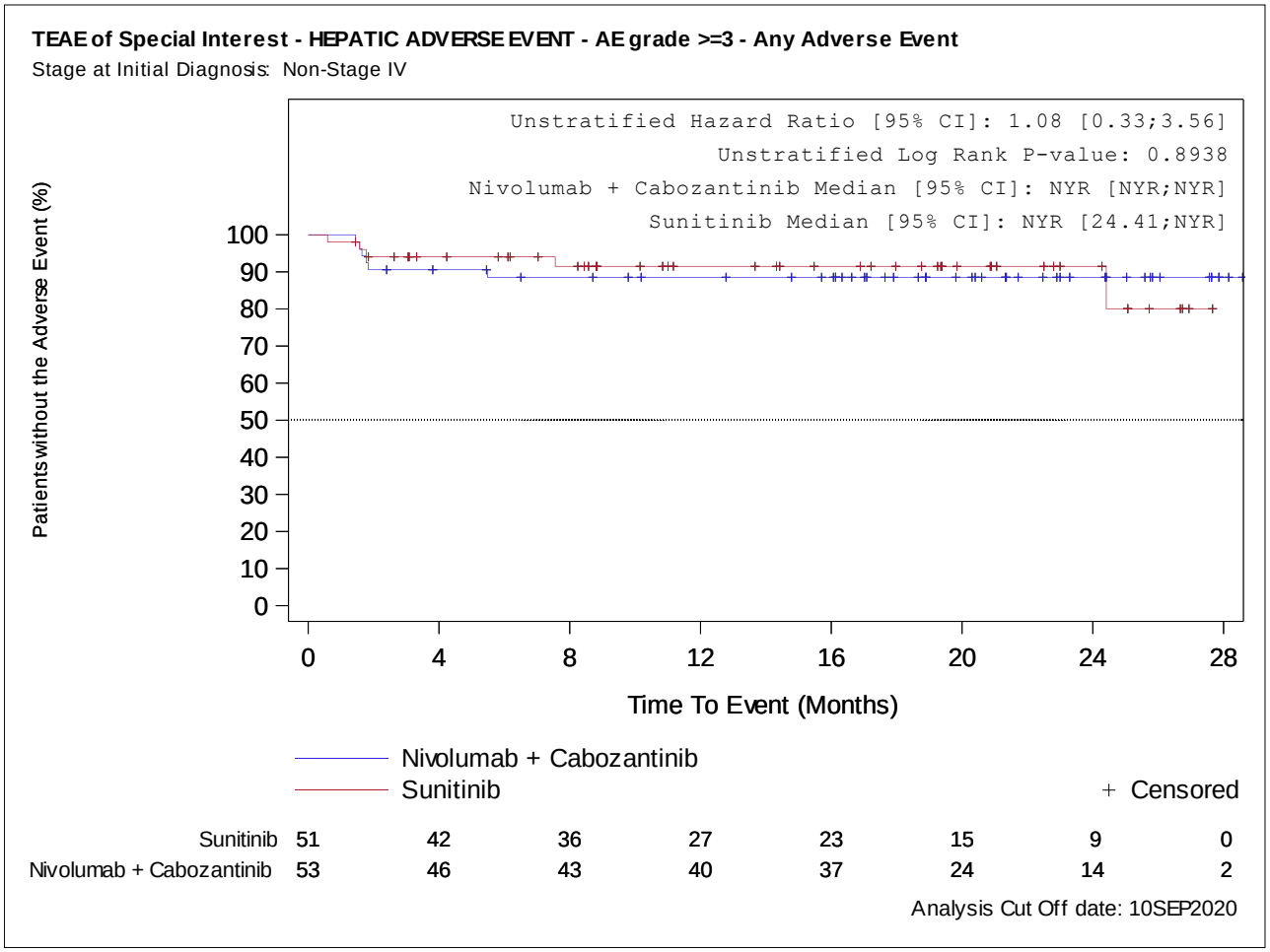

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:13:18

FIGURE 3.31.2.23: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



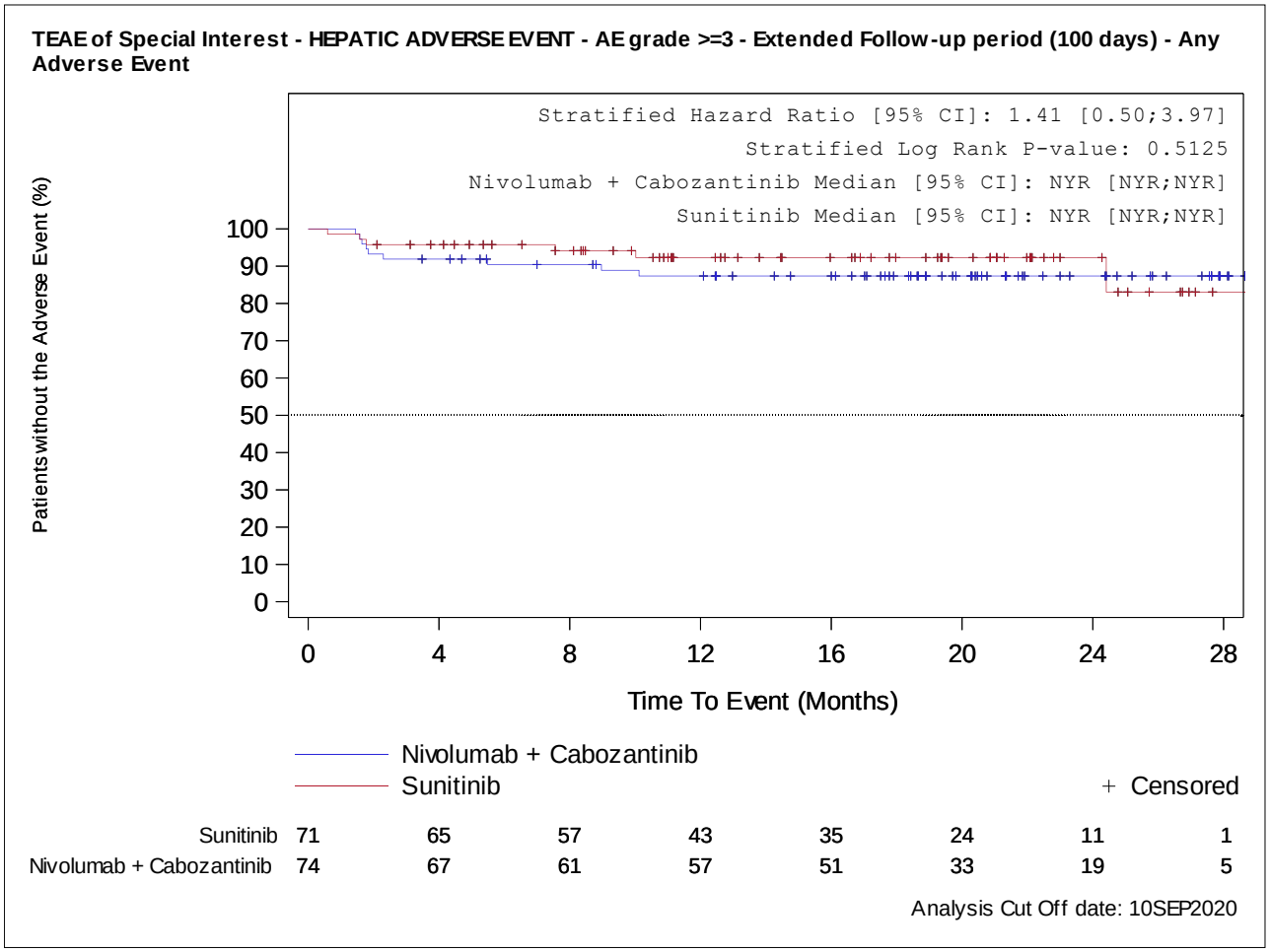

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:13:47

FIGURE 3.31.2.24: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



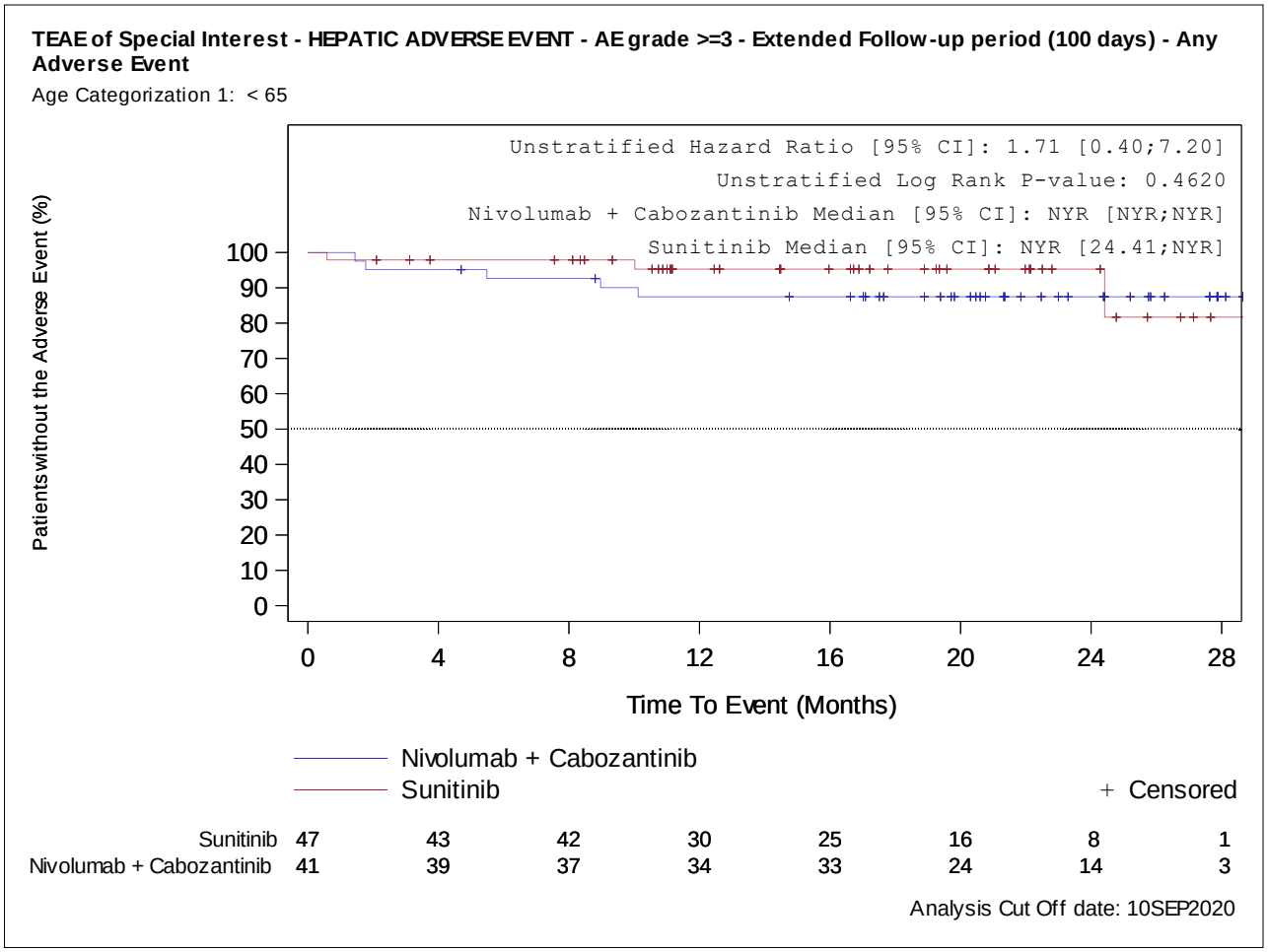

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:13:53

FIGURE 3.32.1: TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



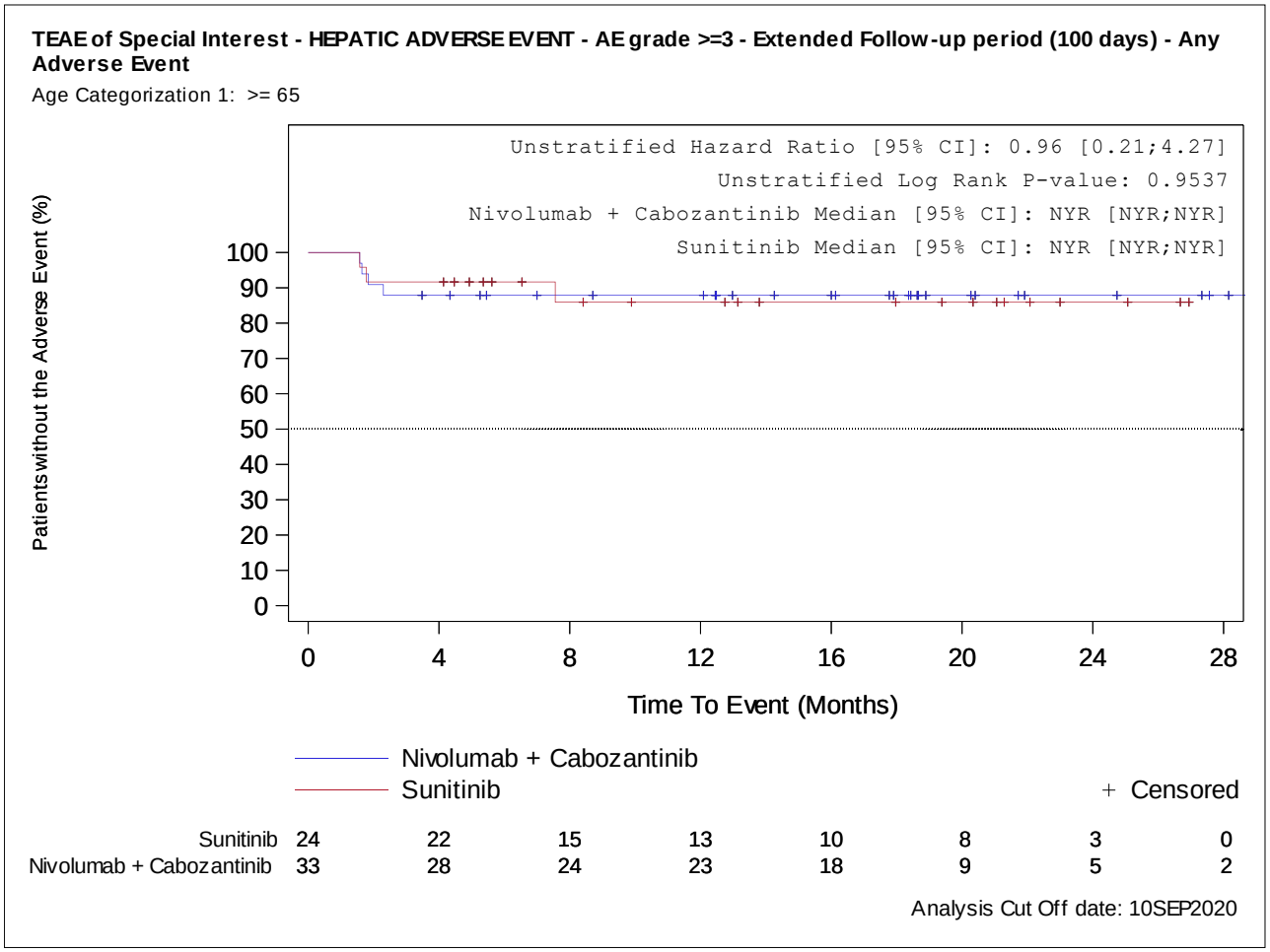

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:17:11

FIGURE 3.32.2.1: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



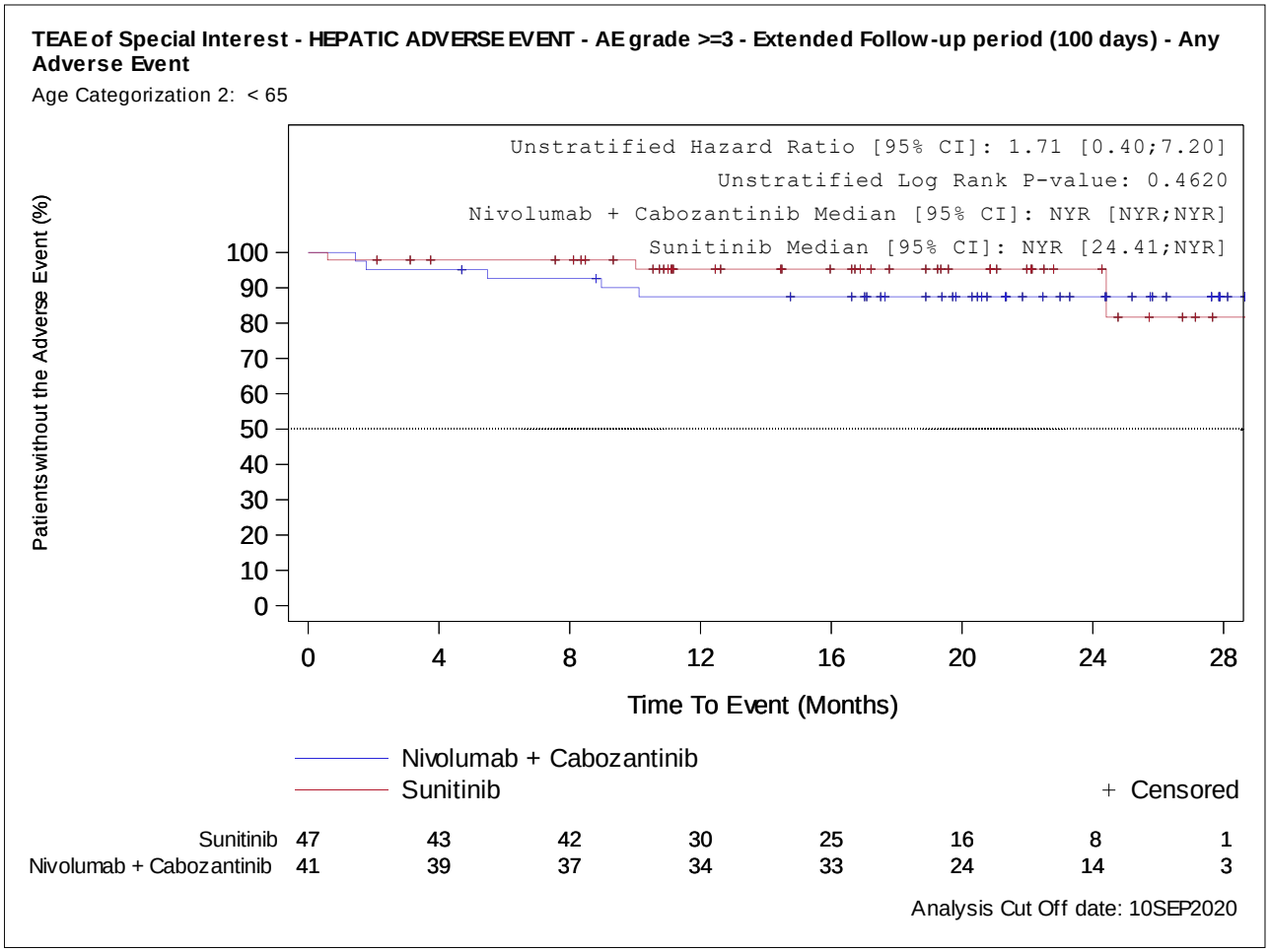

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:17:14

FIGURE 3.32.2.2: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



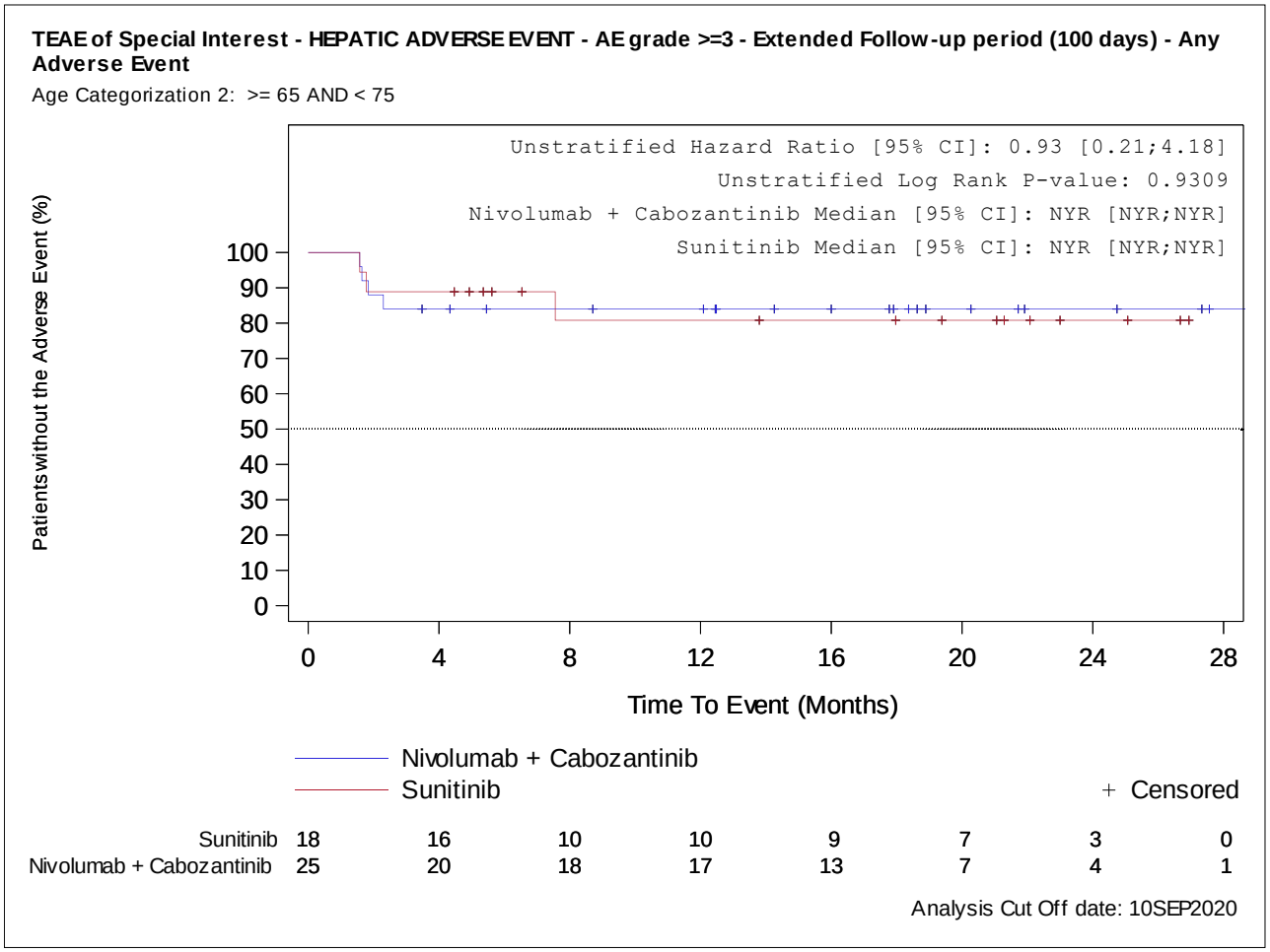

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:17:20

FIGURE 3.32.2.3: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



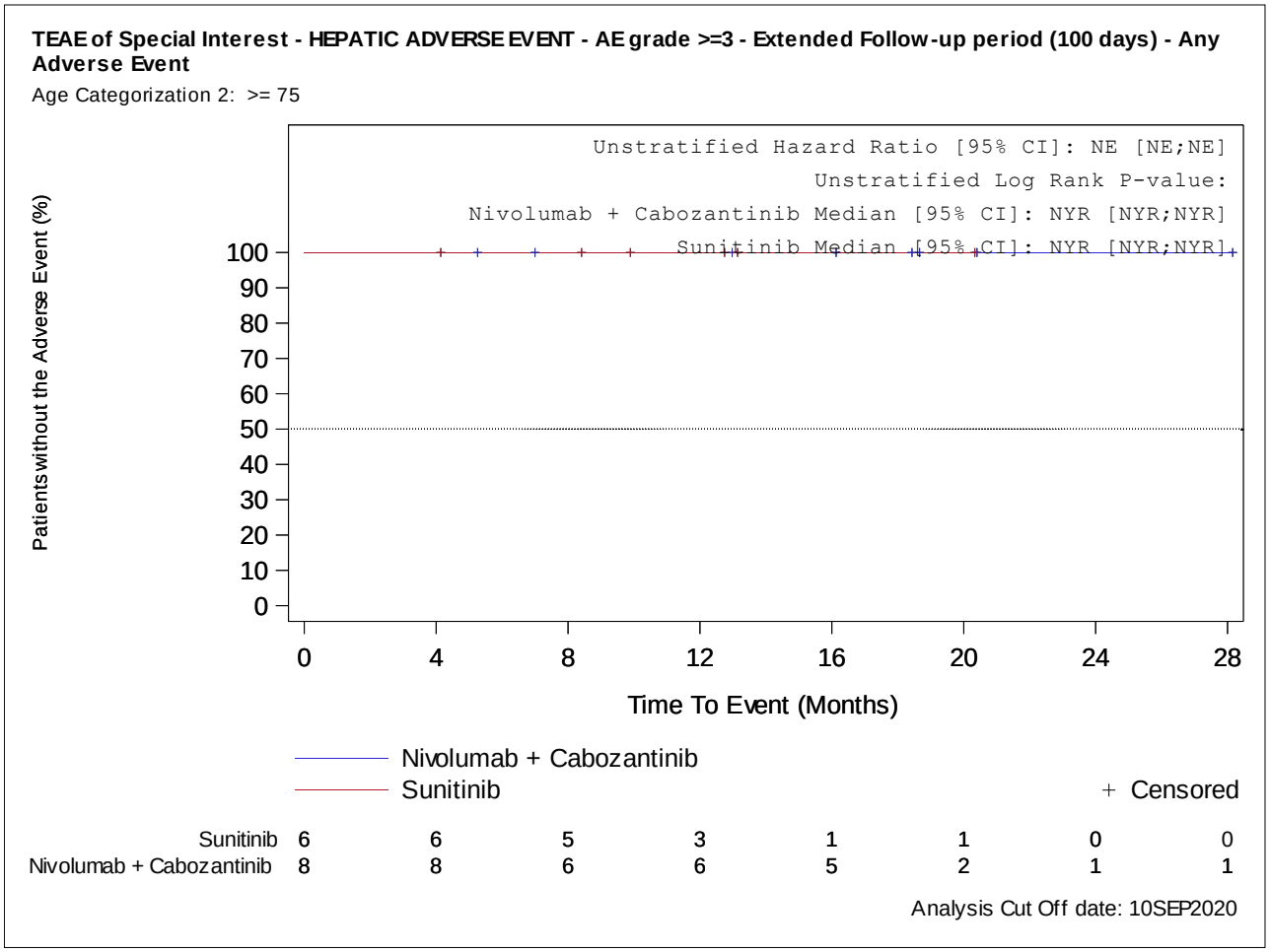

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:17:26

FIGURE 3.32.2.4: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



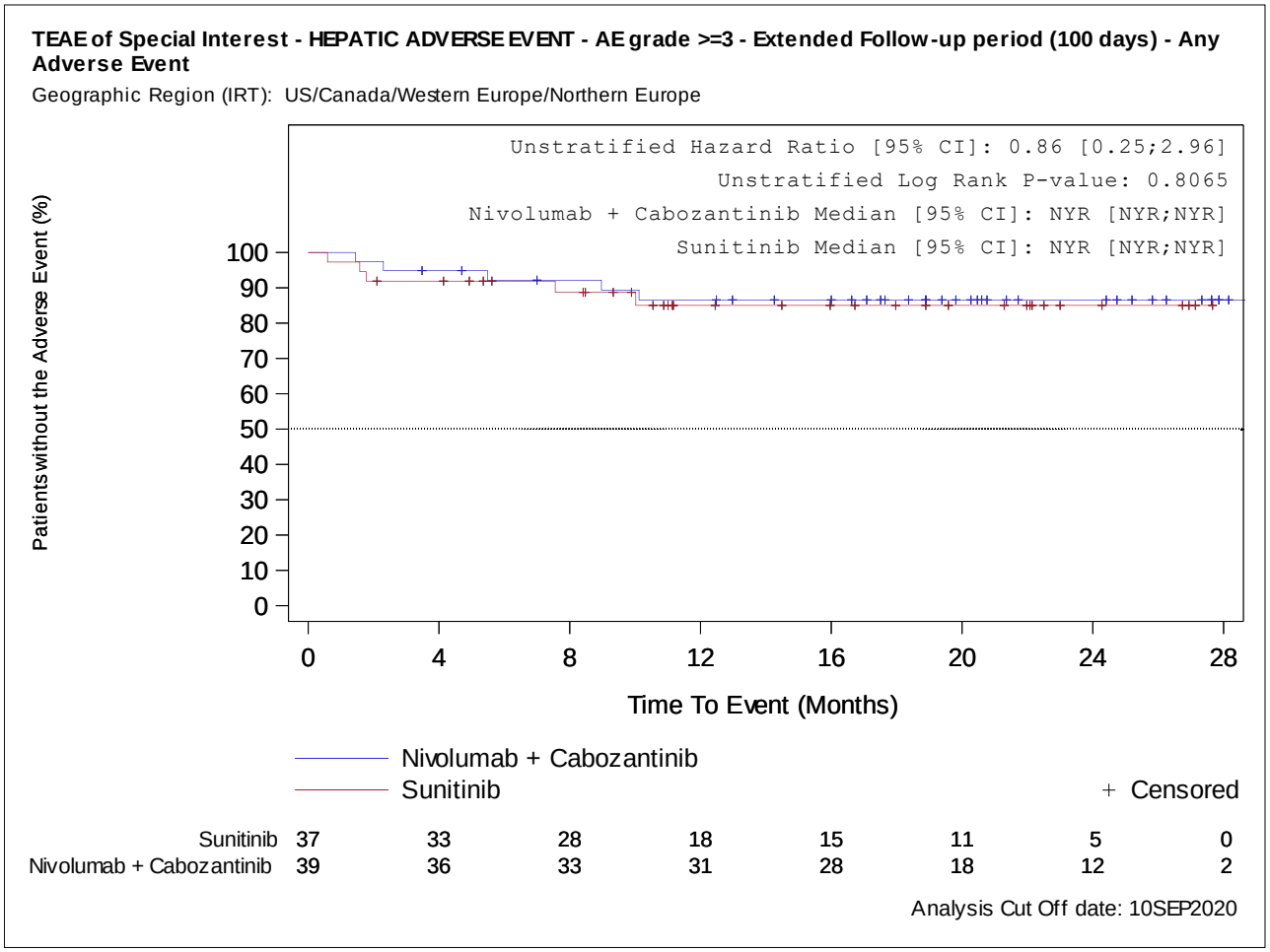

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:17:32

FIGURE 3.32.2.5: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



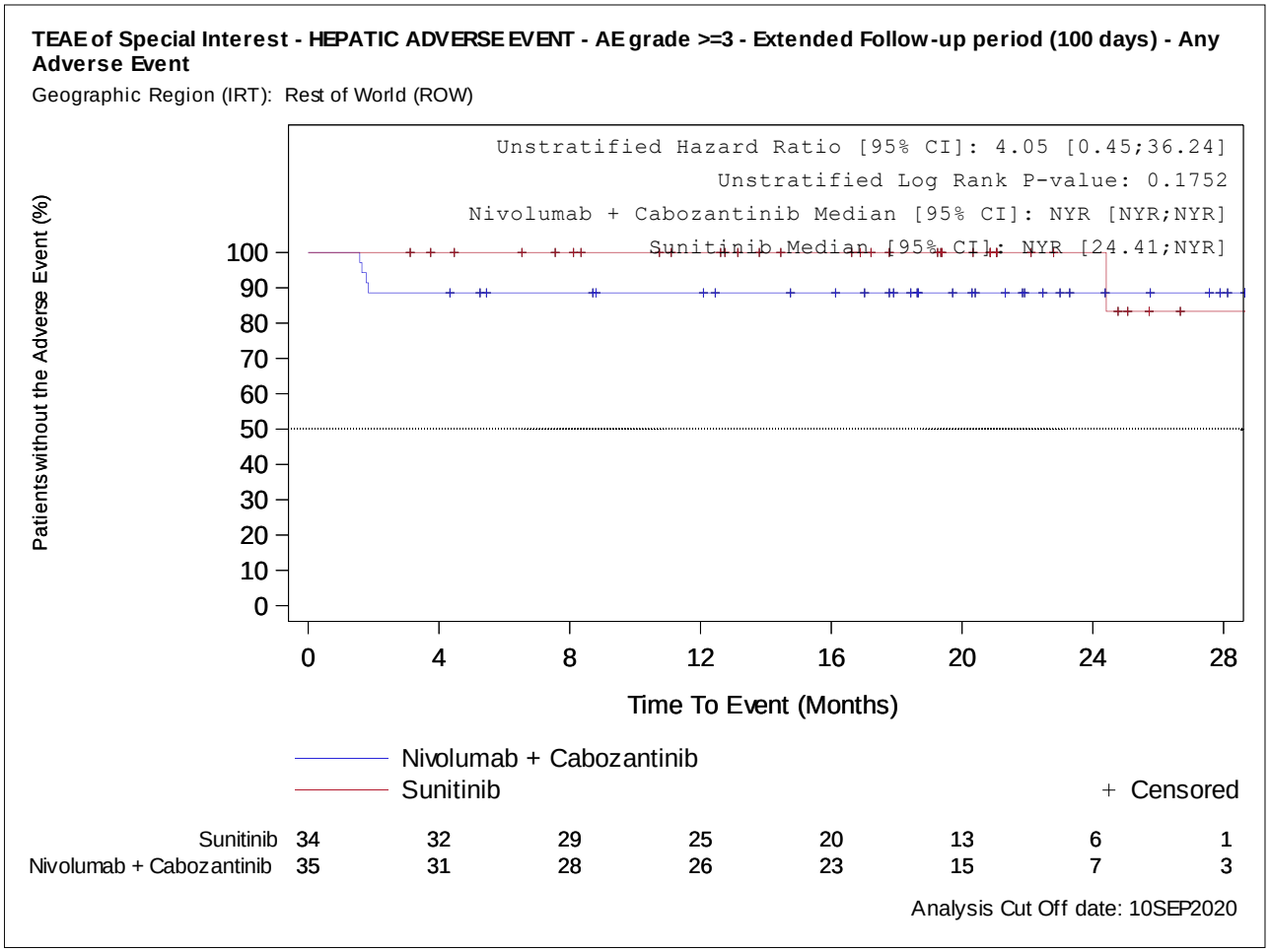

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:17:38

FIGURE 3.32.2.6: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



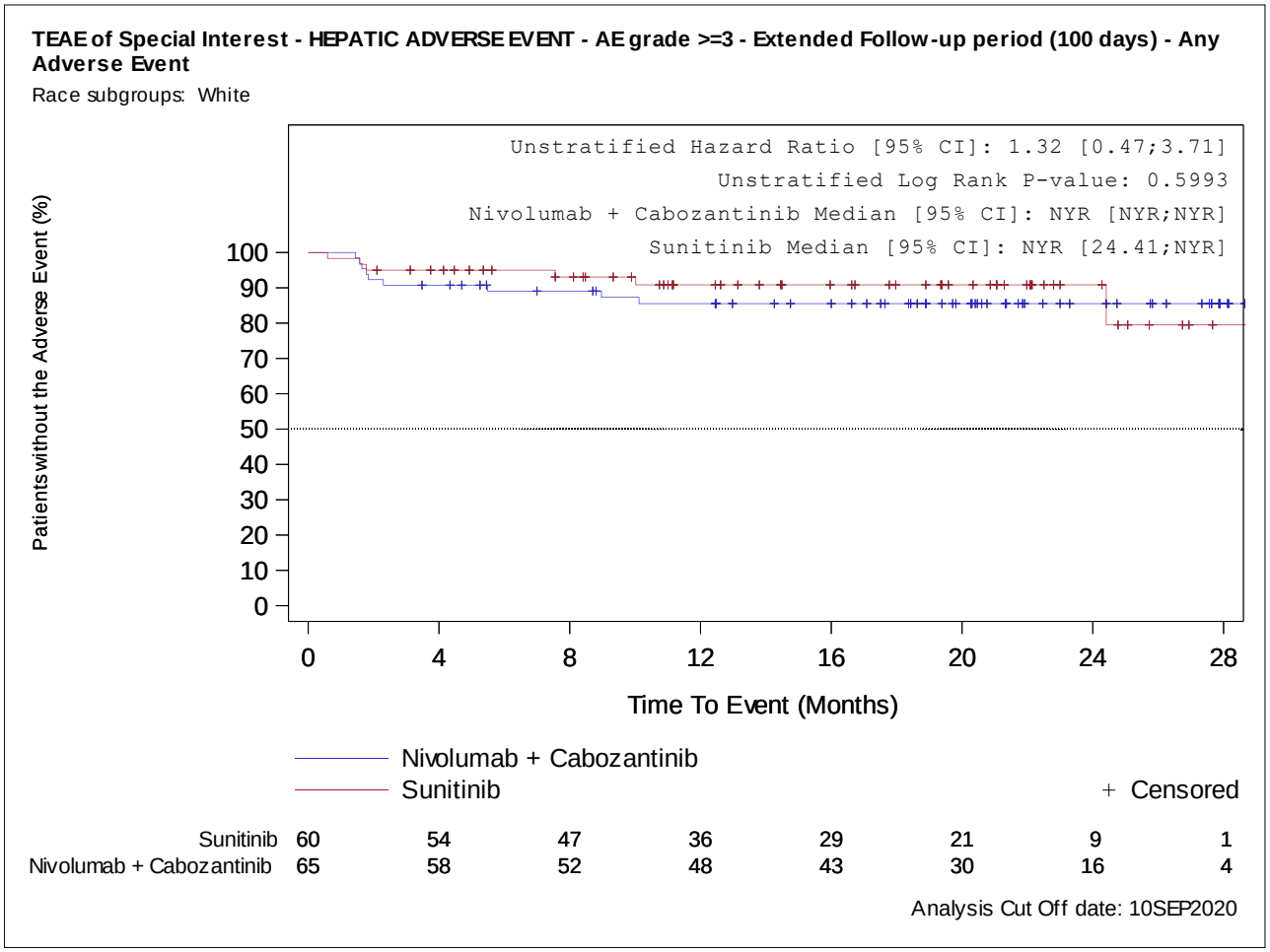

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:17:44

FIGURE 3.32.2.7: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



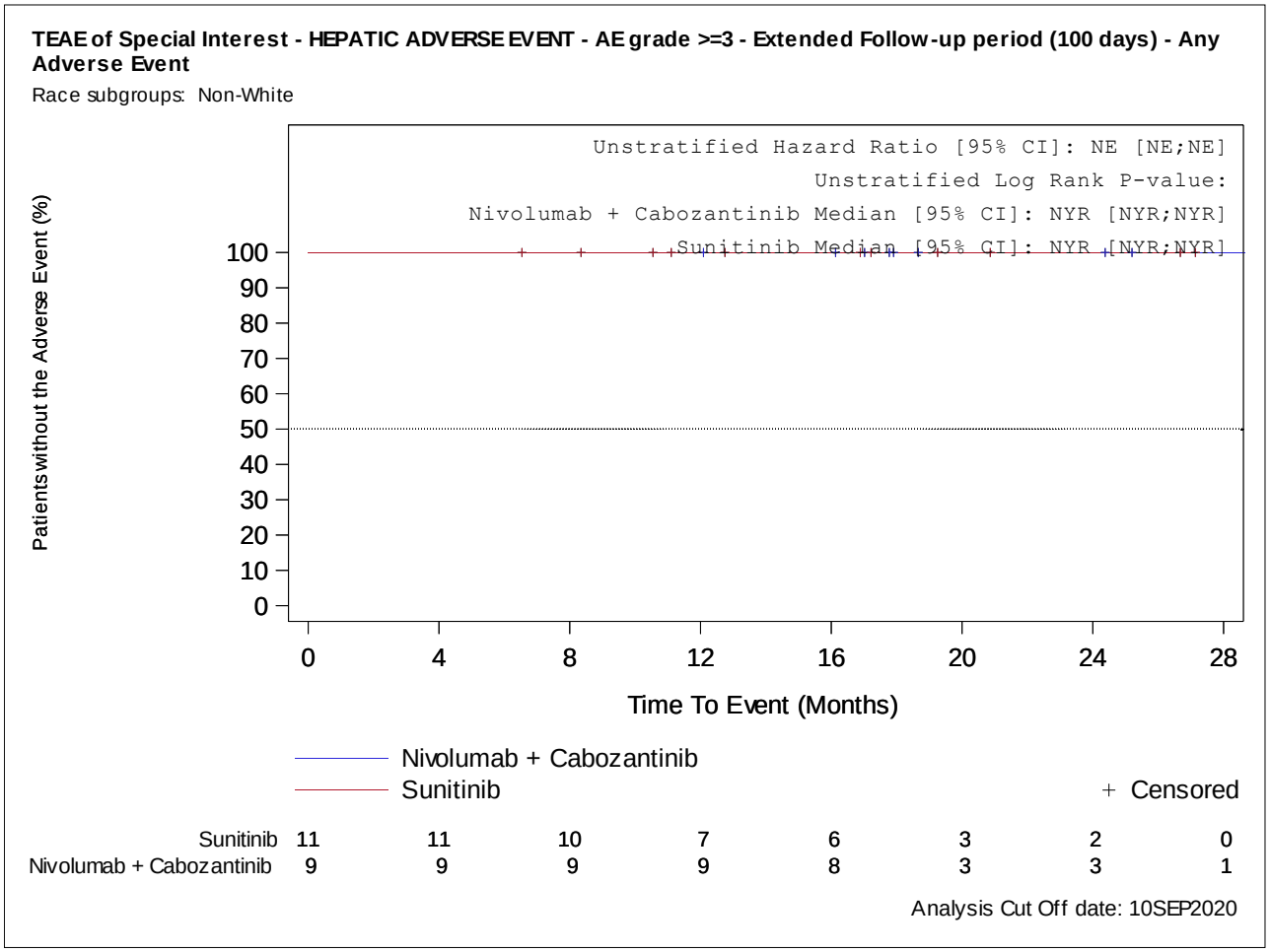

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:17:49

FIGURE 3.32.2.8: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



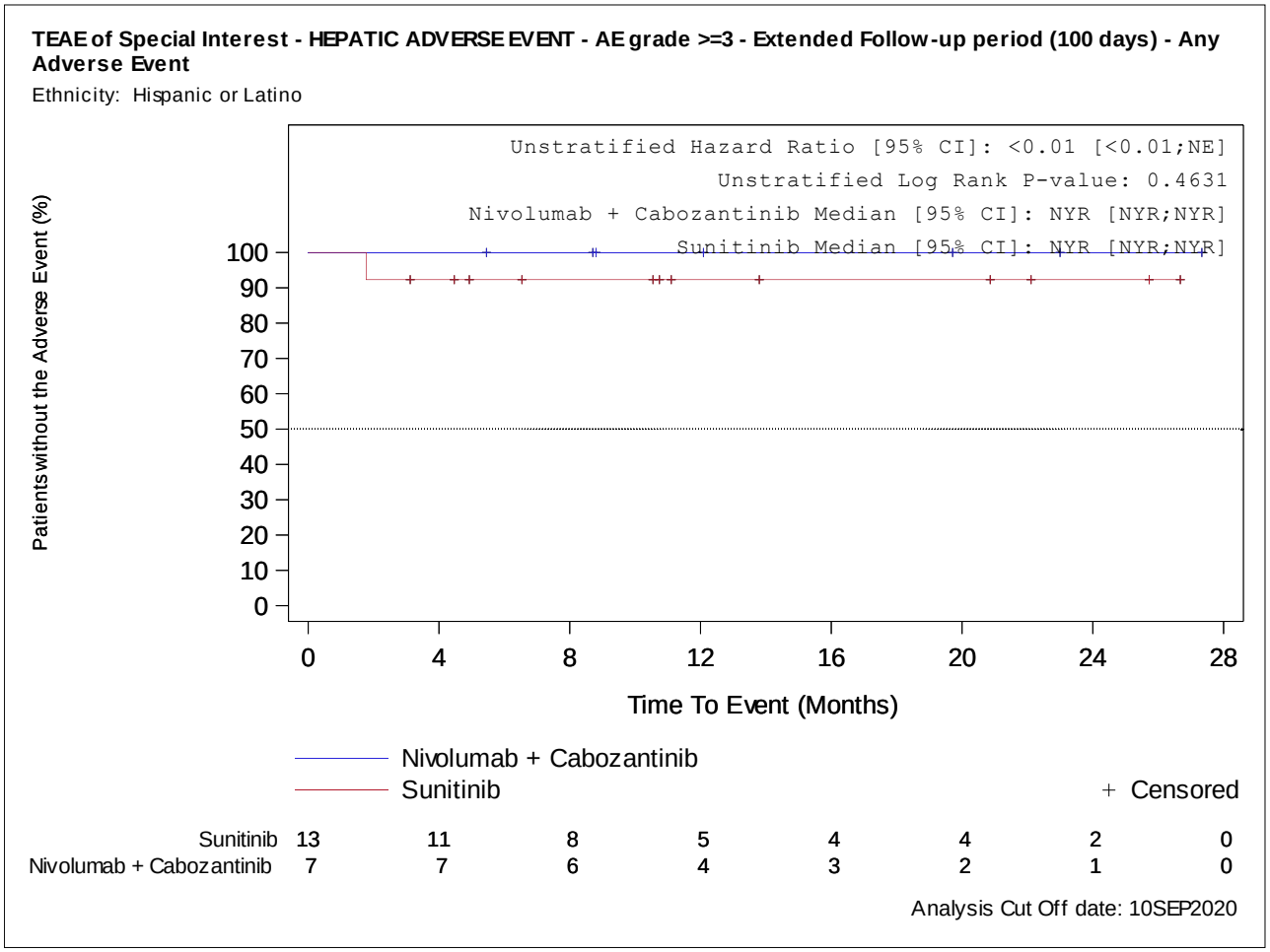

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:17:55

FIGURE 3.32.2.9: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



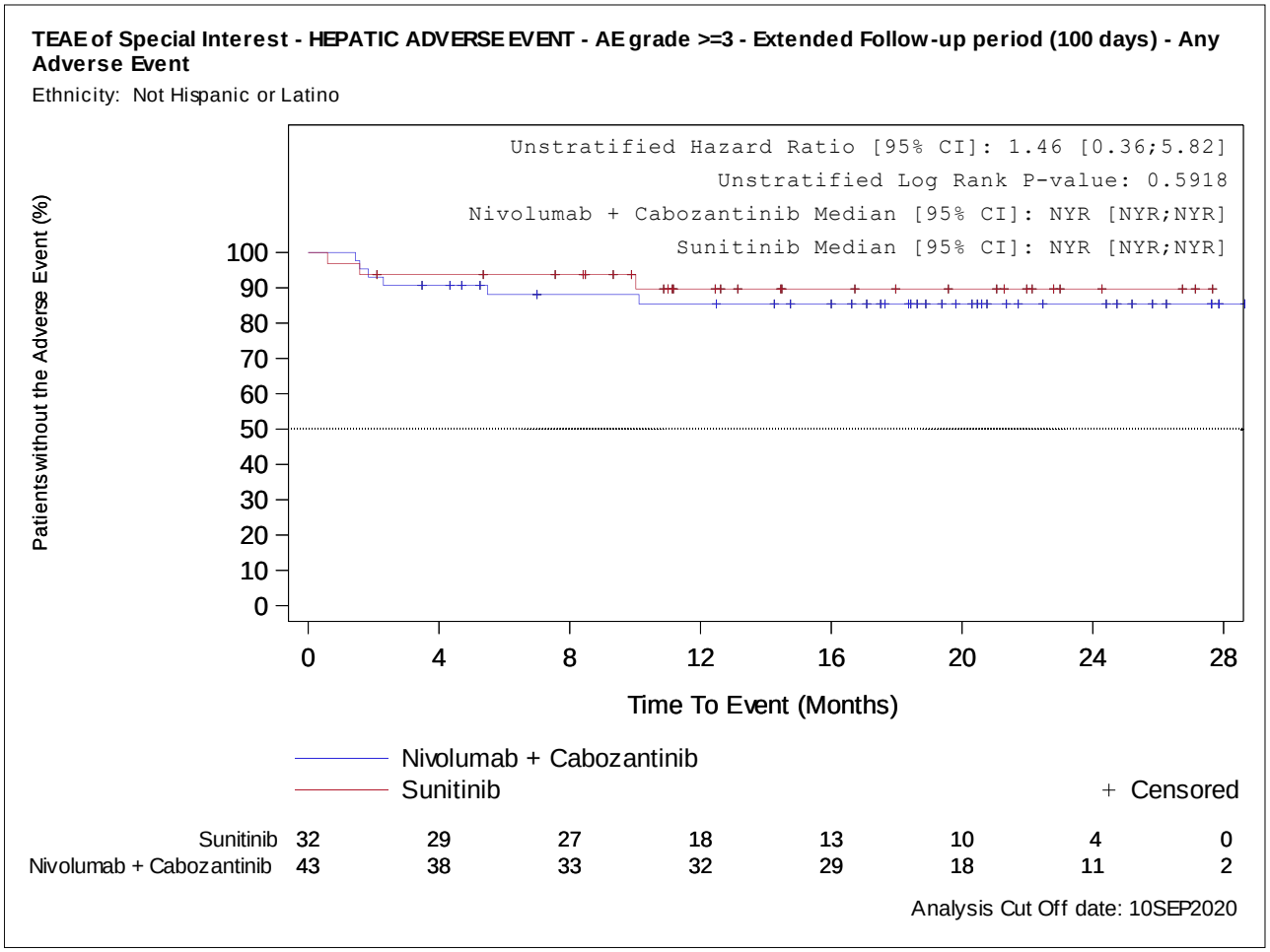

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:18:01

FIGURE 3.32.2.10: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



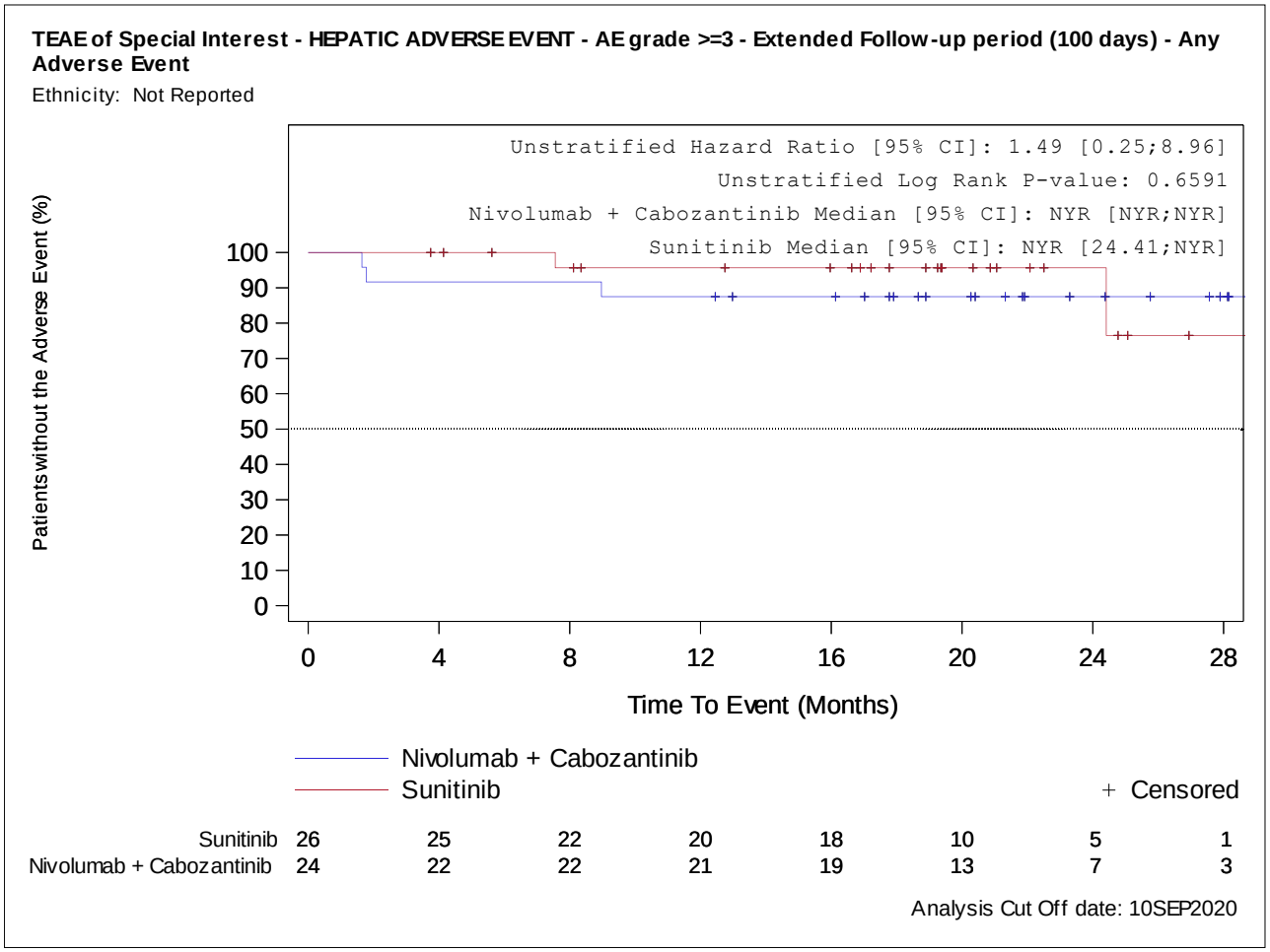

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:18:06

FIGURE 3.32.2.11: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



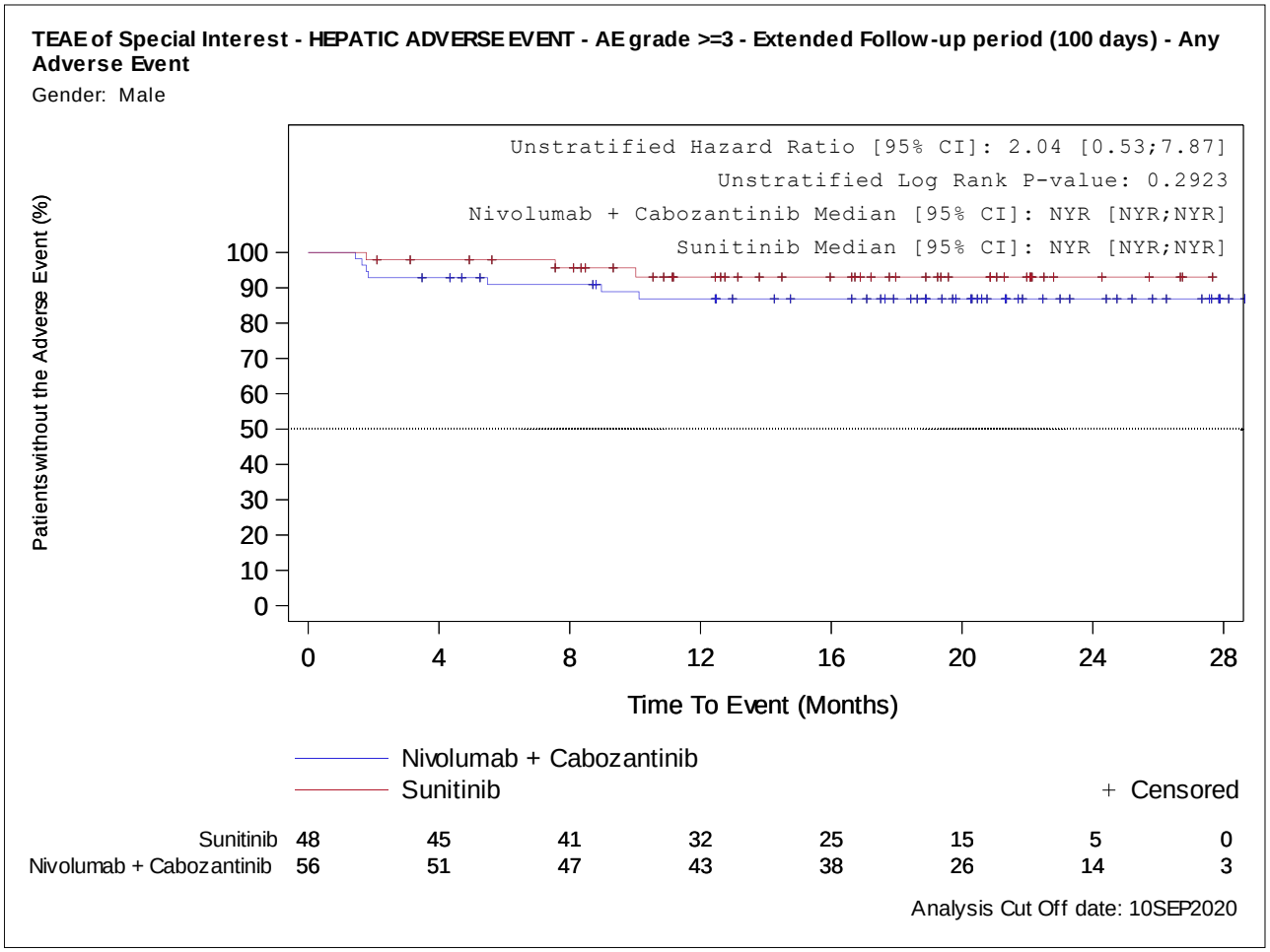

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:18:12

FIGURE 3.32.2.12: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



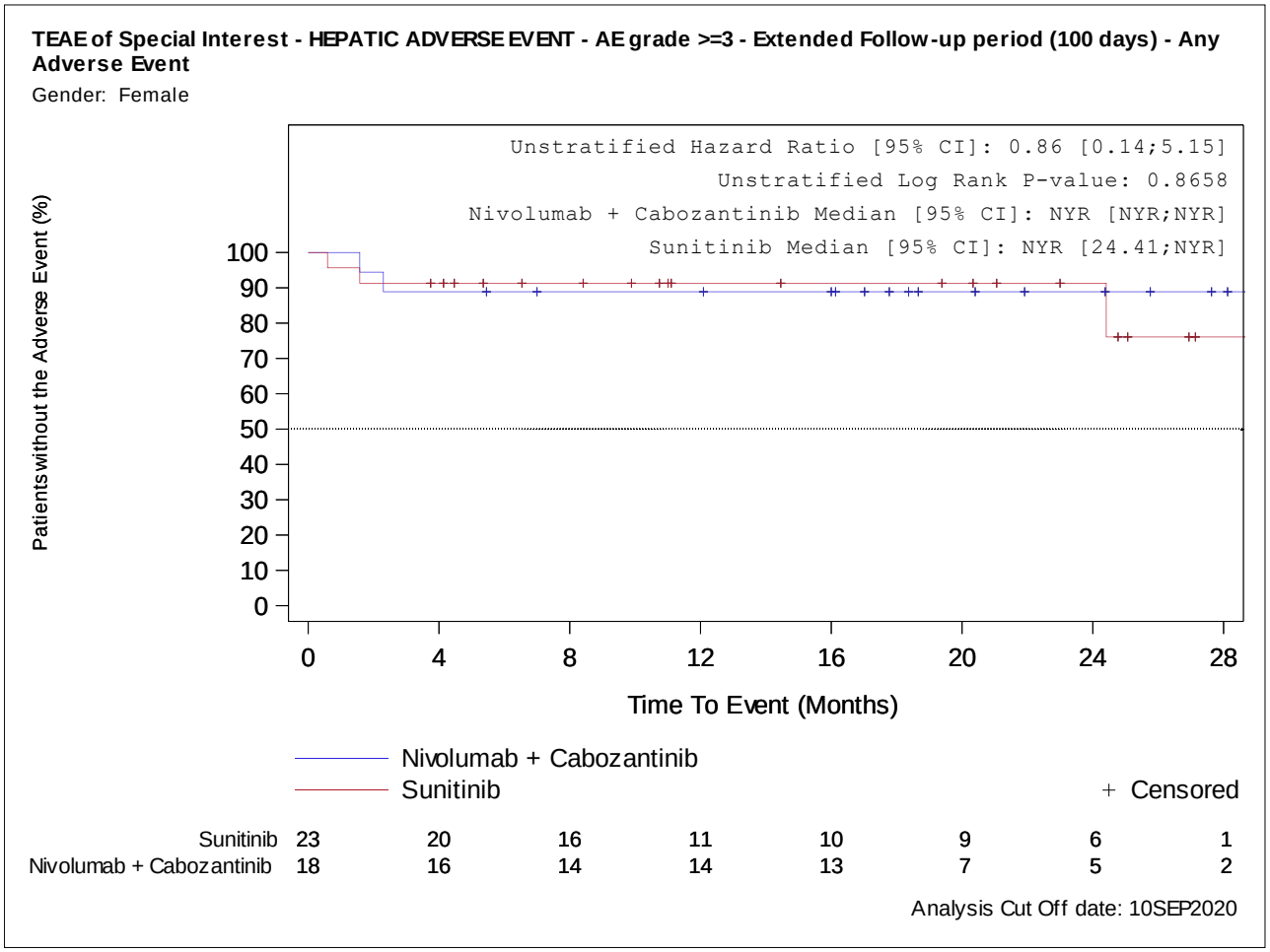

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:18:18

FIGURE 3.32.2.13: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



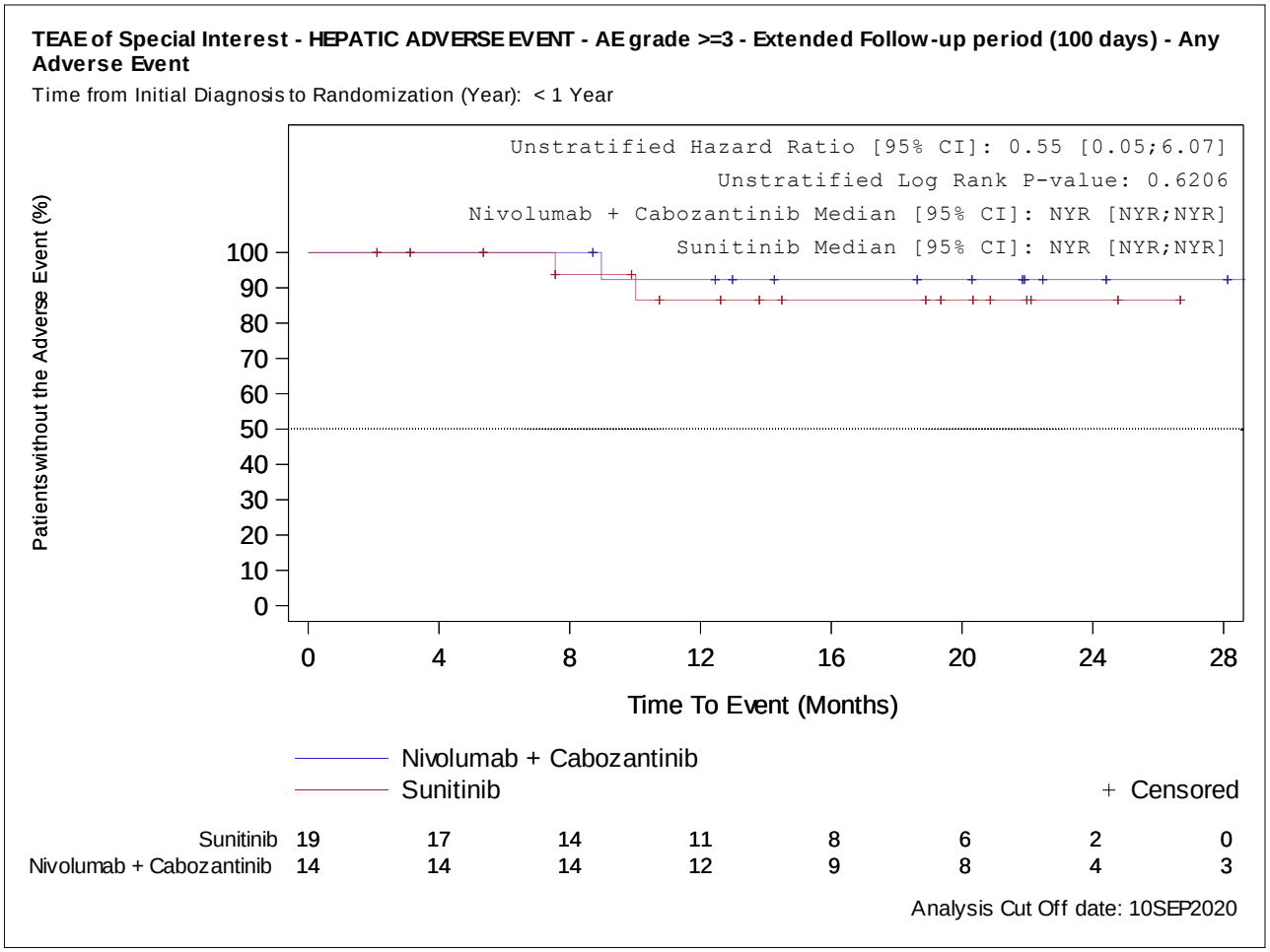

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:18:25

FIGURE 3.32.2.14: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



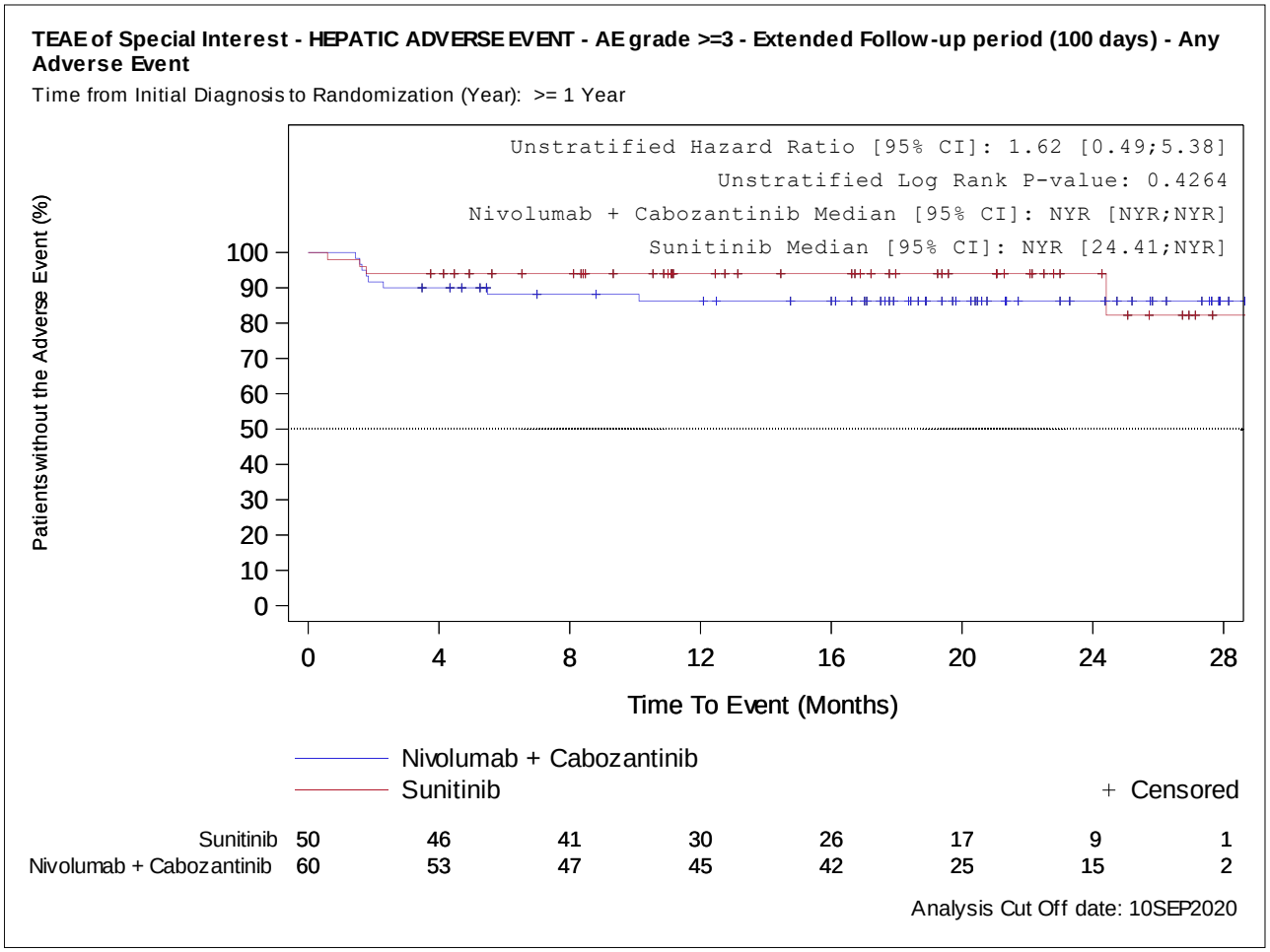

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:18:31

FIGURE 3.32.2.15: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



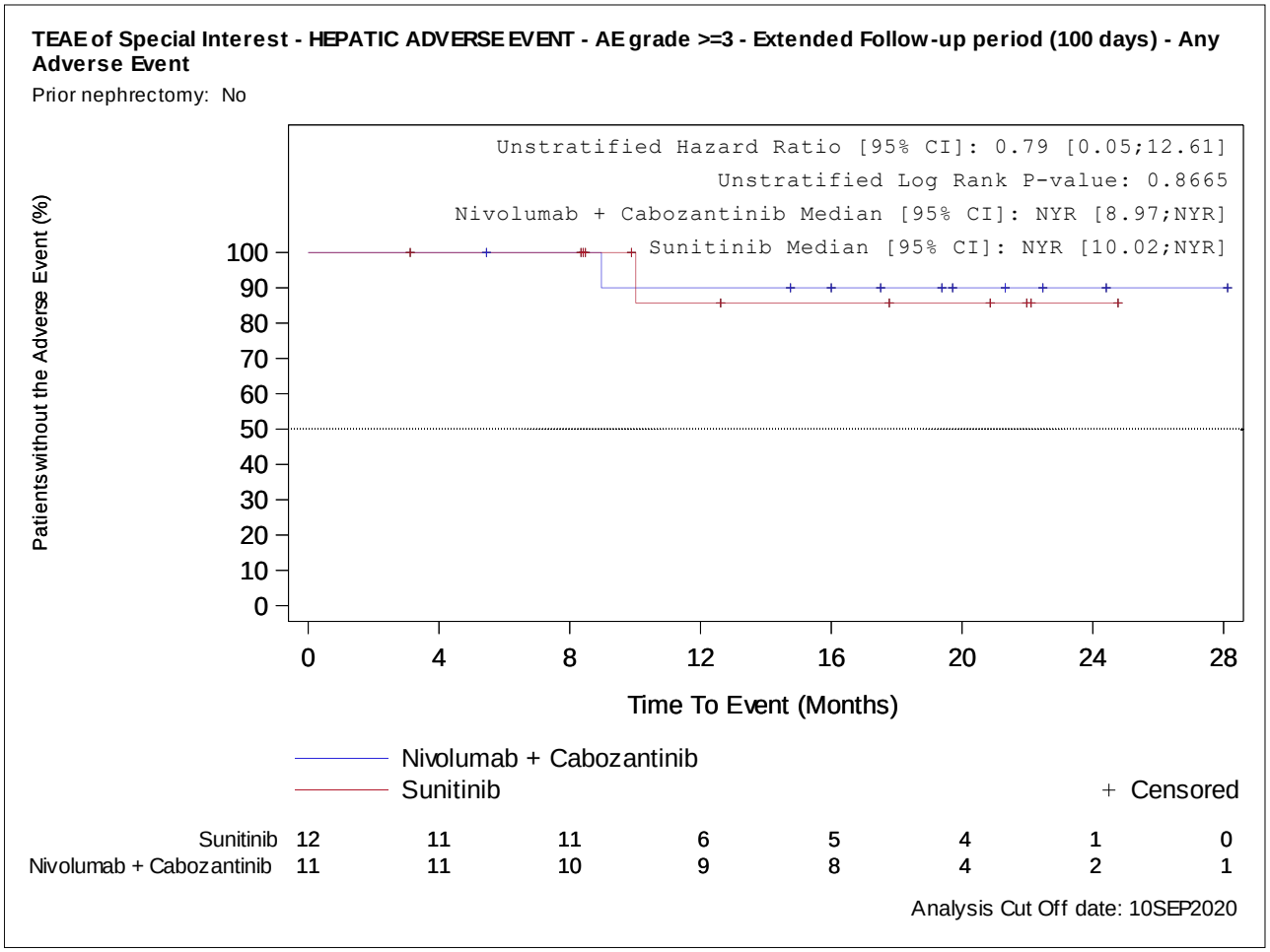

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:18:48

FIGURE 3.32.2.16: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



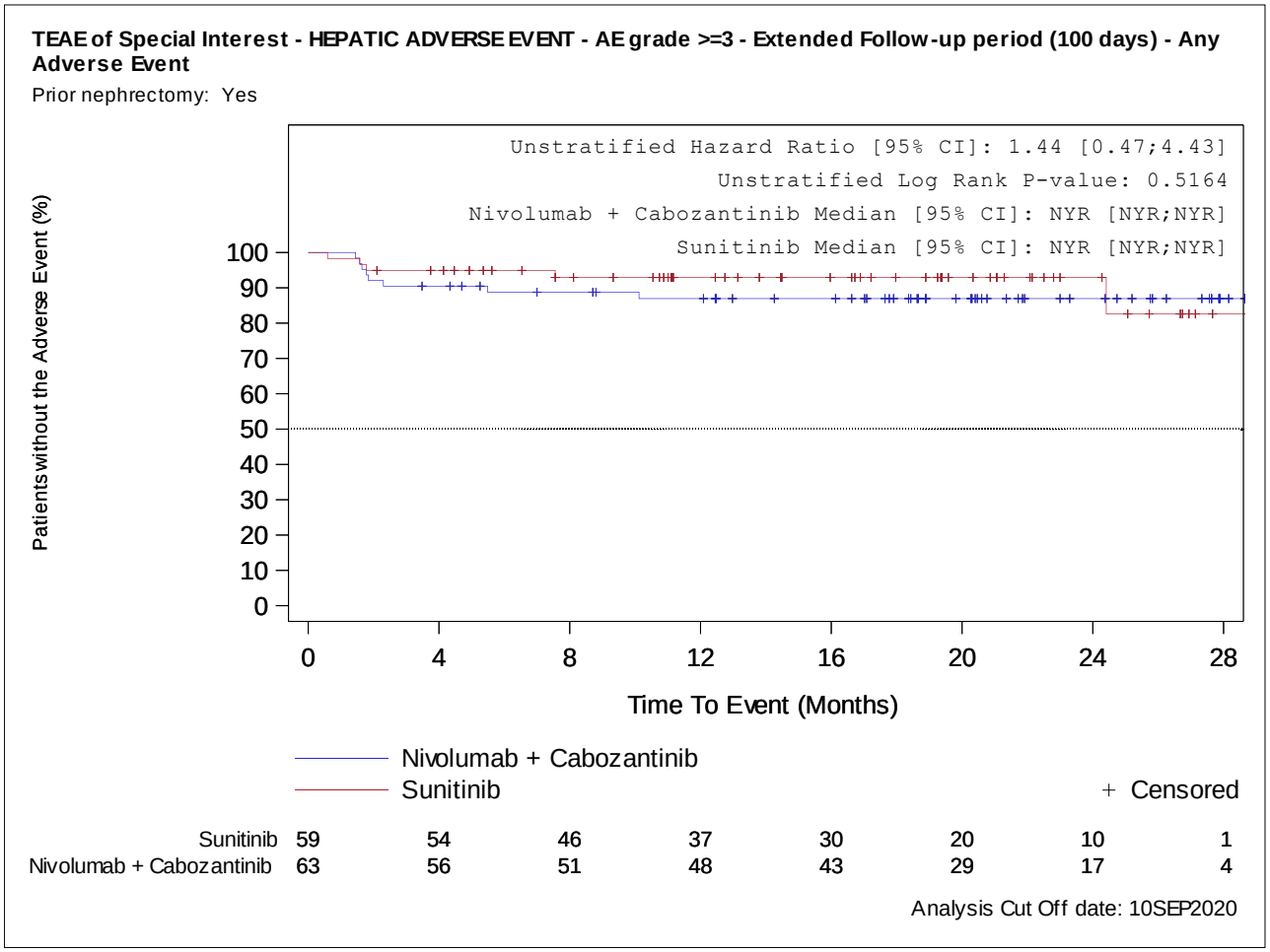

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:18:54

FIGURE 3.32.2.17: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



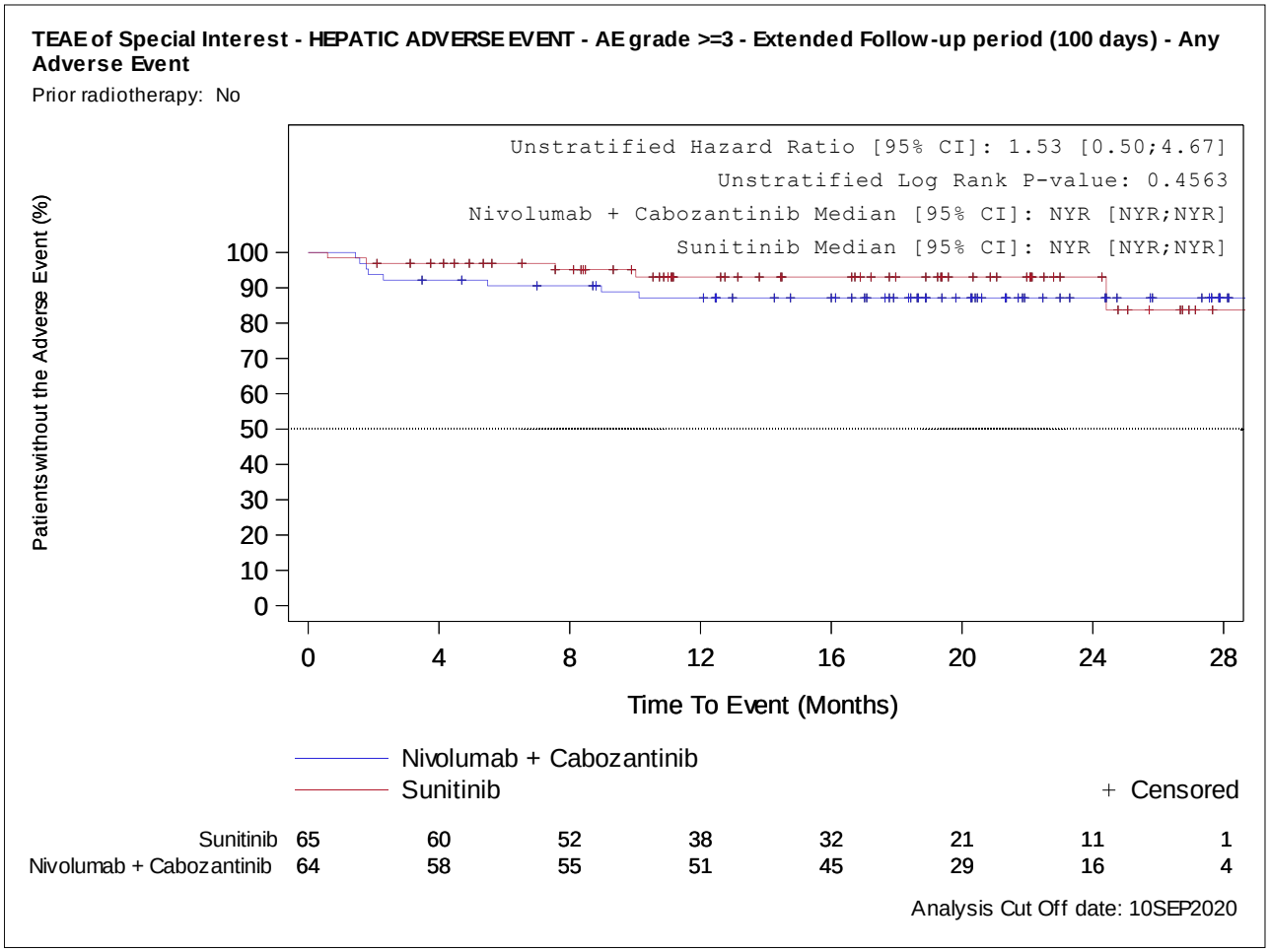

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:19:47

FIGURE 3.32.2.18: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



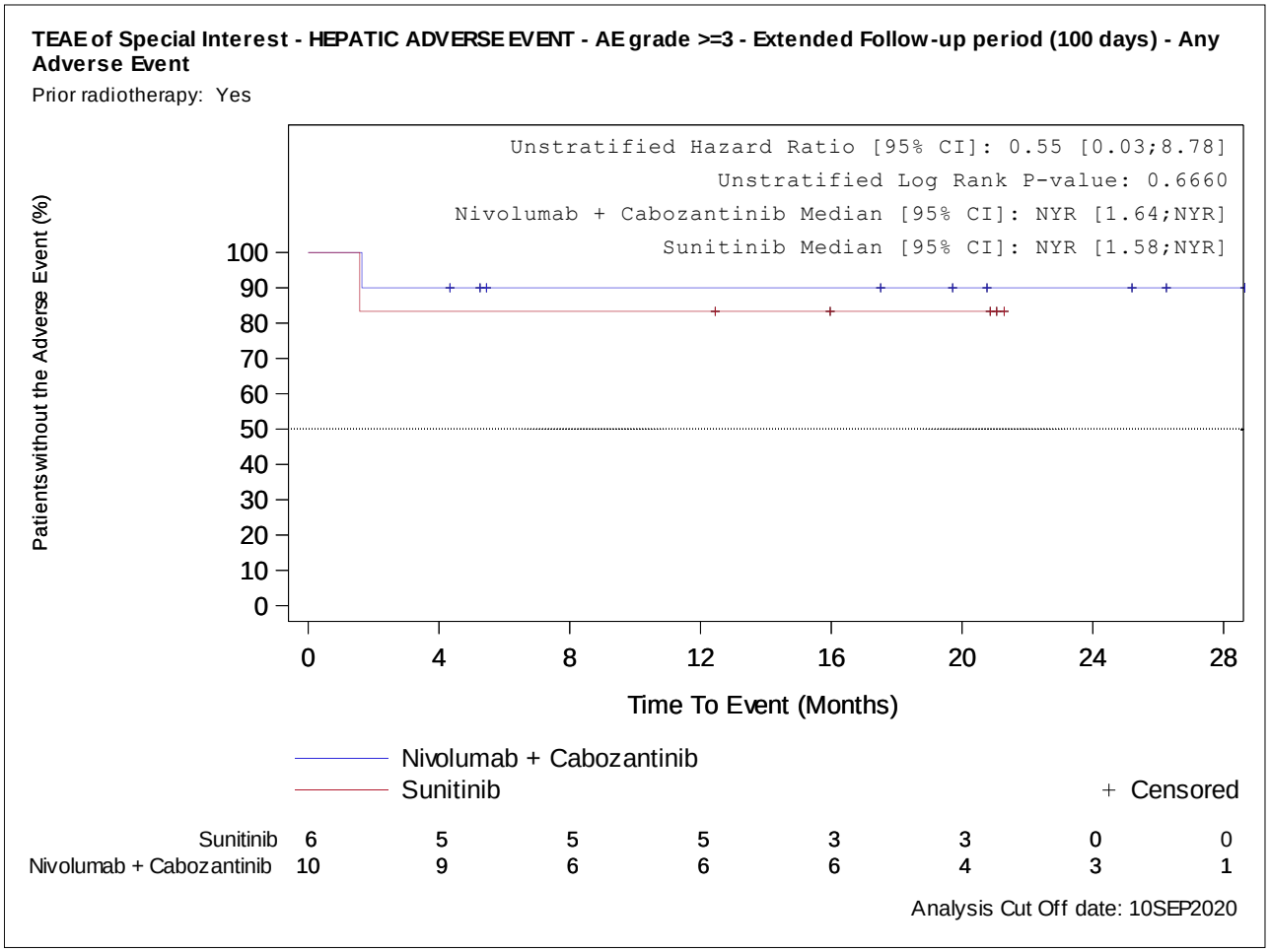

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:19:52

FIGURE 3.32.2.19: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



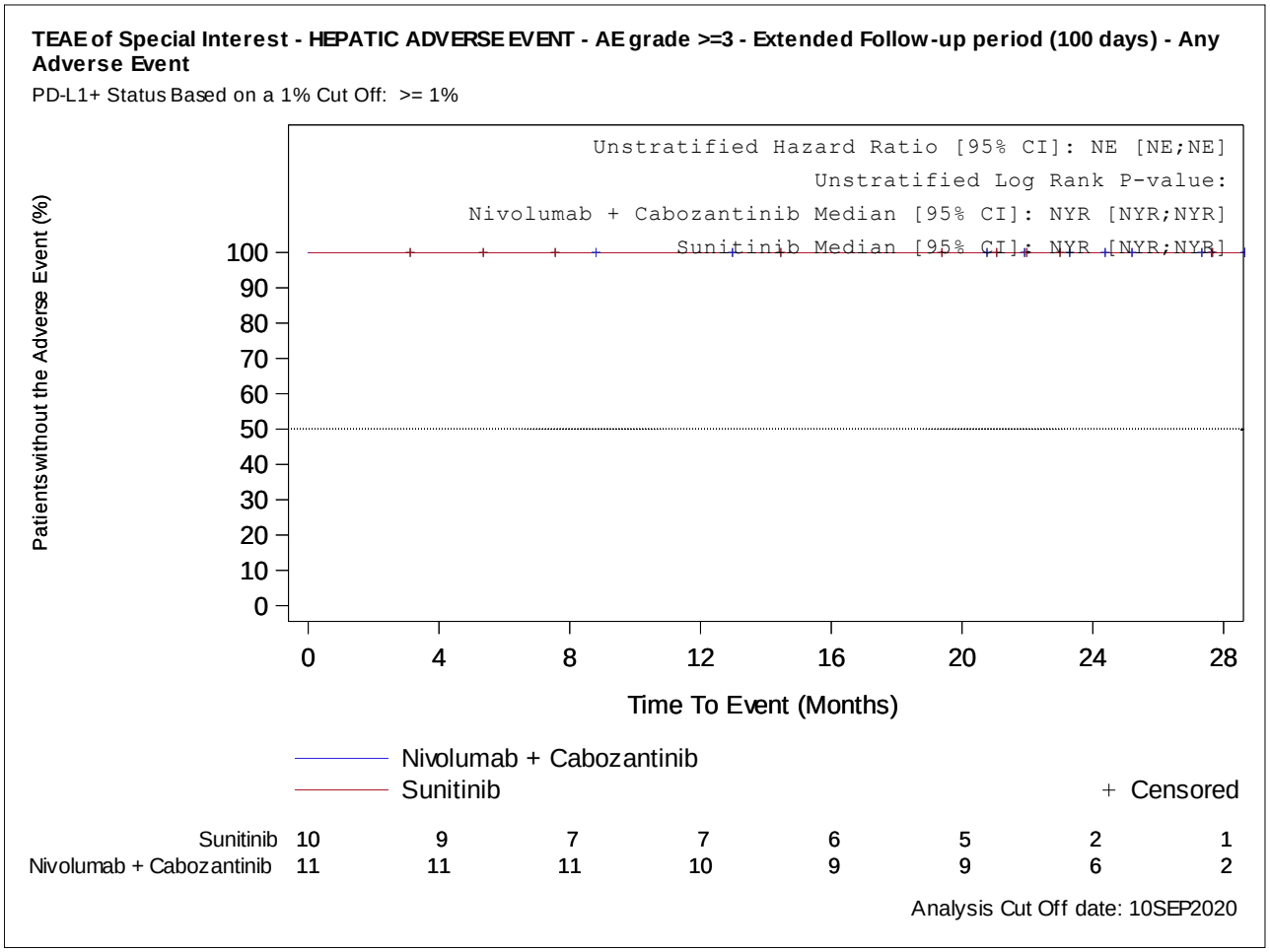

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:19:58

FIGURE 3.32.2.20: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



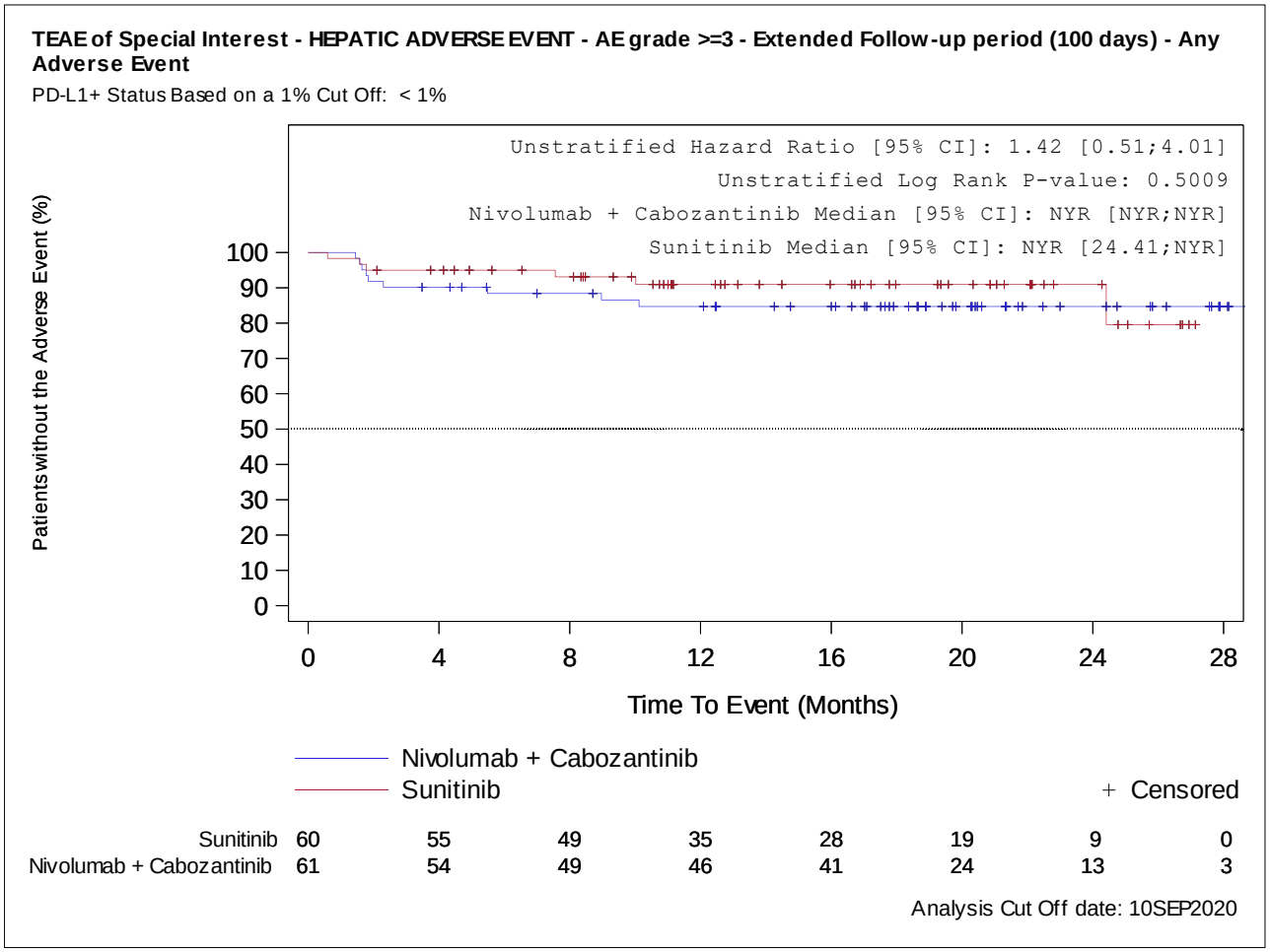

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:20:04

FIGURE 3.32.2.21: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off:  >= 1%



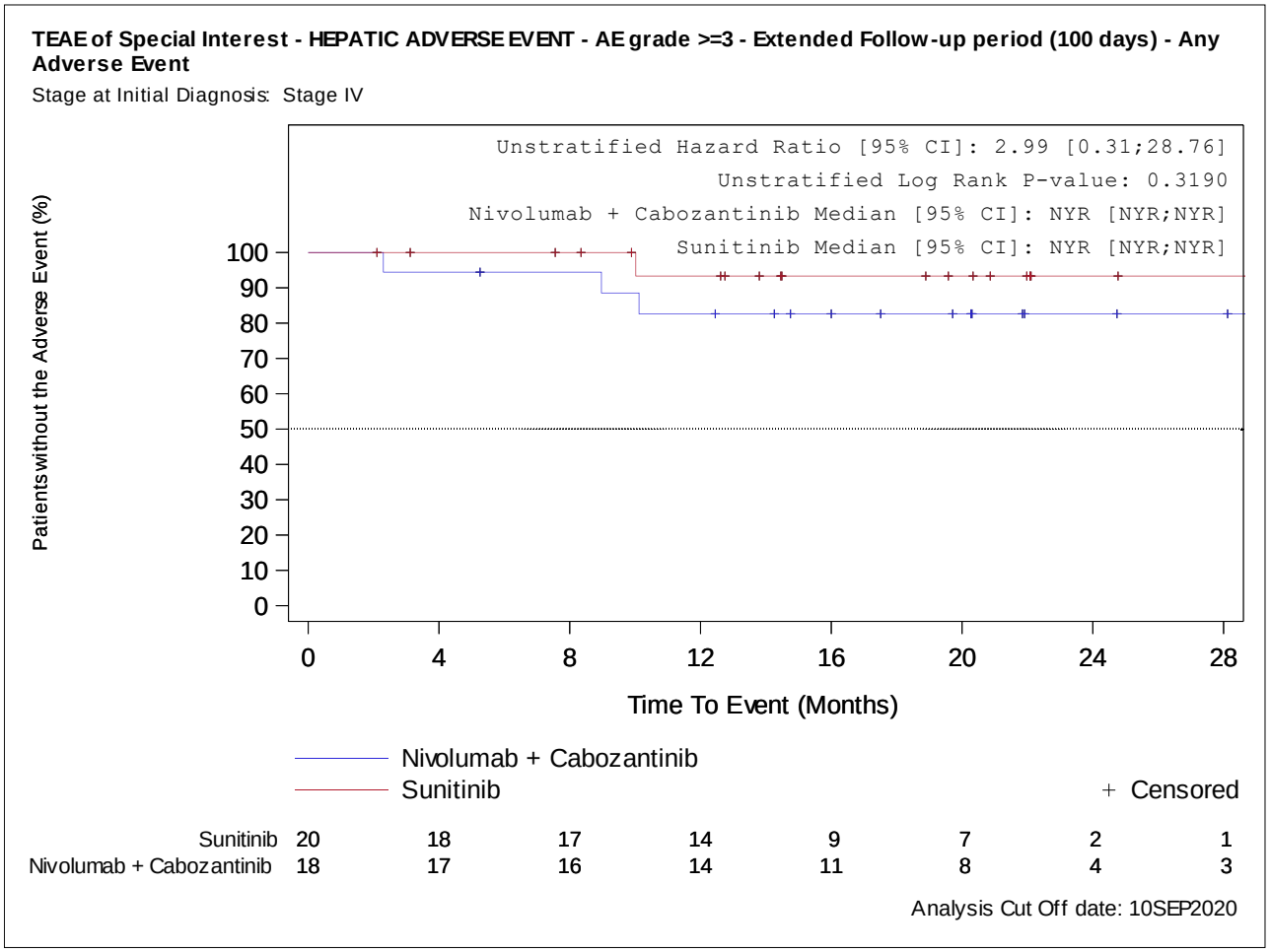

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:20:10

FIGURE 3.32.2.22: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



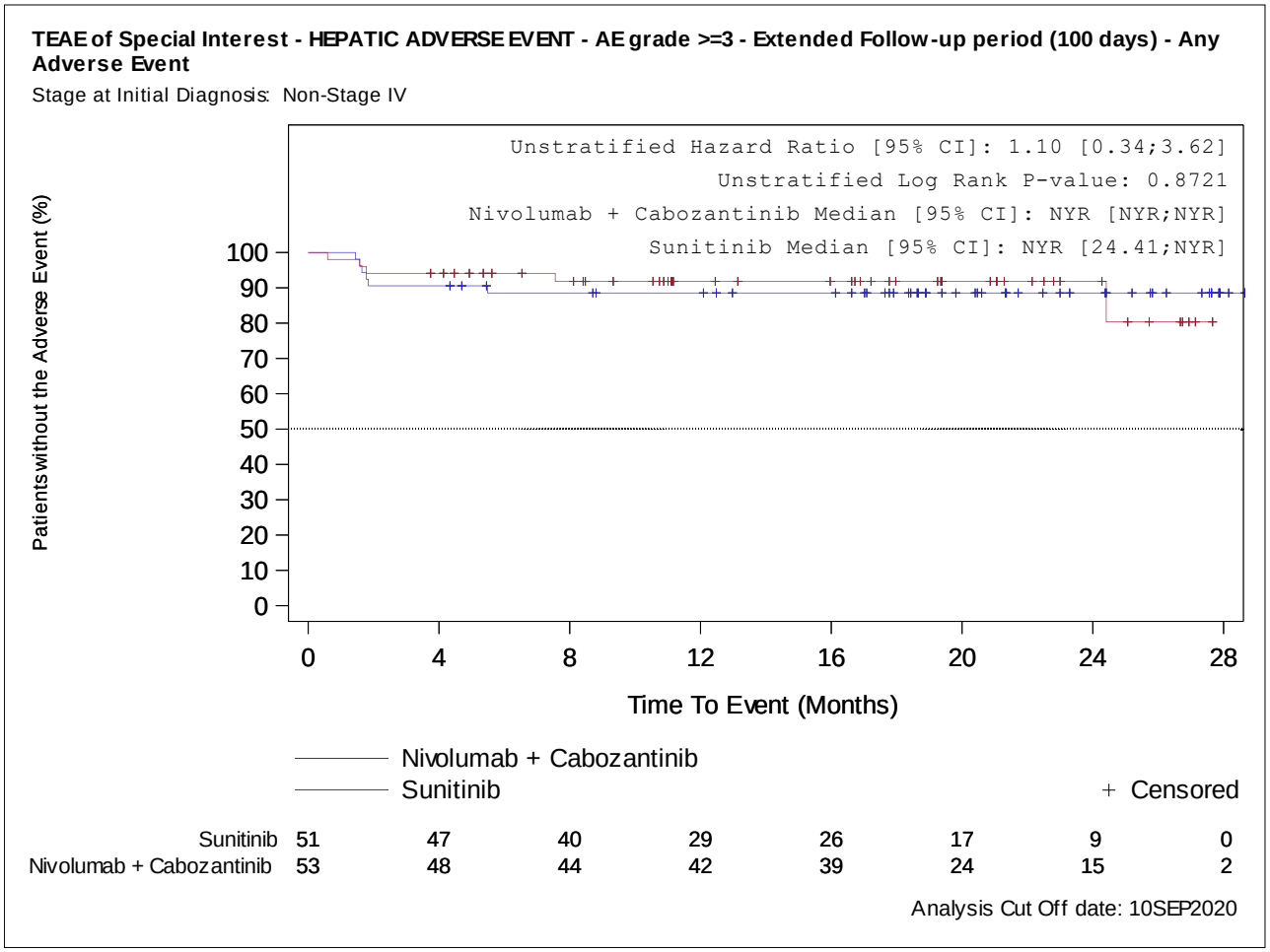

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:20:17

FIGURE 3.32.2.23: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



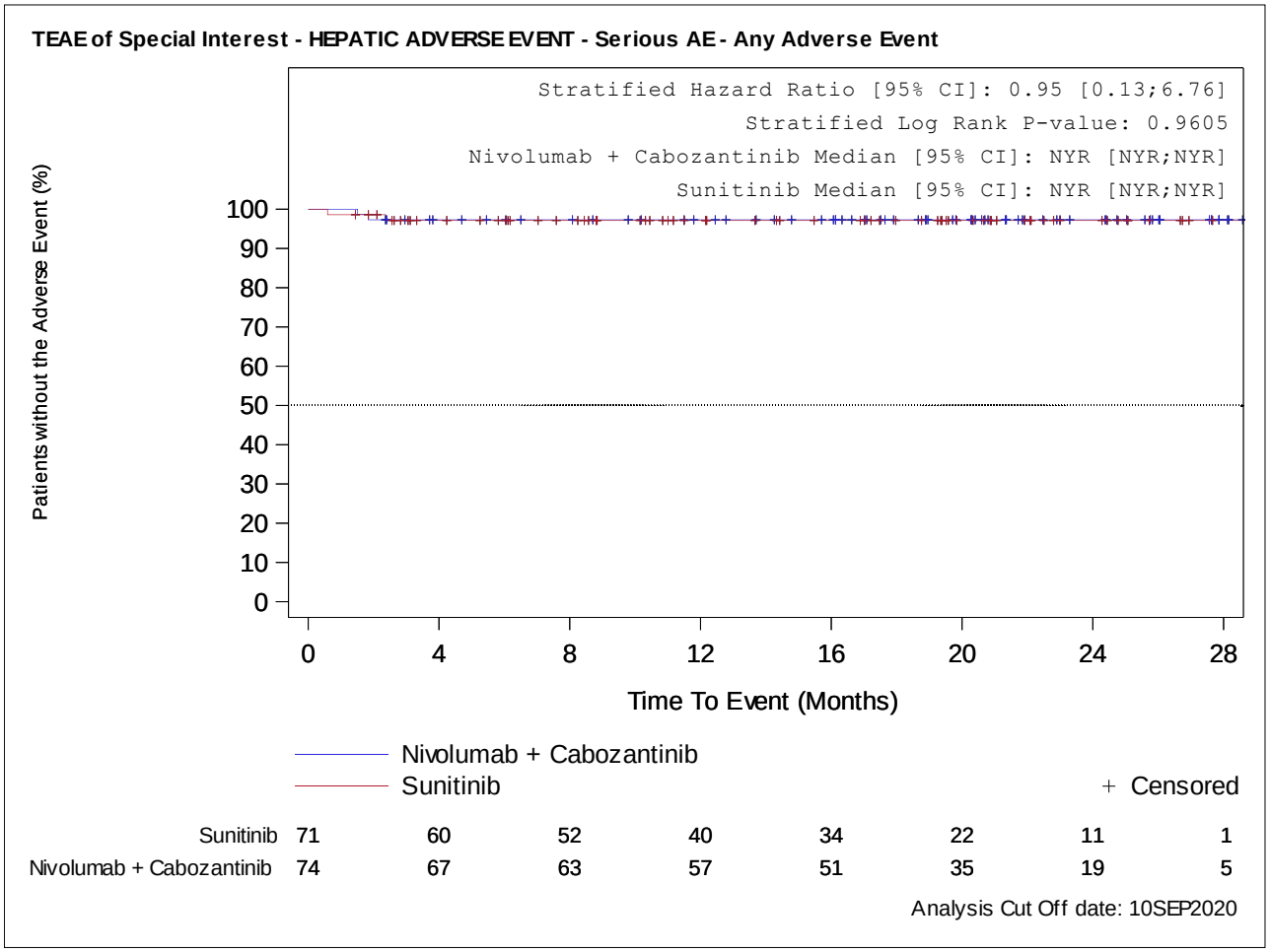

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:20:46

FIGURE 3.32.2.24: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



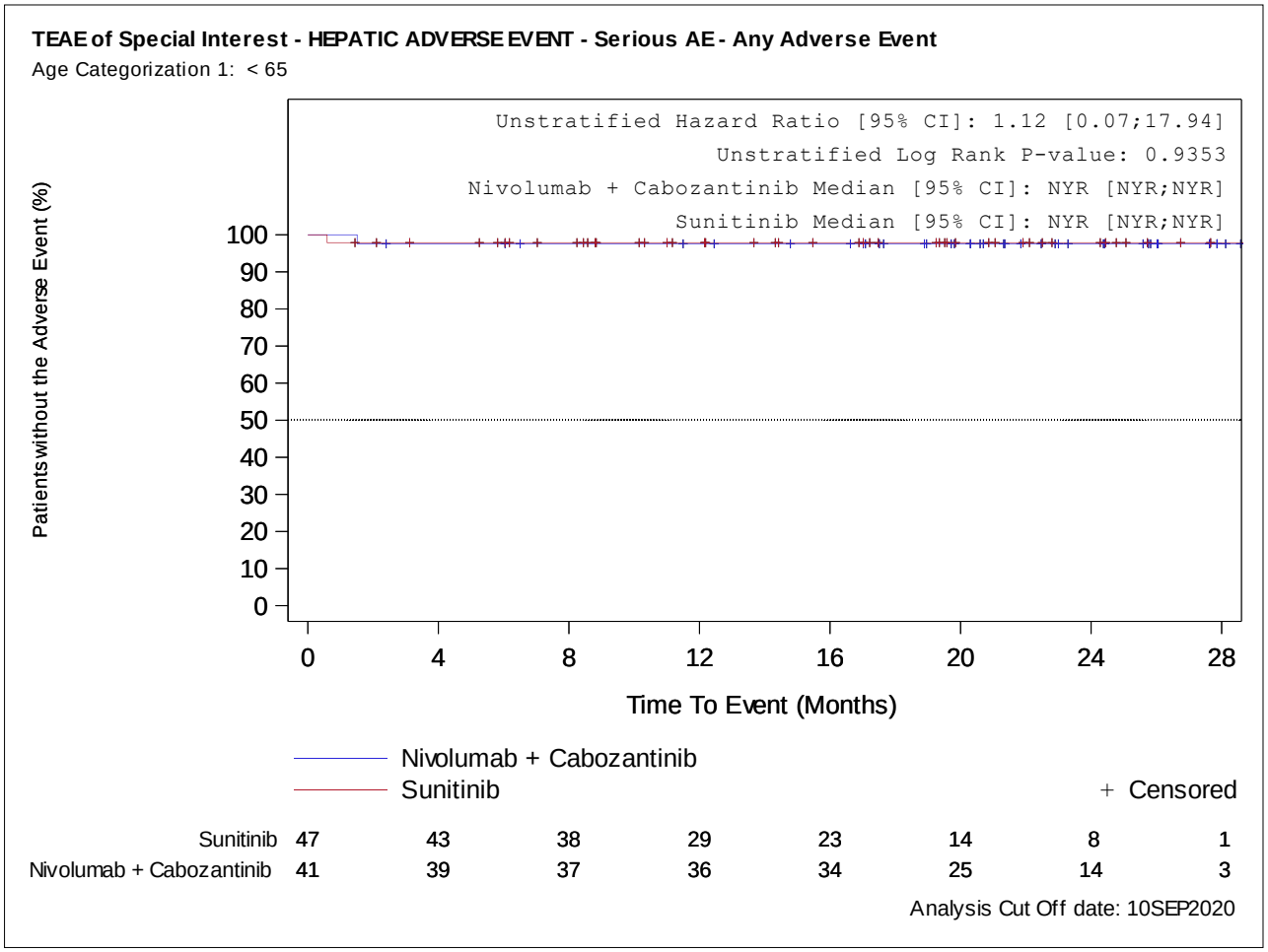

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:20:52

FIGURE 3.33.1: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



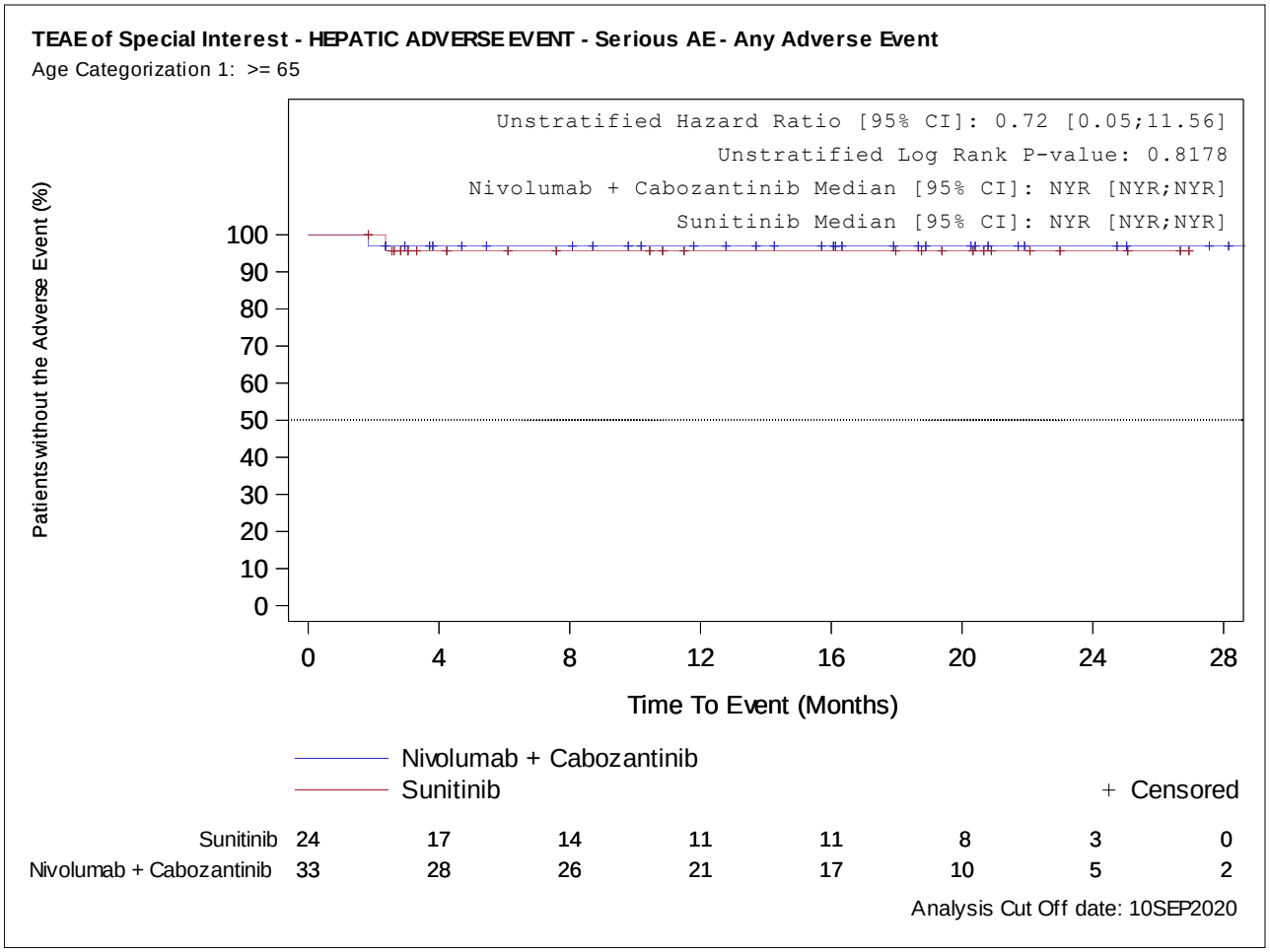

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:24:08

FIGURE 3.33.2.1: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



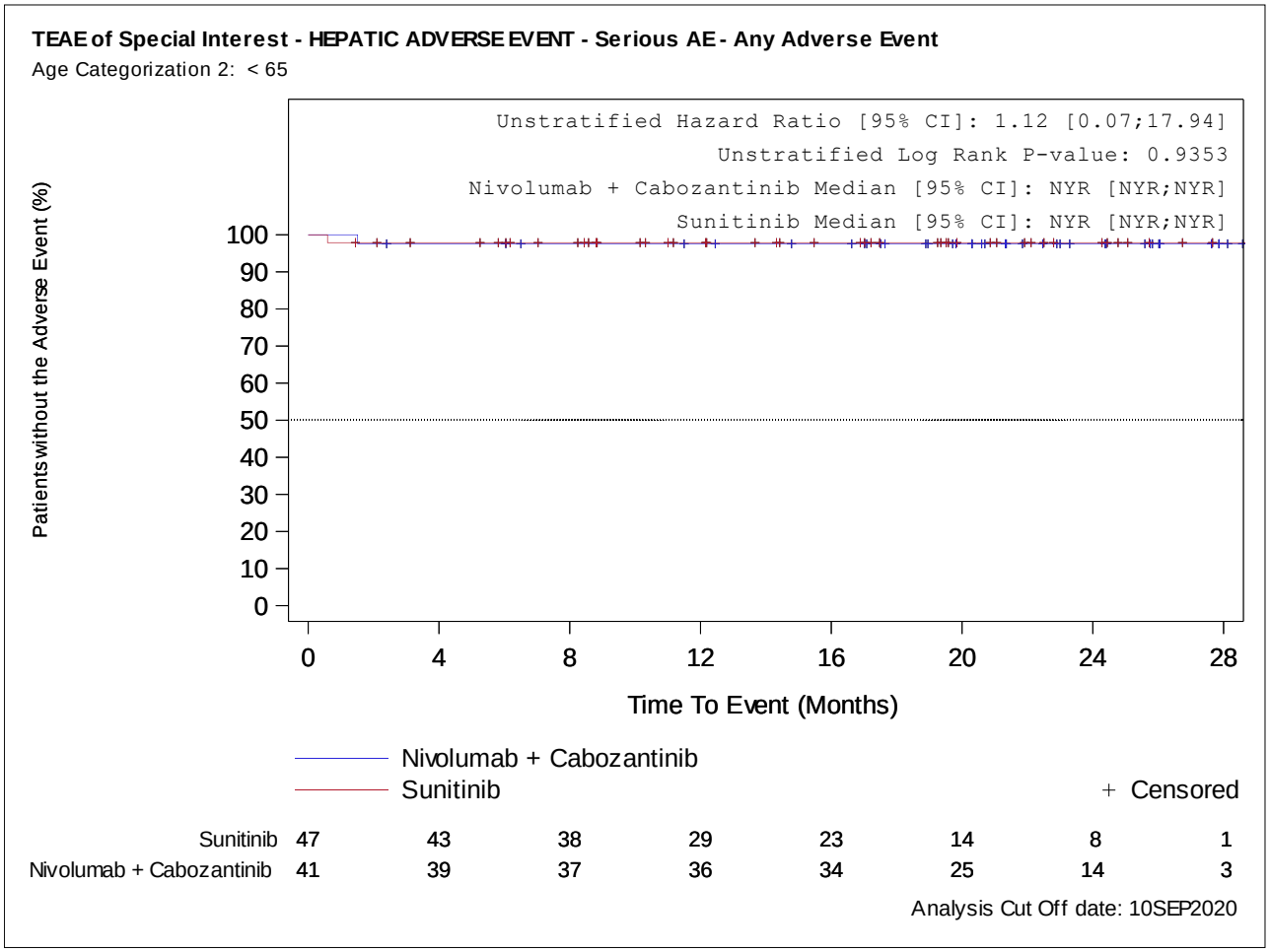

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:24:11

FIGURE 3.33.2.2: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



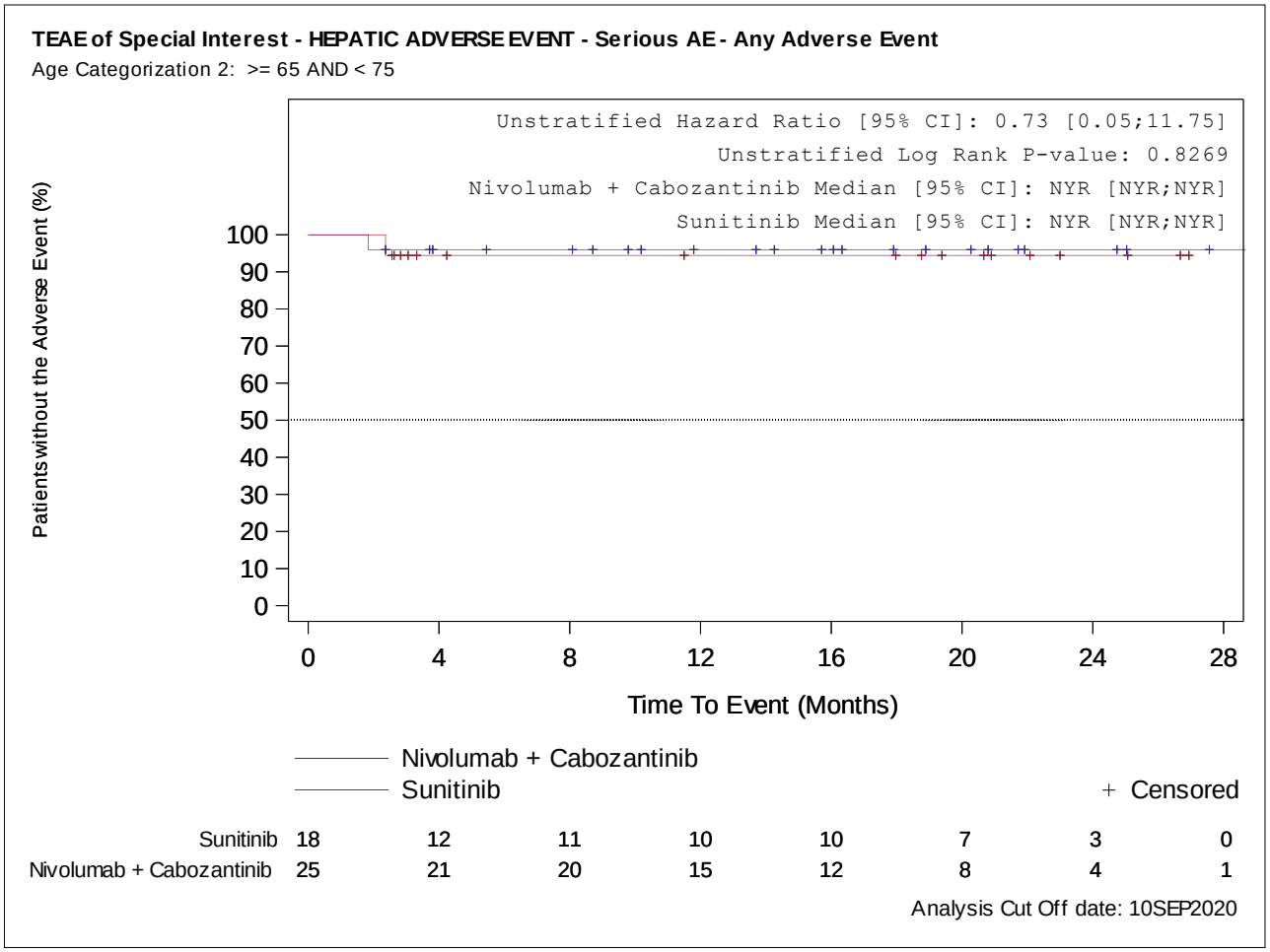

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:24:18

FIGURE 3.33.2.3: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



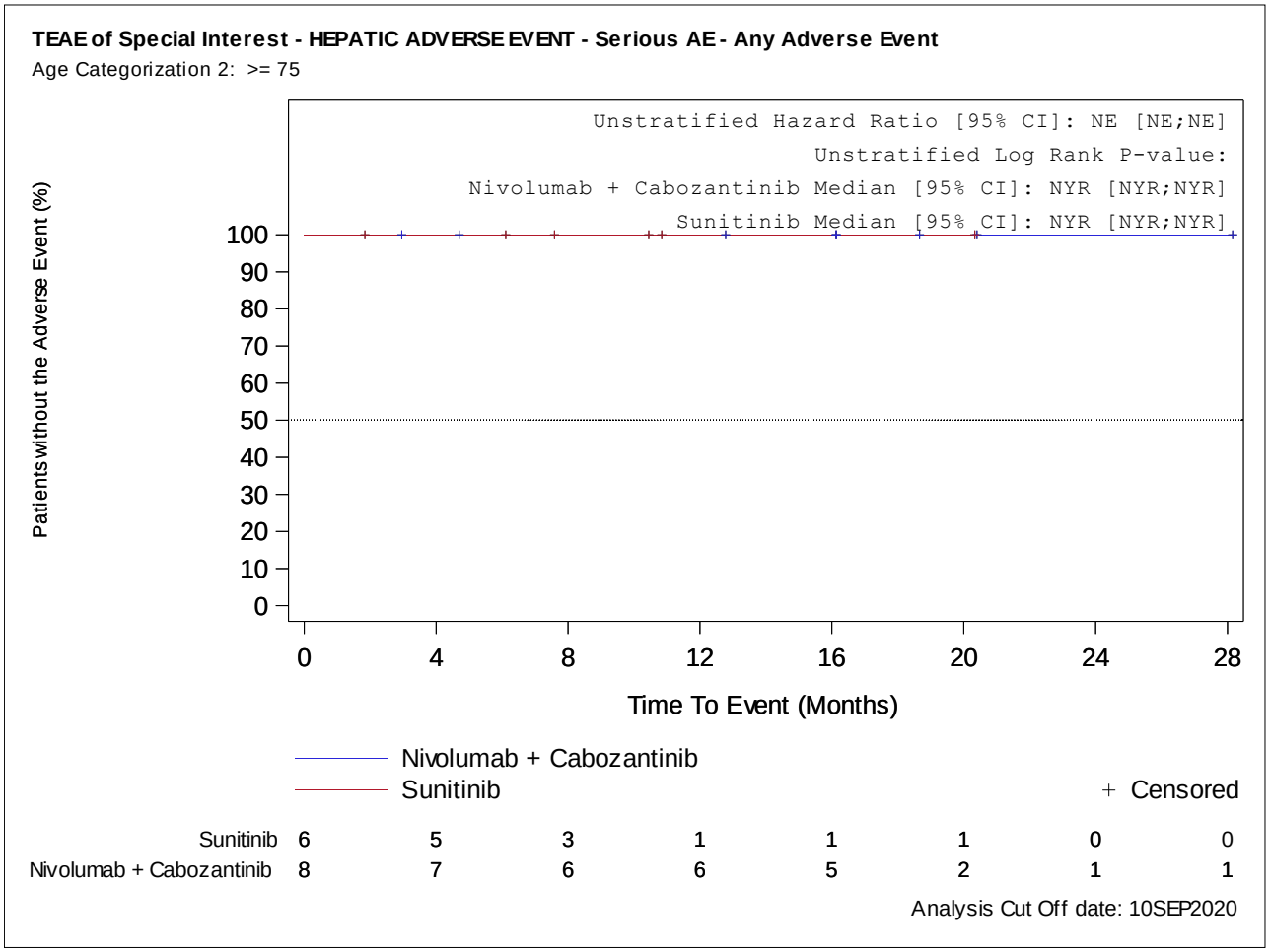

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:24:23

FIGURE 3.33.2.4: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



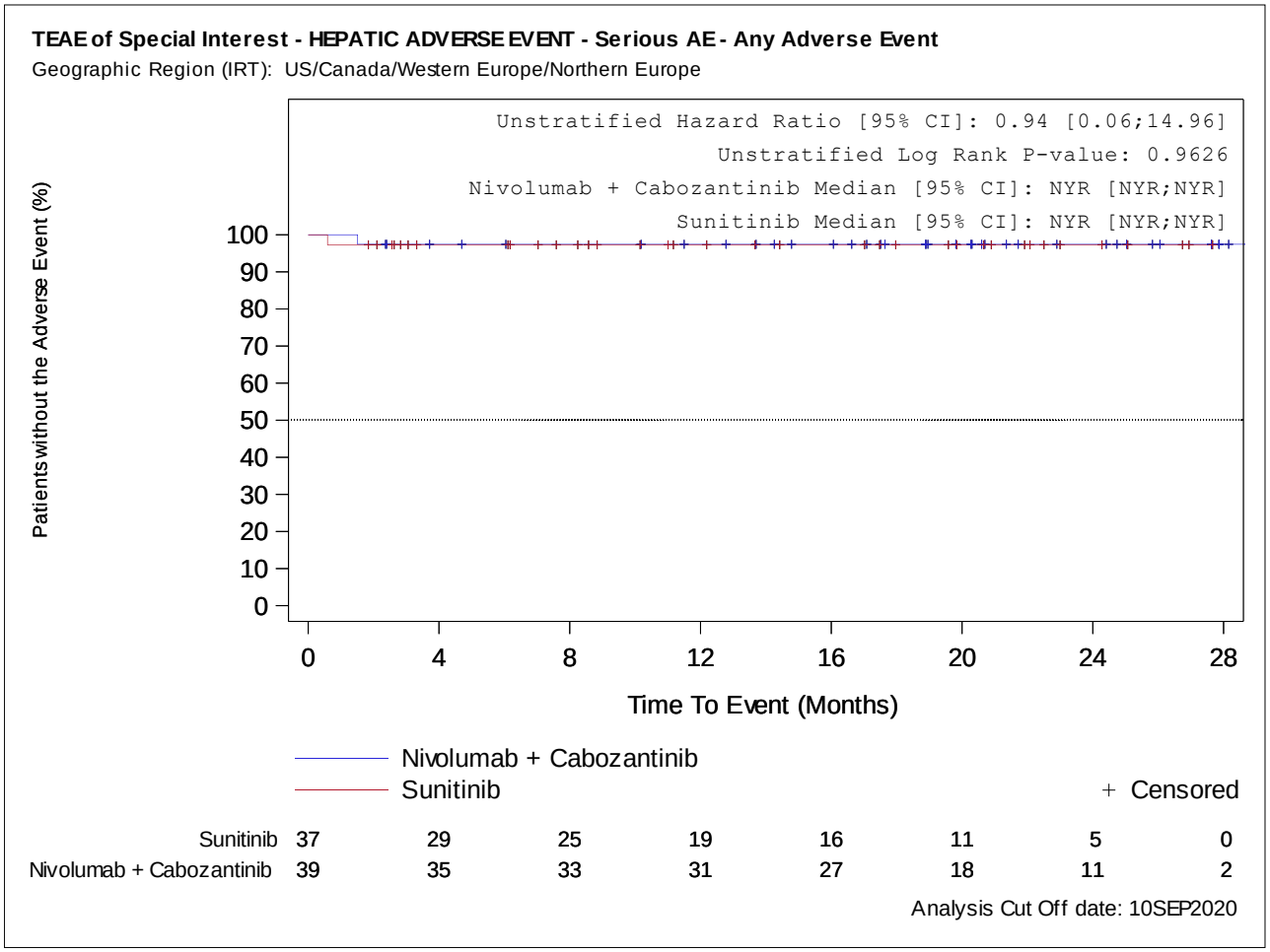

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:24:29

FIGURE 3.33.2.5: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



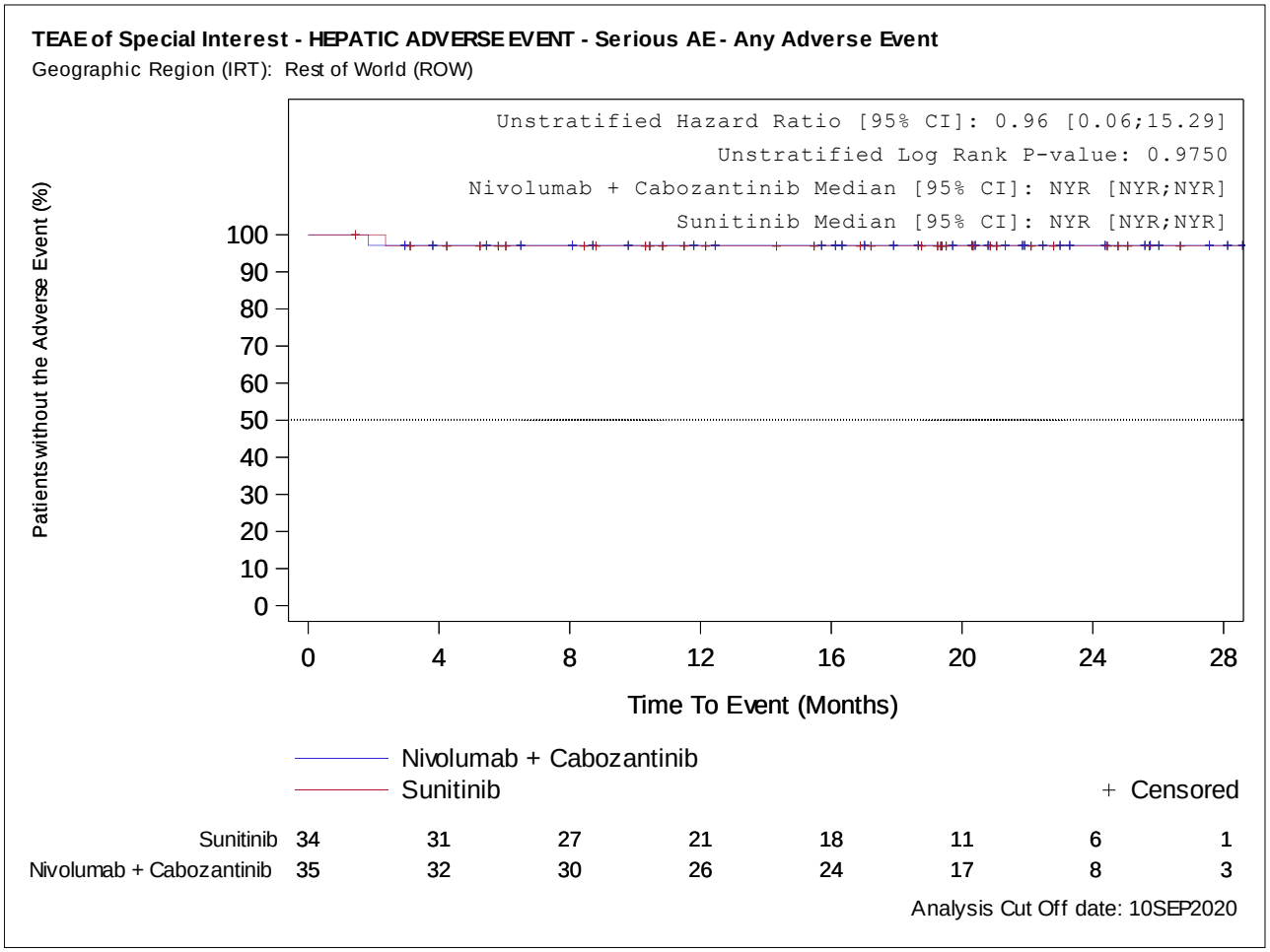

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:24:35

FIGURE 3.33.2.6: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



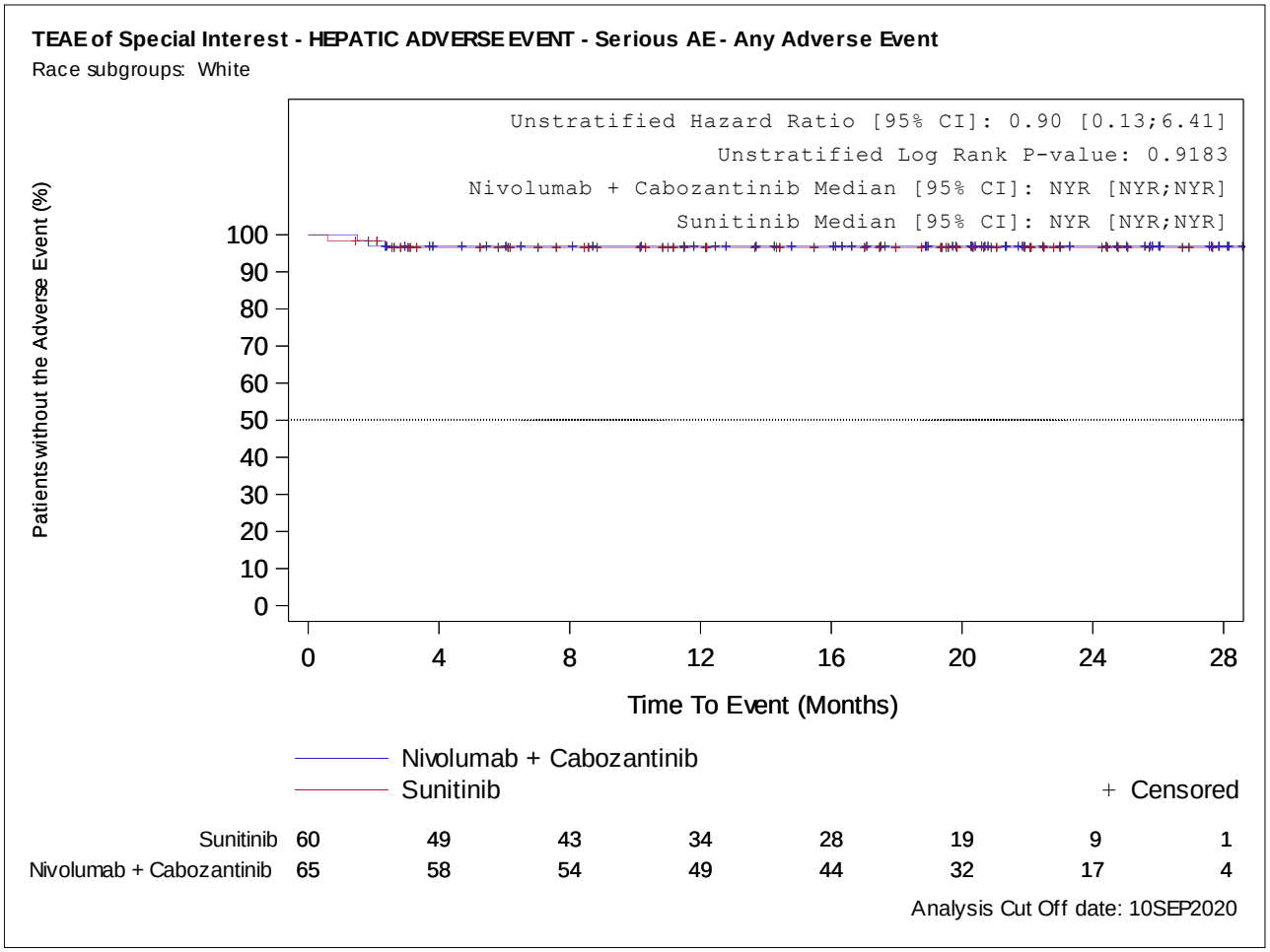

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:24:41

FIGURE 3.33.2.7: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



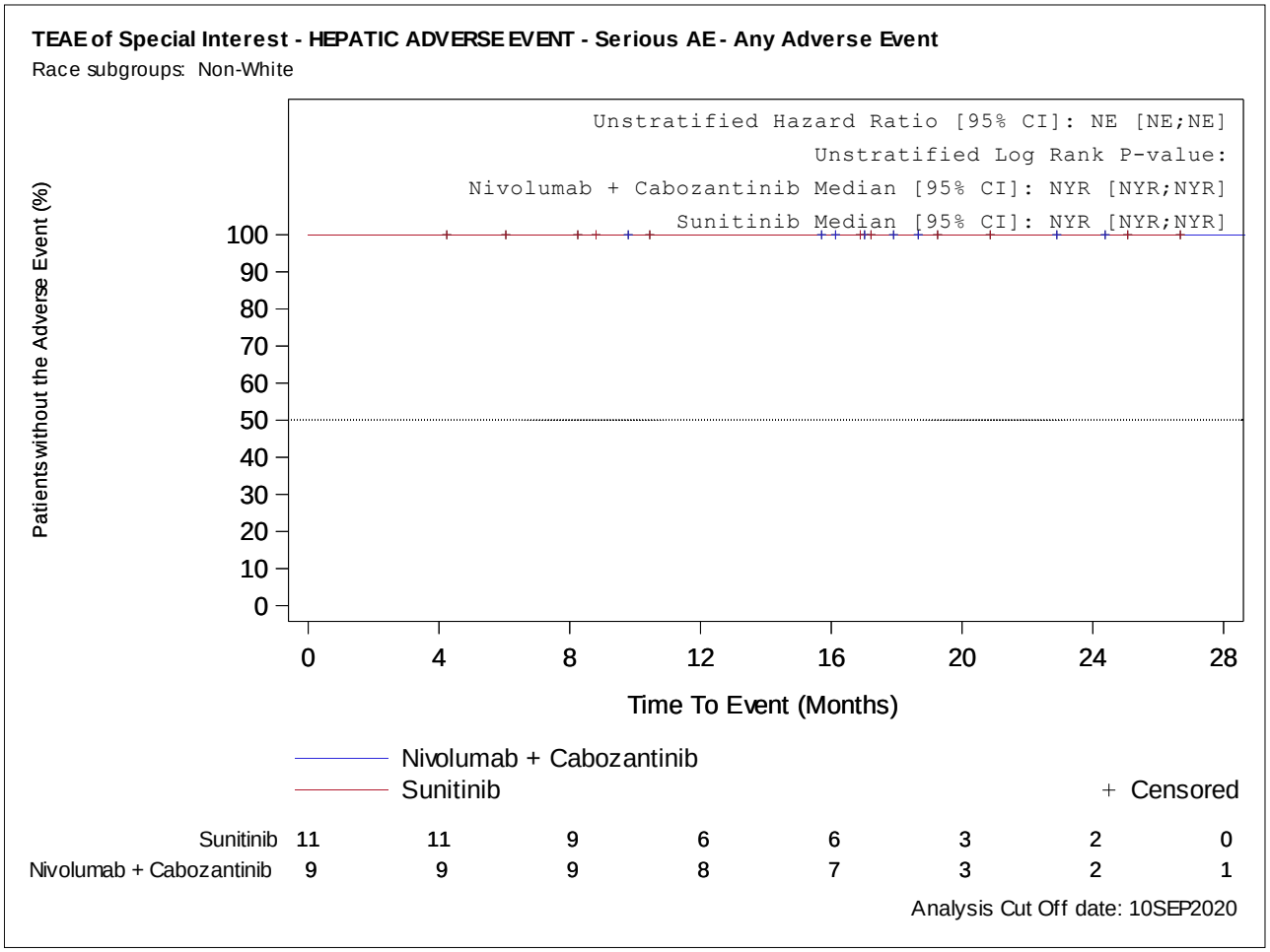

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:24:47

FIGURE 3.33.2.8: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



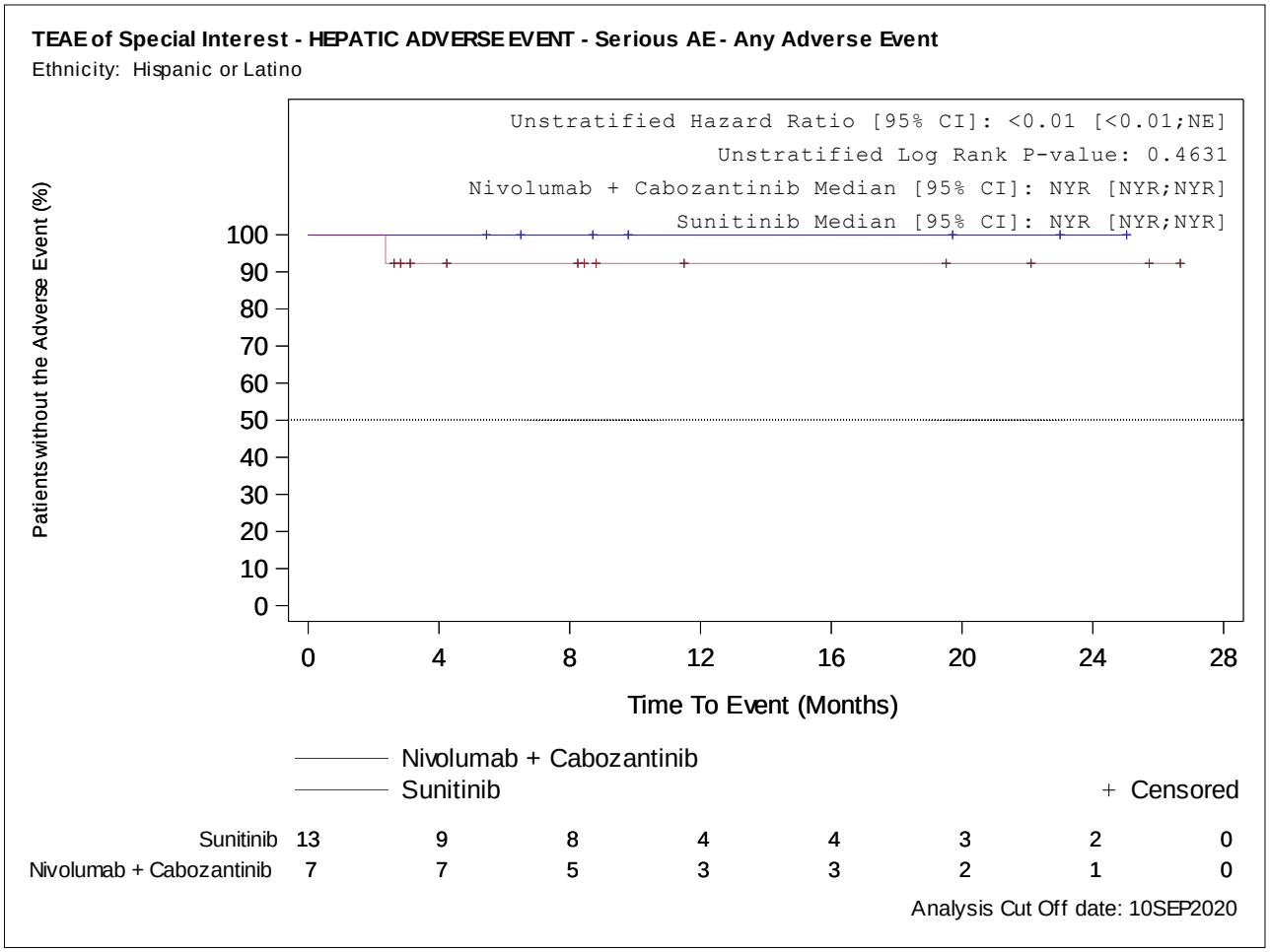

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:24:52

FIGURE 3.33.2.9: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



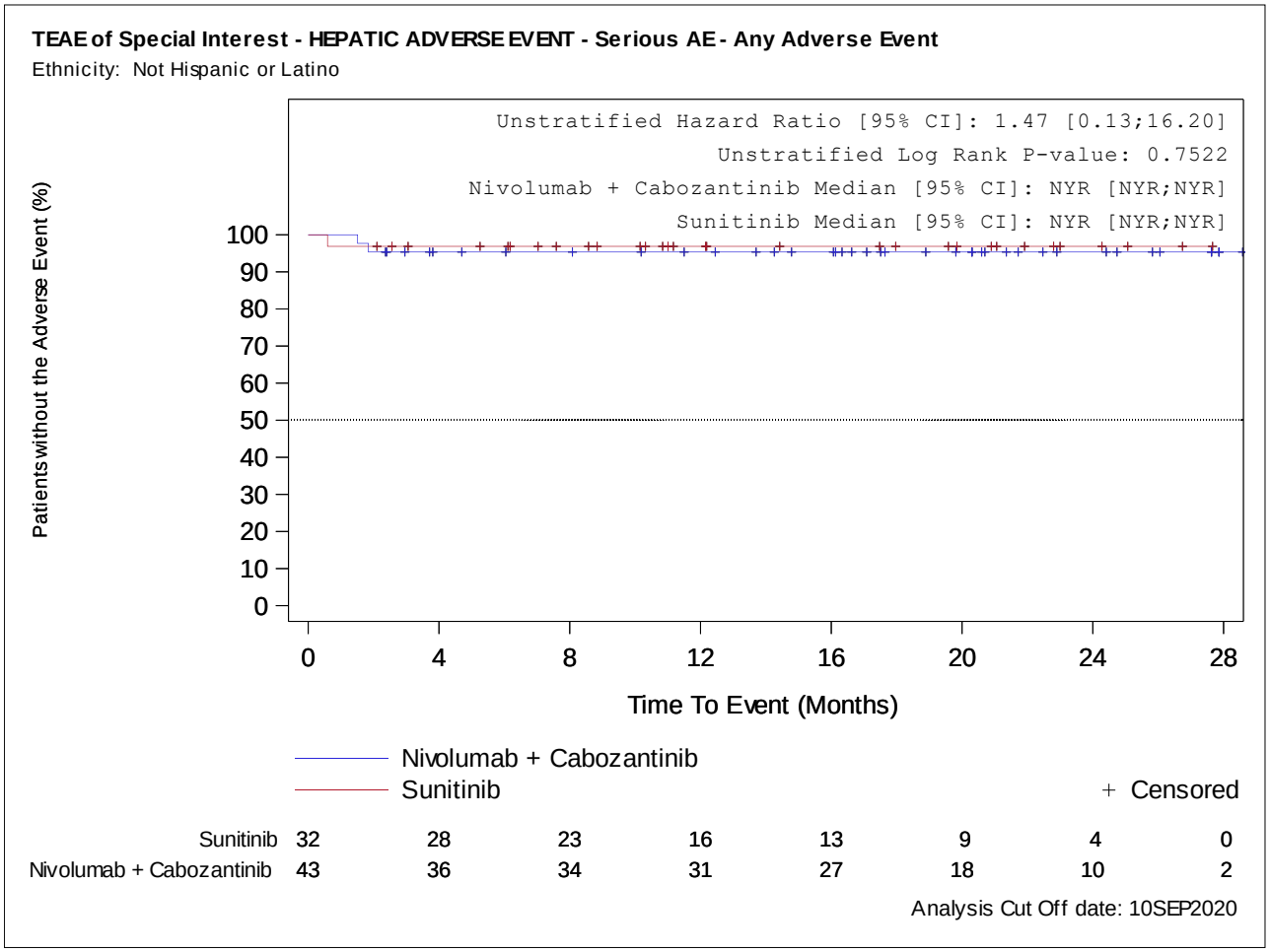

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:24:58

FIGURE 3.33.2.10: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



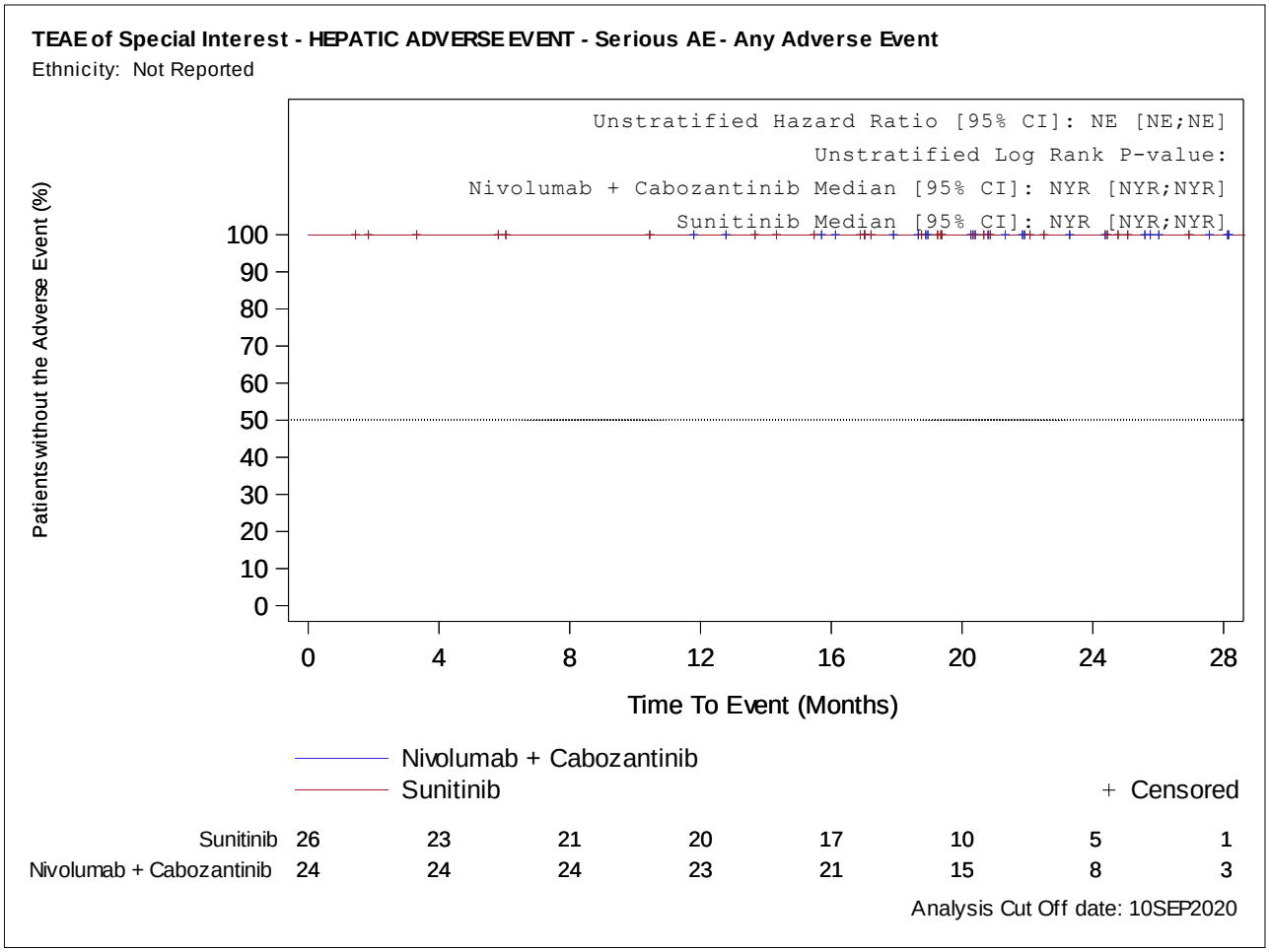

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:25:04

FIGURE 3.33.2.11: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



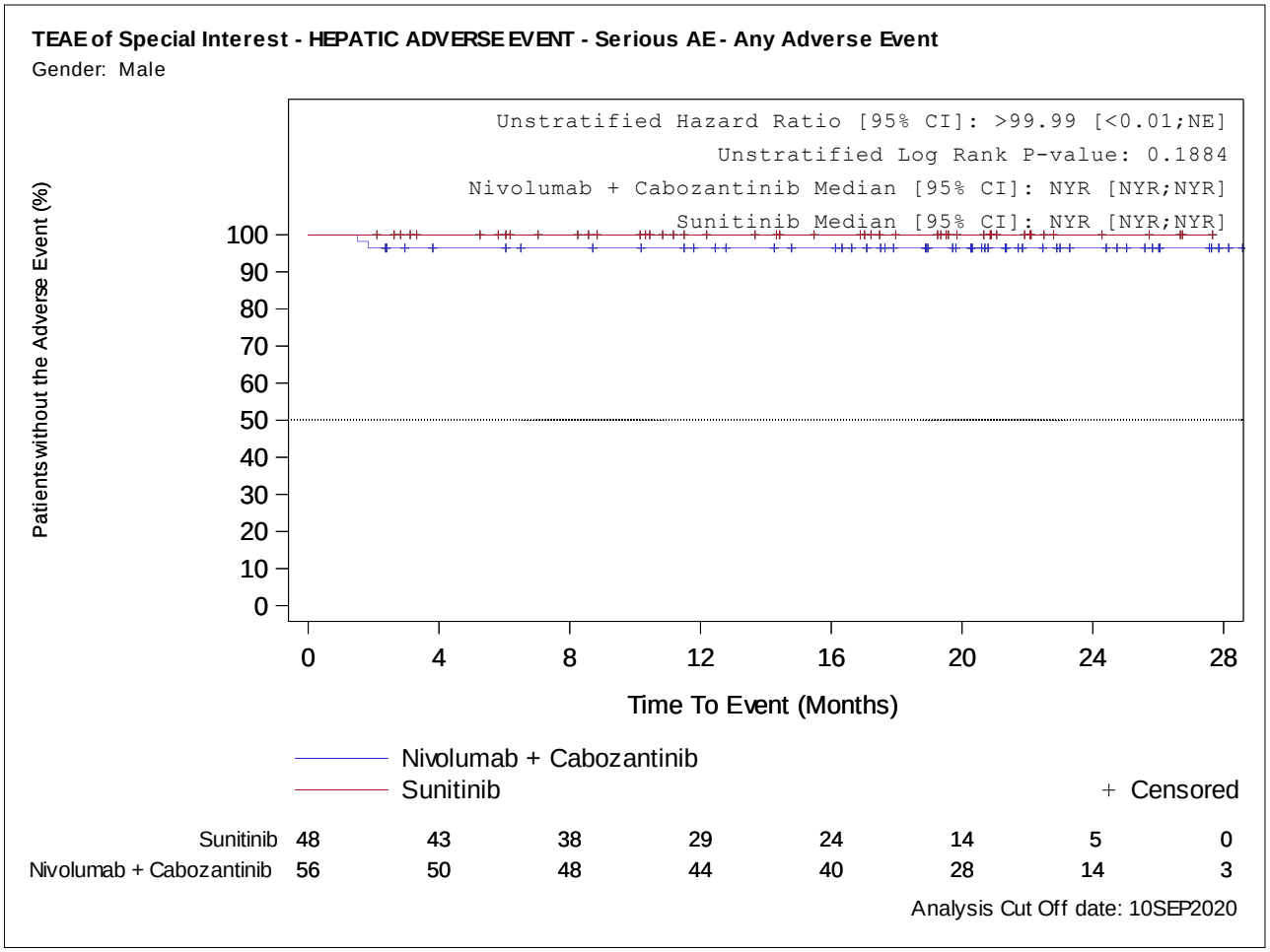

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:25:11

FIGURE 3.33.2.12: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



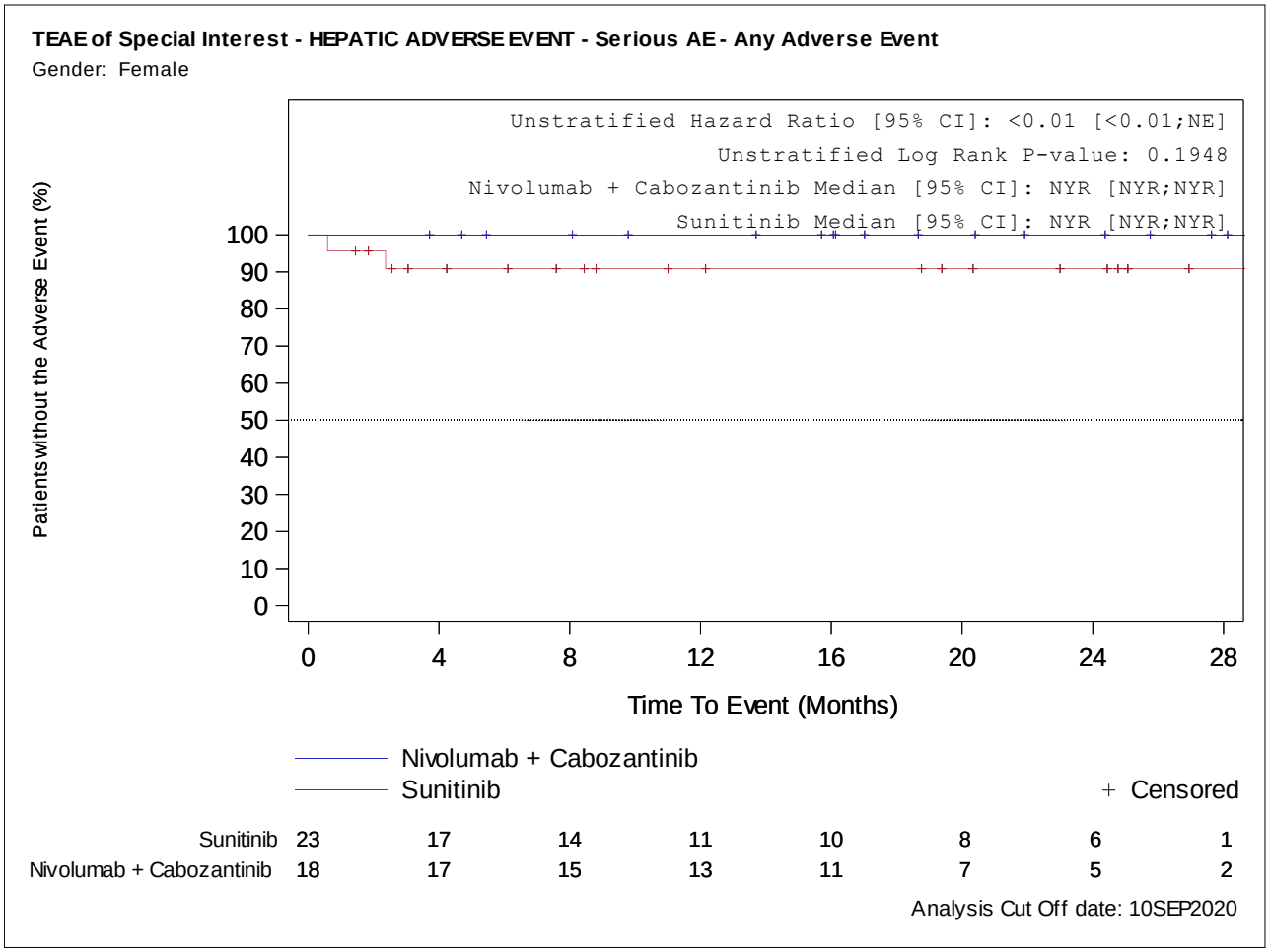

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:25:17

FIGURE 3.33.2.13: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



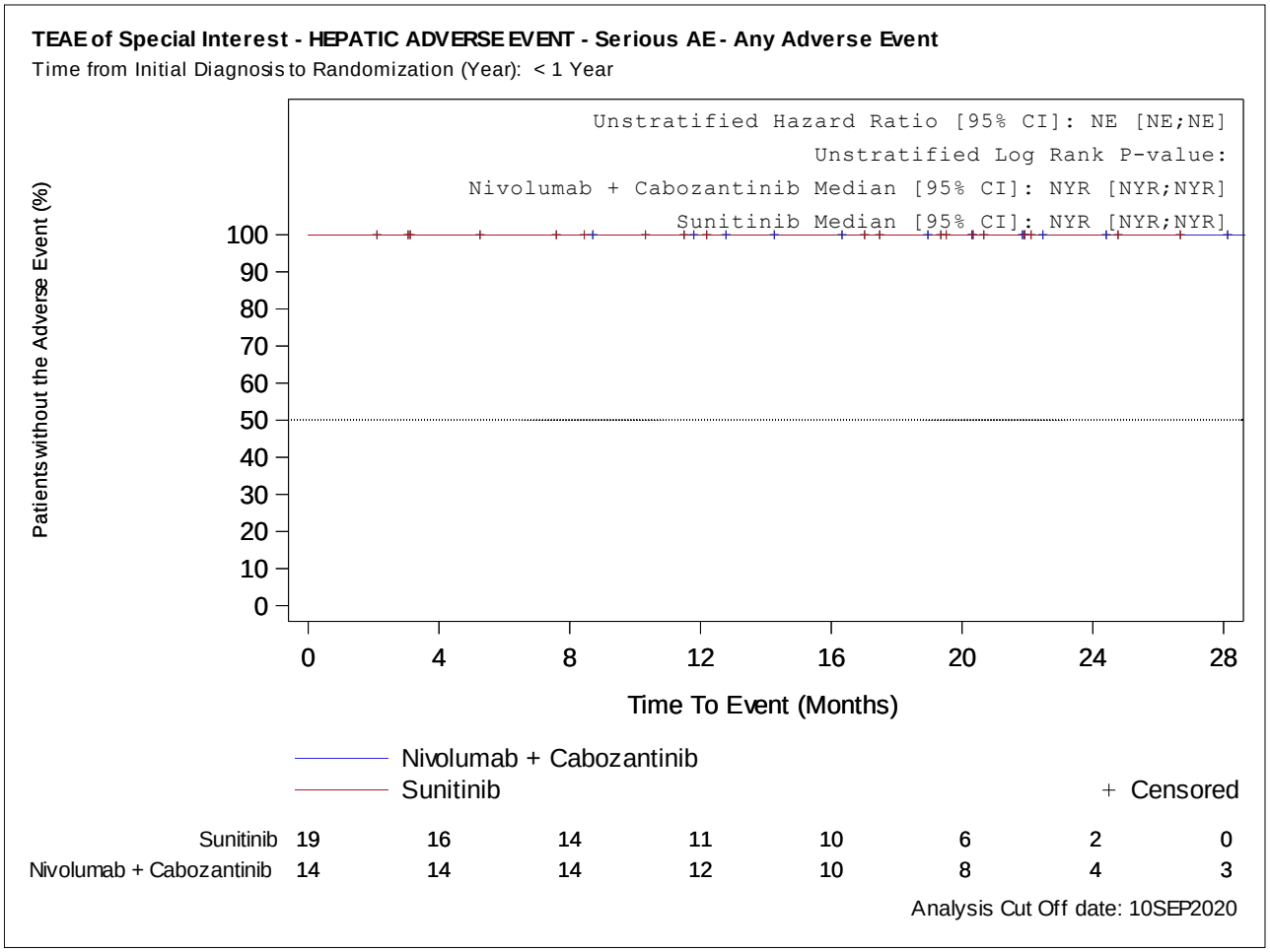

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:25:23

FIGURE 3.33.2.14: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



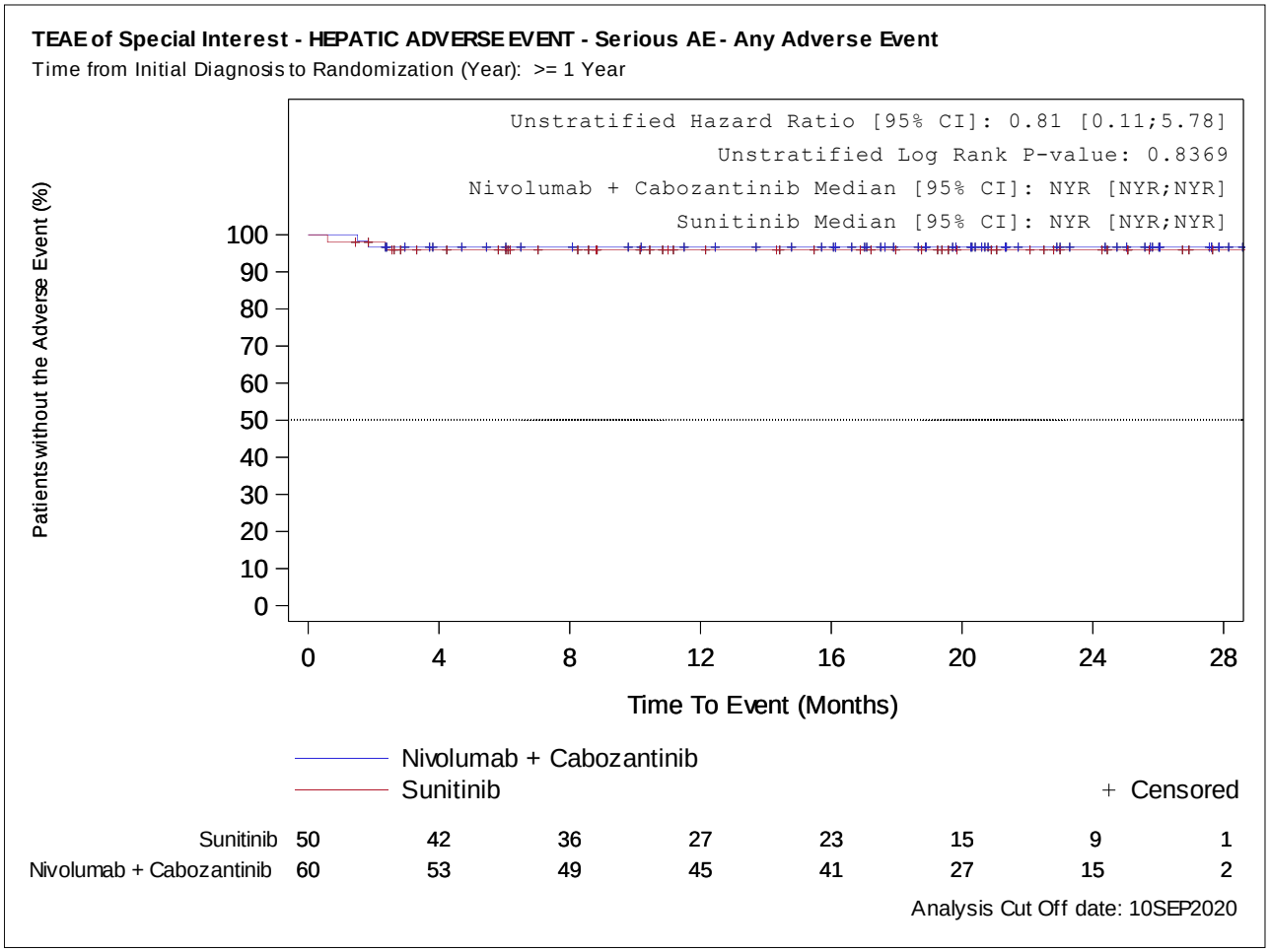

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:25:29

FIGURE 3.33.2.15: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



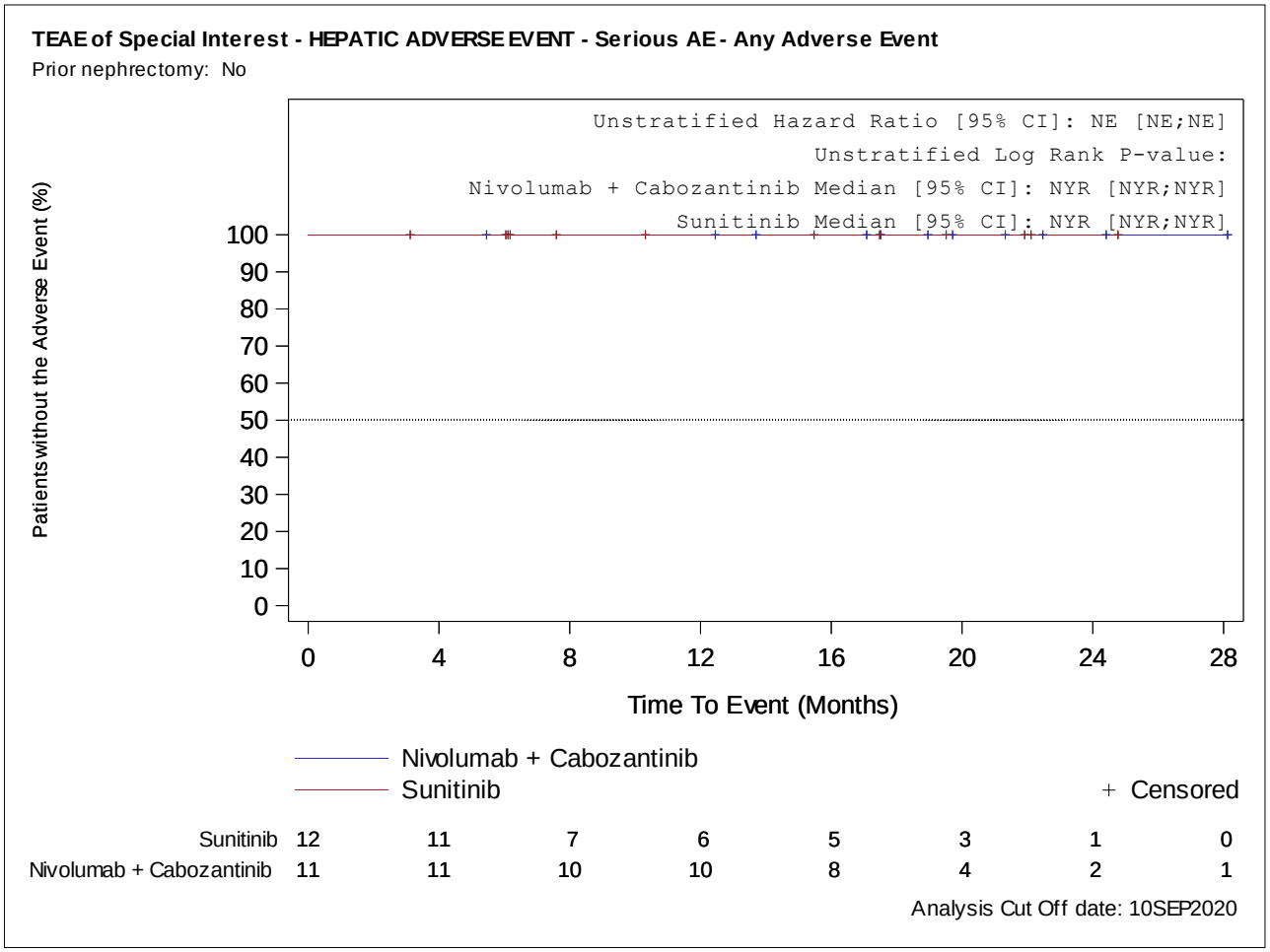

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:25:47

FIGURE 3.33.2.16: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



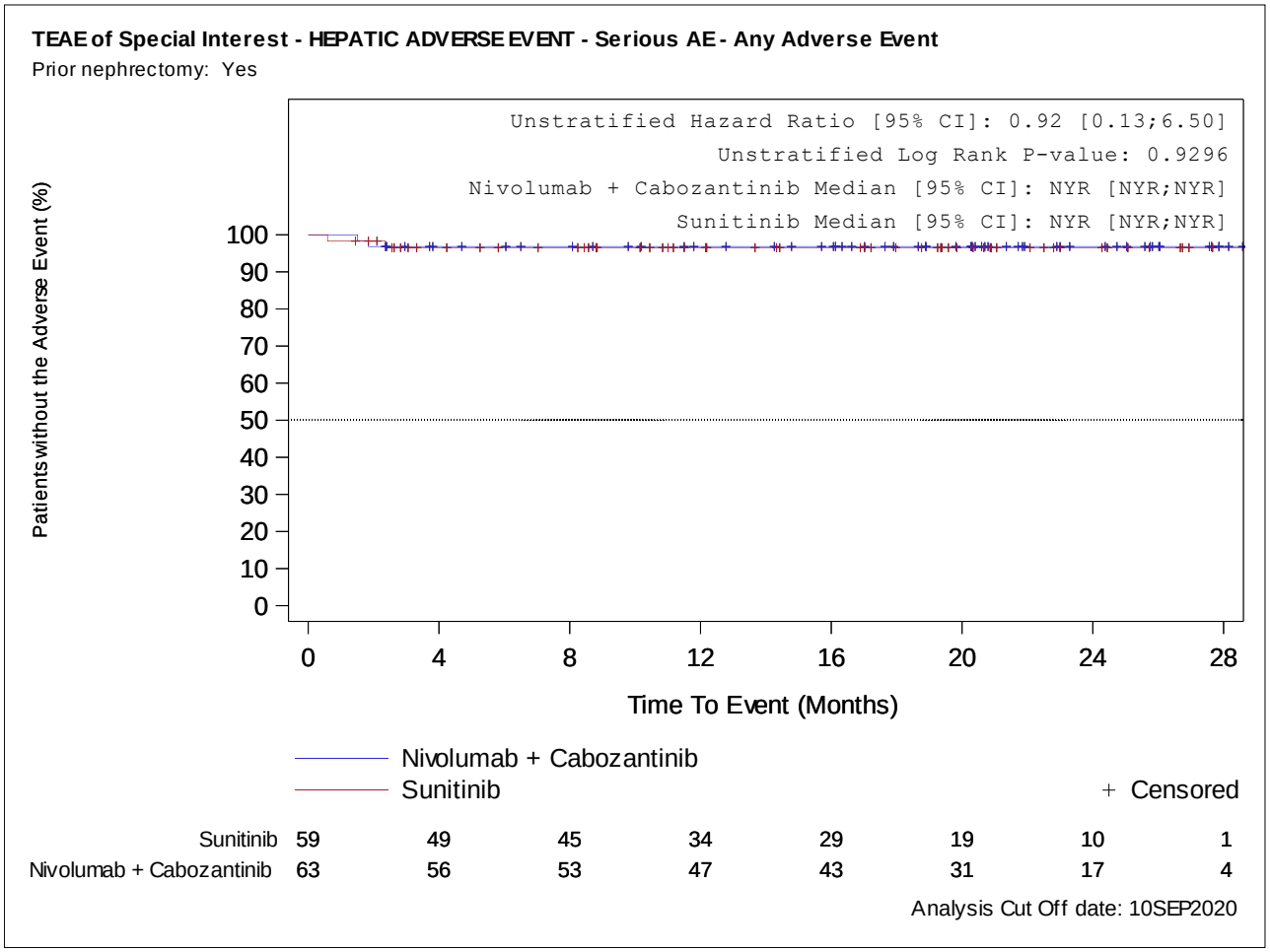

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:25:53

FIGURE 3.33.2.17: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



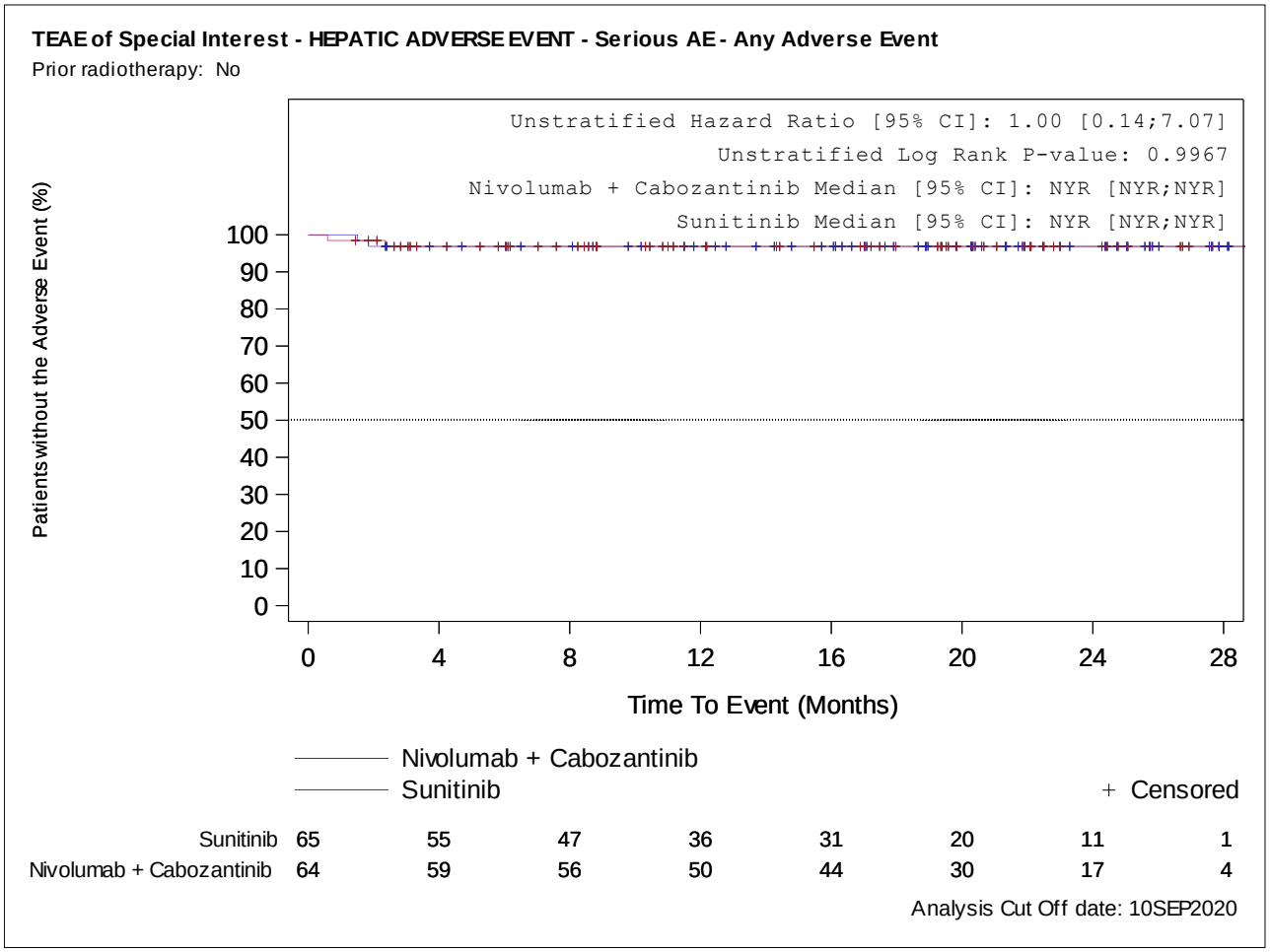

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:26:46

FIGURE 3.33.2.18: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



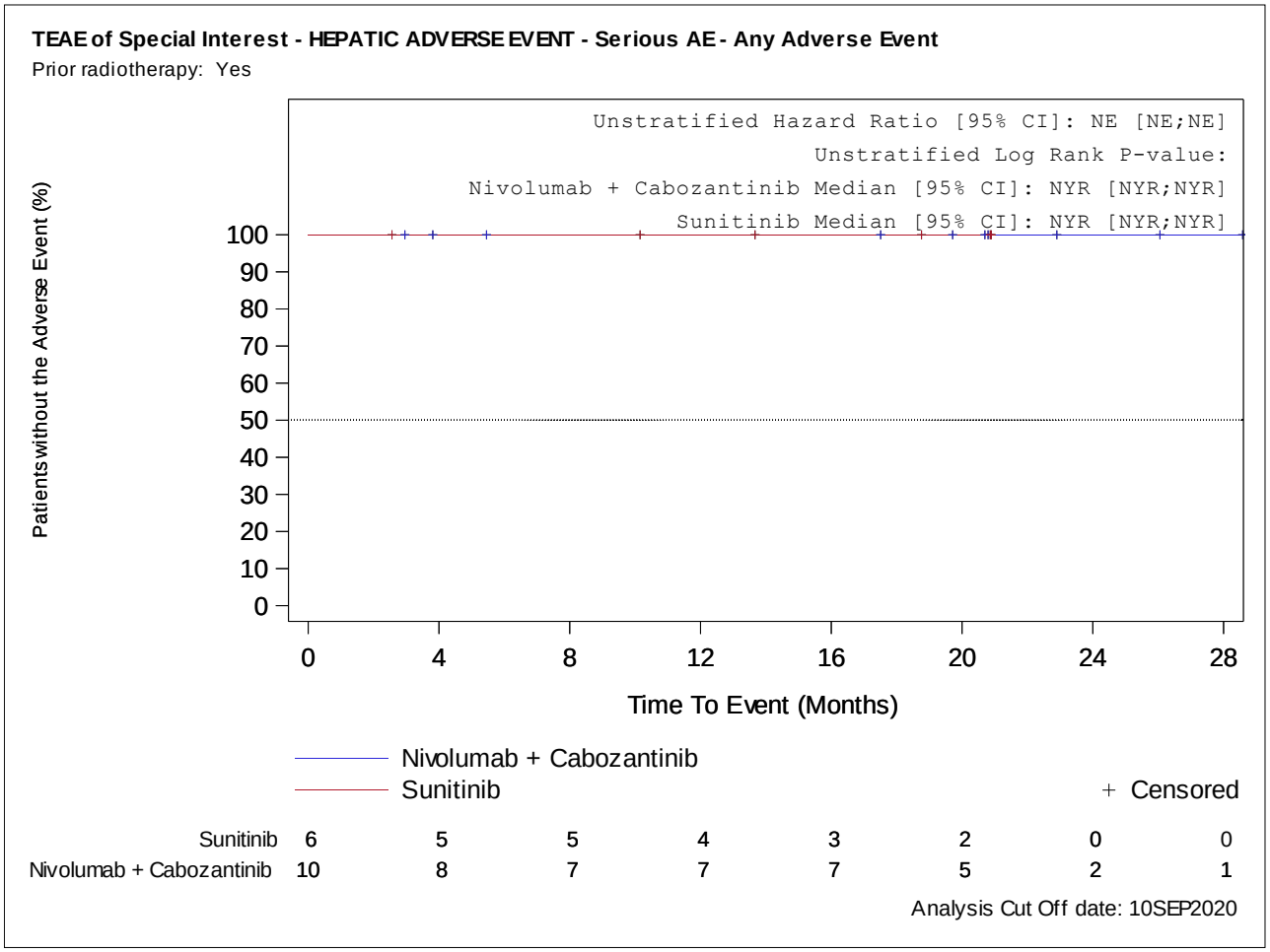

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:26:52

FIGURE 3.33.2.19: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



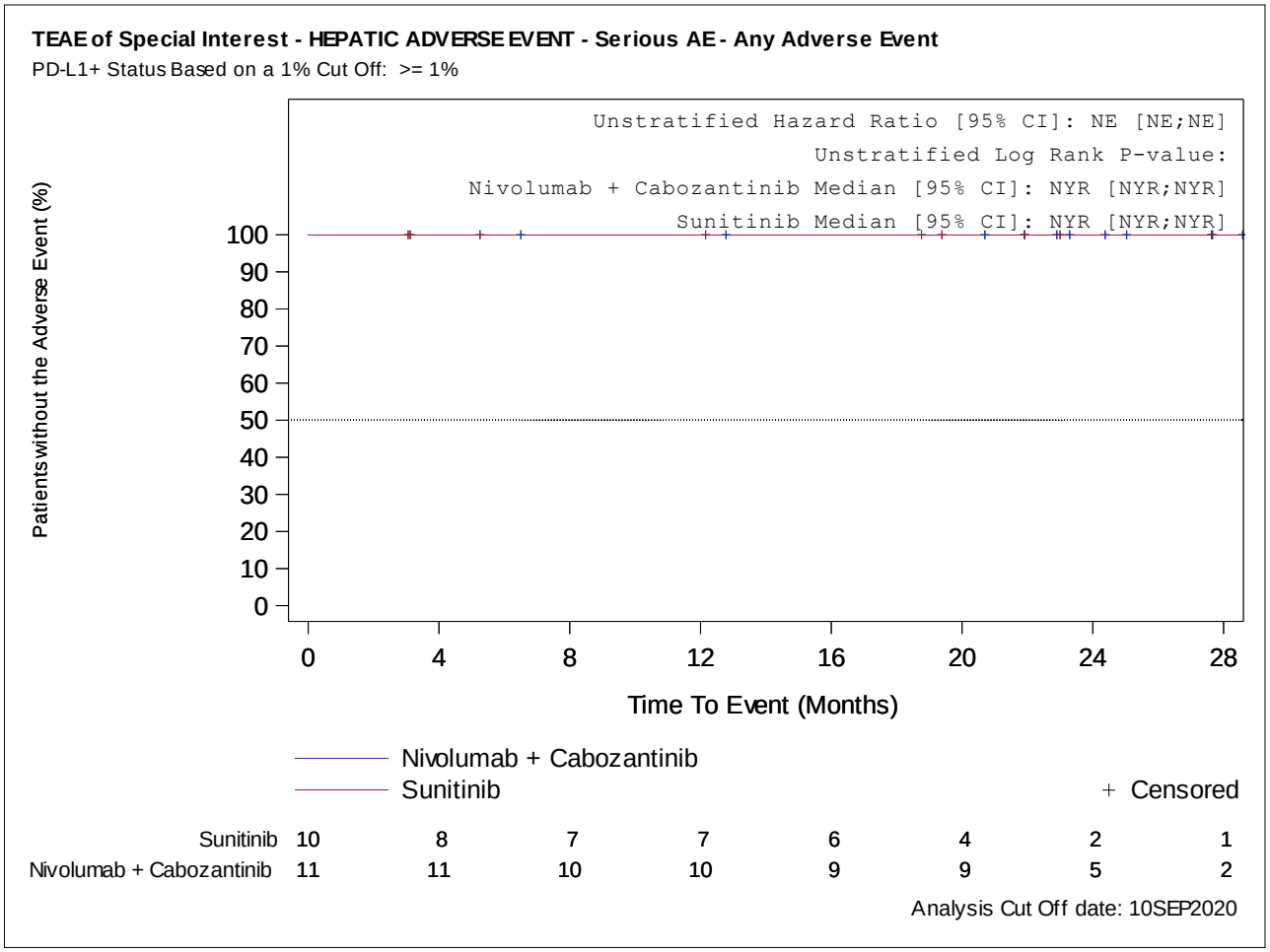

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:26:58

FIGURE 3.33.2.20: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



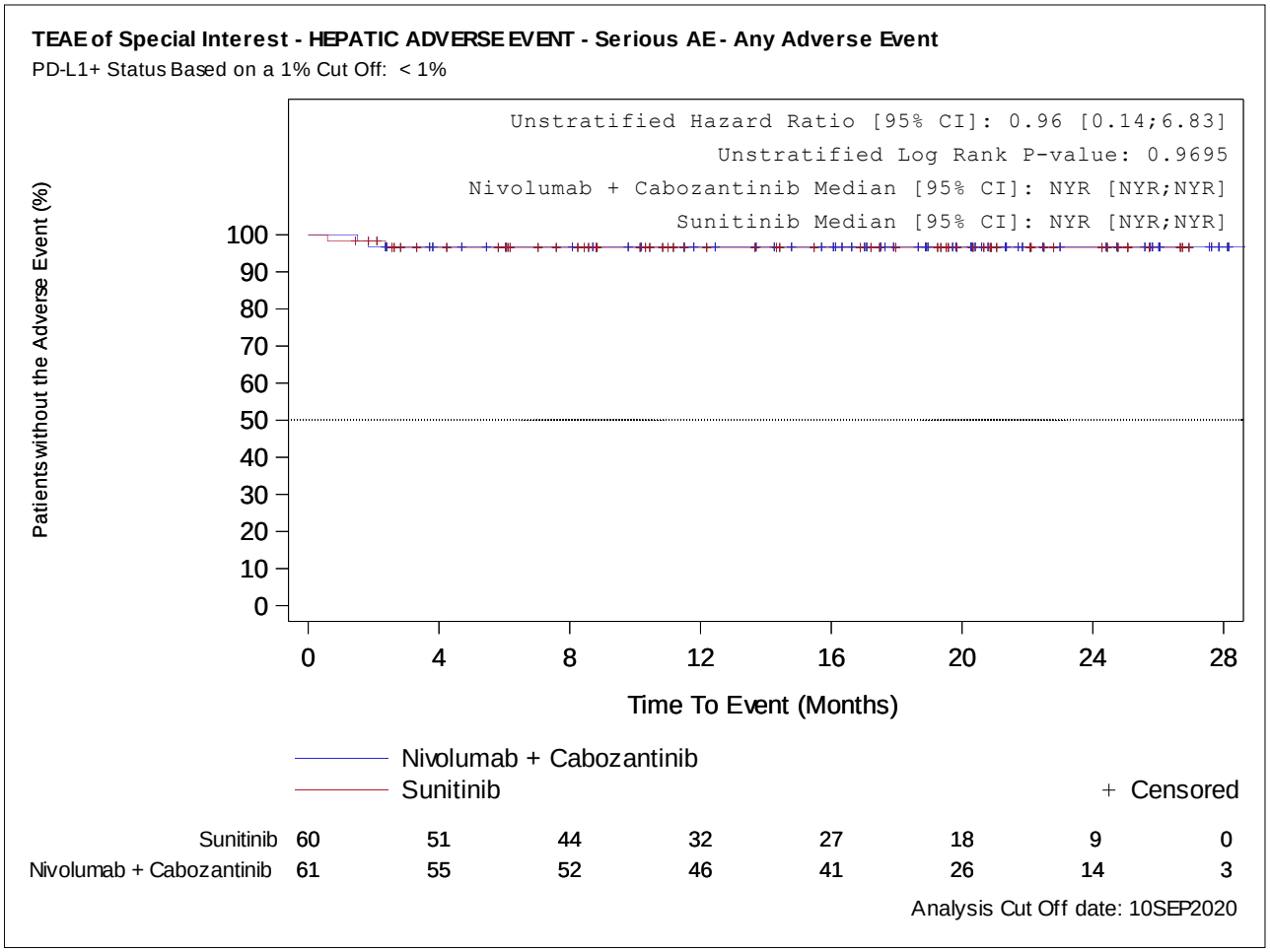

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:27:03

FIGURE 3.33.2.21: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



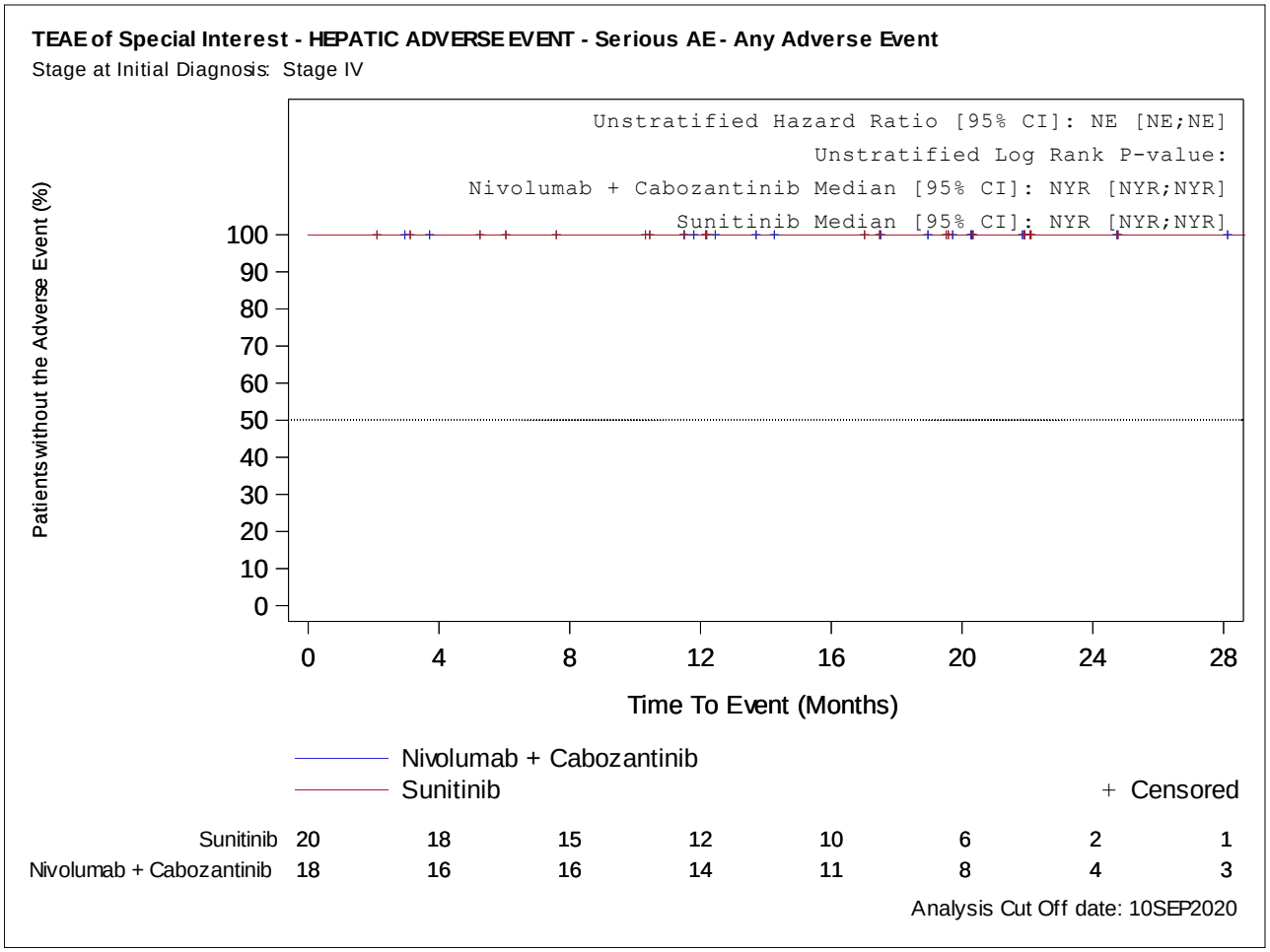

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:27:09

FIGURE 3.33.2.22: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



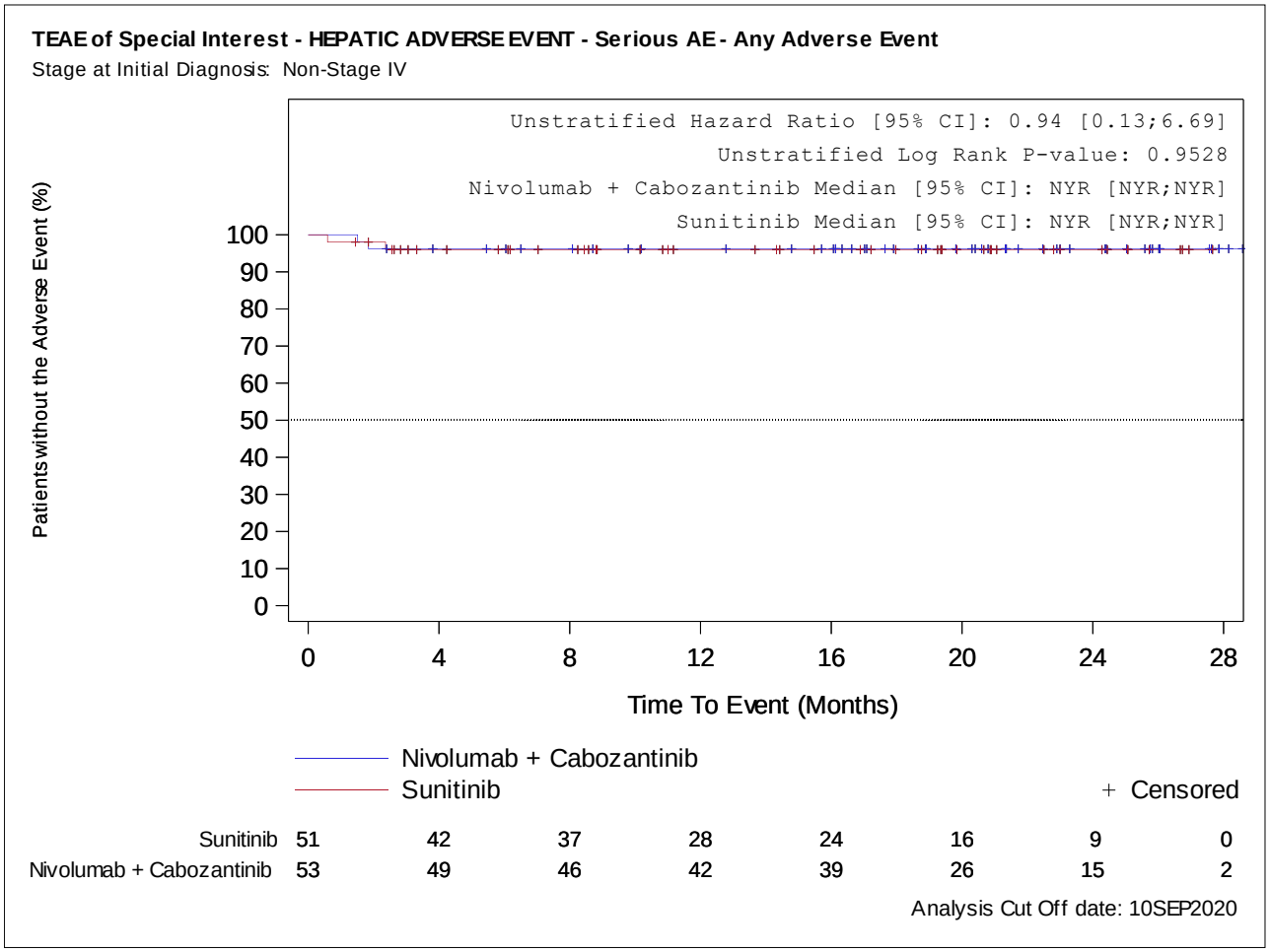

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:27:15

FIGURE 3.33.2.23: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



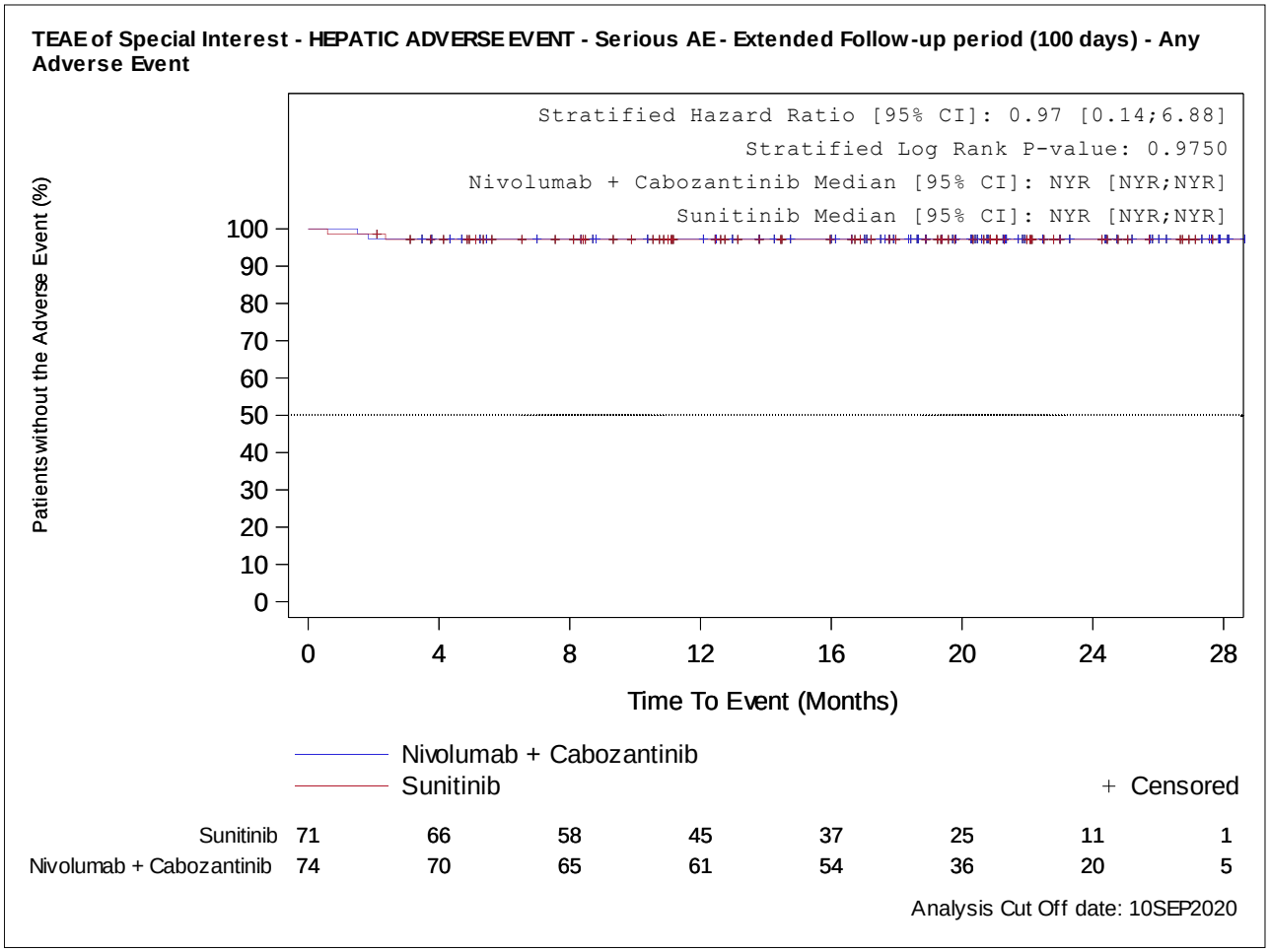

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:27:45

FIGURE 3.33.2.24: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



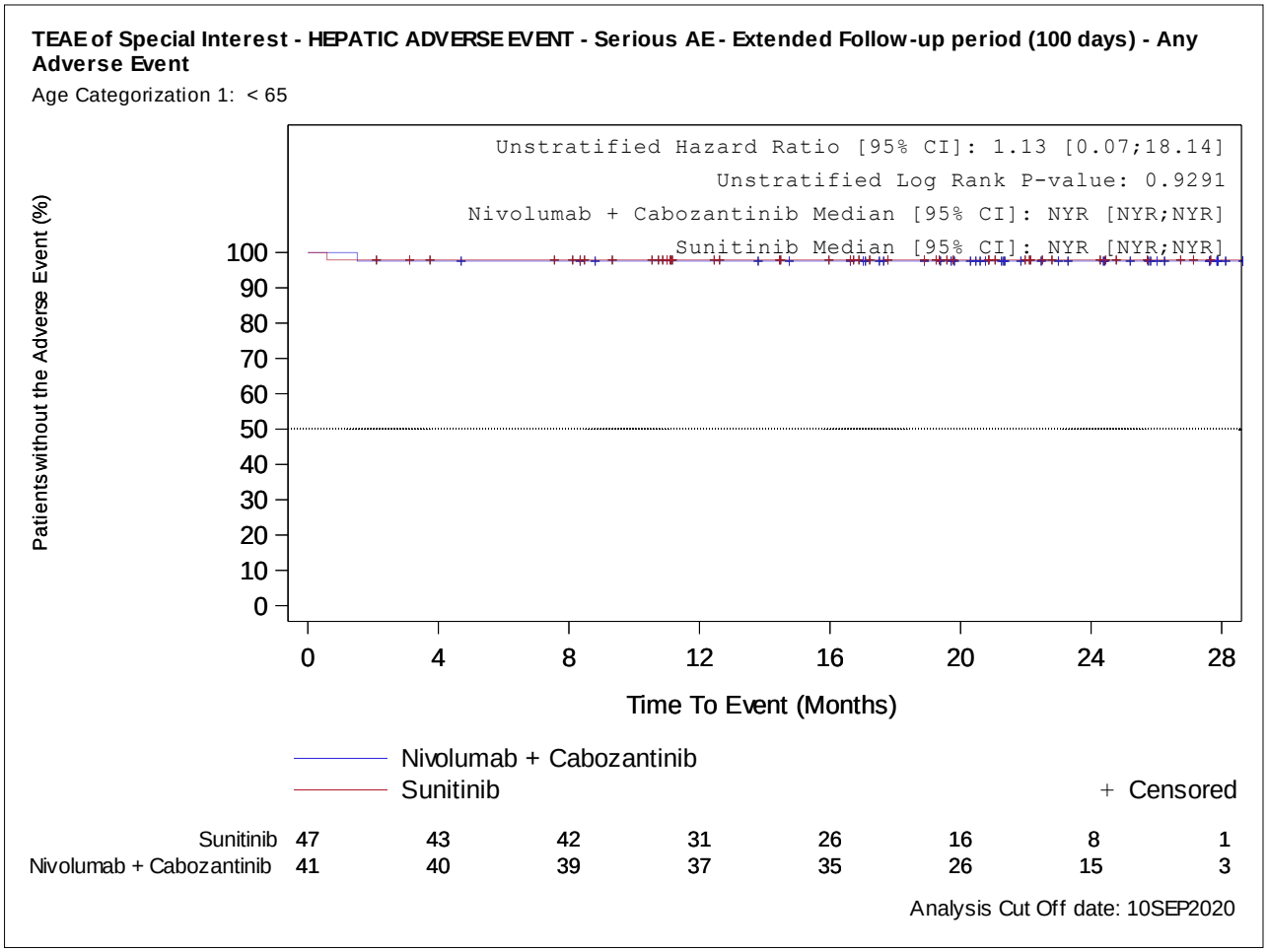

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:27:50

FIGURE 3.34.1: TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



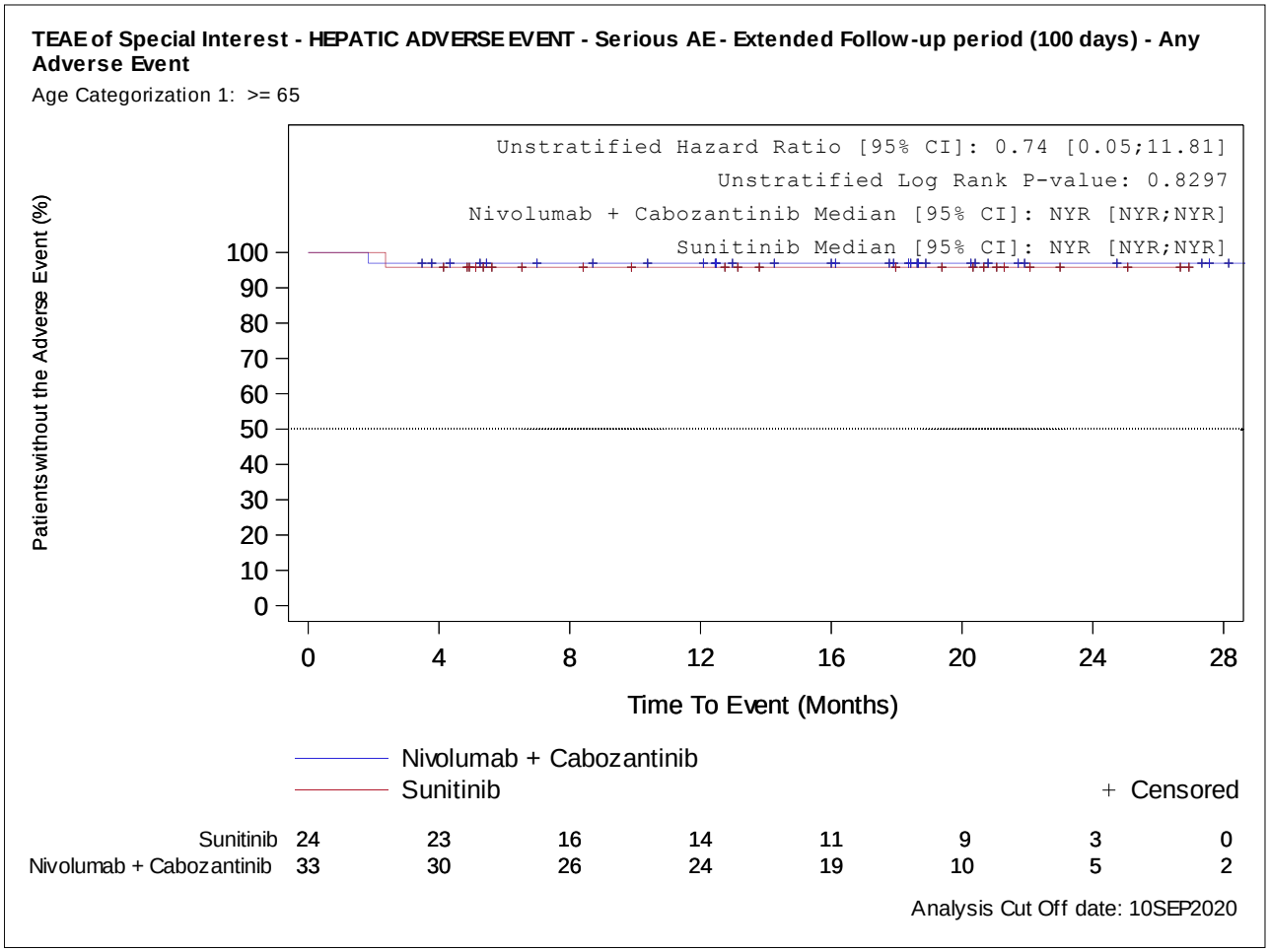

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:31:08

FIGURE 3.34.2.1: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



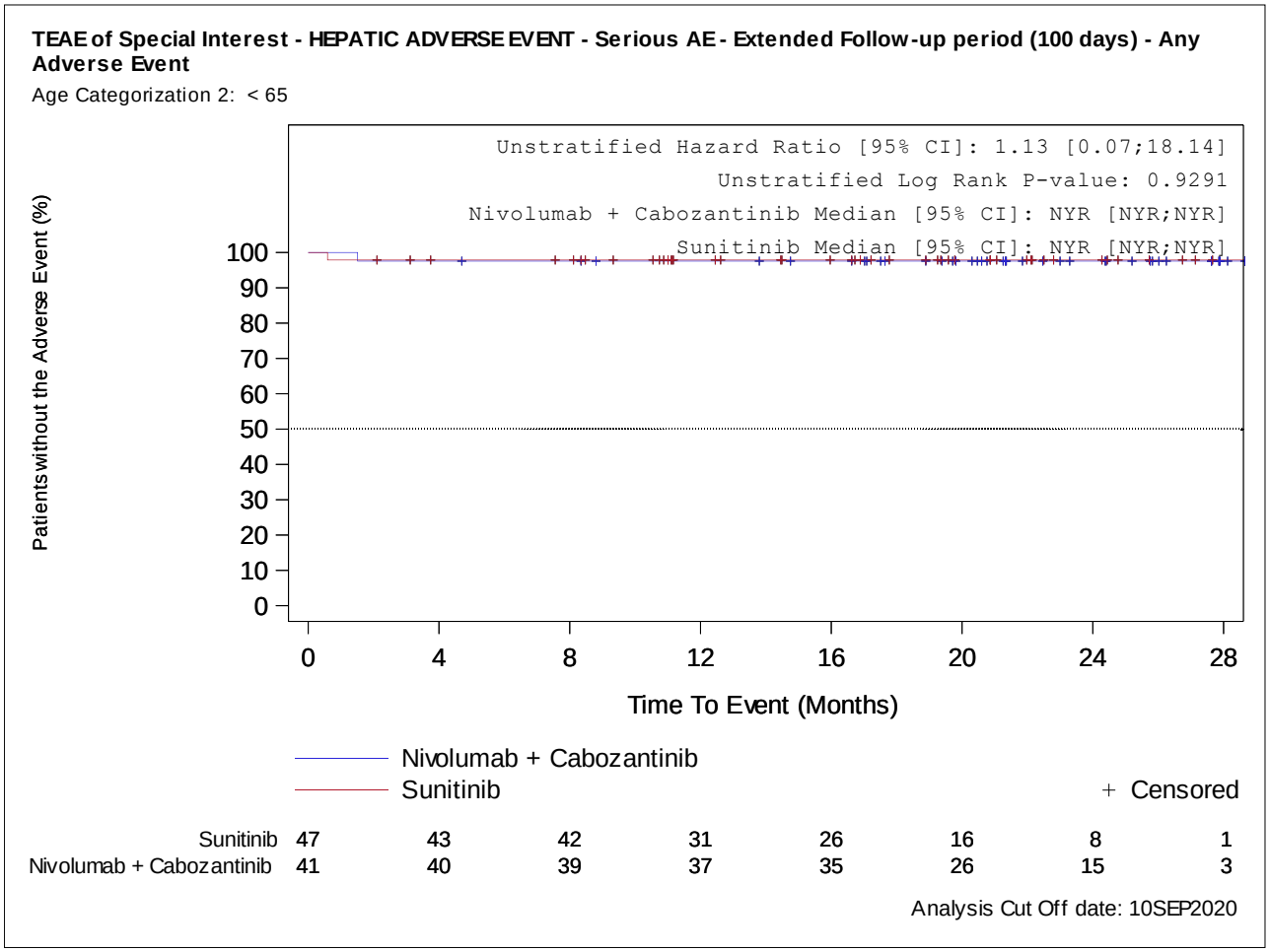

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:31:12

FIGURE 3.34.2.2: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



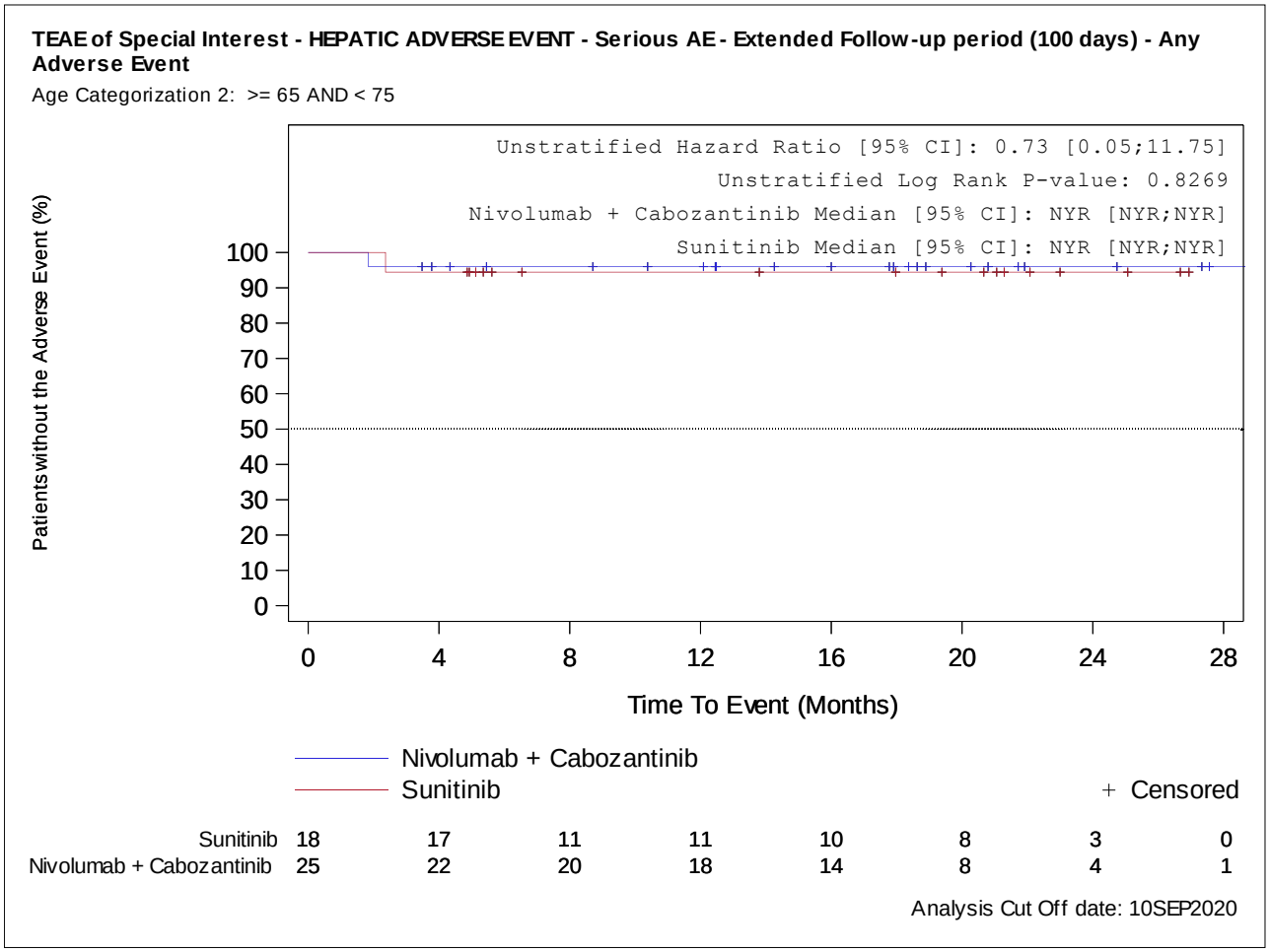

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:31:18

FIGURE 3.34.2.3: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



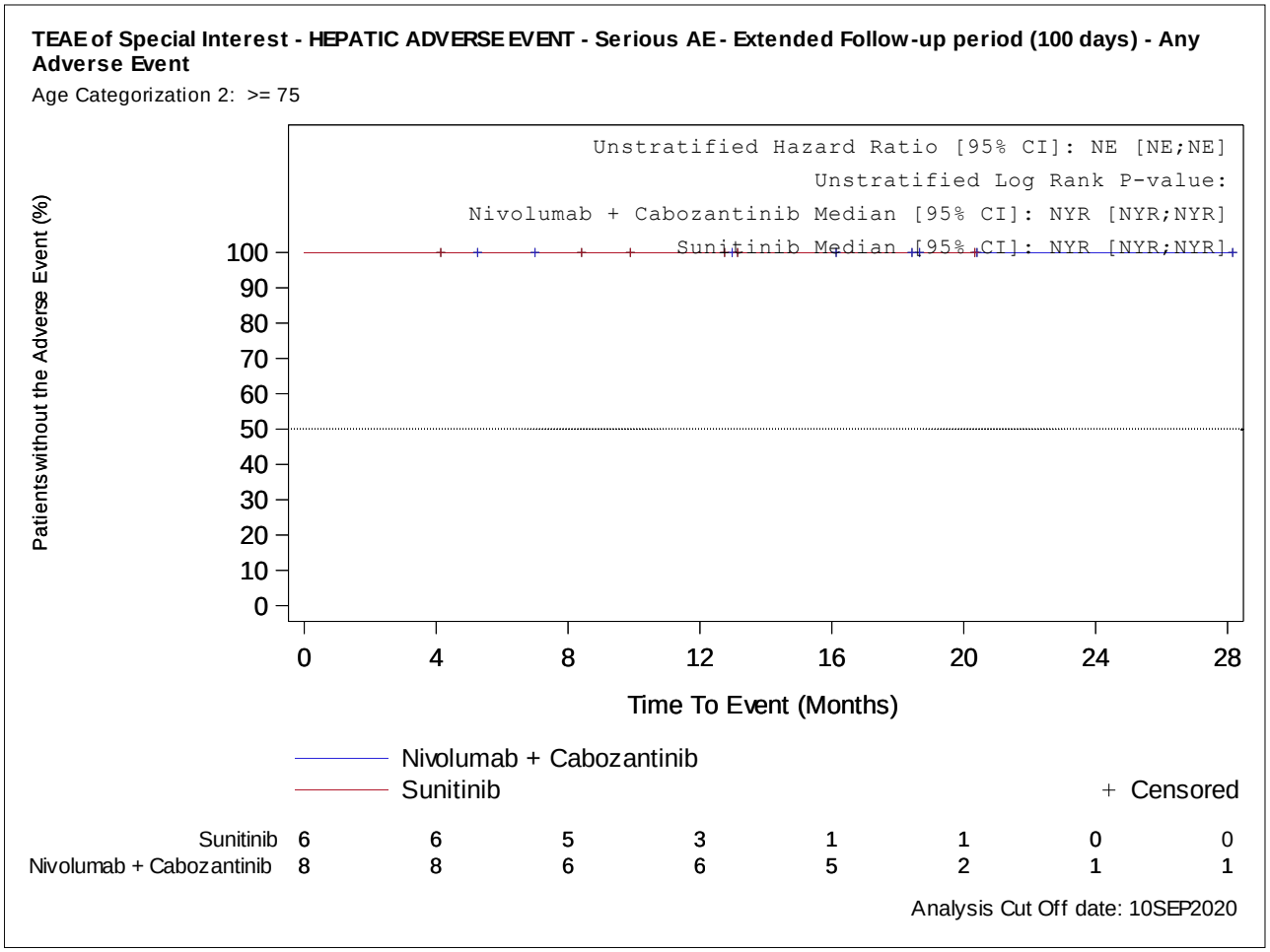

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:31:24

FIGURE 3.34.2.4: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



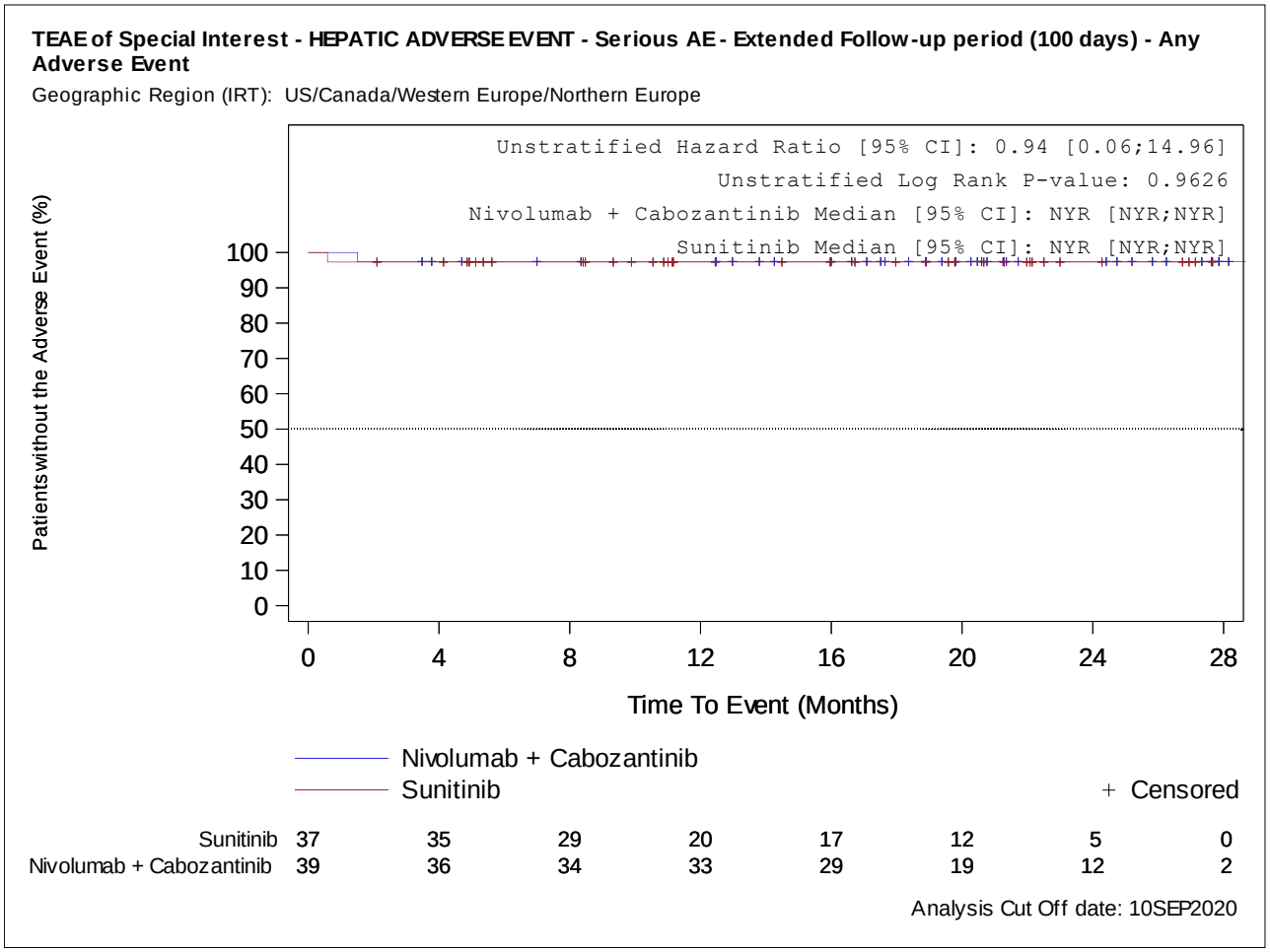

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:31:29

FIGURE 3.34.2.5: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



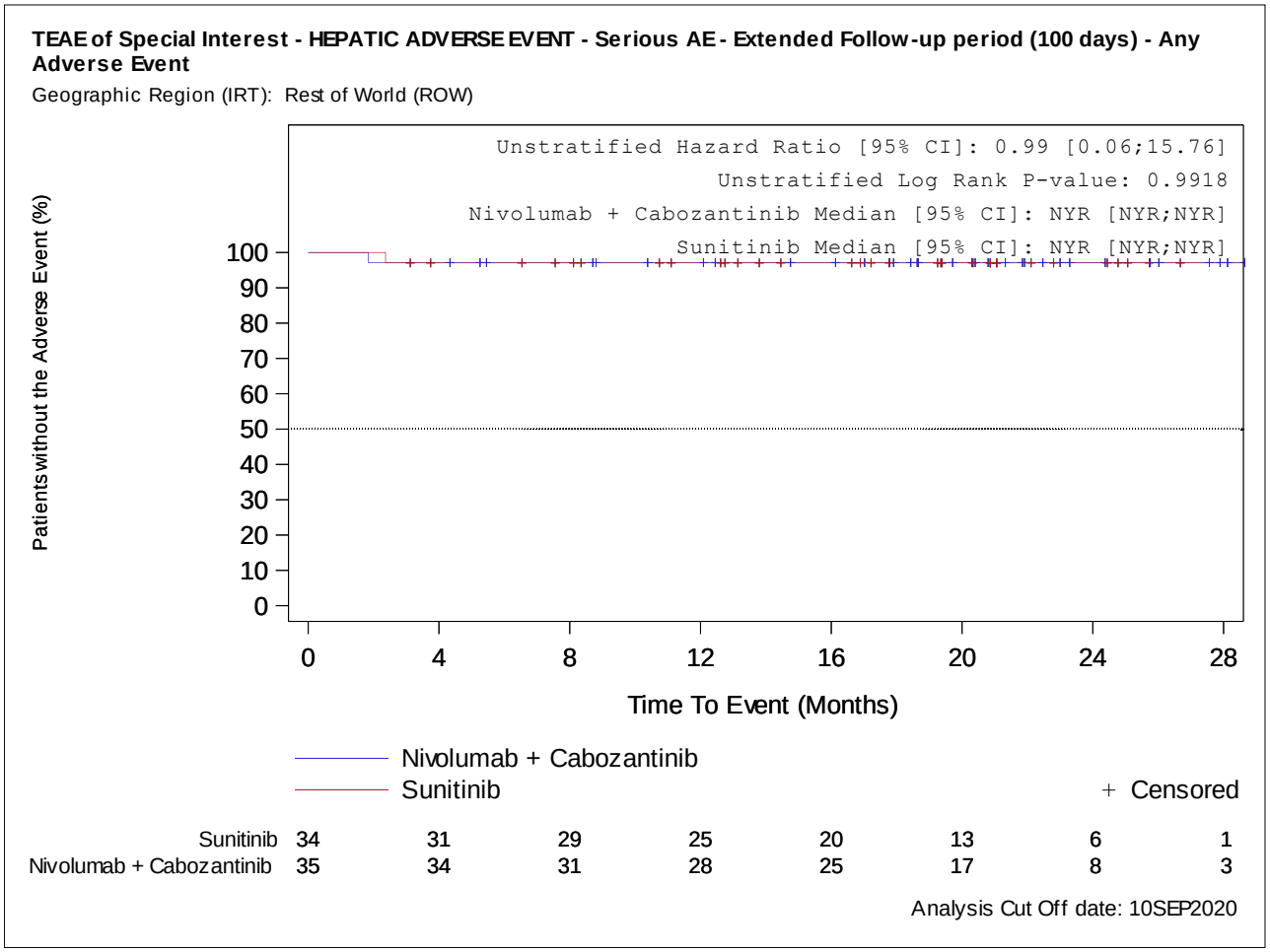

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:31:35

FIGURE 3.34.2.6: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



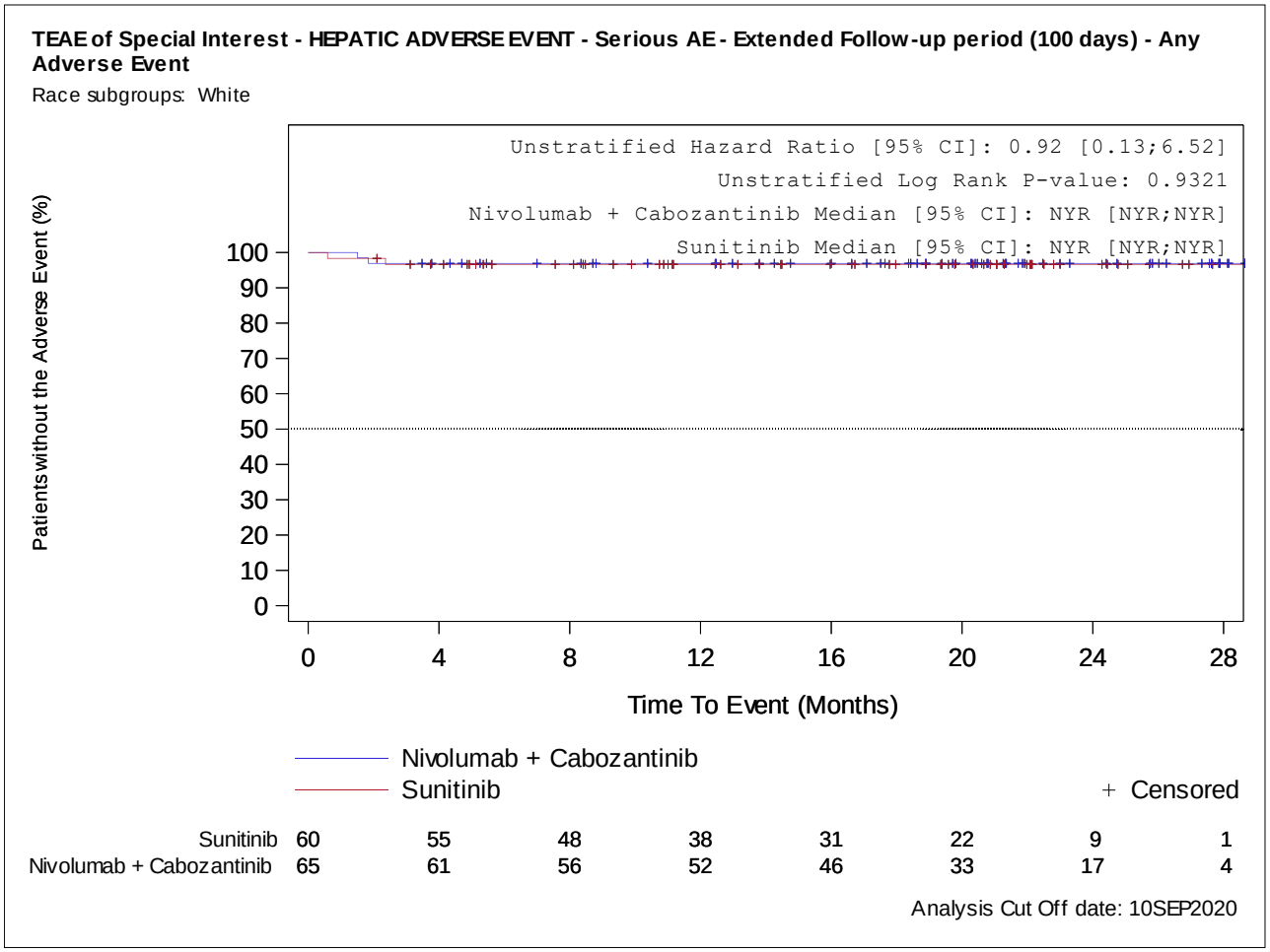

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:31:40

FIGURE 3.34.2.7: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



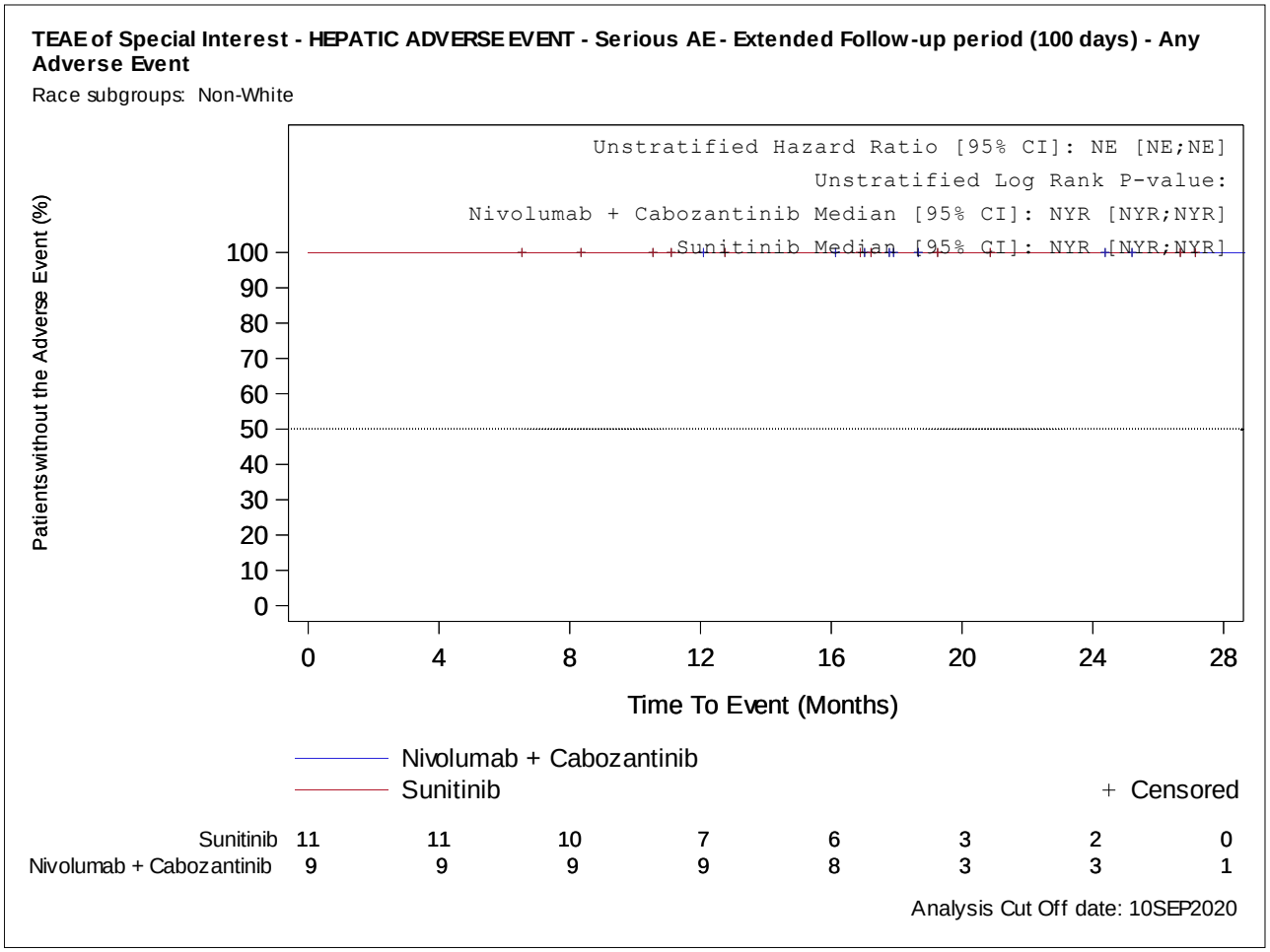

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:31:47

FIGURE 3.34.2.8: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



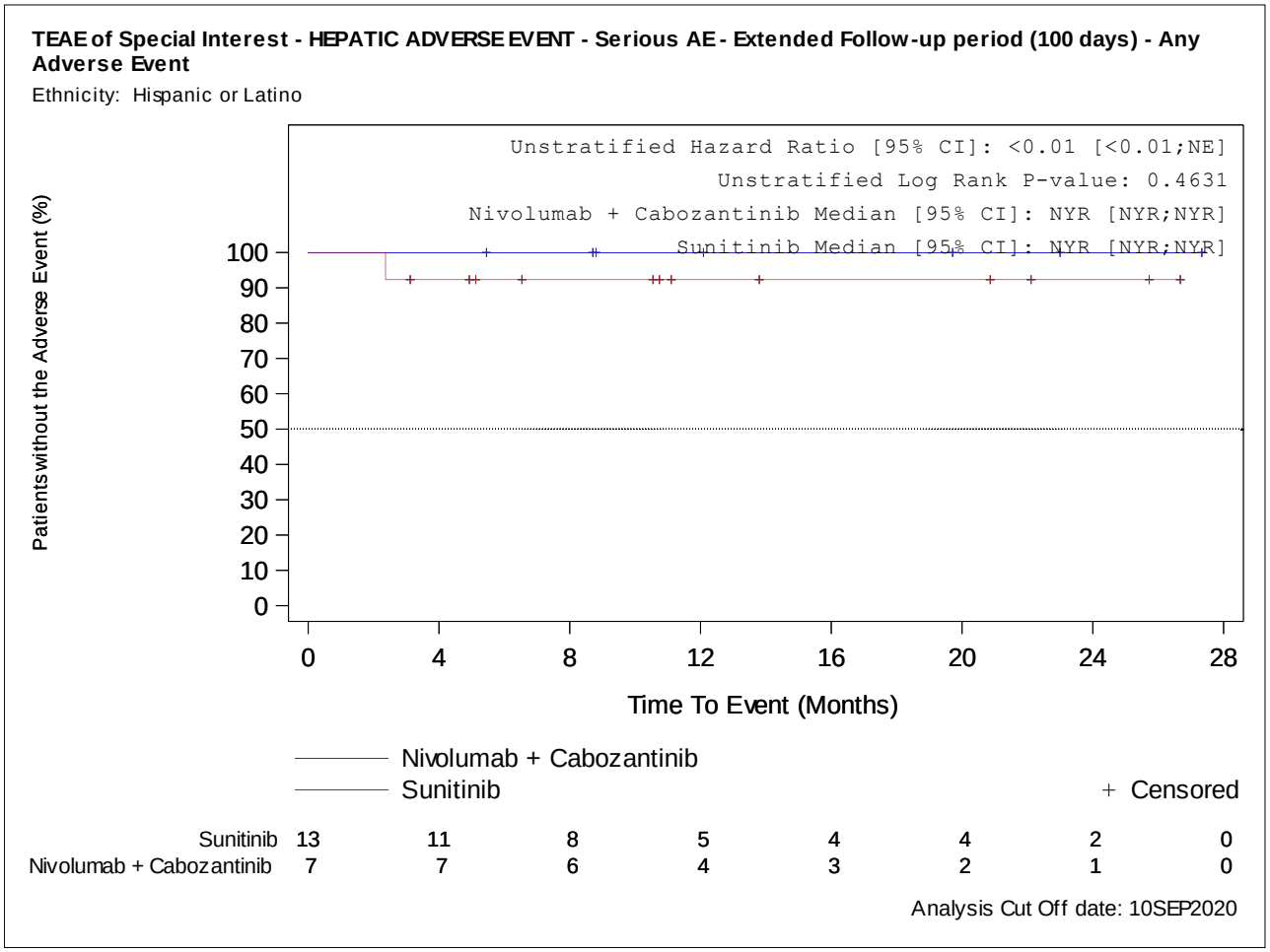

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:31:53

FIGURE 3.34.2.9: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



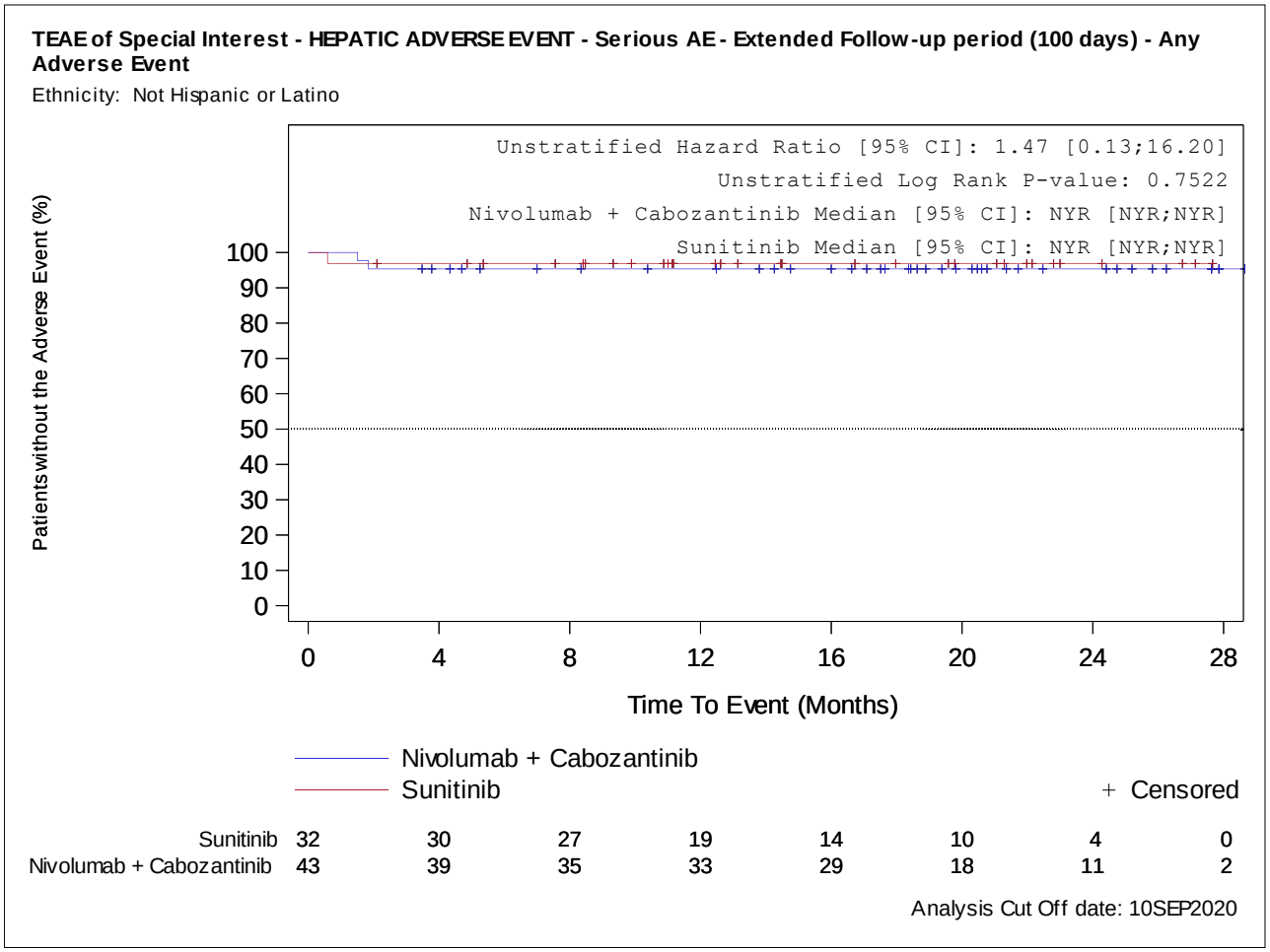

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:31:58

FIGURE 3.34.2.10: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



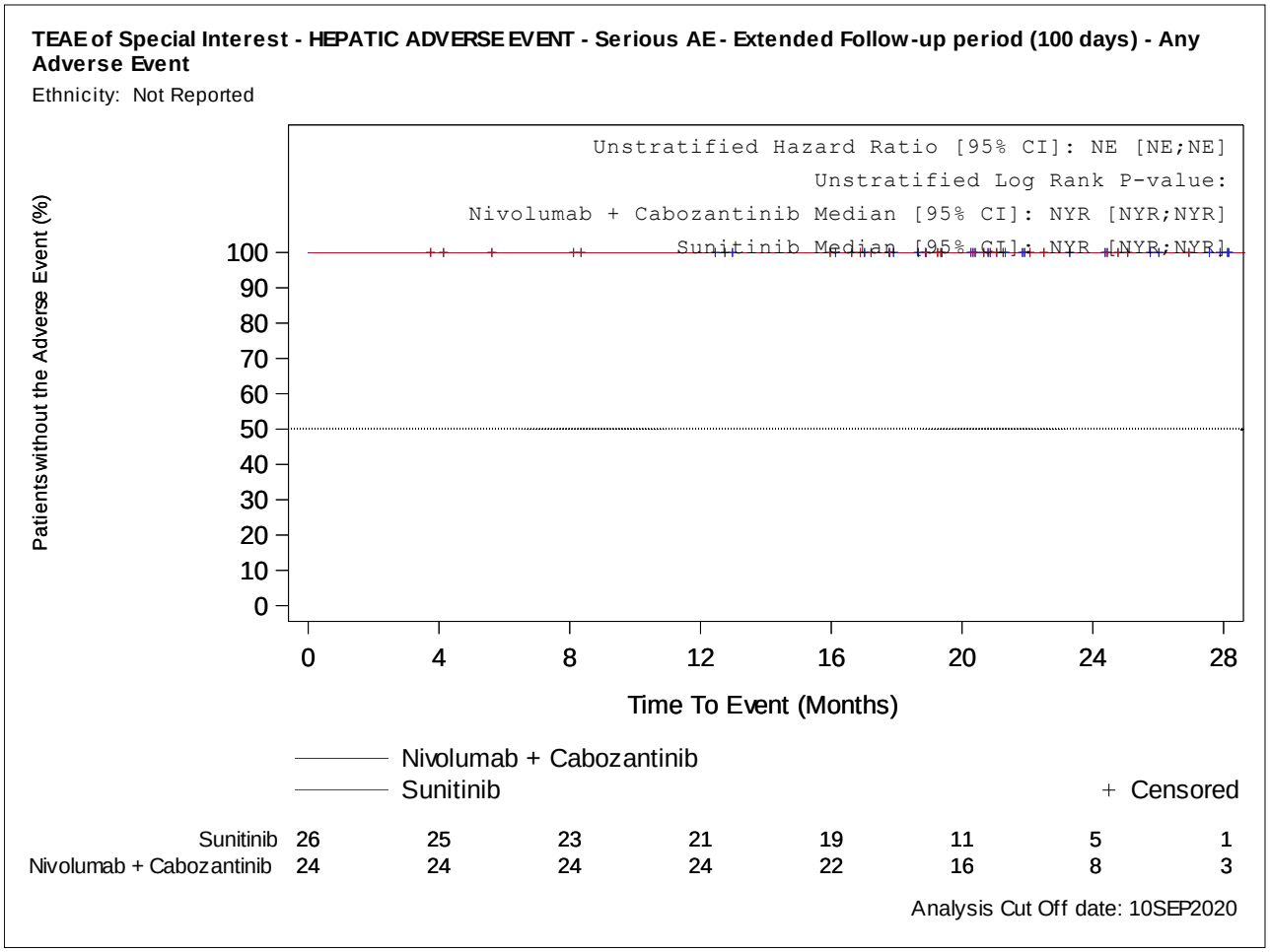

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:32:04

FIGURE 3.34.2.11: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



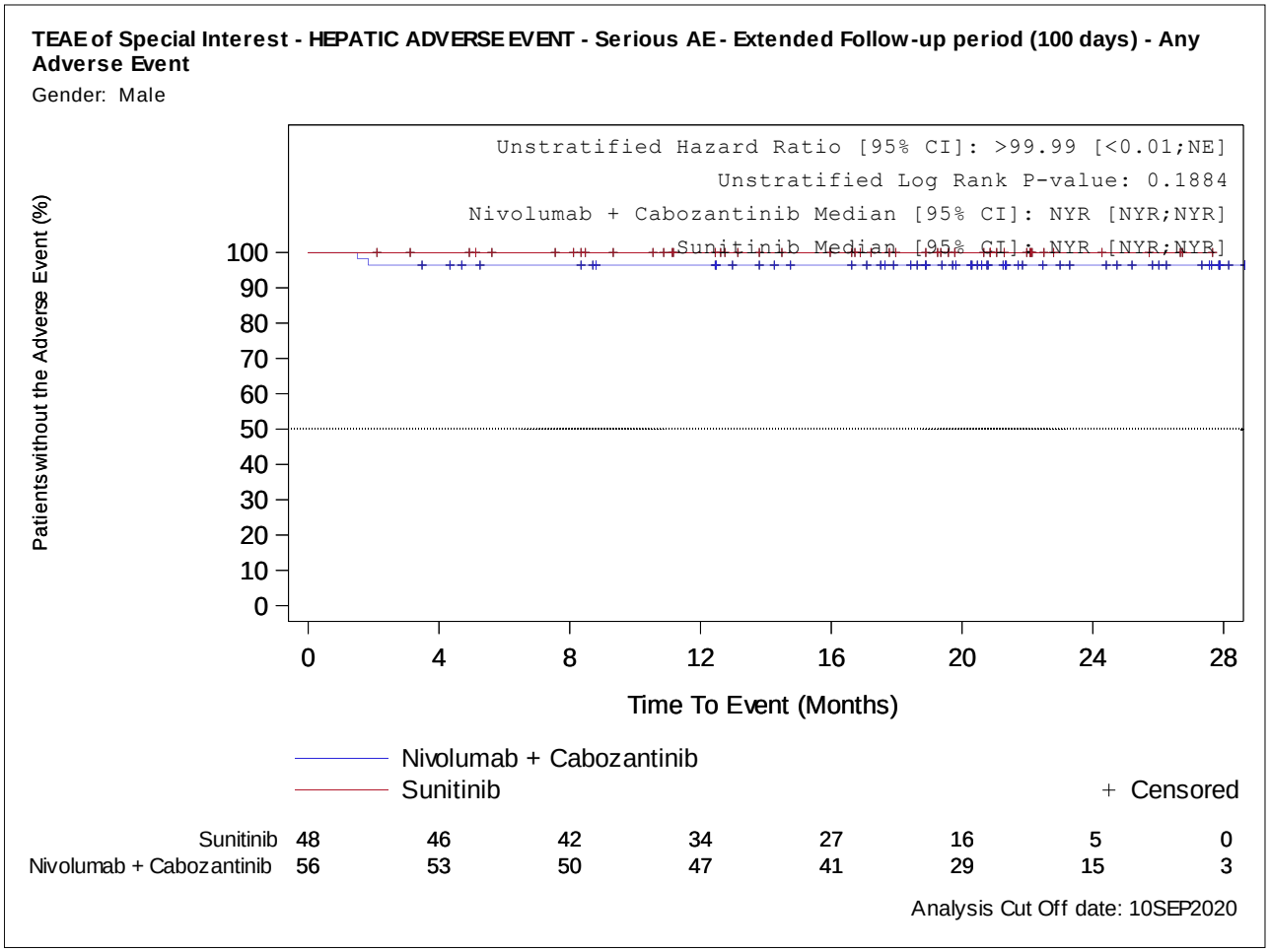

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:32:10

FIGURE 3.34.2.12: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



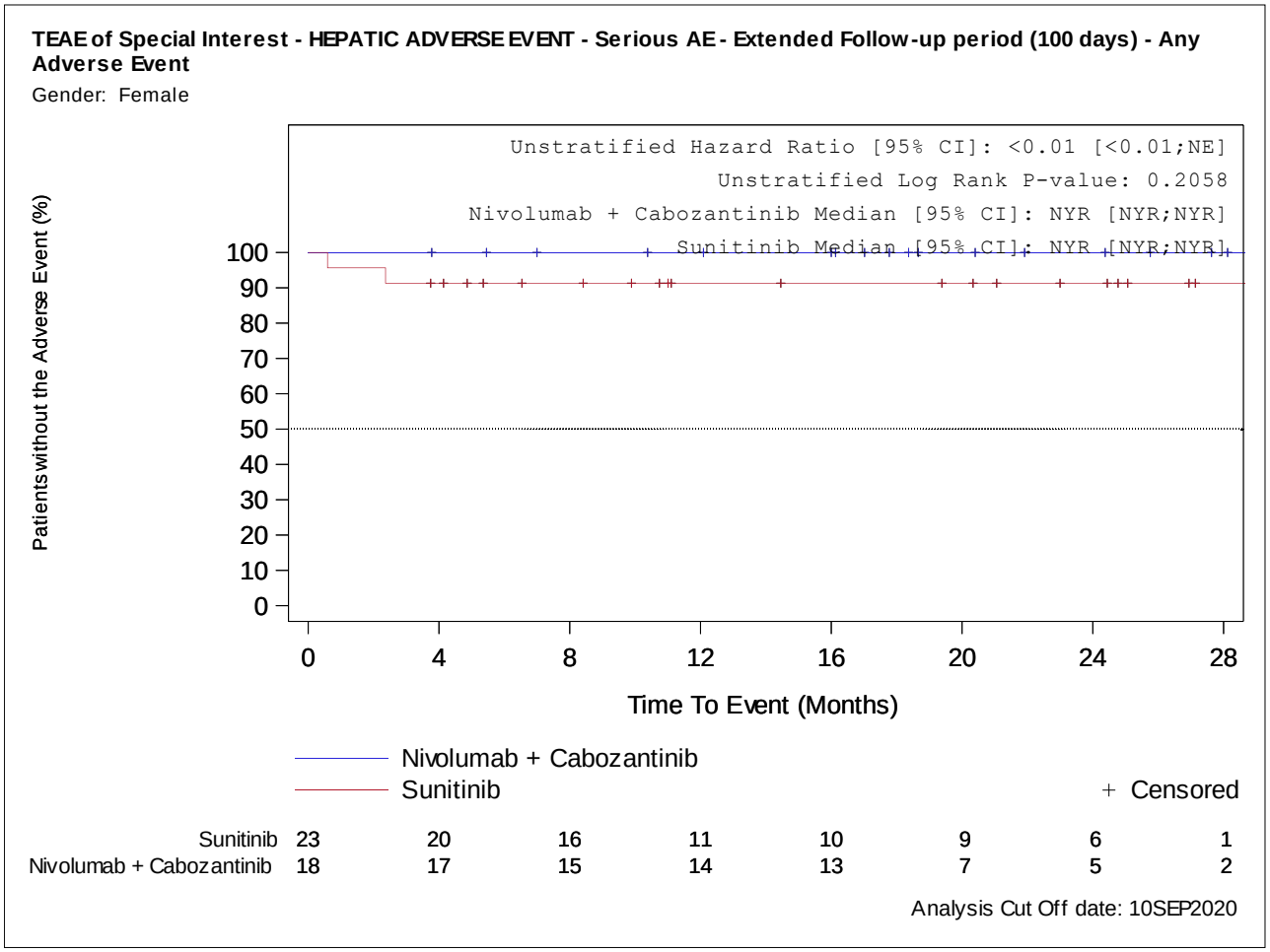

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:32:16

FIGURE 3.34.2.13: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:32:22

FIGURE 3.34.2.14: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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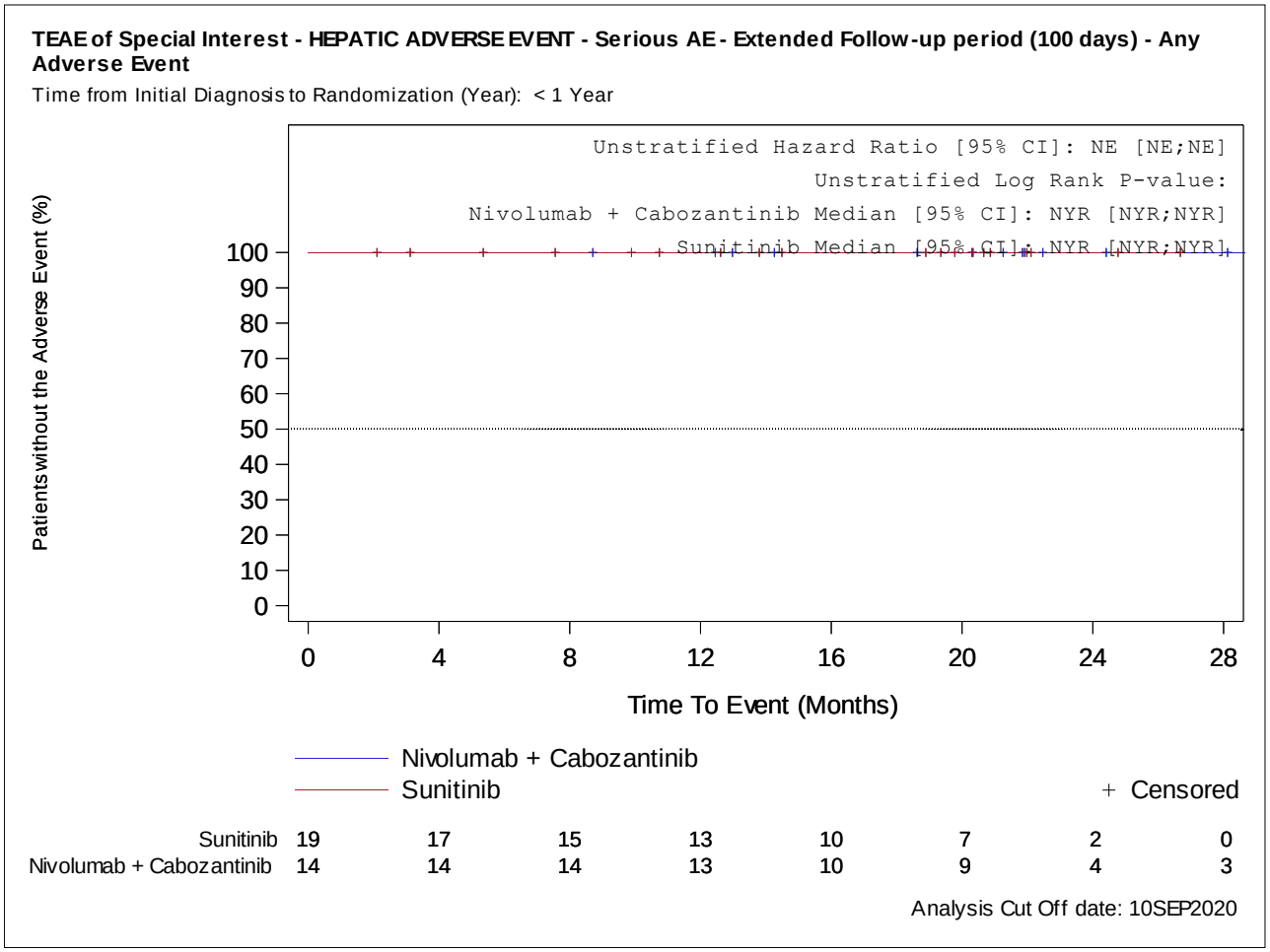
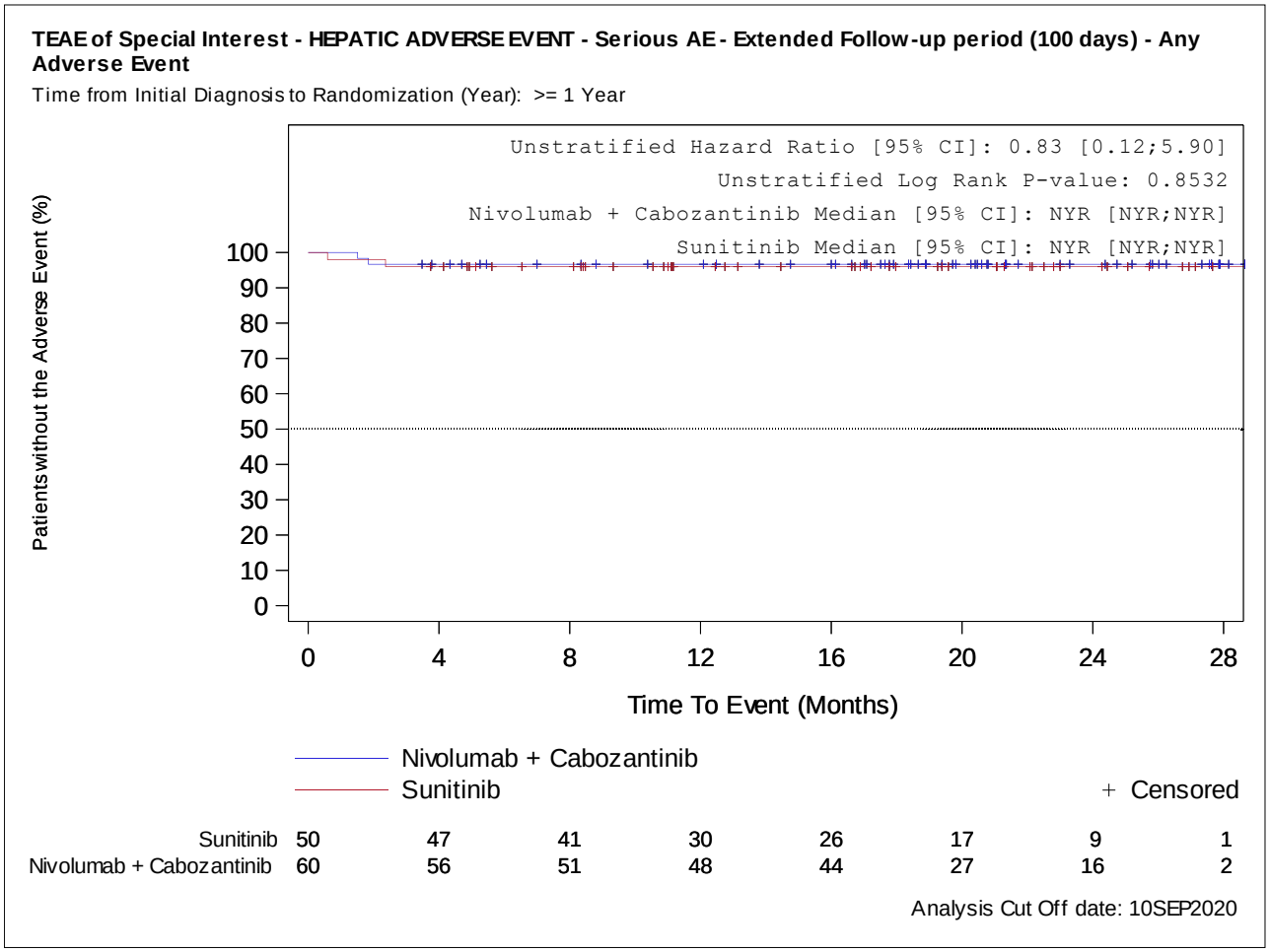
FIGURE 3.34.2.15: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



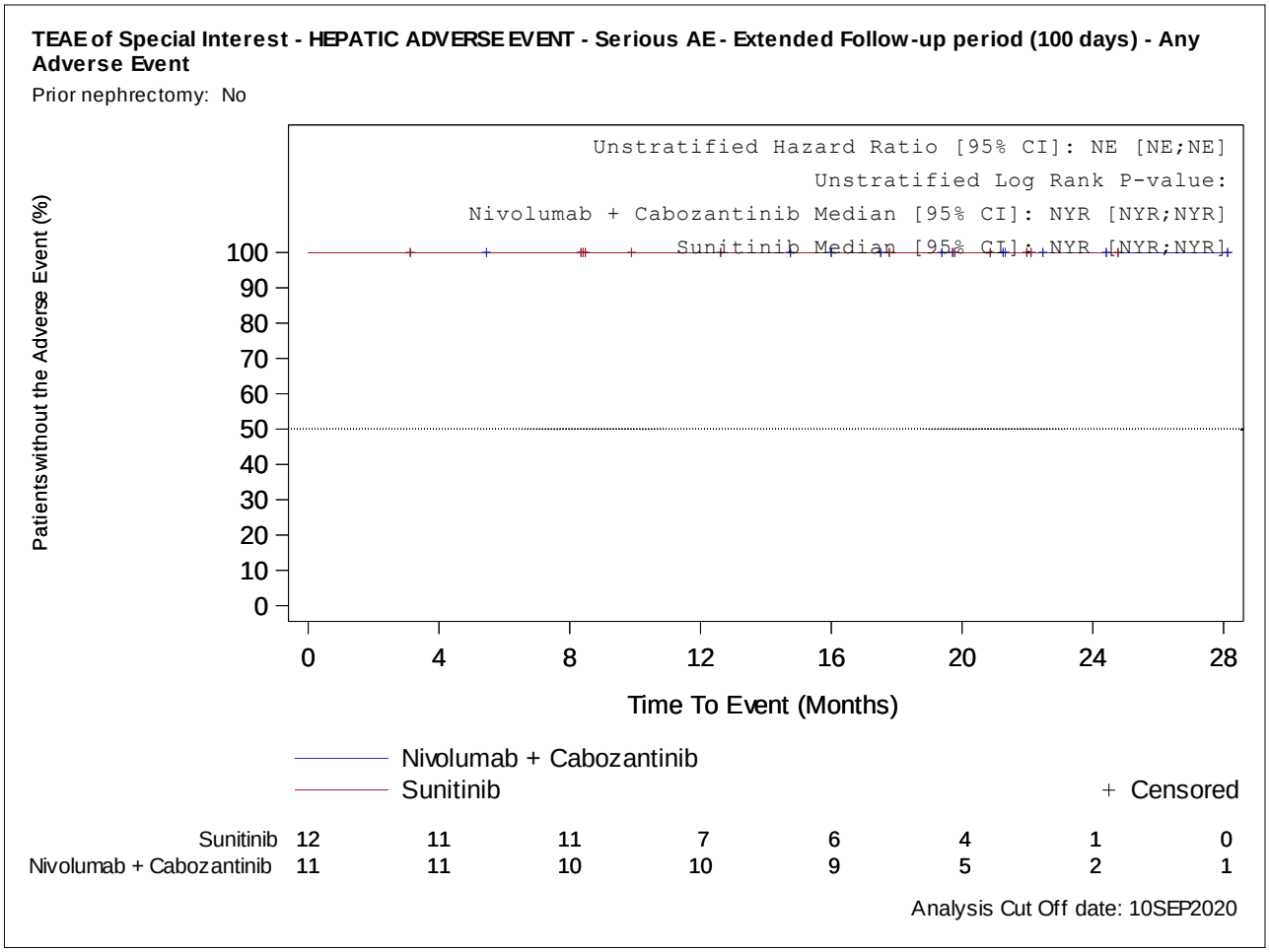

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:32:47

FIGURE 3.34.2.16: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



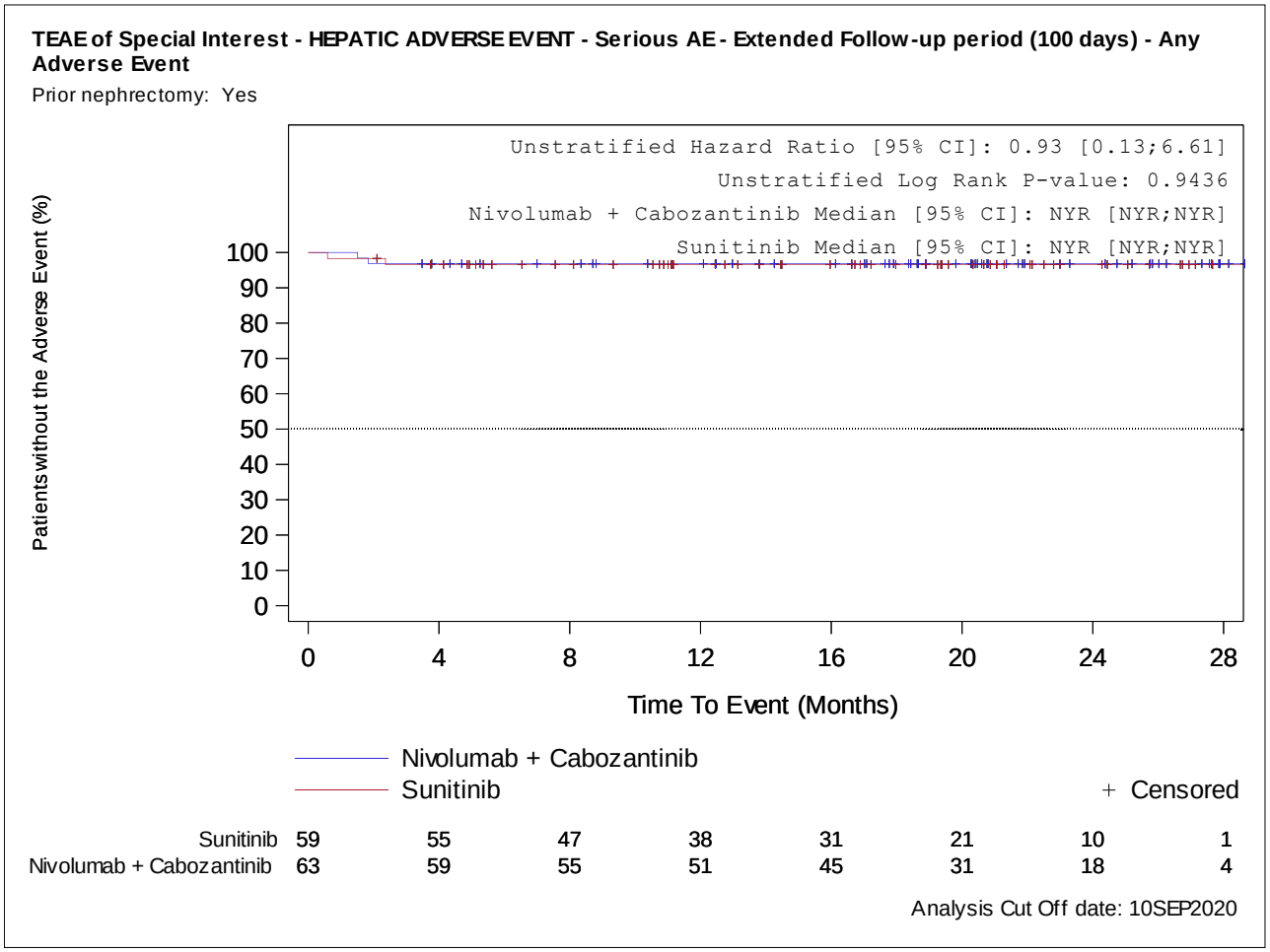

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:32:53

FIGURE 3.34.2.17: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



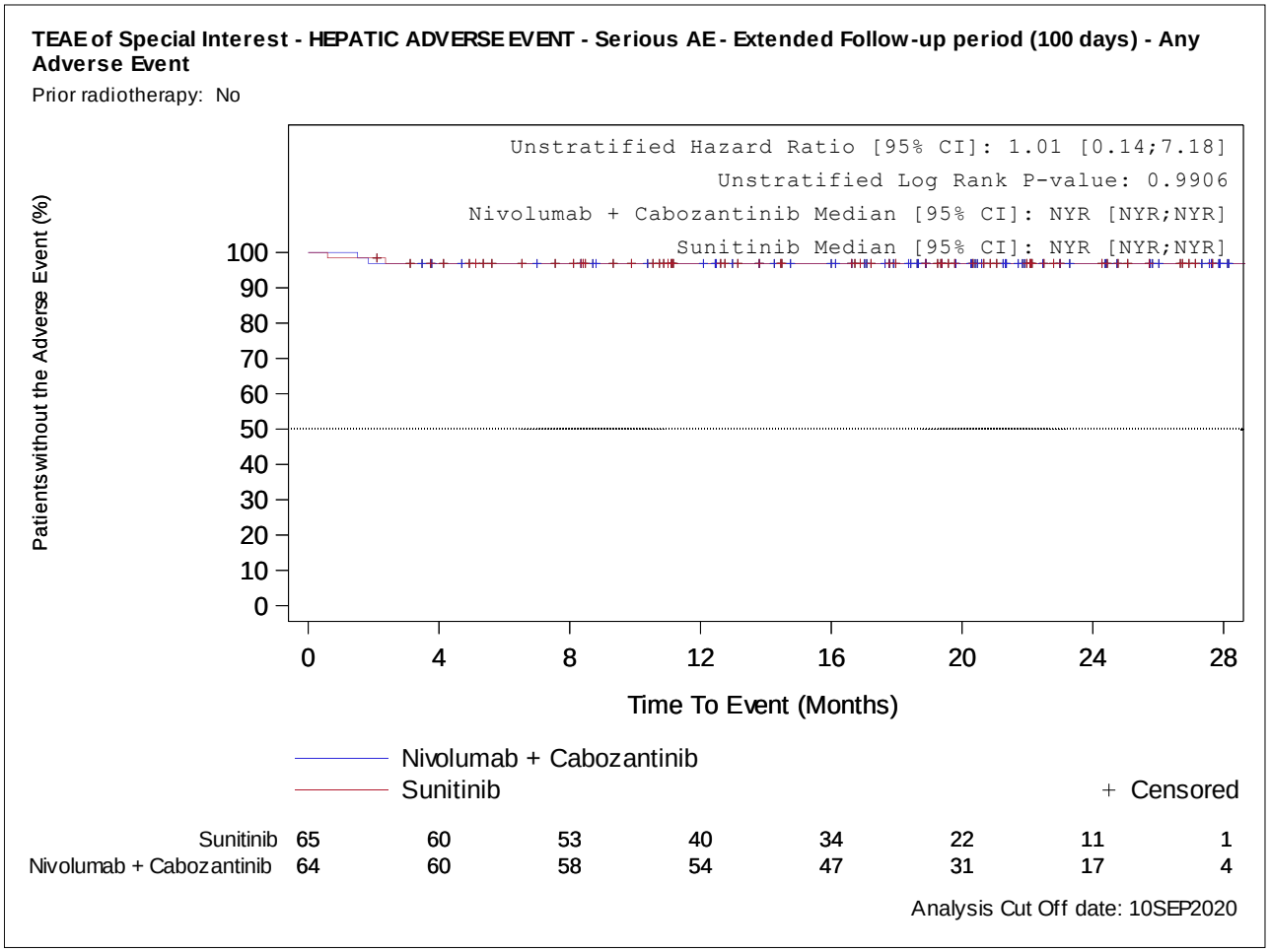

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:33:45

FIGURE 3.34.2.18: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



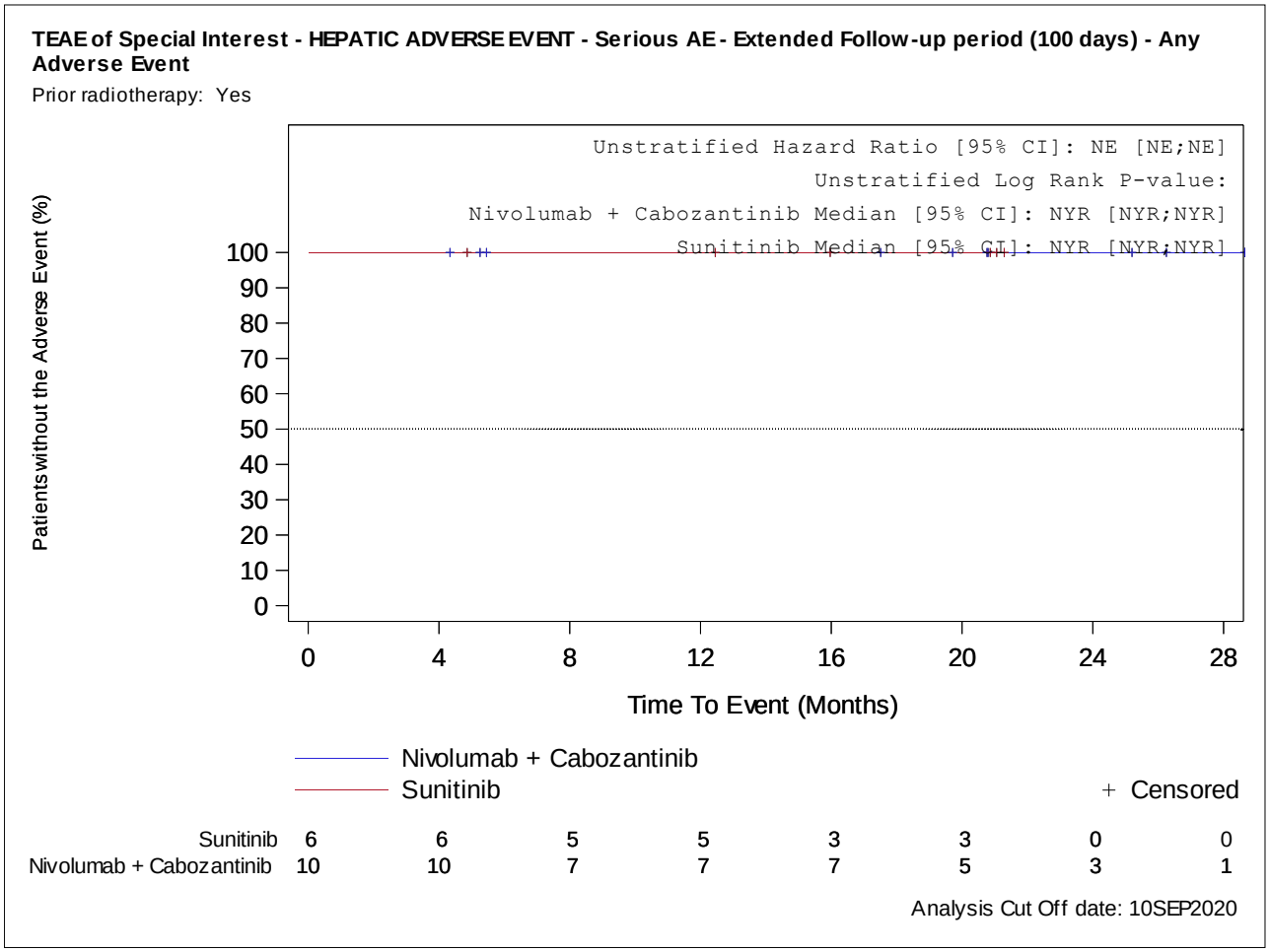

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:33:51

FIGURE 3.34.2.19: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



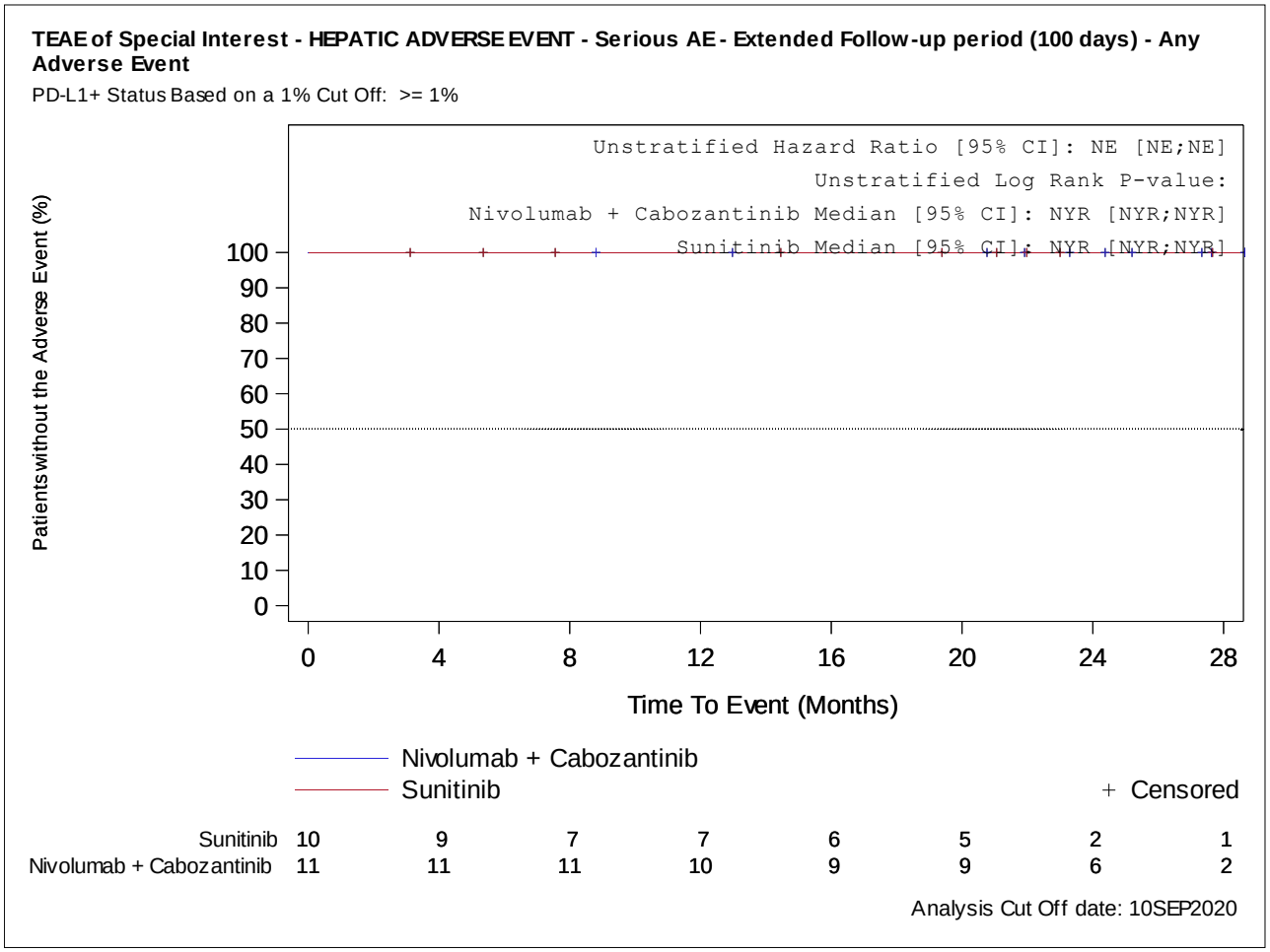

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:33:57

FIGURE 3.34.2.20: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:34:02

FIGURE 3.34.2.21: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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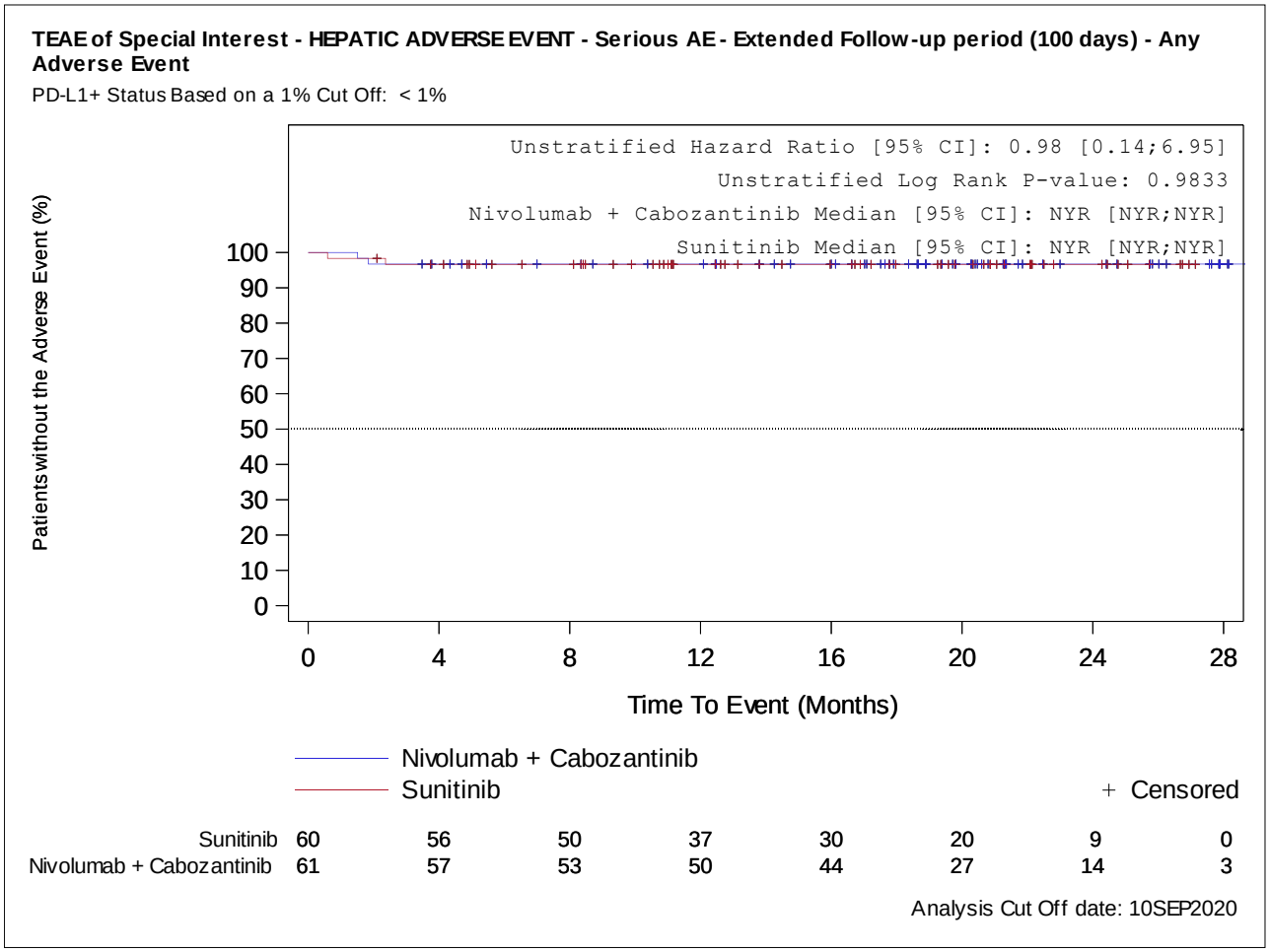
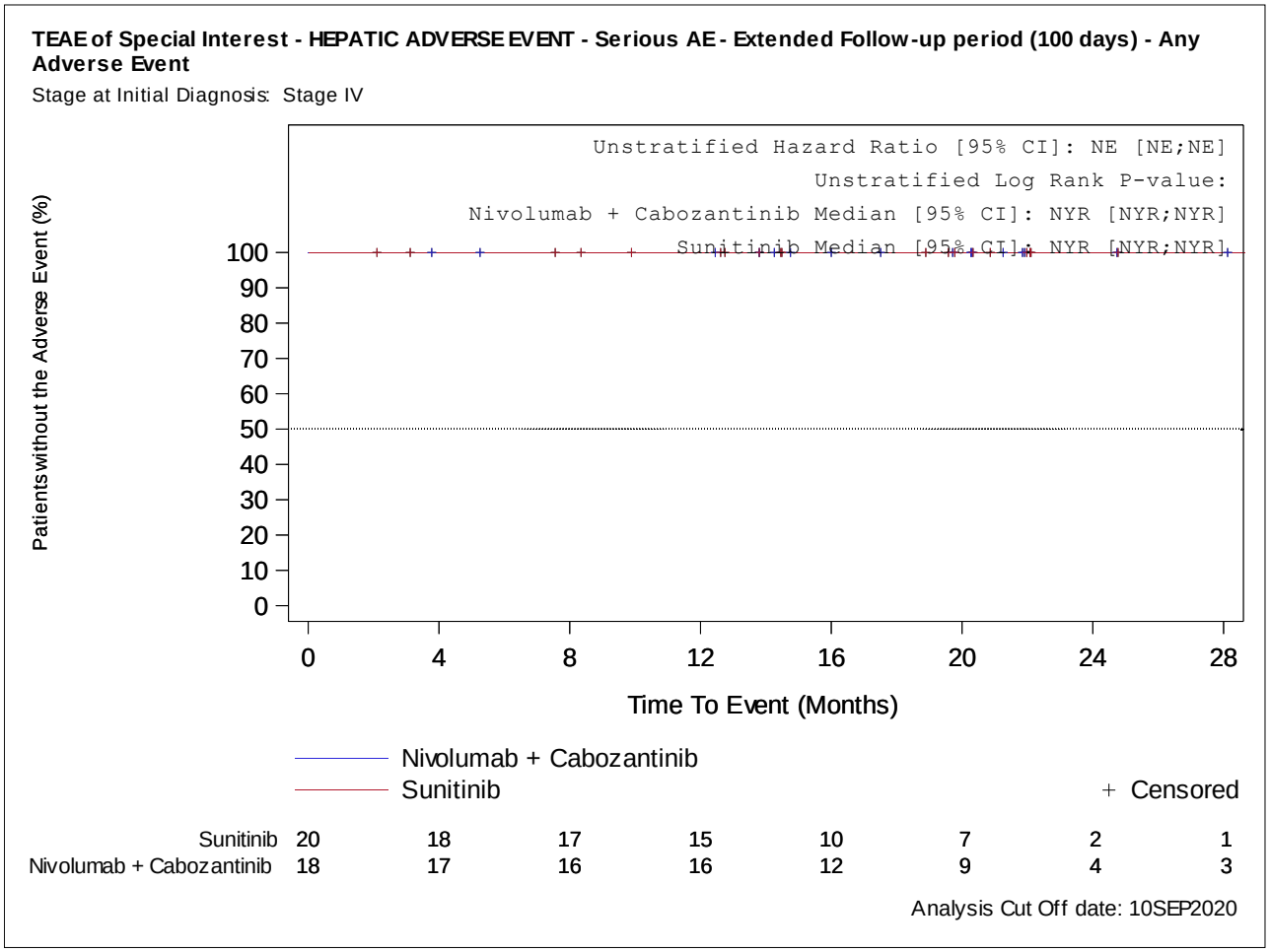
FIGURE 3.34.2.22: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



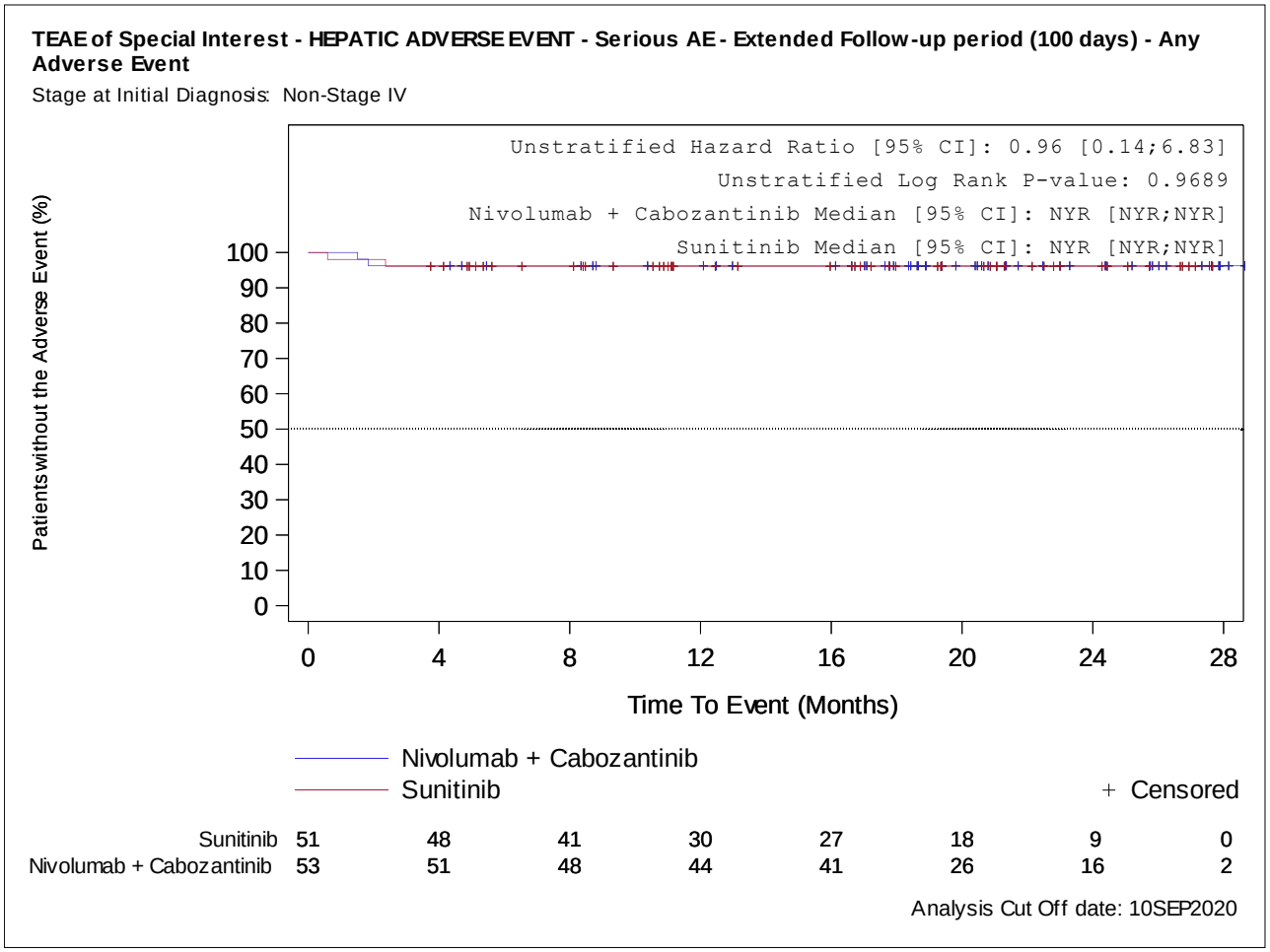

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:34:14

FIGURE 3.34.2.23: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



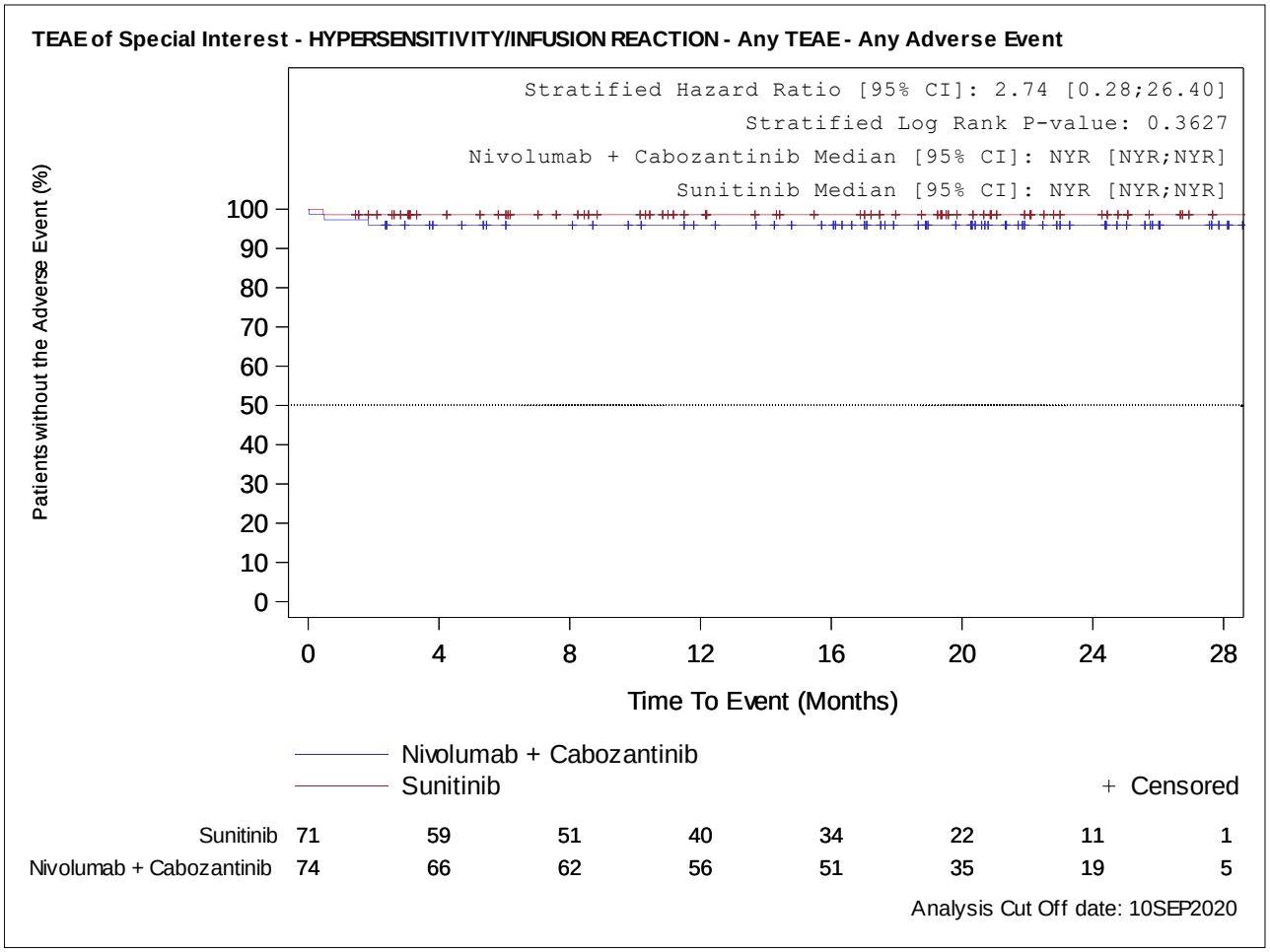

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:34:43

FIGURE 3.34.2.24: Kaplan-Meier curve - TEAE of Special Interest - HEPATIC ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



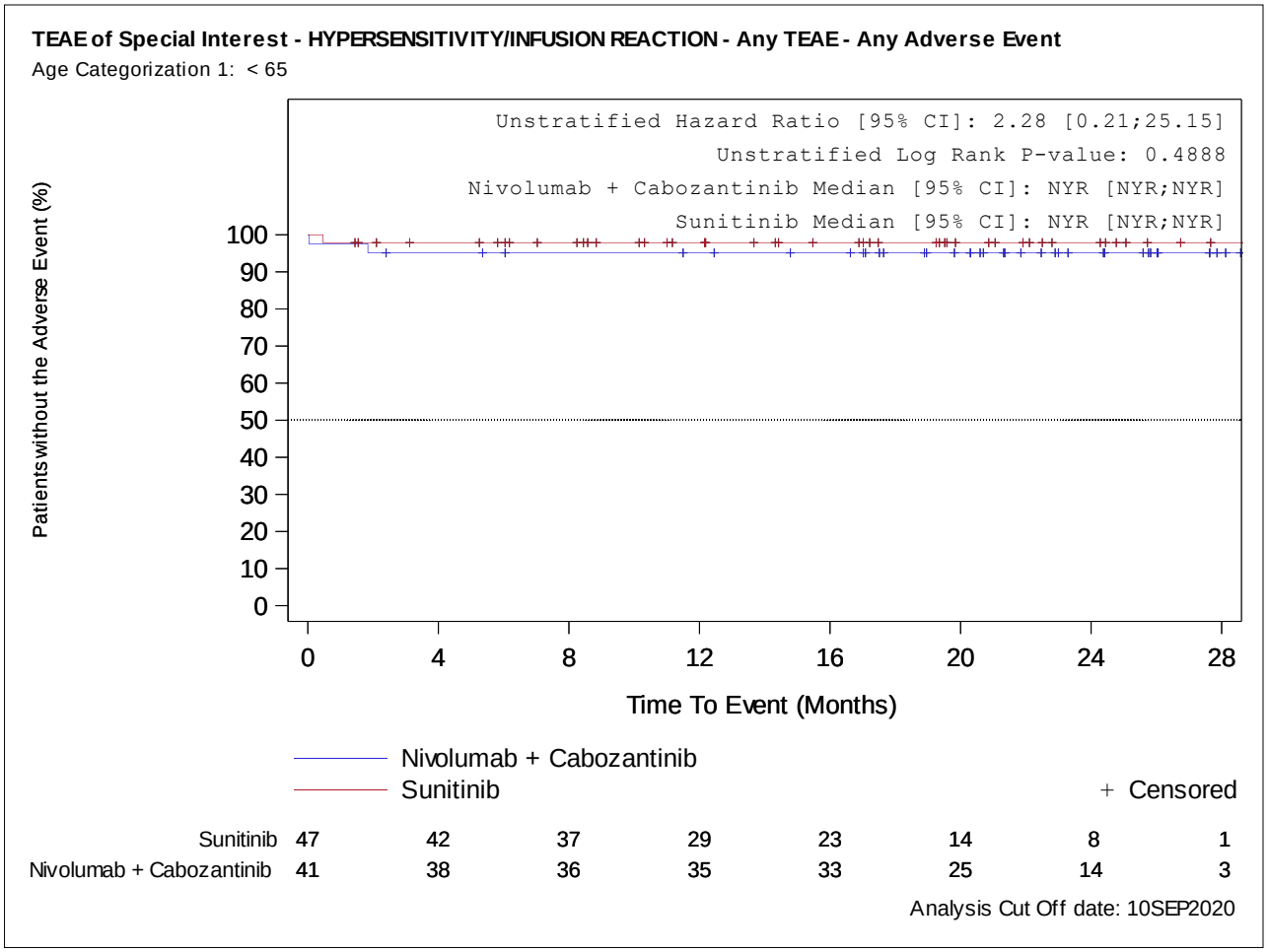

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:34:49

FIGURE 3.35.1: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



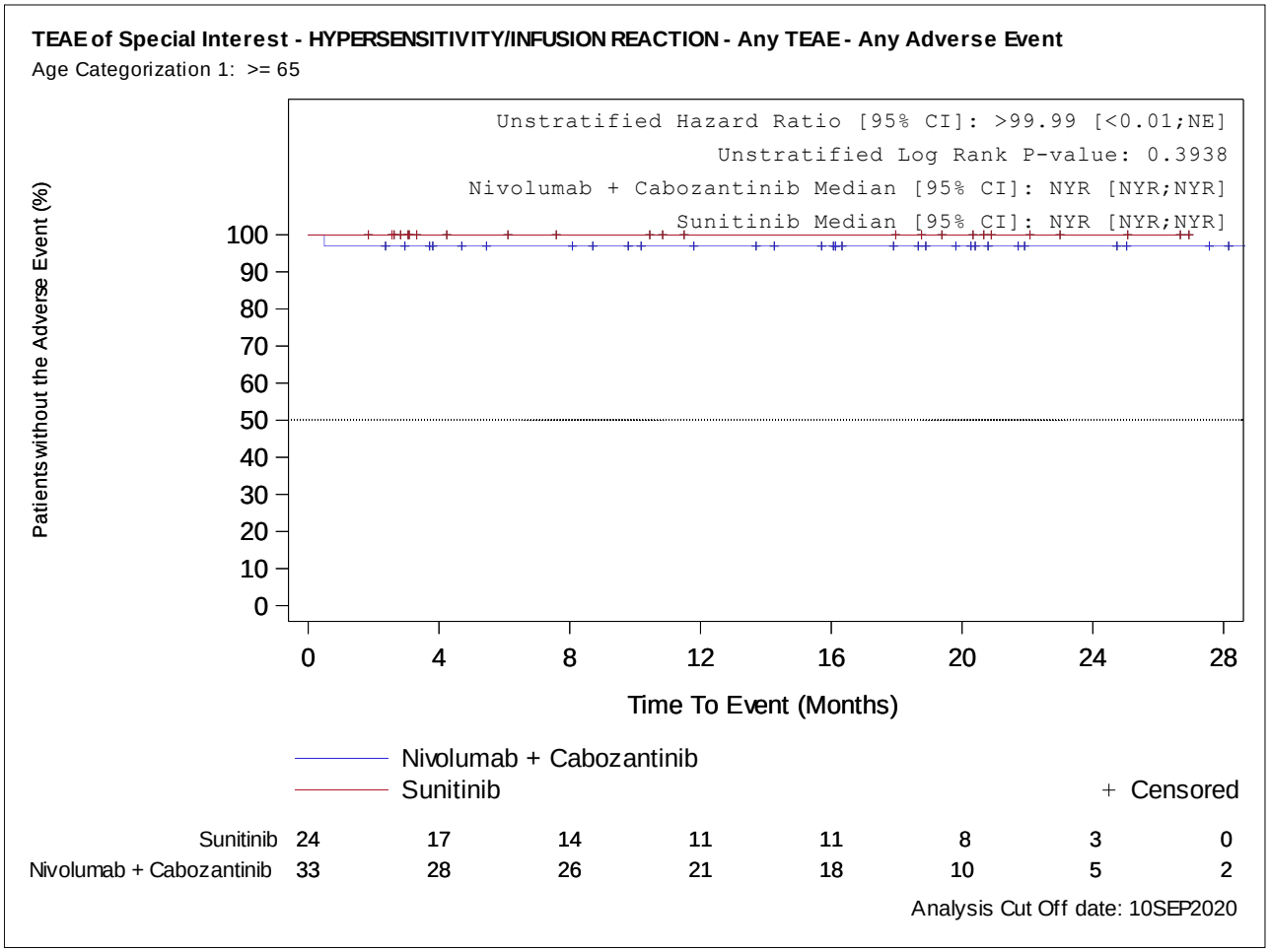

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:38:06

FIGURE 3.35.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



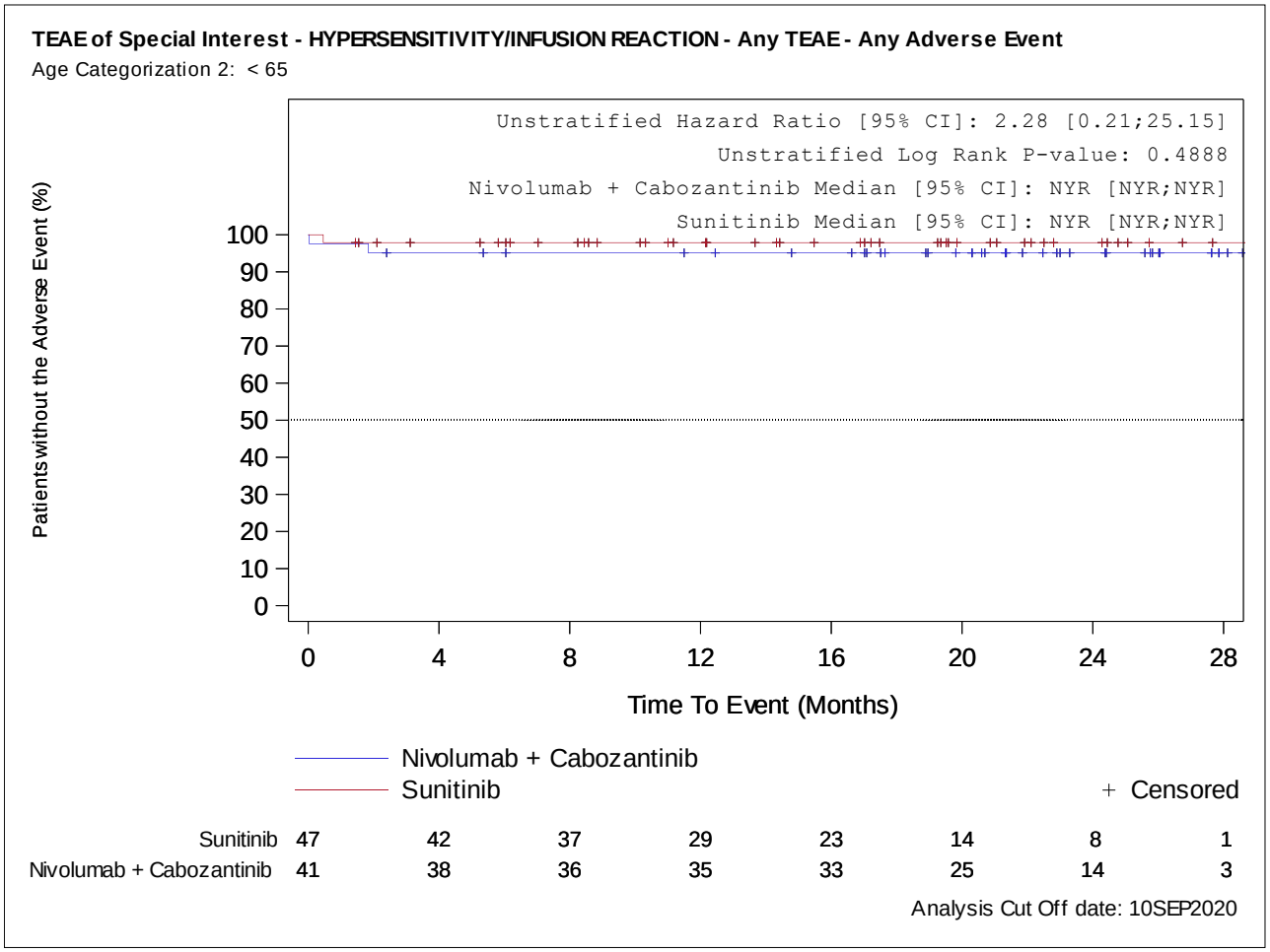

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:38:09

FIGURE 3.35.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



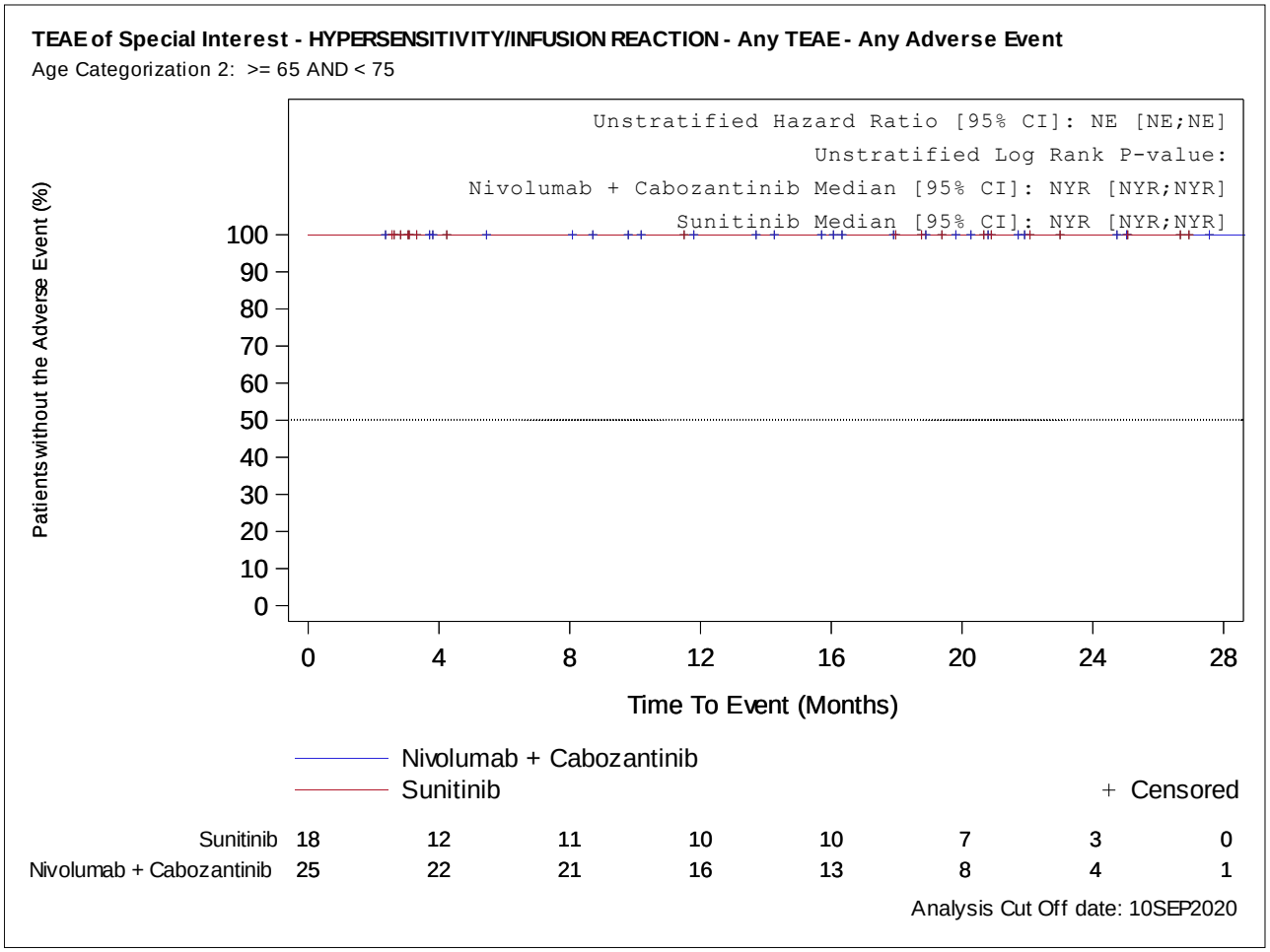

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:38:16

FIGURE 3.35.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



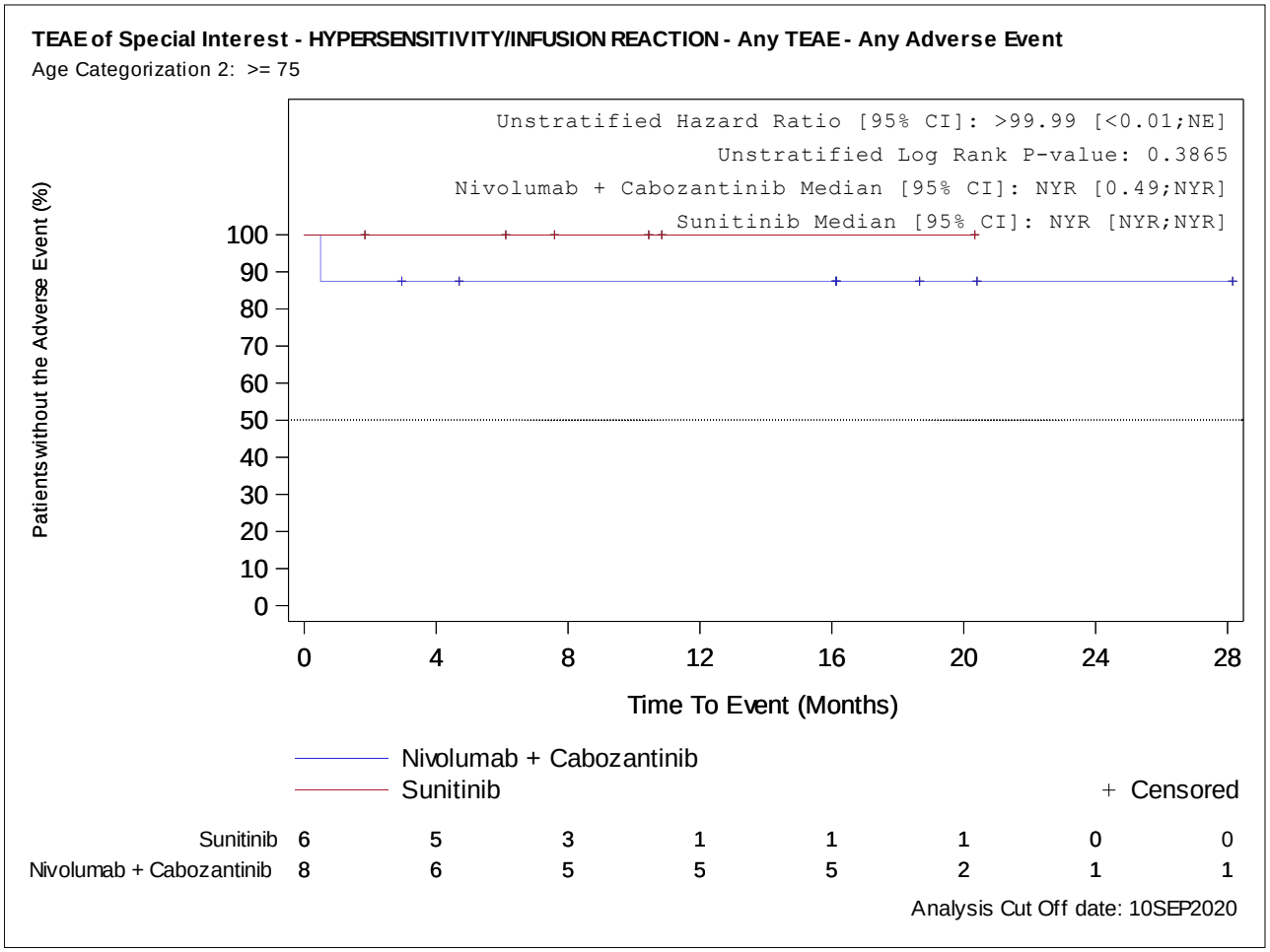

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:38:21

FIGURE 3.35.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



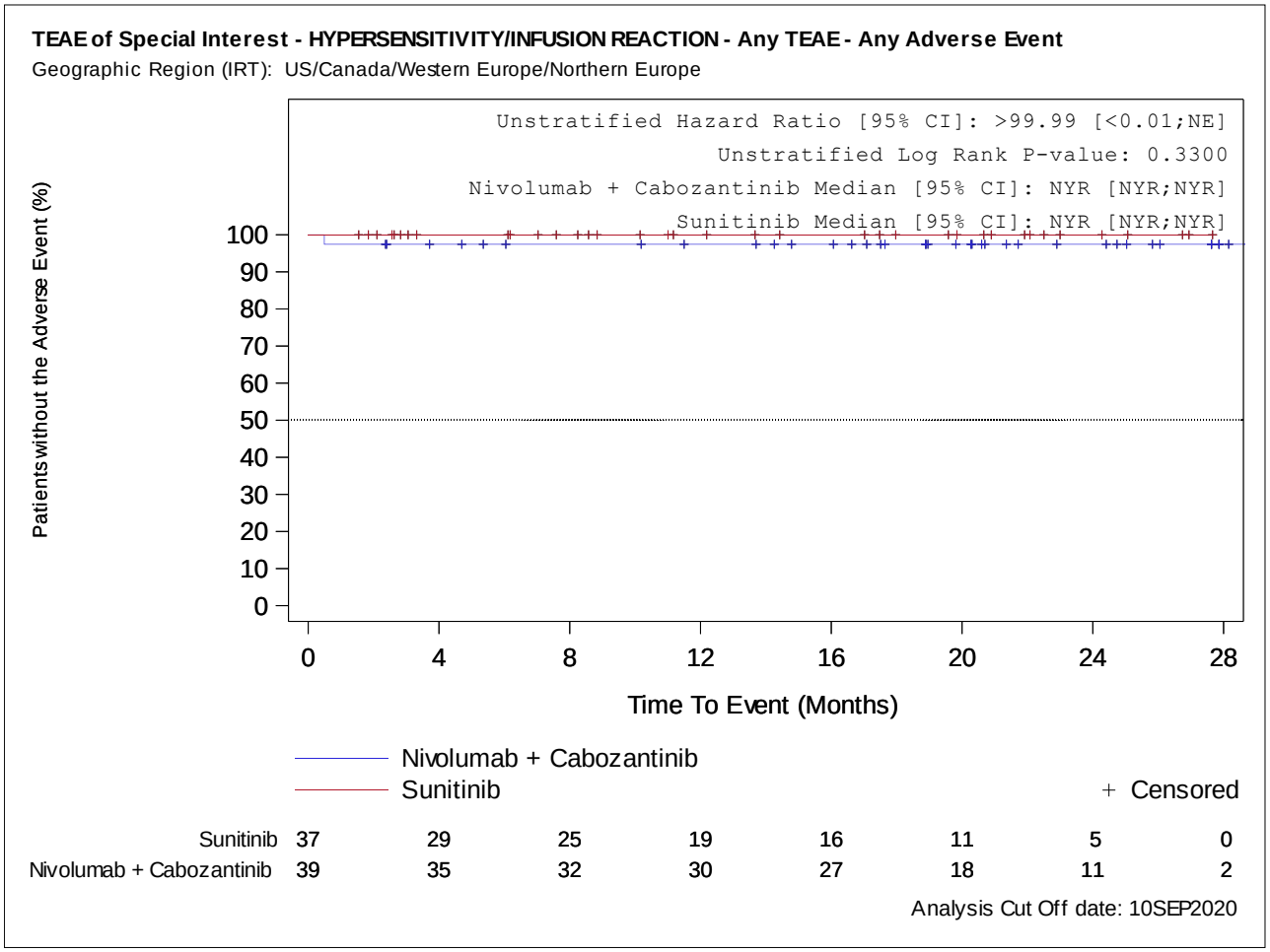

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:38:27

FIGURE 3.35.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



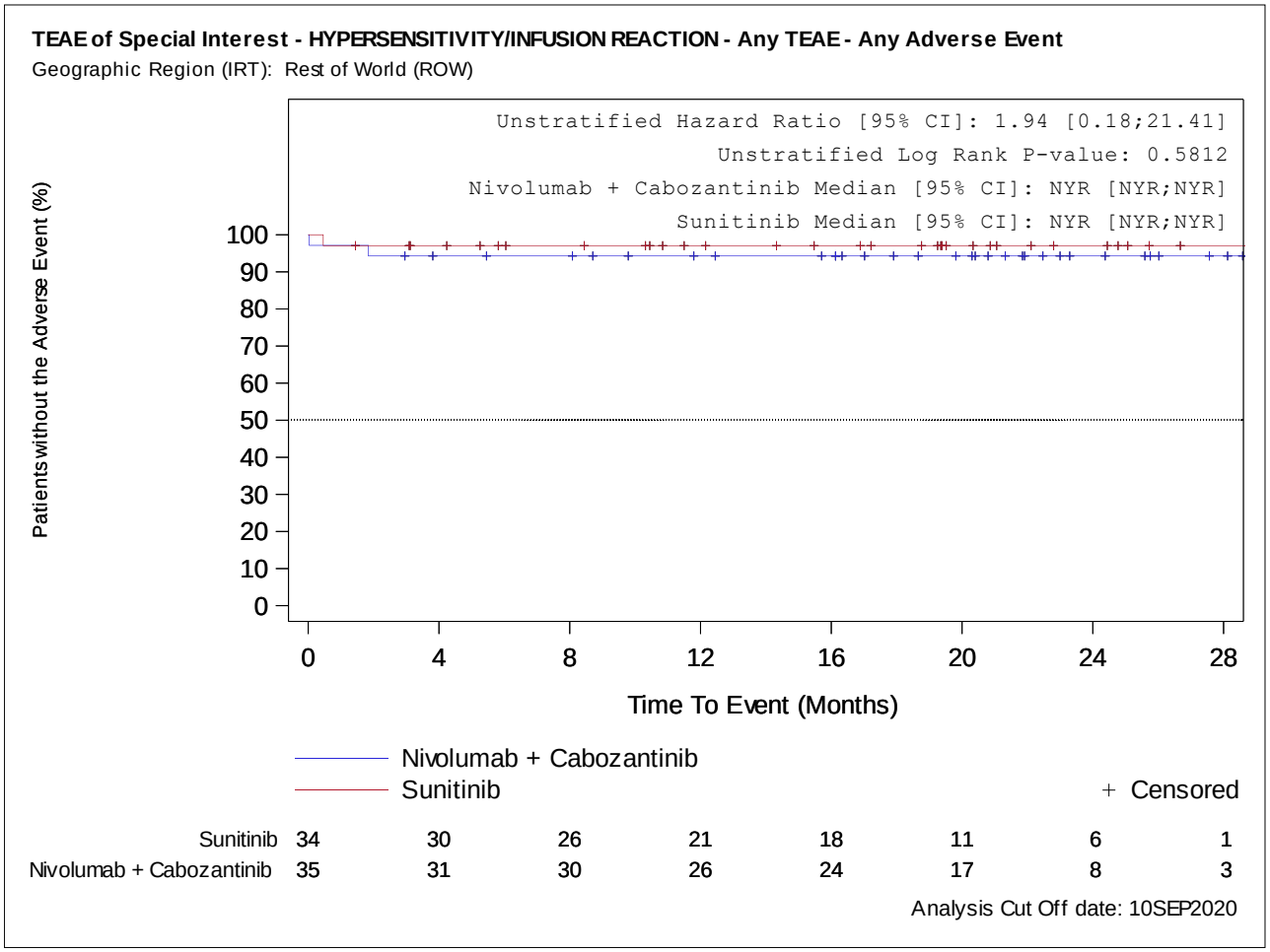

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:38:32

FIGURE 3.35.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



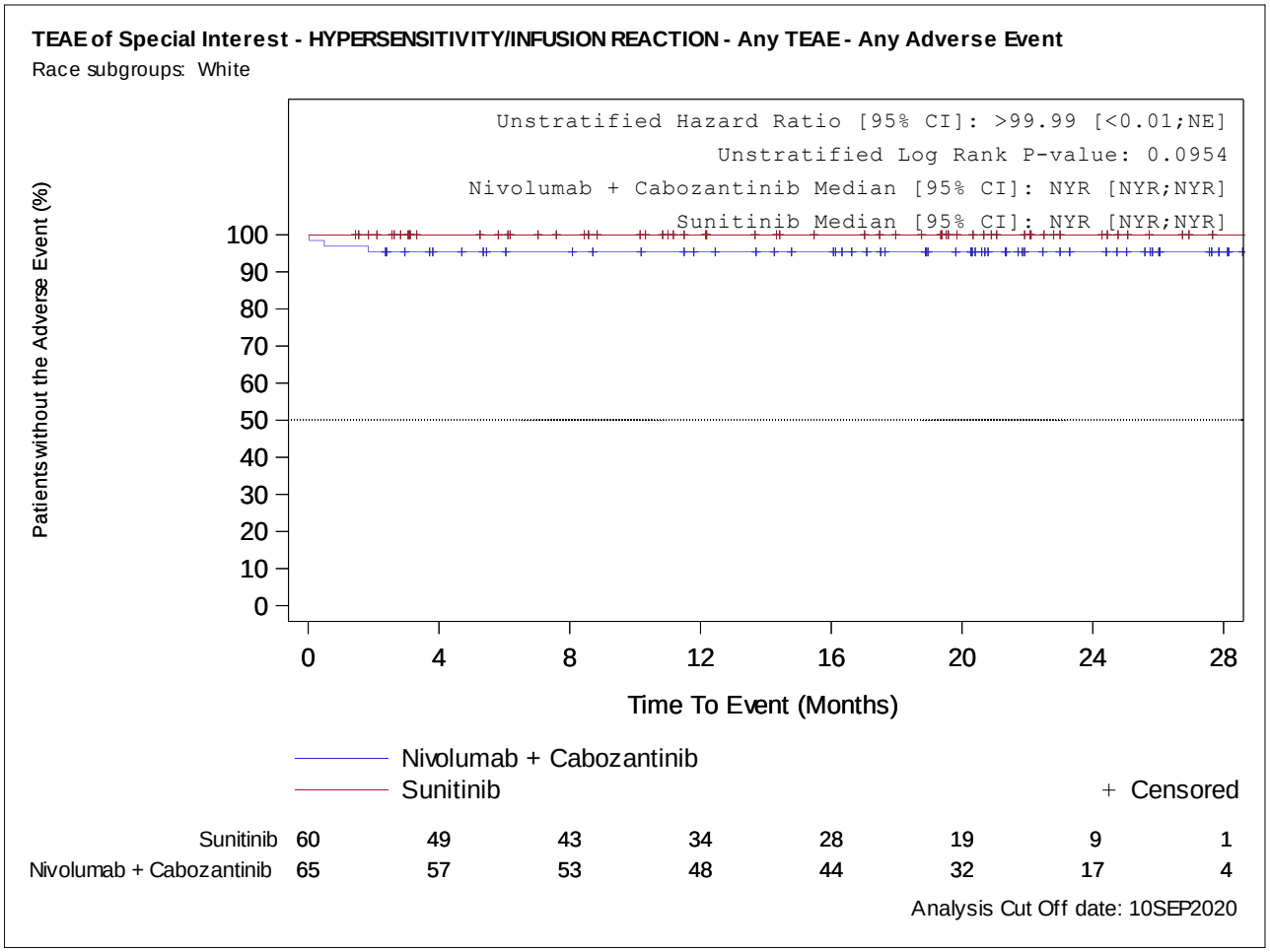

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:38:38

FIGURE 3.35.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



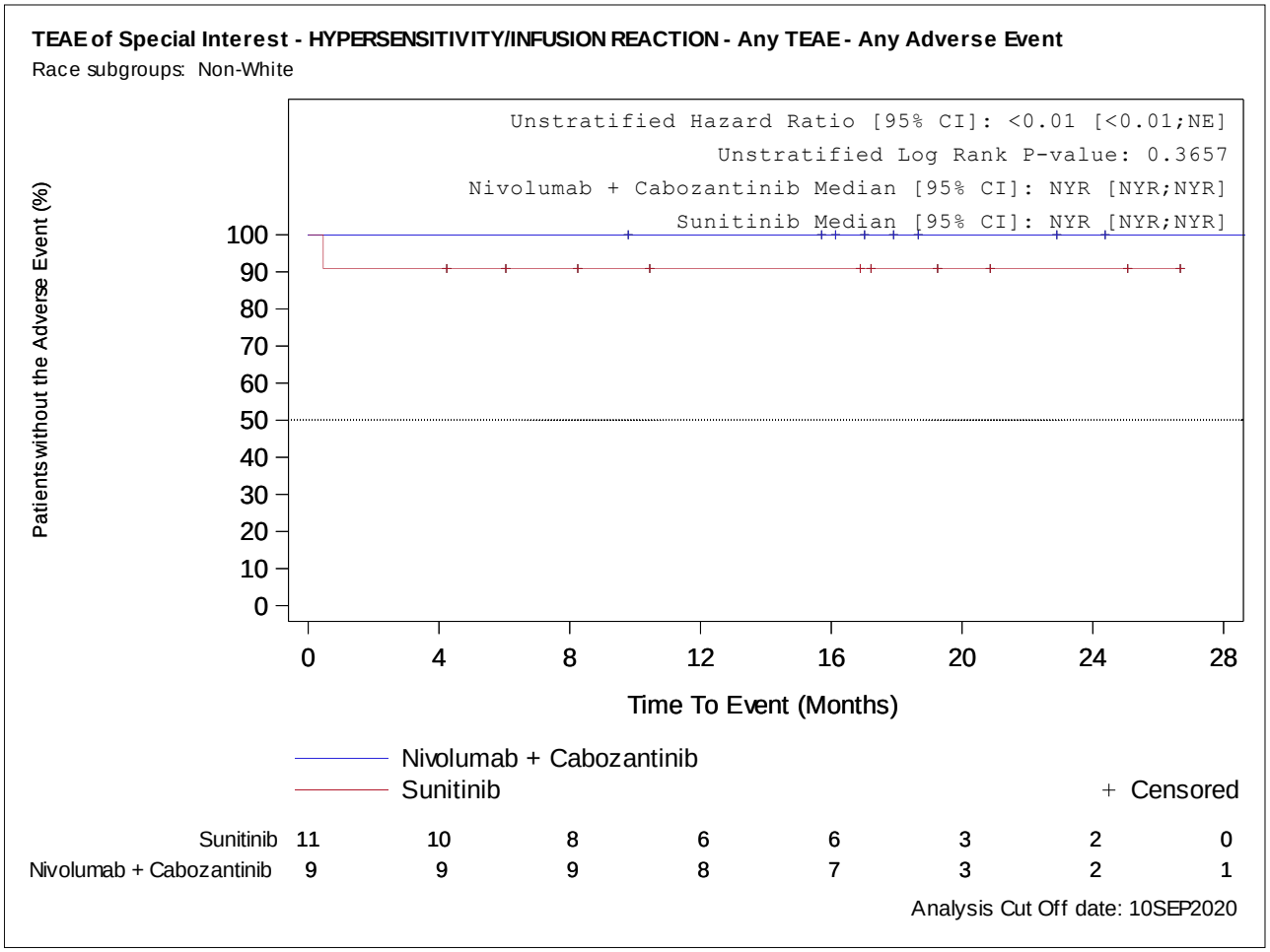

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:38:43

FIGURE 3.35.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



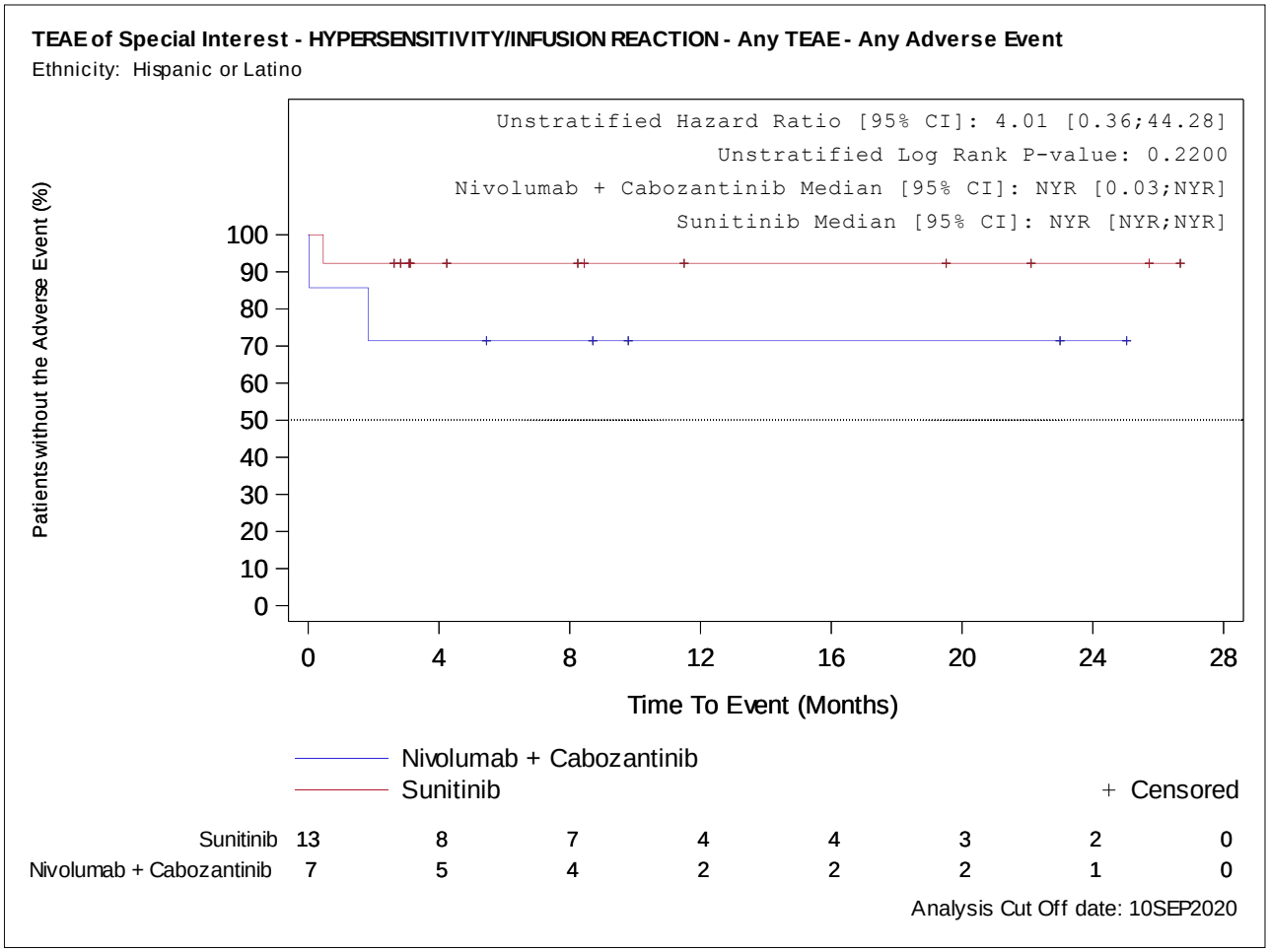

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:38:49

FIGURE 3.35.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



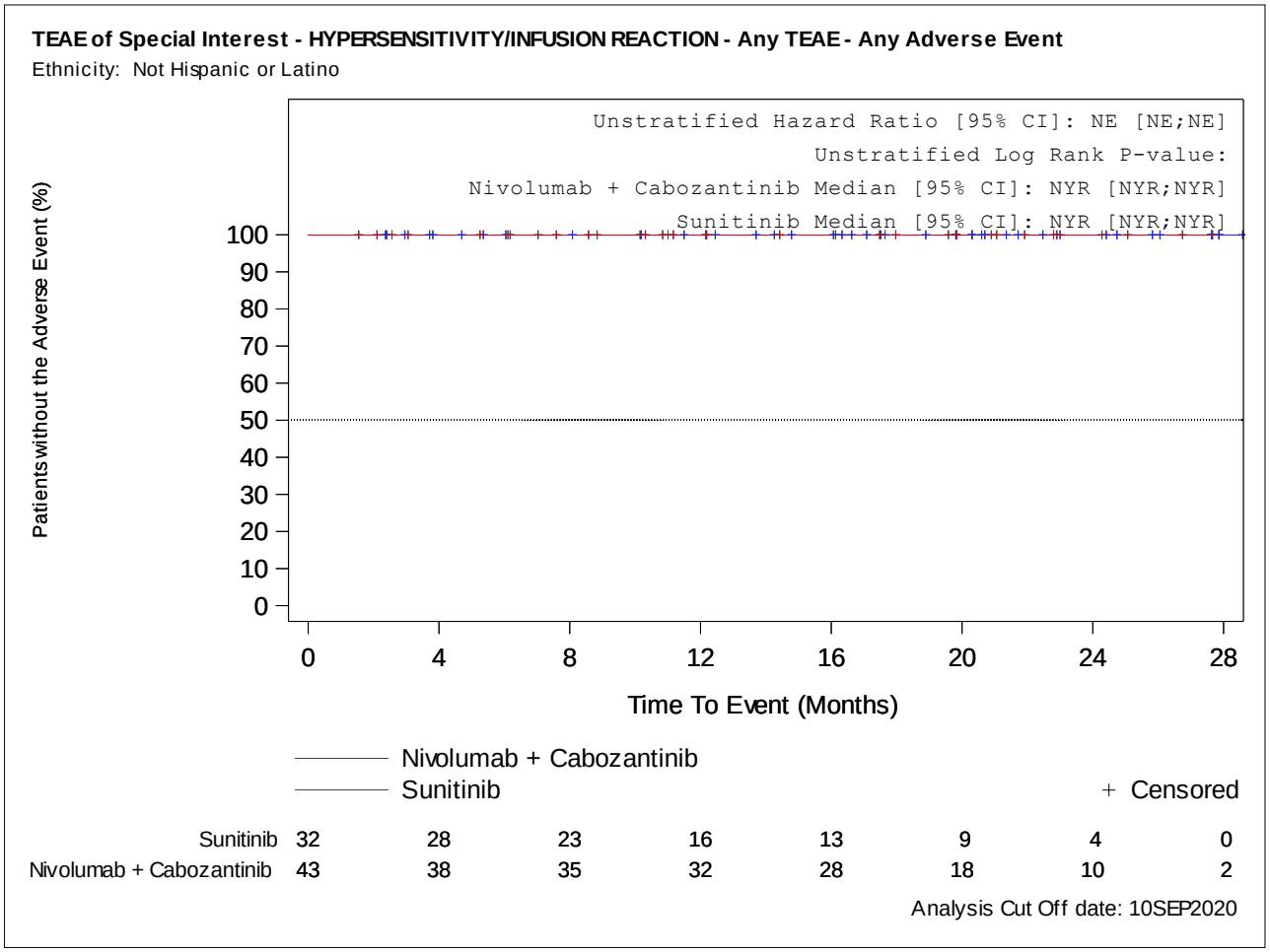

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:38:55

FIGURE 3.35.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



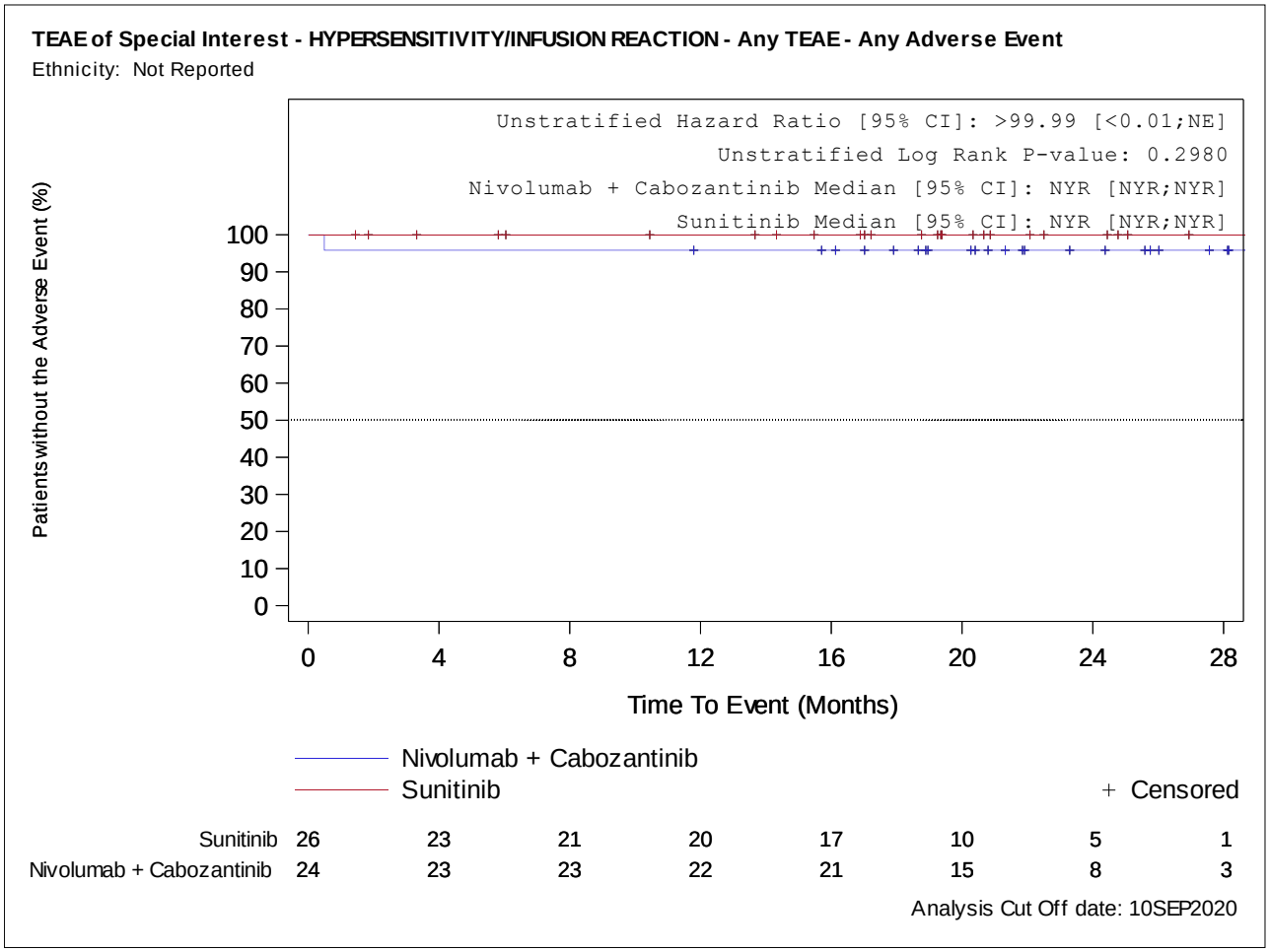

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:39:01

FIGURE 3.35.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



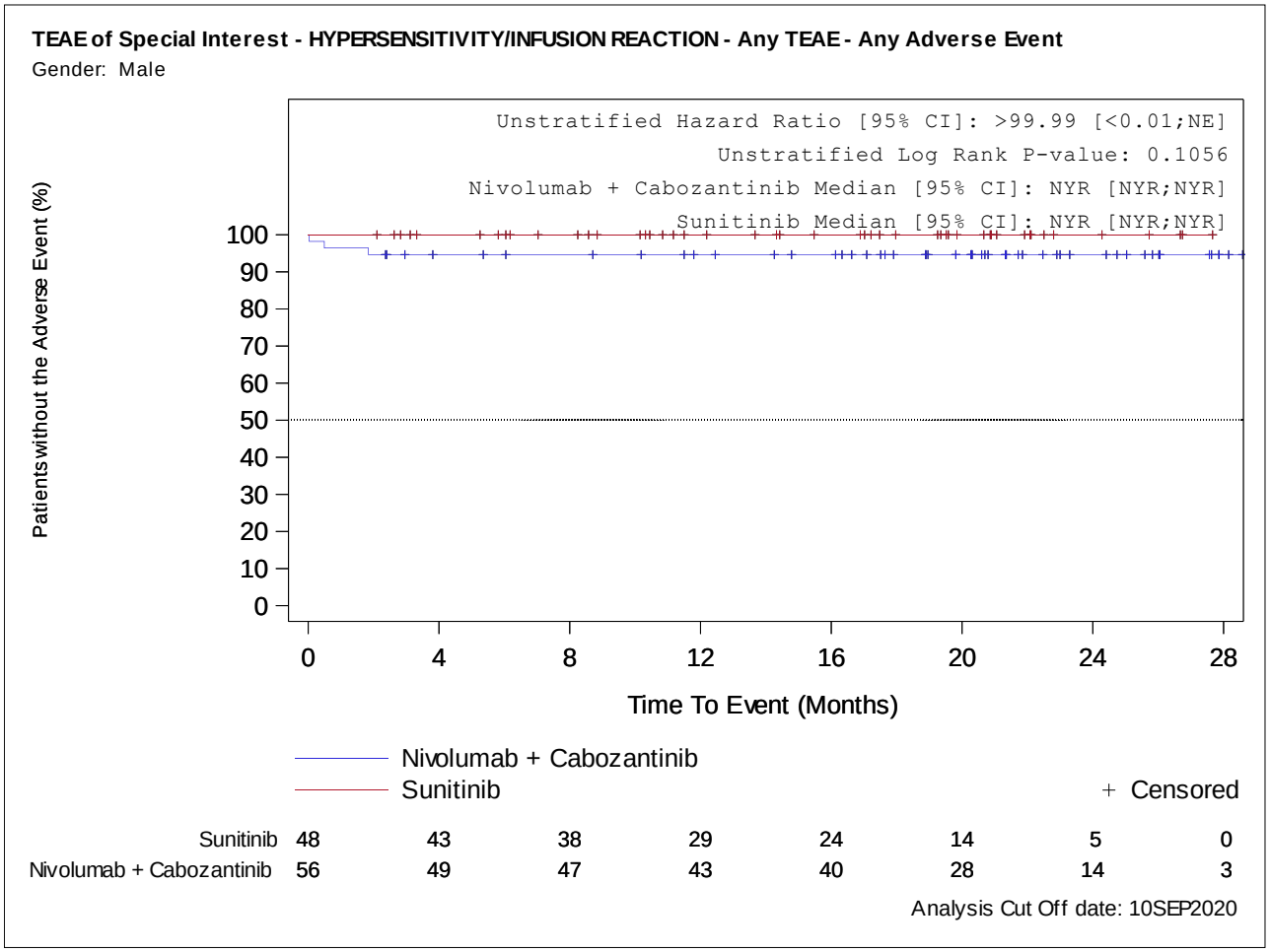

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:39:07

FIGURE 3.35.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



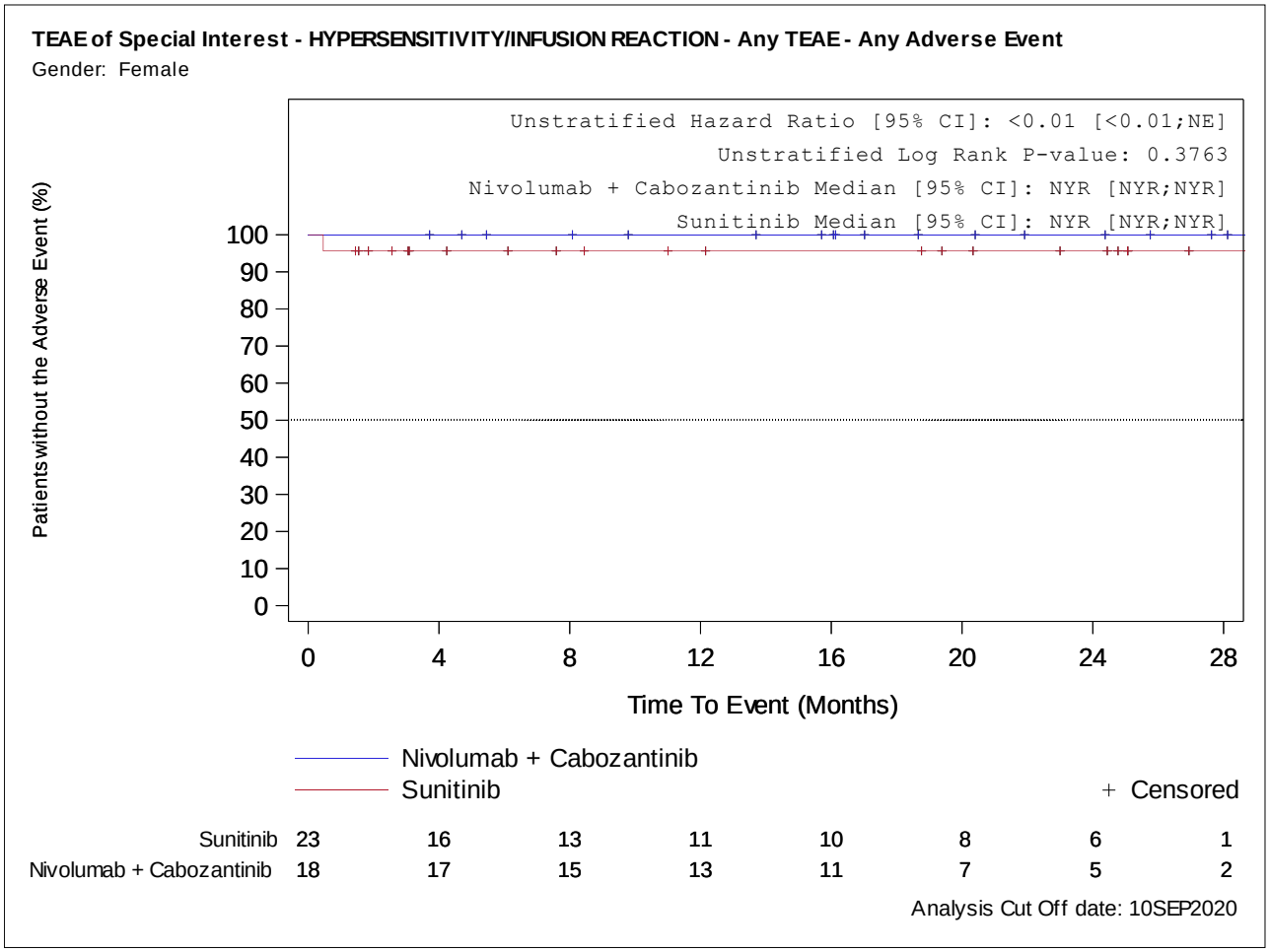

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:39:13

FIGURE 3.35.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



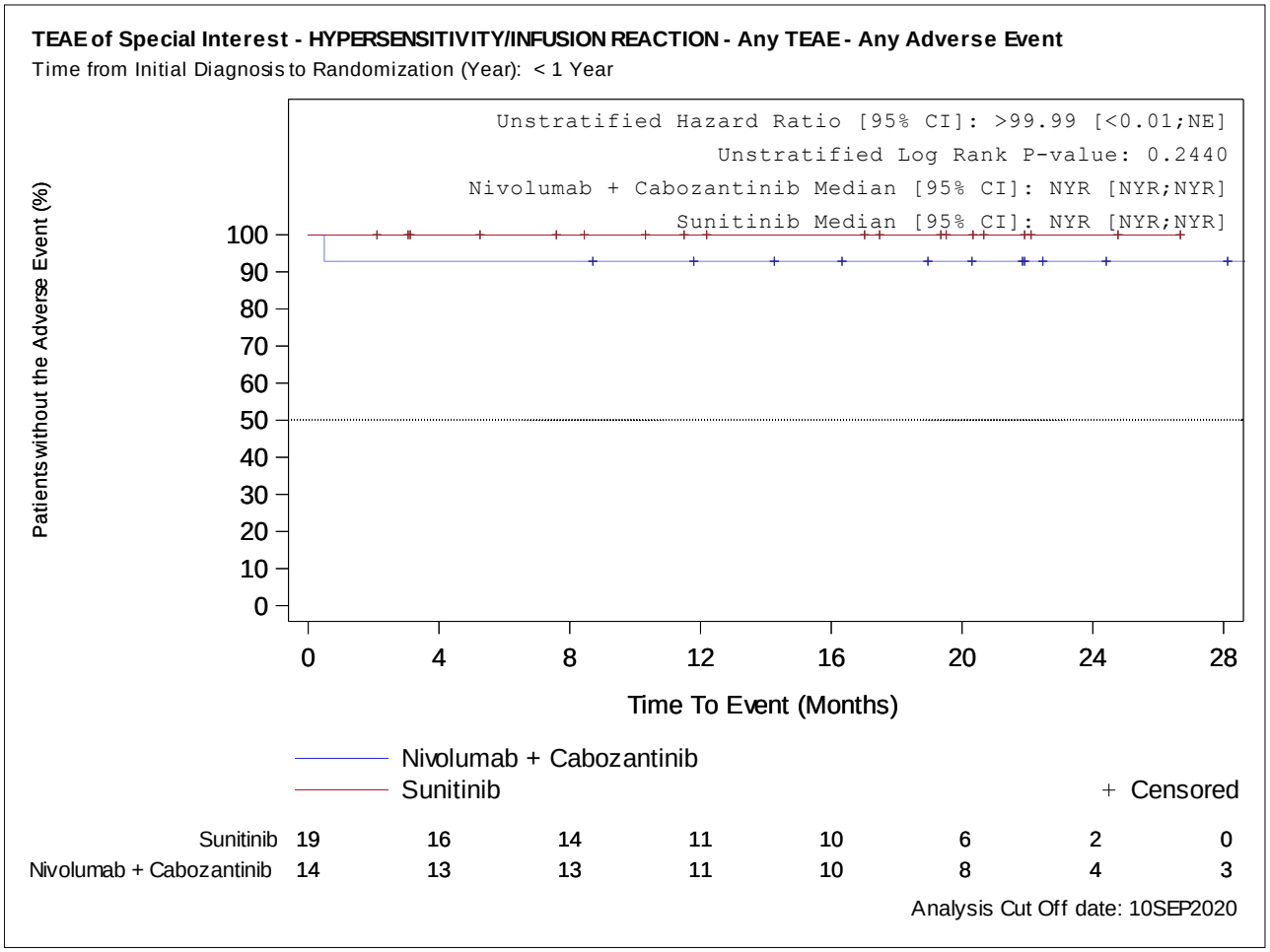

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:39:19

FIGURE 3.35.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



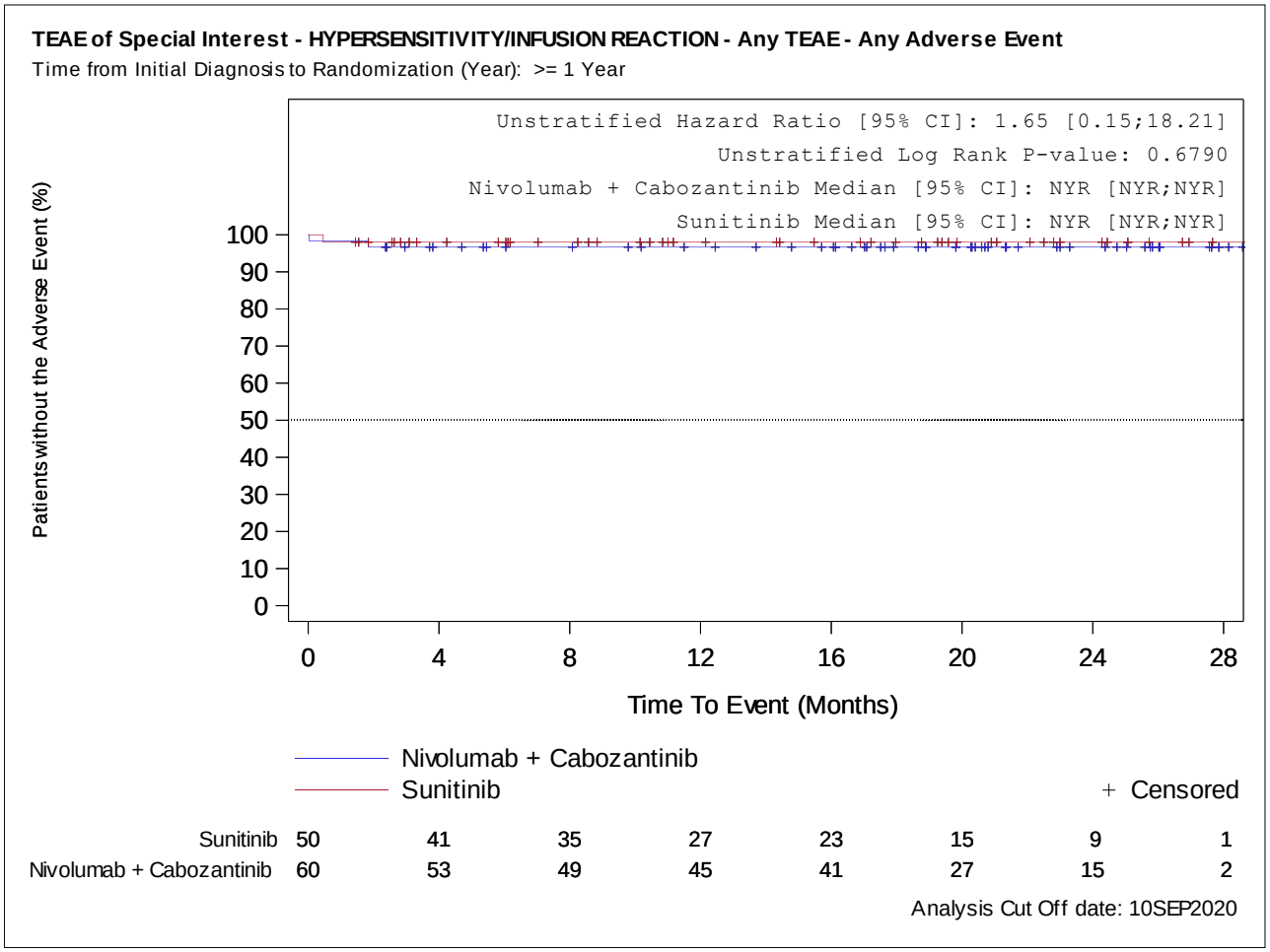

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:39:25

FIGURE 3.35.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



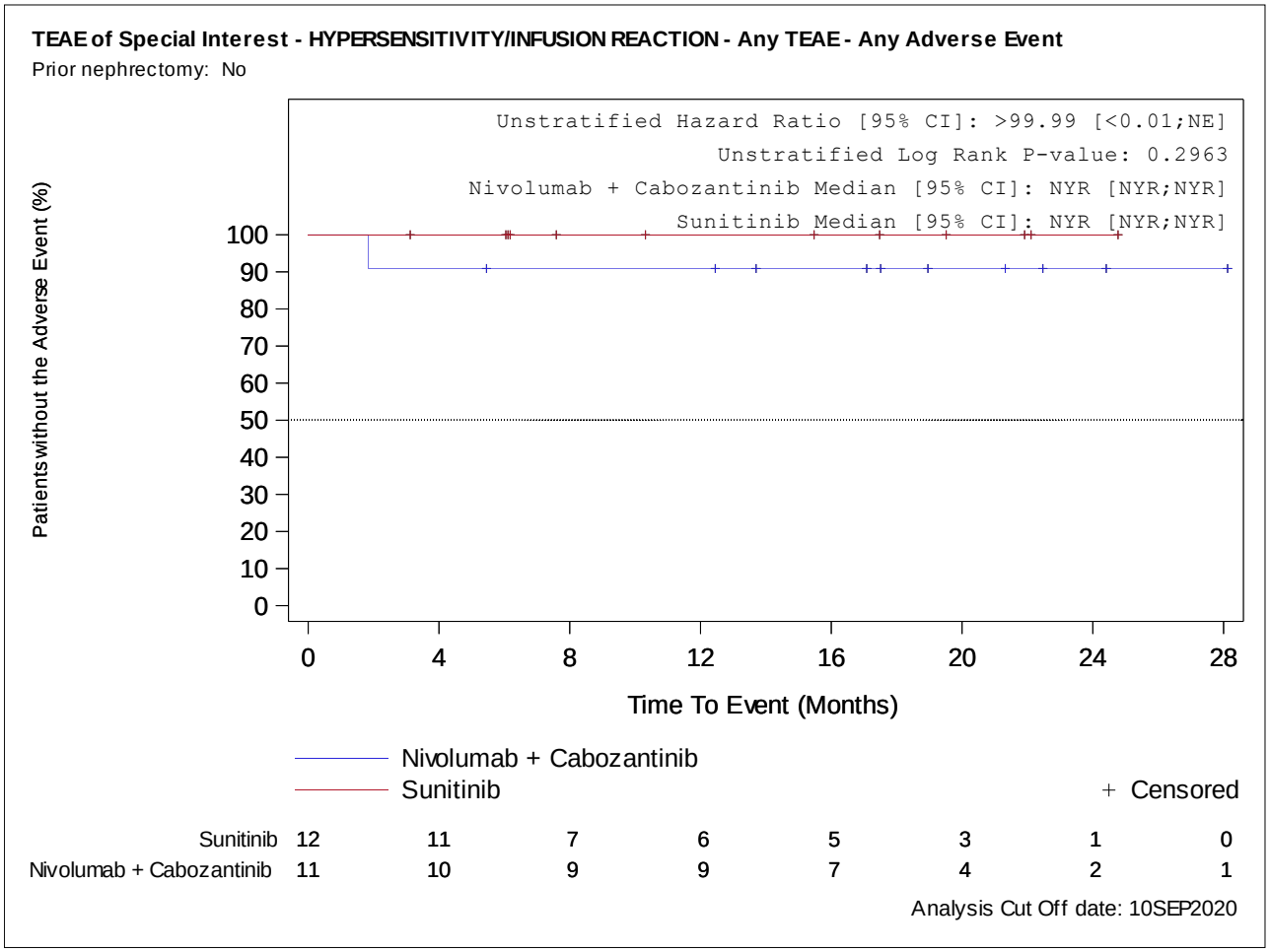

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:39:42

FIGURE 3.35.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:39:48

FIGURE 3.35.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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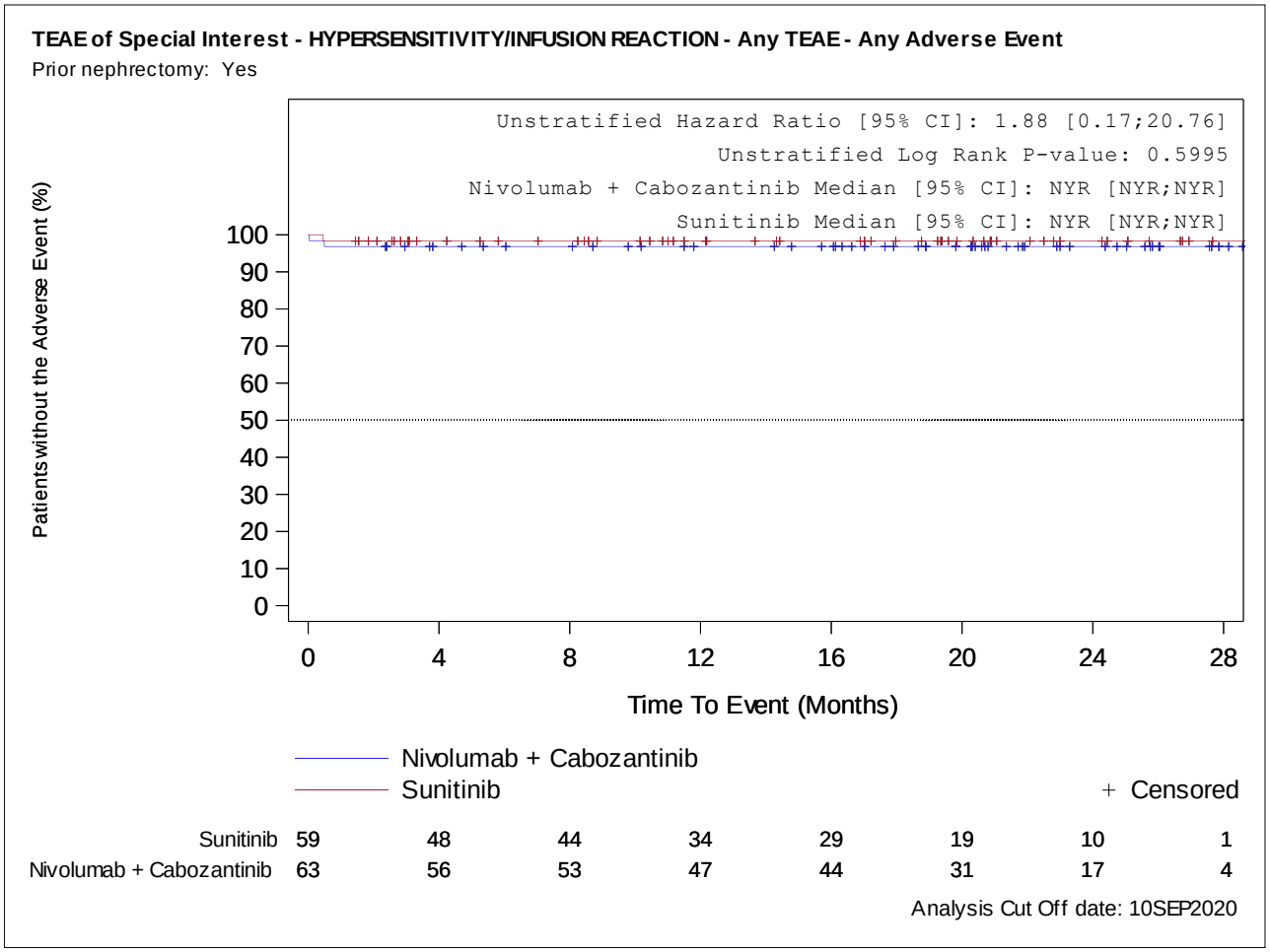
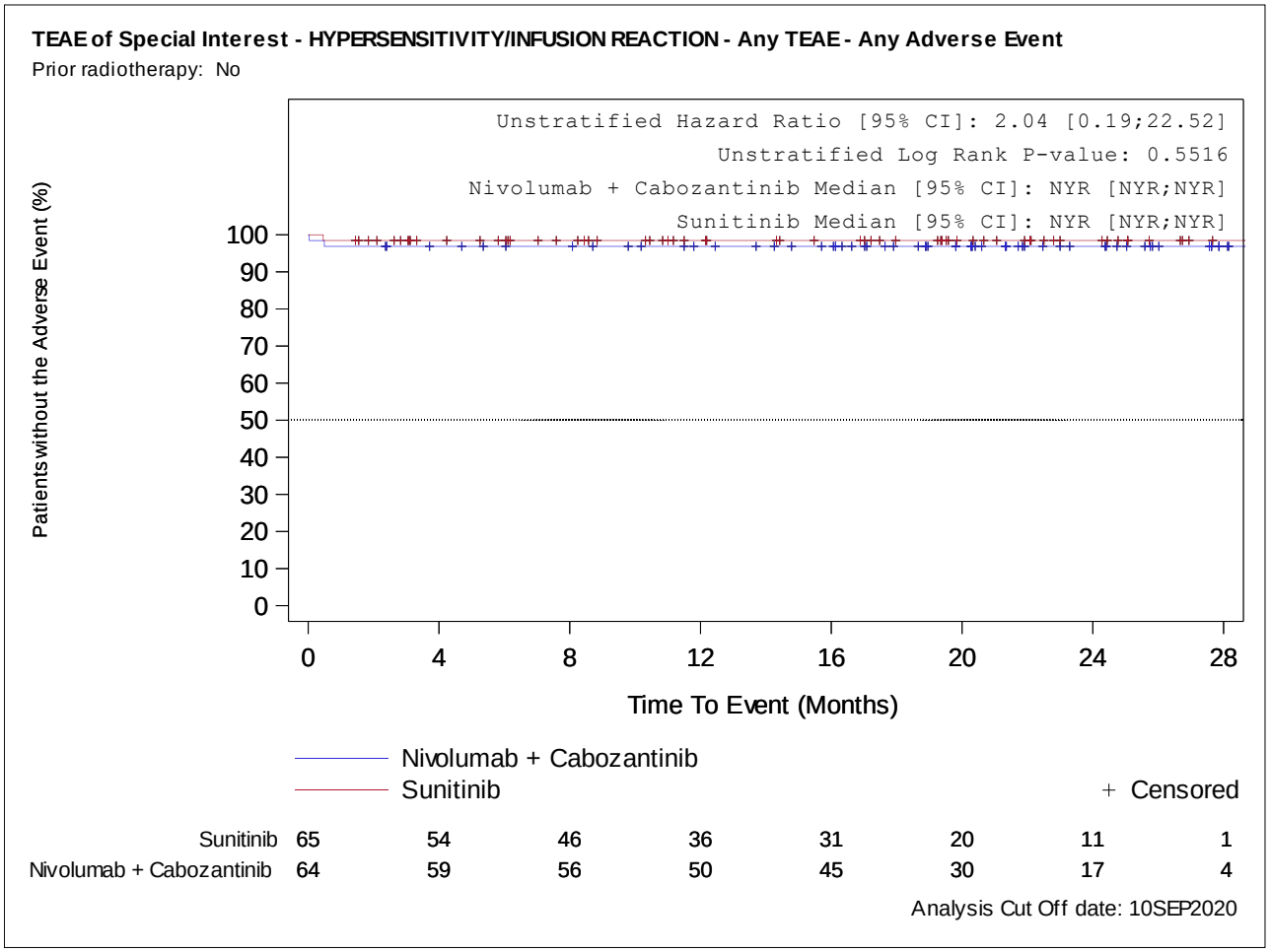
FIGURE 3.35.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:40:47

FIGURE 3.35.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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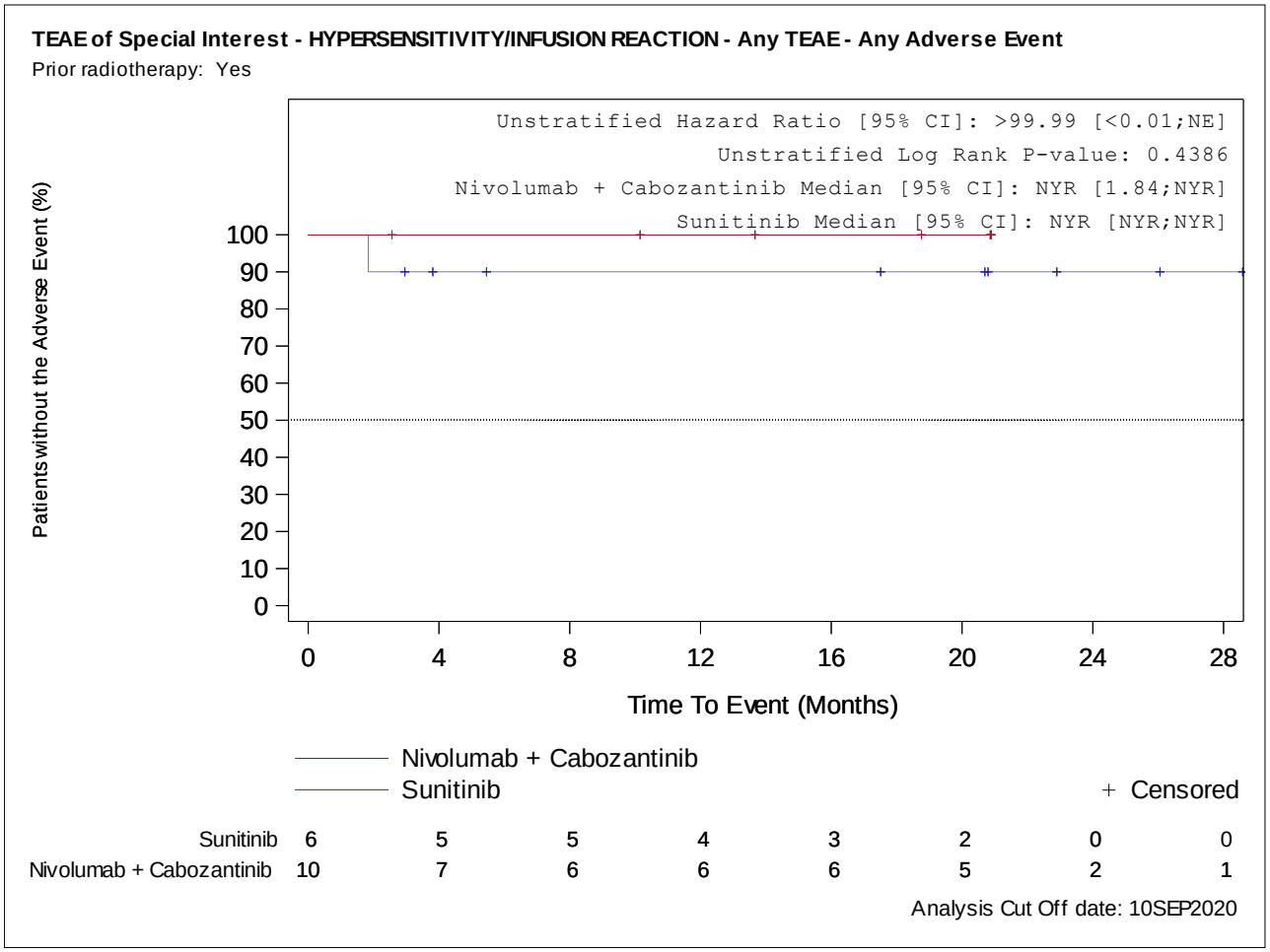
FIGURE 3.35.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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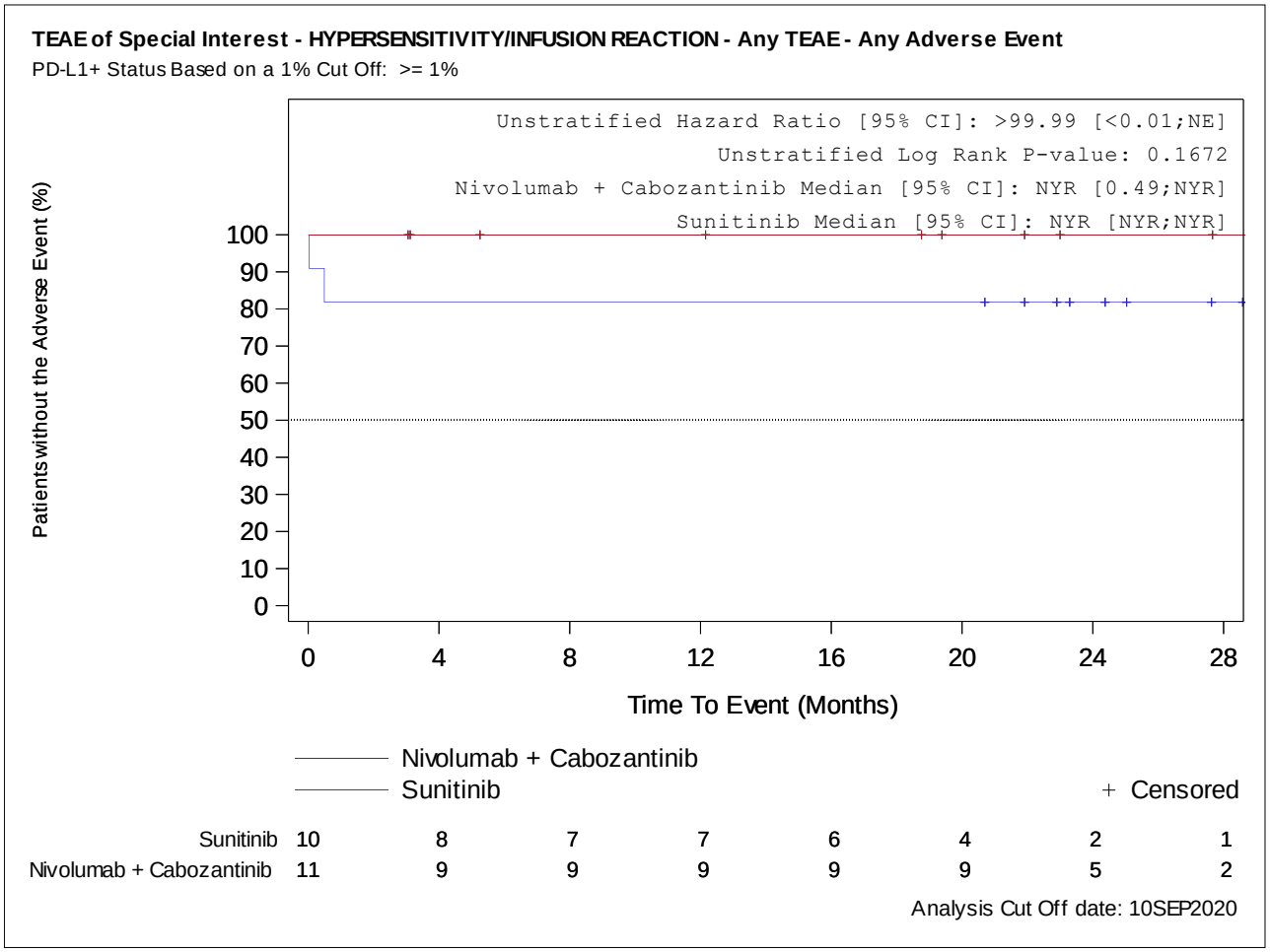
FIGURE 3.35.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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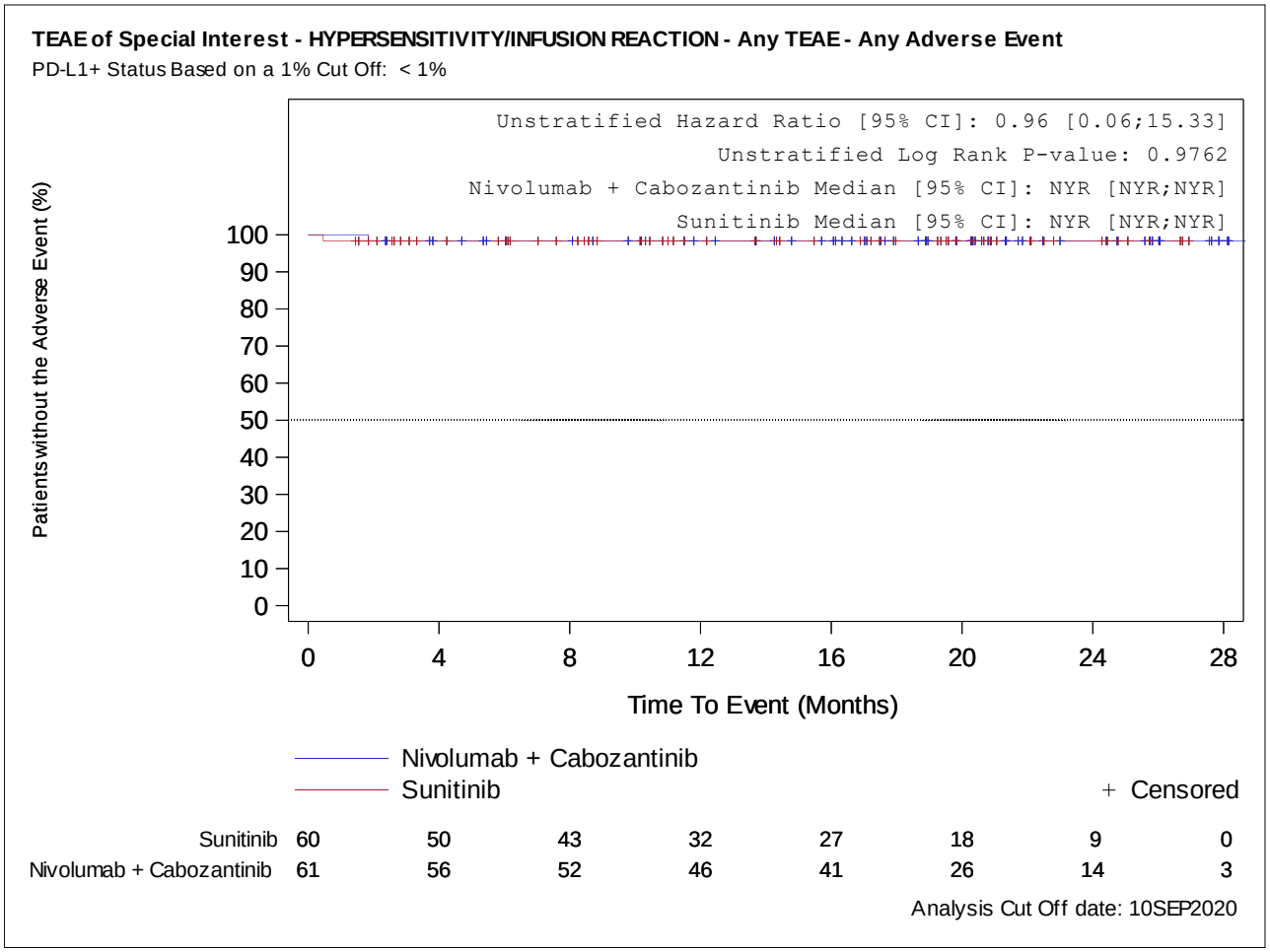
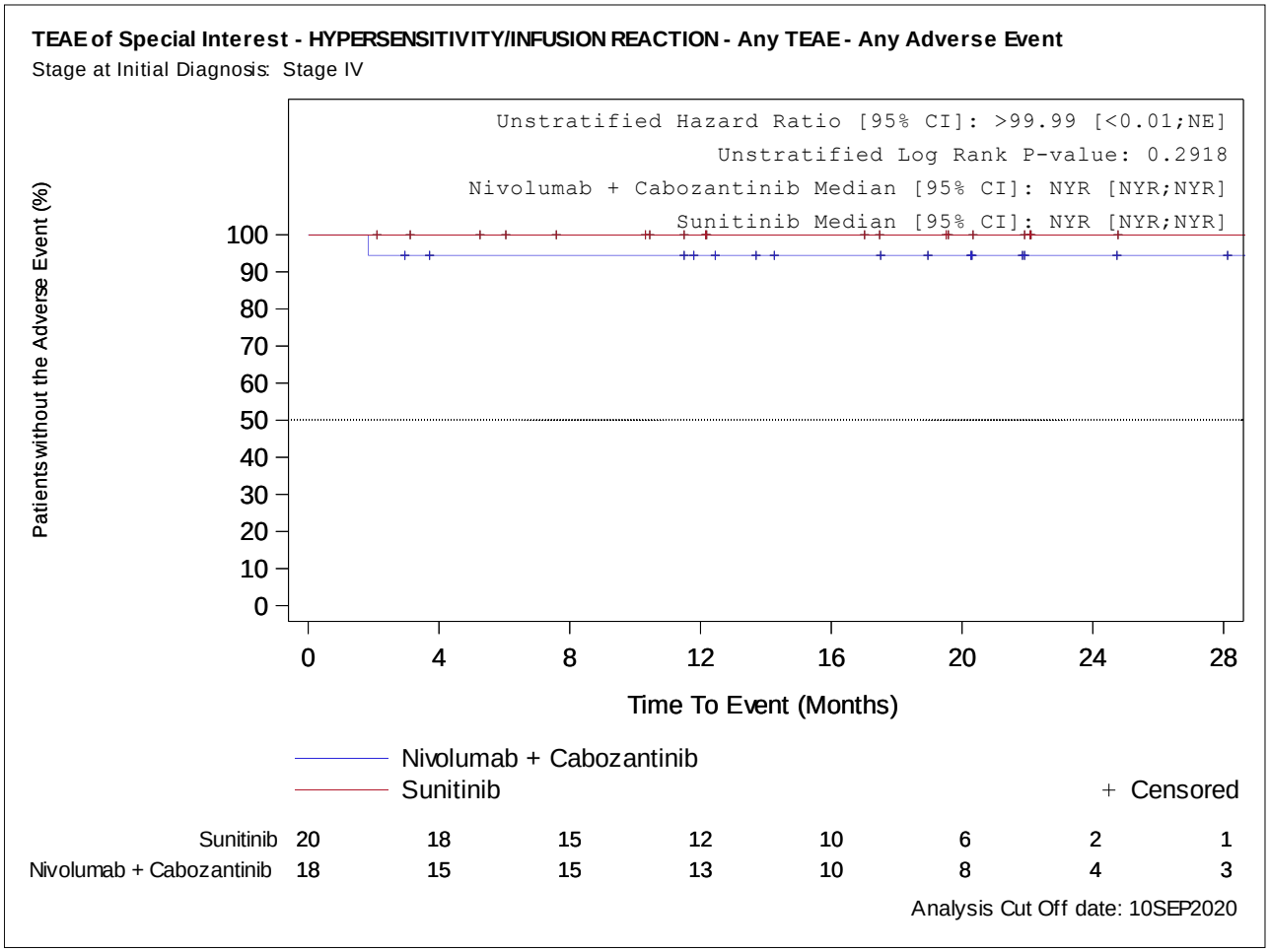
FIGURE 3.35.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



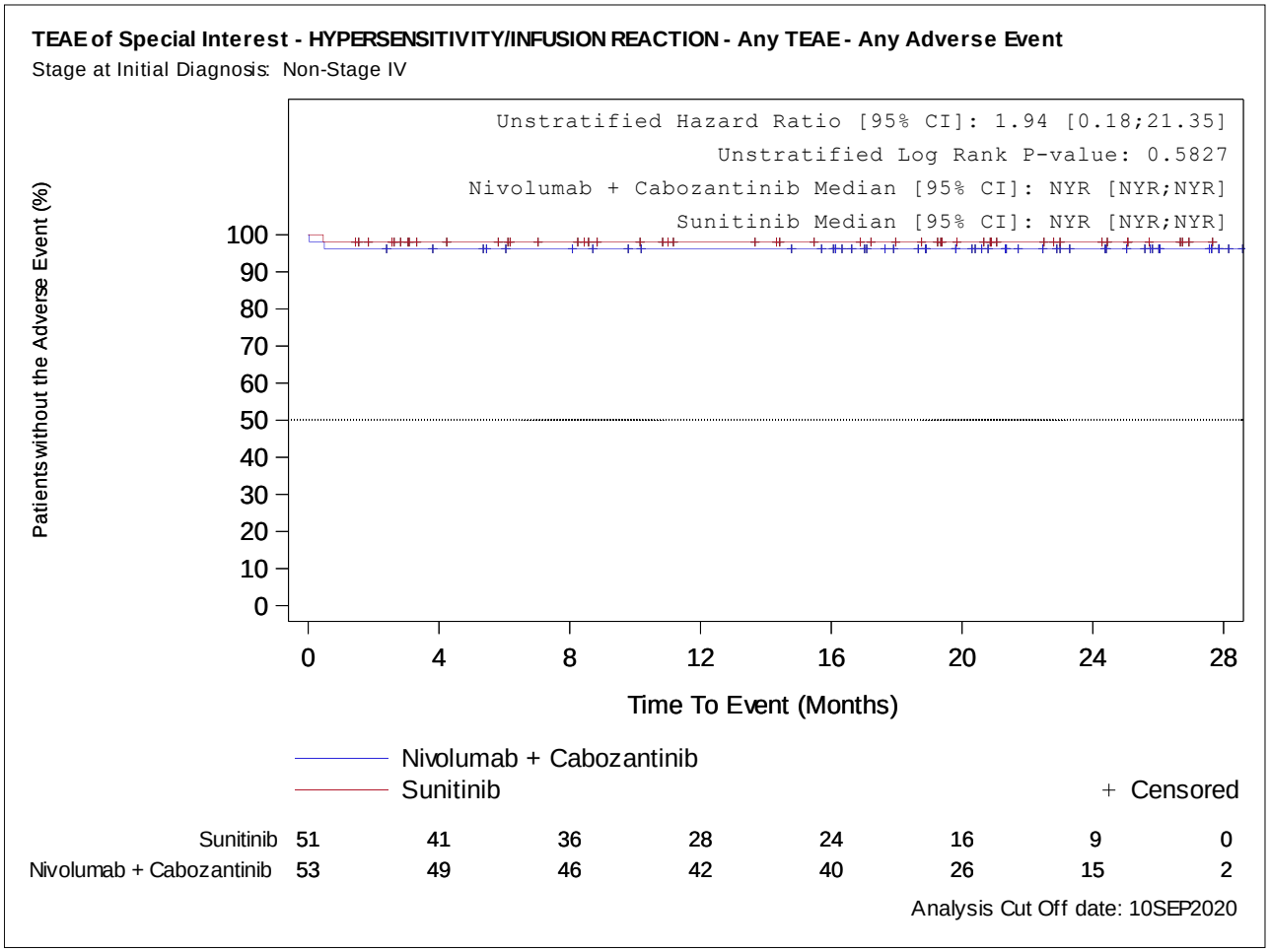

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:41:11

FIGURE 3.35.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



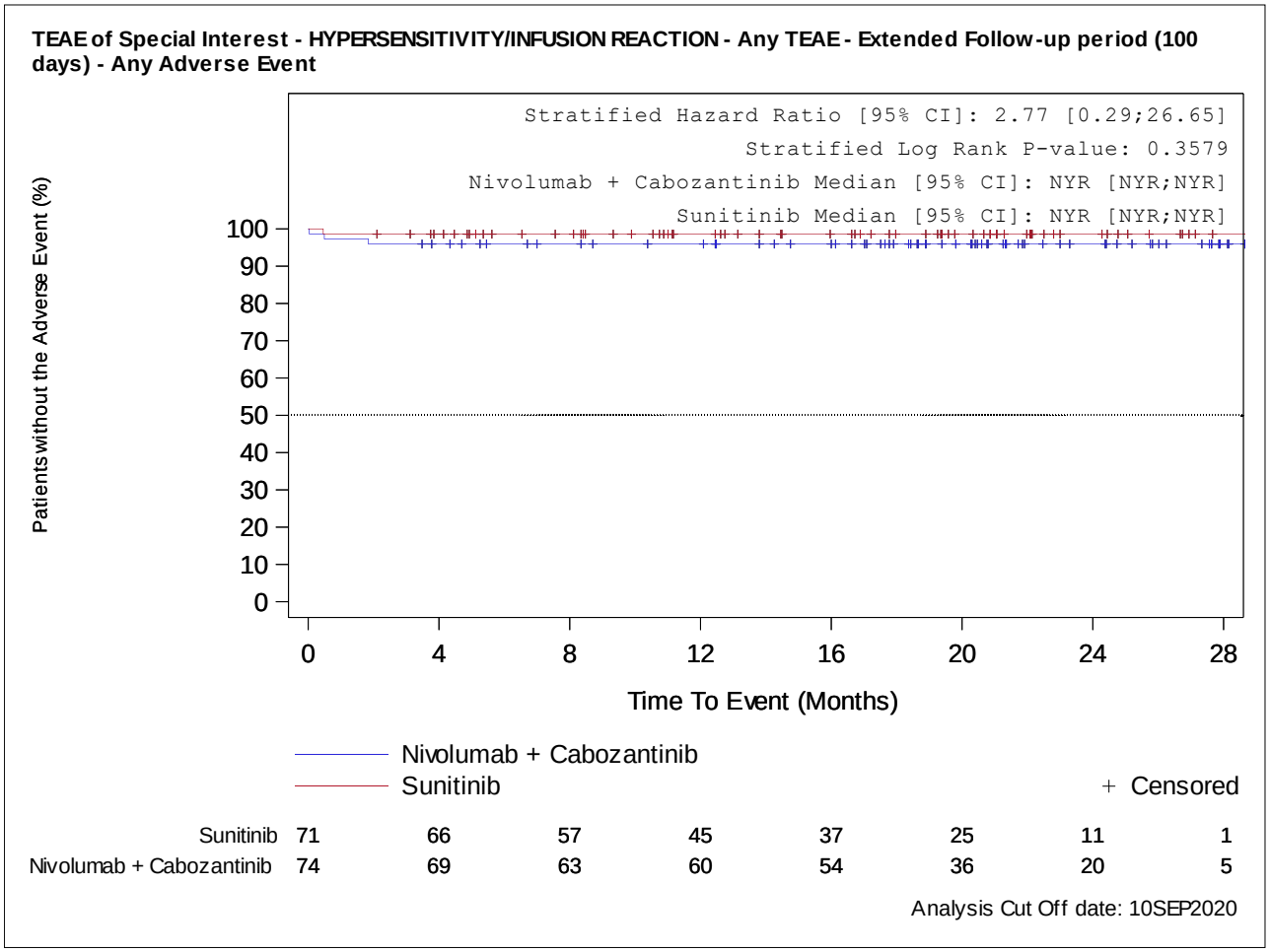

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:41:41

FIGURE 3.35.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



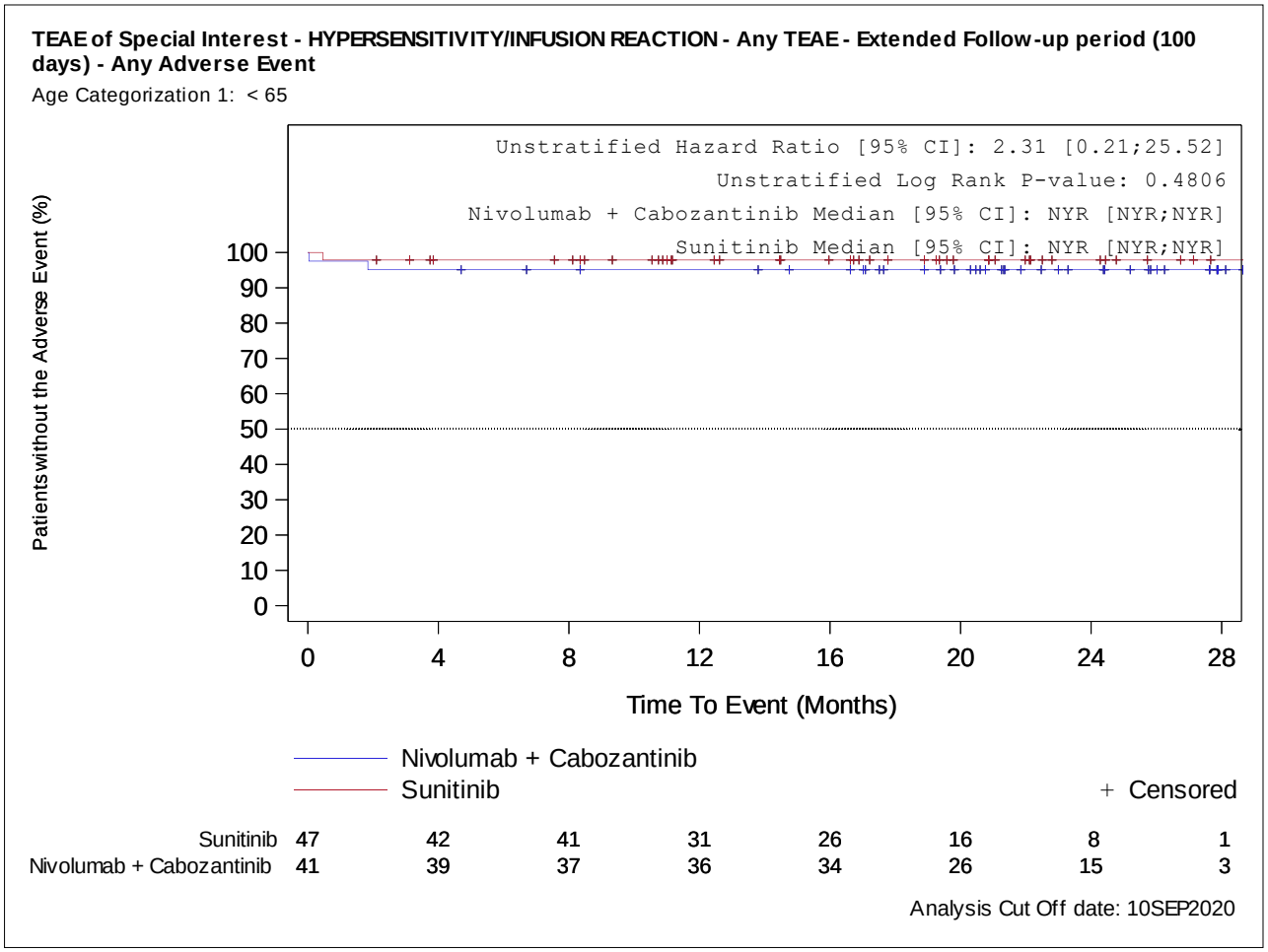

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:41:46

FIGURE 3.36.1: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



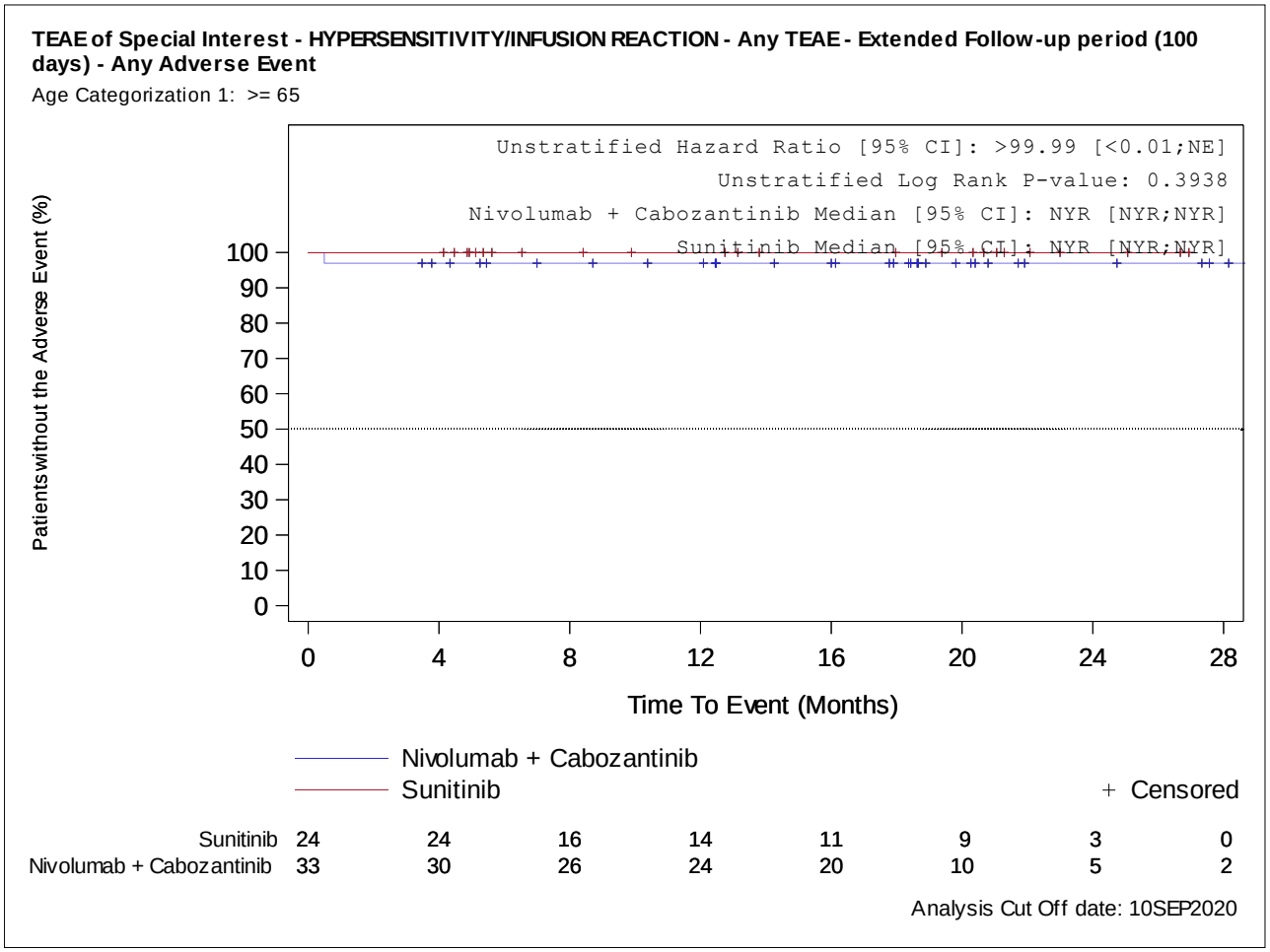

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:45:04

FIGURE 3.36.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



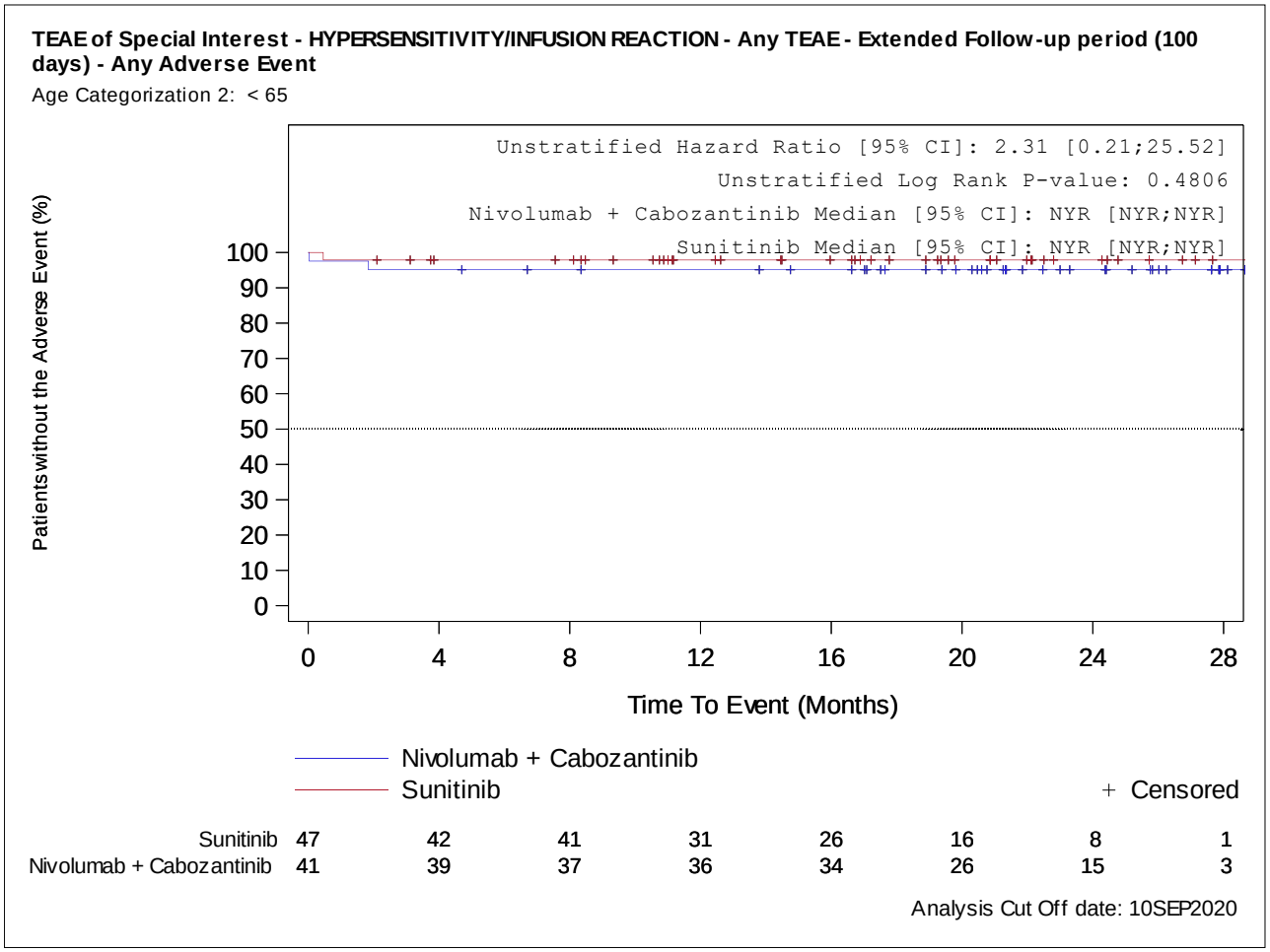

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:45:07

FIGURE 3.36.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



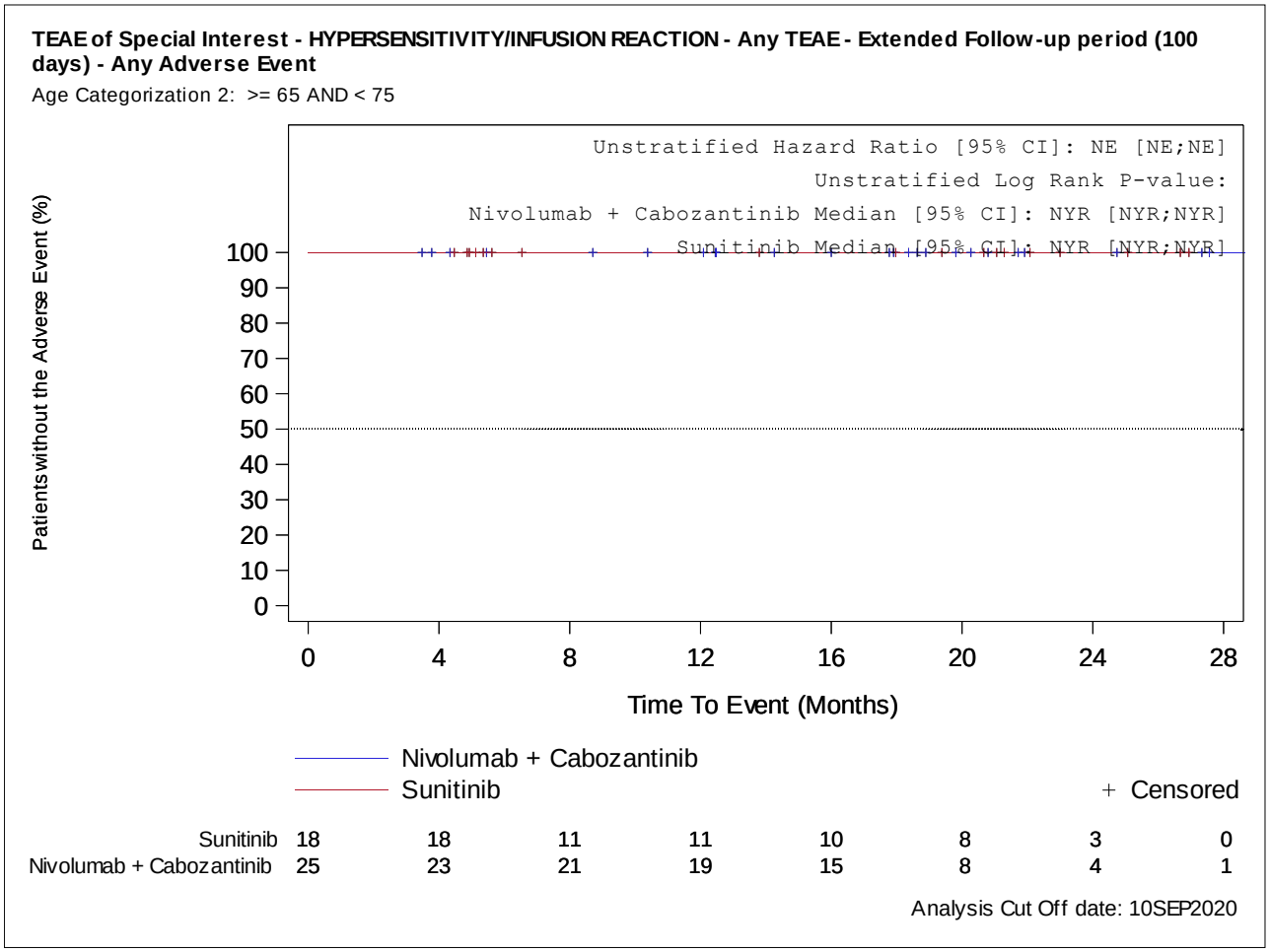

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:45:13

FIGURE 3.36.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



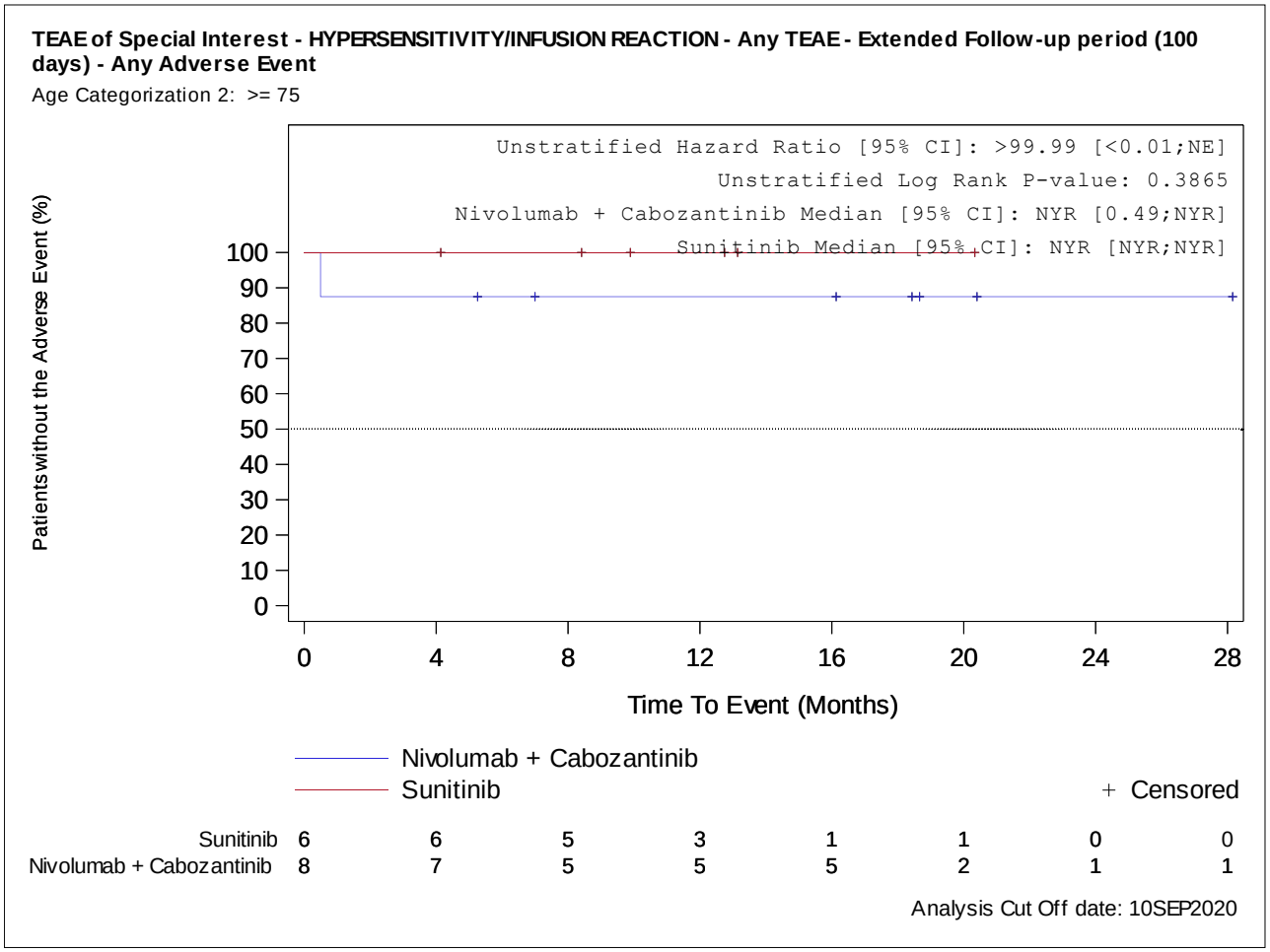

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:45:19

FIGURE 3.36.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



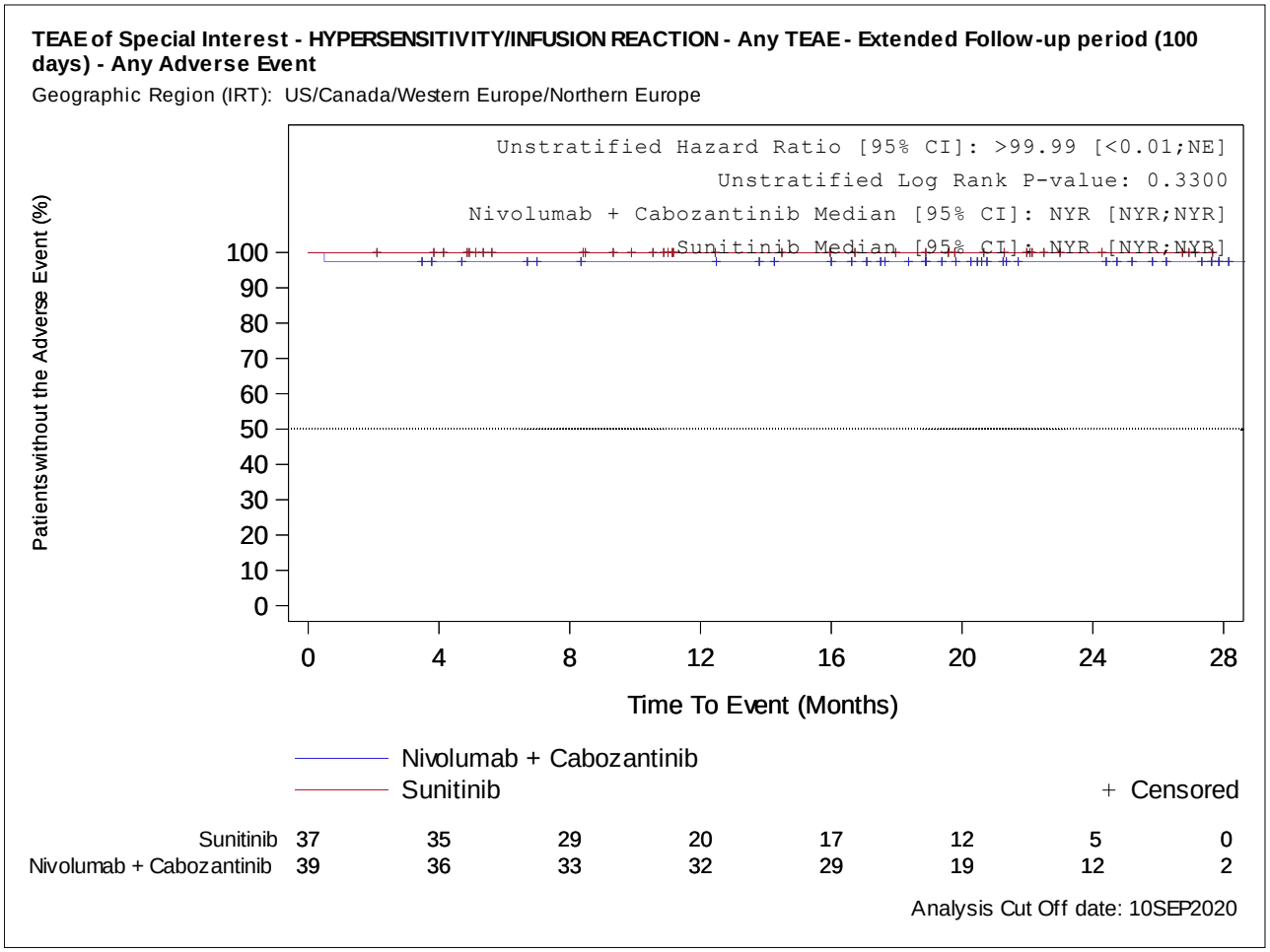

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:45:24

FIGURE 3.36.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



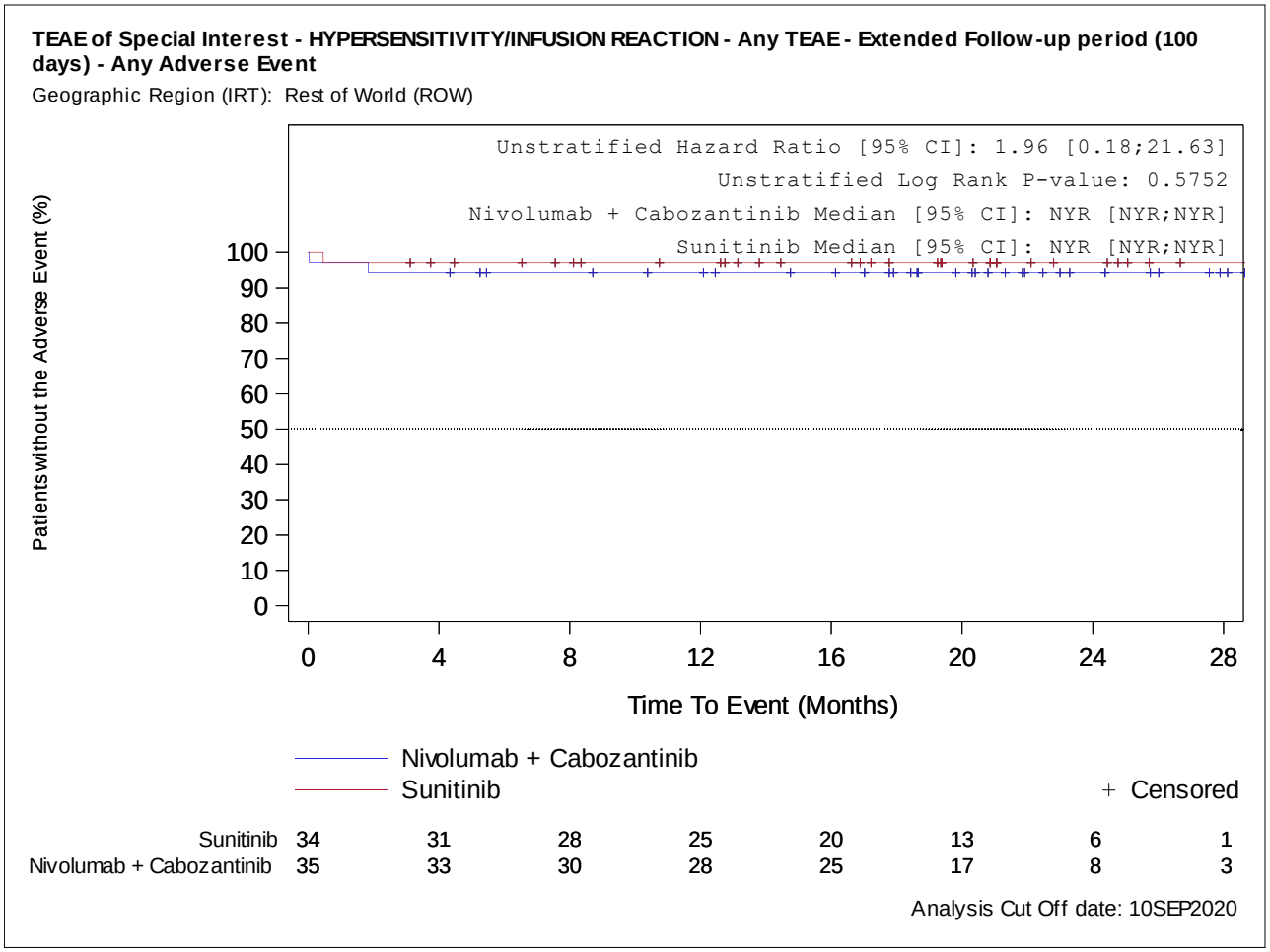

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:45:30

FIGURE 3.36.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



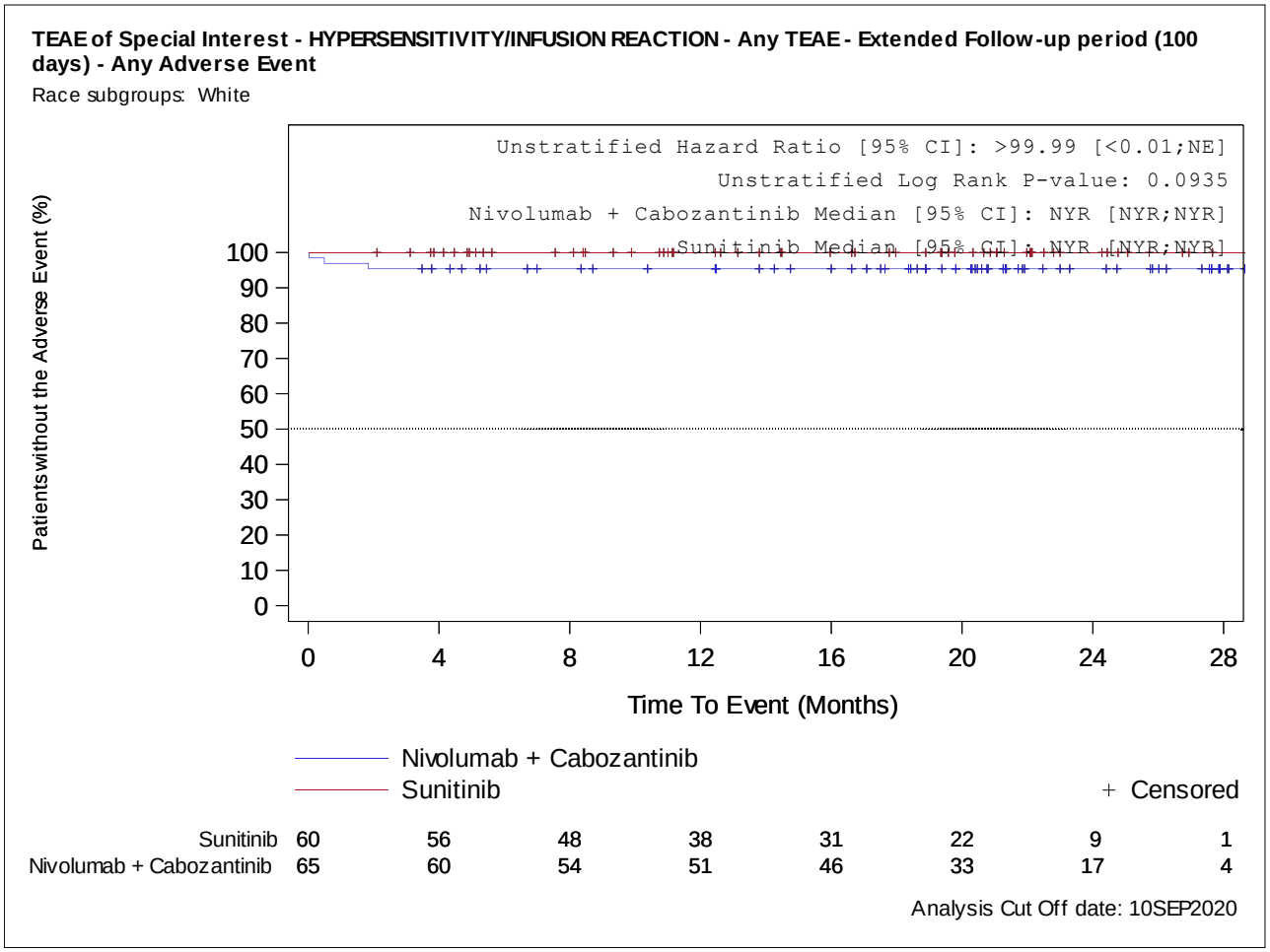

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:45:37

FIGURE 3.36.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



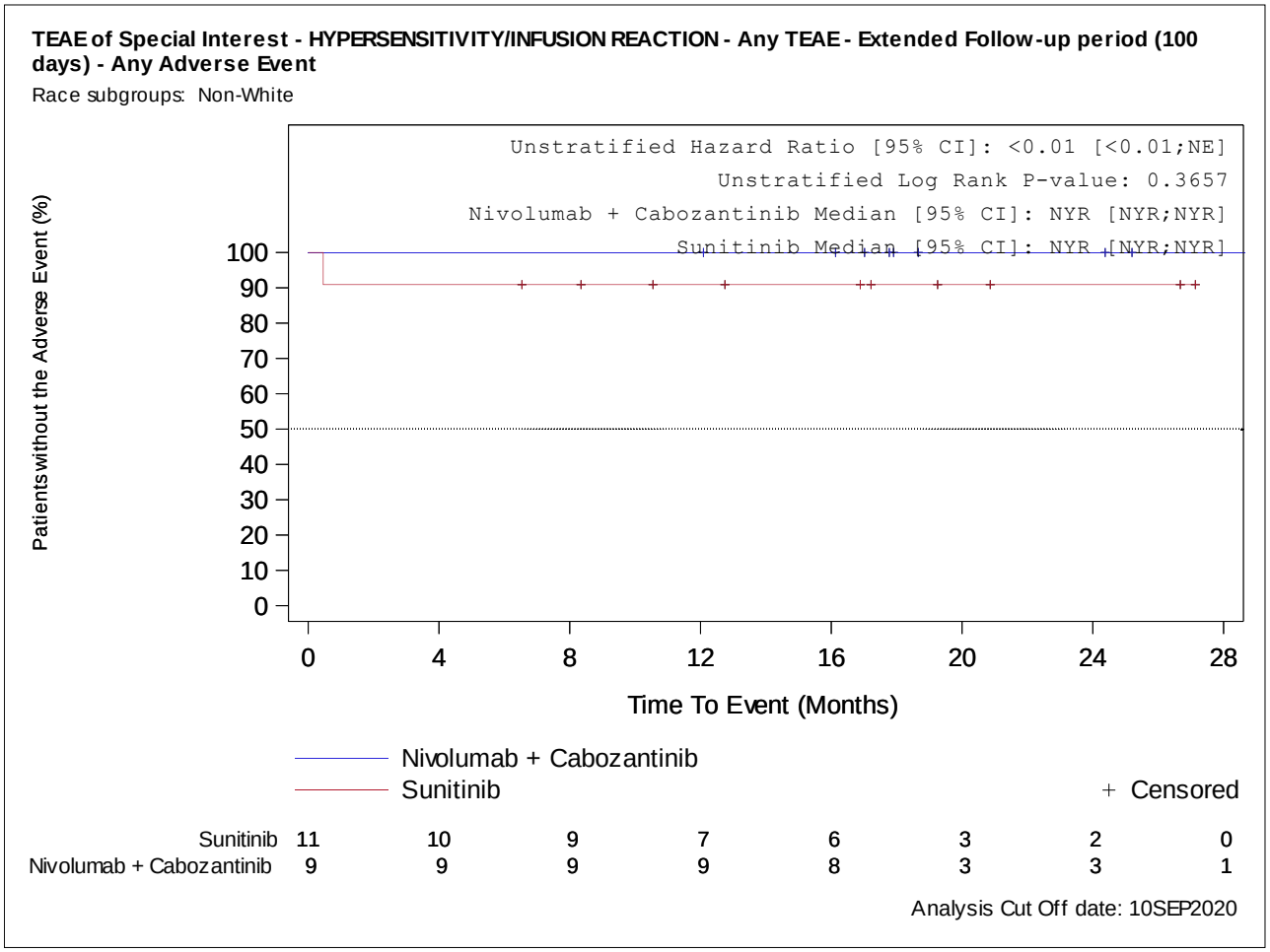

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:45:43

FIGURE 3.36.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



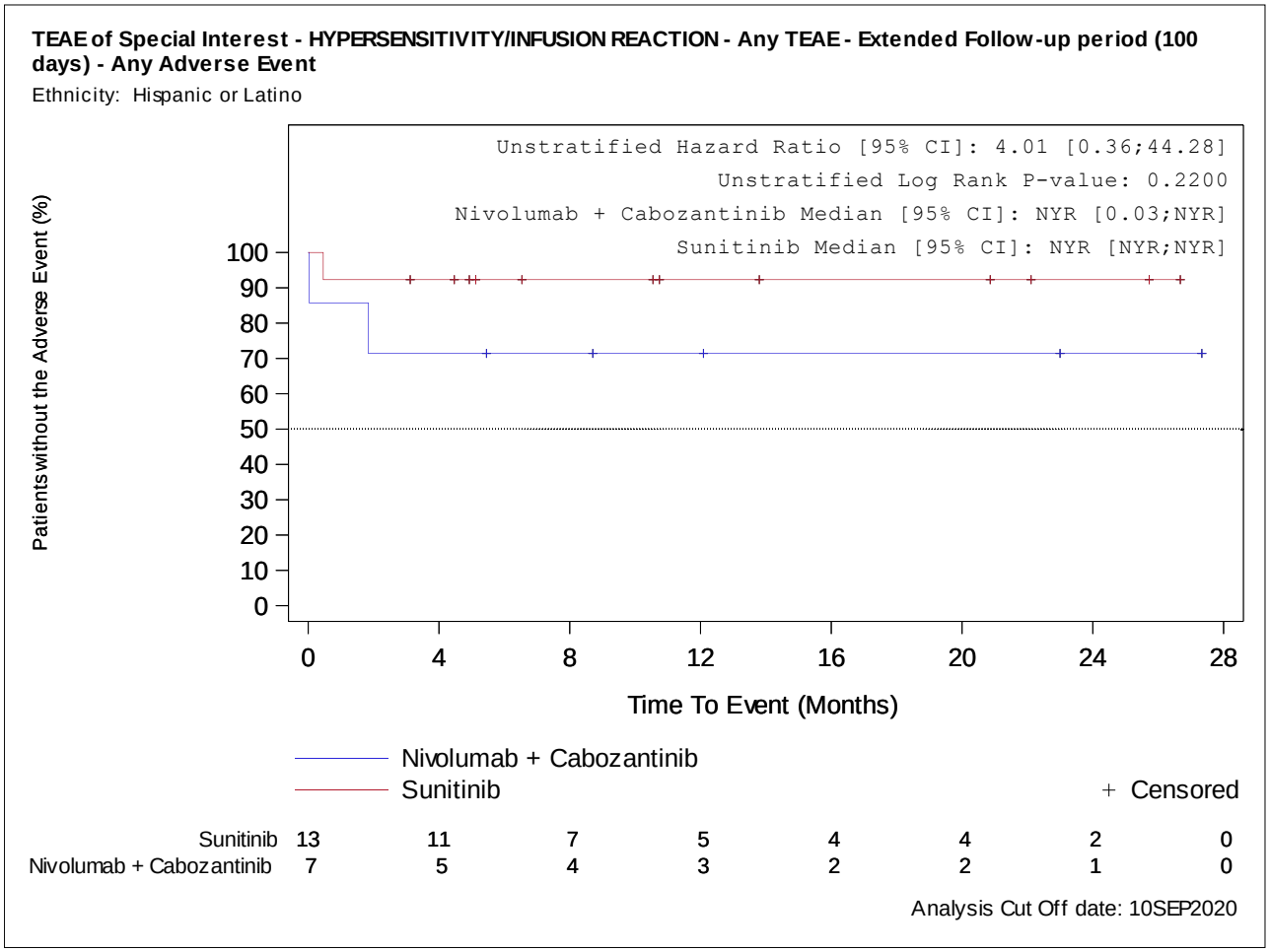

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:45:49

FIGURE 3.36.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



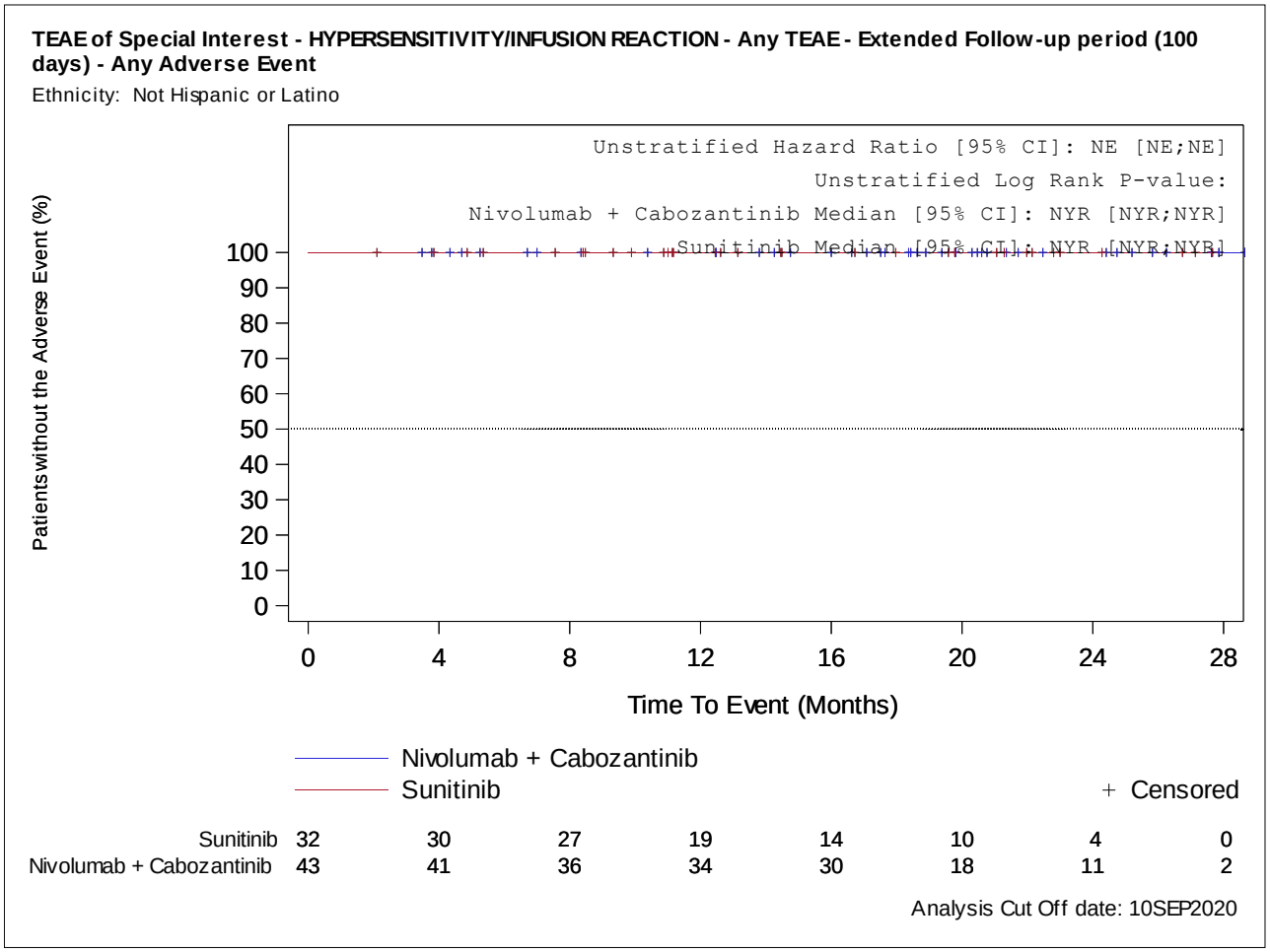

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:45:55

FIGURE 3.36.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



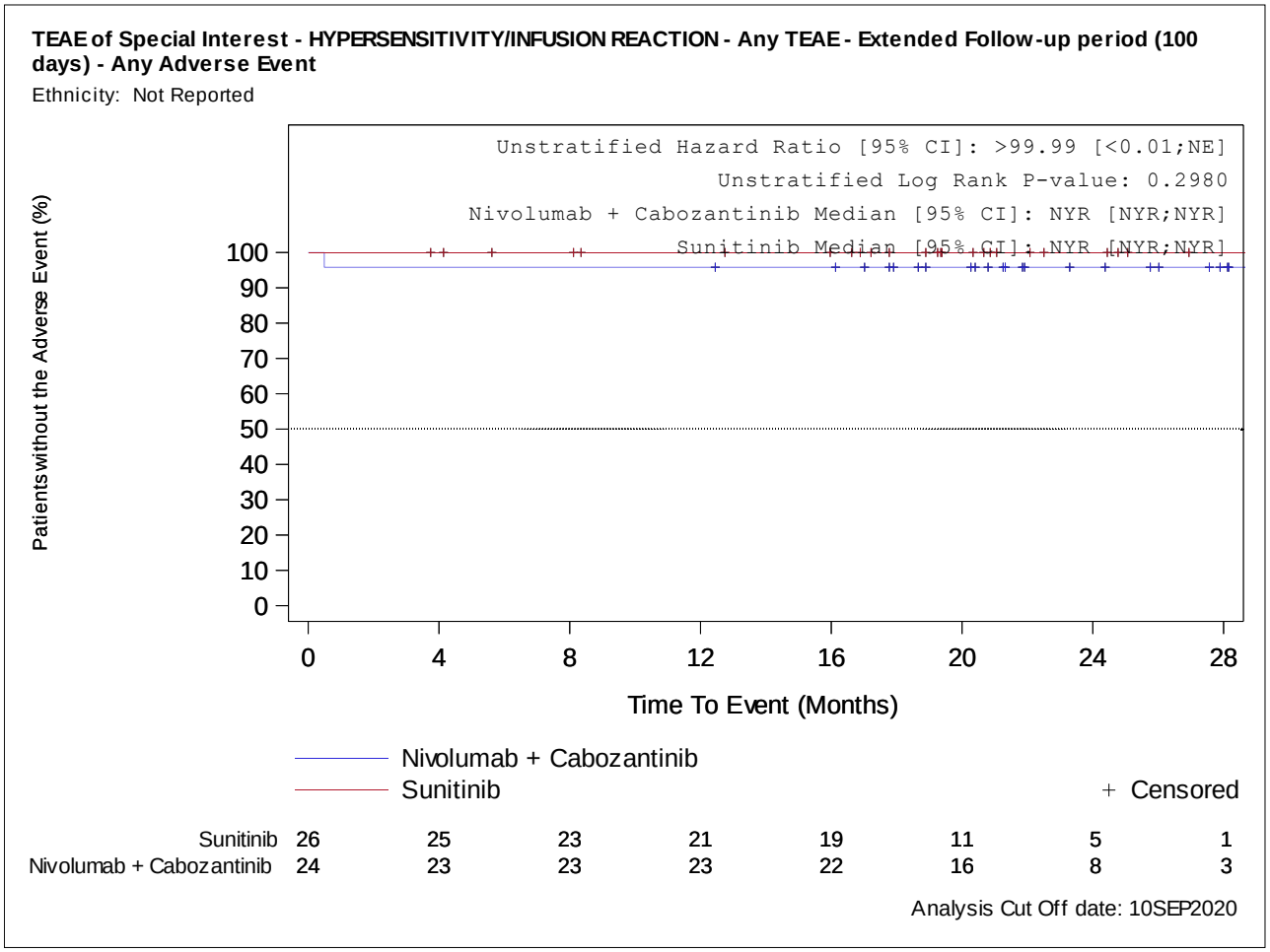

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:46:00

FIGURE 3.36.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



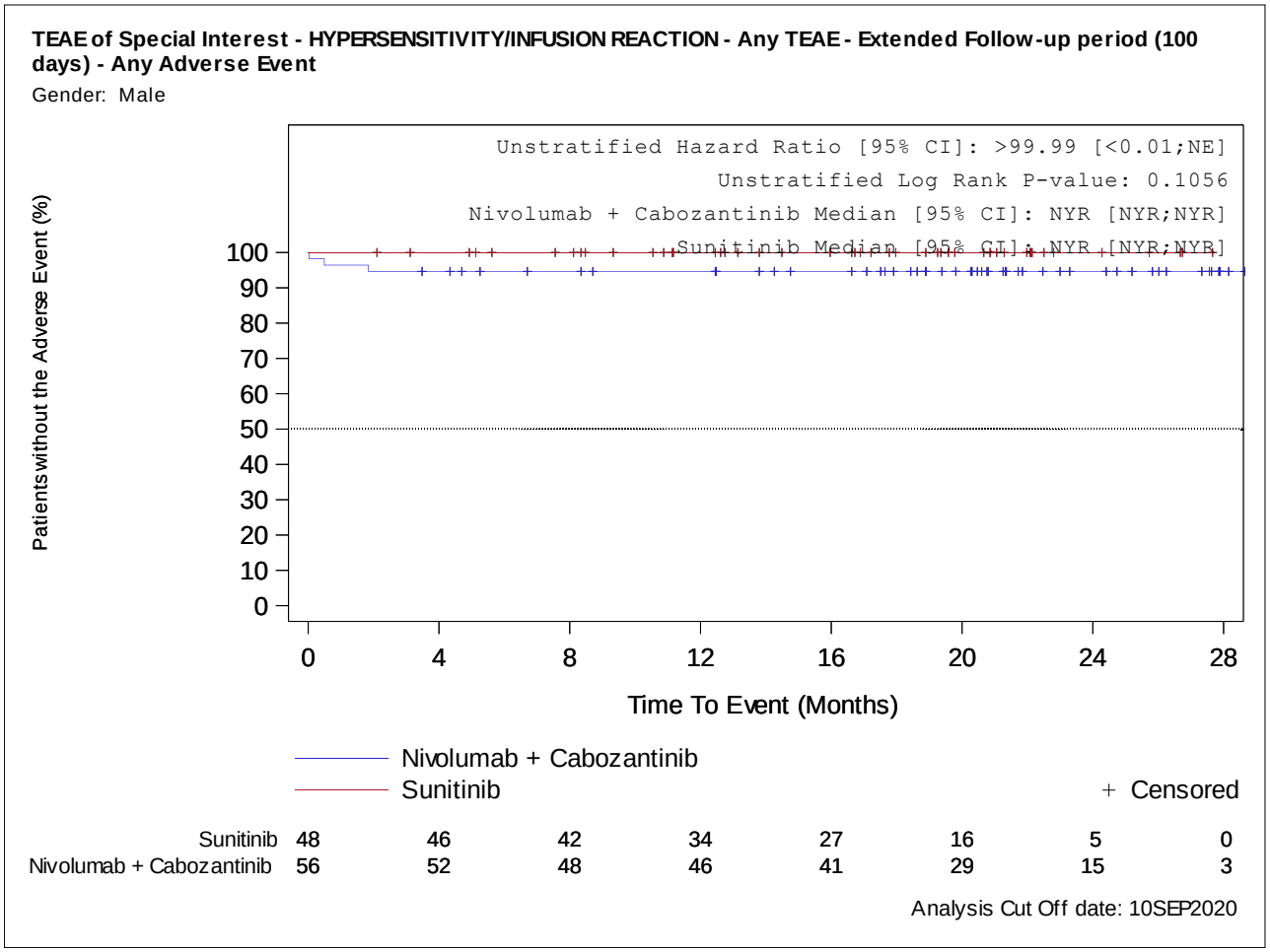

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:46:07

FIGURE 3.36.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



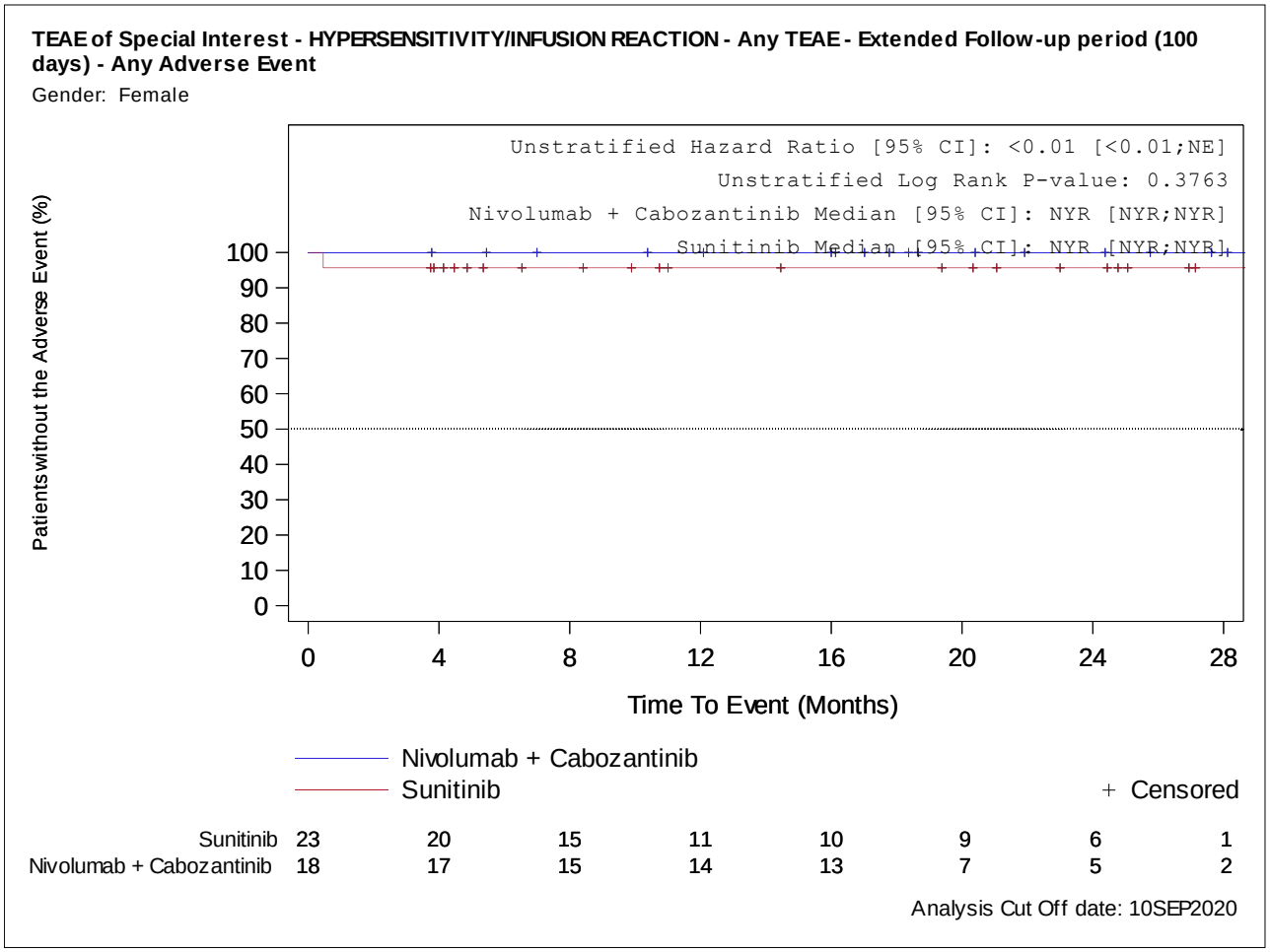

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:46:12

FIGURE 3.36.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



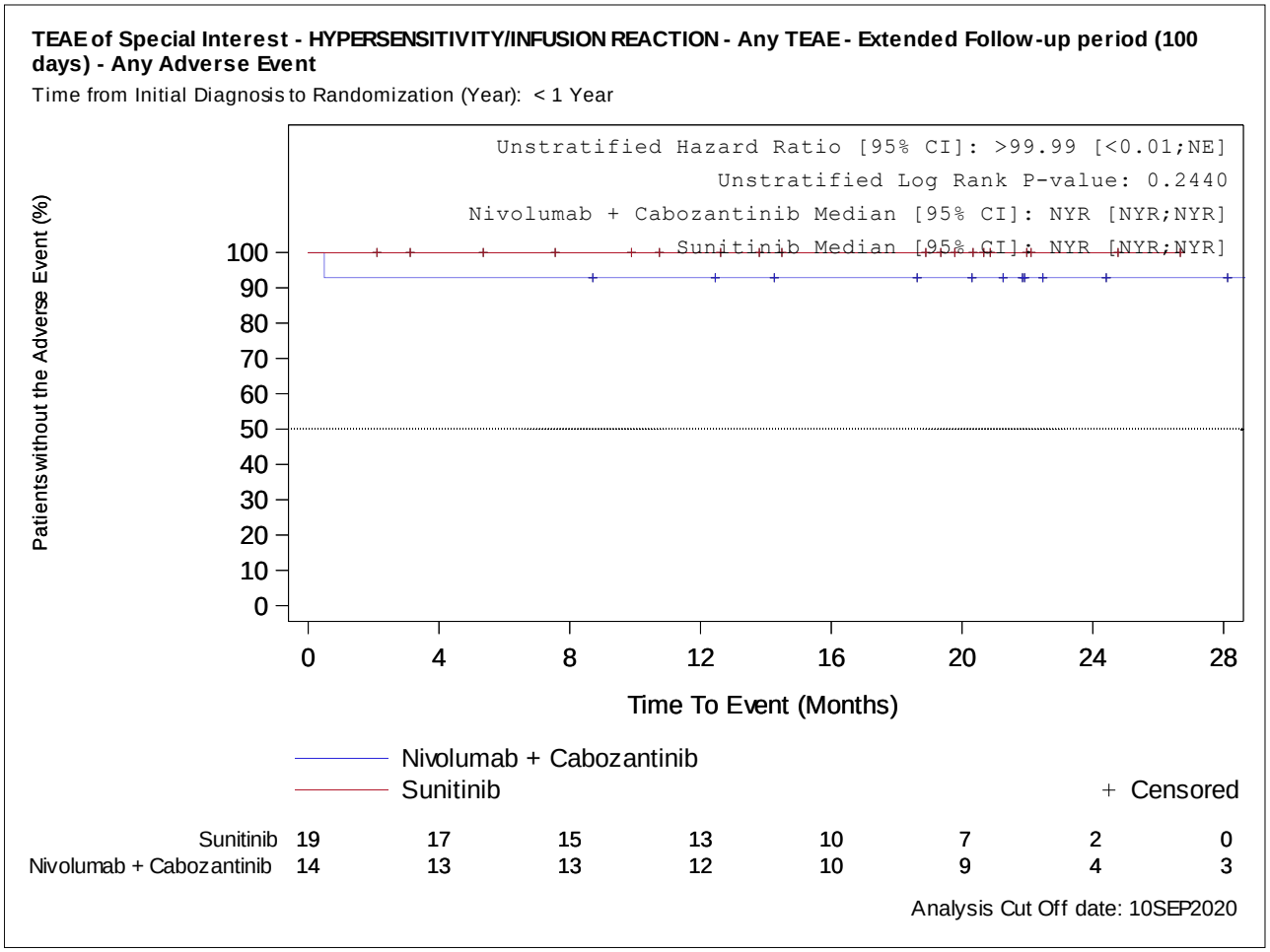

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:46:18

FIGURE 3.36.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



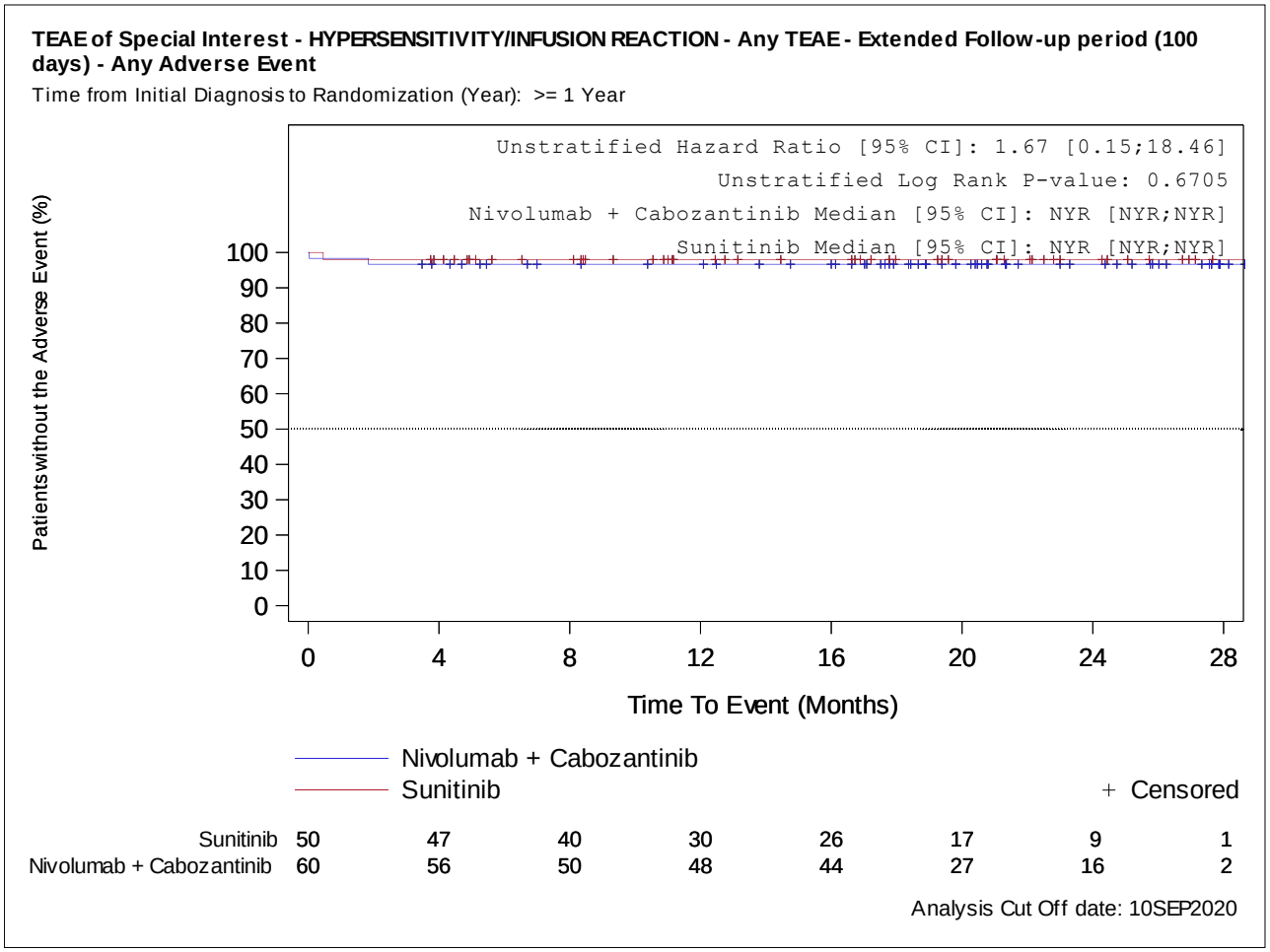

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:46:23

FIGURE 3.36.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



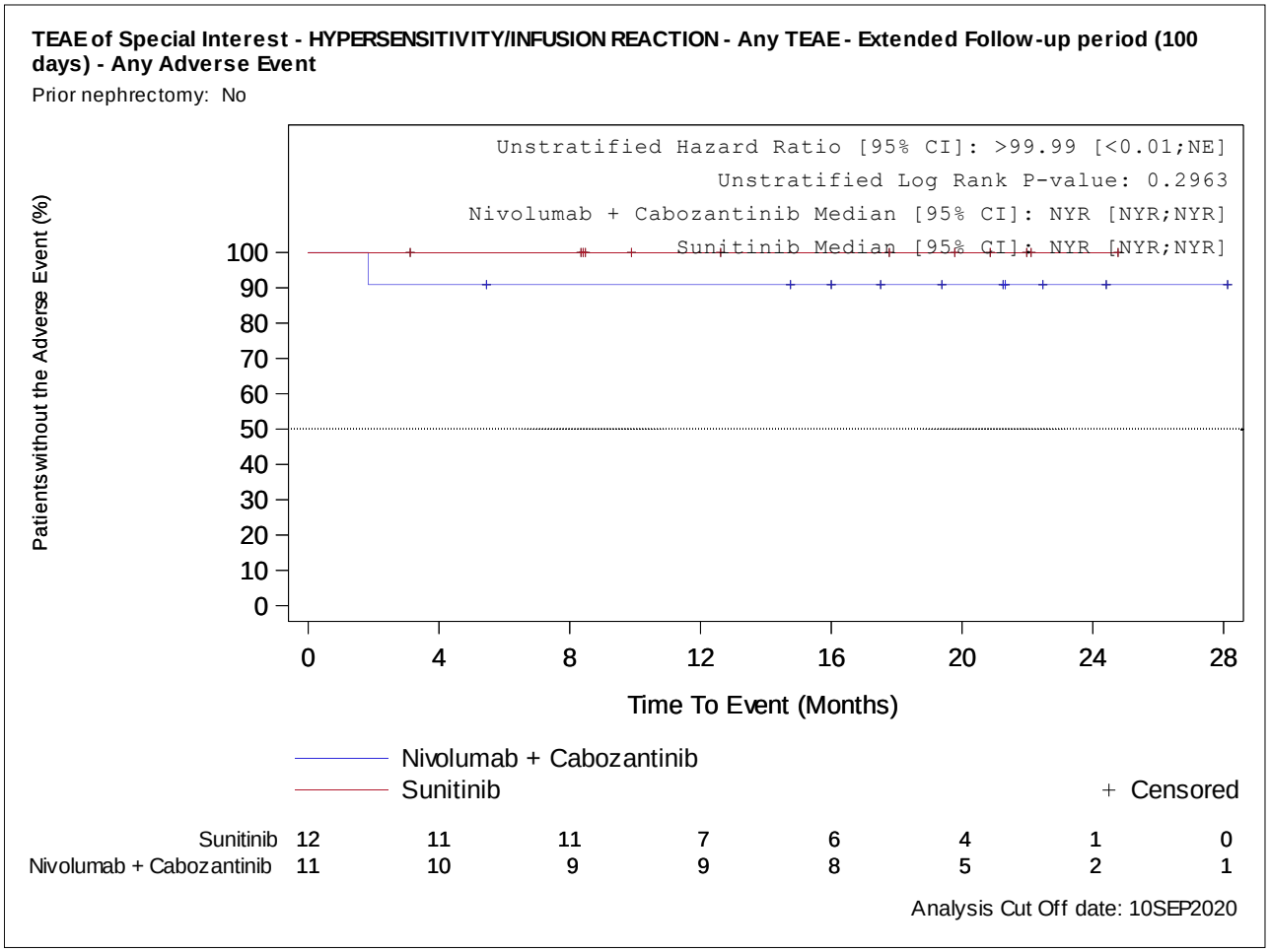

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:46:41

FIGURE 3.36.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



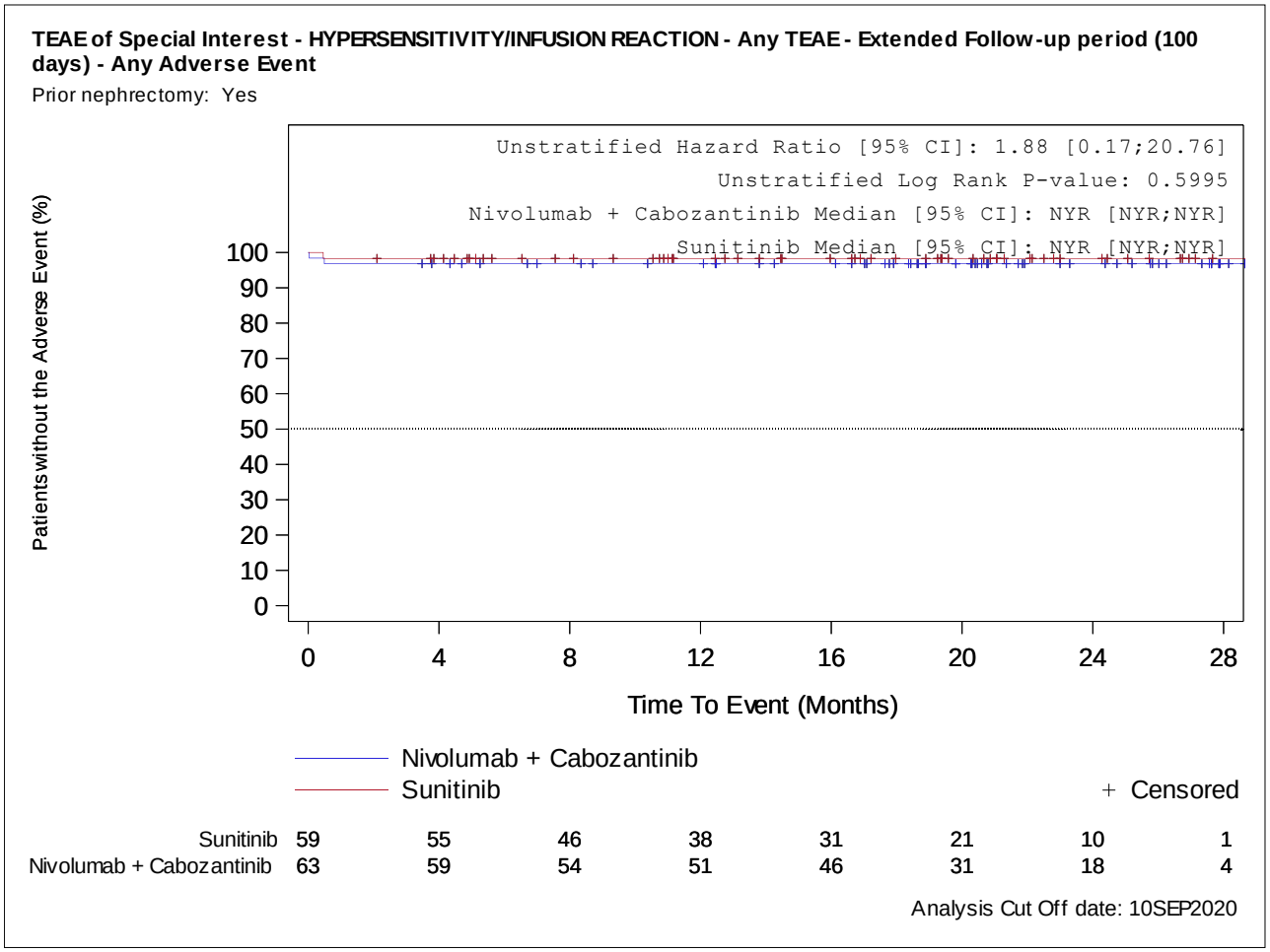

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:46:47

FIGURE 3.36.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



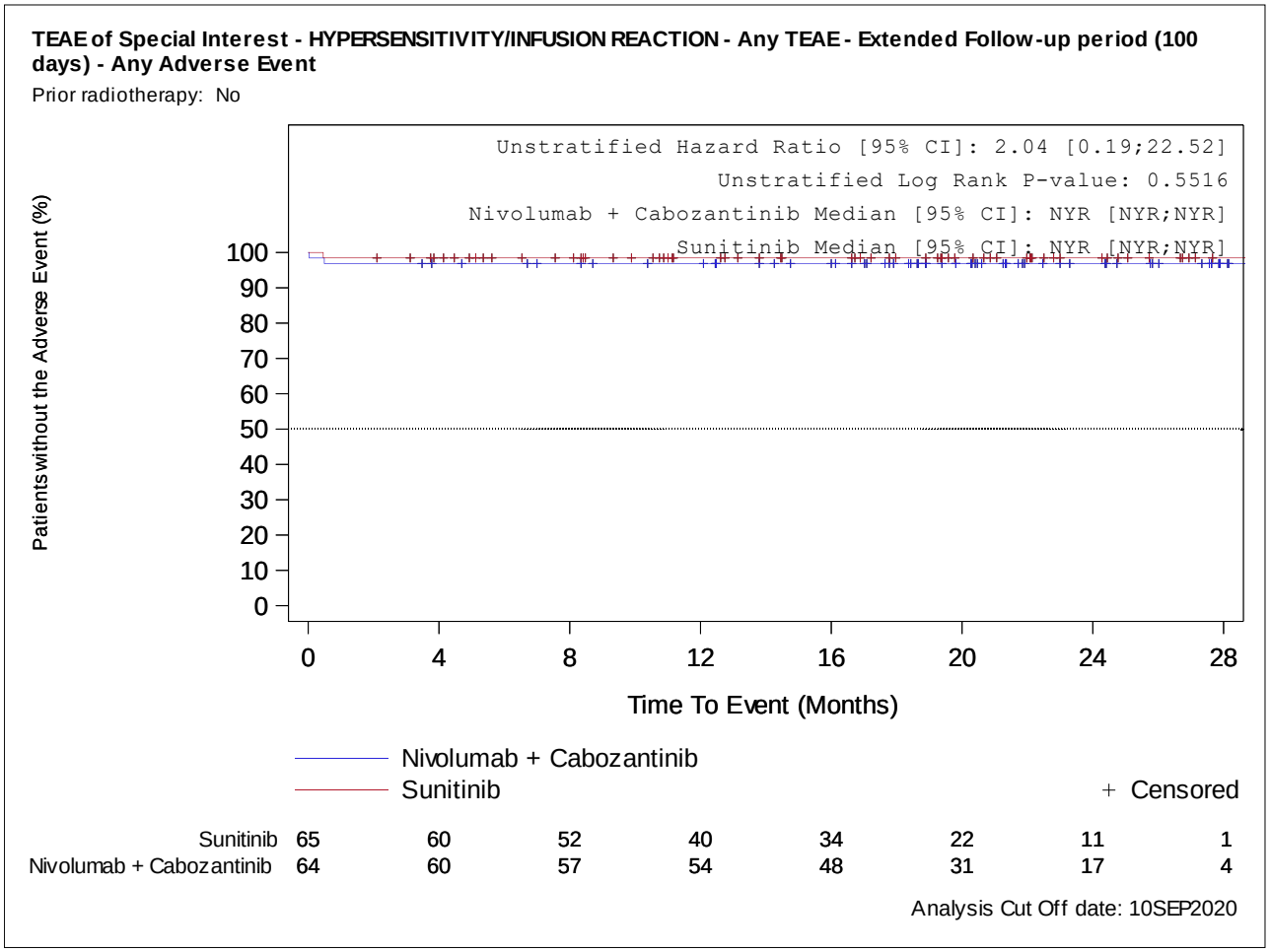

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:47:40

FIGURE 3.36.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



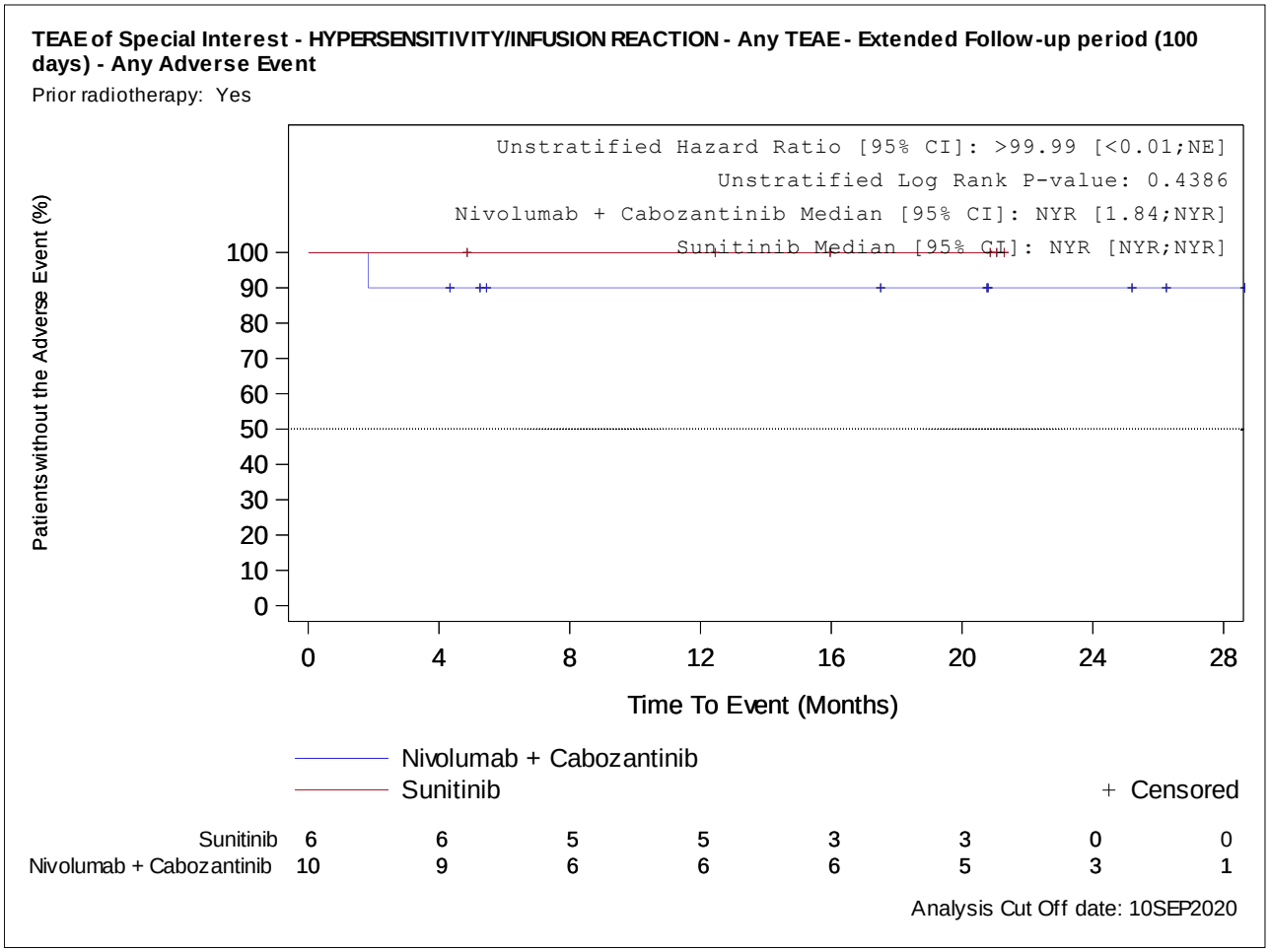

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:47:46

FIGURE 3.36.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



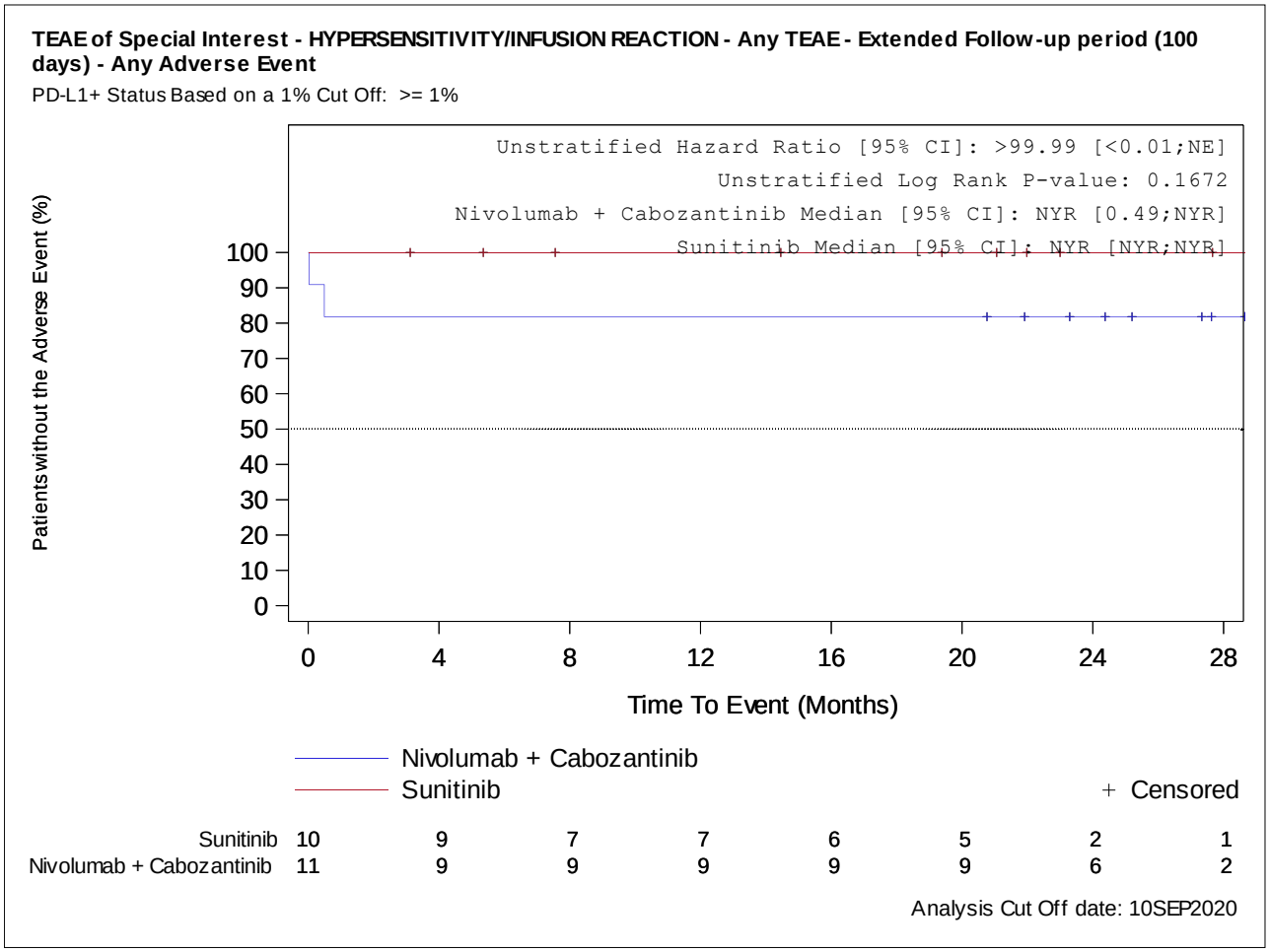

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:47:52

FIGURE 3.36.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



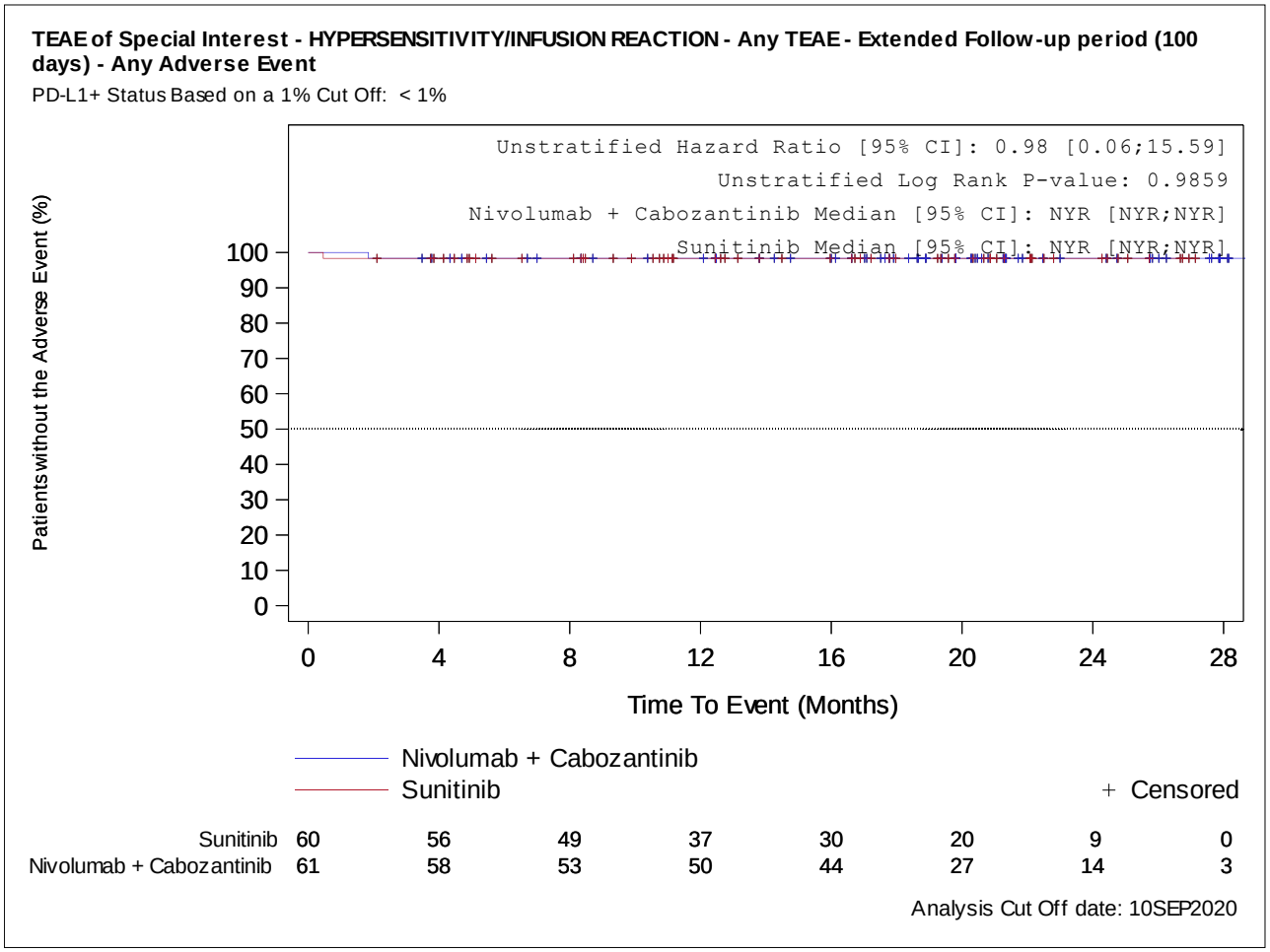

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:47:58

FIGURE 3.36.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



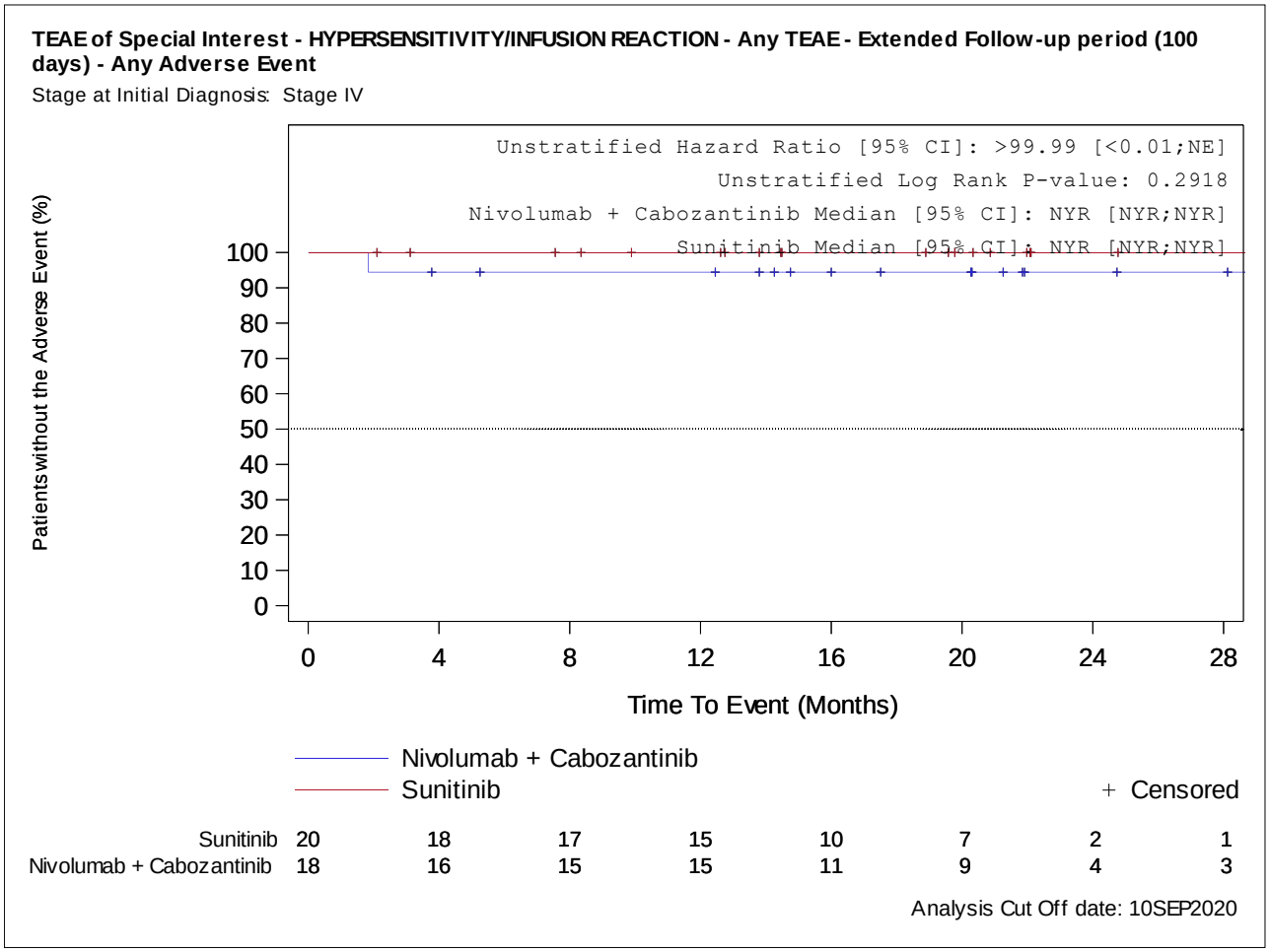

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:48:04

FIGURE 3.36.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



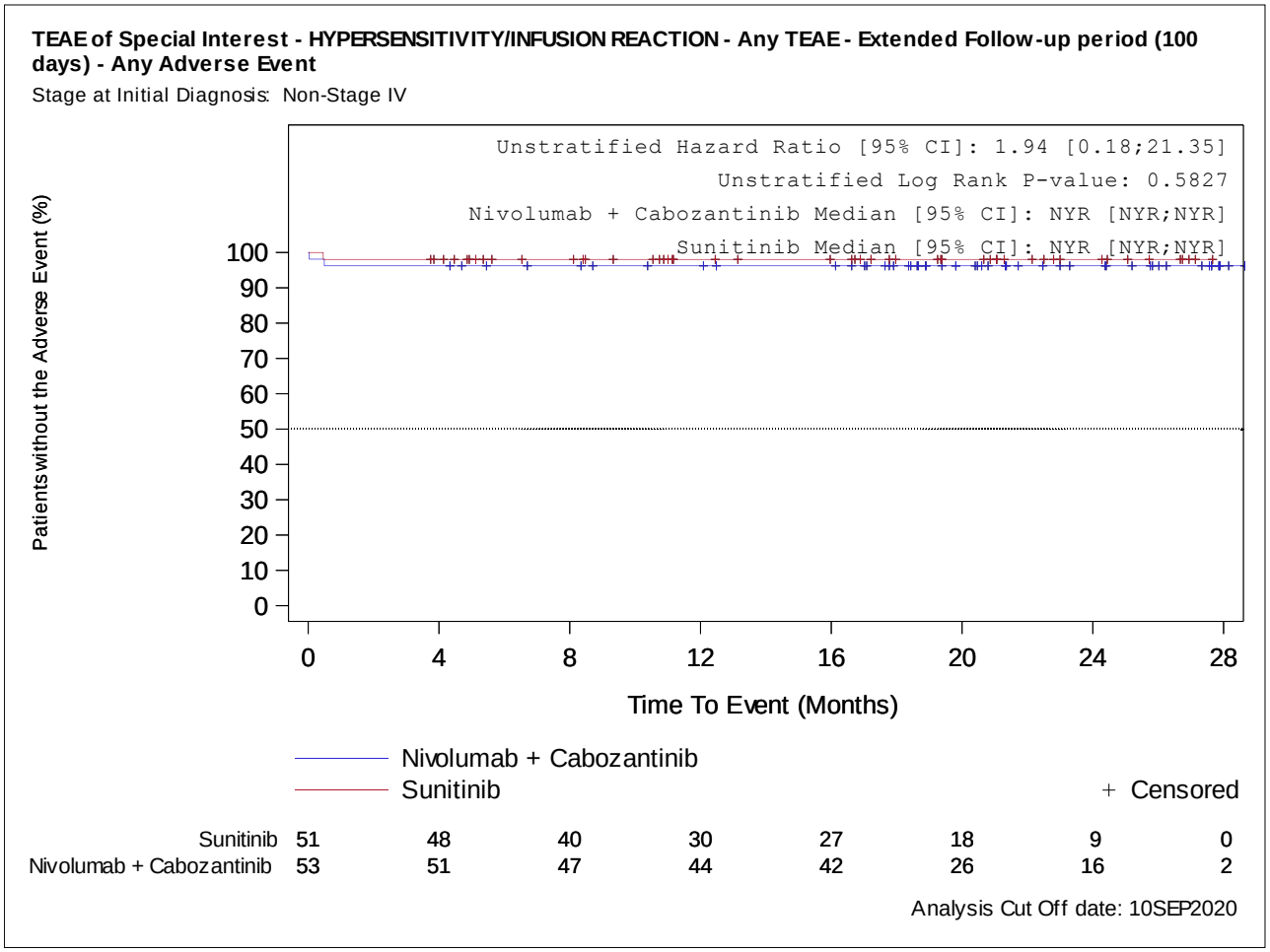

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:48:10

FIGURE 3.36.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



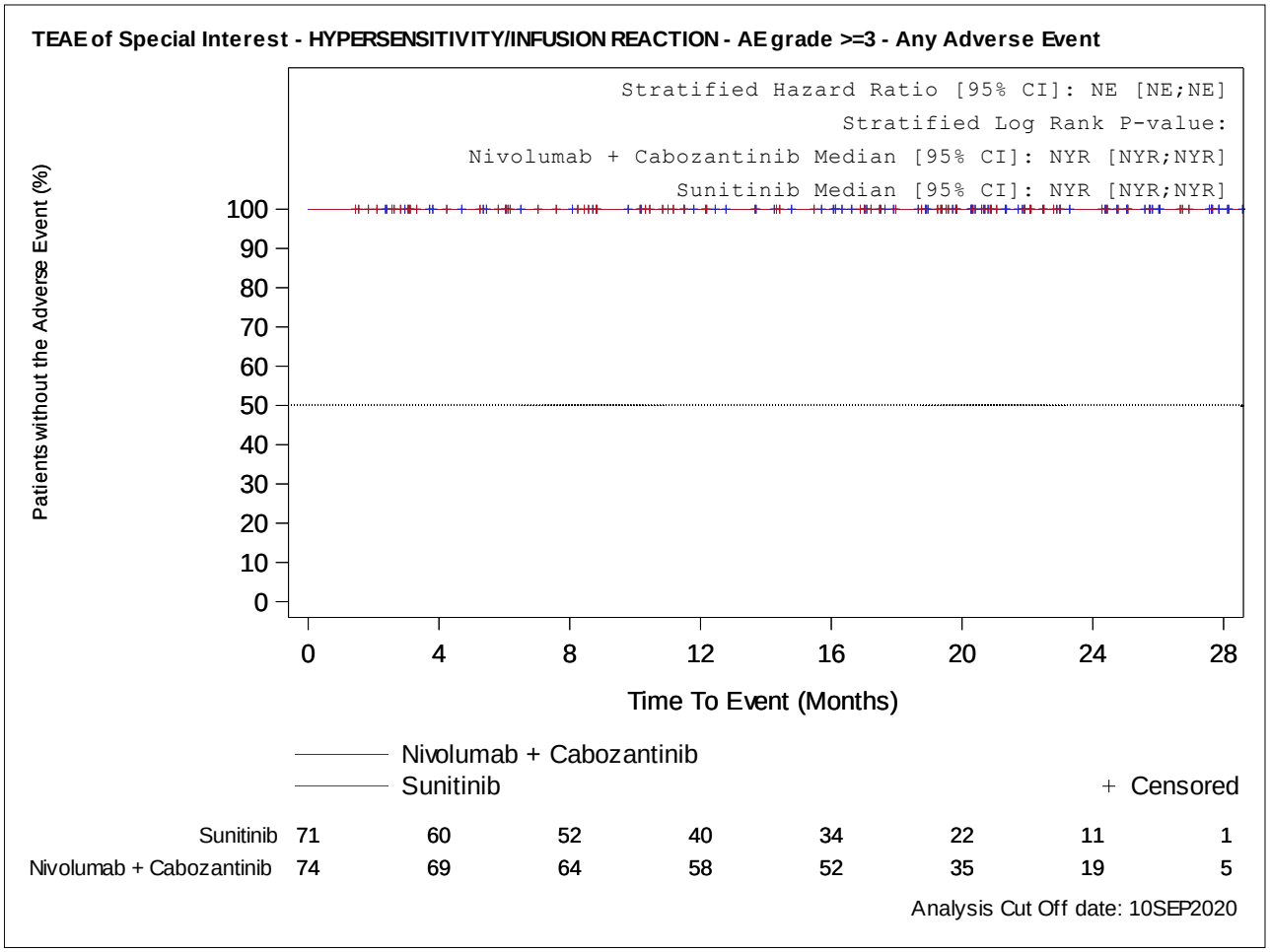

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:48:39

FIGURE 3.36.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



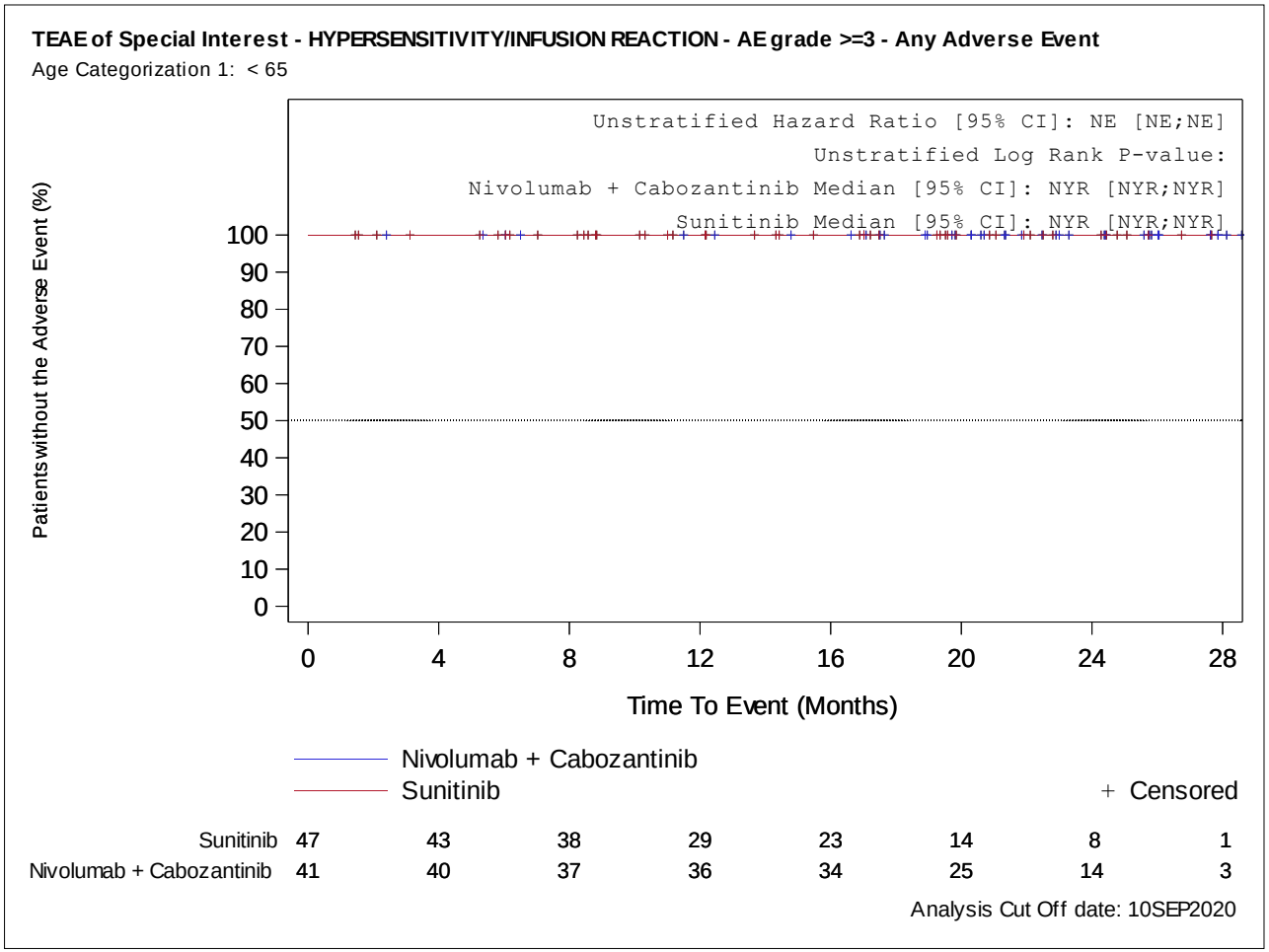

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:48:44

FIGURE 3.37.1: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



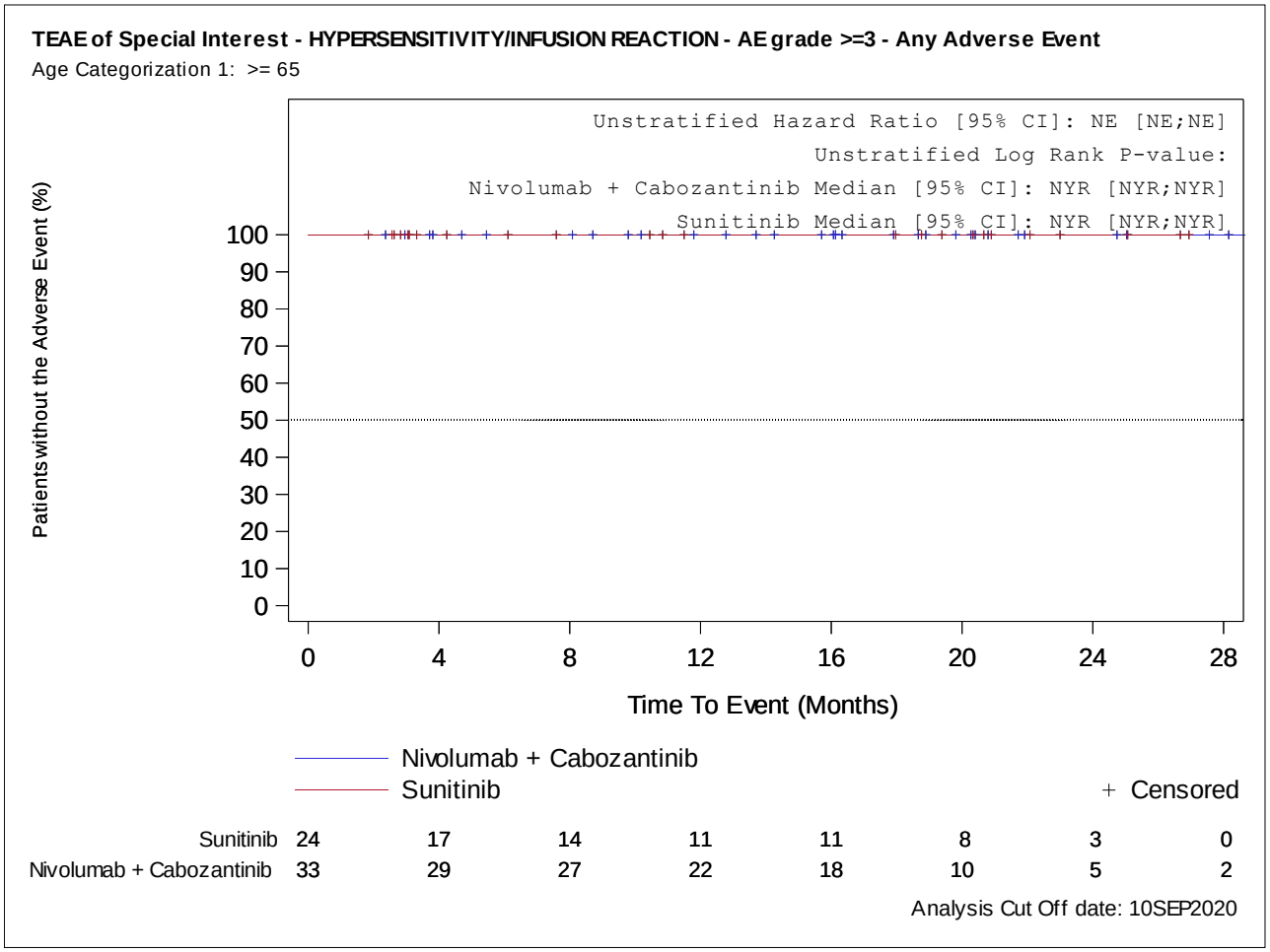

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:52:00

FIGURE 3.37.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



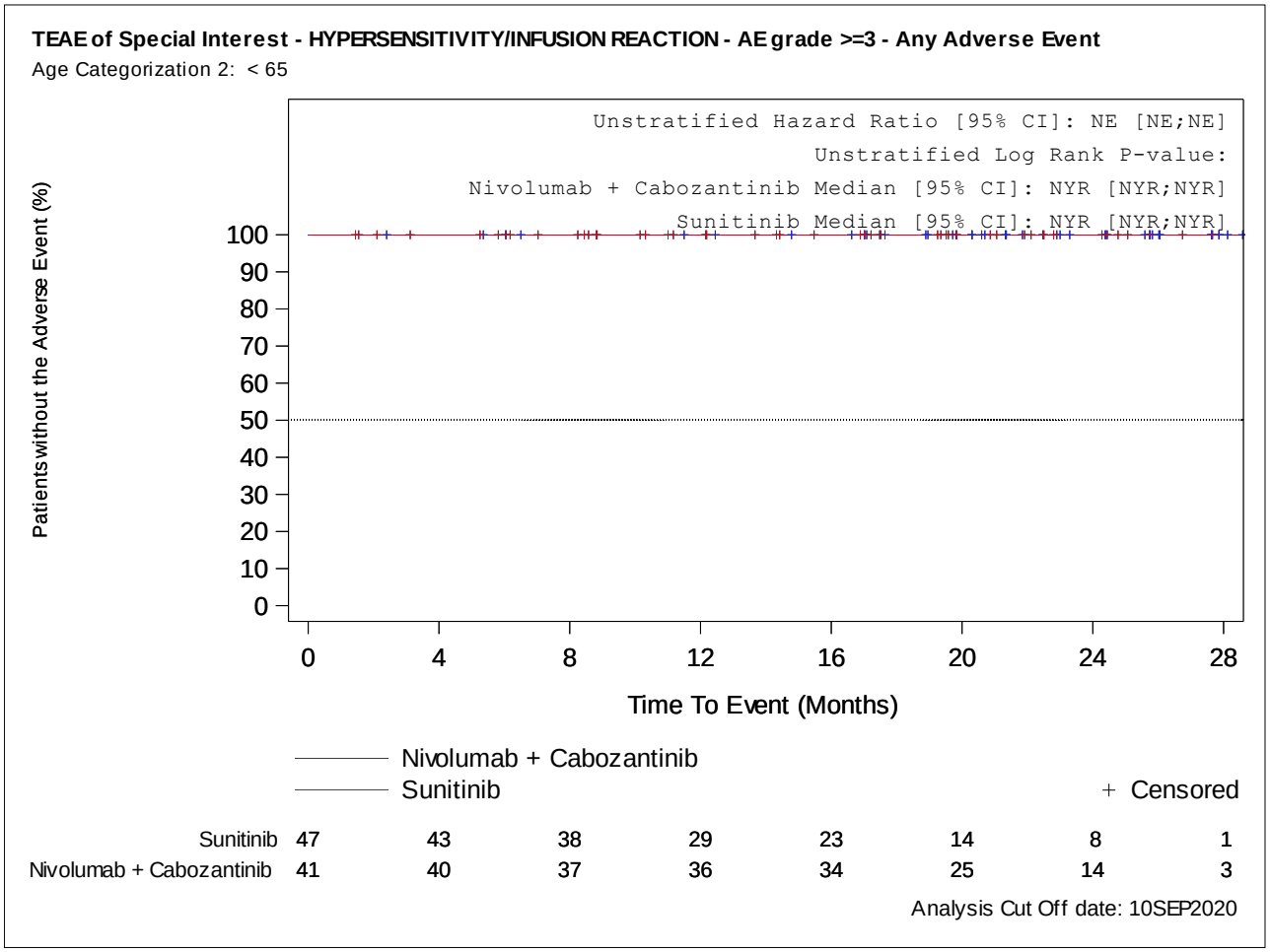

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:52:03

FIGURE 3.37.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



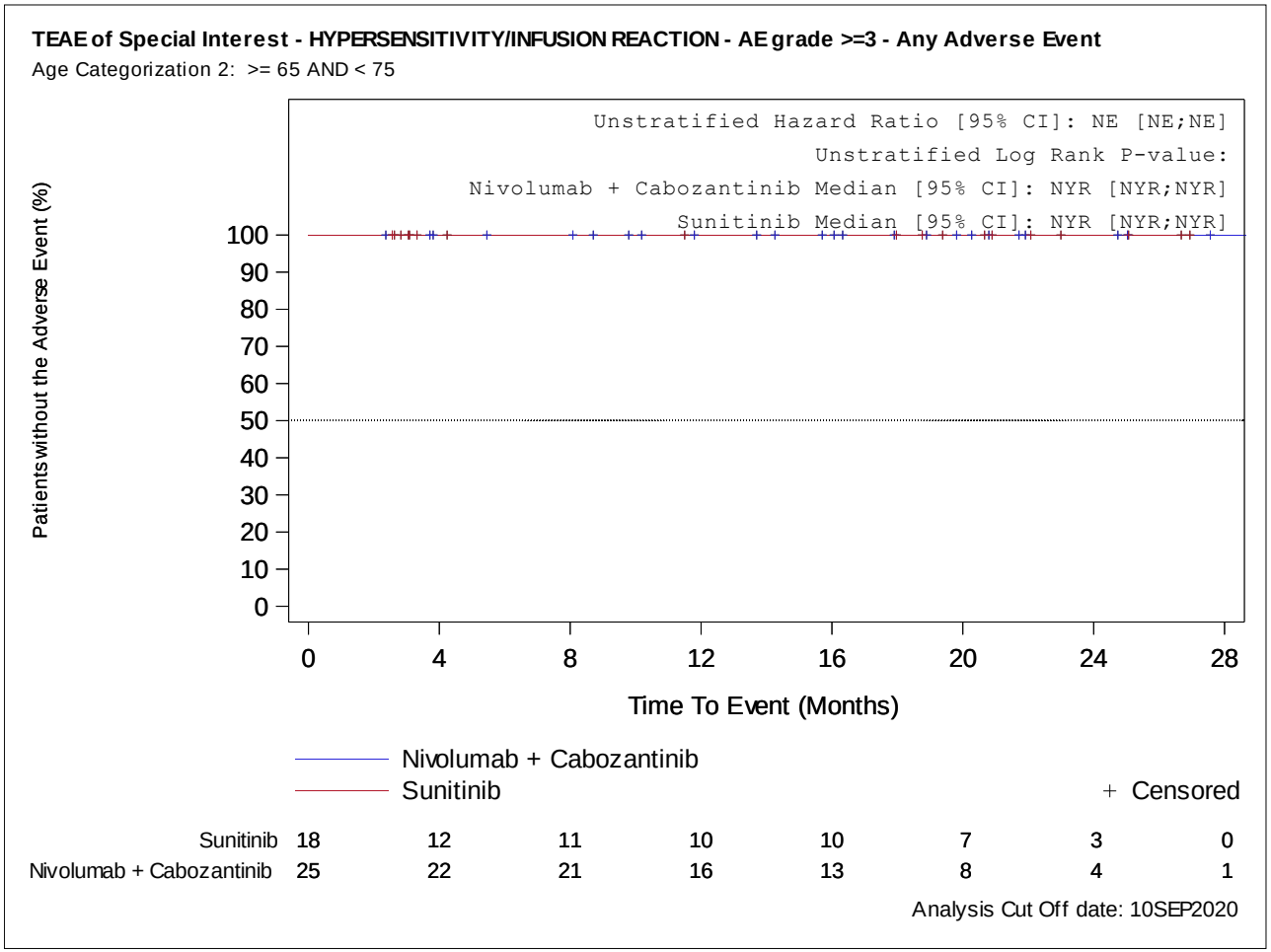

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:52:09

FIGURE 3.37.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



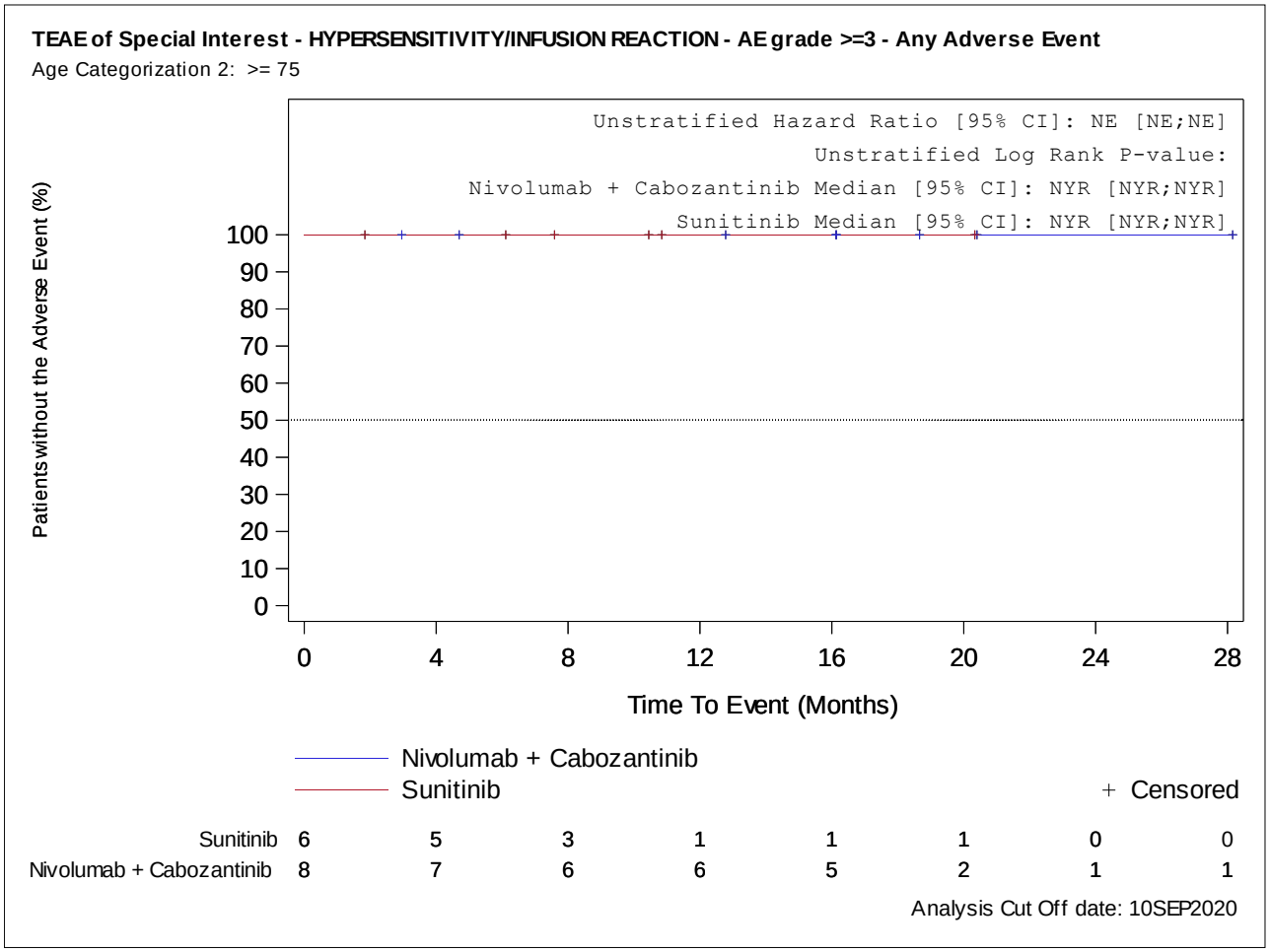

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:52:15

FIGURE 3.37.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



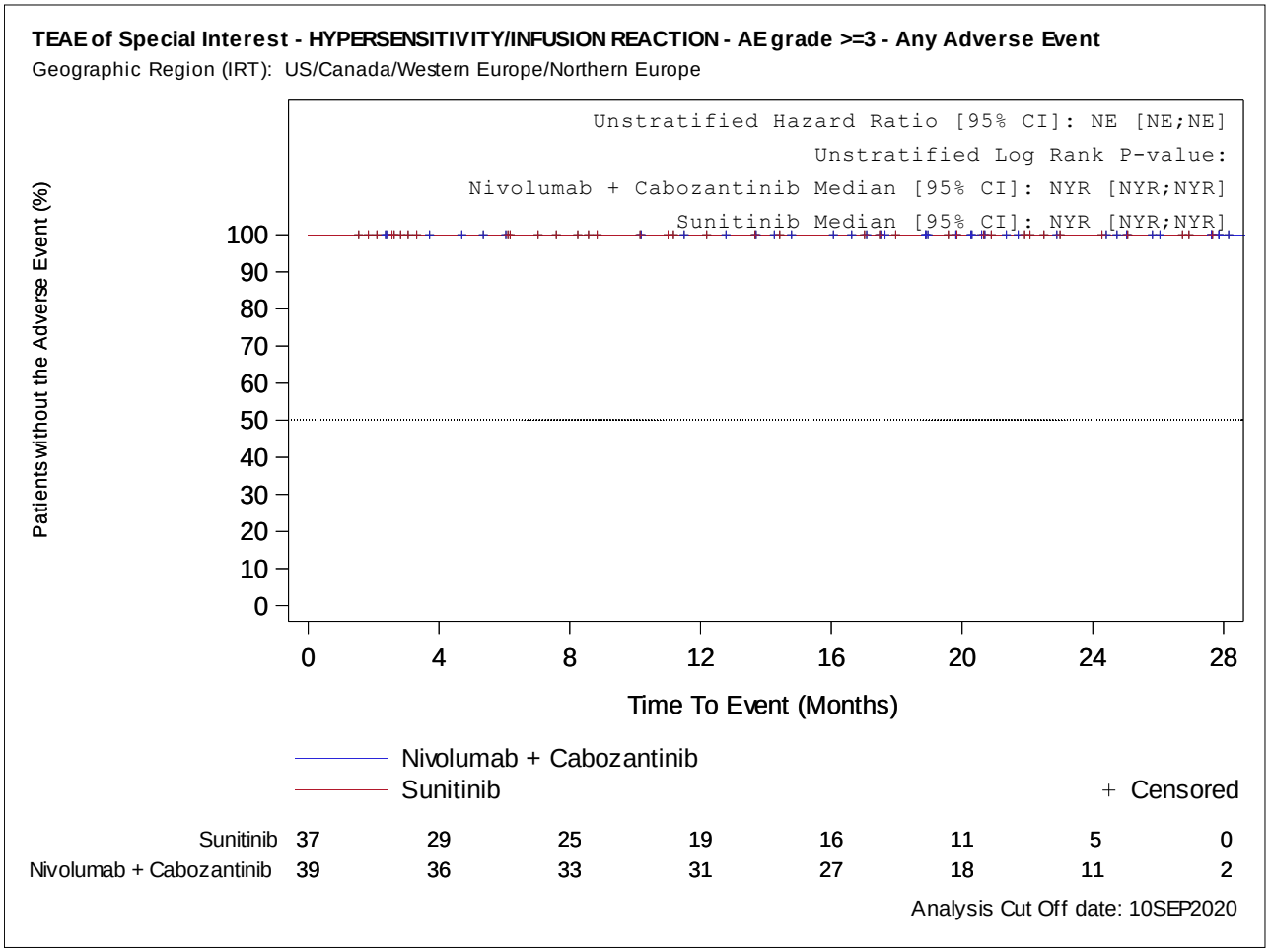

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:52:20

FIGURE 3.37.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



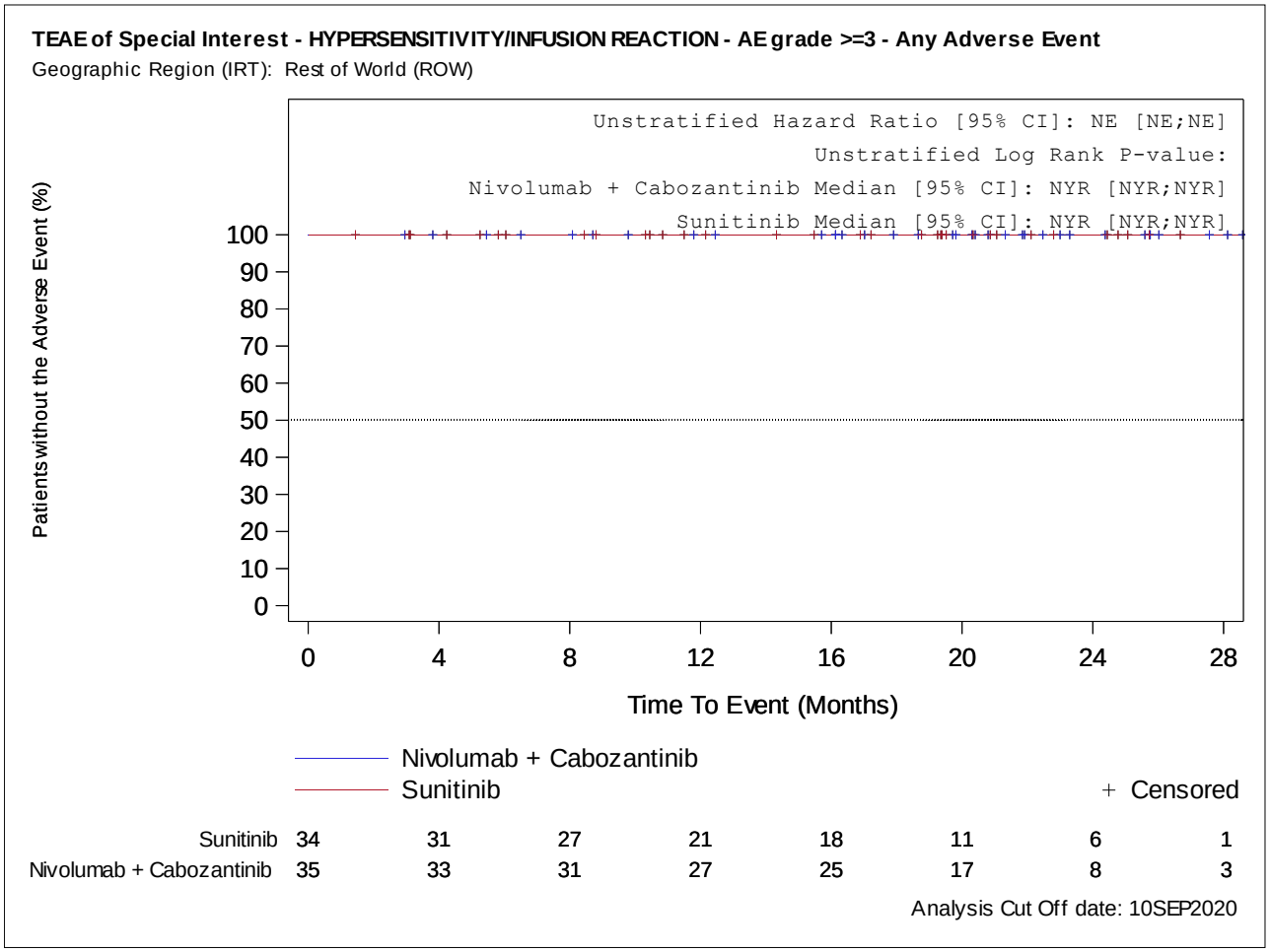

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:52:26

FIGURE 3.37.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



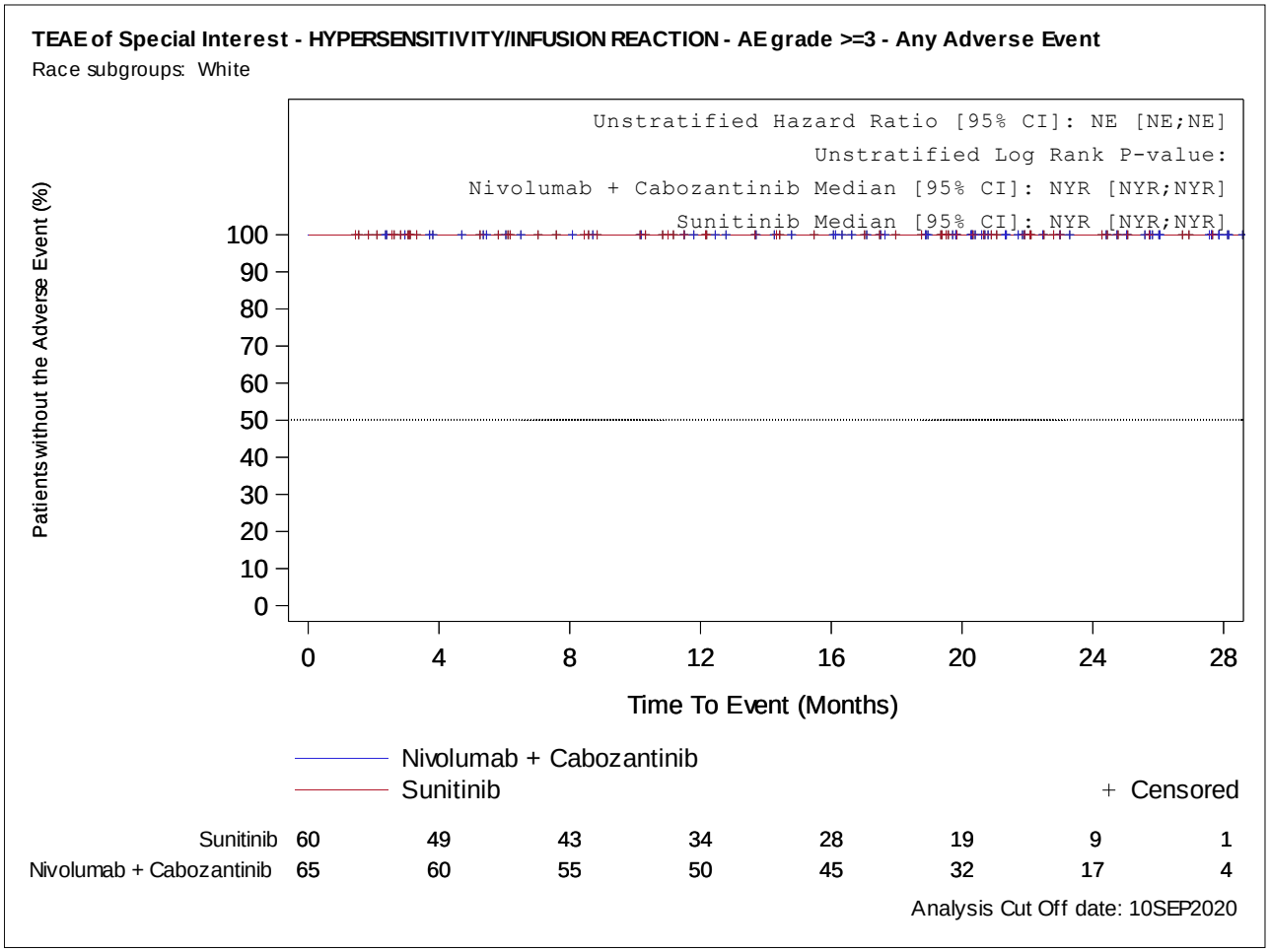

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:52:32

FIGURE 3.37.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:52:38

FIGURE 3.37.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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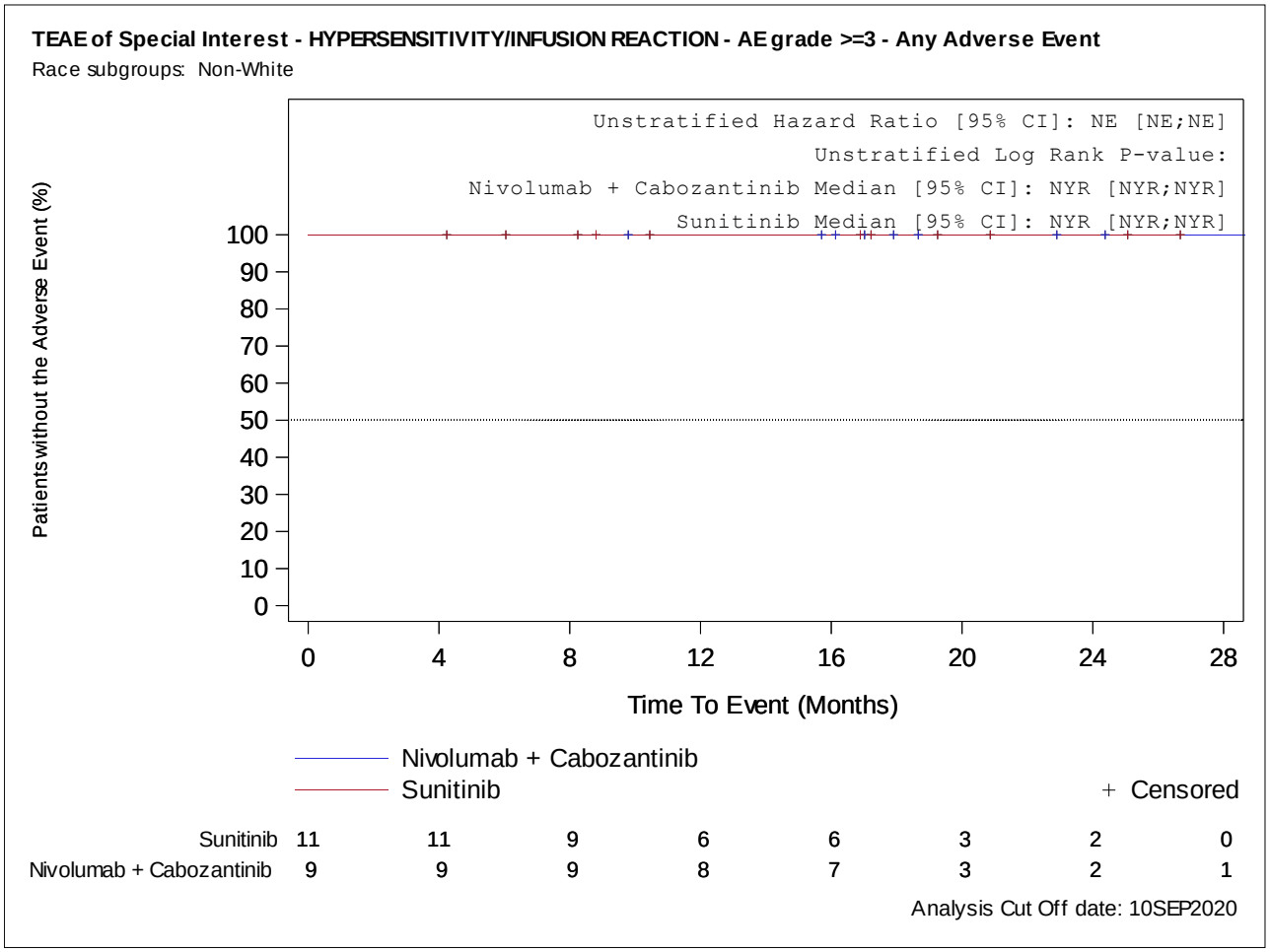
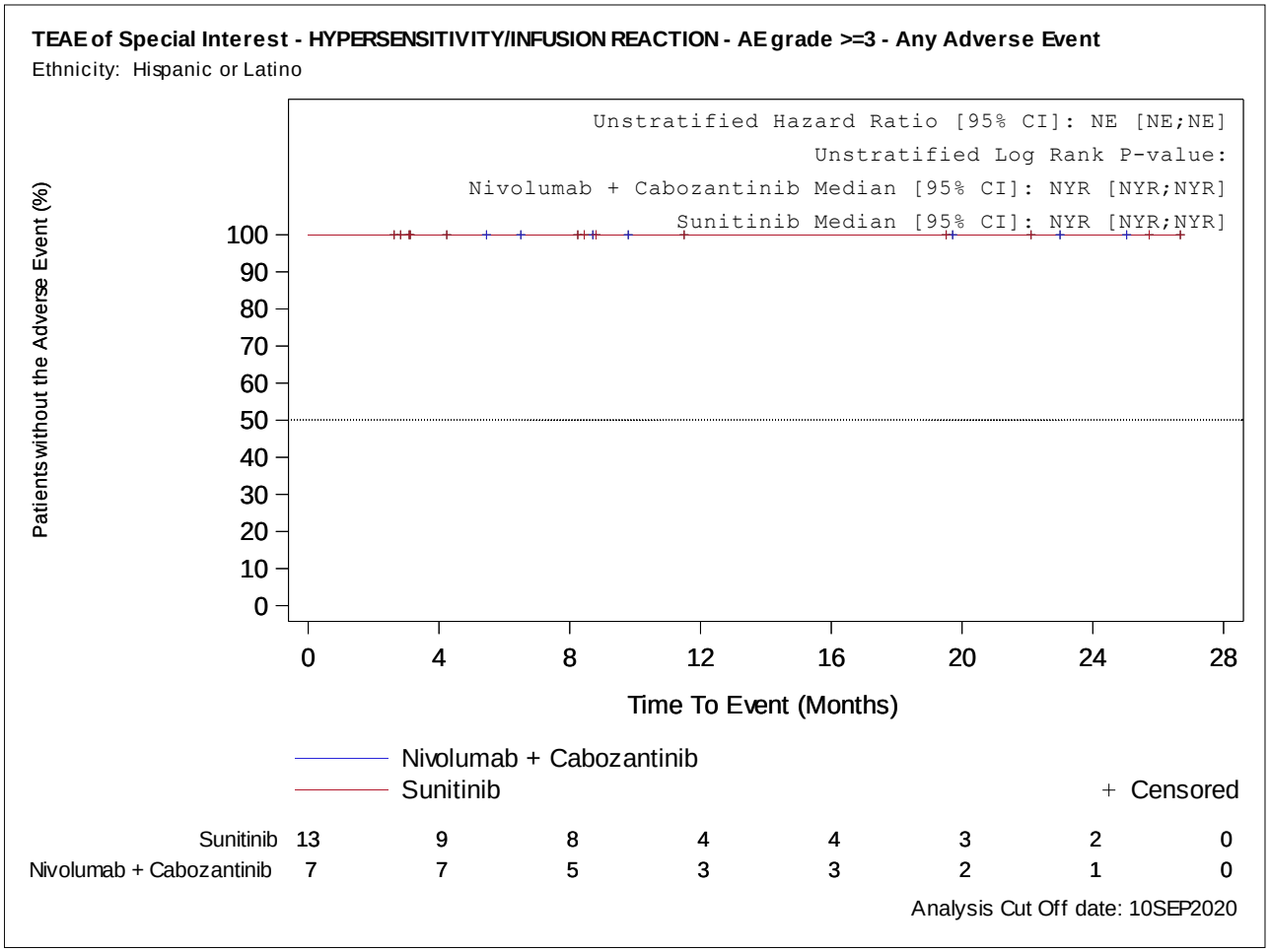
FIGURE 3.37.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:52:51

FIGURE 3.37.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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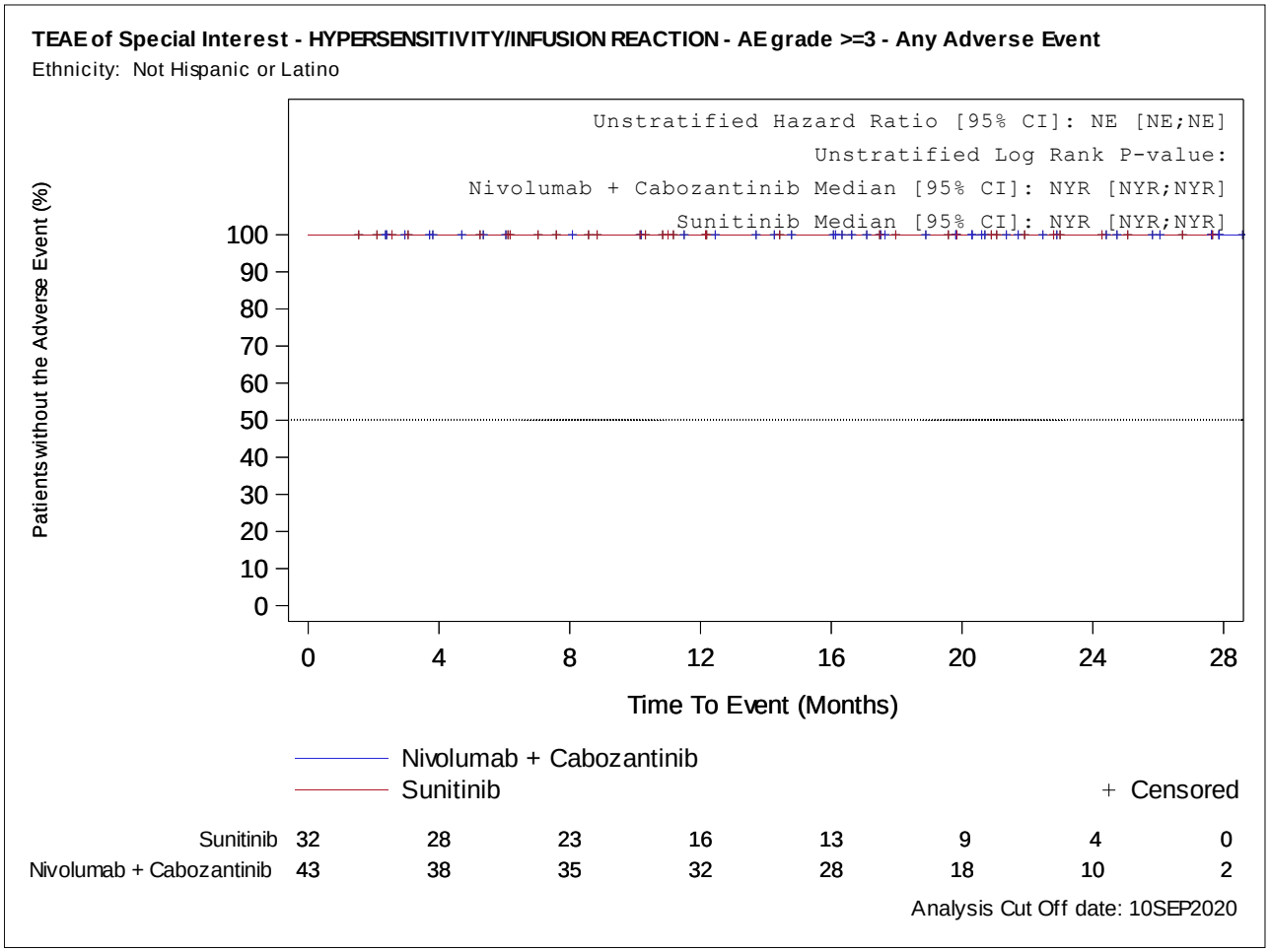
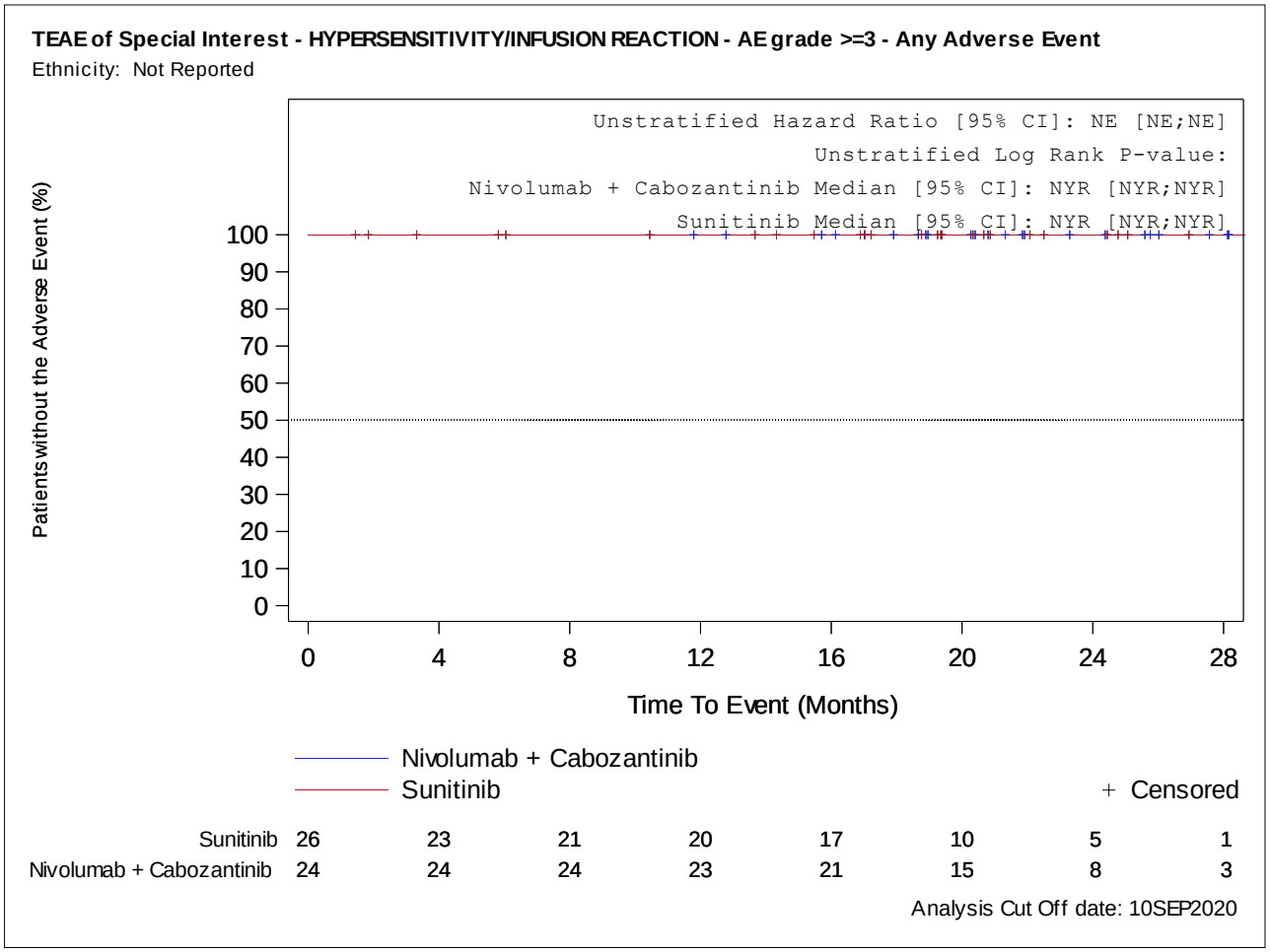
FIGURE 3.37.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



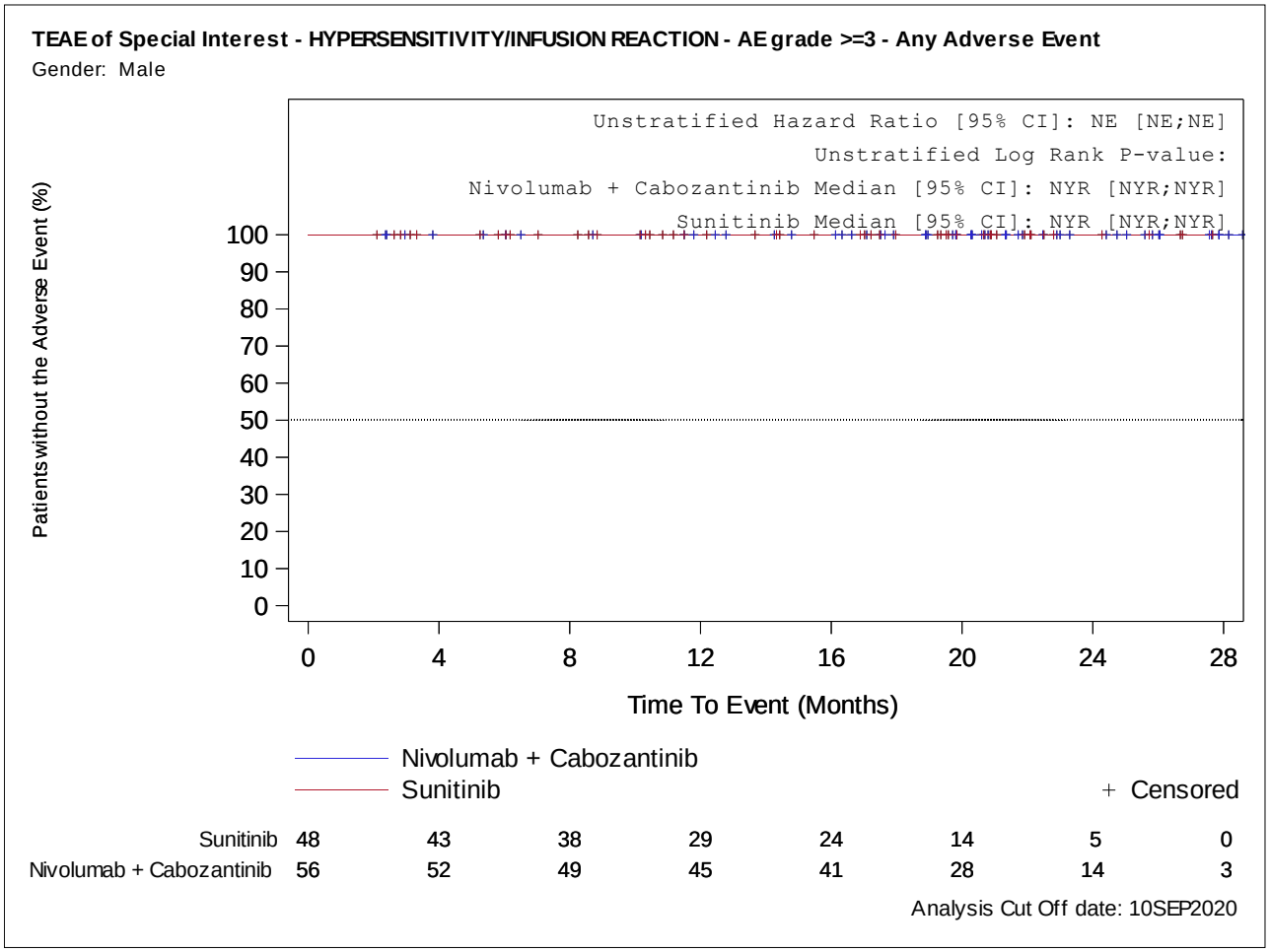

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:53:02

FIGURE 3.37.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



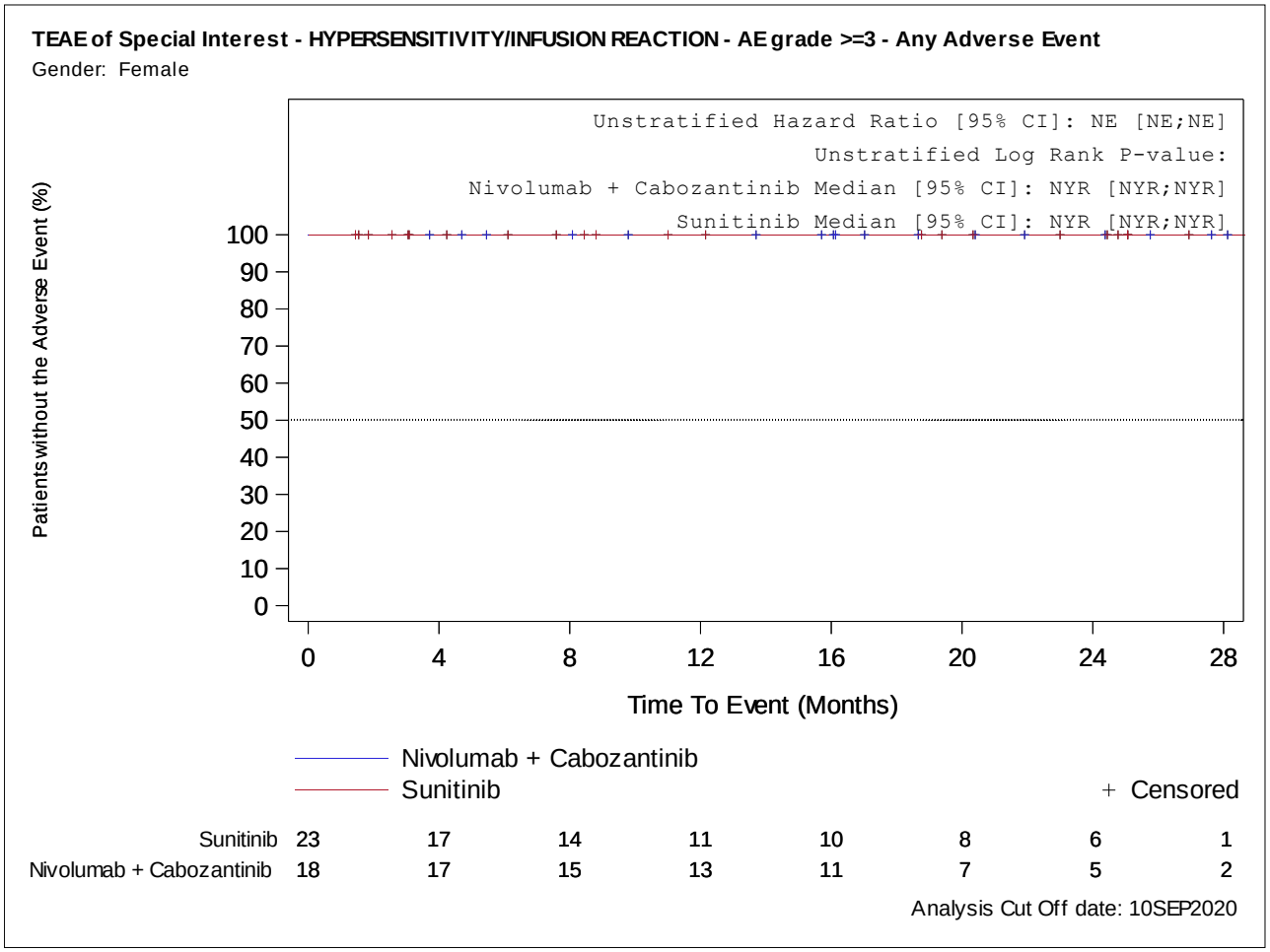

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:53:09

FIGURE 3.37.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



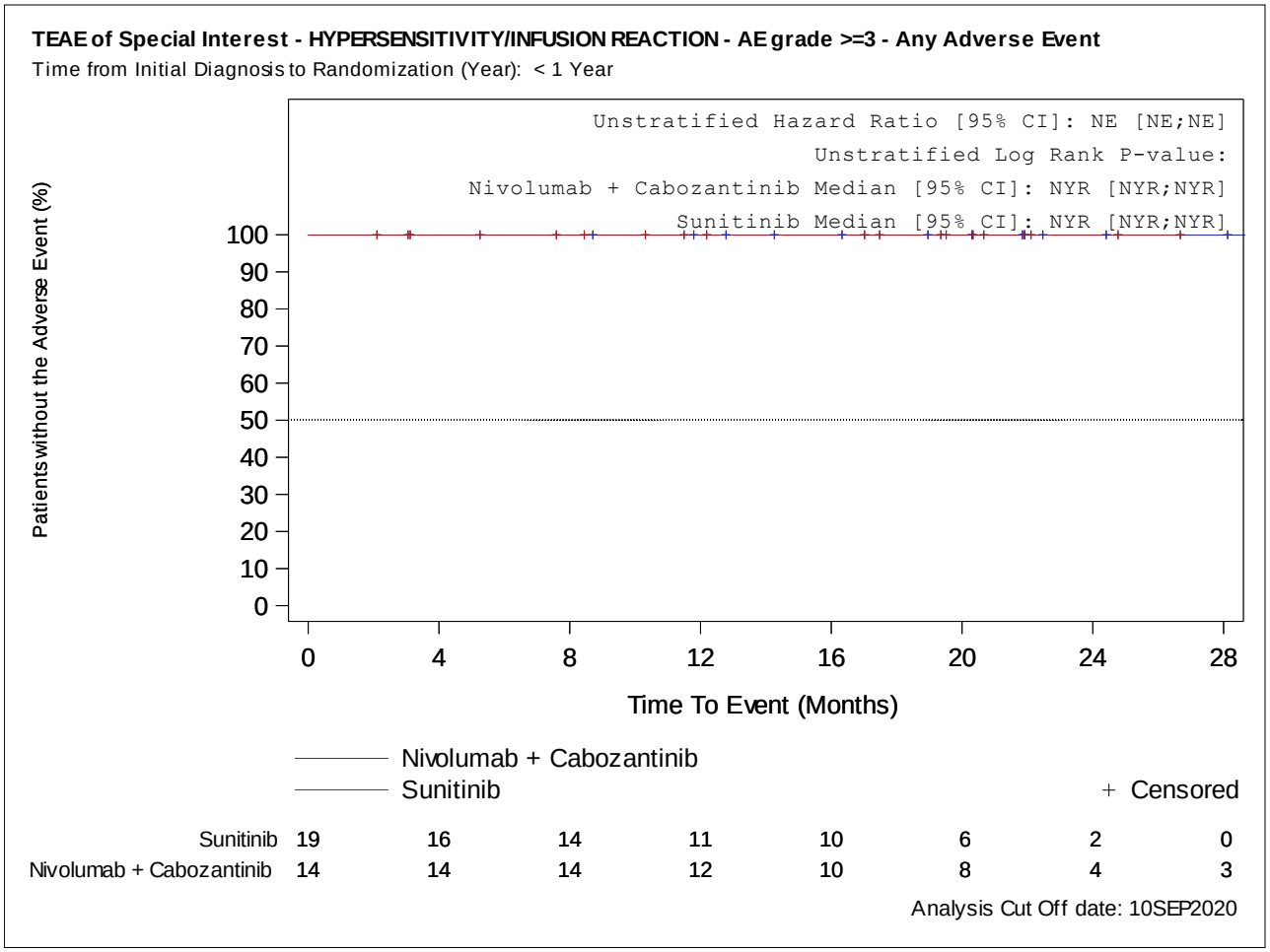

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:53:15

FIGURE 3.37.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



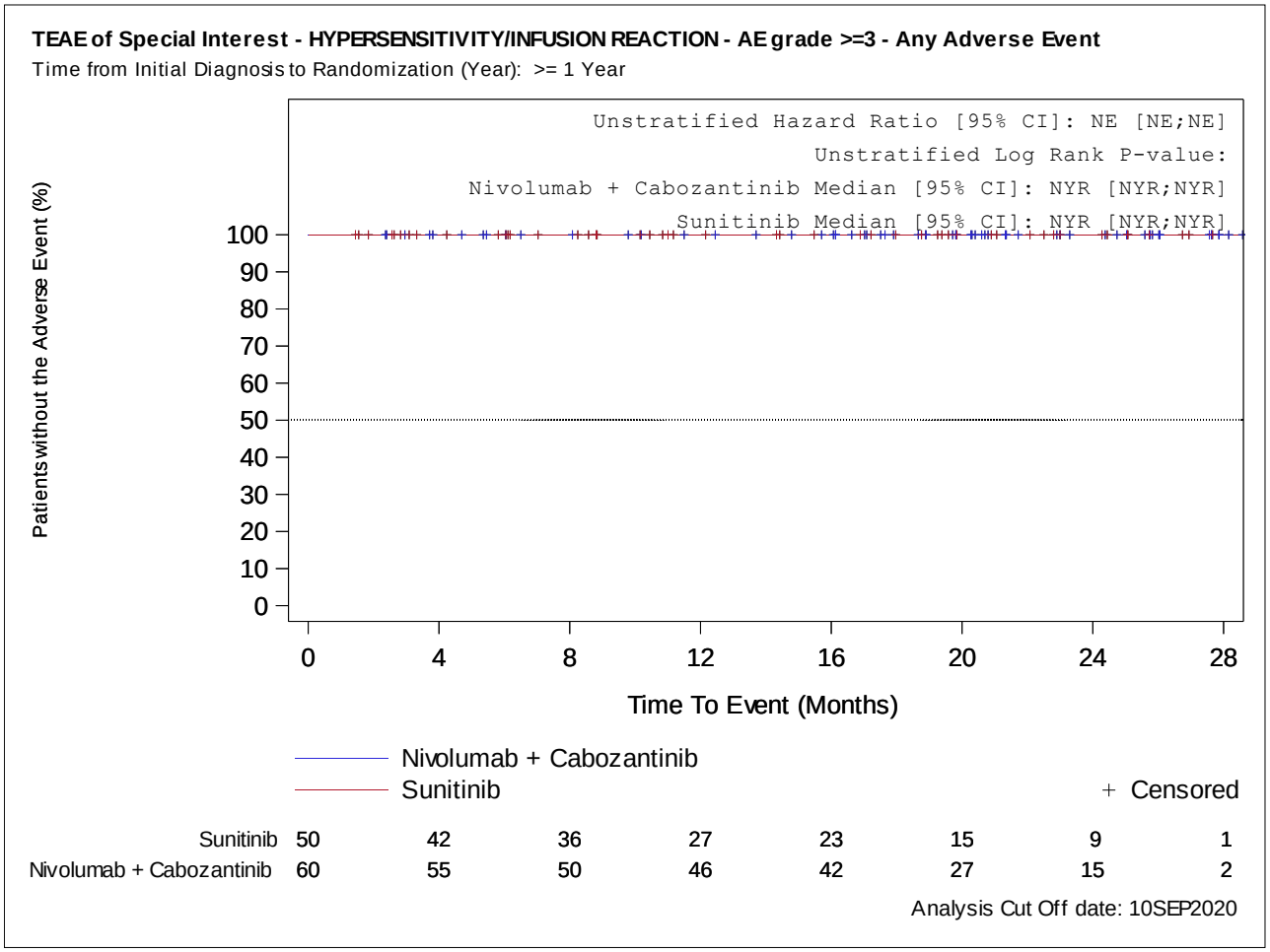

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:53:20

FIGURE 3.37.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



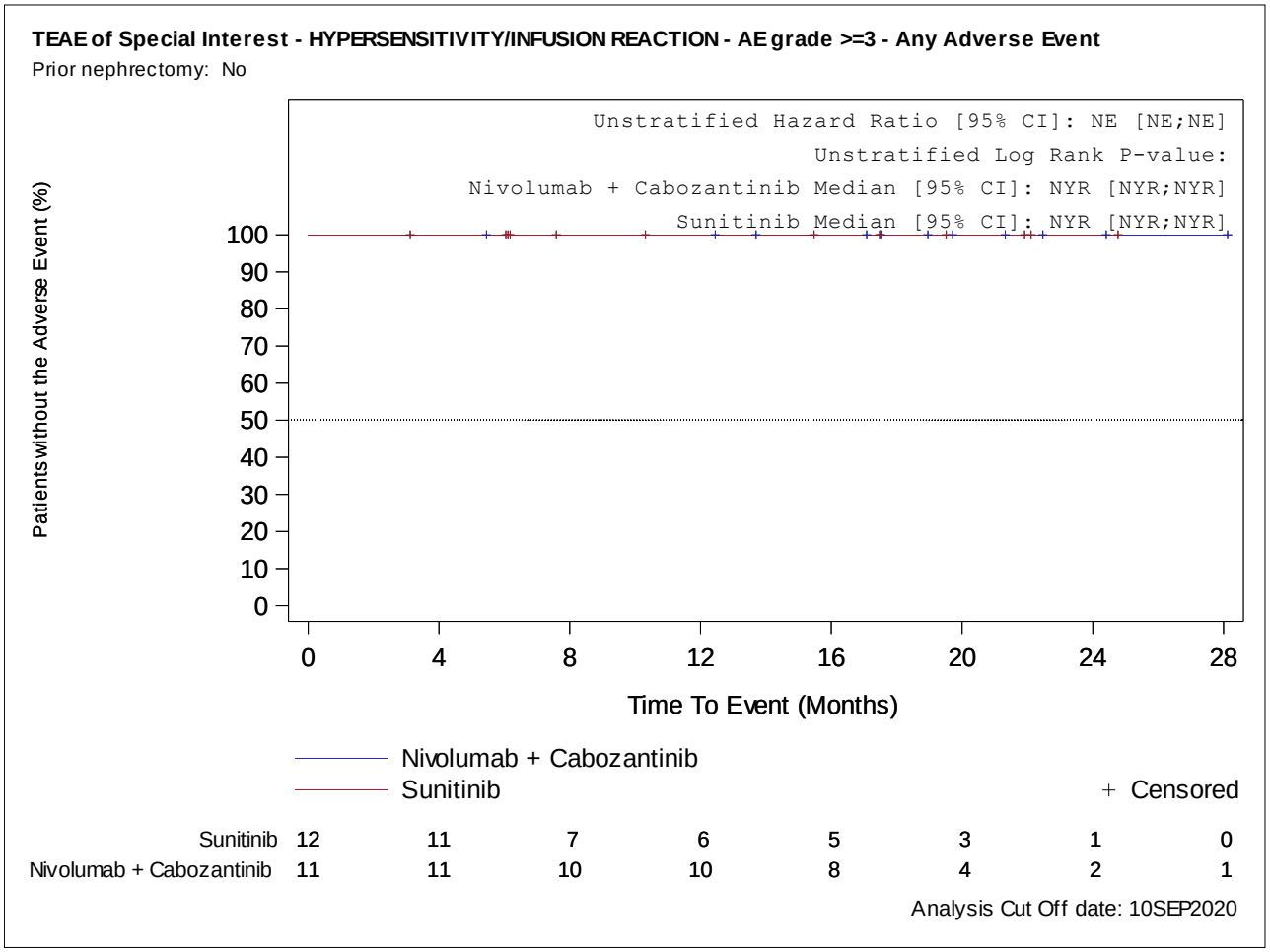

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:53:37

FIGURE 3.37.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



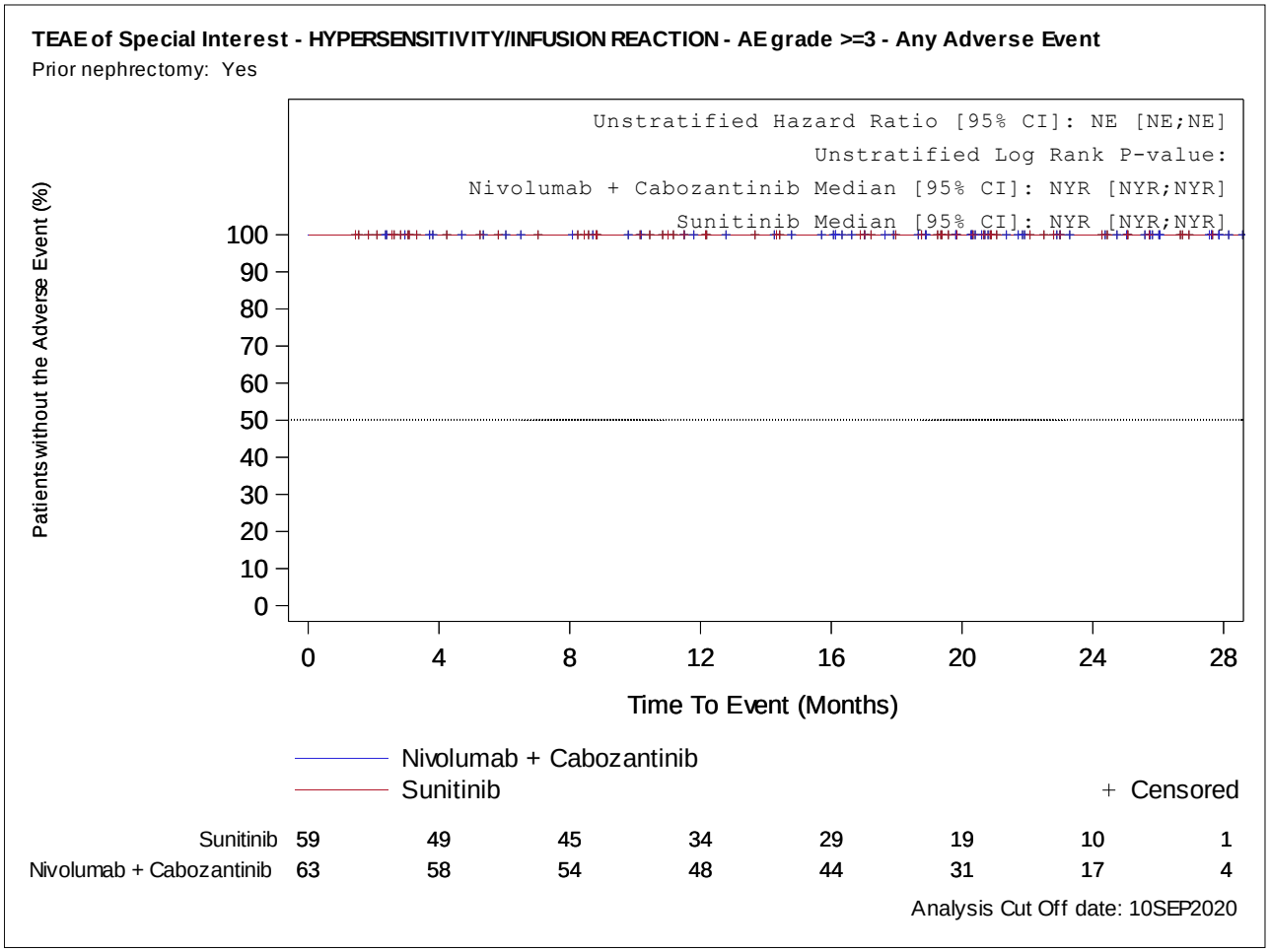

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:53:43

FIGURE 3.37.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



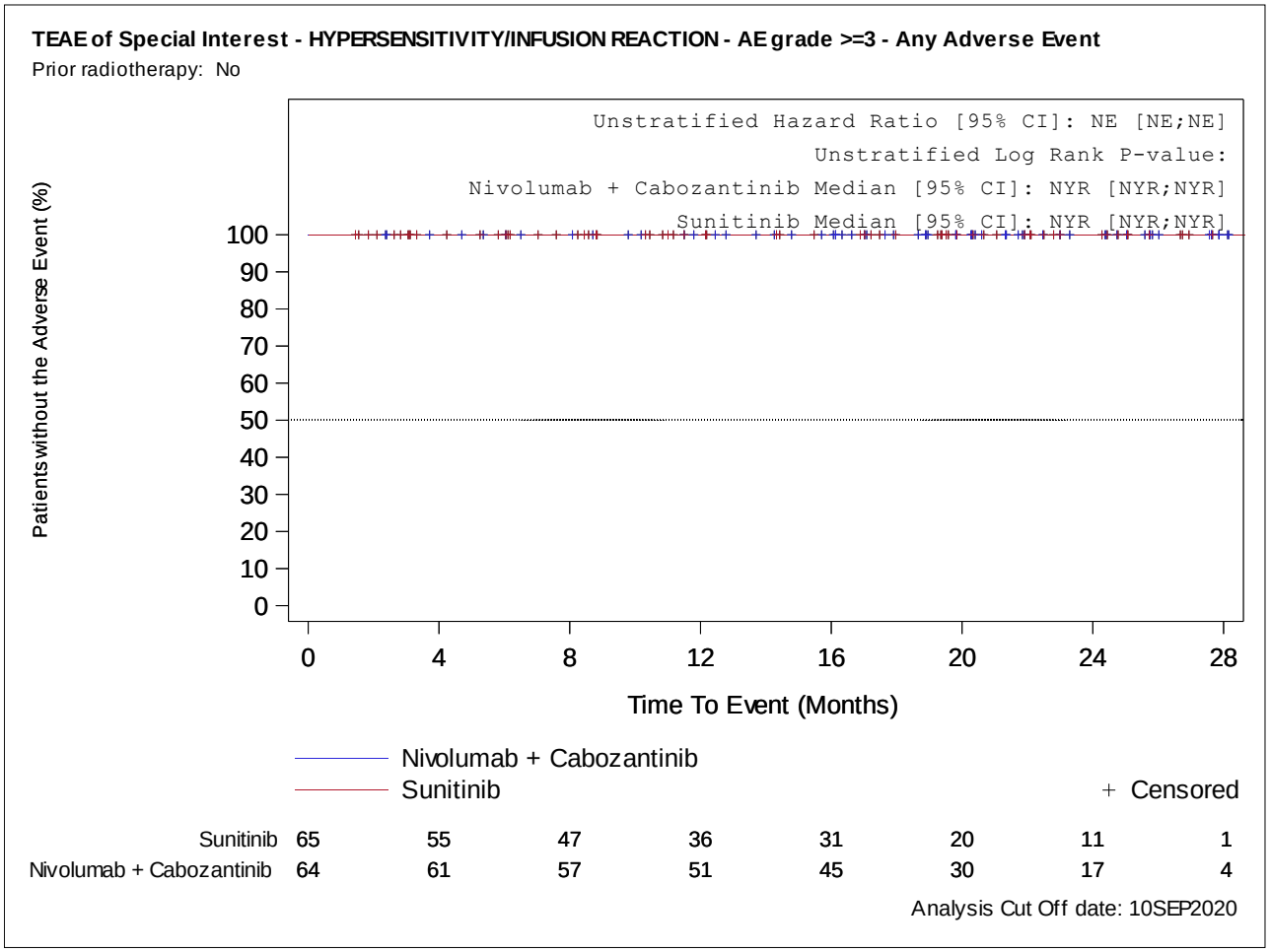

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:54:36

FIGURE 3.37.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



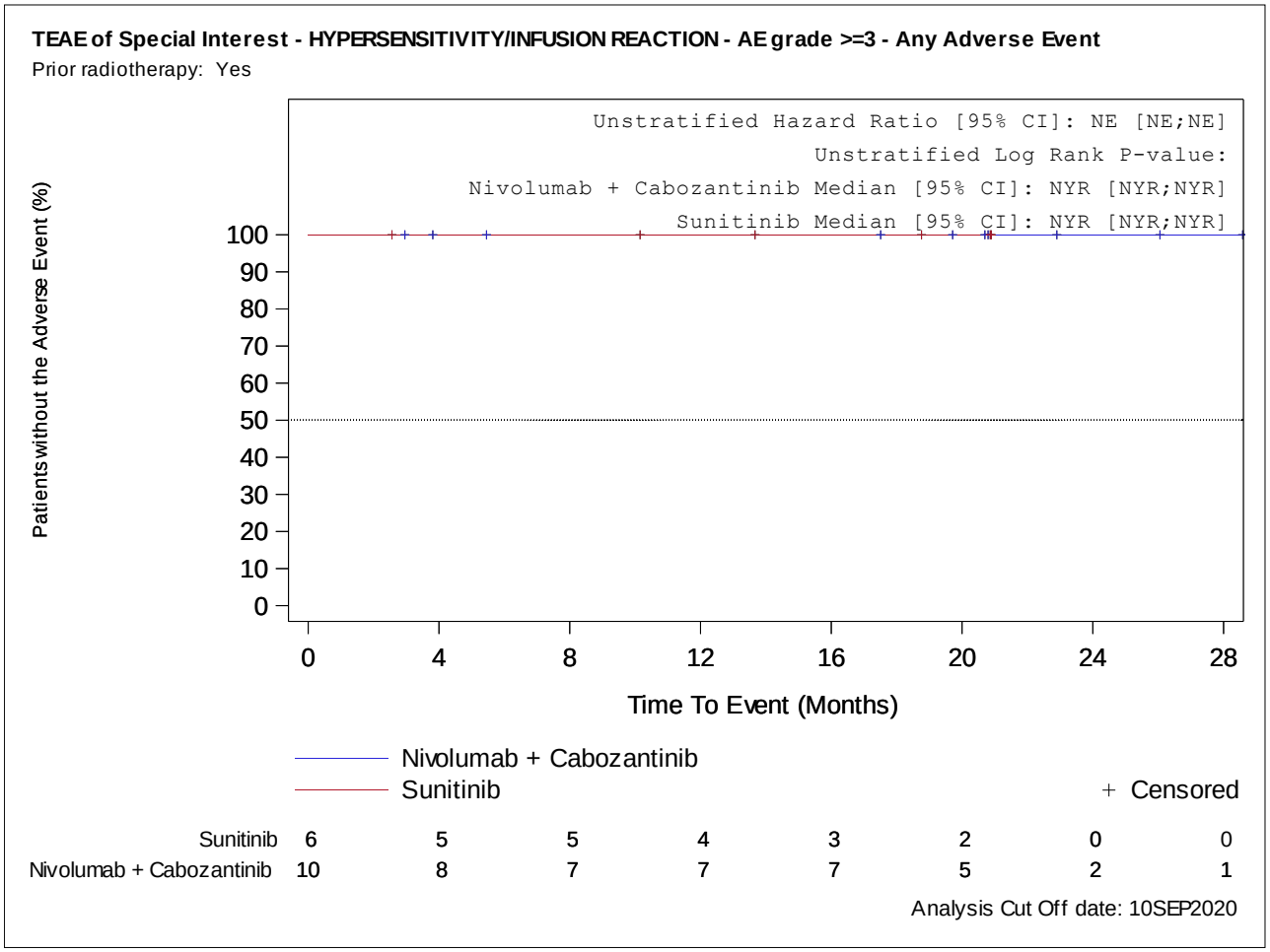

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:54:43

FIGURE 3.37.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



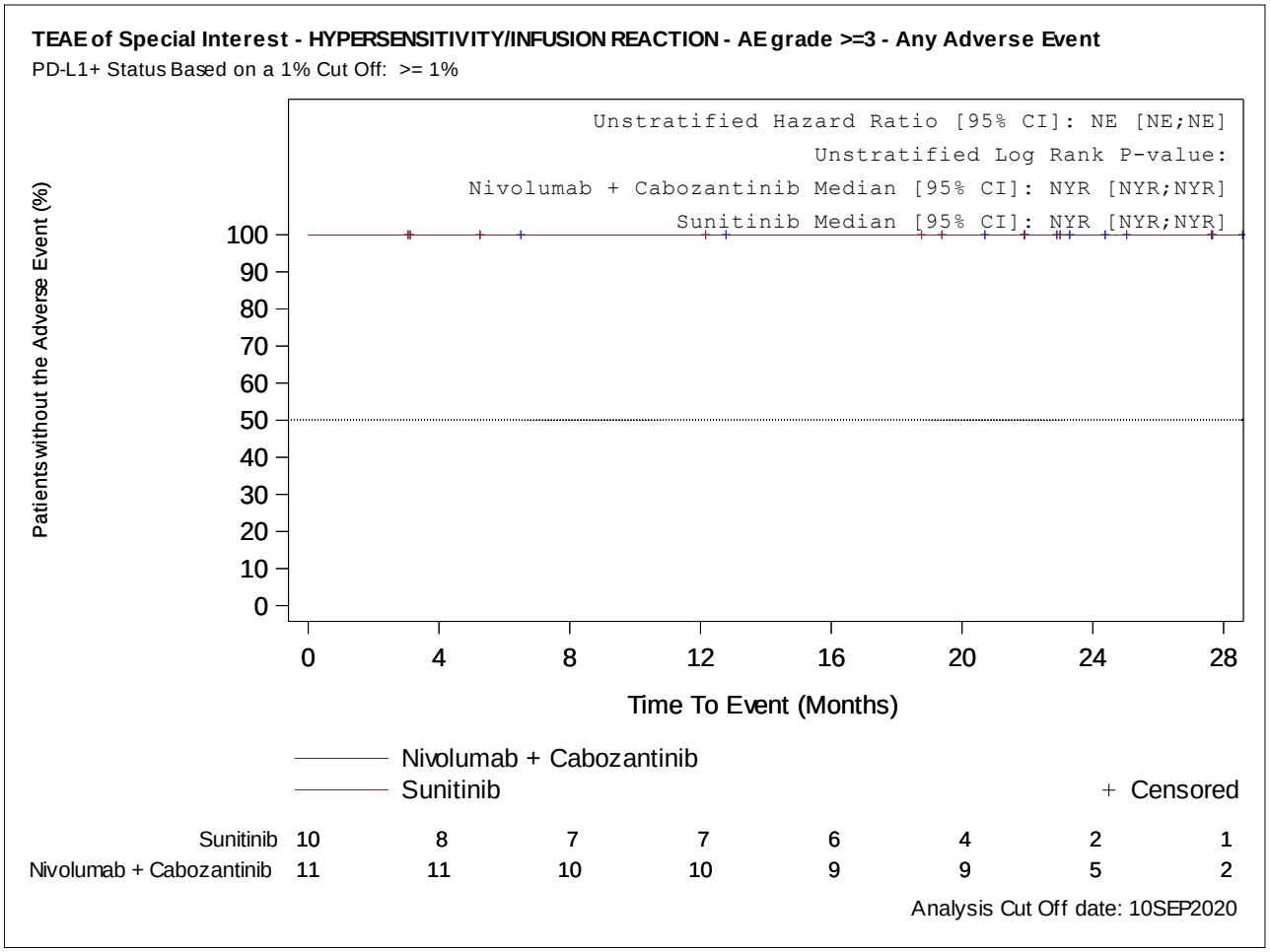

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:54:48

FIGURE 3.37.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



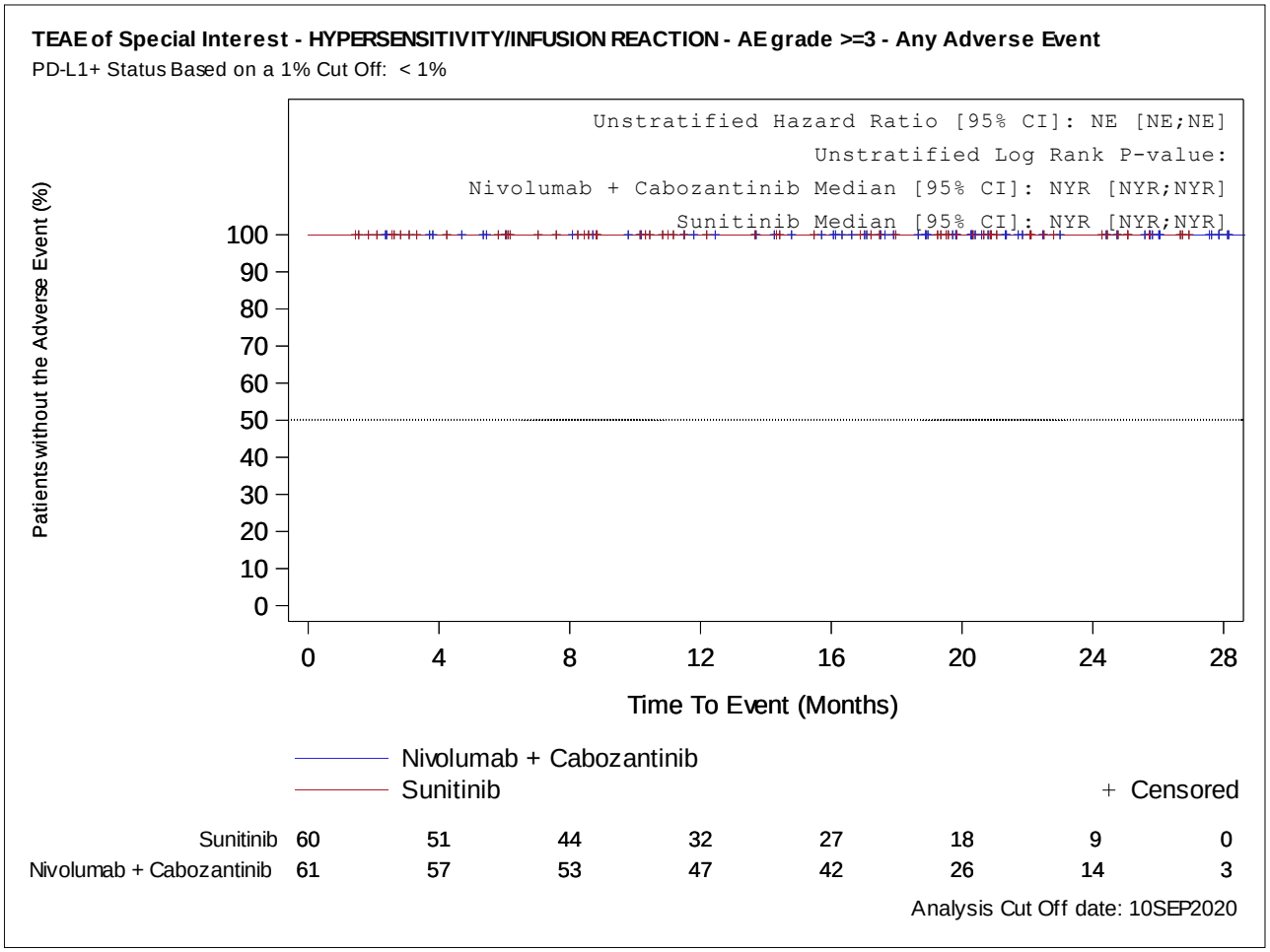

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:54:55

FIGURE 3.37.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



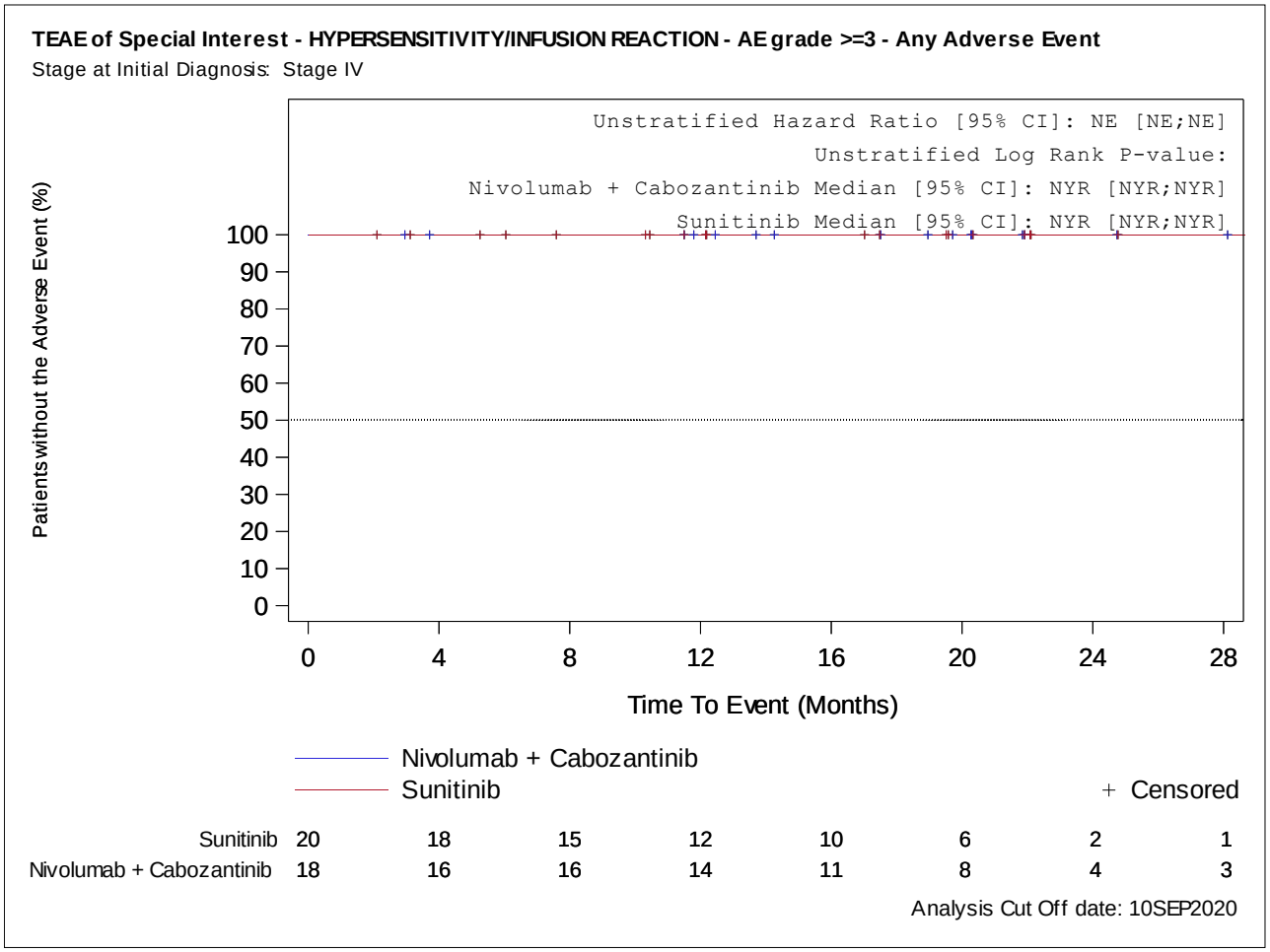

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:55:00

FIGURE 3.37.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



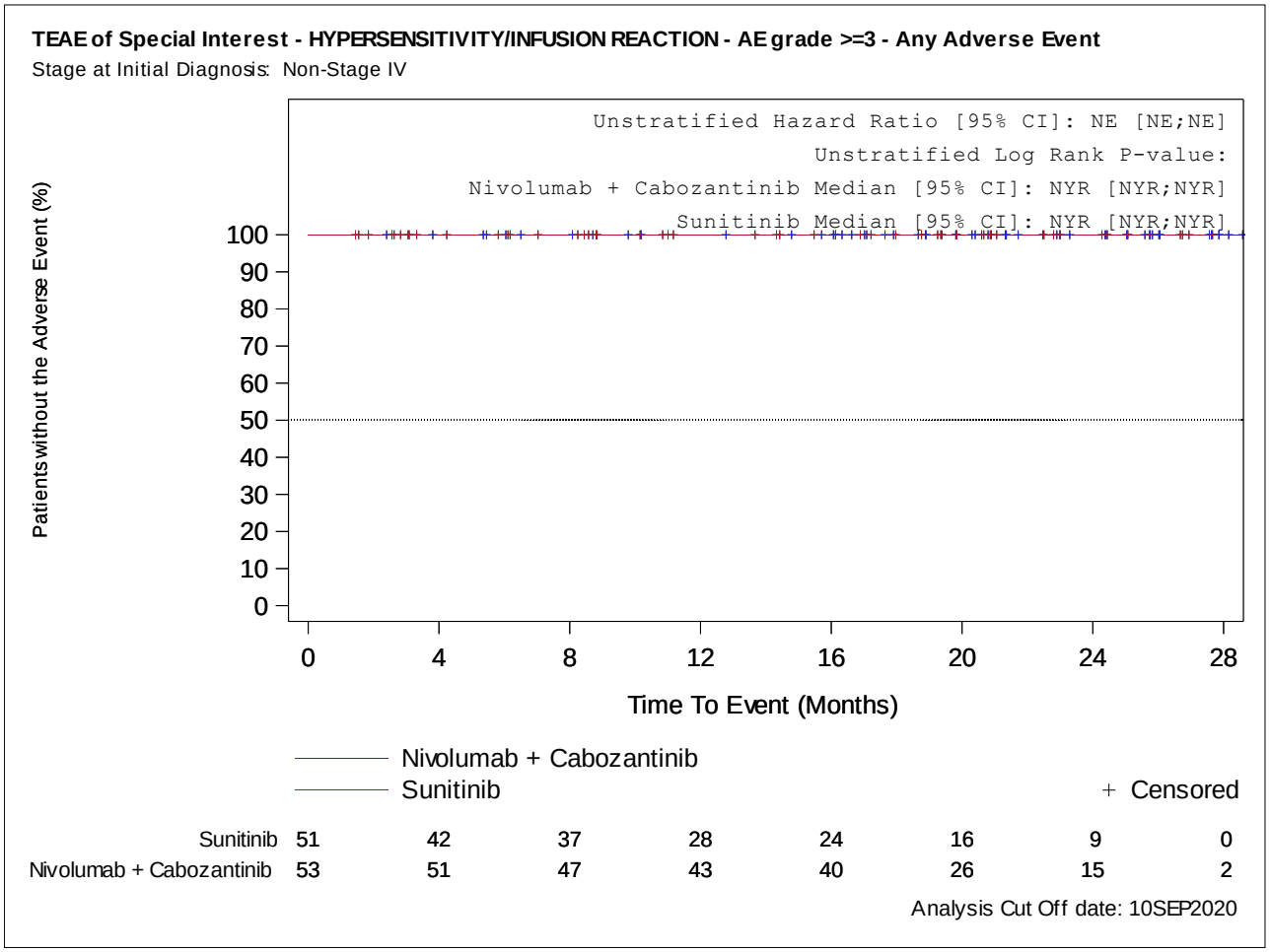

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:55:06

FIGURE 3.37.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



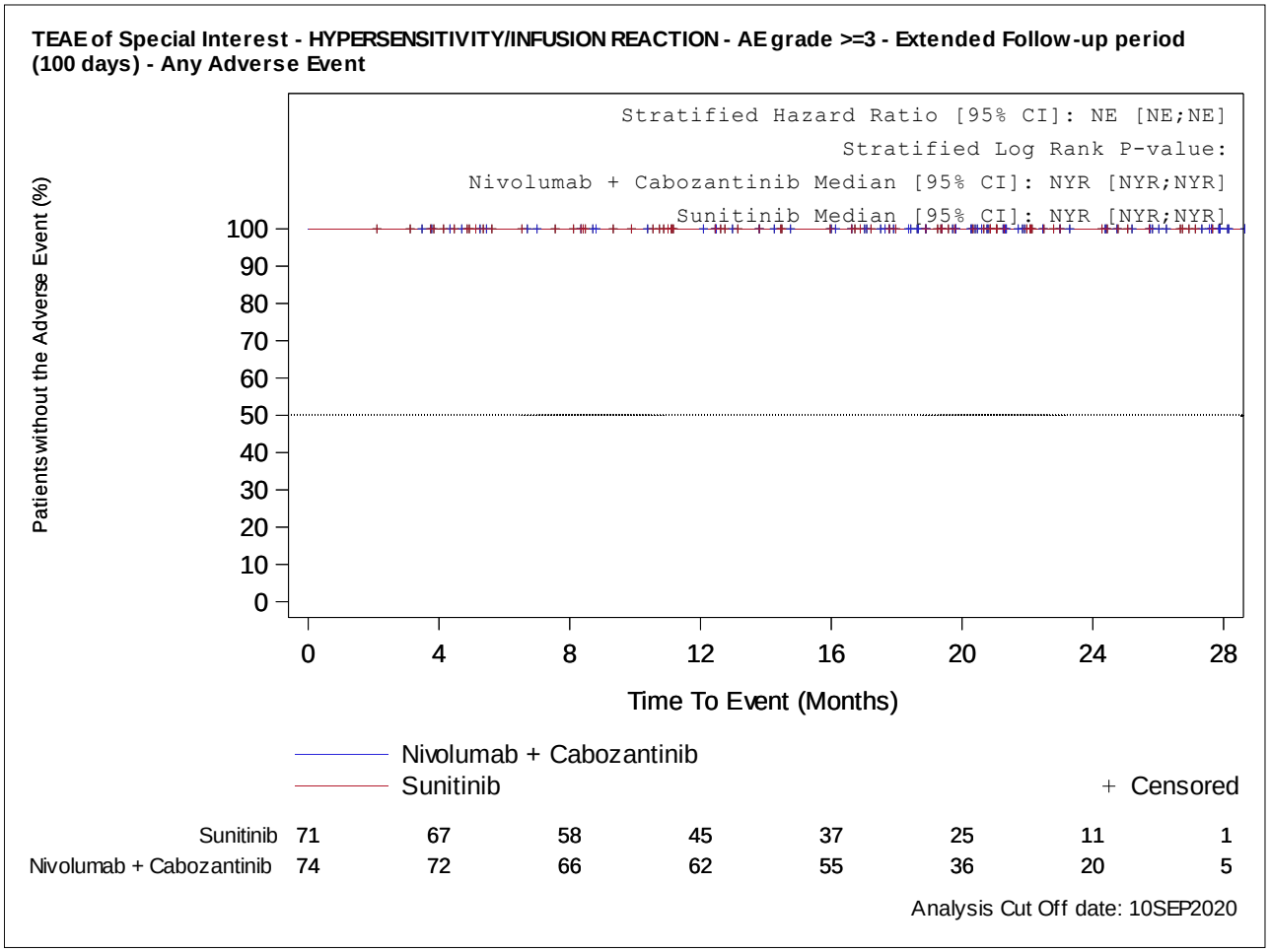

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:55:35

FIGURE 3.37.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:55:40

FIGURE 3.38.1: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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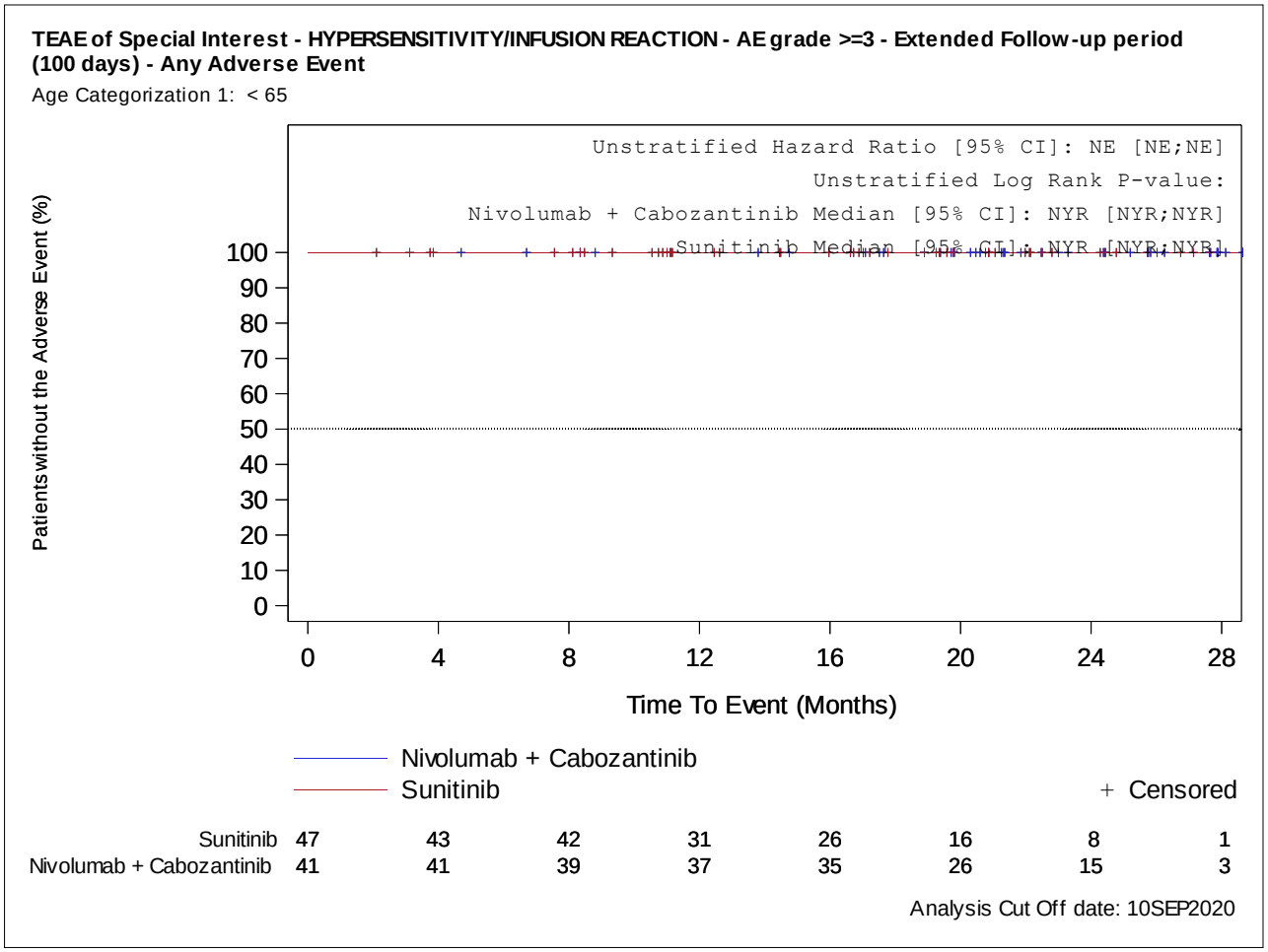
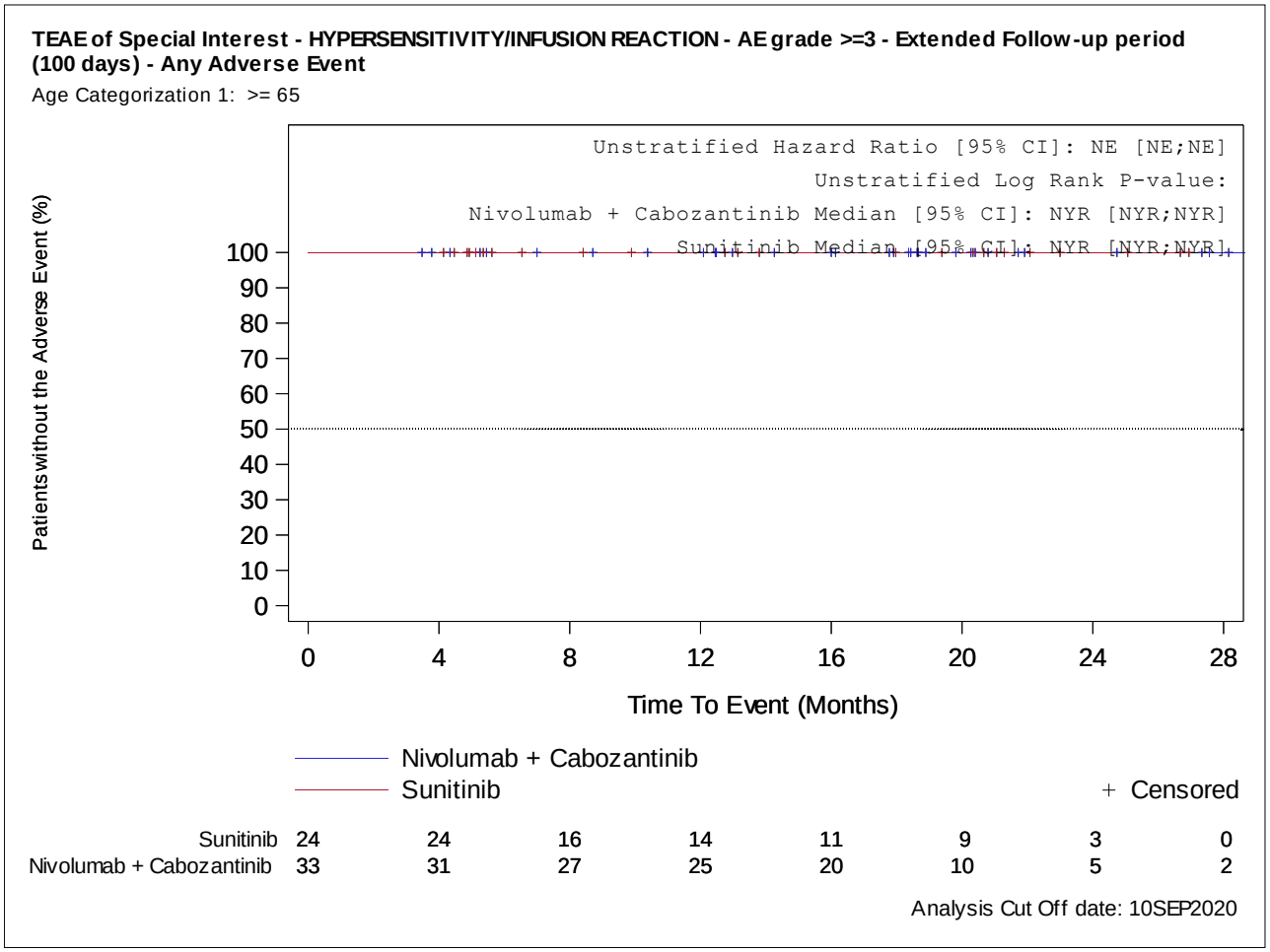
FIGURE 3.38.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



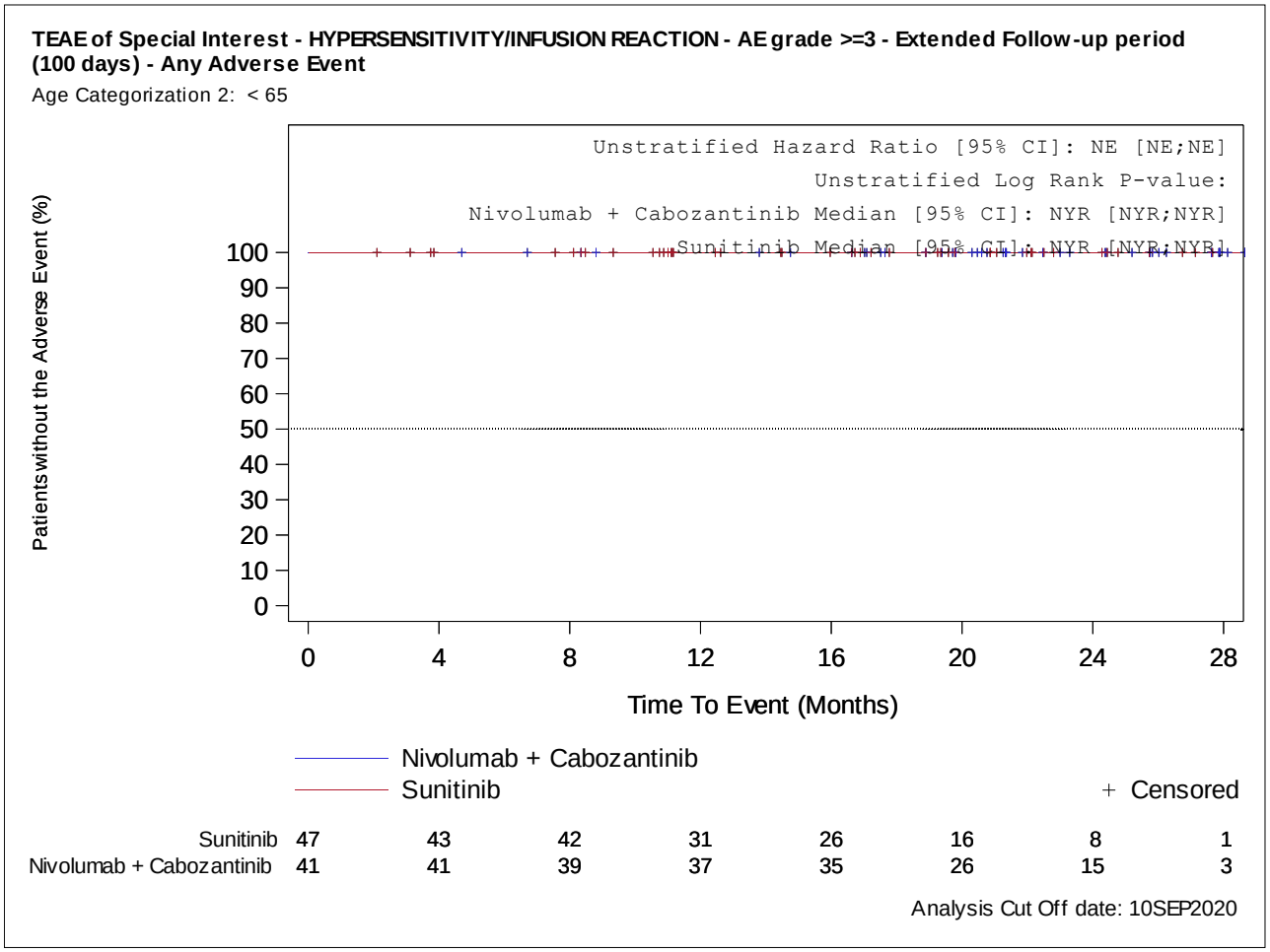

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:59:01

FIGURE 3.38.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



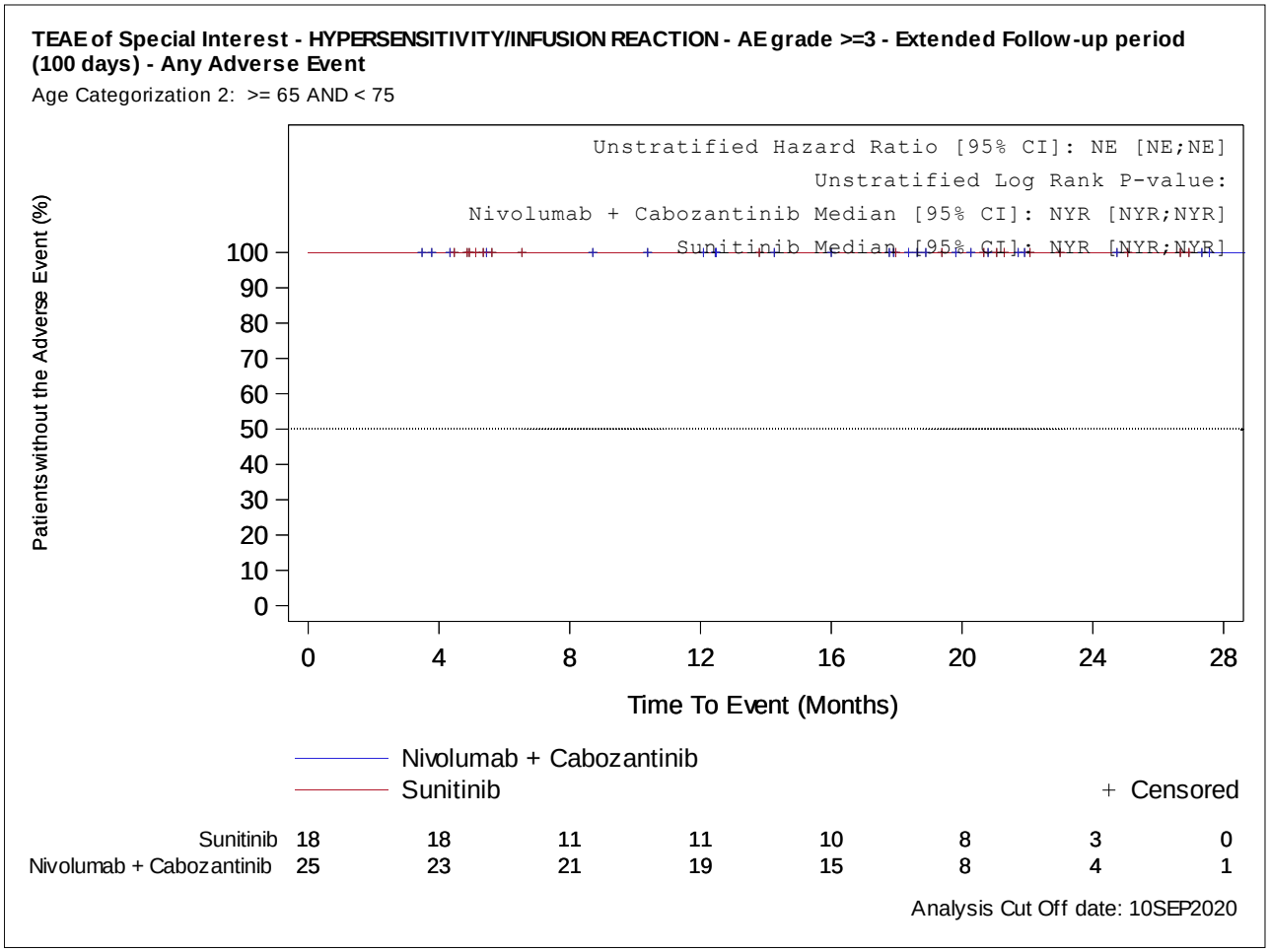

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:59:07

FIGURE 3.38.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



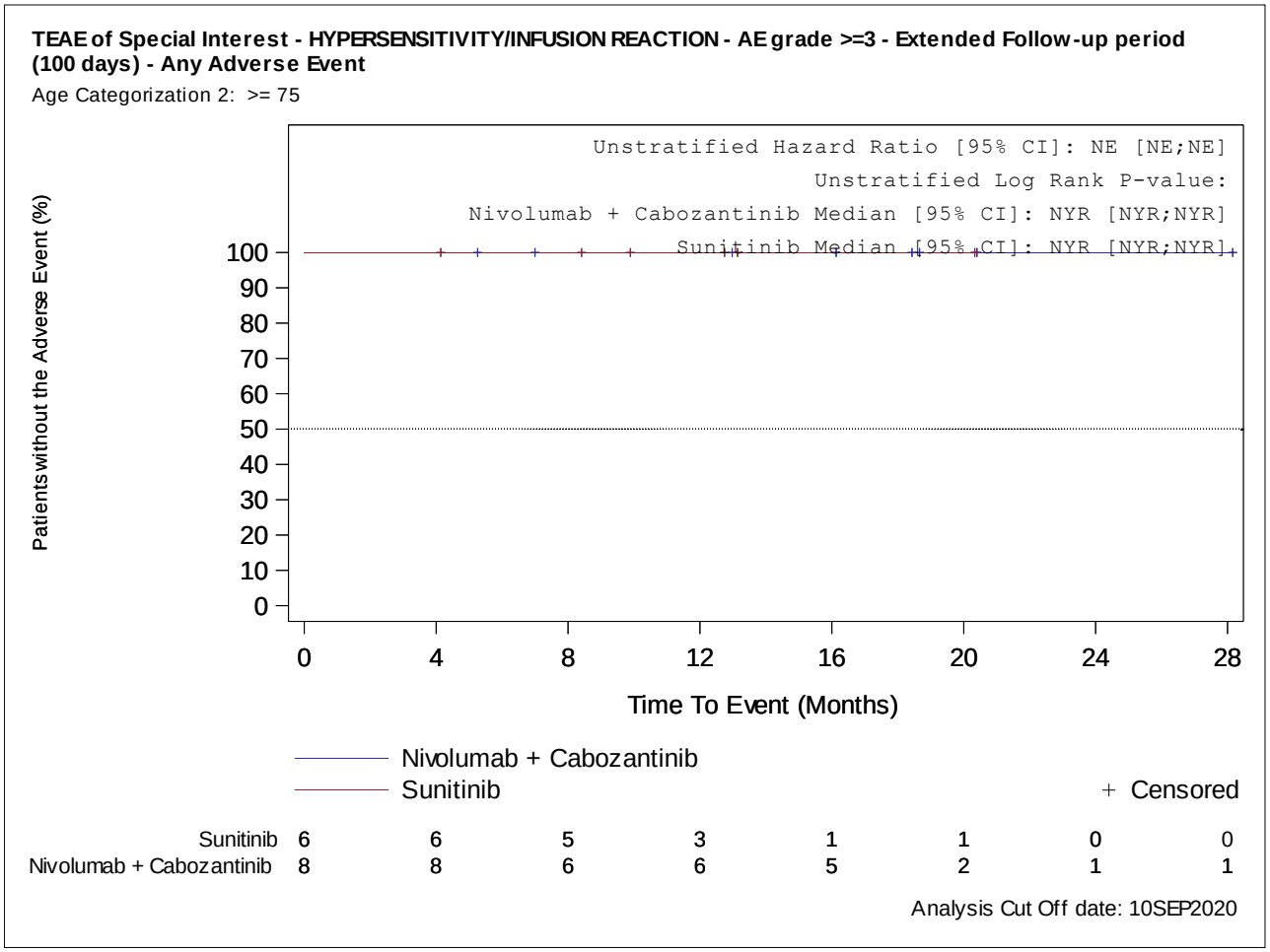

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:59:13

FIGURE 3.38.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



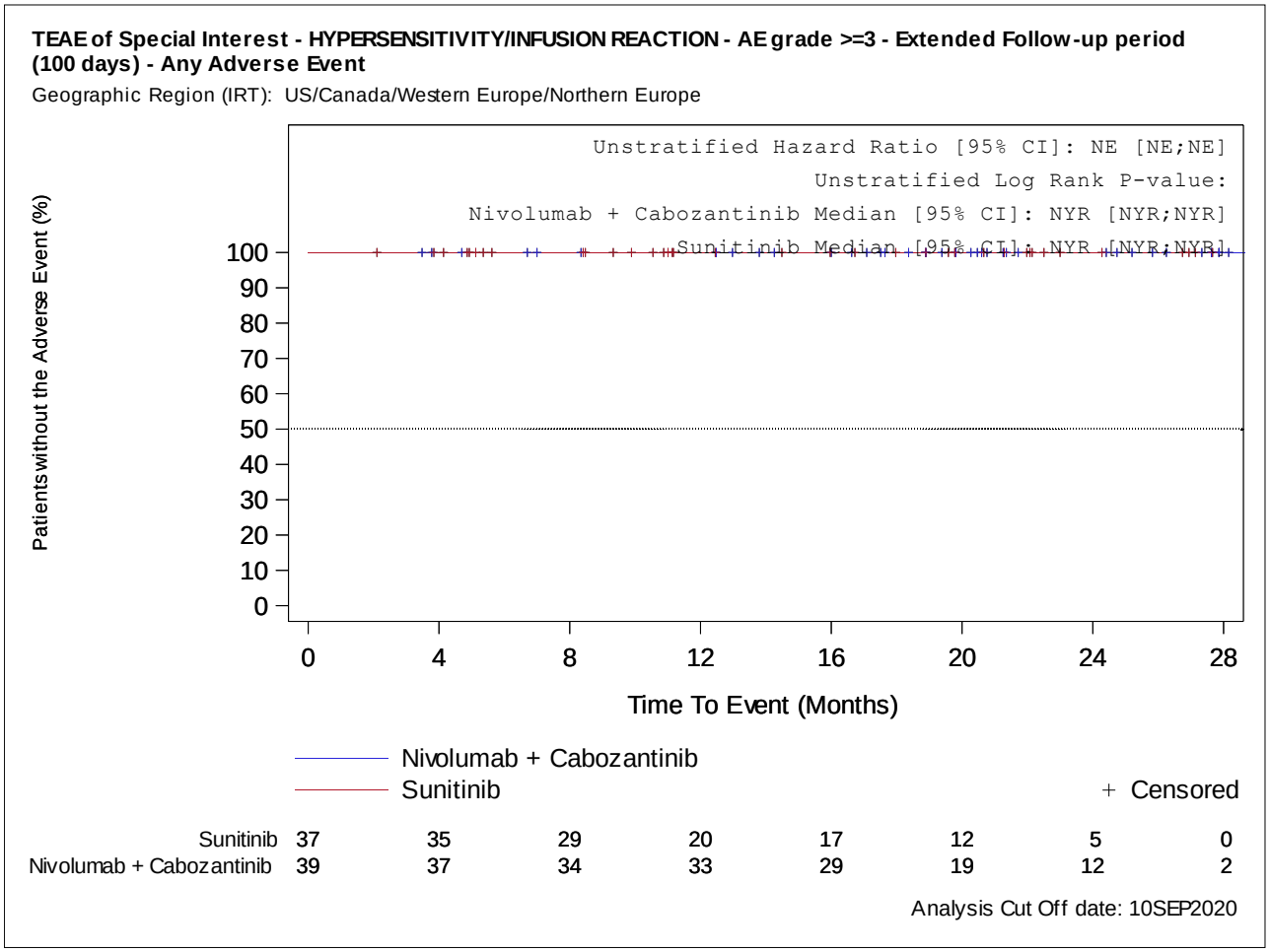

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:59:18

FIGURE 3.38.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



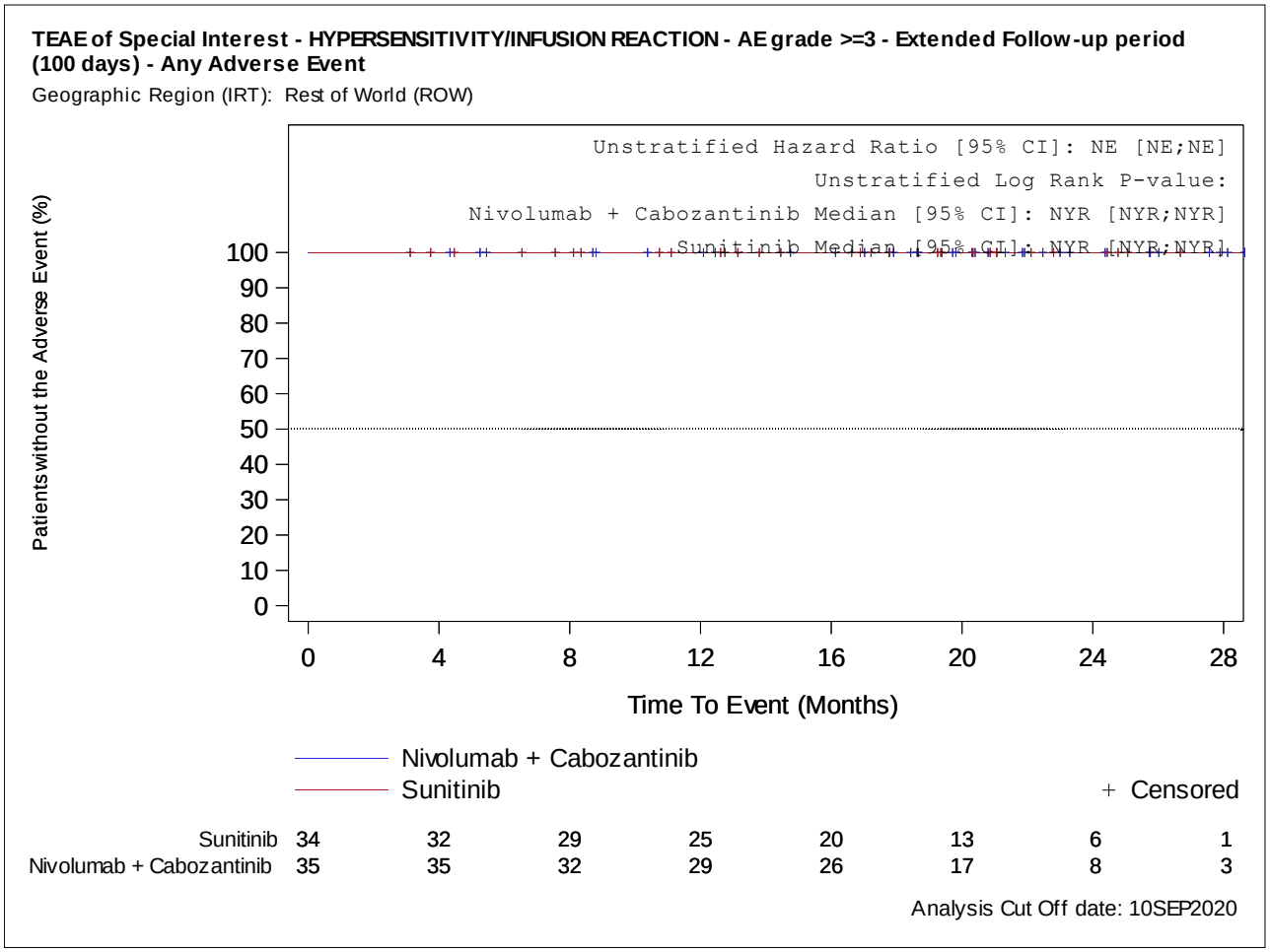

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:59:24

FIGURE 3.38.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



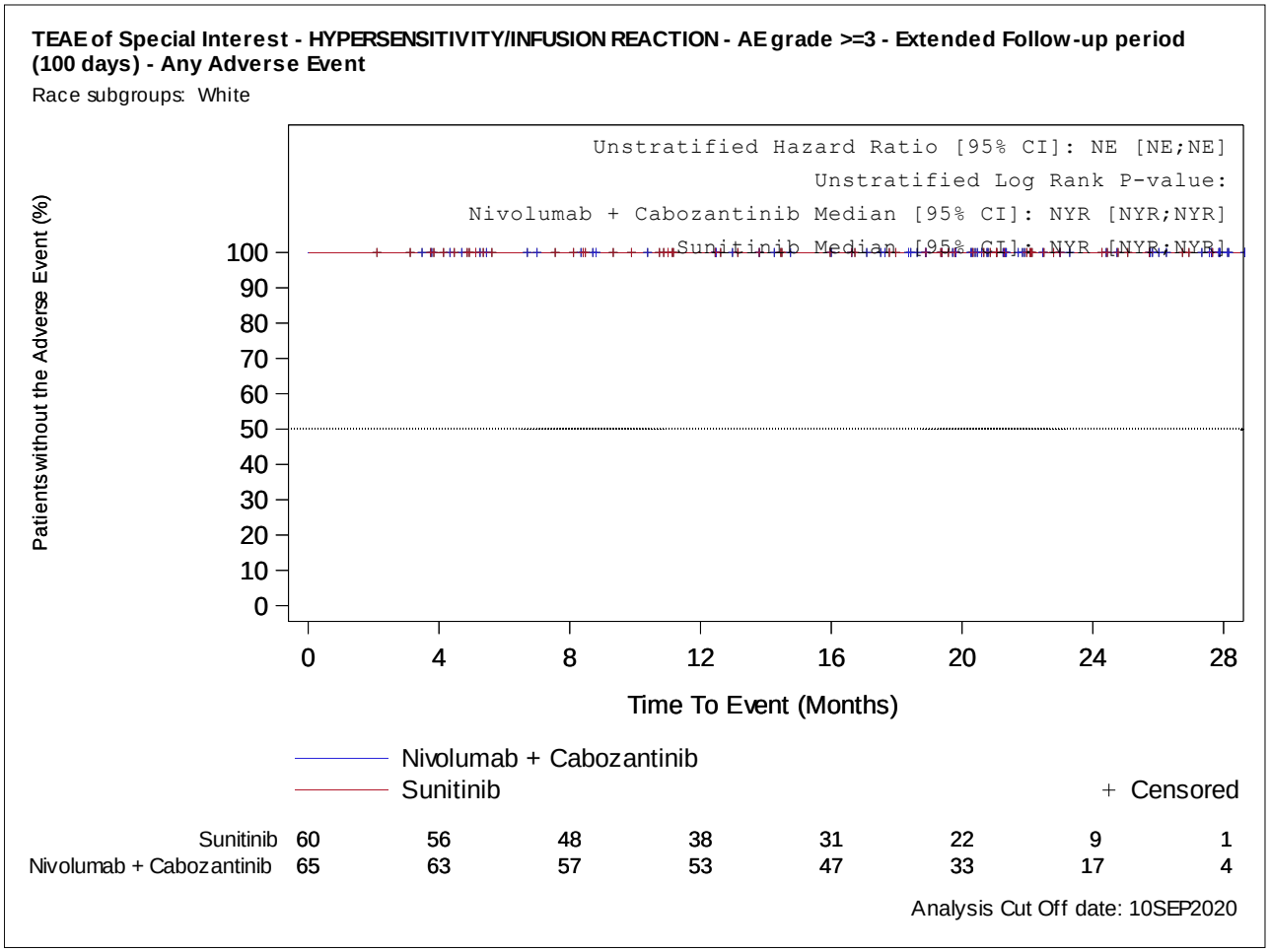

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:59:30

FIGURE 3.38.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



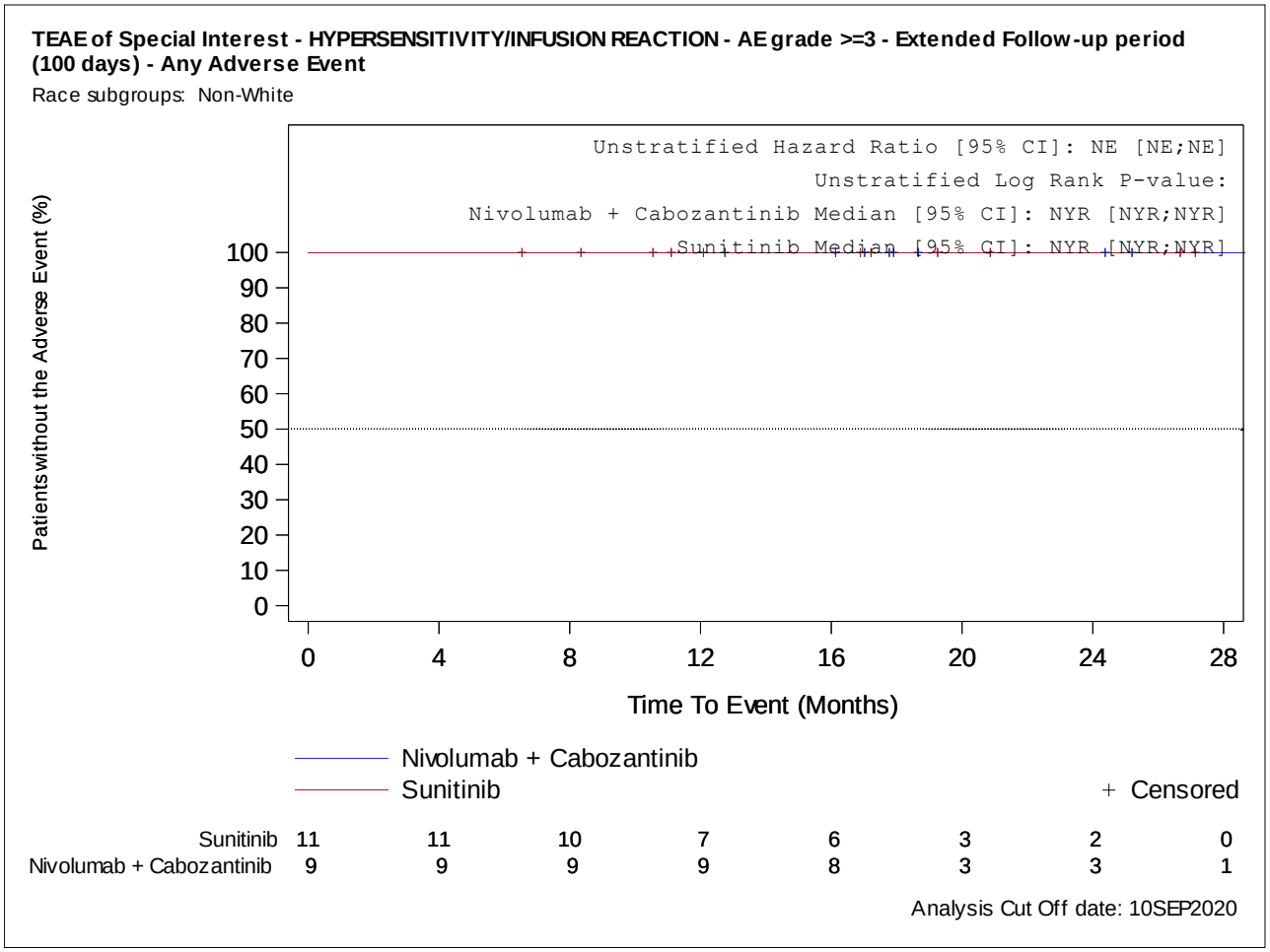

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:59:36

FIGURE 3.38.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



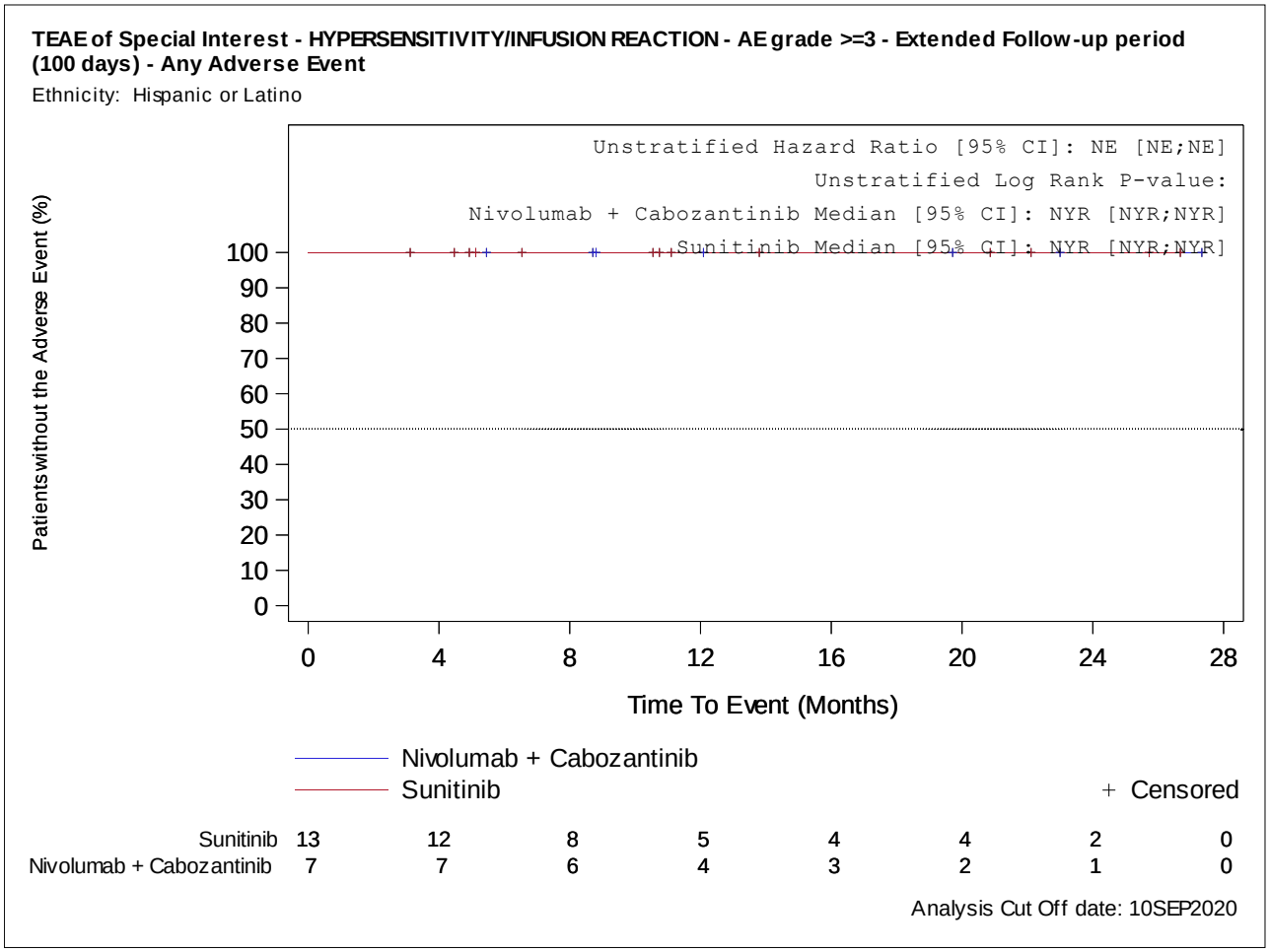

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:59:42

FIGURE 3.38.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



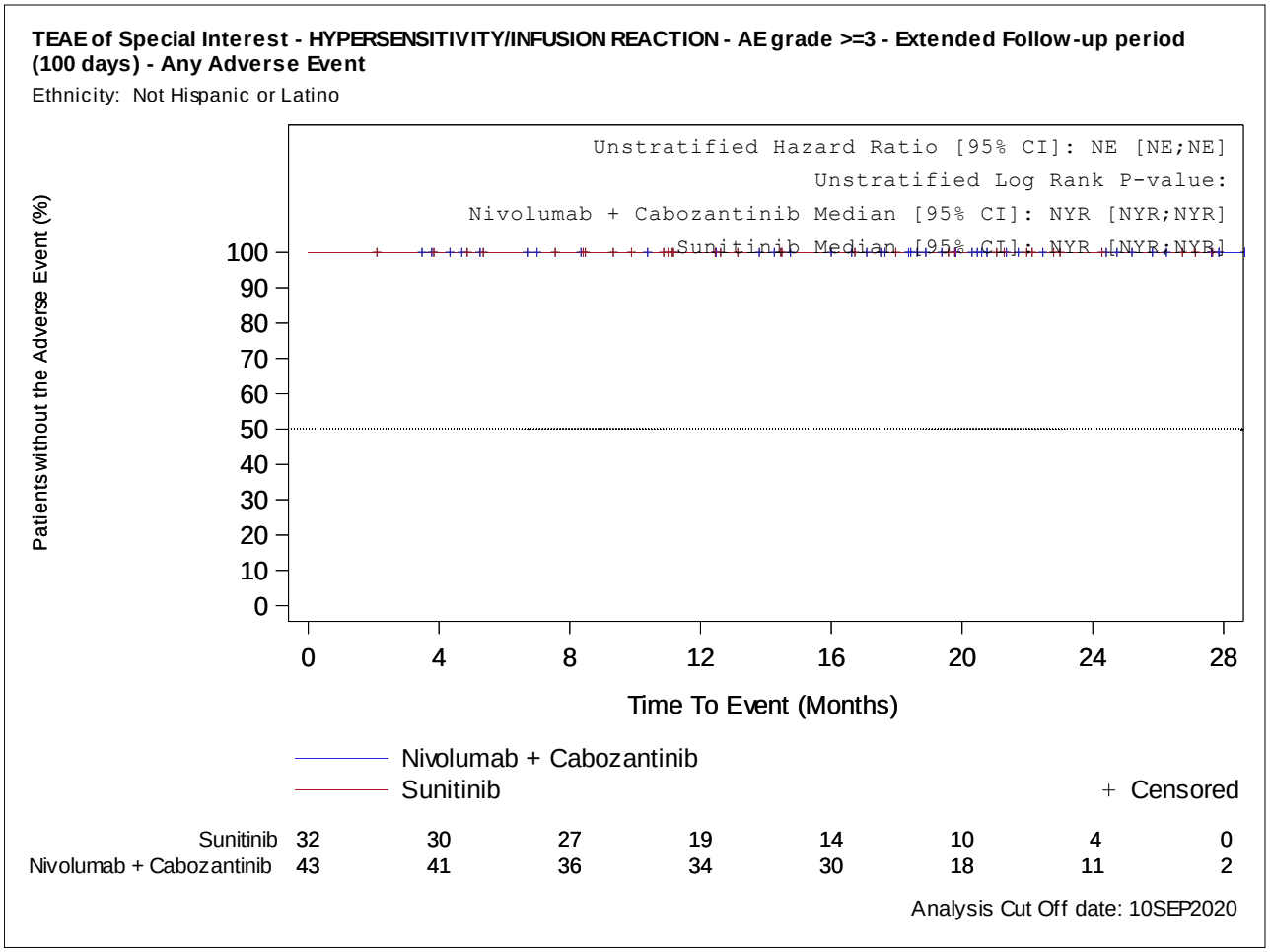

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:59:47

FIGURE 3.38.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



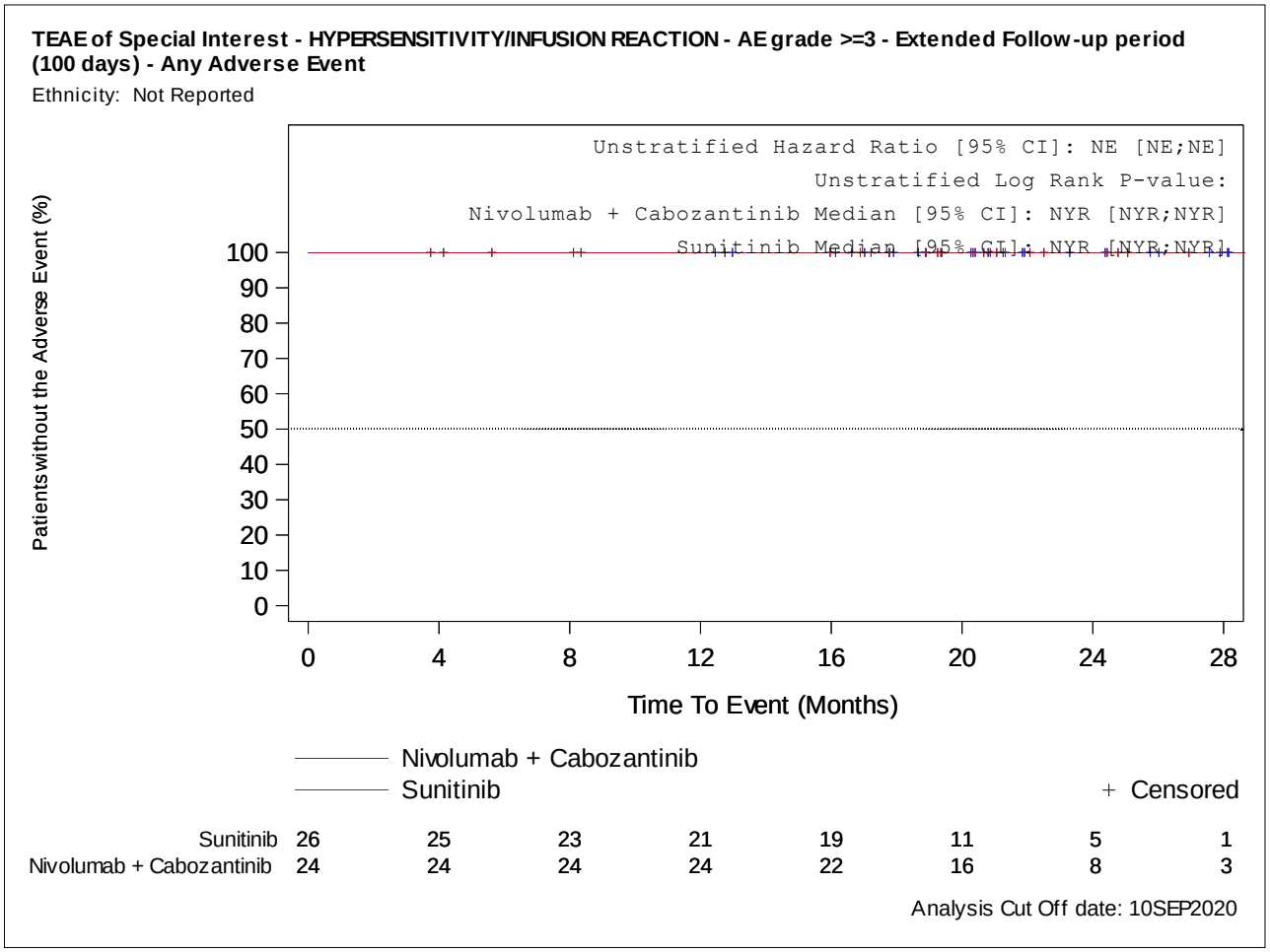

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:59:54

FIGURE 3.38.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



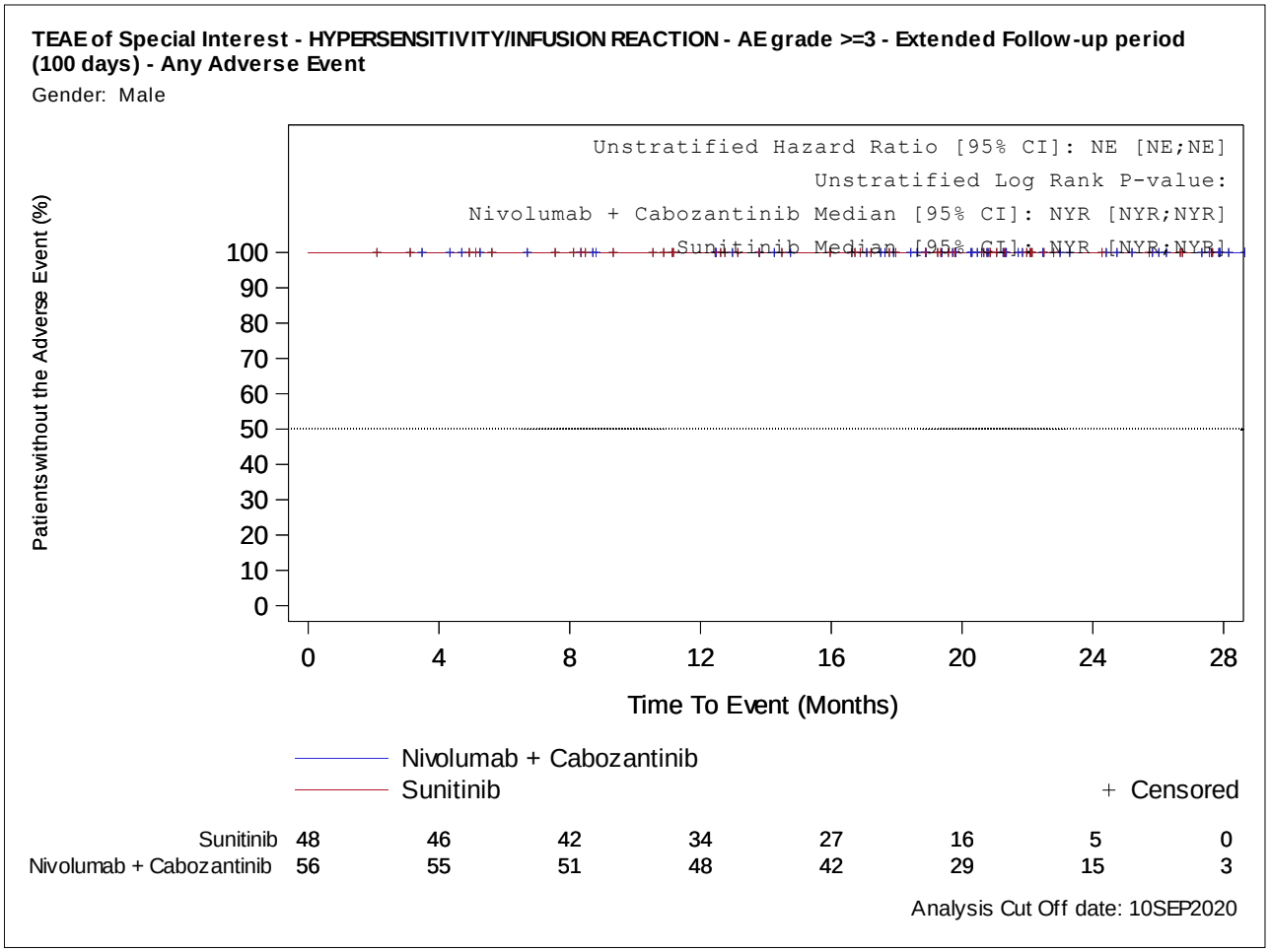

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:59:59

FIGURE 3.38.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



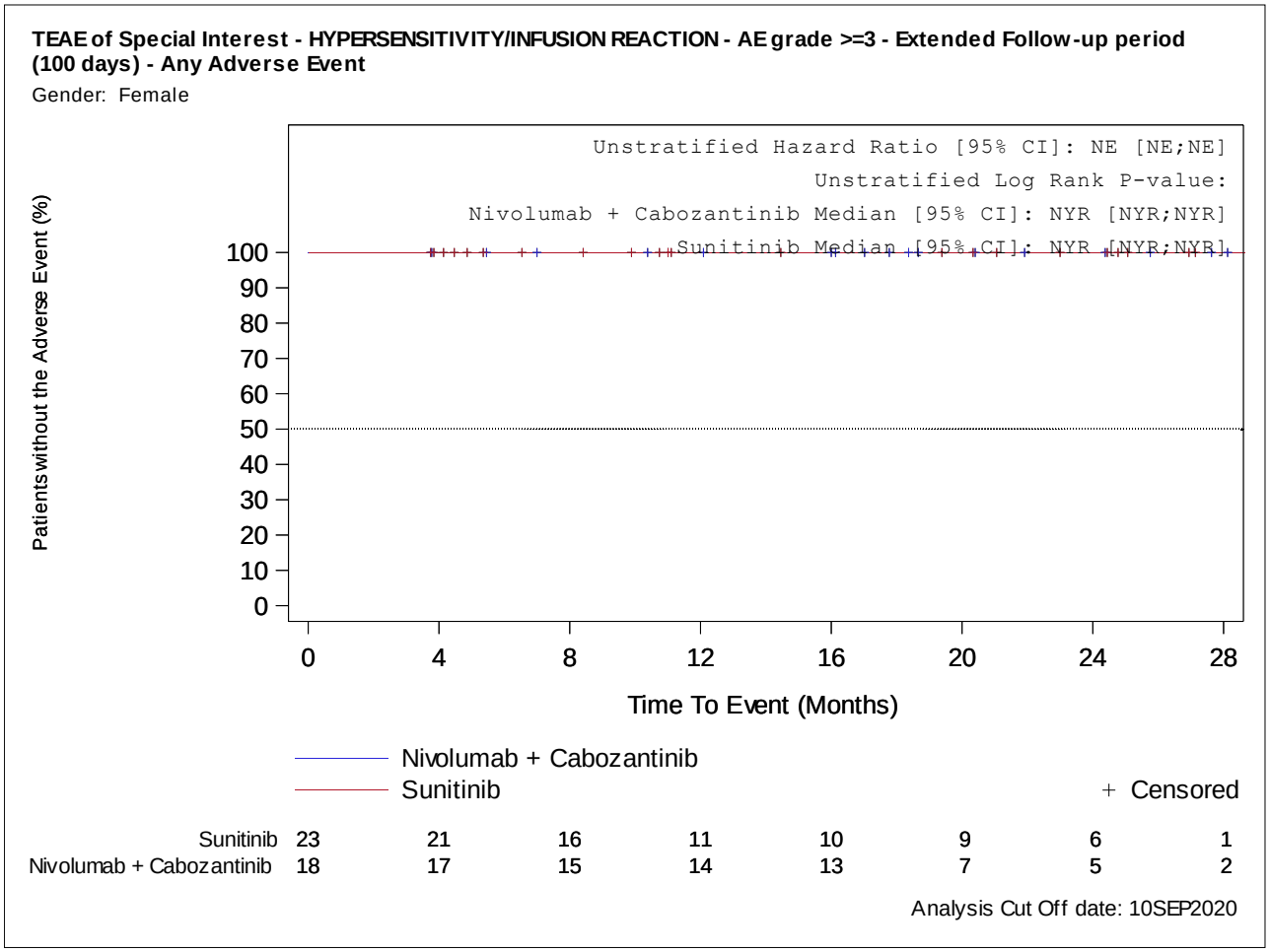

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:00:06

FIGURE 3.38.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



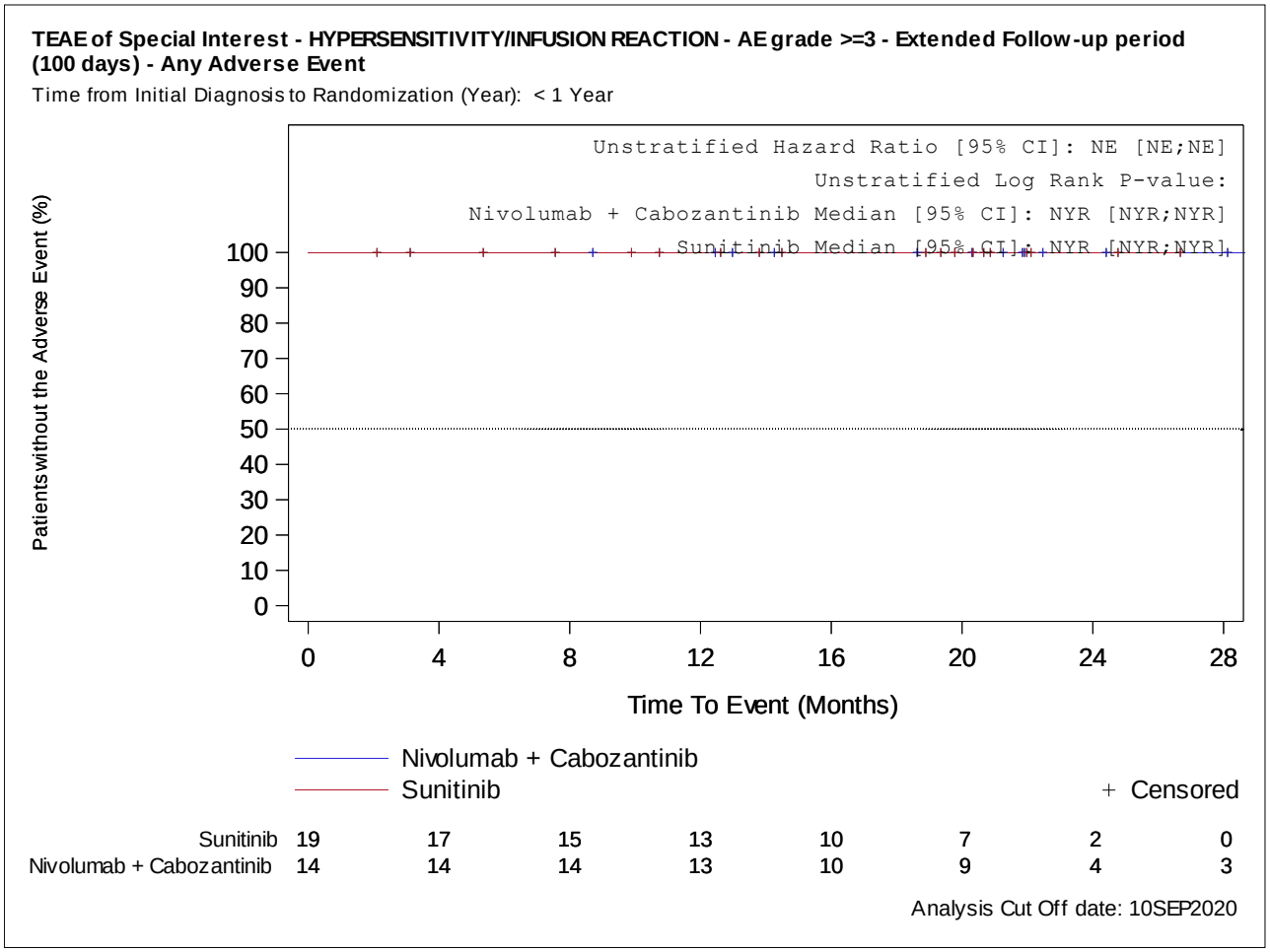

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:00:11

FIGURE 3.38.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



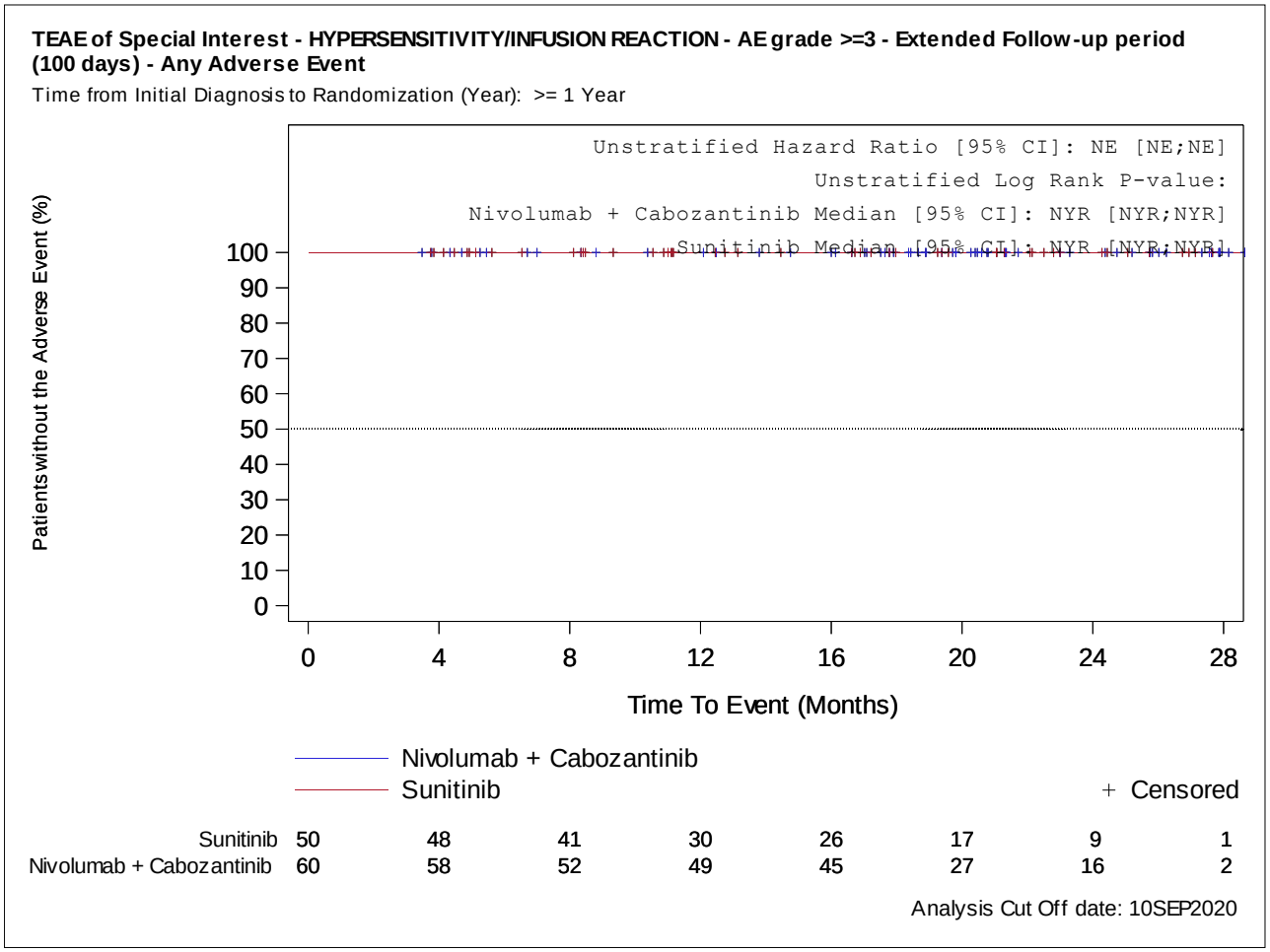

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:00:17

FIGURE 3.38.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



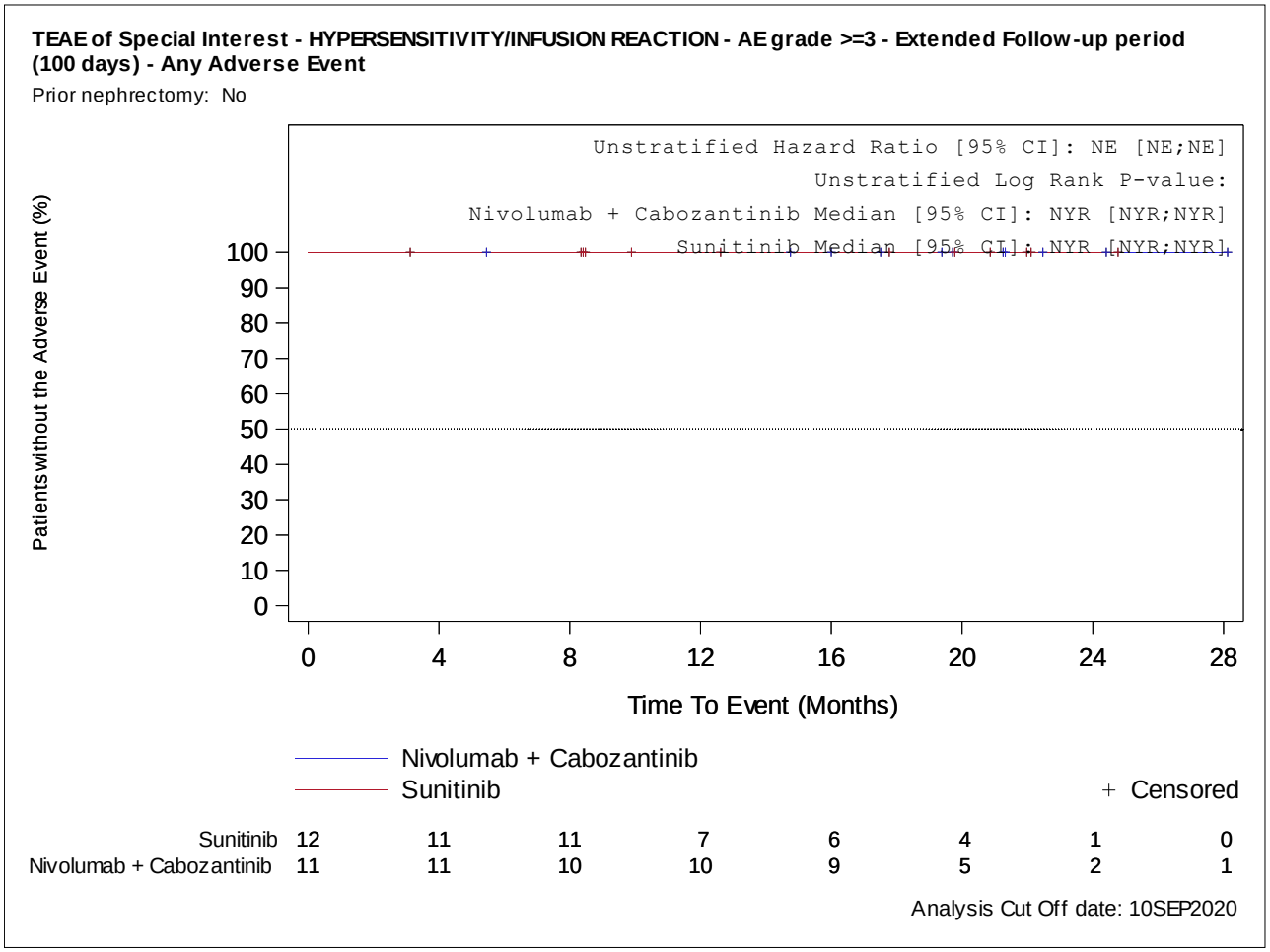

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:00:36

FIGURE 3.38.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



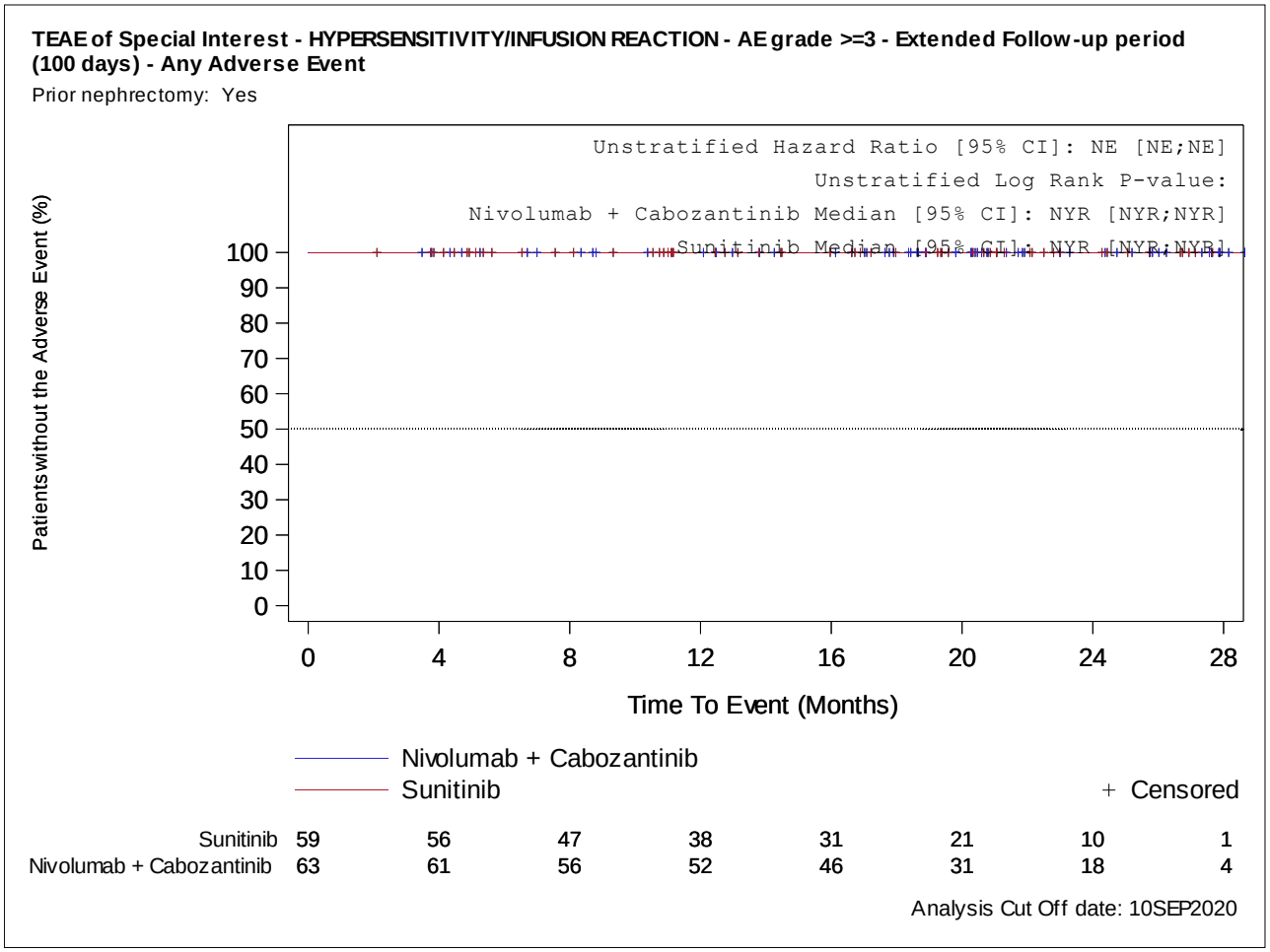

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:00:42

FIGURE 3.38.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



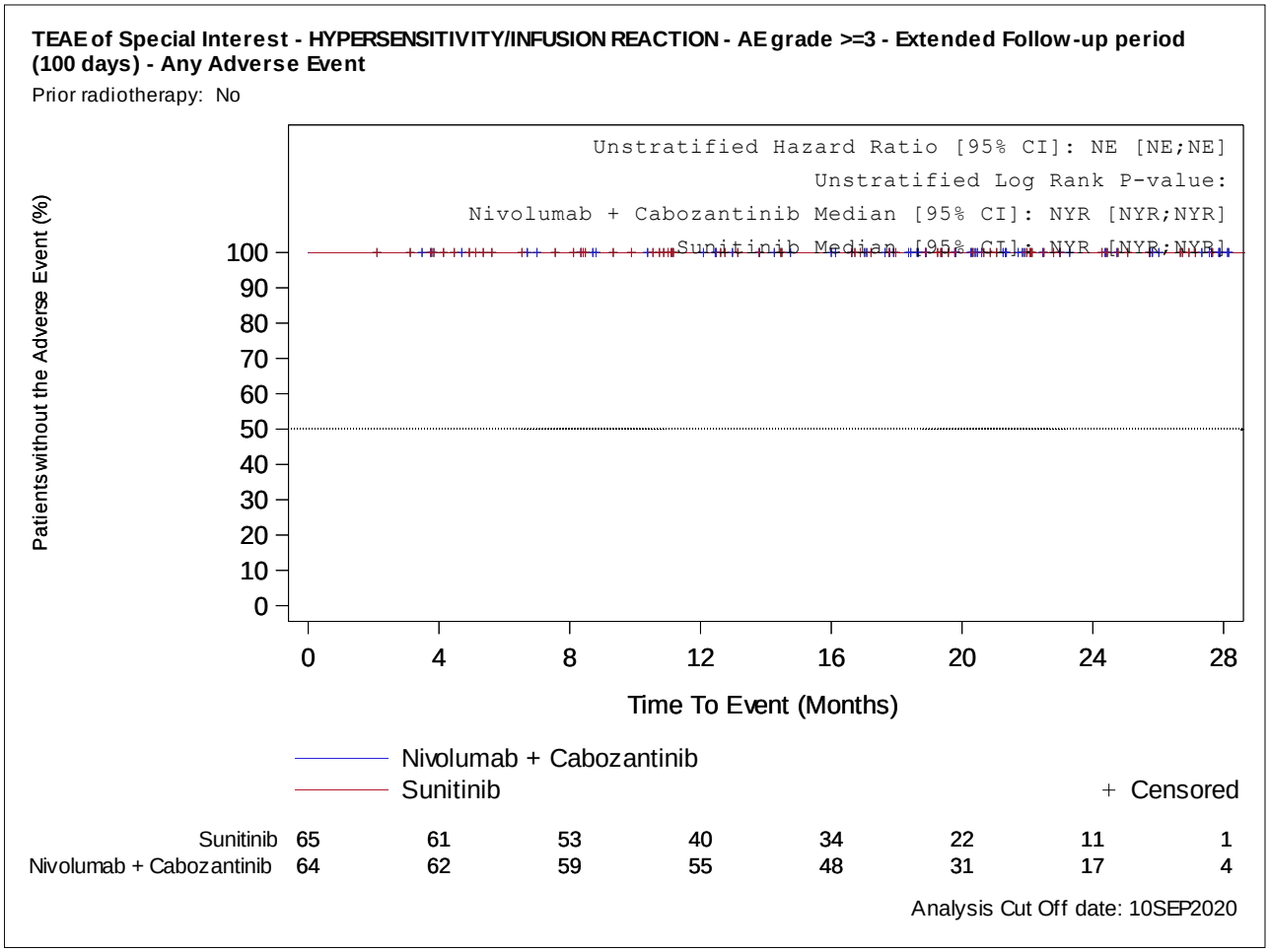

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:01:33

FIGURE 3.38.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



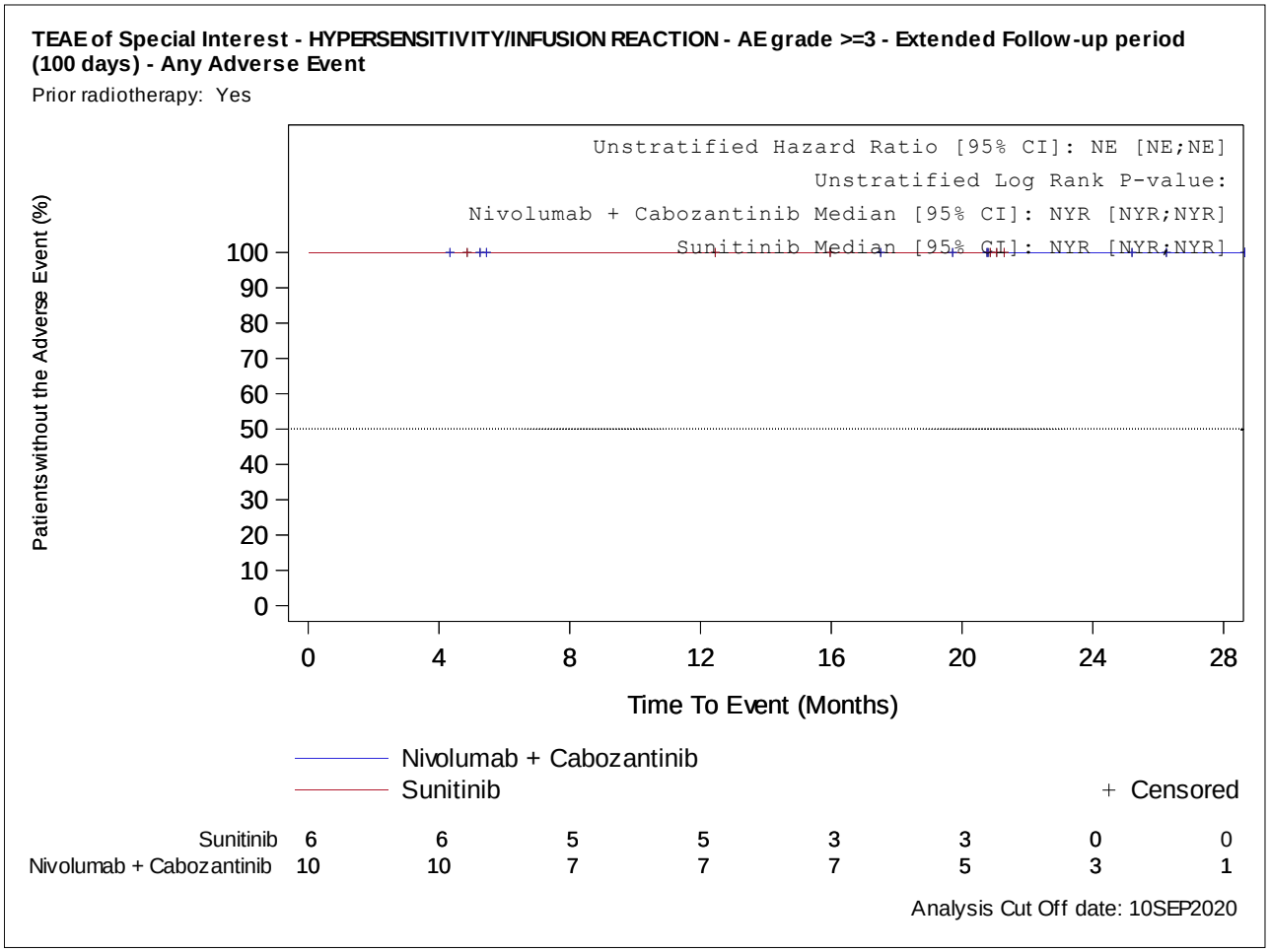

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:01:39

FIGURE 3.38.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



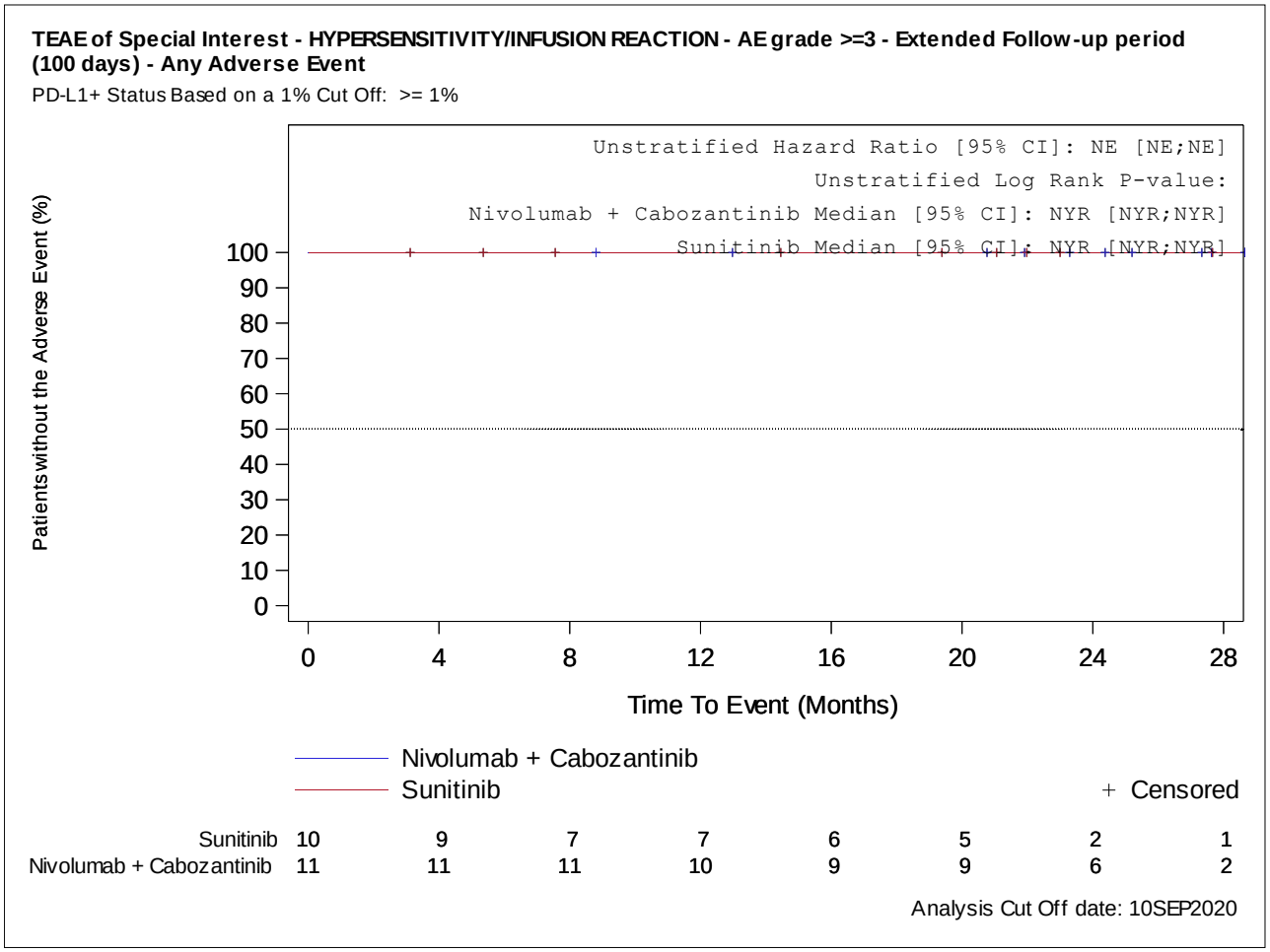

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:01:45

FIGURE 3.38.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy:  Yes



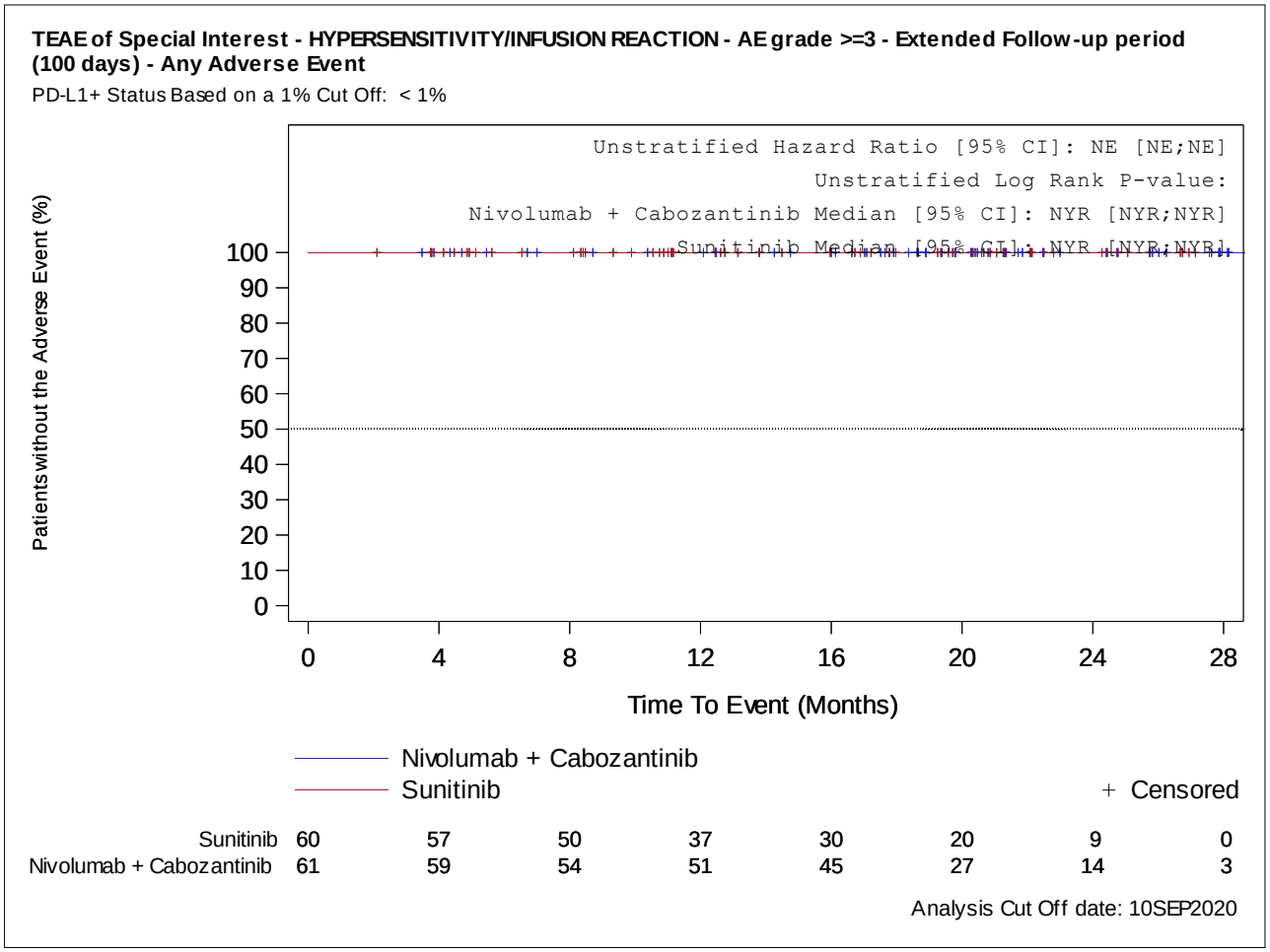

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:01:50

FIGURE 3.38.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



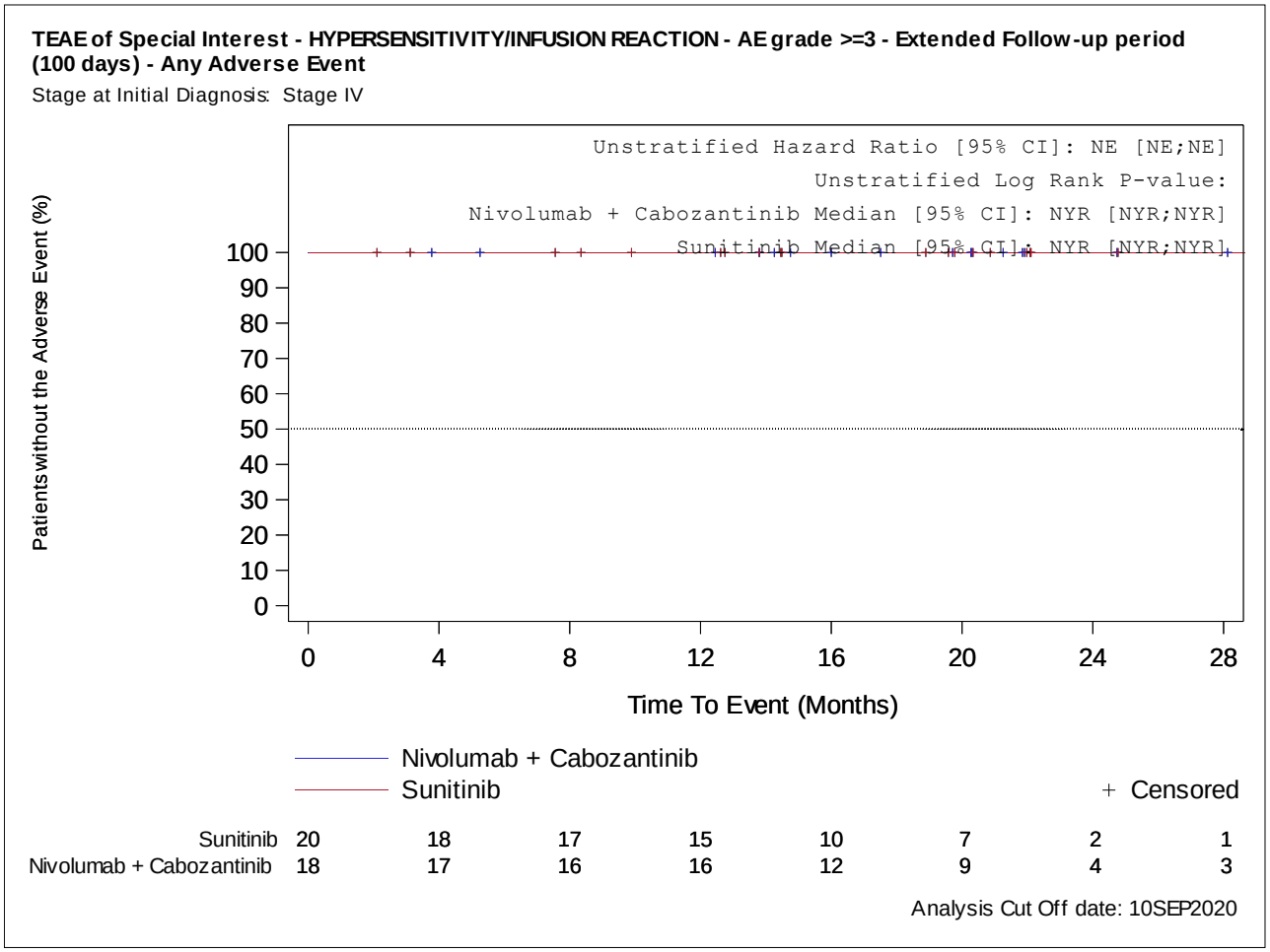

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:01:57

FIGURE 3.38.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



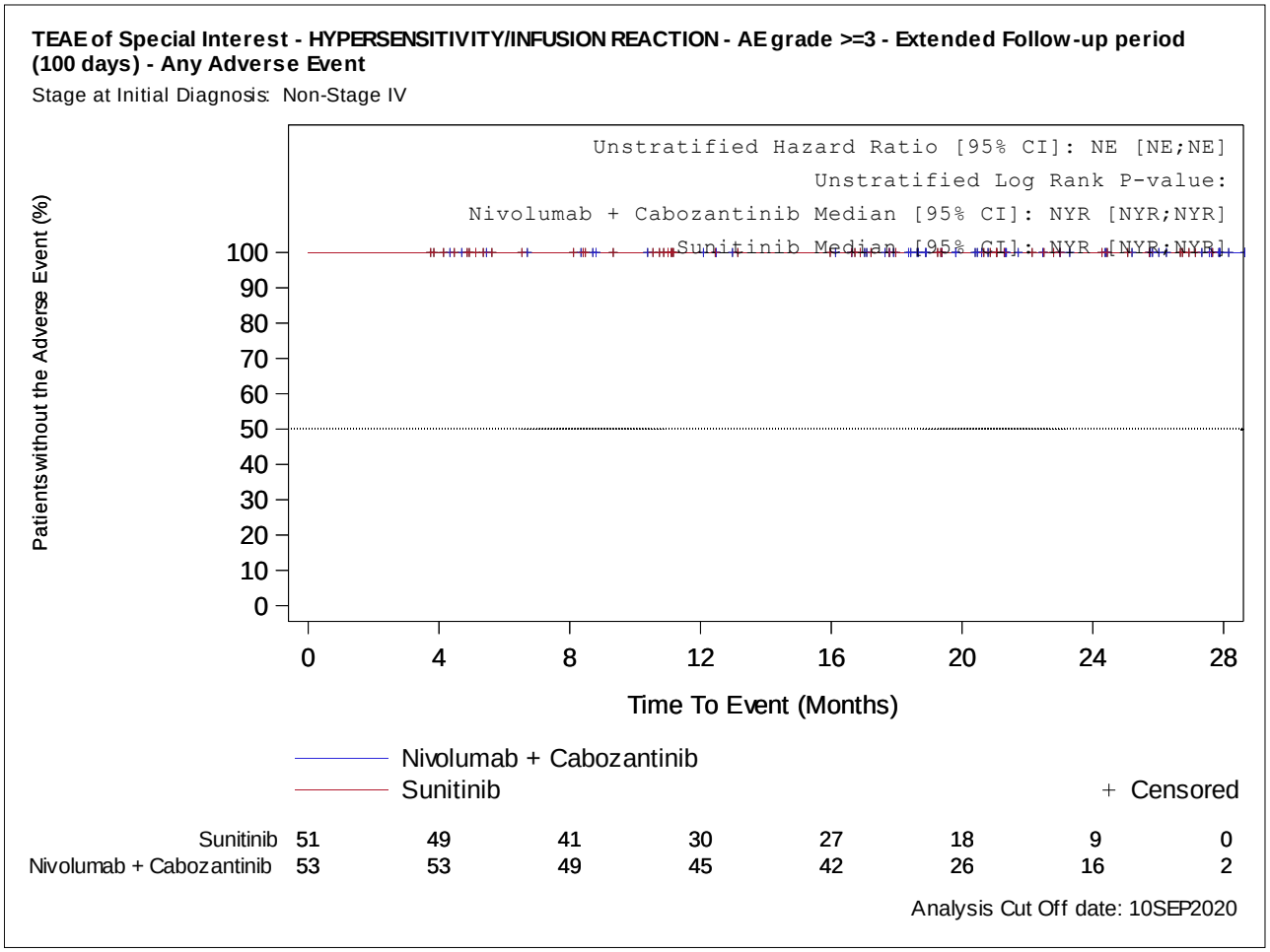

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:02:02

FIGURE 3.38.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



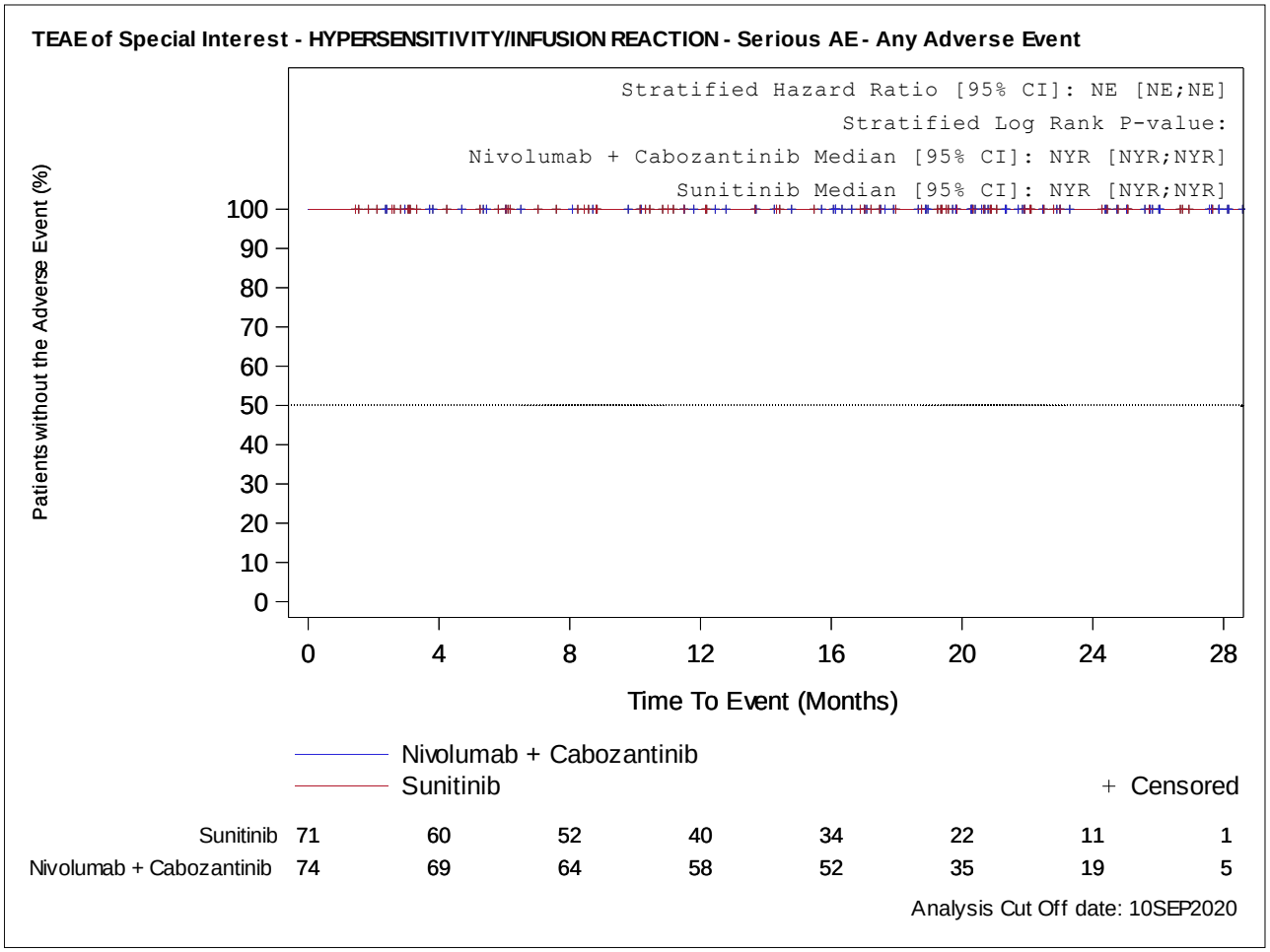

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:02:29

FIGURE 3.38.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



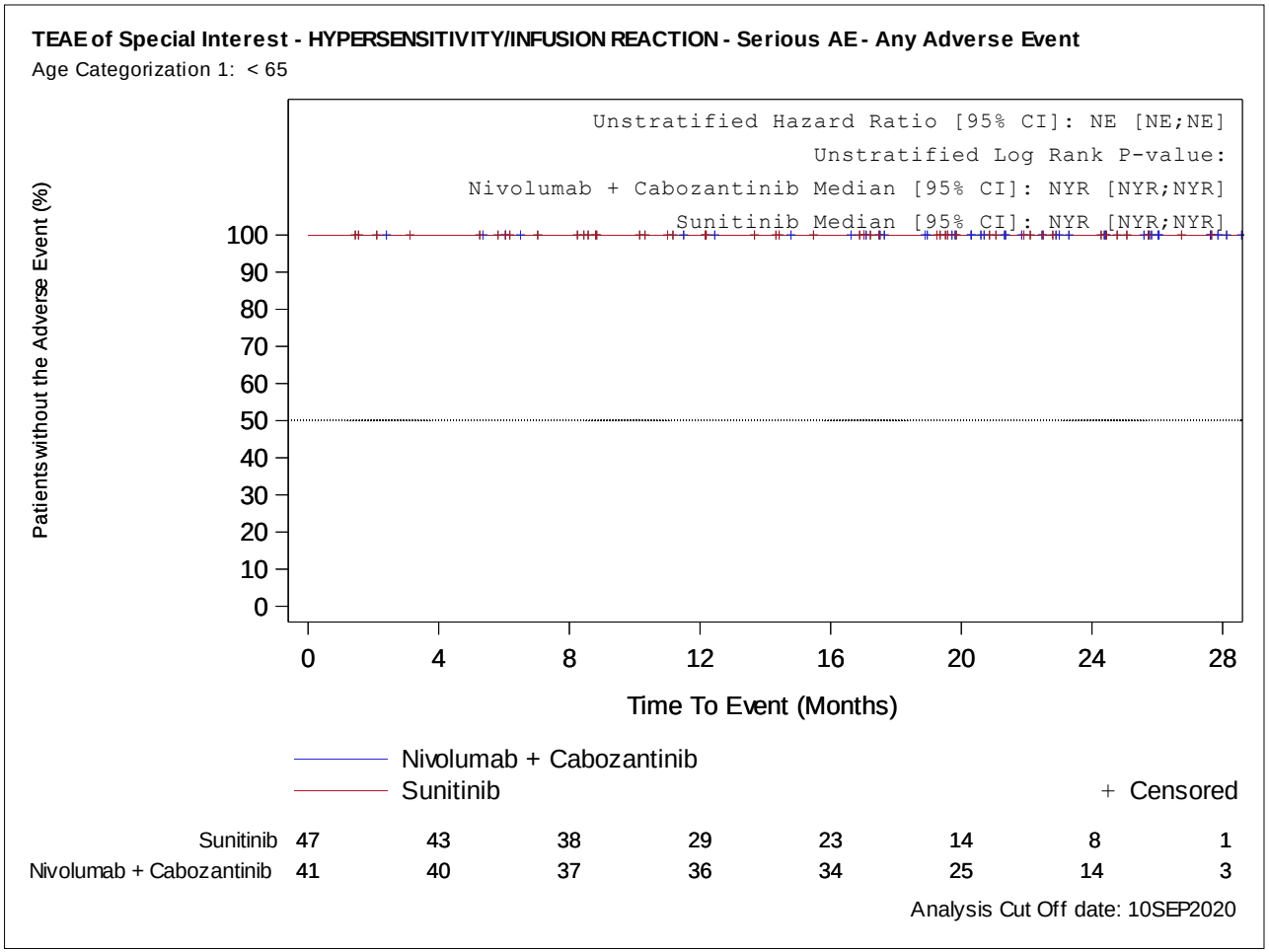

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:02:34

FIGURE 3.39.1: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



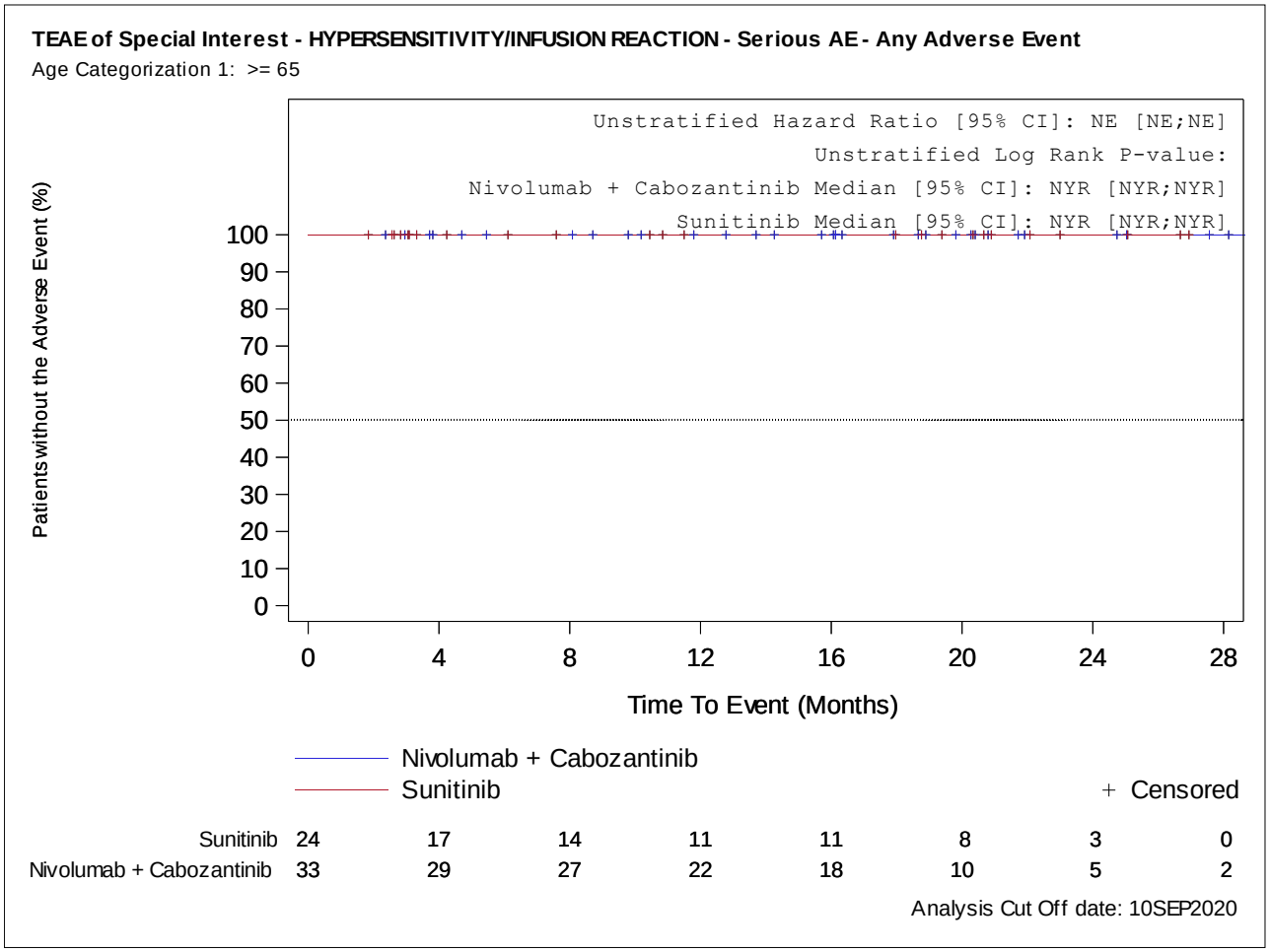

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:05:33

FIGURE 3.39.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



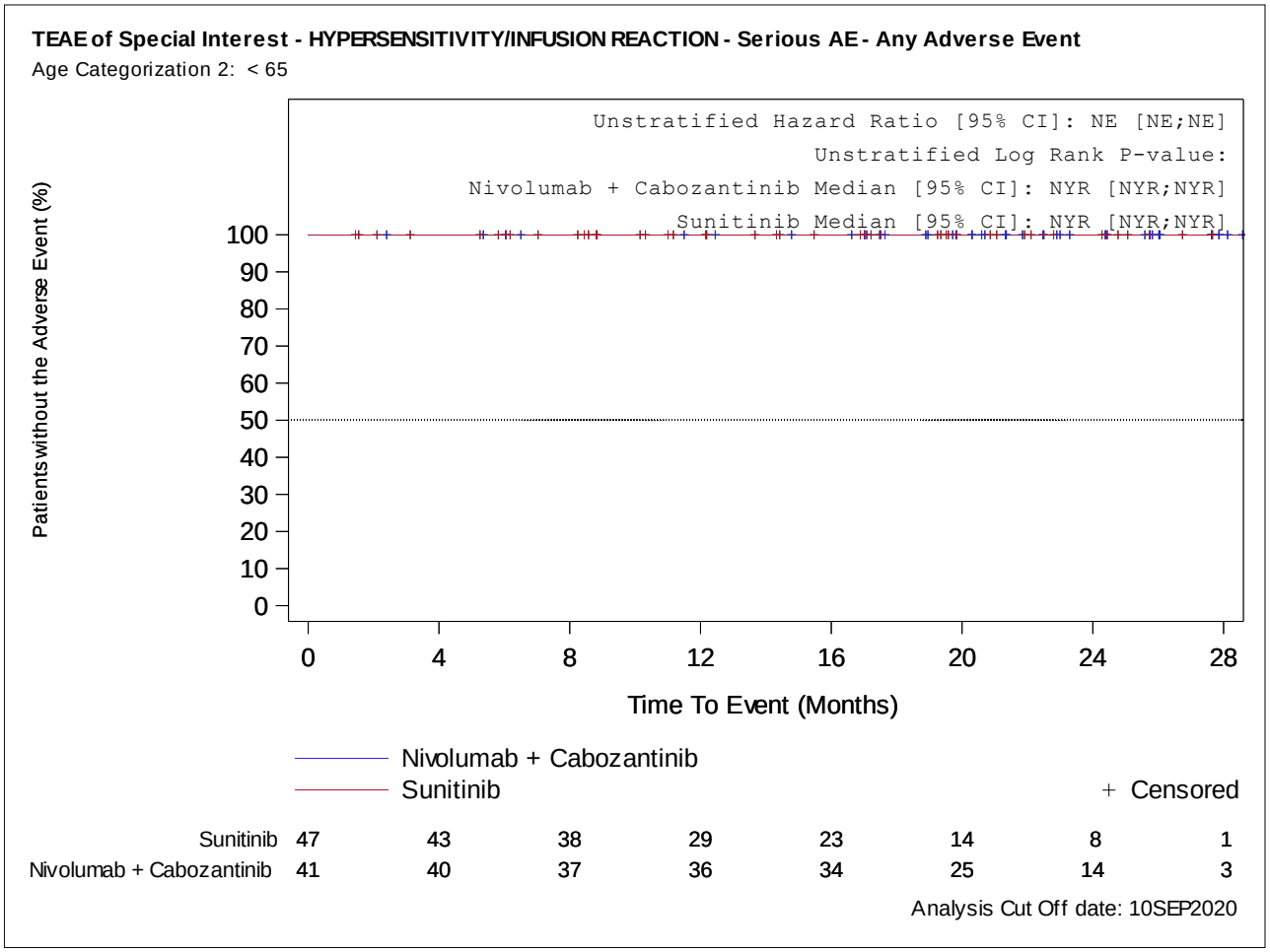

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:05:36

FIGURE 3.39.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:05:41

FIGURE 3.39.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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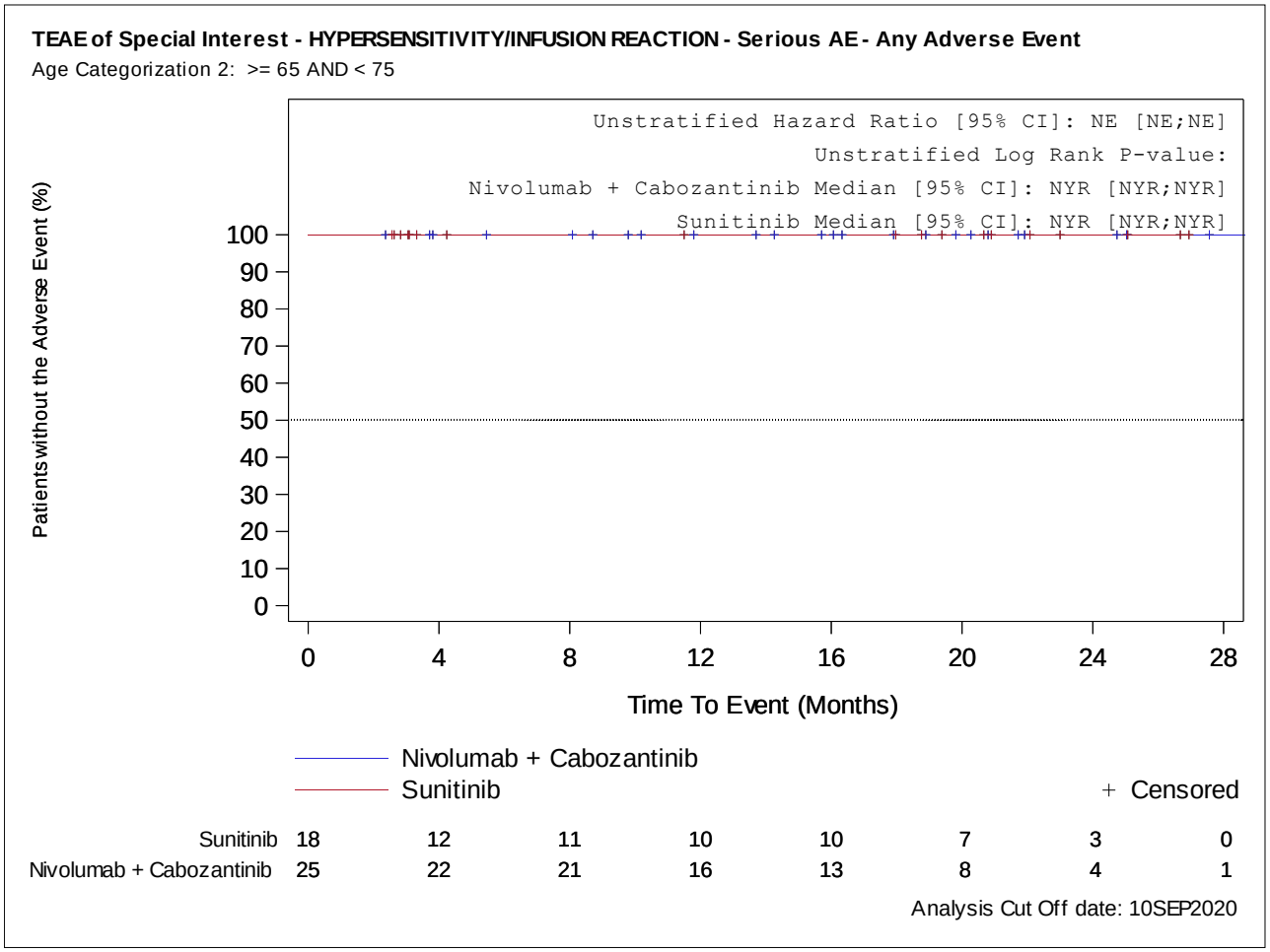
FIGURE 3.39.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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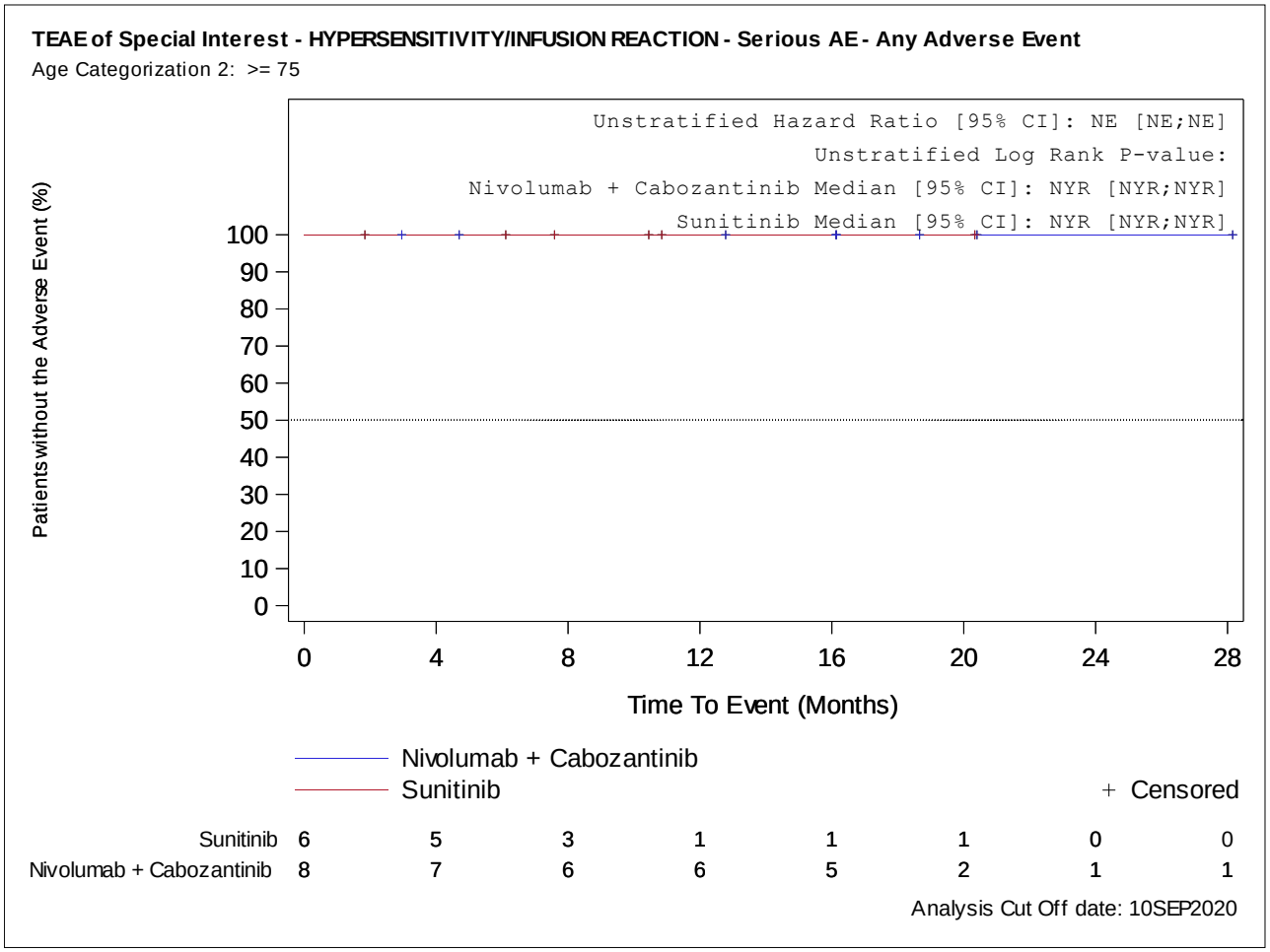
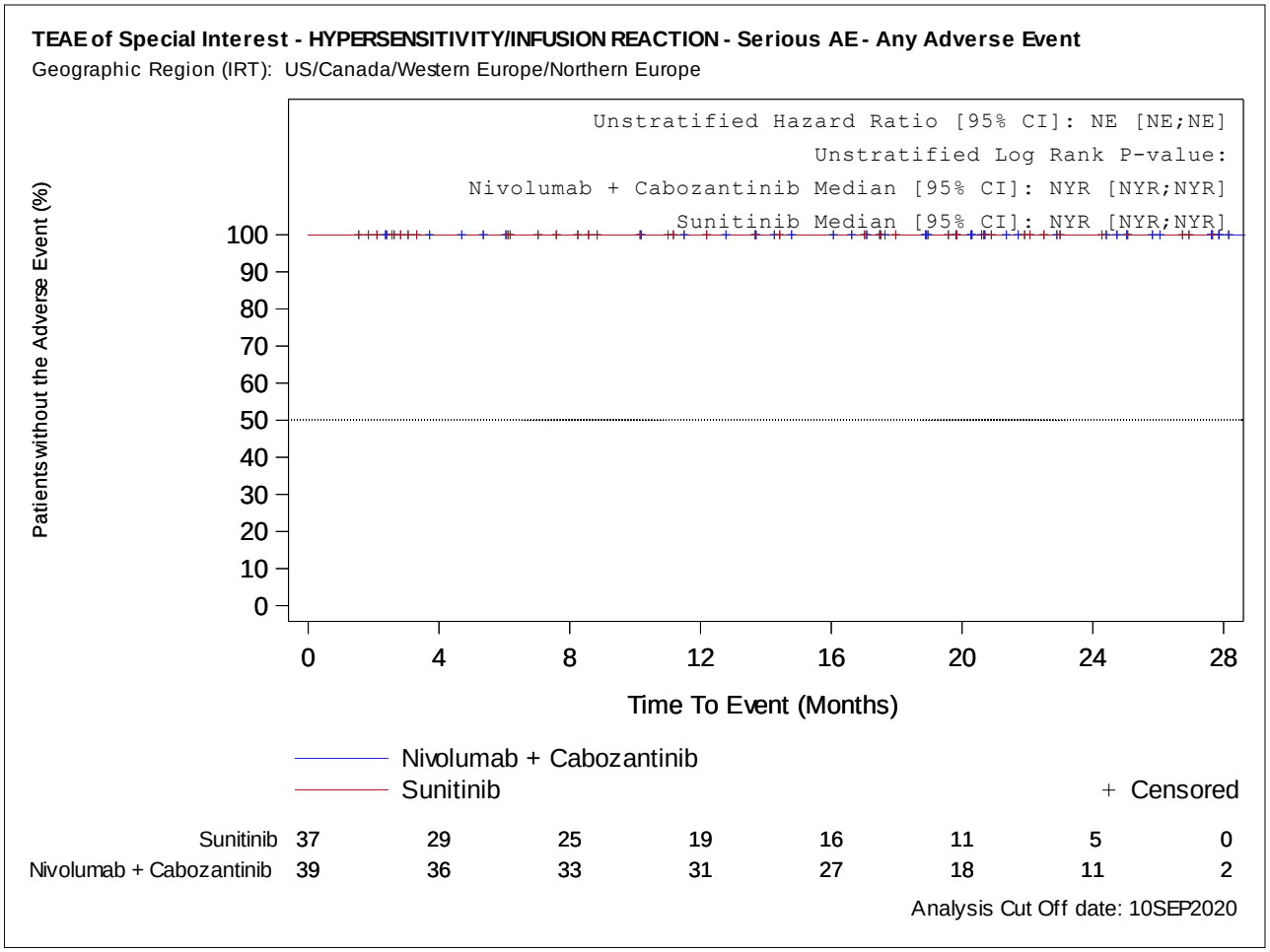
FIGURE 3.39.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



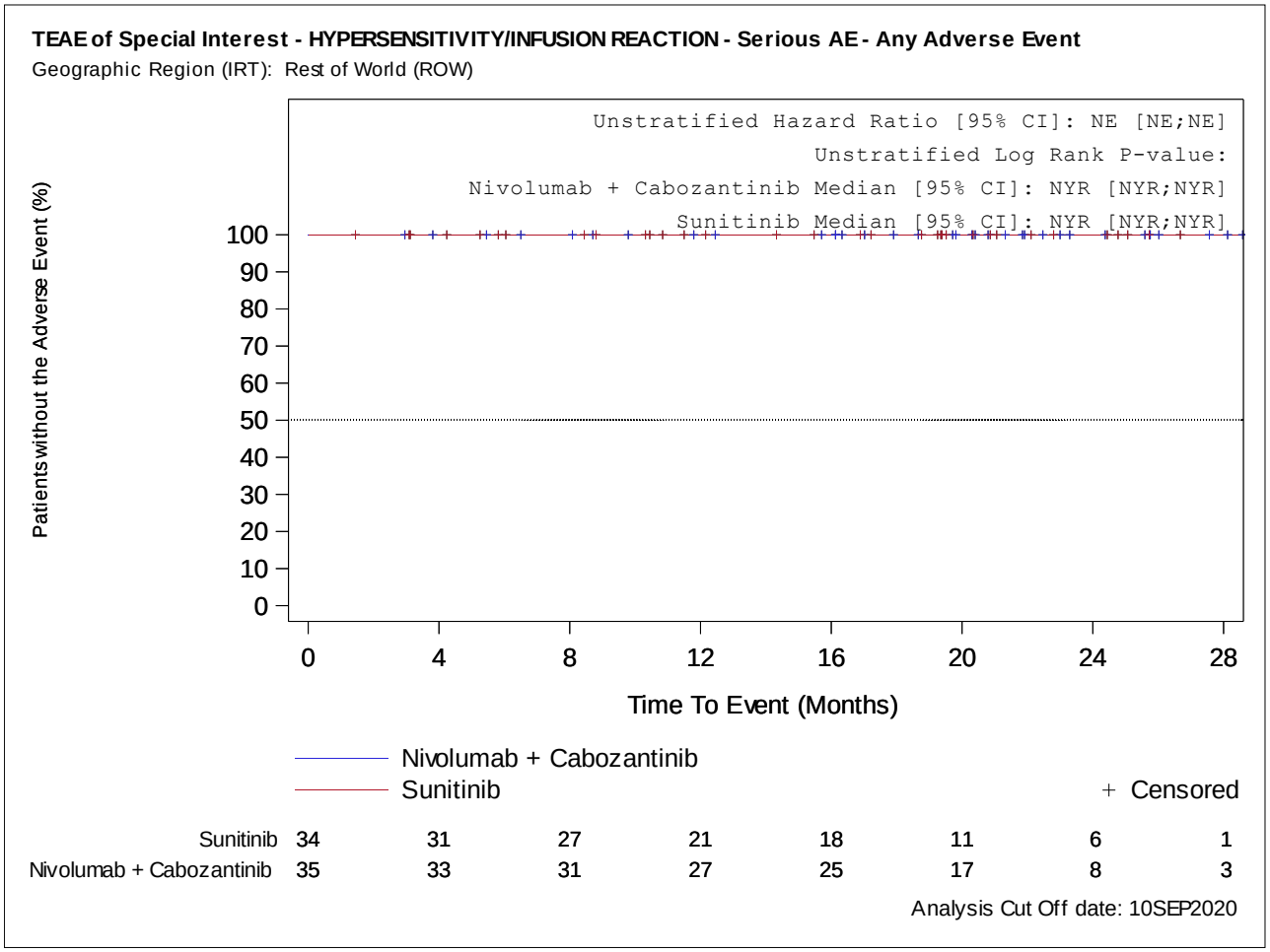

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:05:56

FIGURE 3.39.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



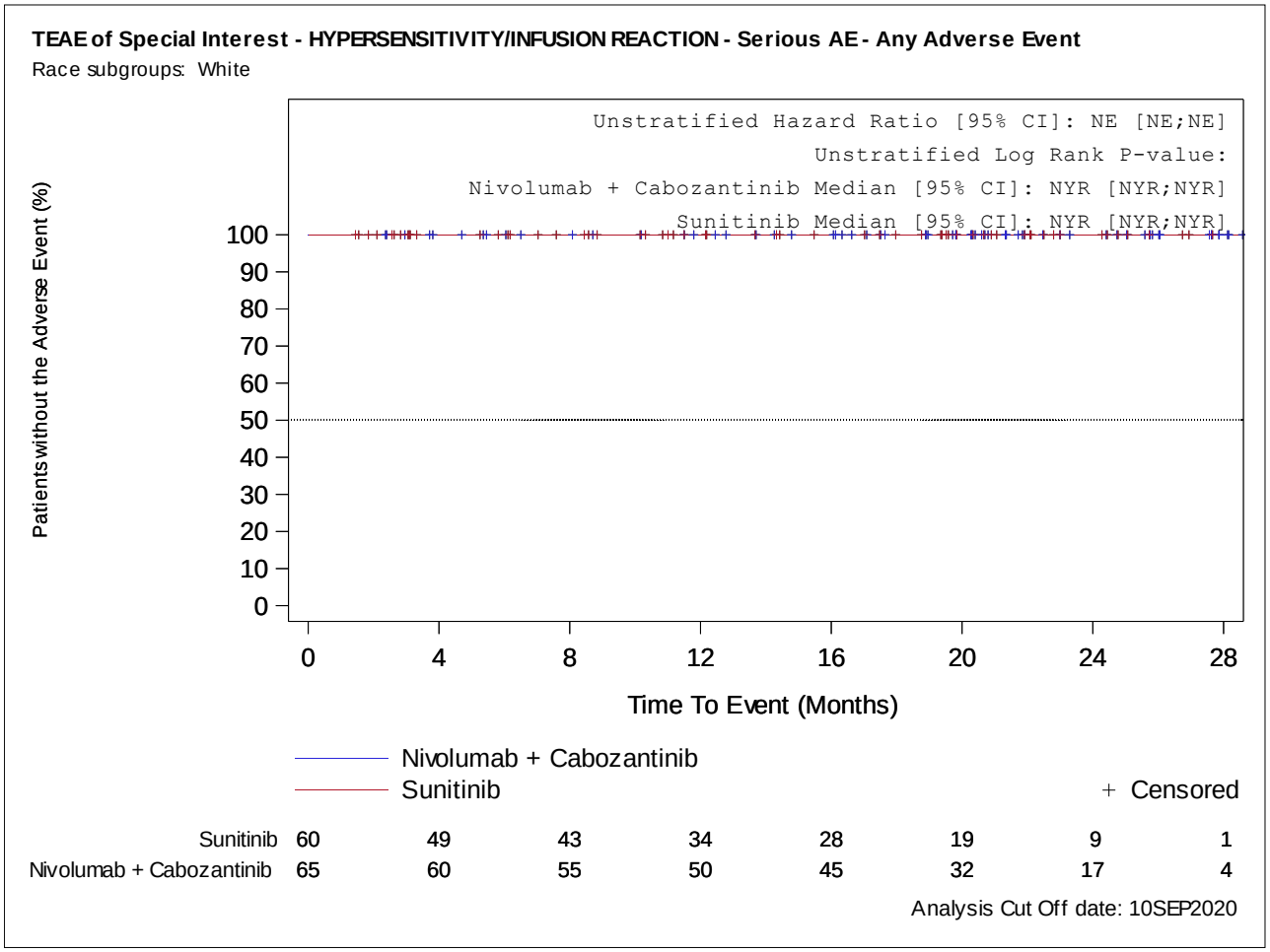

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:06:01

FIGURE 3.39.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



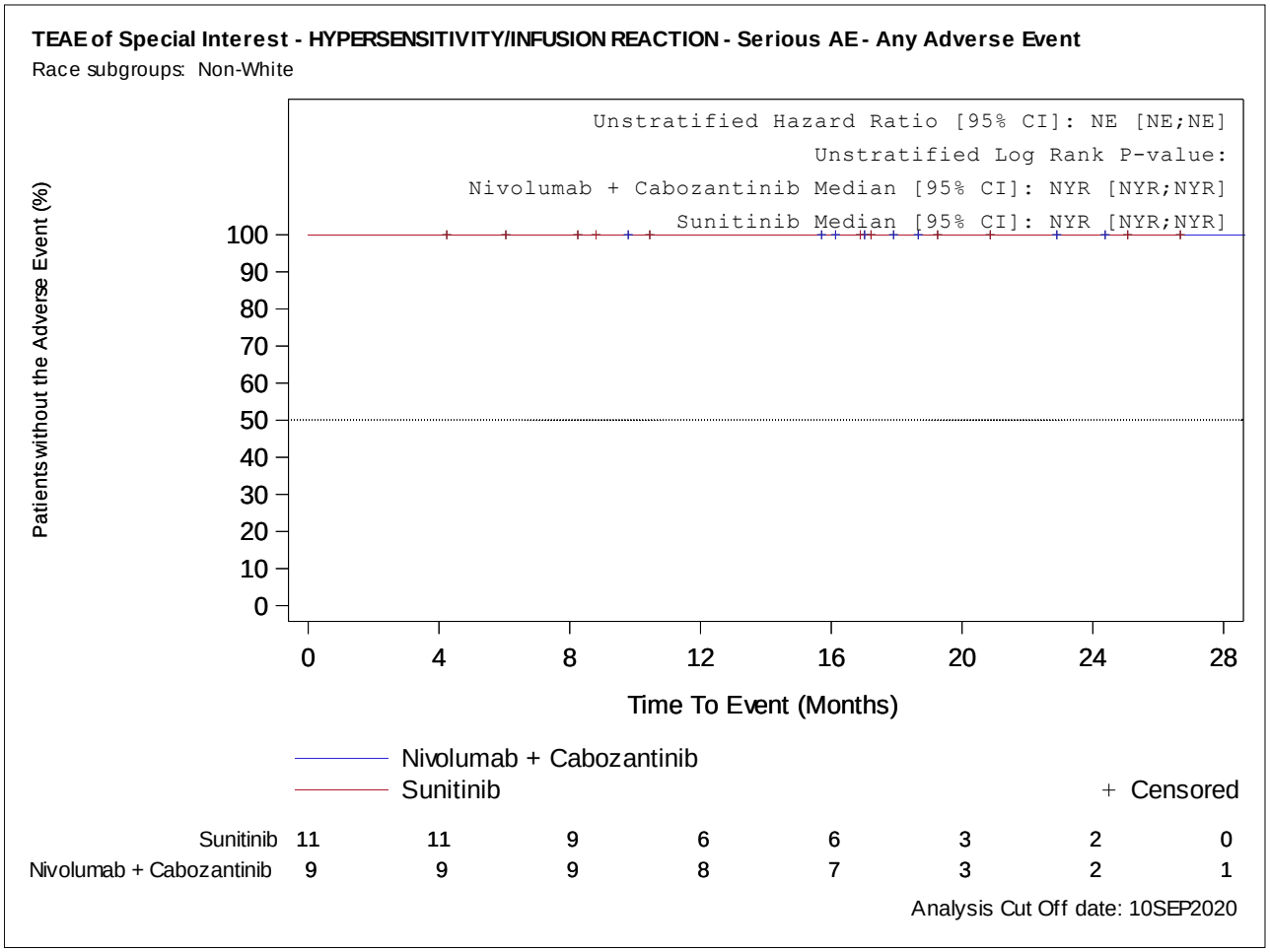

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:06:06

FIGURE 3.39.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



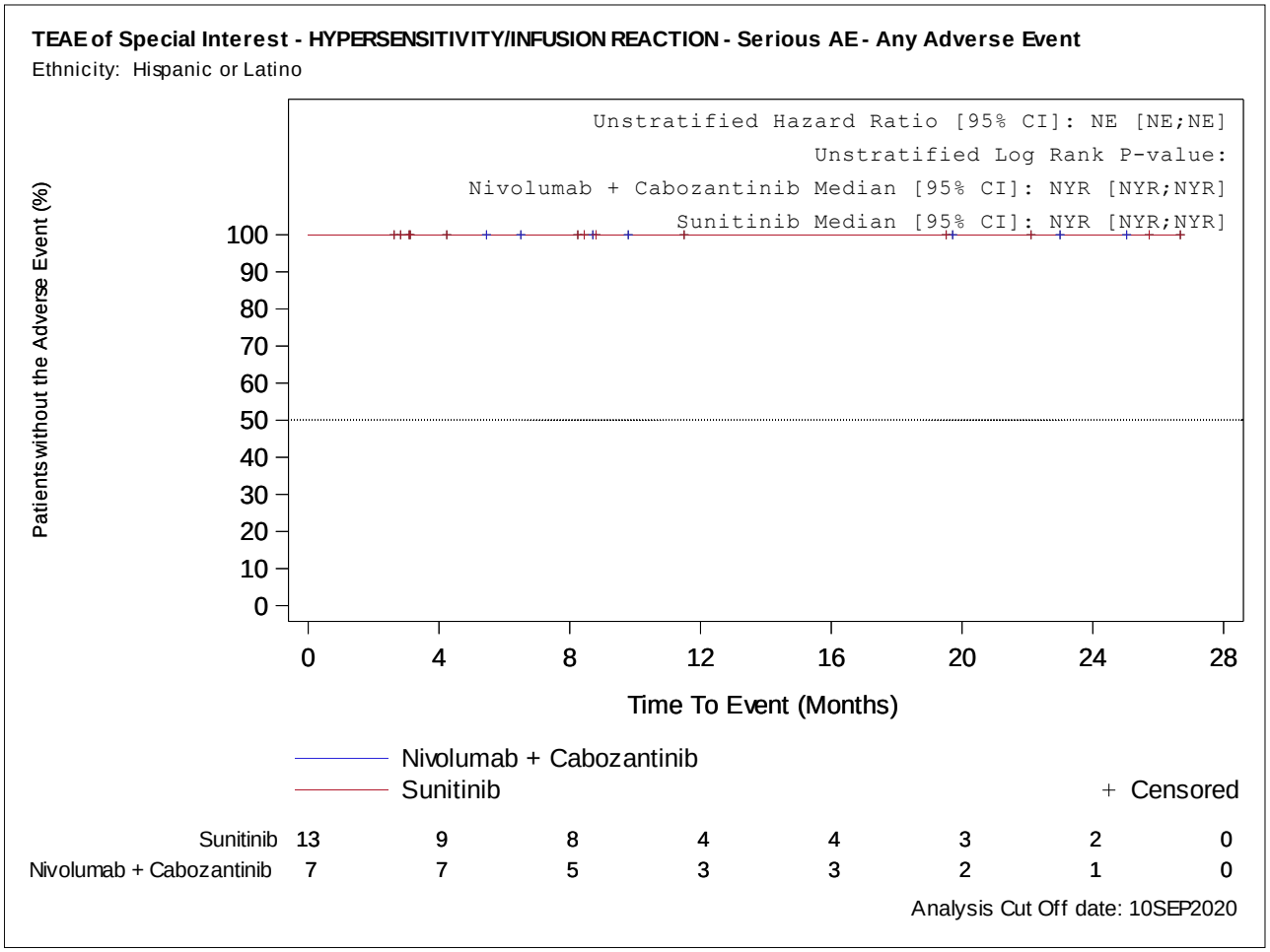

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:06:12

FIGURE 3.39.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



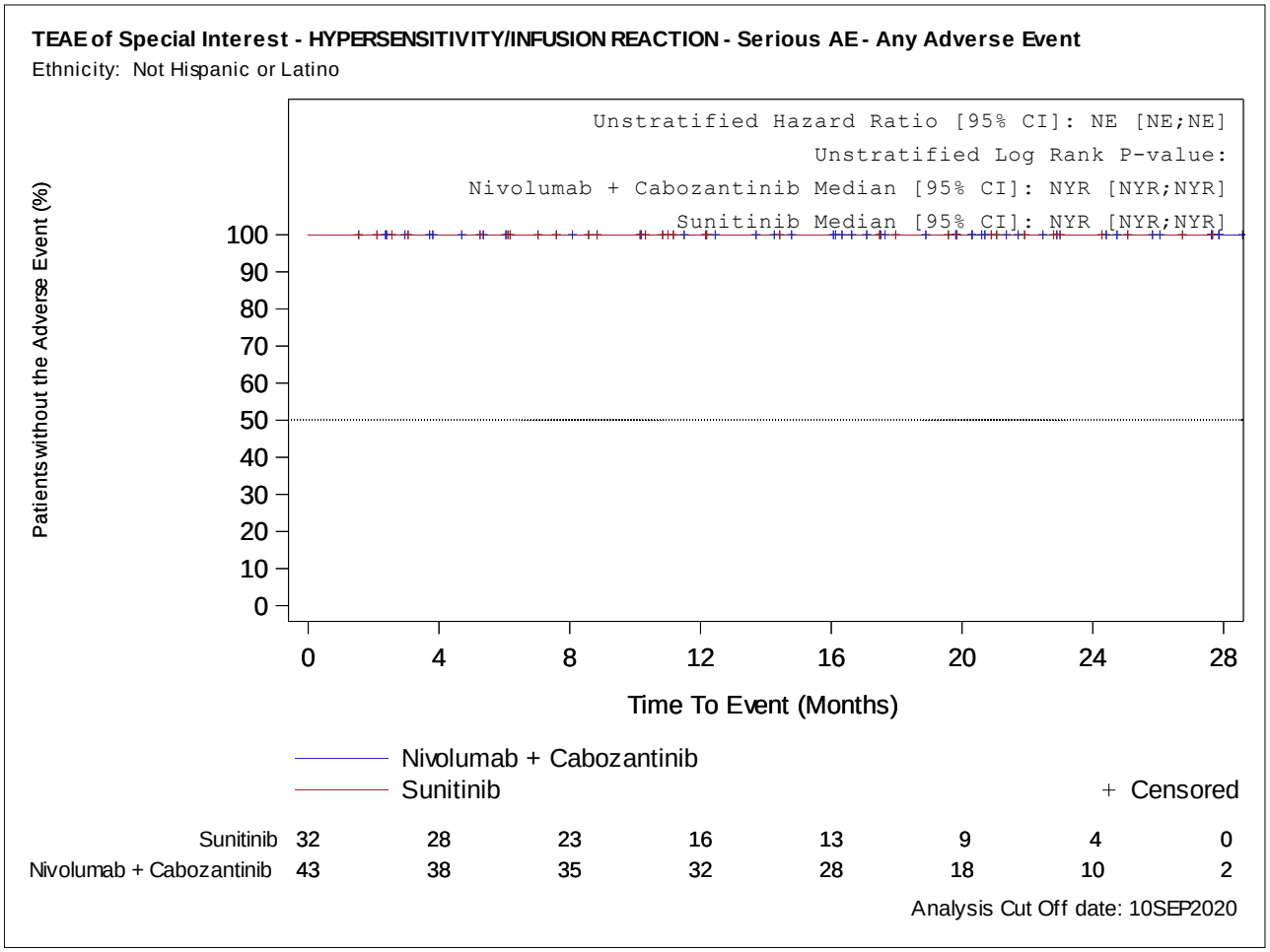

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:06:17

FIGURE 3.39.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



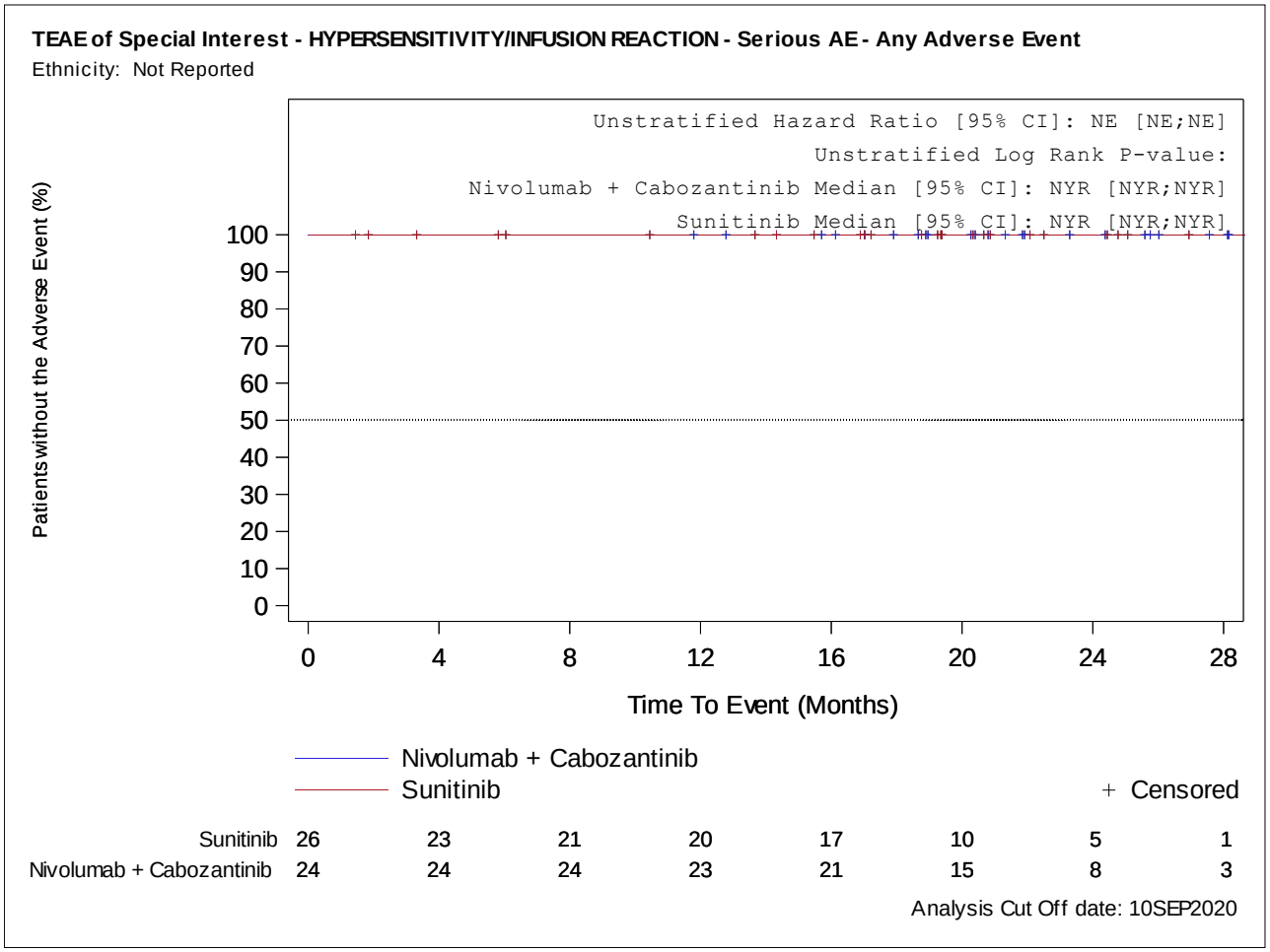

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:06:22

FIGURE 3.39.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



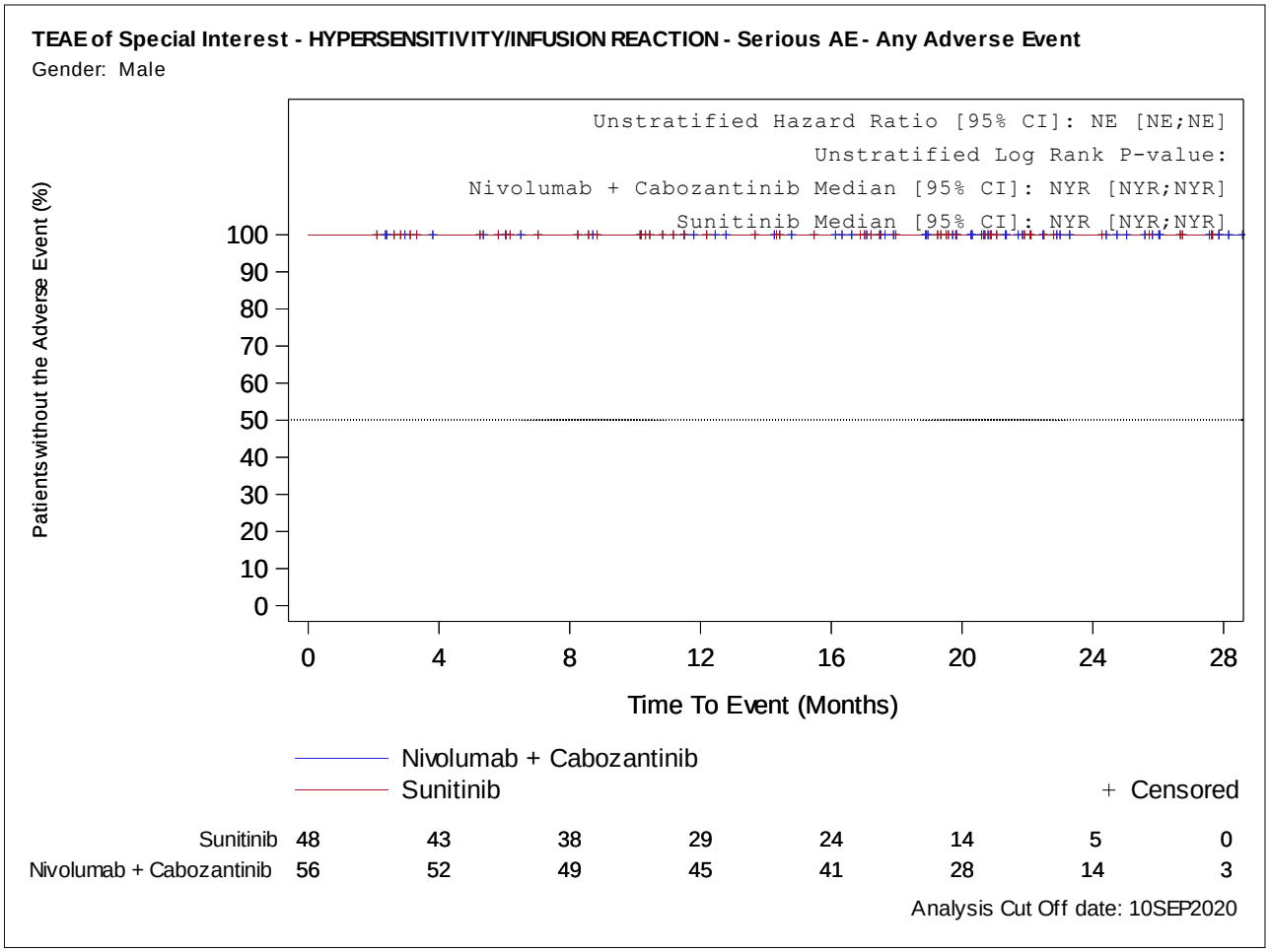

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:06:27

FIGURE 3.39.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:06:32

FIGURE 3.39.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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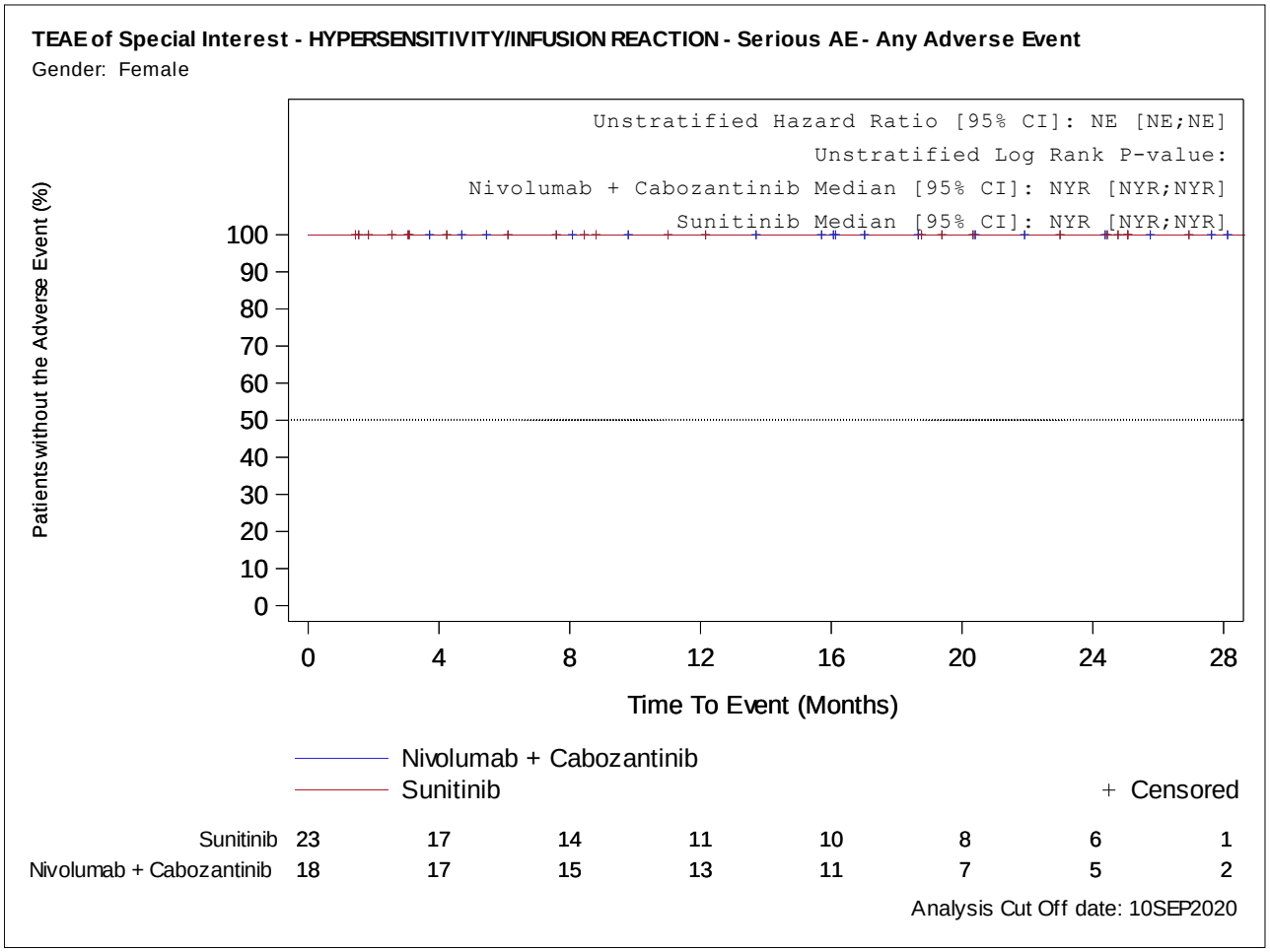
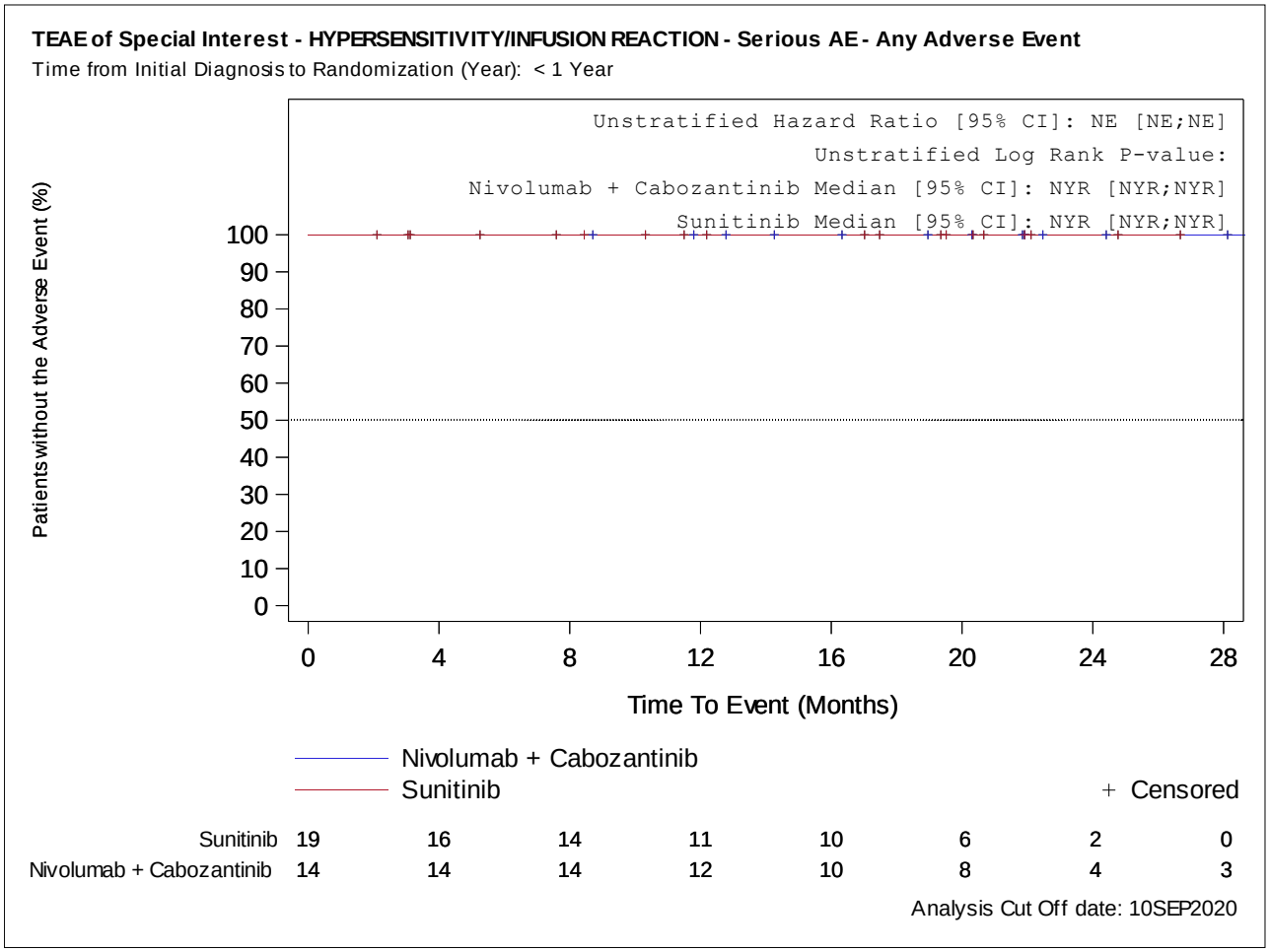
FIGURE 3.39.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



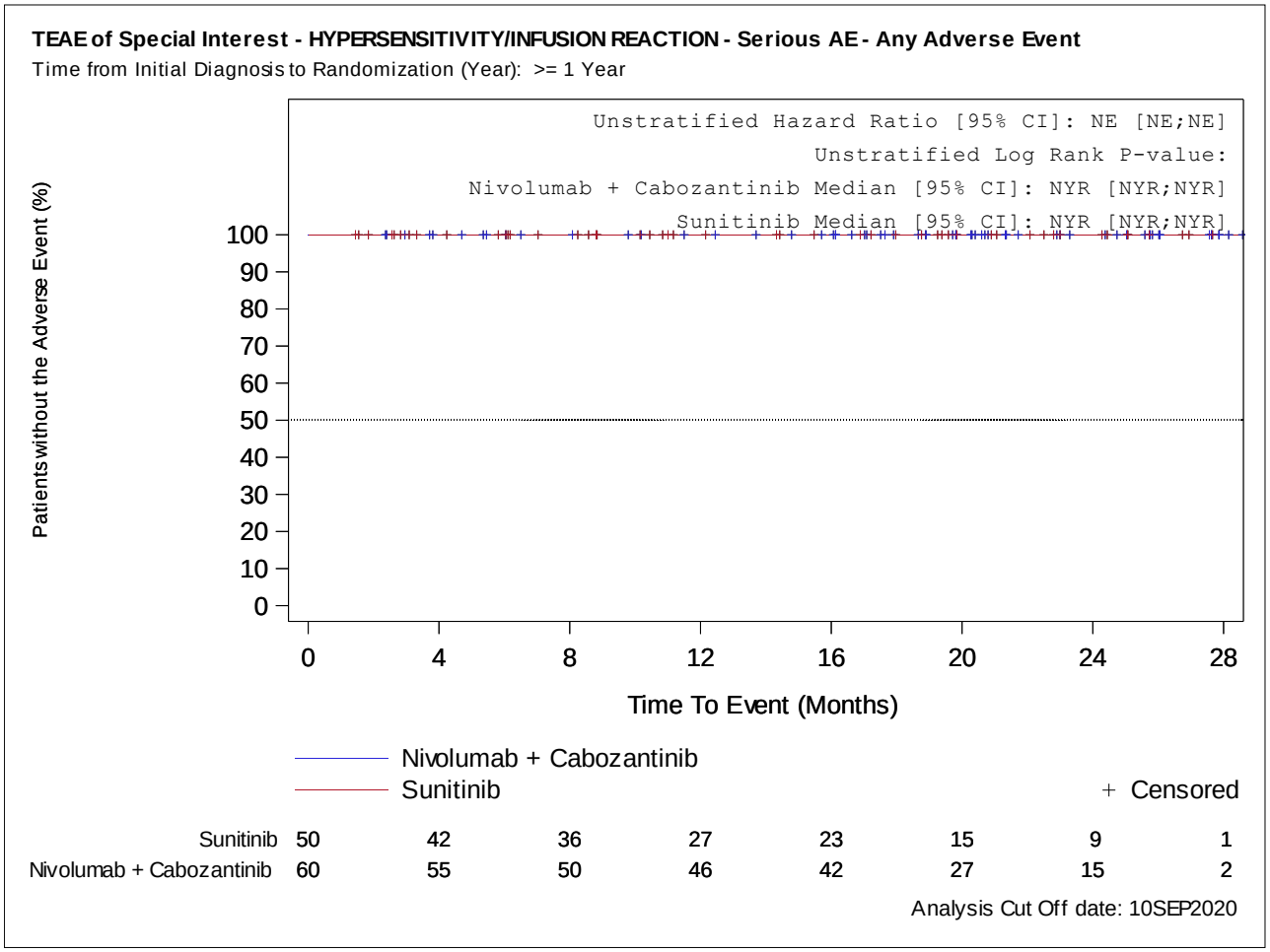

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:06:42

FIGURE 3.39.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



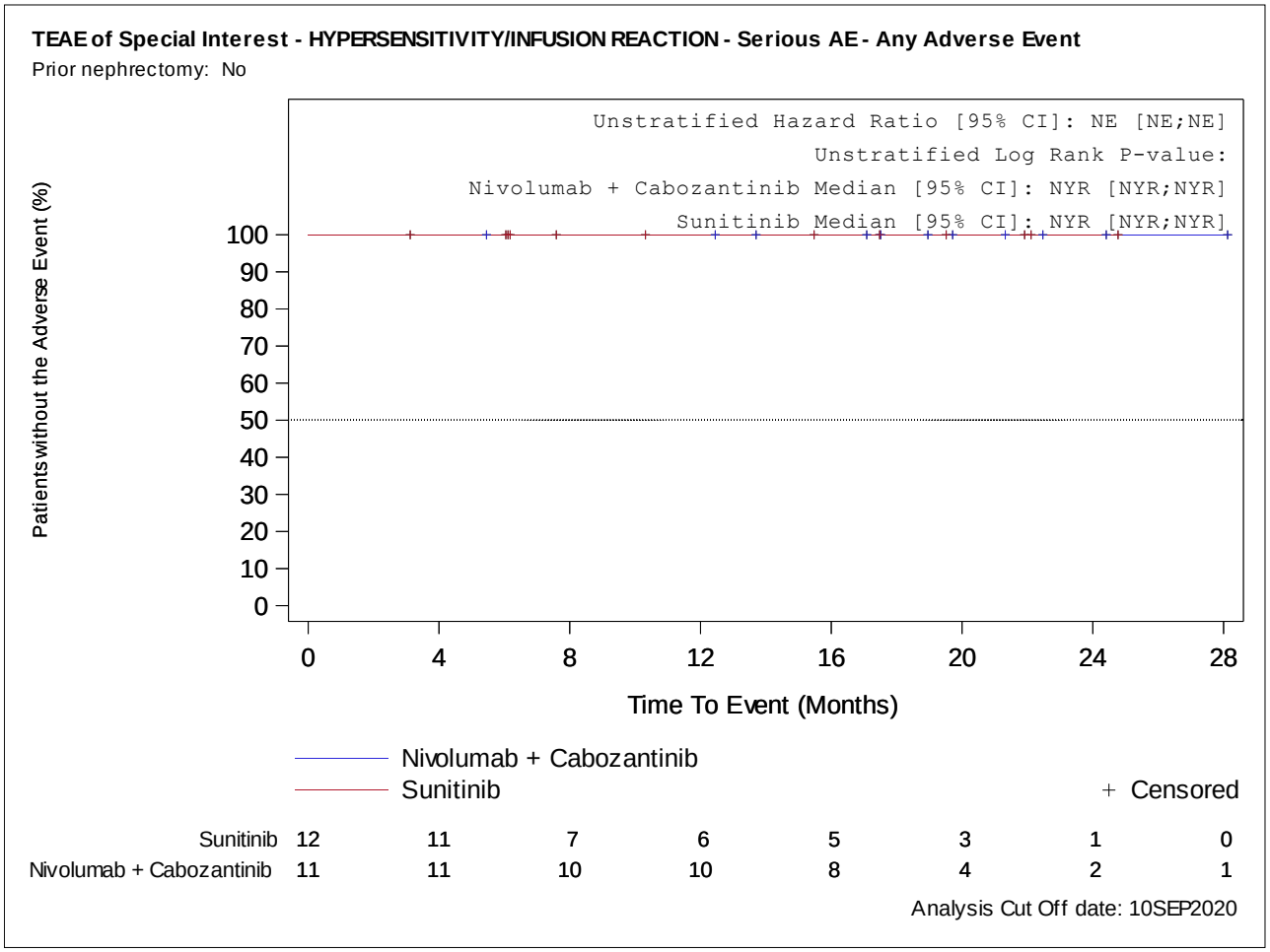

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:06:58

FIGURE 3.39.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



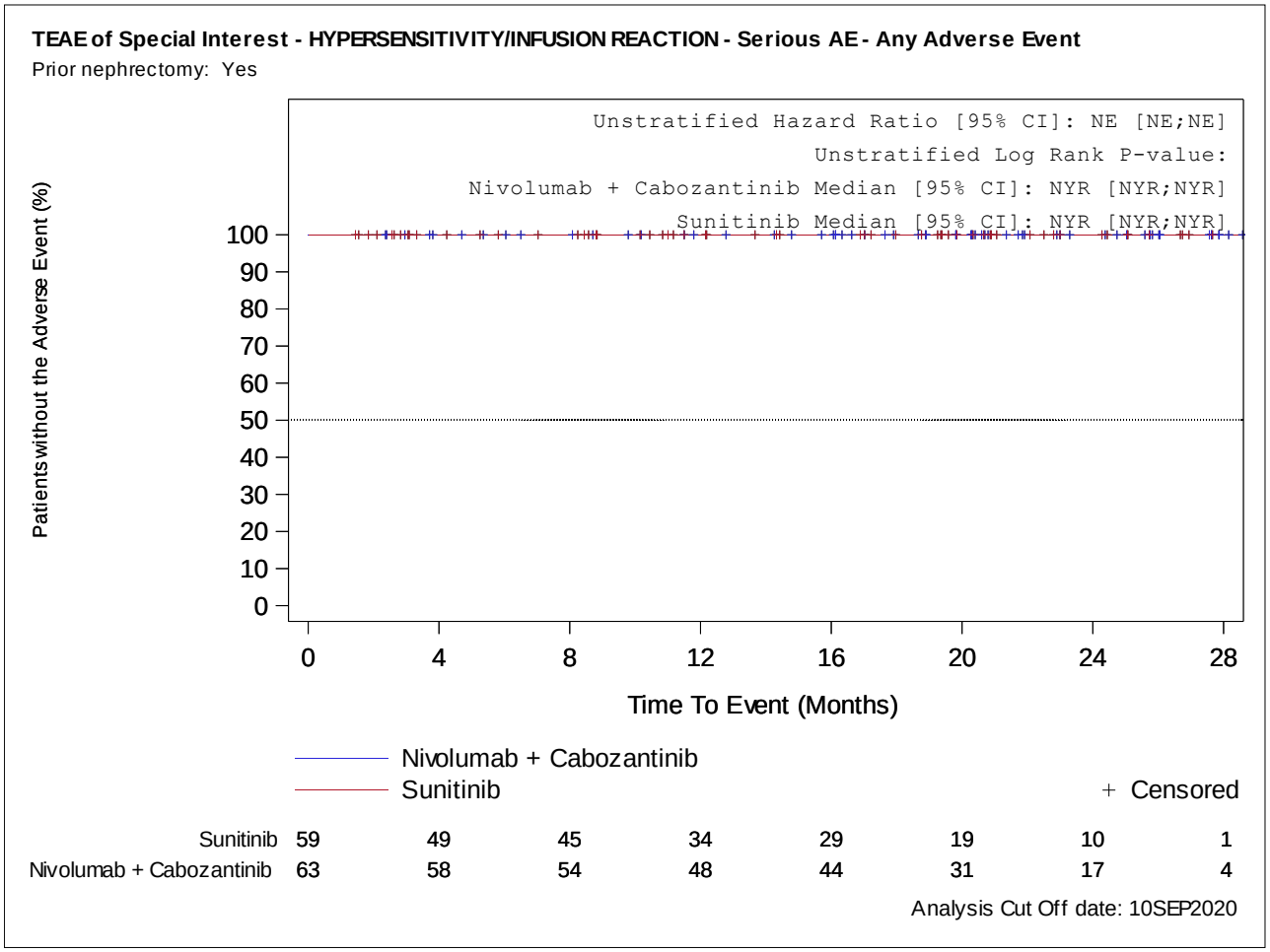

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:07:03

FIGURE 3.39.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



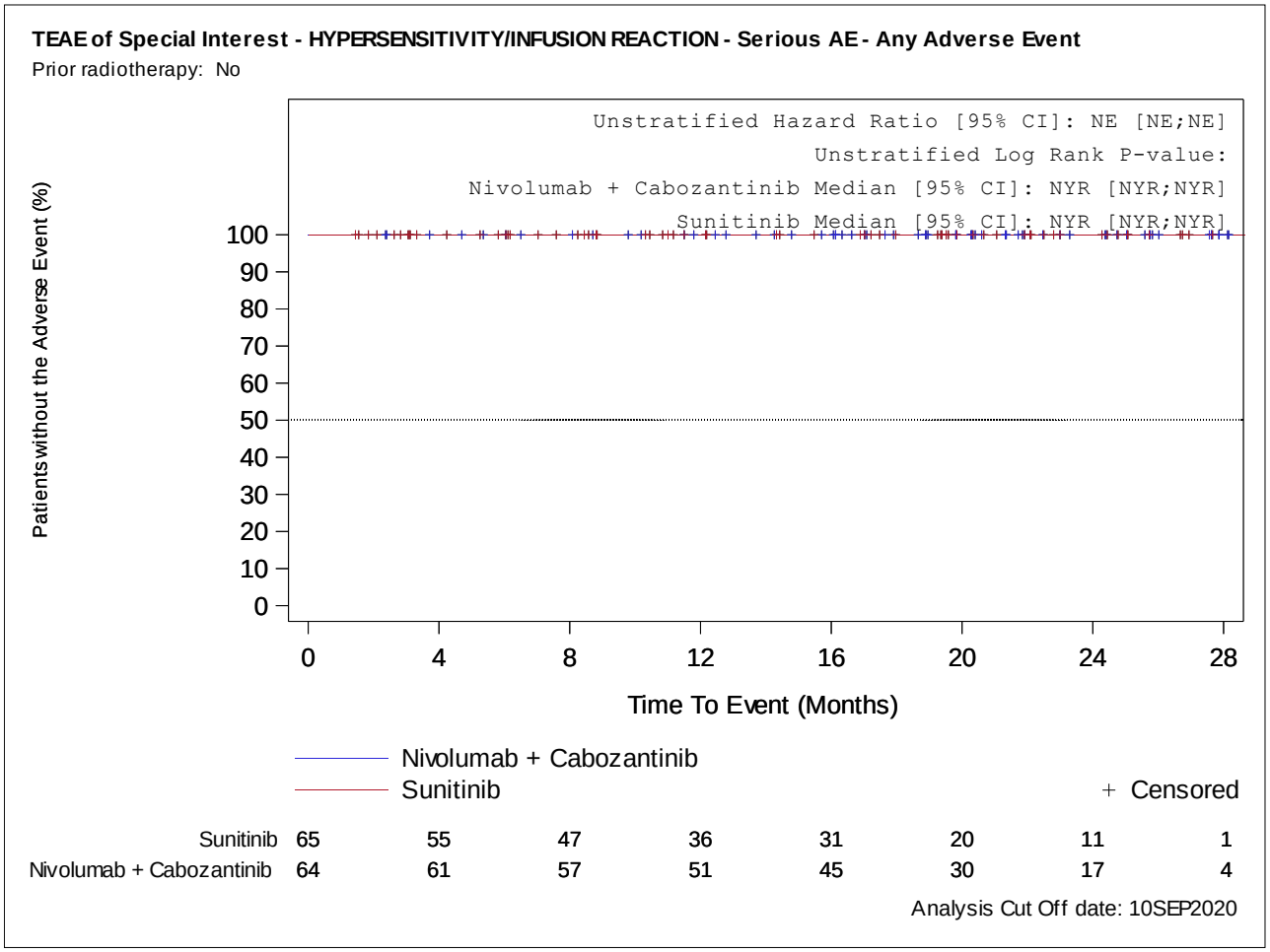

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:07:50

FIGURE 3.39.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



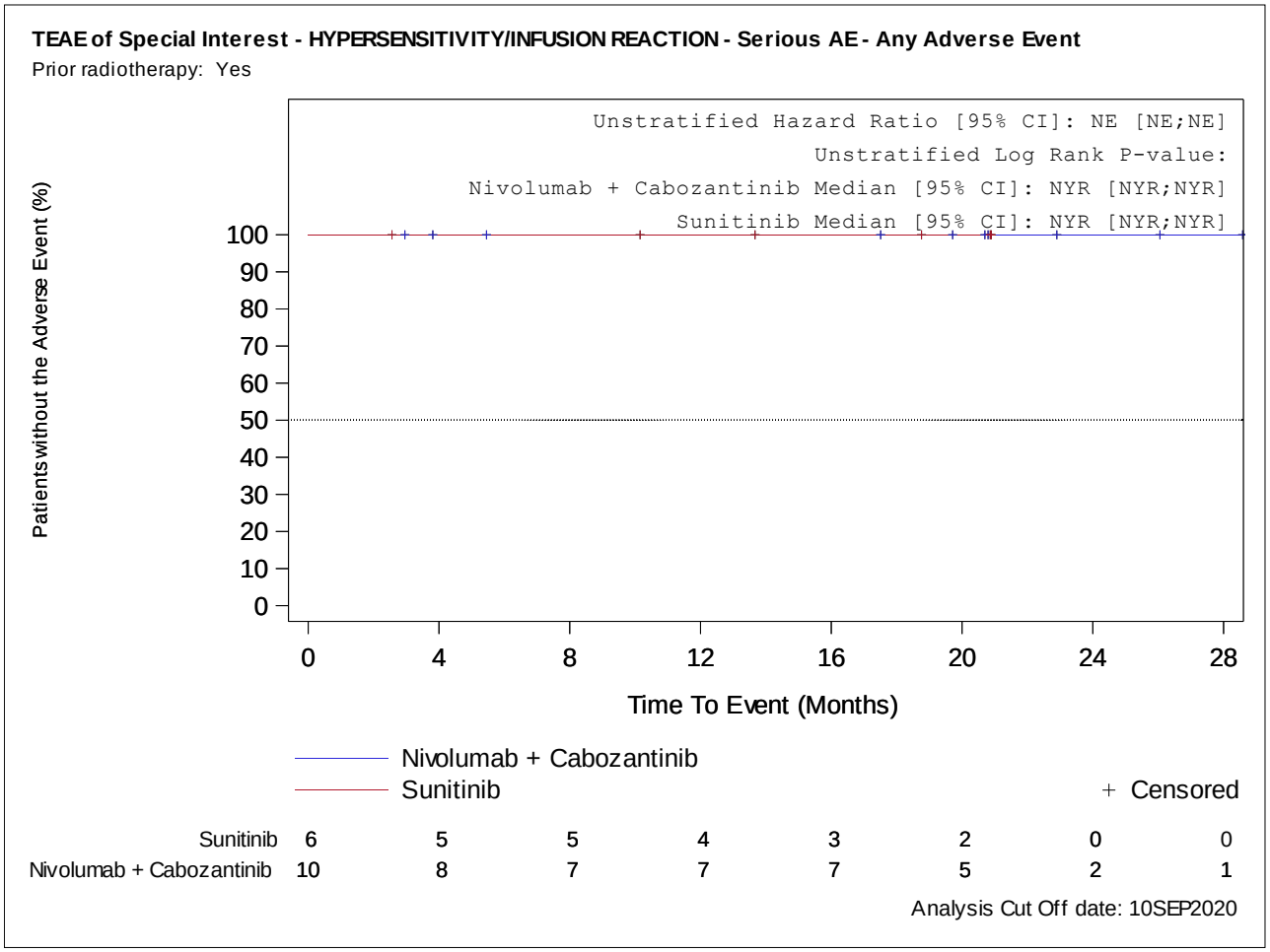

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:07:55

FIGURE 3.39.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



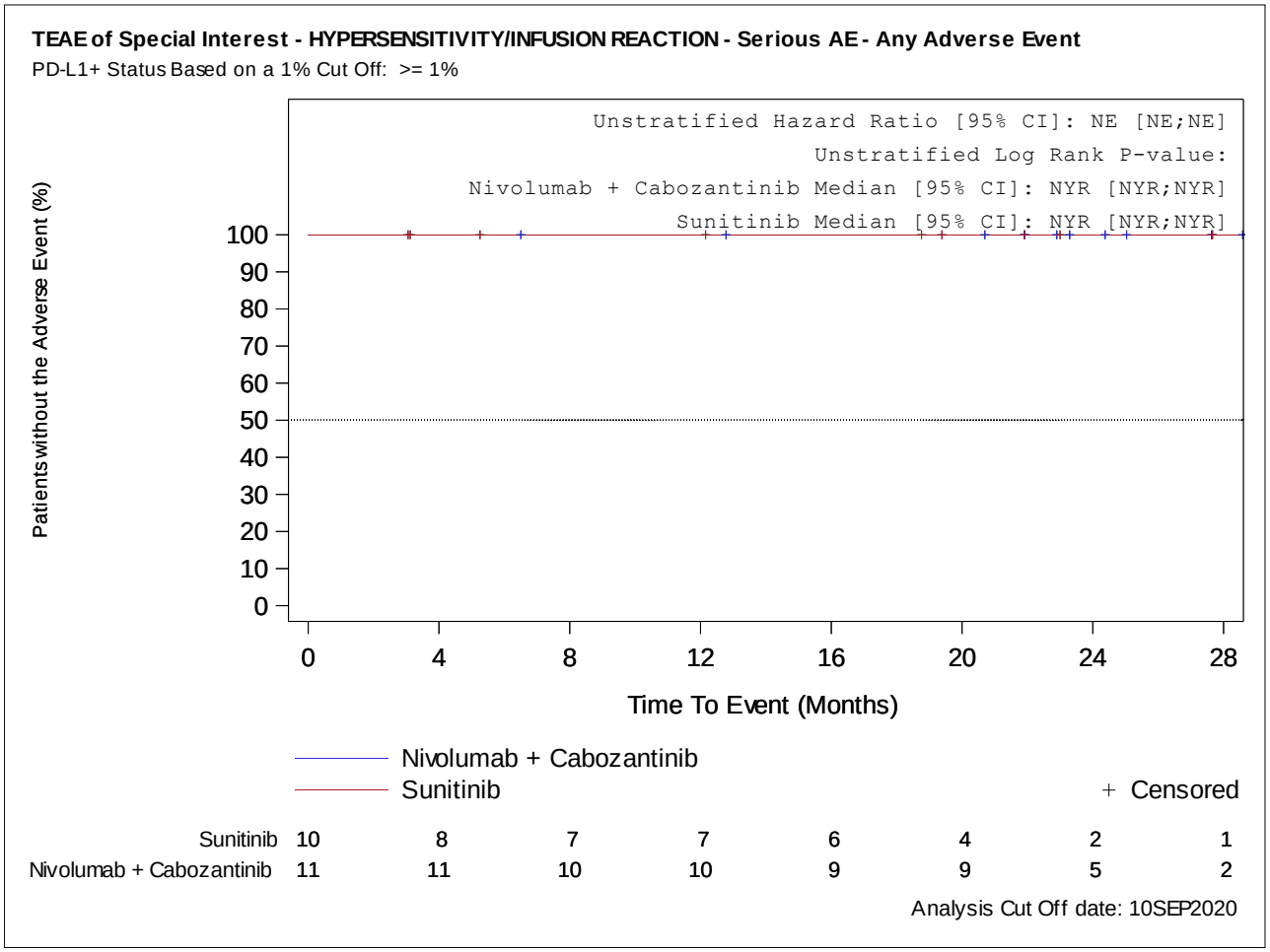

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:08:01

FIGURE 3.39.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



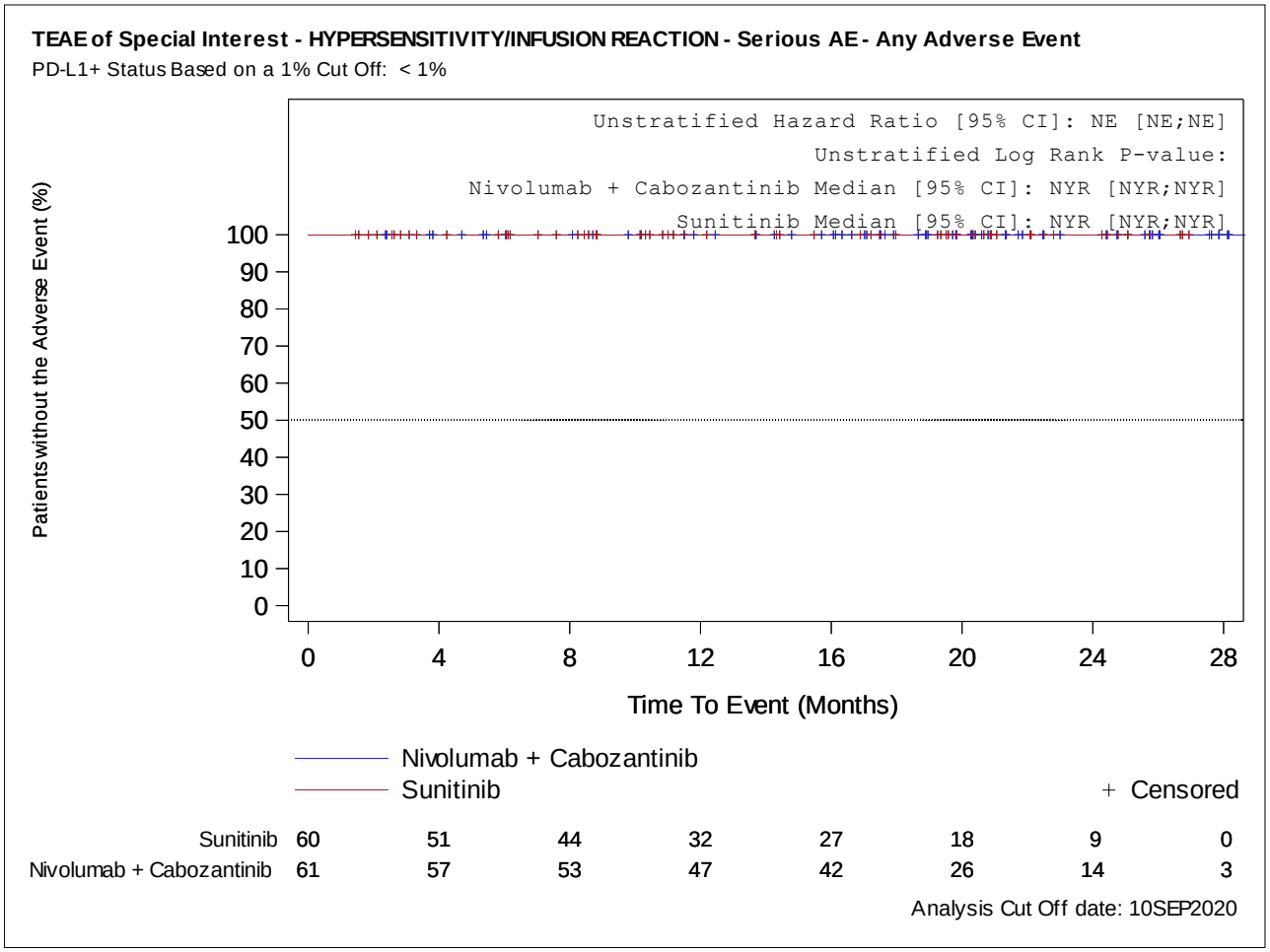

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:08:06

FIGURE 3.39.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



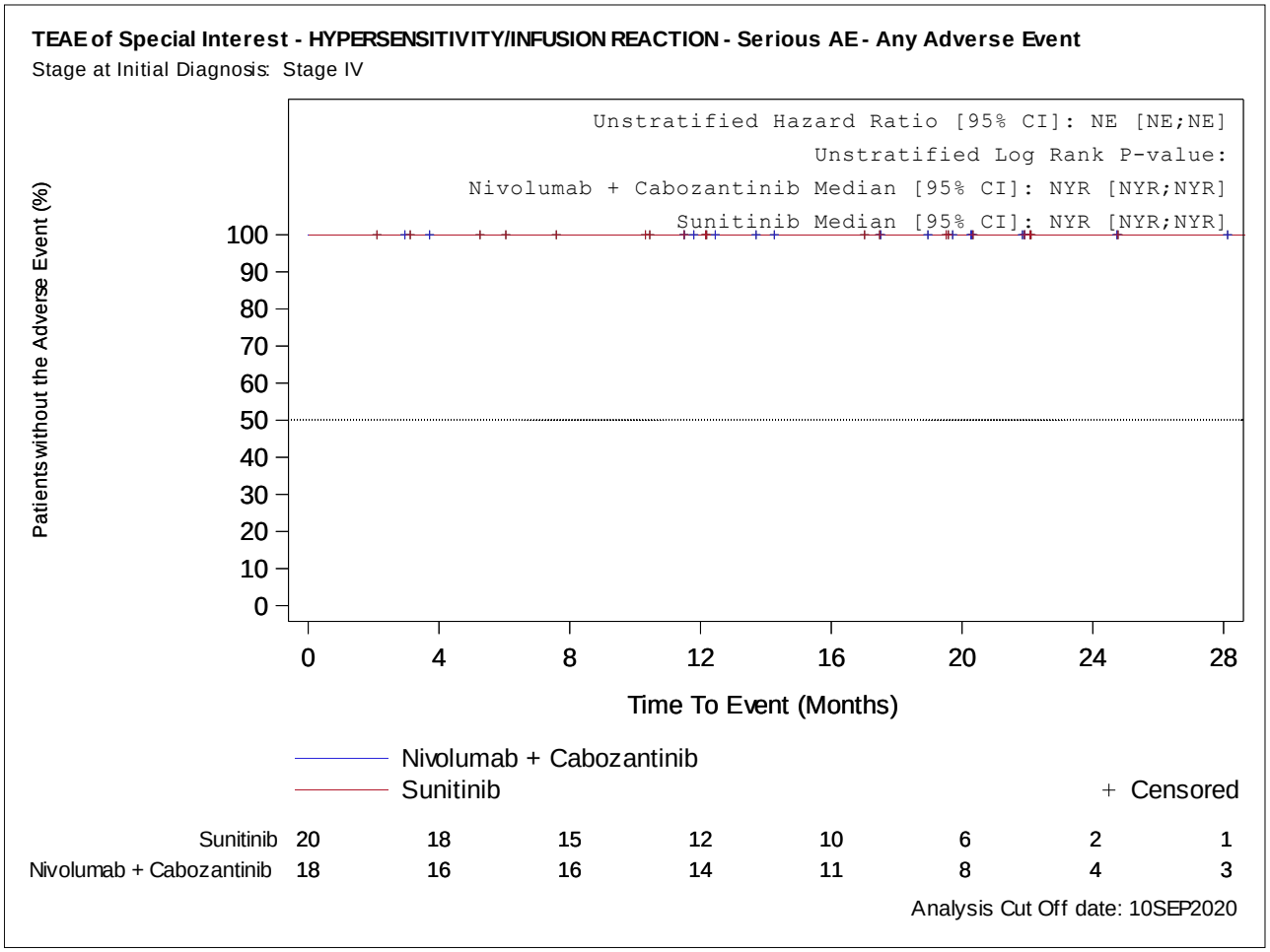

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:08:11

FIGURE 3.39.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



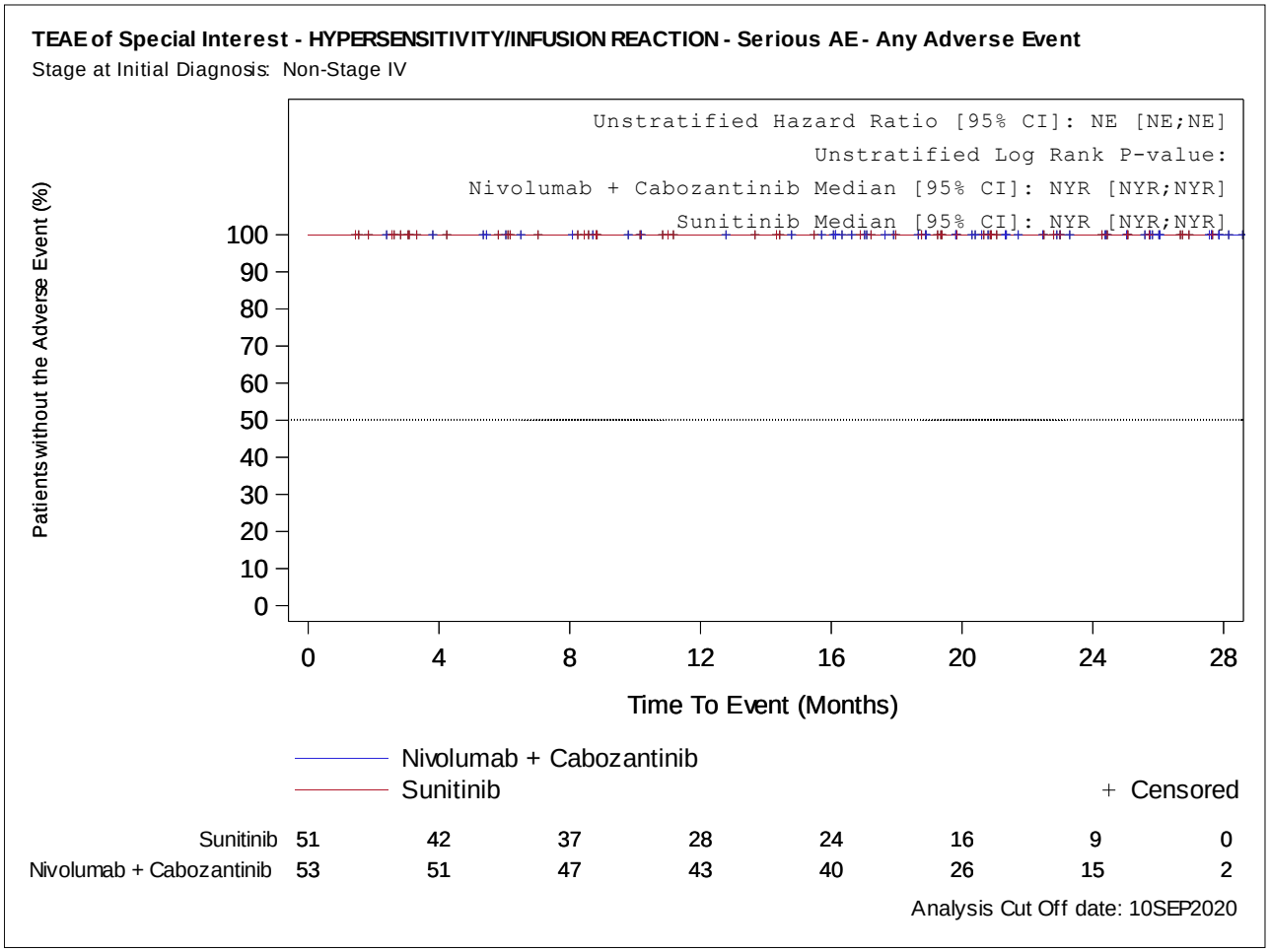

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:08:16

FIGURE 3.39.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



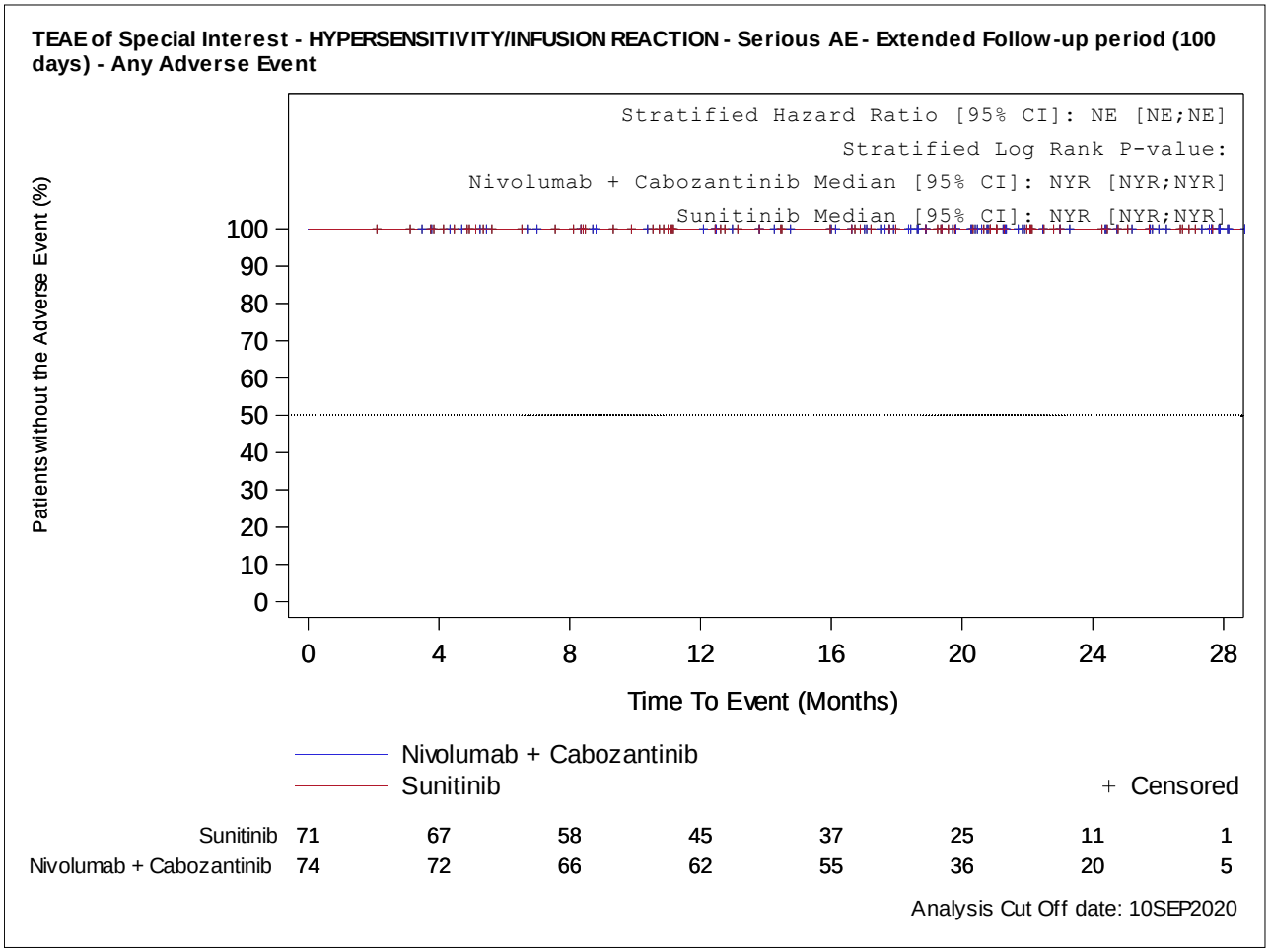

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:08:43

FIGURE 3.39.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



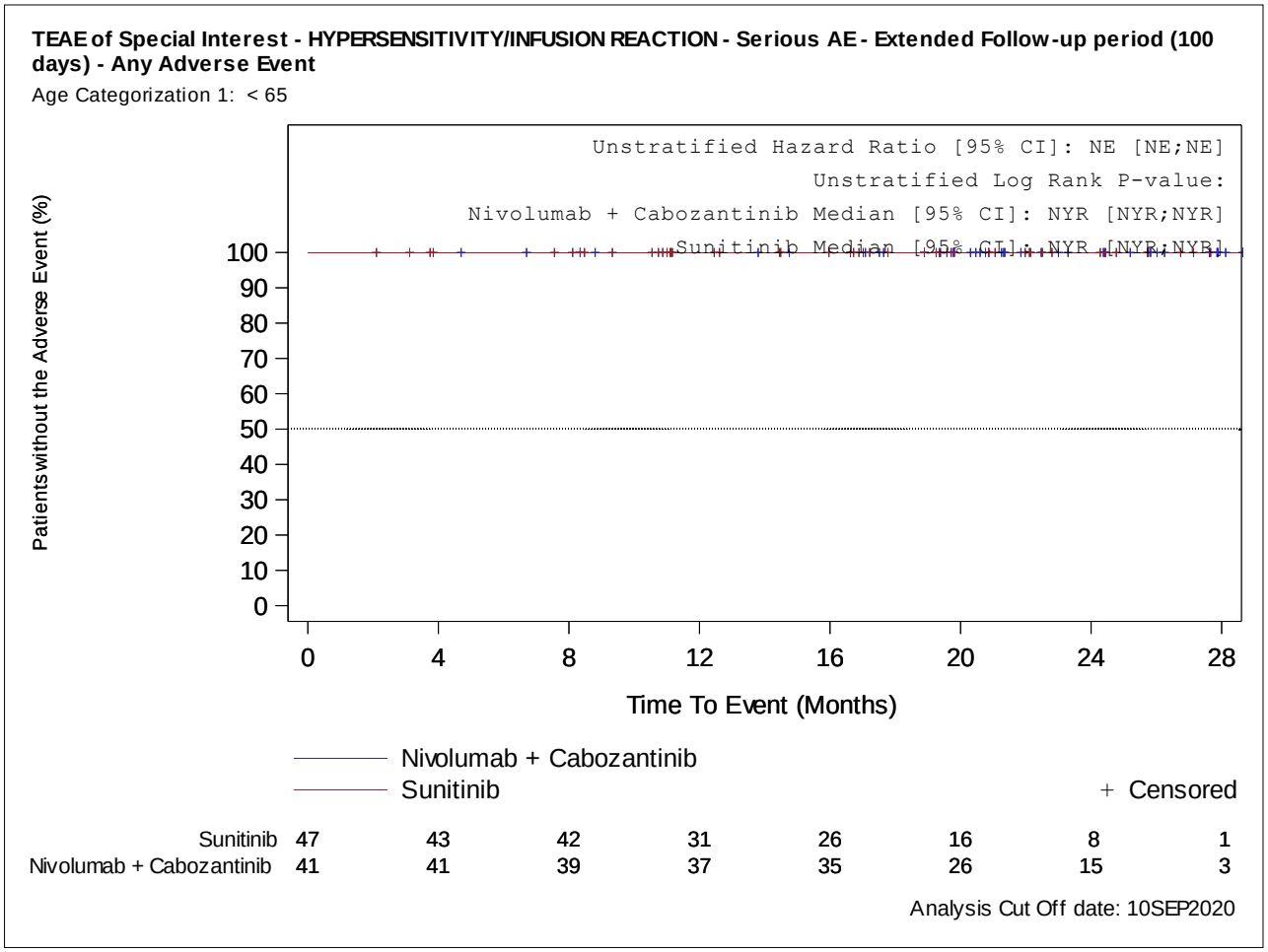

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:08:48

FIGURE 3.40.1: TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



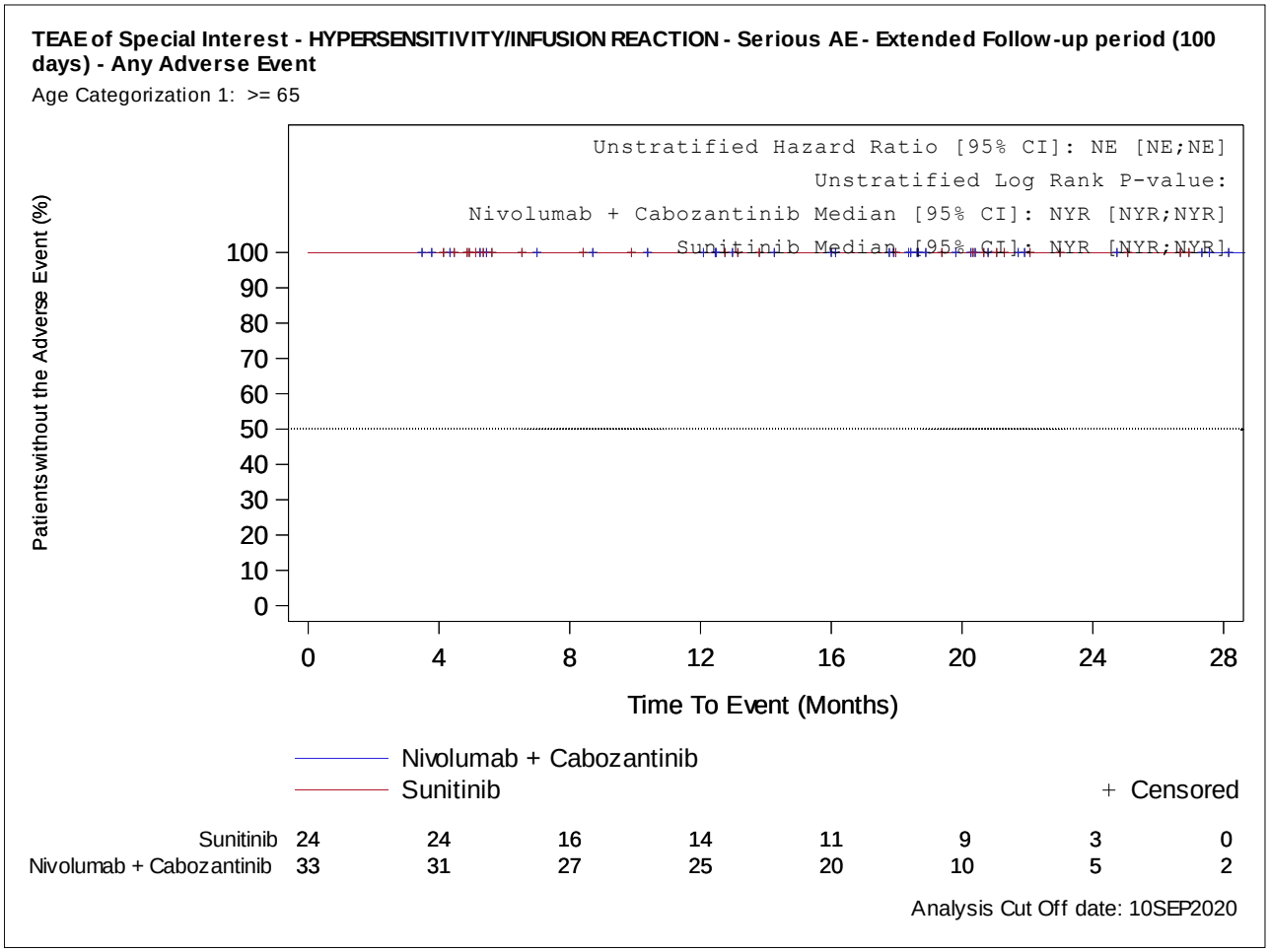

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:11:47

FIGURE 3.40.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:11:50

FIGURE 3.40.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
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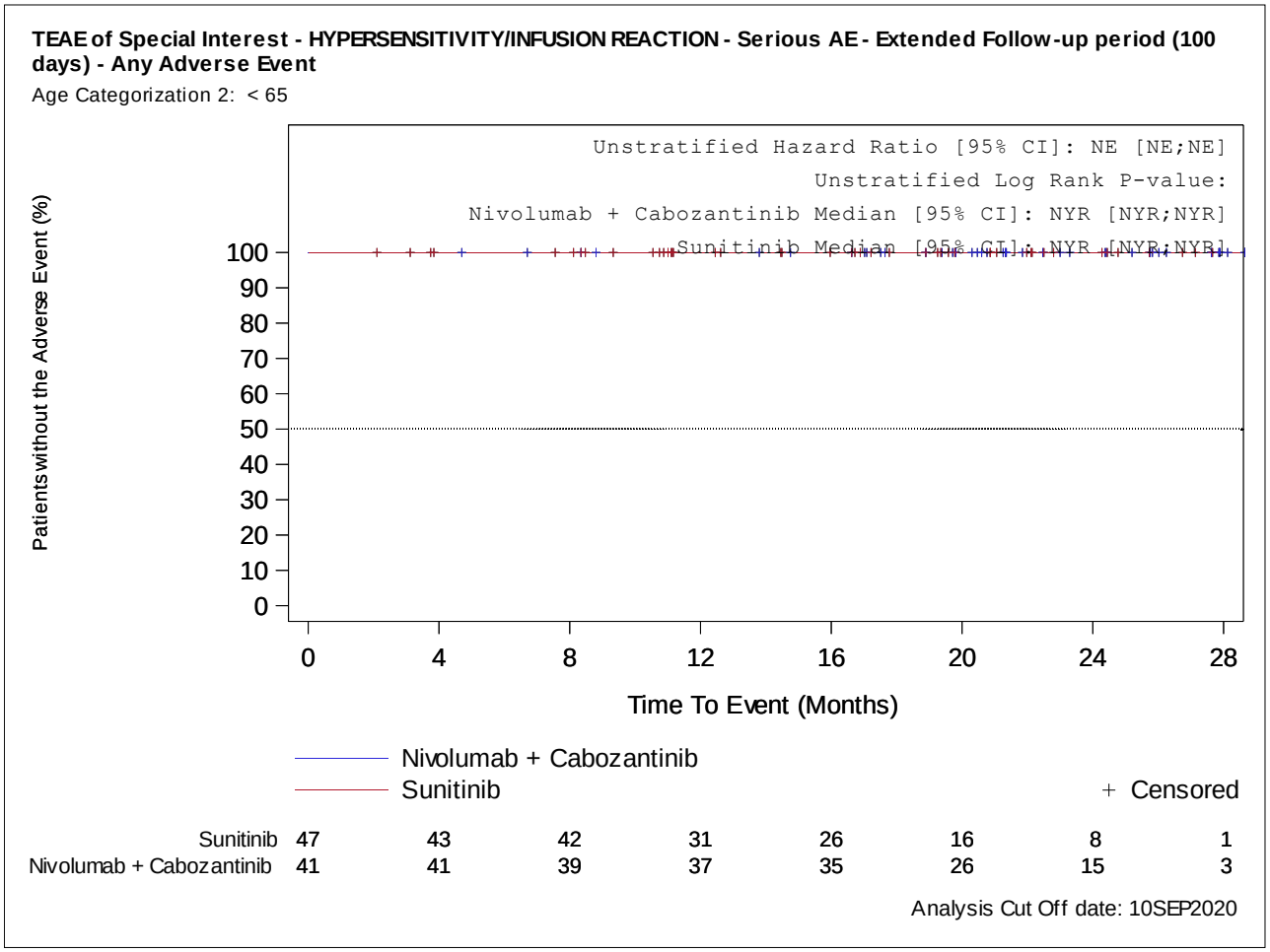
FIGURE 3.40.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  < 65




Analysis Cut Off date: 10SEP2020
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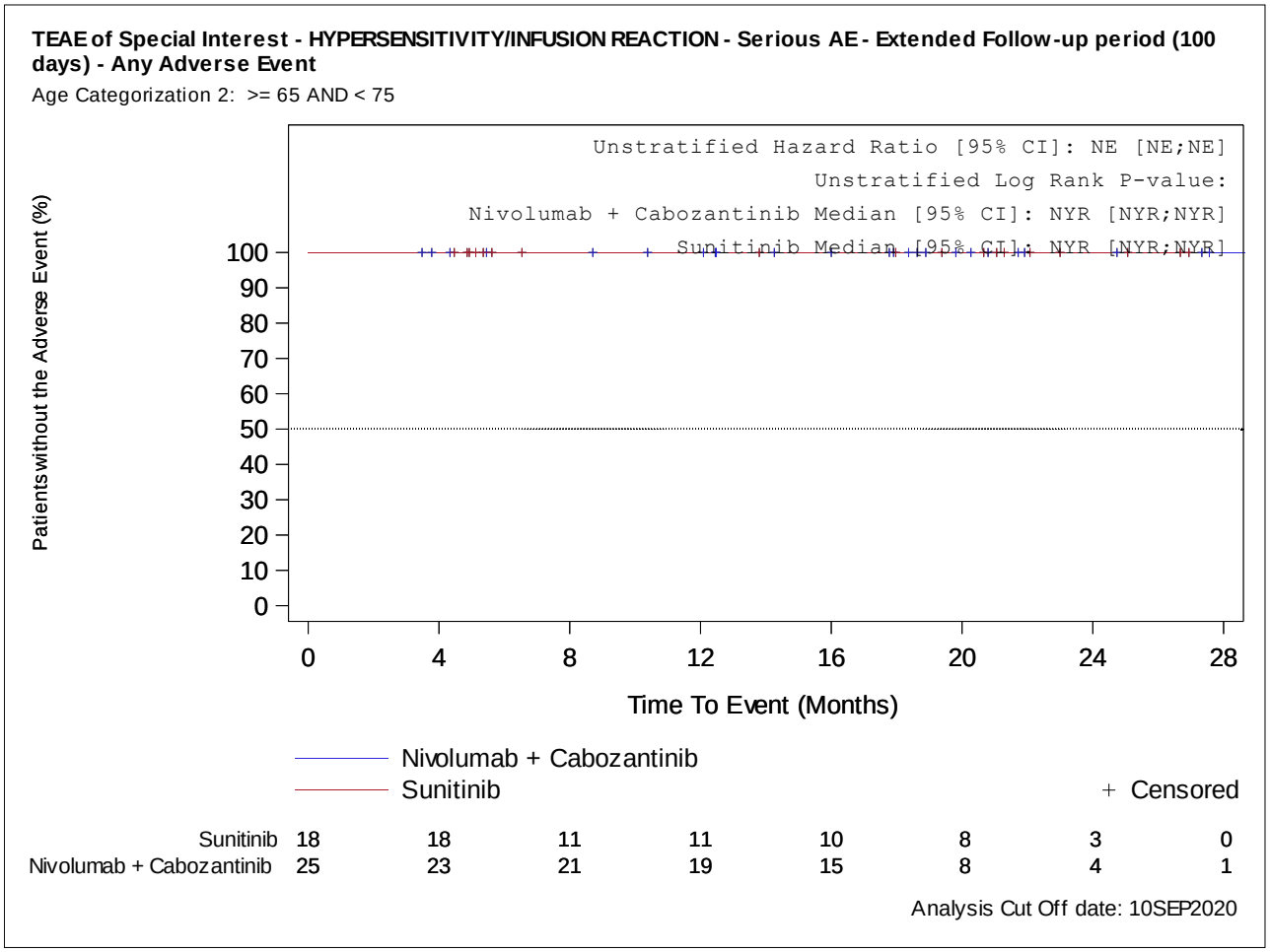
FIGURE 3.40.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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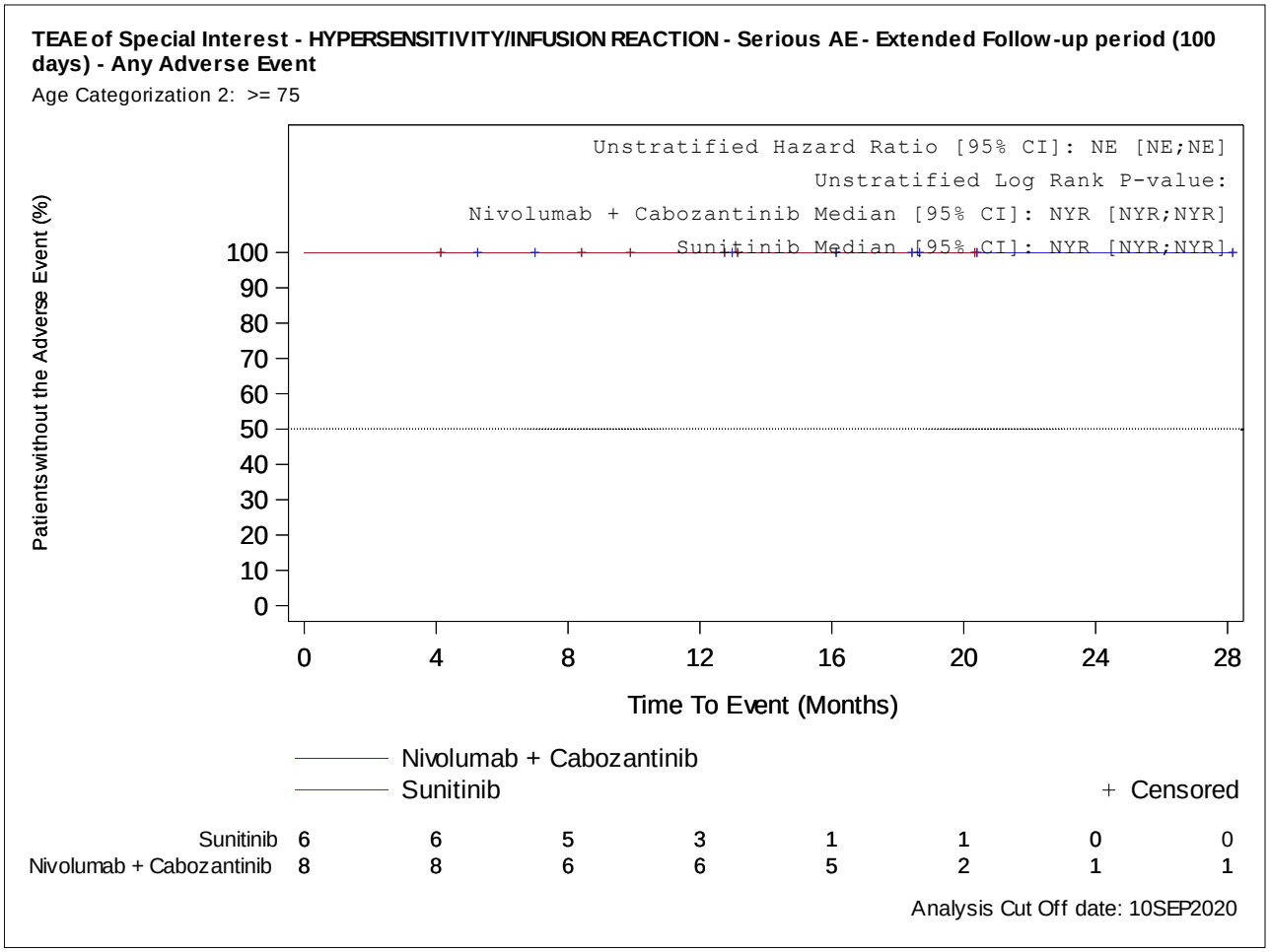
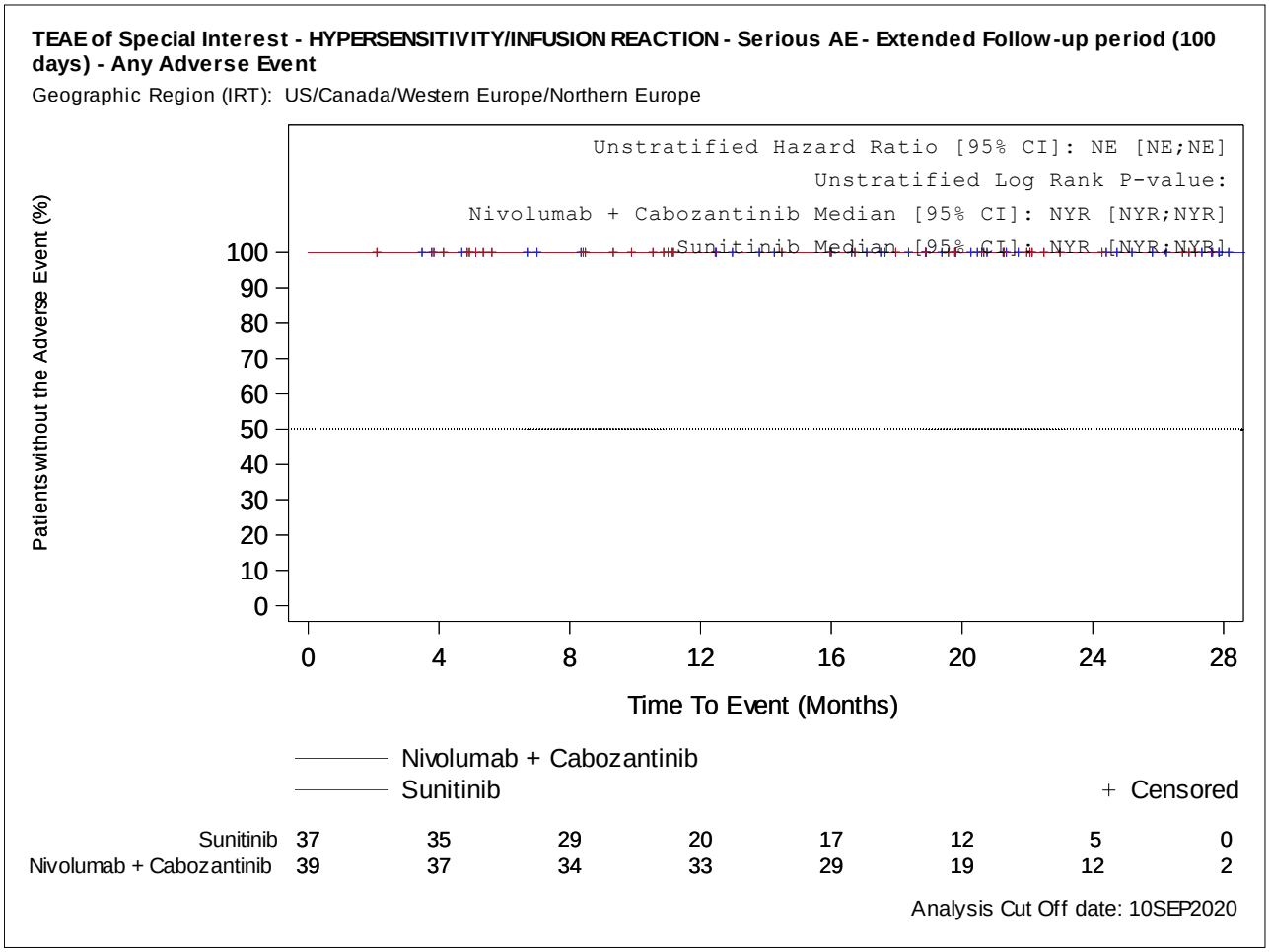
FIGURE 3.40.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



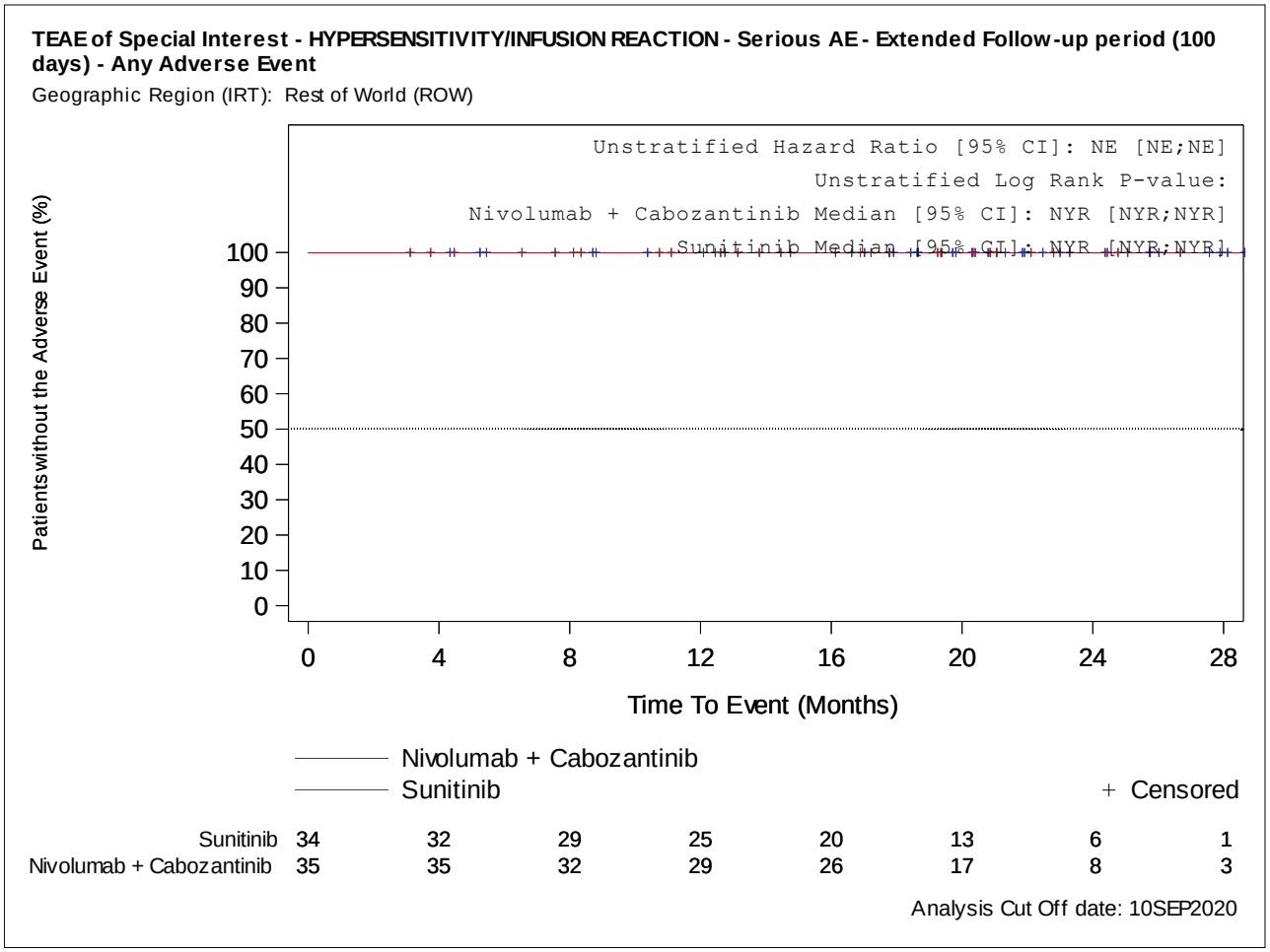

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:12:10

FIGURE 3.40.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



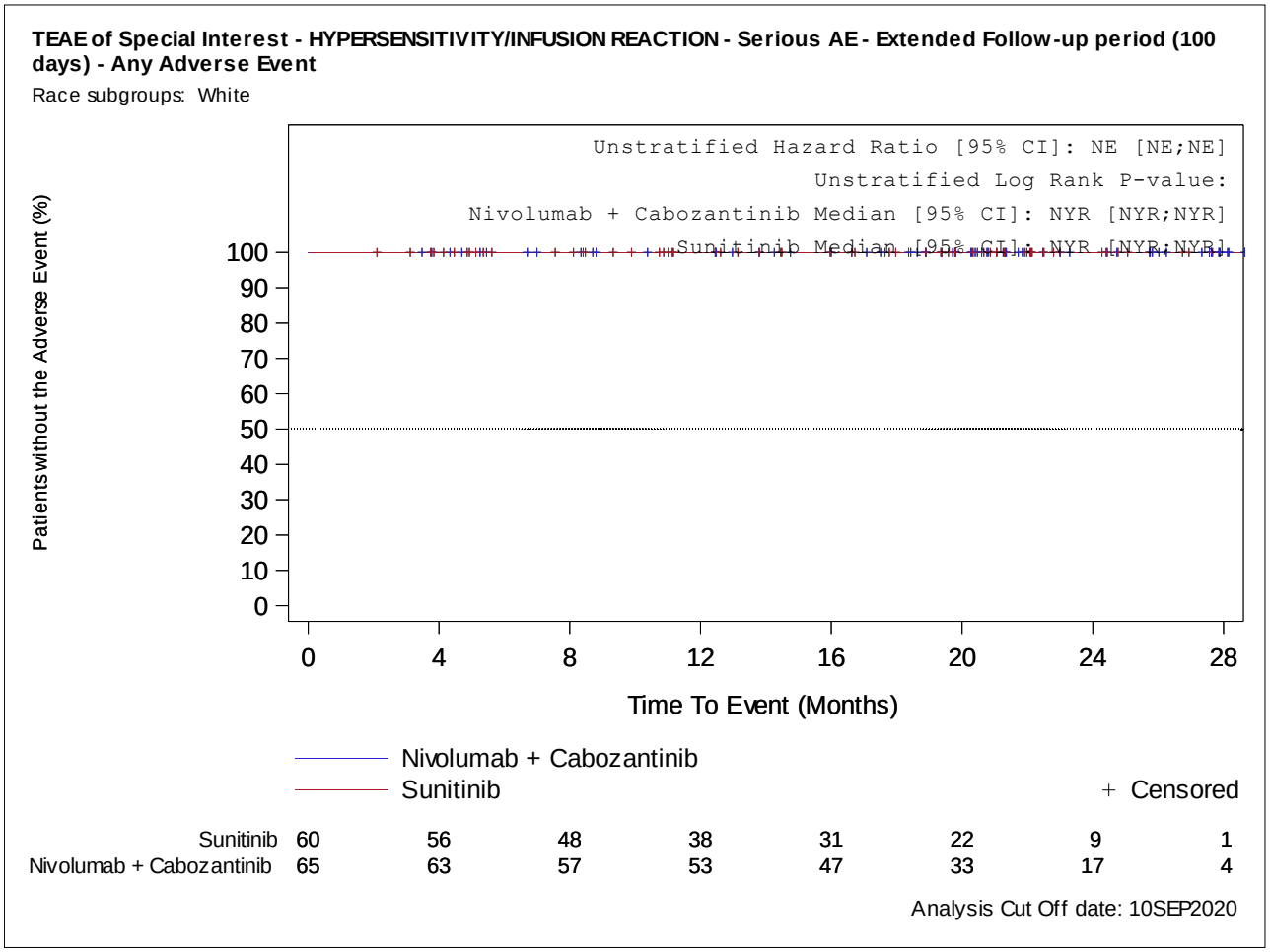

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:12:16

FIGURE 3.40.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



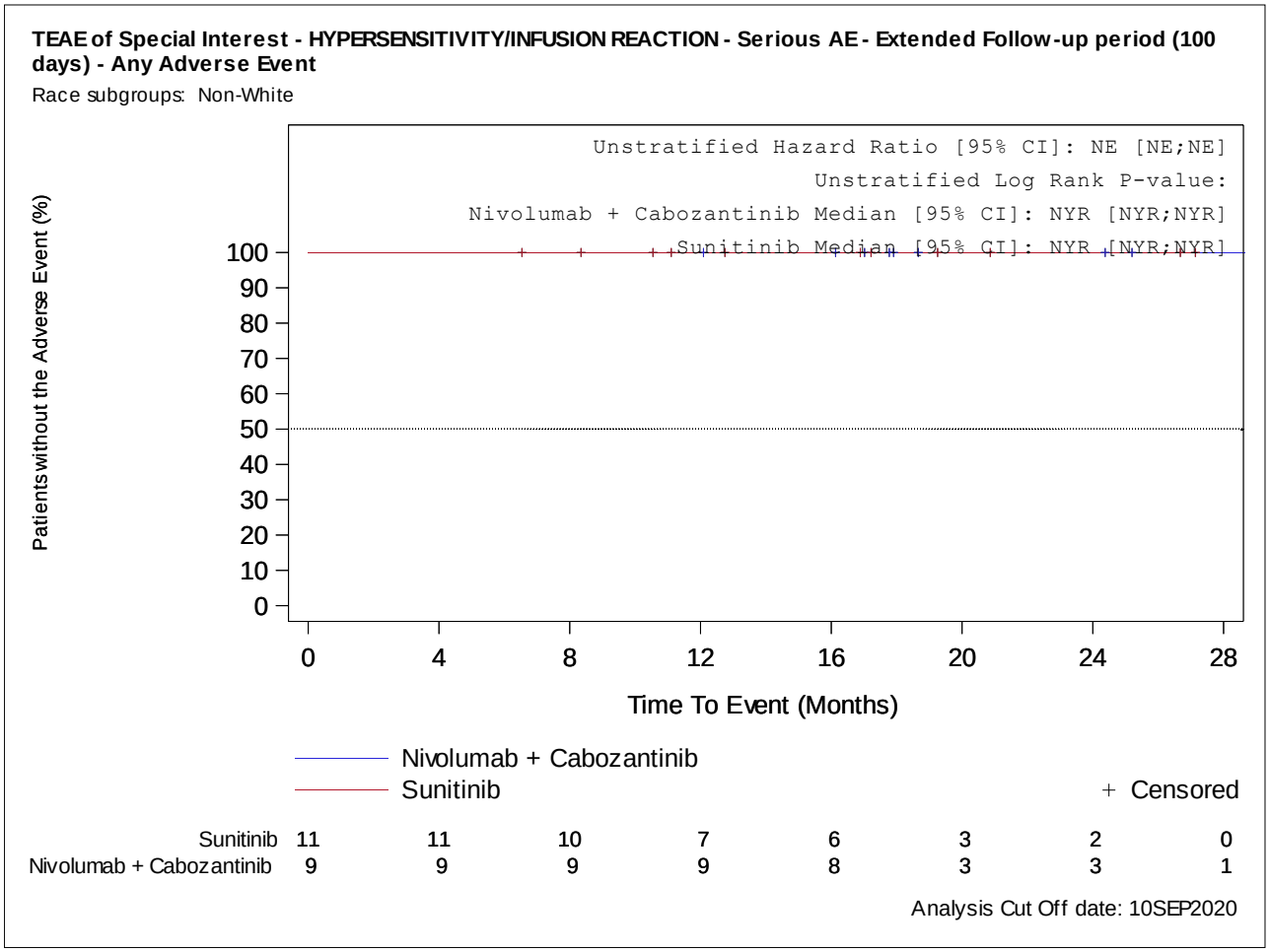

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:12:21

FIGURE 3.40.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



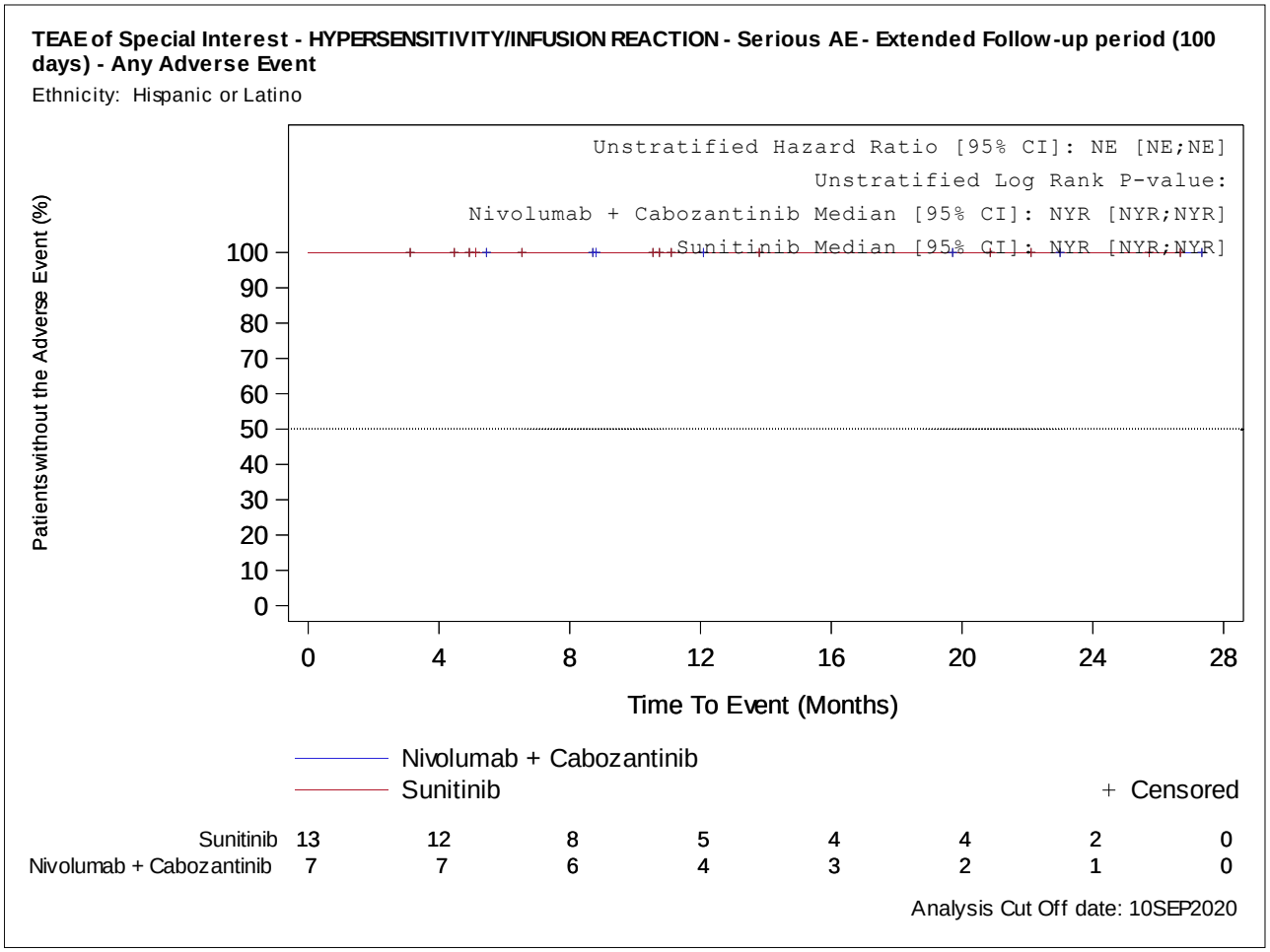

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:12:26

FIGURE 3.40.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



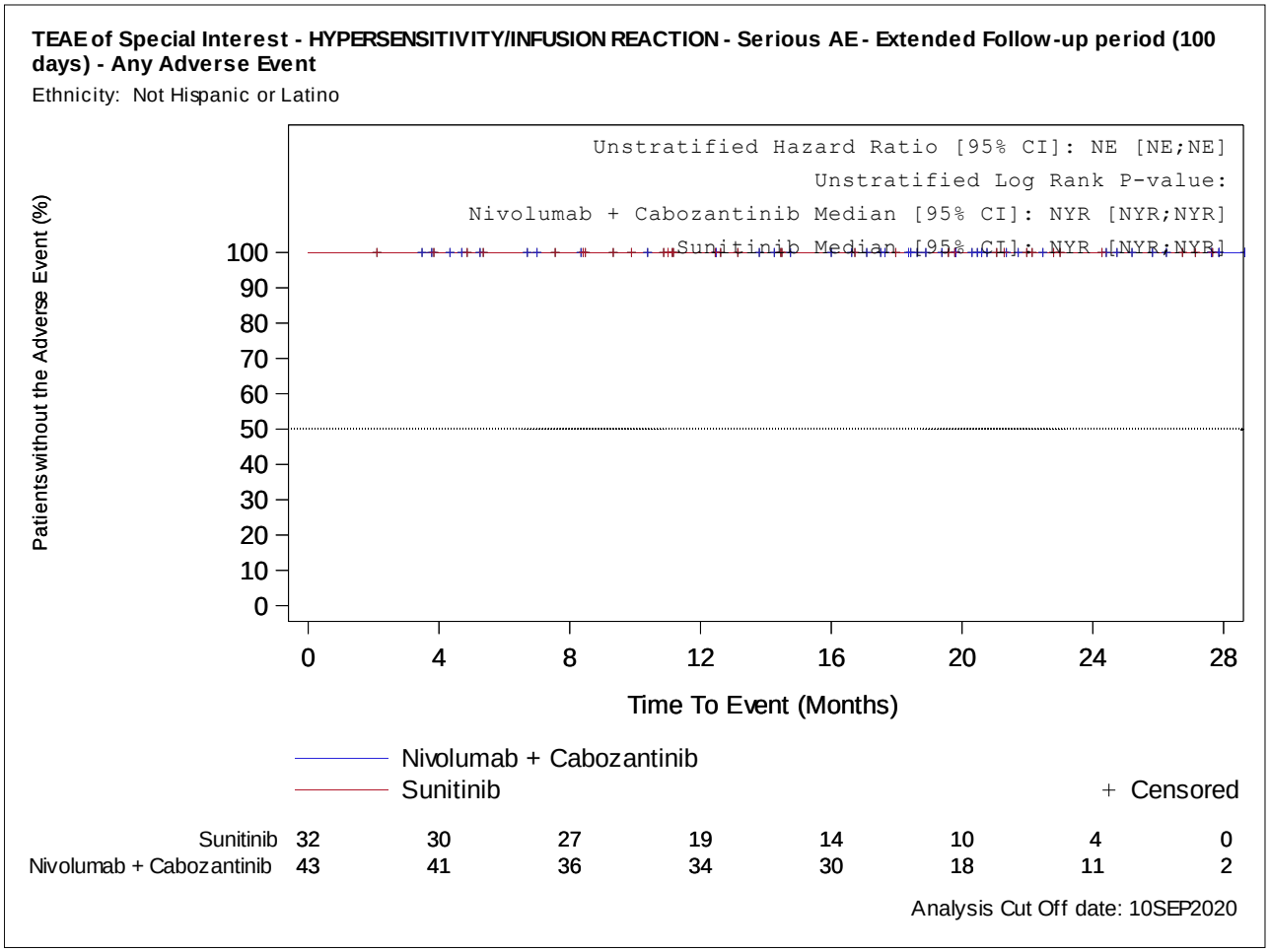

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:12:32

FIGURE 3.40.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



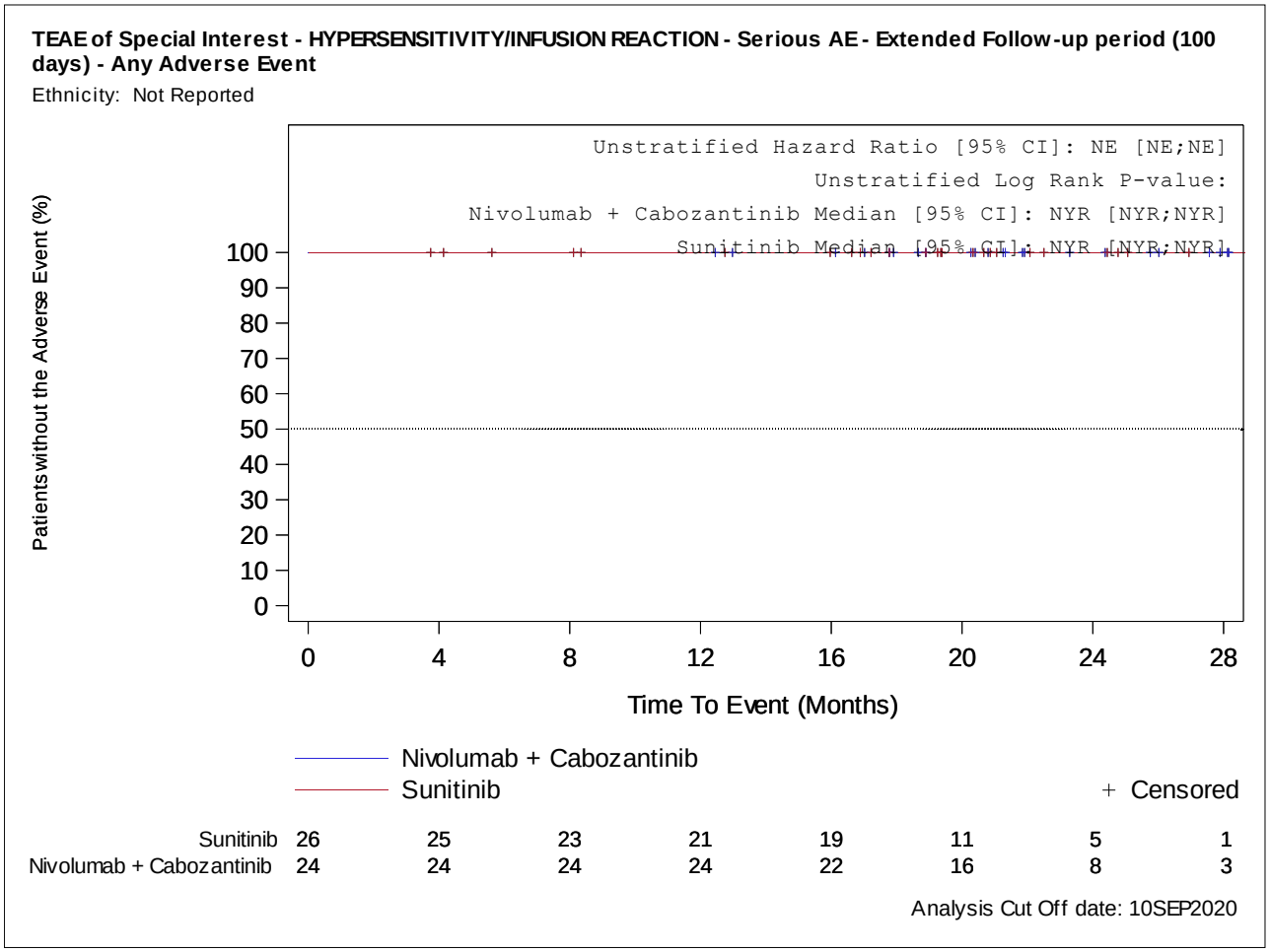

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:12:37

FIGURE 3.40.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



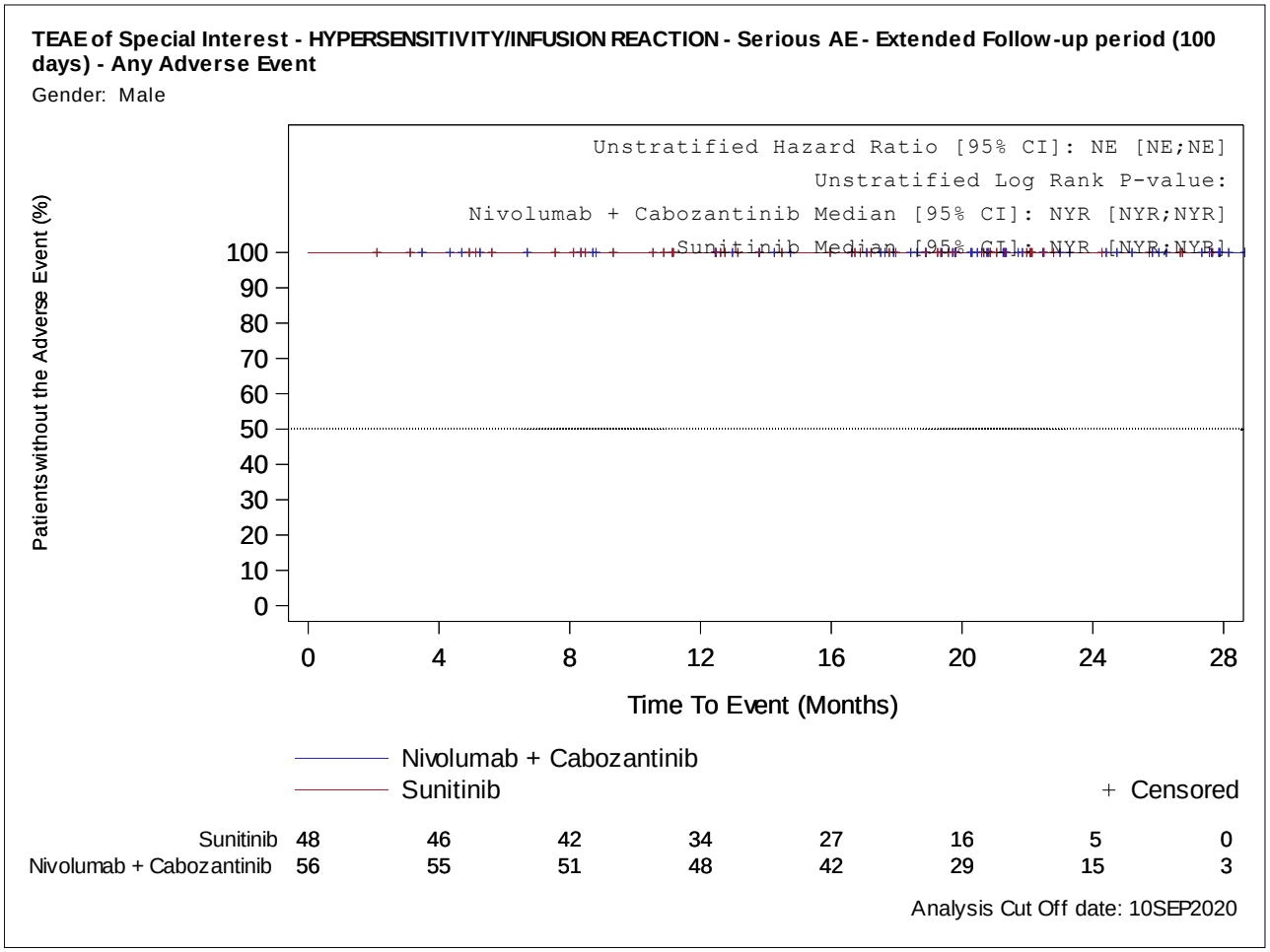

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:12:43

FIGURE 3.40.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



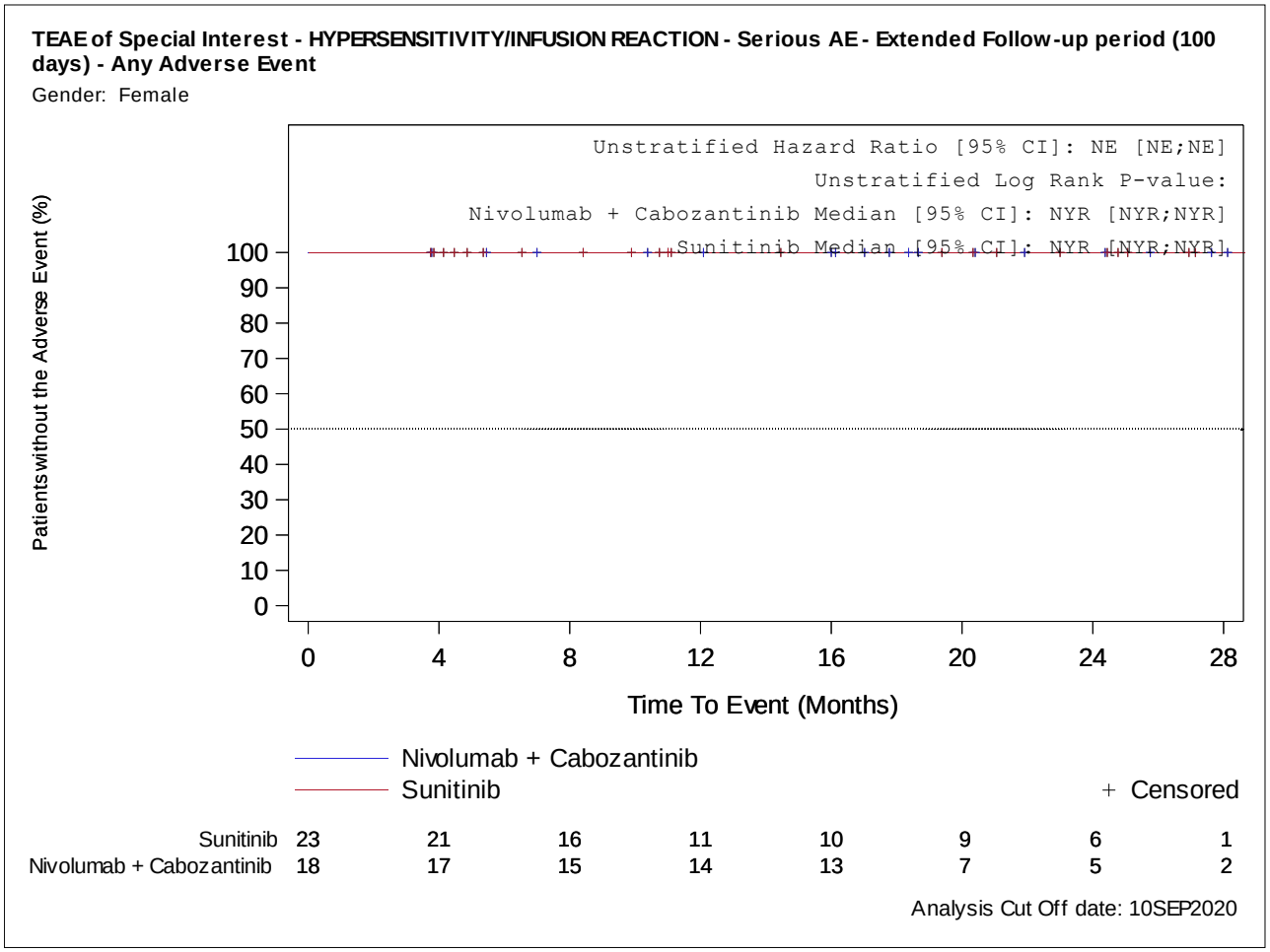

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:12:48

FIGURE 3.40.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



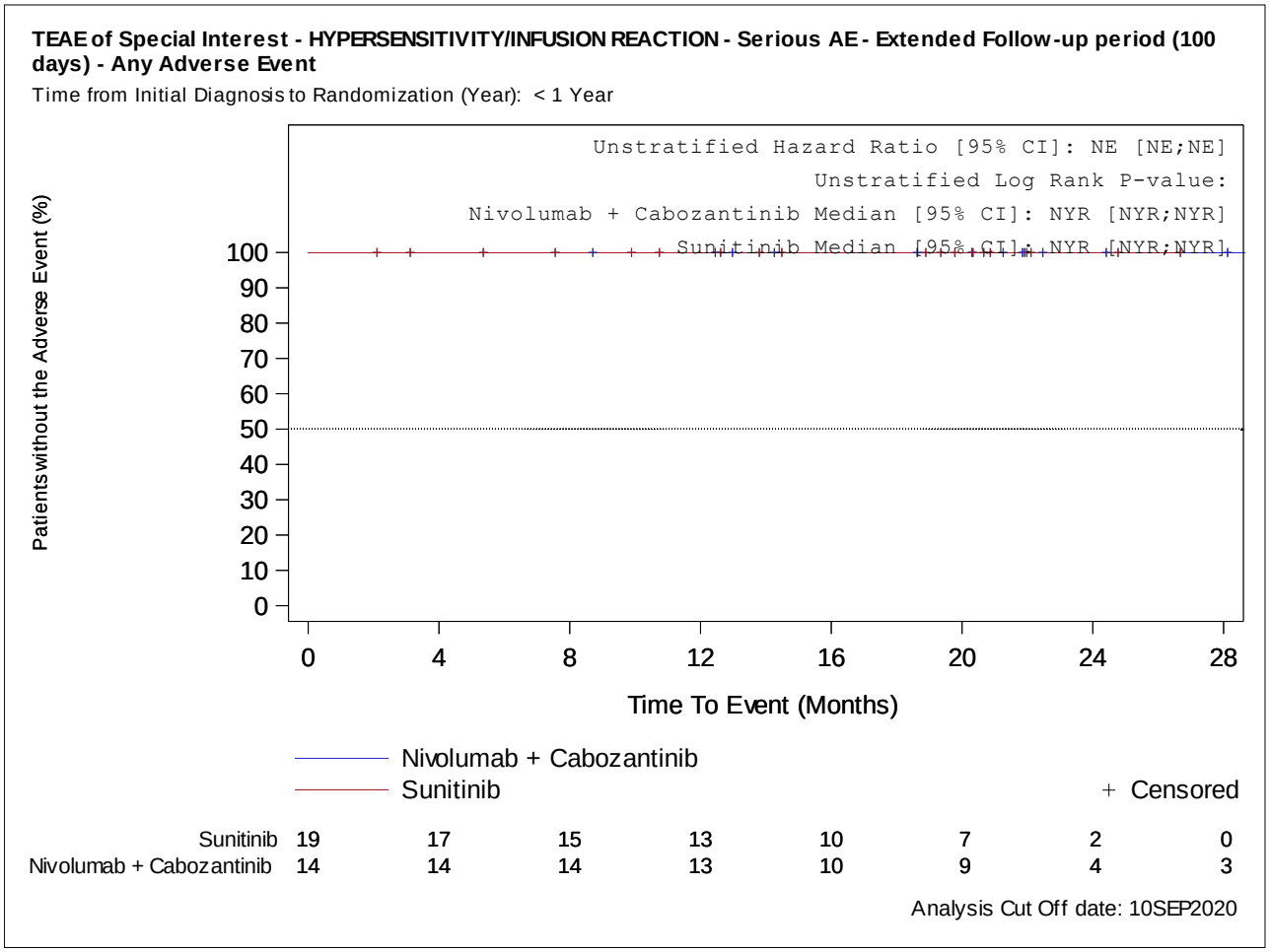

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:12:53

FIGURE 3.40.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



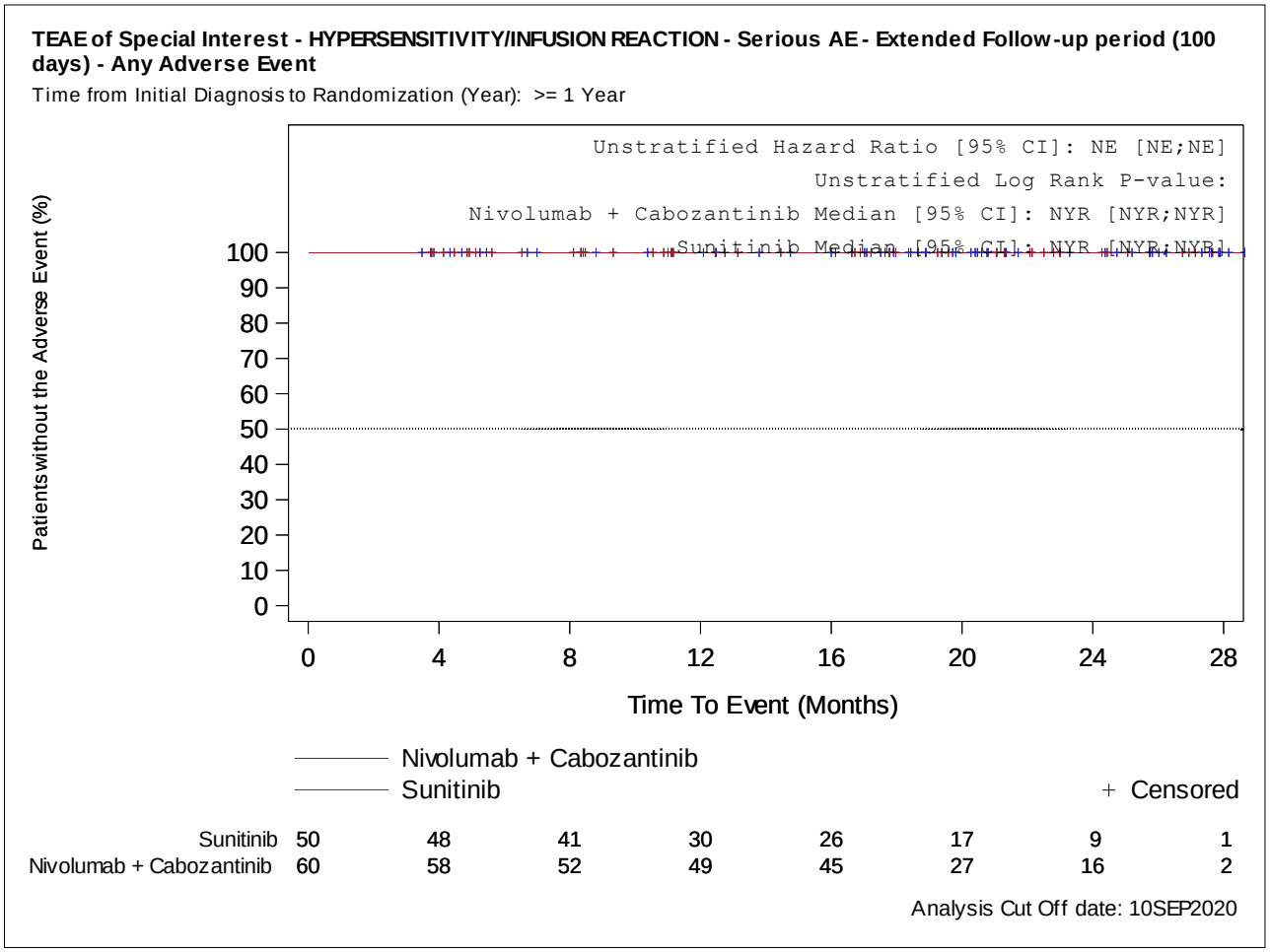

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:12:58

FIGURE 3.40.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



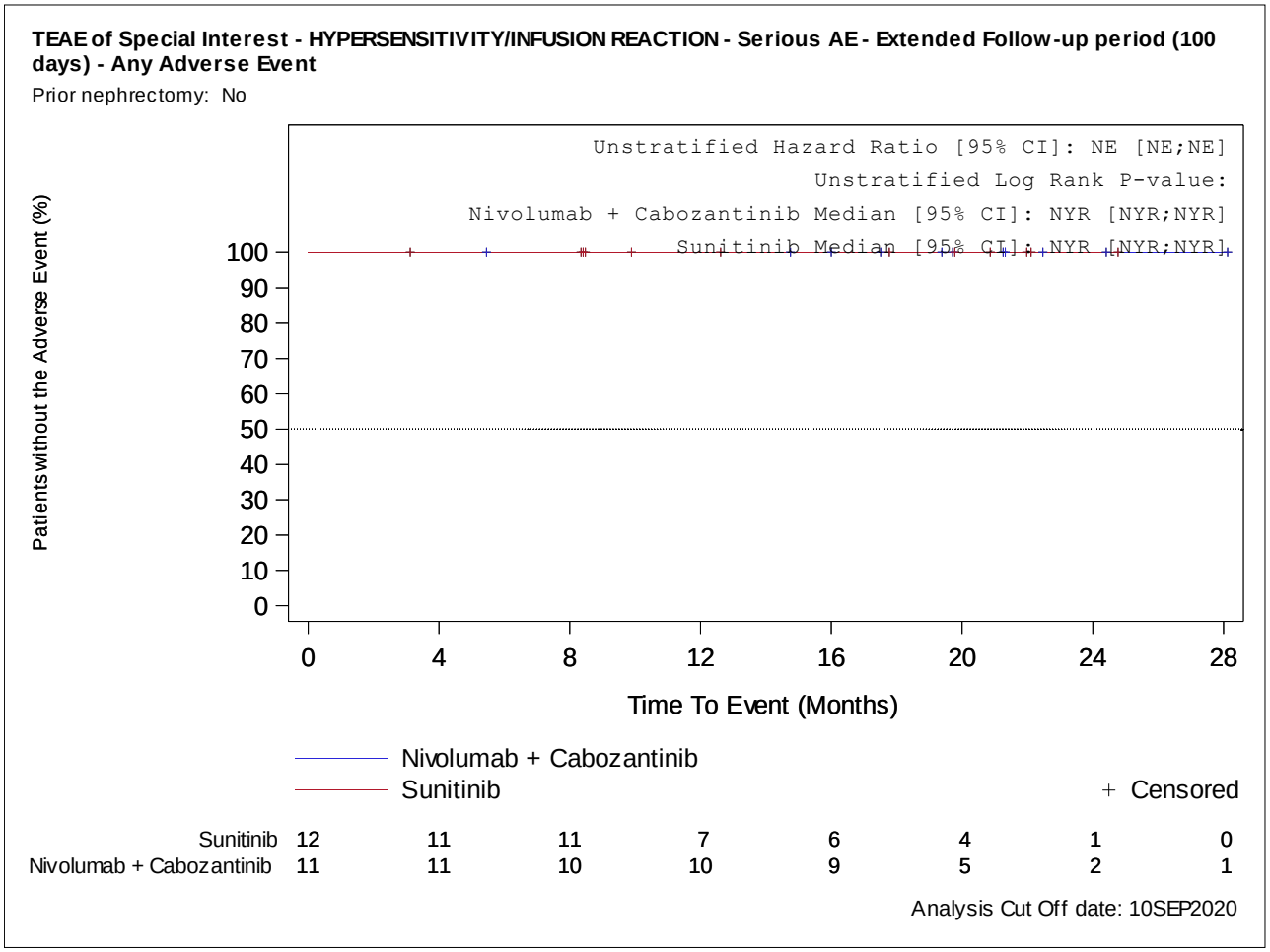

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:13:13

FIGURE 3.40.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:13:18

FIGURE 3.40.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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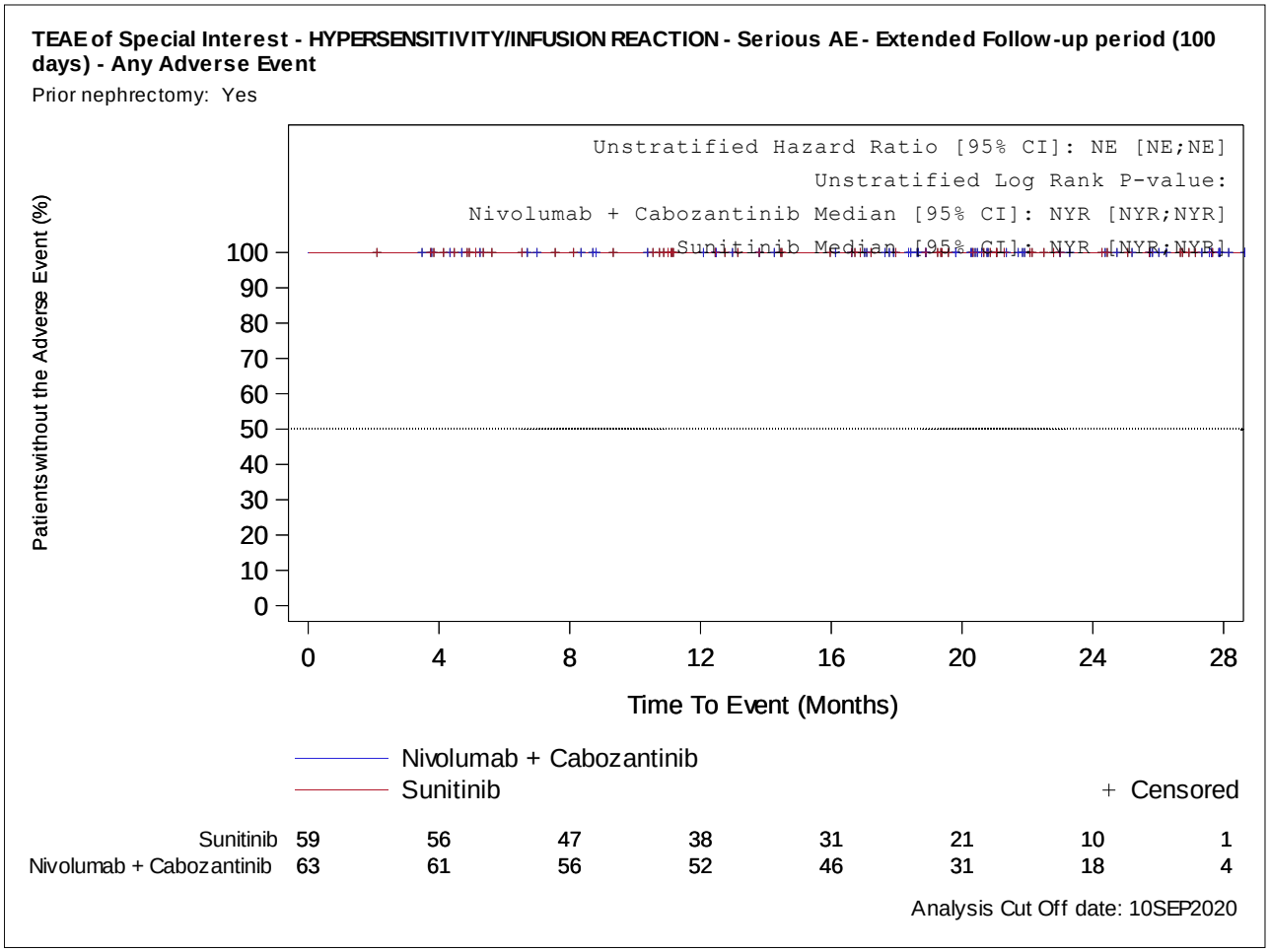
FIGURE 3.40.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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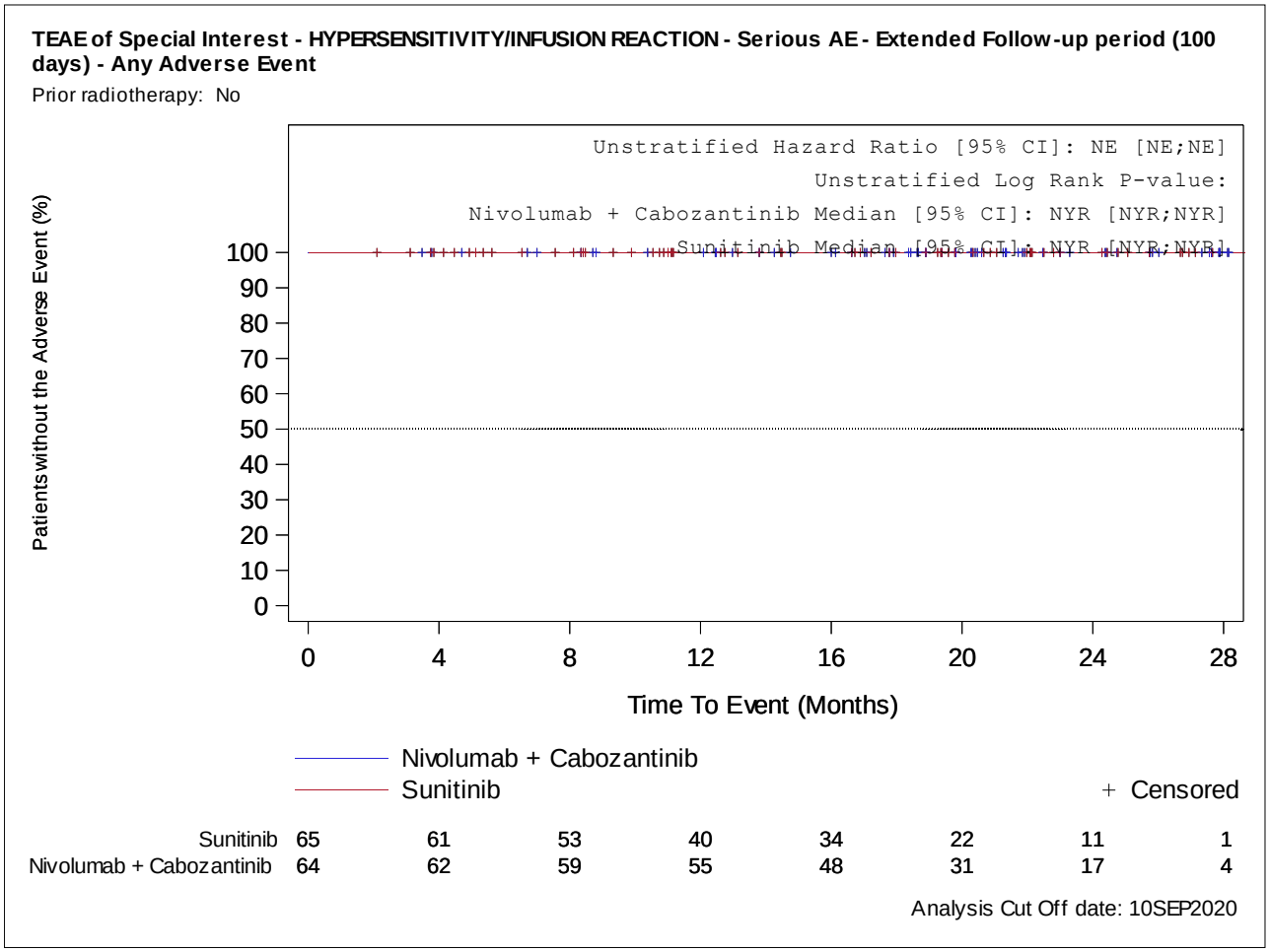
FIGURE 3.40.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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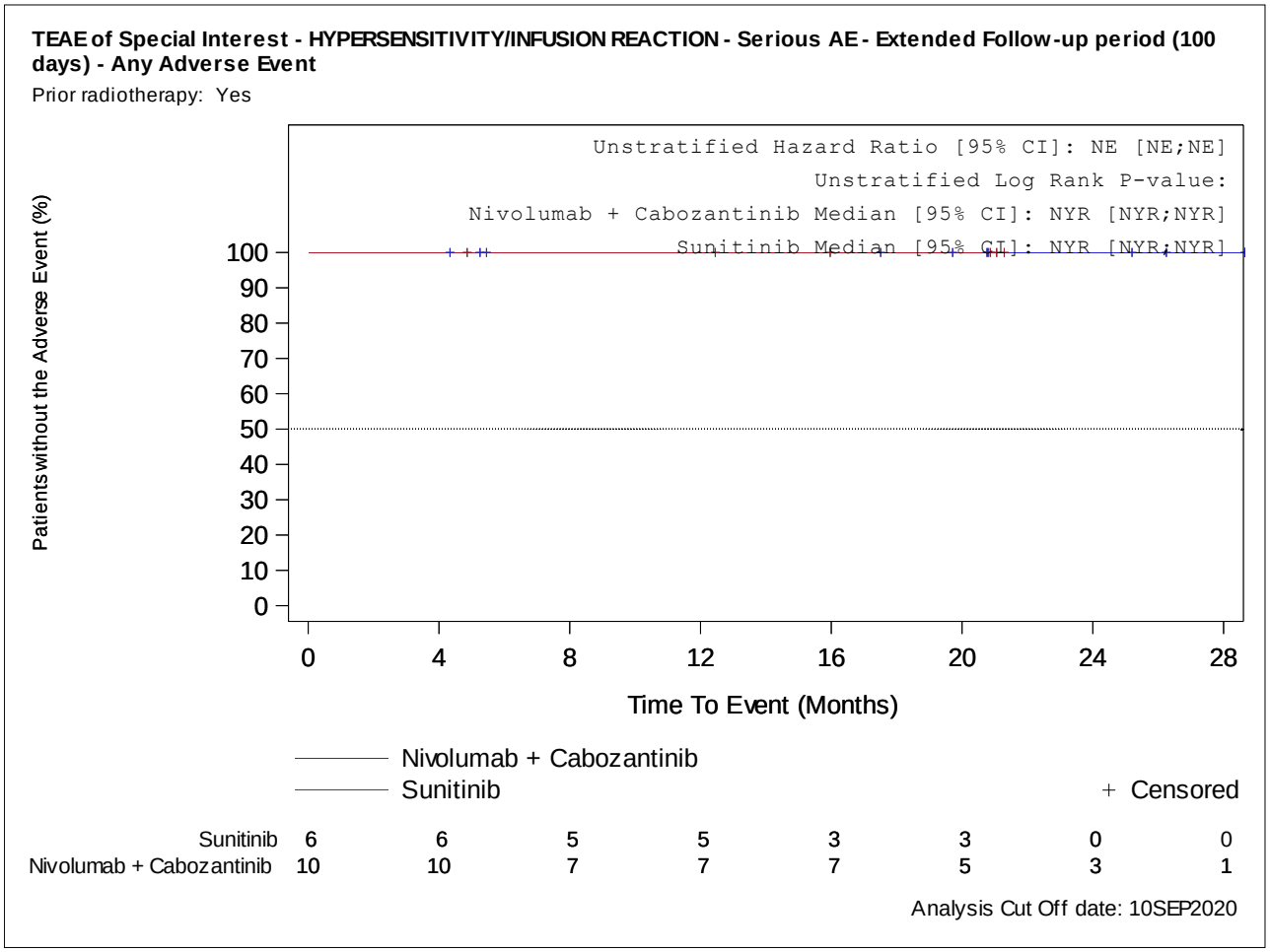
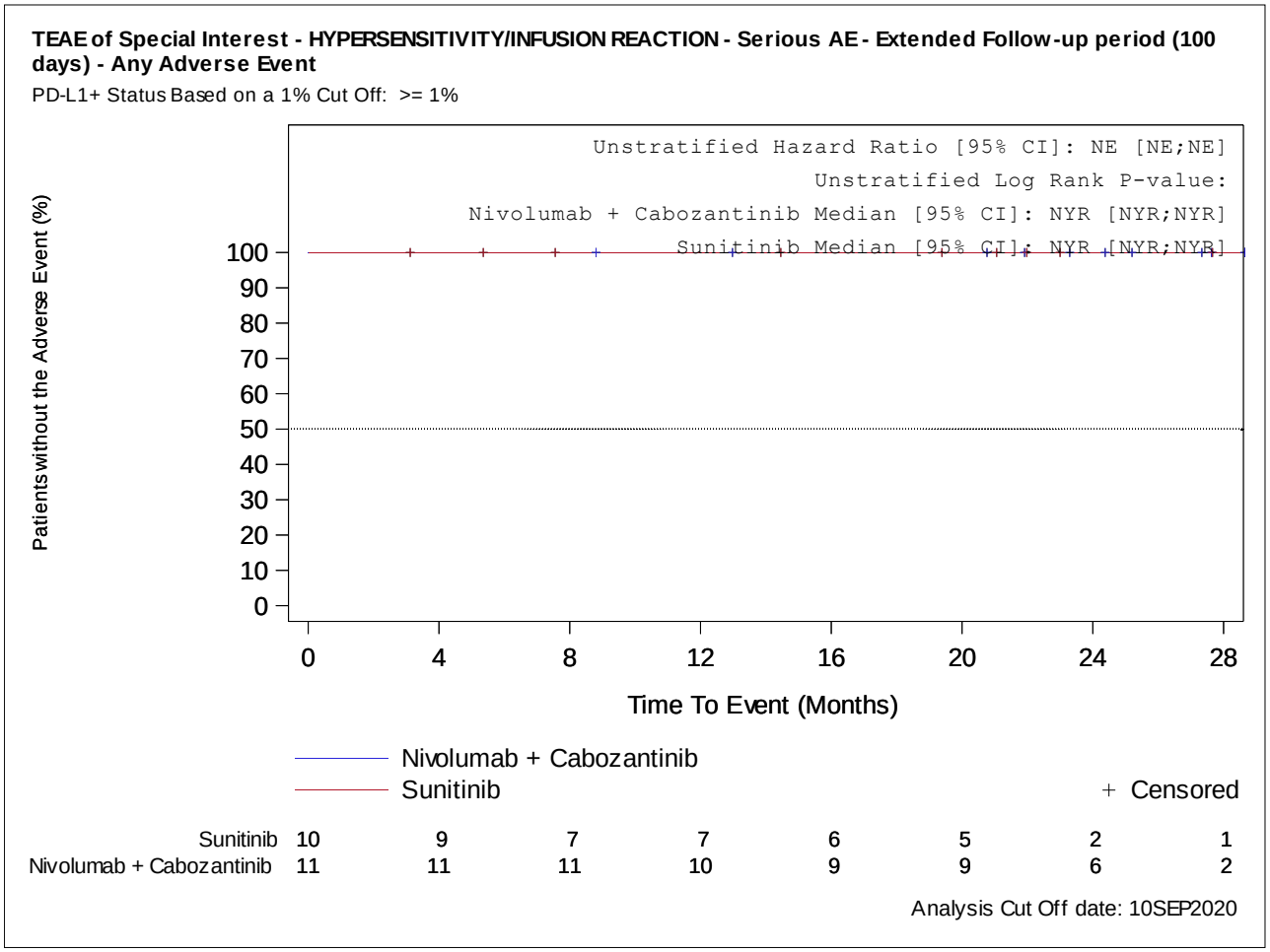
FIGURE 3.40.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



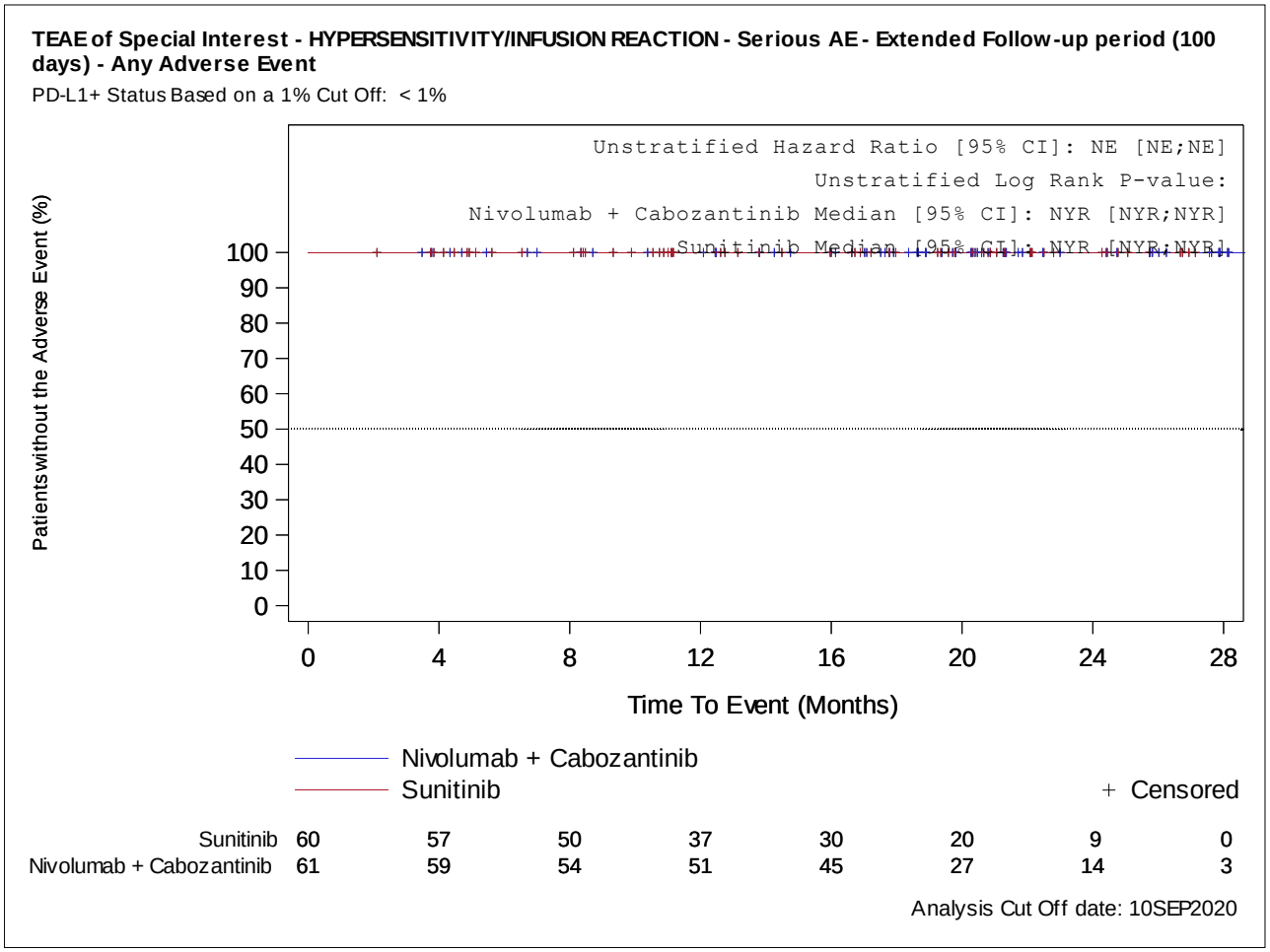

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:14:21

FIGURE 3.40.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



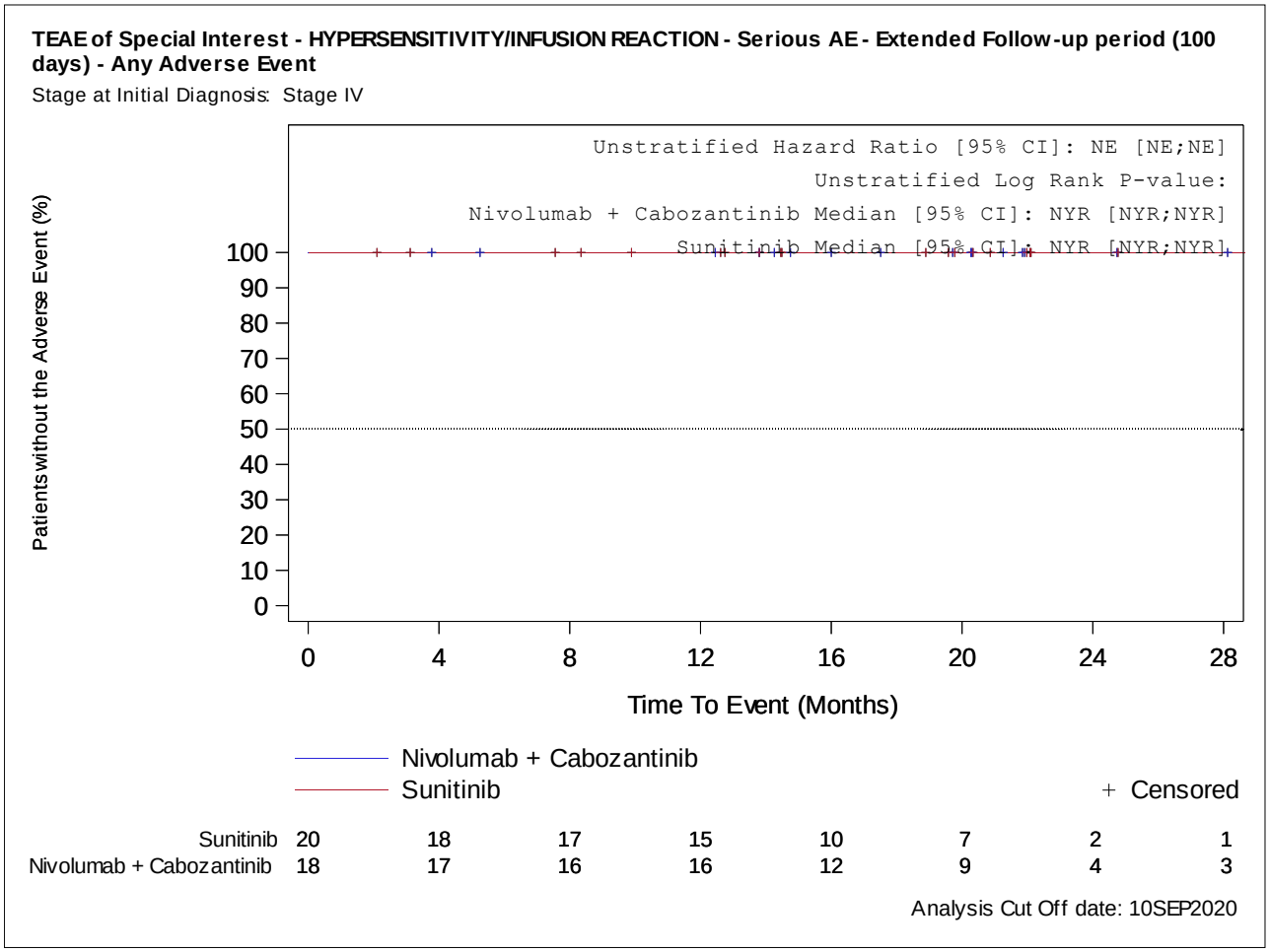

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:14:27

FIGURE 3.40.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



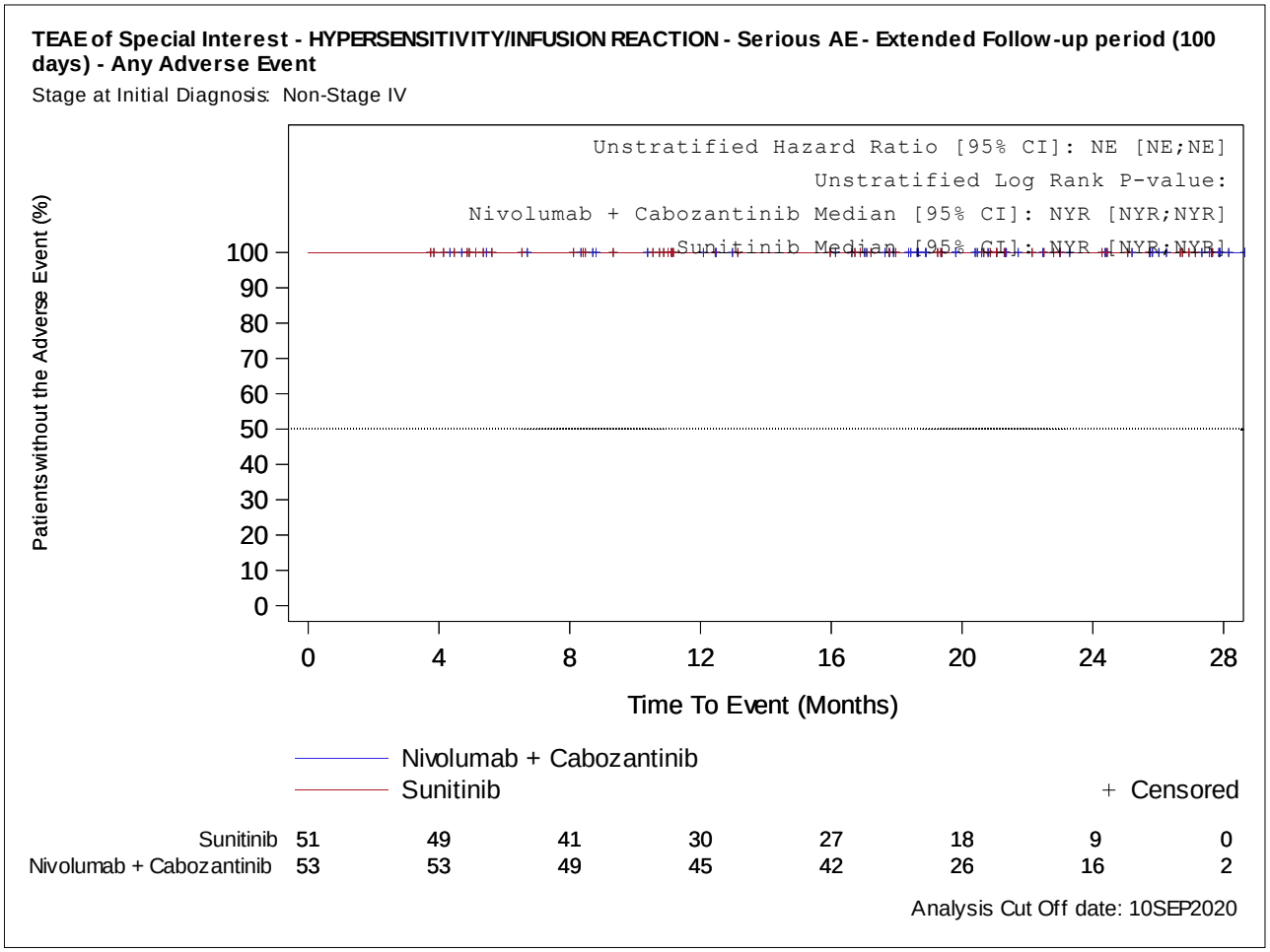

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:14:32

FIGURE 3.40.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



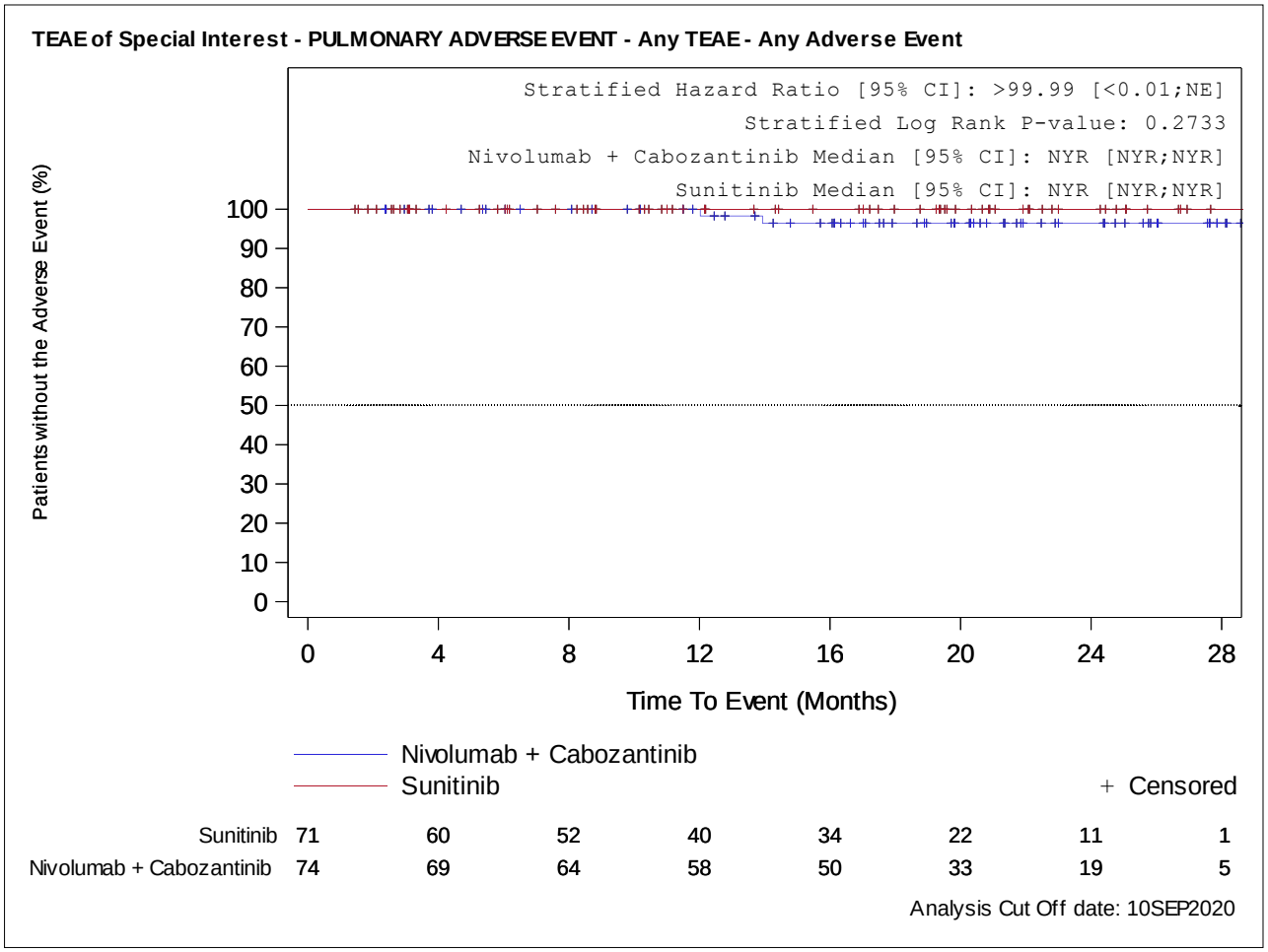

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:14:58

FIGURE 3.40.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY/INFUSION REACTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



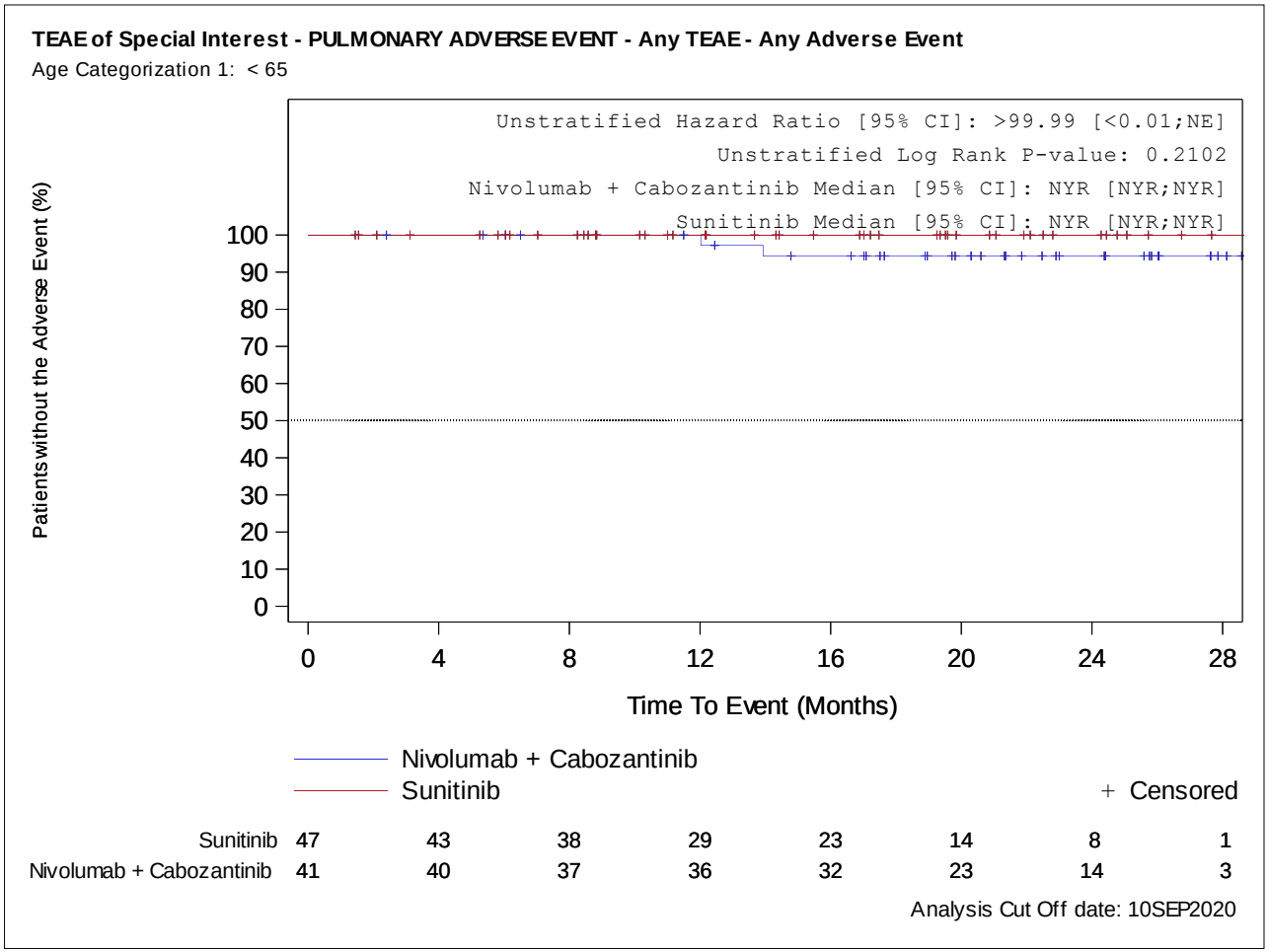

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:15:03

FIGURE 3.41.1: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



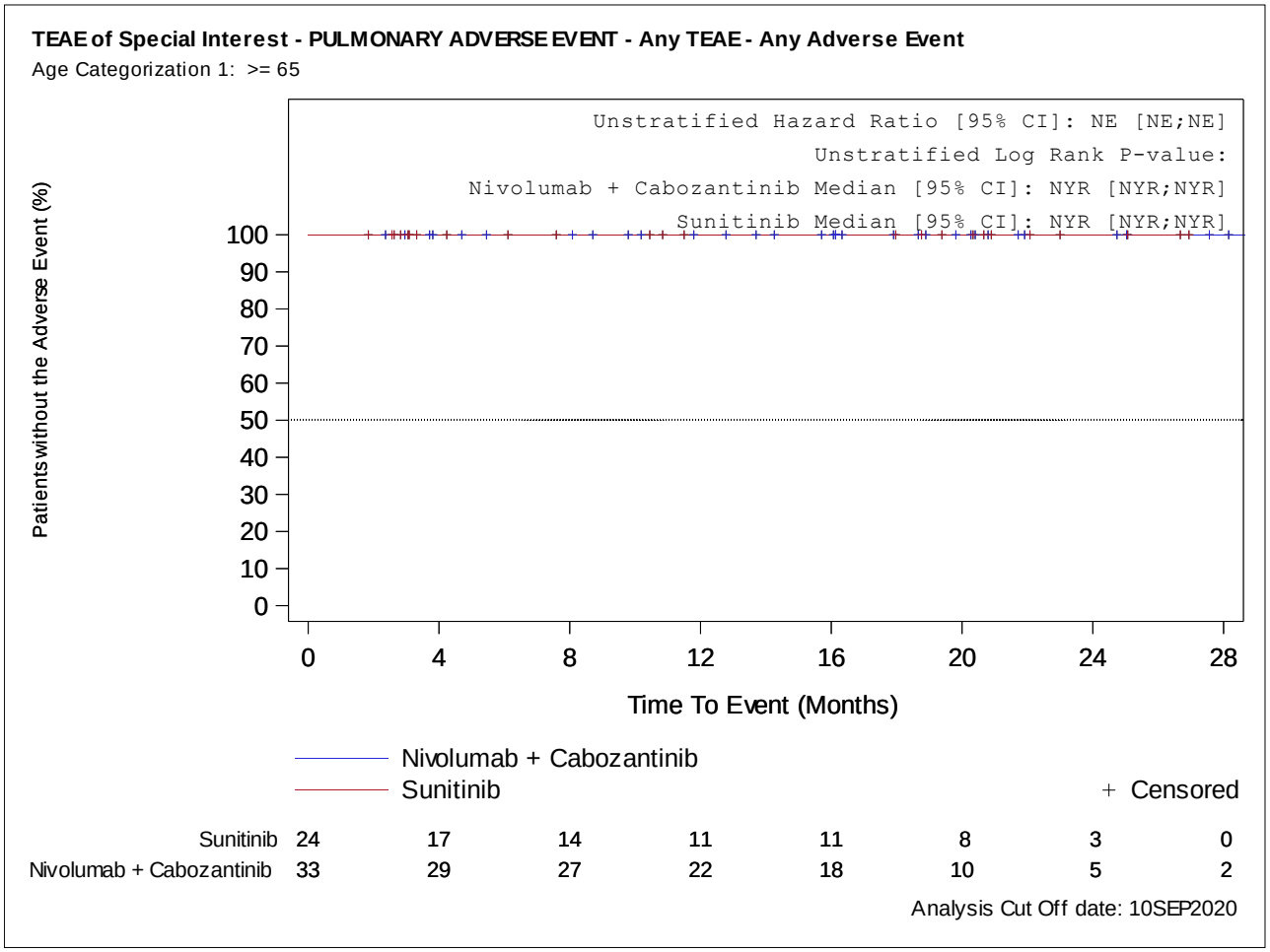

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:17:59

FIGURE 3.41.2.1: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



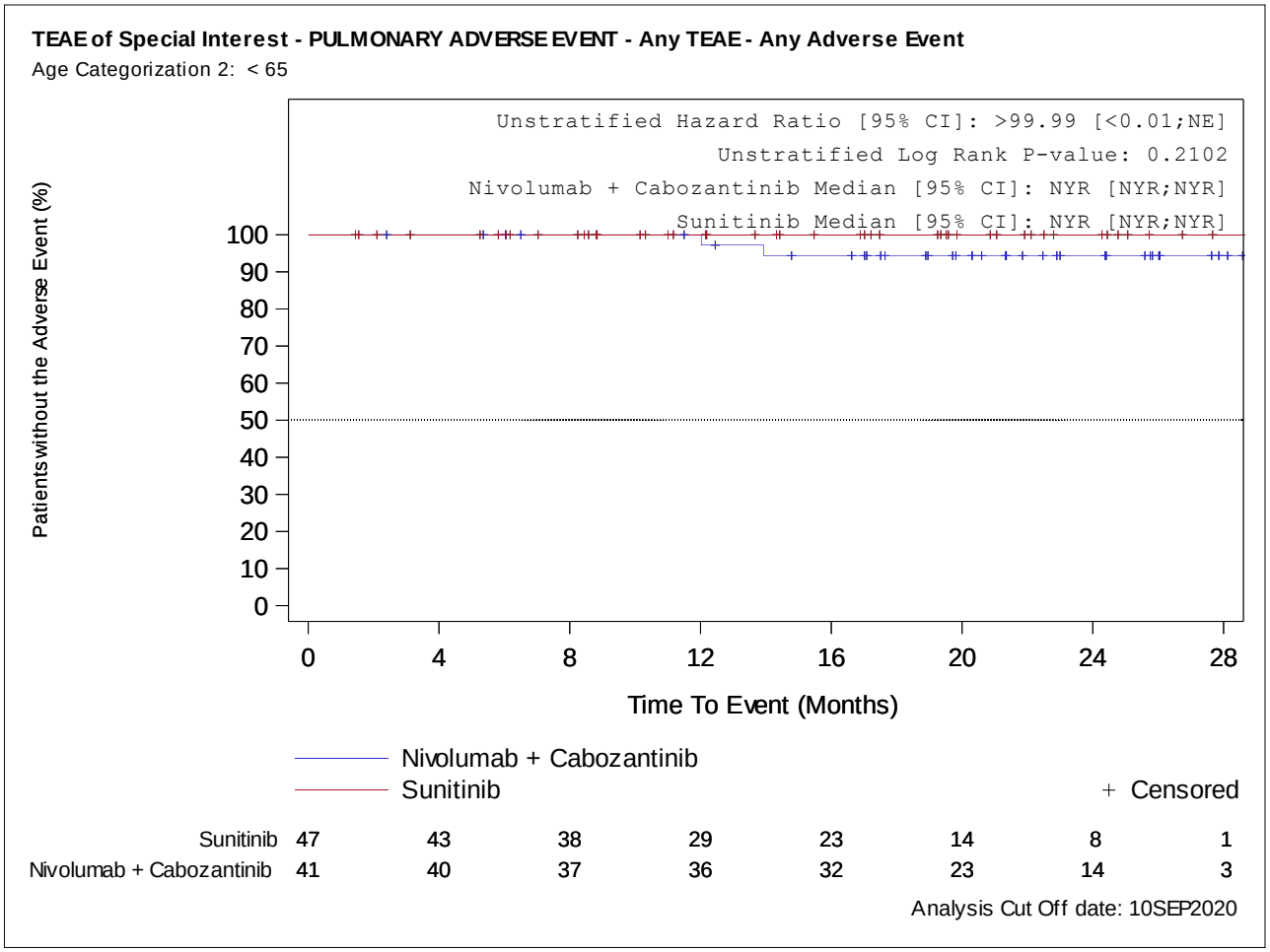

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:18:02

FIGURE 3.41.2.2: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



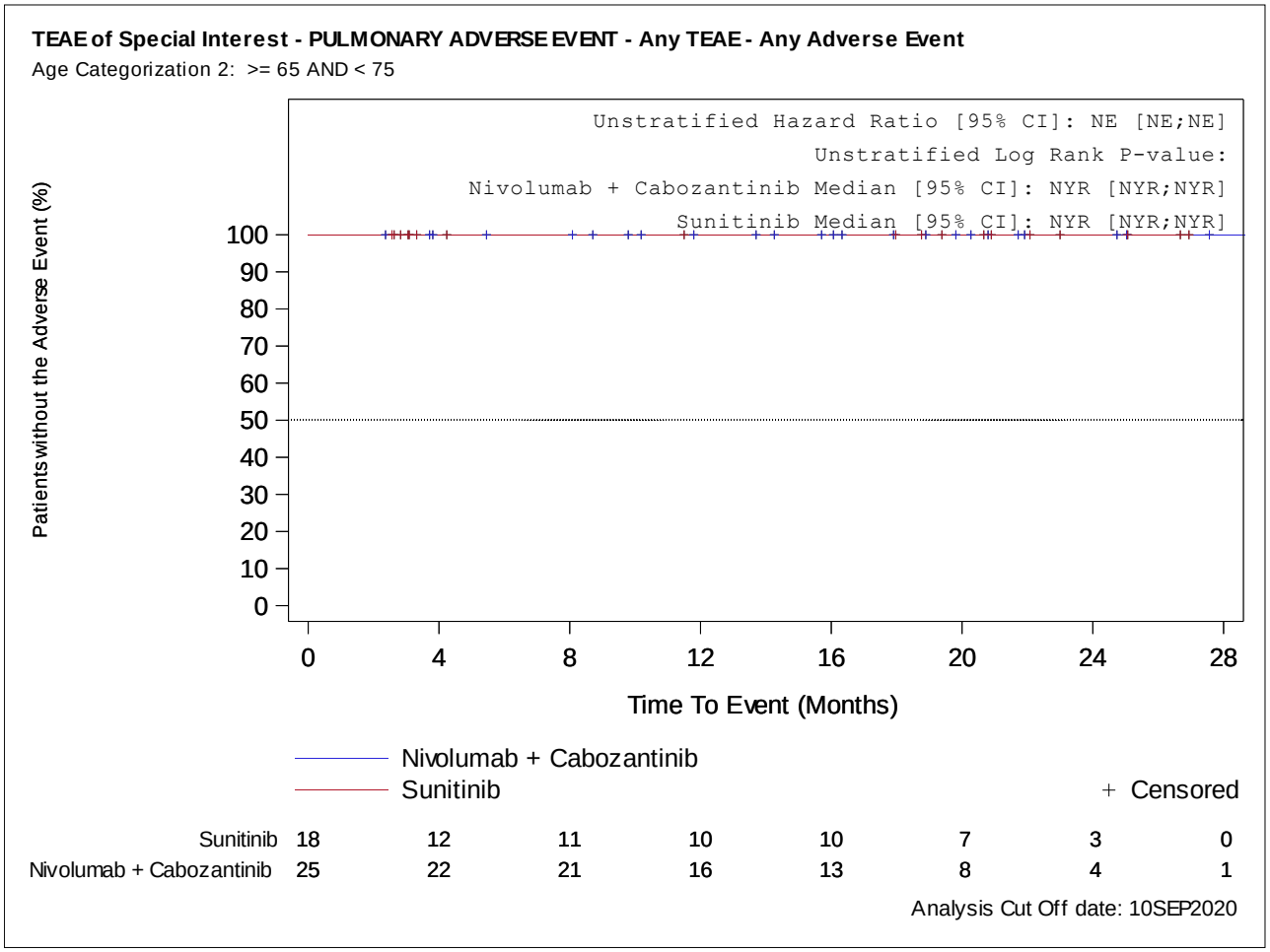

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:18:07

FIGURE 3.41.2.3: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



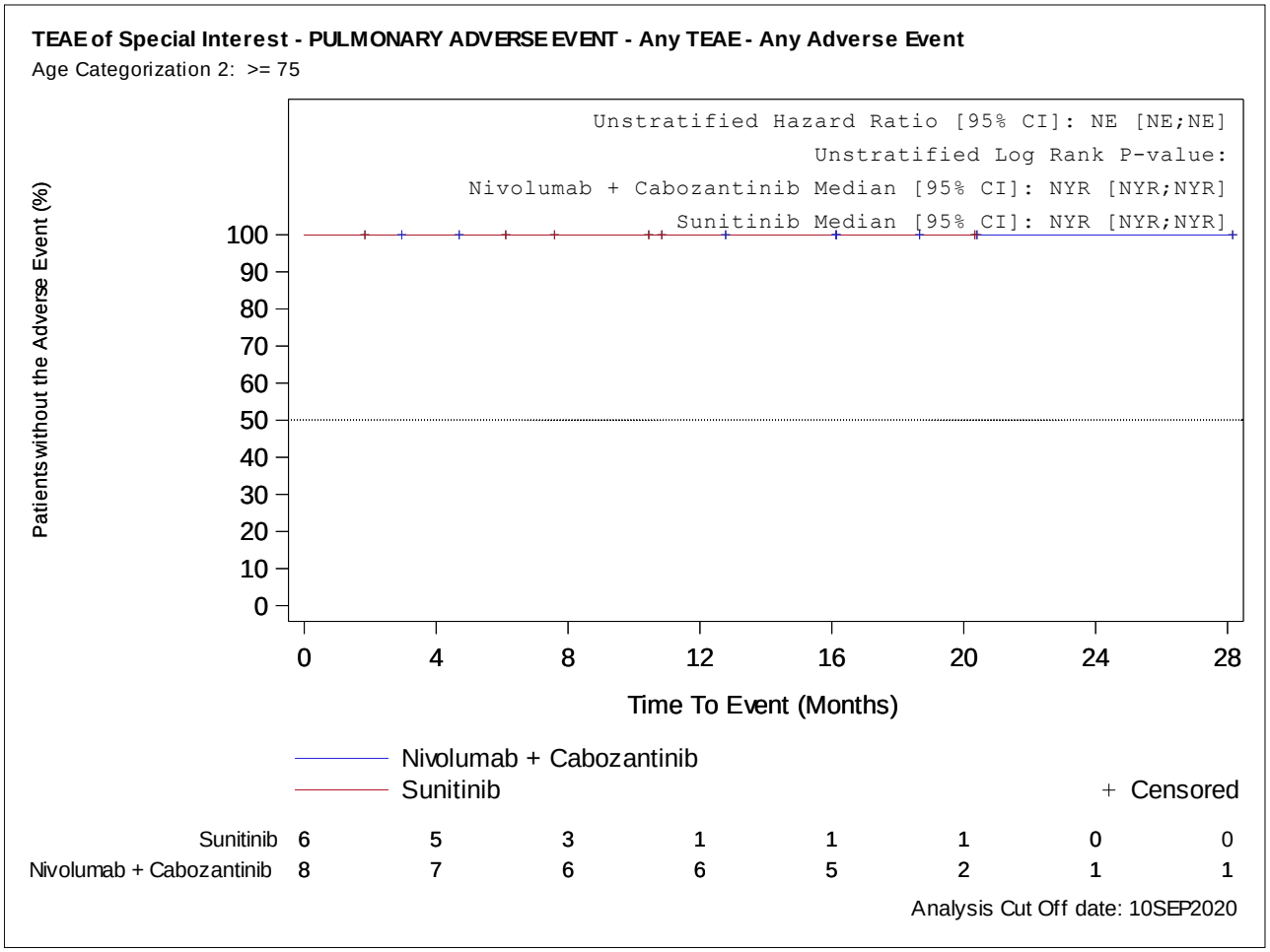

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:18:12

FIGURE 3.41.2.4: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



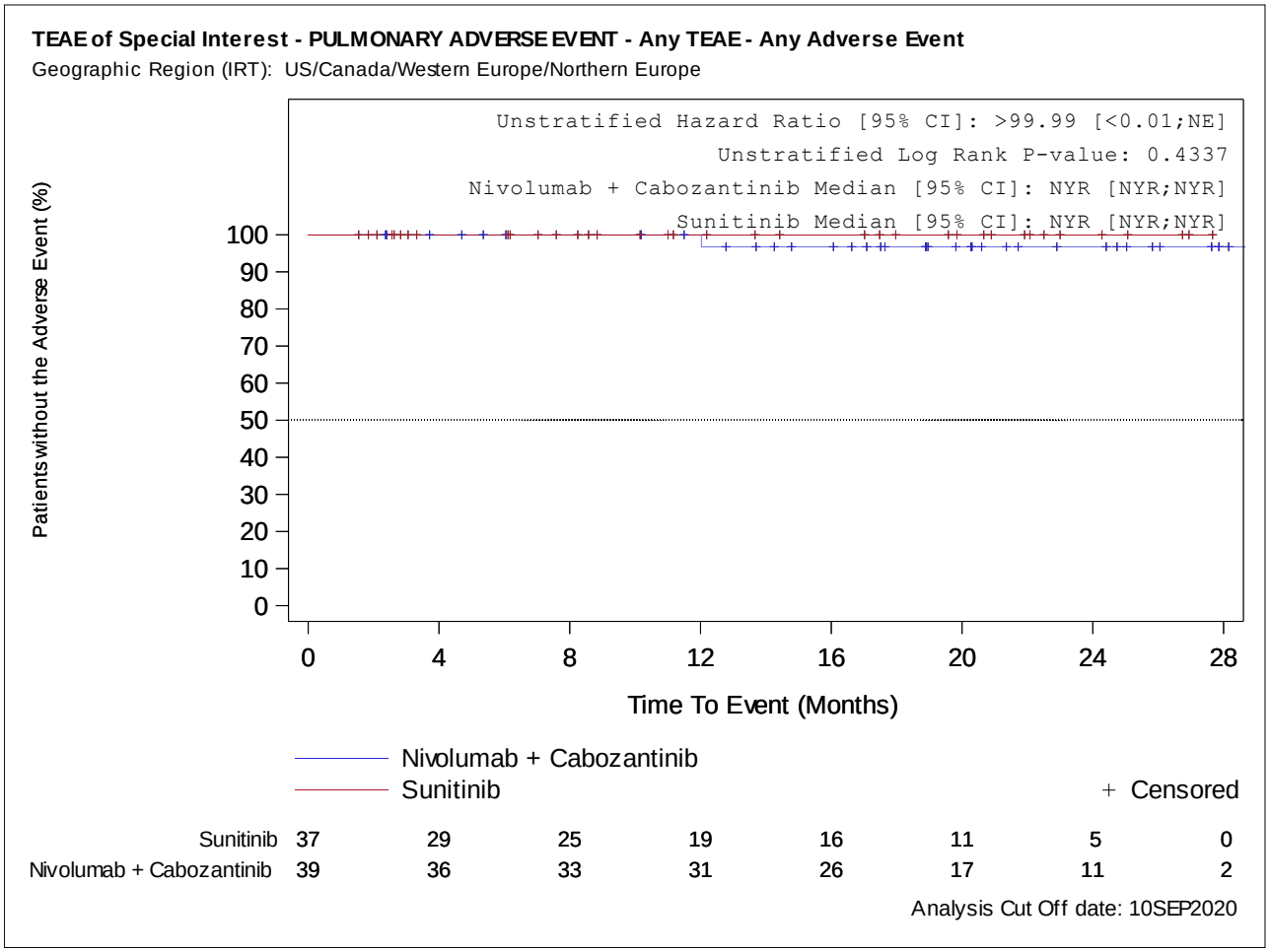

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:18:18

FIGURE 3.41.2.5: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



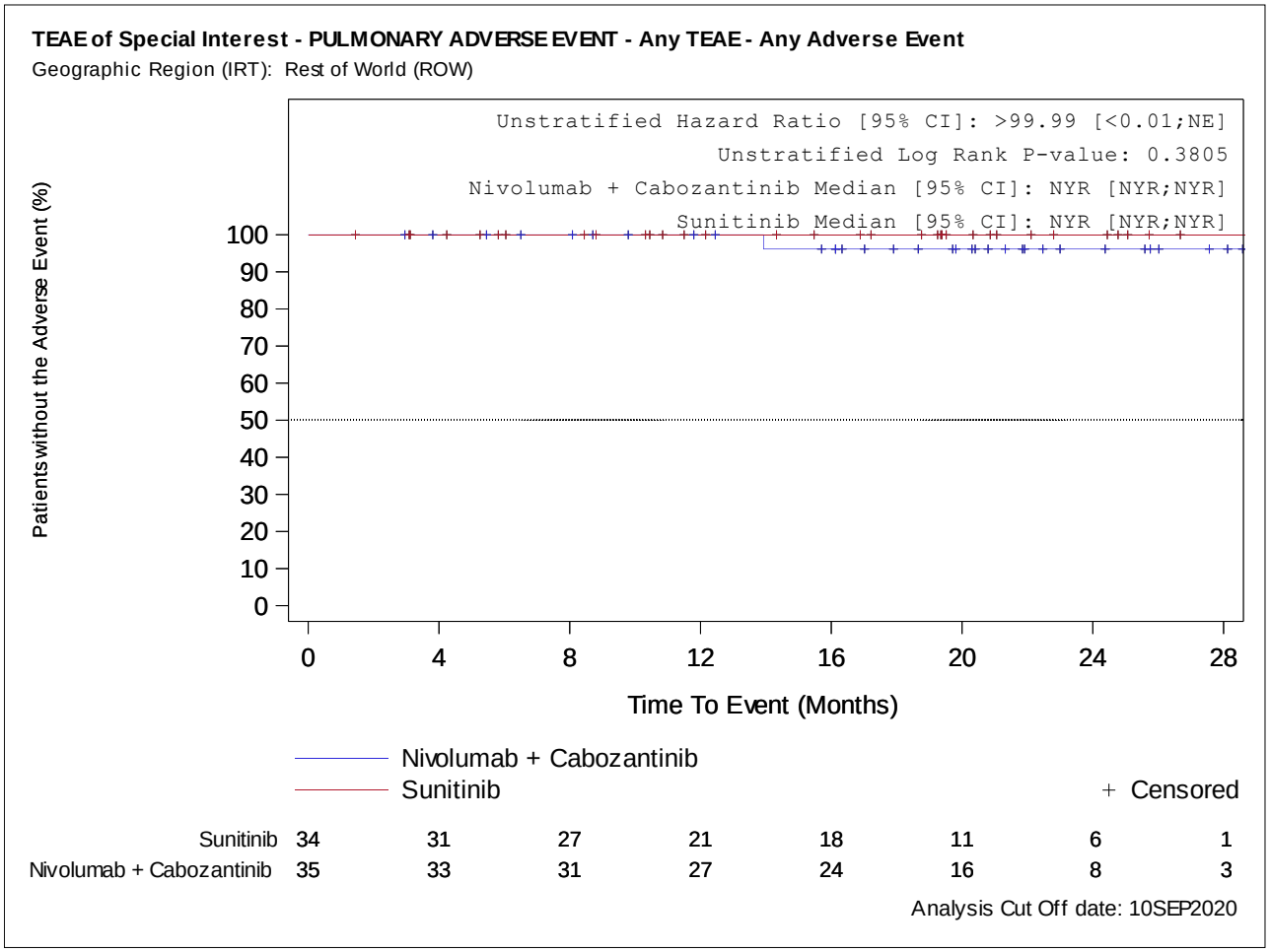

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:18:23

FIGURE 3.41.2.6: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



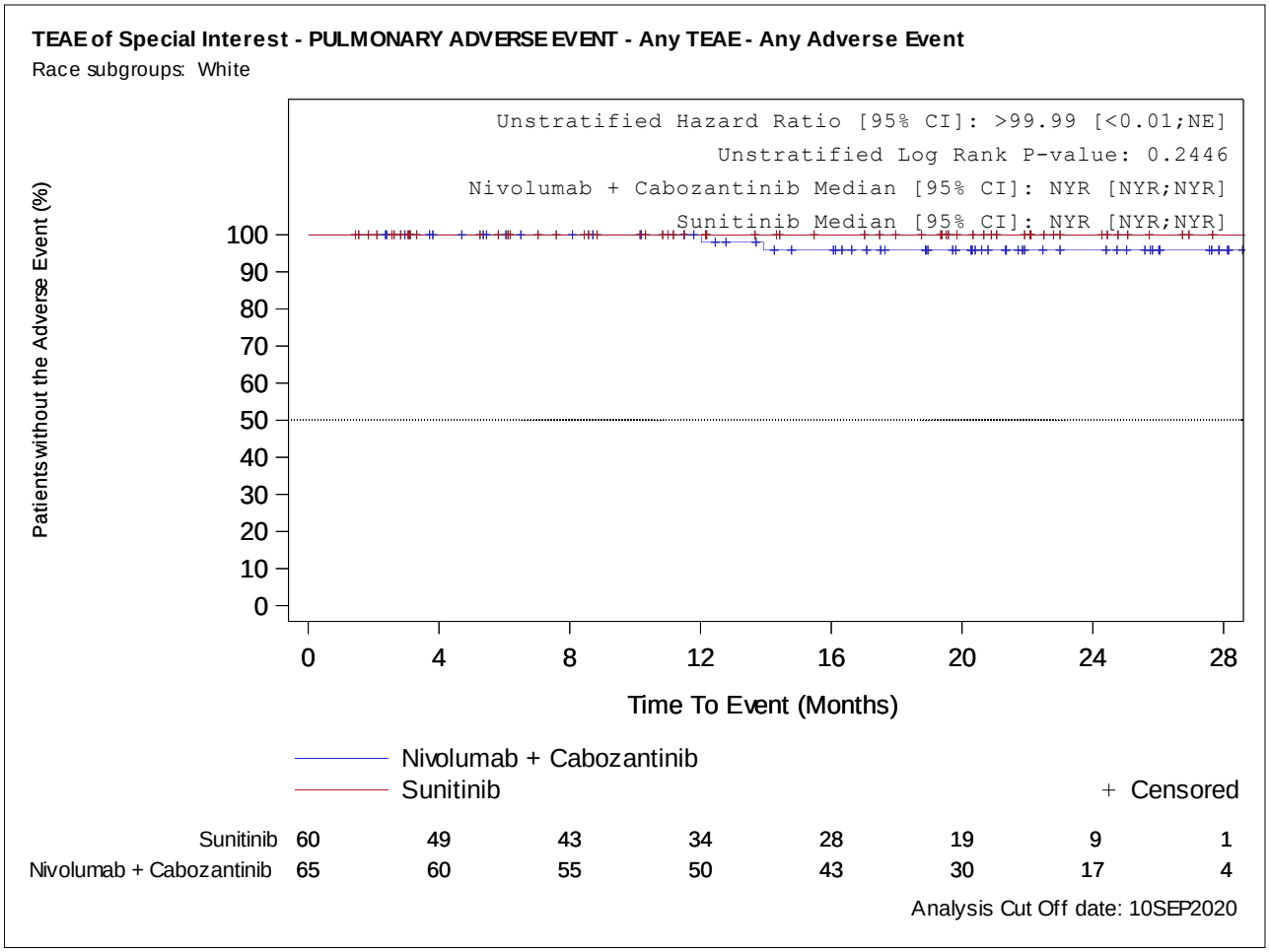

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:18:28

FIGURE 3.41.2.7: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



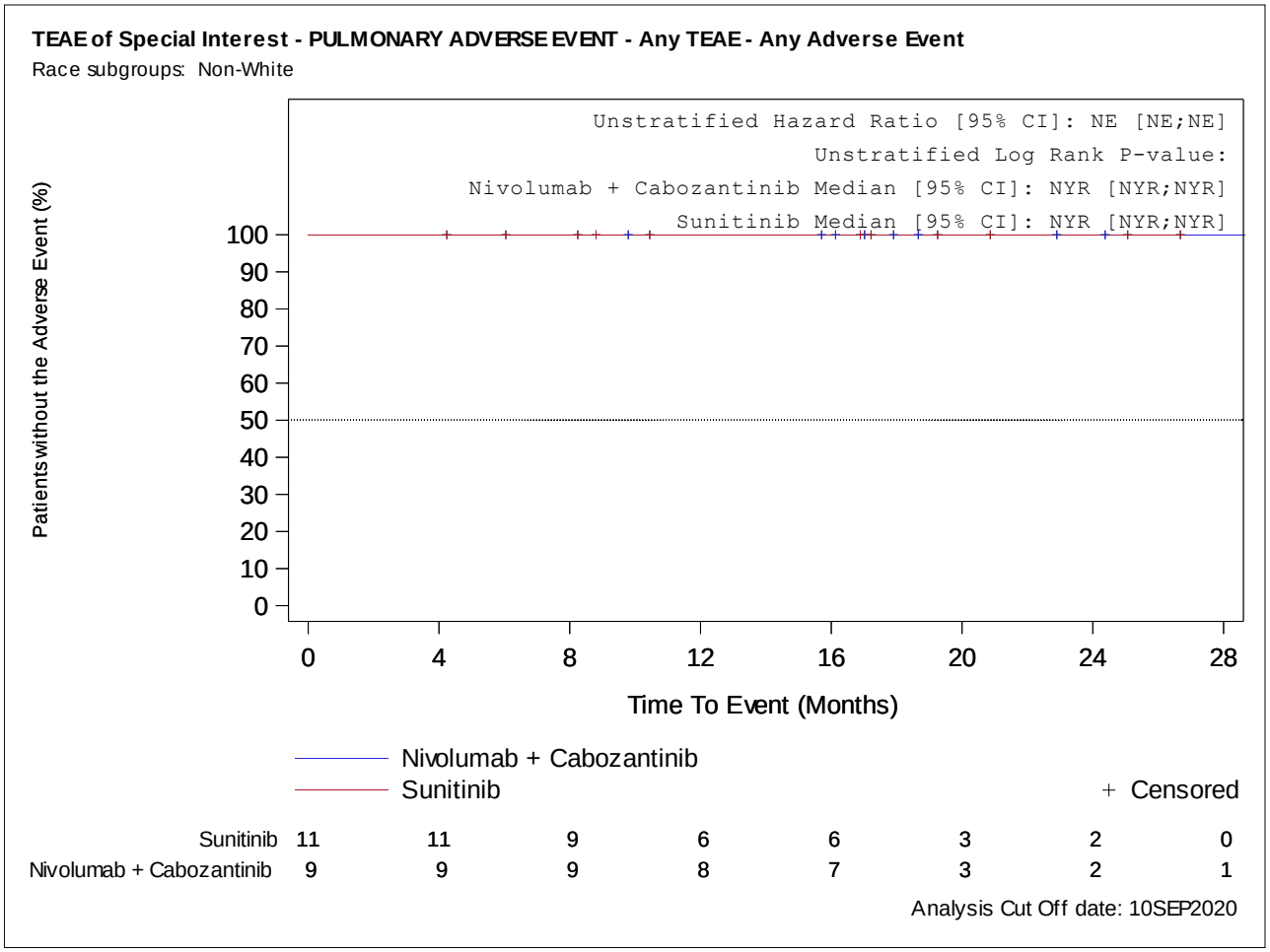

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:18:33

FIGURE 3.41.2.8: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



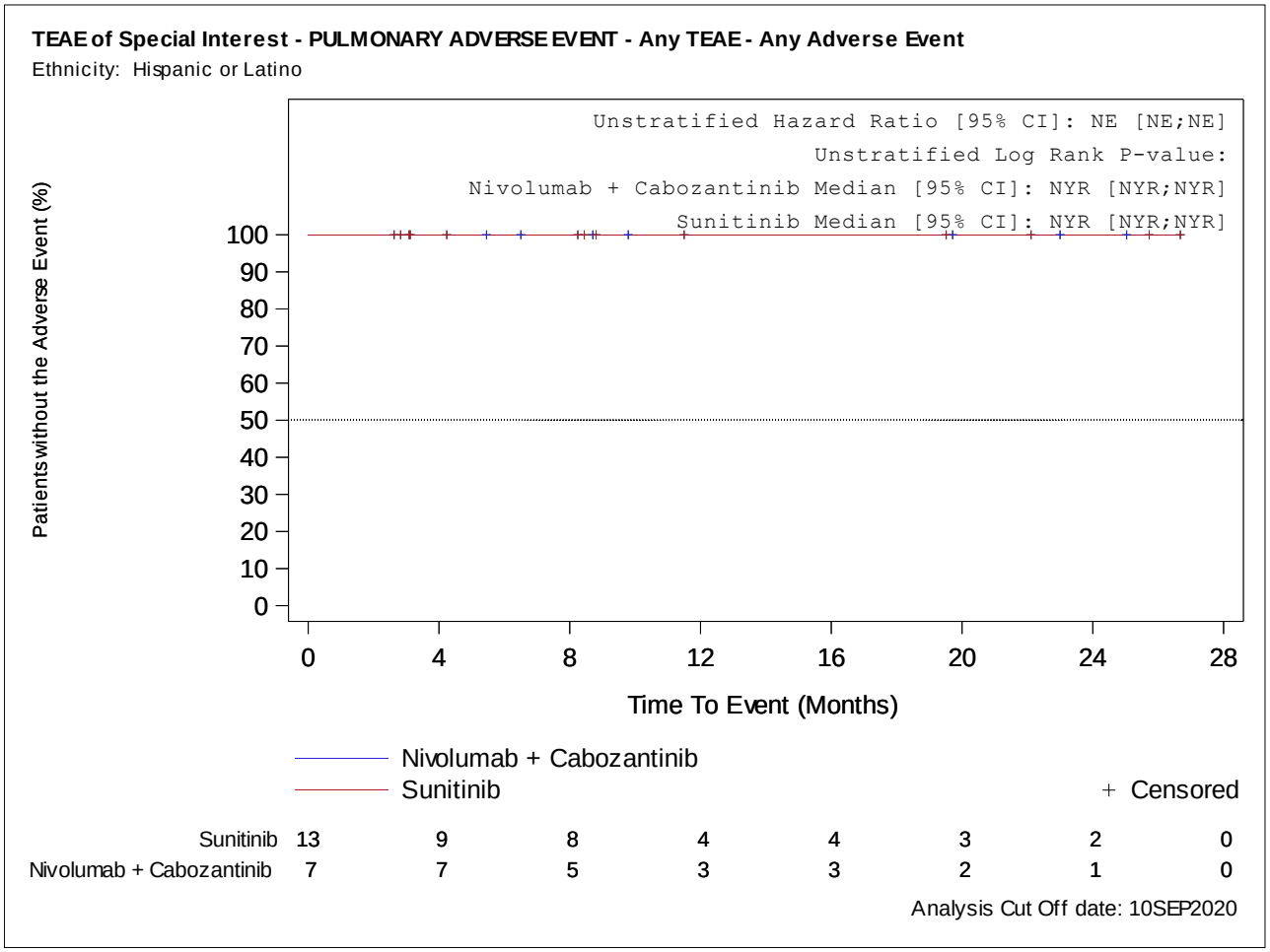

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:18:38

FIGURE 3.41.2.9: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



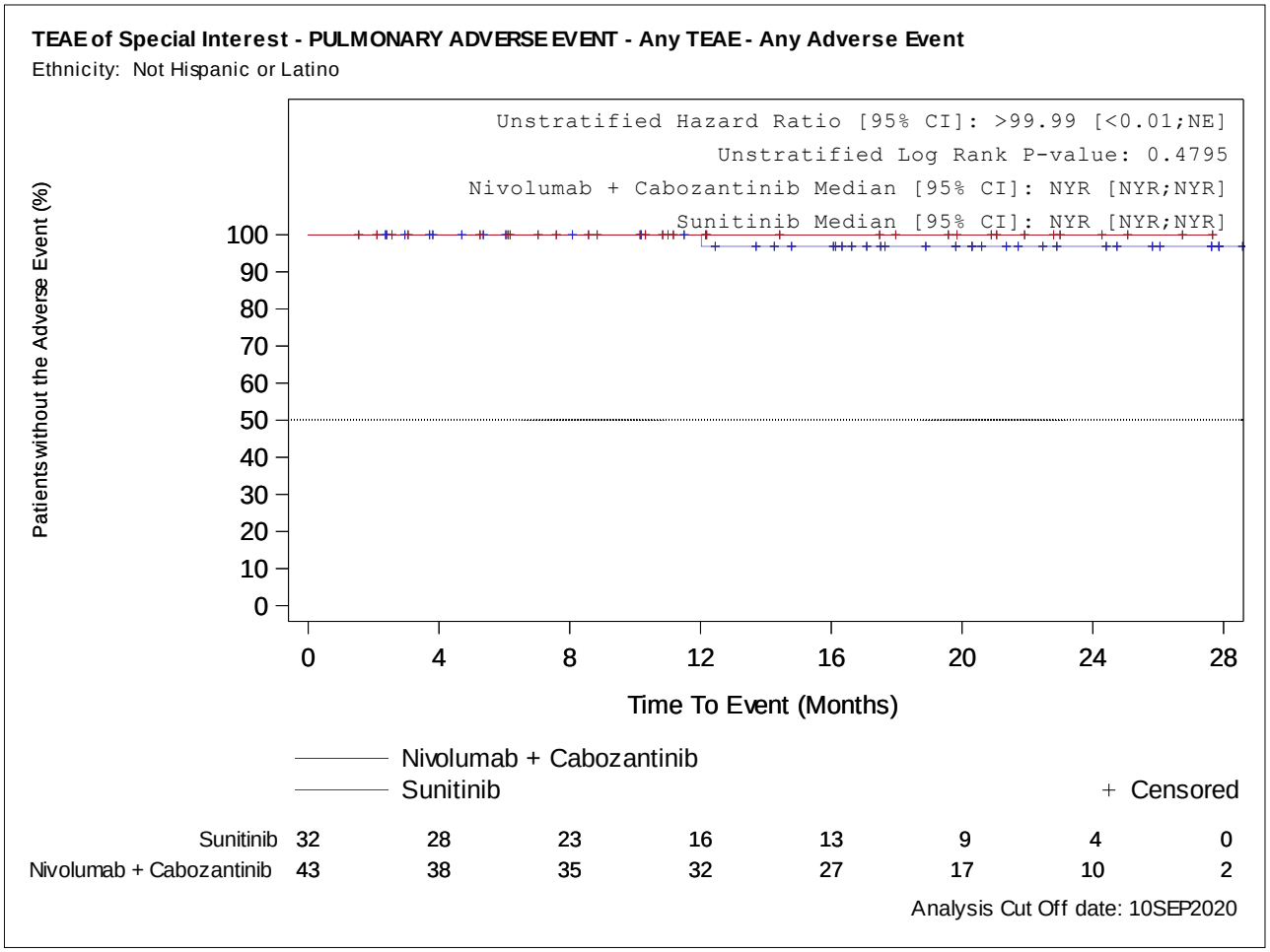

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:18:43

FIGURE 3.41.2.10: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



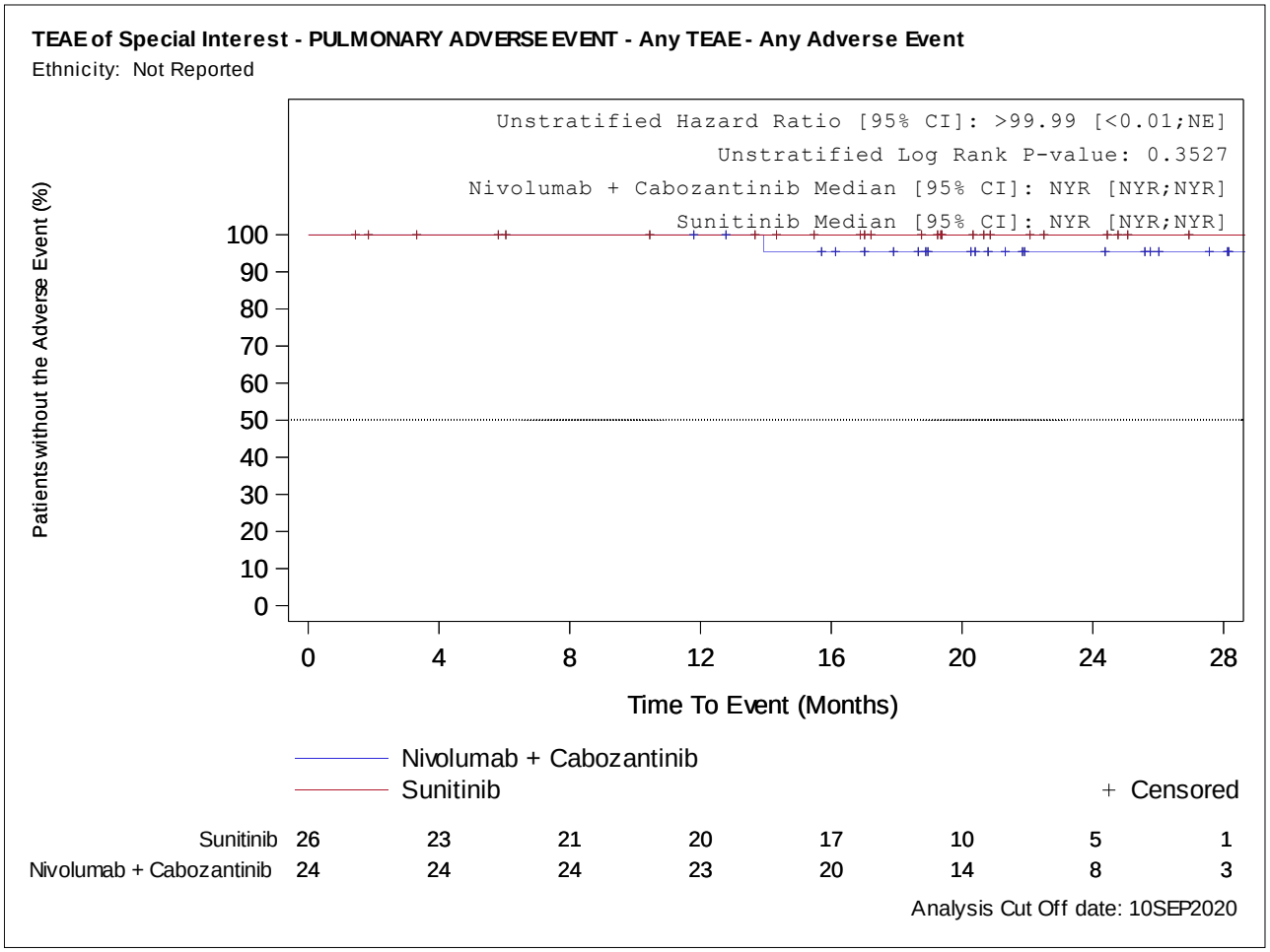

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:18:48

FIGURE 3.41.2.11: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



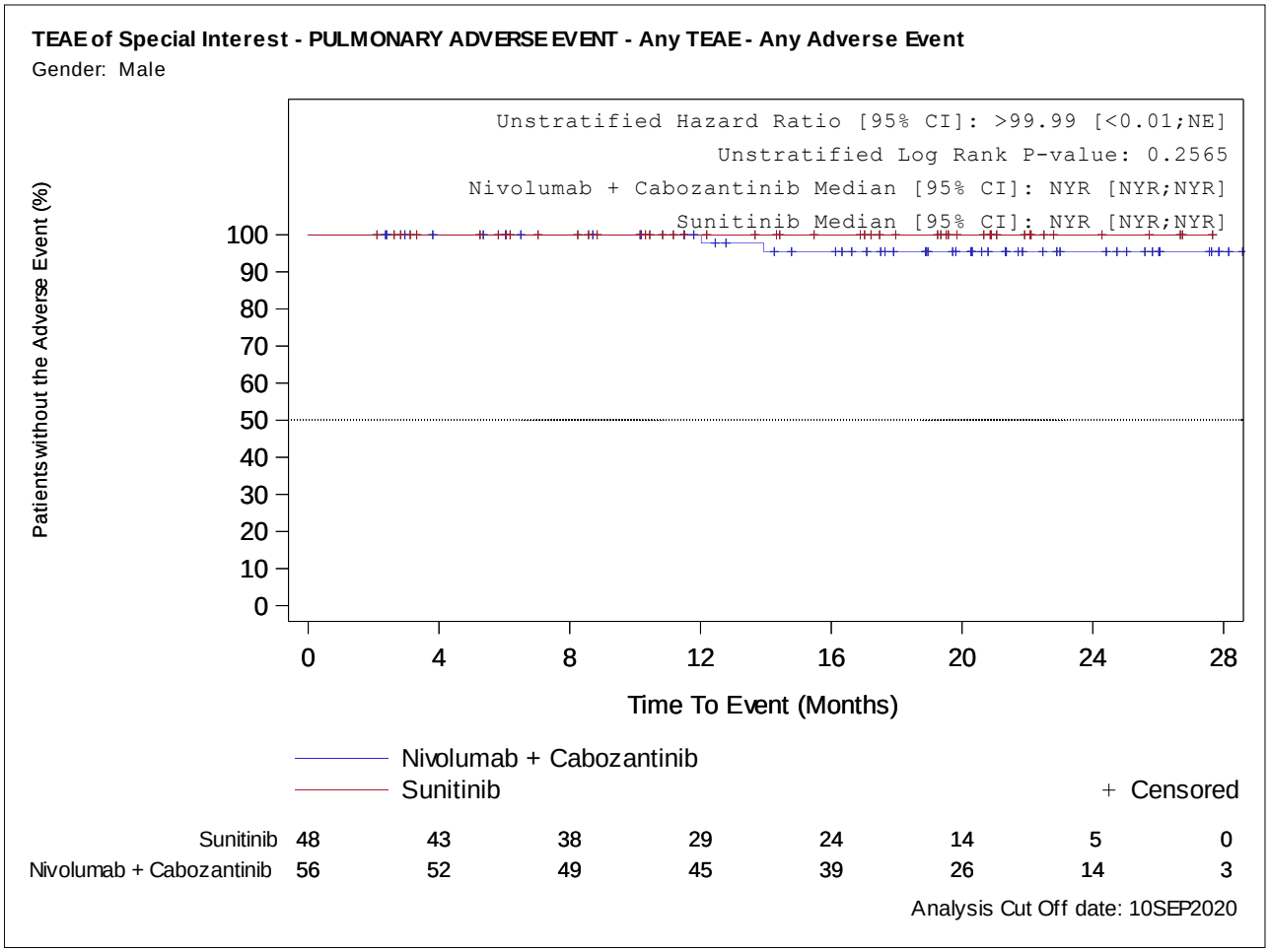

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:18:53

FIGURE 3.41.2.12: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



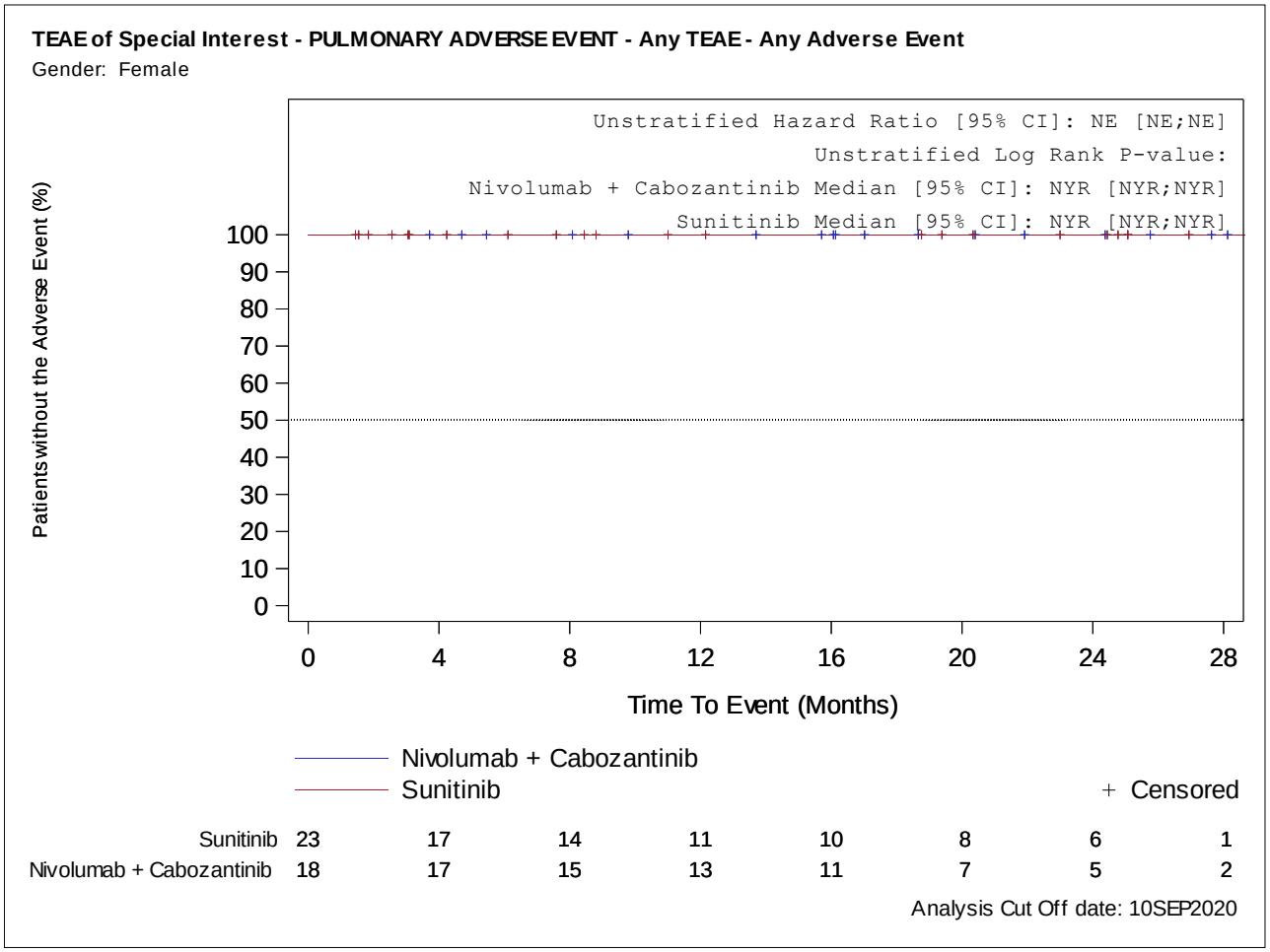

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:18:59

FIGURE 3.41.2.13: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



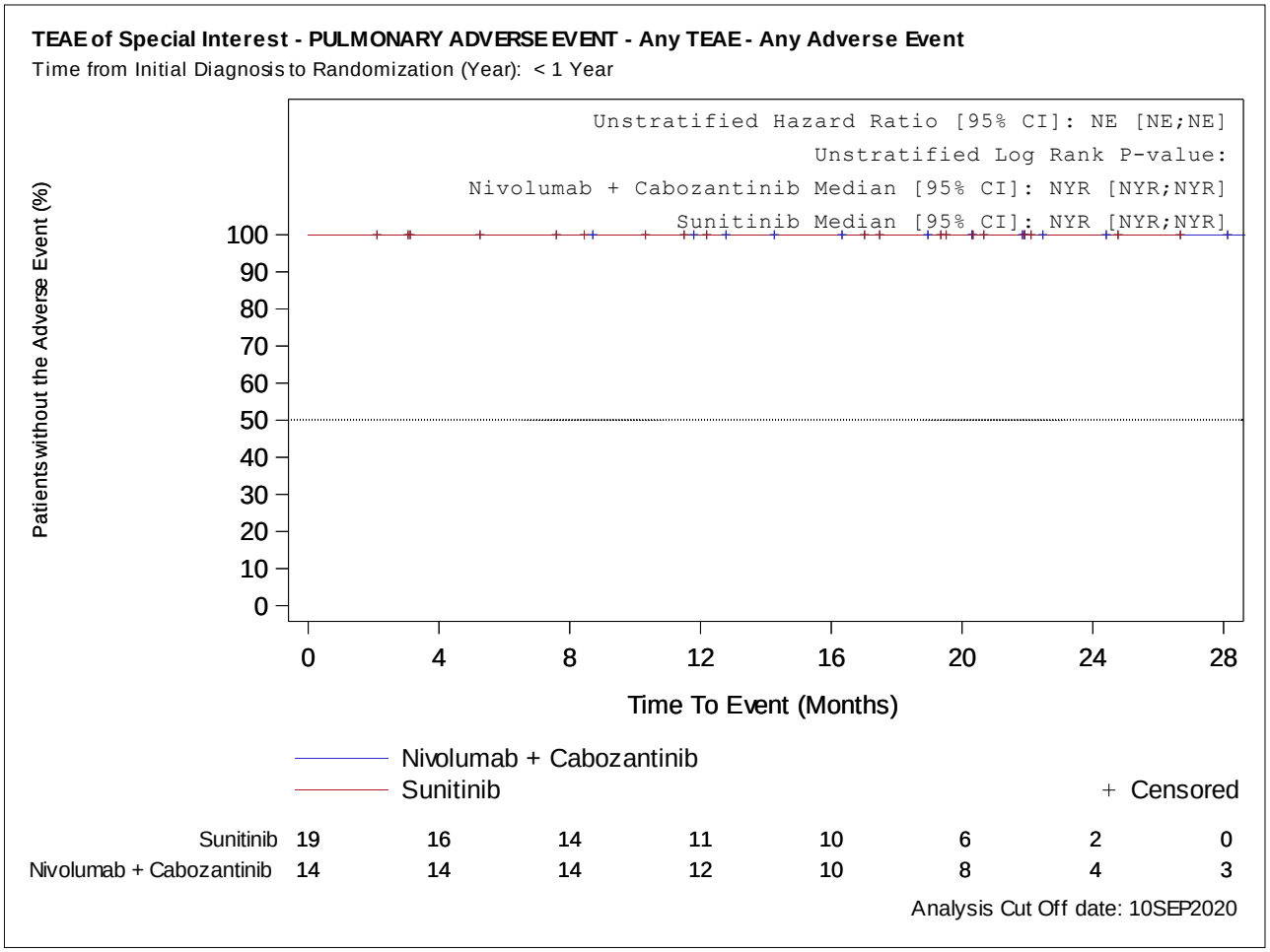

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:19:04

FIGURE 3.41.2.14: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



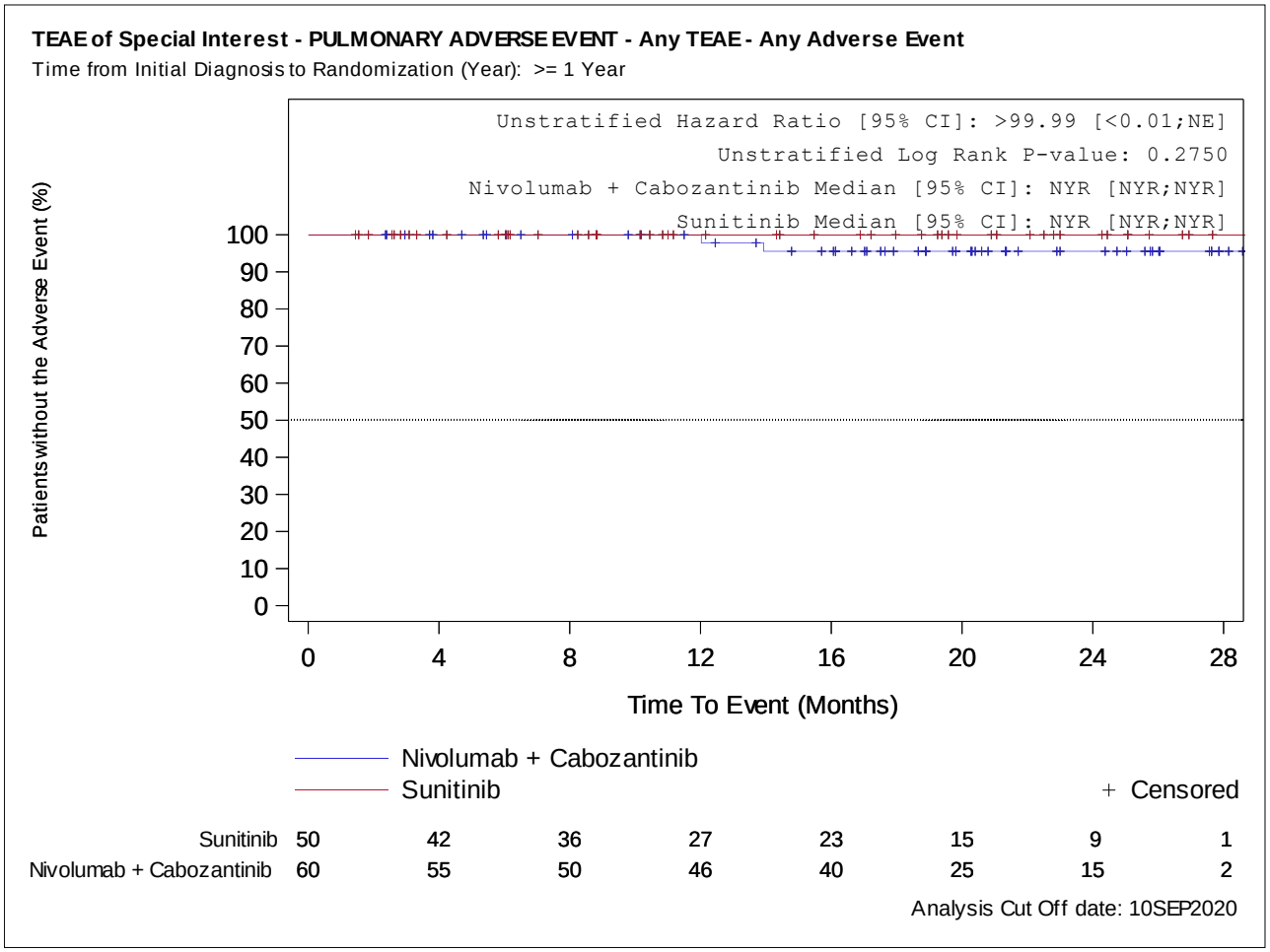

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:19:09

FIGURE 3.41.2.15: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



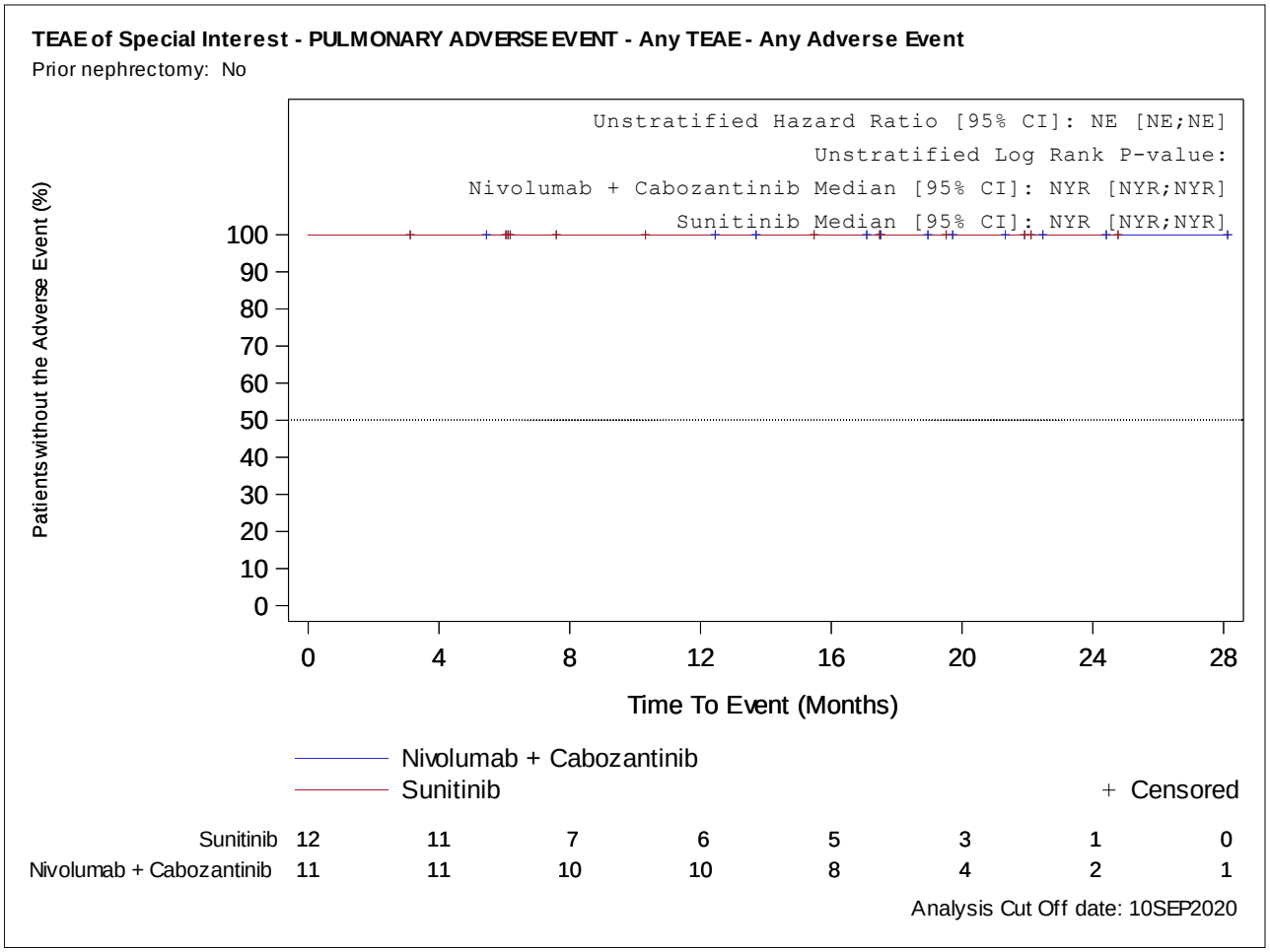

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:19:24

FIGURE 3.41.2.16: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



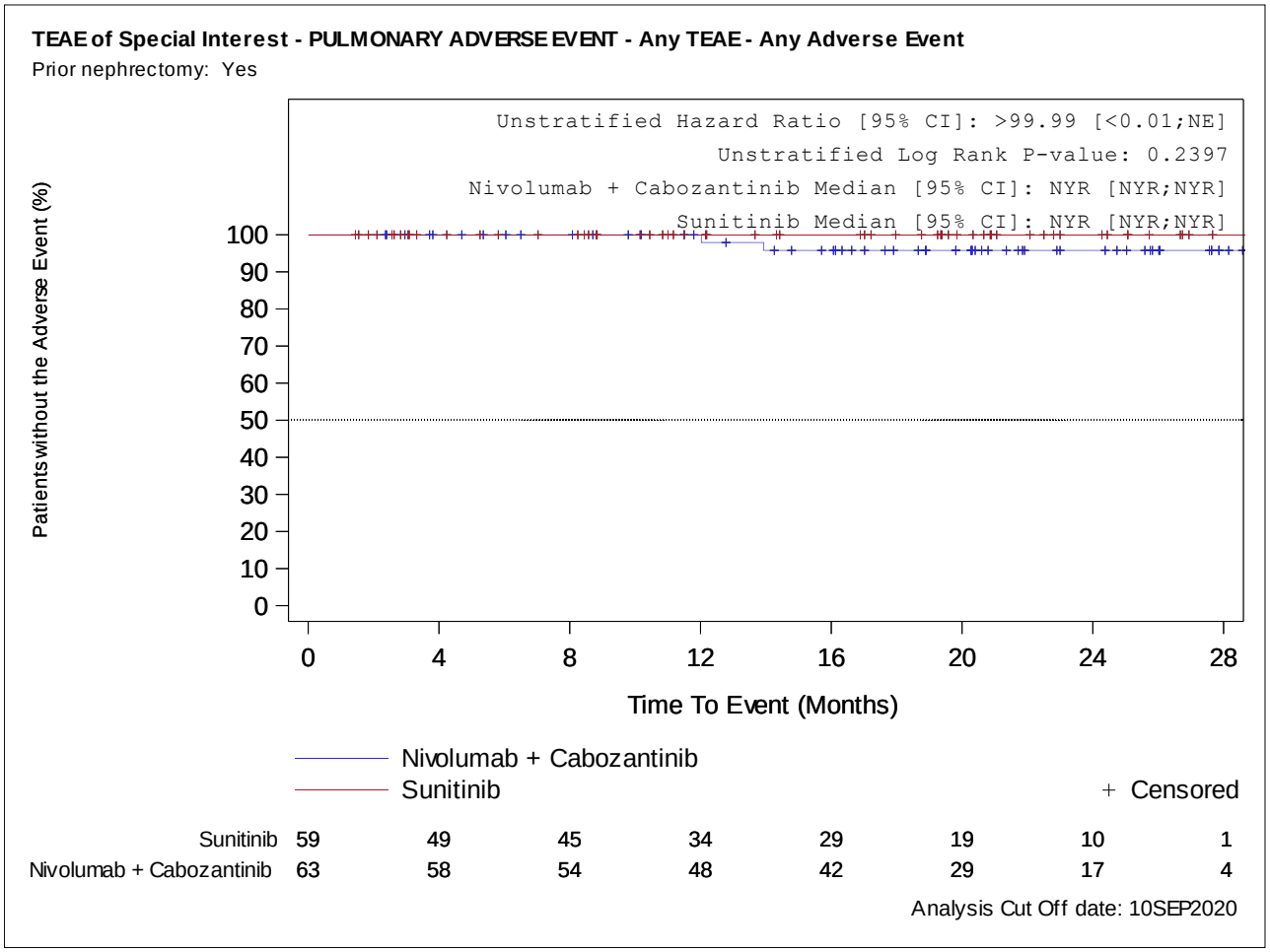

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:19:29

FIGURE 3.41.2.17: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



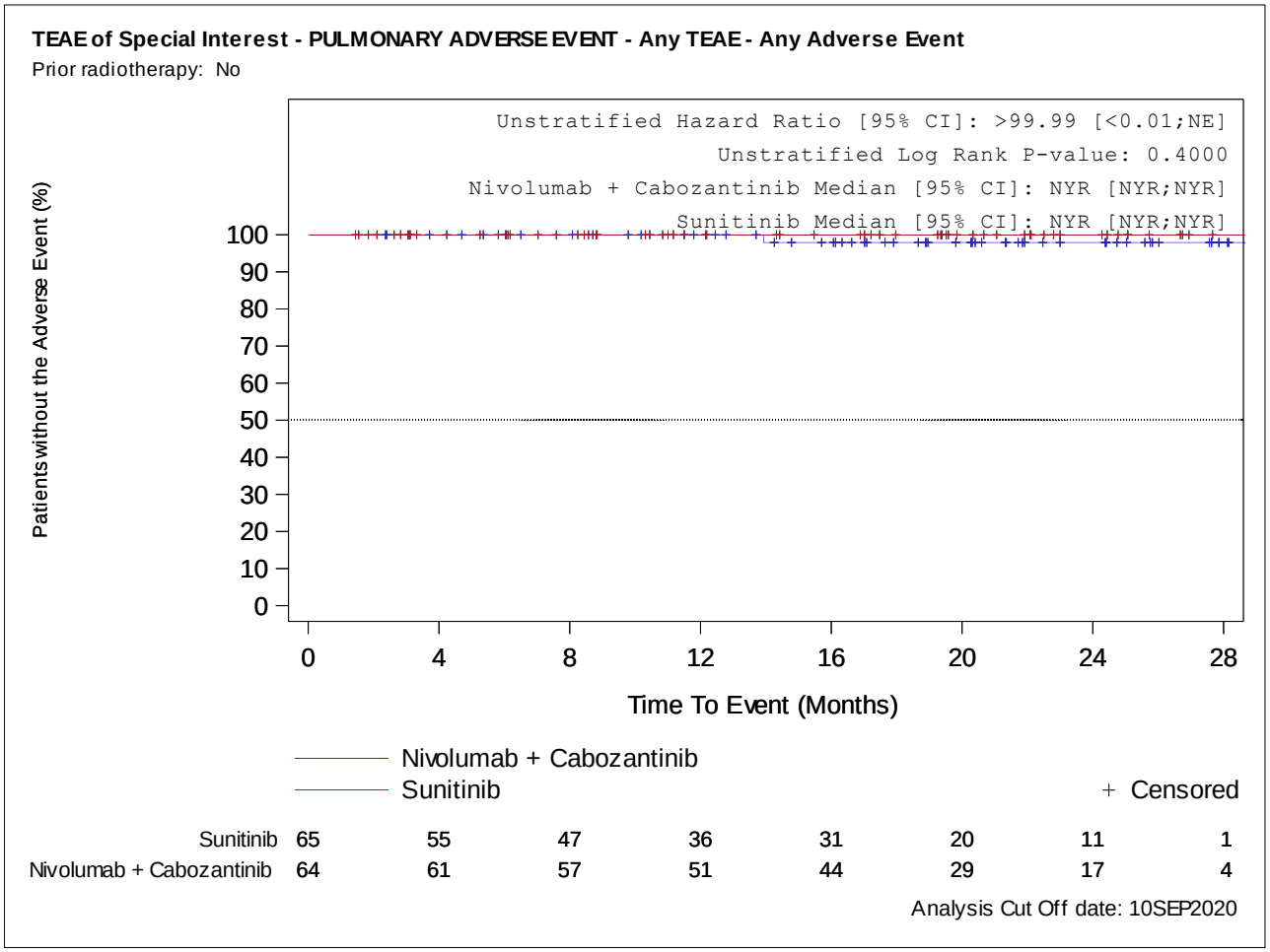

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:20:16

FIGURE 3.41.2.18: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



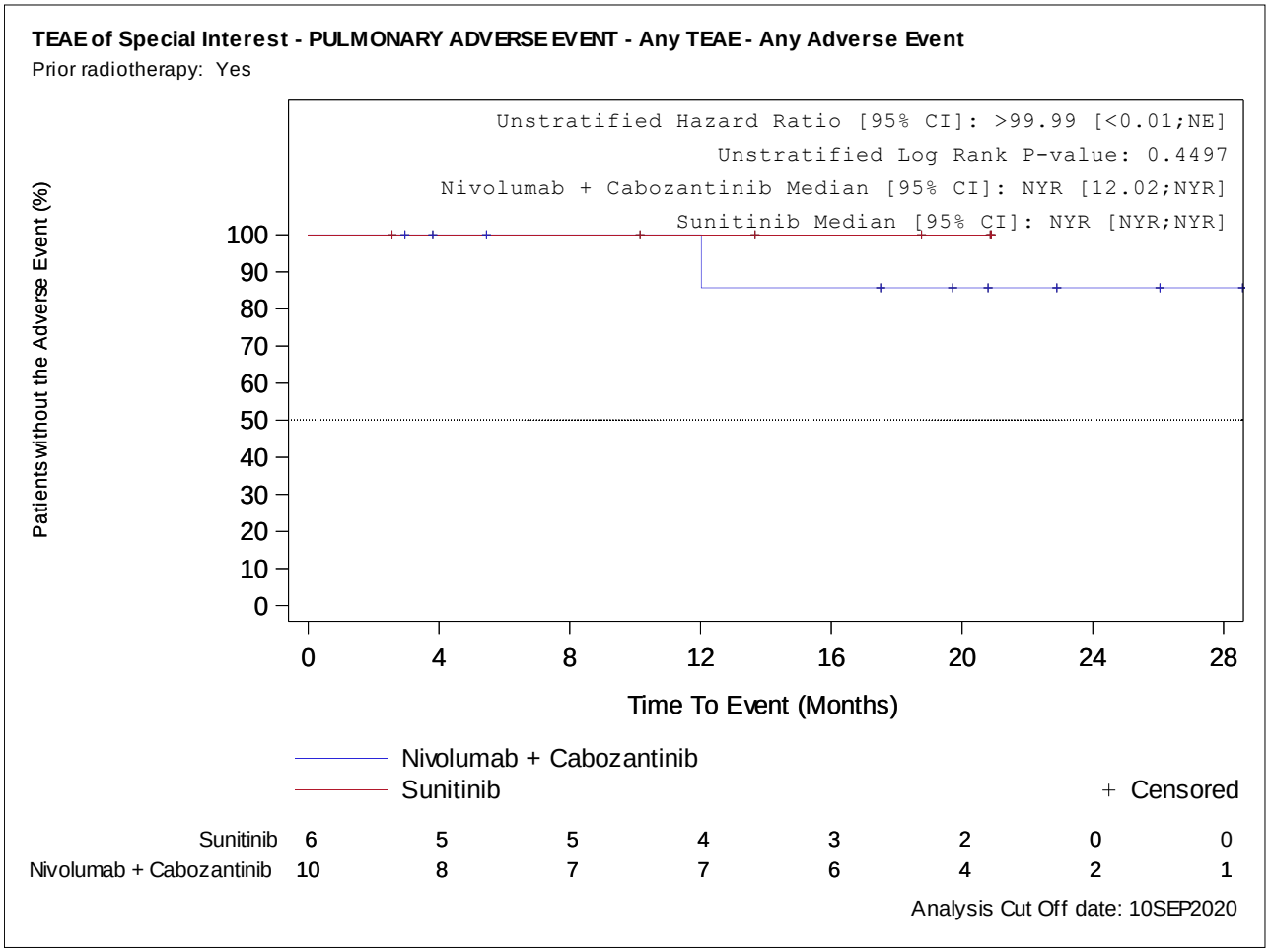

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:20:21

FIGURE 3.41.2.19: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



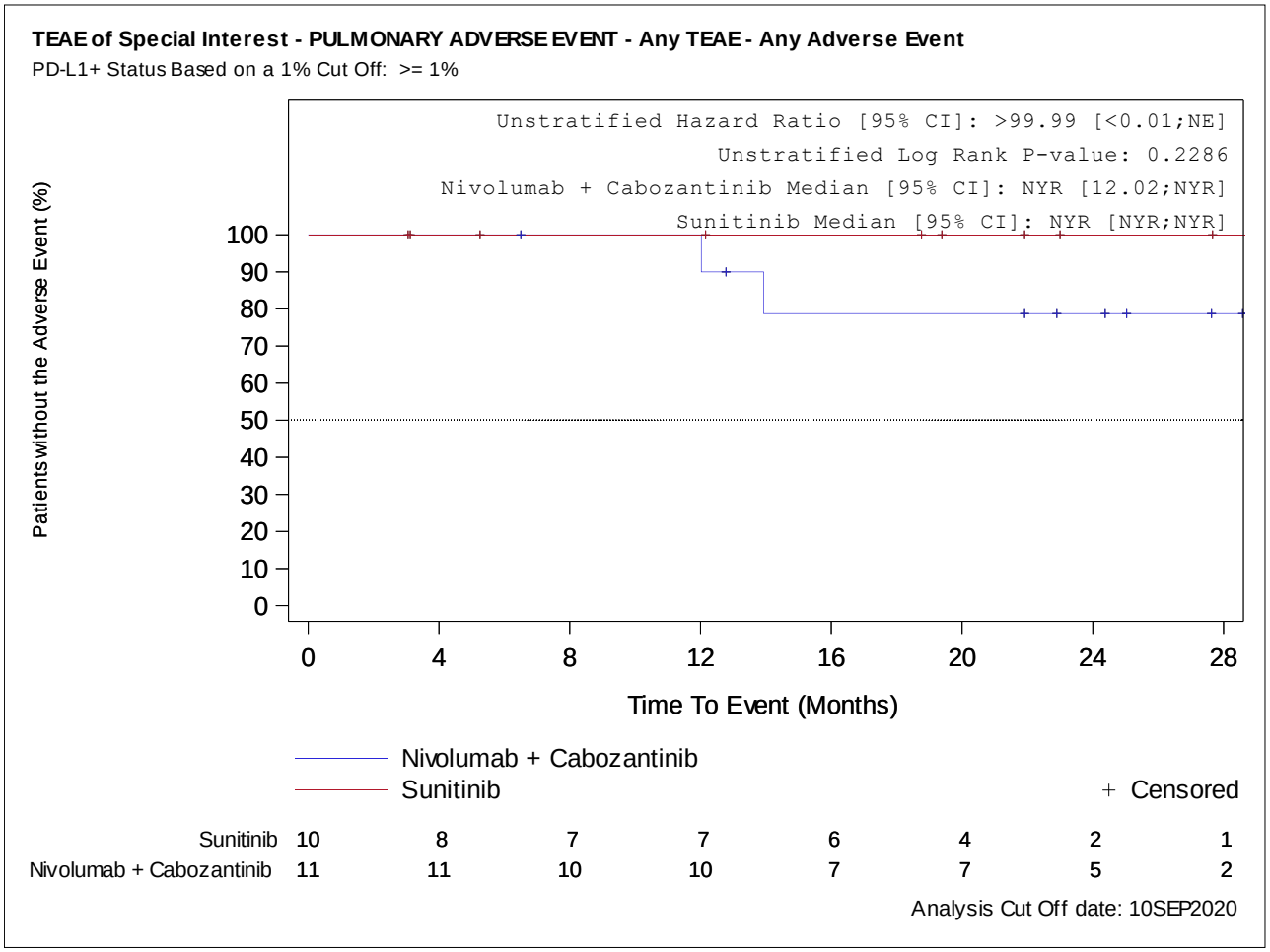

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:20:26

FIGURE 3.41.2.20: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:20:31

FIGURE 3.41.2.21: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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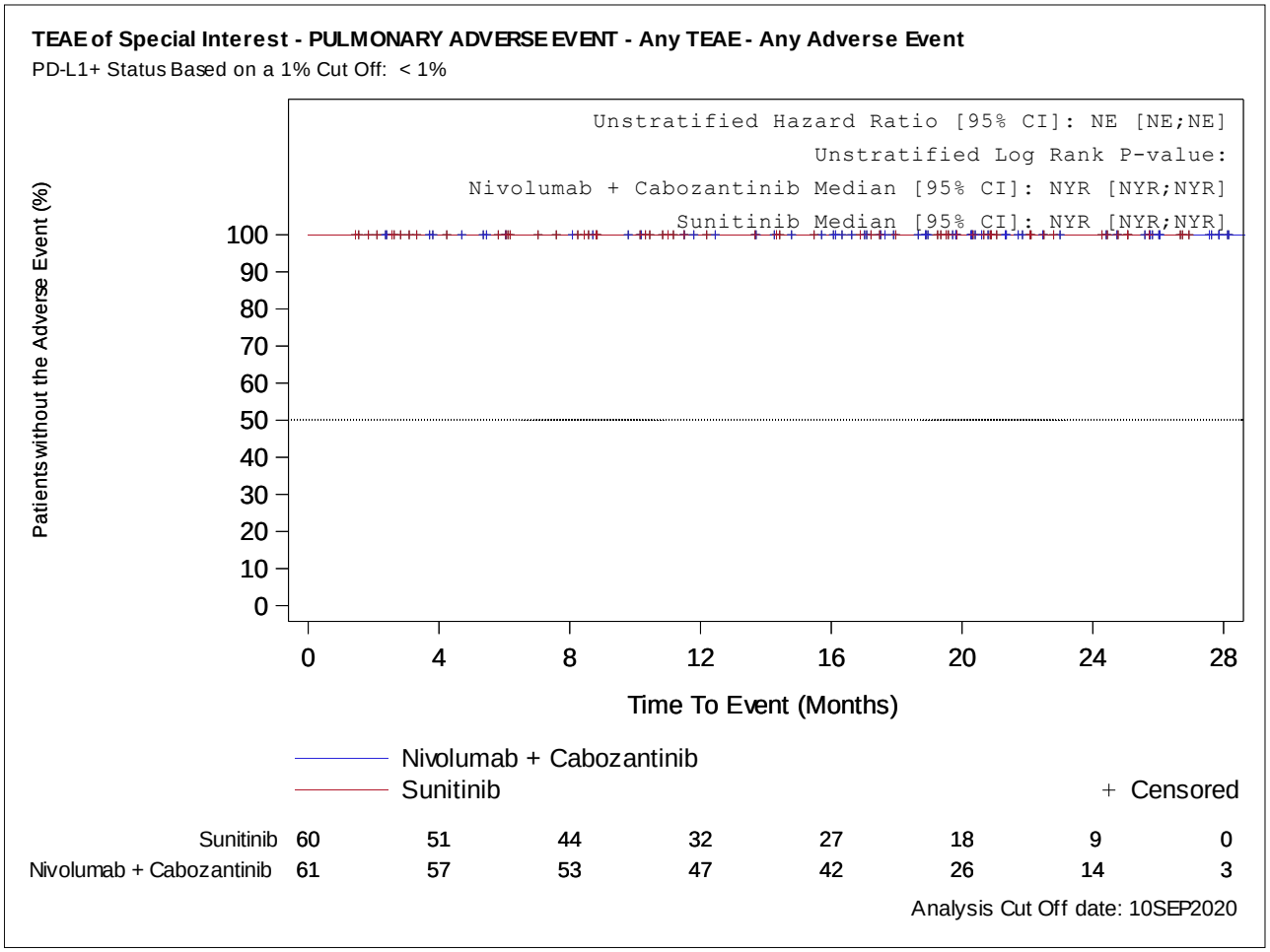
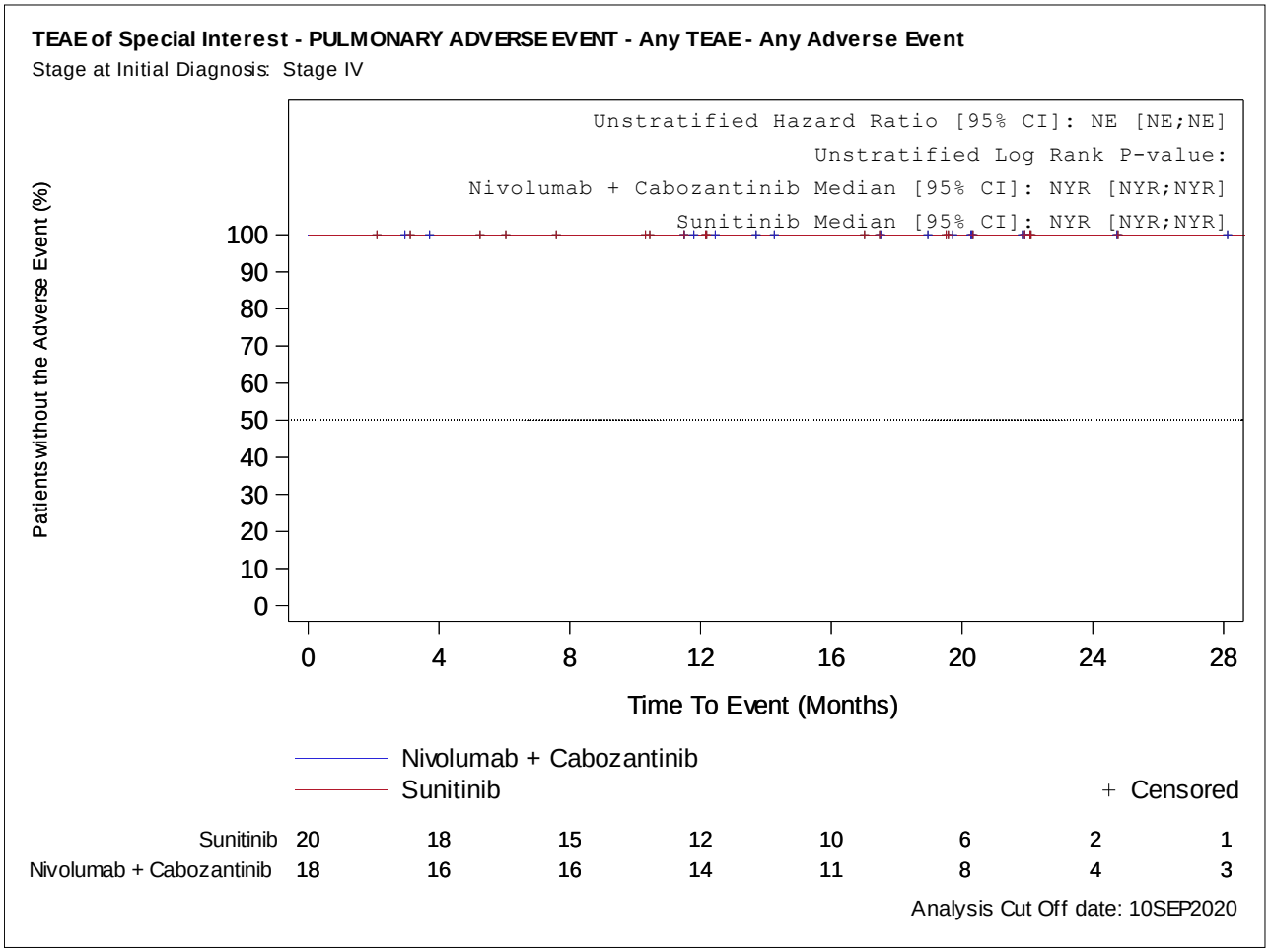
FIGURE 3.41.2.22: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



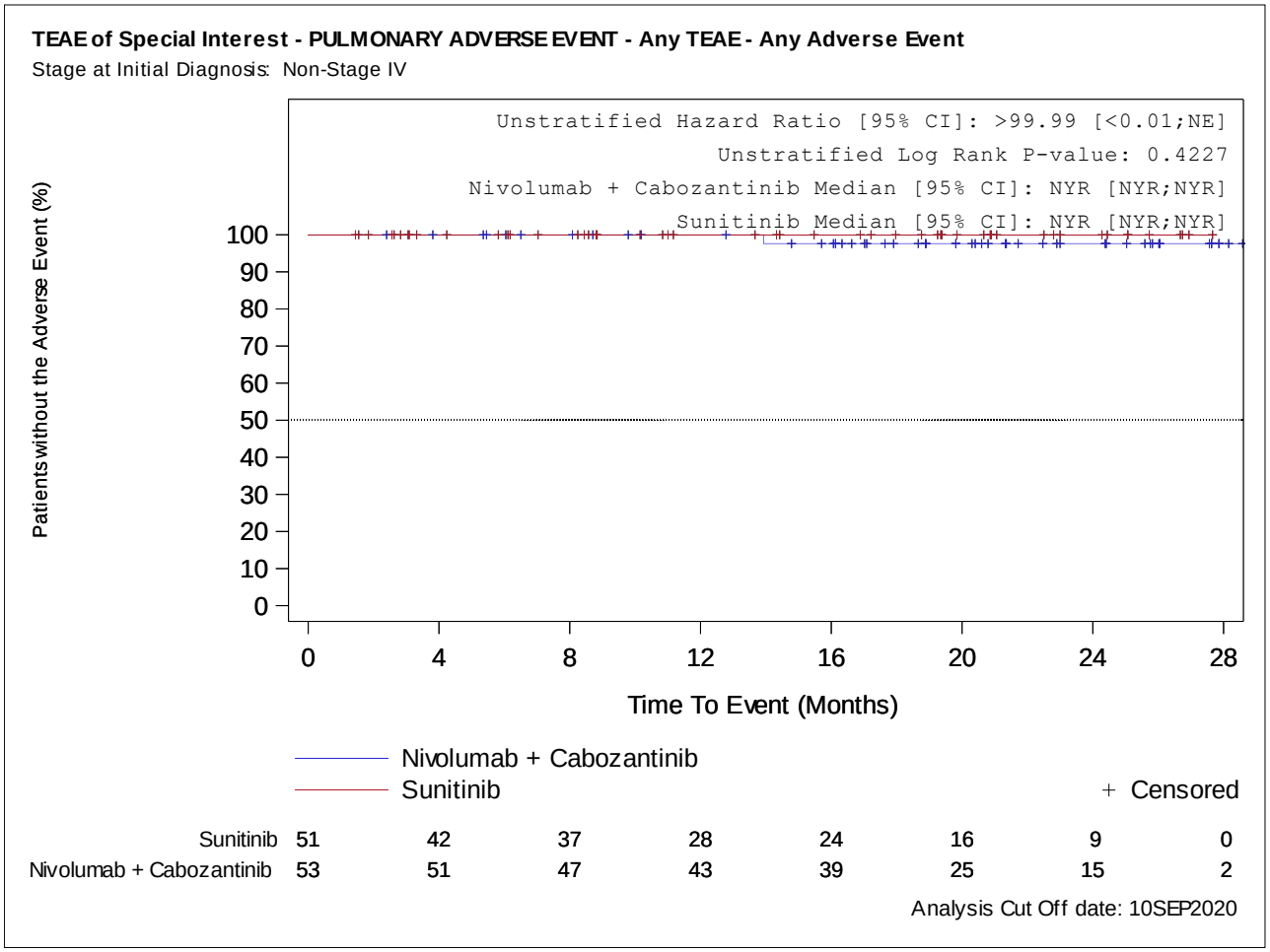

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:20:41

FIGURE 3.41.2.23: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



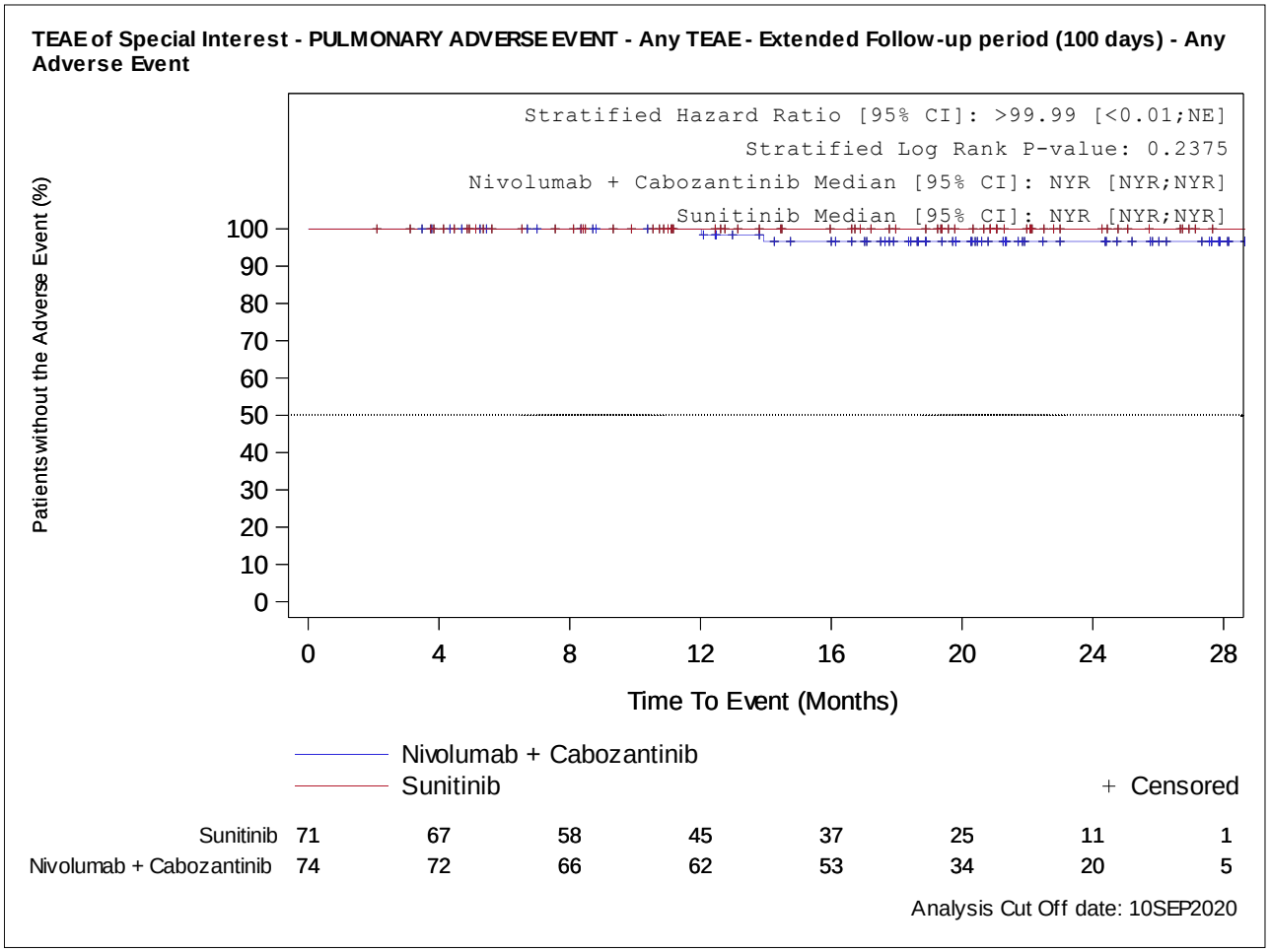

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:21:07

FIGURE 3.41.2.24: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



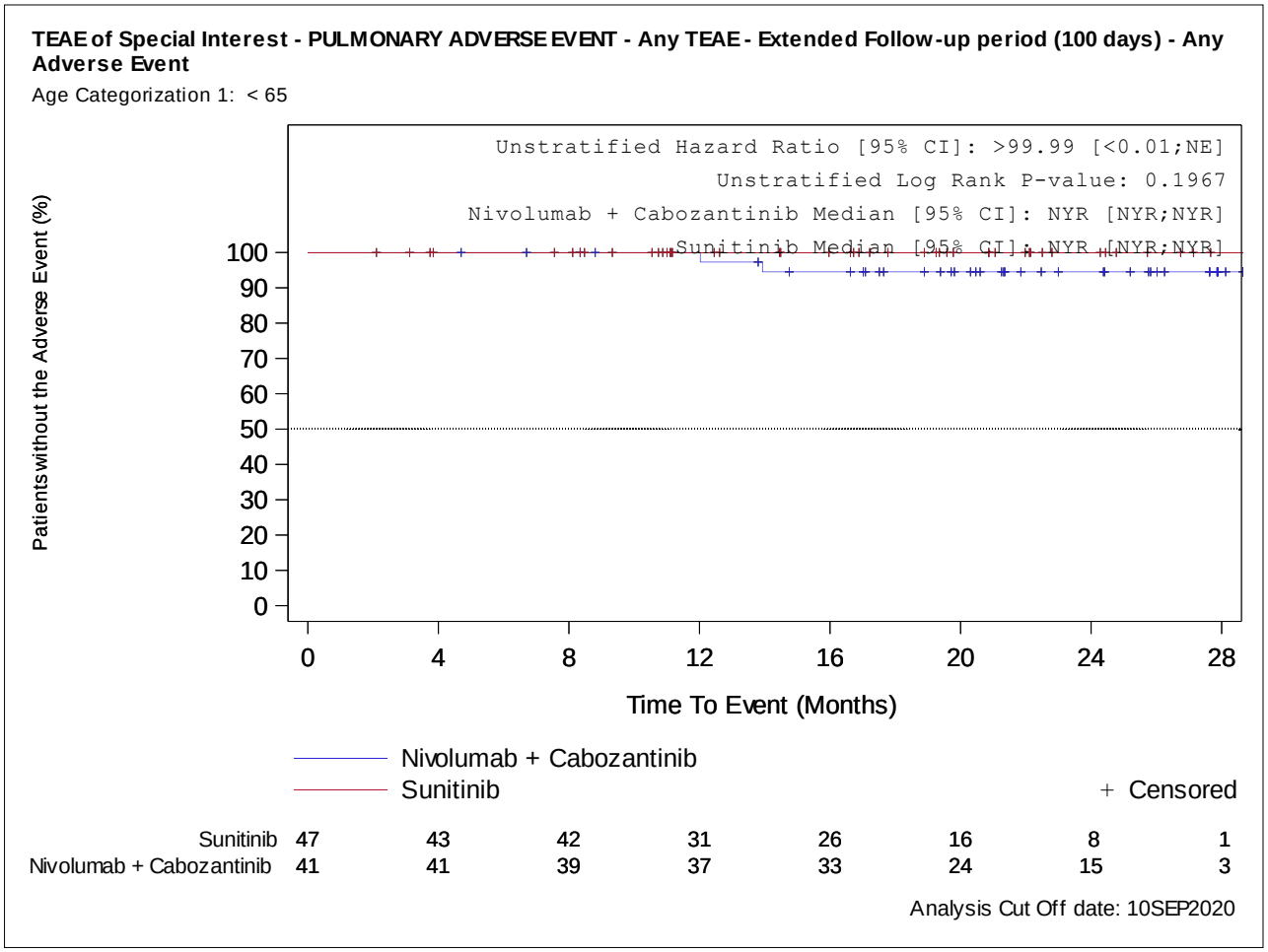

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:21:12

FIGURE 3.42.1: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



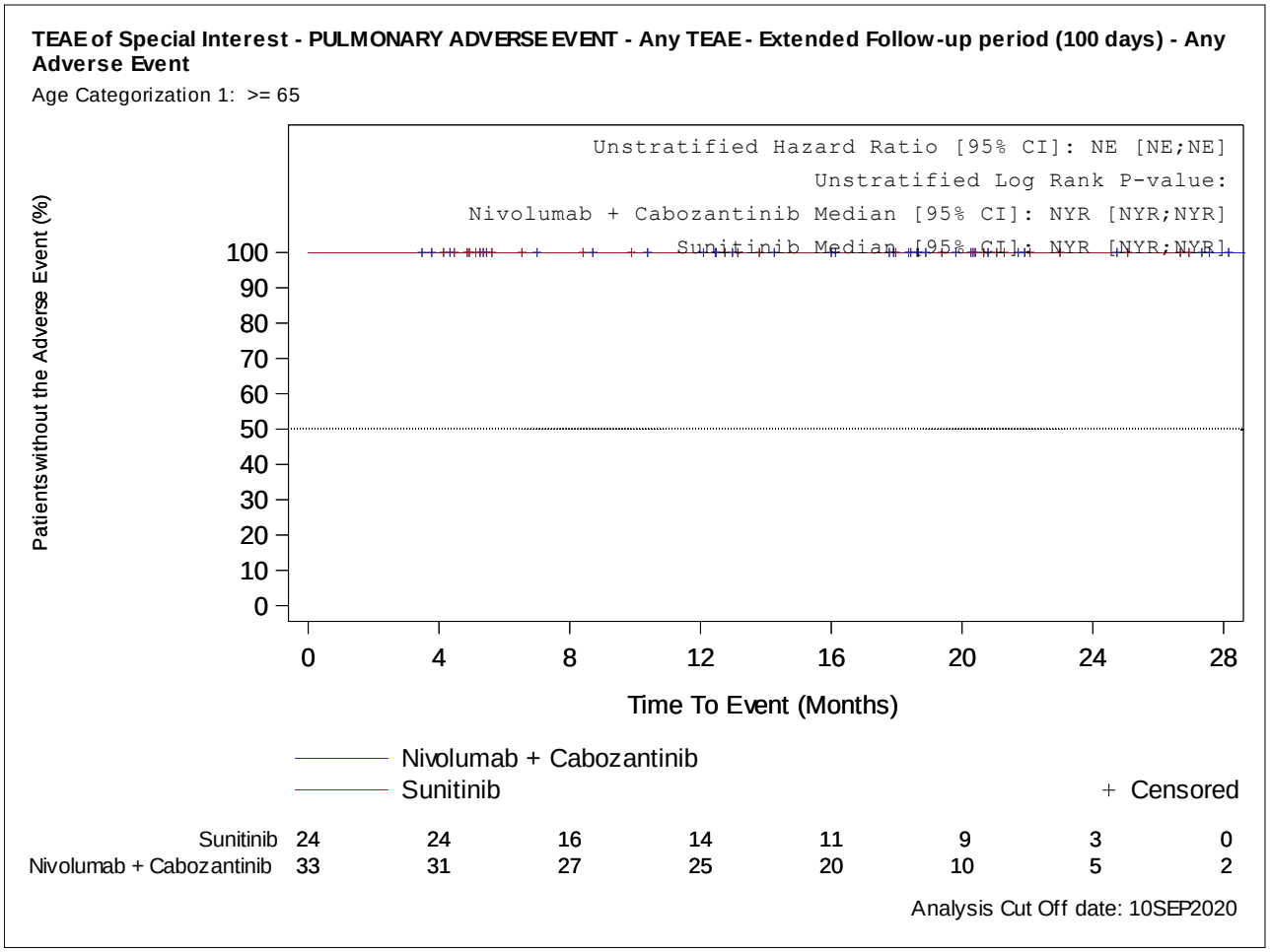

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:24:12

FIGURE 3.42.2.1: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



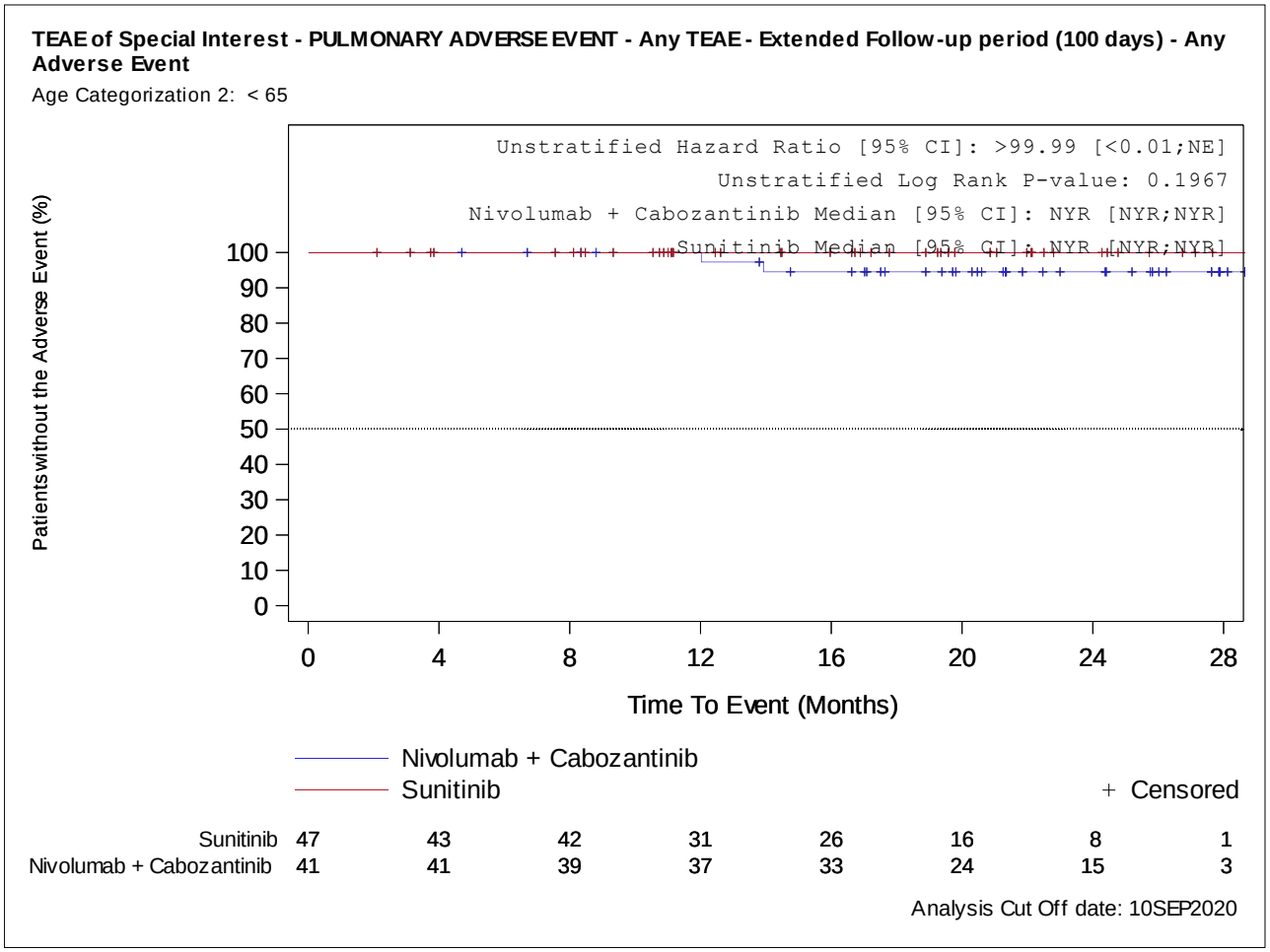

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:24:15

FIGURE 3.42.2.2: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



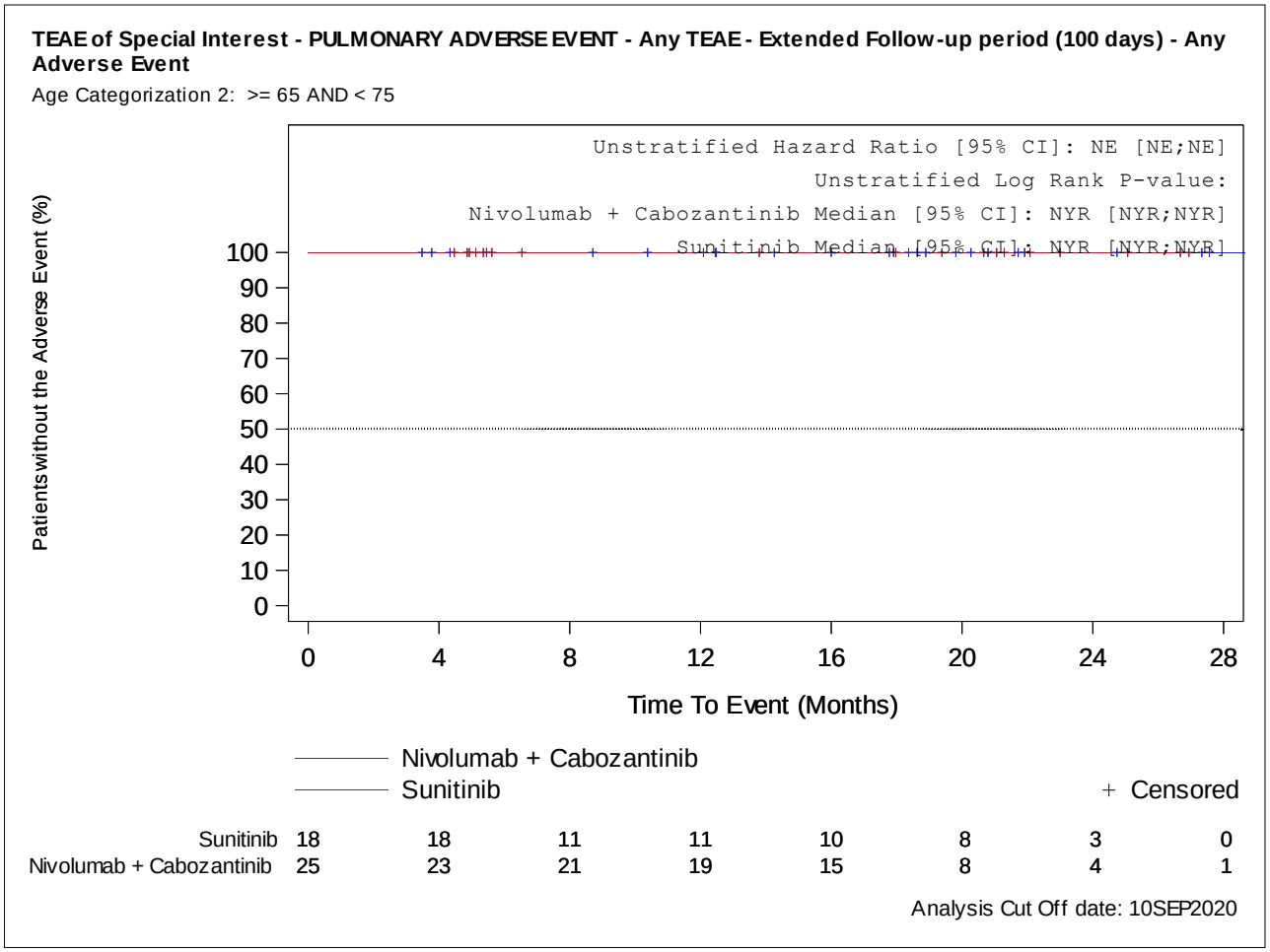

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:24:21

FIGURE 3.42.2.3: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



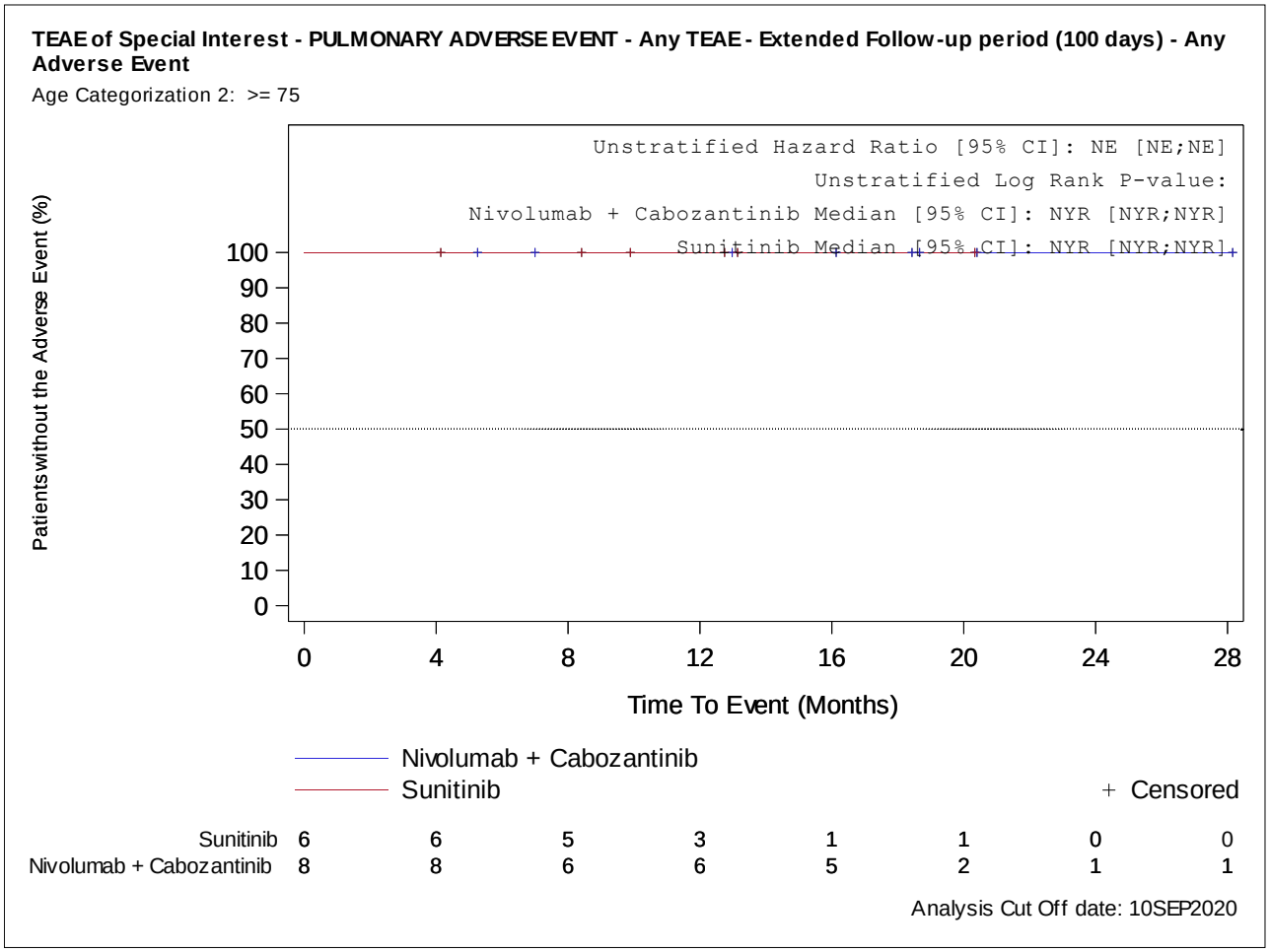

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:24:27

FIGURE 3.42.2.4: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



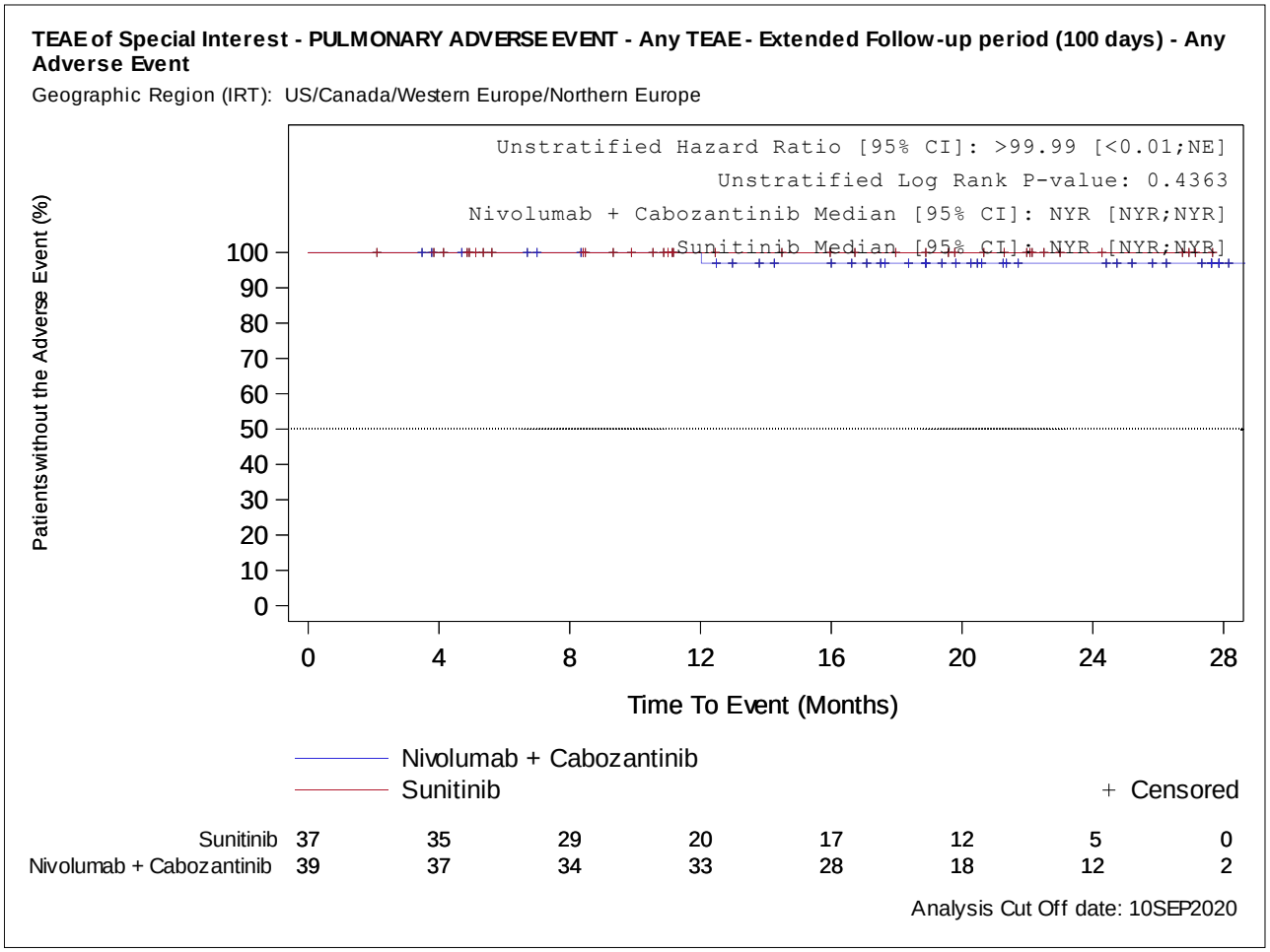

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:24:32

FIGURE 3.42.2.5: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



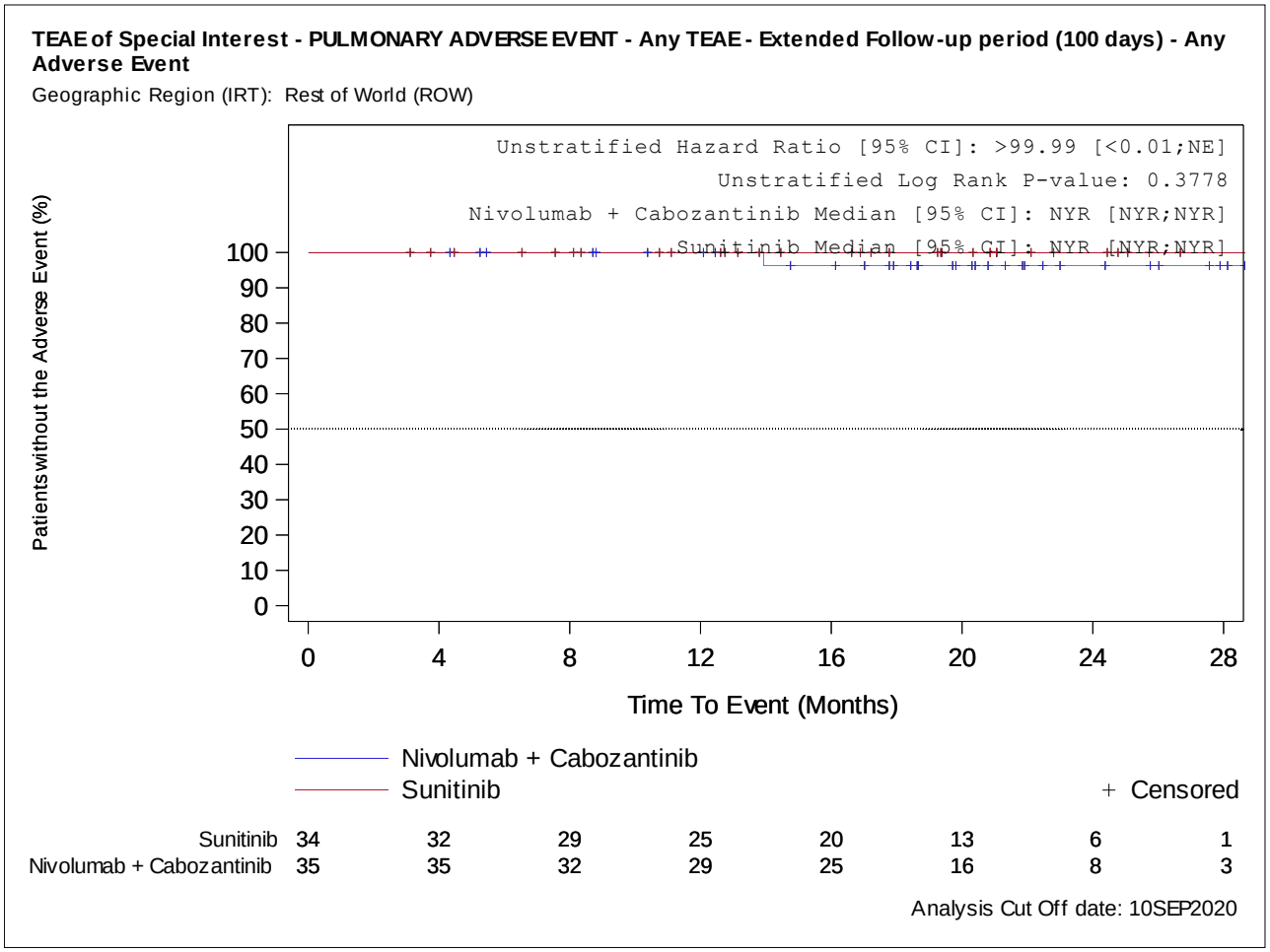

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:24:37

FIGURE 3.42.2.6: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



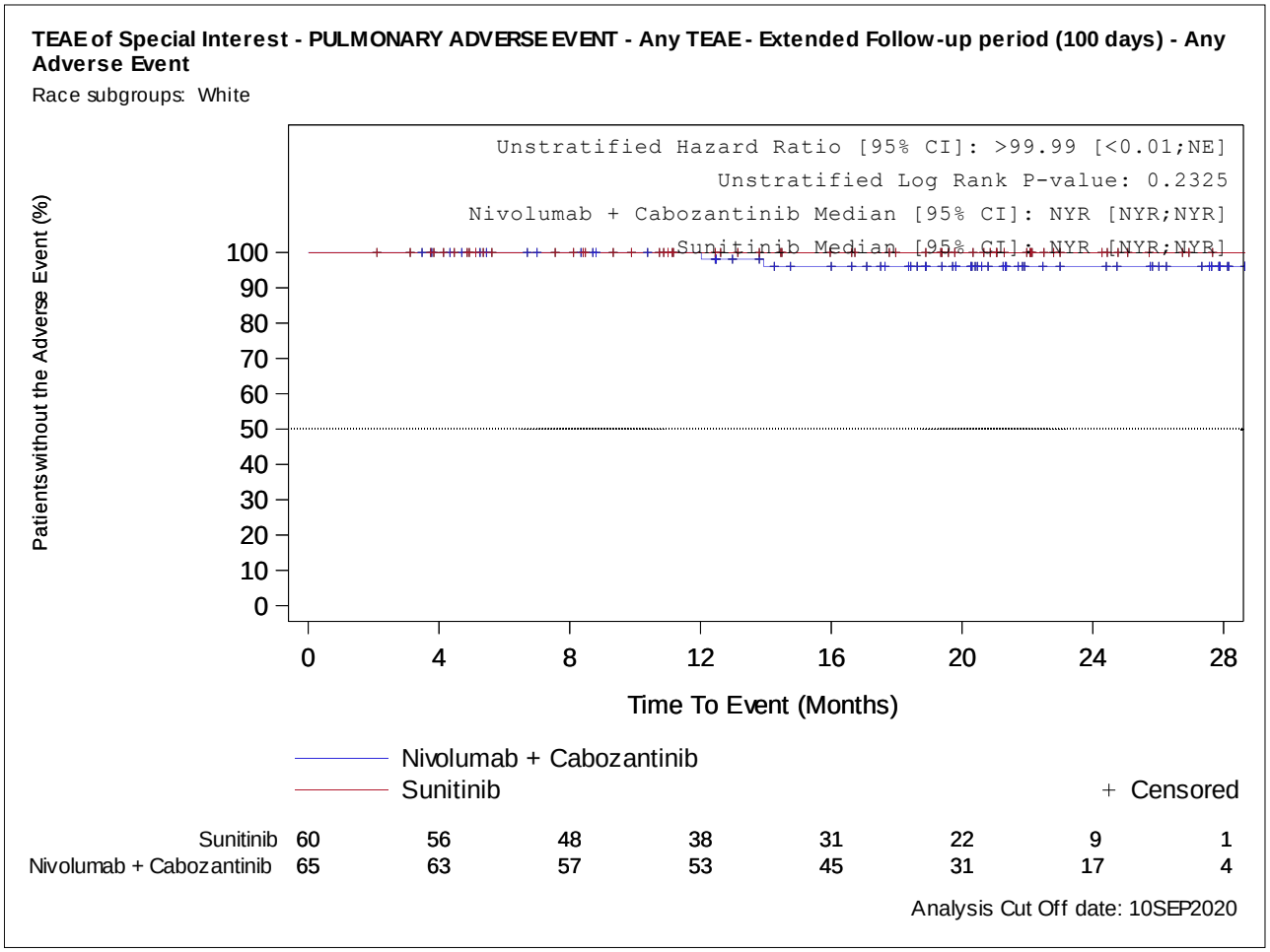

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:24:42

FIGURE 3.42.2.7: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



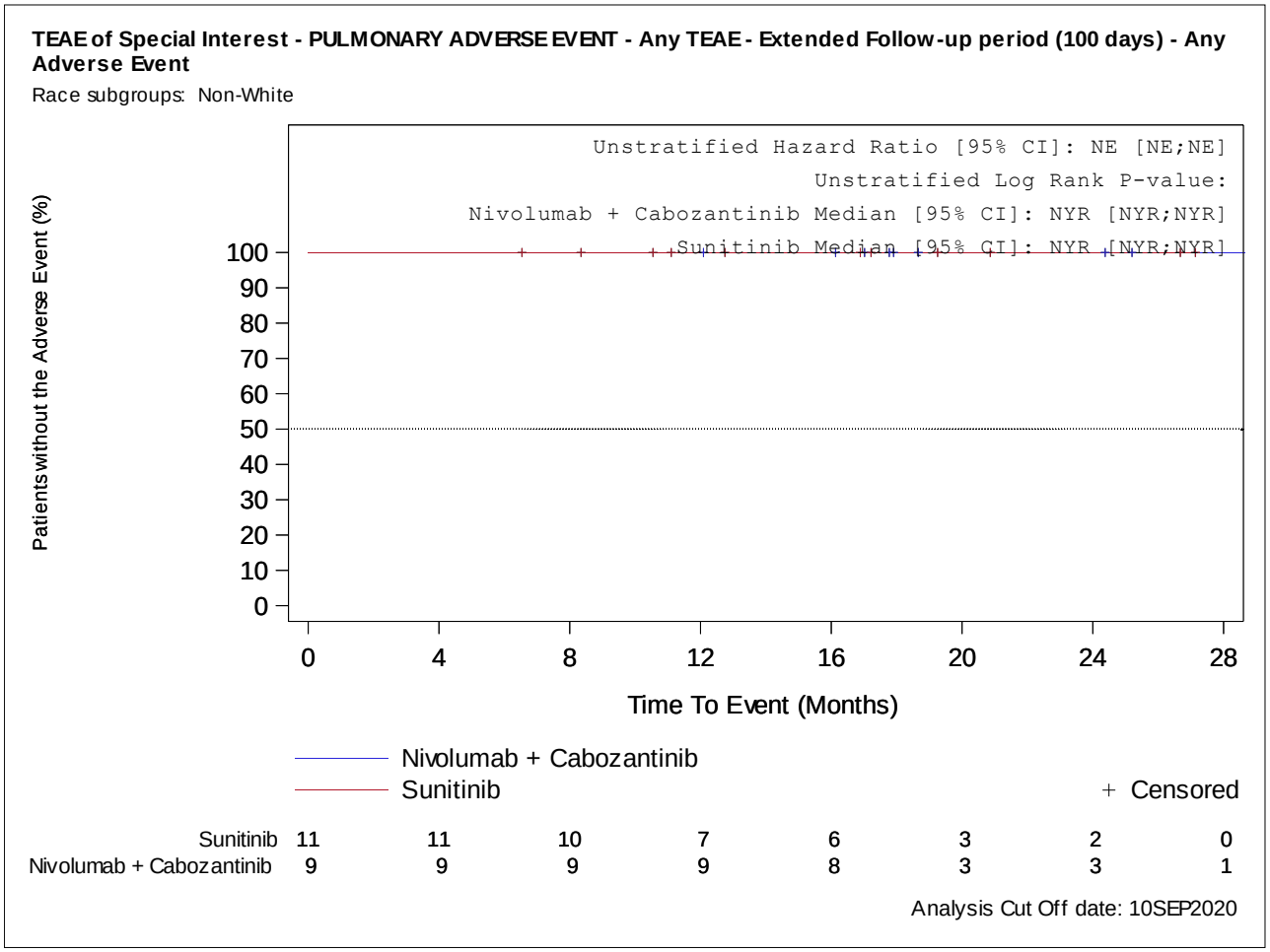

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:24:47

FIGURE 3.42.2.8: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



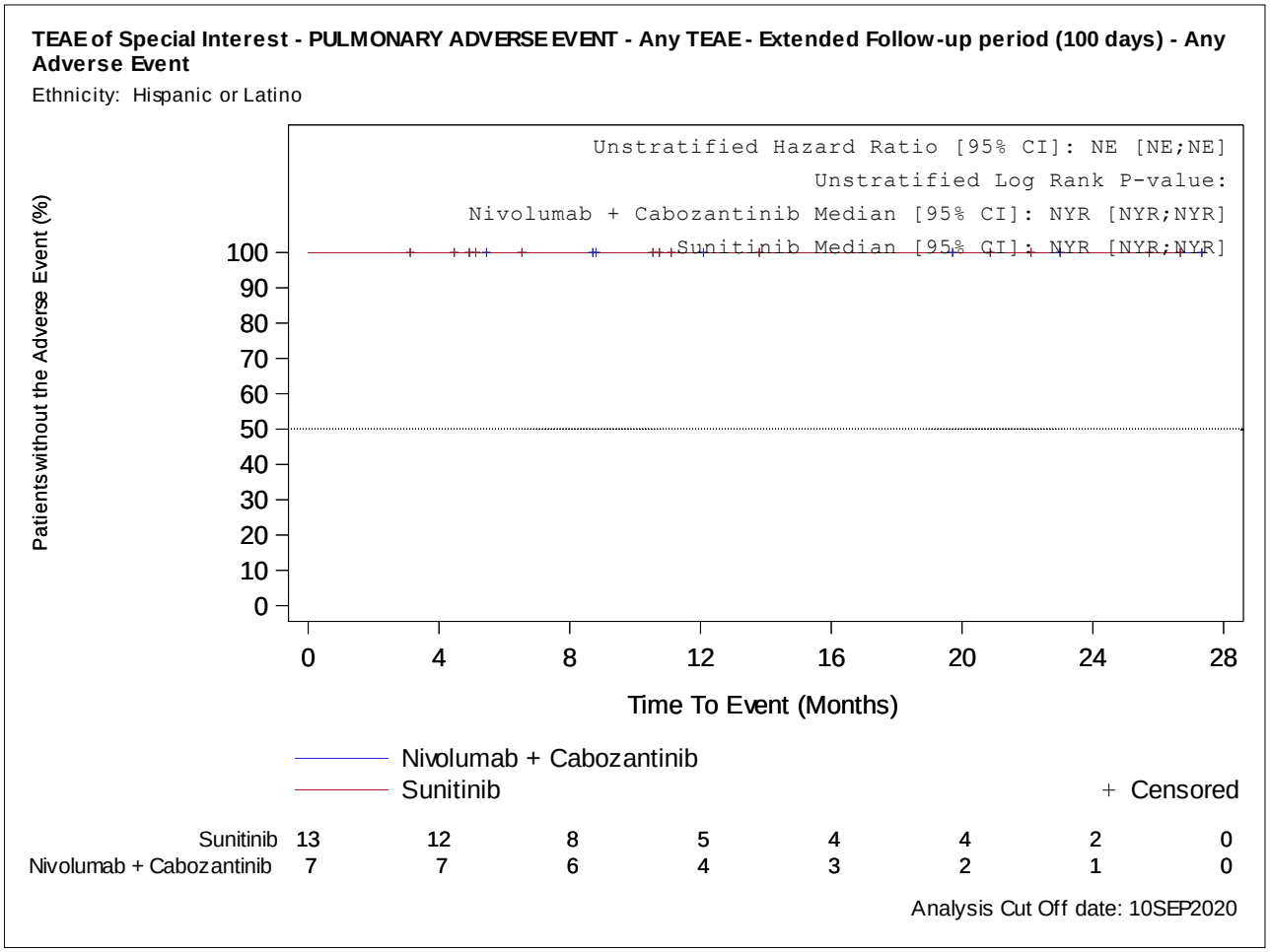

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:24:52

FIGURE 3.42.2.9: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



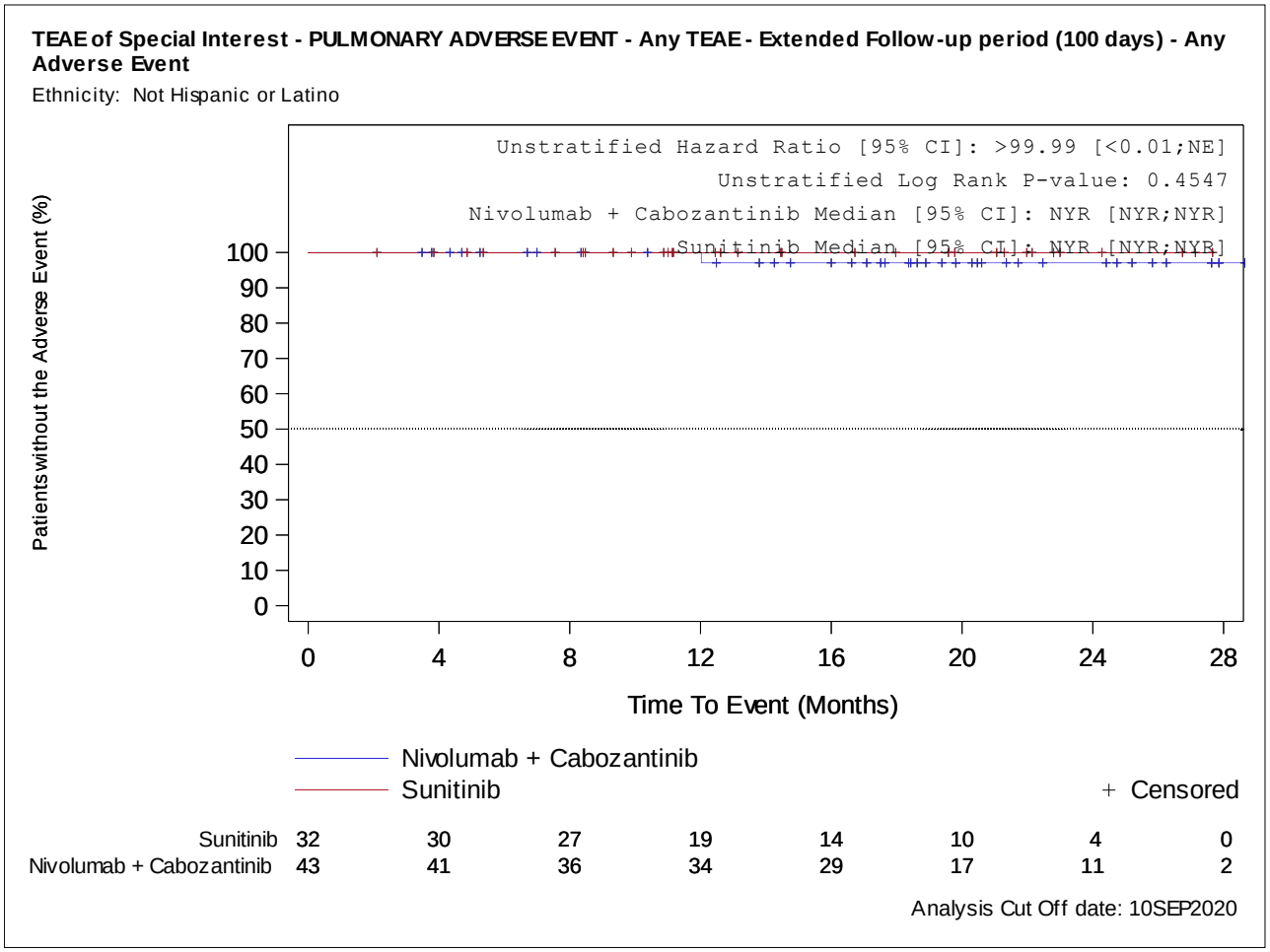

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:24:57

FIGURE 3.42.2.10: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



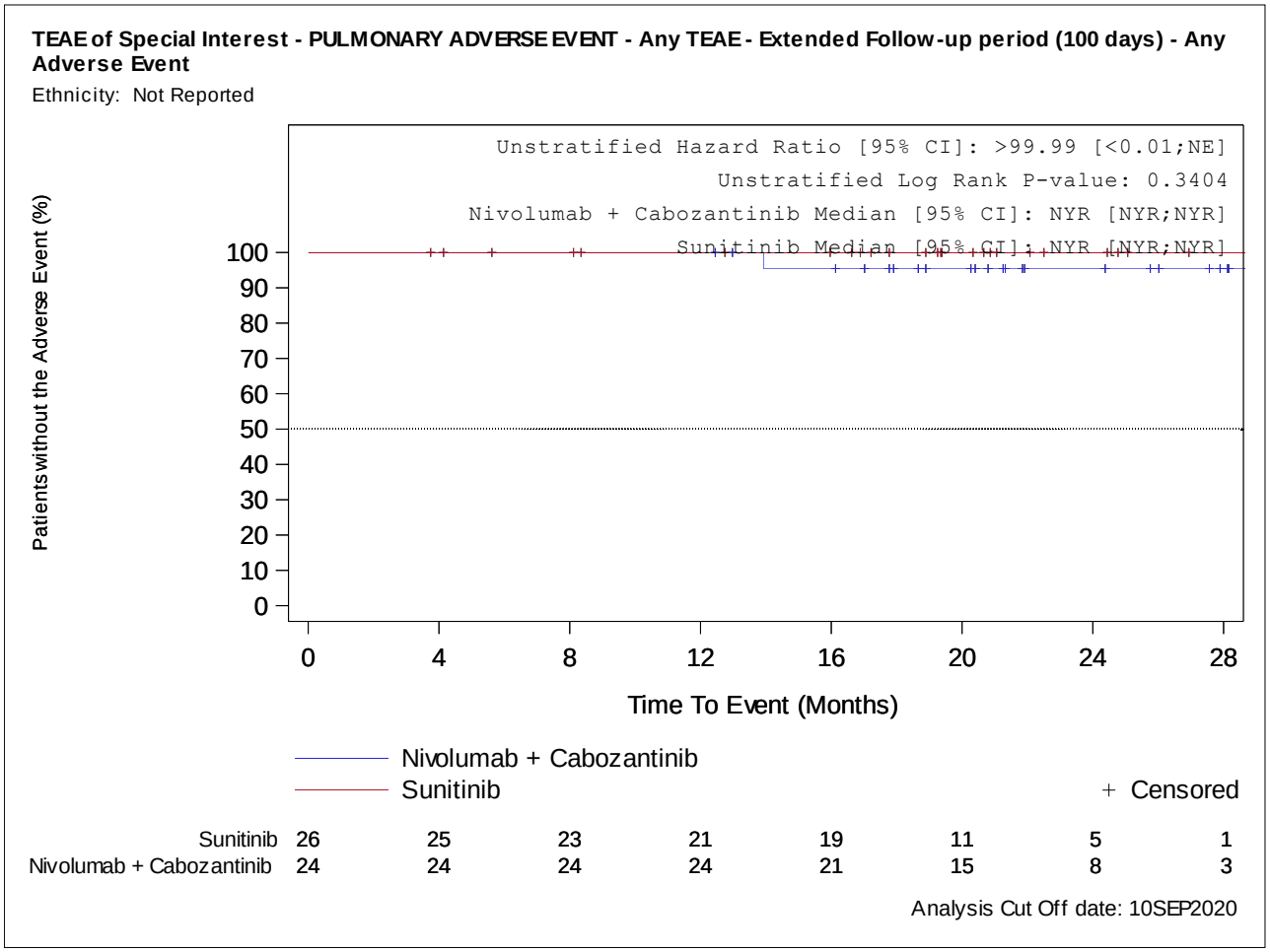

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:25:02

FIGURE 3.42.2.11: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



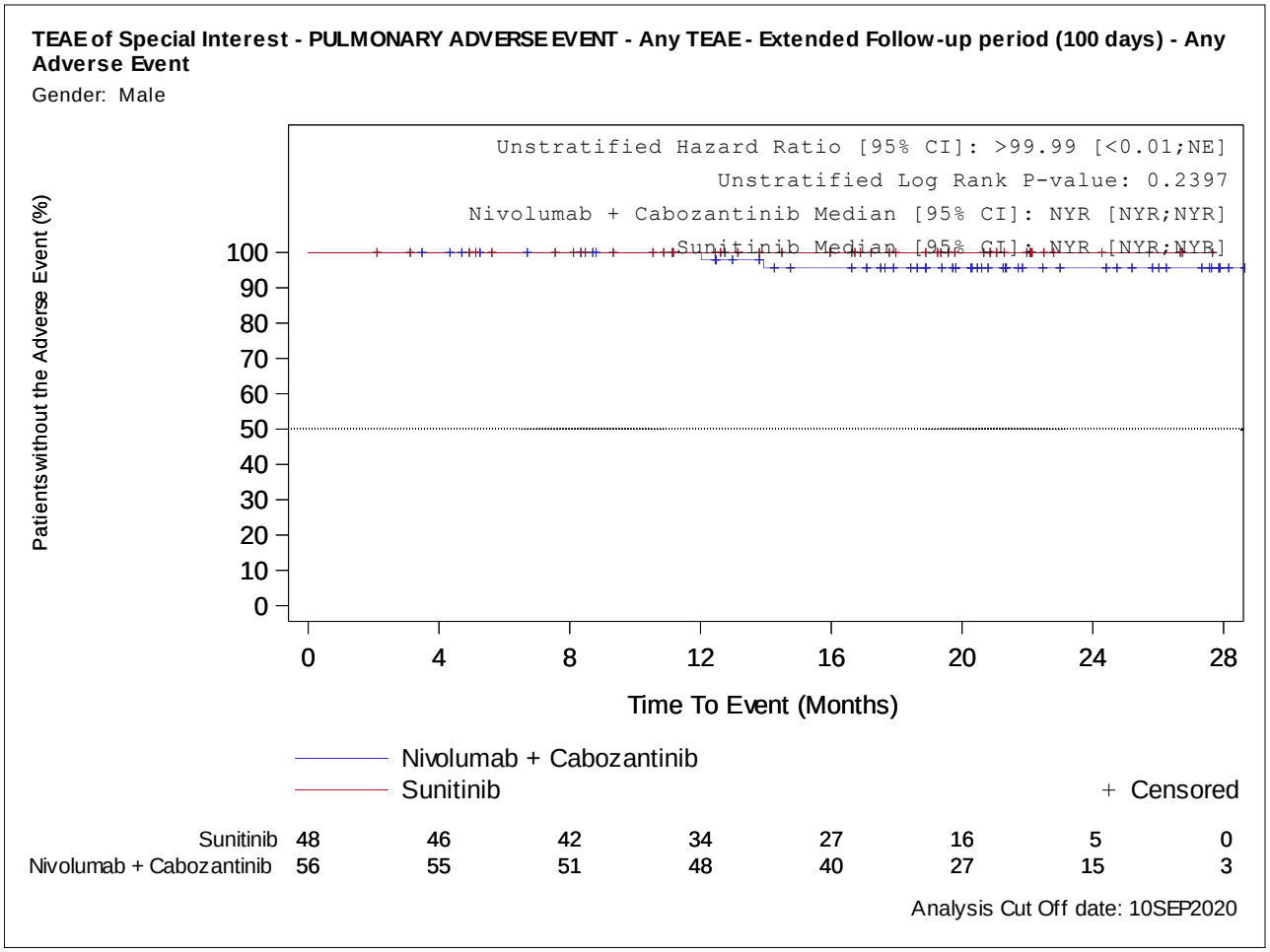

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:25:07

FIGURE 3.42.2.12: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



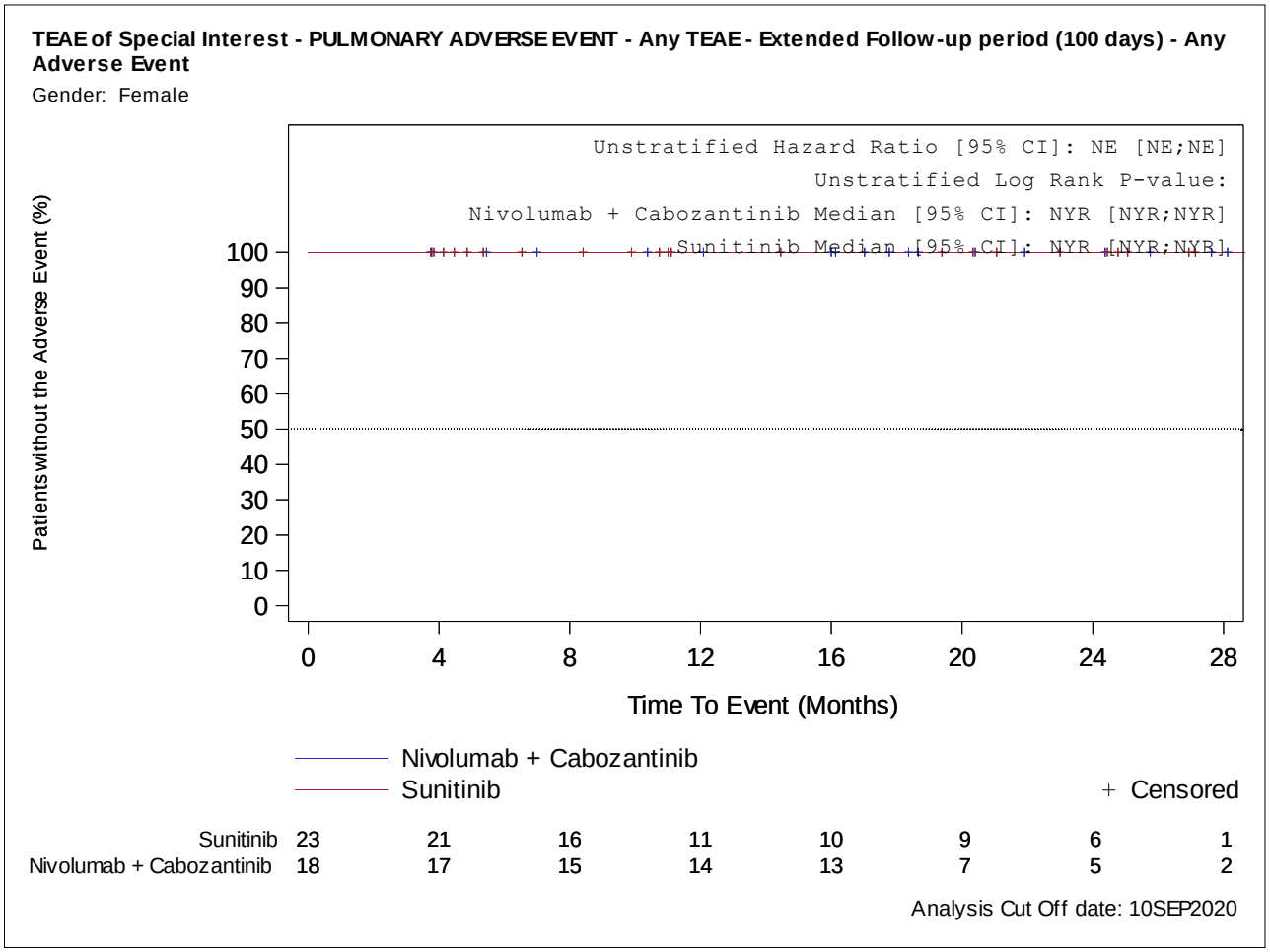

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:25:12

FIGURE 3.42.2.13: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



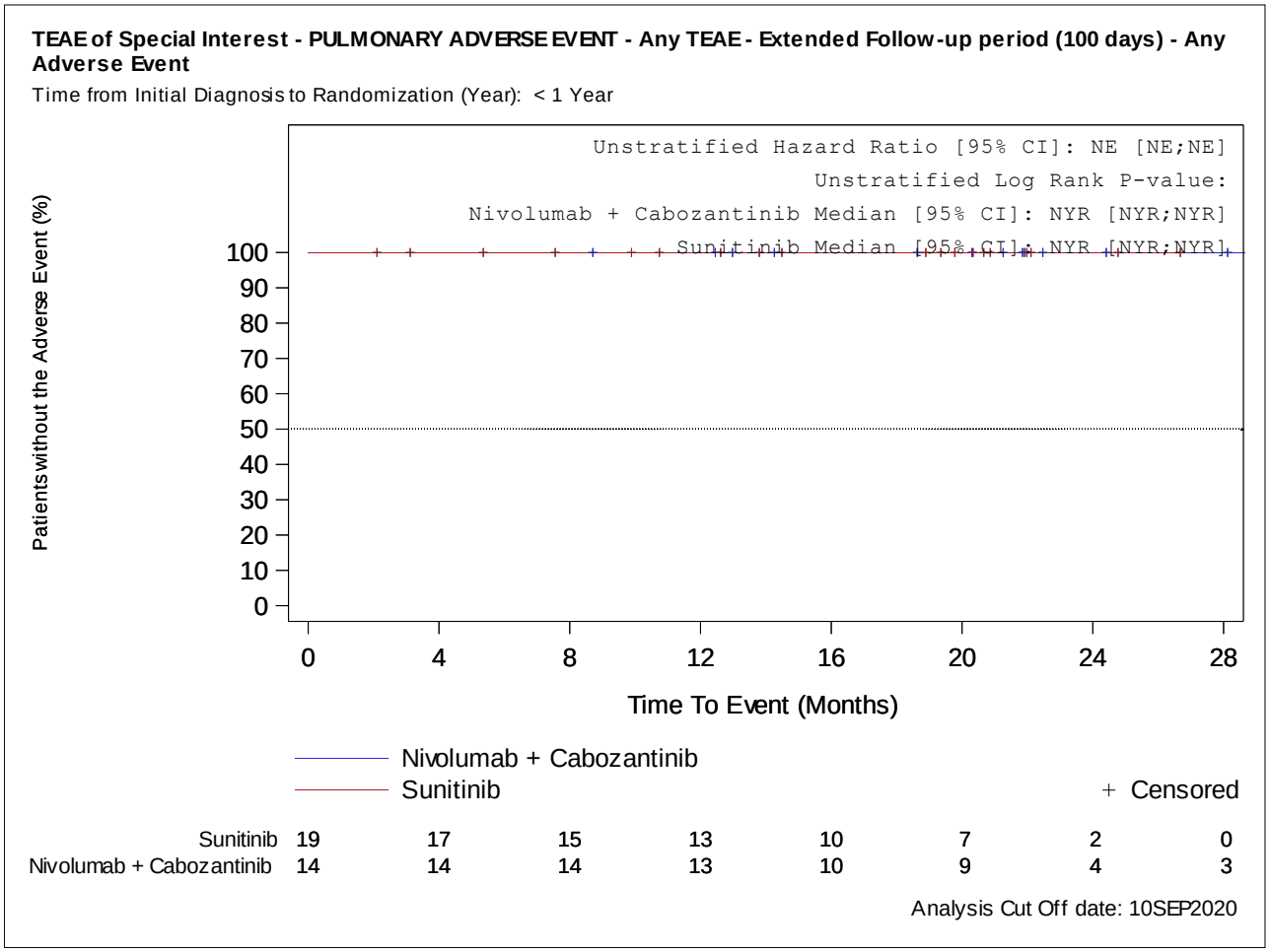

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:25:18

FIGURE 3.42.2.14: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



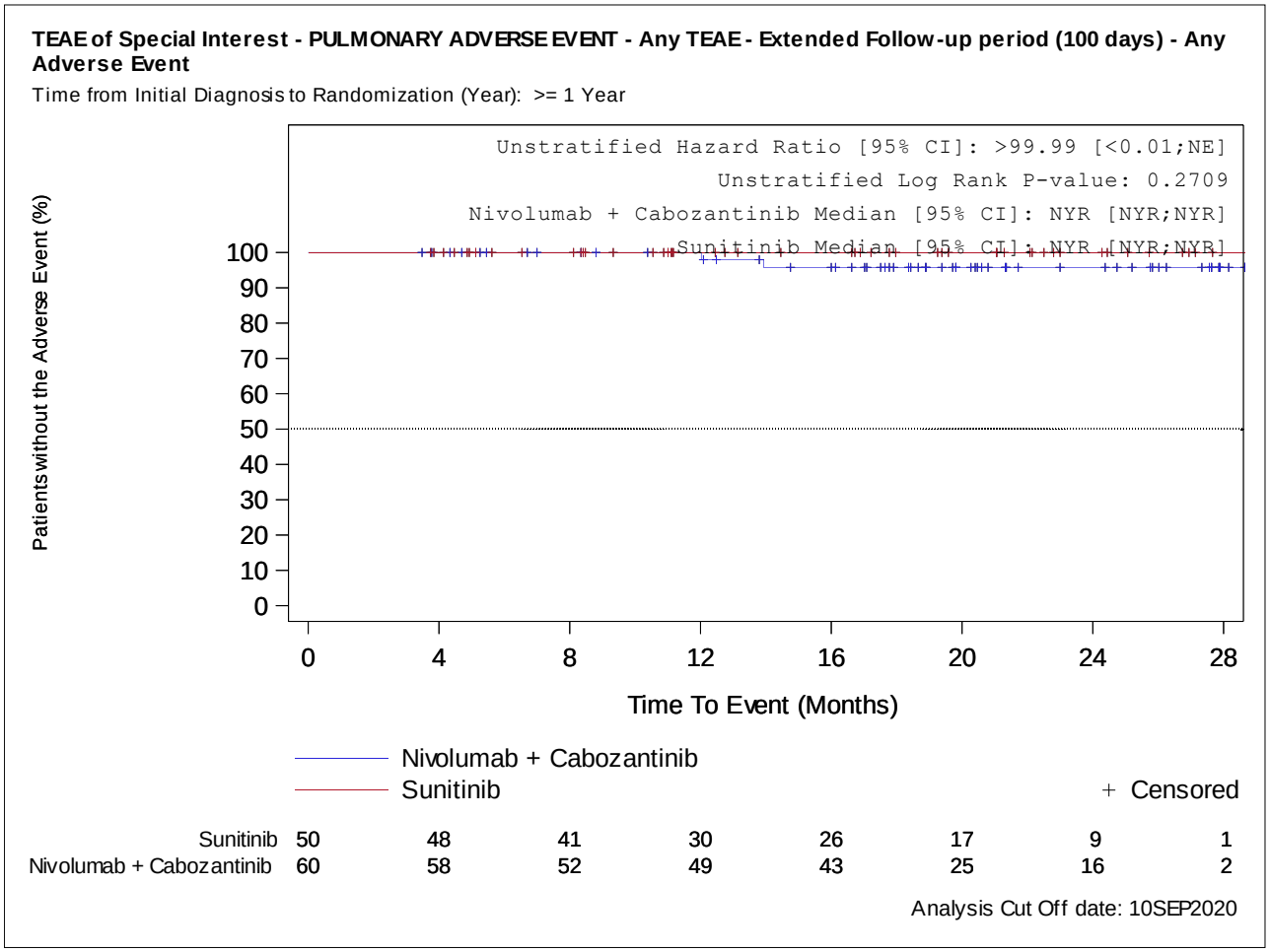

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:25:23

FIGURE 3.42.2.15: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



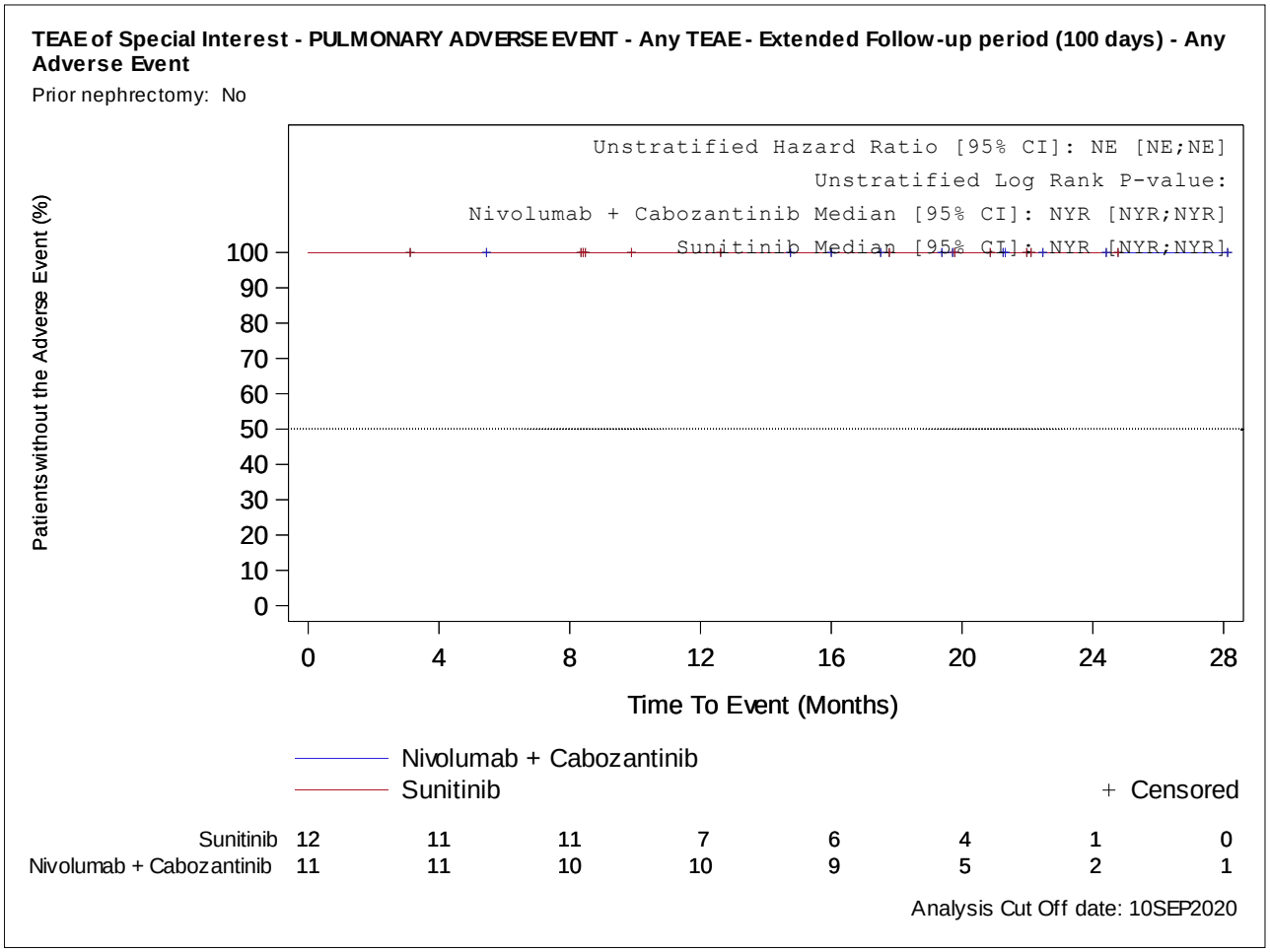

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:25:38

FIGURE 3.42.2.16: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



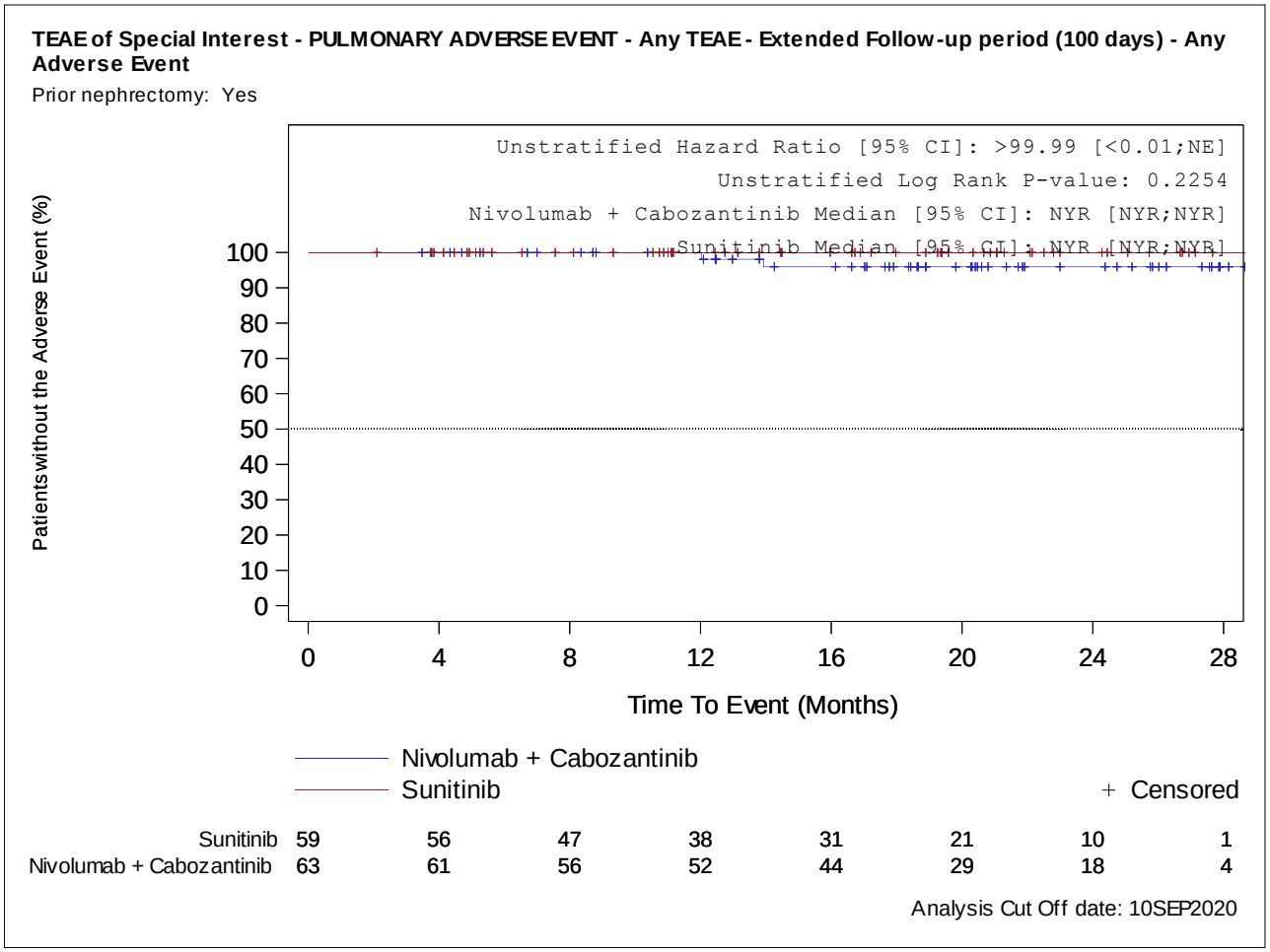

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:25:43

FIGURE 3.42.2.17: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



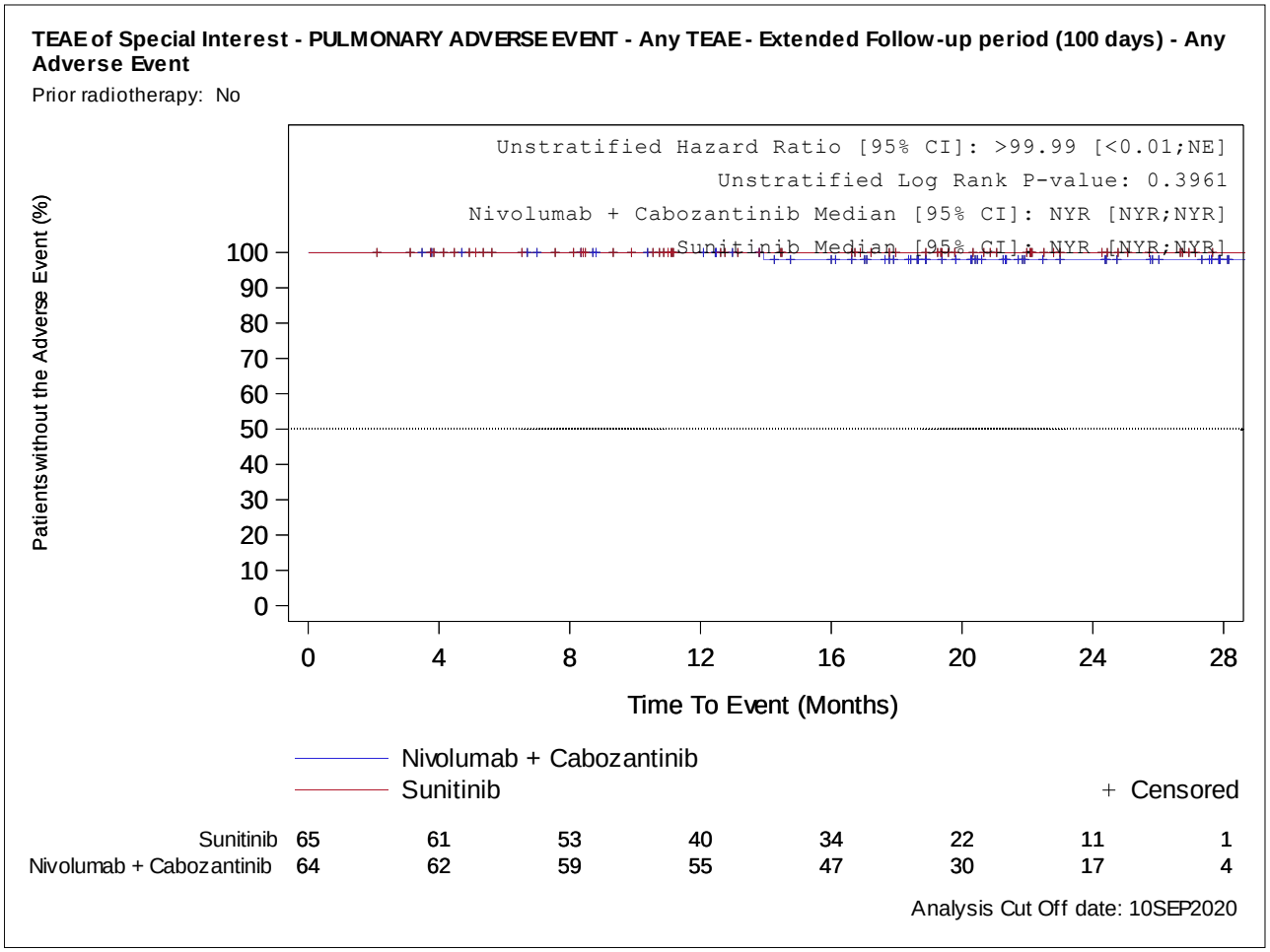

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:31

FIGURE 3.42.2.18: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



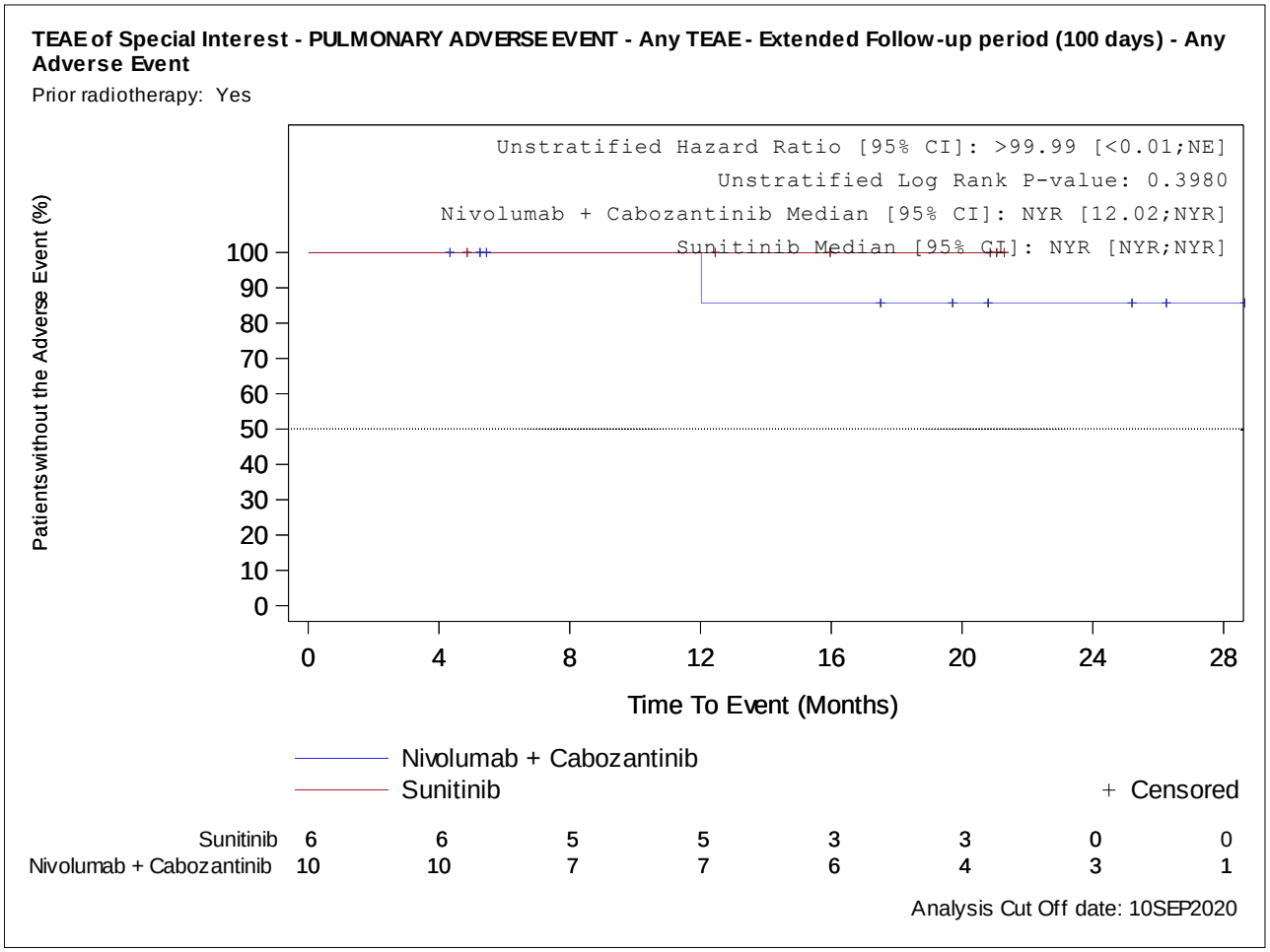

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:36

FIGURE 3.42.2.19: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



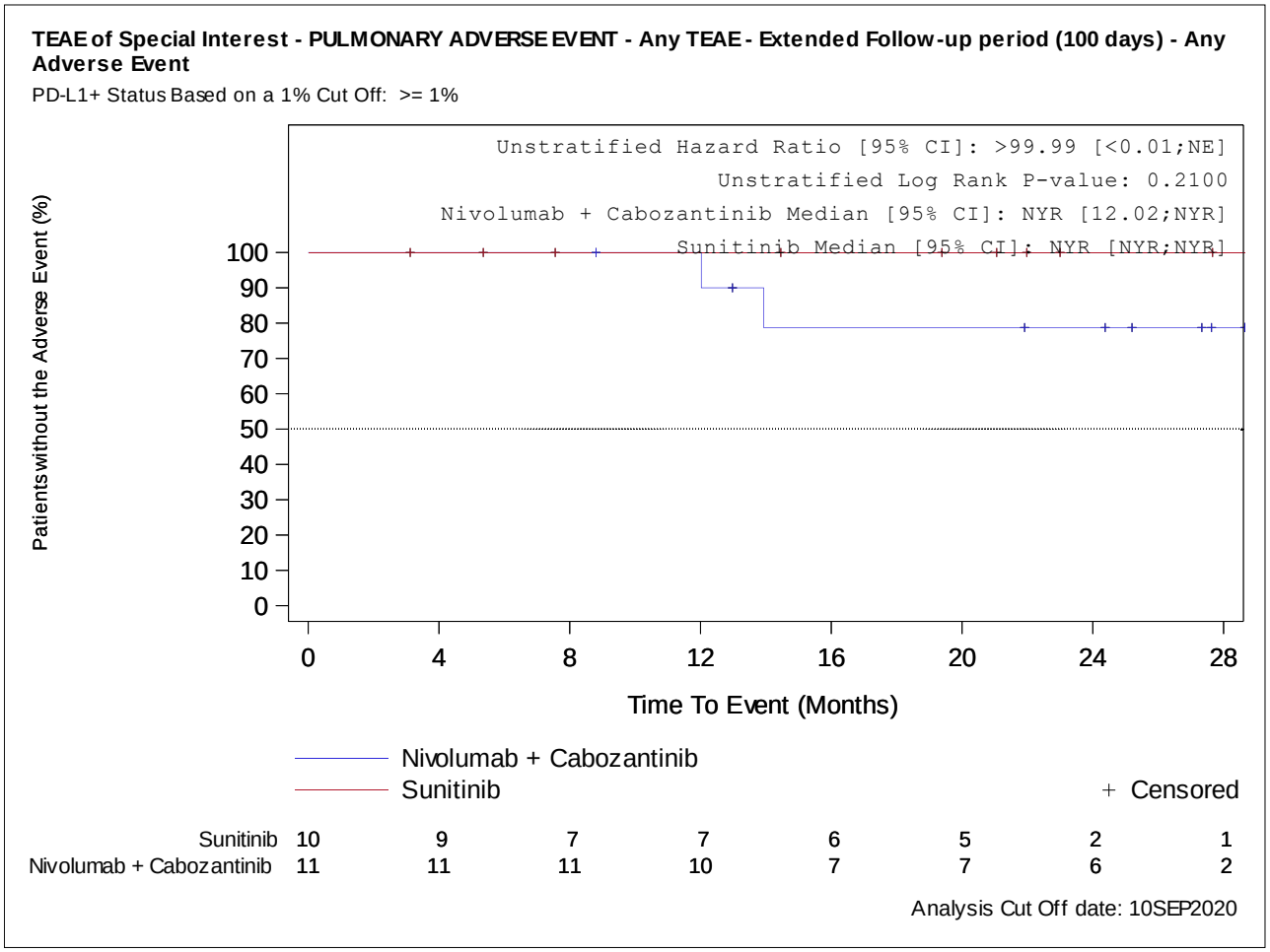

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:42

FIGURE 3.42.2.20: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



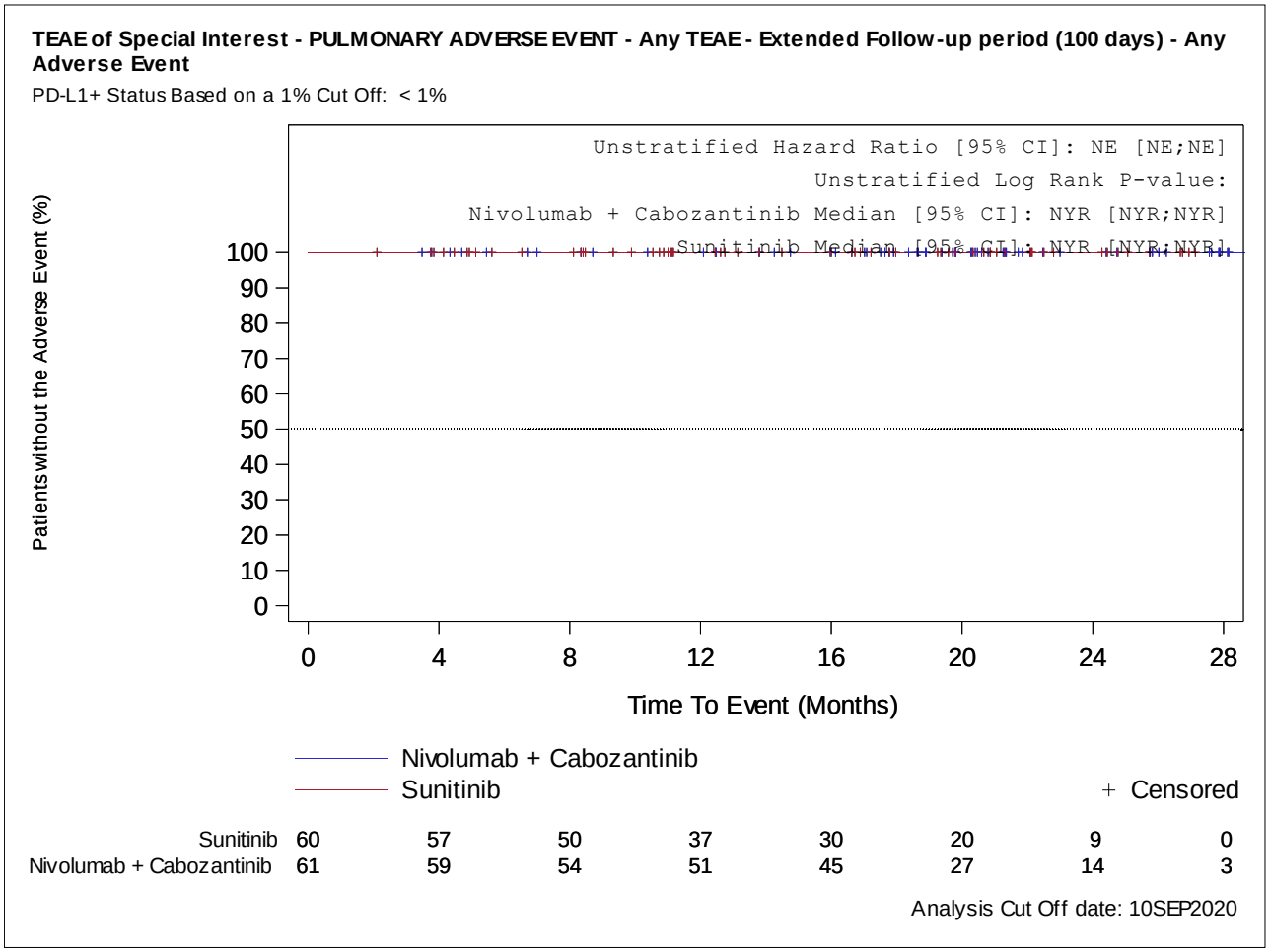

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:47

FIGURE 3.42.2.21: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



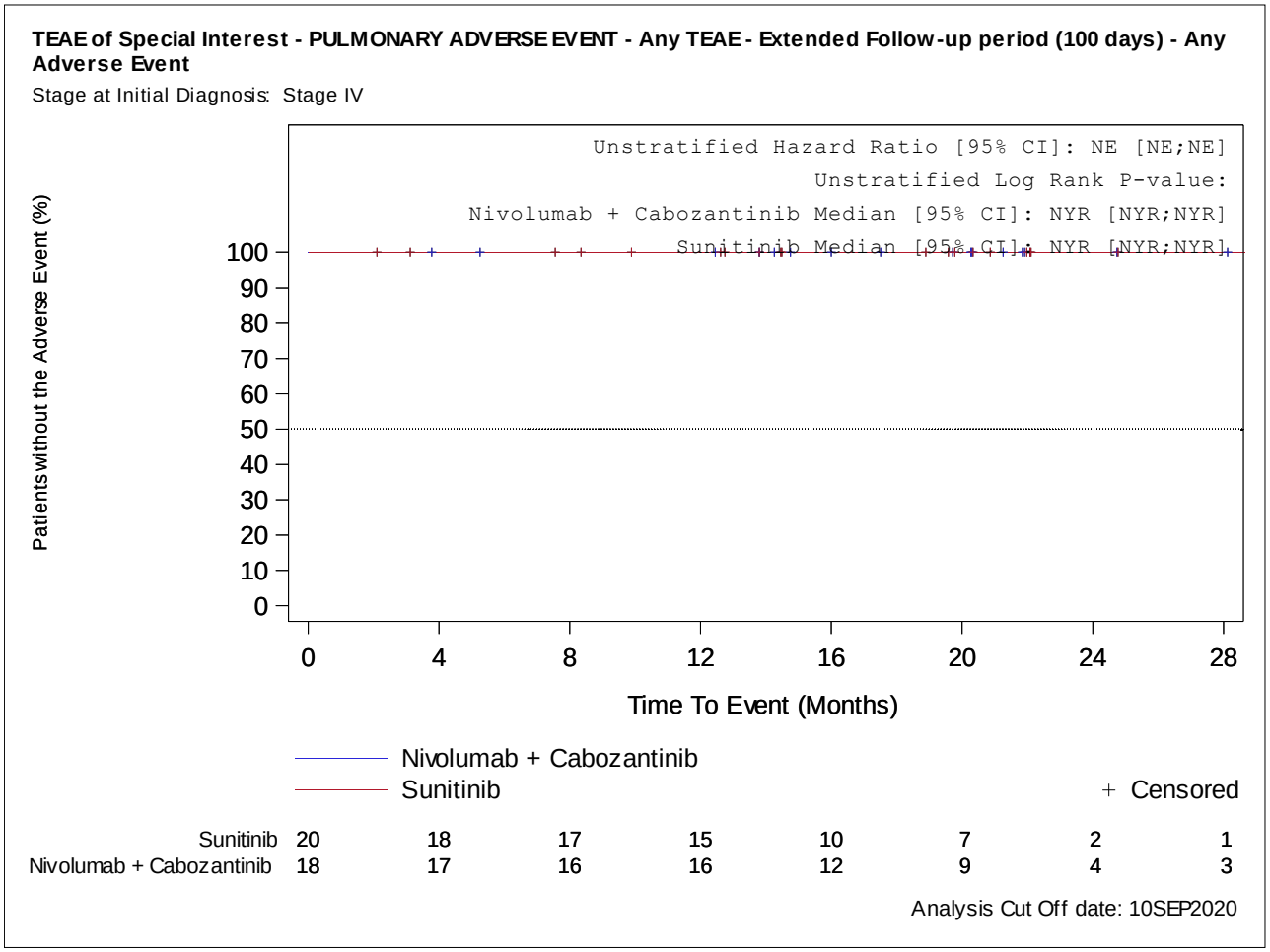

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:52

FIGURE 3.42.2.22: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



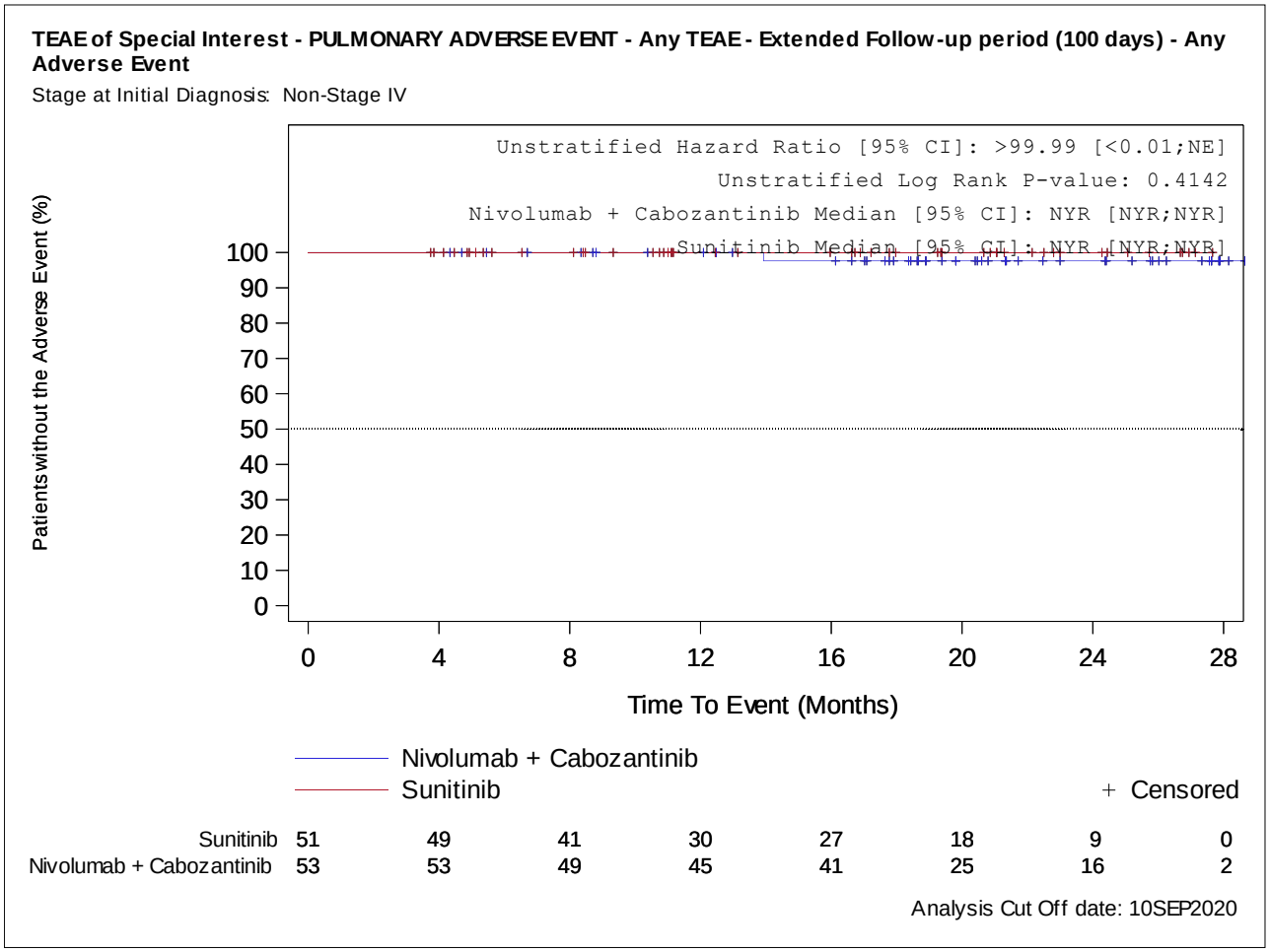

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:58

FIGURE 3.42.2.23: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



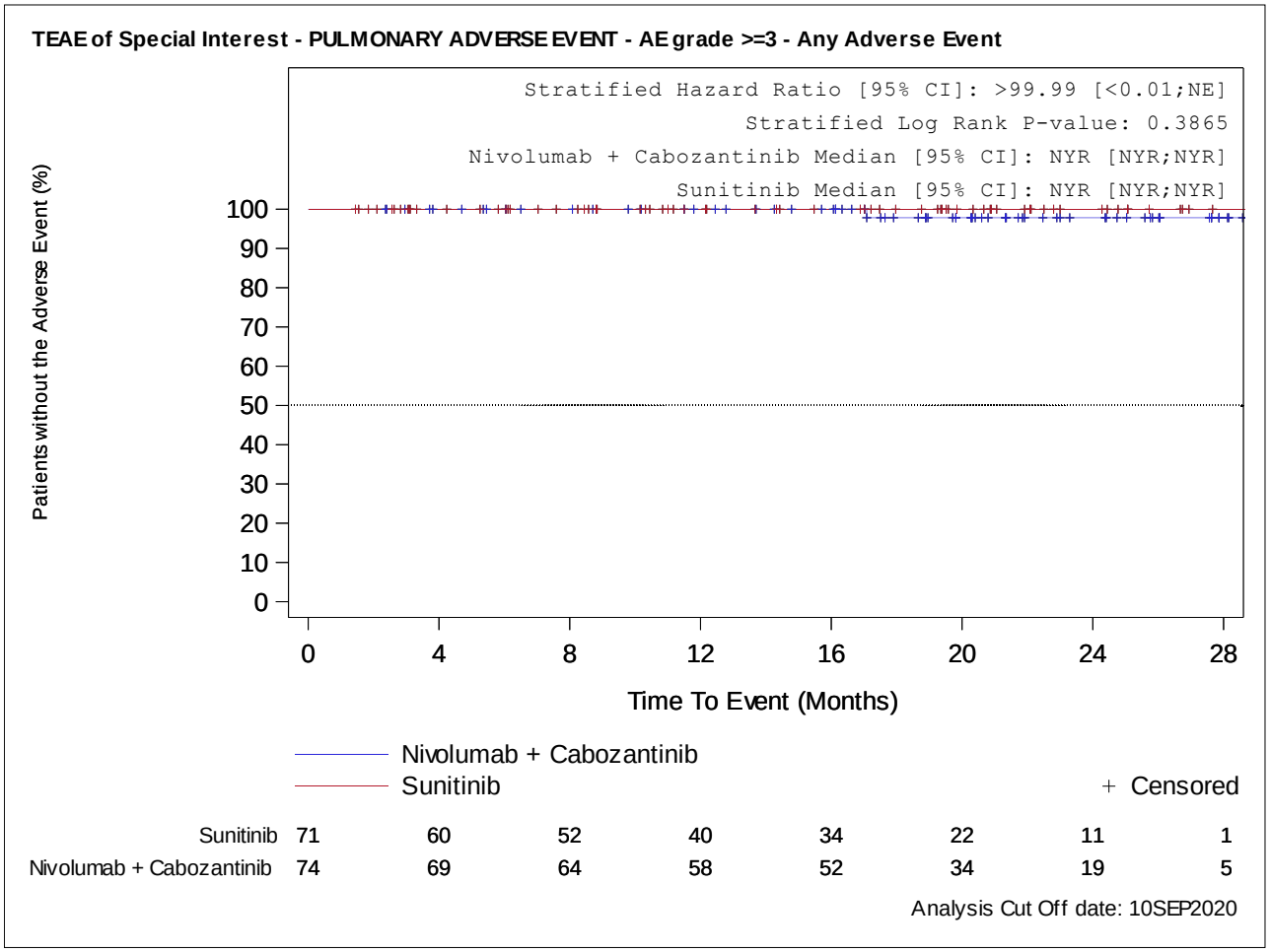

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:27:24

FIGURE 3.42.2.24: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:27:30

FIGURE 3.43.1: TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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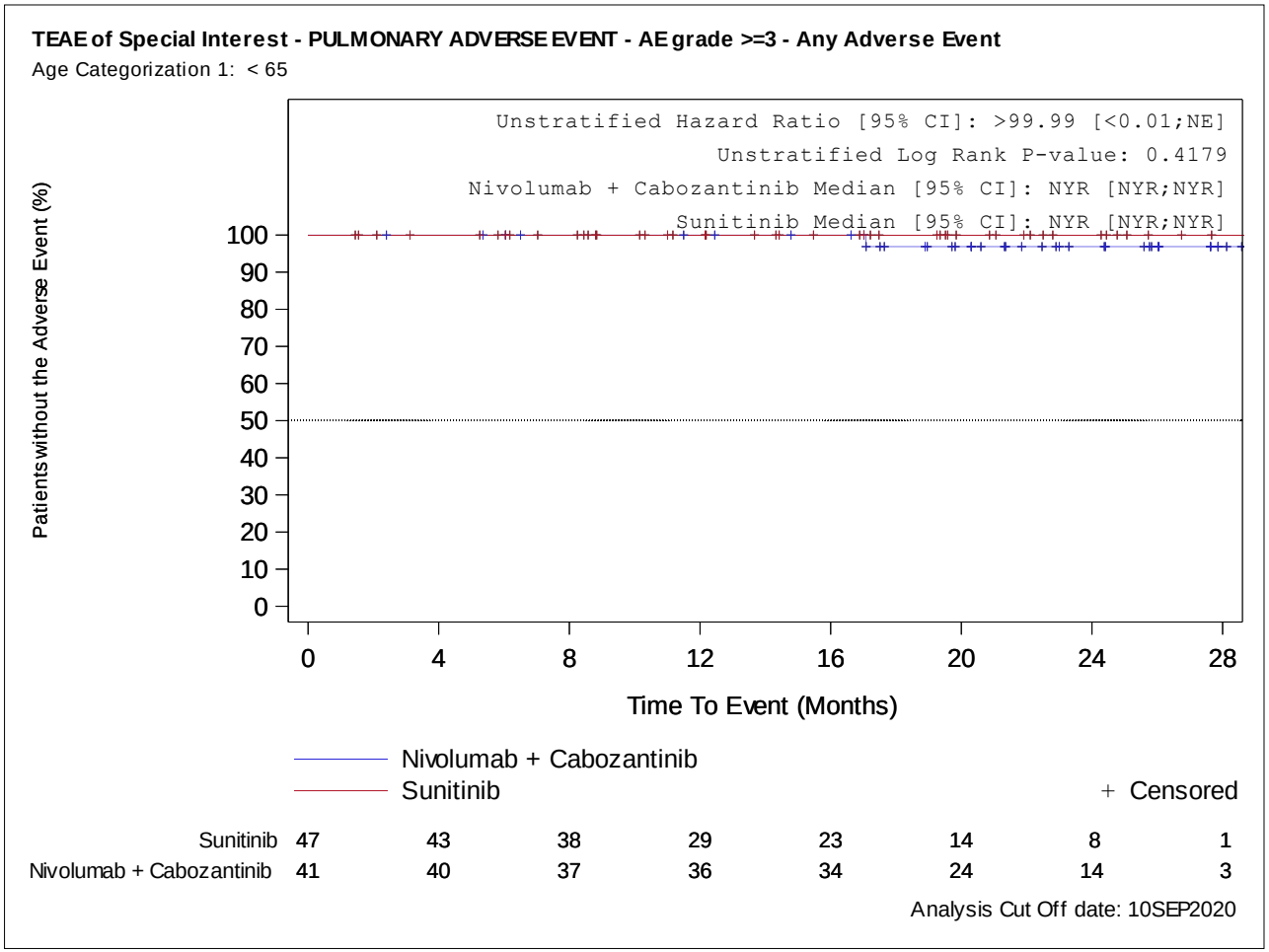
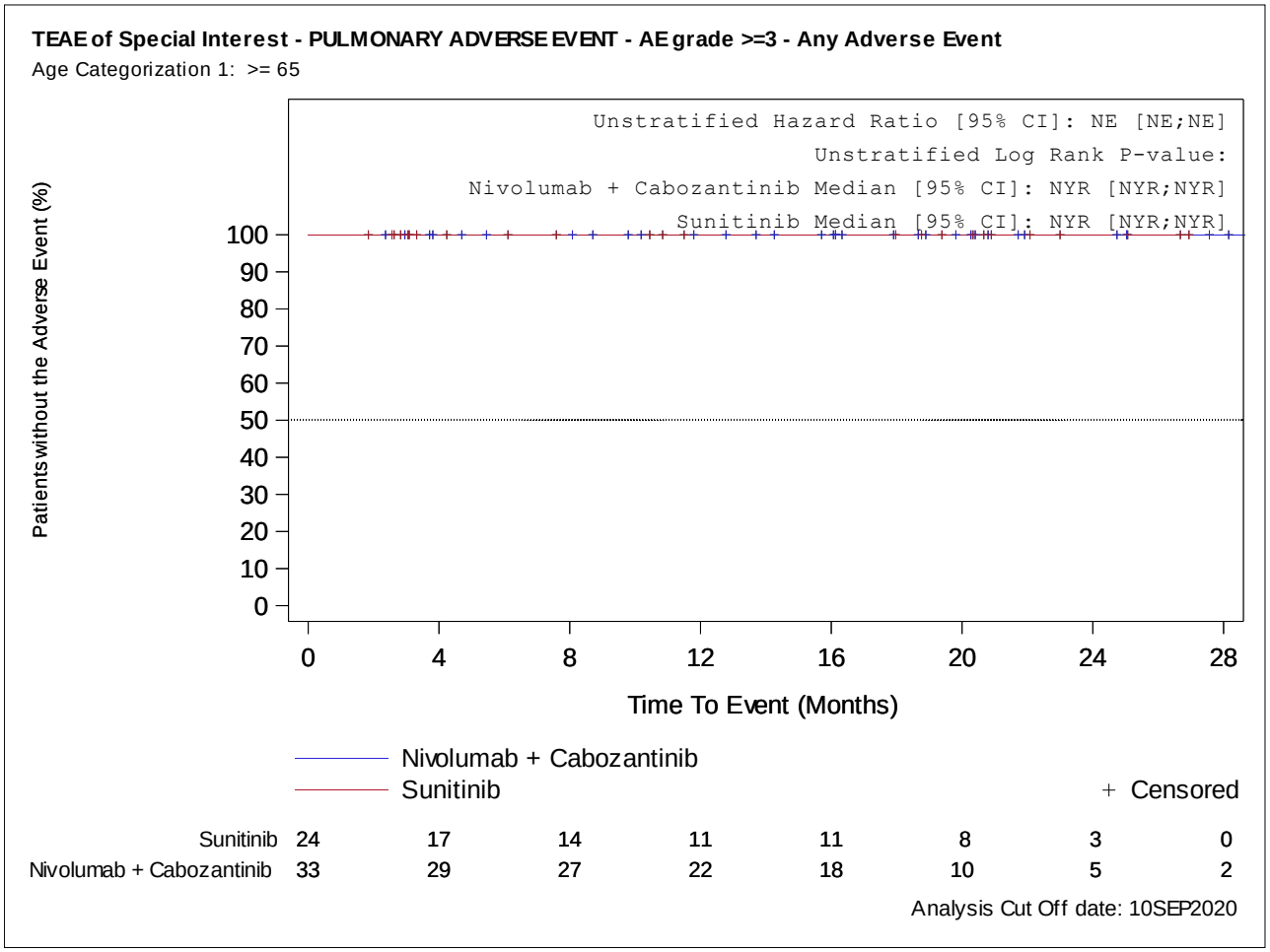
FIGURE 3.43.2.1: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



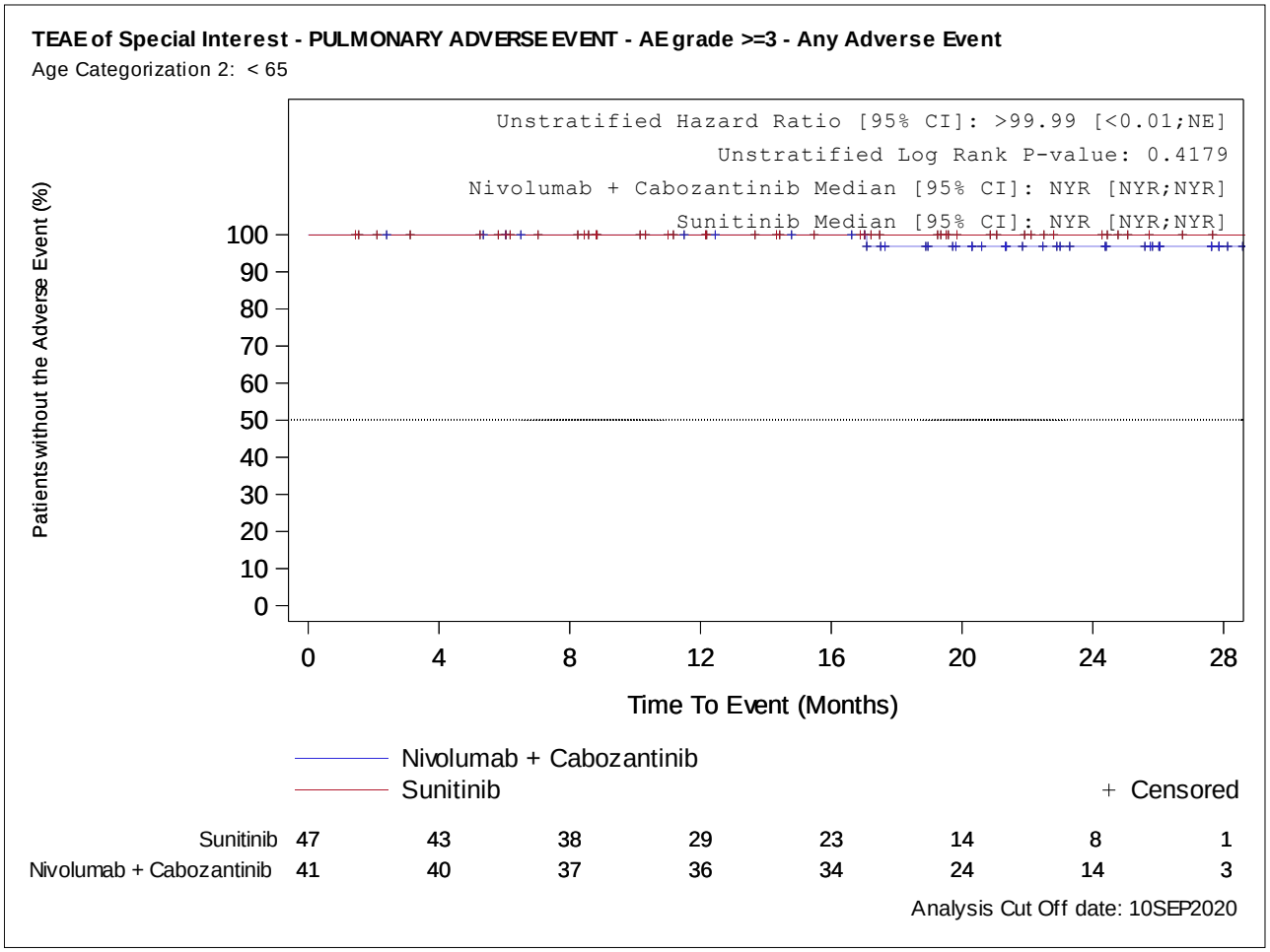

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:30:28

FIGURE 3.43.2.2: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



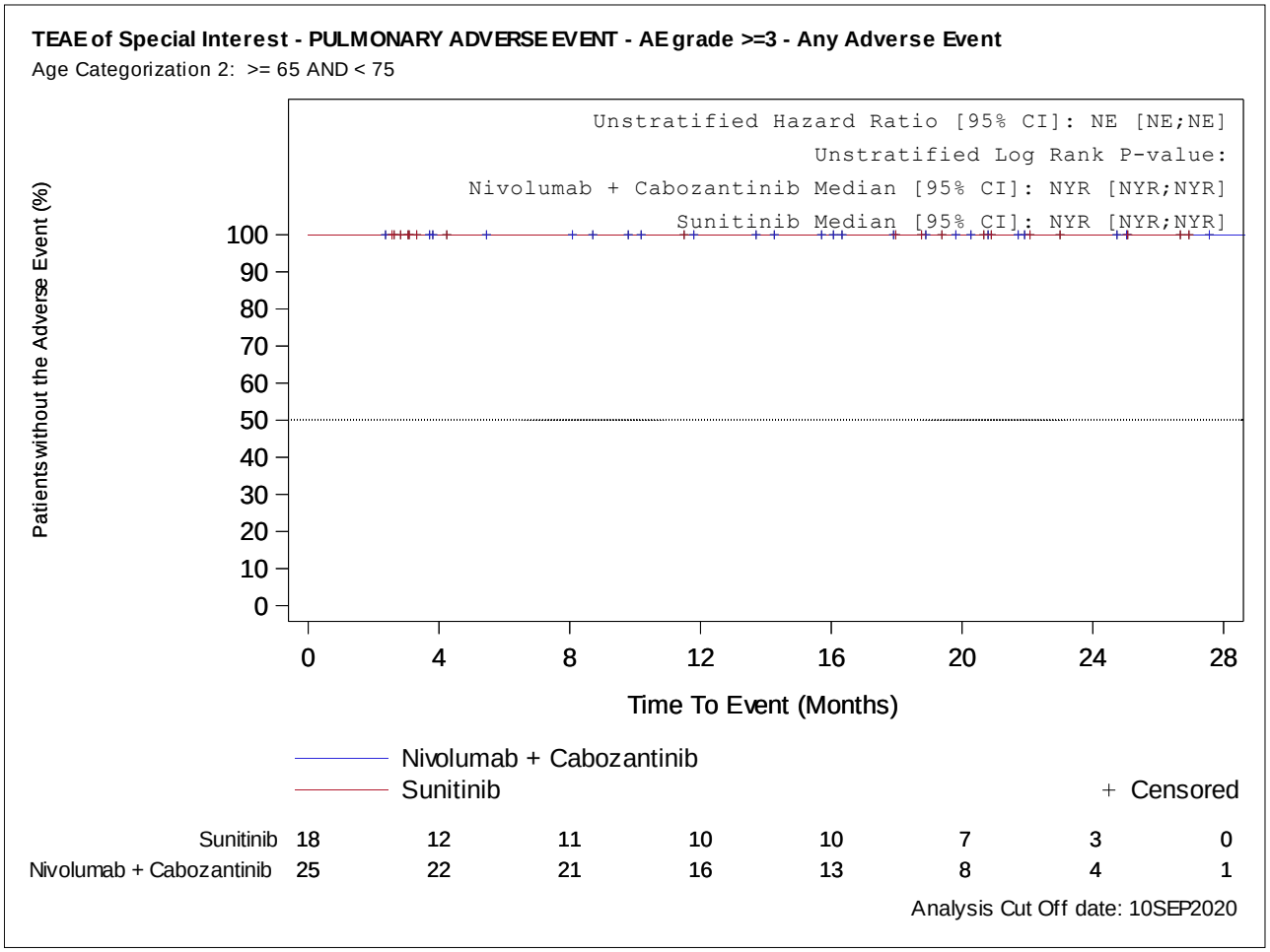

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:30:33

FIGURE 3.43.2.3: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



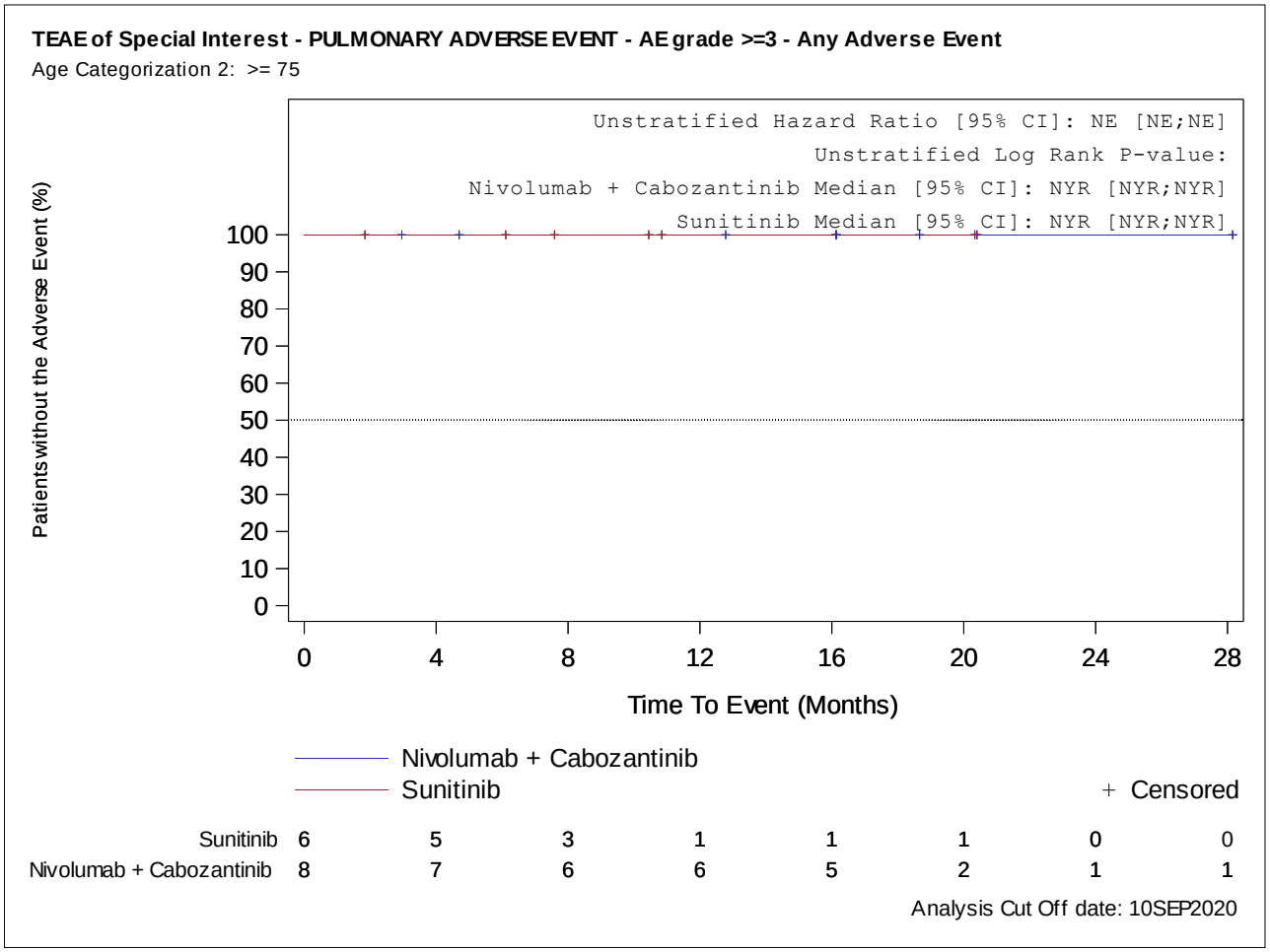

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:30:38

FIGURE 3.43.2.4: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



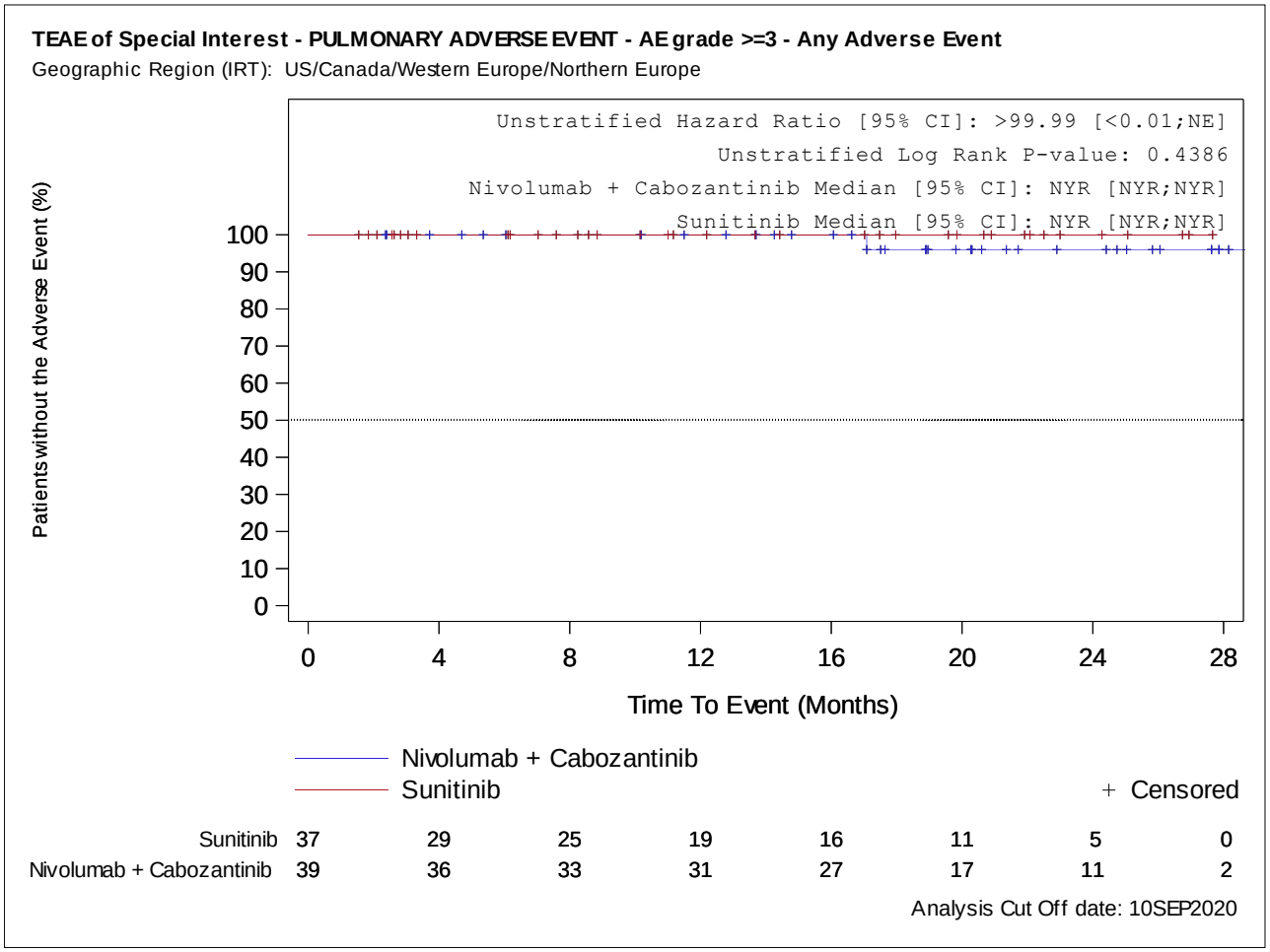

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:30:44

FIGURE 3.43.2.5: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



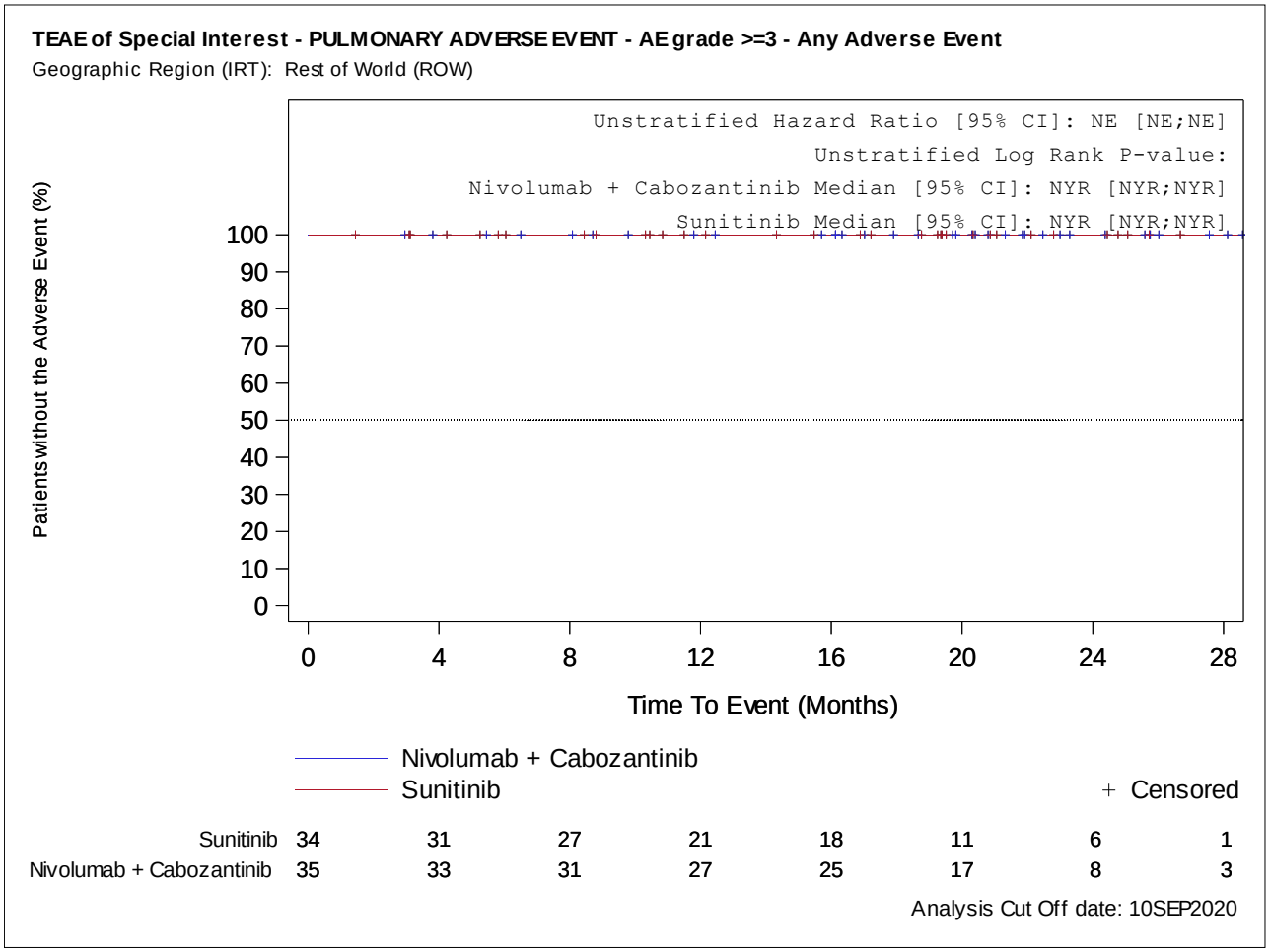

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:30:49

FIGURE 3.43.2.6: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



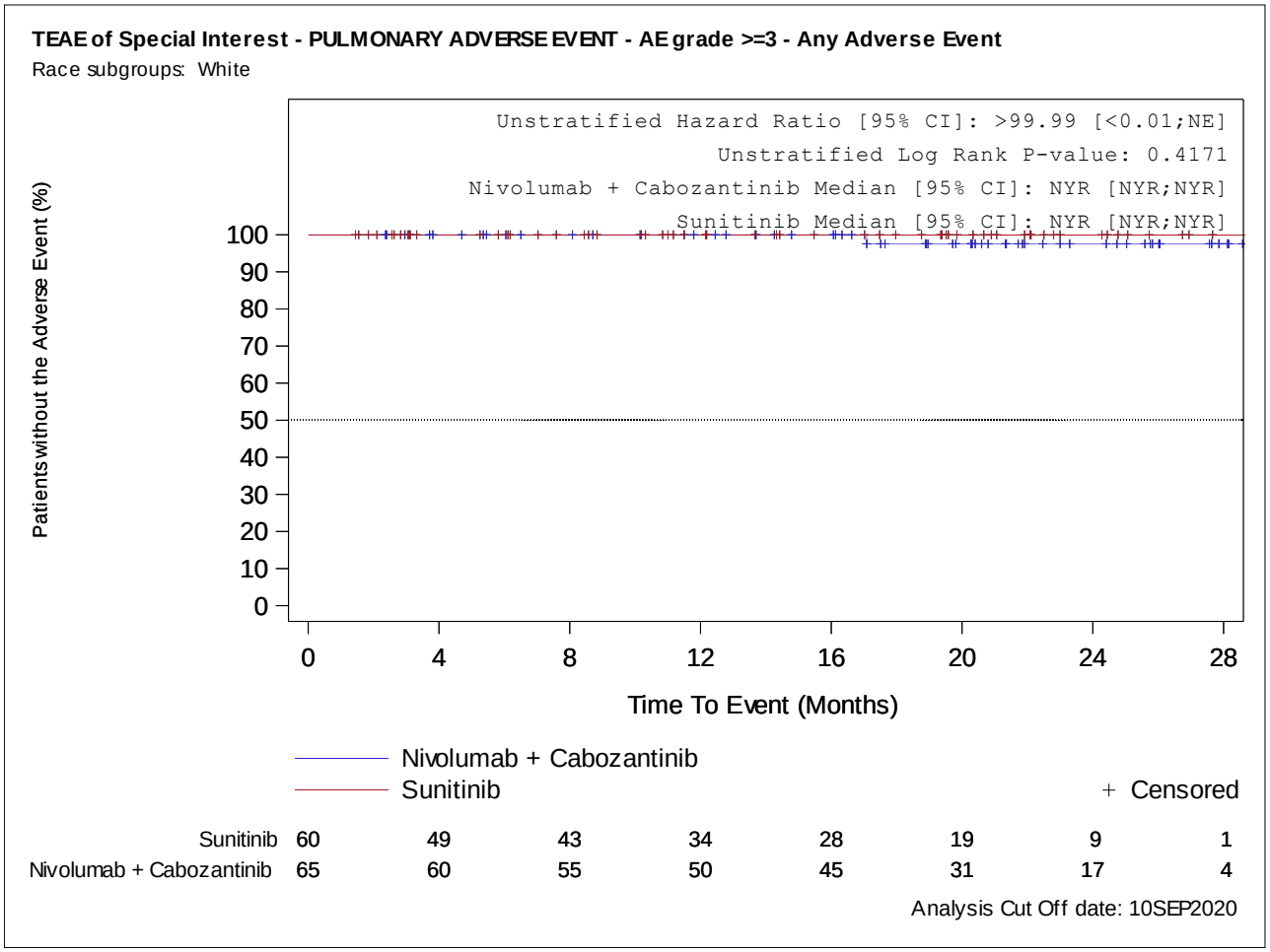

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:30:54

FIGURE 3.43.2.7: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



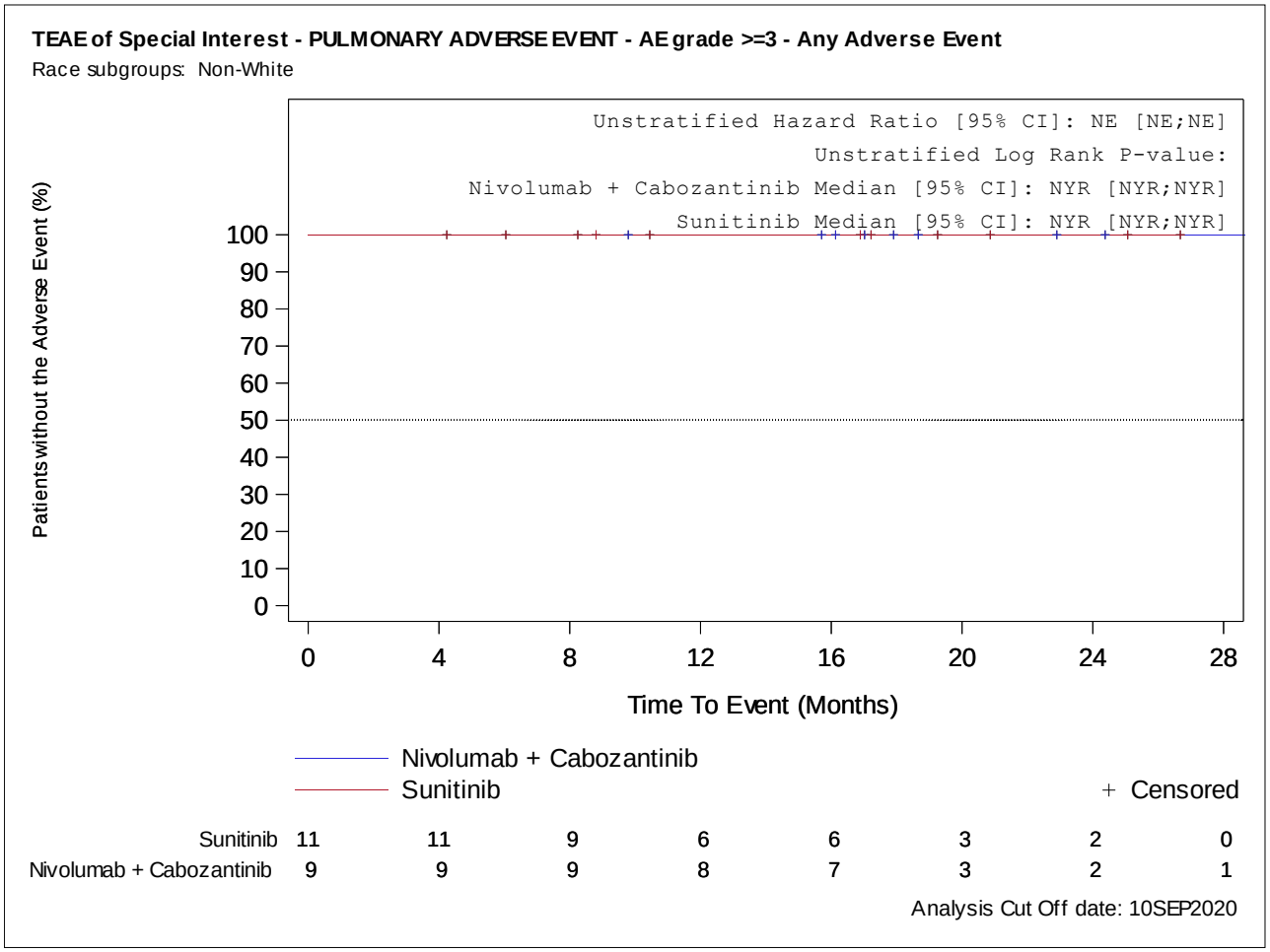

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:30:59

FIGURE 3.43.2.8: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



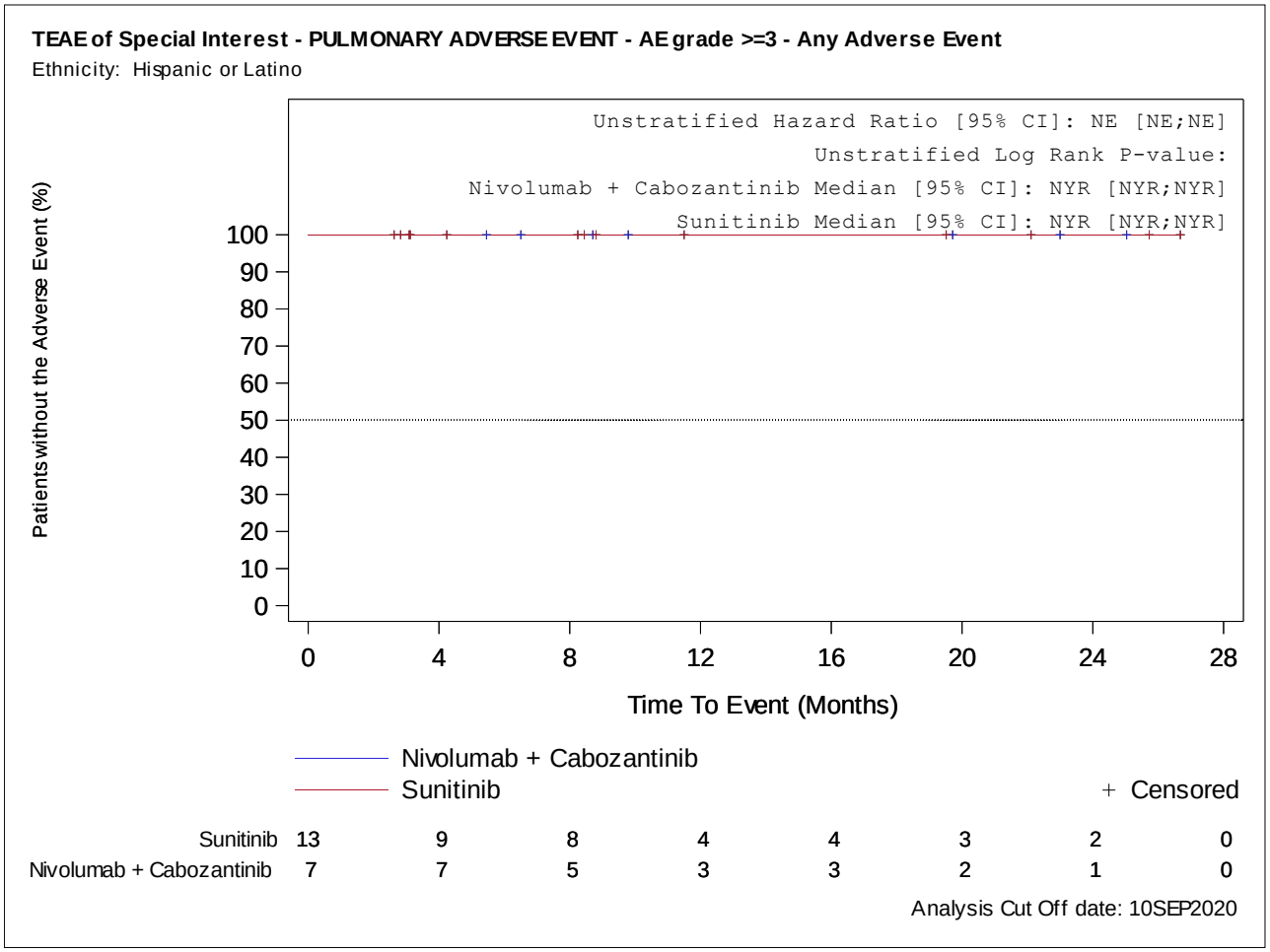

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:31:05

FIGURE 3.43.2.9: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



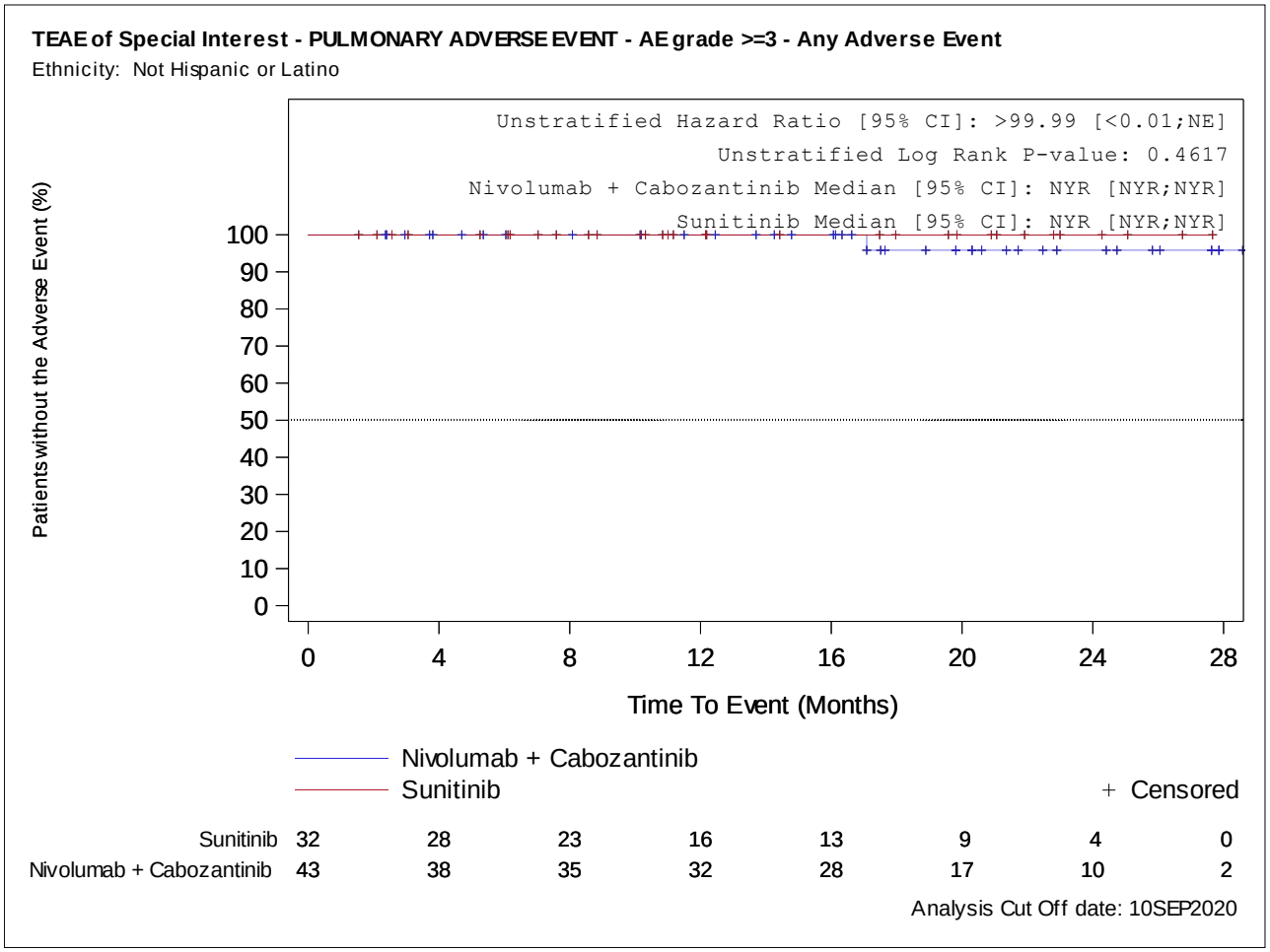

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:31:10

FIGURE 3.43.2.10: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



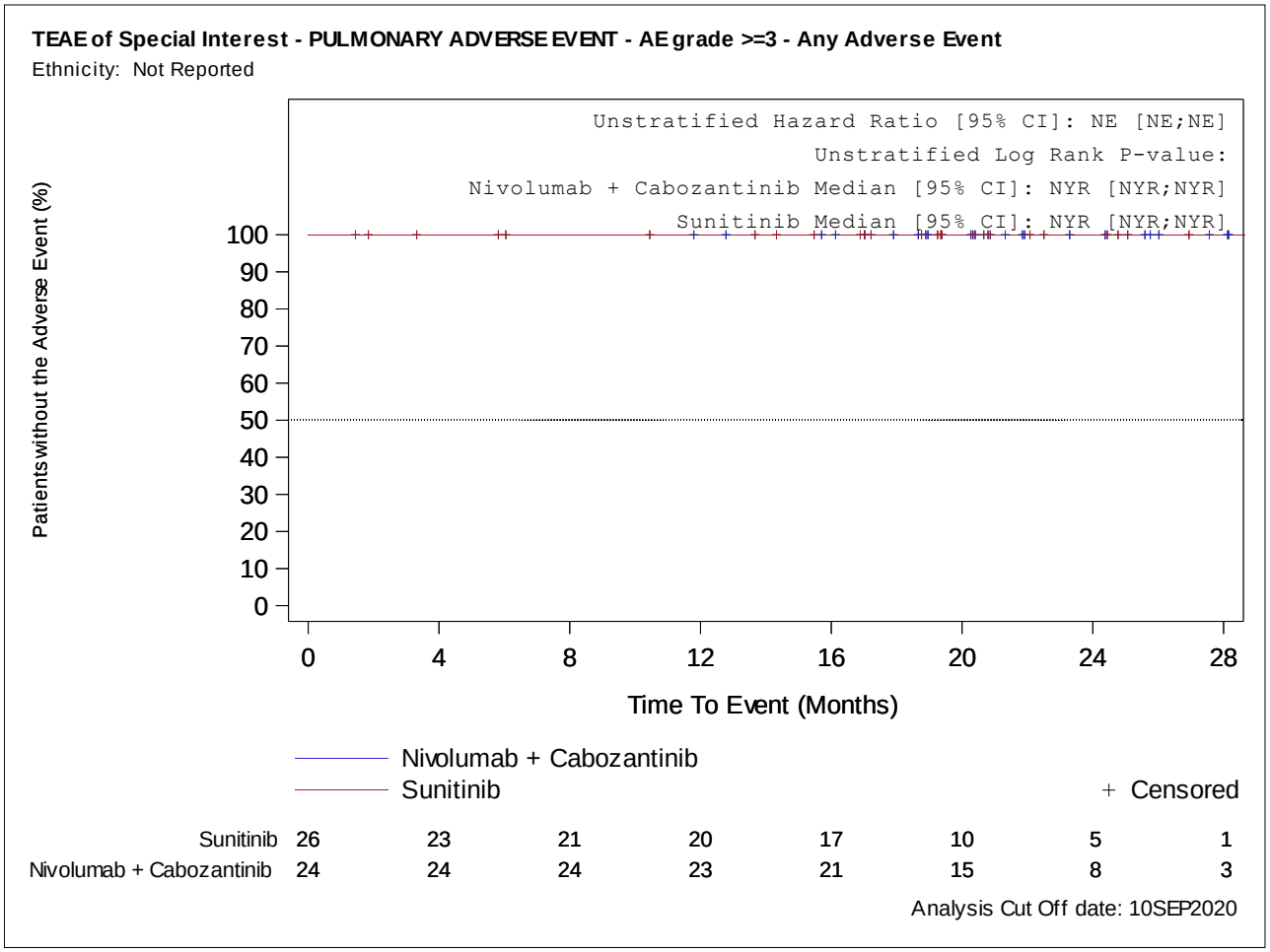

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:31:15

FIGURE 3.43.2.11: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



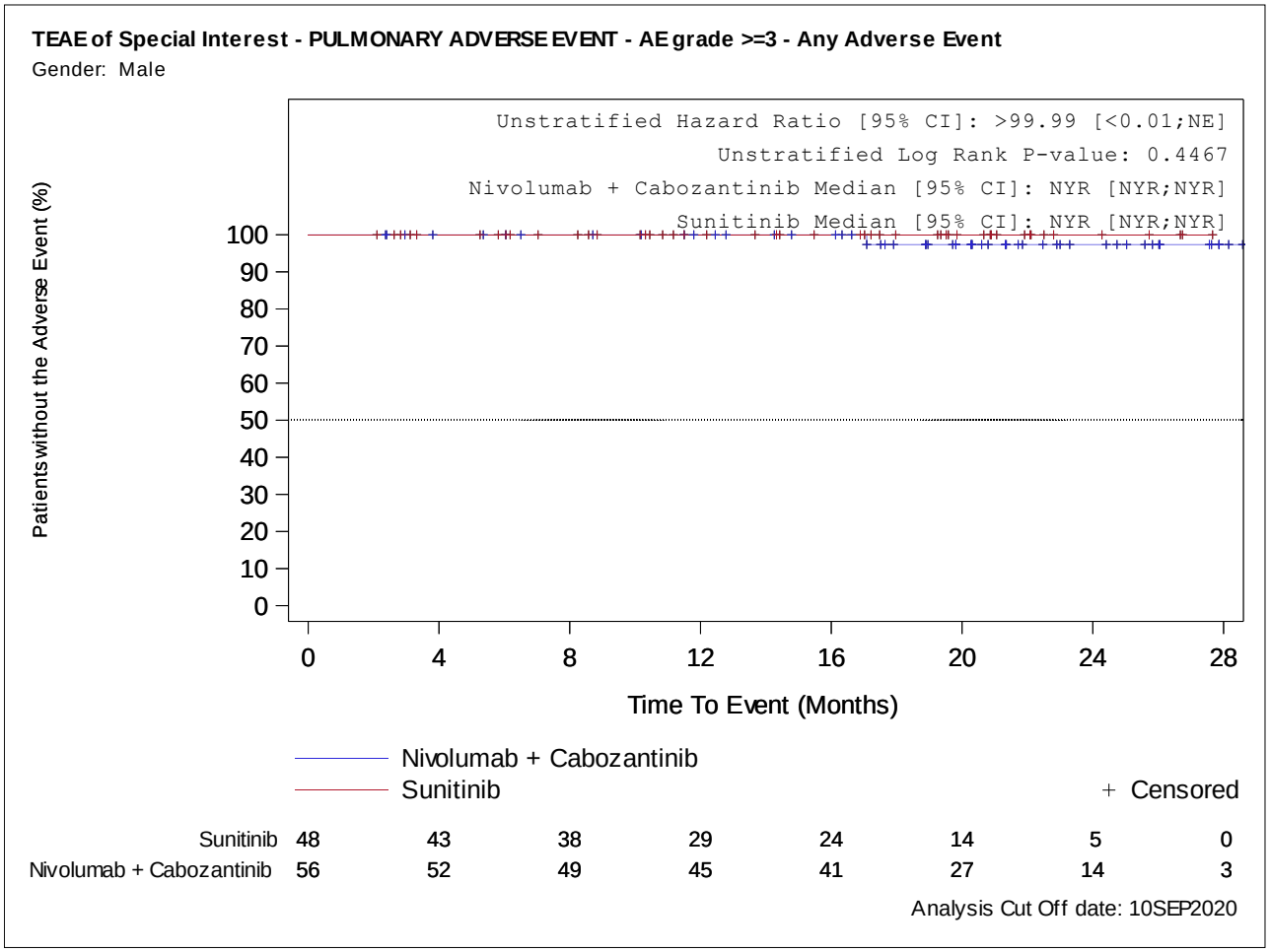

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:31:20

FIGURE 3.43.2.12: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



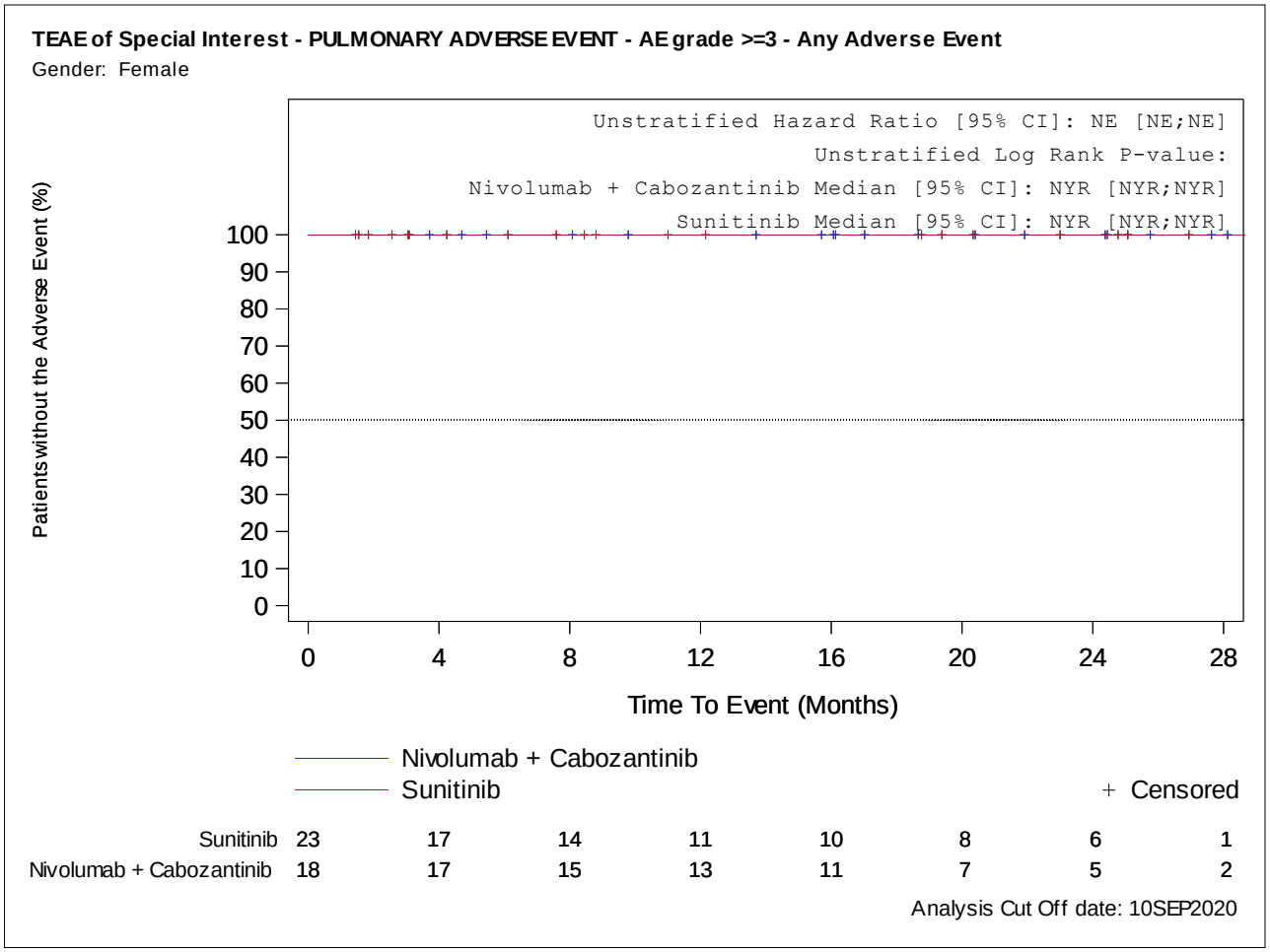

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:31:25

FIGURE 3.43.2.13: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



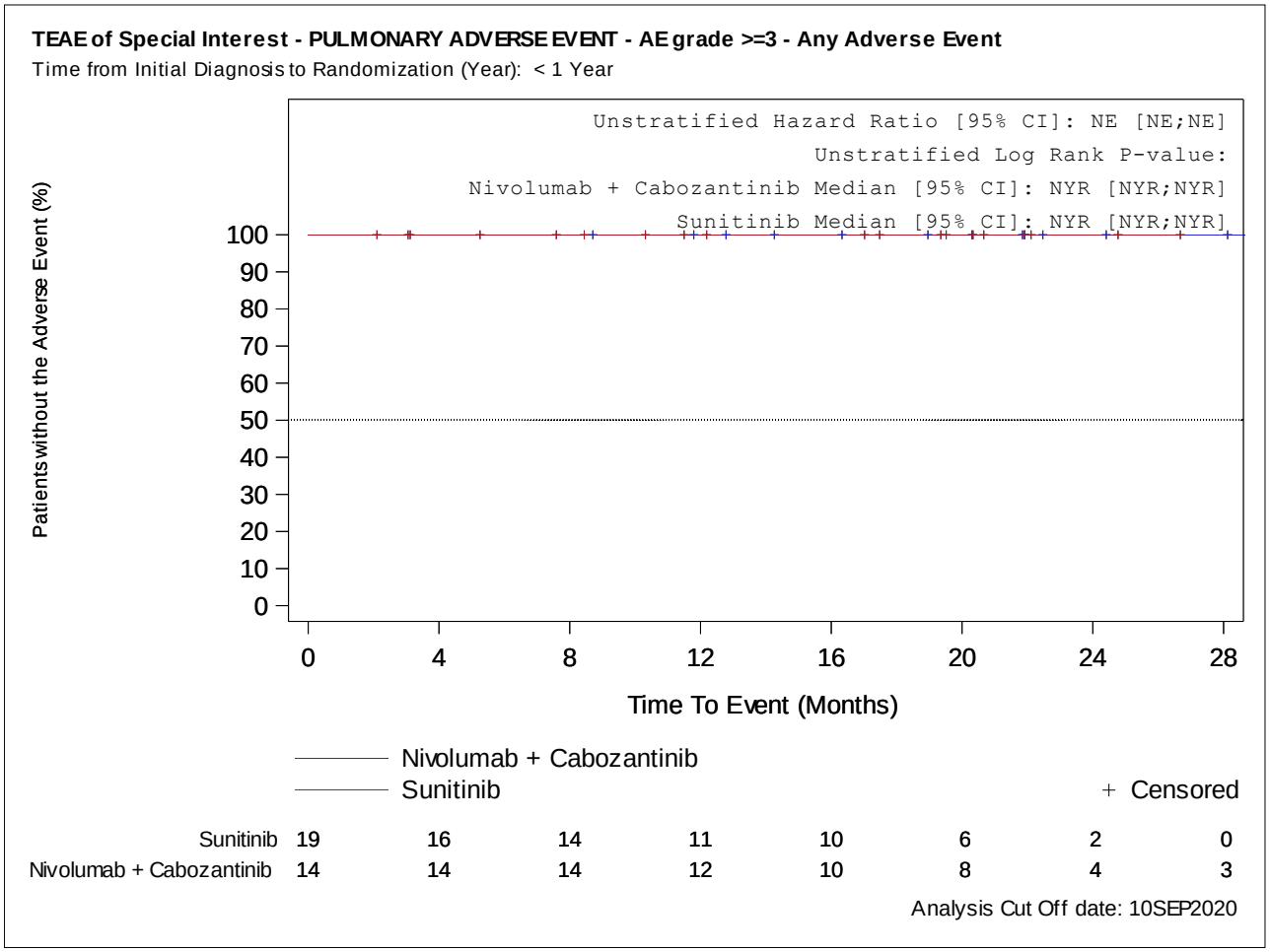

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:31:31

FIGURE 3.43.2.14: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



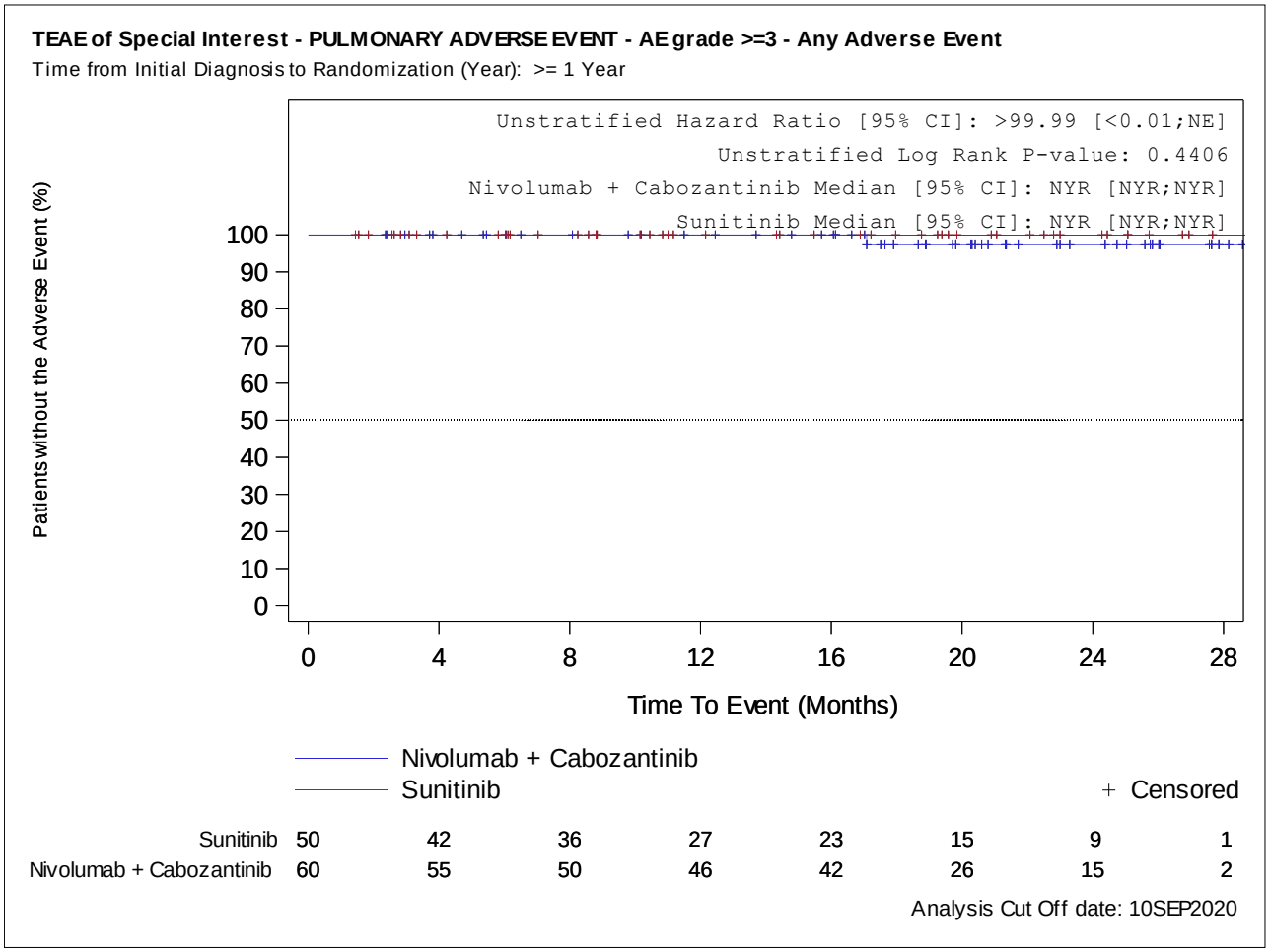

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:31:35

FIGURE 3.43.2.15: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



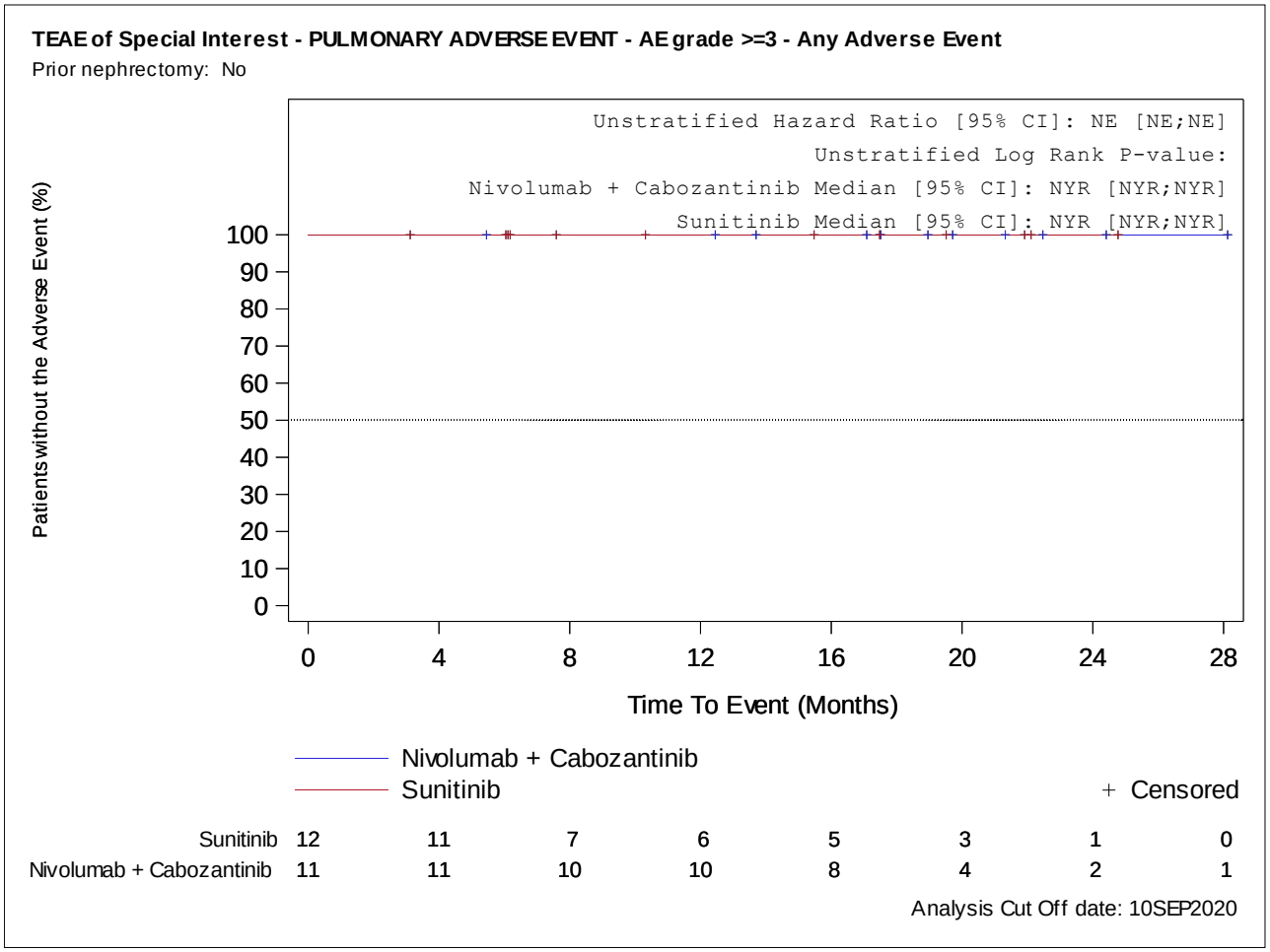

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:31:50

FIGURE 3.43.2.16: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



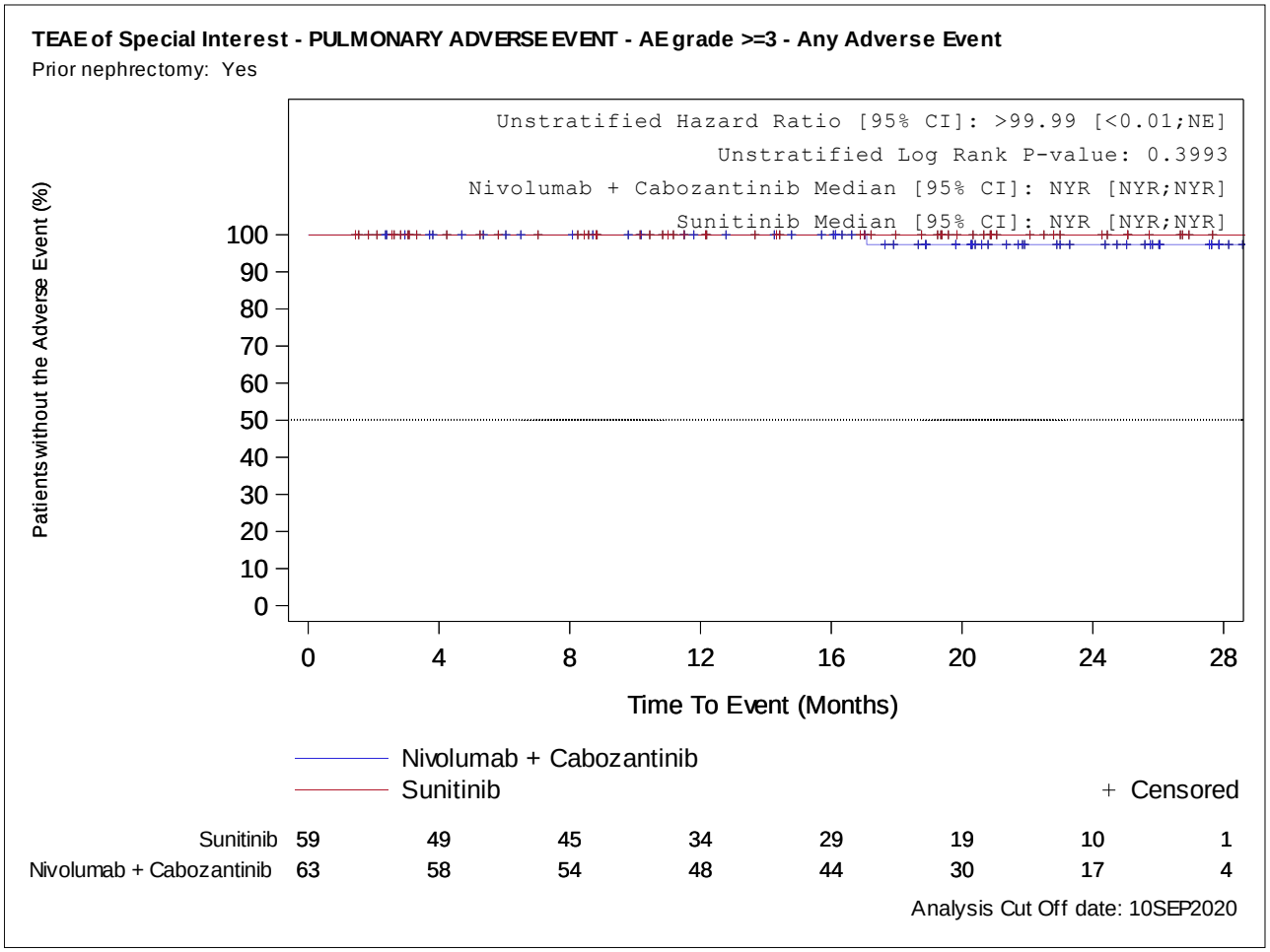

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:31:55

FIGURE 3.43.2.17: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



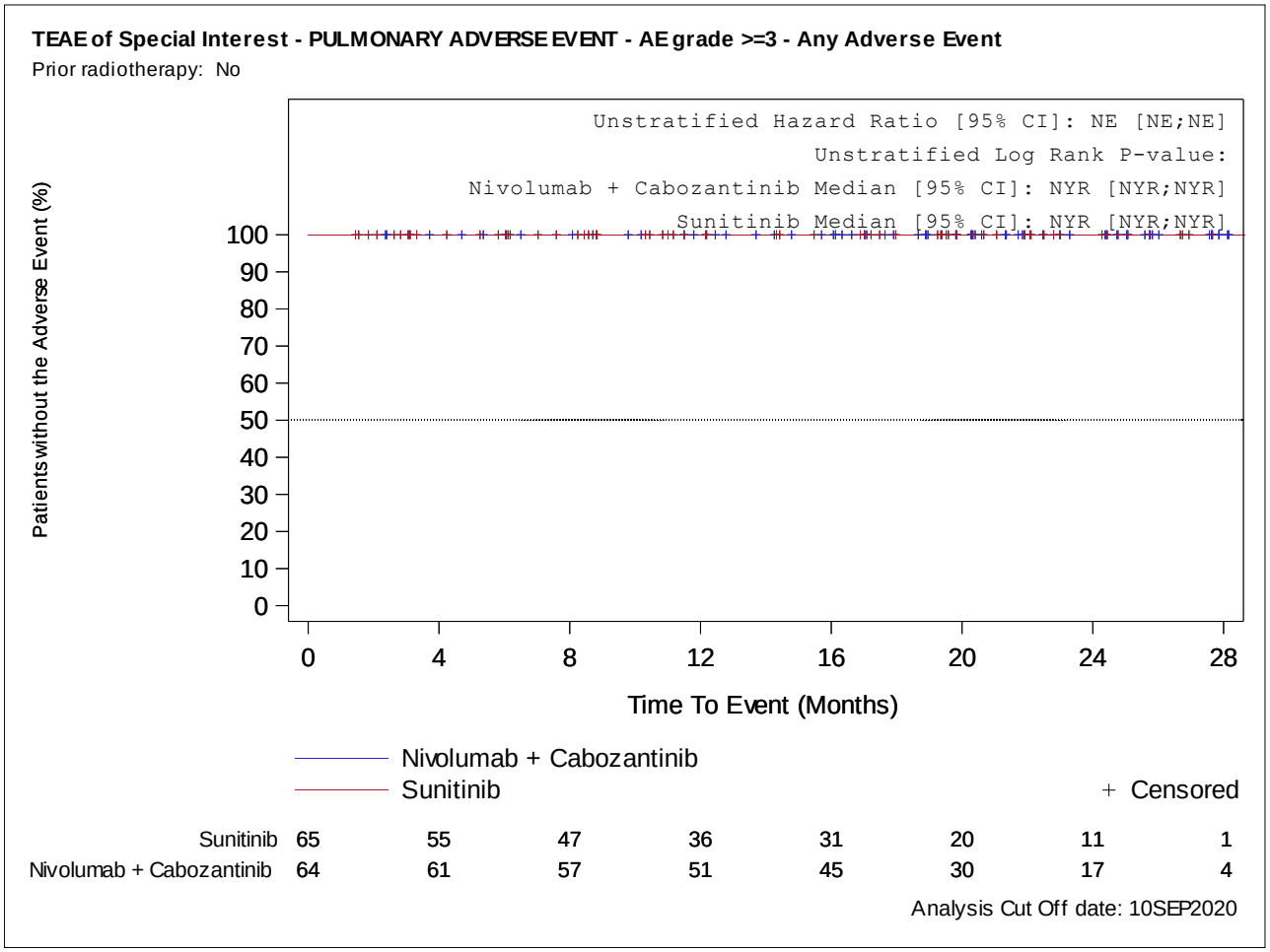

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:32:43

FIGURE 3.43.2.18: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



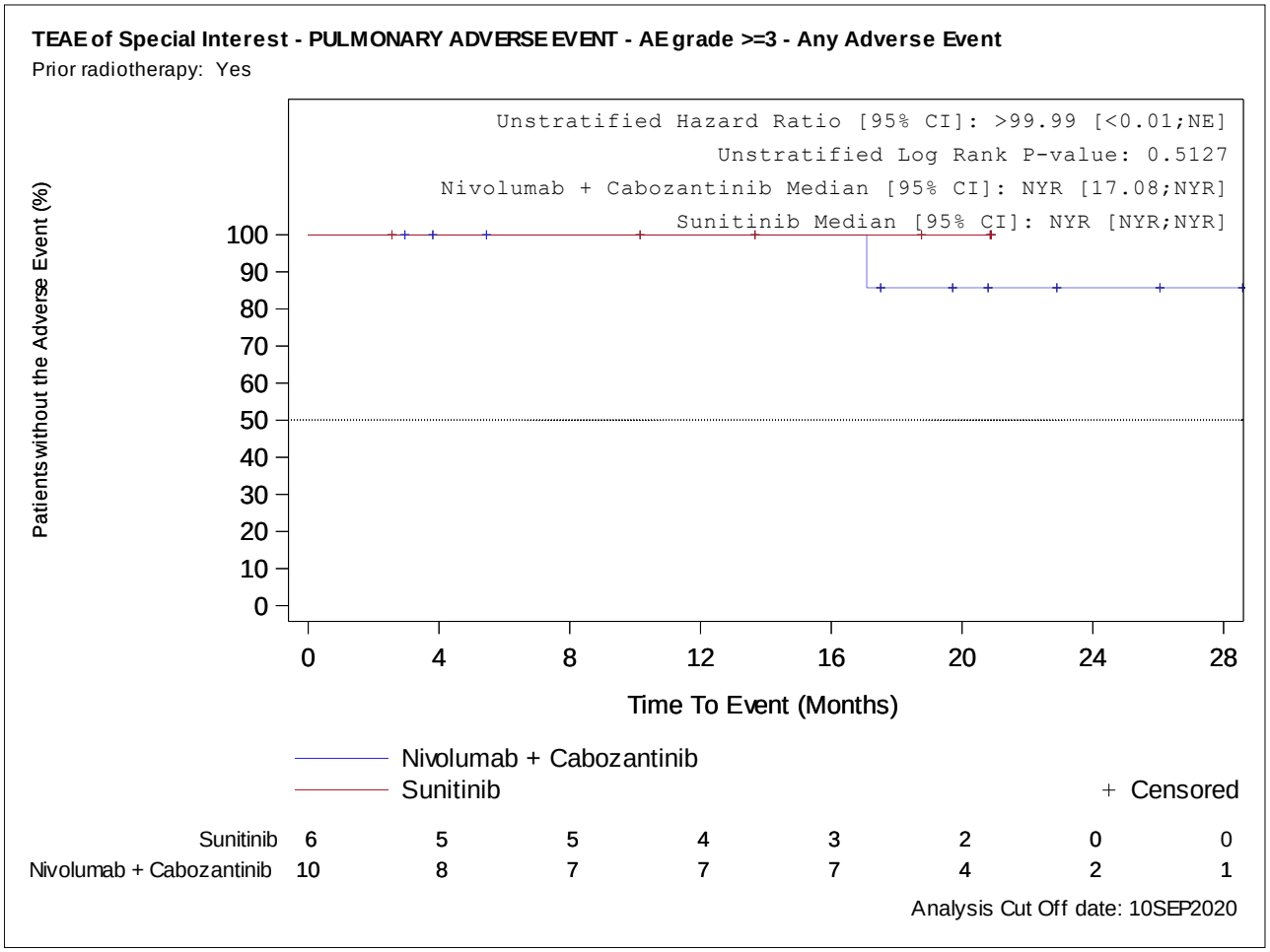

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:32:48

FIGURE 3.43.2.19: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



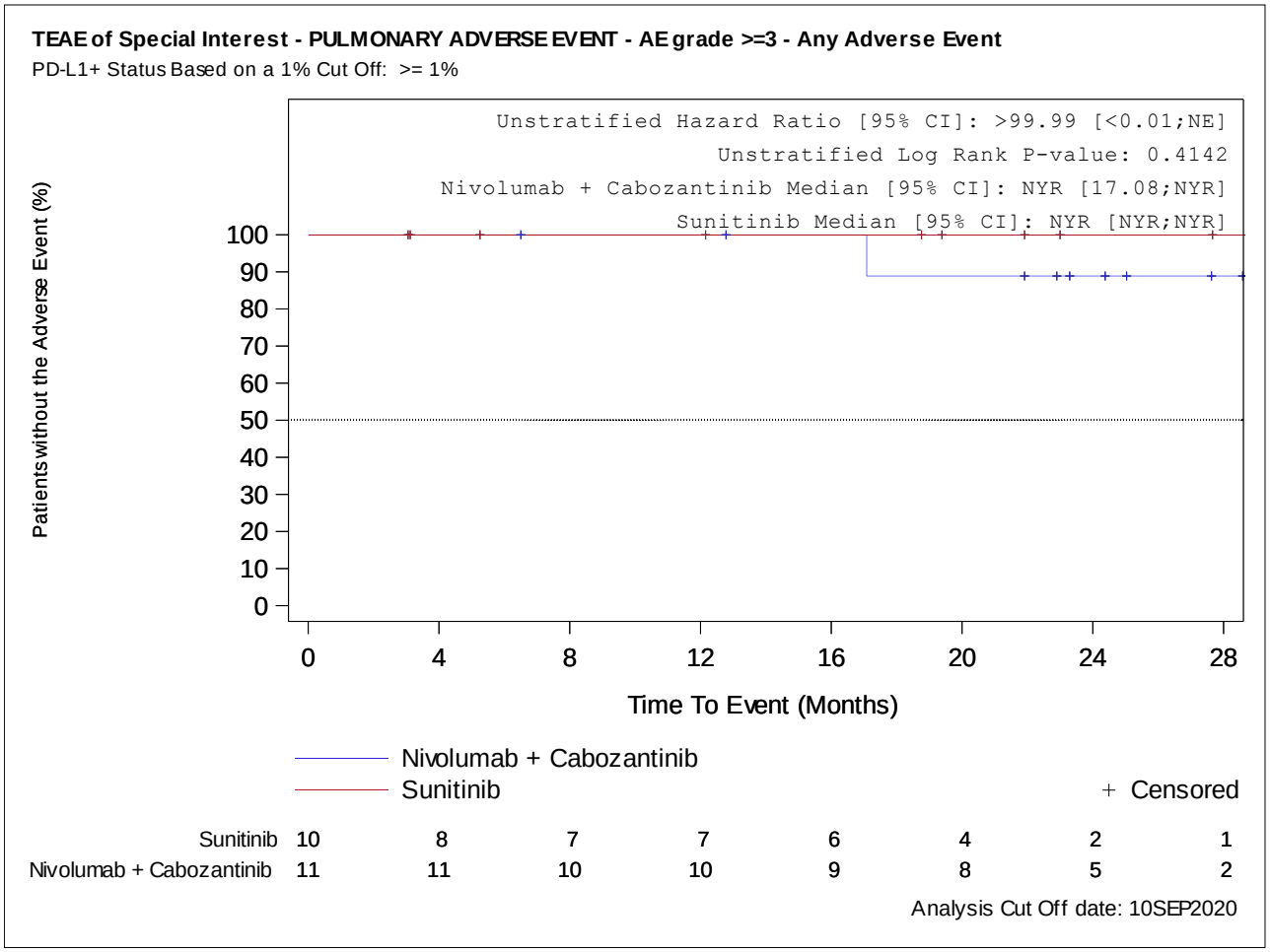

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:32:53

FIGURE 3.43.2.20: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



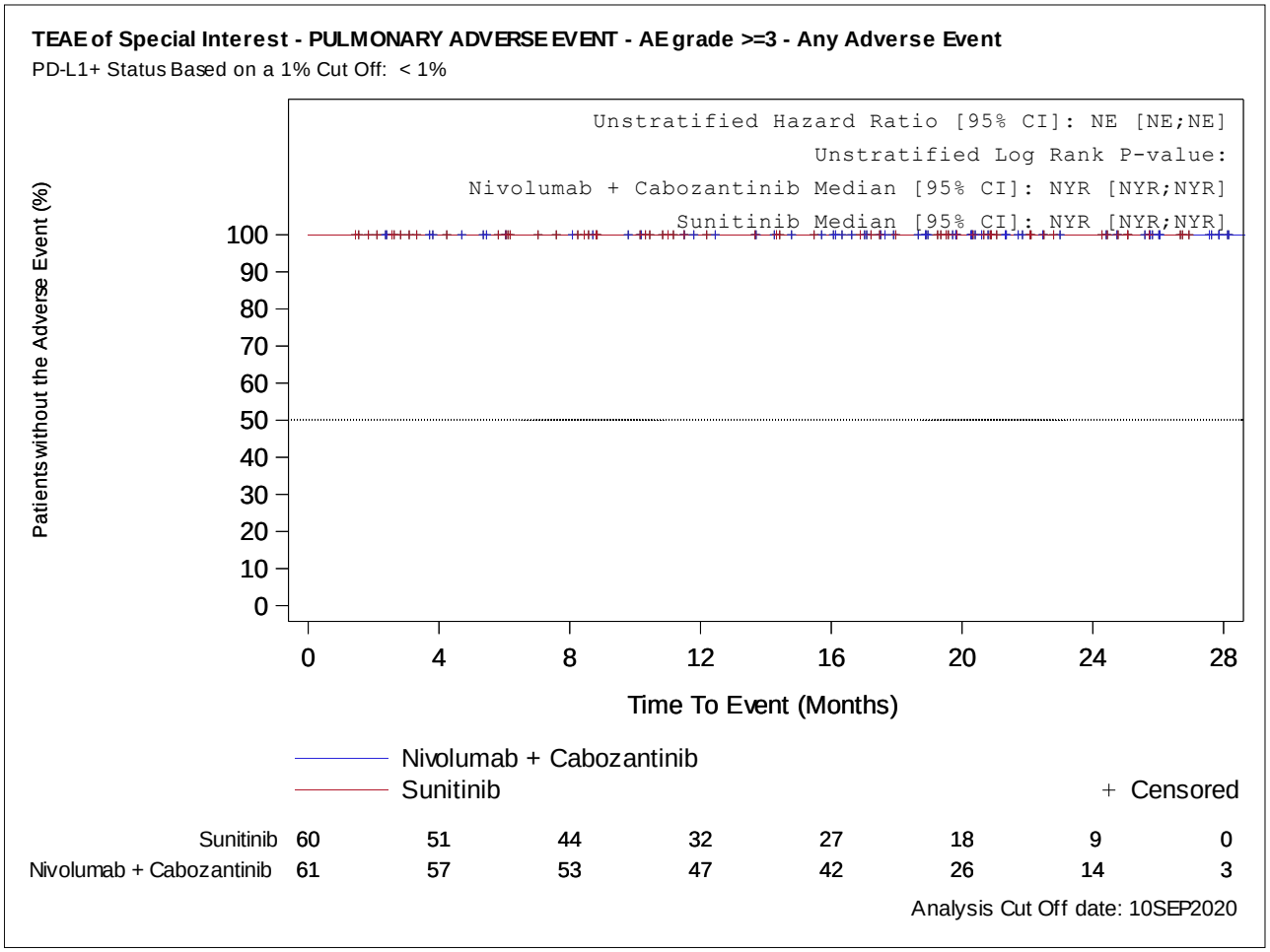

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:32:58

FIGURE 3.43.2.21: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



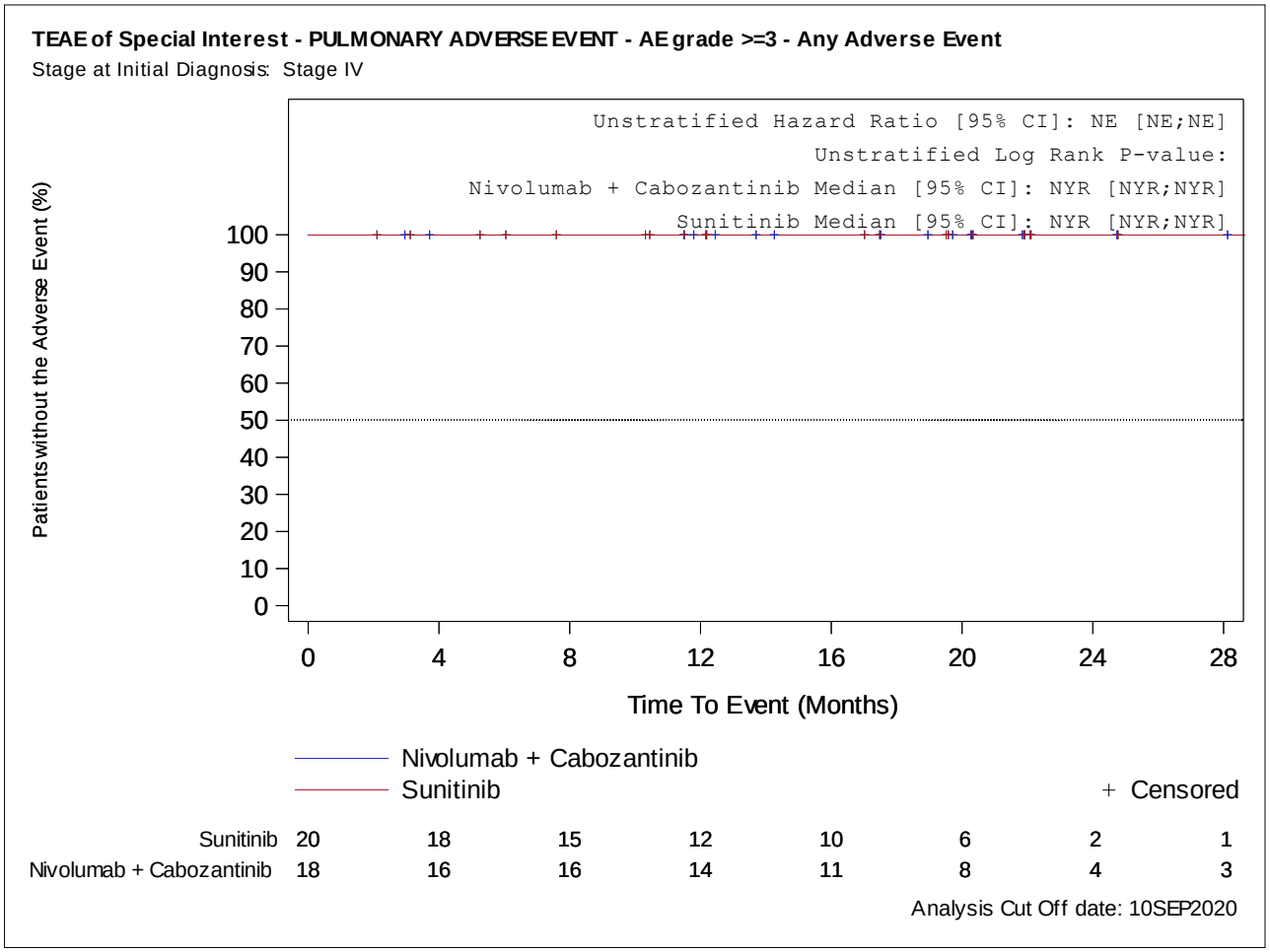

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:33:03

FIGURE 3.43.2.22: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



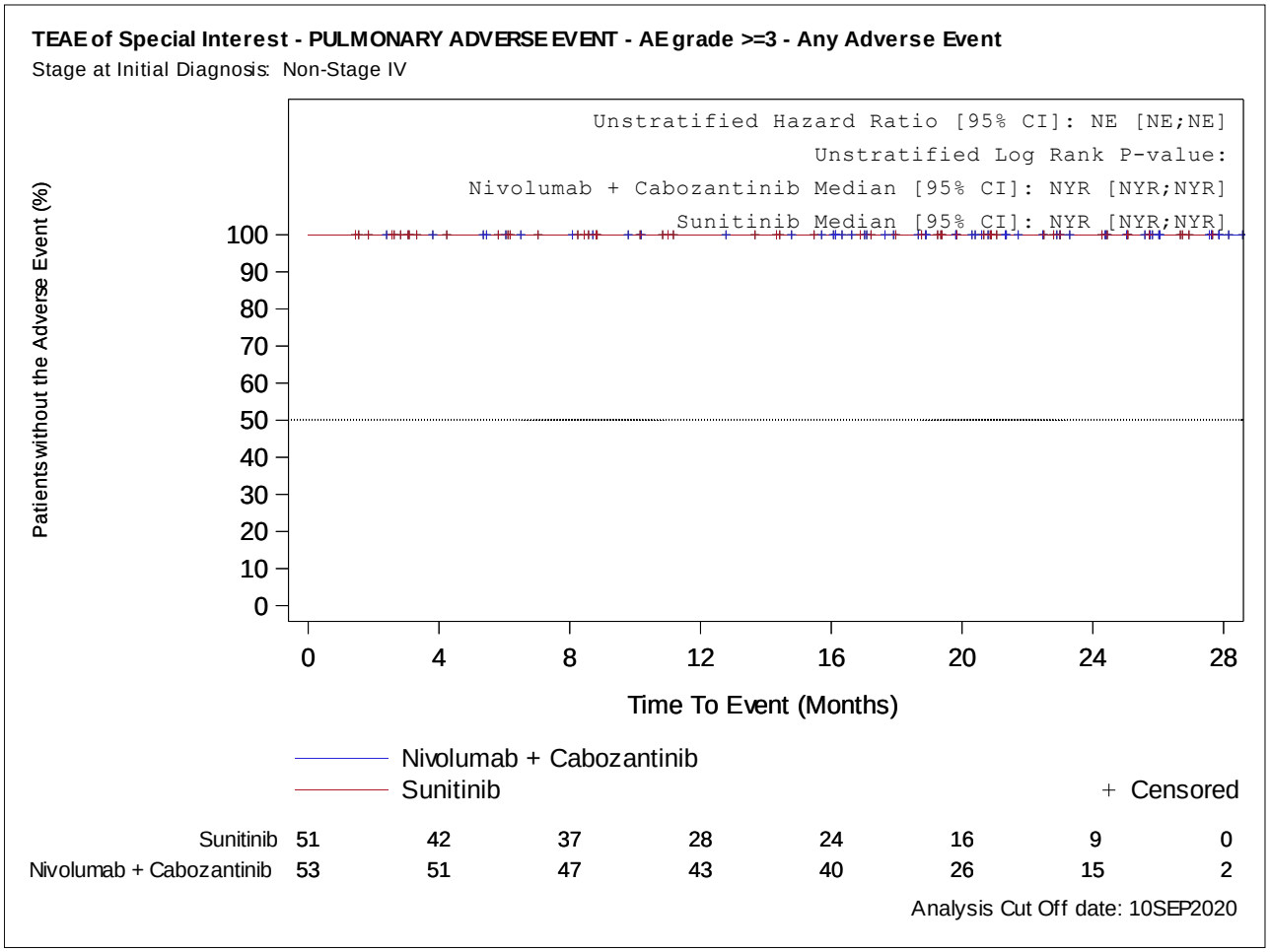

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:33:09

FIGURE 3.43.2.23: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



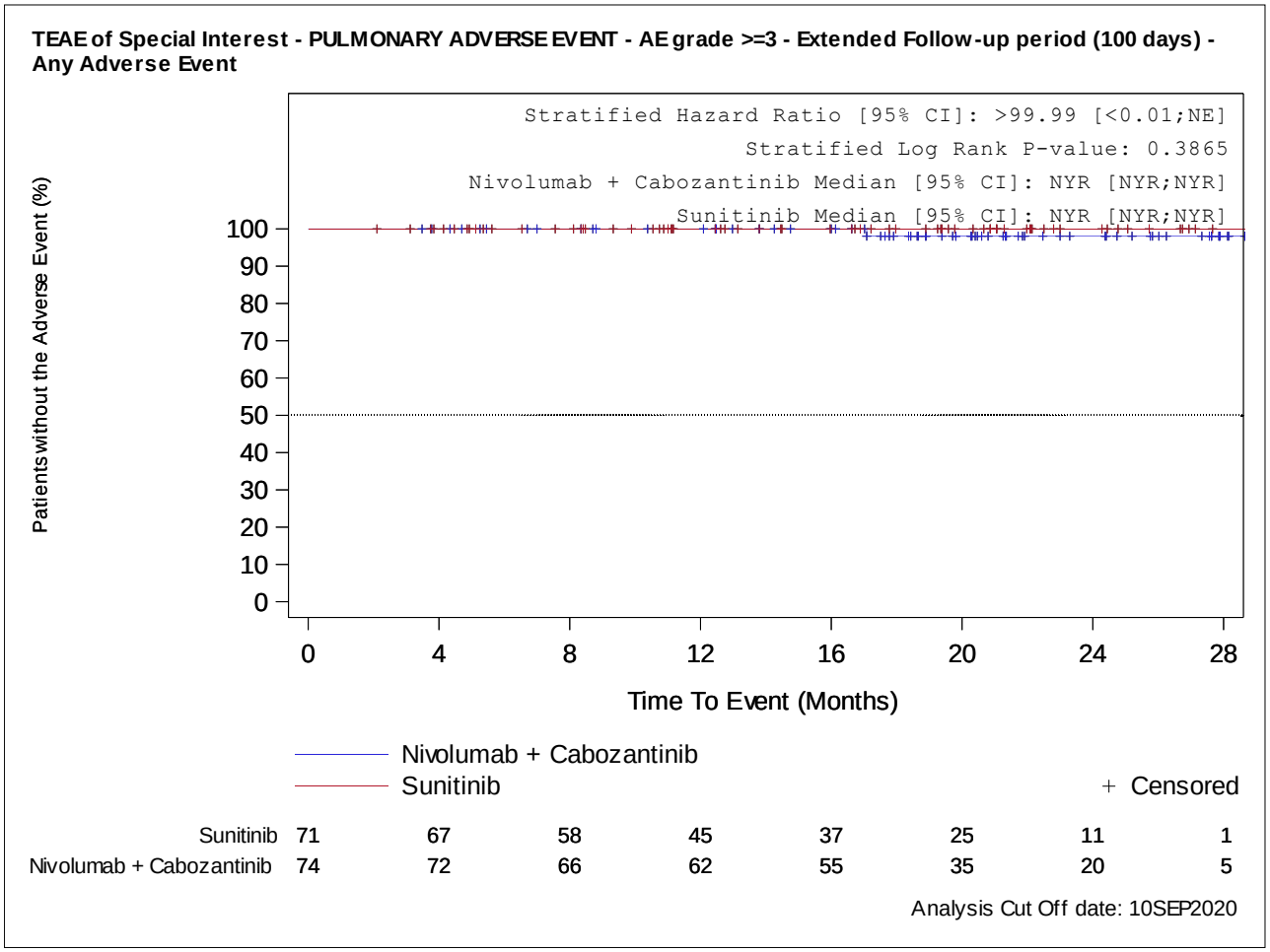

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:33:34

FIGURE 3.43.2.24: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



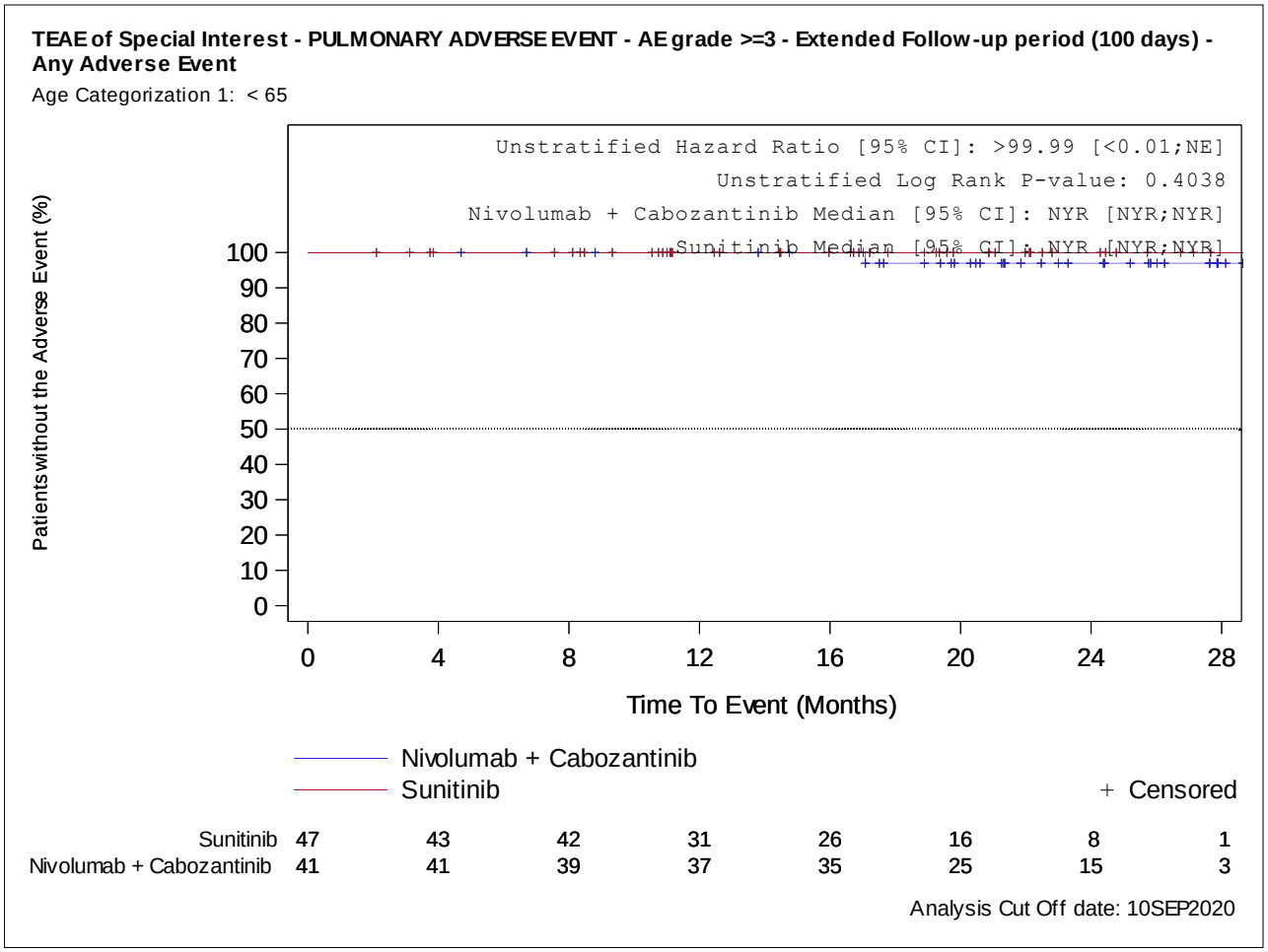

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:33:39

FIGURE 3.44.1: TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



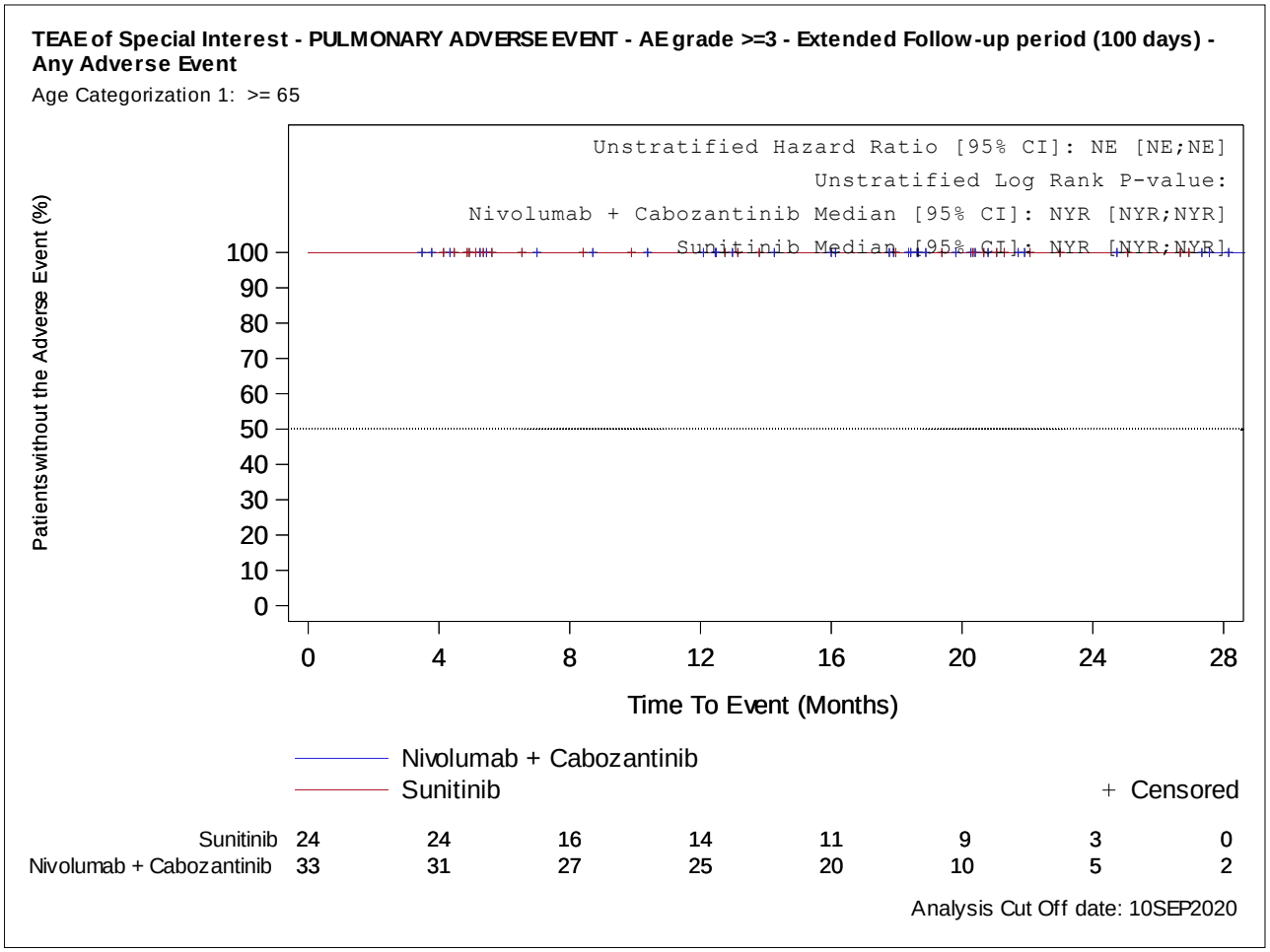

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:36:36

FIGURE 3.44.2.1: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



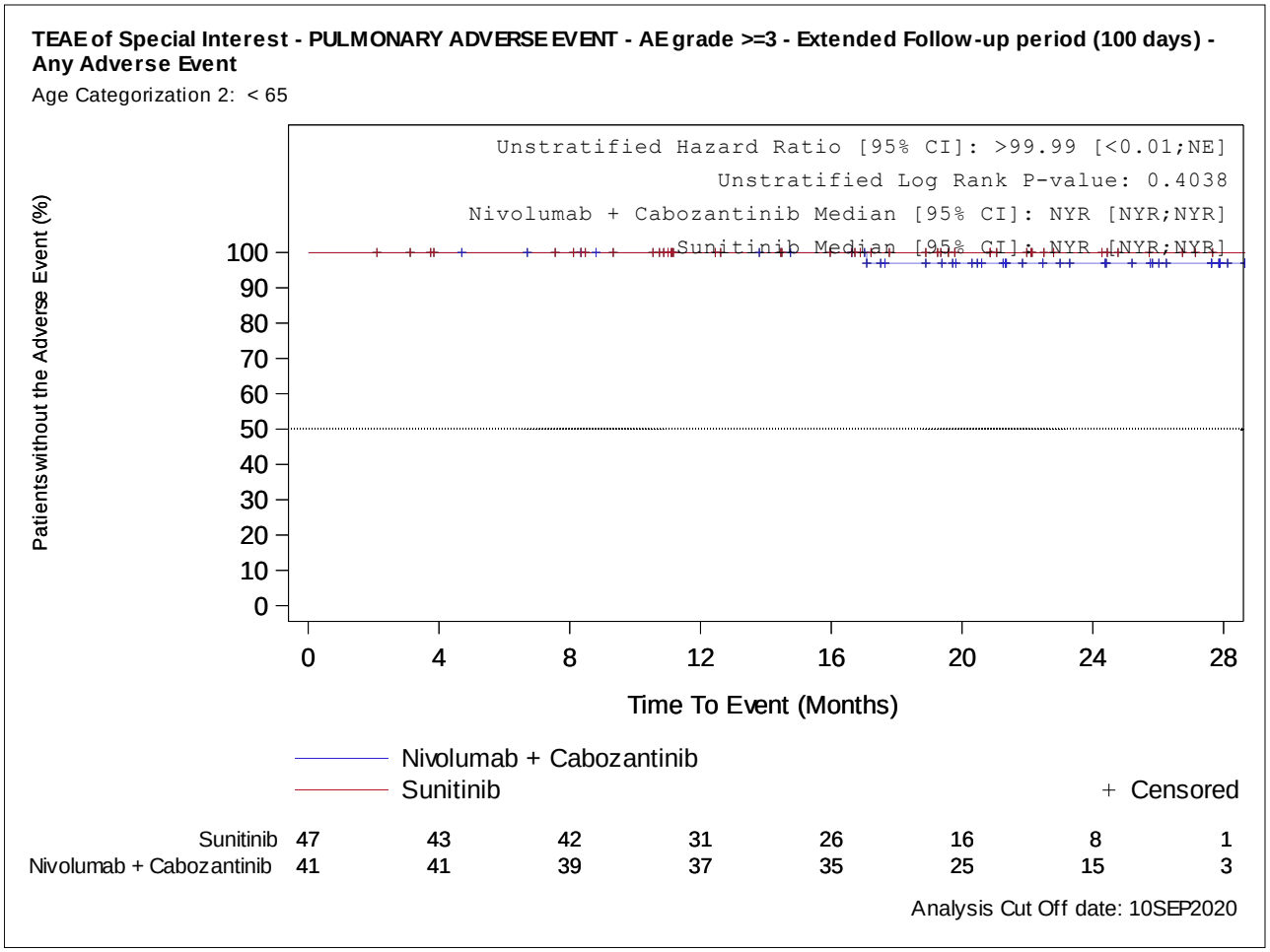

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:36:39

FIGURE 3.44.2.2: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



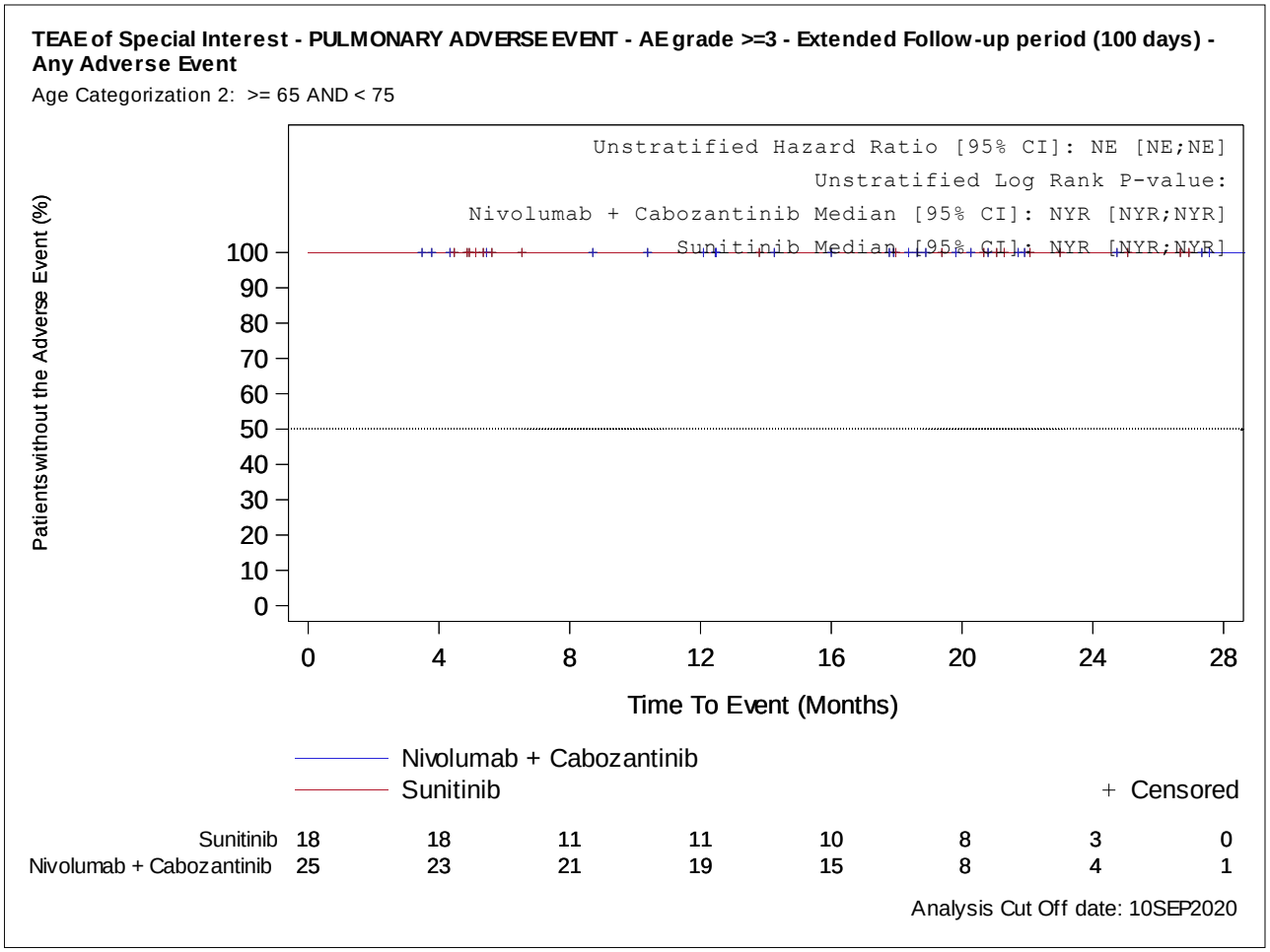

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:36:45

FIGURE 3.44.2.3: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



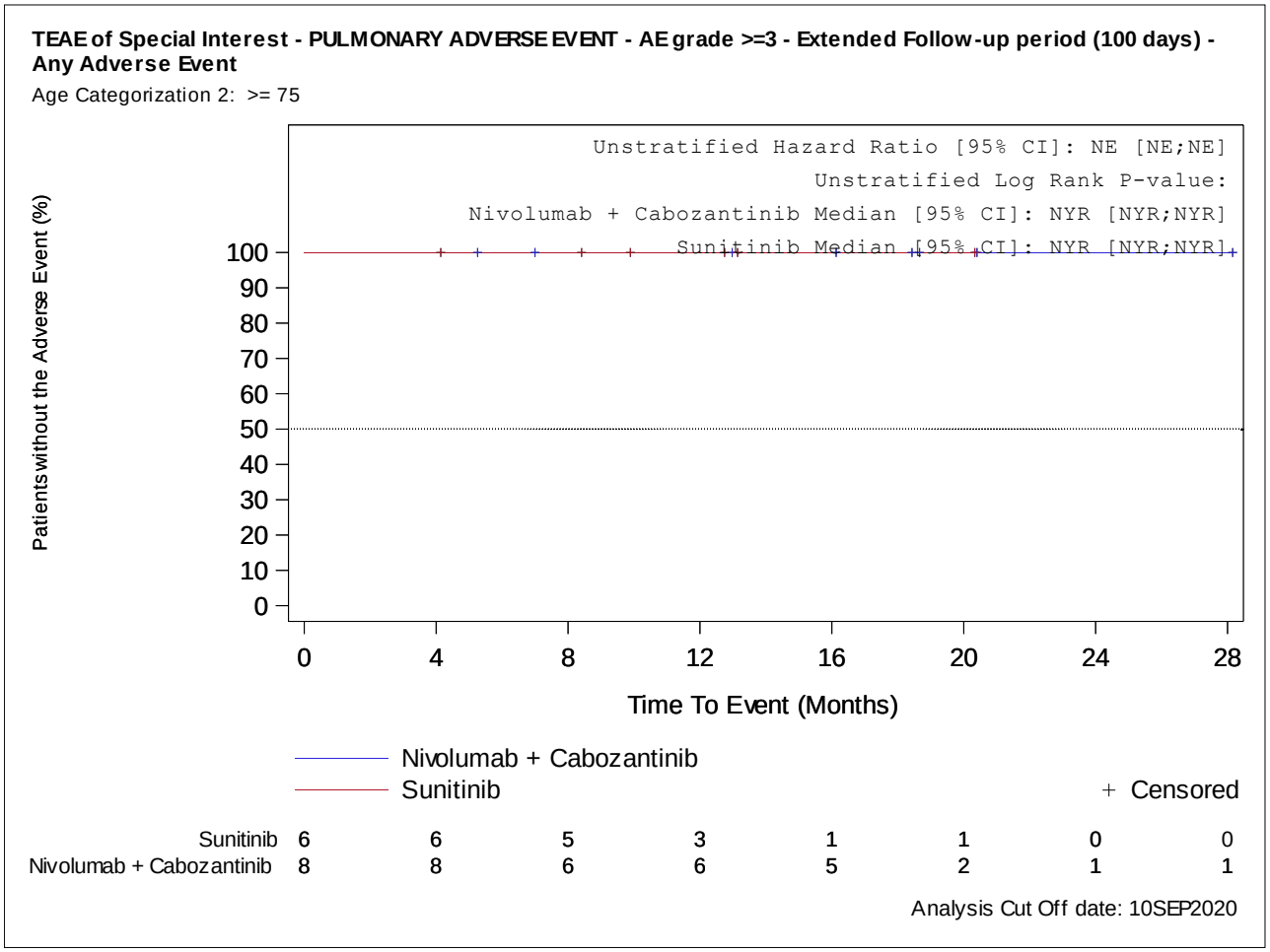

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:36:50

FIGURE 3.44.2.4: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



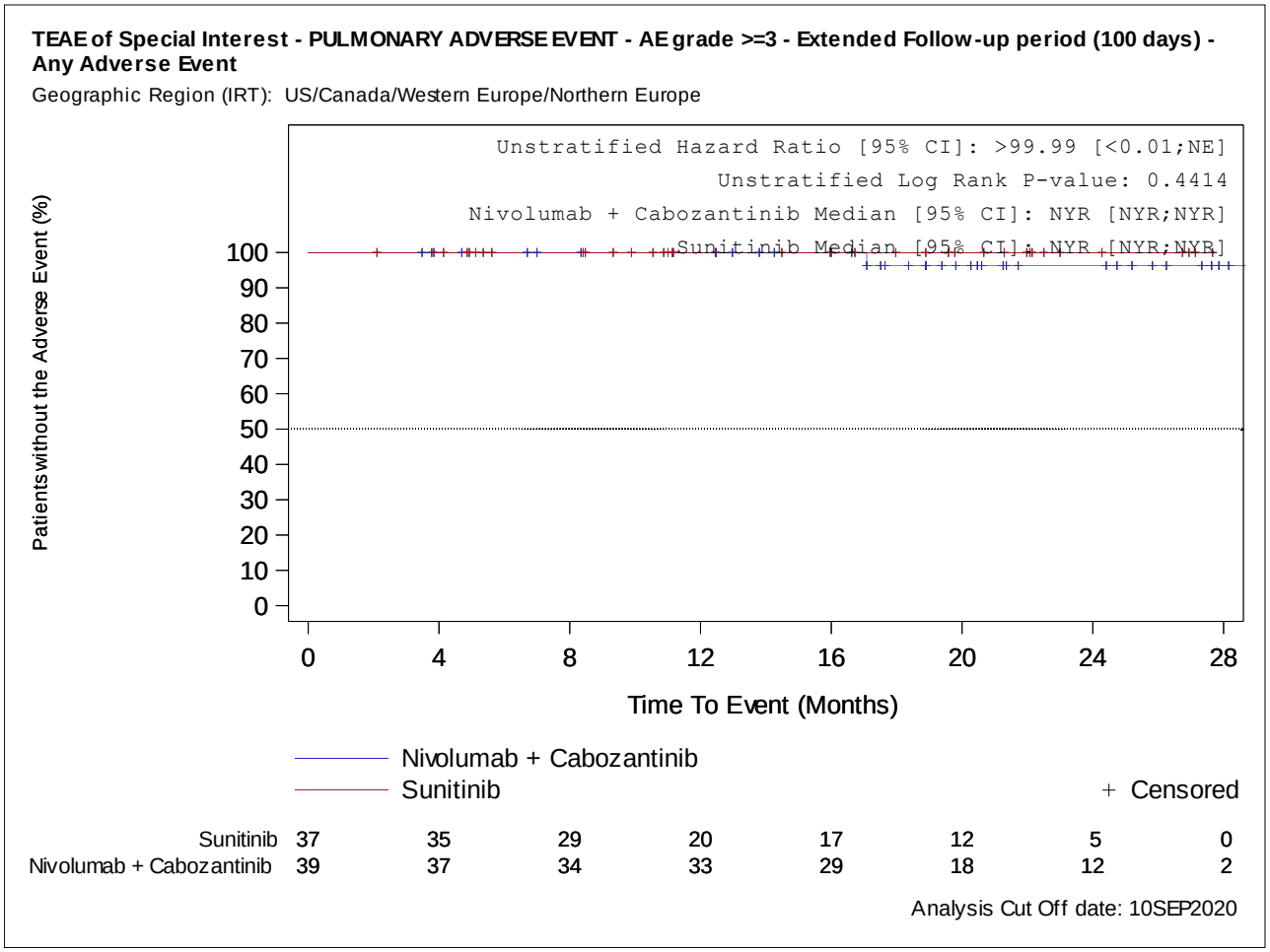

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:36:56

FIGURE 3.44.2.5: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



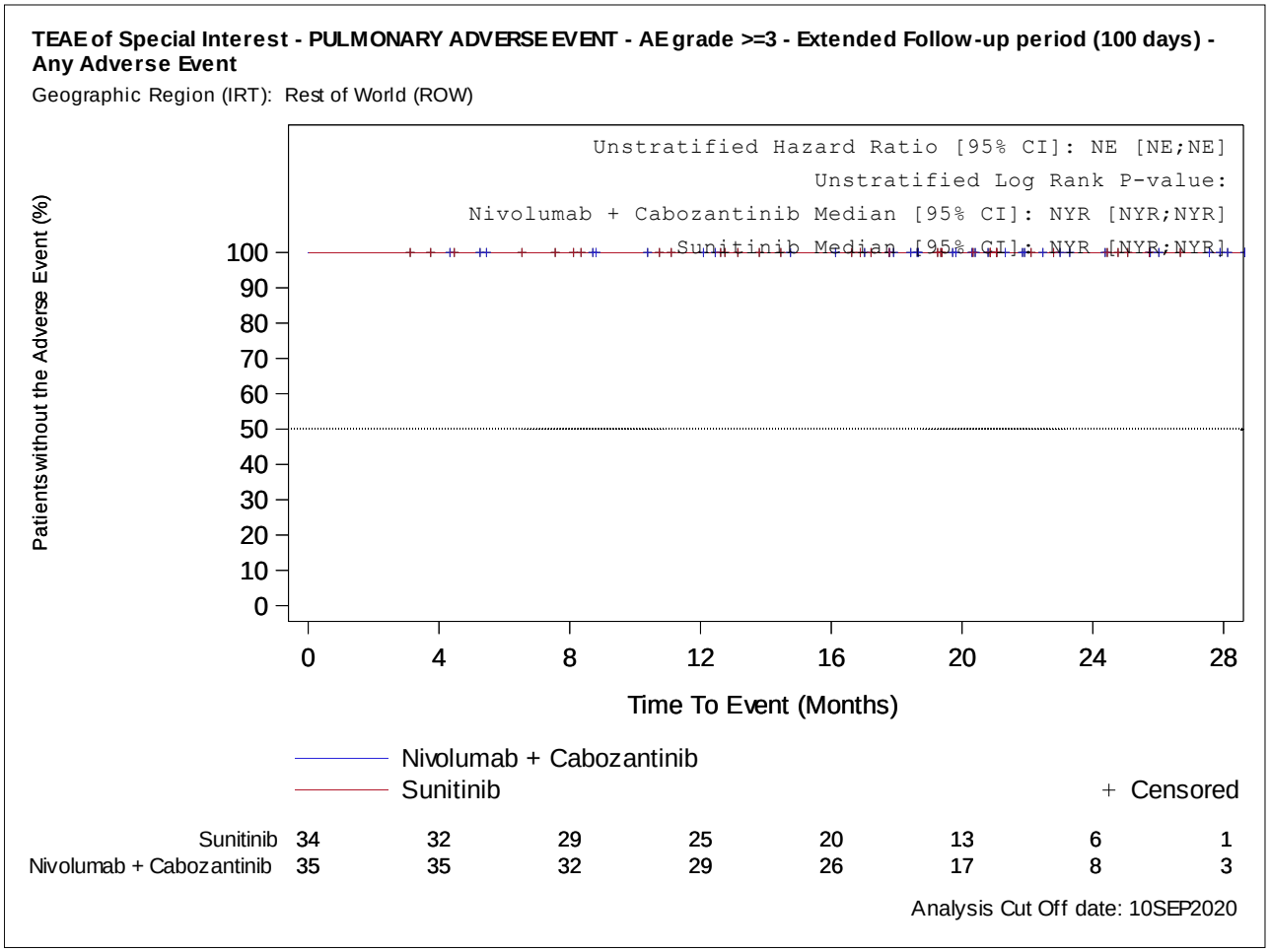

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:37:00

FIGURE 3.44.2.6: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



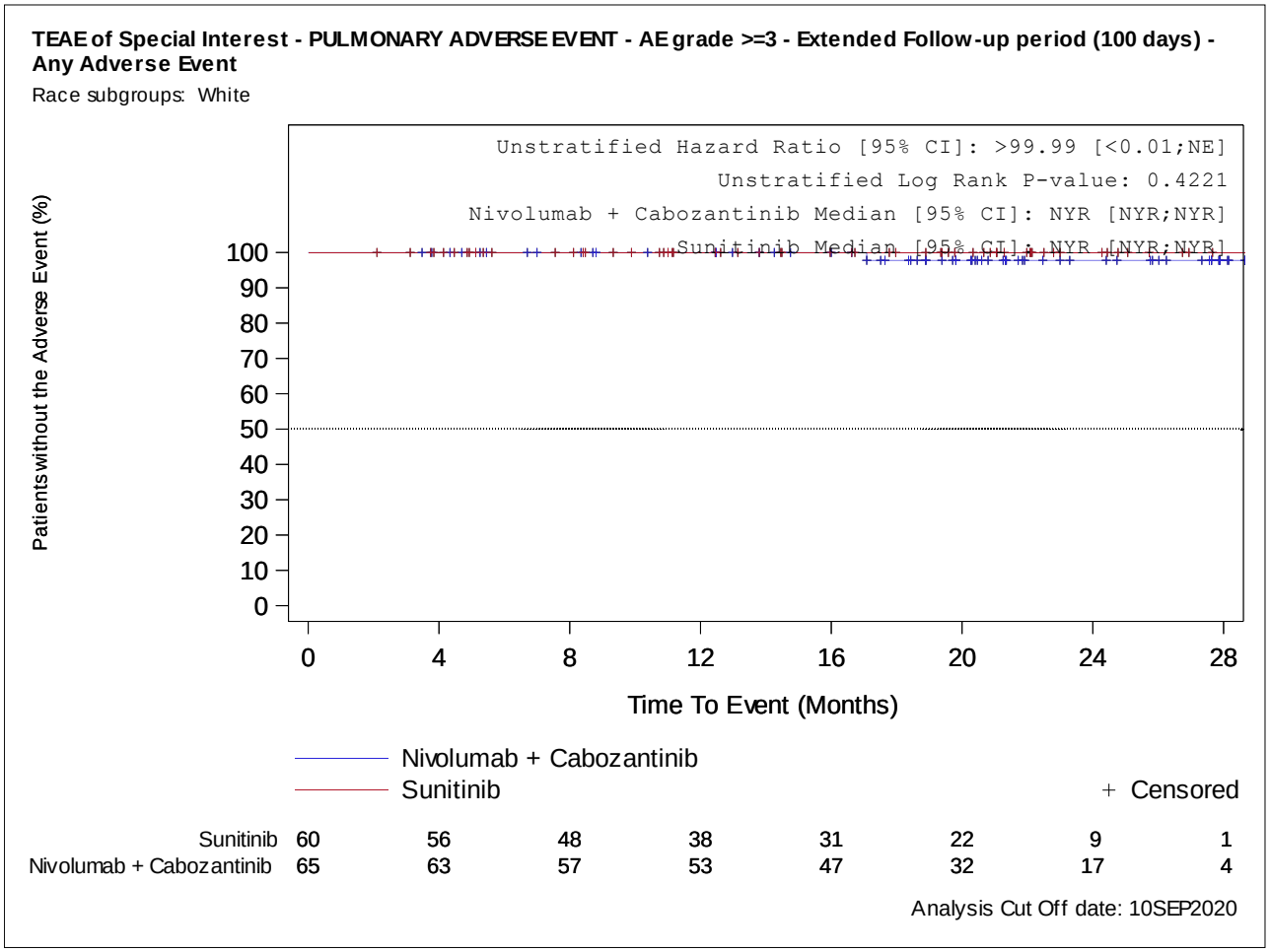

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:37:06

FIGURE 3.44.2.7: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



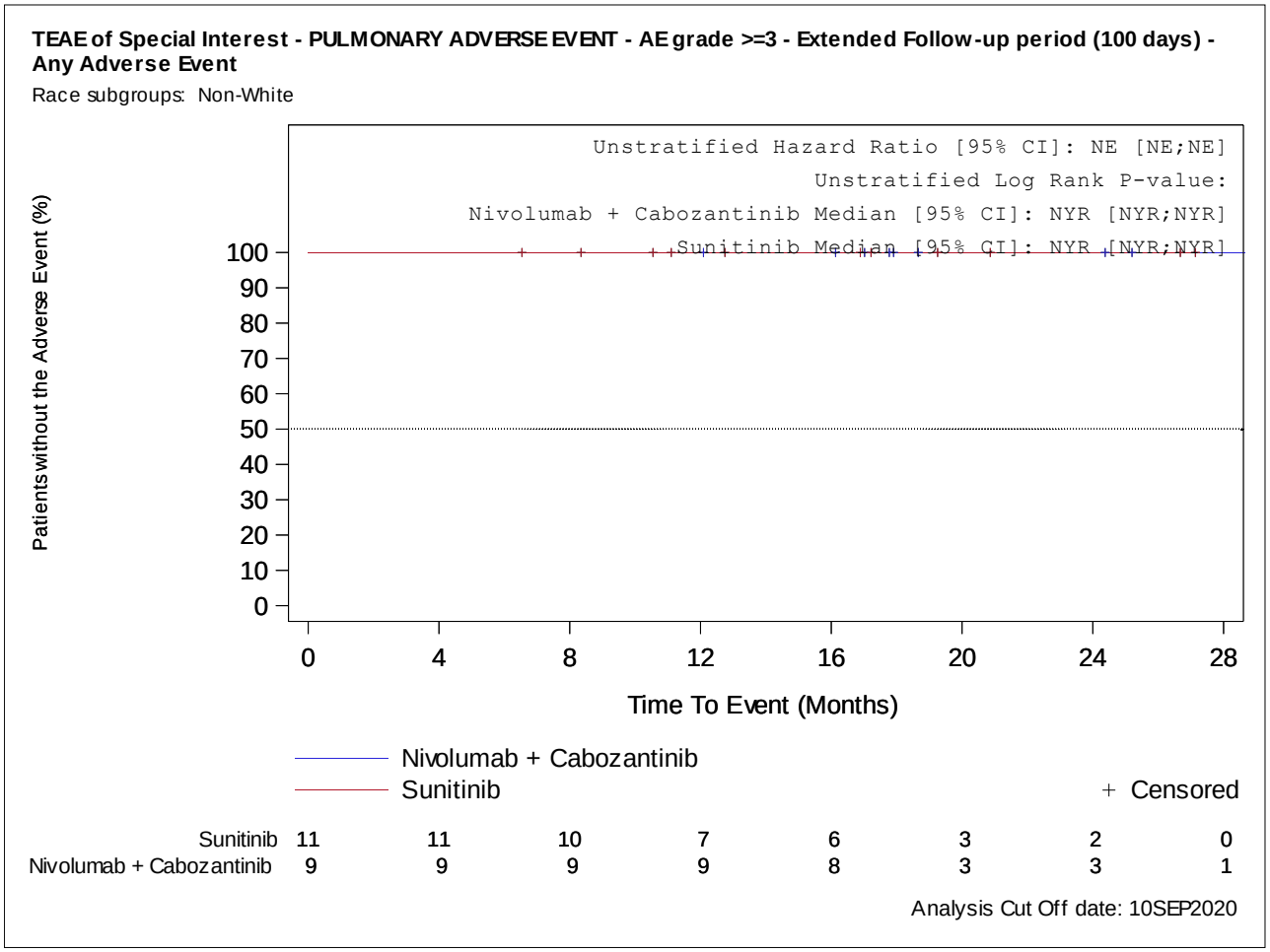

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:37:11

FIGURE 3.44.2.8: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



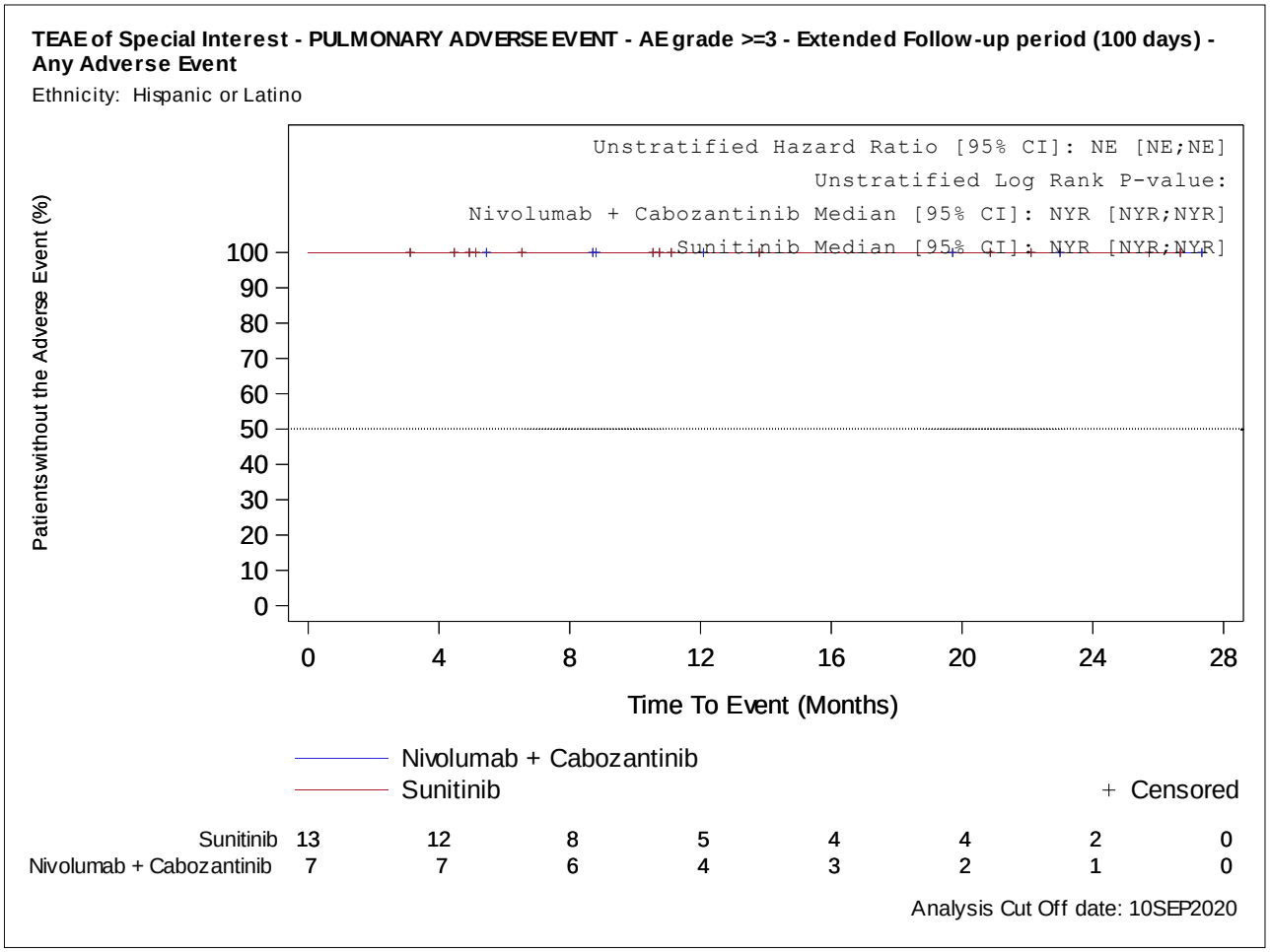

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:37:16

FIGURE 3.44.2.9: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



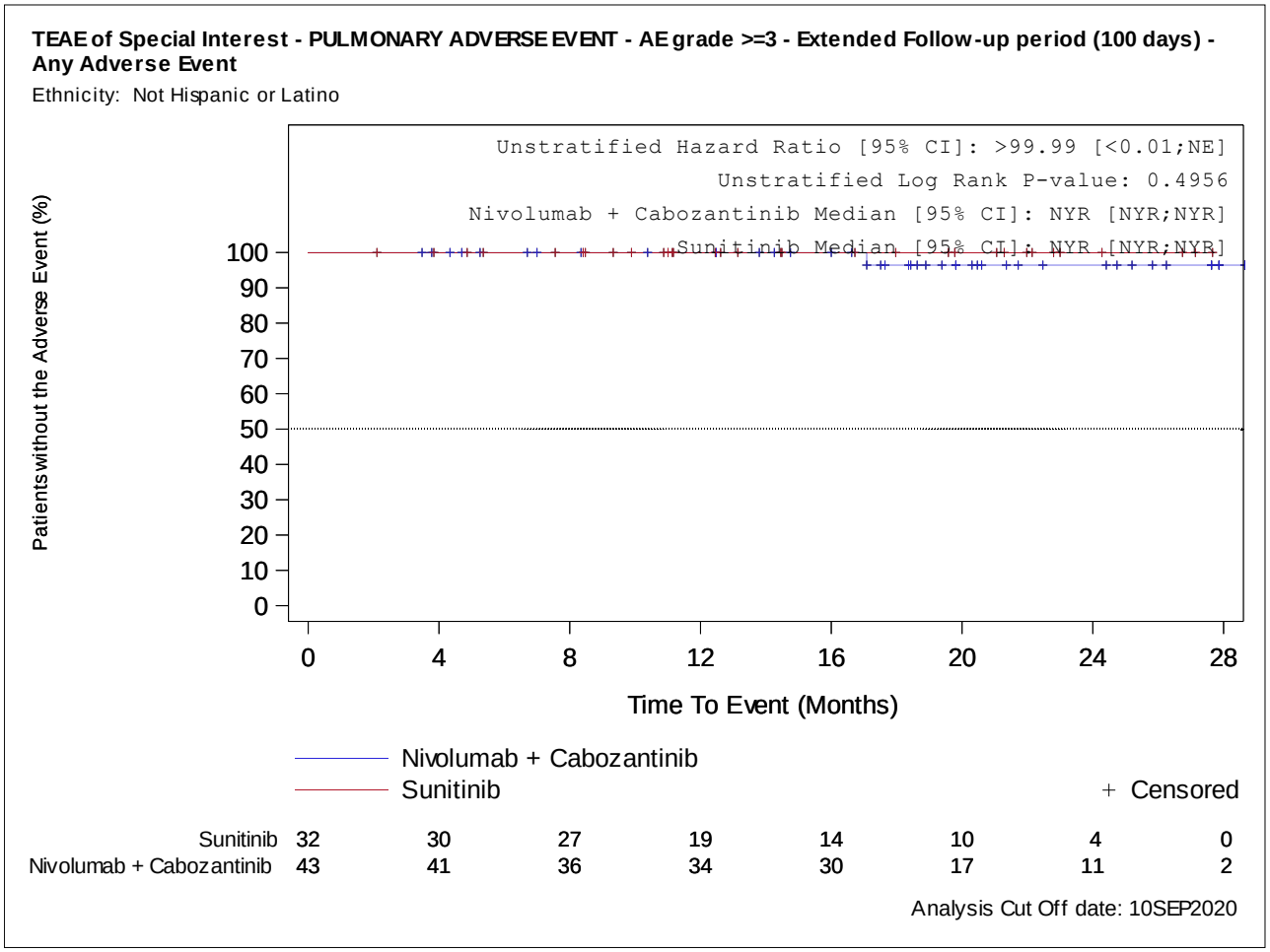

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:37:22

FIGURE 3.44.2.10: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



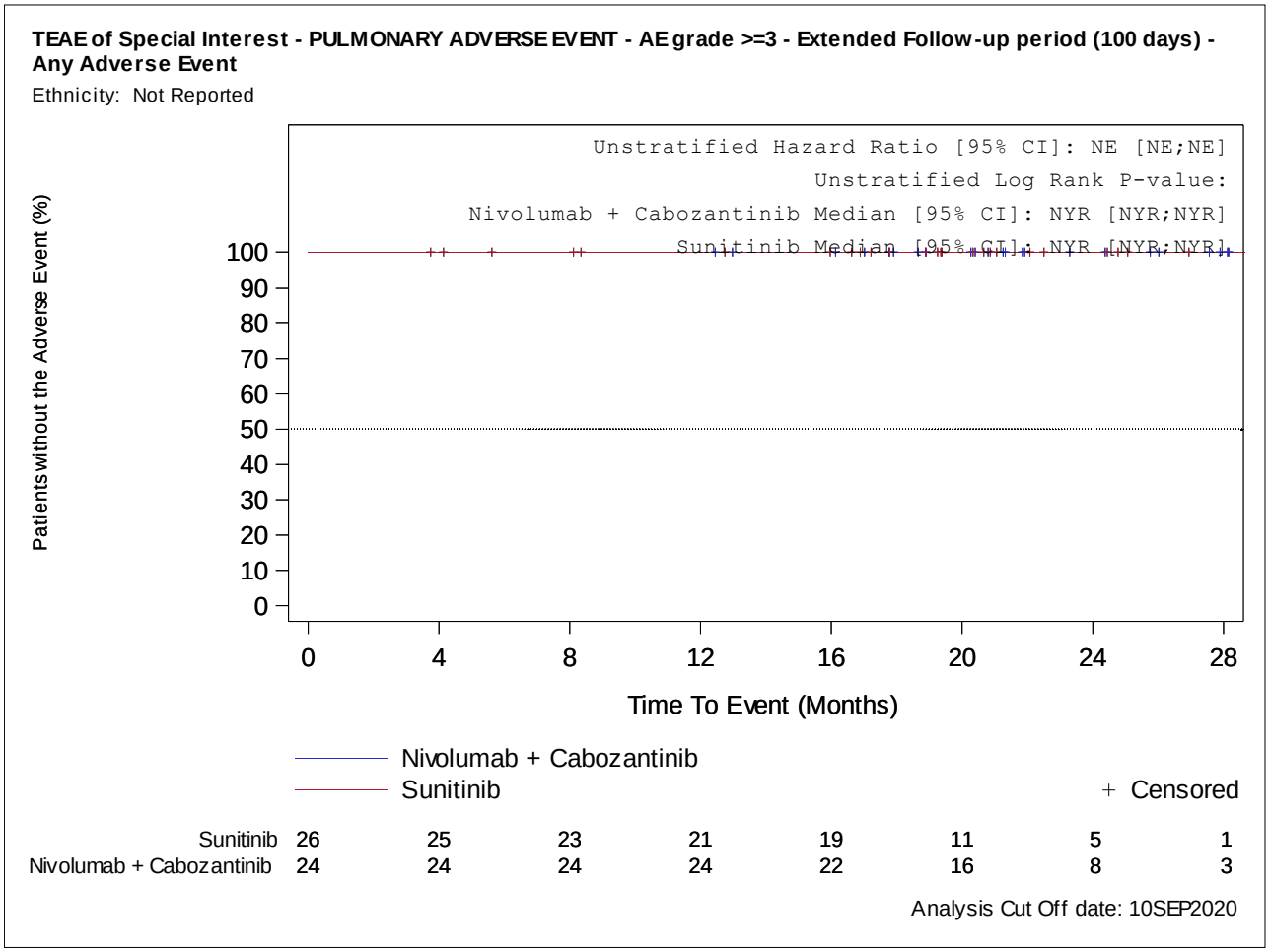

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:37:27

FIGURE 3.44.2.11: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



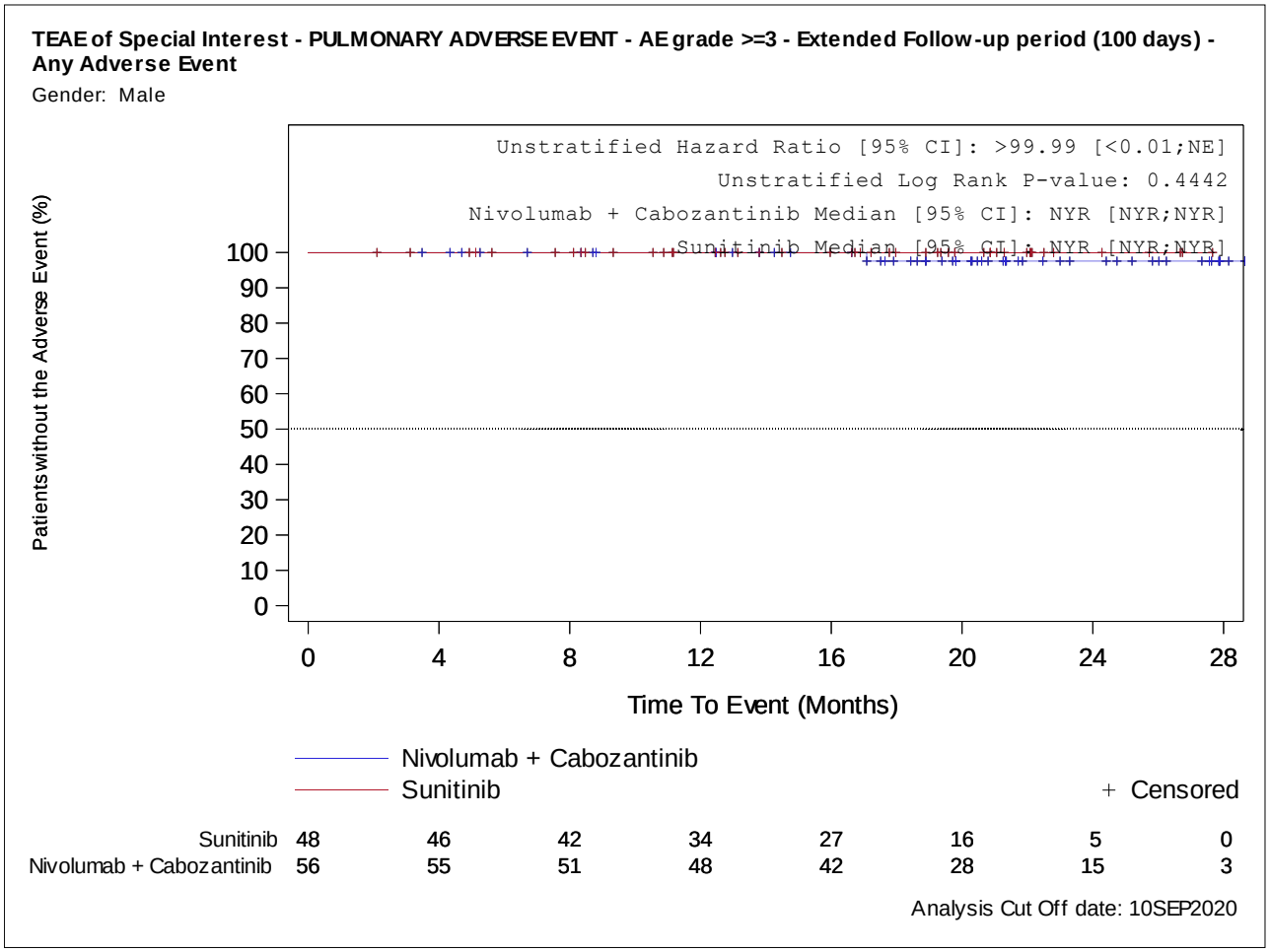

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:37:32

FIGURE 3.44.2.12: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



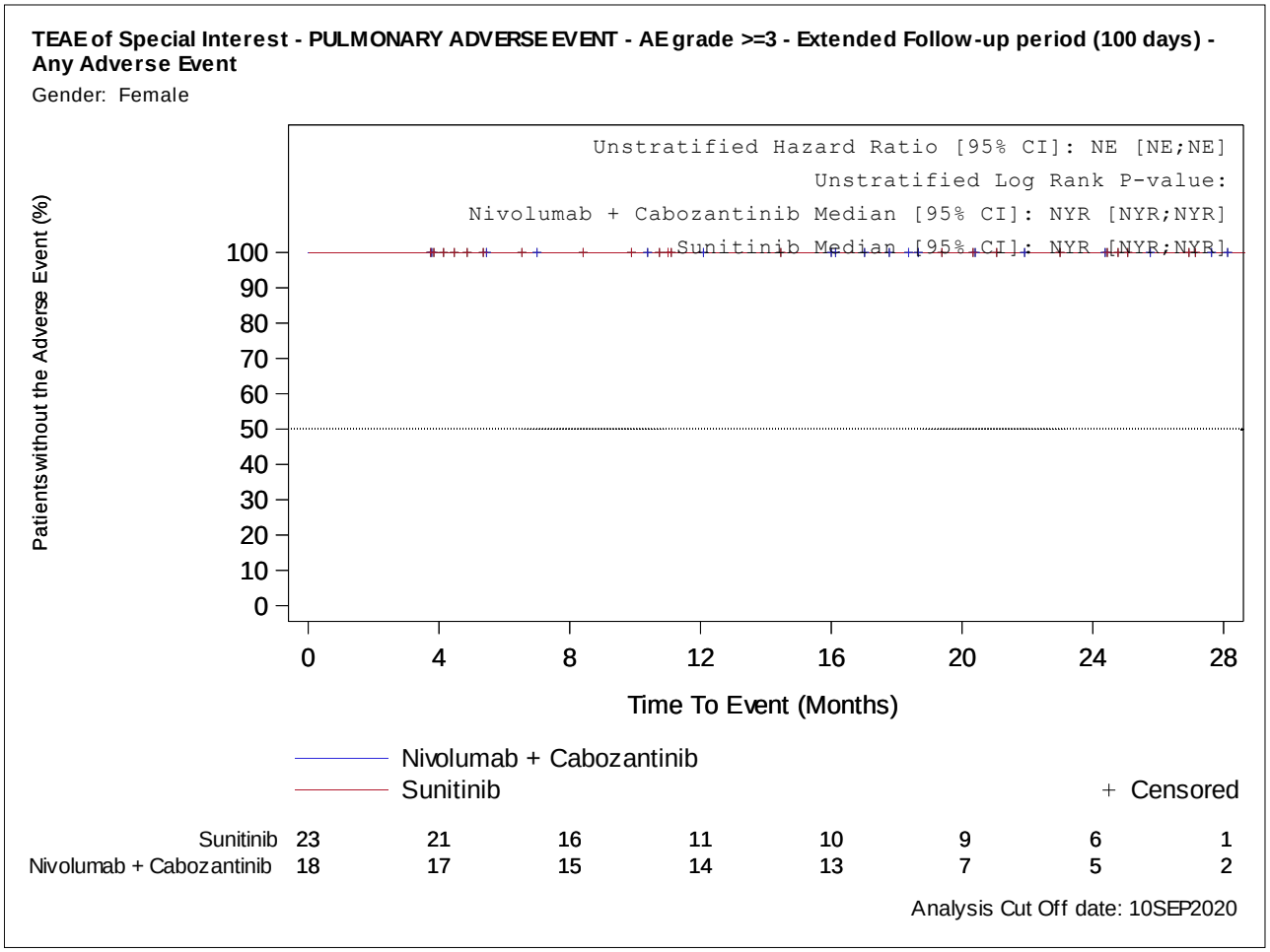

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:37:37

FIGURE 3.44.2.13: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



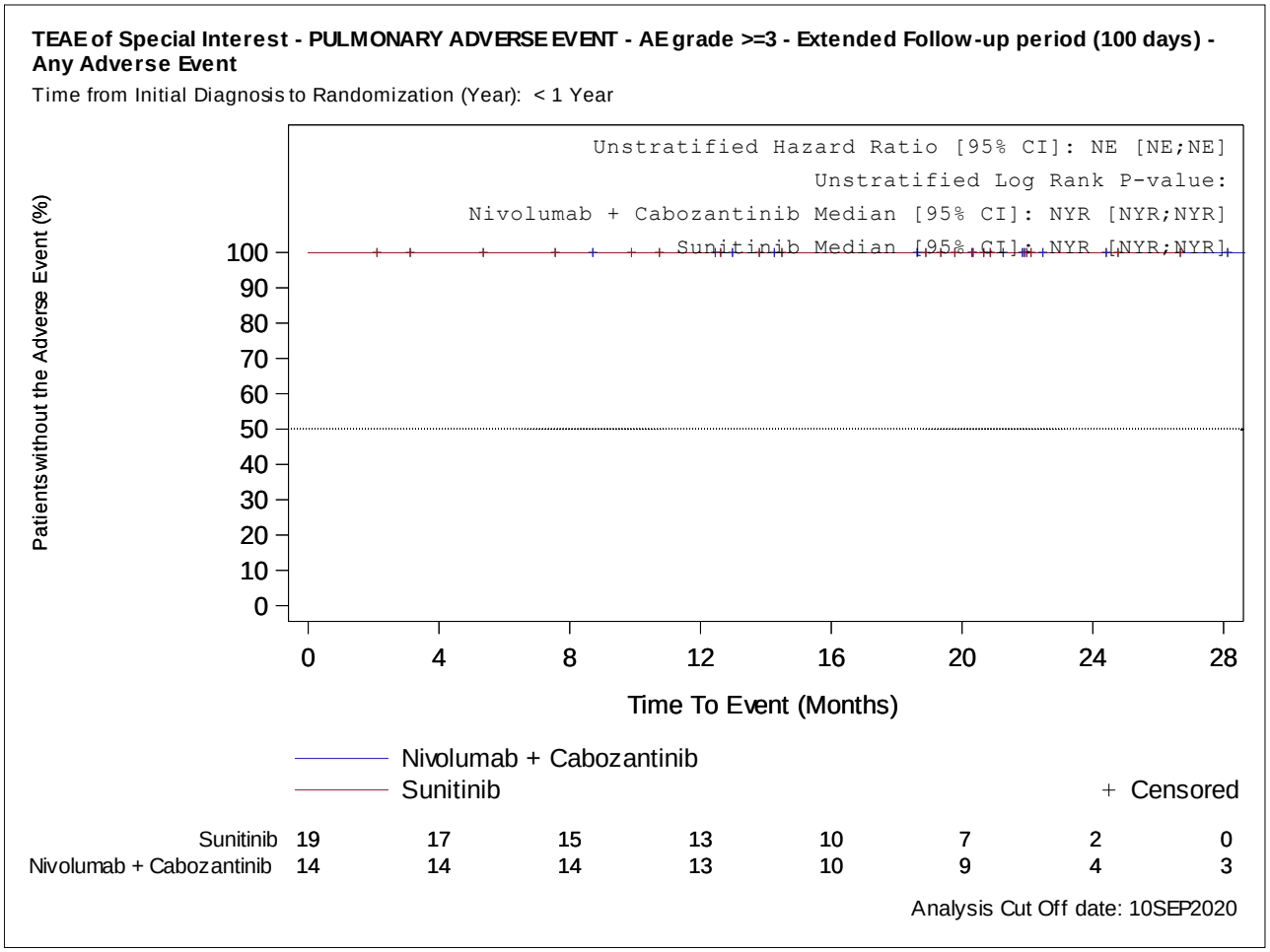

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:37:42

FIGURE 3.44.2.14: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



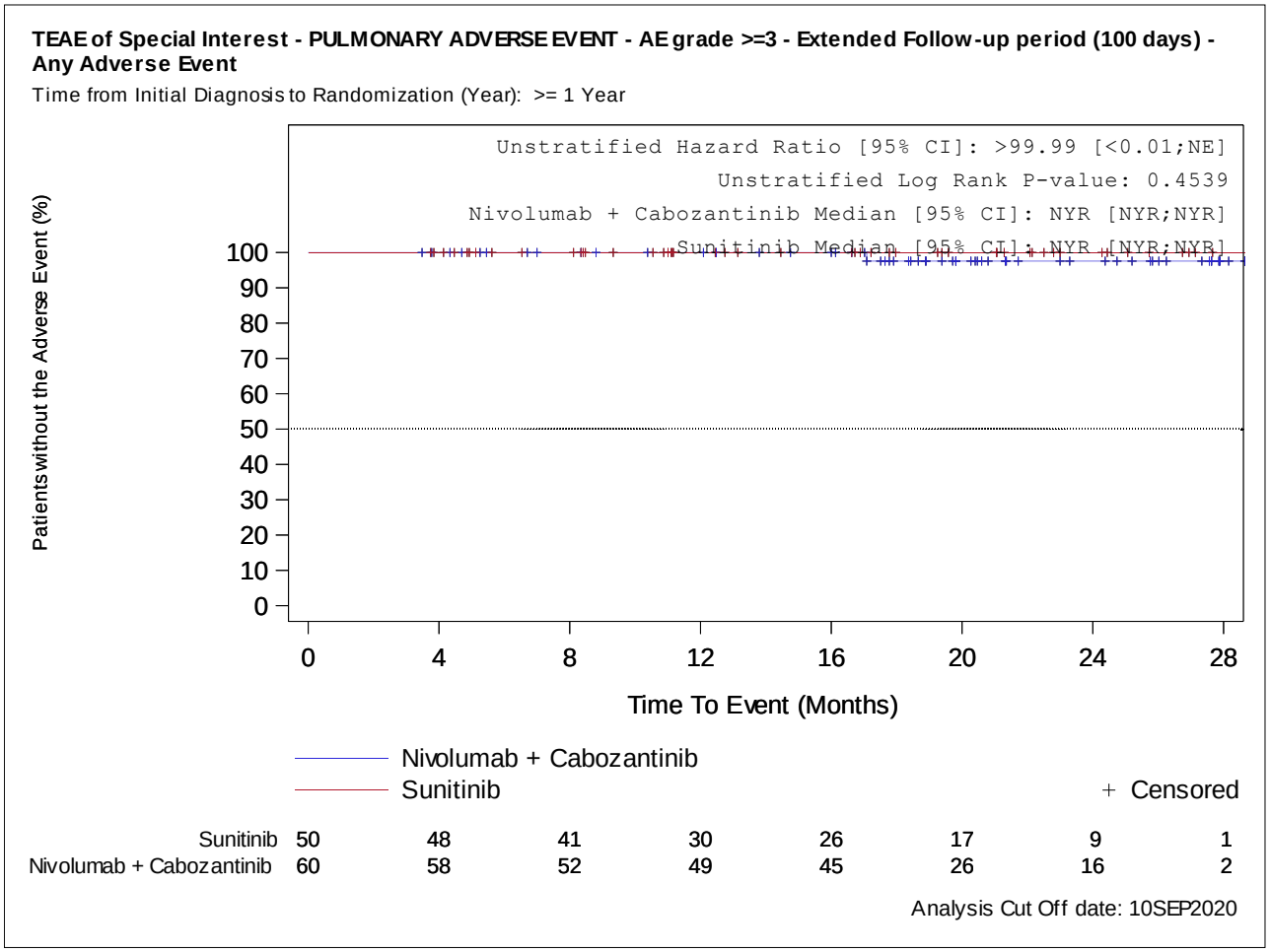

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:37:47

FIGURE 3.44.2.15: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



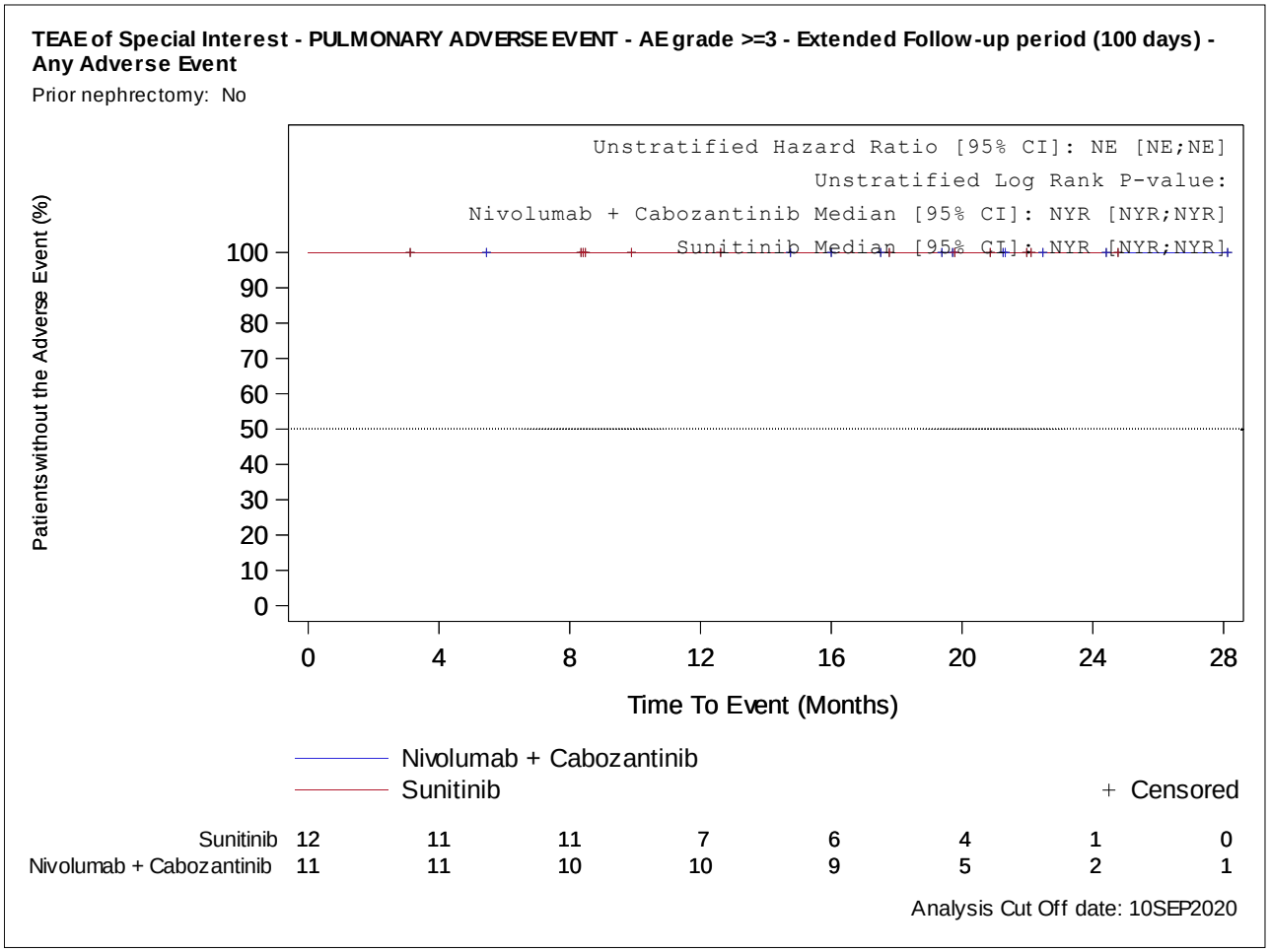

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:38:04

FIGURE 3.44.2.16: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



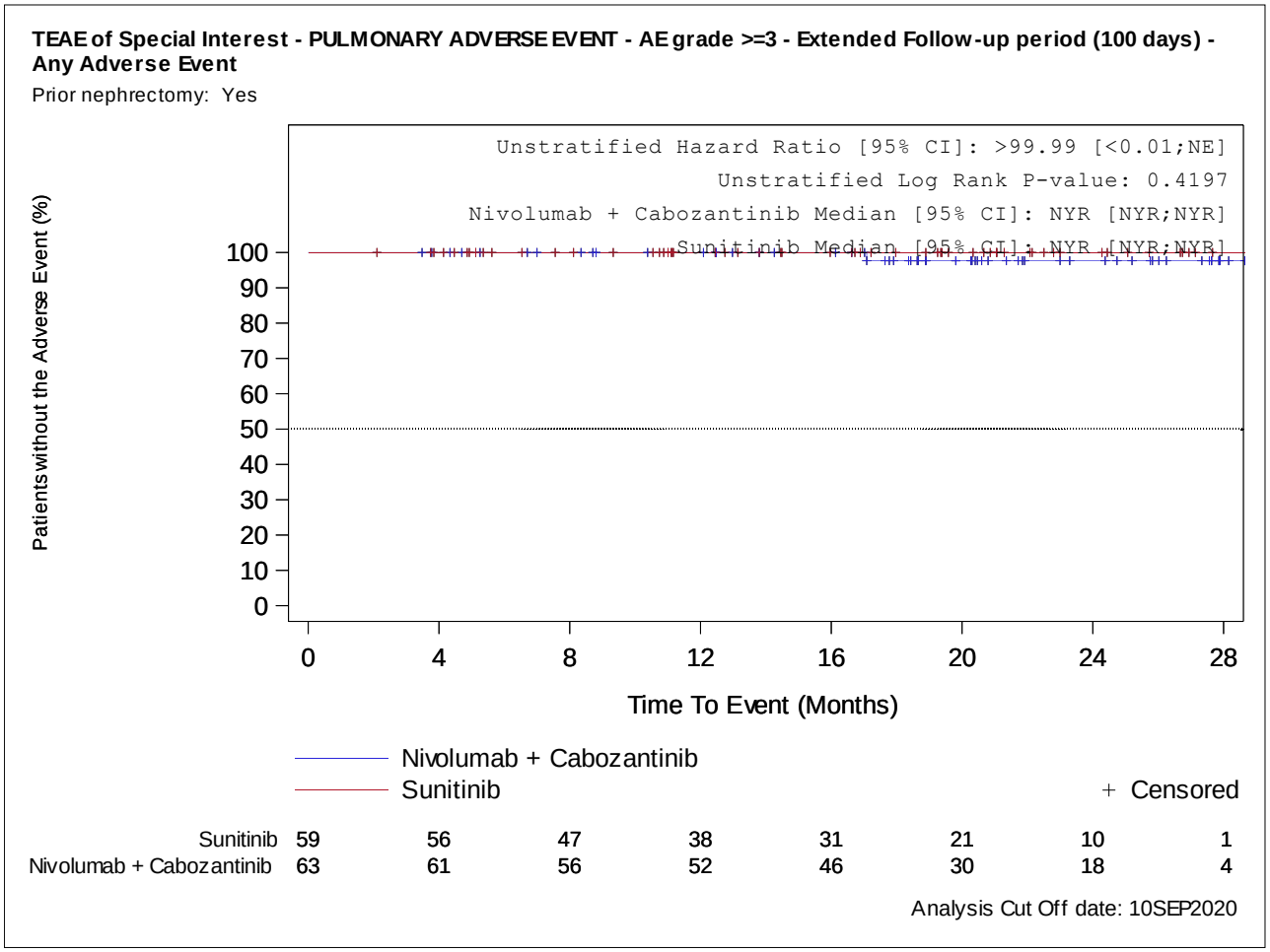

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:38:09

FIGURE 3.44.2.17: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



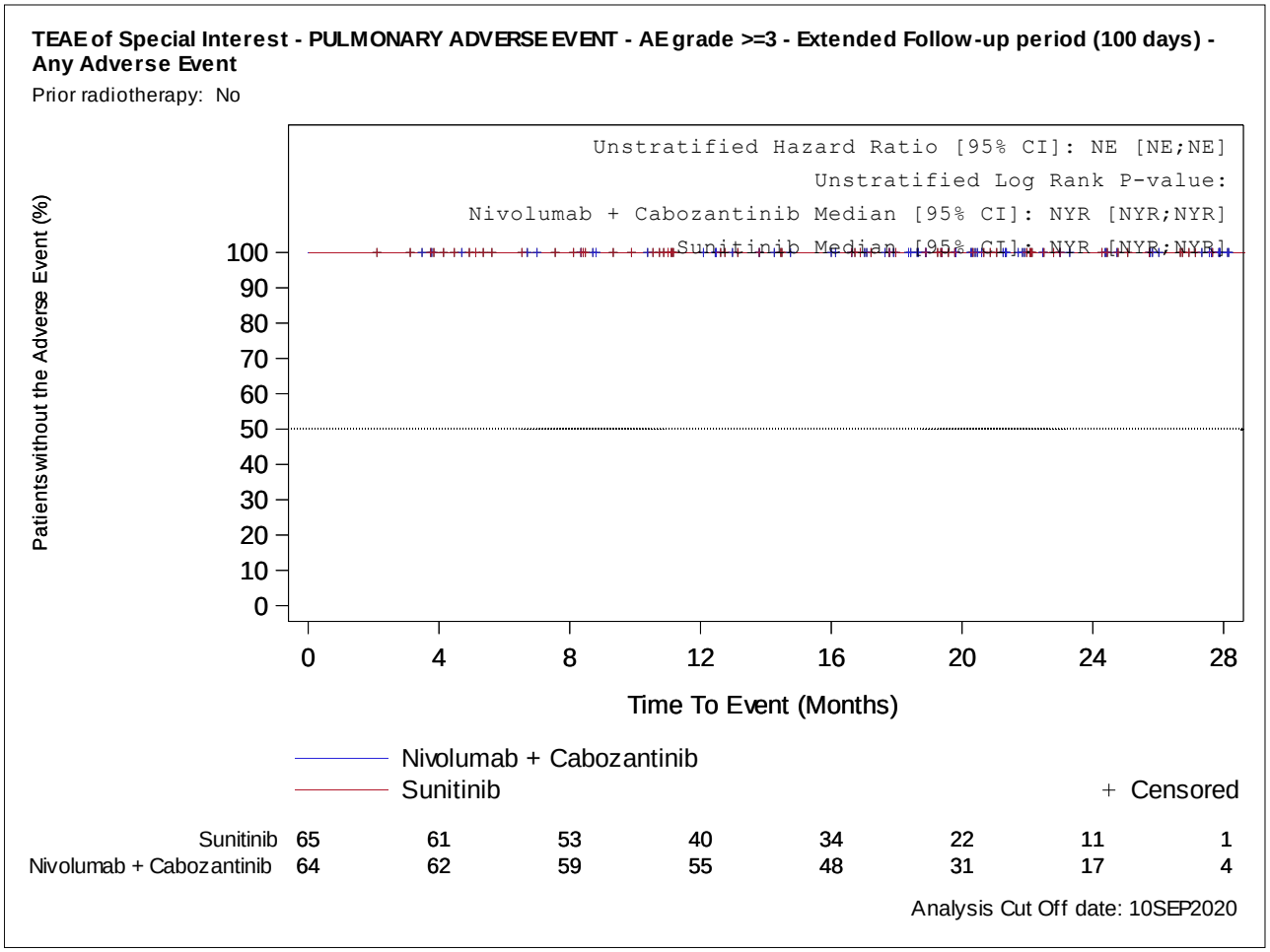

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:38:58

FIGURE 3.44.2.18: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



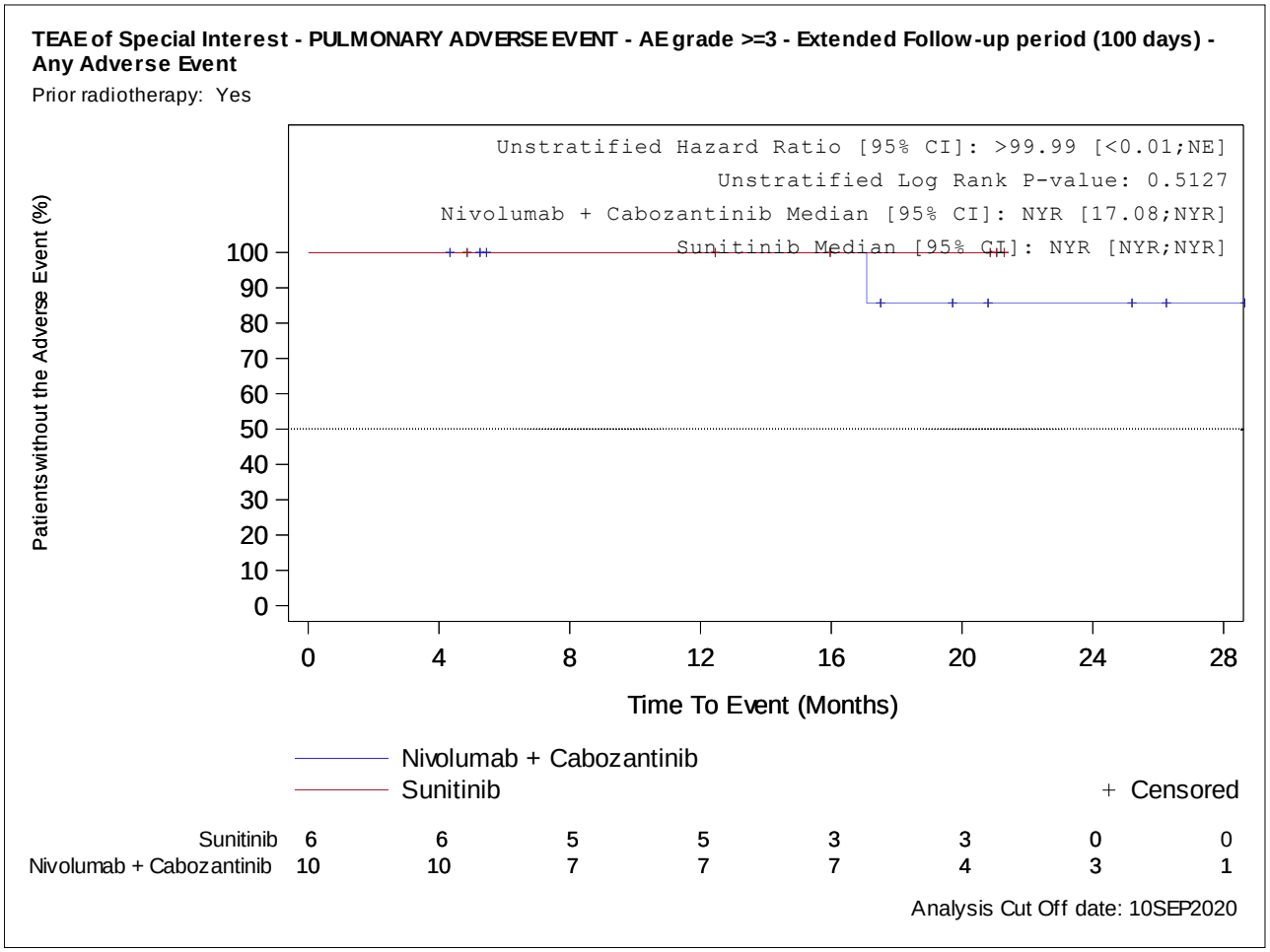

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:39:03

FIGURE 3.44.2.19: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



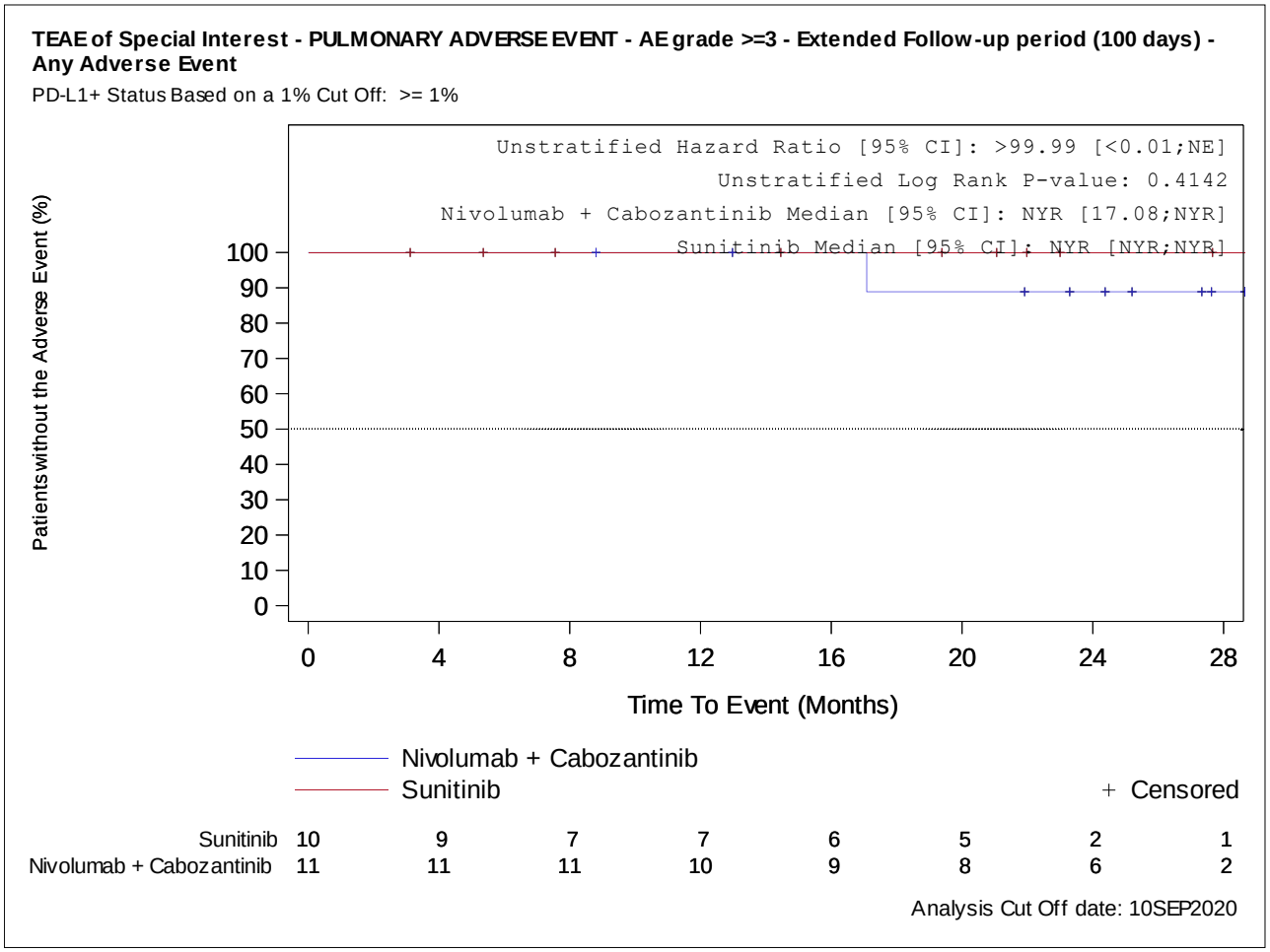

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:39:08

FIGURE 3.44.2.20: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



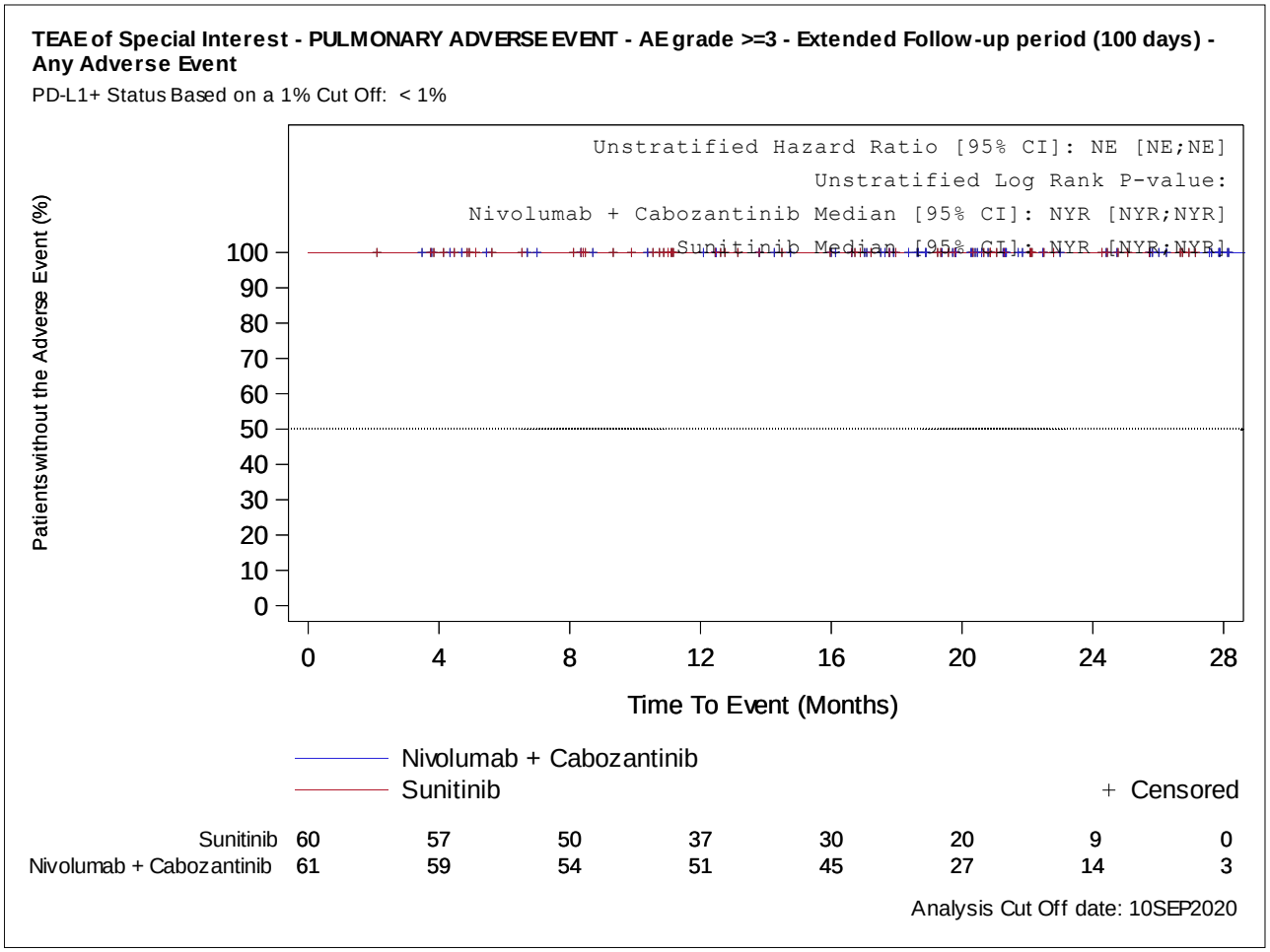

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:39:14

FIGURE 3.44.2.21: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



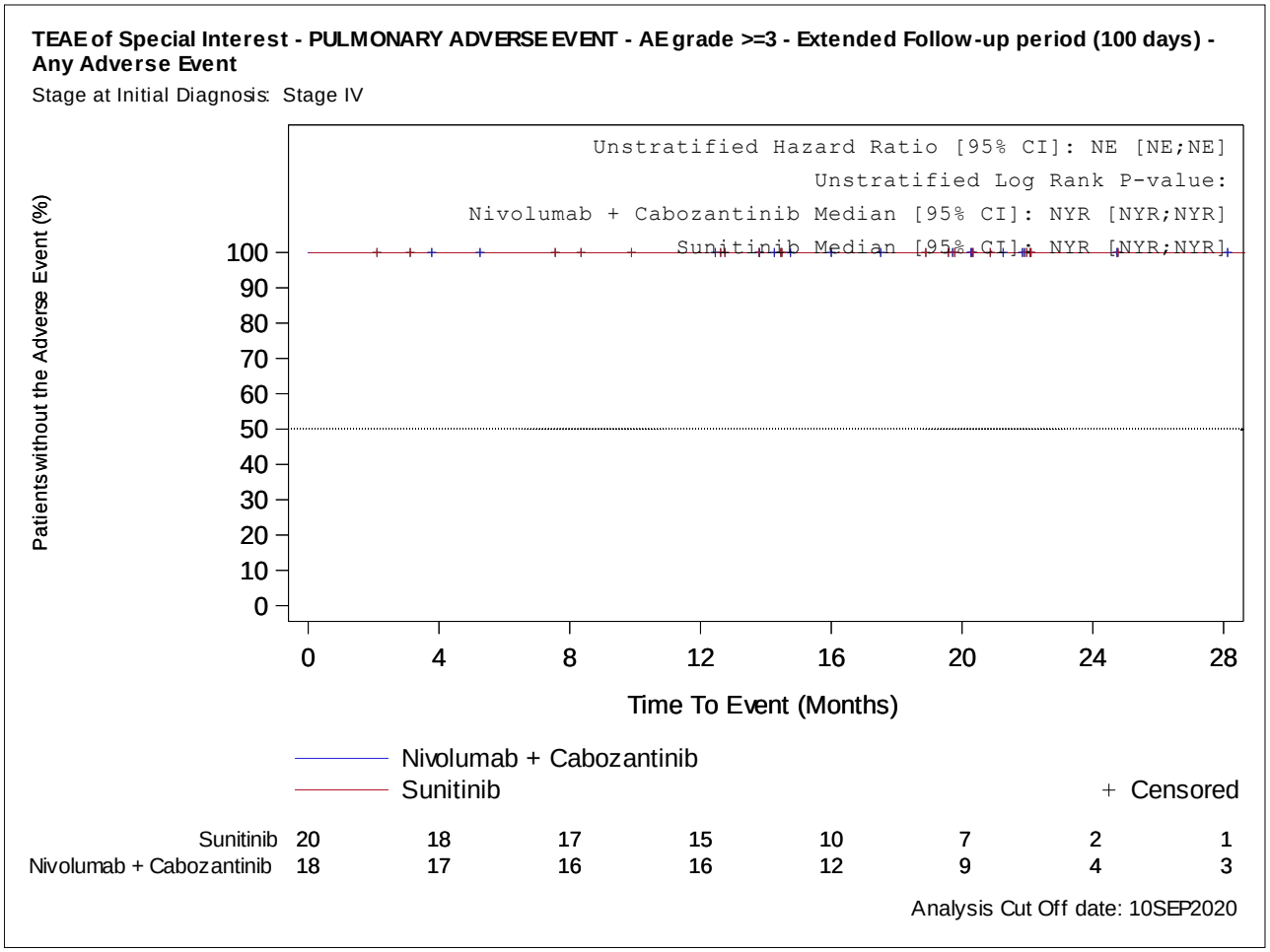

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:39:19

FIGURE 3.44.2.22: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



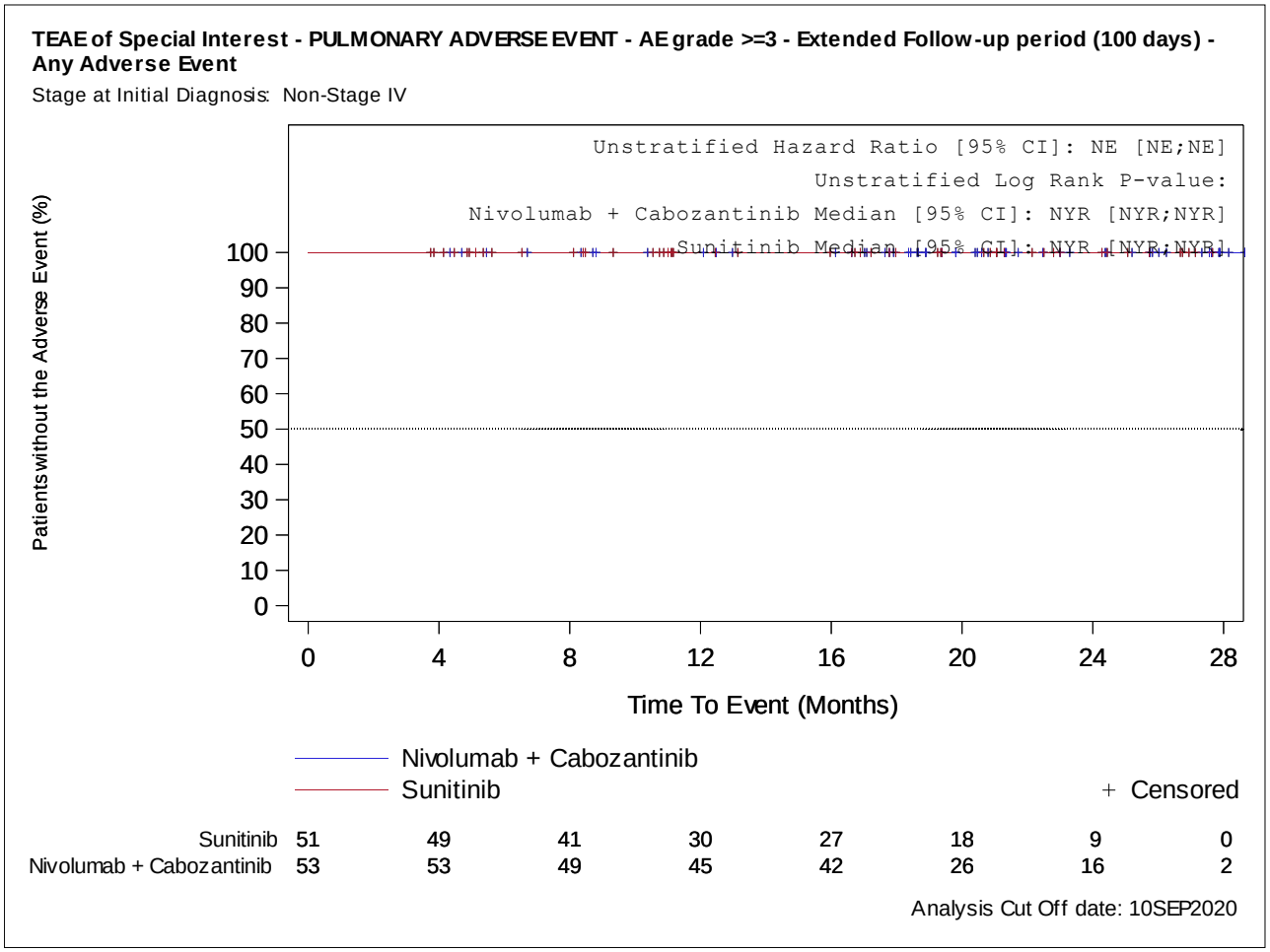

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:39:25

FIGURE 3.44.2.23: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



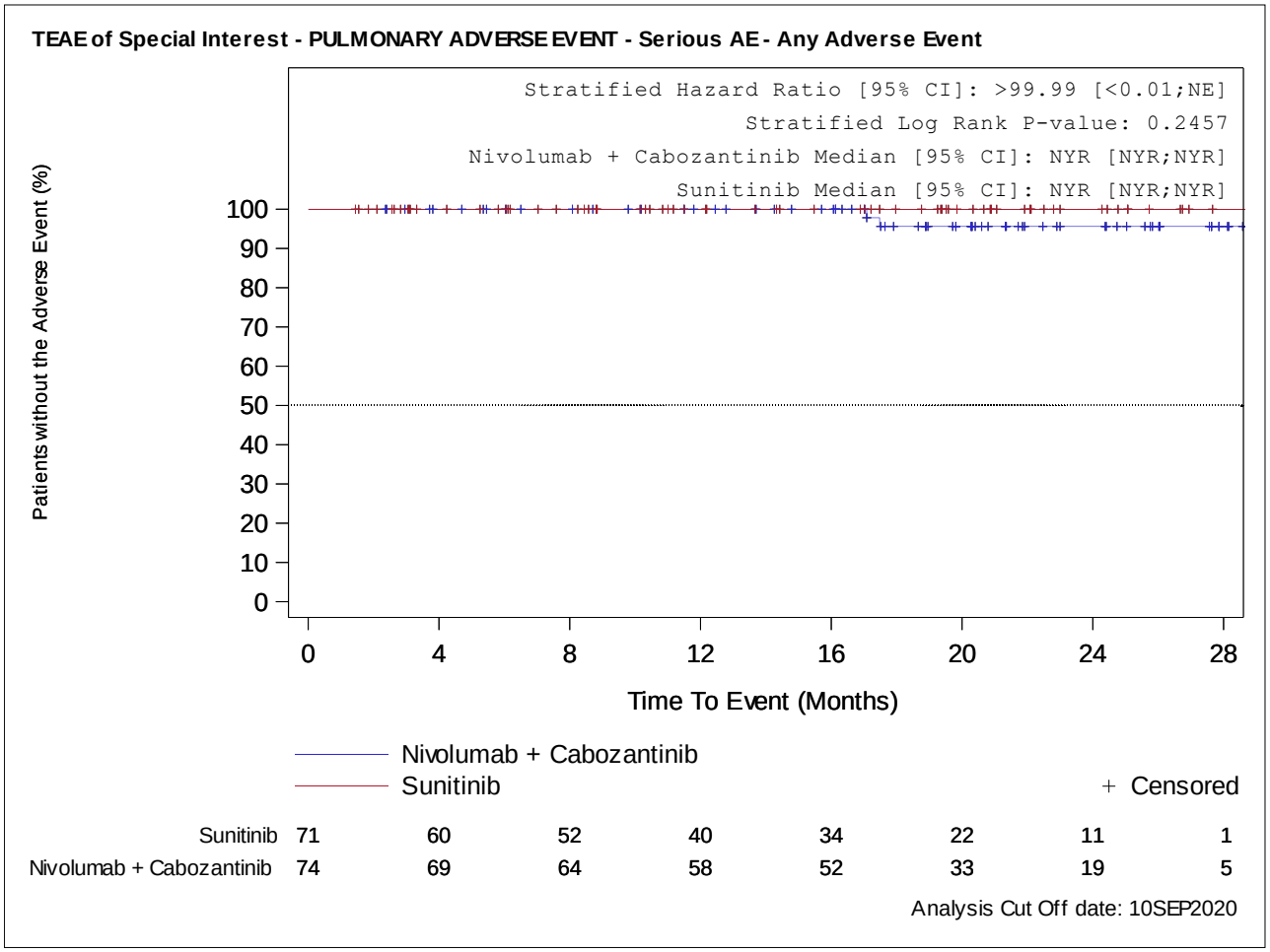

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:39:51

FIGURE 3.44.2.24: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



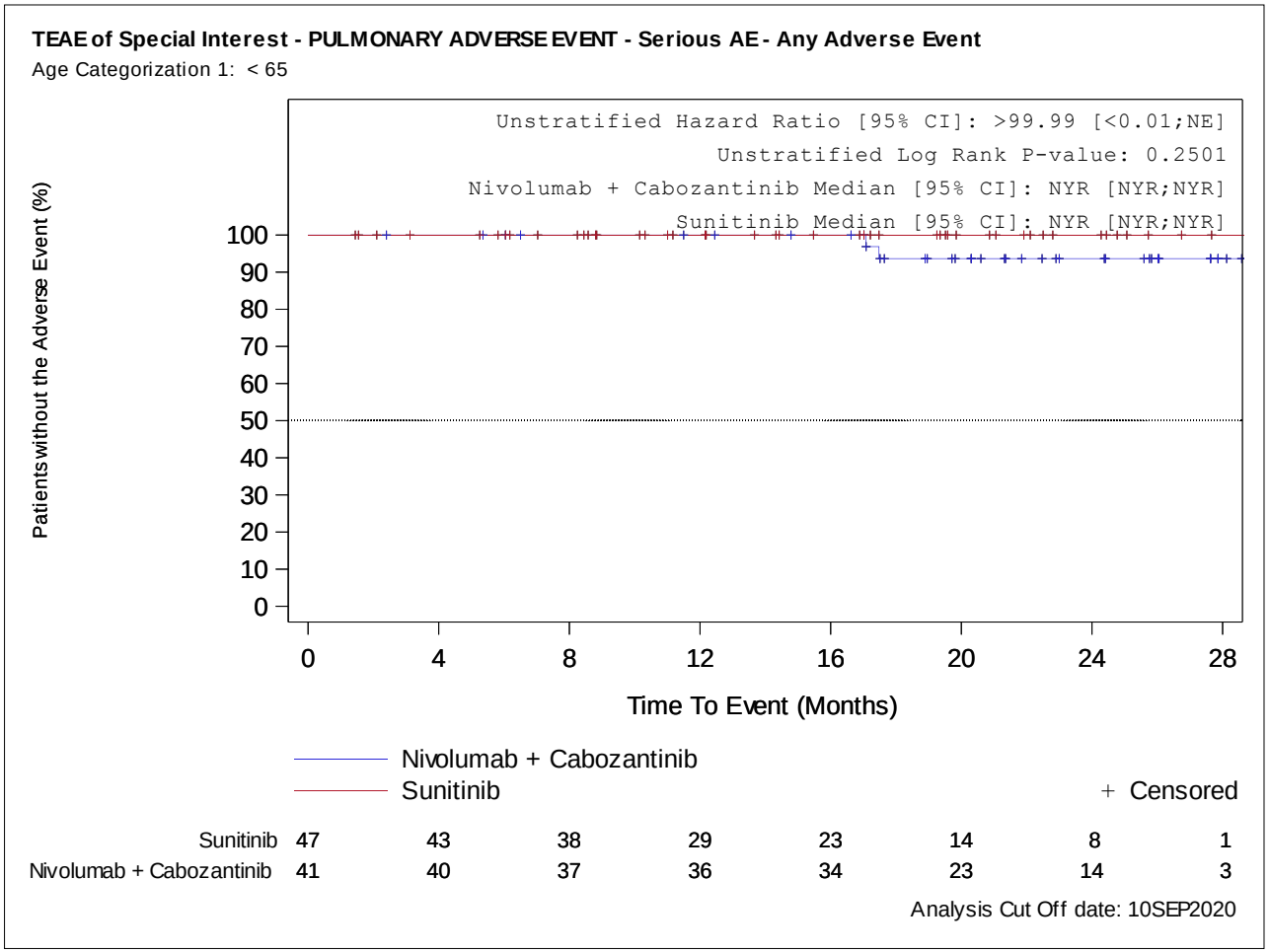

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:39:57

FIGURE 3.45.1: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



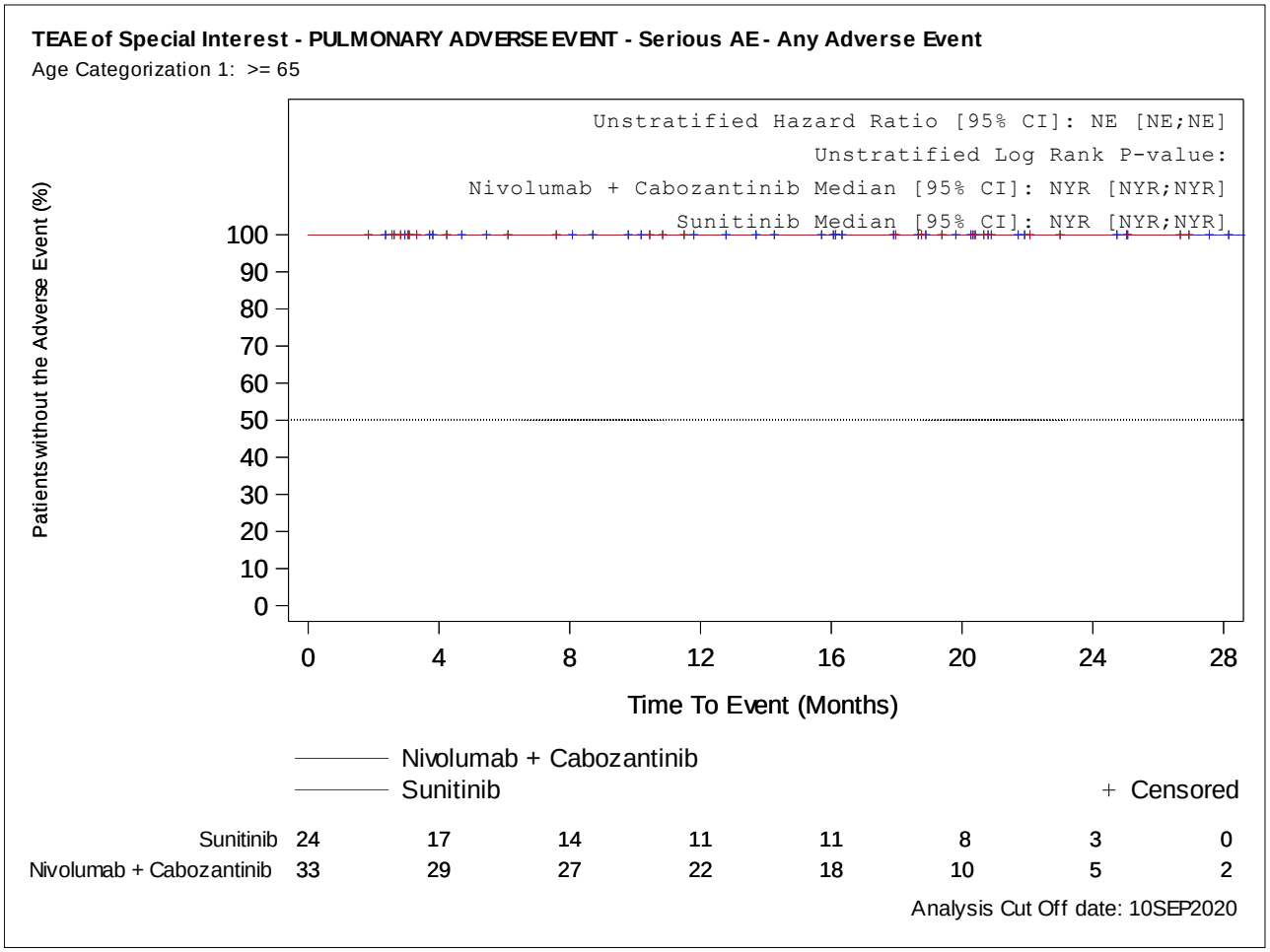

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:42:52

FIGURE 3.45.2.1: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



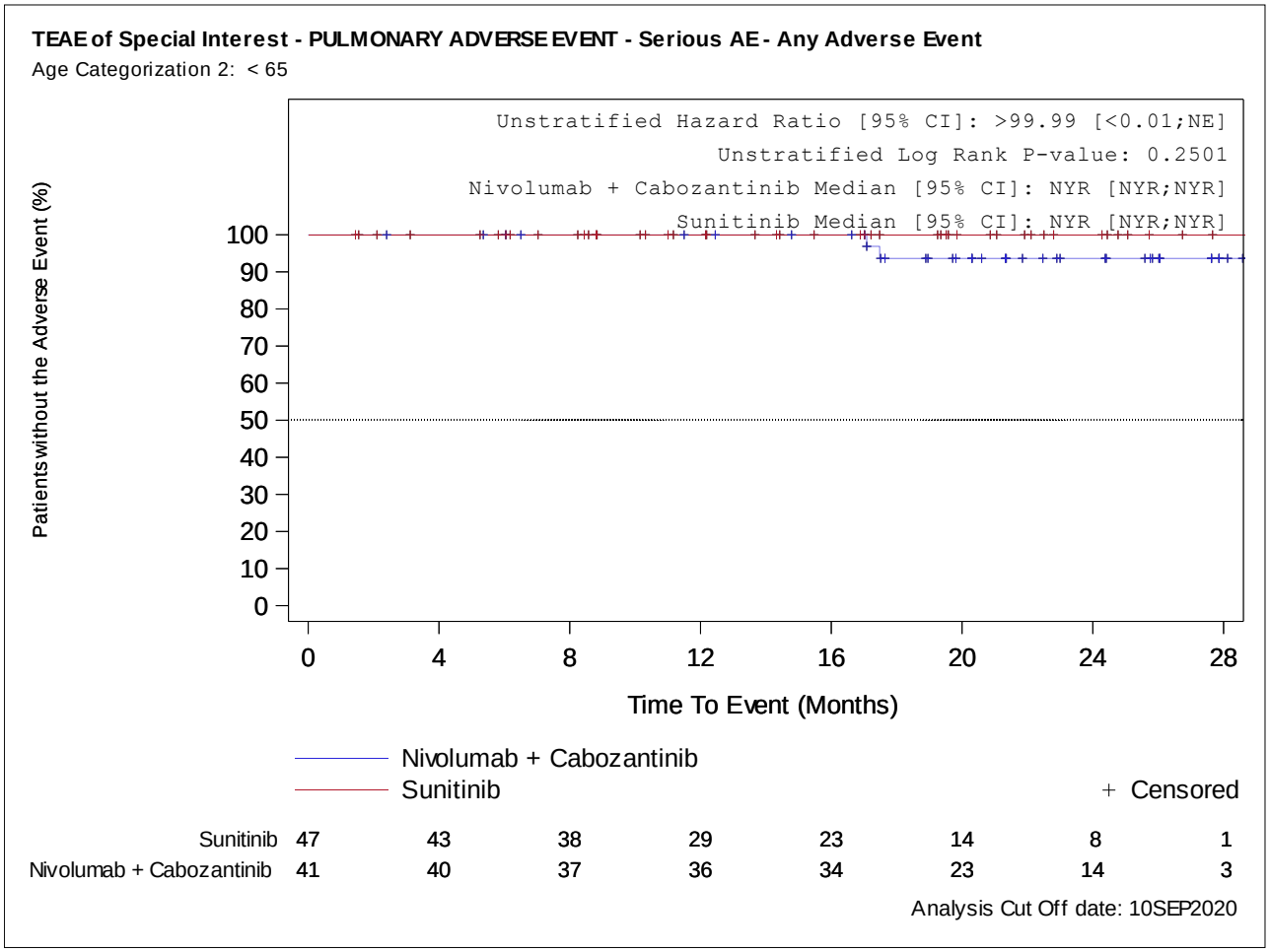

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:42:56

FIGURE 3.45.2.2: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



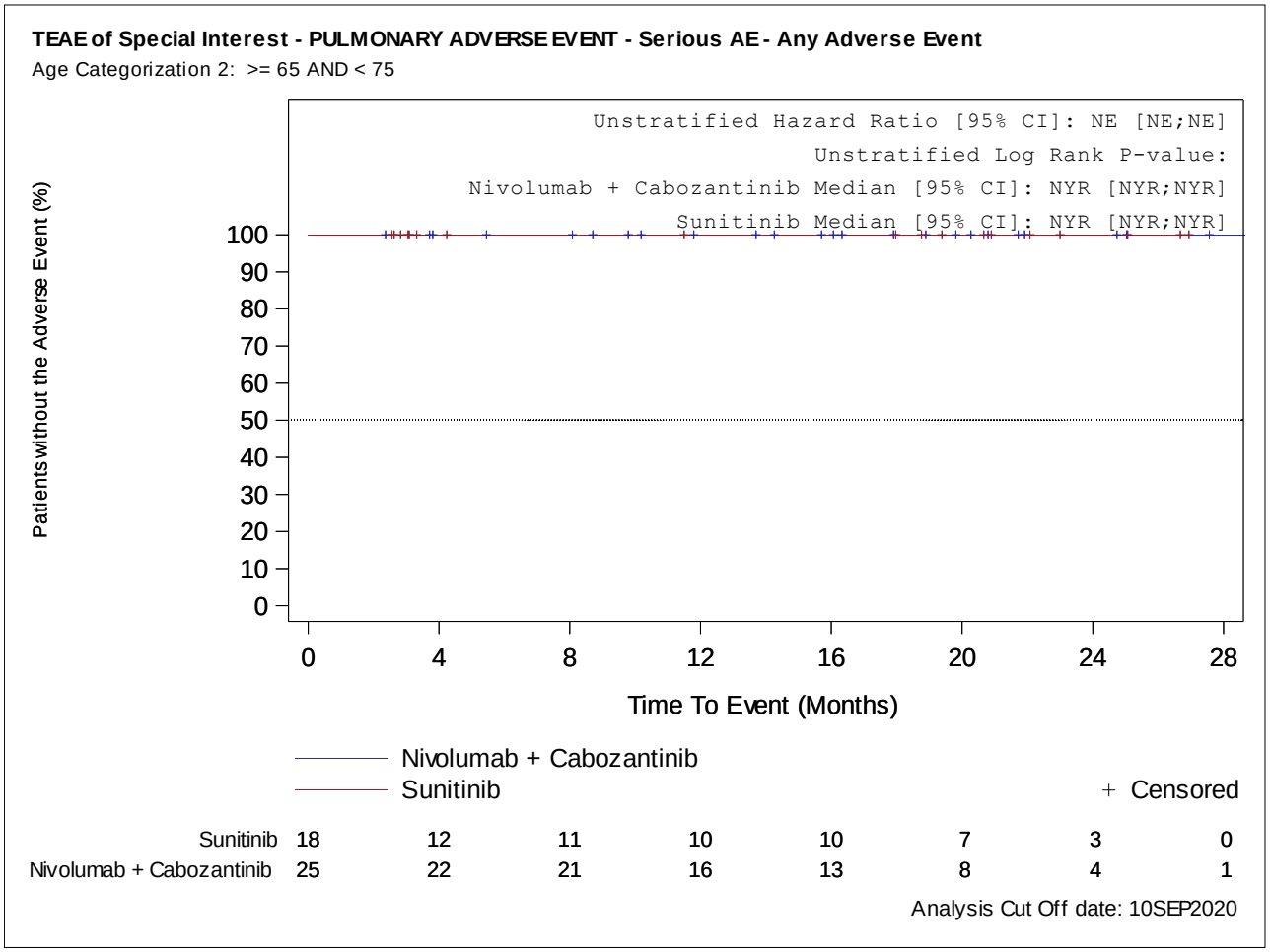

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:43:01

FIGURE 3.45.2.3: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



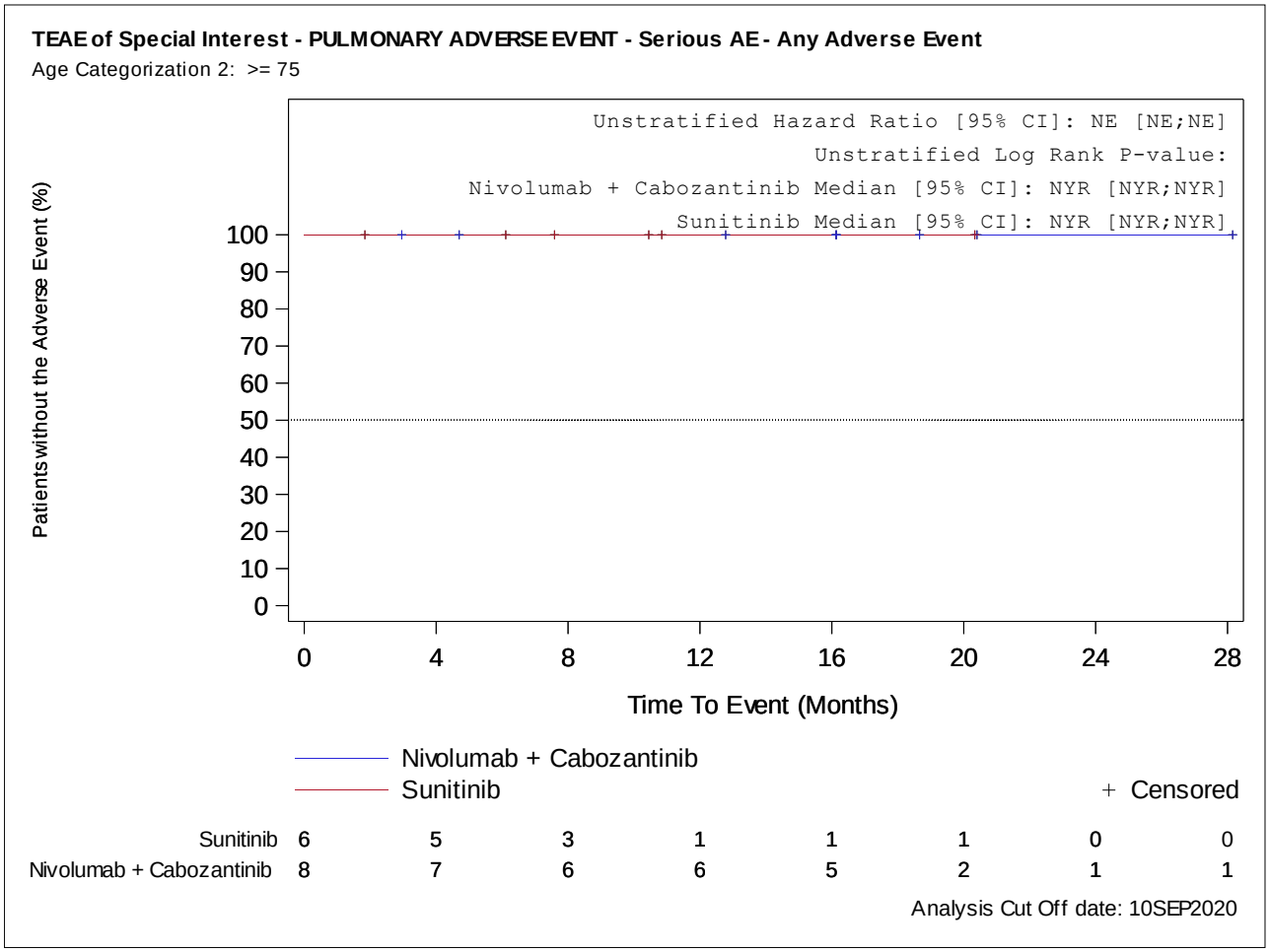

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:43:07

FIGURE 3.45.2.4: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



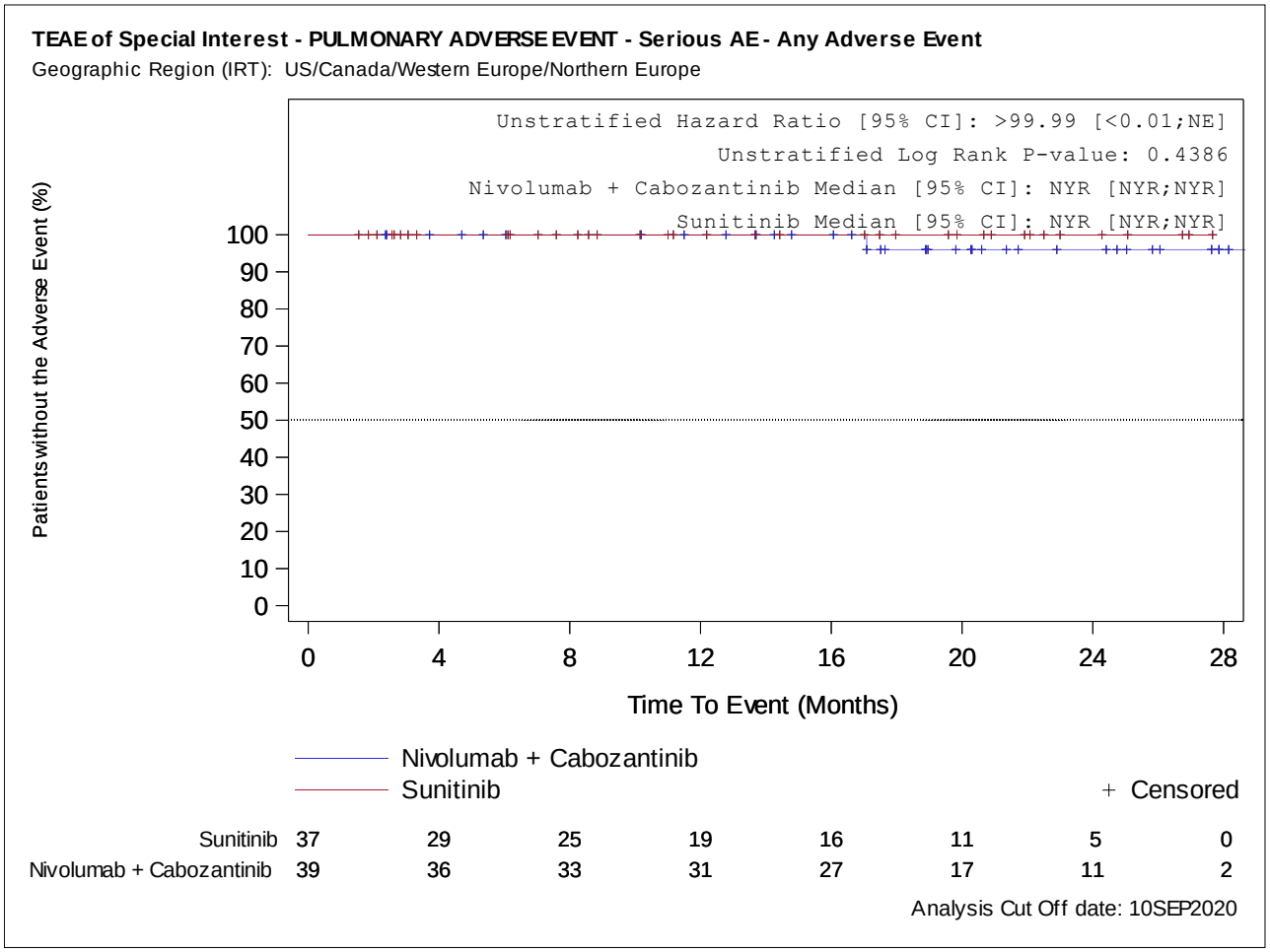

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:43:12

FIGURE 3.45.2.5: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



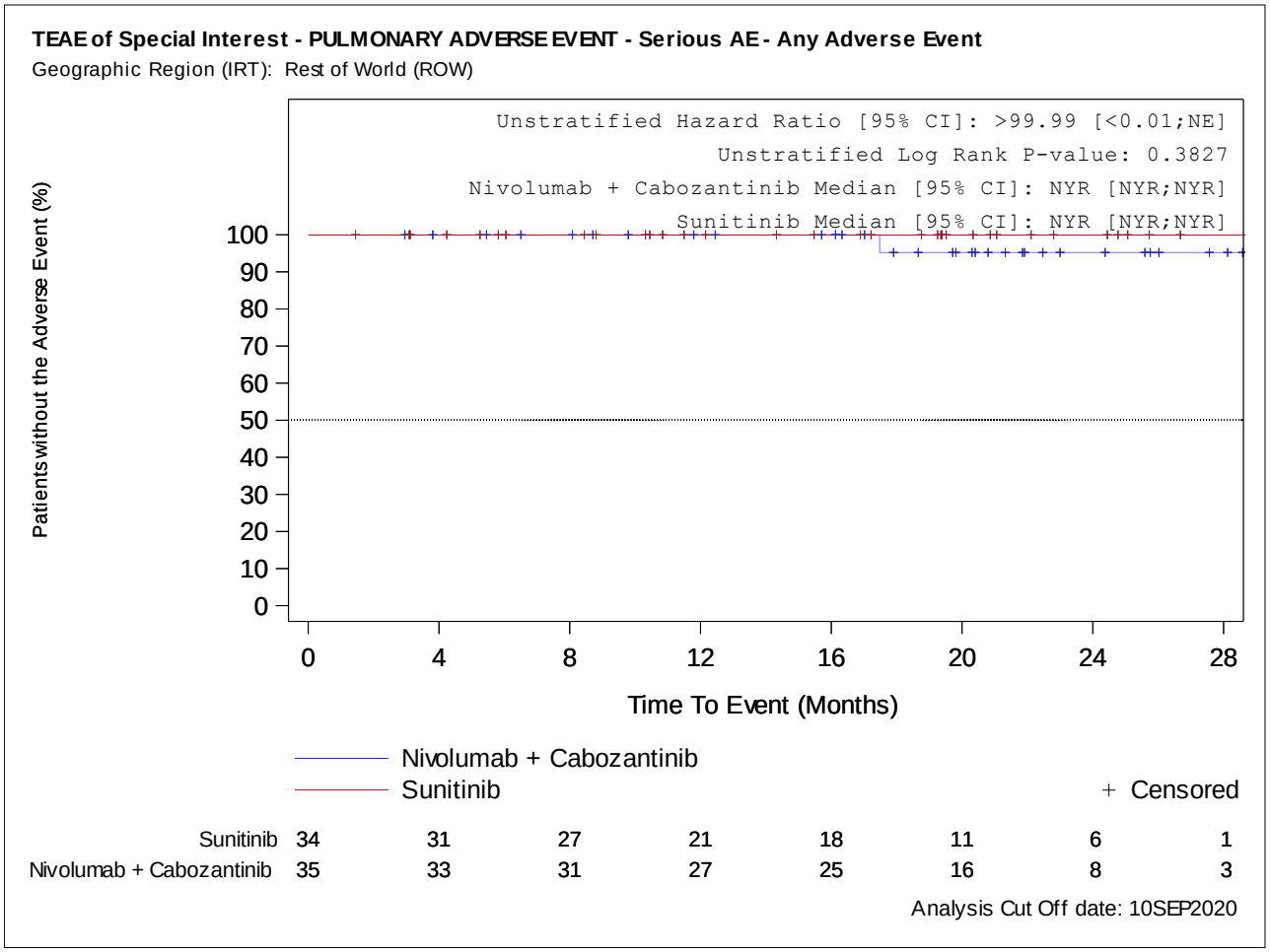

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:43:18

FIGURE 3.45.2.6: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



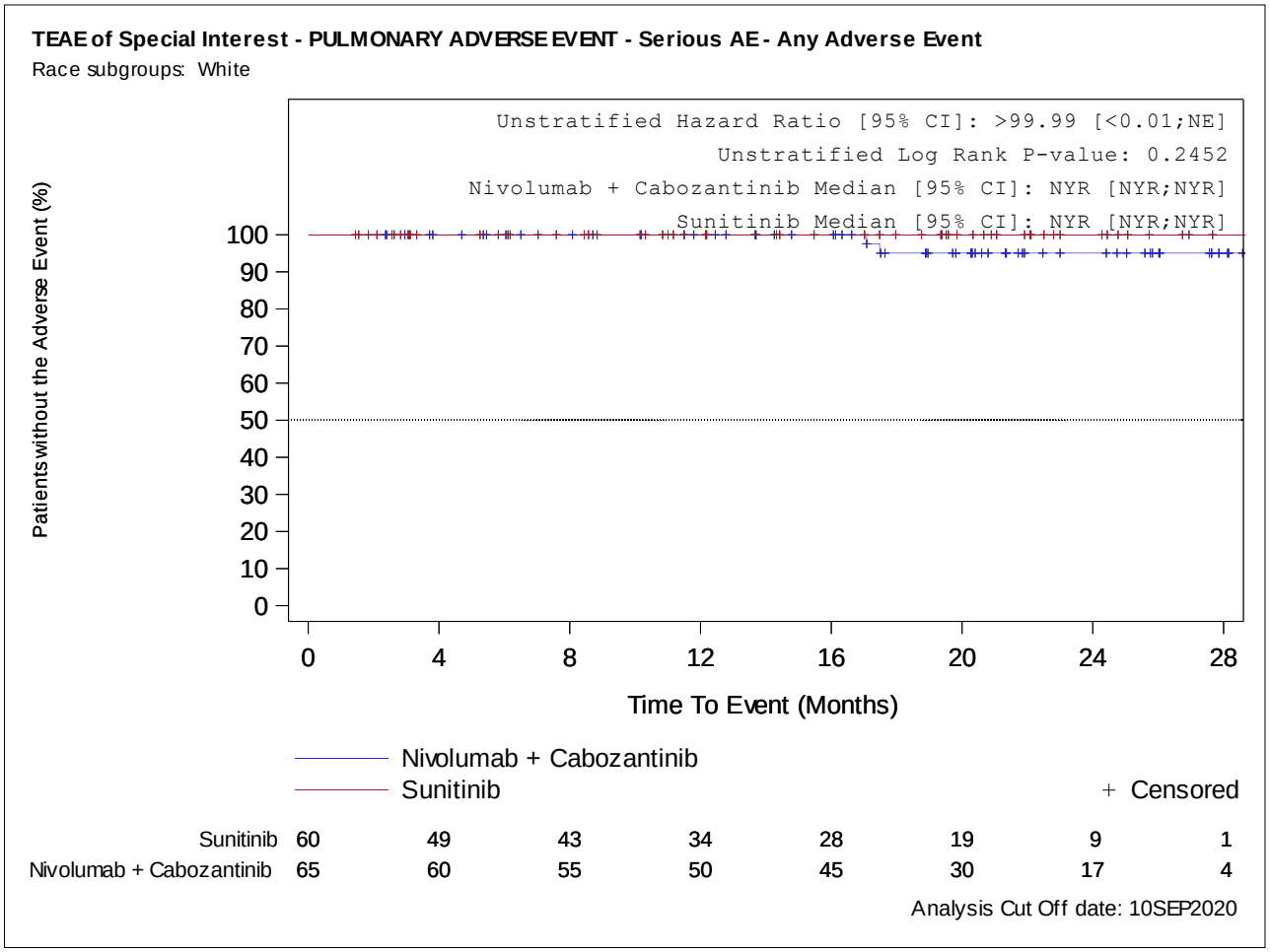

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:43:23

FIGURE 3.45.2.7: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



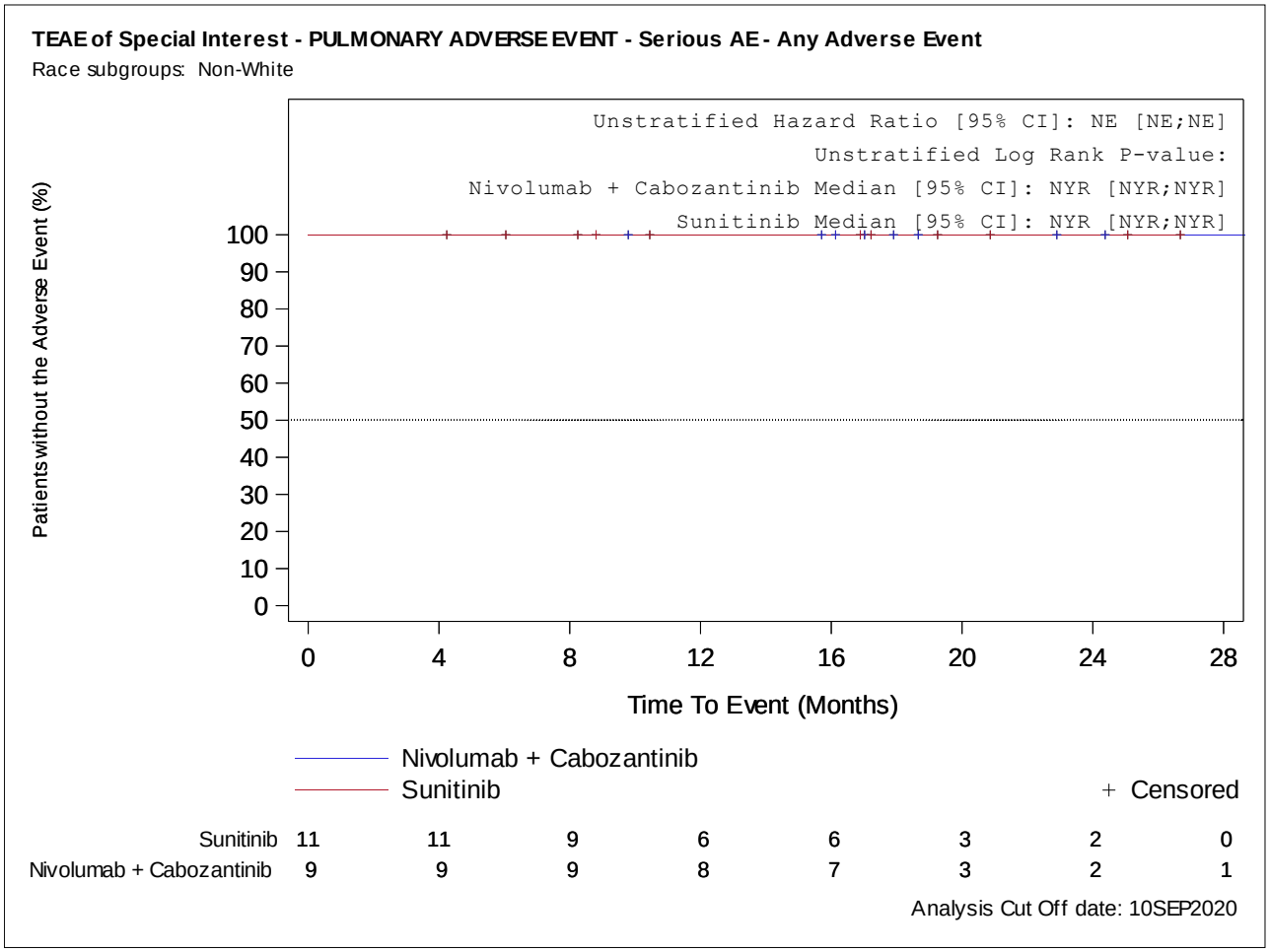

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:43:28

FIGURE 3.45.2.8: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



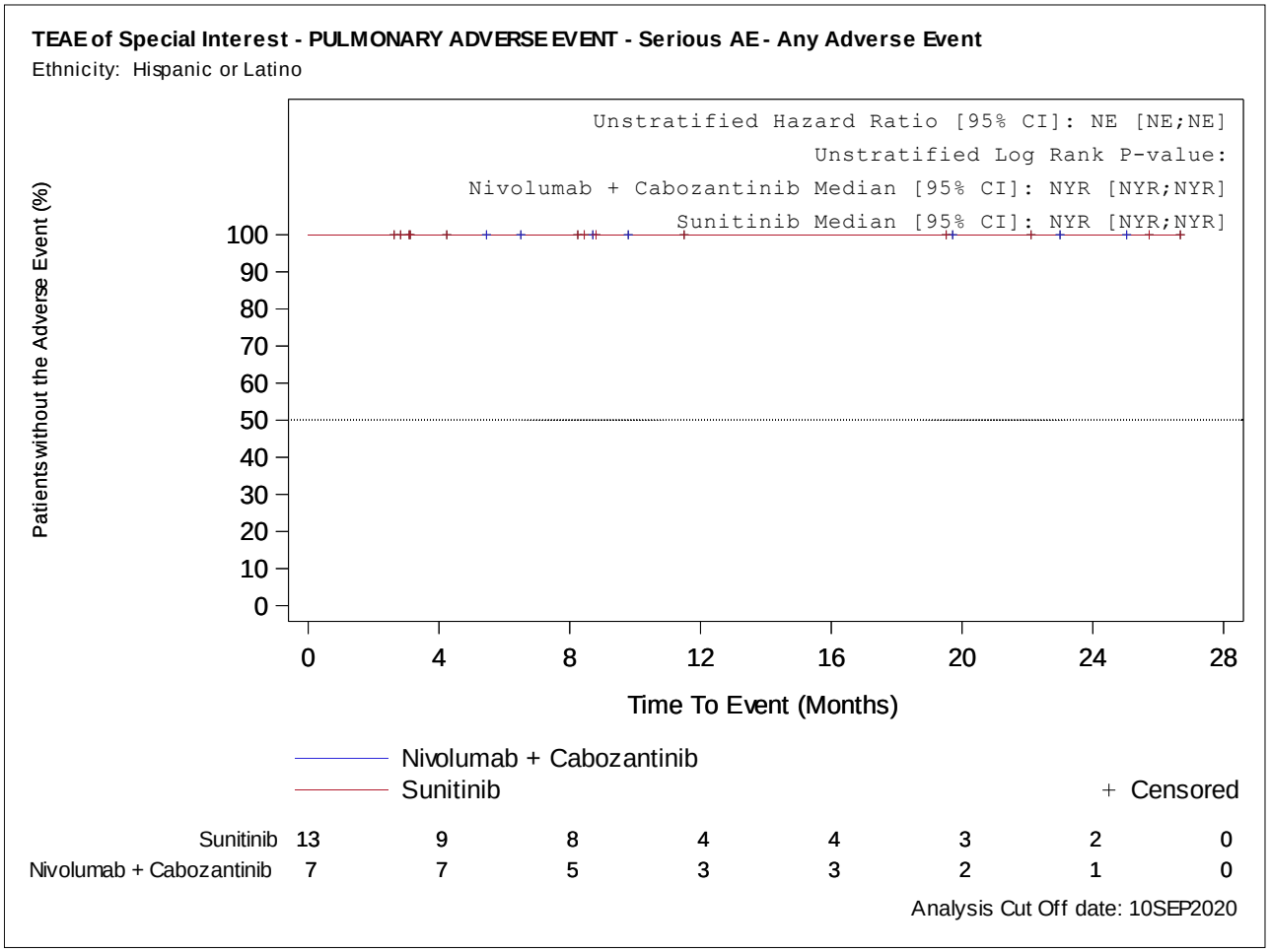

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:43:34

FIGURE 3.45.2.9: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



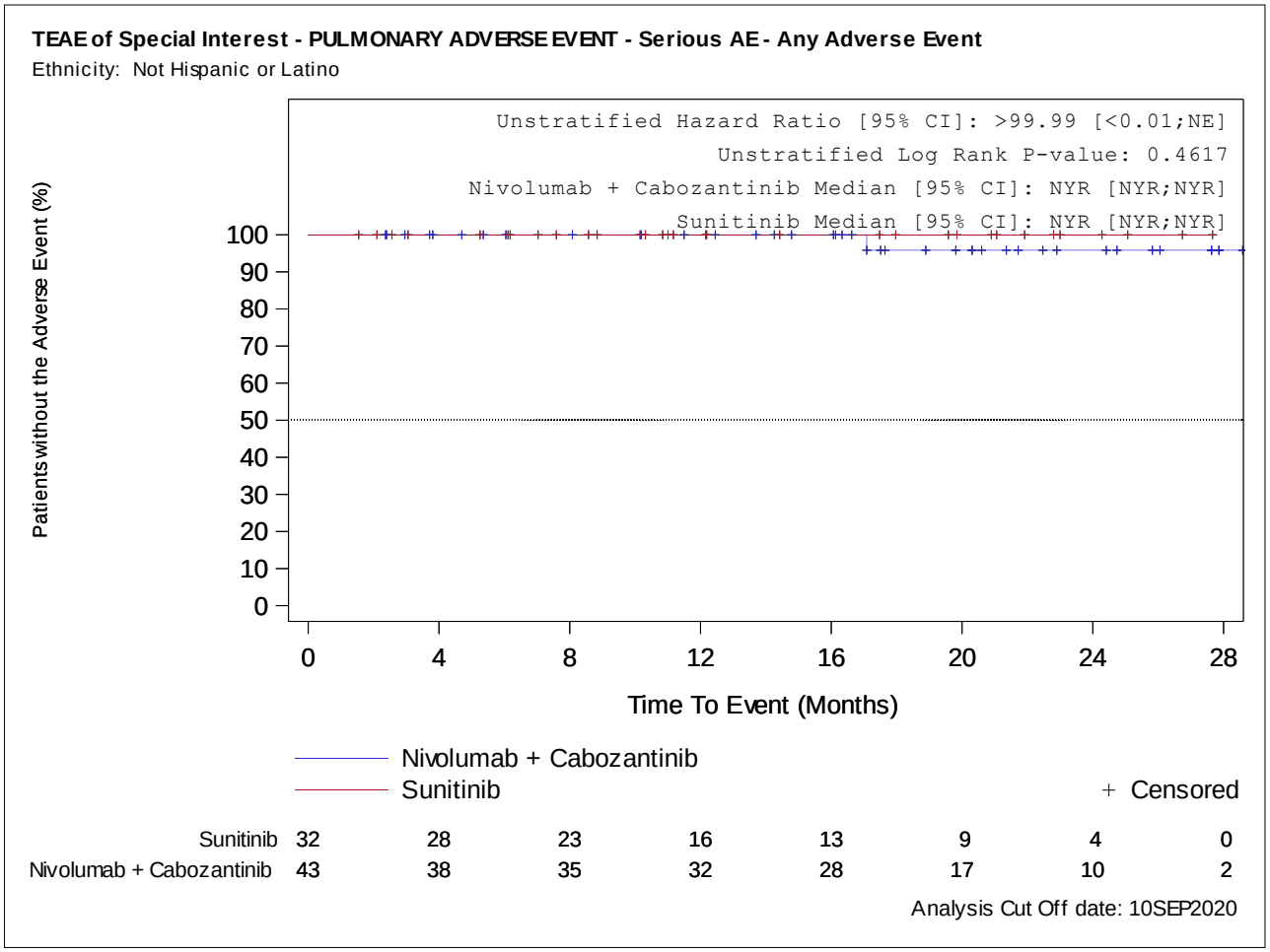

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:43:39

FIGURE 3.45.2.10: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



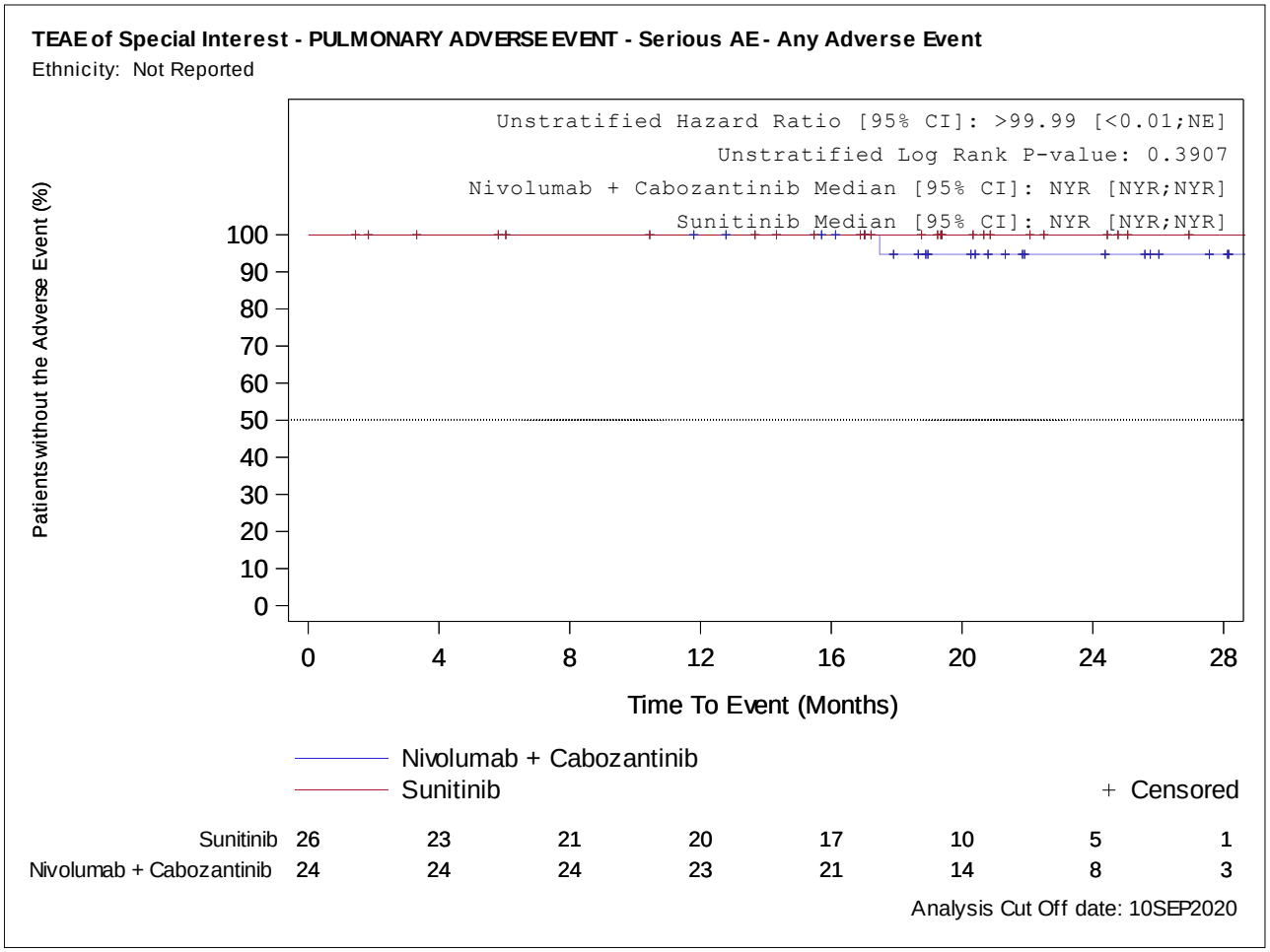

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:43:45

FIGURE 3.45.2.11: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



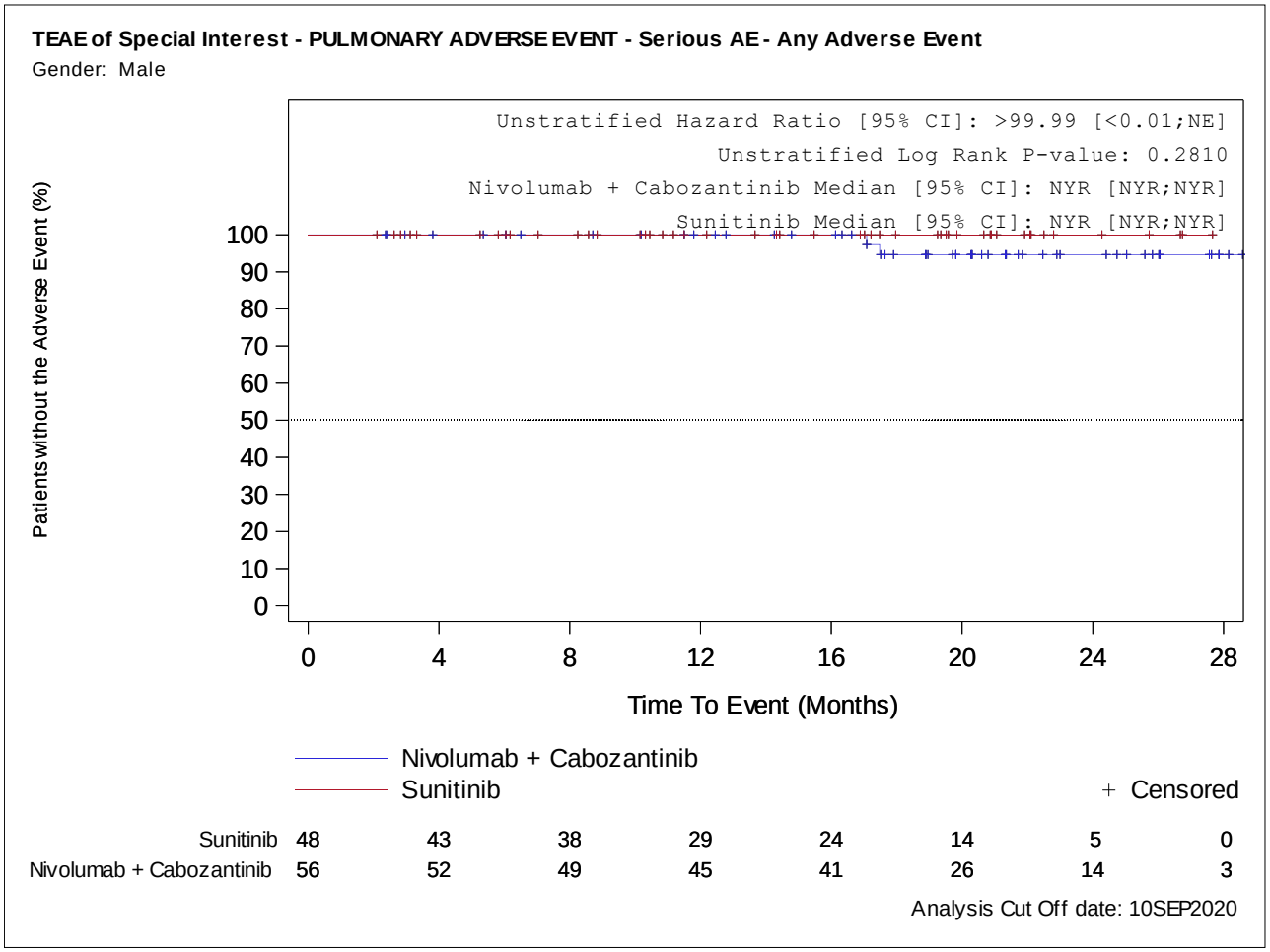

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:43:50

FIGURE 3.45.2.12: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



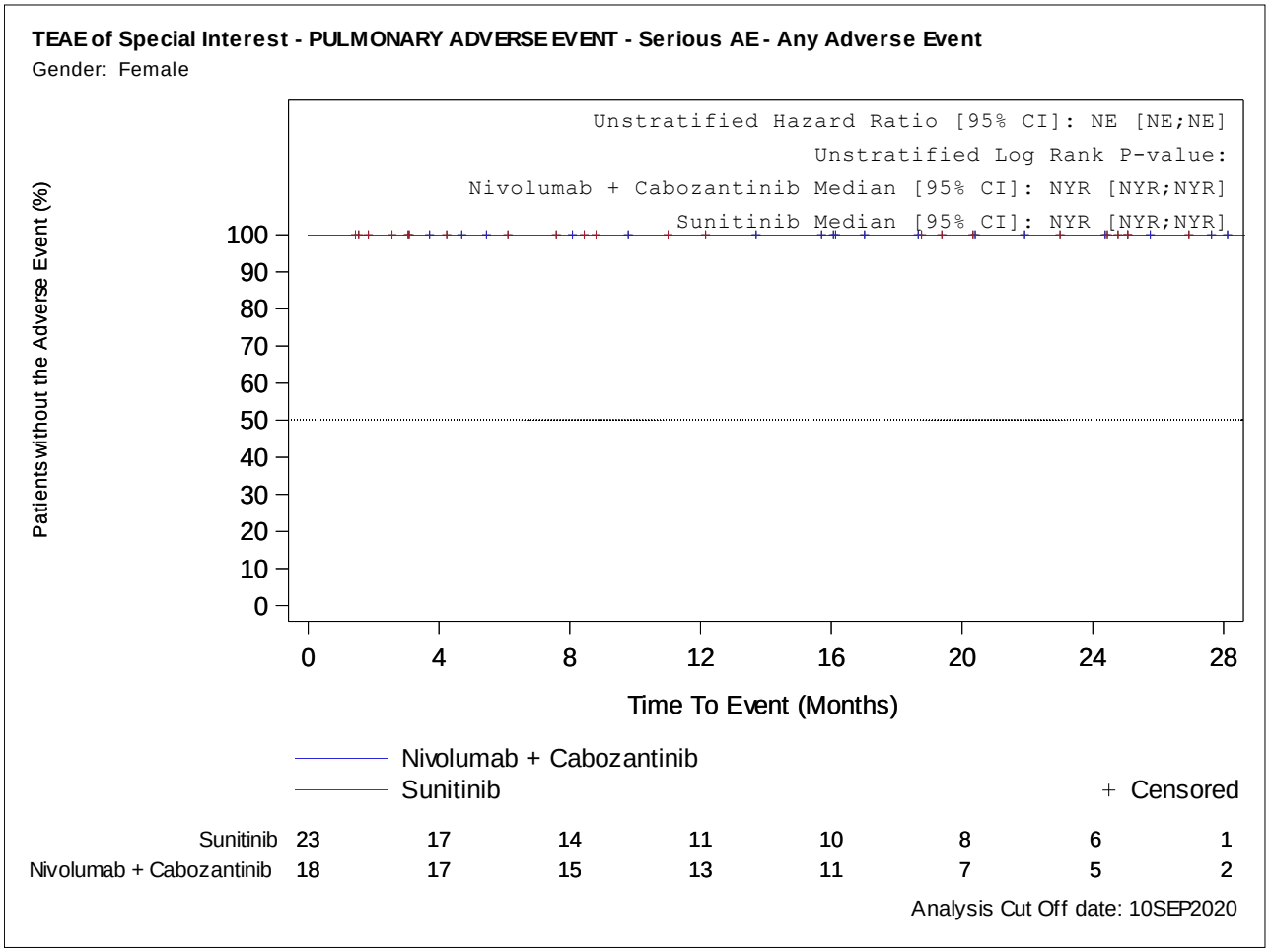

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:43:56

FIGURE 3.45.2.13: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



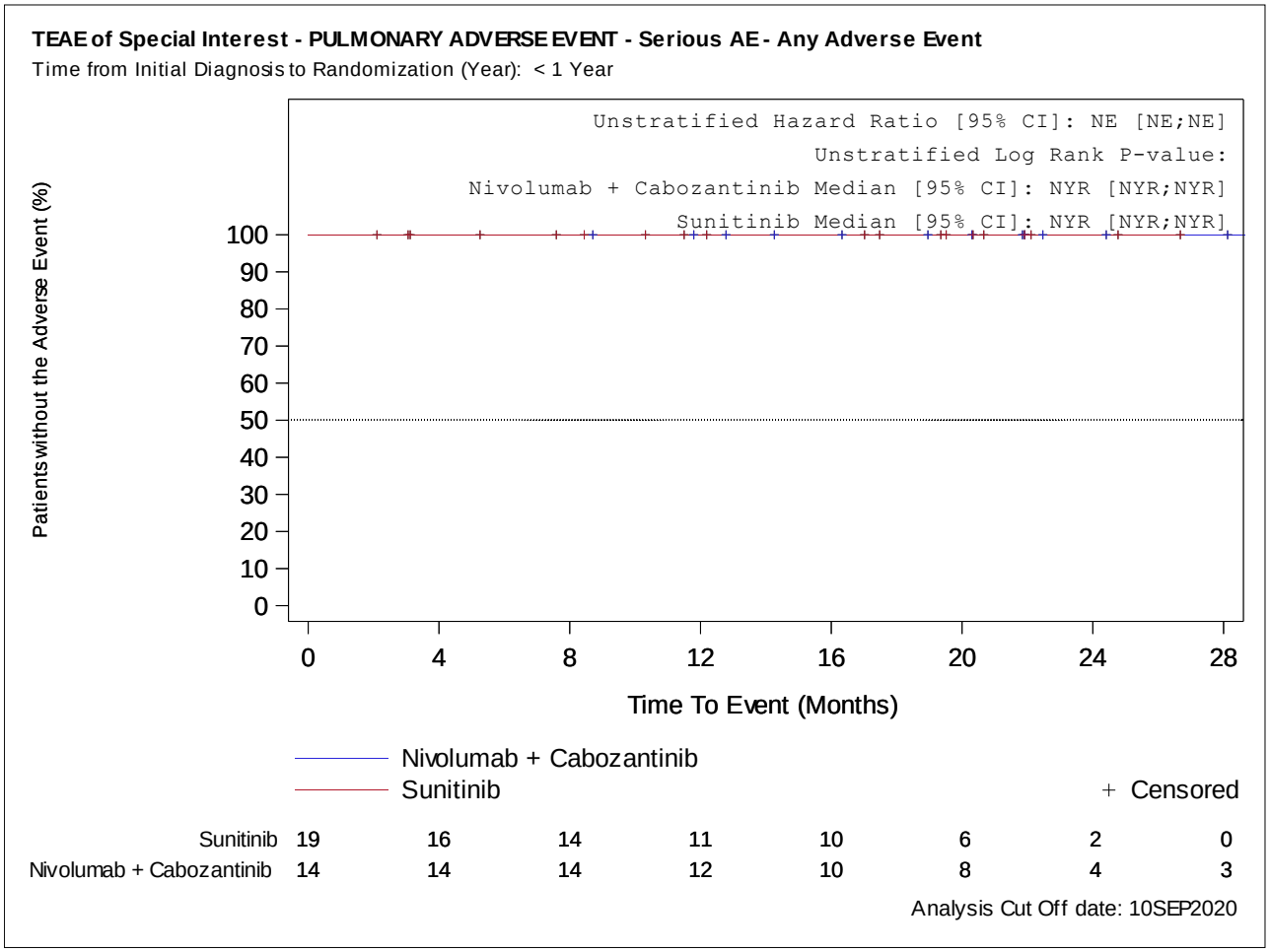

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:44:01

FIGURE 3.45.2.14: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



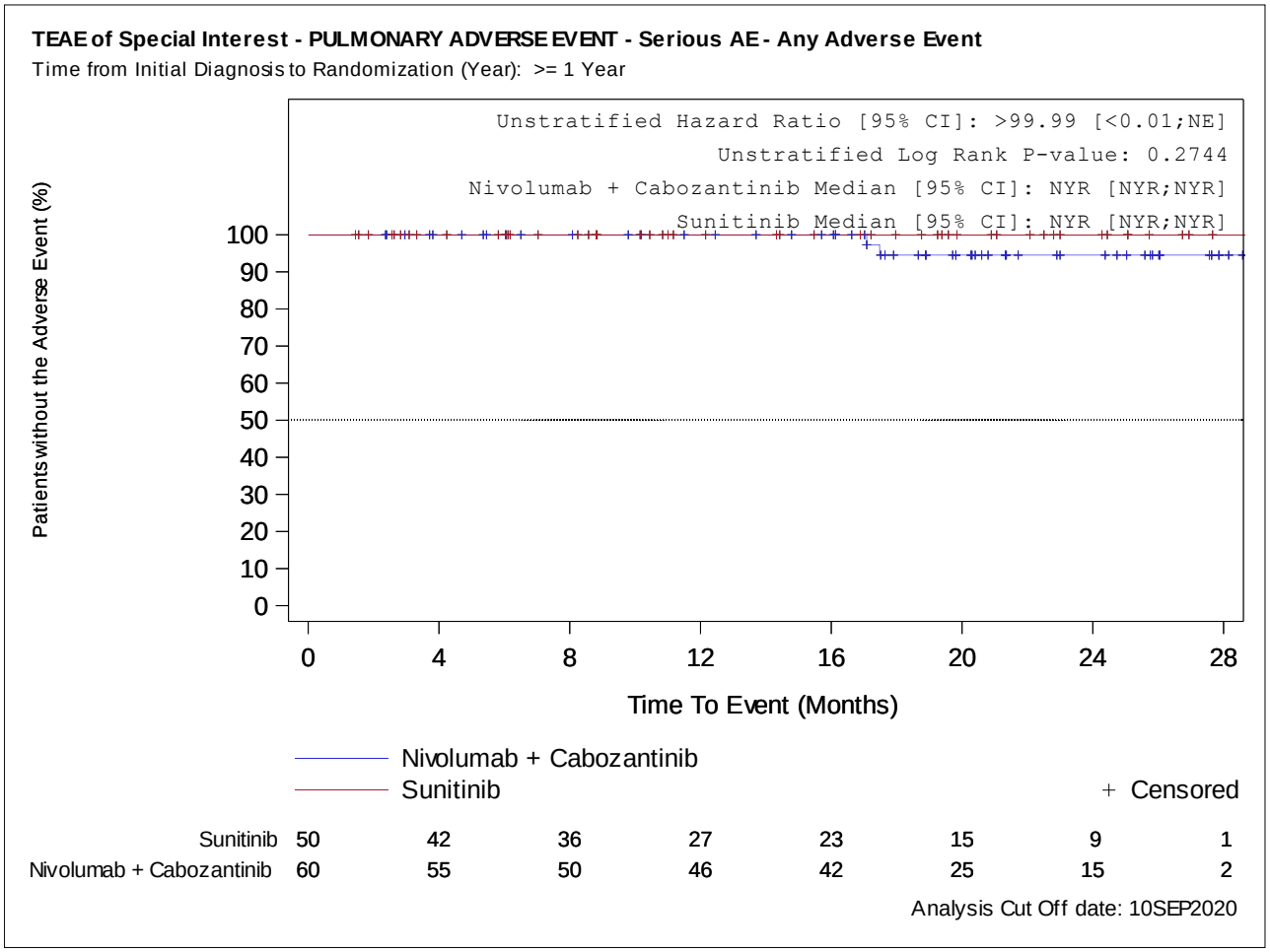

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:44:06

FIGURE 3.45.2.15: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



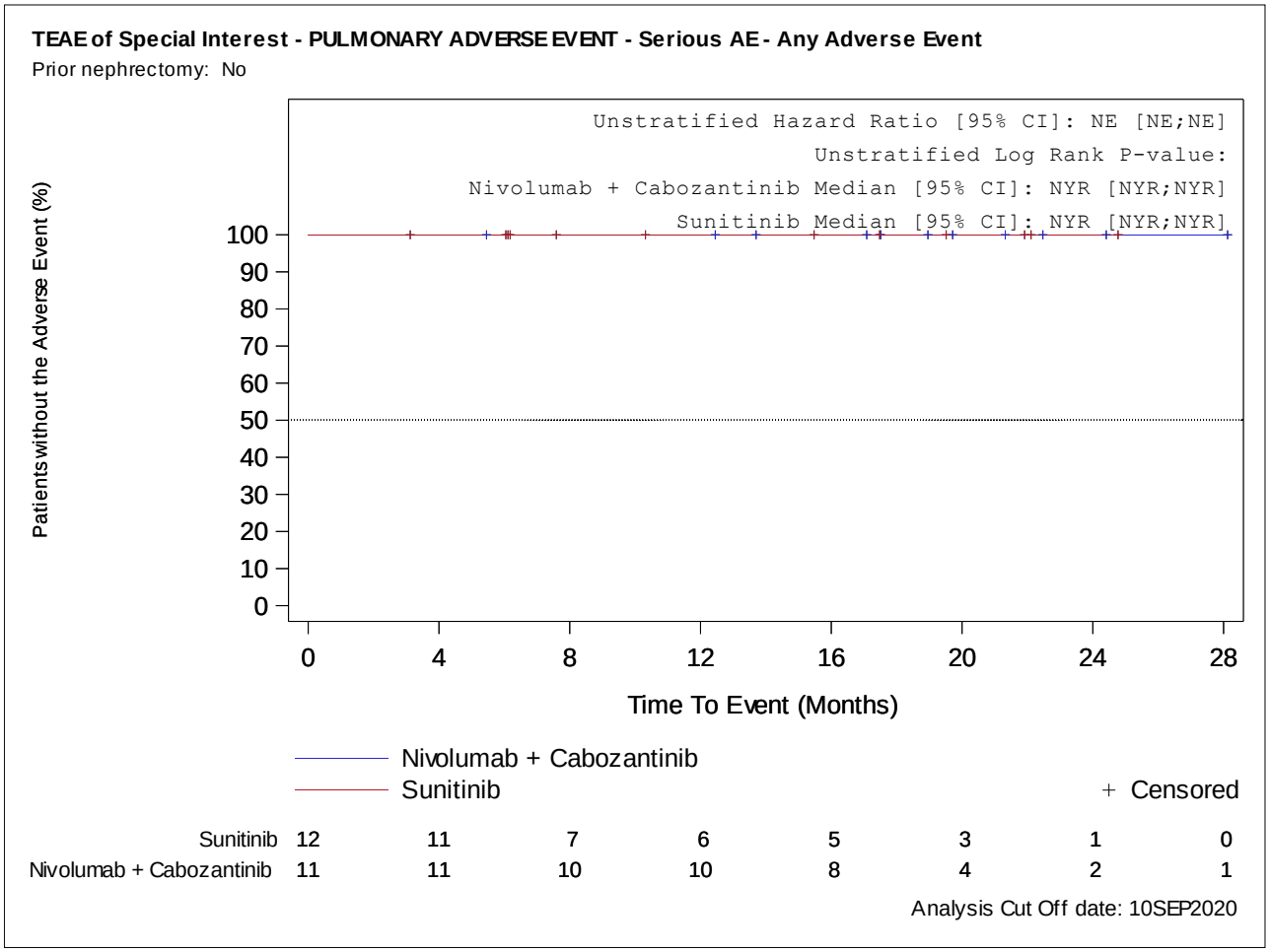

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:44:22

FIGURE 3.45.2.16: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



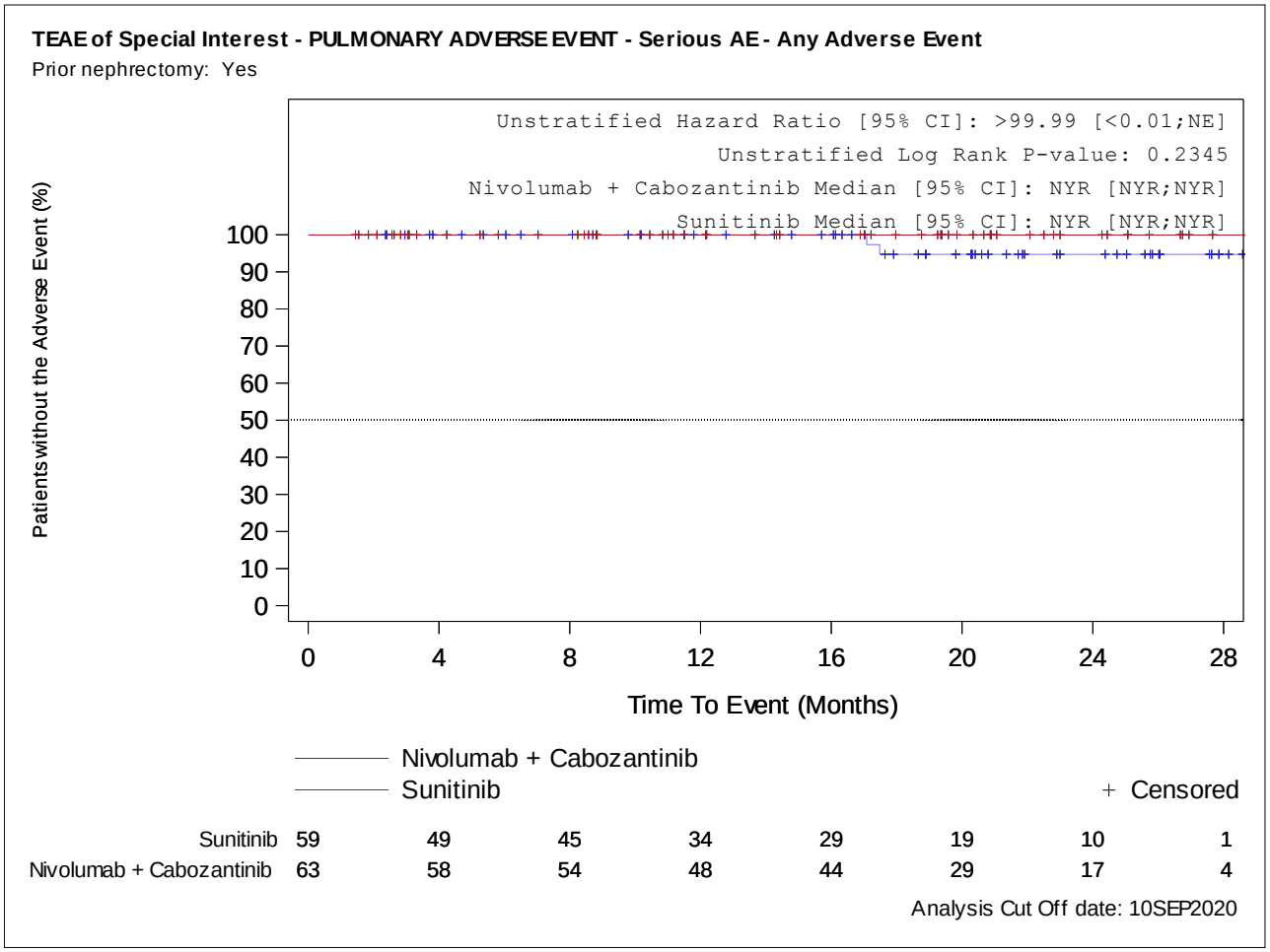

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:44:27

FIGURE 3.45.2.17: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



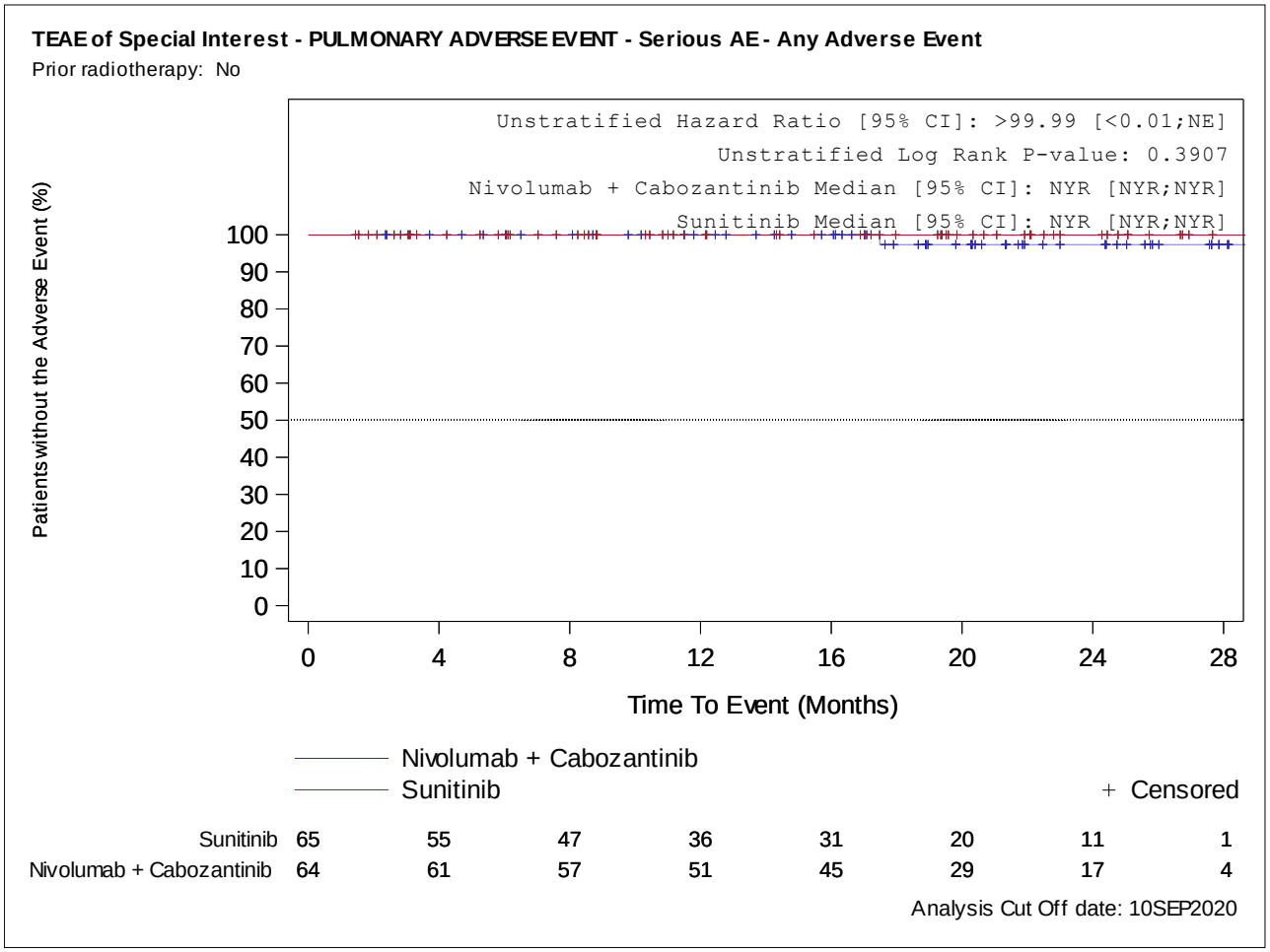

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:14

FIGURE 3.45.2.18: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



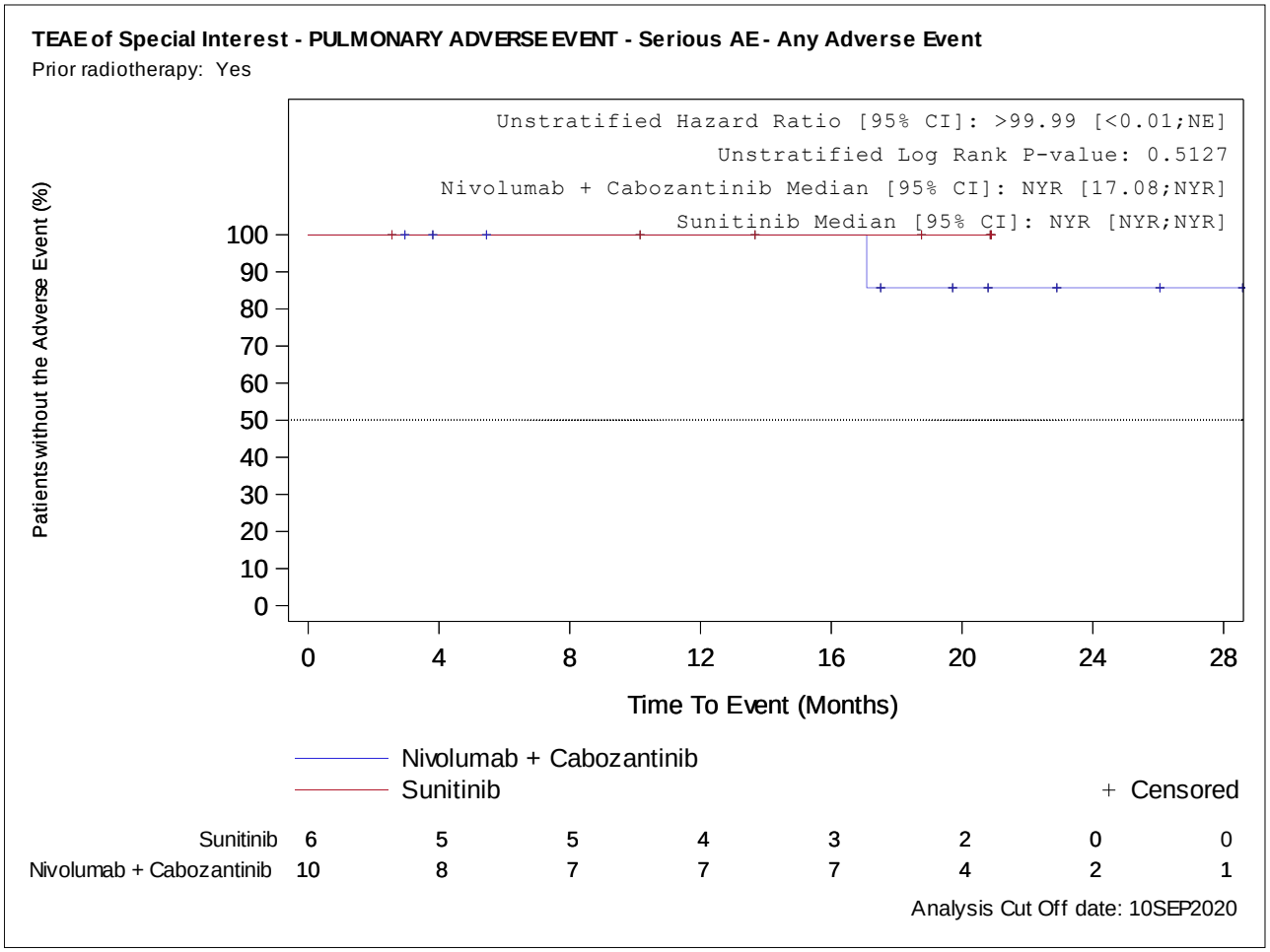

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:19

FIGURE 3.45.2.19: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



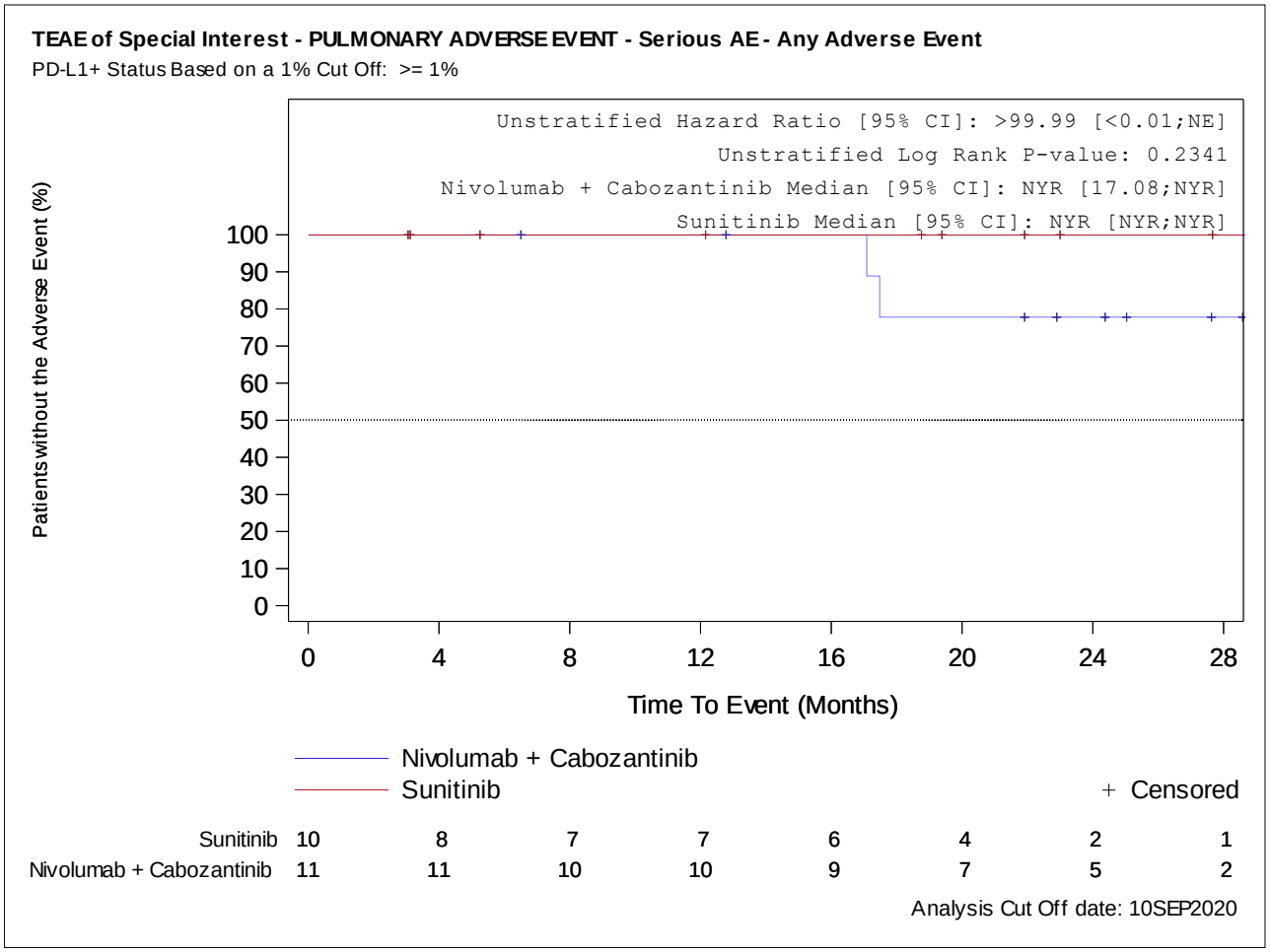

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:25

FIGURE 3.45.2.20: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



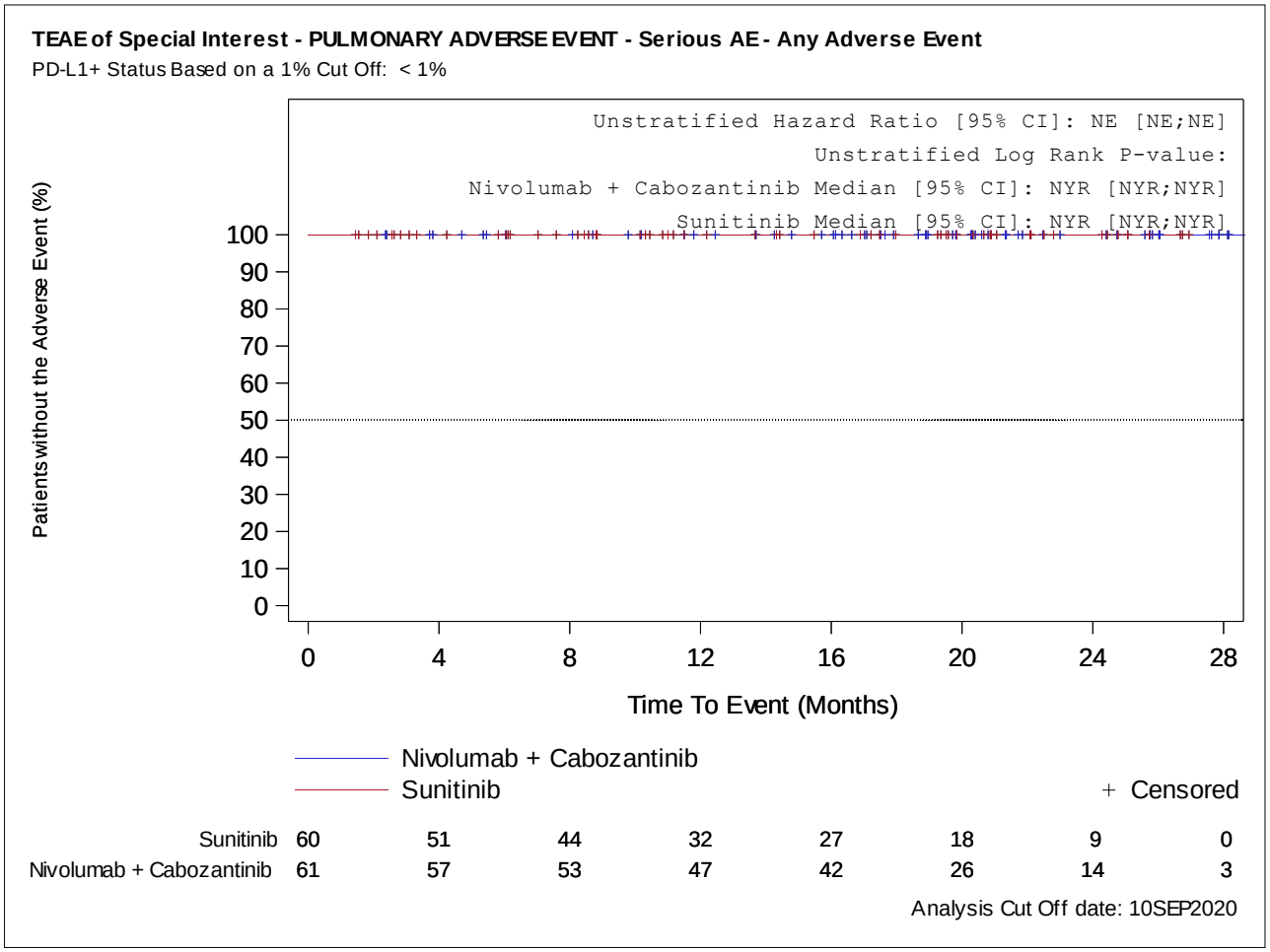

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:30

FIGURE 3.45.2.21: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



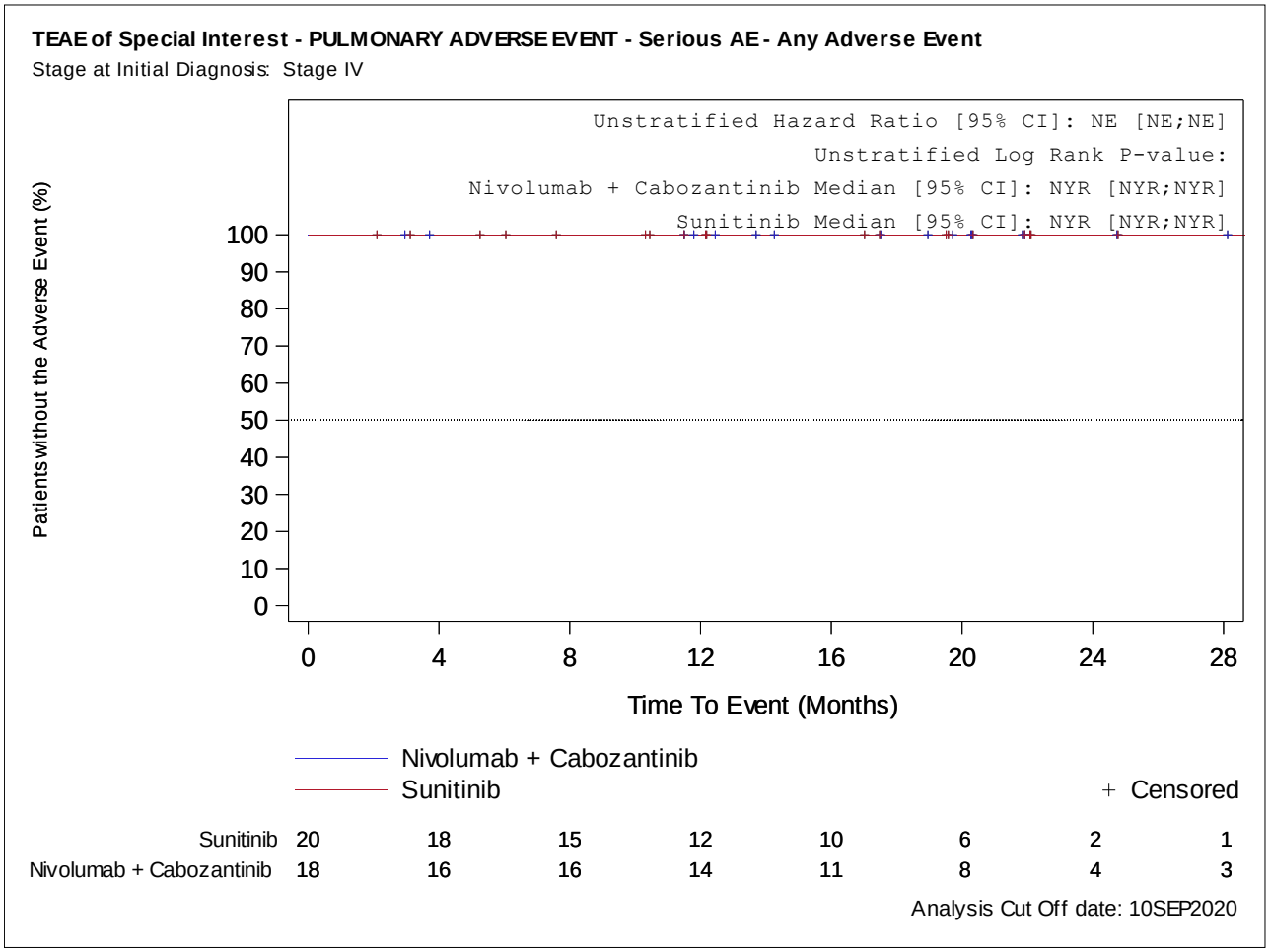

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:35

FIGURE 3.45.2.22: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



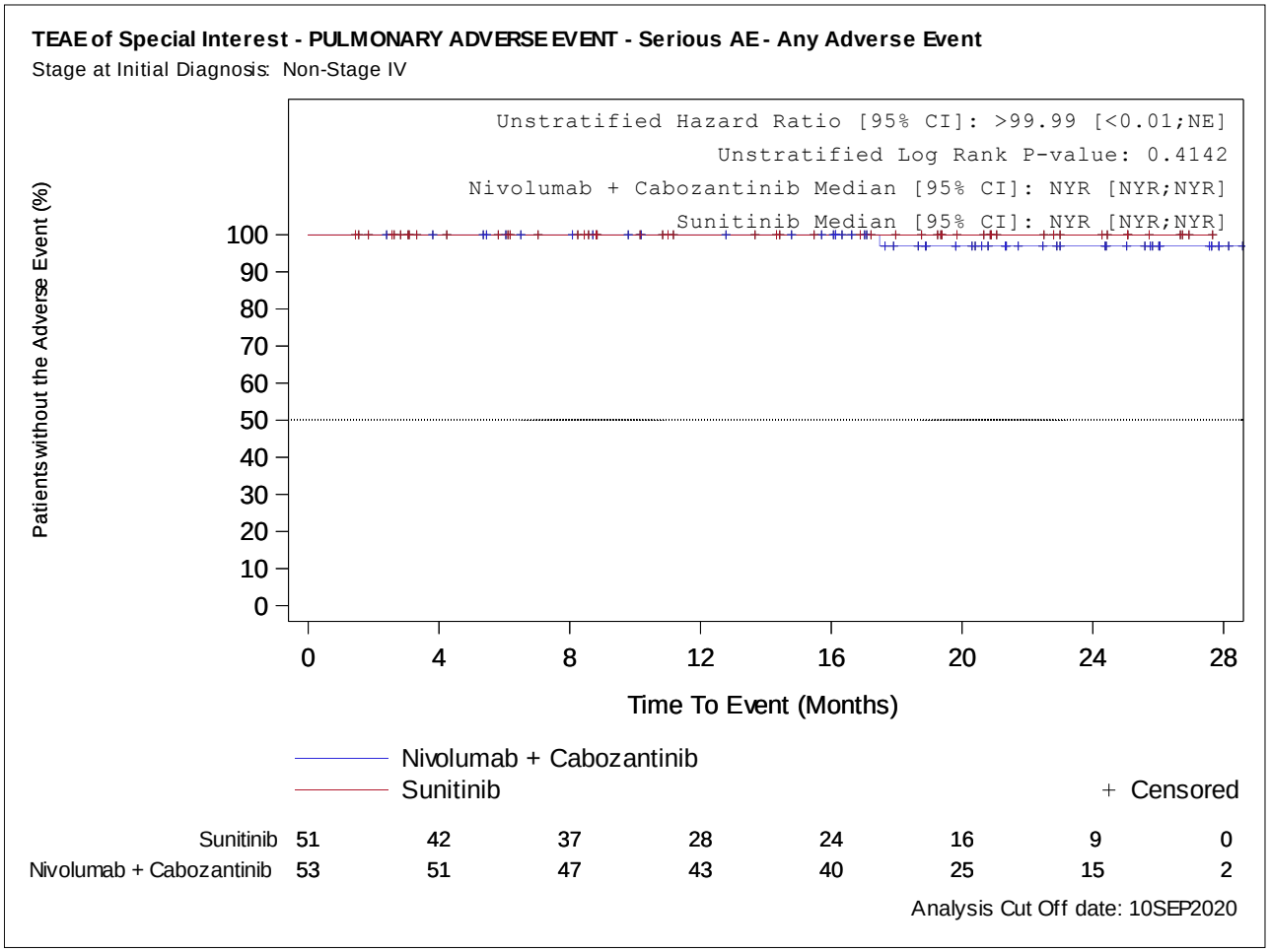

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:40

FIGURE 3.45.2.23: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



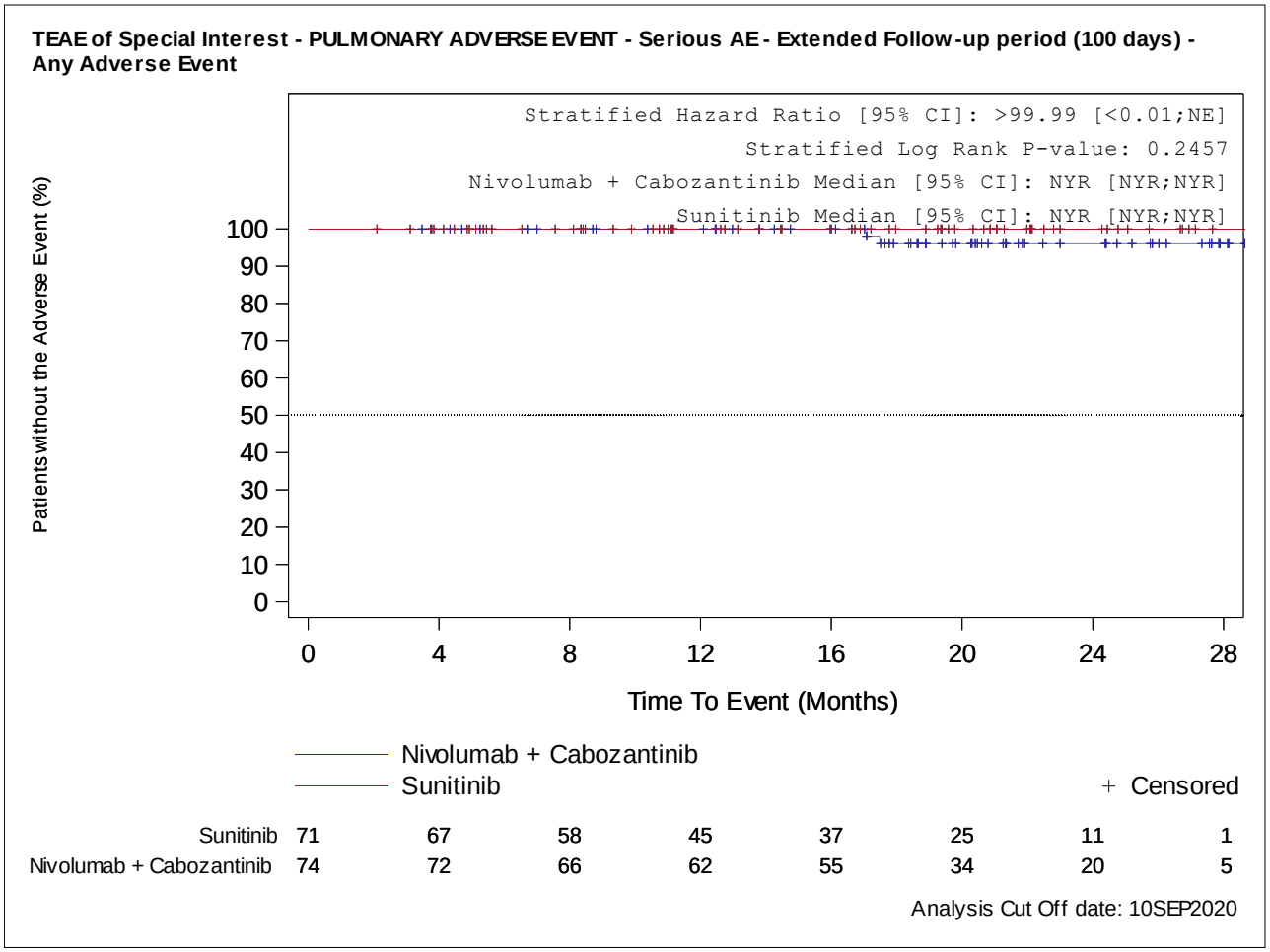

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:46:06

FIGURE 3.45.2.24: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



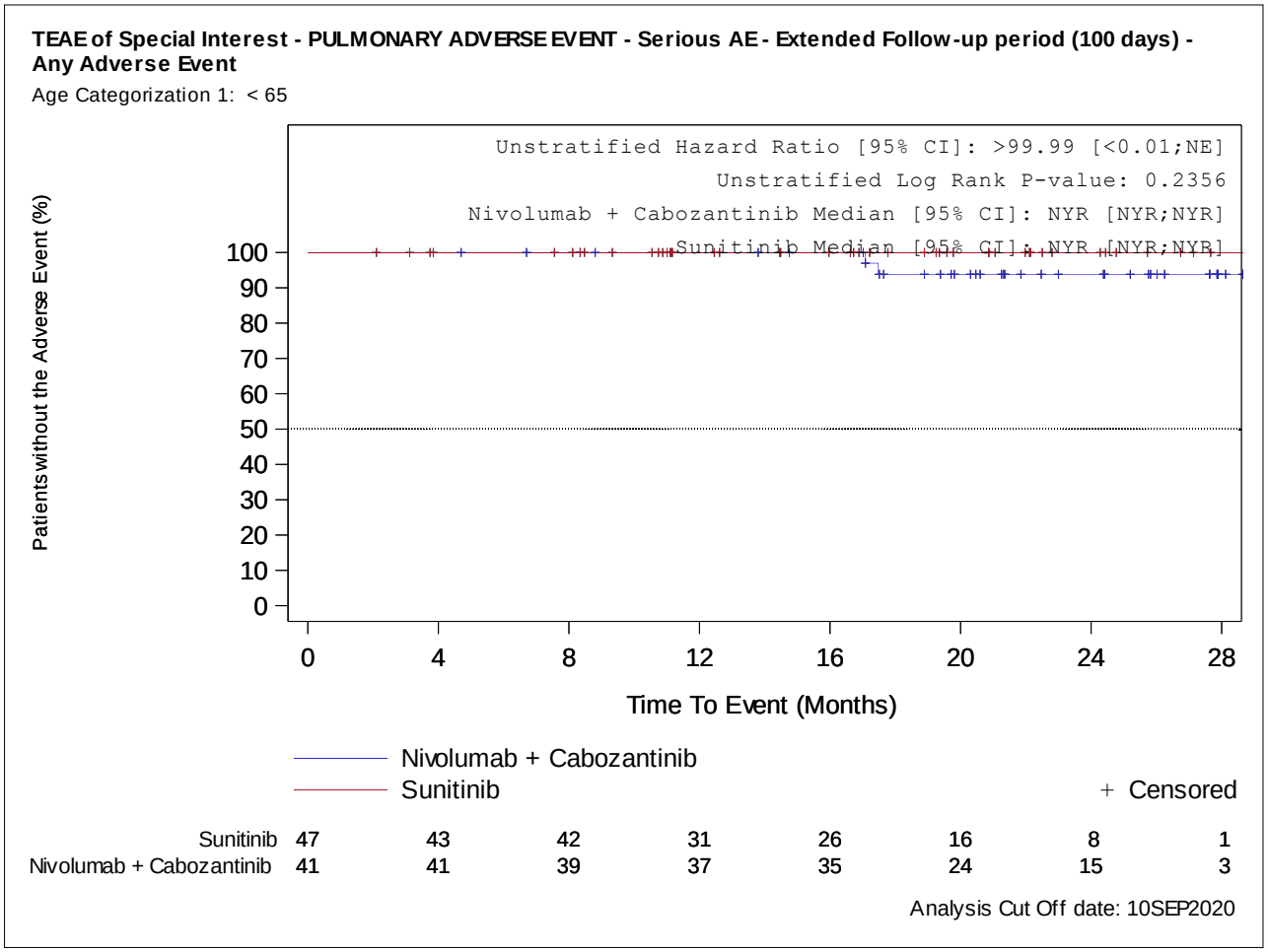

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:46:11

FIGURE 3.46.1: TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



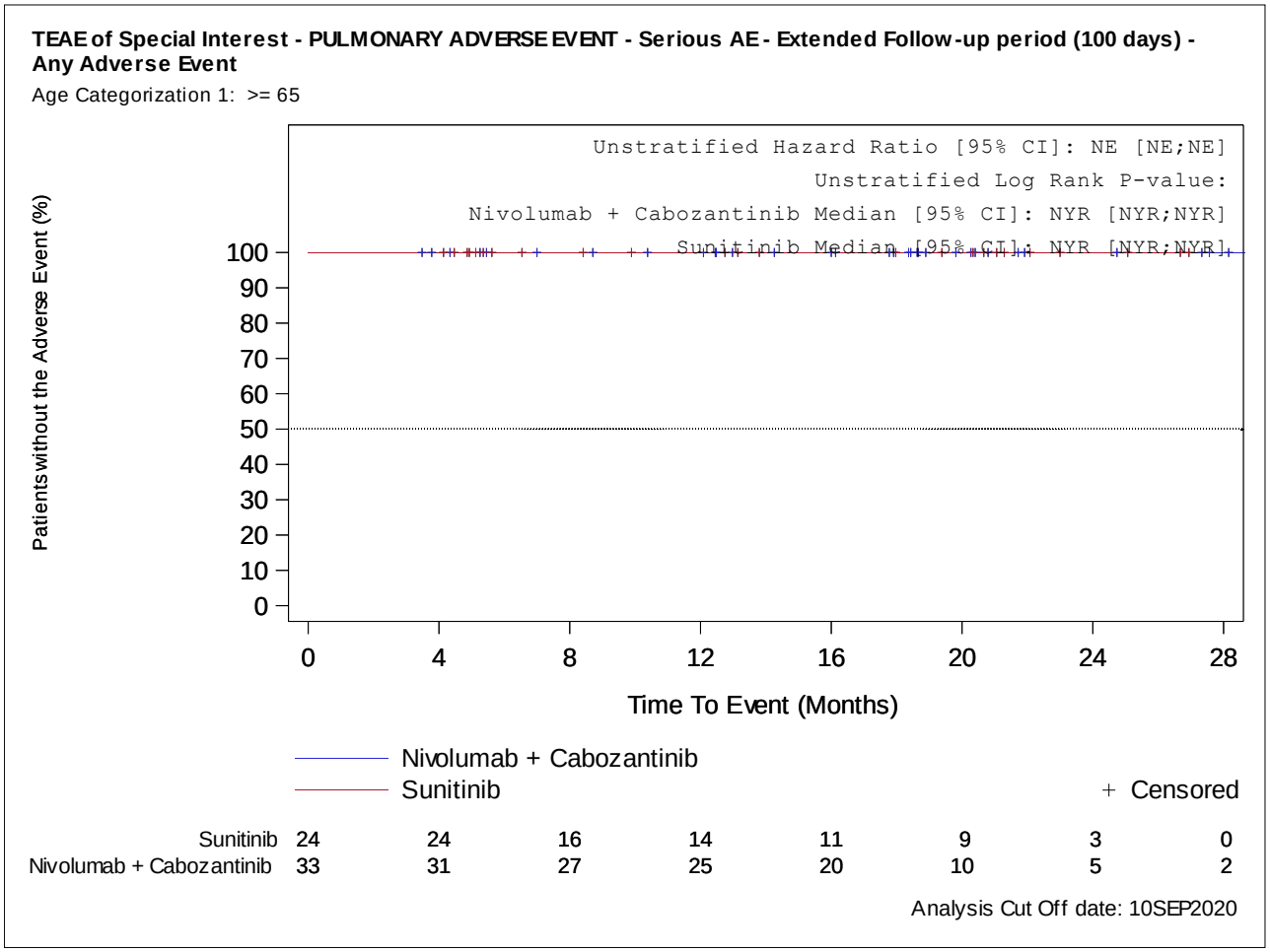

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:49:07

FIGURE 3.46.2.1: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



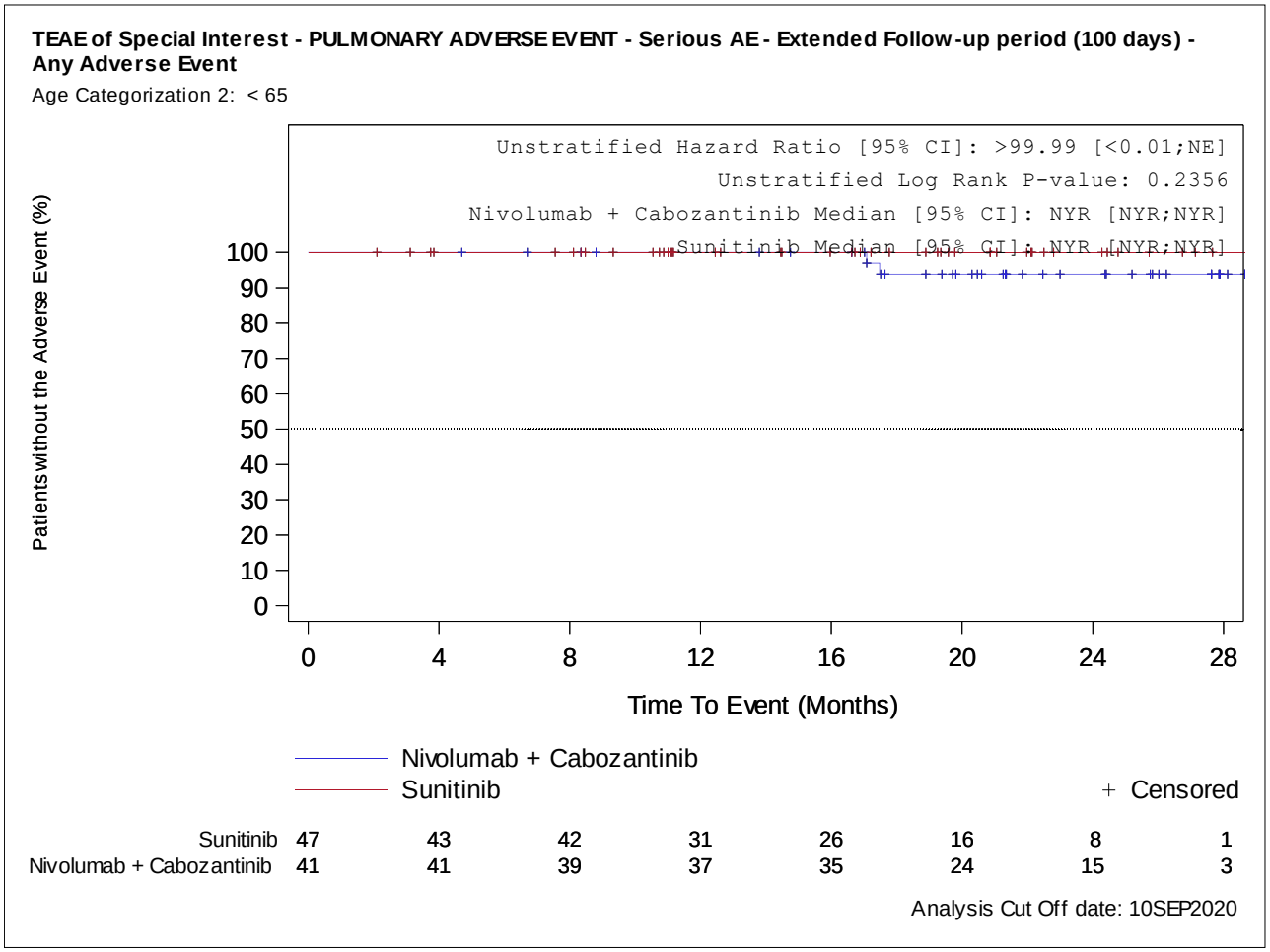

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:49:10

FIGURE 3.46.2.2: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



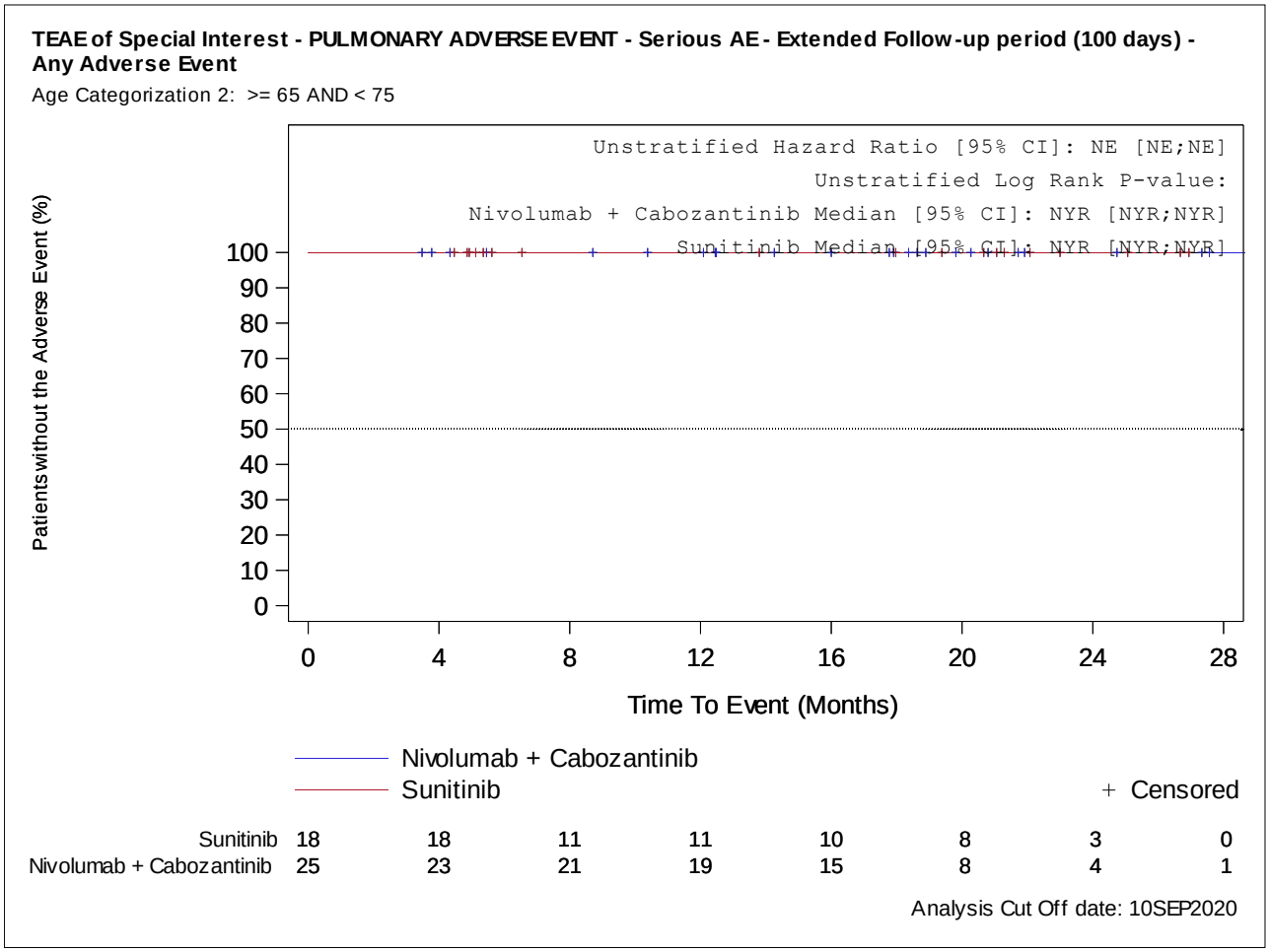

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:49:16

FIGURE 3.46.2.3: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



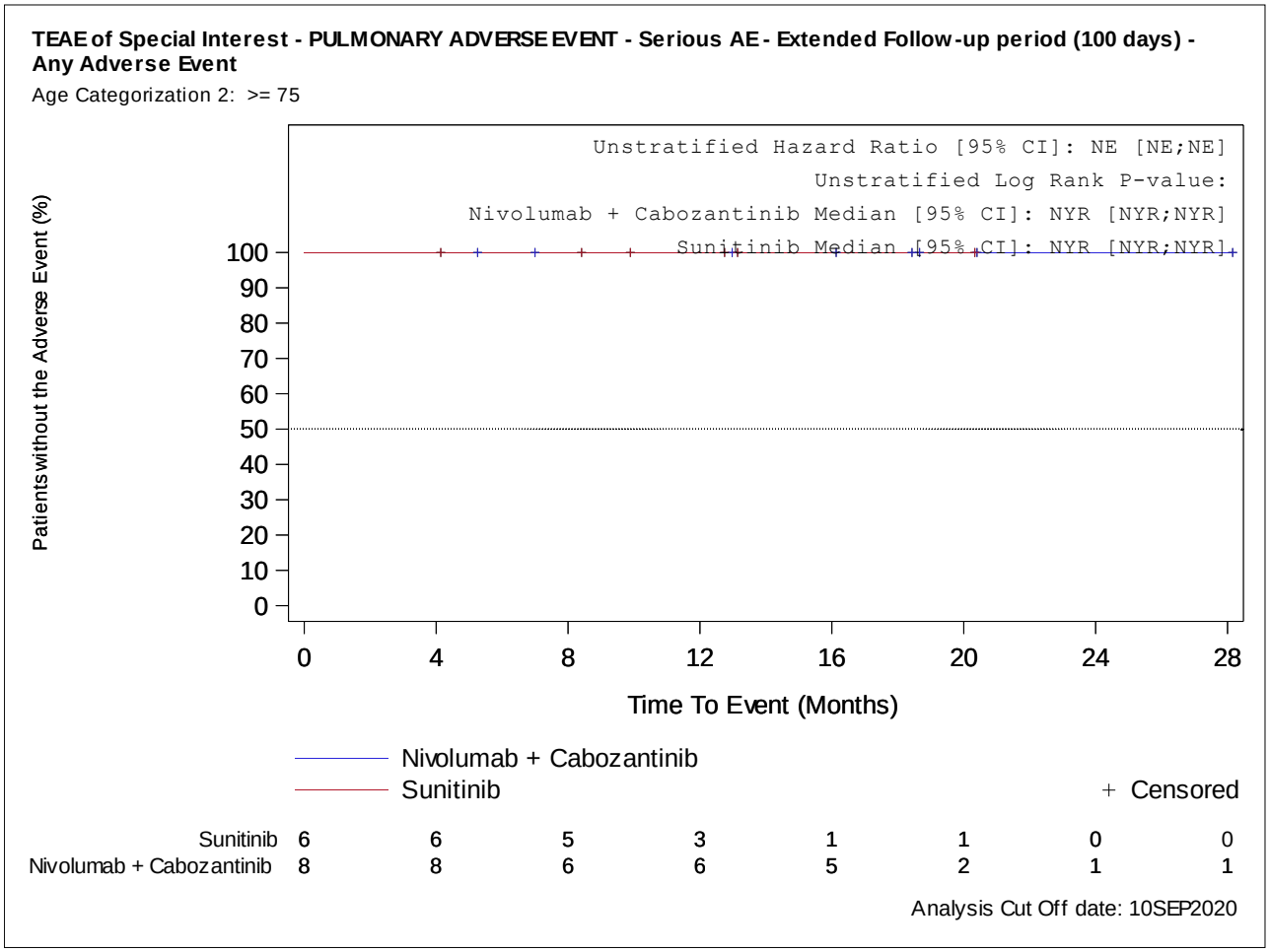

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:49:21

FIGURE 3.46.2.4: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



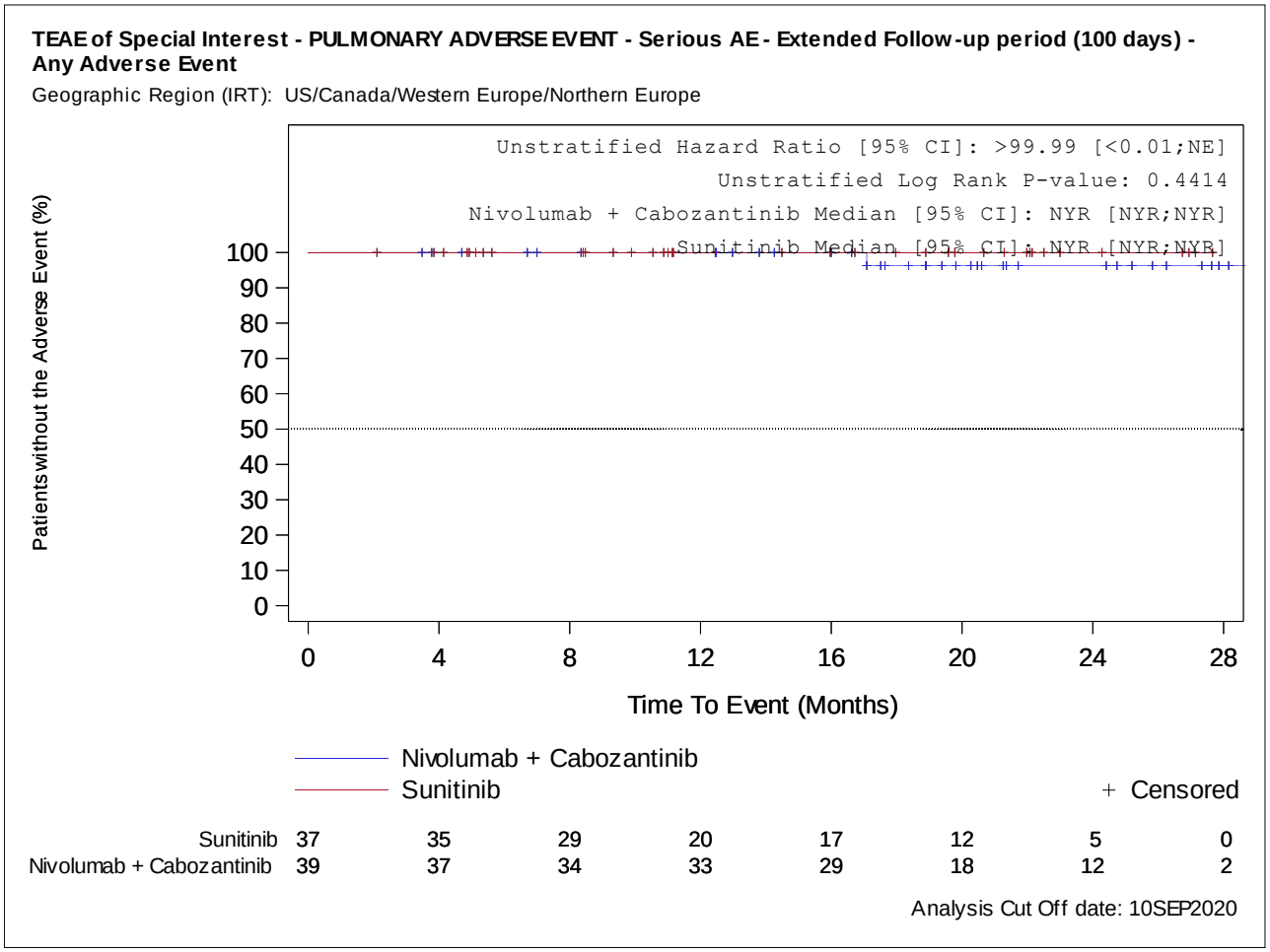

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:49:26

FIGURE 3.46.2.5: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



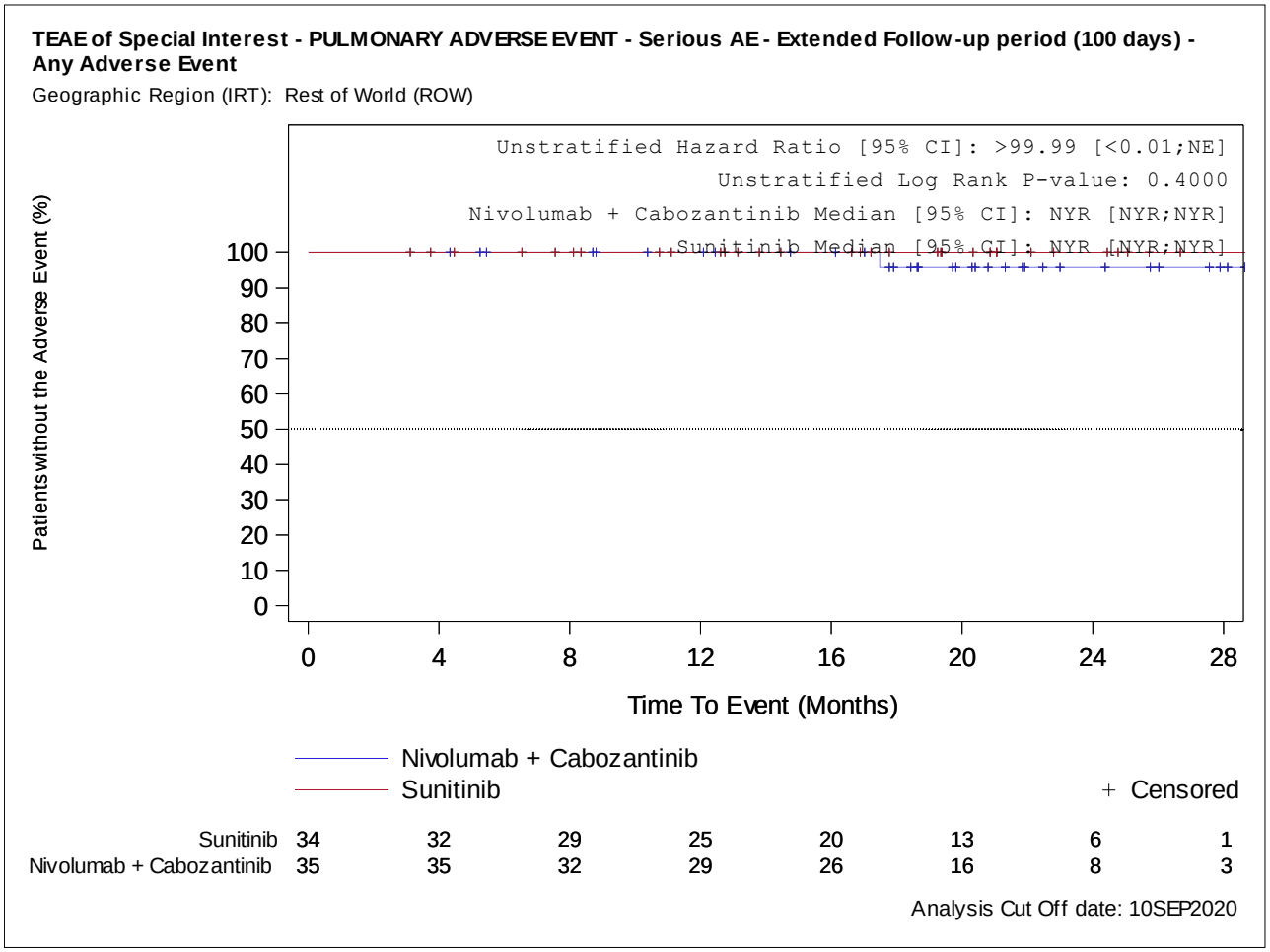

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:49:31

FIGURE 3.46.2.6: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



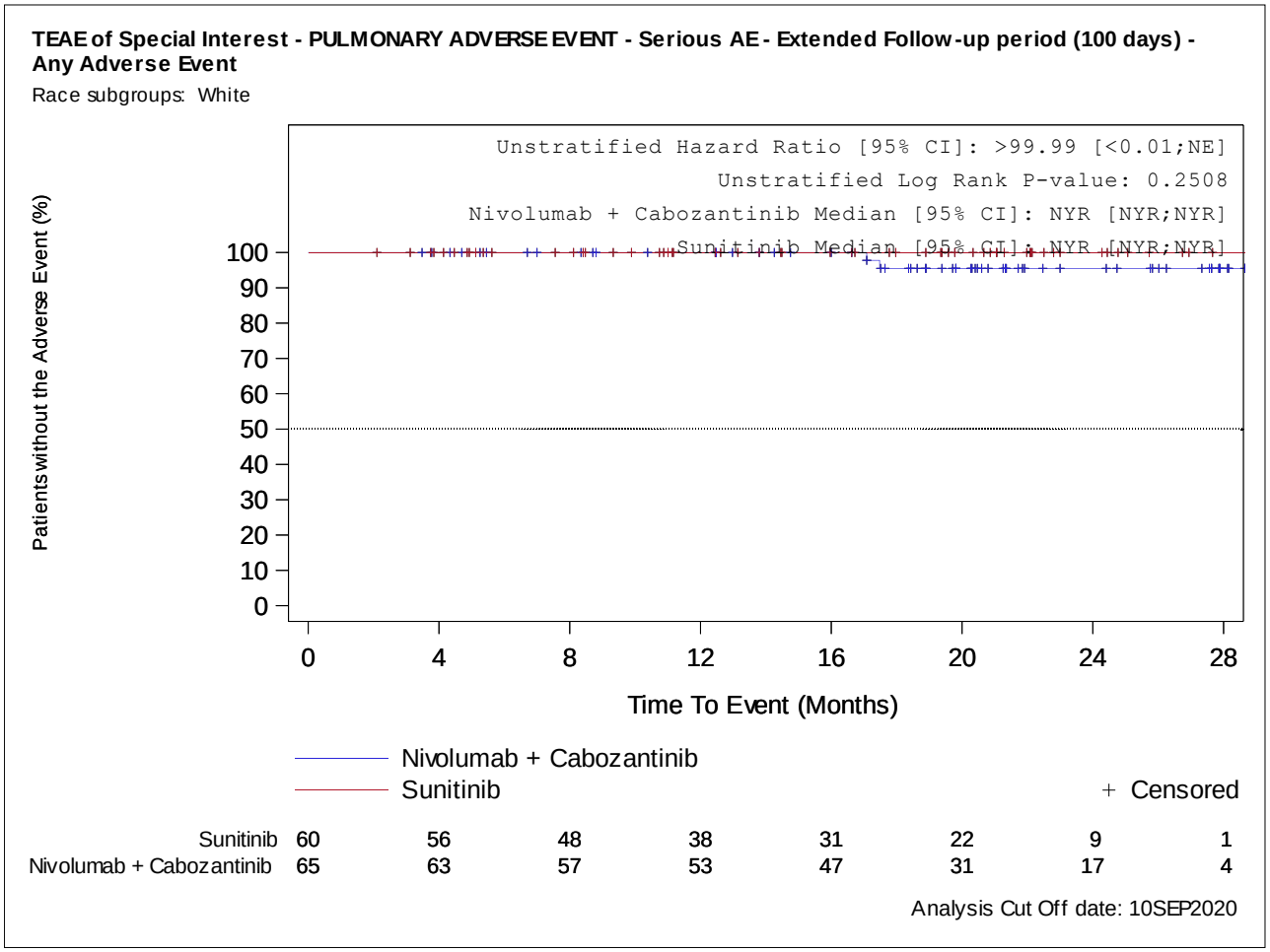

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:49:36

FIGURE 3.46.2.7: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



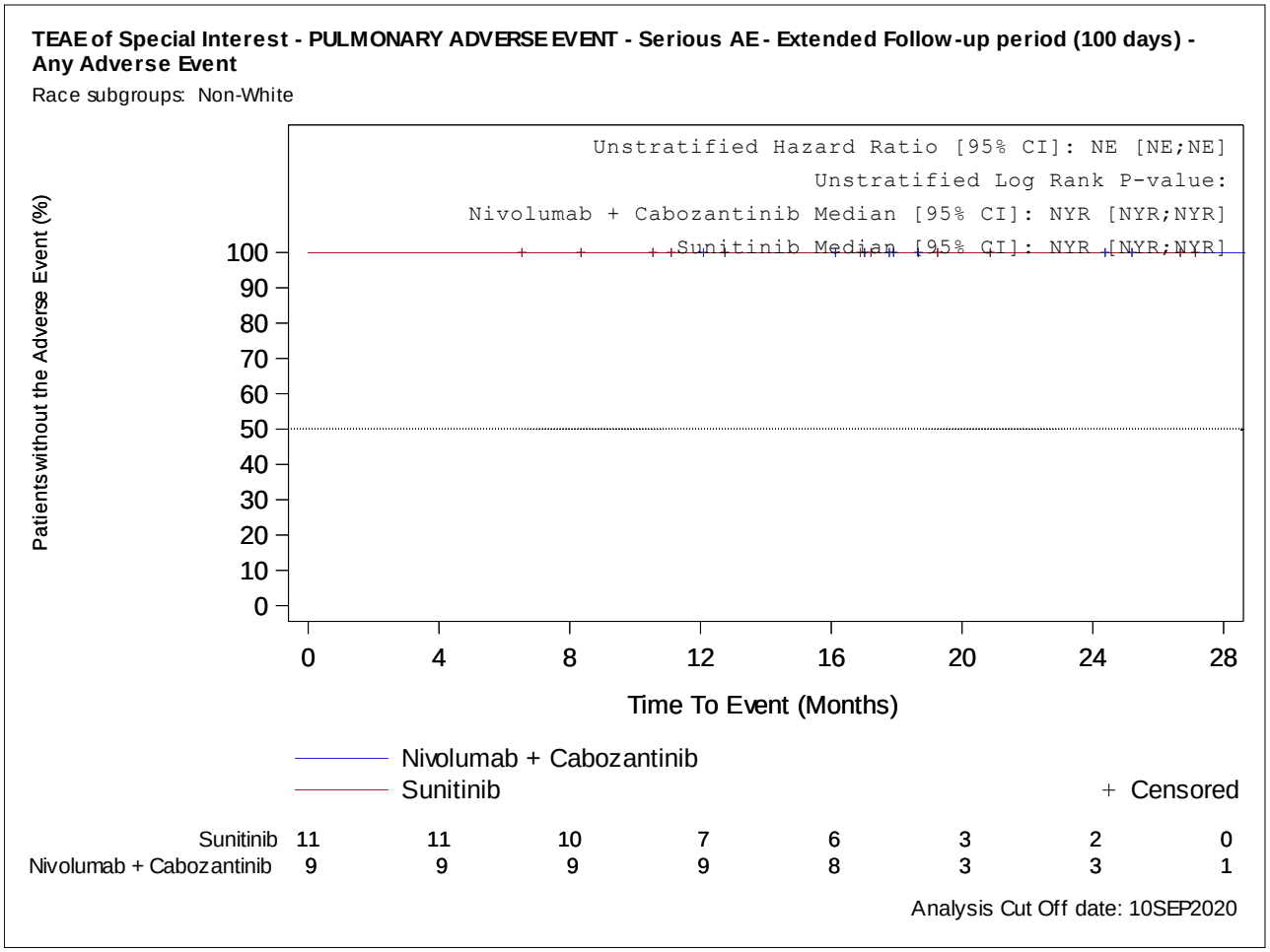

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:49:42

FIGURE 3.46.2.8: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



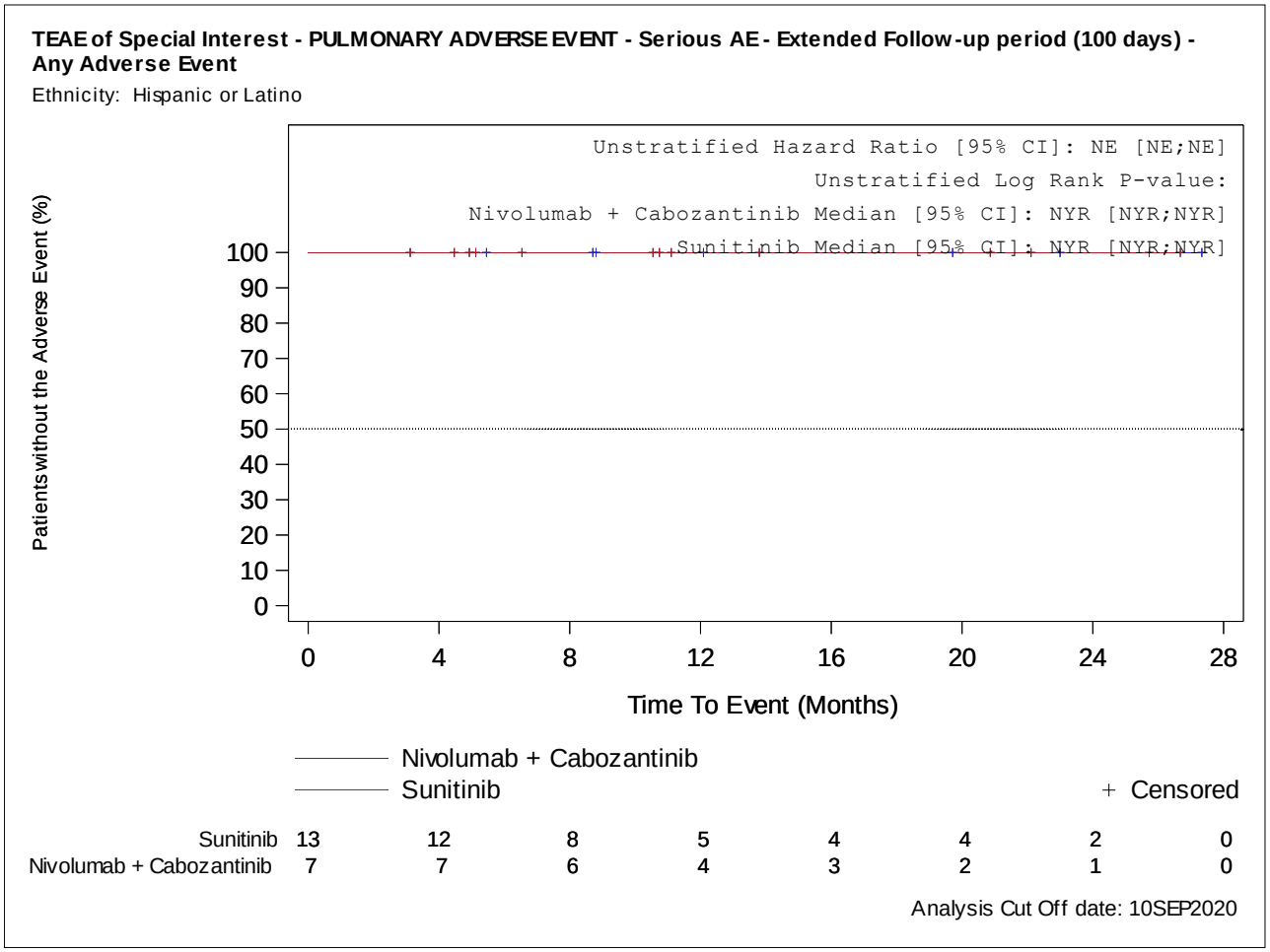

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:49:47

FIGURE 3.46.2.9: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



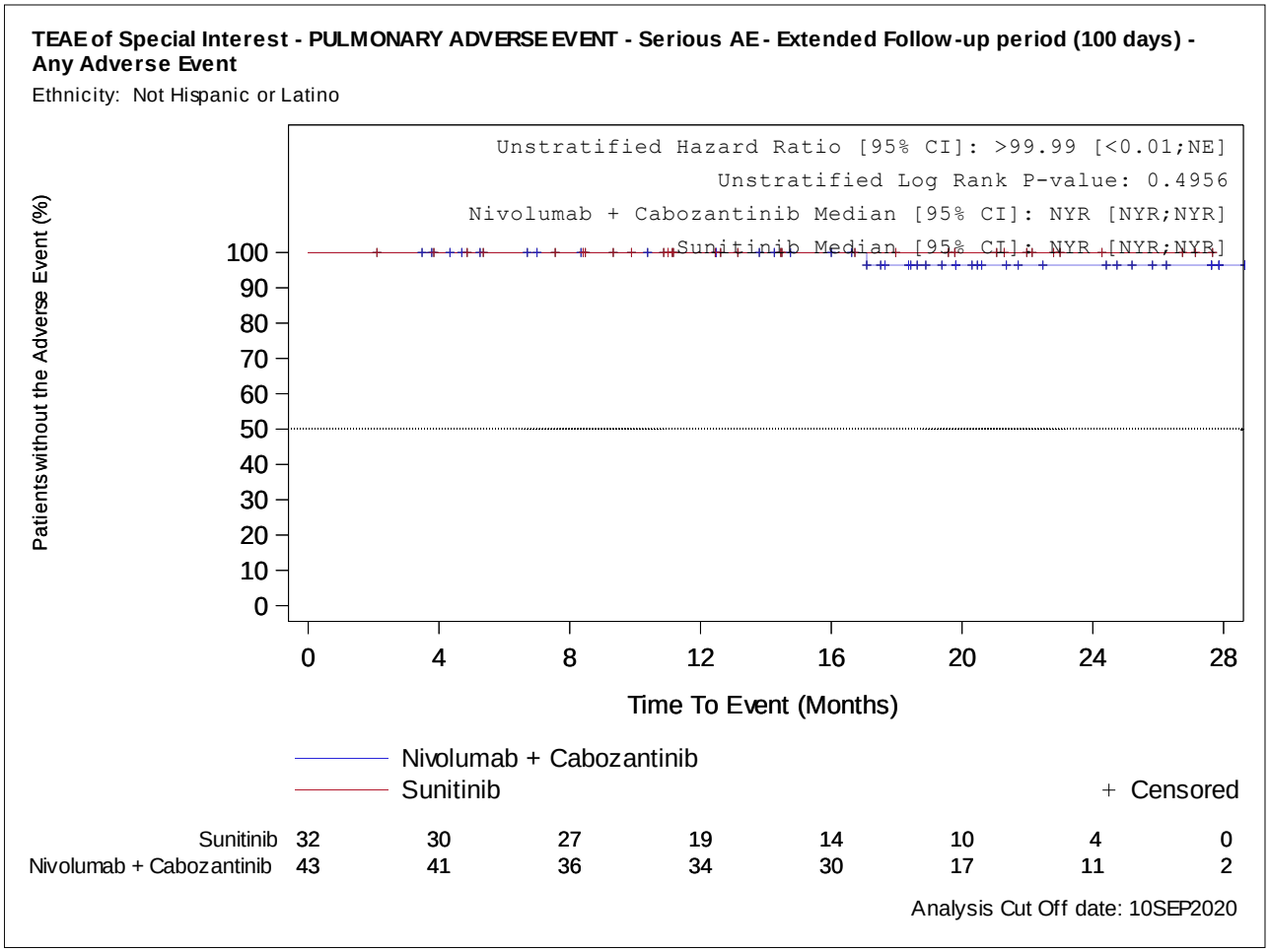

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:49:52

FIGURE 3.46.2.10: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



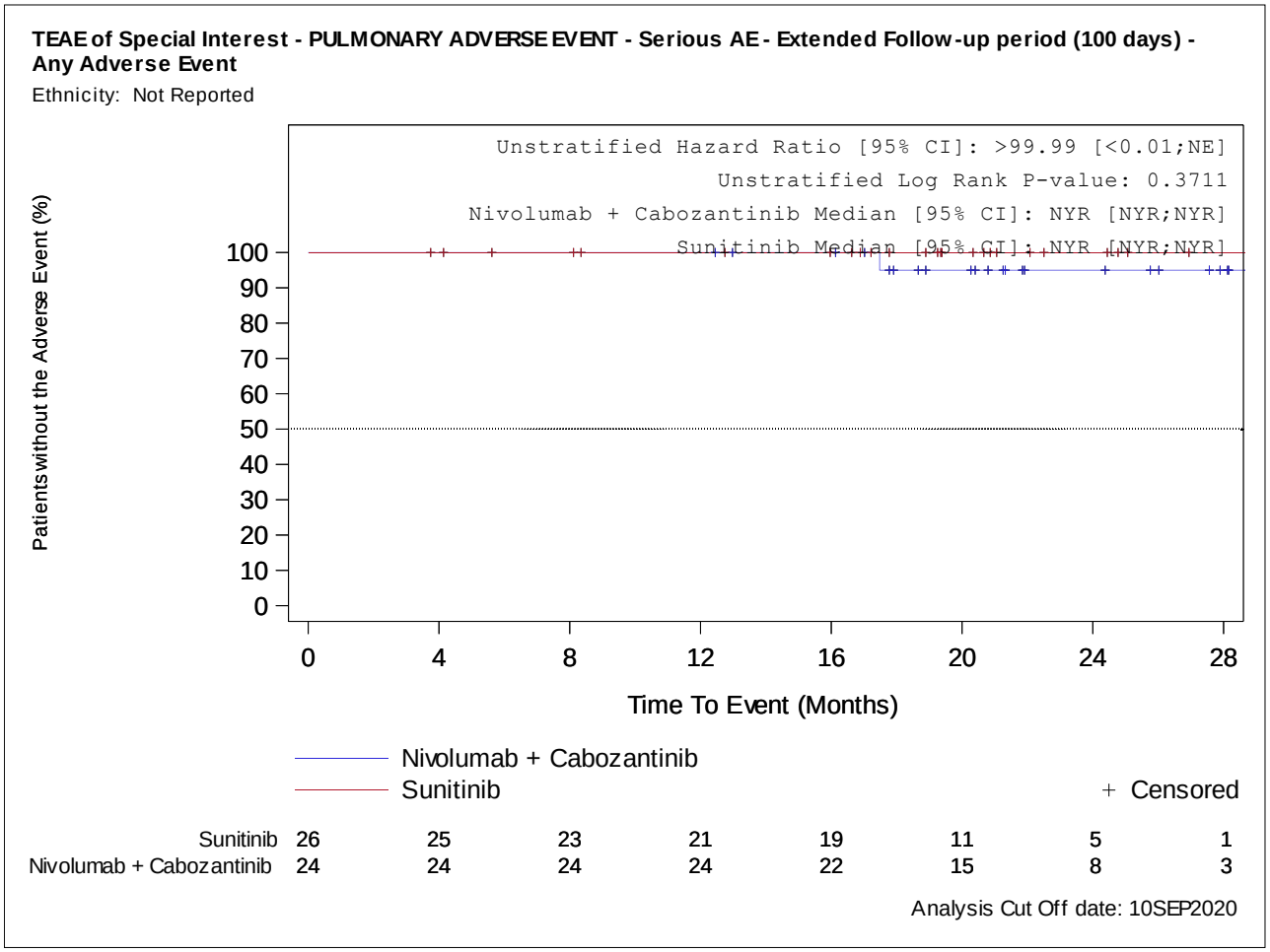

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:49:58

FIGURE 3.46.2.11: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



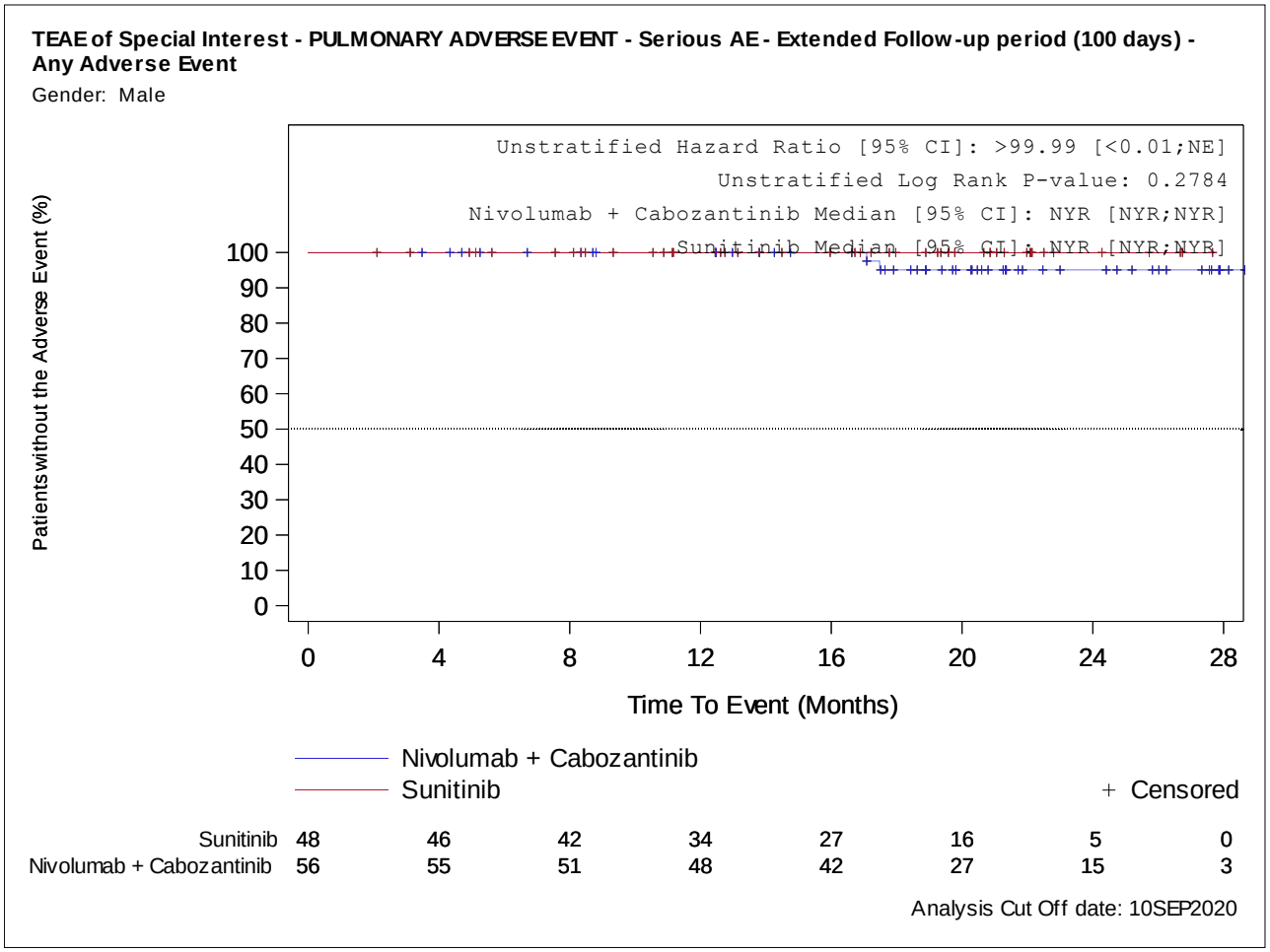

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:50:03

FIGURE 3.46.2.12: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



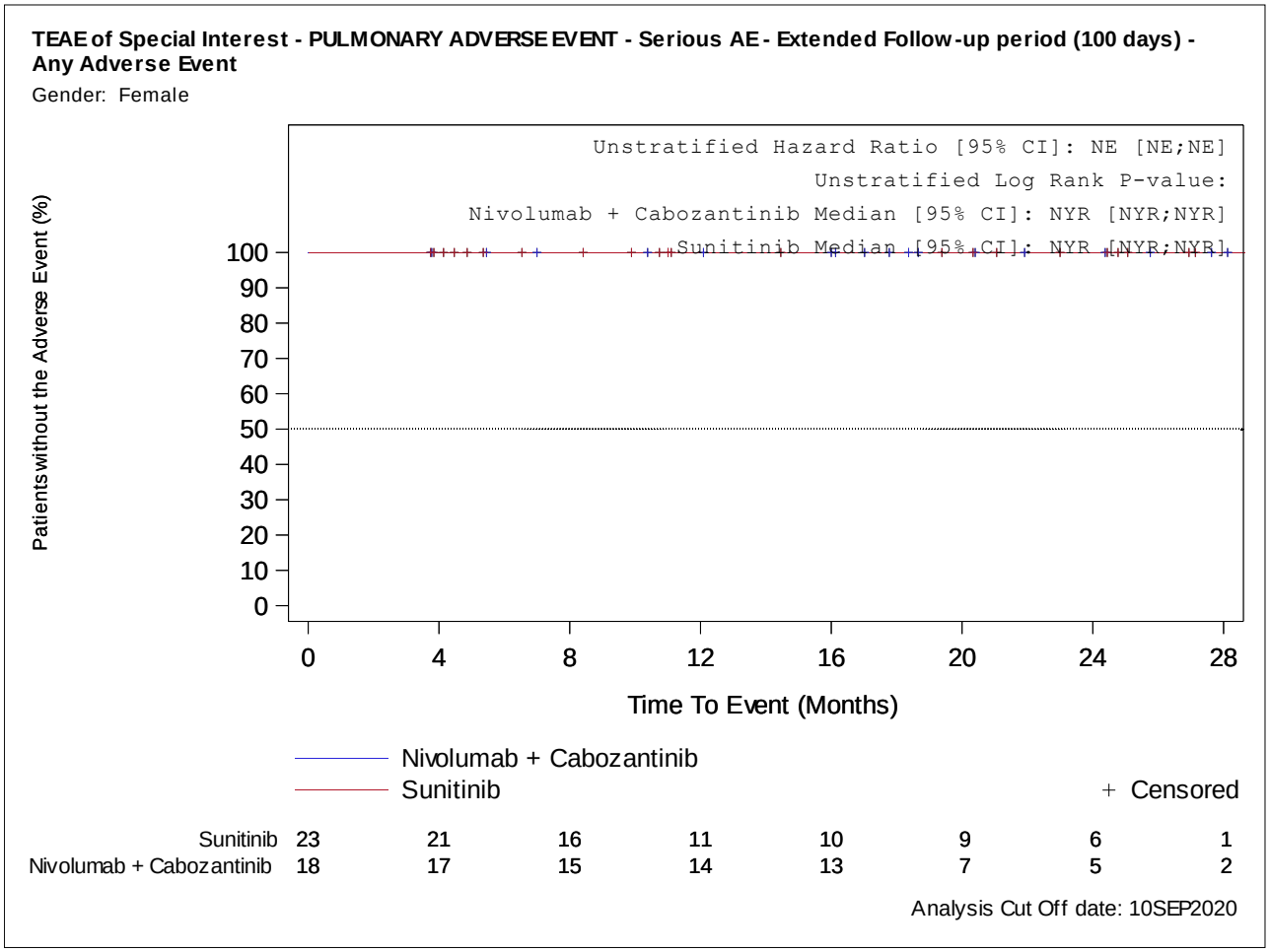

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:50:08

FIGURE 3.46.2.13: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



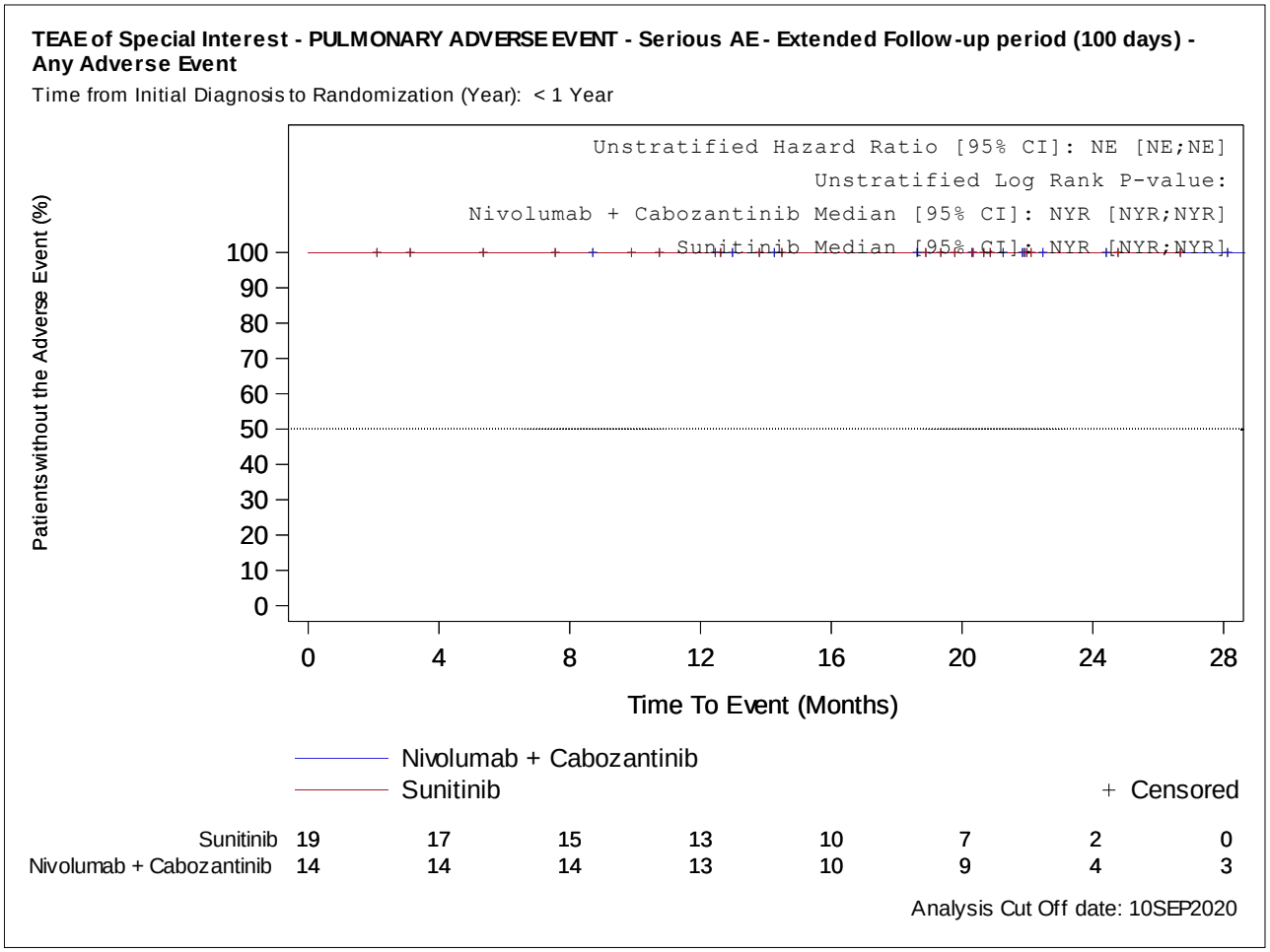

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:50:13

FIGURE 3.46.2.14: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



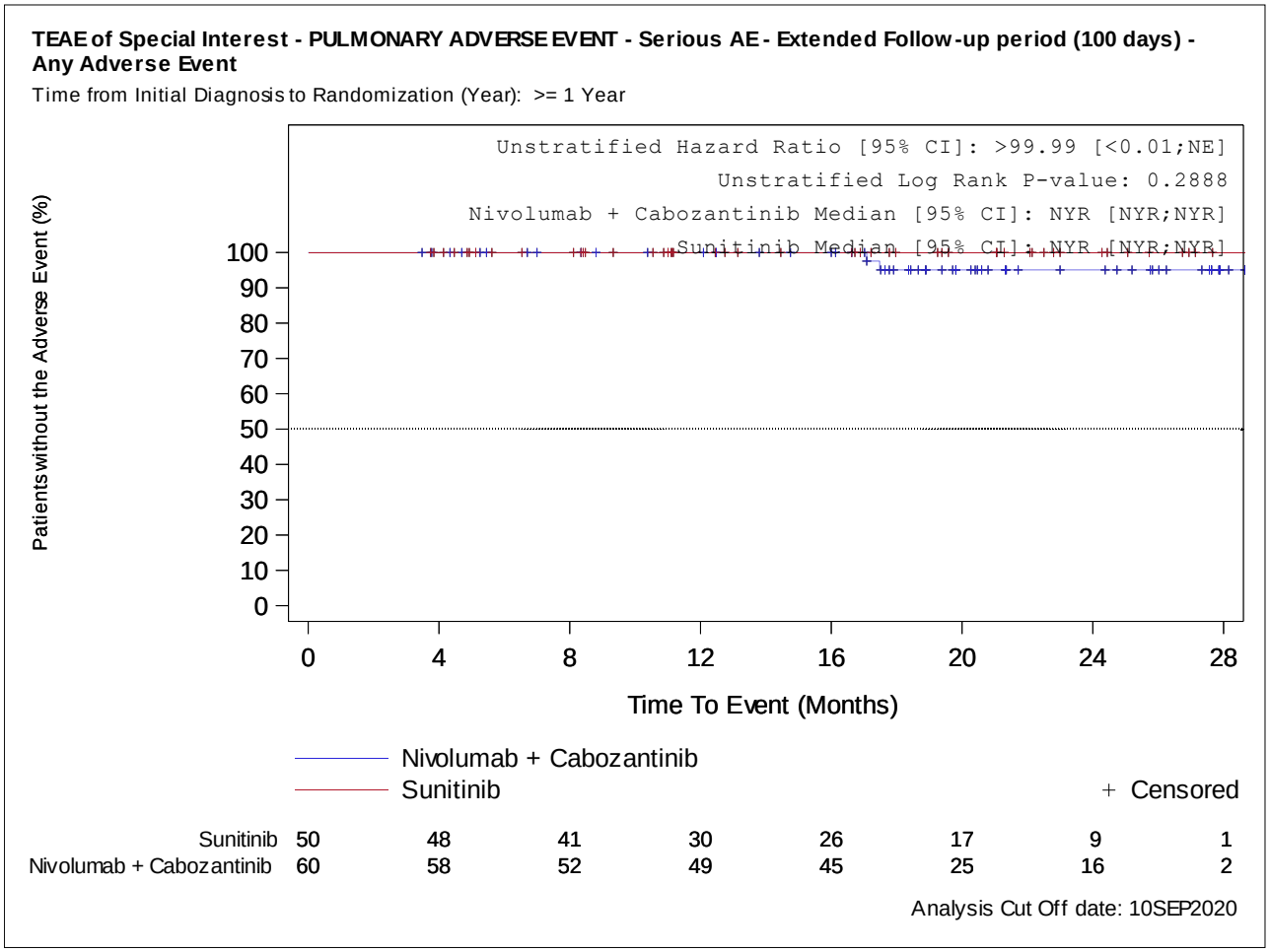

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:50:19

FIGURE 3.46.2.15: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



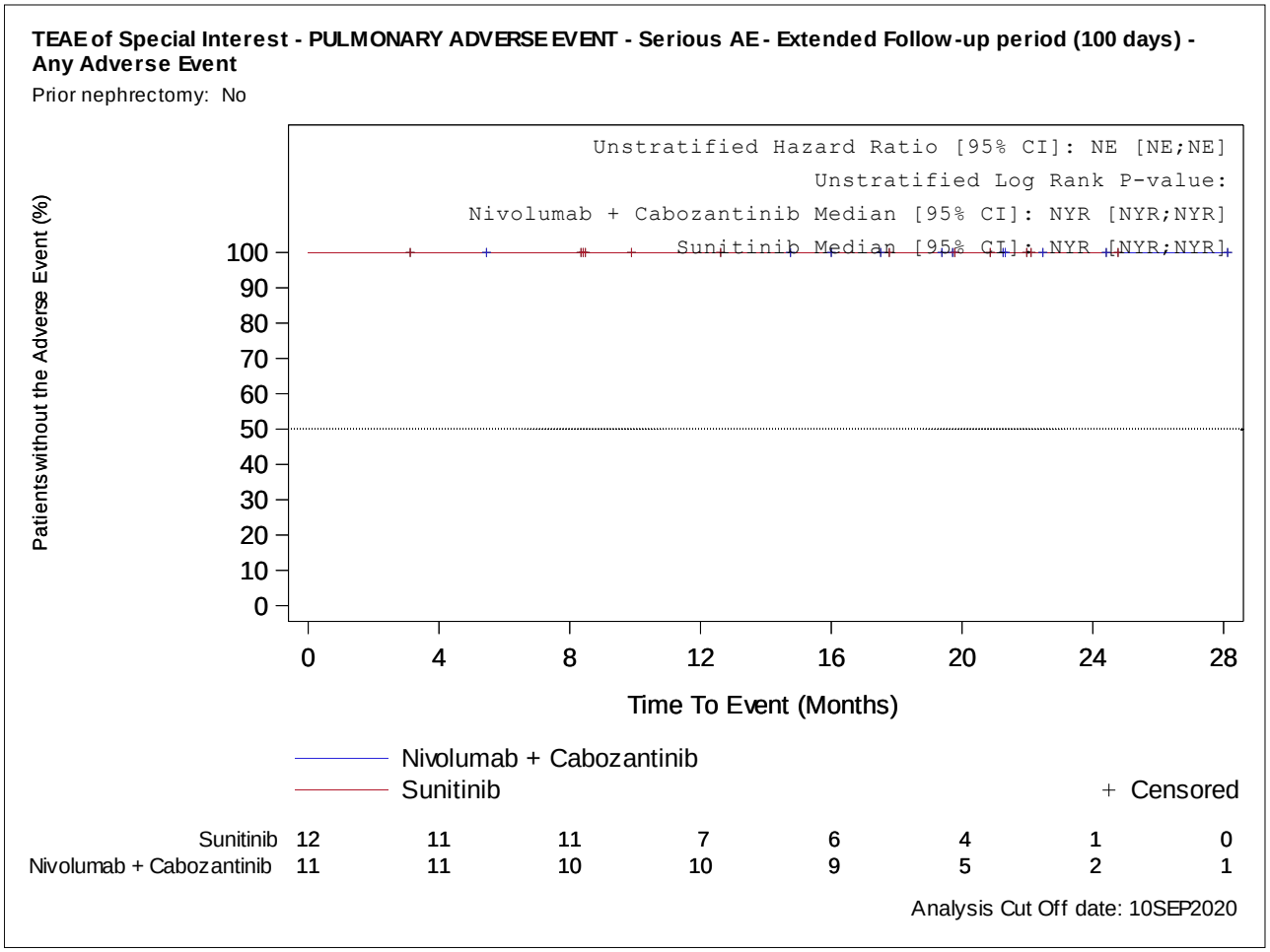

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:50:34

FIGURE 3.46.2.16: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



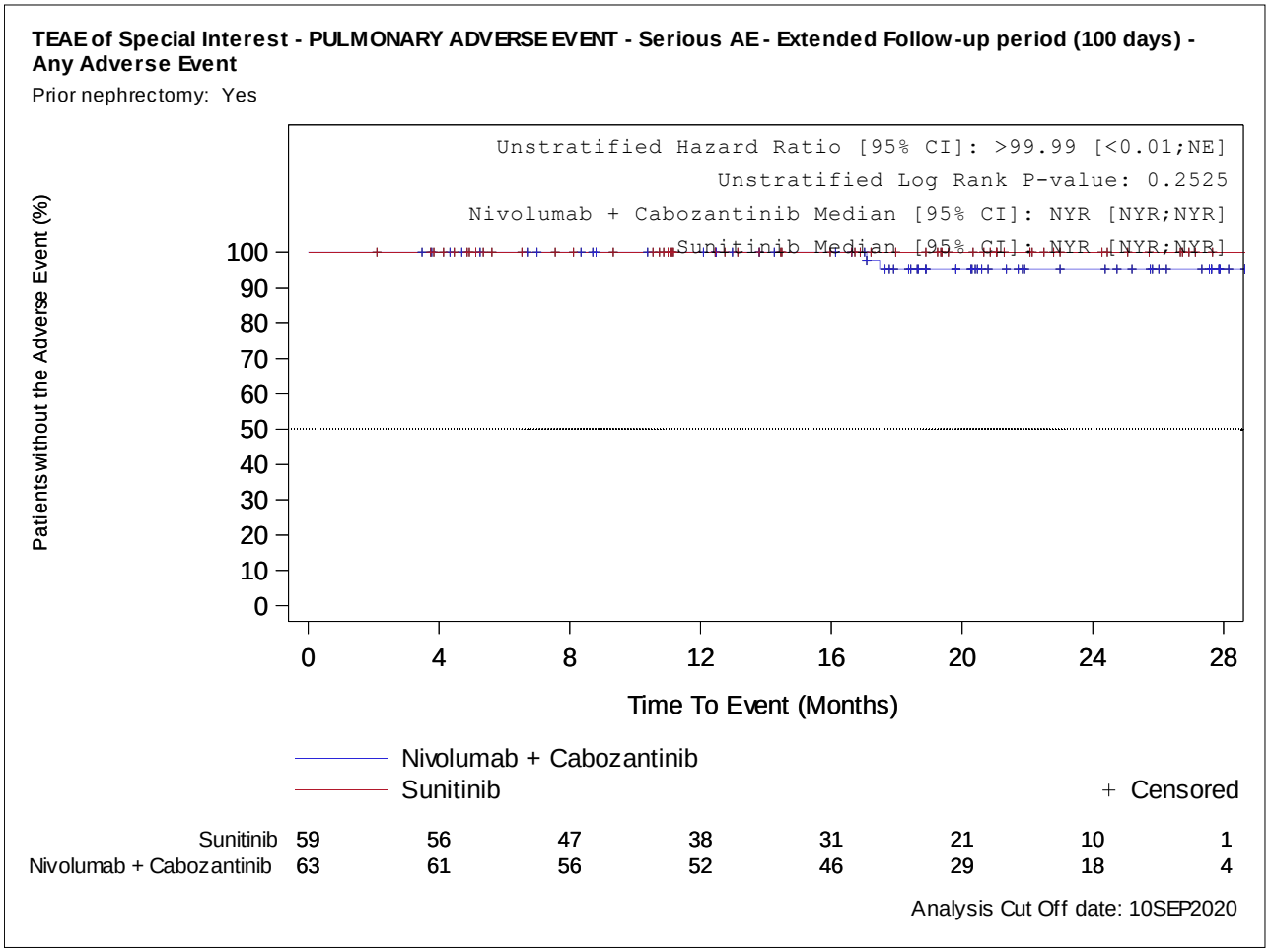

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:50:40

FIGURE 3.46.2.17: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



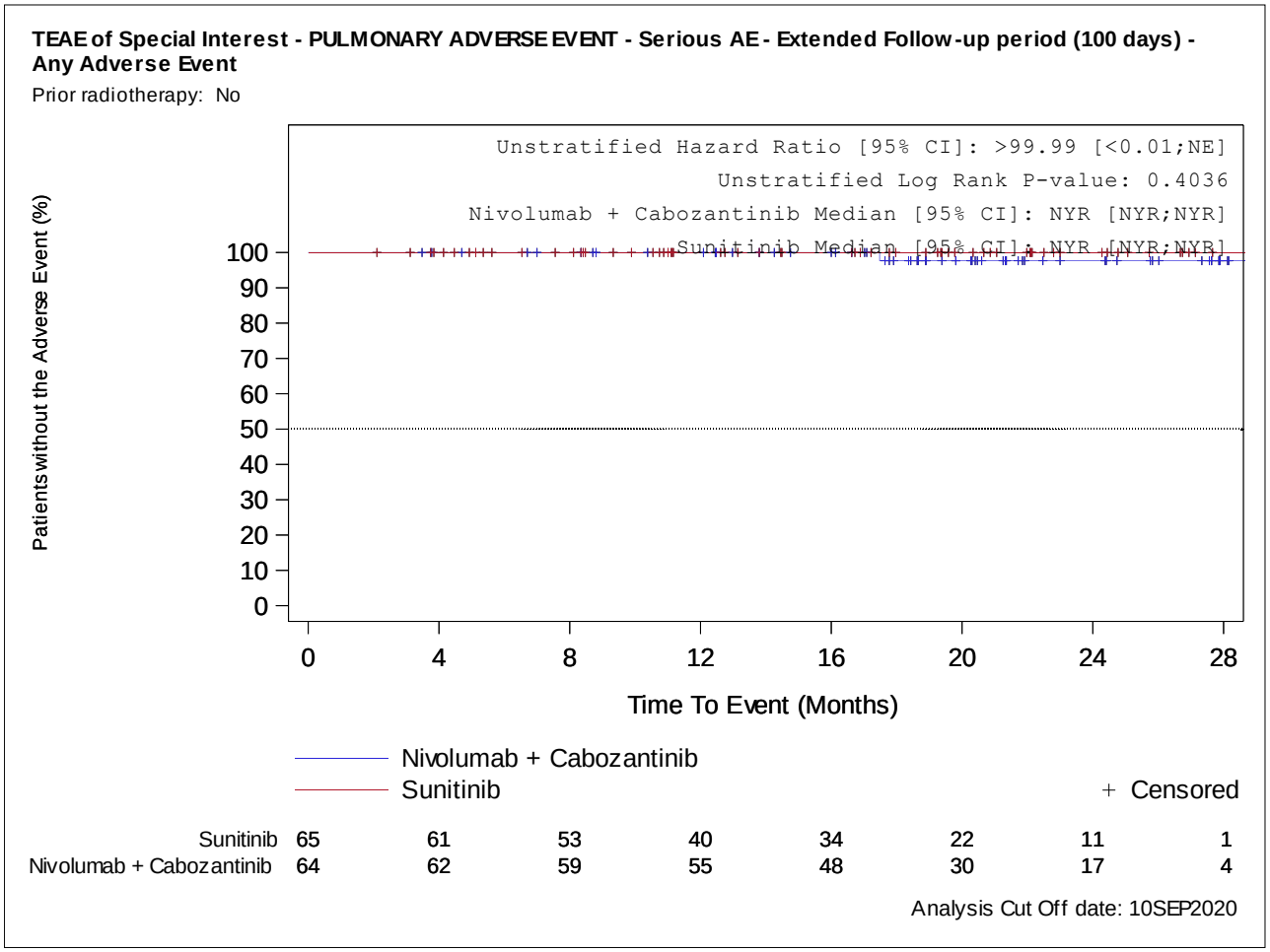

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:51:27

FIGURE 3.46.2.18: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



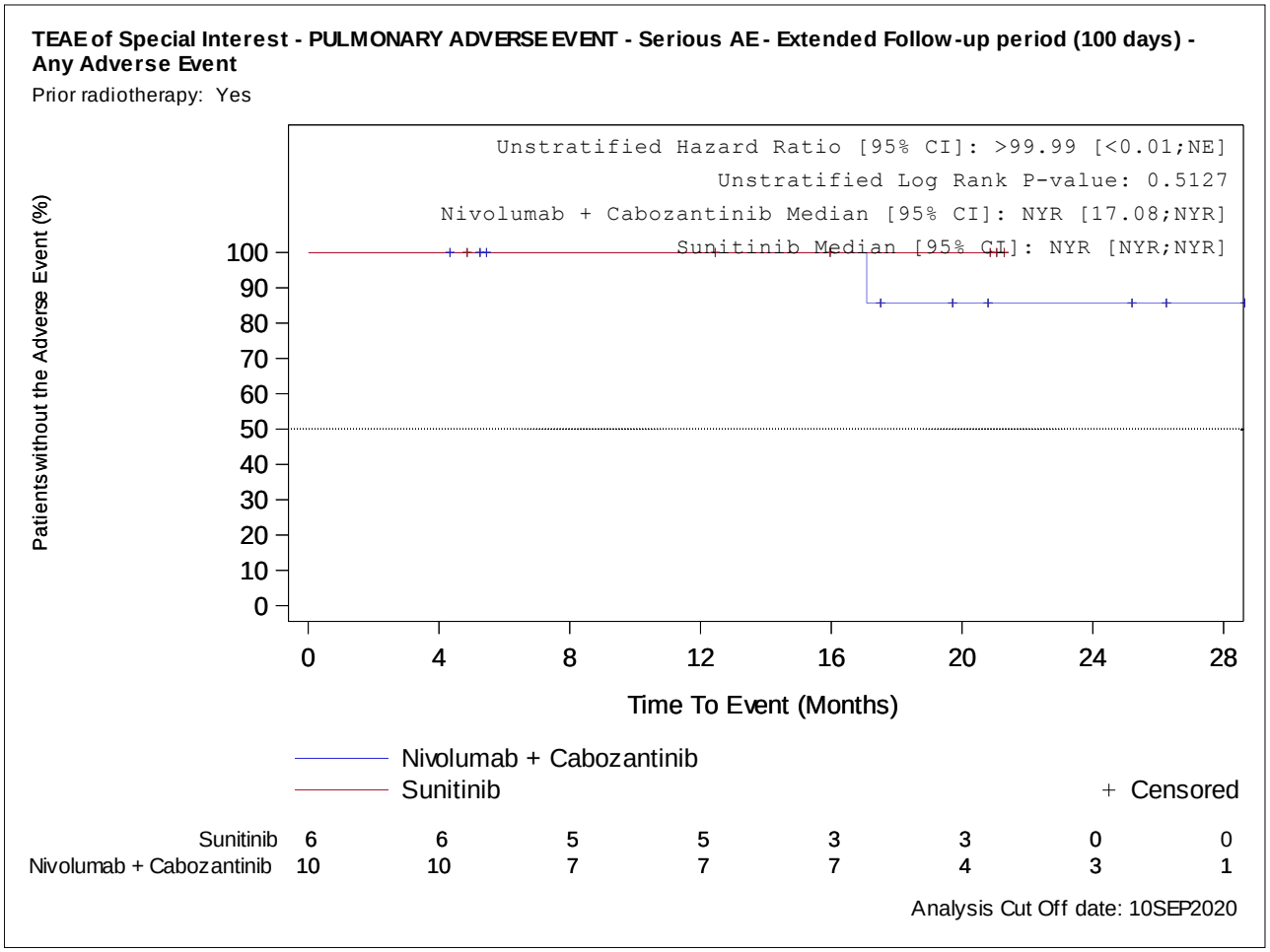

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:51:32

FIGURE 3.46.2.19: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



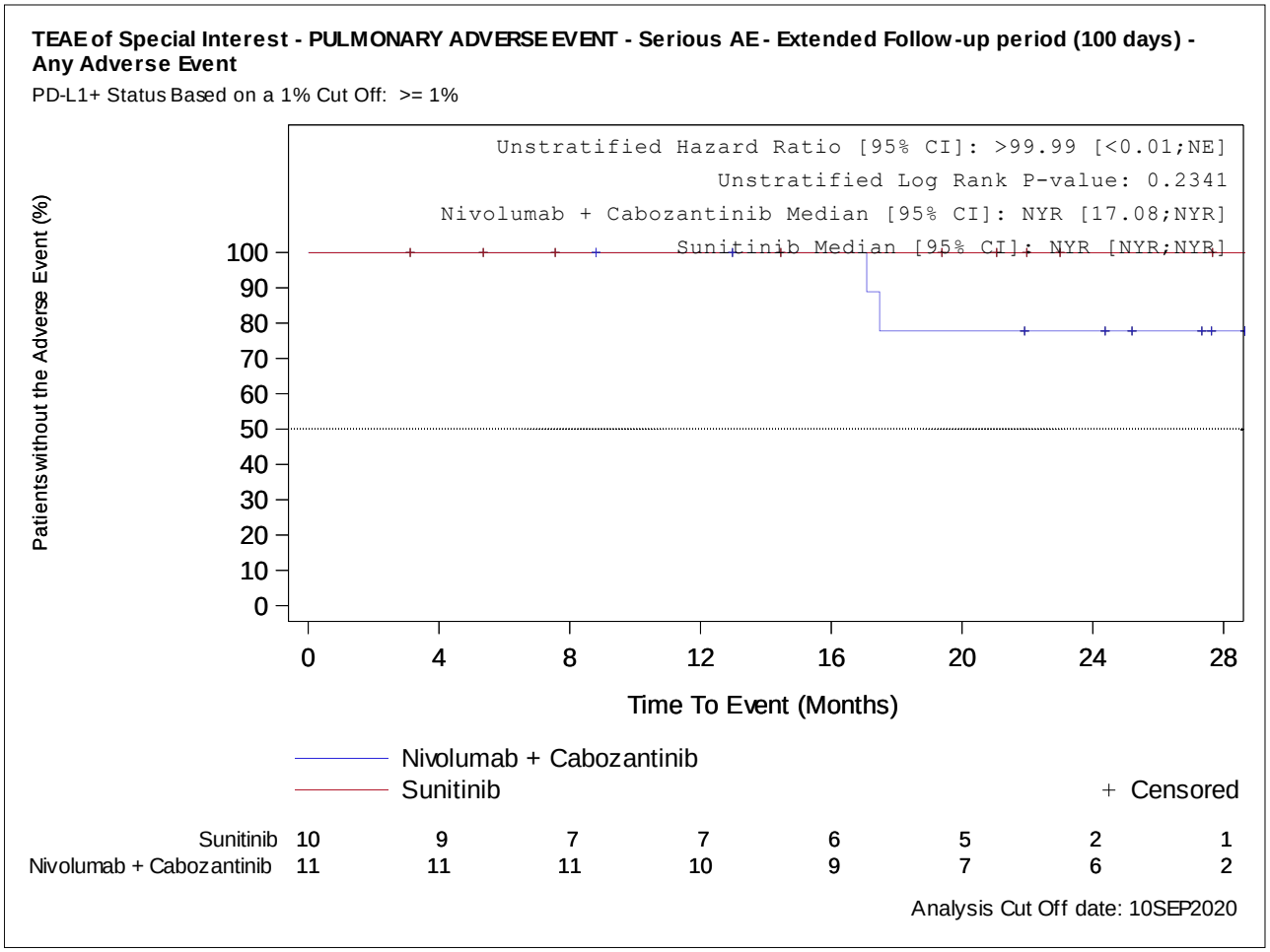

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:51:38

FIGURE 3.46.2.20: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:51:43

FIGURE 3.46.2.21: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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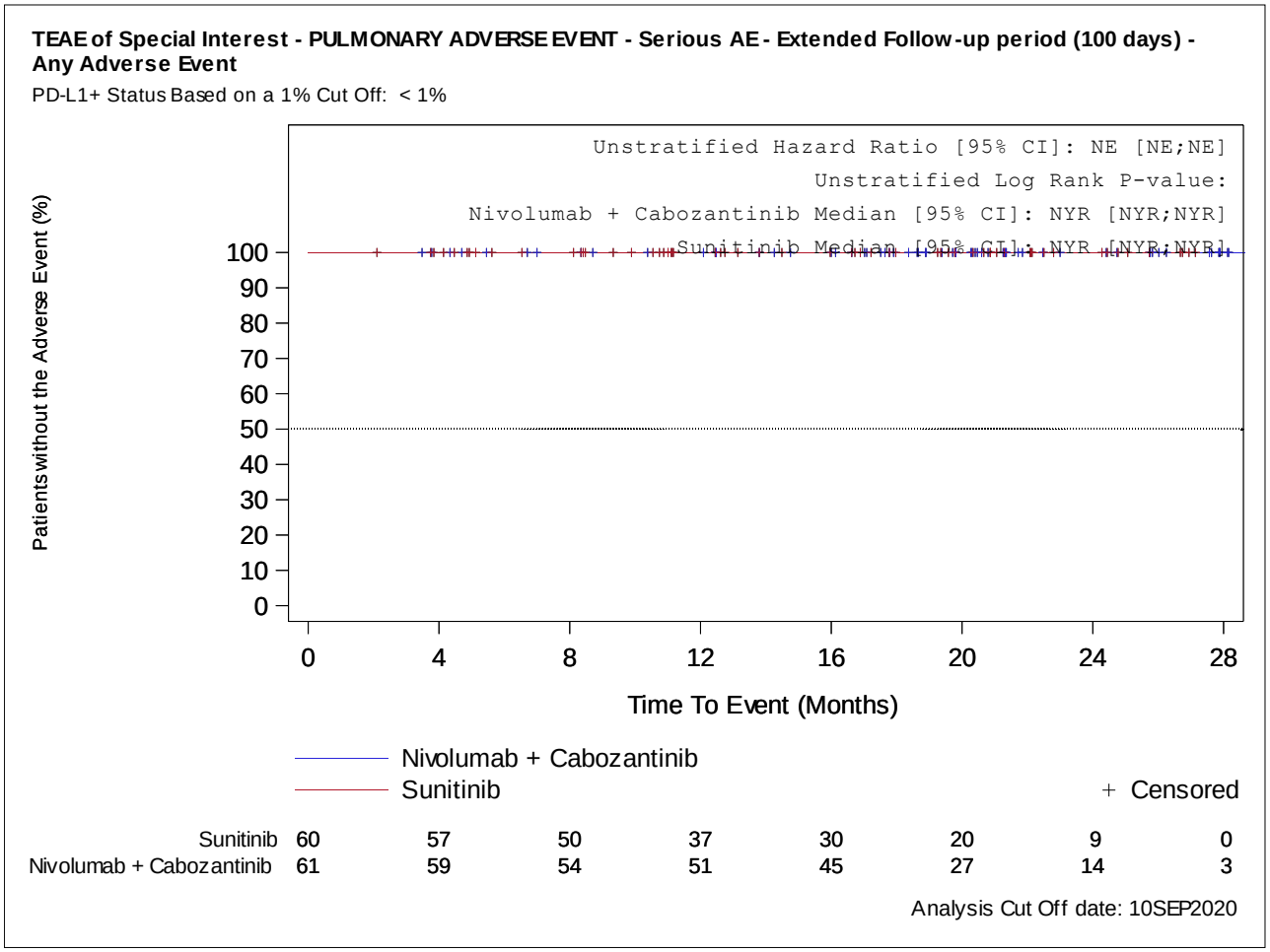
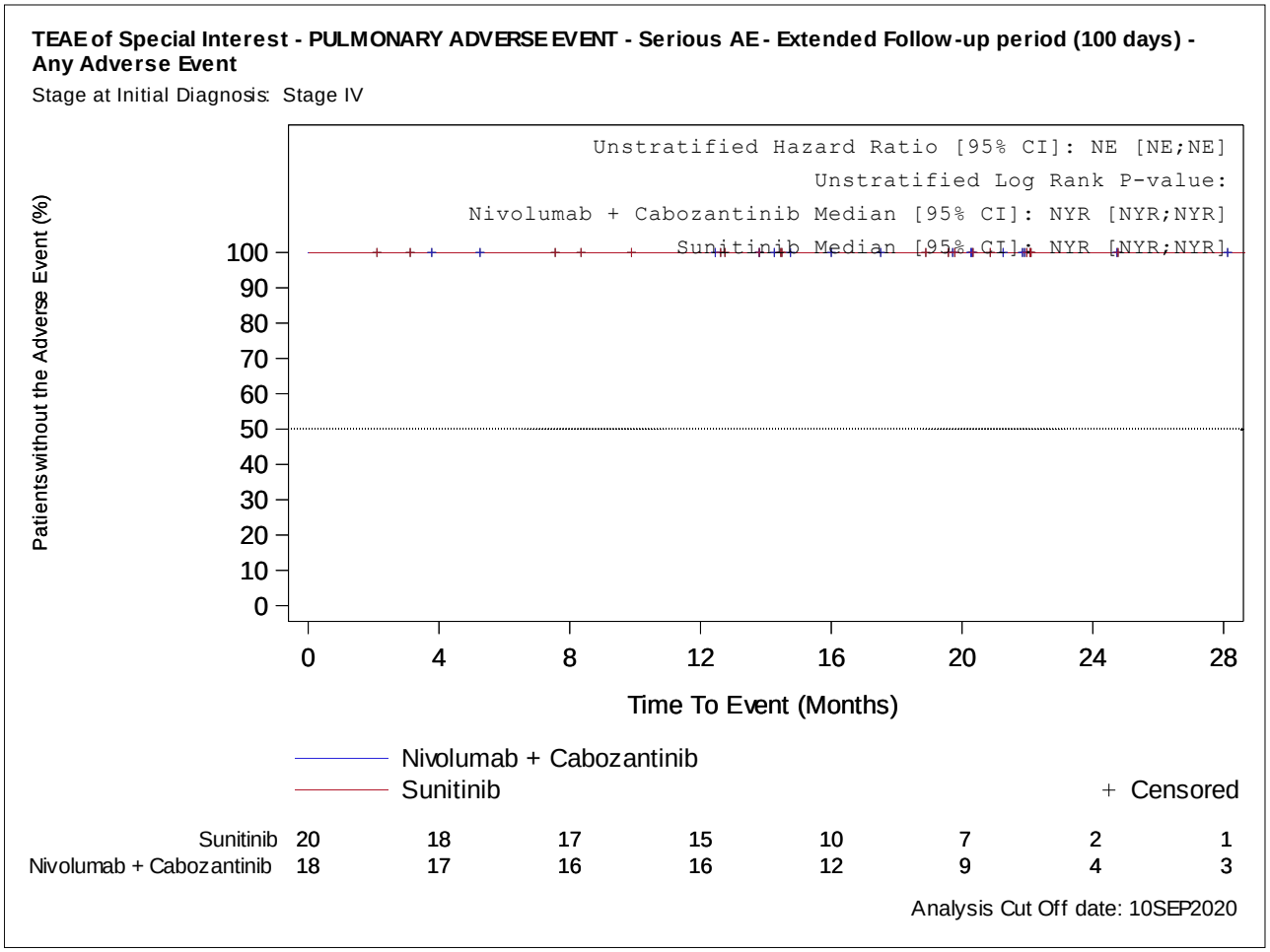
FIGURE 3.46.2.22: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



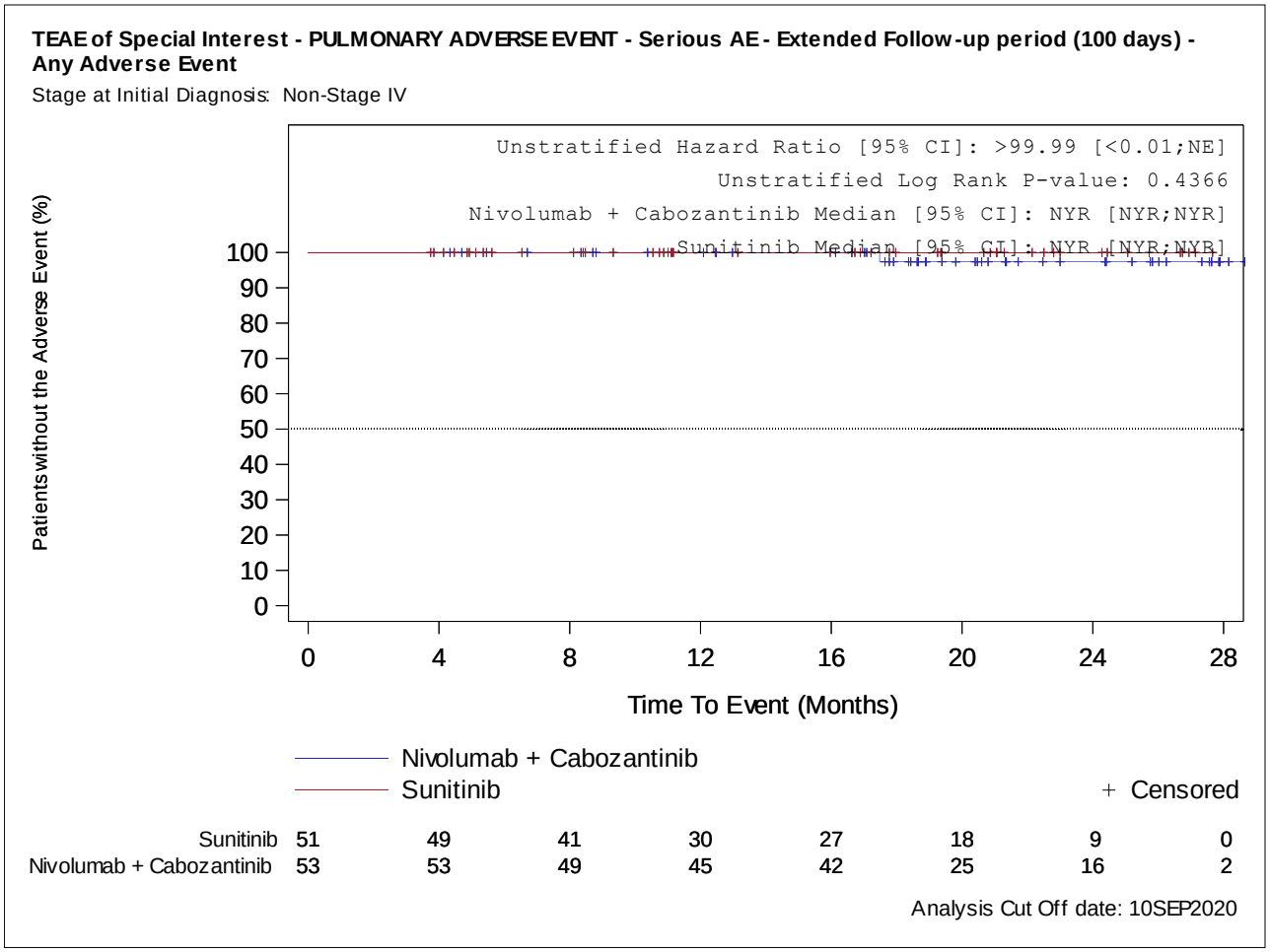

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:51:53

FIGURE 3.46.2.23: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



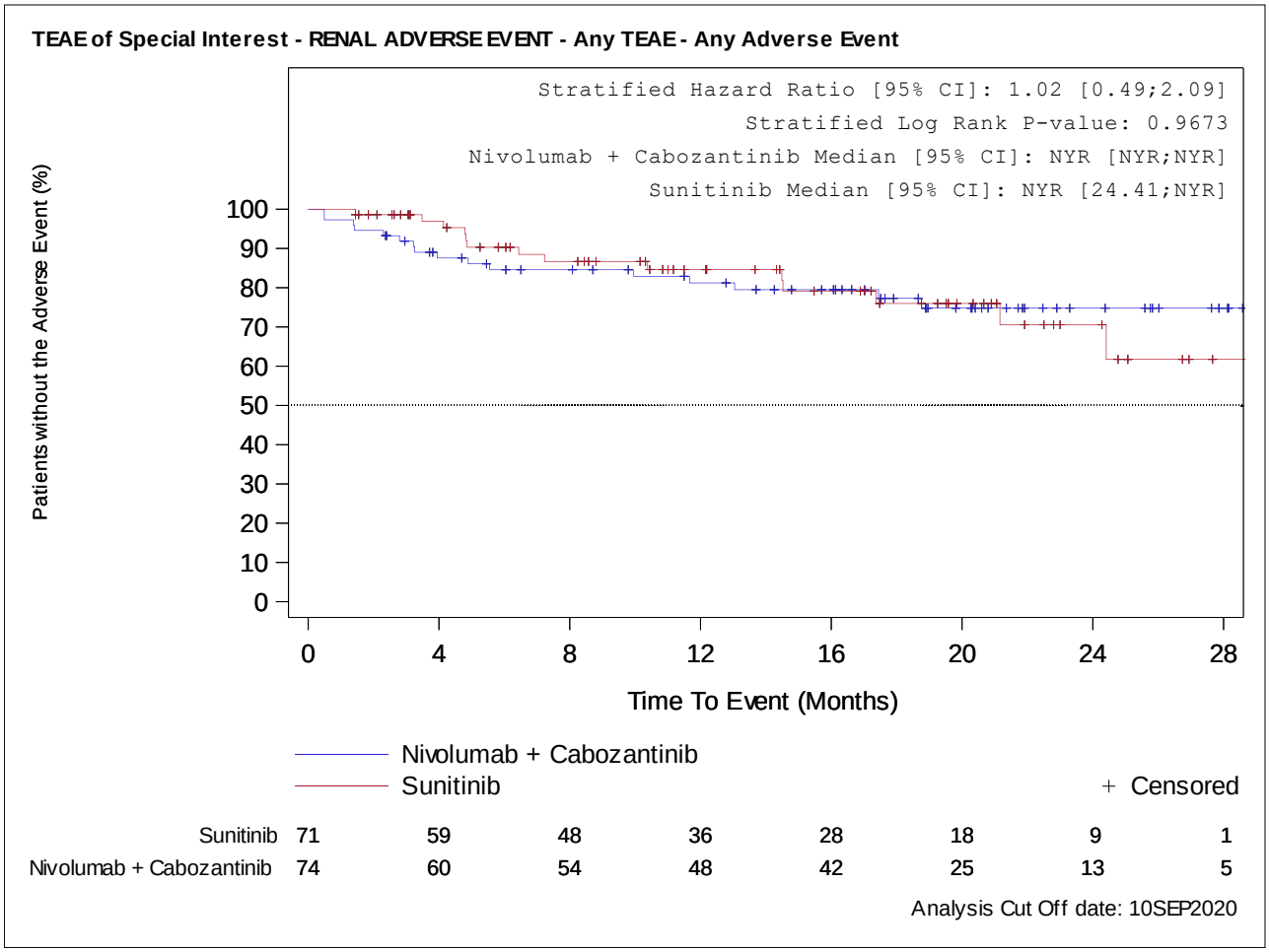

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:52:20

FIGURE 3.46.2.24: Kaplan-Meier curve - TEAE of Special Interest - PULMONARY ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



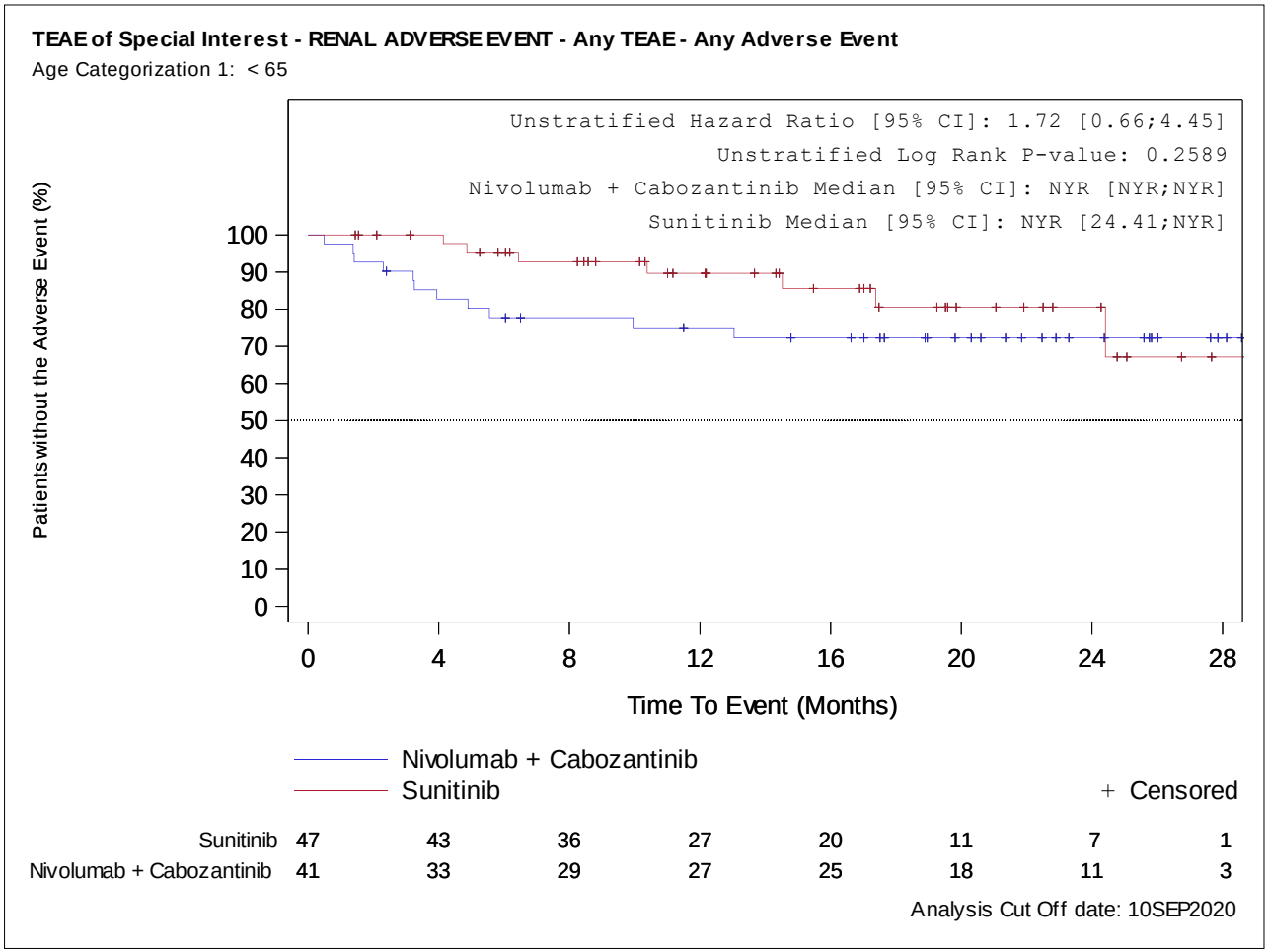

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:52:25

FIGURE 3.47.1: TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



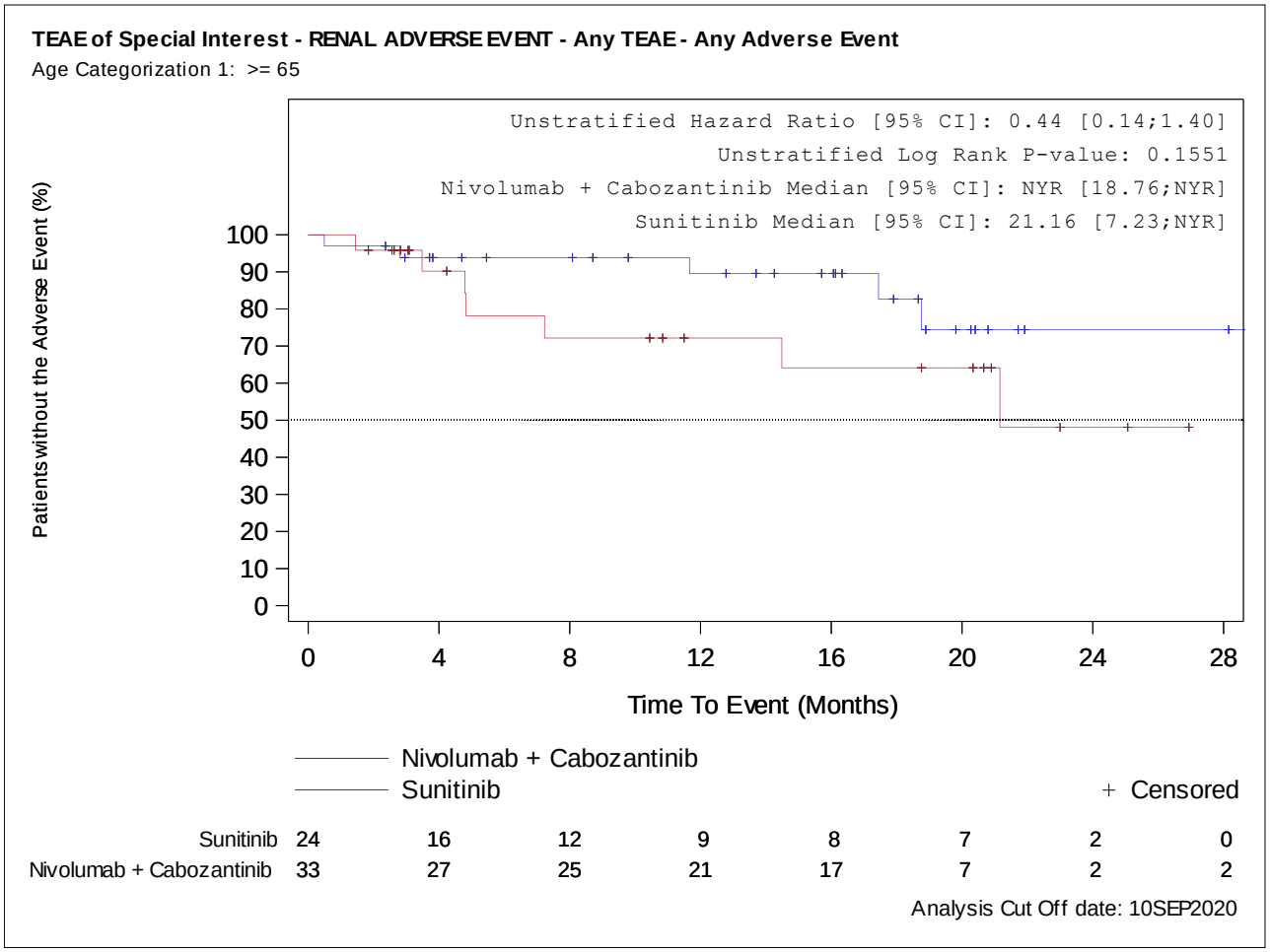

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:55:22

FIGURE 3.47.2.1: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



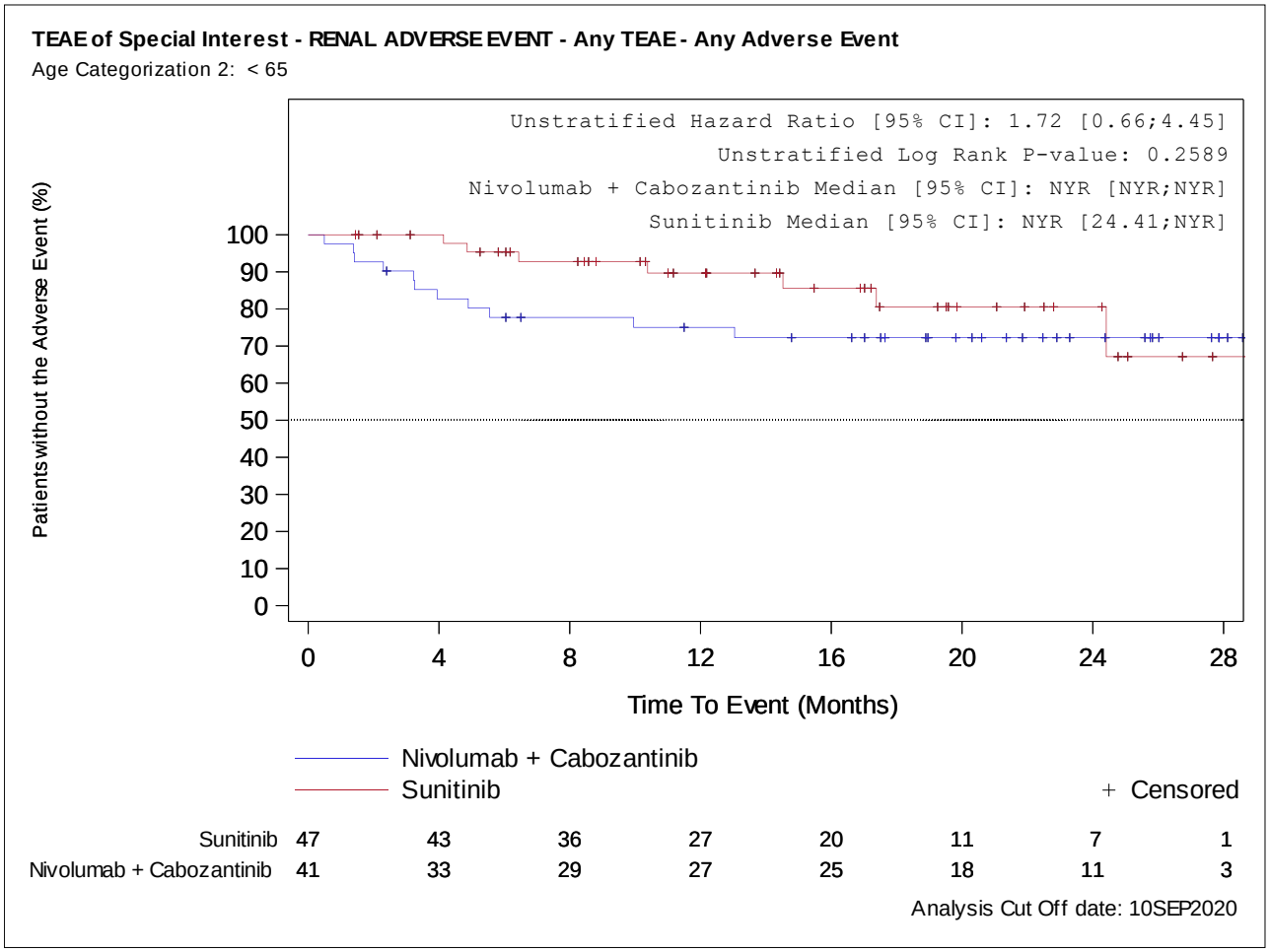

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:55:25

FIGURE 3.47.2.2: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



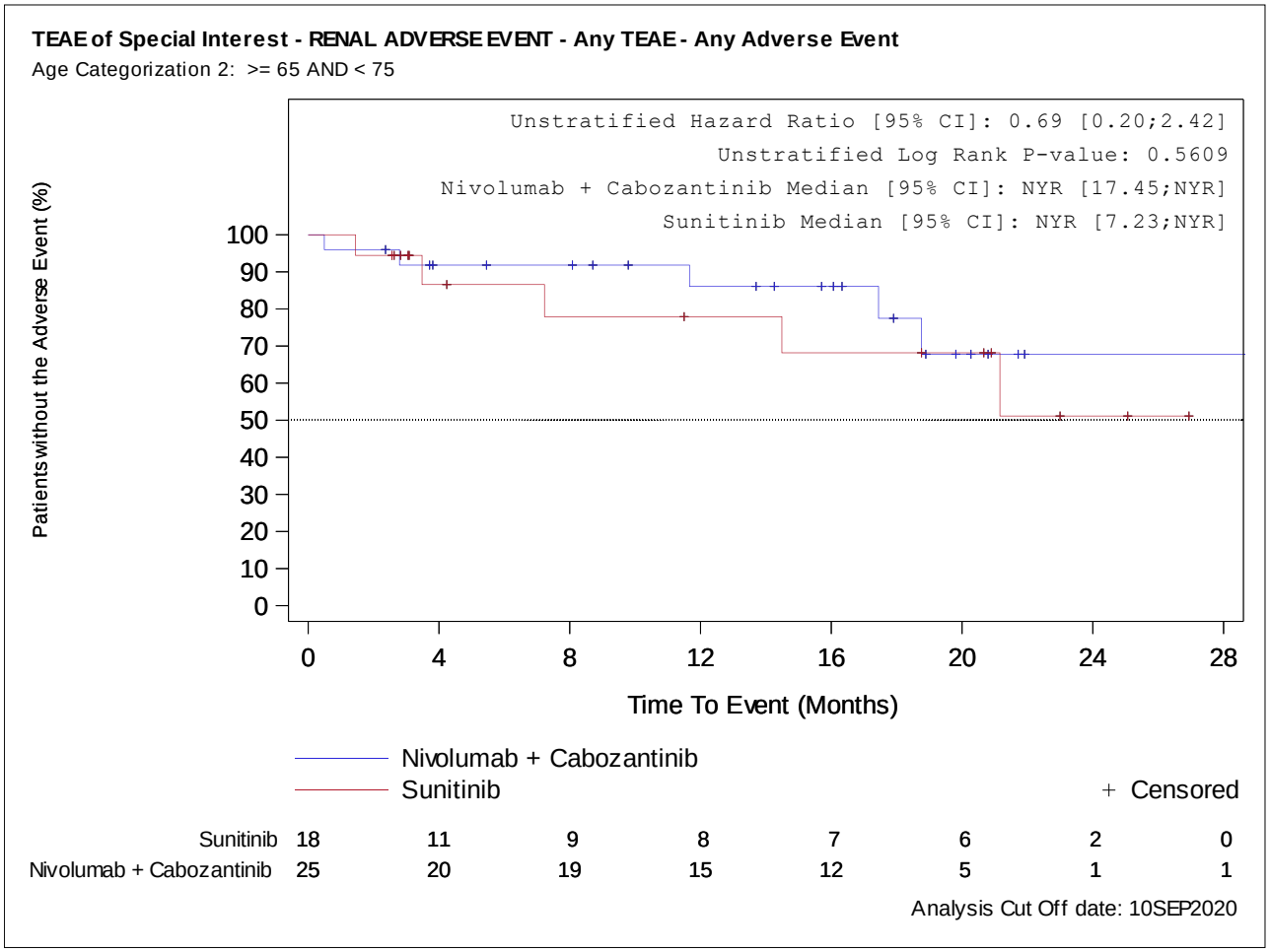

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:55:30

FIGURE 3.47.2.3: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



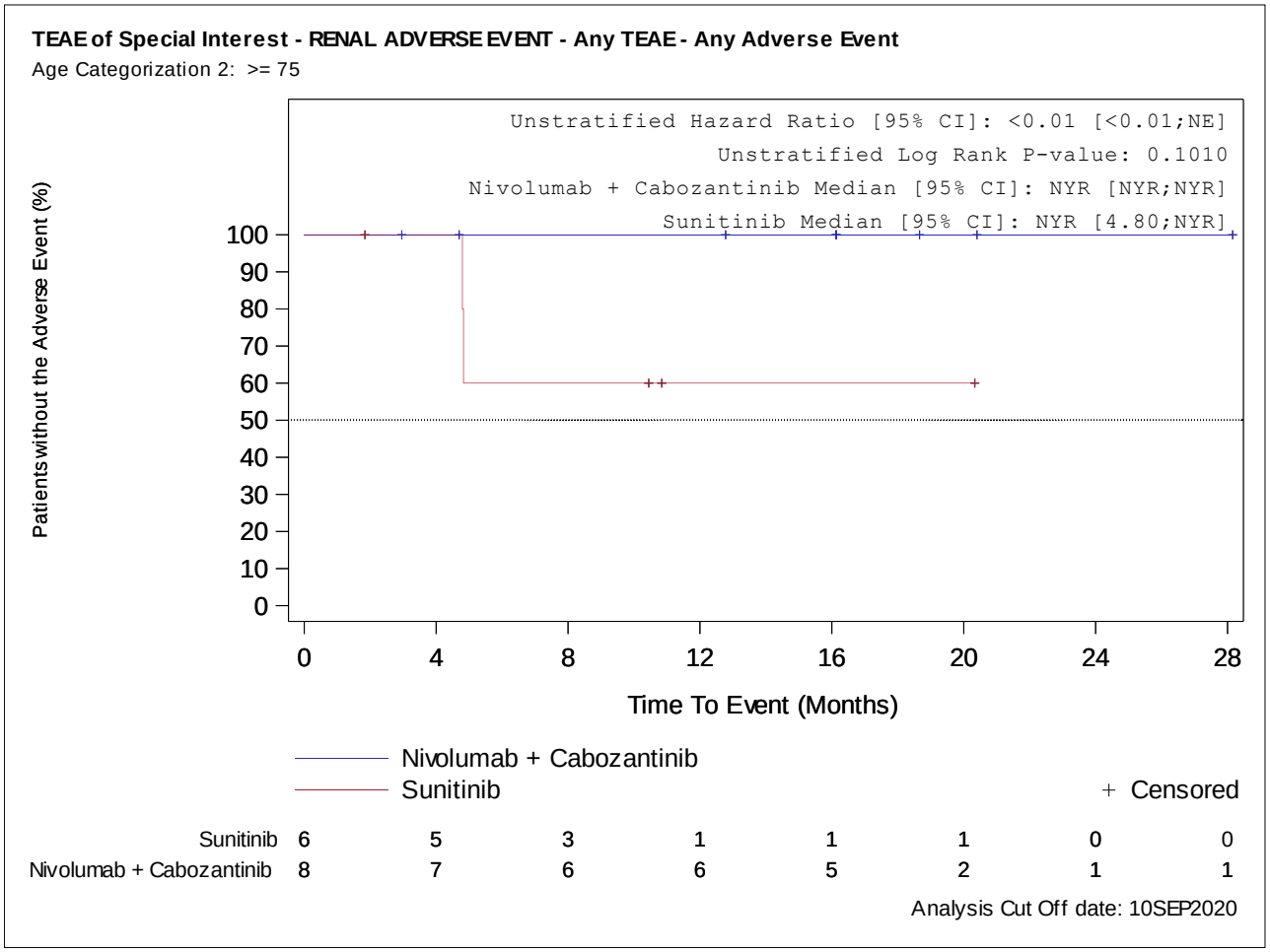

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:55:35

FIGURE 3.47.2.4: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



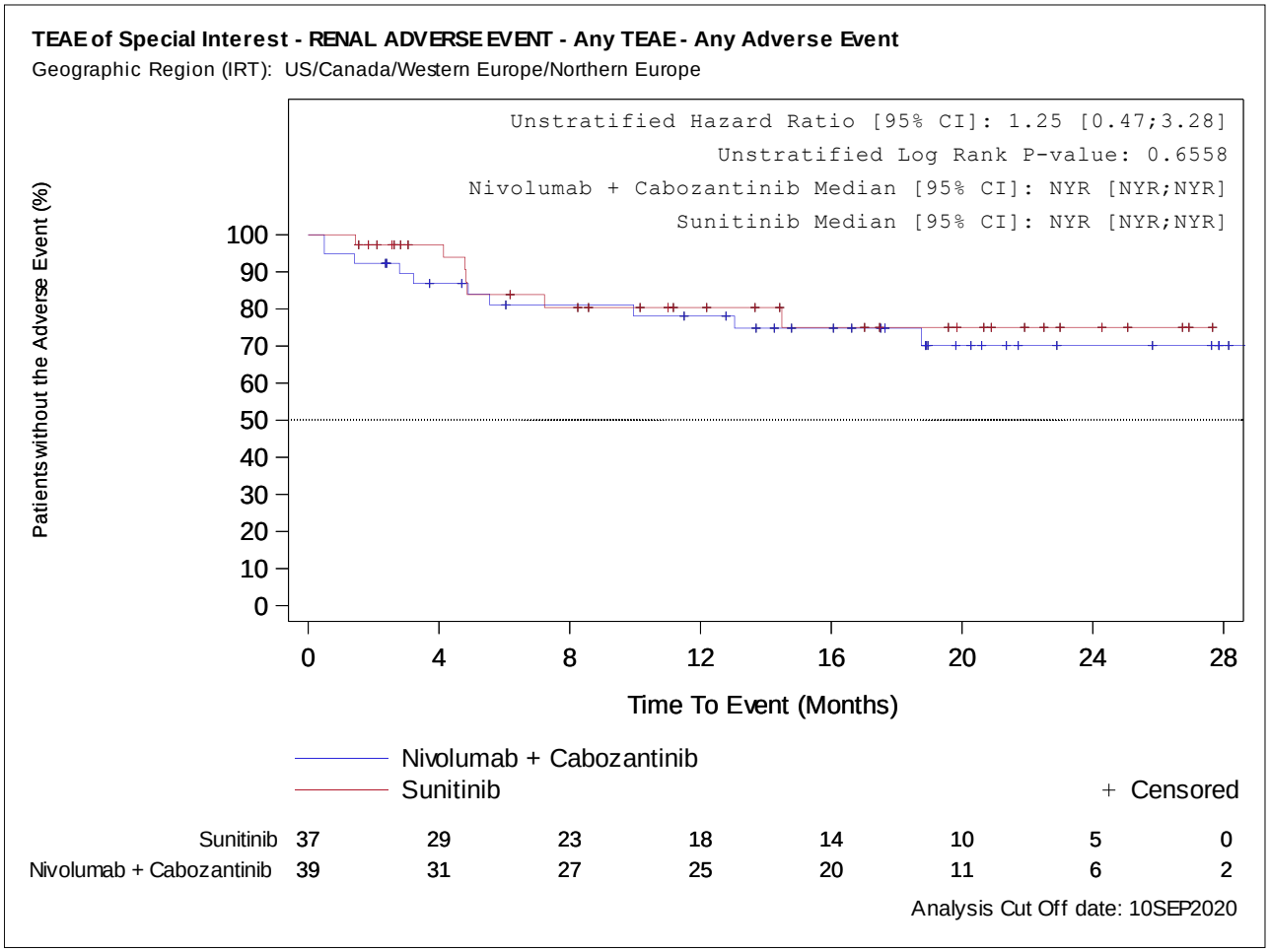

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:55:40

FIGURE 3.47.2.5: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



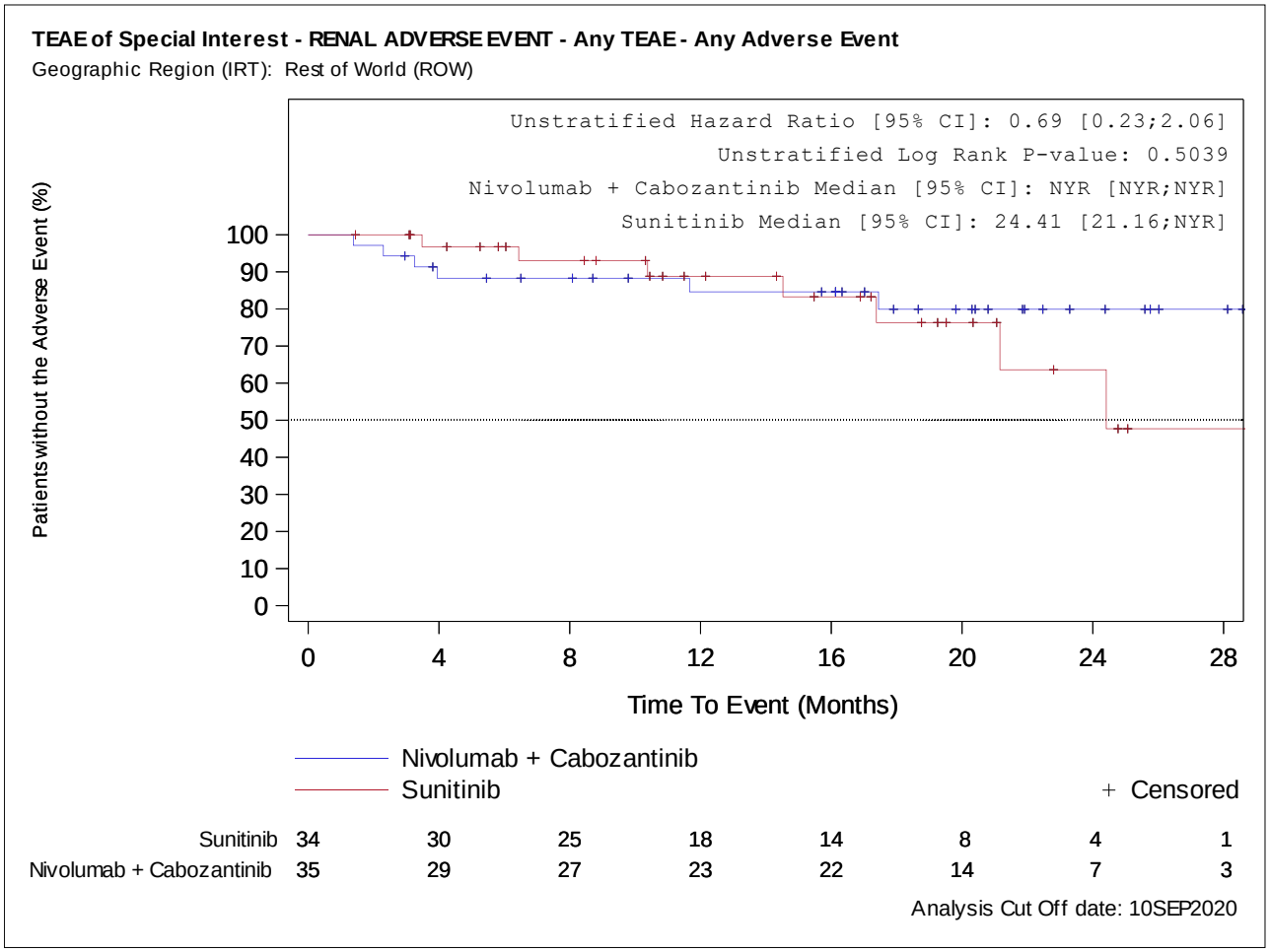

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:55:45

FIGURE 3.47.2.6: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



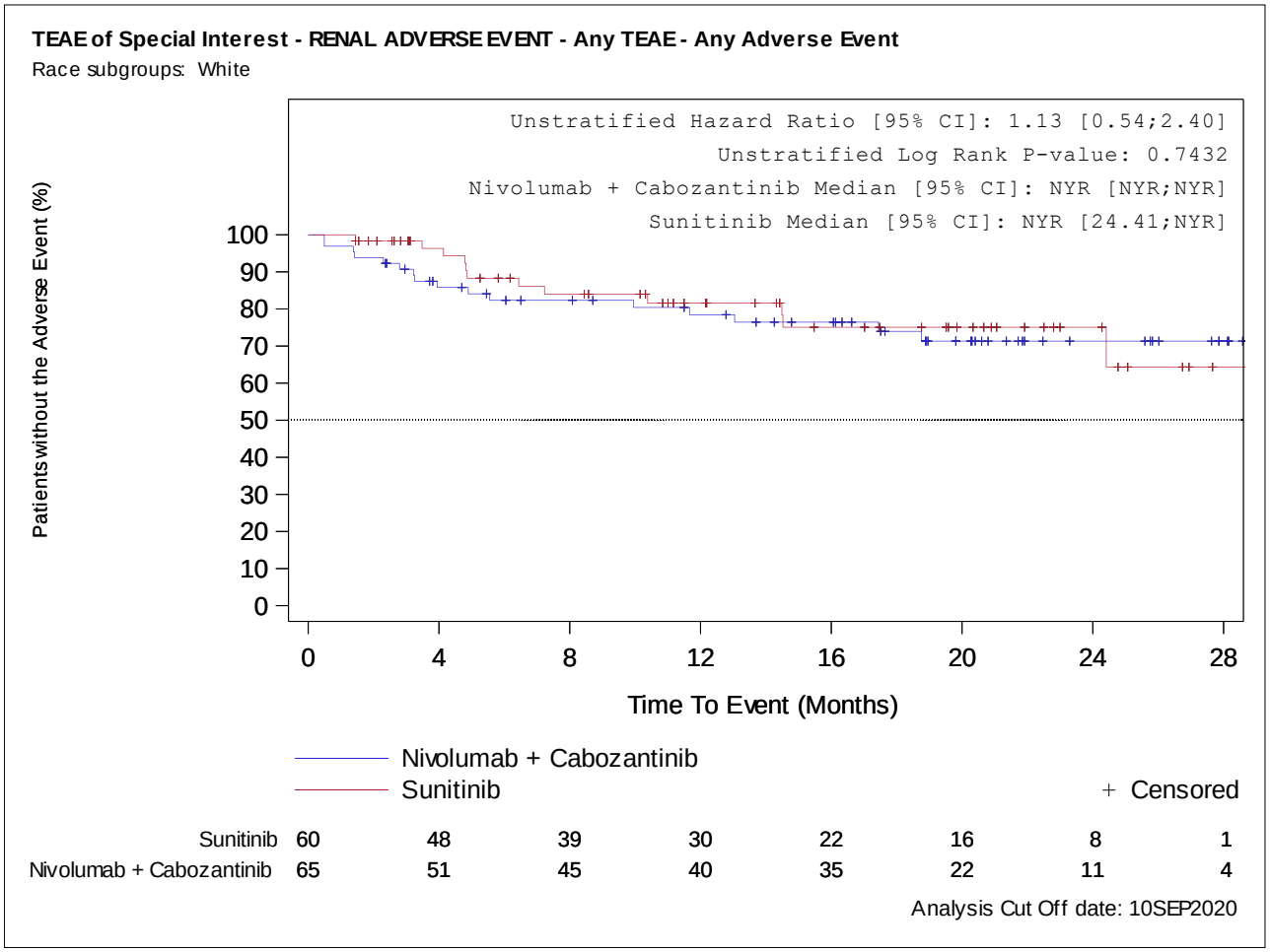

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:55:51

FIGURE 3.47.2.7: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



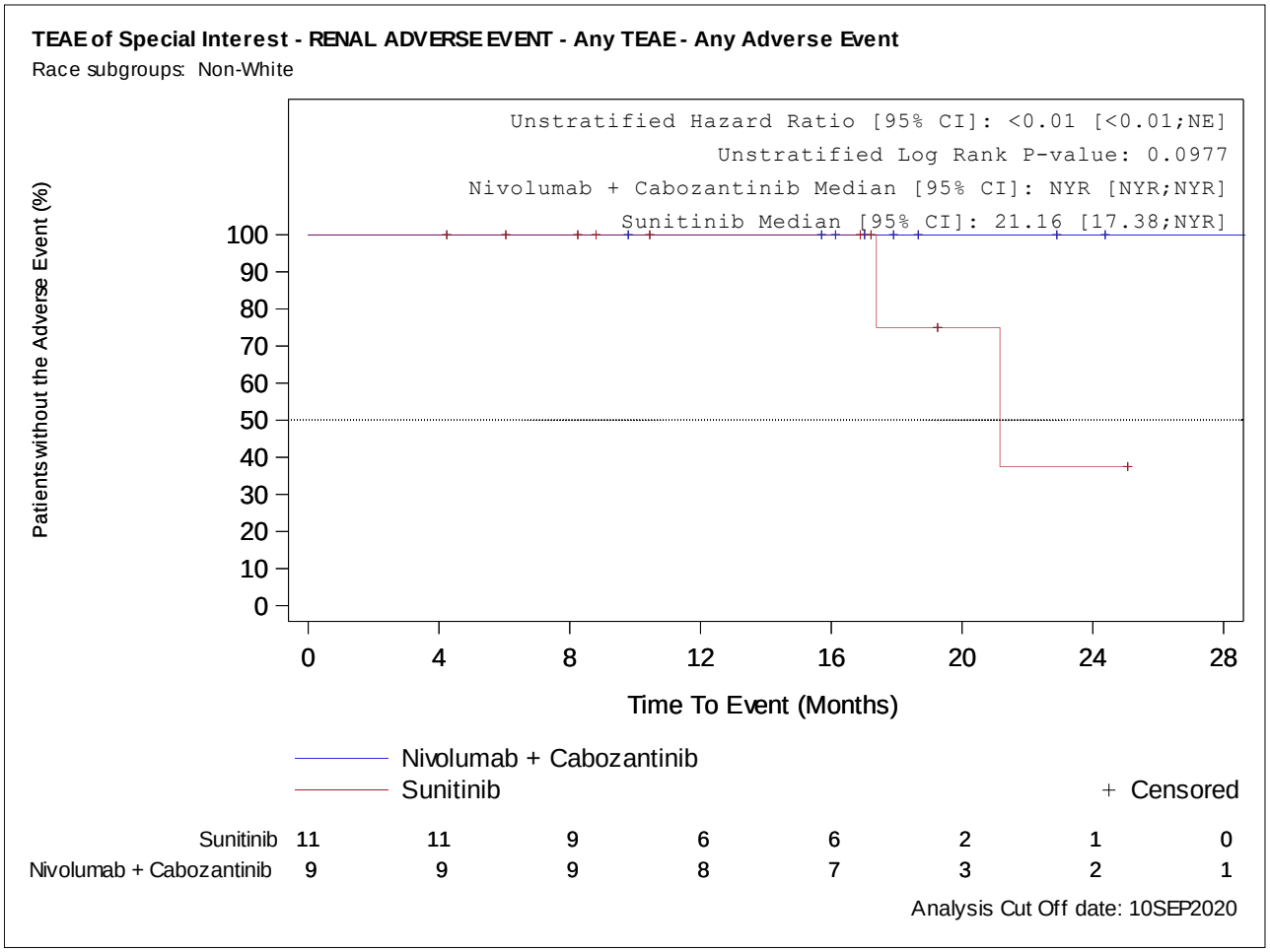

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:55:56

FIGURE 3.47.2.8: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



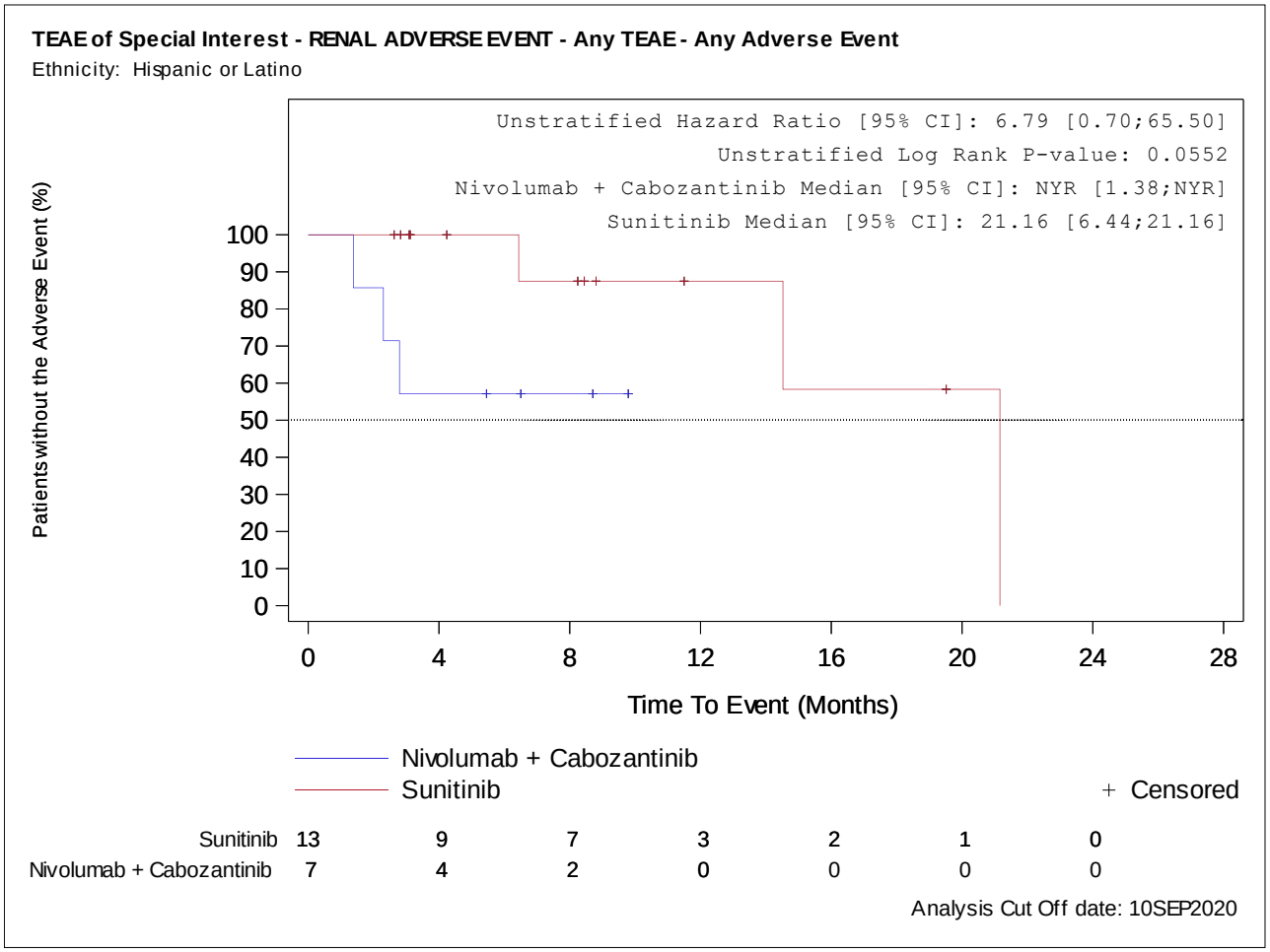

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:56:01

FIGURE 3.47.2.9: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



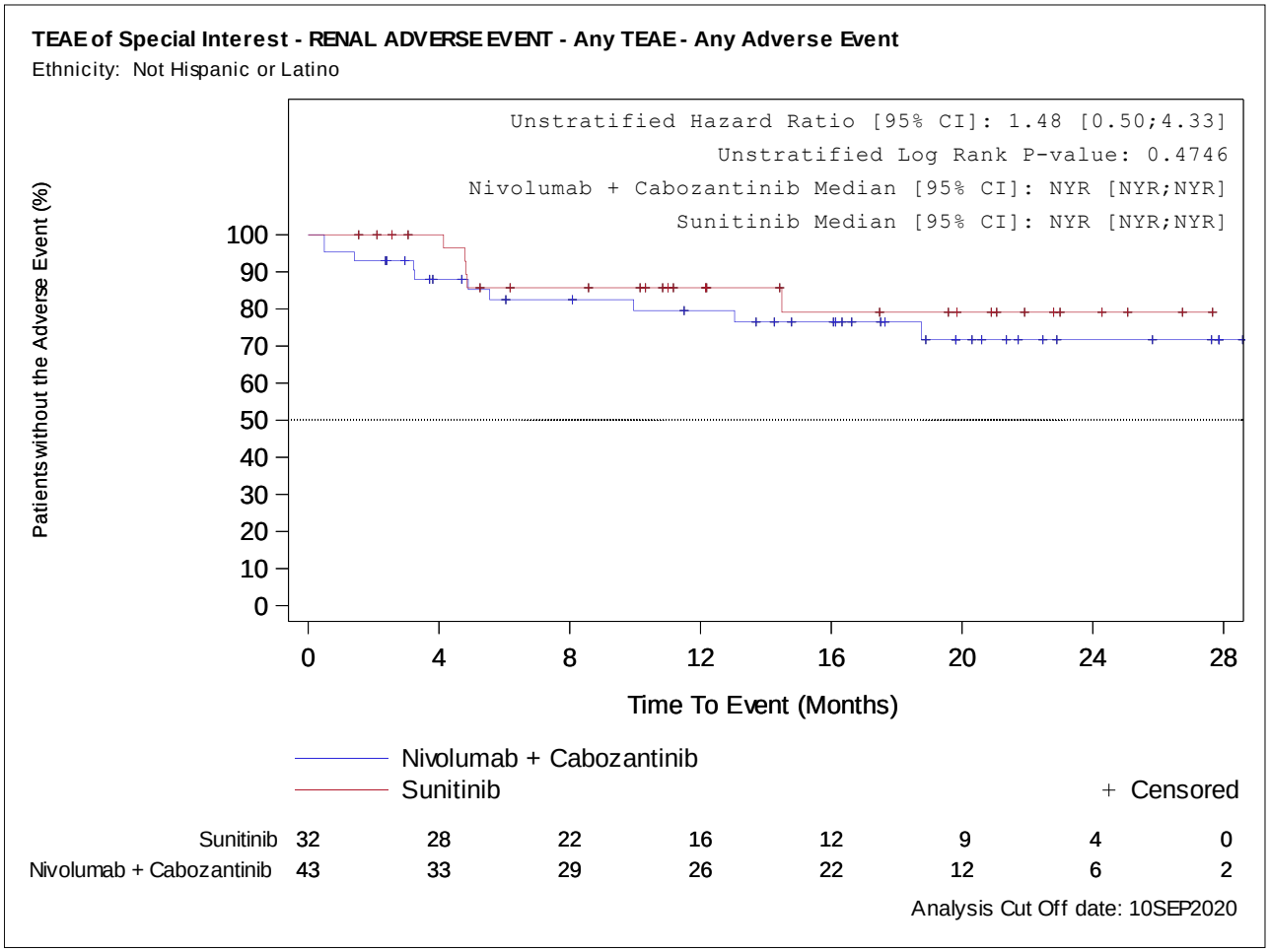

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:56:06

FIGURE 3.47.2.10: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



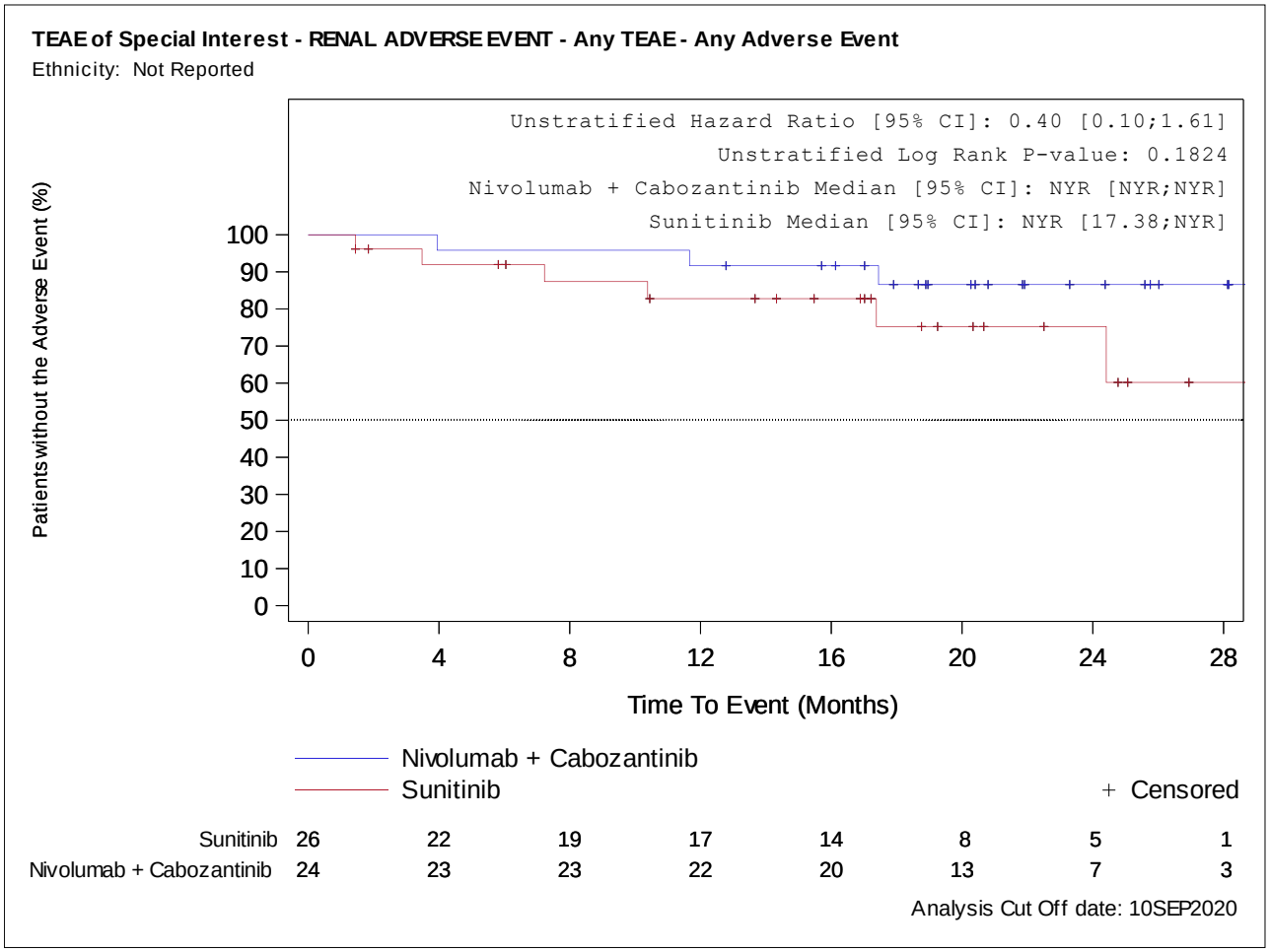

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:56:11

FIGURE 3.47.2.11: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



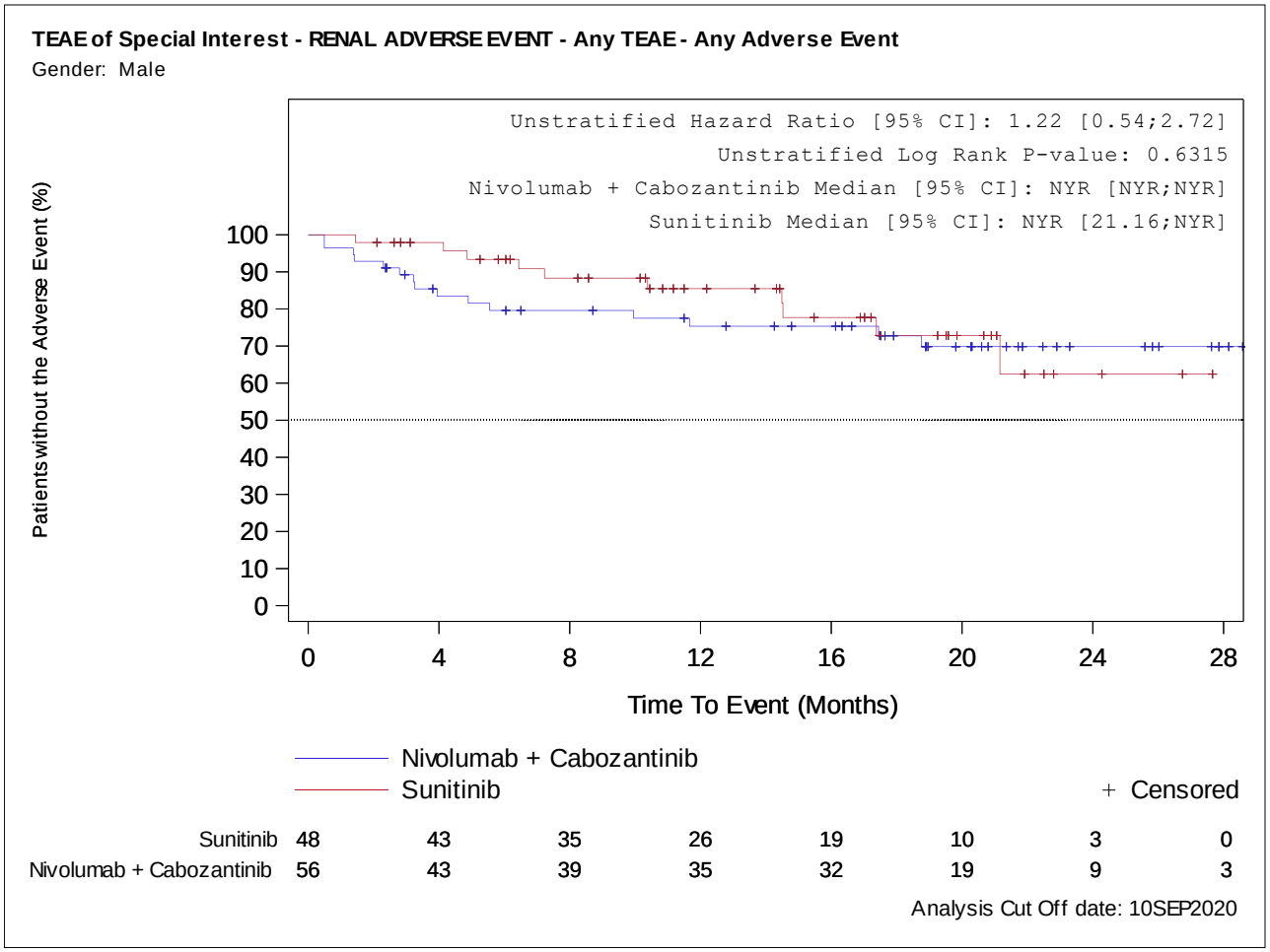

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:56:16

FIGURE 3.47.2.12: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



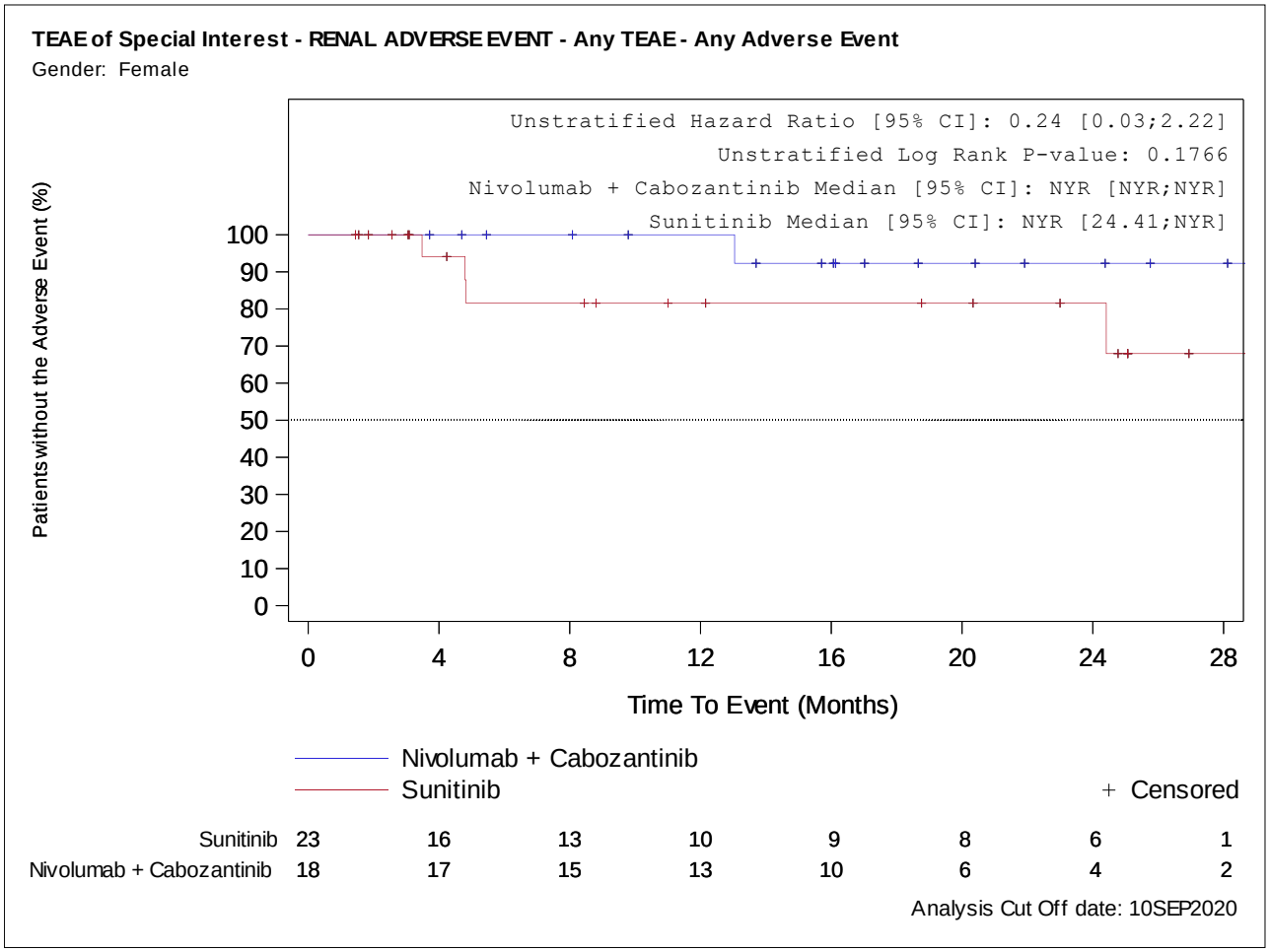

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:56:22

FIGURE 3.47.2.13: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



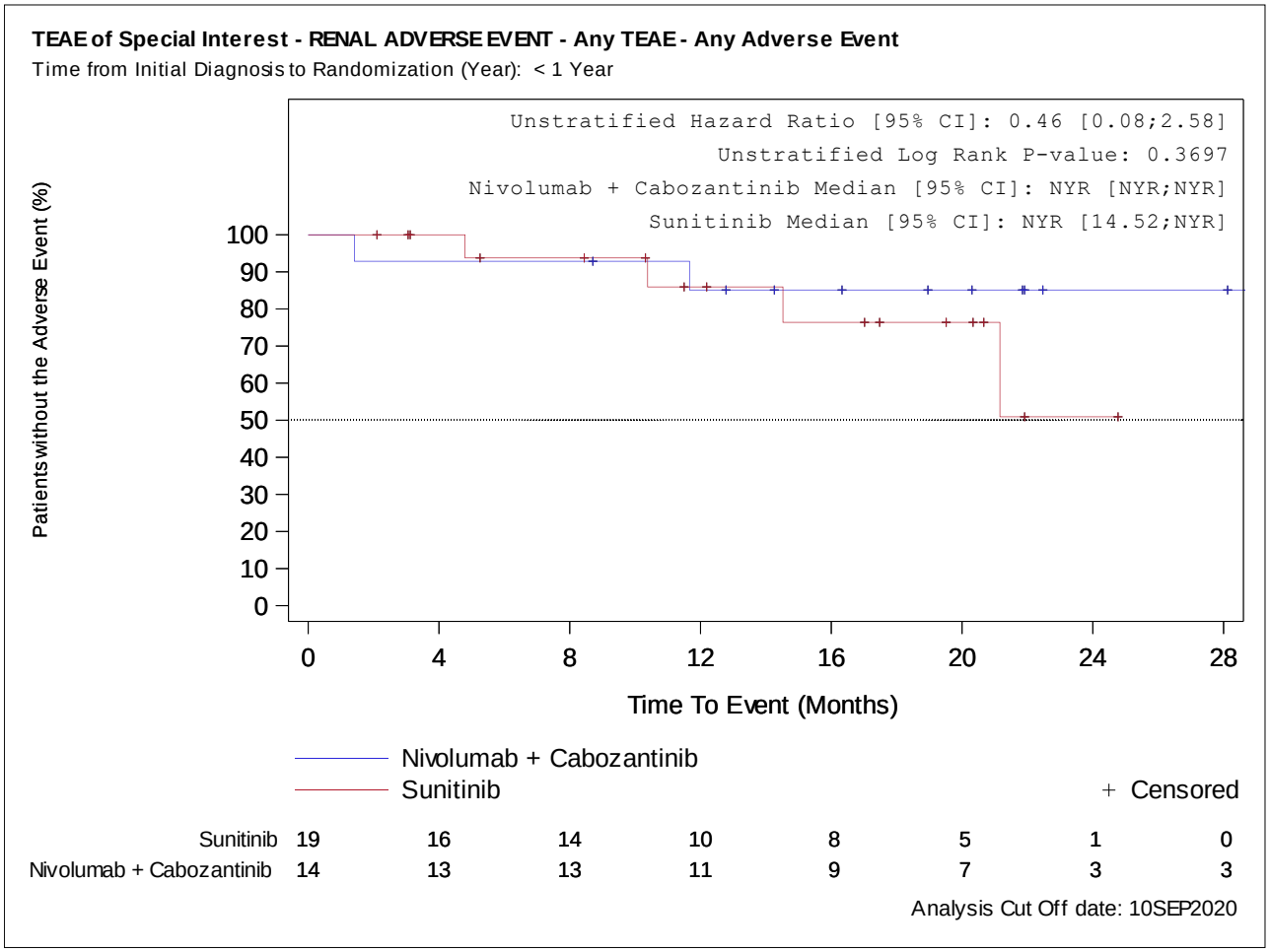

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:56:27

FIGURE 3.47.2.14: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



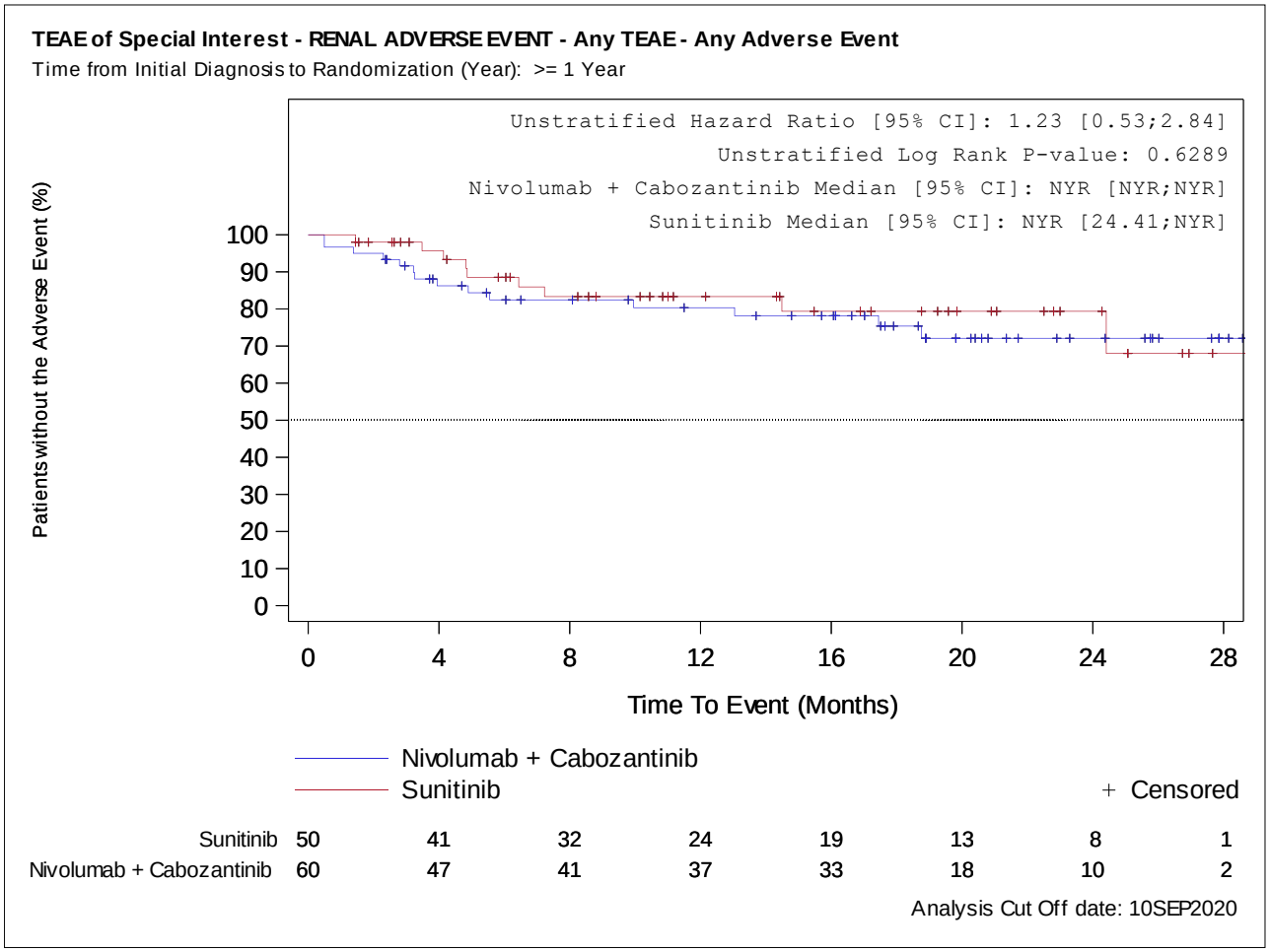

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:56:32

FIGURE 3.47.2.15: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



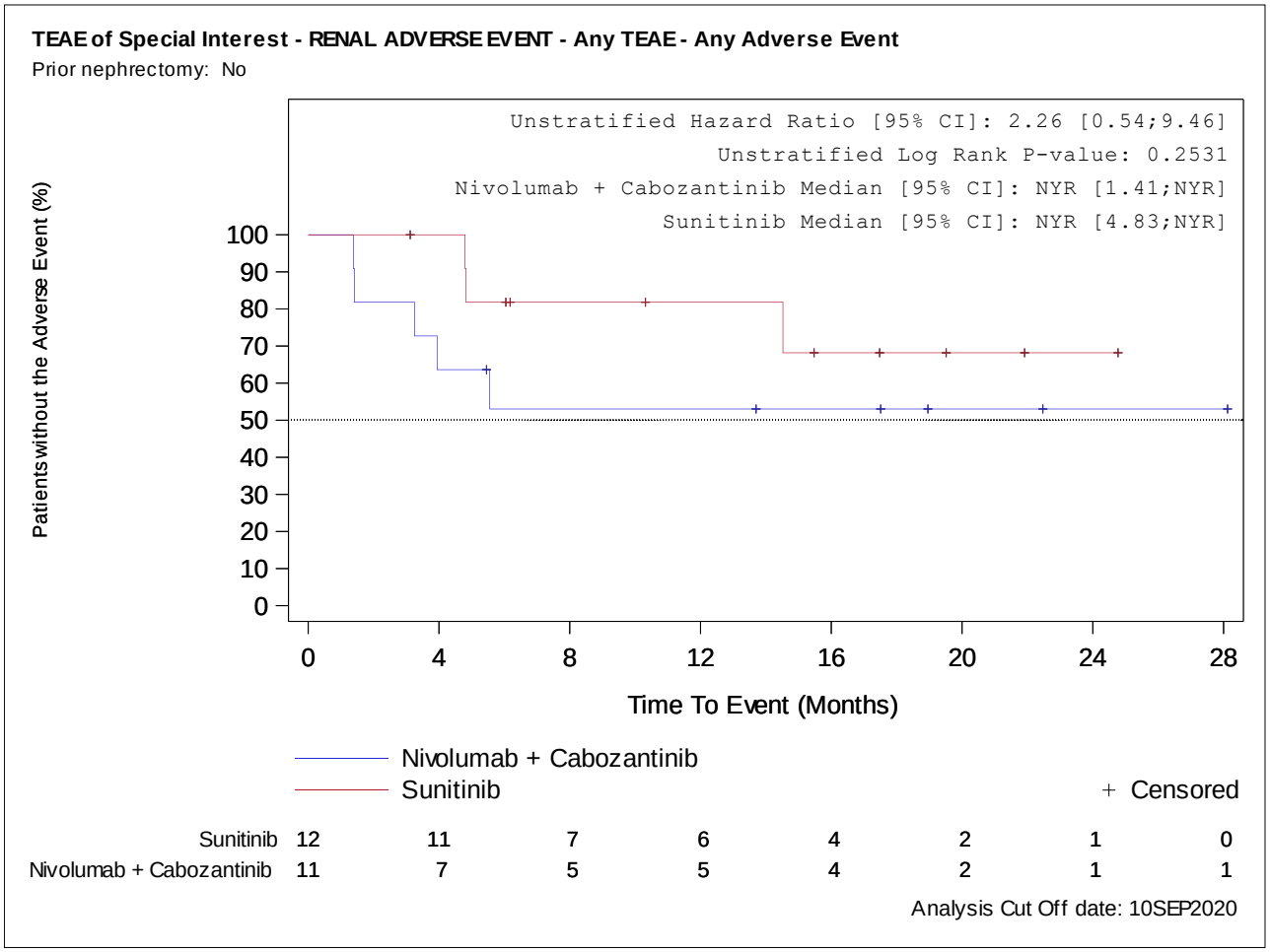

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:56:47

FIGURE 3.47.2.16: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



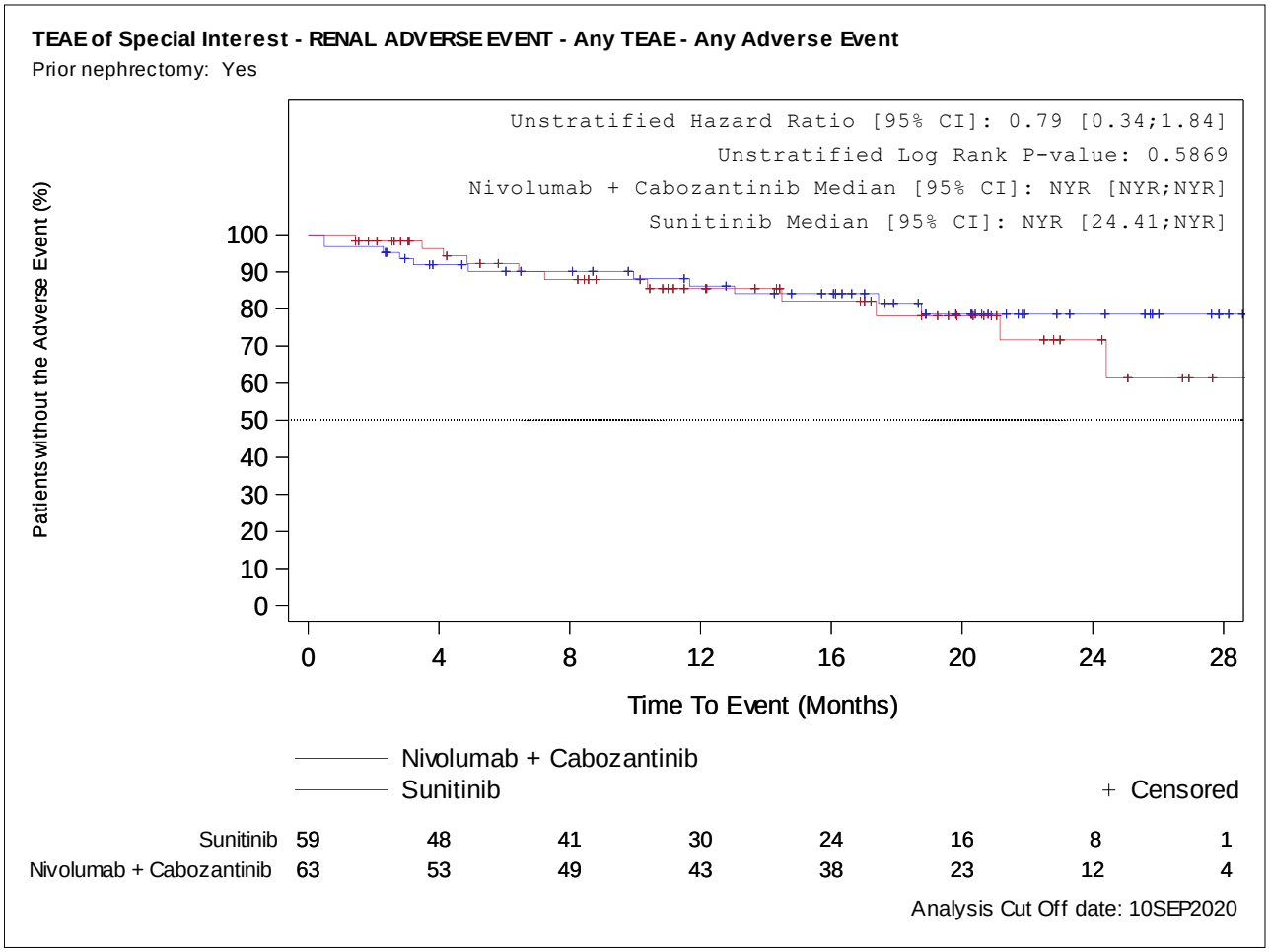

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:56:53

FIGURE 3.47.2.17: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



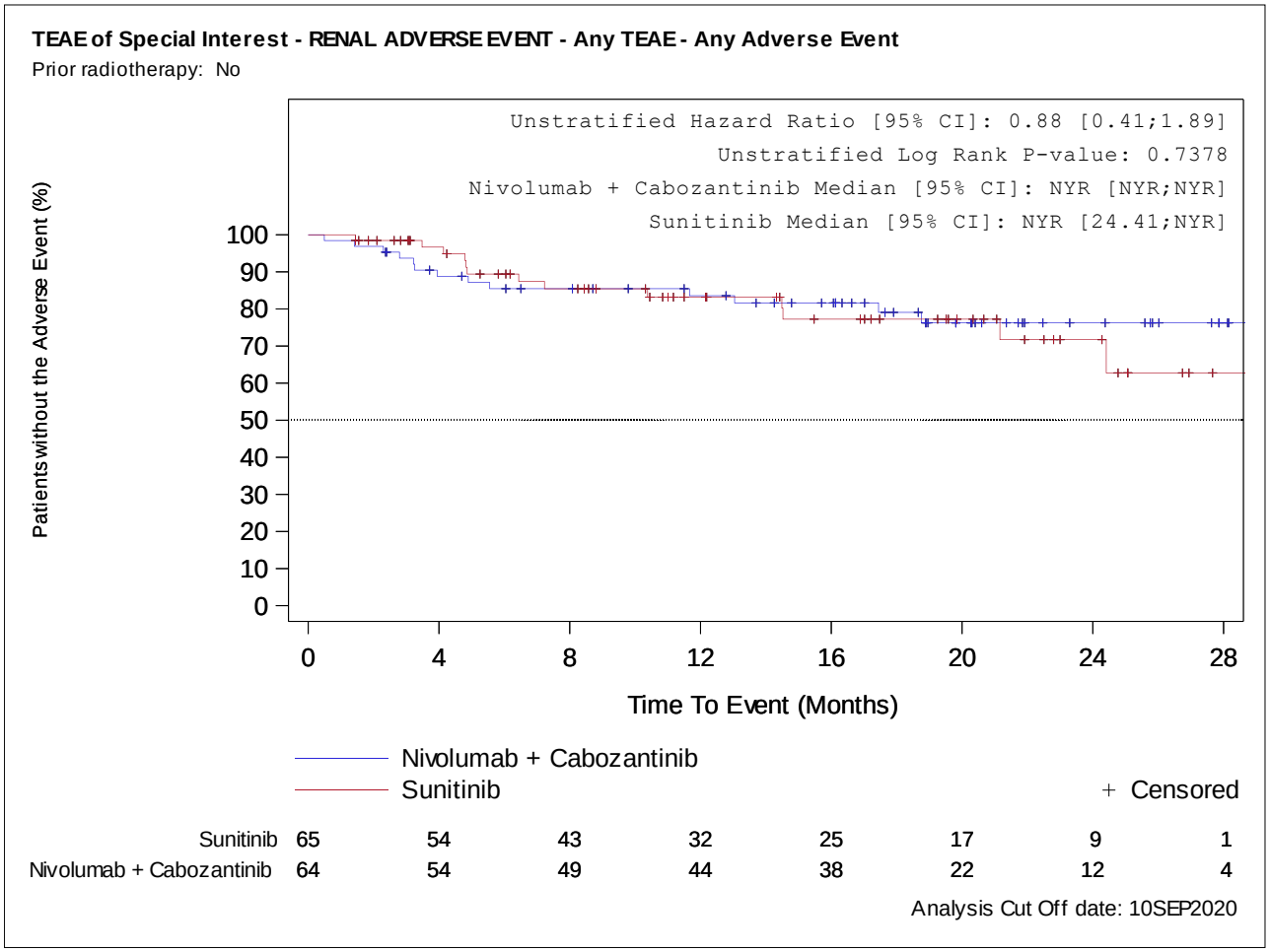

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:57:40

FIGURE 3.47.2.18: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



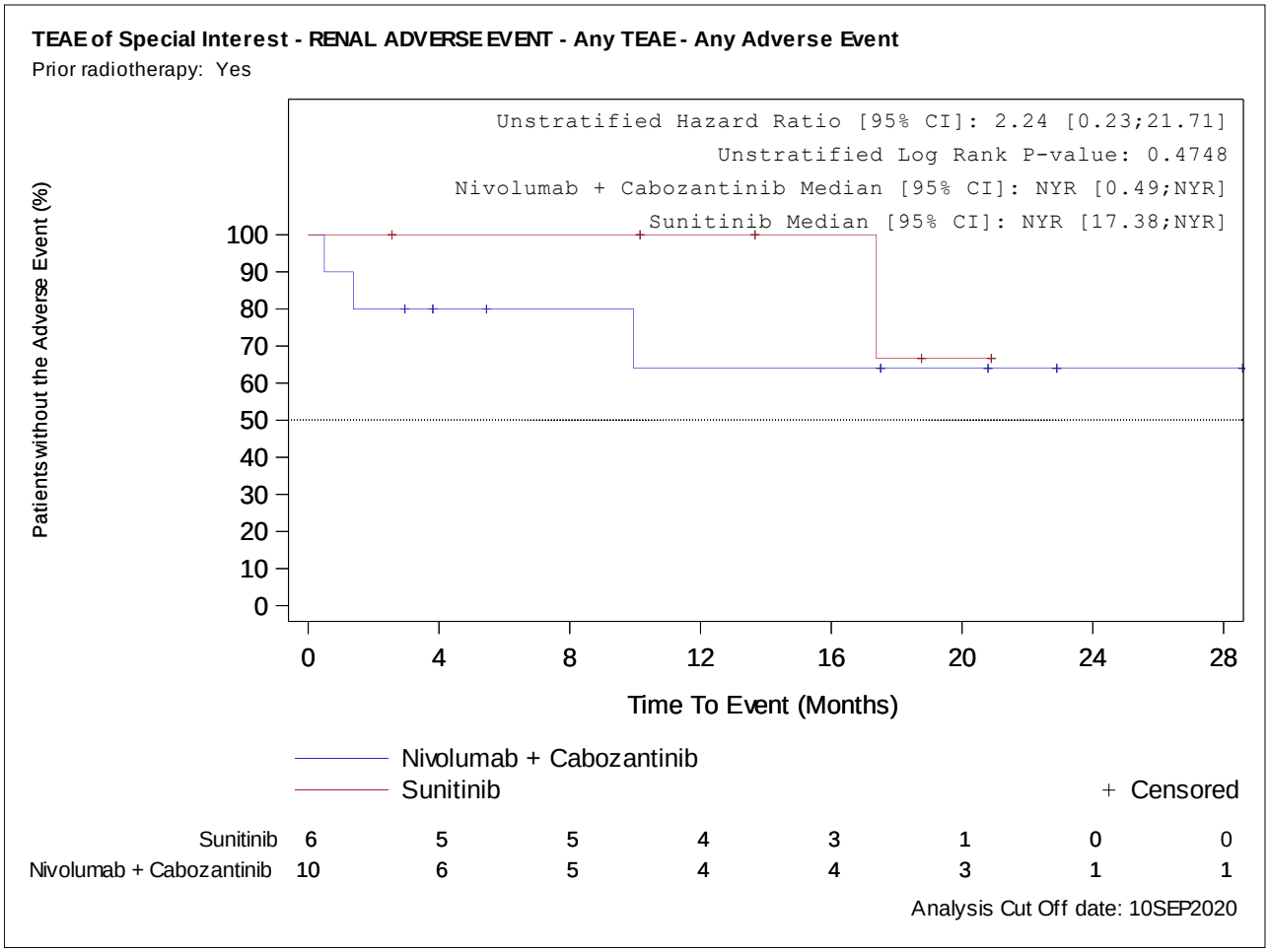

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:57:45

FIGURE 3.47.2.19: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



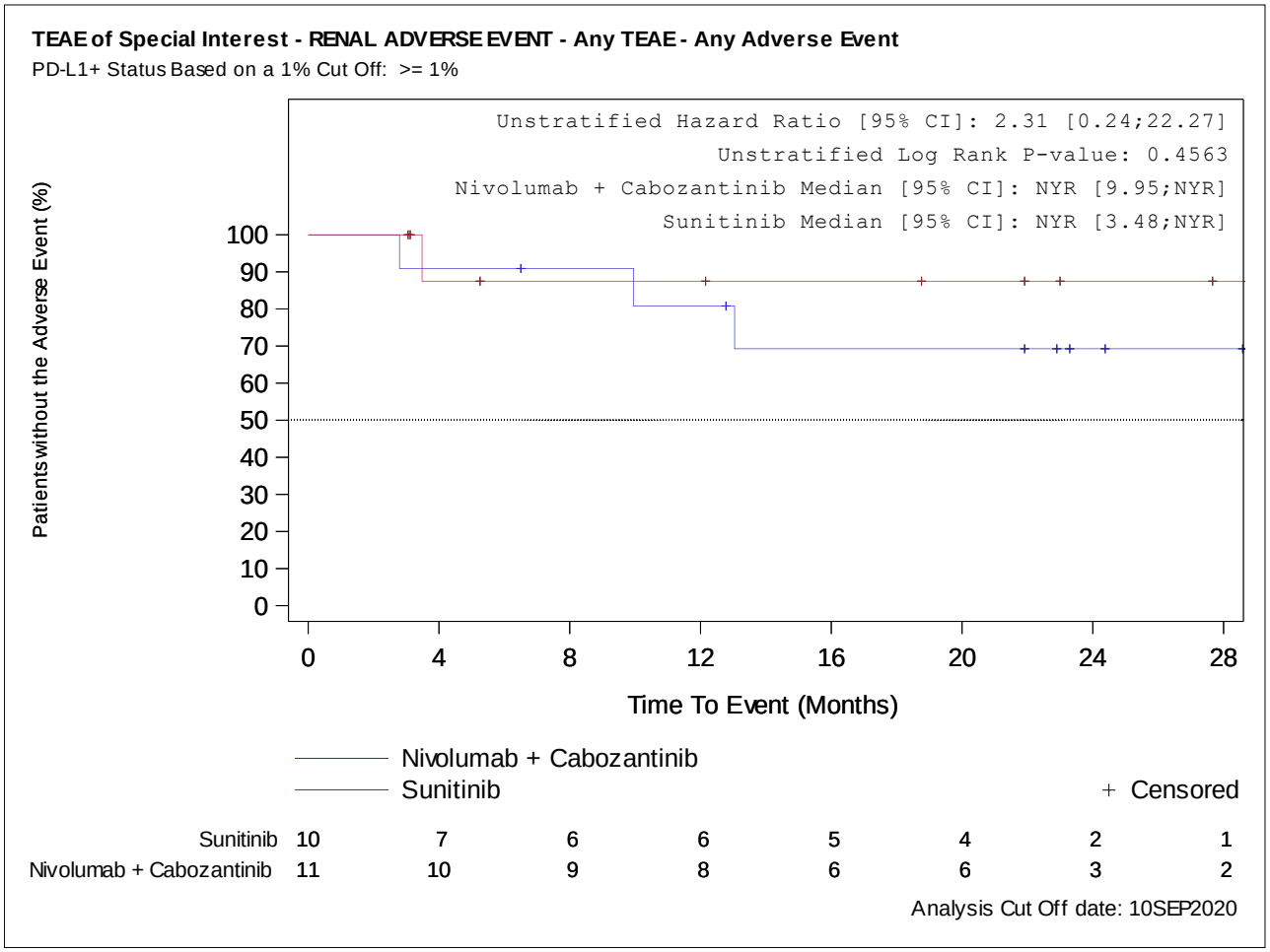

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:57:50

FIGURE 3.47.2.20: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



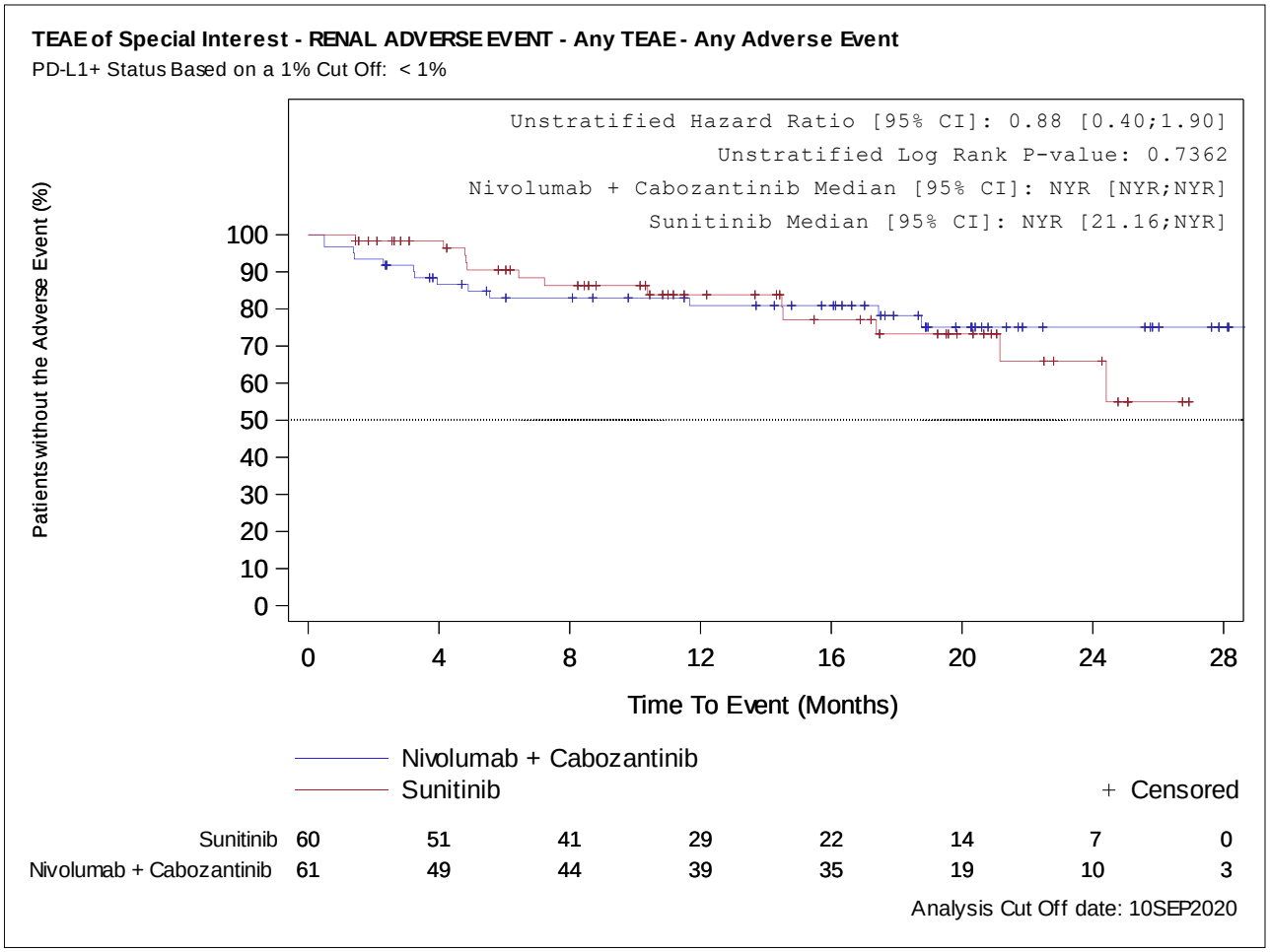

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:57:56

FIGURE 3.47.2.21: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



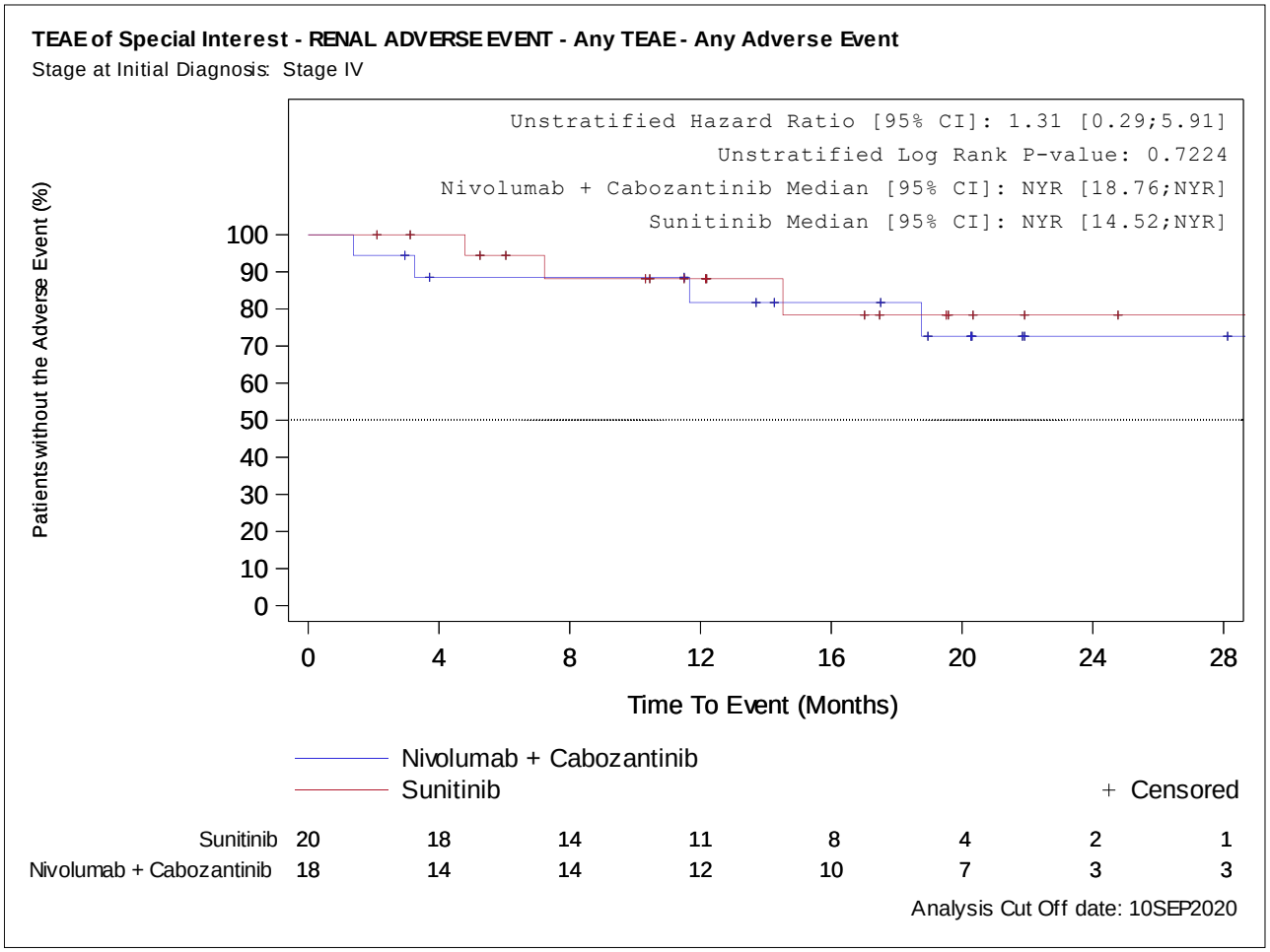

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:58:01

FIGURE 3.47.2.22: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



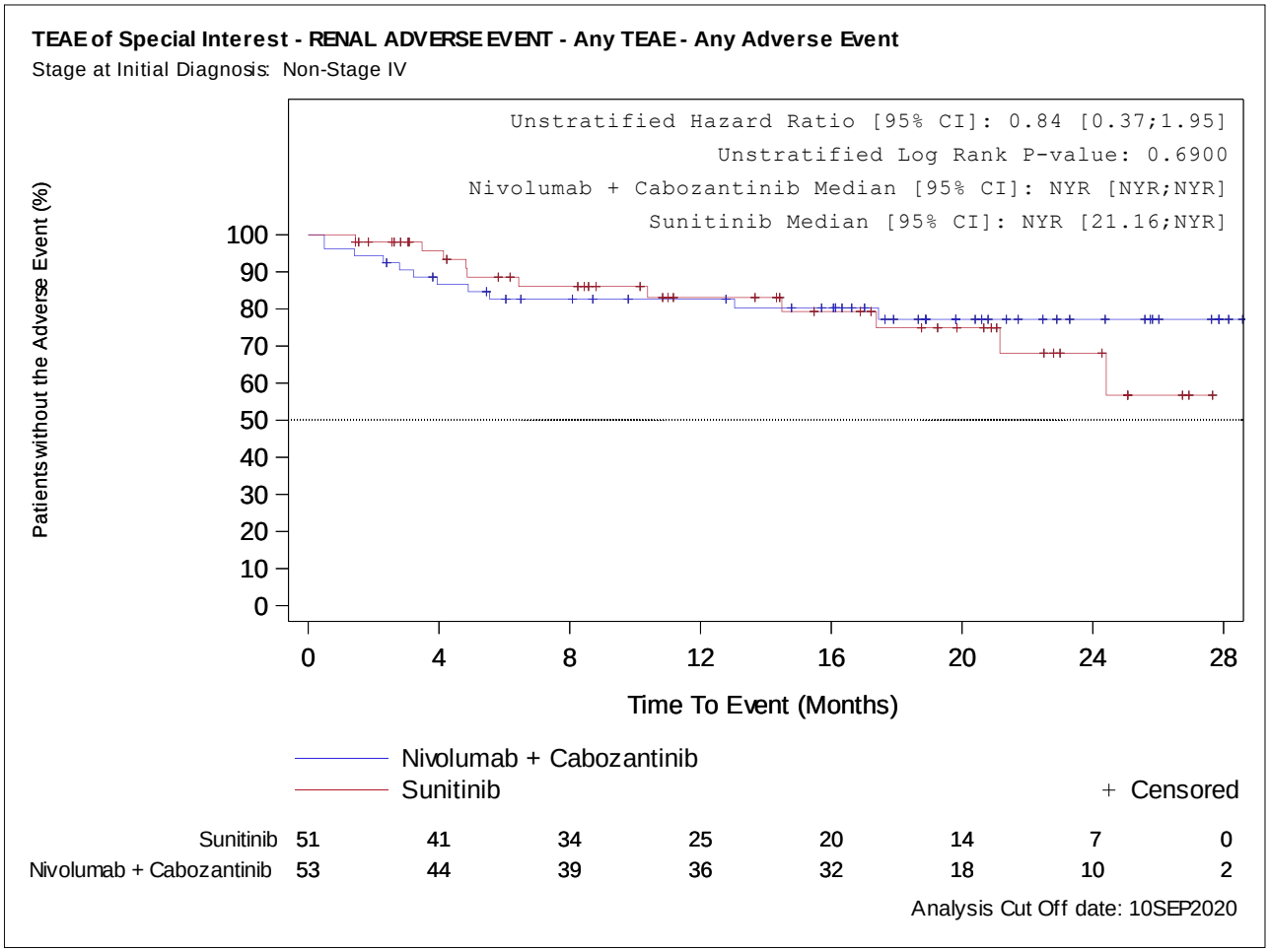

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:58:06

FIGURE 3.47.2.23: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



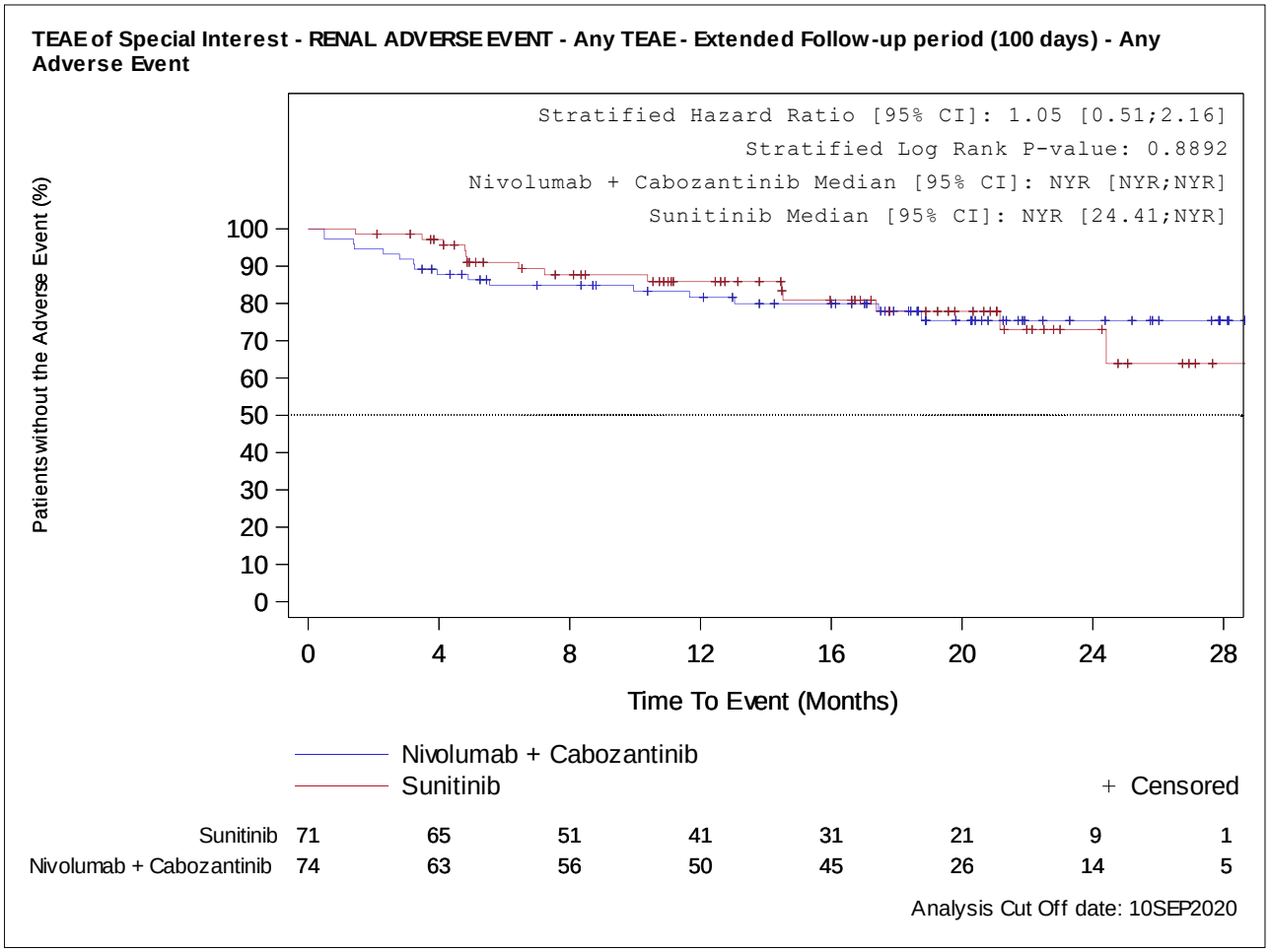

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:58:33

FIGURE 3.47.2.24: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



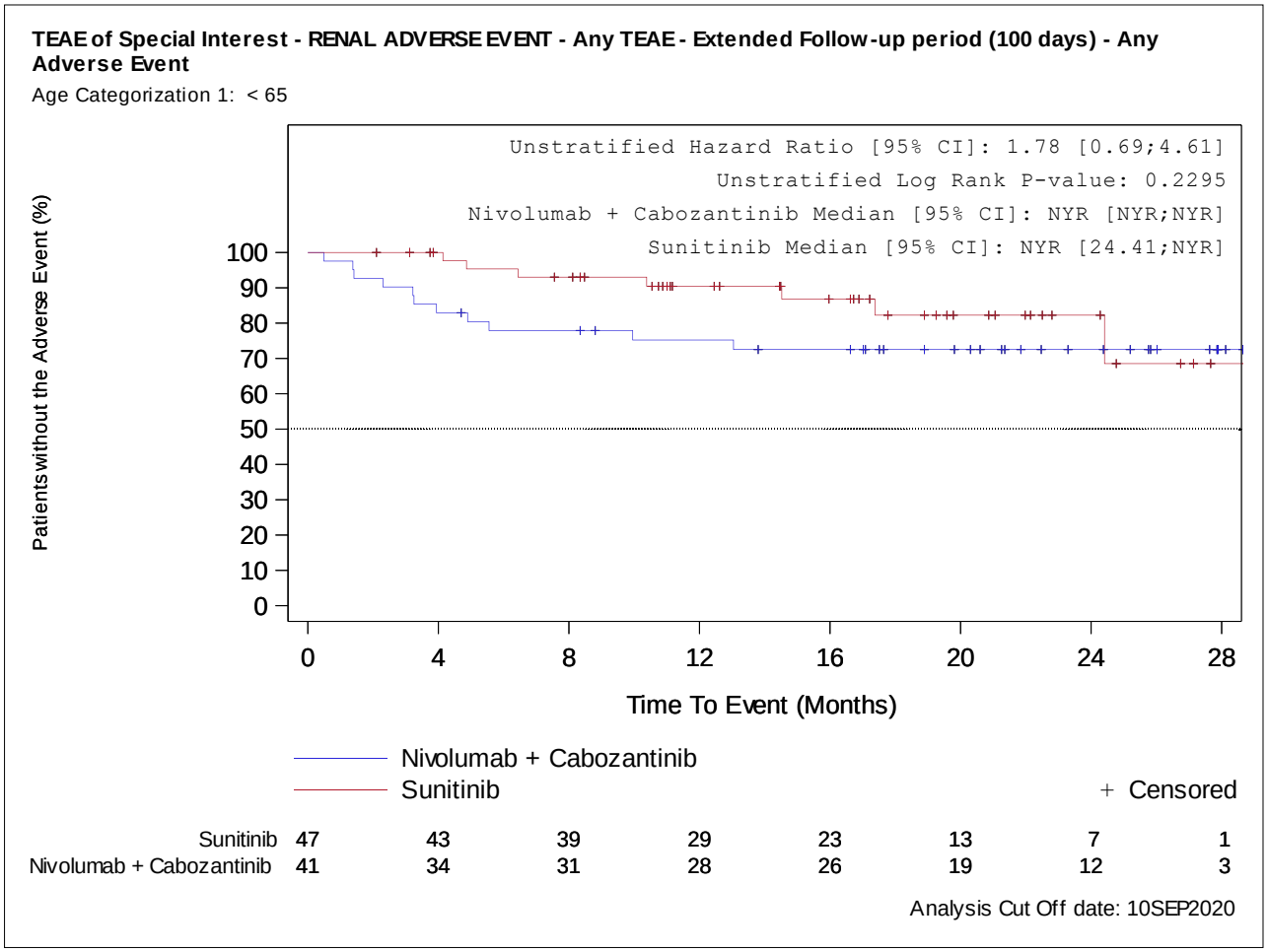

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:58:38

FIGURE 3.48.1: TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



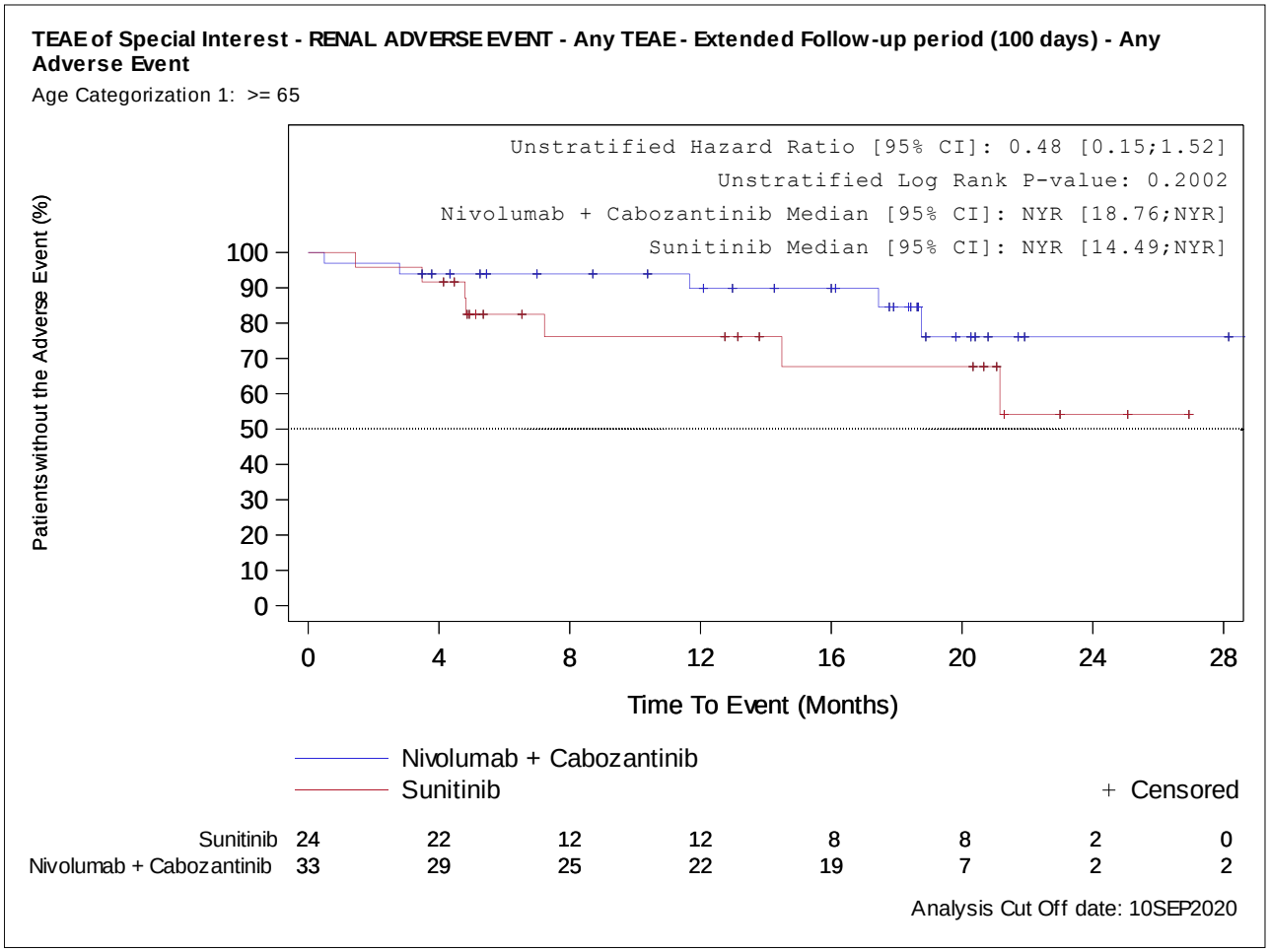

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:01:34

FIGURE 3.48.2.1: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



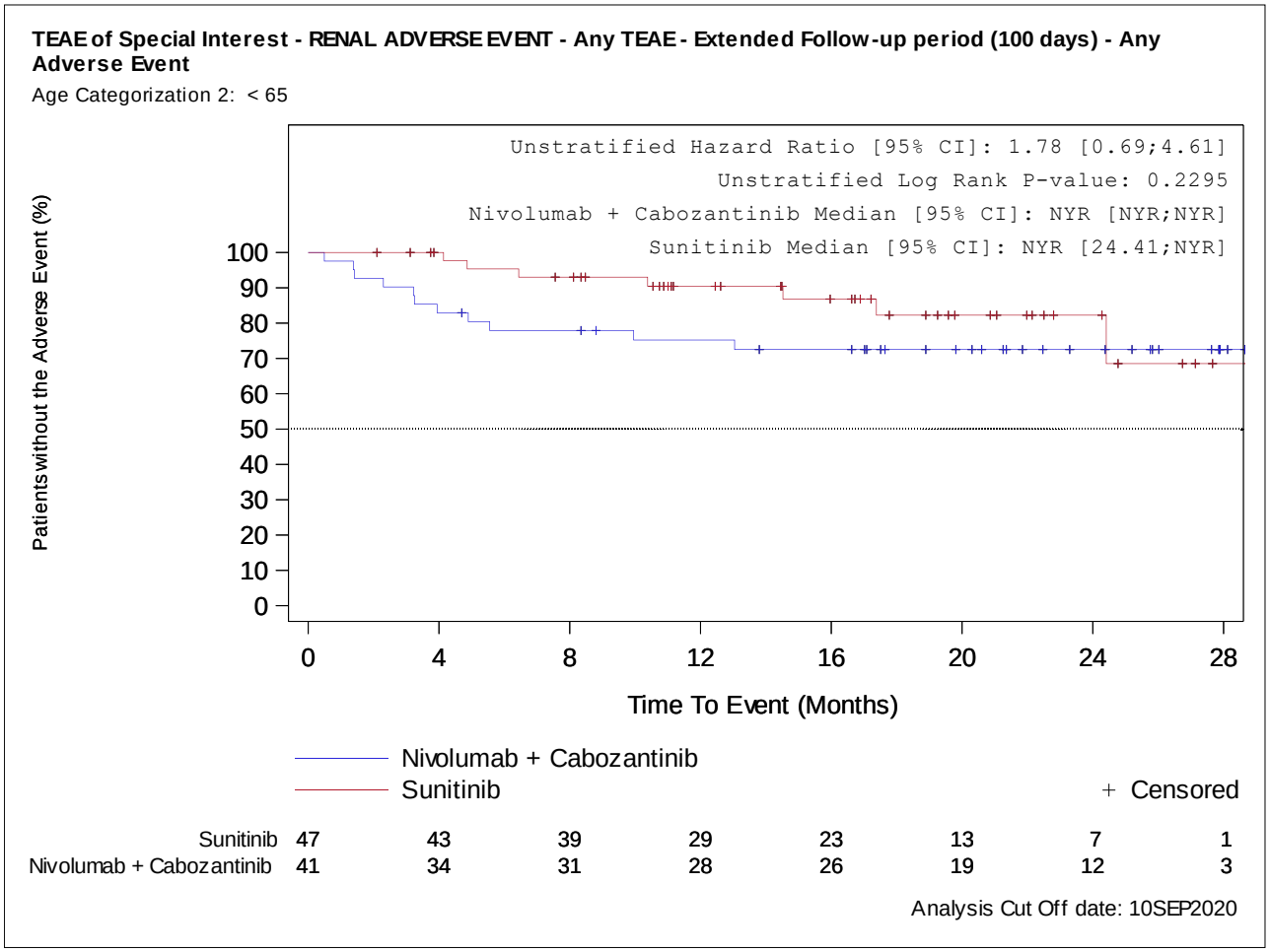

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:01:37

FIGURE 3.48.2.2: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



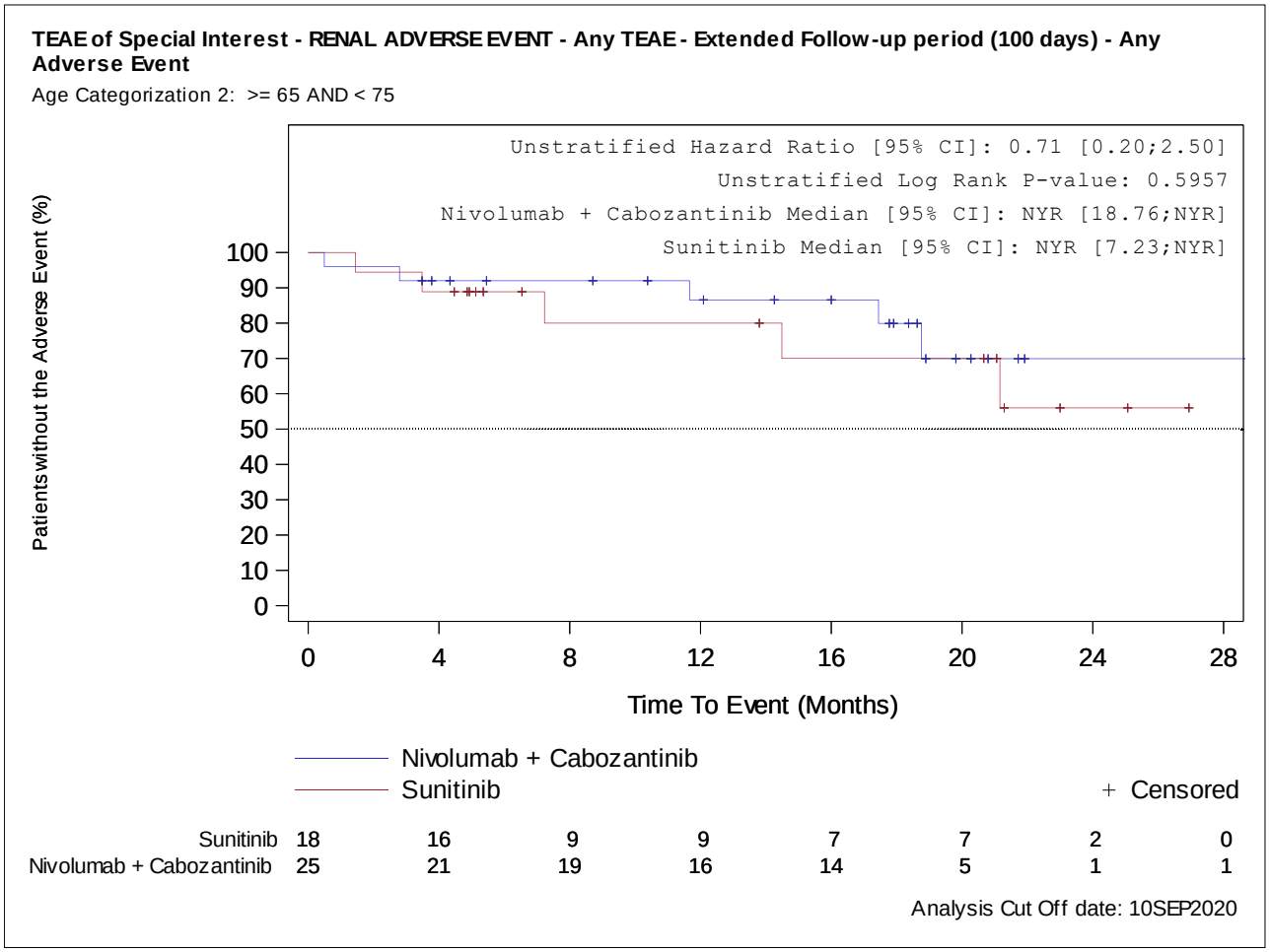

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:01:42

FIGURE 3.48.2.3: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



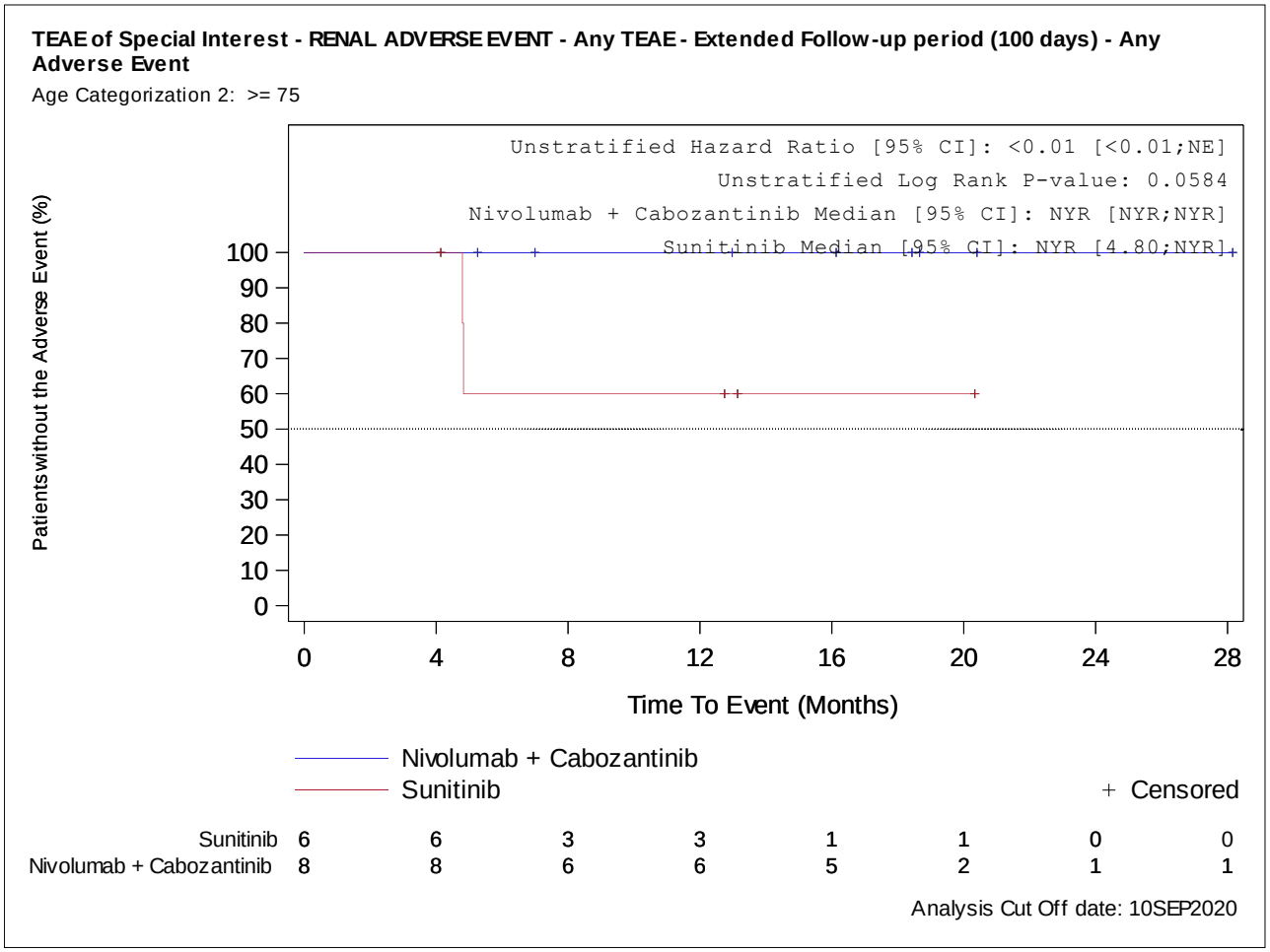

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:01:48

FIGURE 3.48.2.4: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



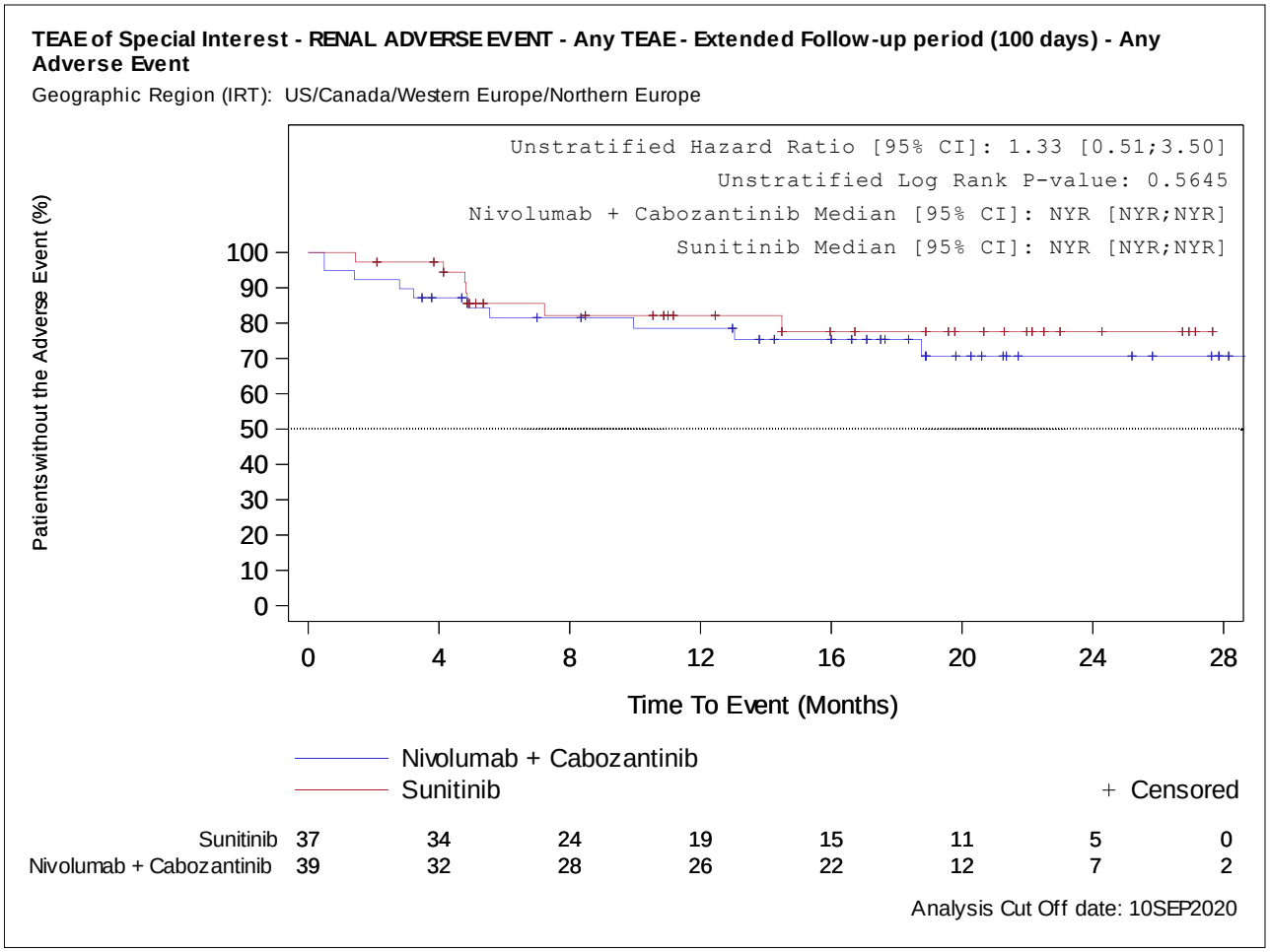

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:01:53

FIGURE 3.48.2.5: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



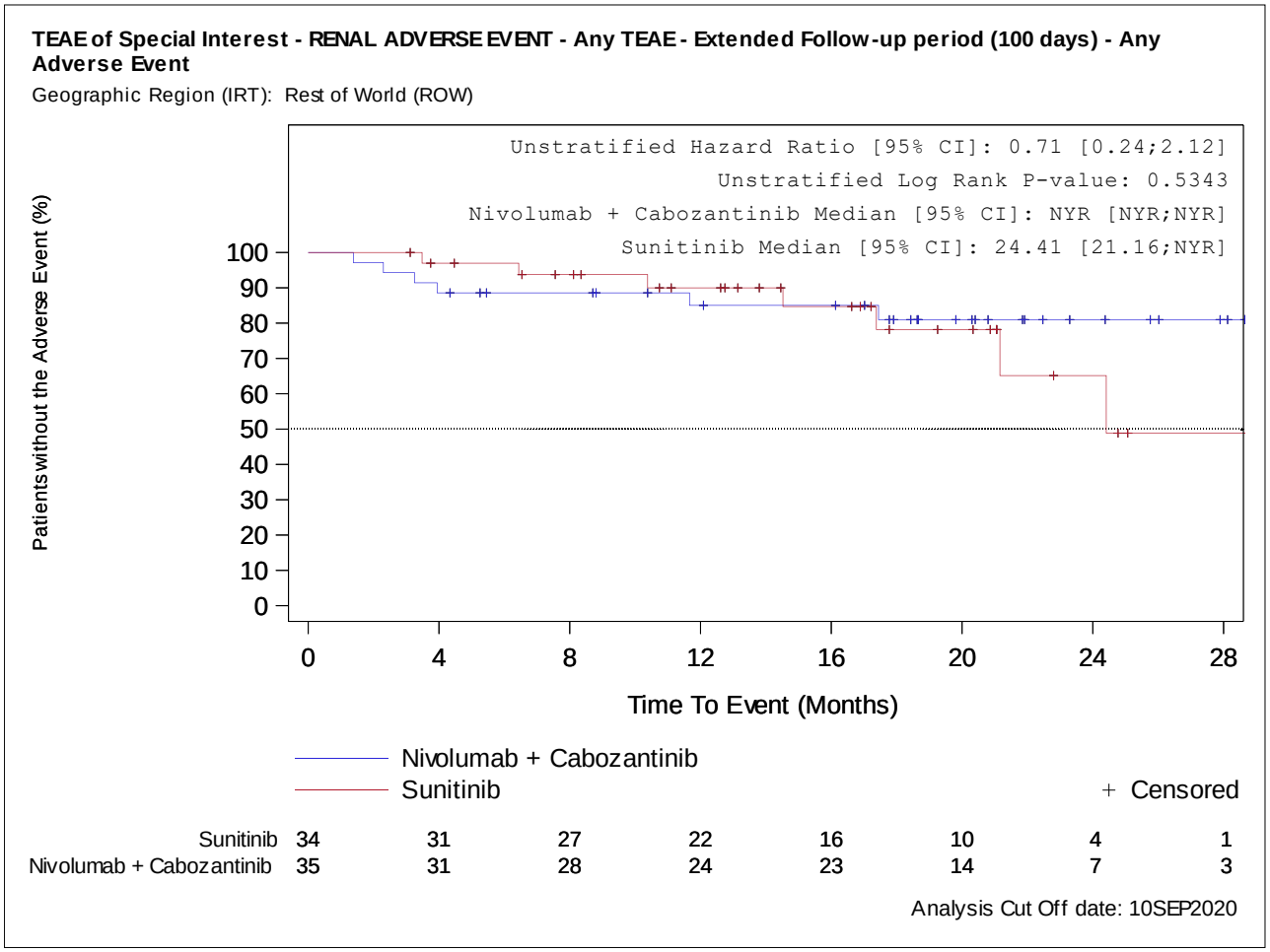

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:01:58

FIGURE 3.48.2.6: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



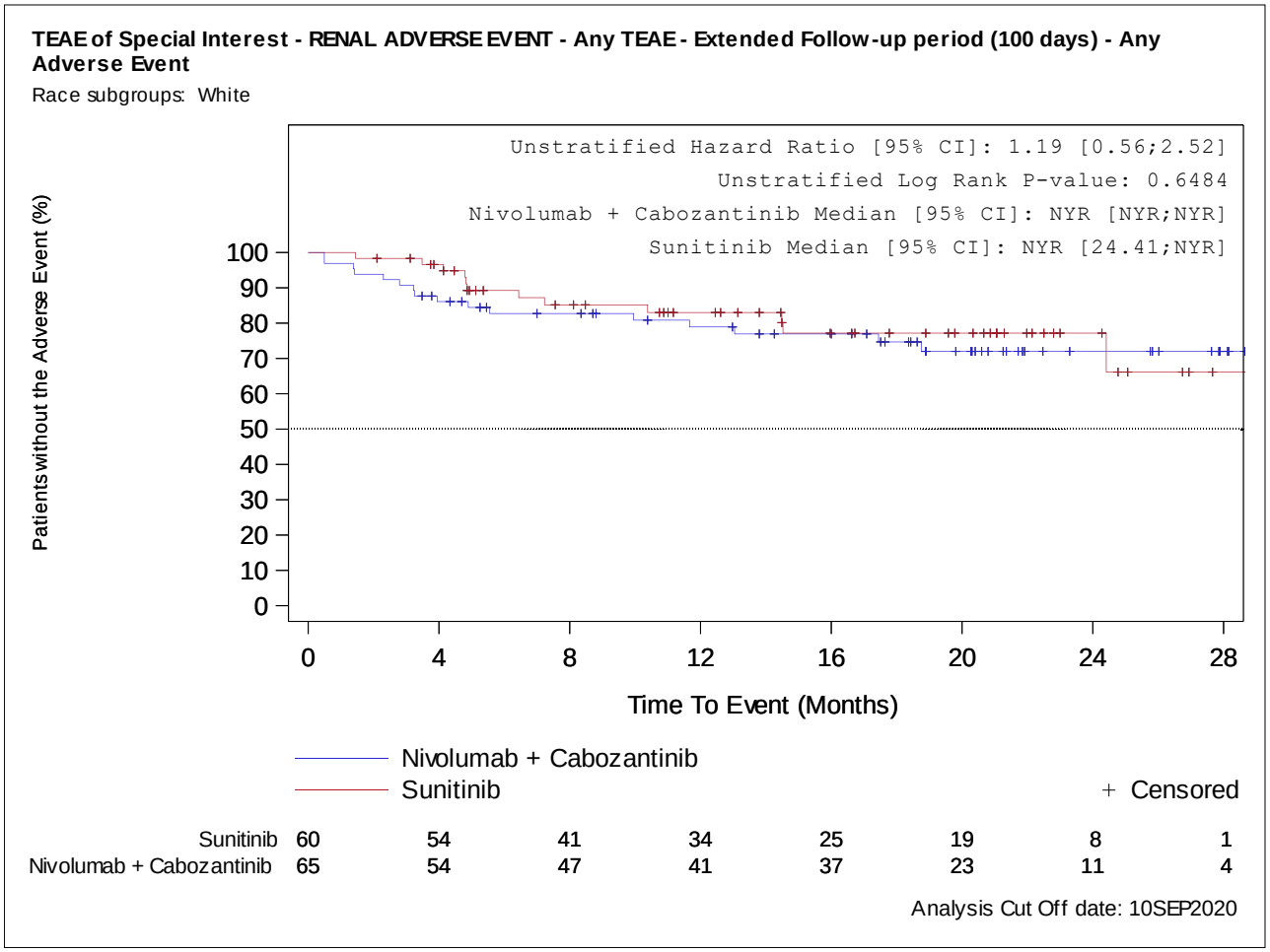

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:02:04

FIGURE 3.48.2.7: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



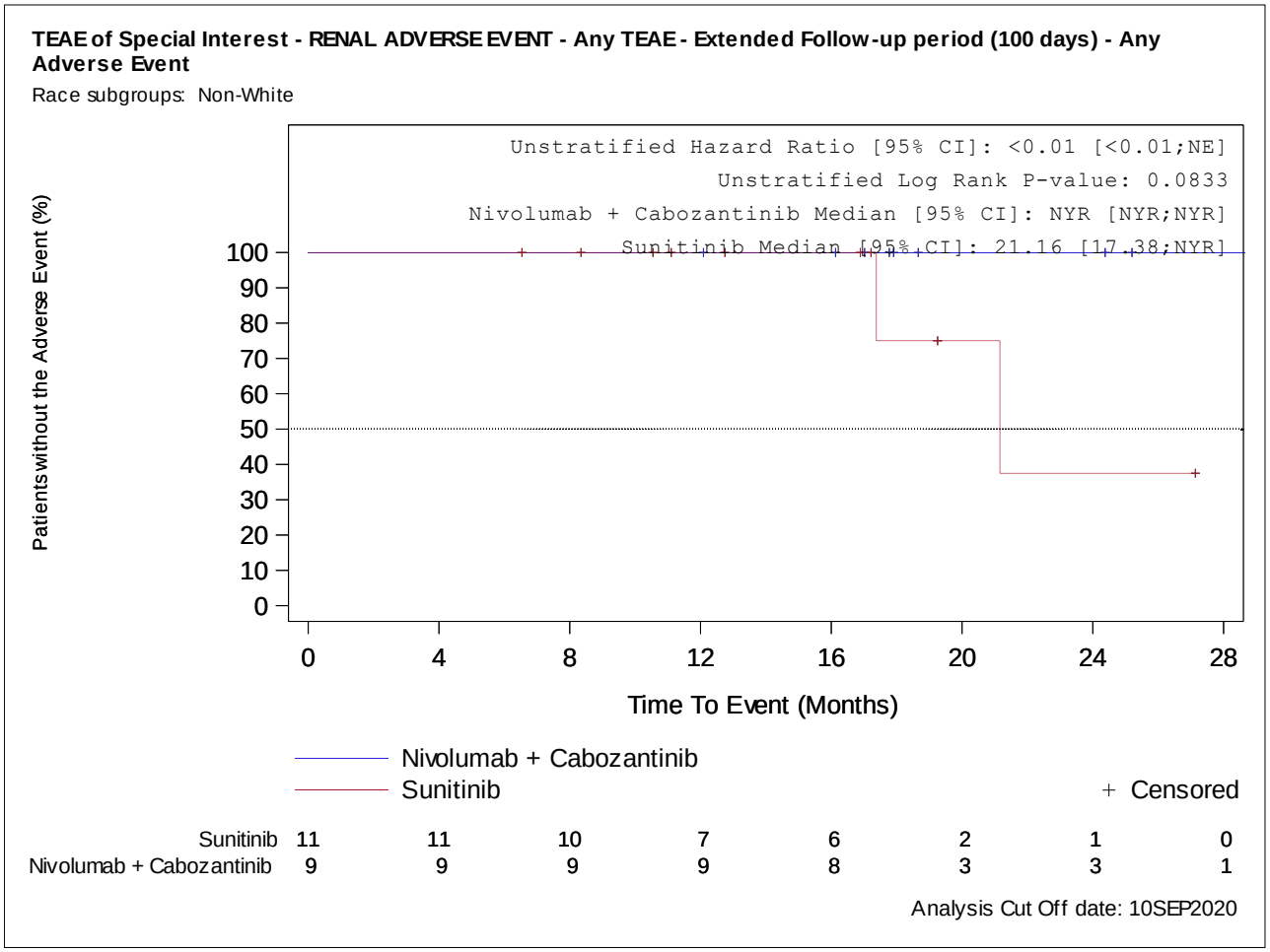

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:02:09

FIGURE 3.48.2.8: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



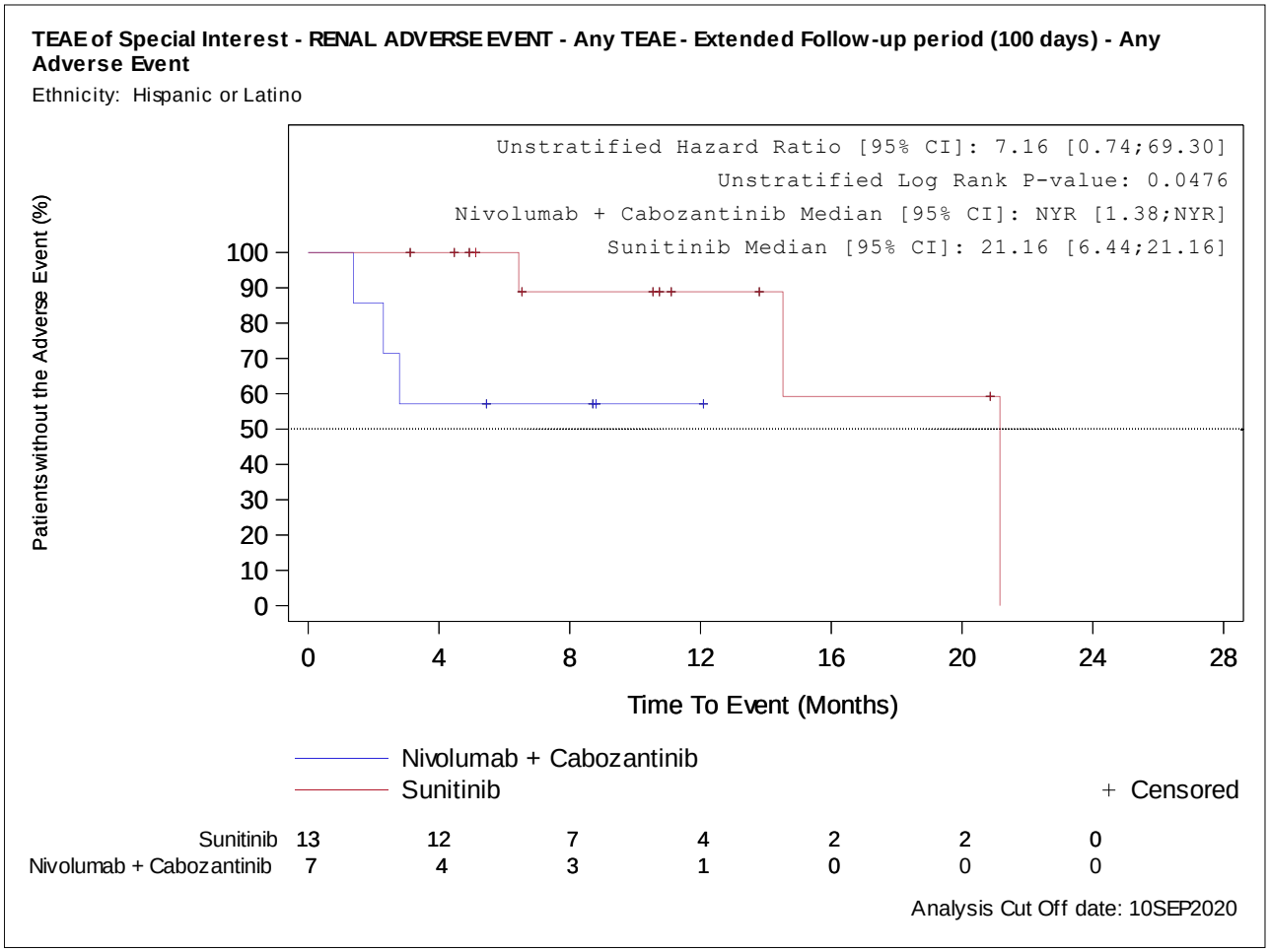

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:02:14

FIGURE 3.48.2.9: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



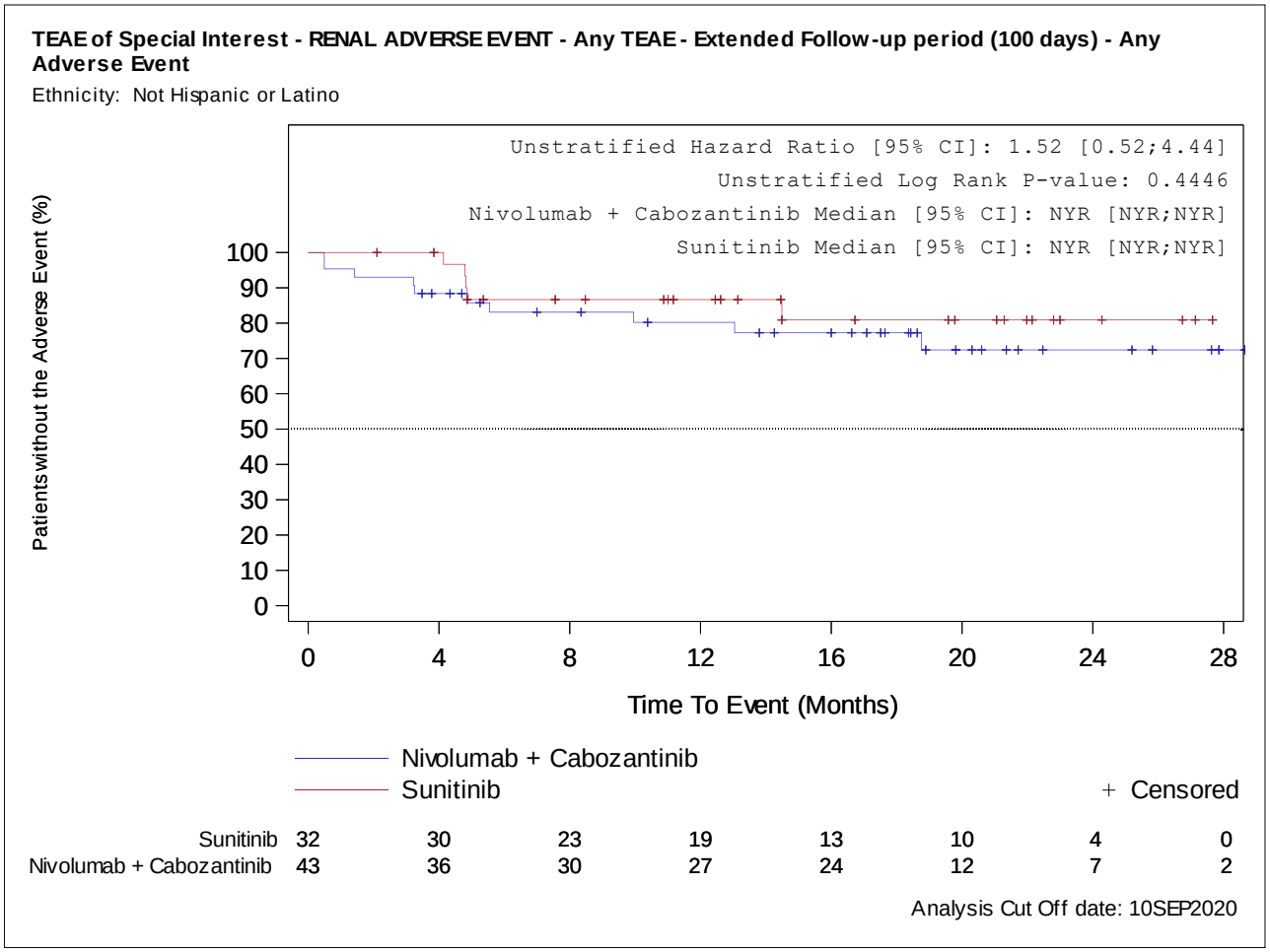

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:02:19

FIGURE 3.48.2.10: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



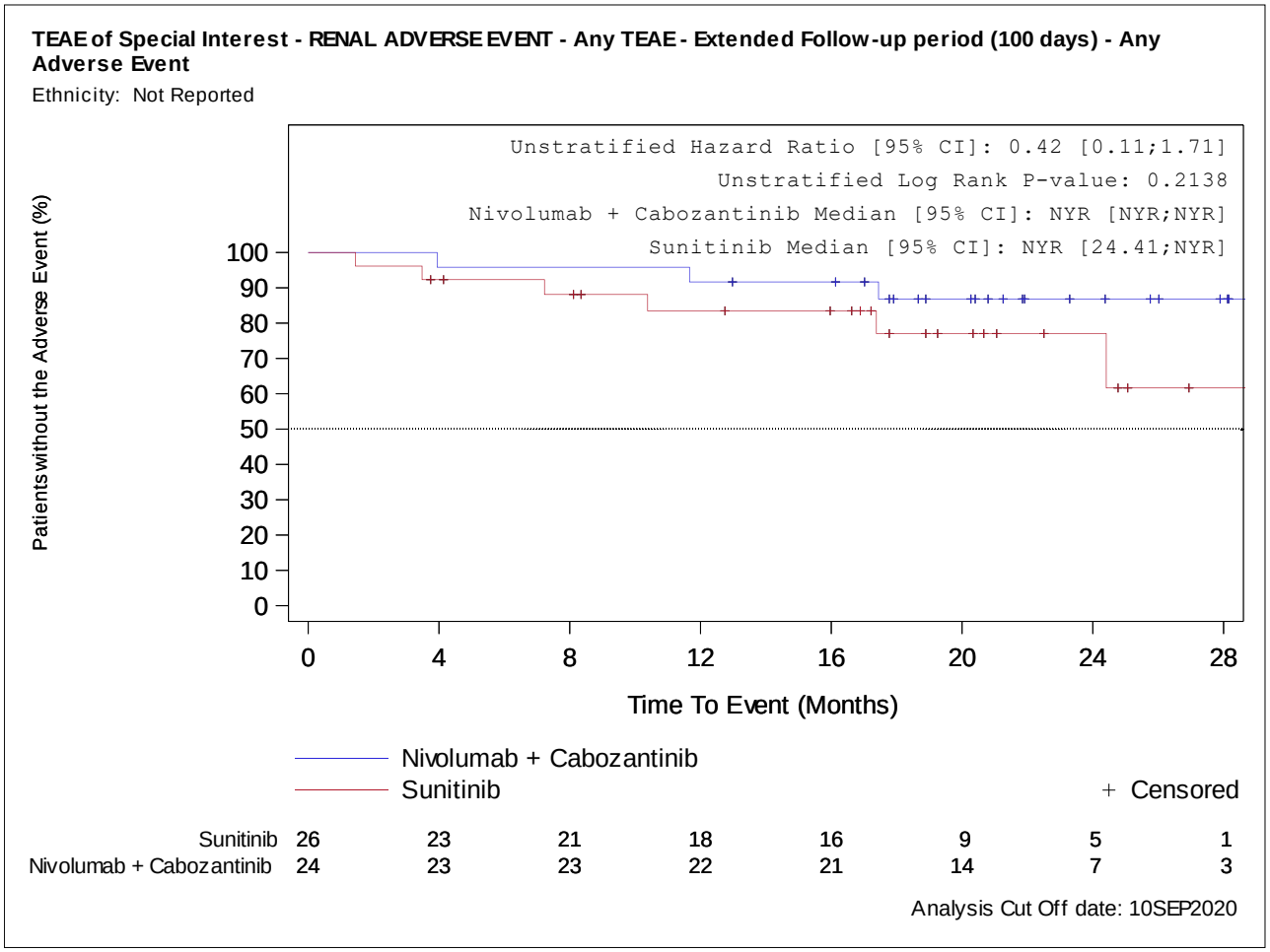

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:02:25

FIGURE 3.48.2.11: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



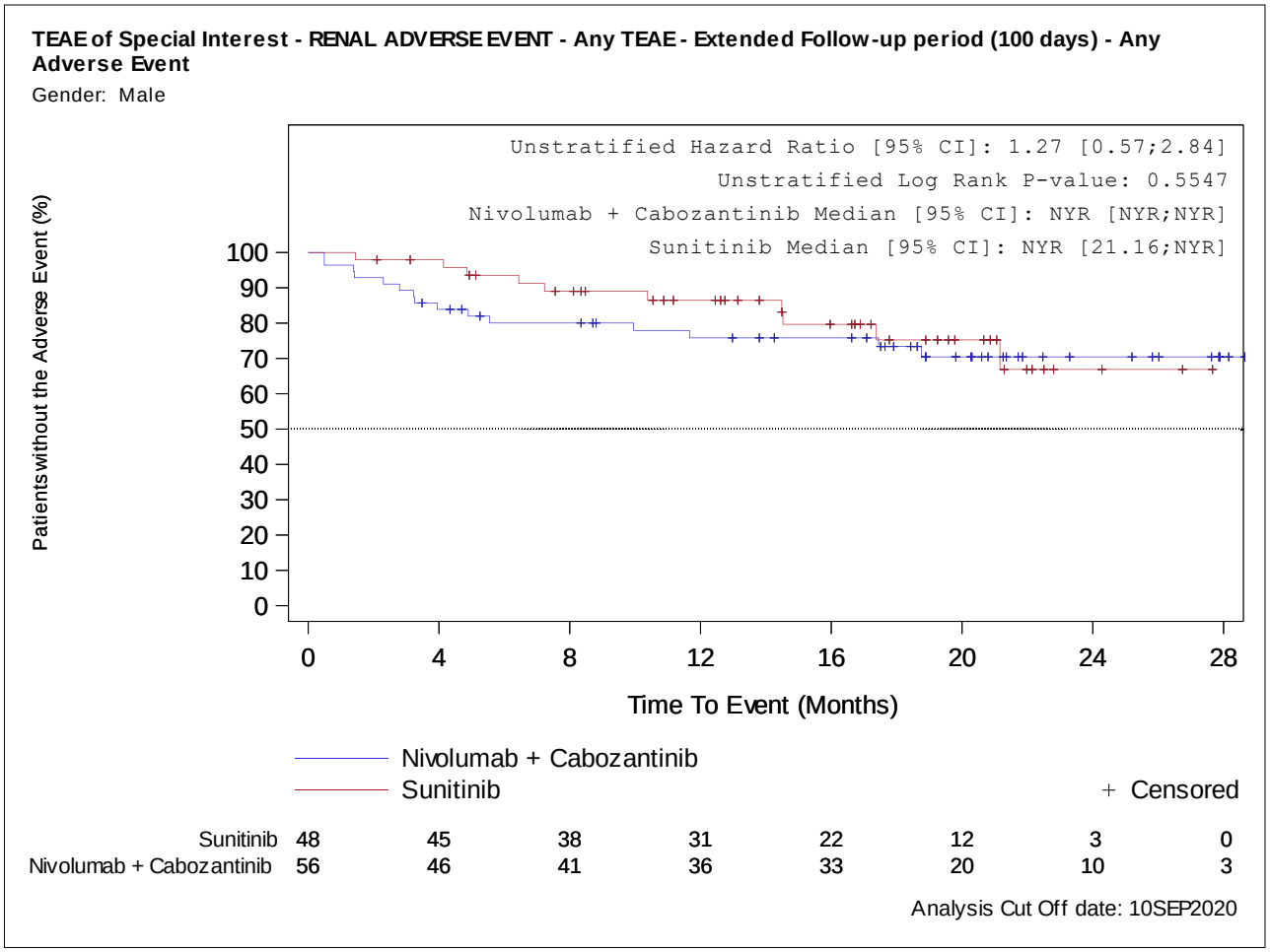

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:02:30

FIGURE 3.48.2.12: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



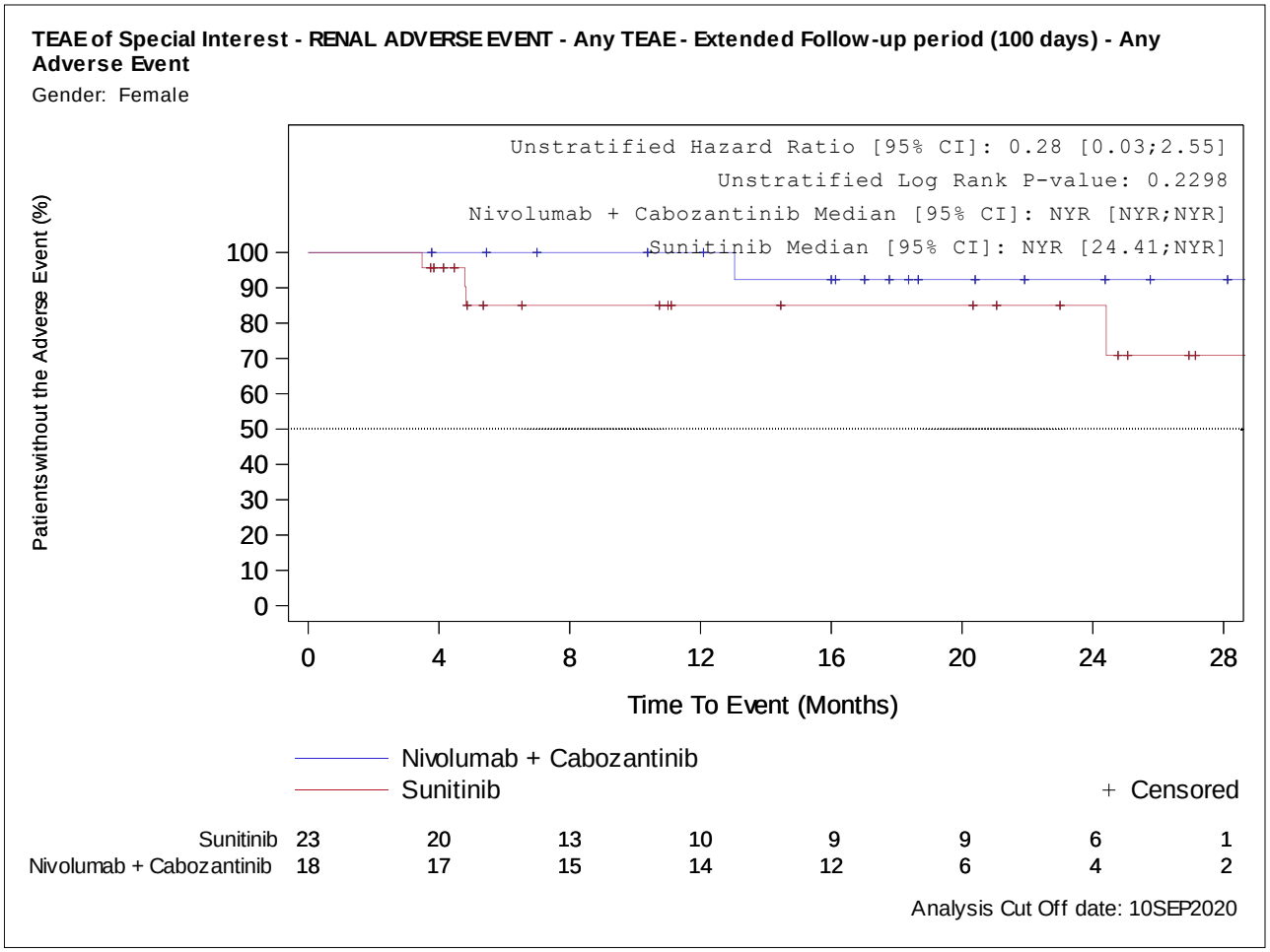

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:02:36

FIGURE 3.48.2.13: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



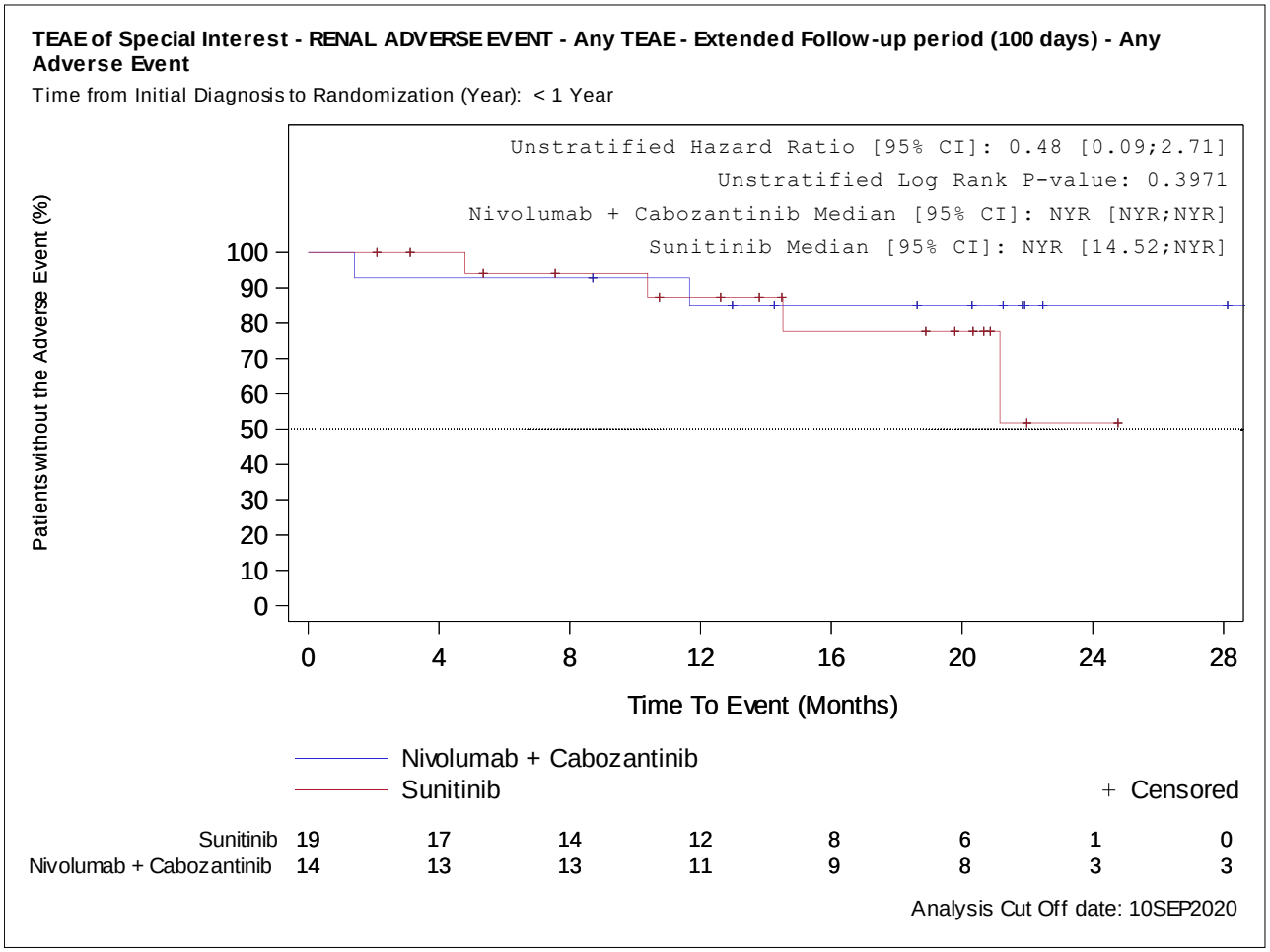

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:02:42

FIGURE 3.48.2.14: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



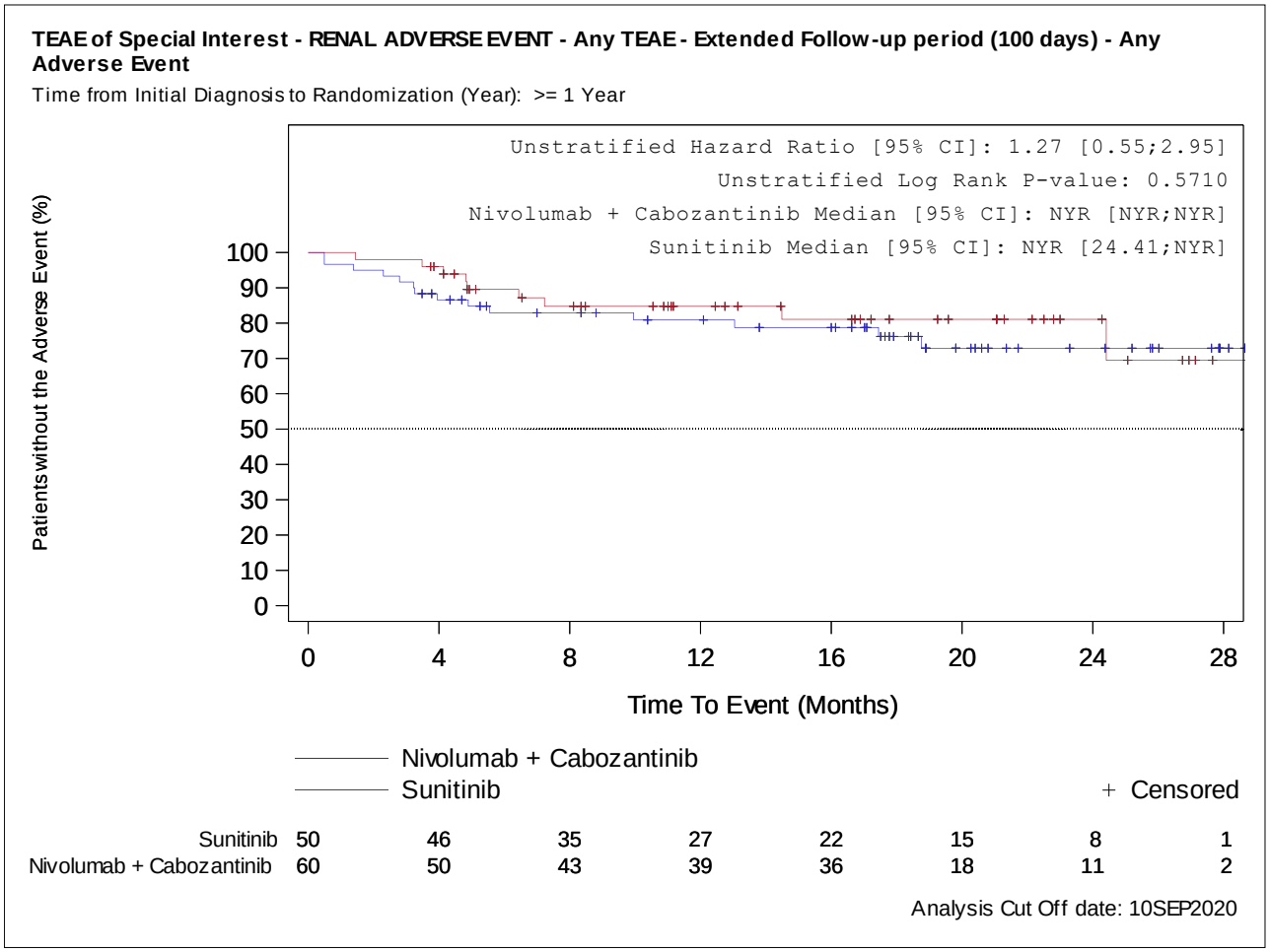

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:02:47

FIGURE 3.48.2.15: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



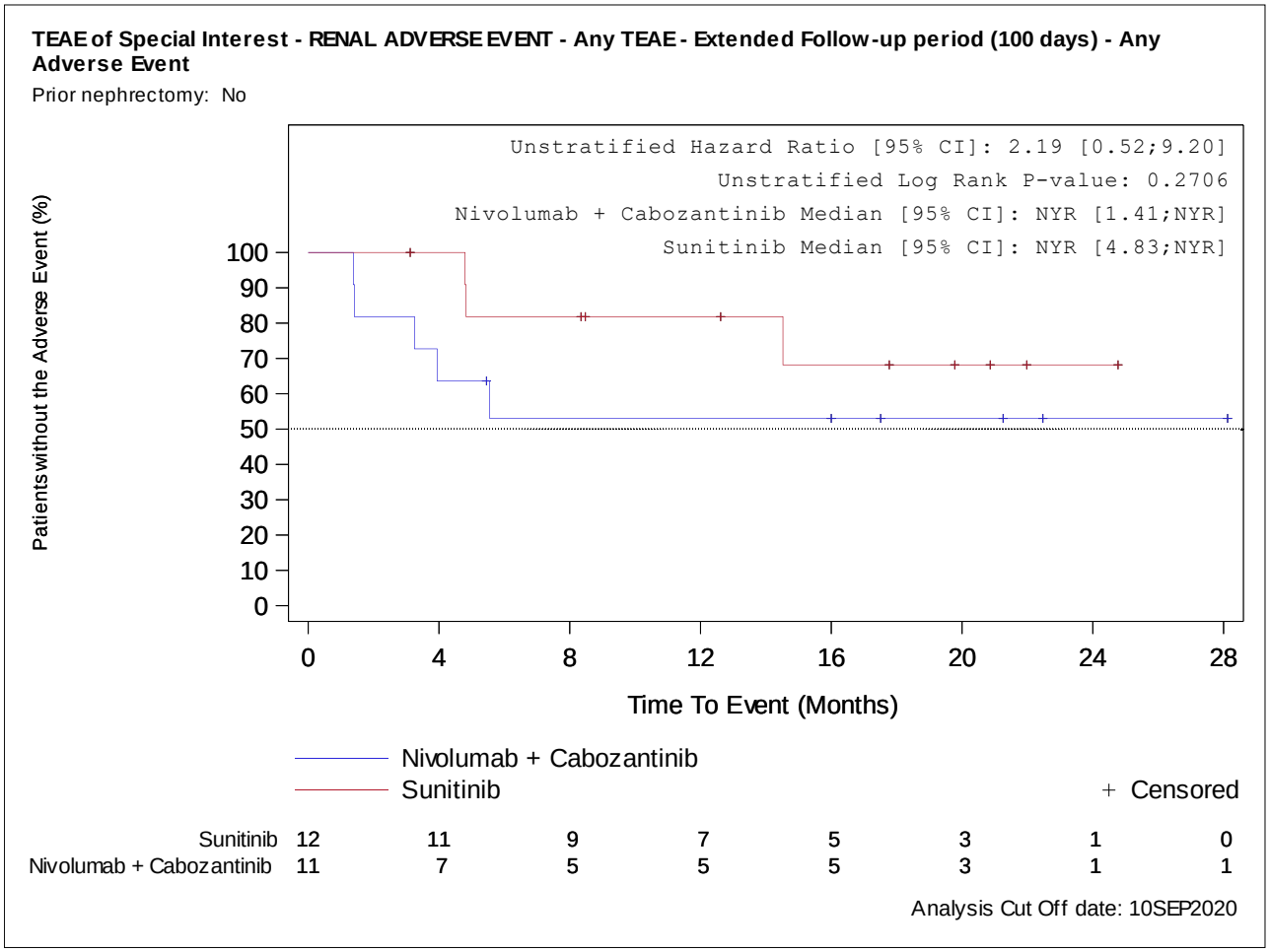

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:03:02

FIGURE 3.48.2.16: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



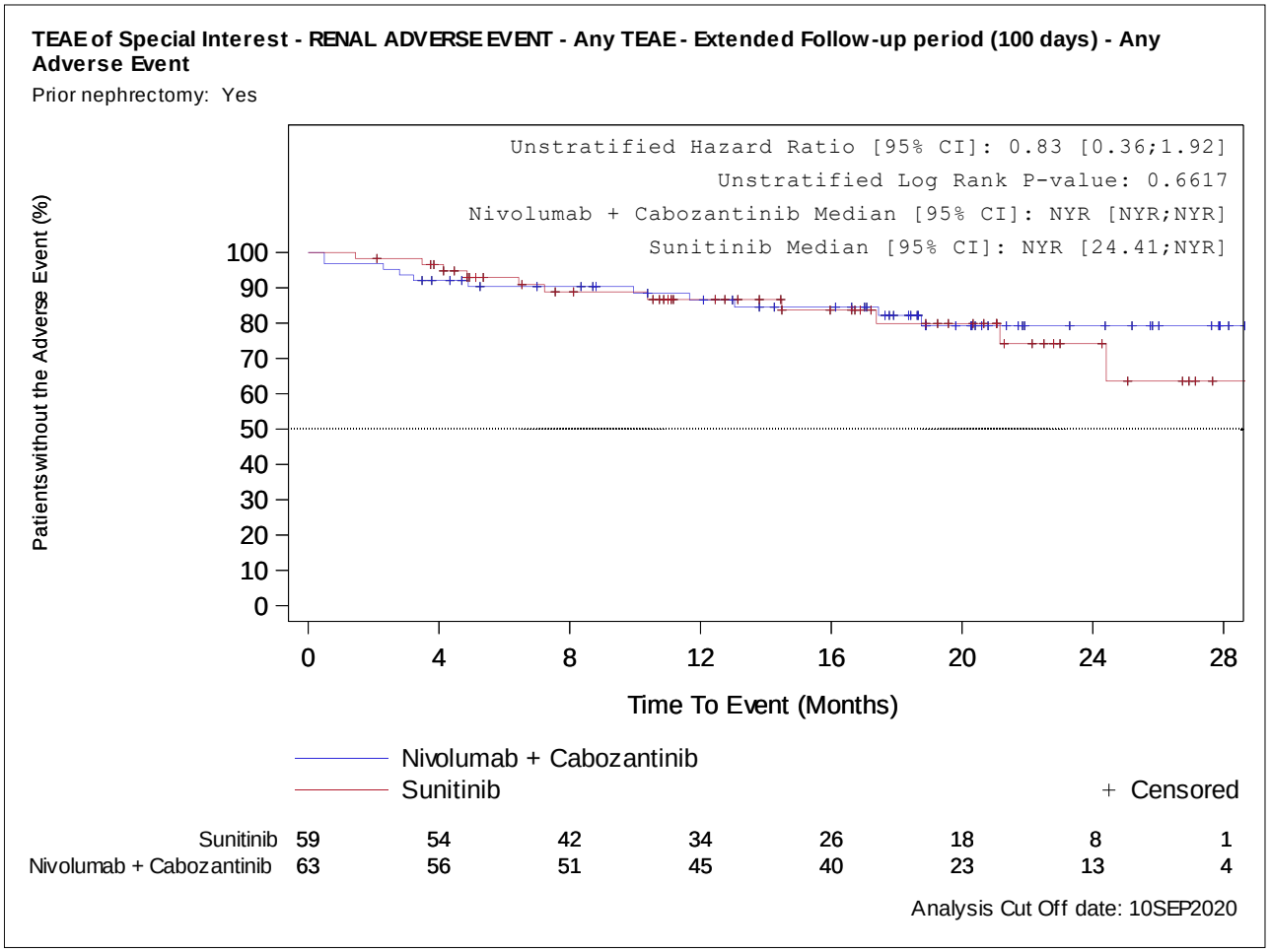

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:03:07

FIGURE 3.48.2.17: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



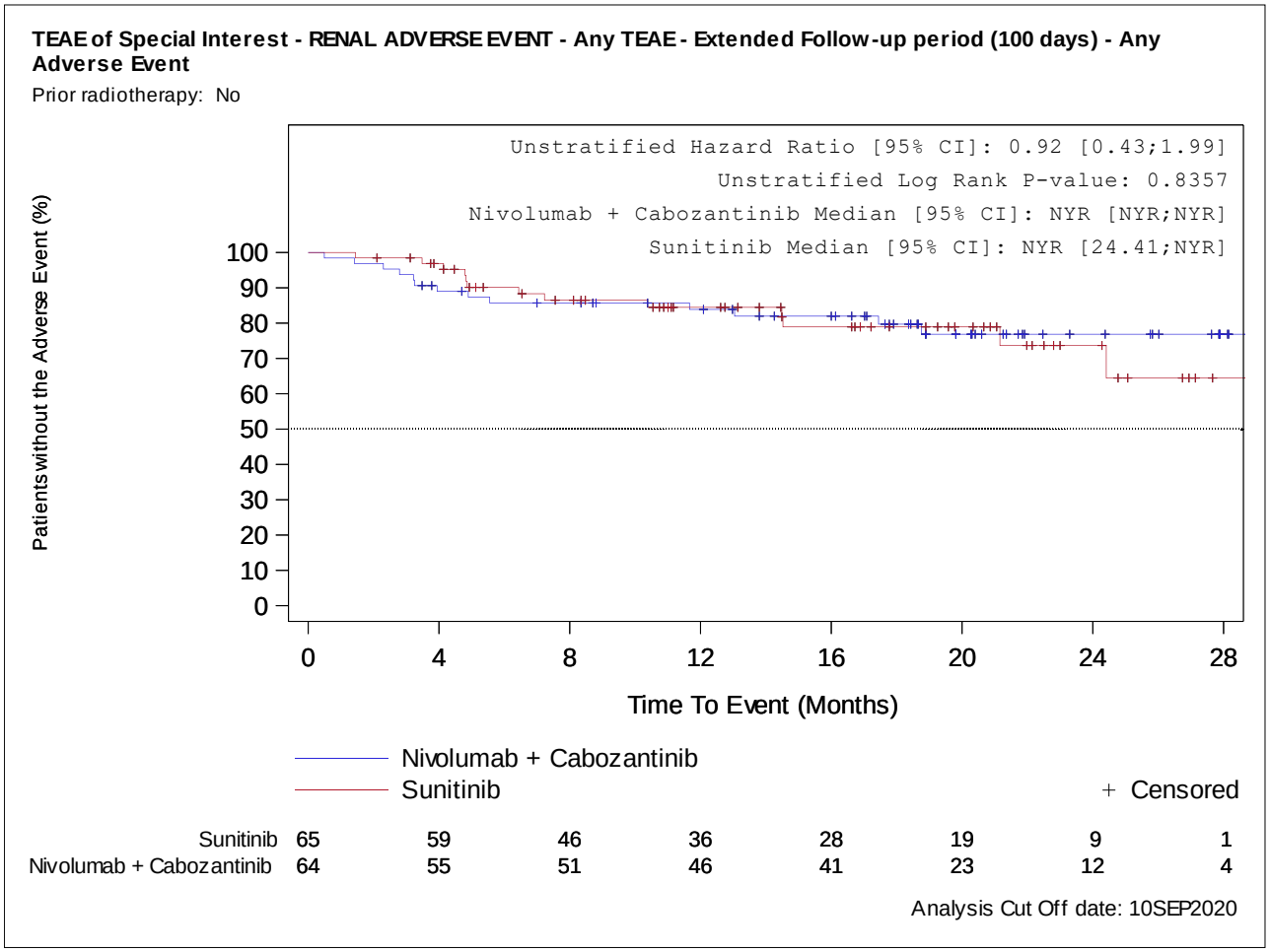

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:03:54

FIGURE 3.48.2.18: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



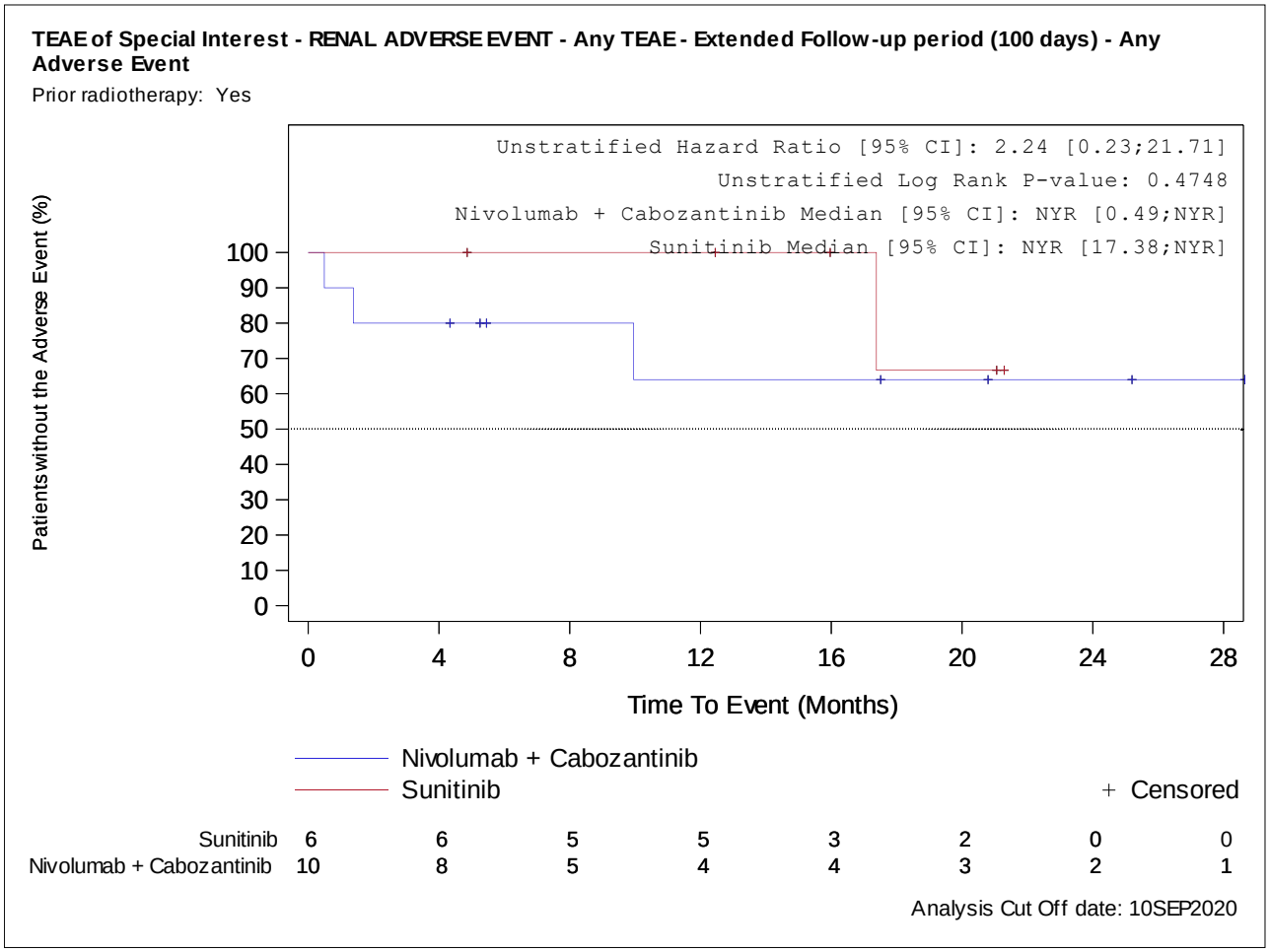

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:00

FIGURE 3.48.2.19: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



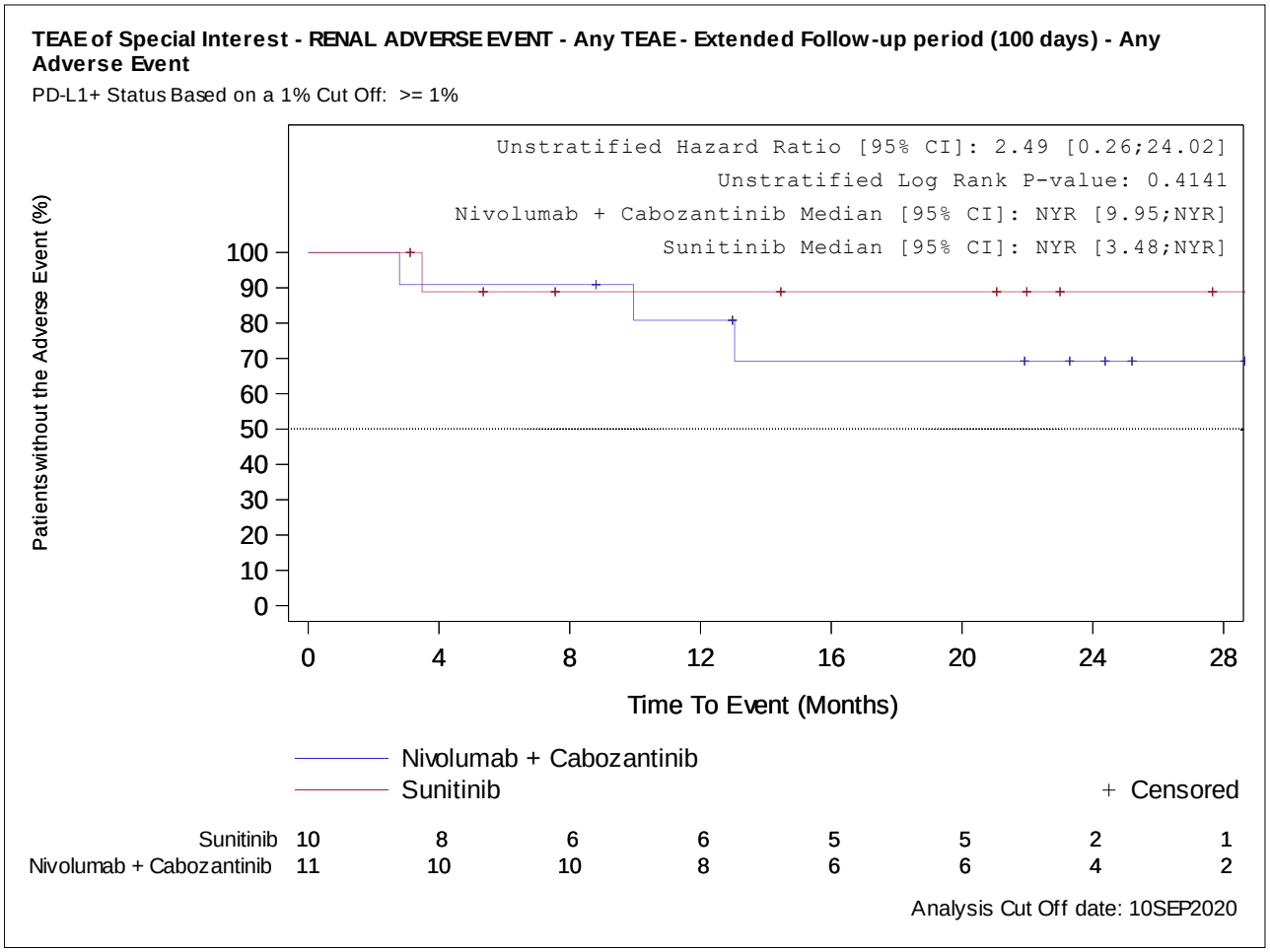

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:05

FIGURE 3.48.2.20: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:10

FIGURE 3.48.2.21: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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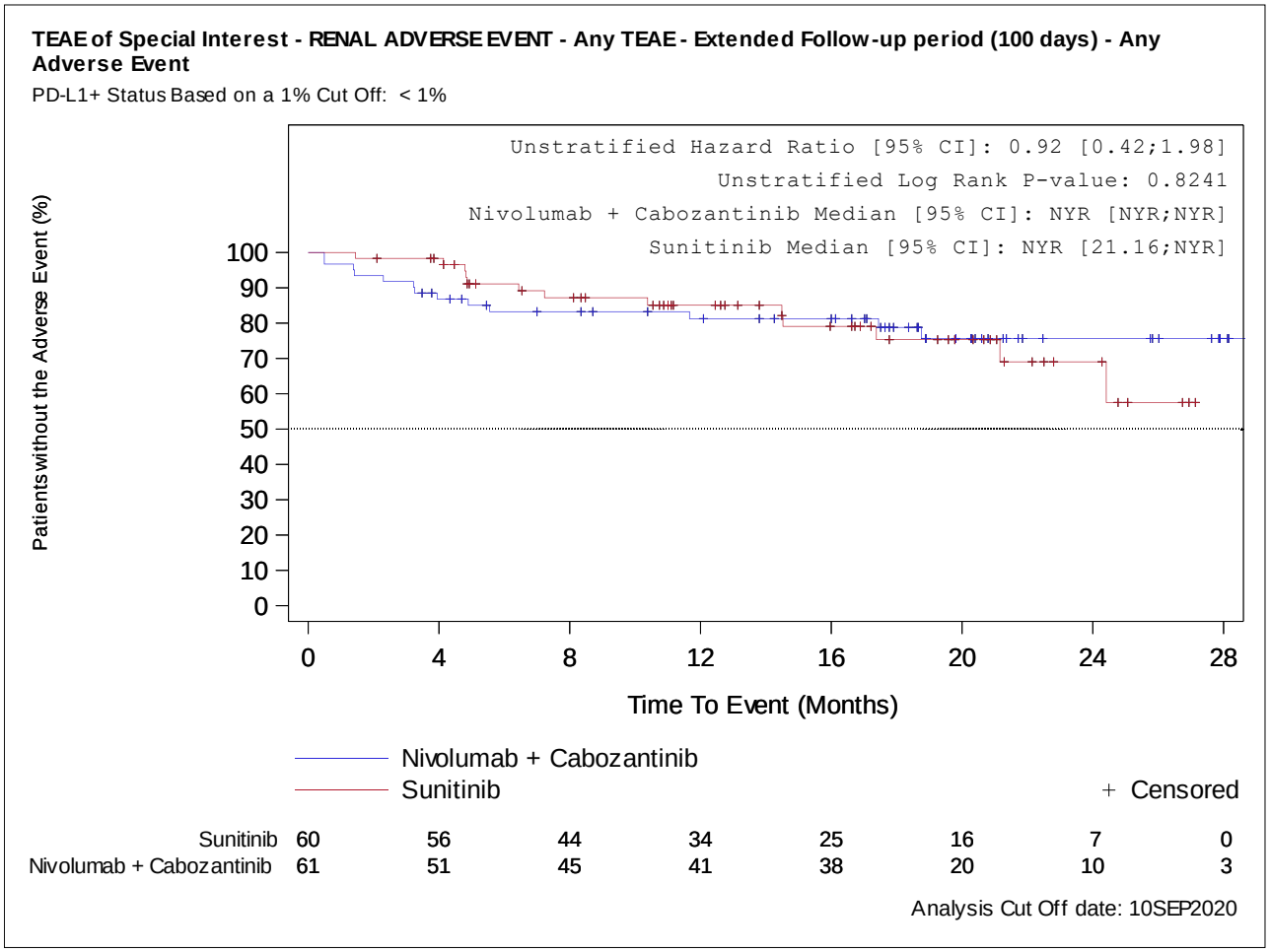
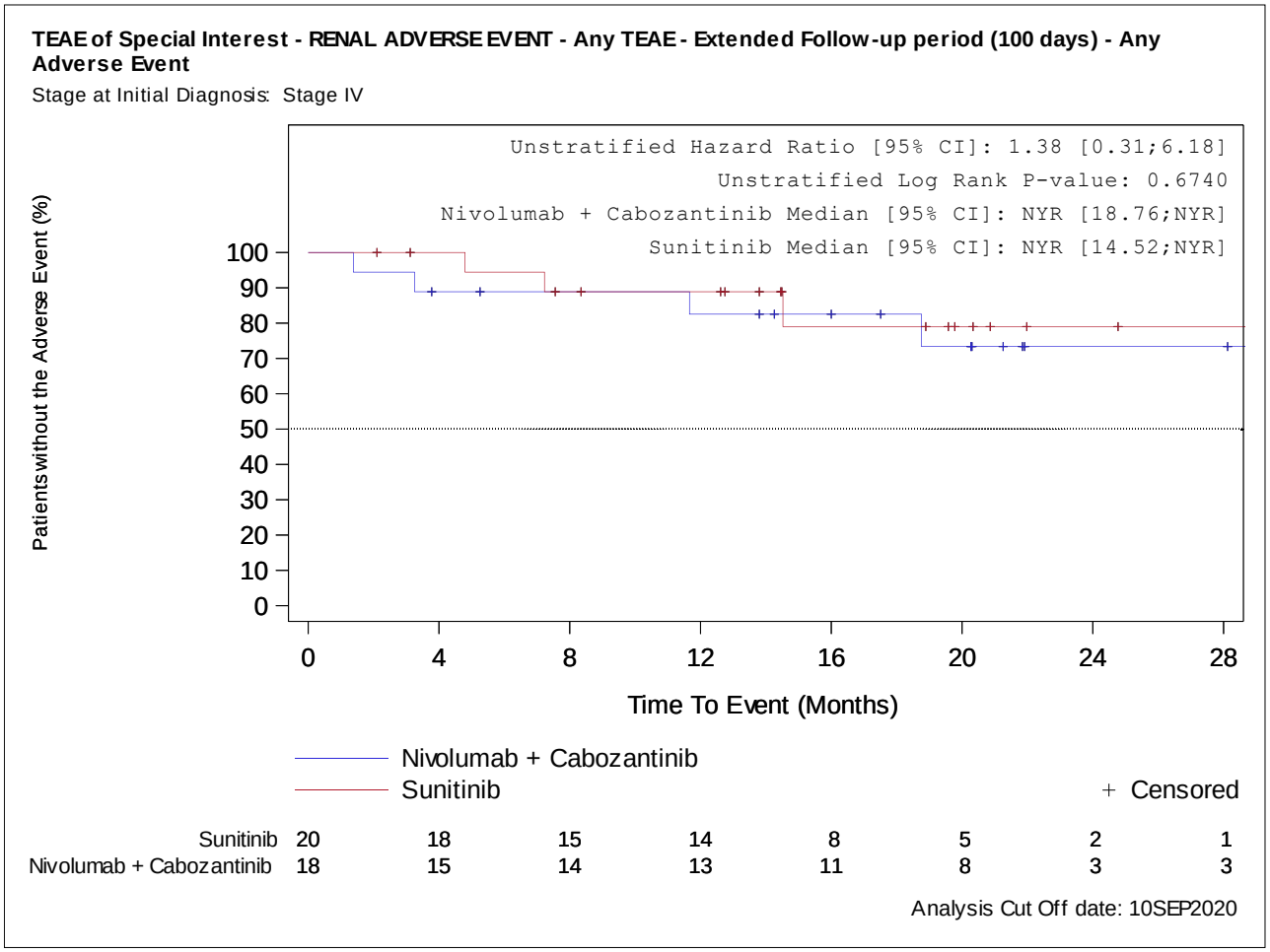
FIGURE 3.48.2.22: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



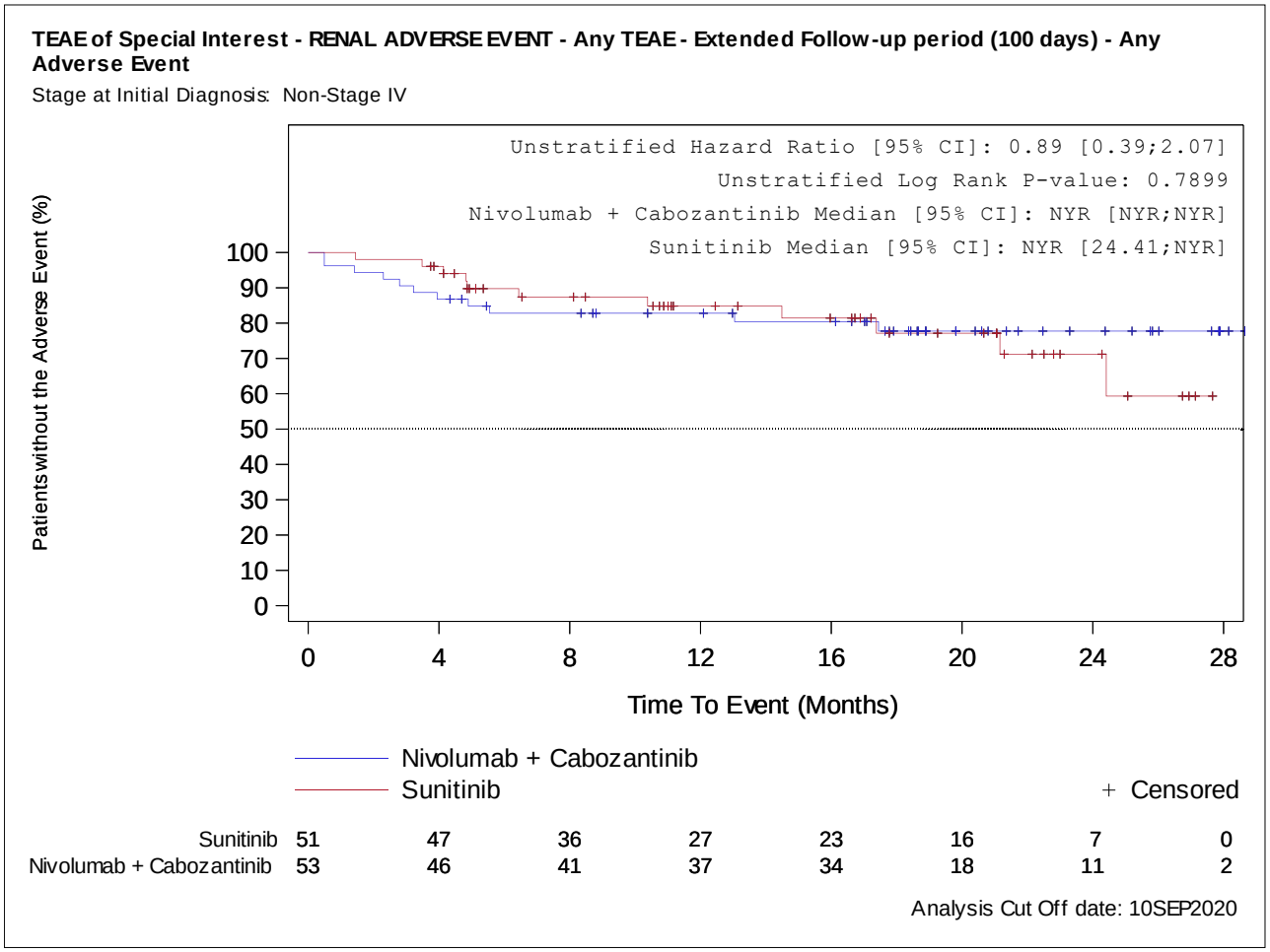

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:20

FIGURE 3.48.2.23: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



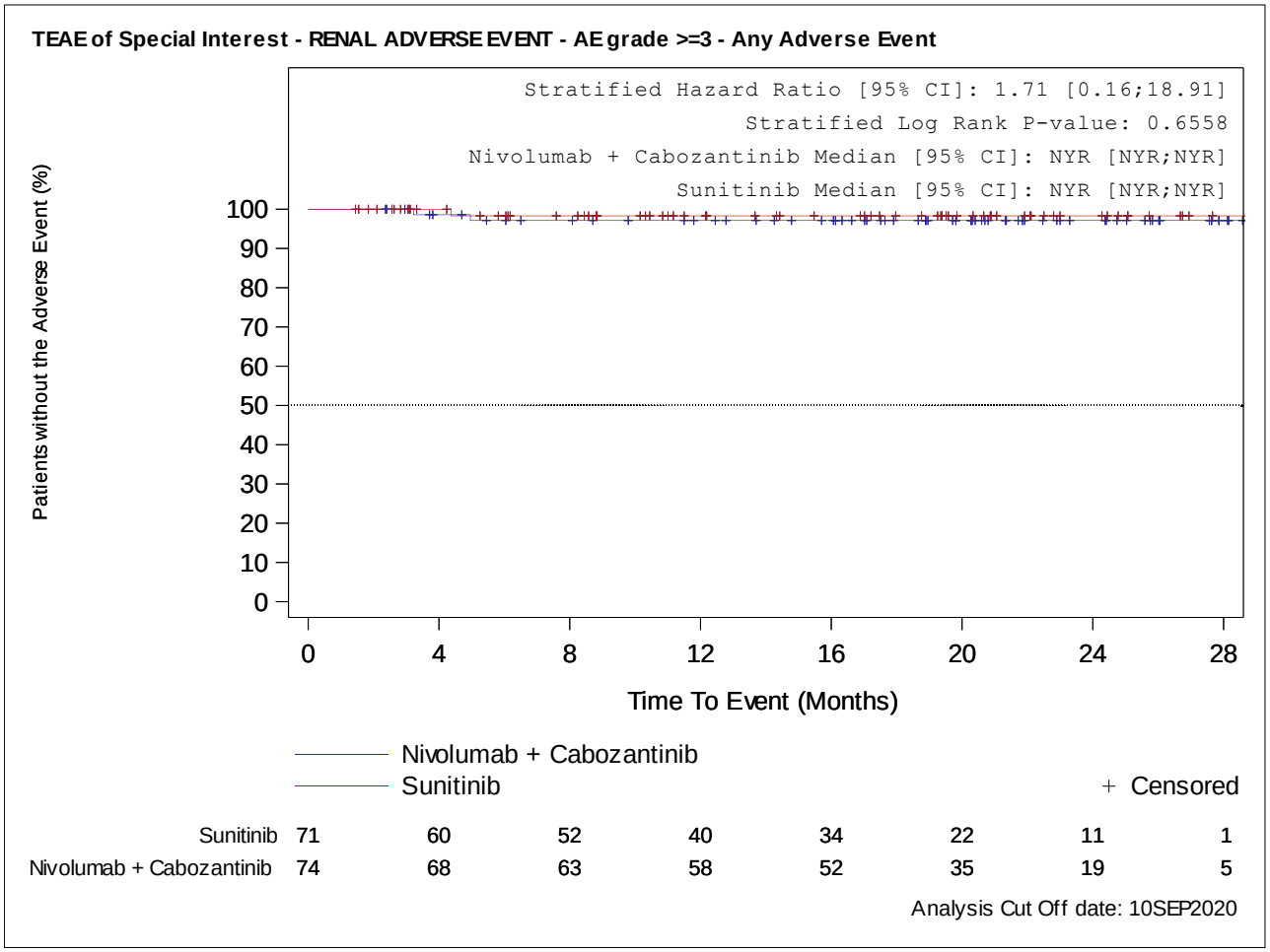

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:46

FIGURE 3.48.2.24: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



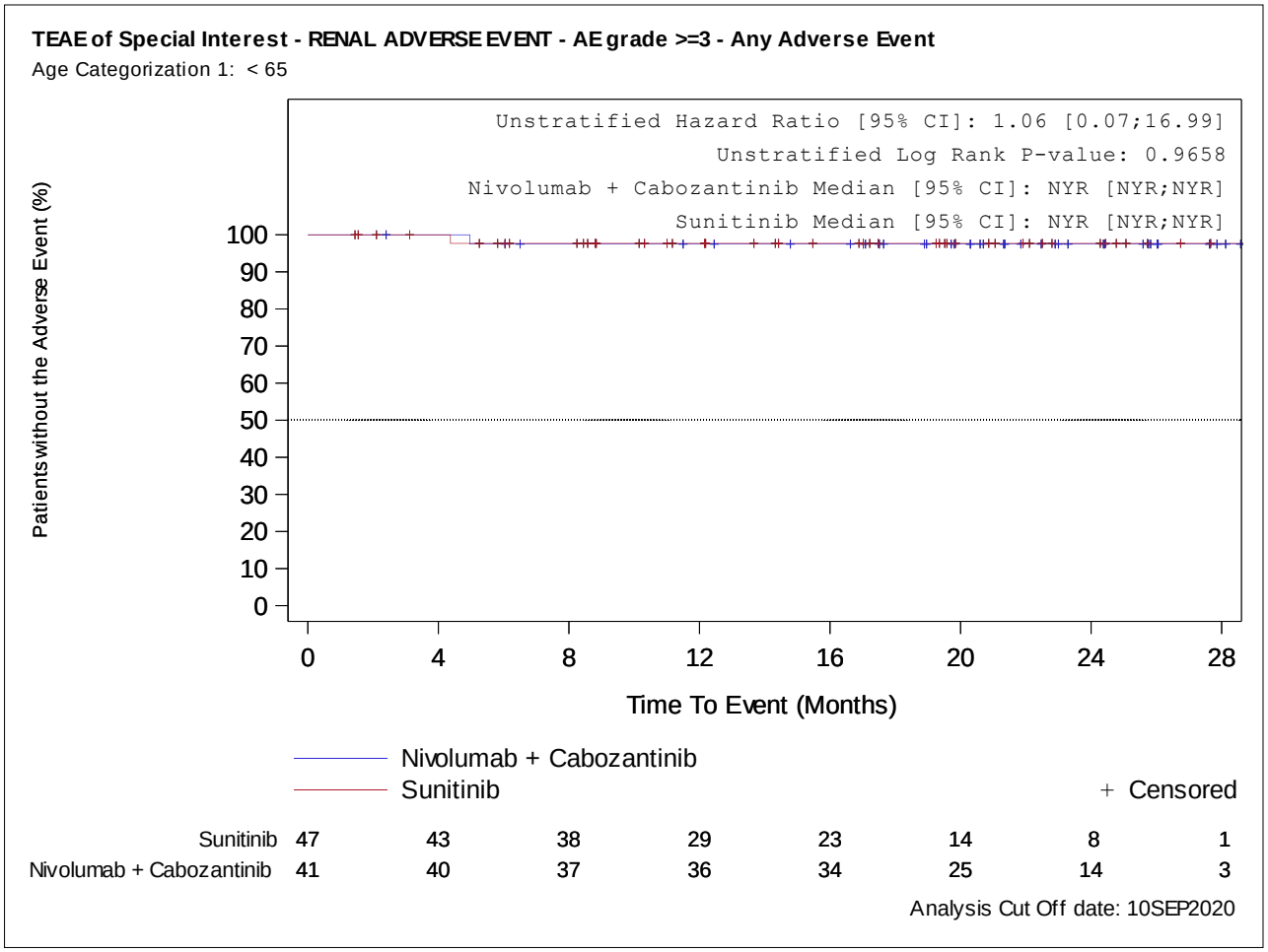

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:51

FIGURE 3.49.1: TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



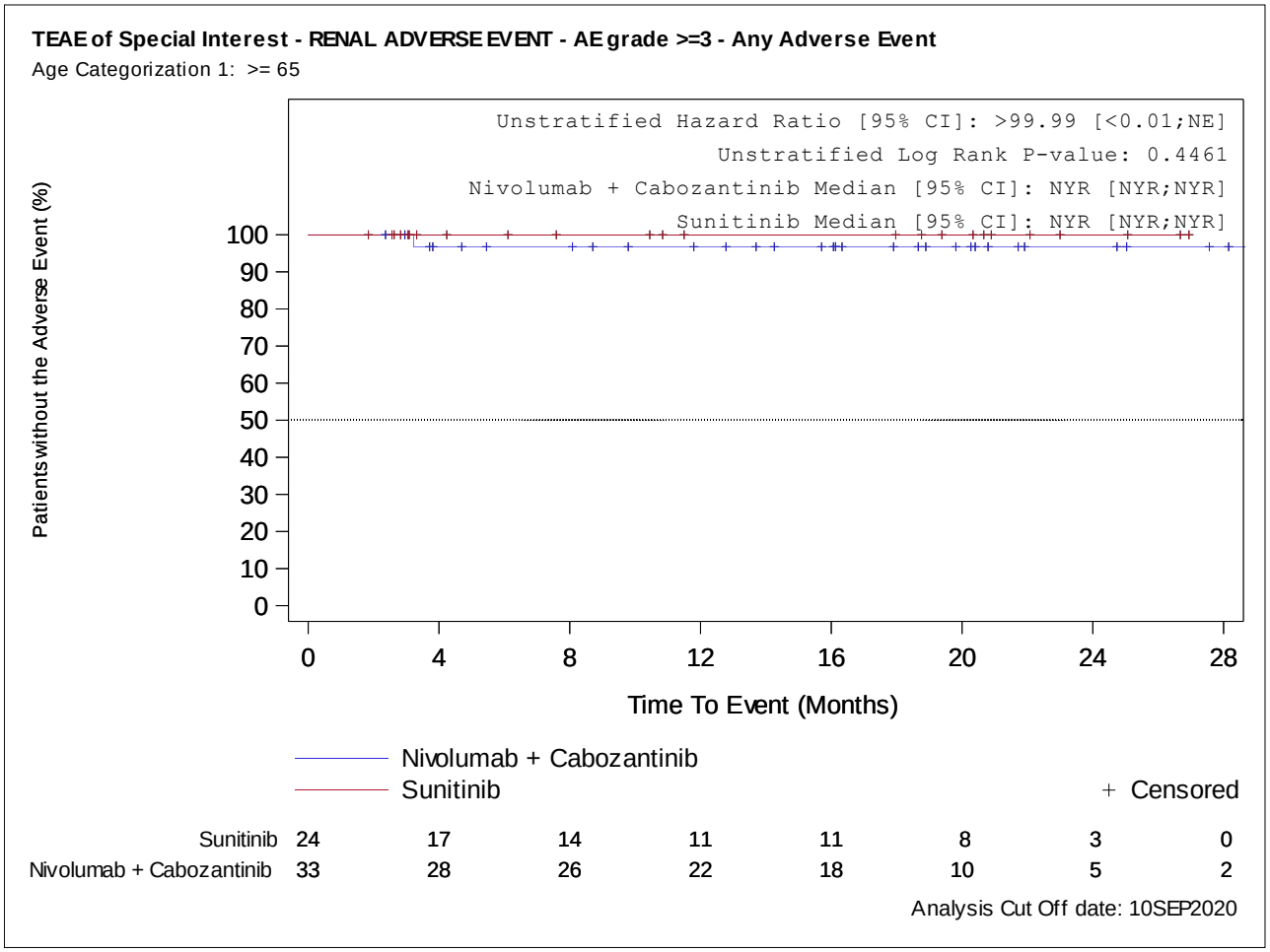

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:07:47

FIGURE 3.49.2.1: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



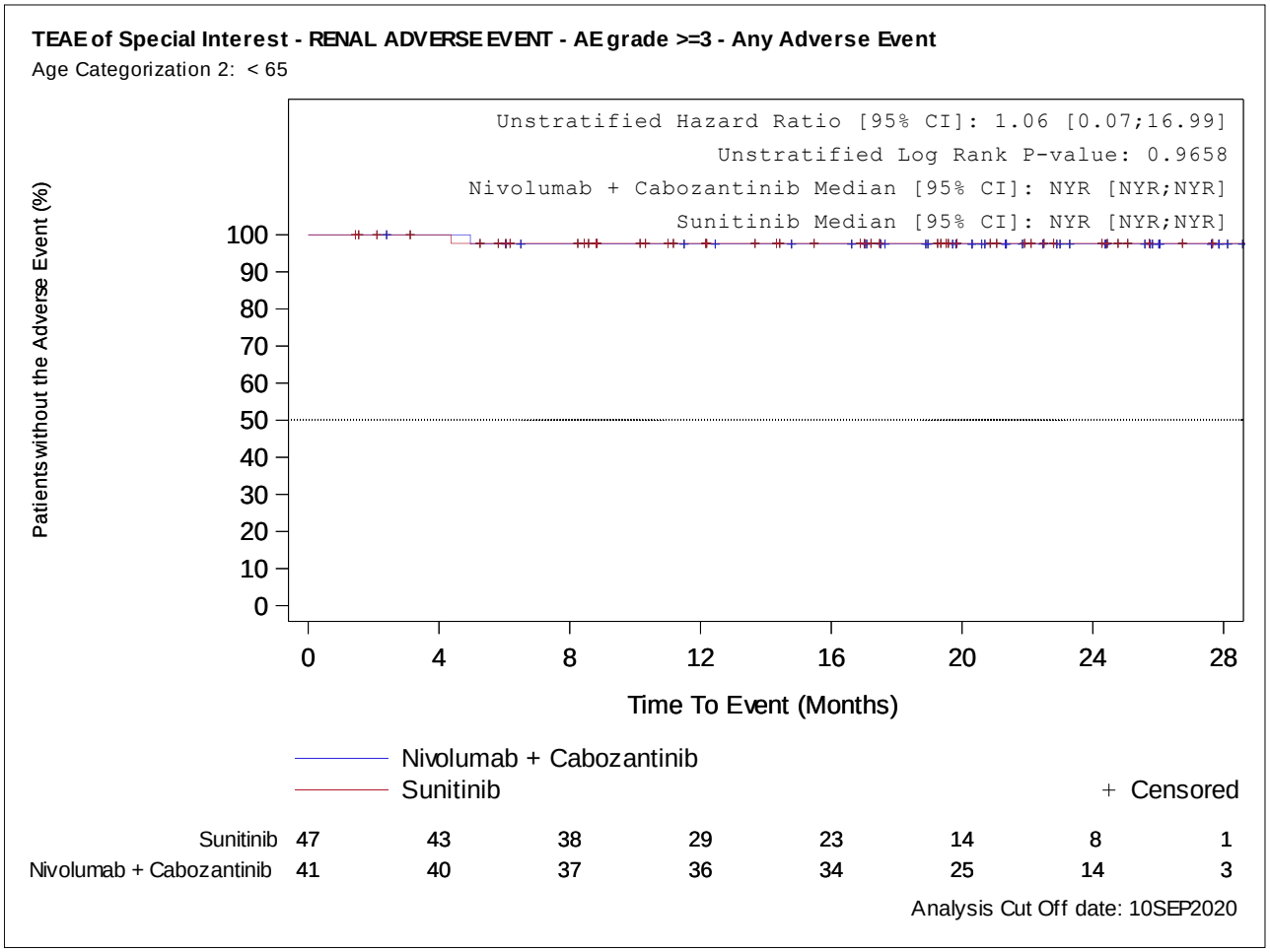

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:07:50

FIGURE 3.49.2.2: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



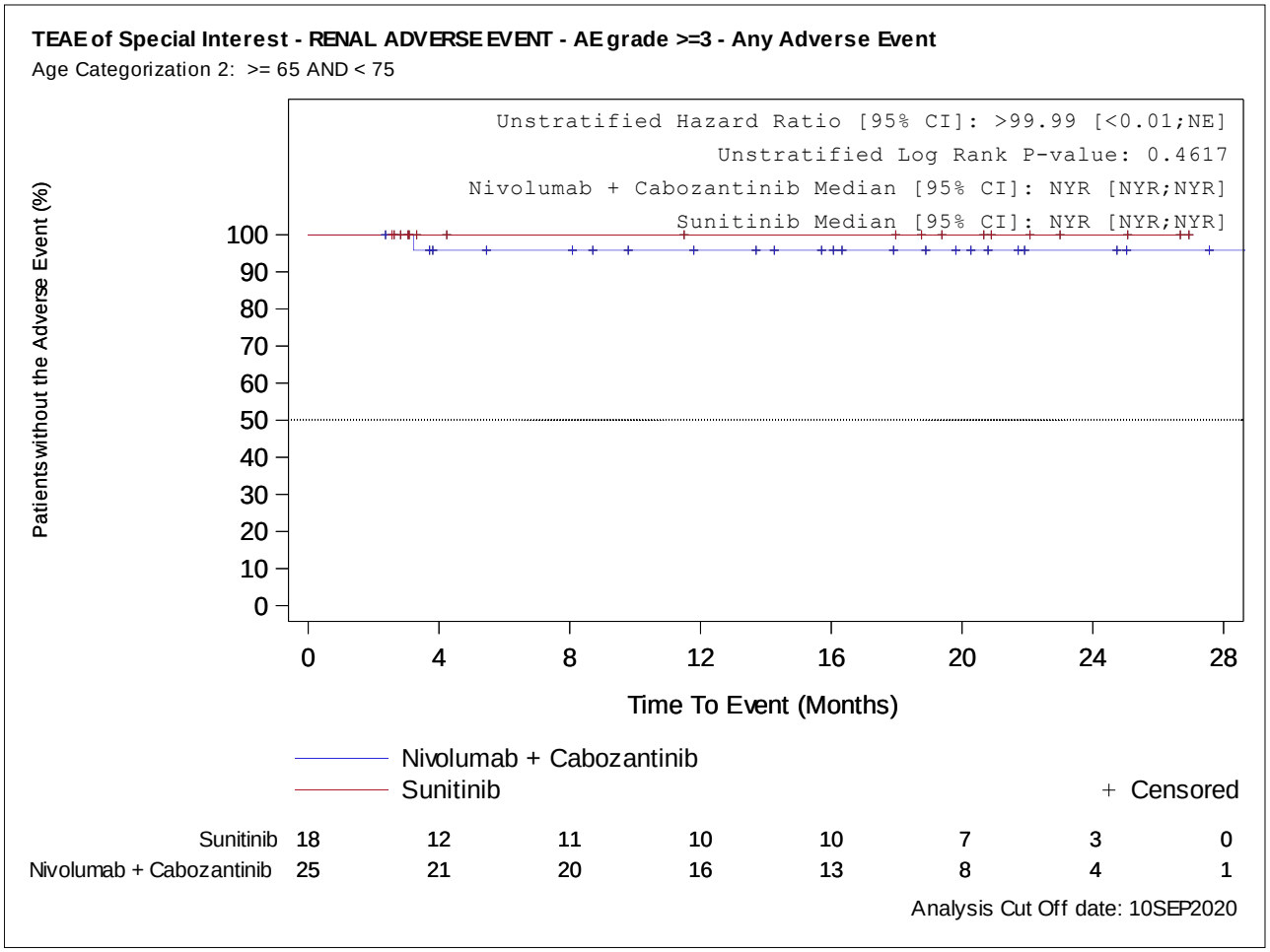

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:07:56

FIGURE 3.49.2.3: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



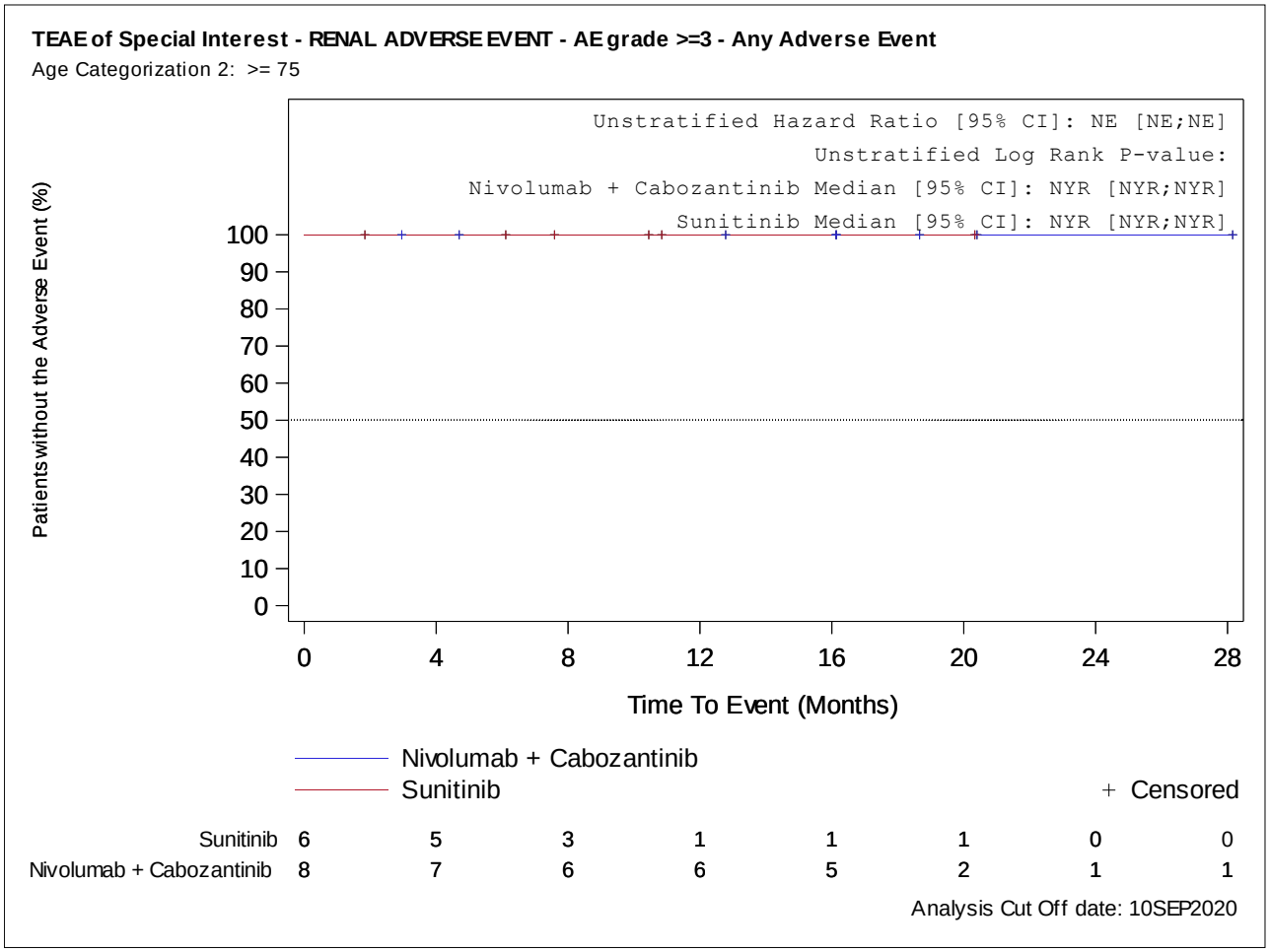

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:08:01

FIGURE 3.49.2.4: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



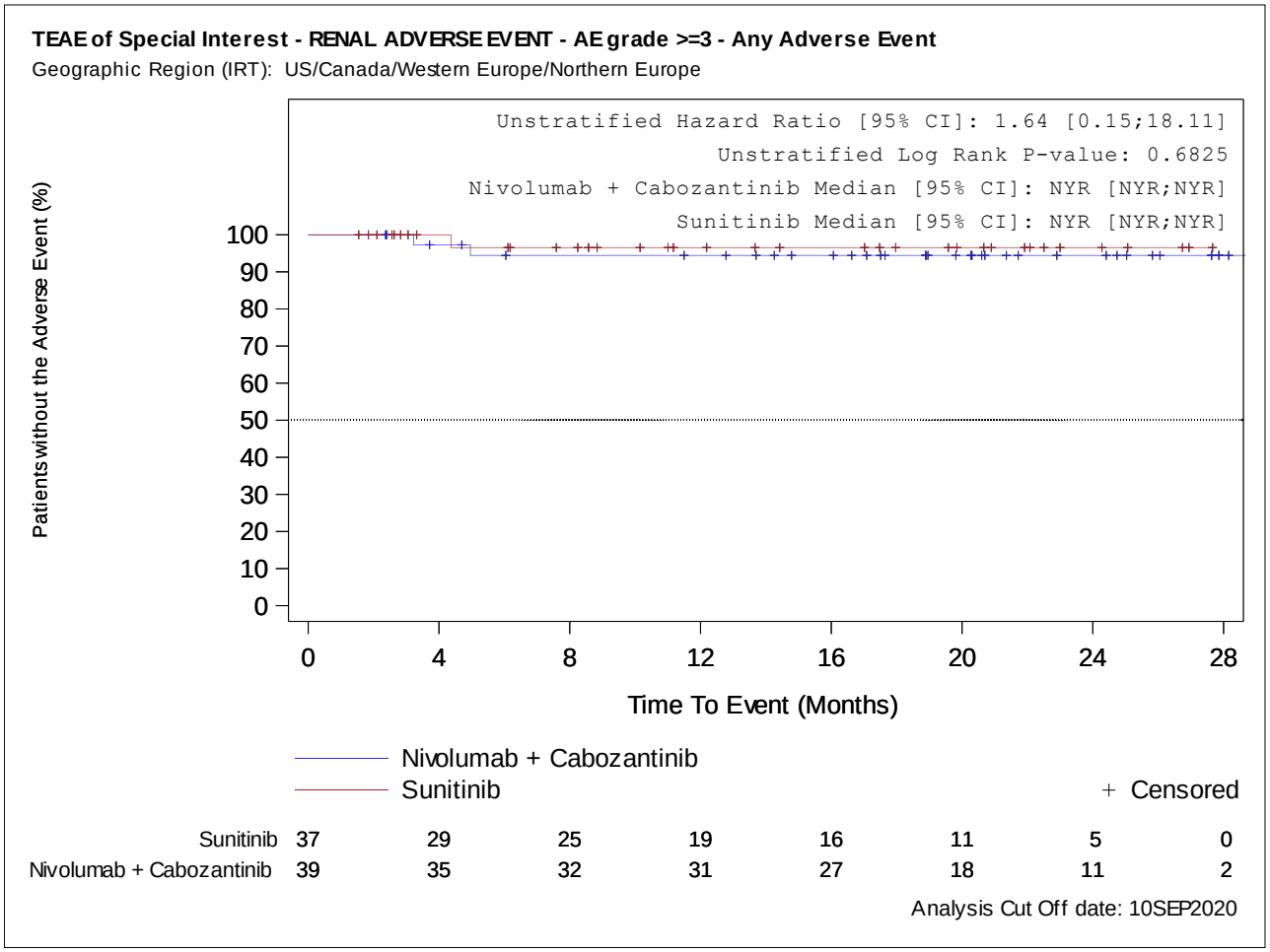

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:08:06

FIGURE 3.49.2.5: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



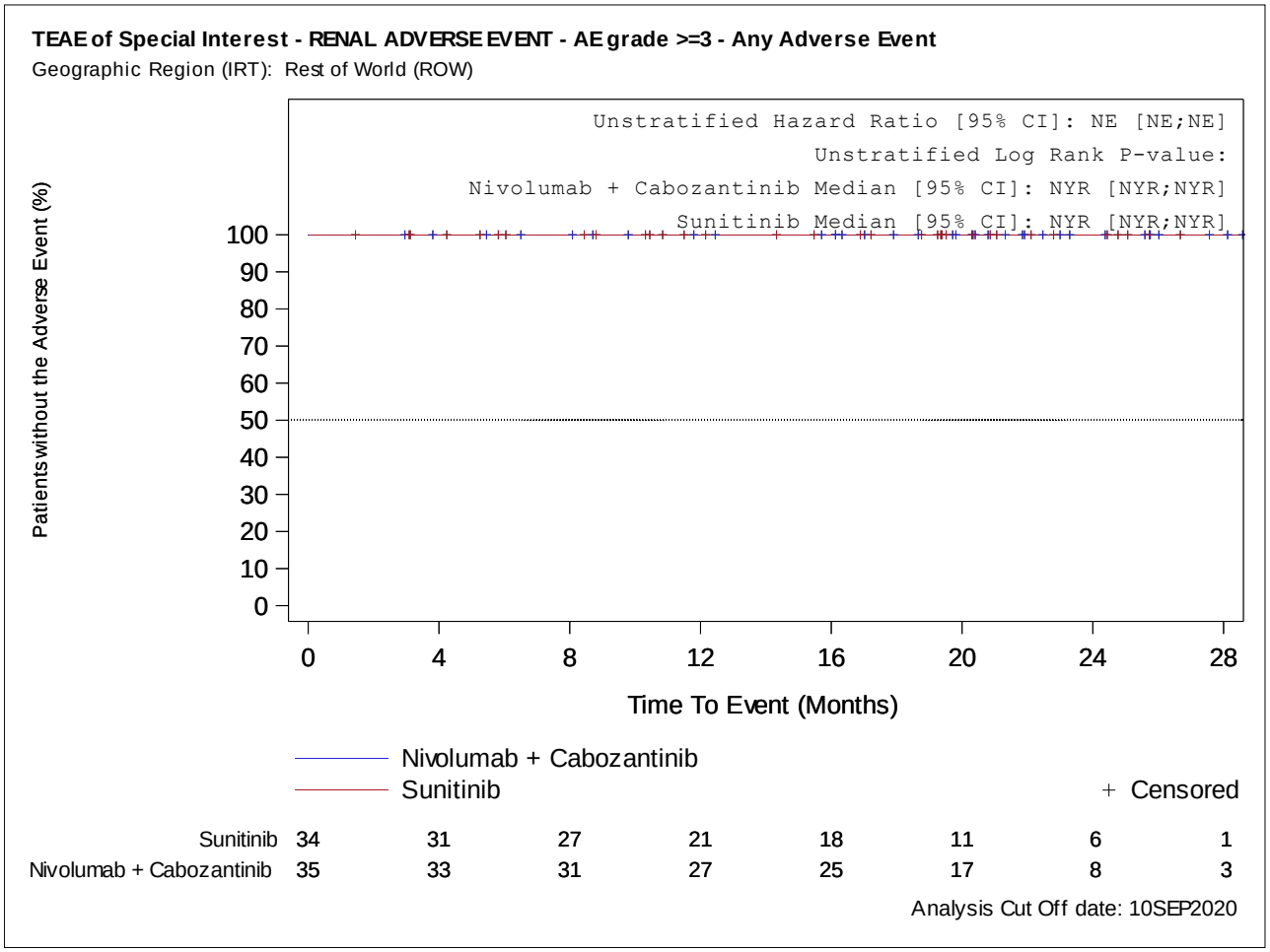

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:08:11

FIGURE 3.49.2.6: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



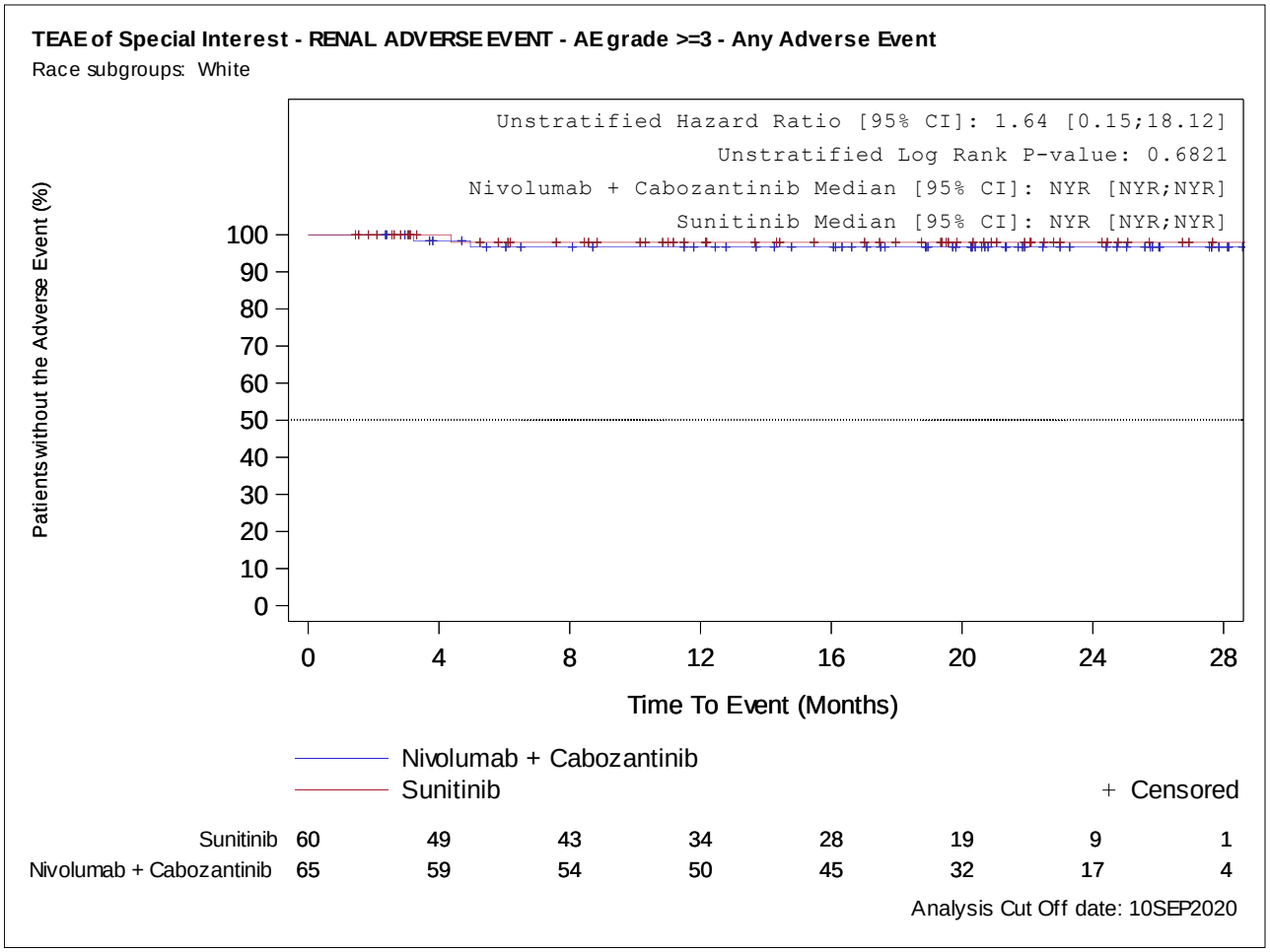

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:08:16

FIGURE 3.49.2.7: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



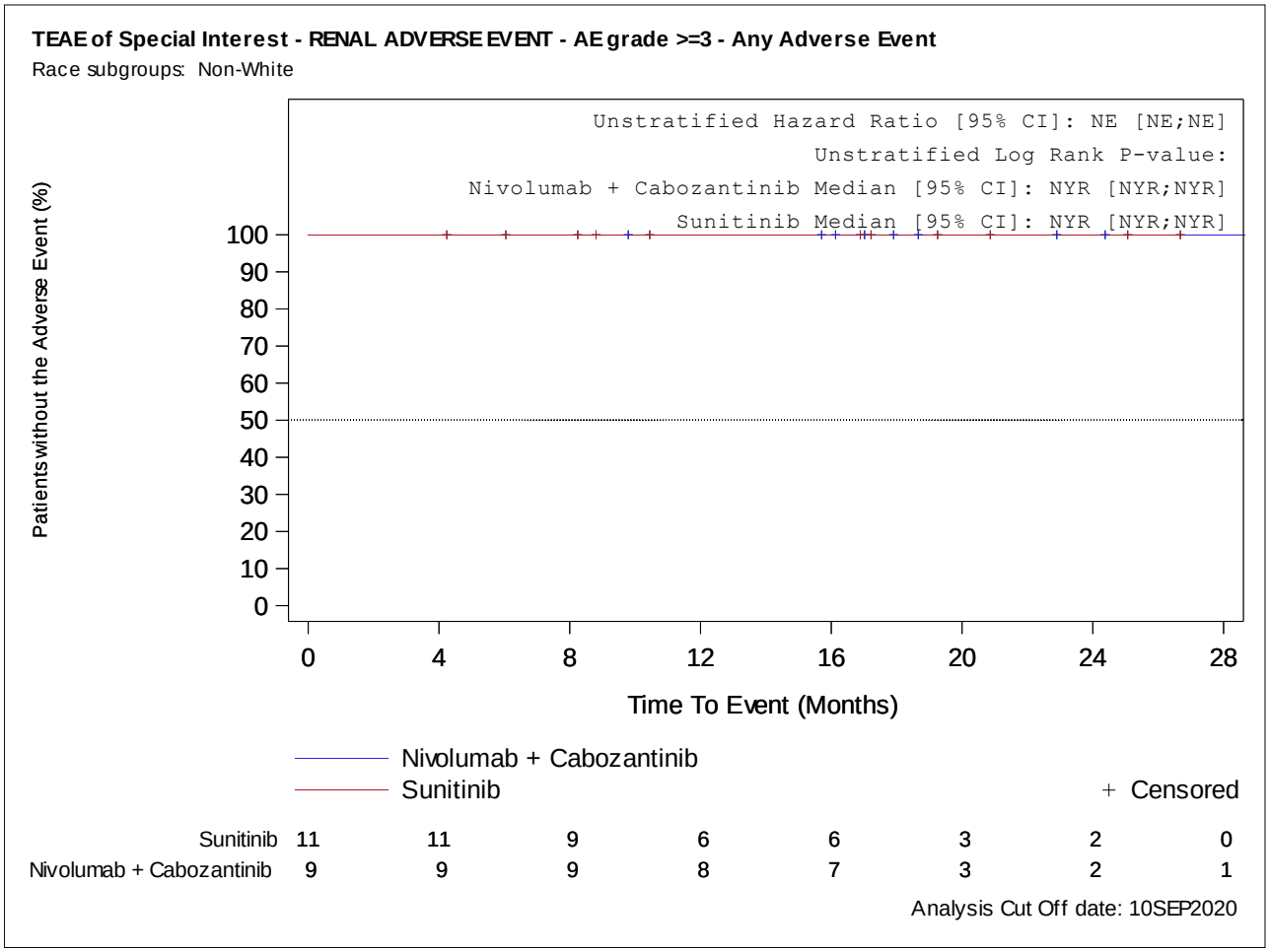

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:08:21

FIGURE 3.49.2.8: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



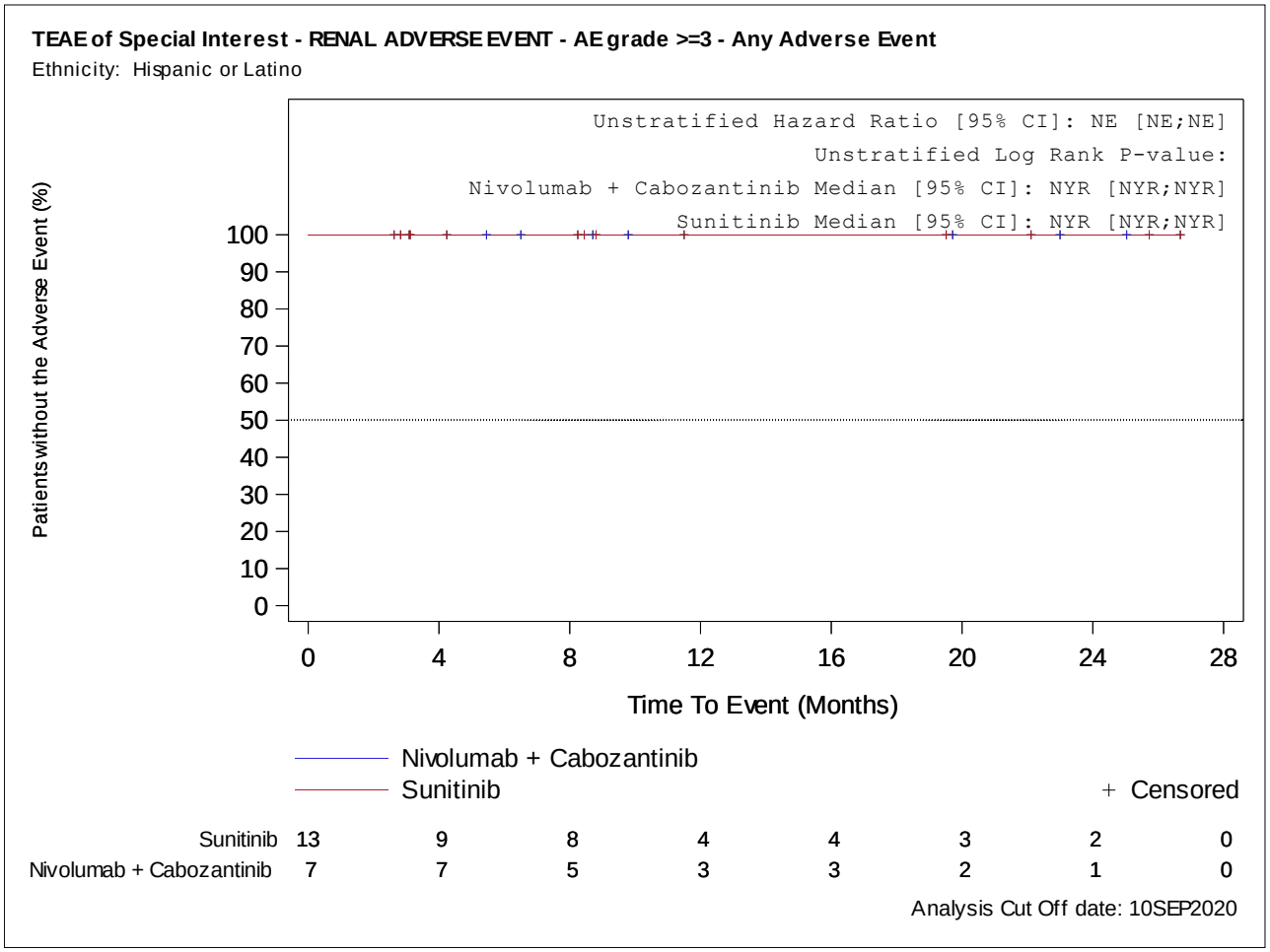

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:08:27

FIGURE 3.49.2.9: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



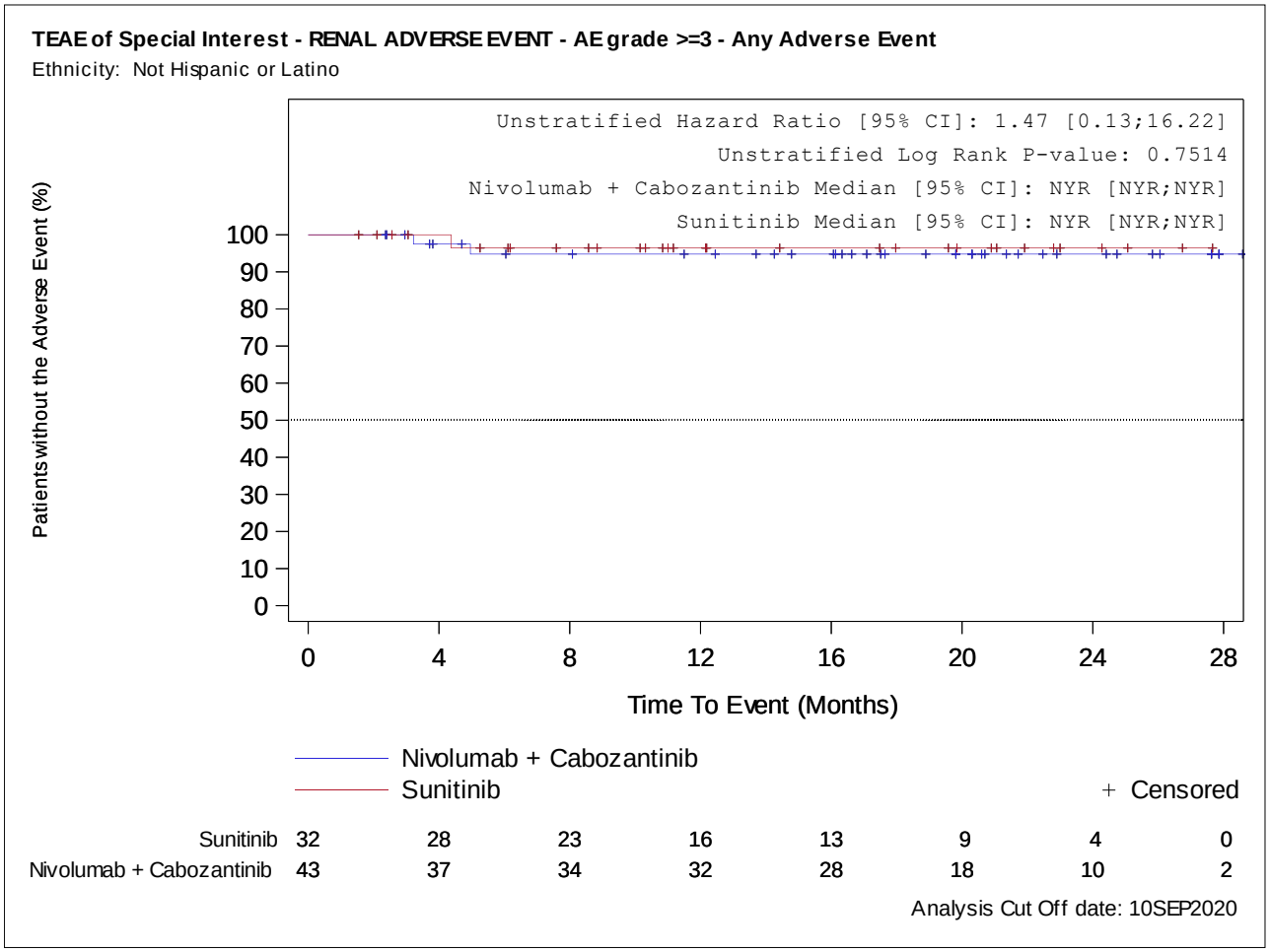

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:08:32

FIGURE 3.49.2.10: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



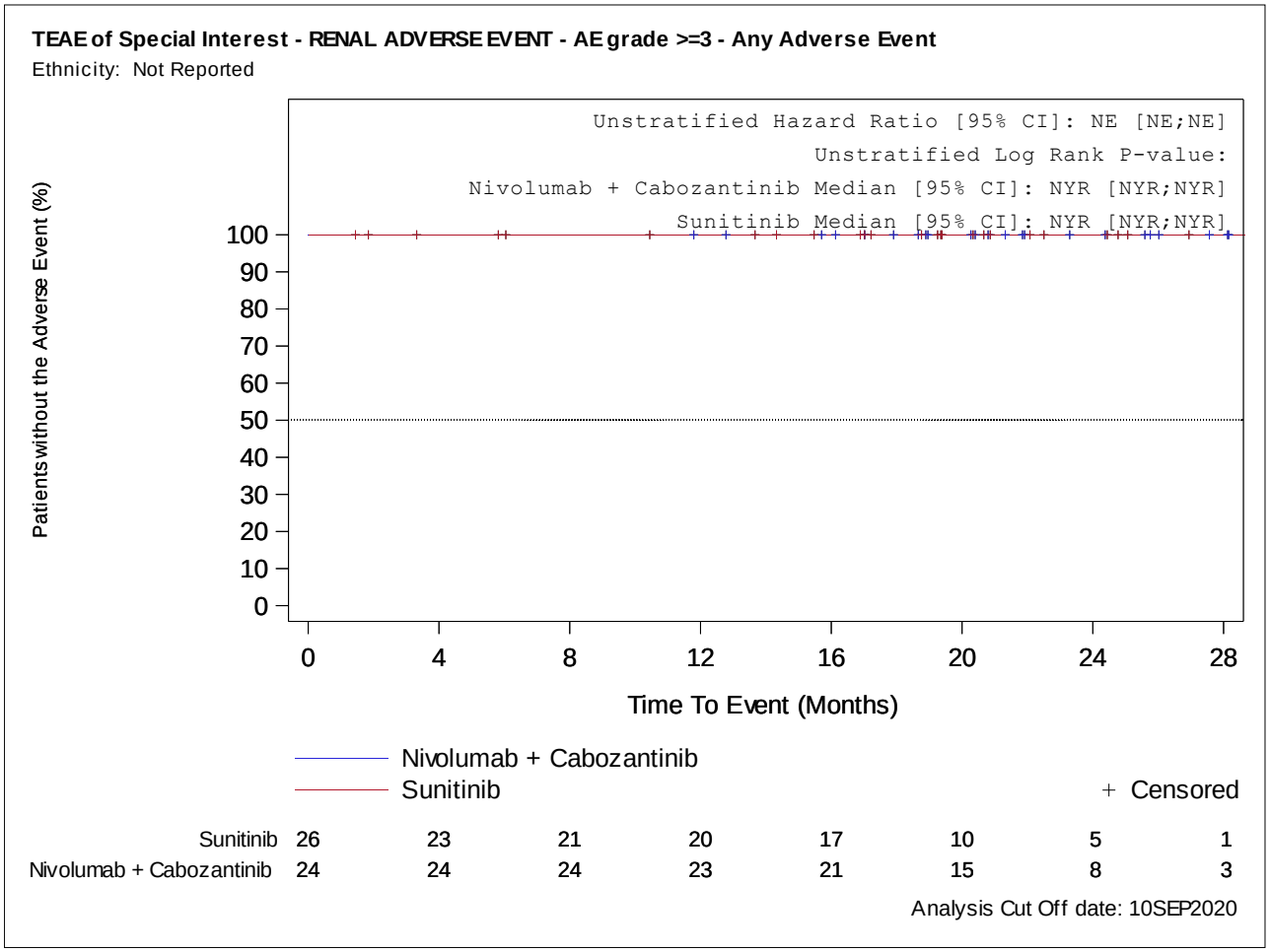

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:08:37

FIGURE 3.49.2.11: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



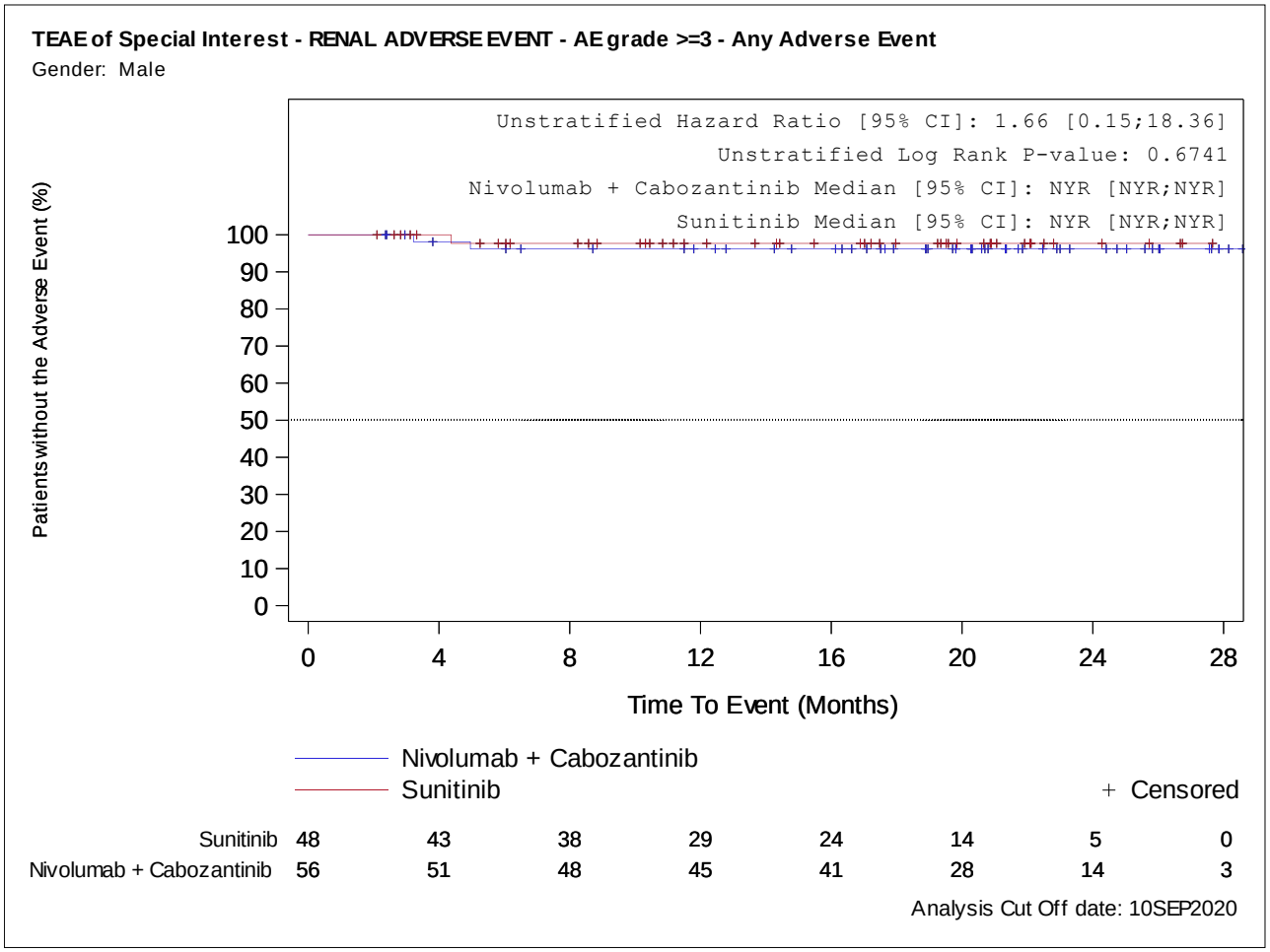

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:08:42

FIGURE 3.49.2.12: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



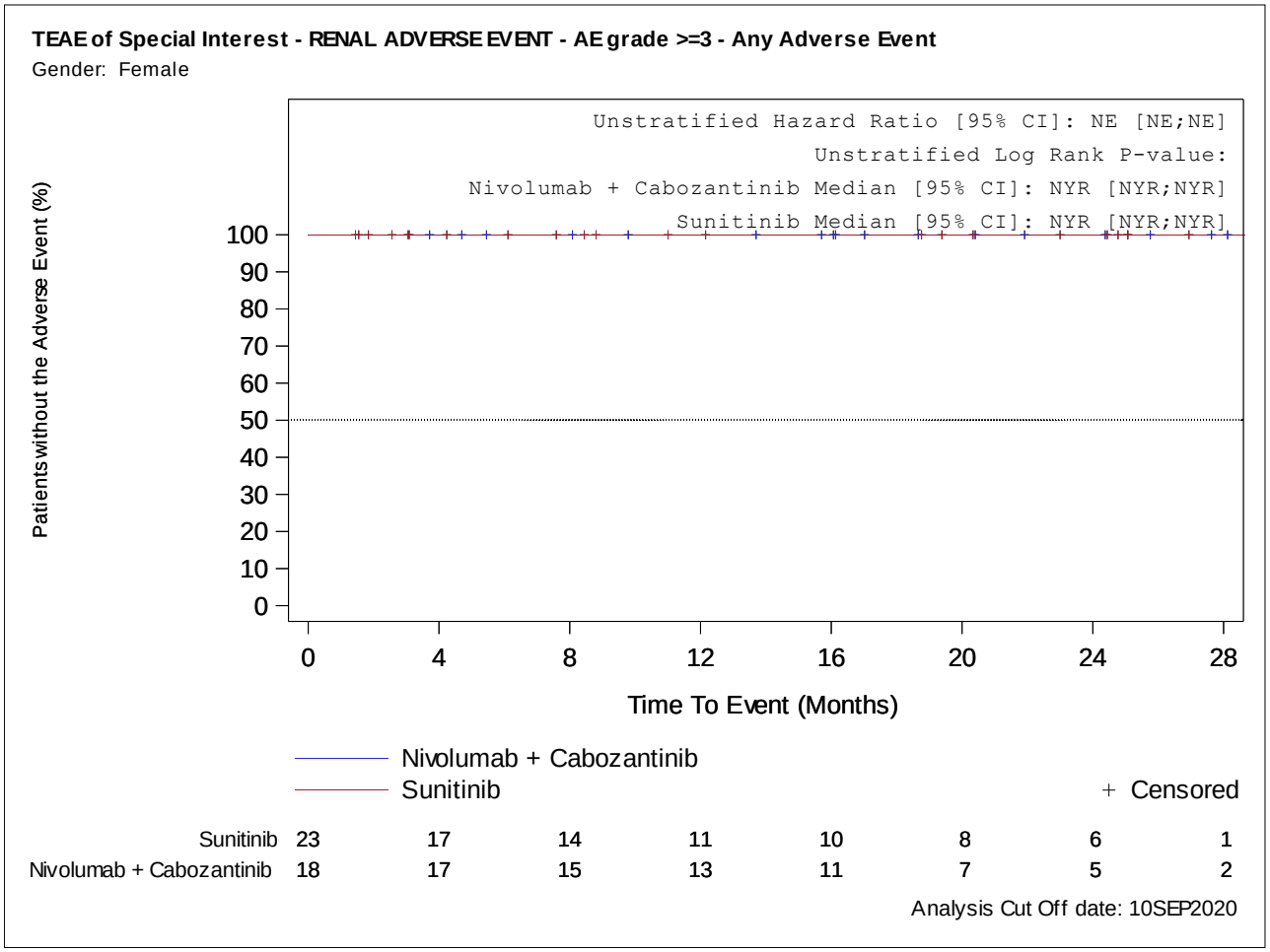

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:08:48

FIGURE 3.49.2.13: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



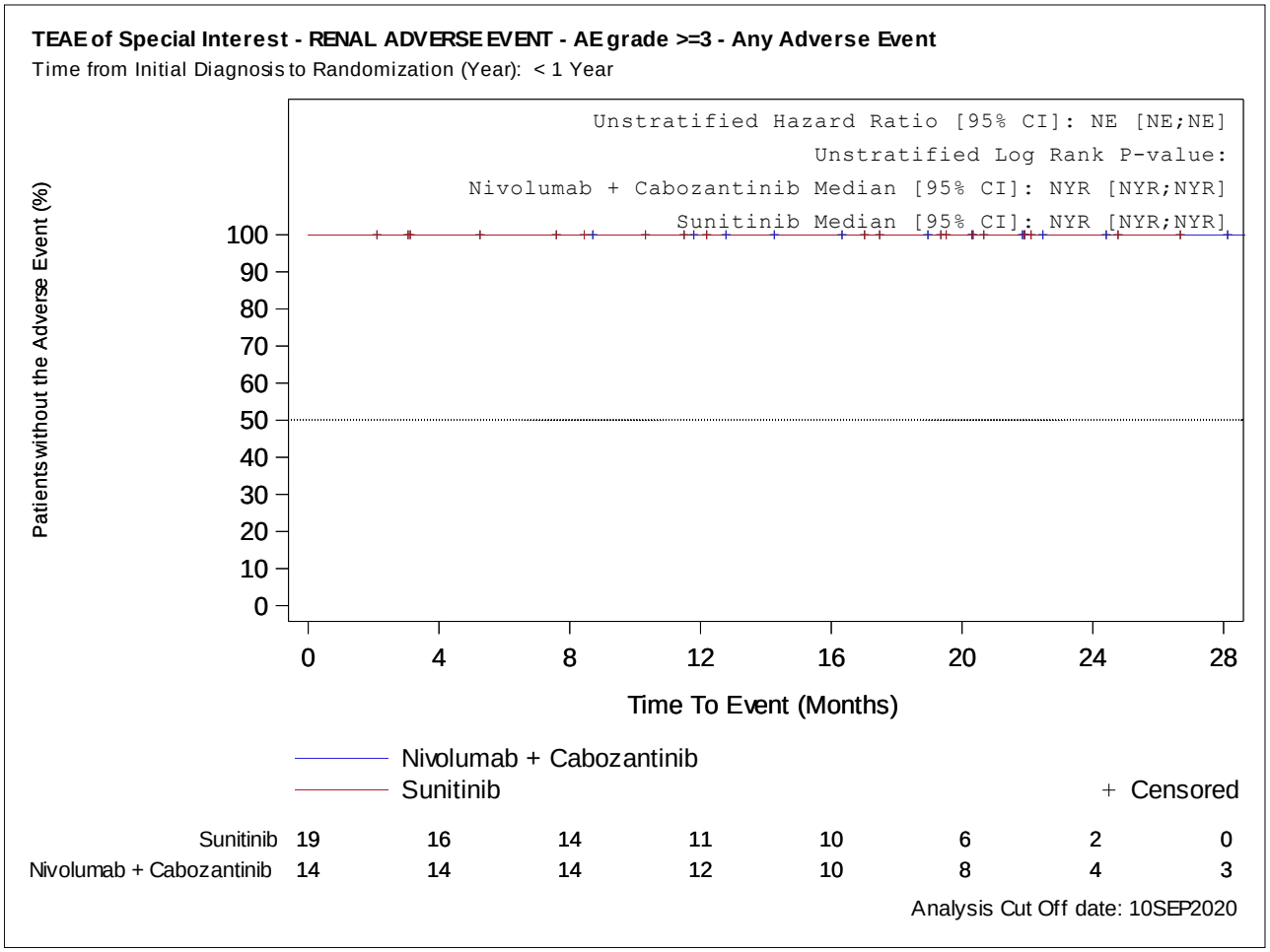

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:08:53

FIGURE 3.49.2.14: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



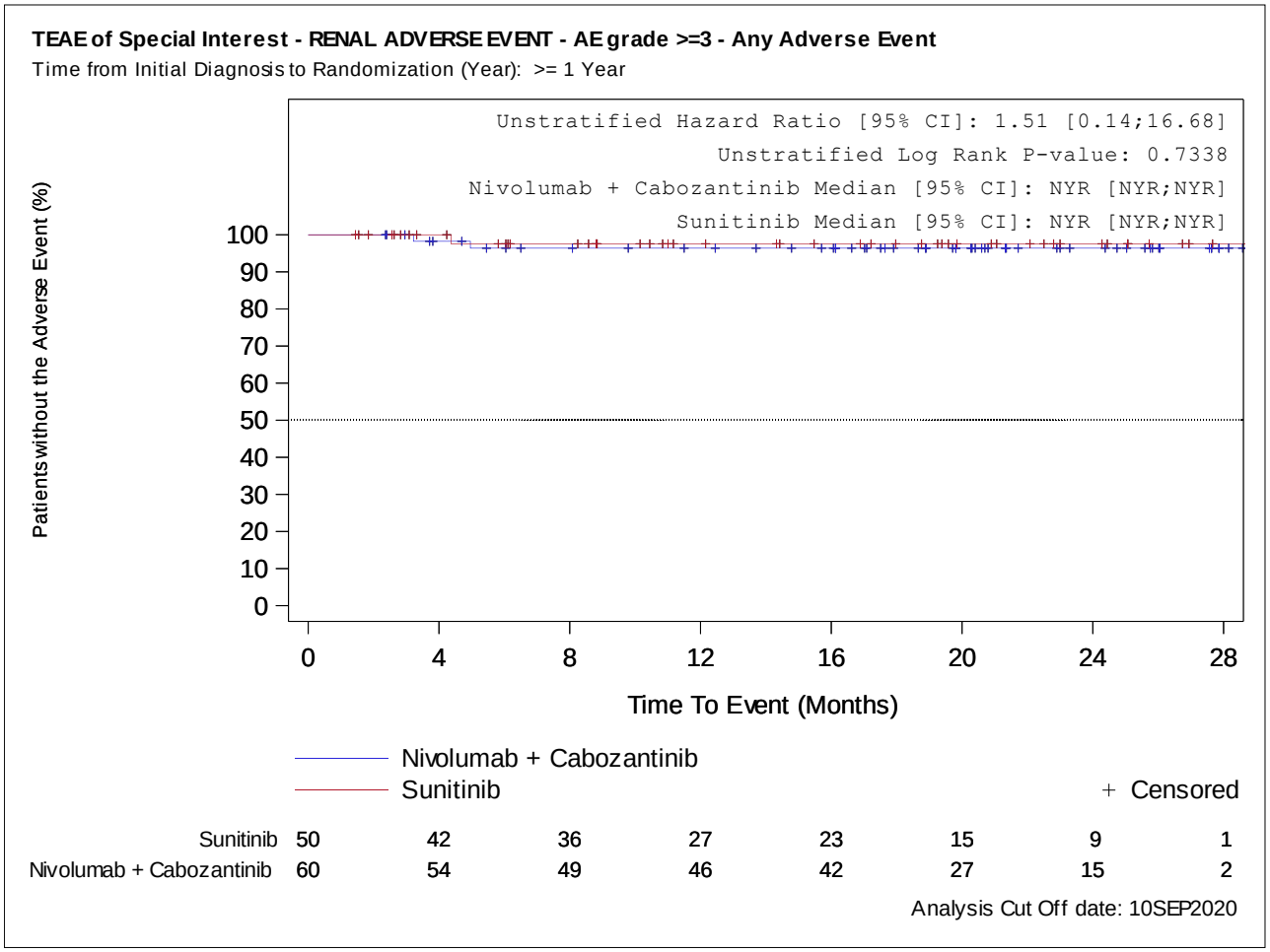

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:08:58

FIGURE 3.49.2.15: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



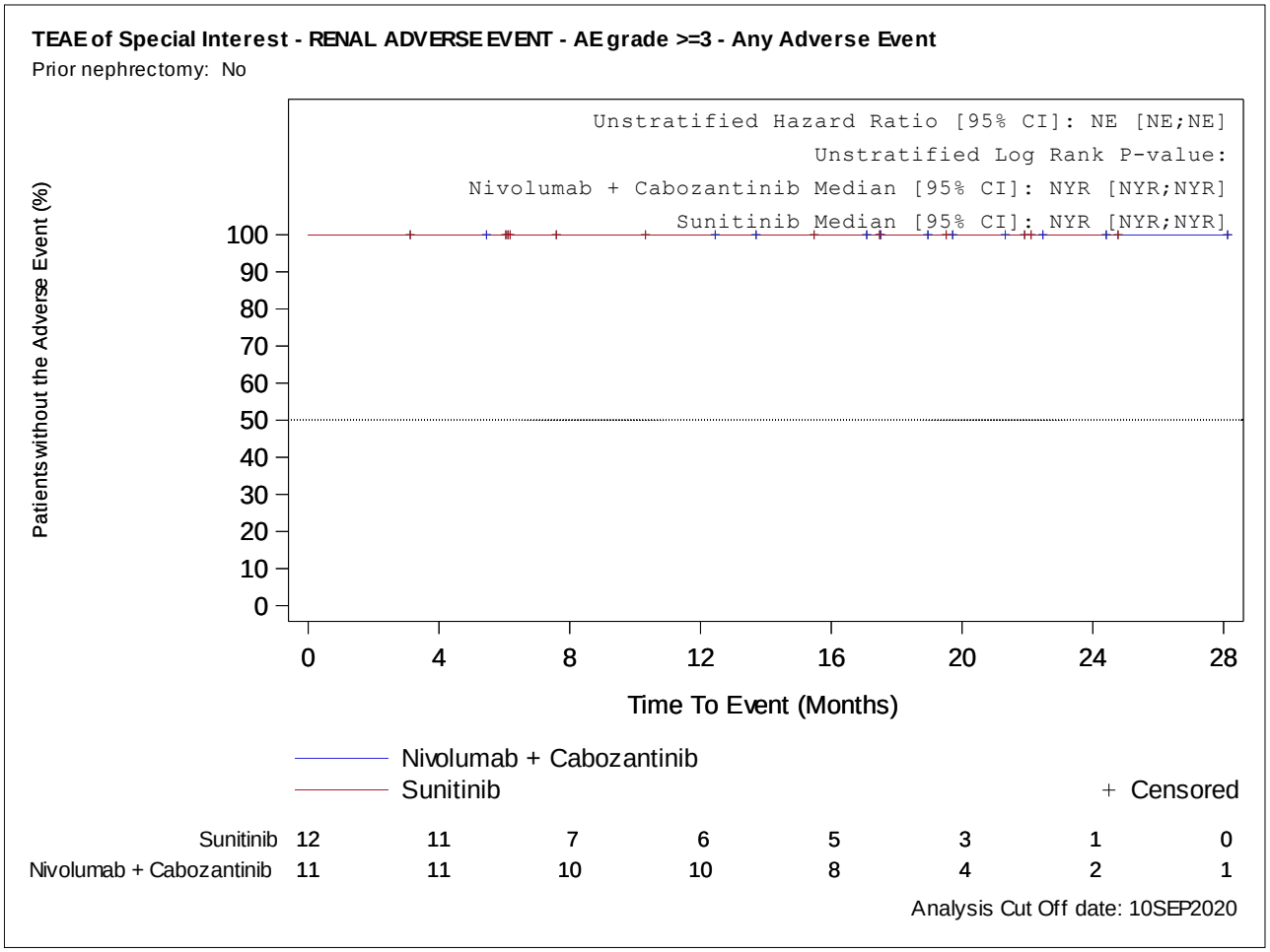

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:09:14

FIGURE 3.49.2.16: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



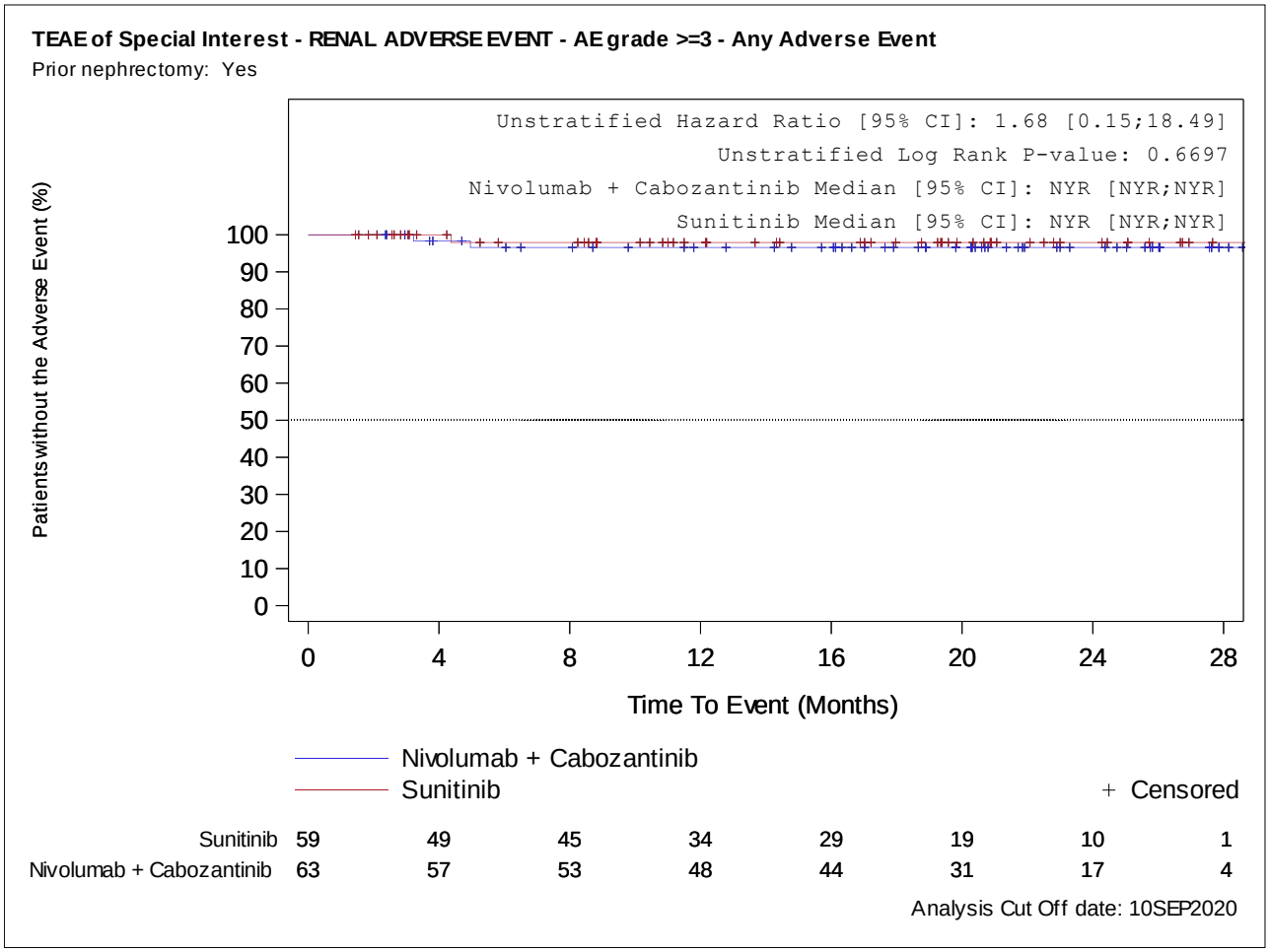

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:09:19

FIGURE 3.49.2.17: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



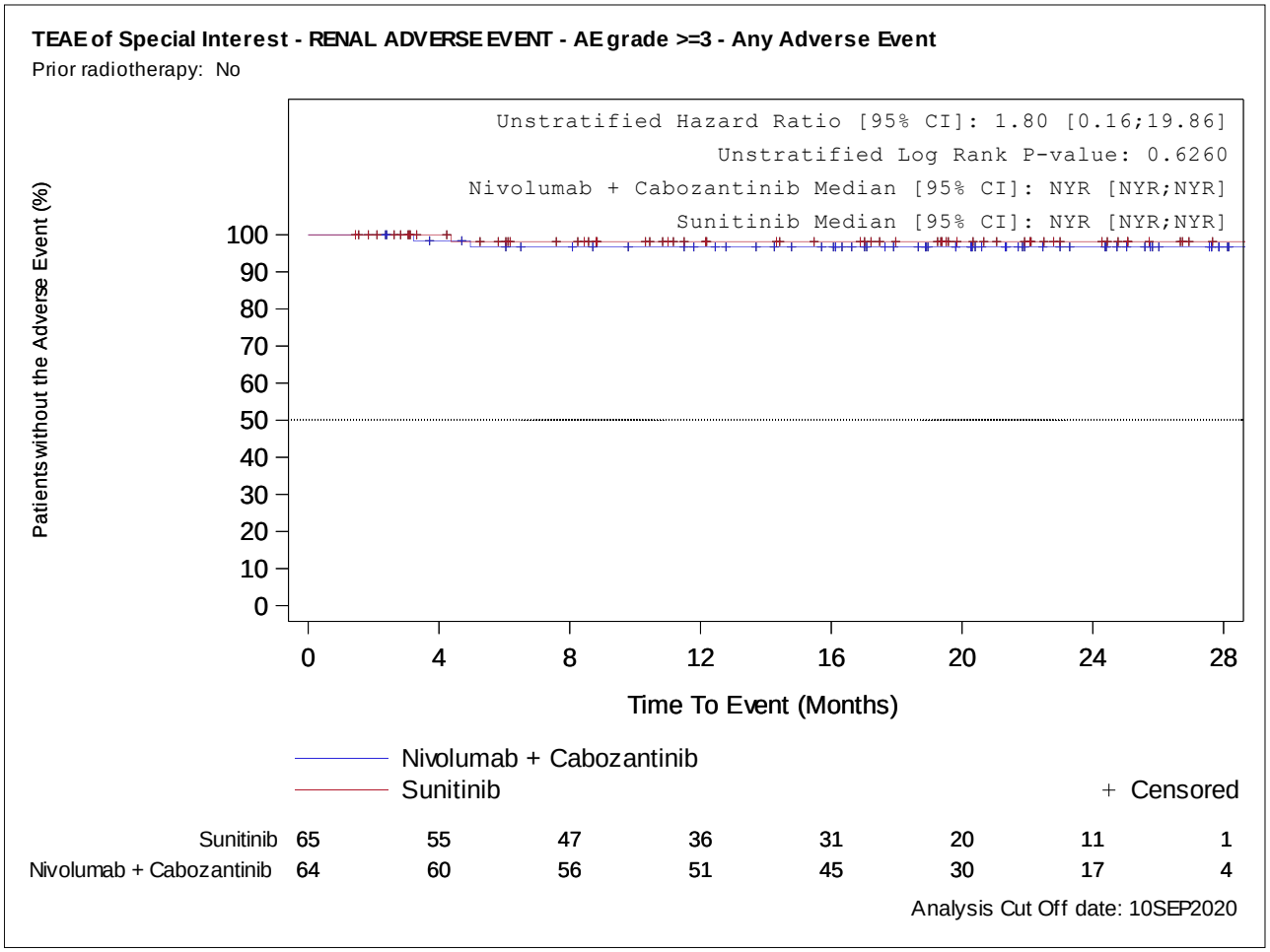

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:06

FIGURE 3.49.2.18: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



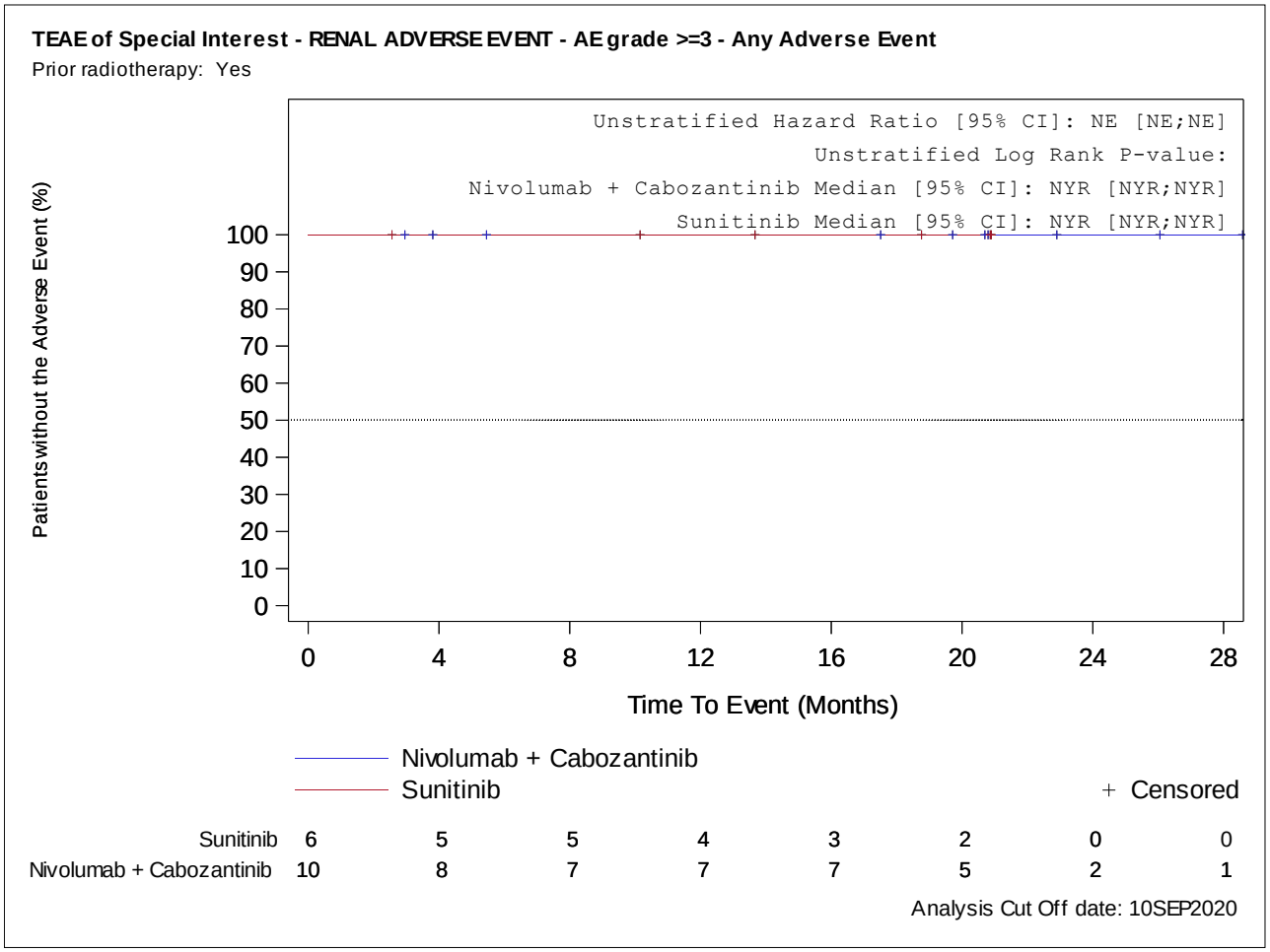

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:11

FIGURE 3.49.2.19: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



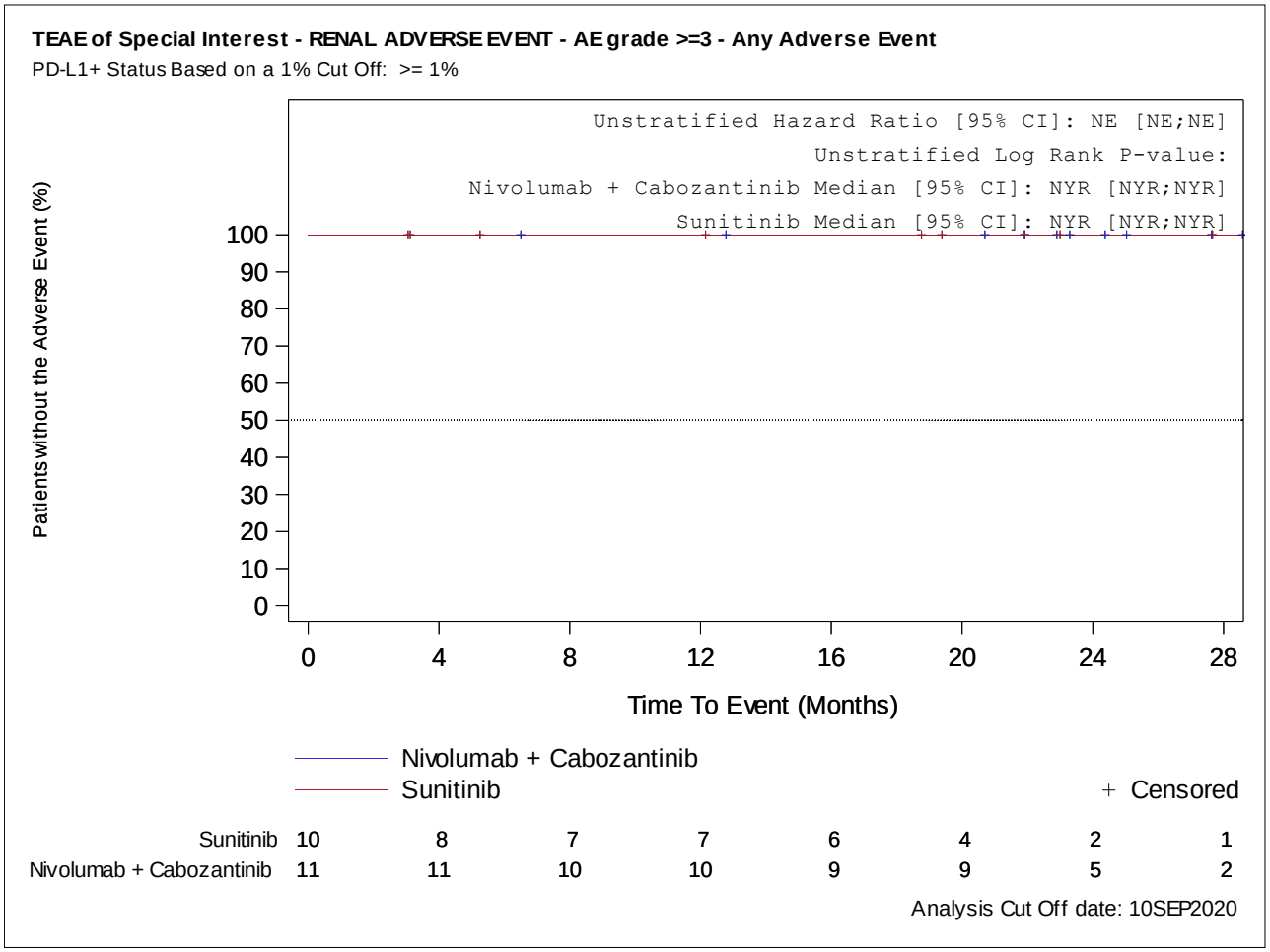

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:16

FIGURE 3.49.2.20: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



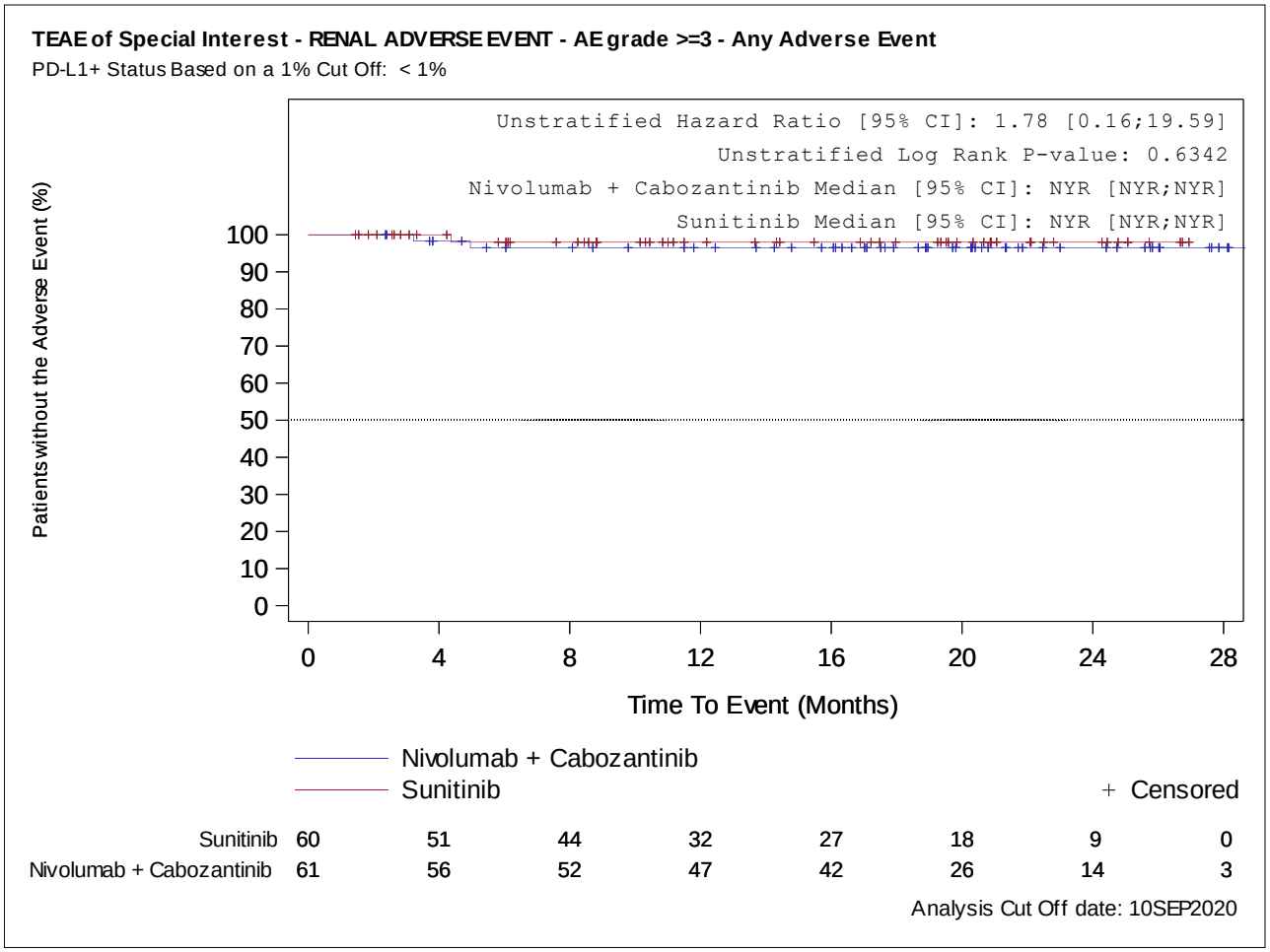

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:21

FIGURE 3.49.2.21: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



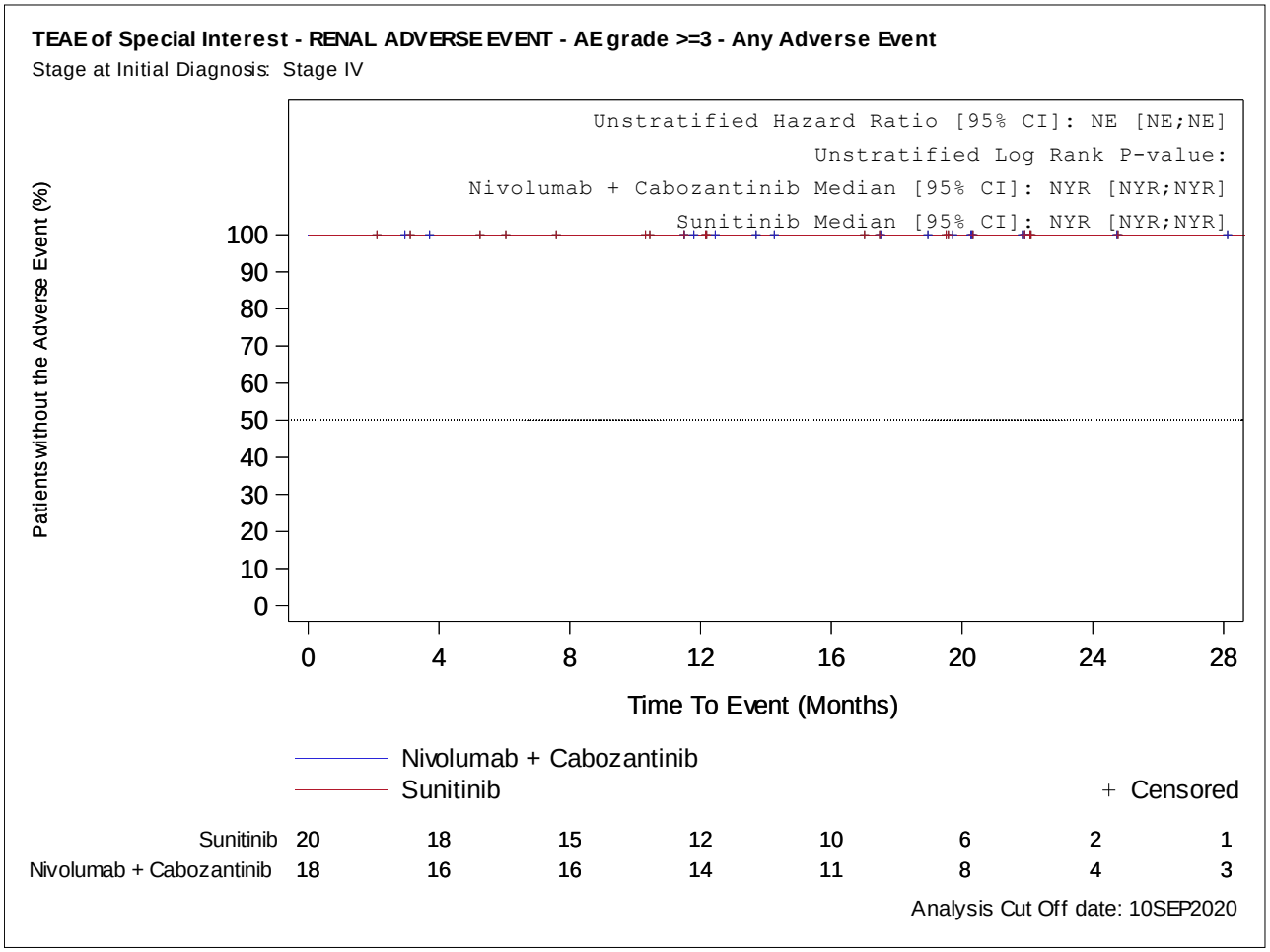

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:27

FIGURE 3.49.2.22: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



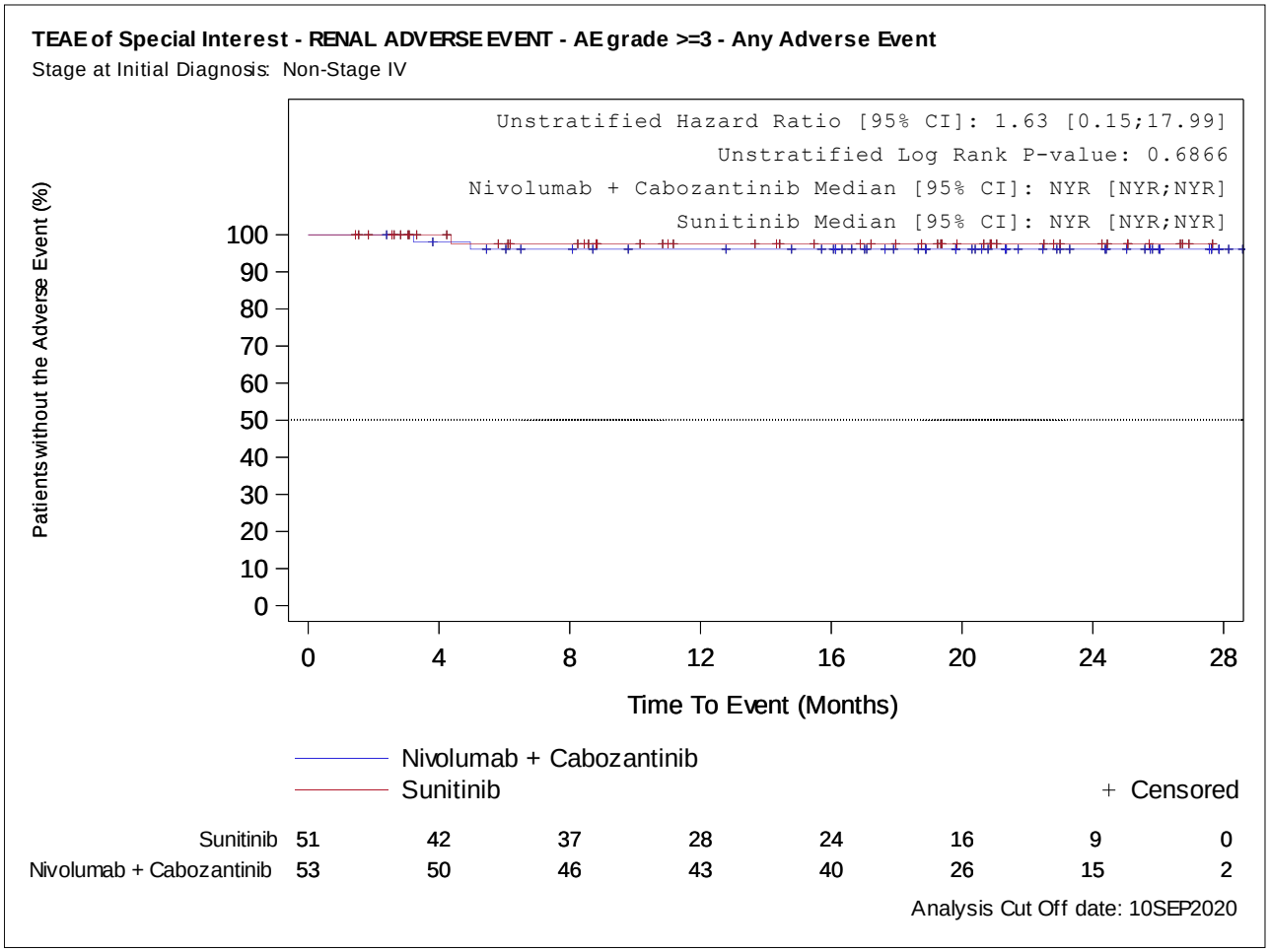

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:32

FIGURE 3.49.2.23: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



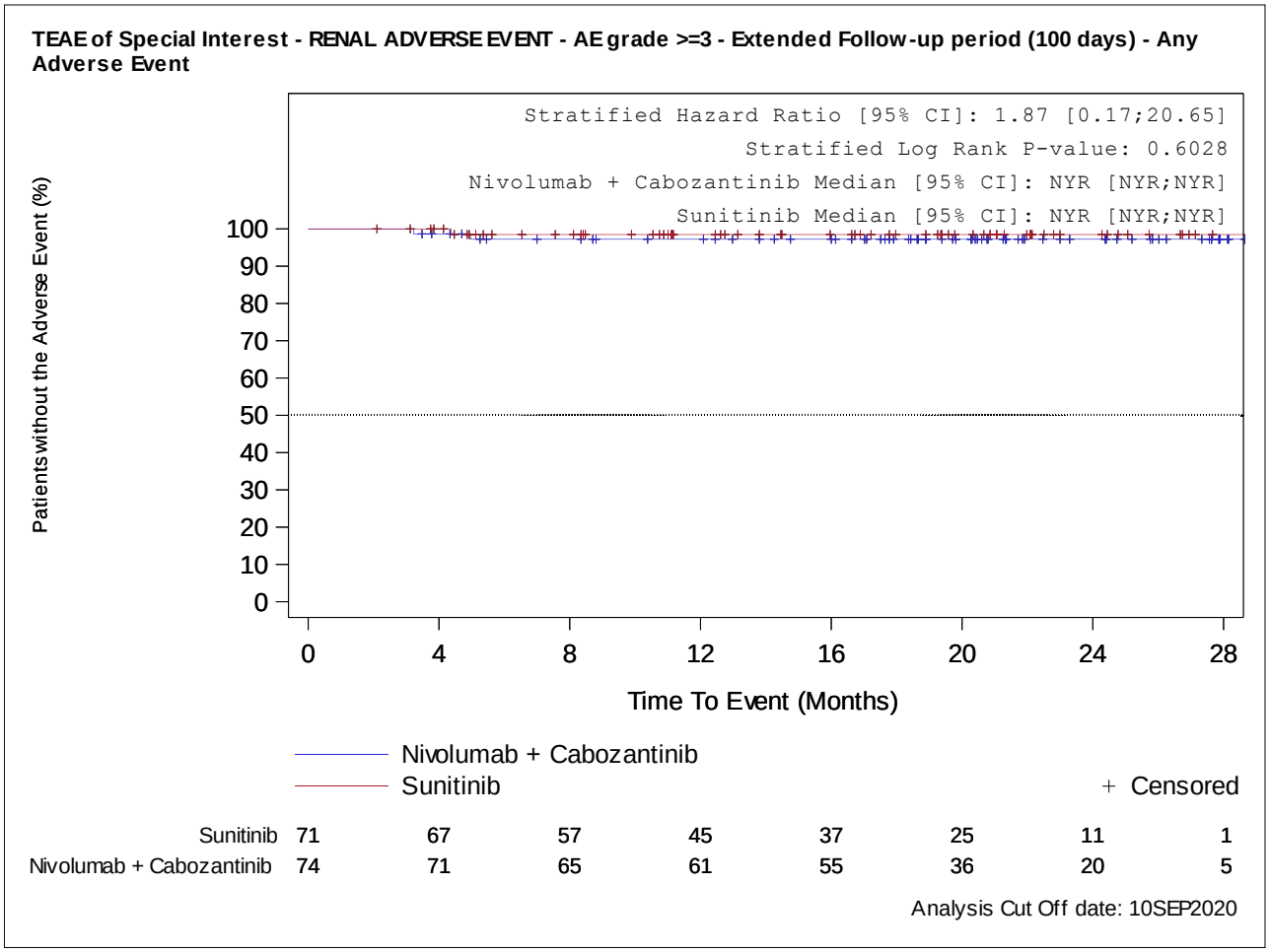

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:57

FIGURE 3.49.2.24: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



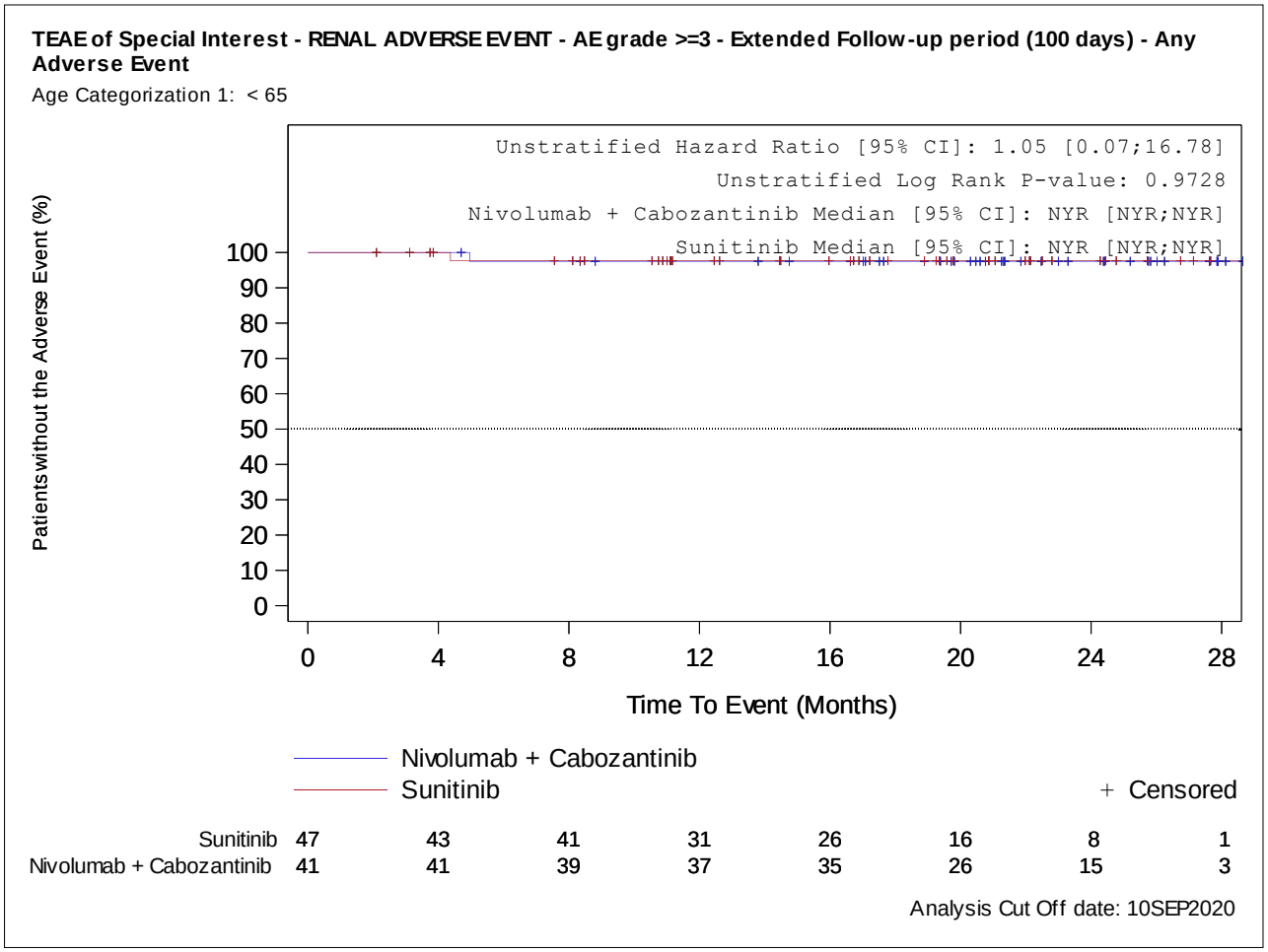

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:11:03

FIGURE 3.50.1: TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



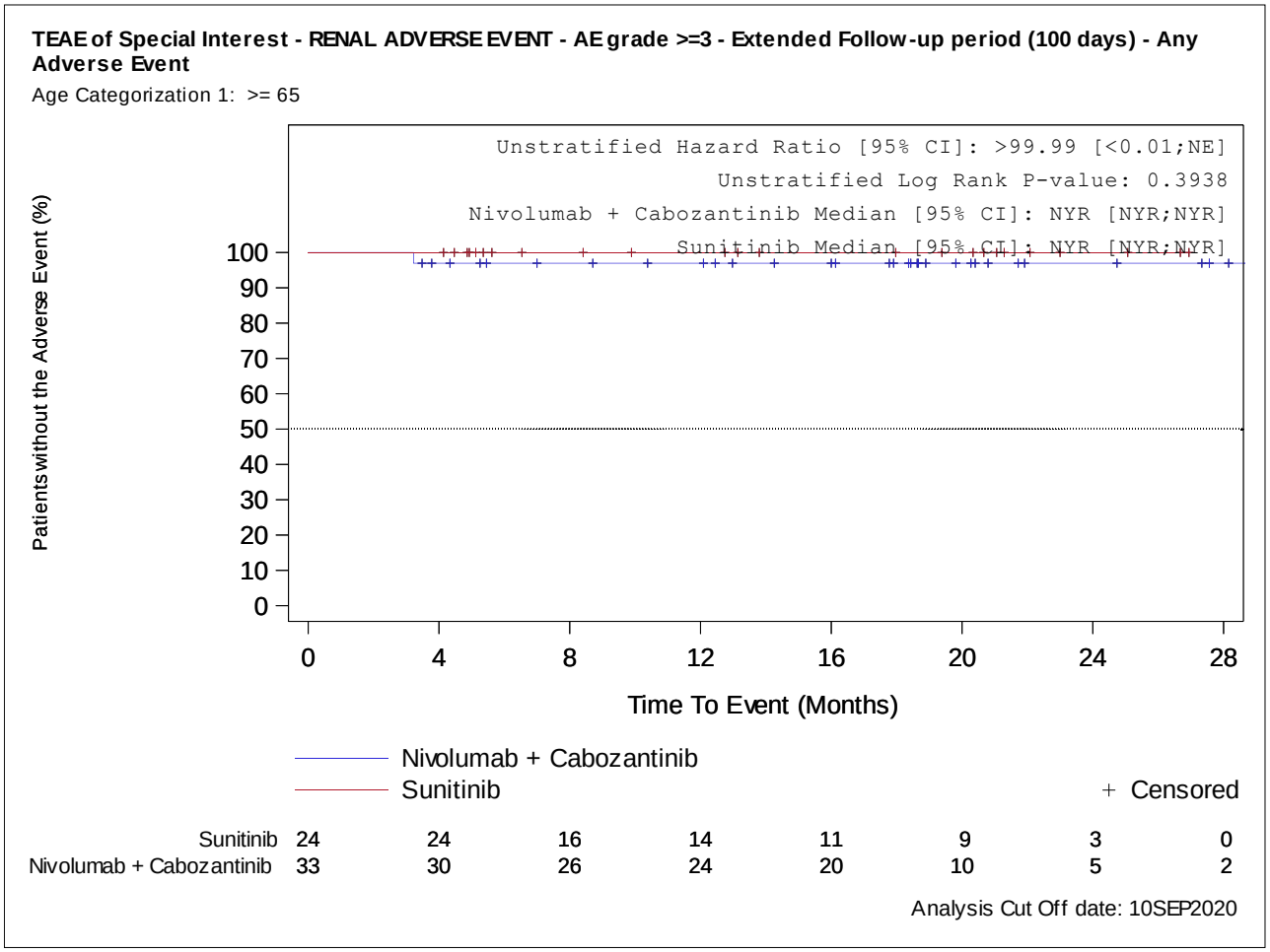

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:13:59

FIGURE 3.50.2.1: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  < 65



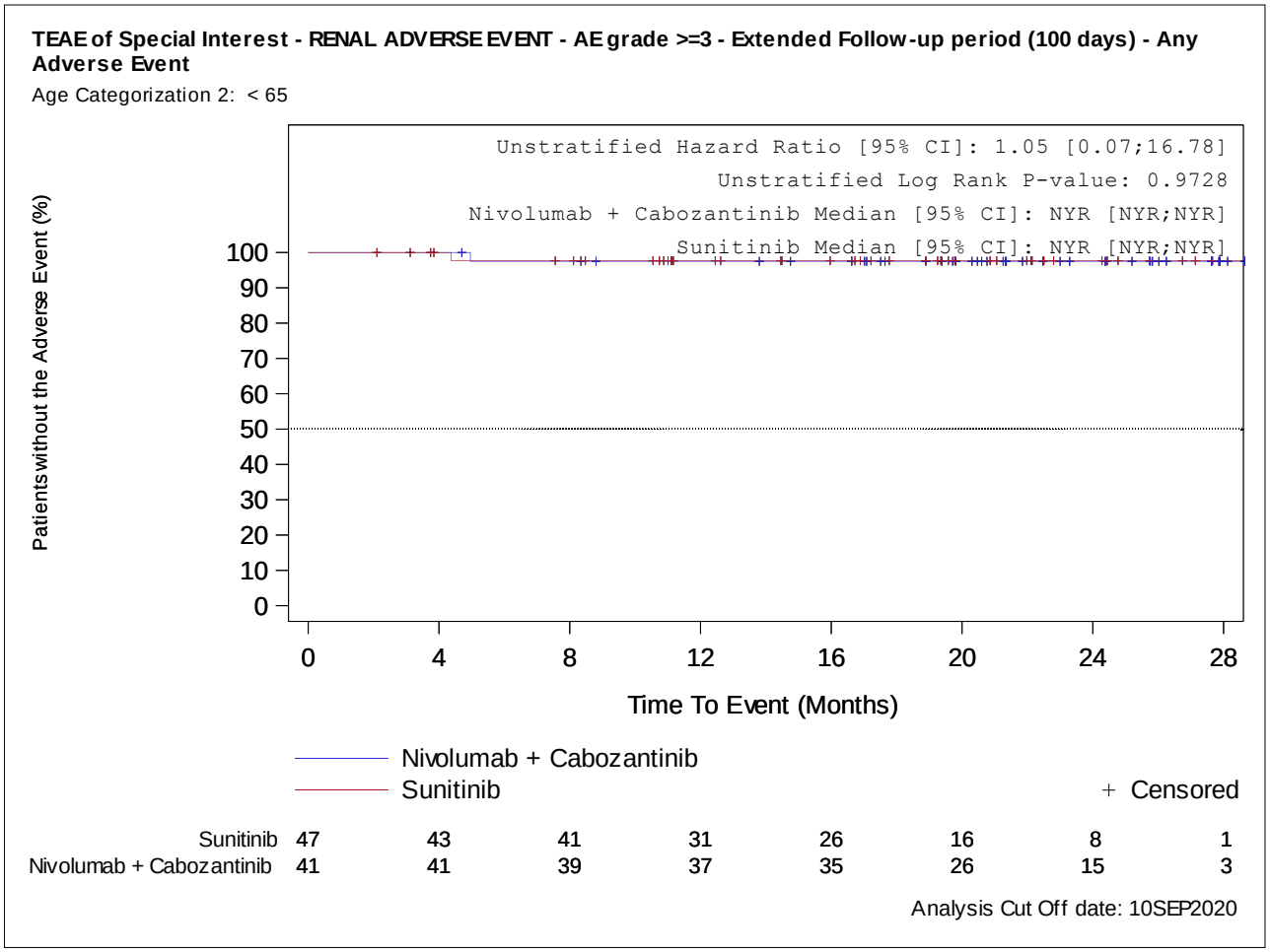

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:14:02

FIGURE 3.50.2.2: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



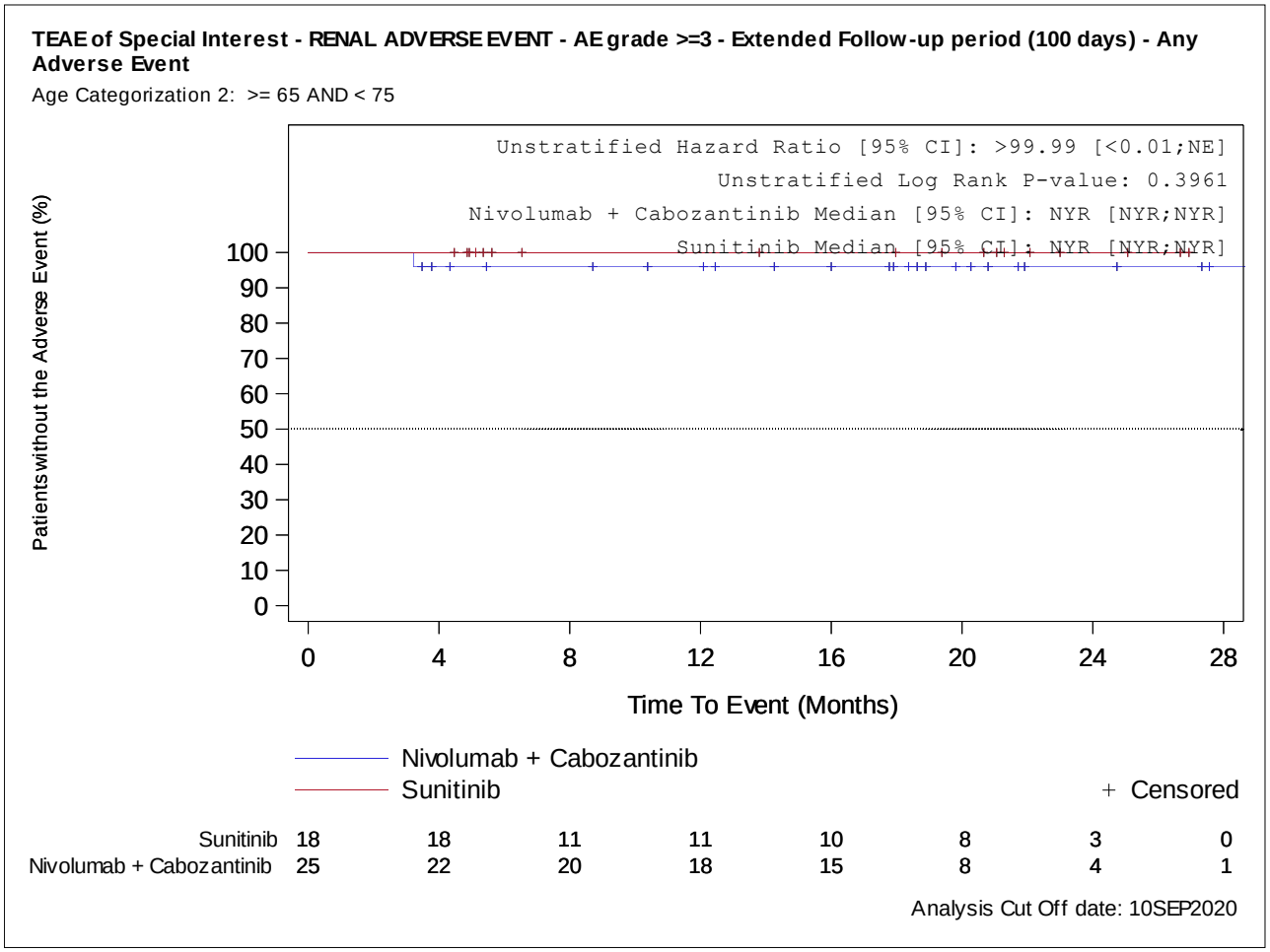

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:14:08

FIGURE 3.50.2.3: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  < 65



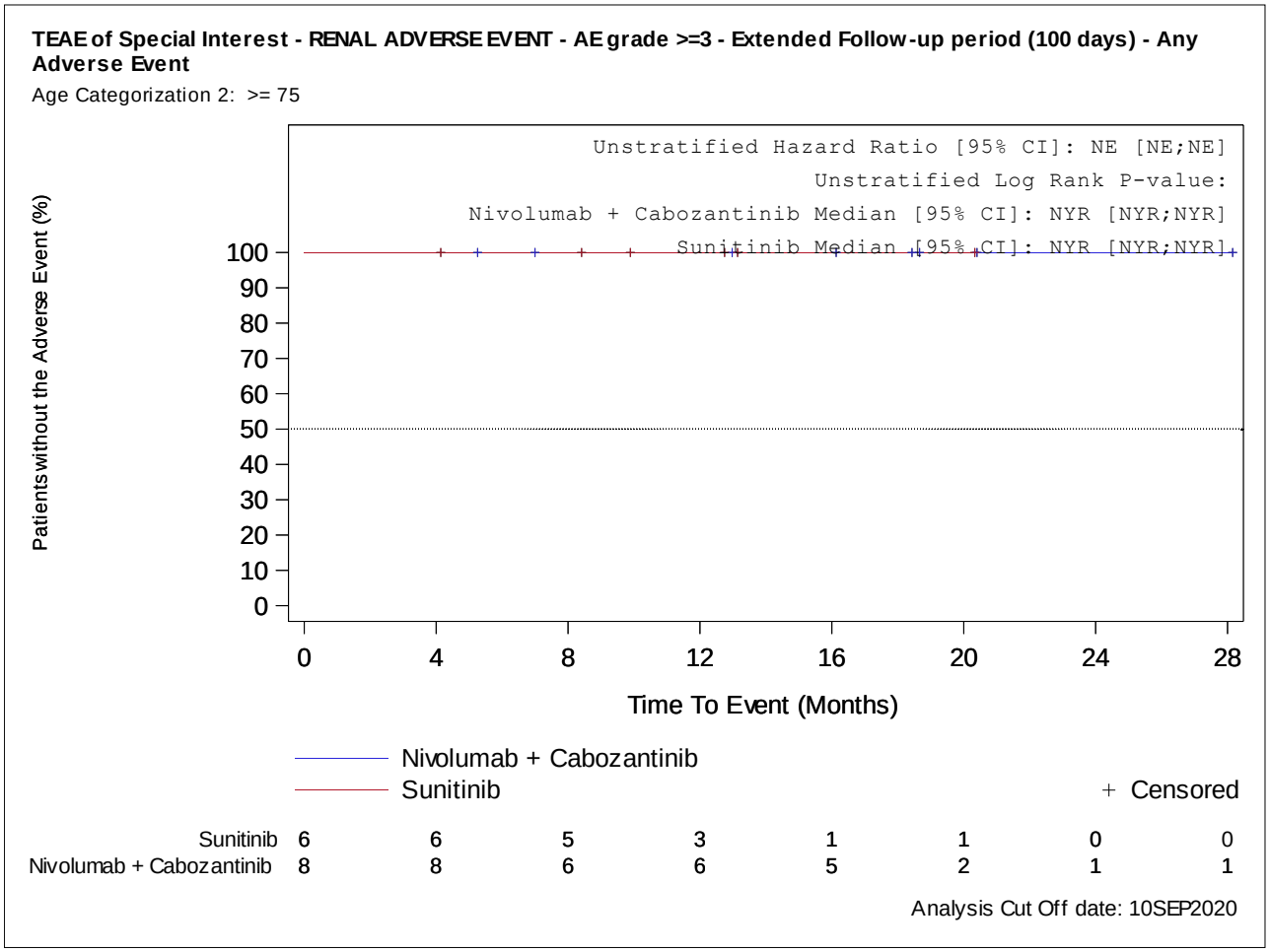

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:14:13

FIGURE 3.50.2.4: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



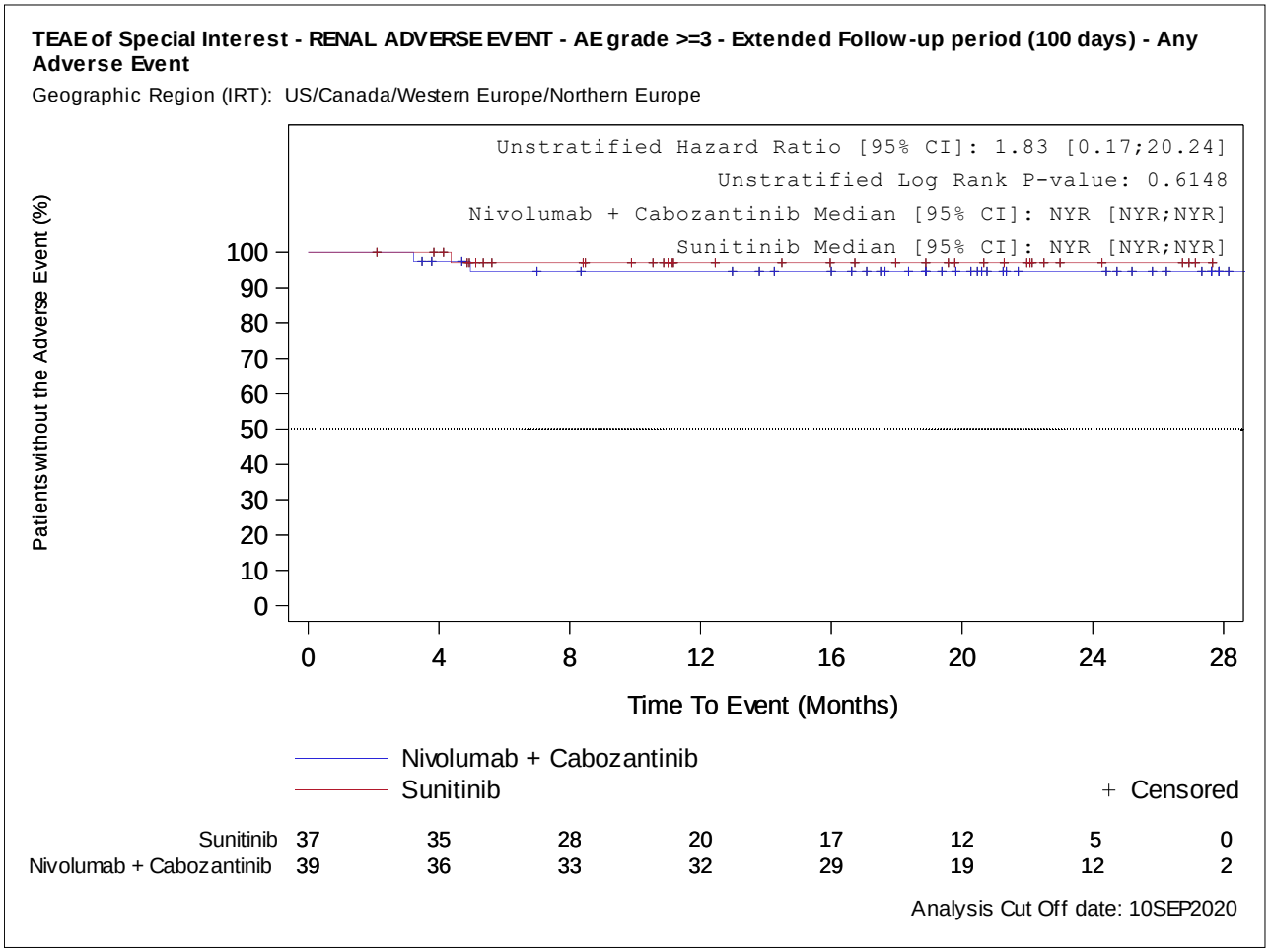

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:14:18

FIGURE 3.50.2.5: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



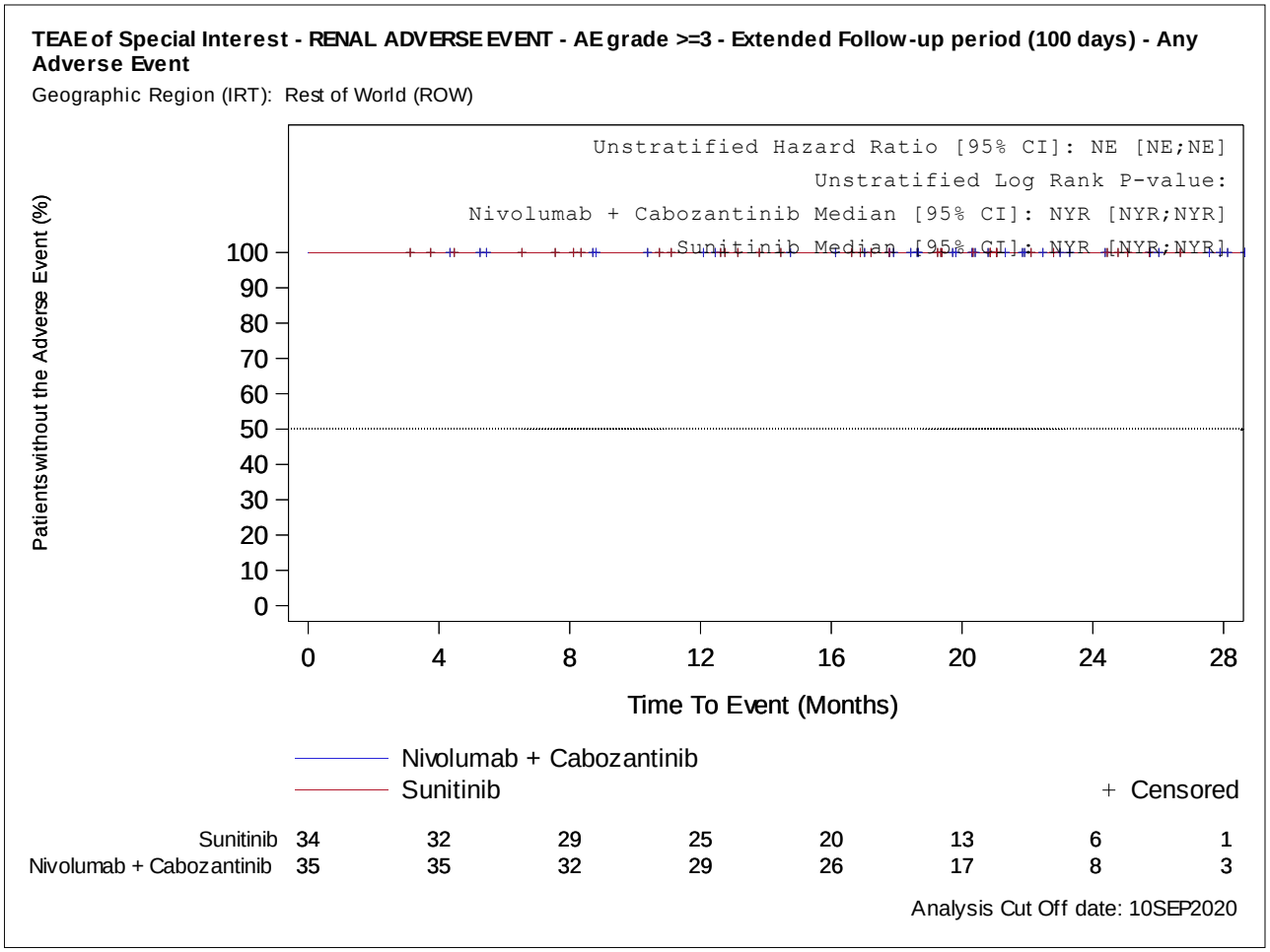

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:14:23

FIGURE 3.50.2.6: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



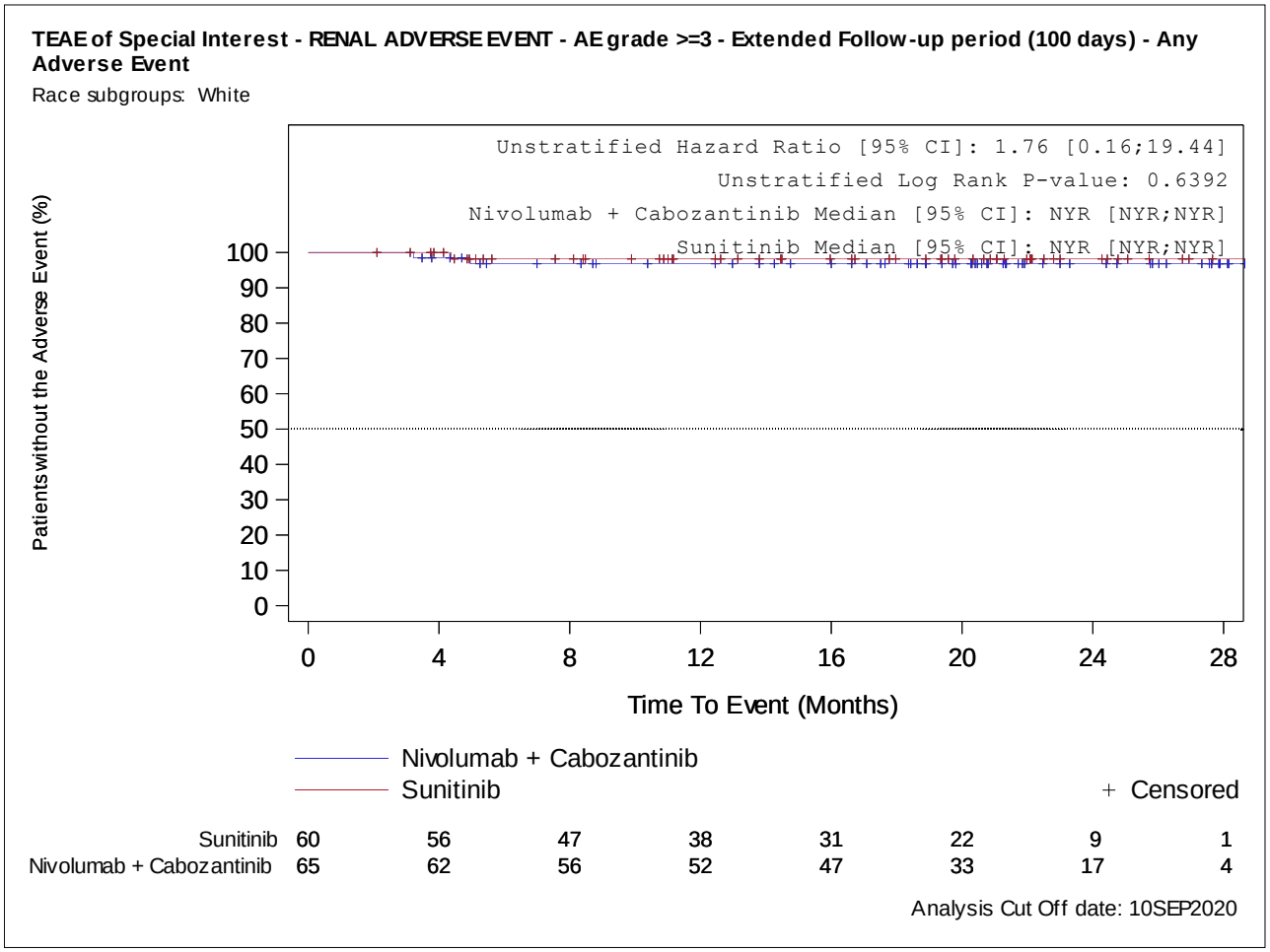

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:14:28

FIGURE 3.50.2.7: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



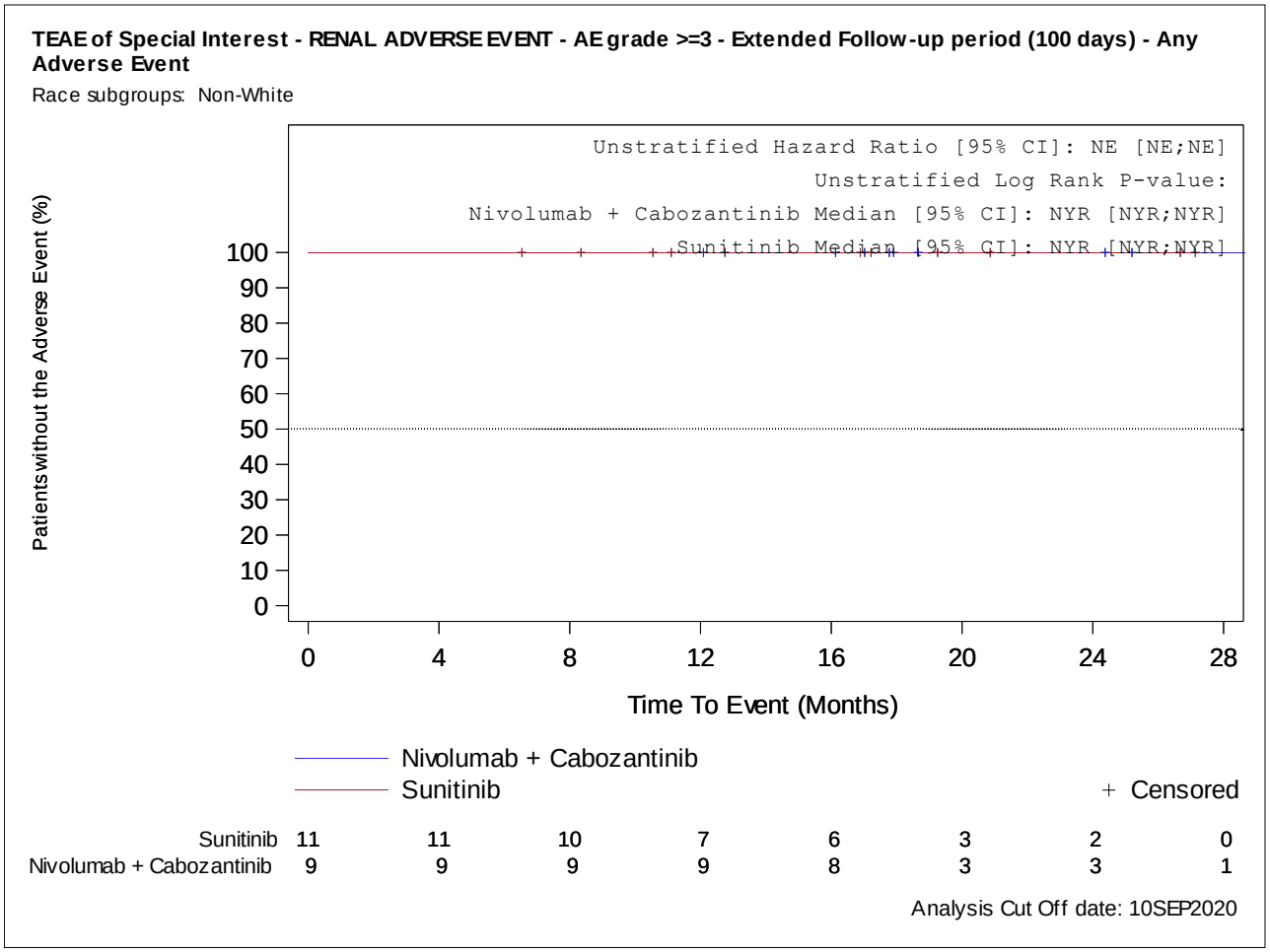

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:14:33

FIGURE 3.50.2.8: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



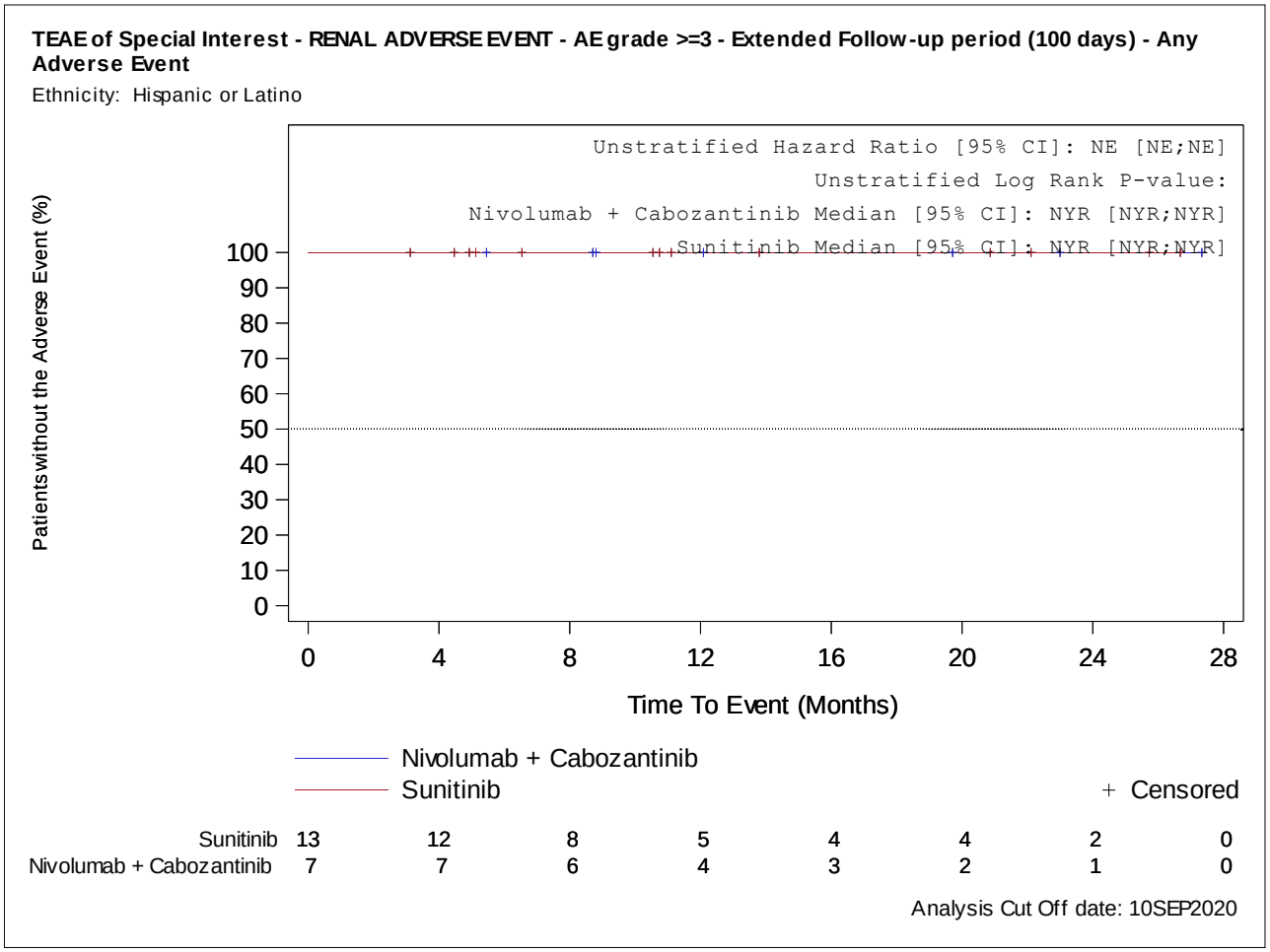

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:14:38

FIGURE 3.50.2.9: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



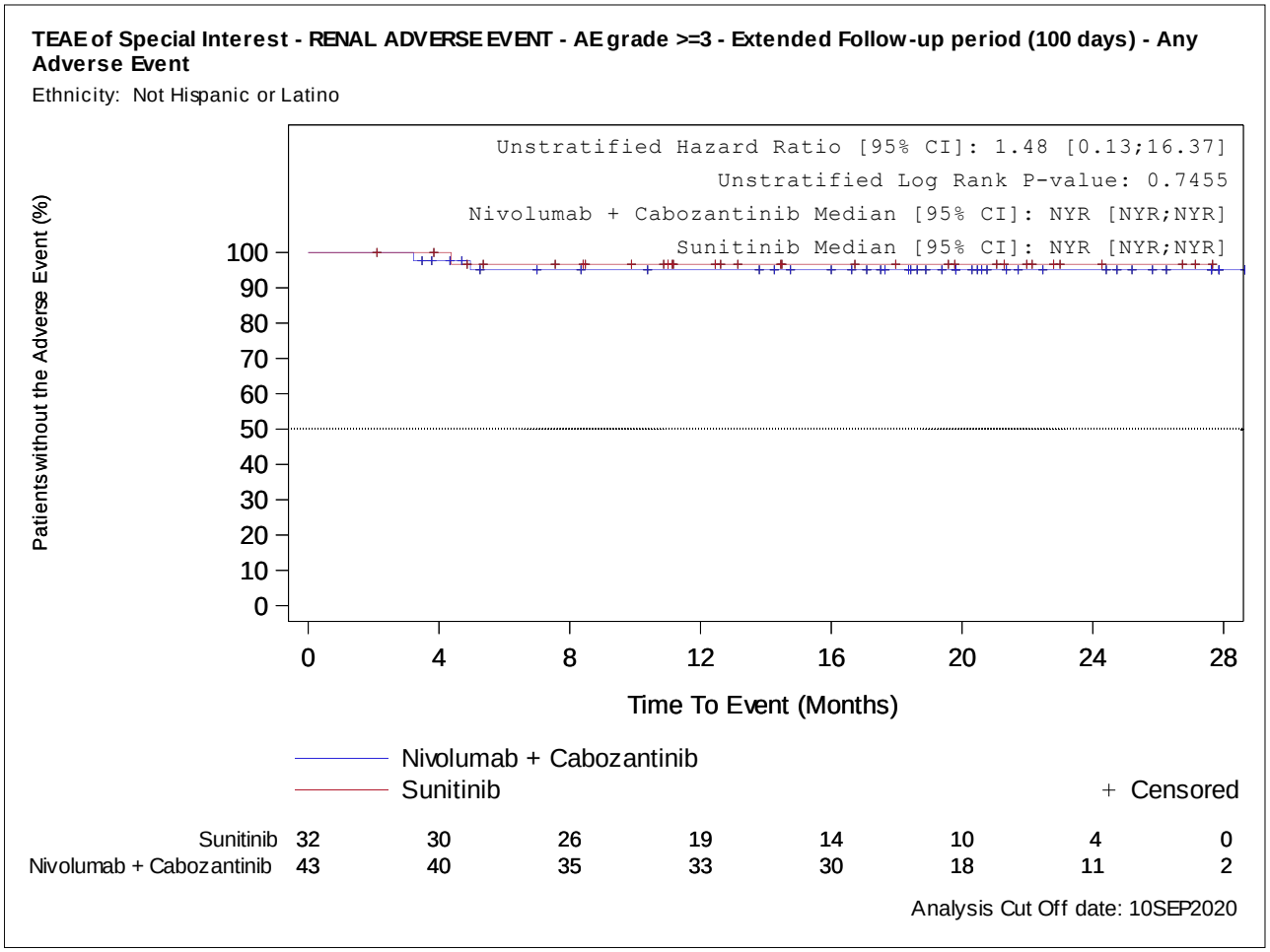

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:14:43

FIGURE 3.50.2.10: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



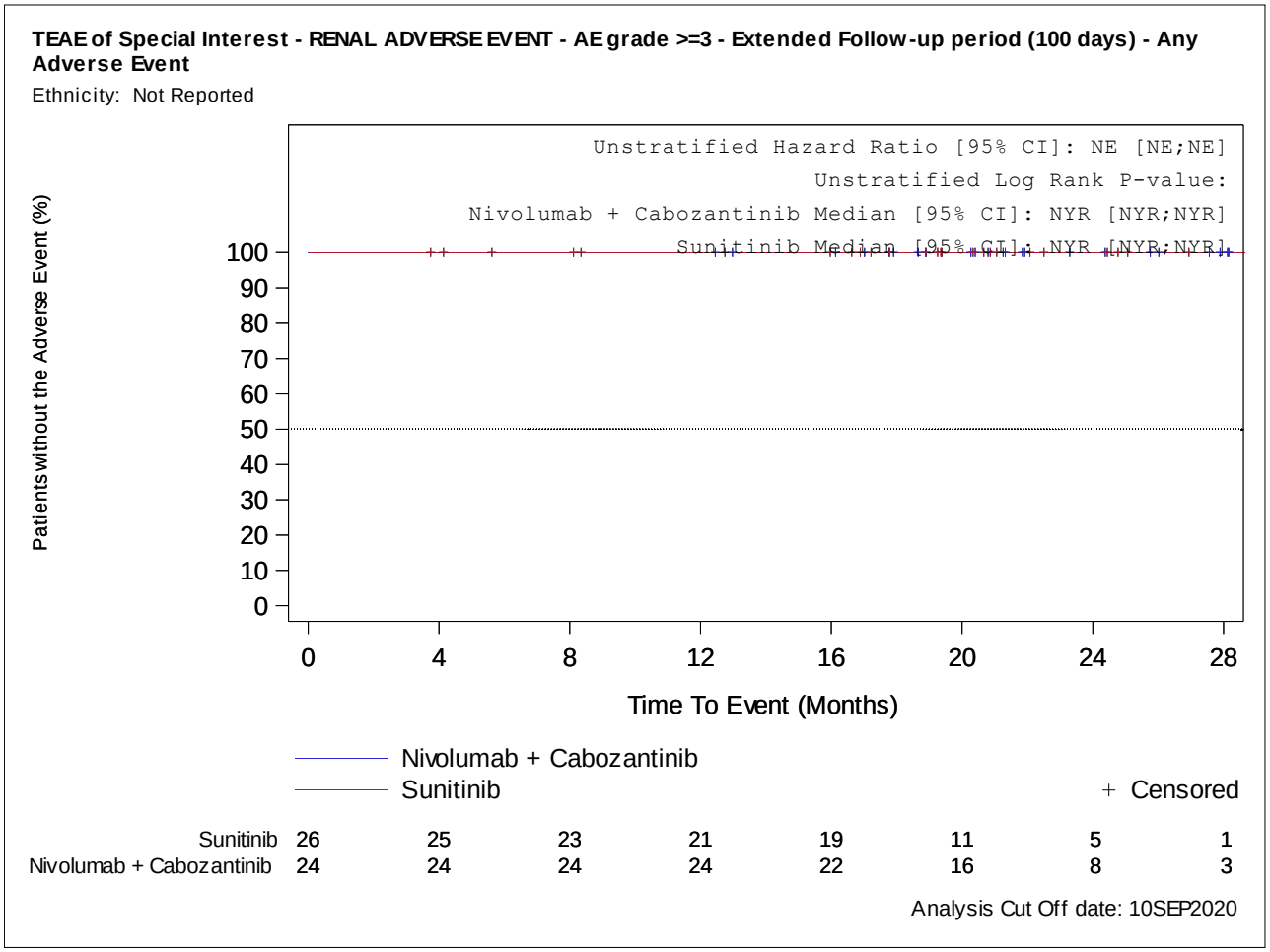

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:14:48

FIGURE 3.50.2.11: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



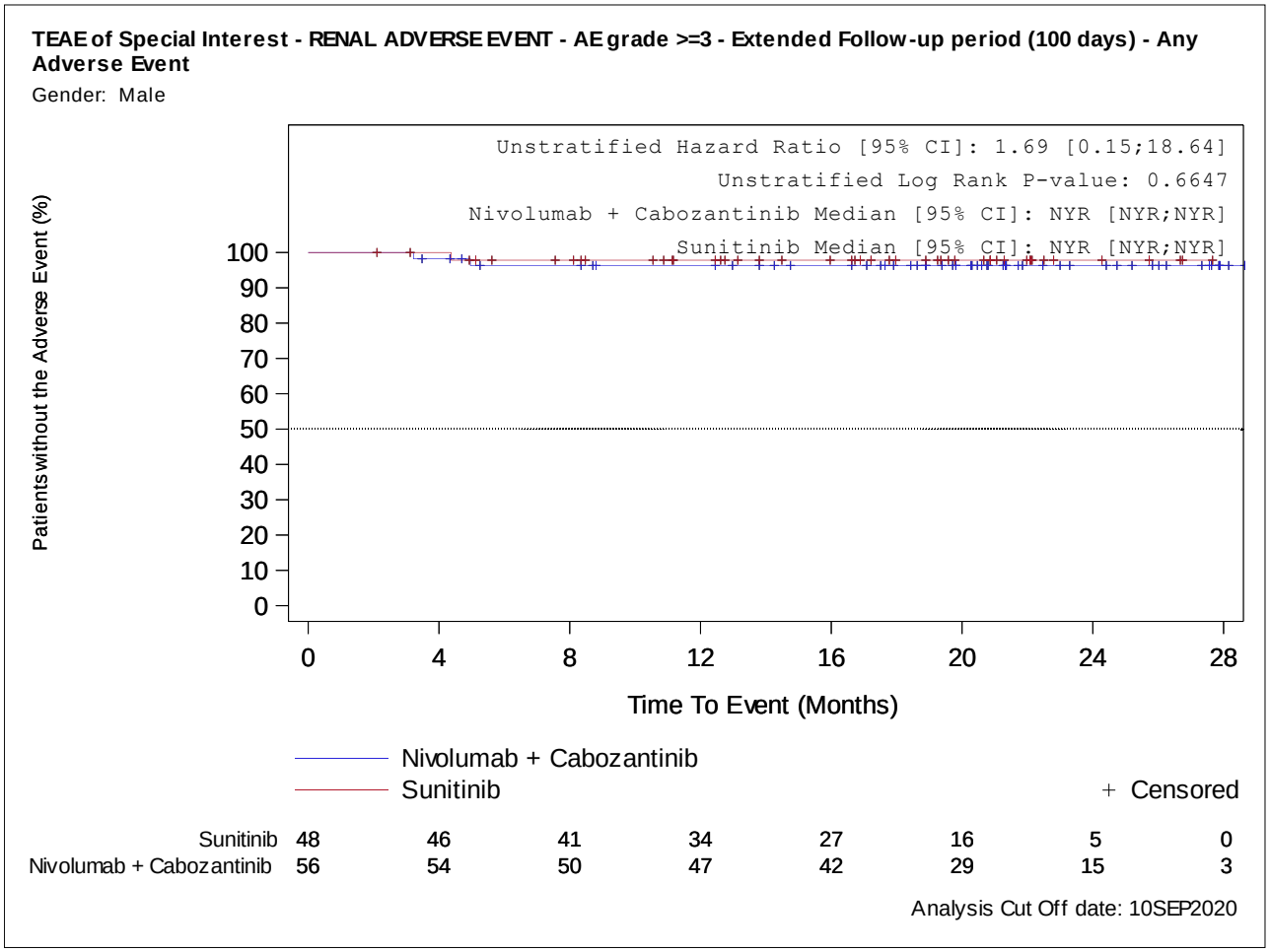

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:14:54

FIGURE 3.50.2.12: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



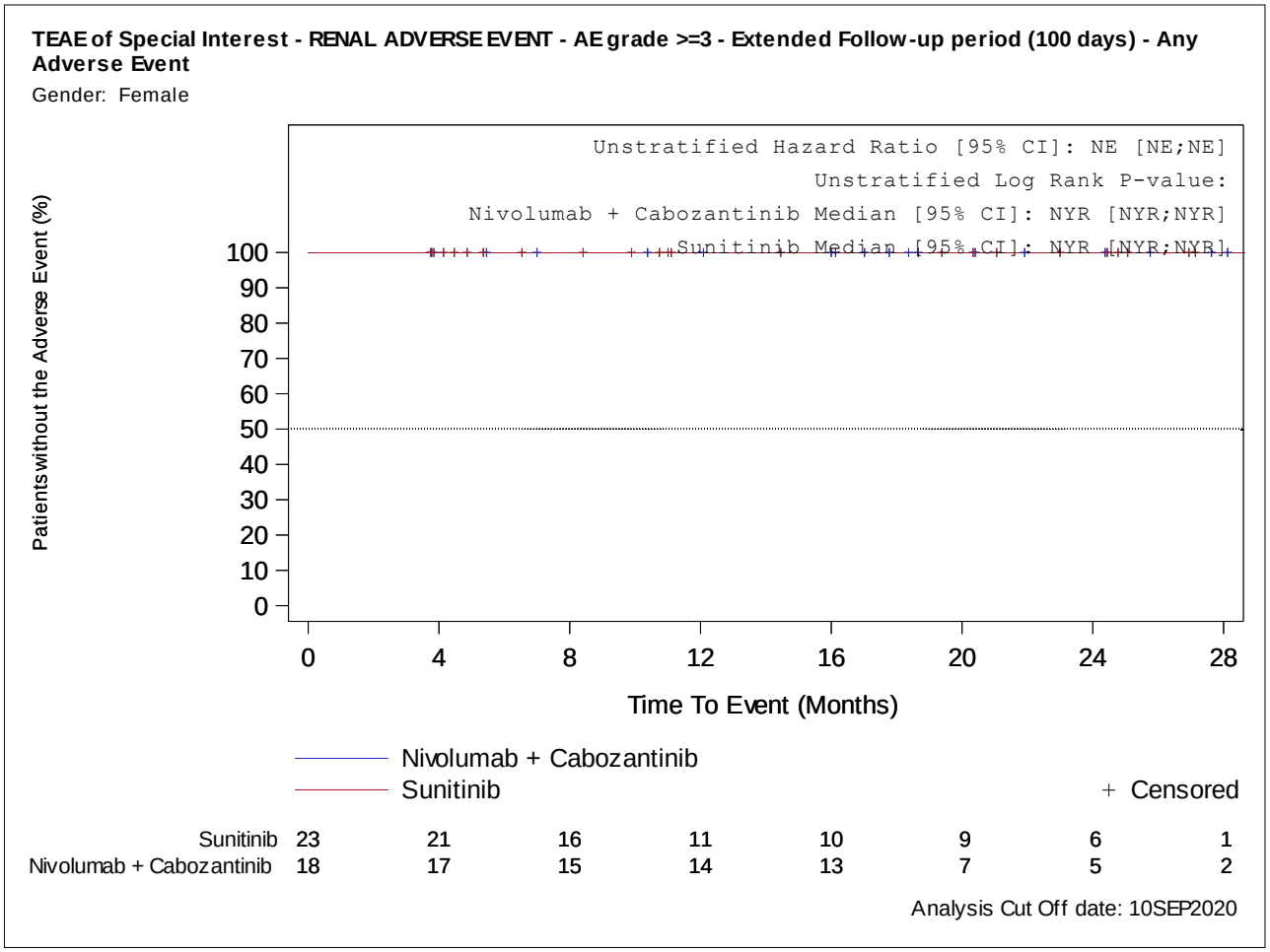

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:14:58

FIGURE 3.50.2.13: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



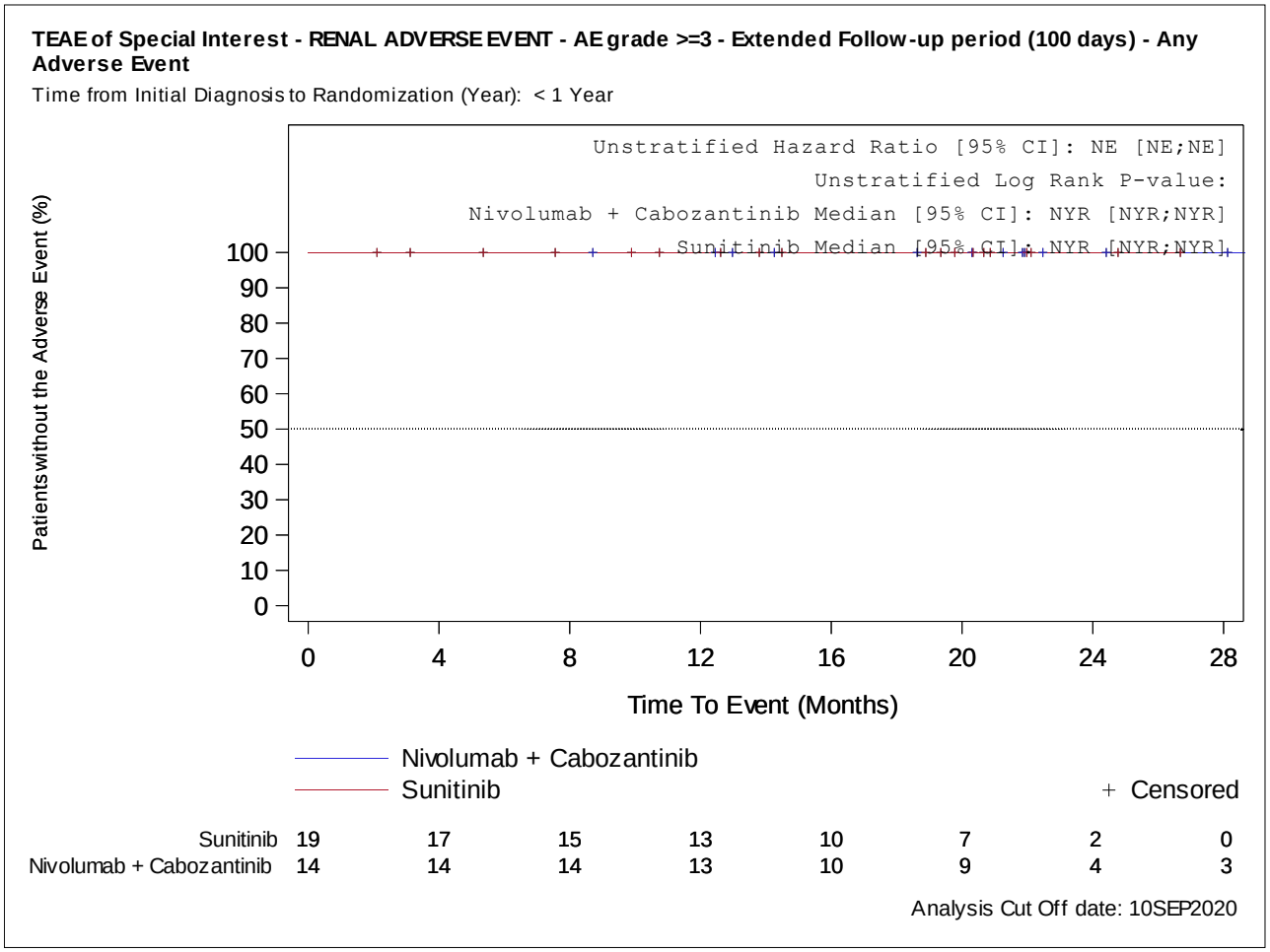

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:15:04

FIGURE 3.50.2.14: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



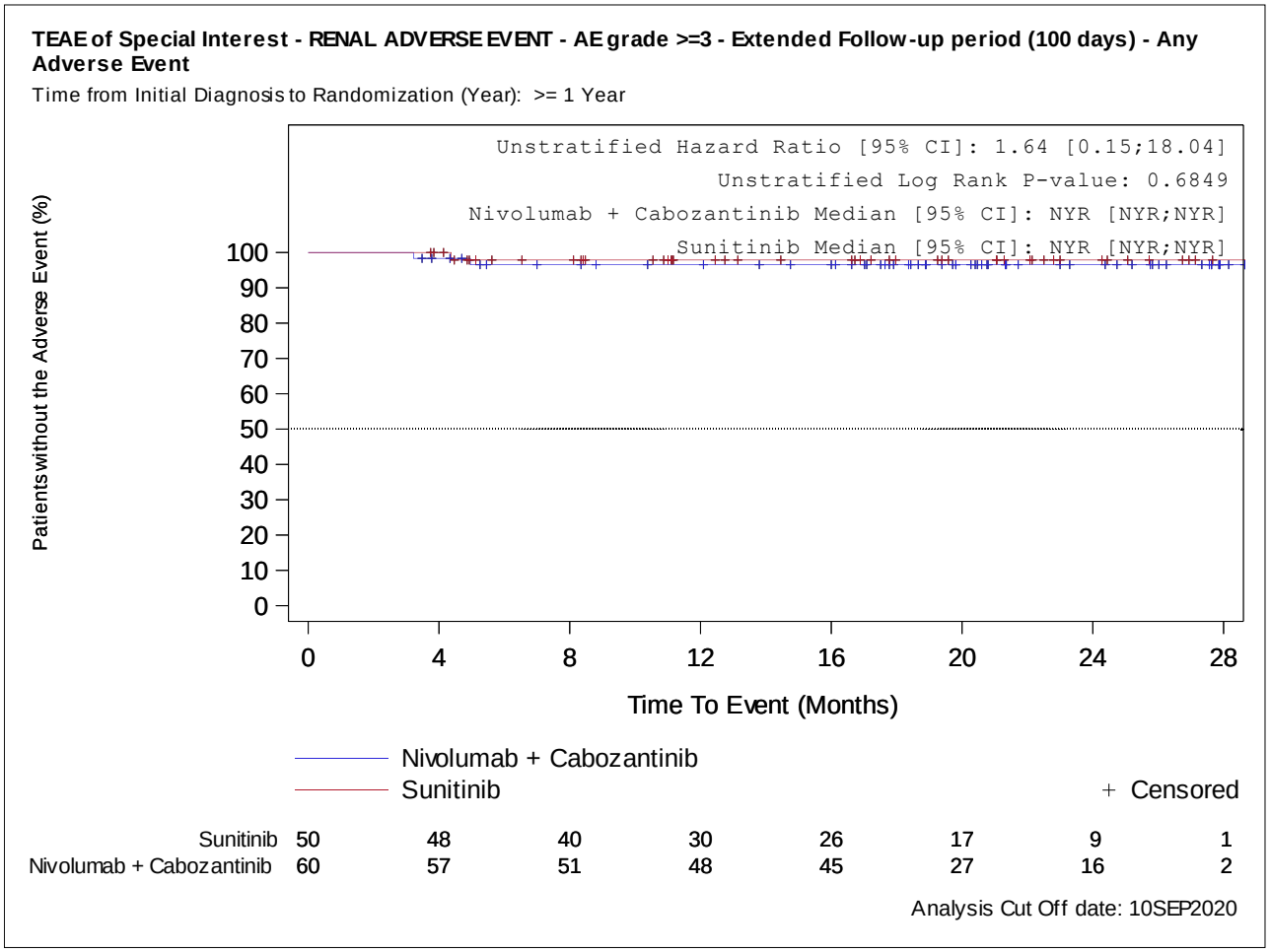

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:15:09

FIGURE 3.50.2.15: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



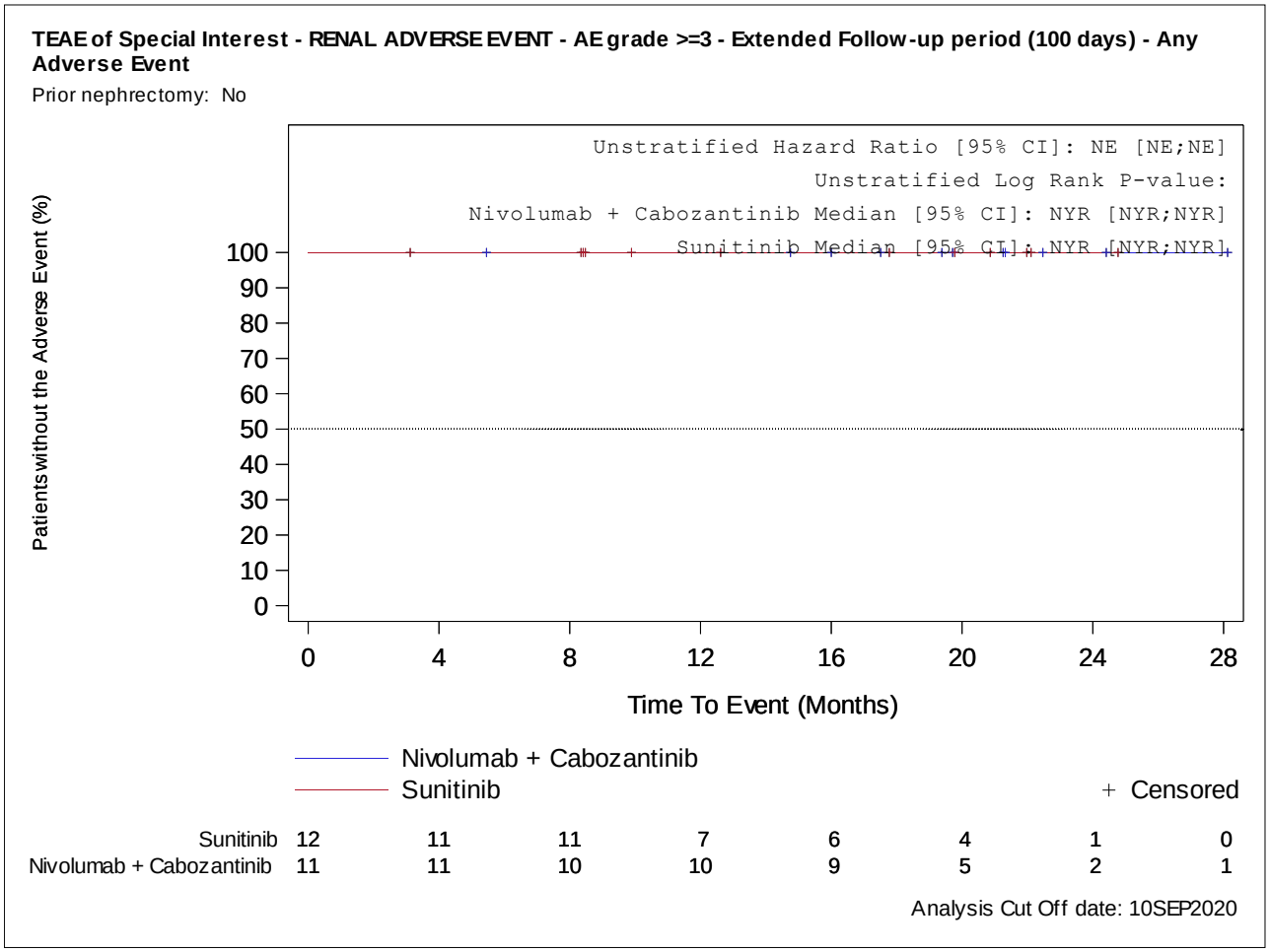

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:15:24

FIGURE 3.50.2.16: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



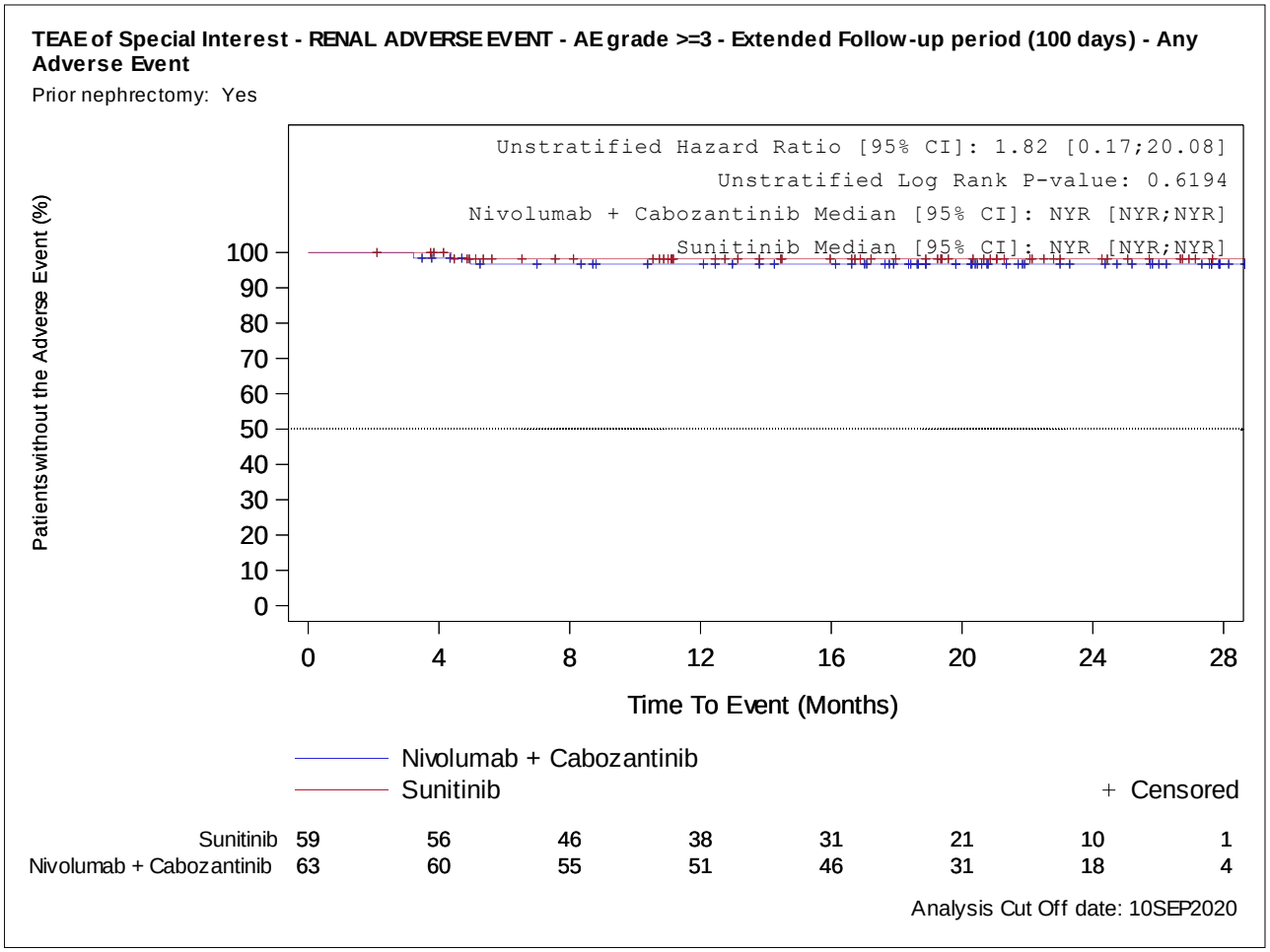

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:15:30

FIGURE 3.50.2.17: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



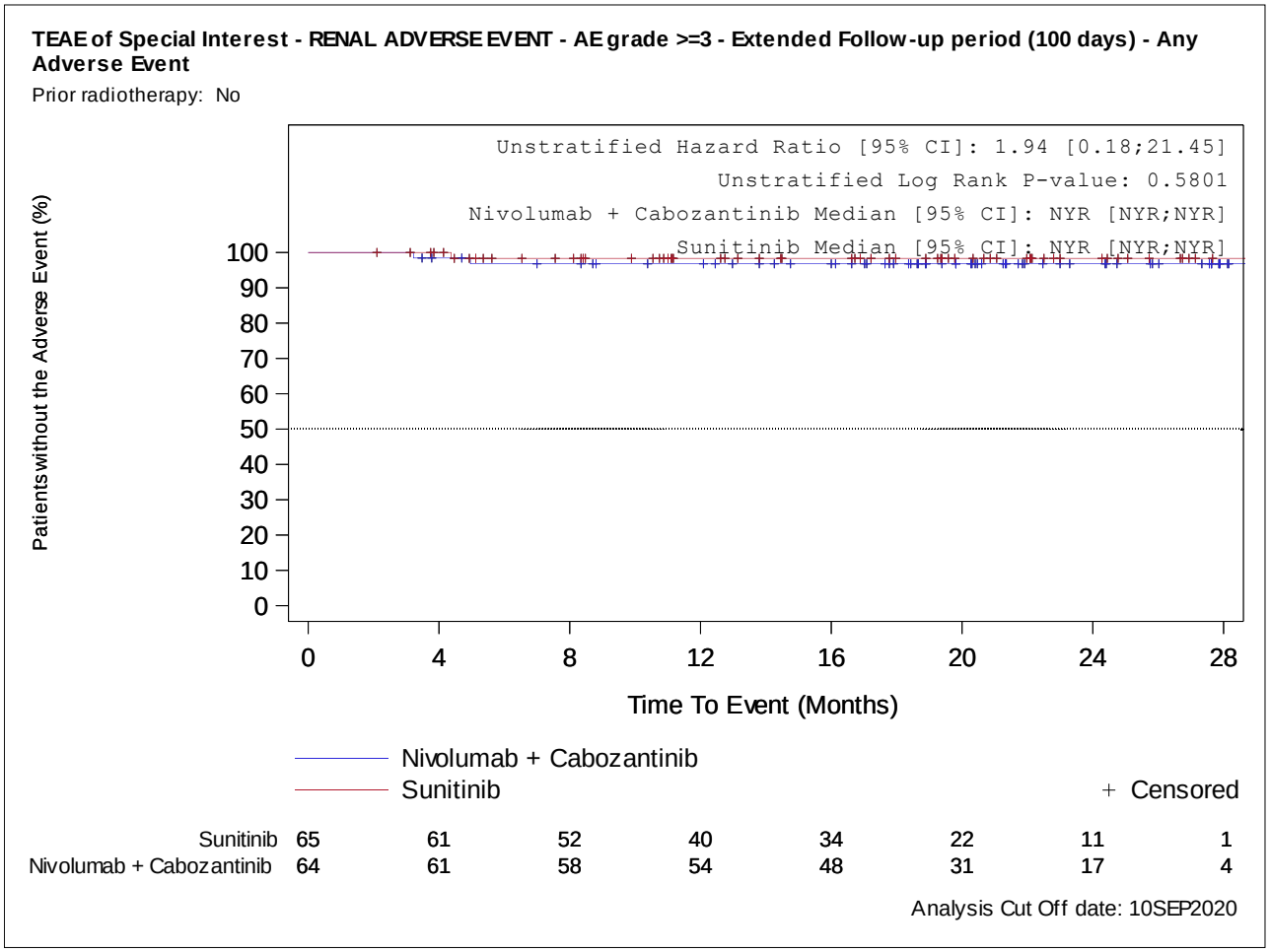

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:16:16

FIGURE 3.50.2.18: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



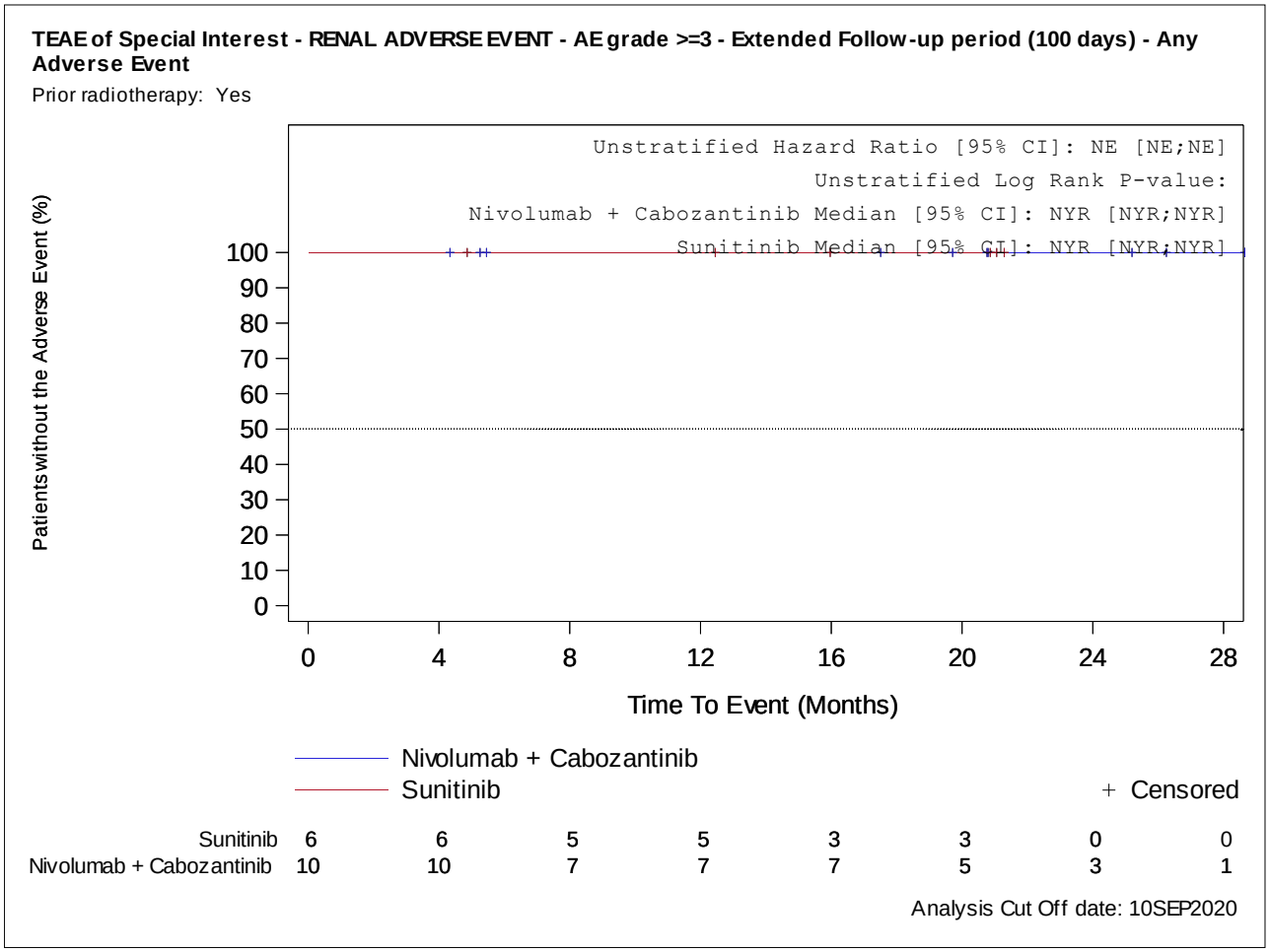

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:16:21

FIGURE 3.50.2.19: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



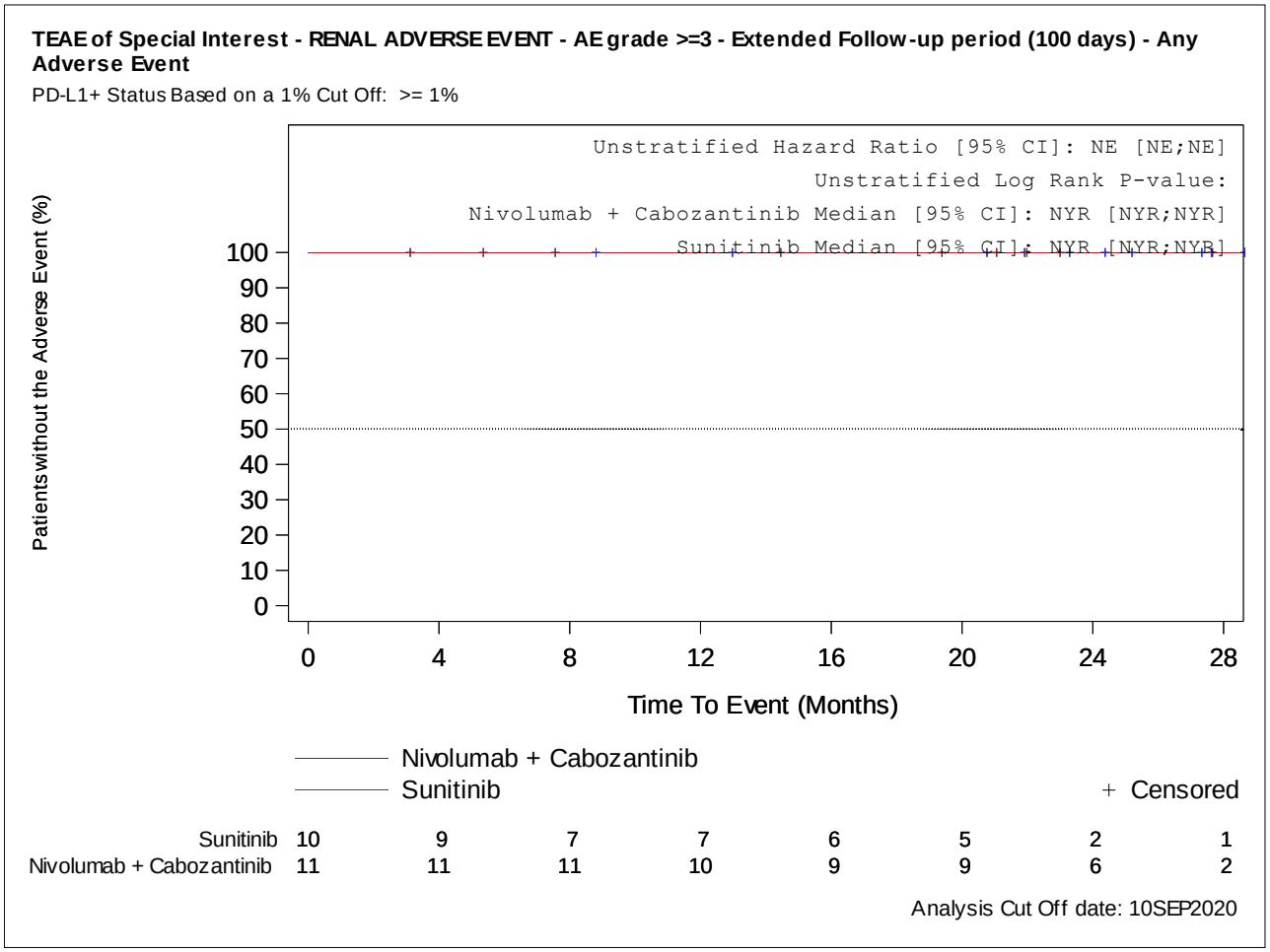

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:16:26

FIGURE 3.50.2.20: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



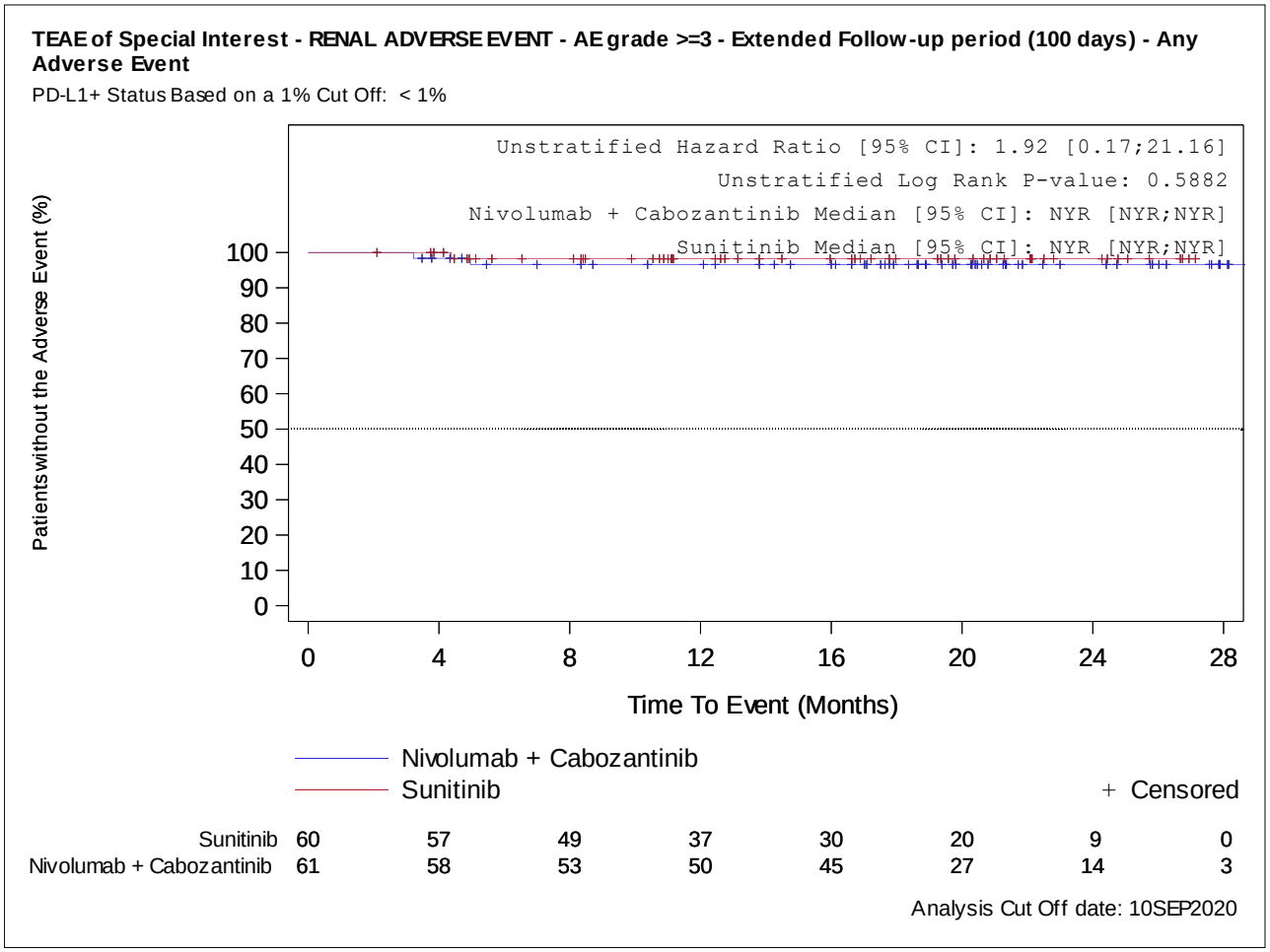

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:16:32

FIGURE 3.50.2.21: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



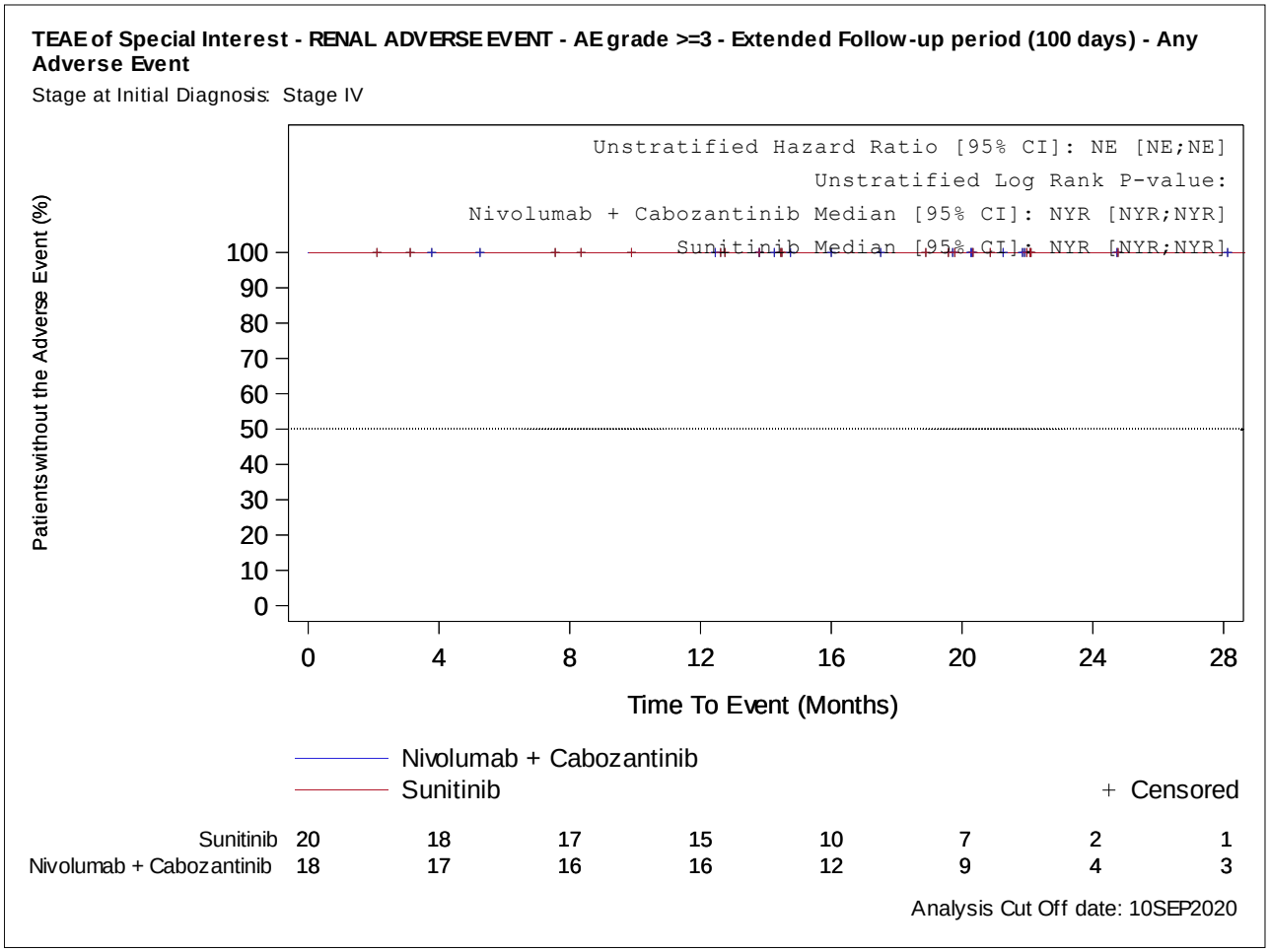

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:16:37

FIGURE 3.50.2.22: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



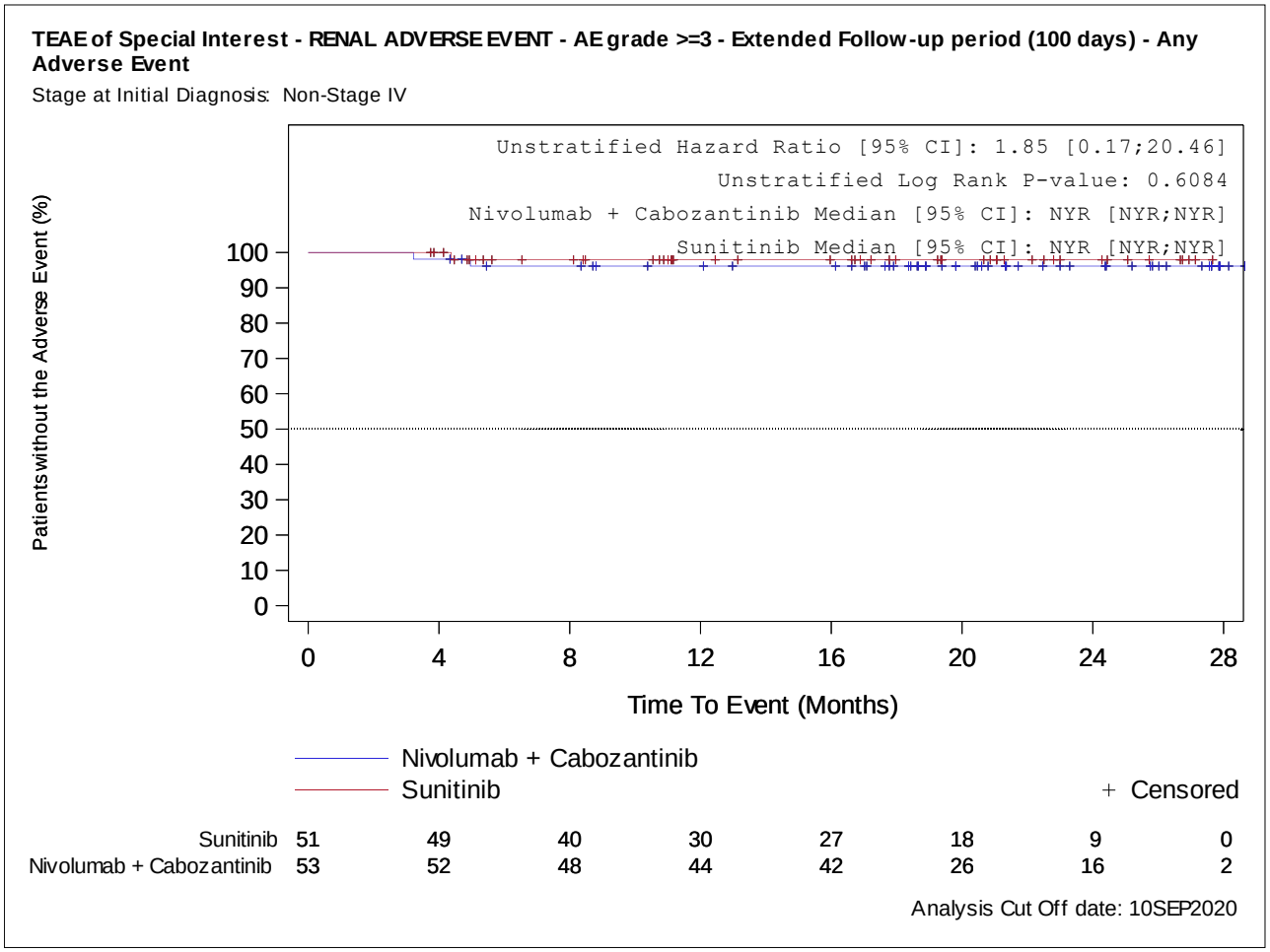

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:16:42

FIGURE 3.50.2.23: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



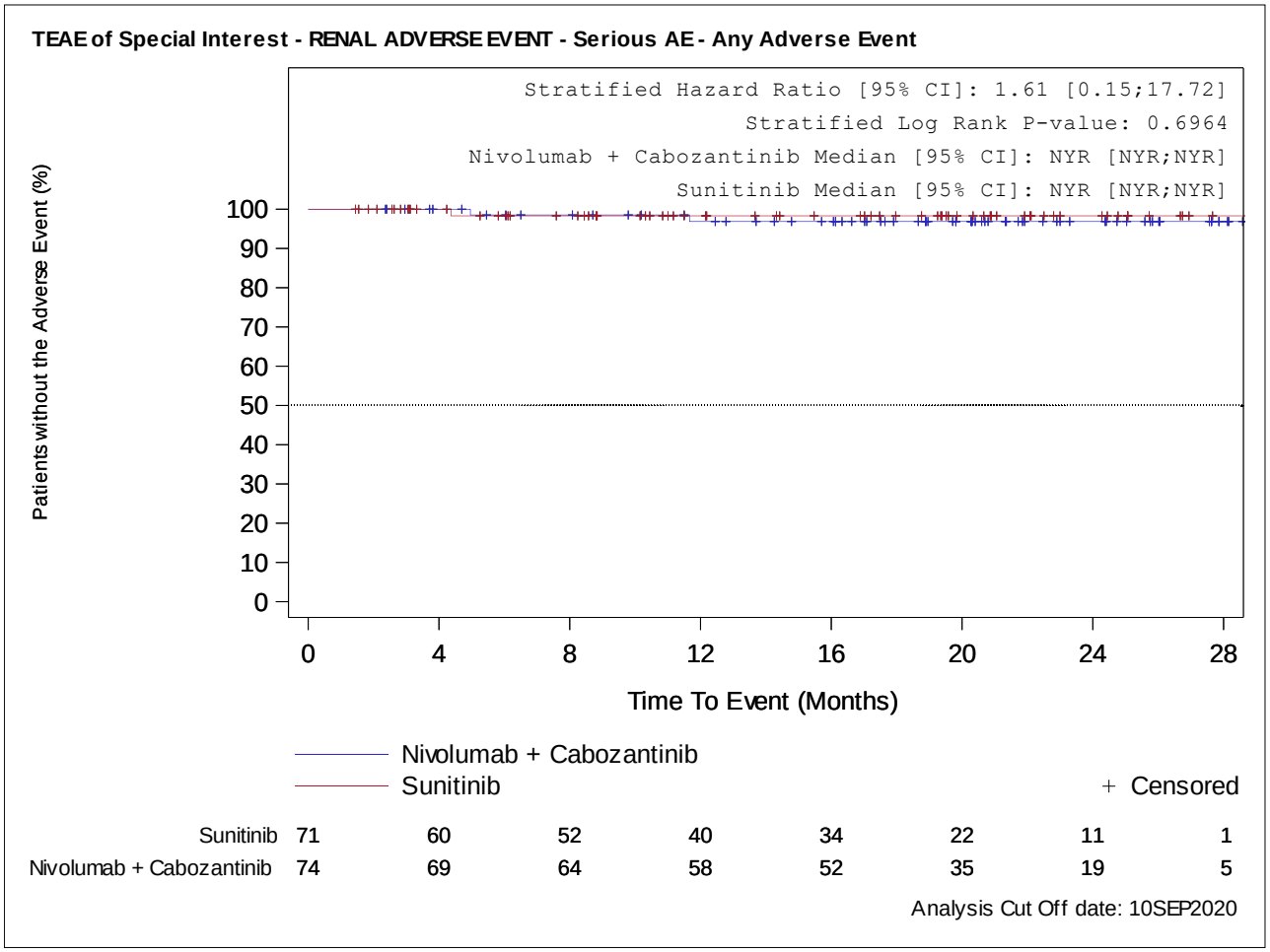

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:17:08

FIGURE 3.50.2.24: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



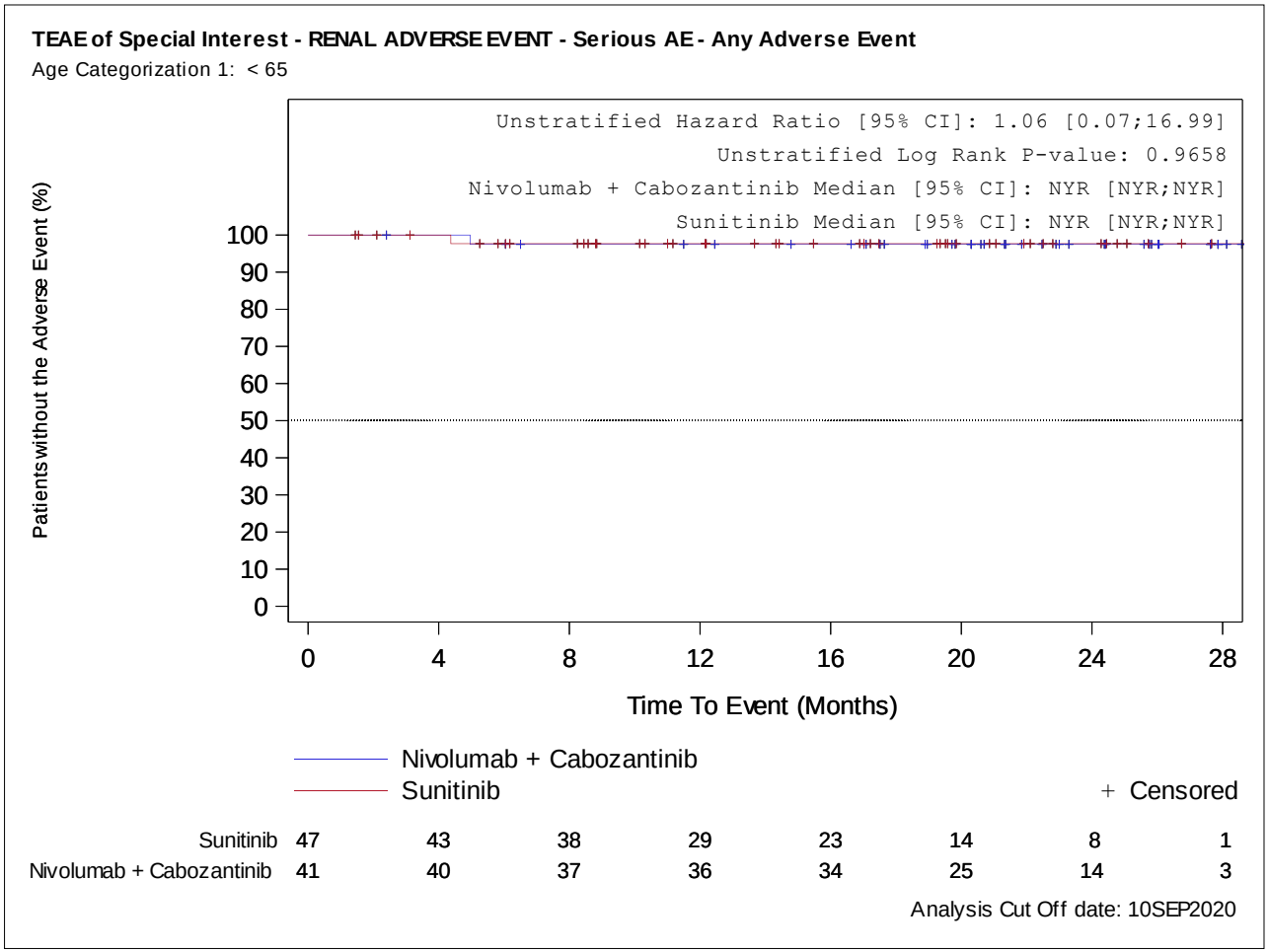

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:17:13

FIGURE 3.51.1: TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



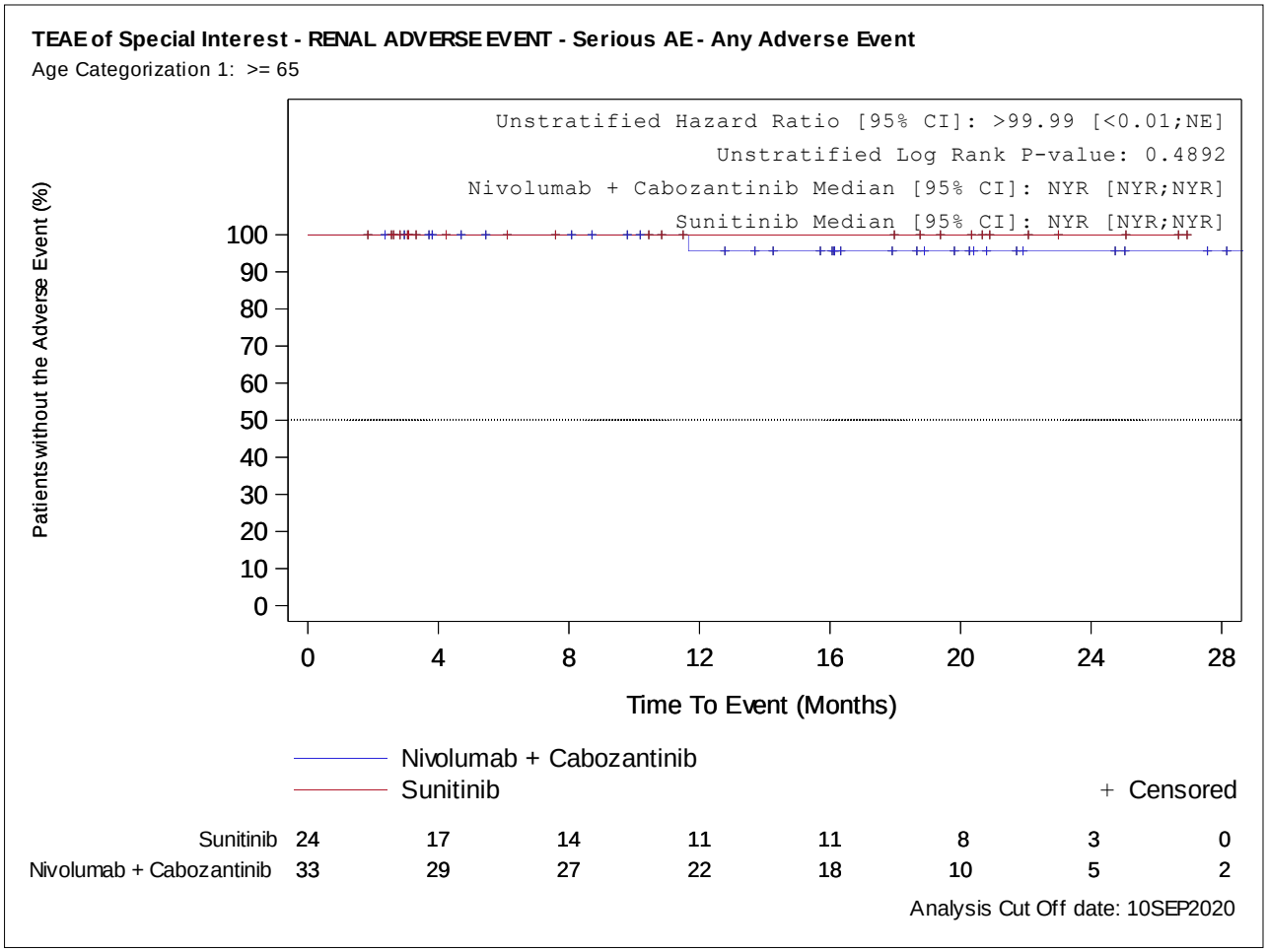

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:20:07

FIGURE 3.51.2.1: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



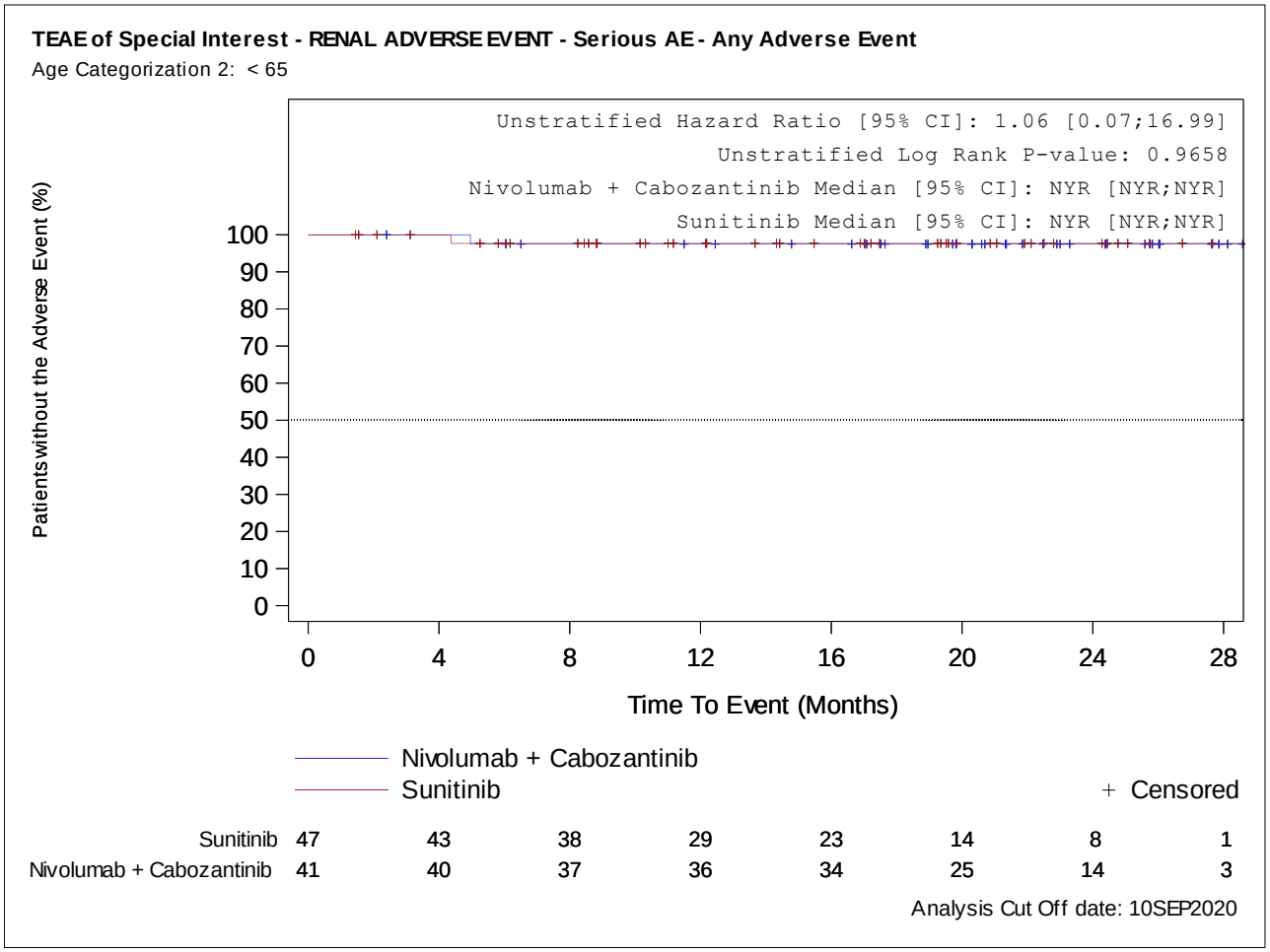

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:20:11

FIGURE 3.51.2.2: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



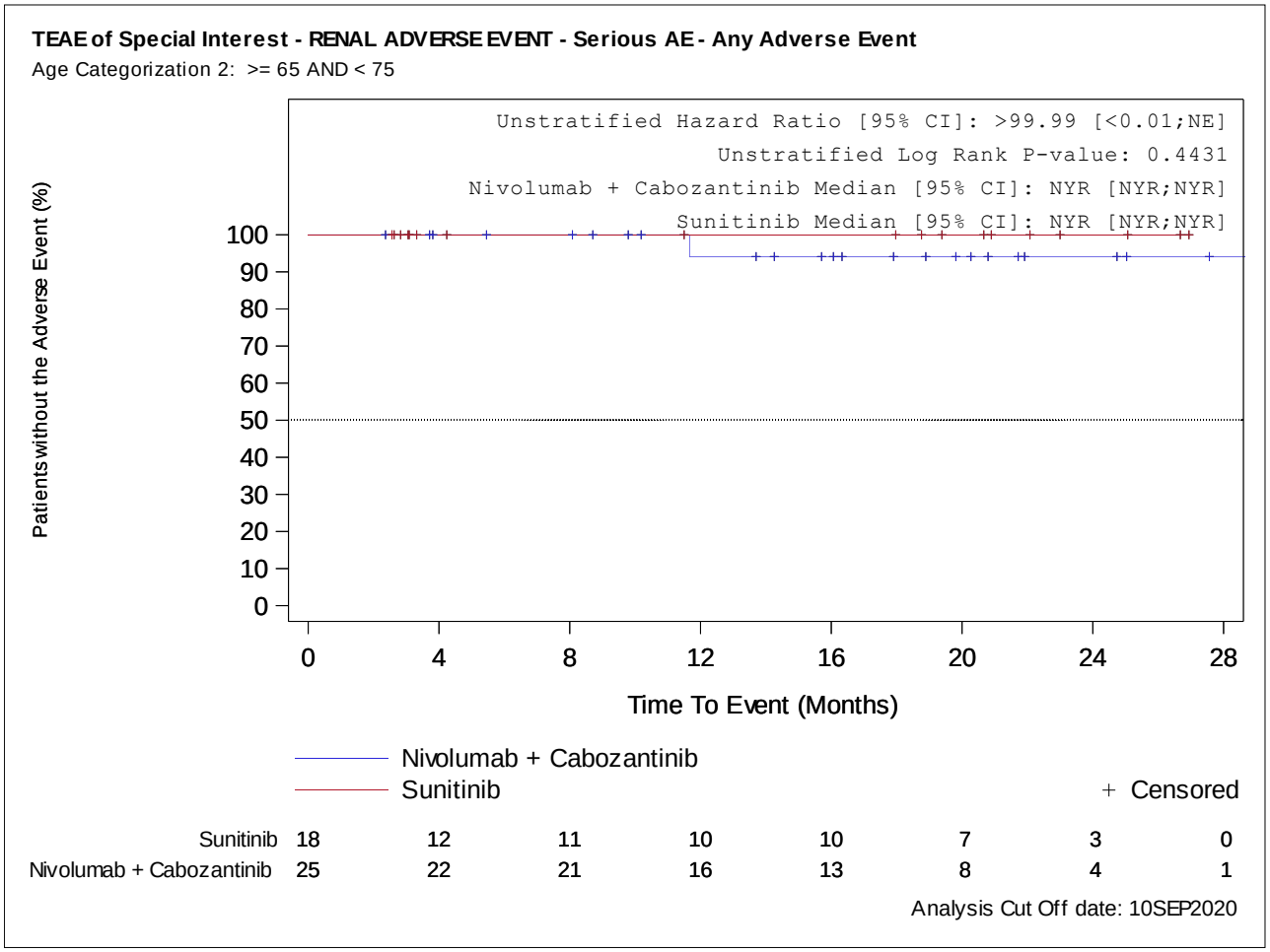

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:20:16

FIGURE 3.51.2.3: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



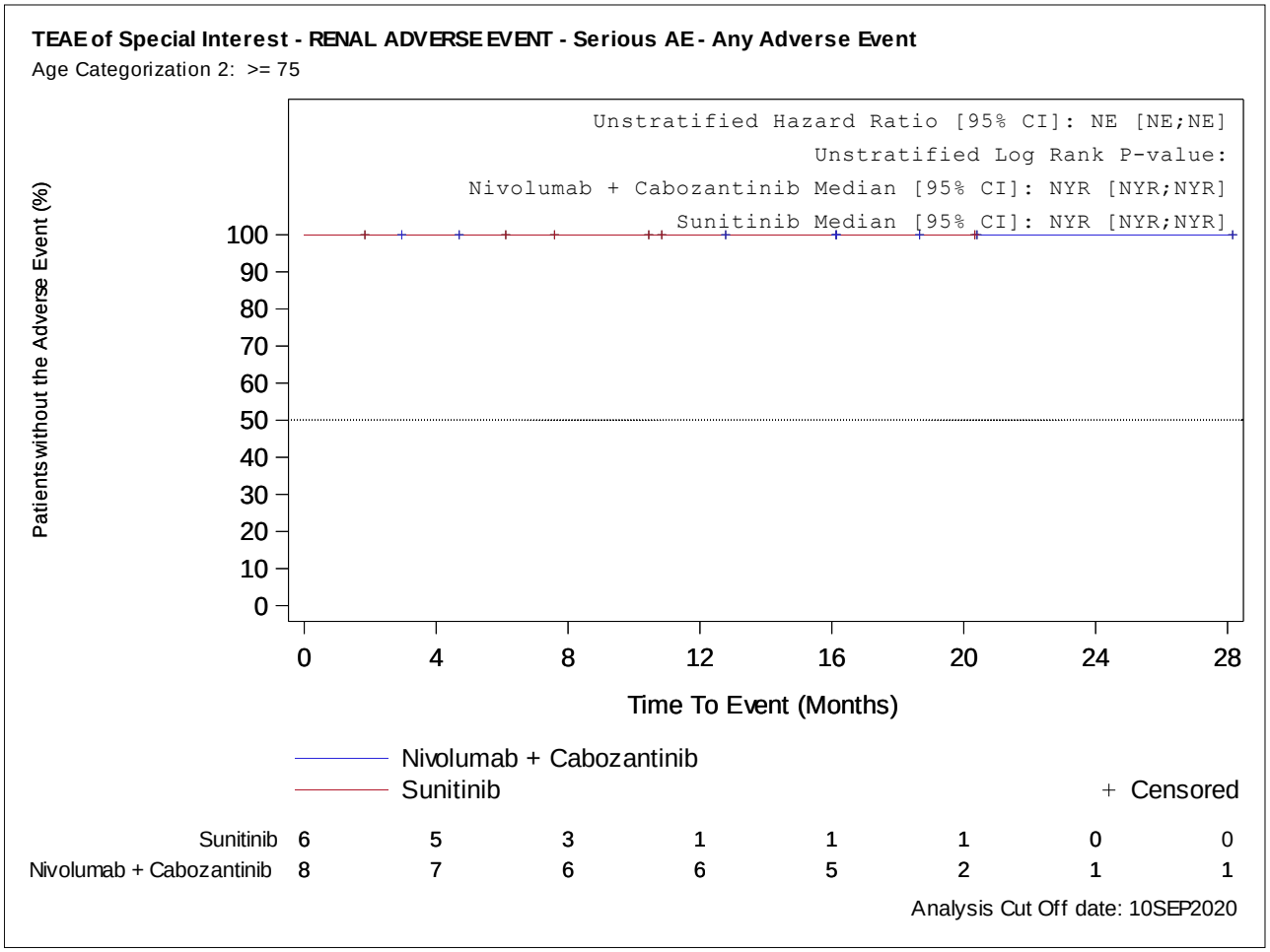

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:20:21

FIGURE 3.51.2.4: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



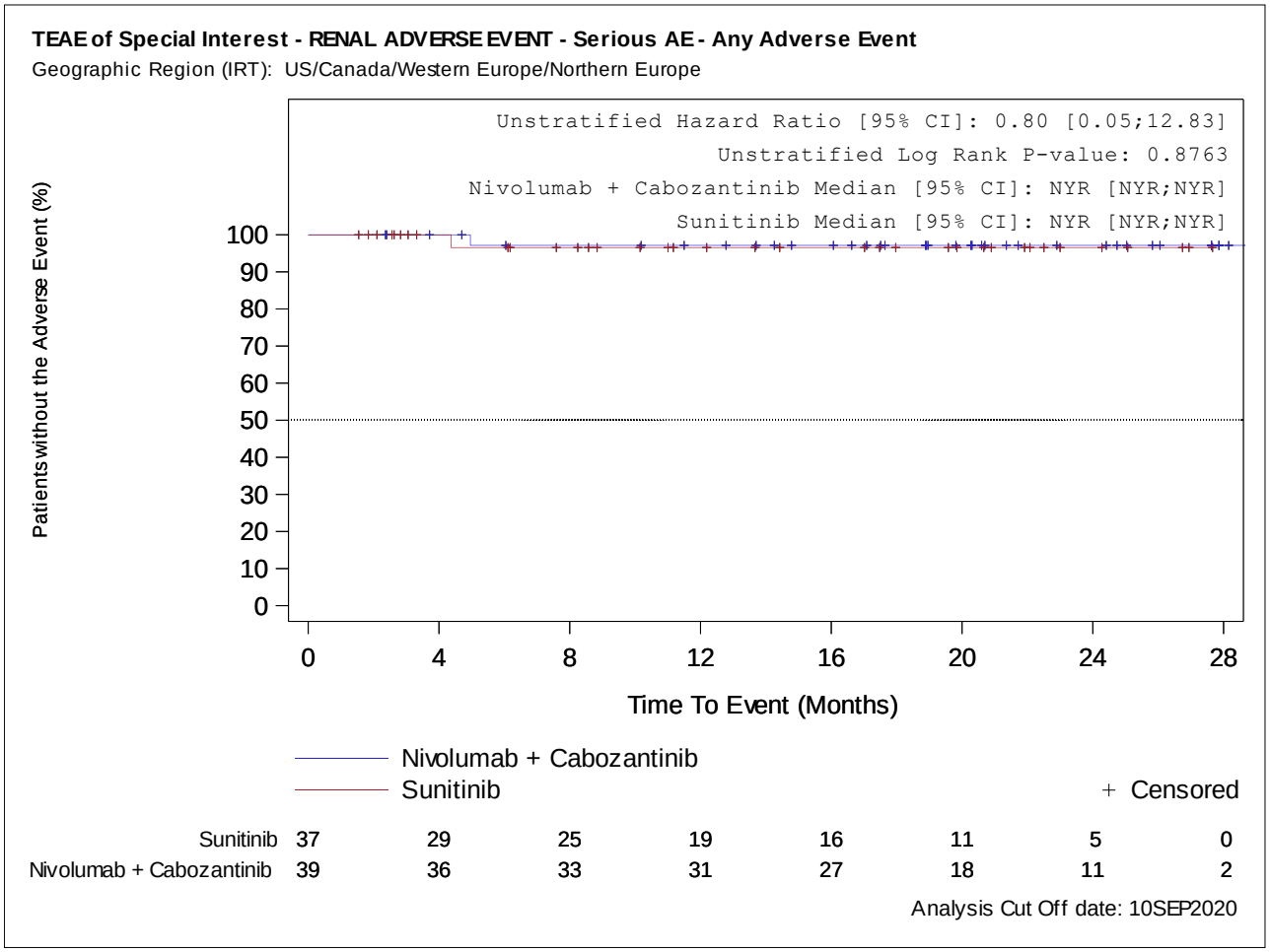

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:20:26

FIGURE 3.51.2.5: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



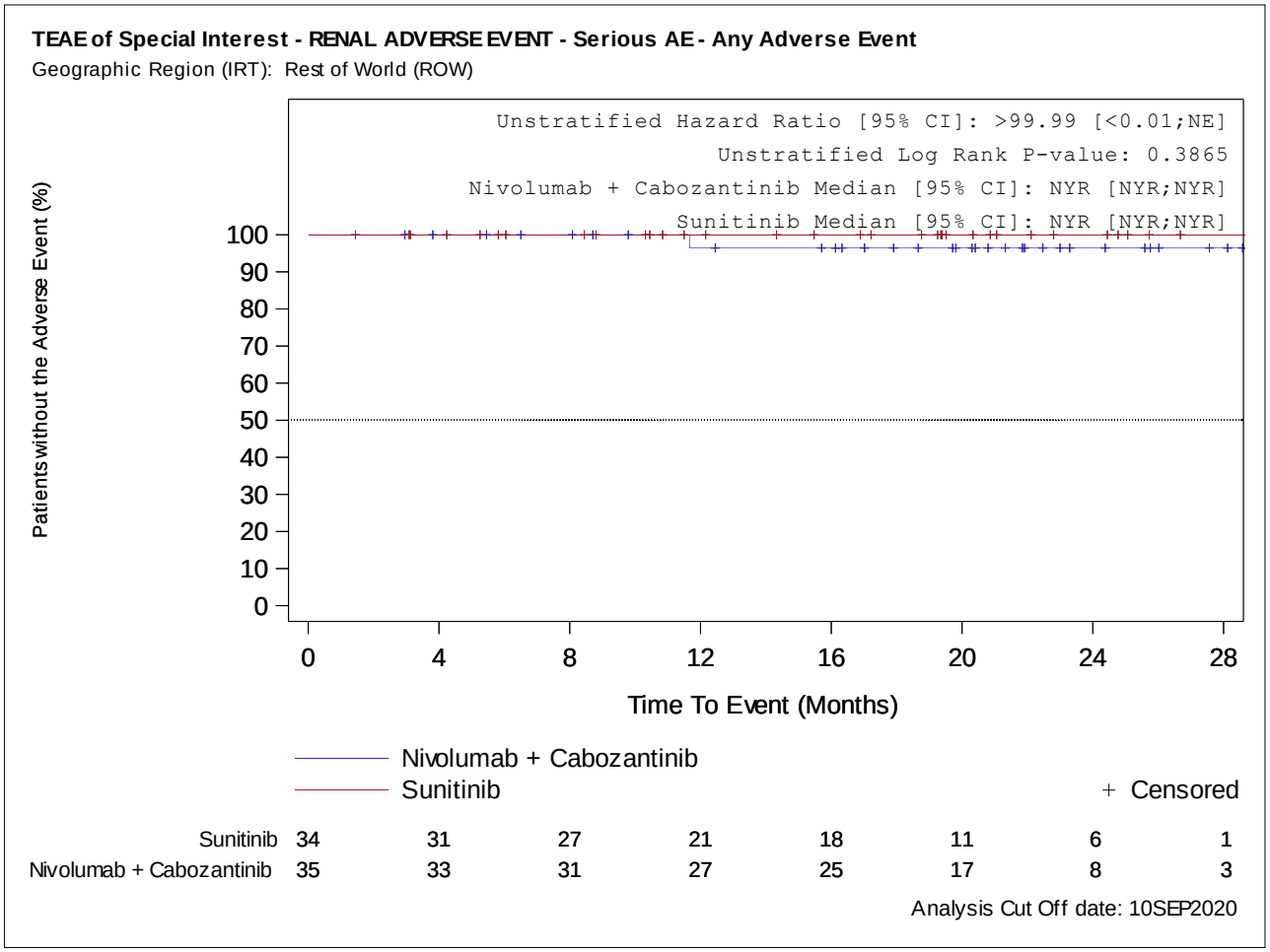

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:20:31

FIGURE 3.51.2.6: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



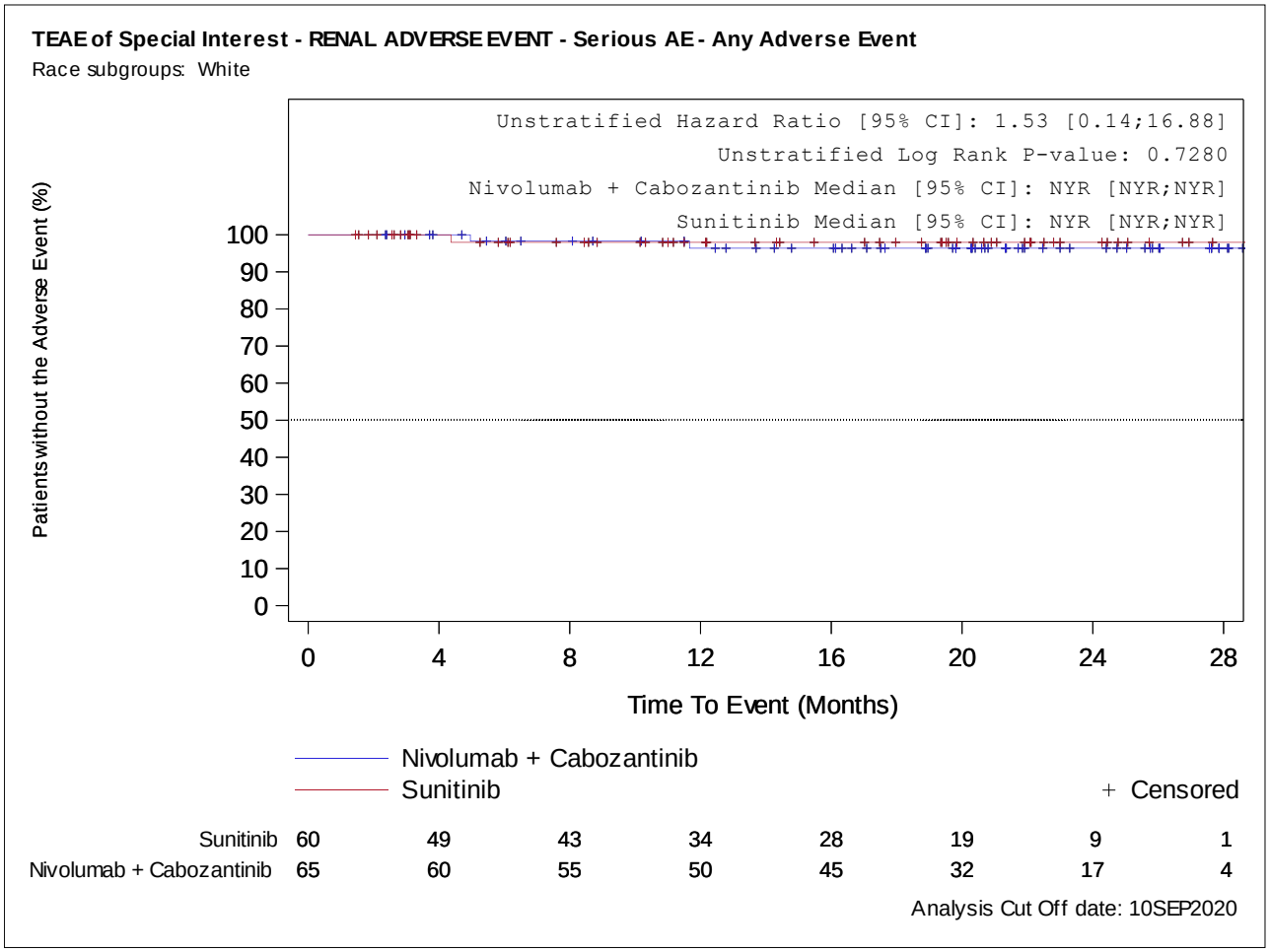

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:20:37

FIGURE 3.51.2.7: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



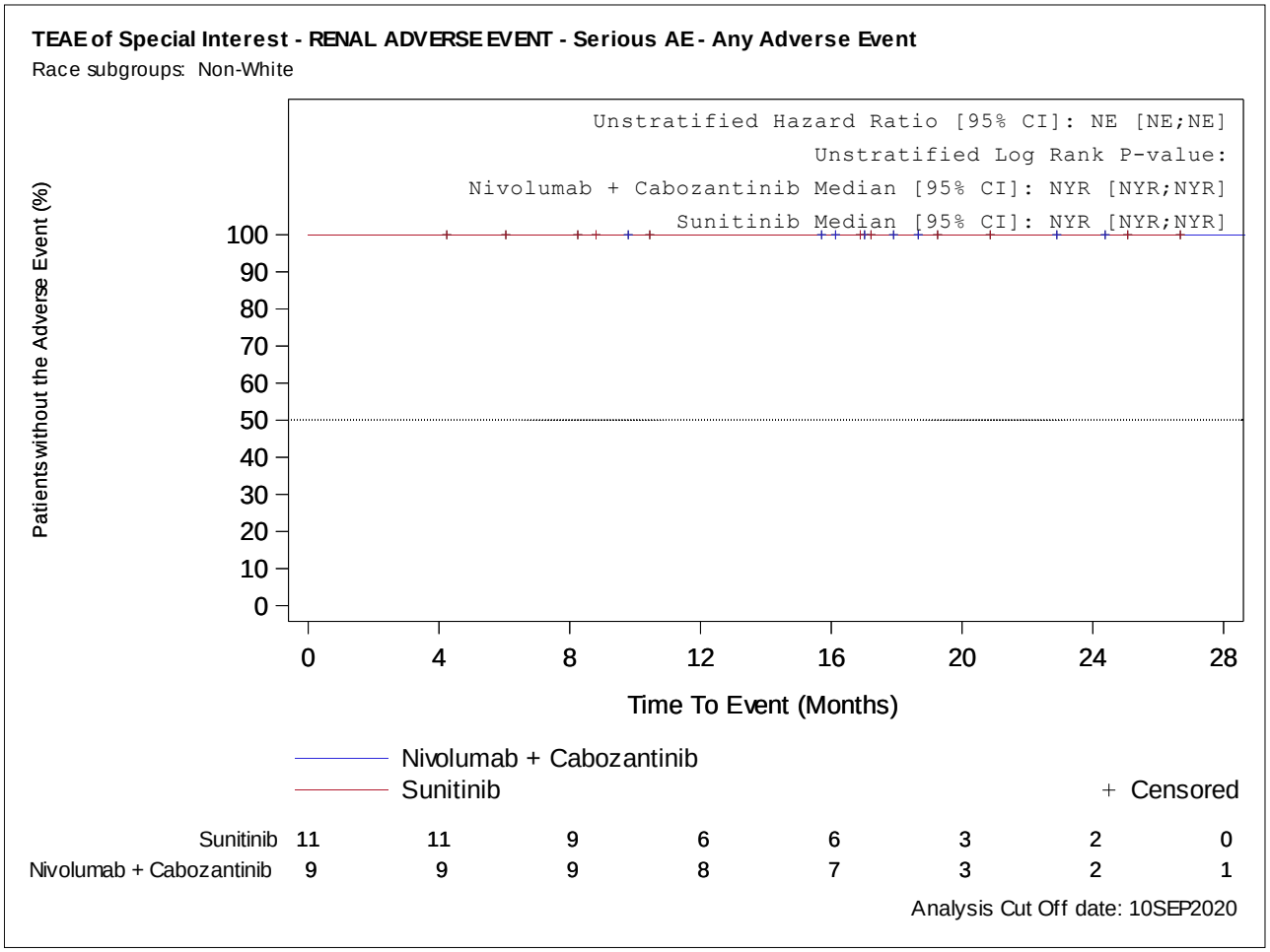

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:20:42

FIGURE 3.51.2.8: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



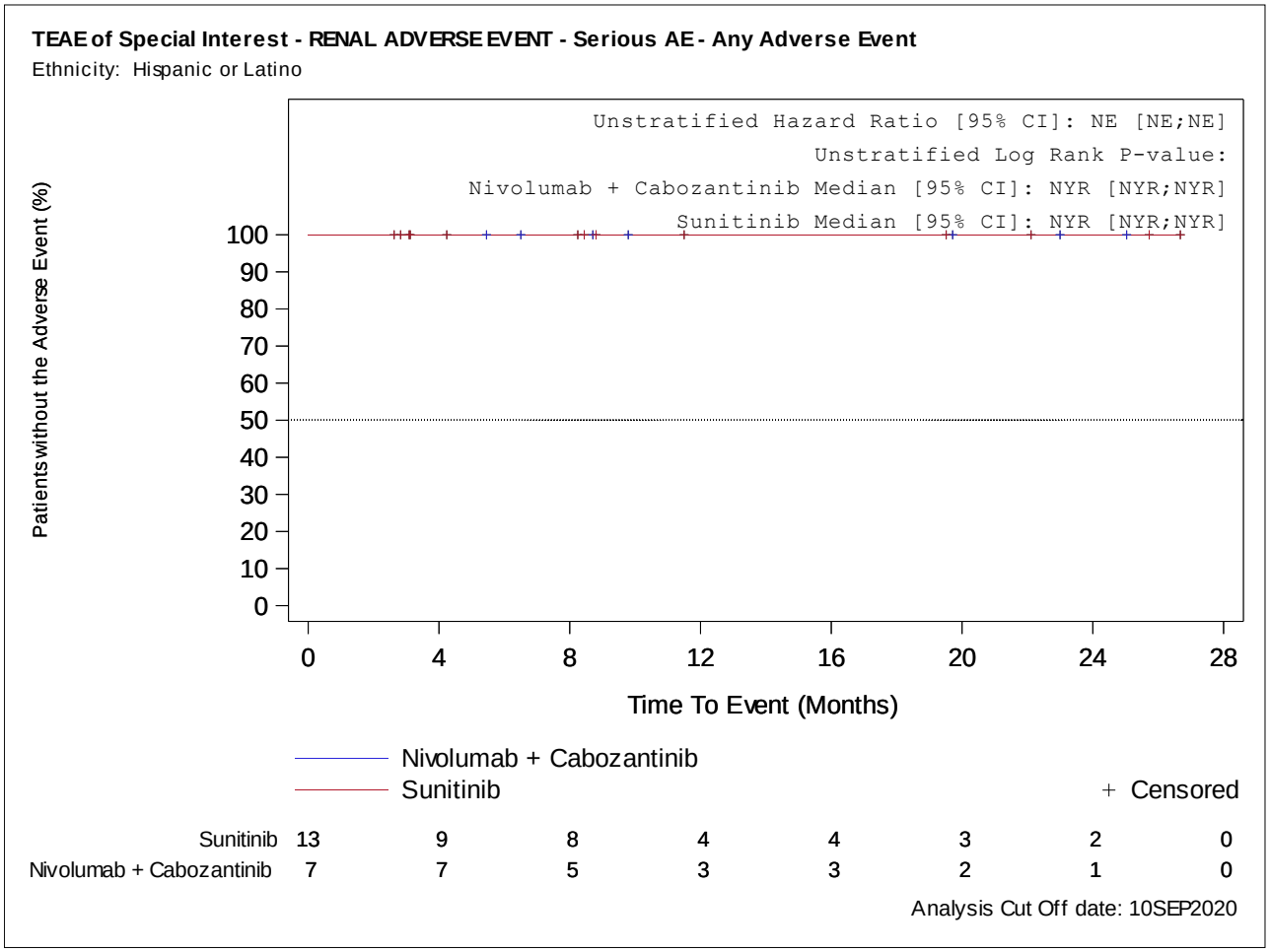

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:20:47

FIGURE 3.51.2.9: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



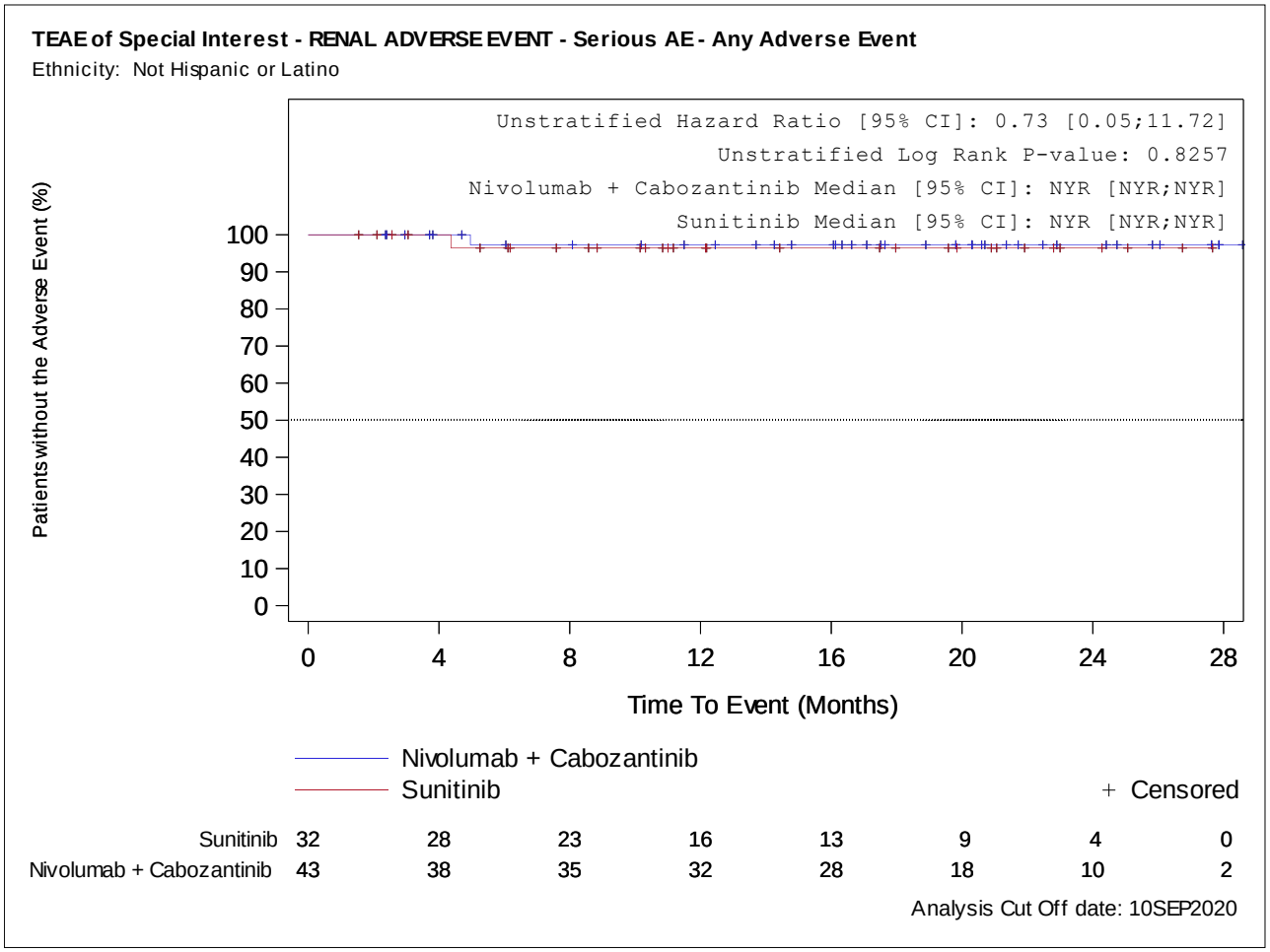

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:20:52

FIGURE 3.51.2.10: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



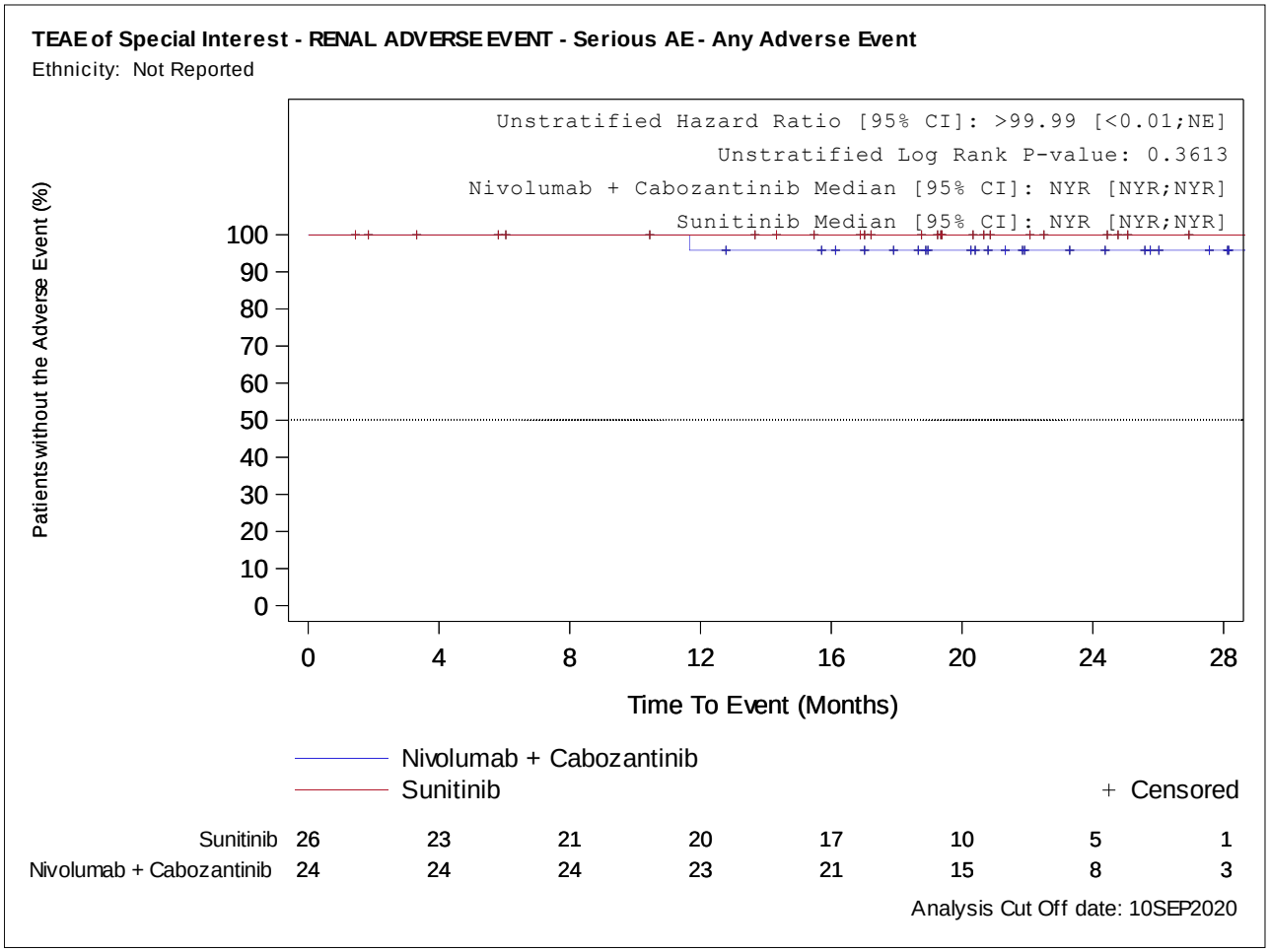

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:20:57

FIGURE 3.51.2.11: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



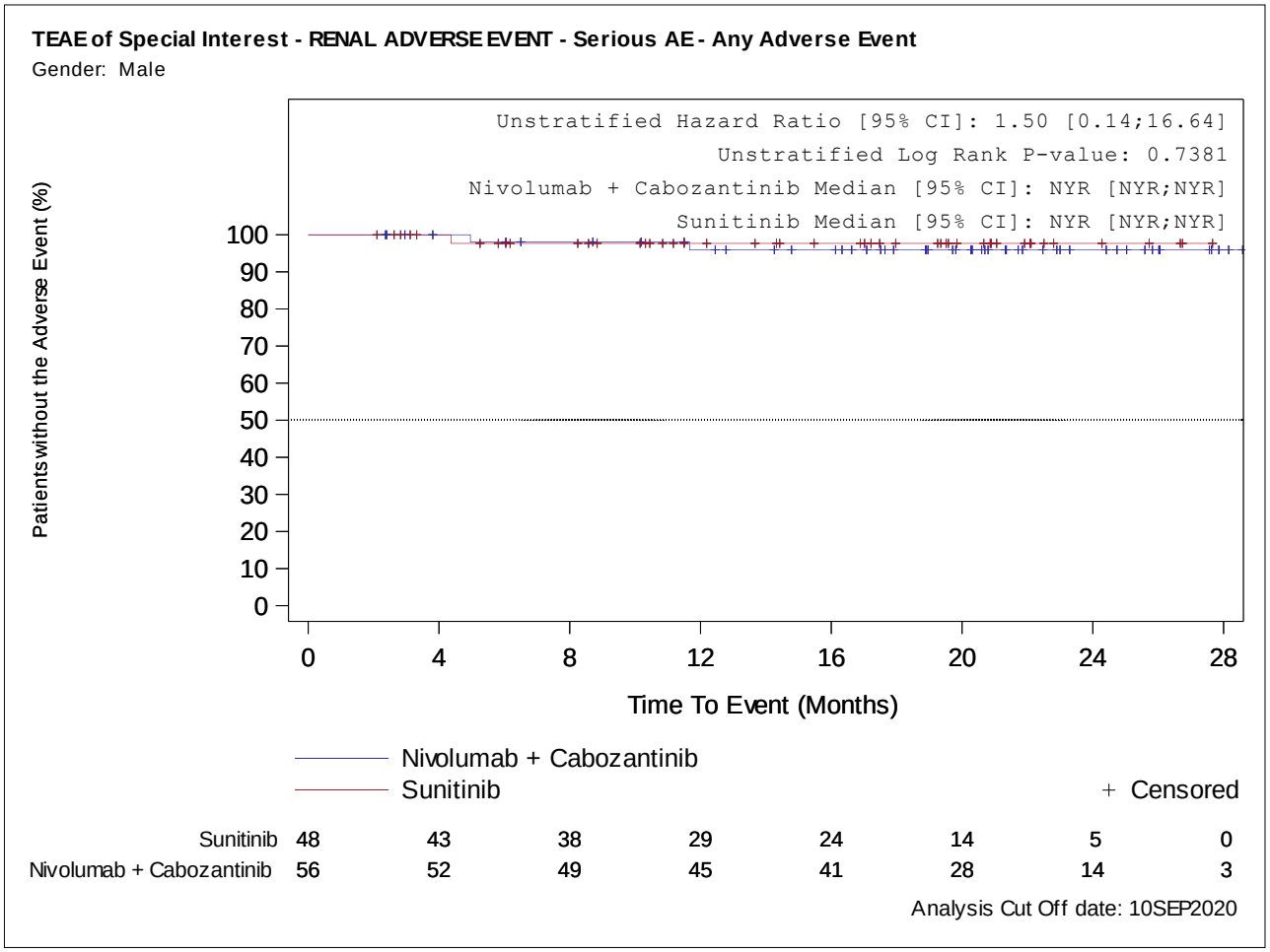

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:21:02

FIGURE 3.51.2.12: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



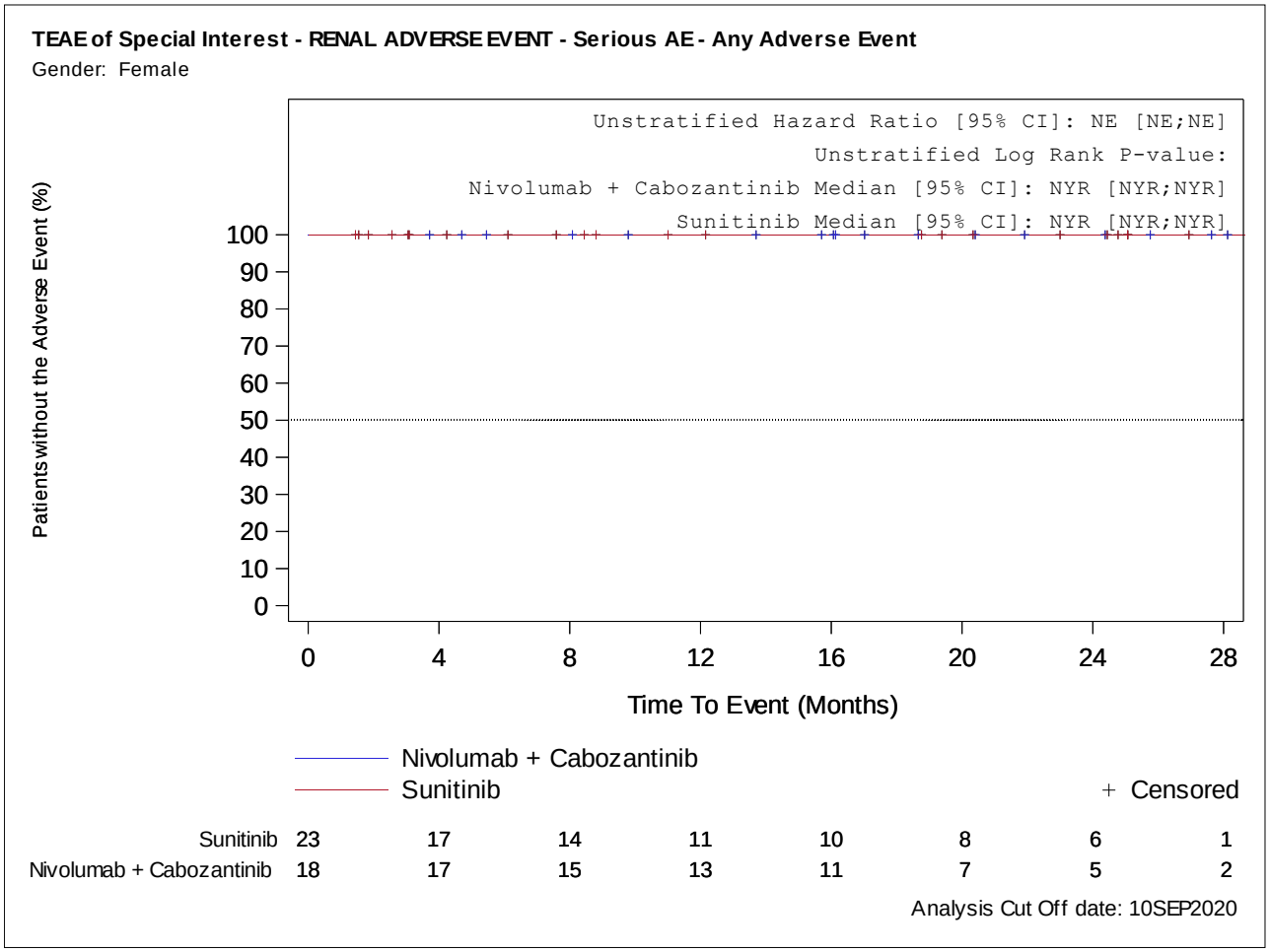

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:21:07

FIGURE 3.51.2.13: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



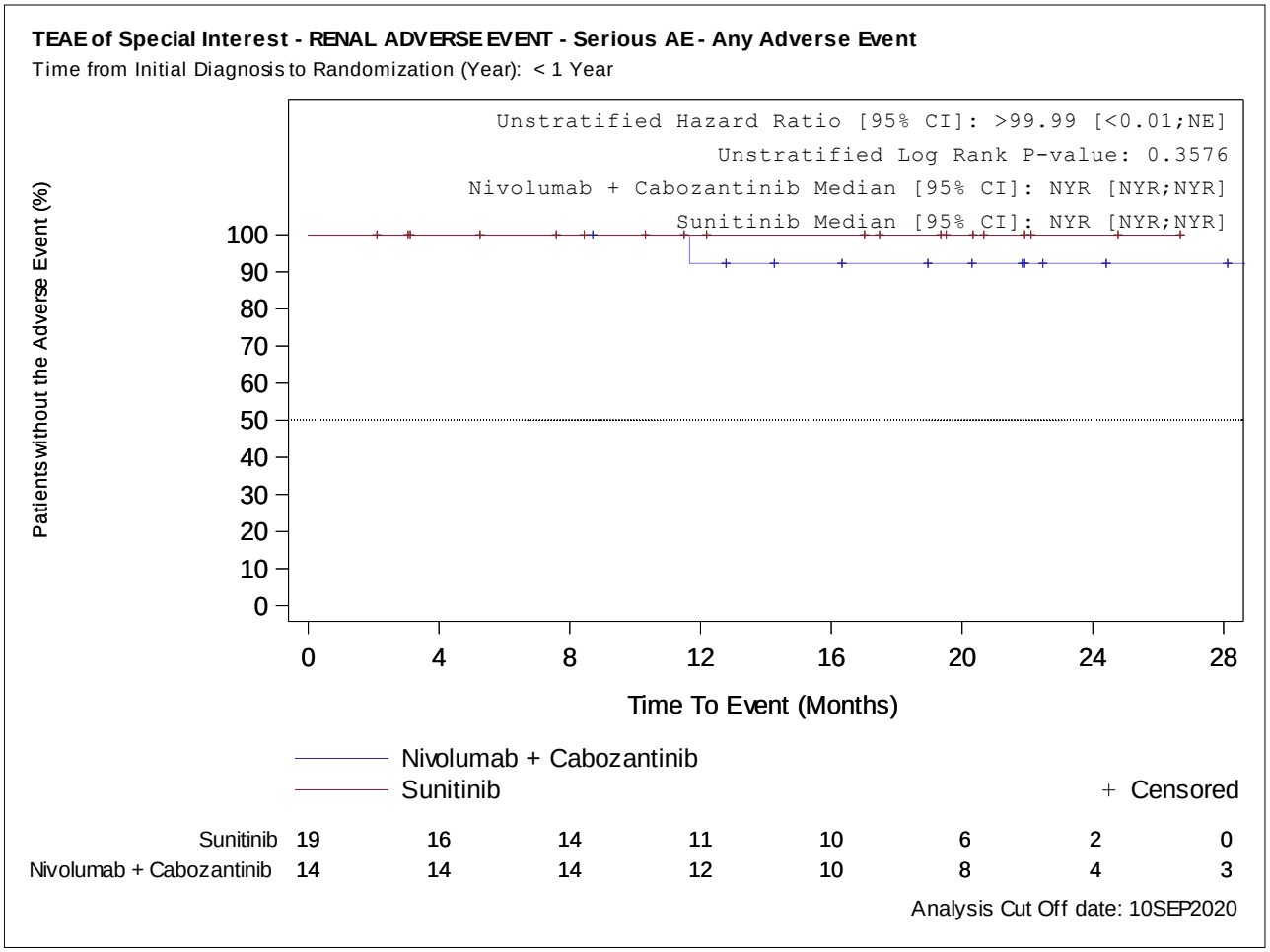

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:21:12

FIGURE 3.51.2.14: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



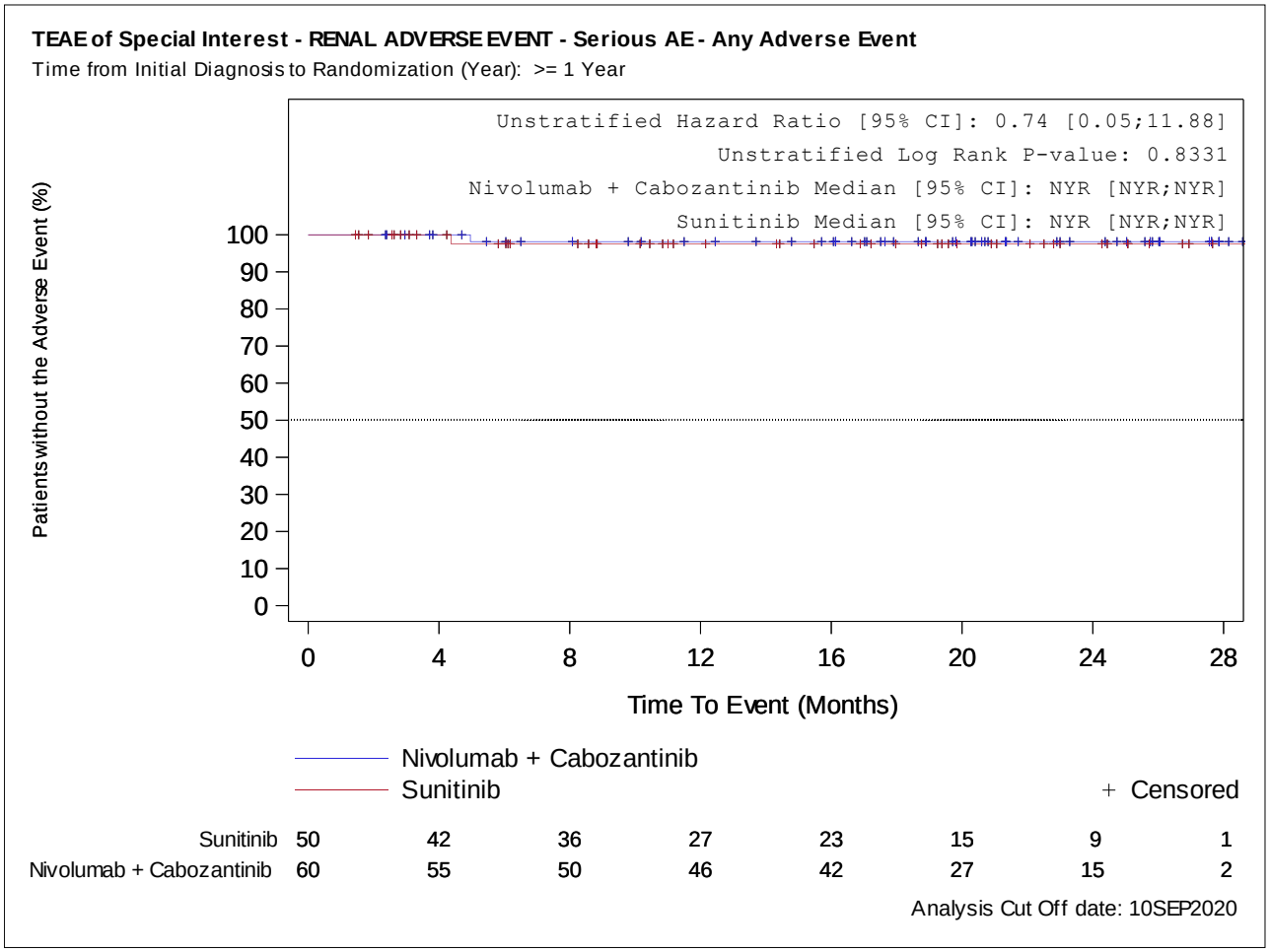

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:21:17

FIGURE 3.51.2.15: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



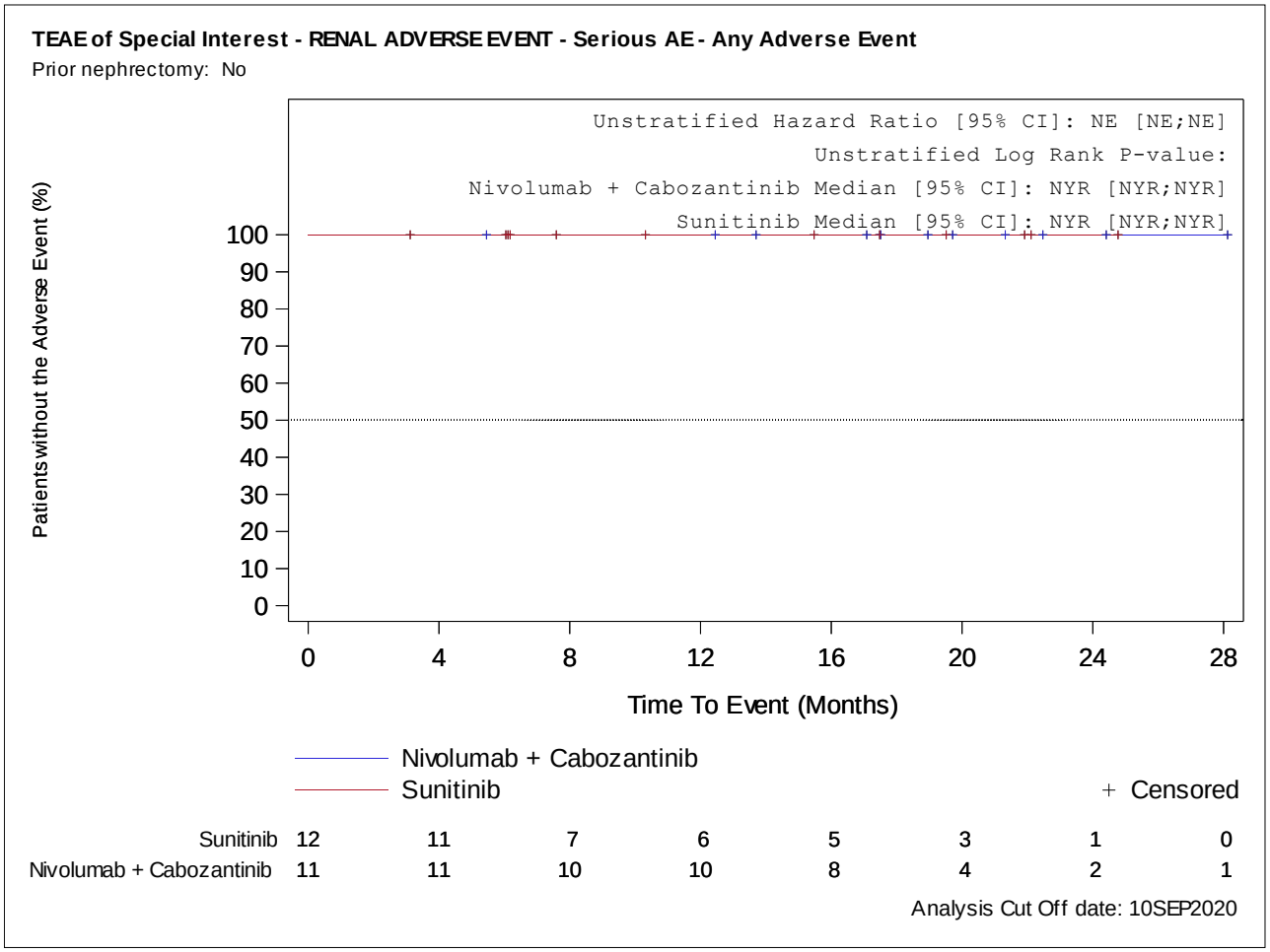

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:21:33

FIGURE 3.51.2.16: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



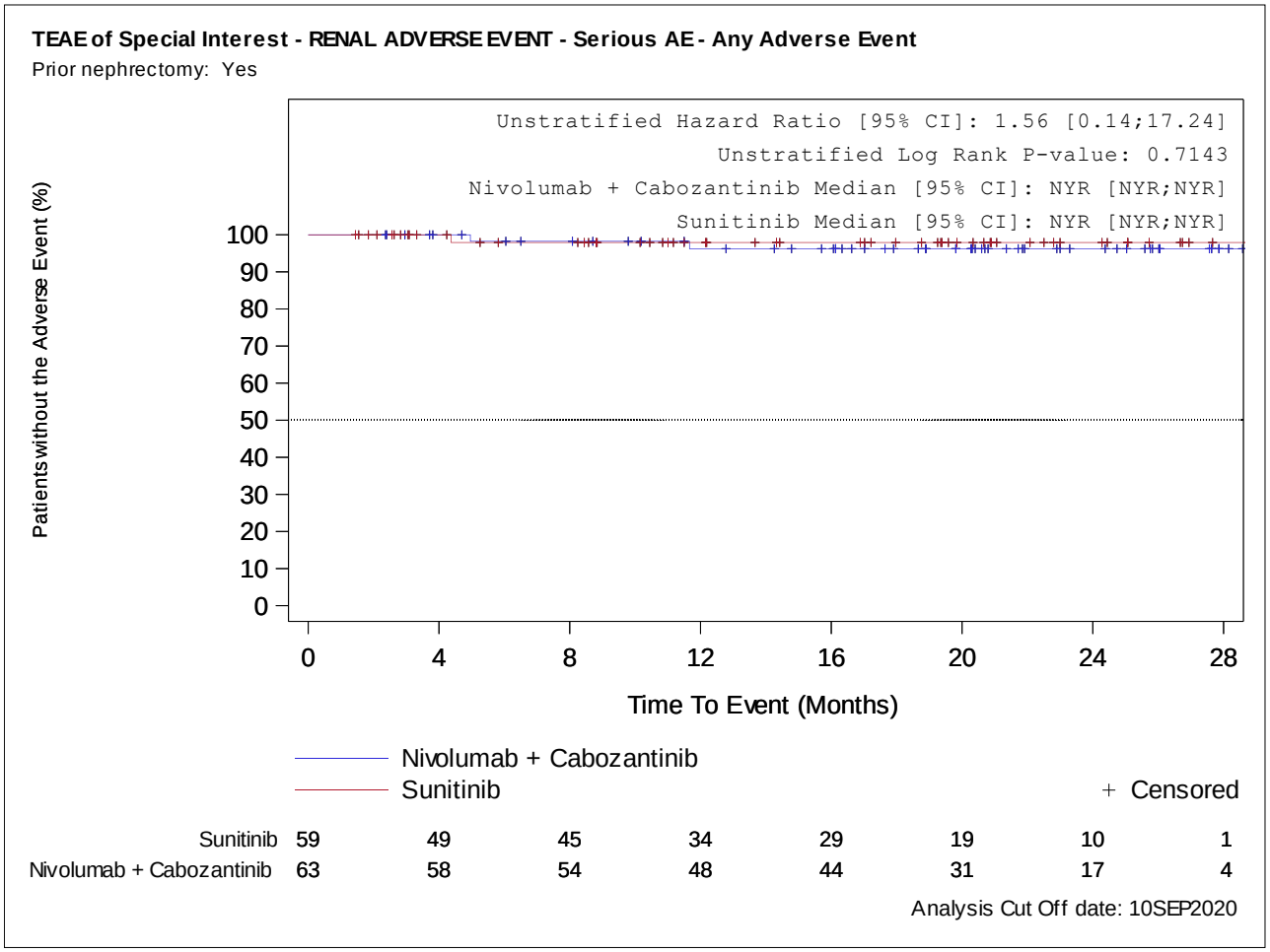

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:21:38

FIGURE 3.51.2.17: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



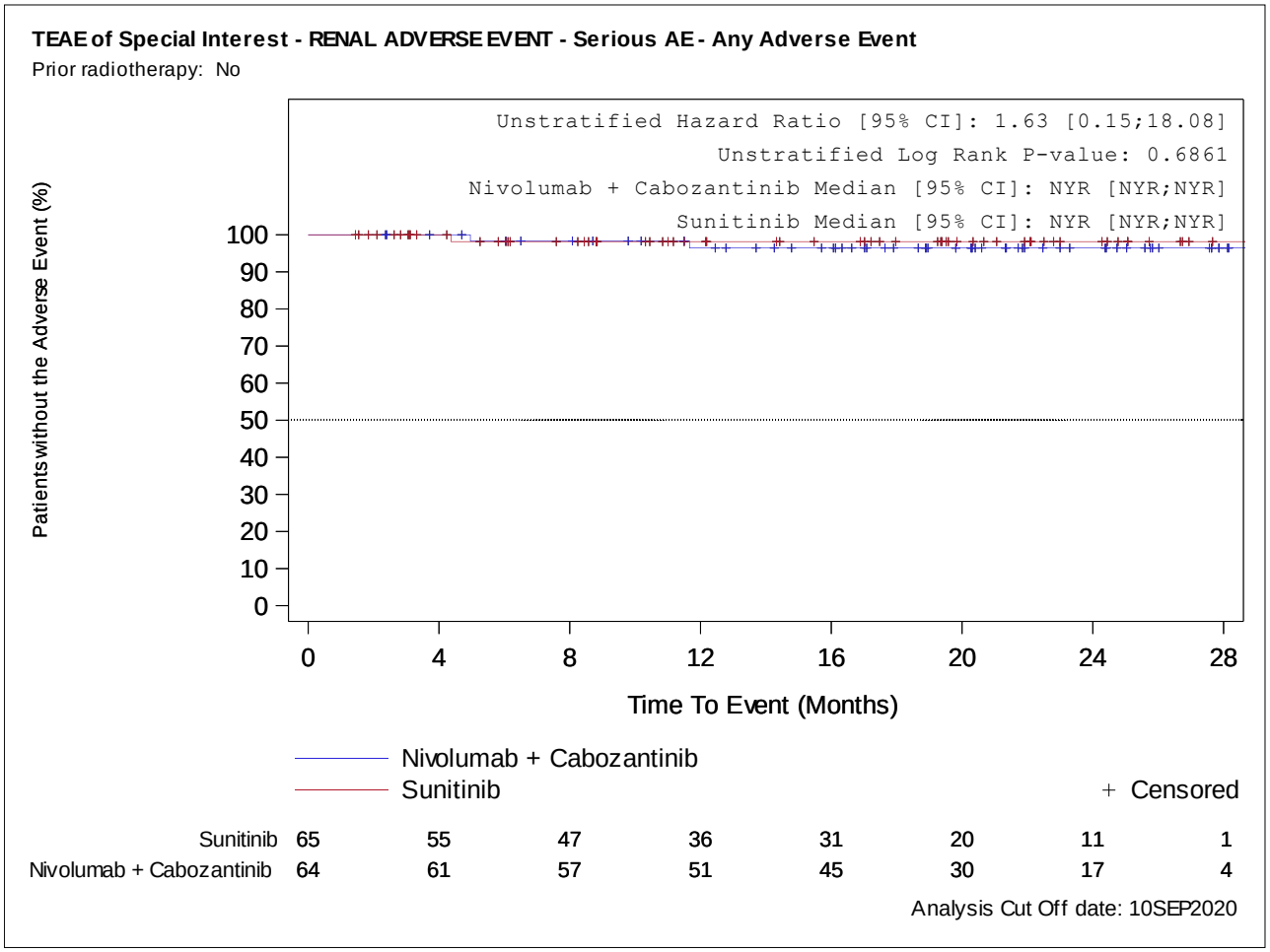

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:25

FIGURE 3.51.2.18: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



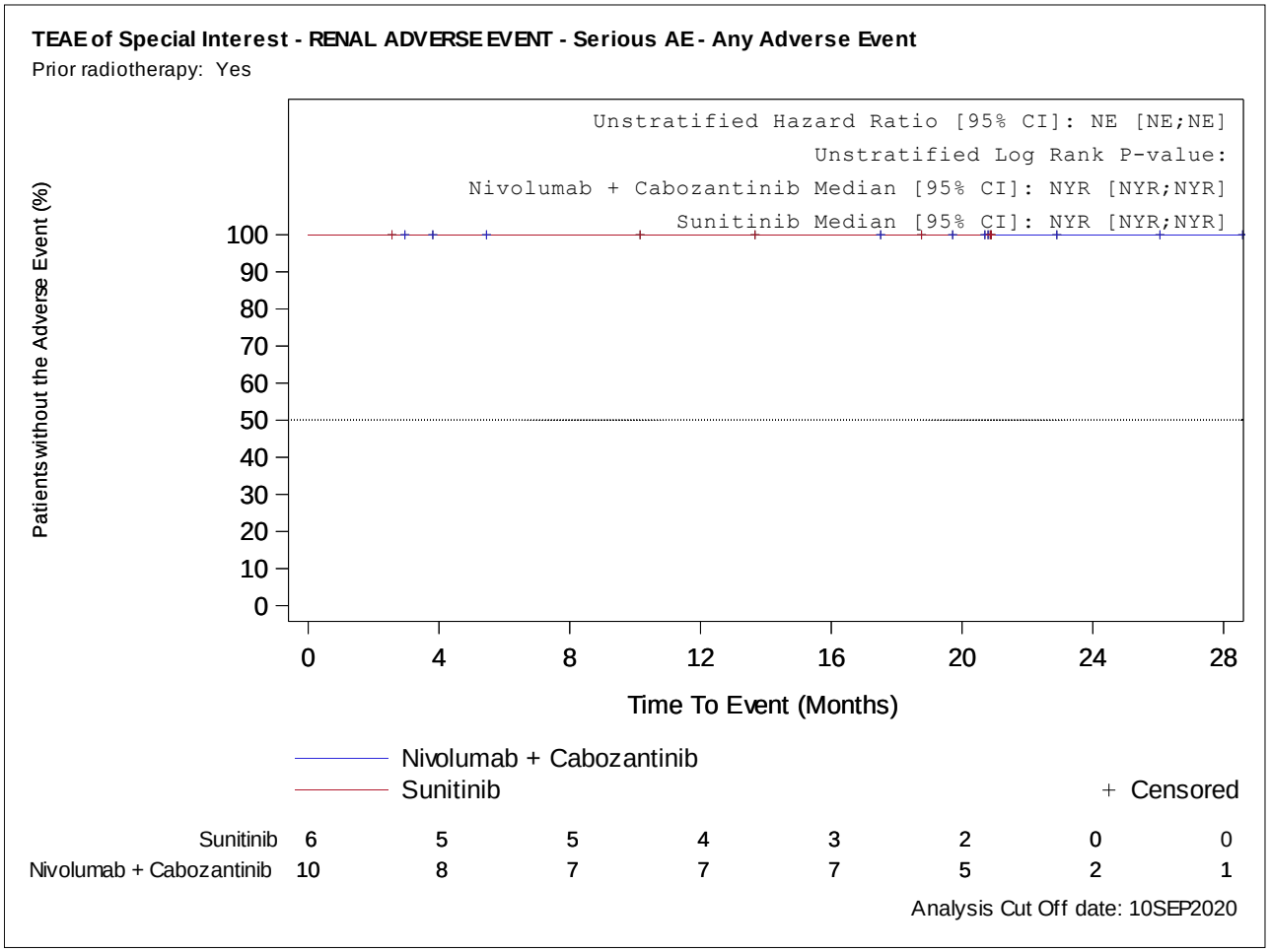

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:31

FIGURE 3.51.2.19: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



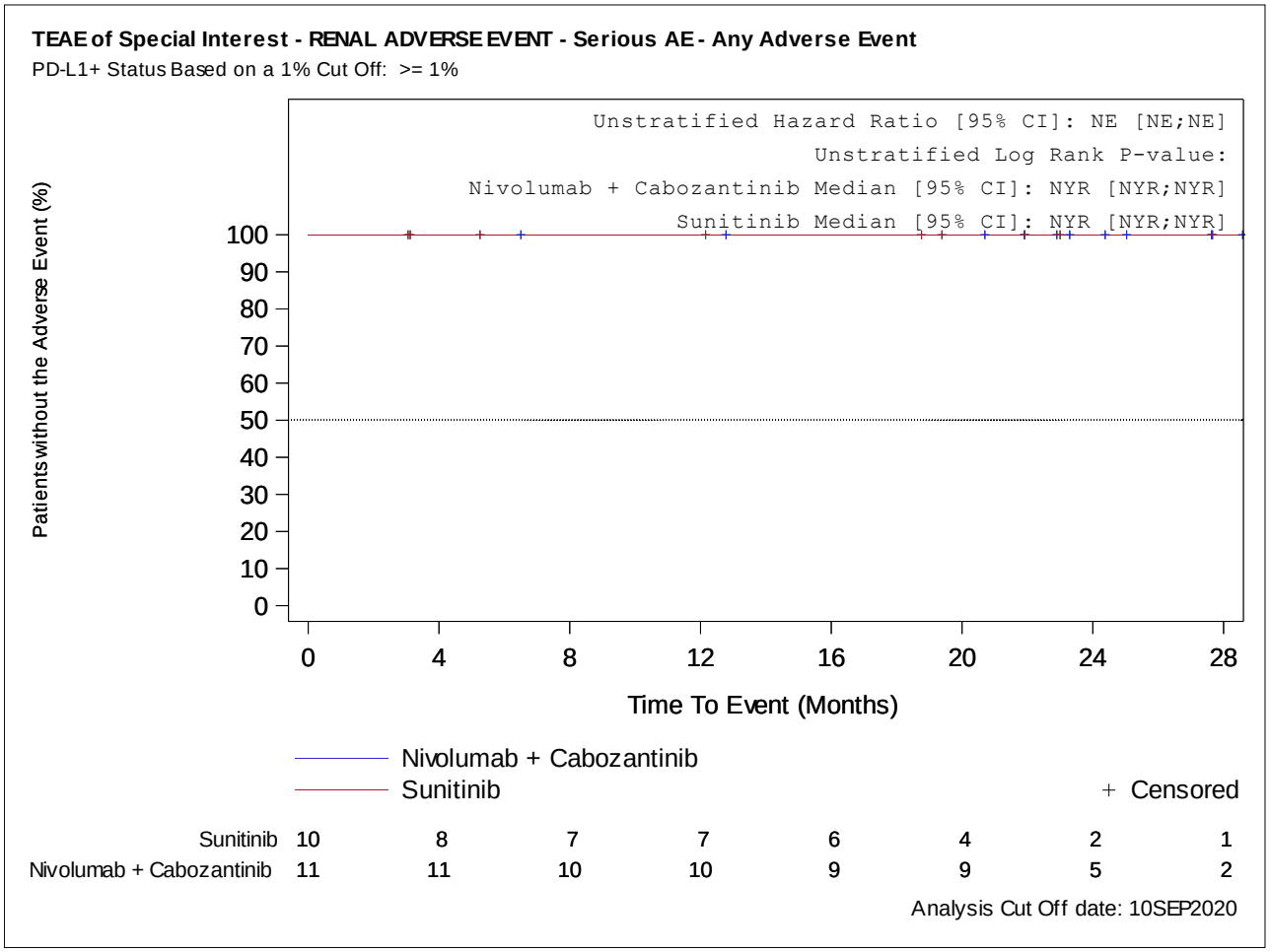

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:36

FIGURE 3.51.2.20: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



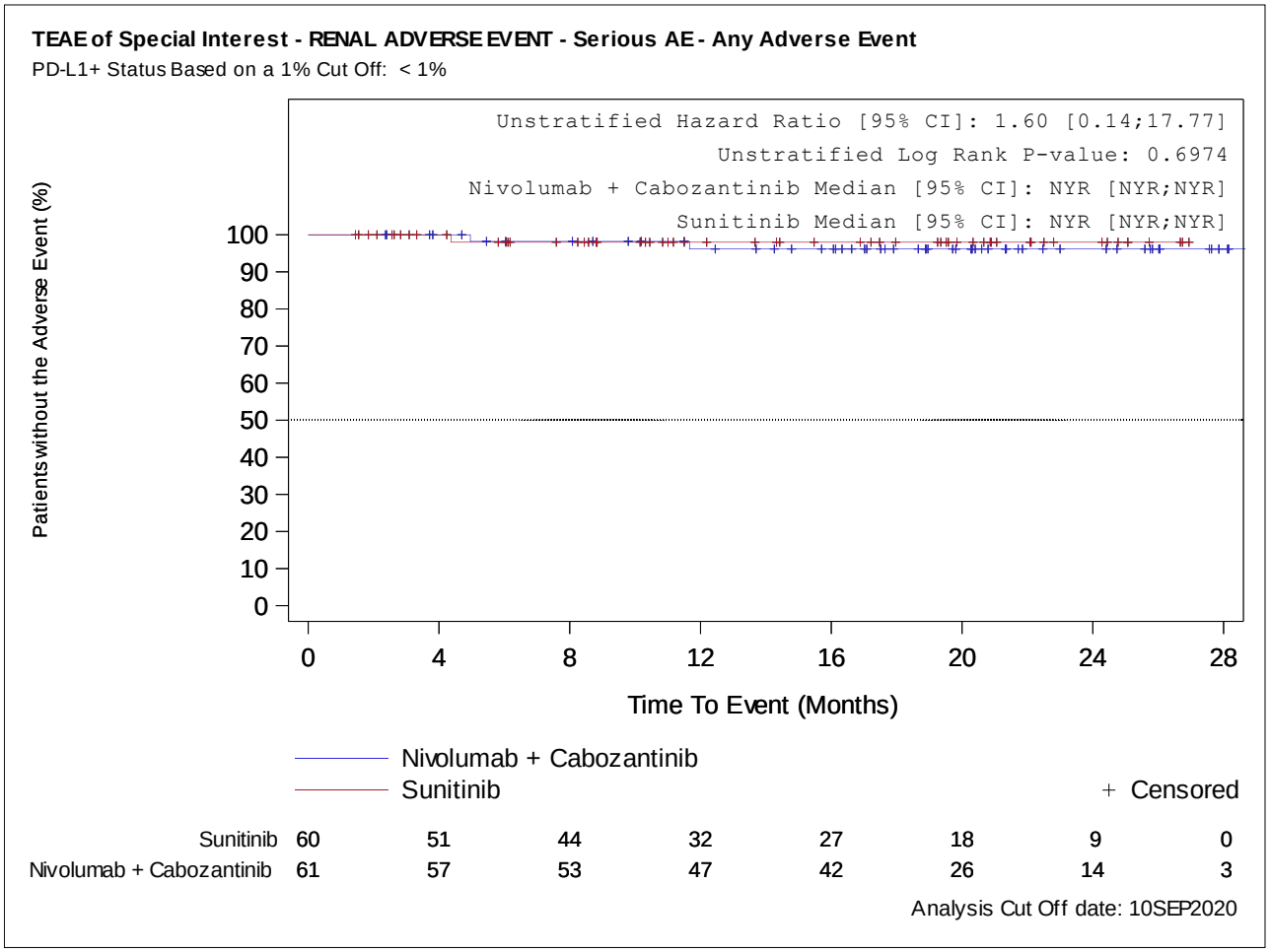

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:41

FIGURE 3.51.2.21: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



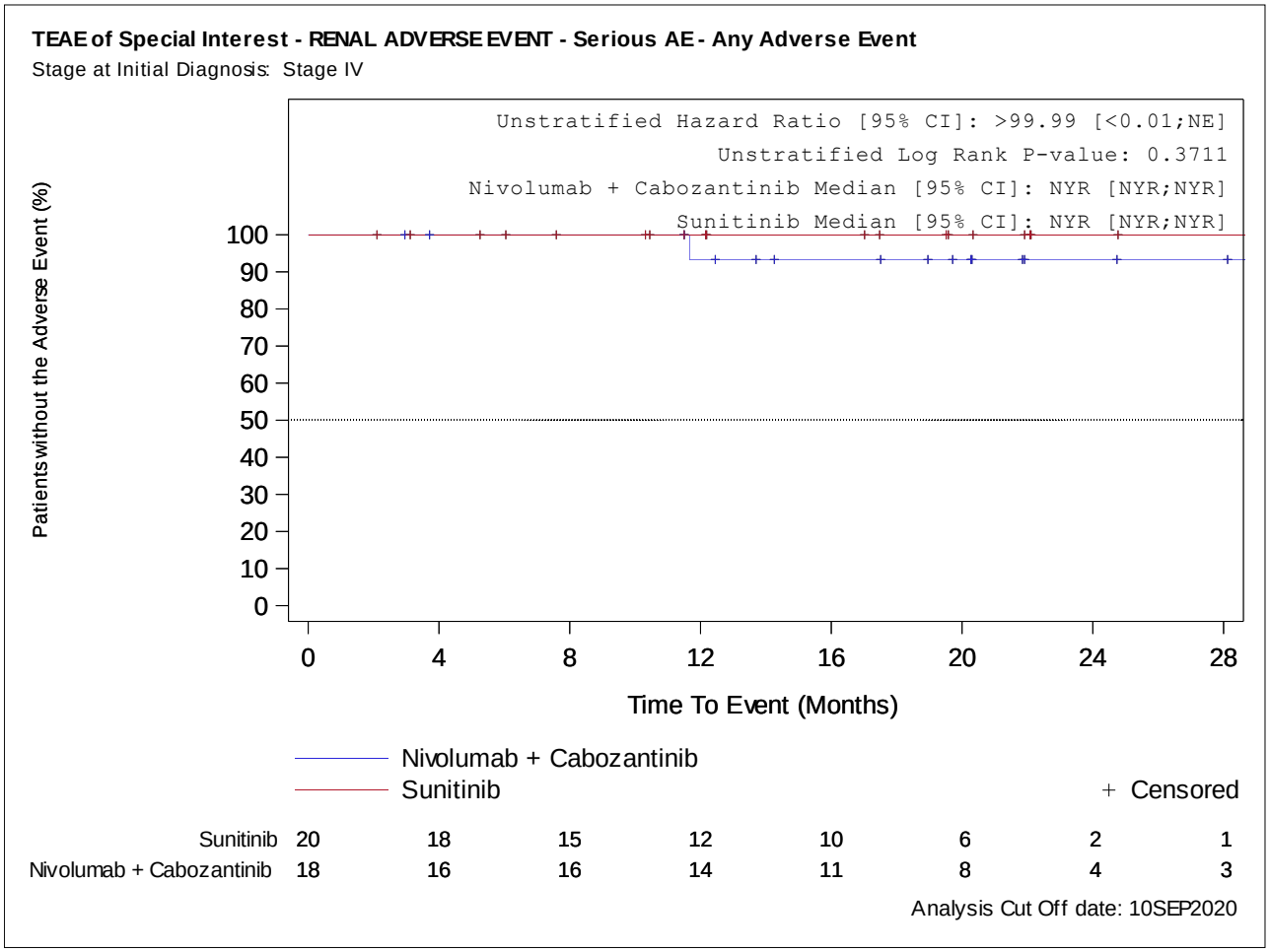

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:47

FIGURE 3.51.2.22: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



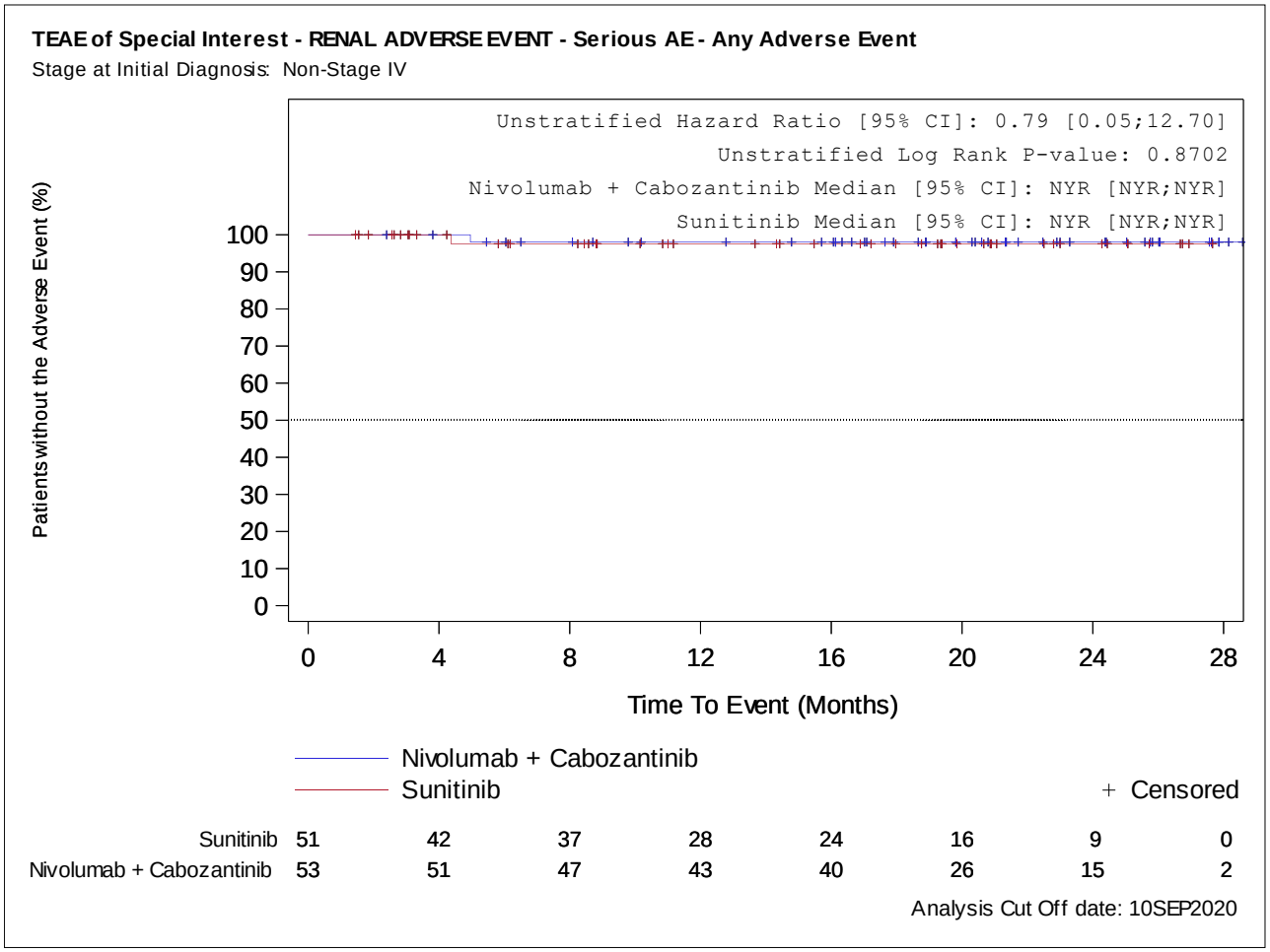

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:52

FIGURE 3.51.2.23: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



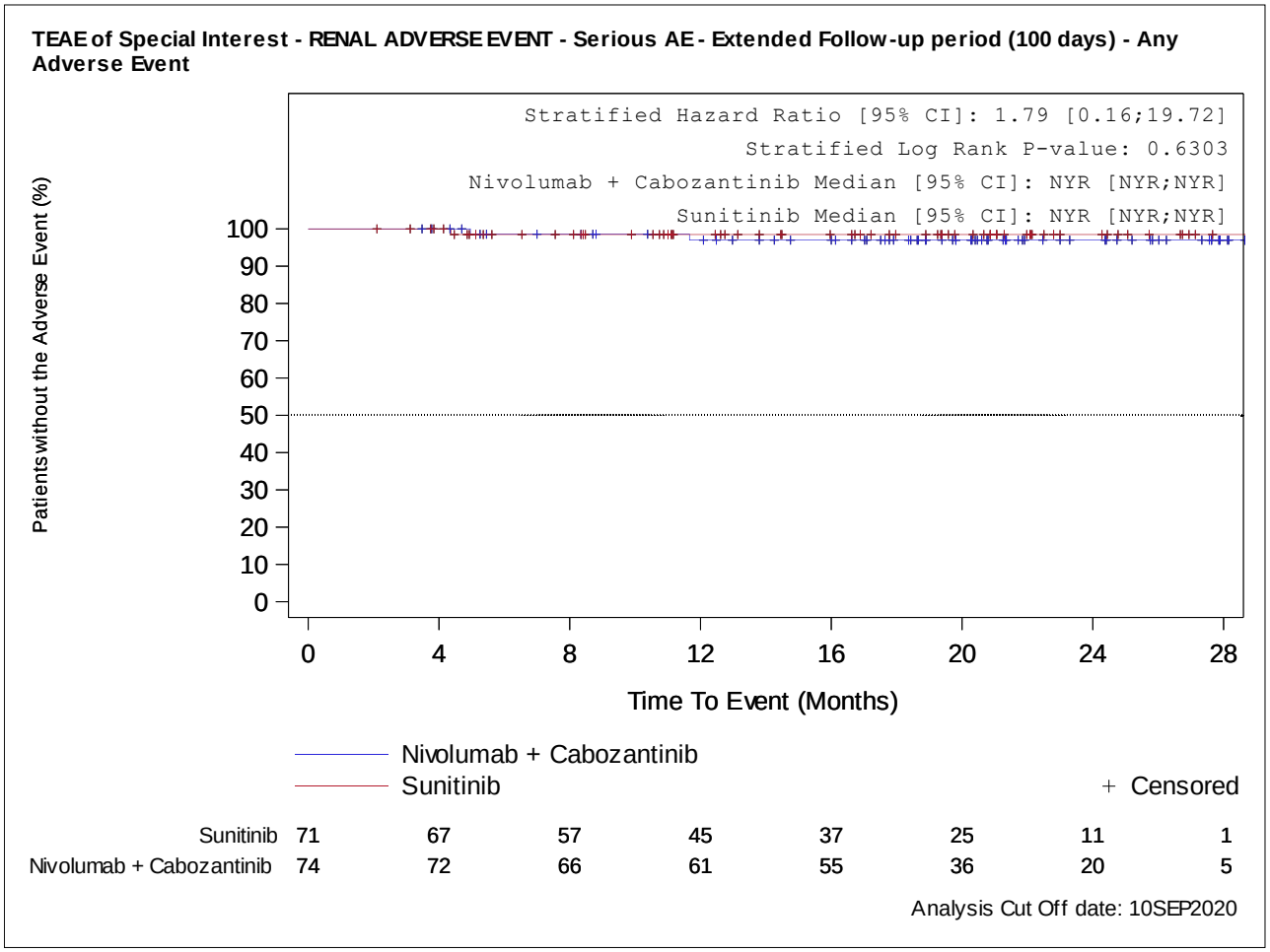

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:23:18

FIGURE 3.51.2.24: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



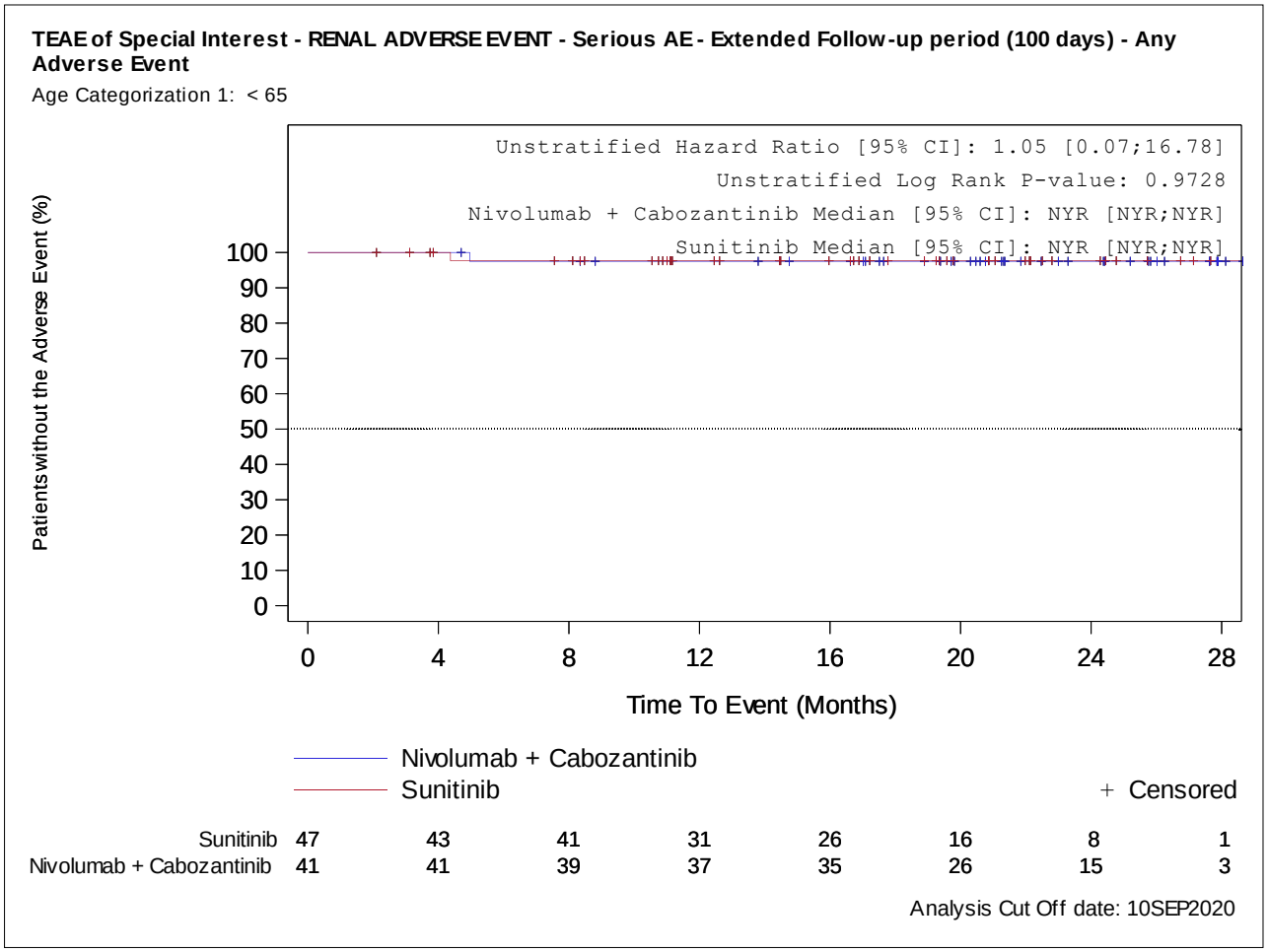

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:23:23

FIGURE 3.52.1: TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:26:17

FIGURE 3.52.2.1: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  < 65




Analysis Cut Off date: 10SEP2020
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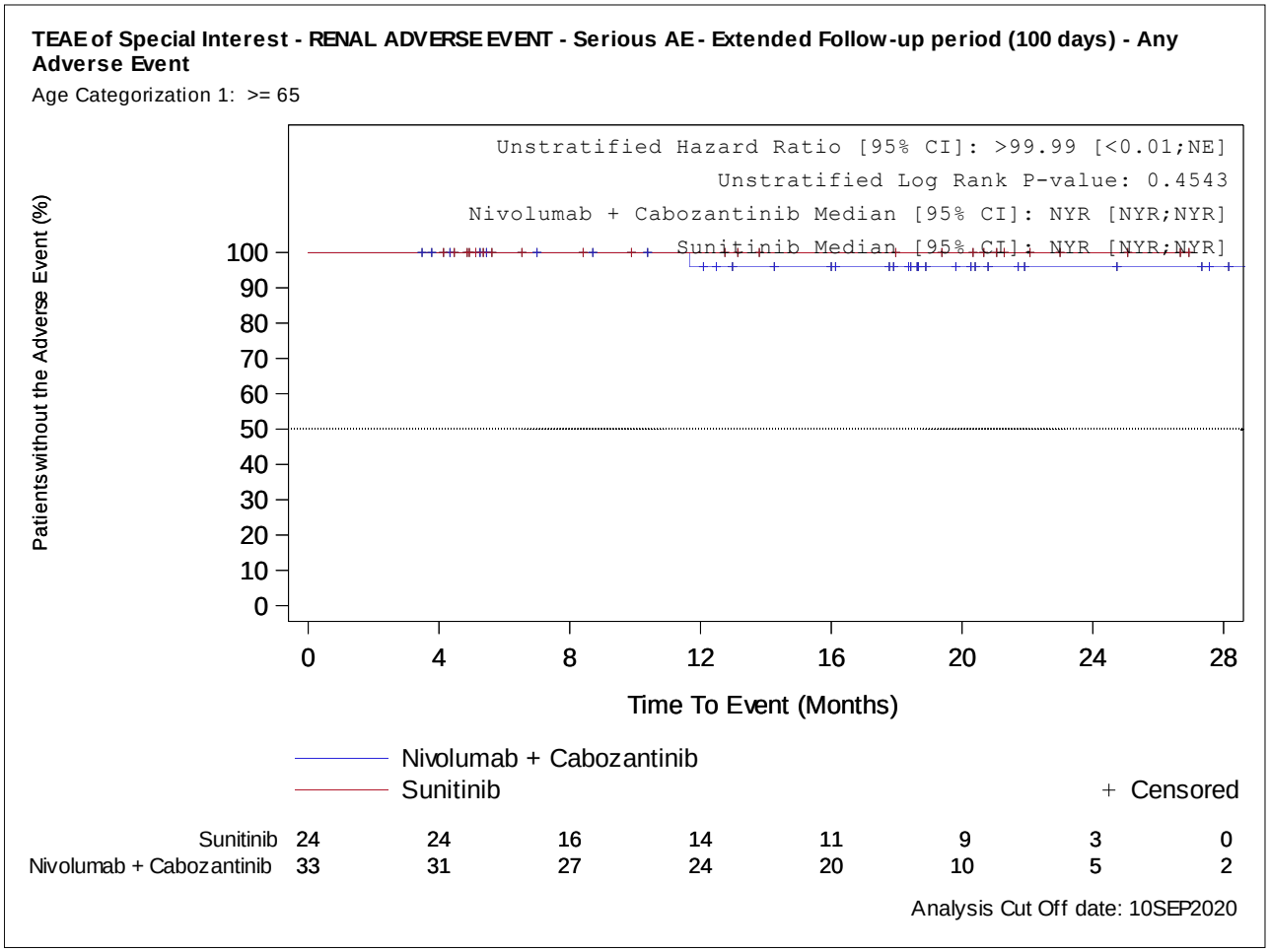
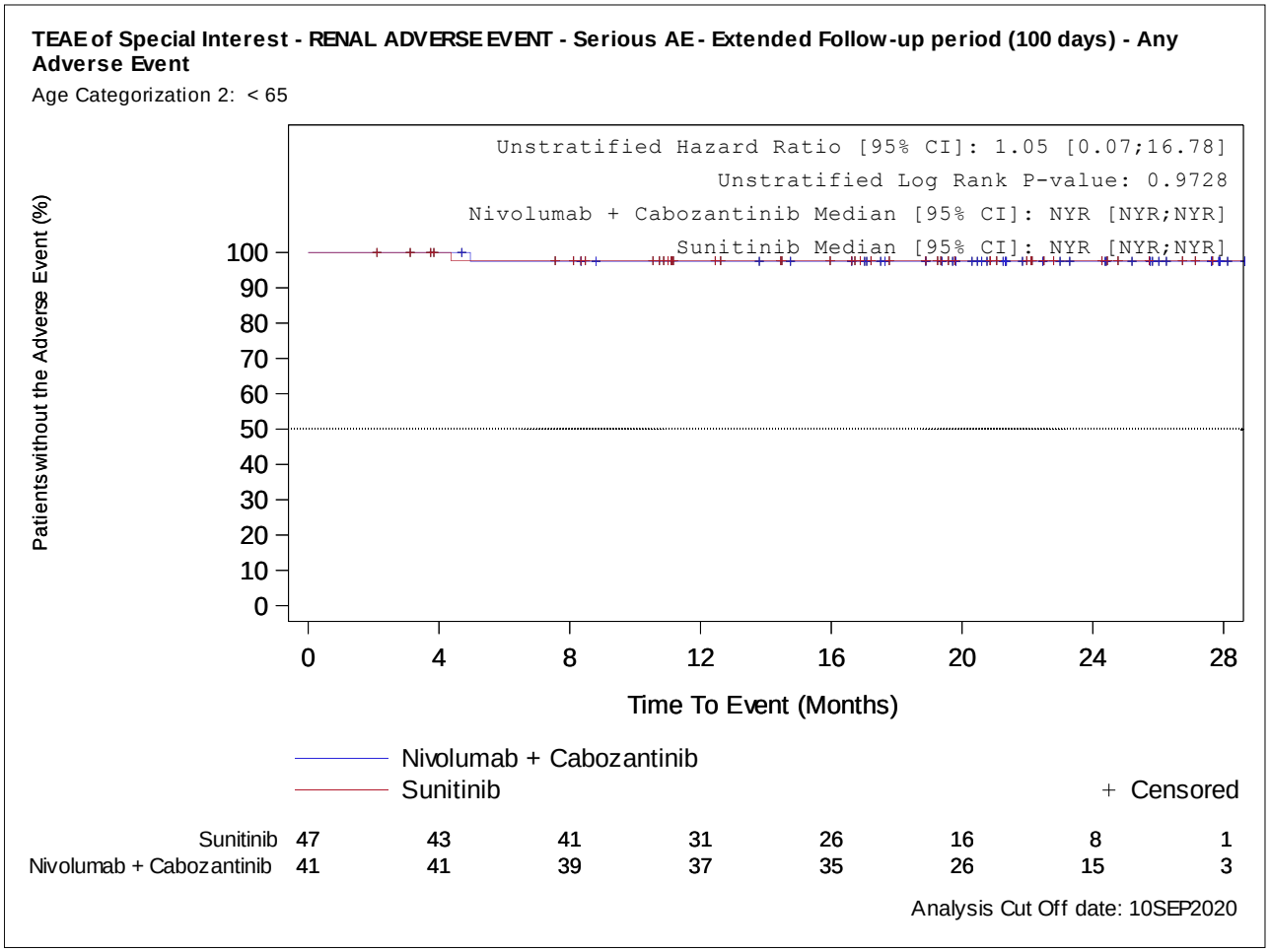
FIGURE 3.52.2.2: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



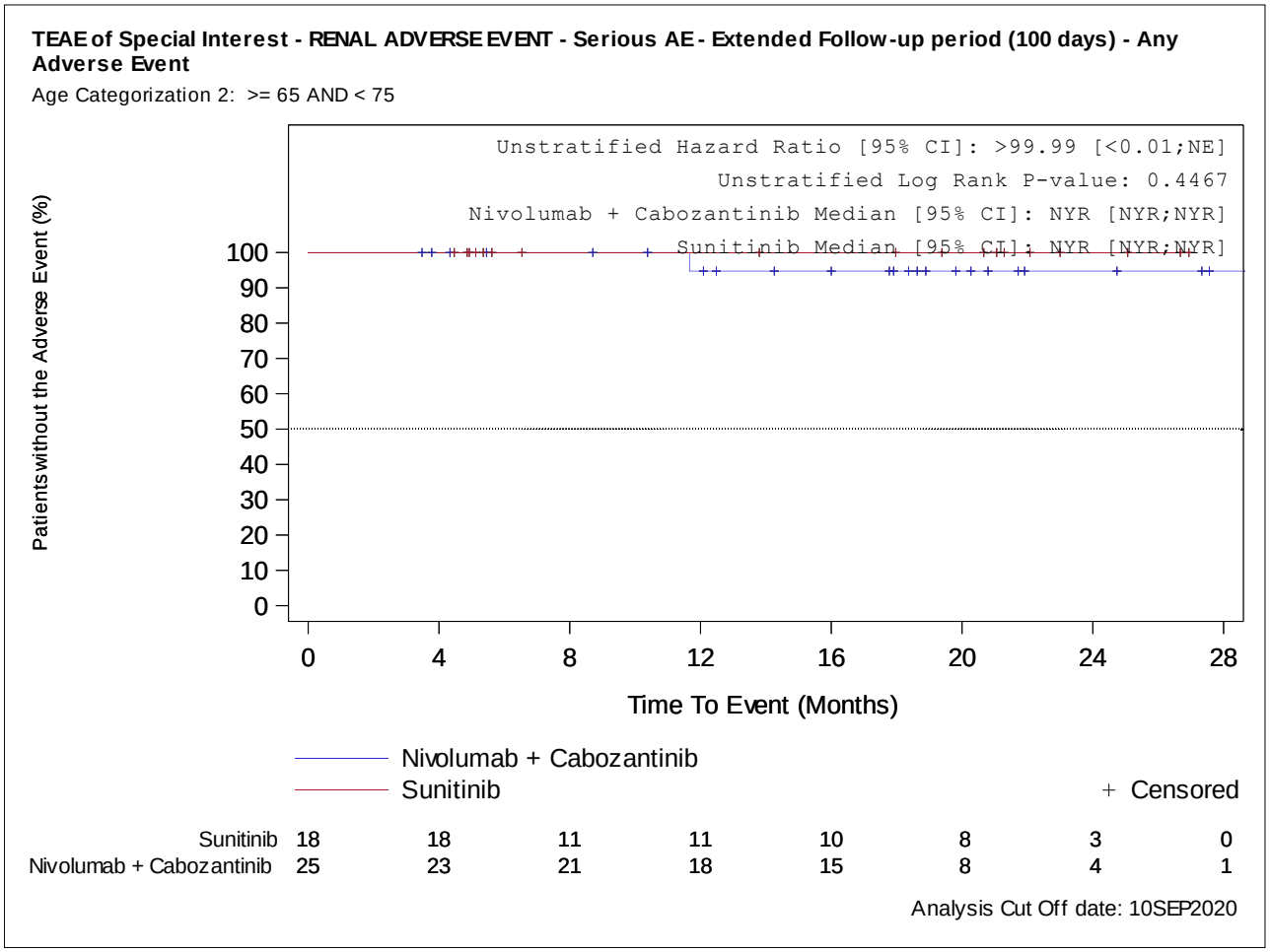

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:26:25

FIGURE 3.52.2.3: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



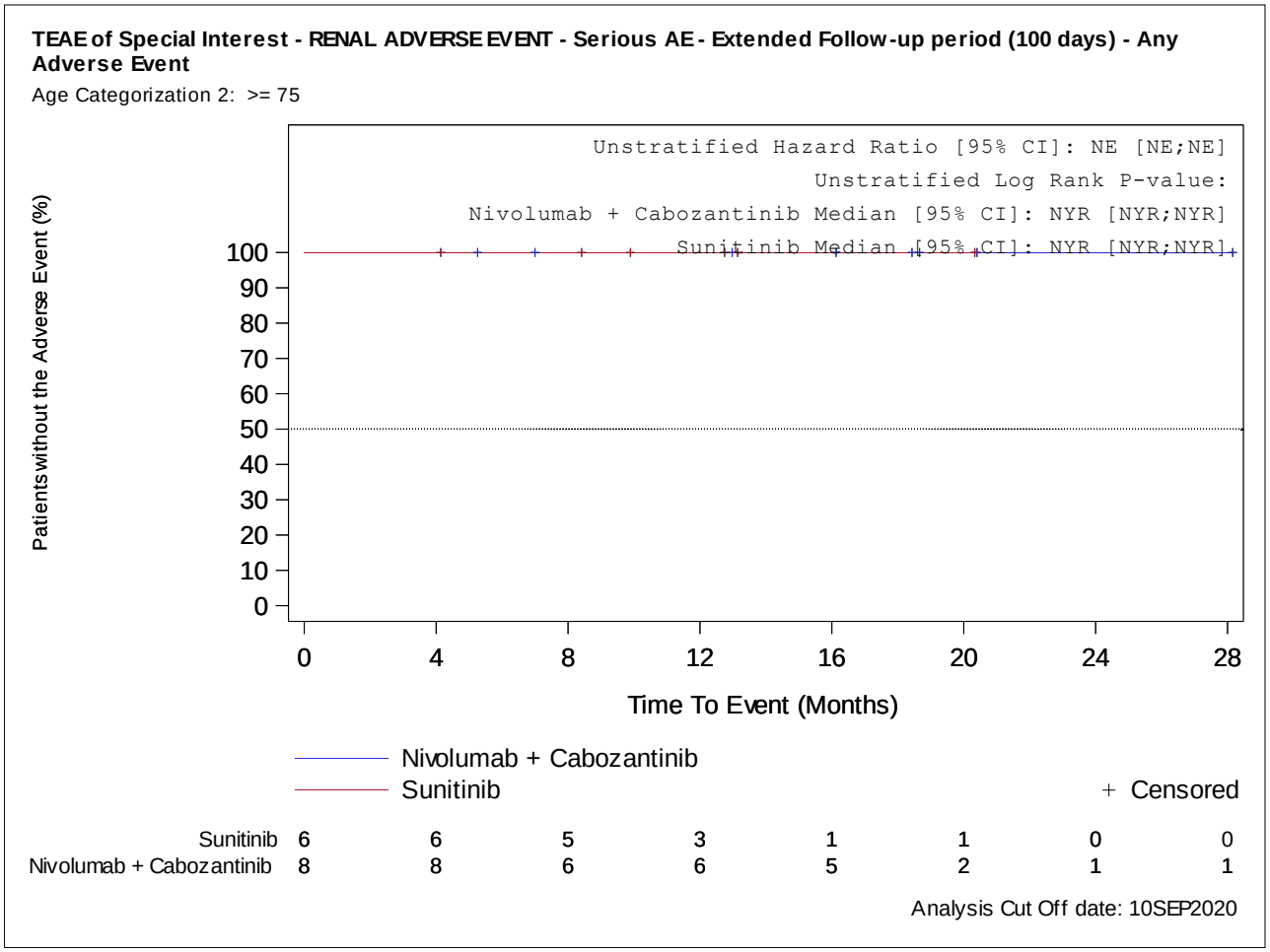

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:26:31

FIGURE 3.52.2.4: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



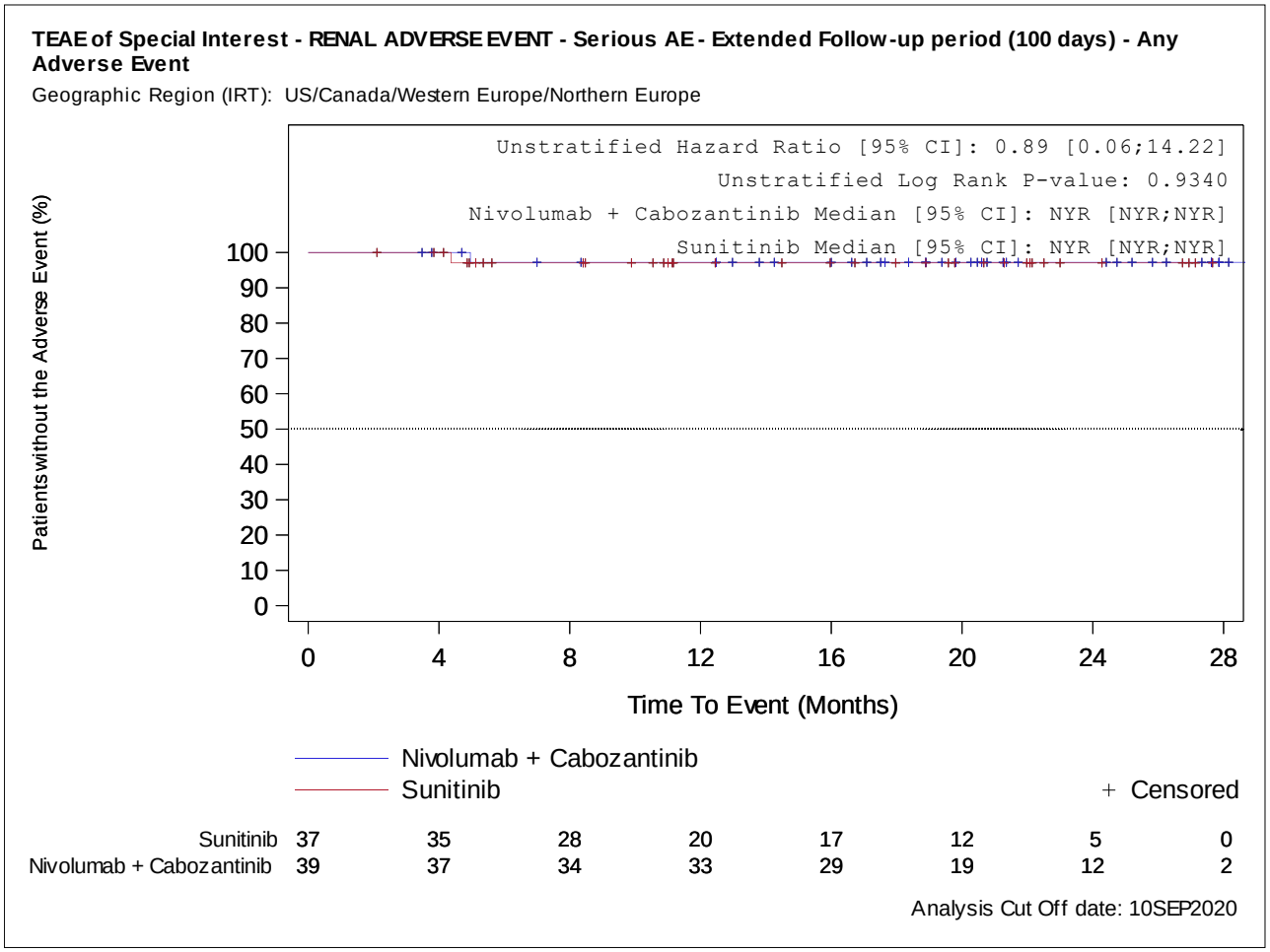

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:26:36

FIGURE 3.52.2.5: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



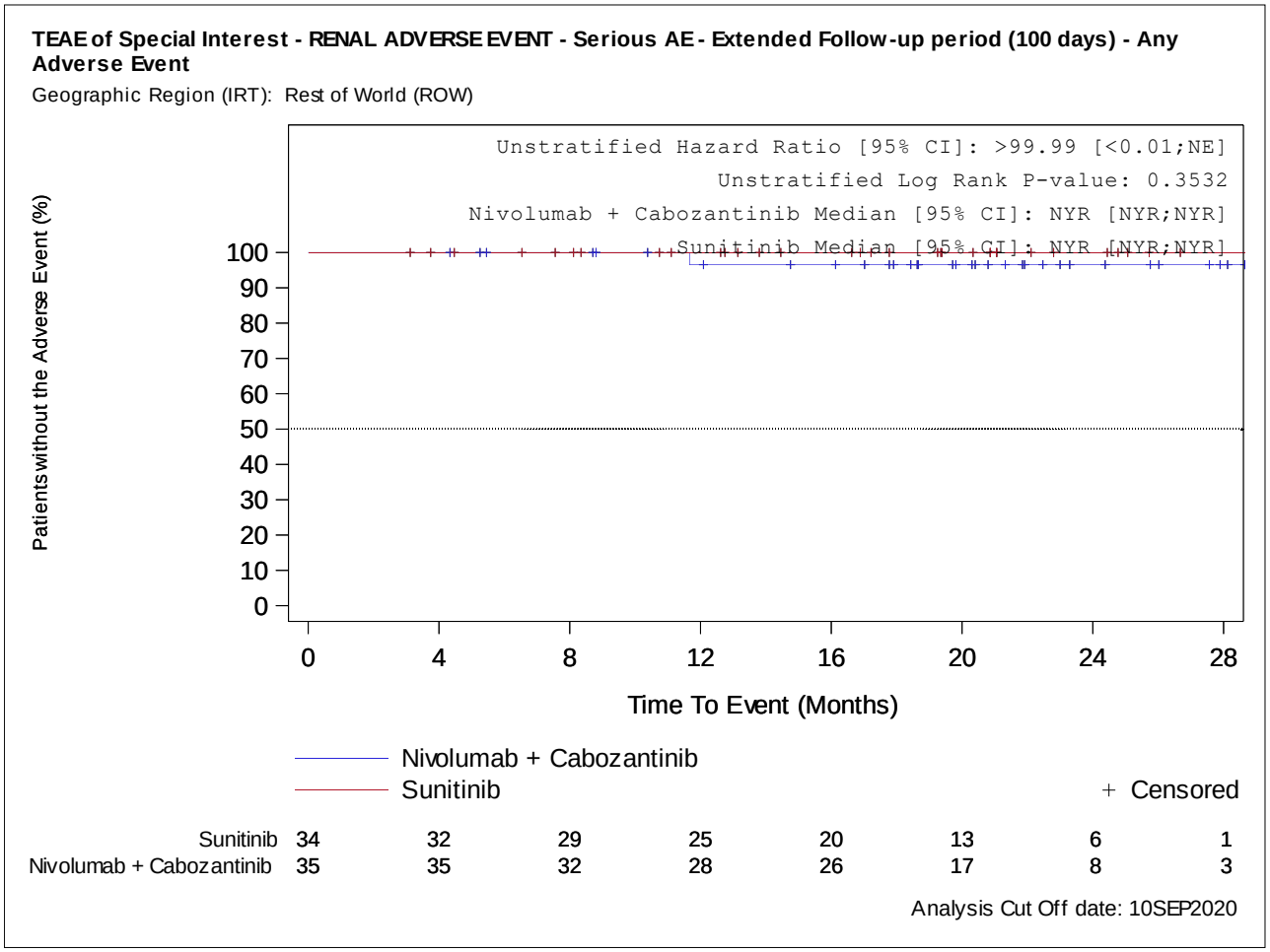

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:26:41

FIGURE 3.52.2.6: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



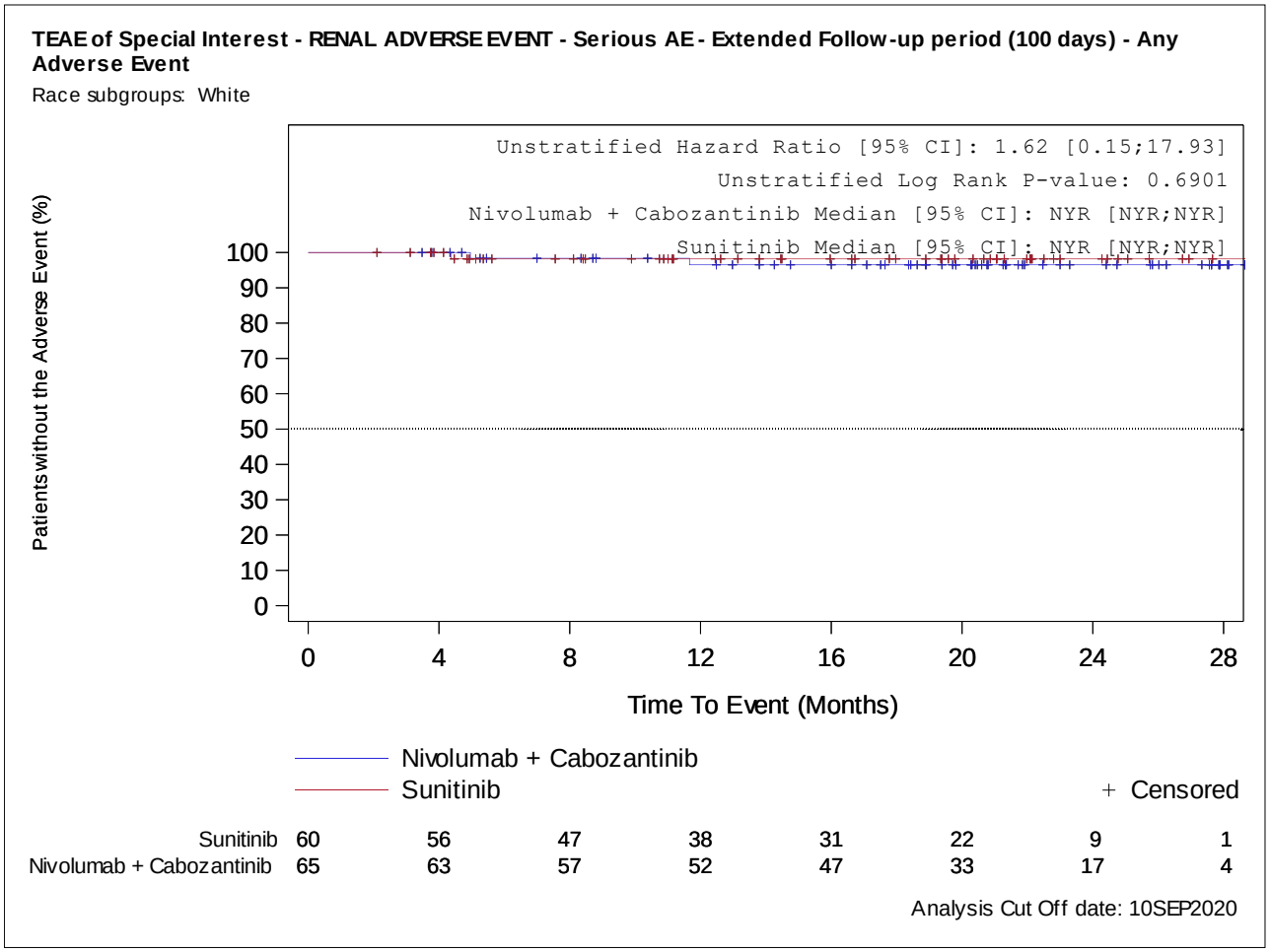

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:26:47

FIGURE 3.52.2.7: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



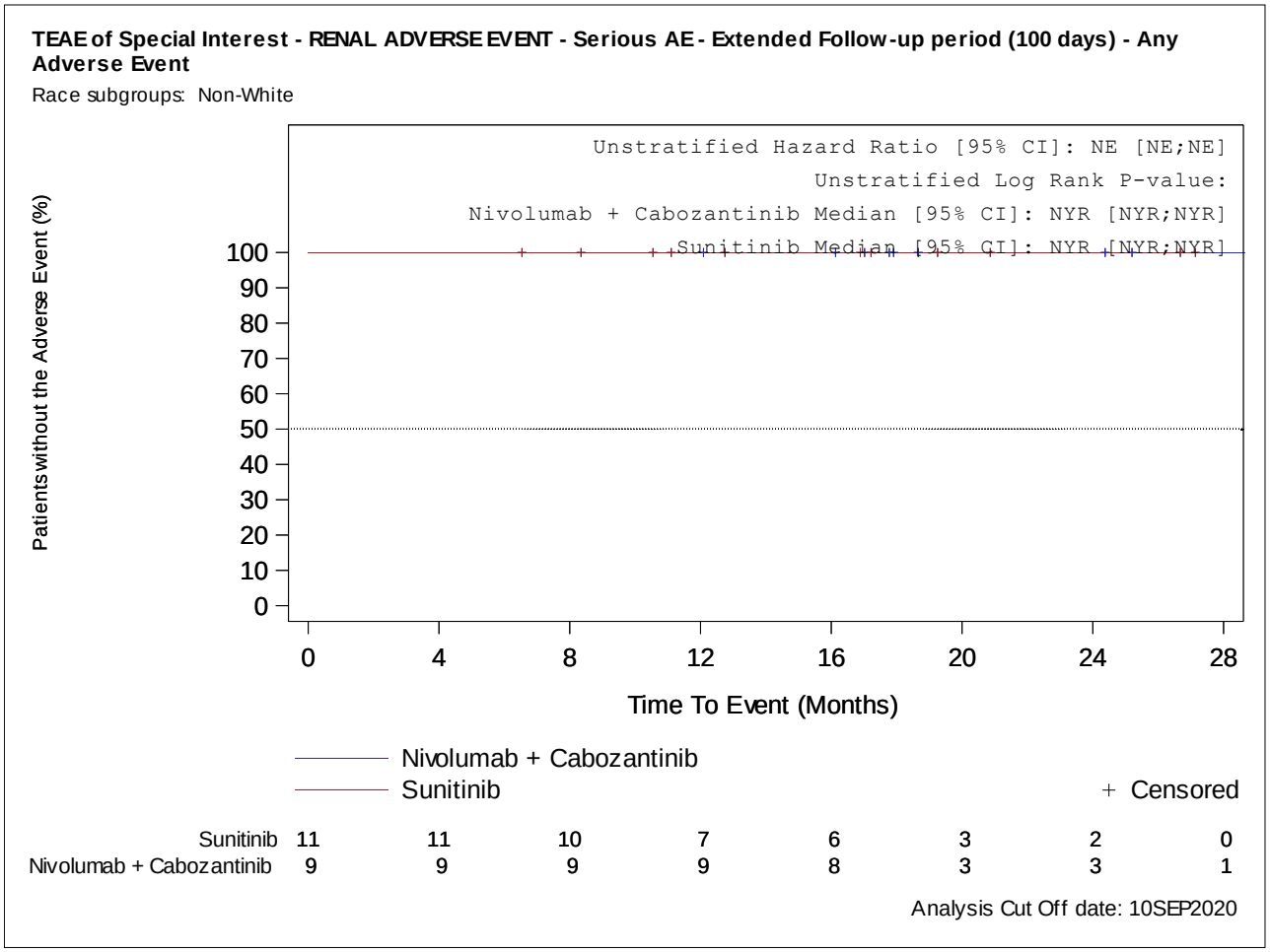

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:26:52

FIGURE 3.52.2.8: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



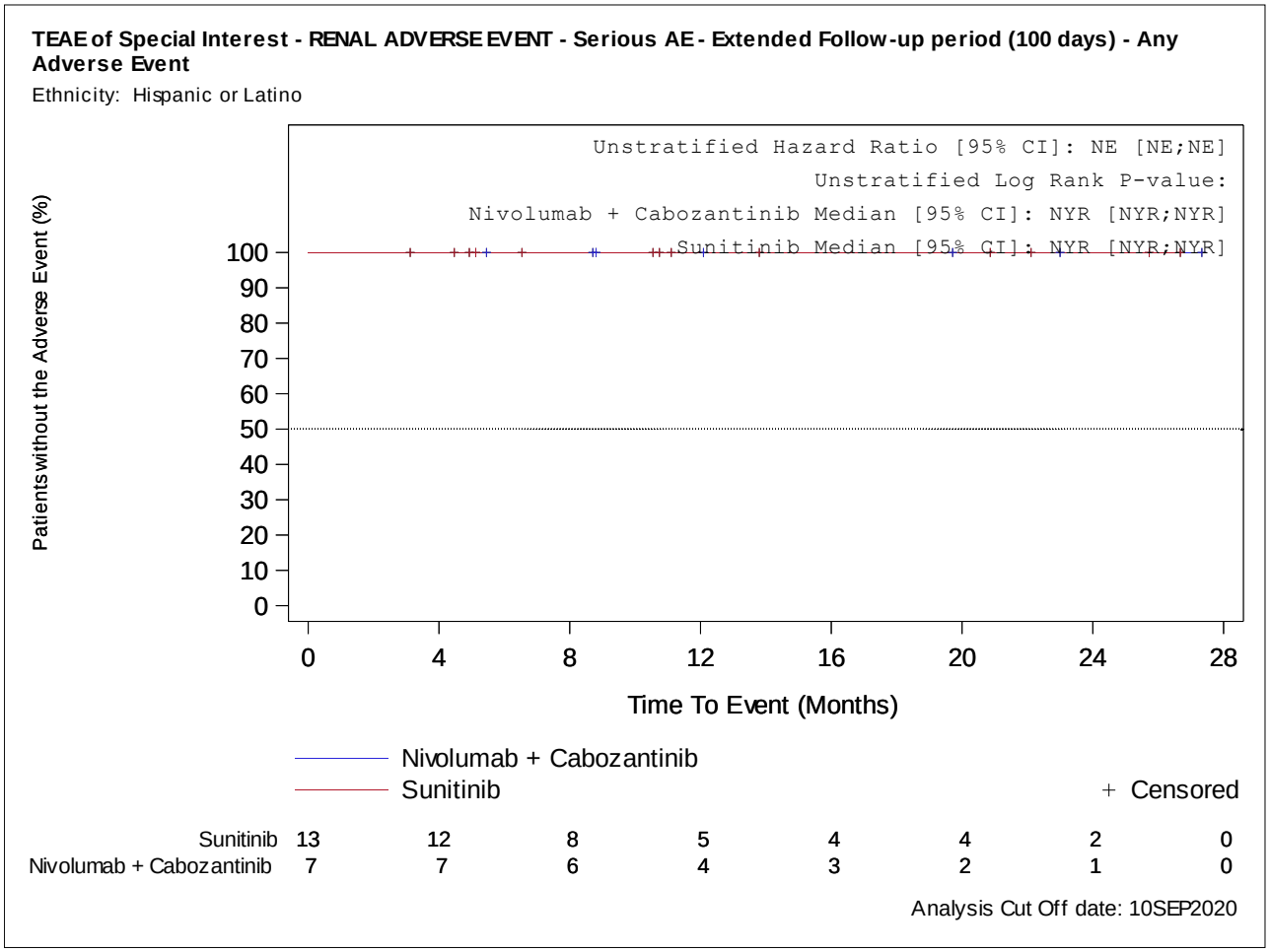

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:26:57

FIGURE 3.52.2.9: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



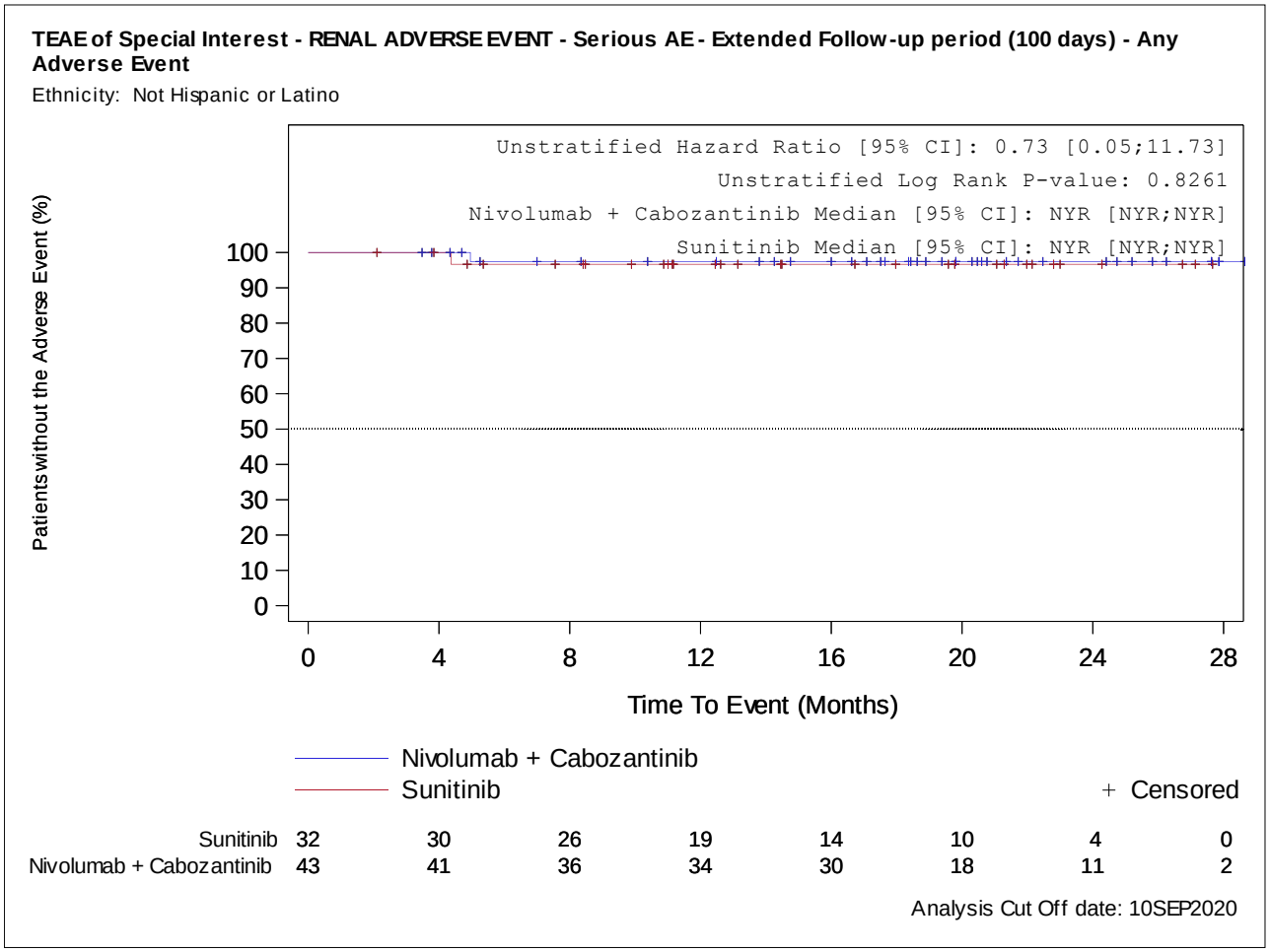

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:27:03

FIGURE 3.52.2.10: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



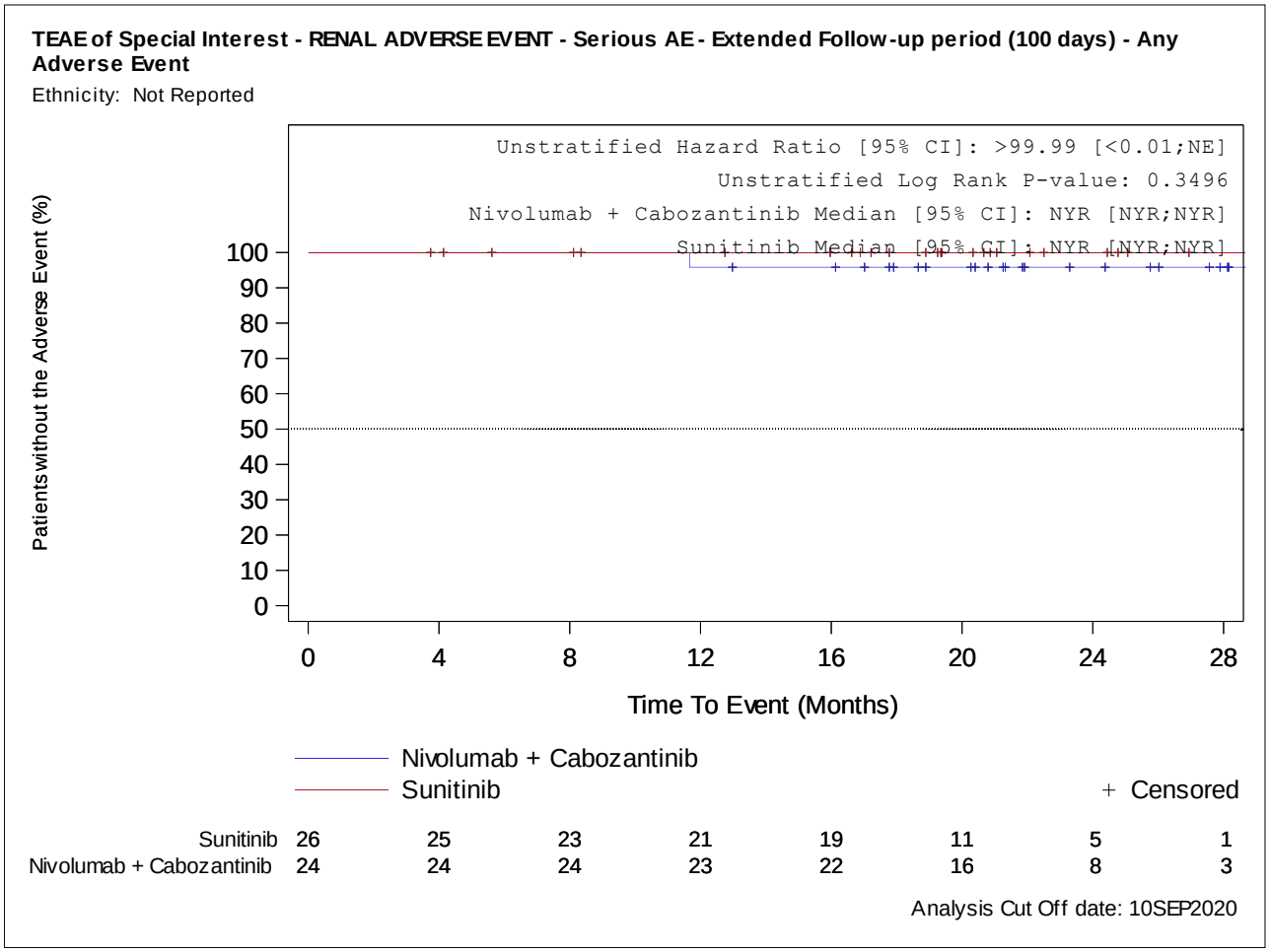

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:27:08

FIGURE 3.52.2.11: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



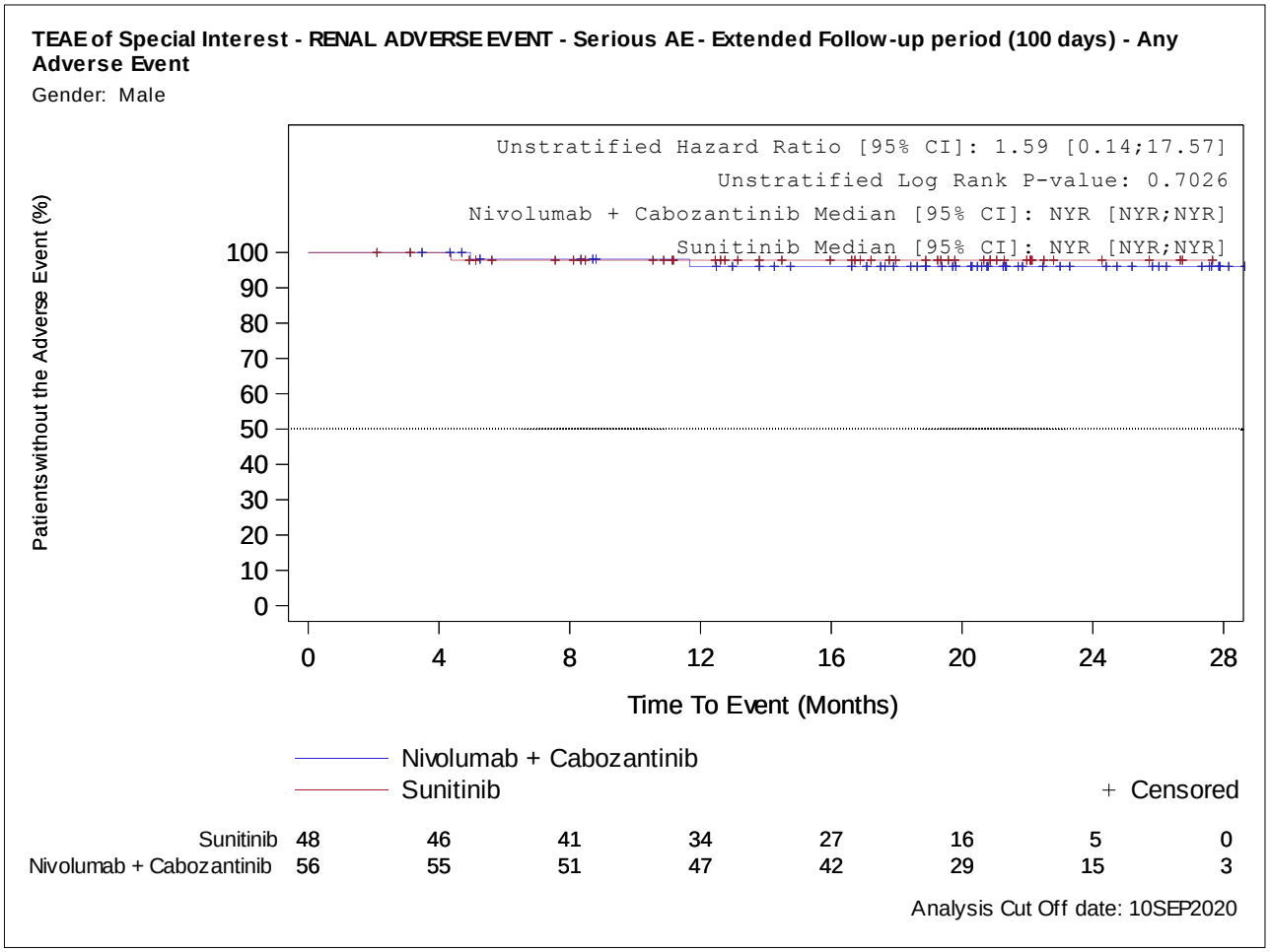

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:27:13

FIGURE 3.52.2.12: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



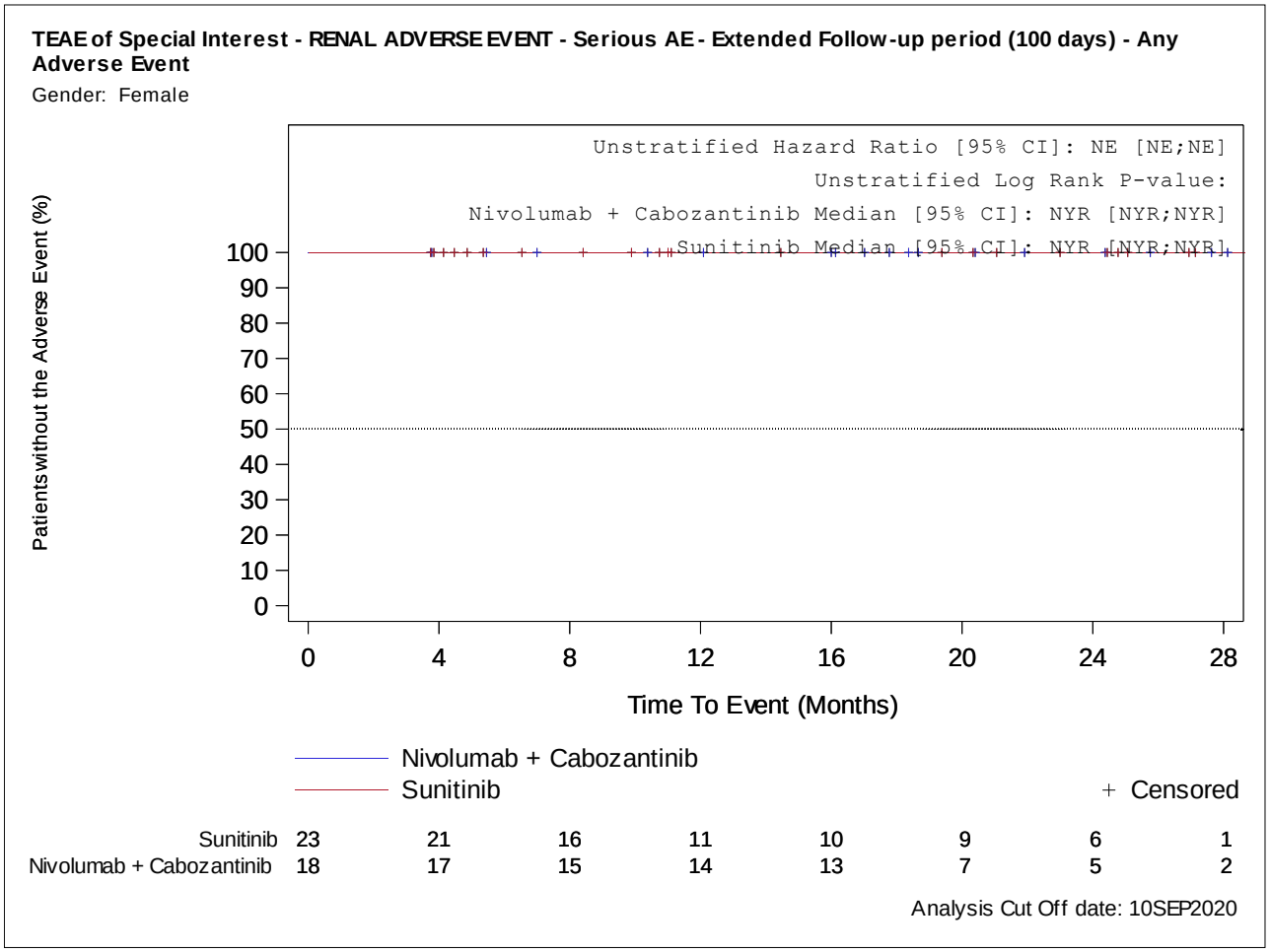

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:27:18

FIGURE 3.52.2.13: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



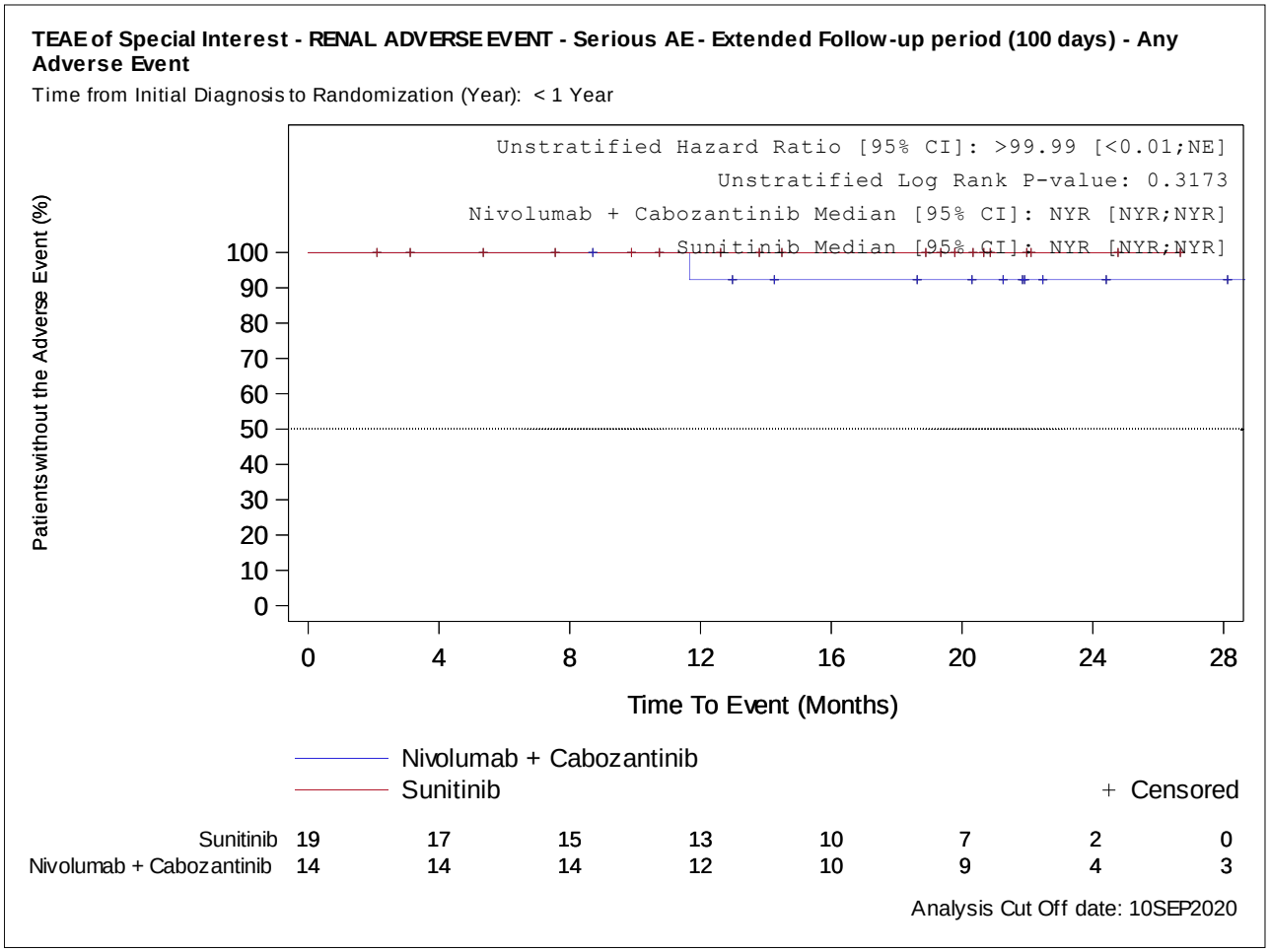

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:27:23

FIGURE 3.52.2.14: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



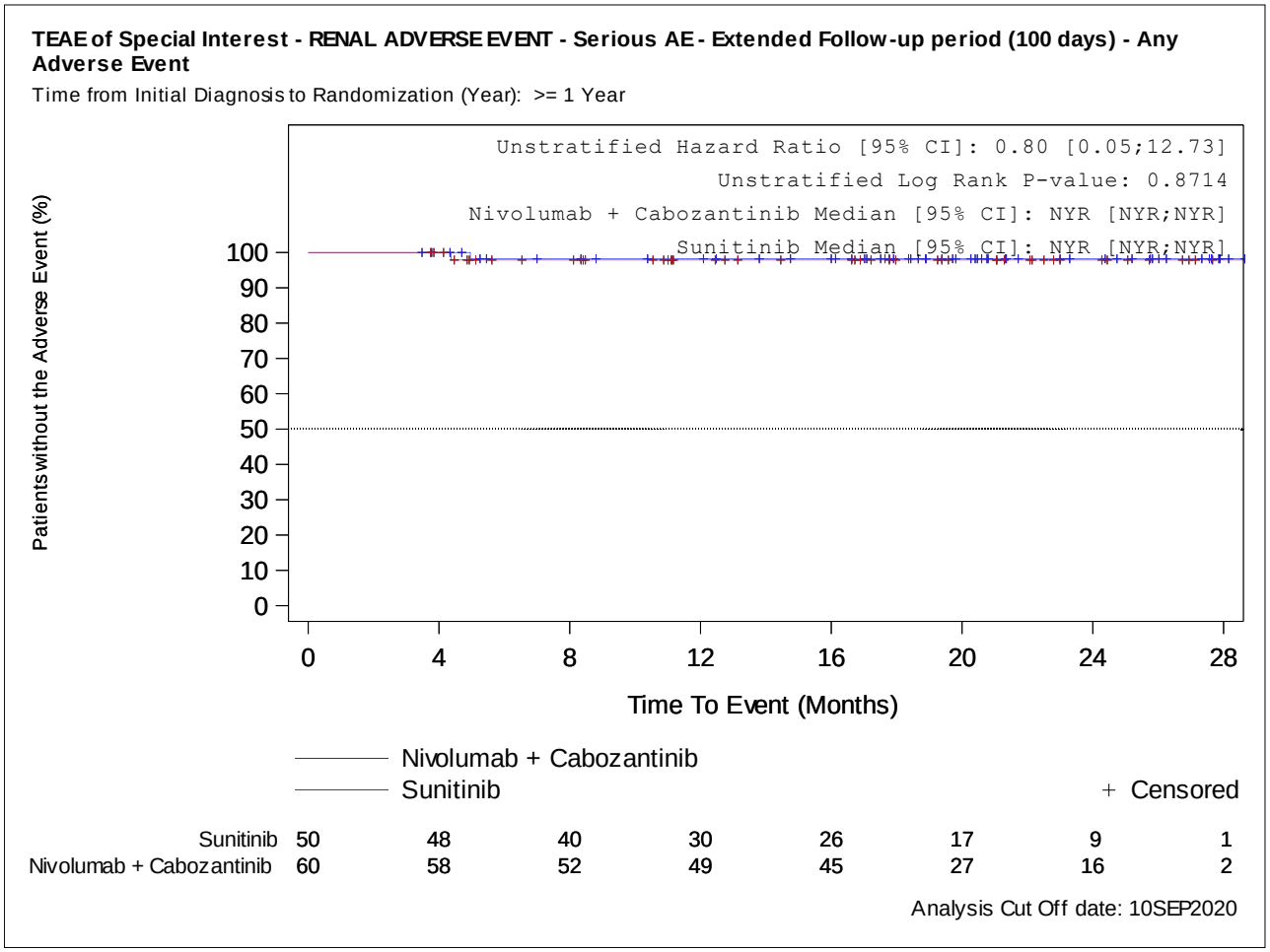

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:27:28

FIGURE 3.52.2.15: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



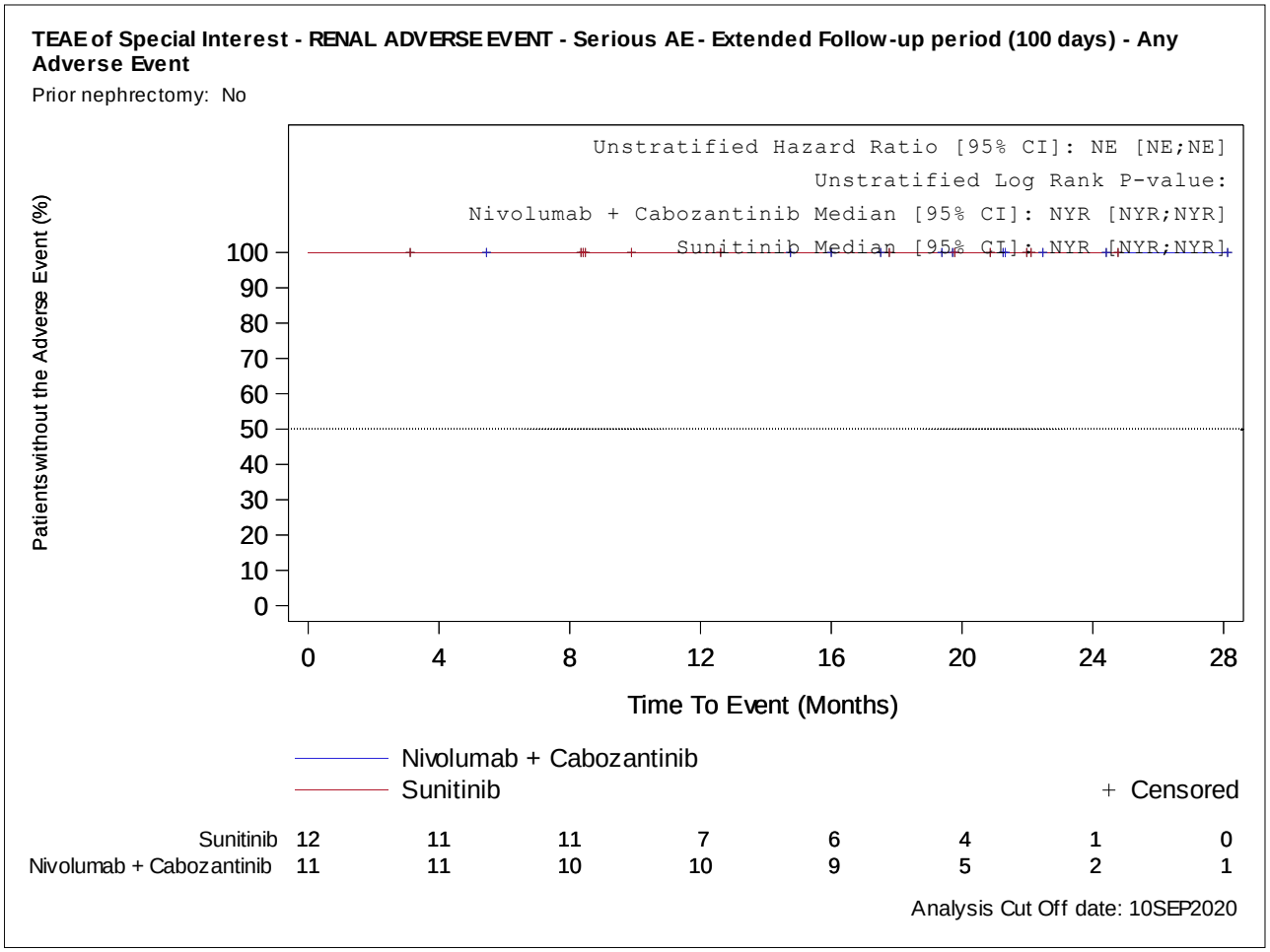

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:27:44

FIGURE 3.52.2.16: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



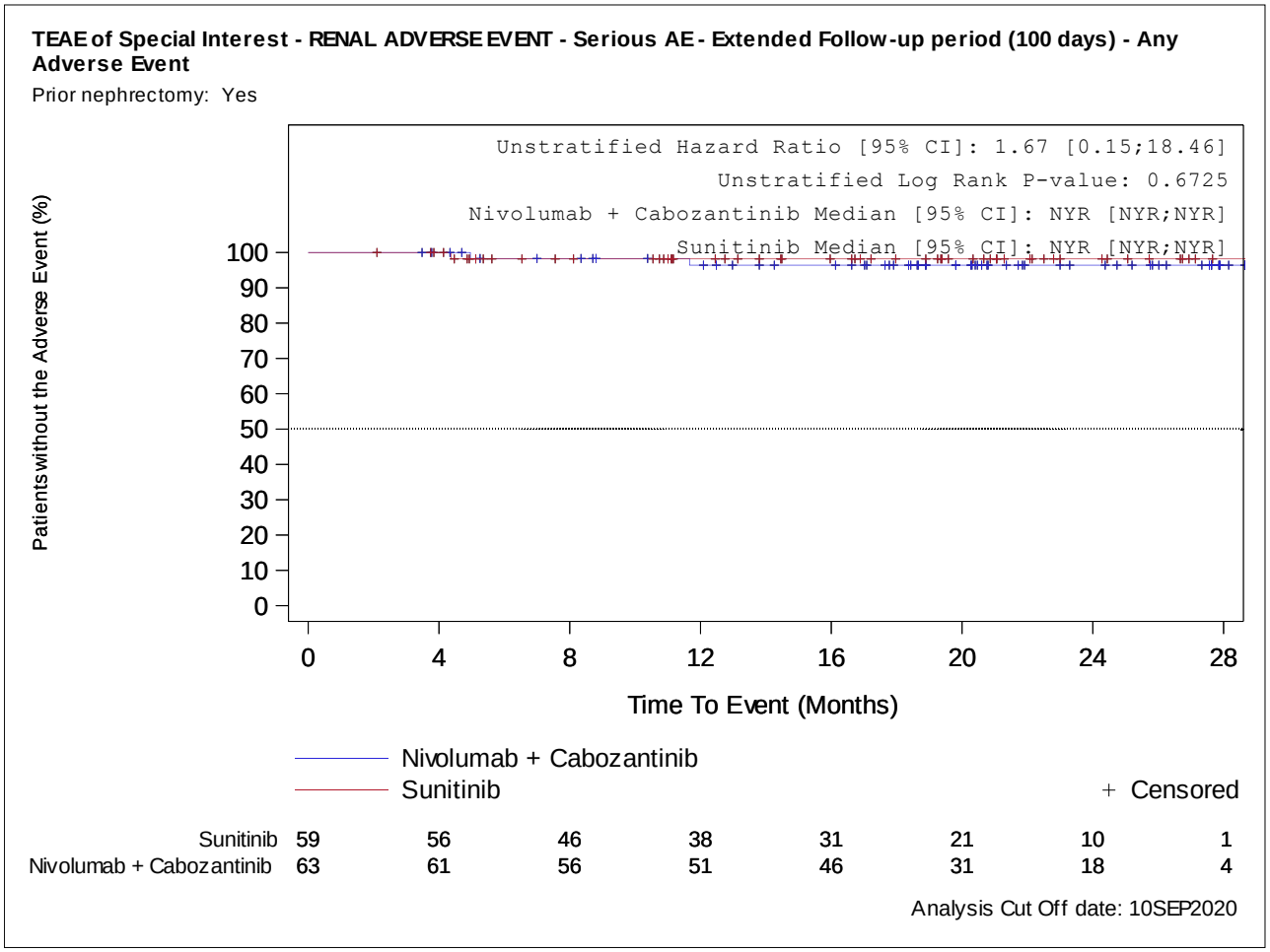

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:27:49

FIGURE 3.52.2.17: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



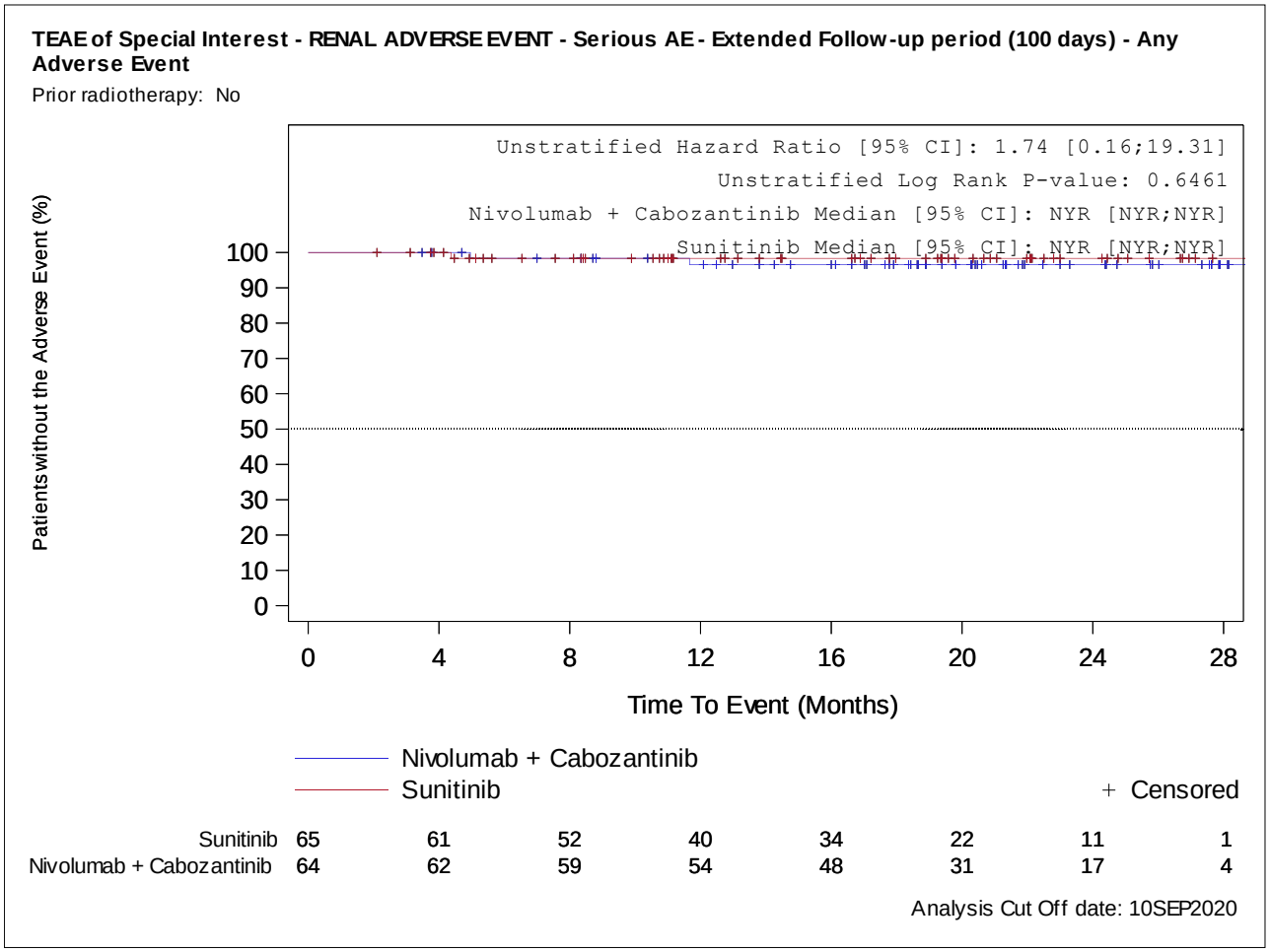

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:35

FIGURE 3.52.2.18: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



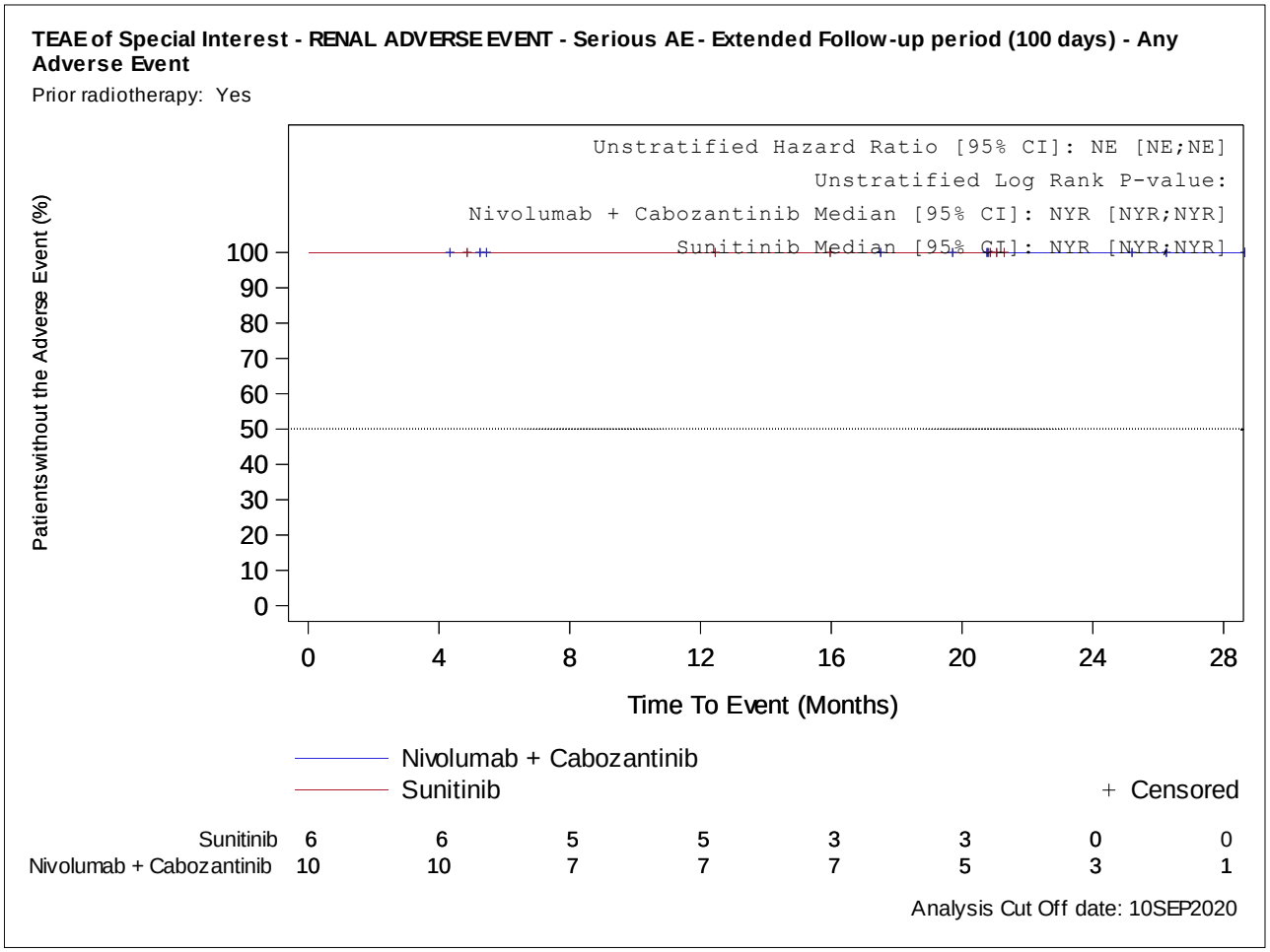

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:40

FIGURE 3.52.2.19: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



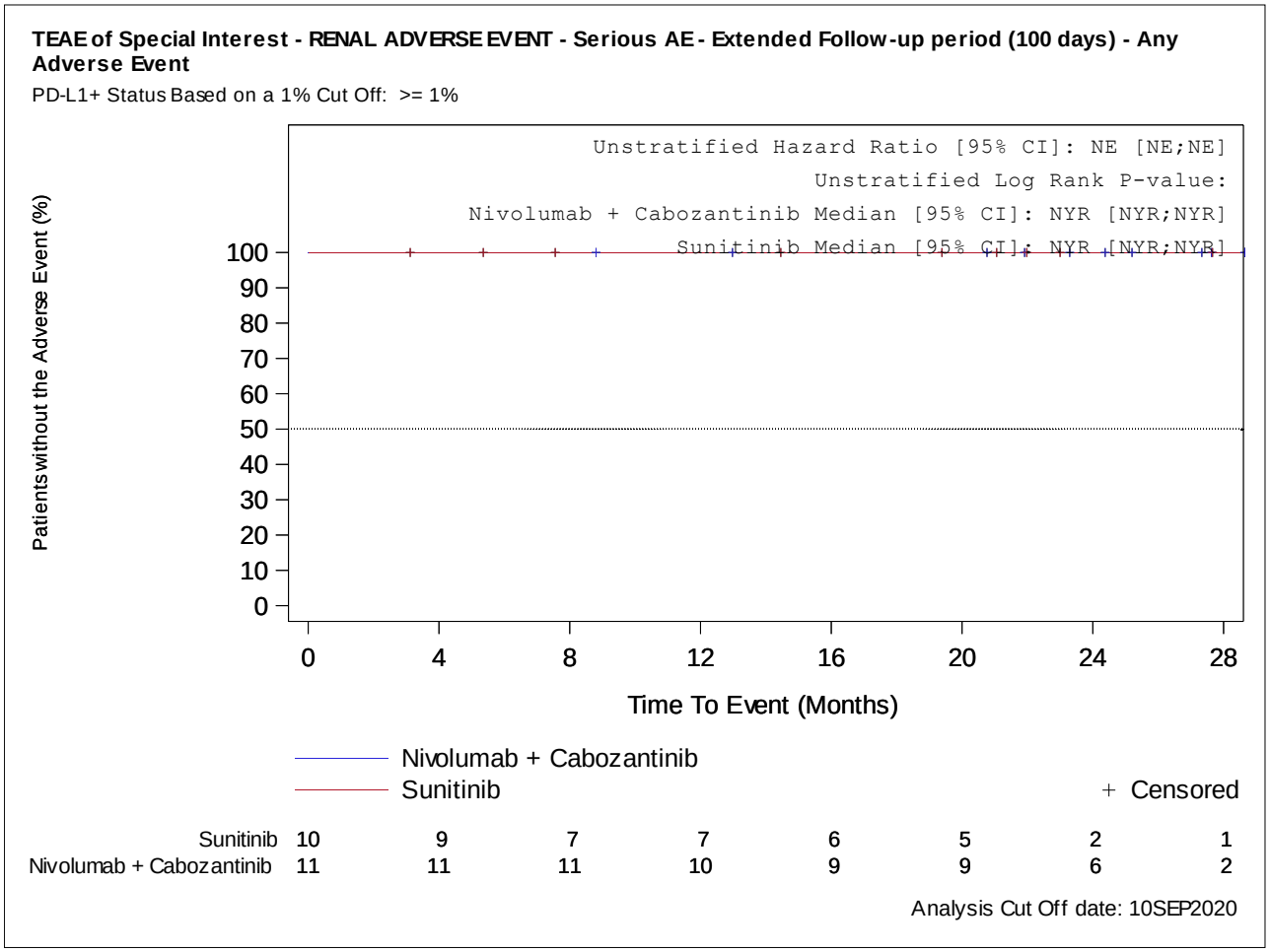

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:45

FIGURE 3.52.2.20: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



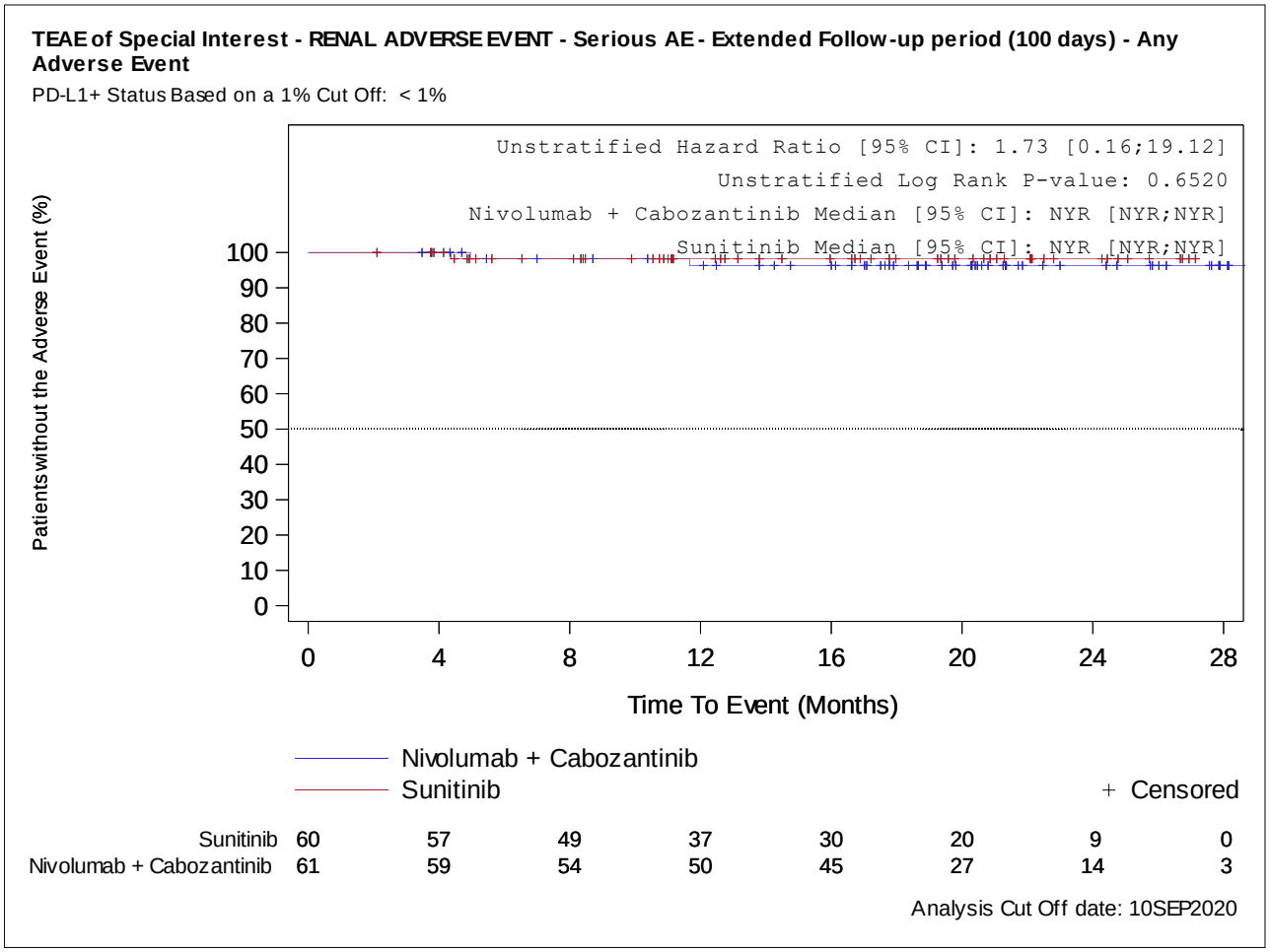

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:51

FIGURE 3.52.2.21: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



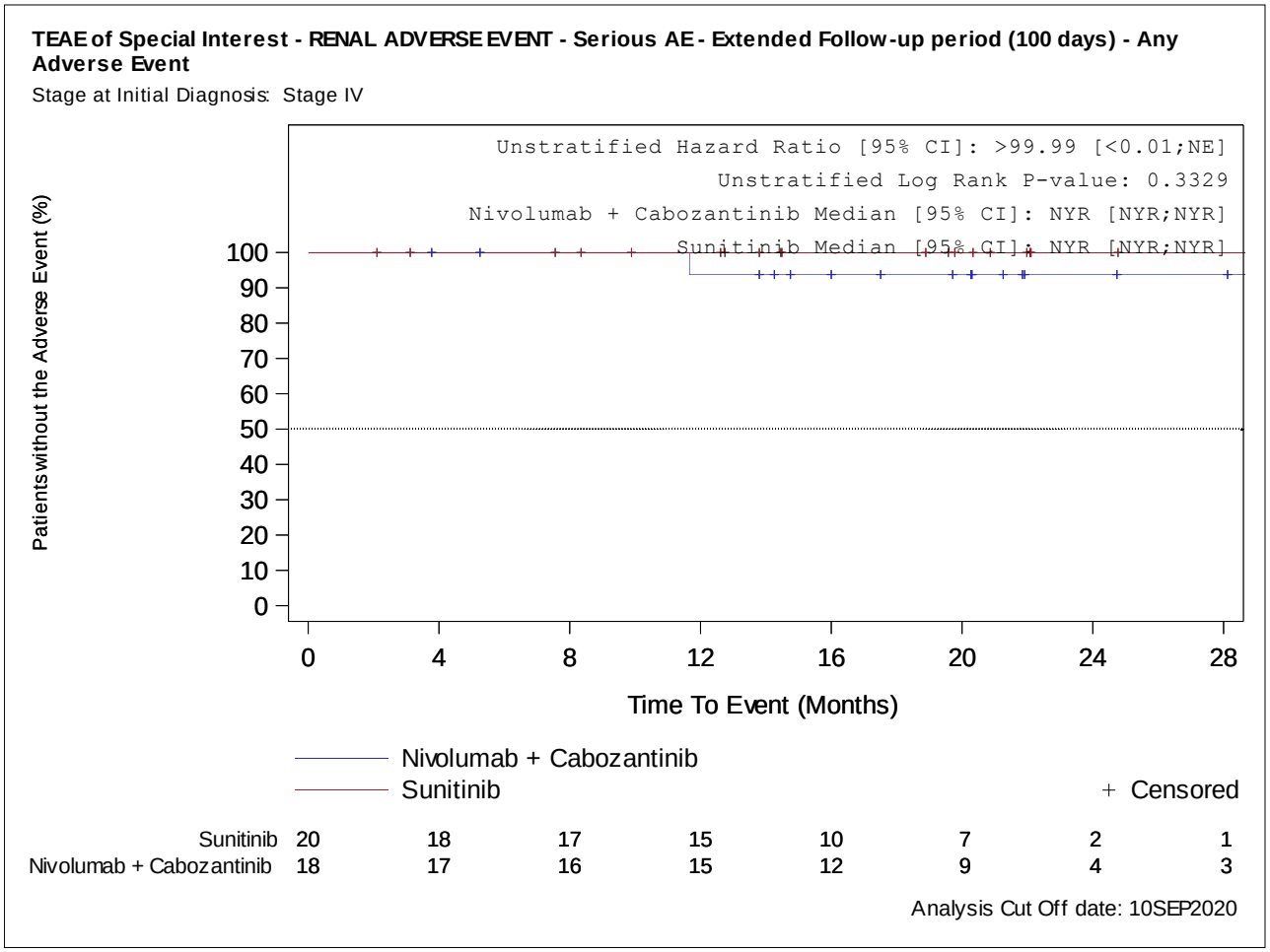

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:56

FIGURE 3.52.2.22: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



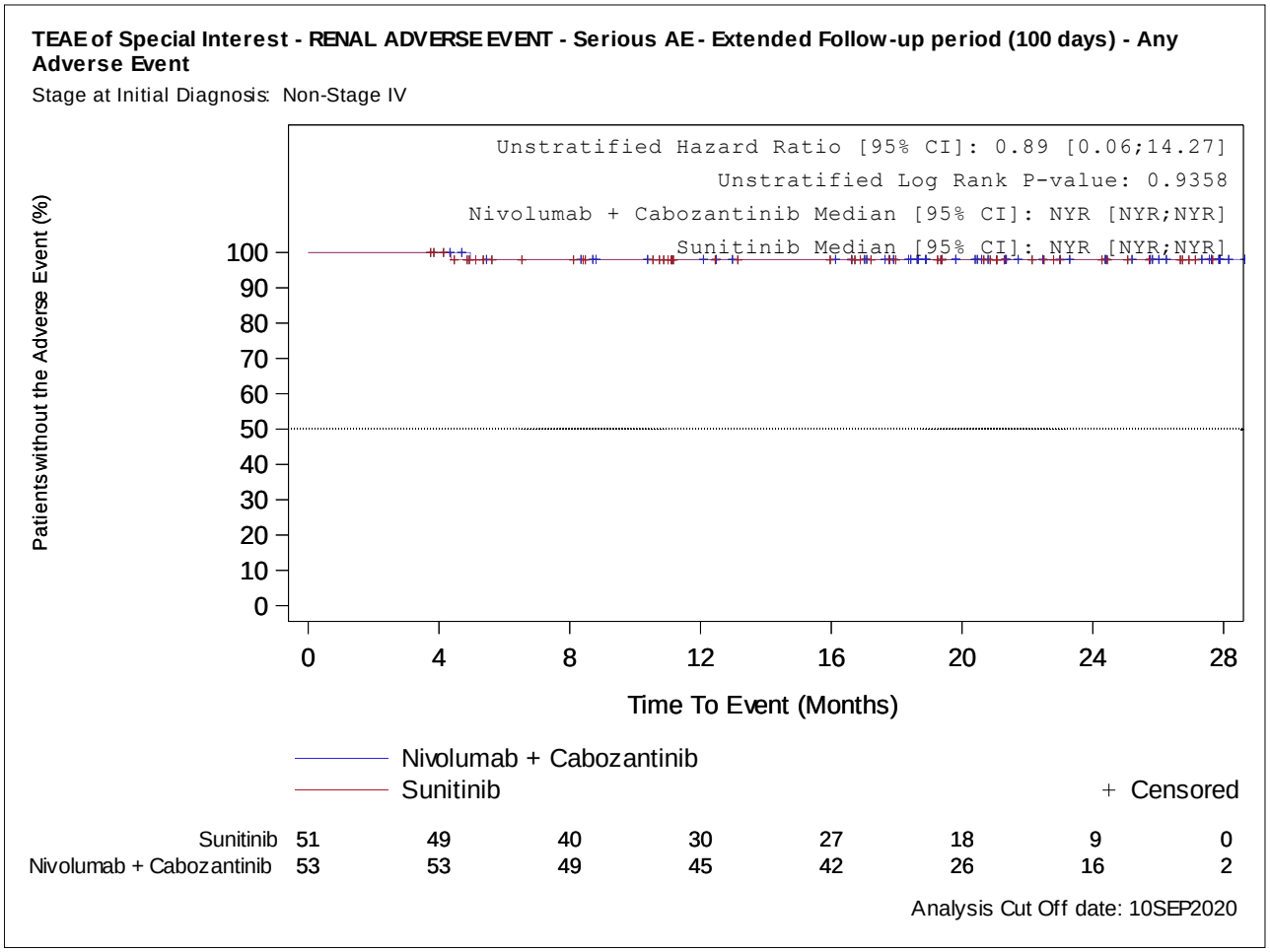

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:29:01

FIGURE 3.52.2.23: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



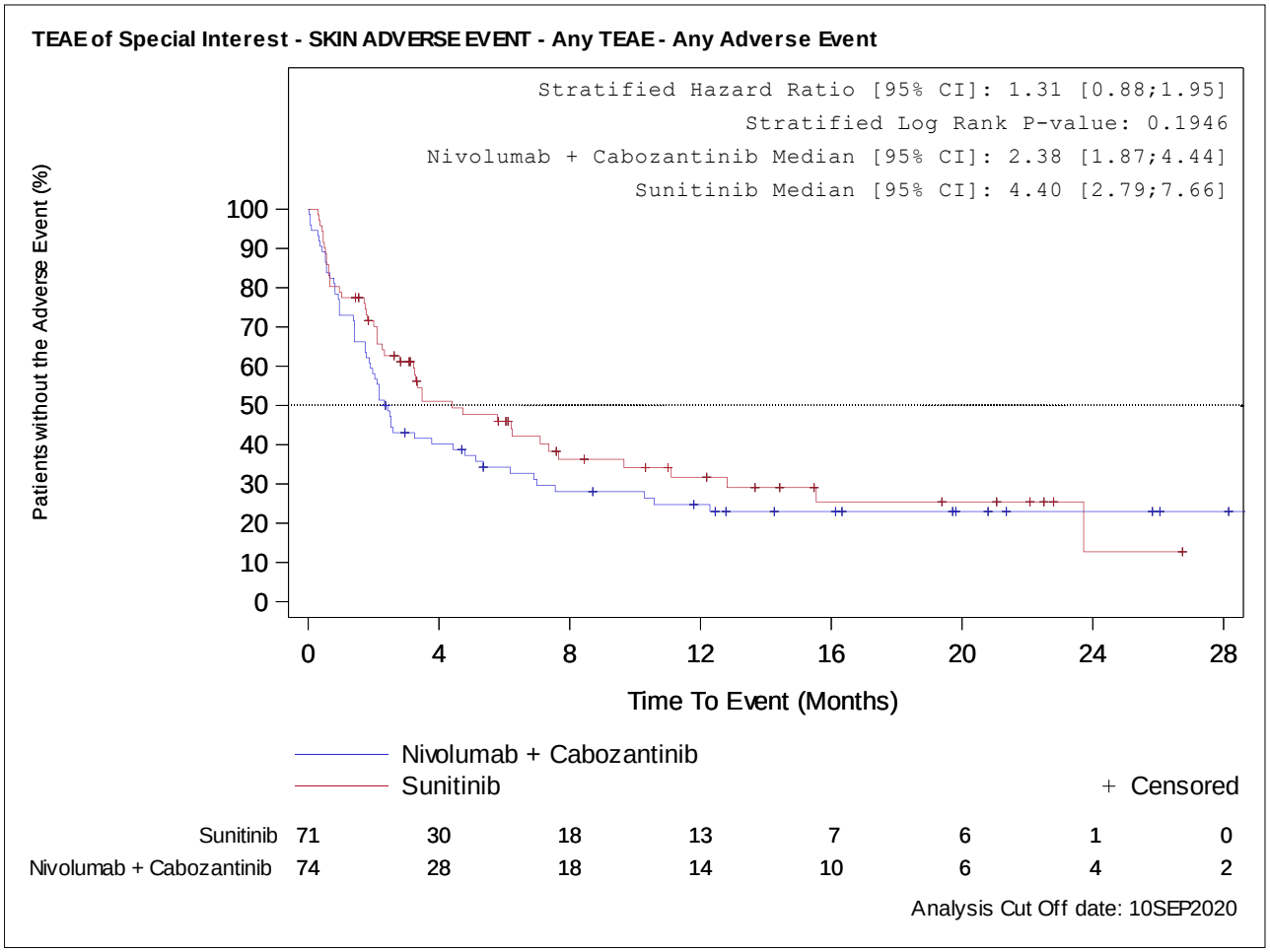

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:29:27

FIGURE 3.52.2.24: Kaplan-Meier curve - TEAE of Special Interest - RENAL ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



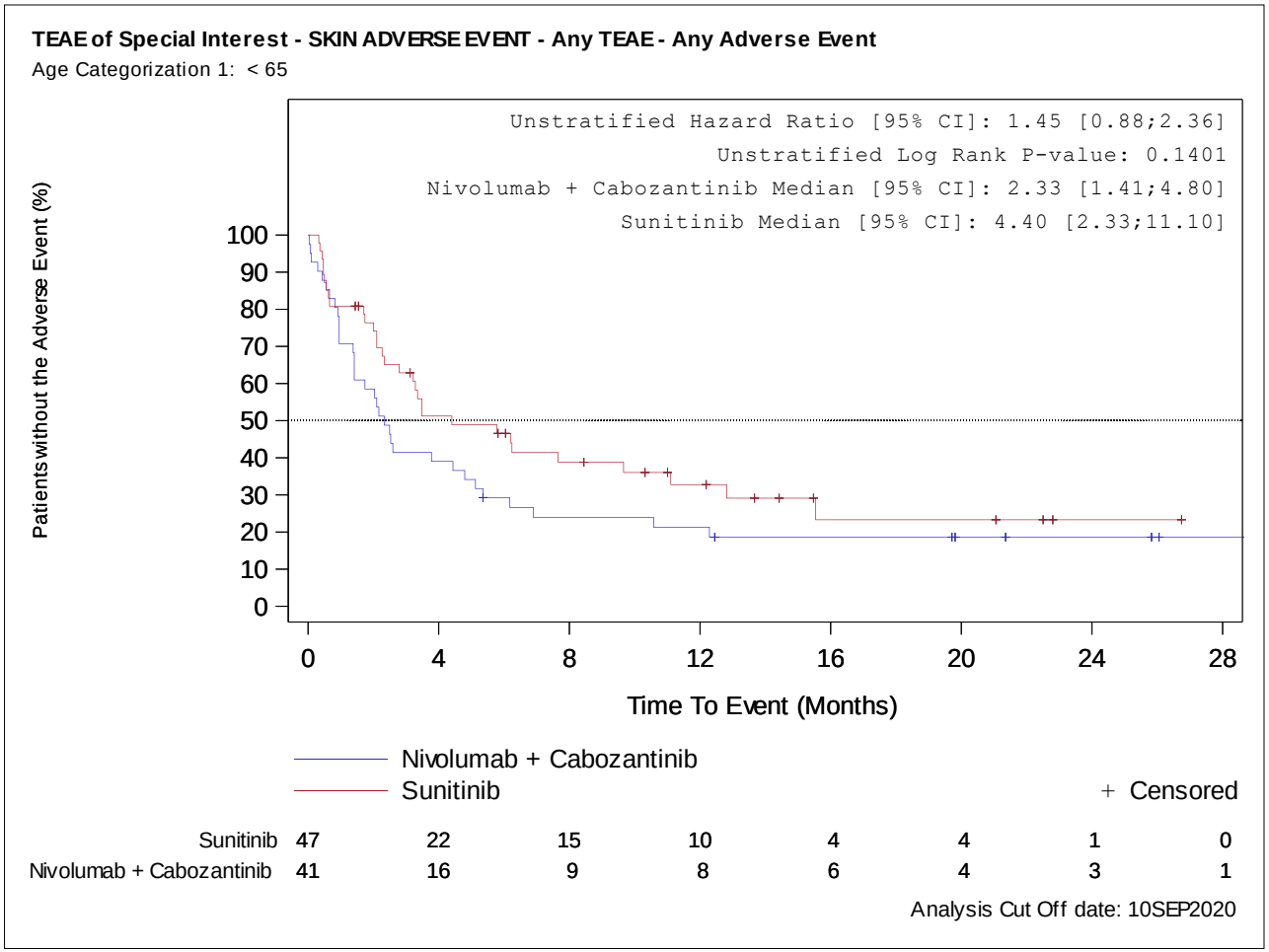

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:29:33

FIGURE 3.53.1: TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



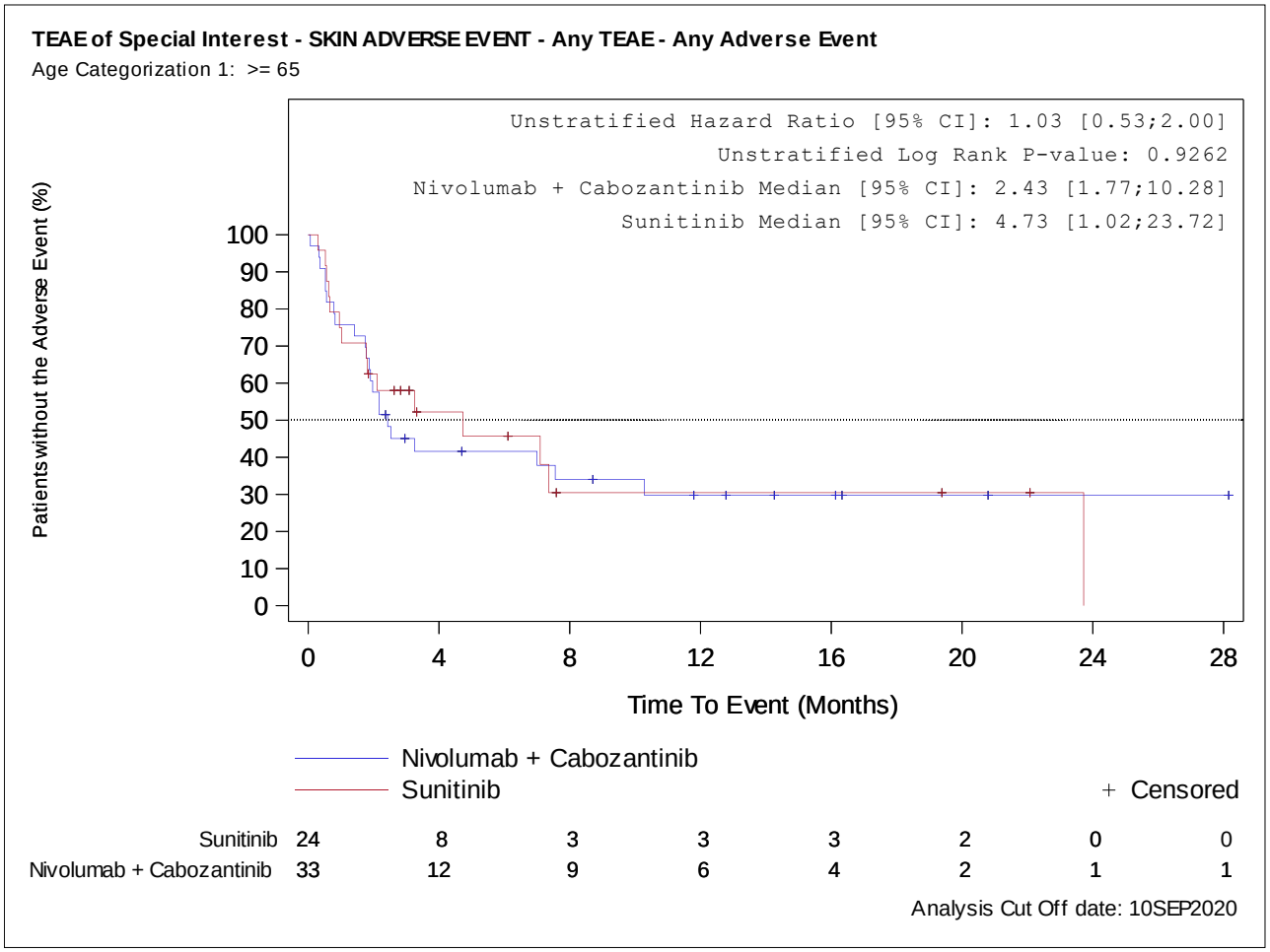

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:32:31

FIGURE 3.53.2.1: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



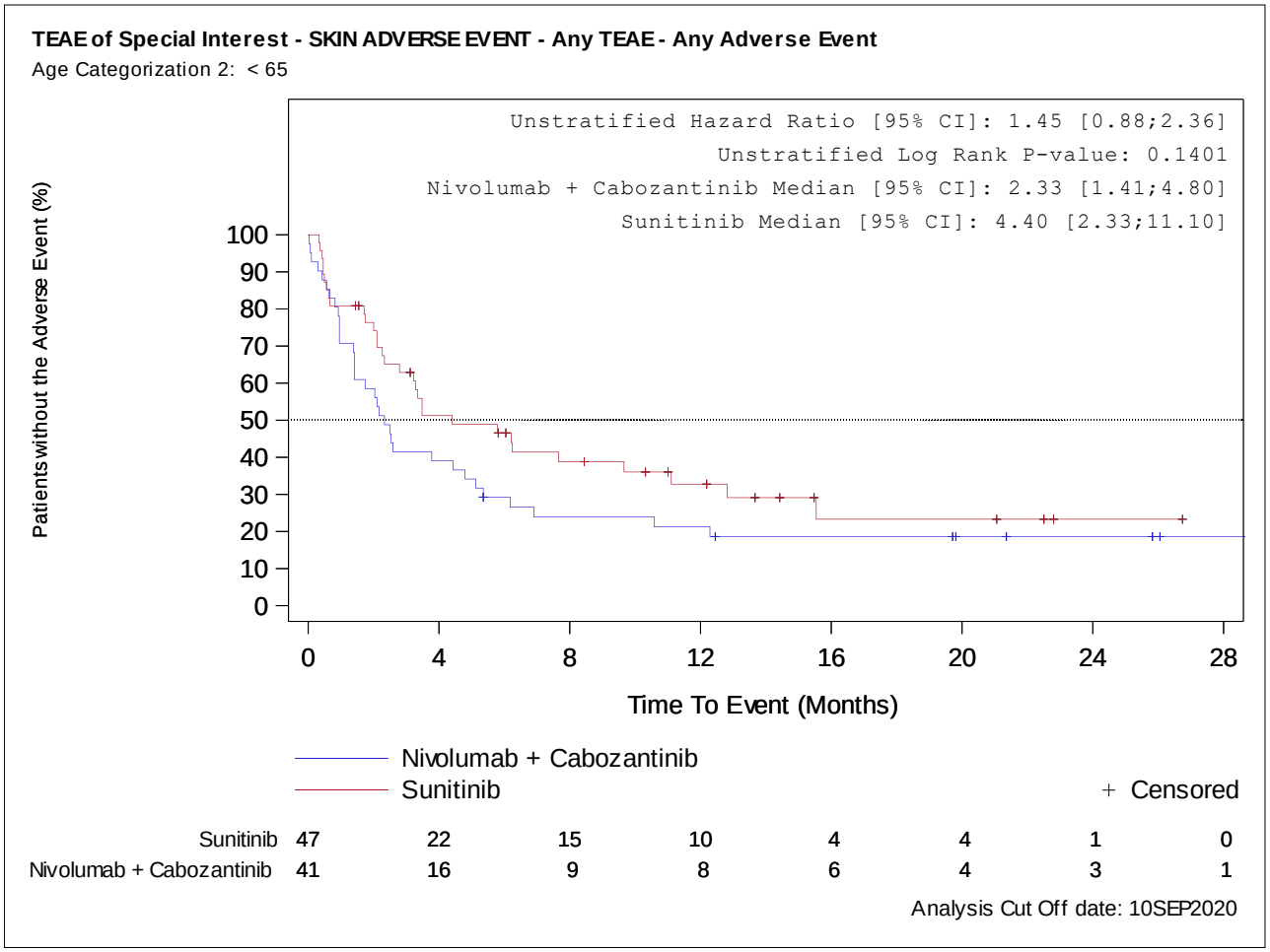

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:32:34

FIGURE 3.53.2.2: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



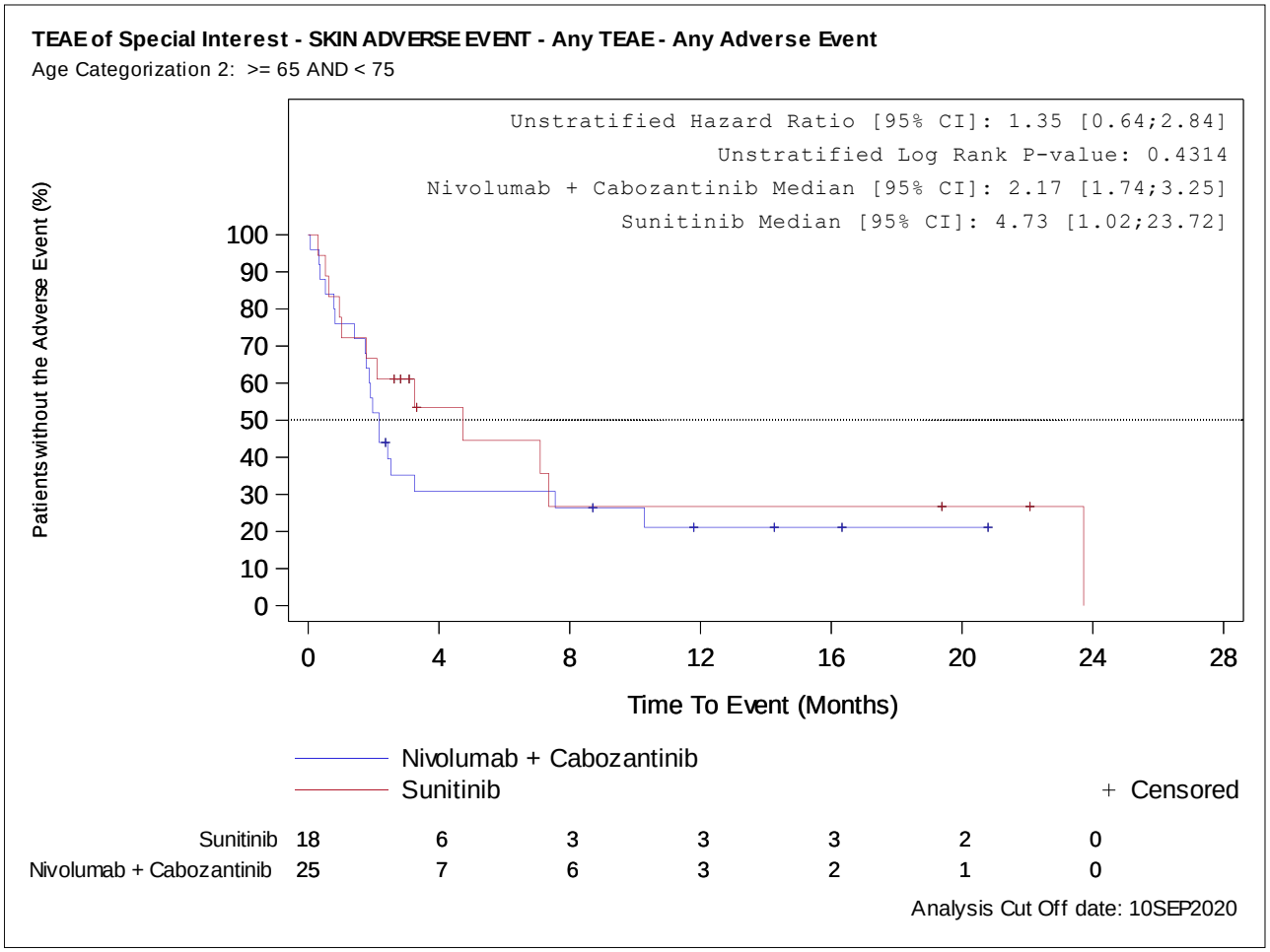

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:32:39

FIGURE 3.53.2.3: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



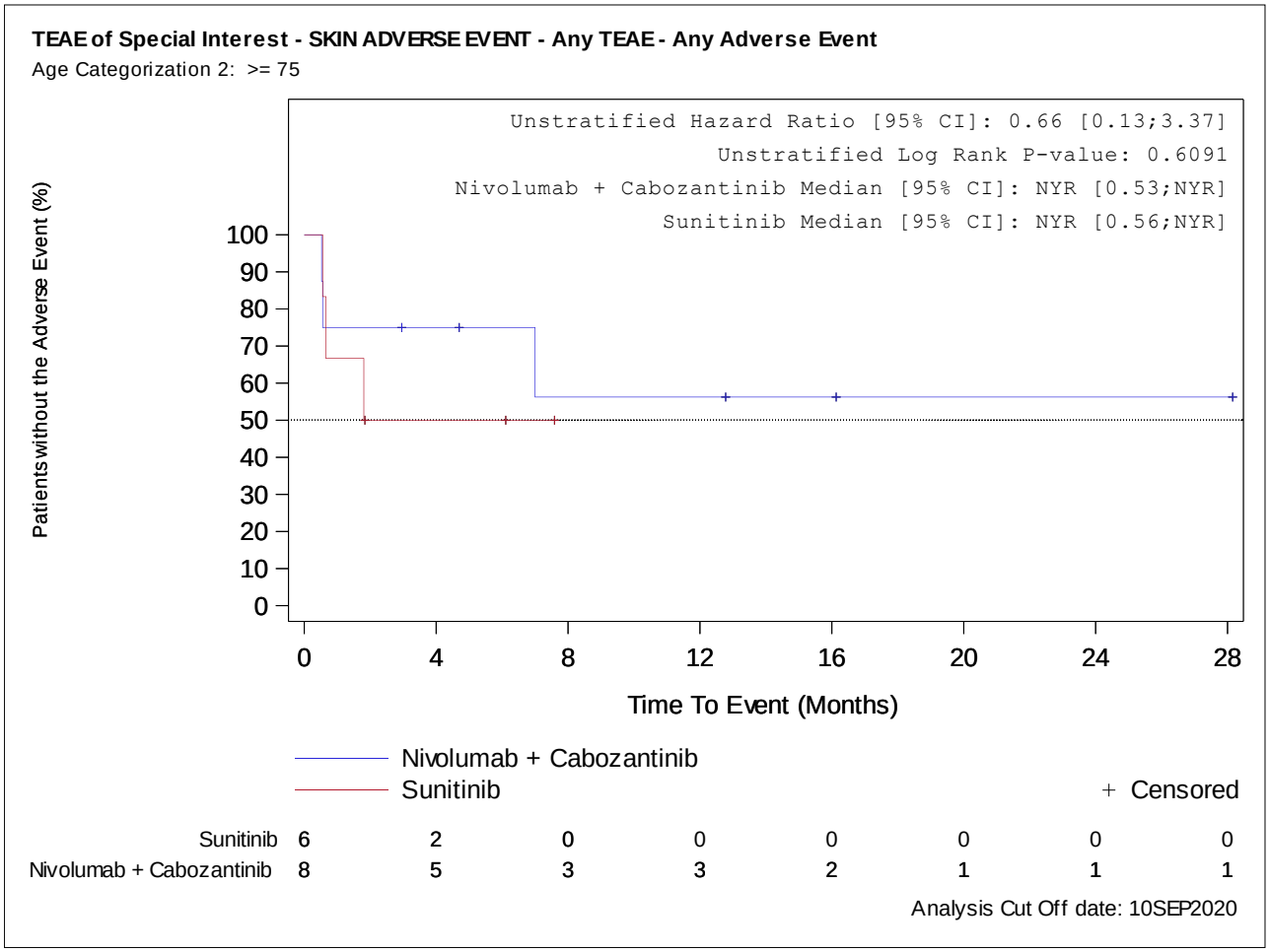

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:32:44

FIGURE 3.53.2.4: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



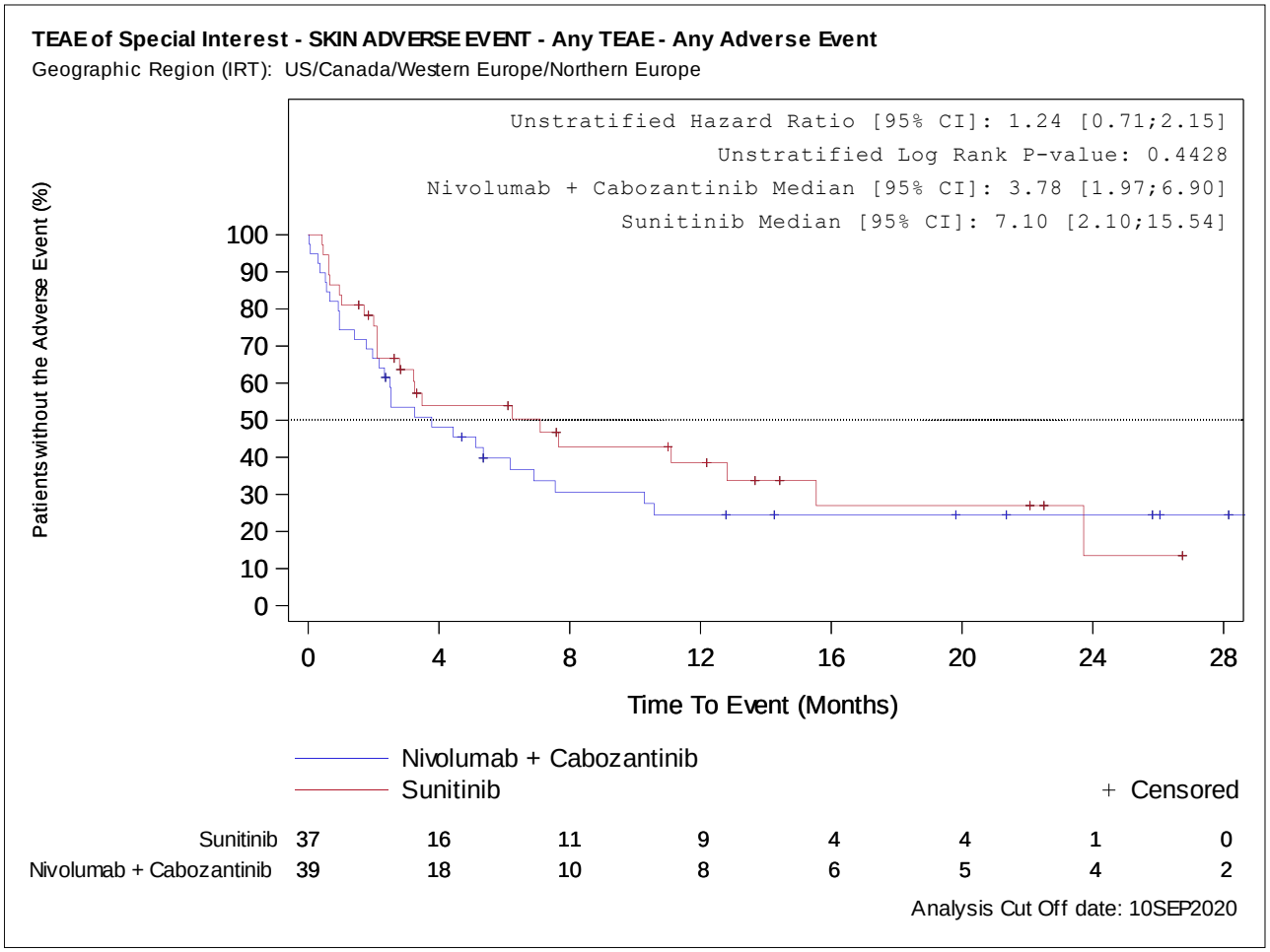

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:32:49

FIGURE 3.53.2.5: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



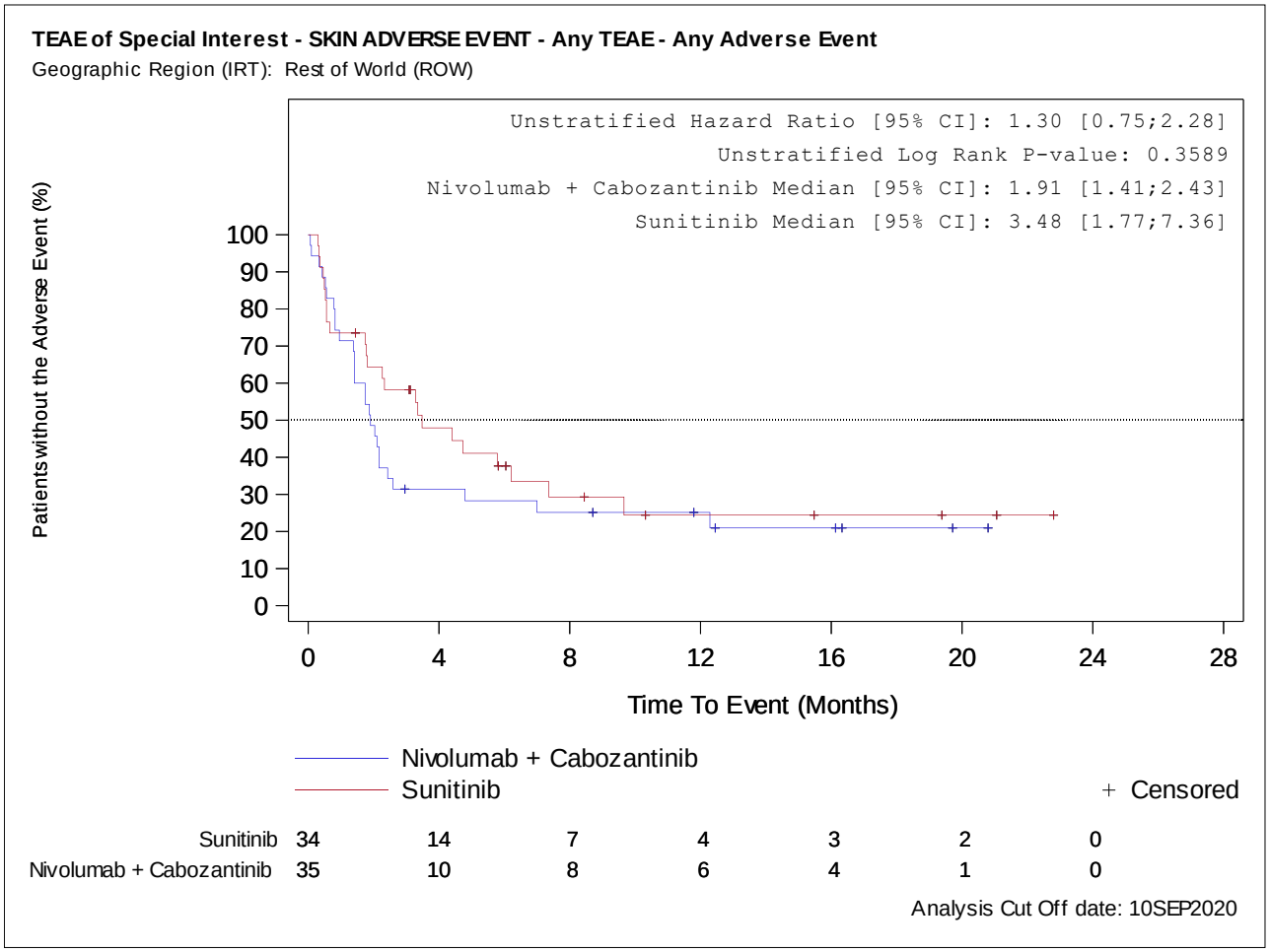

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:32:54

FIGURE 3.53.2.6: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



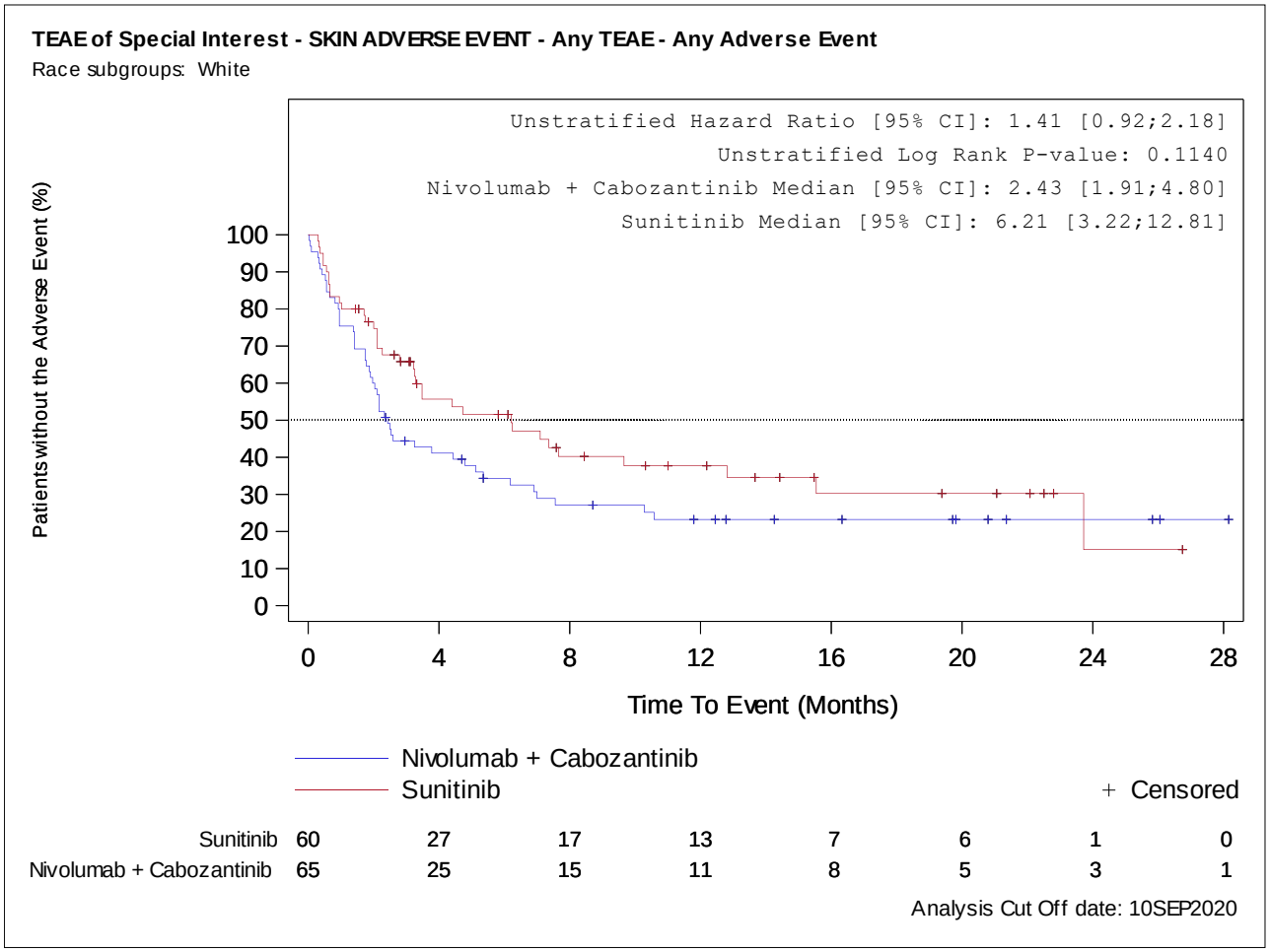

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:32:59

FIGURE 3.53.2.7: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



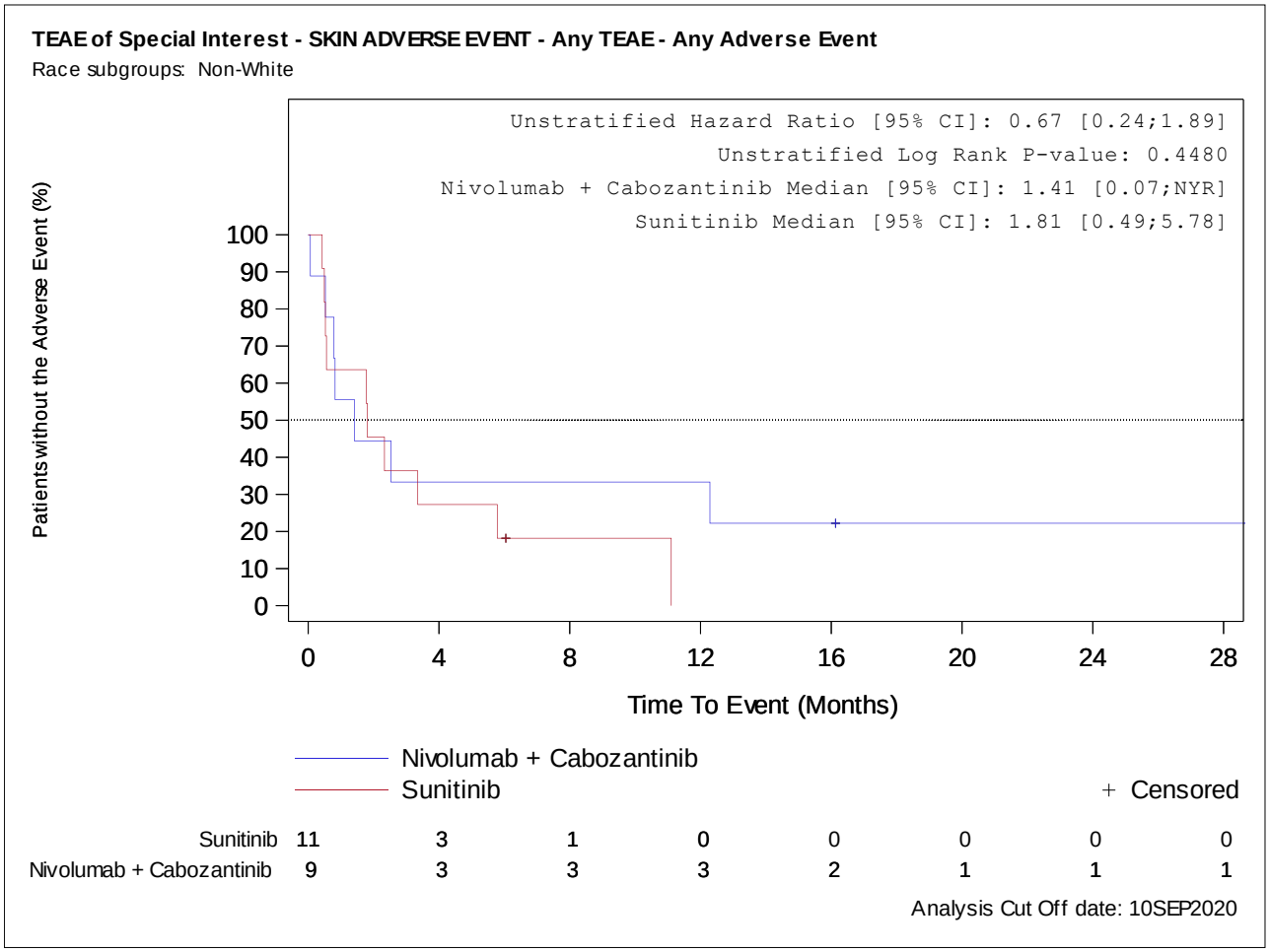

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:33:04

FIGURE 3.53.2.8: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



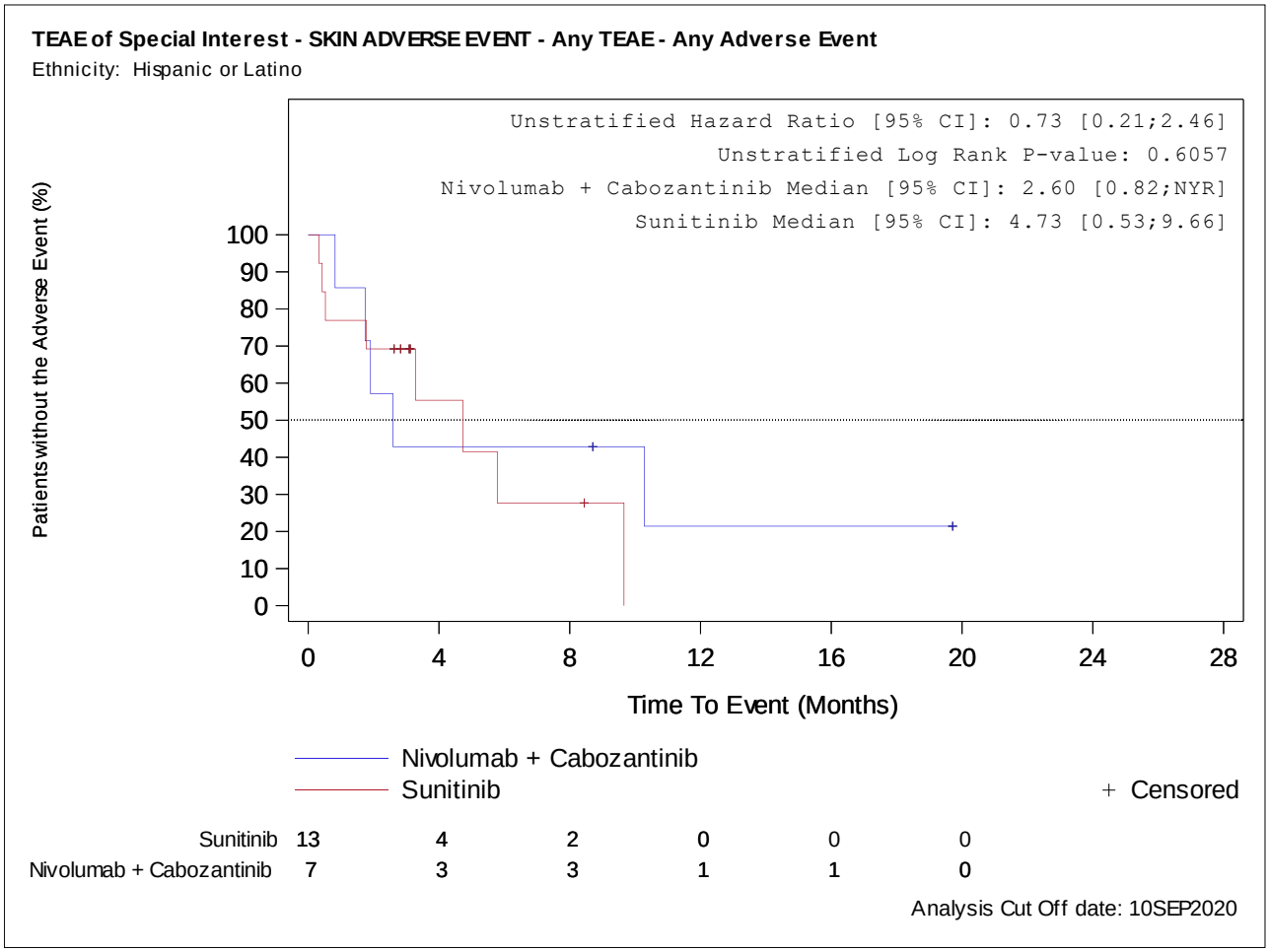

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:33:09

FIGURE 3.53.2.9: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



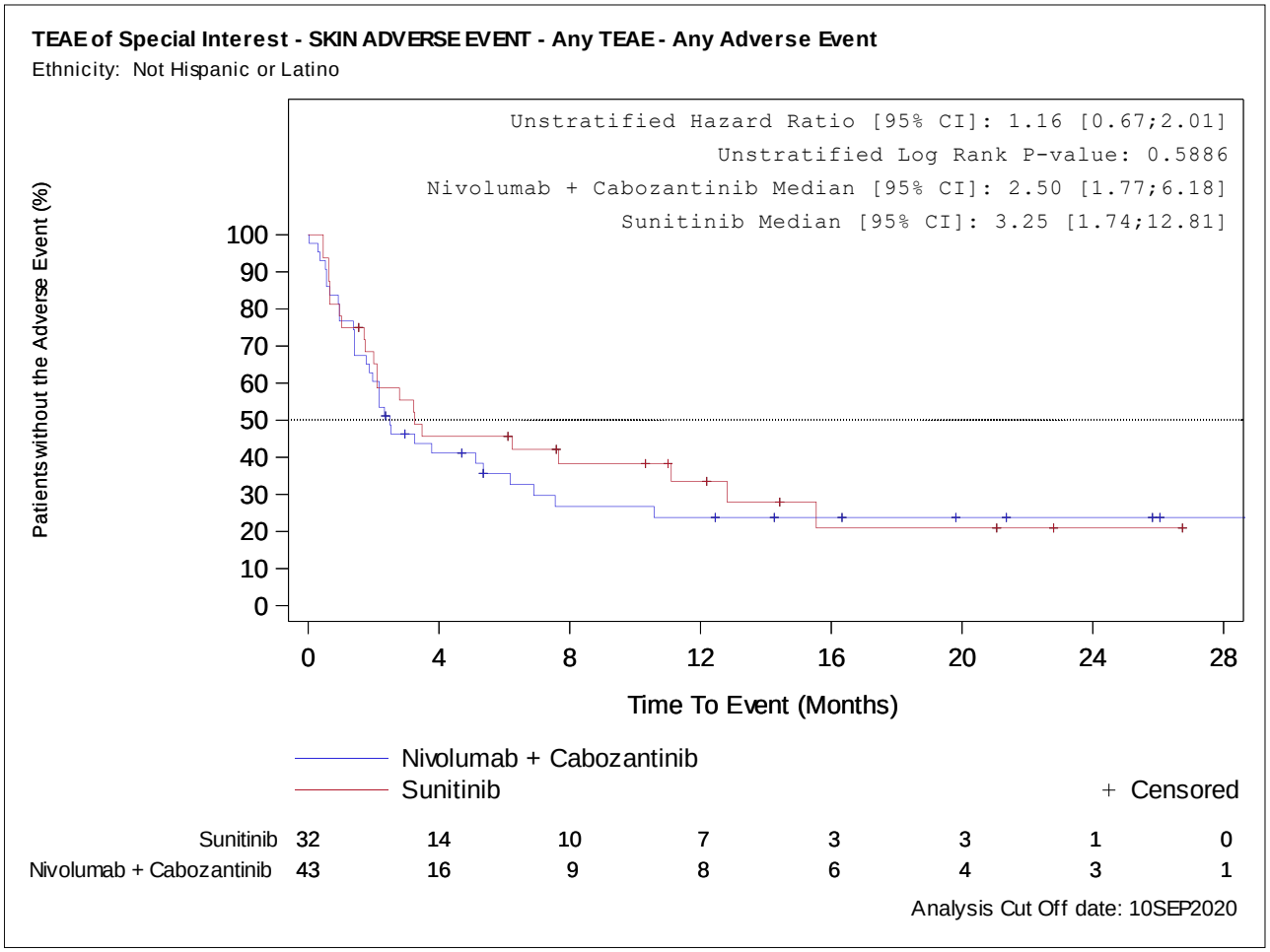

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:33:14

FIGURE 3.53.2.10: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



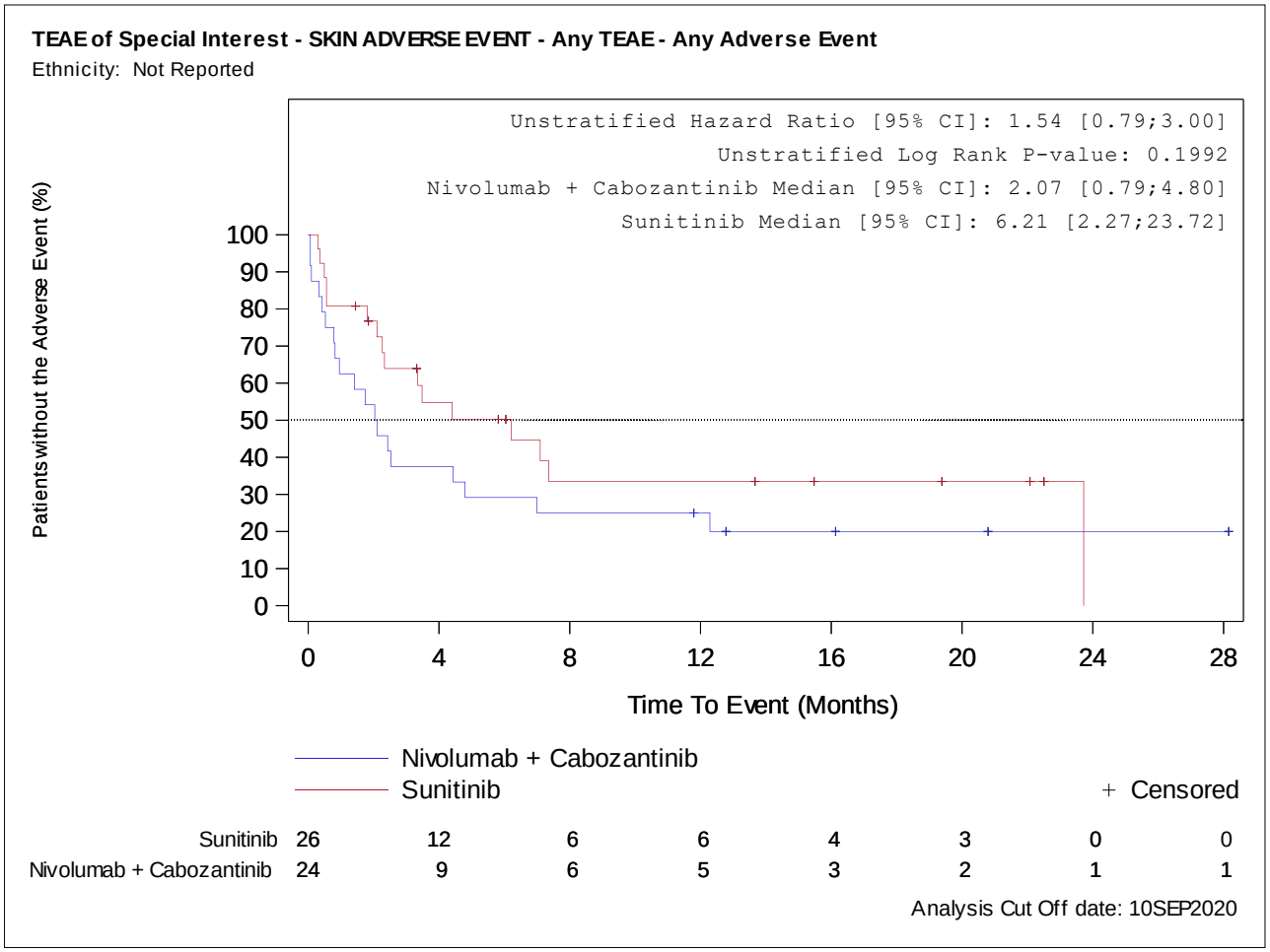

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:33:20

FIGURE 3.53.2.11: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



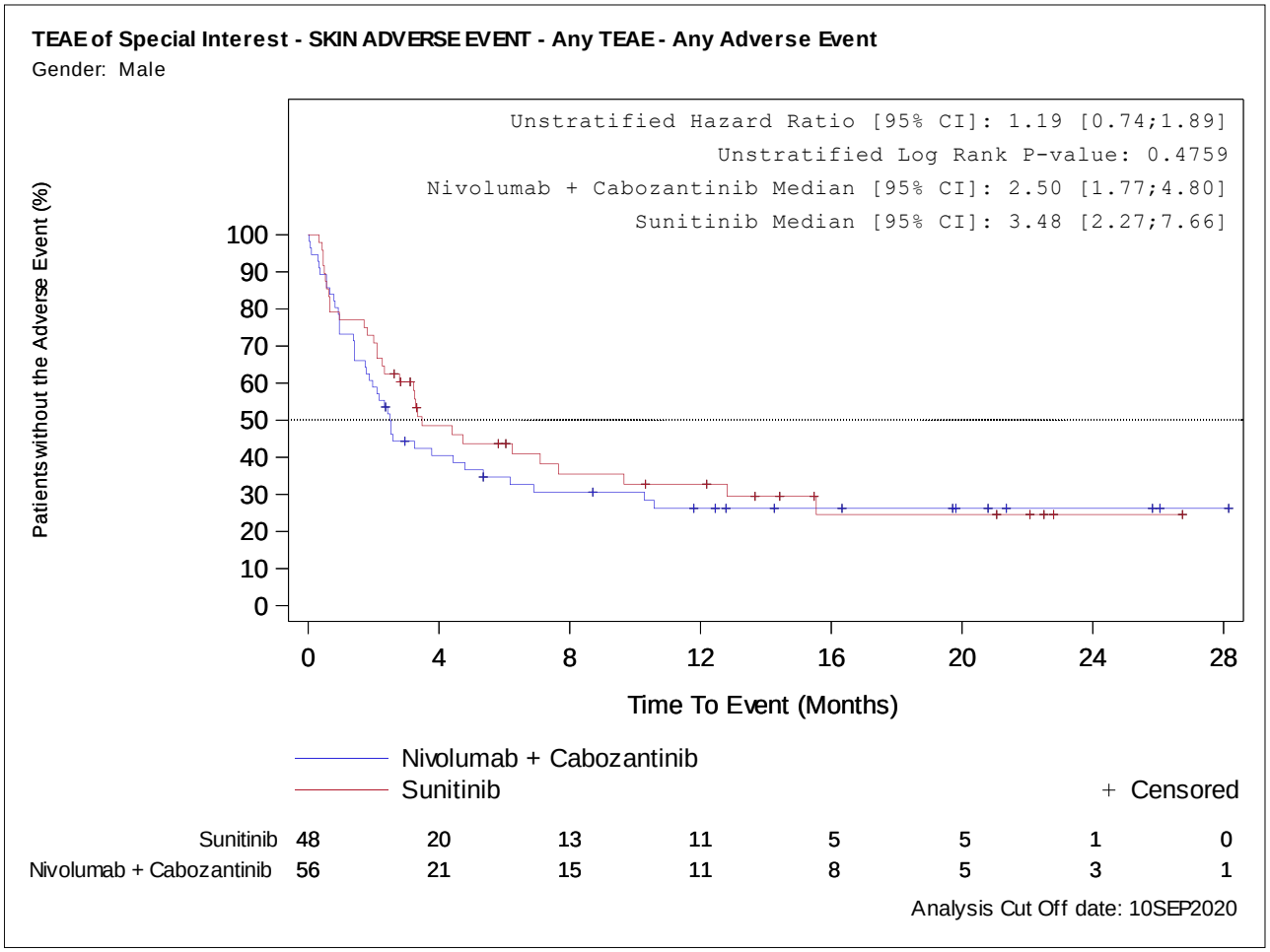

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:33:25

FIGURE 3.53.2.12: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



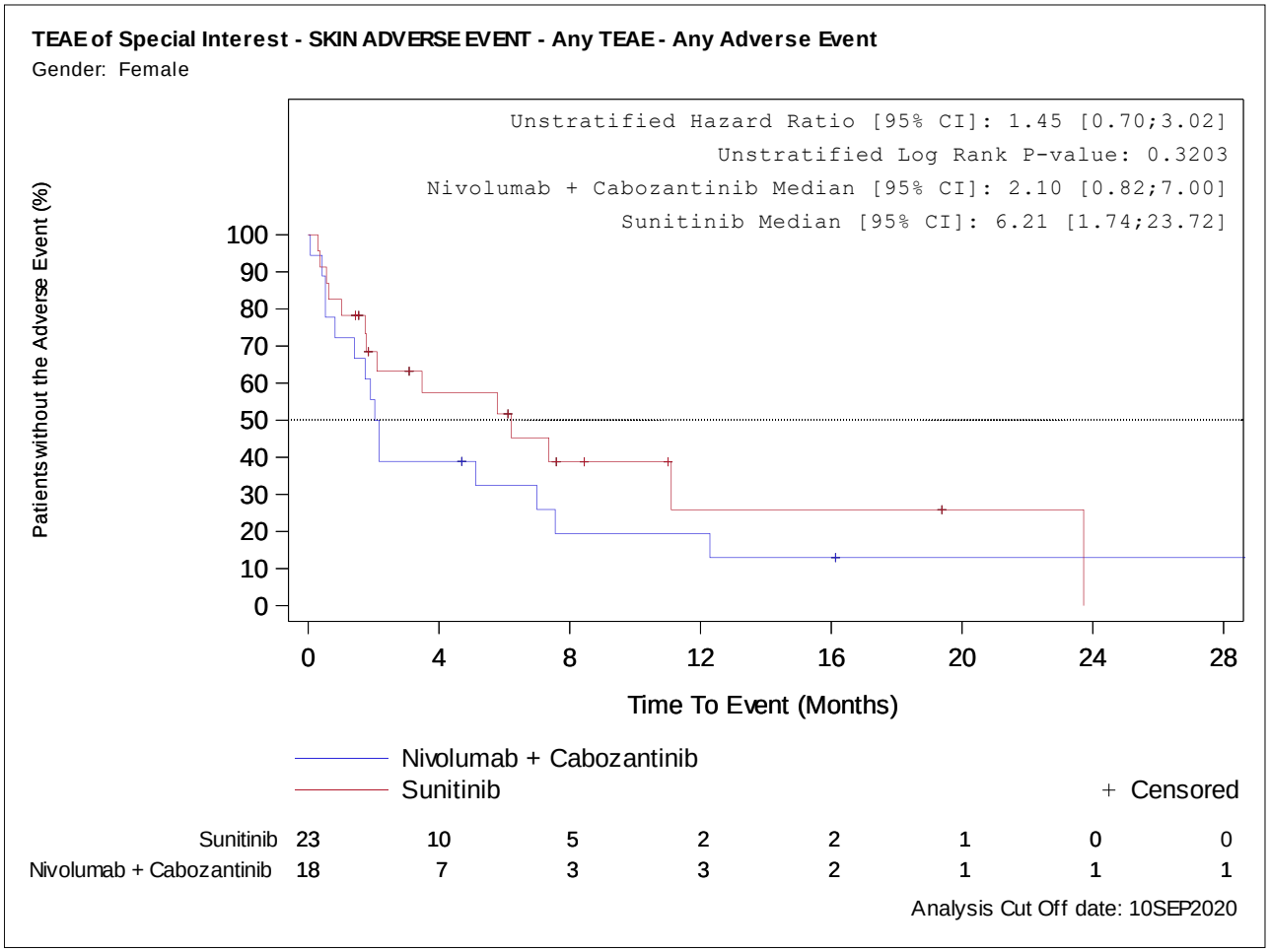

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:33:31

FIGURE 3.53.2.13: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



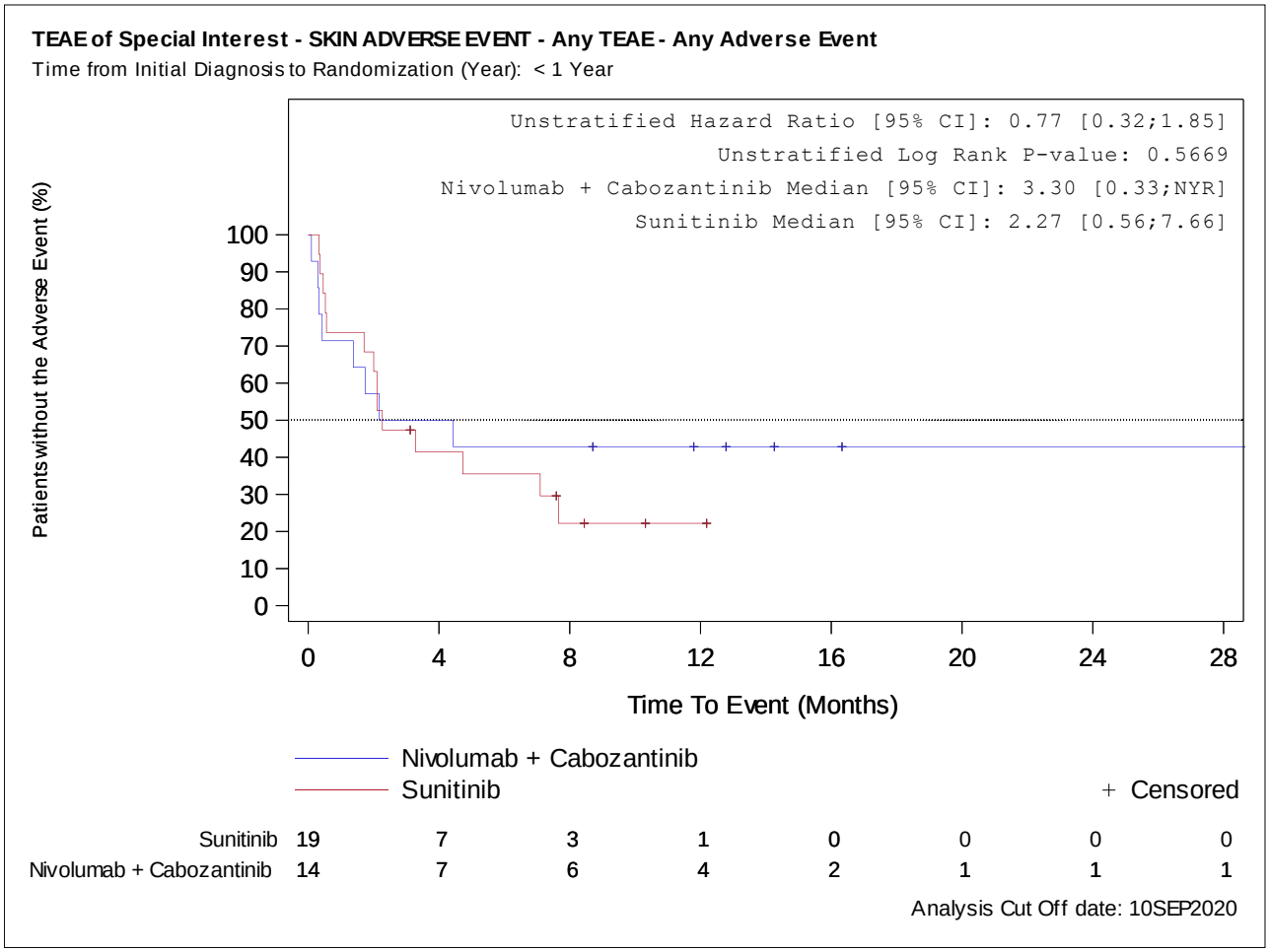

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:33:36

FIGURE 3.53.2.14: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



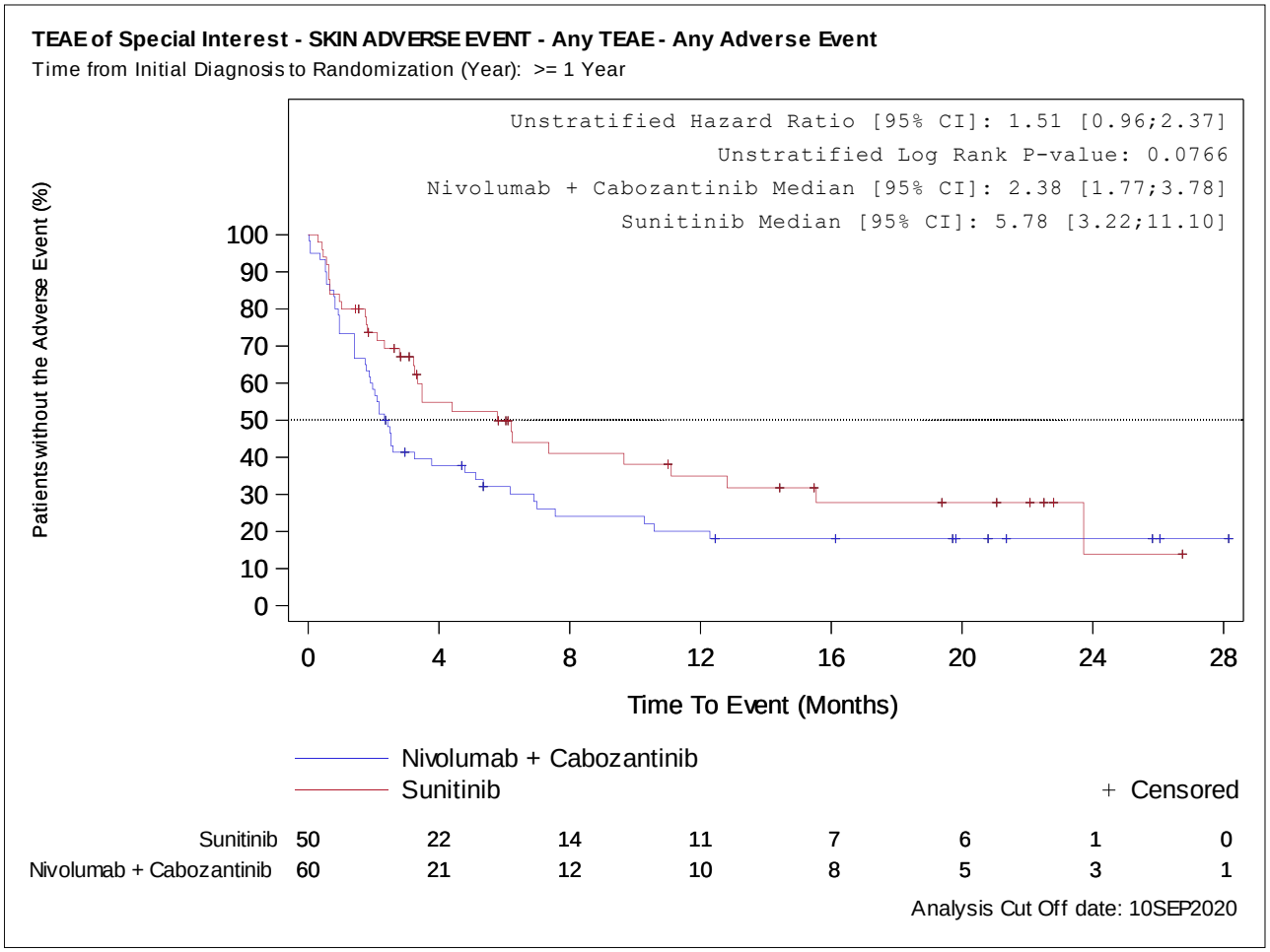

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:33:41

FIGURE 3.53.2.15: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



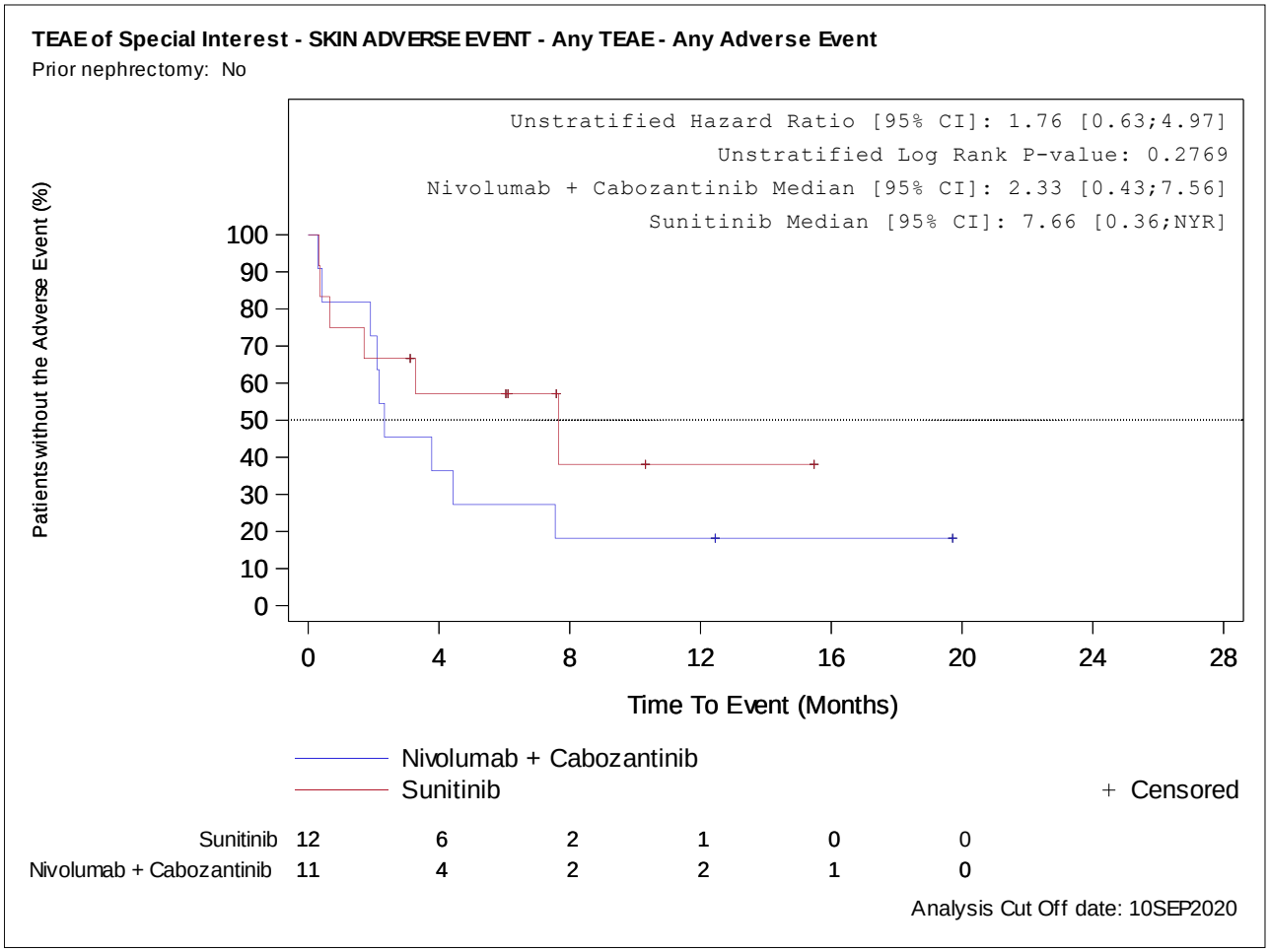

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:33:56

FIGURE 3.53.2.16: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



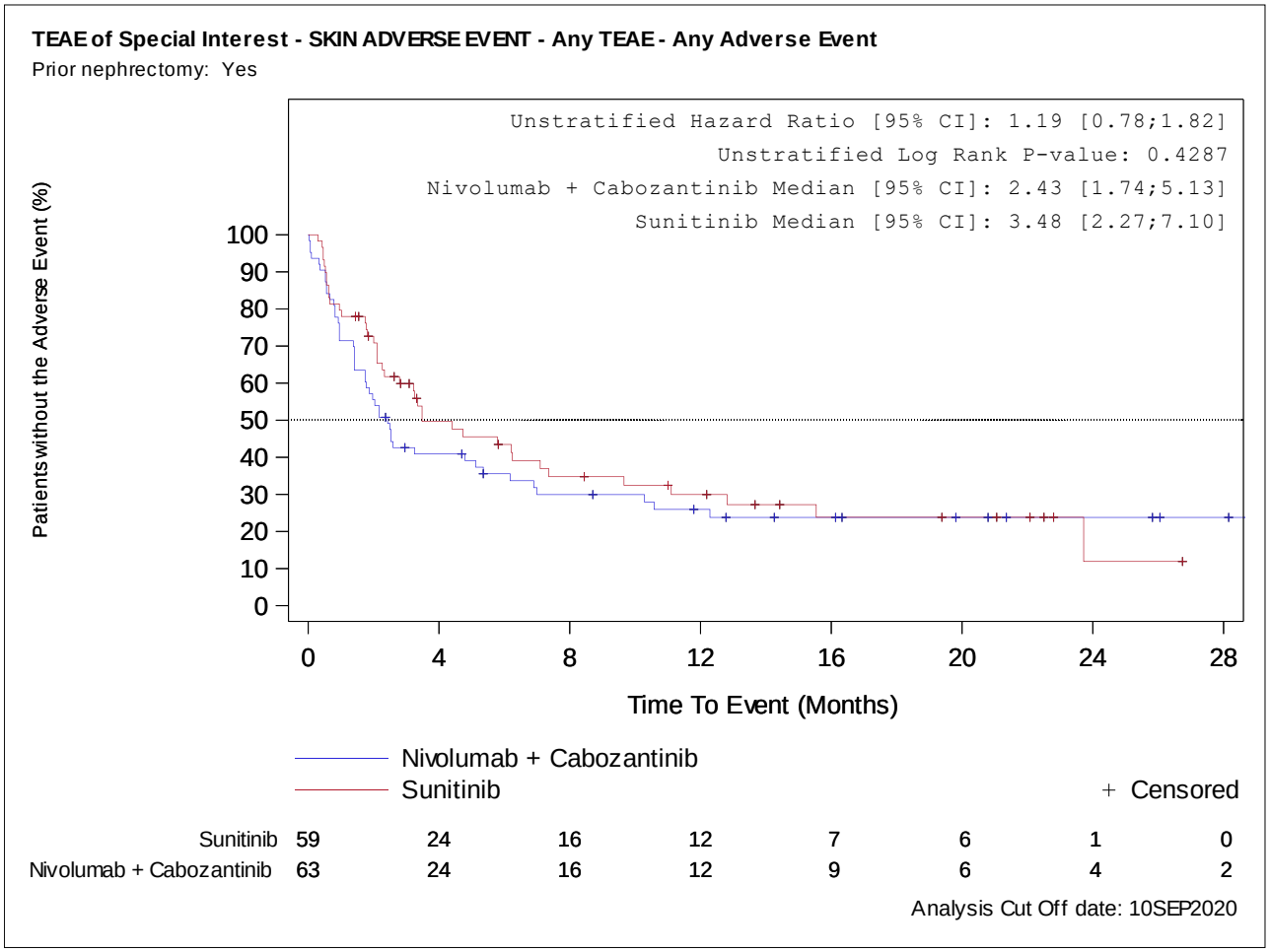

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:34:01

FIGURE 3.53.2.17: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



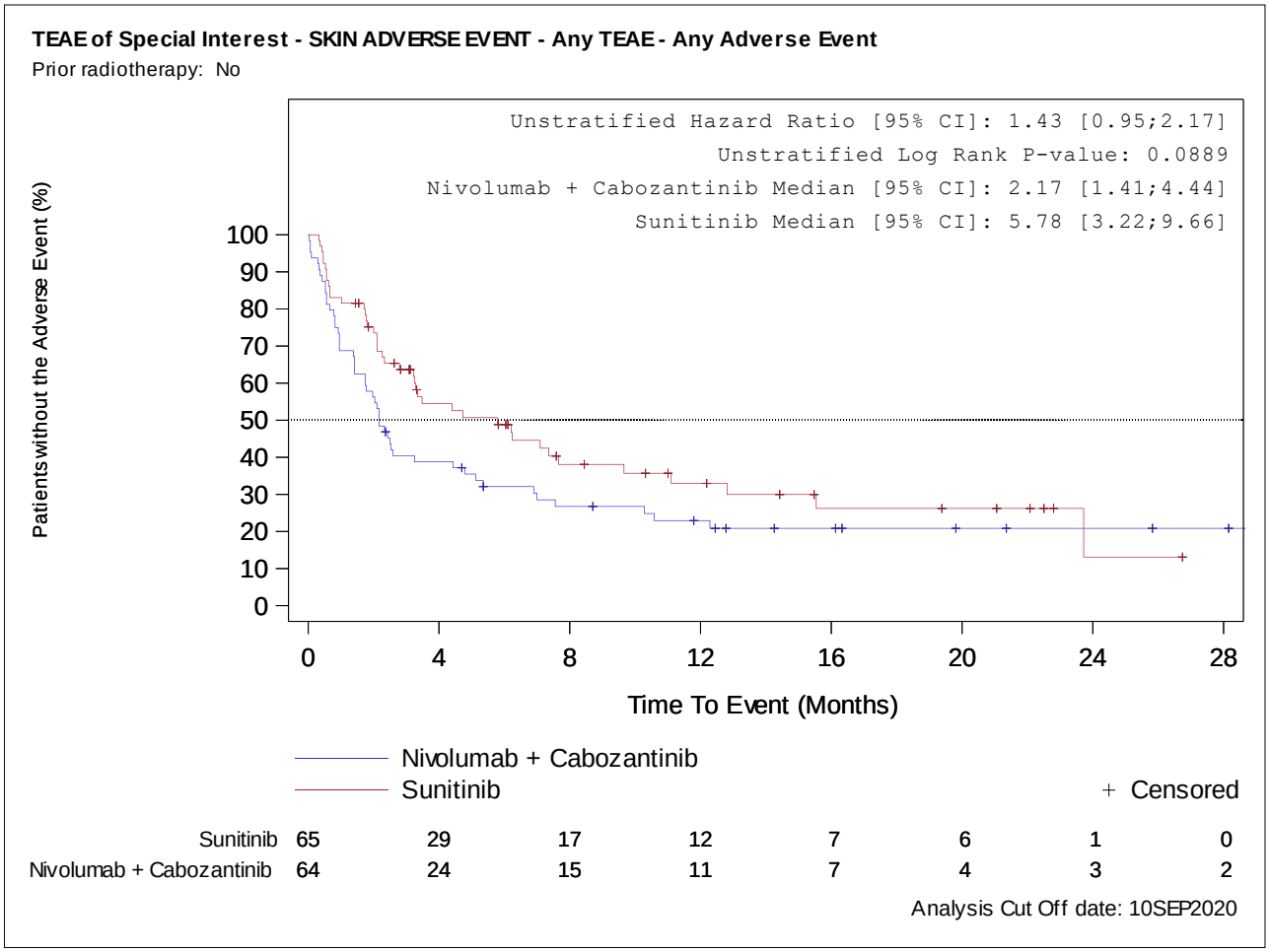

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:34:48

FIGURE 3.53.2.18: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



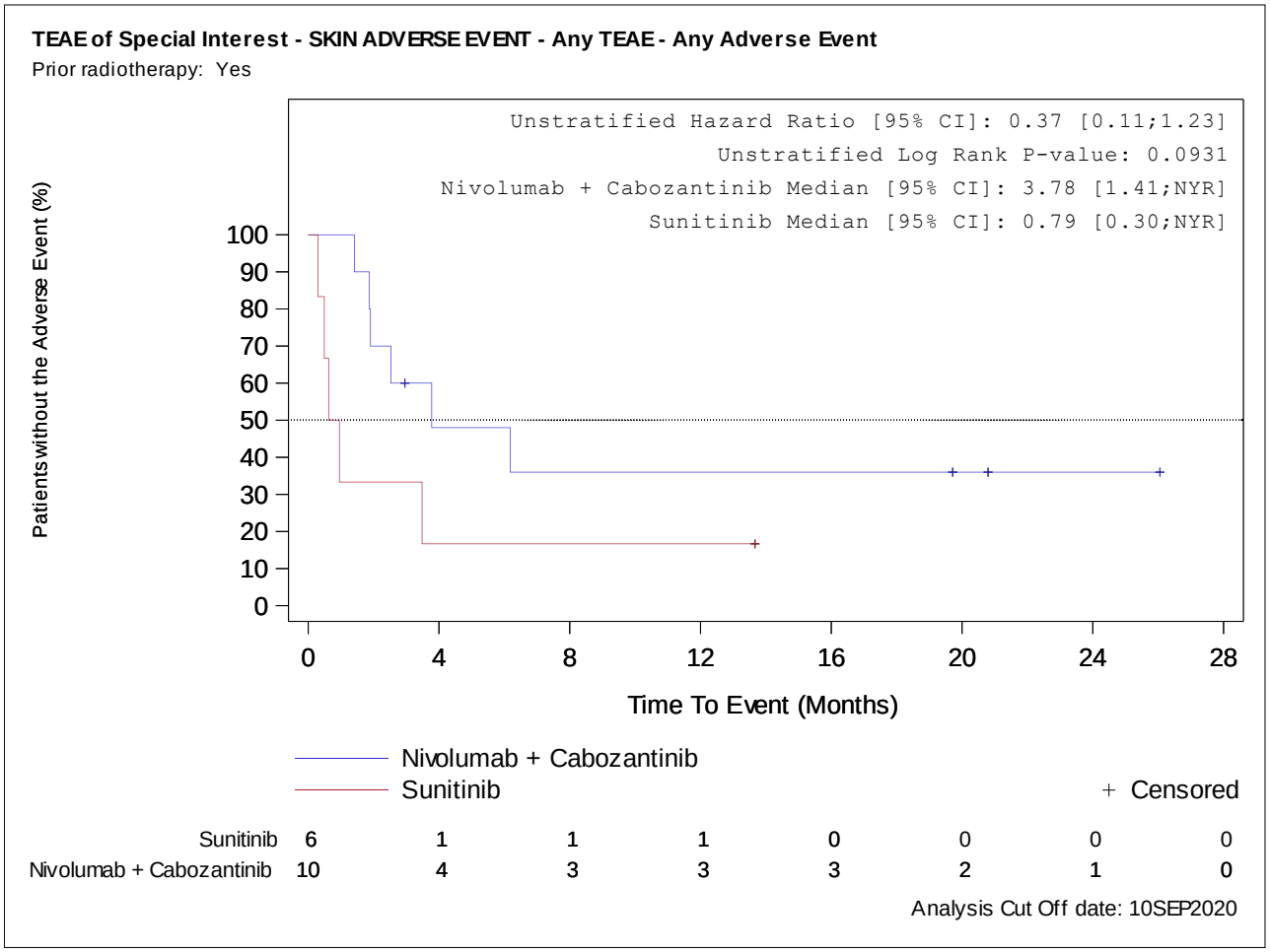

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:34:53

FIGURE 3.53.2.19: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



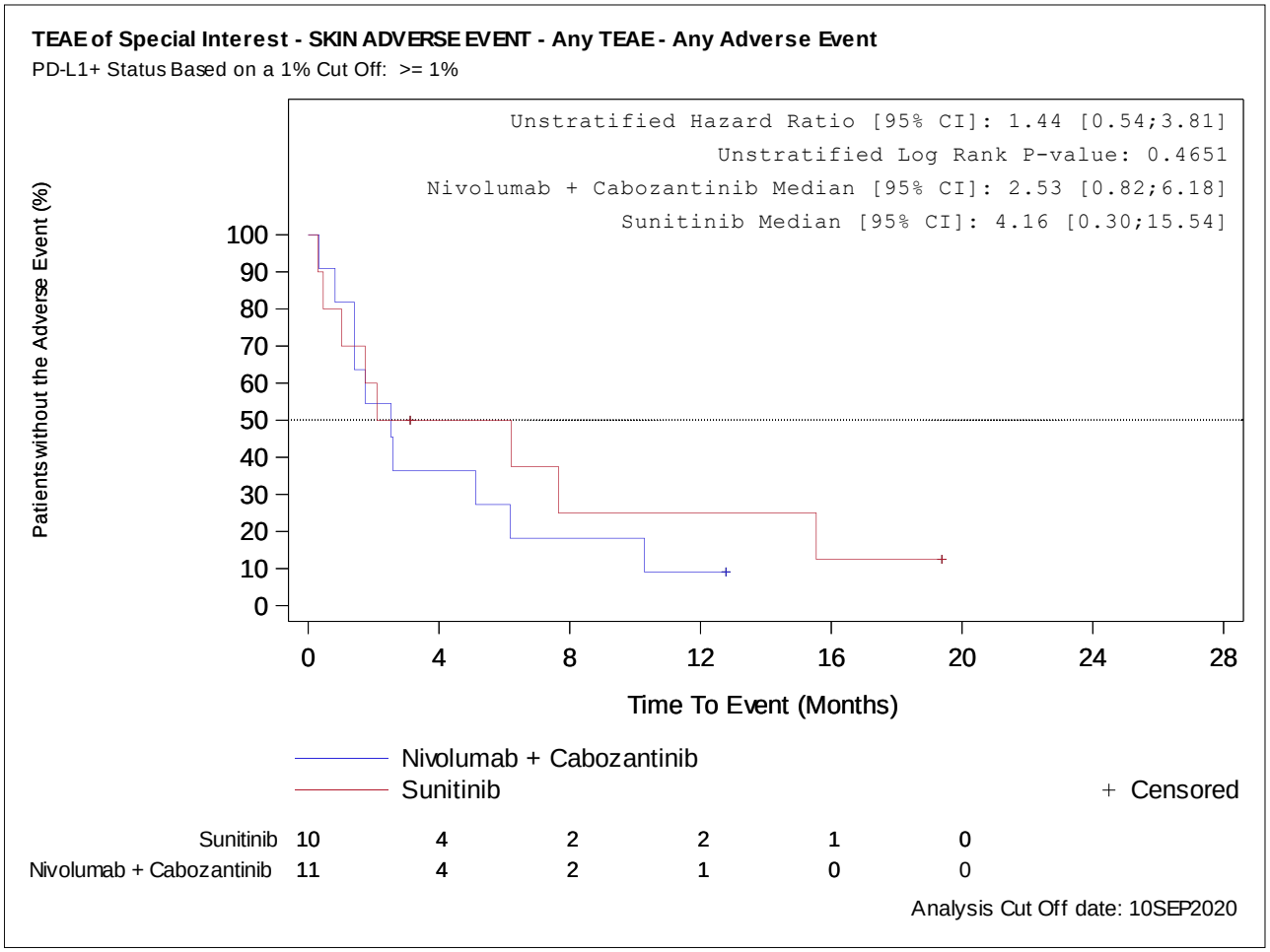

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:34:59

FIGURE 3.53.2.20: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



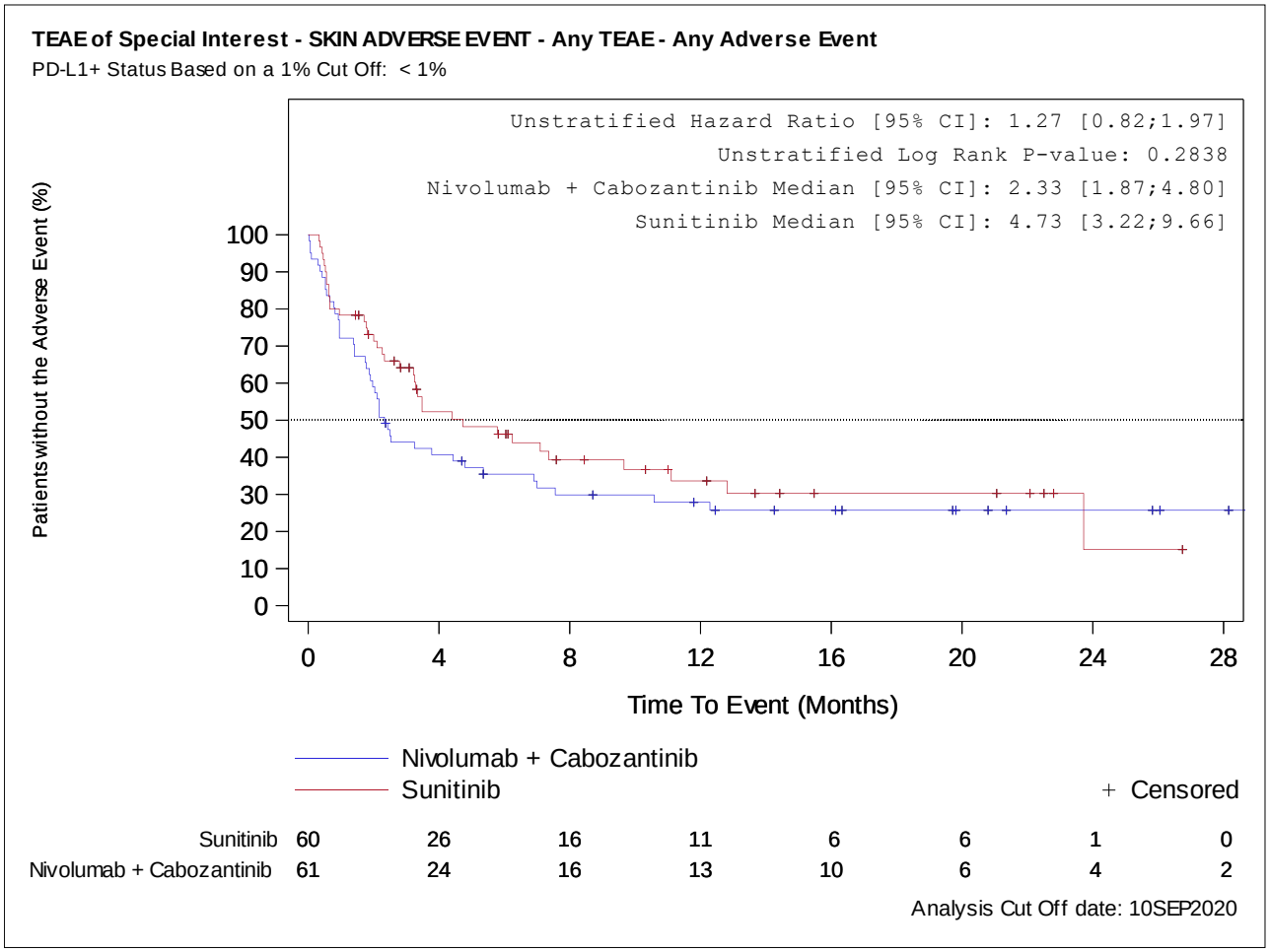

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:35:04

FIGURE 3.53.2.21: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



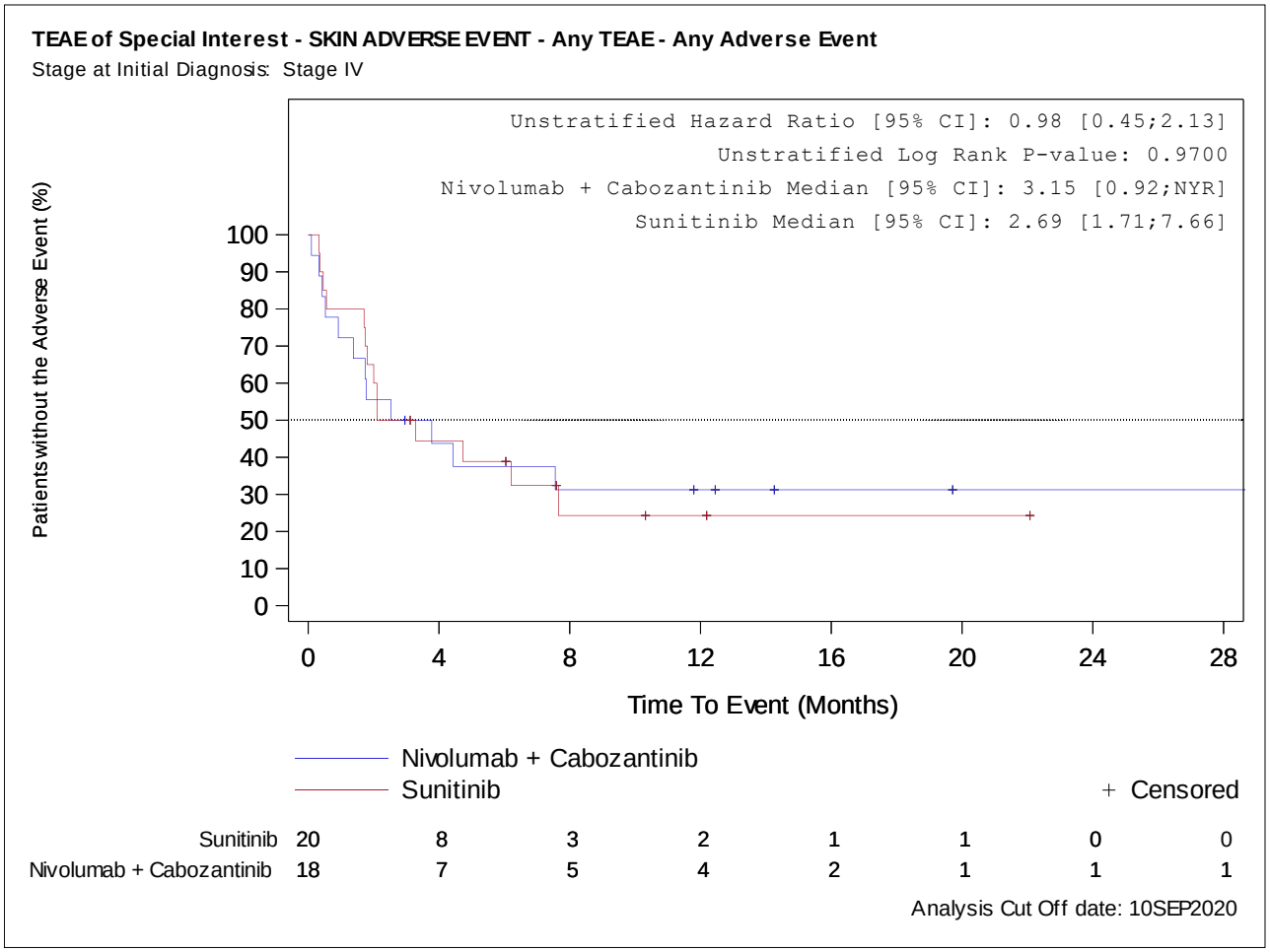

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:35:09

FIGURE 3.53.2.22: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



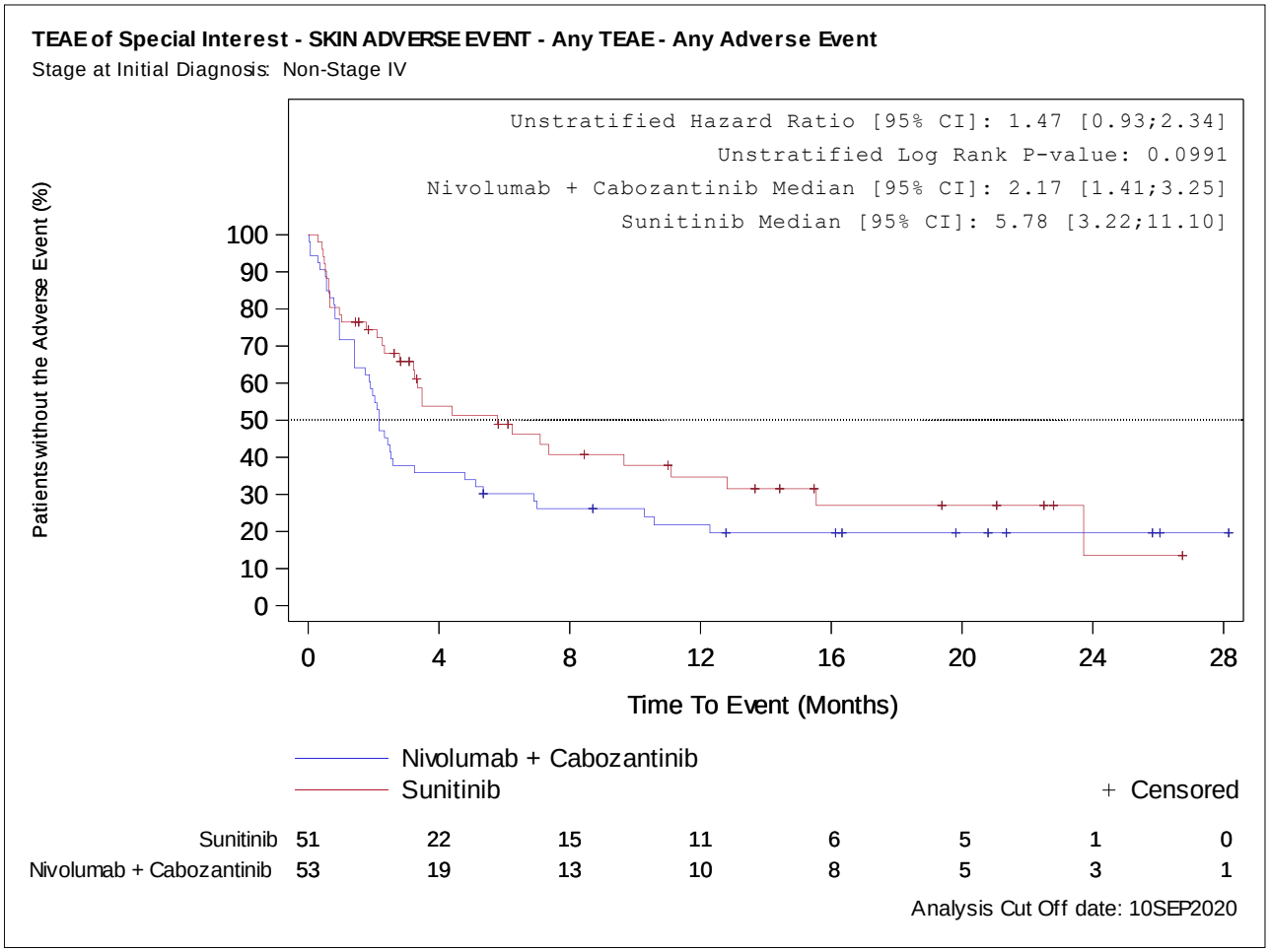

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:35:15

FIGURE 3.53.2.23: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



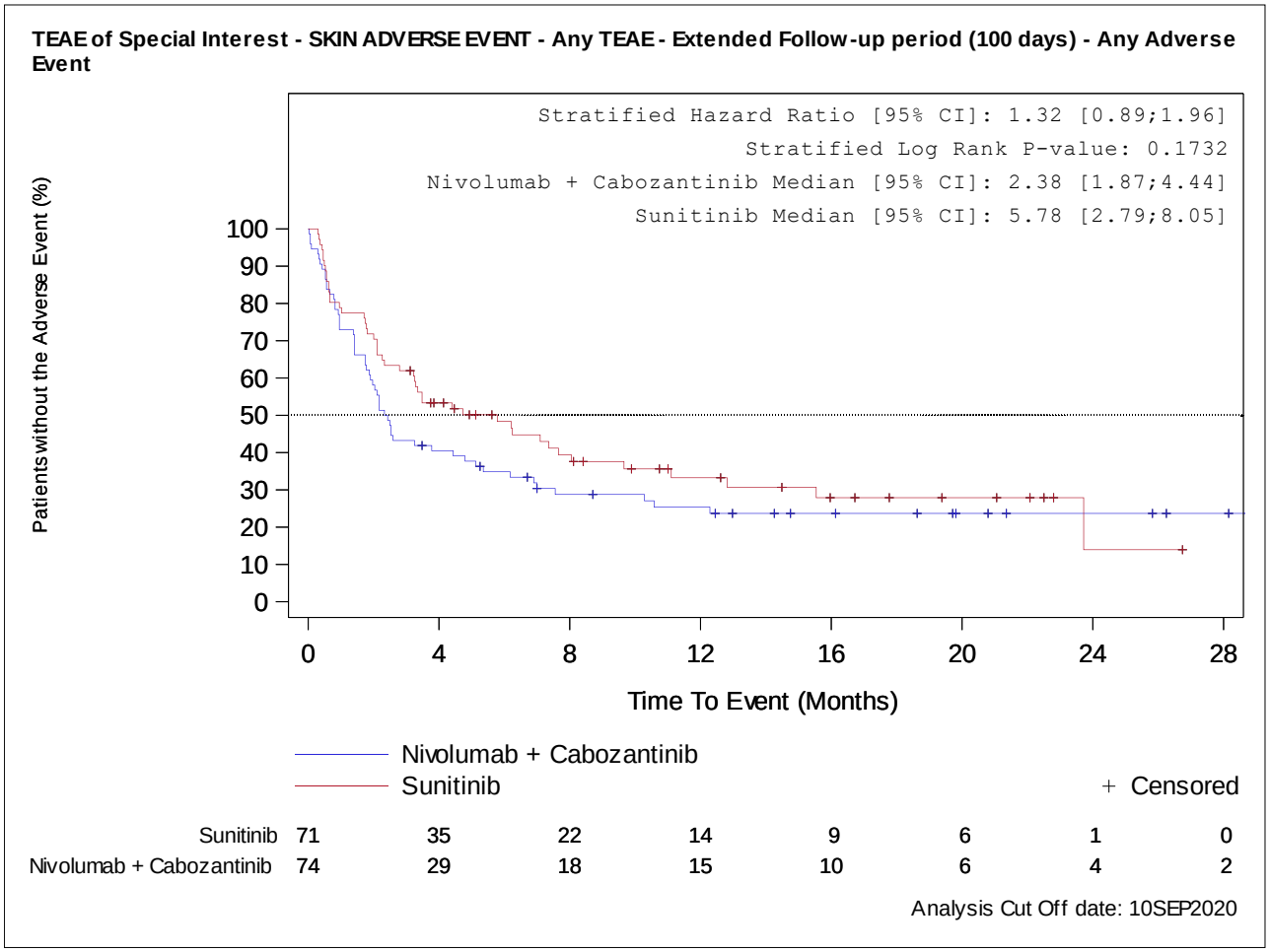

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:35:41

FIGURE 3.53.2.24: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



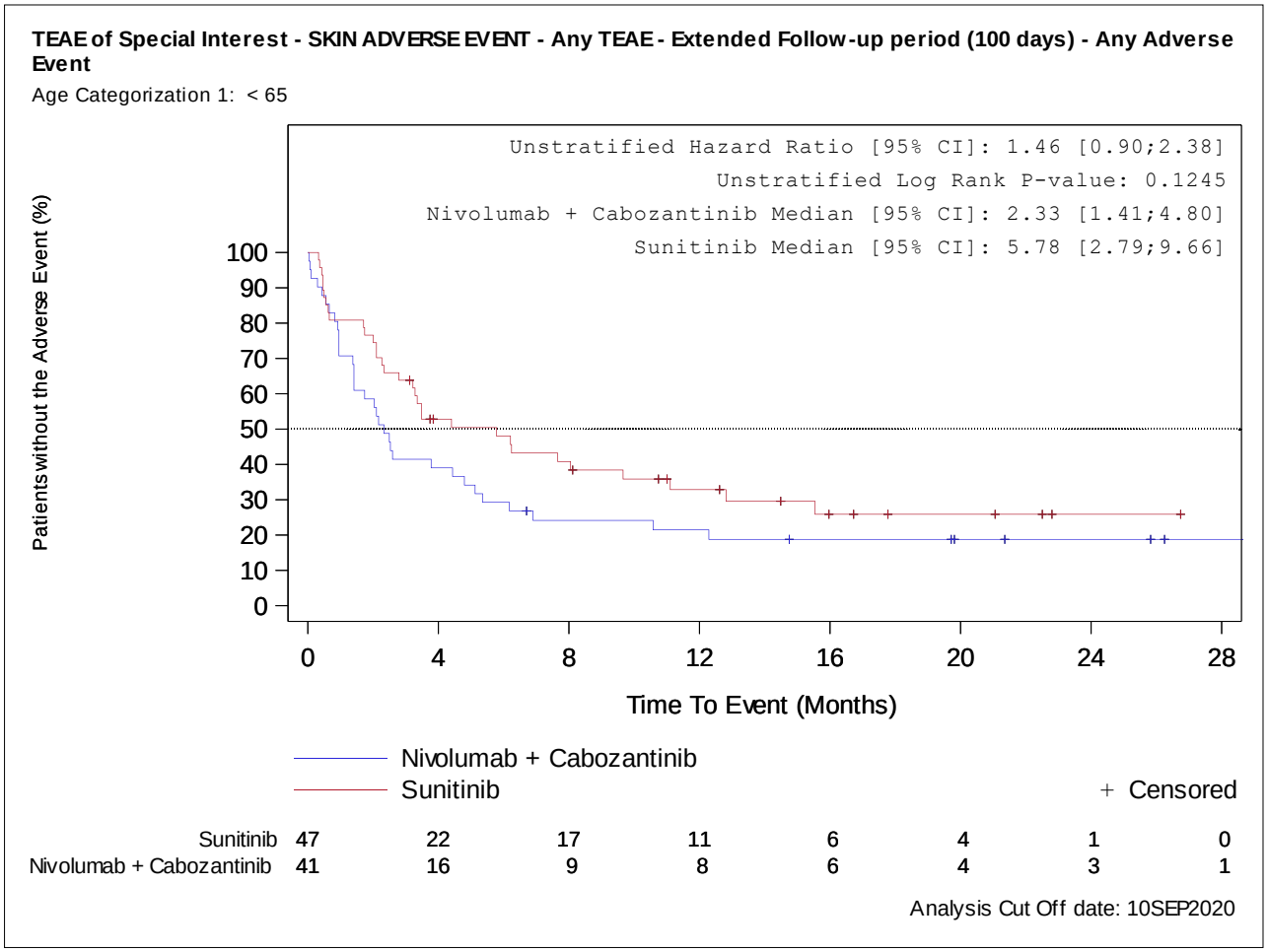

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:35:46

FIGURE 3.54.1: TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



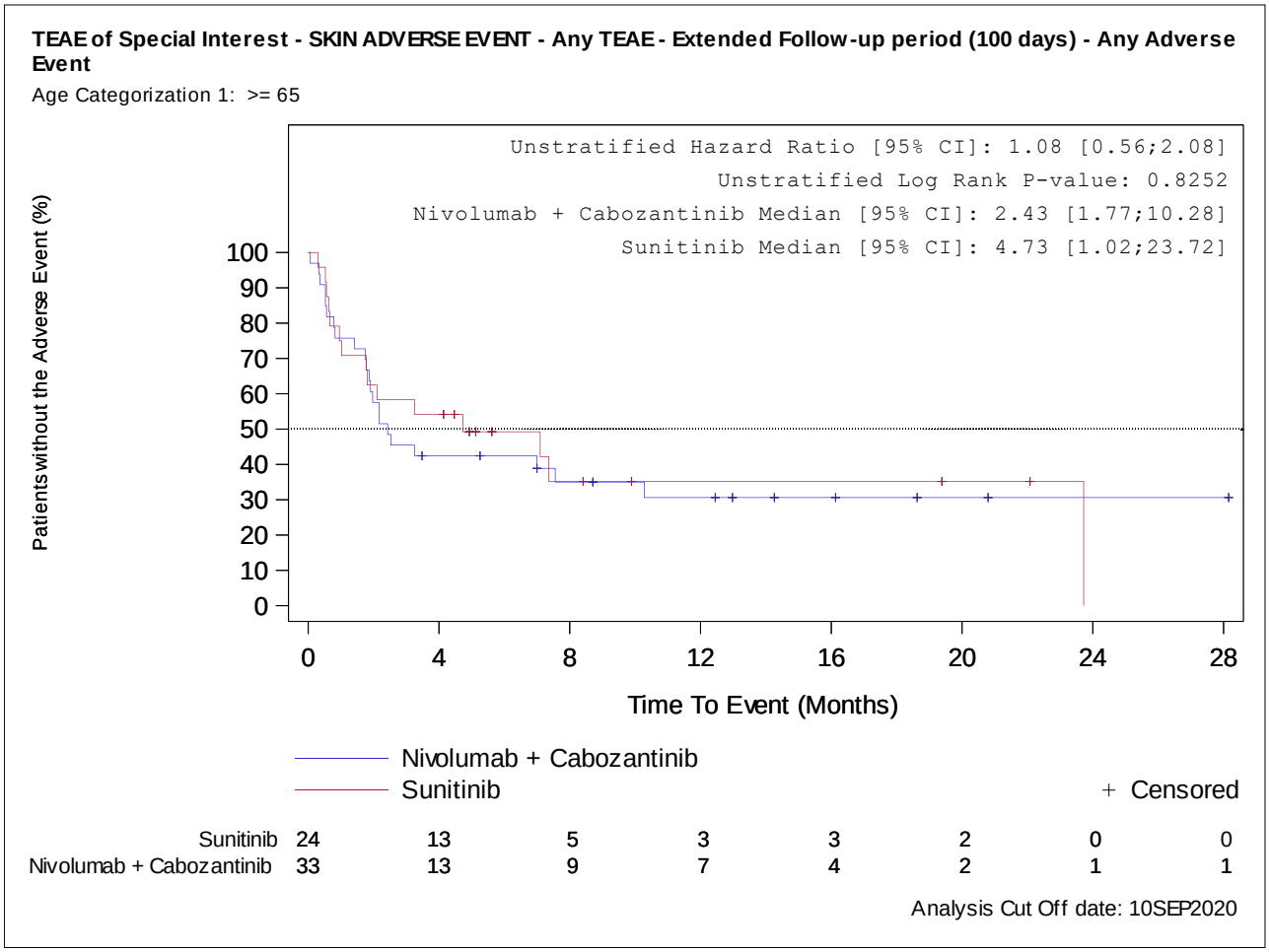

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:38:42

FIGURE 3.54.2.1: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



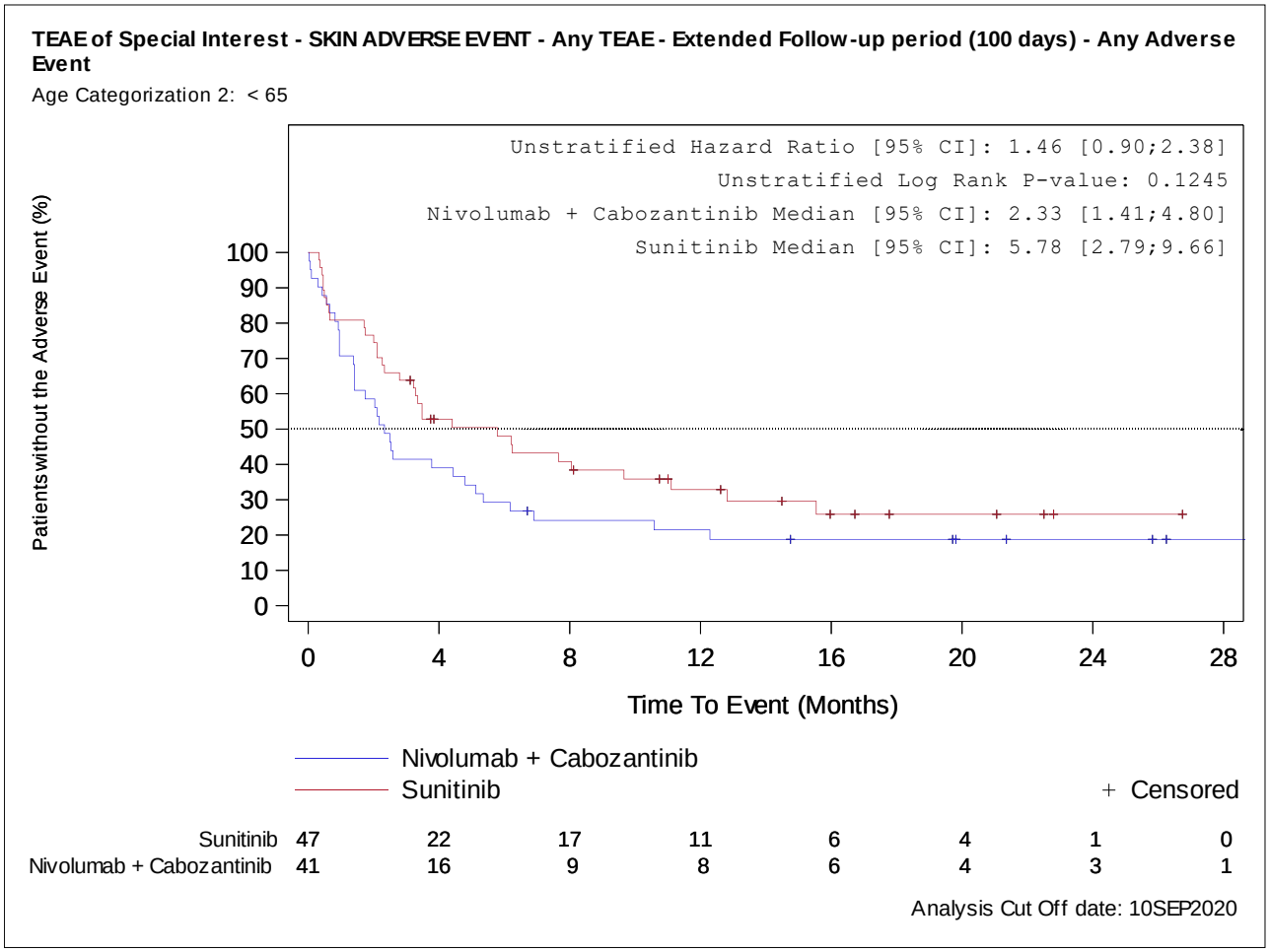

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:38:45

FIGURE 3.54.2.2: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



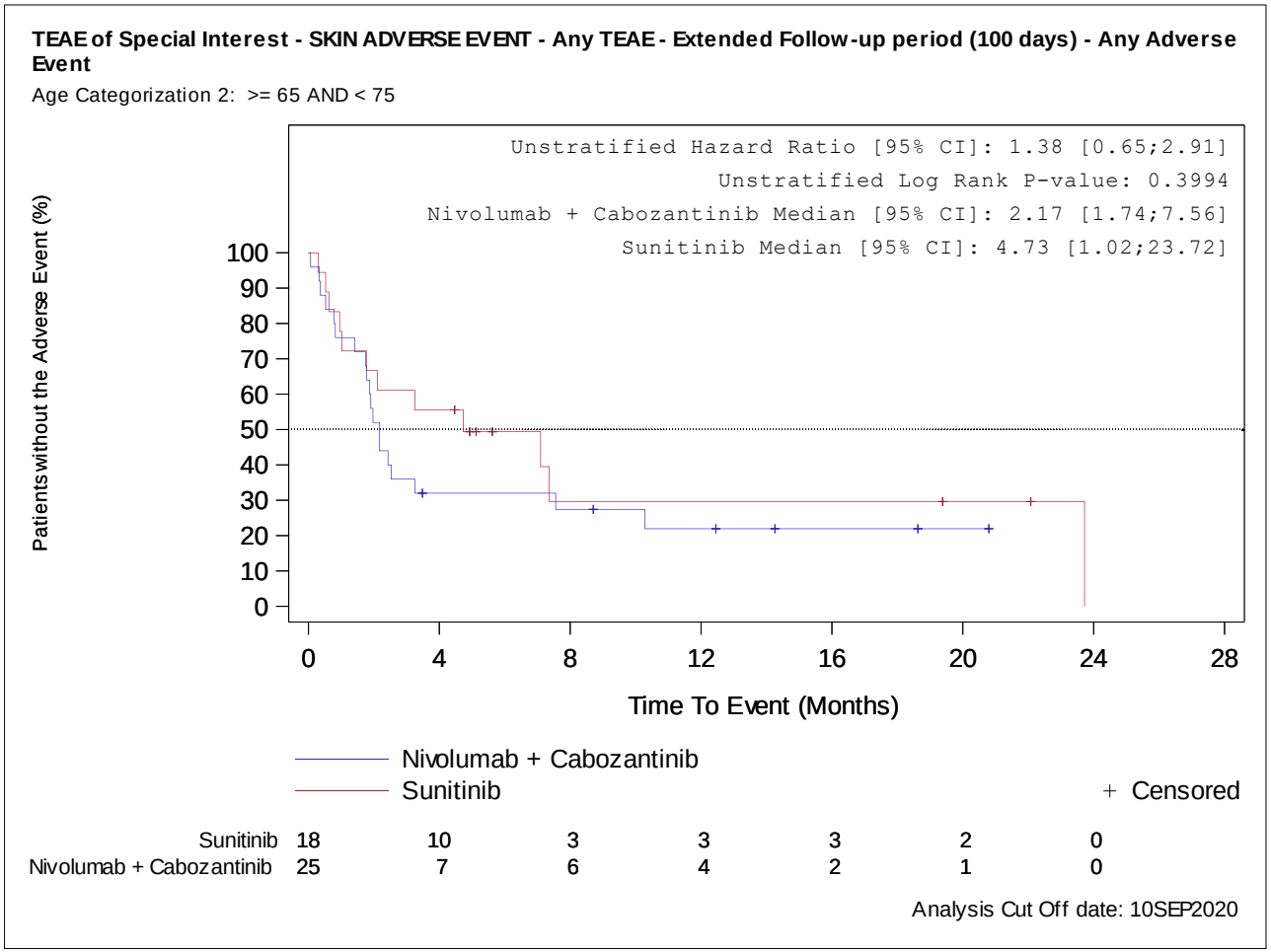

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:38:50

FIGURE 3.54.2.3: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



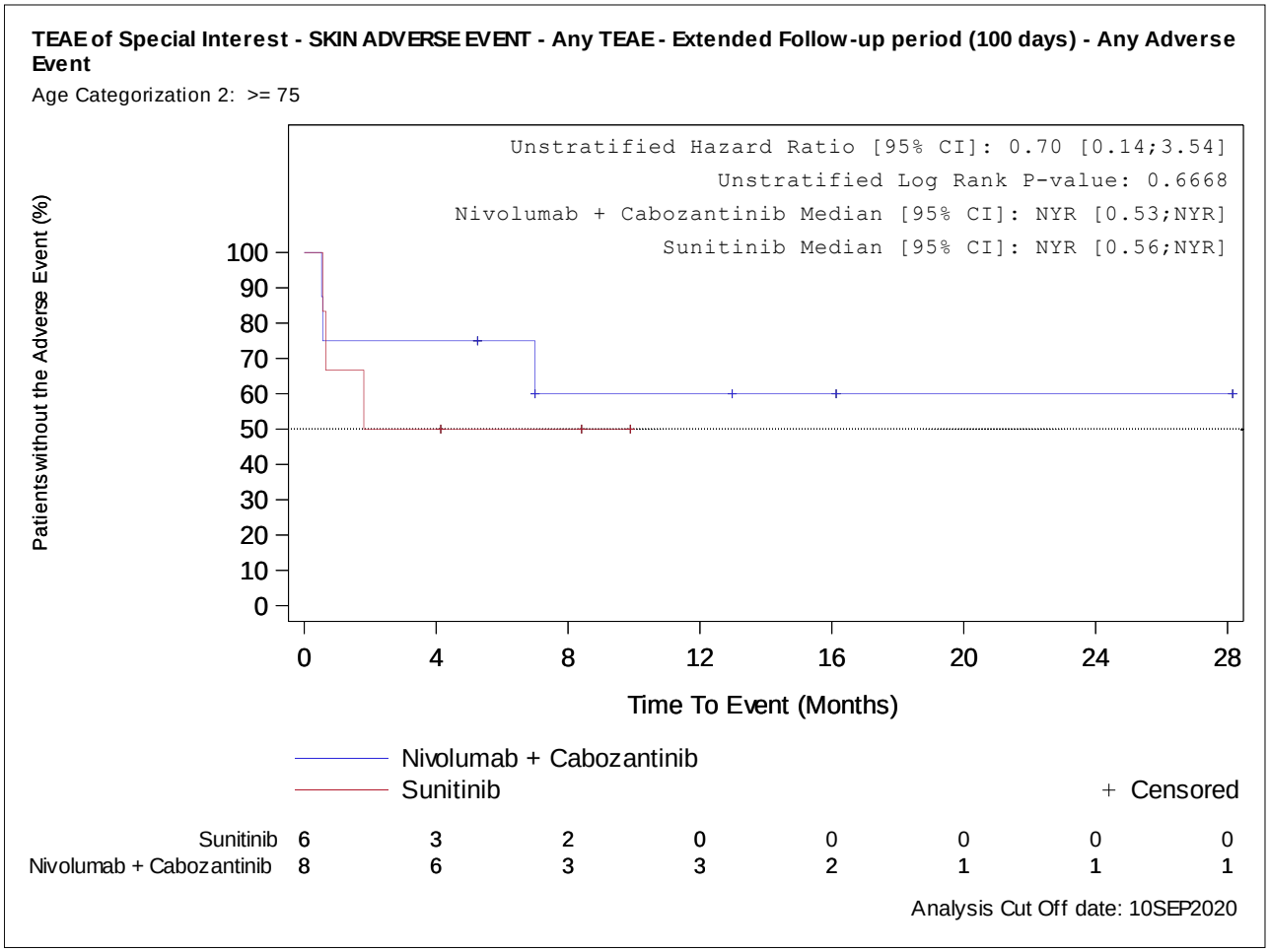

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:38:55

FIGURE 3.54.2.4: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



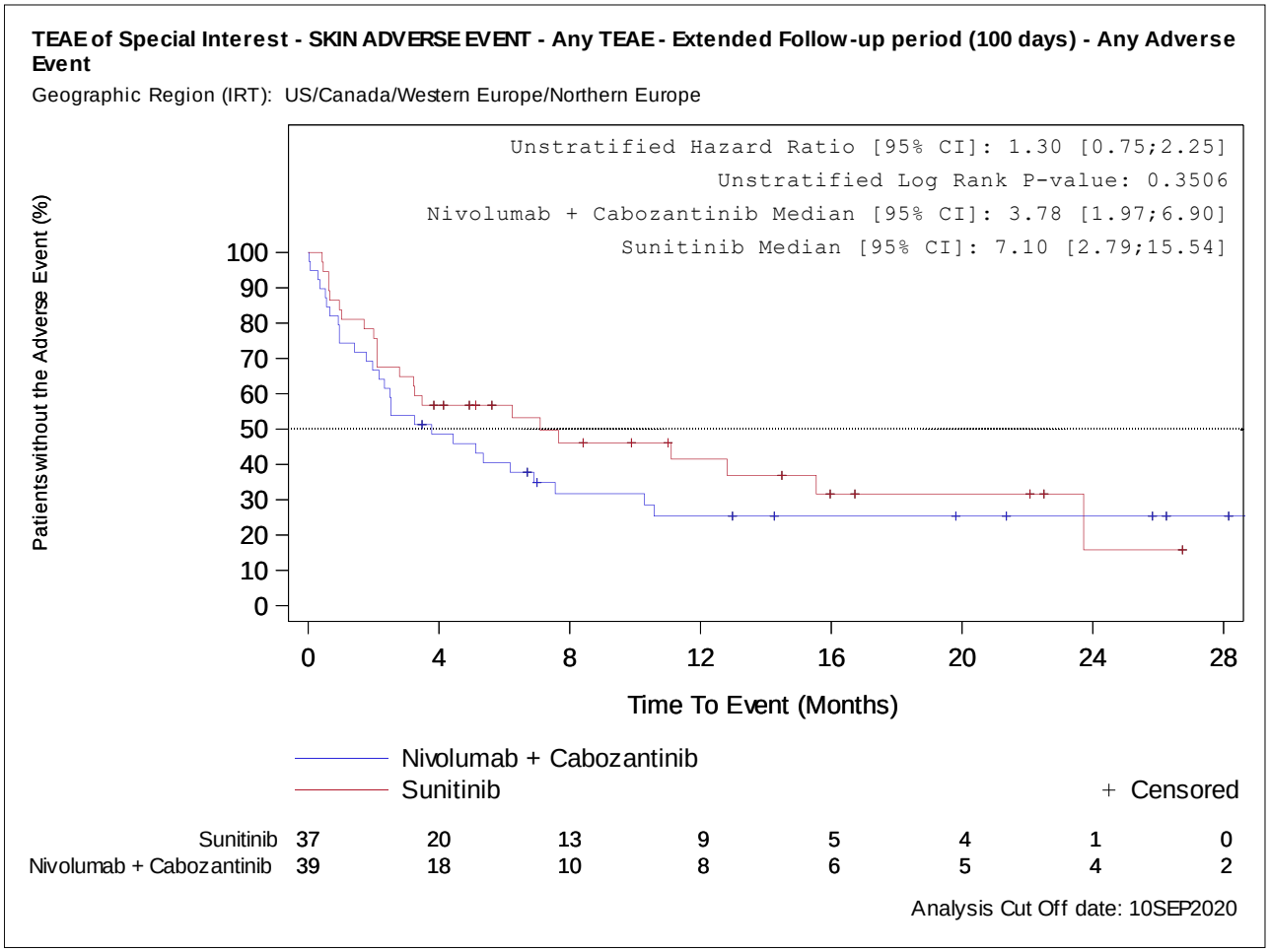

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:39:01

FIGURE 3.54.2.5: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



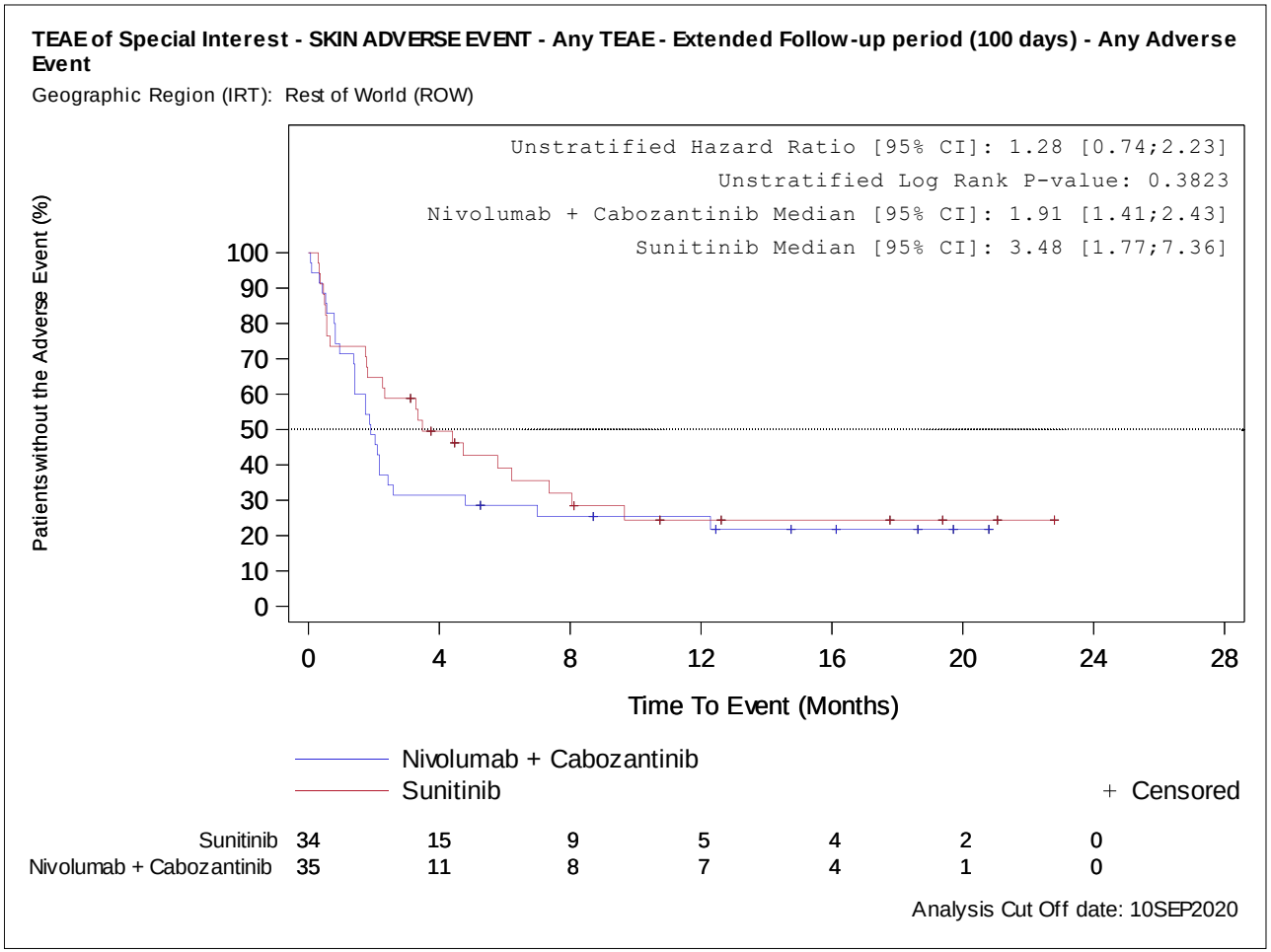

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:39:07

FIGURE 3.54.2.6: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



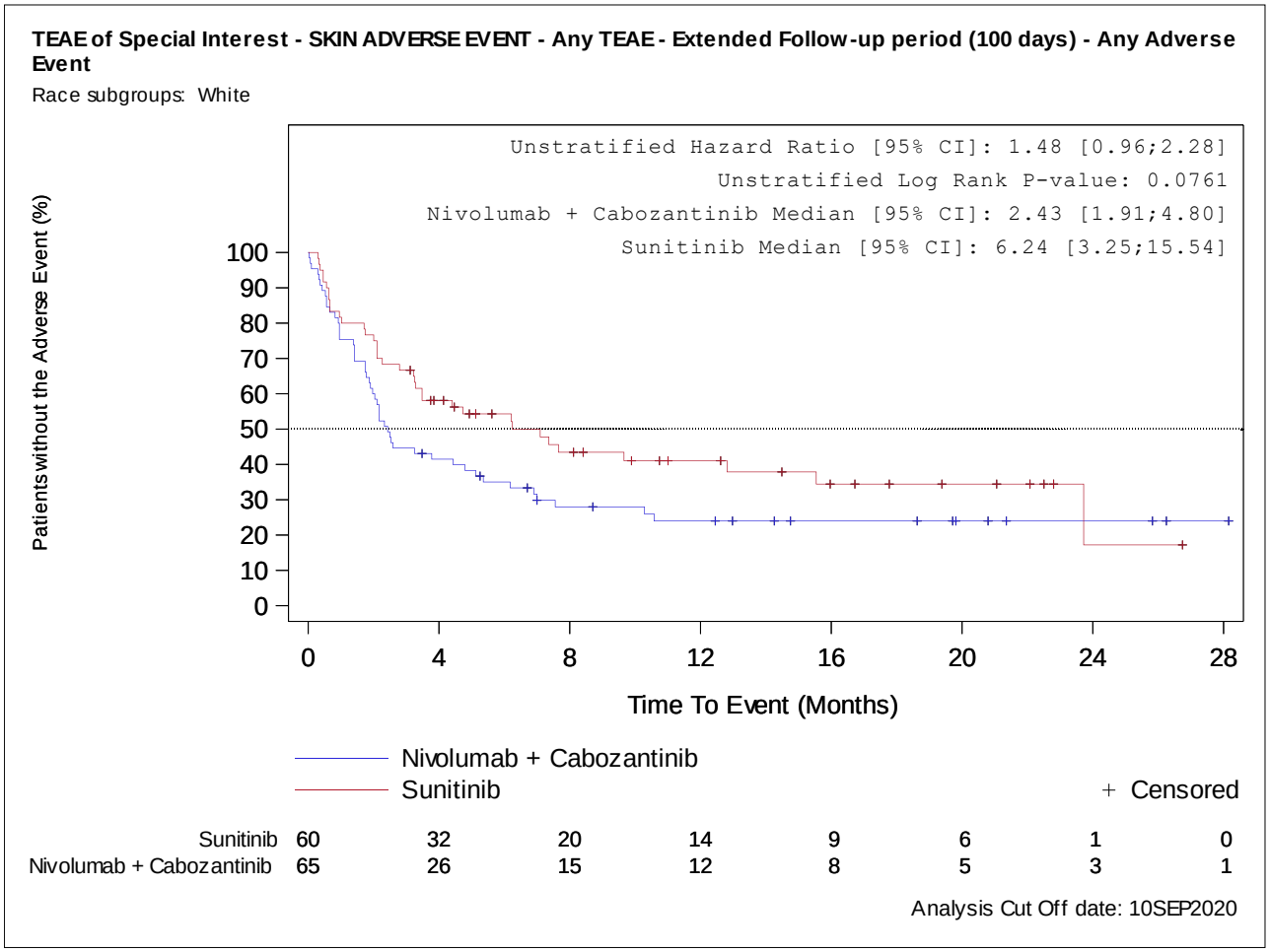

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:39:12

FIGURE 3.54.2.7: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



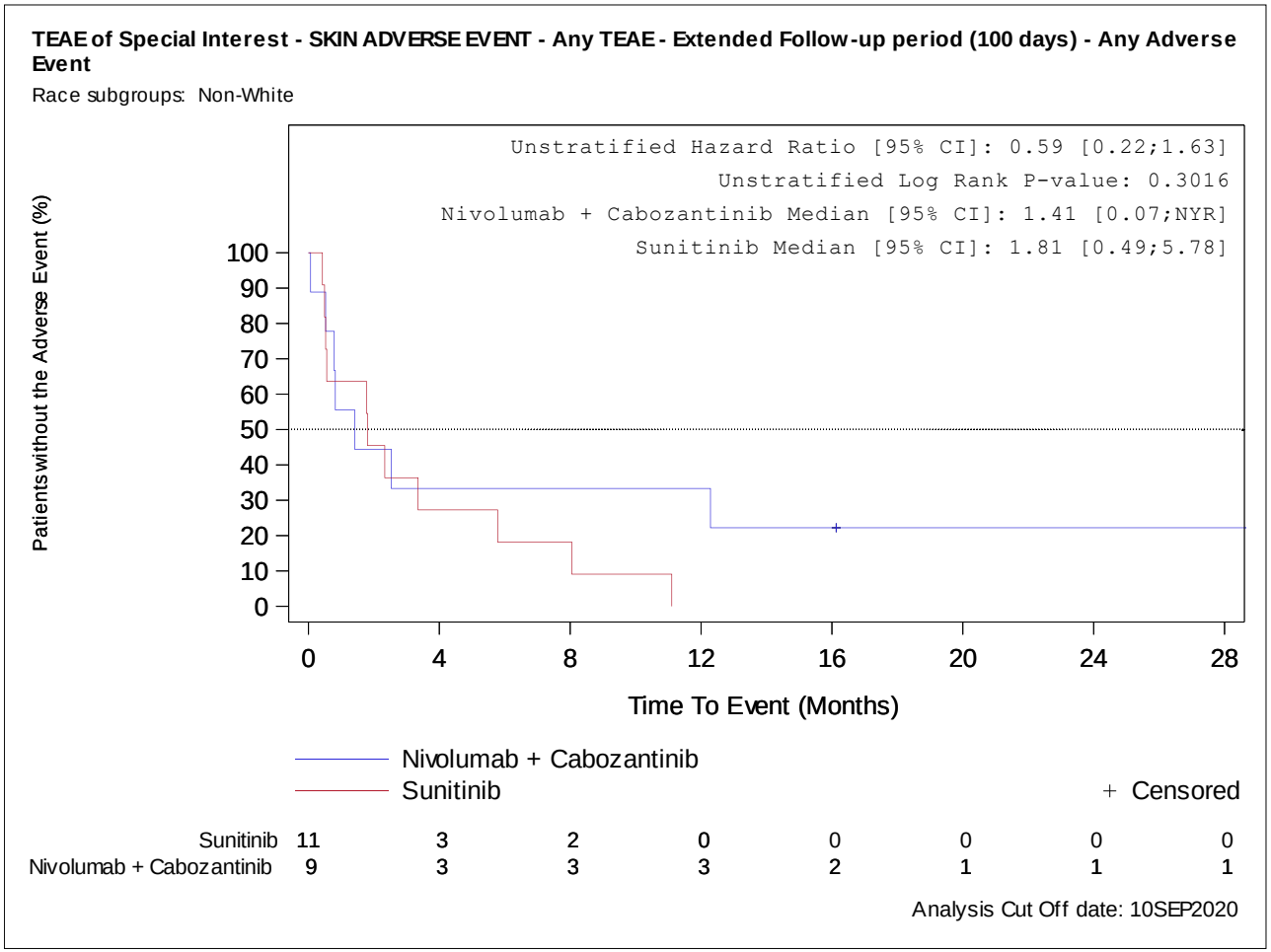

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:39:17

FIGURE 3.54.2.8: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



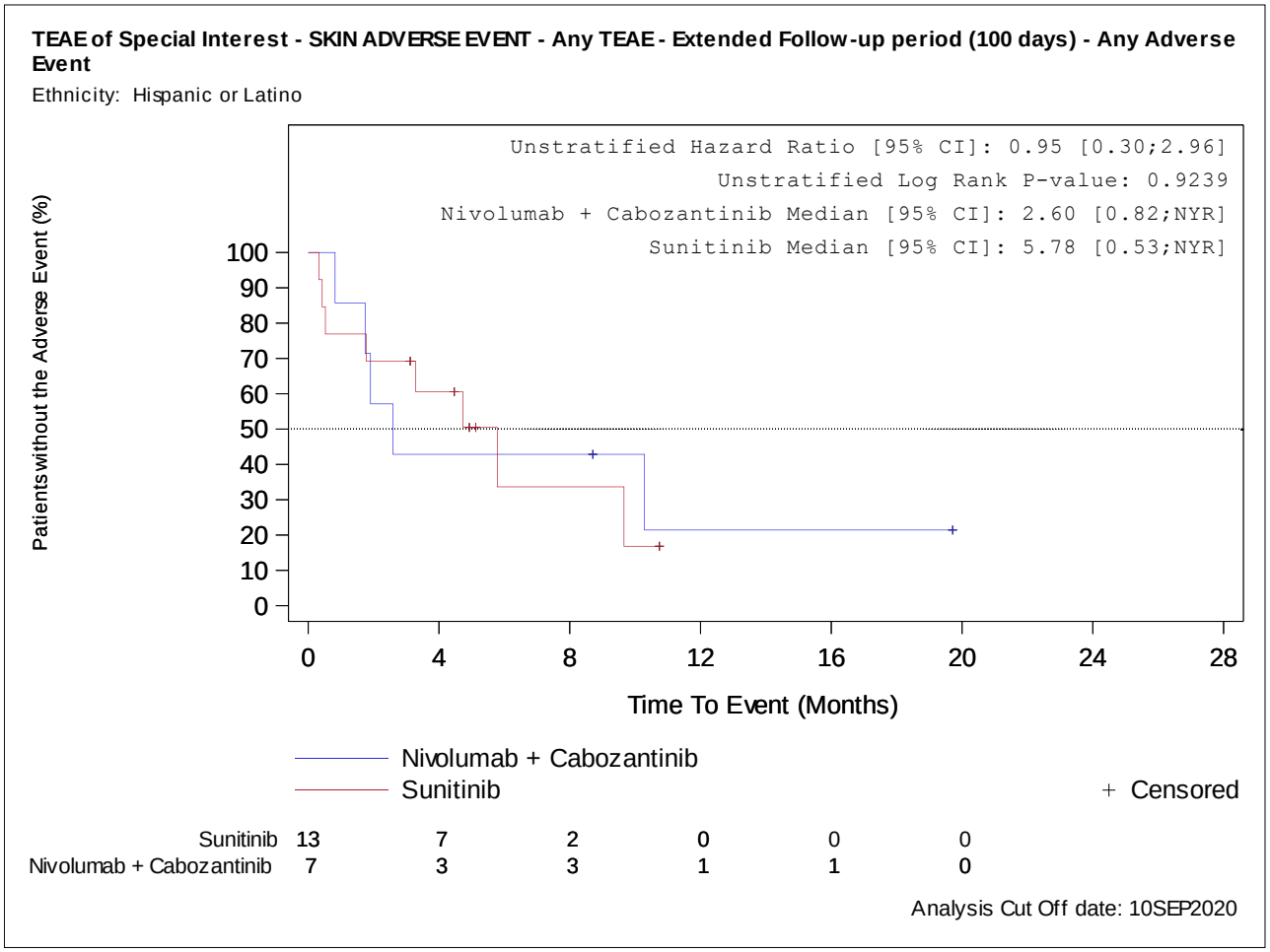

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:39:23

FIGURE 3.54.2.9: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



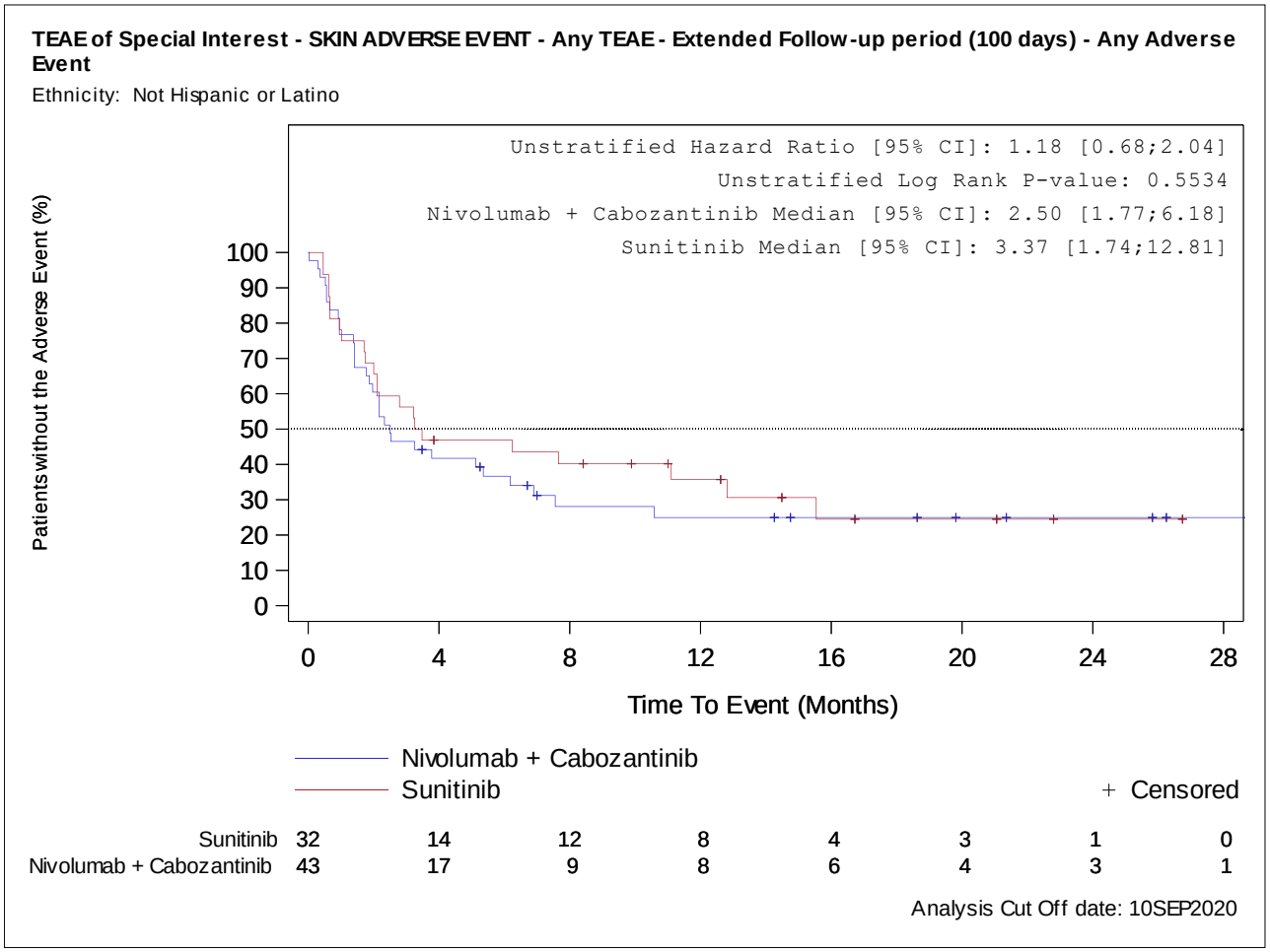

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:39:28

FIGURE 3.54.2.10: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



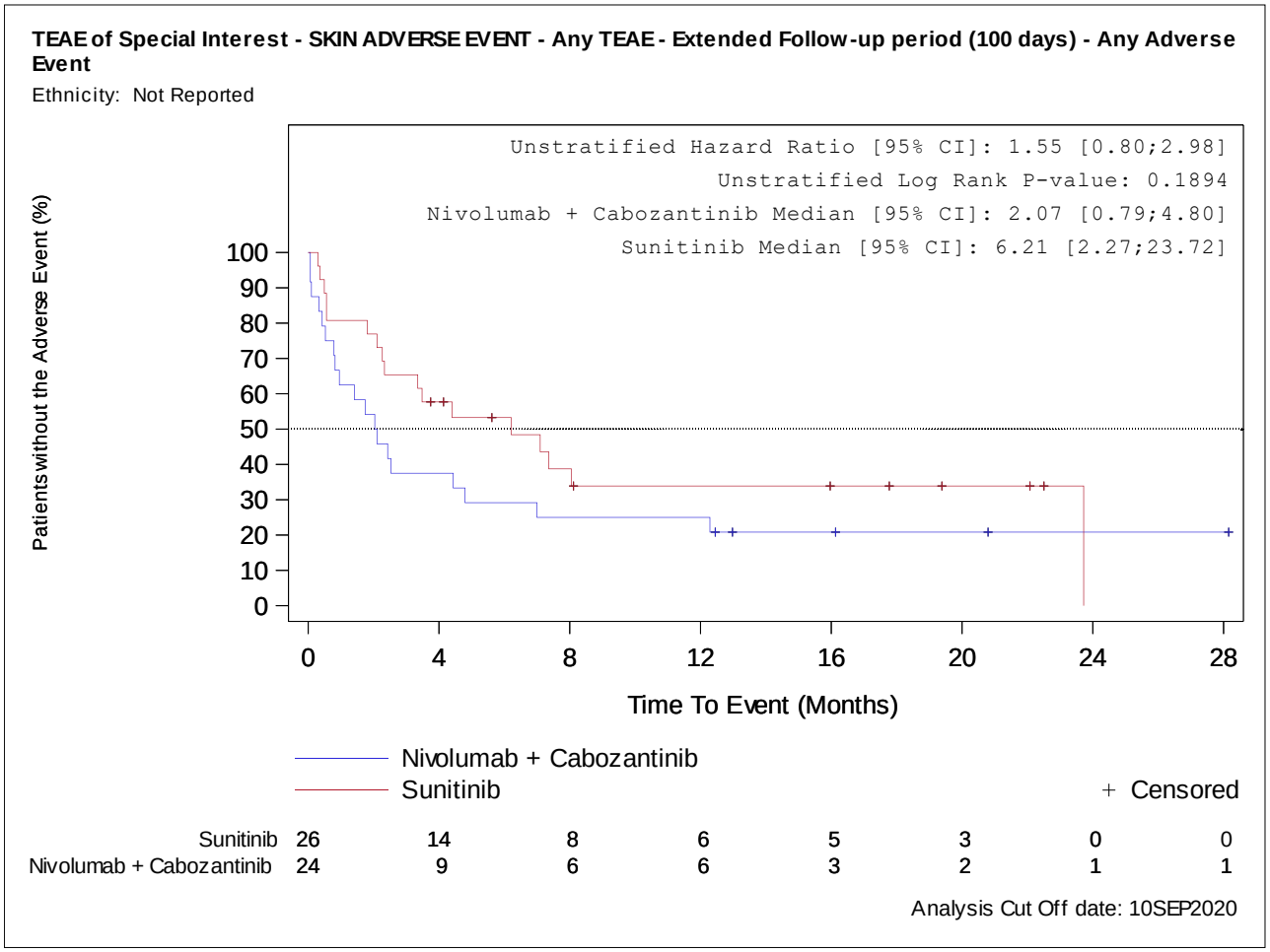

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:39:33

FIGURE 3.54.2.11: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



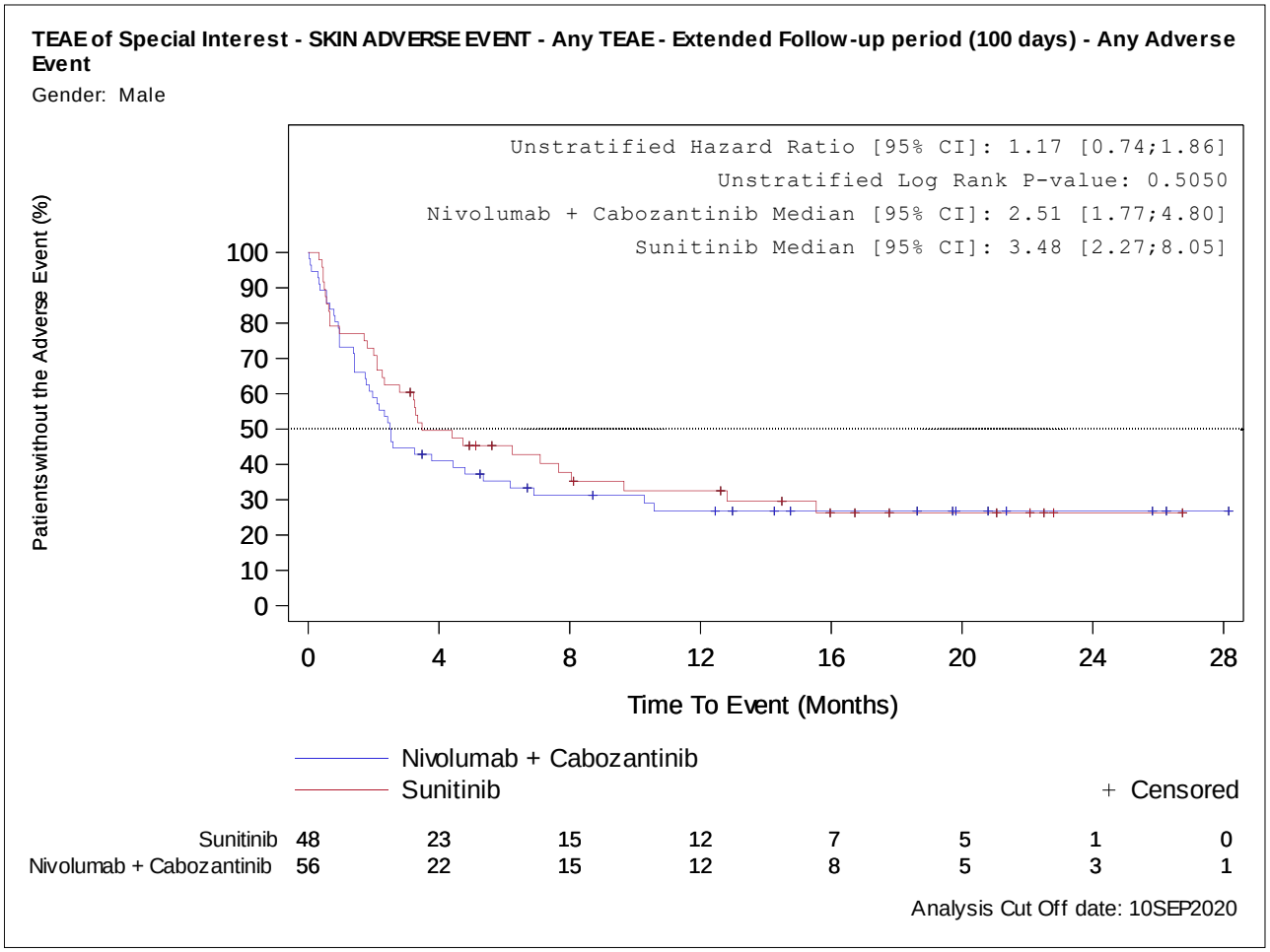

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:39:38

FIGURE 3.54.2.12: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



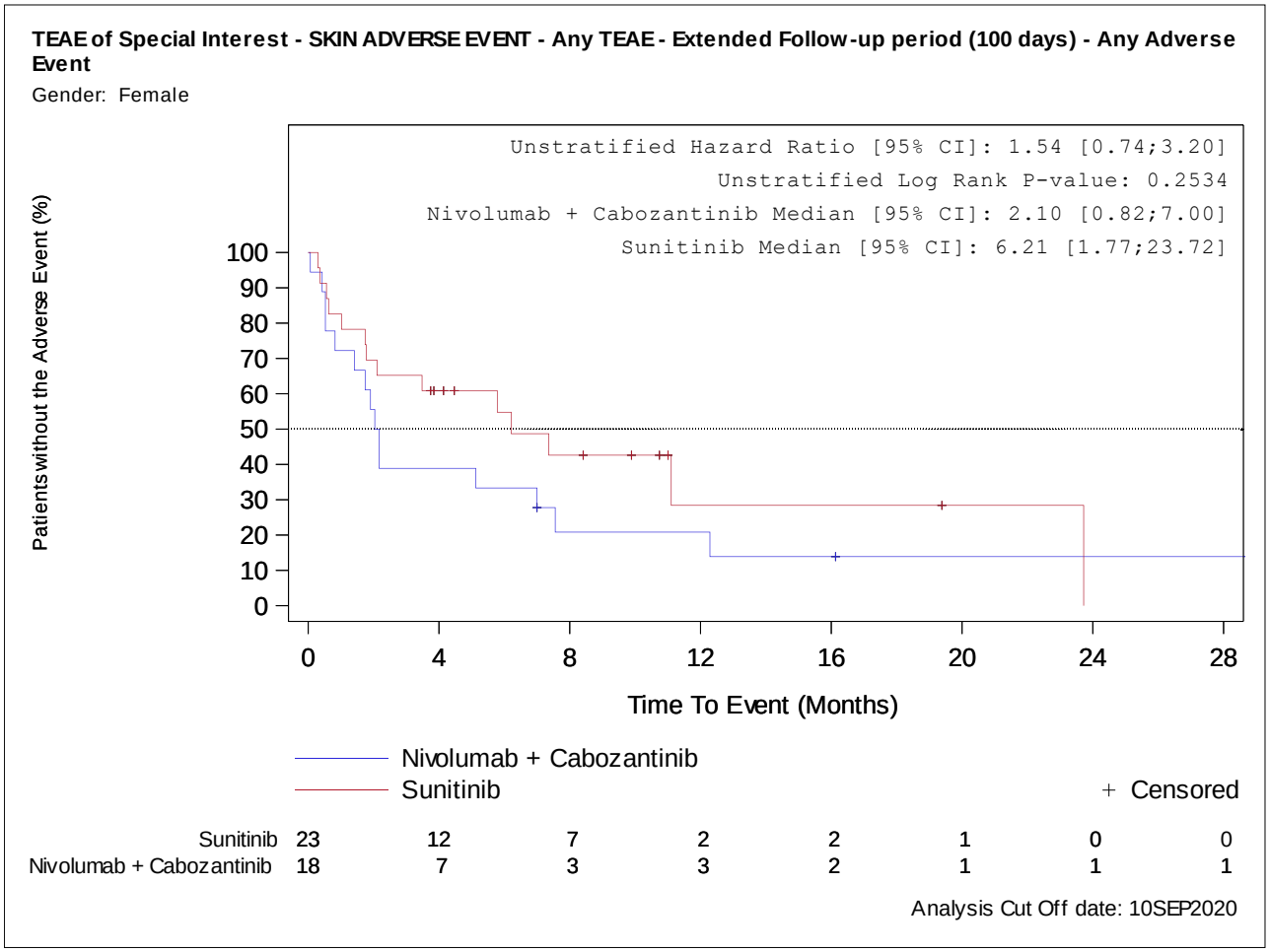

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:39:44

FIGURE 3.54.2.13: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



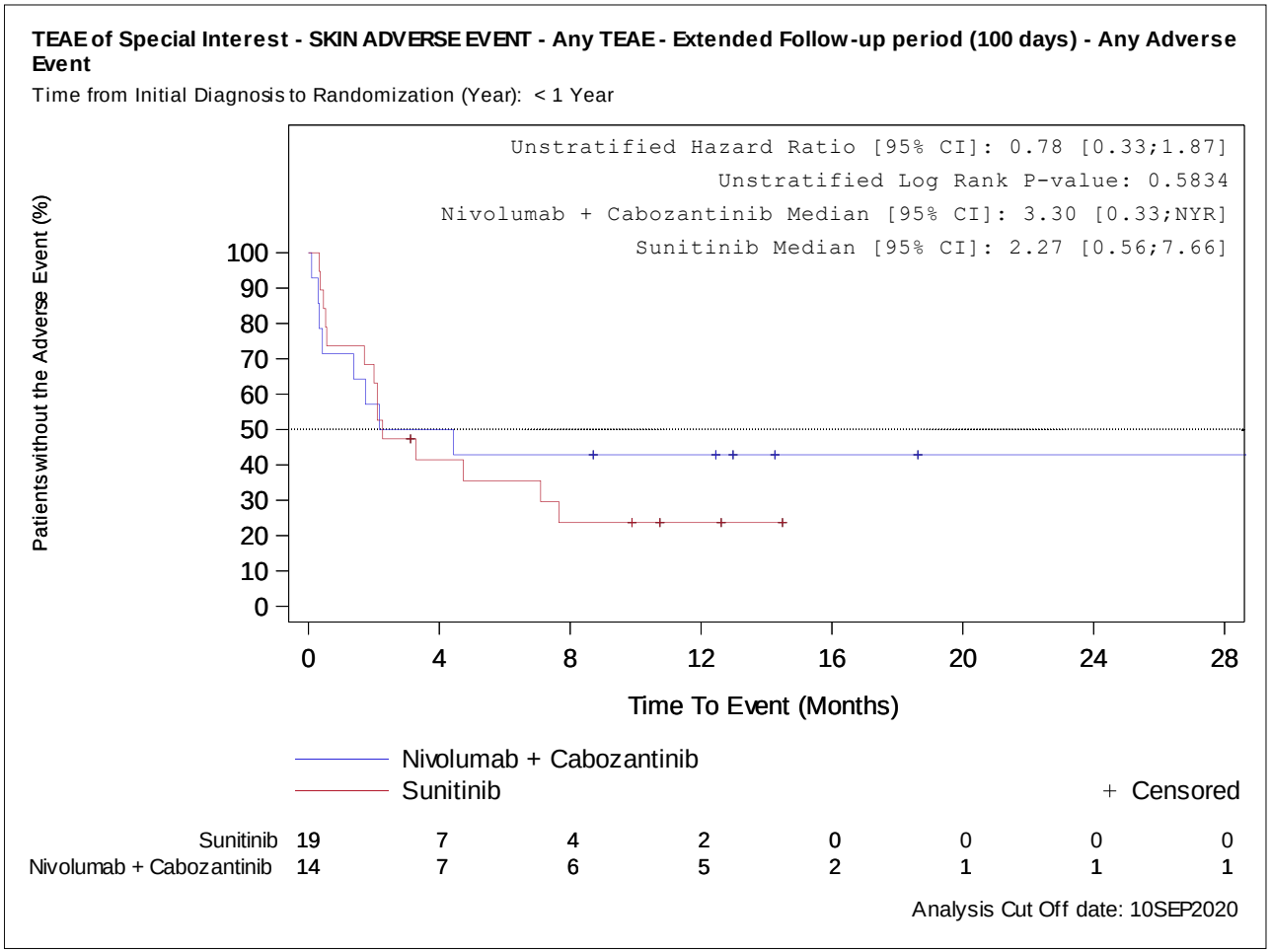

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:39:49

FIGURE 3.54.2.14: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



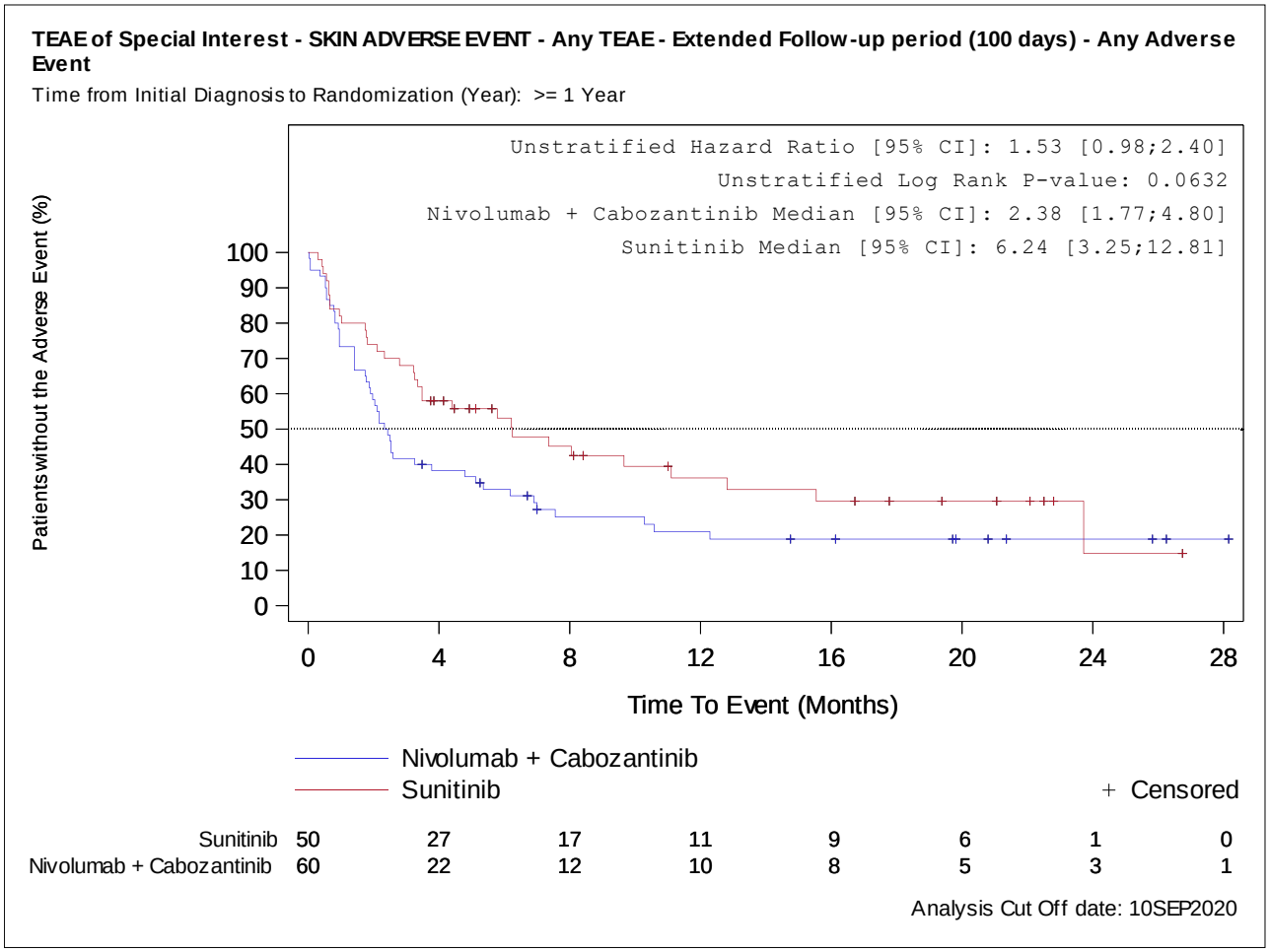

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:39:53

FIGURE 3.54.2.15: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



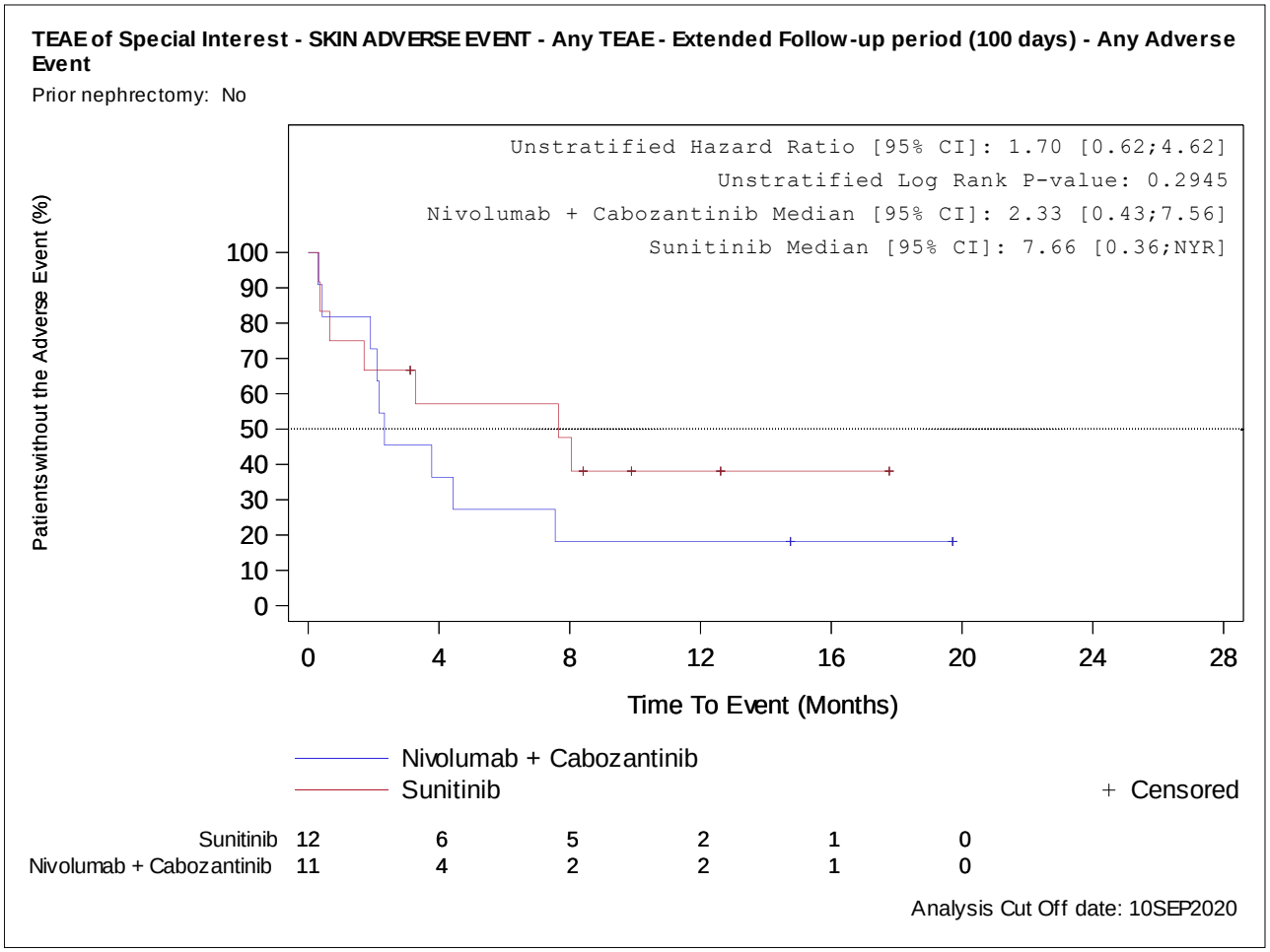

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:40:08

FIGURE 3.54.2.16: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



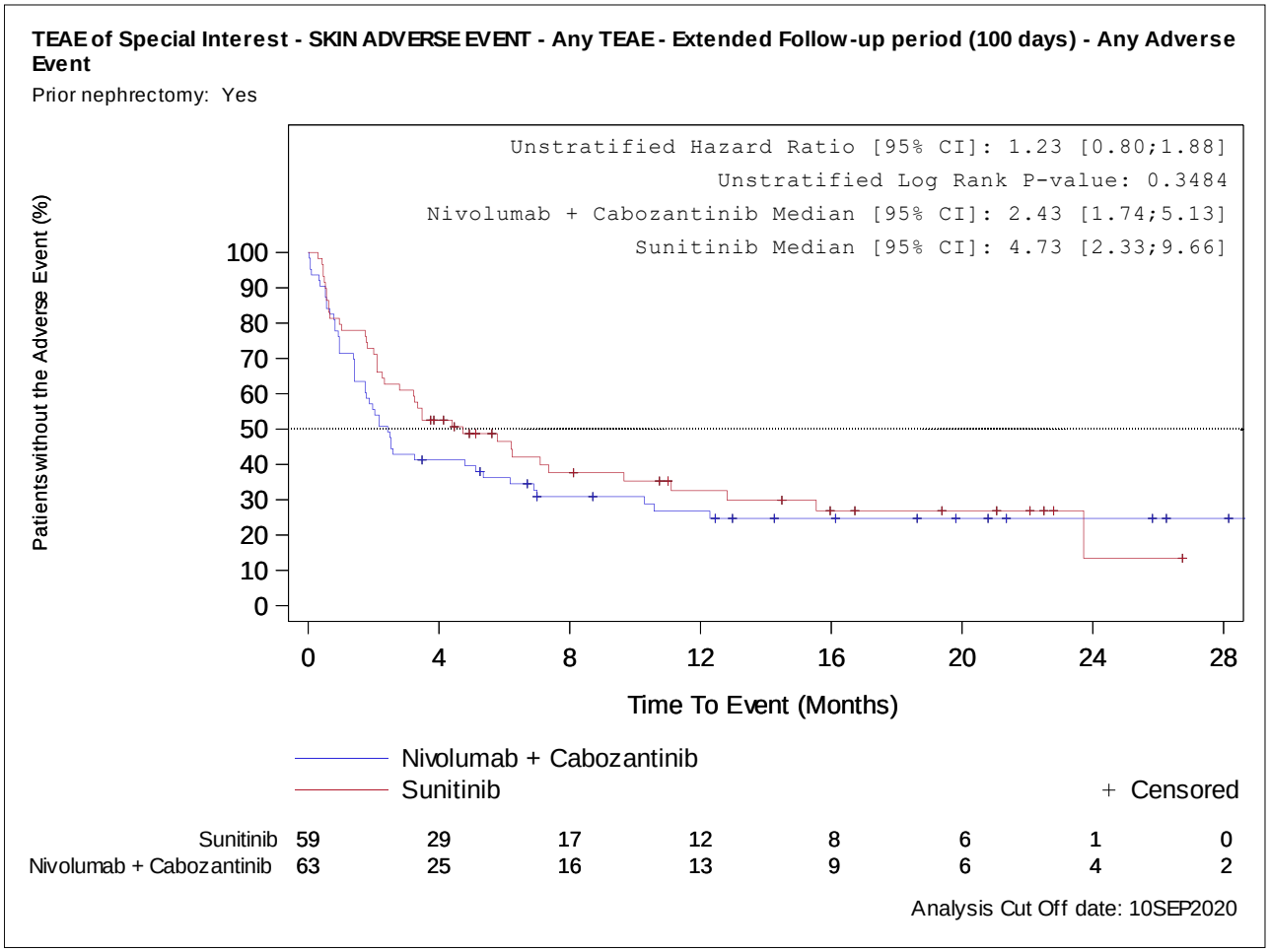

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:40:14

FIGURE 3.54.2.17: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



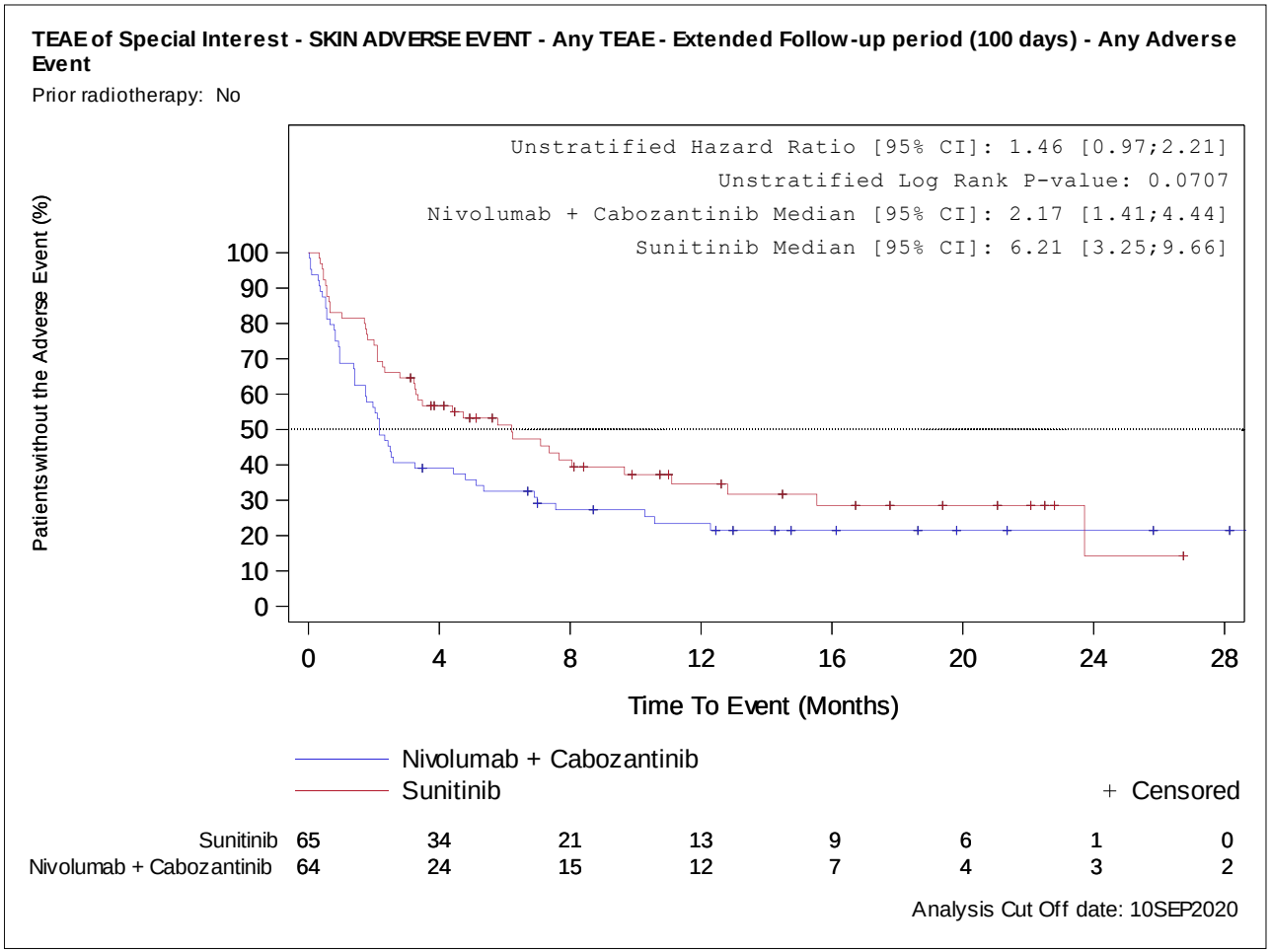

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:01

FIGURE 3.54.2.18: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



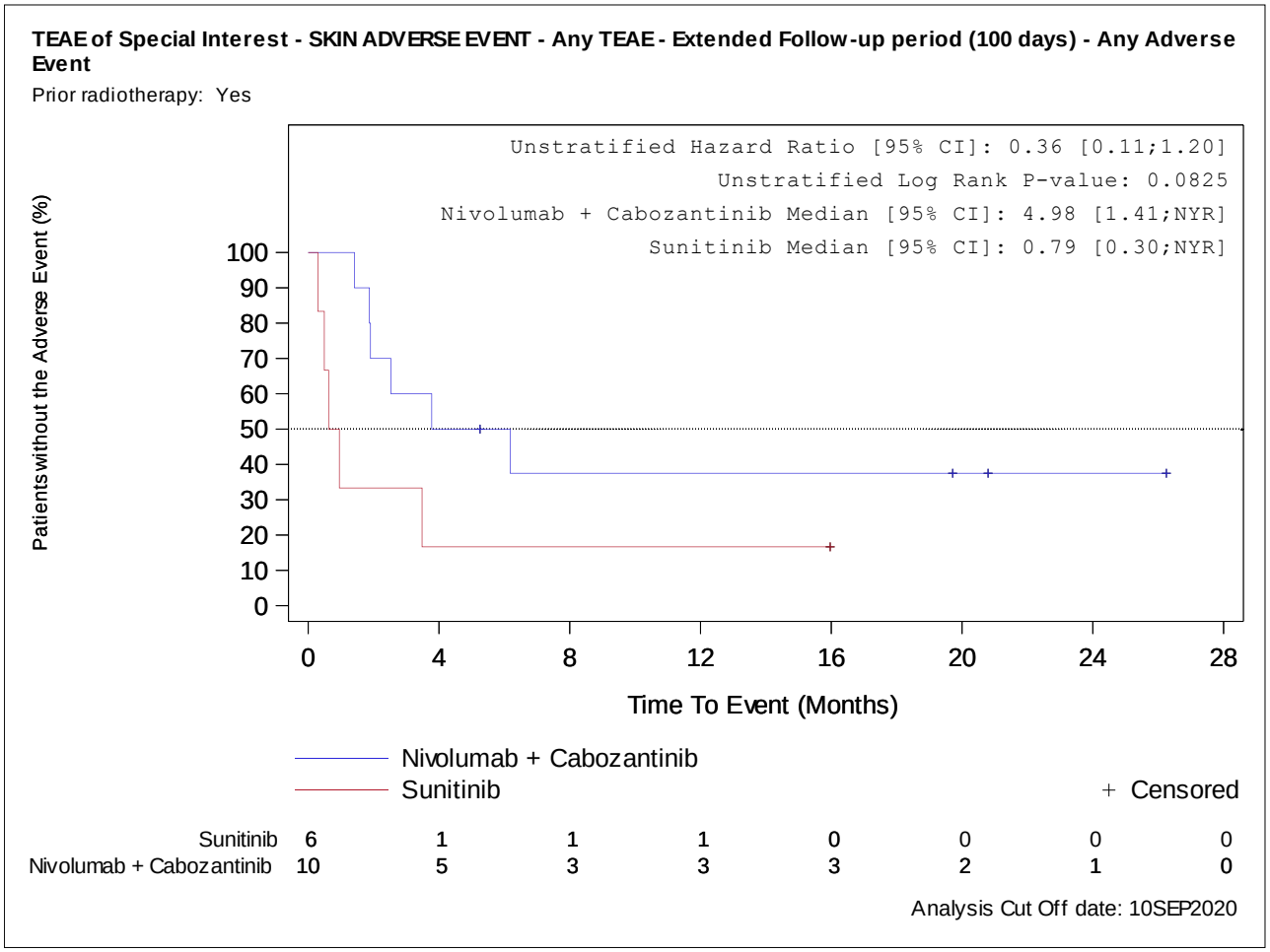

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:07

FIGURE 3.54.2.19: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



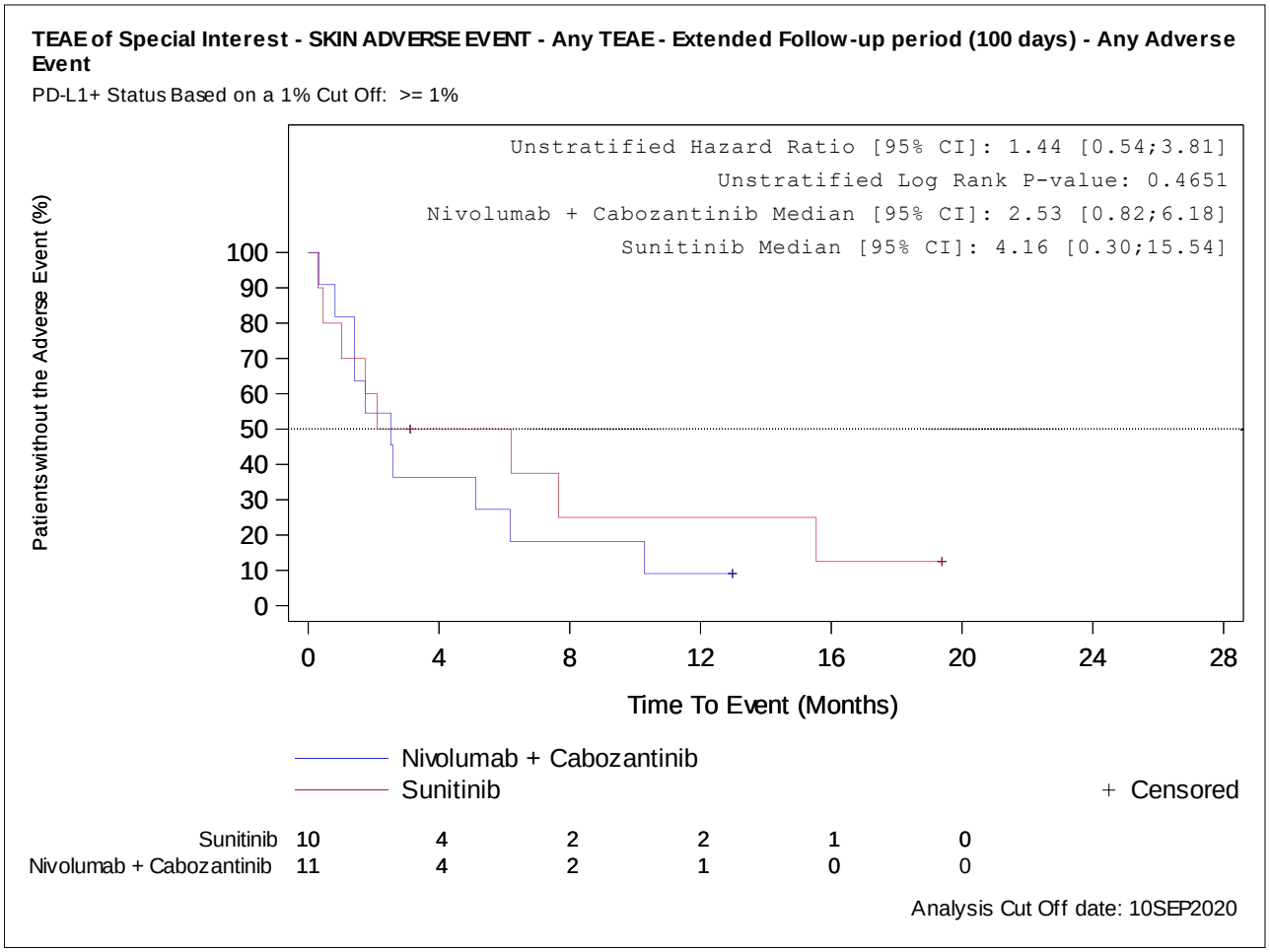

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:12

FIGURE 3.54.2.20: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



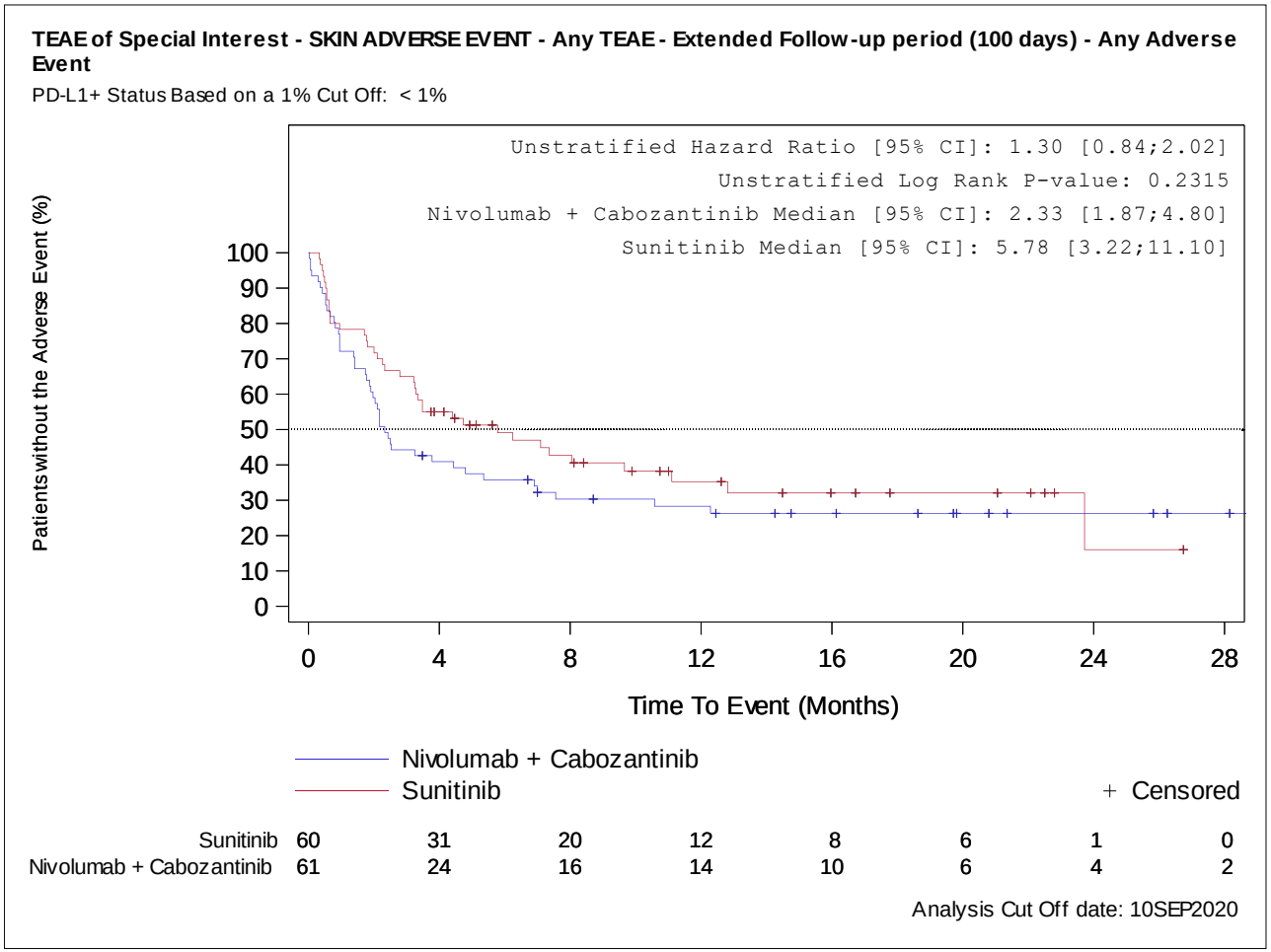

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:17

FIGURE 3.54.2.21: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



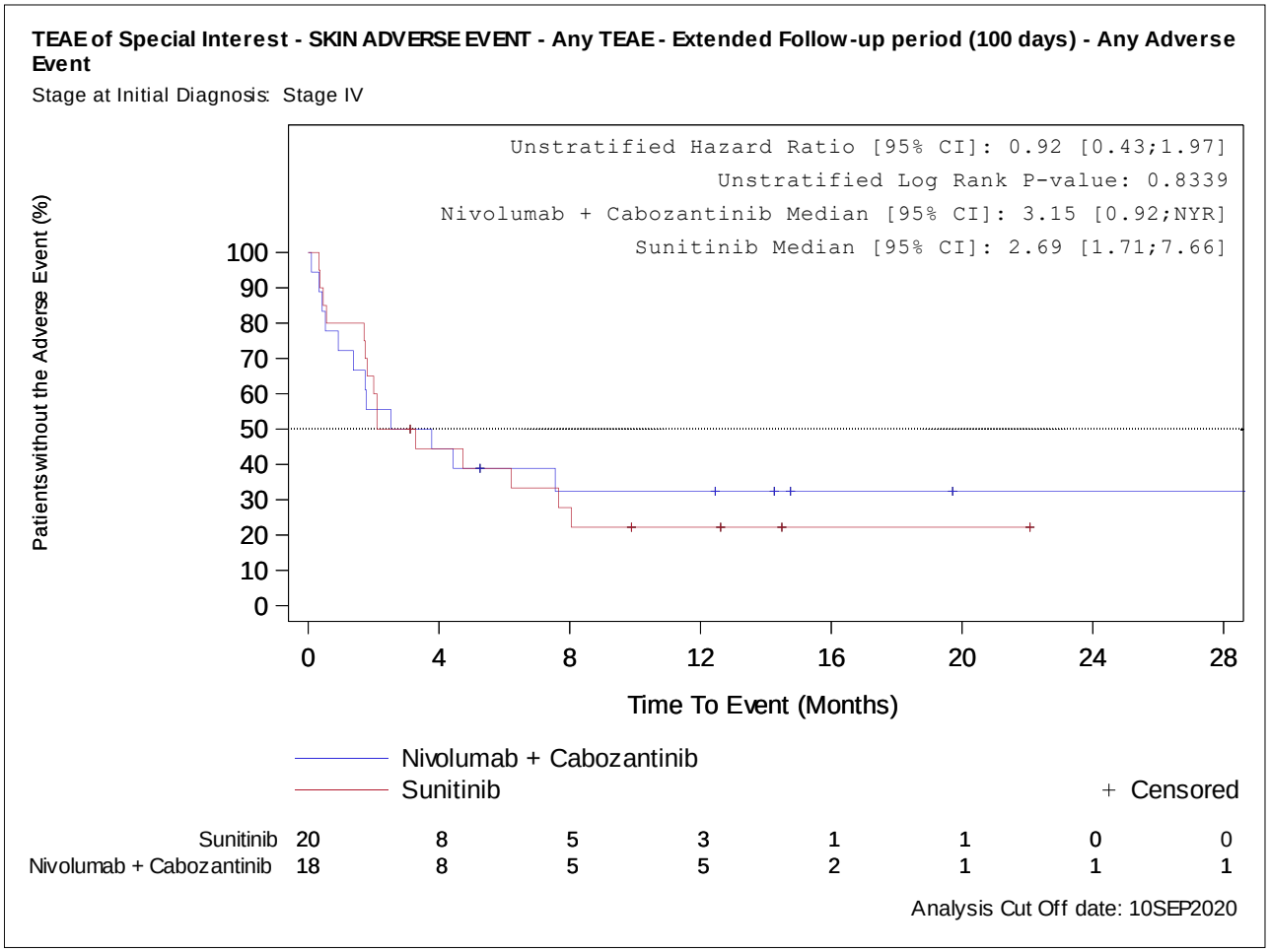

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:22

FIGURE 3.54.2.22: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



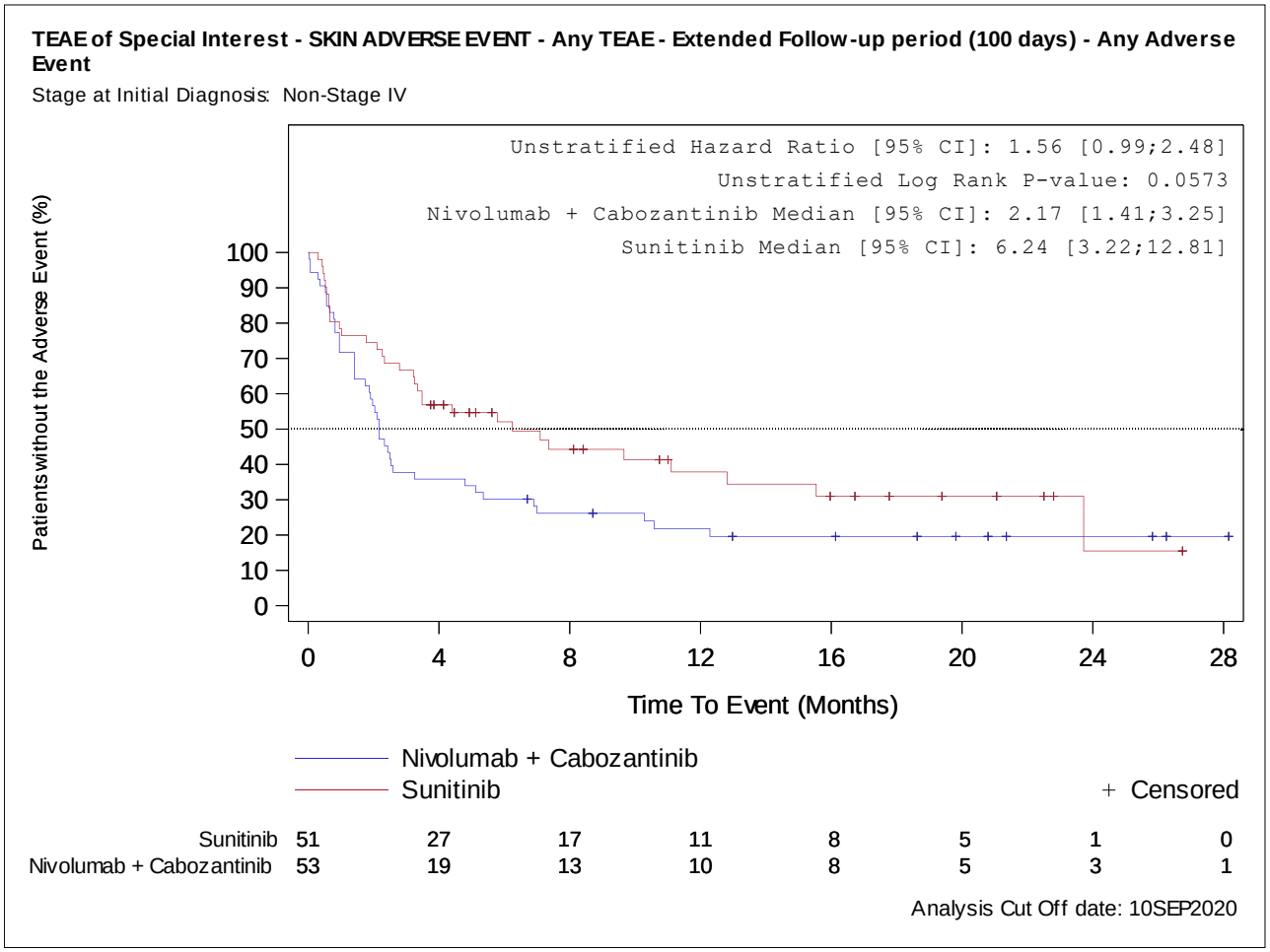

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:28

FIGURE 3.54.2.23: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



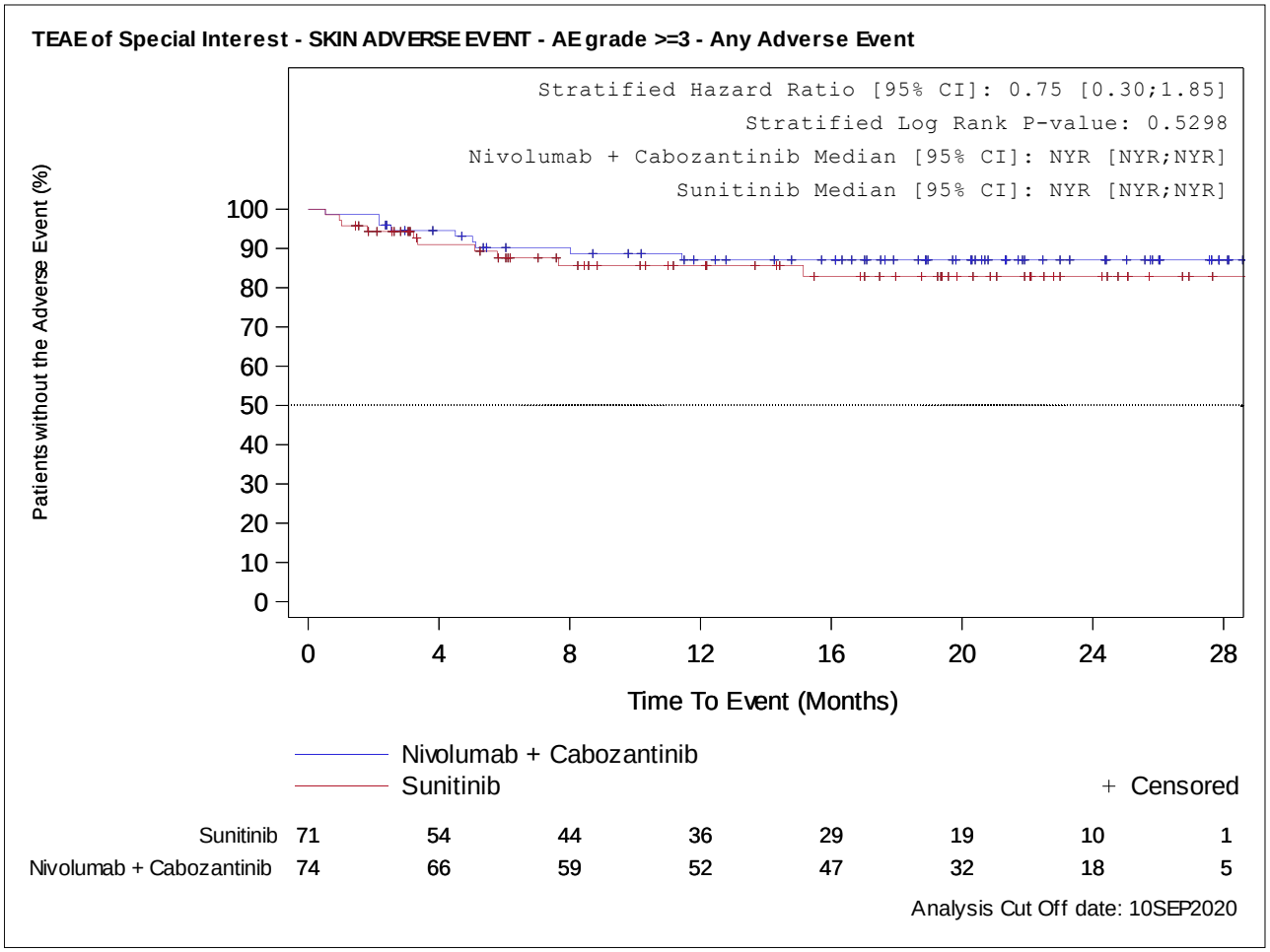

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:54

FIGURE 3.54.2.24: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



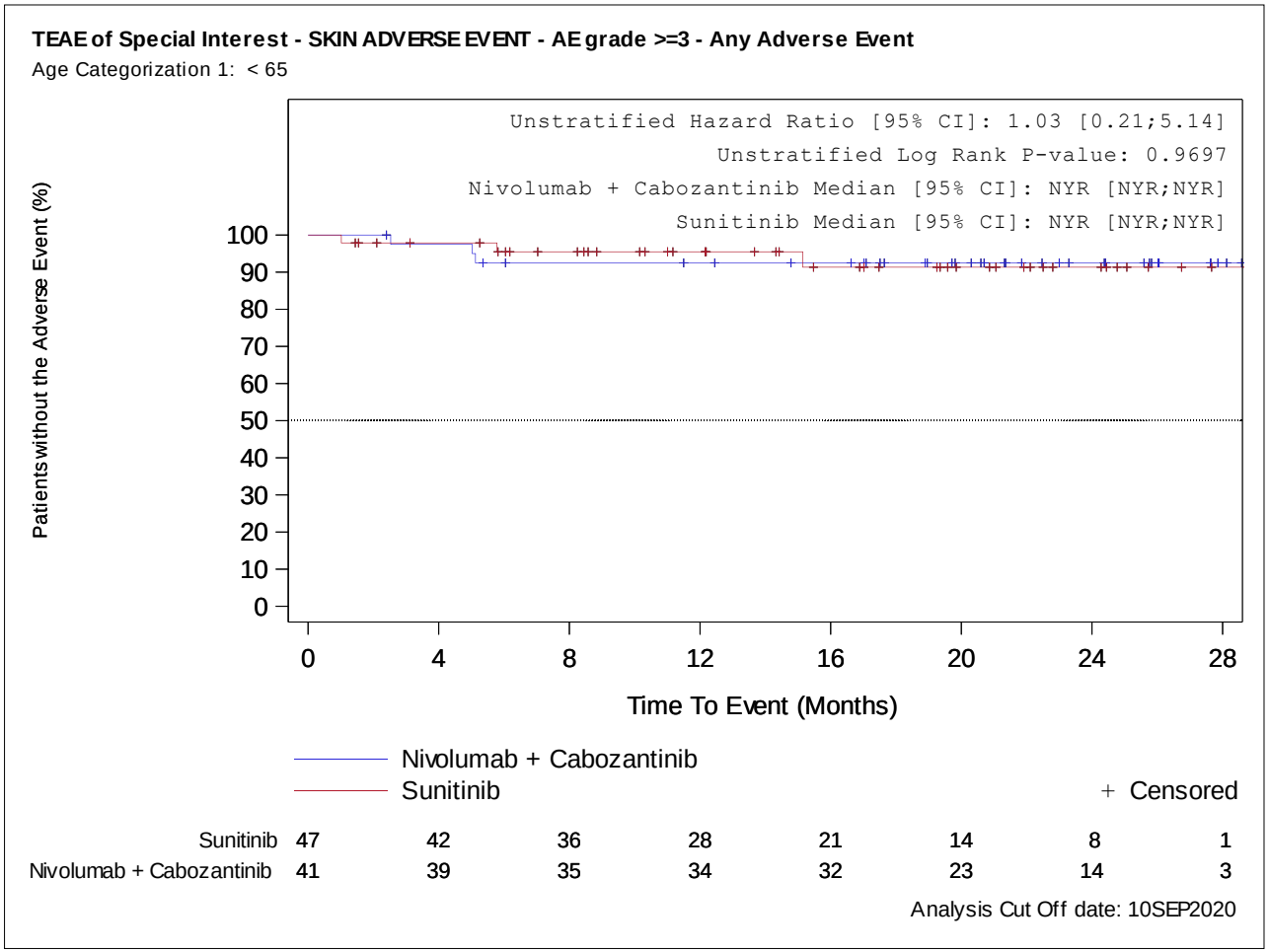

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:59

FIGURE 3.55.1: TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



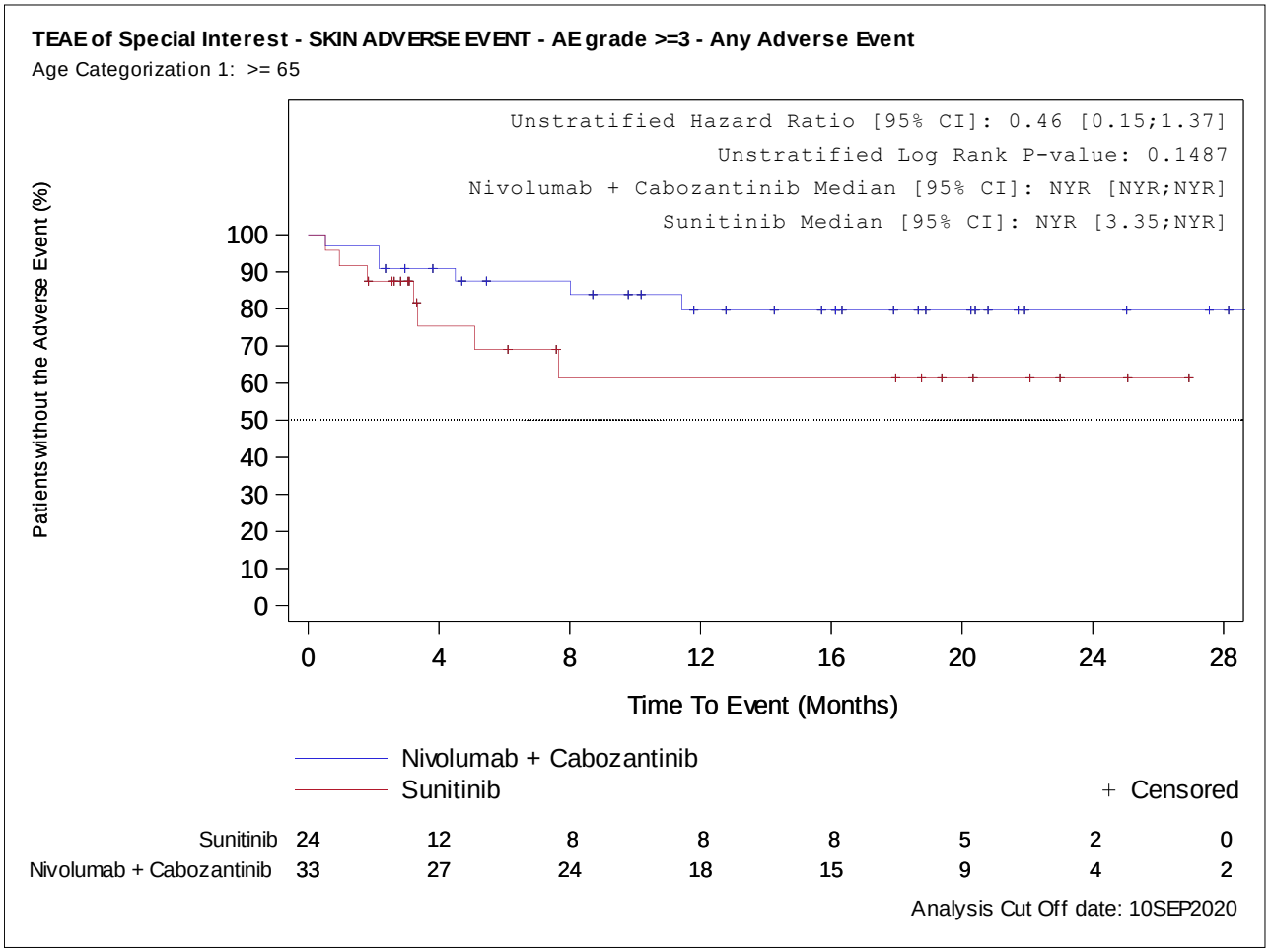

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:44:57

FIGURE 3.55.2.1: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



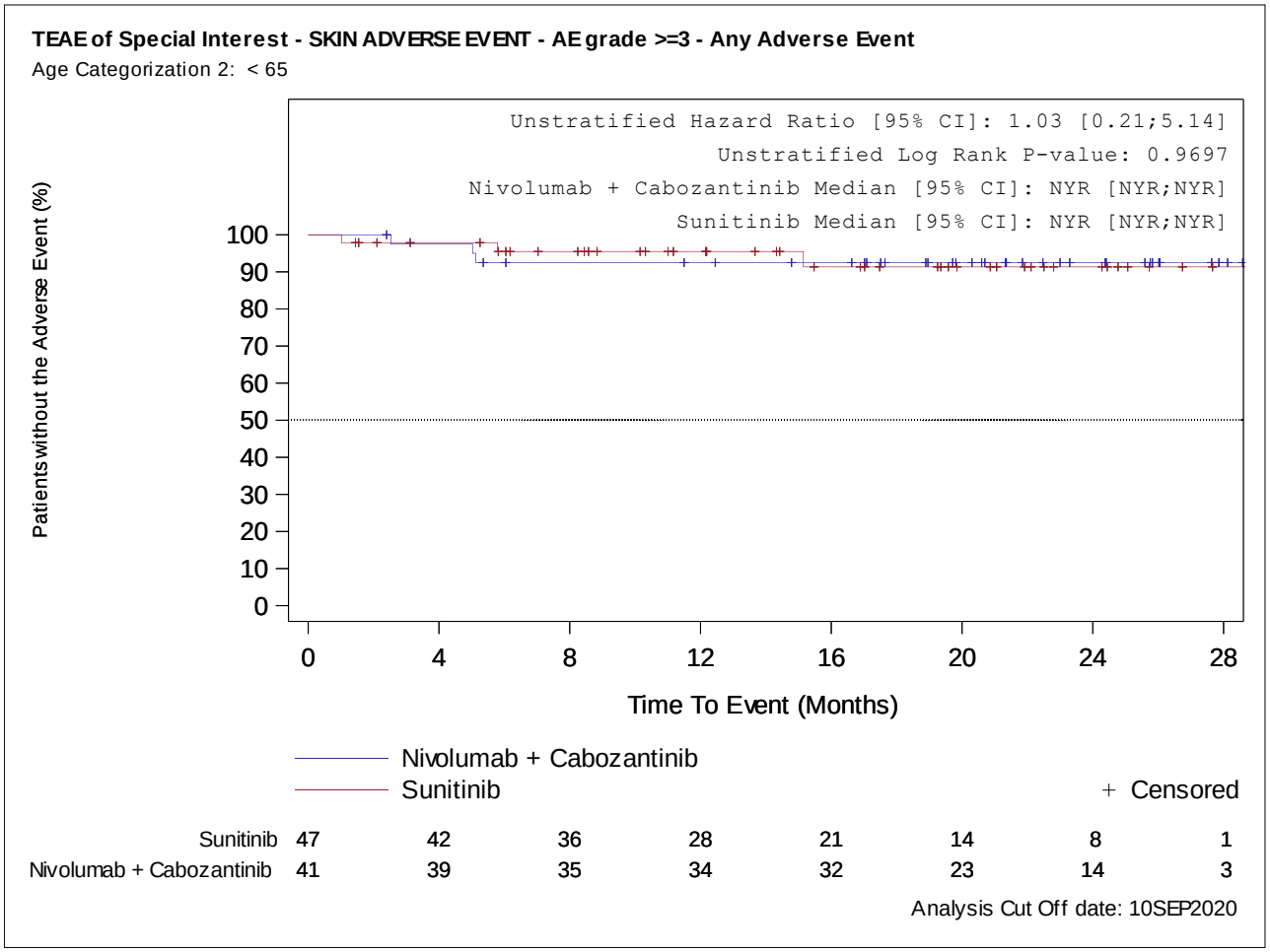

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:45:00

FIGURE 3.55.2.2: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



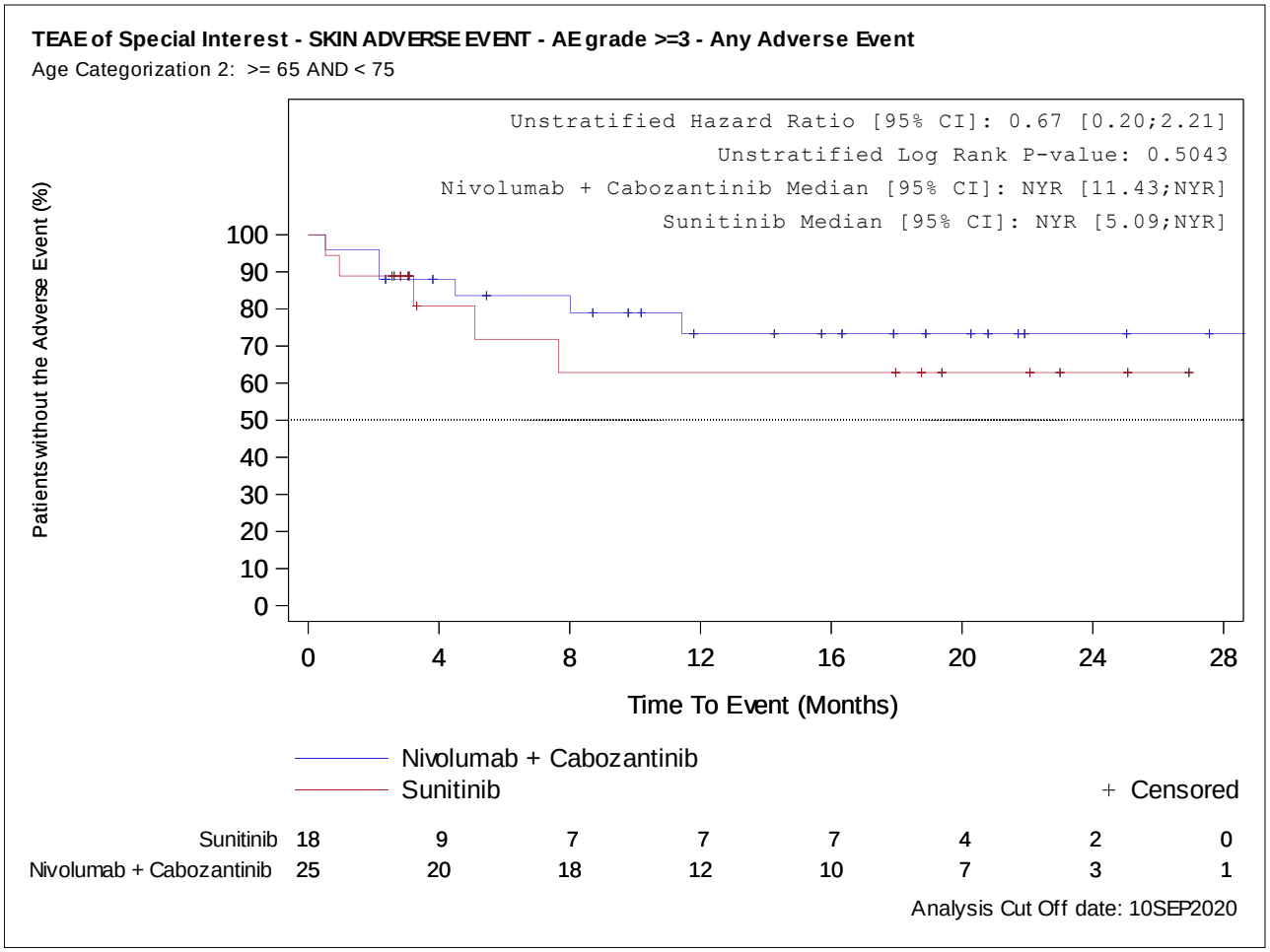

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:45:06

FIGURE 3.55.2.3: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



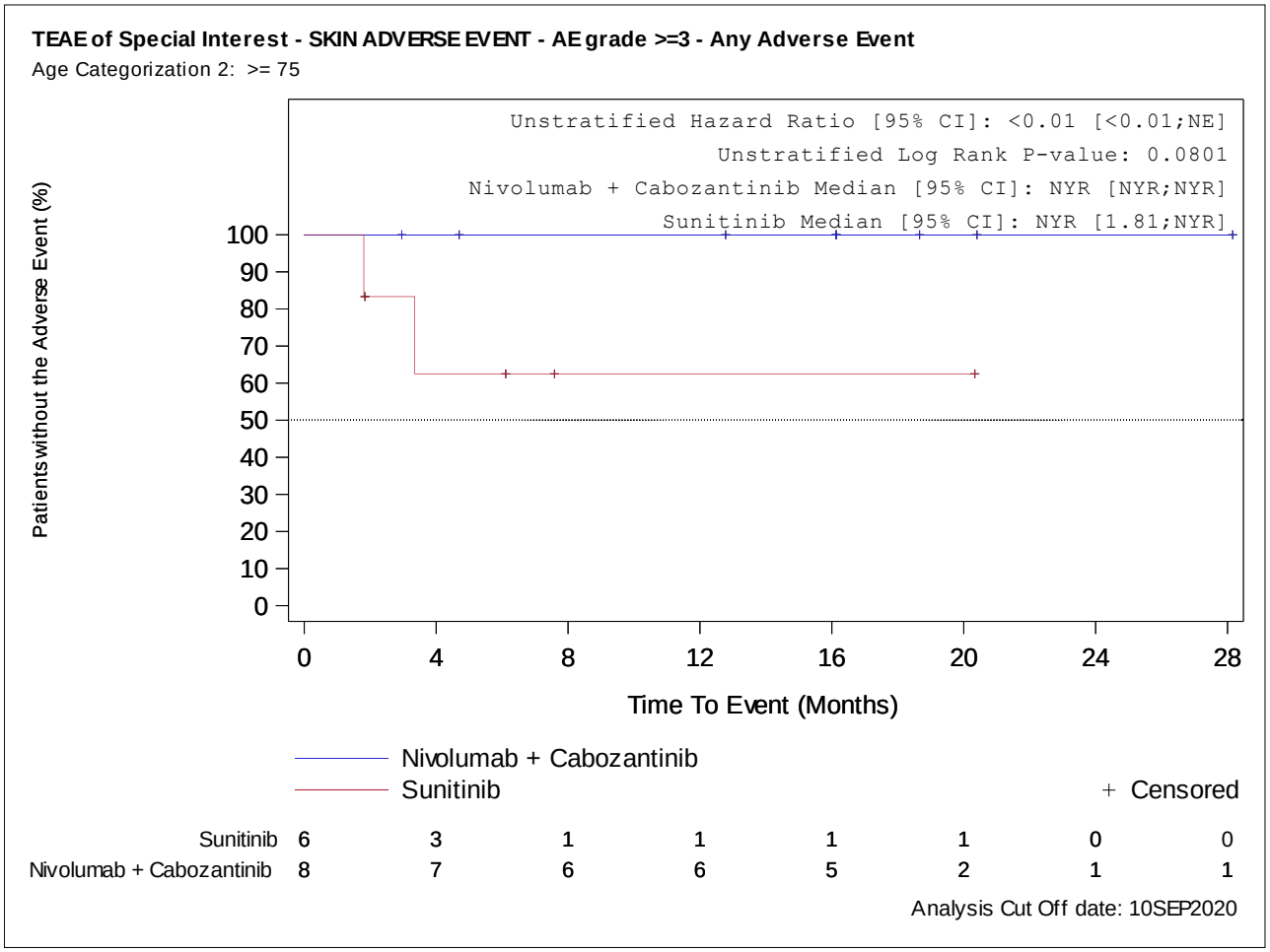

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:45:11

FIGURE 3.55.2.4: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



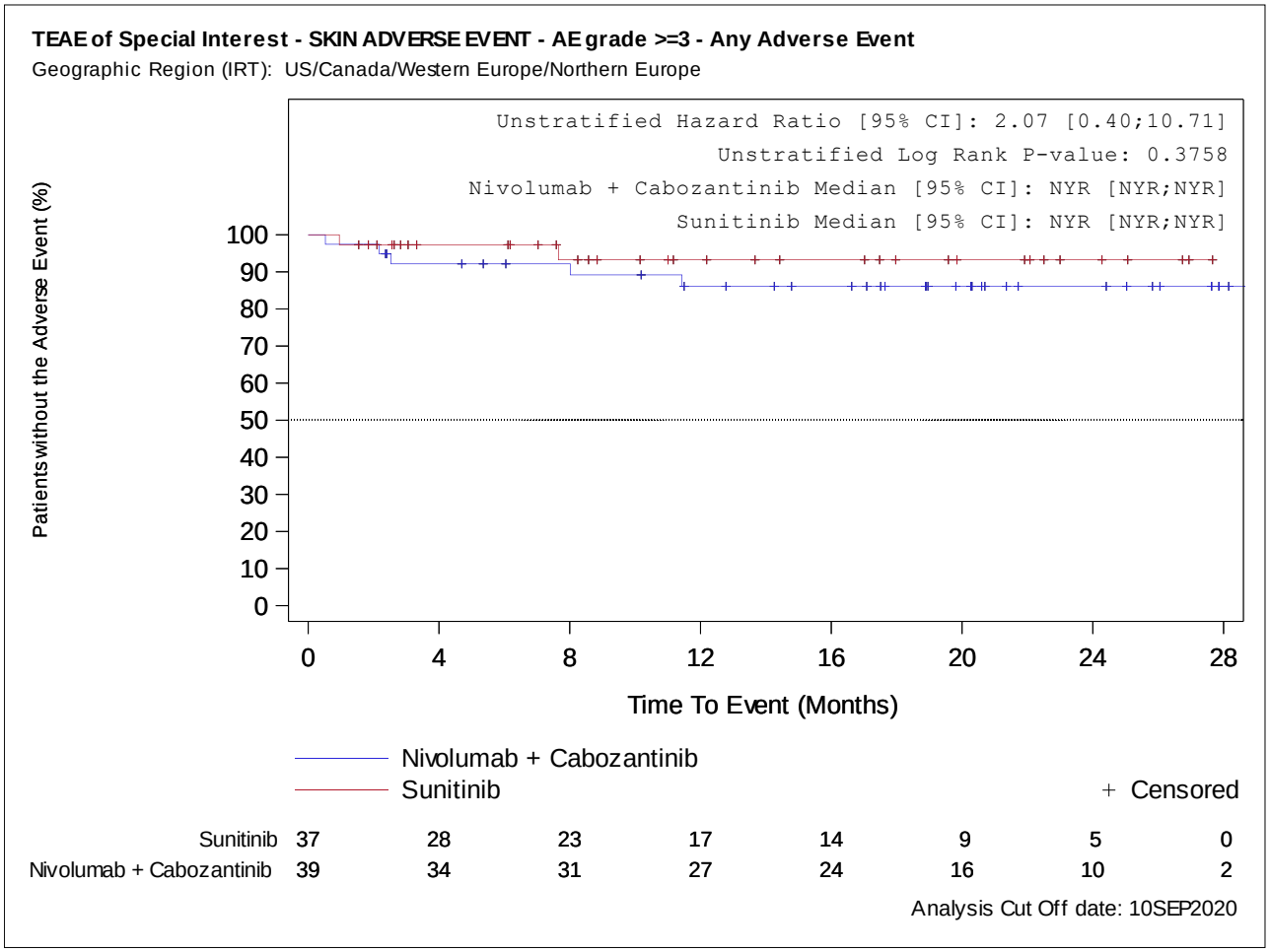

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:45:16

FIGURE 3.55.2.5: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



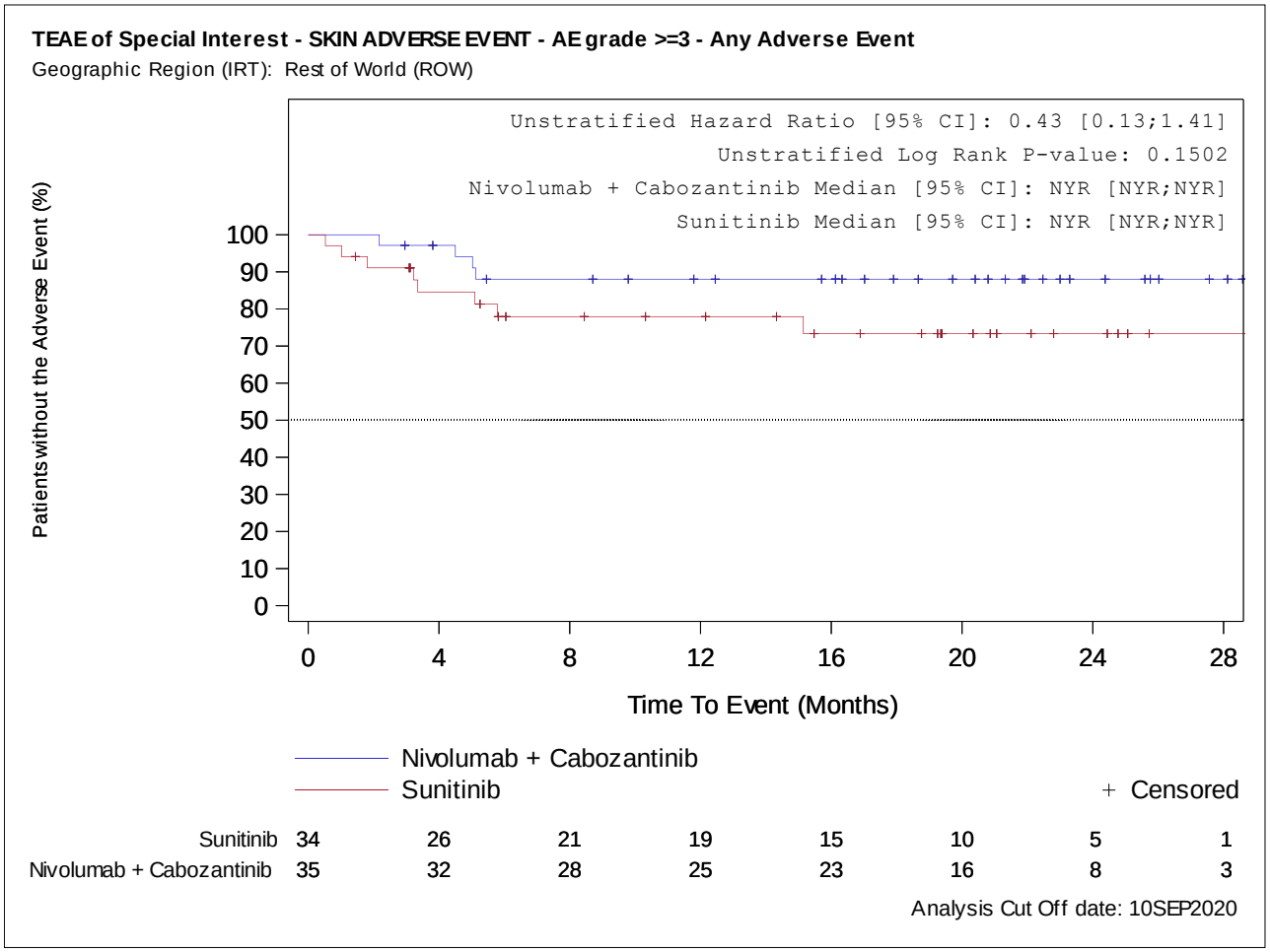

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:45:21

FIGURE 3.55.2.6: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



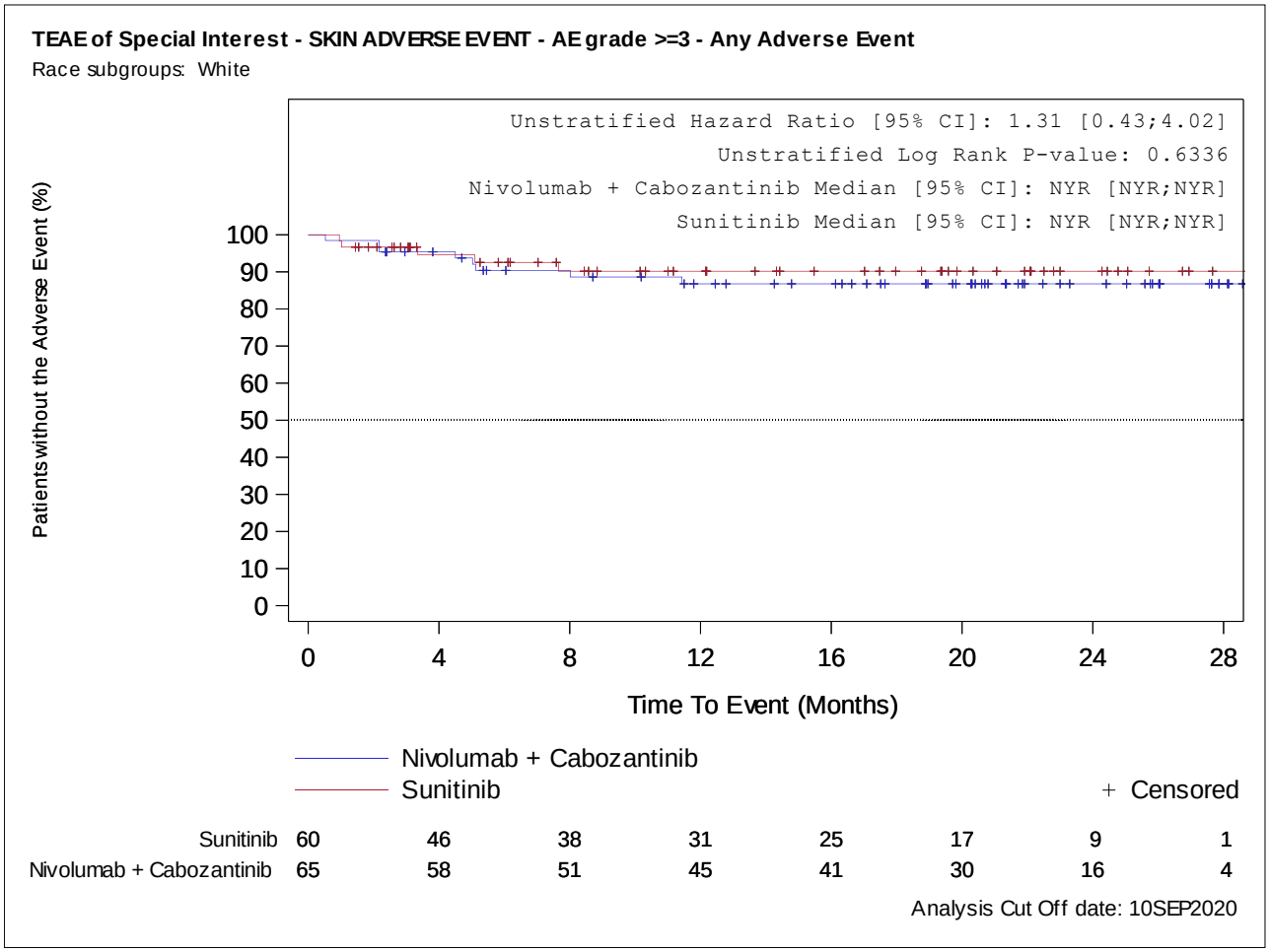

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:45:26

FIGURE 3.55.2.7: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



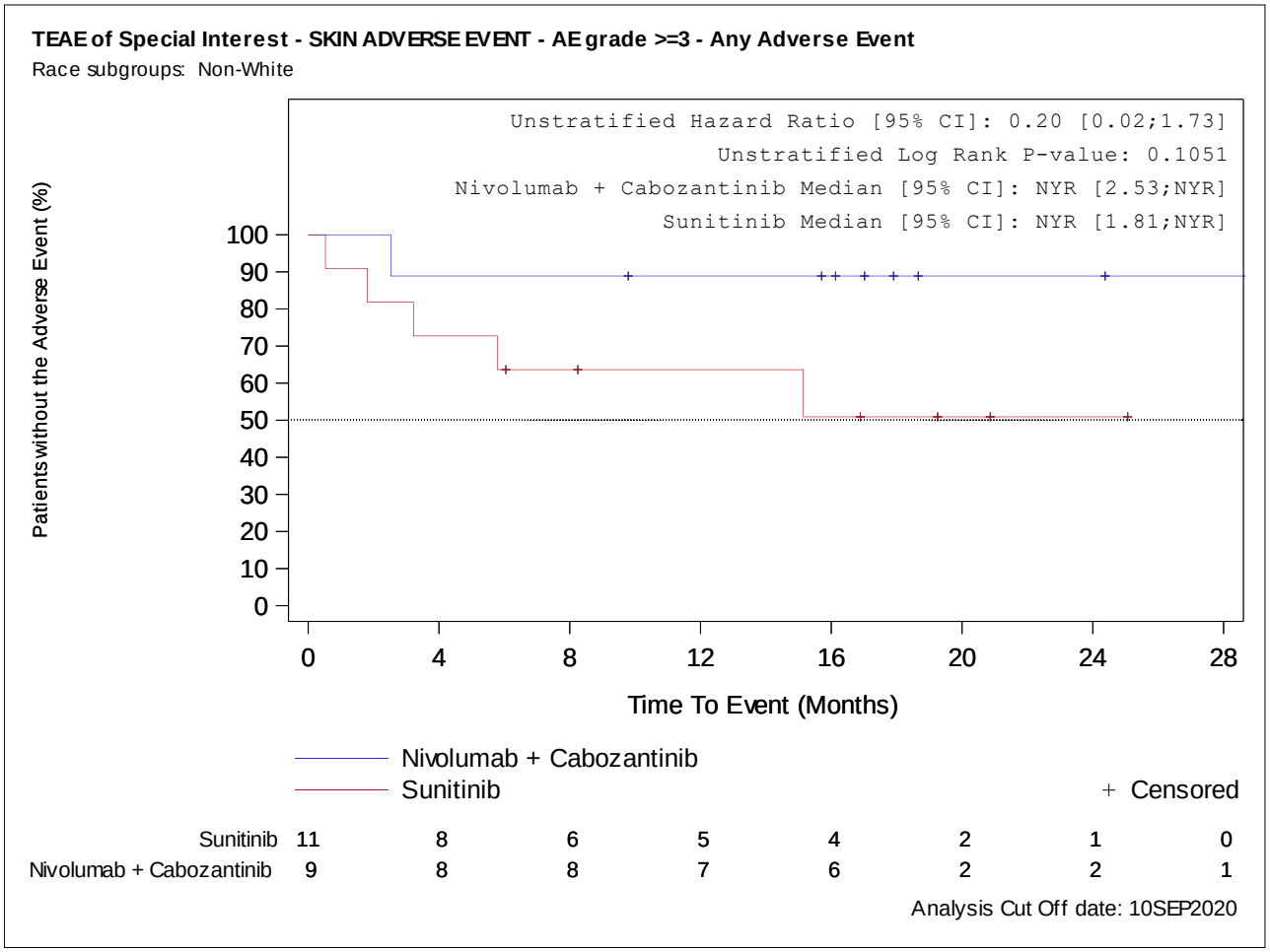

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:45:31

FIGURE 3.55.2.8: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



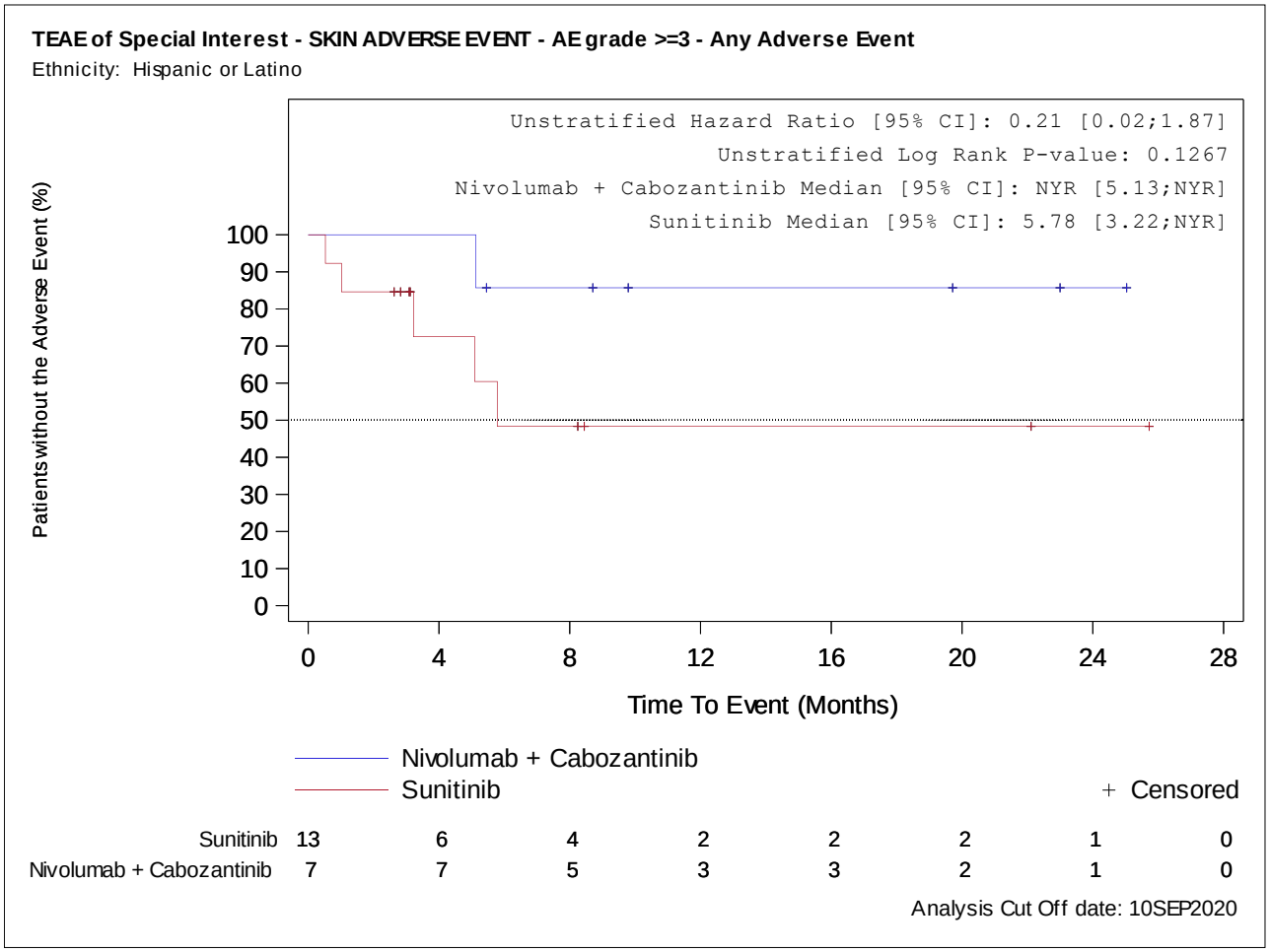

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:45:36

FIGURE 3.55.2.9: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



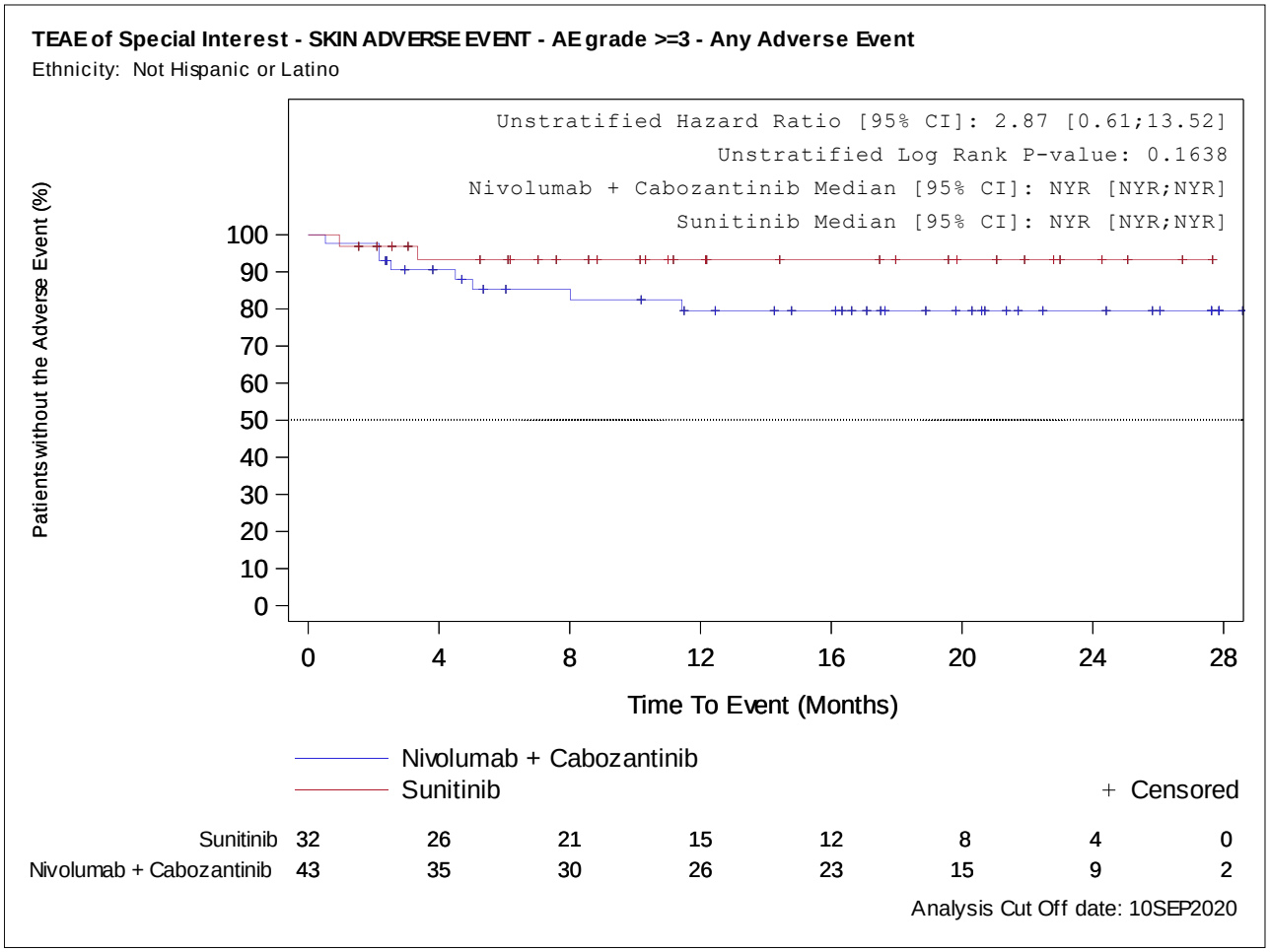

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:45:41

FIGURE 3.55.2.10: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



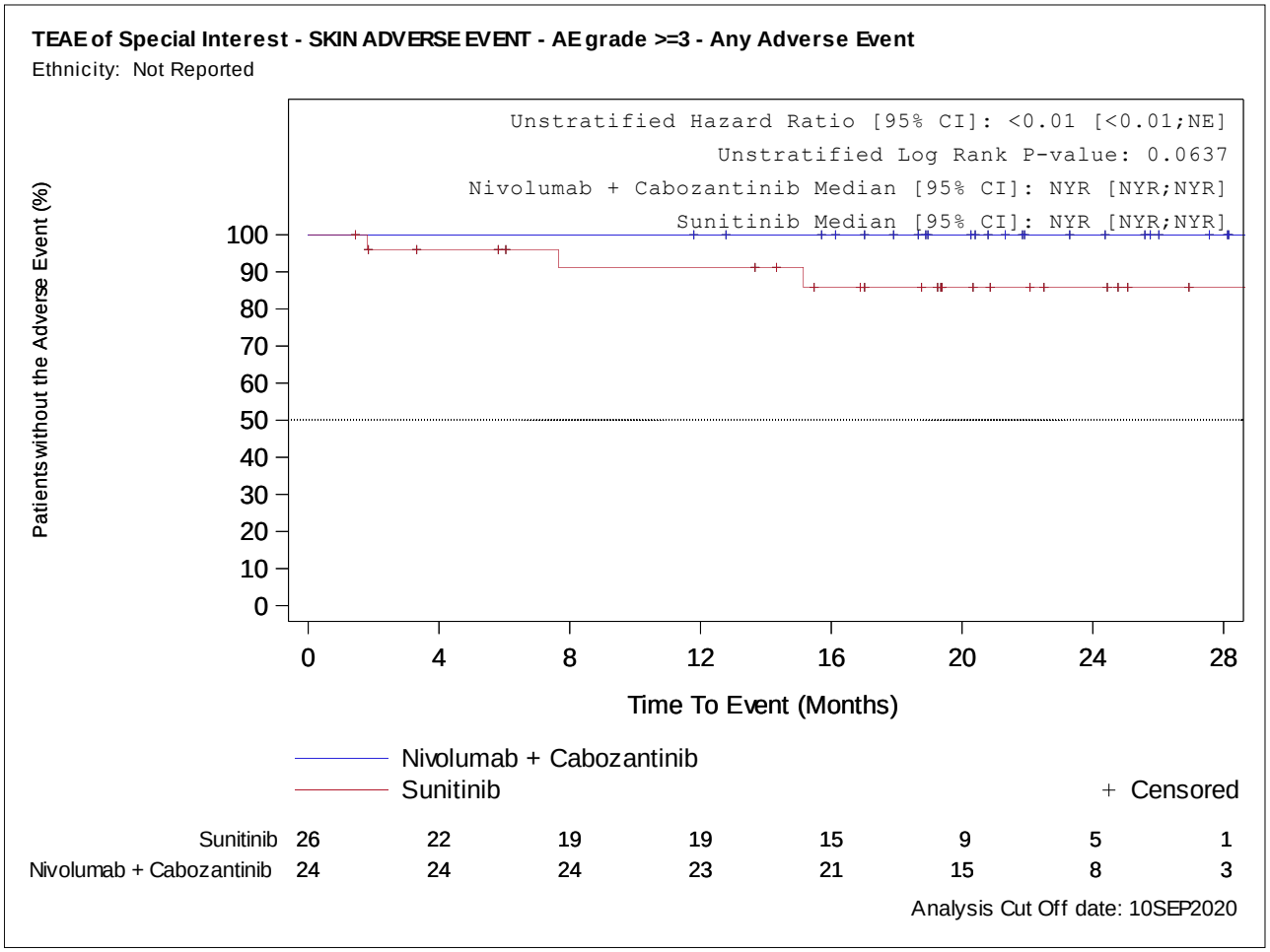

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:45:46

FIGURE 3.55.2.11: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



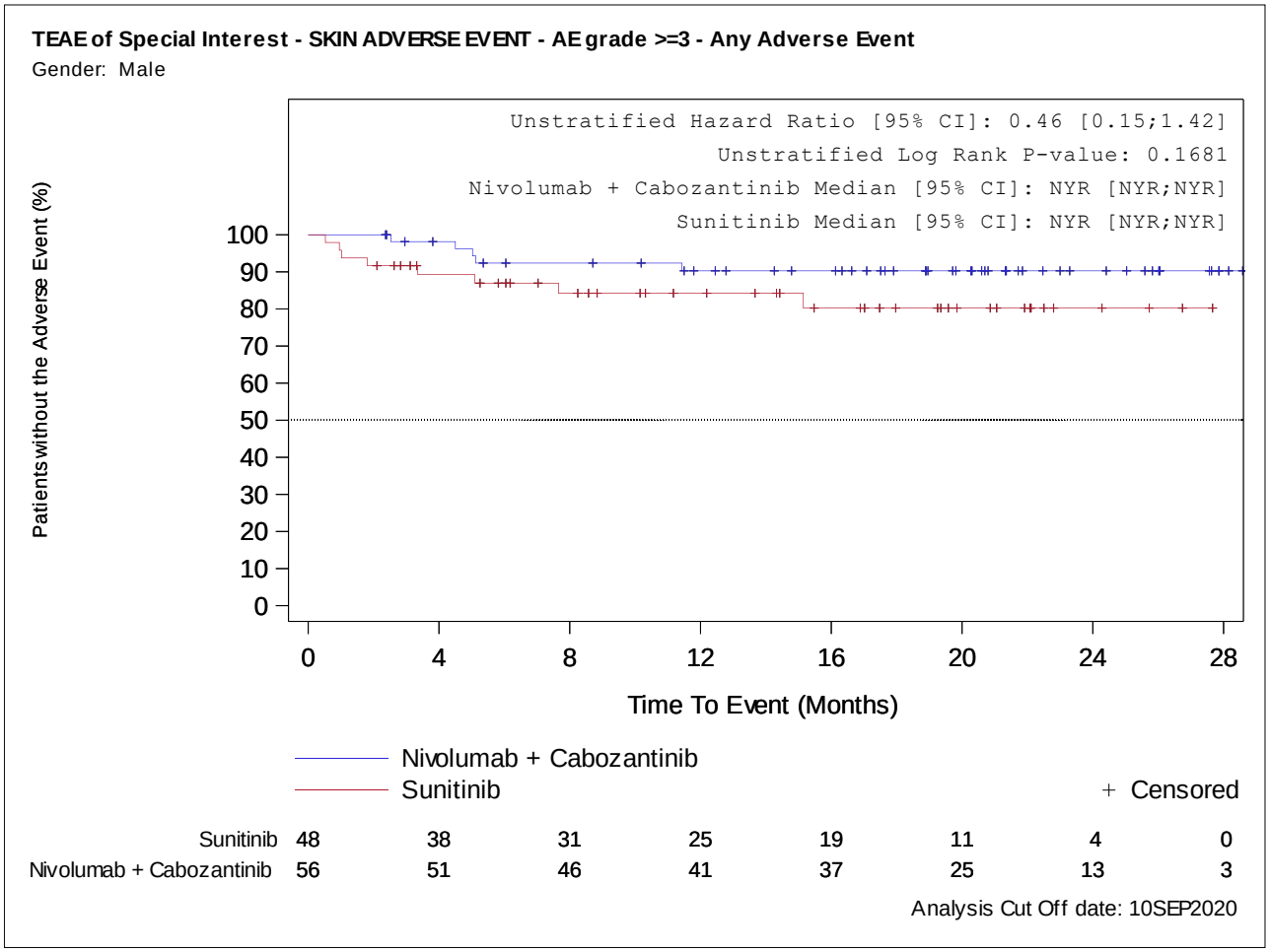

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:45:52

FIGURE 3.55.2.12: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



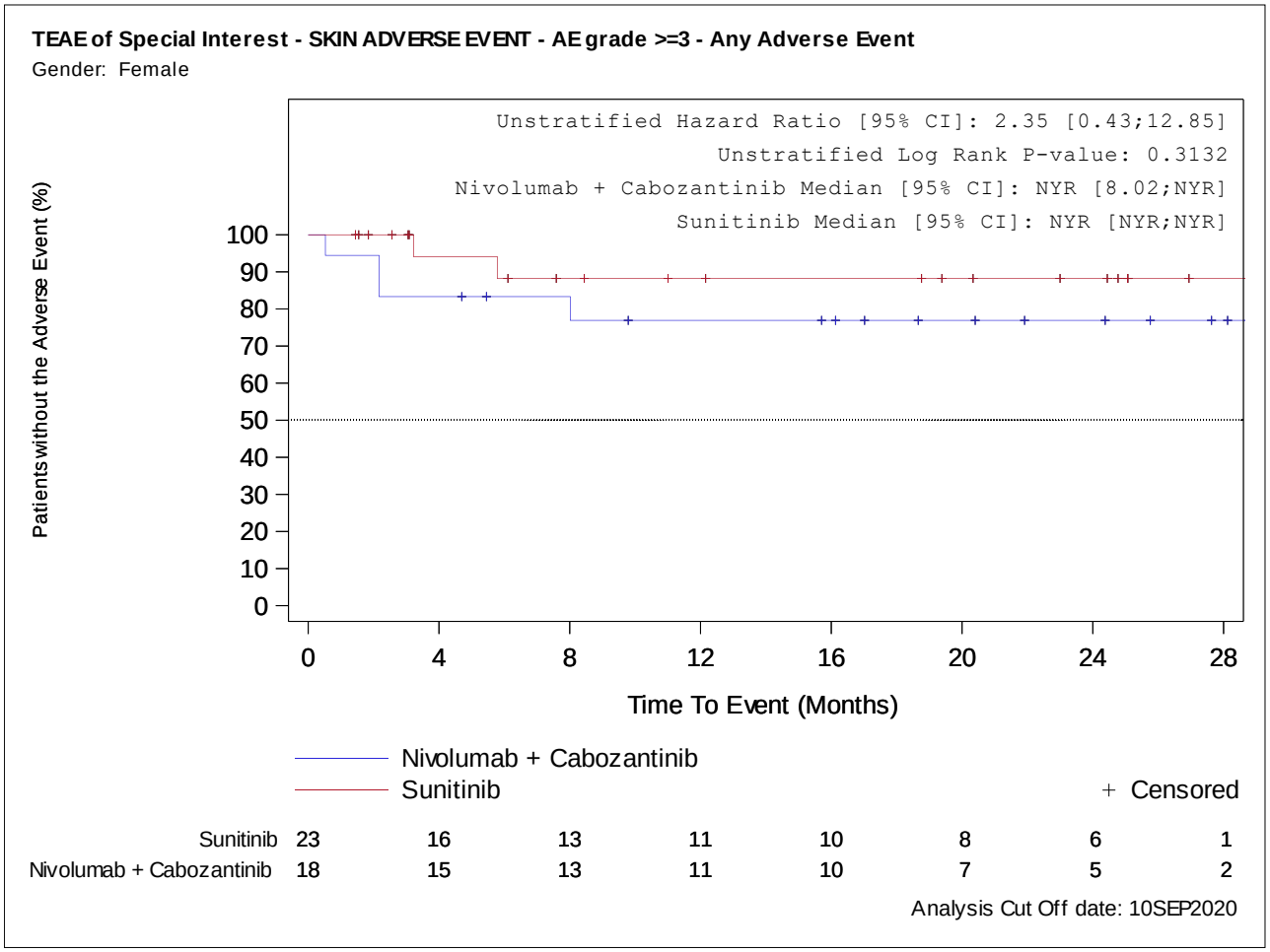

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:45:57

FIGURE 3.55.2.13: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



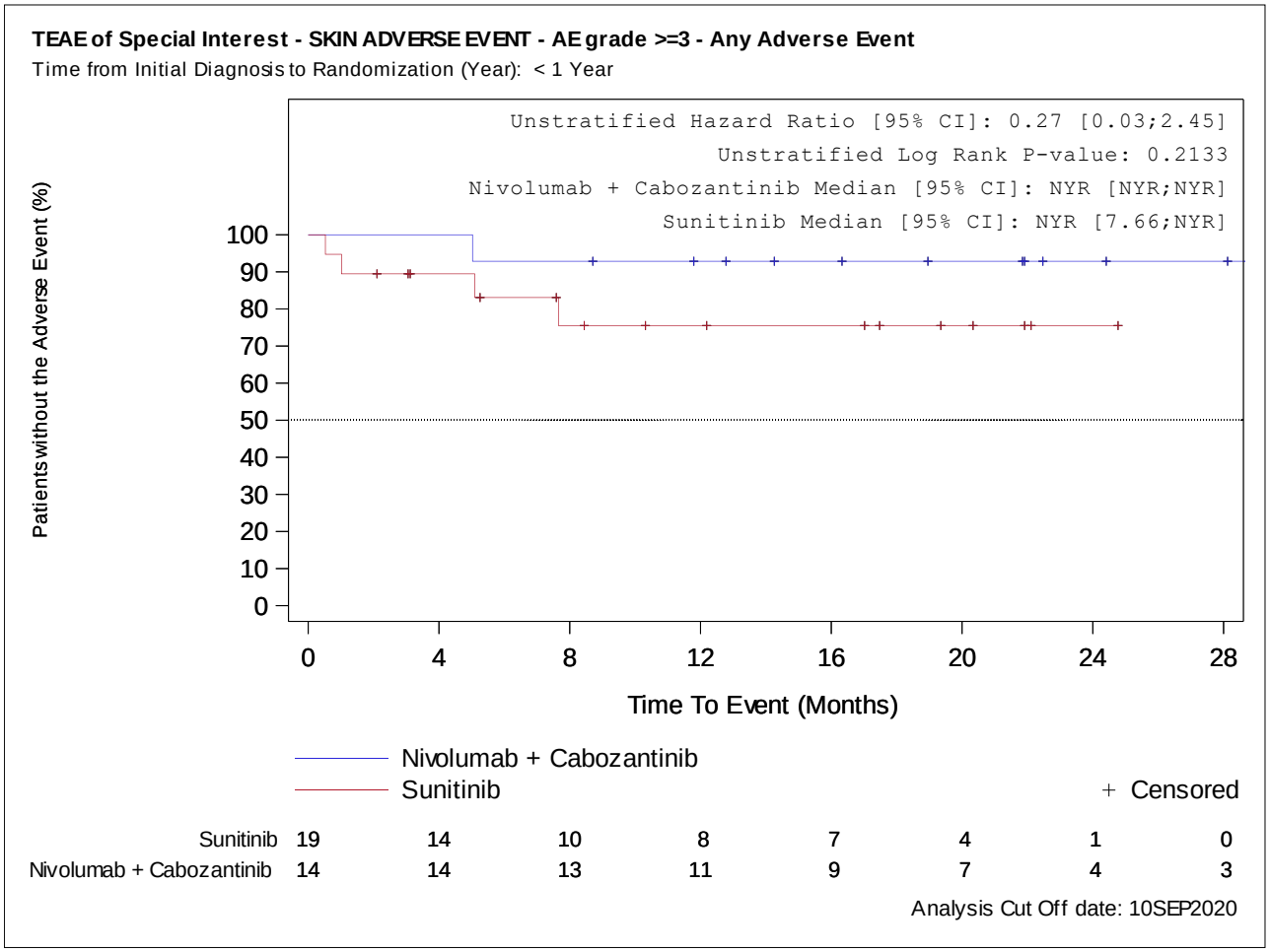

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:46:03

FIGURE 3.55.2.14: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



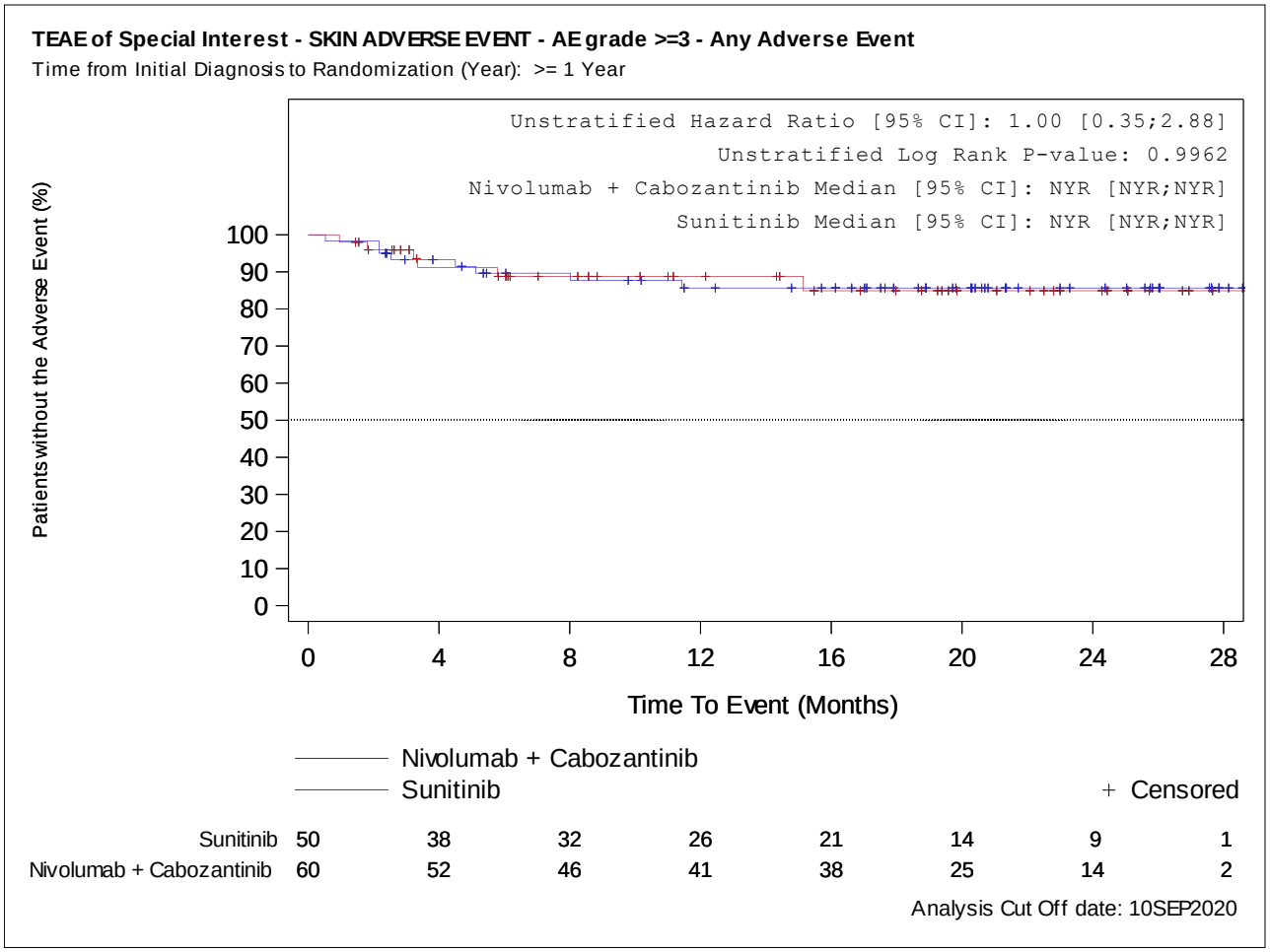

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:46:08

FIGURE 3.55.2.15: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



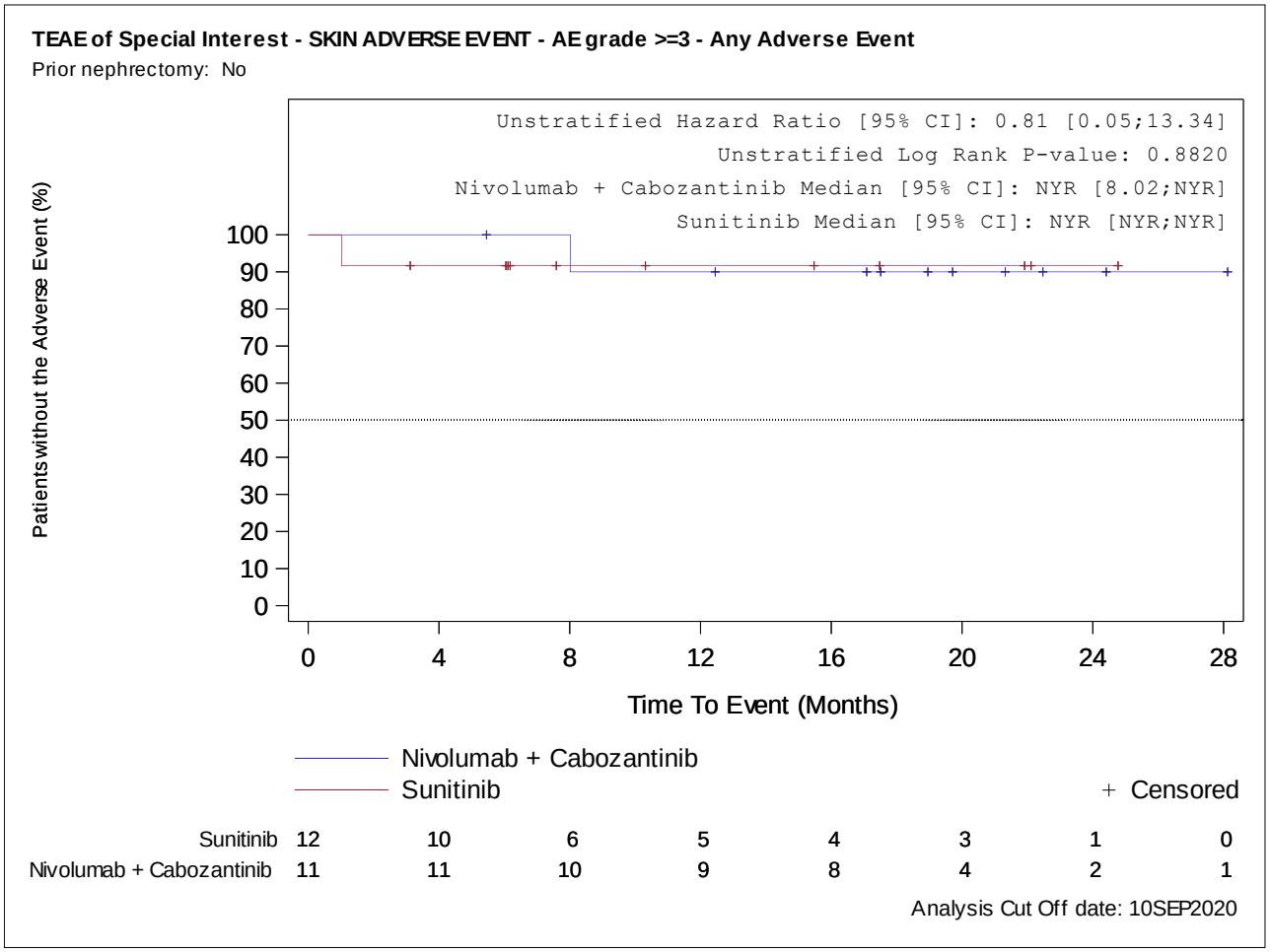

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:46:23

FIGURE 3.55.2.16: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



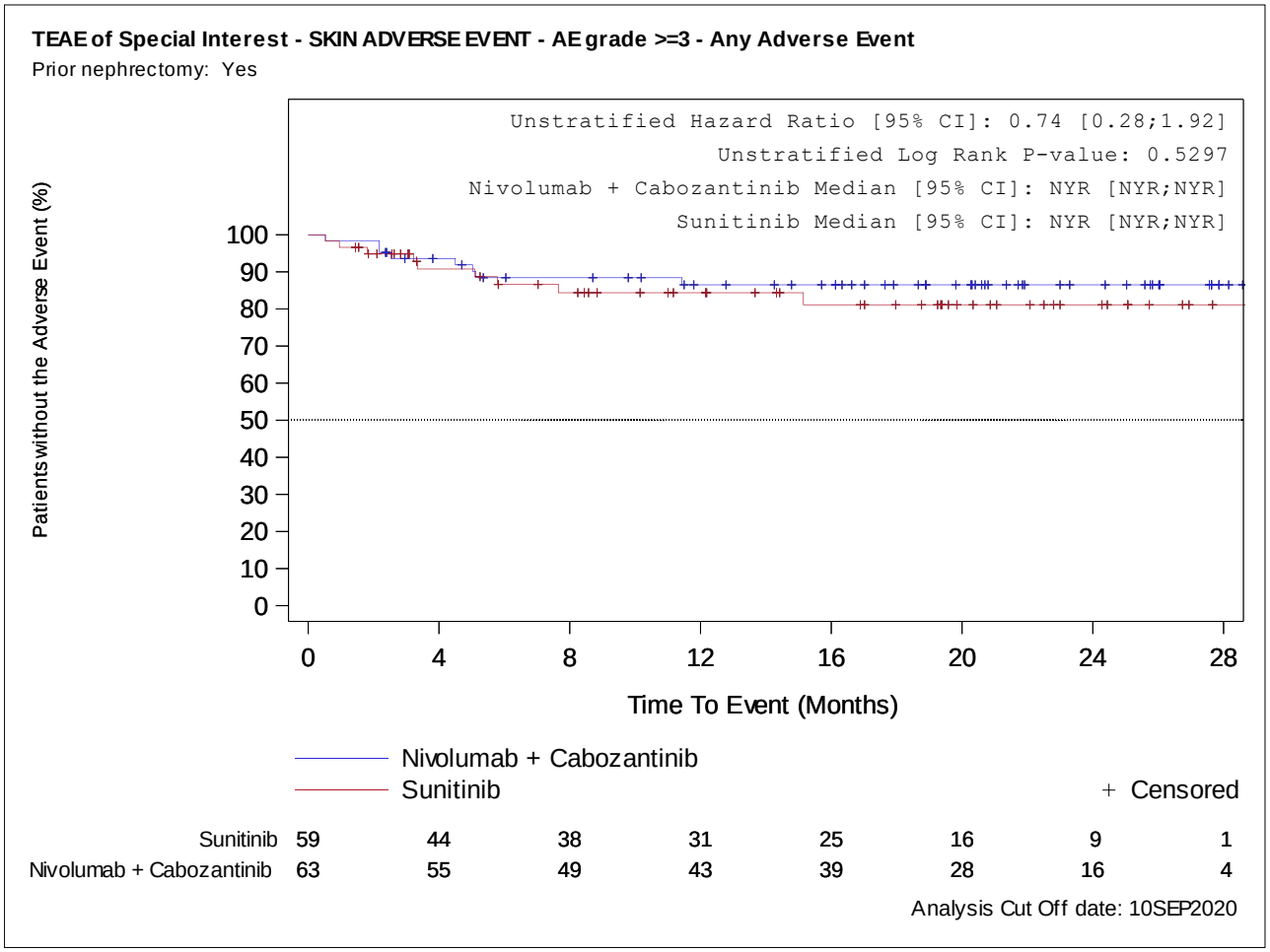

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:46:28

FIGURE 3.55.2.17: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



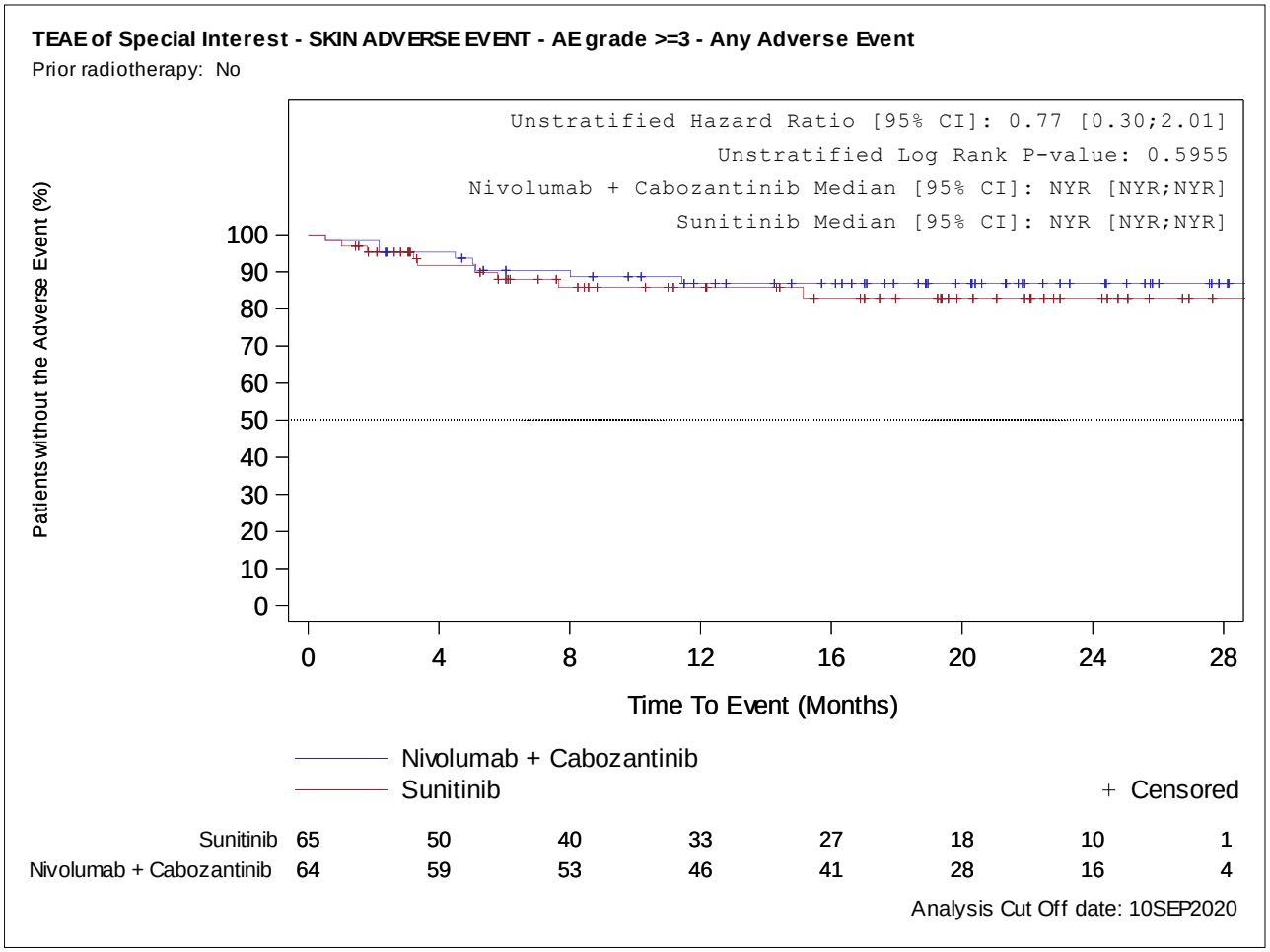

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:47:16

FIGURE 3.55.2.18: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:47:21

FIGURE 3.55.2.19: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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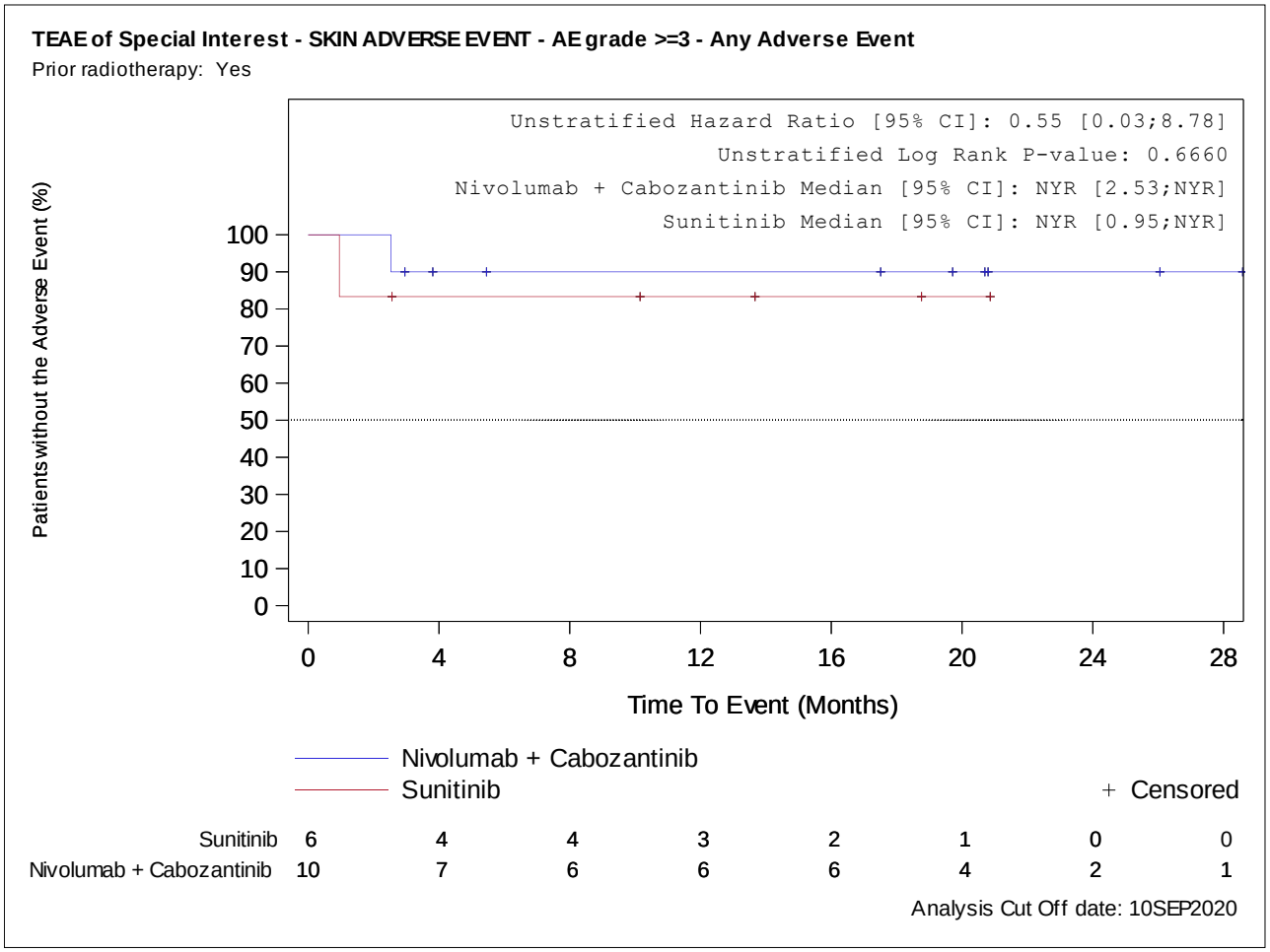
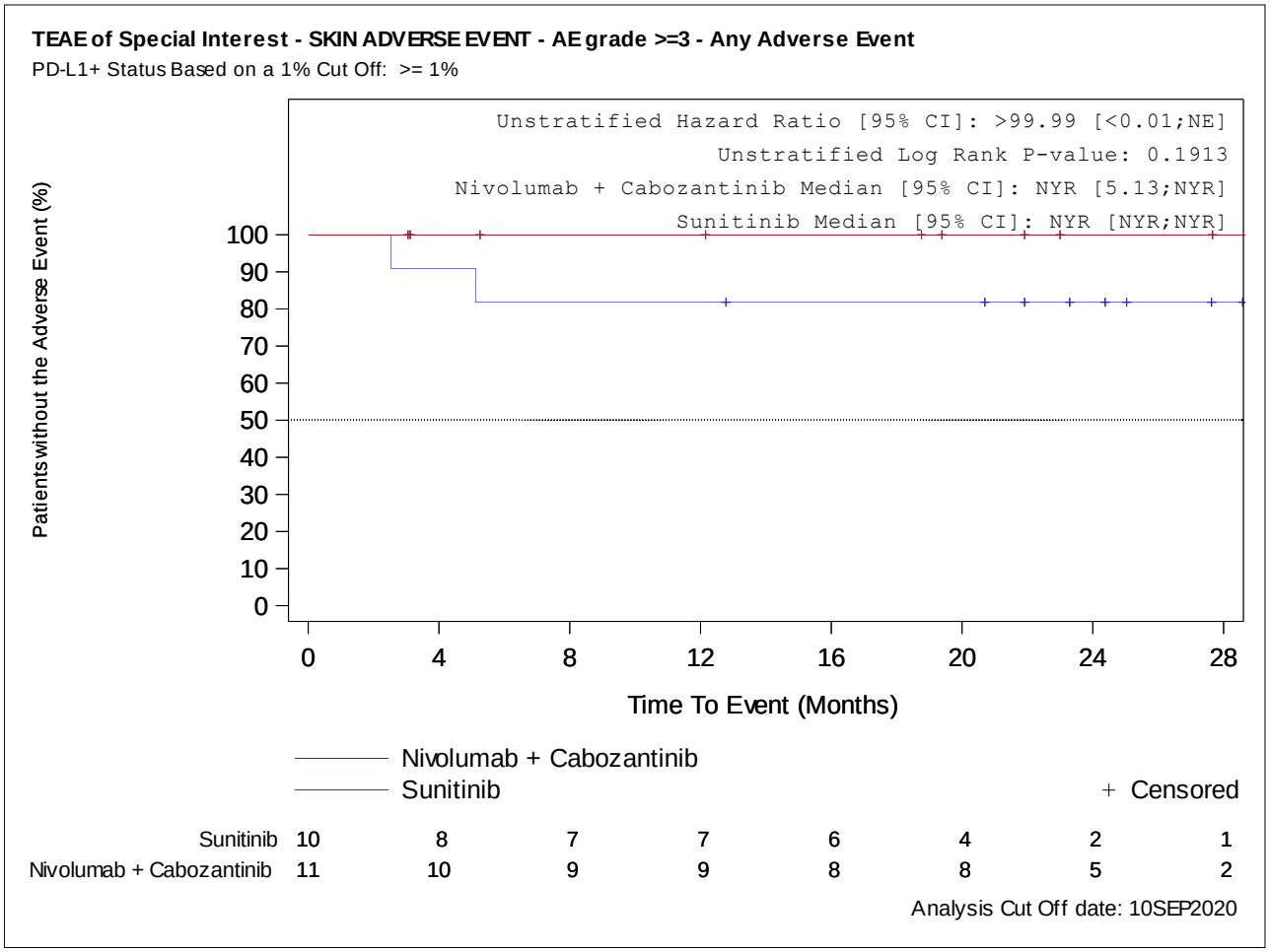
FIGURE 3.55.2.20: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



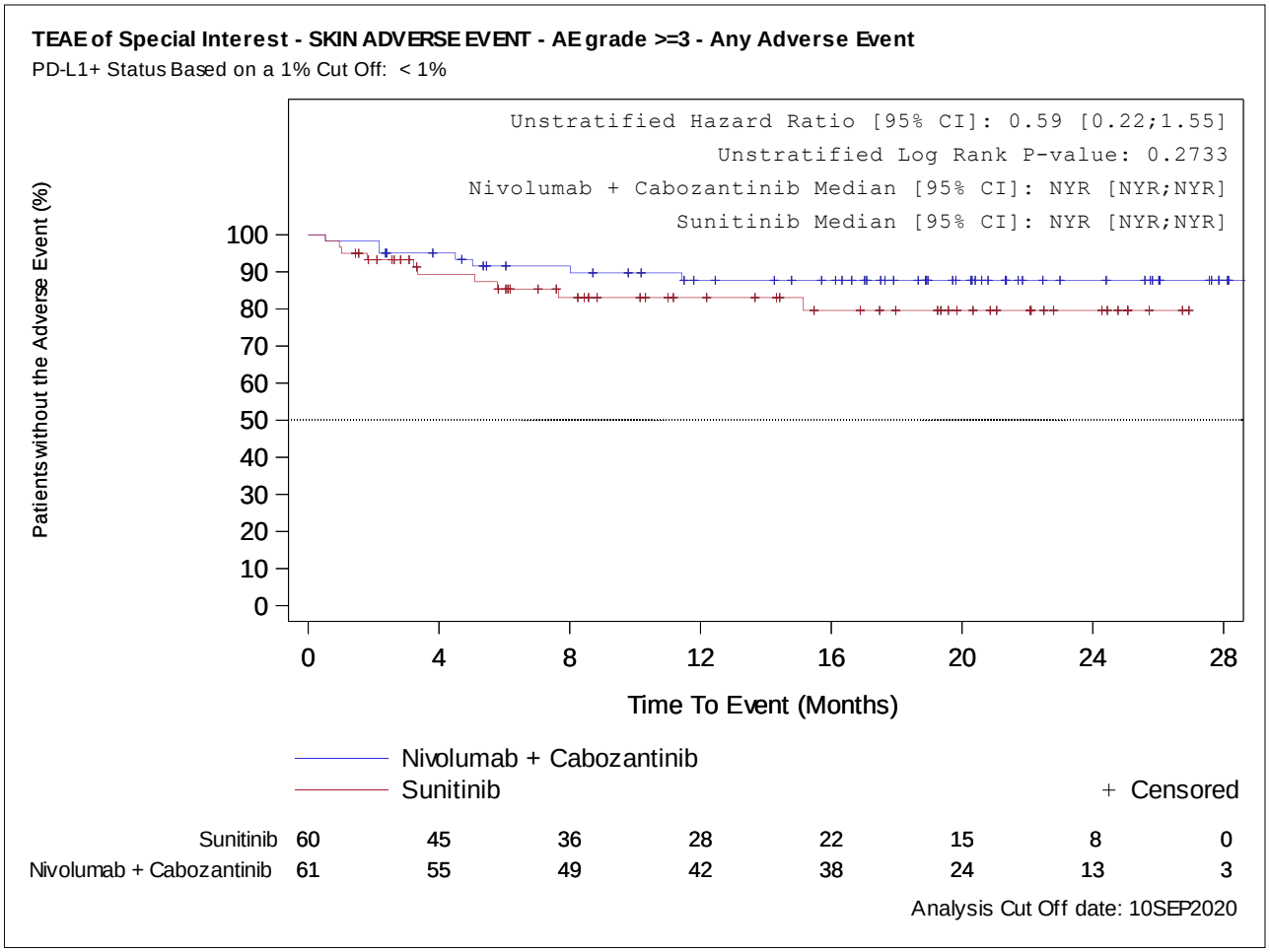

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:47:31

FIGURE 3.55.2.21: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



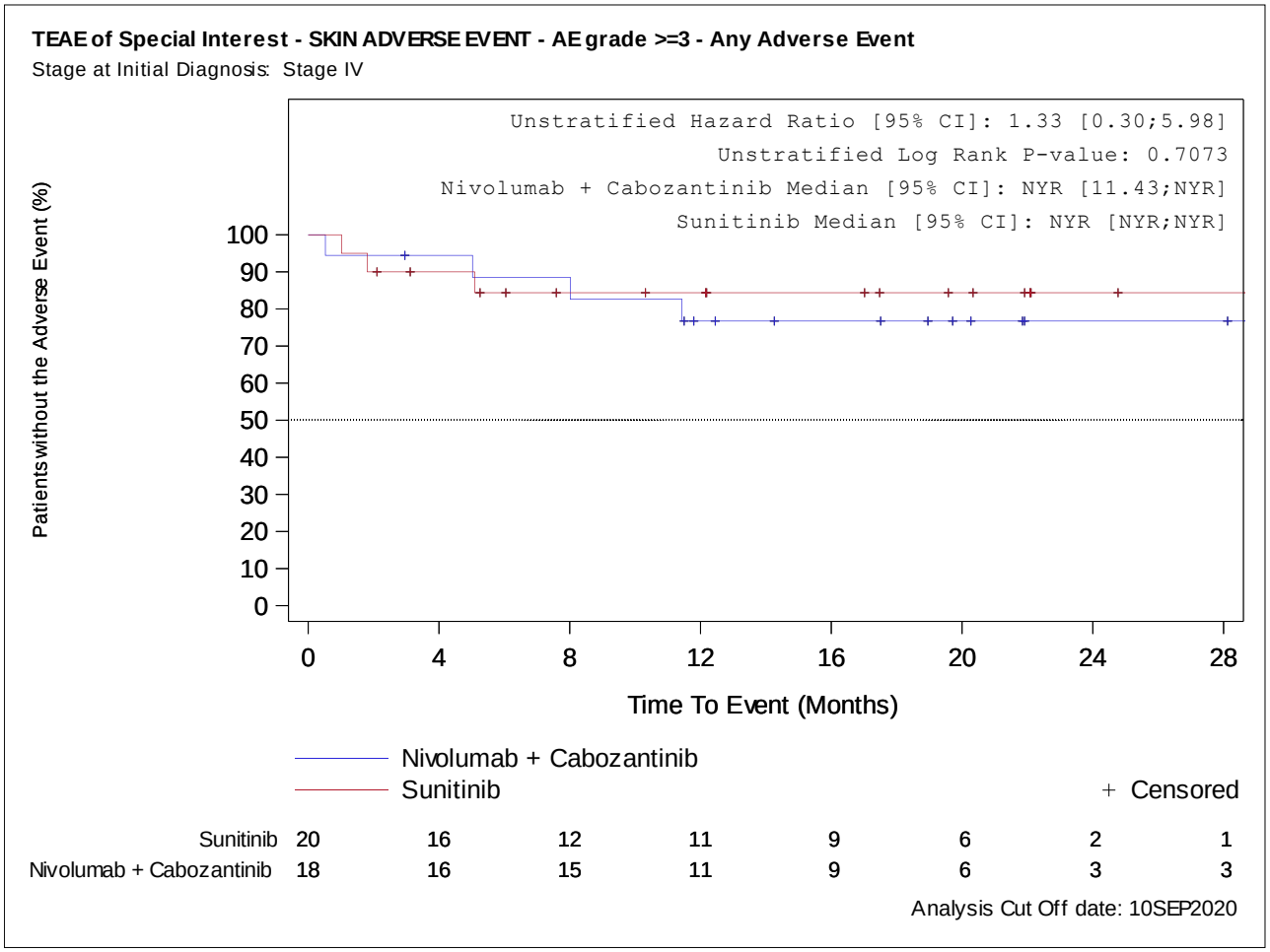

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:47:37

FIGURE 3.55.2.22: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



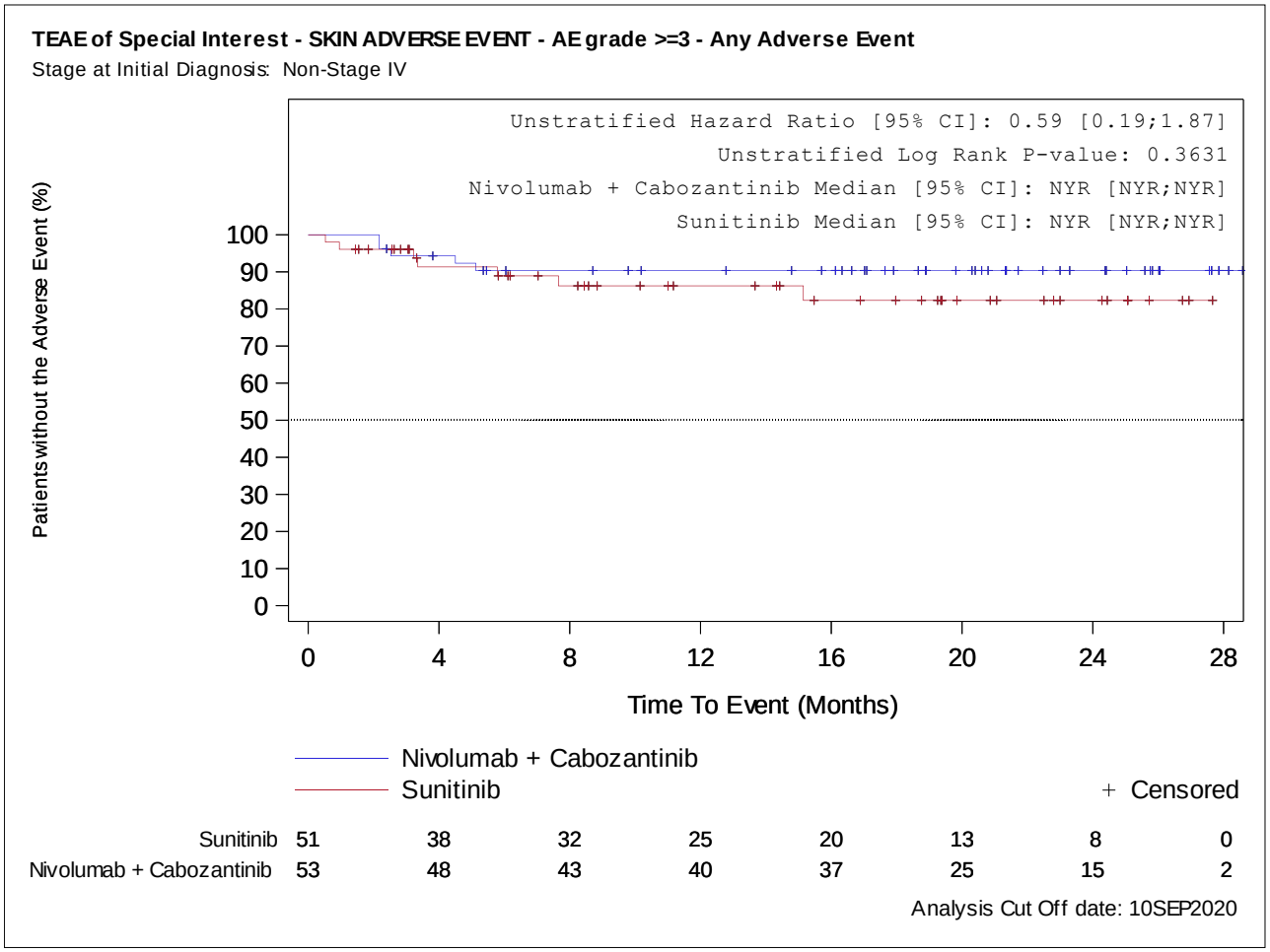

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:47:42

FIGURE 3.55.2.23: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



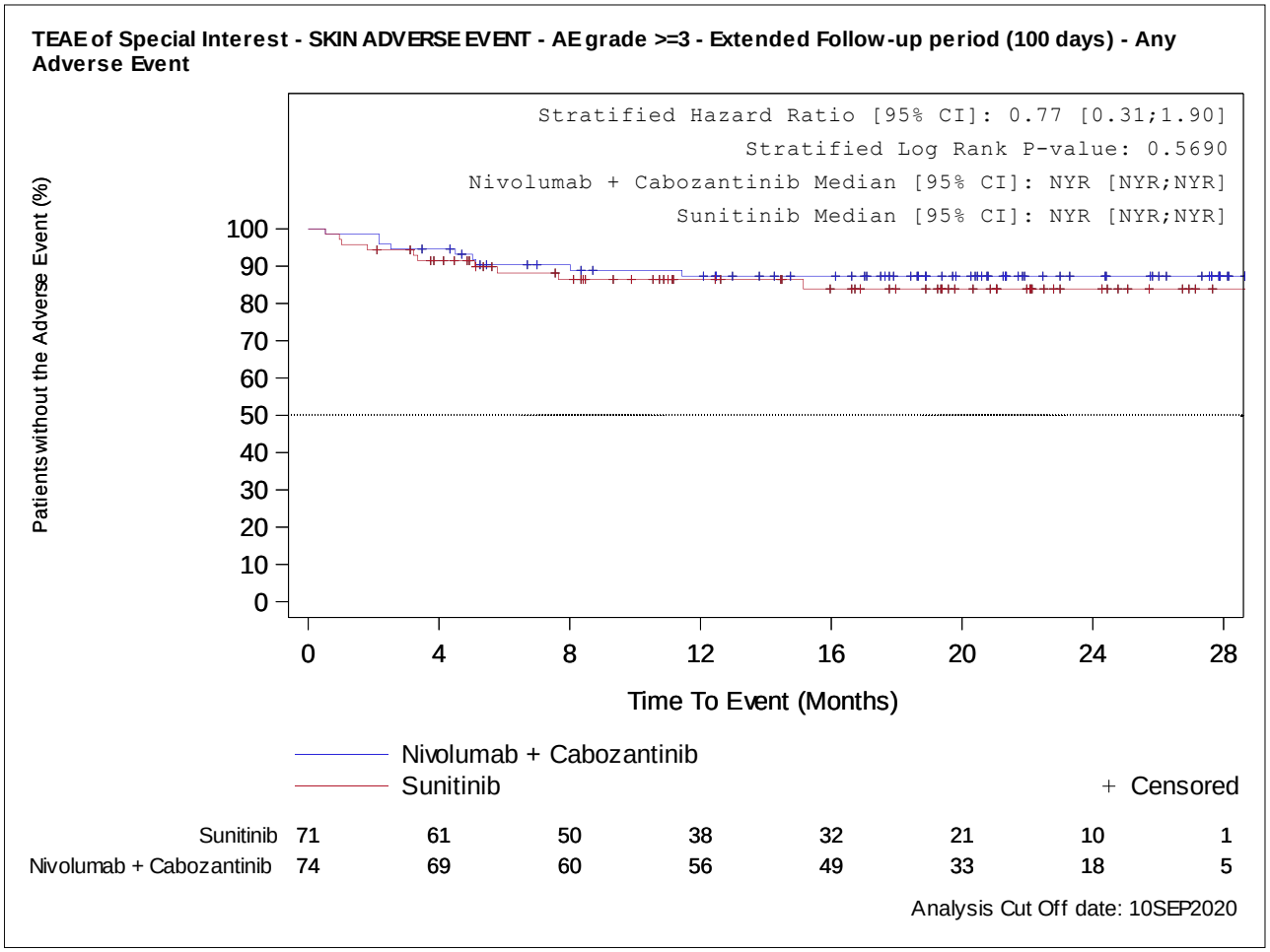

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:48:08

FIGURE 3.55.2.24: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



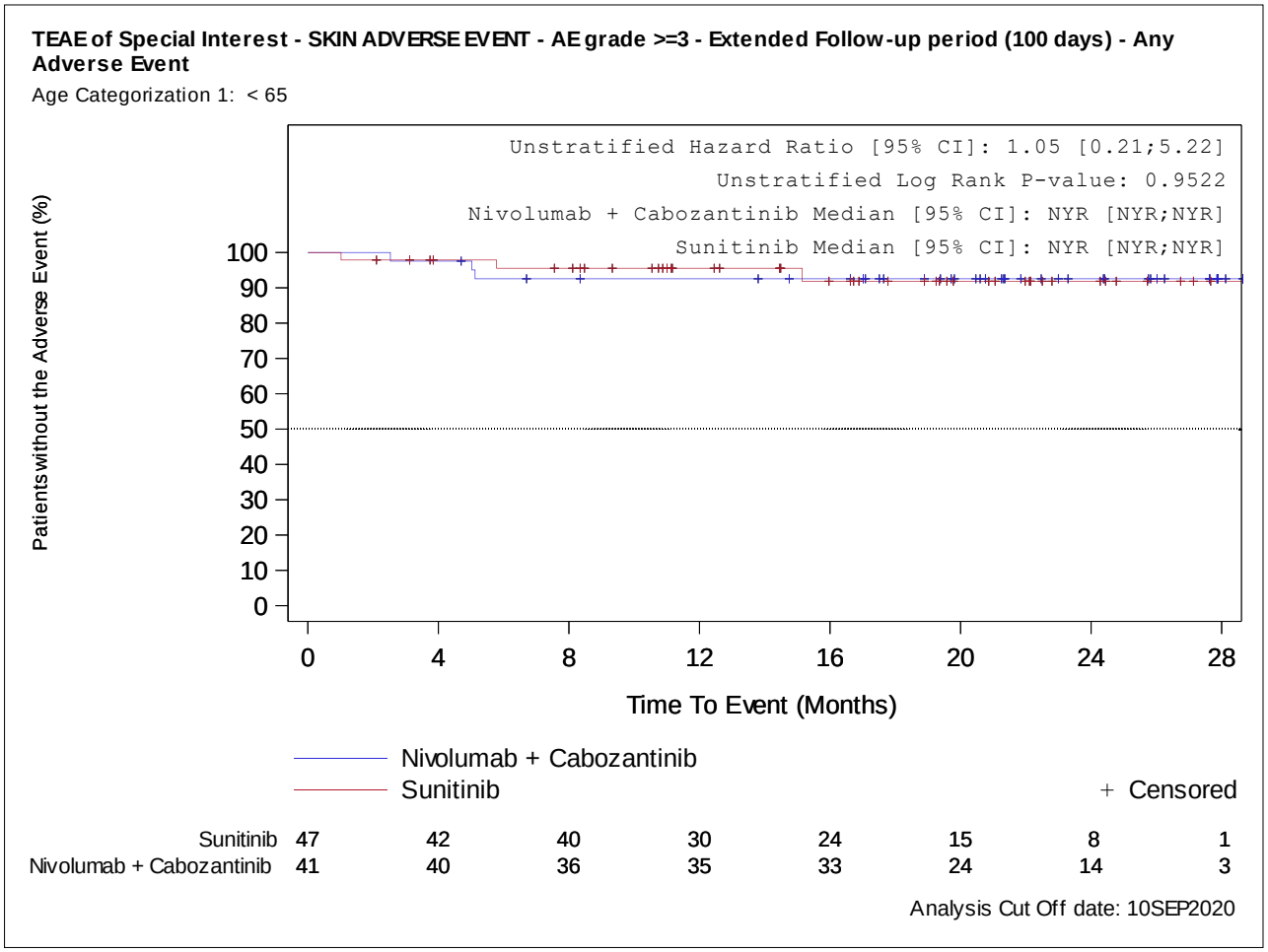

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:48:13

FIGURE 3.56.1: TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



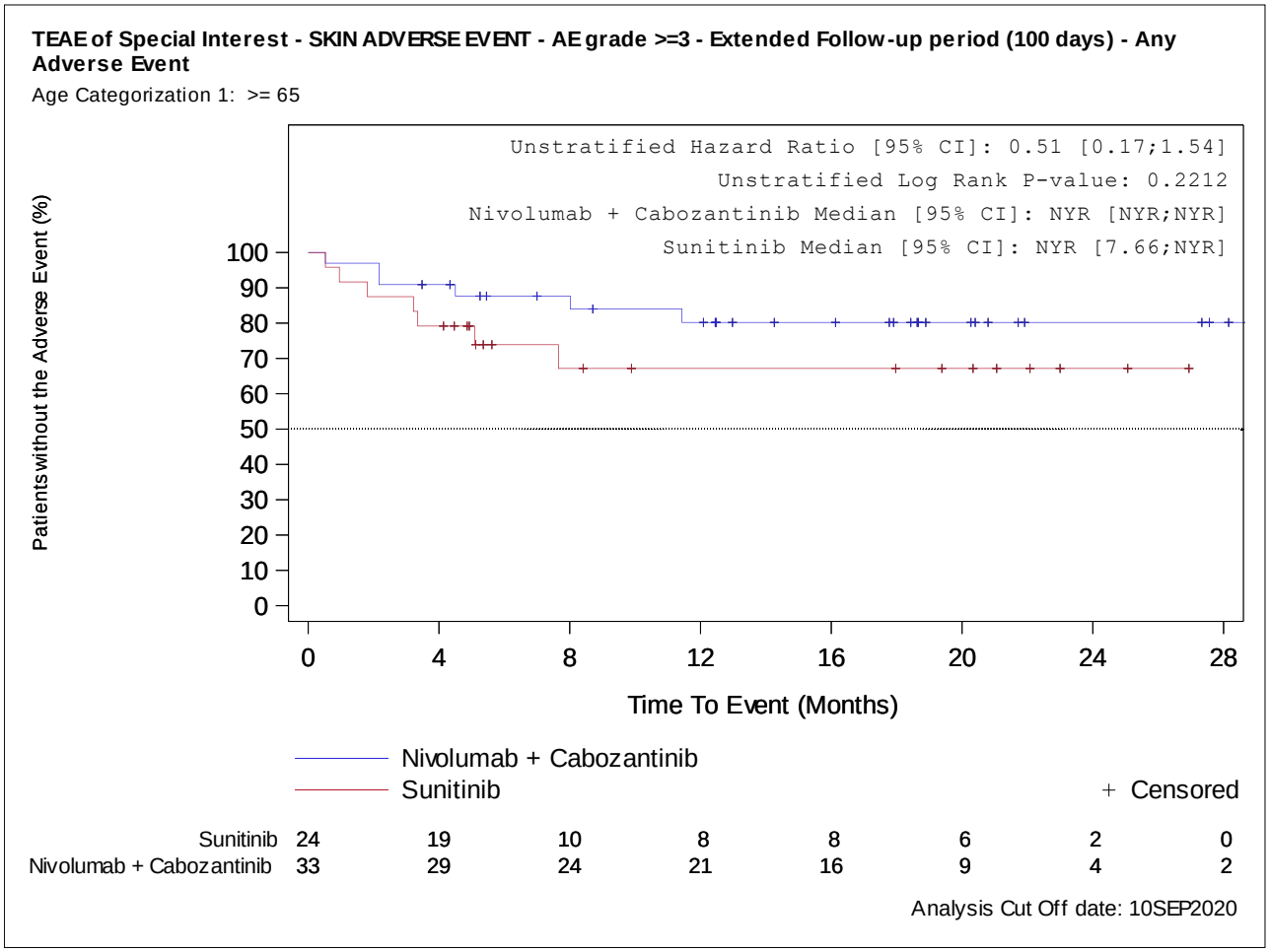

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:51:12

FIGURE 3.56.2.1: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  < 65



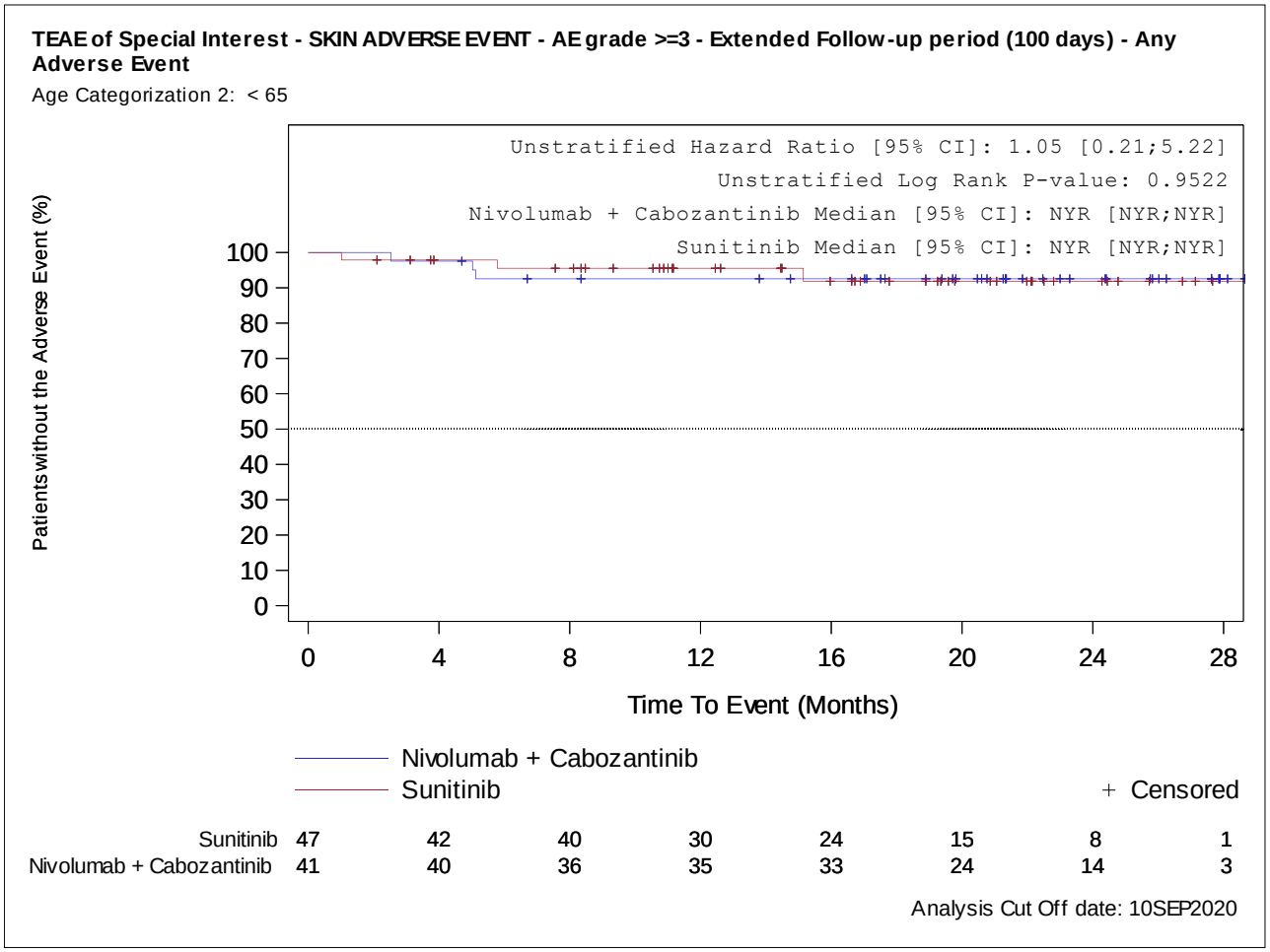

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:51:15

FIGURE 3.56.2.2: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



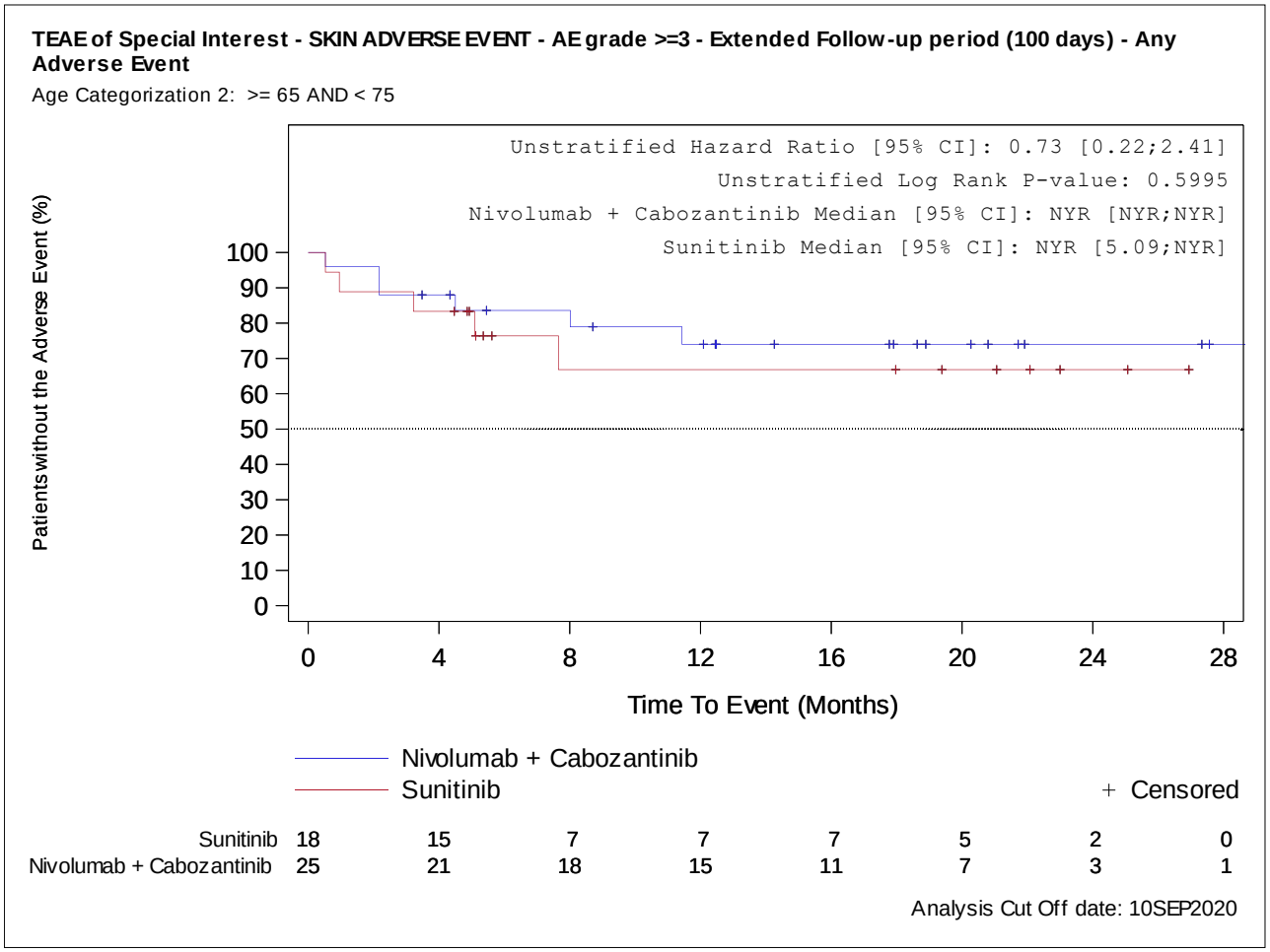

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:51:20

FIGURE 3.56.2.3: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  < 65



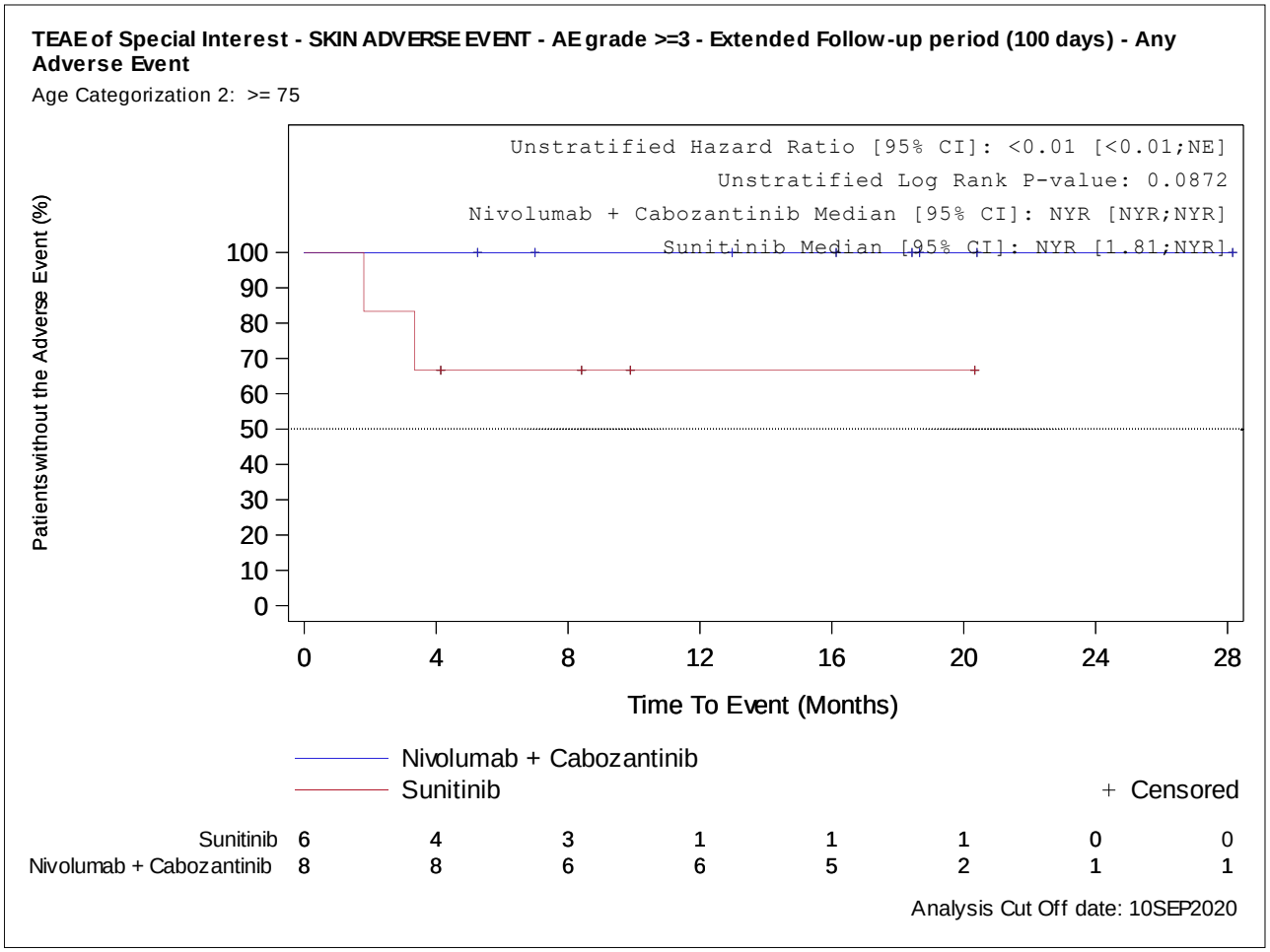

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:51:25

FIGURE 3.56.2.4: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



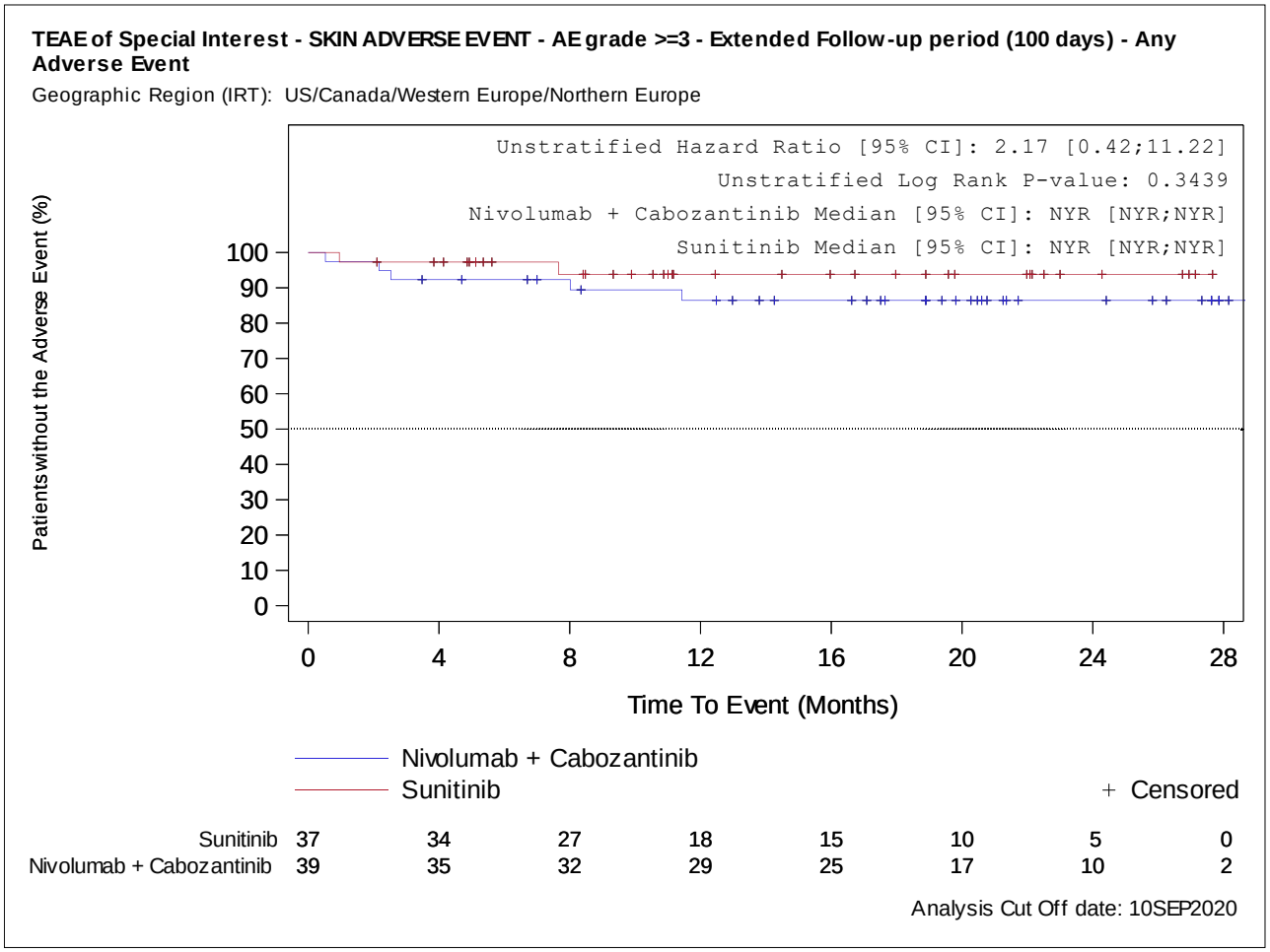

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:51:31

FIGURE 3.56.2.5: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



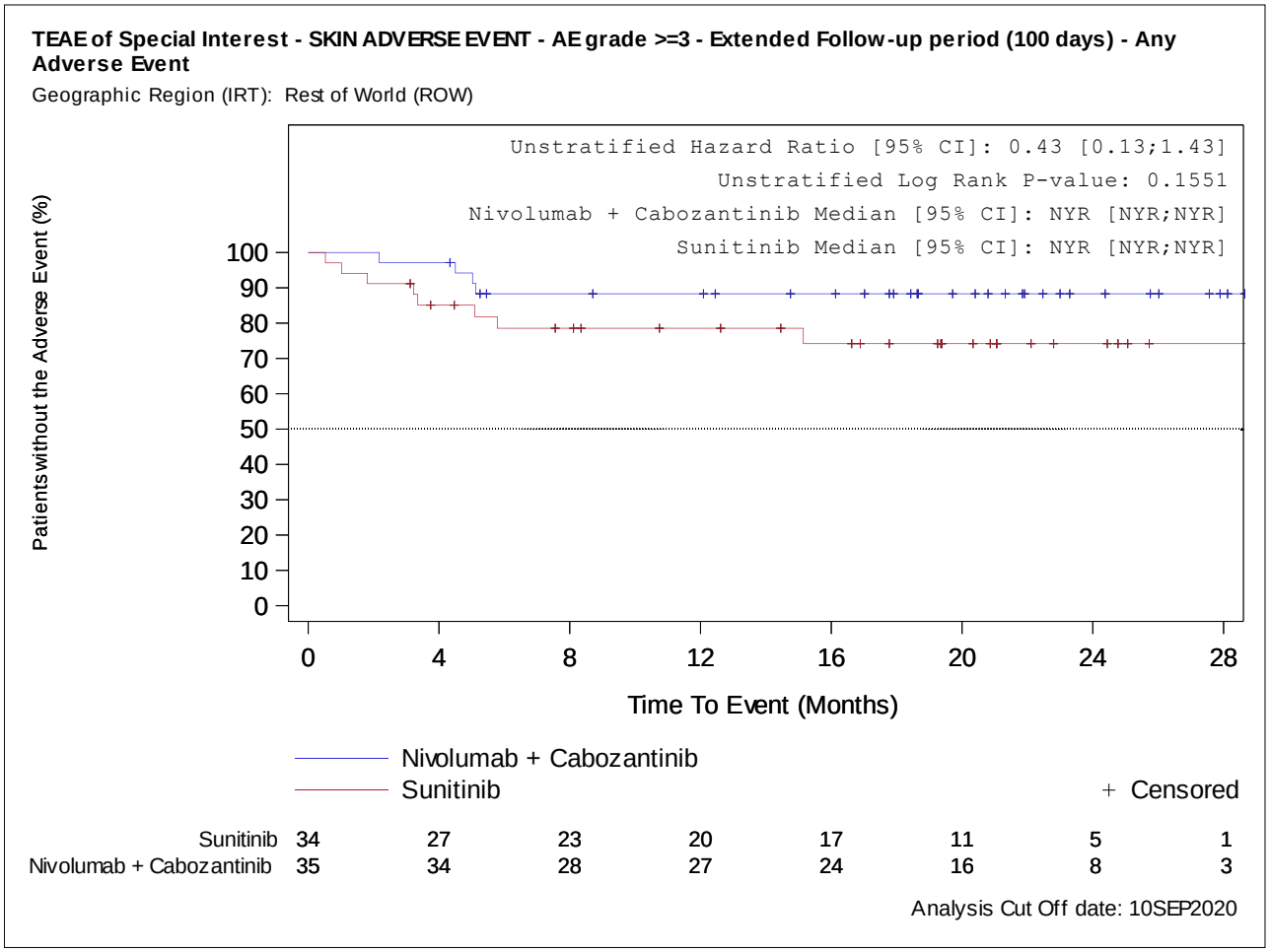

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:51:36

FIGURE 3.56.2.6: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



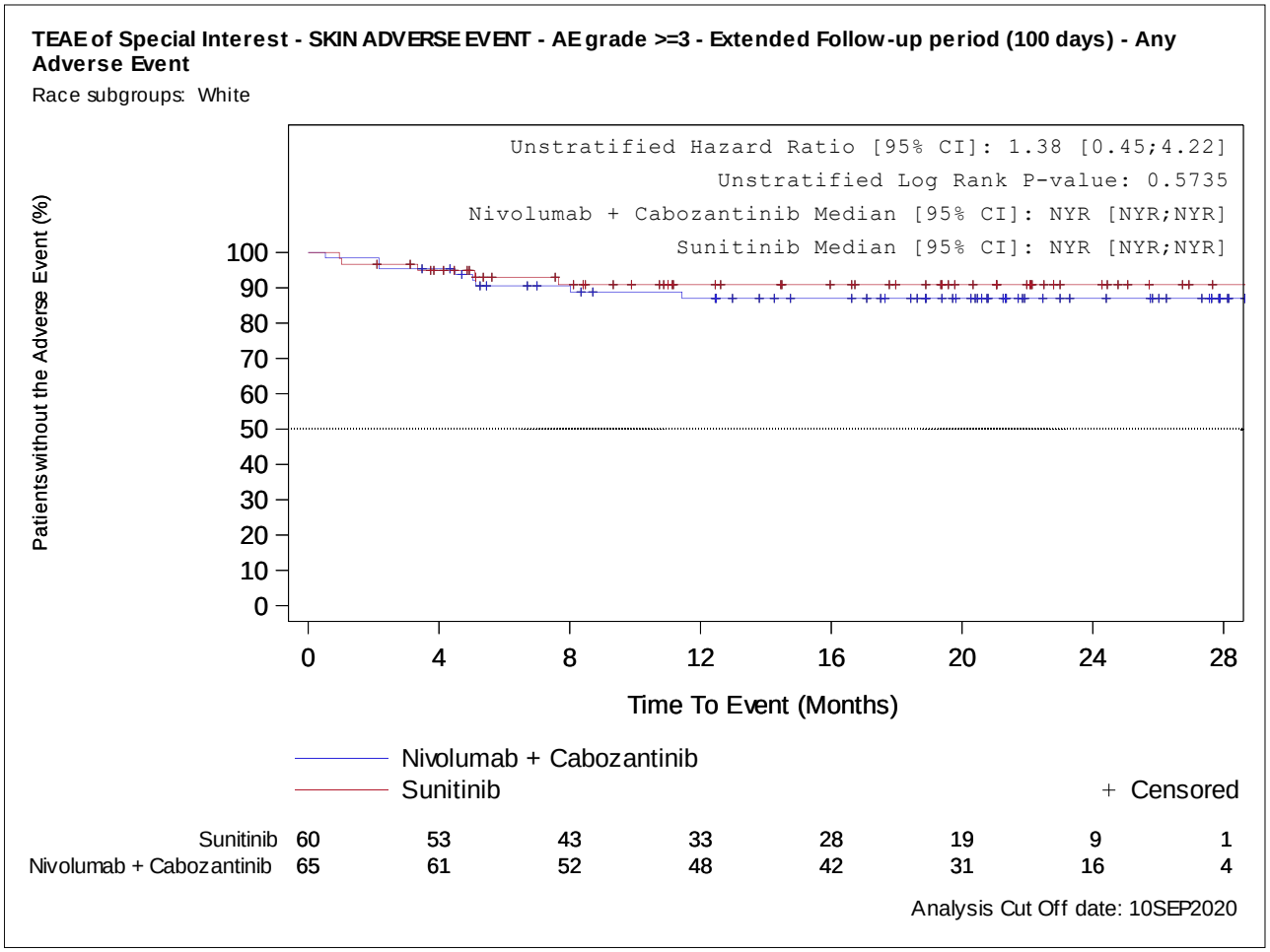

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:51:41

FIGURE 3.56.2.7: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



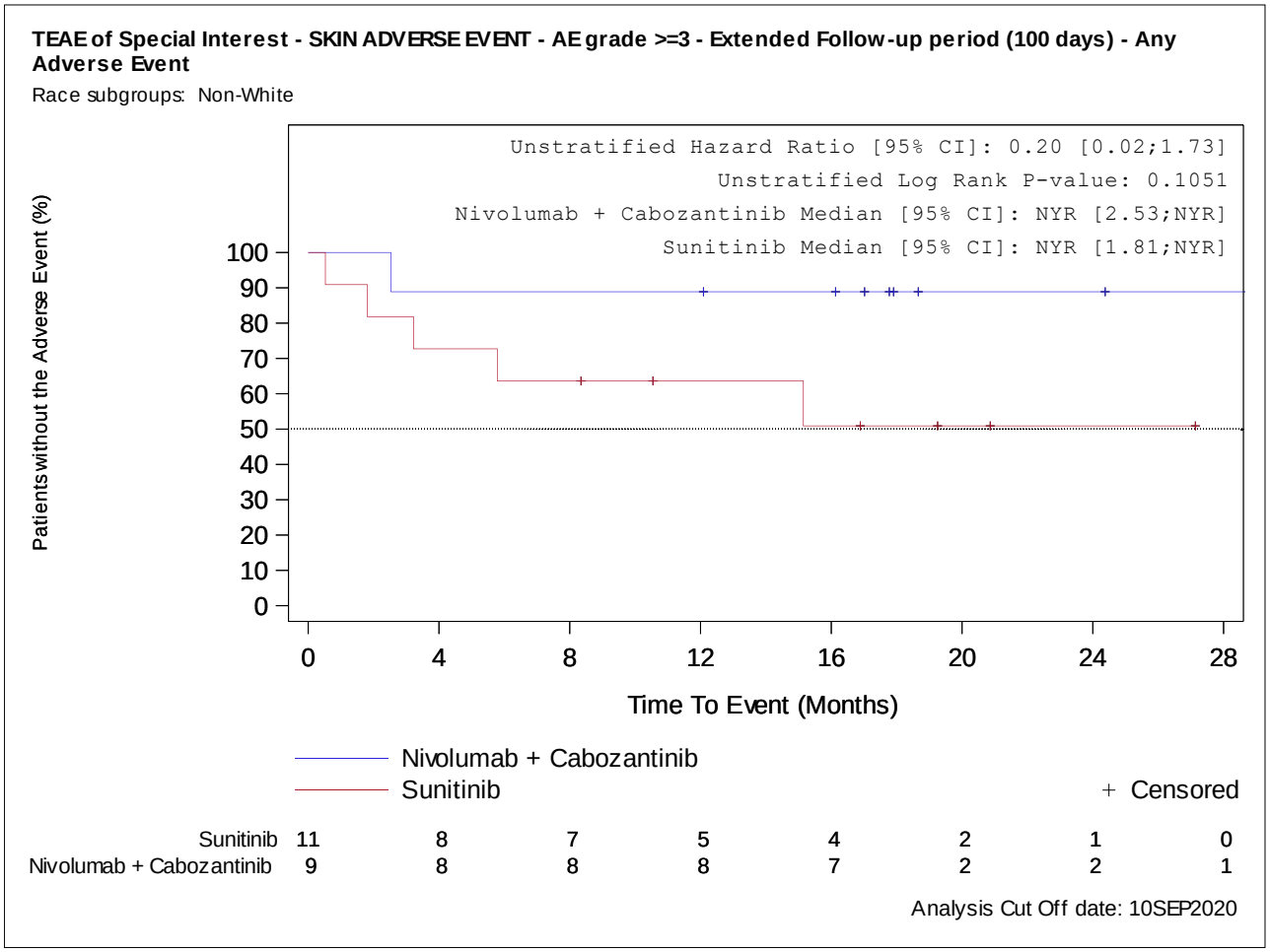

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:51:46

FIGURE 3.56.2.8: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



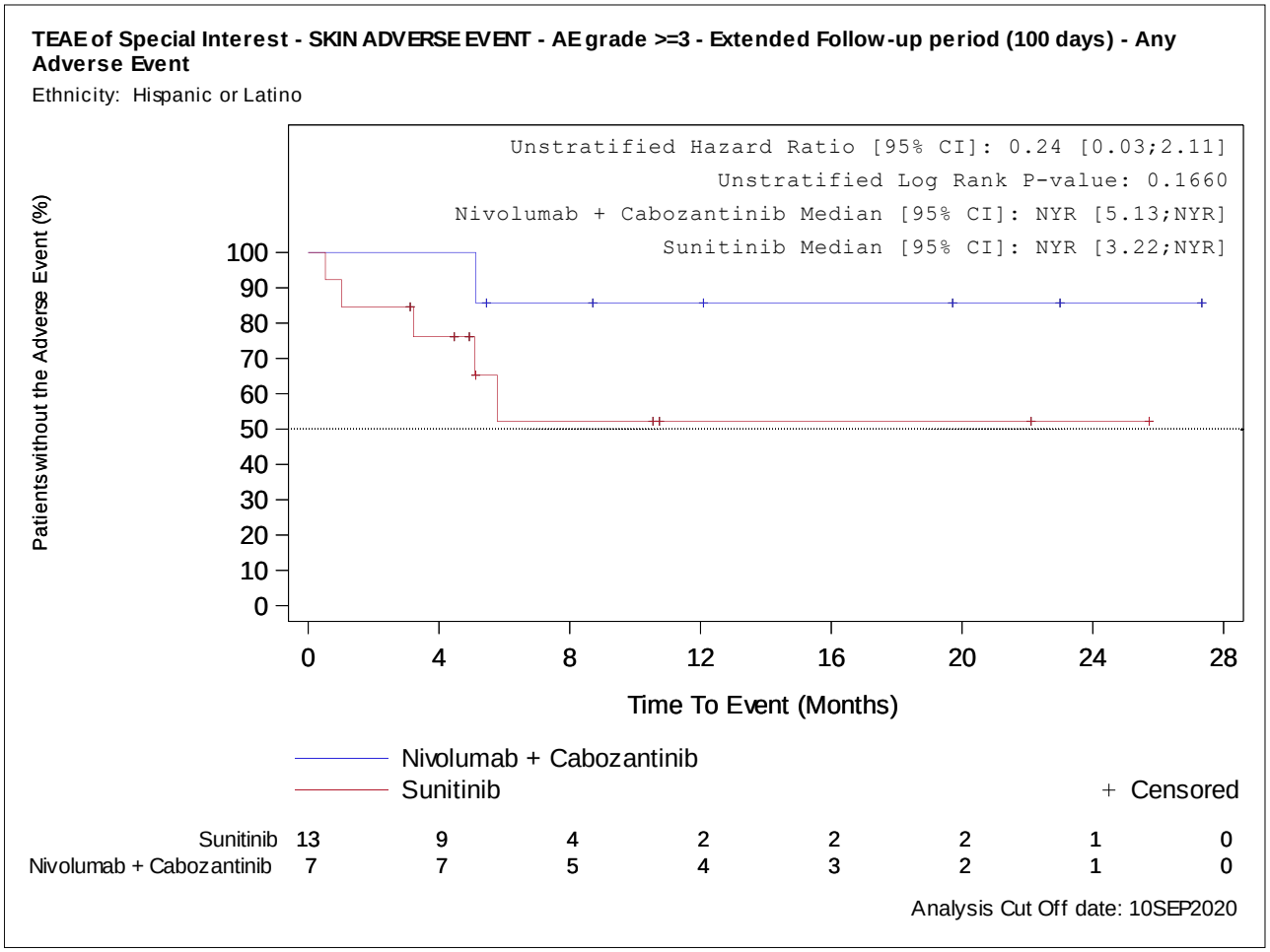

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:51:52

FIGURE 3.56.2.9: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



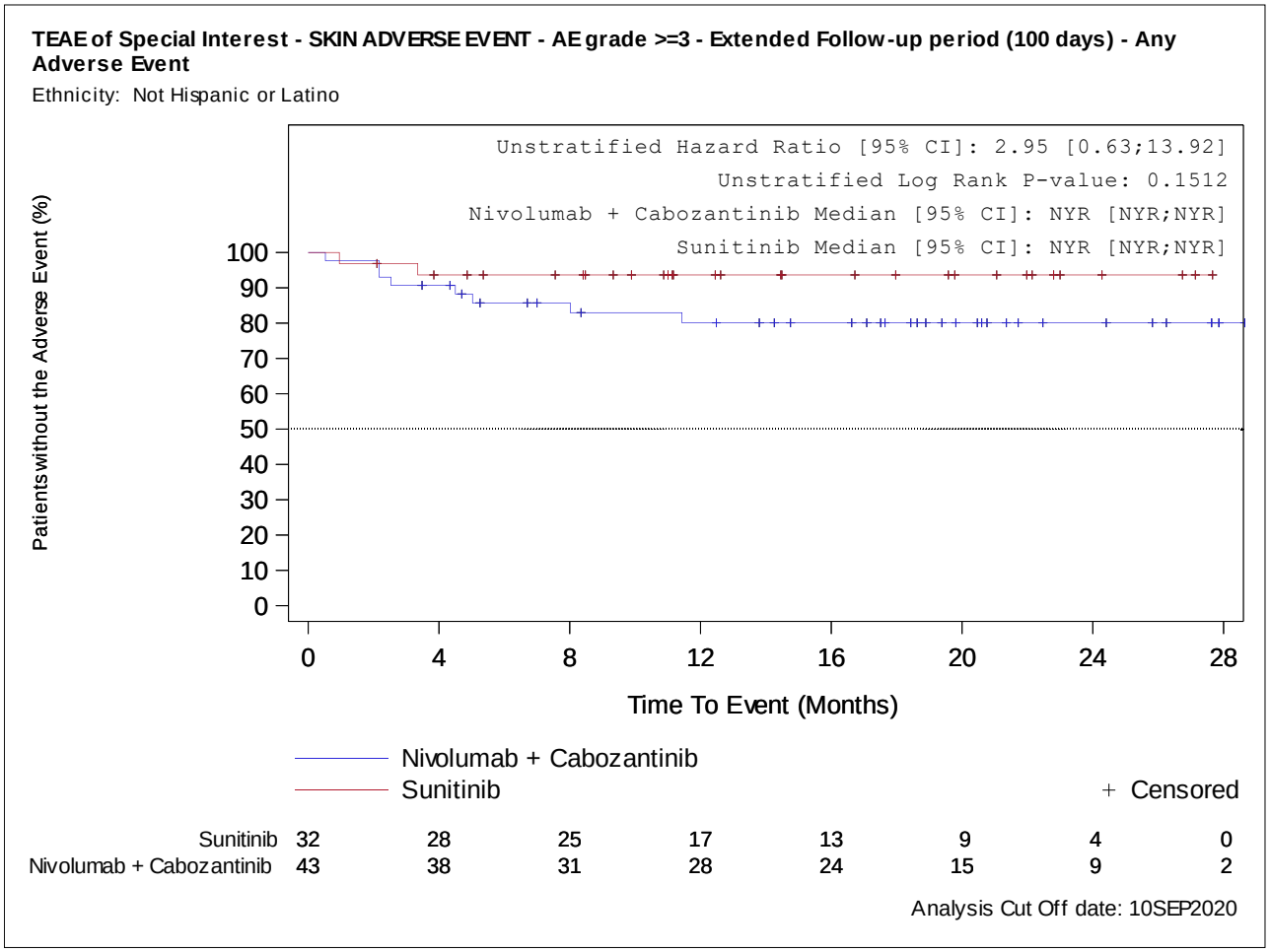

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:51:57

FIGURE 3.56.2.10: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



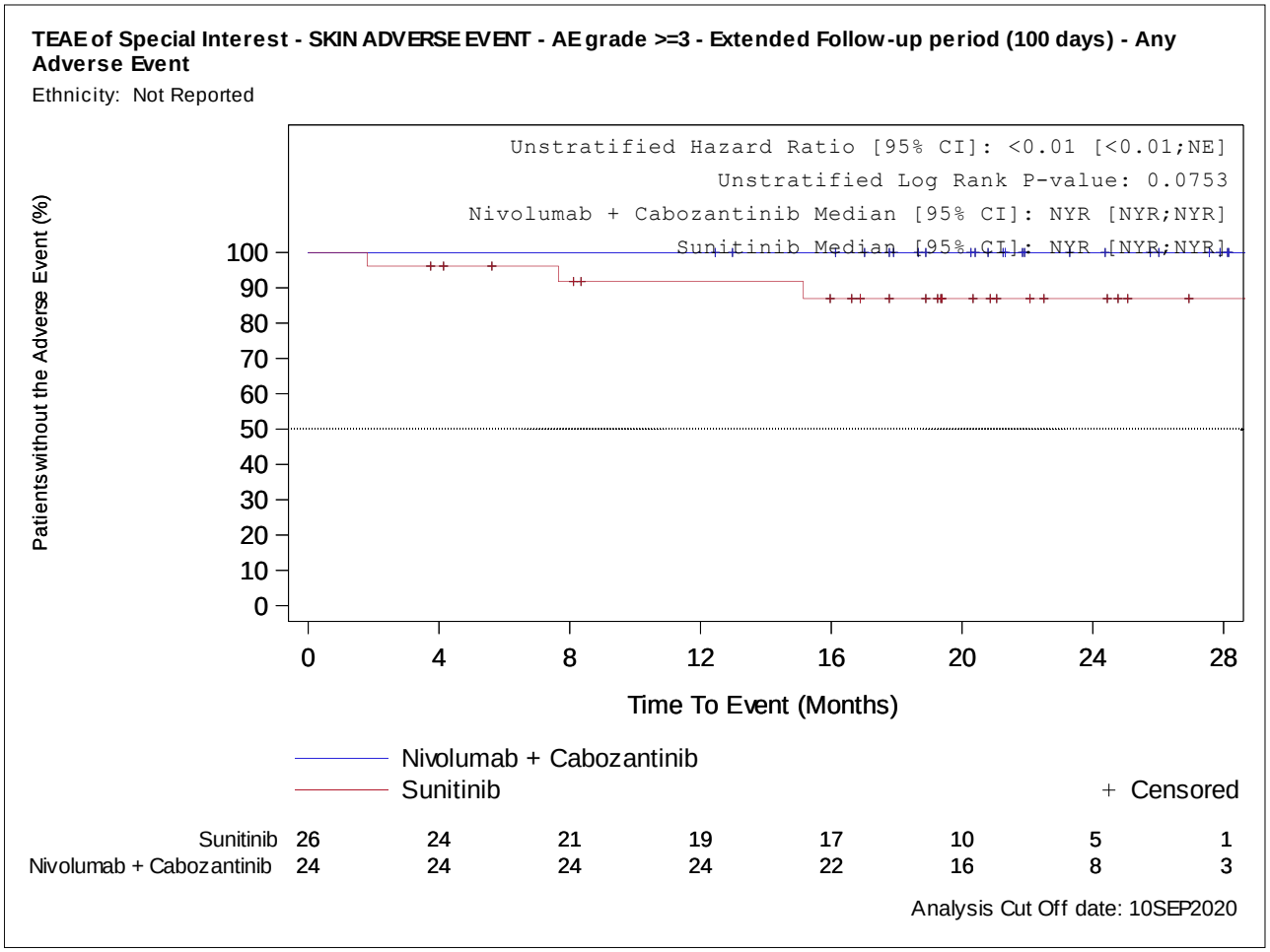

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:52:03

FIGURE 3.56.2.11: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



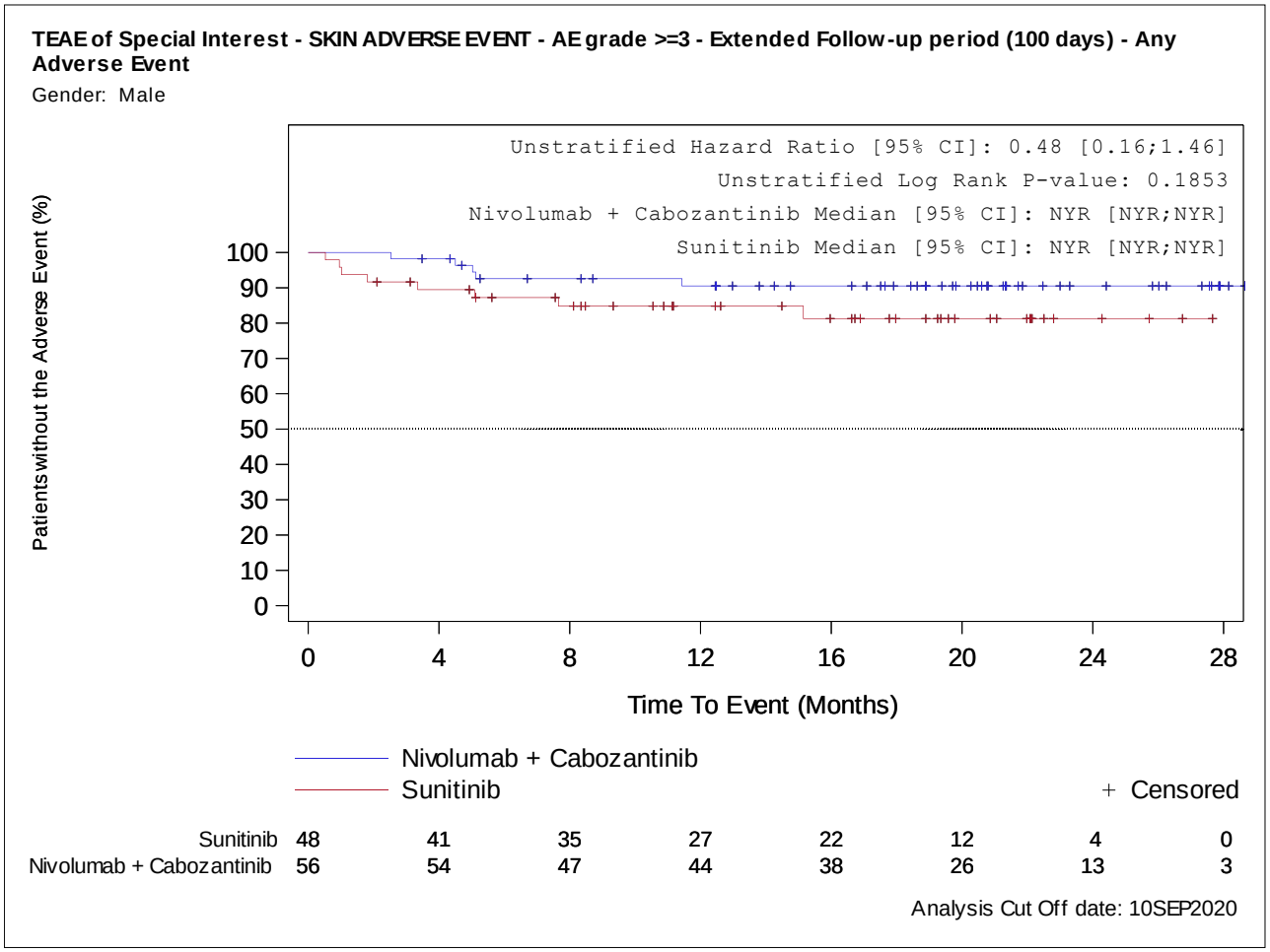

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:52:08

FIGURE 3.56.2.12: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



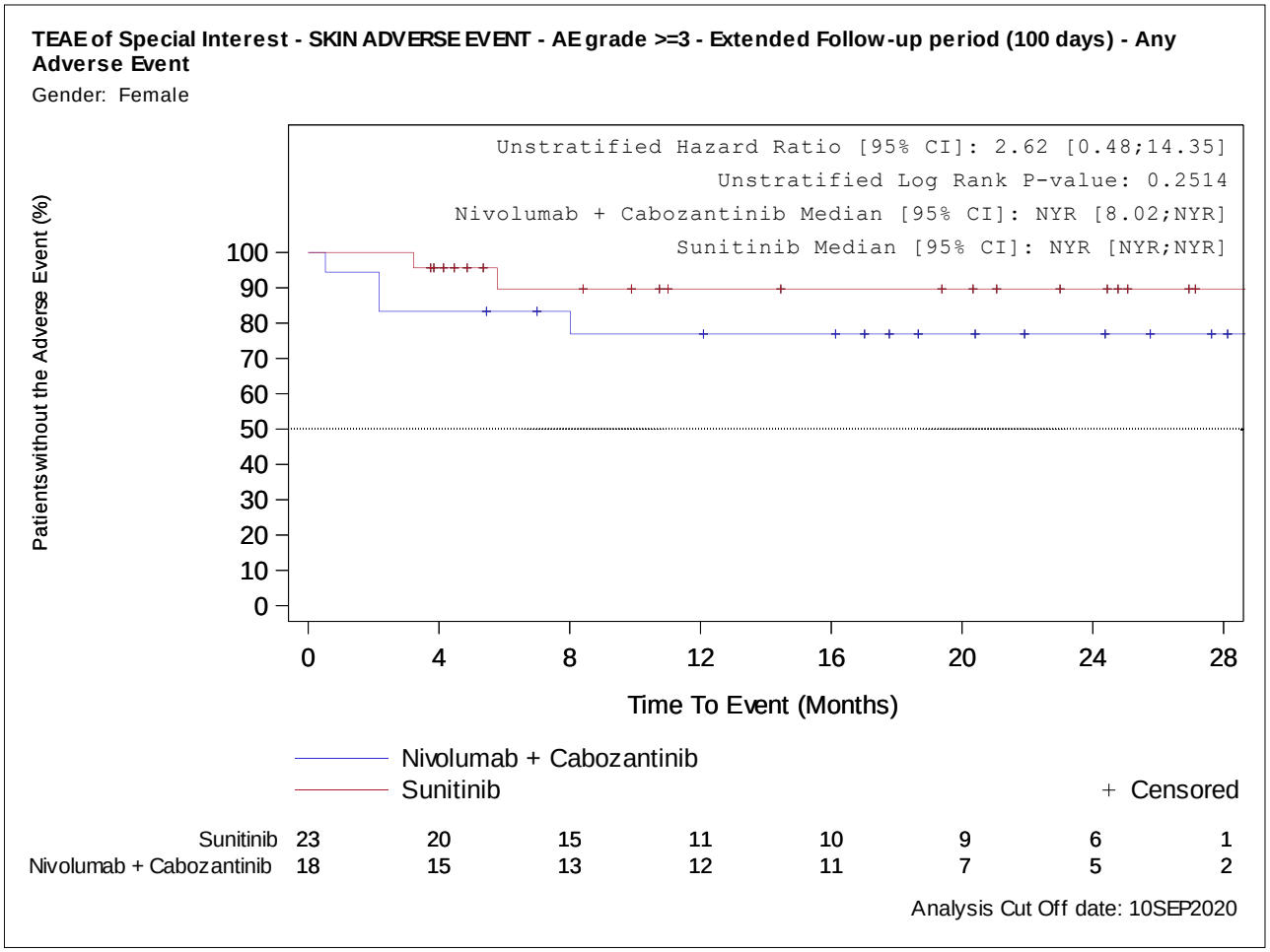

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:52:13

FIGURE 3.56.2.13: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



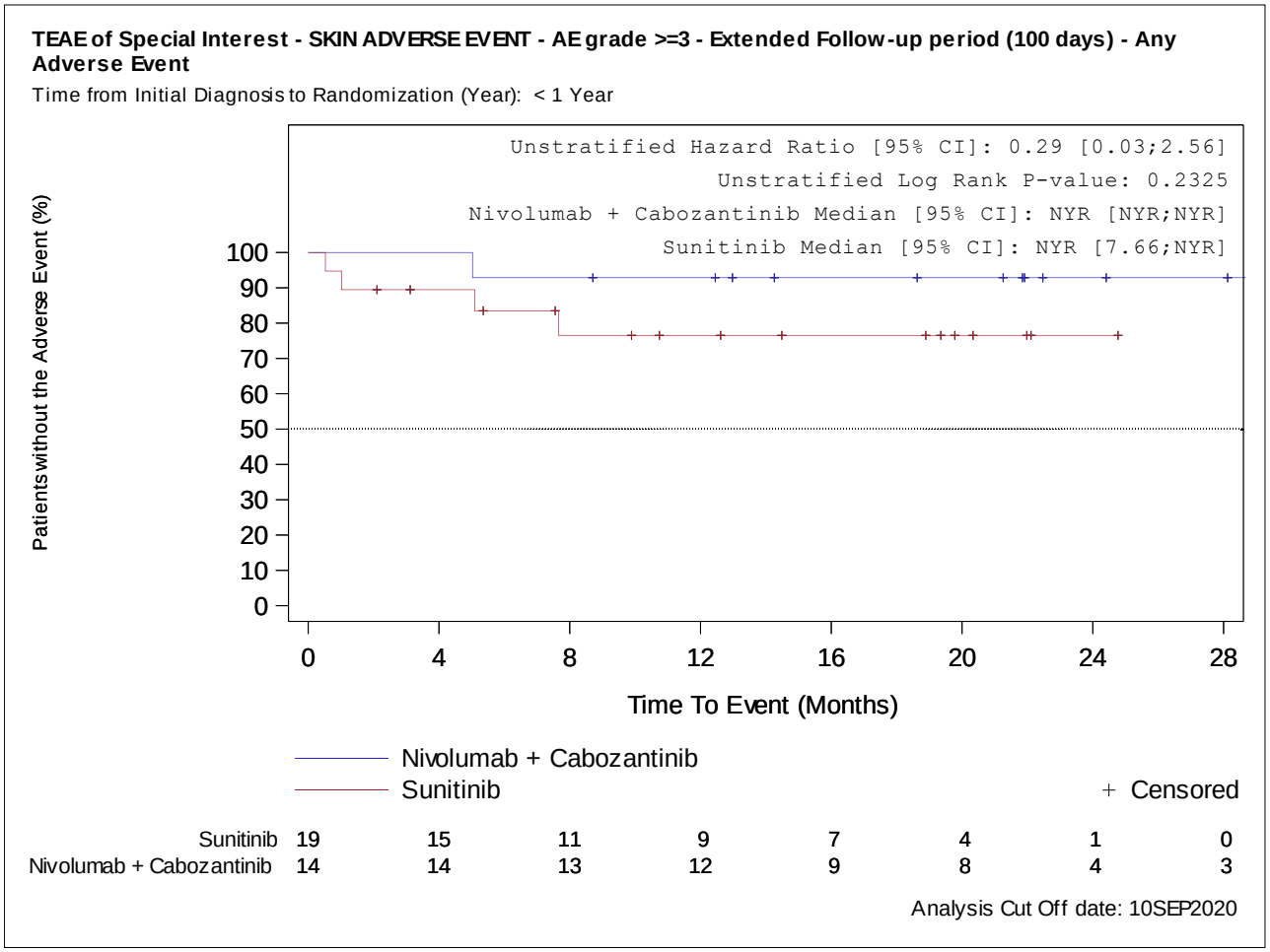

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:52:19

FIGURE 3.56.2.14: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



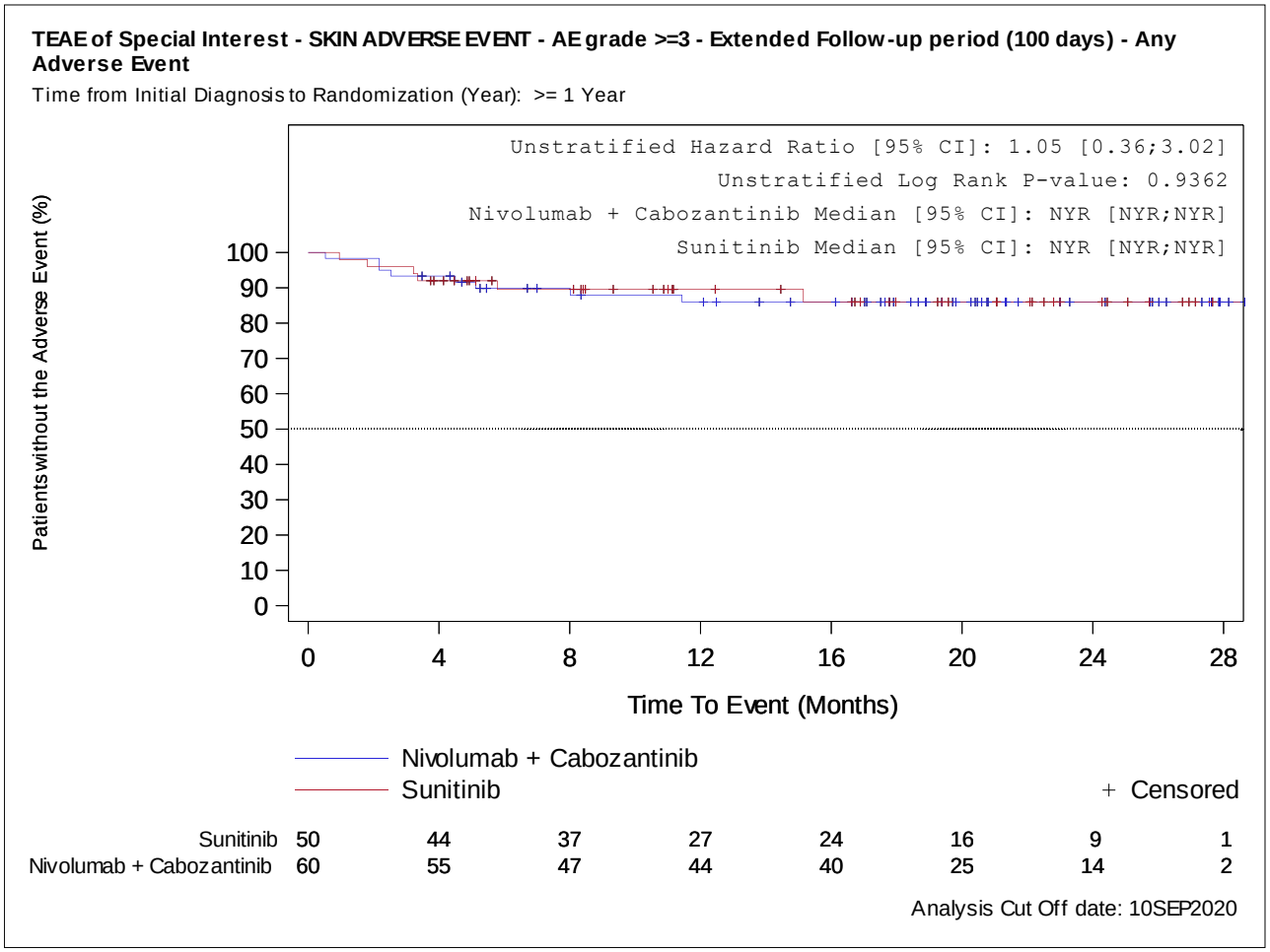

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:52:24

FIGURE 3.56.2.15: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



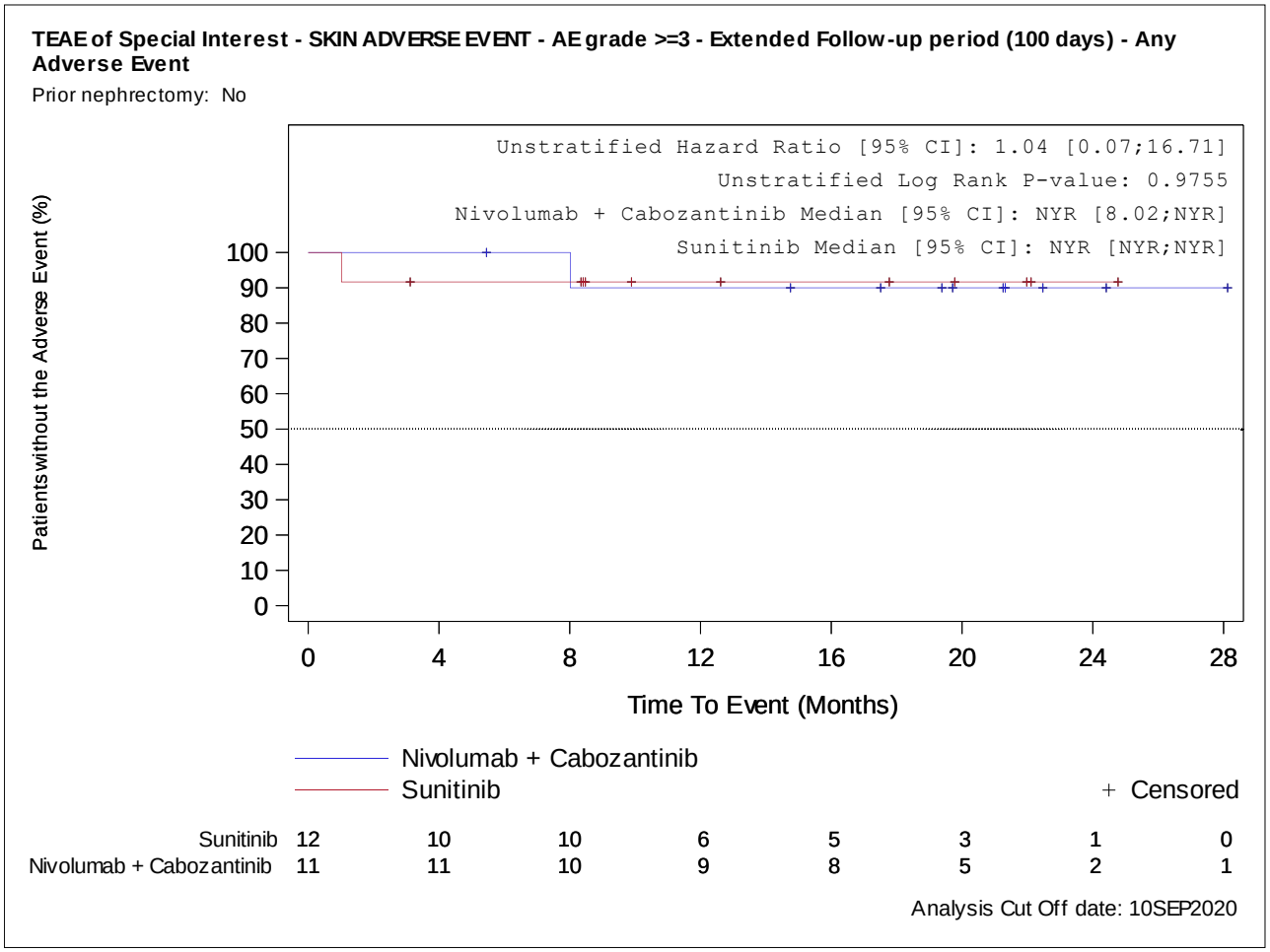

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:52:39

FIGURE 3.56.2.16: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



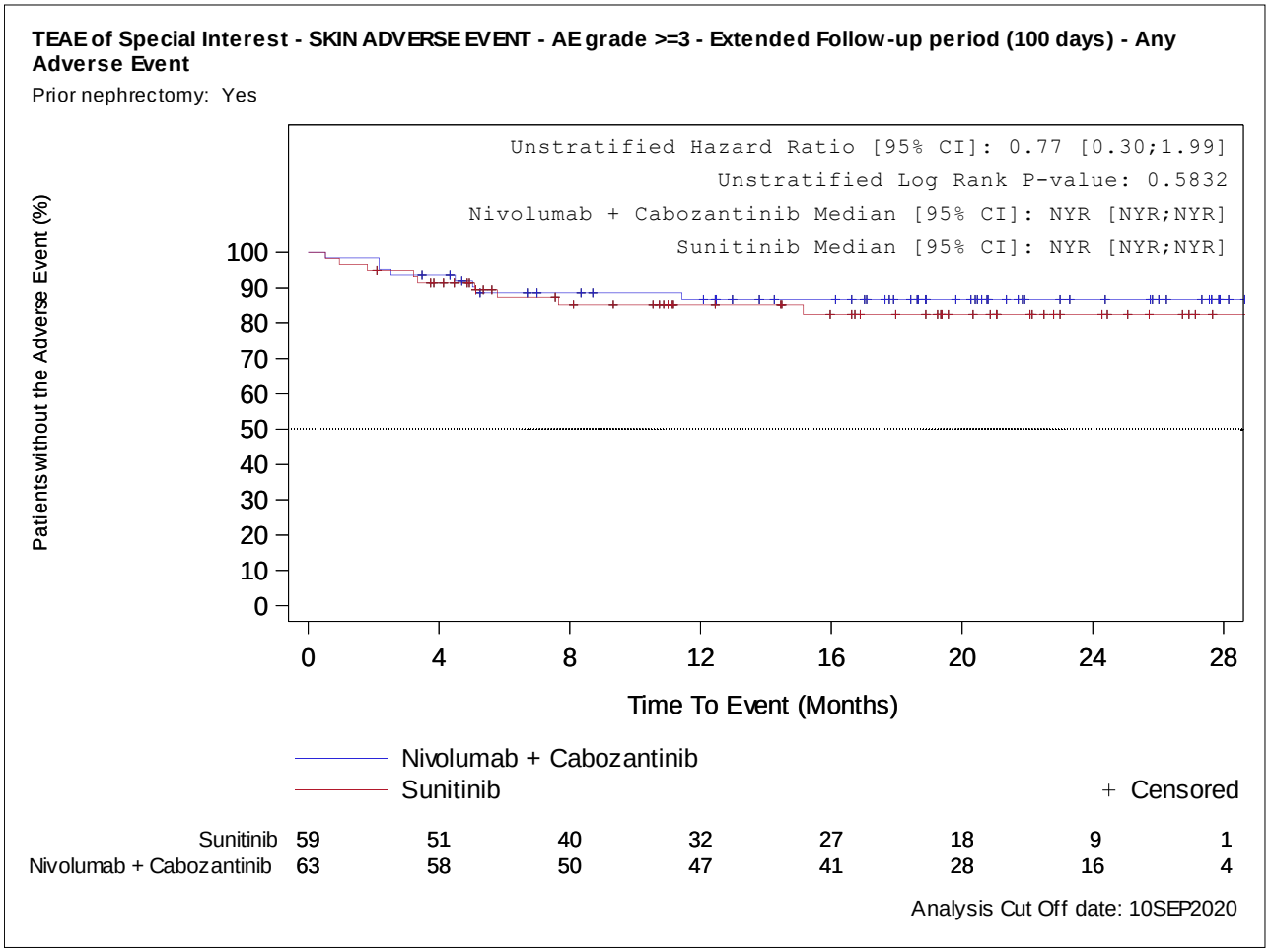

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:52:45

FIGURE 3.56.2.17: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



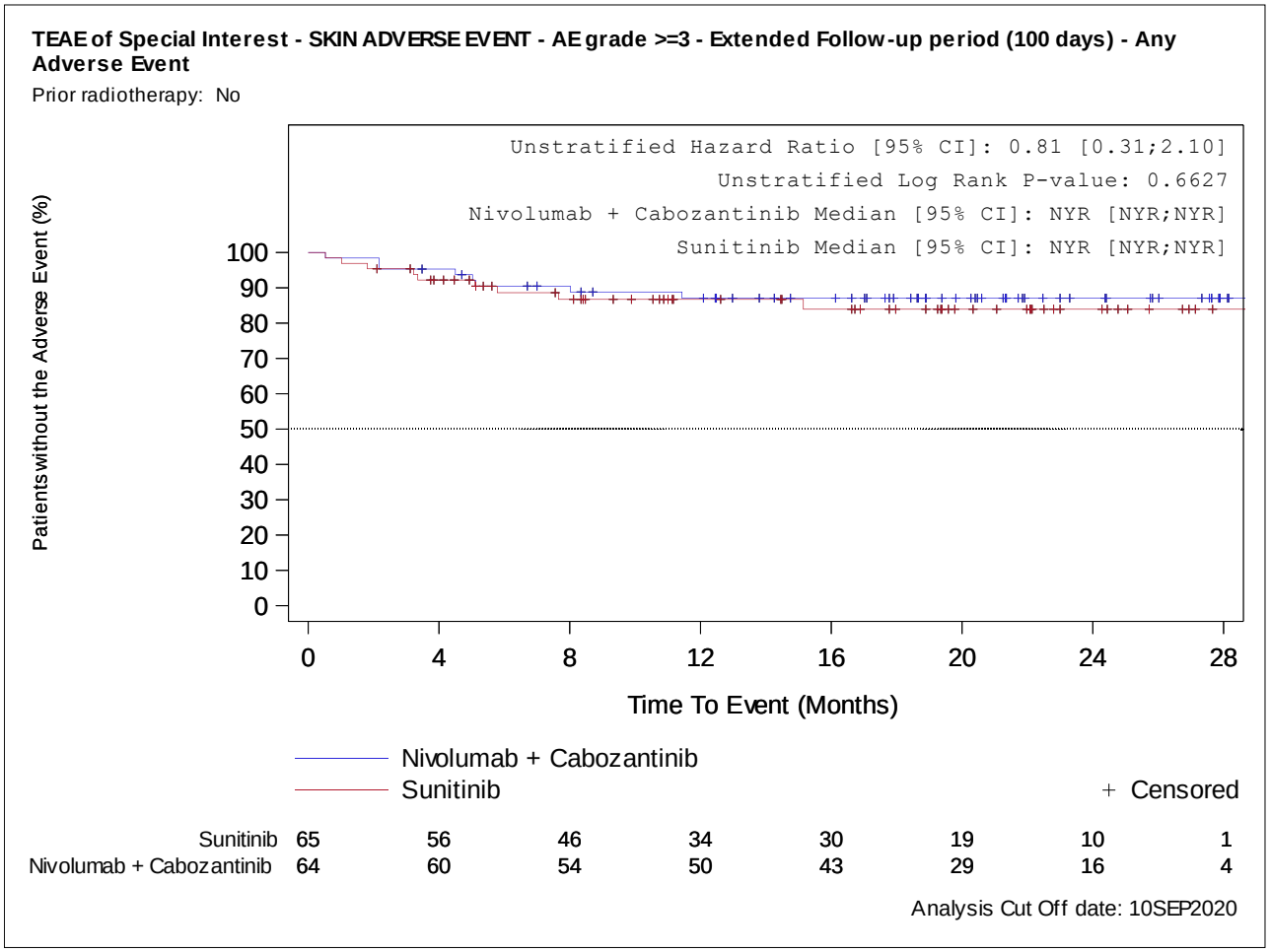

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:53:32

FIGURE 3.56.2.18: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



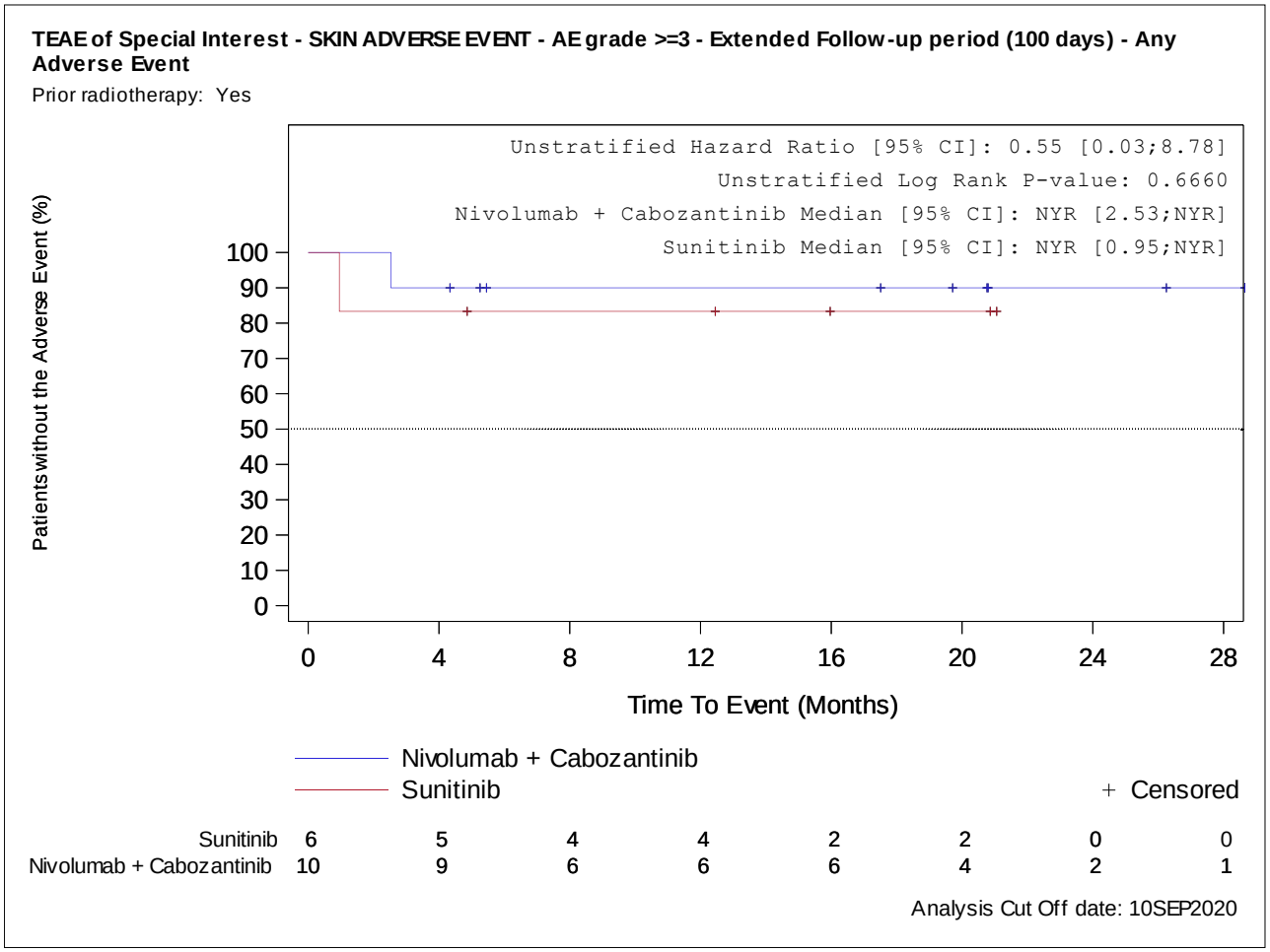

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:53:38

FIGURE 3.56.2.19: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



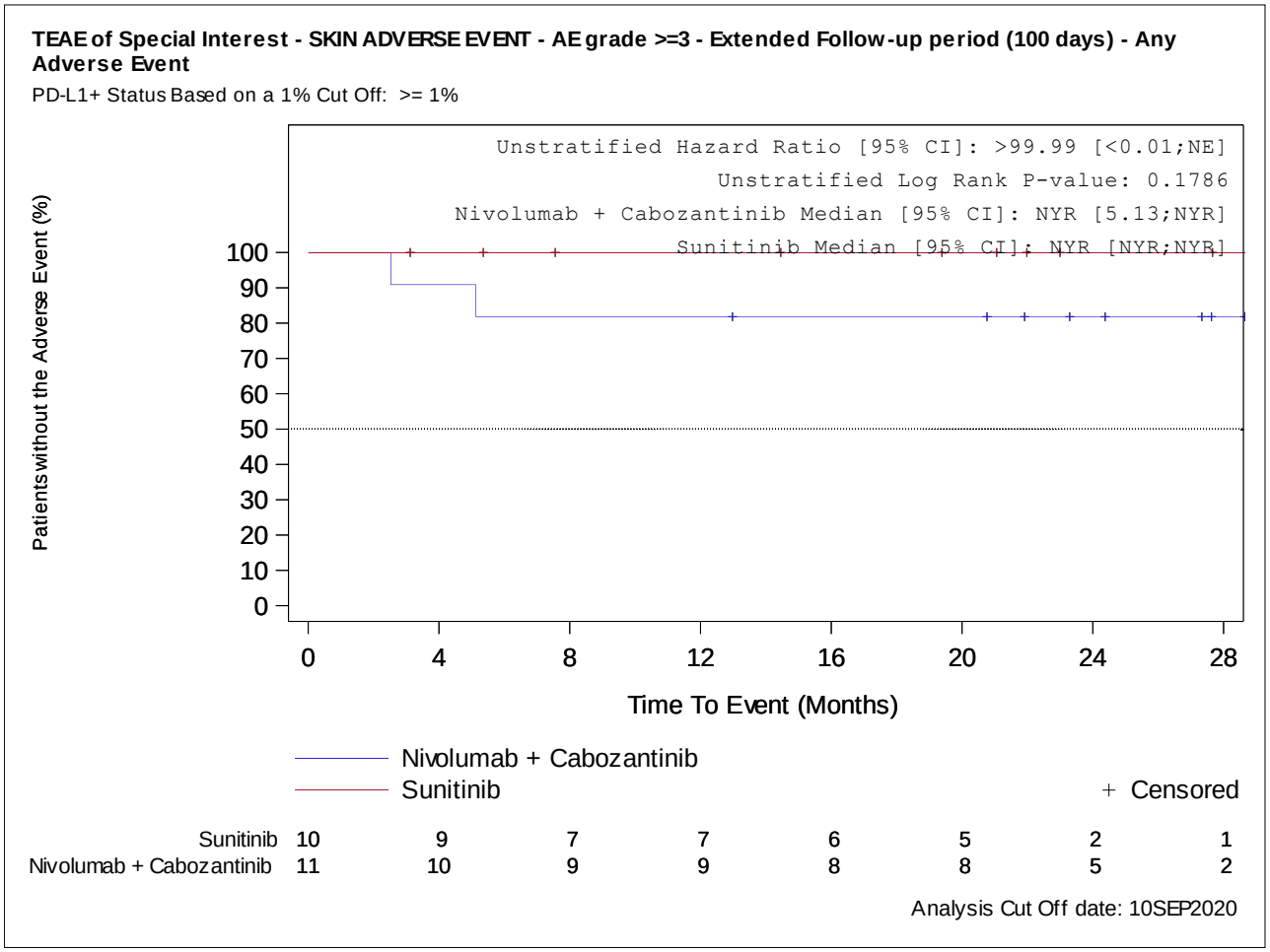

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:53:43

FIGURE 3.56.2.20: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



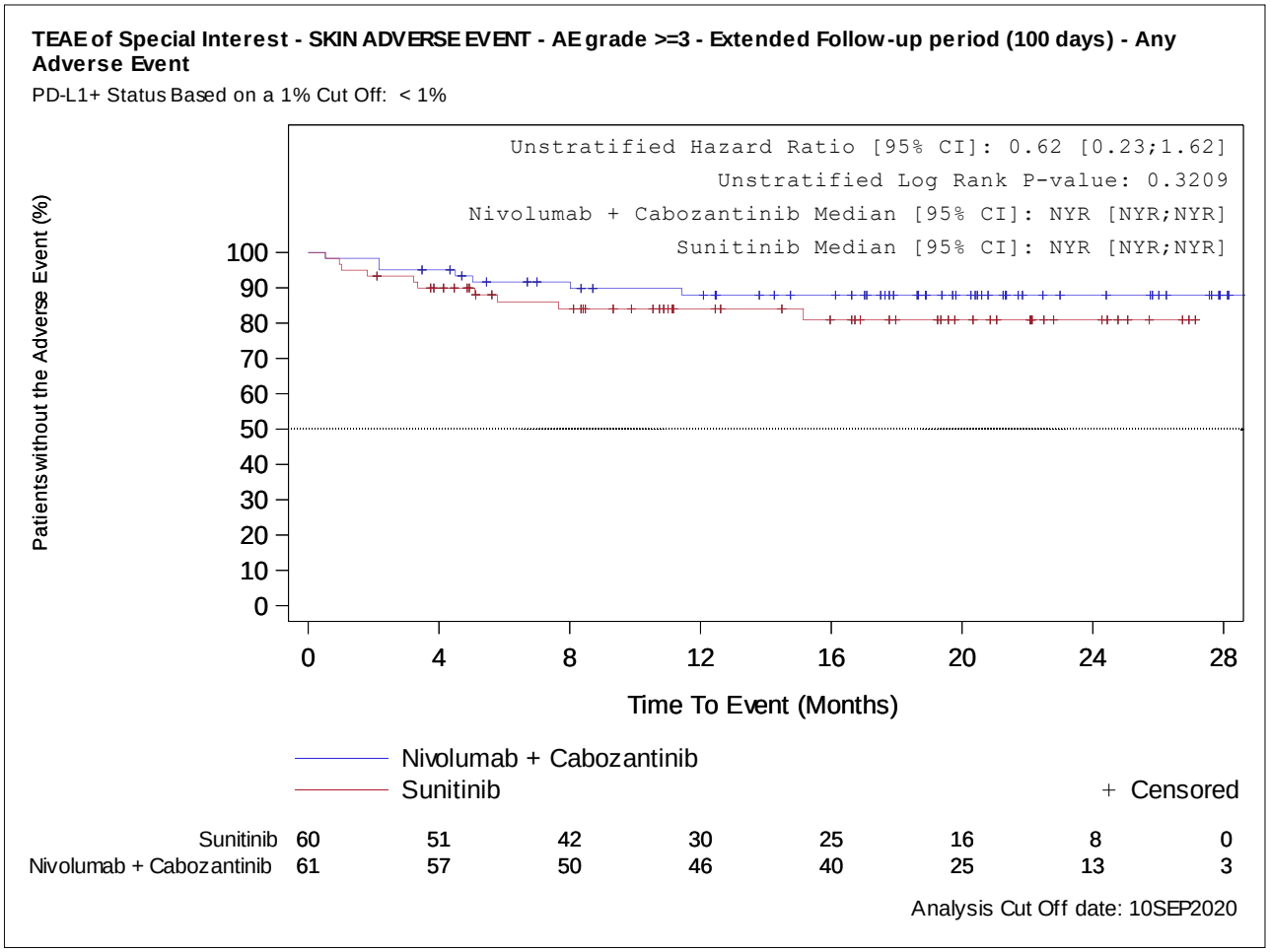

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:53:48

FIGURE 3.56.2.21: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off:  >= 1%



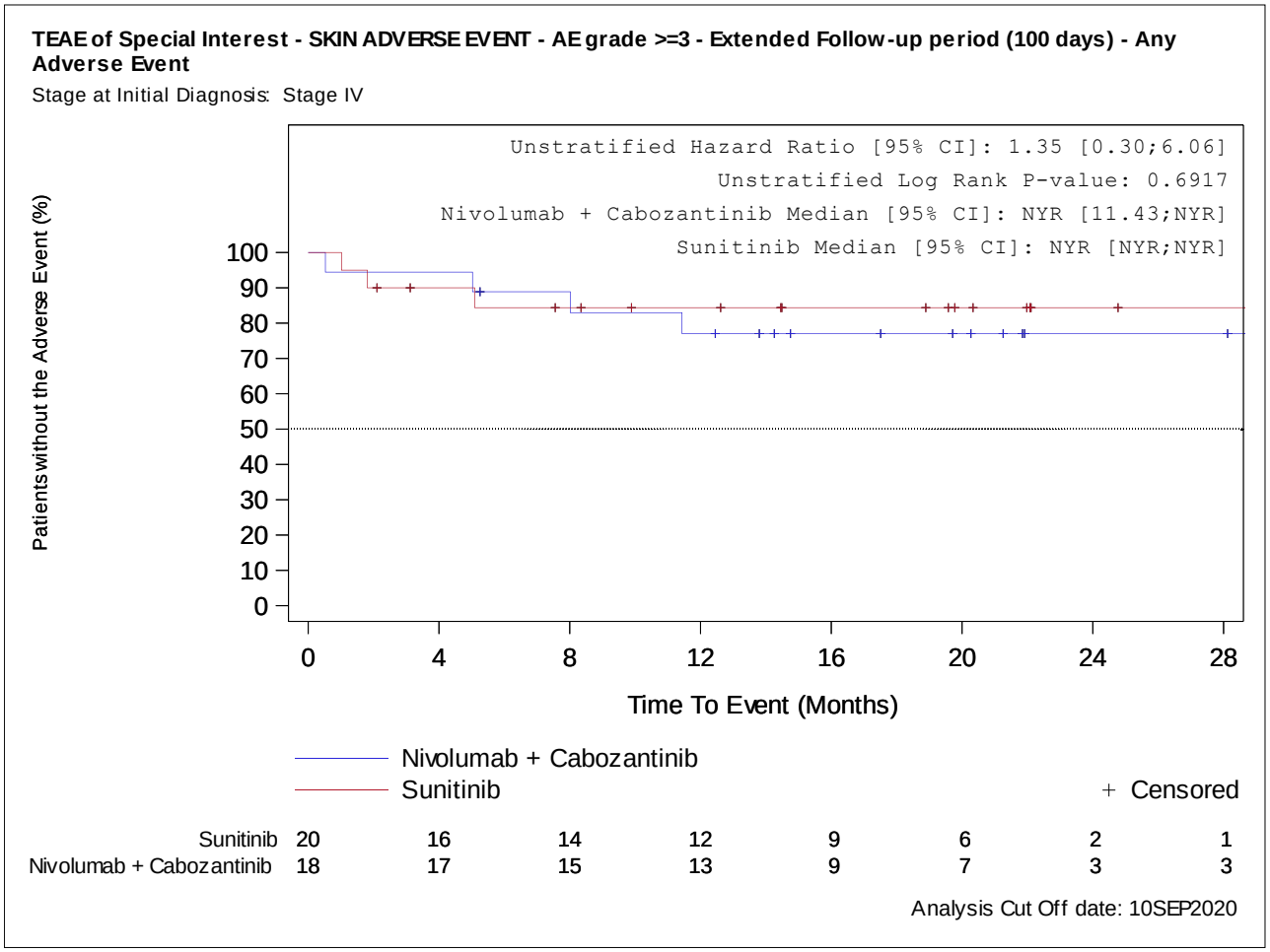

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:53:53

FIGURE 3.56.2.22: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



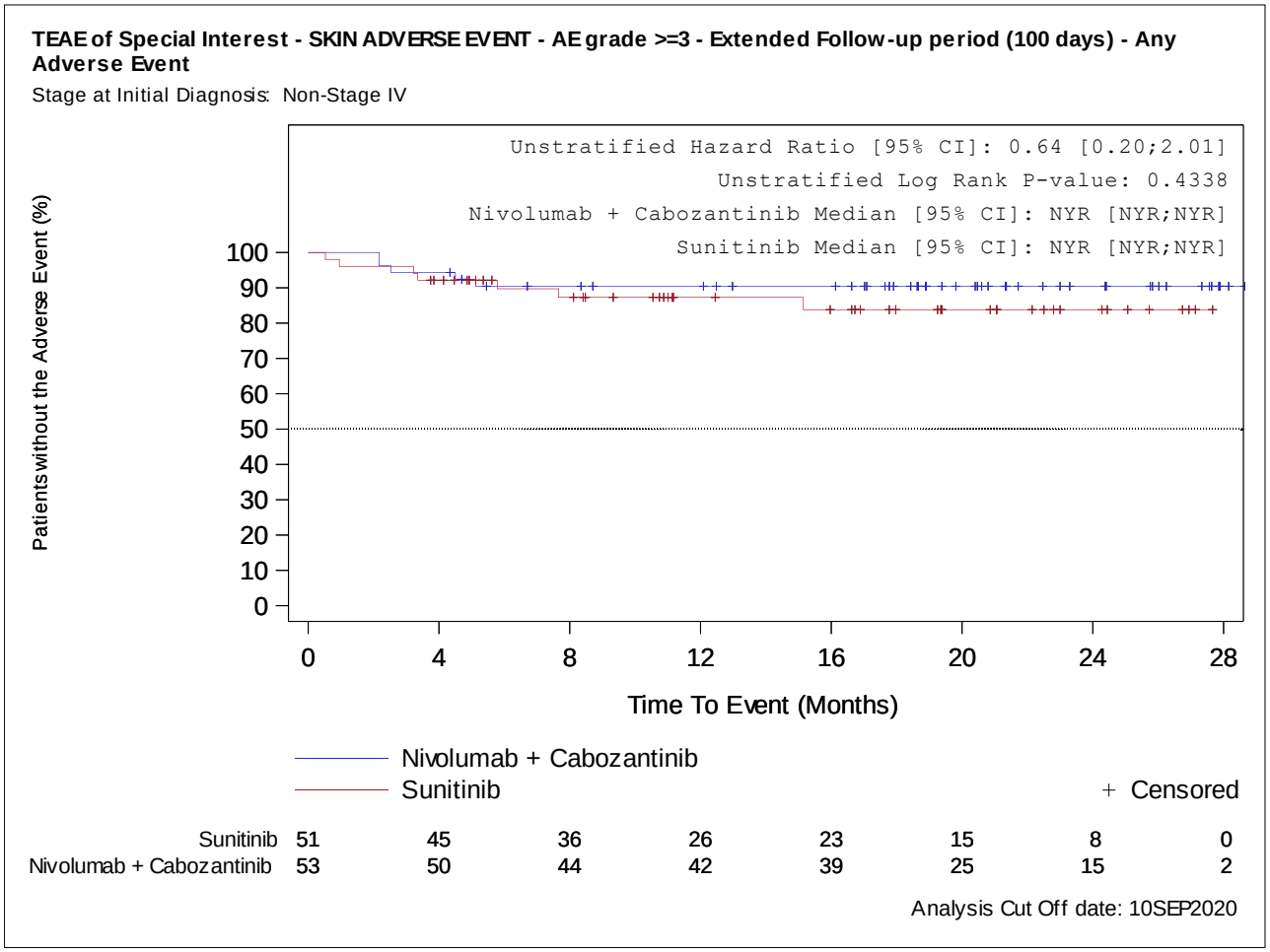

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:53:59

FIGURE 3.56.2.23: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



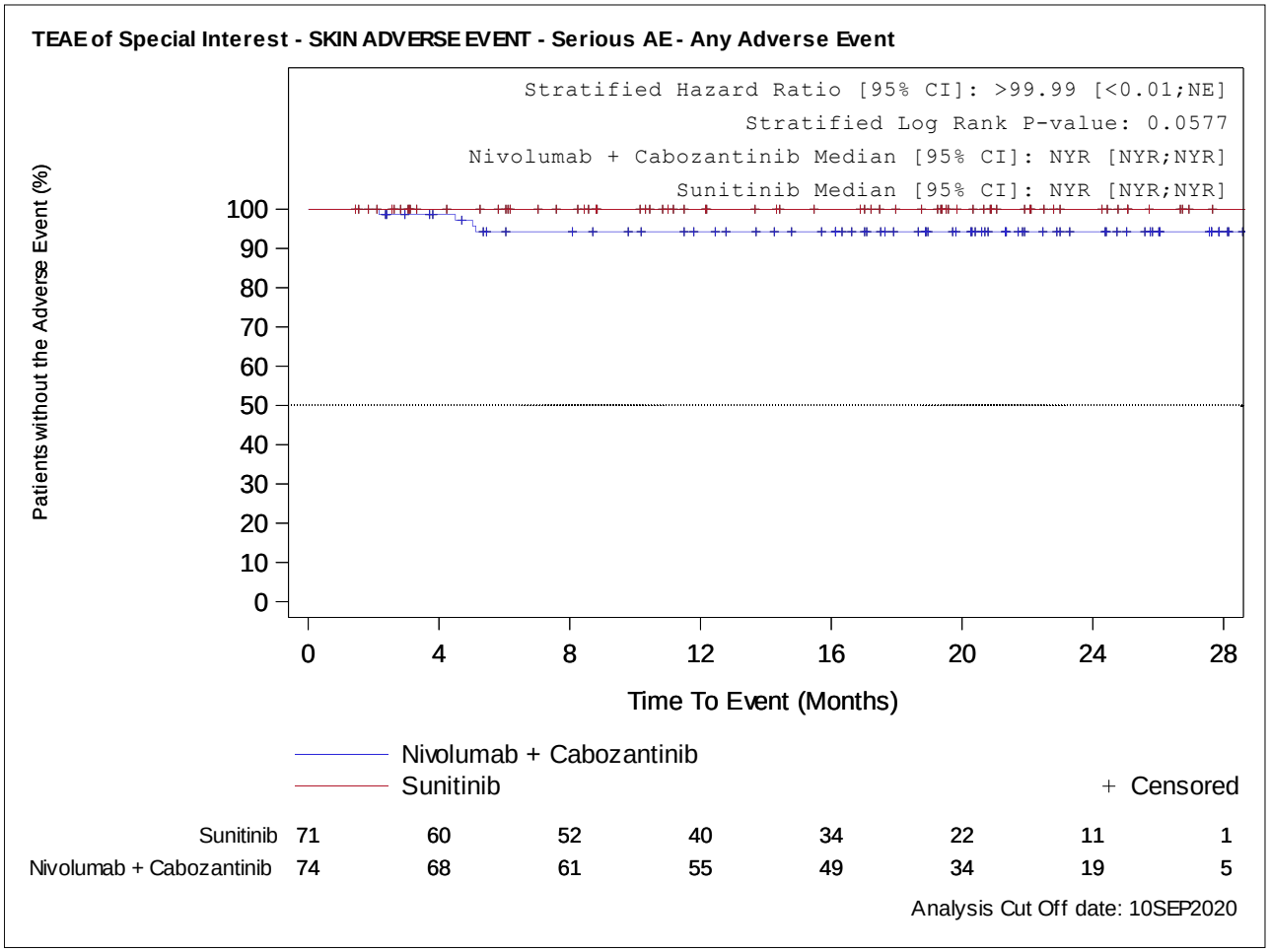

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:54:25

FIGURE 3.56.2.24: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



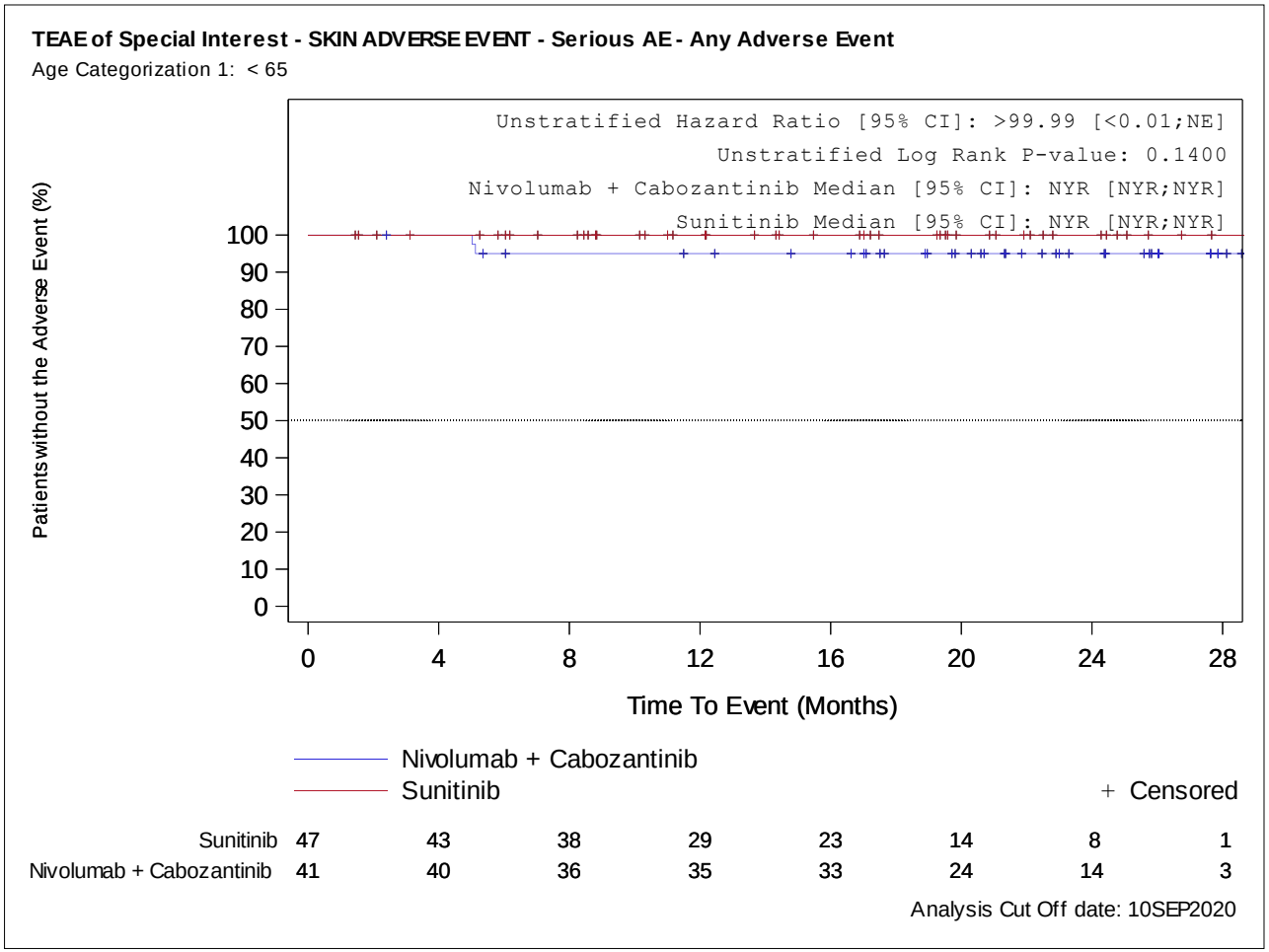

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:54:30

FIGURE 3.57.1: TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



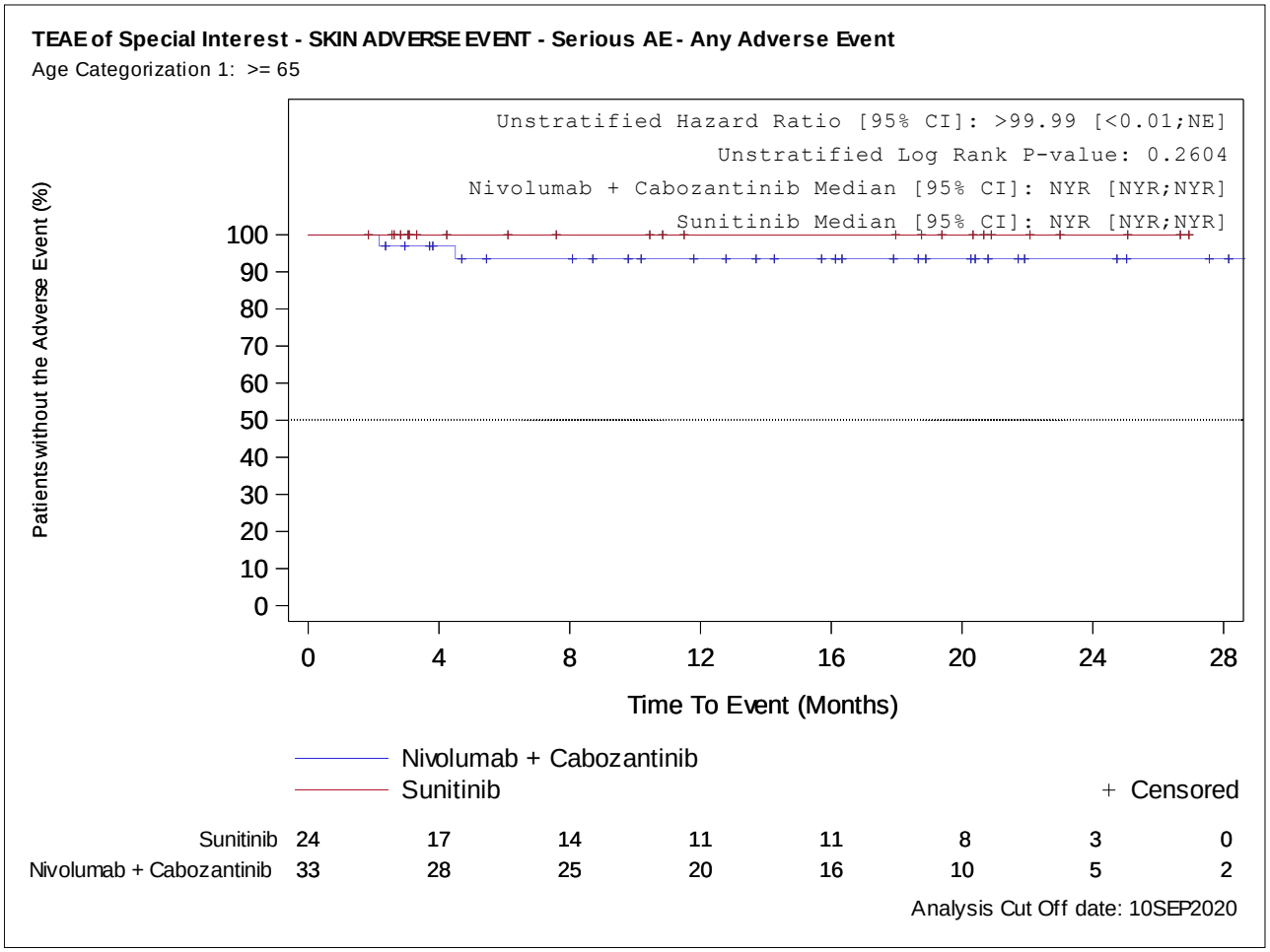

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:57:26

FIGURE 3.57.2.1: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



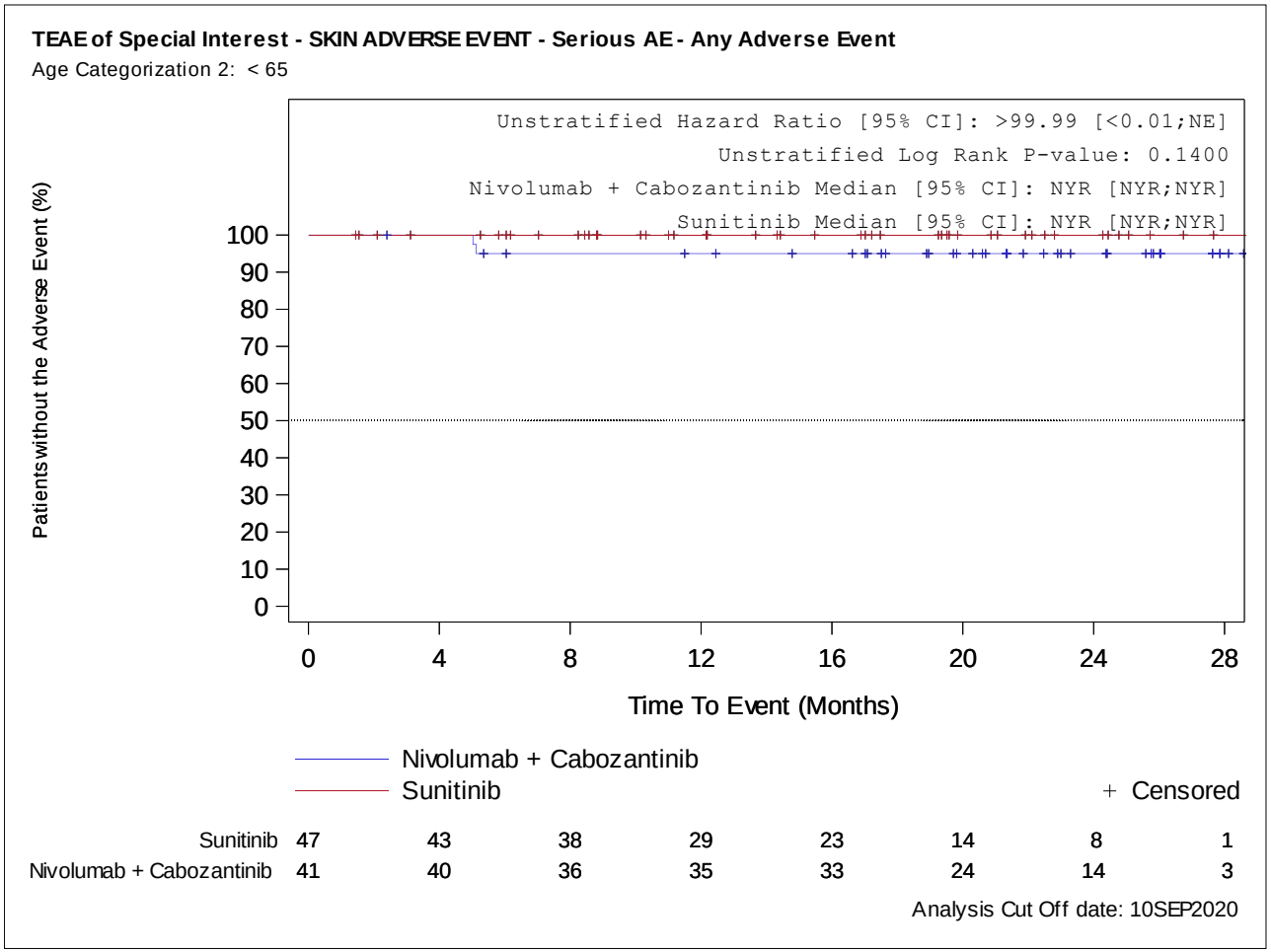

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:57:30

FIGURE 3.57.2.2: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



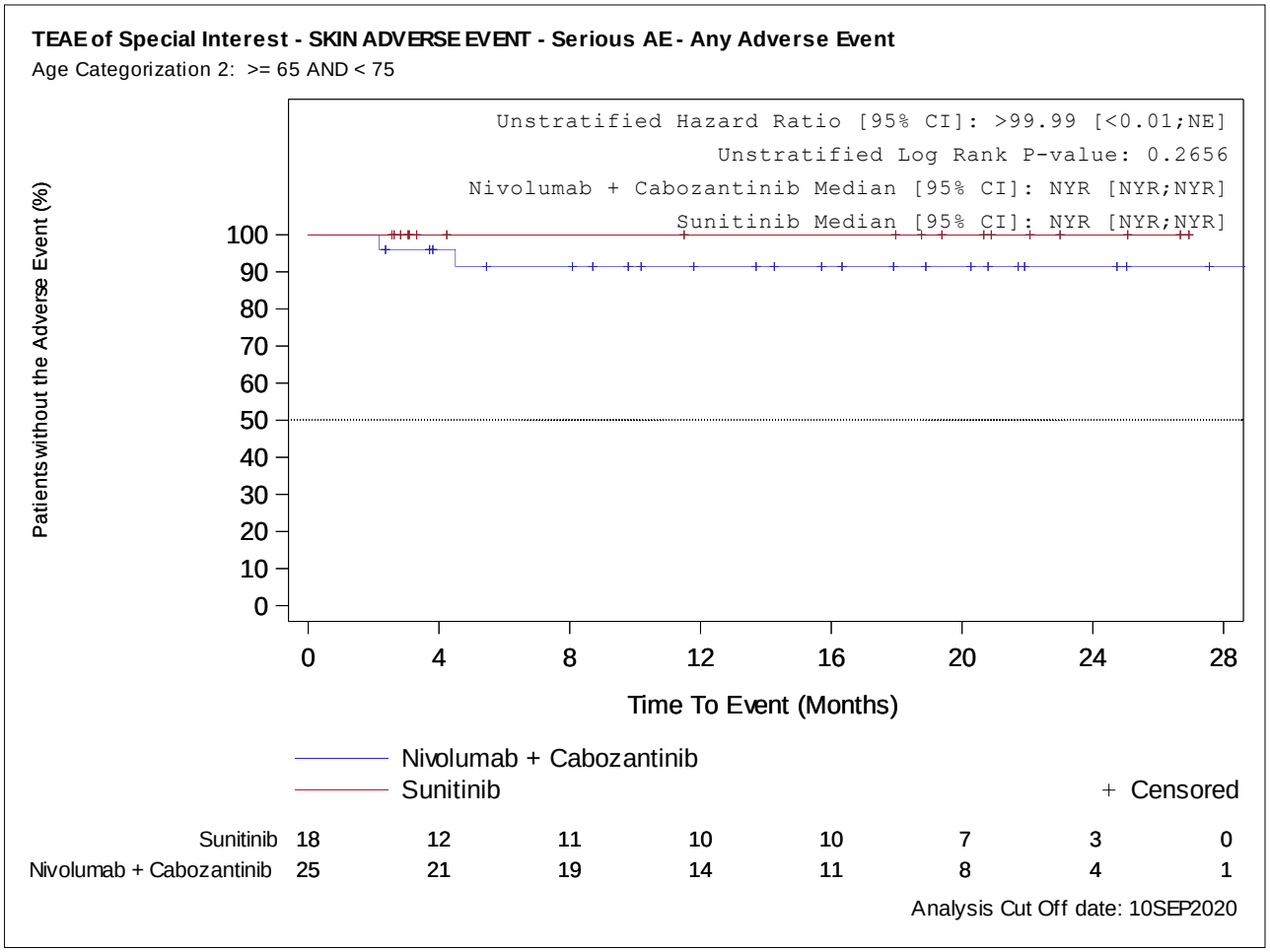

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:57:35

FIGURE 3.57.2.3: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



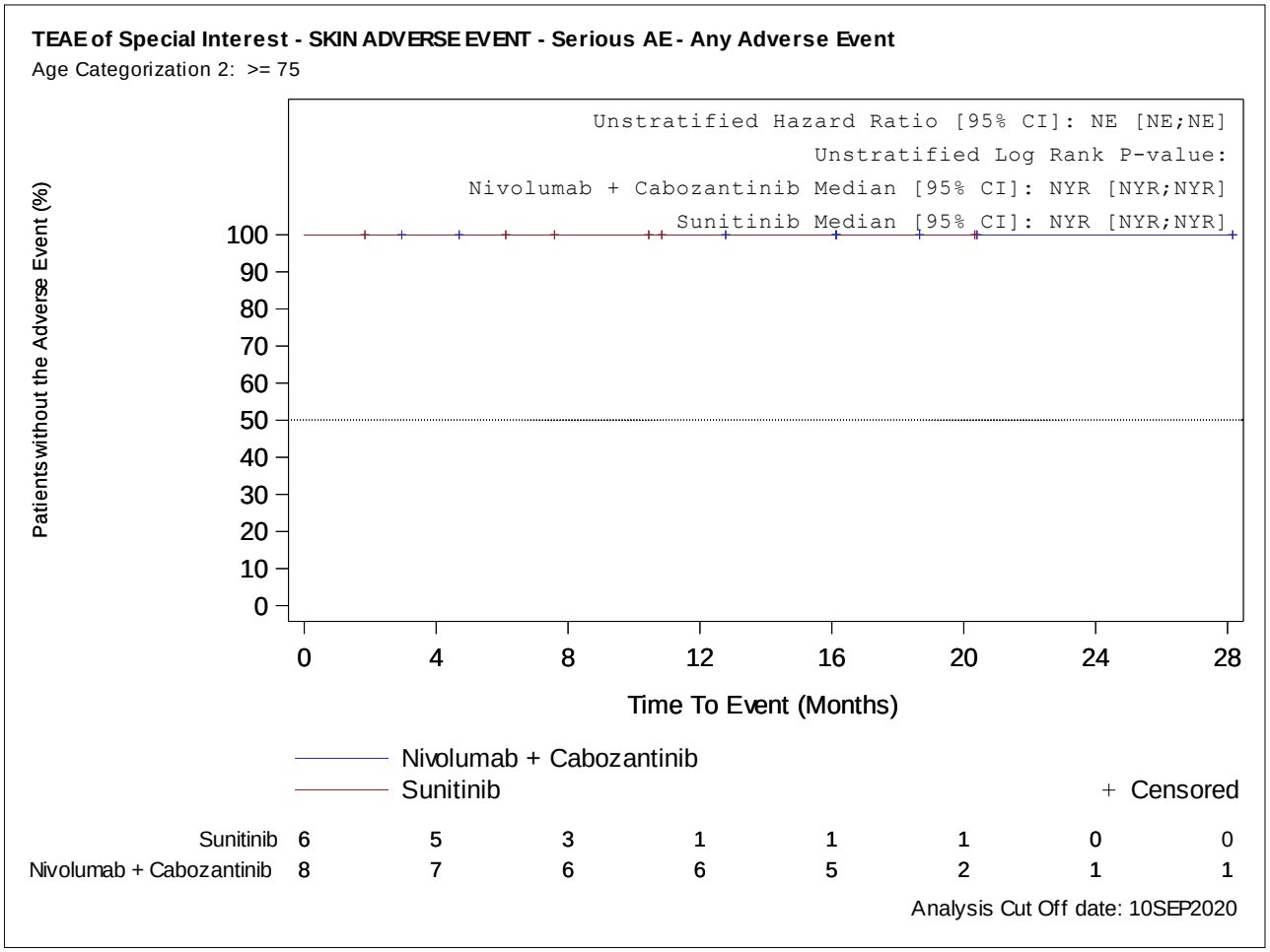

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:57:40

FIGURE 3.57.2.4: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



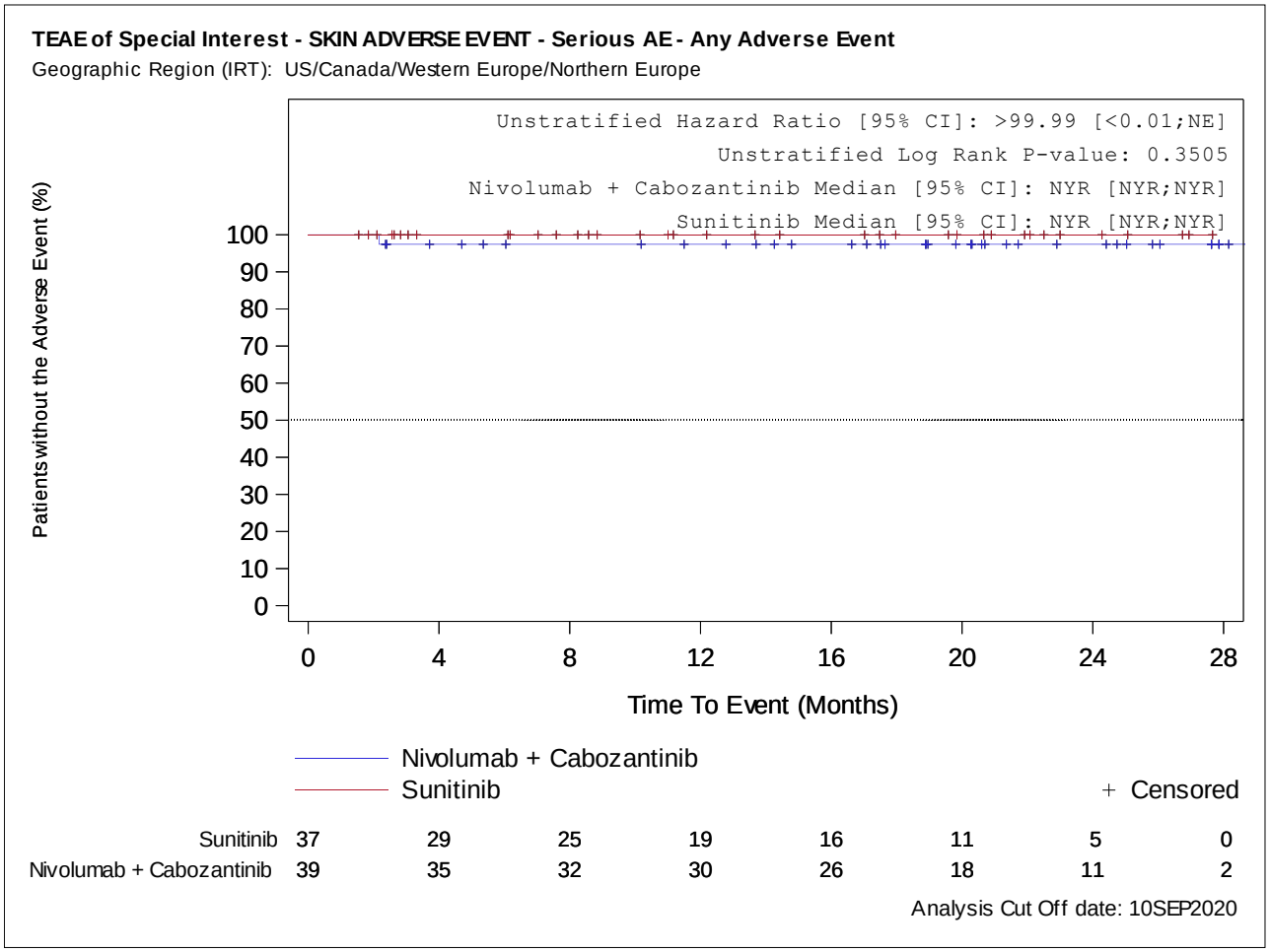

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:57:45

FIGURE 3.57.2.5: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



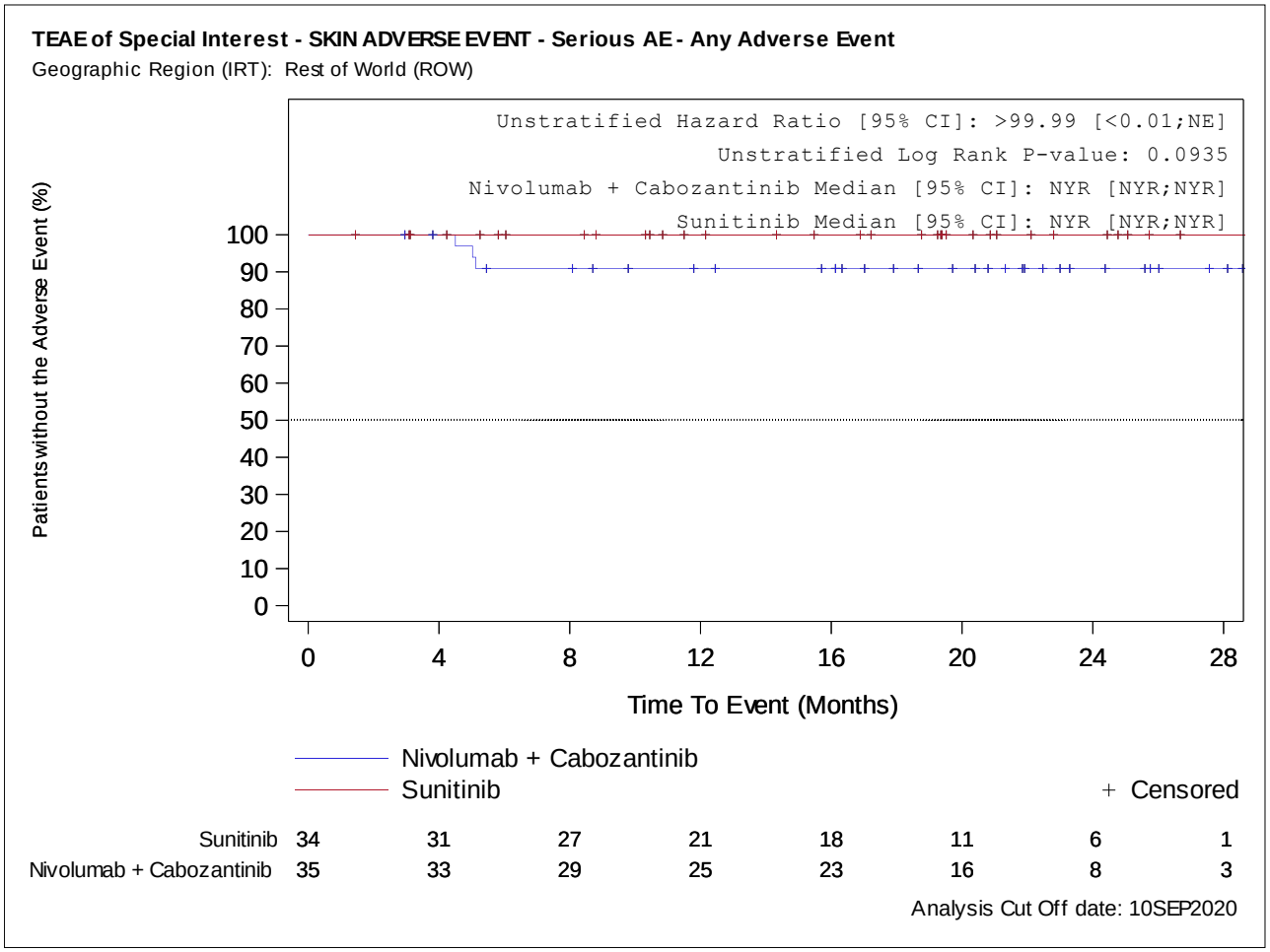

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:57:50

FIGURE 3.57.2.6: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



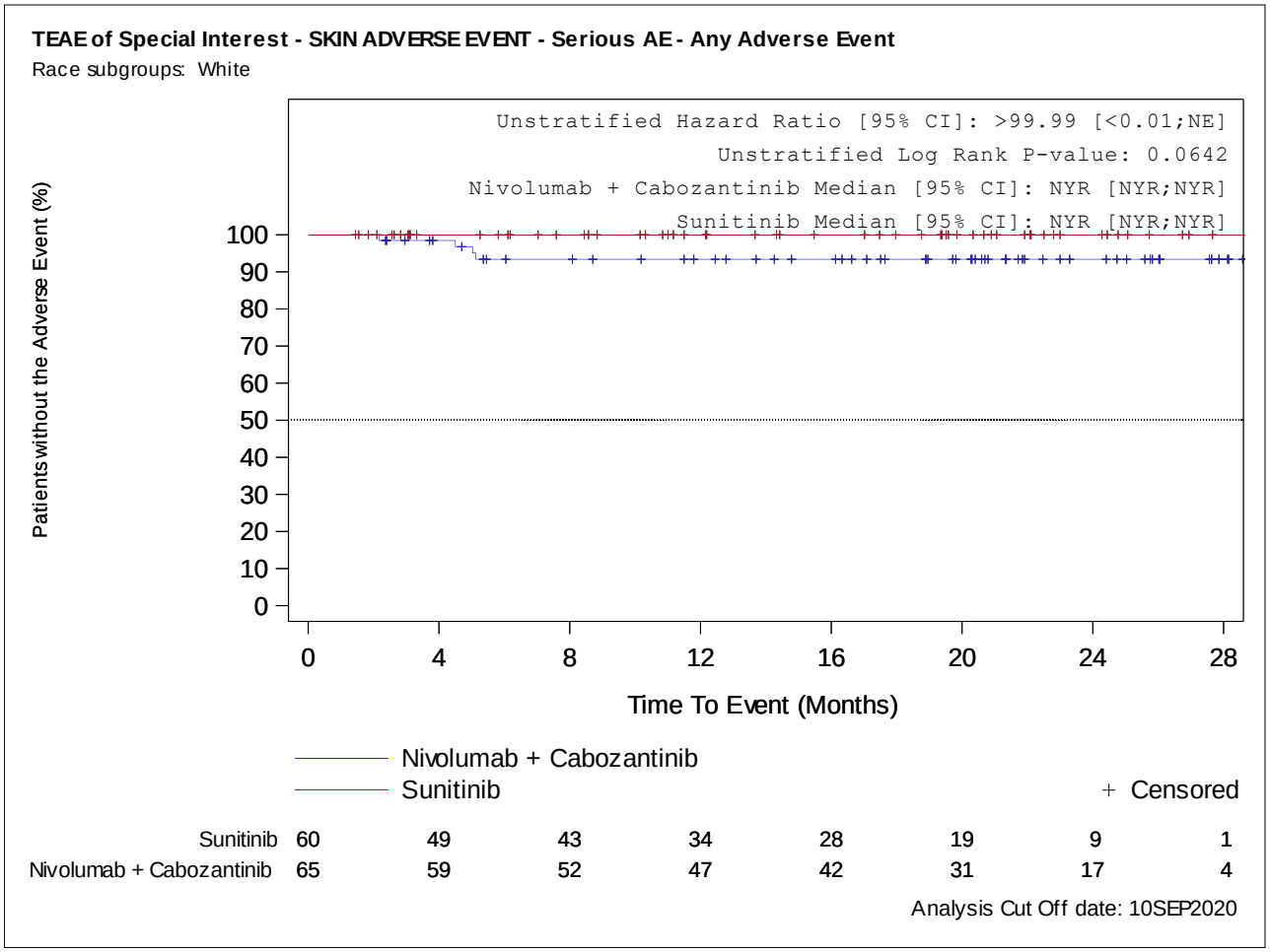

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:57:55

FIGURE 3.57.2.7: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



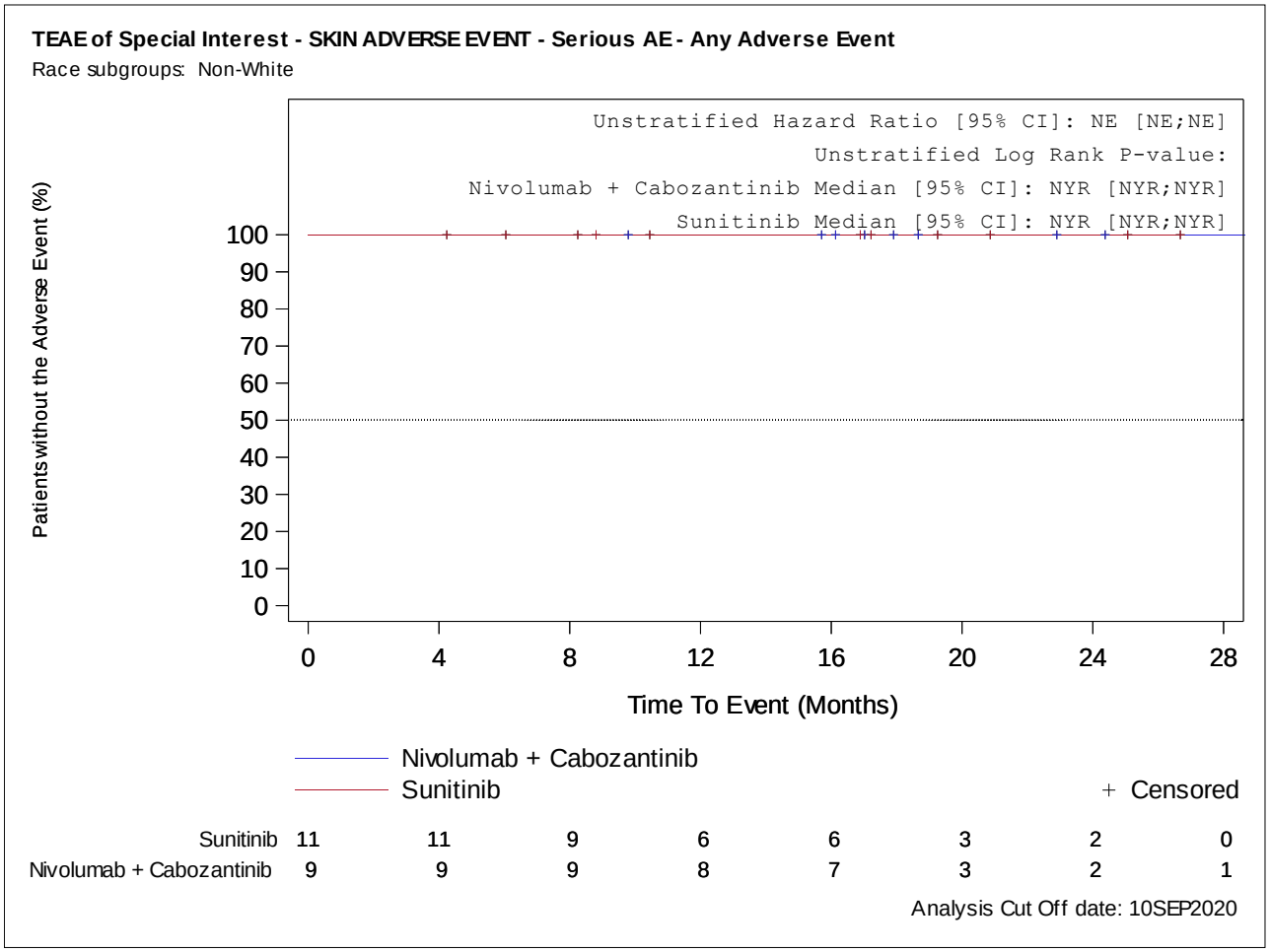

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:58:00

FIGURE 3.57.2.8: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



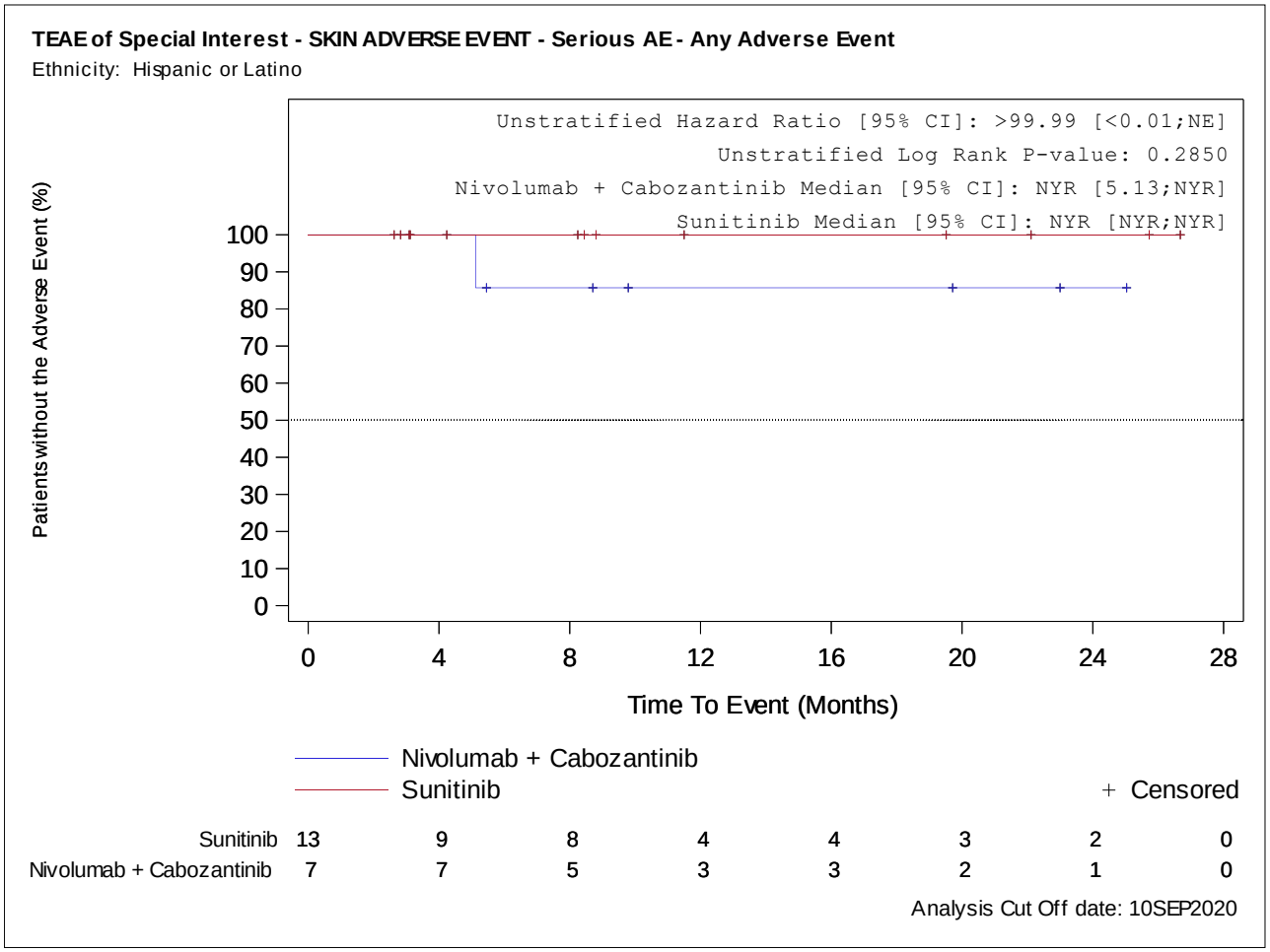

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:58:05

FIGURE 3.57.2.9: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



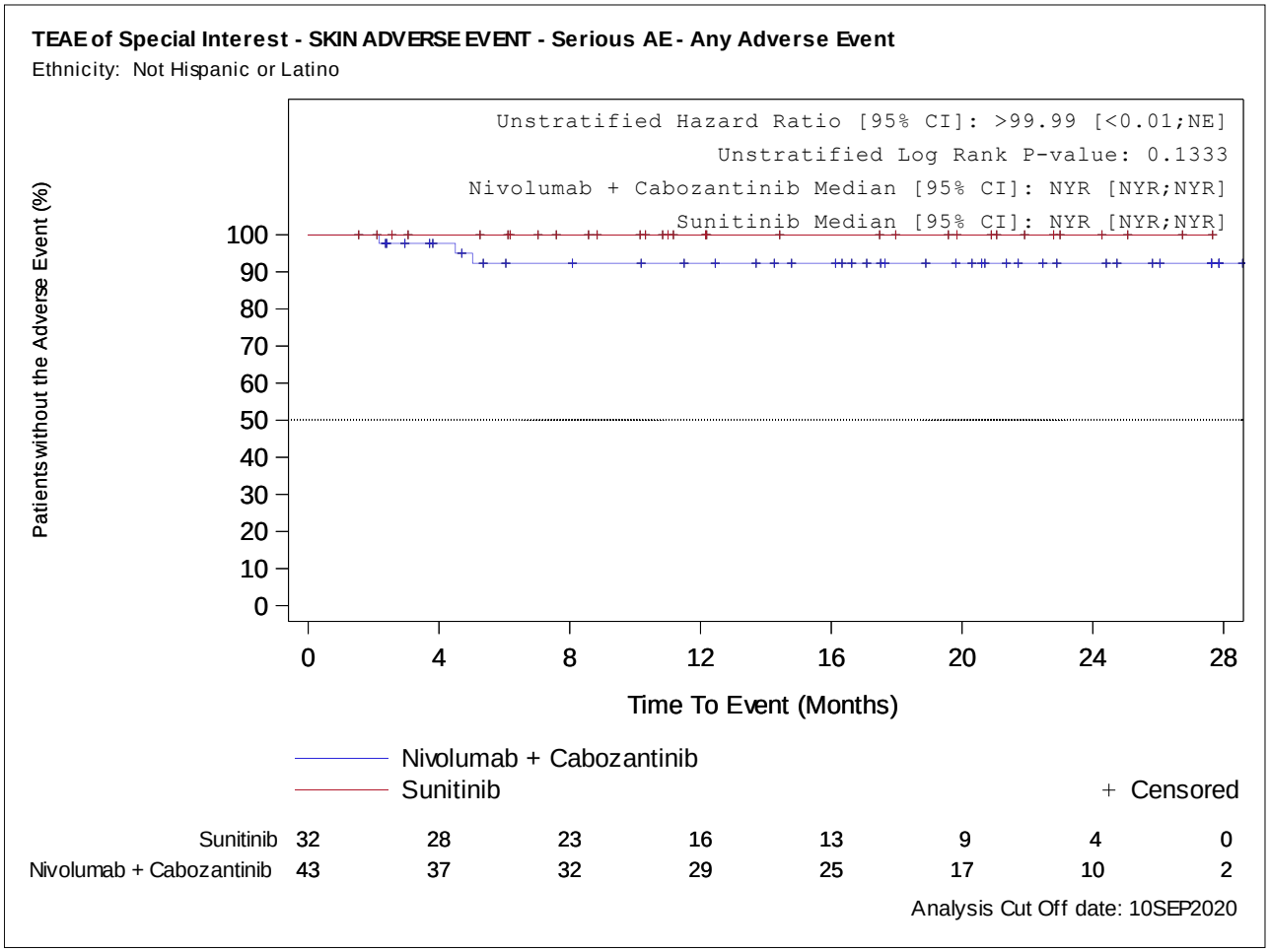

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:58:10

FIGURE 3.57.2.10: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



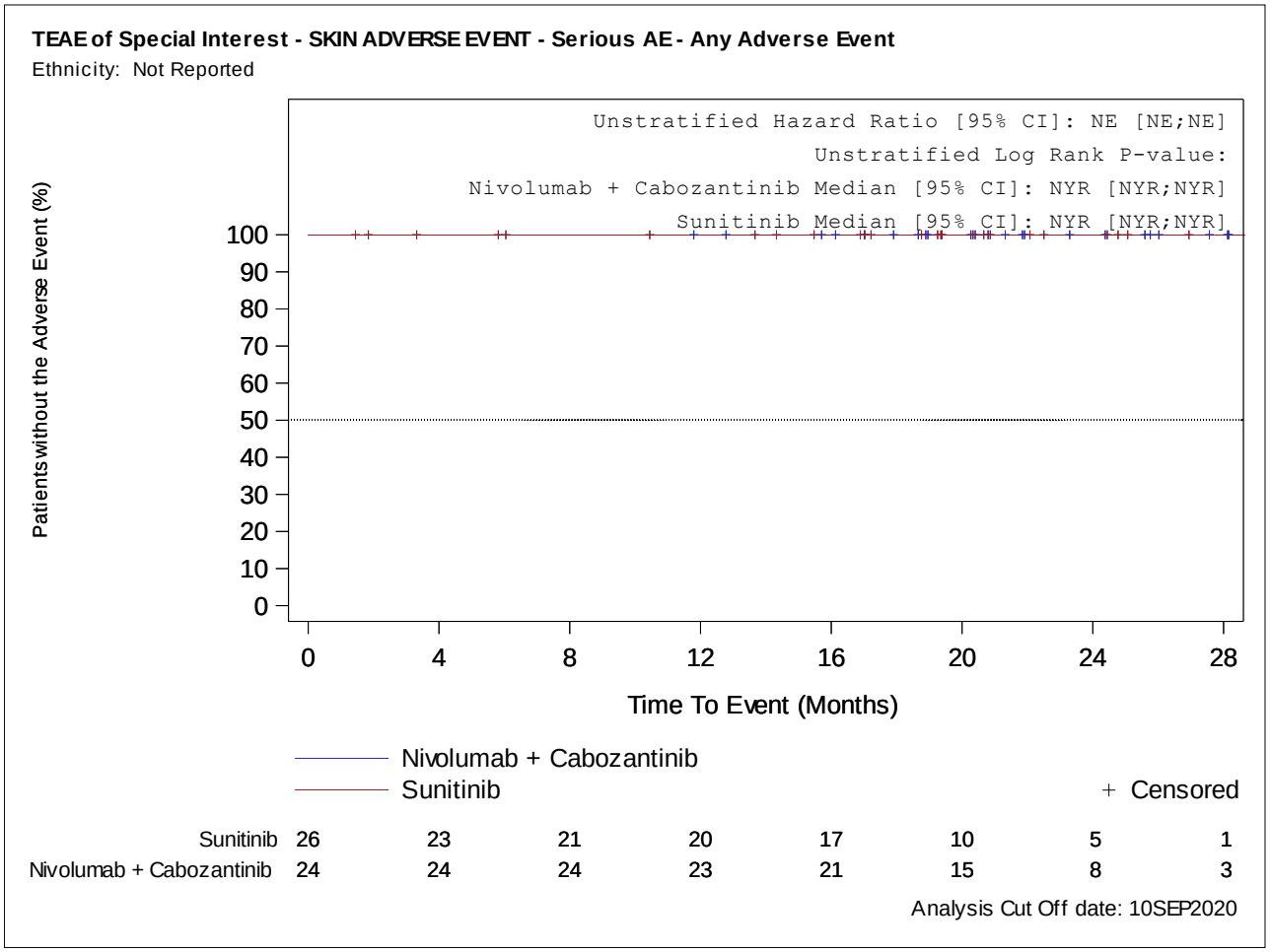

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:58:15

FIGURE 3.57.2.11: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



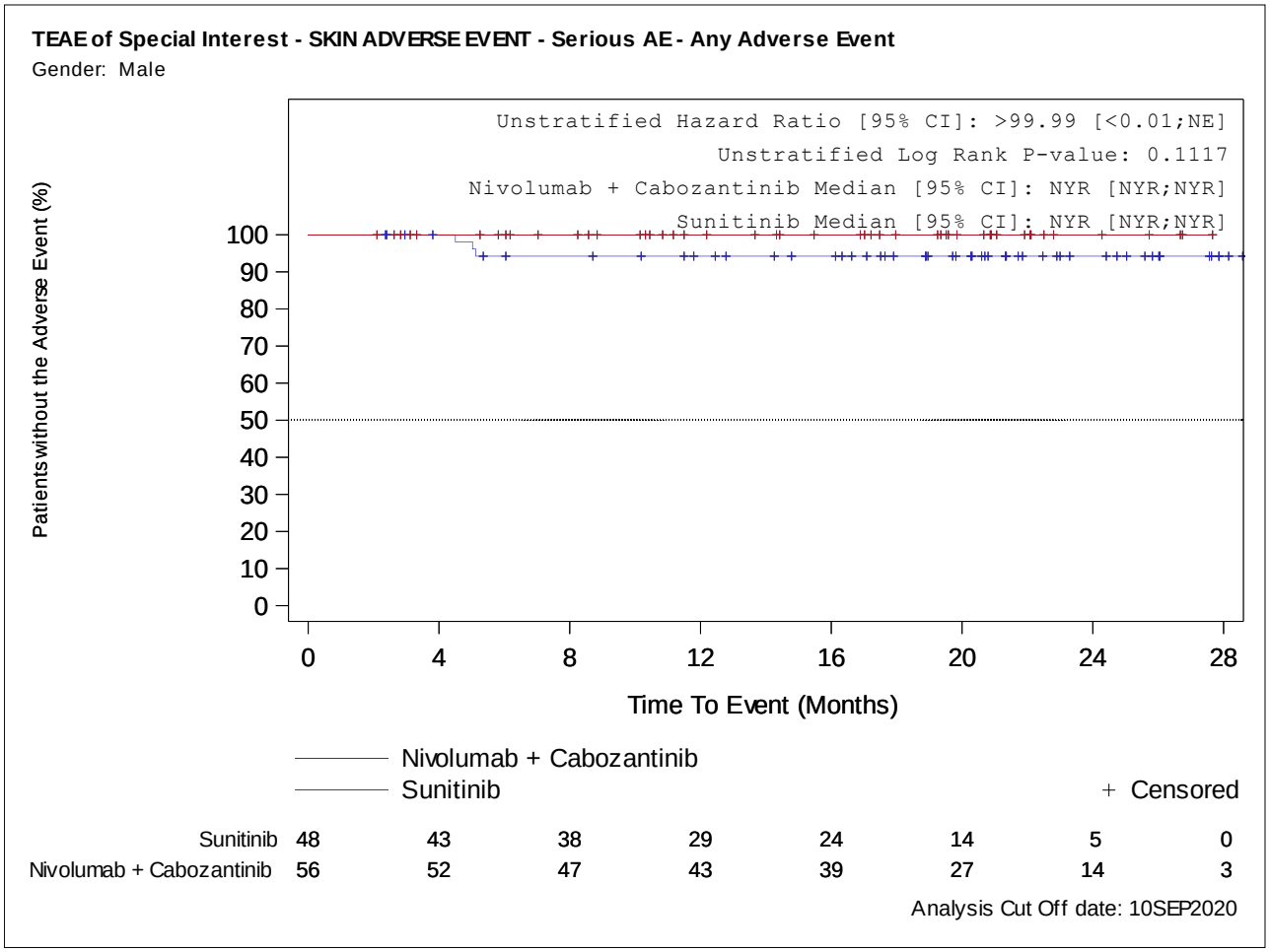

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:58:21

FIGURE 3.57.2.12: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



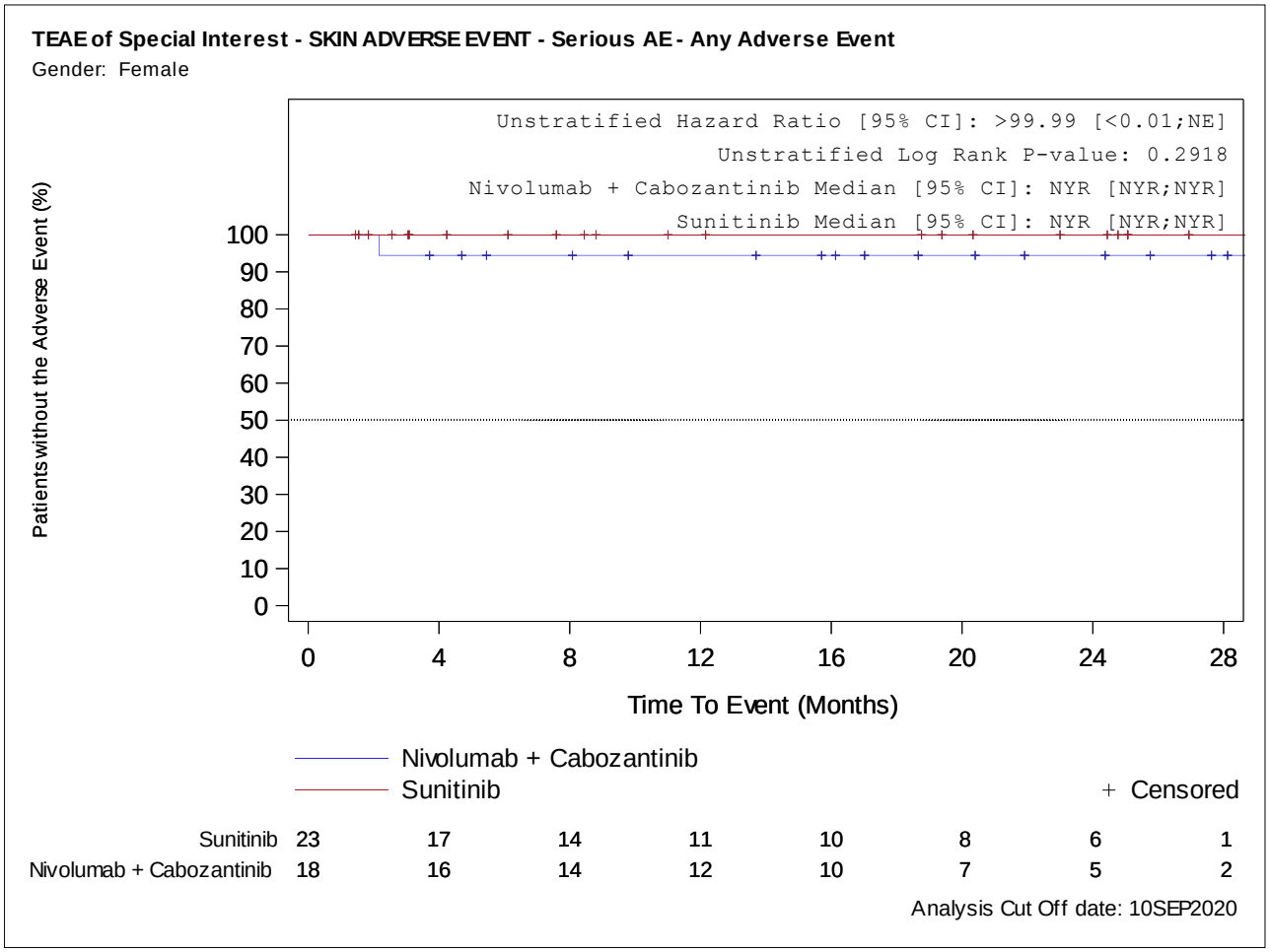

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:58:26

FIGURE 3.57.2.13: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



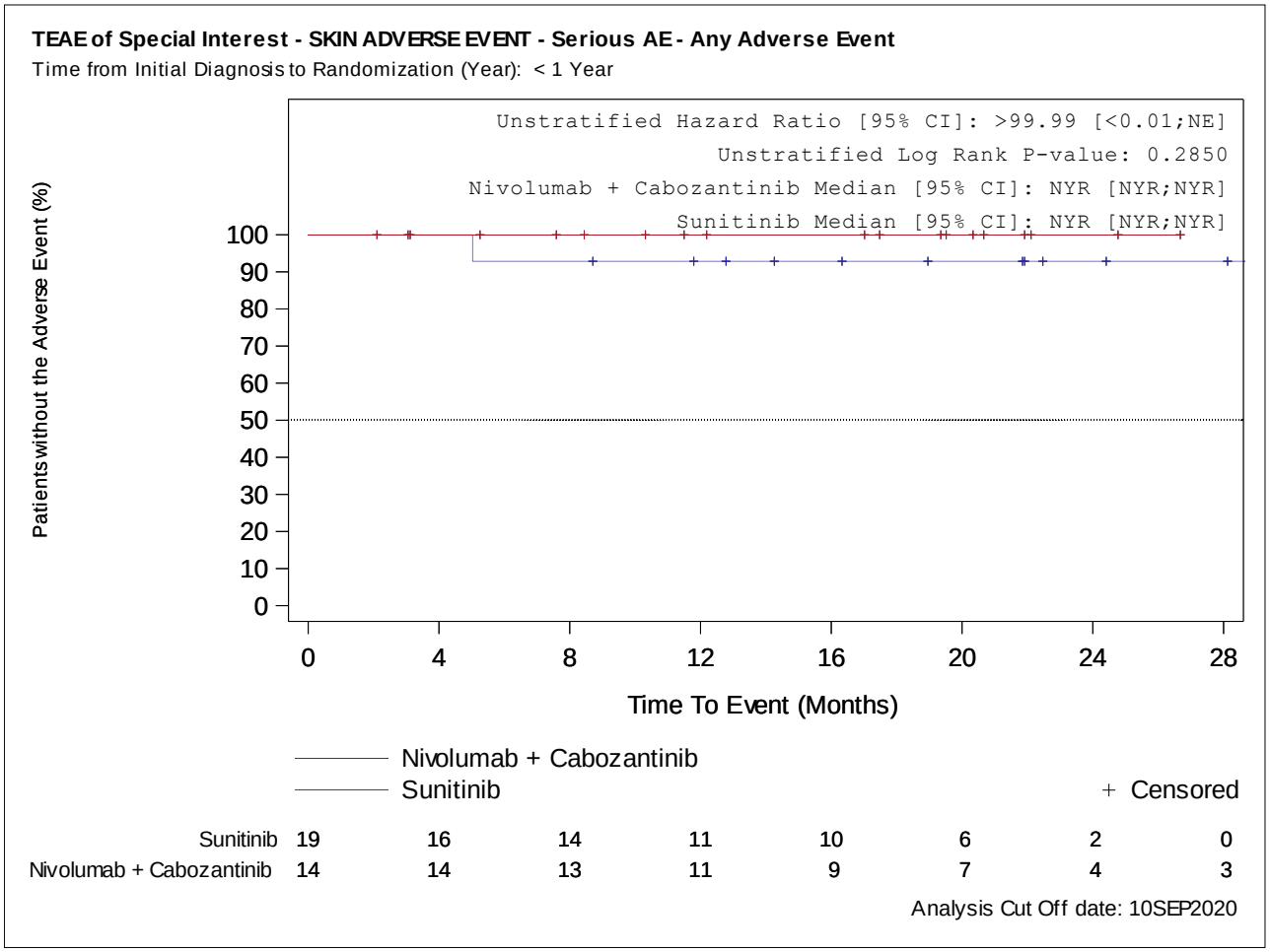

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:58:31

FIGURE 3.57.2.14: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



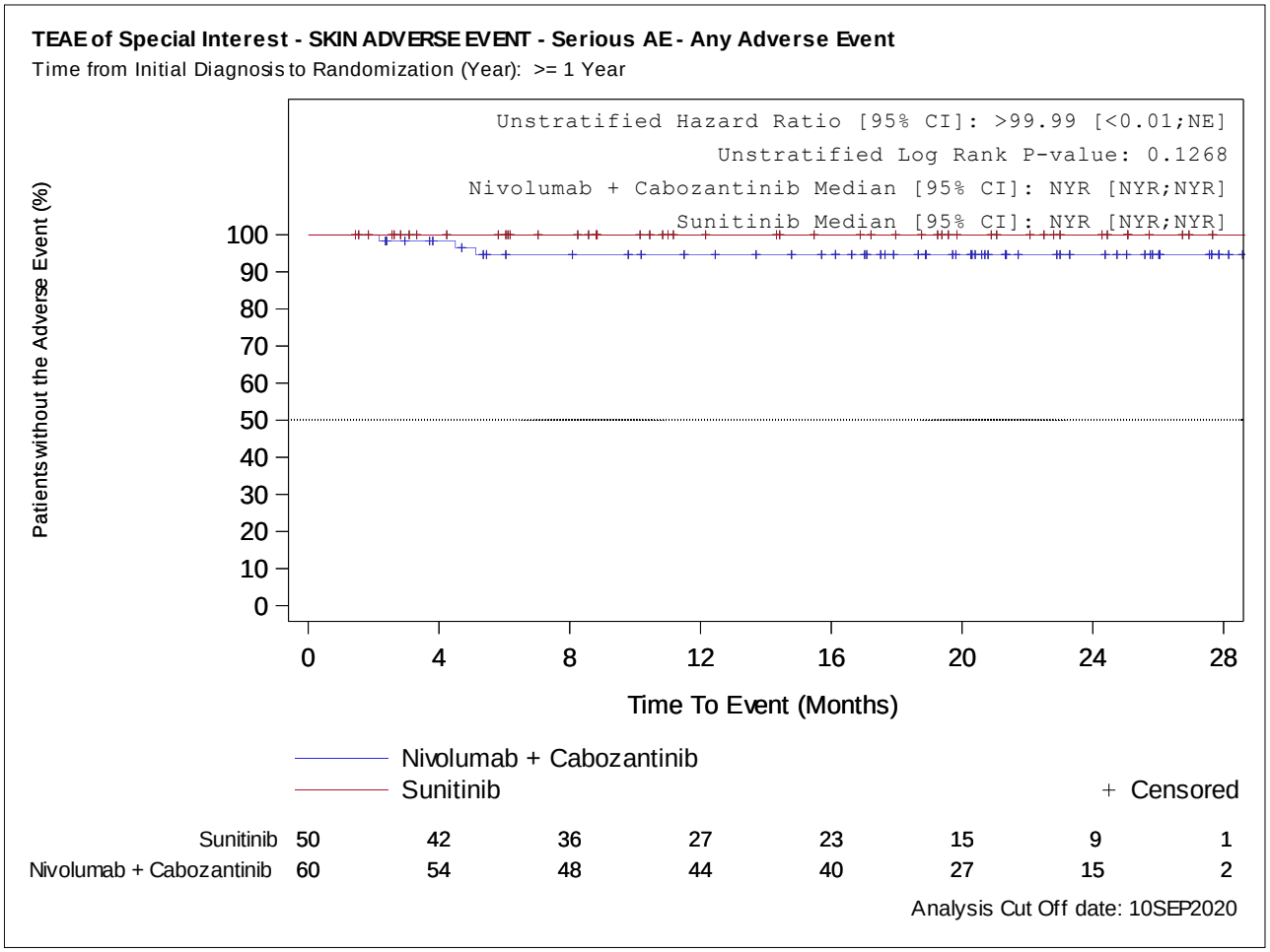

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:58:37

FIGURE 3.57.2.15: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



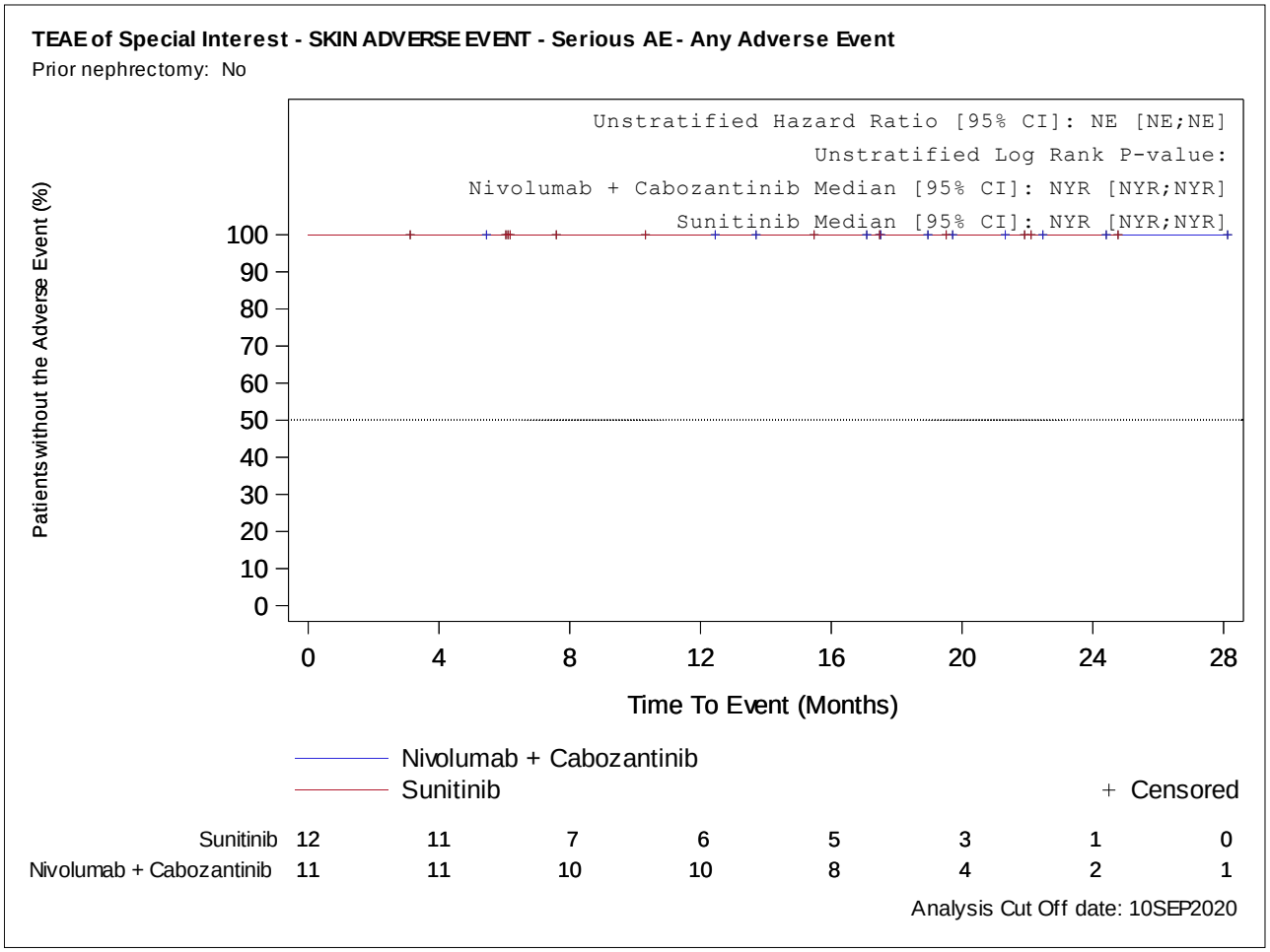

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:58:52

FIGURE 3.57.2.16: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



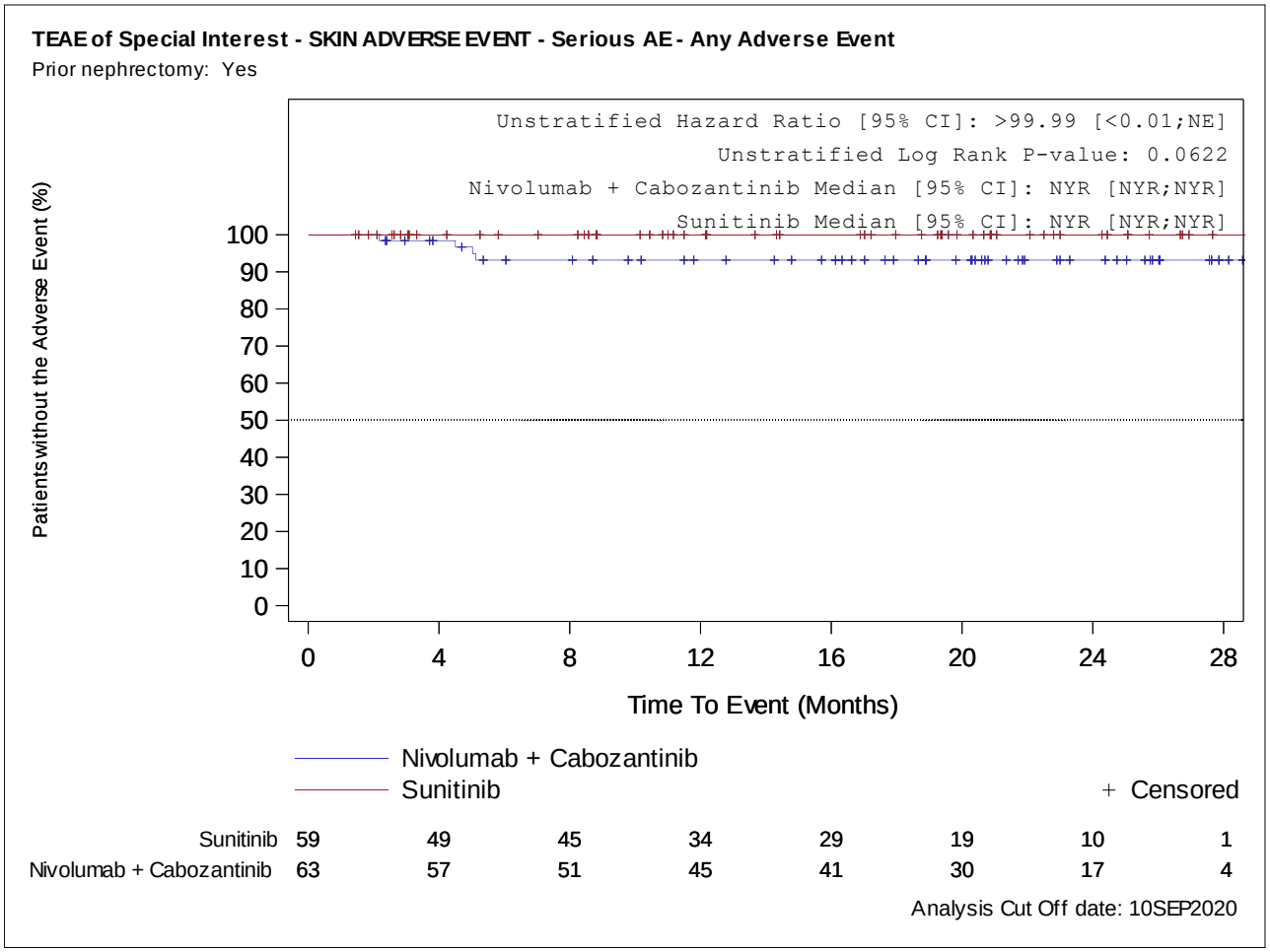

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:58:57

FIGURE 3.57.2.17: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



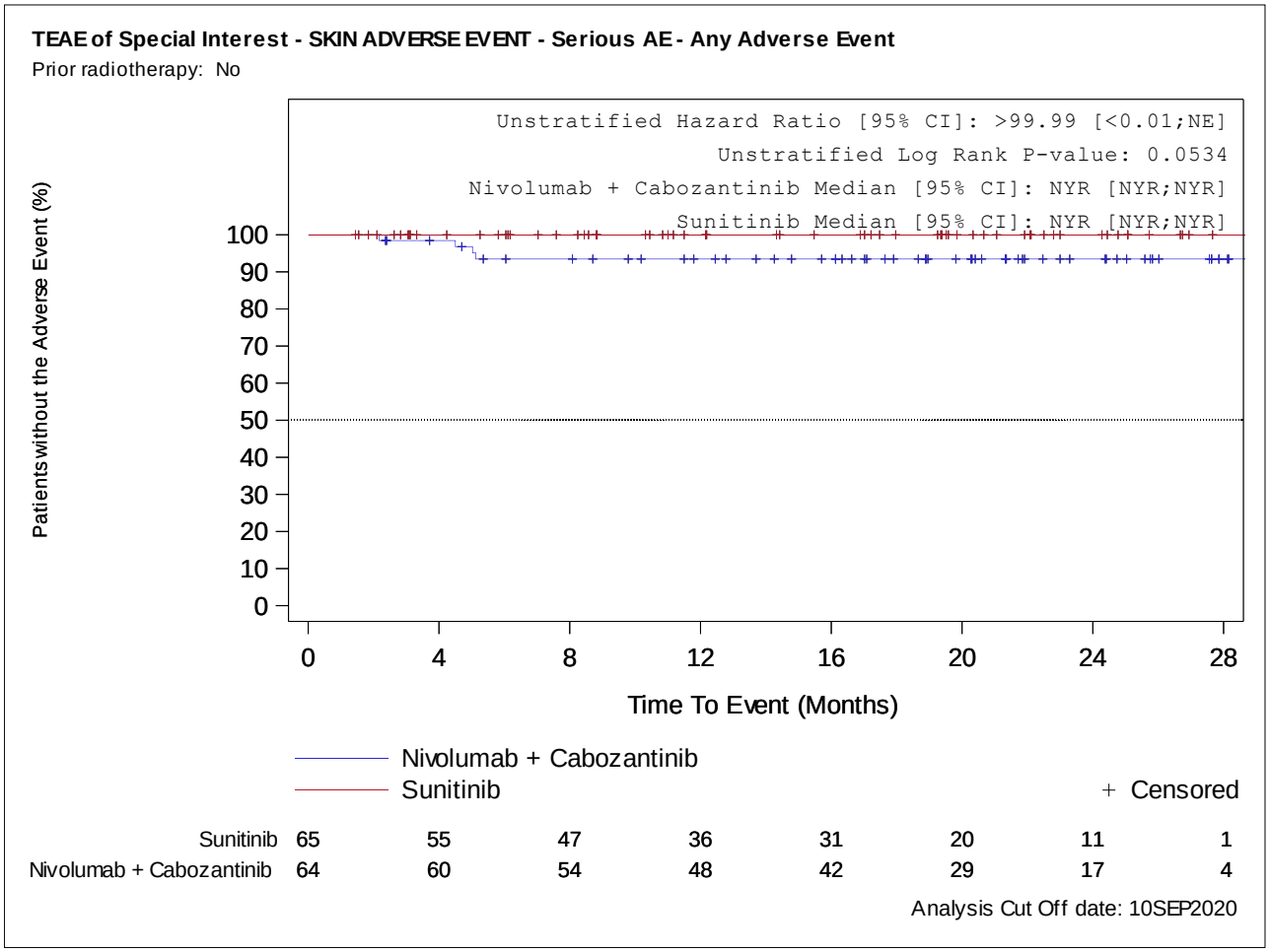

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:59:44

FIGURE 3.57.2.18: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



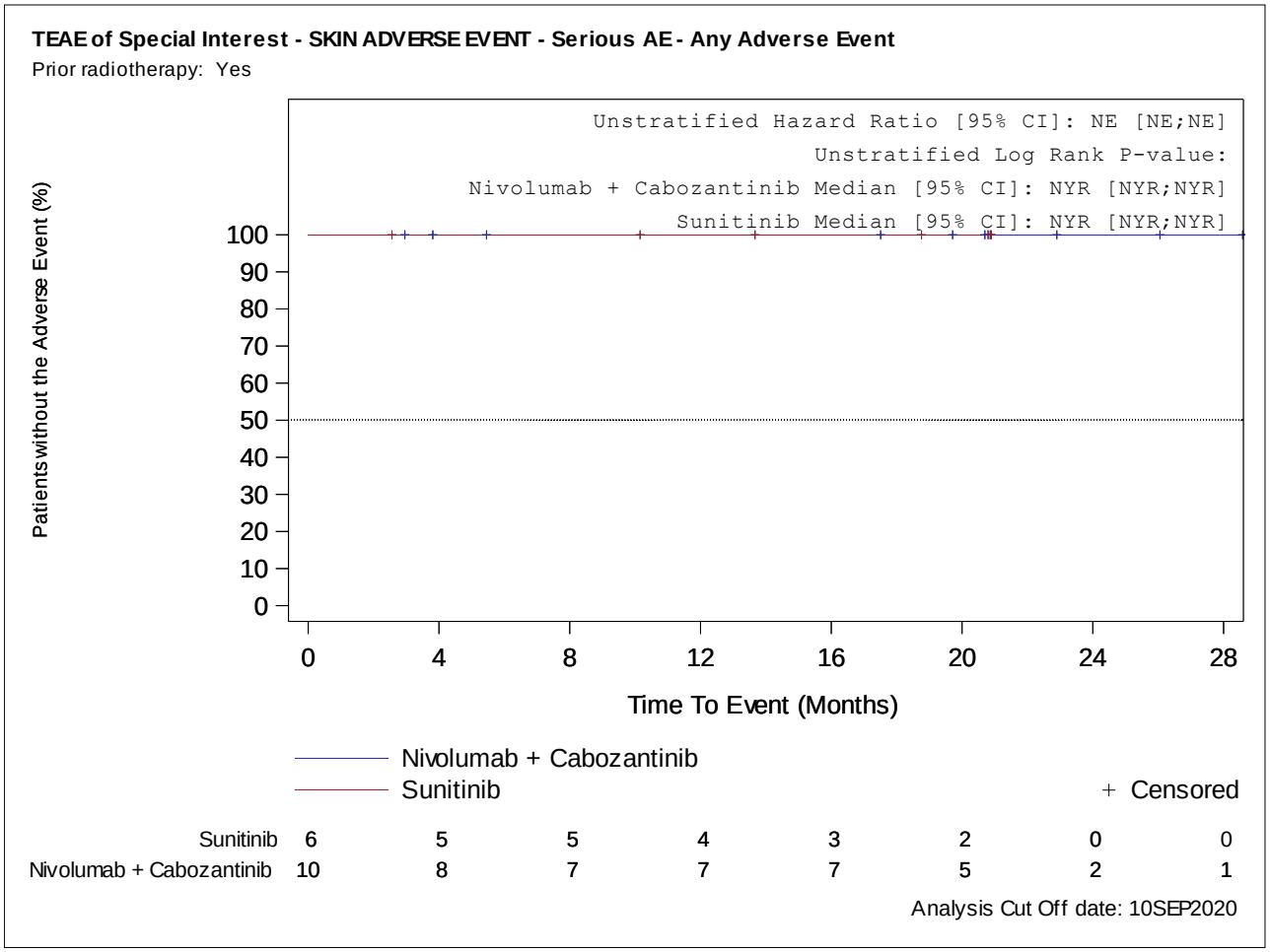

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:59:49

FIGURE 3.57.2.19: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



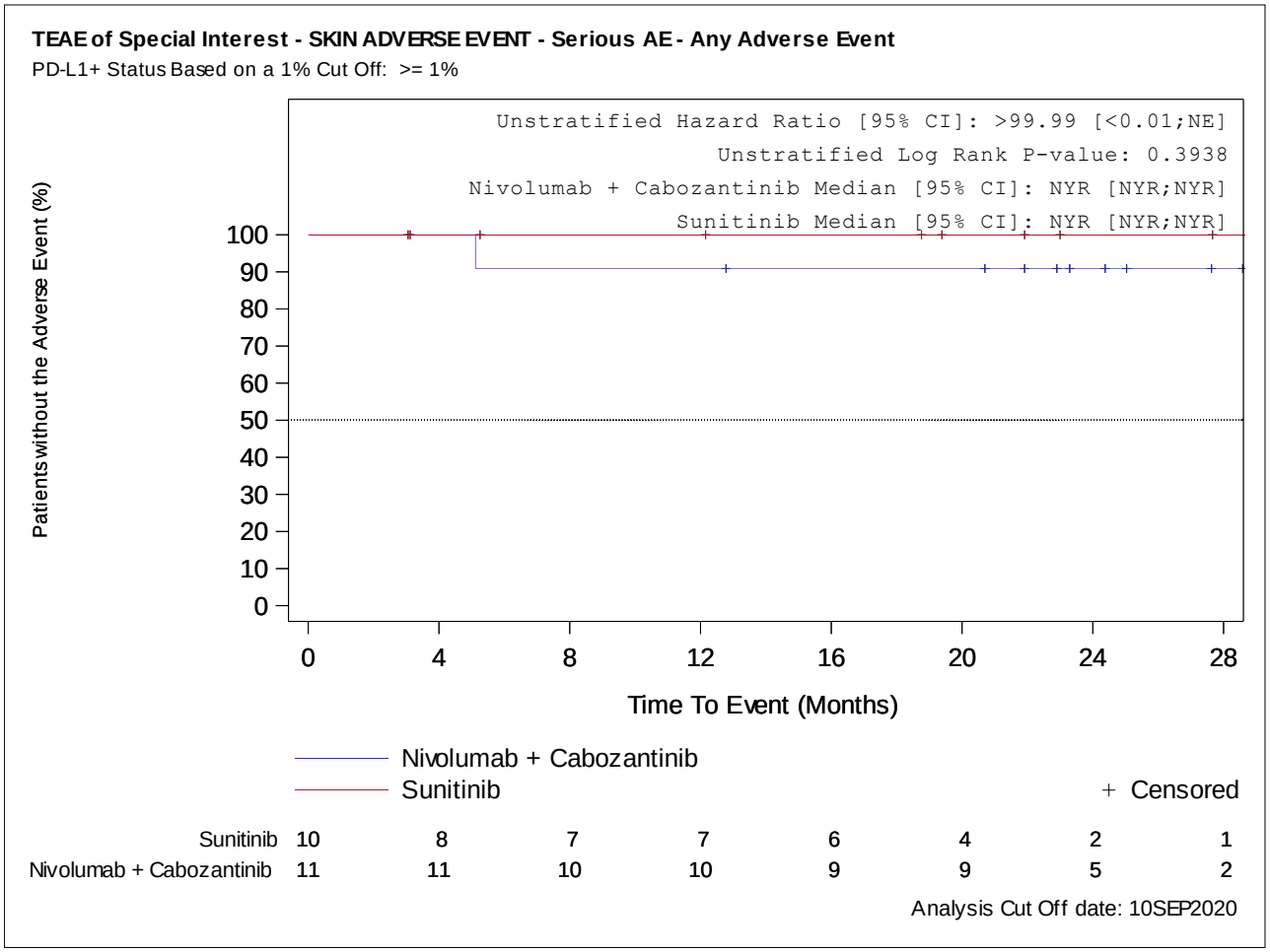

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:59:55

FIGURE 3.57.2.20: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



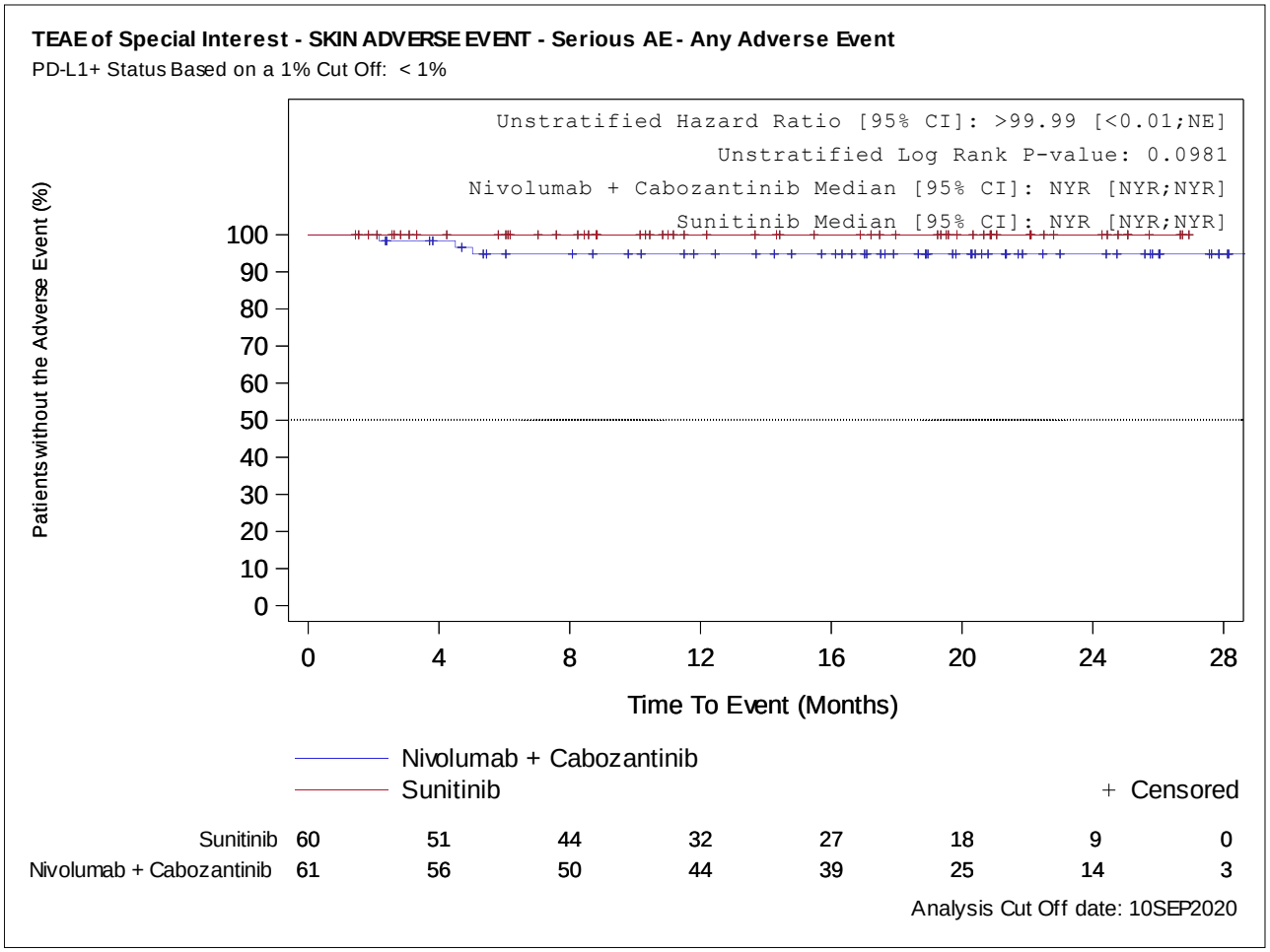

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 24:00:00

FIGURE 3.57.2.21: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off:  >= 1%



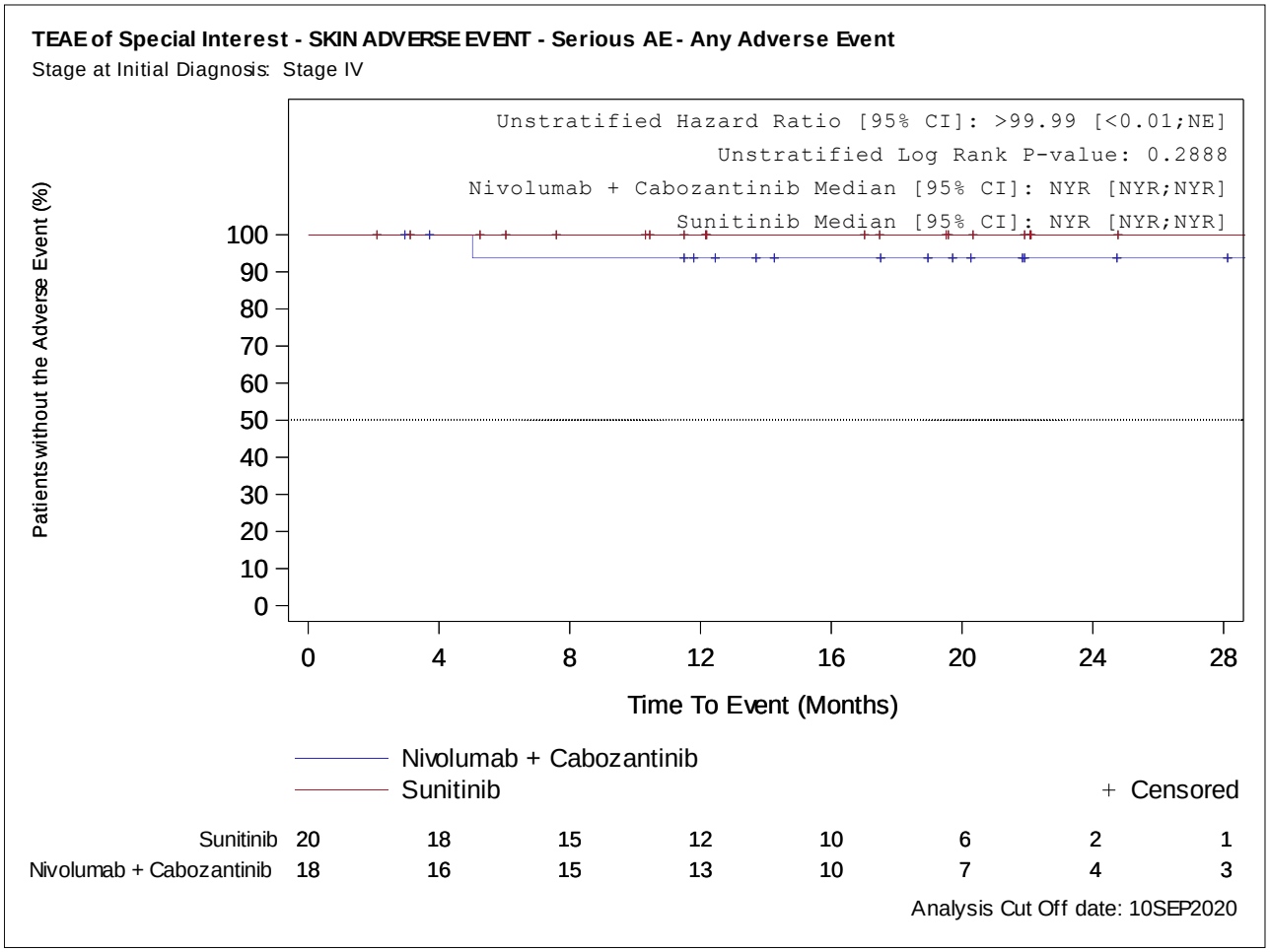

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:00:05

FIGURE 3.57.2.22: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



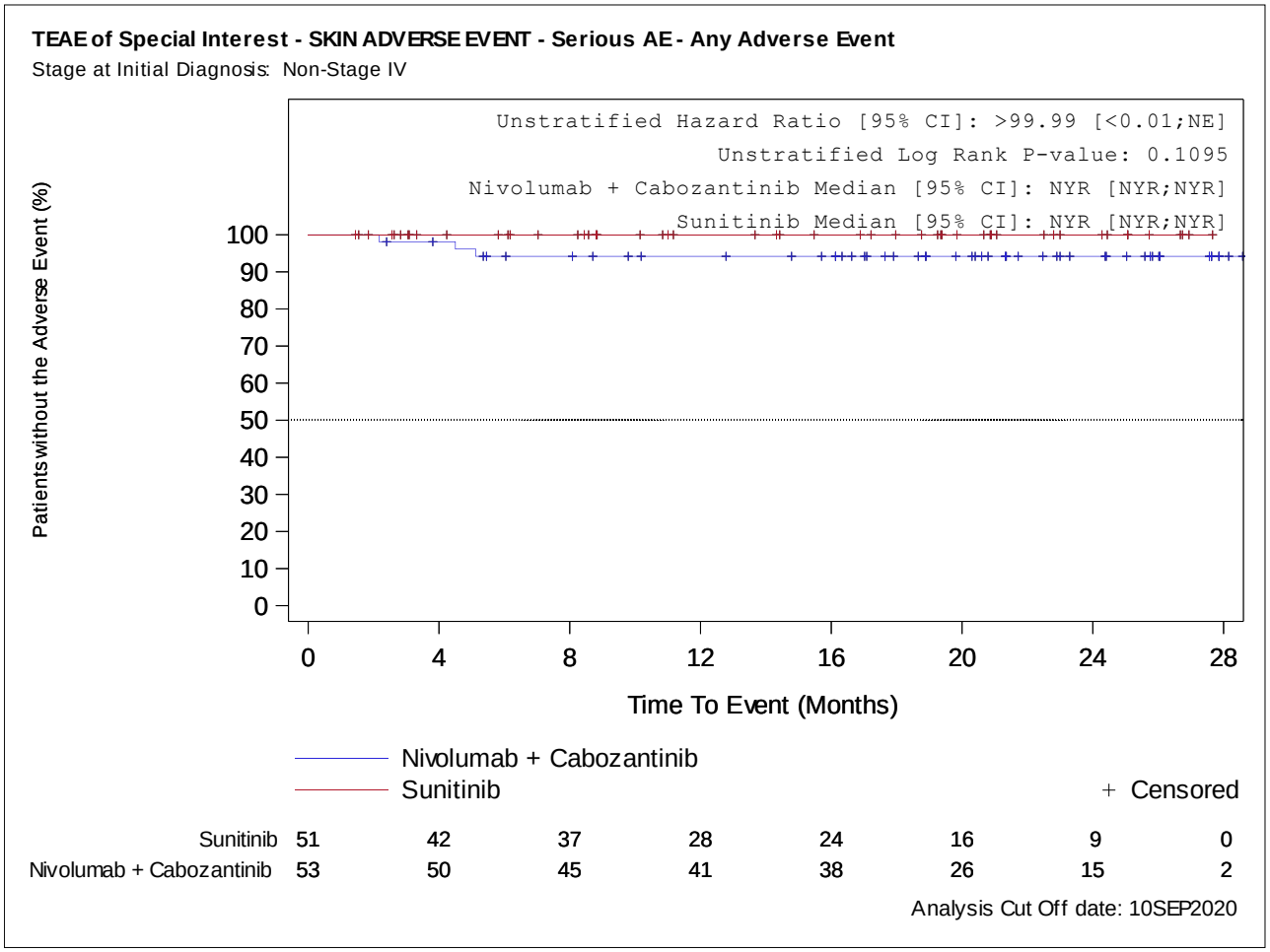

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:00:11

FIGURE 3.57.2.23: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



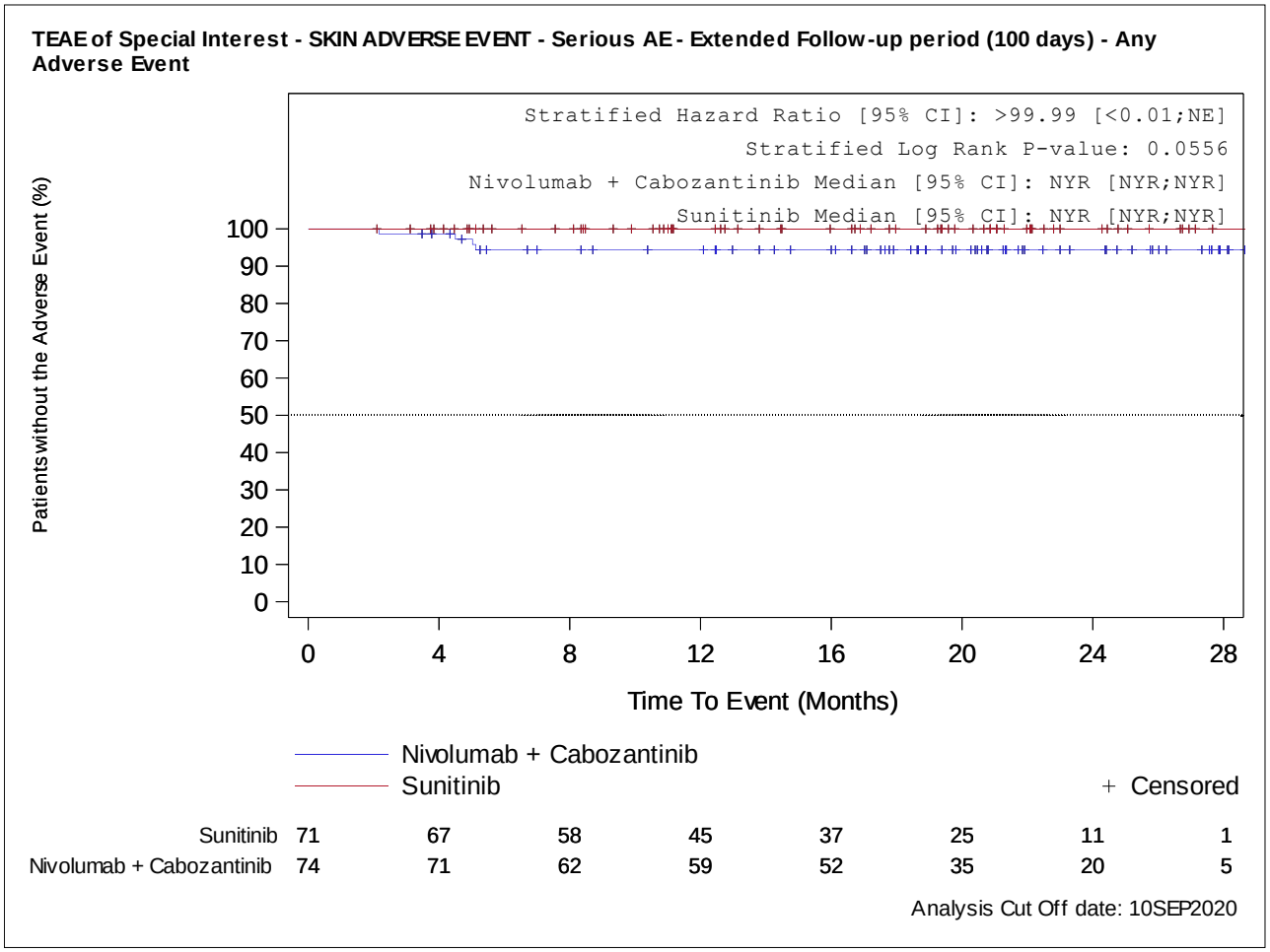

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:00:37

FIGURE 3.57.2.24: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



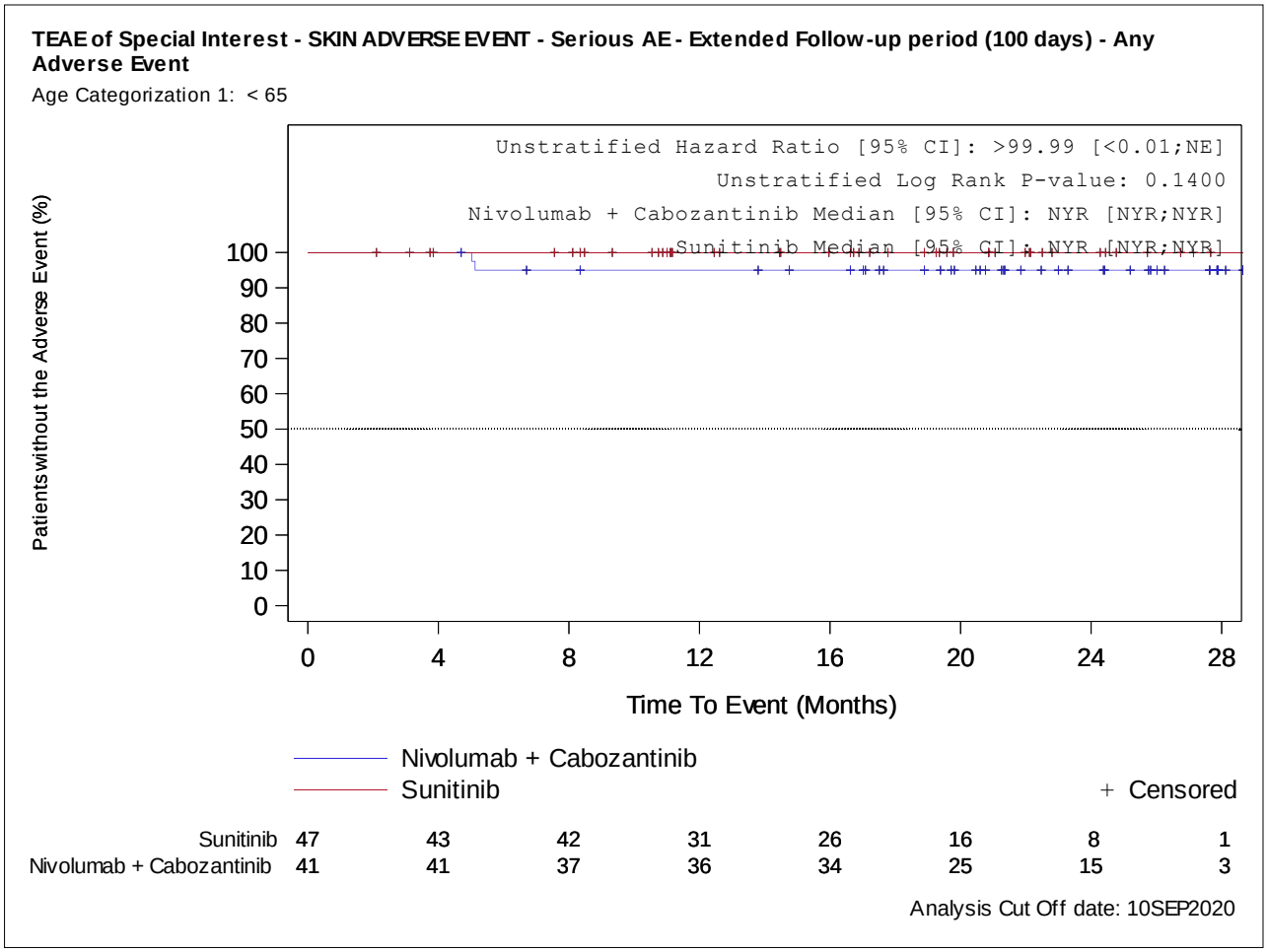

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:00:42

FIGURE 3.58.1: TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



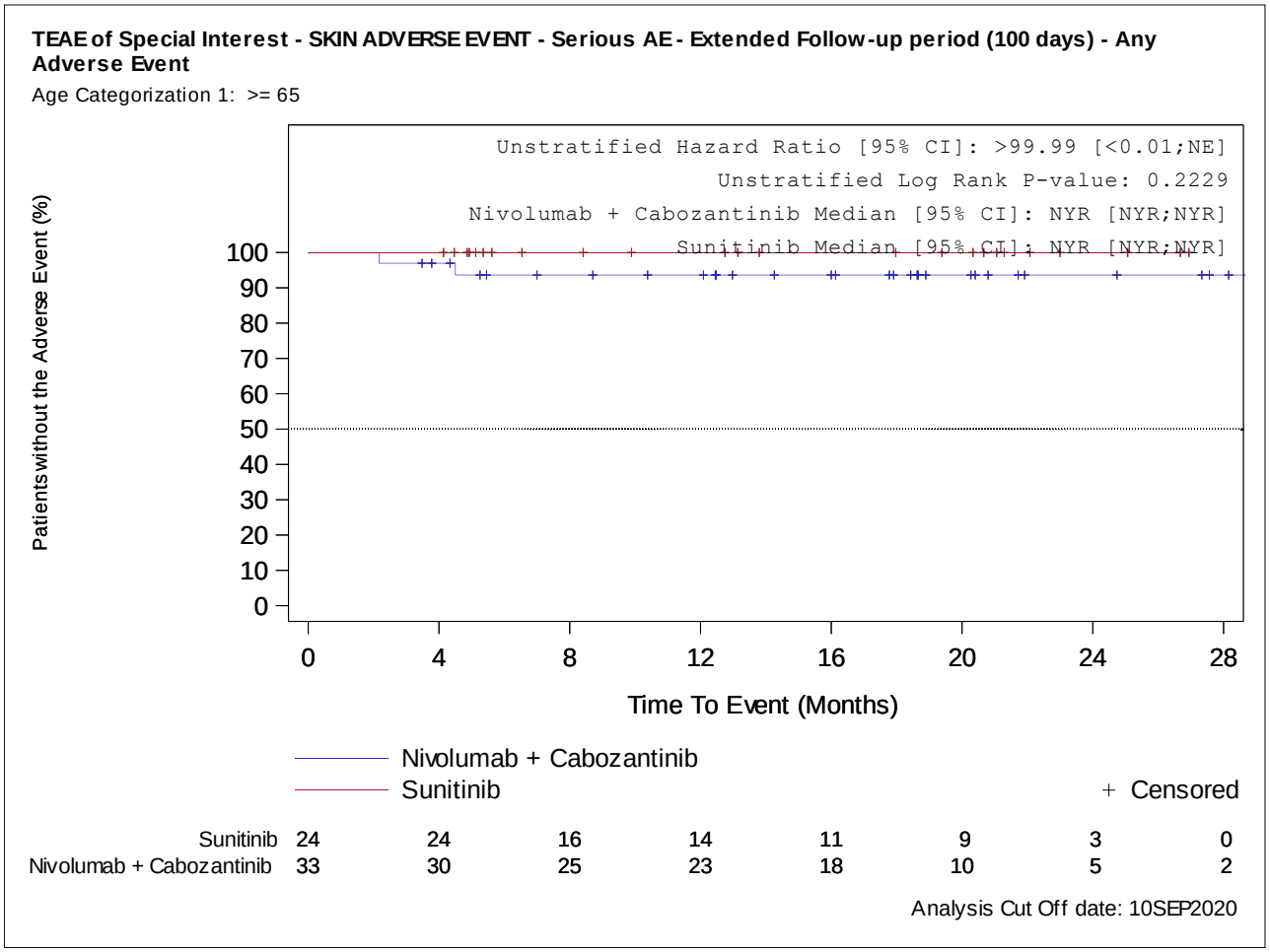

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:03:40

FIGURE 3.58.2.1: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  < 65



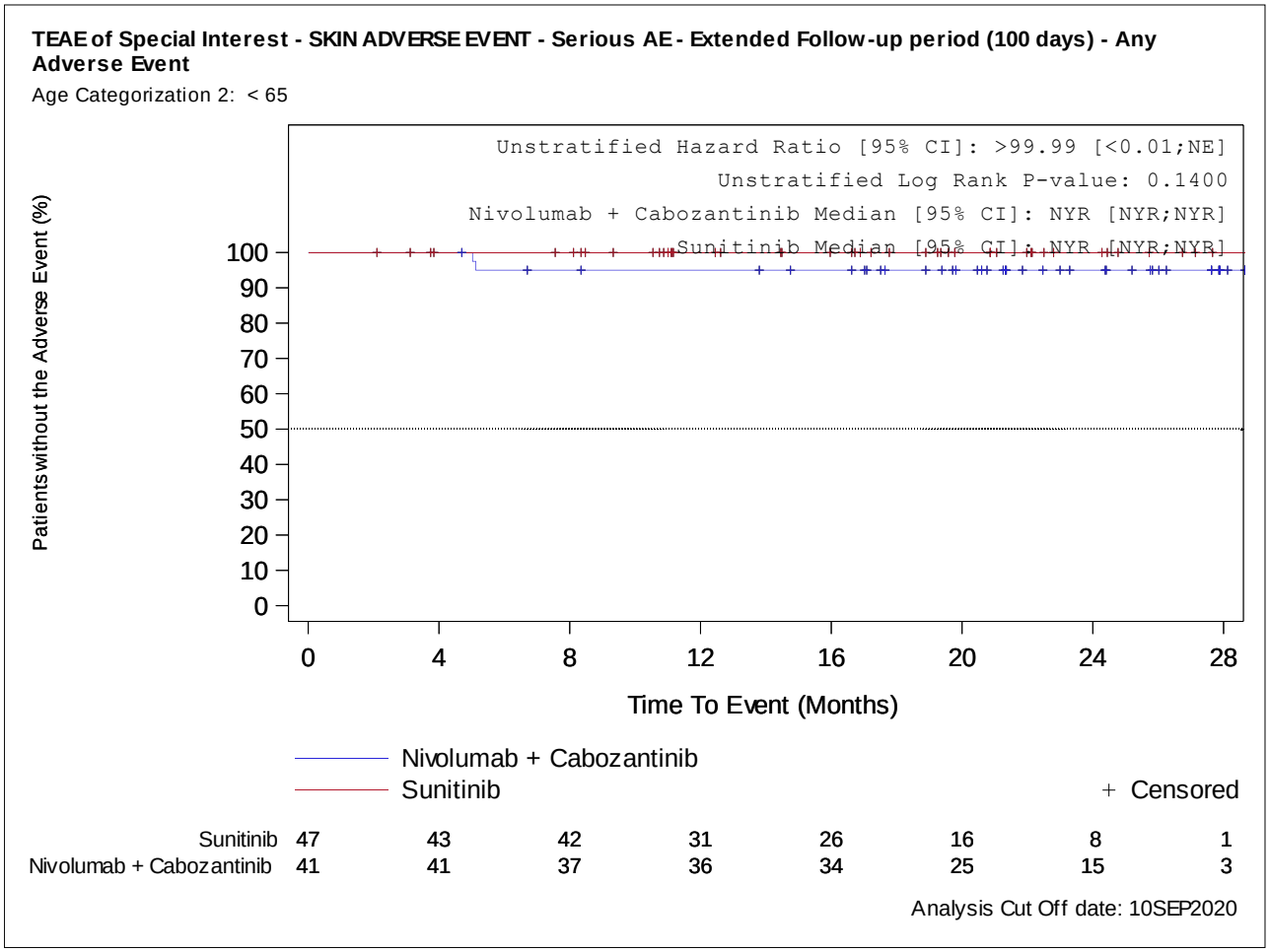

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:03:43

FIGURE 3.58.2.2: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



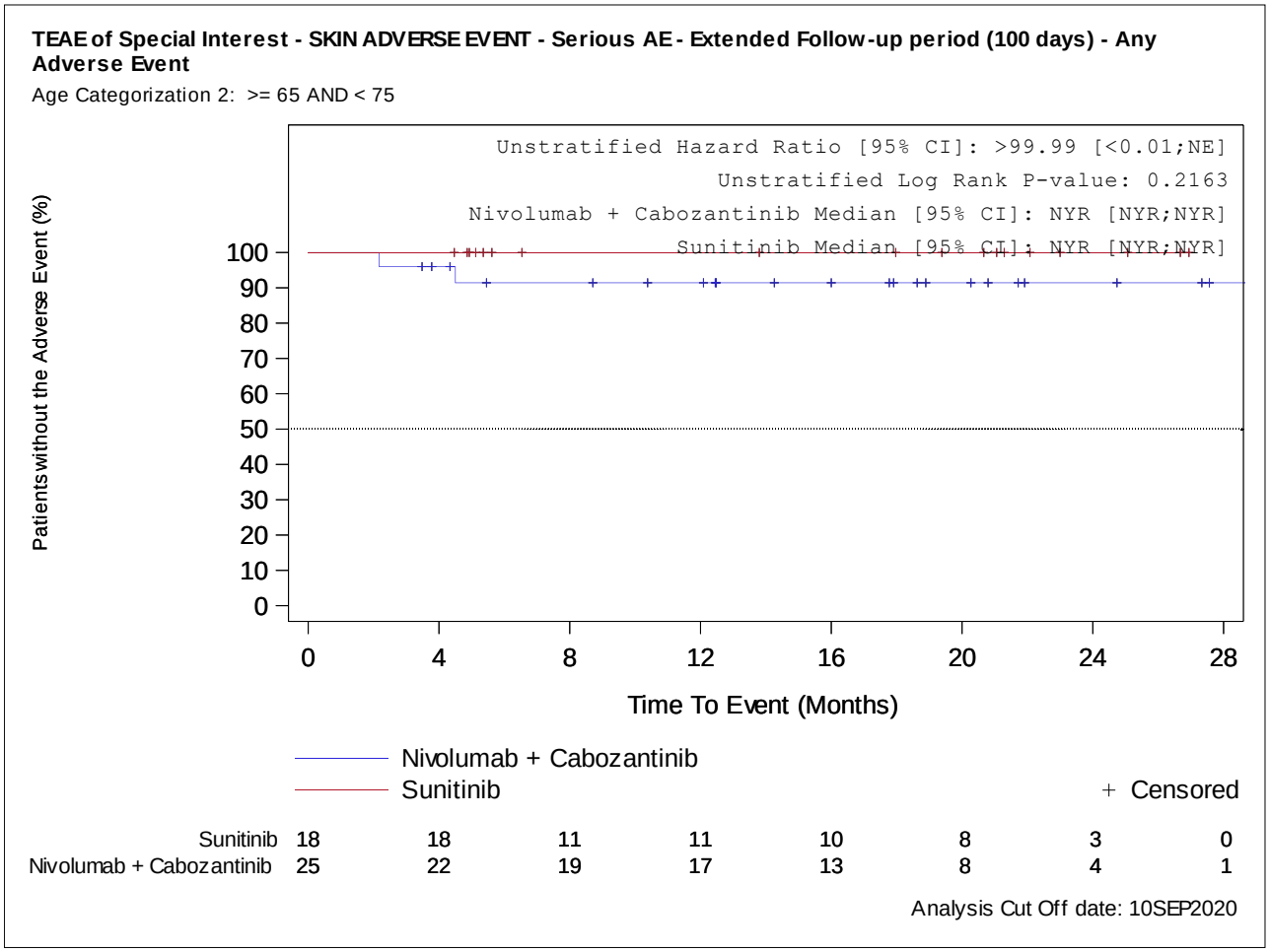

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:03:48

FIGURE 3.58.2.3: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  < 65



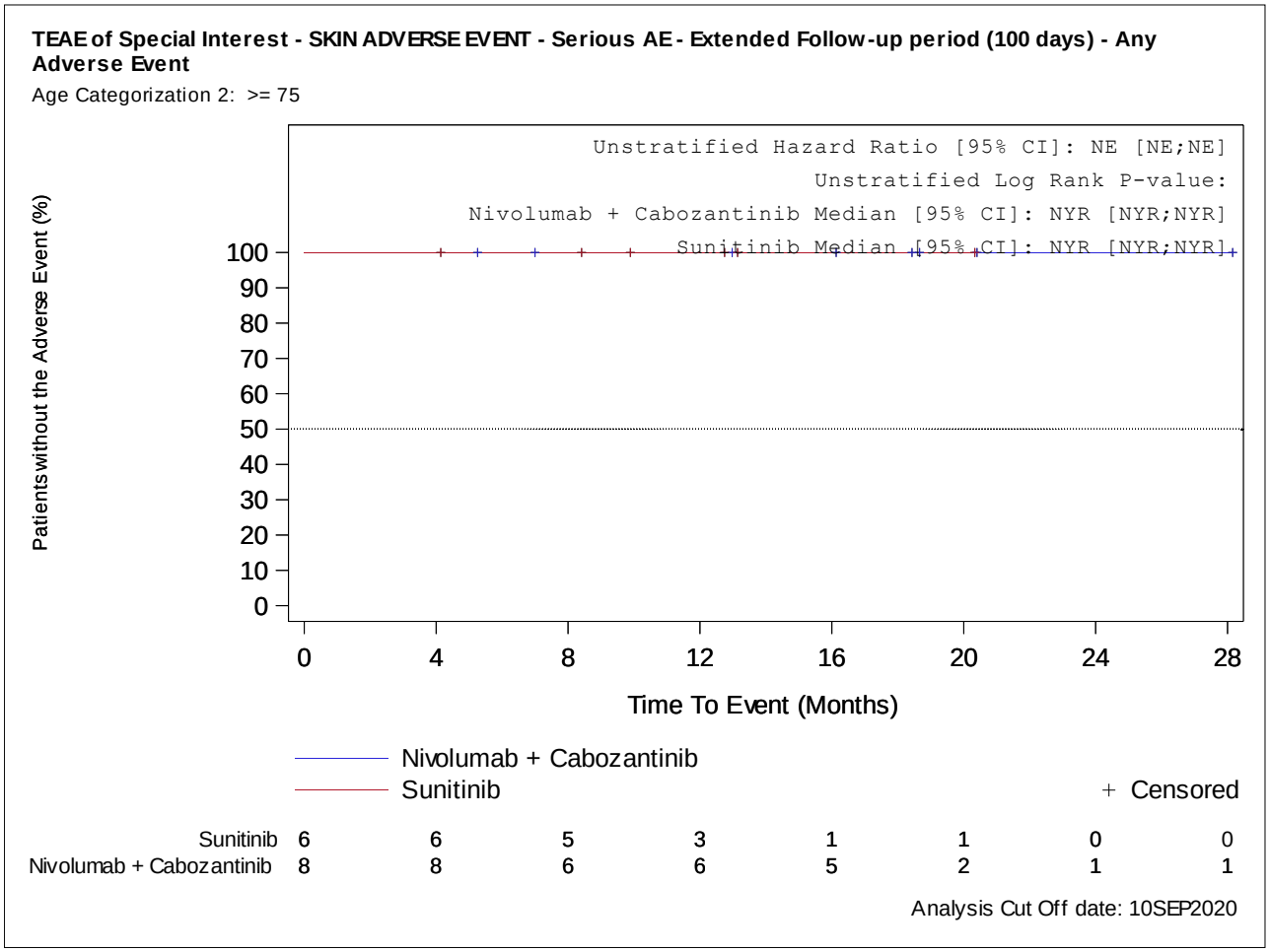

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:03:54

FIGURE 3.58.2.4: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



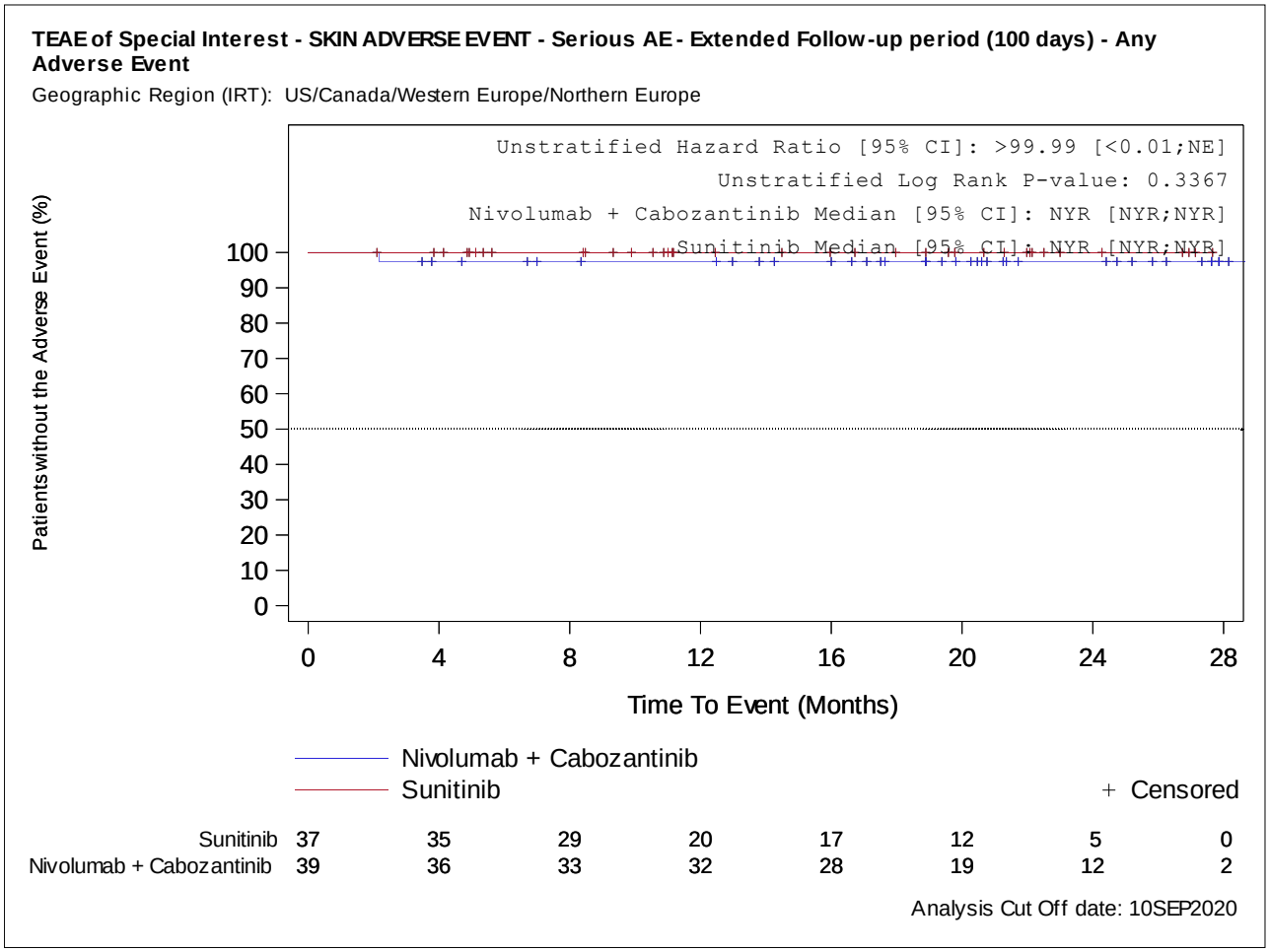

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:03:59

FIGURE 3.58.2.5: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



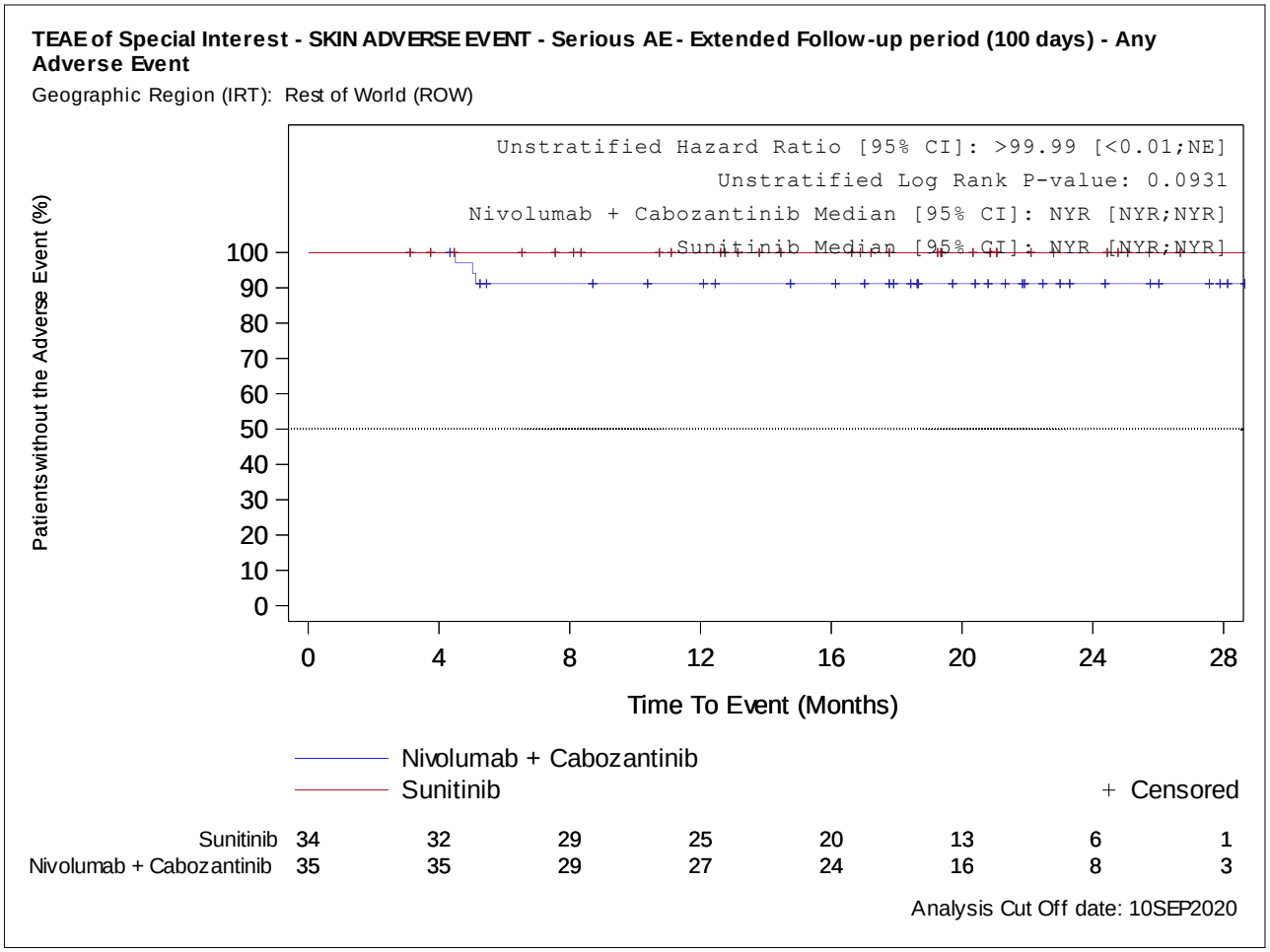

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:04:04

FIGURE 3.58.2.6: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



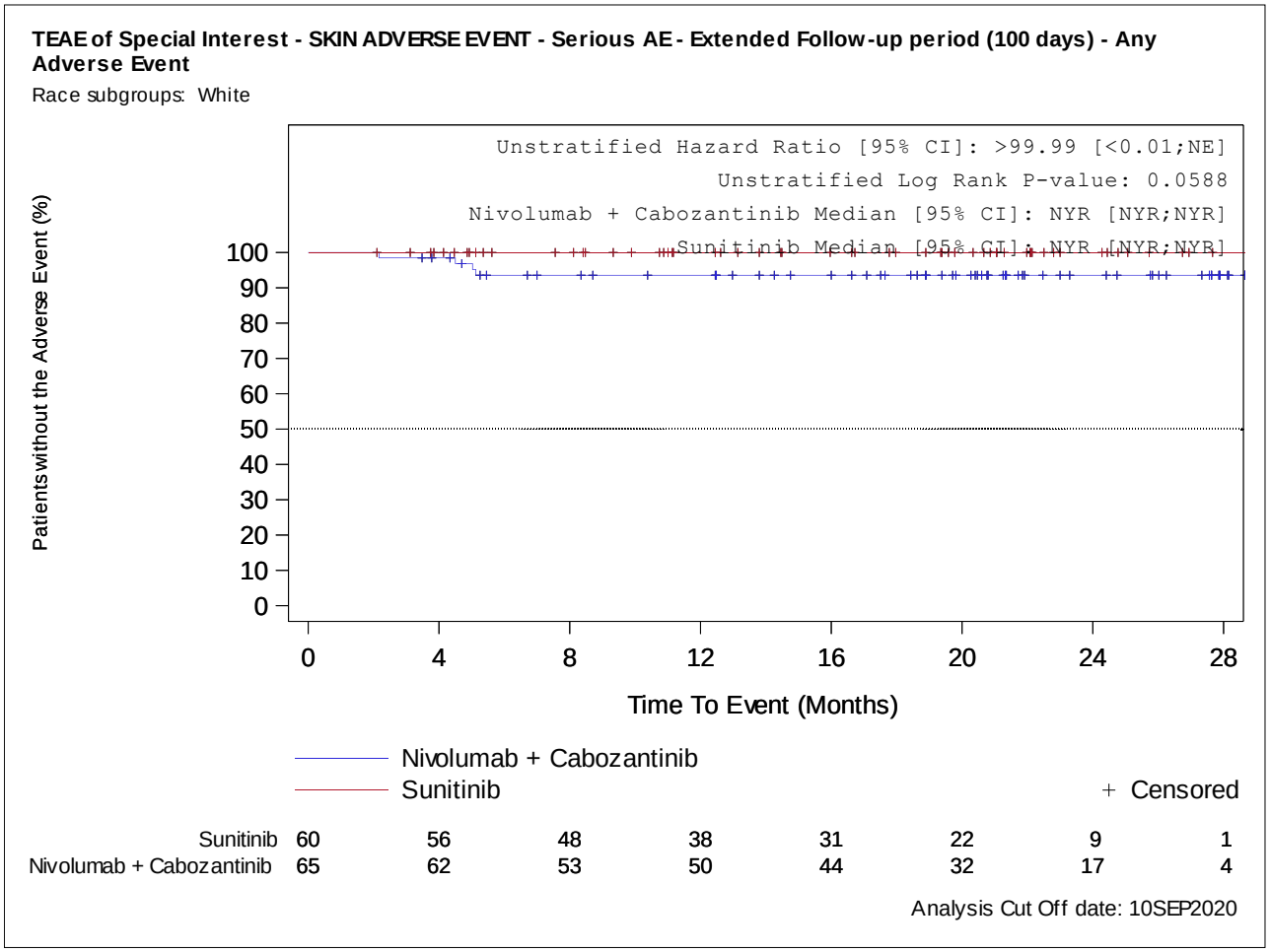

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:04:09

FIGURE 3.58.2.7: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



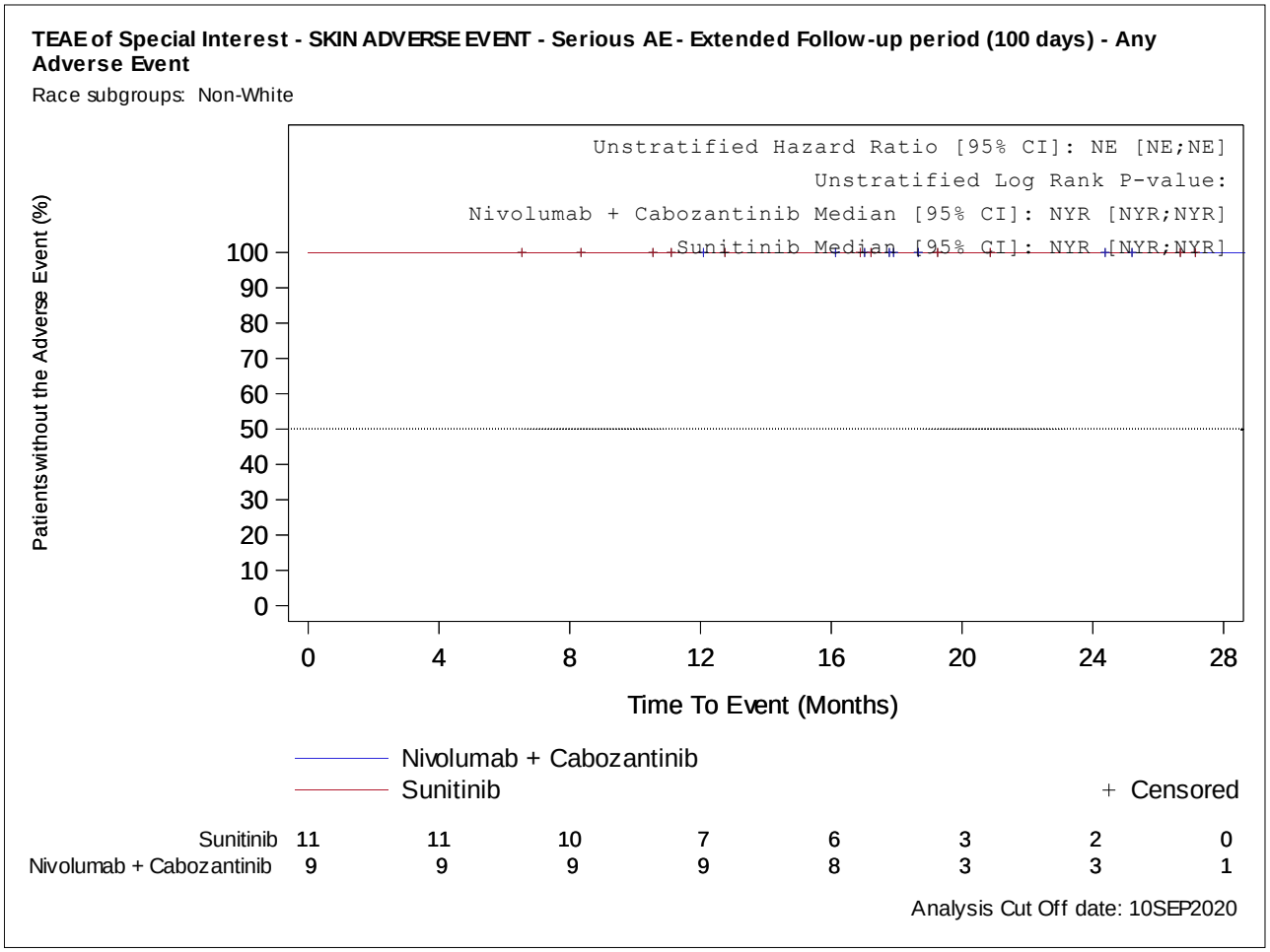

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:04:14

FIGURE 3.58.2.8: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



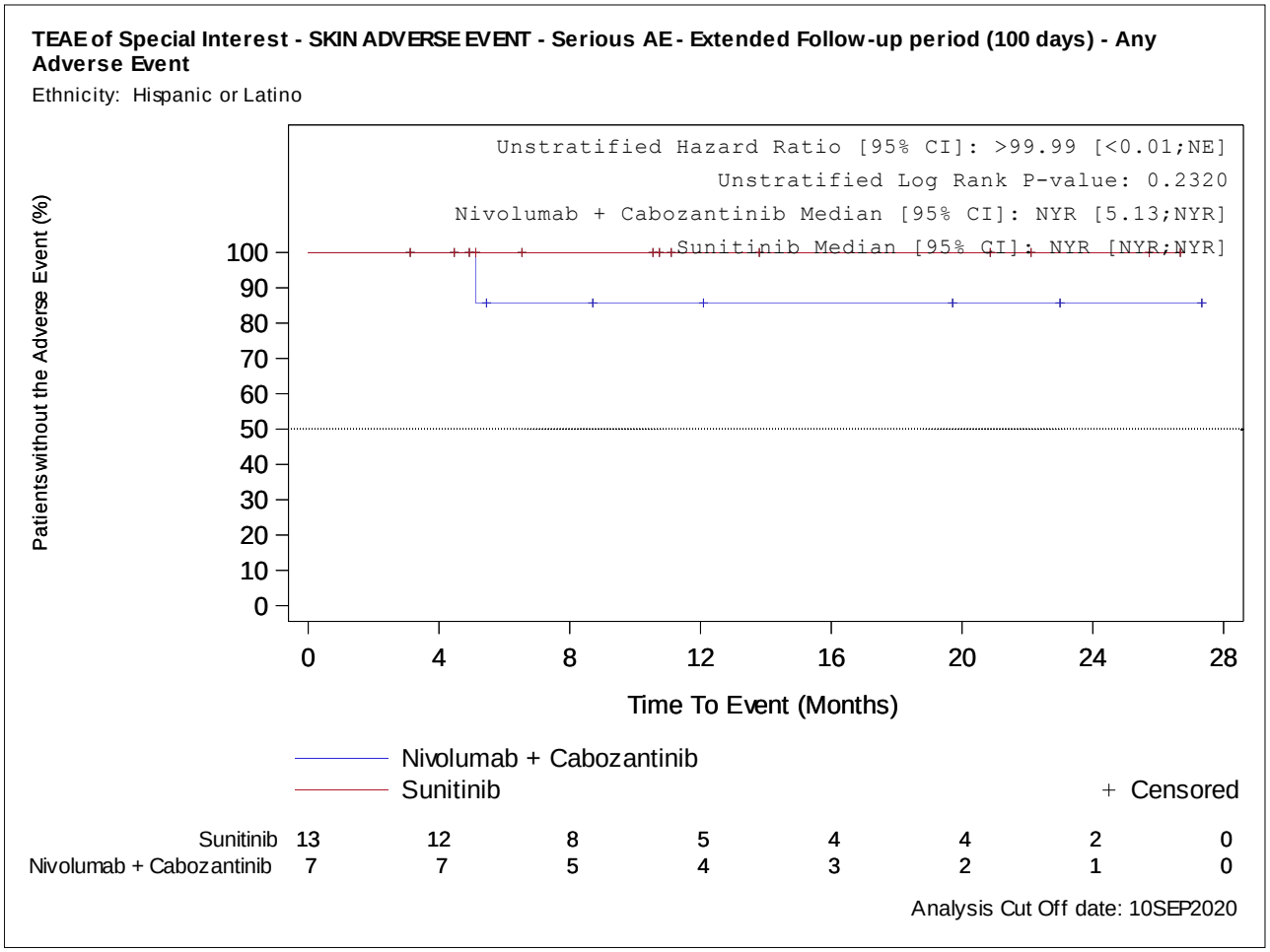

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:04:20

FIGURE 3.58.2.9: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:04:25

FIGURE 3.58.2.10: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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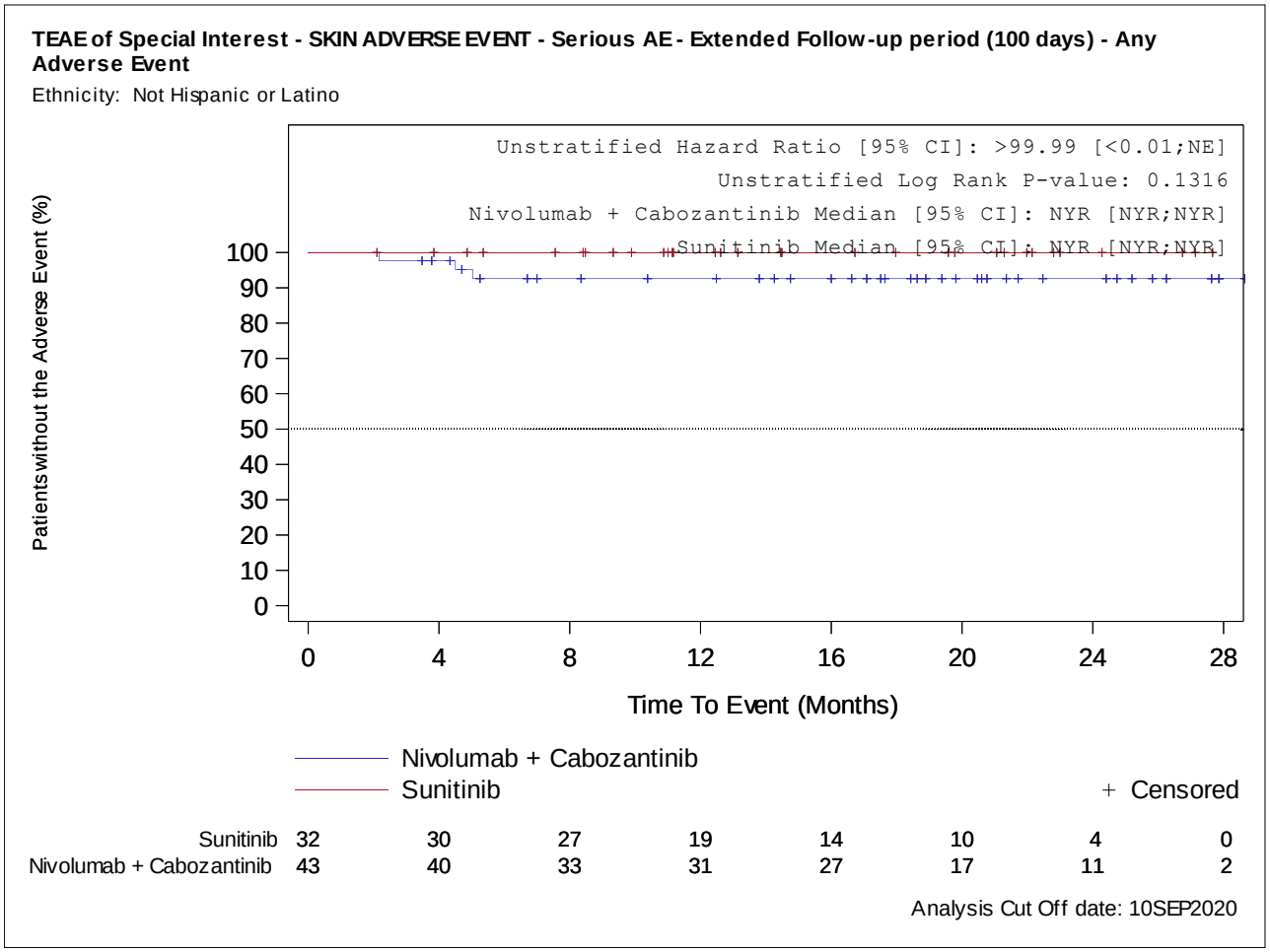
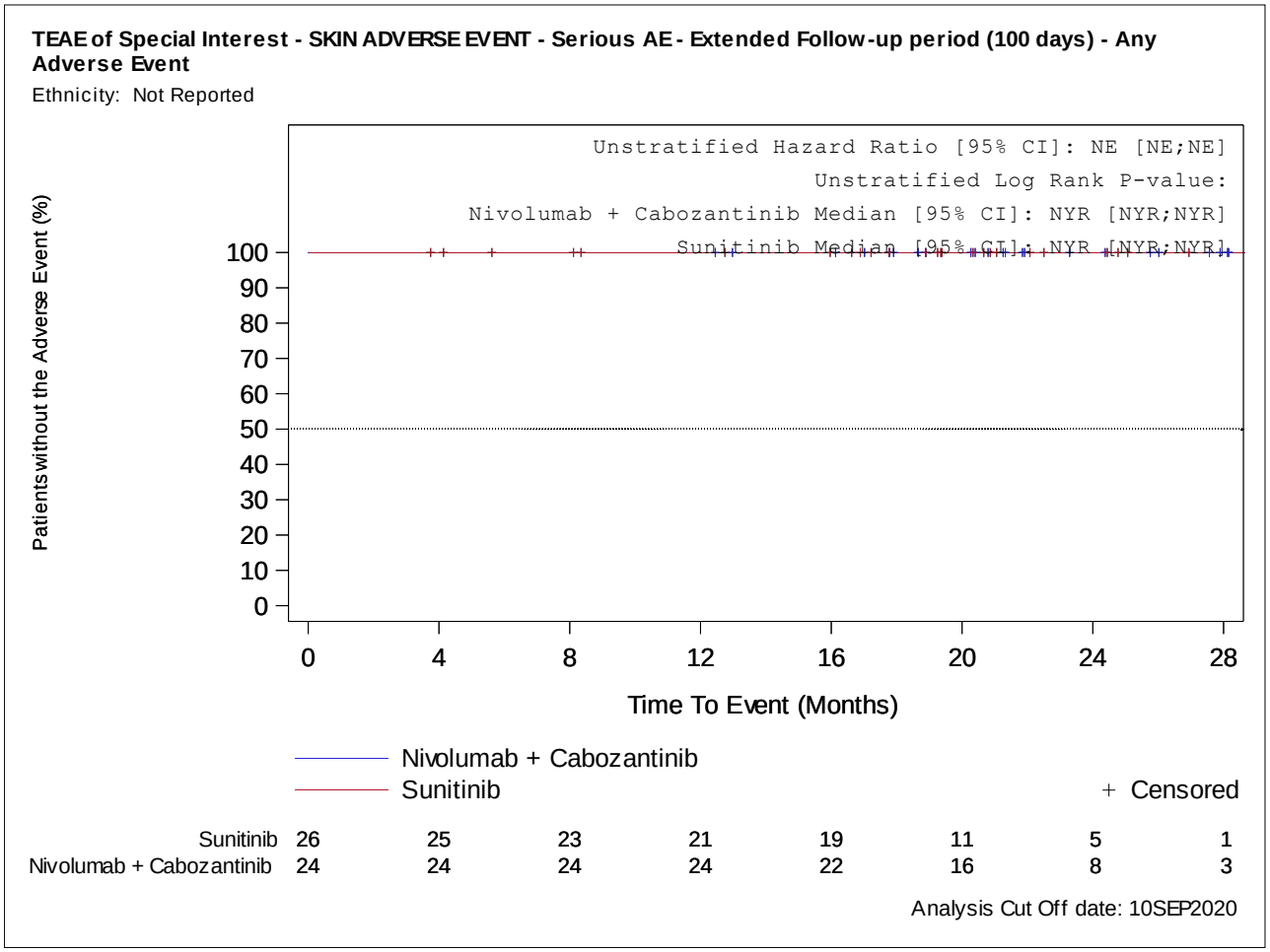
FIGURE 3.58.2.11: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



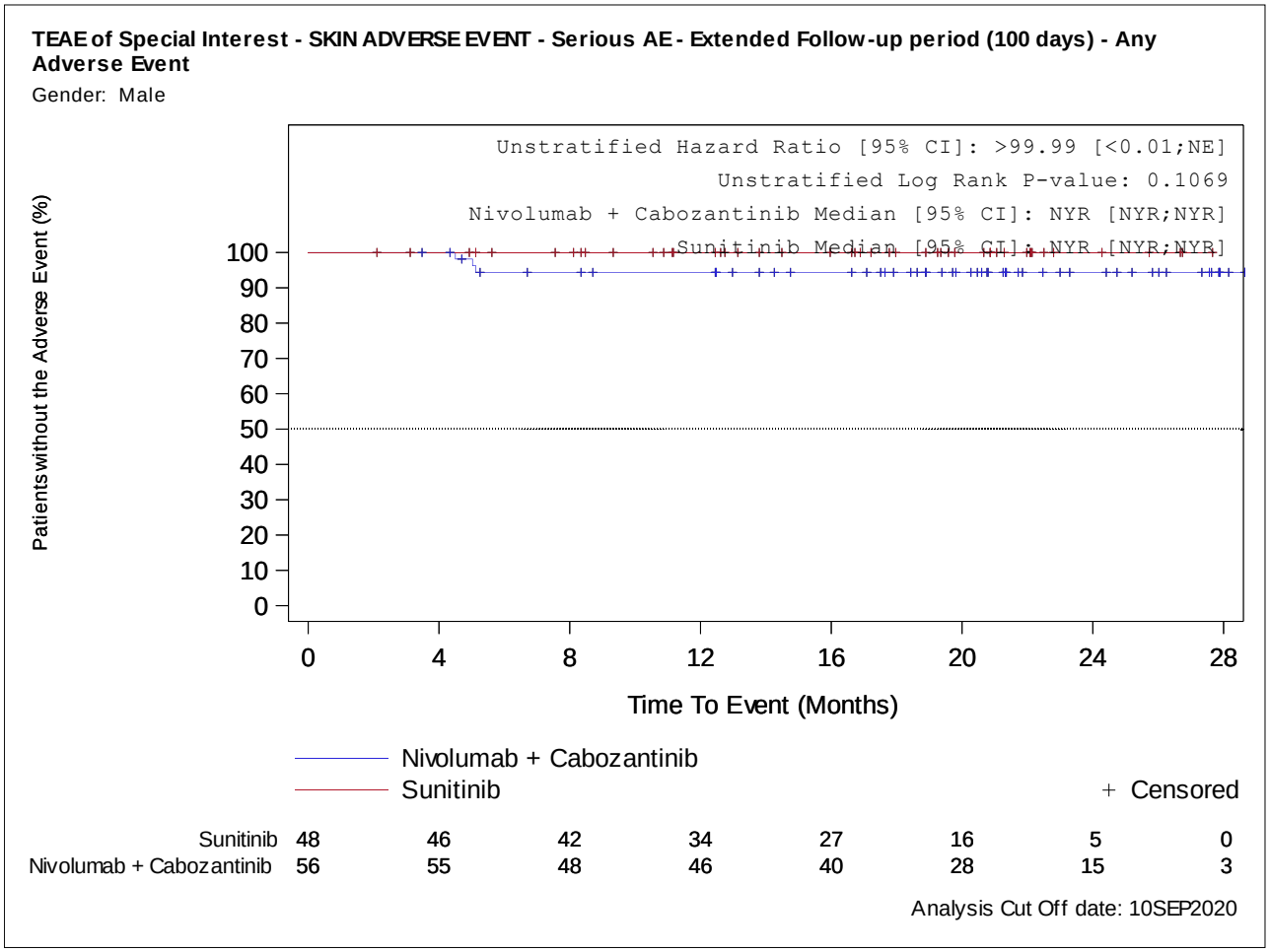

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:04:36

FIGURE 3.58.2.12: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



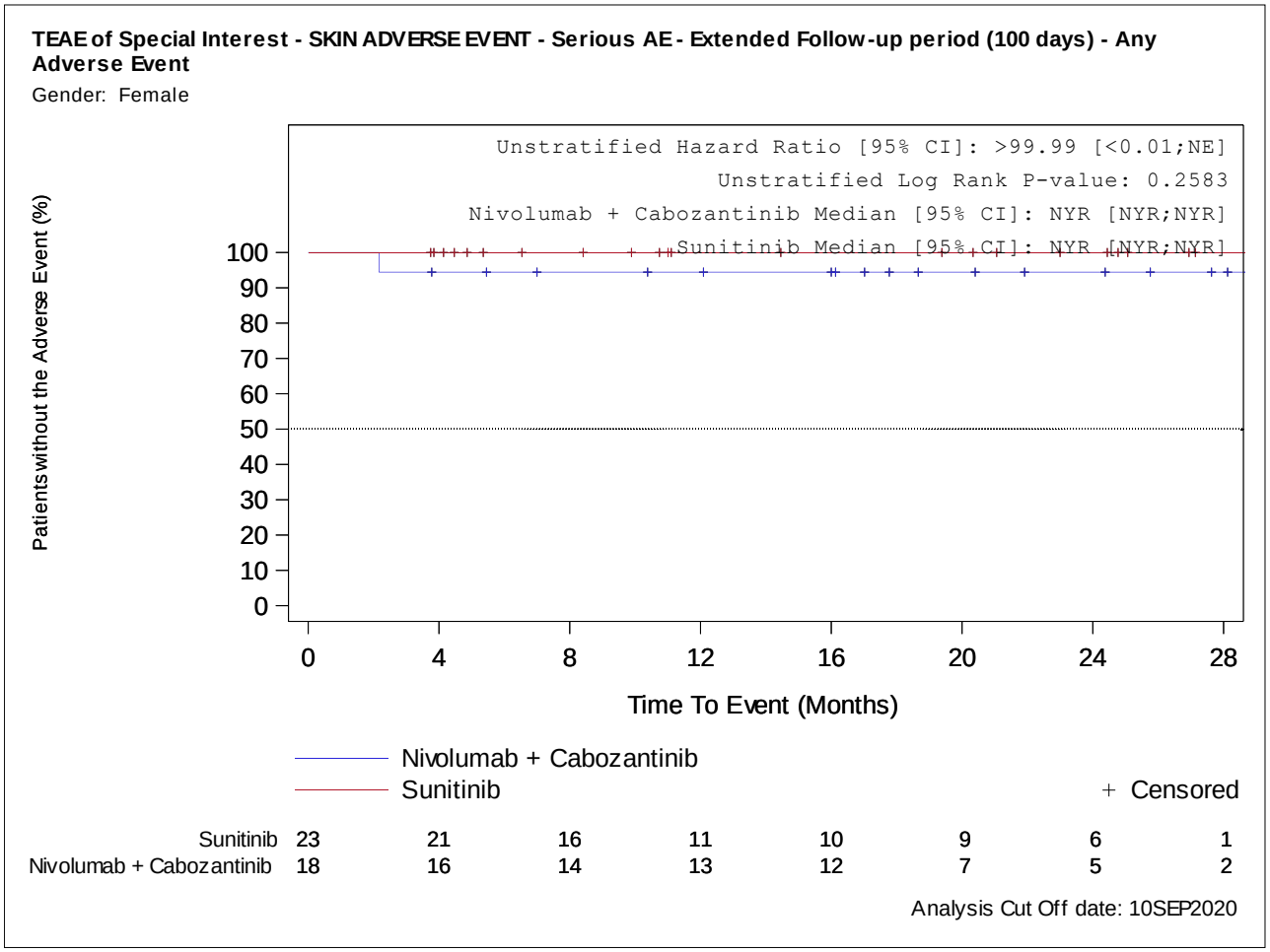

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:04:41

FIGURE 3.58.2.13: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



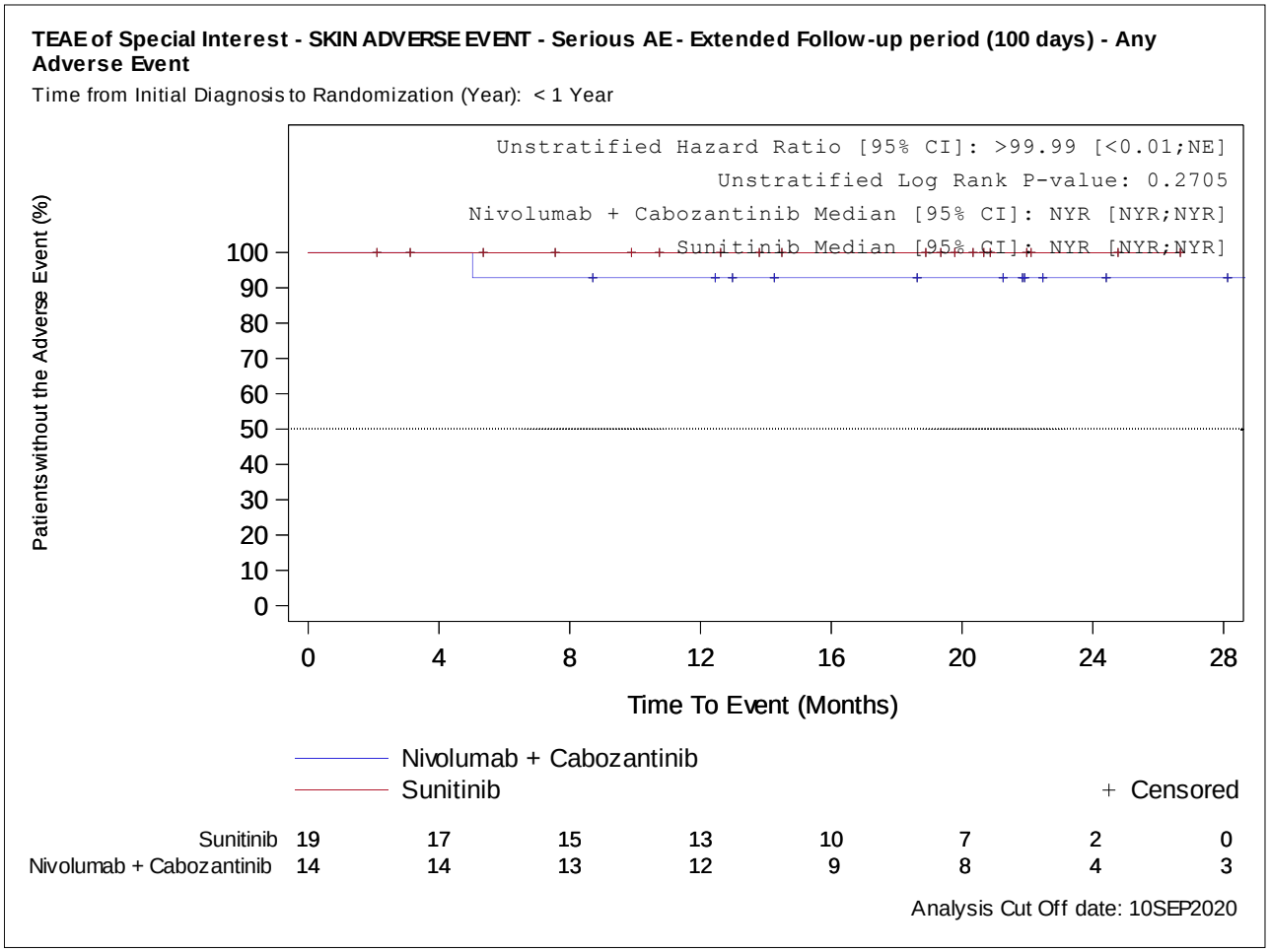

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:04:47

FIGURE 3.58.2.14: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



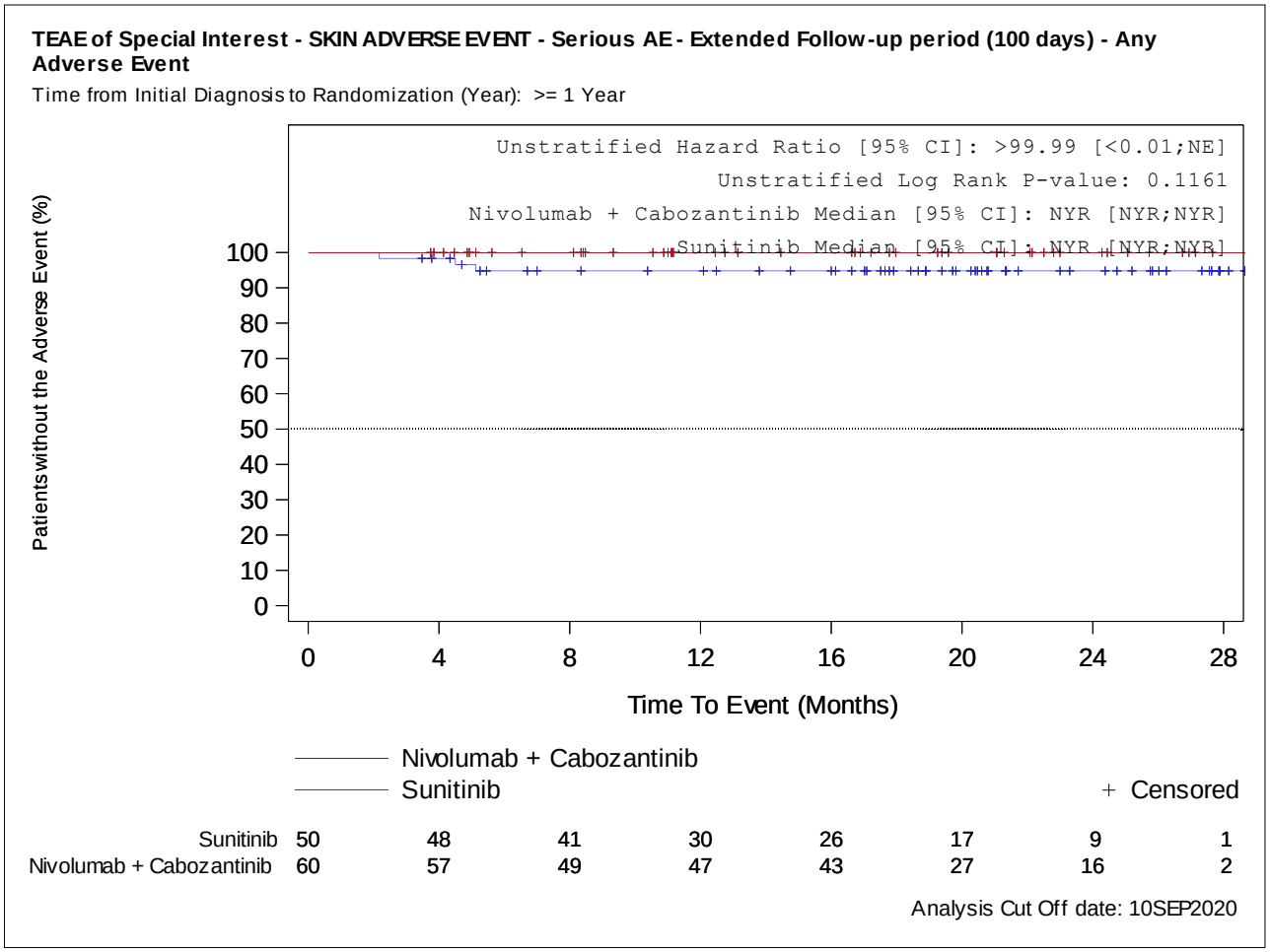

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:04:51

FIGURE 3.58.2.15: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



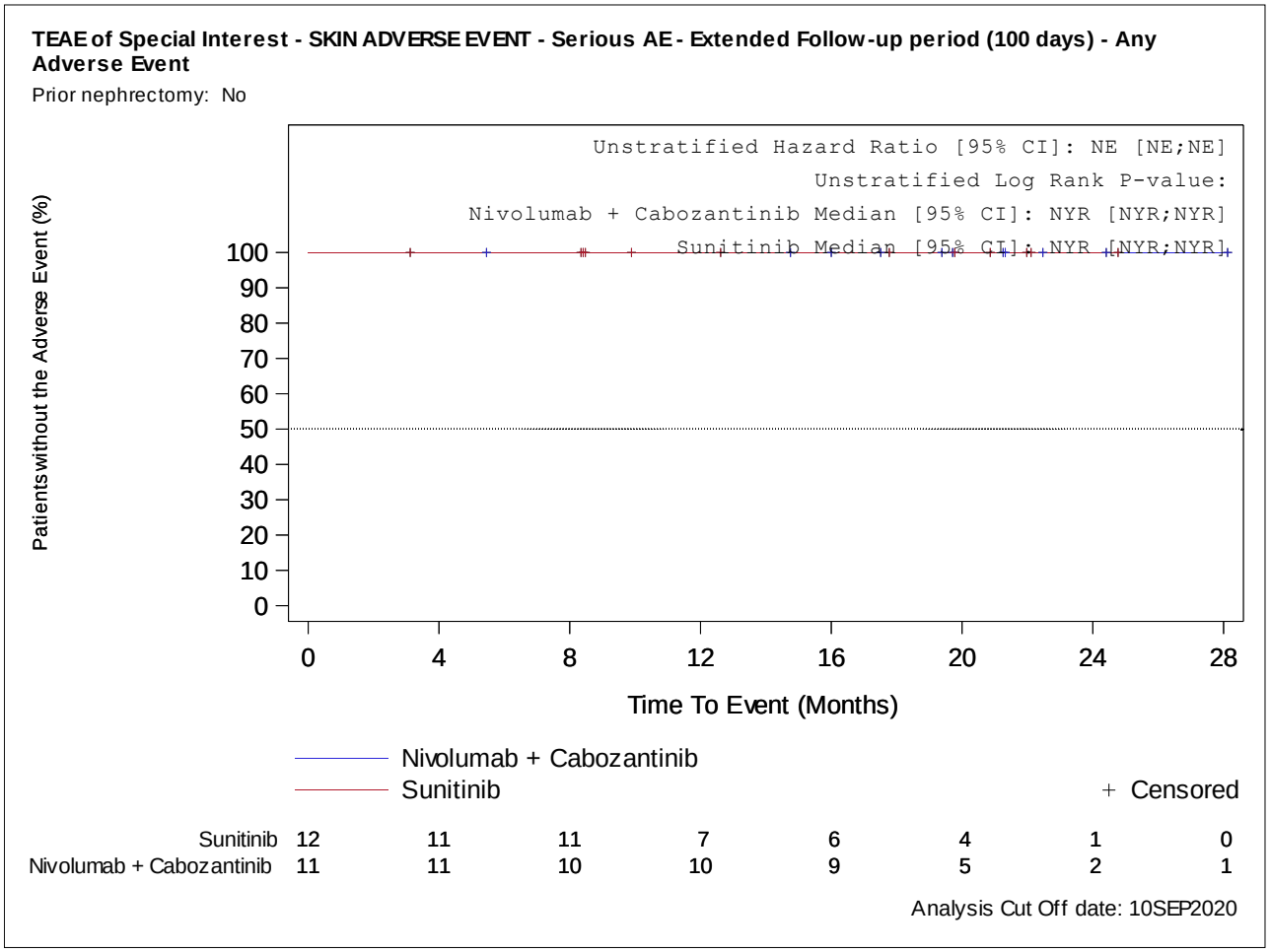

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:05:07

FIGURE 3.58.2.16: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



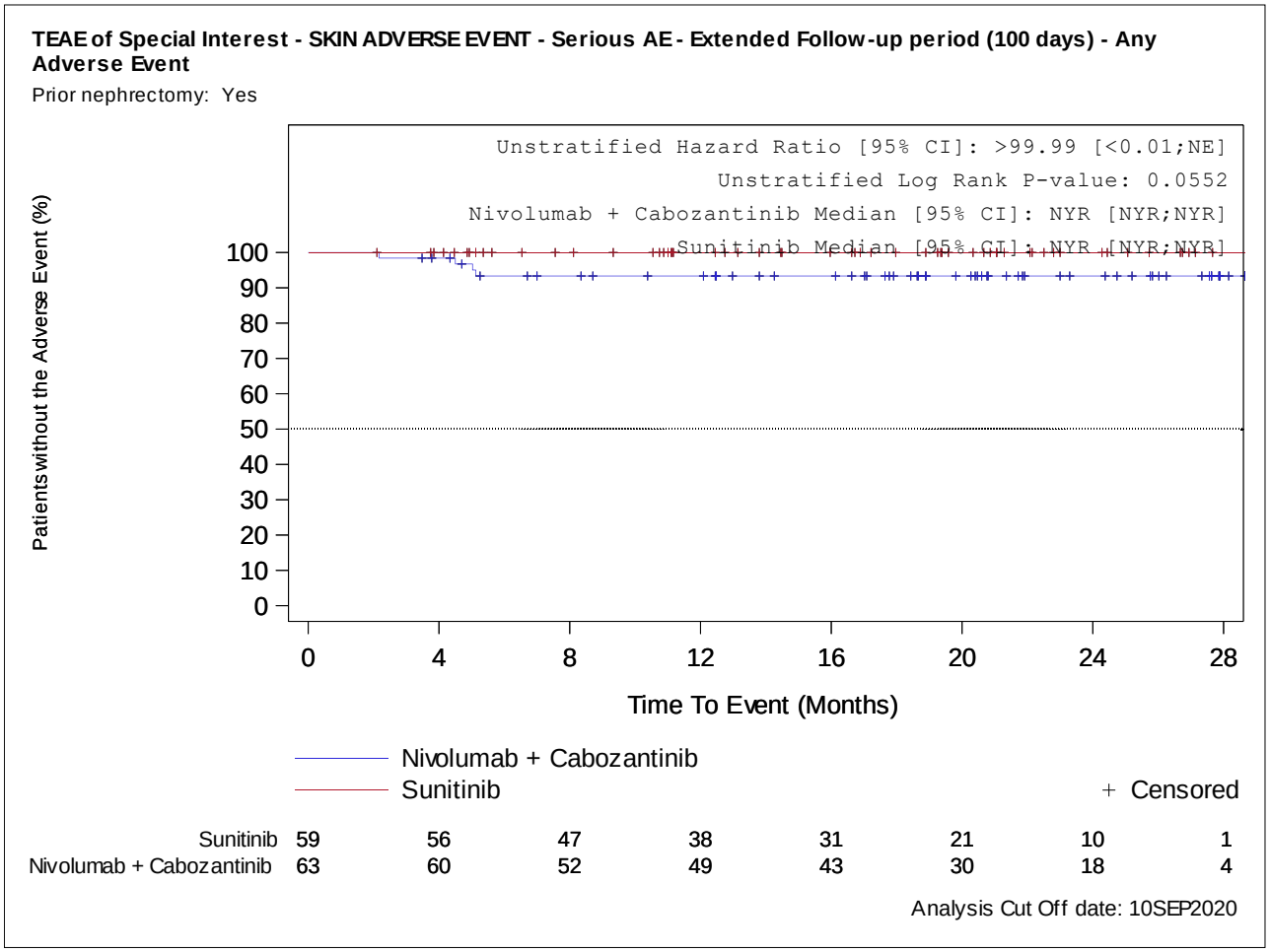

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:05:12

FIGURE 3.58.2.17: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



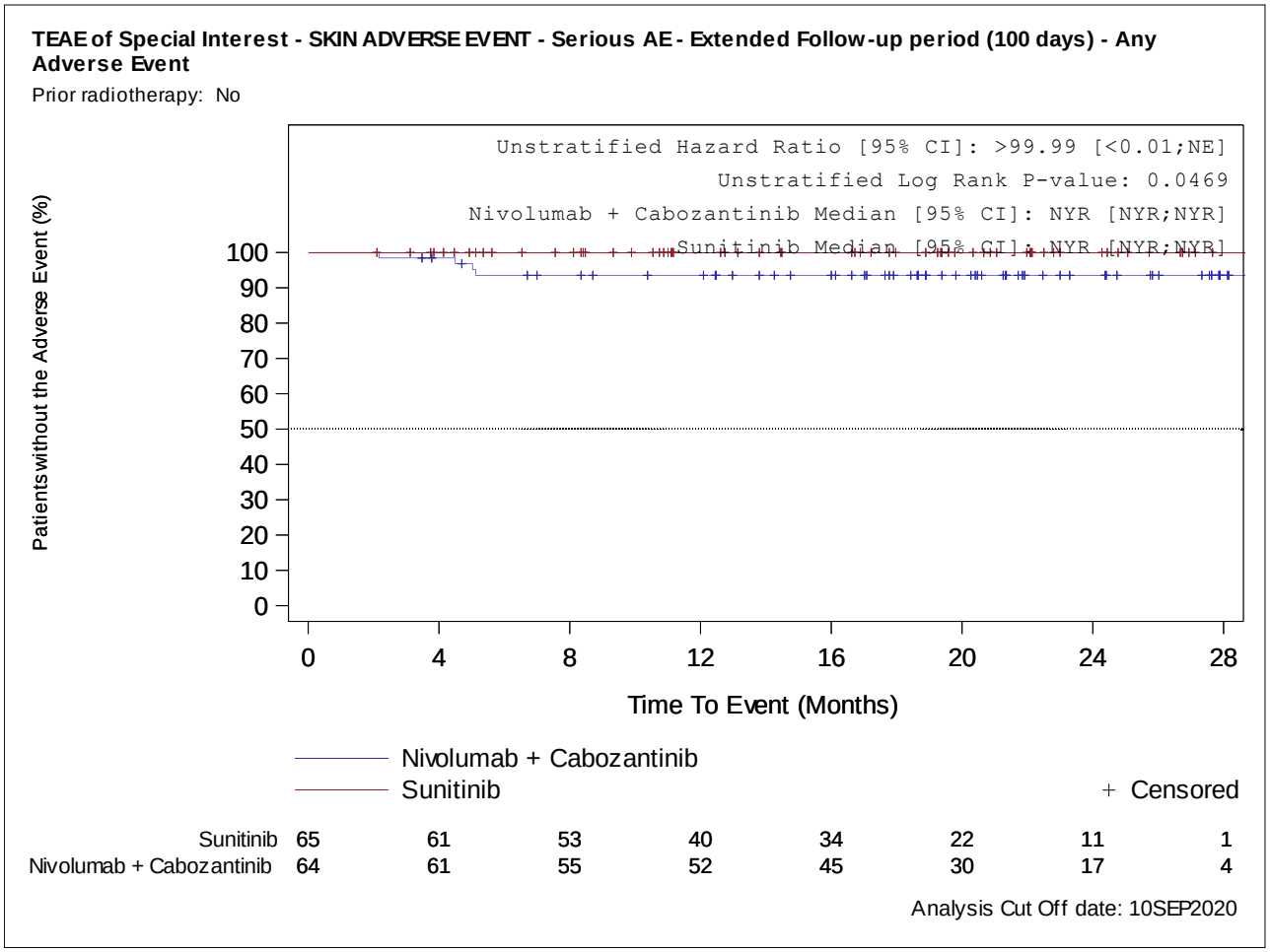

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:05:59

FIGURE 3.58.2.18: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



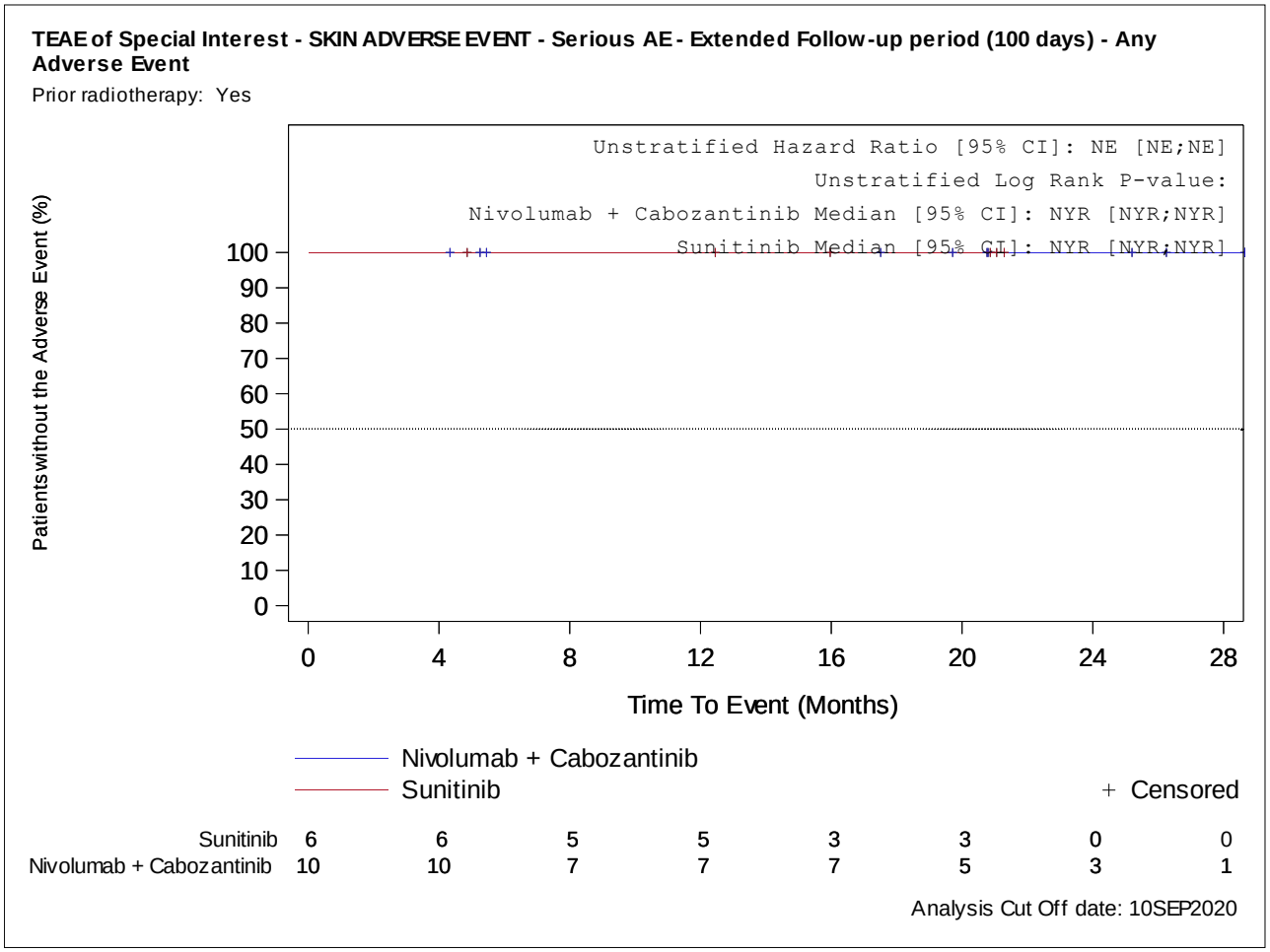

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:06:05

FIGURE 3.58.2.19: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



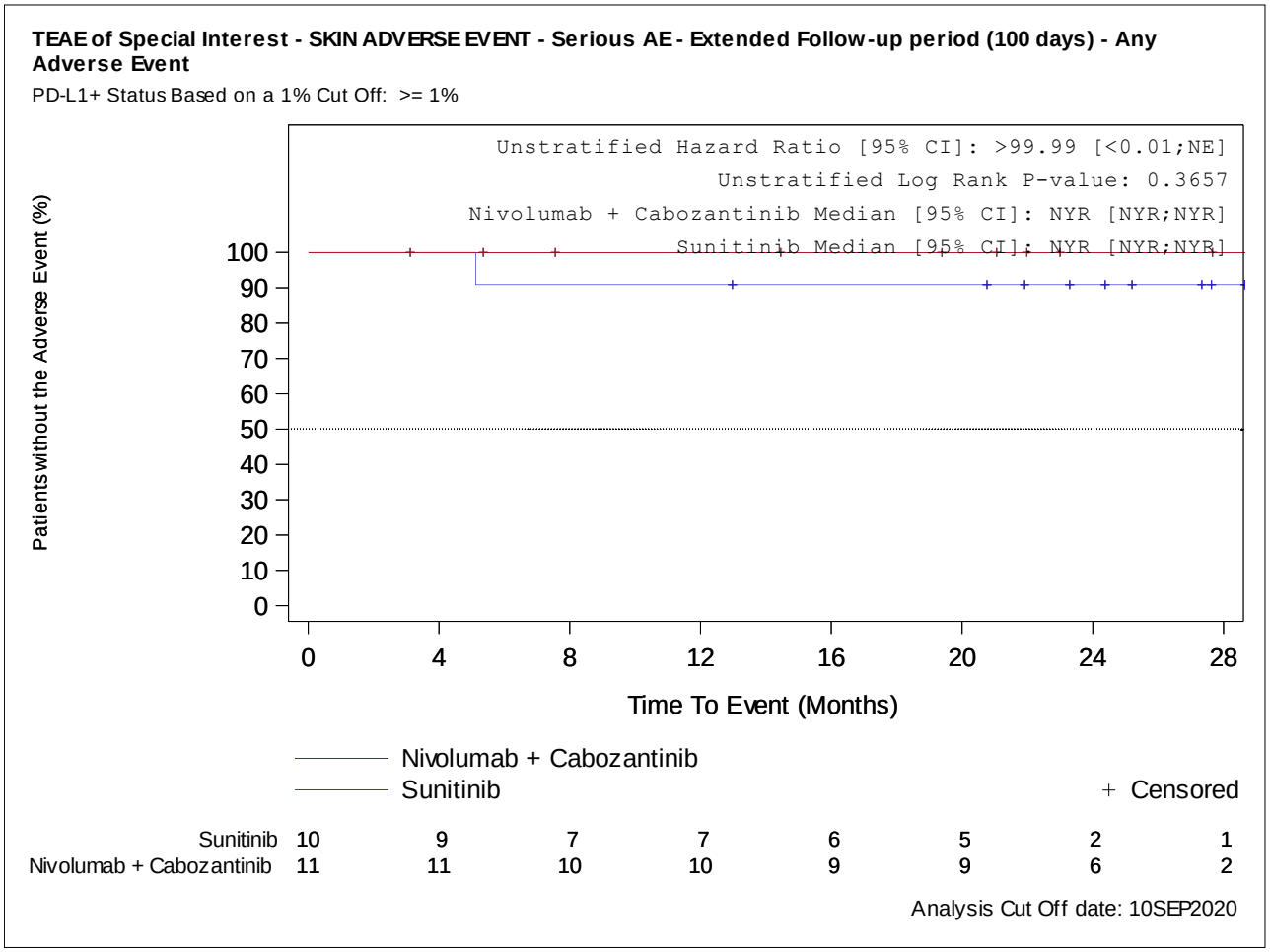

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:06:10

FIGURE 3.58.2.20: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:06:15

FIGURE 3.58.2.21: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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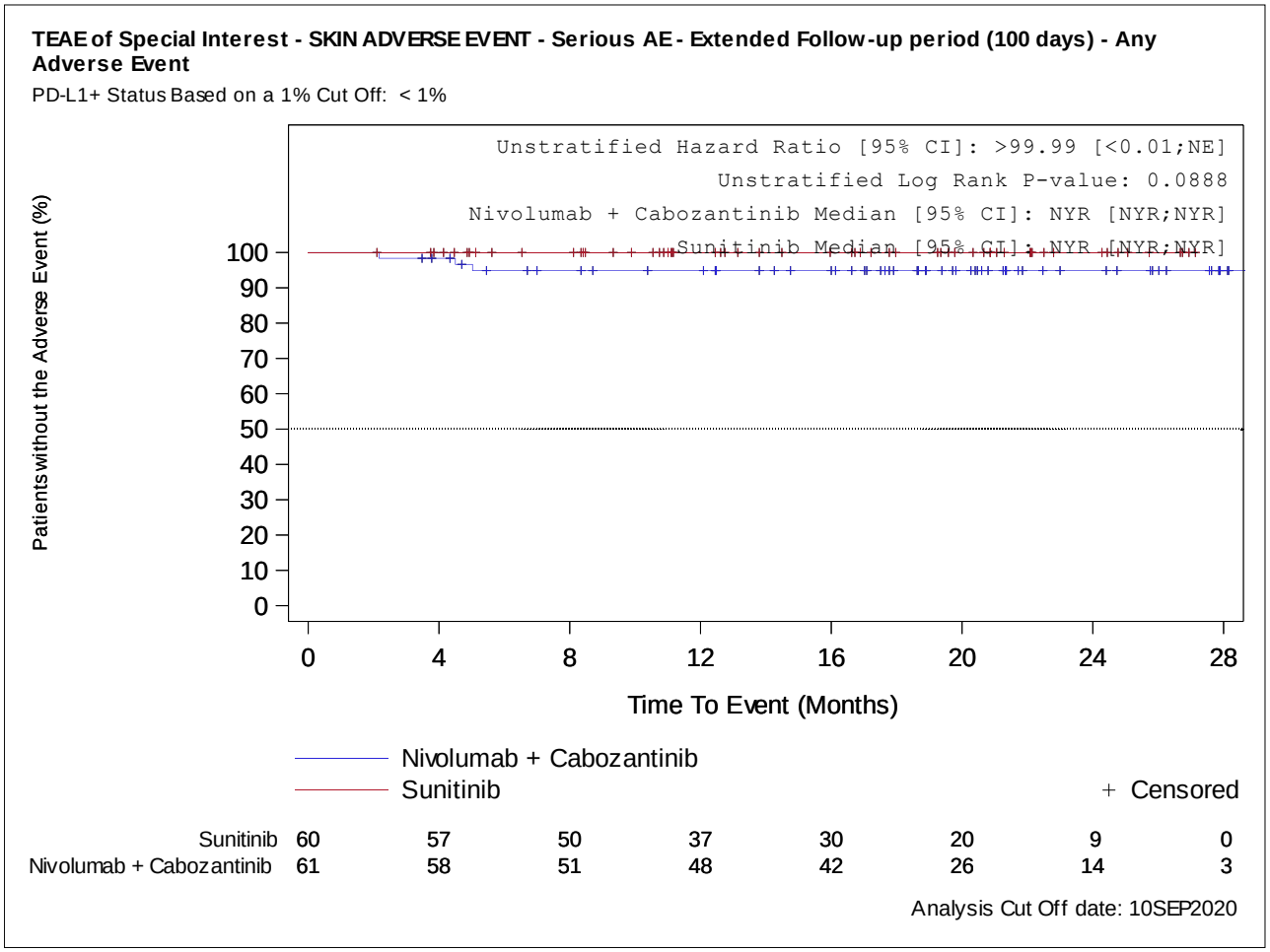
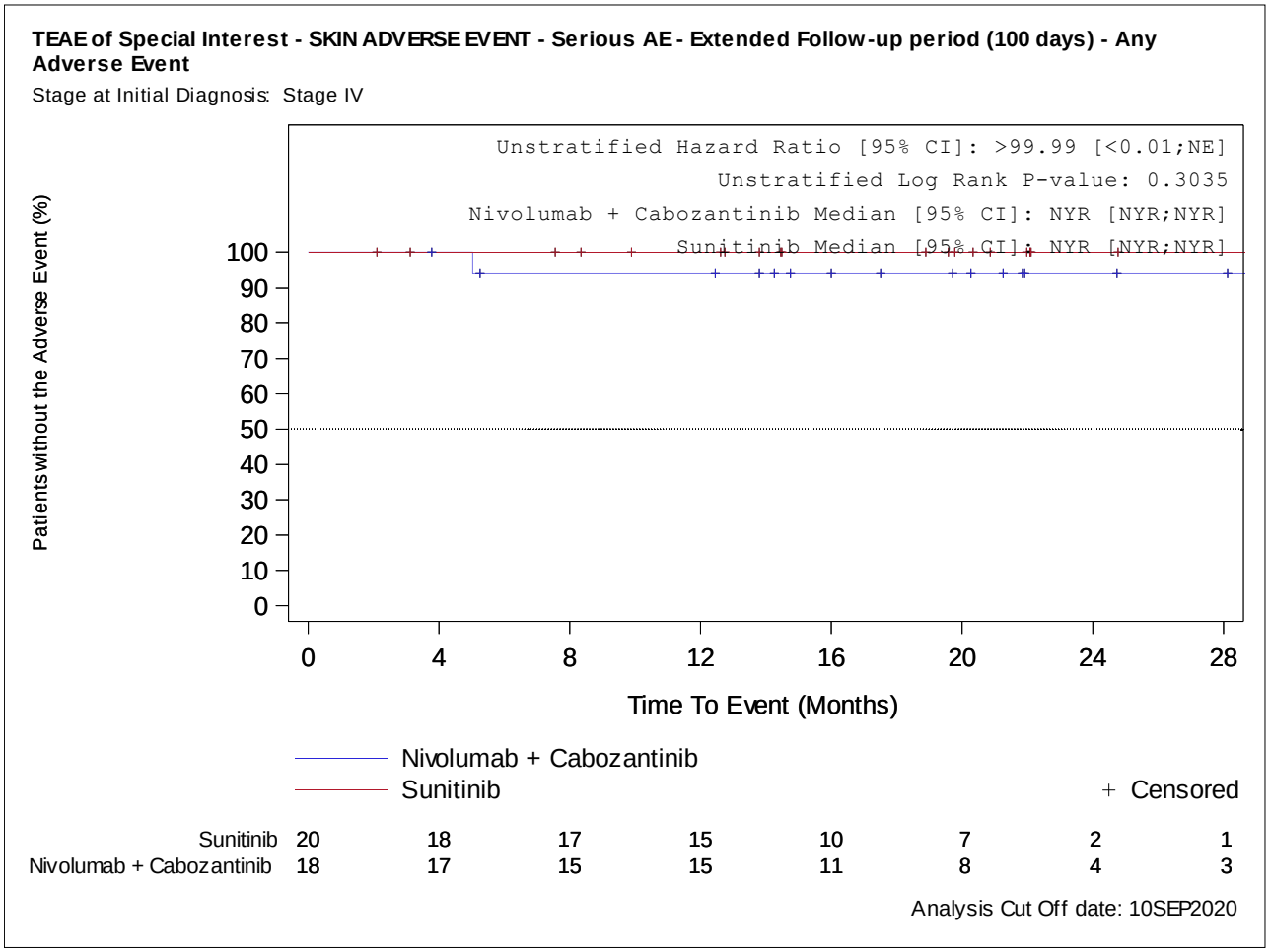
FIGURE 3.58.2.22: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



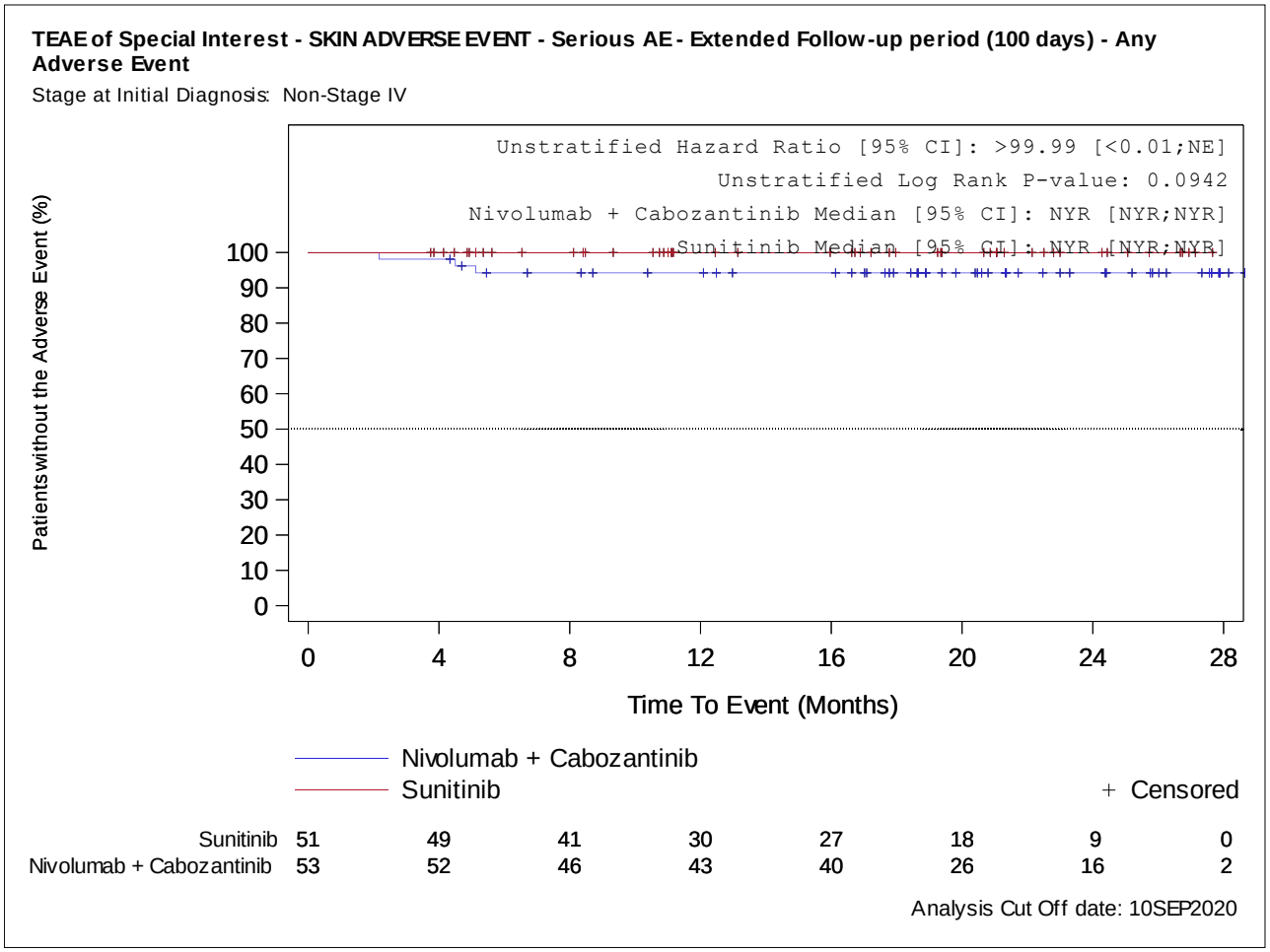

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:06:26

FIGURE 3.58.2.23: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



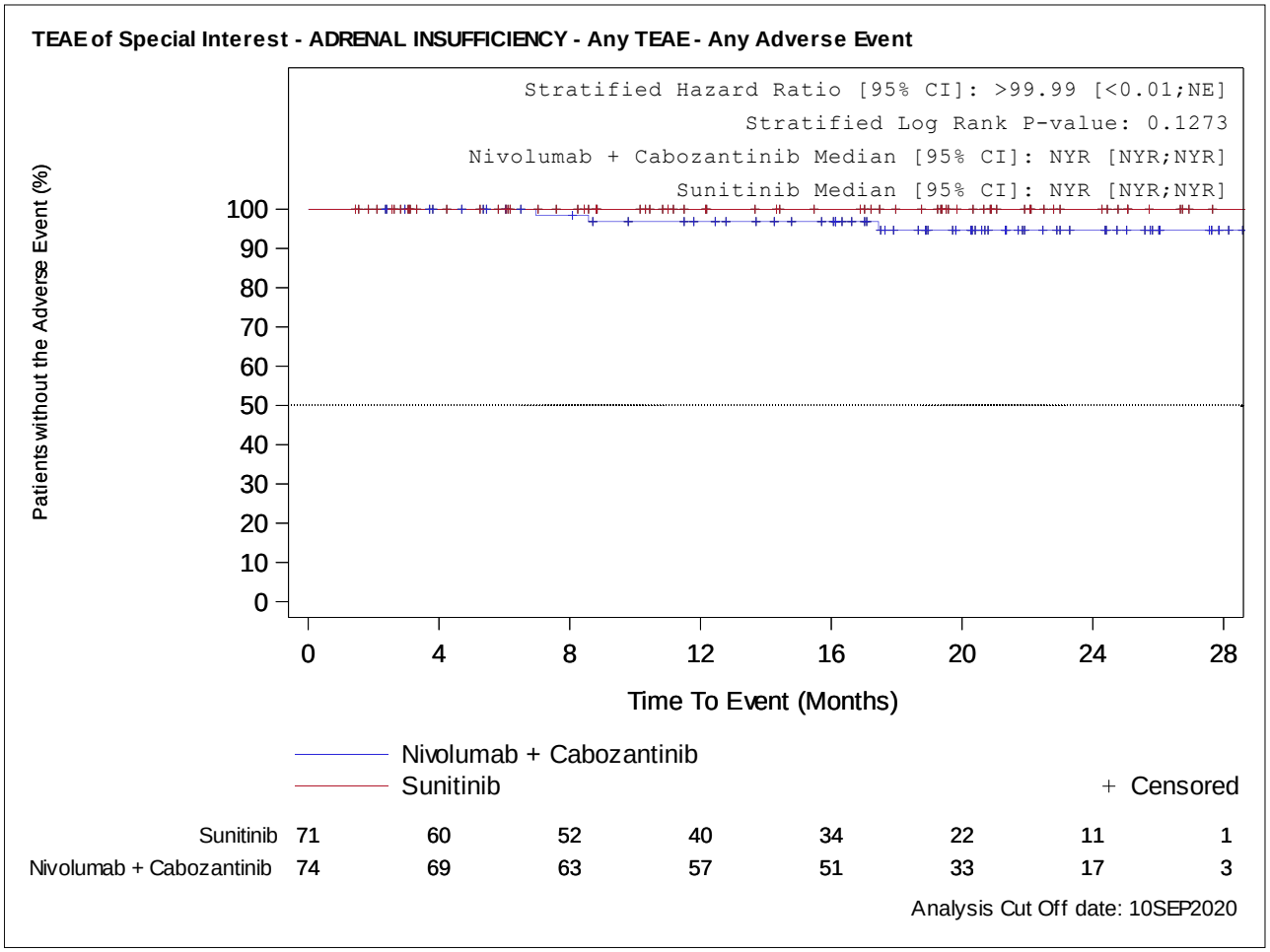

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:06:53

FIGURE 3.58.2.24: Kaplan-Meier curve - TEAE of Special Interest - SKIN ADVERSE EVENT - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:06:58

FIGURE 3.59.1: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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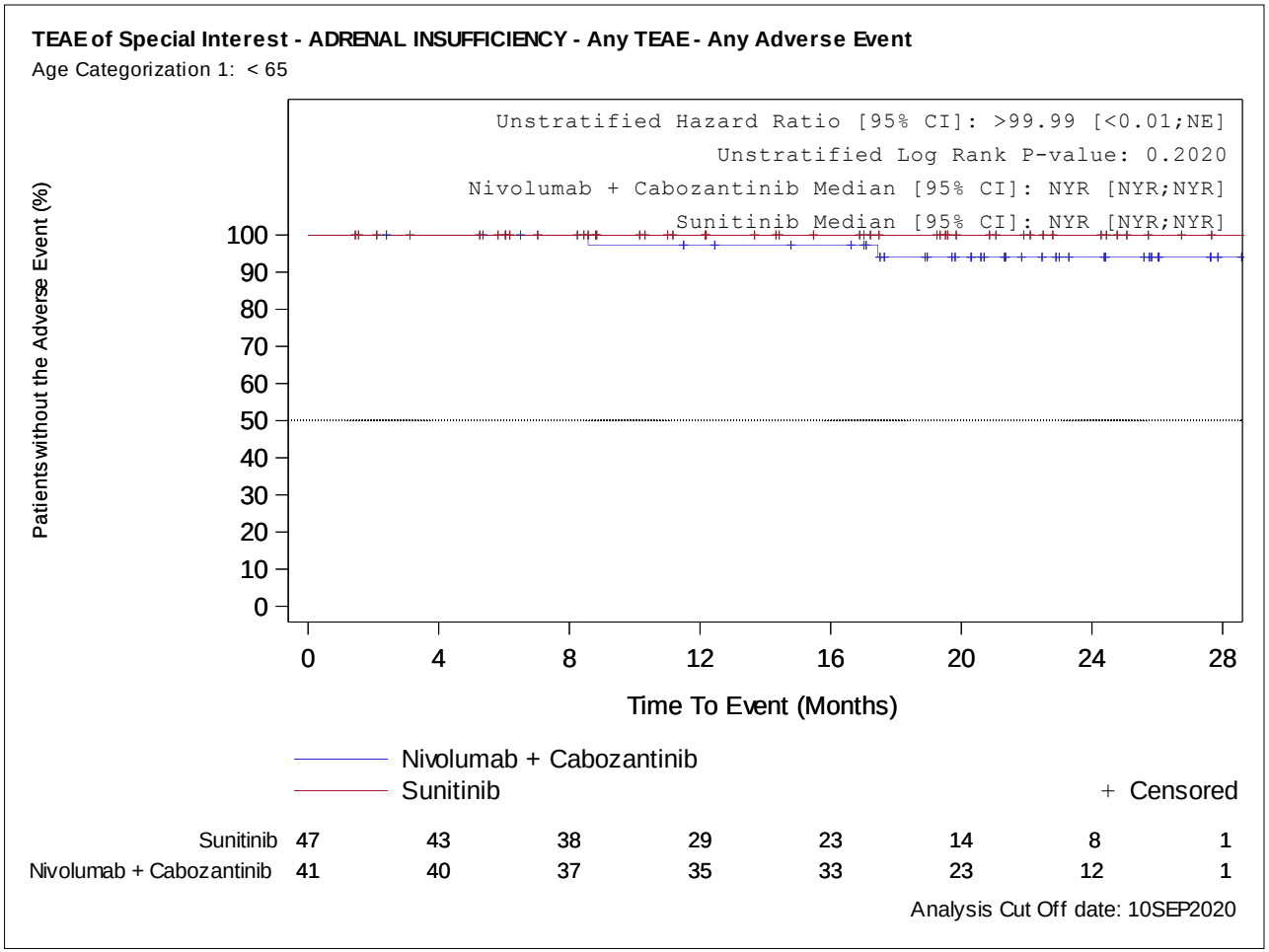
FIGURE 3.59.2.1: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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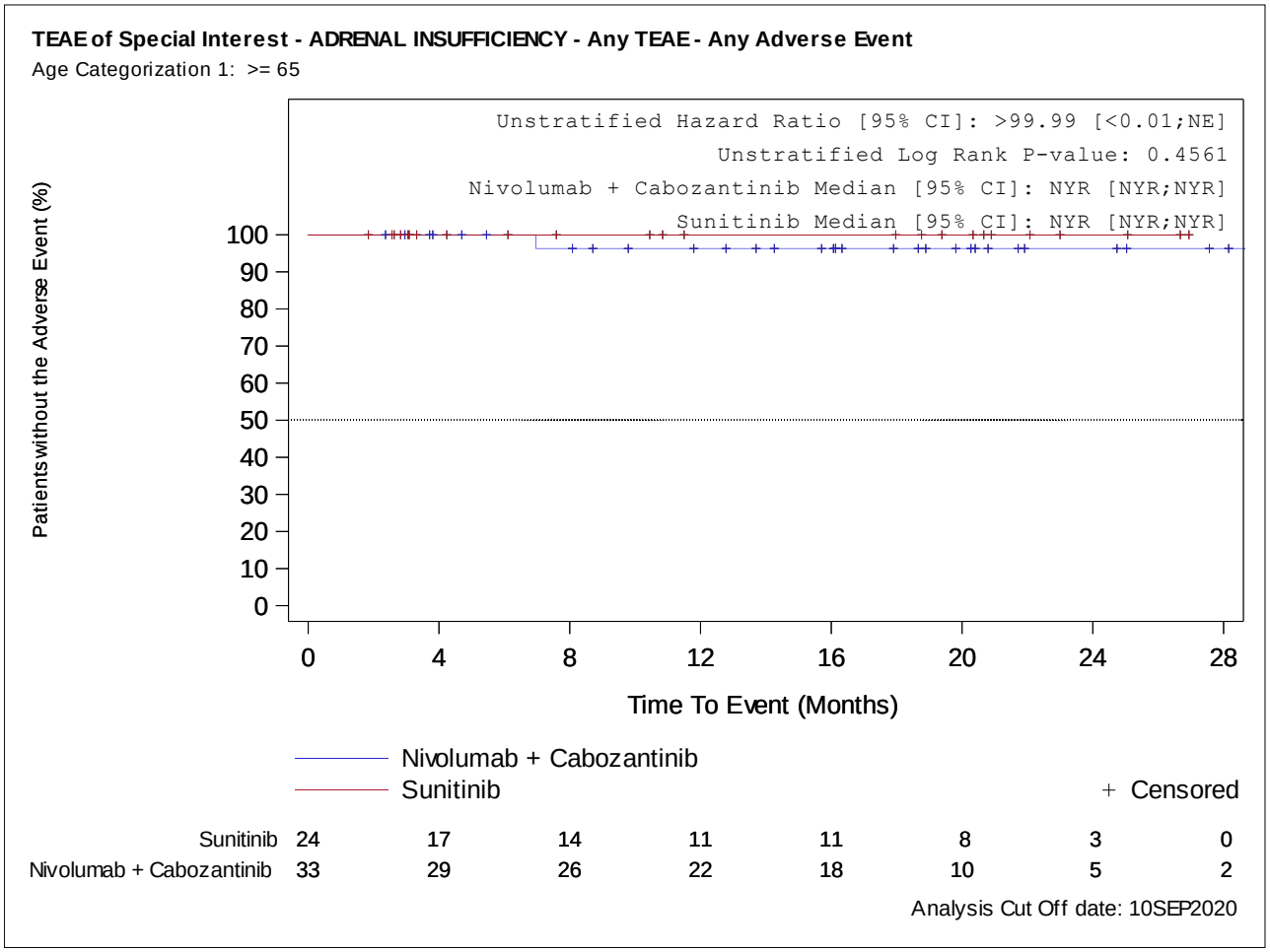
FIGURE 3.59.2.2: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
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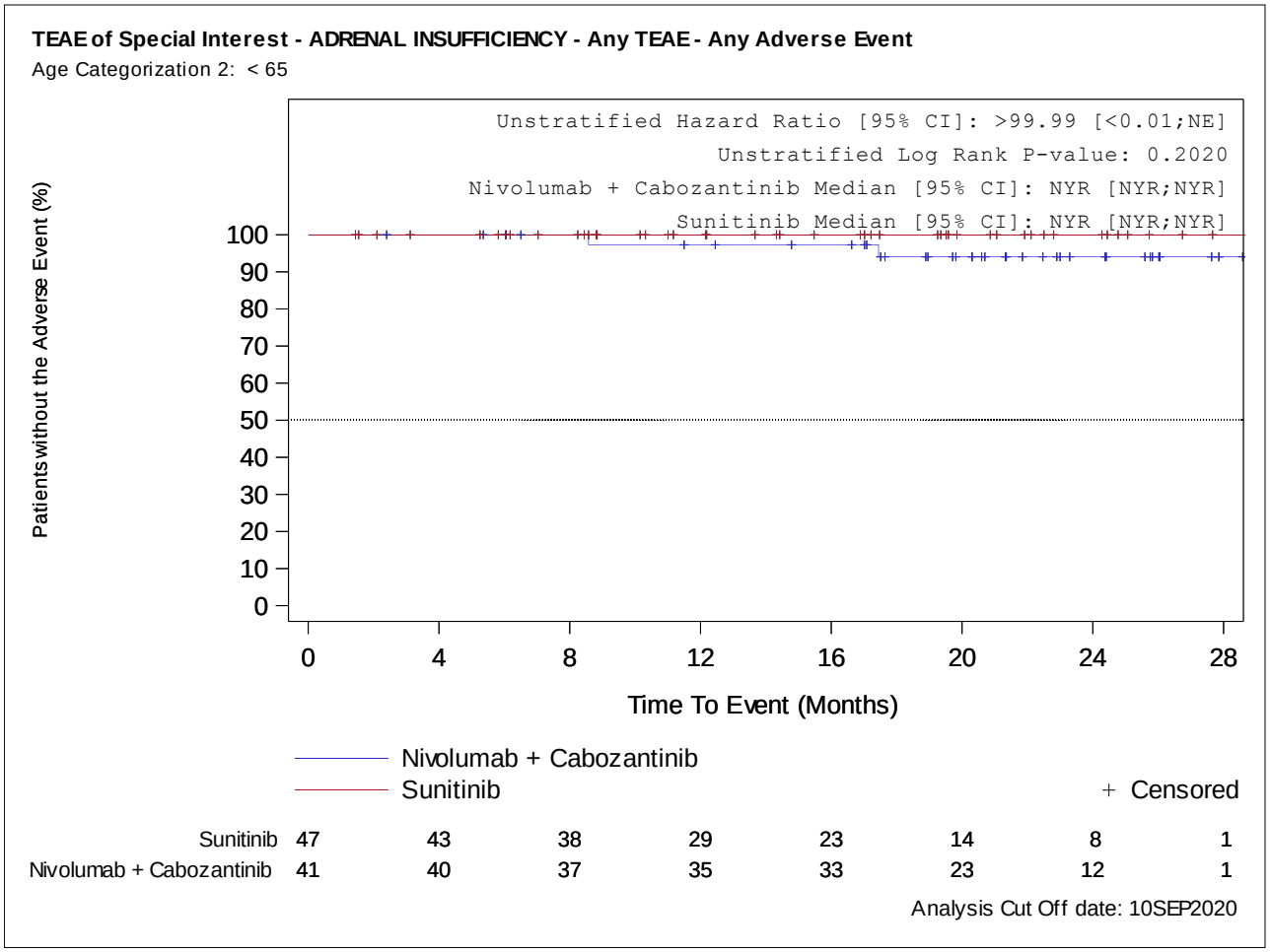
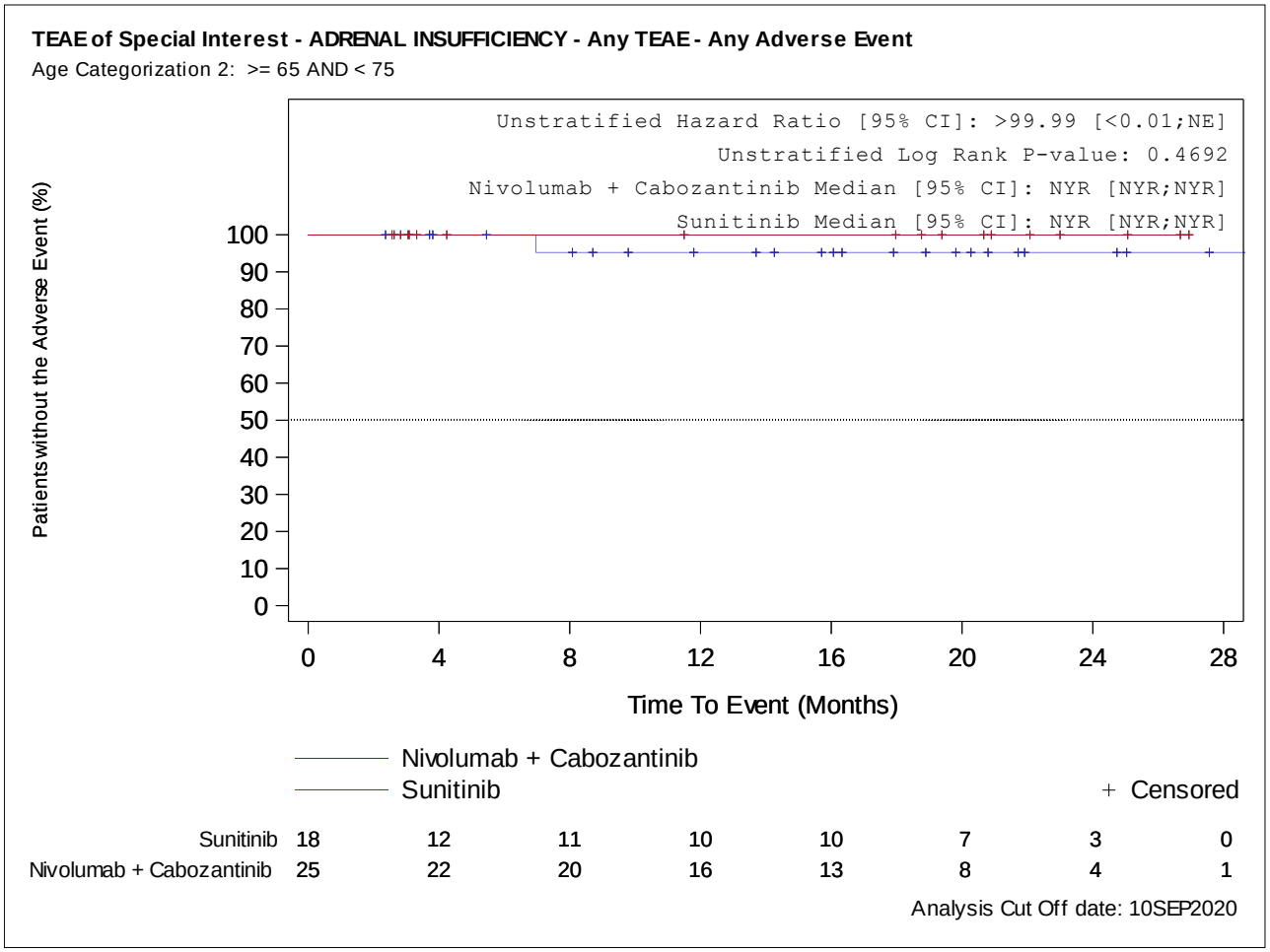
FIGURE 3.59.2.3: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:10:07

FIGURE 3.59.2.4: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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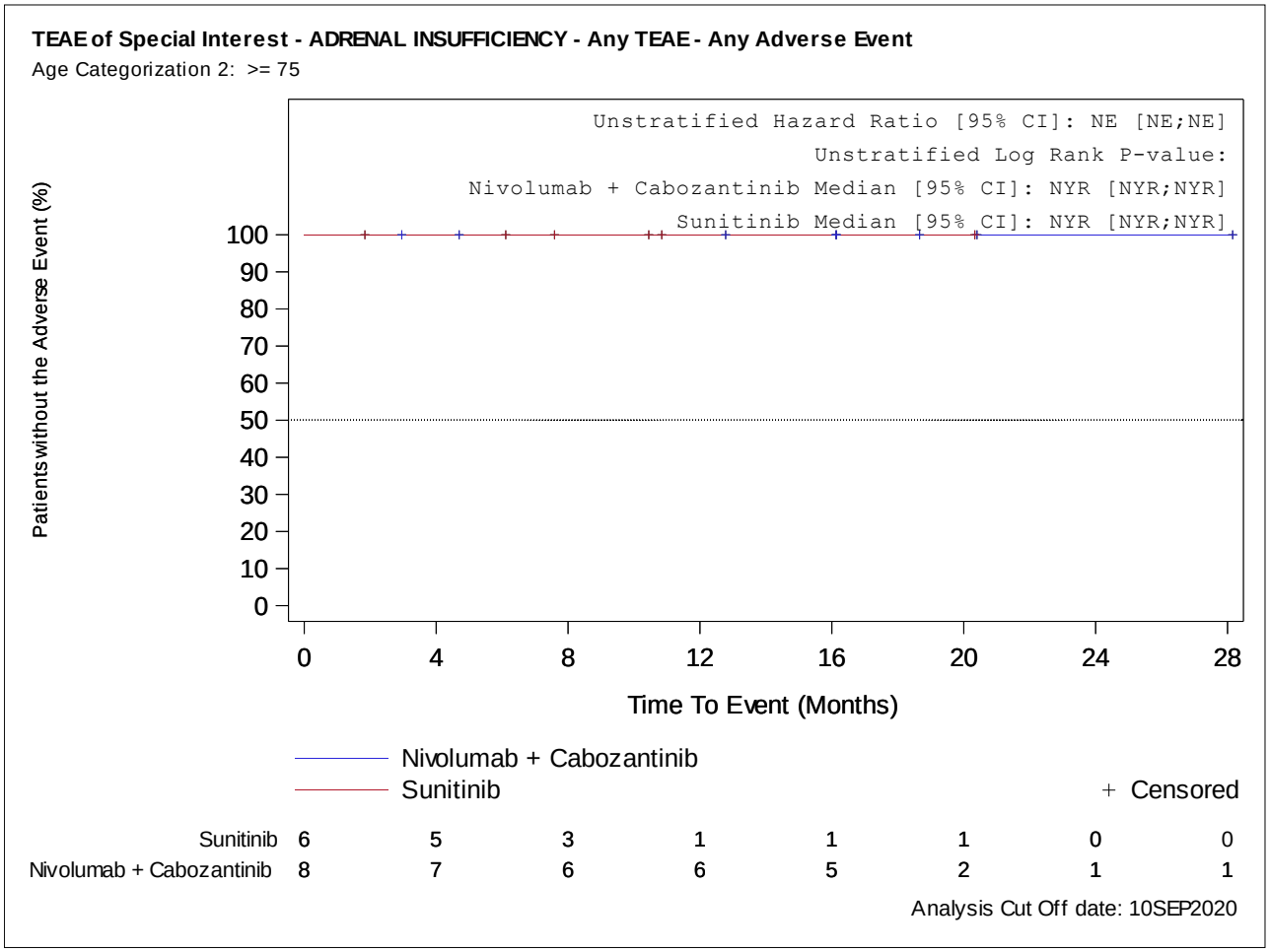
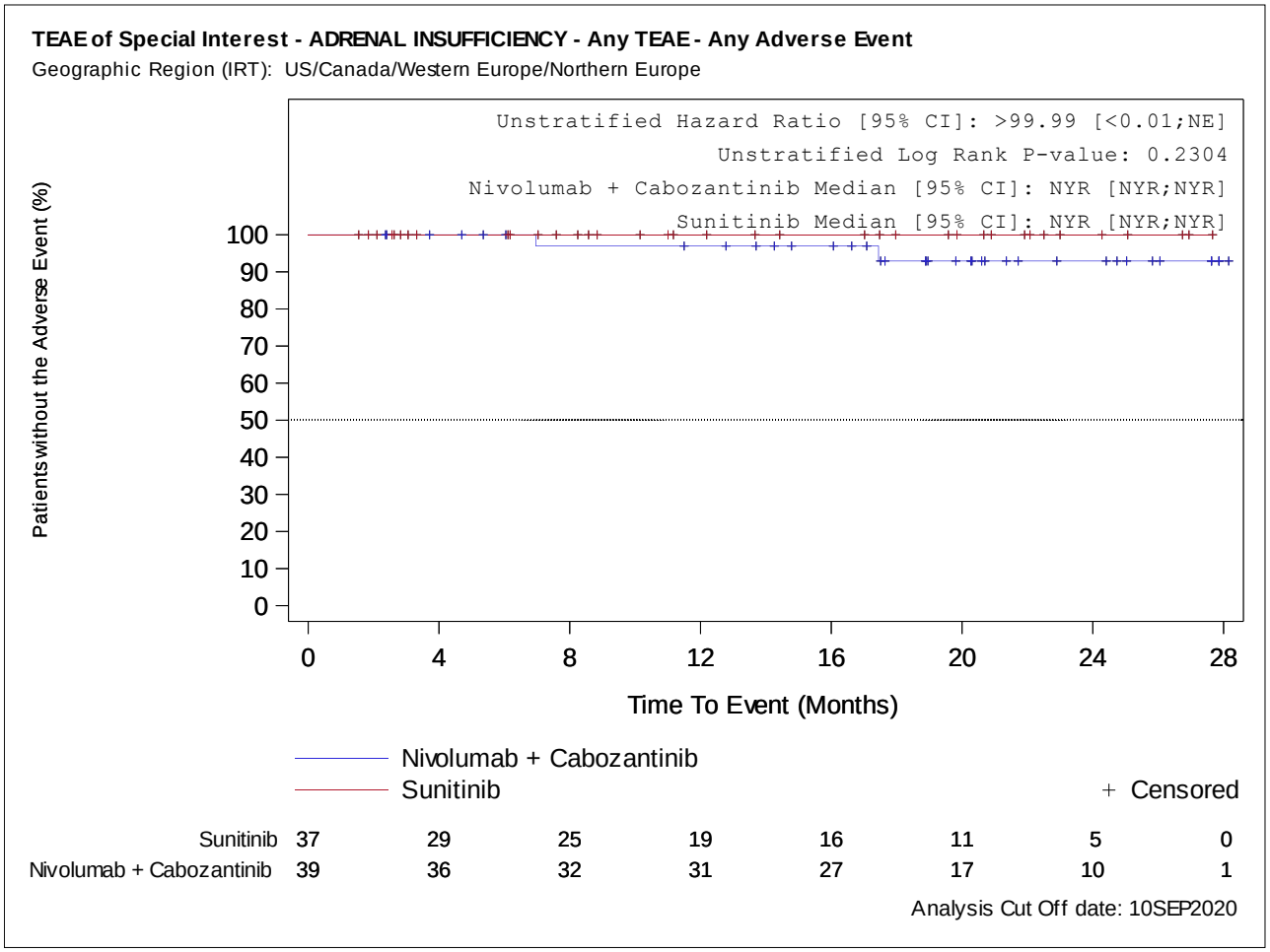
FIGURE 3.59.2.5: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



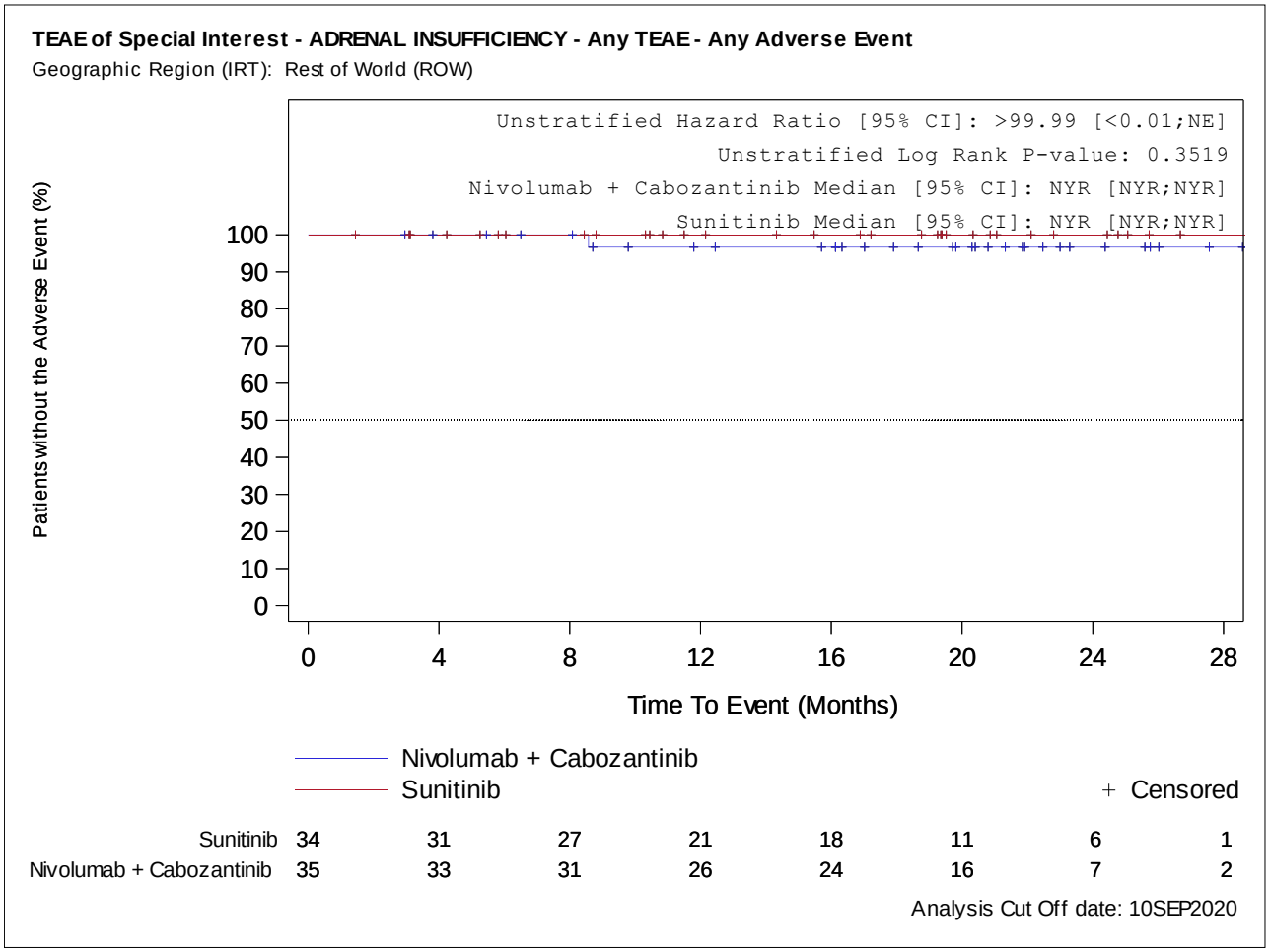

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:10:17

FIGURE 3.59.2.6: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



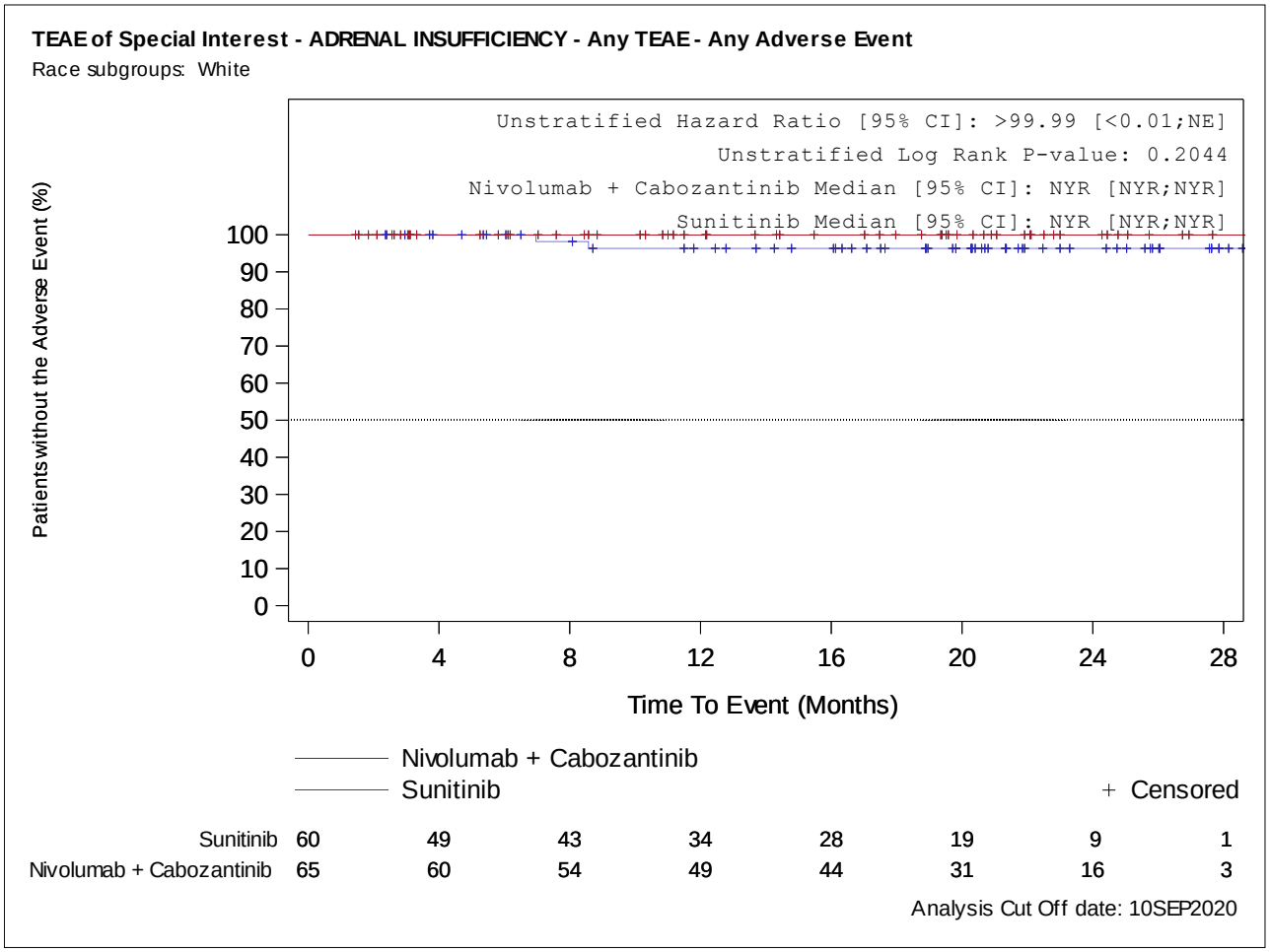

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:10:22

FIGURE 3.59.2.7: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:10:27

FIGURE 3.59.2.8: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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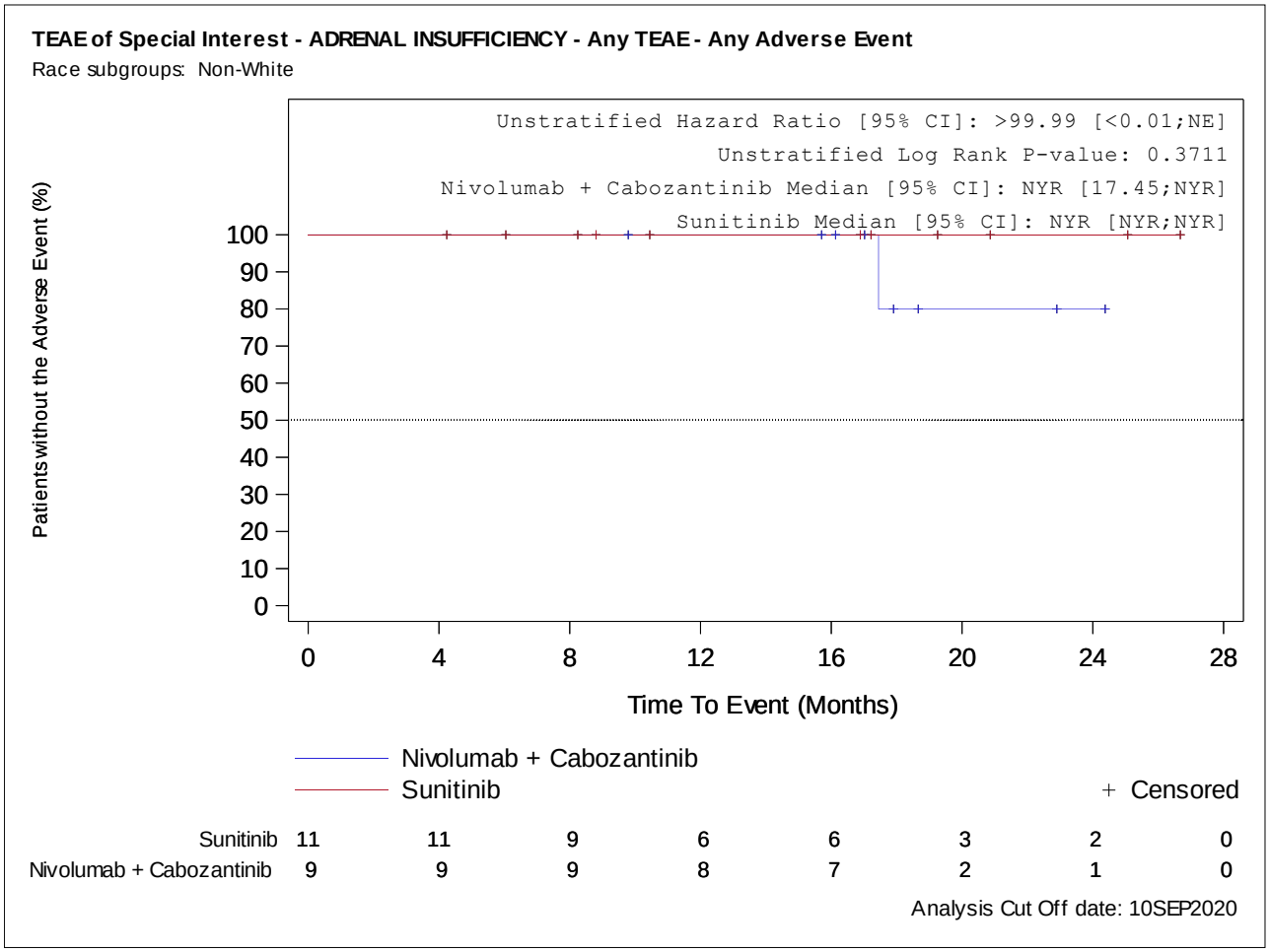
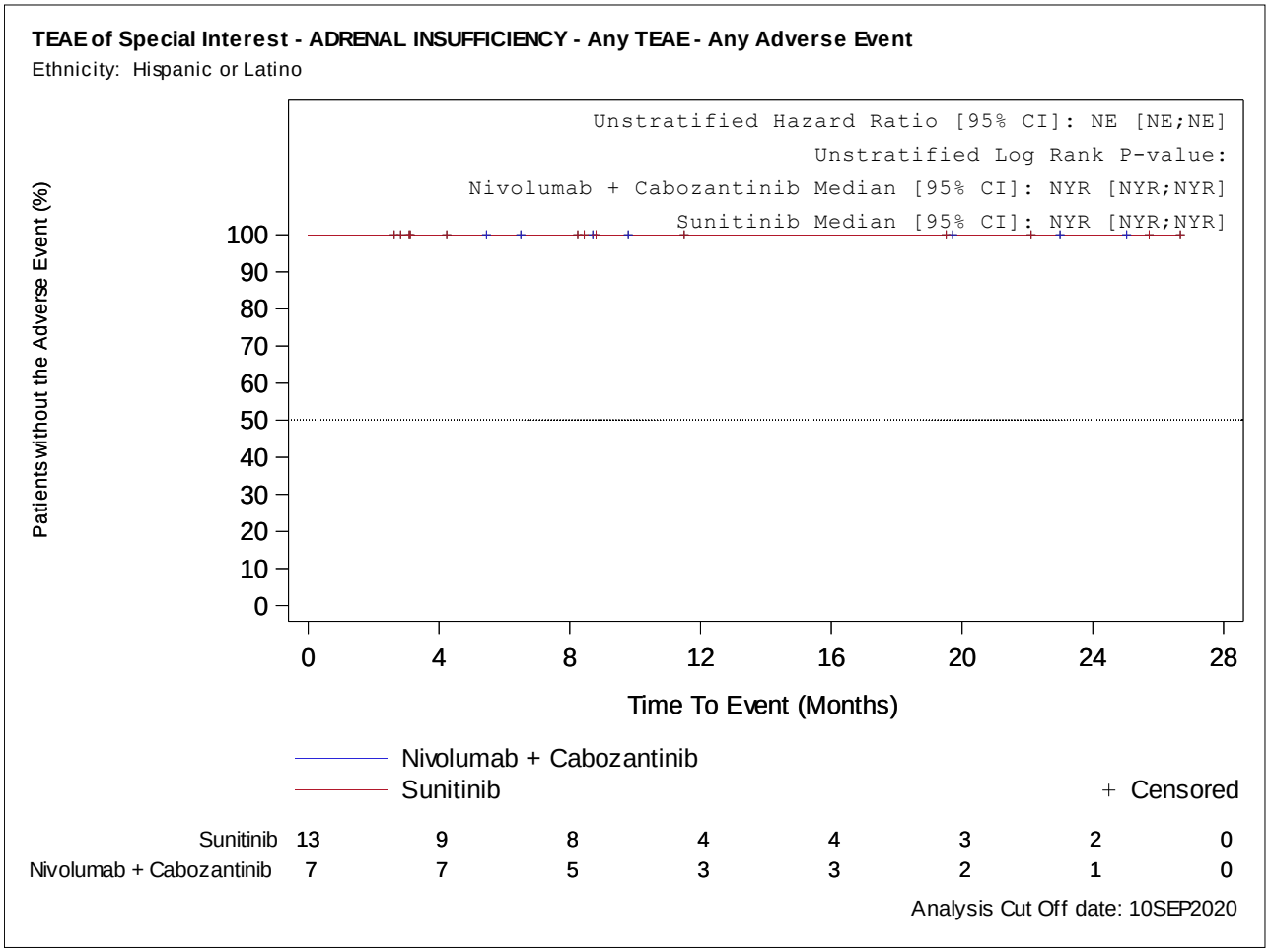
FIGURE 3.59.2.9: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



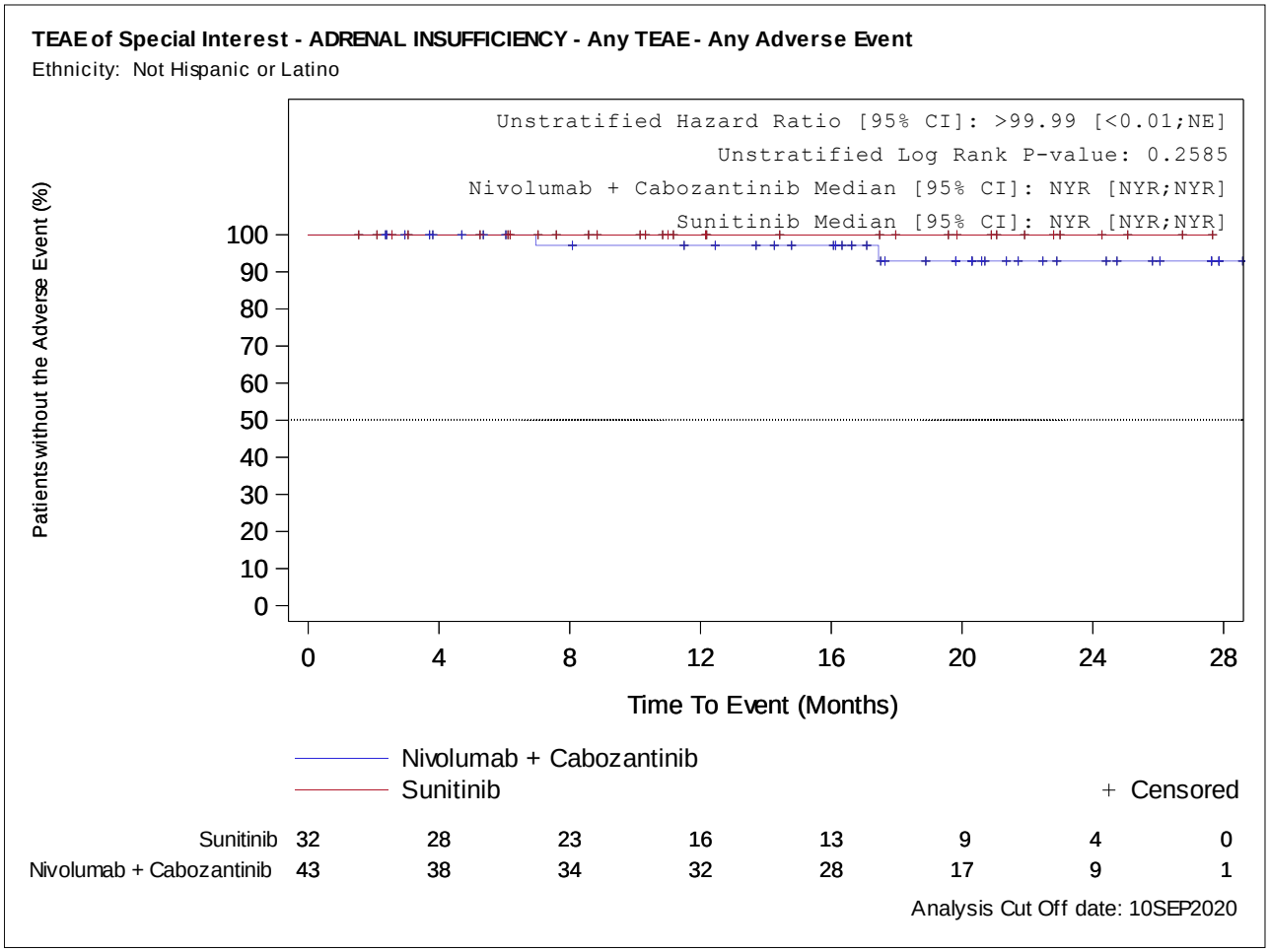

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:10:38

FIGURE 3.59.2.10: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



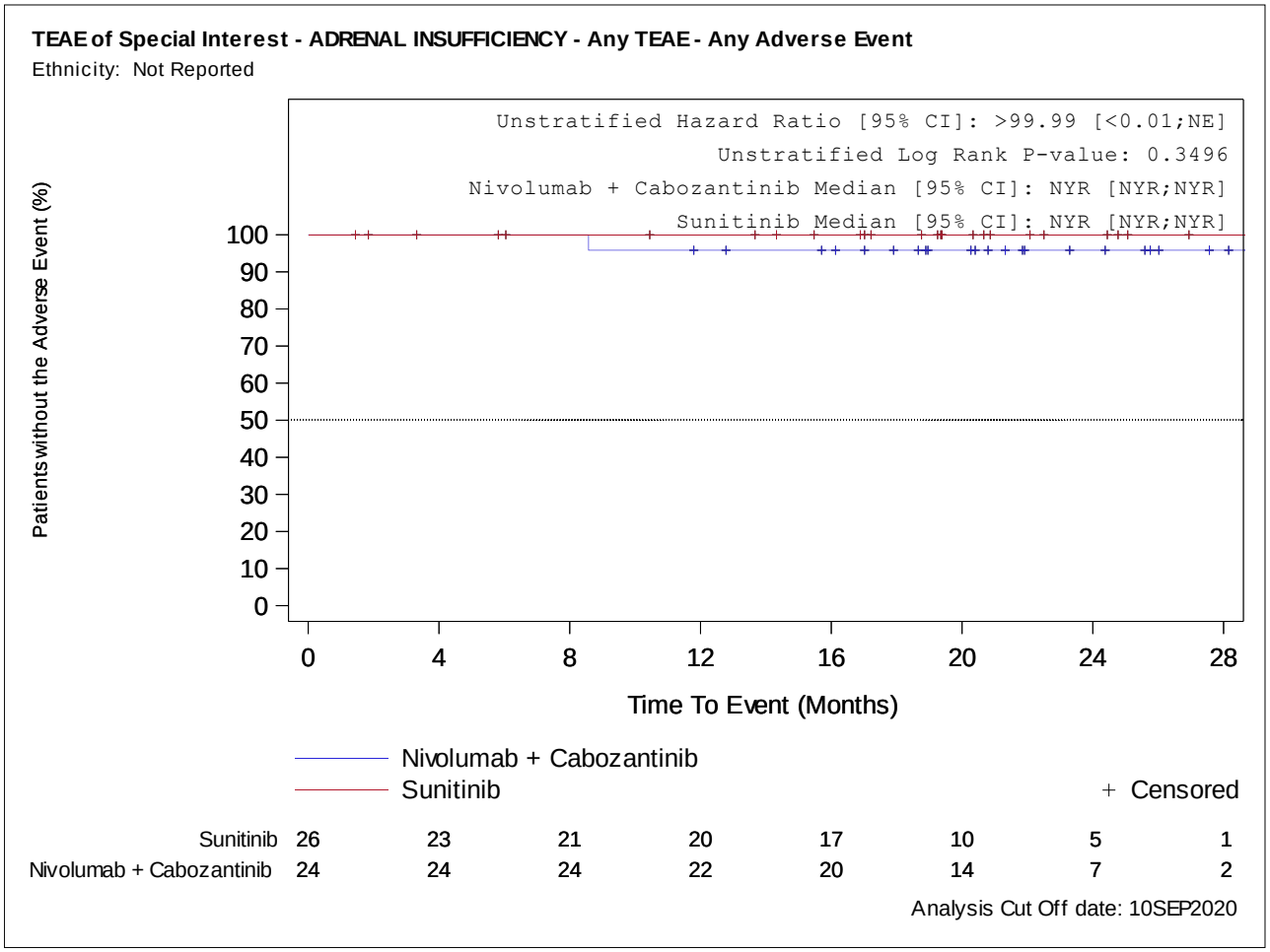

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:10:44

FIGURE 3.59.2.11: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:10:49

FIGURE 3.59.2.12: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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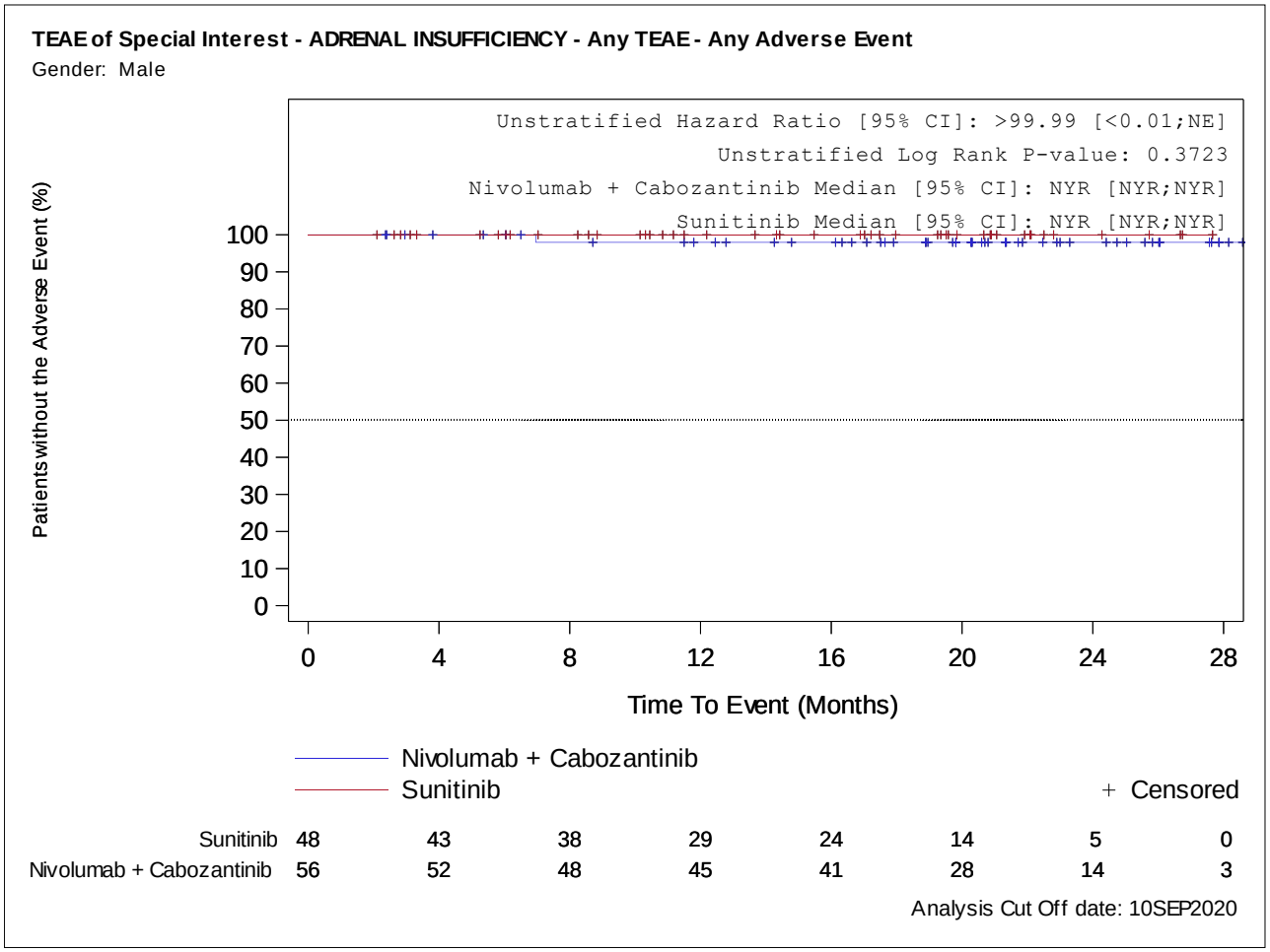
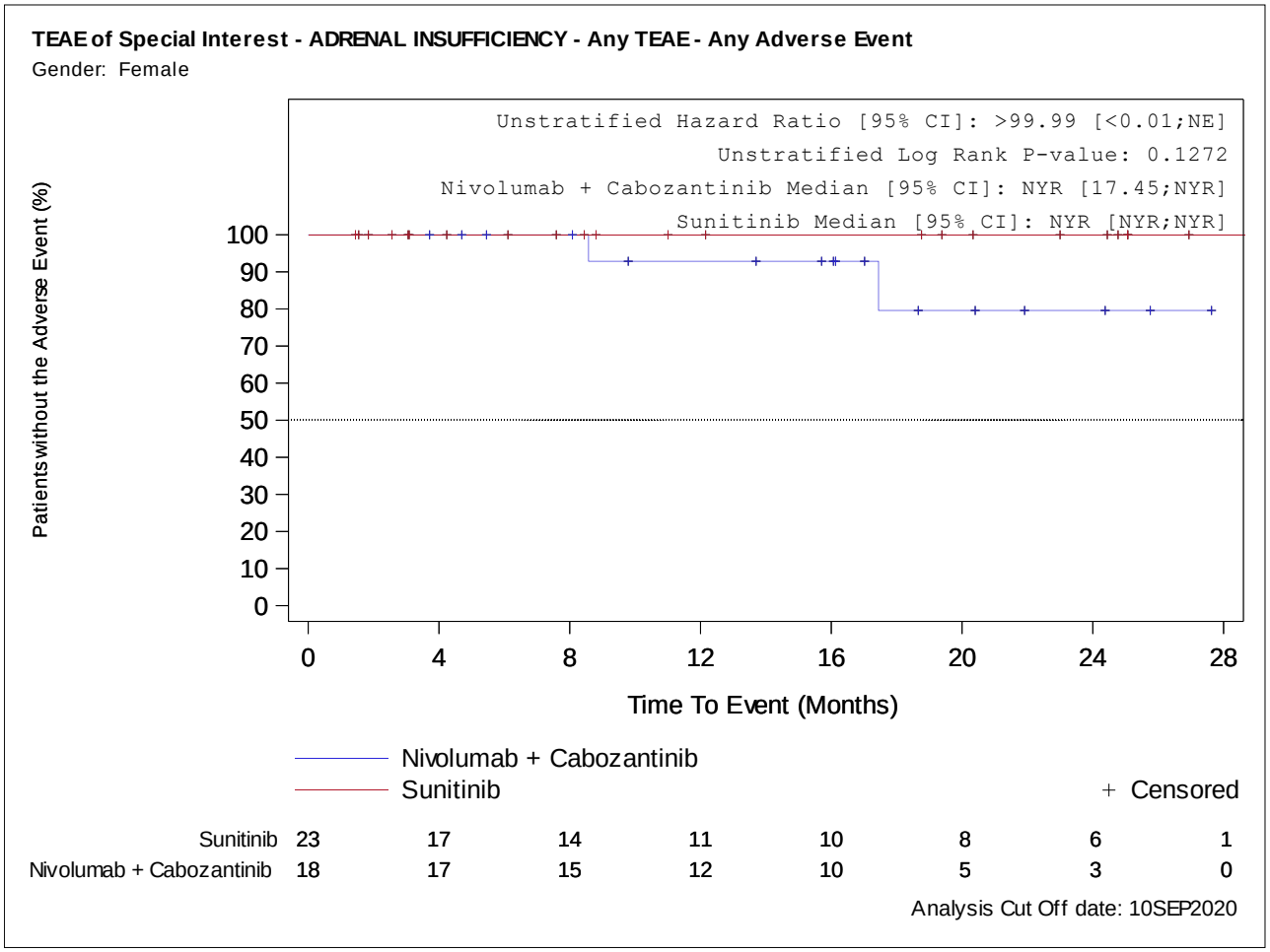
FIGURE 3.59.2.13: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



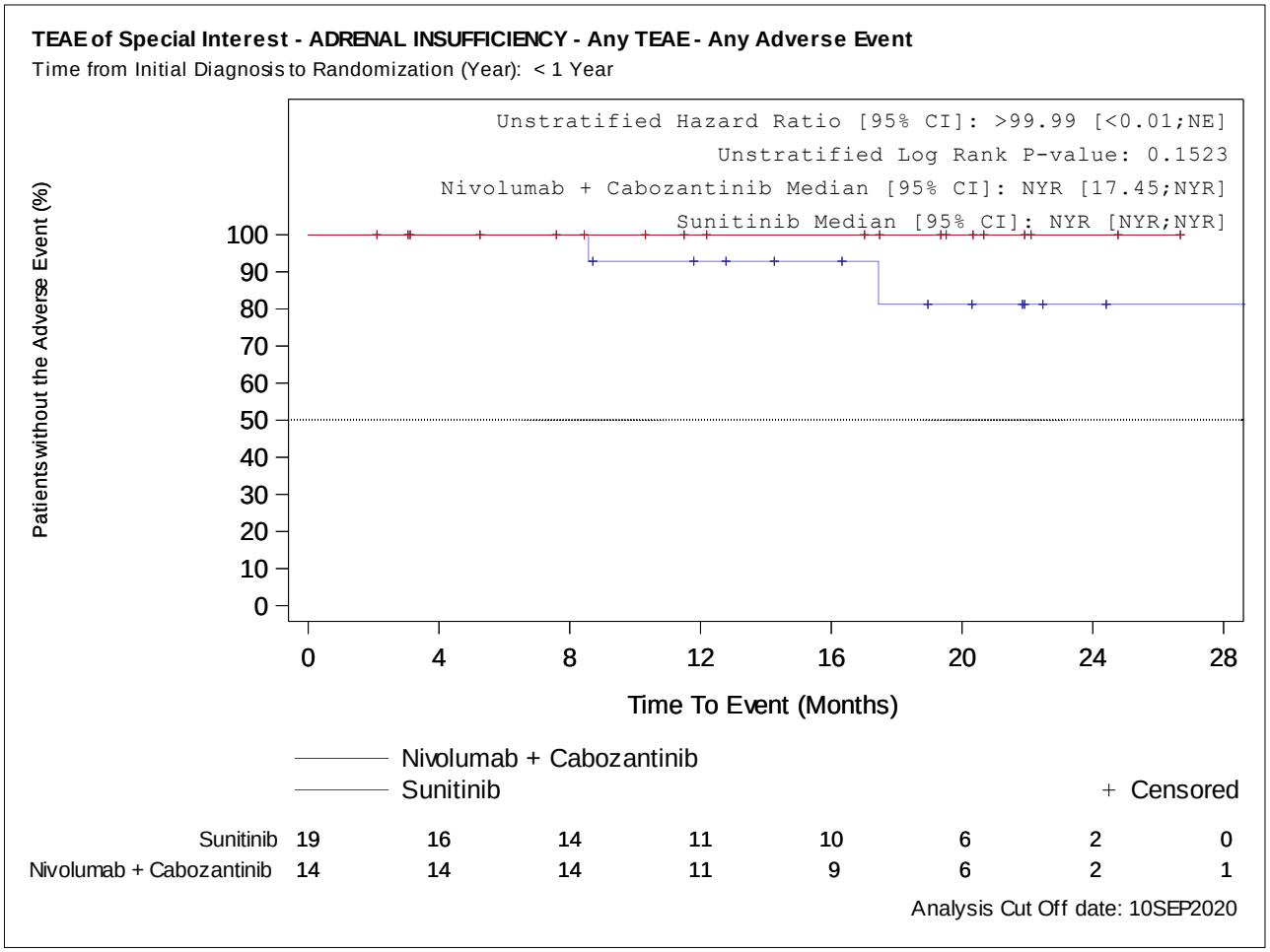

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:11:00

FIGURE 3.59.2.14: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:11:05

FIGURE 3.59.2.15: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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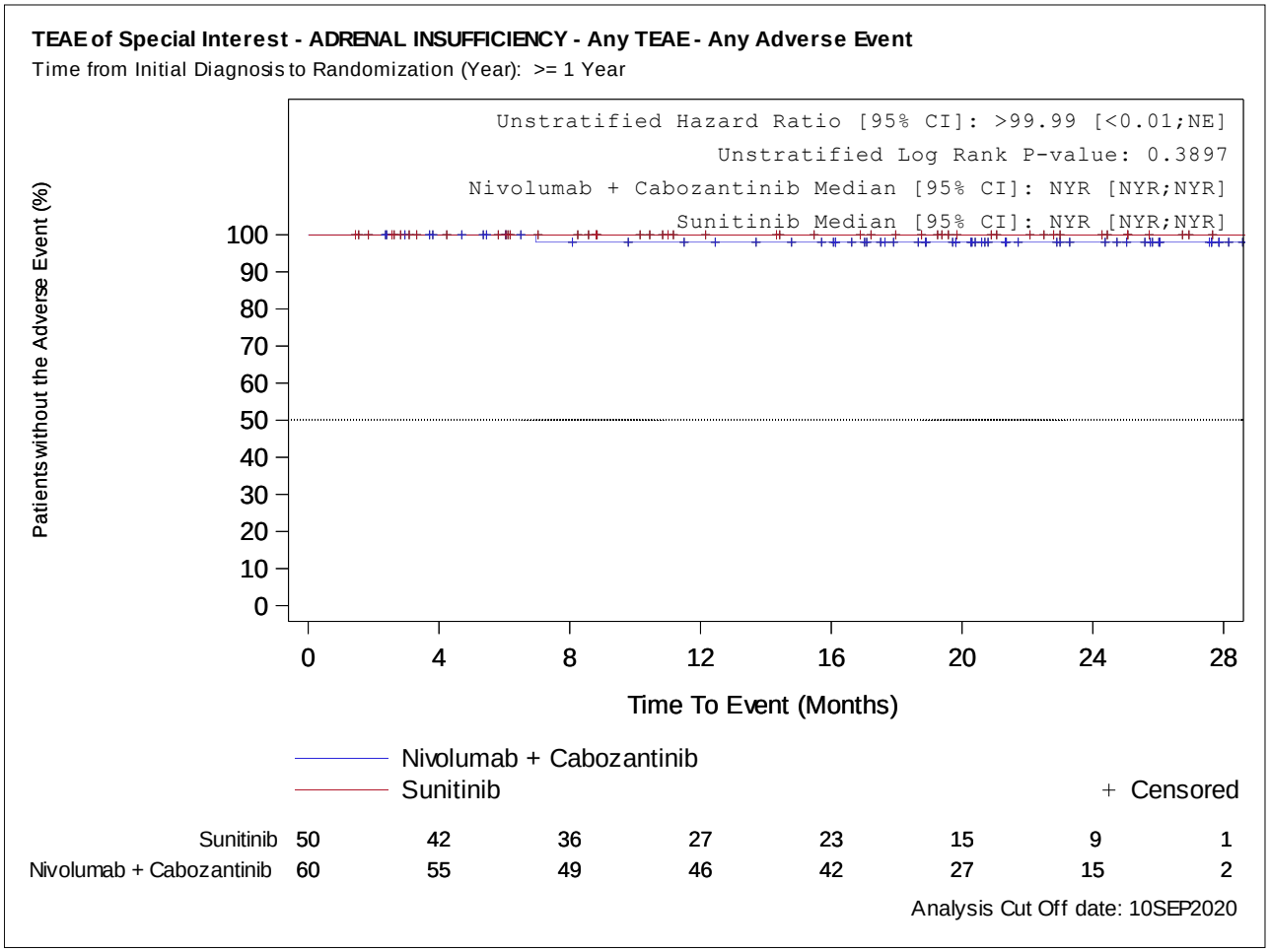
FIGURE 3.59.2.16: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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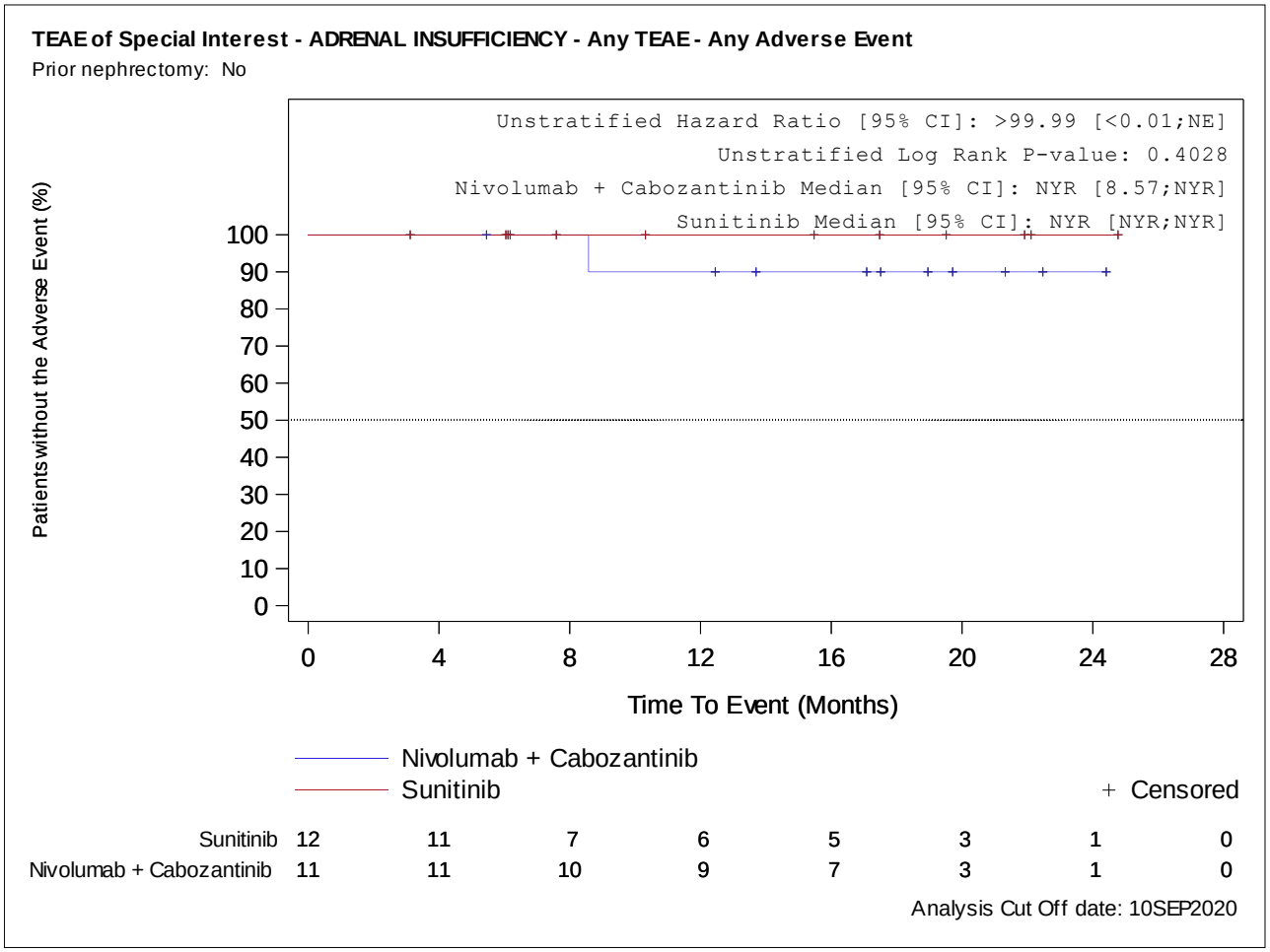
FIGURE 3.59.2.17: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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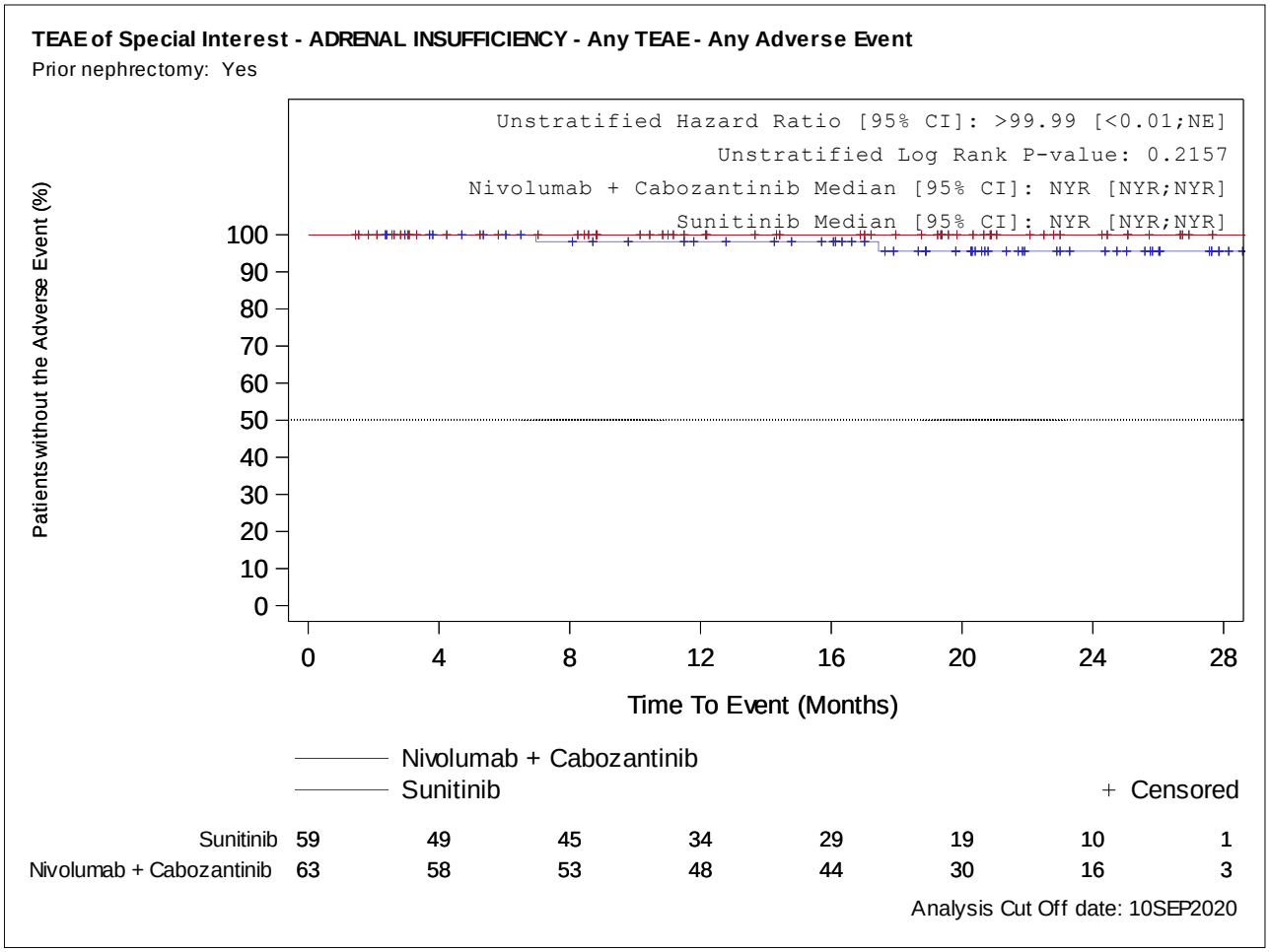
FIGURE 3.59.2.18: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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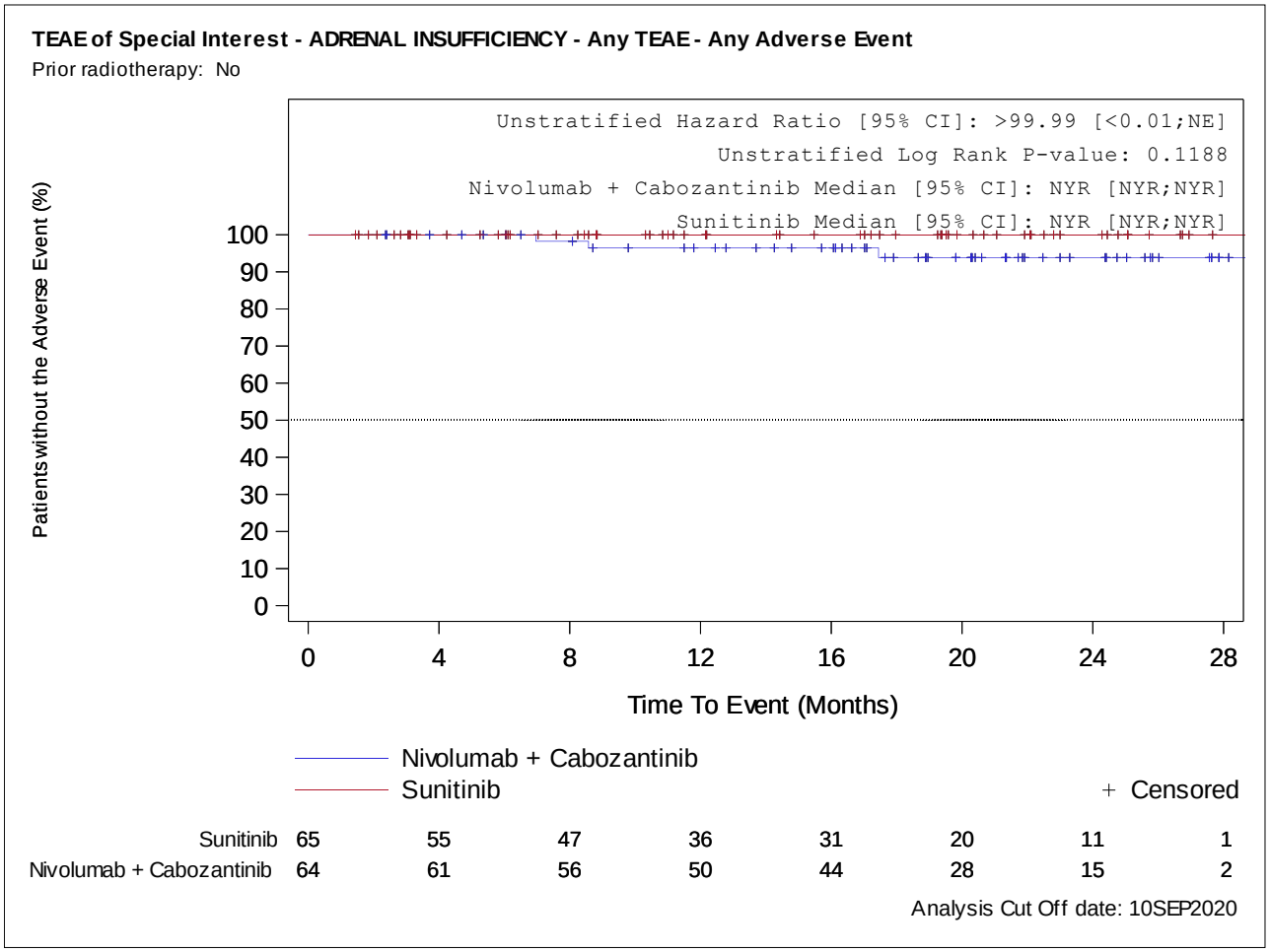
FIGURE 3.59.2.19: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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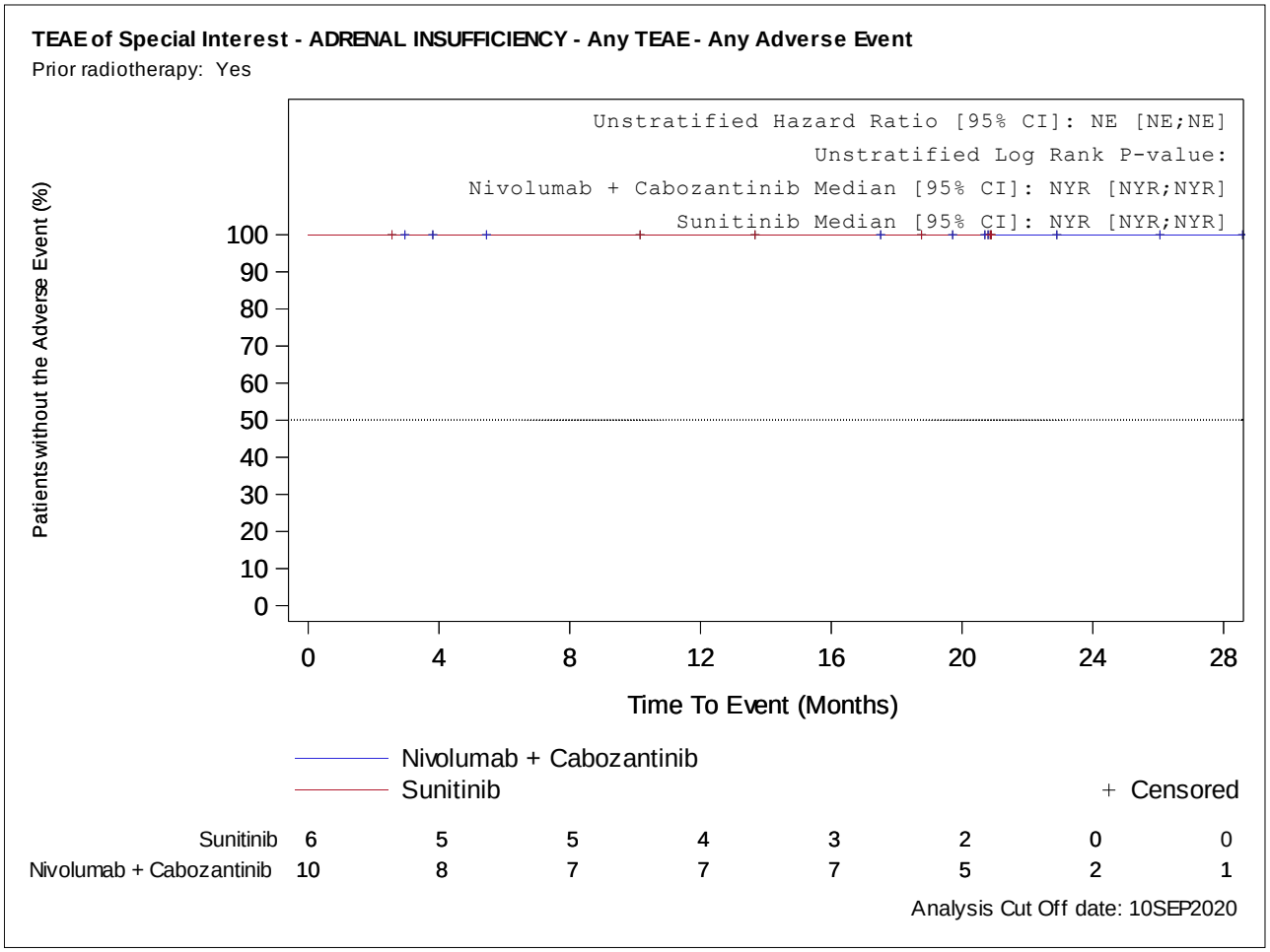
FIGURE 3.59.2.20: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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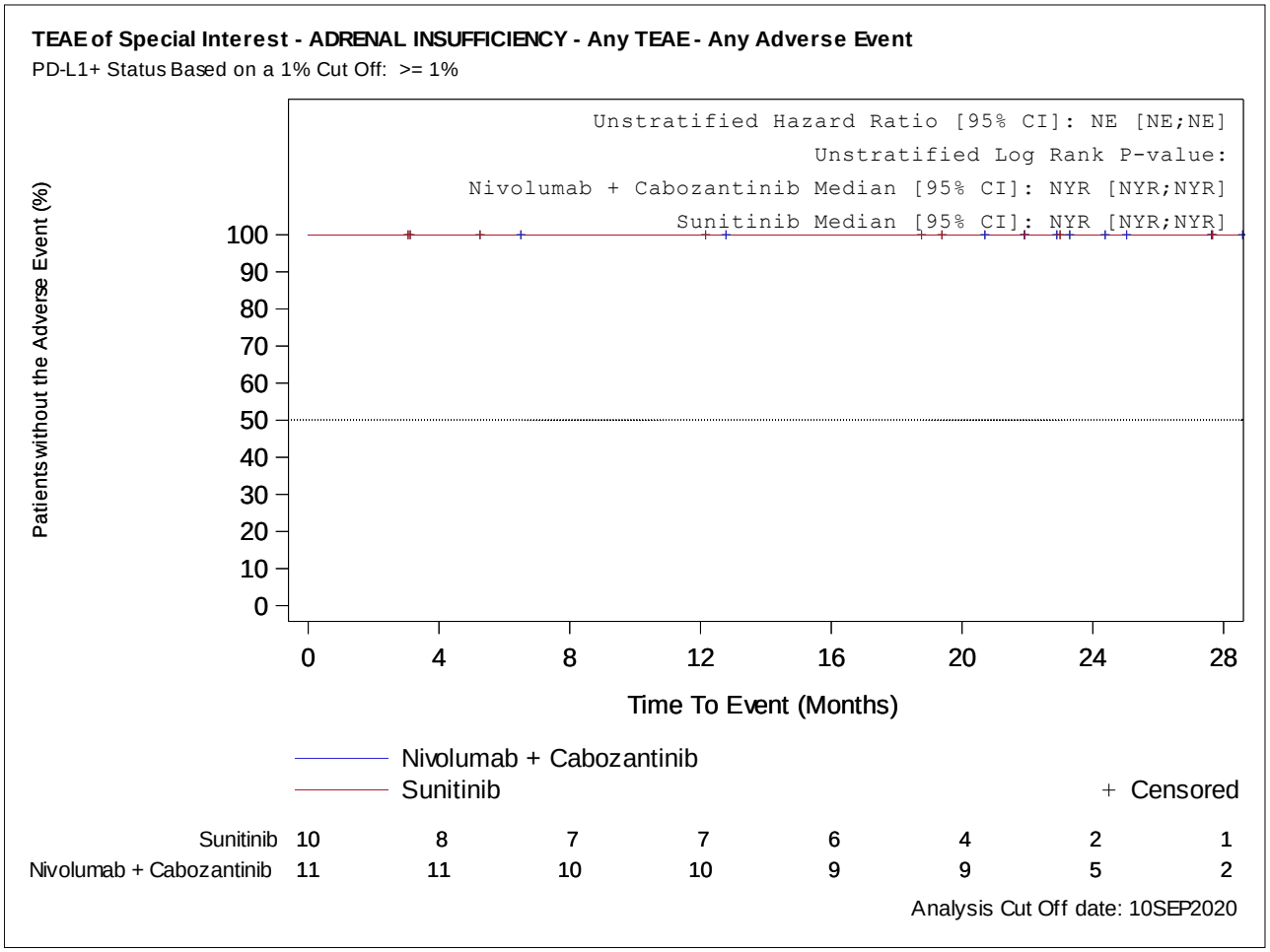
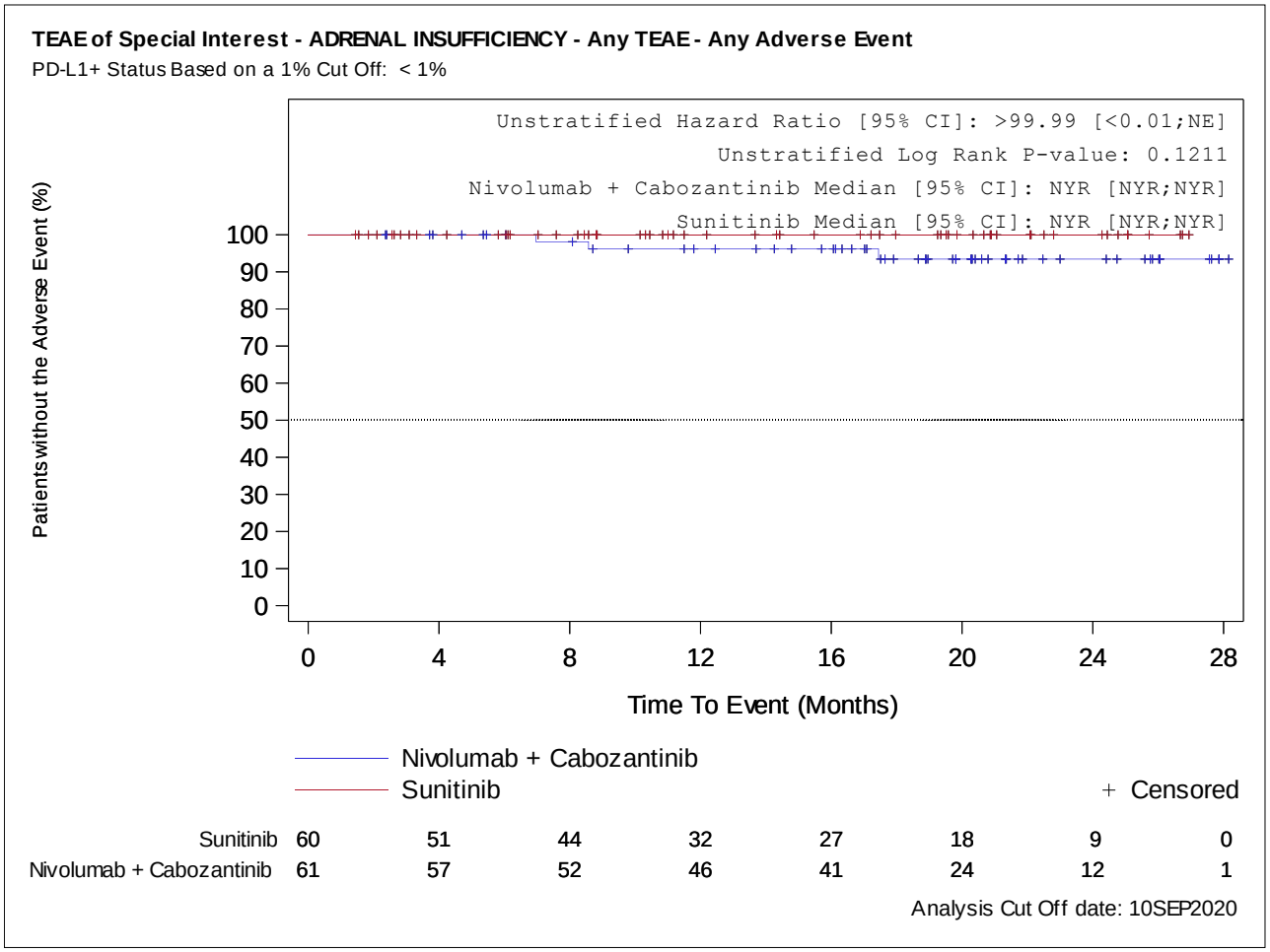
FIGURE 3.59.2.21: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



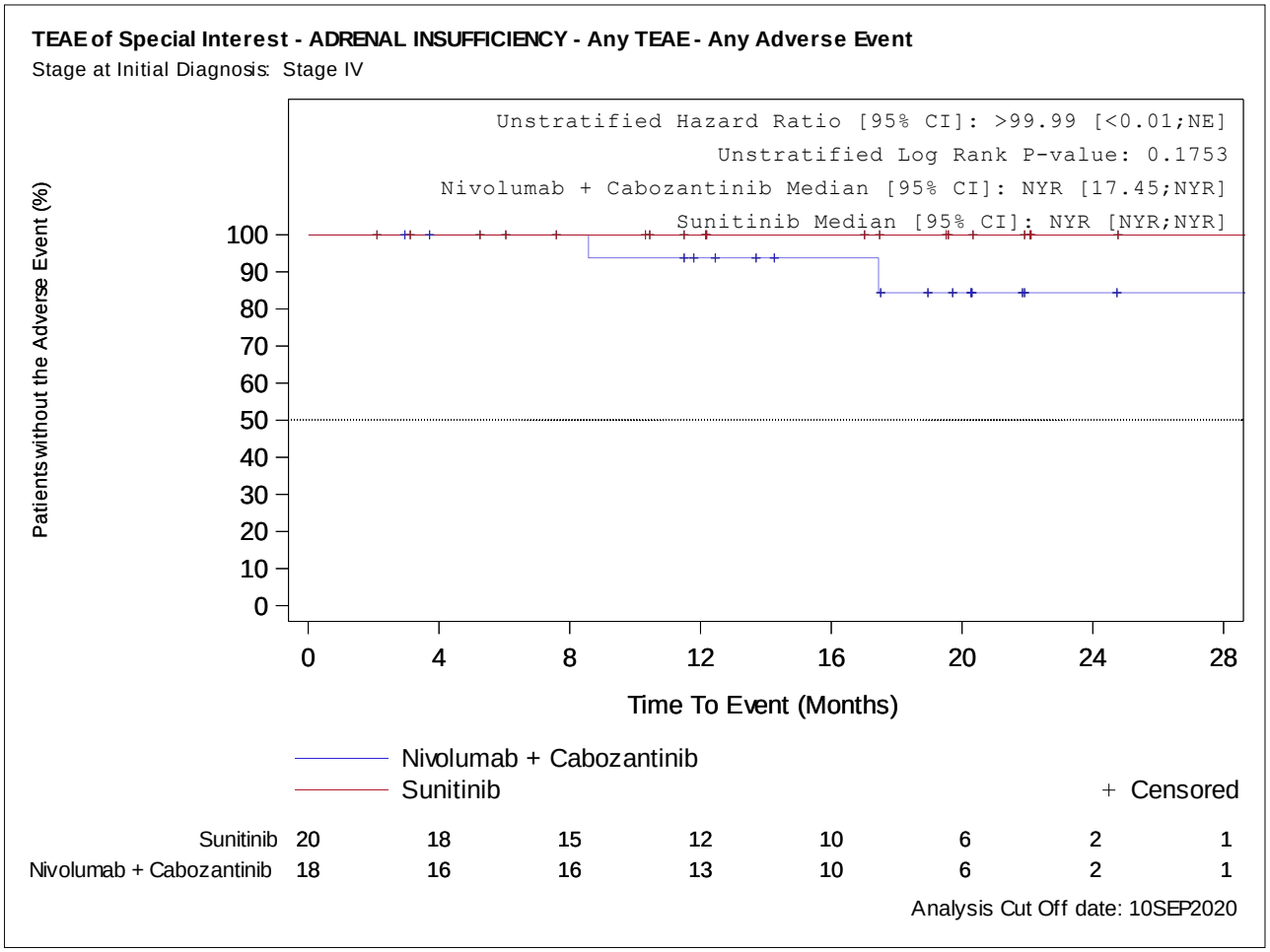

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:12:34

FIGURE 3.59.2.22: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



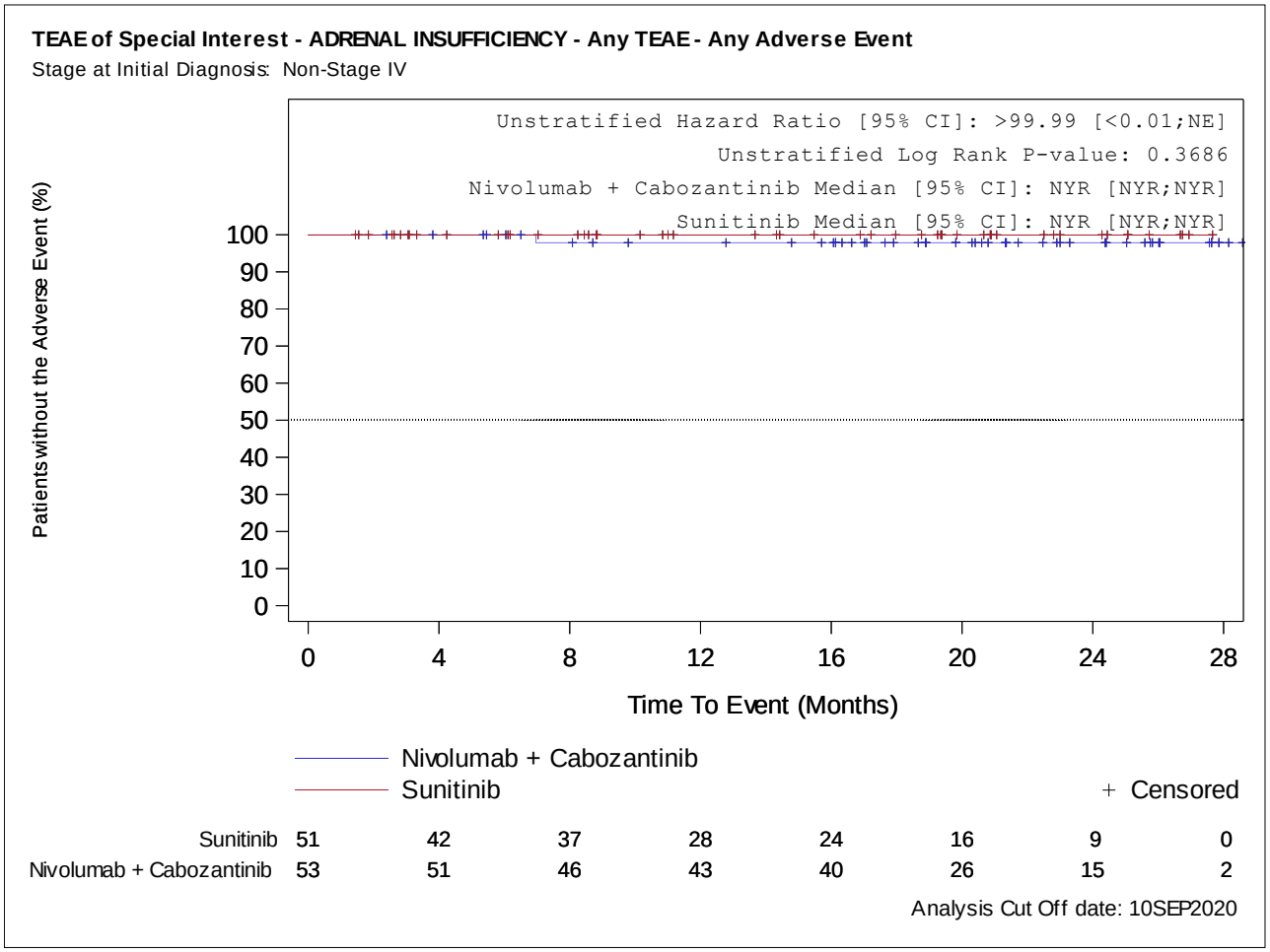

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:12:39

FIGURE 3.59.2.23: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



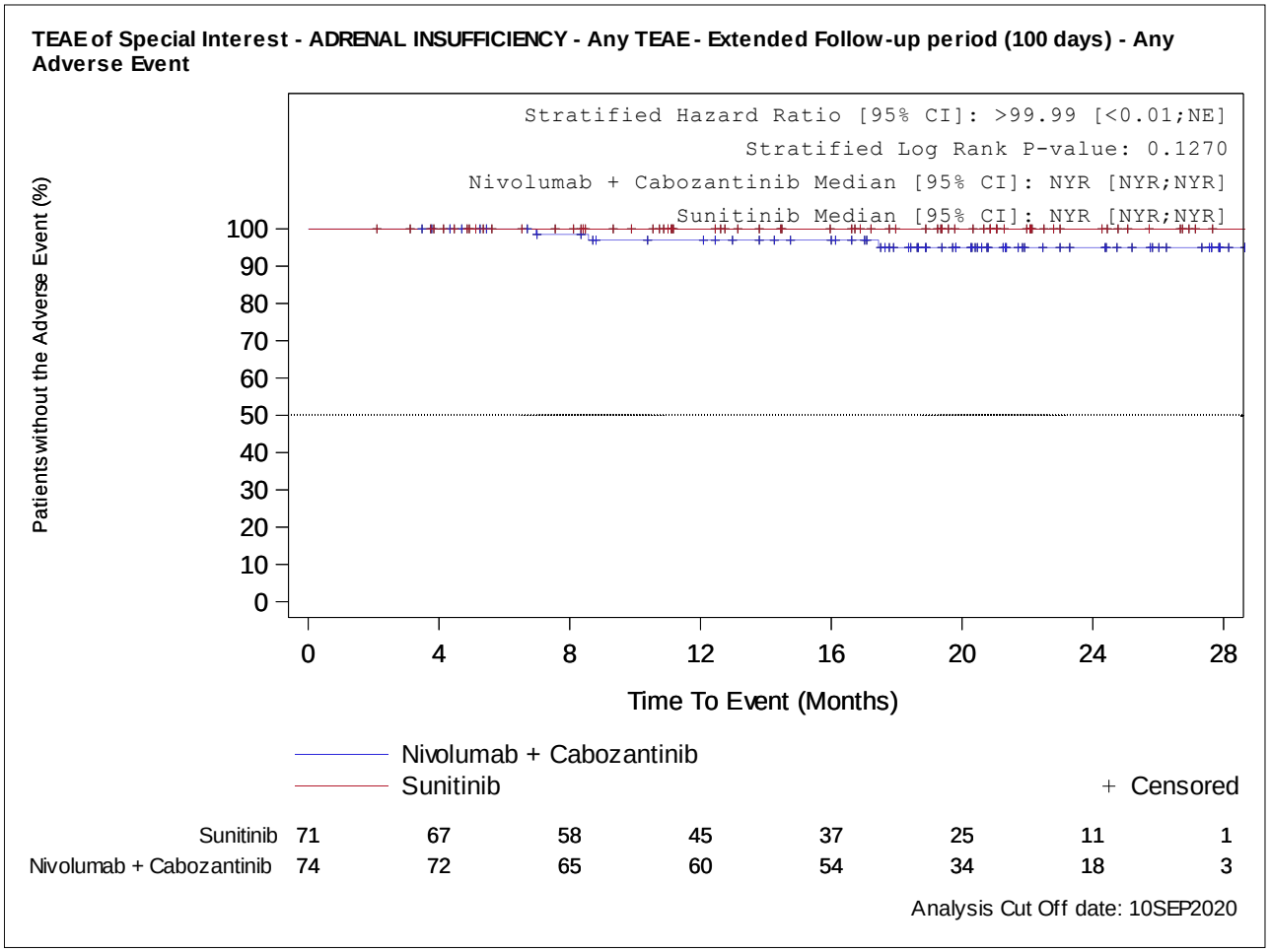

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:13:05

FIGURE 3.59.2.24: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



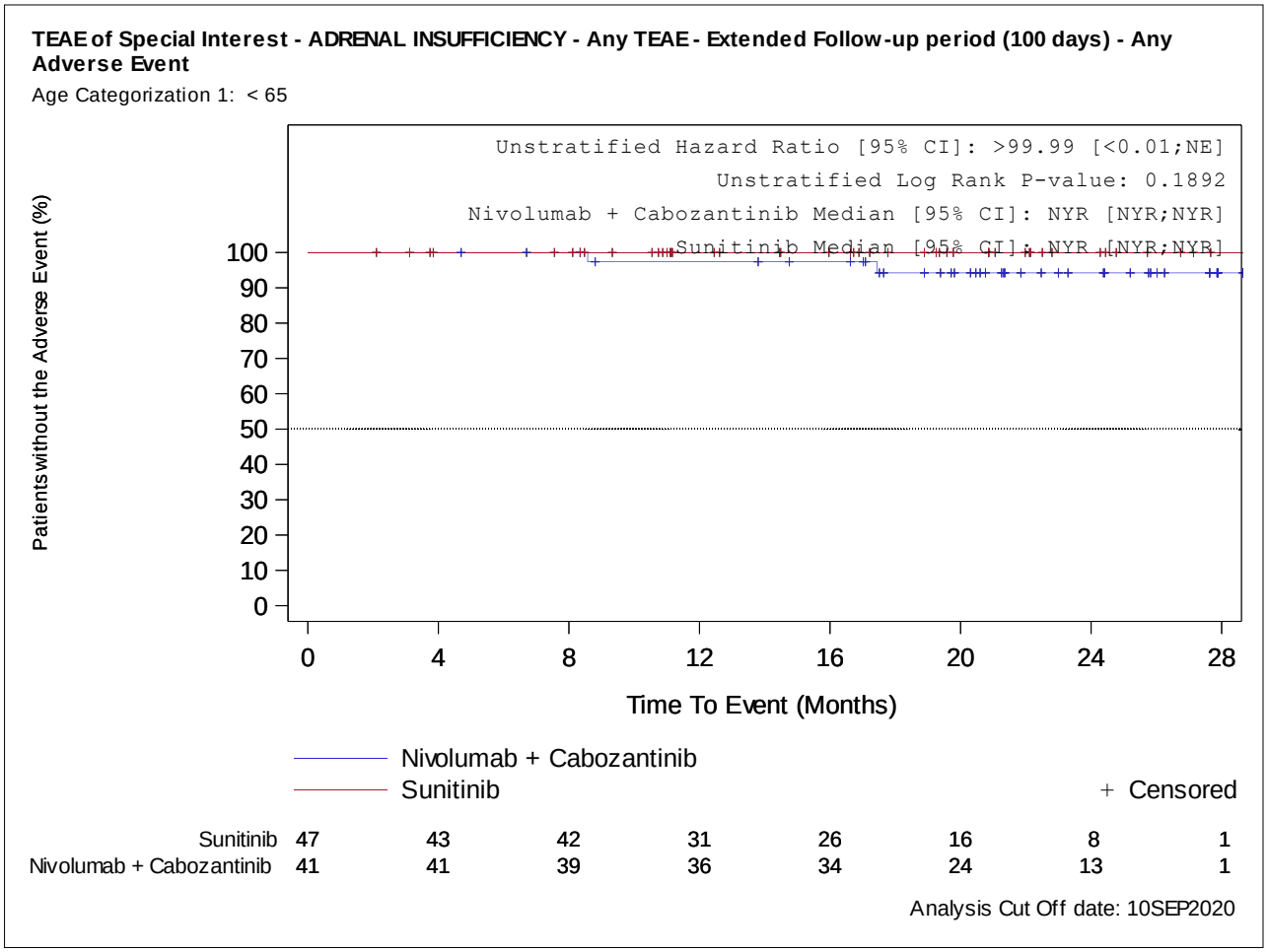

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:13:10

FIGURE 3.60.1: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



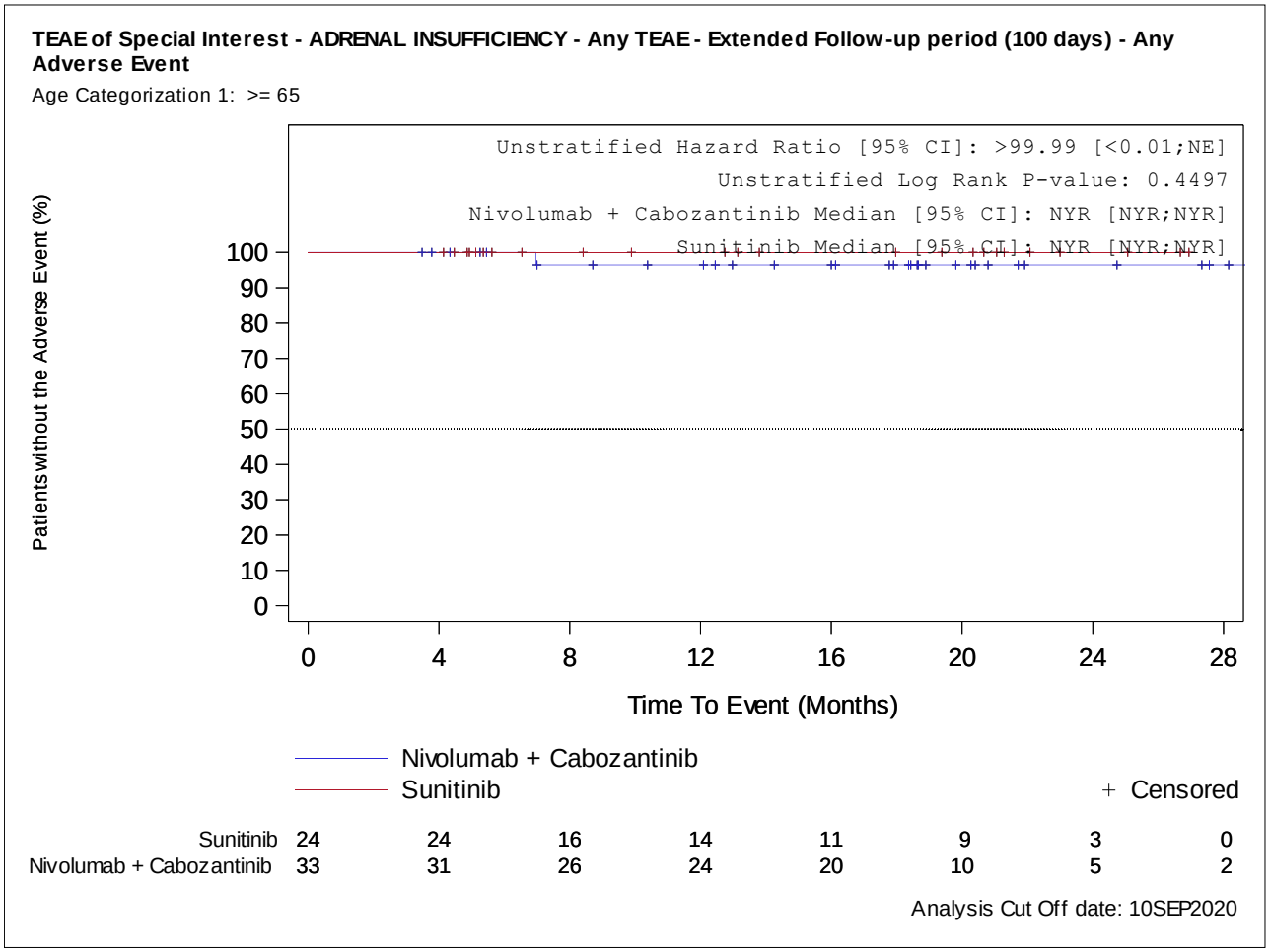

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:16:05

FIGURE 3.60.2.1: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  < 65



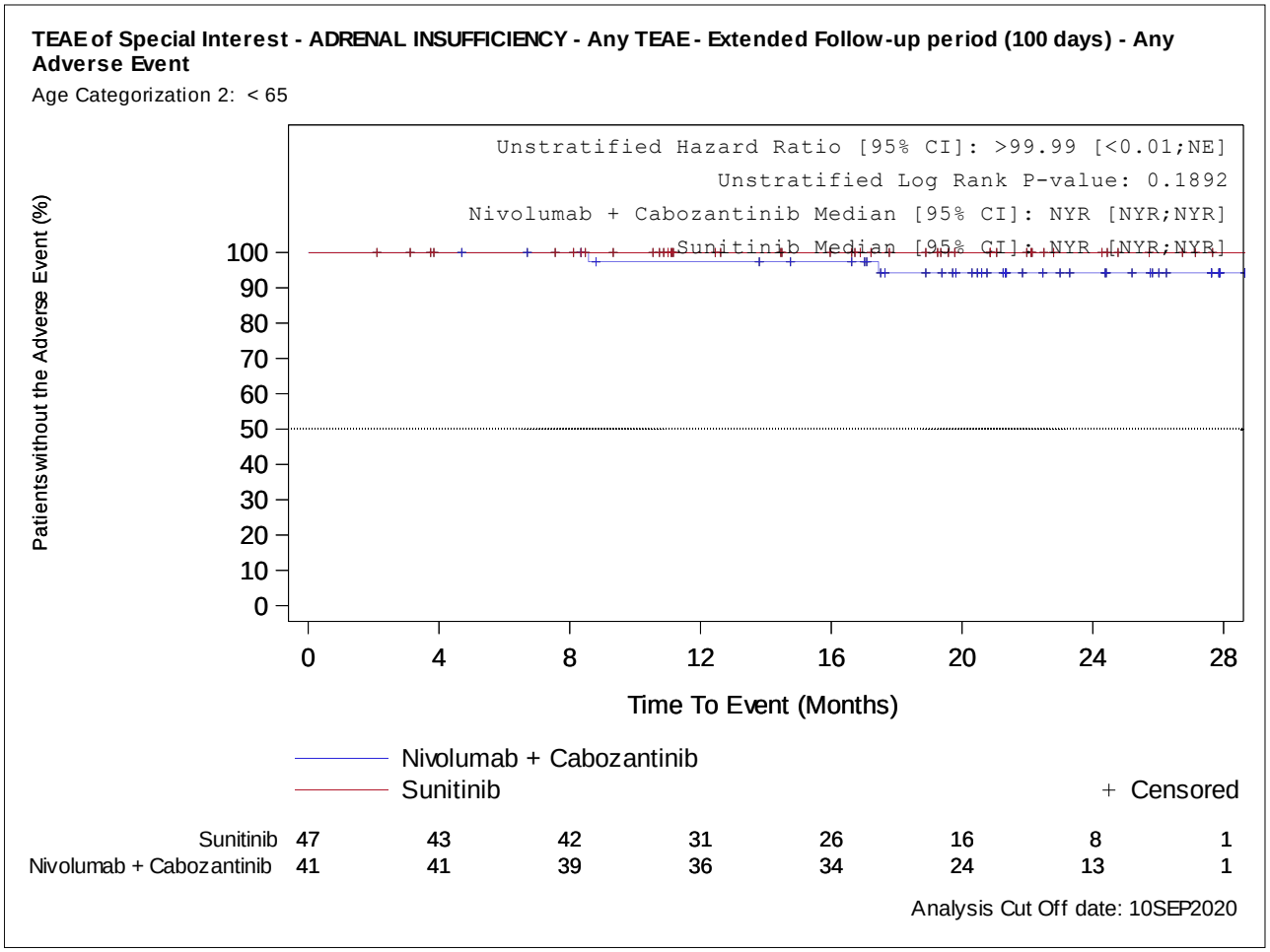

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:16:08

FIGURE 3.60.2.2: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



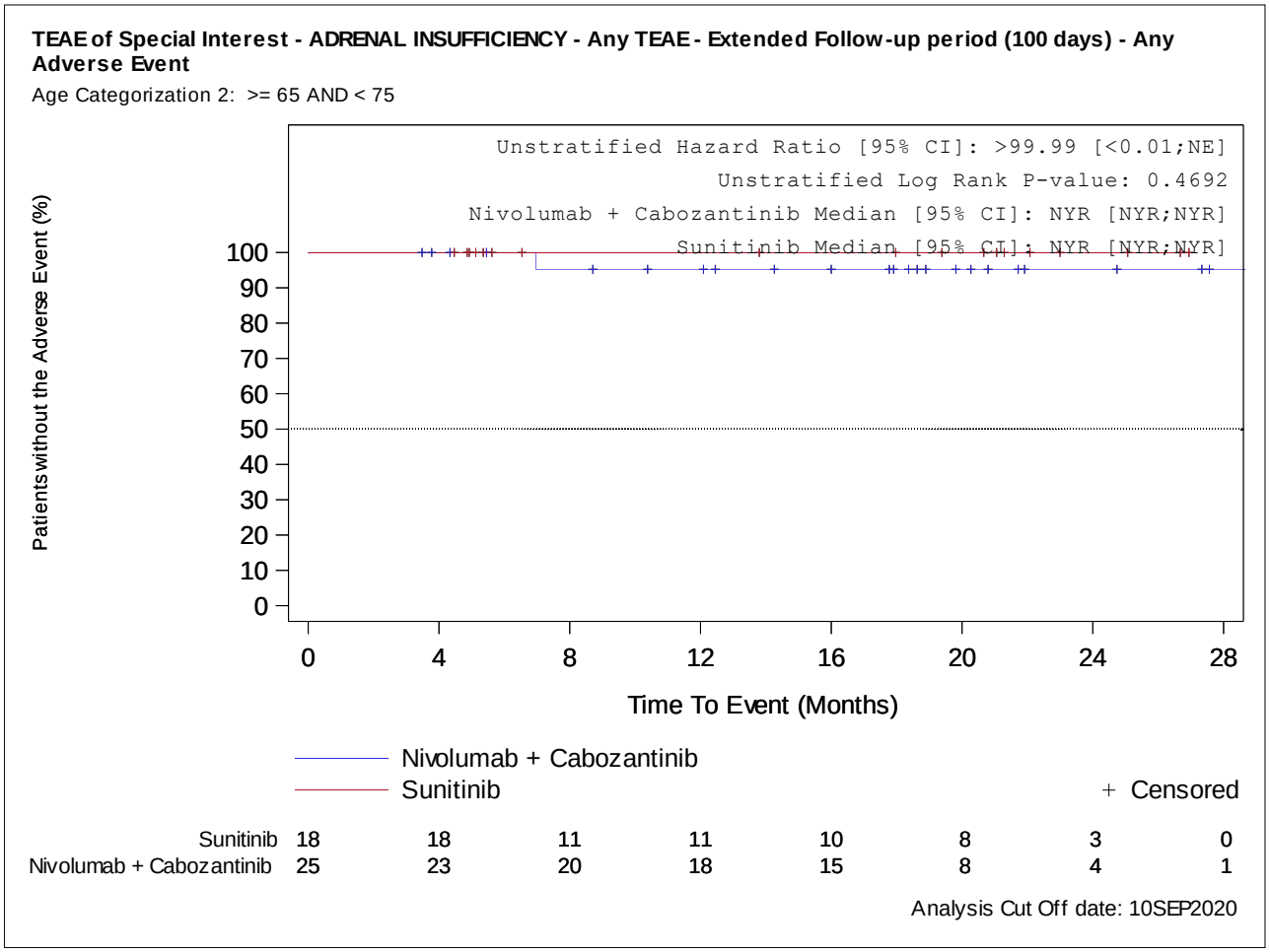

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:16:14

FIGURE 3.60.2.3: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



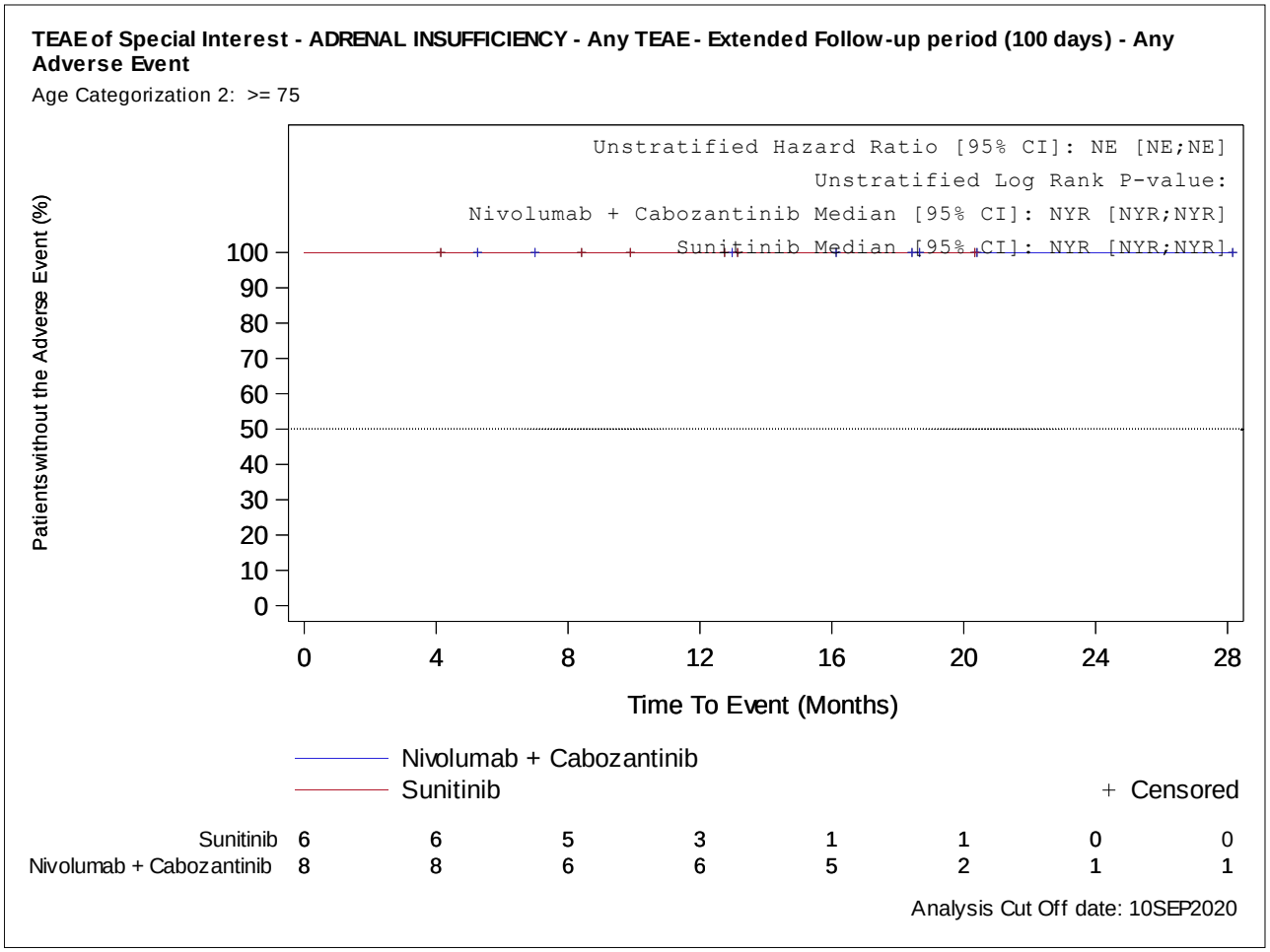

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:16:19

FIGURE 3.60.2.4: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



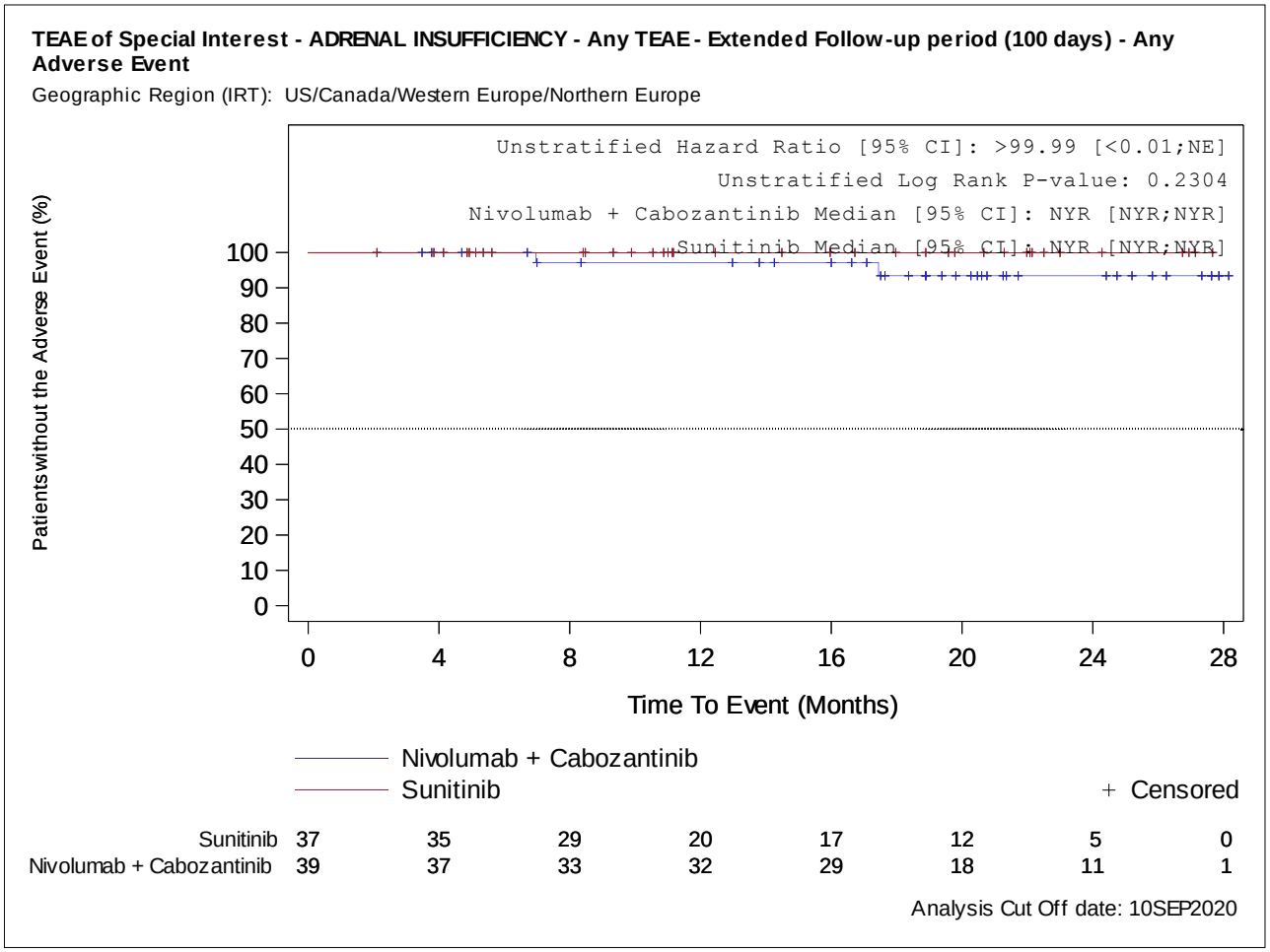

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:16:24

FIGURE 3.60.2.5: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



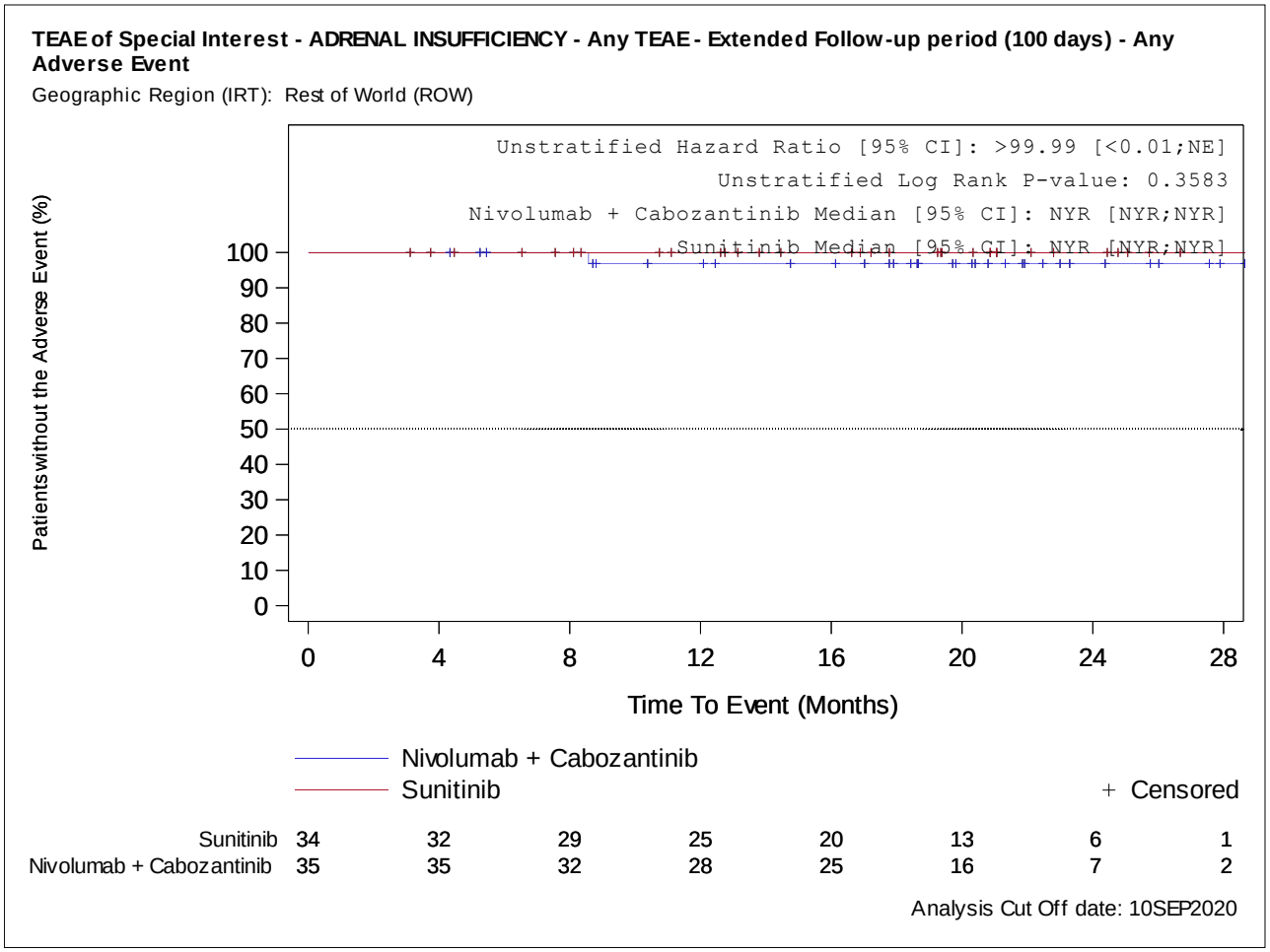

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:16:29

FIGURE 3.60.2.6: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



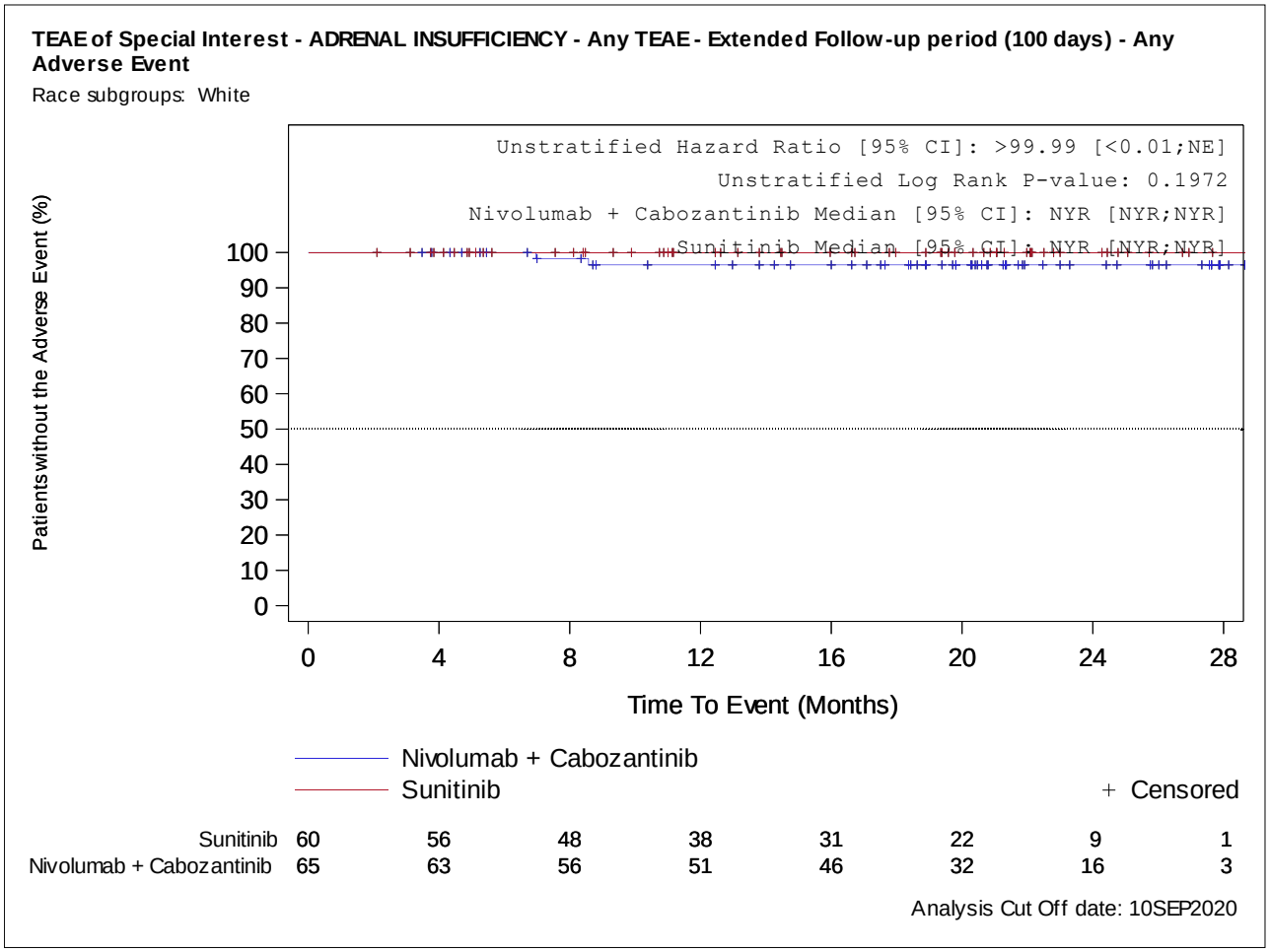

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:16:34

FIGURE 3.60.2.7: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



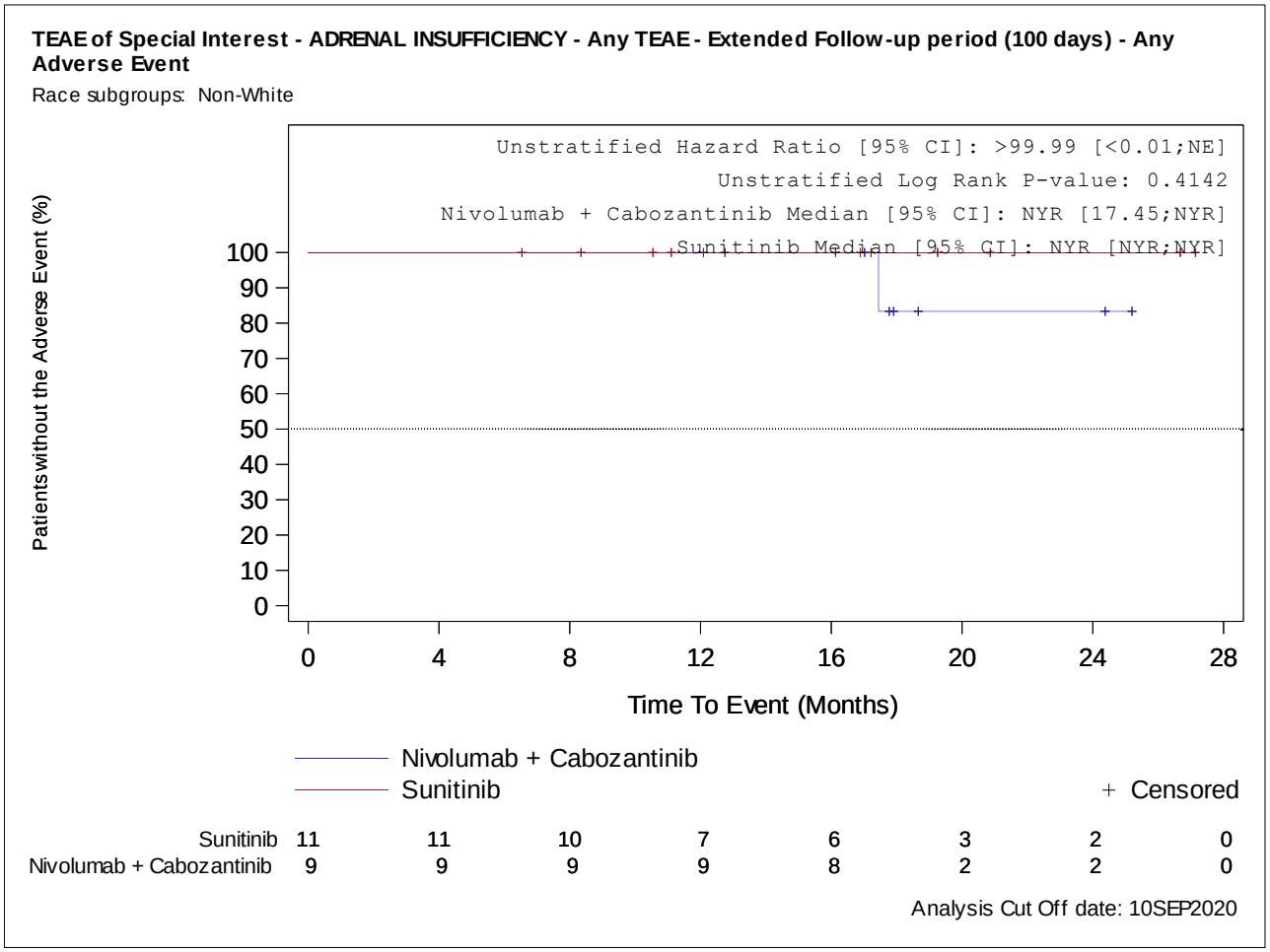

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:16:39

FIGURE 3.60.2.8: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



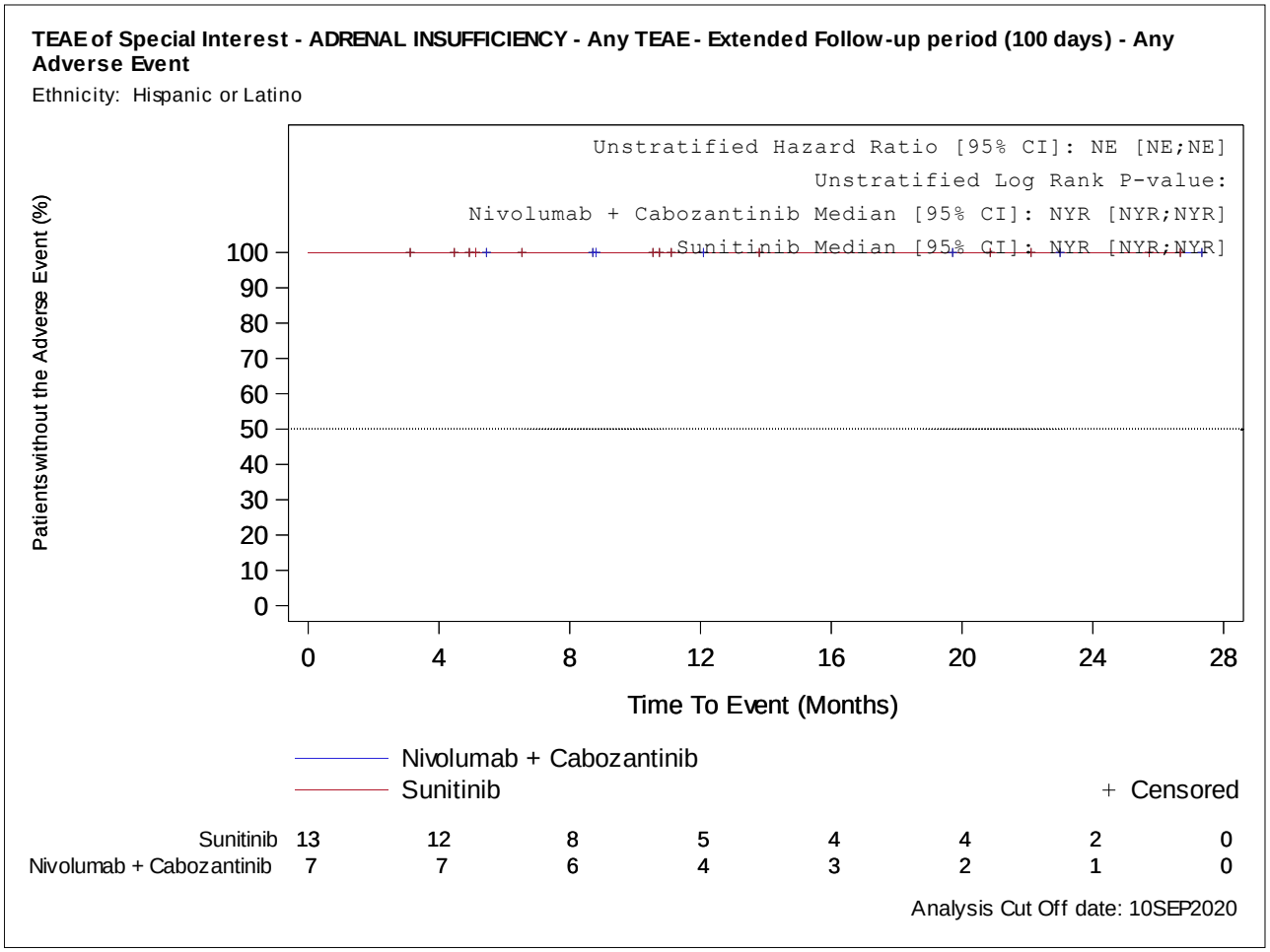

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:16:44

FIGURE 3.60.2.9: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



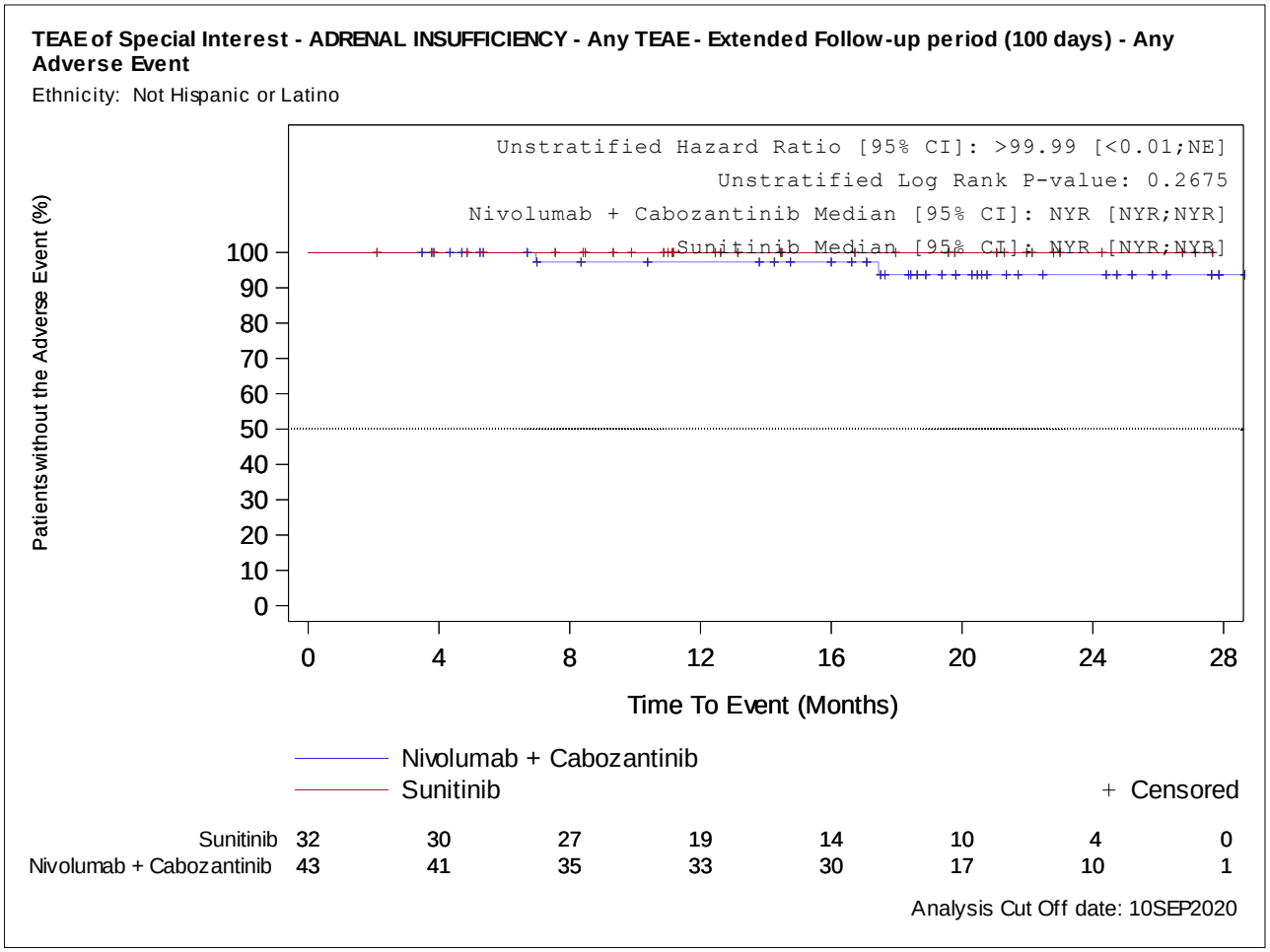

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:16:48

FIGURE 3.60.2.10: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:16:53

FIGURE 3.60.2.11: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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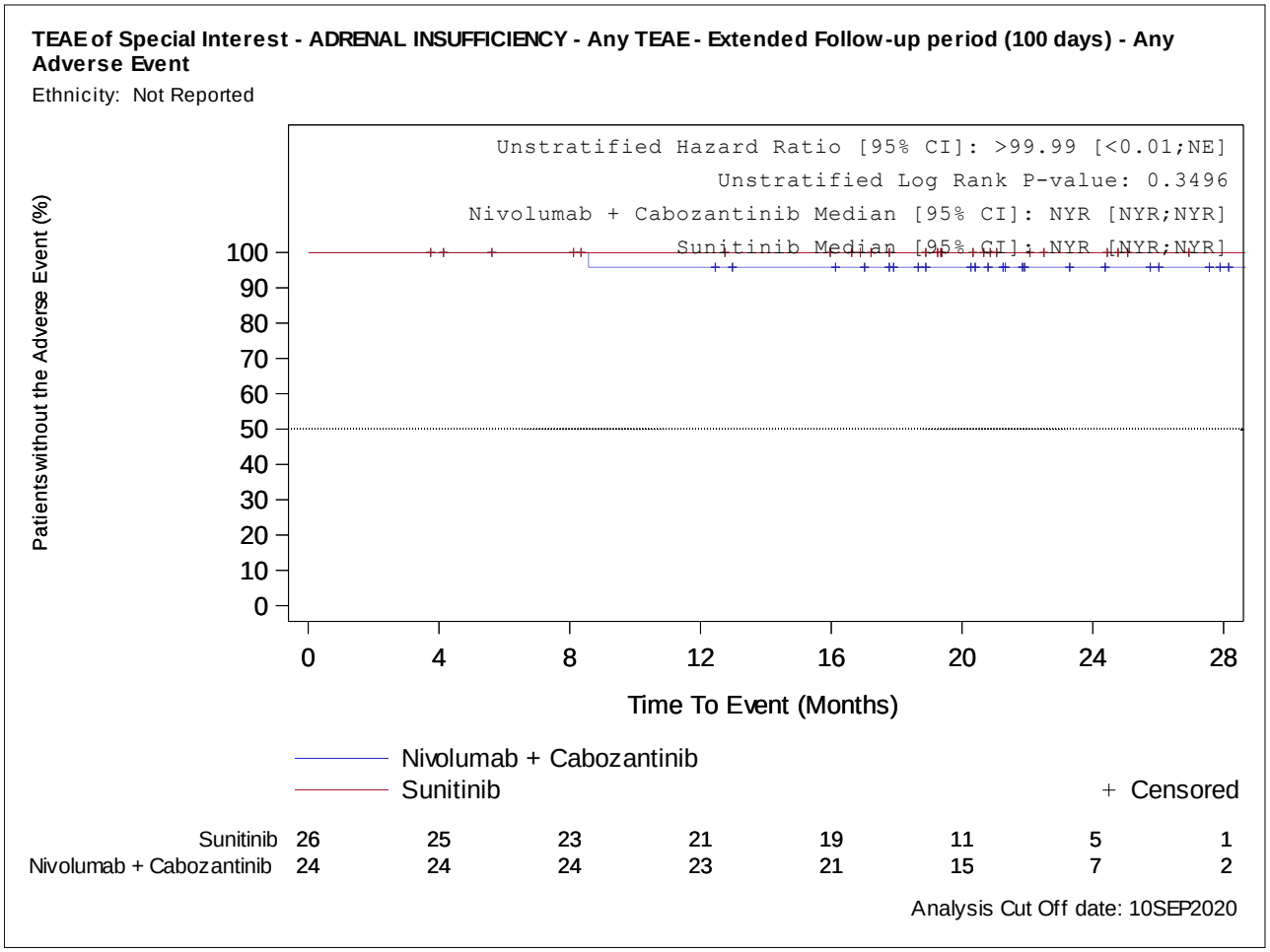
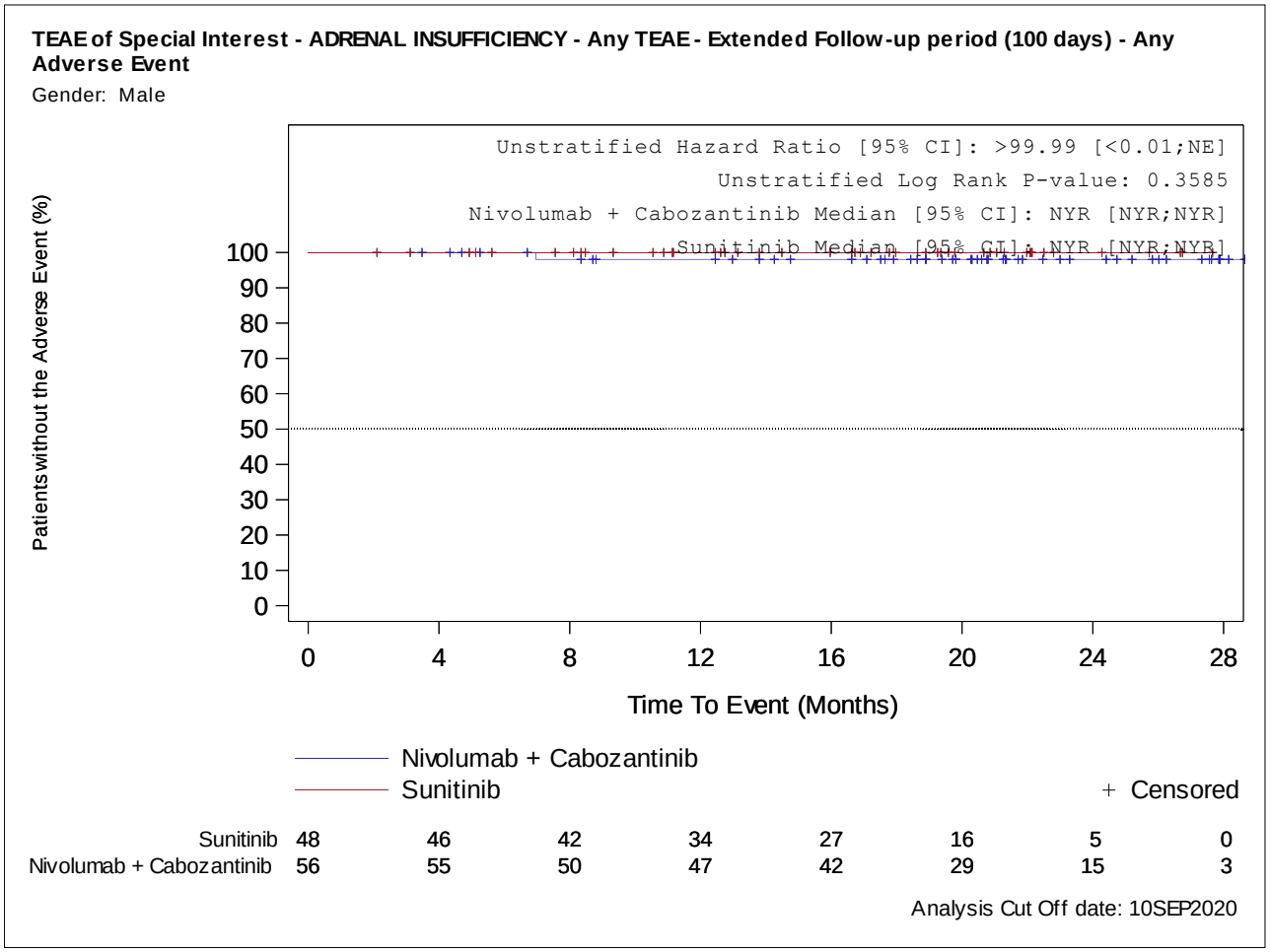
FIGURE 3.60.2.12: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



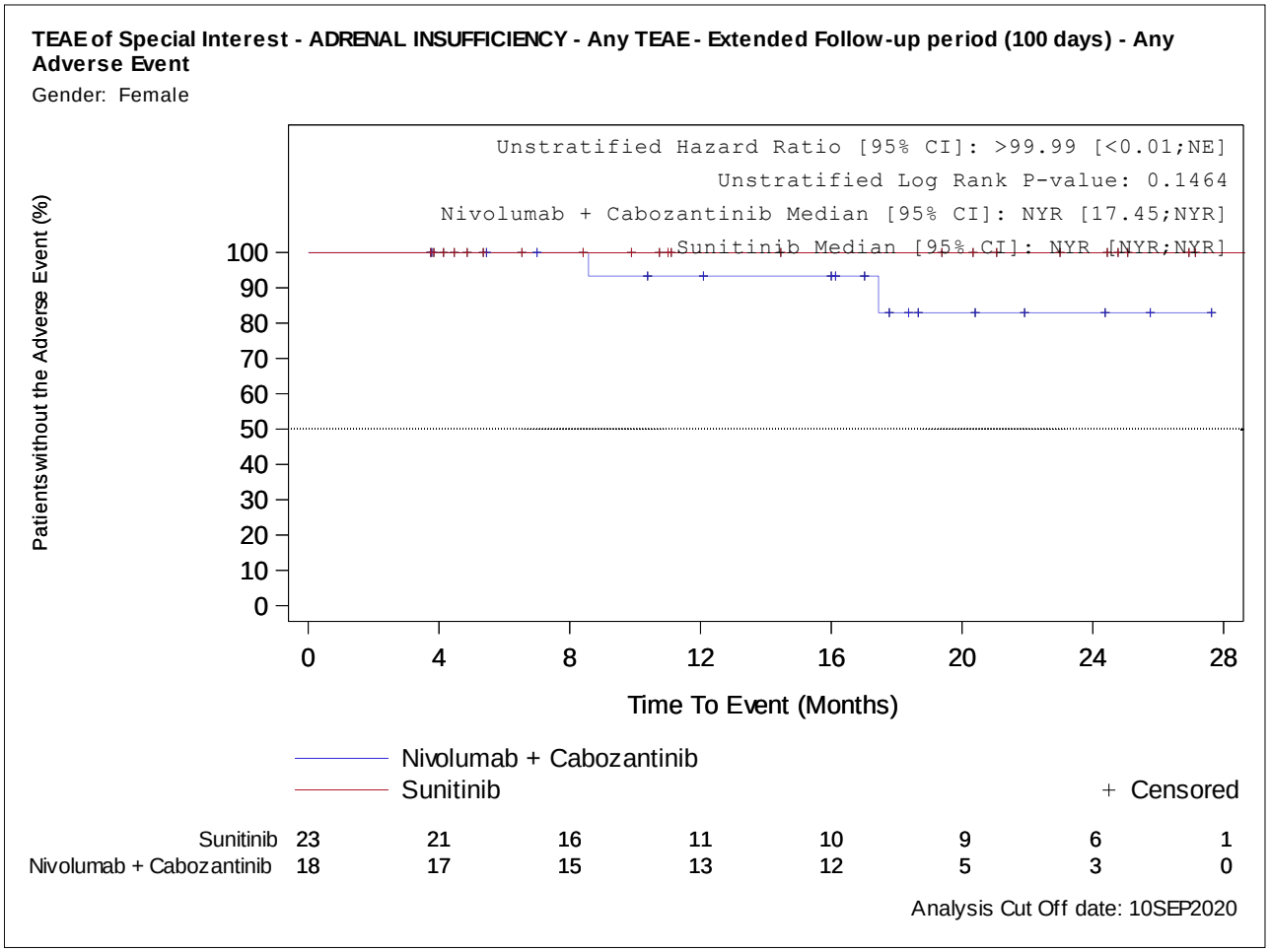

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:17:04

FIGURE 3.60.2.13: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



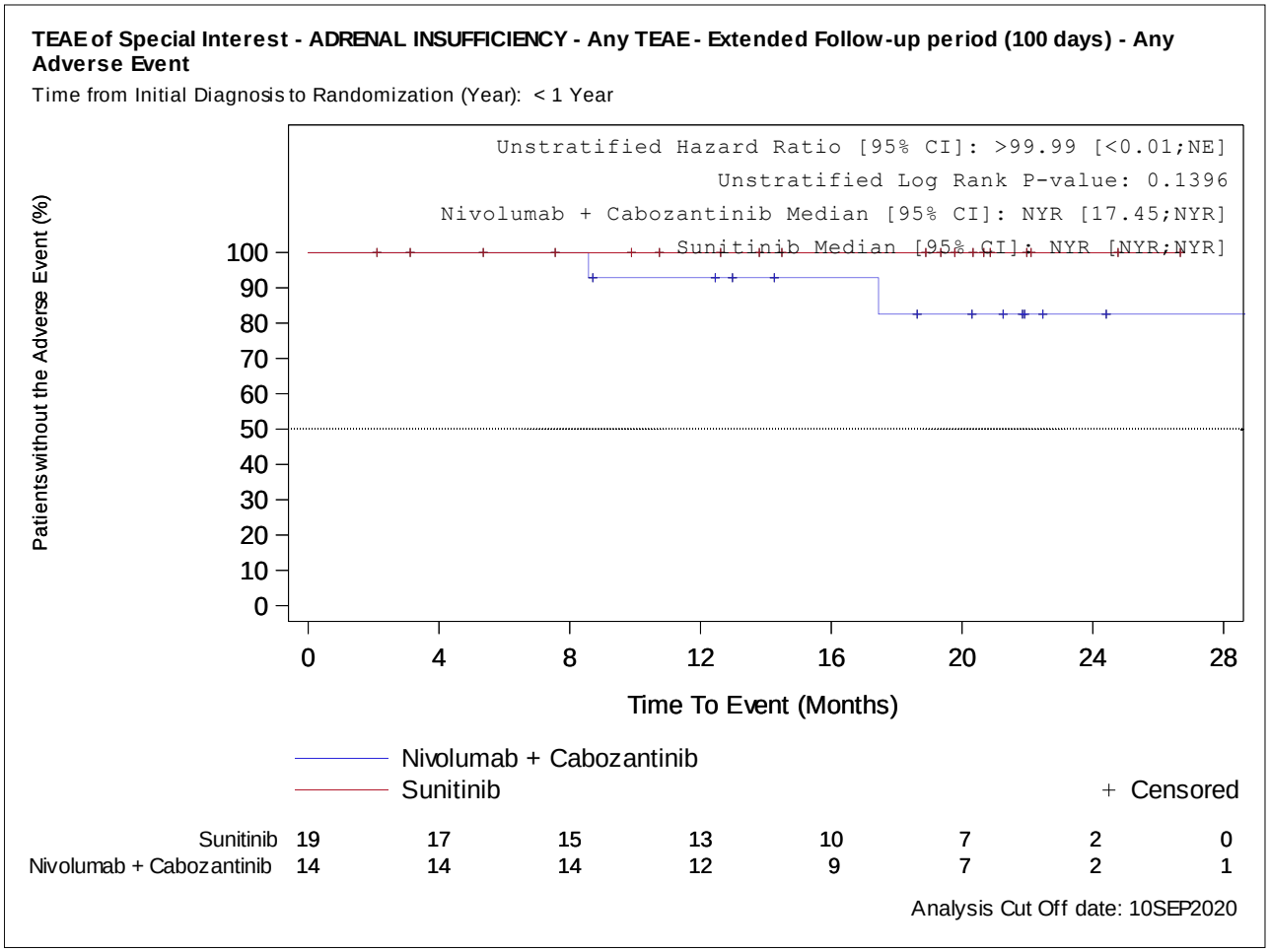

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:17:09

FIGURE 3.60.2.14: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



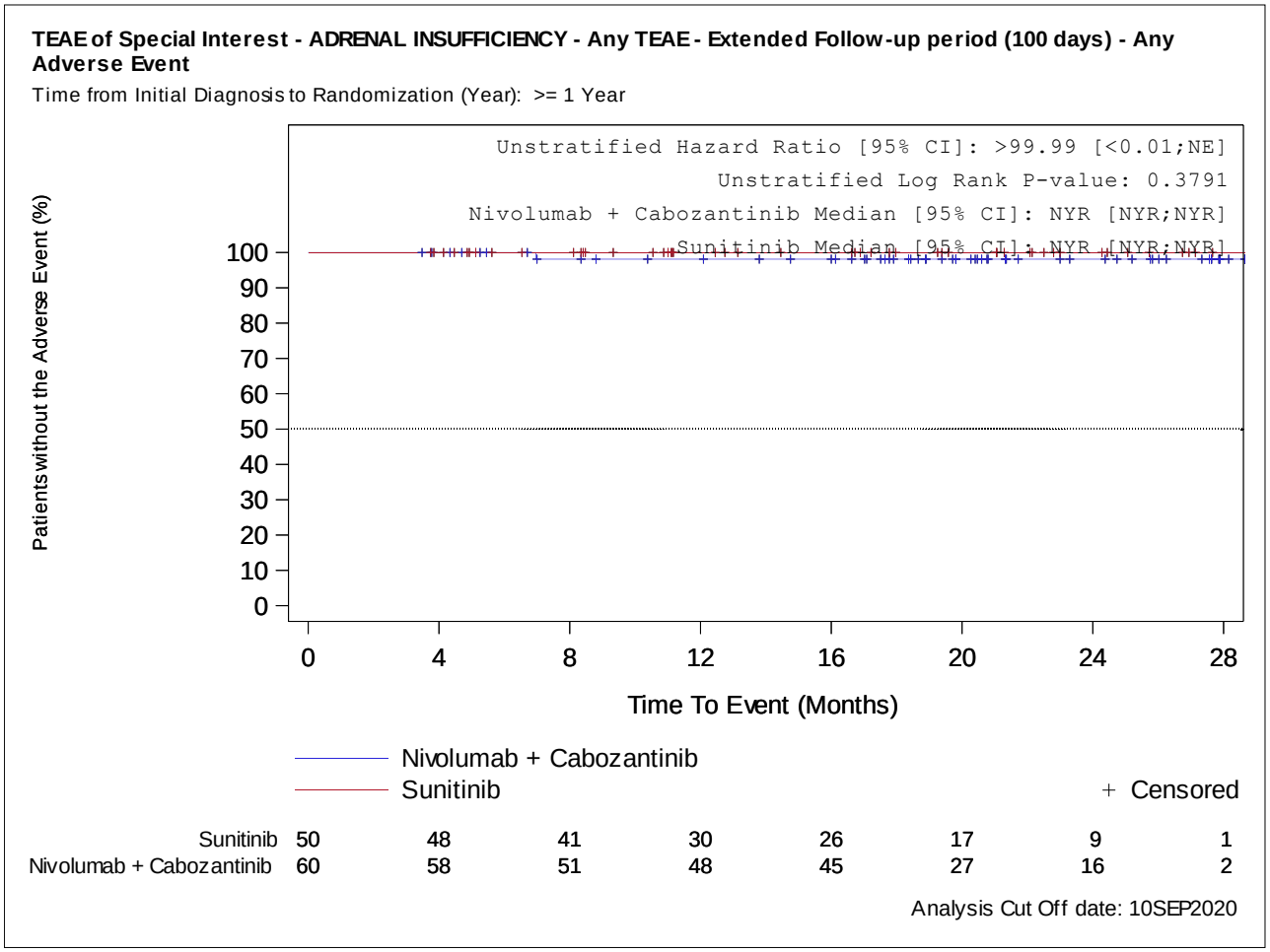

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:17:14

FIGURE 3.60.2.15: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



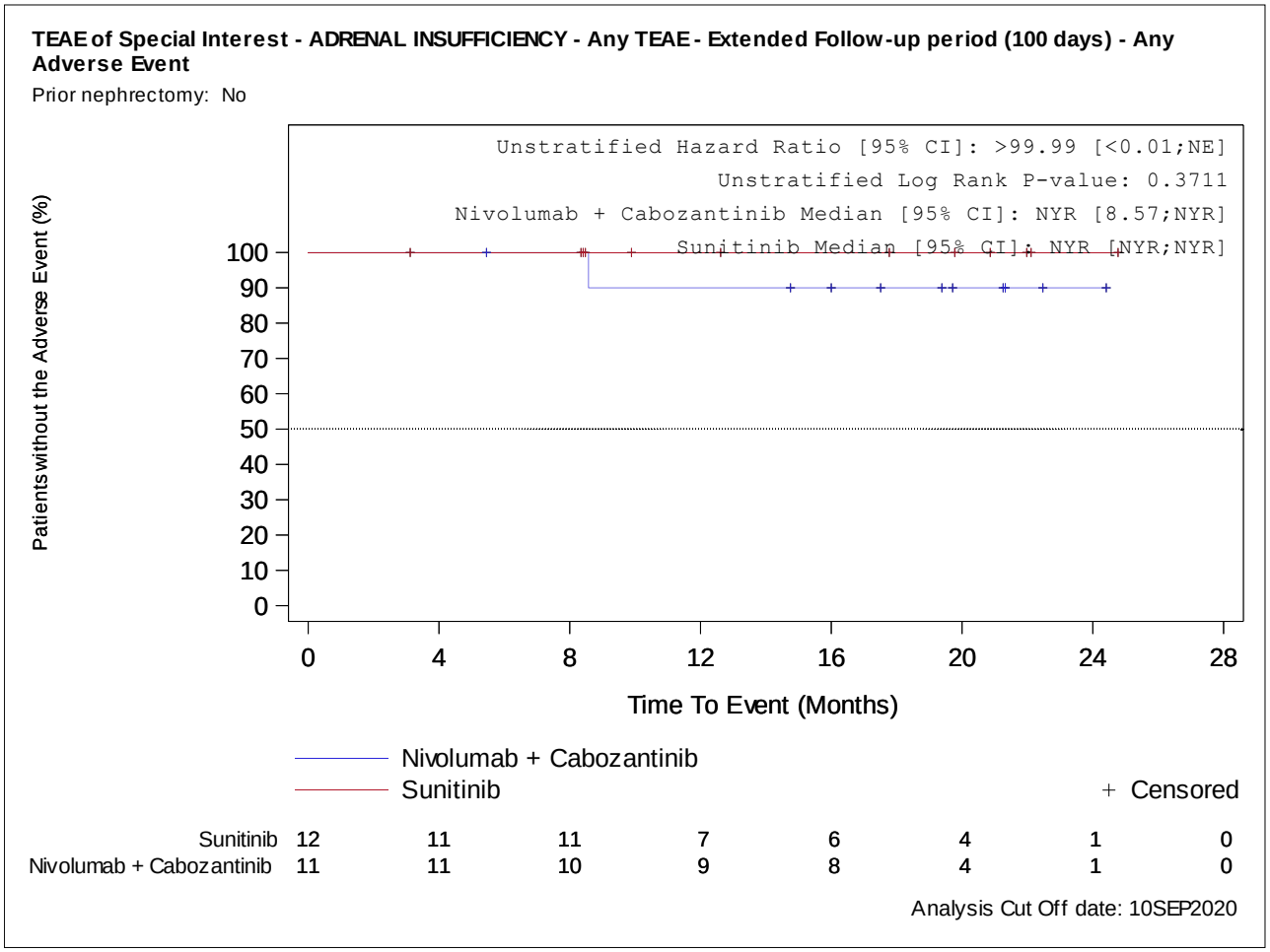

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:17:30

FIGURE 3.60.2.16: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



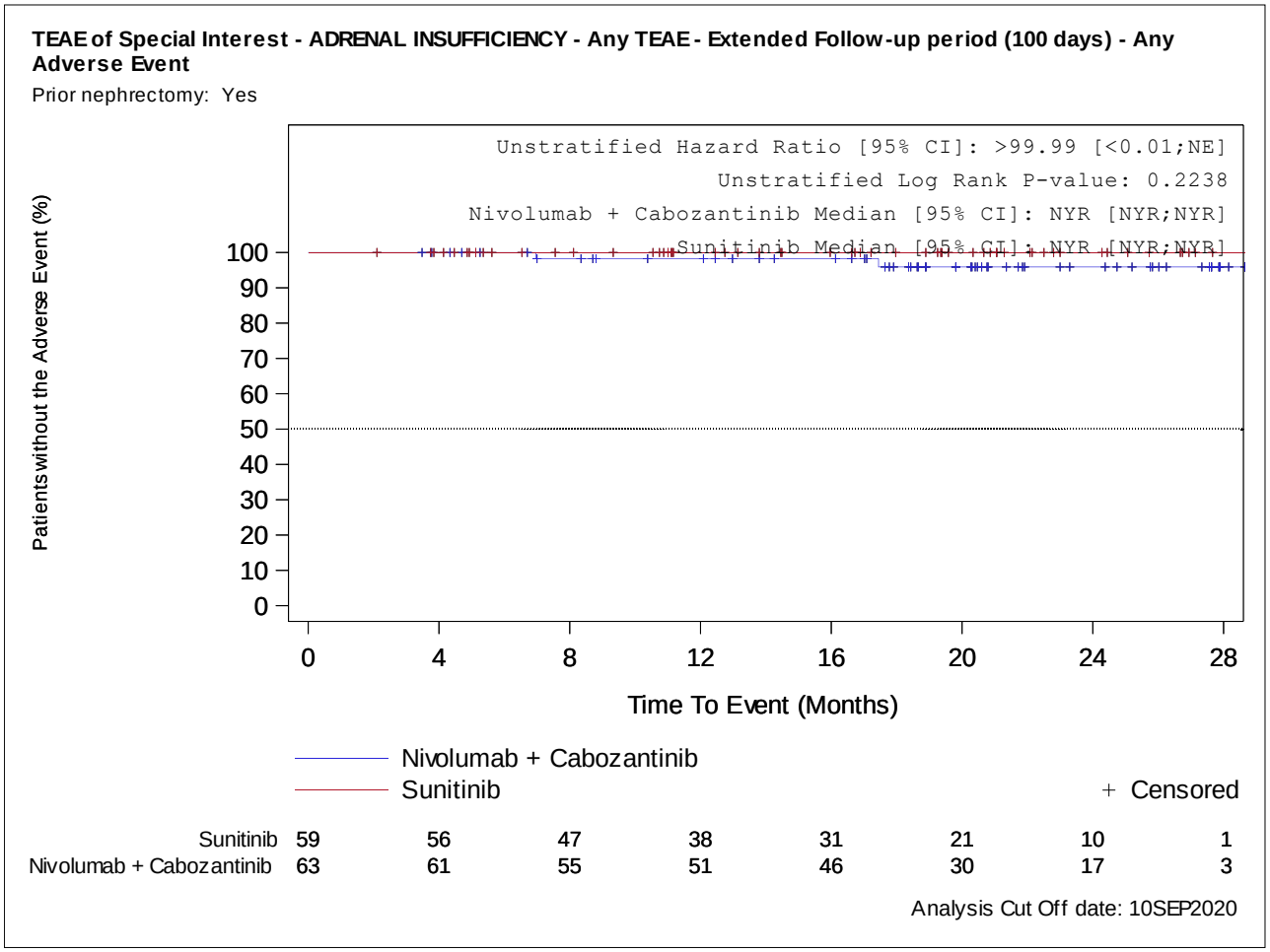

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:17:35

FIGURE 3.60.2.17: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



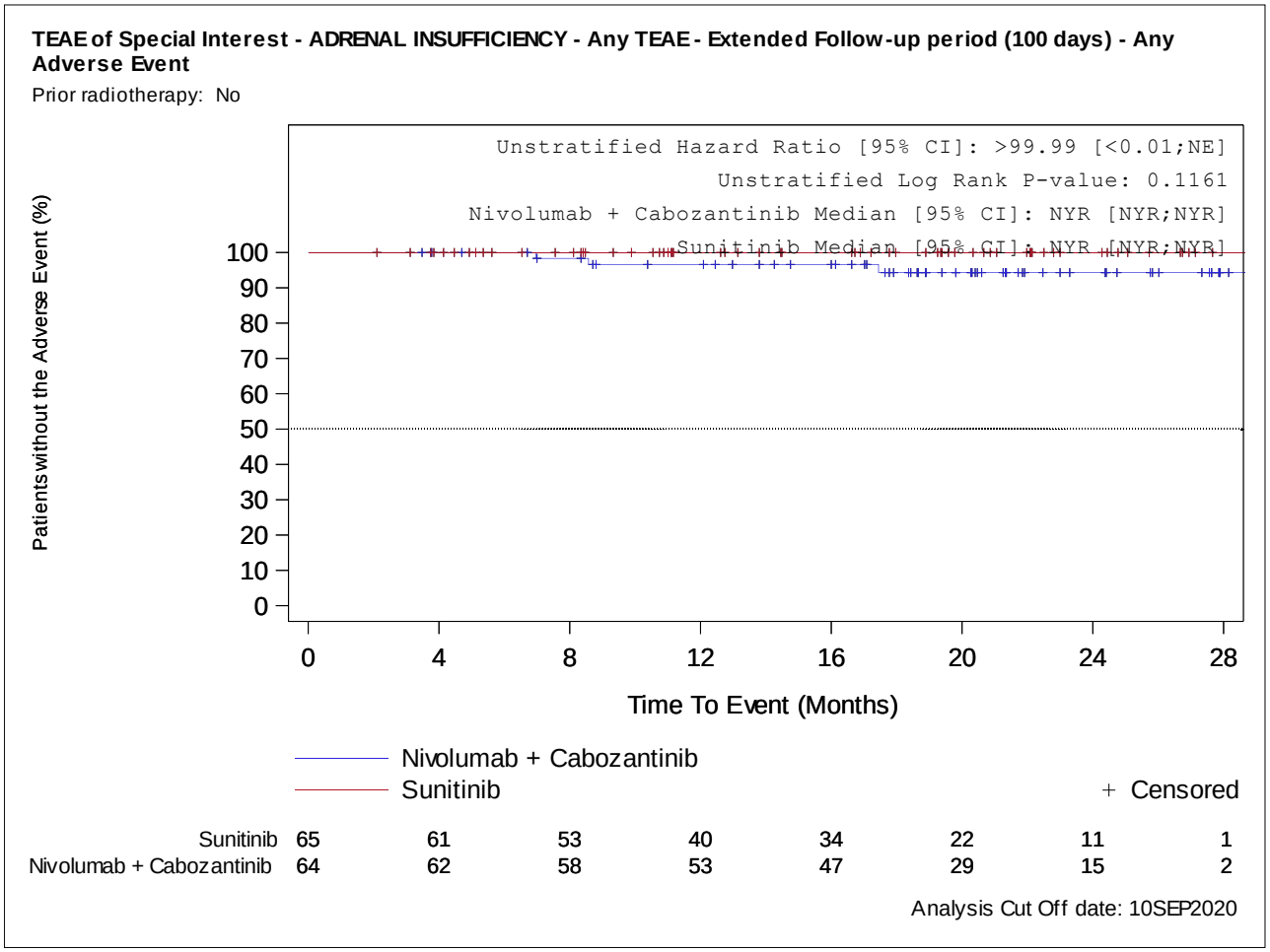

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:18:23

FIGURE 3.60.2.18: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



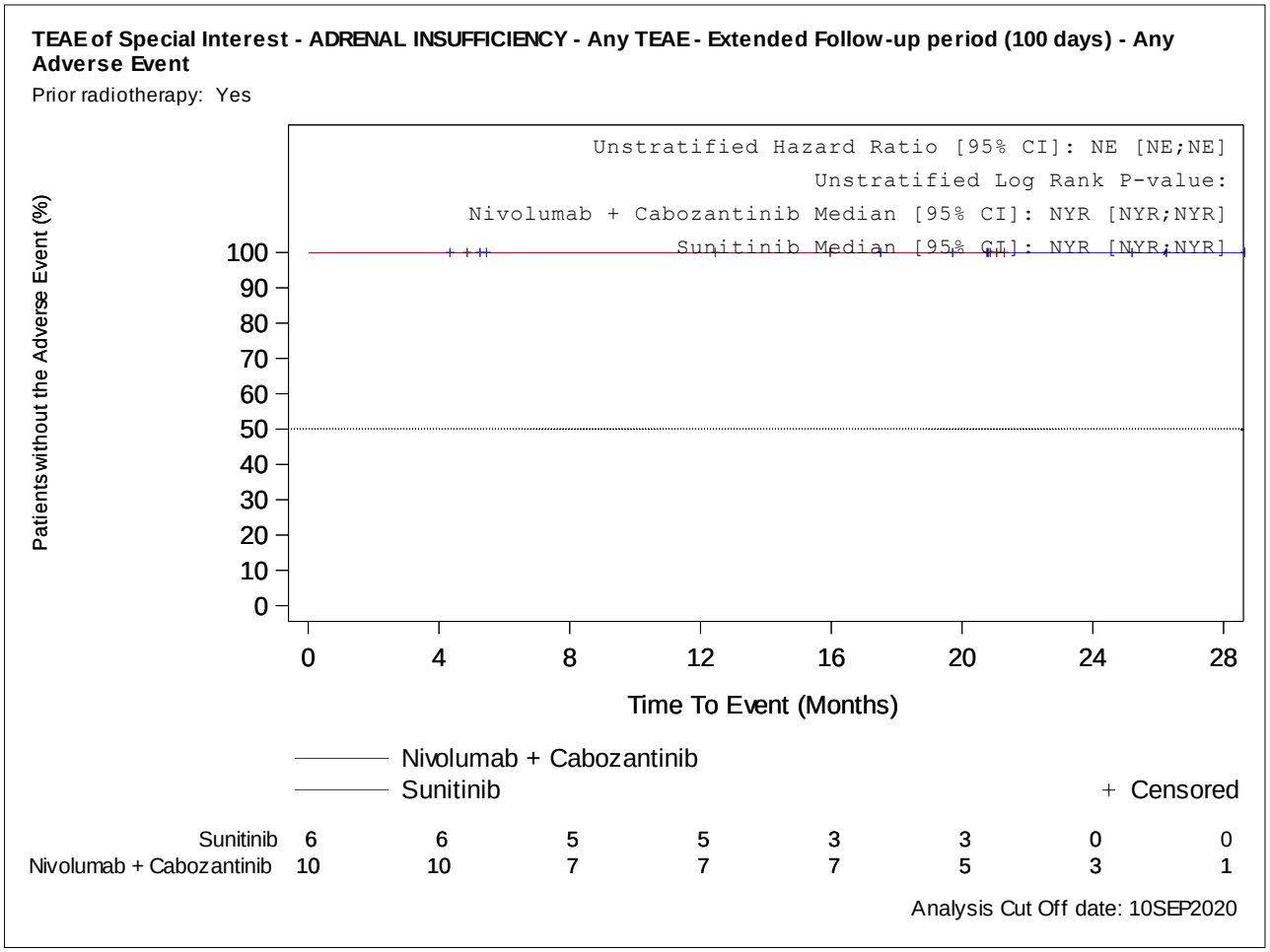

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:18:28

FIGURE 3.60.2.19: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



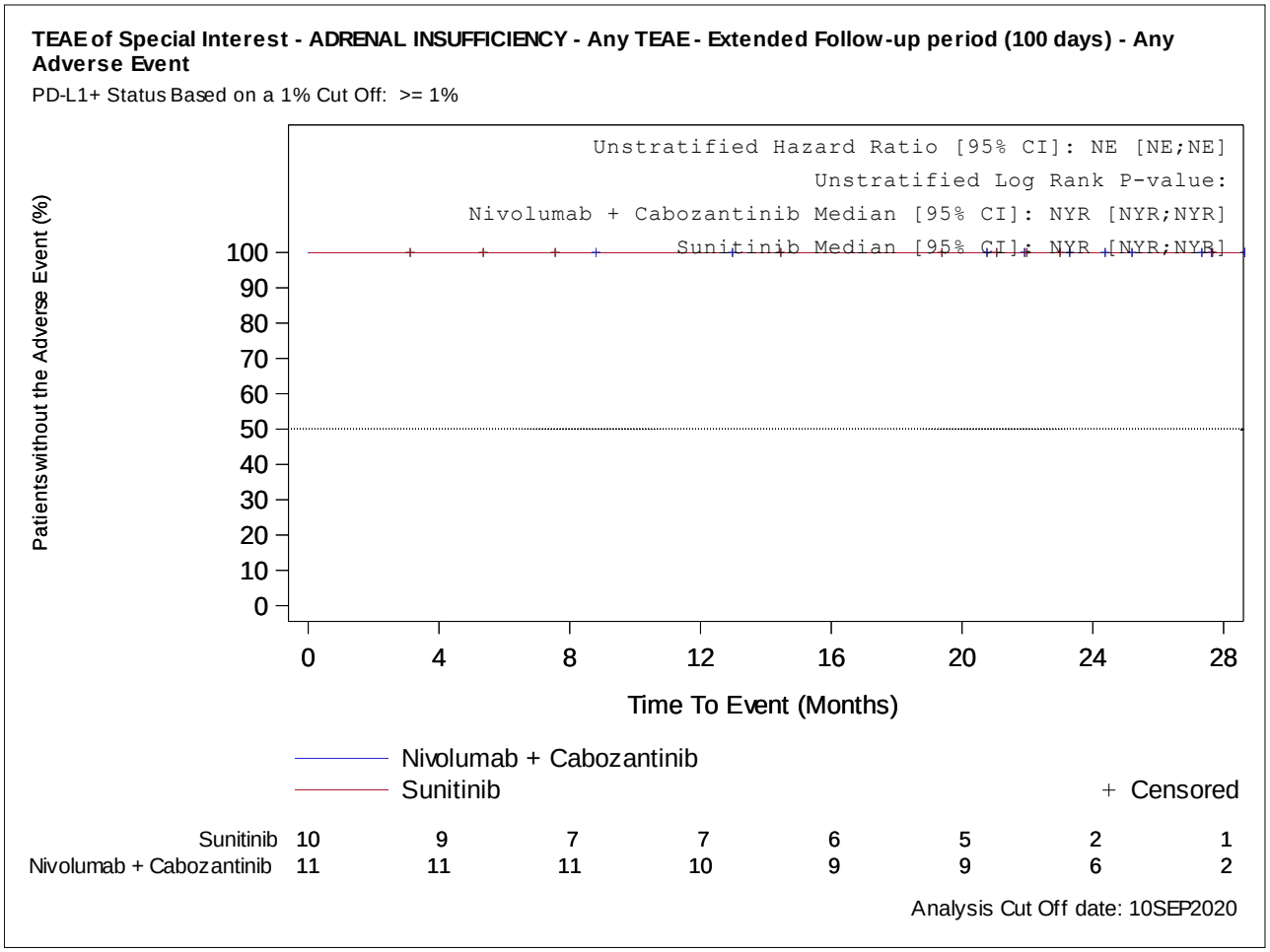

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:18:34

FIGURE 3.60.2.20: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:18:39

FIGURE 3.60.2.21: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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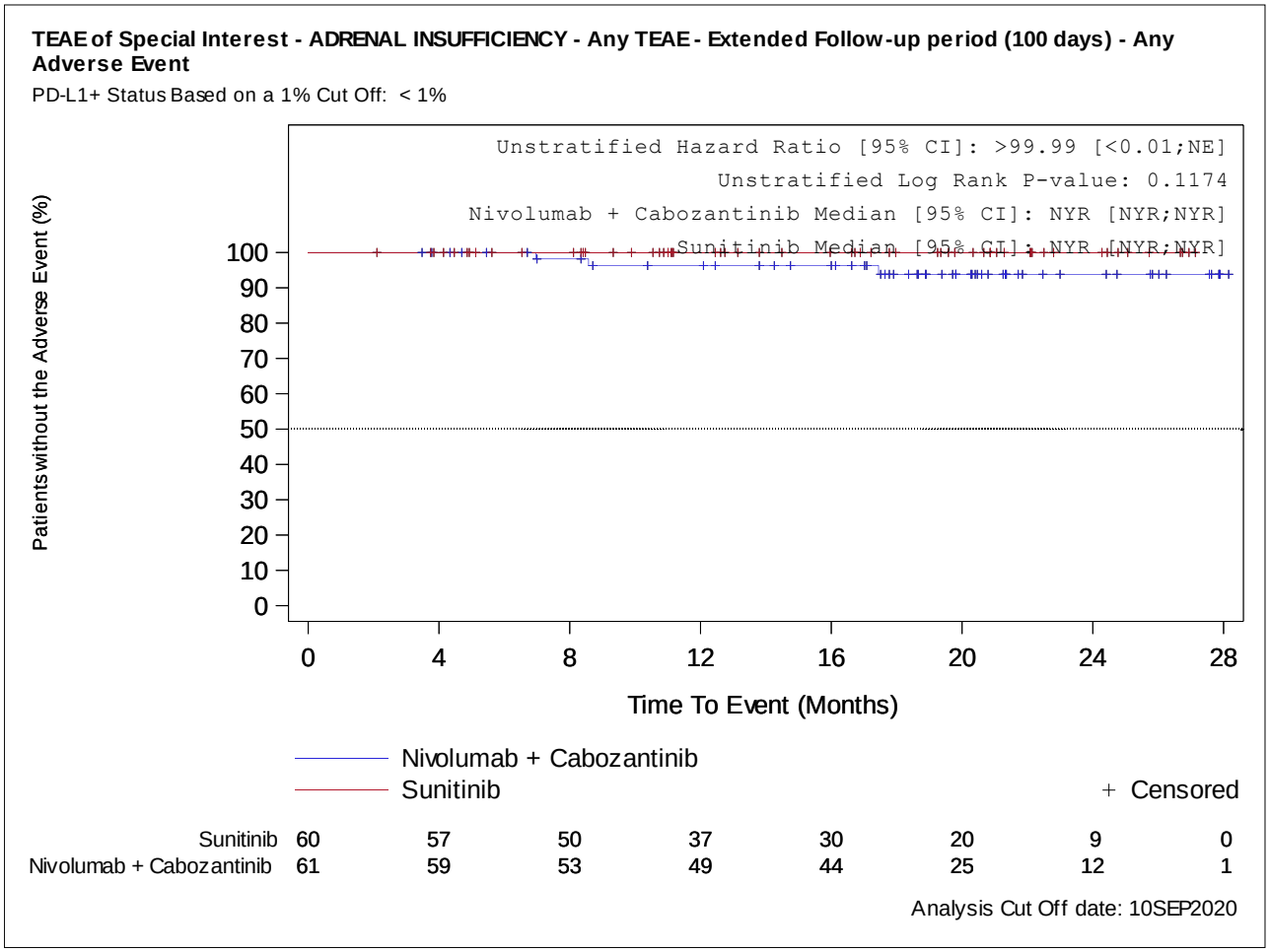
FIGURE 3.60.2.22: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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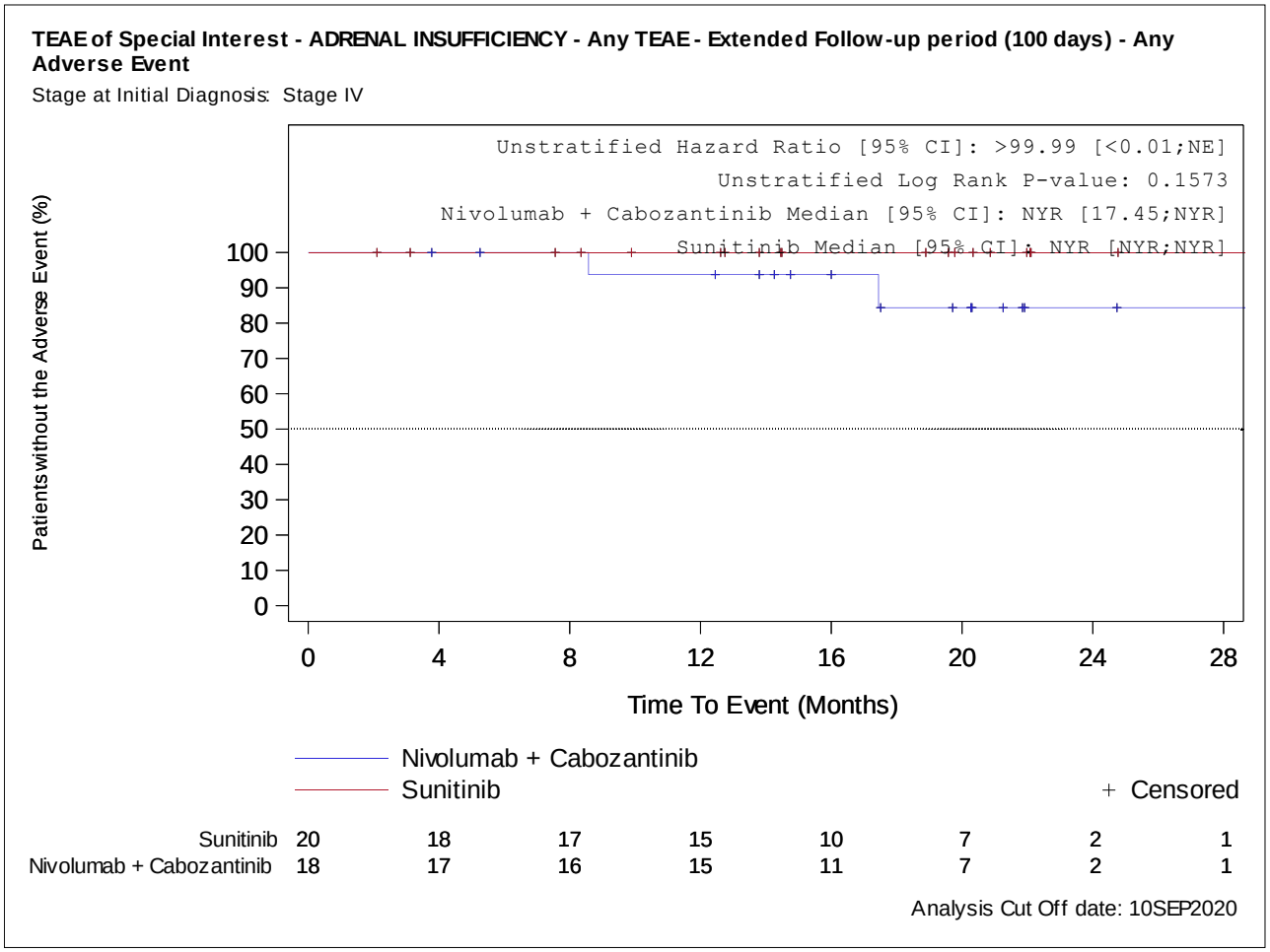
FIGURE 3.60.2.23: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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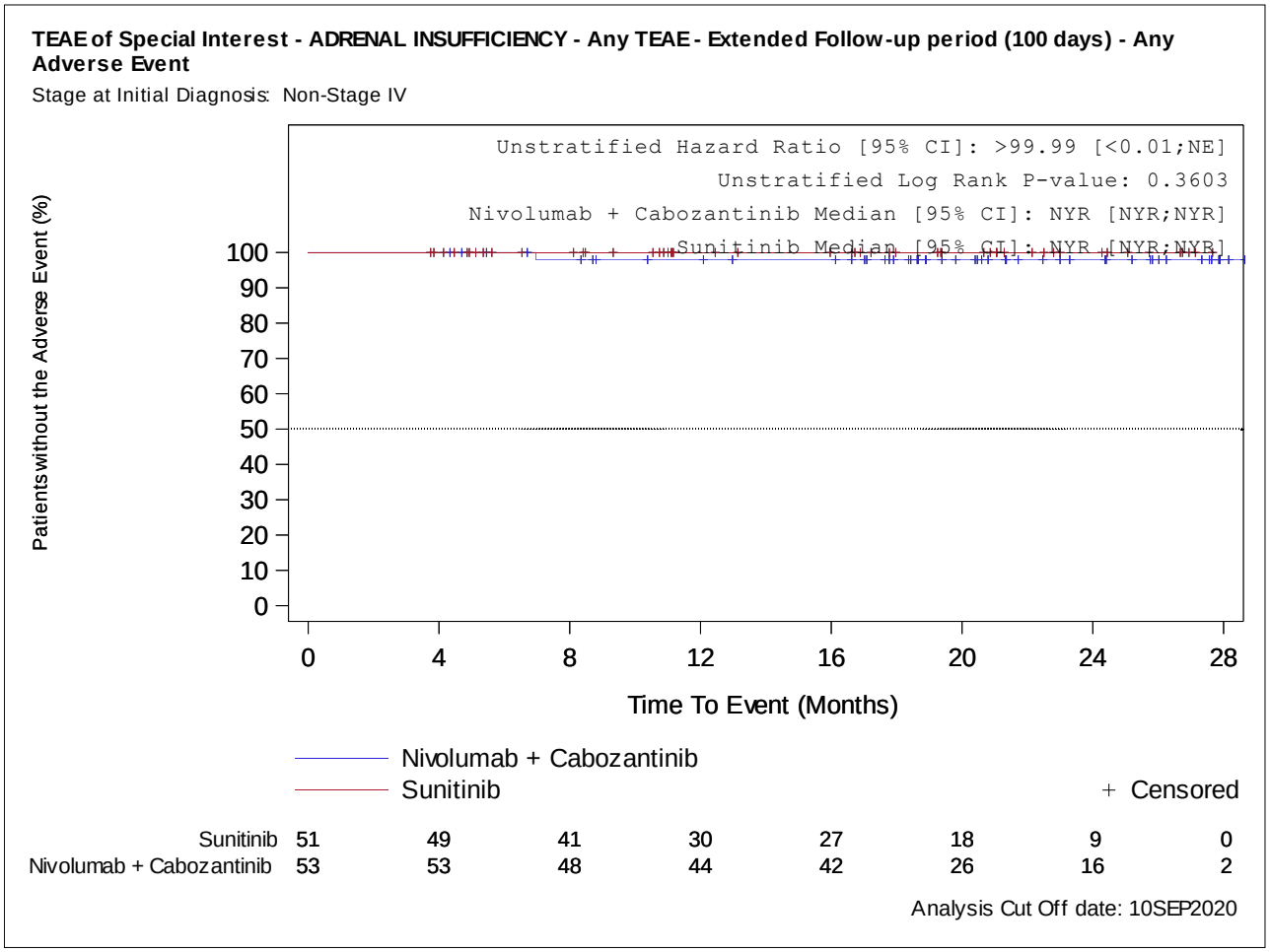
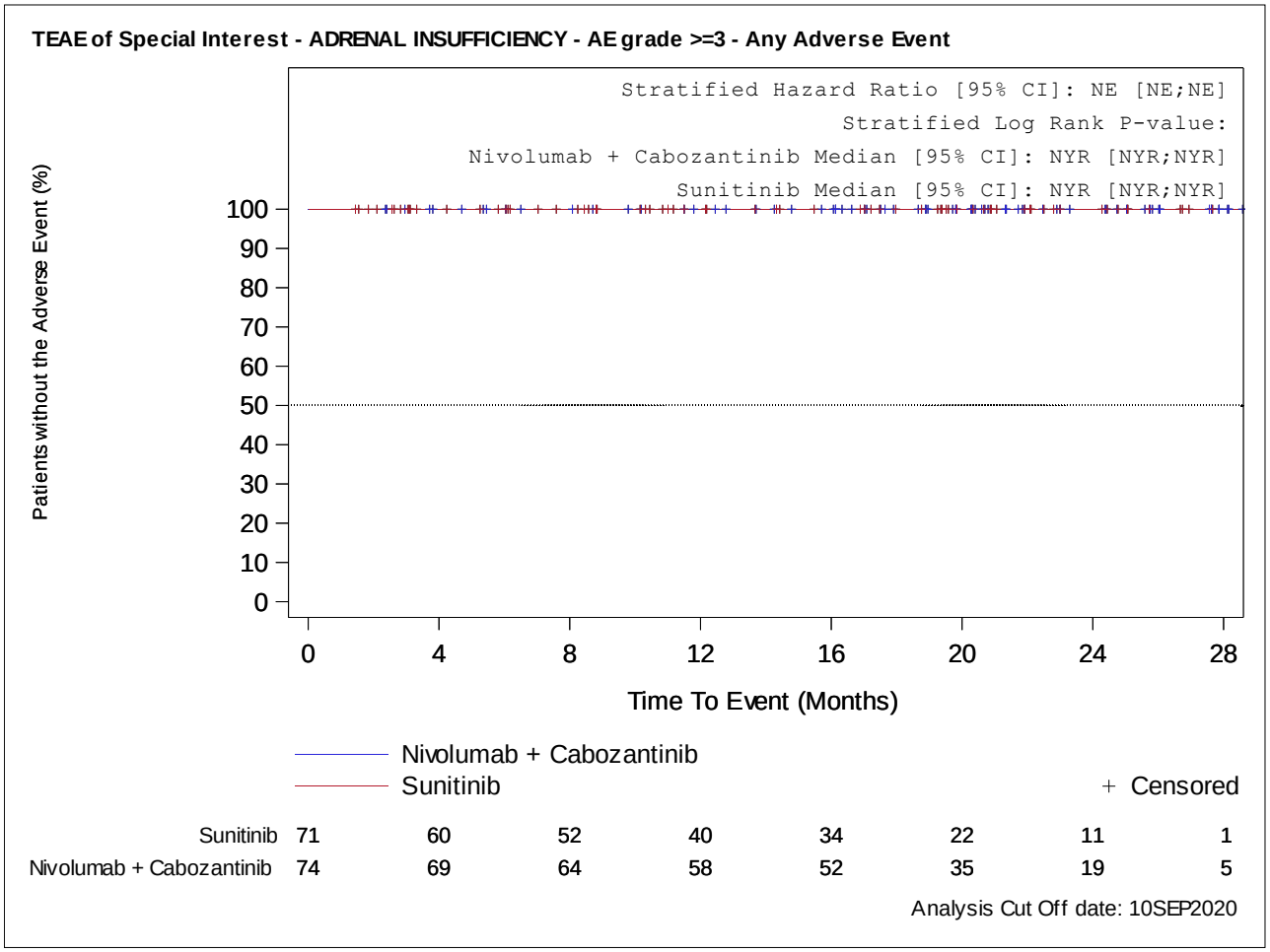
FIGURE 3.60.2.24: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



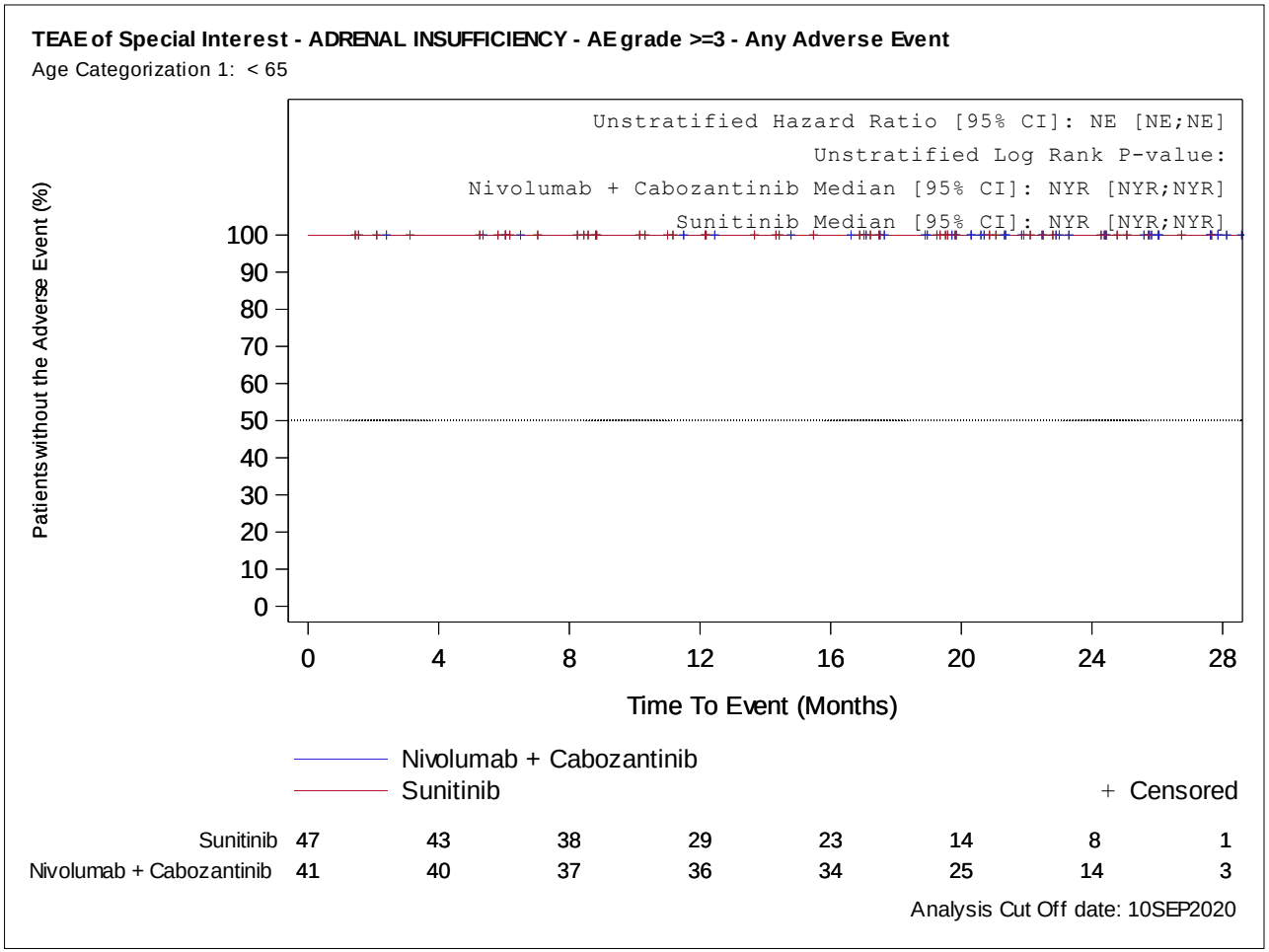

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:19:22

FIGURE 3.61.1: TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



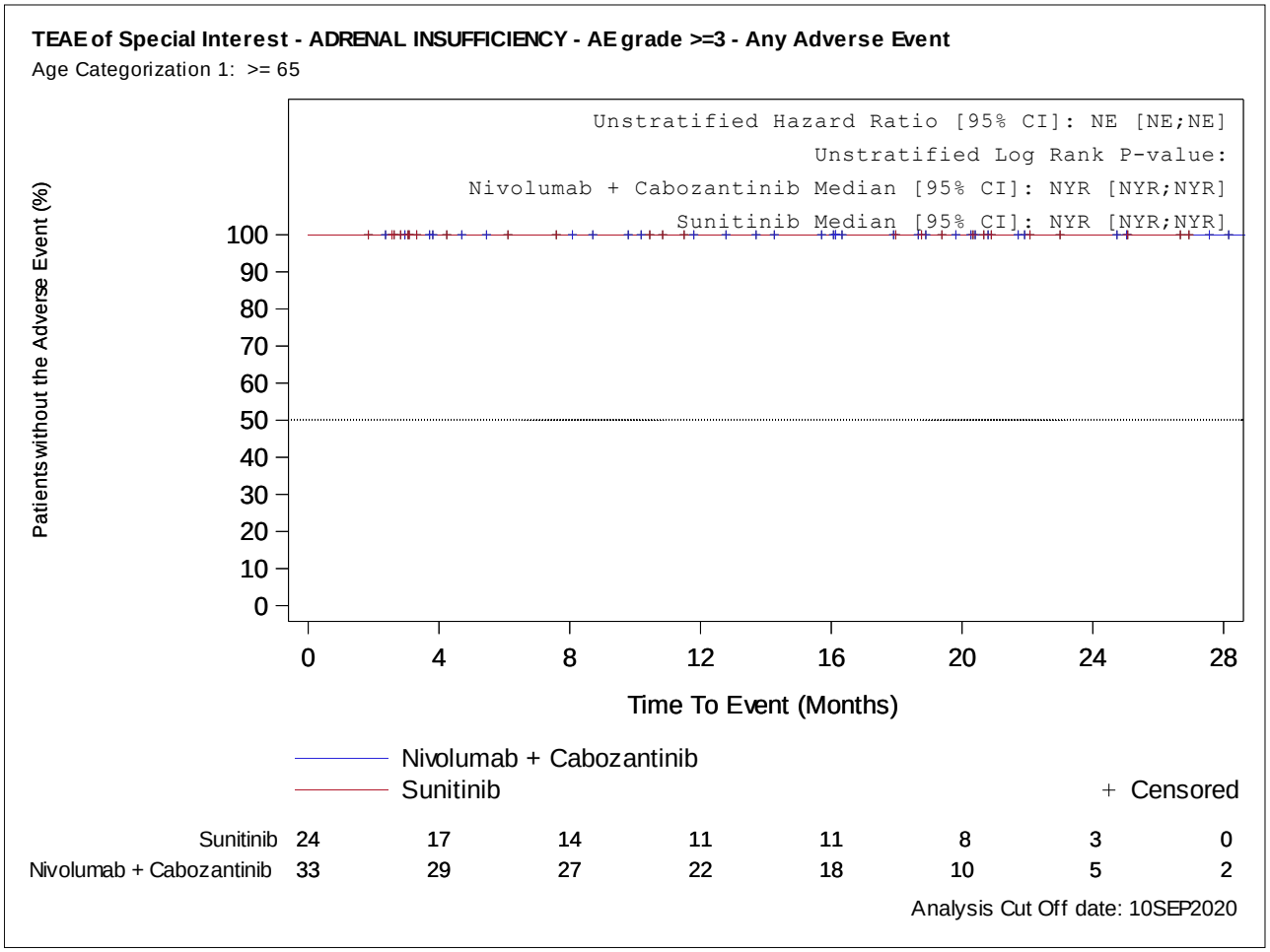

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:22:17

FIGURE 3.61.2.1: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



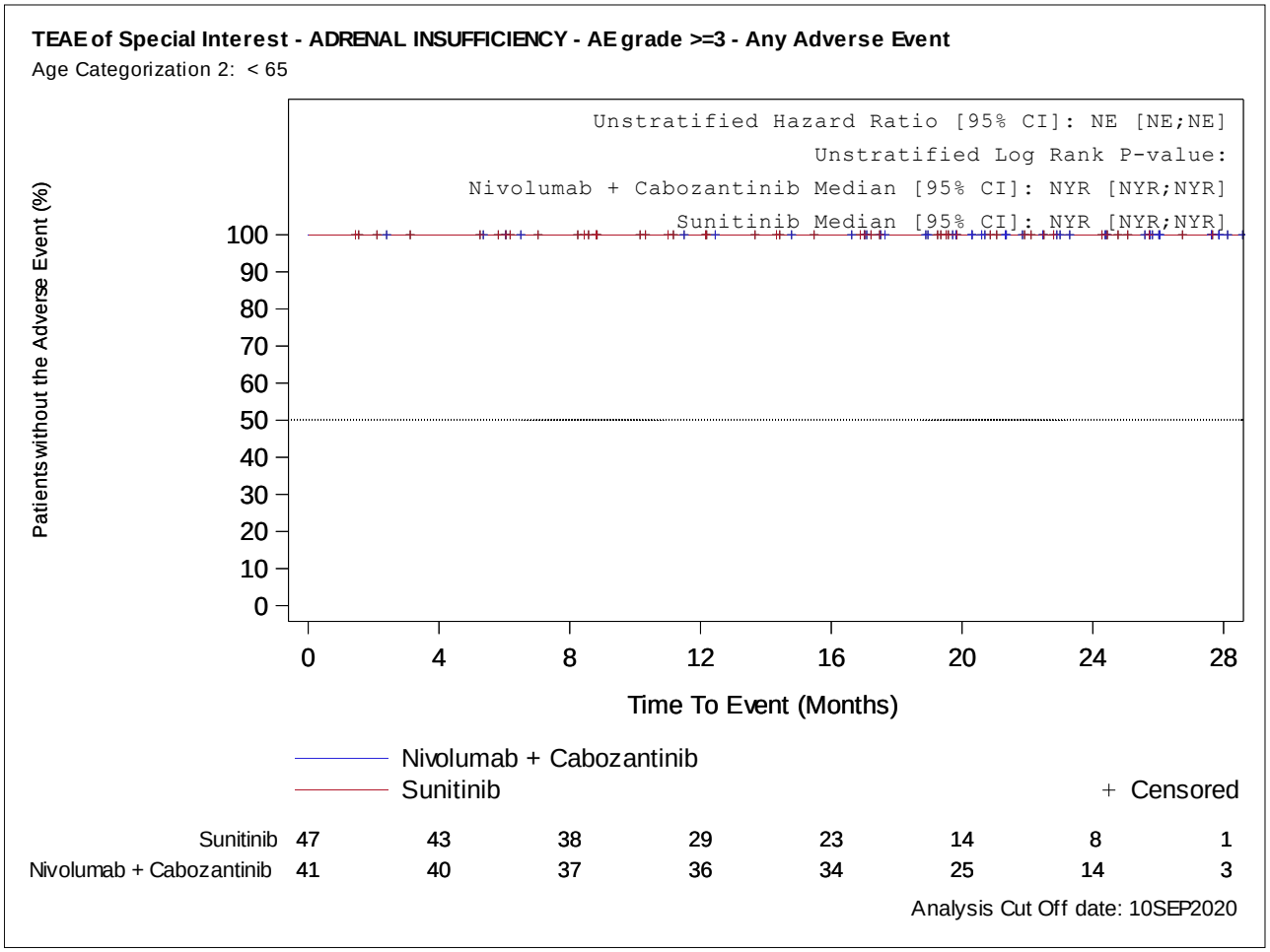

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:22:20

FIGURE 3.61.2.2: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



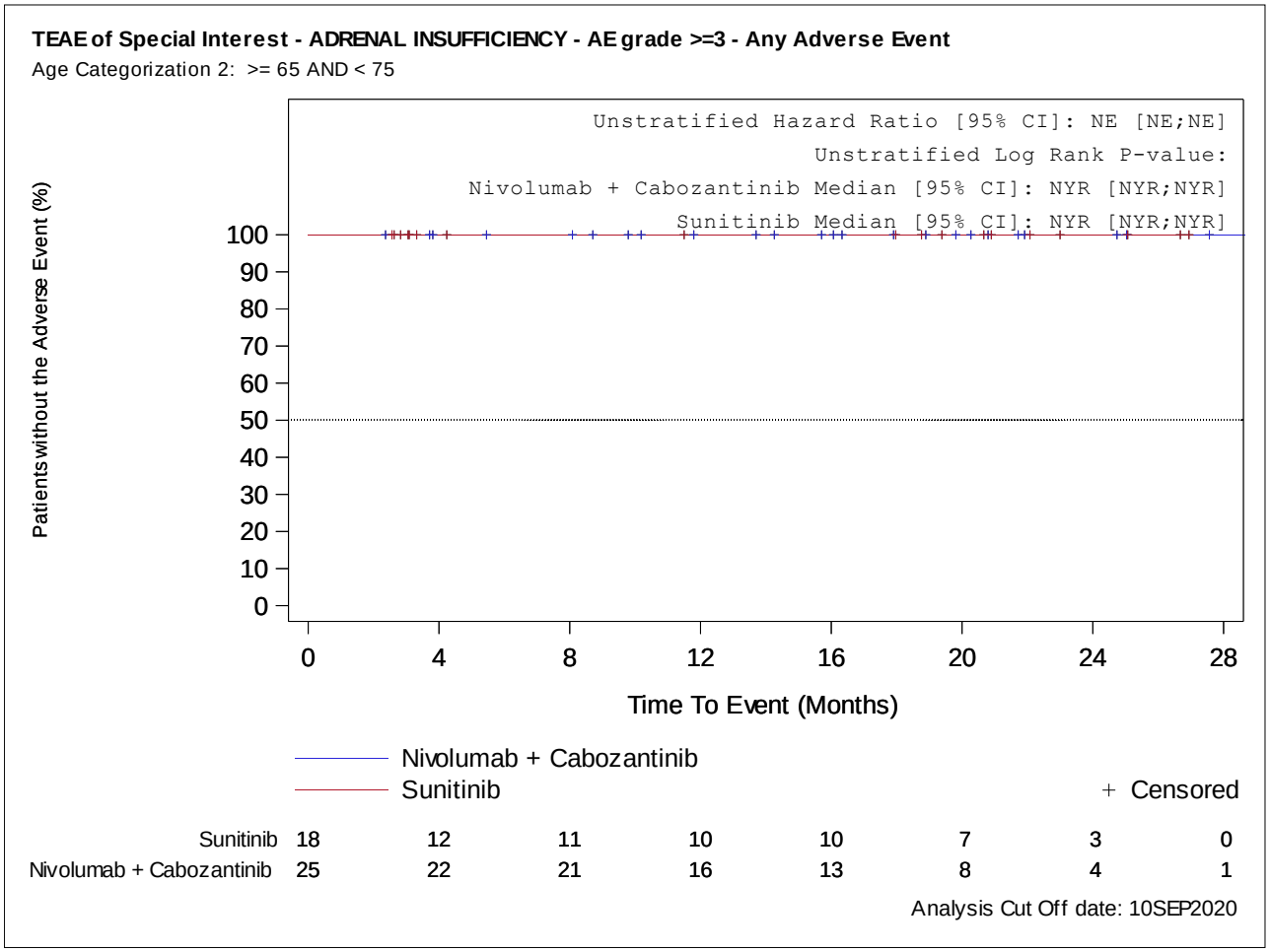

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:22:25

FIGURE 3.61.2.3: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



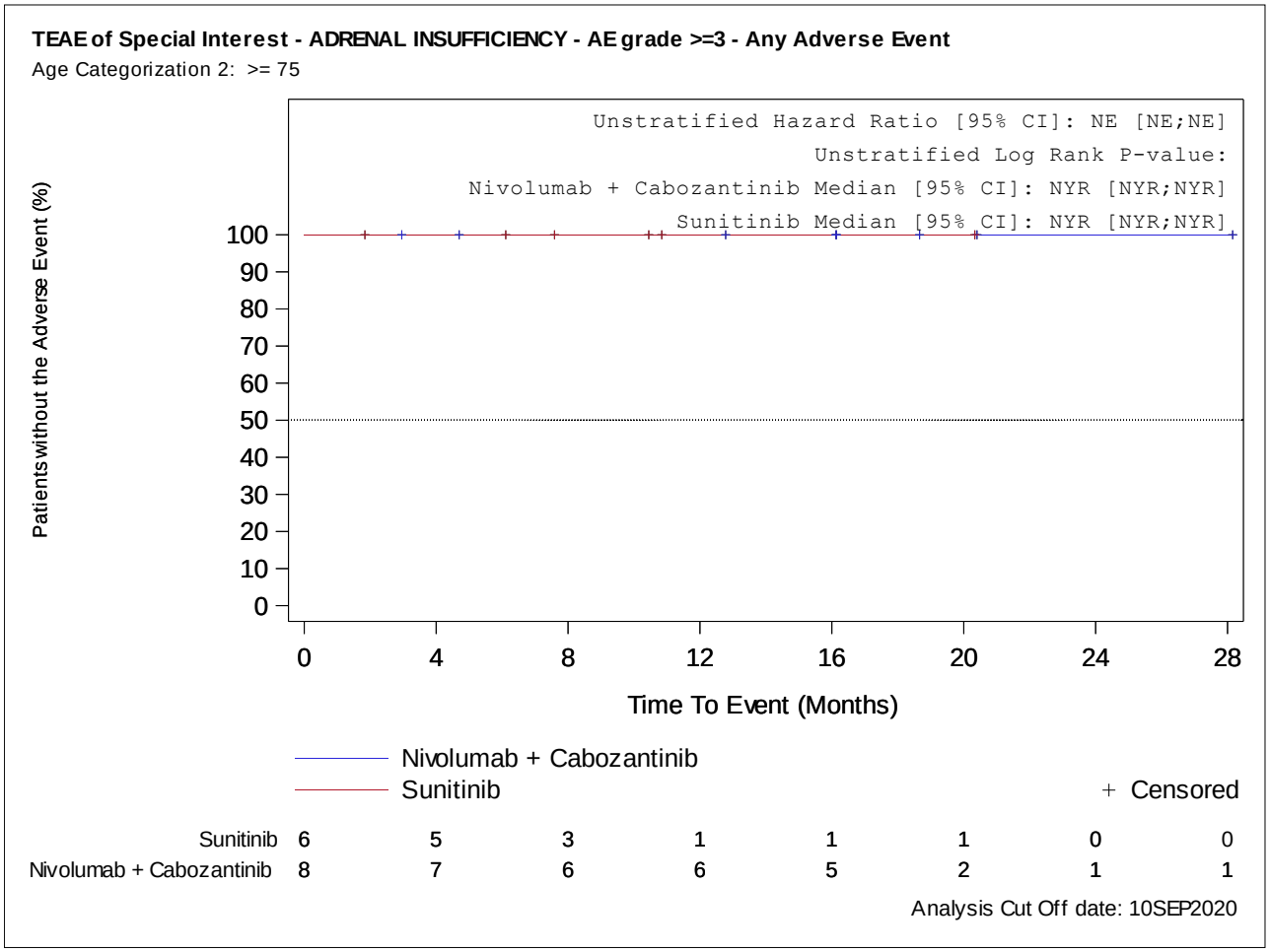

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:22:30

FIGURE 3.61.2.4: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



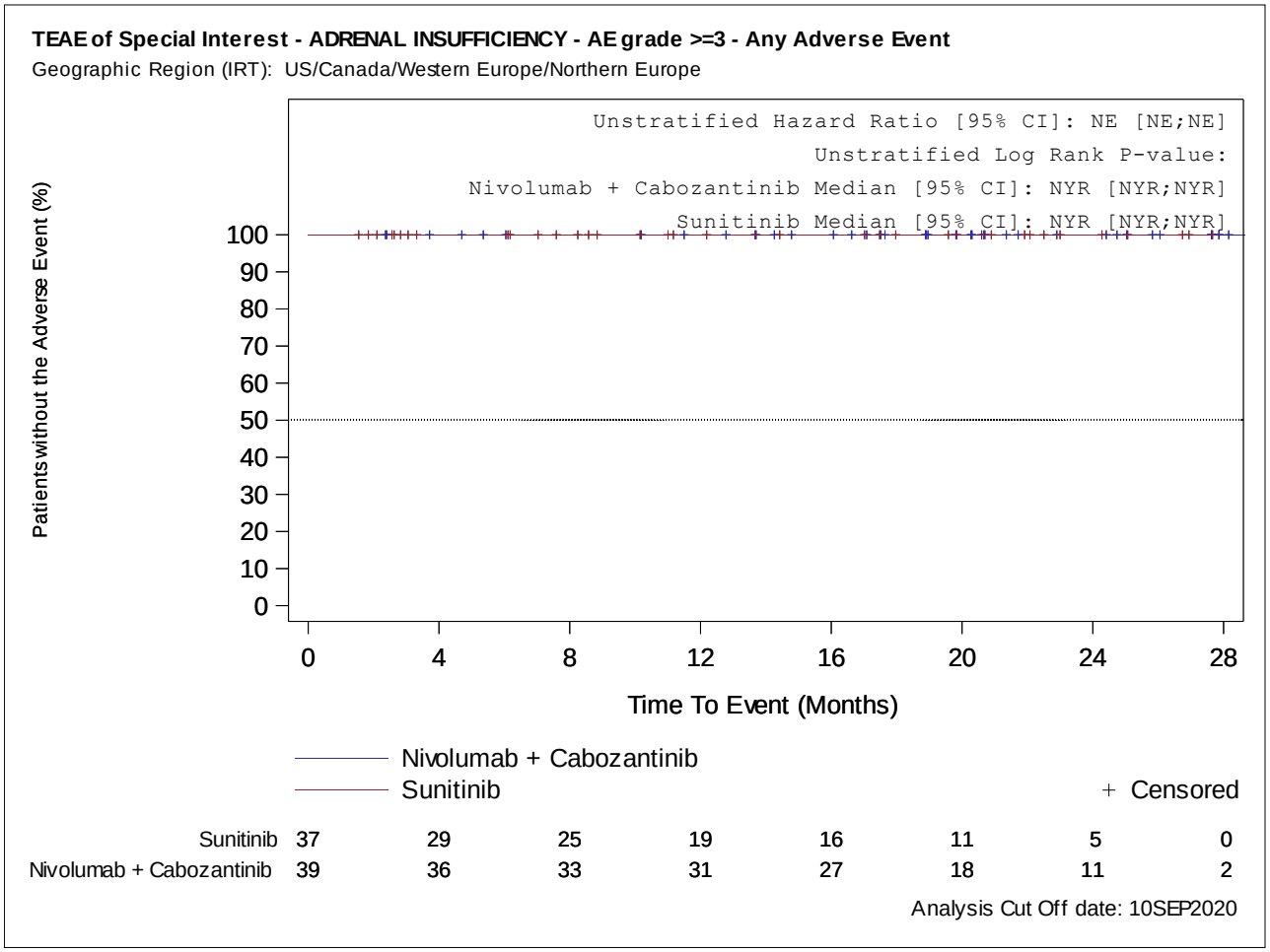

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:22:35

FIGURE 3.61.2.5: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



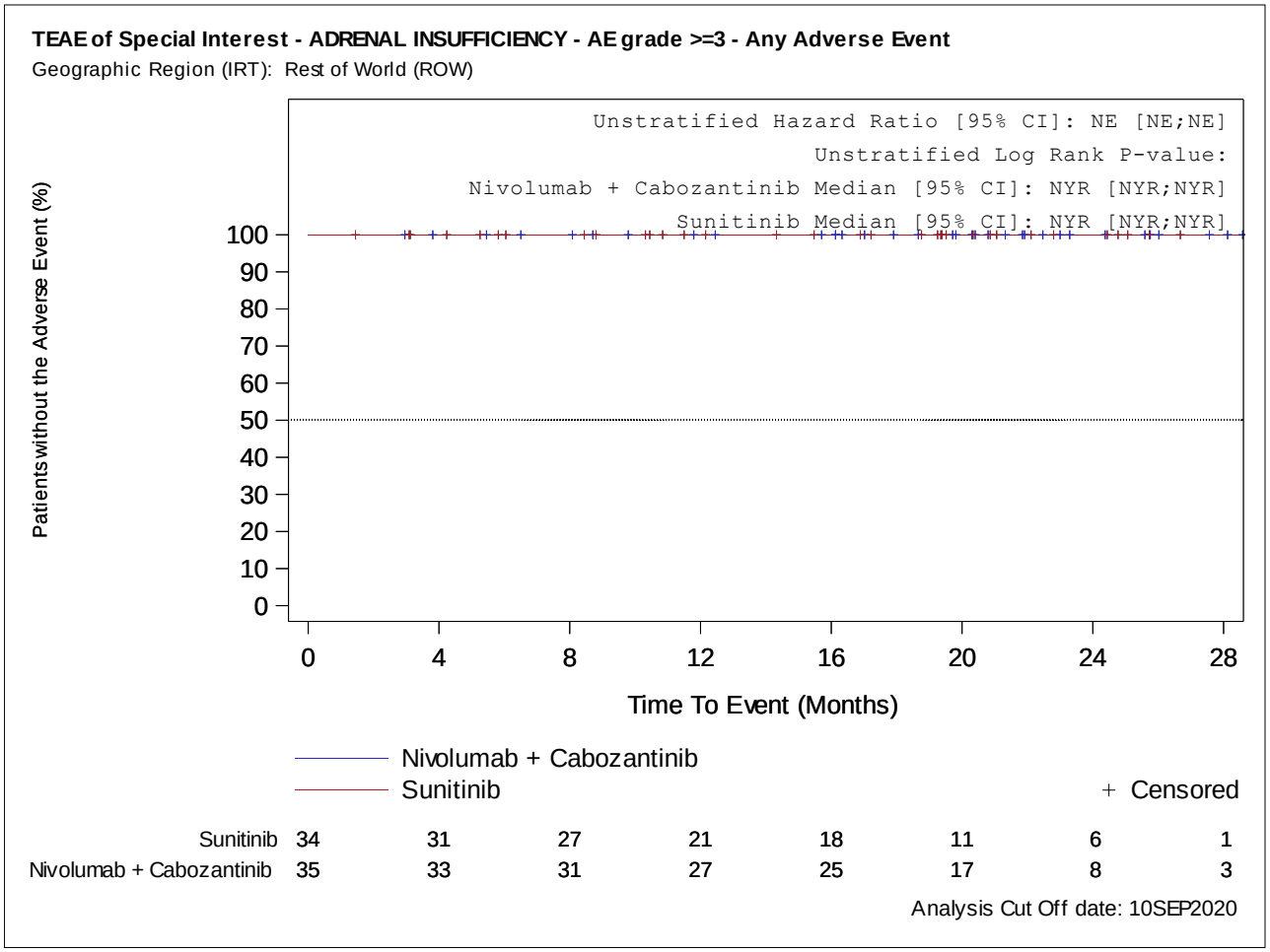

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:22:41

FIGURE 3.61.2.6: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



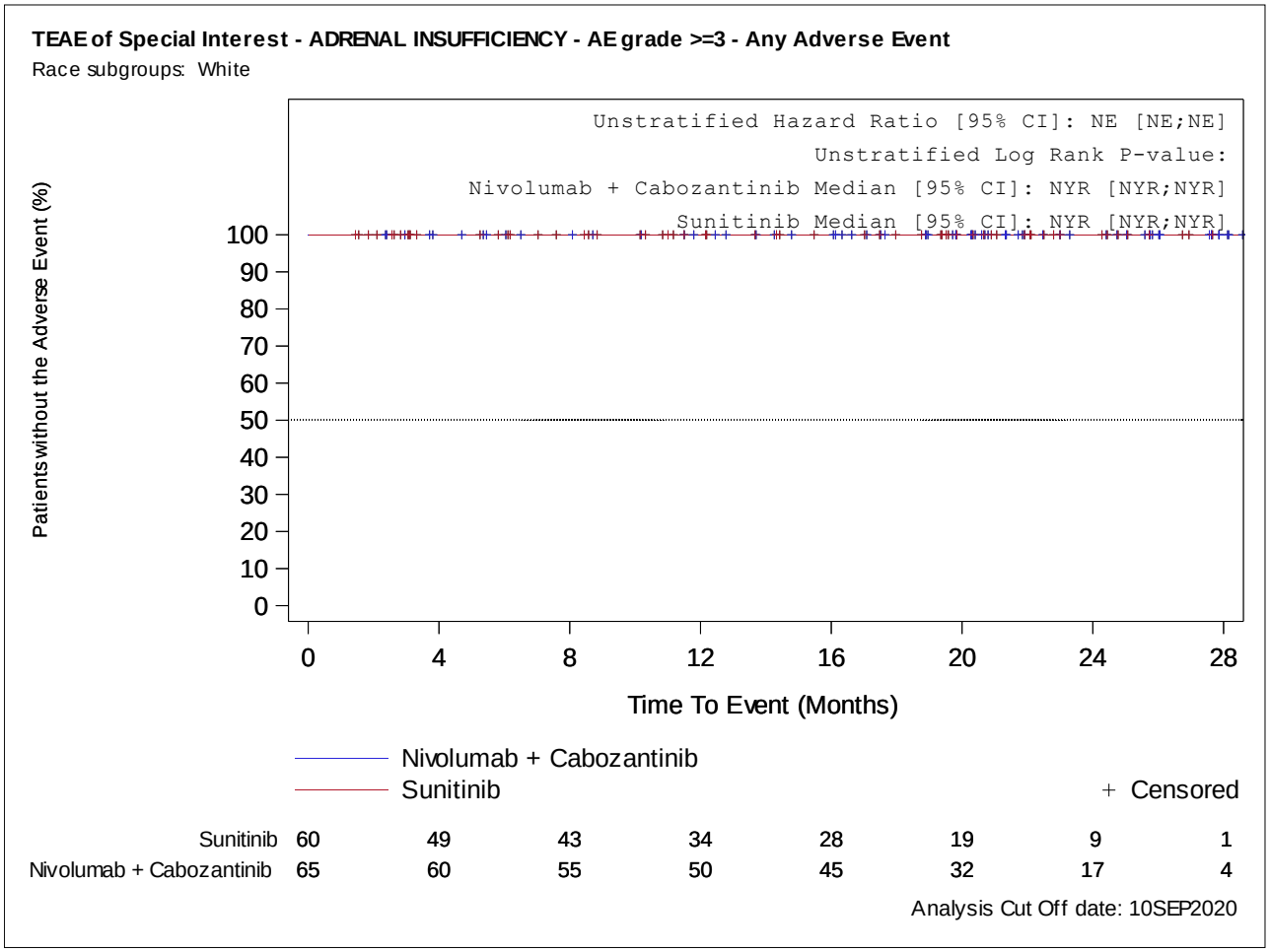

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:22:46

FIGURE 3.61.2.7: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:22:51

FIGURE 3.61.2.8: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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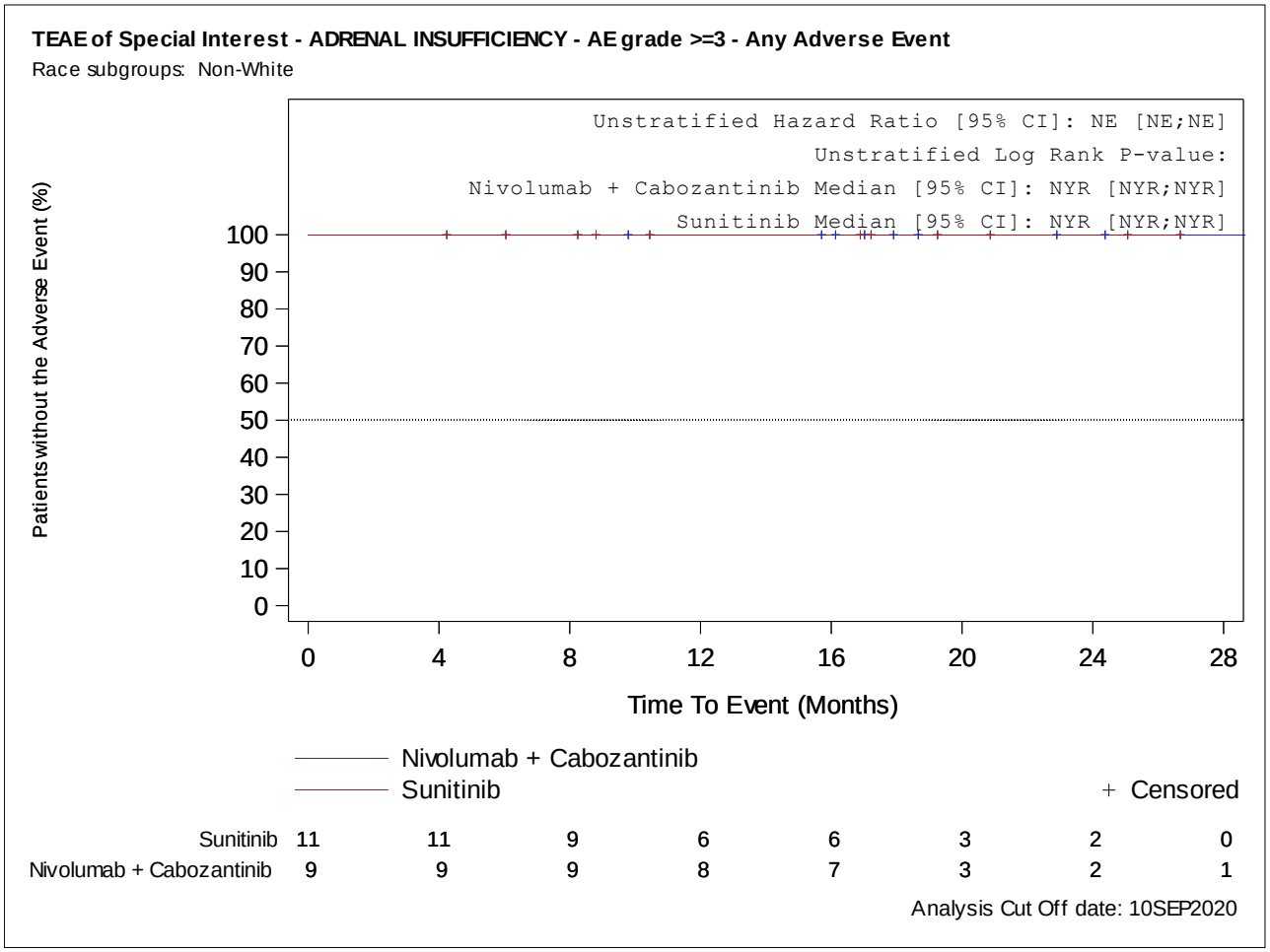
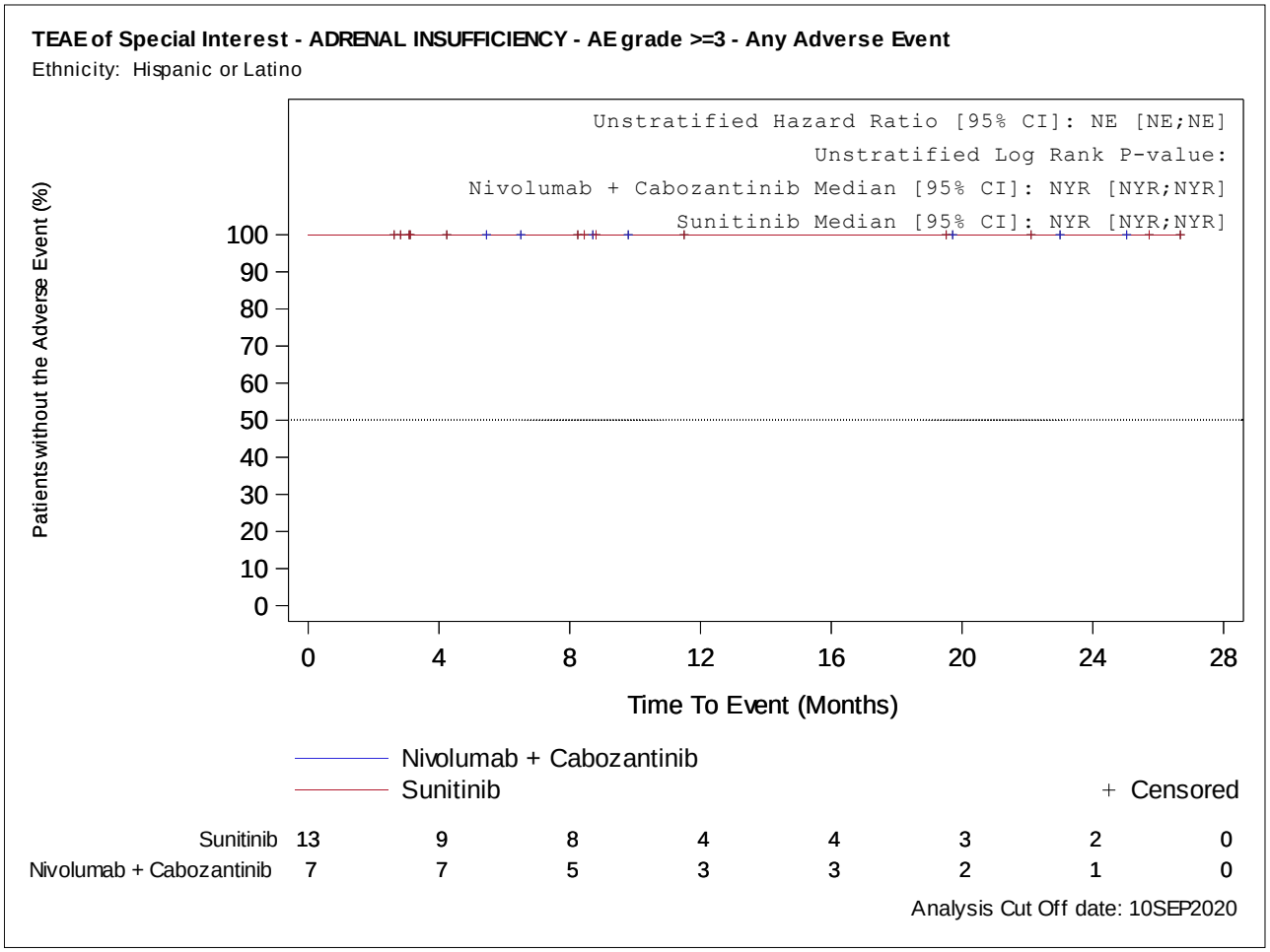
FIGURE 3.61.2.9: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



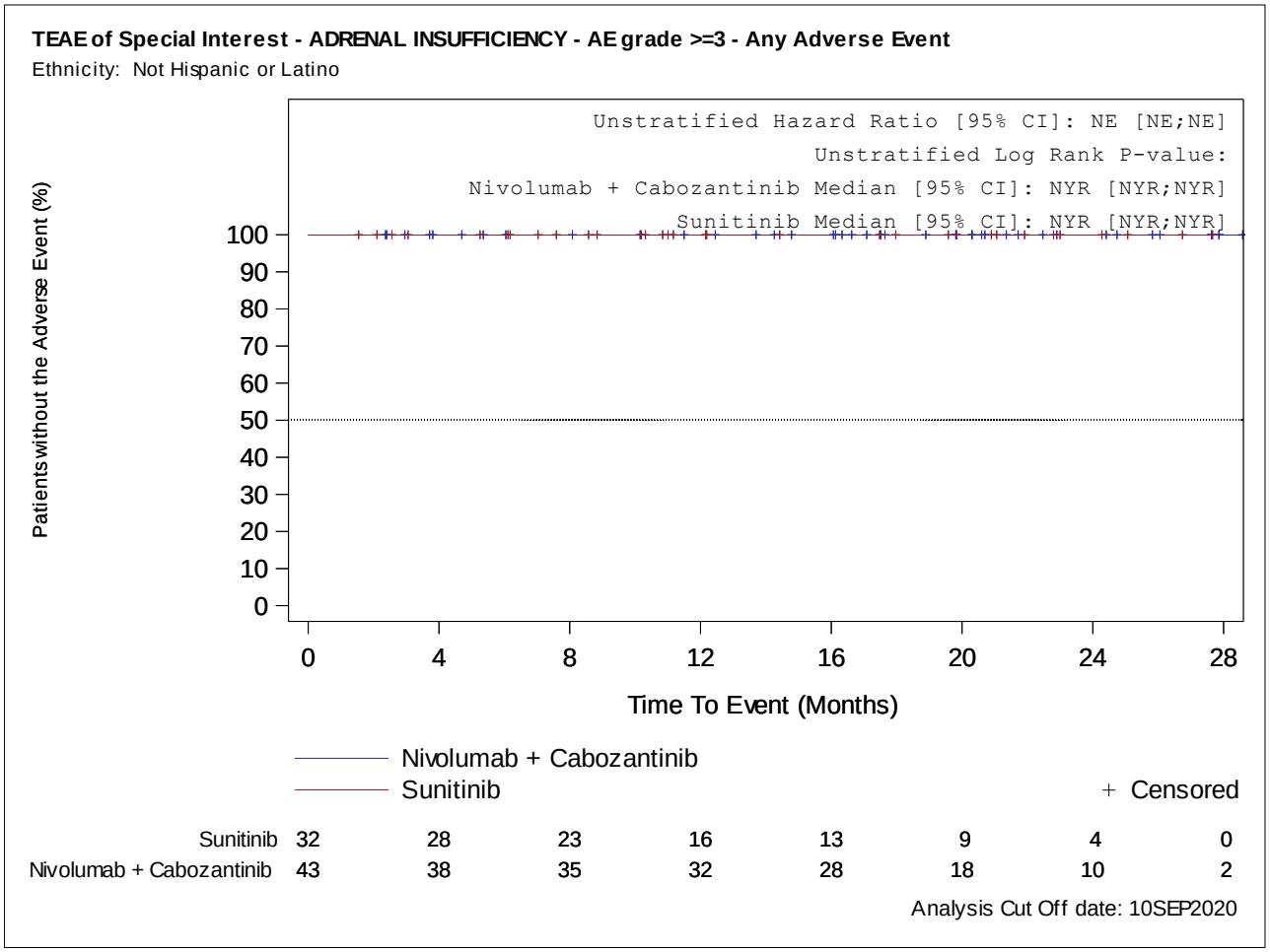

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:23:01

FIGURE 3.61.2.10: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



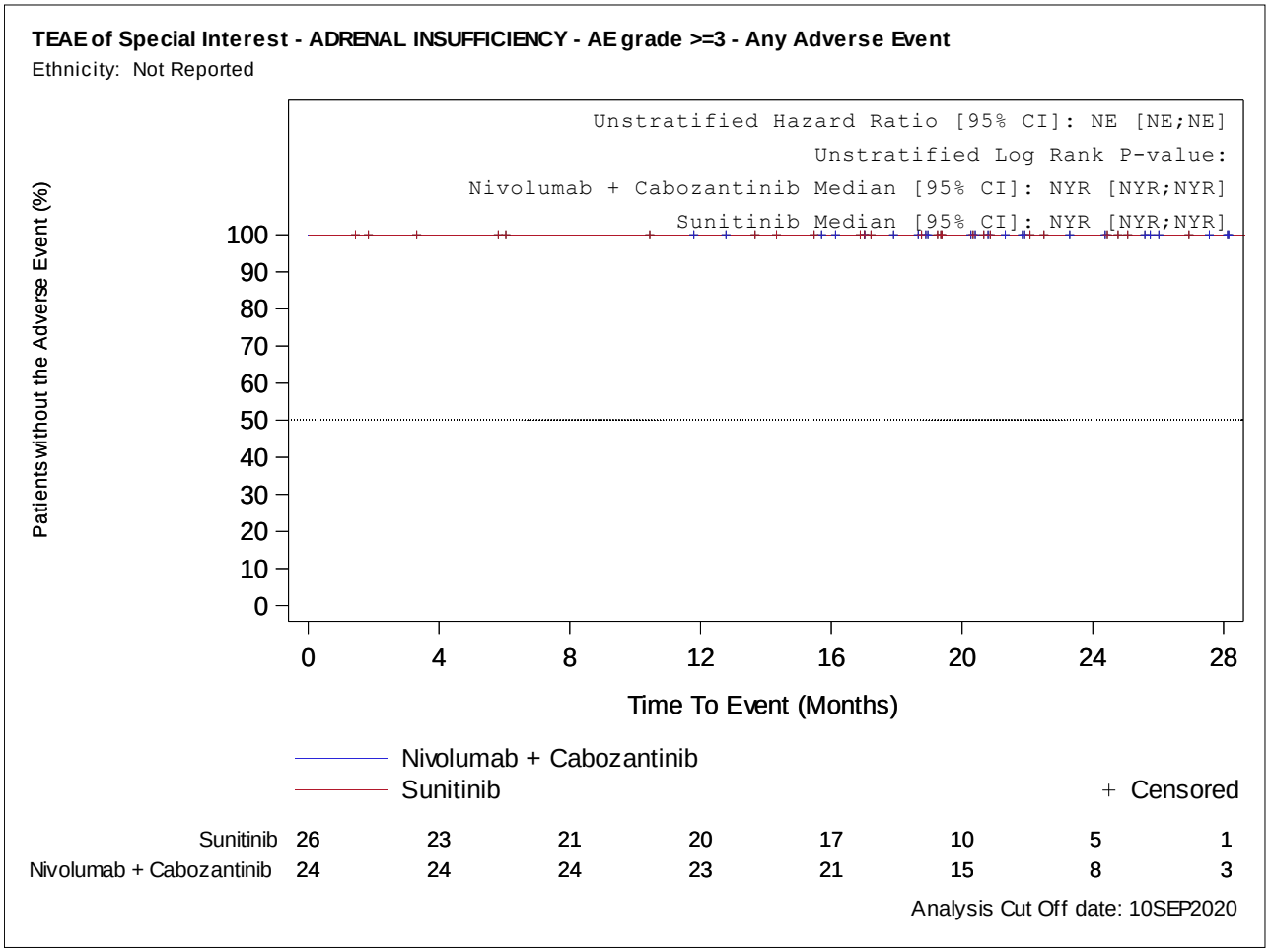

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:23:06

FIGURE 3.61.2.11: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



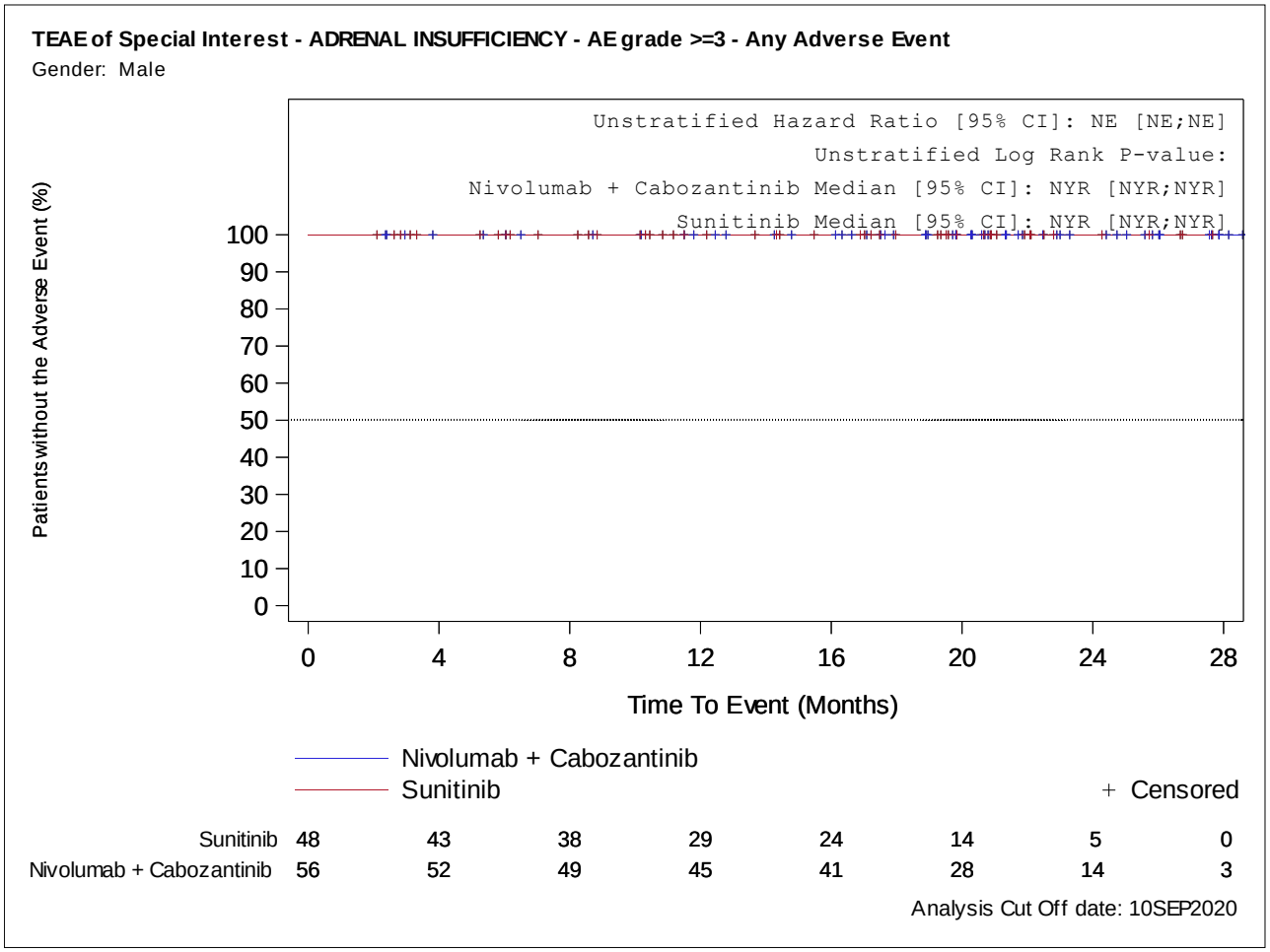

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:23:12

FIGURE 3.61.2.12: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



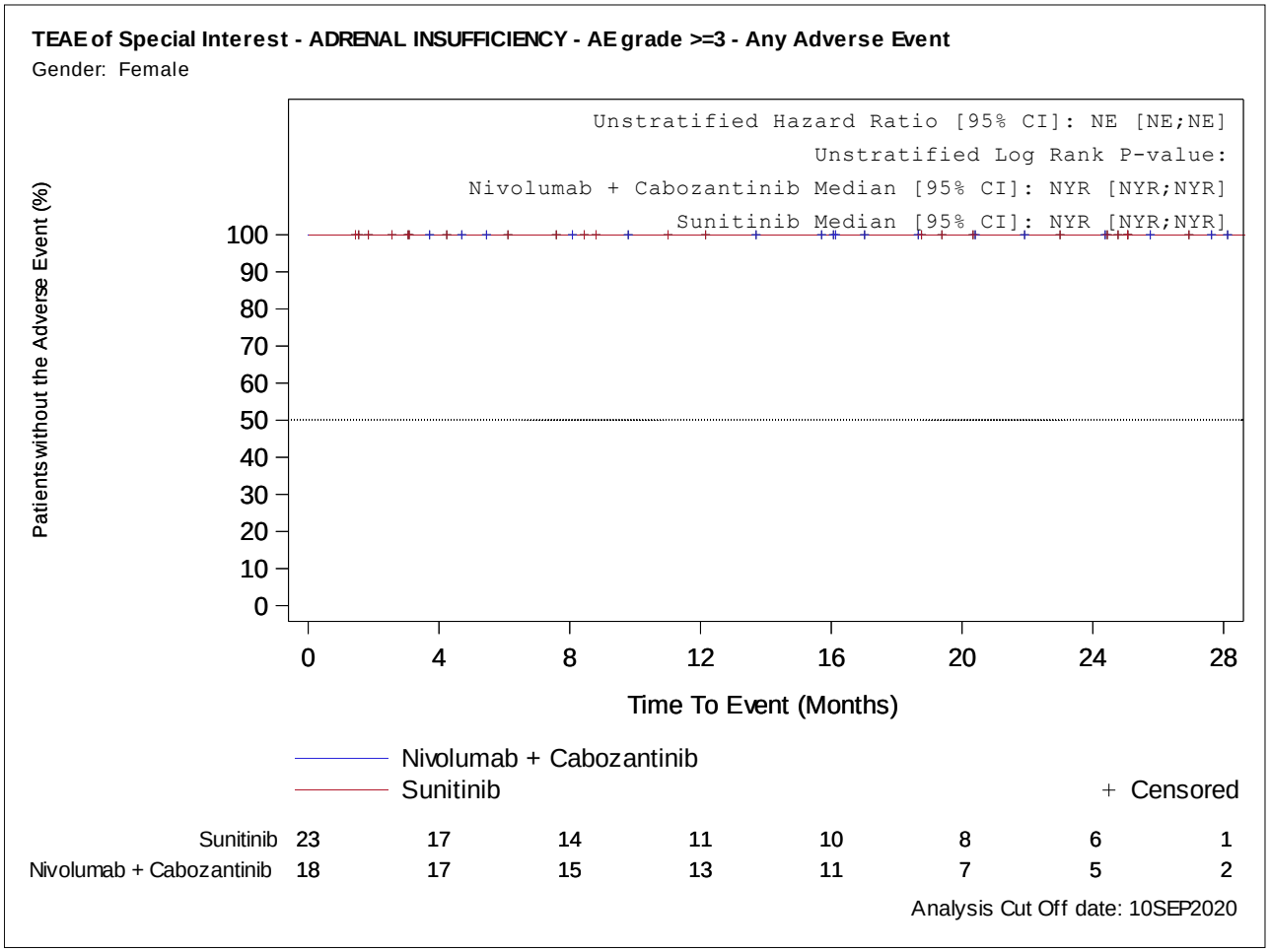

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:23:17

FIGURE 3.61.2.13: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



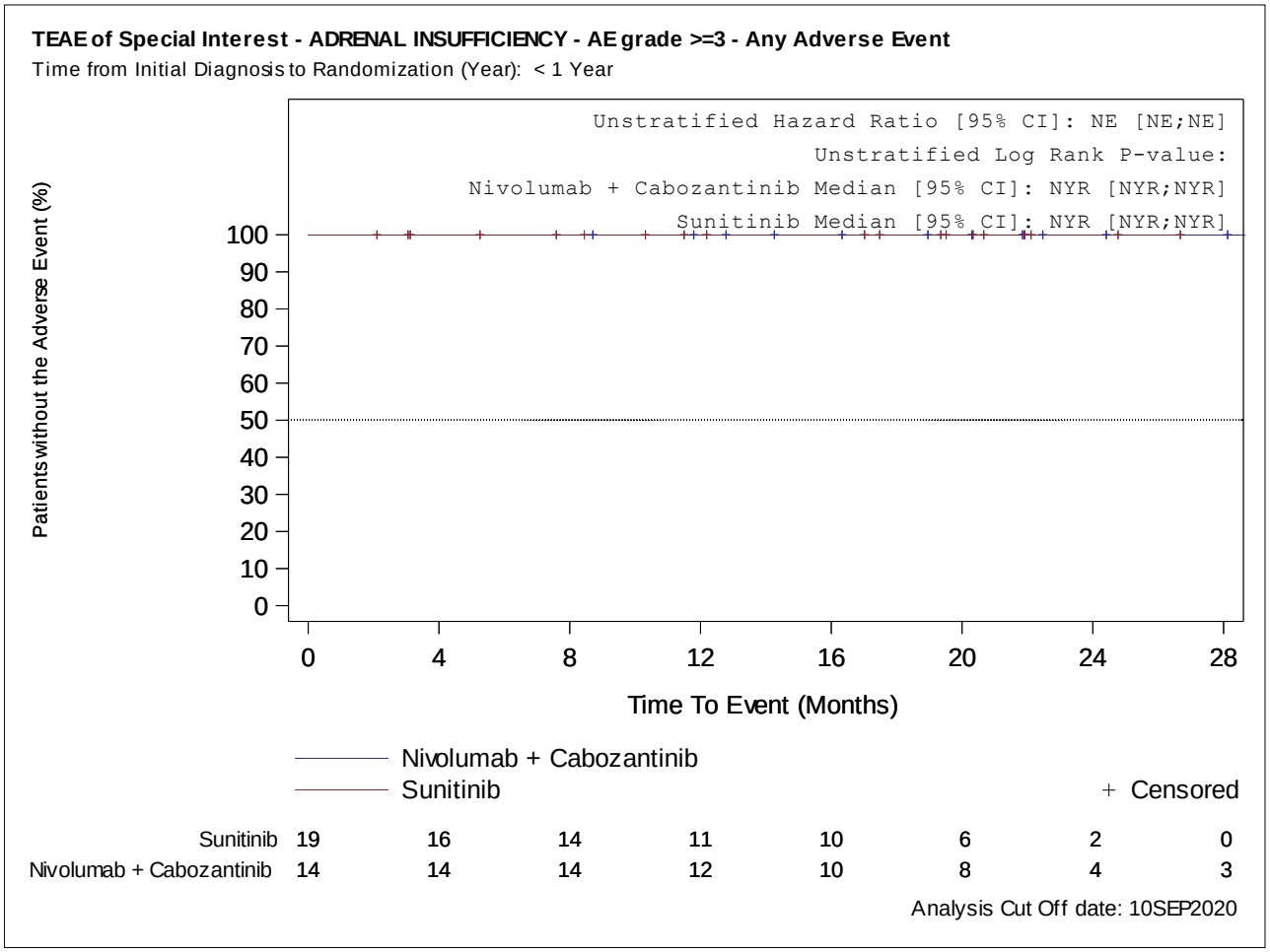

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:23:22

FIGURE 3.61.2.14: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



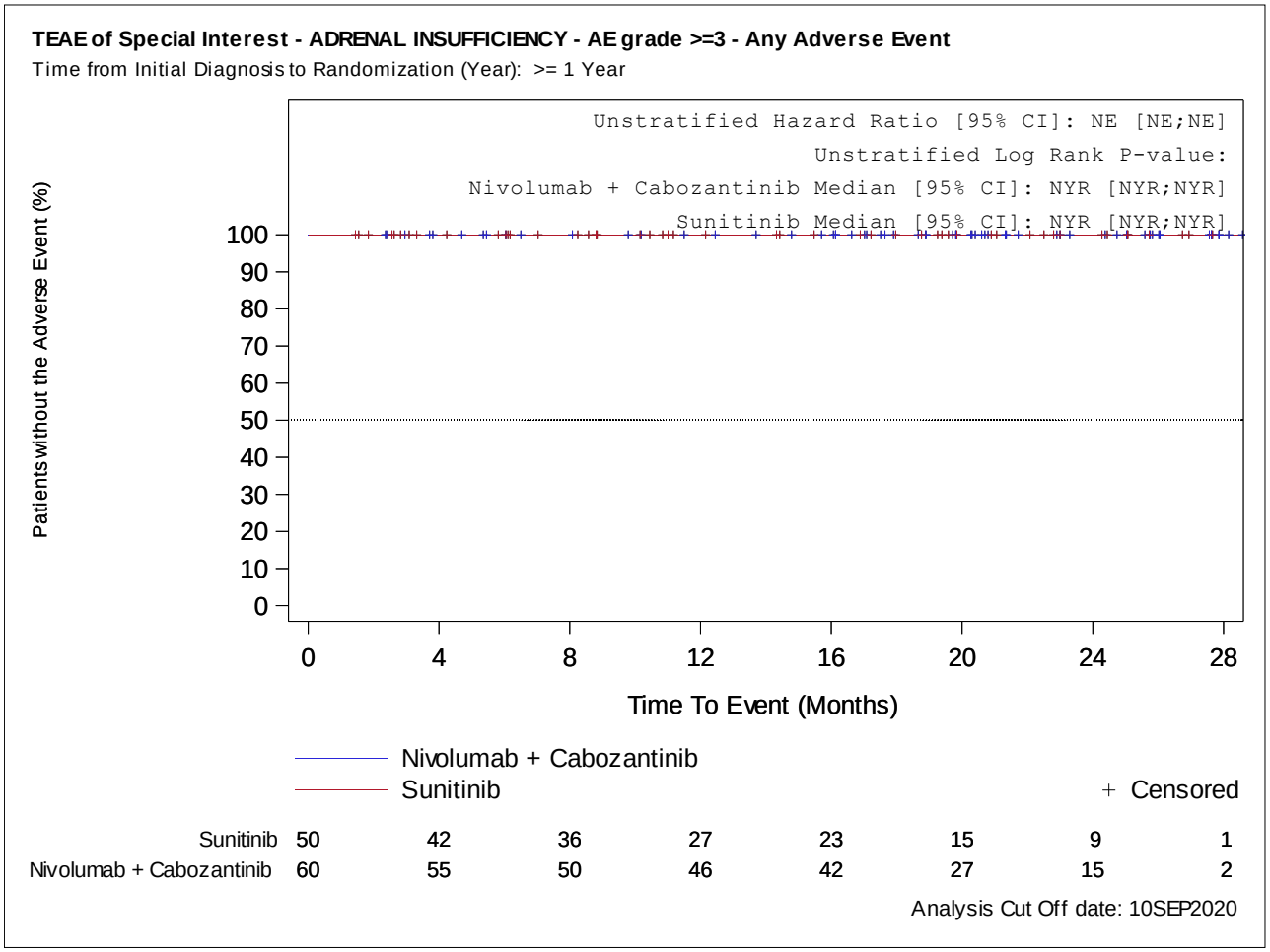

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:23:27

FIGURE 3.61.2.15: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



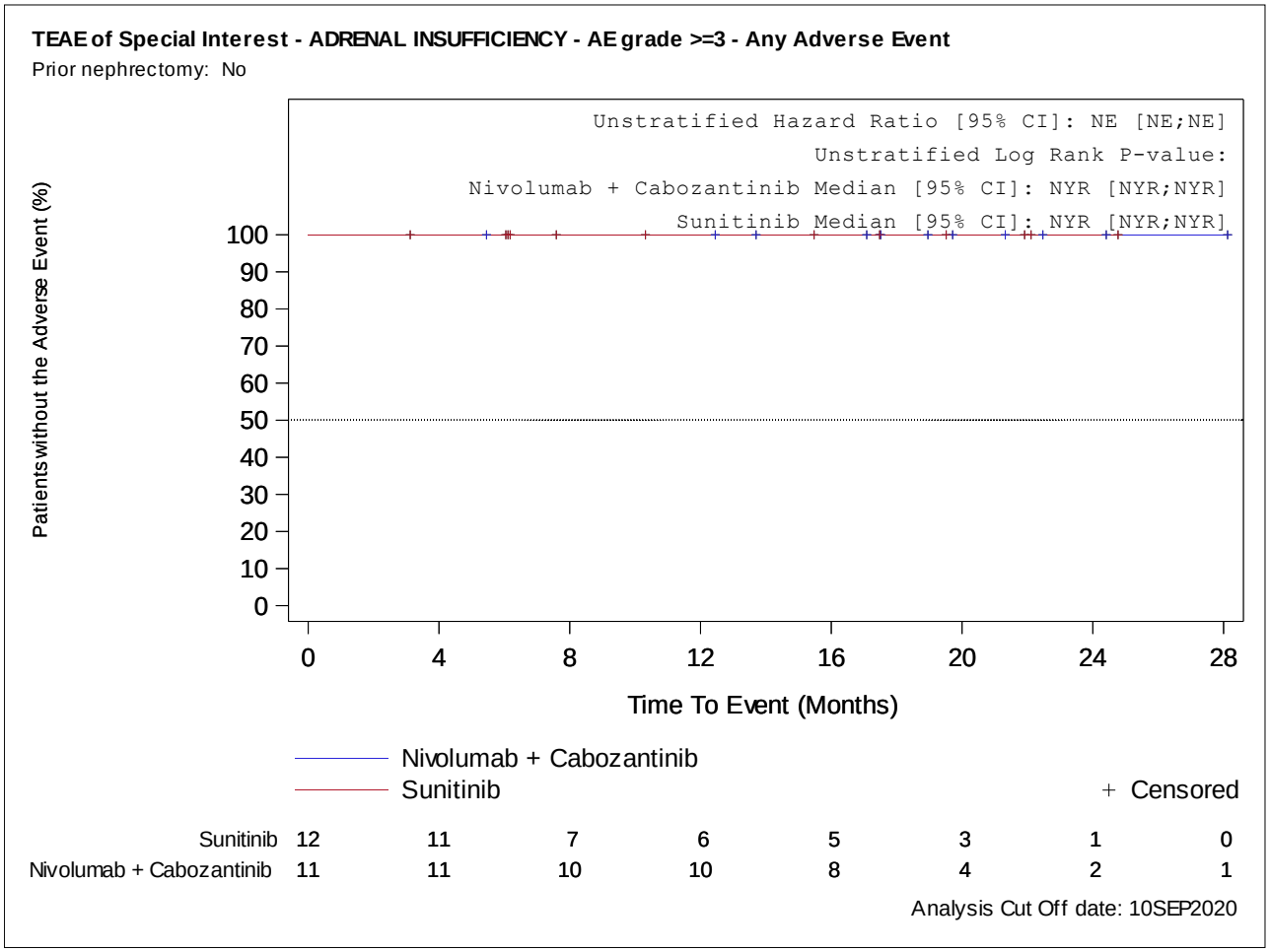

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:23:43

FIGURE 3.61.2.16: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



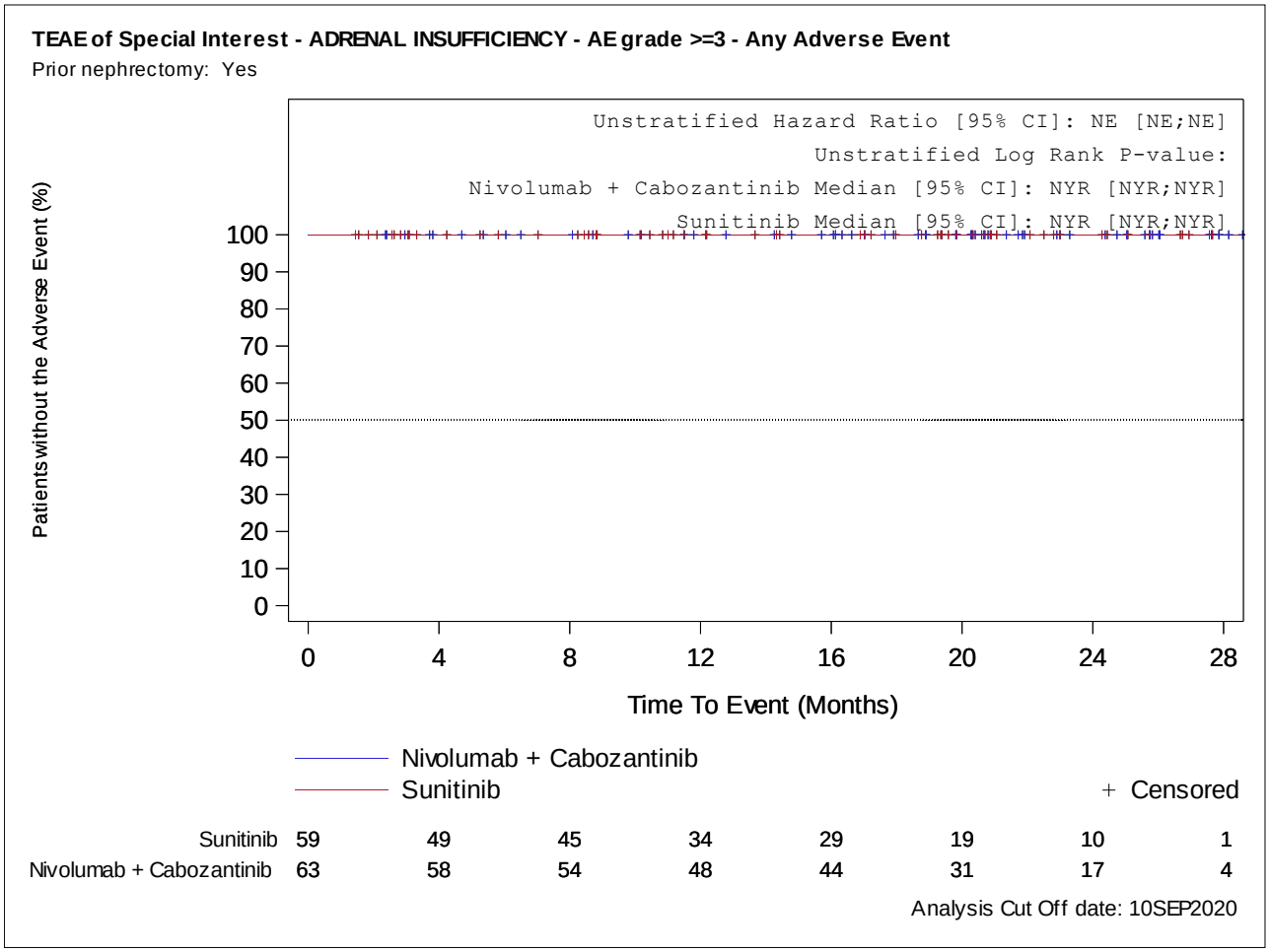

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:23:48

FIGURE 3.61.2.17: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



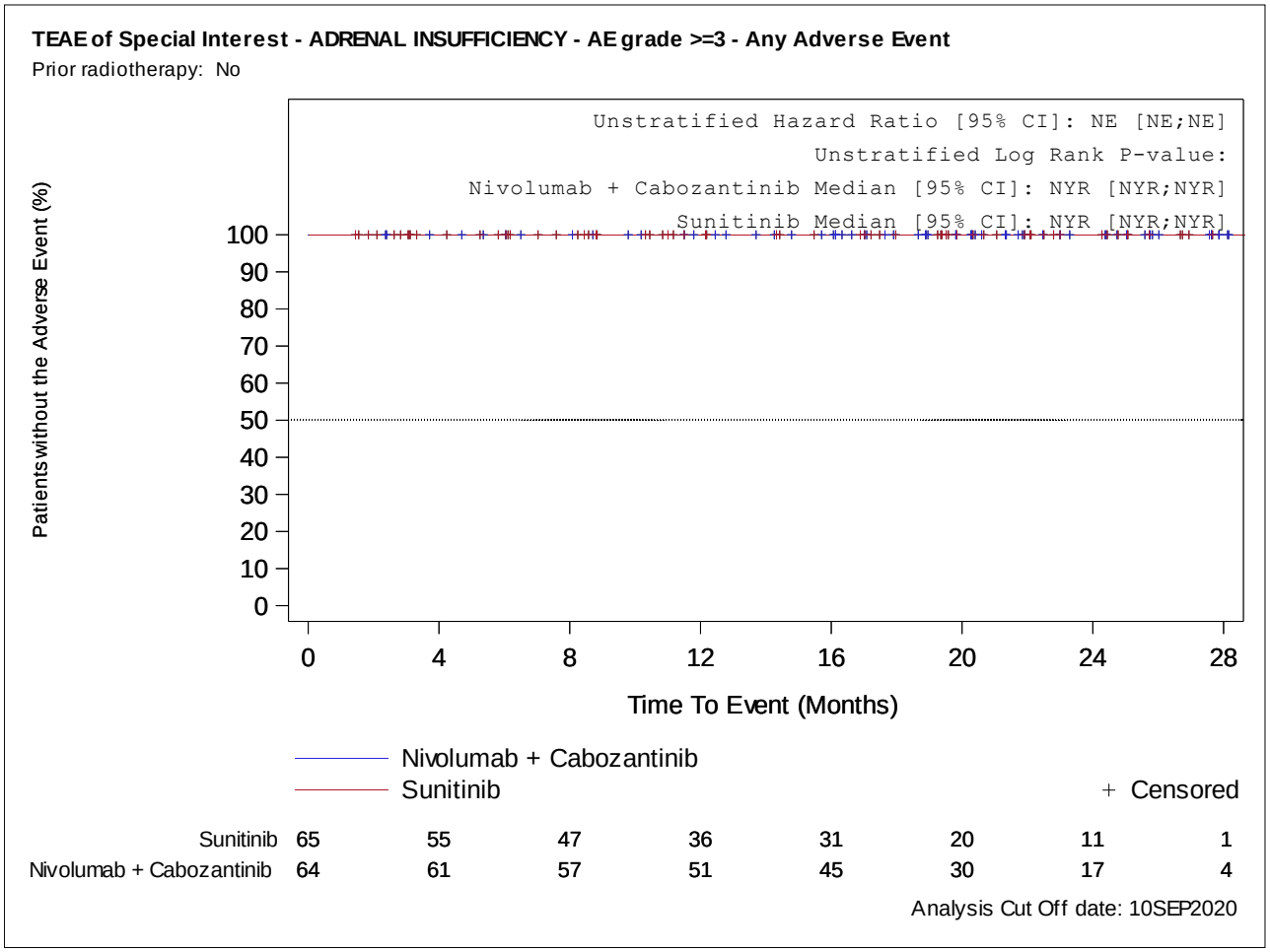

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:35

FIGURE 3.61.2.18: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



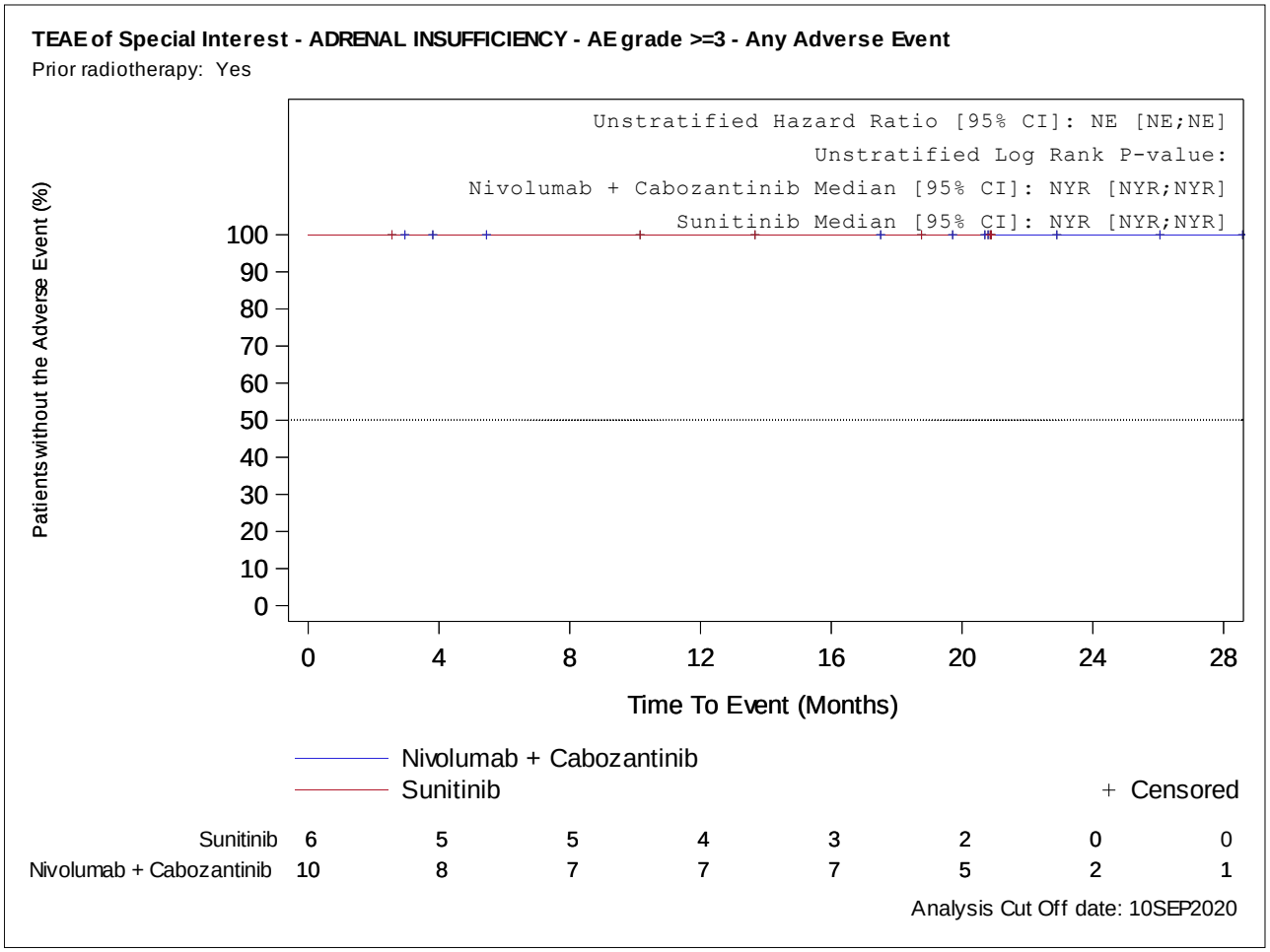

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:40

FIGURE 3.61.2.19: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



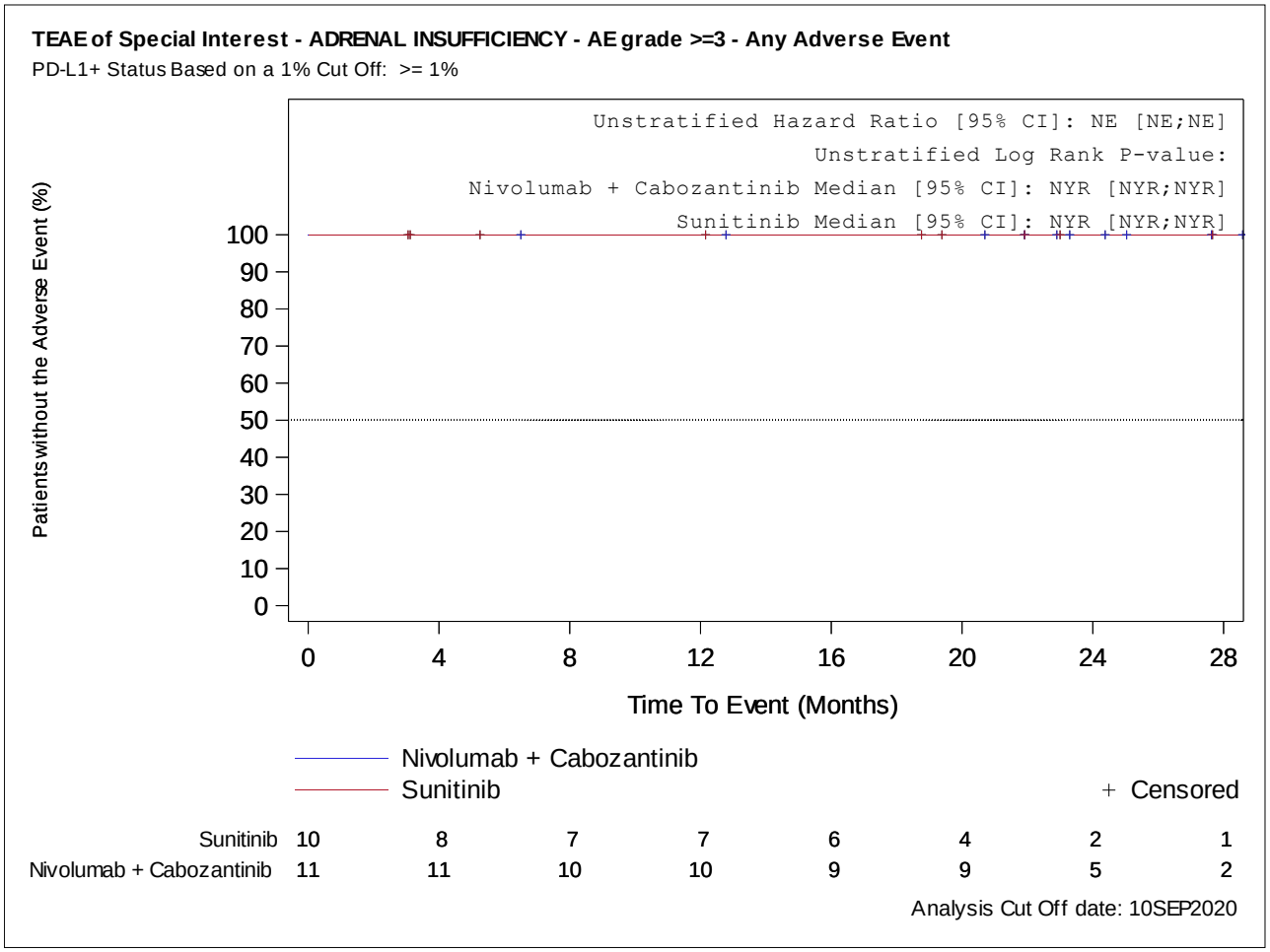

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:46

FIGURE 3.61.2.20: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



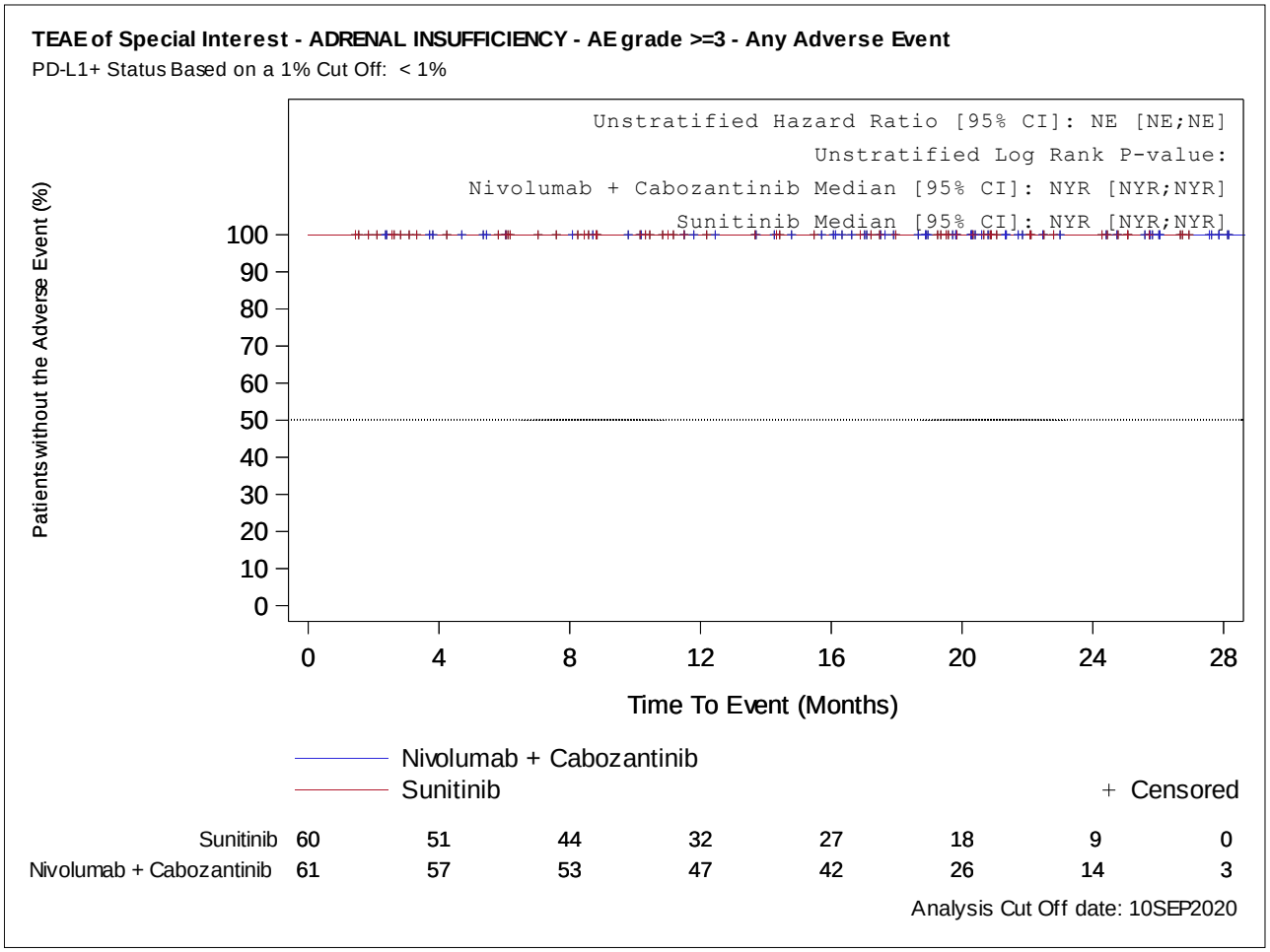

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:51

FIGURE 3.61.2.21: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



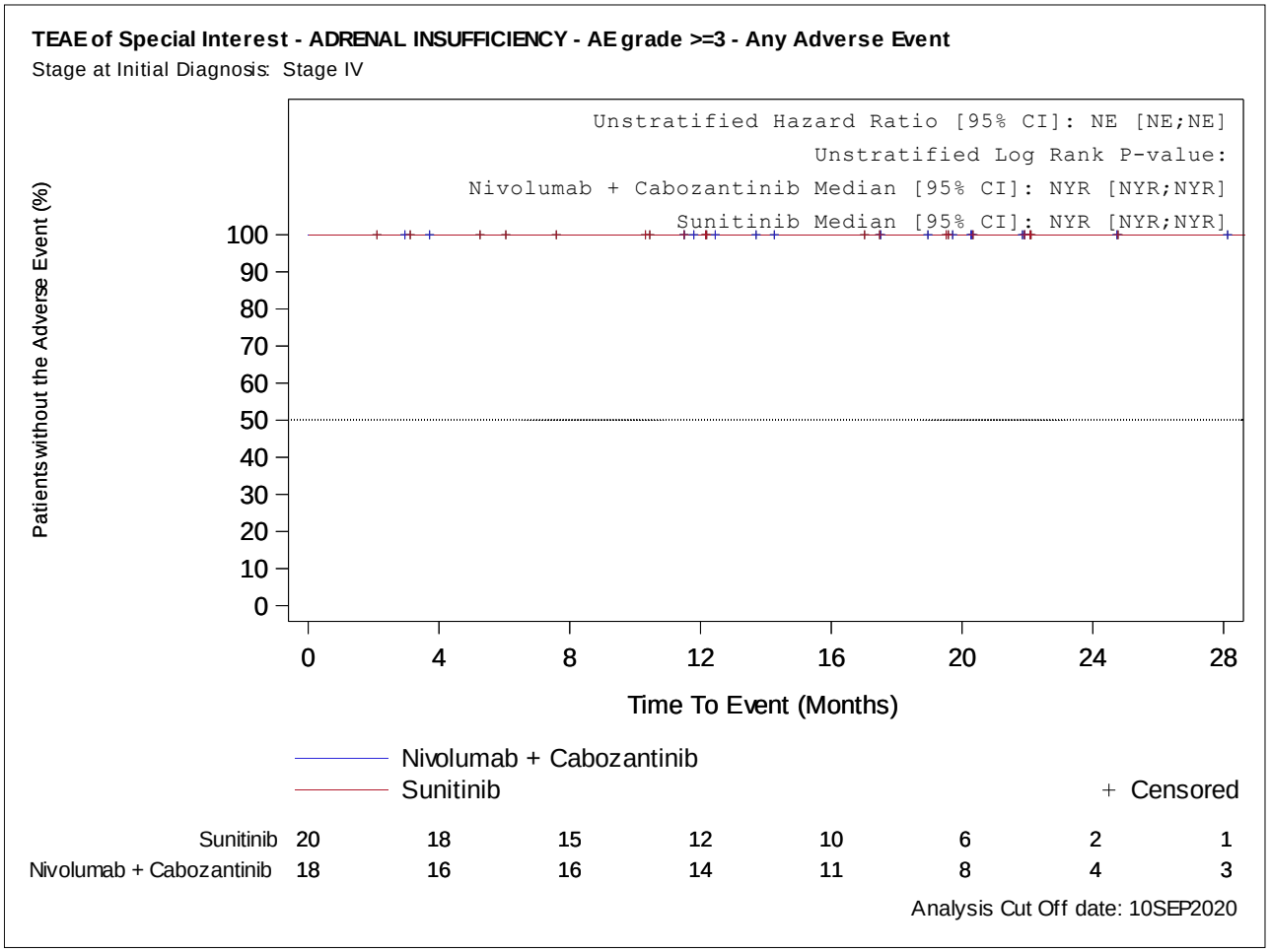

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:56

FIGURE 3.61.2.22: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



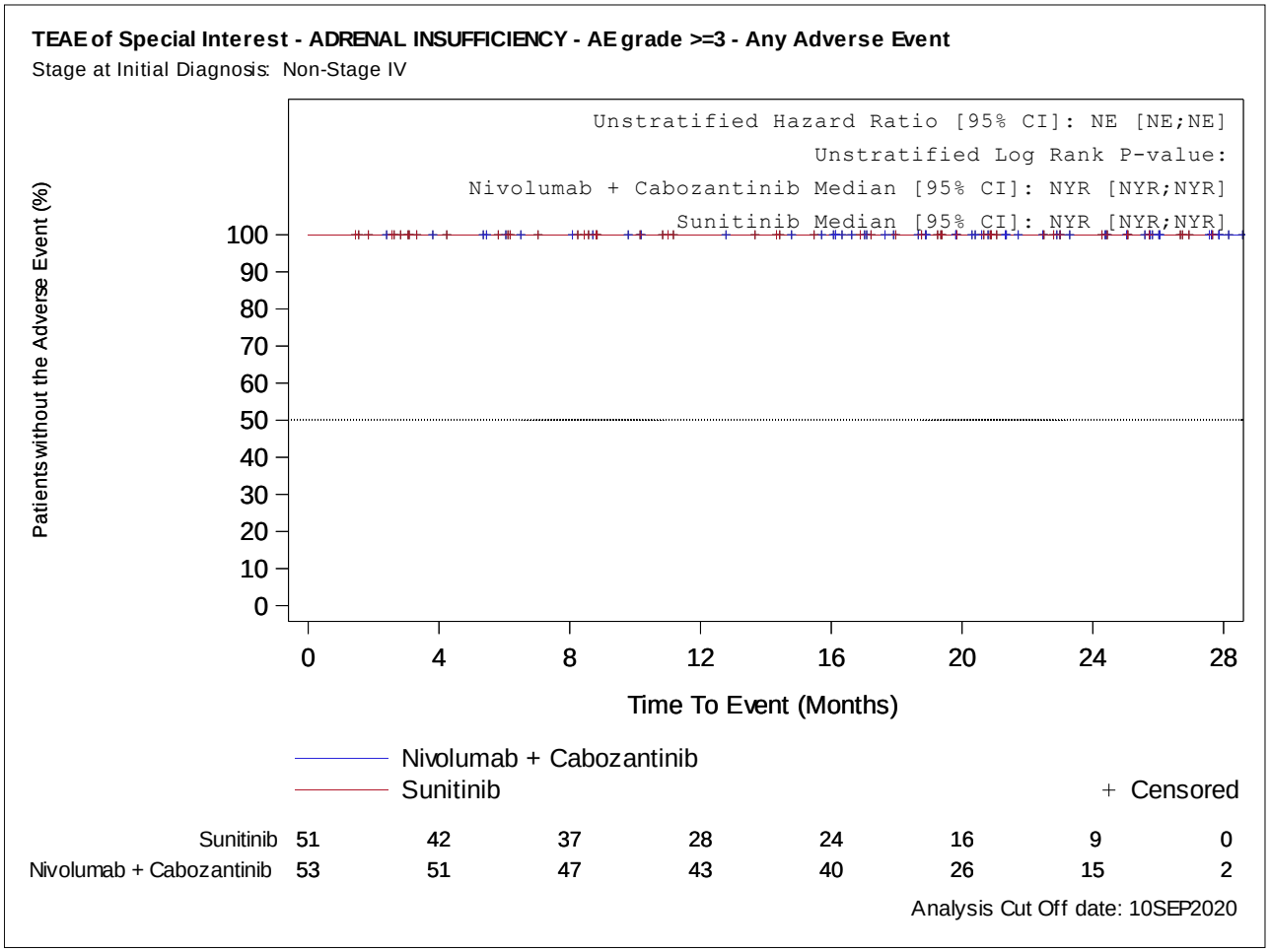

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:25:02

FIGURE 3.61.2.23: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



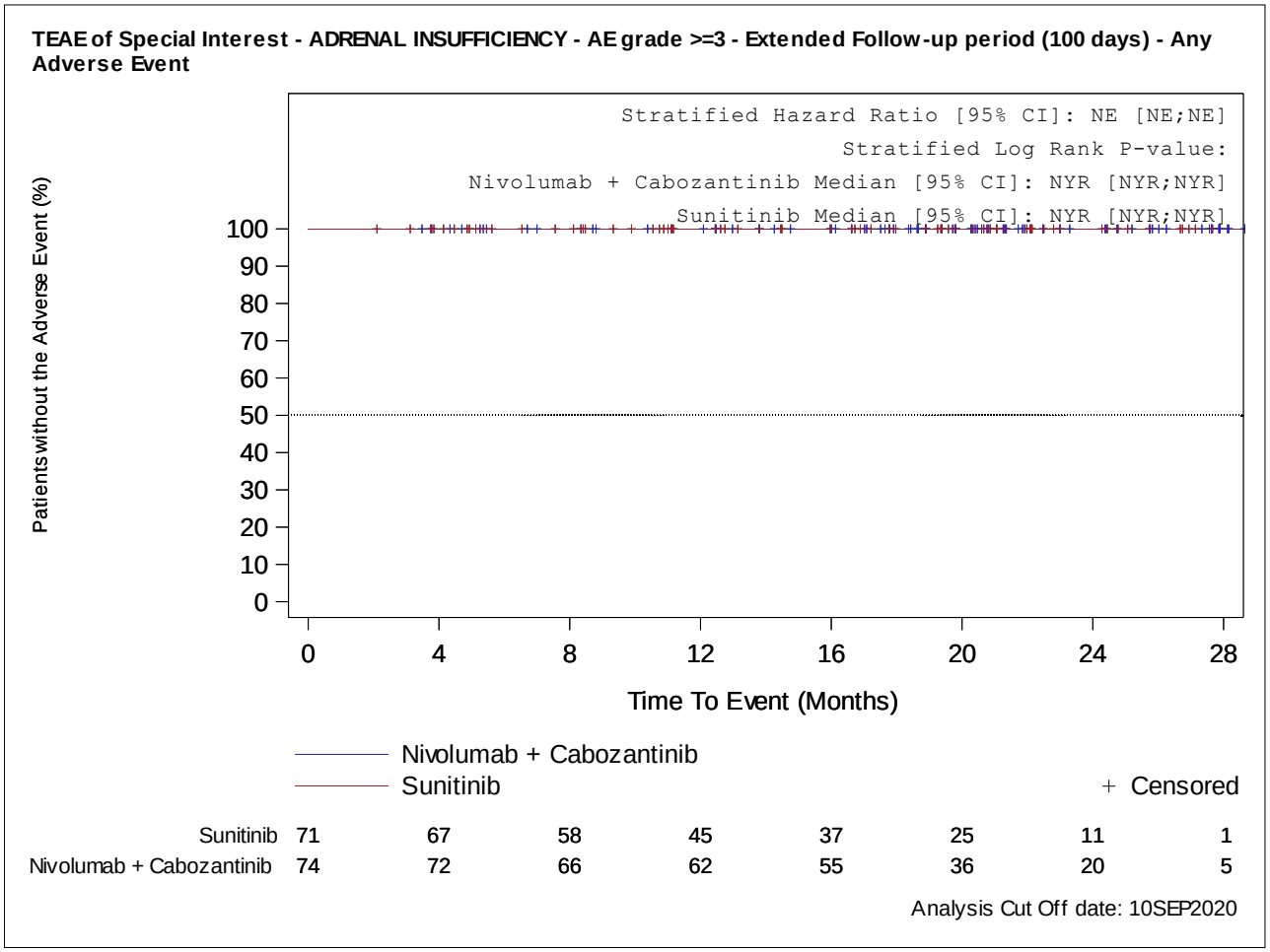

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:25:28

FIGURE 3.61.2.24: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



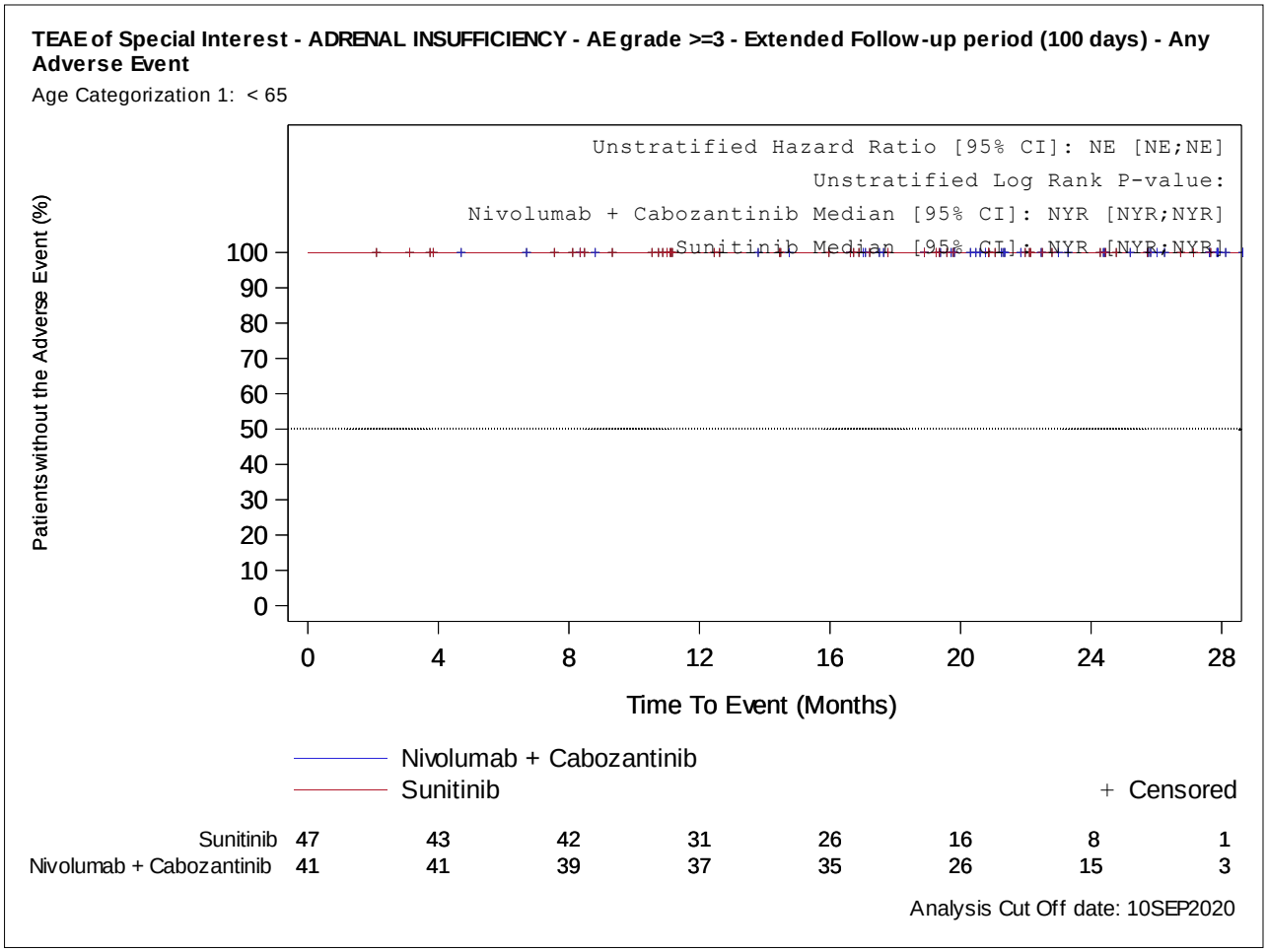

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:25:33

FIGURE 3.62.1: TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



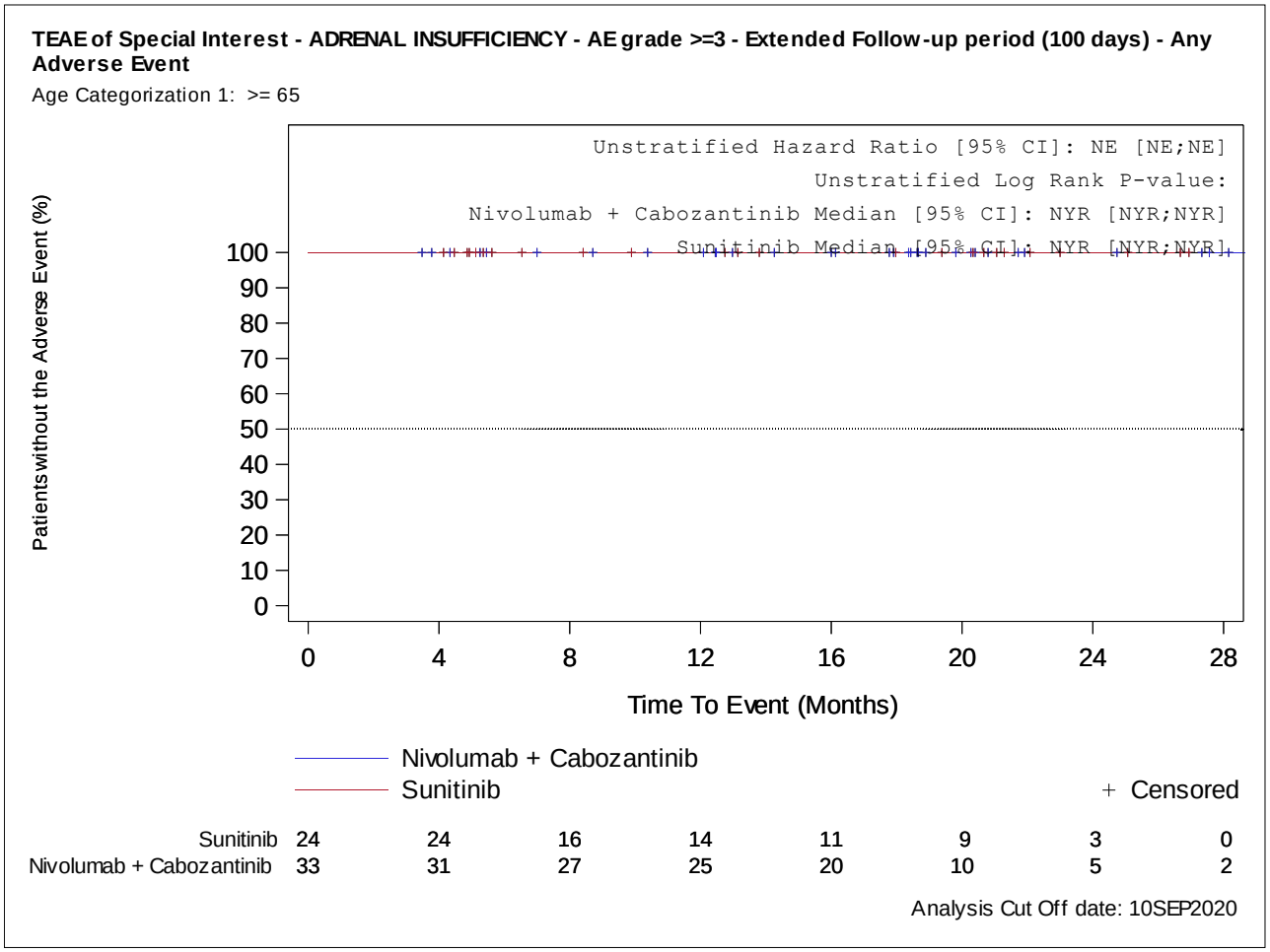

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:28:29

FIGURE 3.62.2.1: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



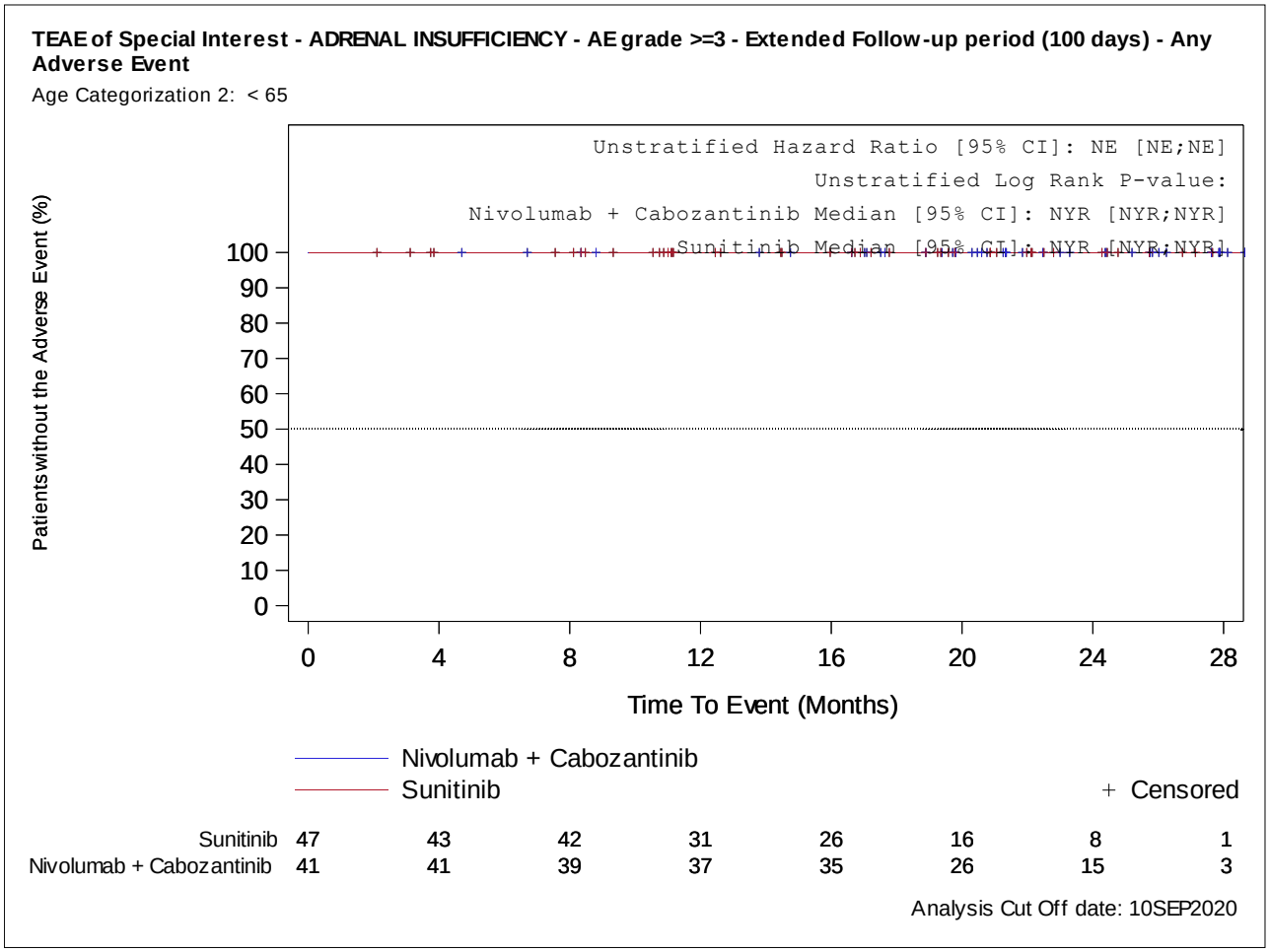

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:28:32

FIGURE 3.62.2.2: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



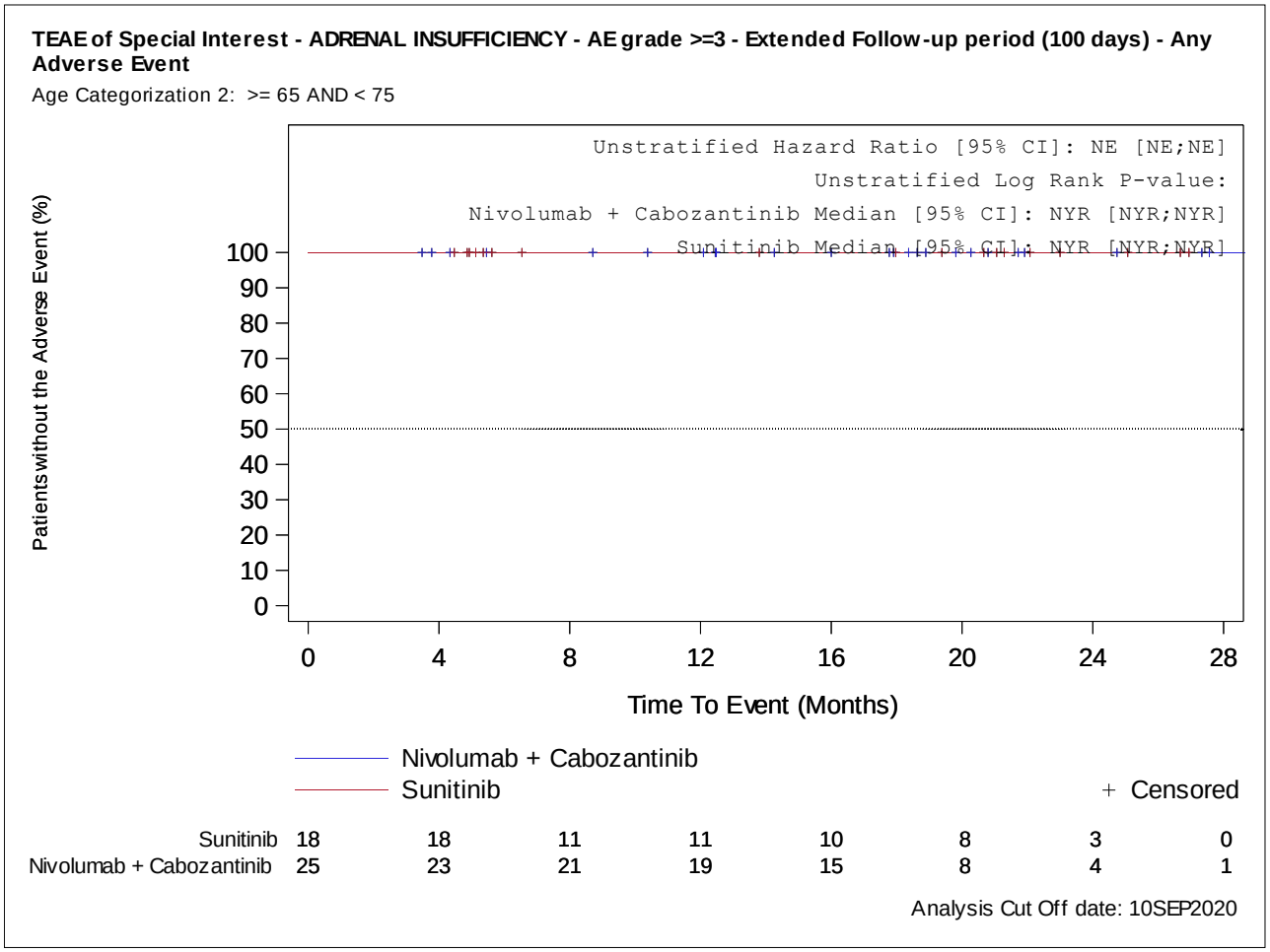

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:28:38

FIGURE 3.62.2.3: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



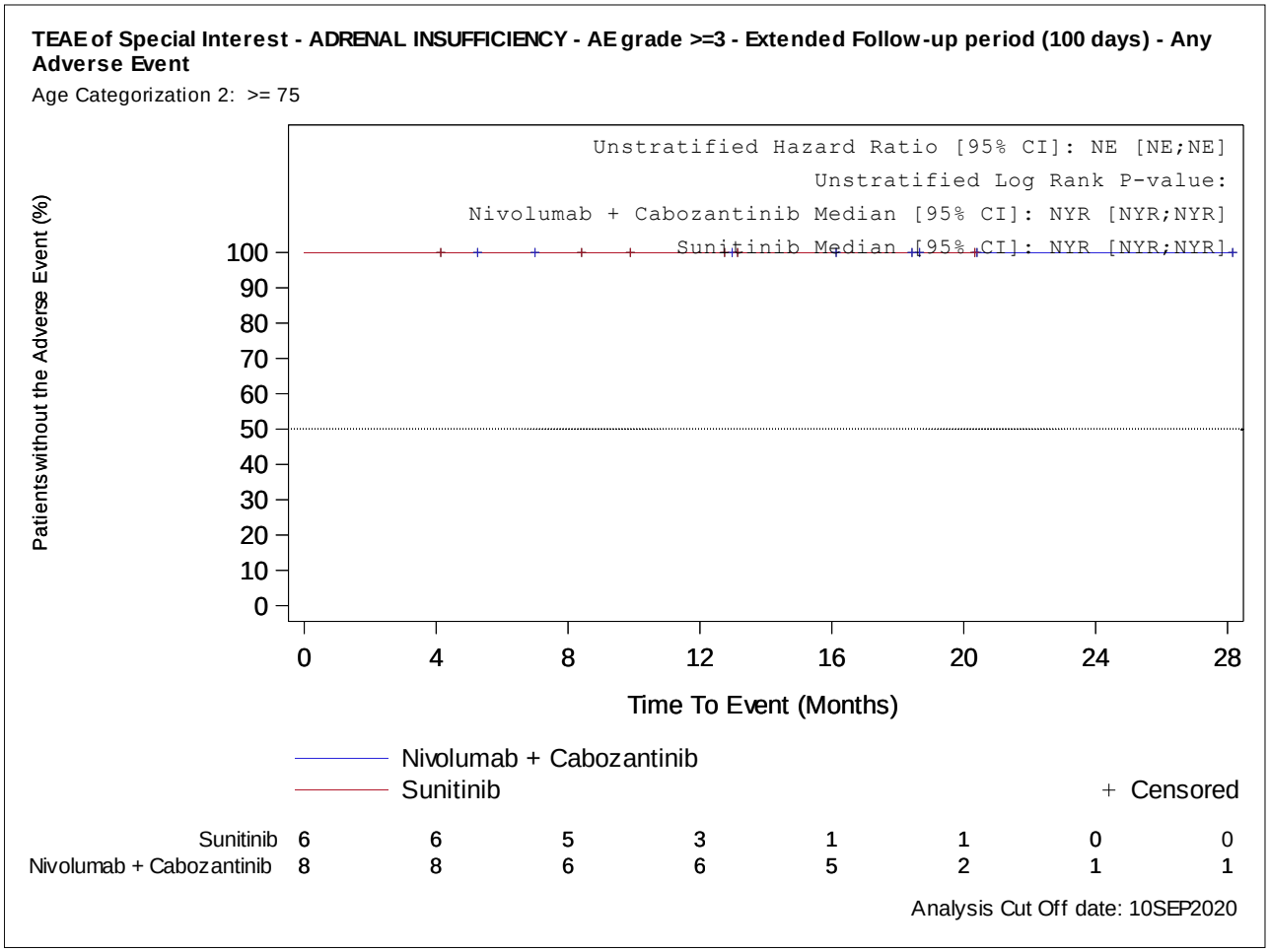

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:28:43

FIGURE 3.62.2.4: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



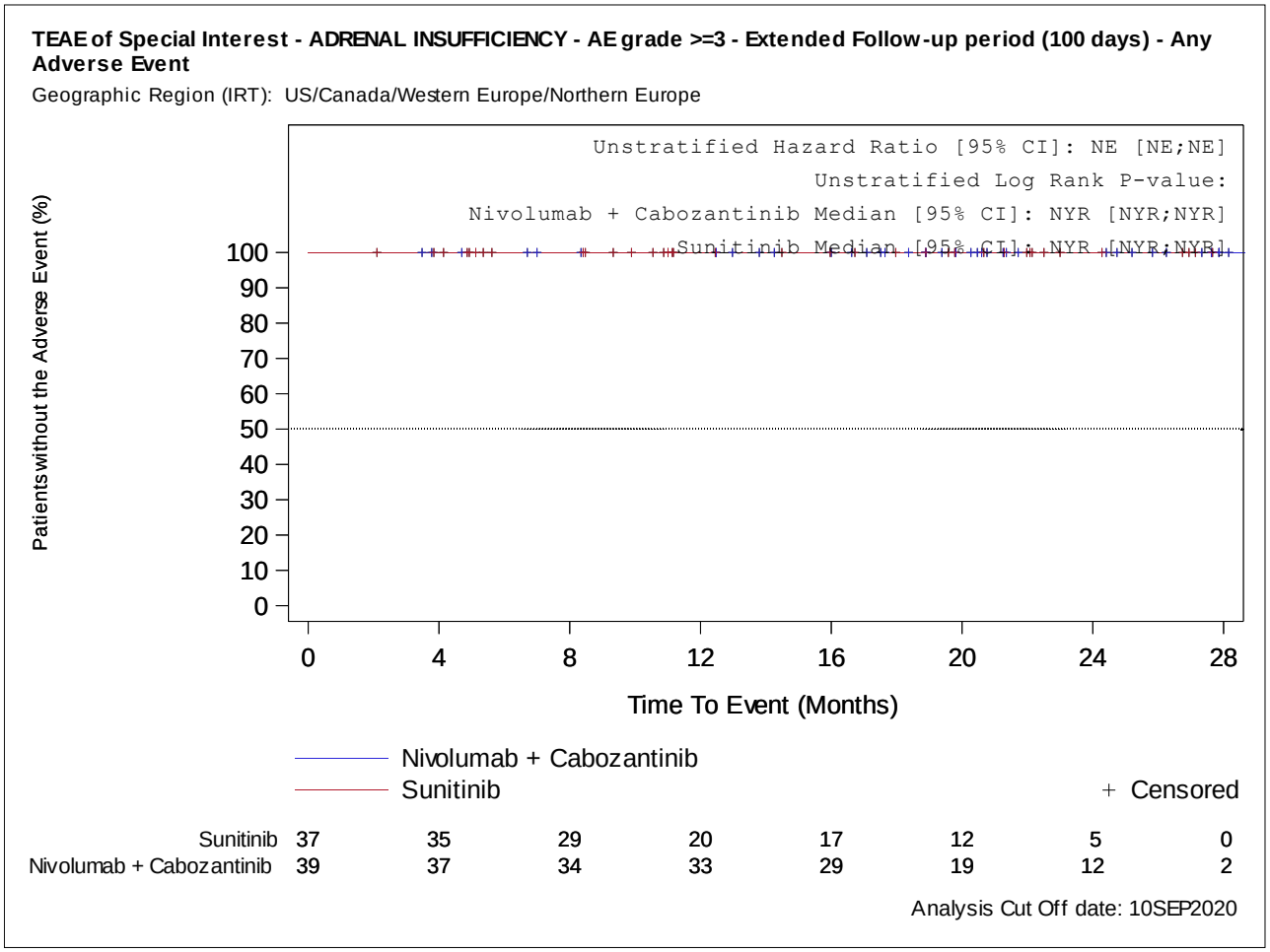

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:28:48

FIGURE 3.62.2.5: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



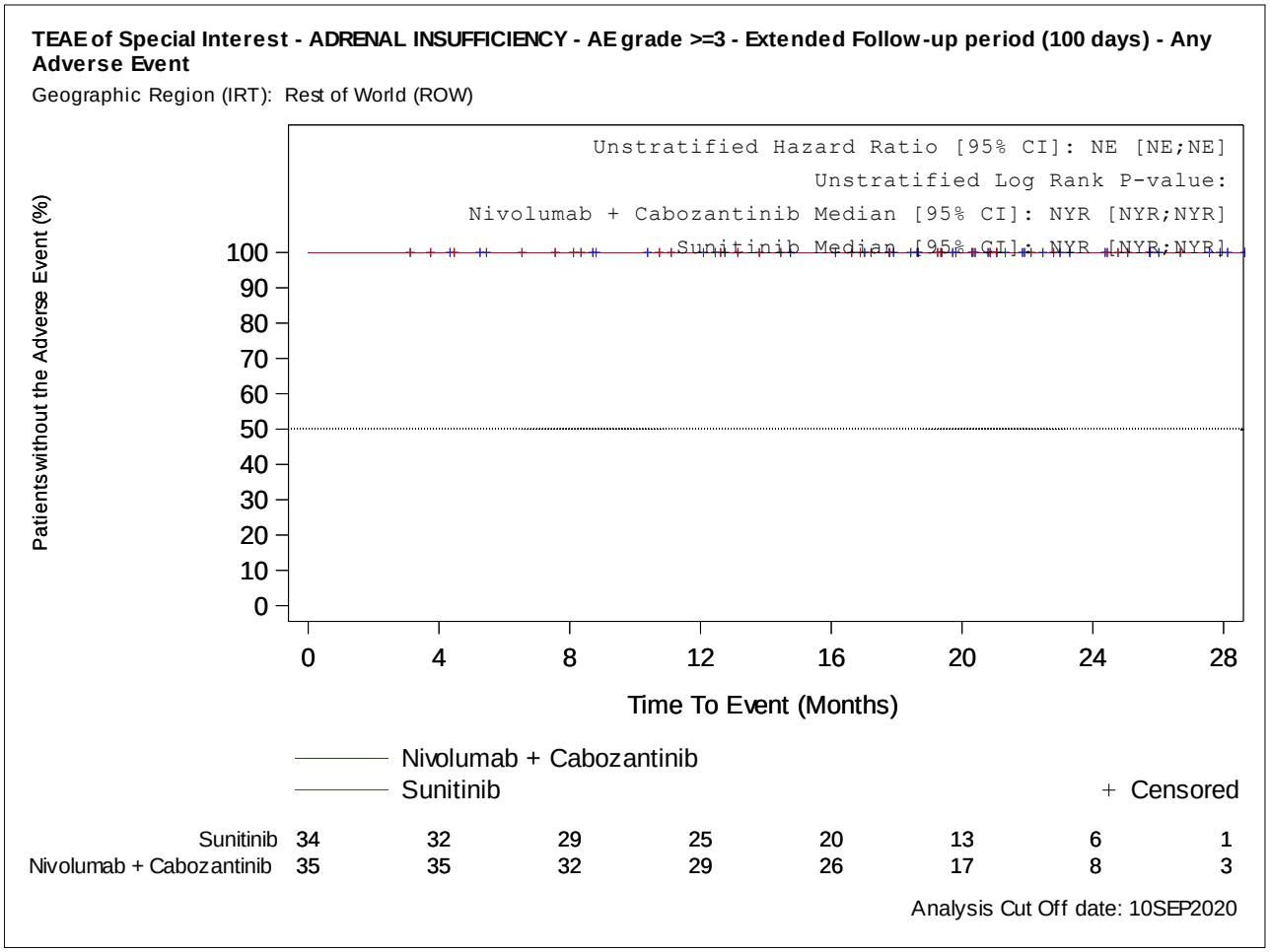

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:28:53

FIGURE 3.62.2.6: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



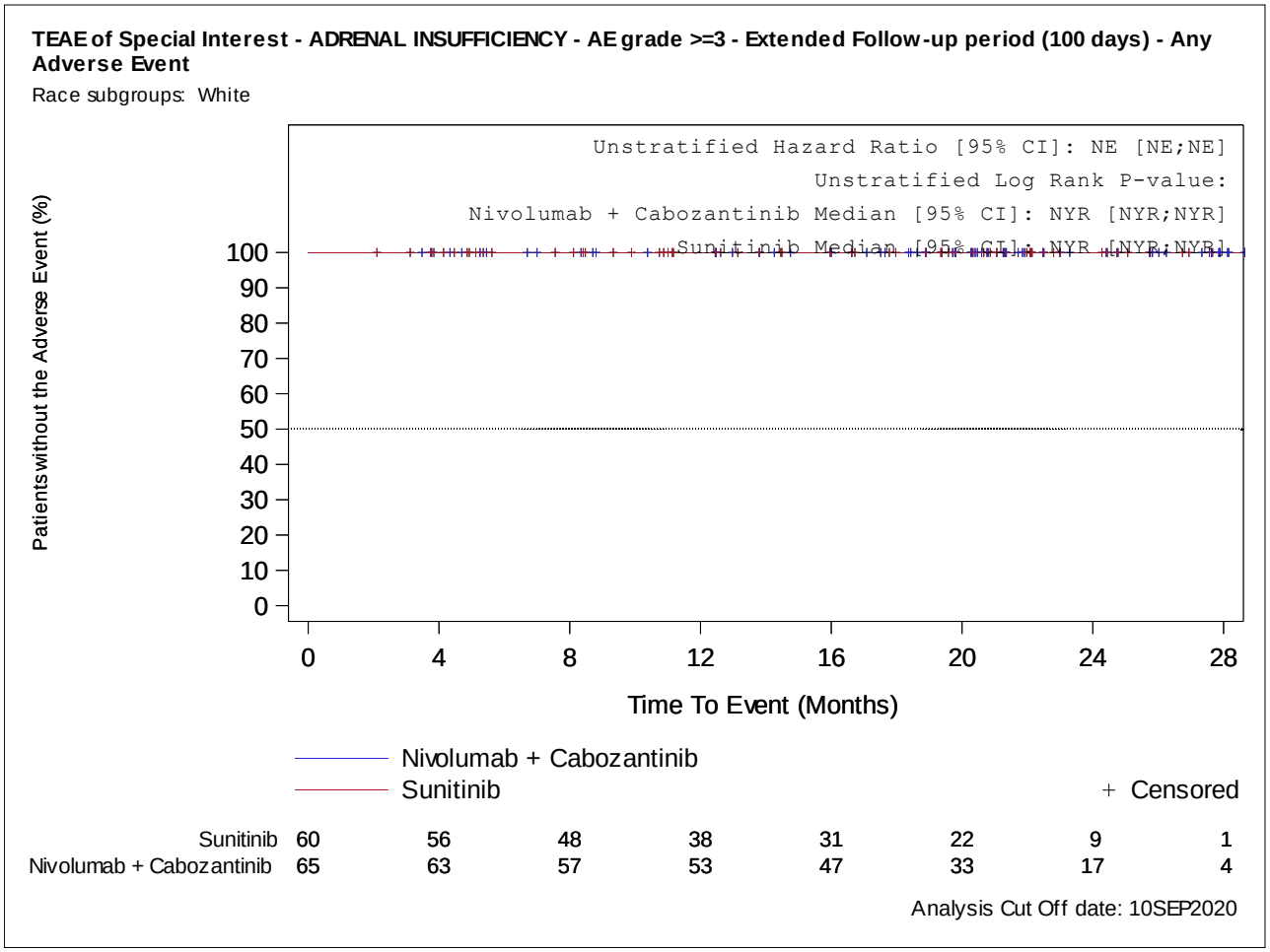

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:28:58

FIGURE 3.62.2.7: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



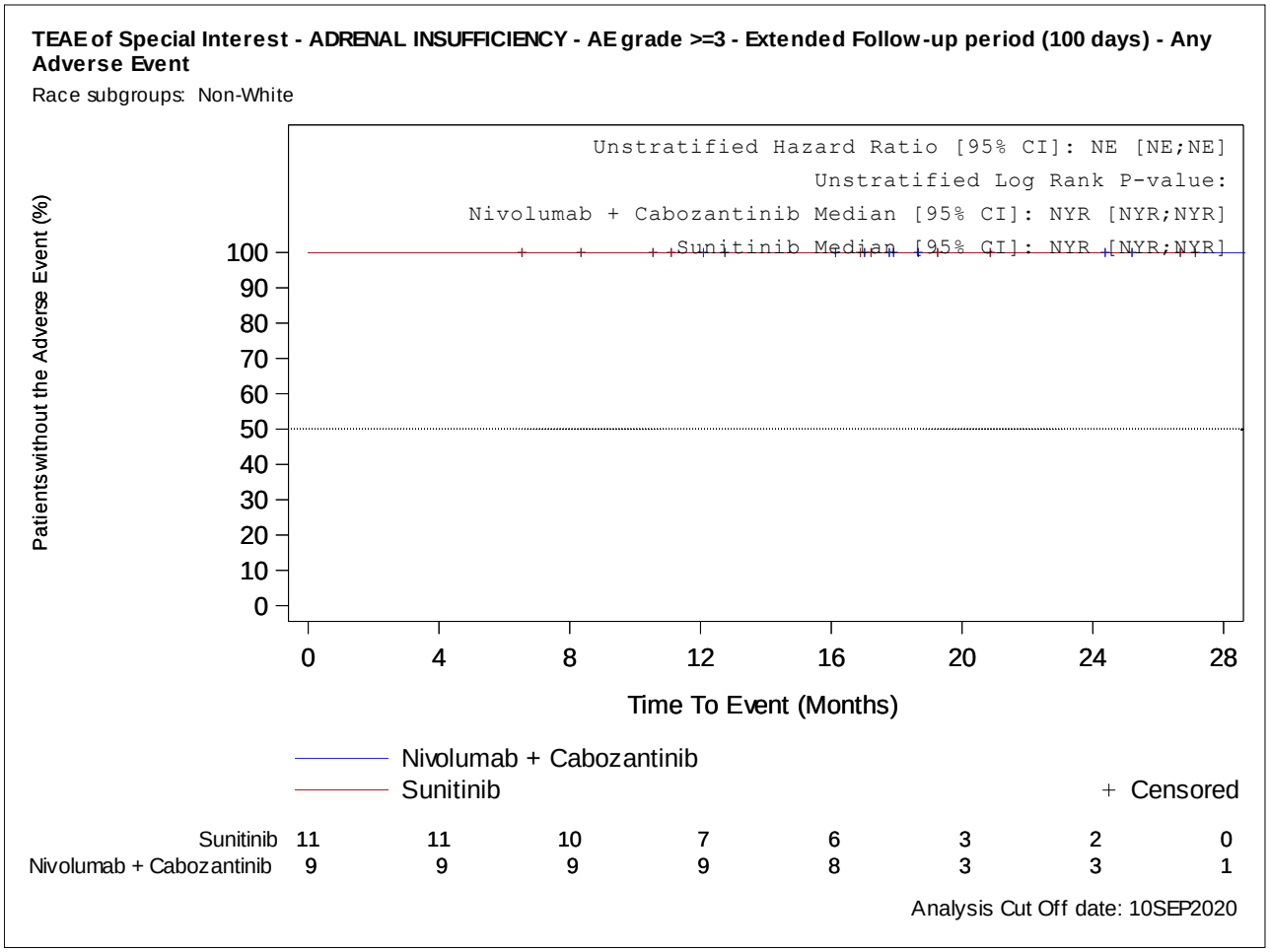

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:29:03

FIGURE 3.62.2.8: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



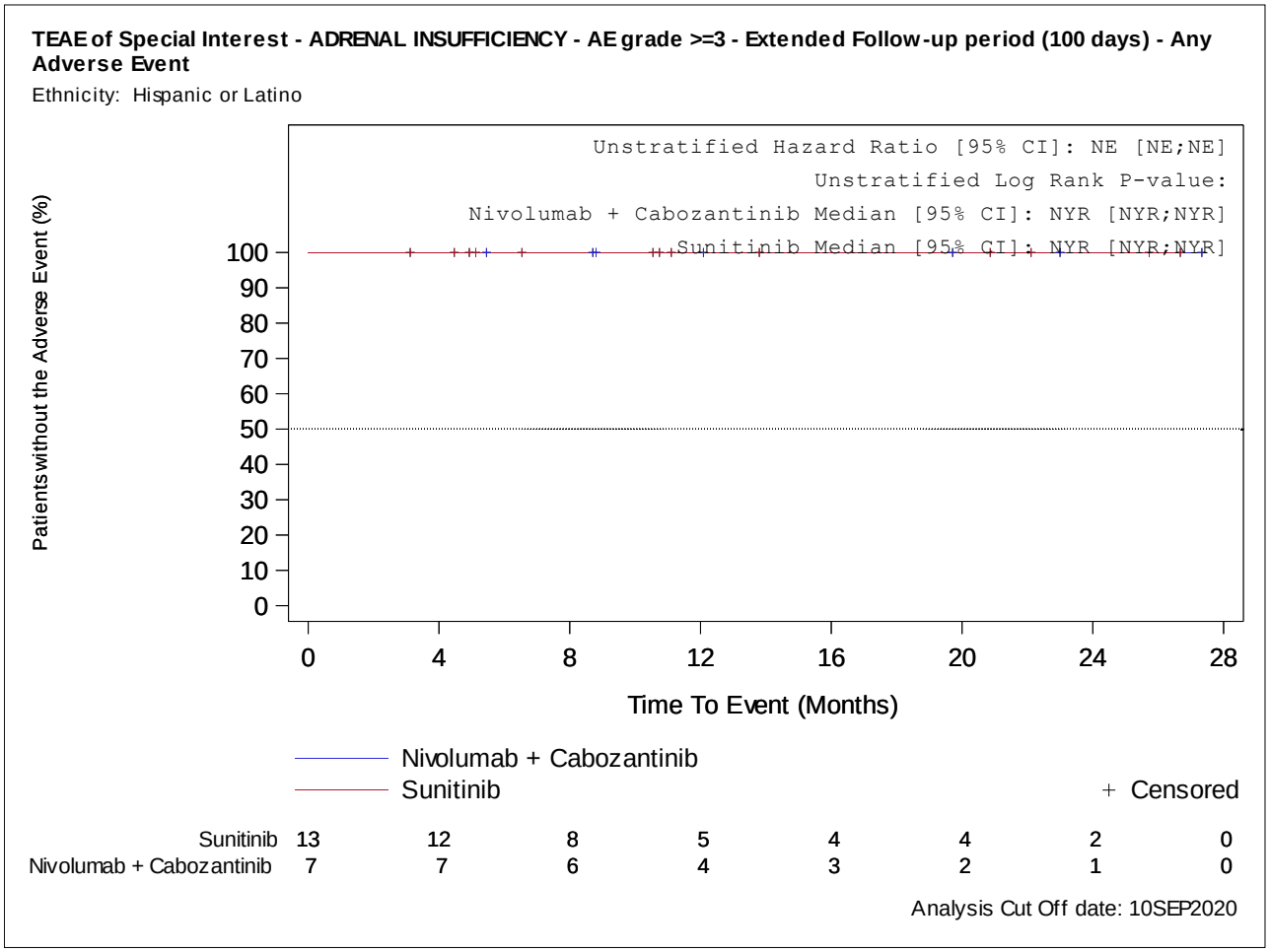

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:29:08

FIGURE 3.62.2.9: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



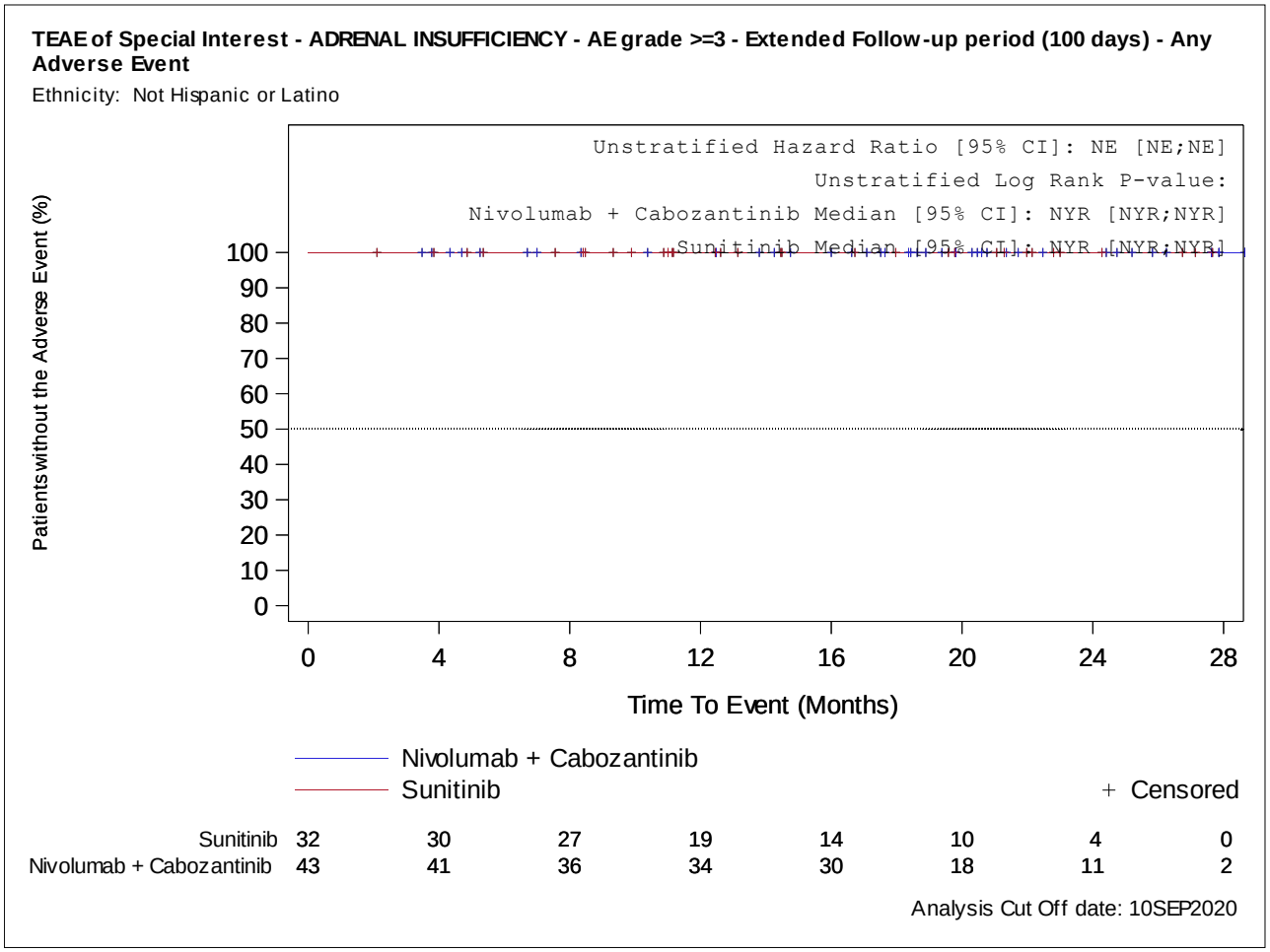

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:29:13

FIGURE 3.62.2.10: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity:  Hispanic or Latino



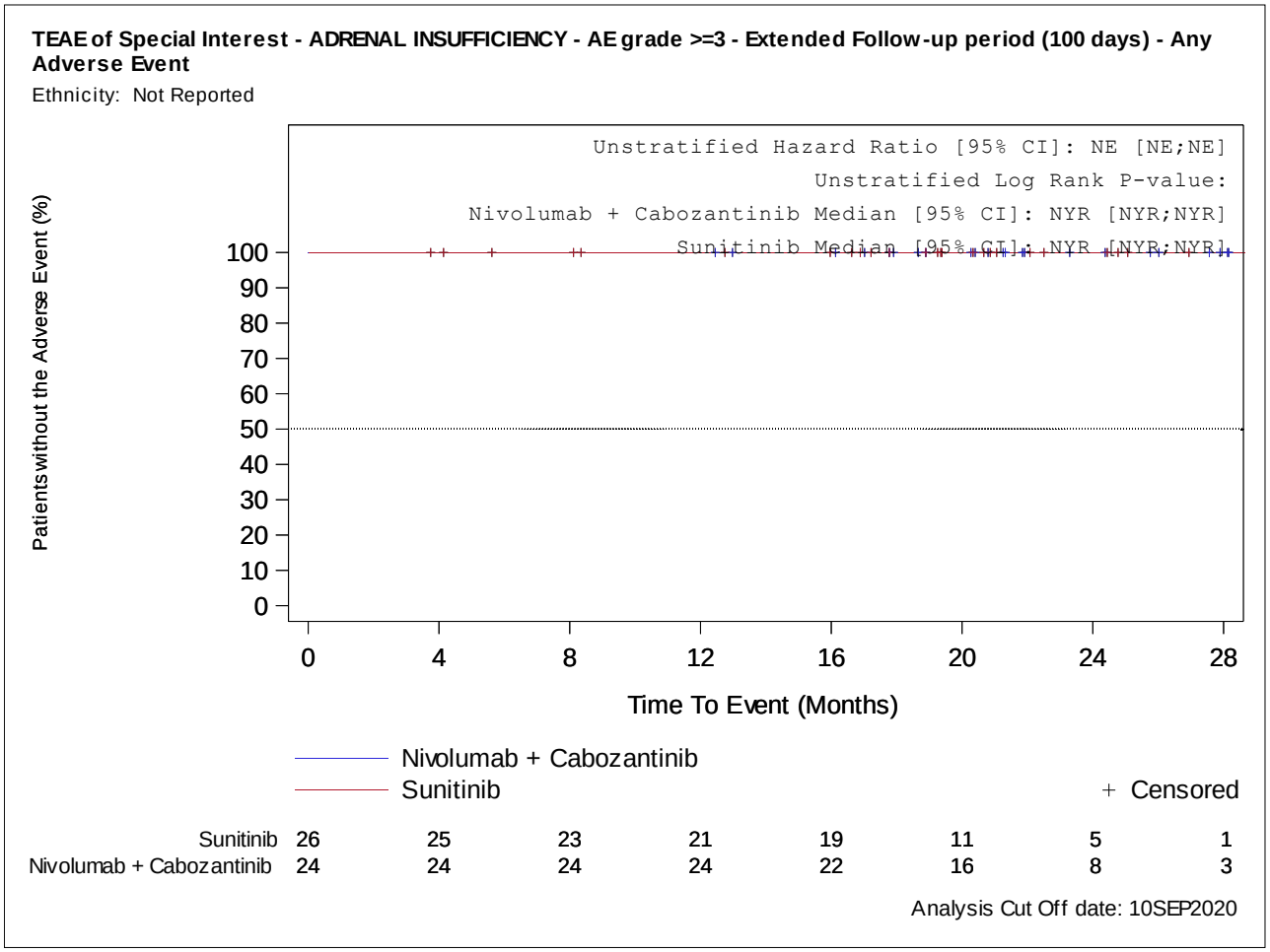

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:29:18

FIGURE 3.62.2.11: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



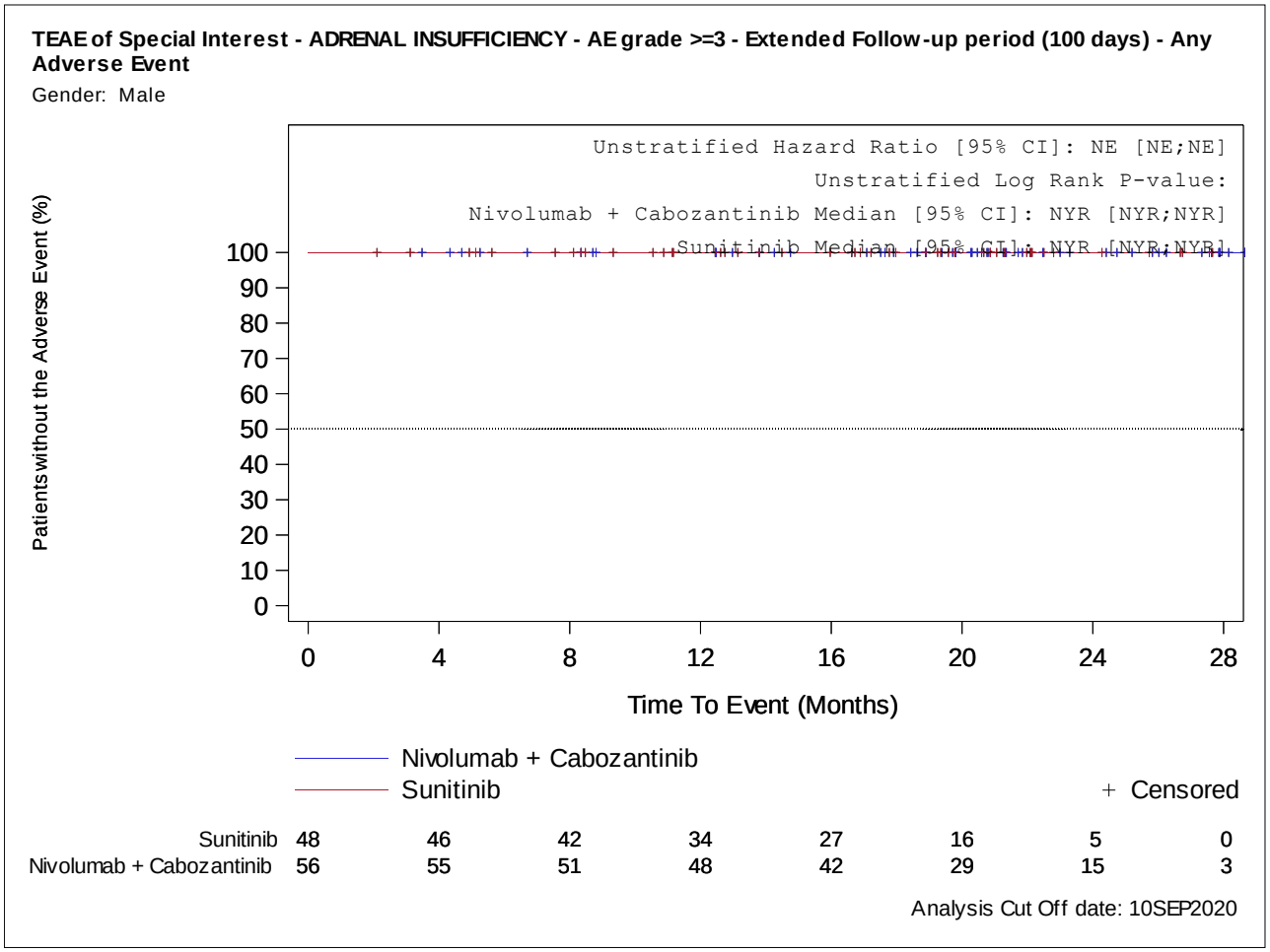

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:29:23

FIGURE 3.62.2.12: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



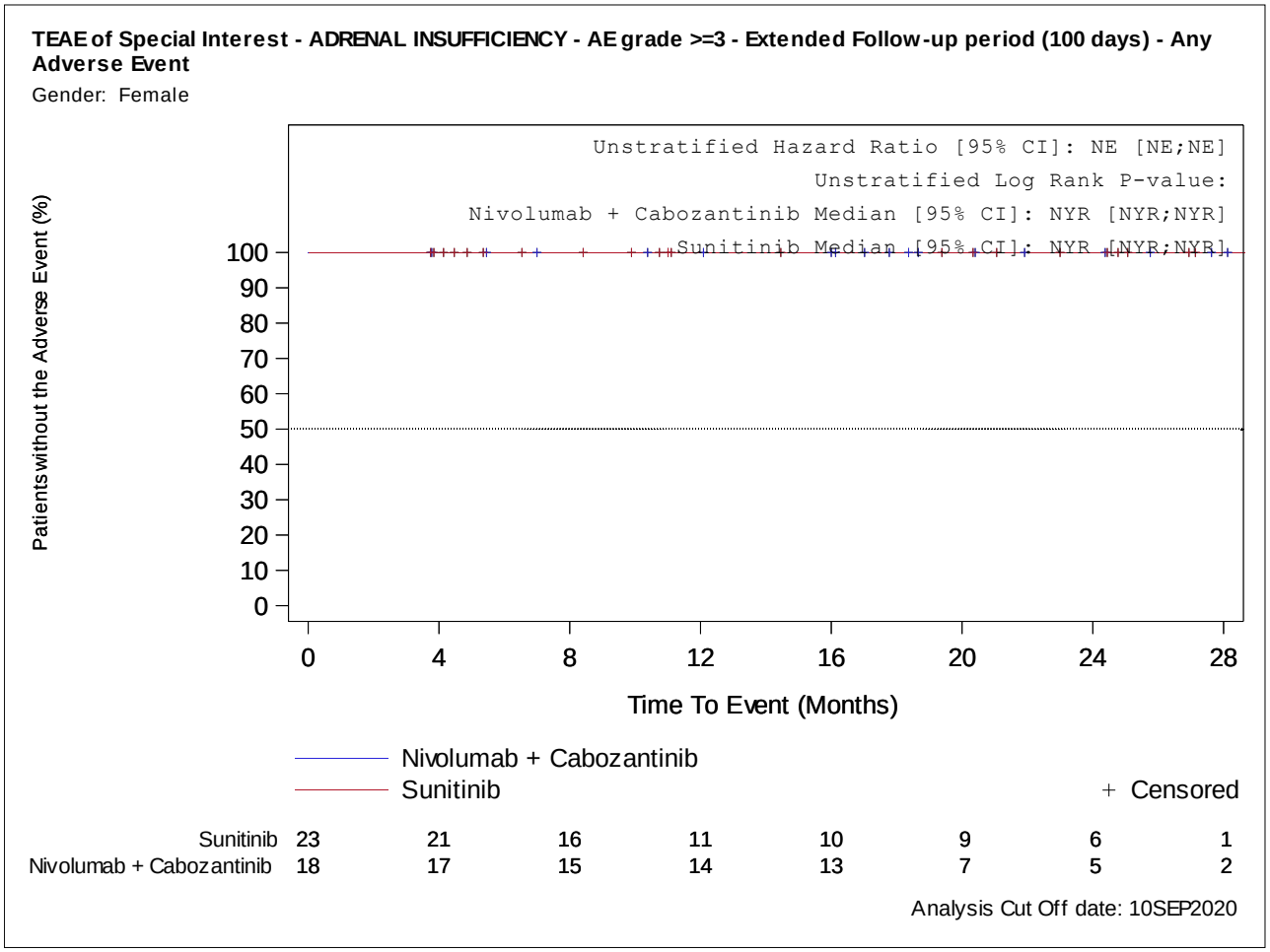

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:29:28

FIGURE 3.62.2.13: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



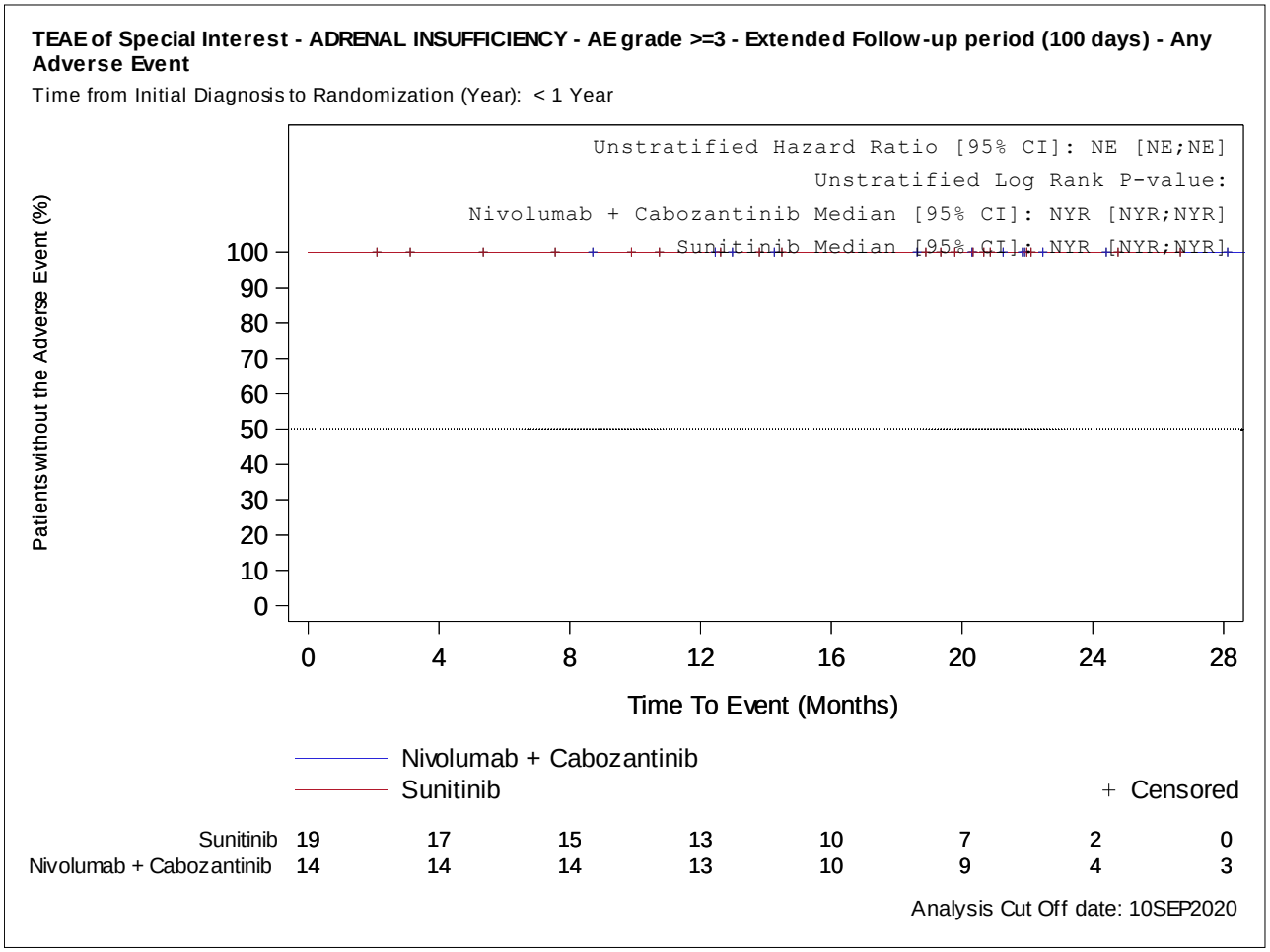

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:29:34

FIGURE 3.62.2.14: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:29:40

FIGURE 3.62.2.15: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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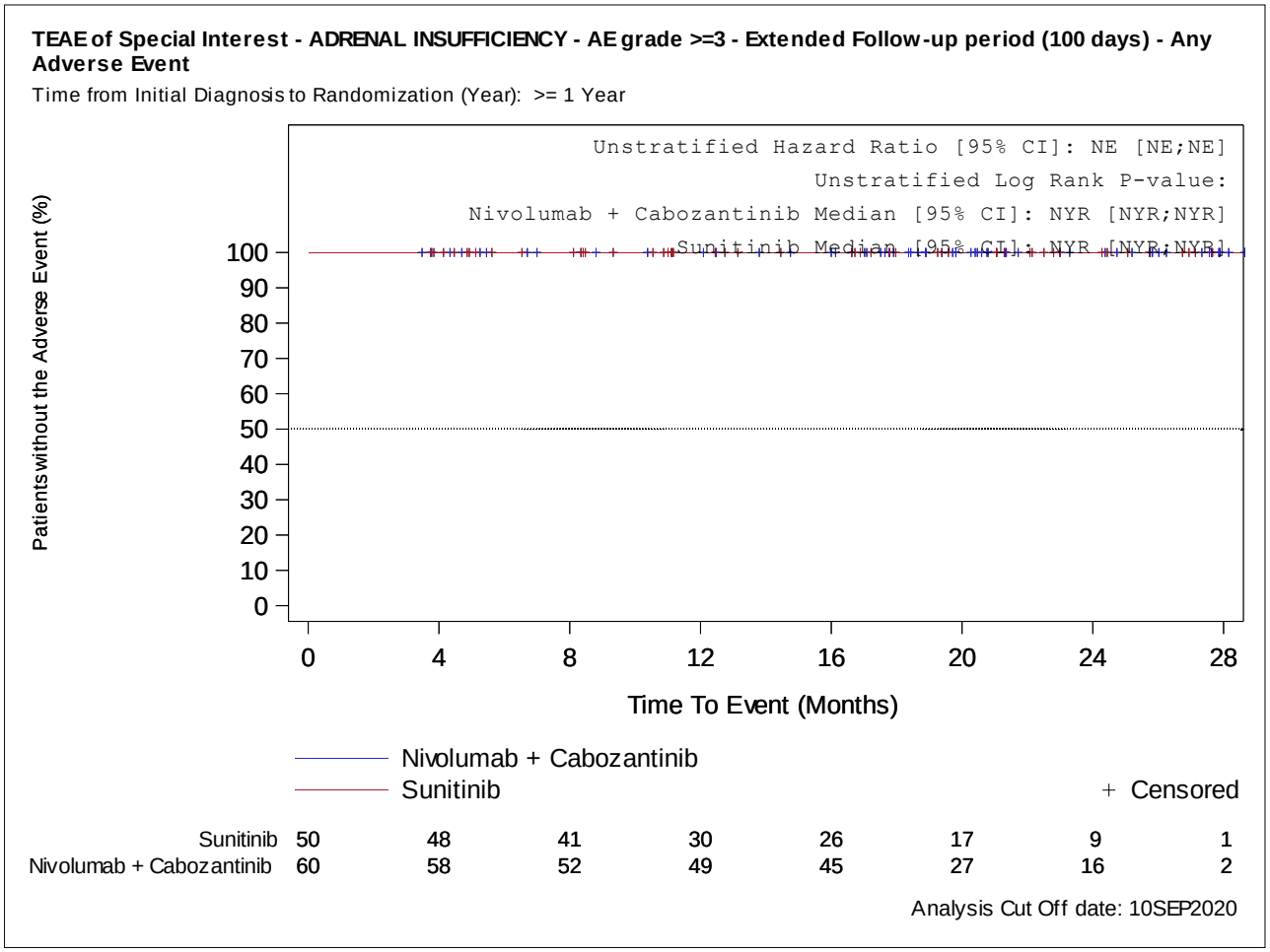
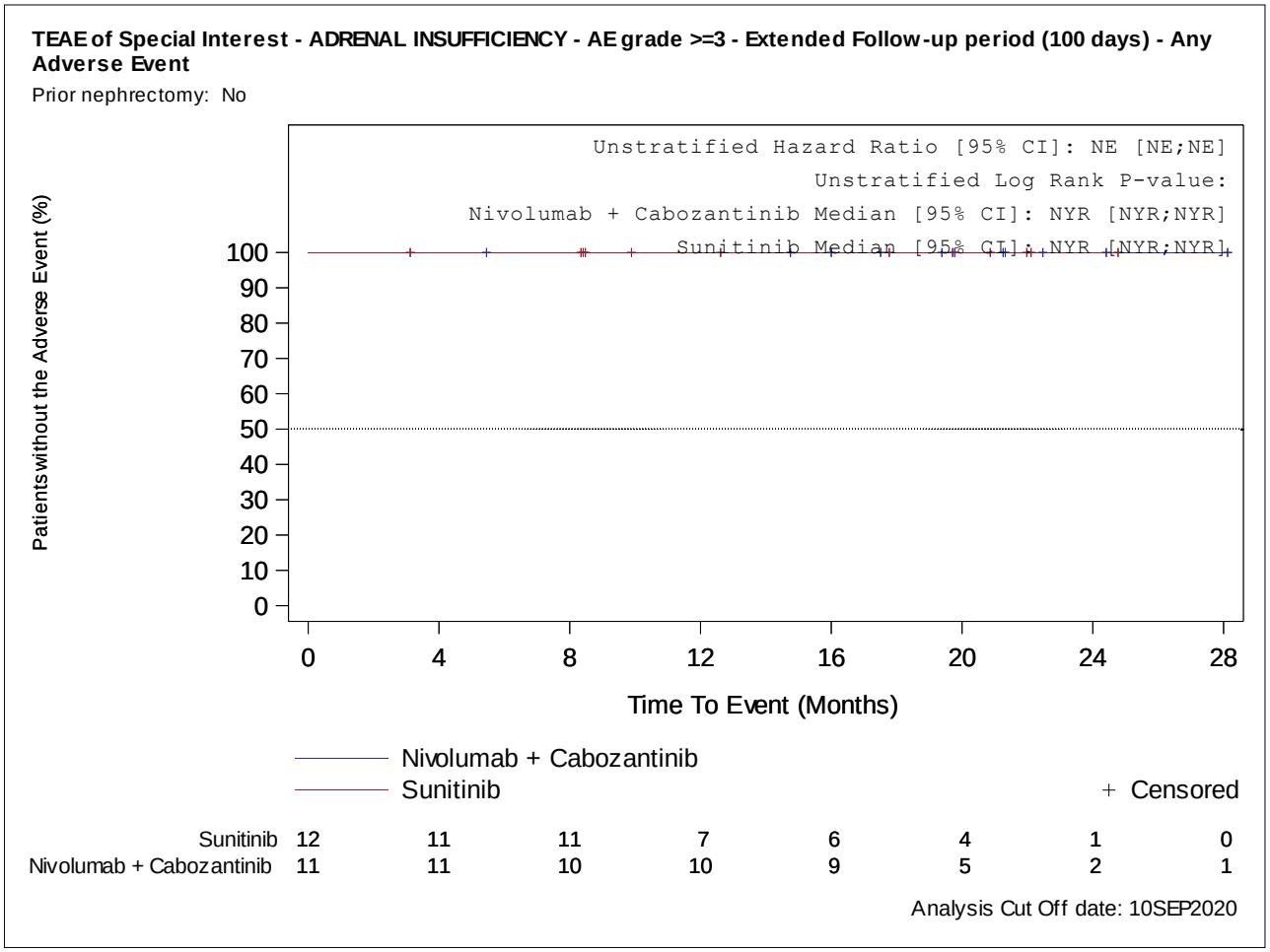
FIGURE 3.62.2.16: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:30:00

FIGURE 3.62.2.17: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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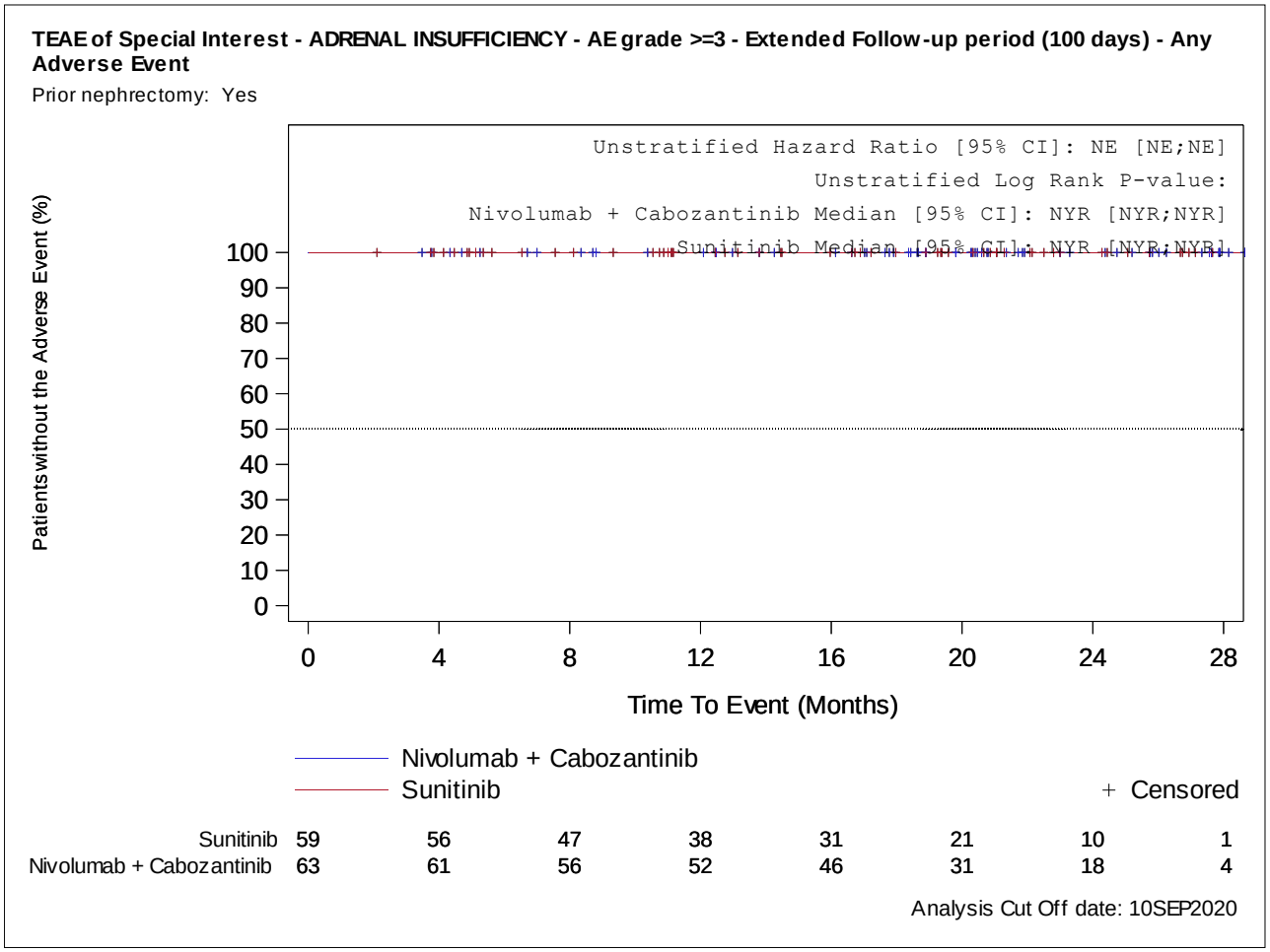
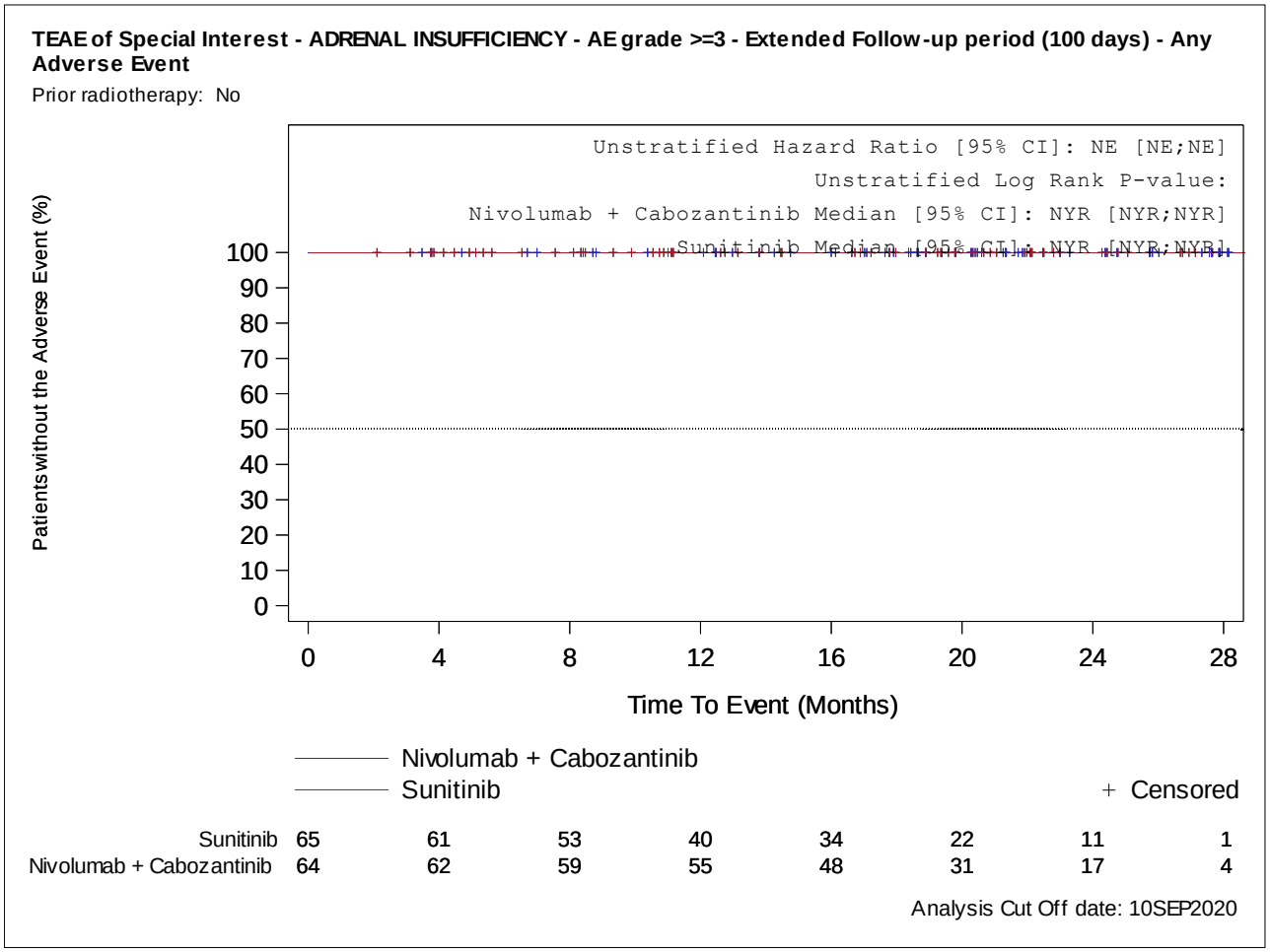
FIGURE 3.62.2.18: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy:  Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:30:53

FIGURE 3.62.2.19: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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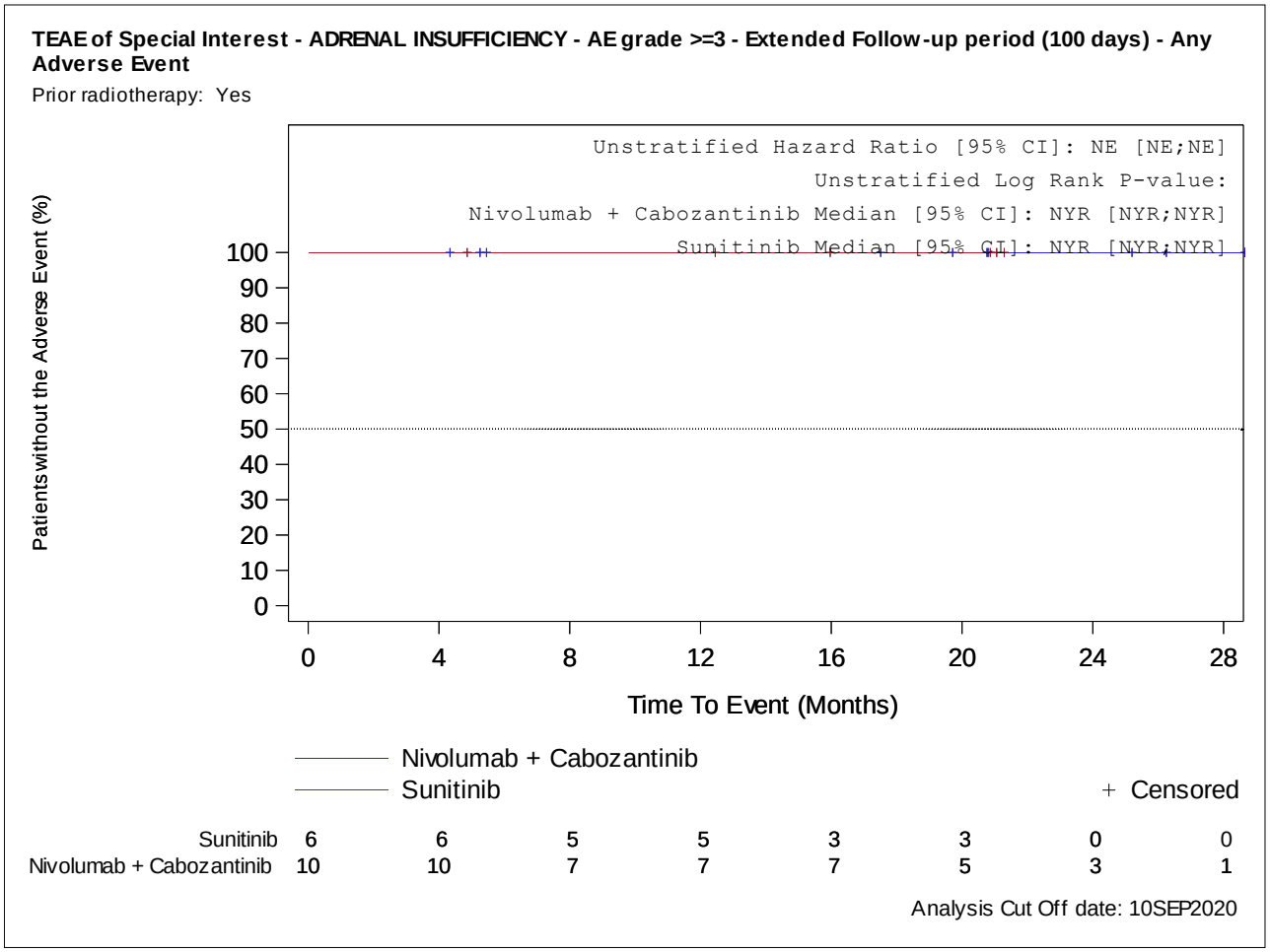
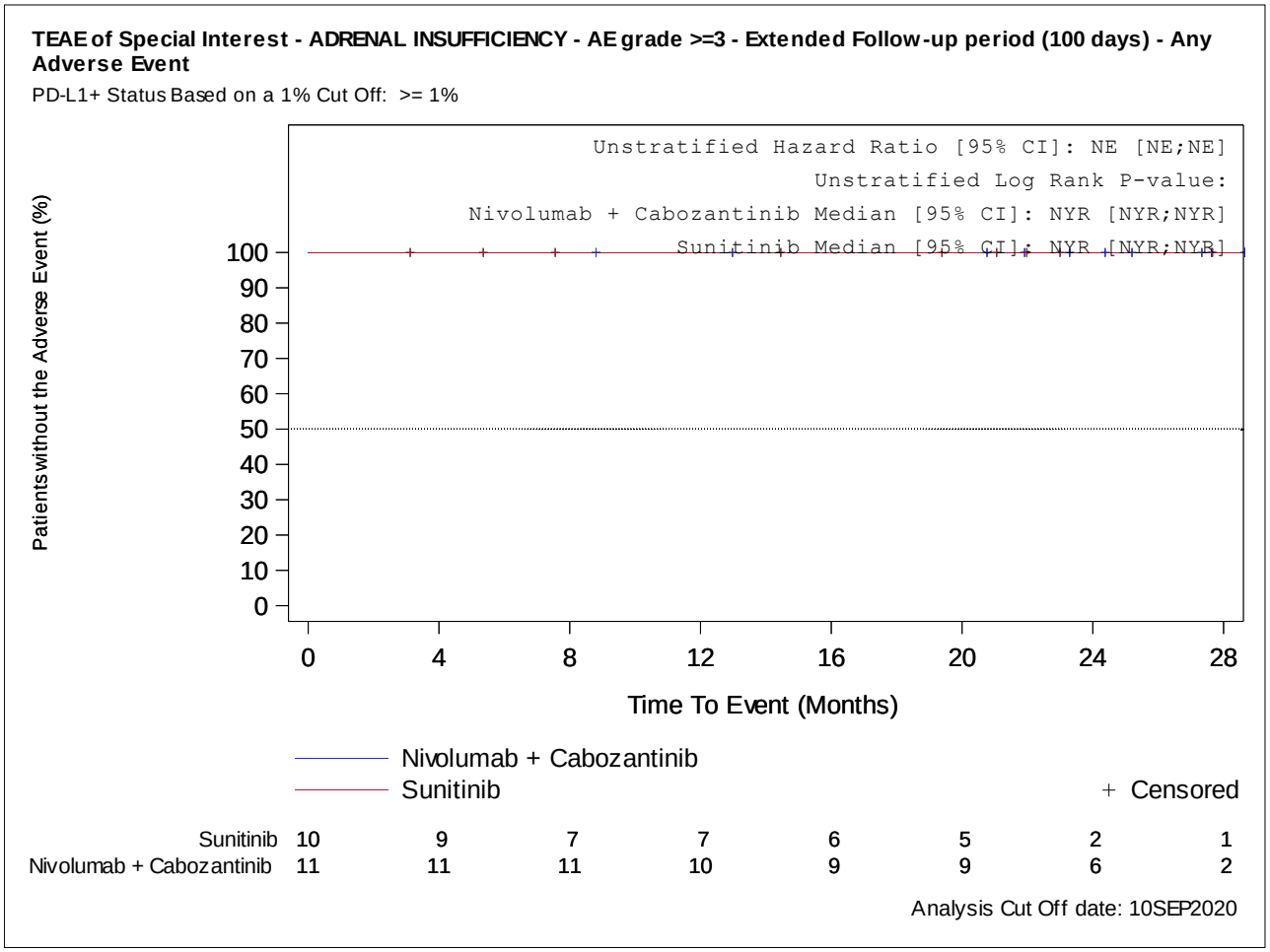
FIGURE 3.62.2.20: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:31:03

FIGURE 3.62.2.21: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off:  >= 1%




Analysis Cut Off date: 10SEP2020
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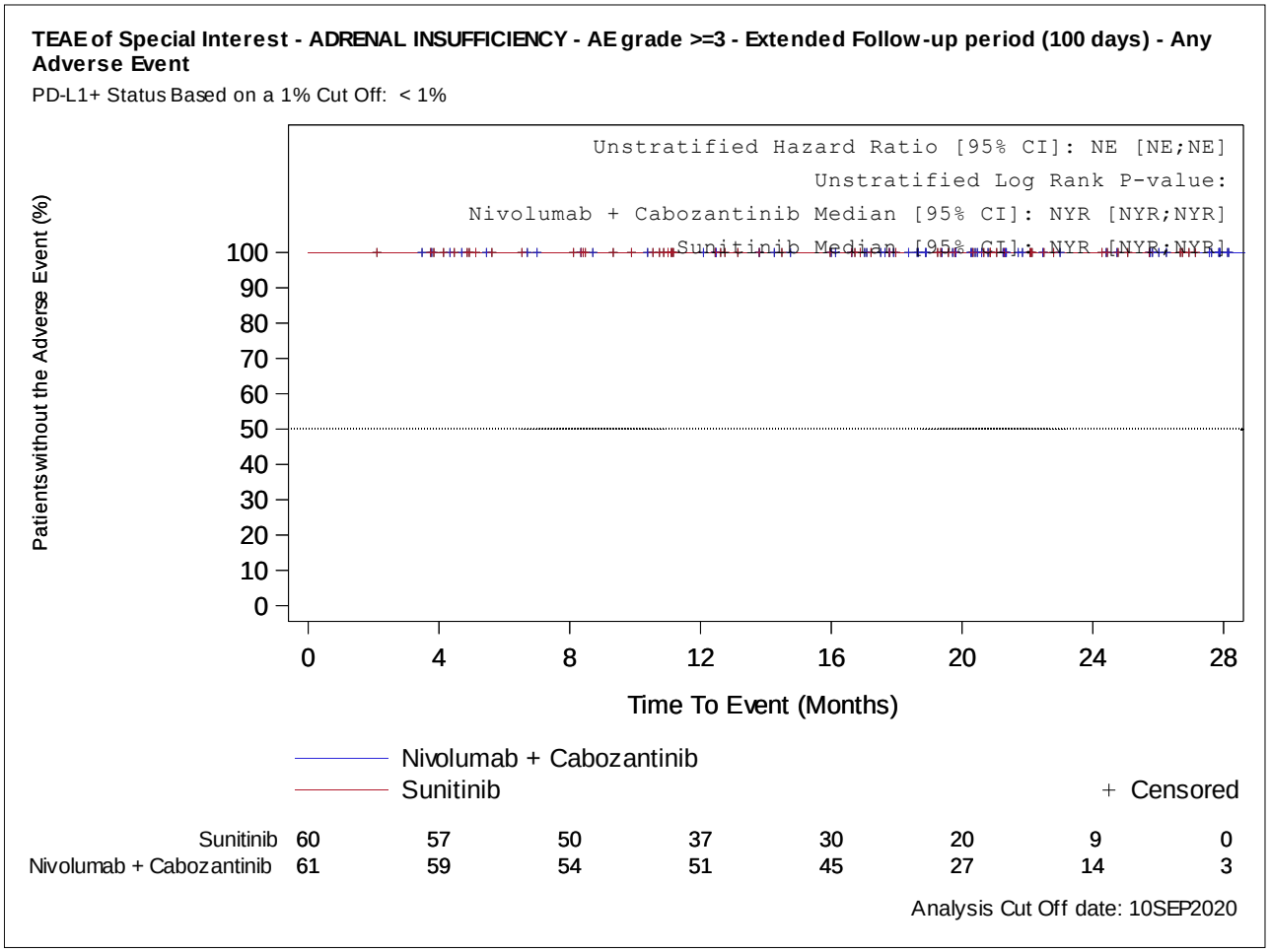
FIGURE 3.62.2.22: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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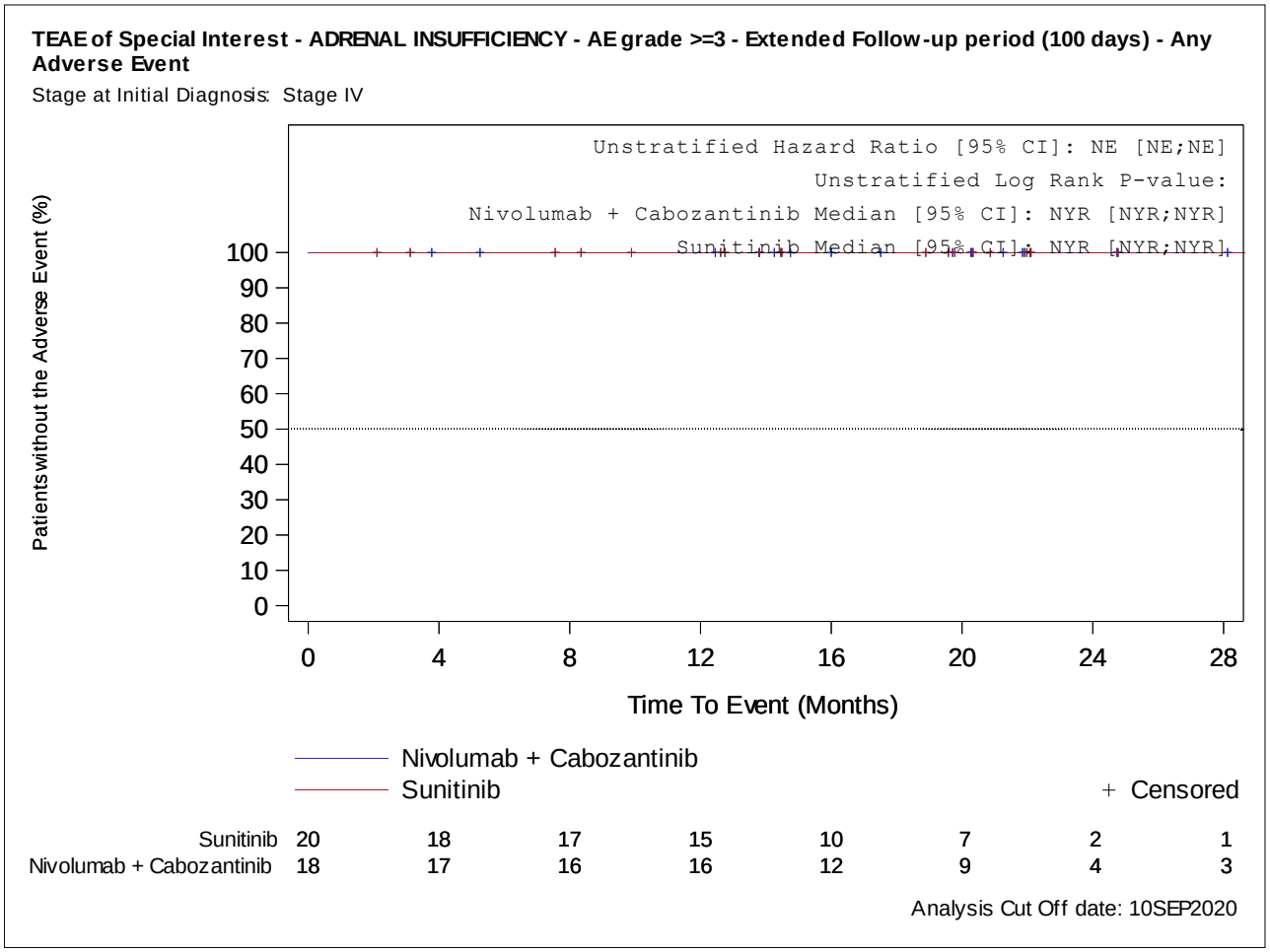
FIGURE 3.62.2.23: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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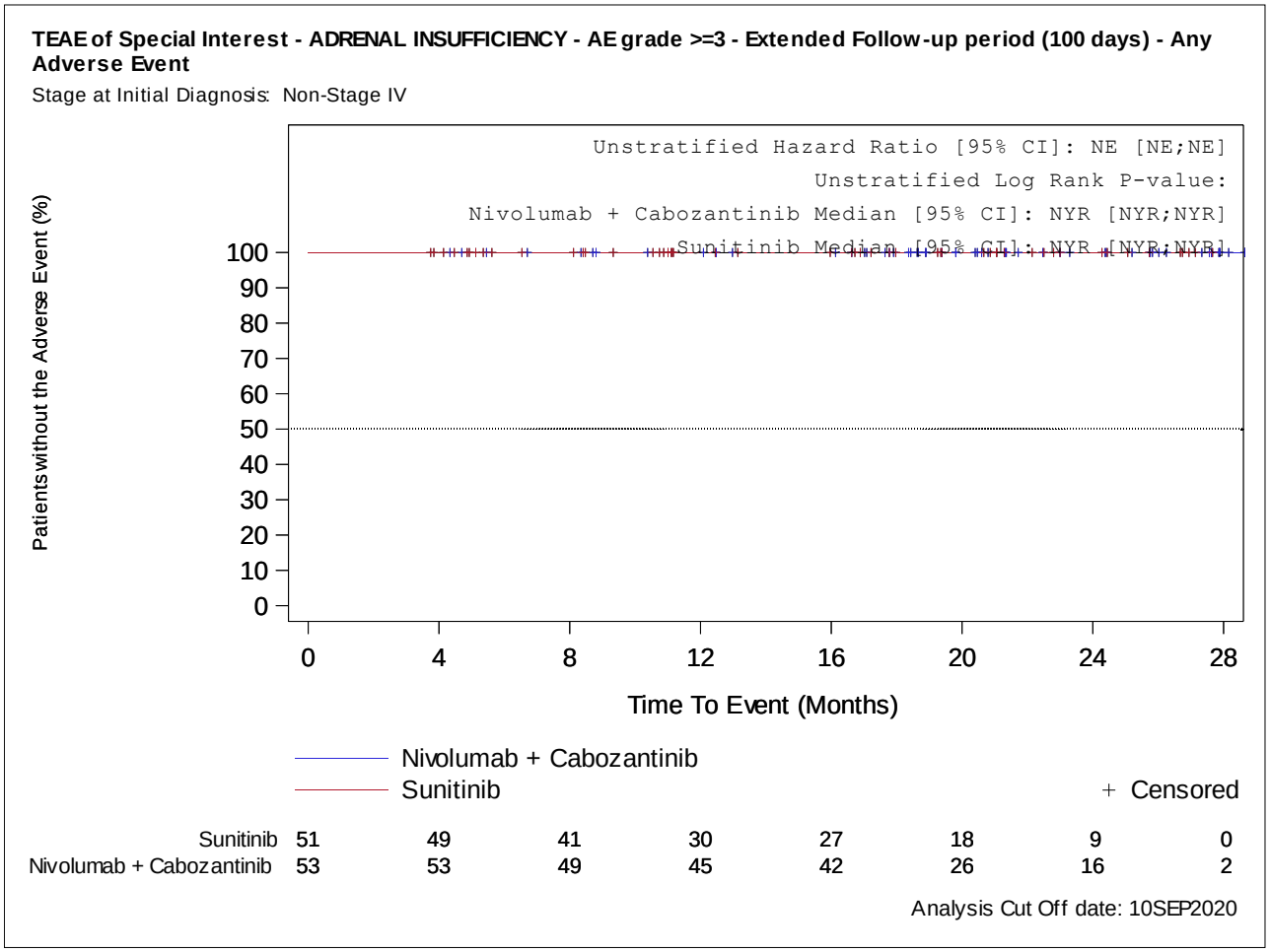
FIGURE 3.62.2.24: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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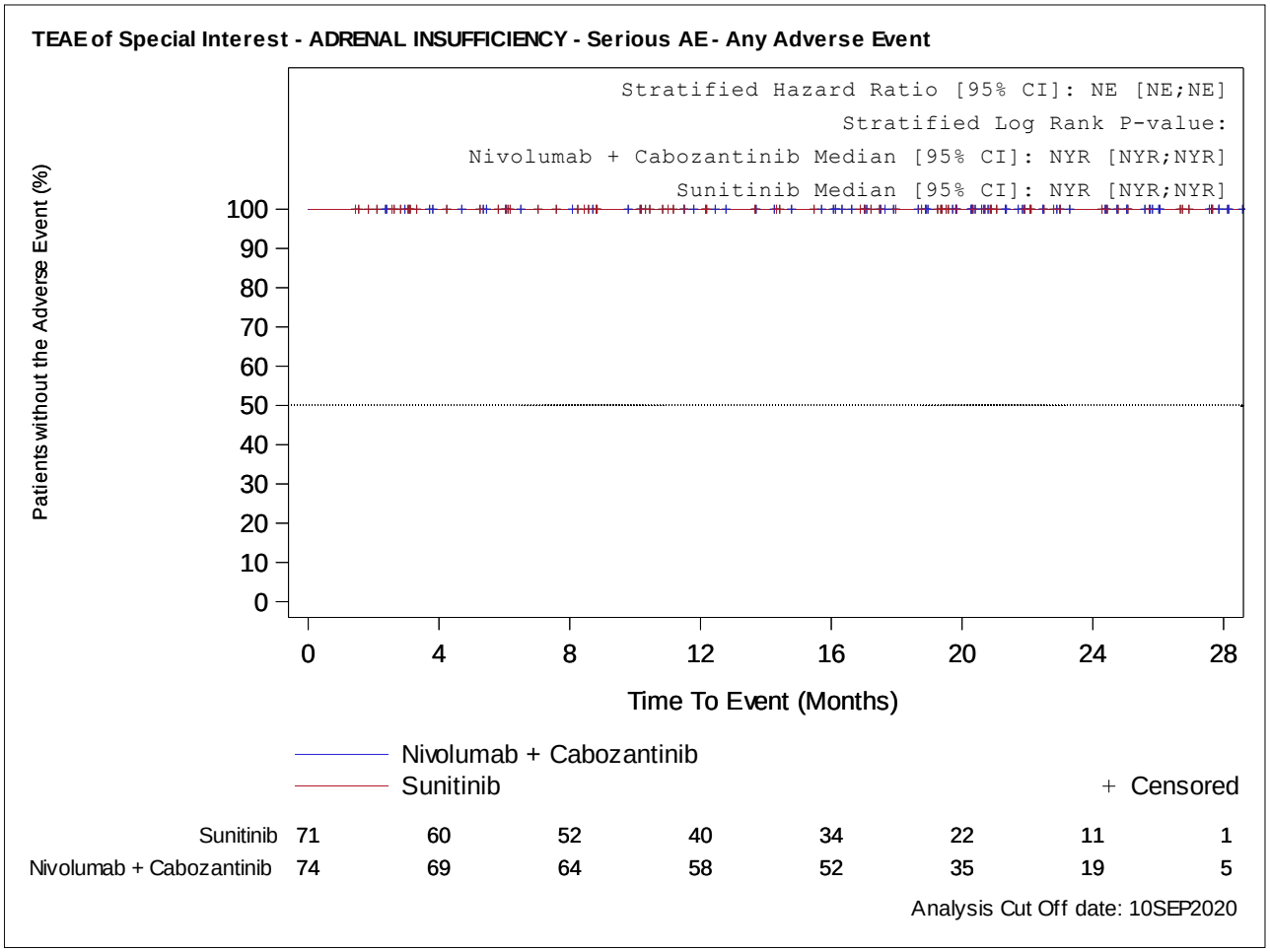
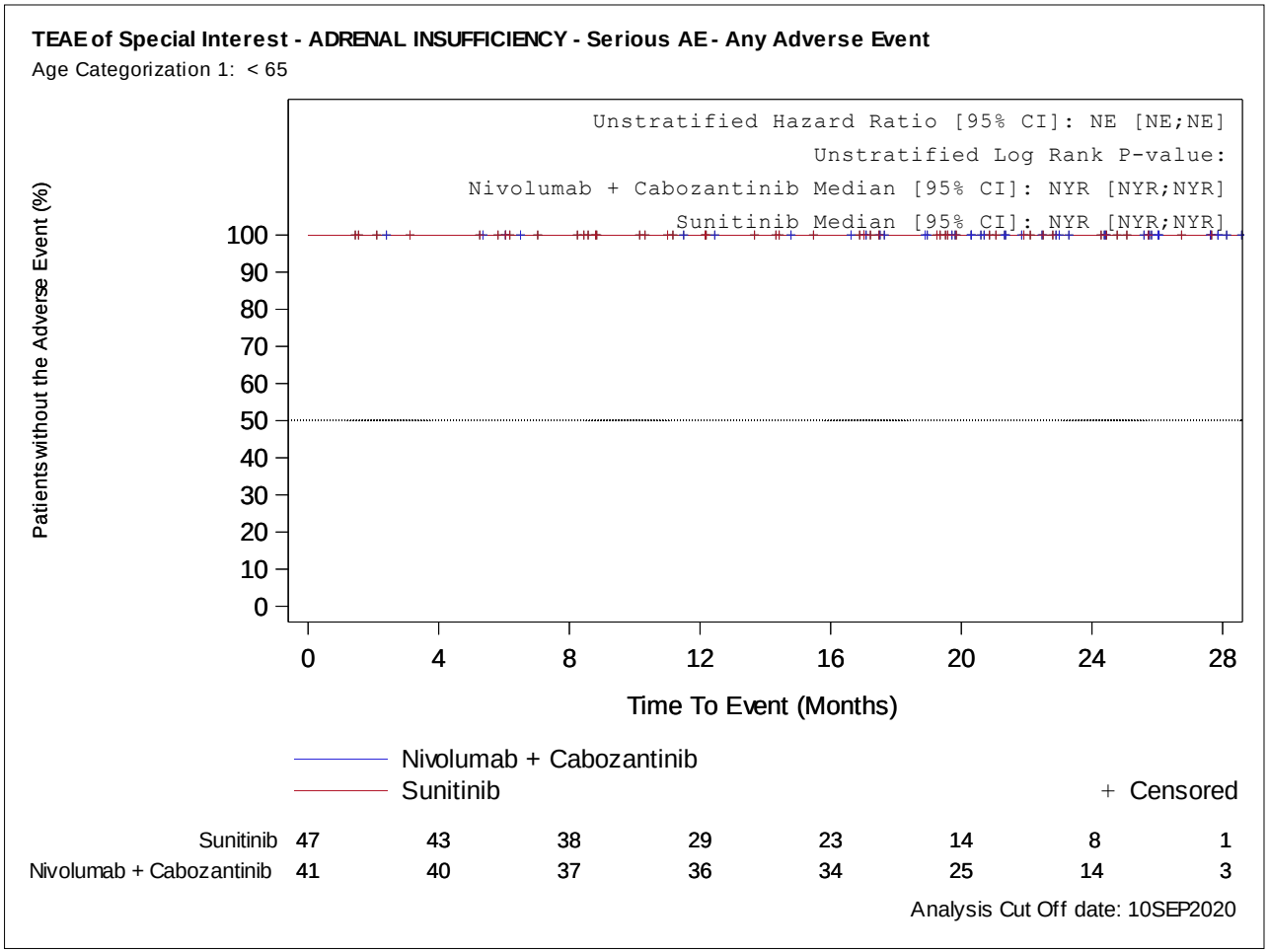
FIGURE 3.63.1: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:34:43

FIGURE 3.63.2.1: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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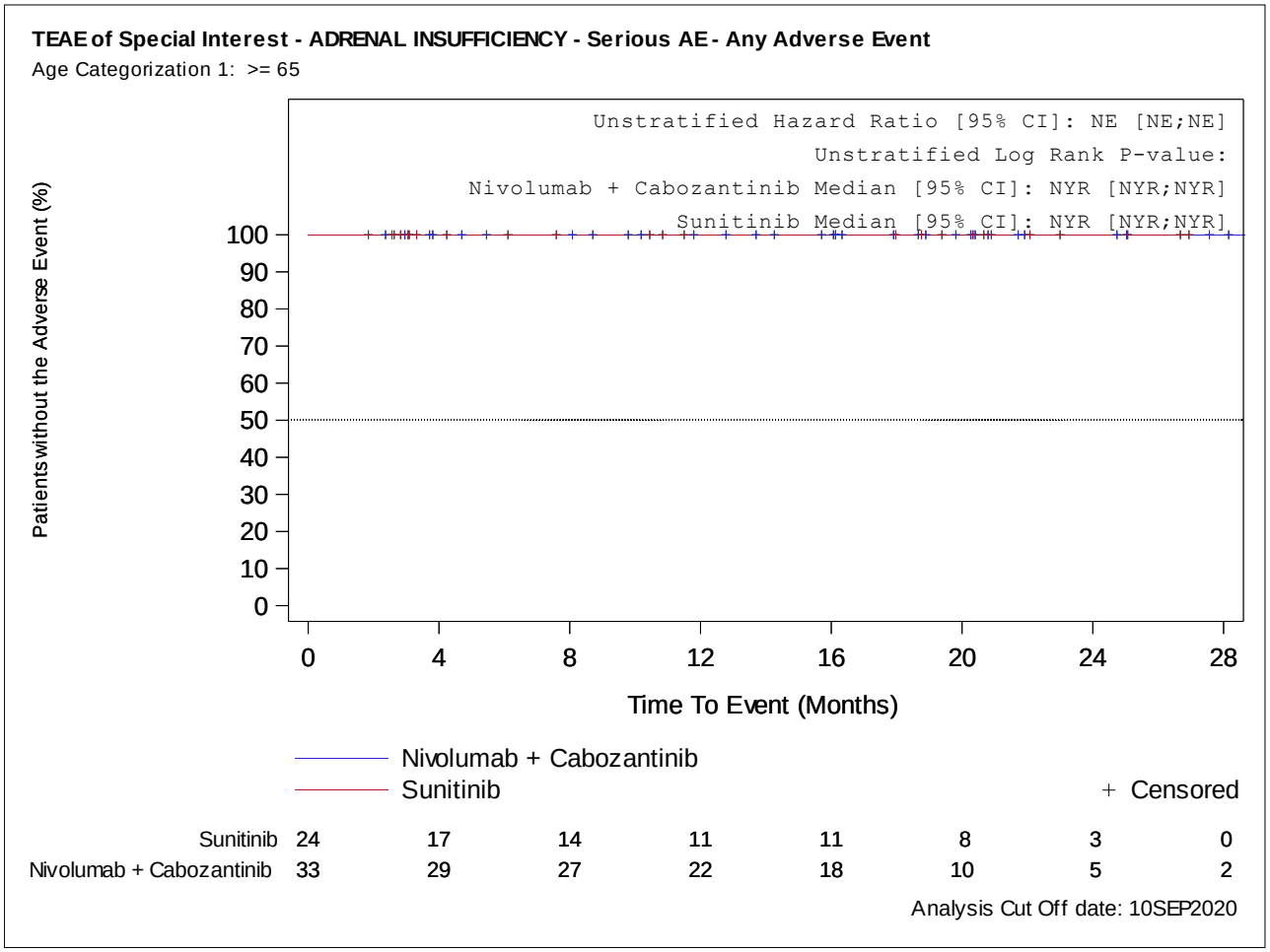
FIGURE 3.63.2.2: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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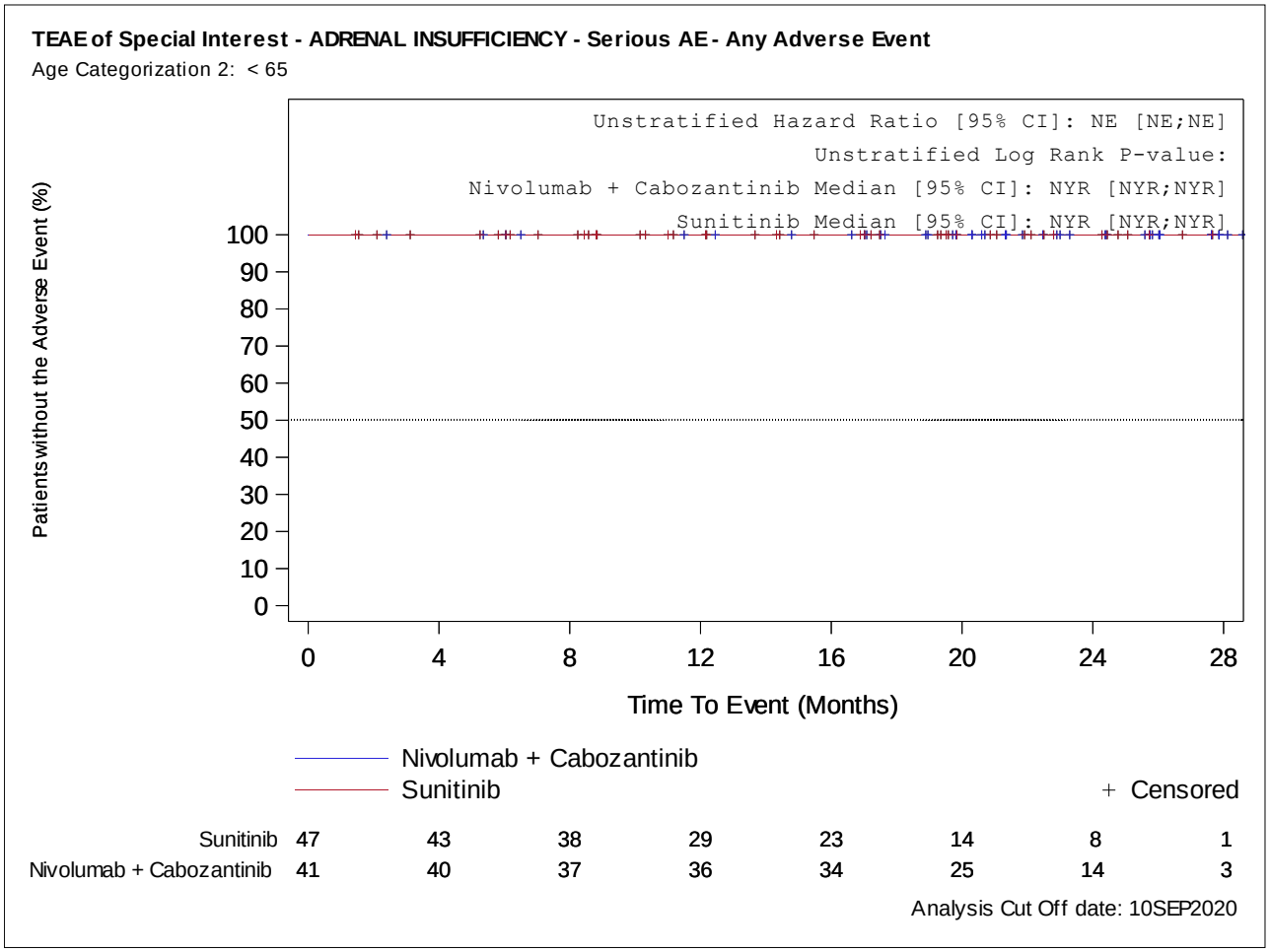
FIGURE 3.63.2.3: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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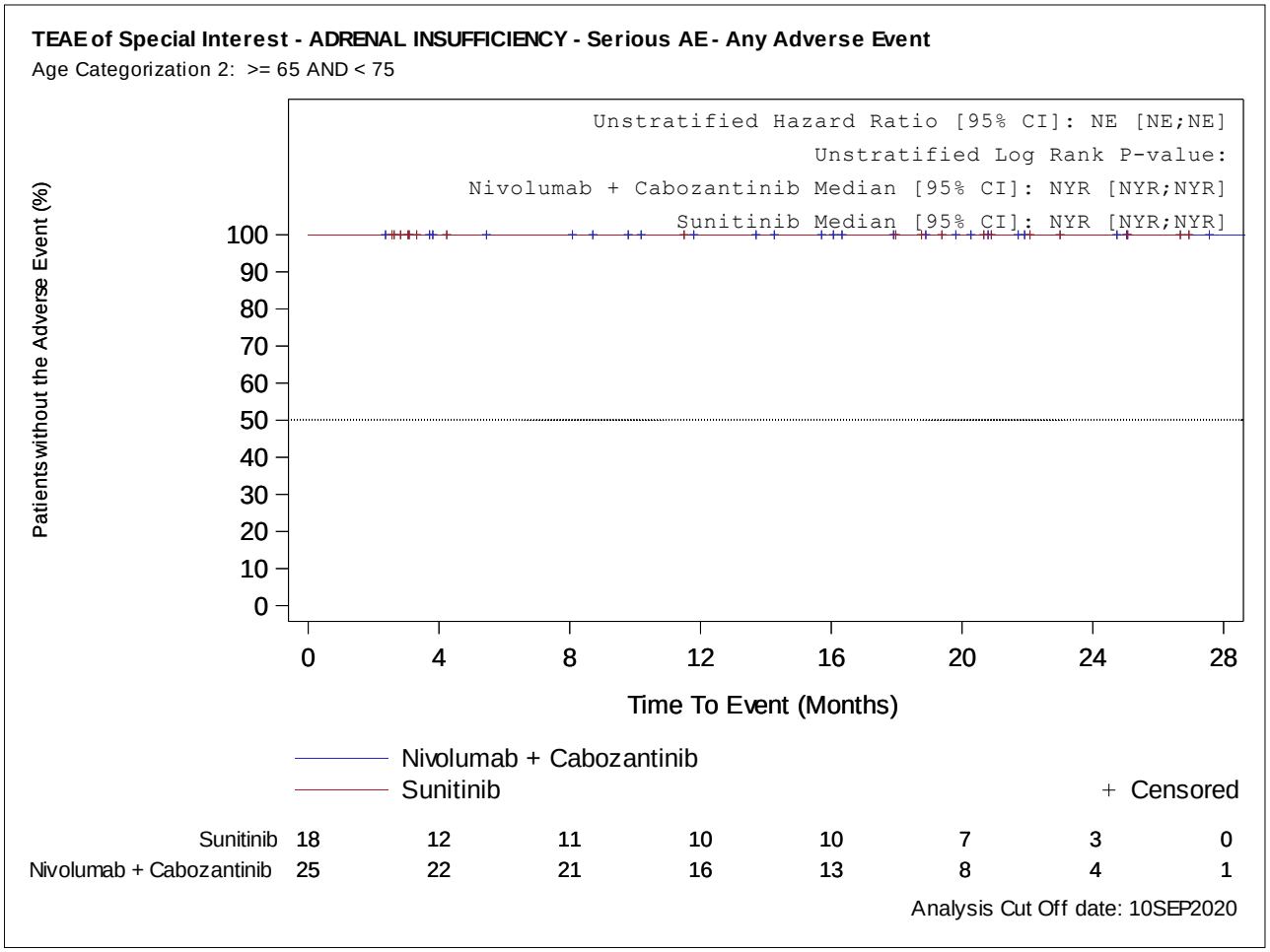
FIGURE 3.63.2.4: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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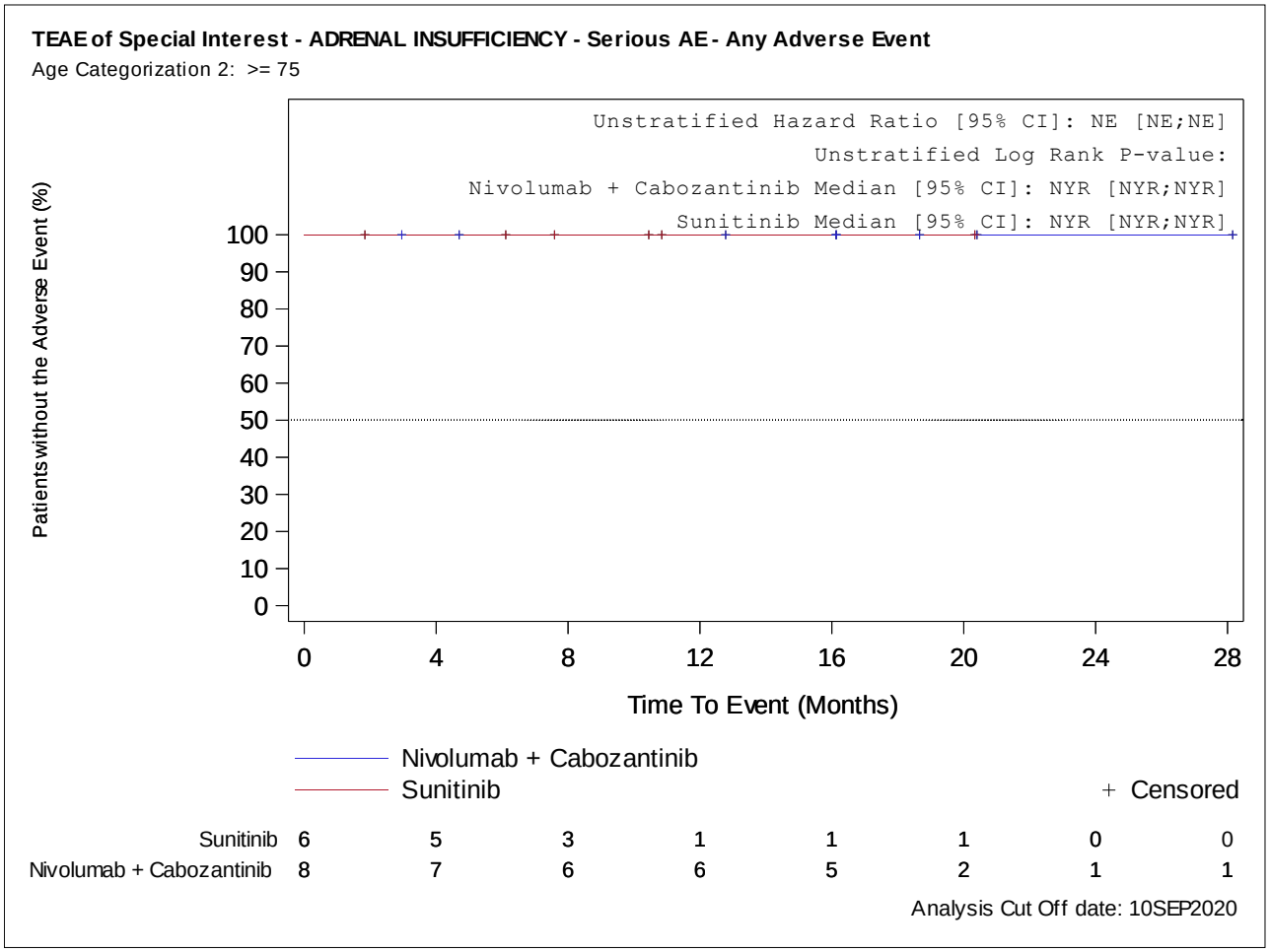
FIGURE 3.63.2.5: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75




Analysis Cut Off date: 10SEP2020
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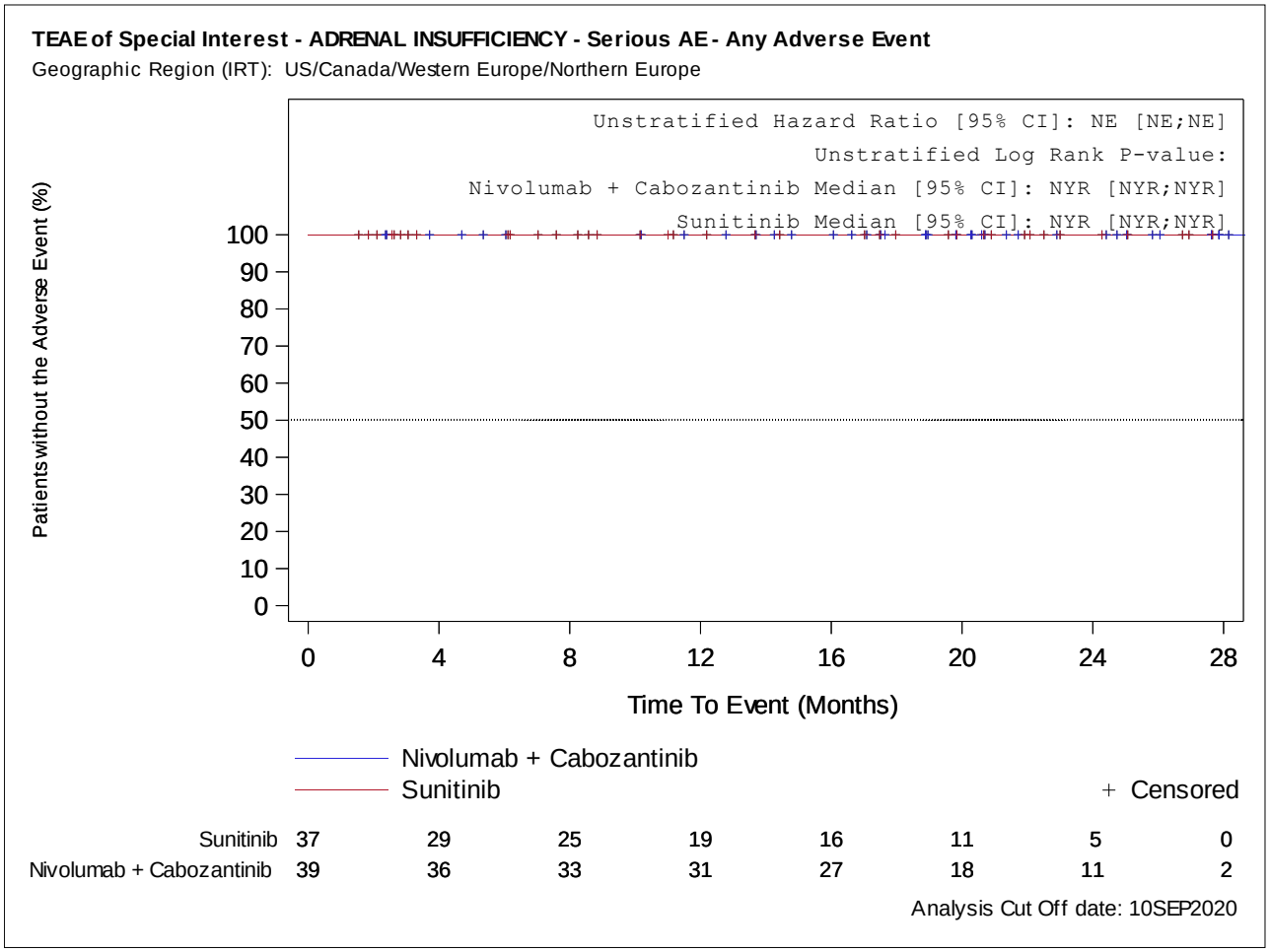
FIGURE 3.63.2.6: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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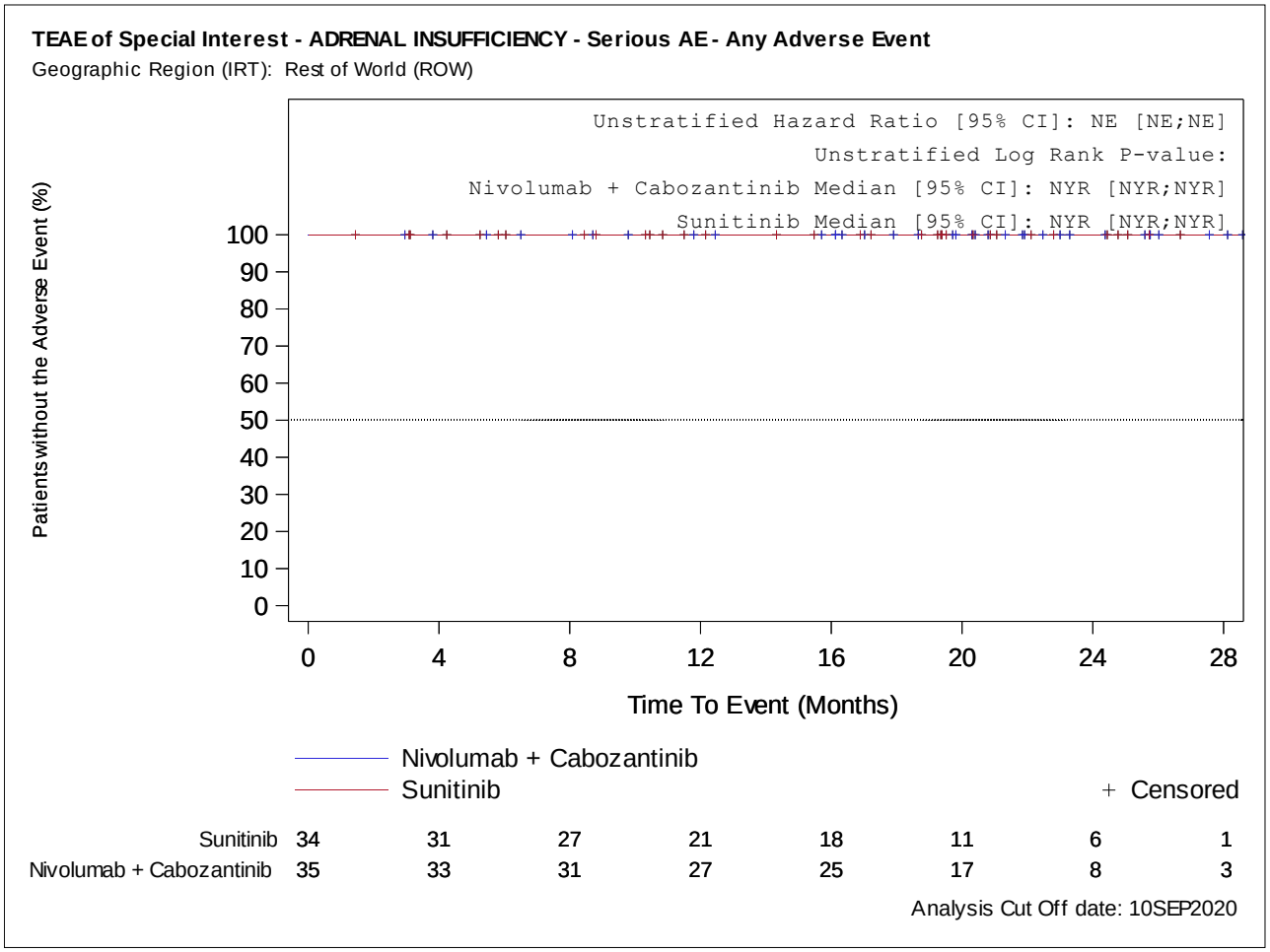
FIGURE 3.63.2.7: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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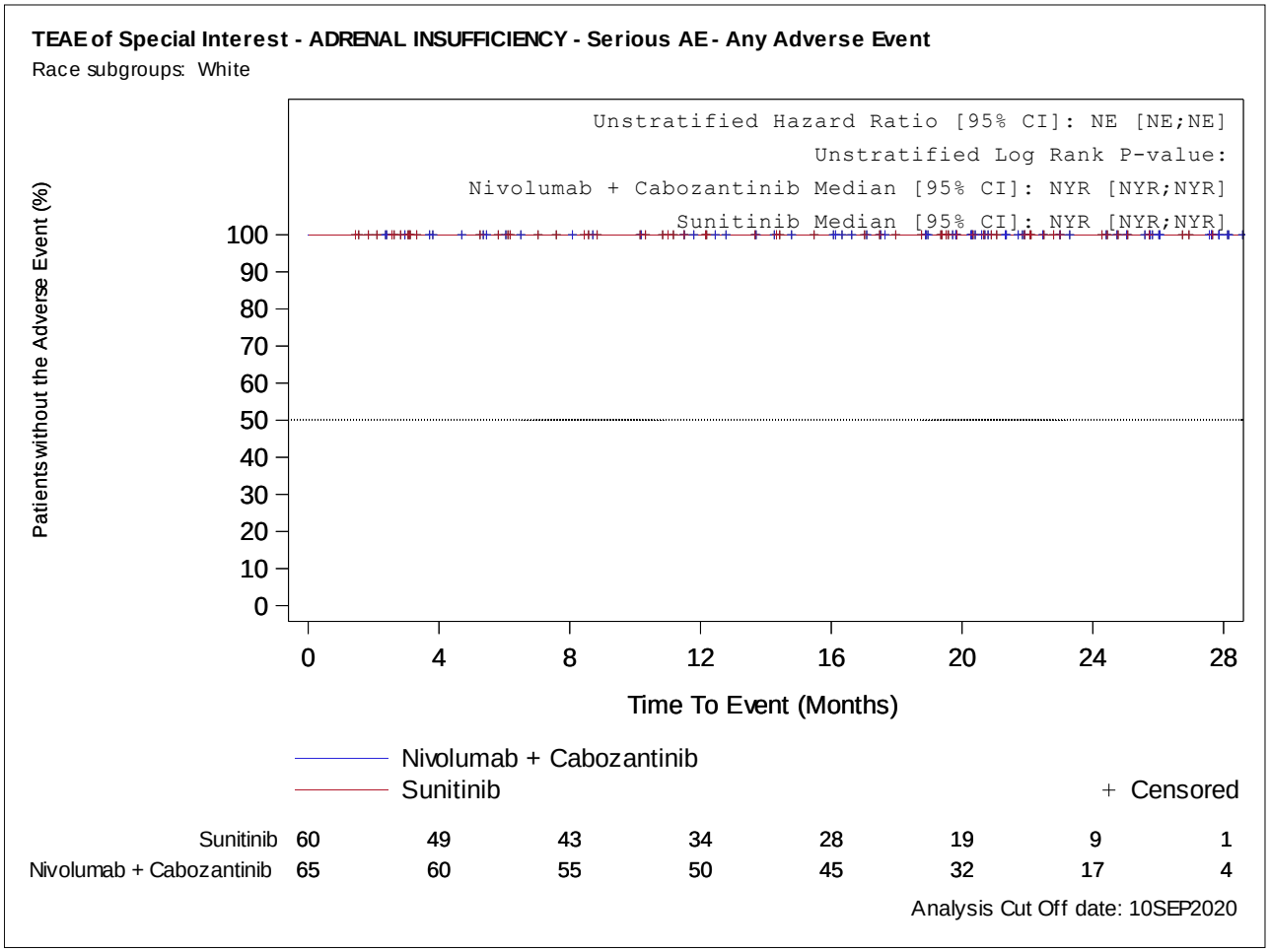
FIGURE 3.63.2.8: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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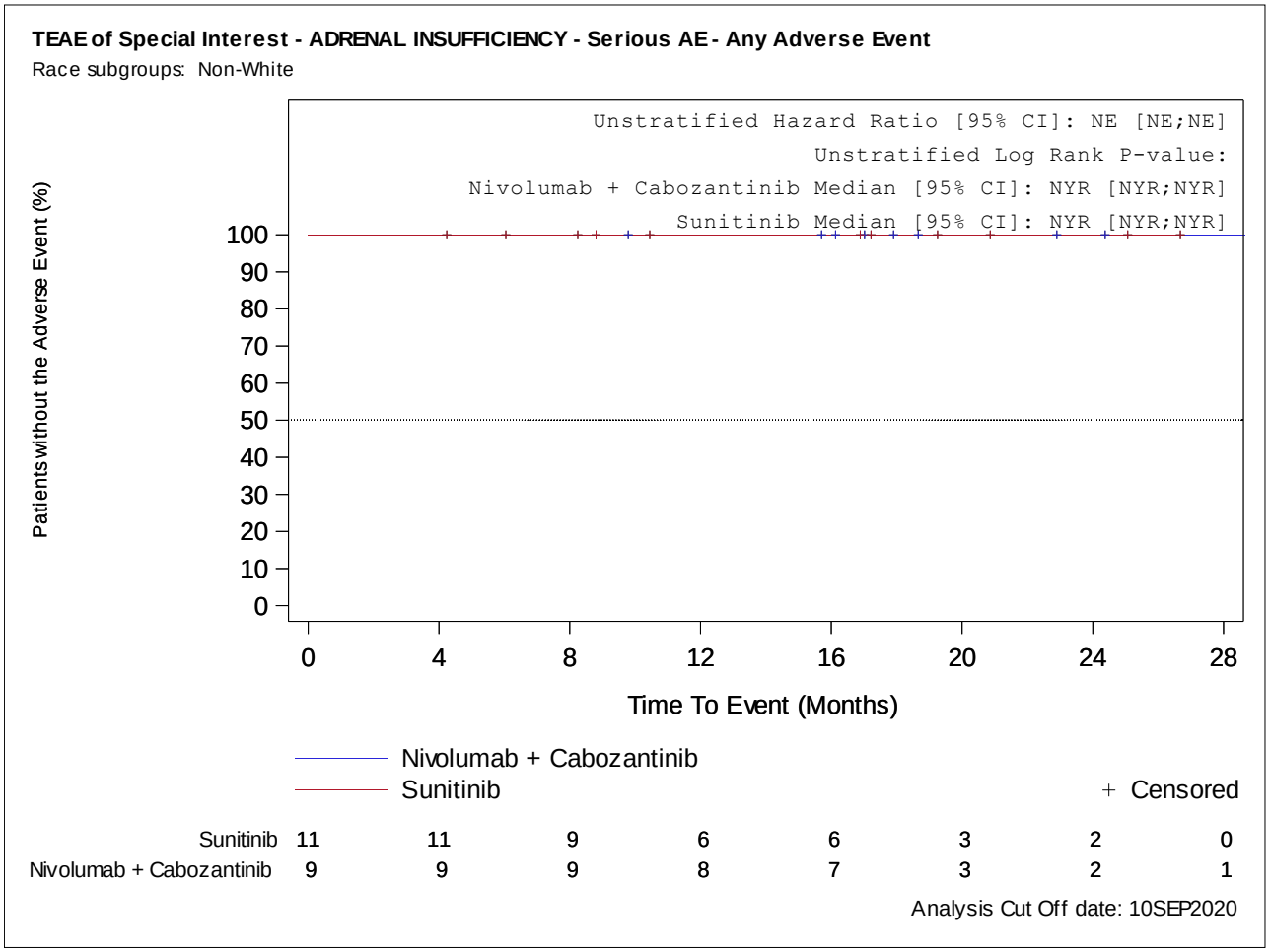
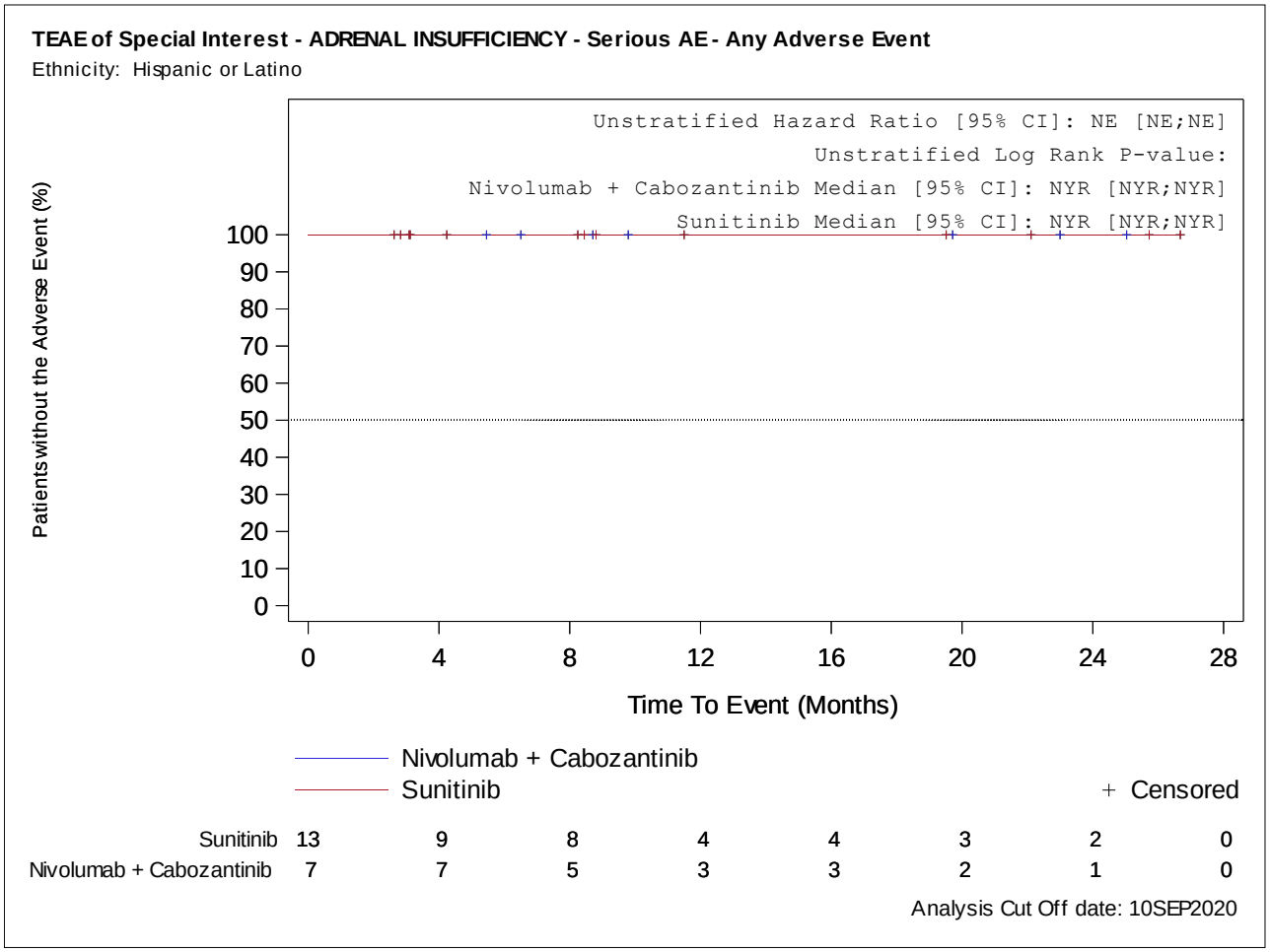
FIGURE 3.63.2.9: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:35:28

FIGURE 3.63.2.10: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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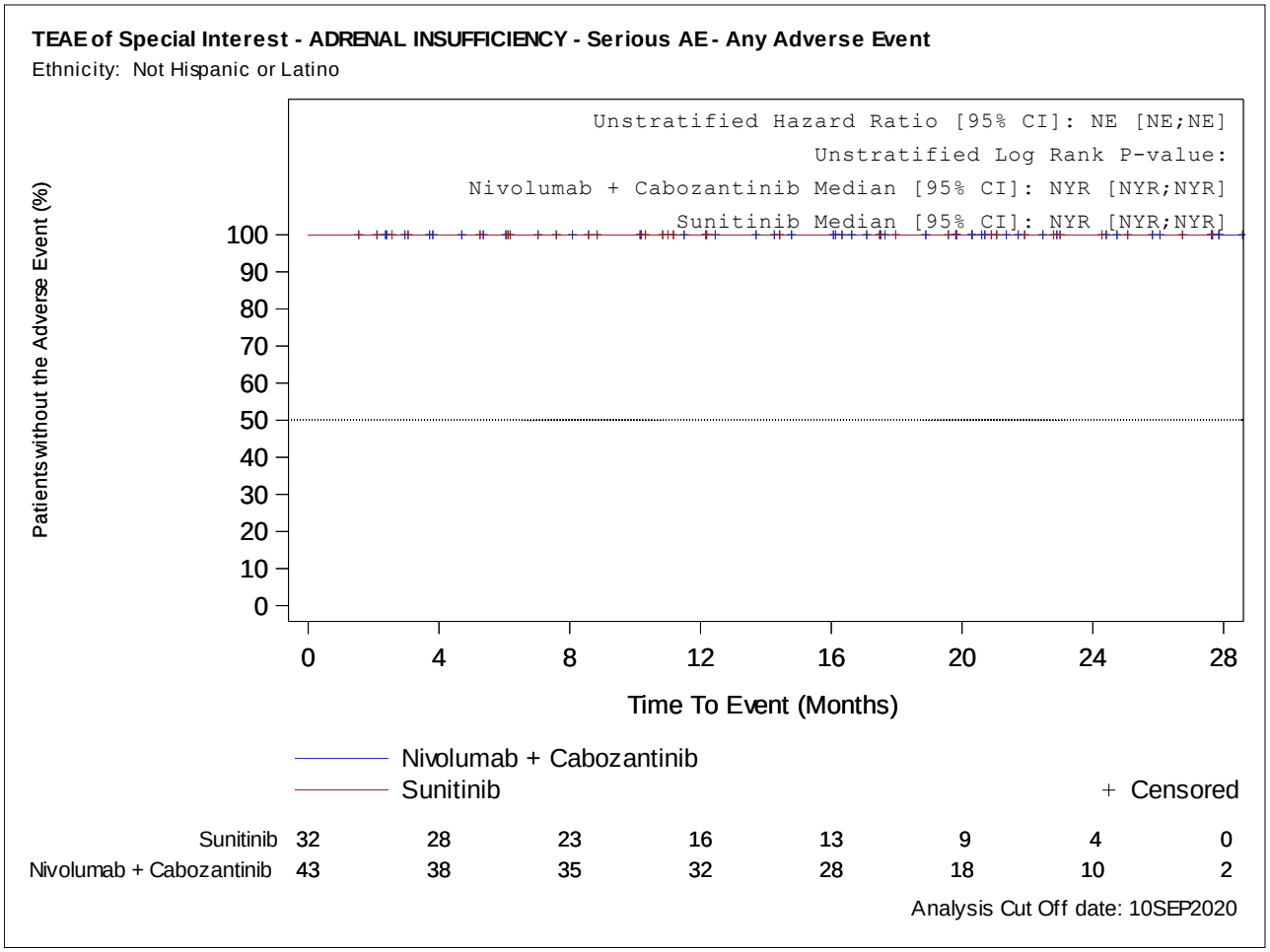
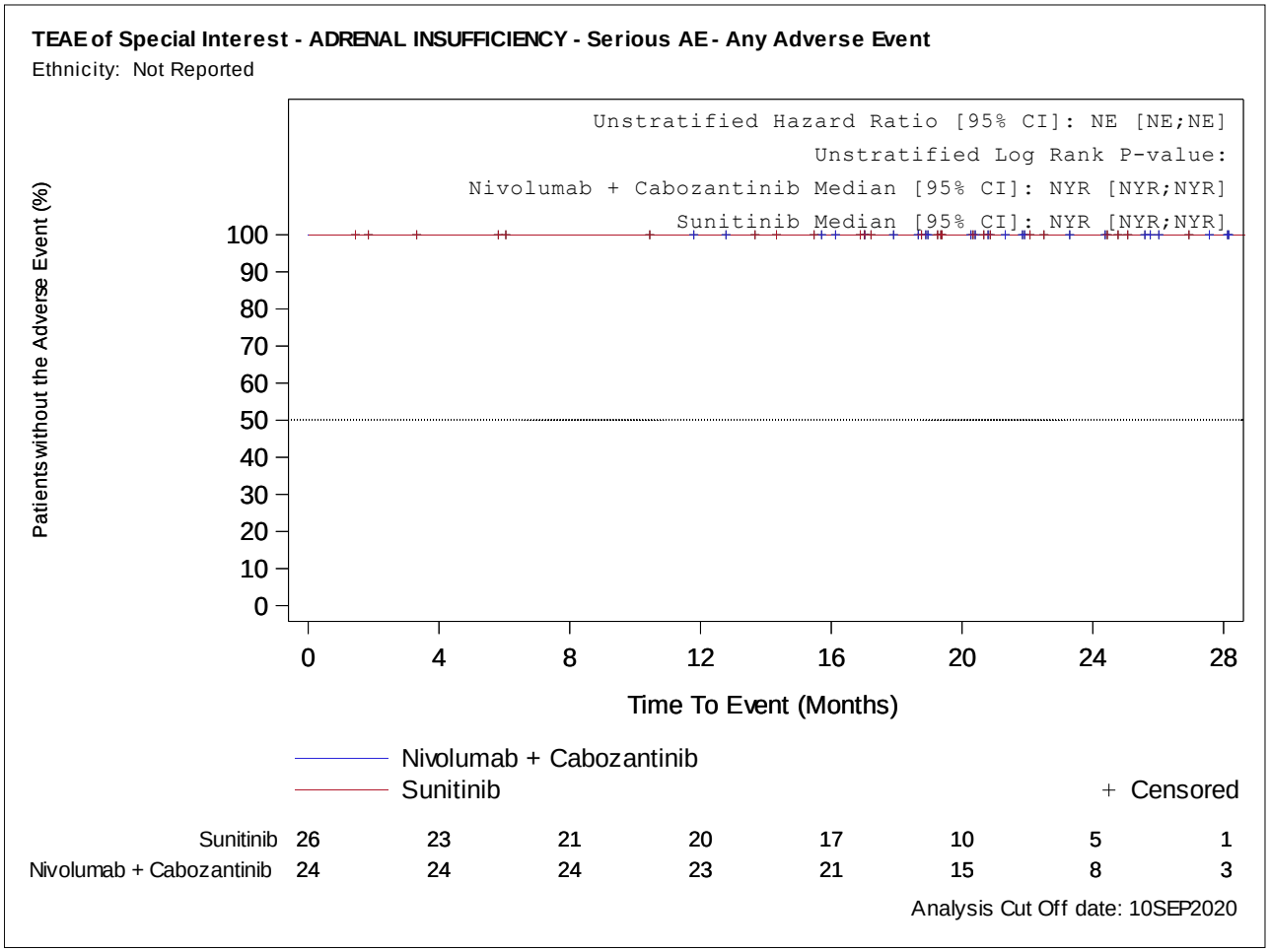
FIGURE 3.63.2.11: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



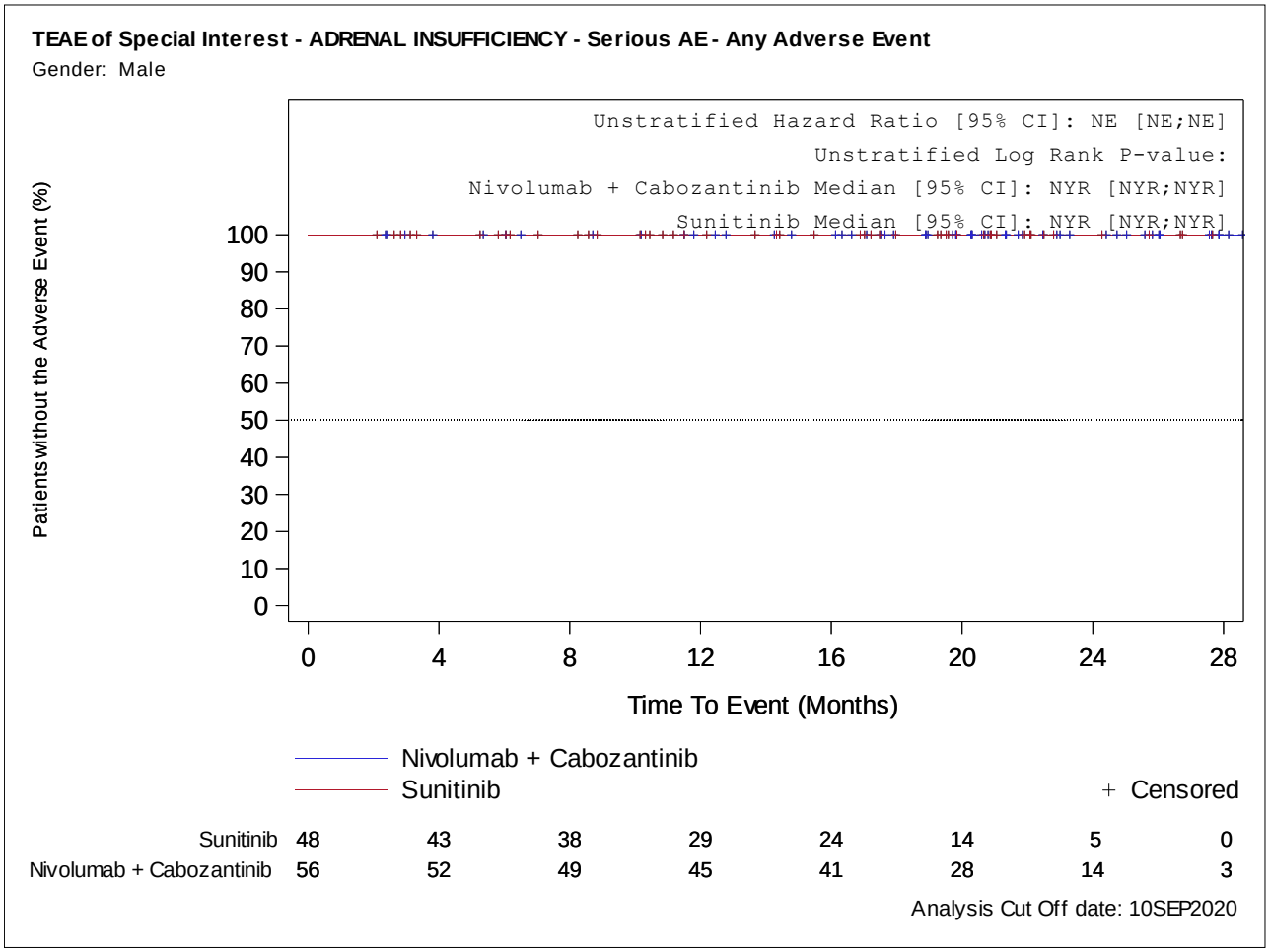

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:35:39

FIGURE 3.63.2.12: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



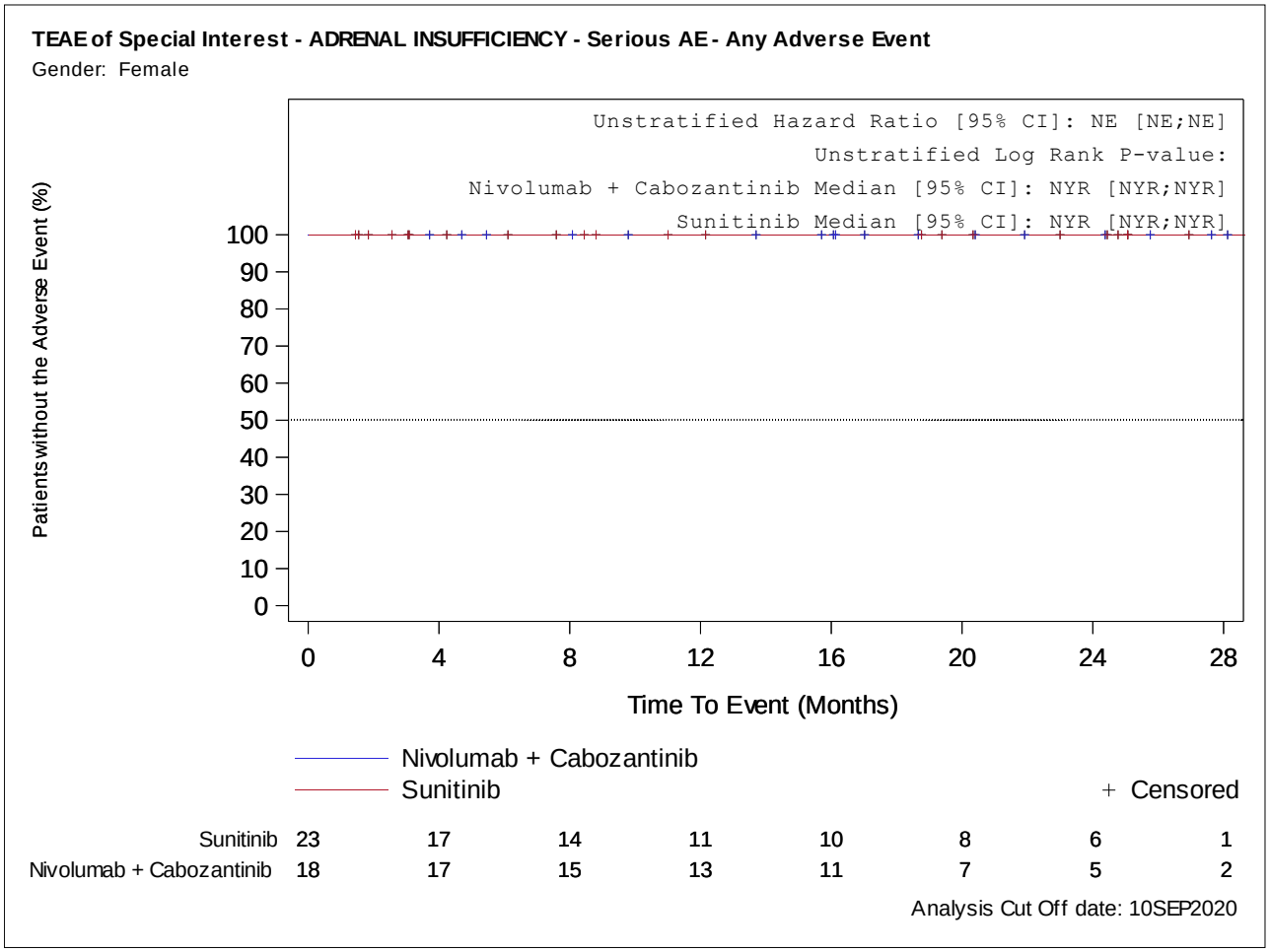

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:35:44

FIGURE 3.63.2.13: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:35:49

FIGURE 3.63.2.14: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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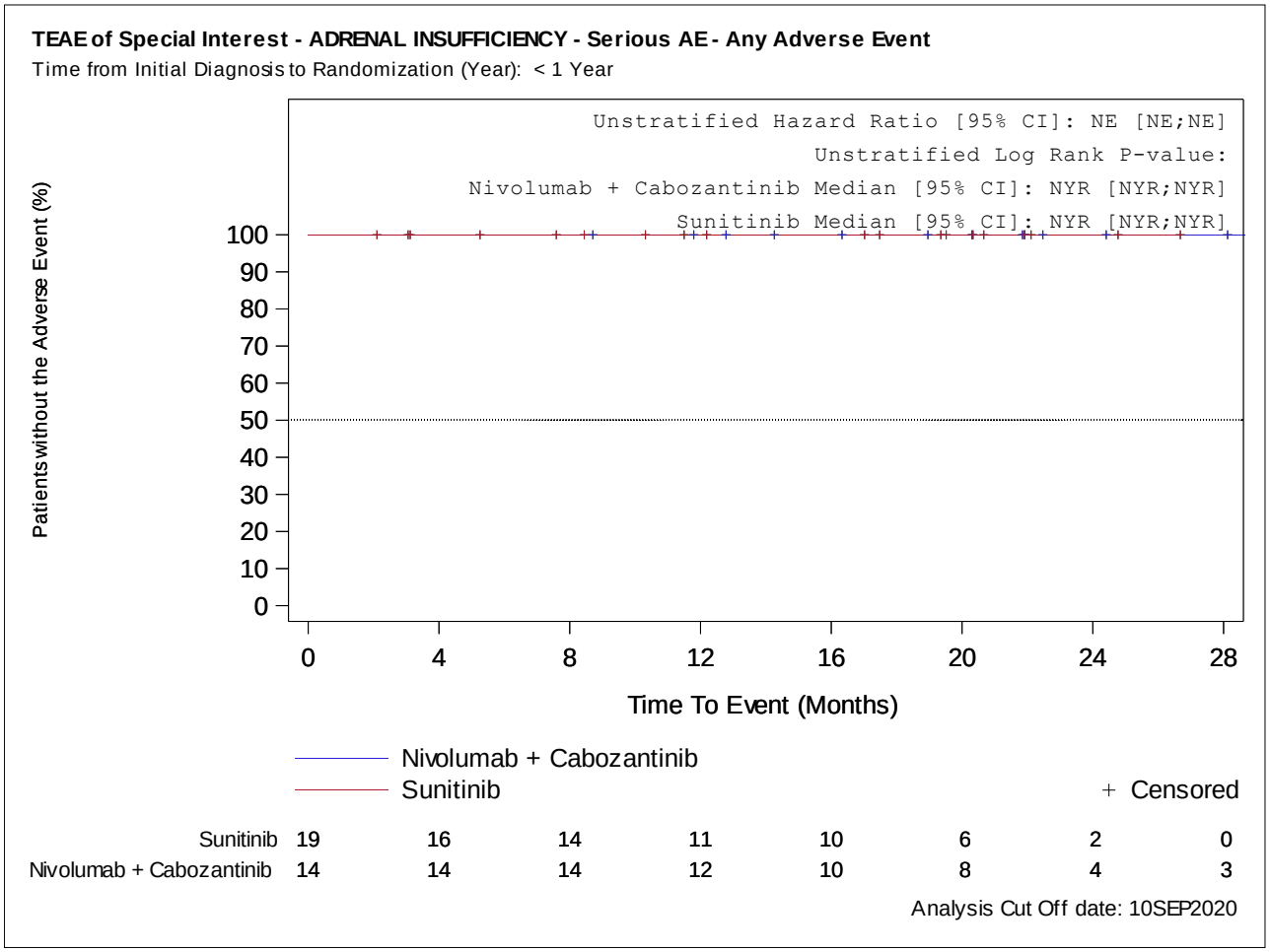
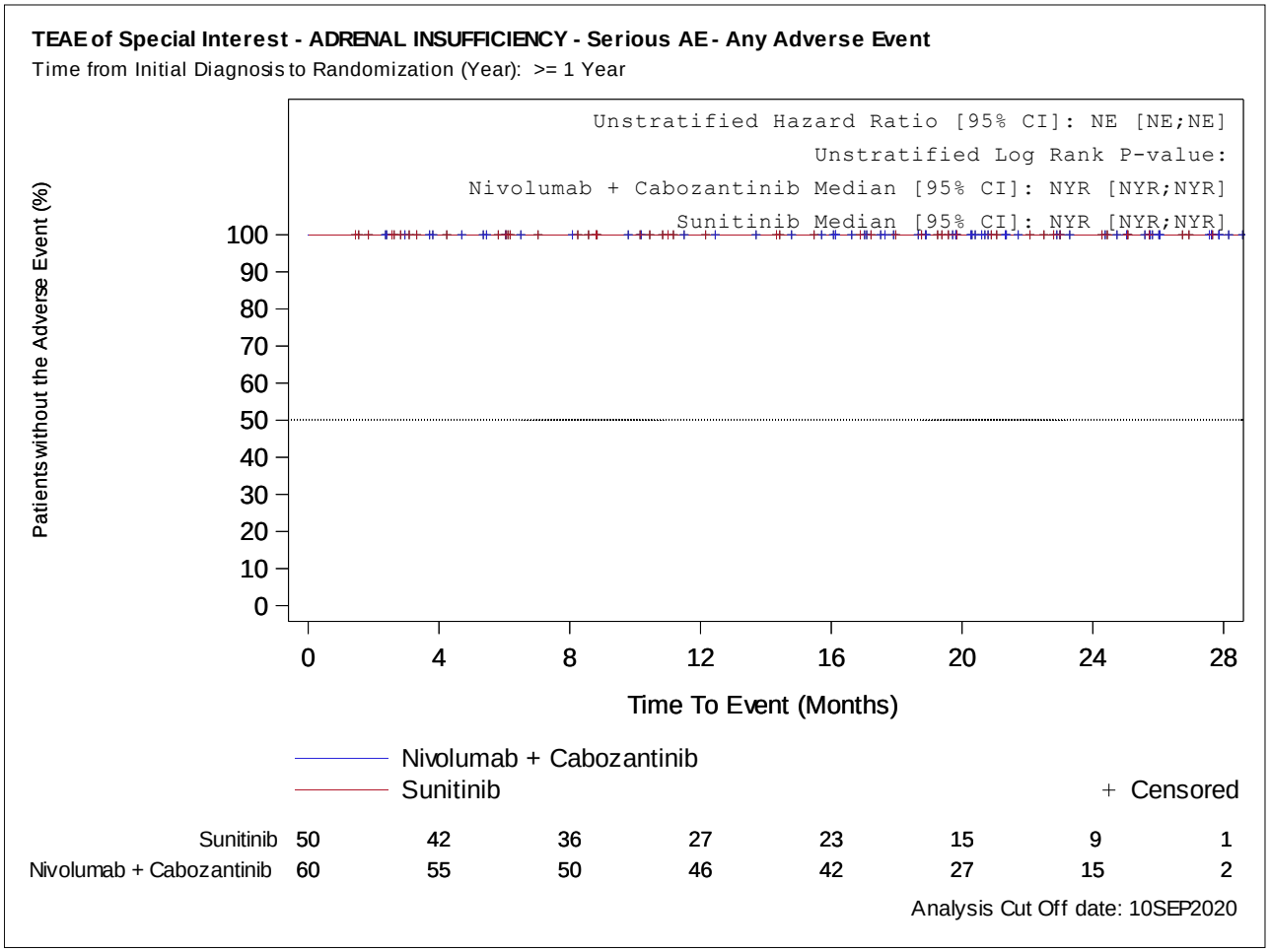
FIGURE 3.63.2.15: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



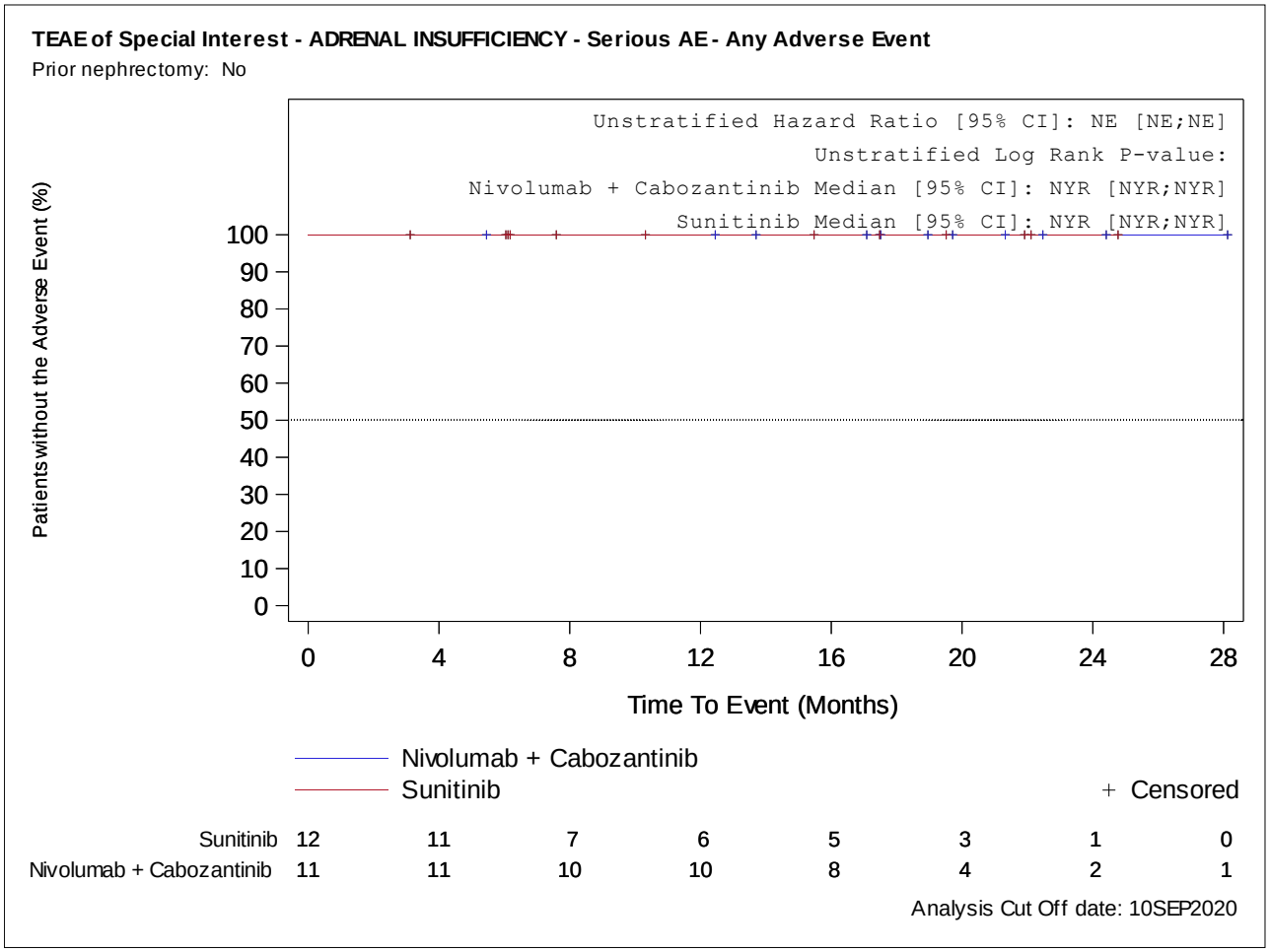

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:36:10

FIGURE 3.63.2.16: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



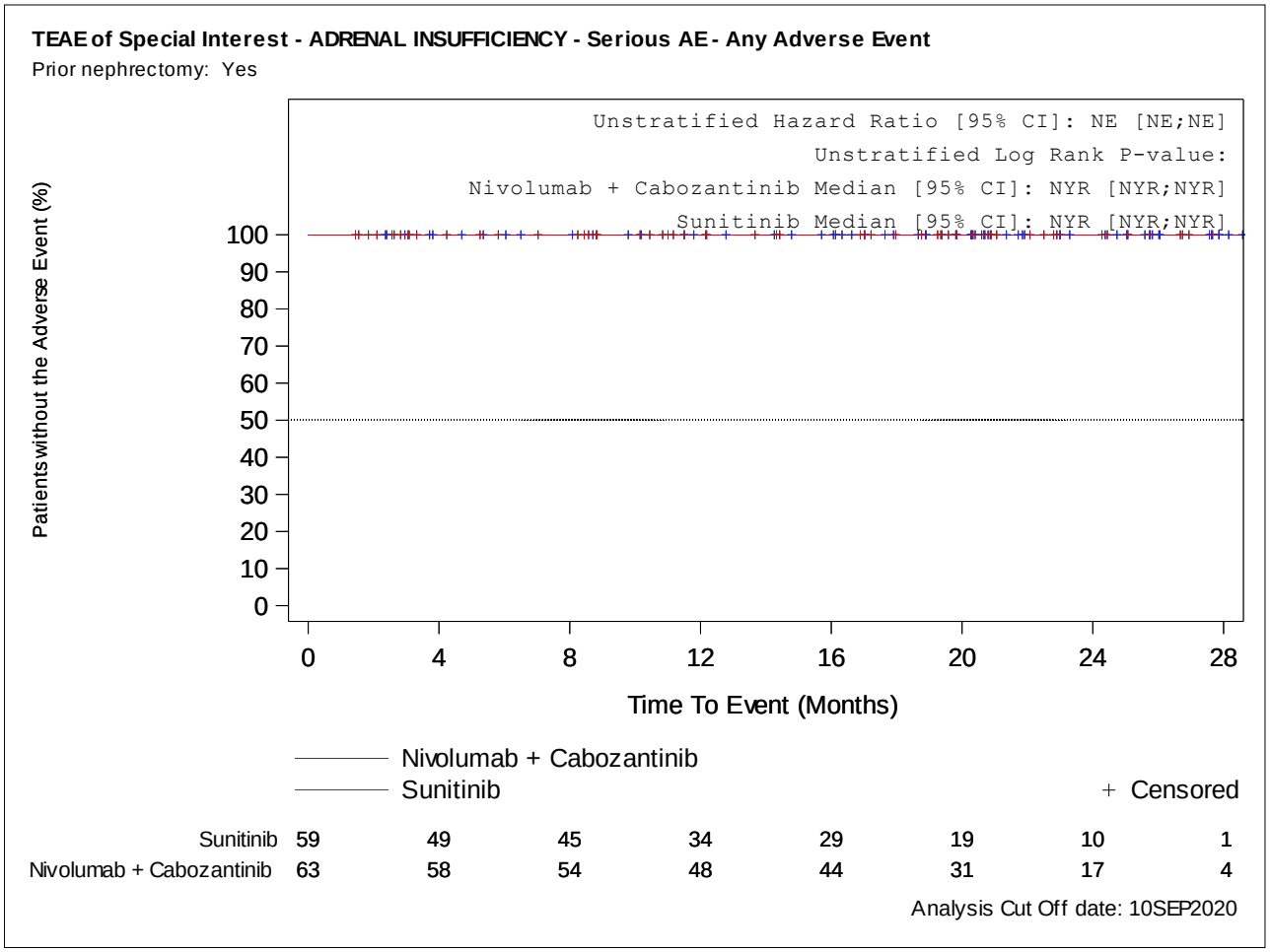

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:36:15

FIGURE 3.63.2.17: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



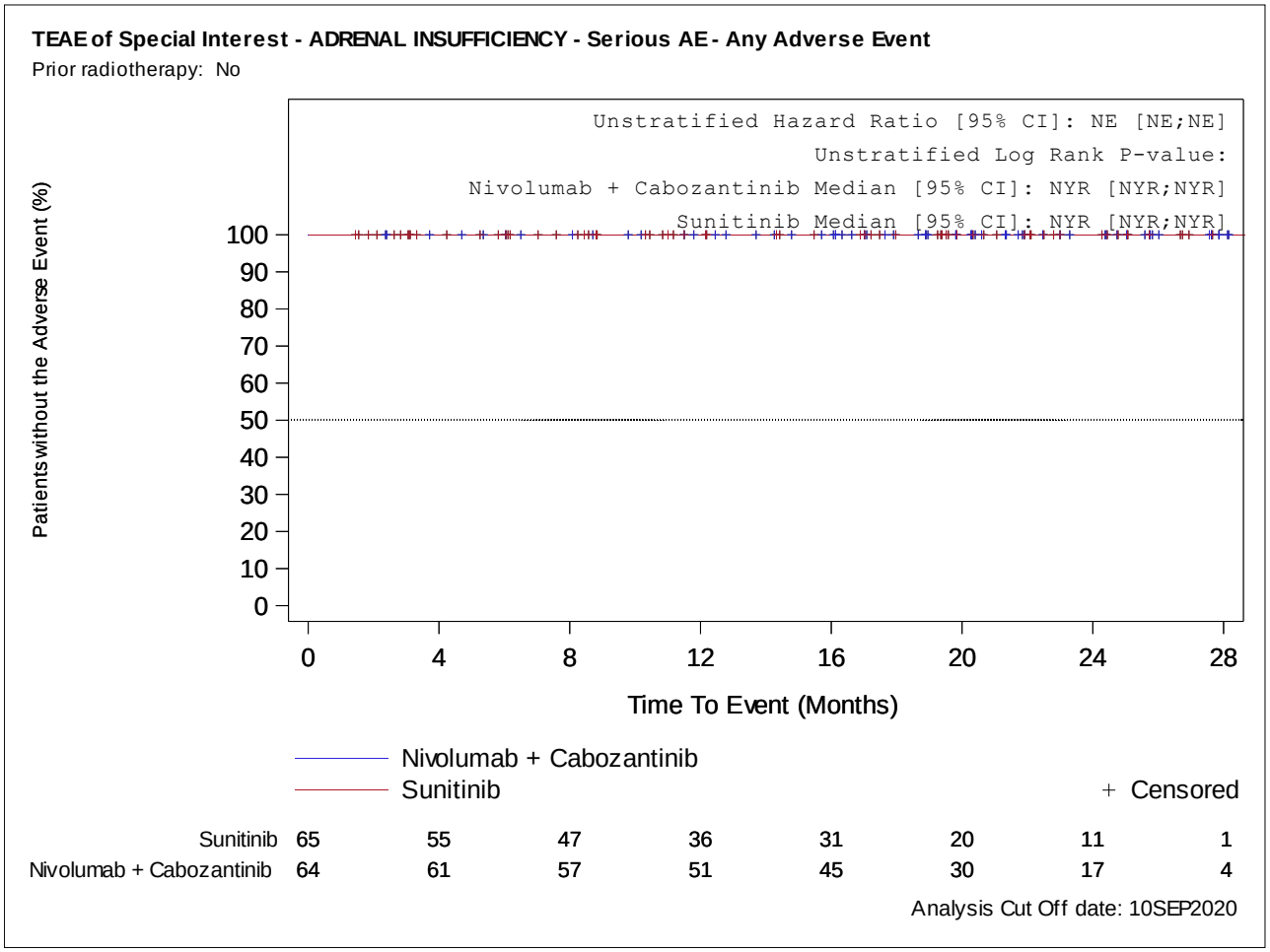

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:01

FIGURE 3.63.2.18: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



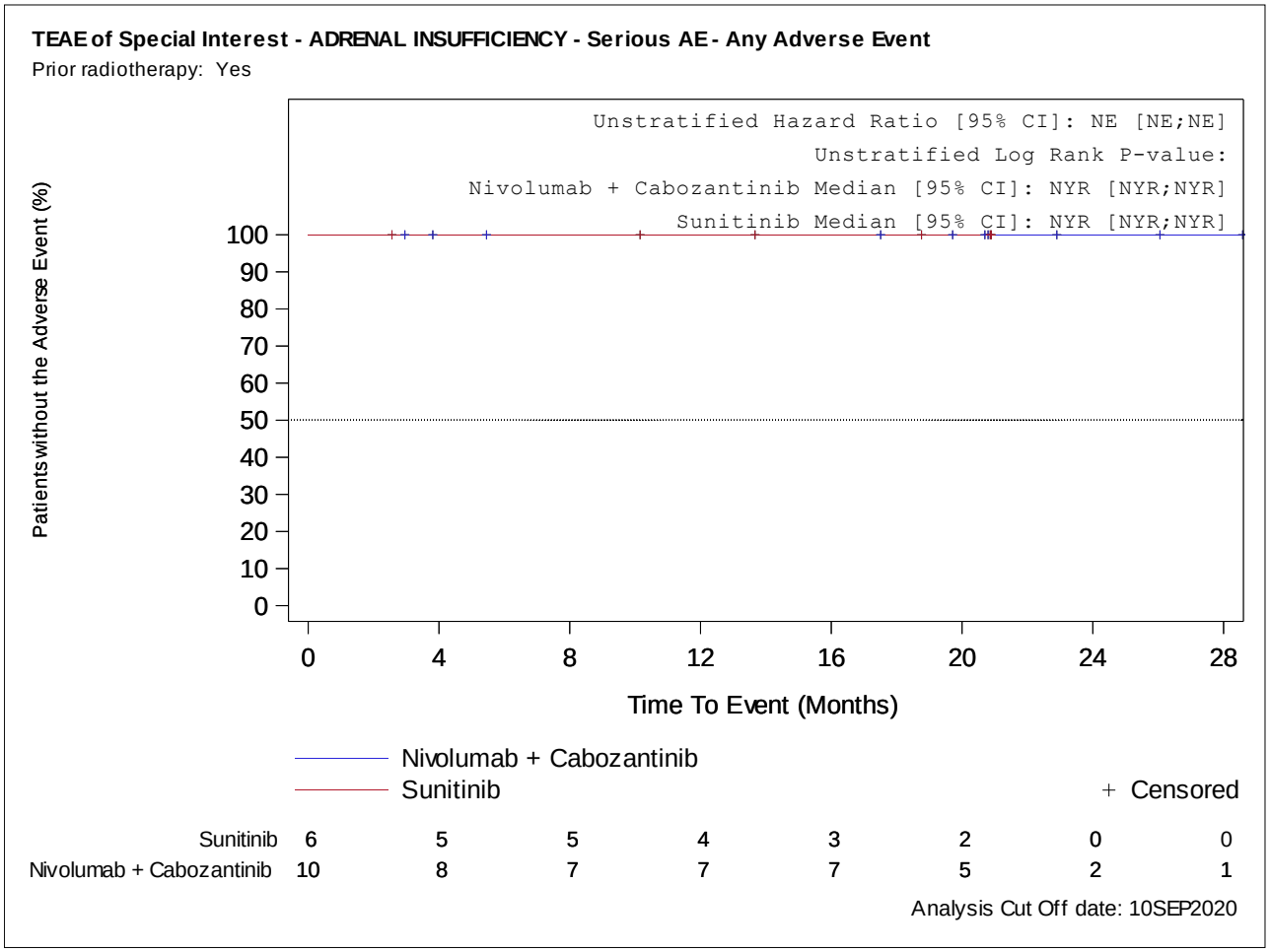

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:07

FIGURE 3.63.2.19: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



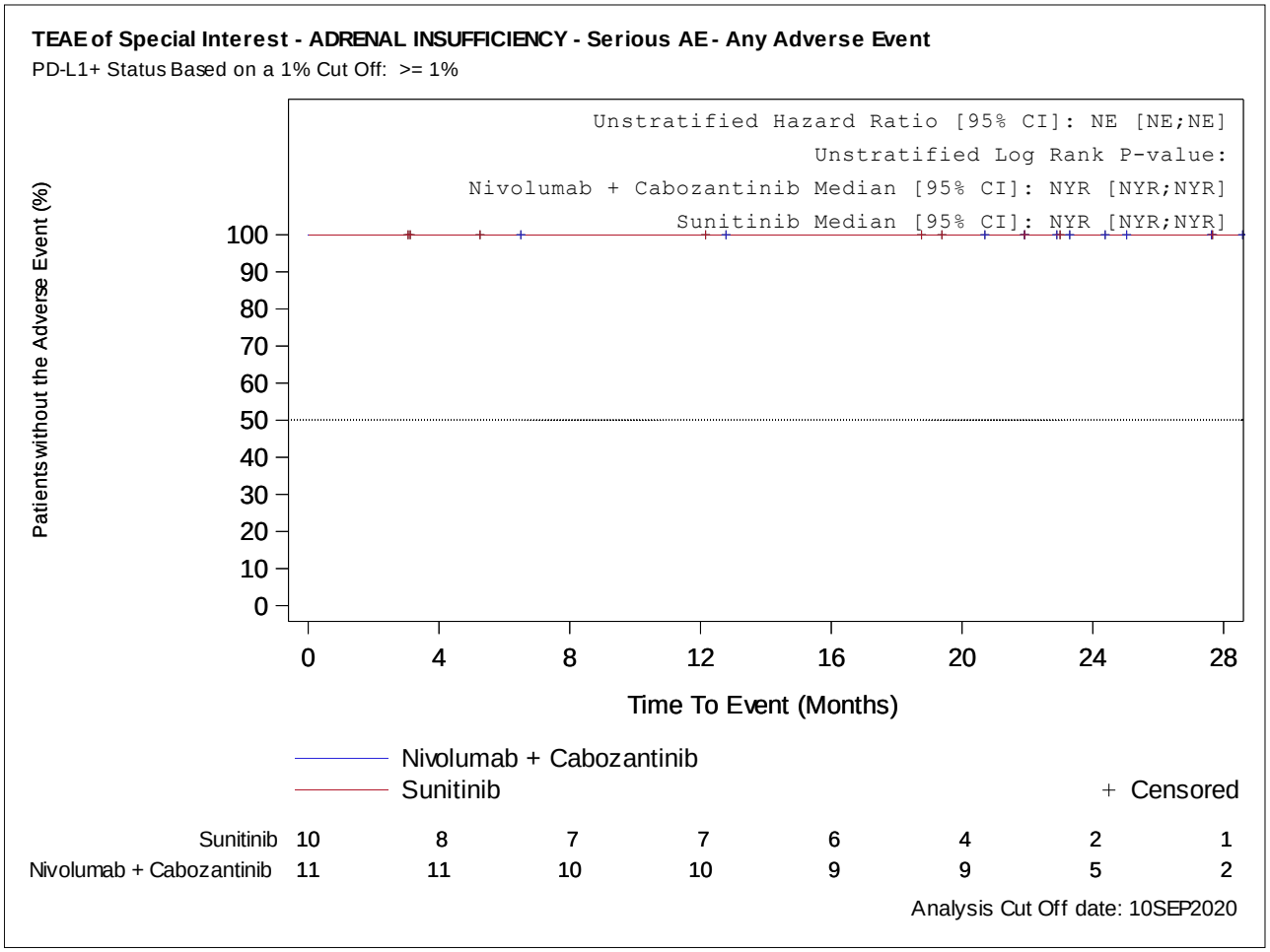

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:12

FIGURE 3.63.2.20: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



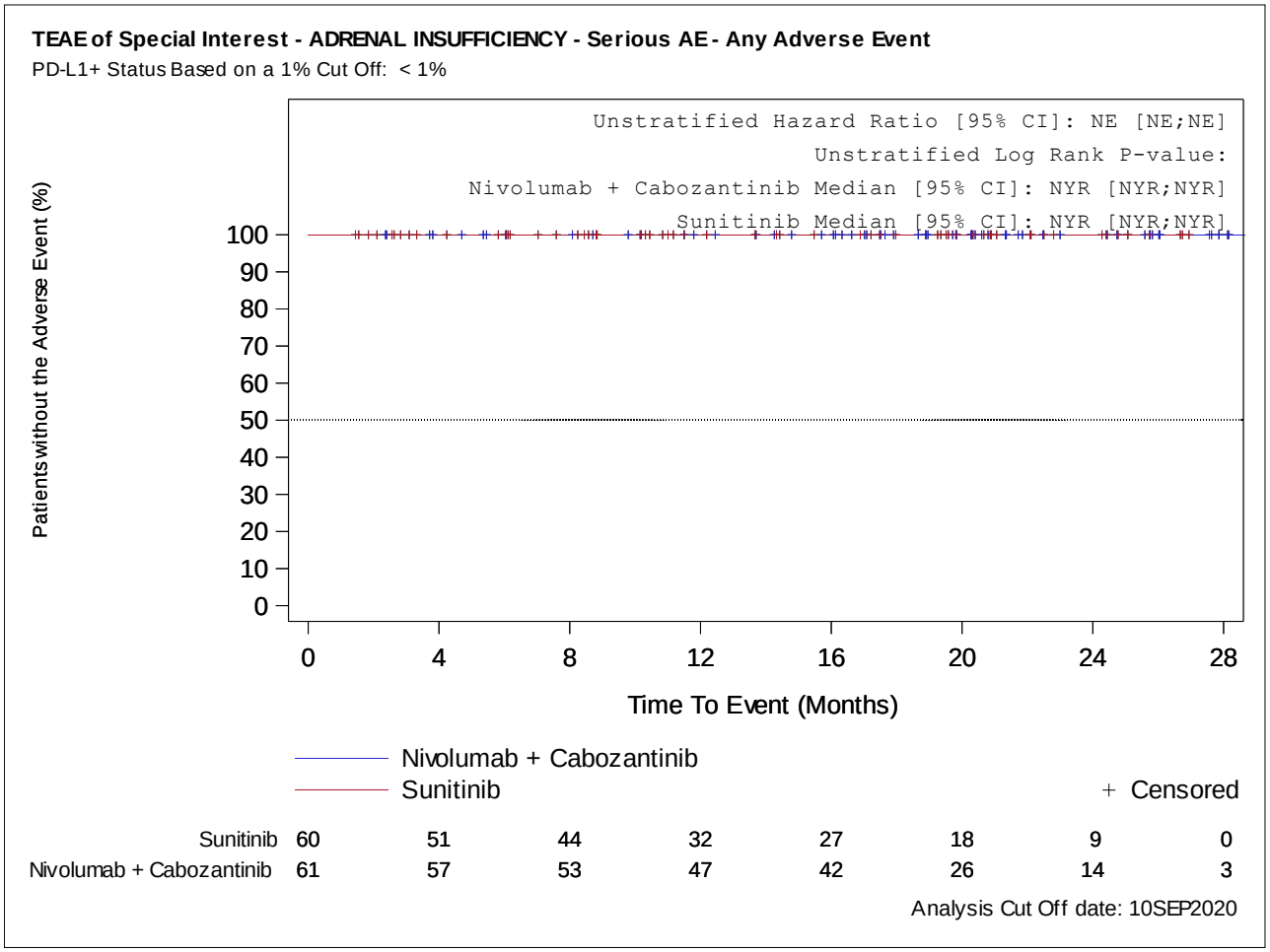

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:17

FIGURE 3.63.2.21: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



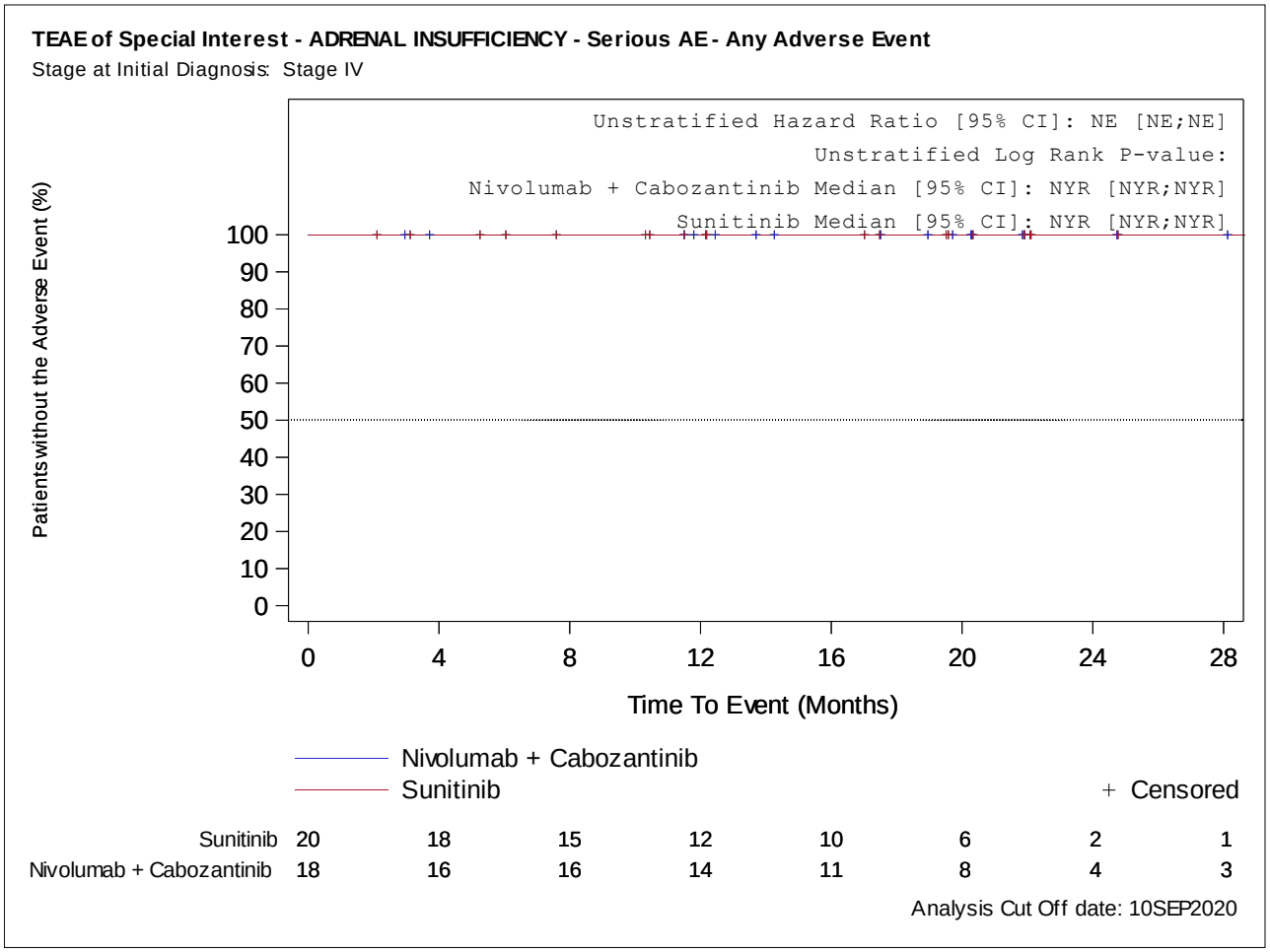

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:22

FIGURE 3.63.2.22: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



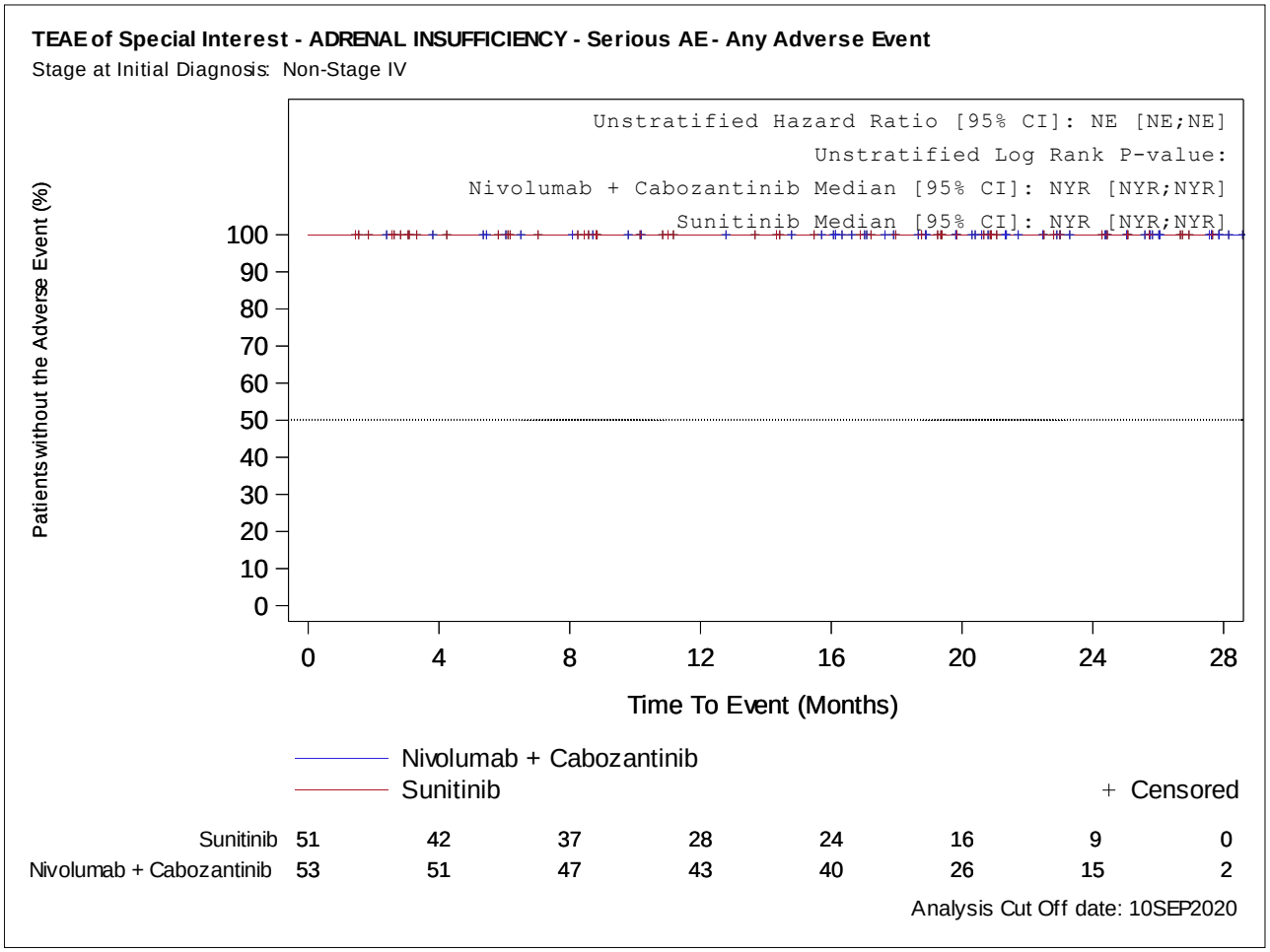

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:27

FIGURE 3.63.2.23: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



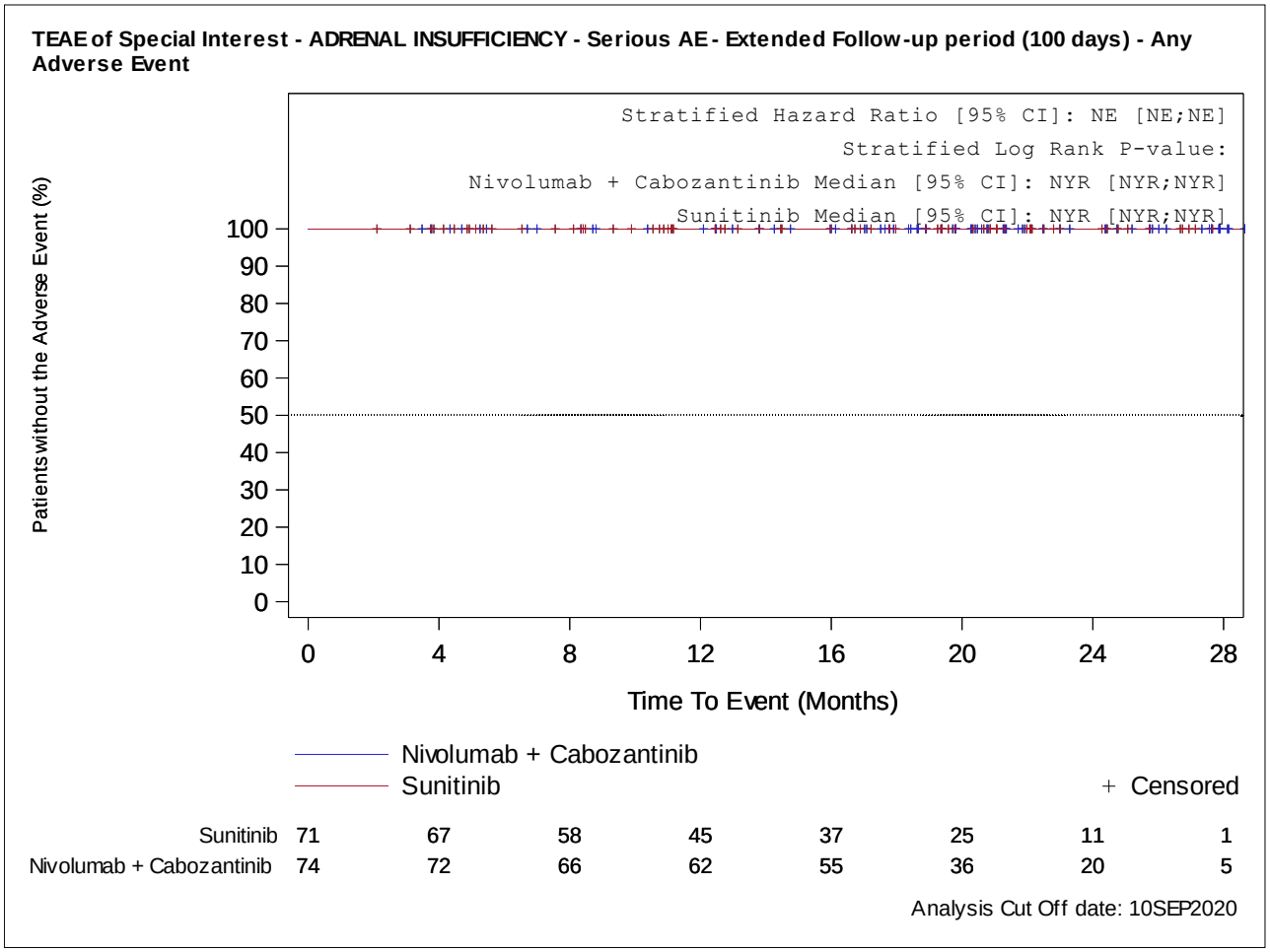

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:54

FIGURE 3.63.2.24: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



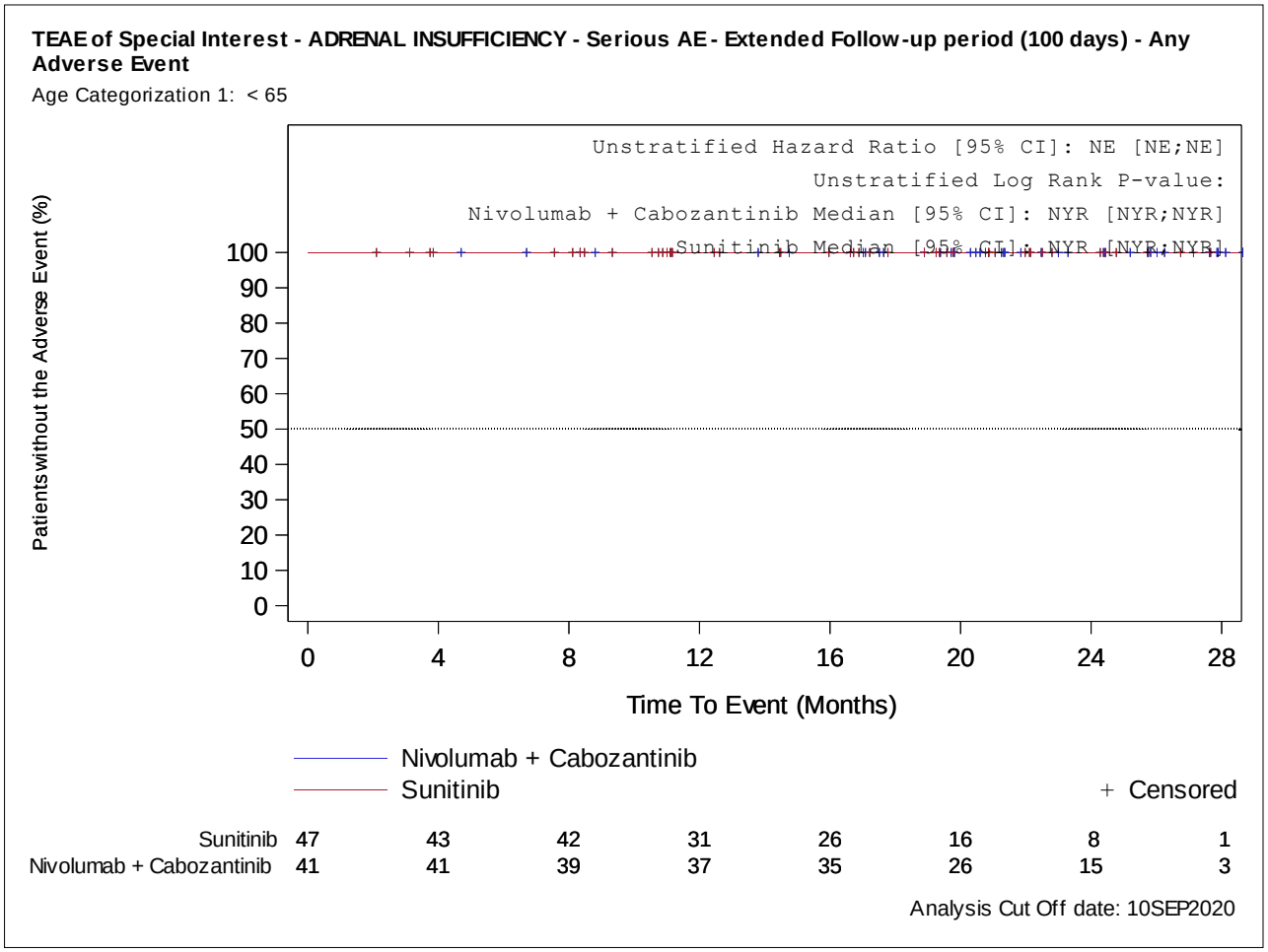

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:59

FIGURE 3.64.1: TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



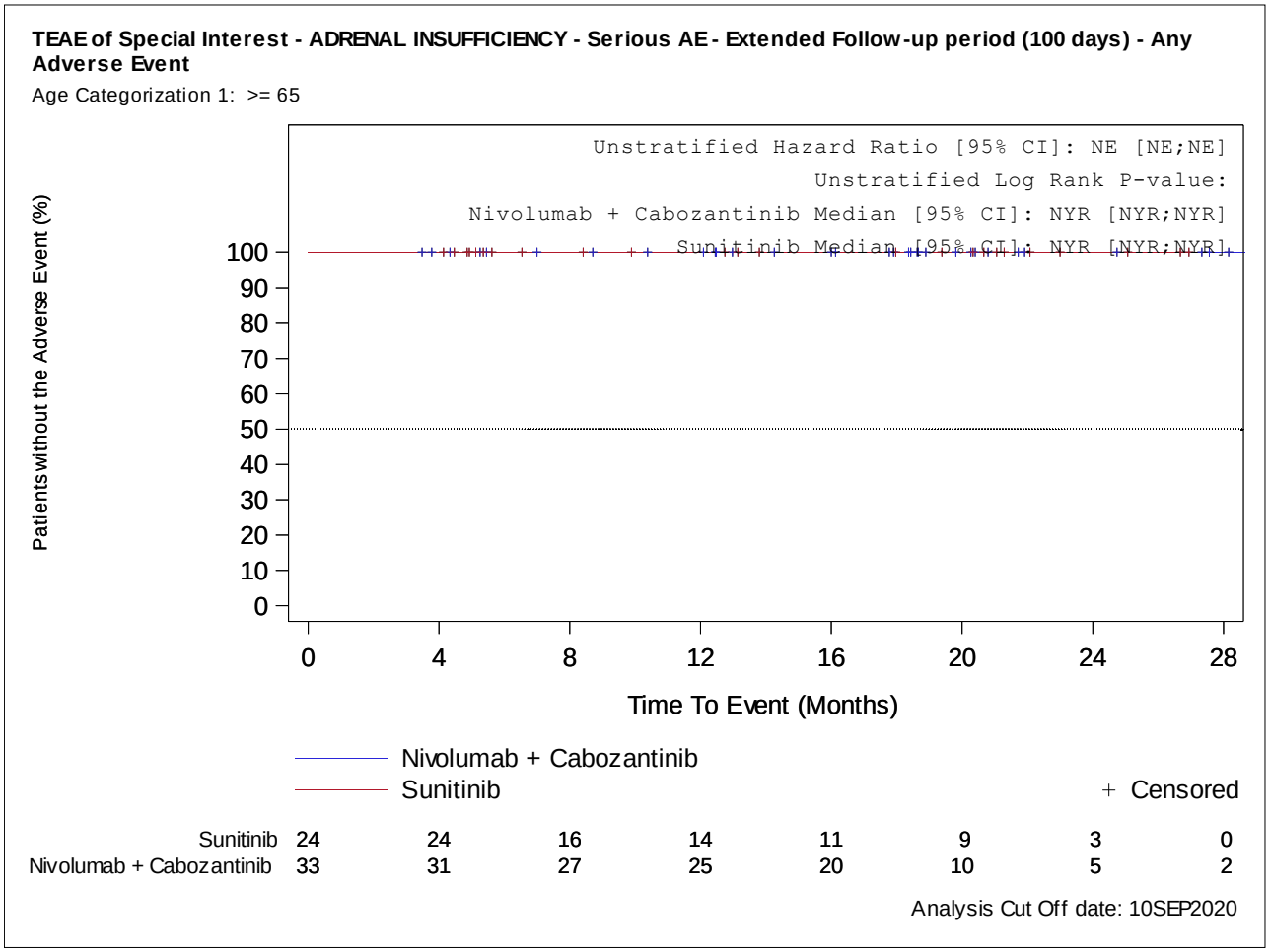

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:40:58

FIGURE 3.64.2.1: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  < 65



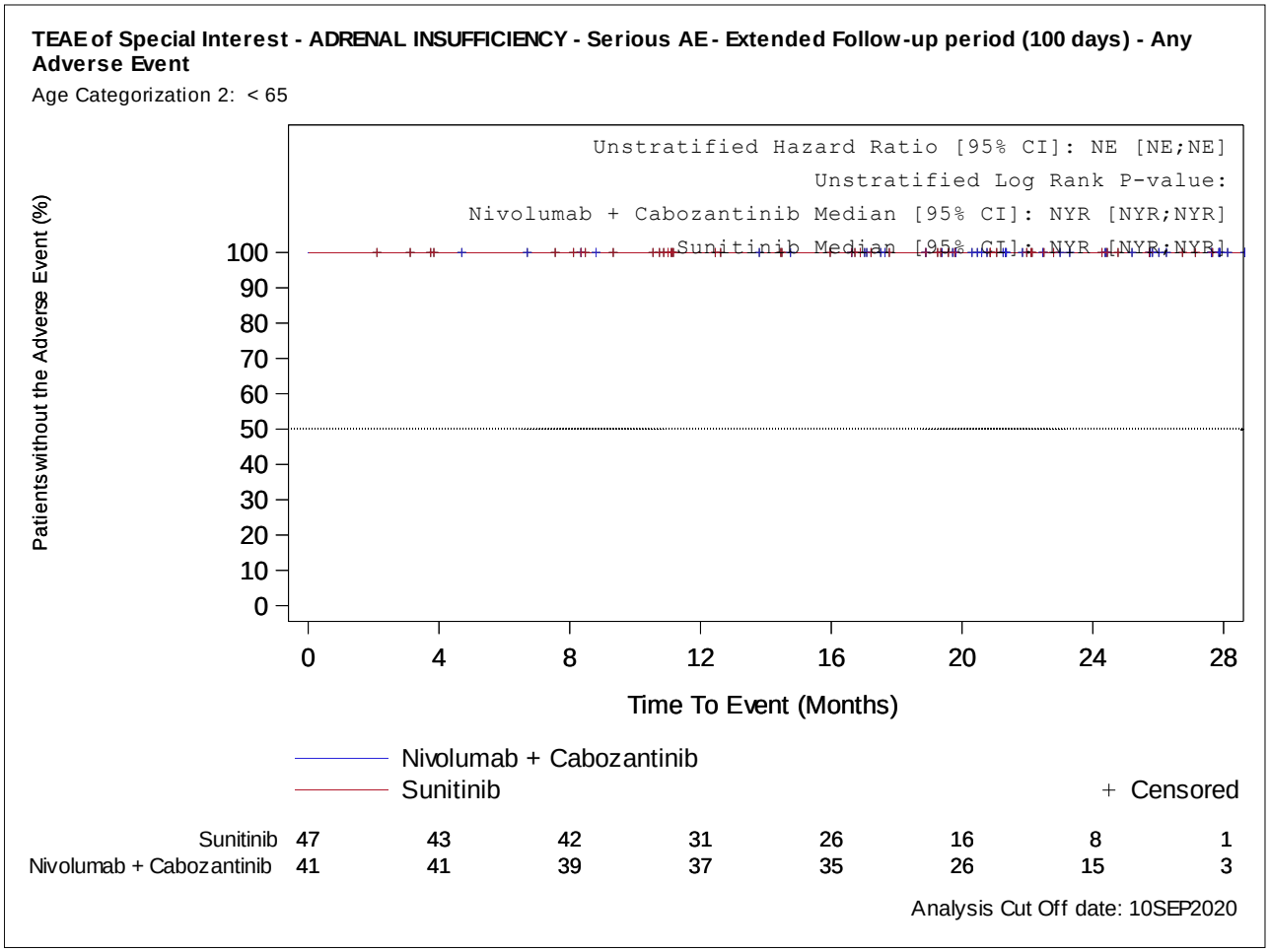

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:41:02

FIGURE 3.64.2.2: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



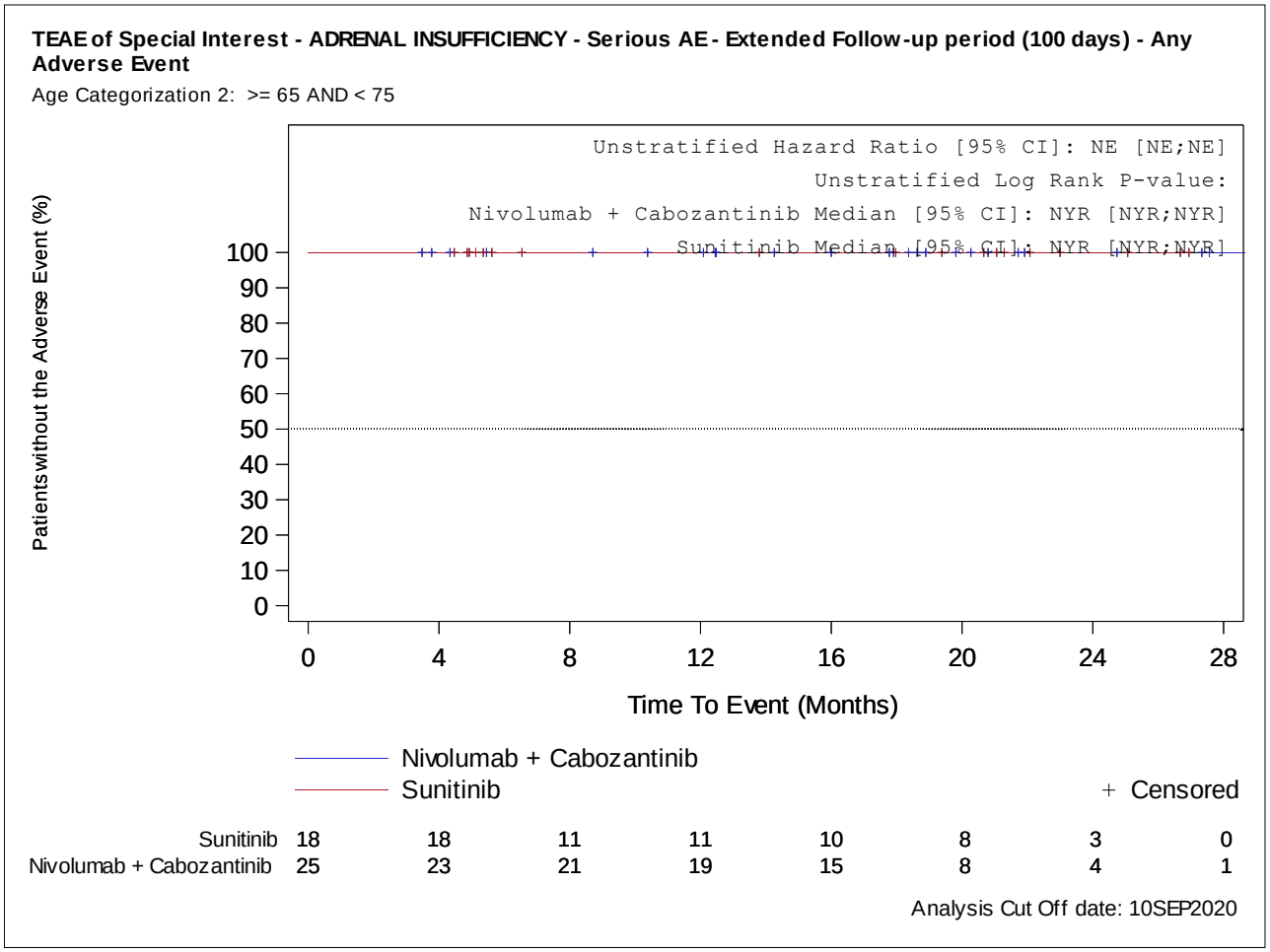

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:41:07

FIGURE 3.64.2.3: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



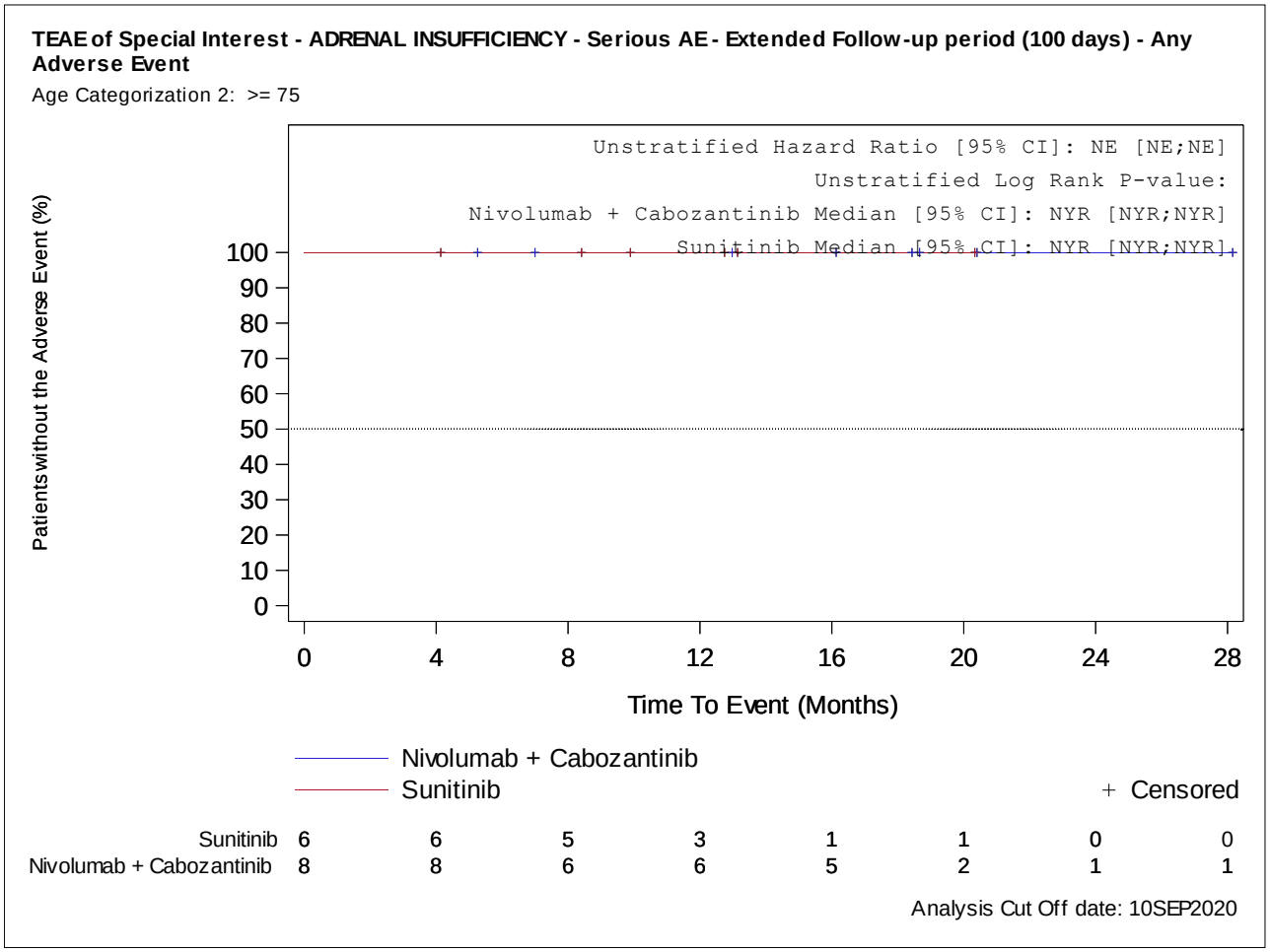

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:41:13

FIGURE 3.64.2.4: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



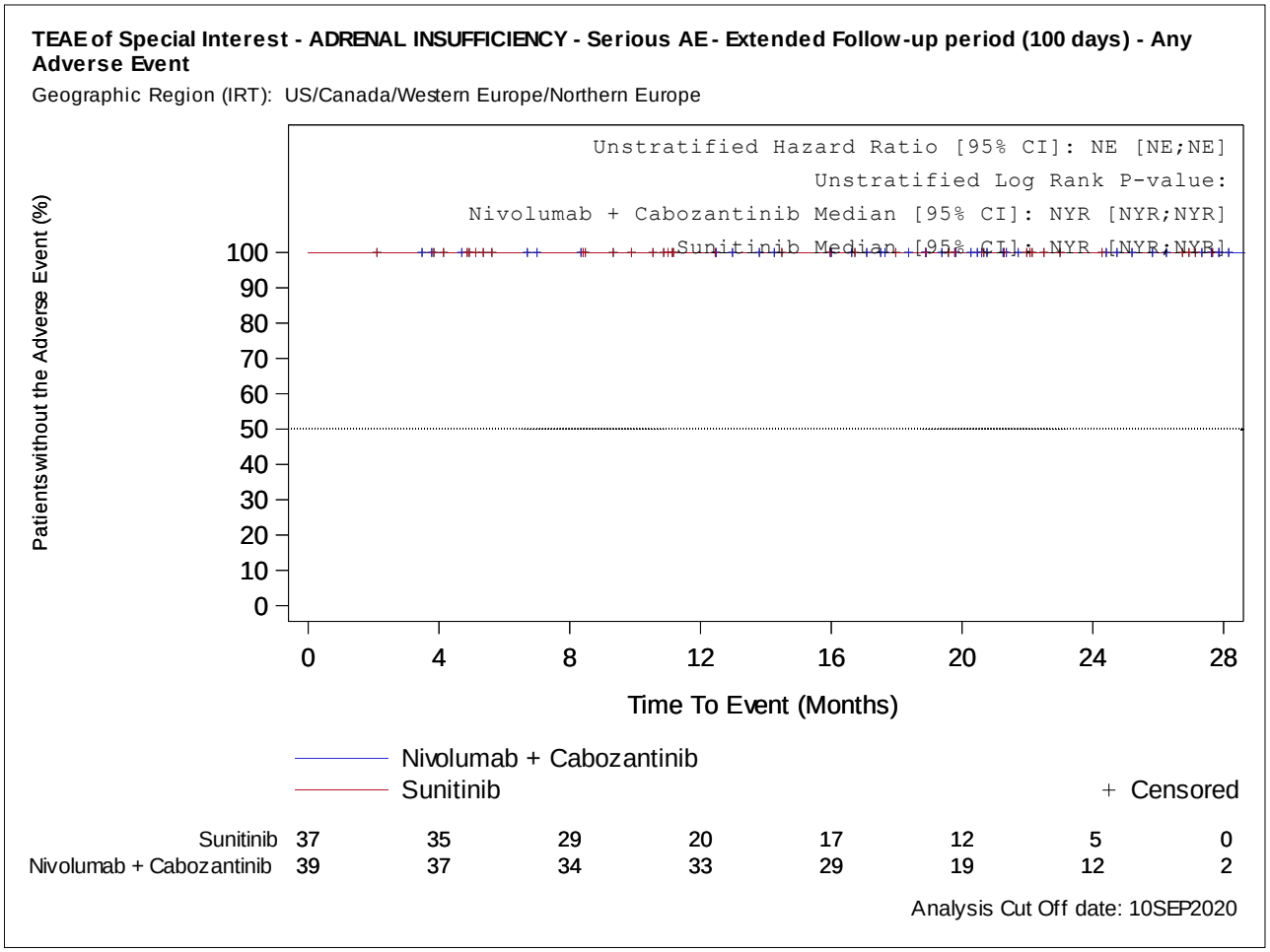

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:41:18

FIGURE 3.64.2.5: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



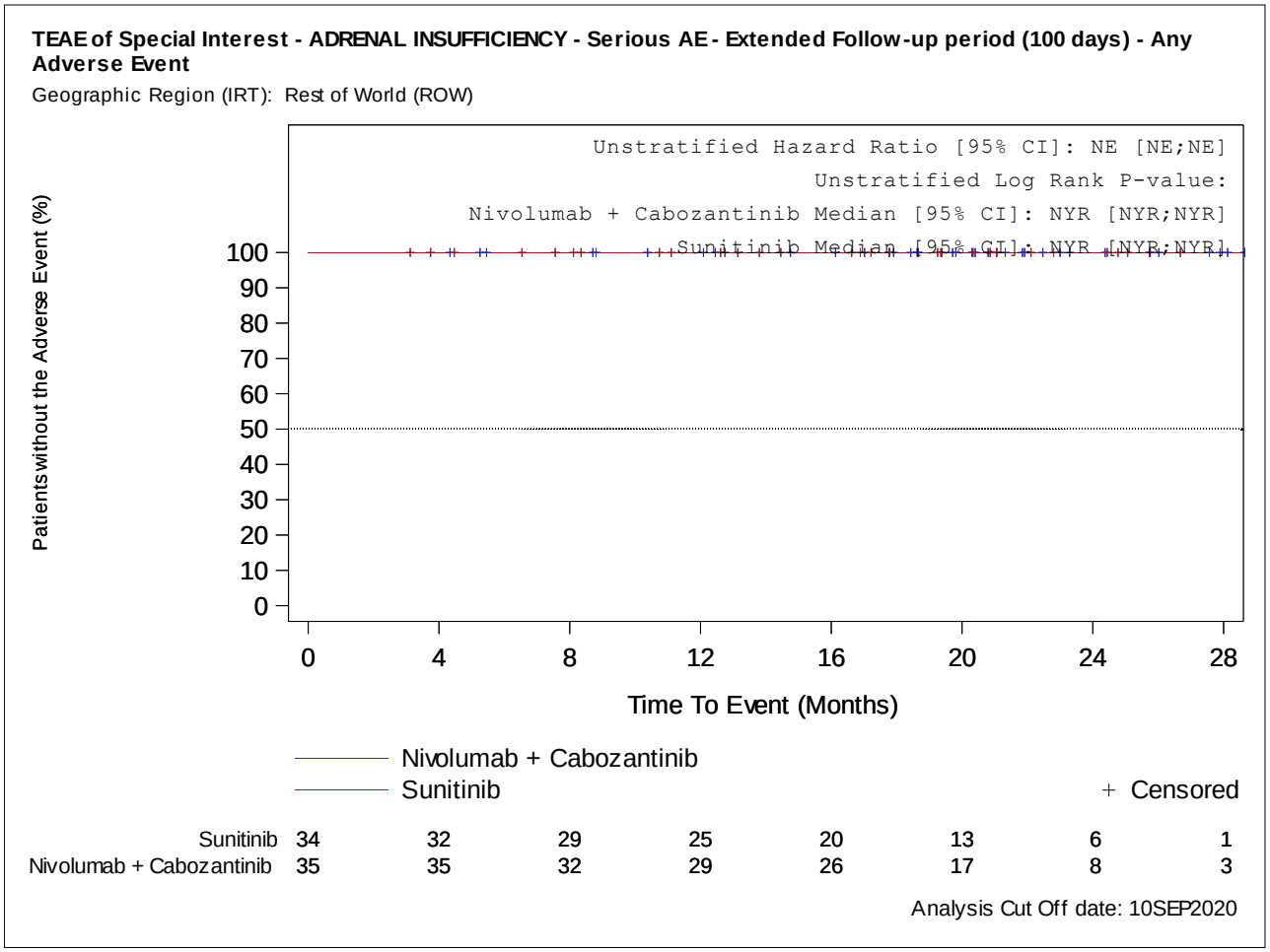

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:41:23

FIGURE 3.64.2.6: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



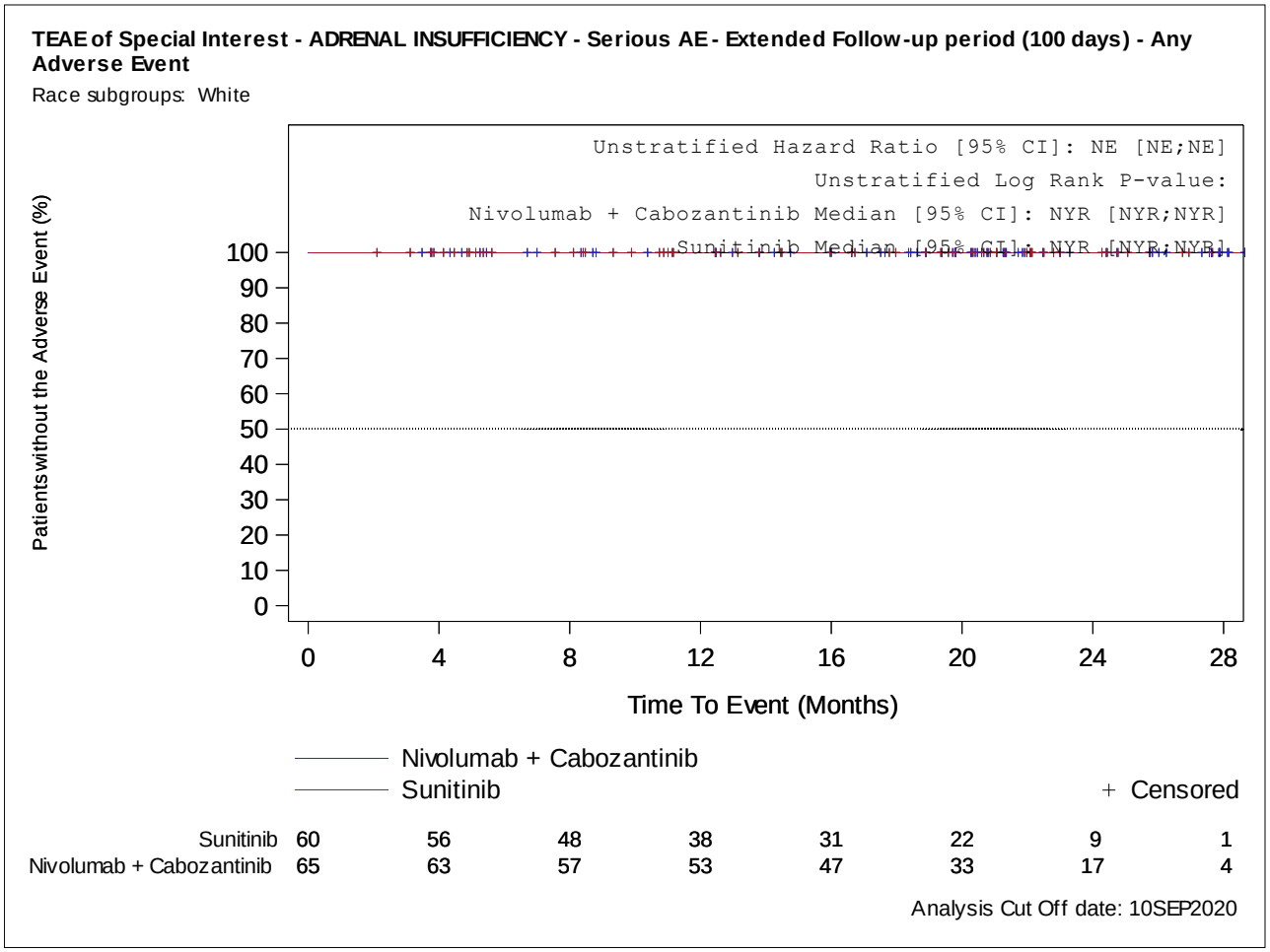

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:41:28

FIGURE 3.64.2.7: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



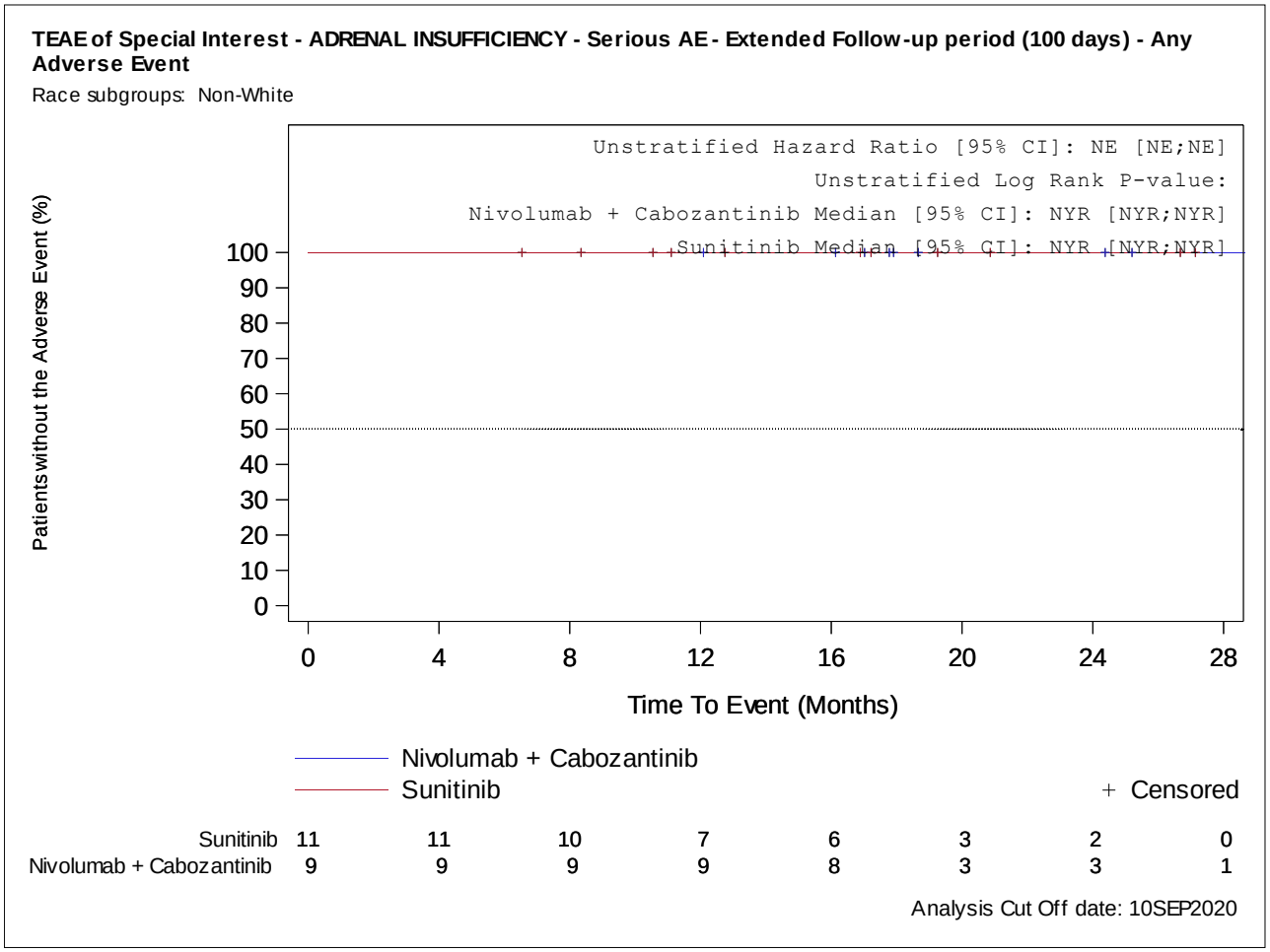

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:41:33

FIGURE 3.64.2.8: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



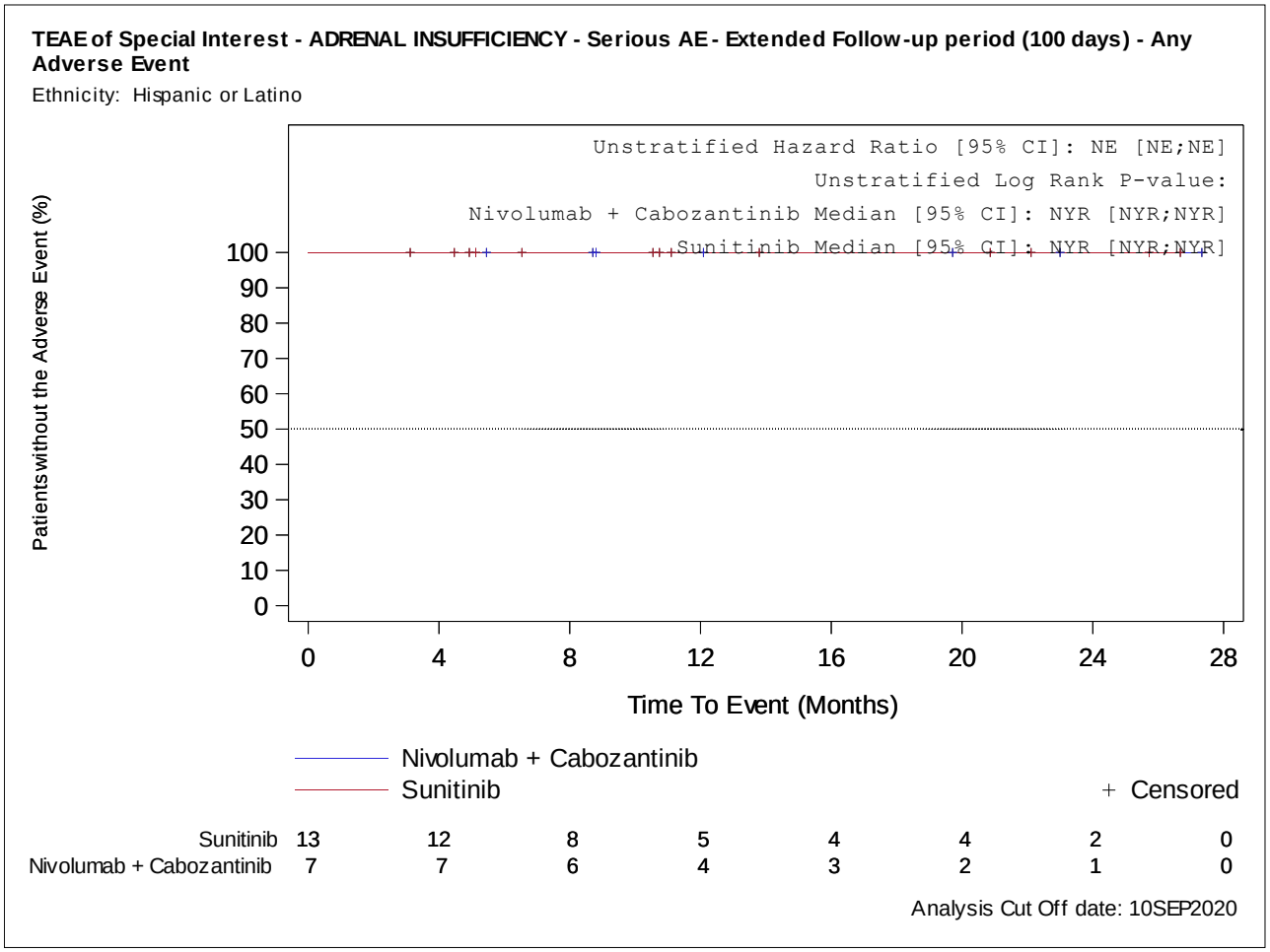

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:41:38

FIGURE 3.64.2.9: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



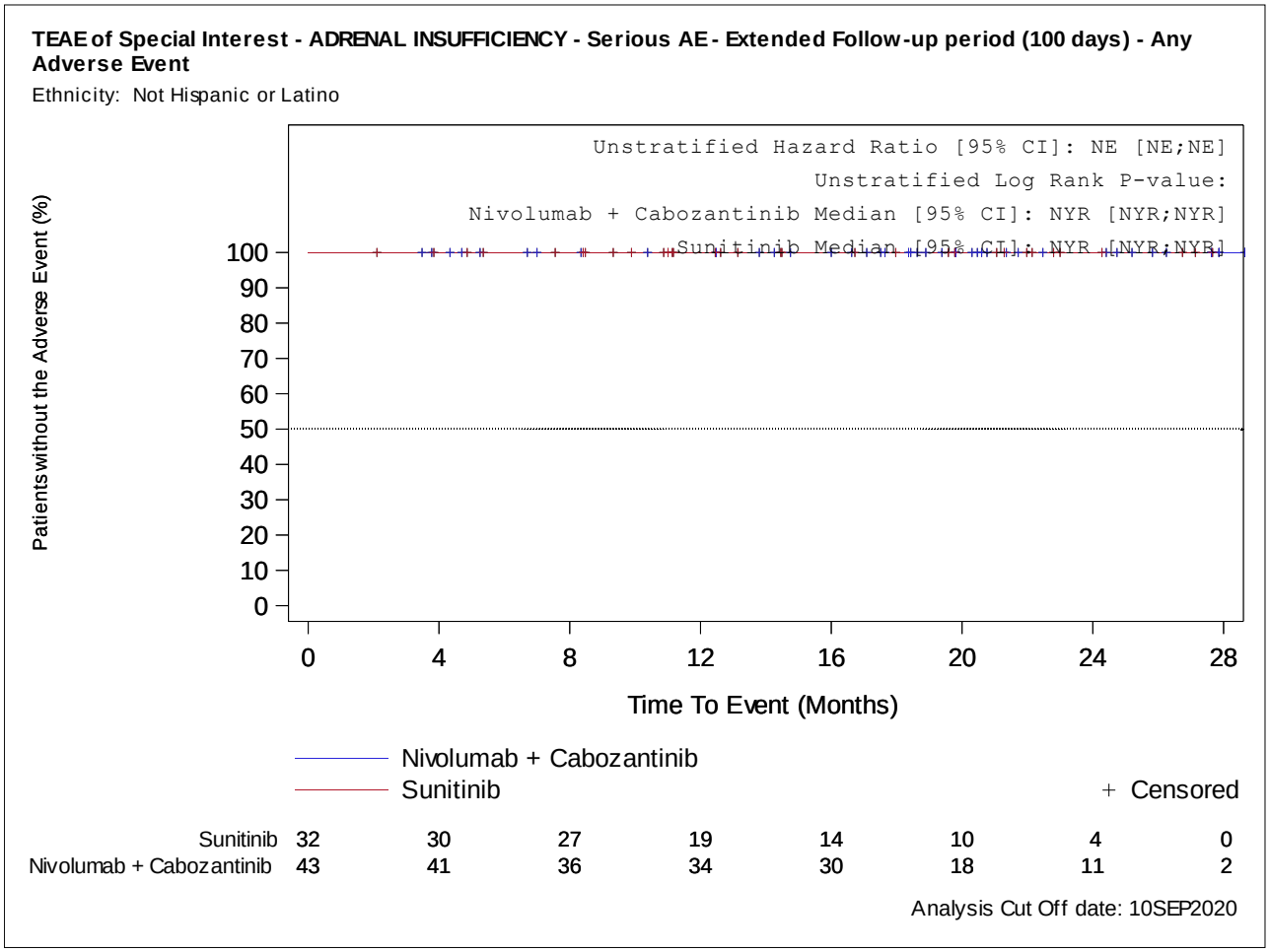

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:41:43

FIGURE 3.64.2.10: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



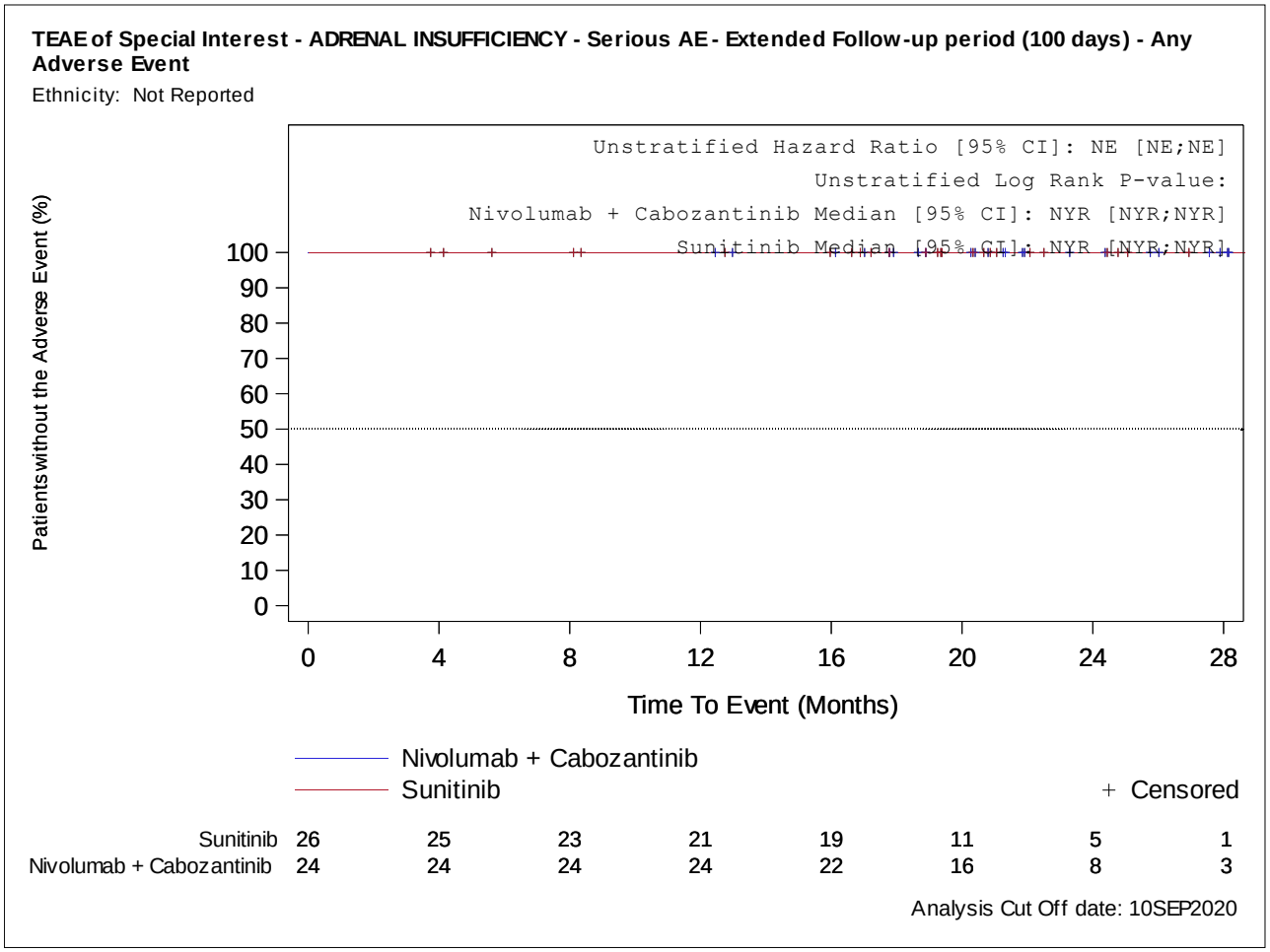

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:41:49

FIGURE 3.64.2.11: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



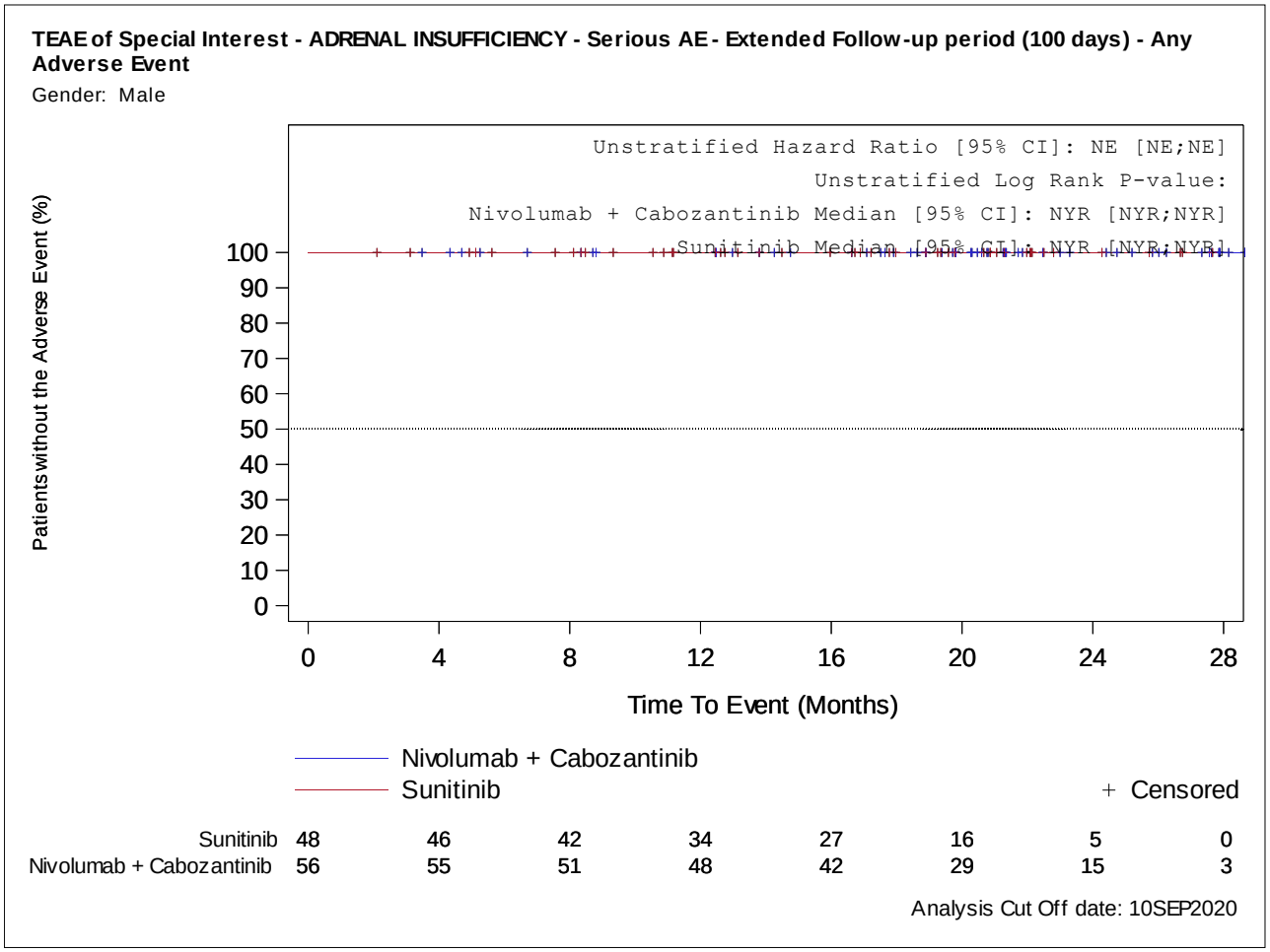

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:41:54

FIGURE 3.64.2.12: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



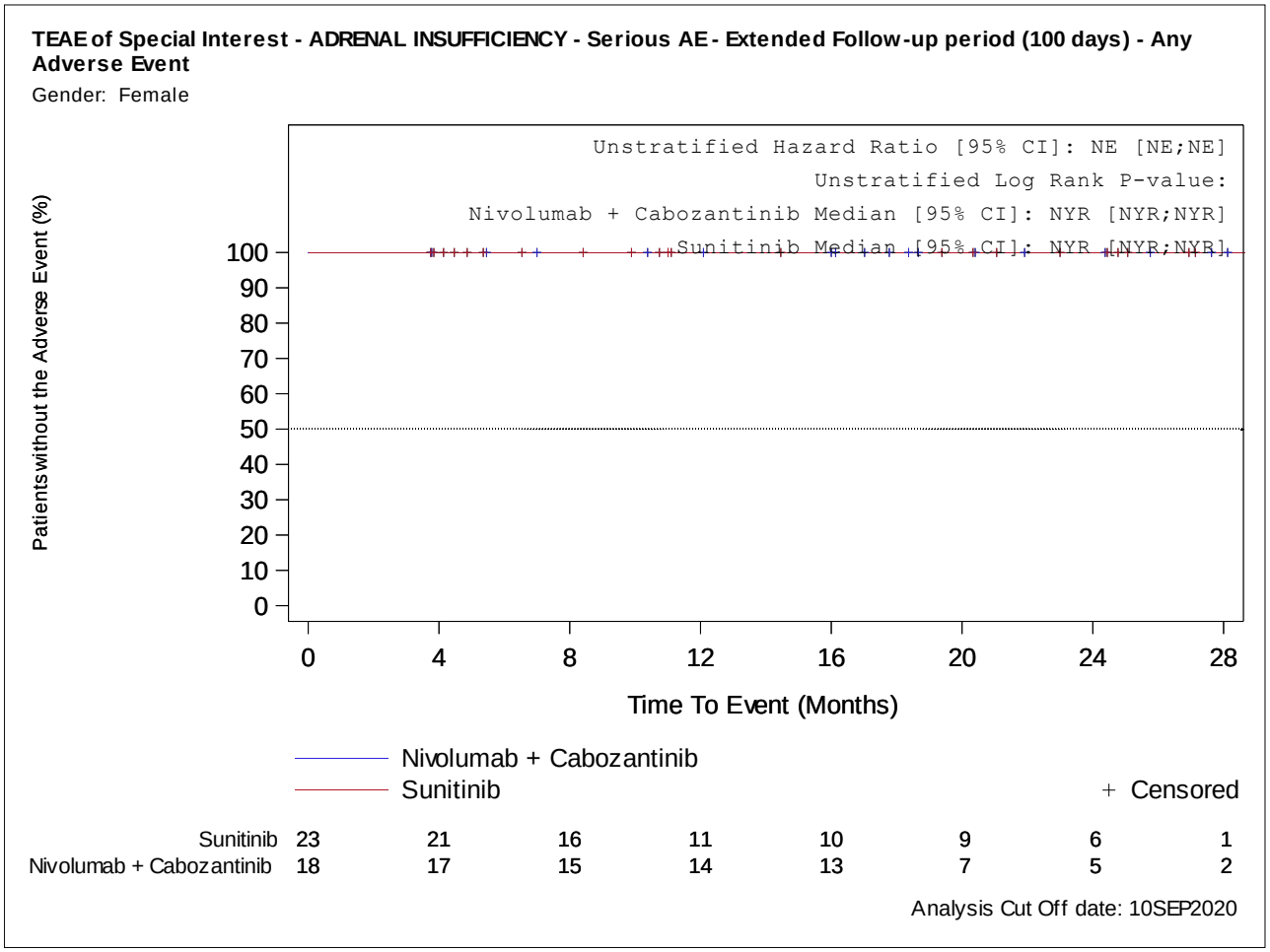

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:41:59

FIGURE 3.64.2.13: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



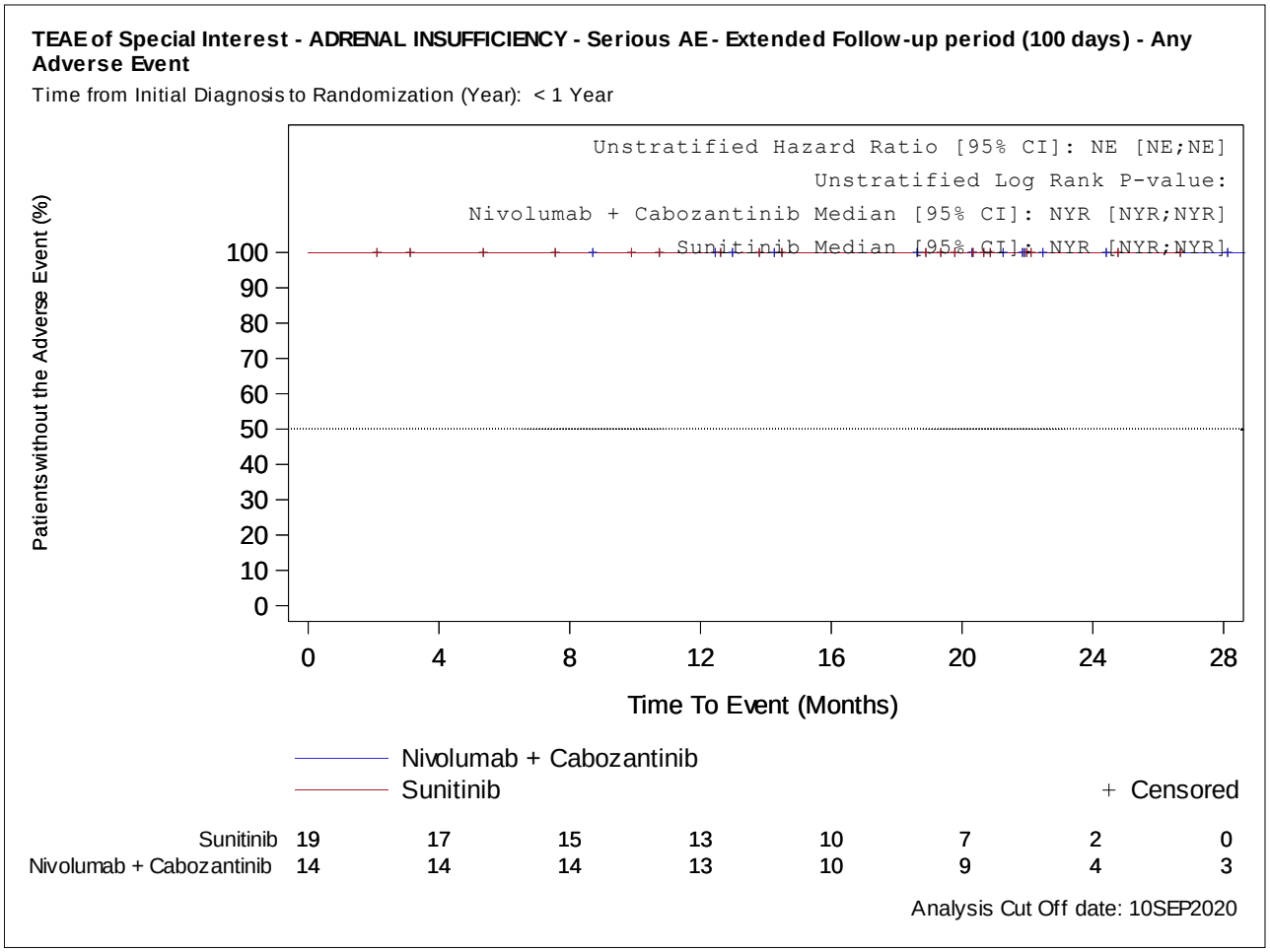

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:42:04

FIGURE 3.64.2.14: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:42:10

FIGURE 3.64.2.15: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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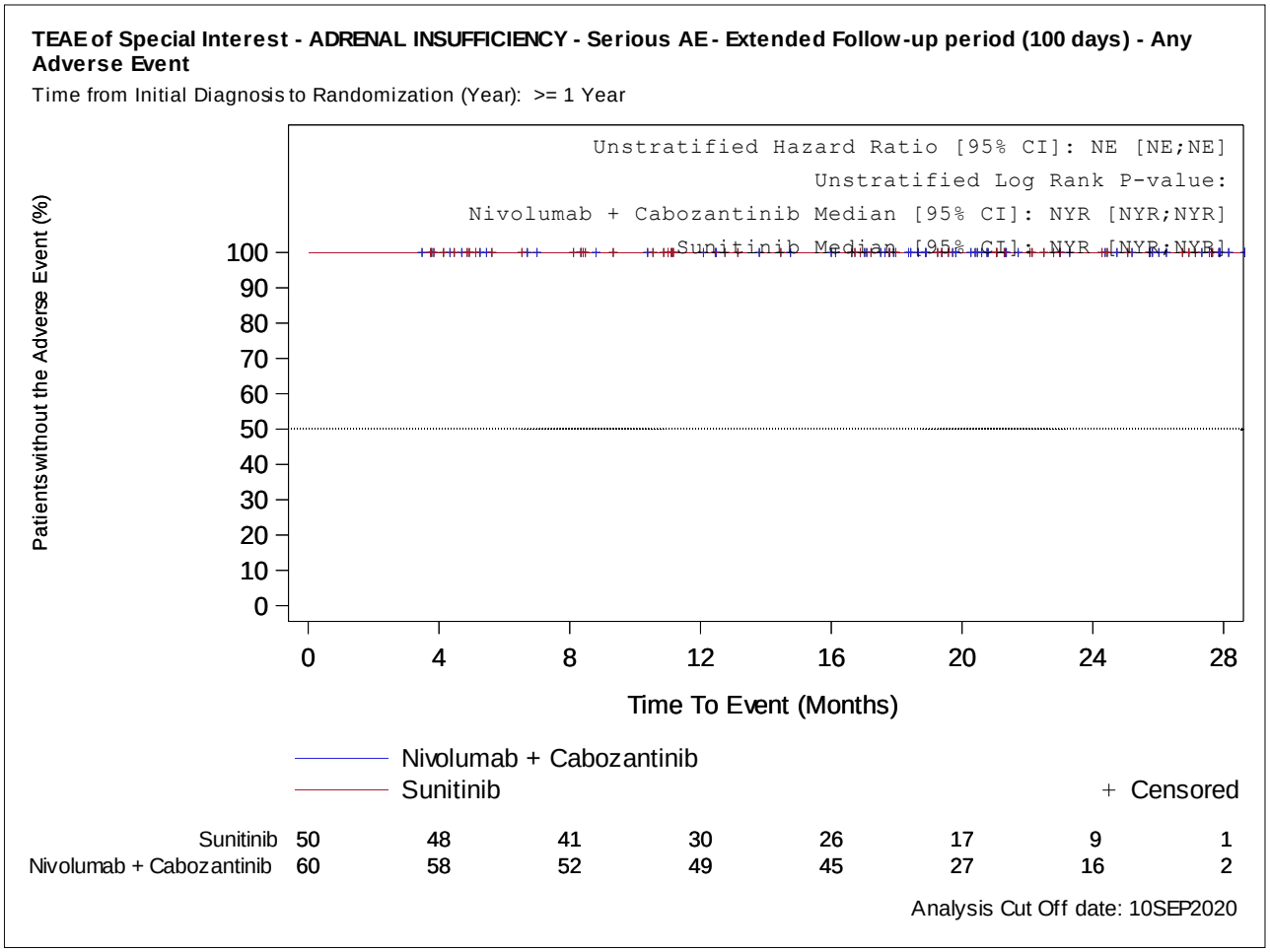
FIGURE 3.64.2.16: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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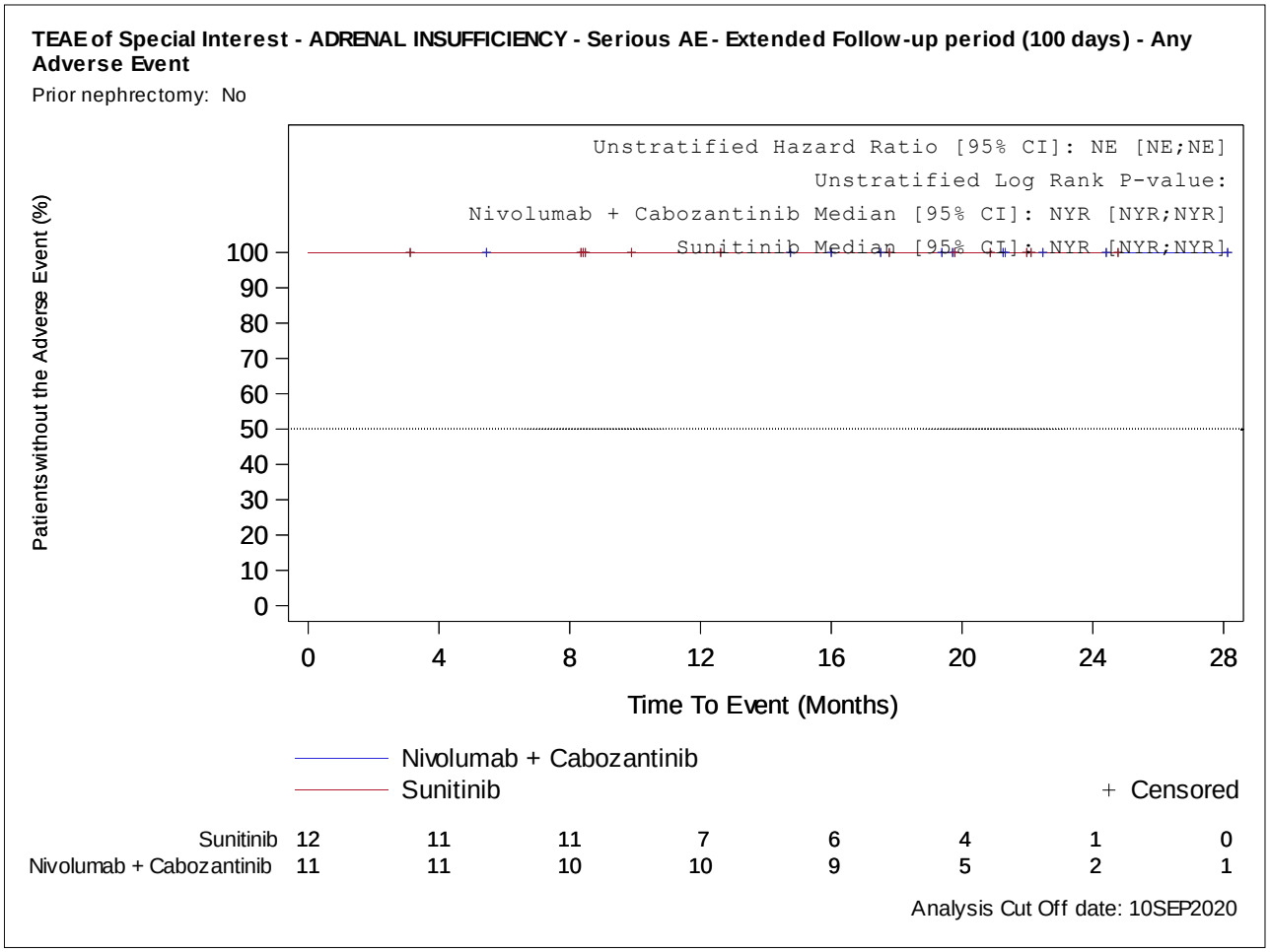
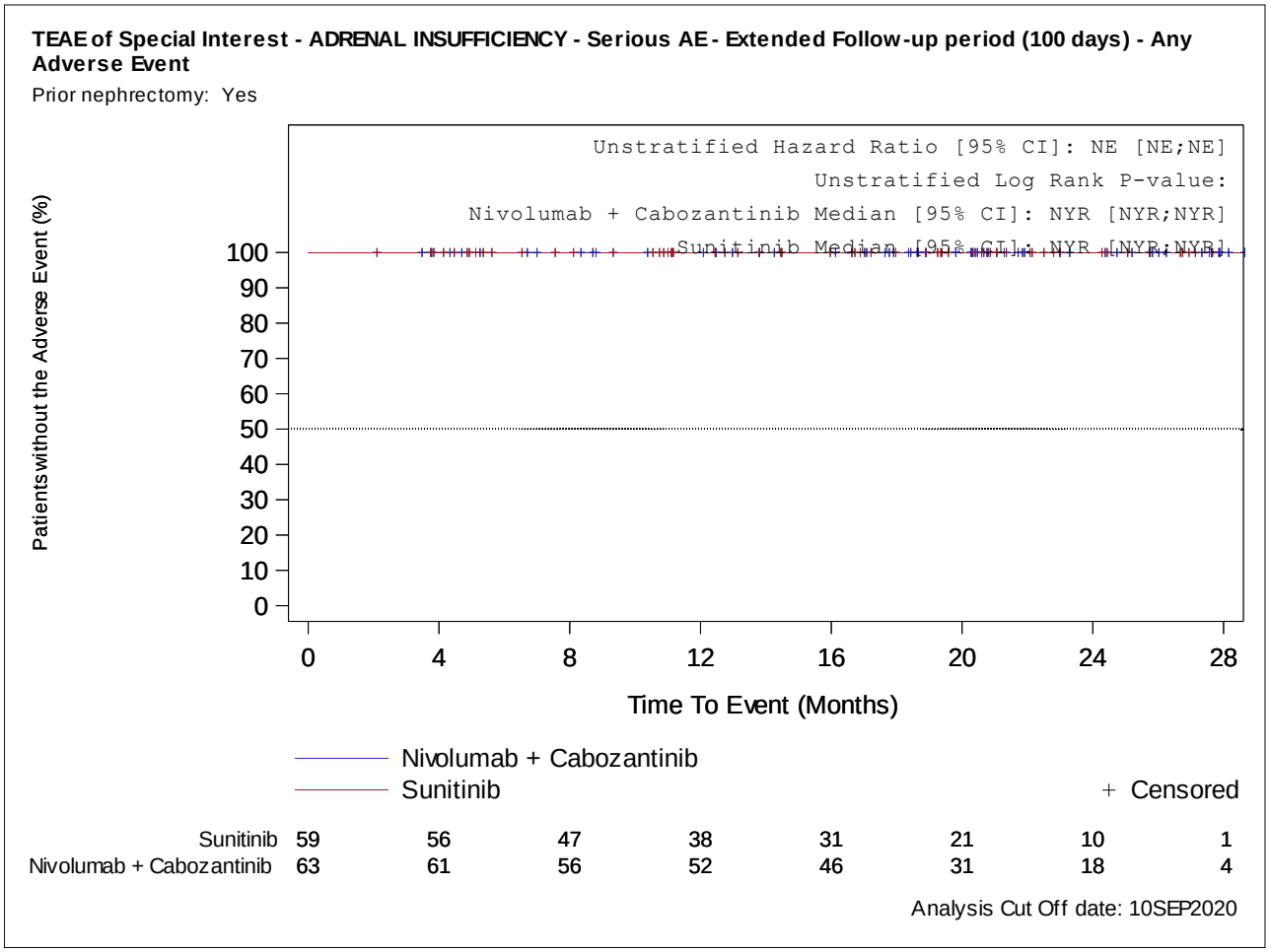
FIGURE 3.64.2.17: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:43:18

FIGURE 3.64.2.18: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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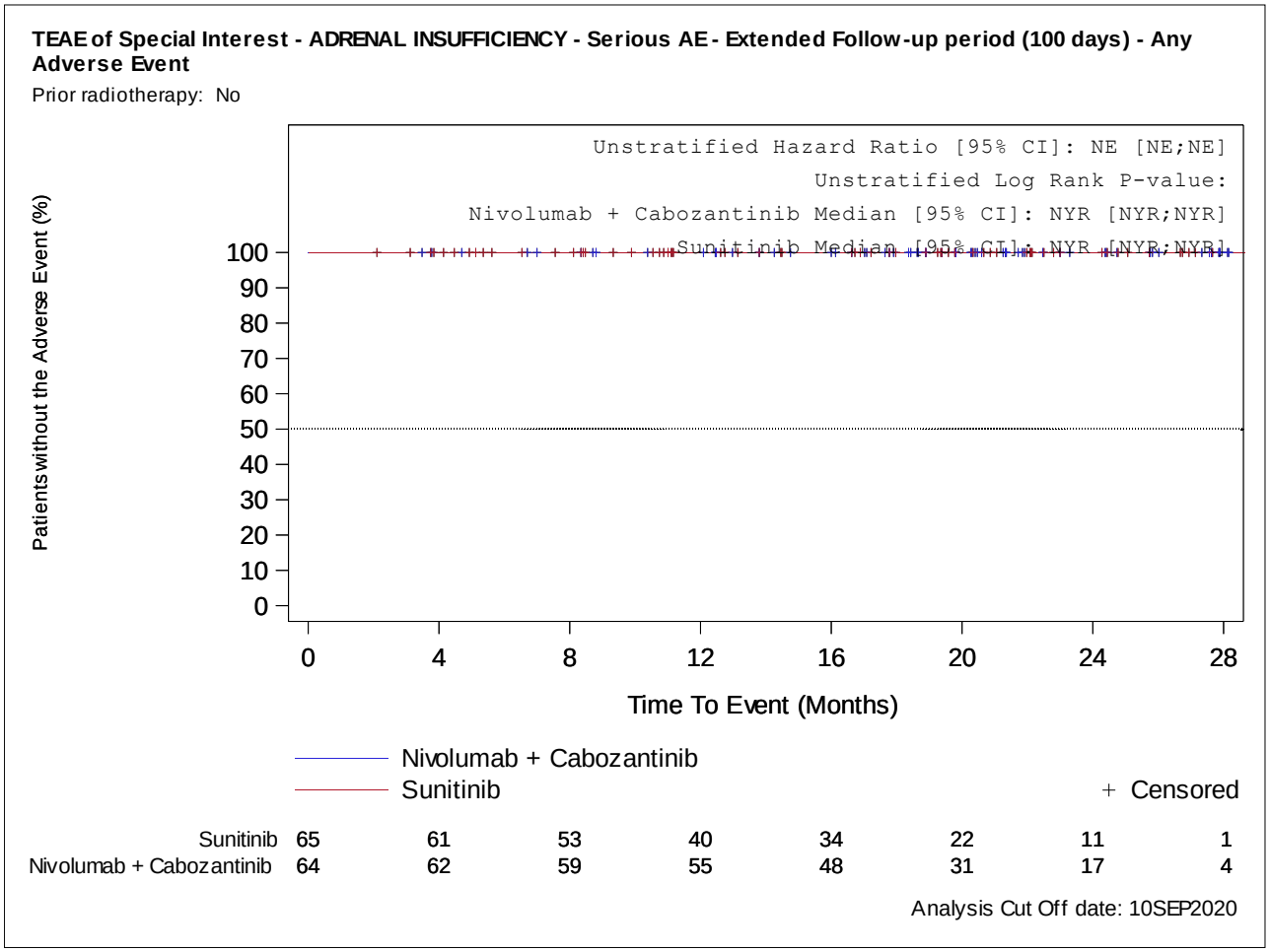
FIGURE 3.64.2.19: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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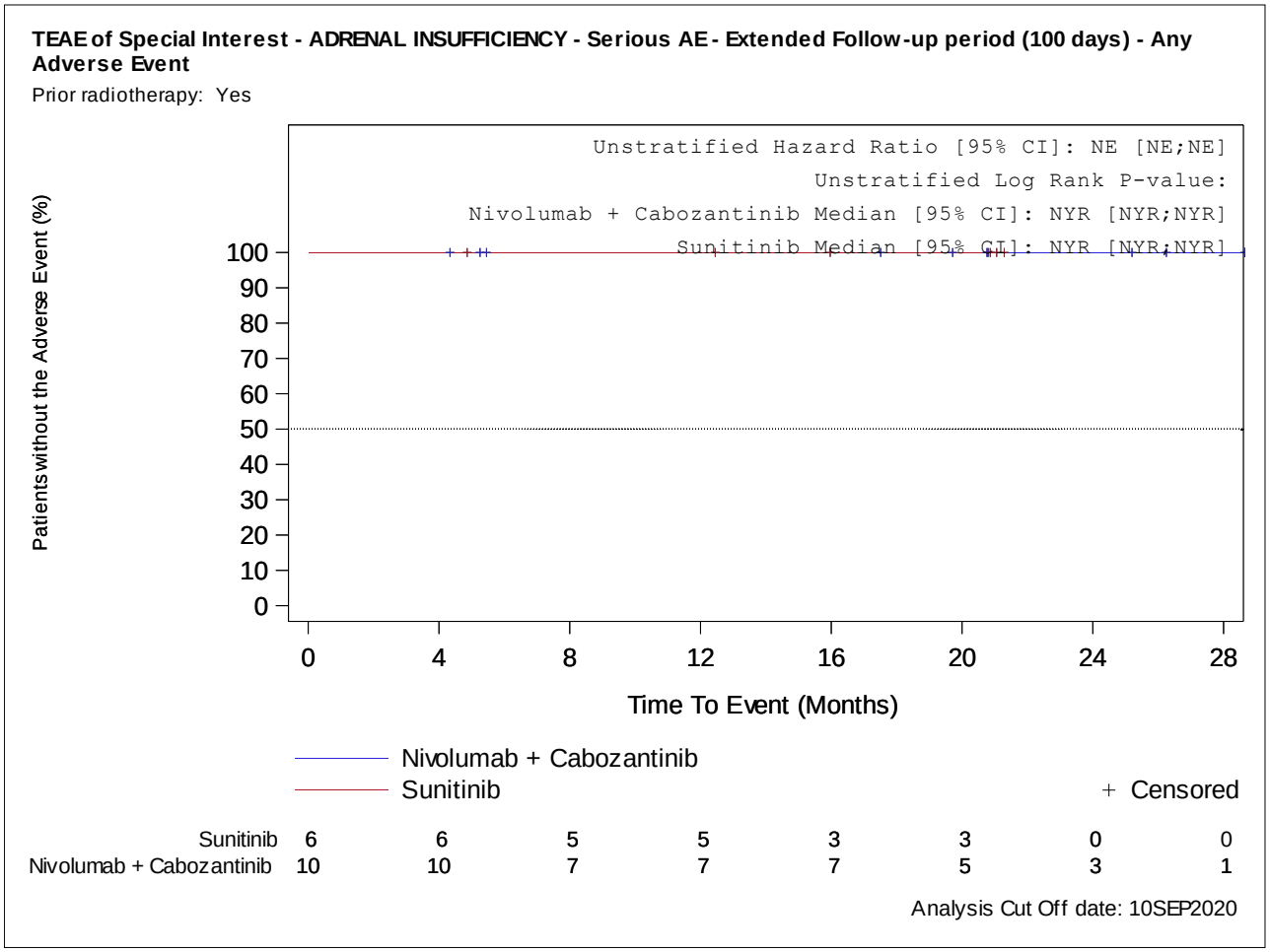
FIGURE 3.64.2.20: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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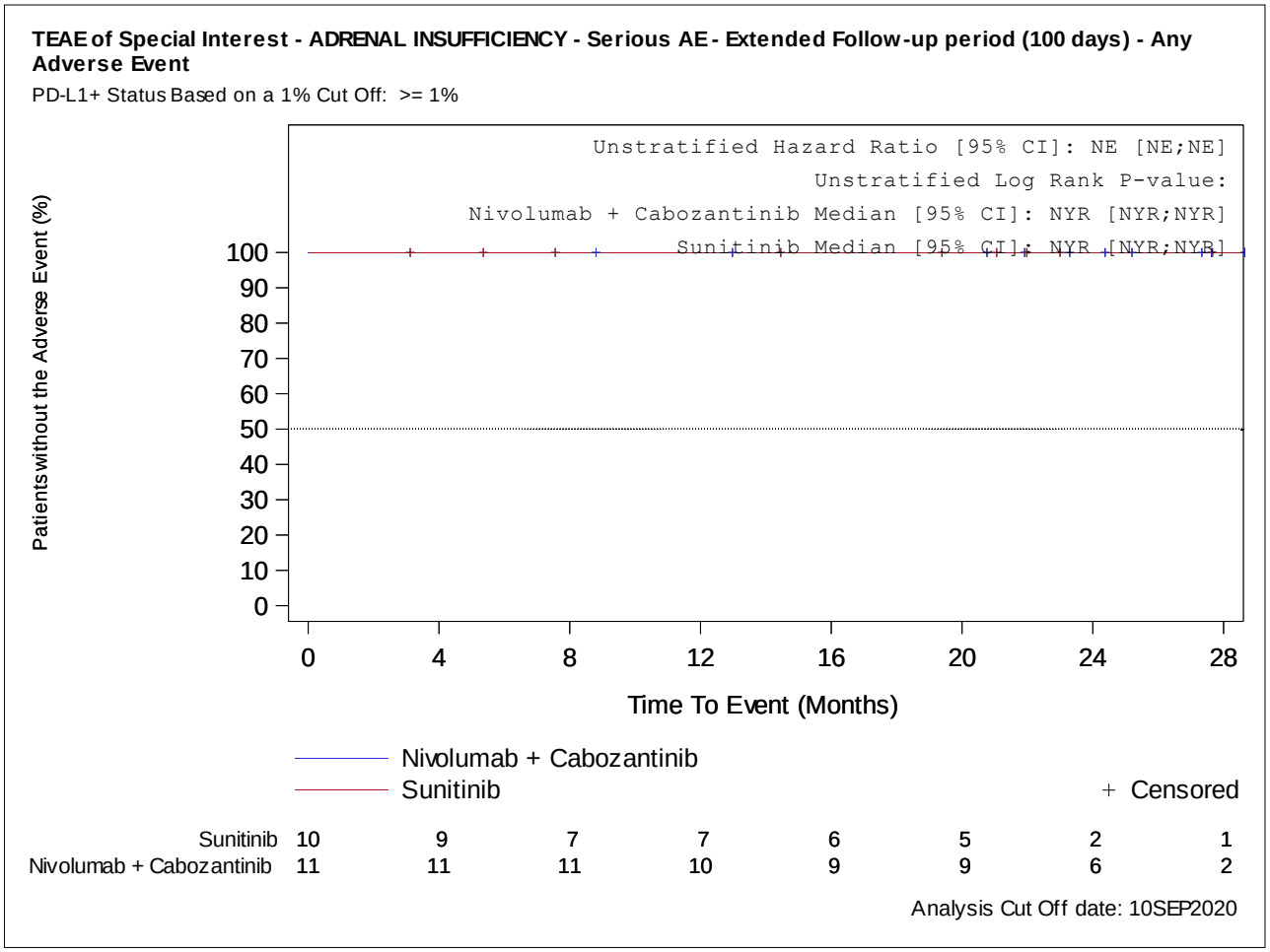
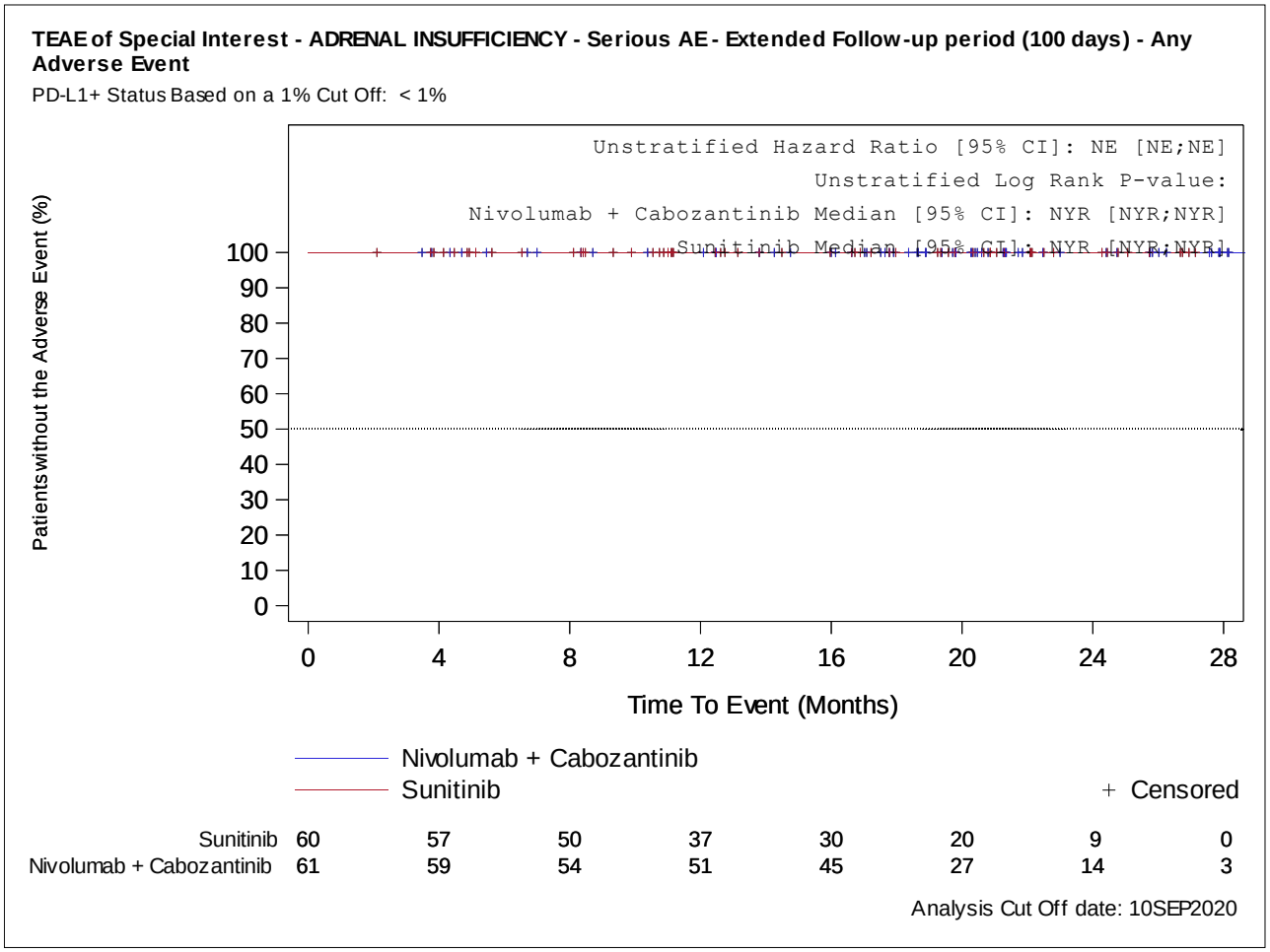
FIGURE 3.64.2.21: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



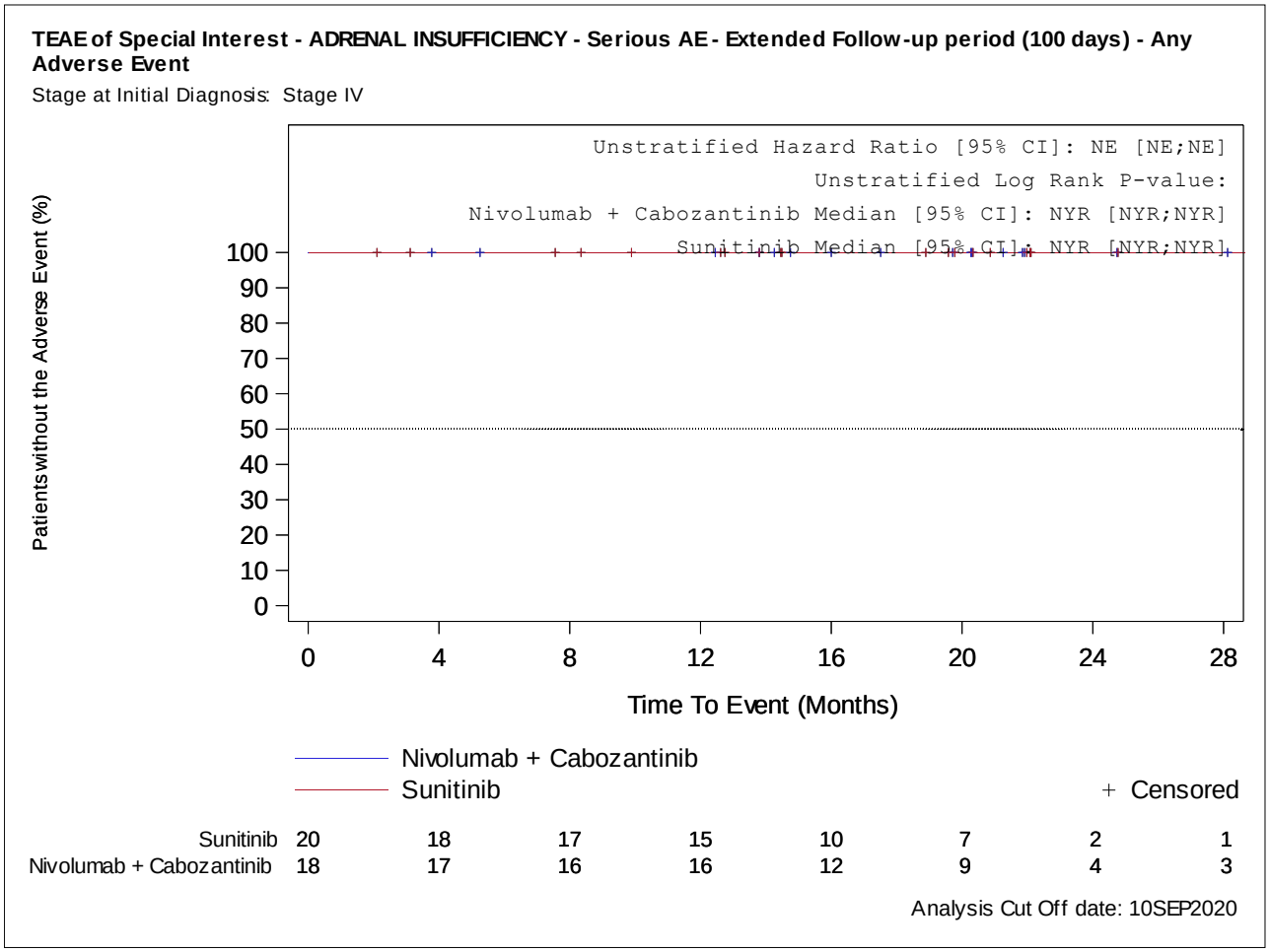

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:43:38

FIGURE 3.64.2.22: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



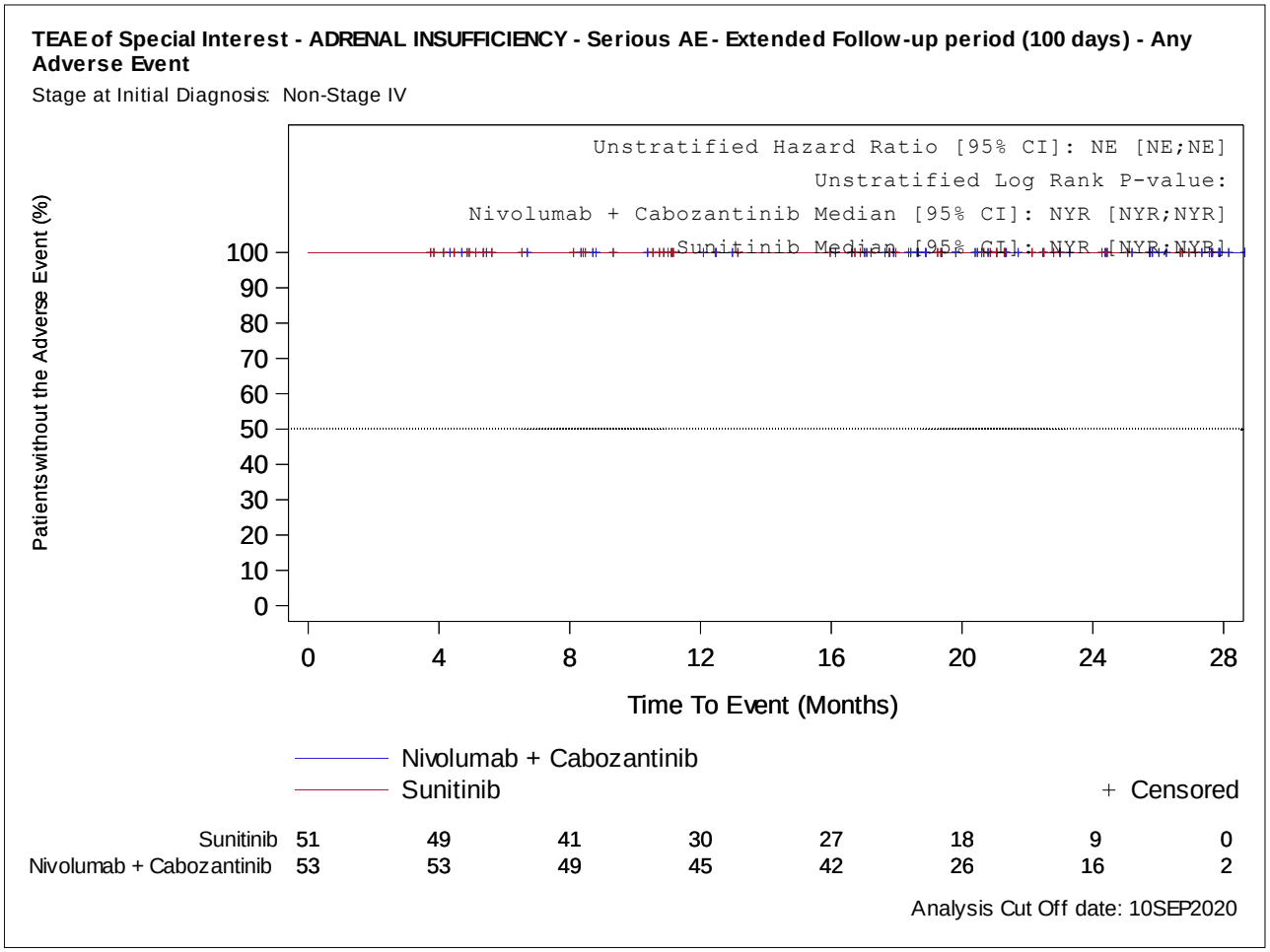

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:43:44

FIGURE 3.64.2.23: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



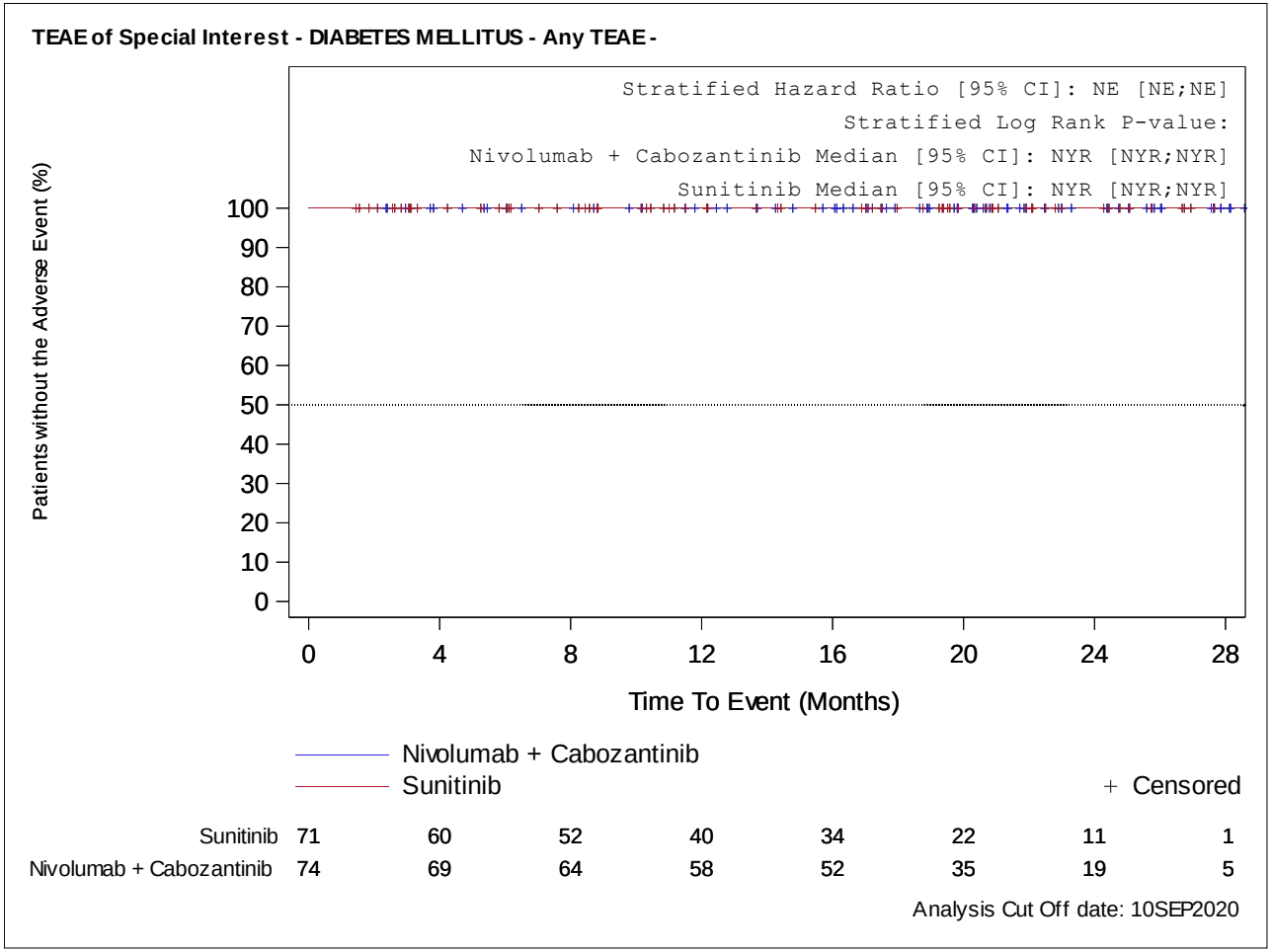

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:44:10

FIGURE 3.64.2.24: Kaplan-Meier curve - TEAE of Special Interest - ADRENAL INSUFFICIENCY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



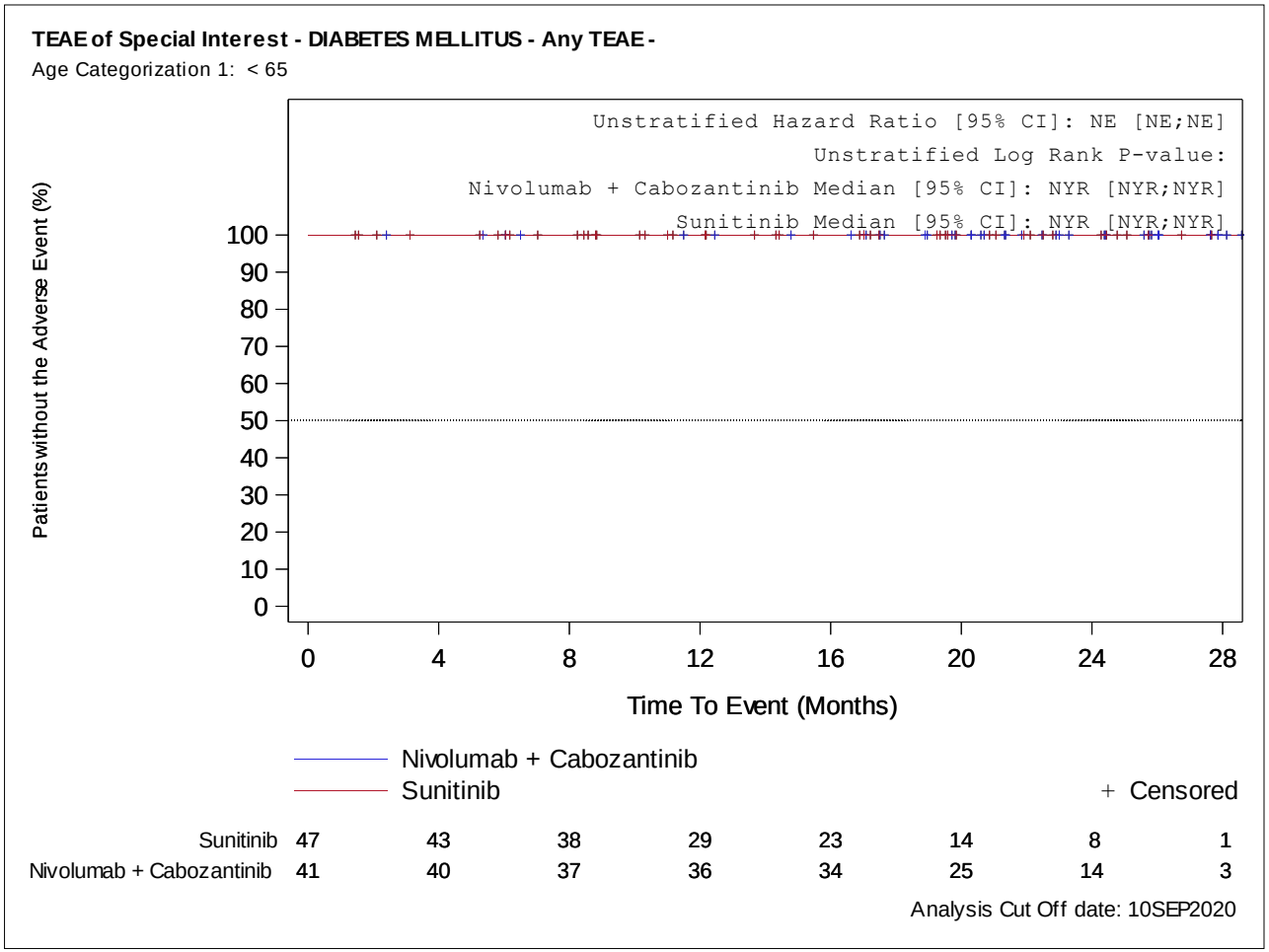

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:44:15

FIGURE 3.65.1: TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



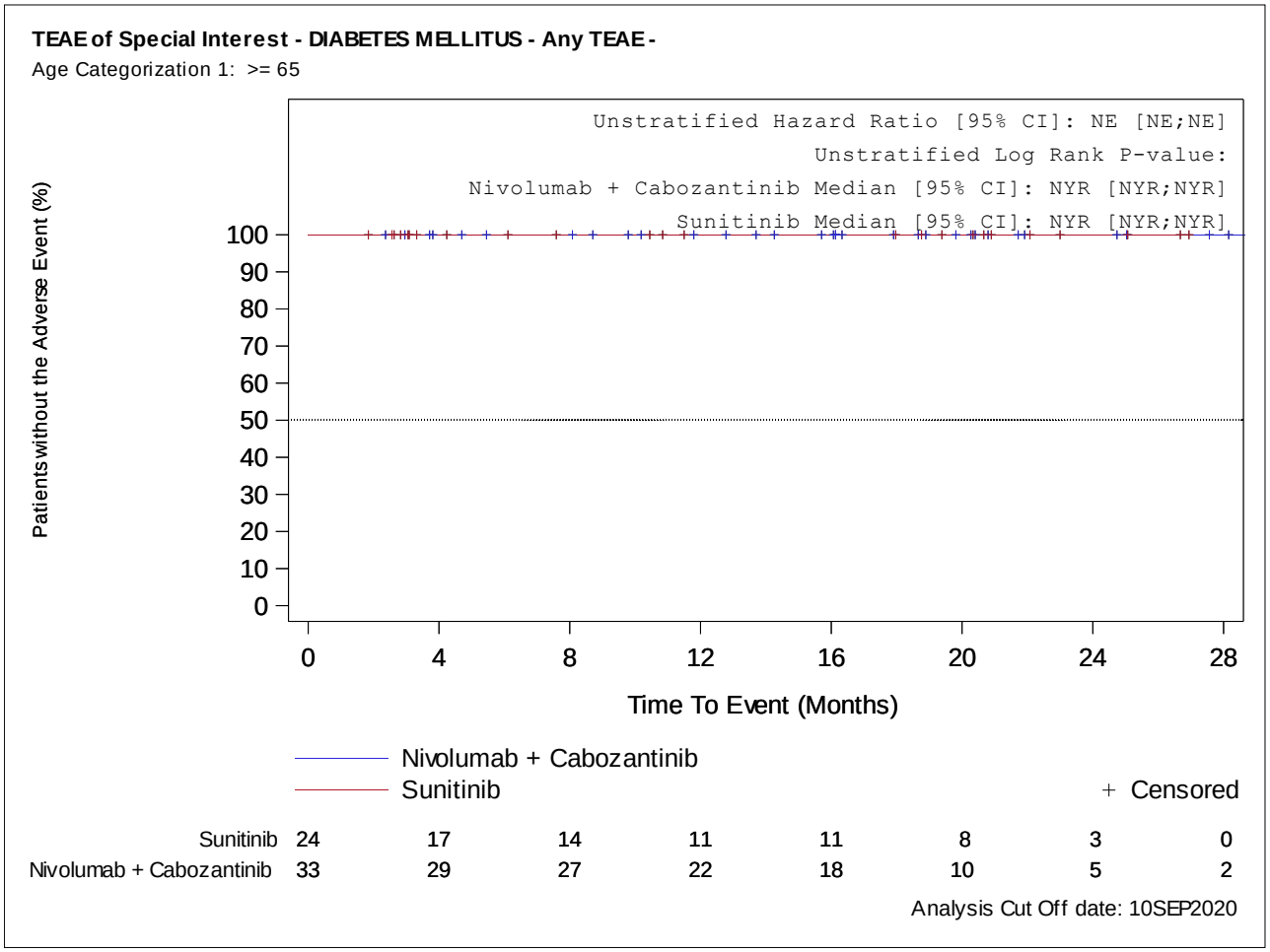

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:34:50

FIGURE 3.65.2.1: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  < 65



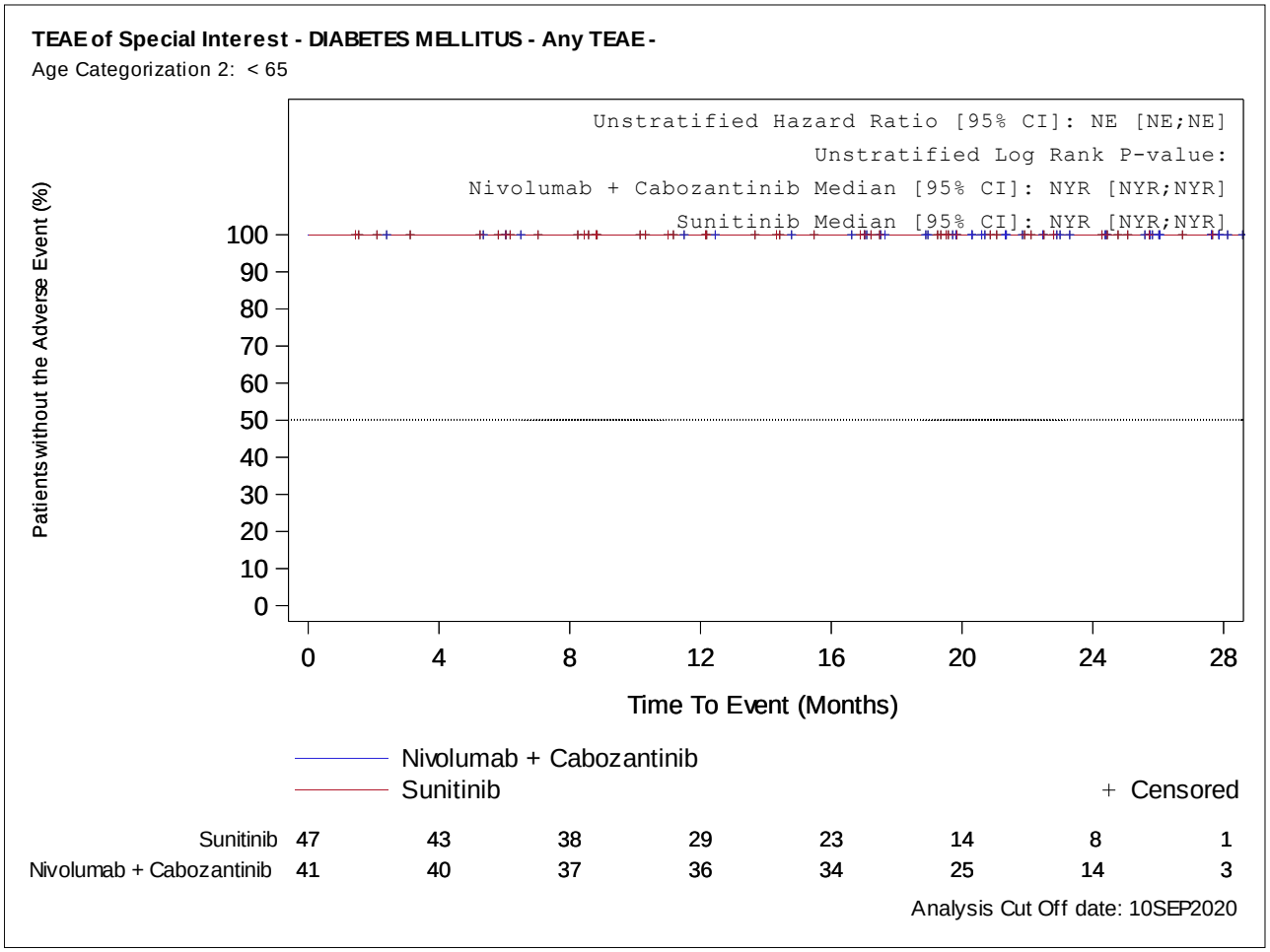

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:34:53

FIGURE 3.65.2.2: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



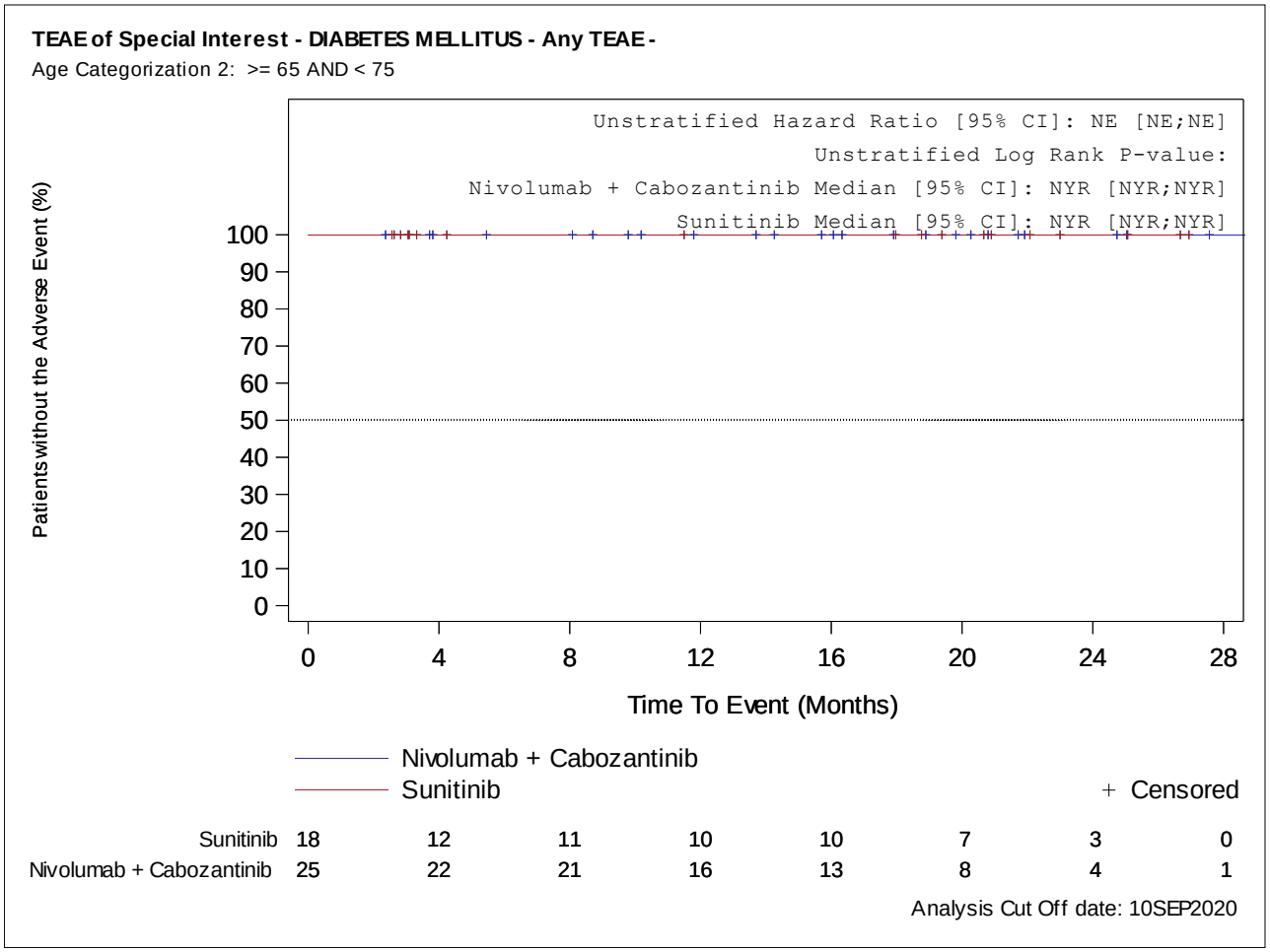

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:34:58

FIGURE 3.65.2.3: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  < 65



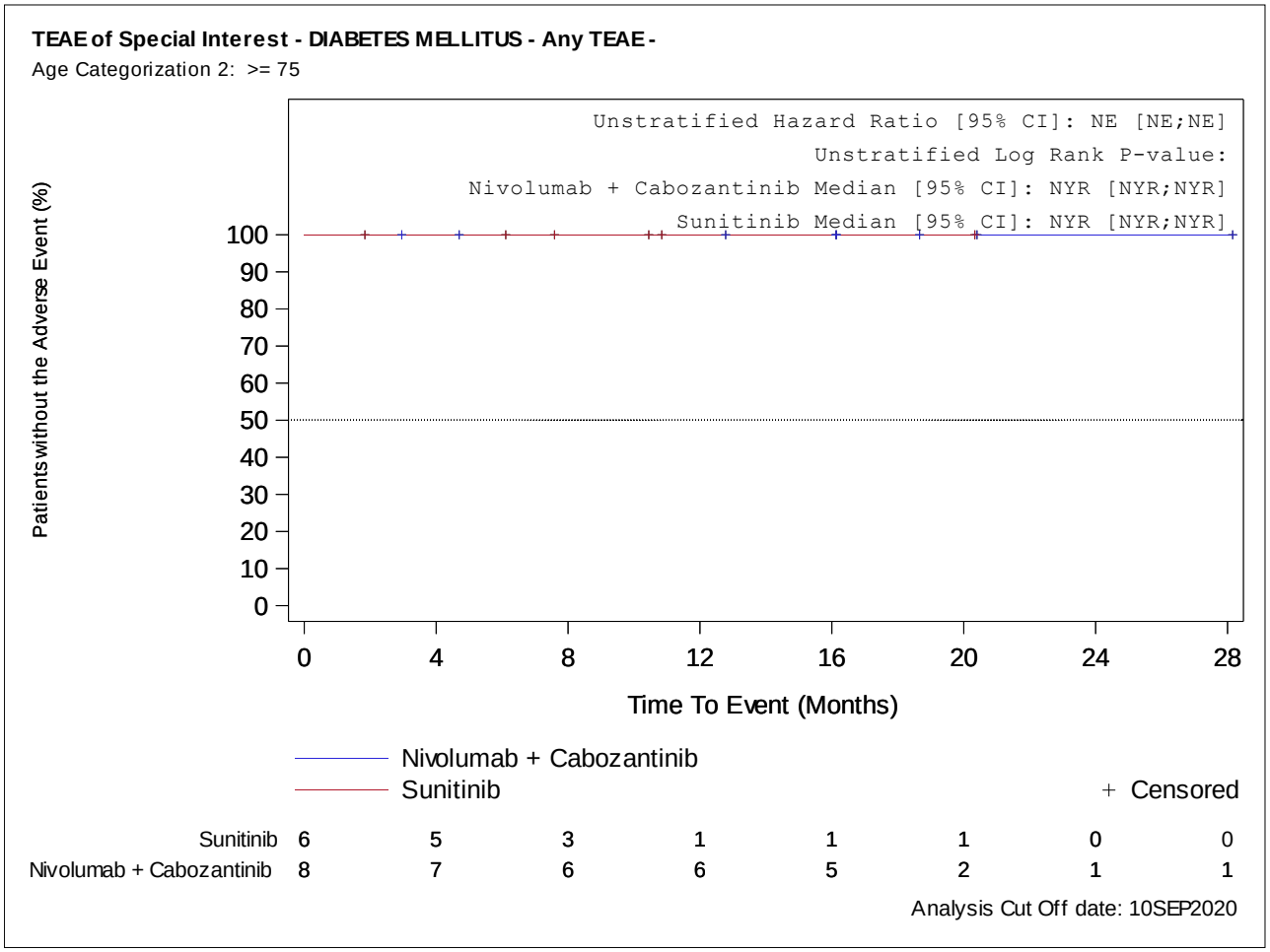

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:35:04

FIGURE 3.65.2.4: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



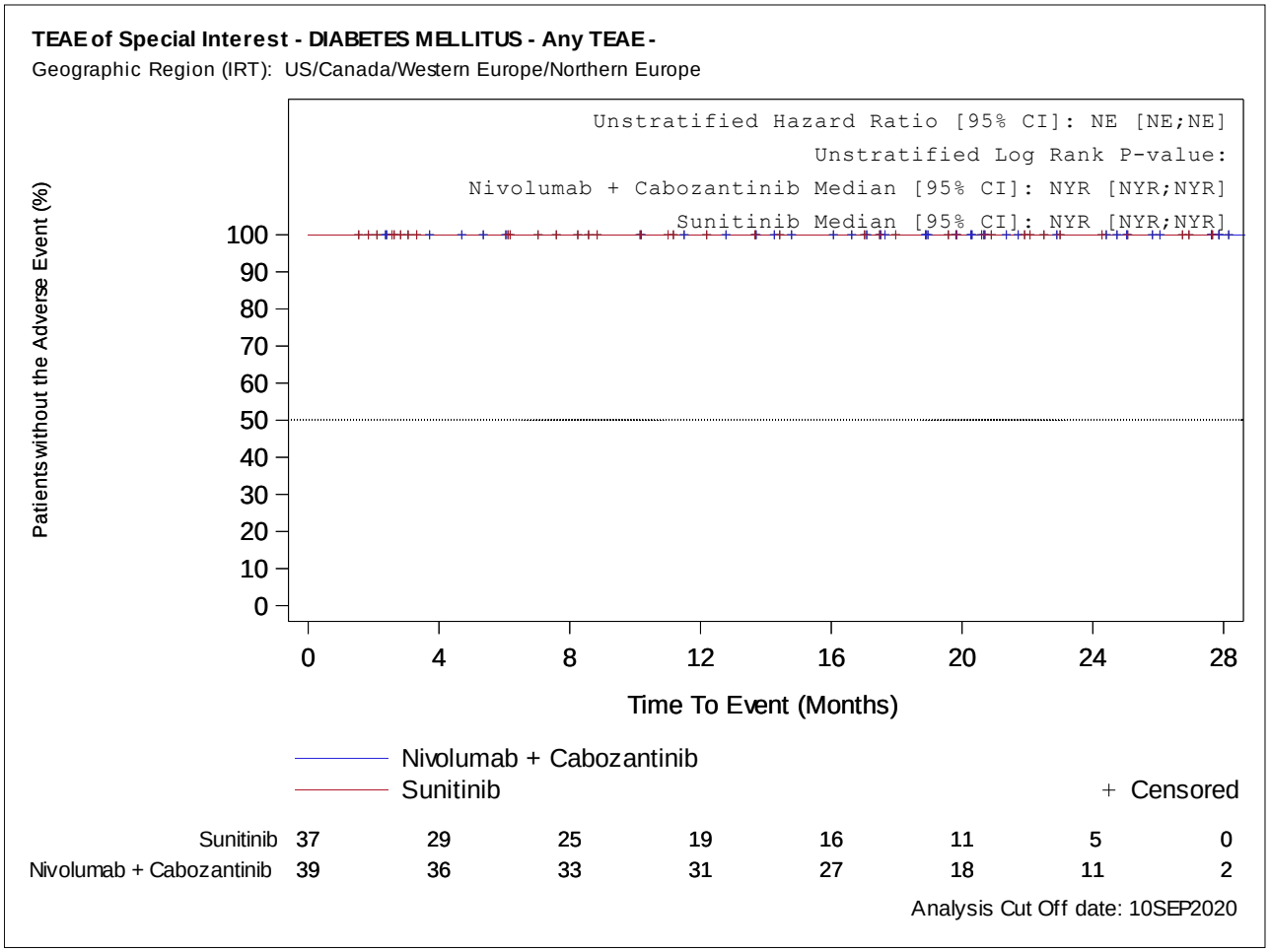

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:35:10

FIGURE 3.65.2.5: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



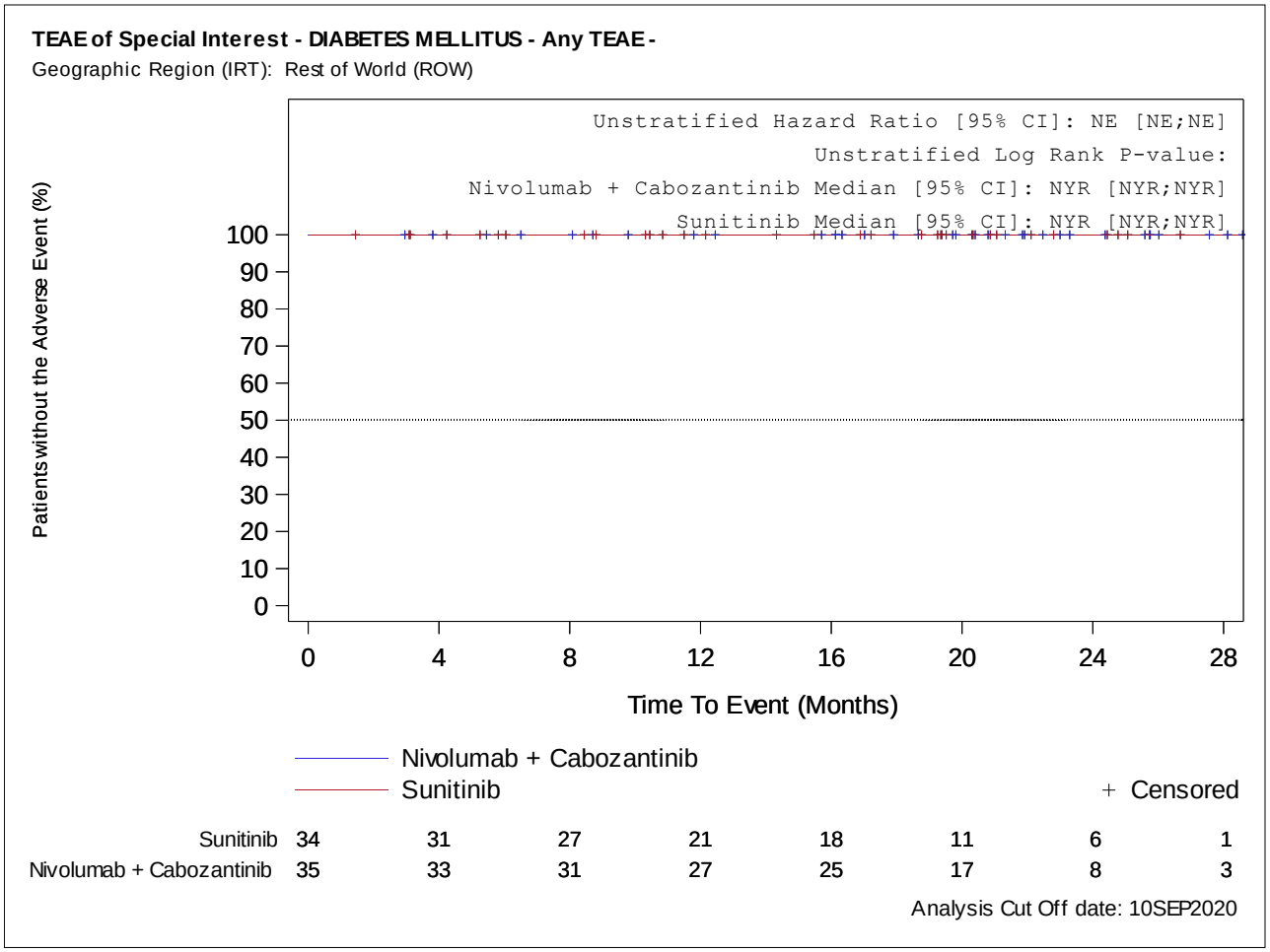

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:35:16

FIGURE 3.65.2.6: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



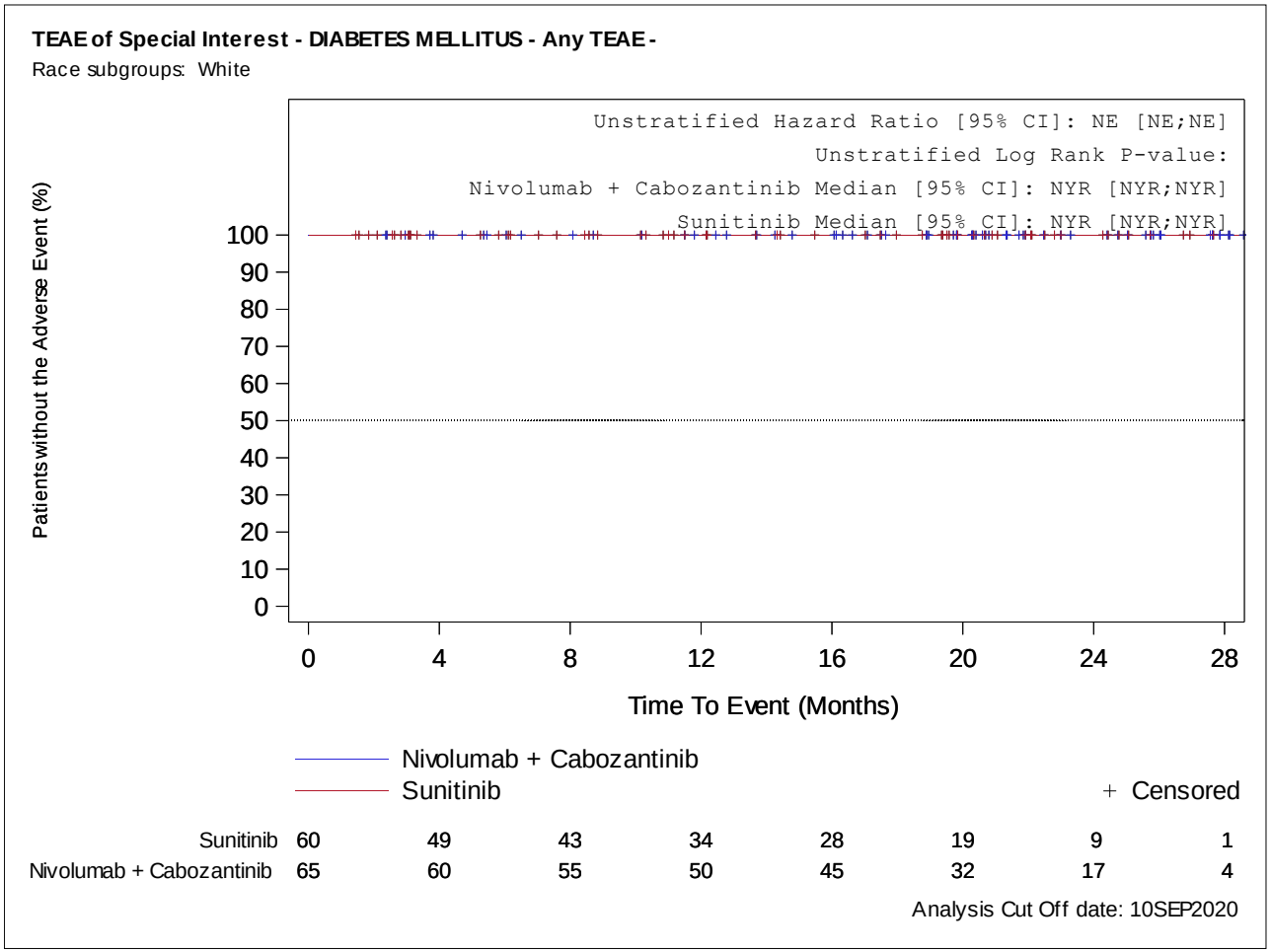

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:35:22

FIGURE 3.65.2.7: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



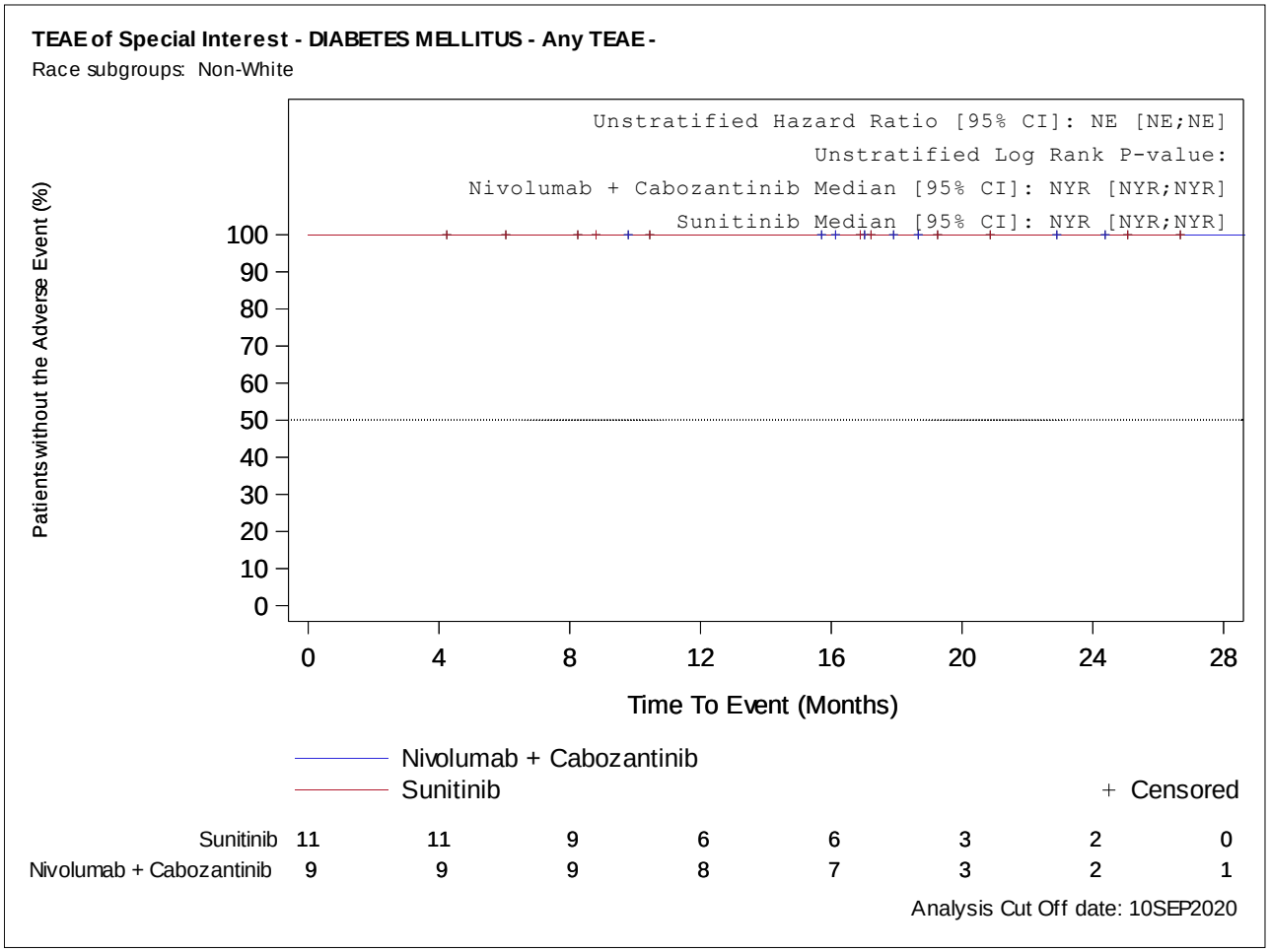

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:35:28

FIGURE 3.65.2.8: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



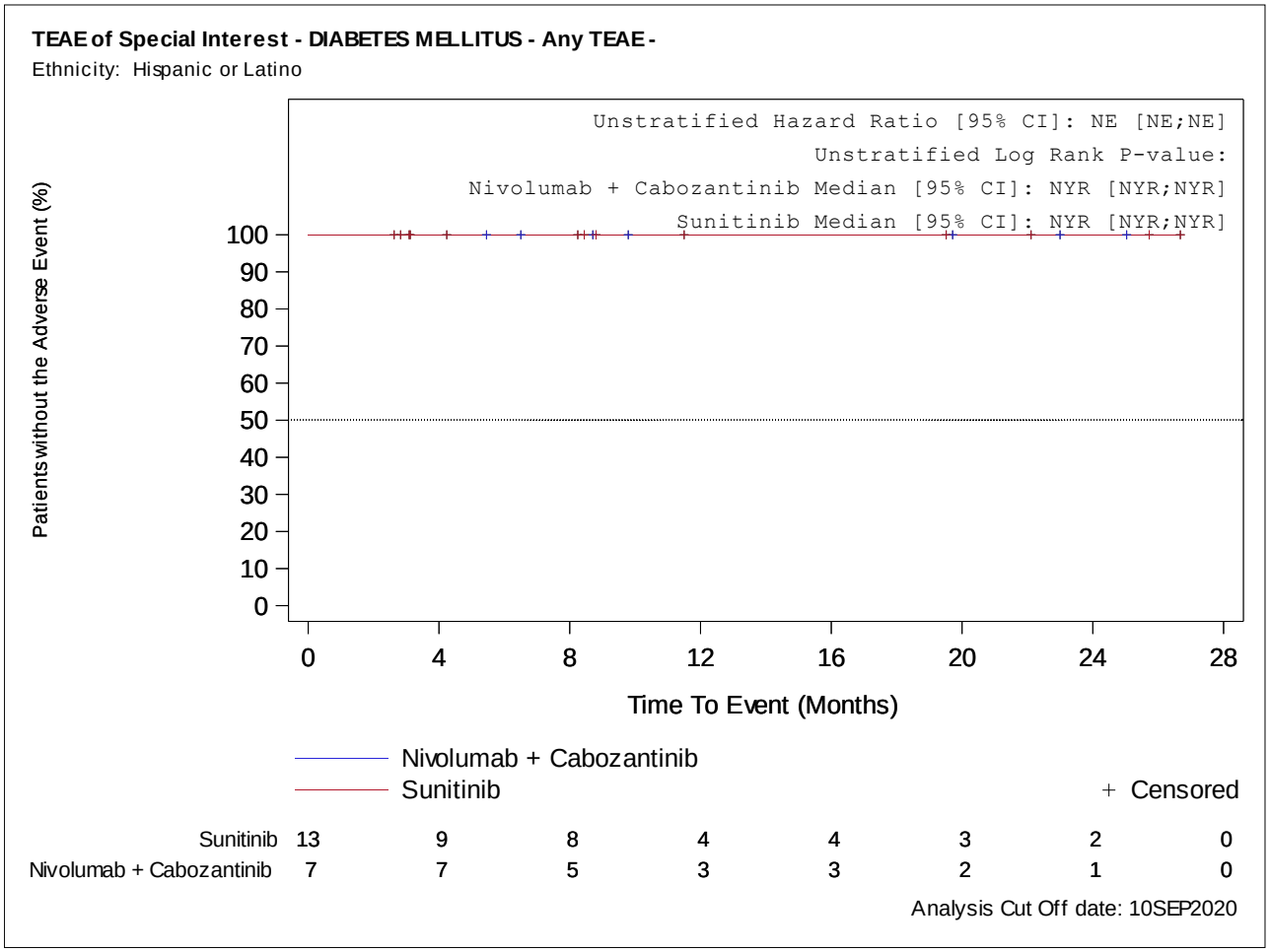

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:35:34

FIGURE 3.65.2.9: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



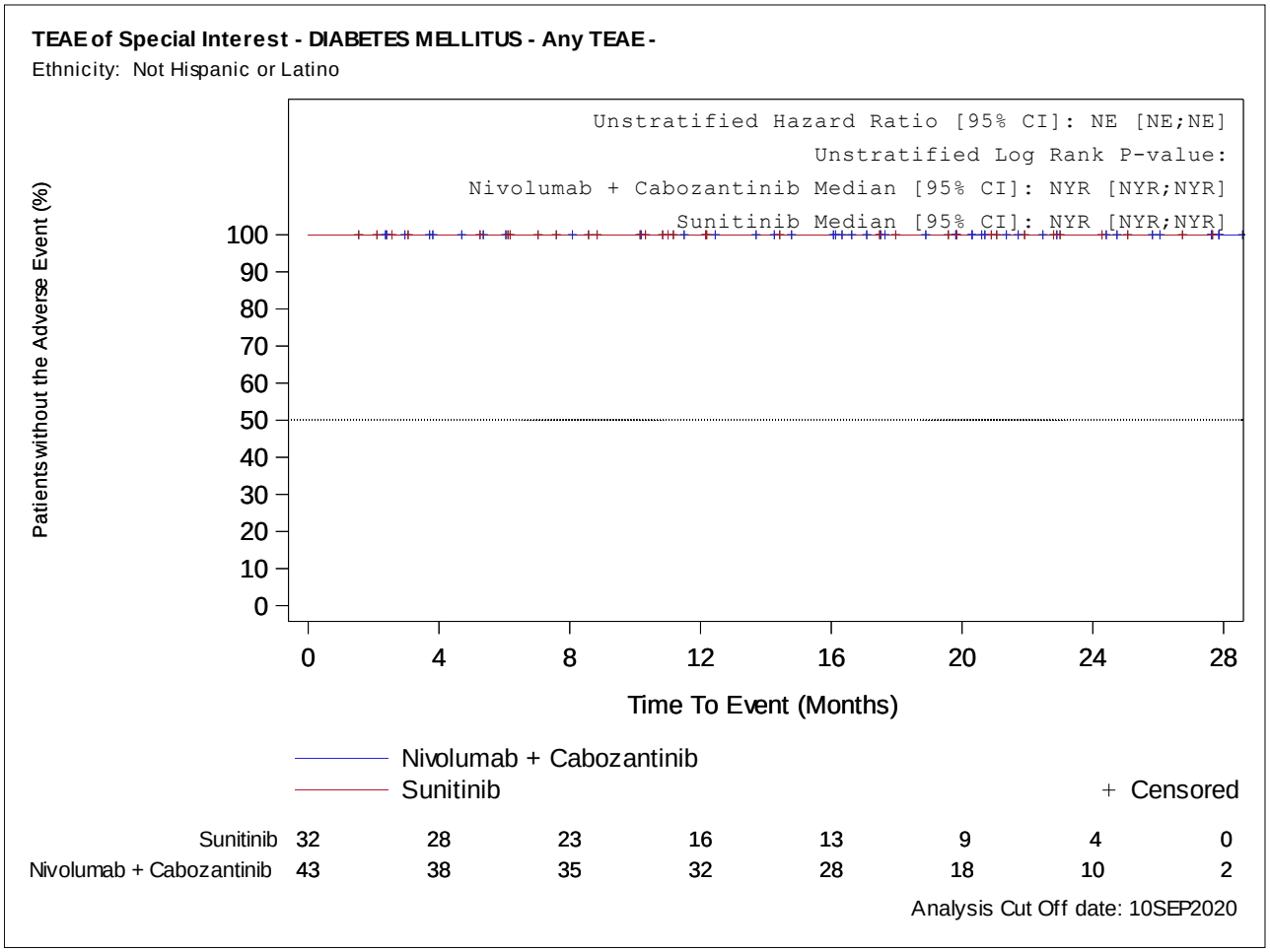

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:35:40

FIGURE 3.65.2.10: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



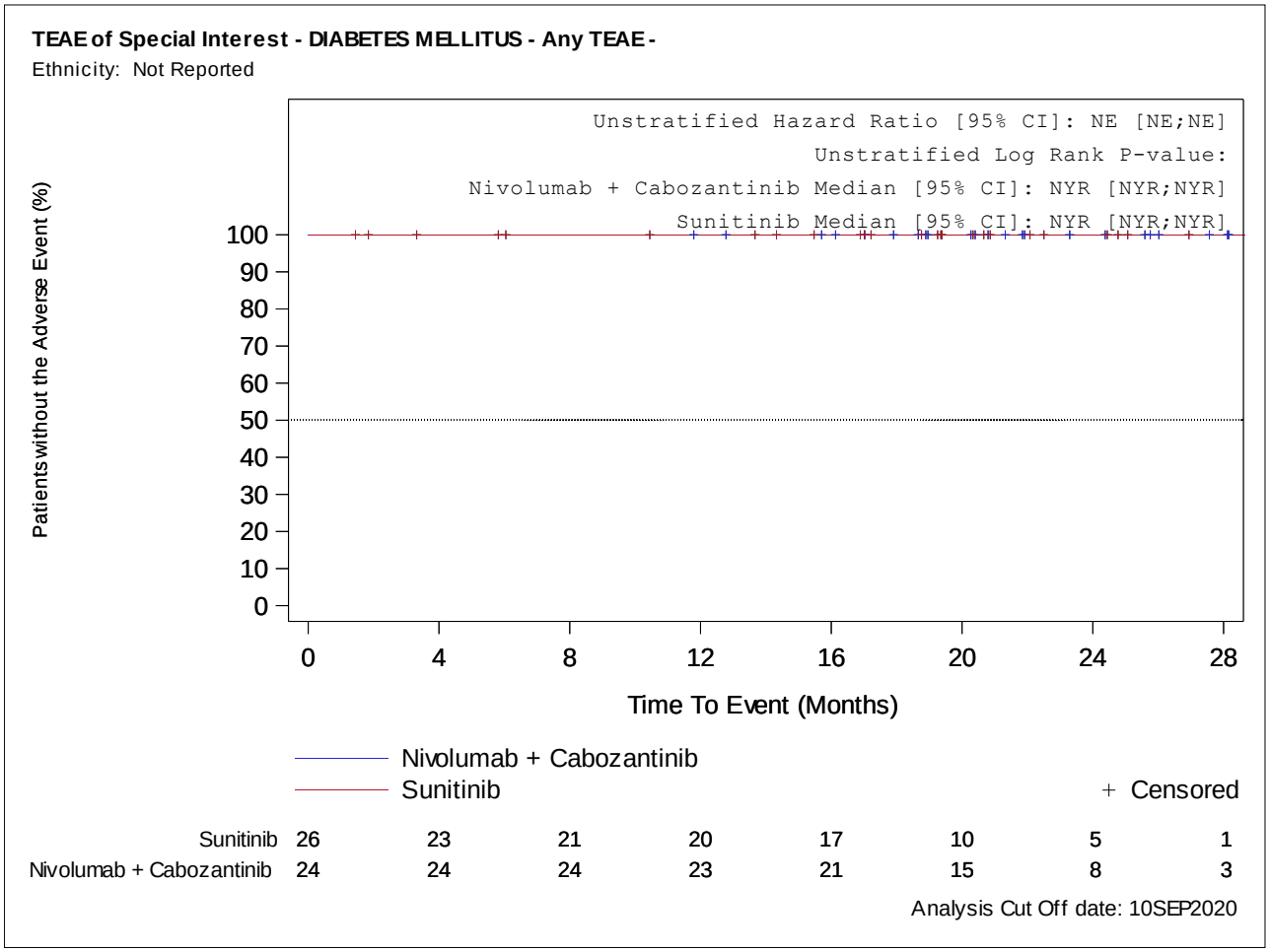

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:35:47

FIGURE 3.65.2.11: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



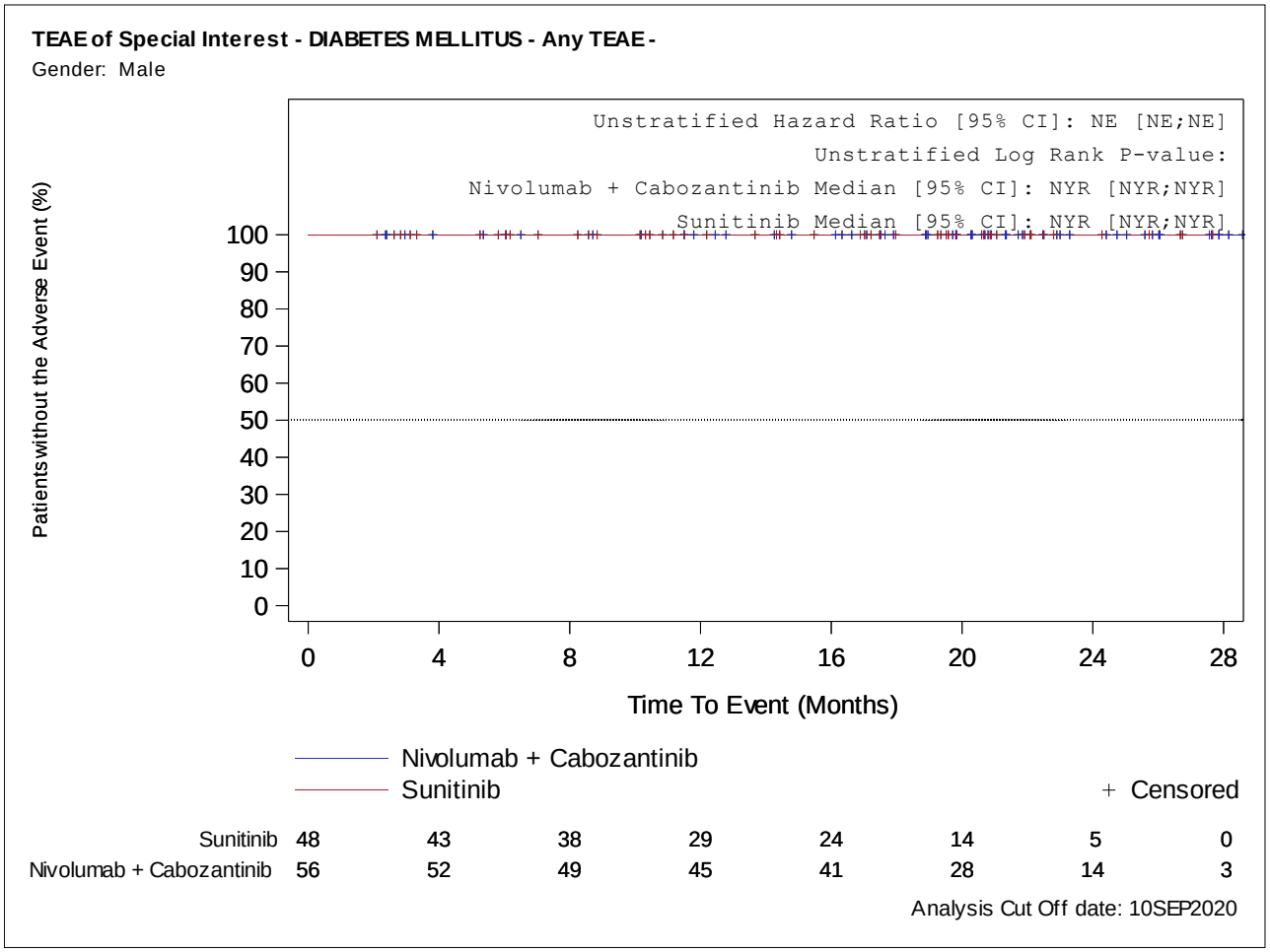

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:35:53

FIGURE 3.65.2.12: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



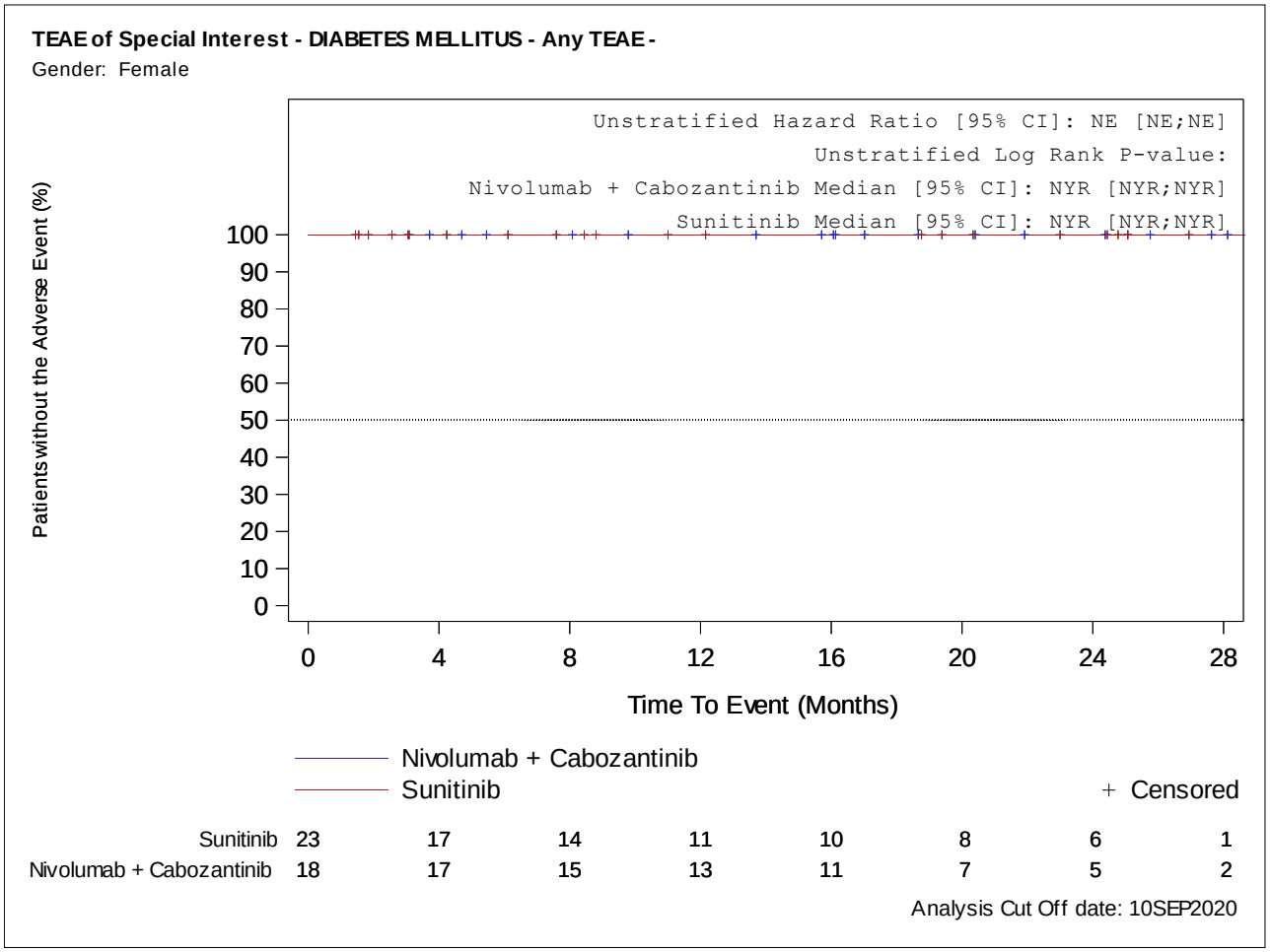

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:36:00

FIGURE 3.65.2.13: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



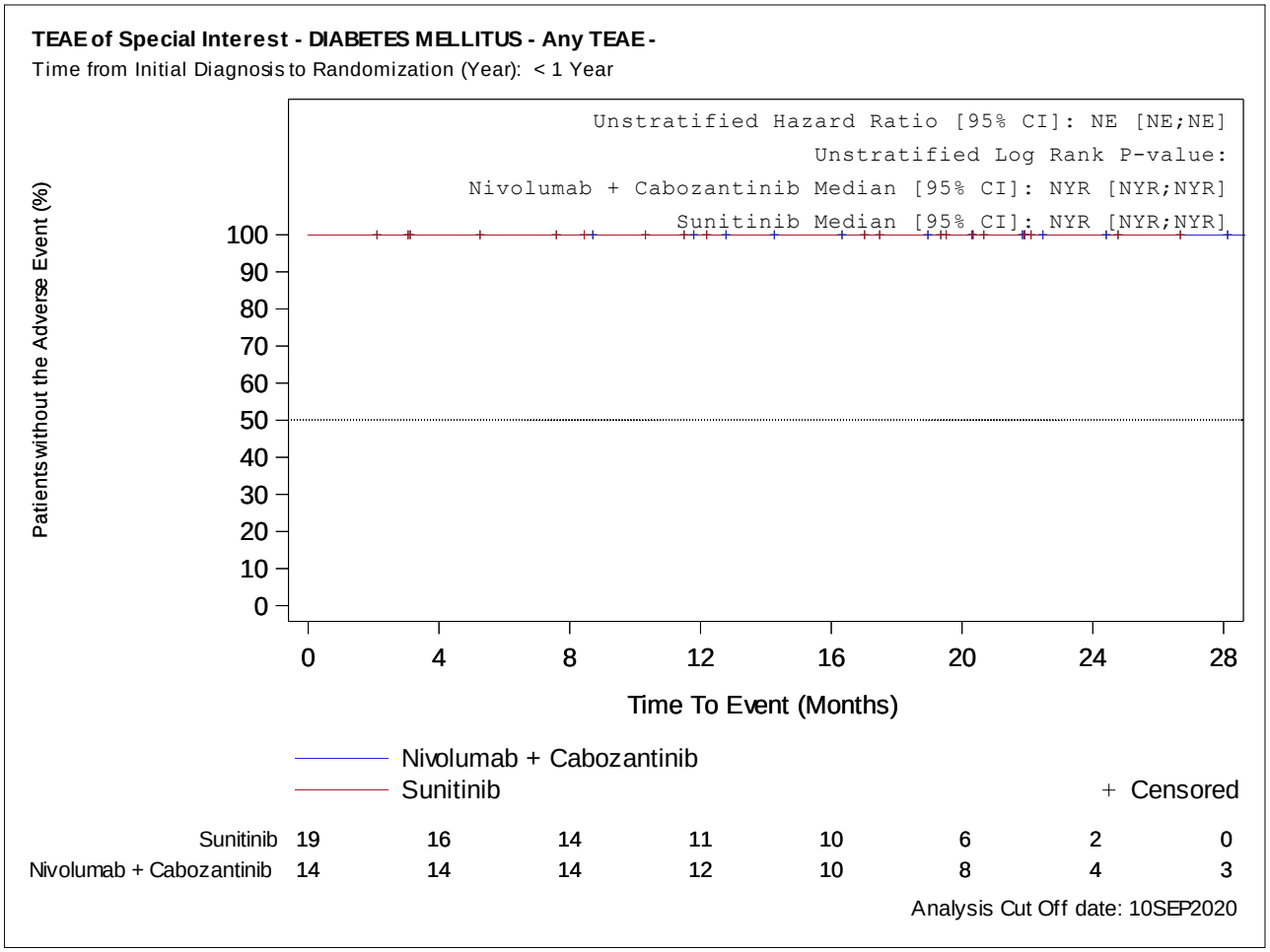

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:36:06

FIGURE 3.65.2.14: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



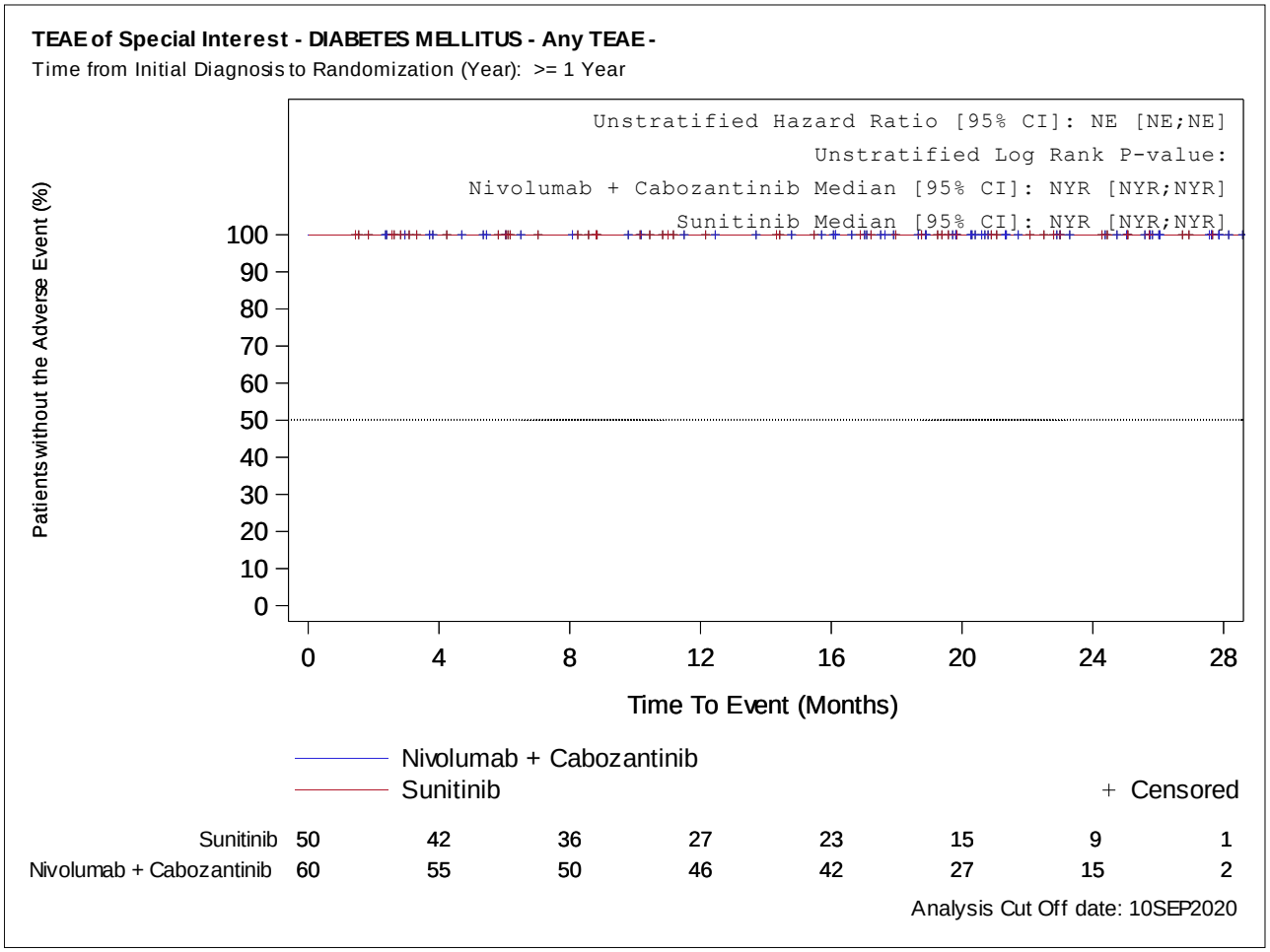

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:36:12

FIGURE 3.65.2.15: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



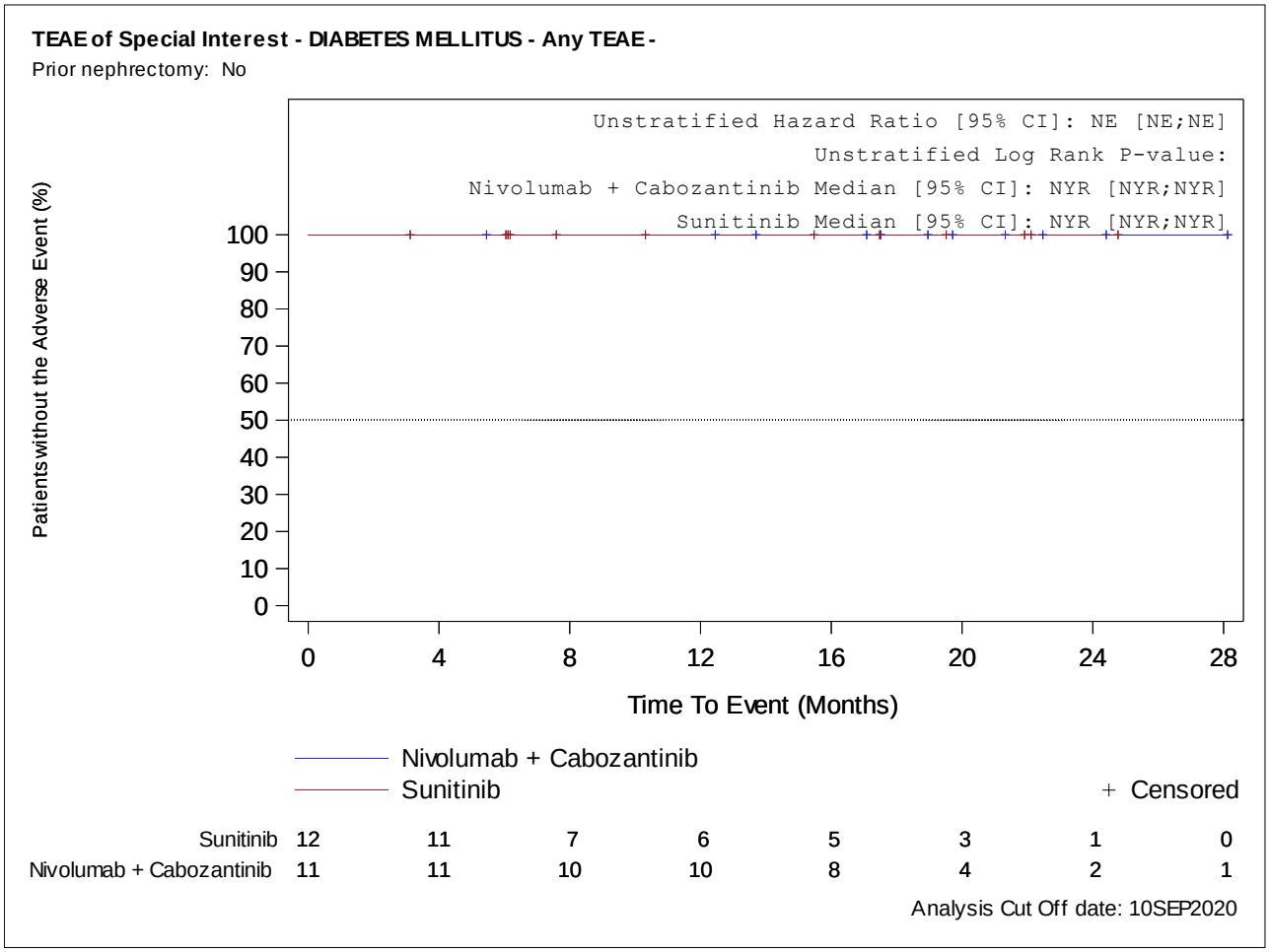

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:36:31

FIGURE 3.65.2.16: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



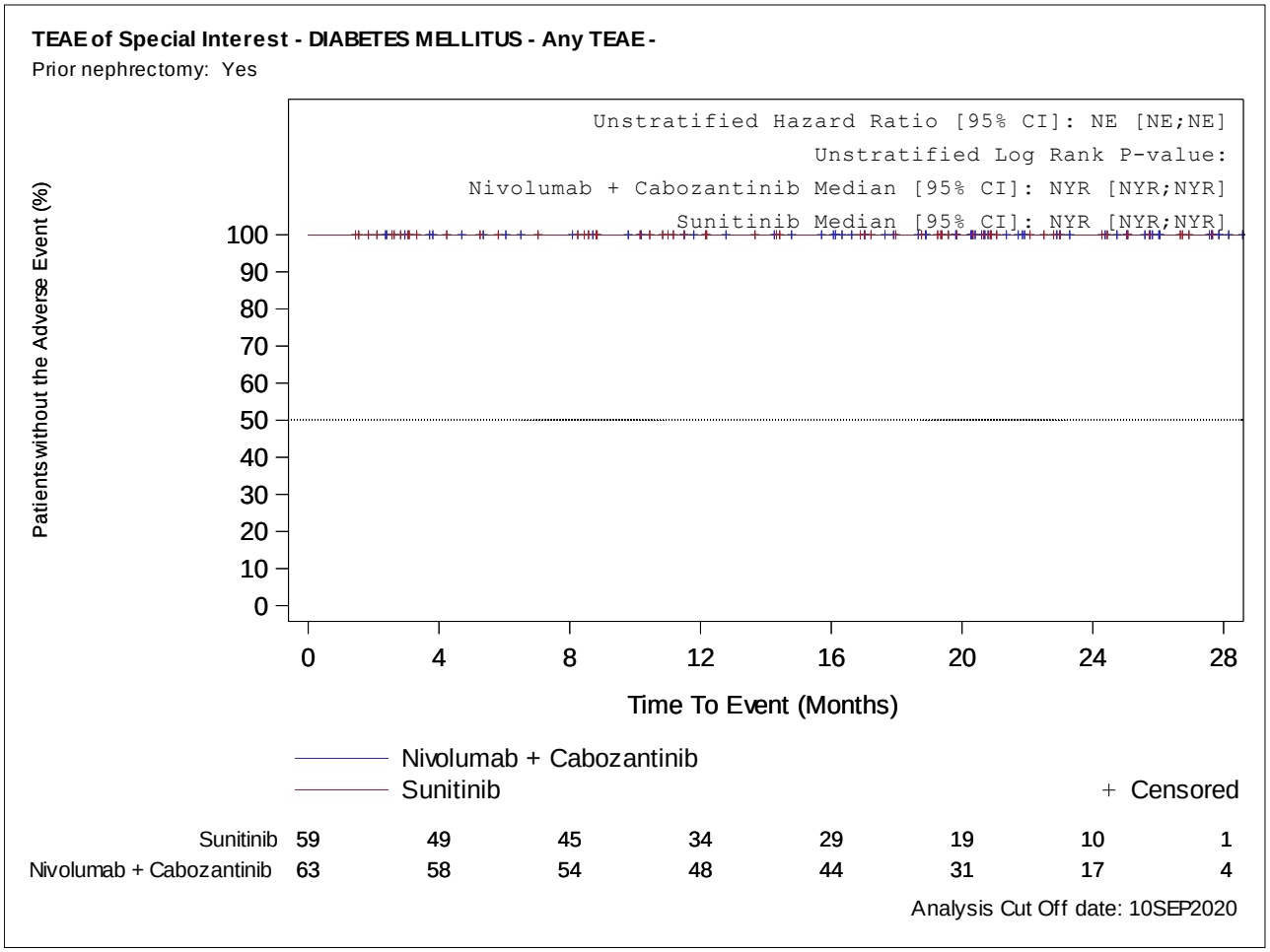

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:36:36

FIGURE 3.65.2.17: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



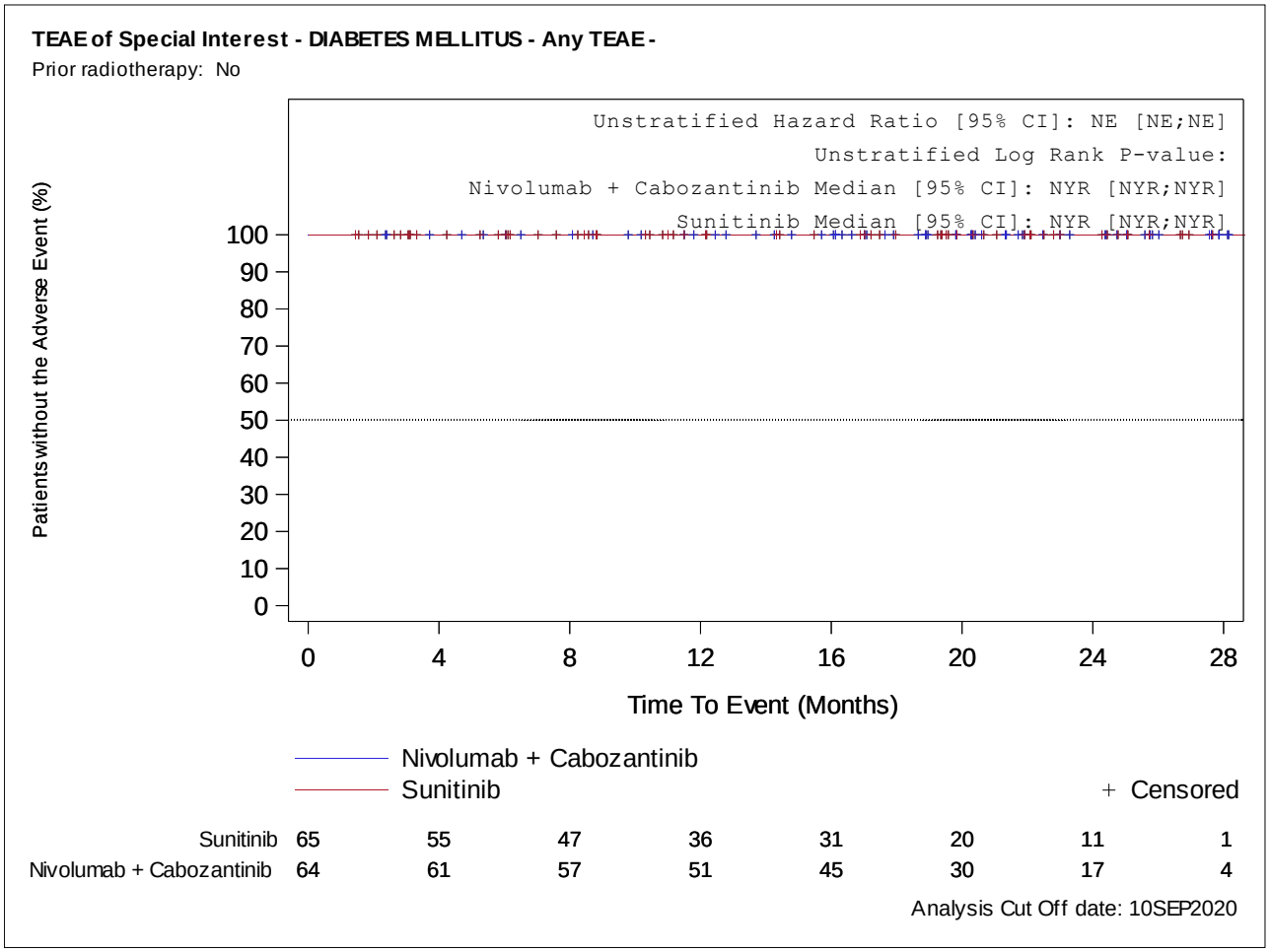

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:37:42

FIGURE 3.65.2.18: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:37:48

FIGURE 3.65.2.19: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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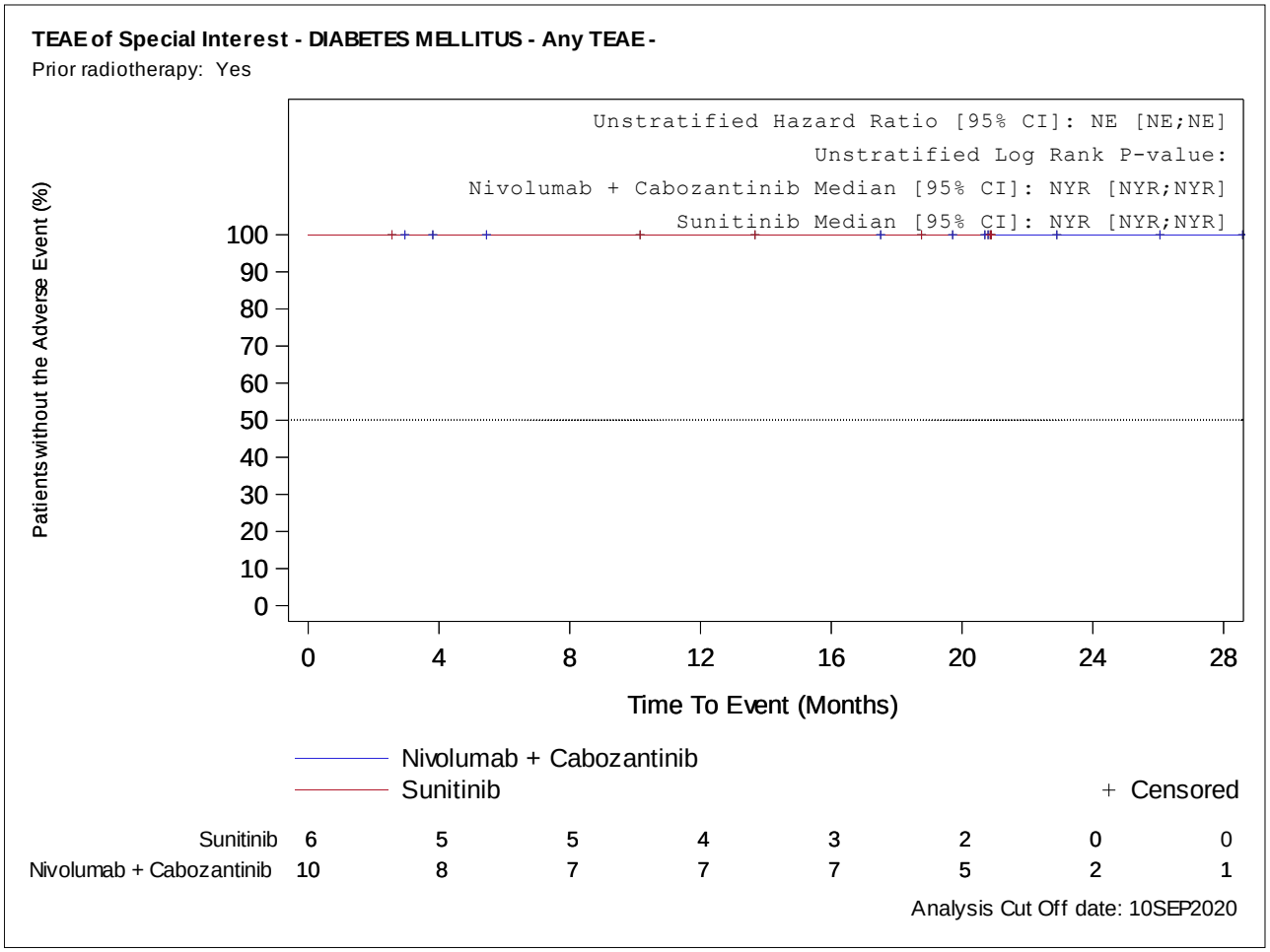
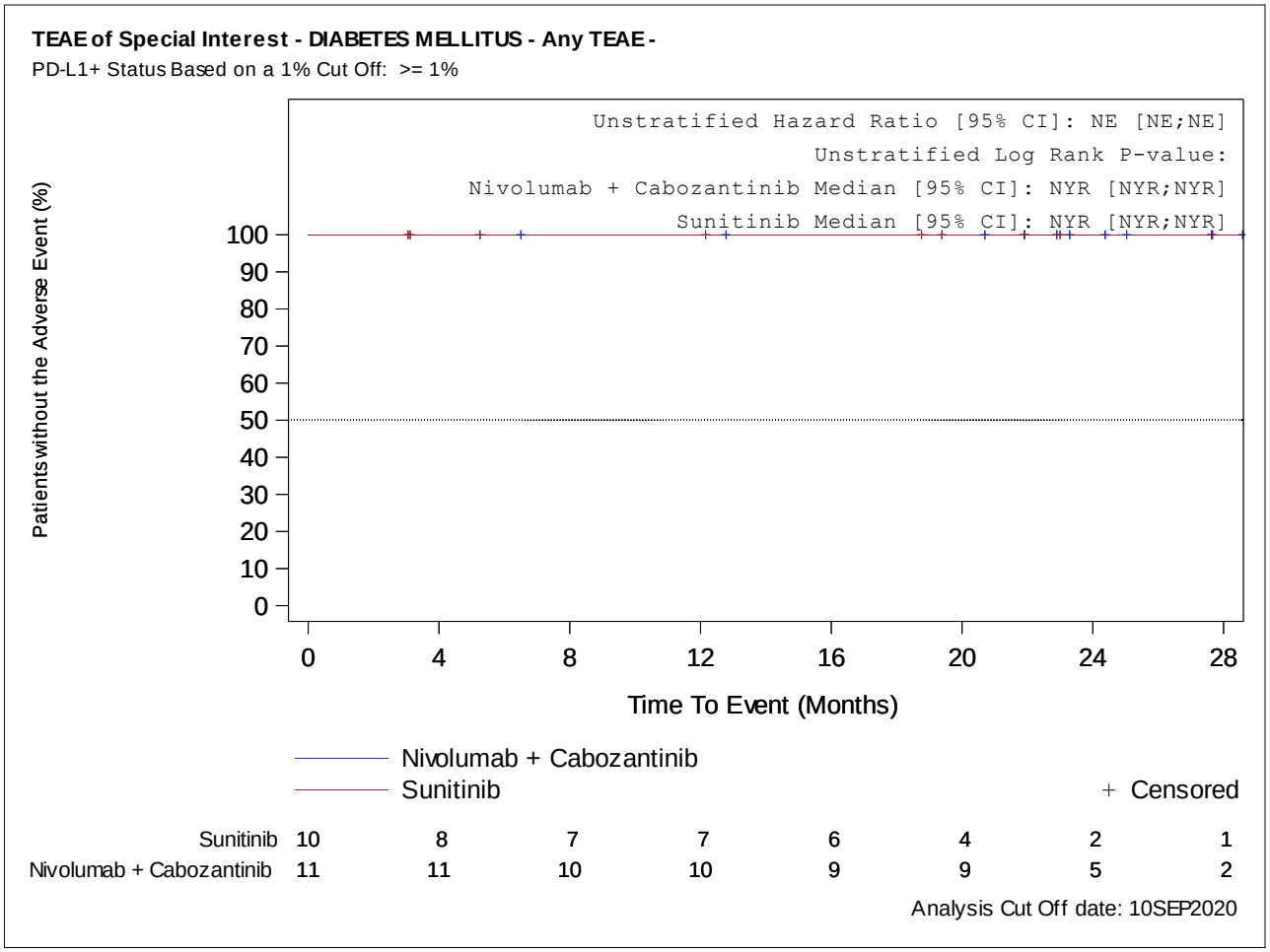
FIGURE 3.65.2.20: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



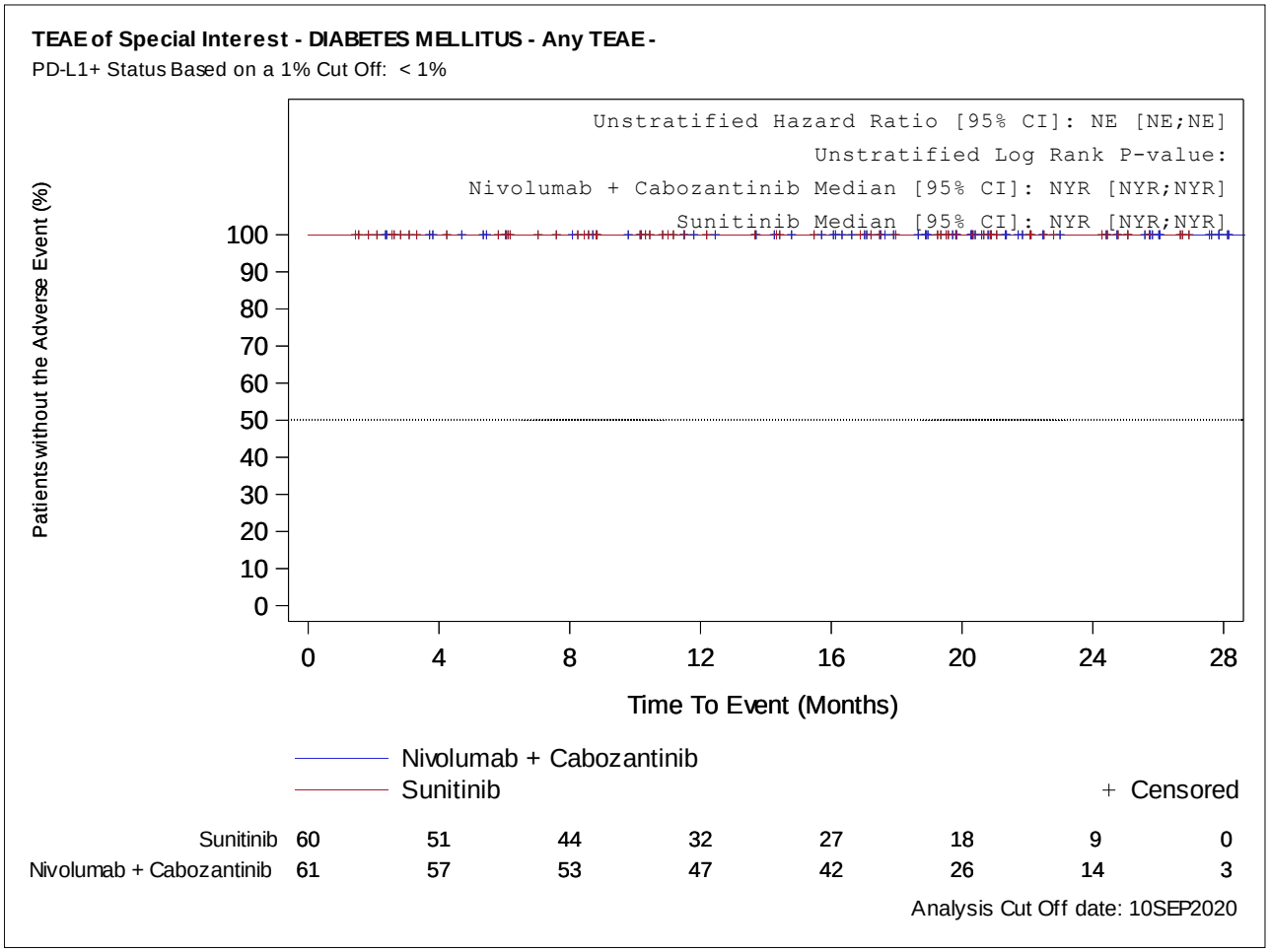

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:37:59

FIGURE 3.65.2.21: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



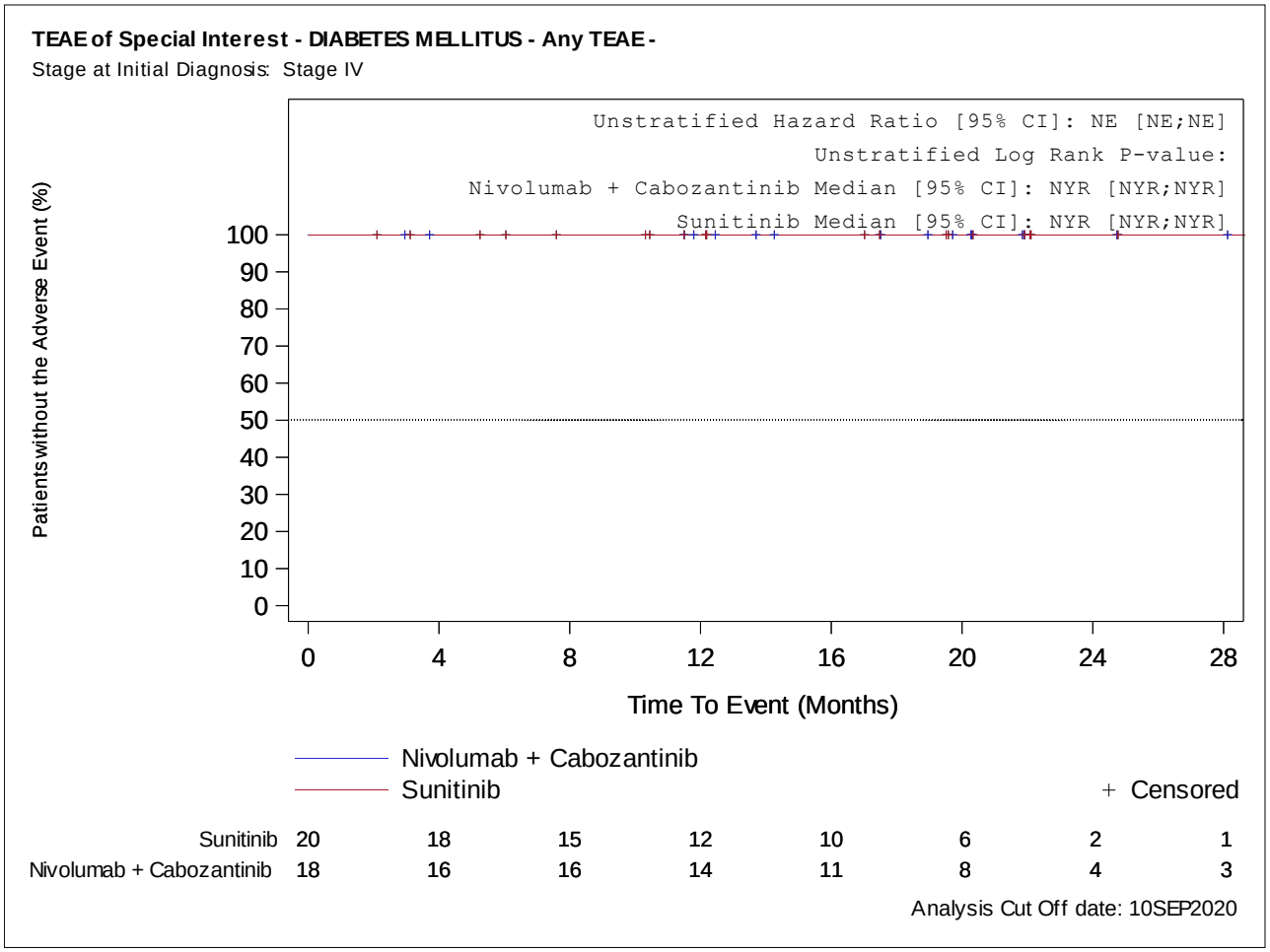

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:38:05

FIGURE 3.65.2.22: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



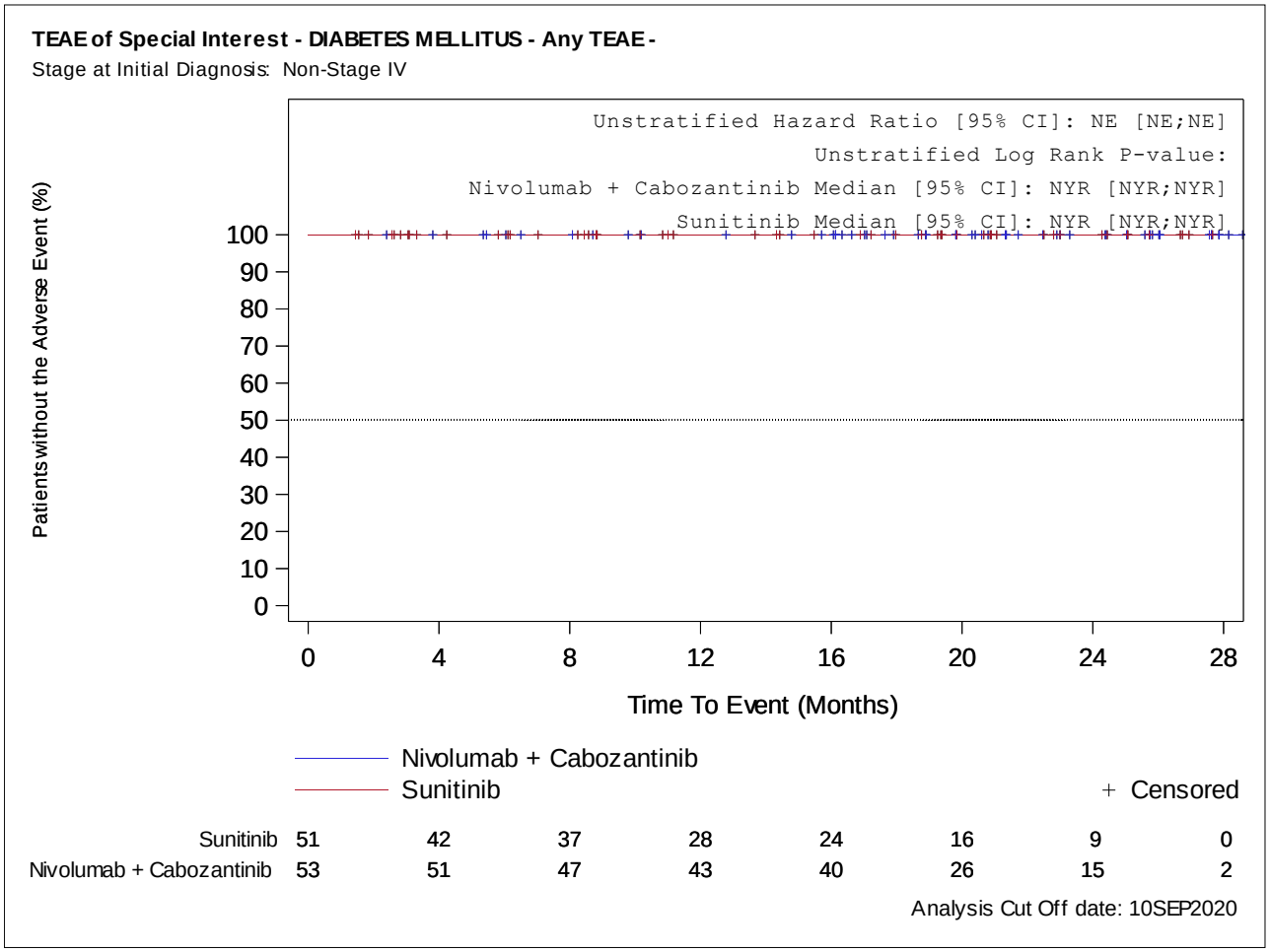

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:38:11

FIGURE 3.65.2.23: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



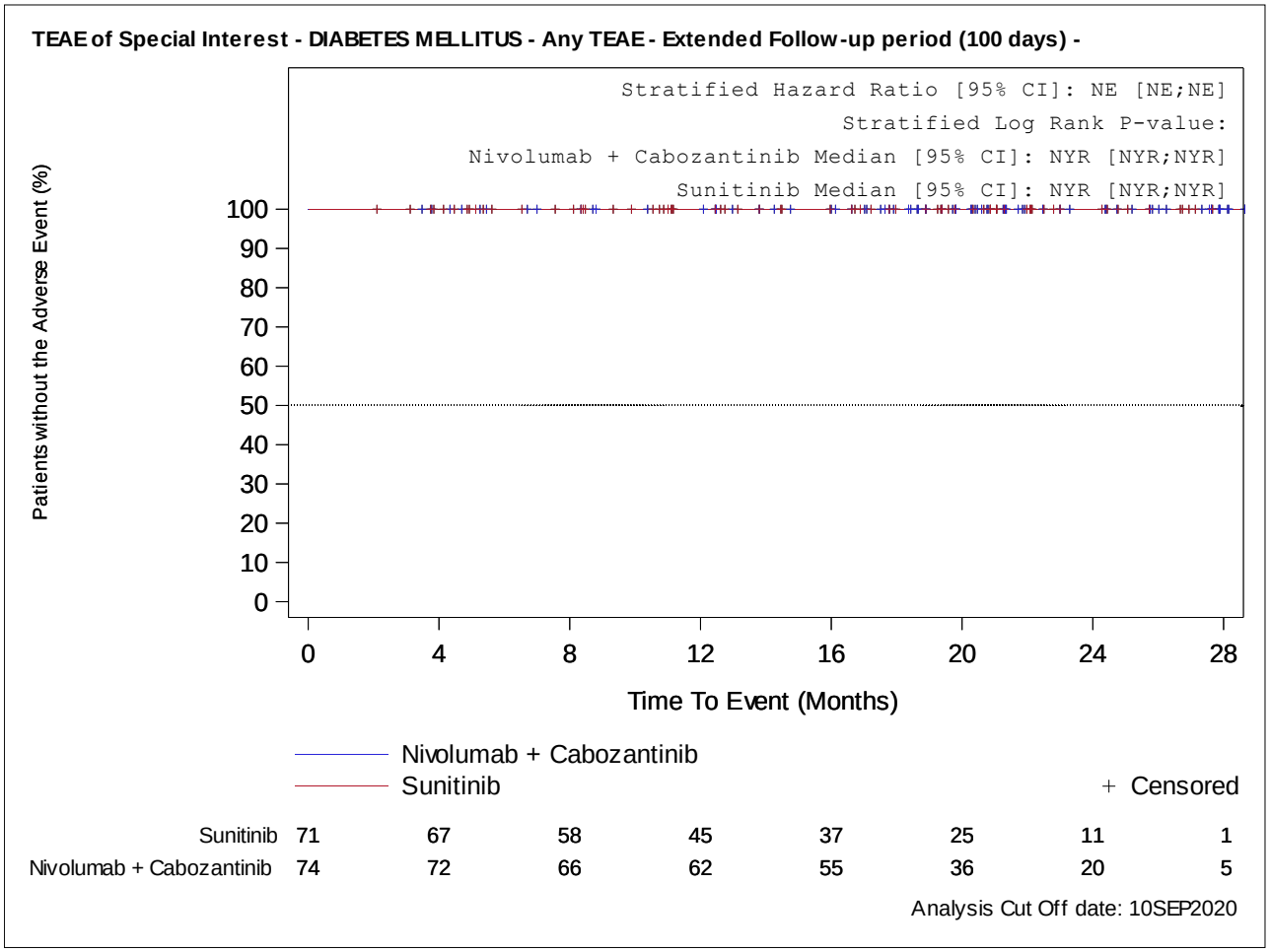

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:38:40

FIGURE 3.65.2.24: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



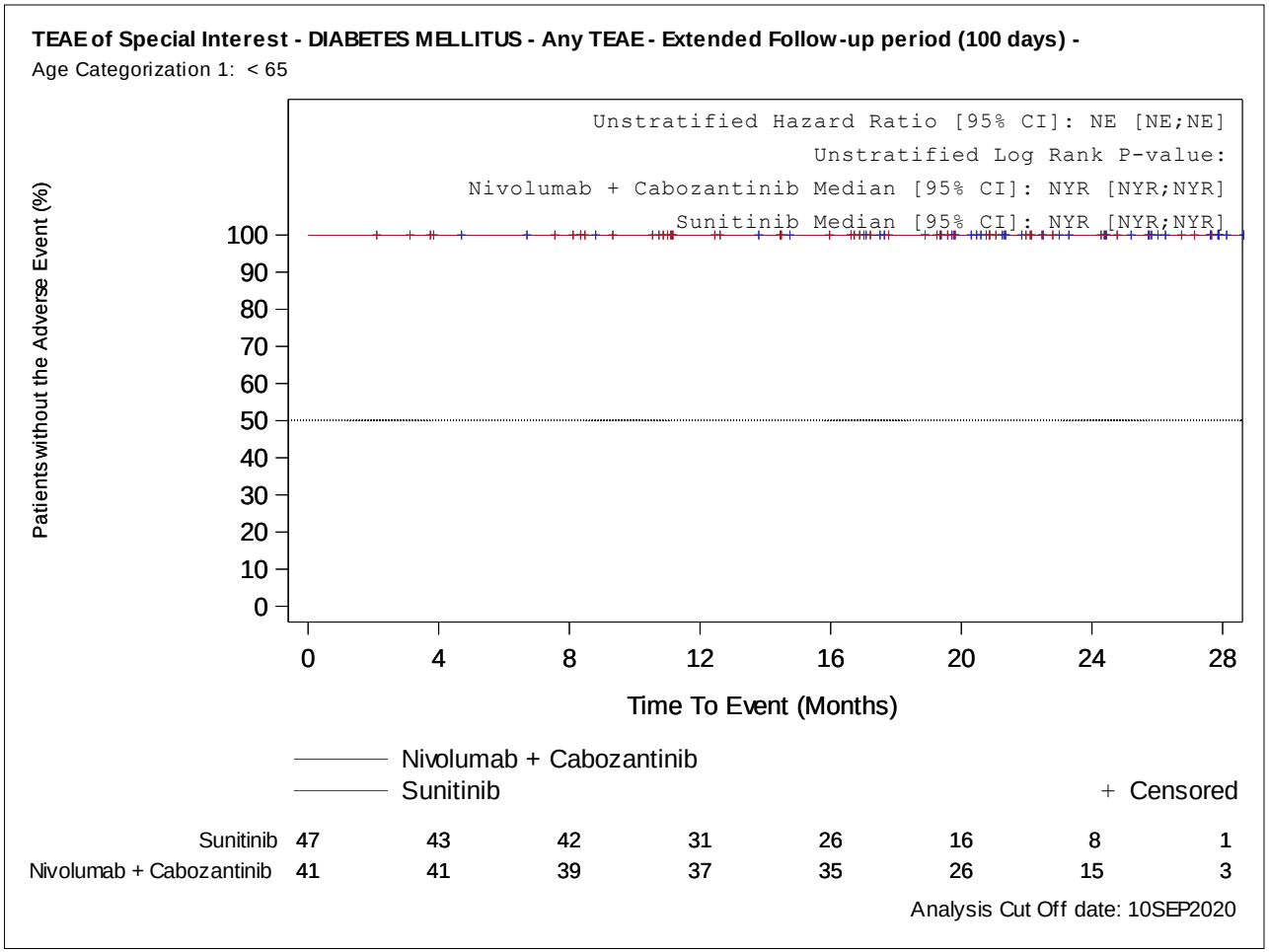

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:38:46

FIGURE 3.66.1: TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



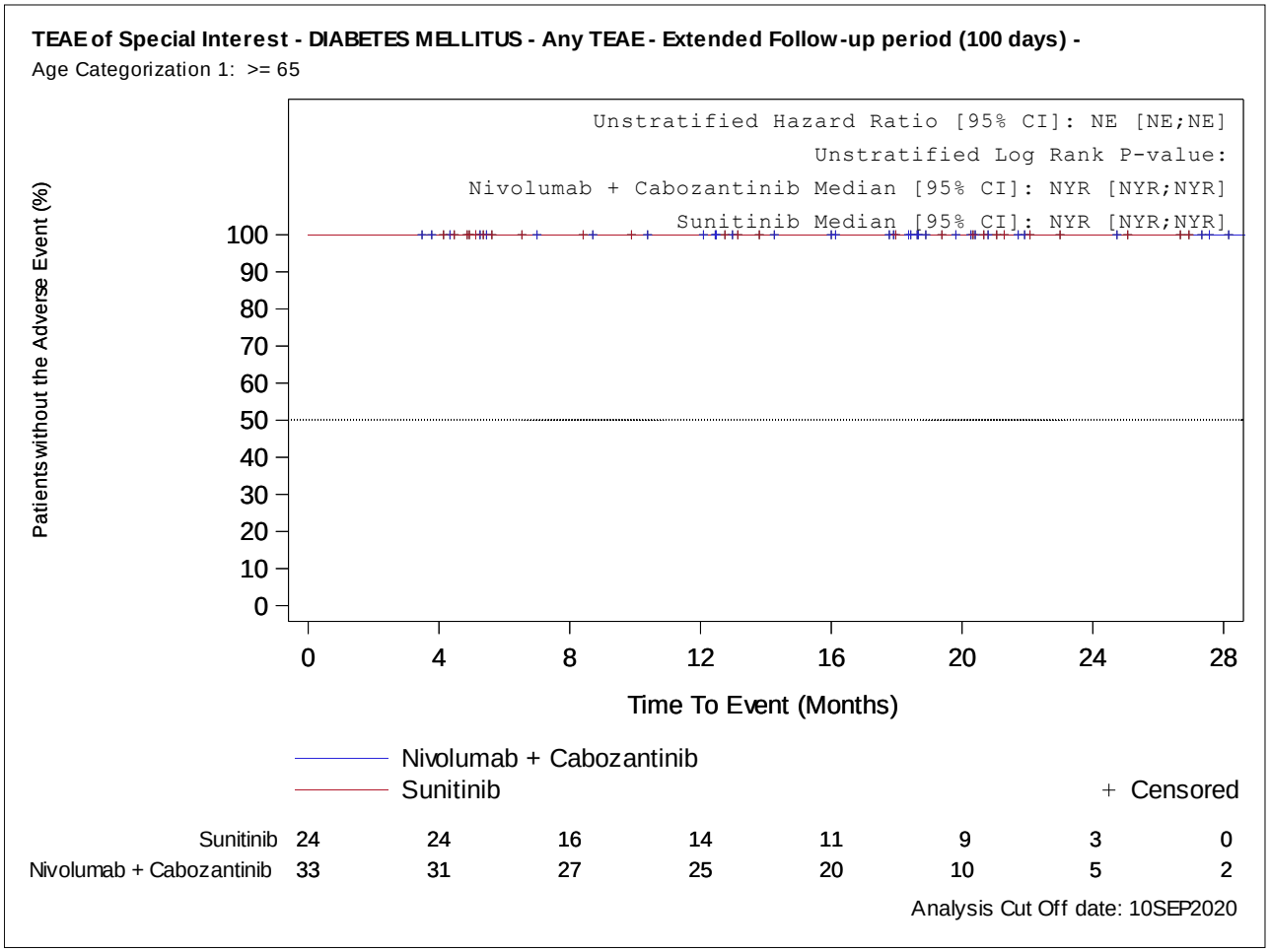

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:42:06

FIGURE 3.66.2.1: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



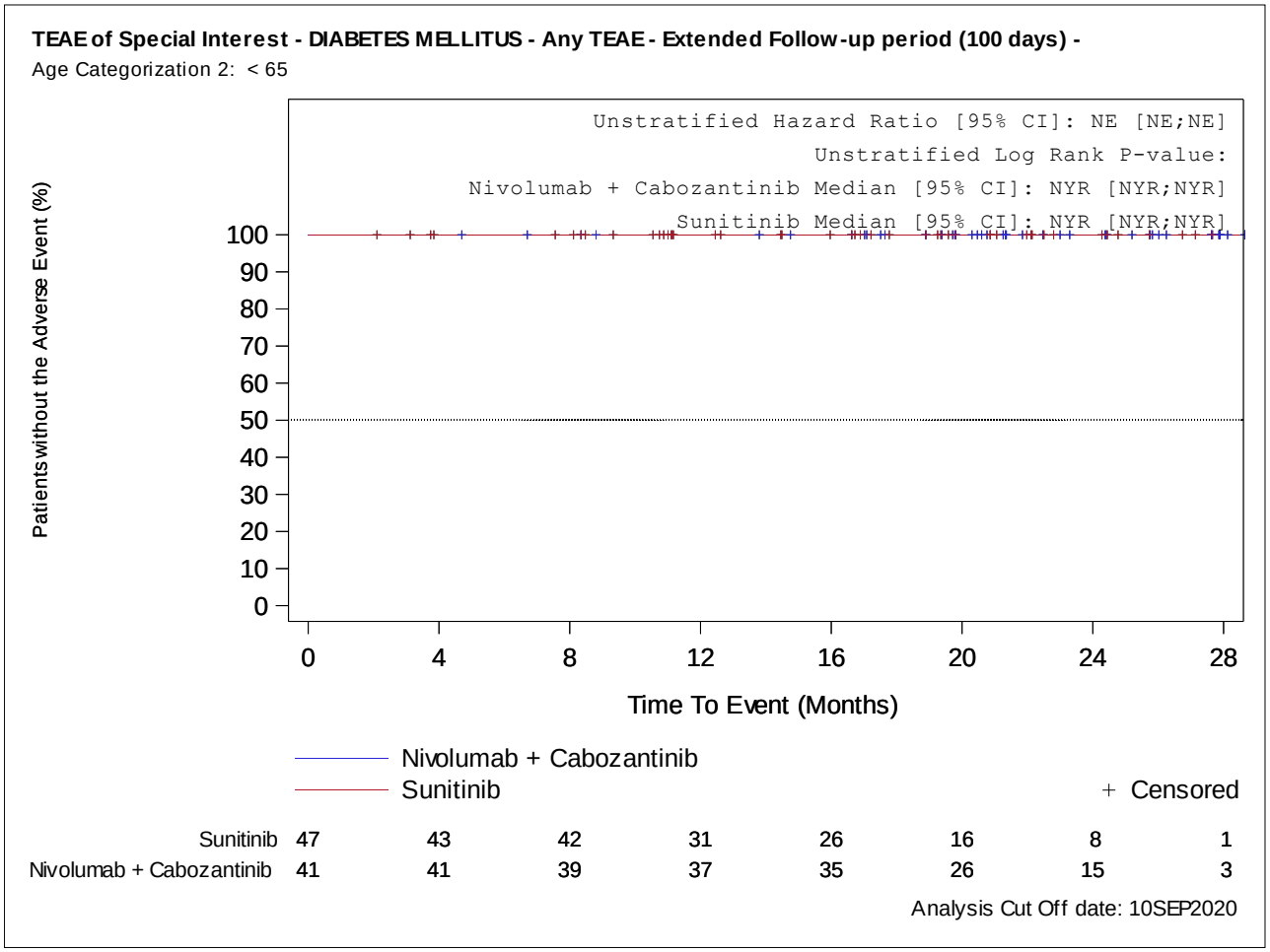

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:42:09

FIGURE 3.66.2.2: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



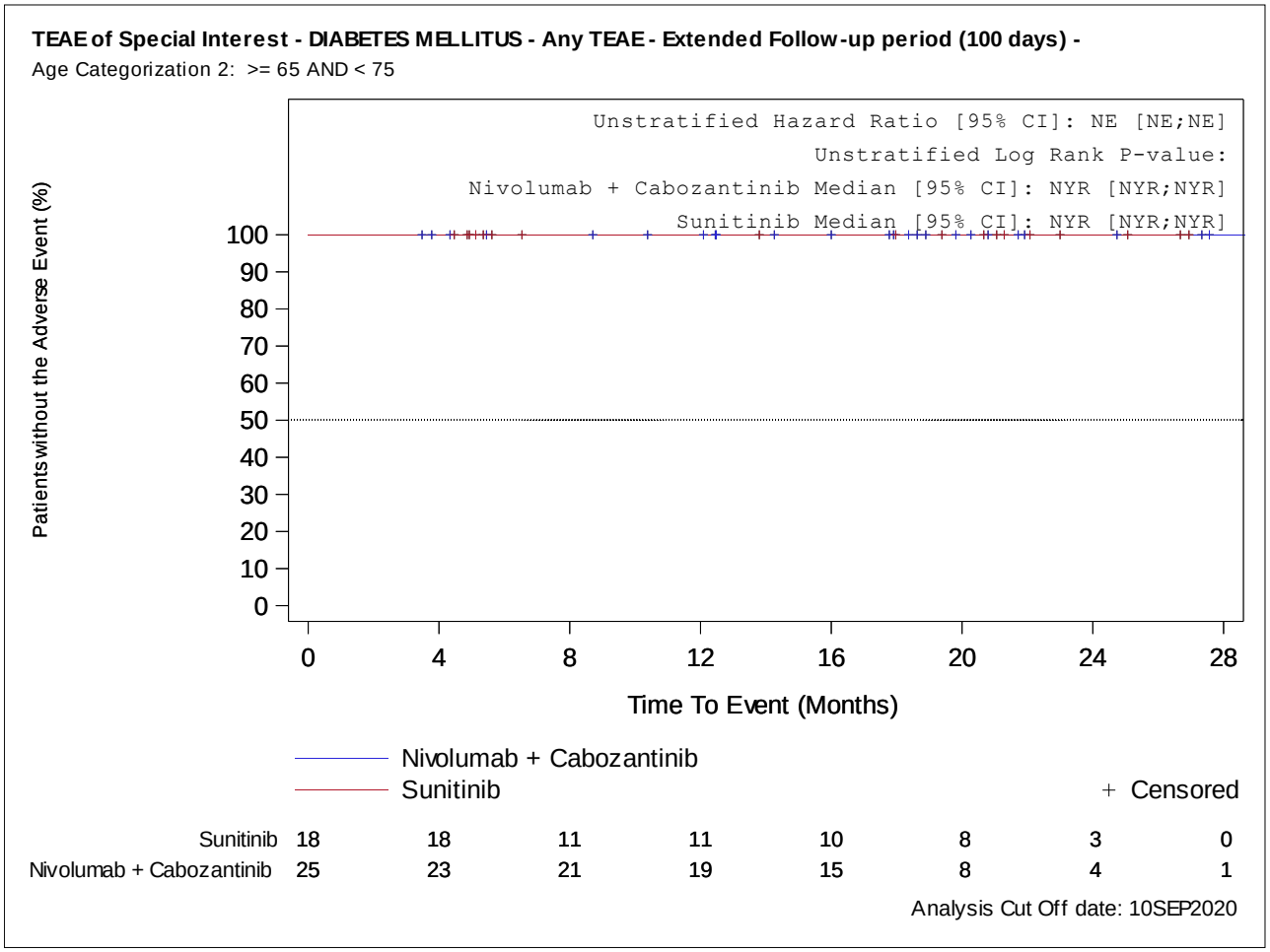

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:42:15

FIGURE 3.66.2.3: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



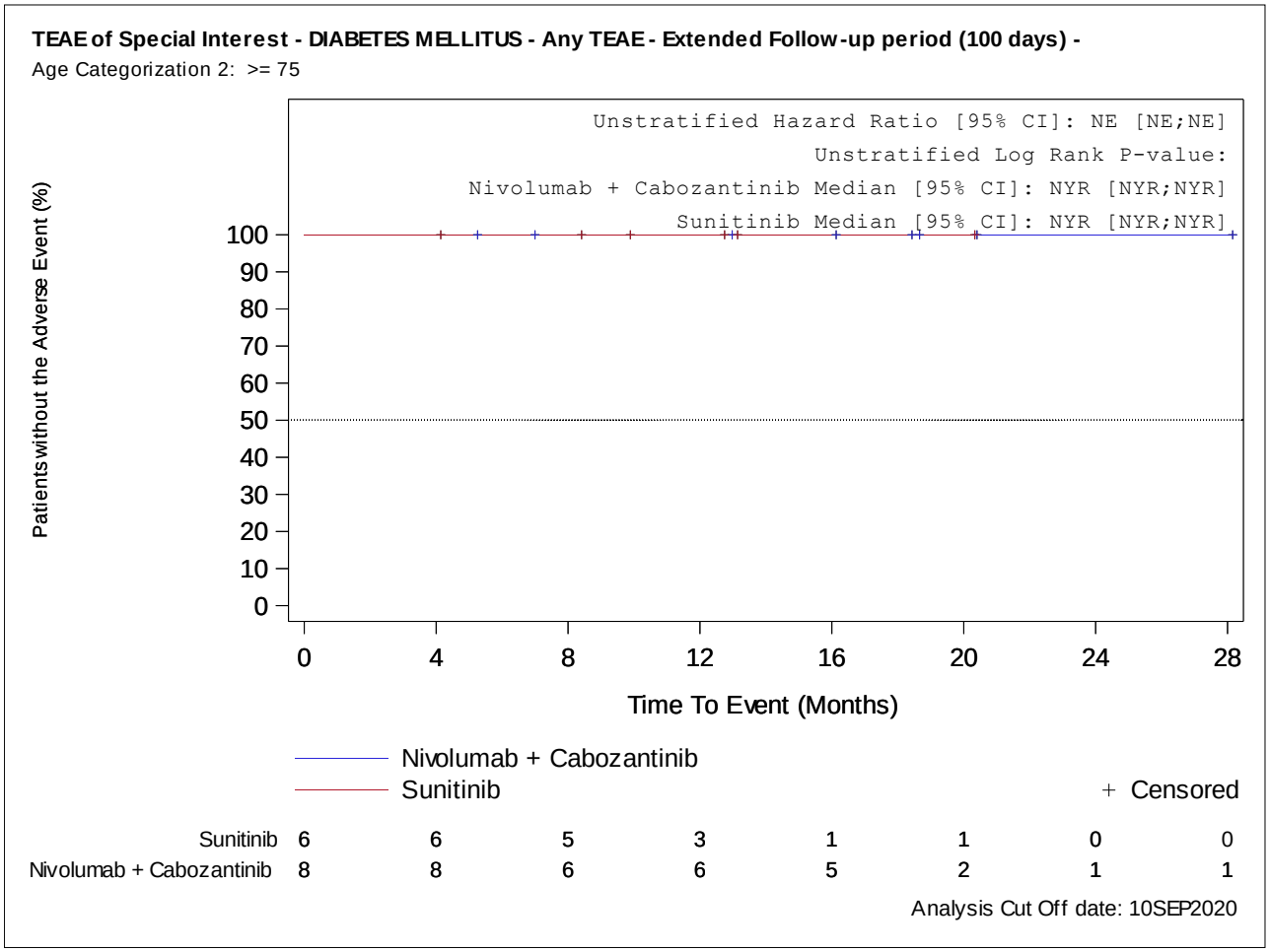

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:42:21

FIGURE 3.66.2.4: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



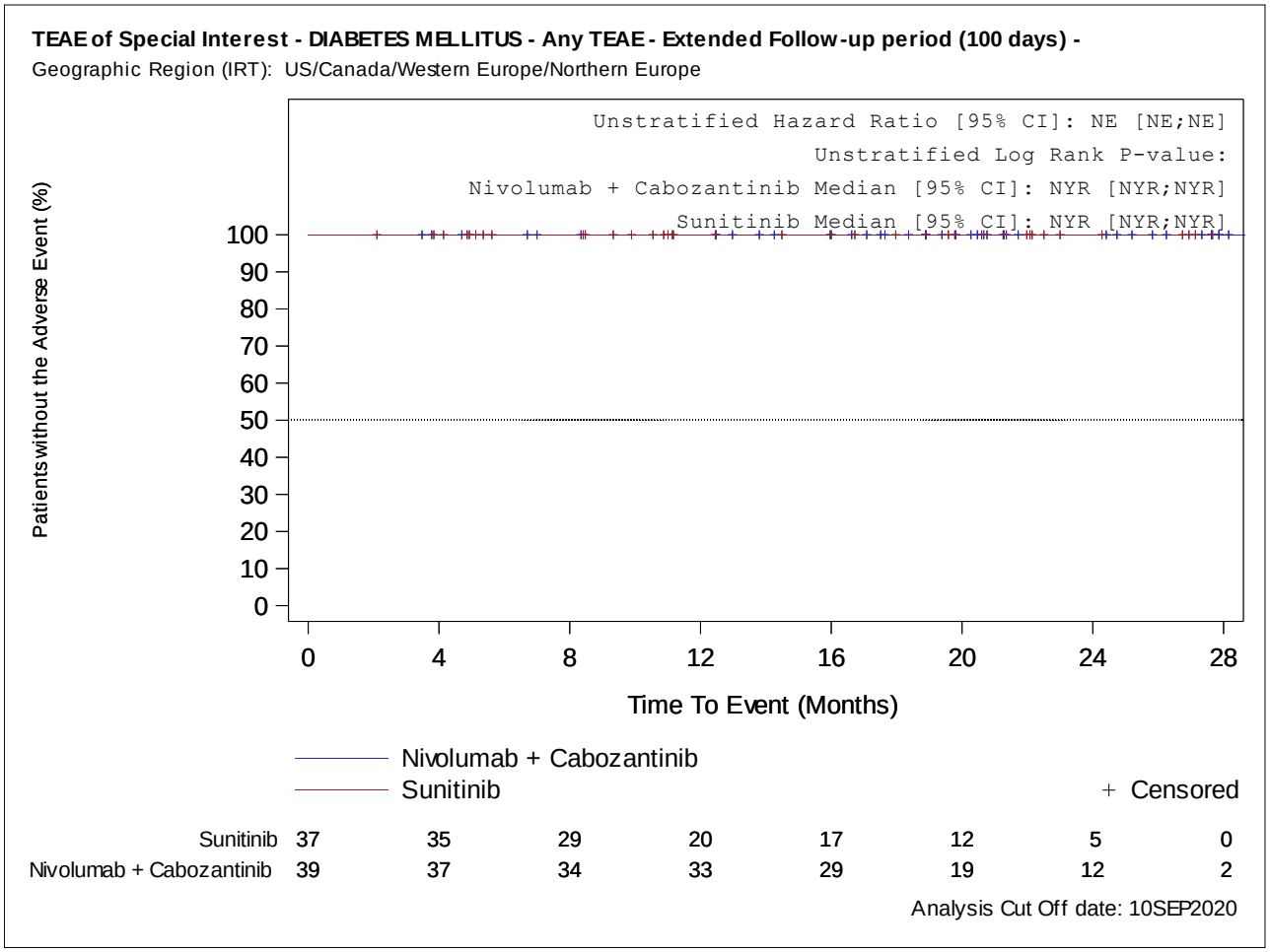

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:42:27

FIGURE 3.66.2.5: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



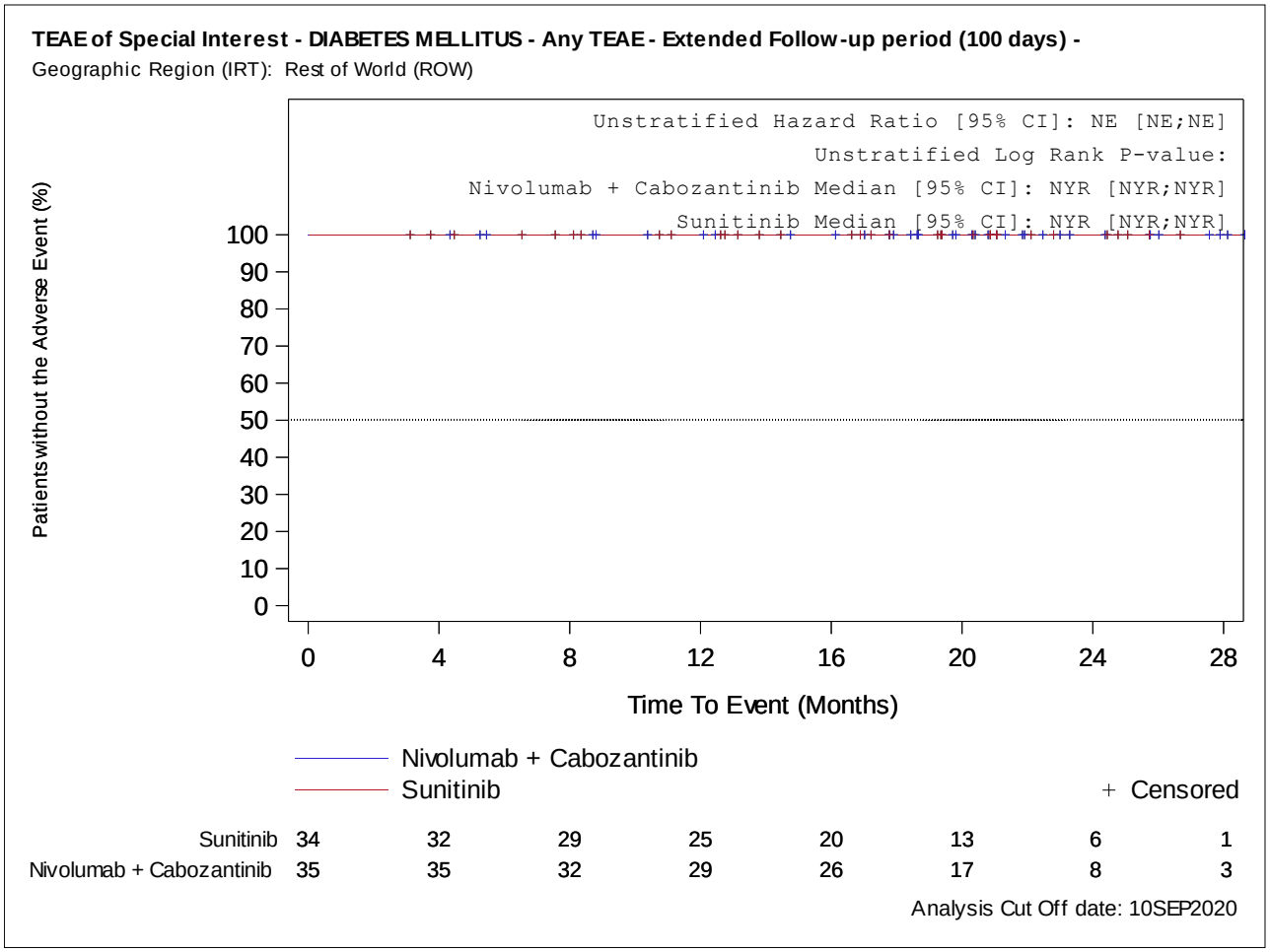

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:42:32

FIGURE 3.66.2.6: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



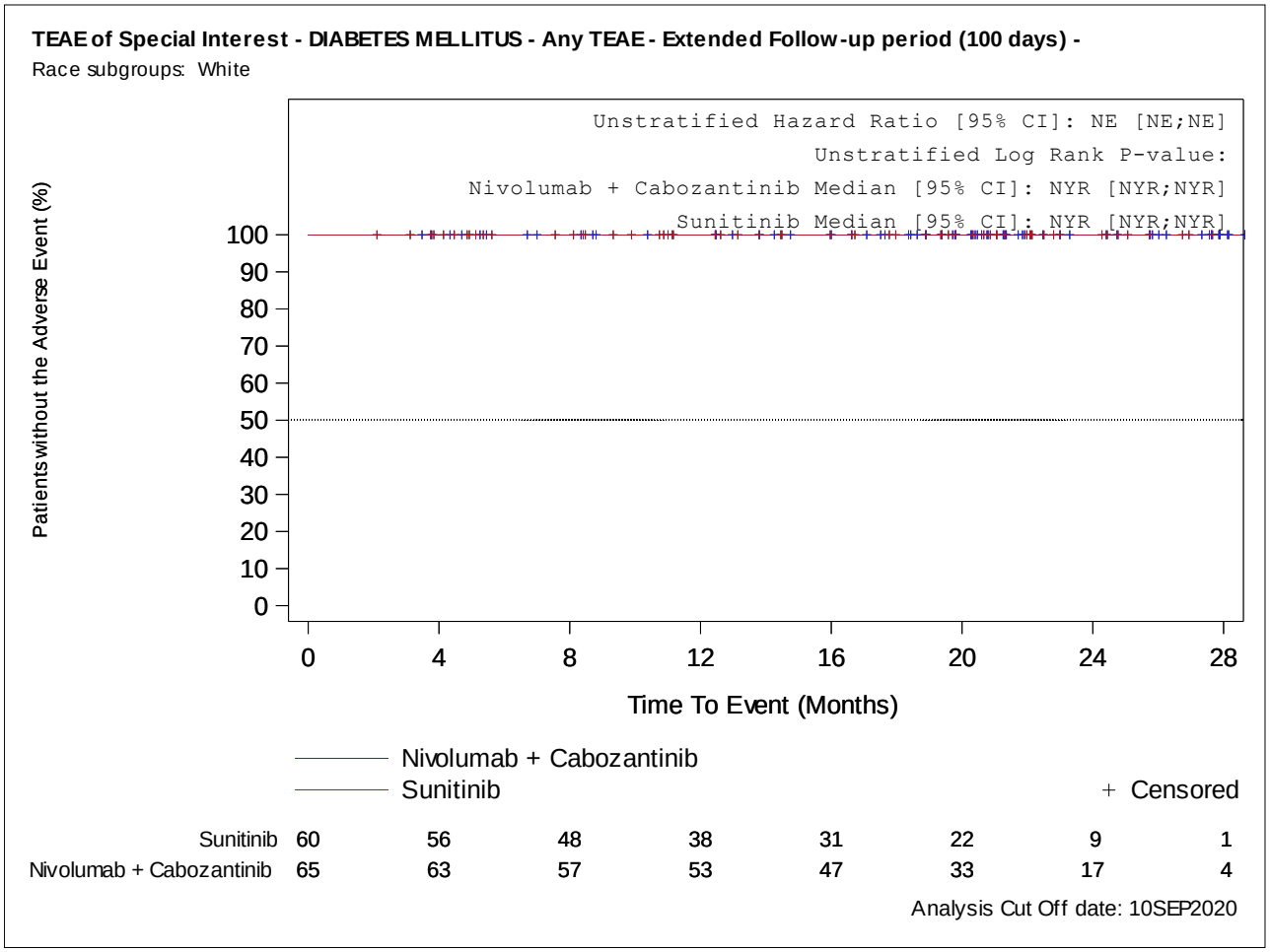

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:42:38

FIGURE 3.66.2.7: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



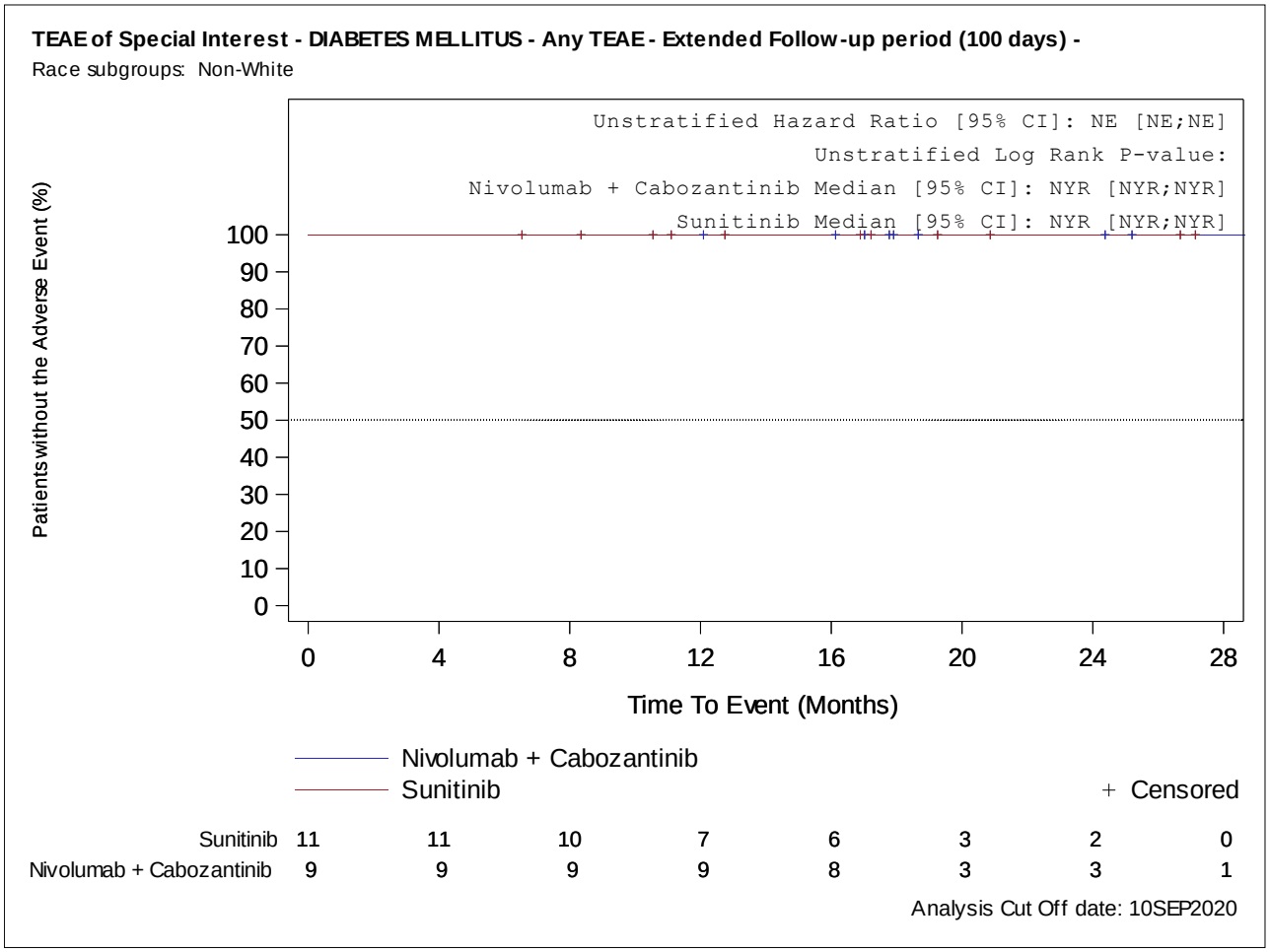

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:42:44

FIGURE 3.66.2.8: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:42:49

FIGURE 3.66.2.9: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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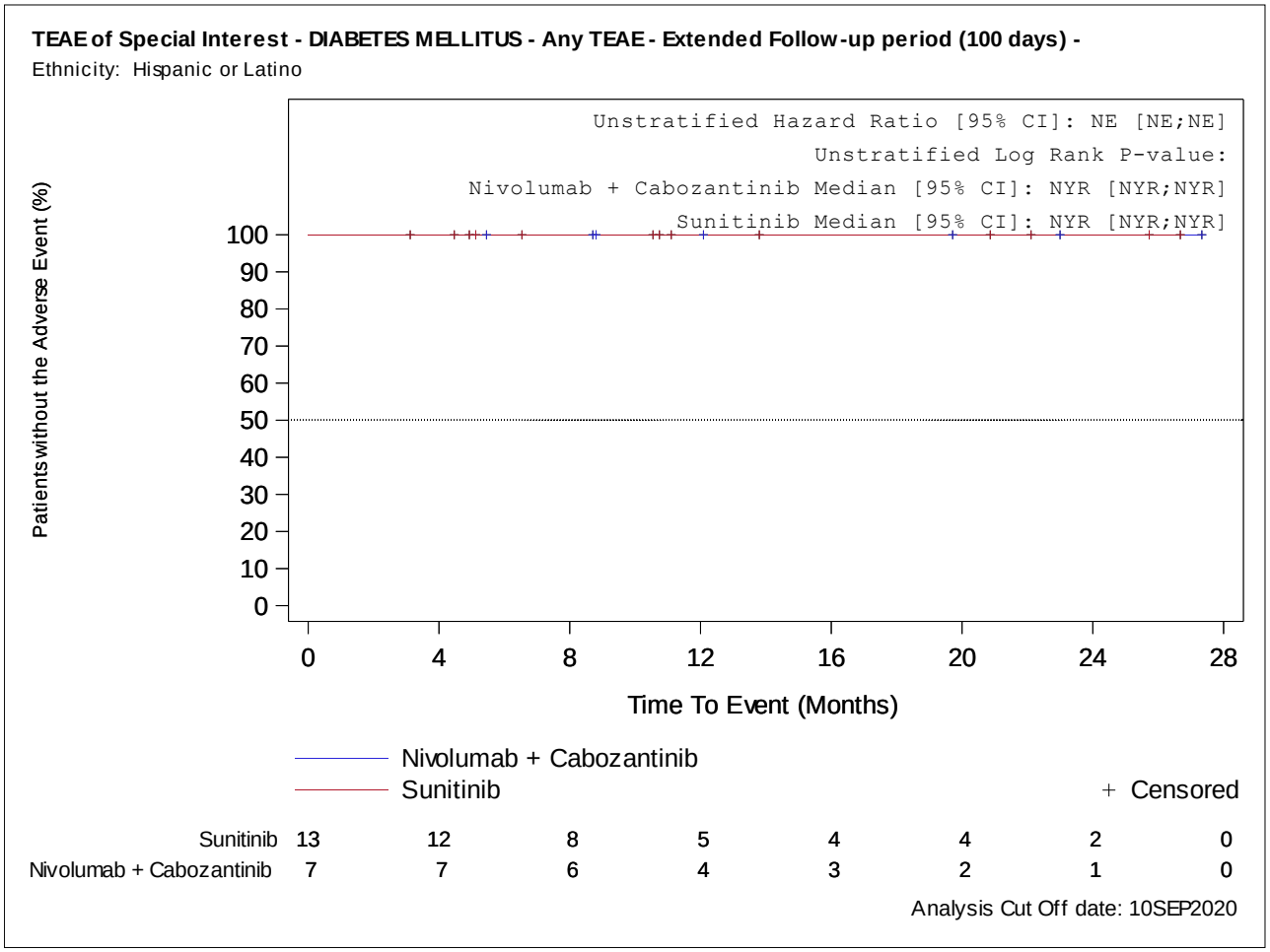
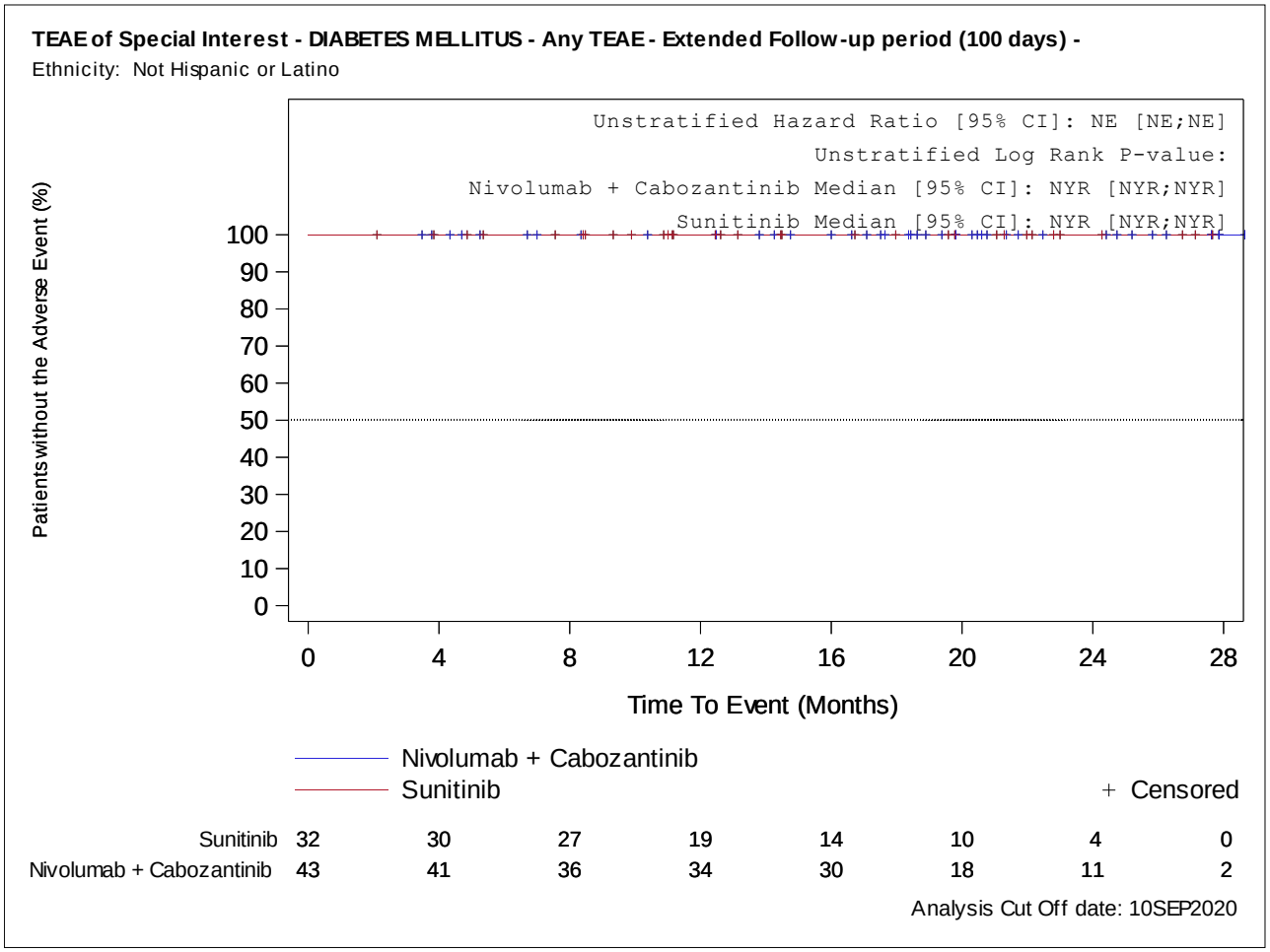
FIGURE 3.66.2.10: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:43:01

FIGURE 3.66.2.11: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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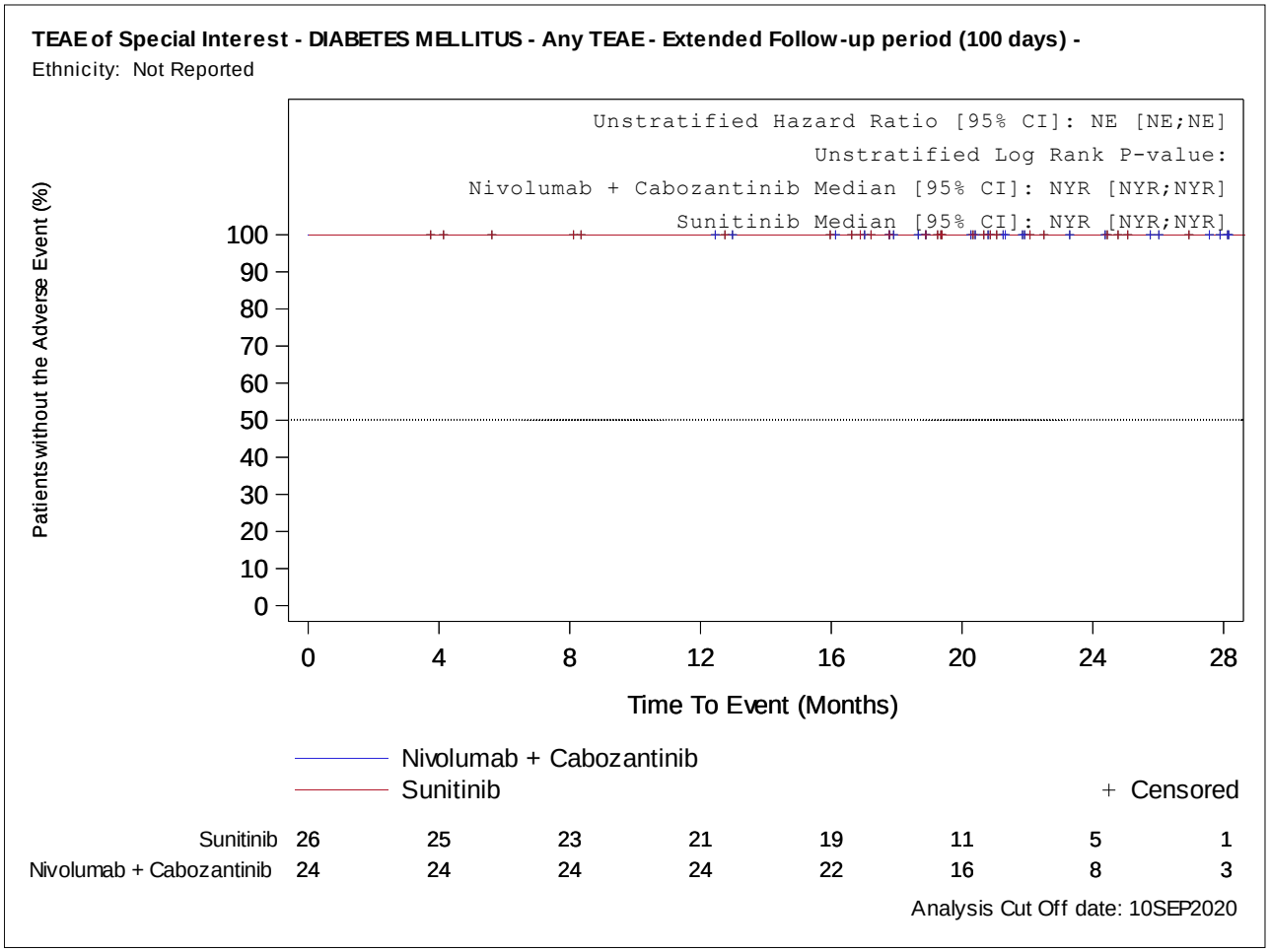
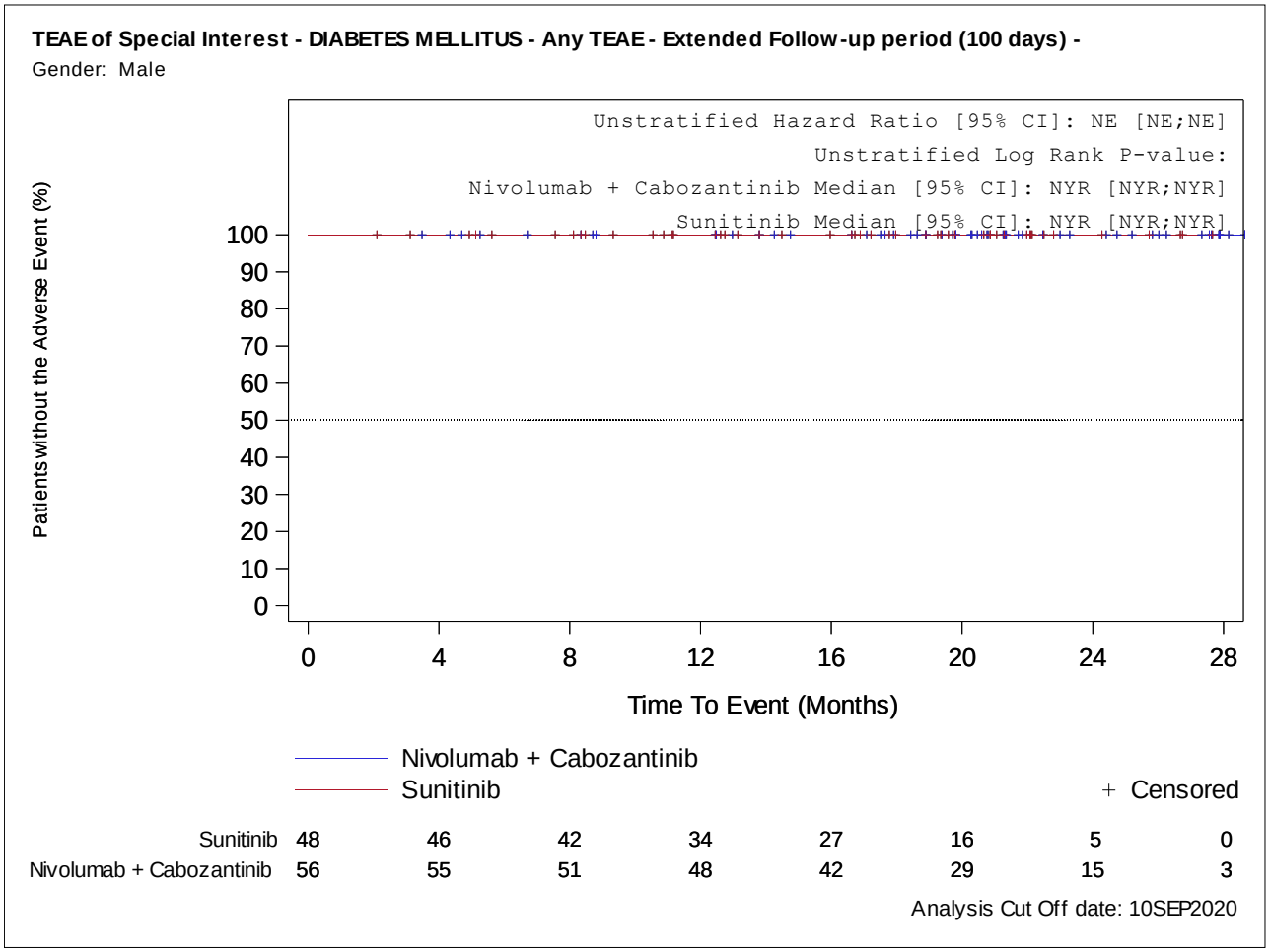
FIGURE 3.66.2.12: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



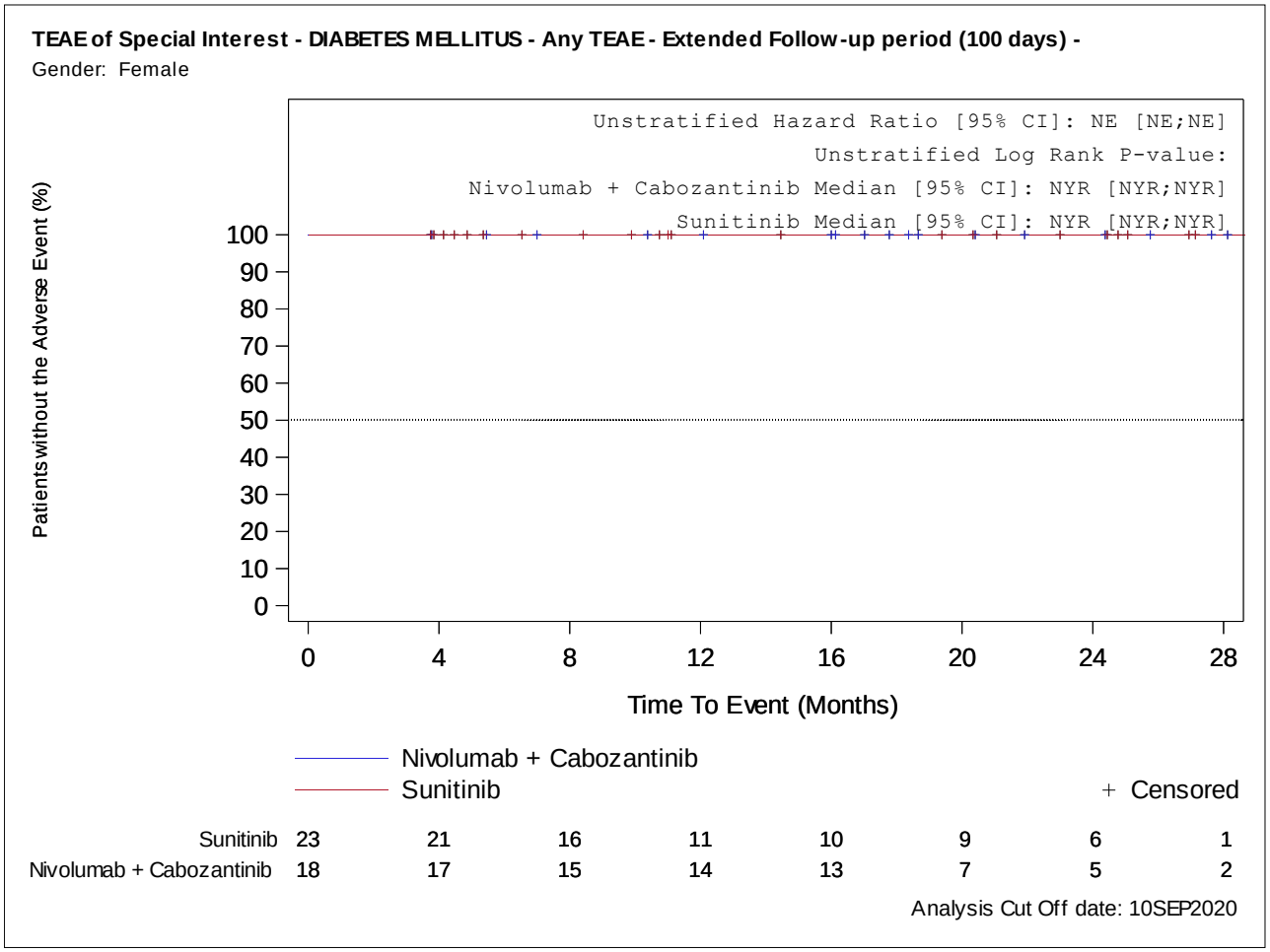

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:43:12

FIGURE 3.66.2.13: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:43:18

FIGURE 3.66.2.14: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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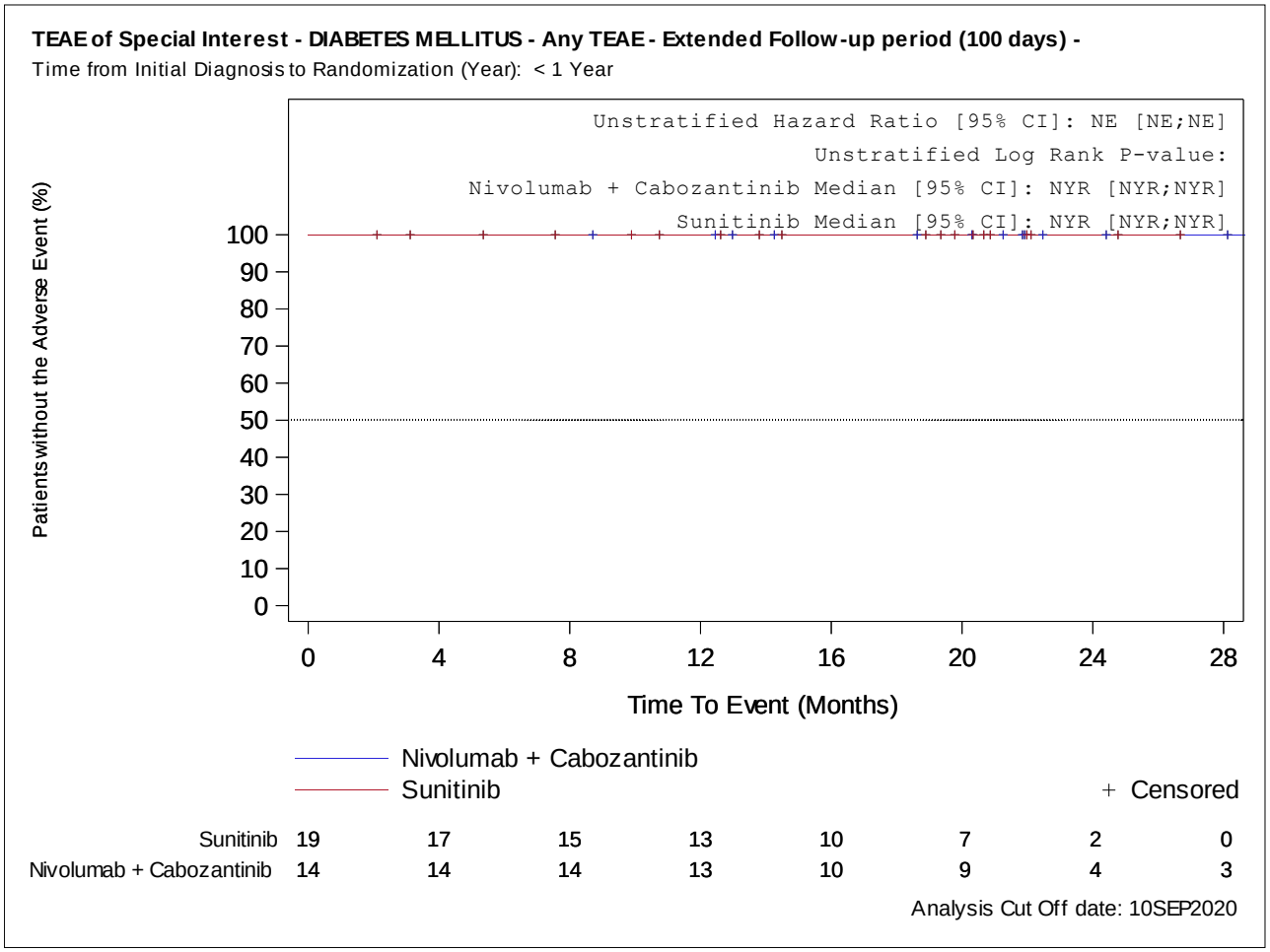
FIGURE 3.66.2.15: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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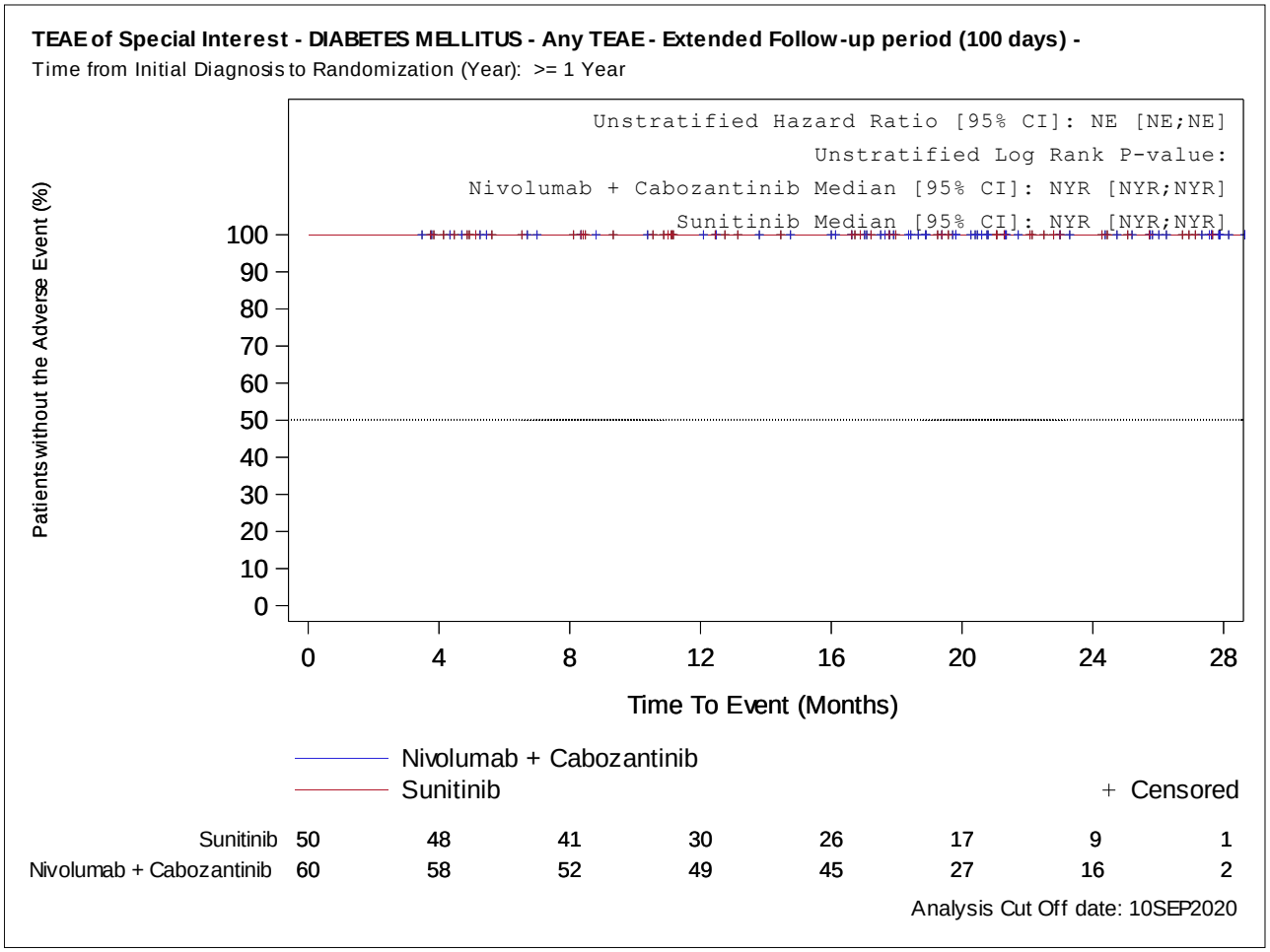
FIGURE 3.66.2.16: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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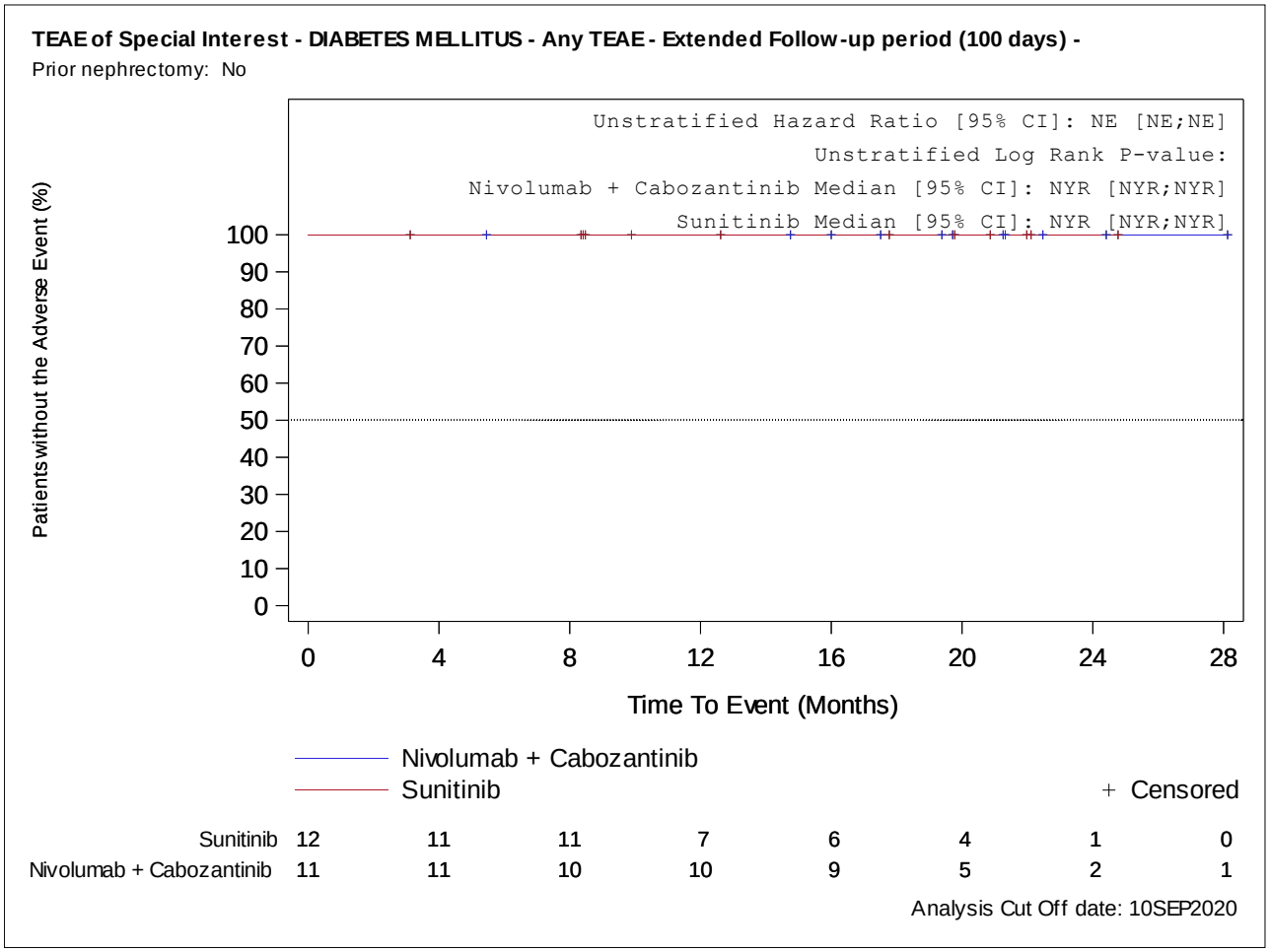
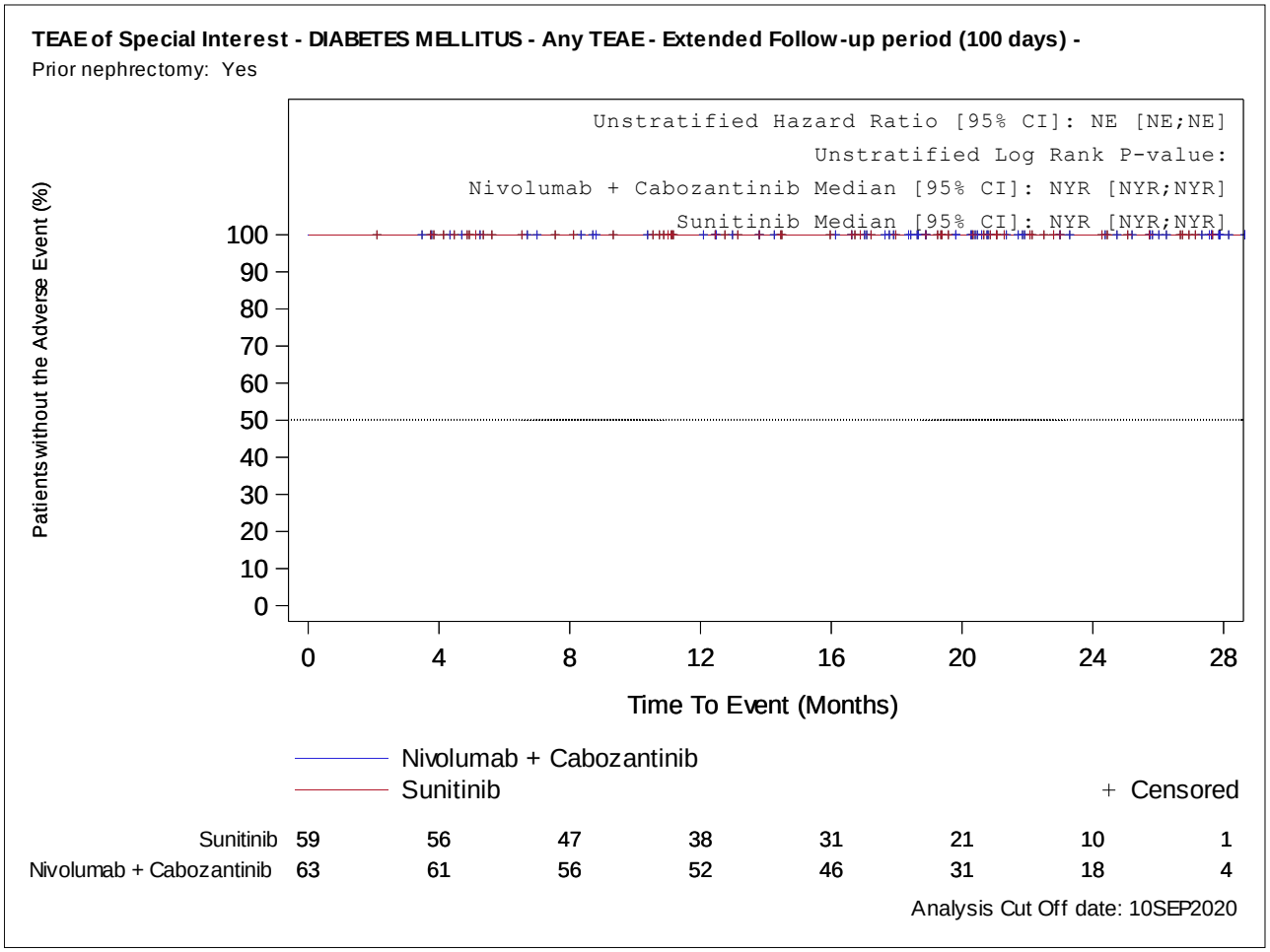
FIGURE 3.66.2.17: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:44:39

FIGURE 3.66.2.18: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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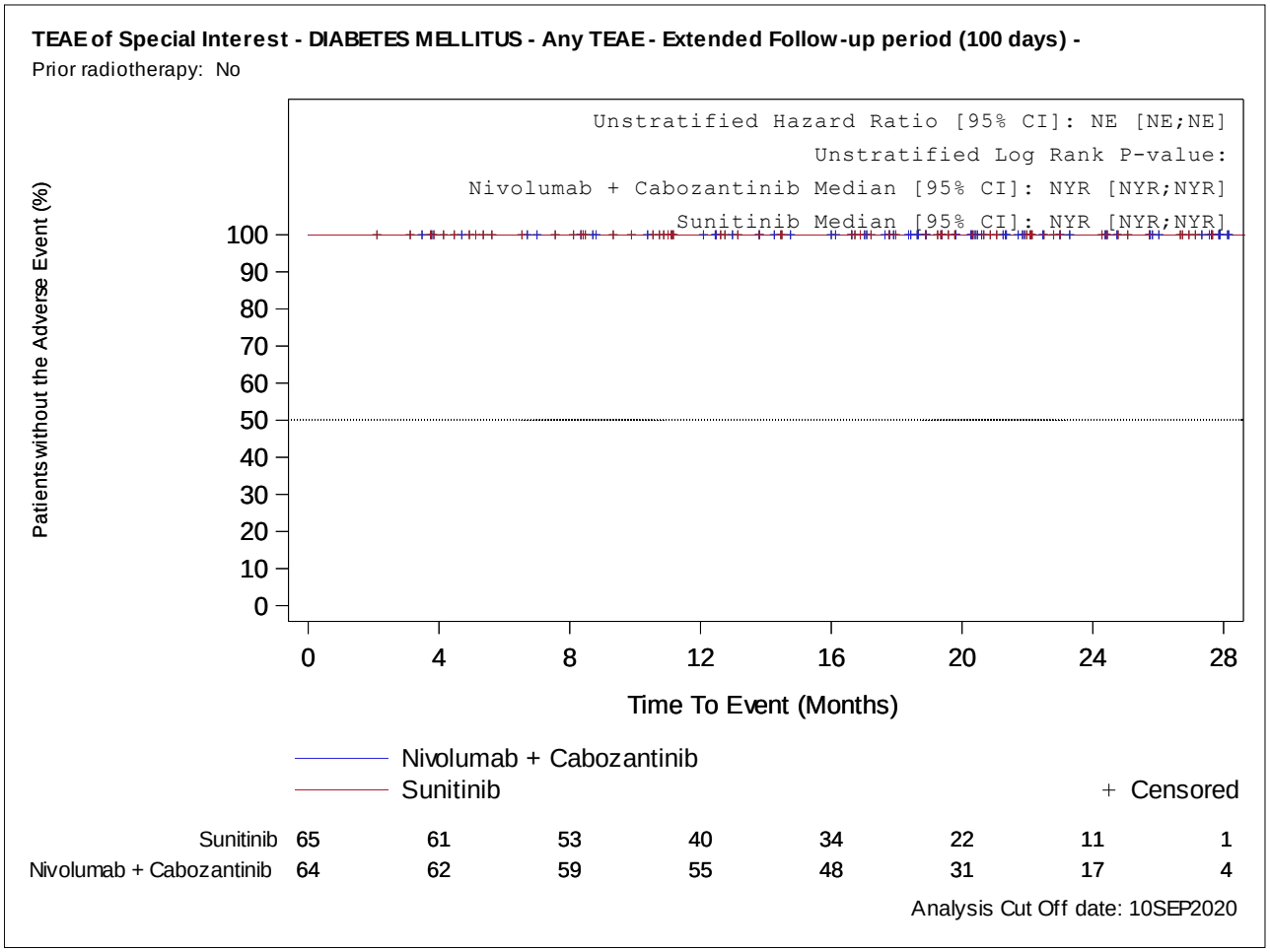
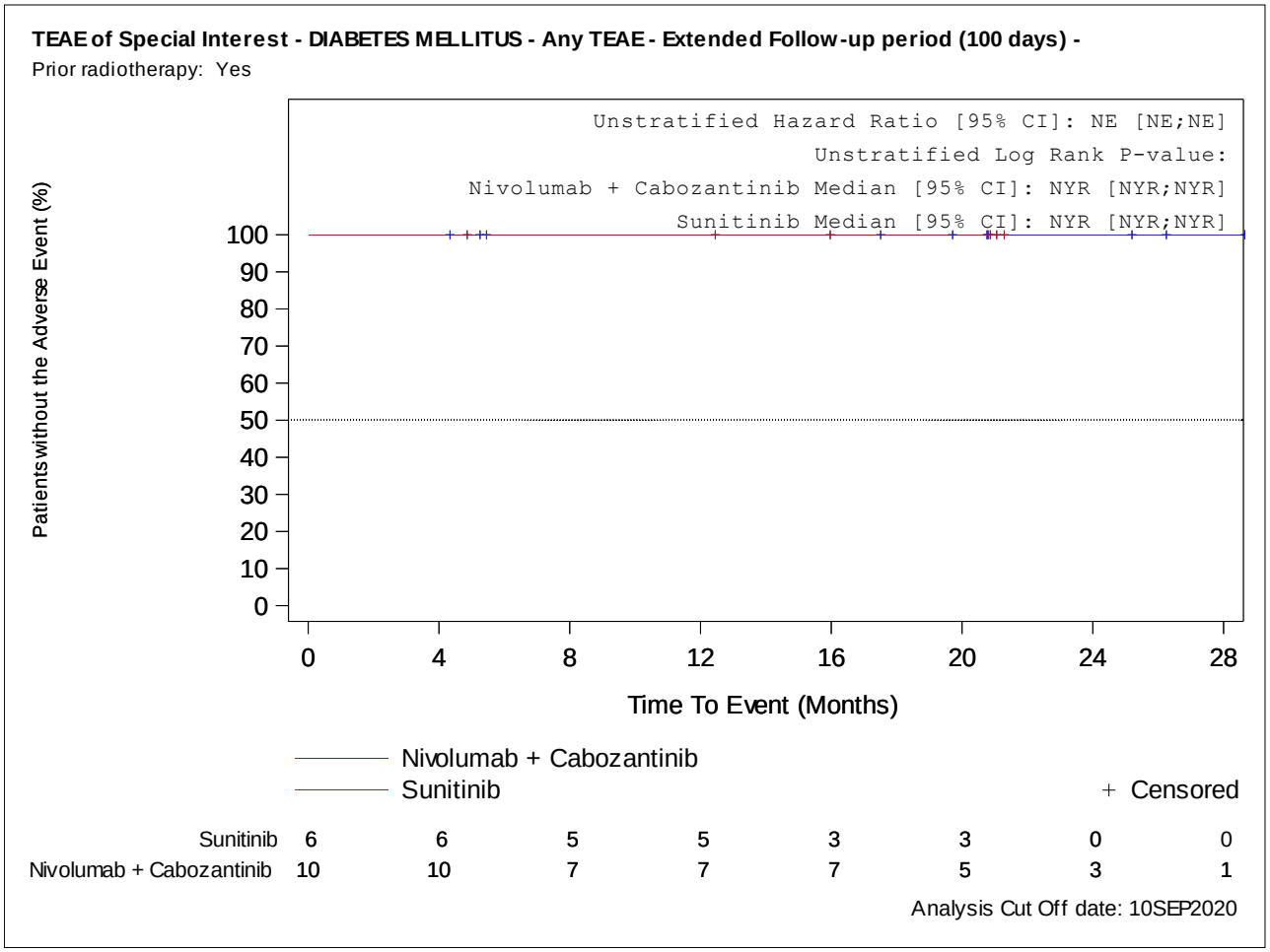
FIGURE 3.66.2.19: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:44:51

FIGURE 3.66.2.20: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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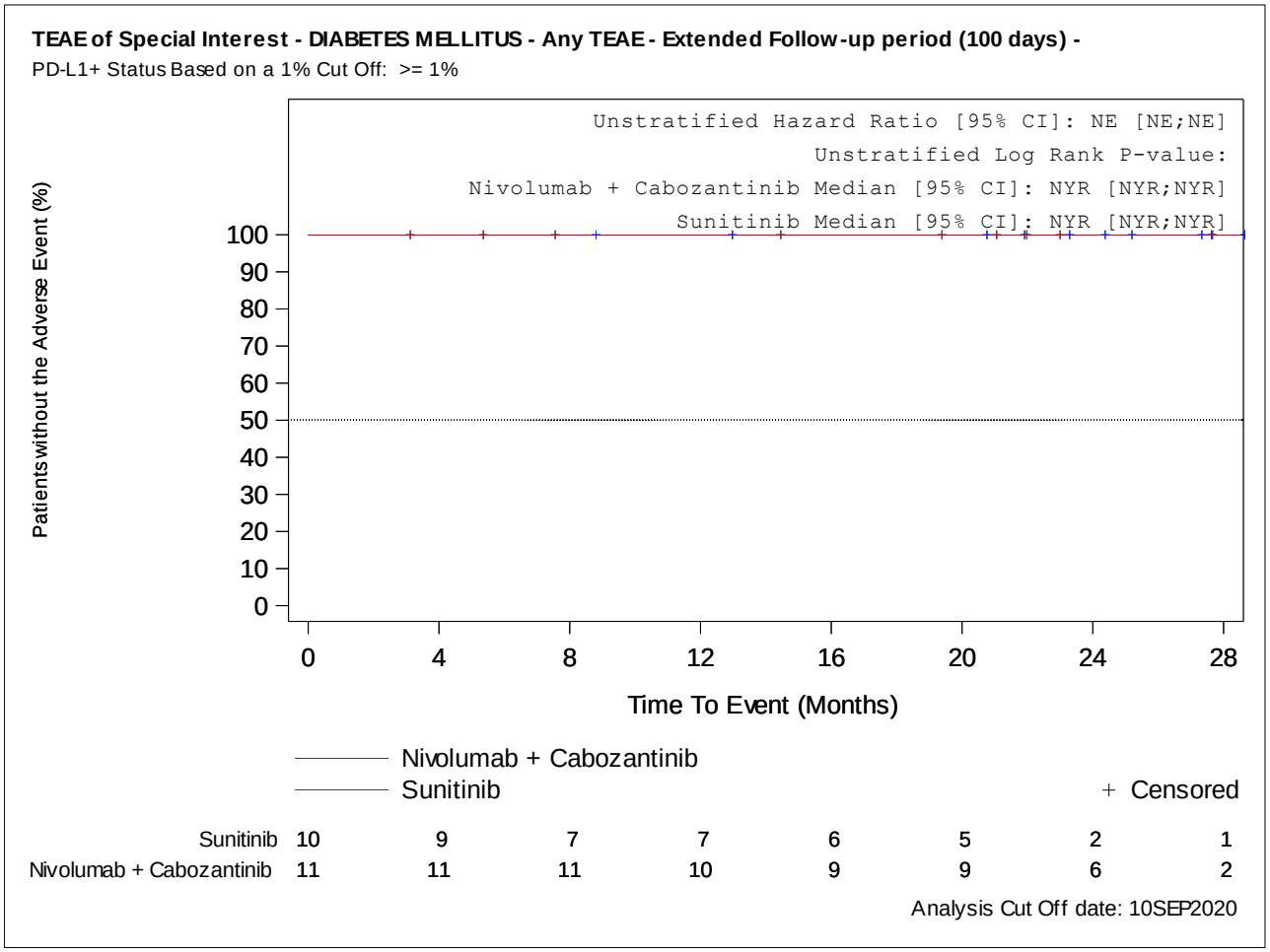
FIGURE 3.66.2.21: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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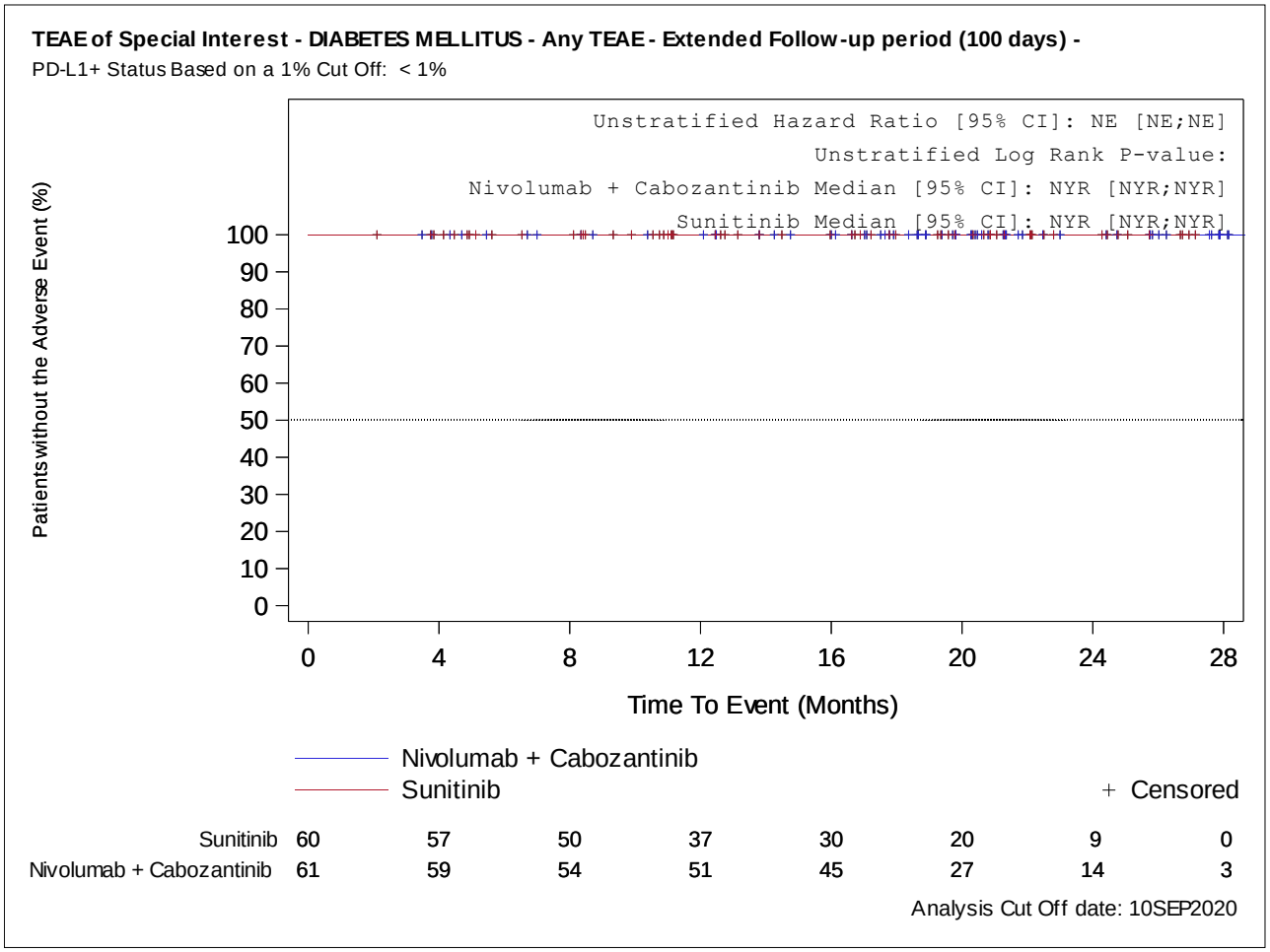
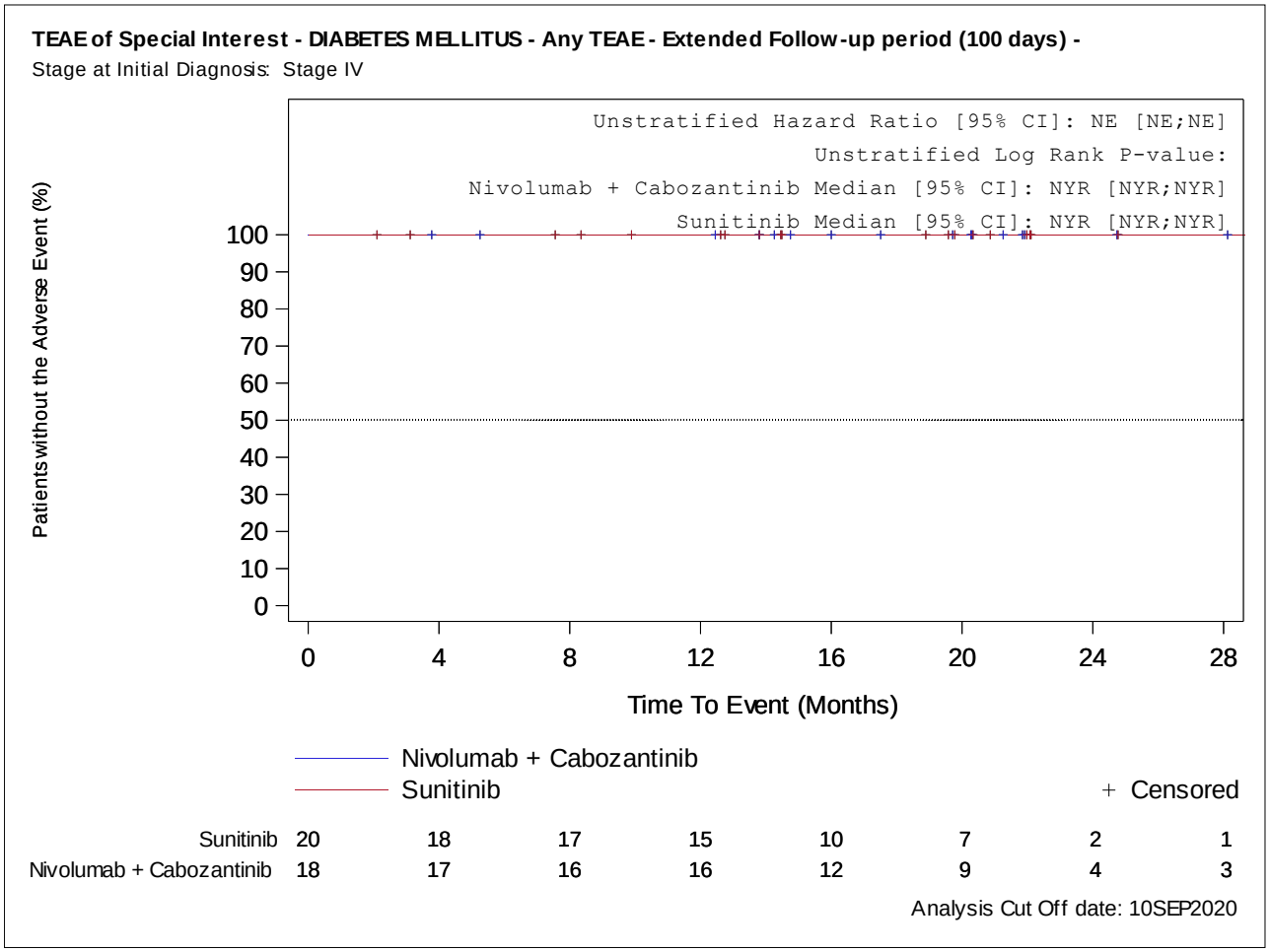
FIGURE 3.66.2.22: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:45:07

FIGURE 3.66.2.23: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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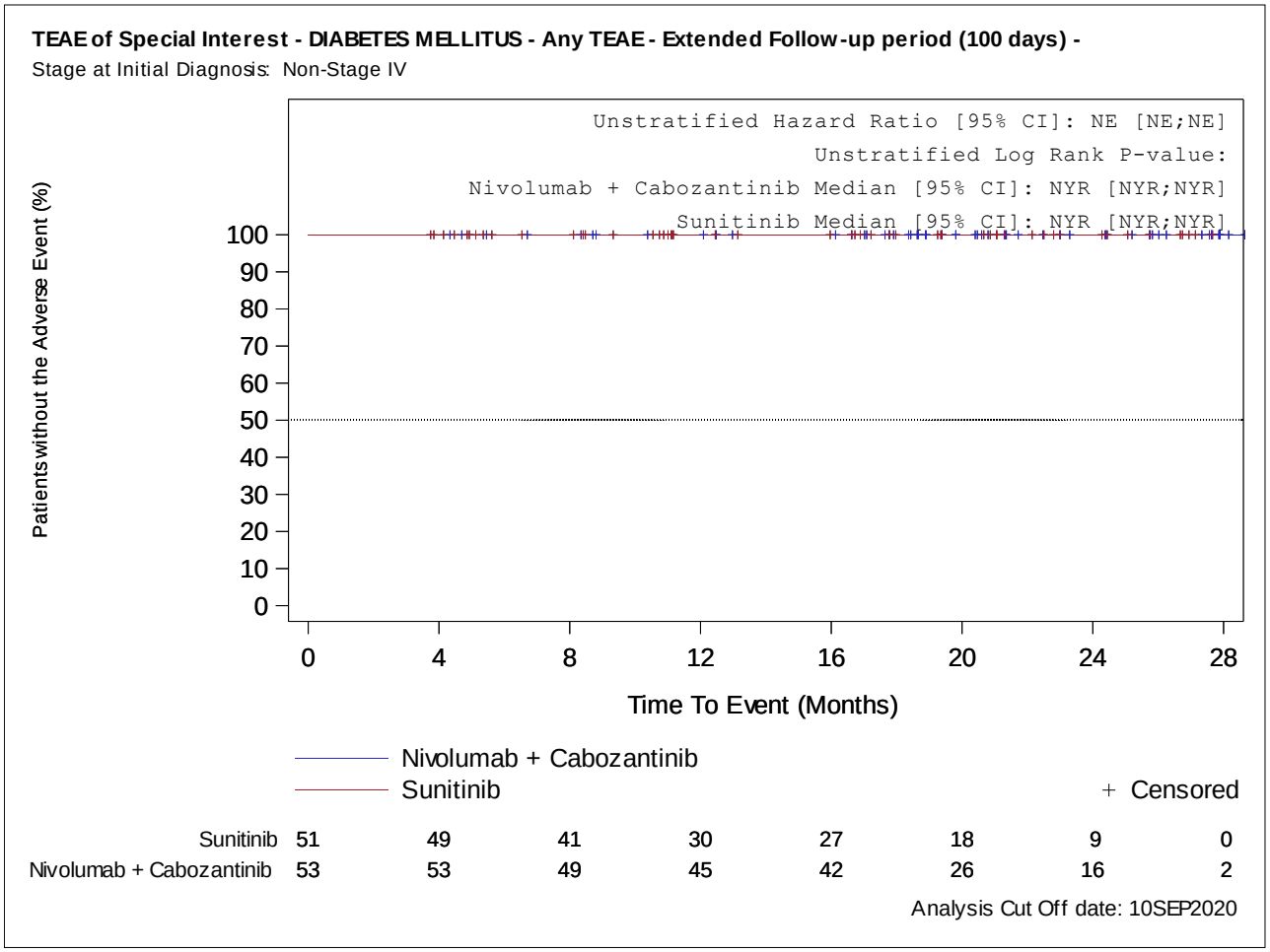
FIGURE 3.66.2.24: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Any TEAE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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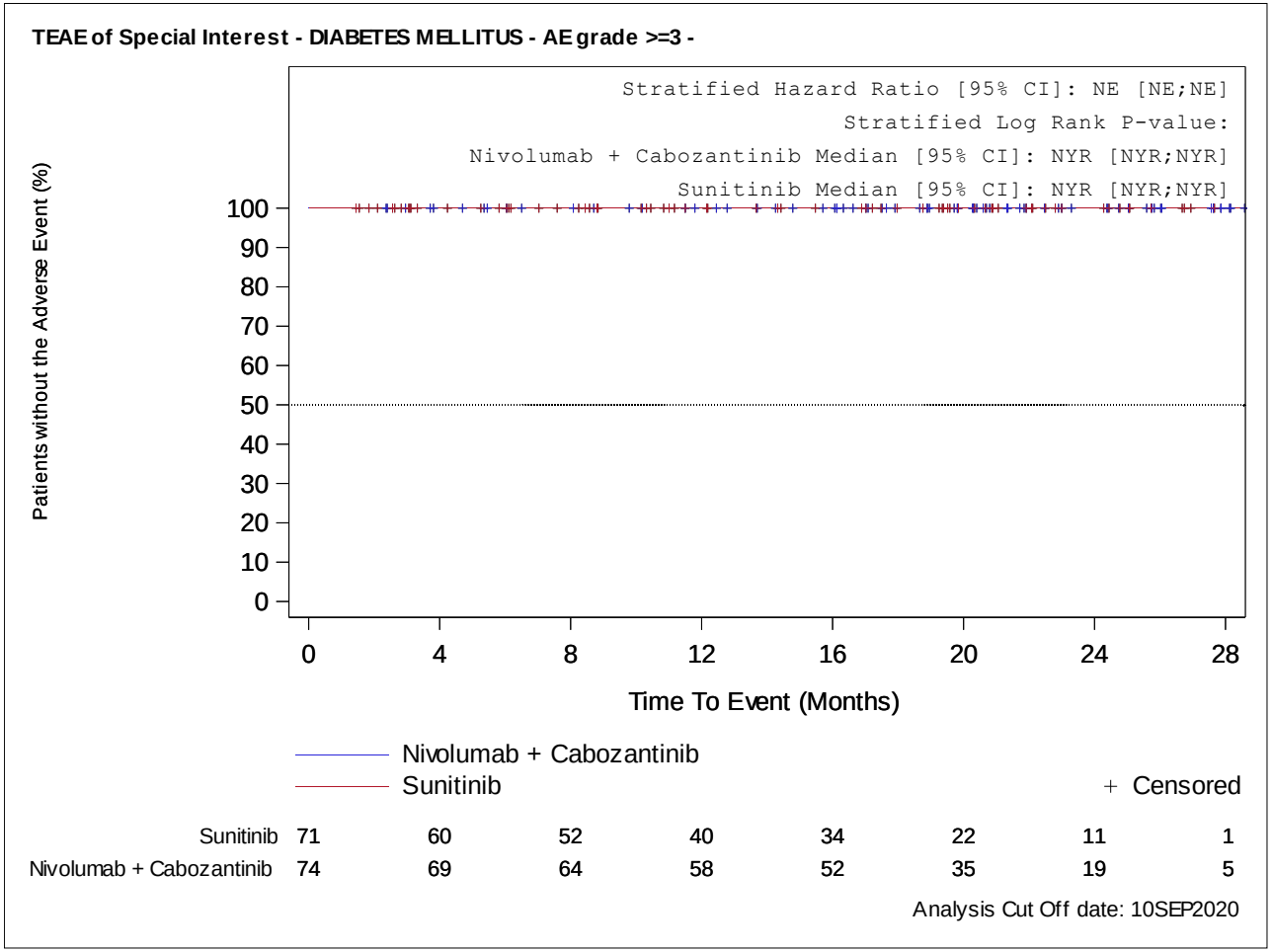
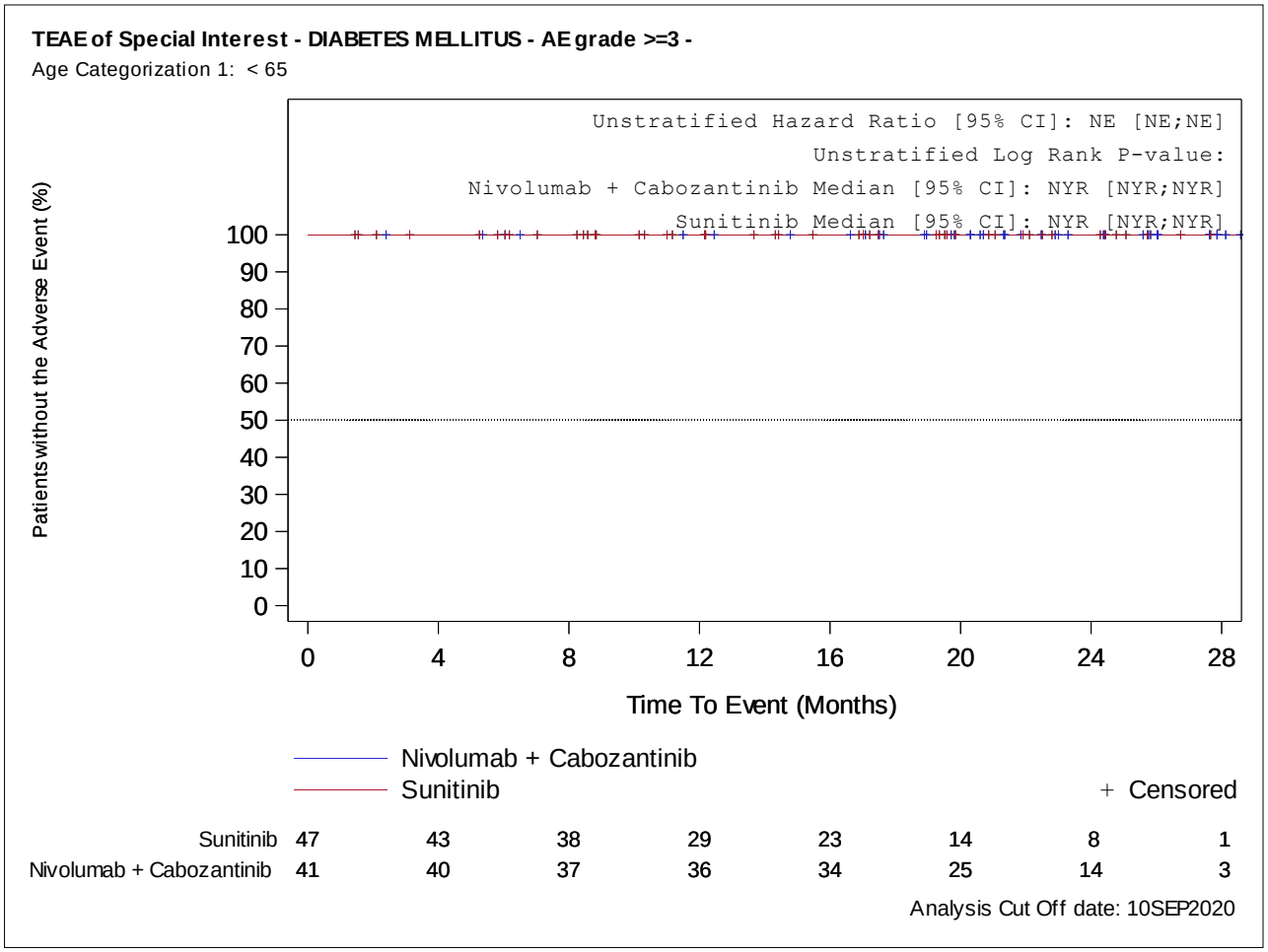
FIGURE 3.67.1: TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



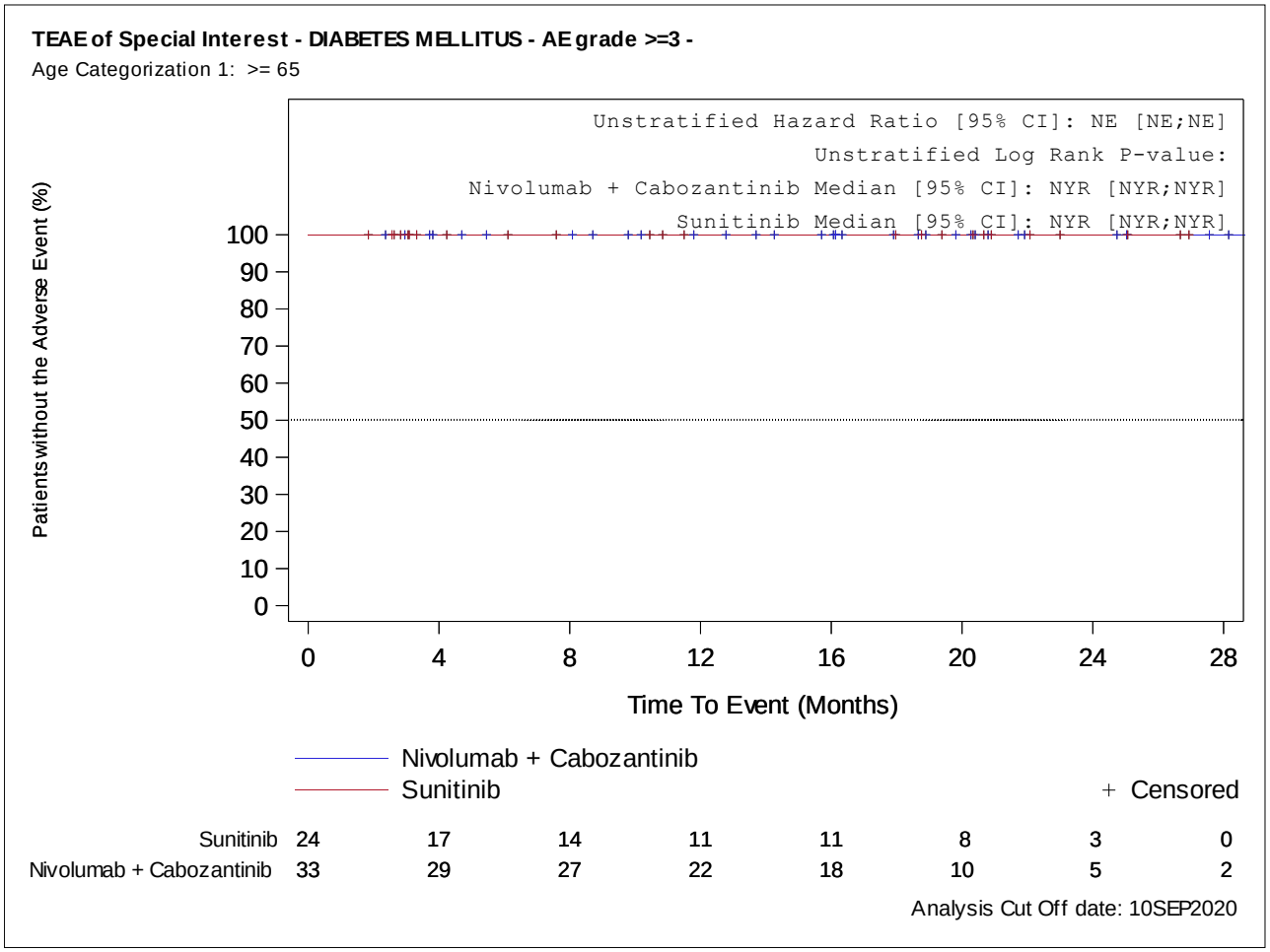

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:48:58

FIGURE 3.67.2.1: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  < 65



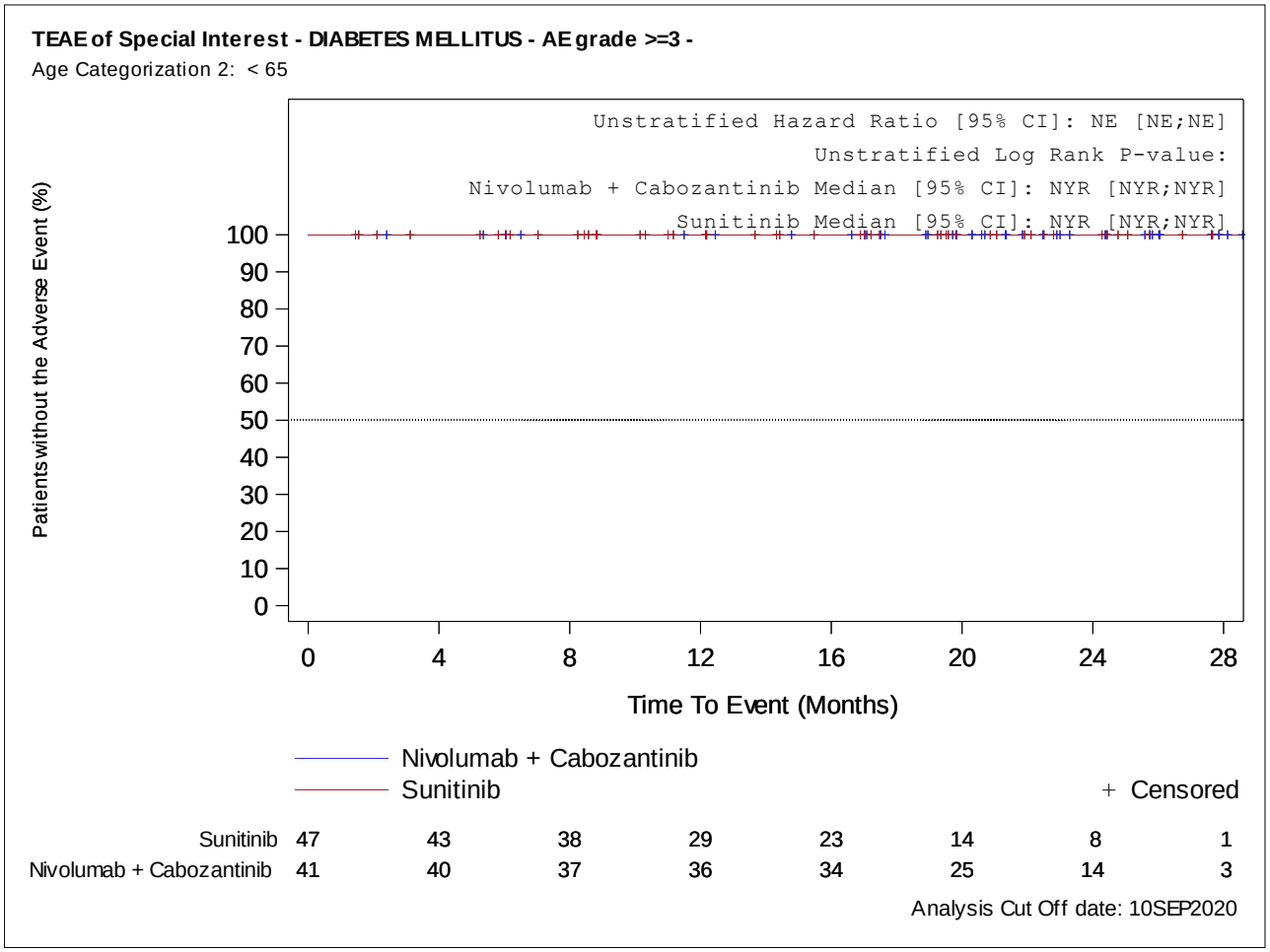

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:49:01

FIGURE 3.67.2.2: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



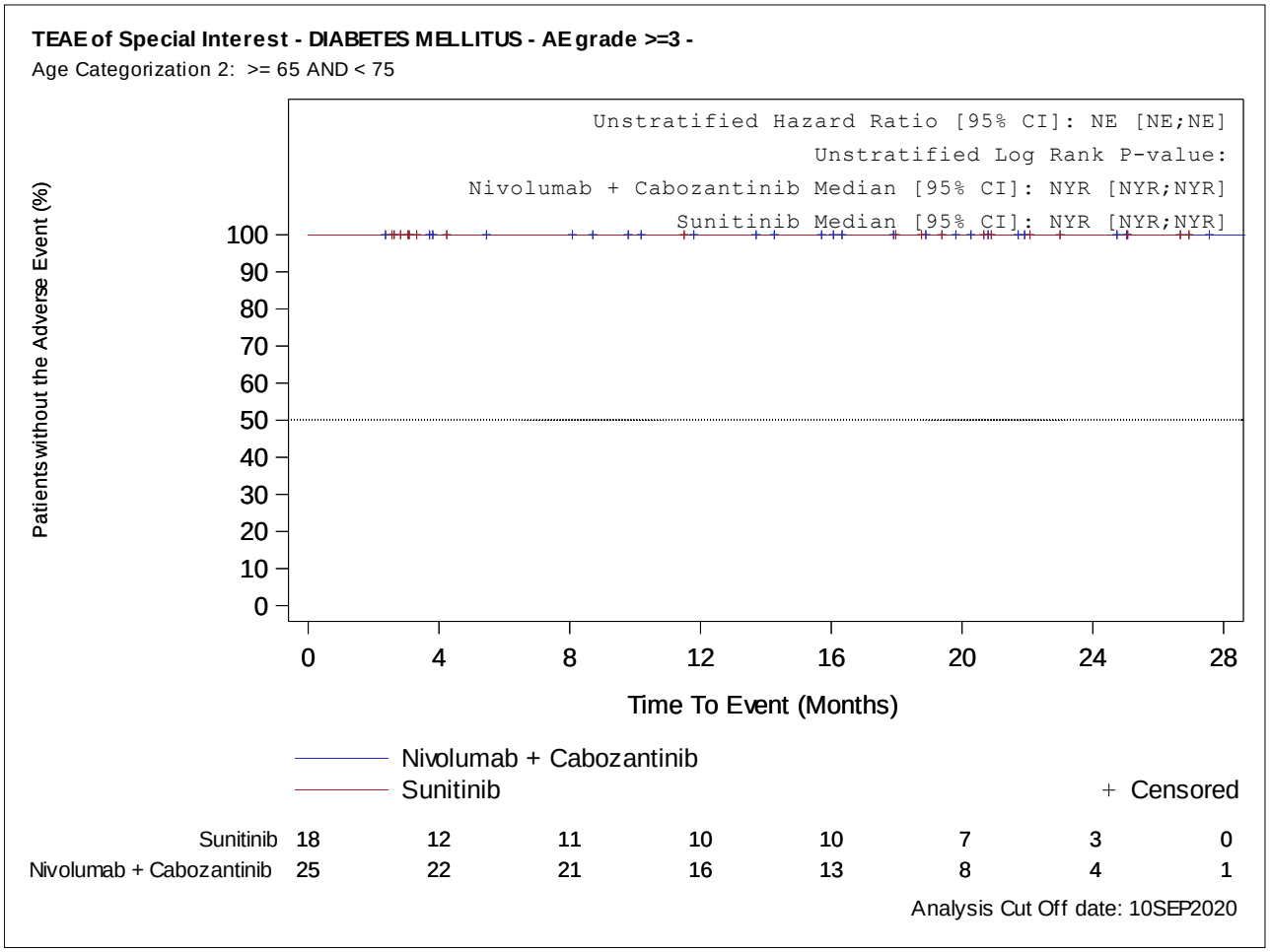

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:49:07

FIGURE 3.67.2.3: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  < 65



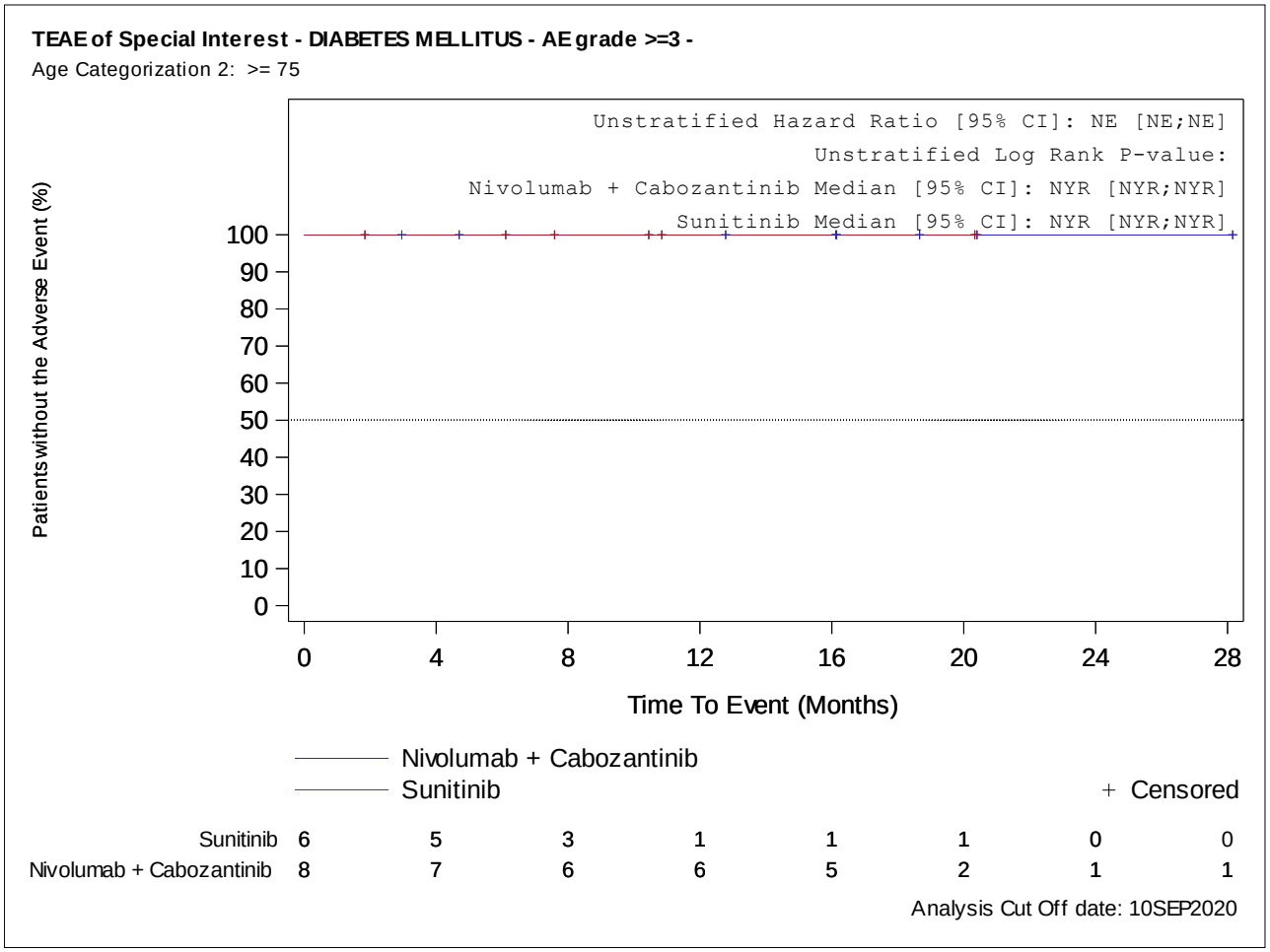

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:49:13

FIGURE 3.67.2.4: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



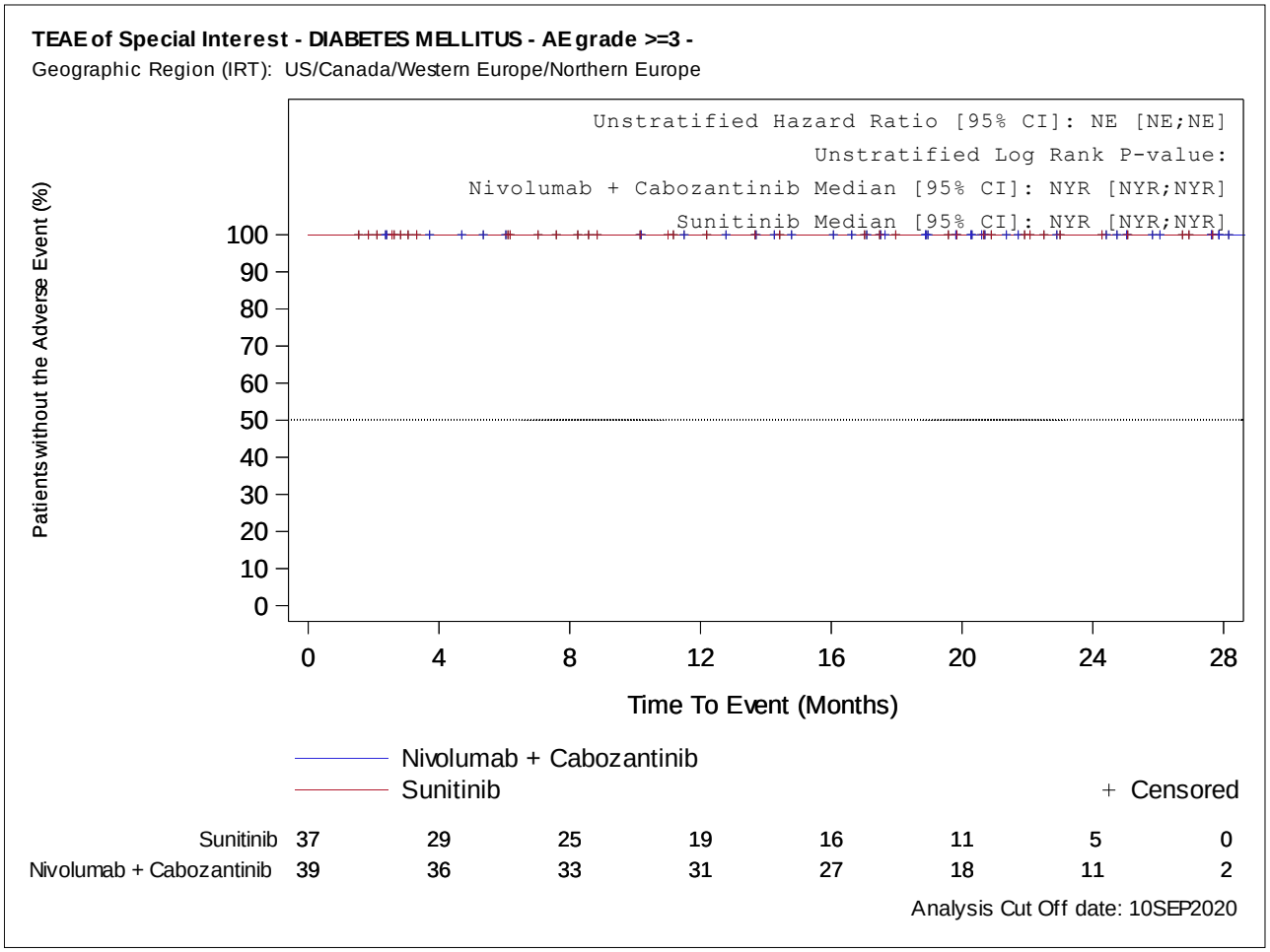

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:49:19

FIGURE 3.67.2.5: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



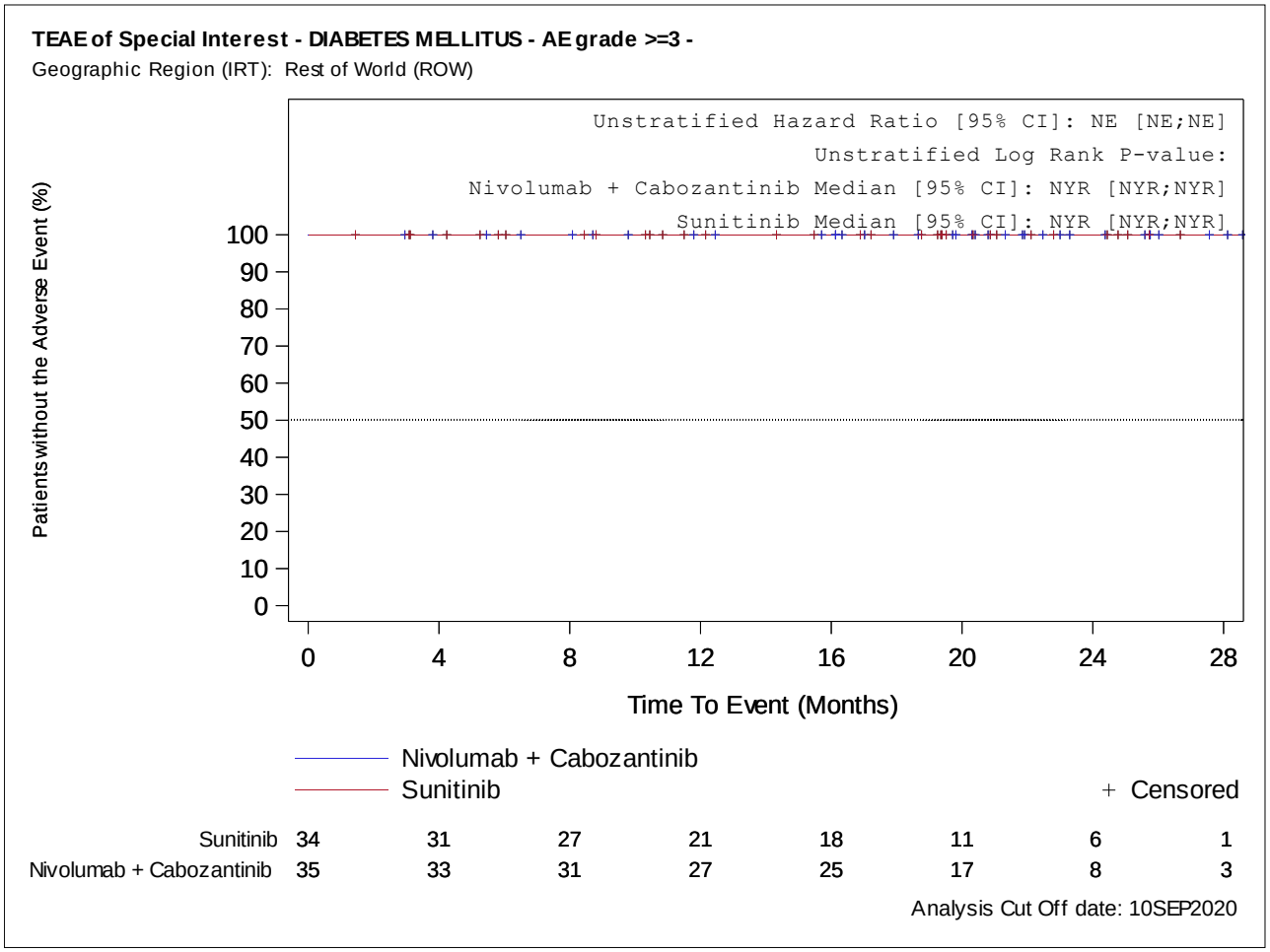

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:49:24

FIGURE 3.67.2.6: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:49:30

FIGURE 3.67.2.7: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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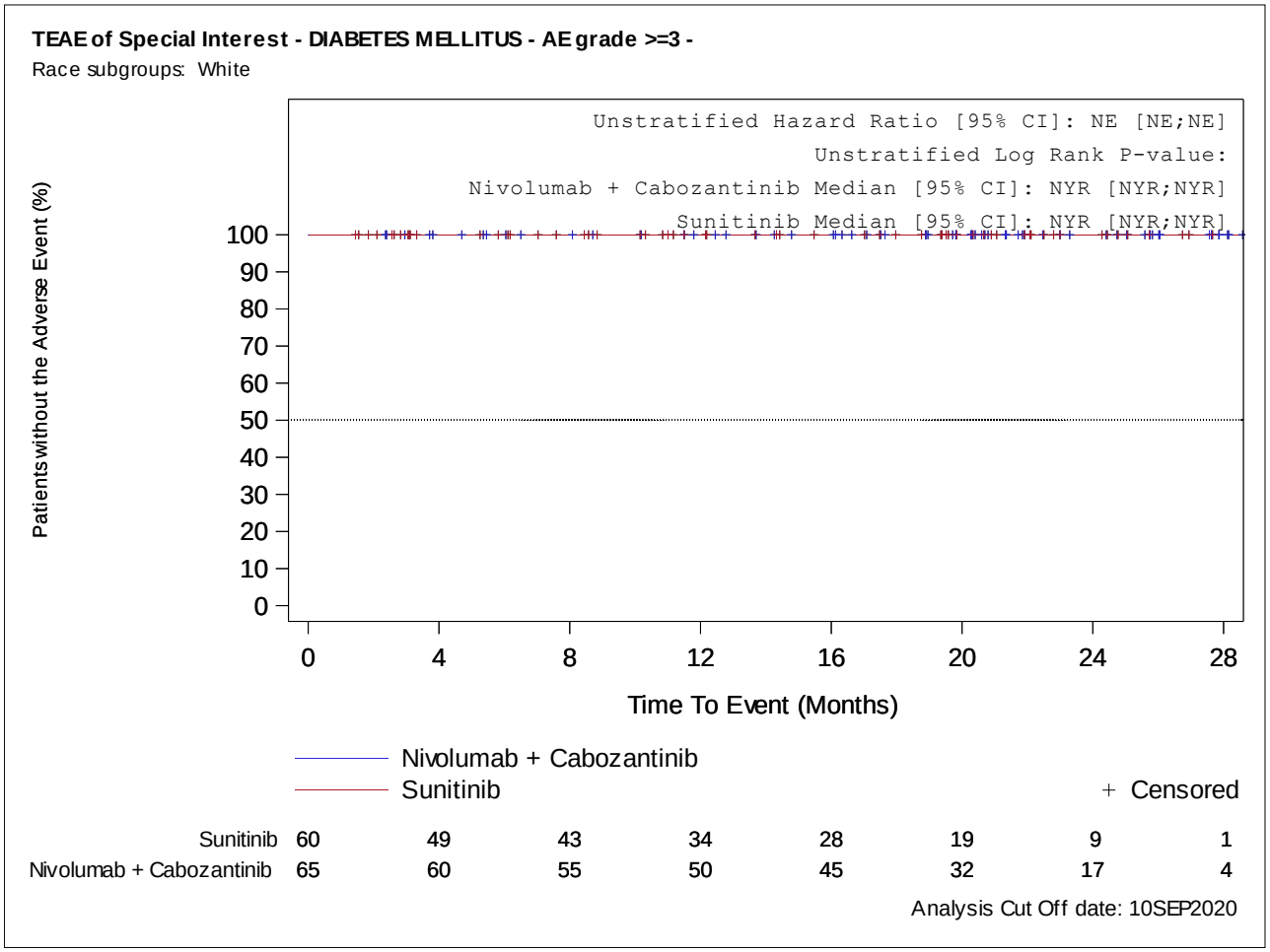
FIGURE 3.67.2.8: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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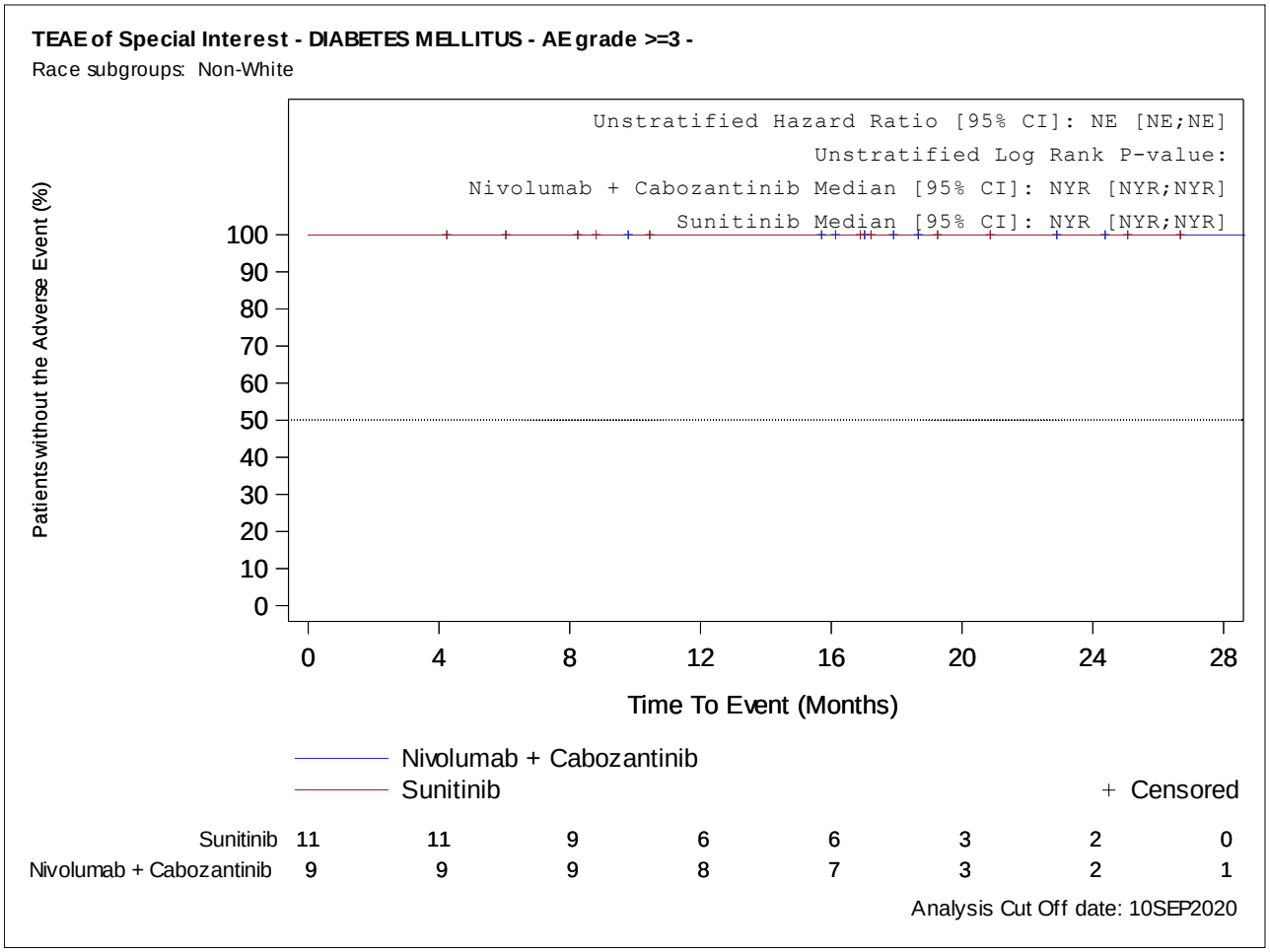
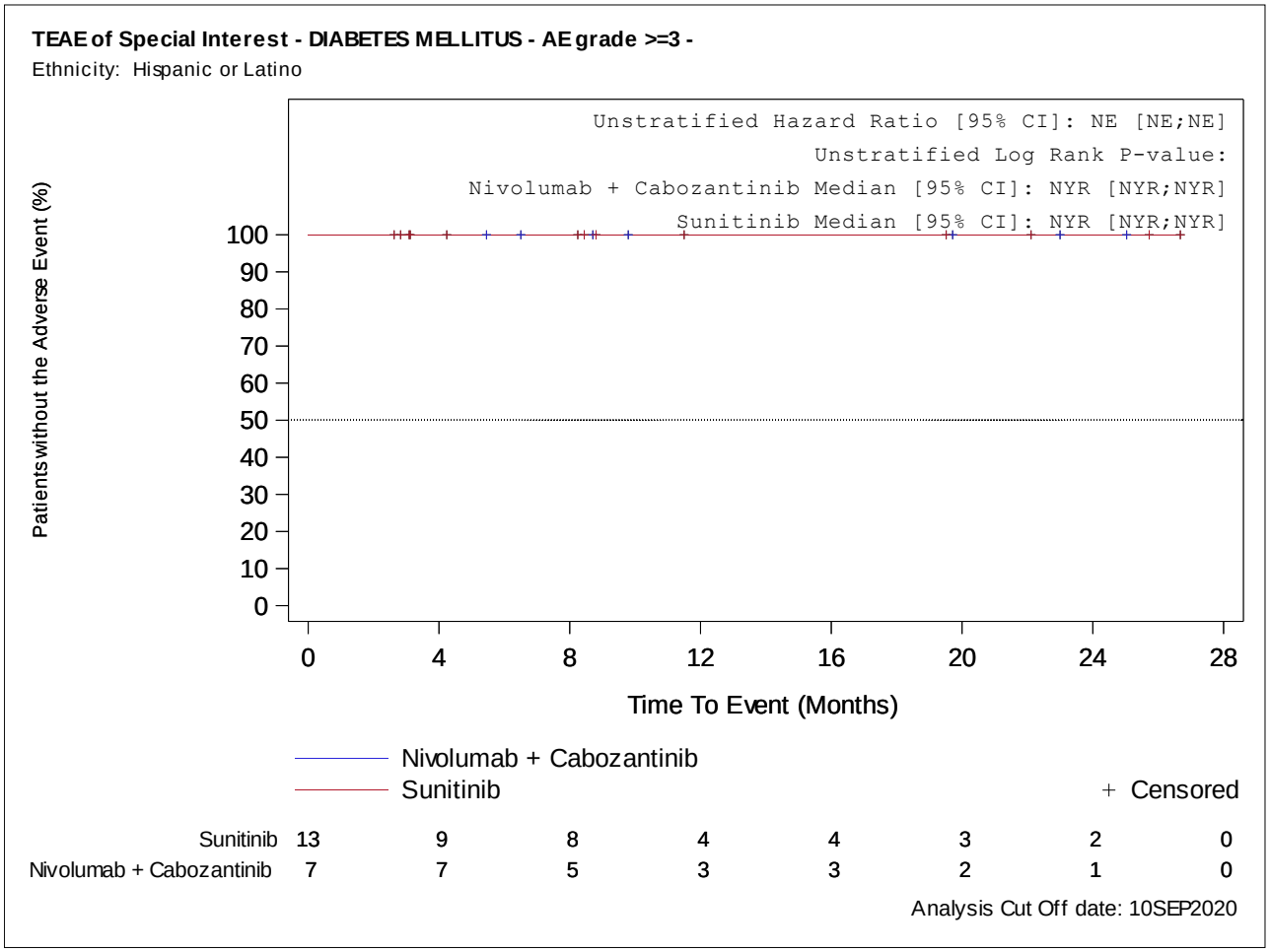
FIGURE 3.67.2.9: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



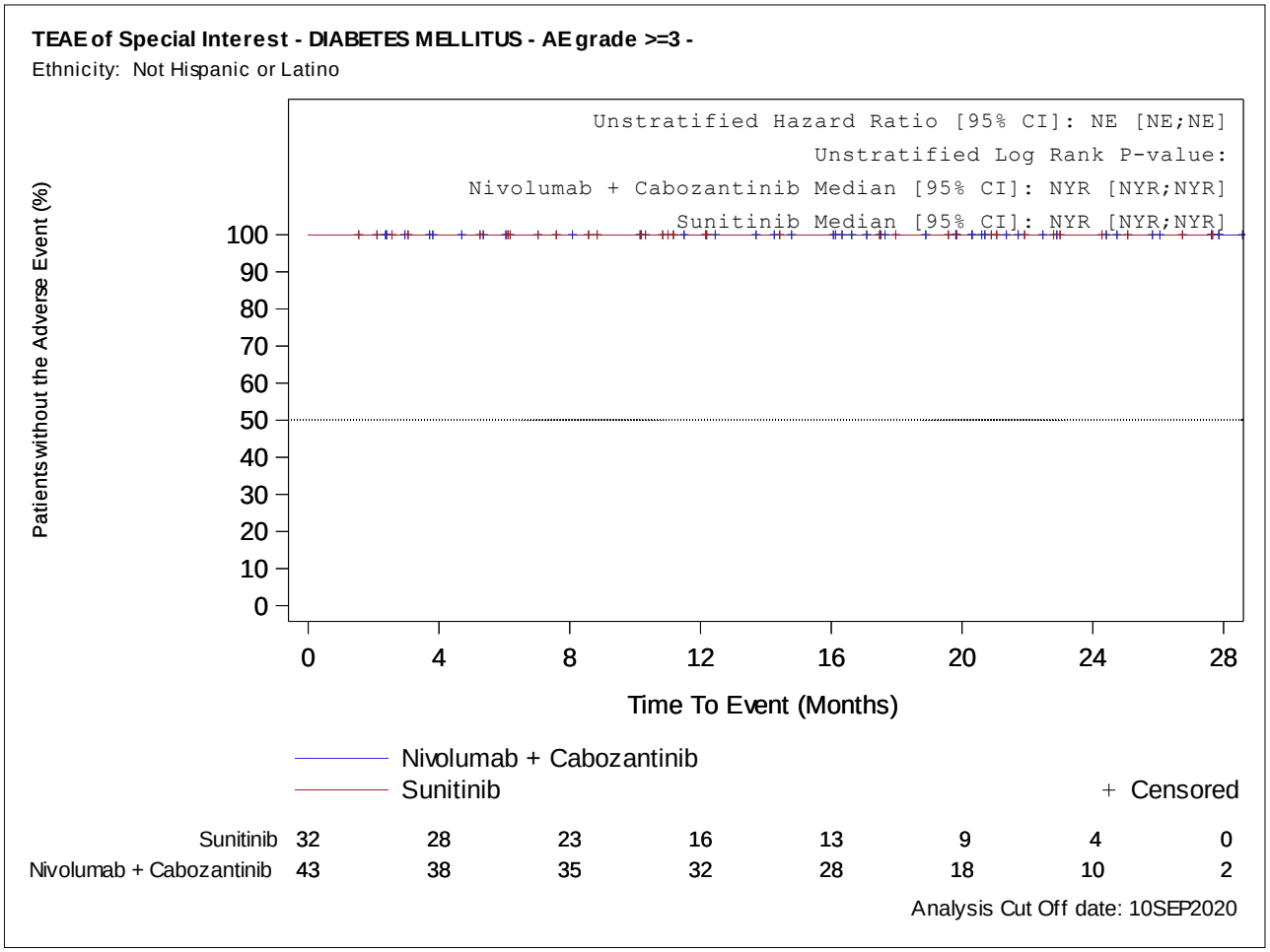

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:49:47

FIGURE 3.67.2.10: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



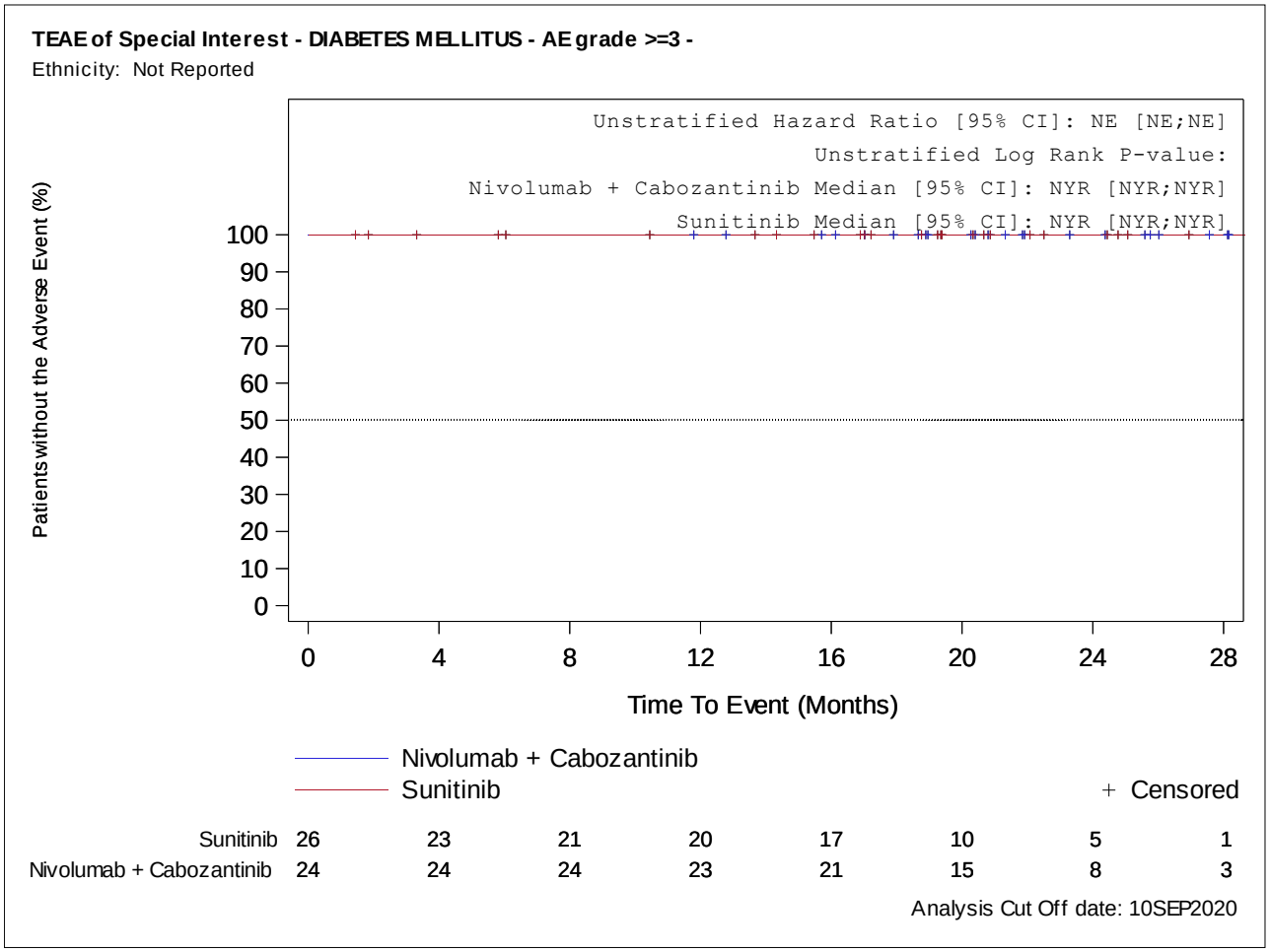

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:49:52

FIGURE 3.67.2.11: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity:  Not Hispanic or Latino



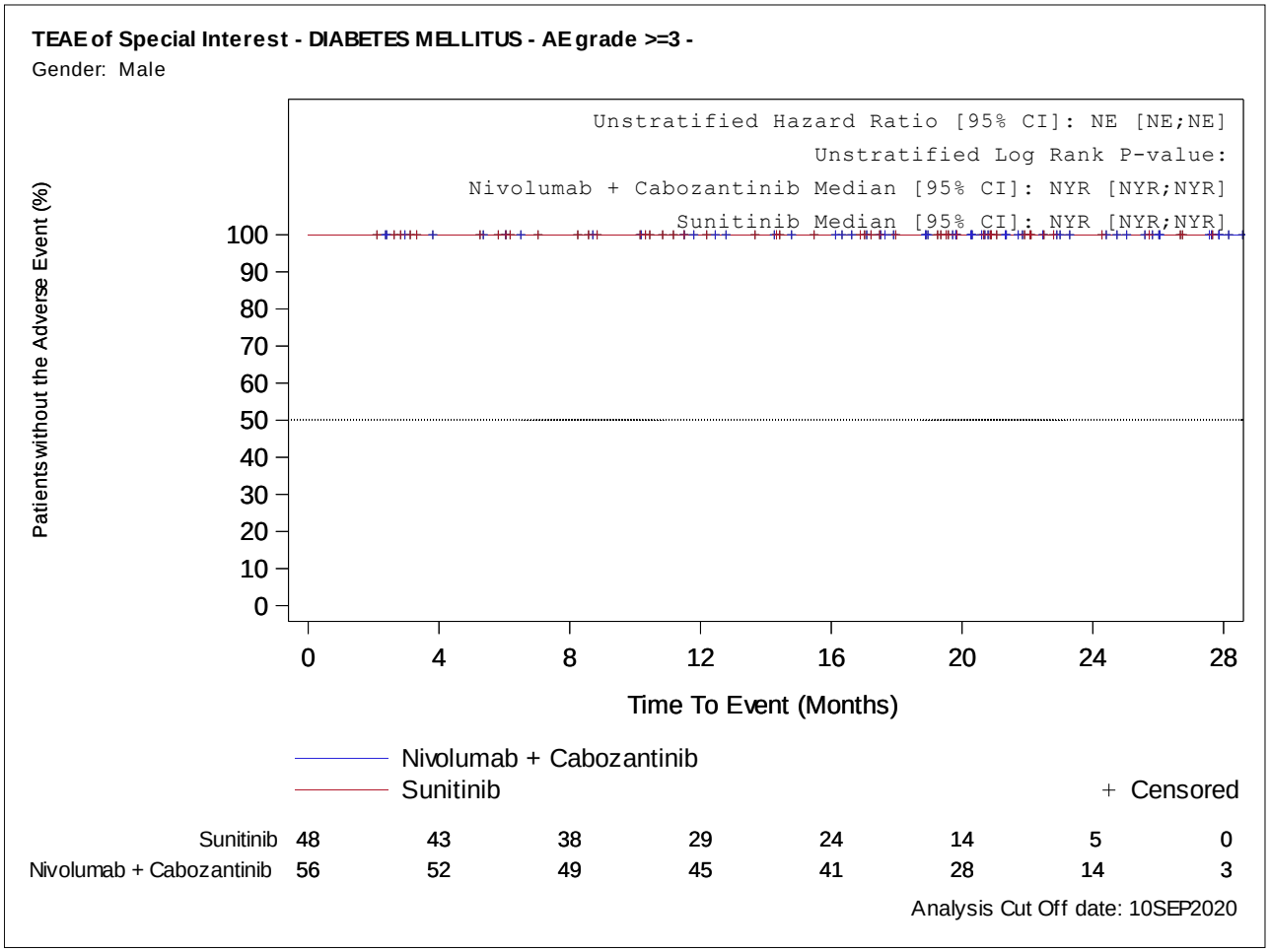

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:49:58

FIGURE 3.67.2.12: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity:  Not Reported



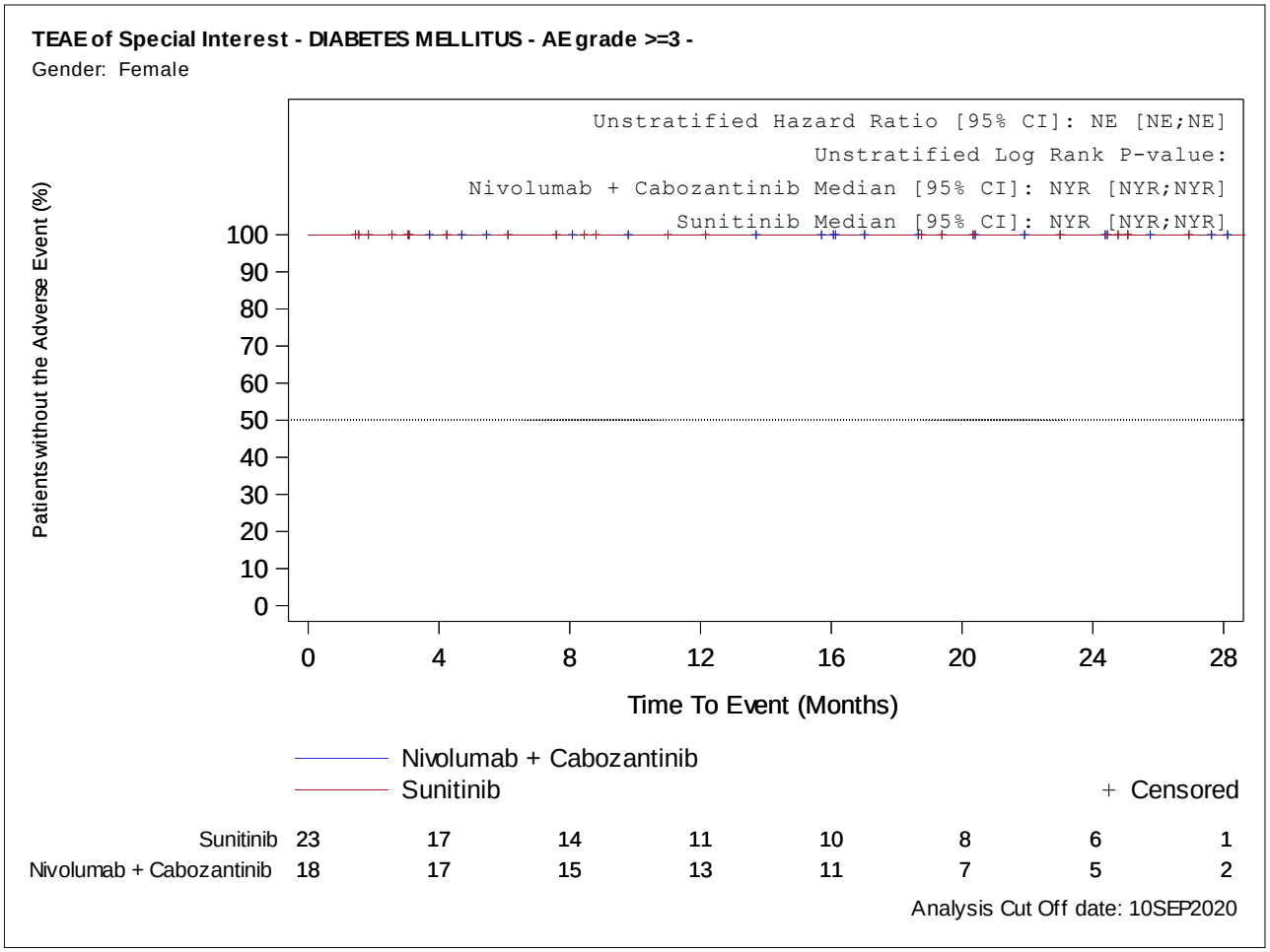

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:50:04

FIGURE 3.67.2.13: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



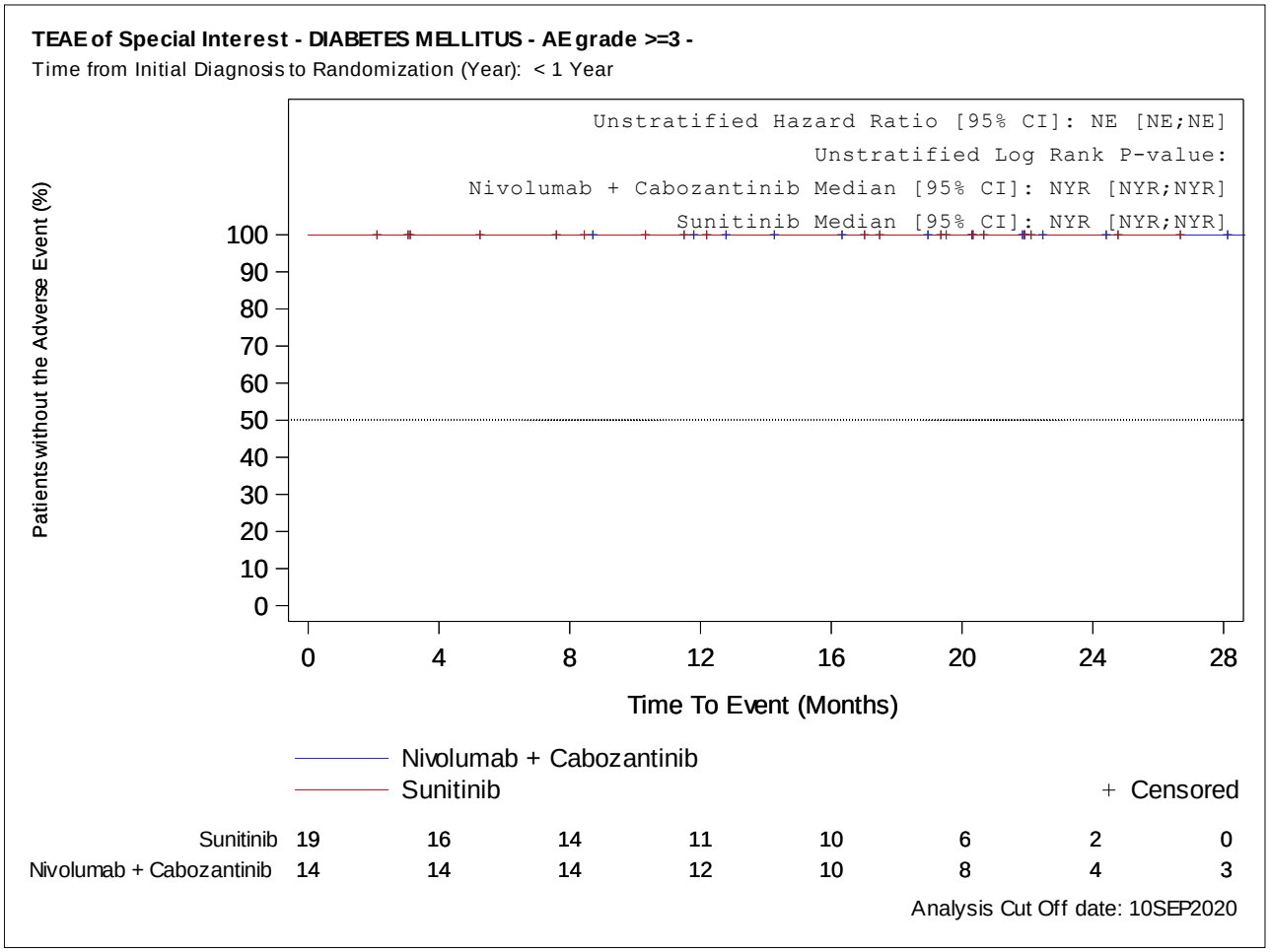

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:50:10

FIGURE 3.67.2.14: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



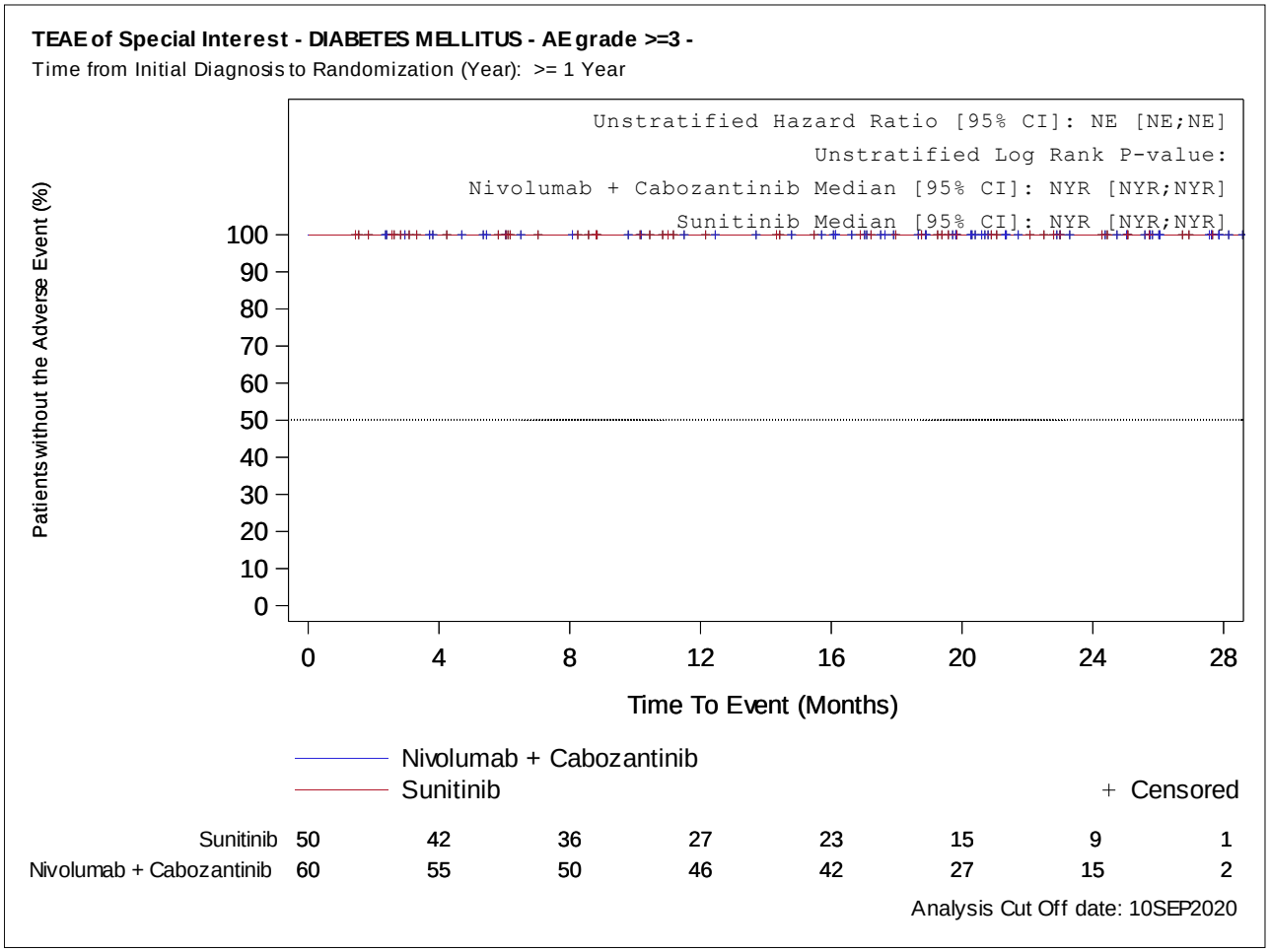

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:50:15

FIGURE 3.67.2.15: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



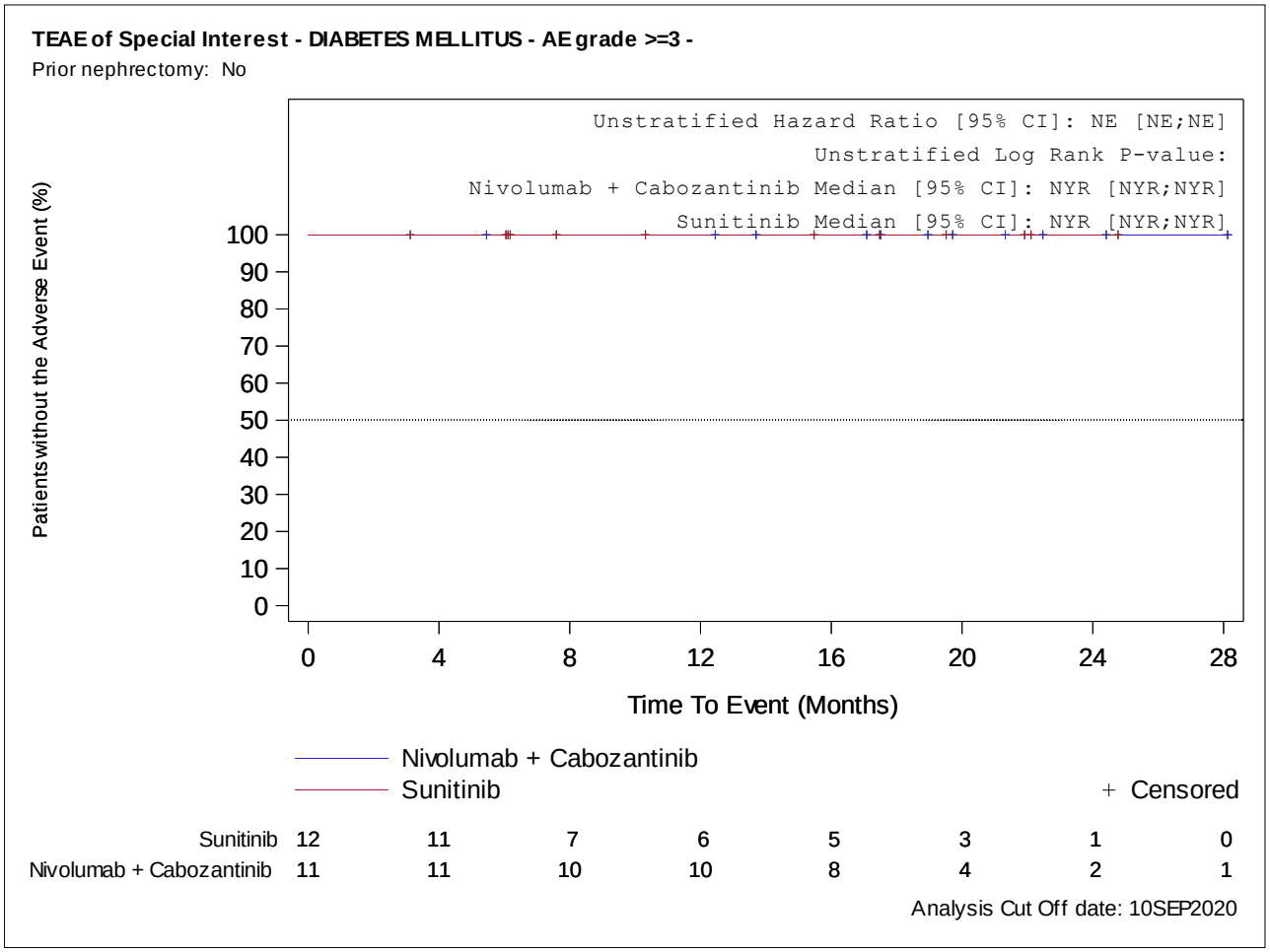

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:50:33

FIGURE 3.67.2.16: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



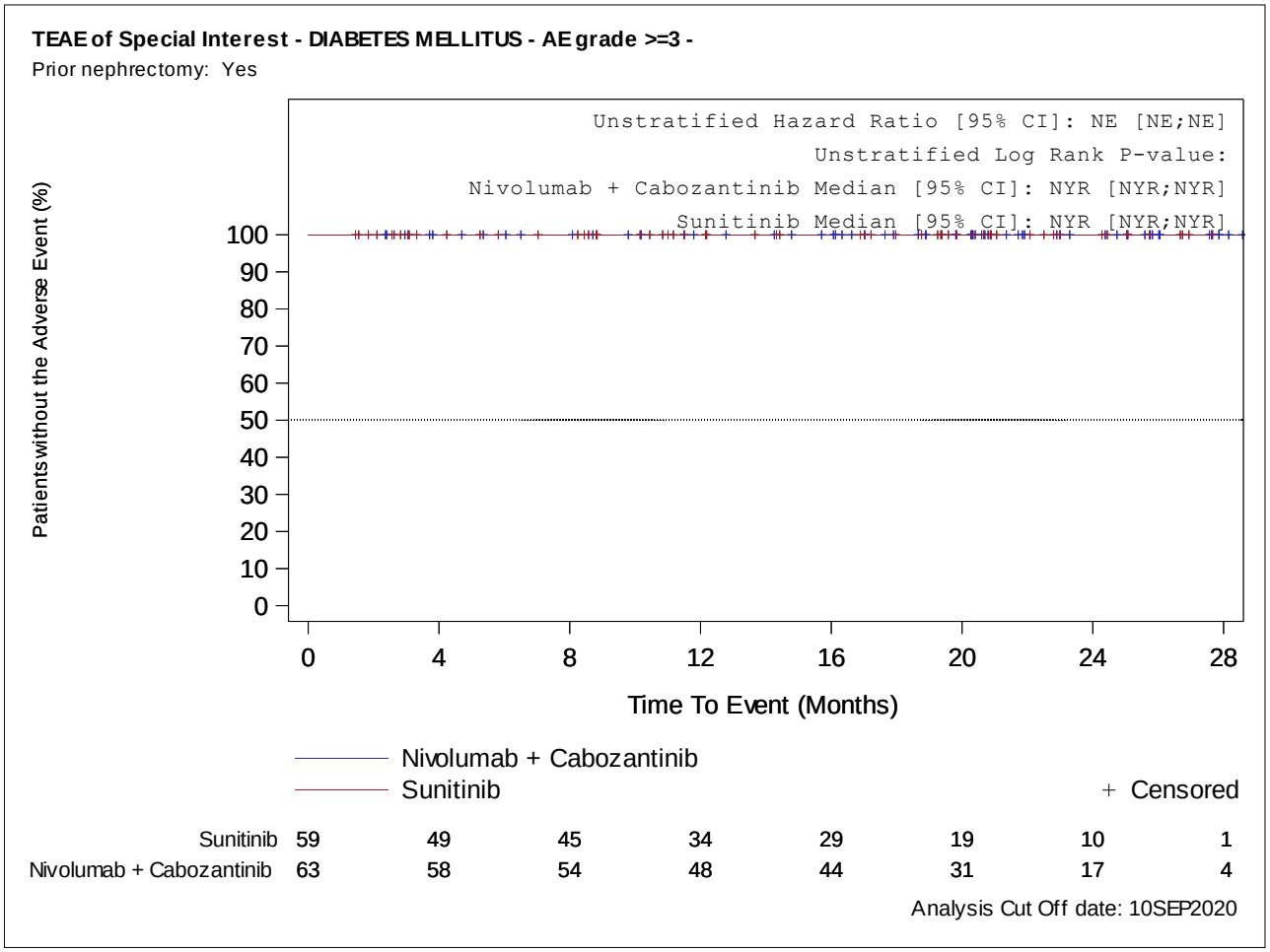

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:50:38

FIGURE 3.67.2.17: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



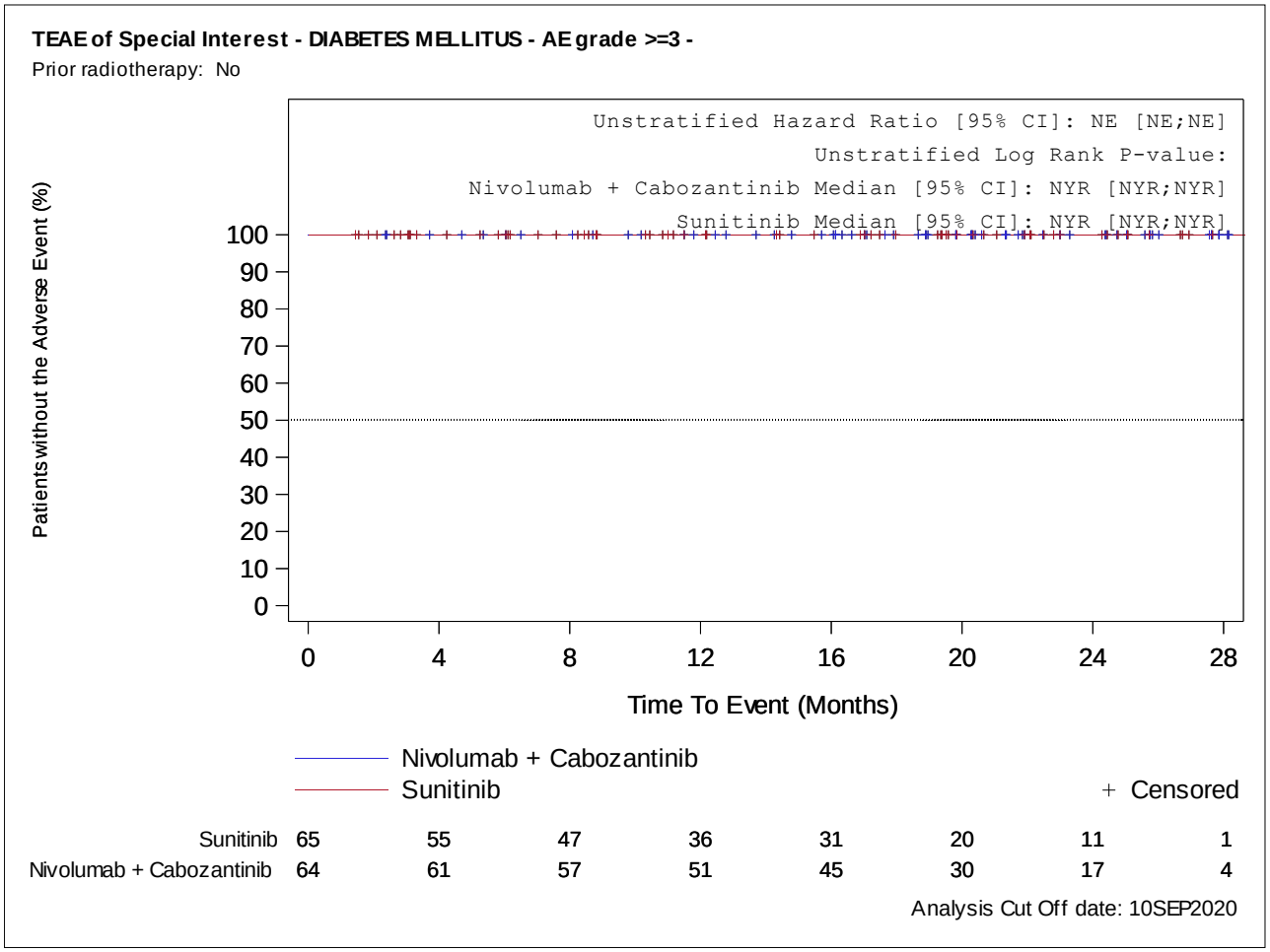

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:51:31

FIGURE 3.67.2.18: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



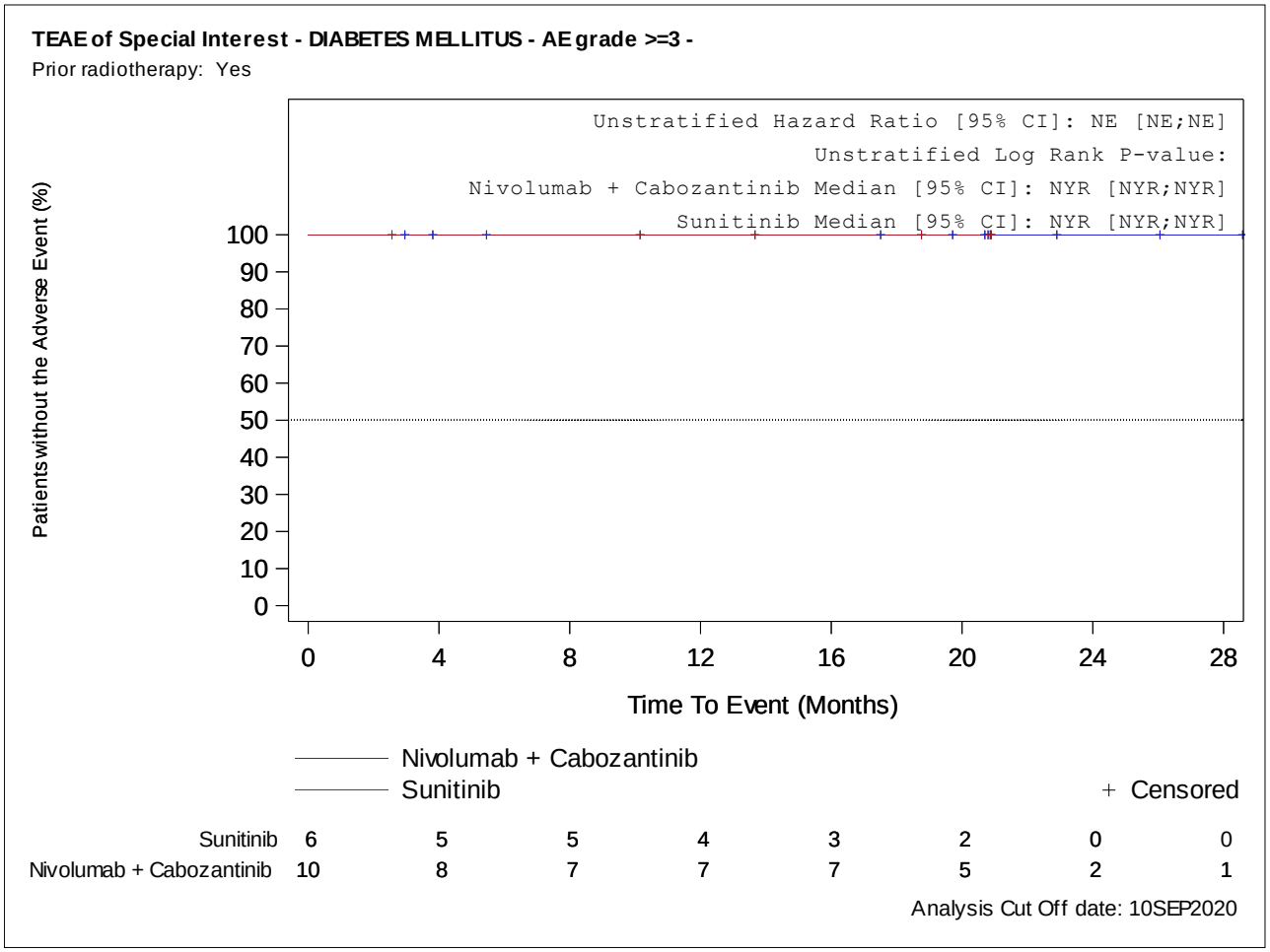

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:51:37

FIGURE 3.67.2.19: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



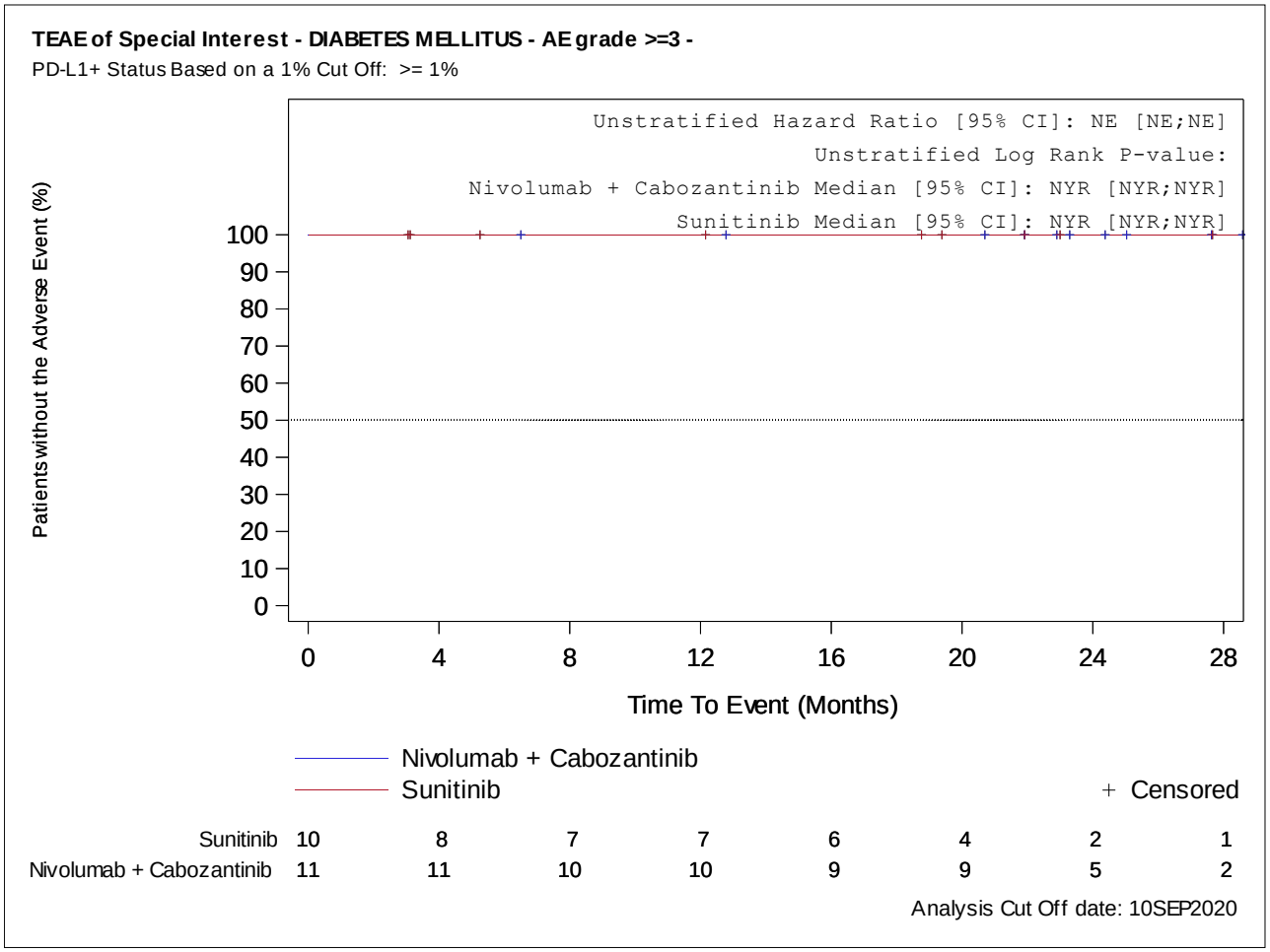

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:51:43

FIGURE 3.67.2.20: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy:  Yes



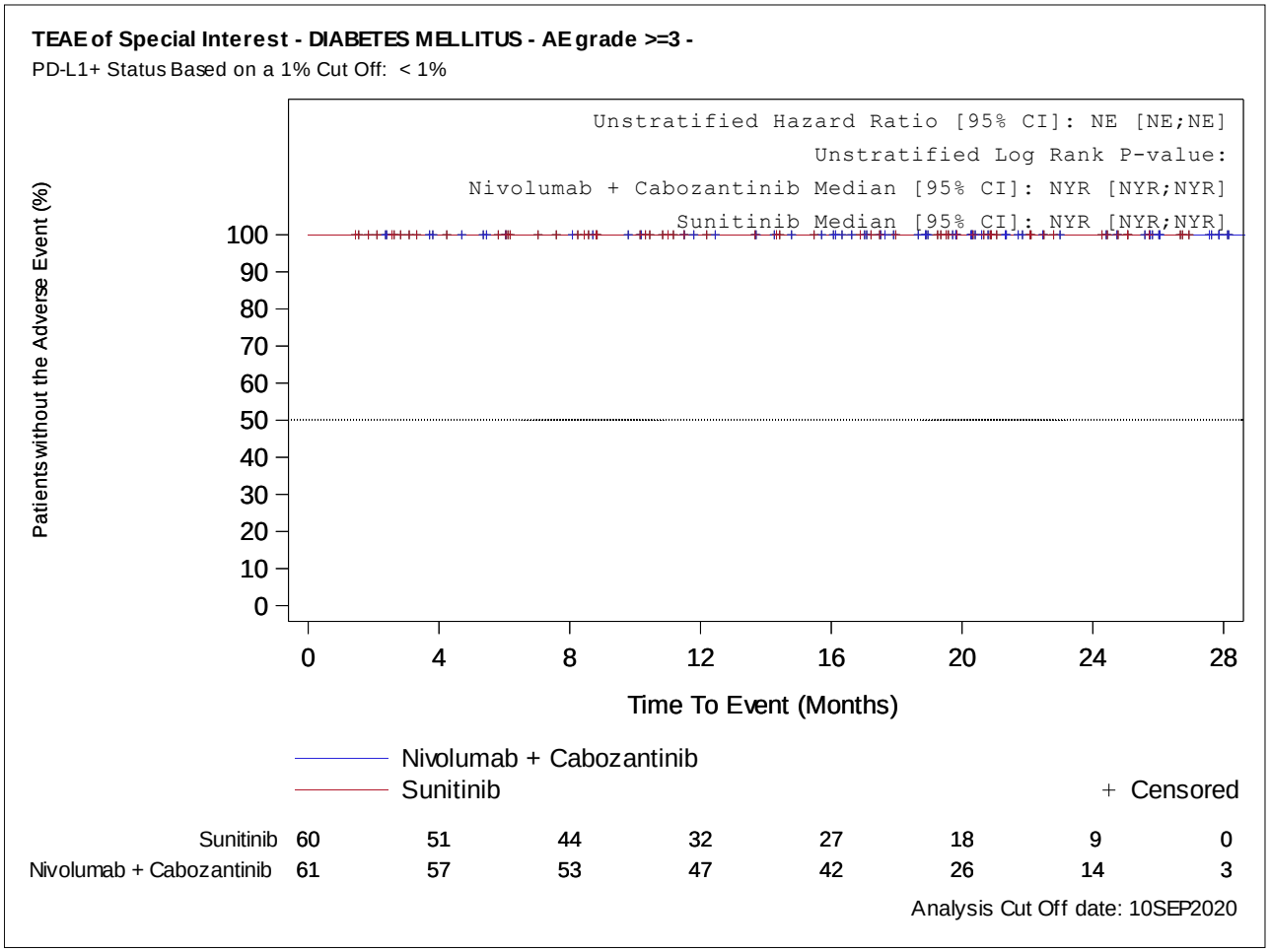

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:51:49

FIGURE 3.67.2.21: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



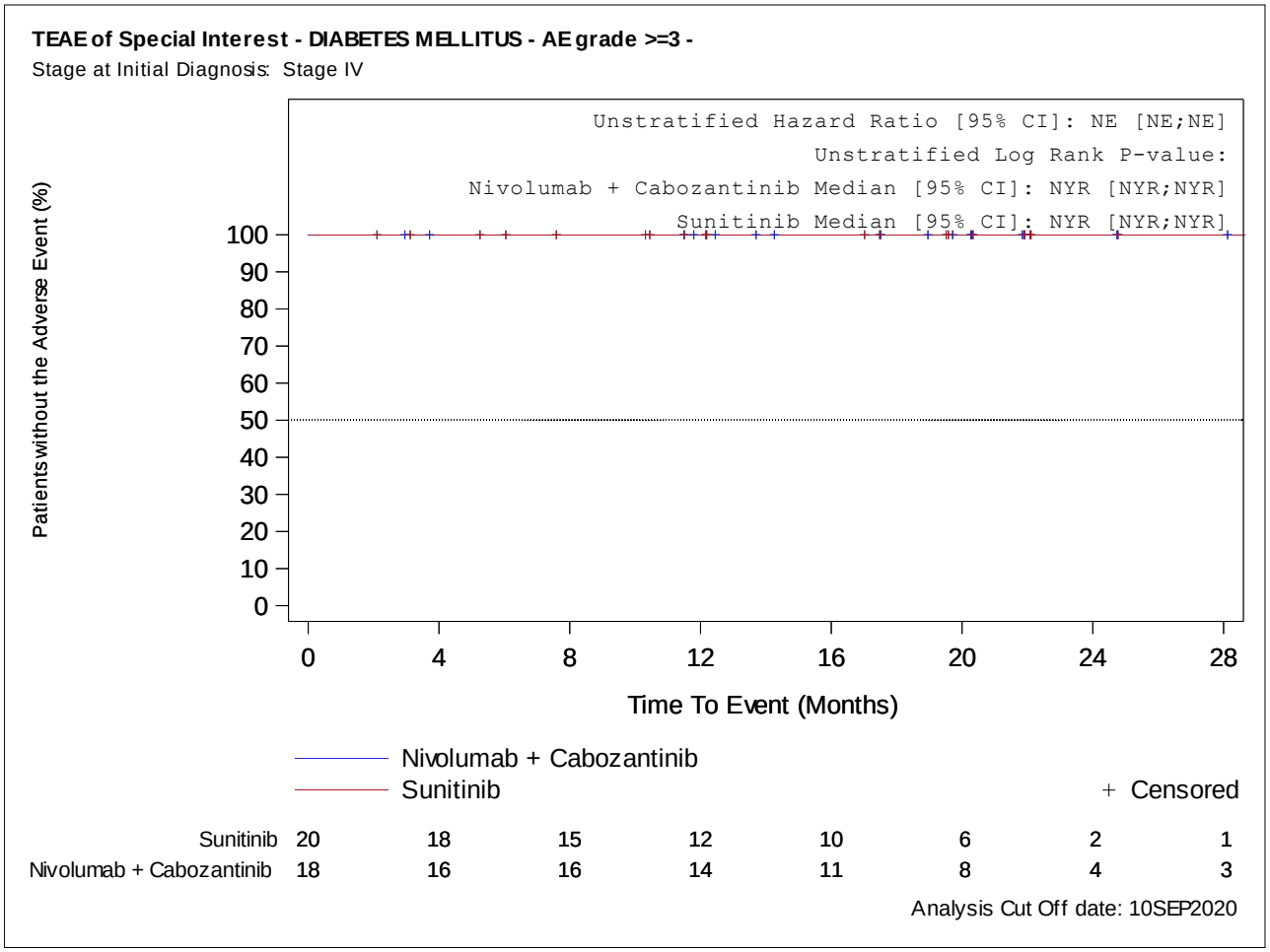

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:51:54

FIGURE 3.67.2.22: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



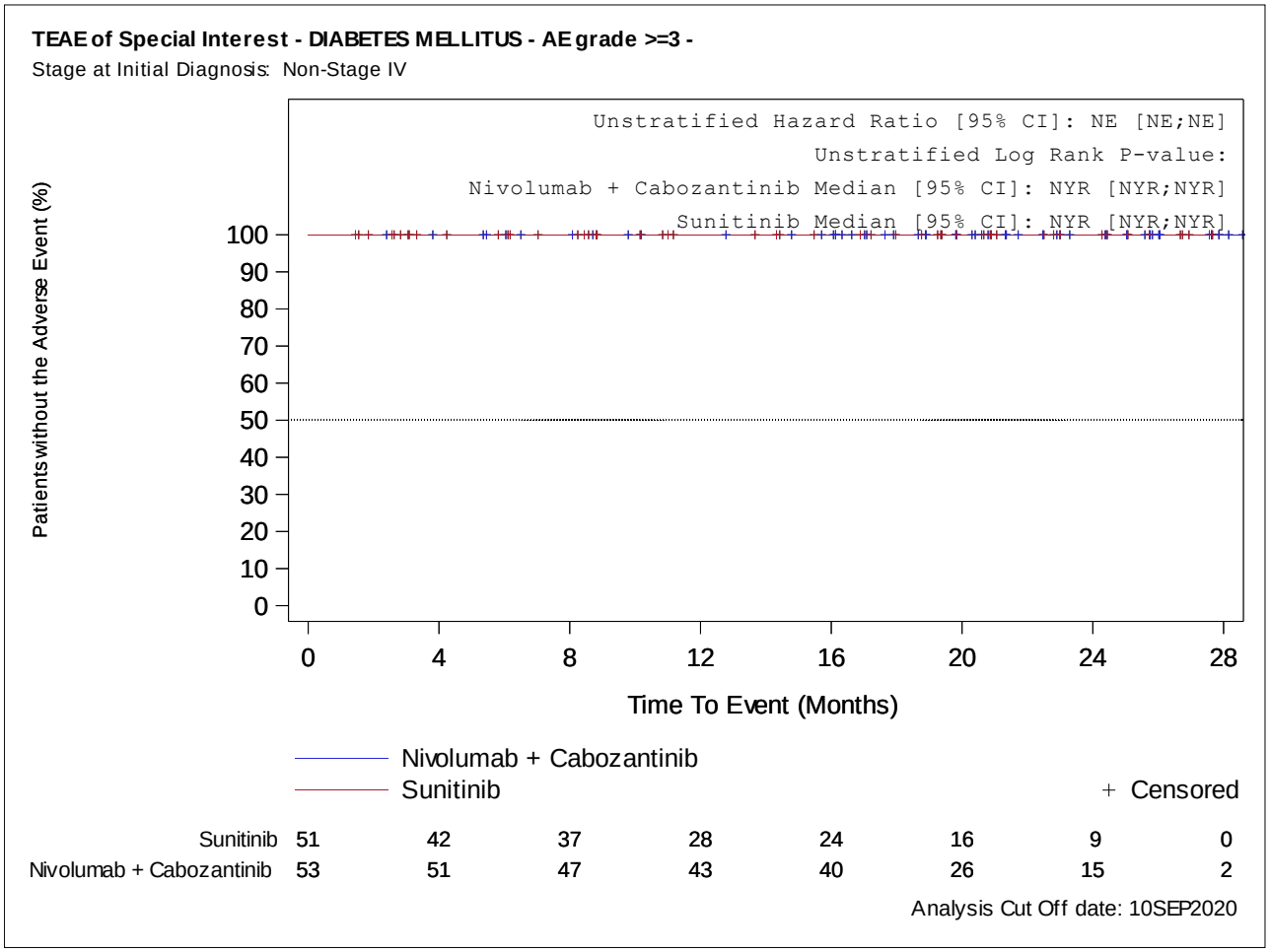

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:52:00

FIGURE 3.67.2.23: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



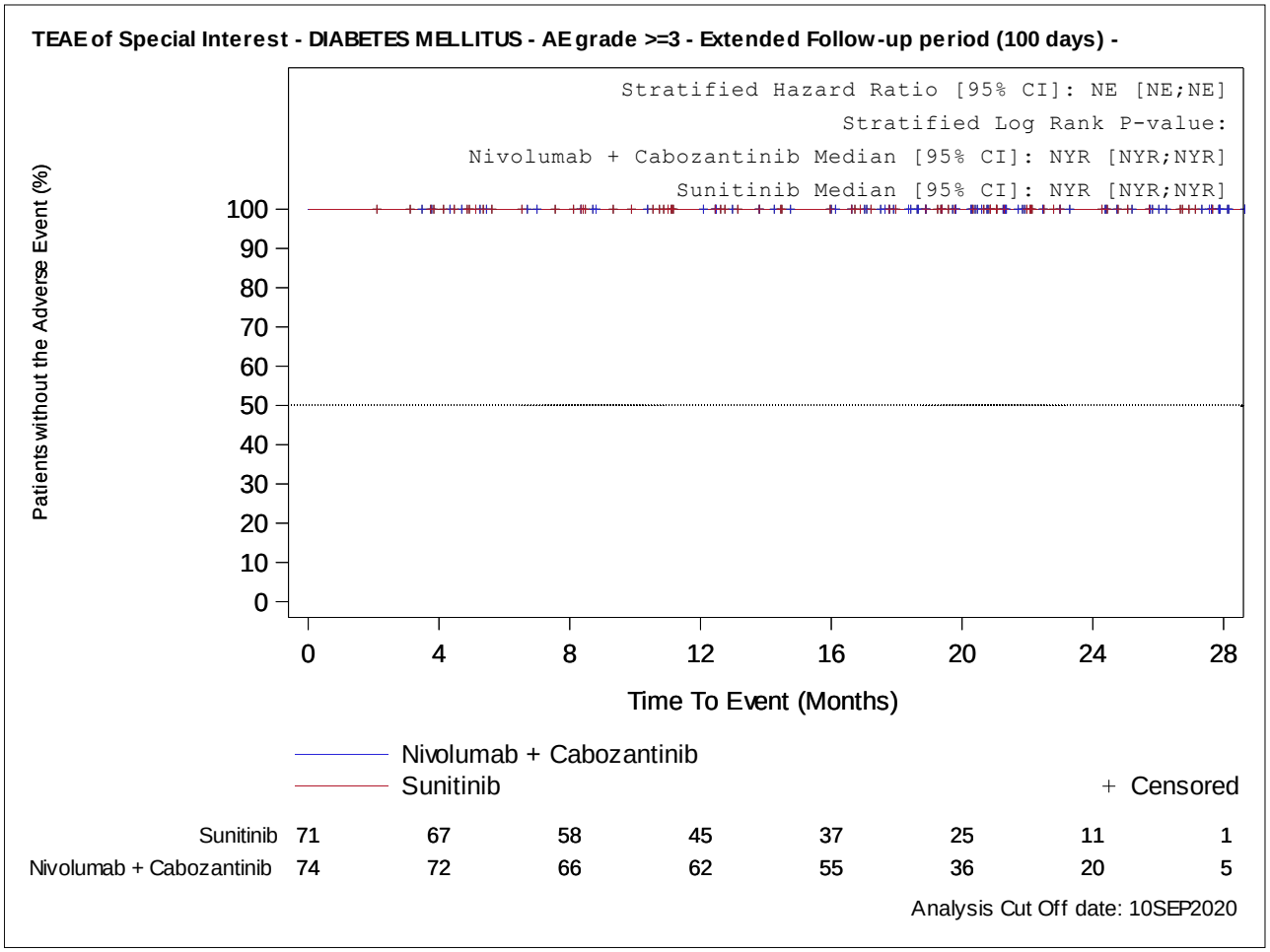

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:52:29

FIGURE 3.67.2.24: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



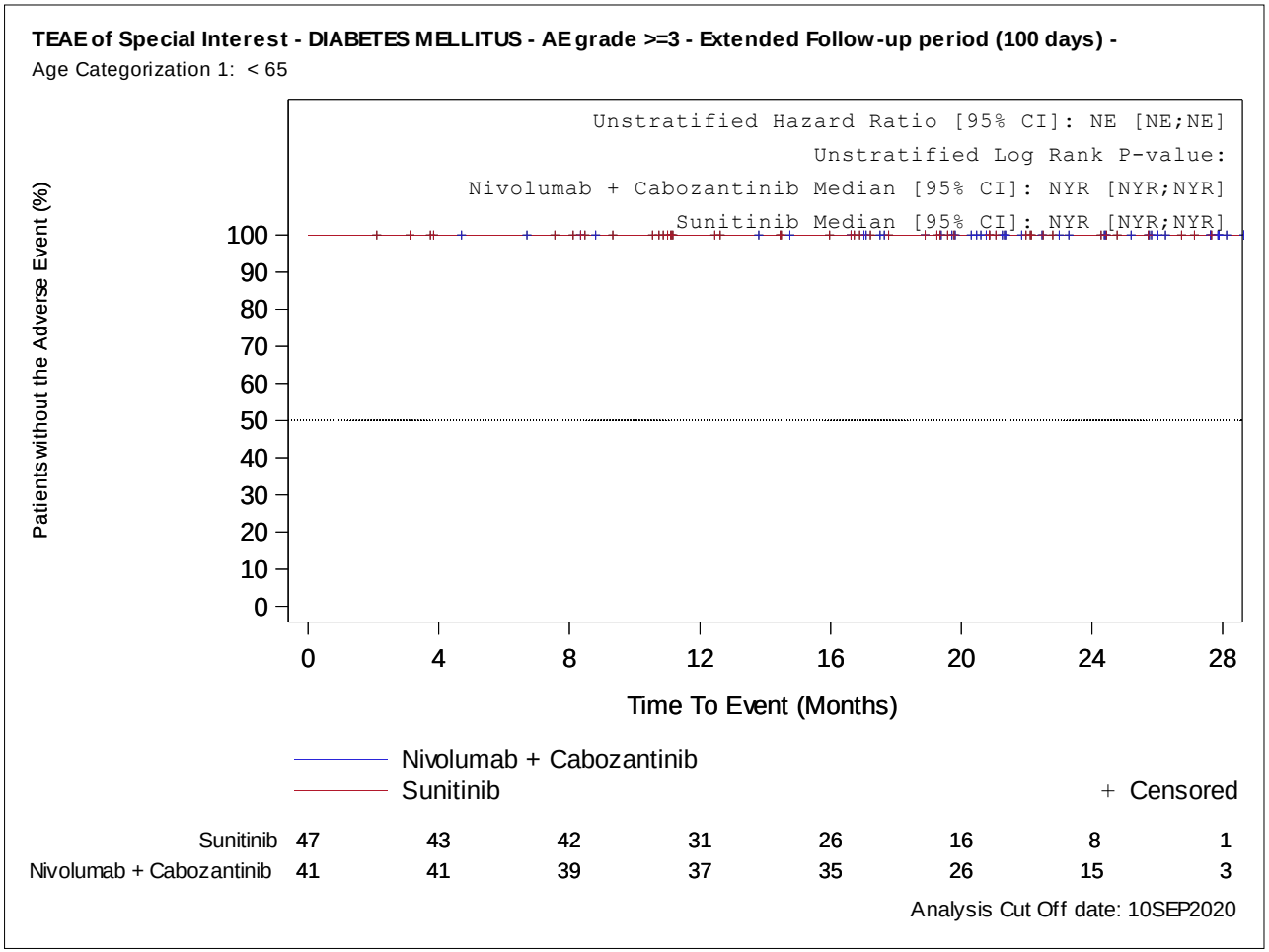

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:52:35

FIGURE 3.68.1: TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



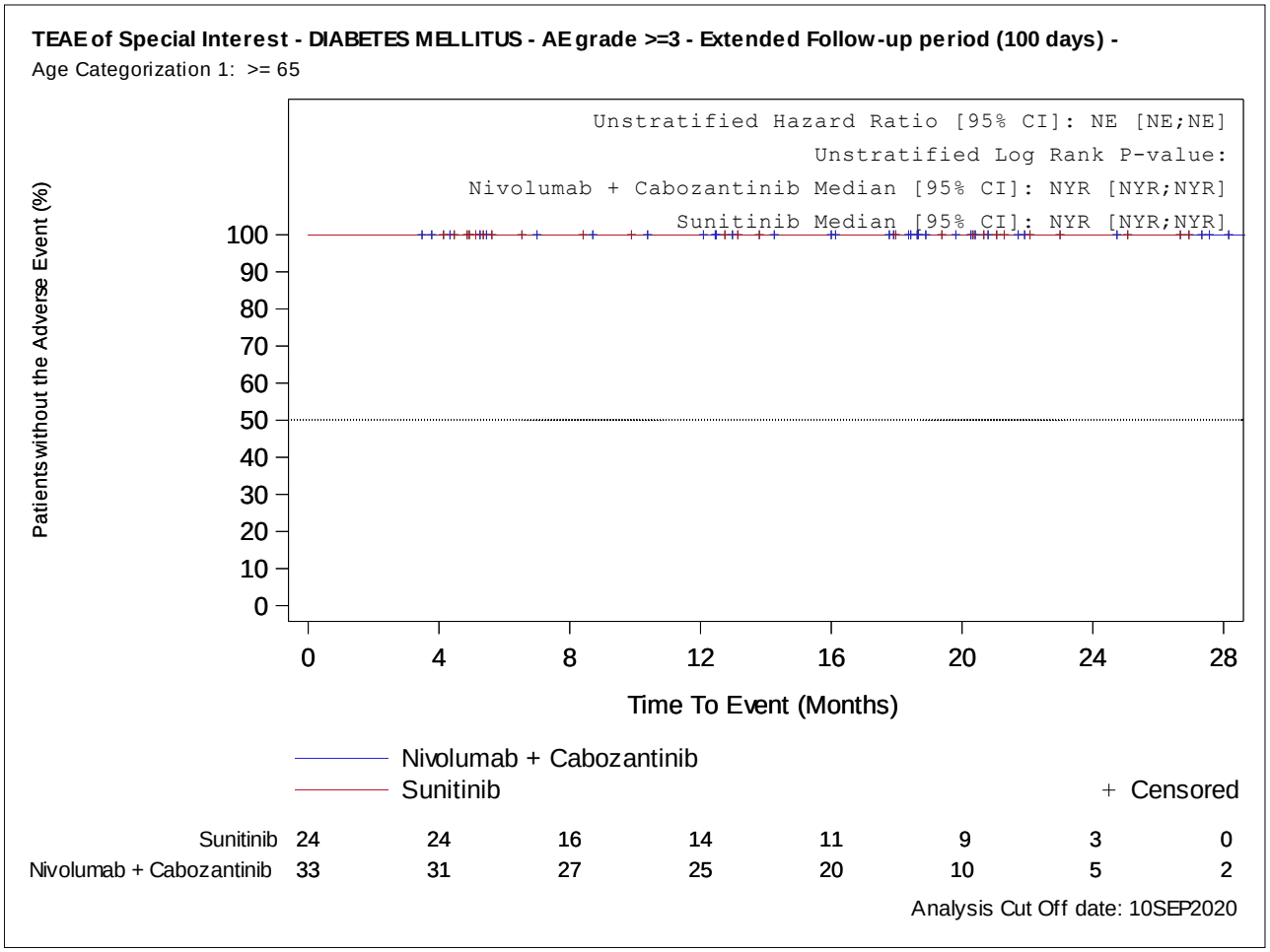

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:55:54

FIGURE 3.68.2.1: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



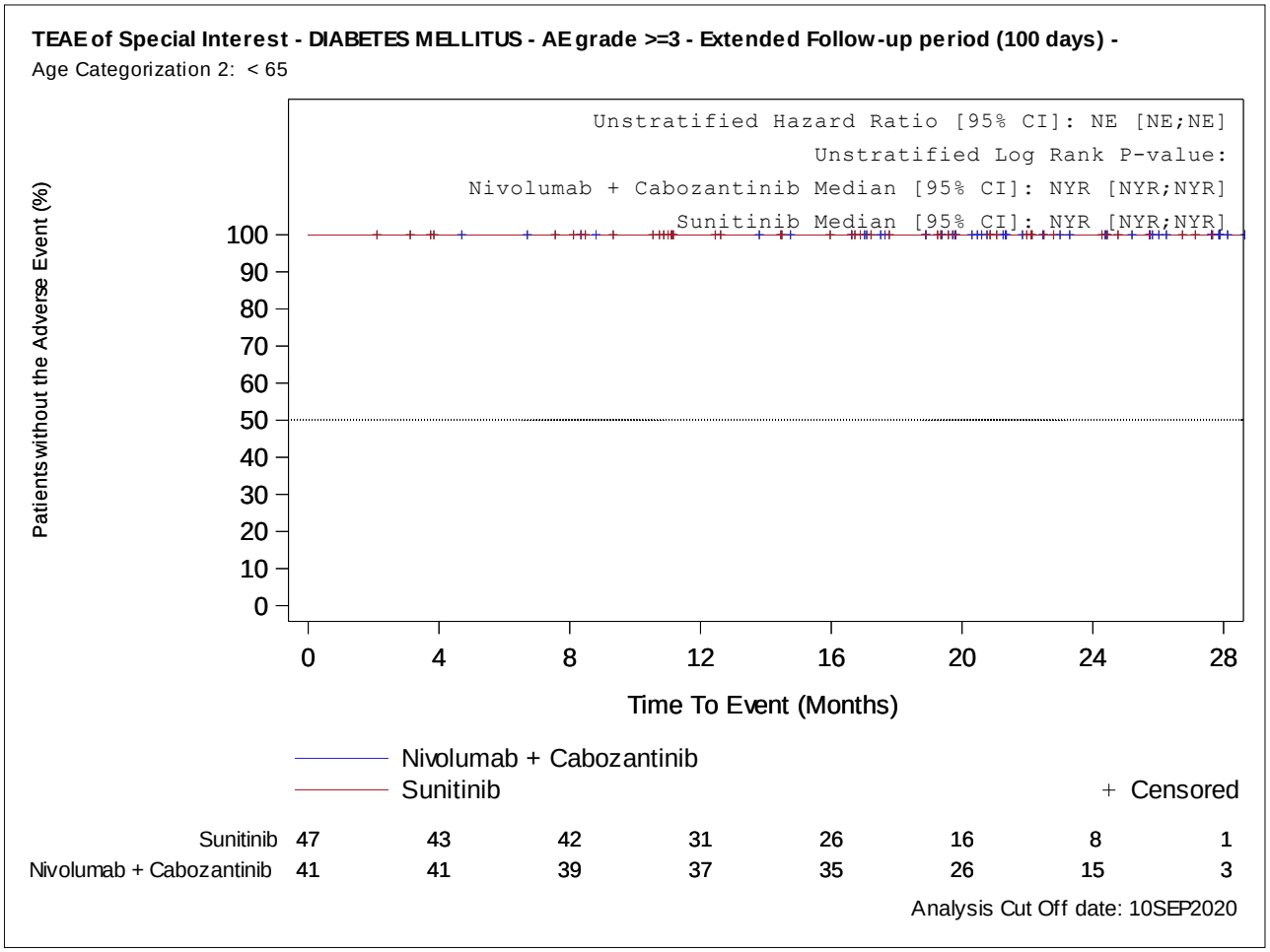

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:55:57

FIGURE 3.68.2.2: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



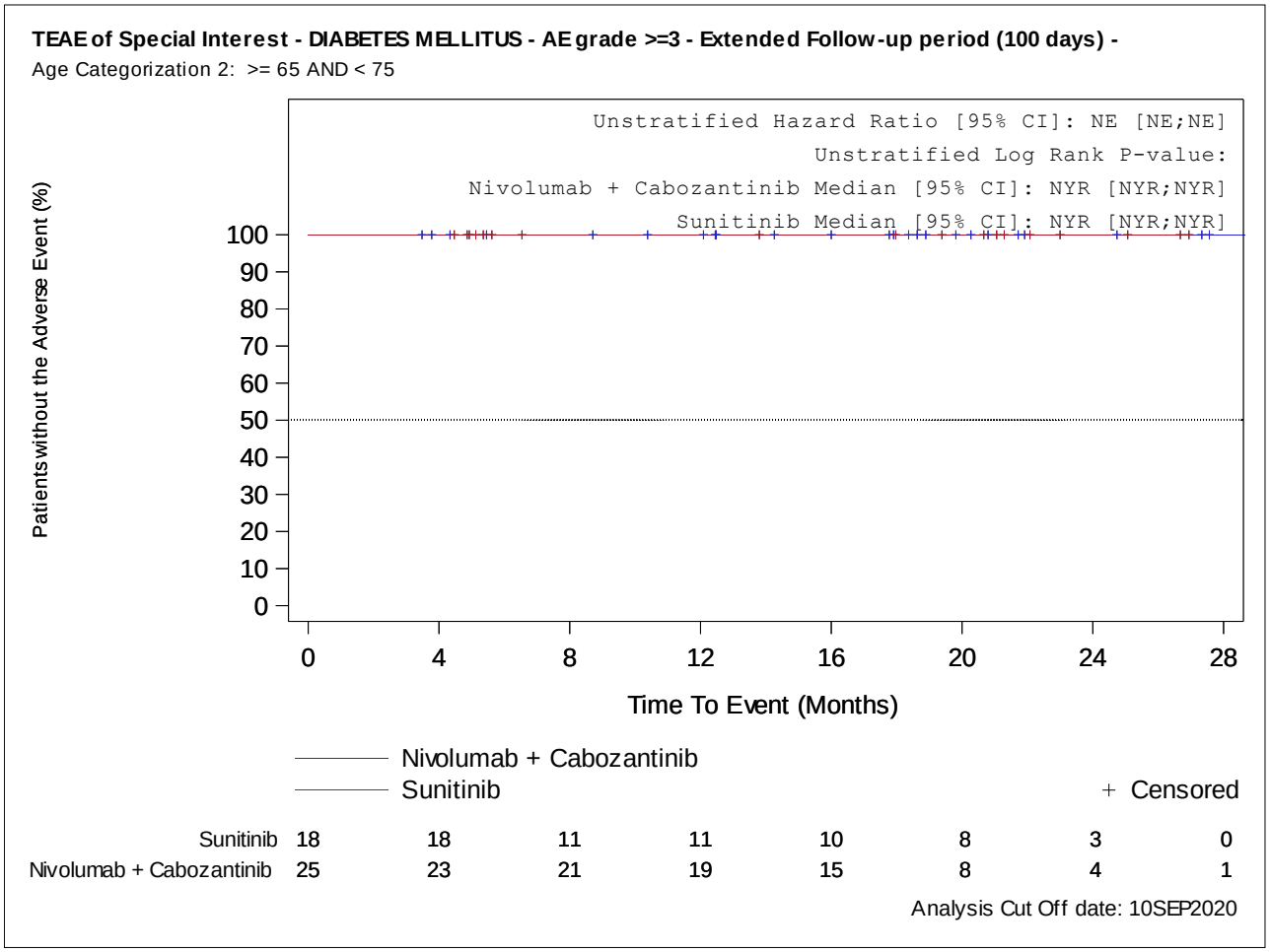

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:56:03

FIGURE 3.68.2.3: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



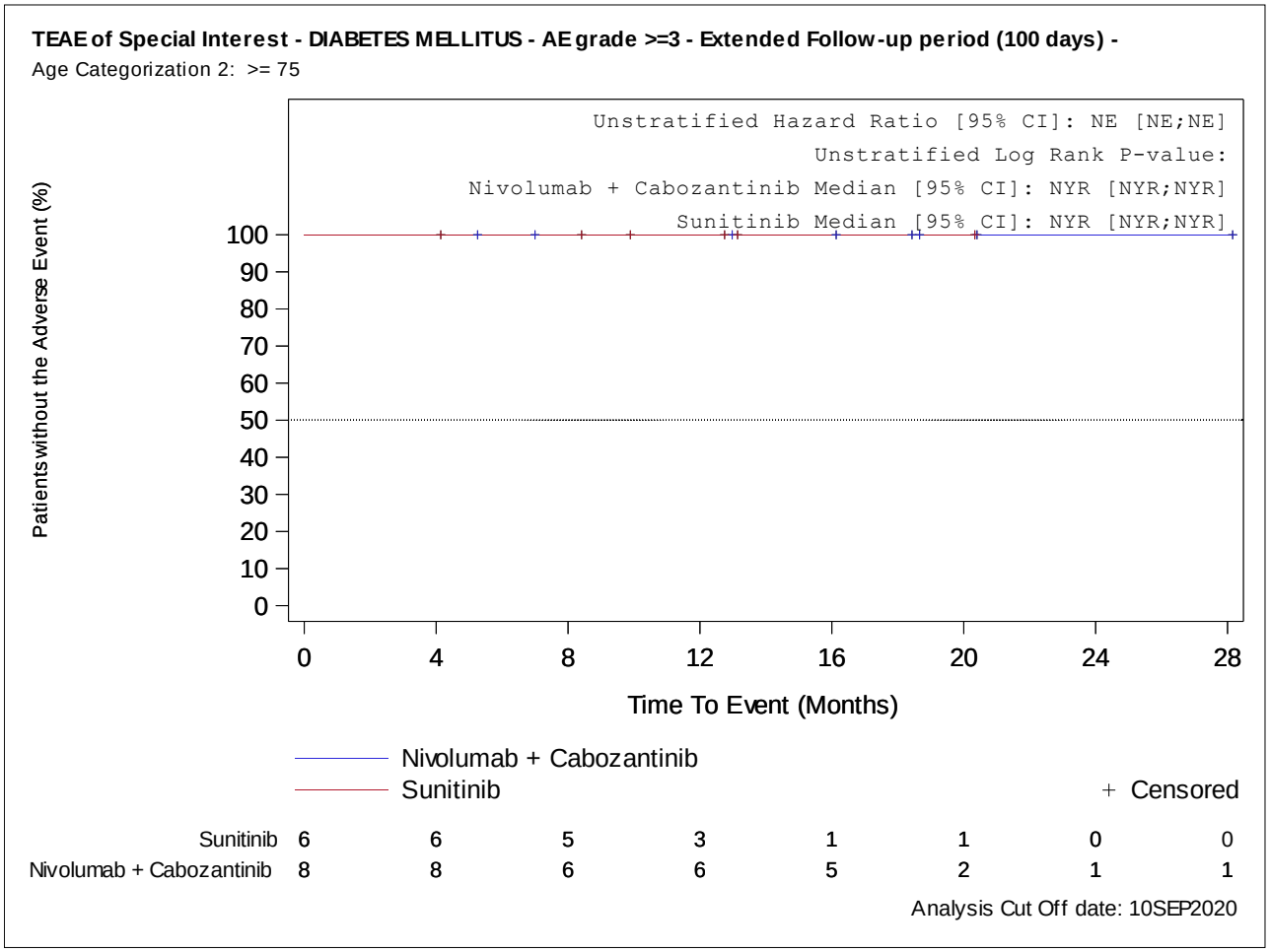

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:56:09

FIGURE 3.68.2.4: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



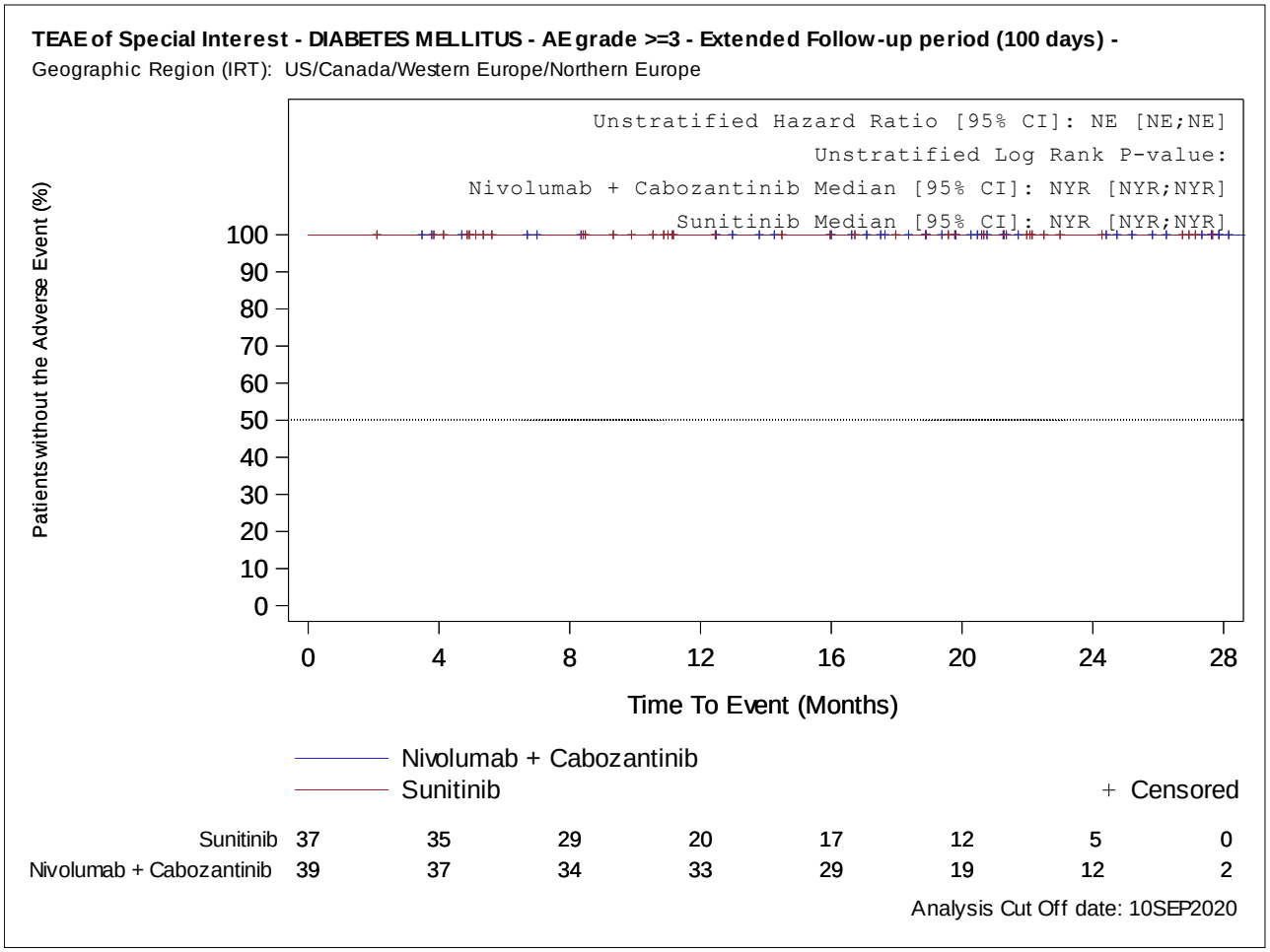

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:56:14

FIGURE 3.68.2.5: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



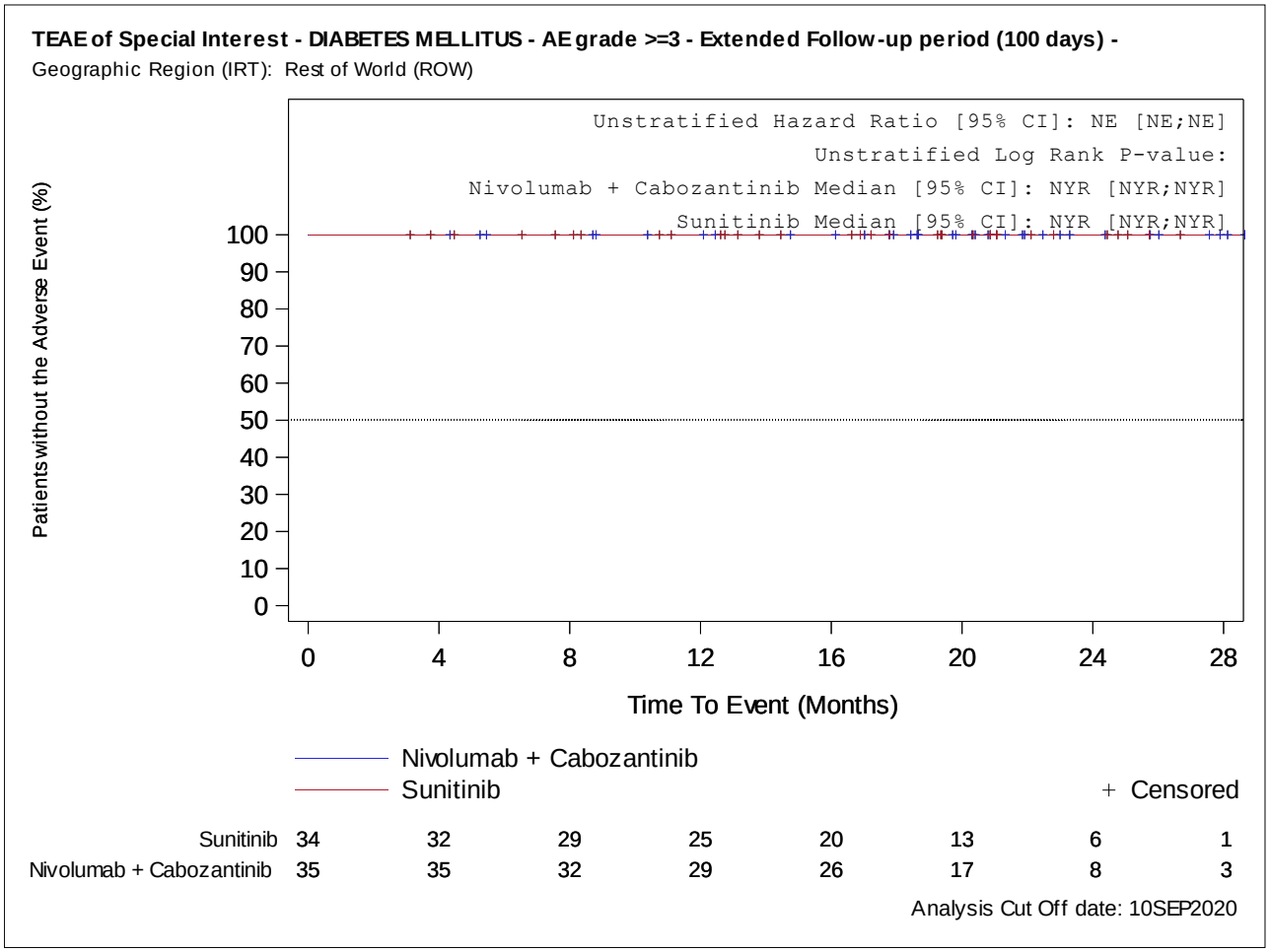

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:56:20

FIGURE 3.68.2.6: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



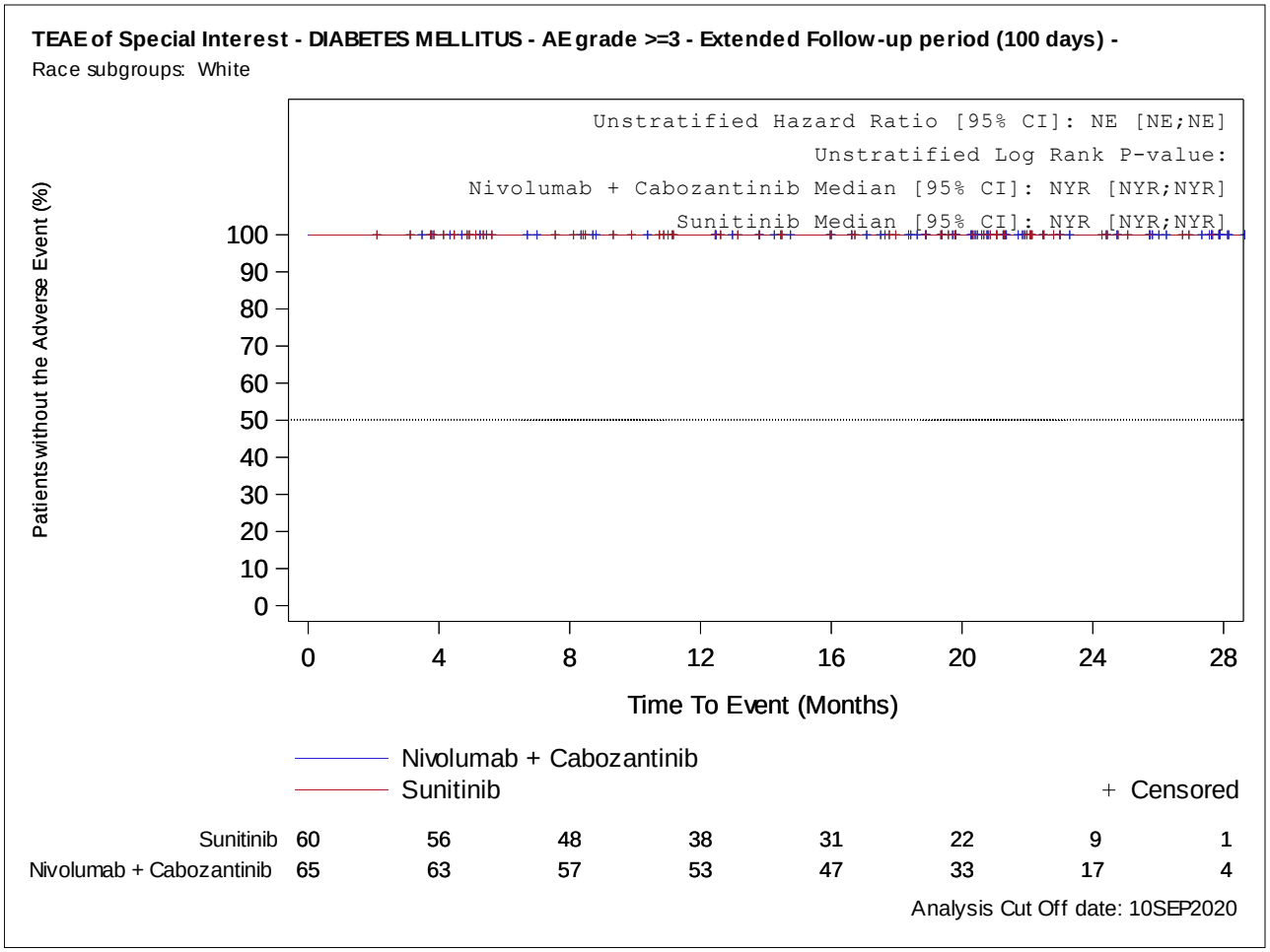

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:56:25

FIGURE 3.68.2.7: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



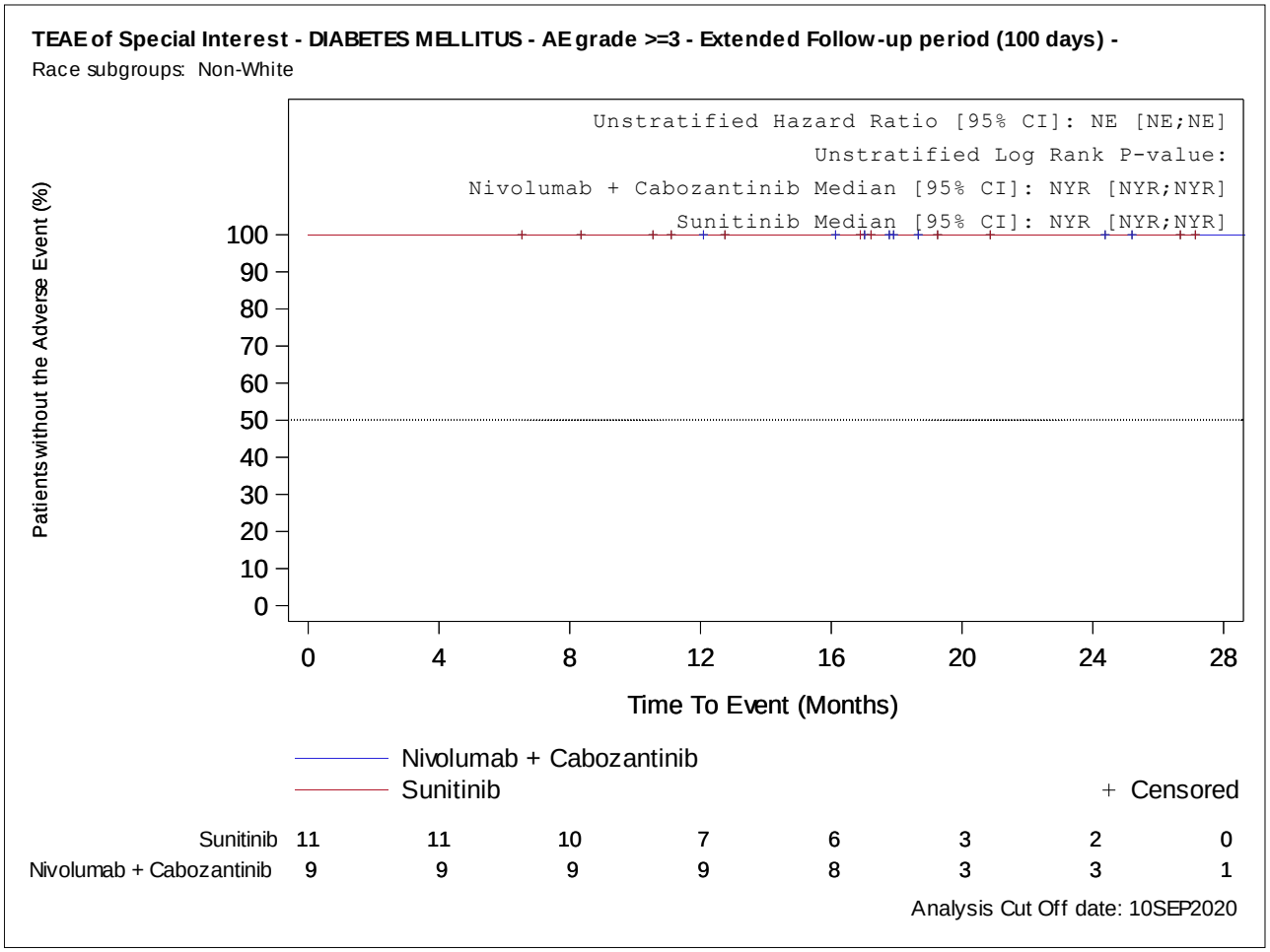

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:56:31

FIGURE 3.68.2.8: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



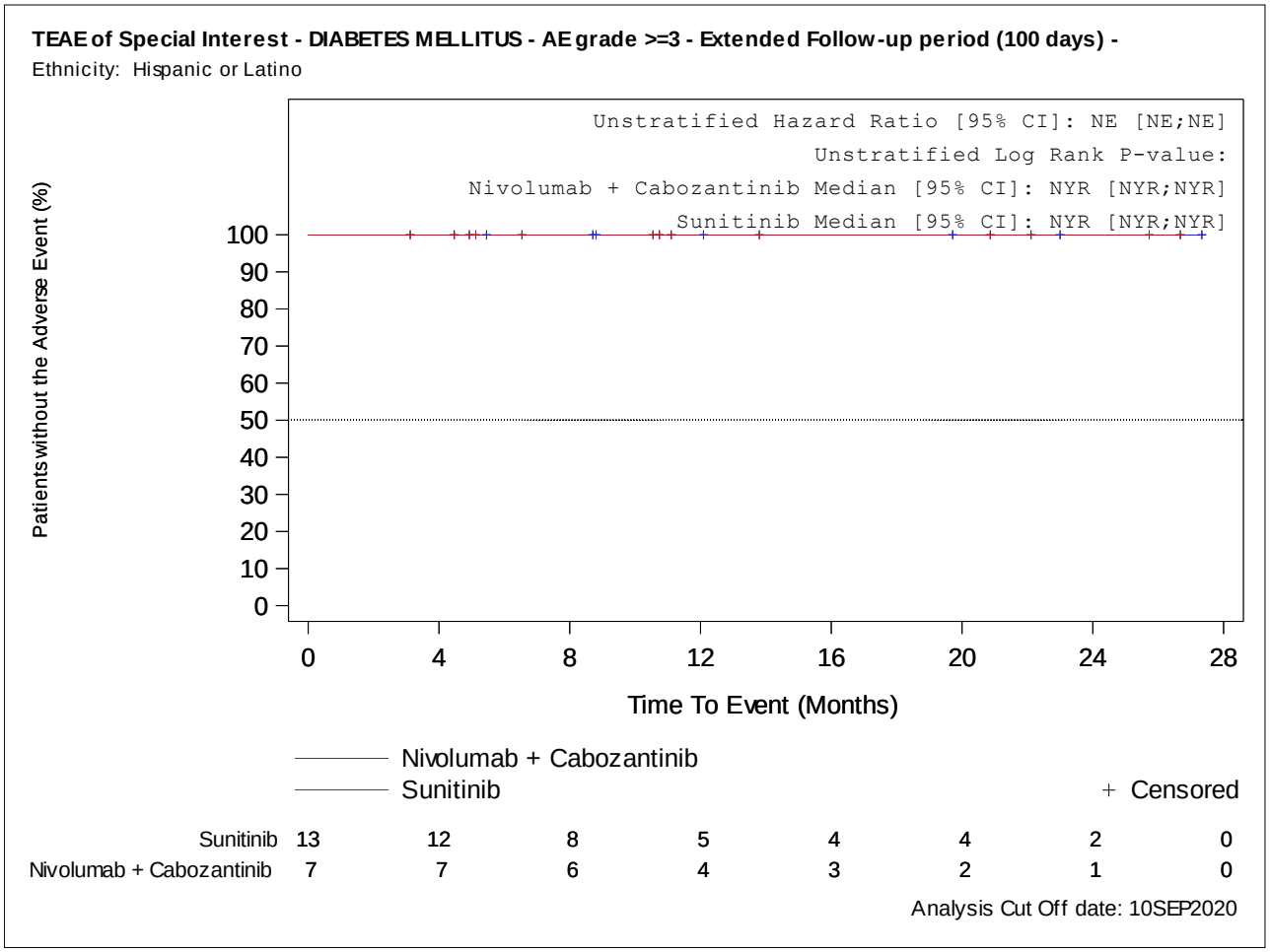

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:56:37

FIGURE 3.68.2.9: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:56:43

FIGURE 3.68.2.10: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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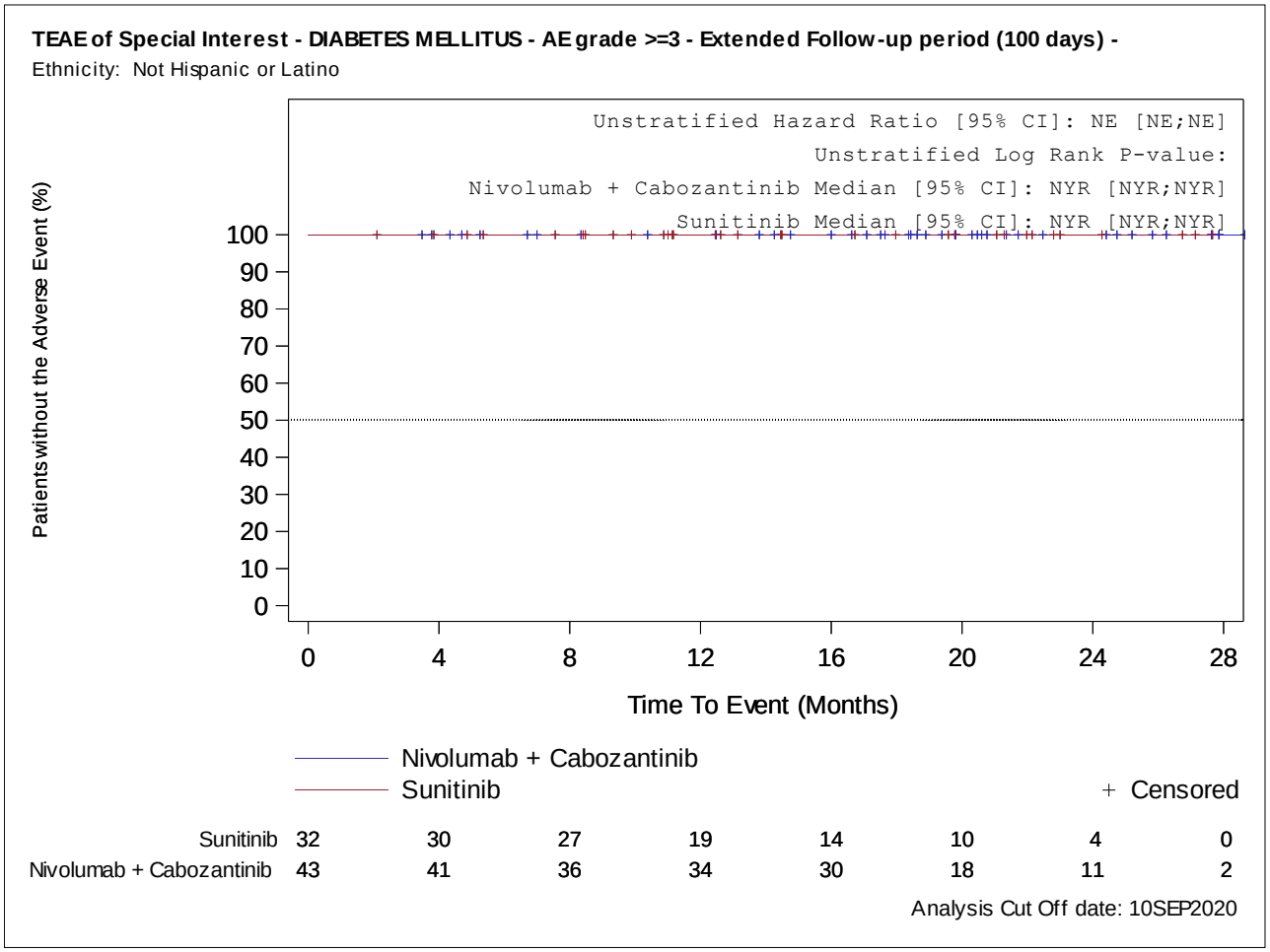
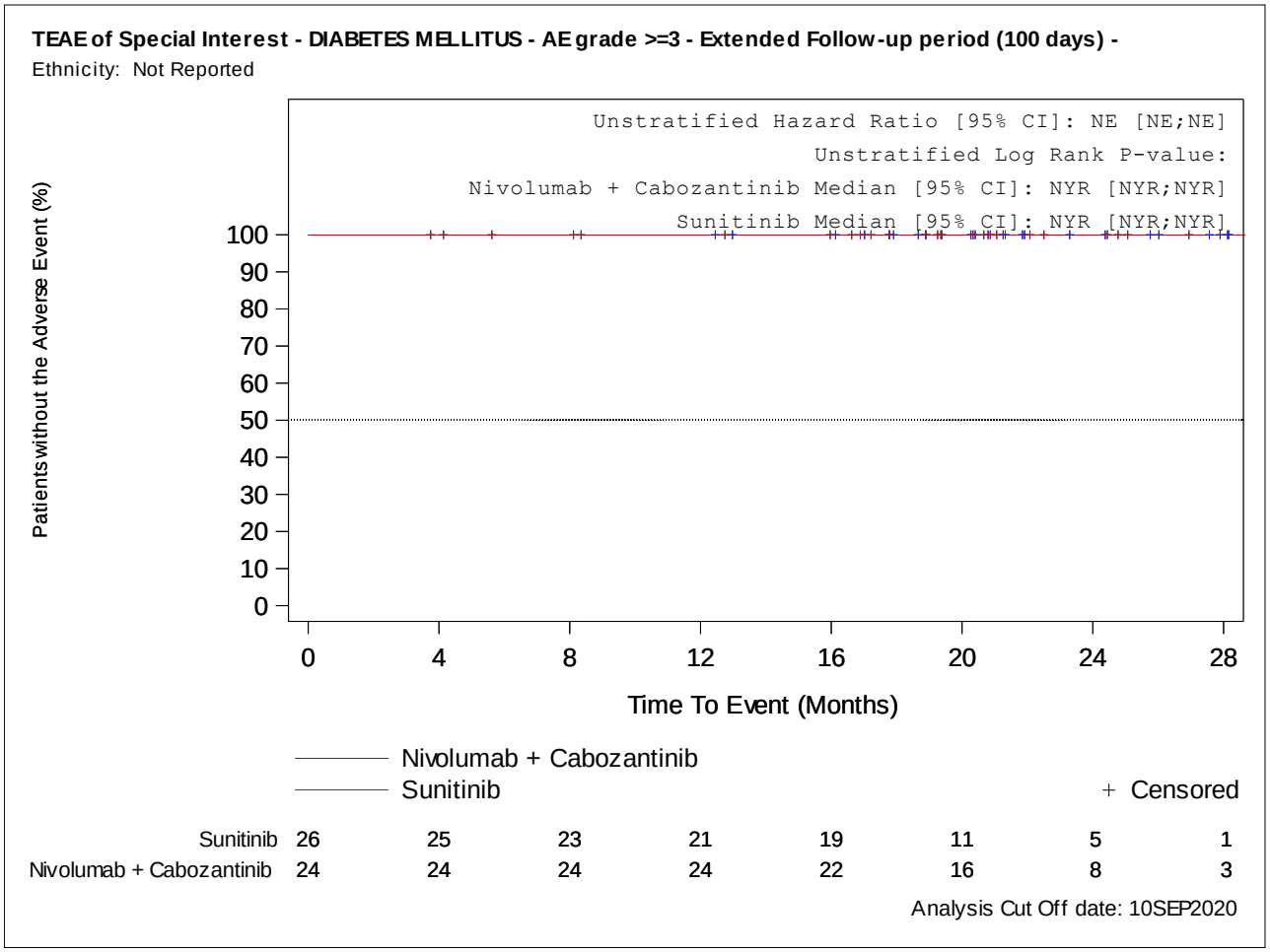
FIGURE 3.68.2.11: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



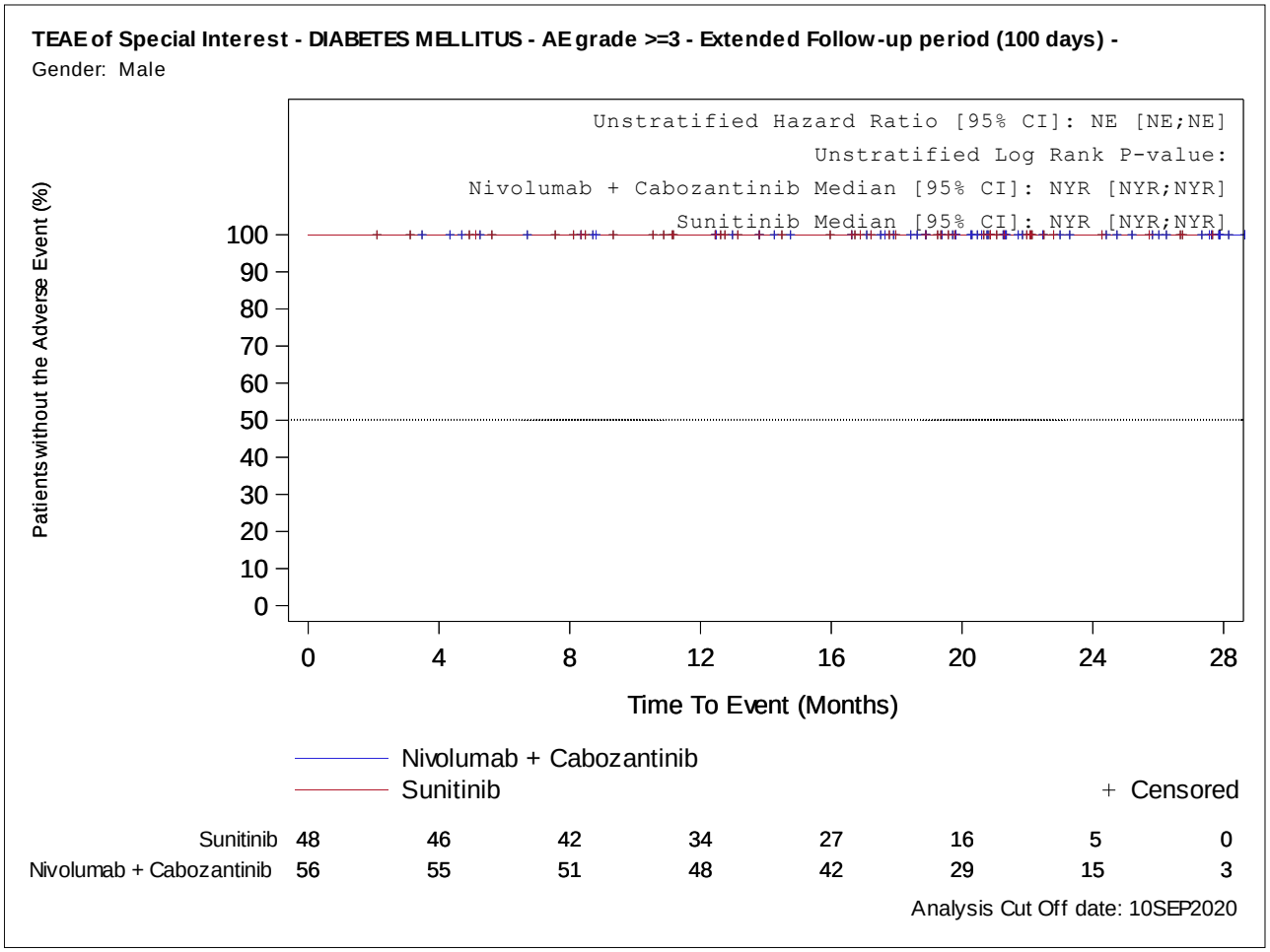

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:56:54

FIGURE 3.68.2.12: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



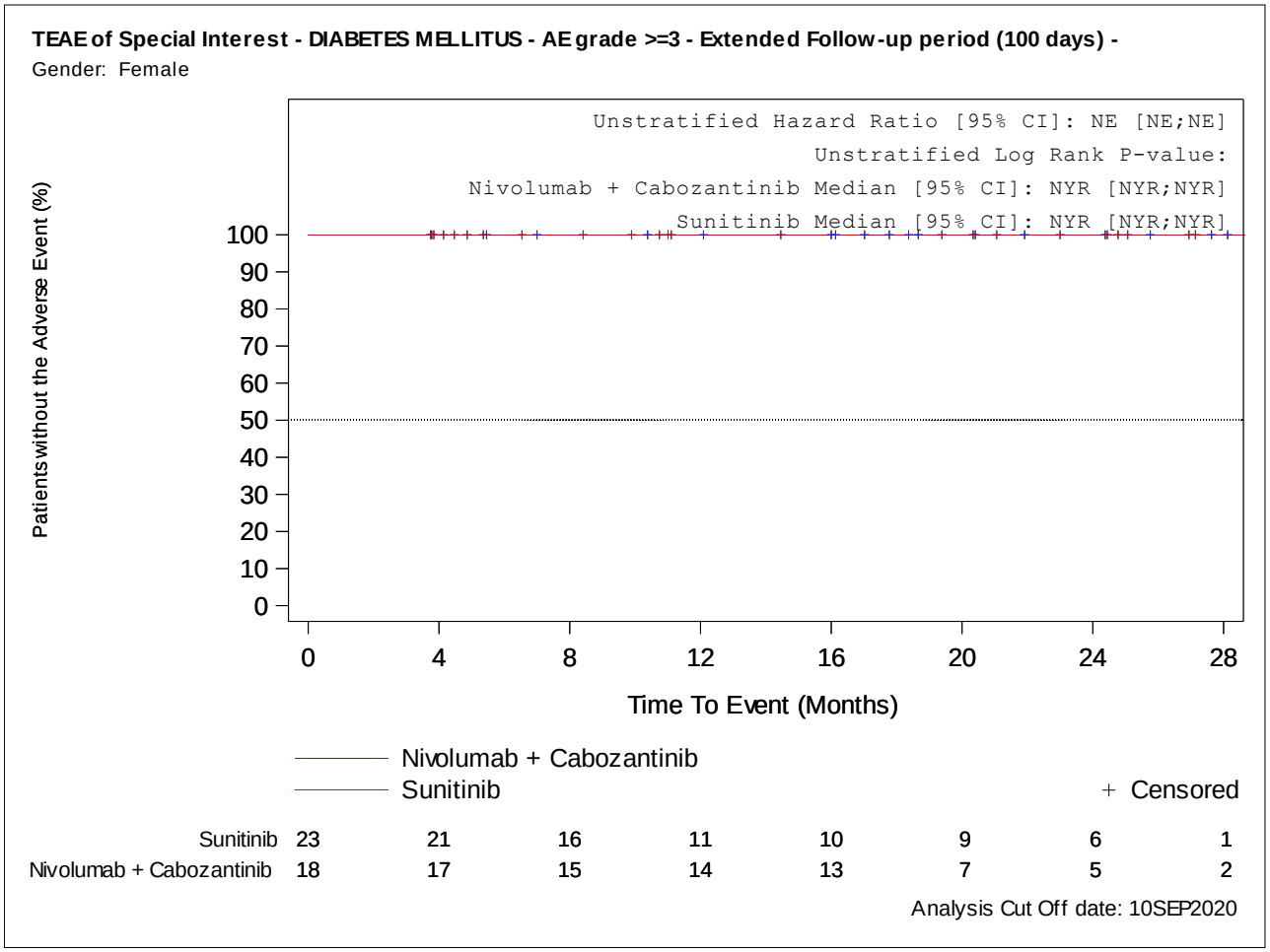

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:56:59

FIGURE 3.68.2.13: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



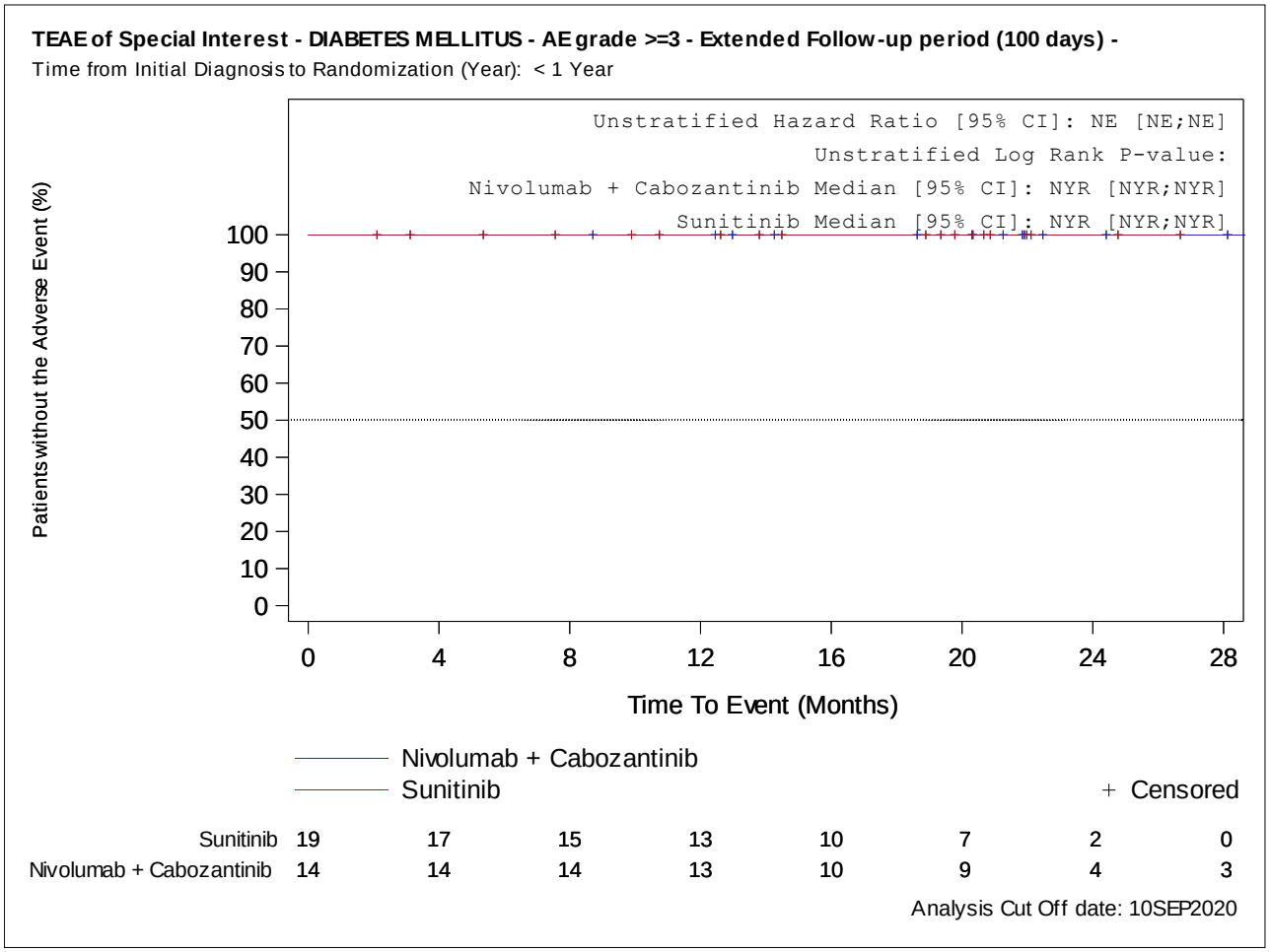

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:57:05

FIGURE 3.68.2.14: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



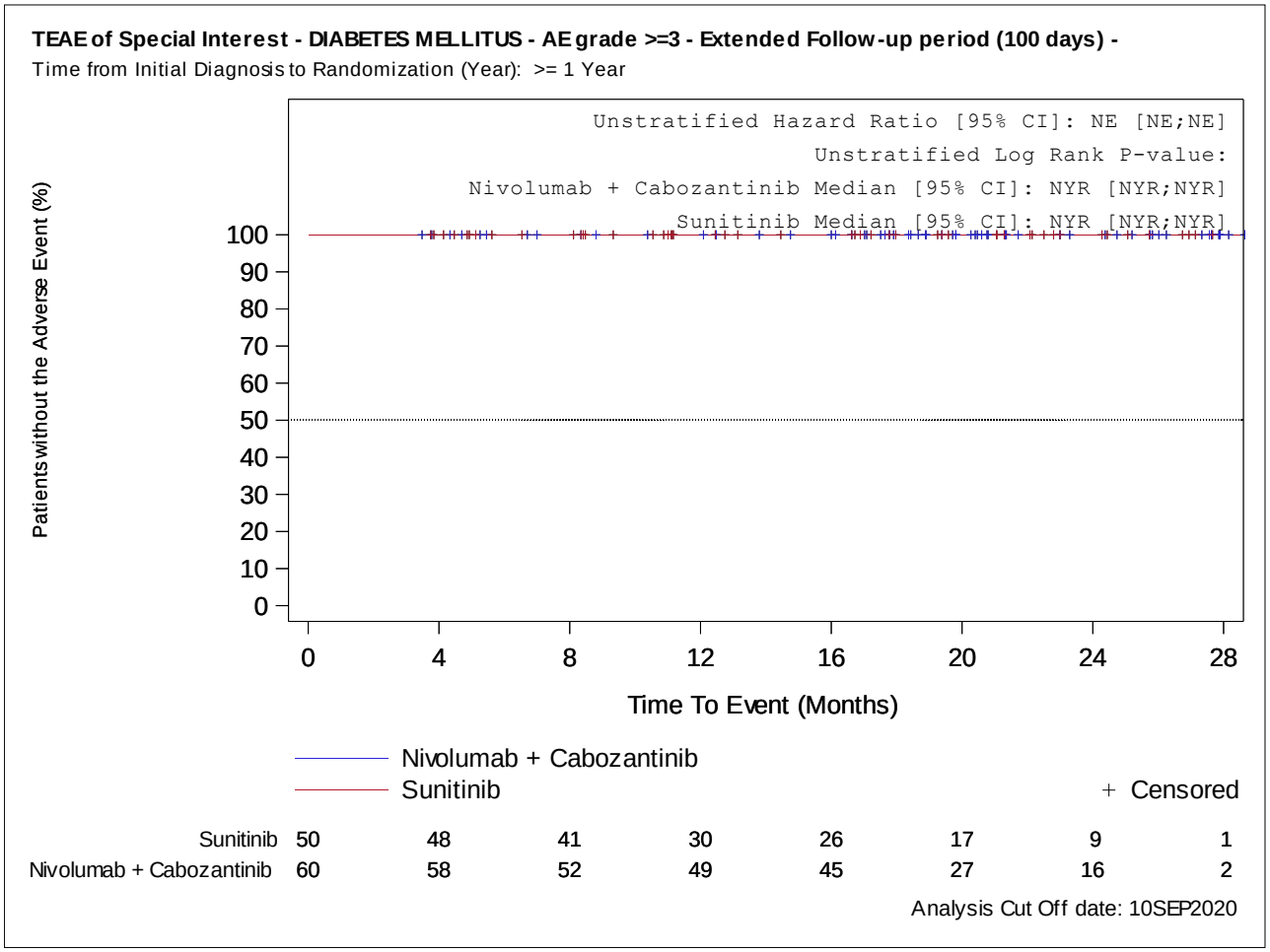

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:57:11

FIGURE 3.68.2.15: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:57:29

FIGURE 3.68.2.16: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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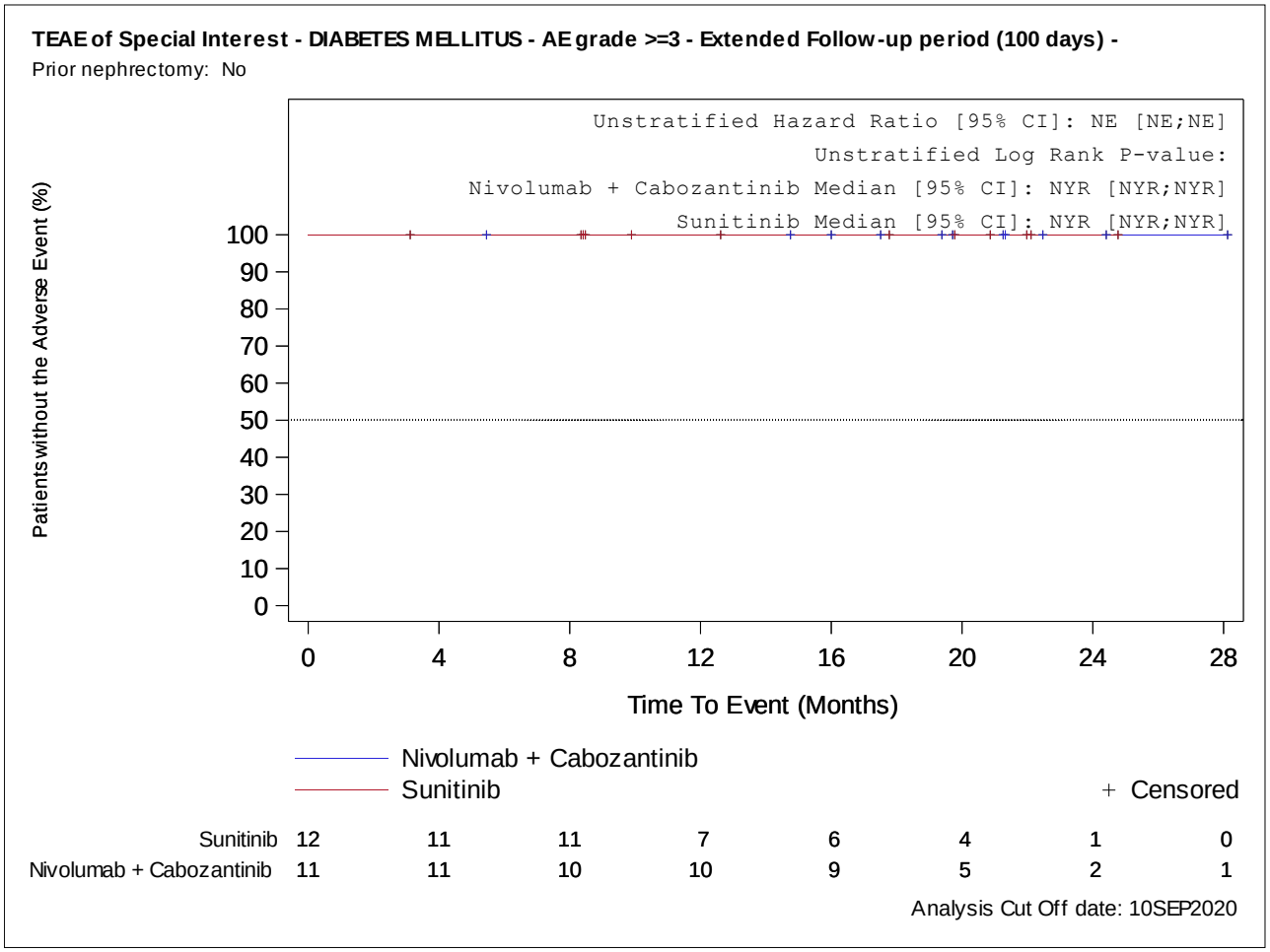
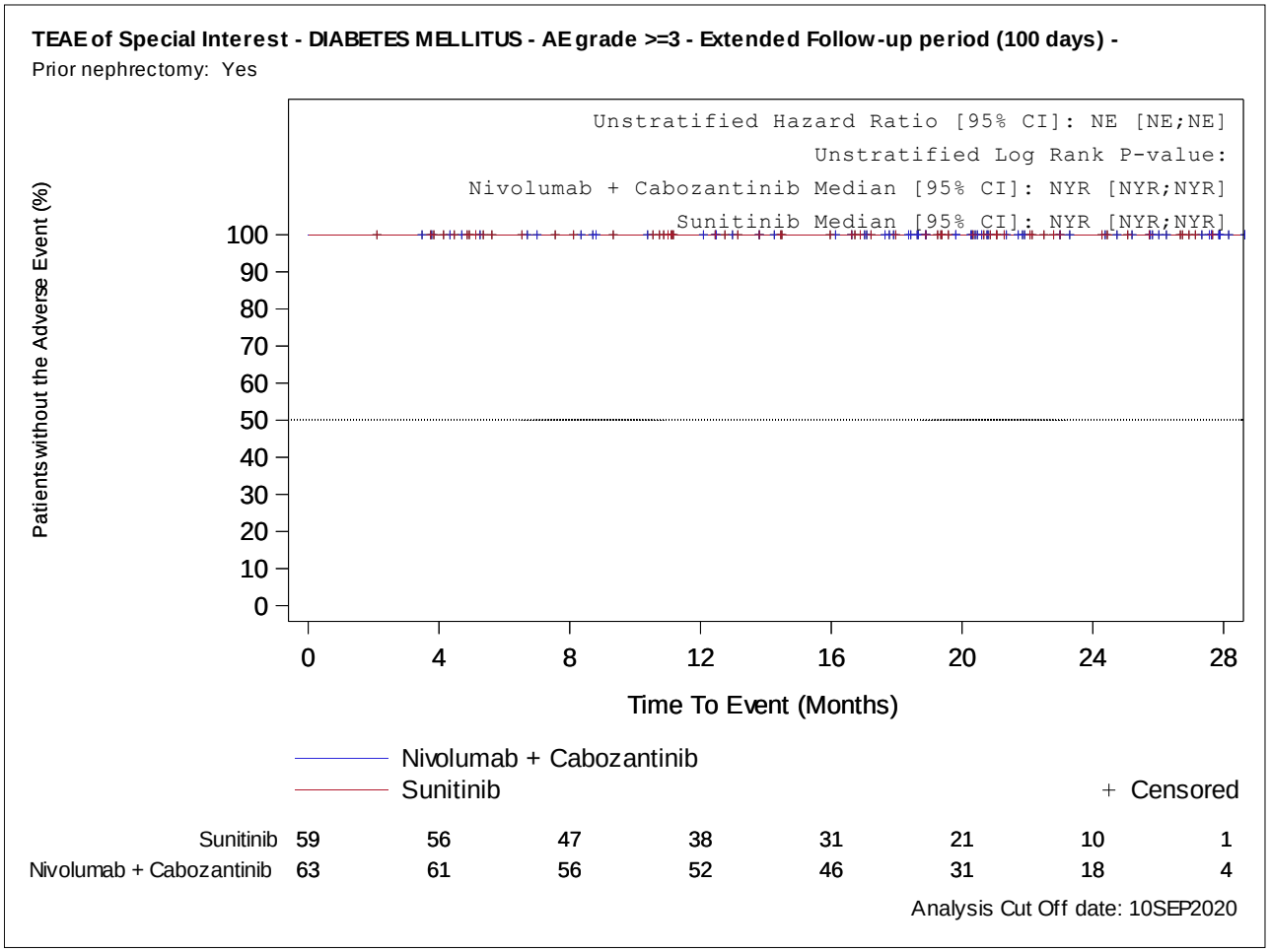
FIGURE 3.68.2.17: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



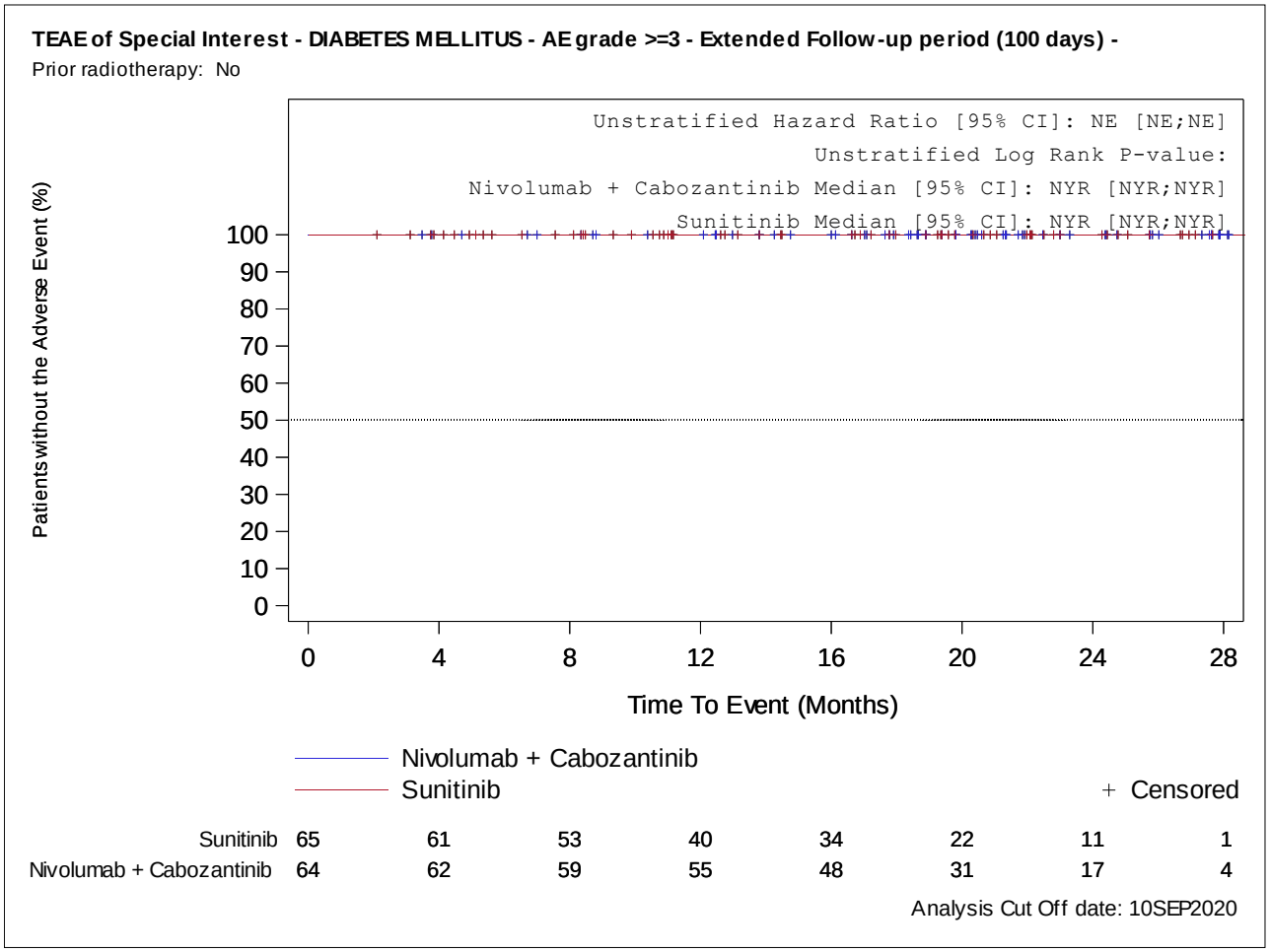

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:58:27

FIGURE 3.68.2.18: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



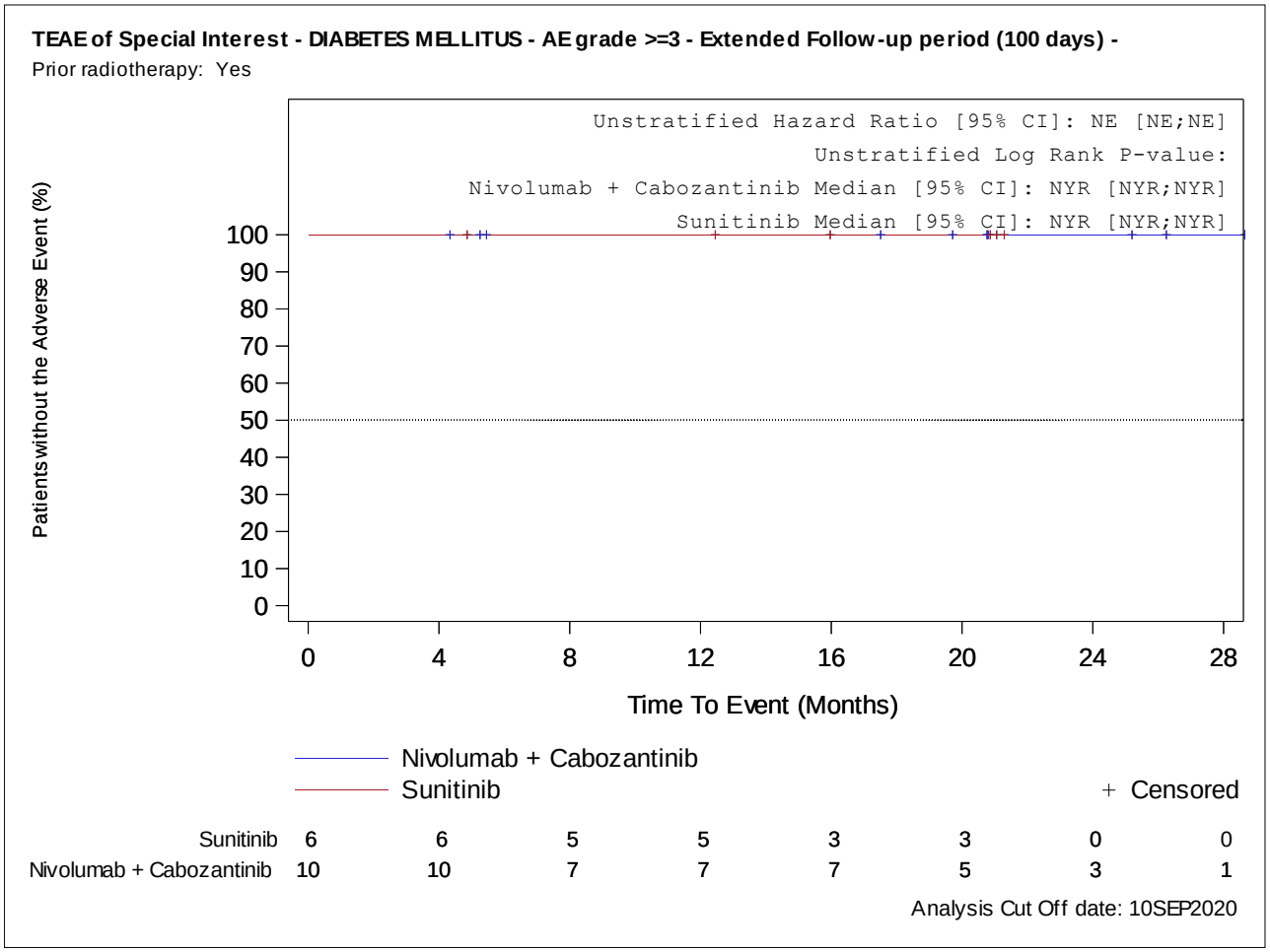

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:58:33

FIGURE 3.68.2.19: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



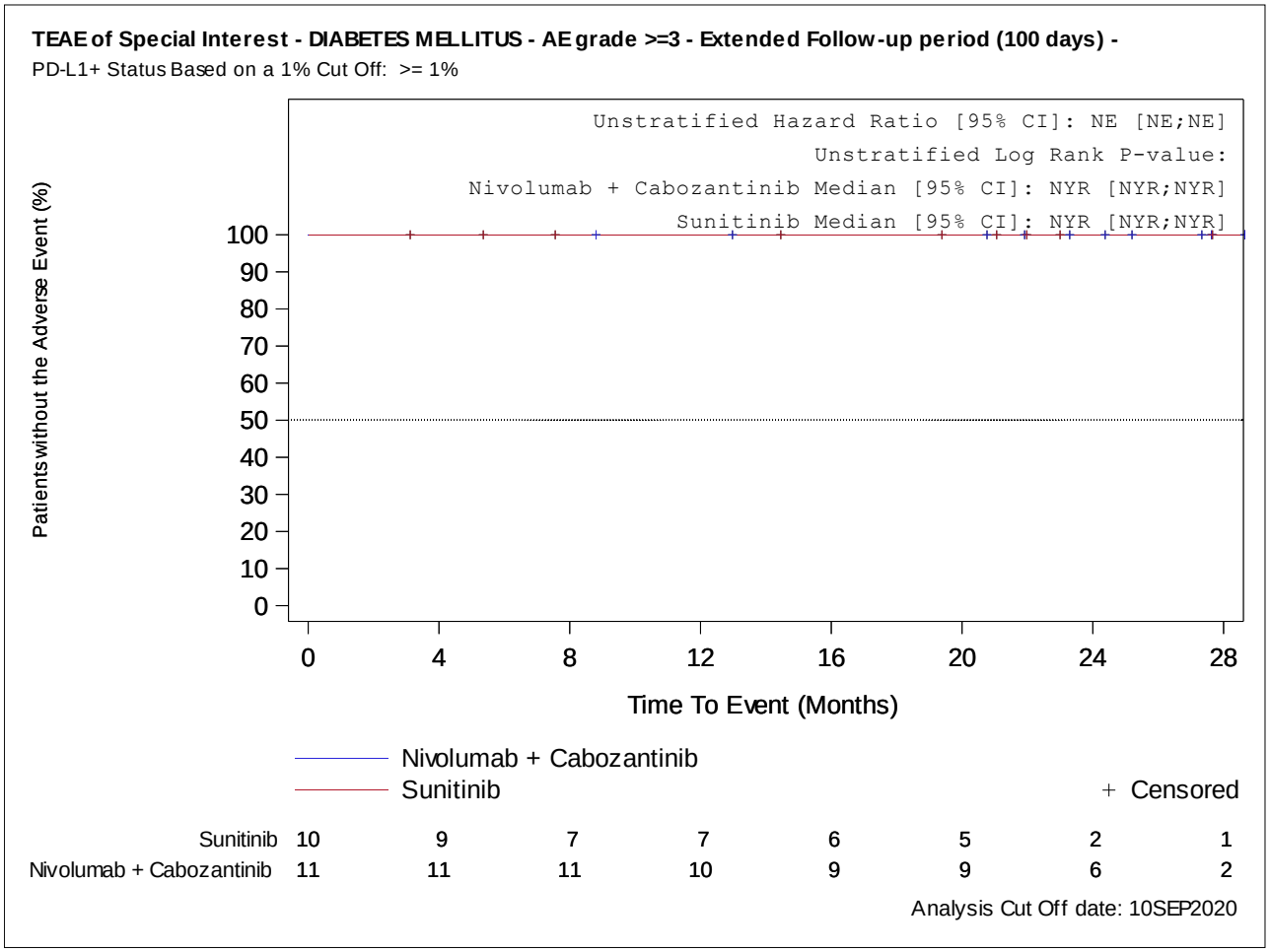

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:58:39

FIGURE 3.68.2.20: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



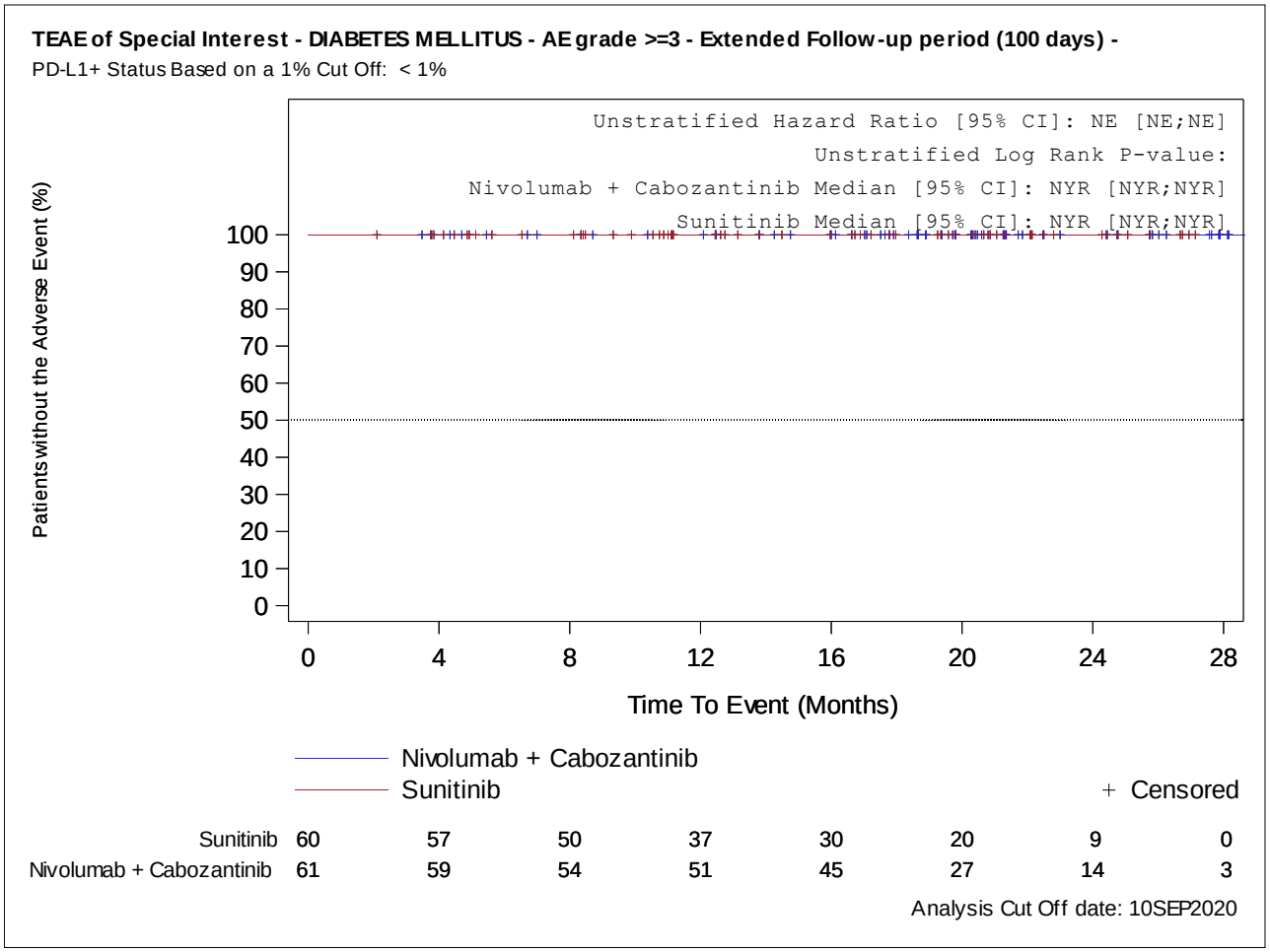

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:58:45

FIGURE 3.68.2.21: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



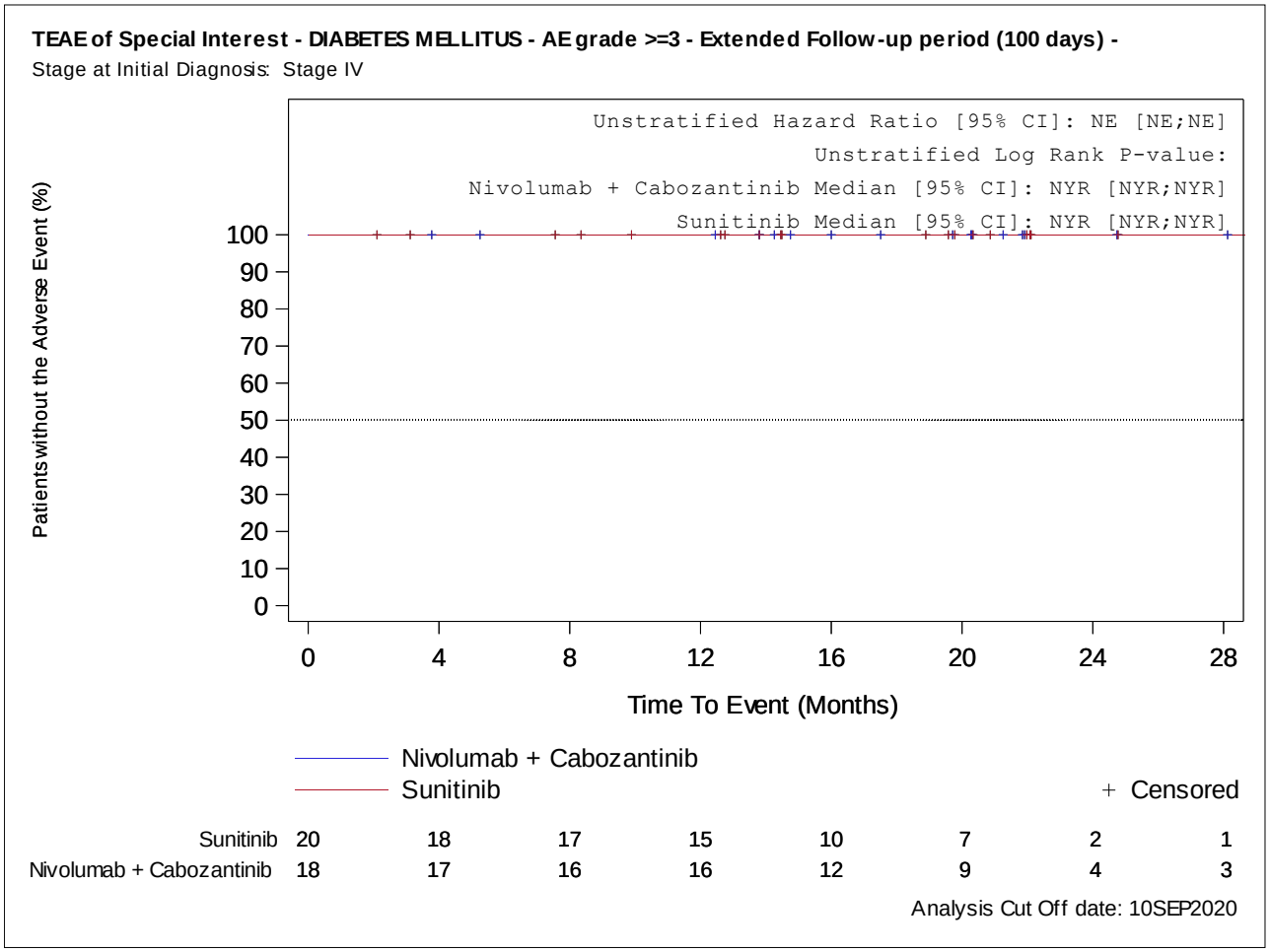

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:58:51

FIGURE 3.68.2.22: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



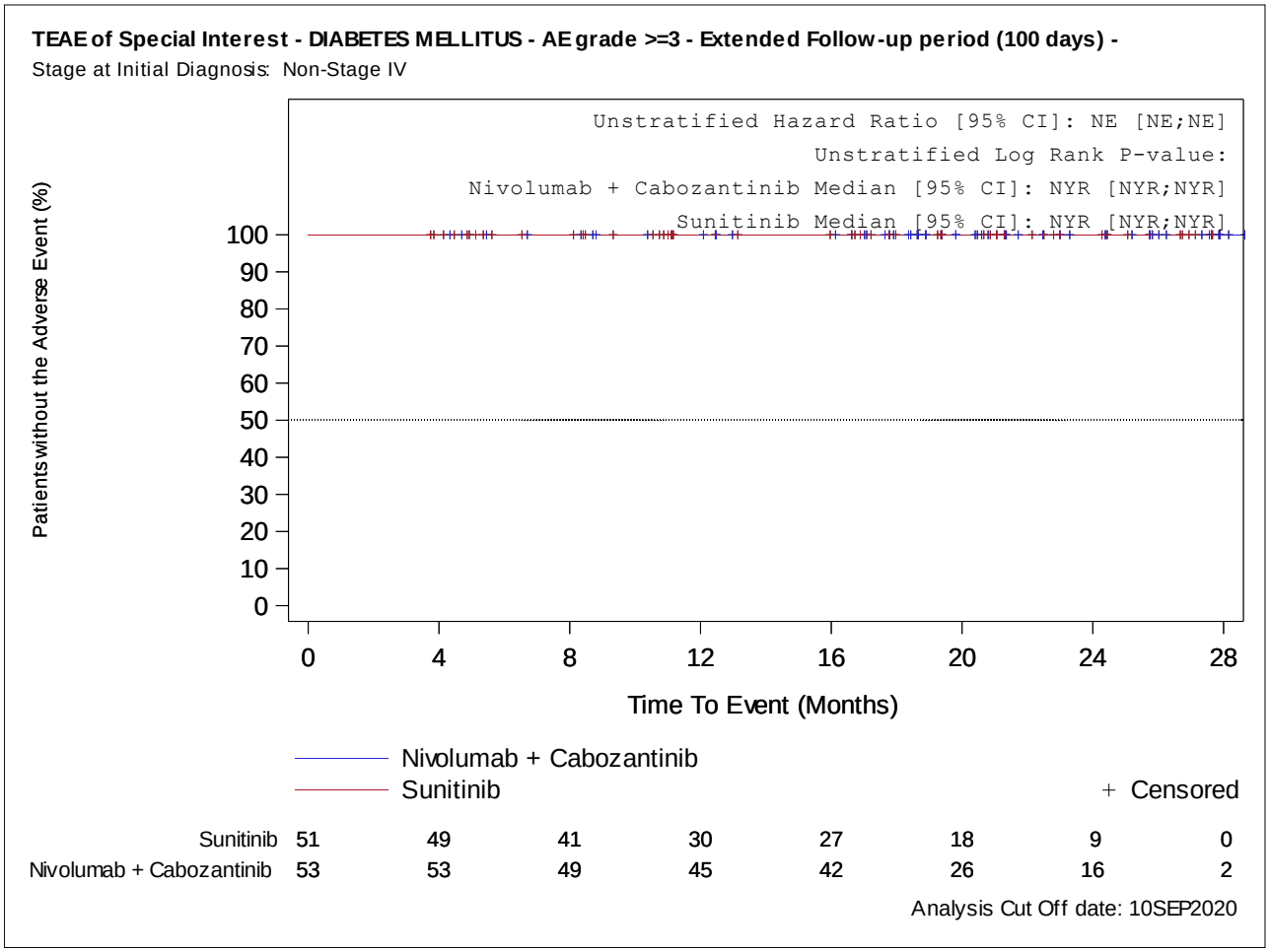

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:58:56

FIGURE 3.68.2.23: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



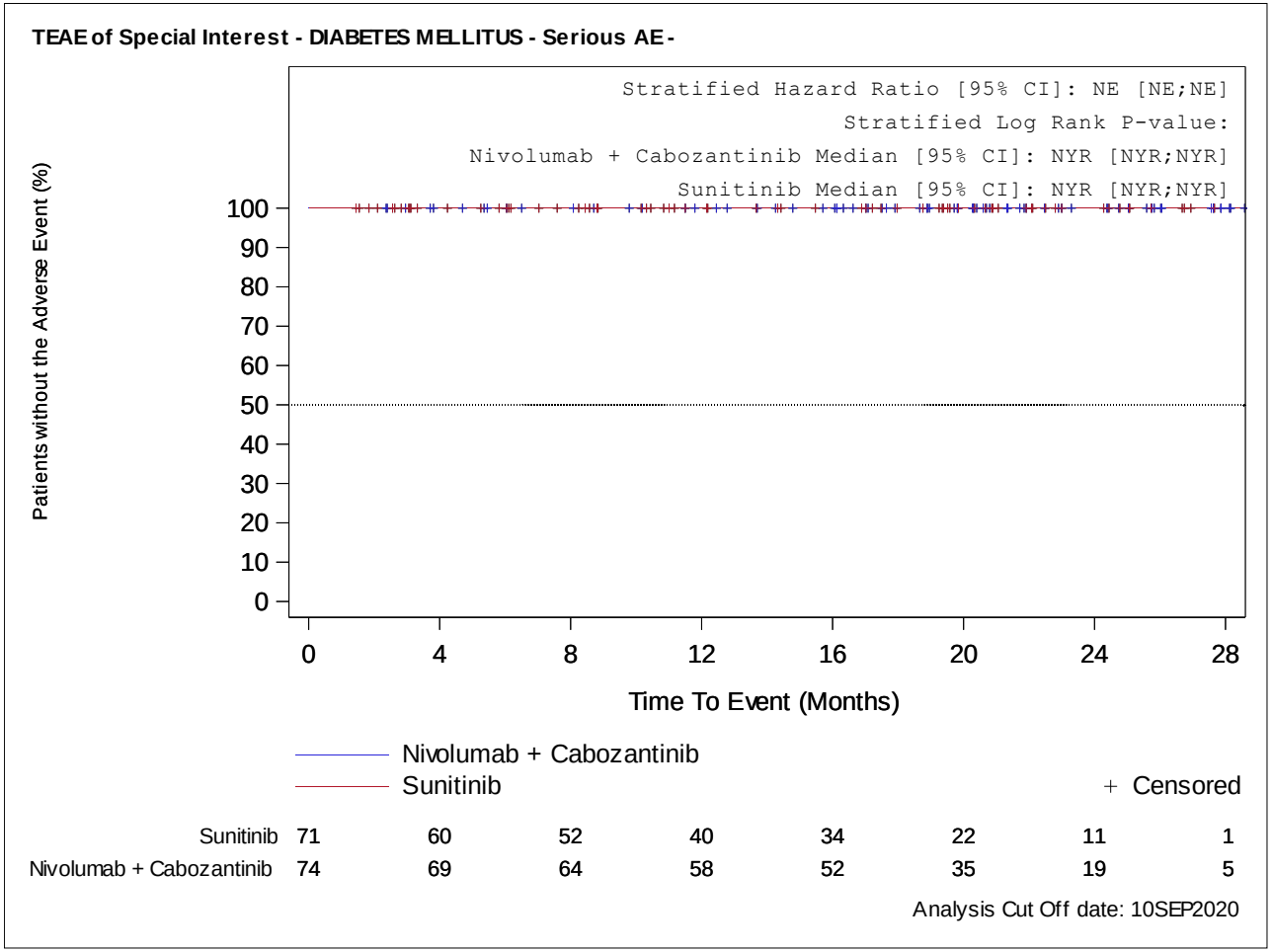

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:59:26

FIGURE 3.68.2.24: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



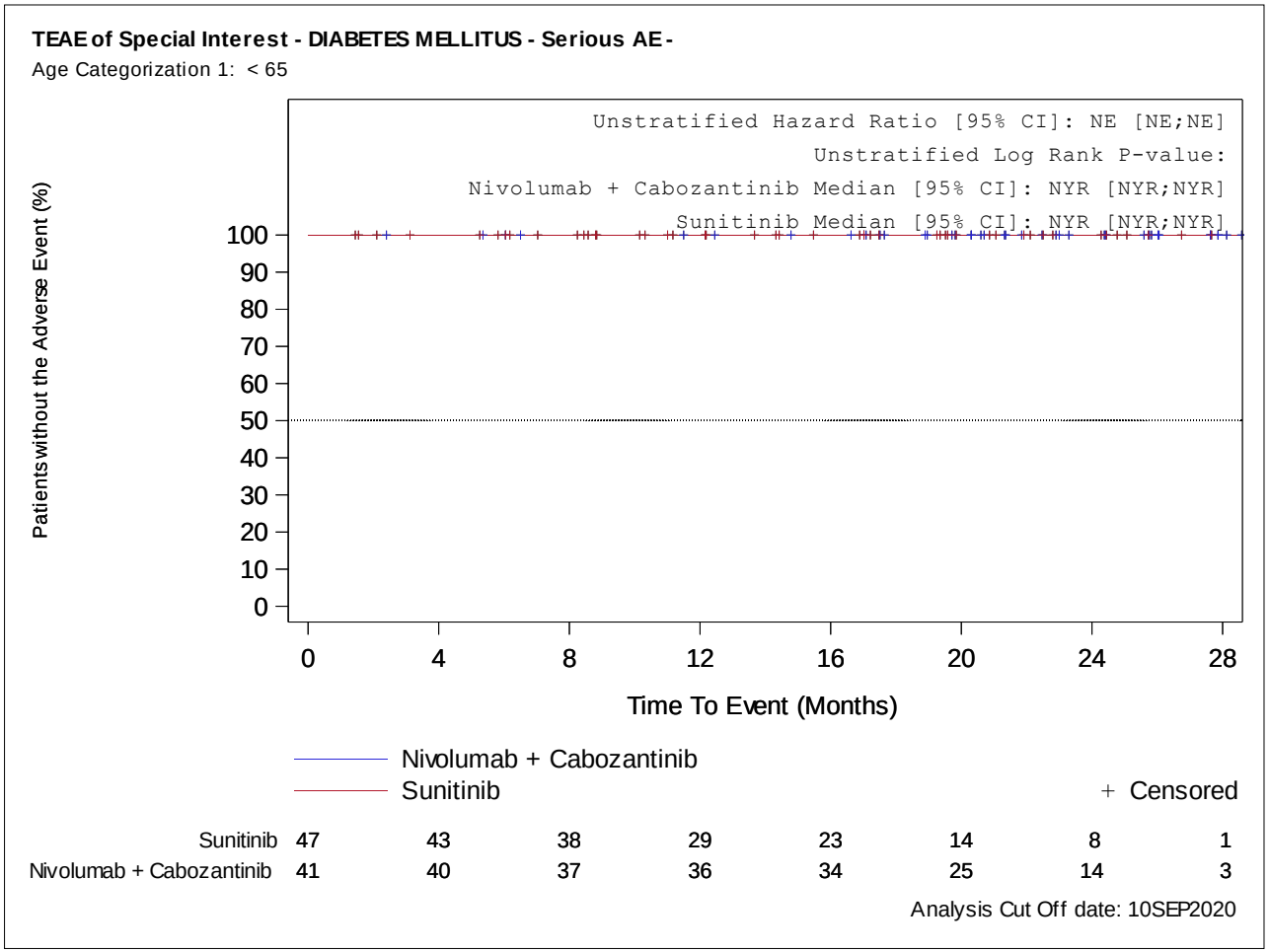

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 19:59:31

FIGURE 3.69.1: TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



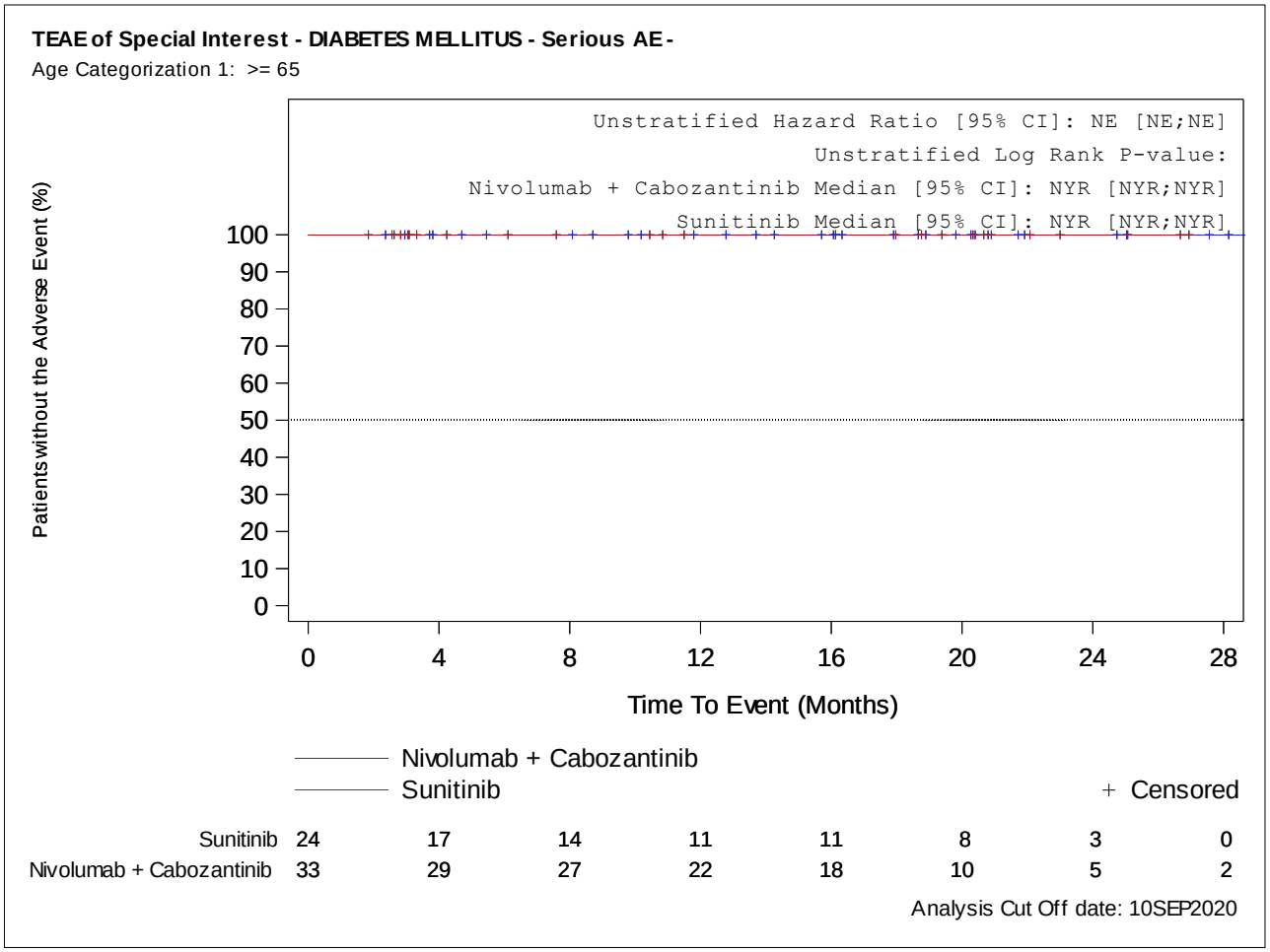

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:02:50

FIGURE 3.69.2.1: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



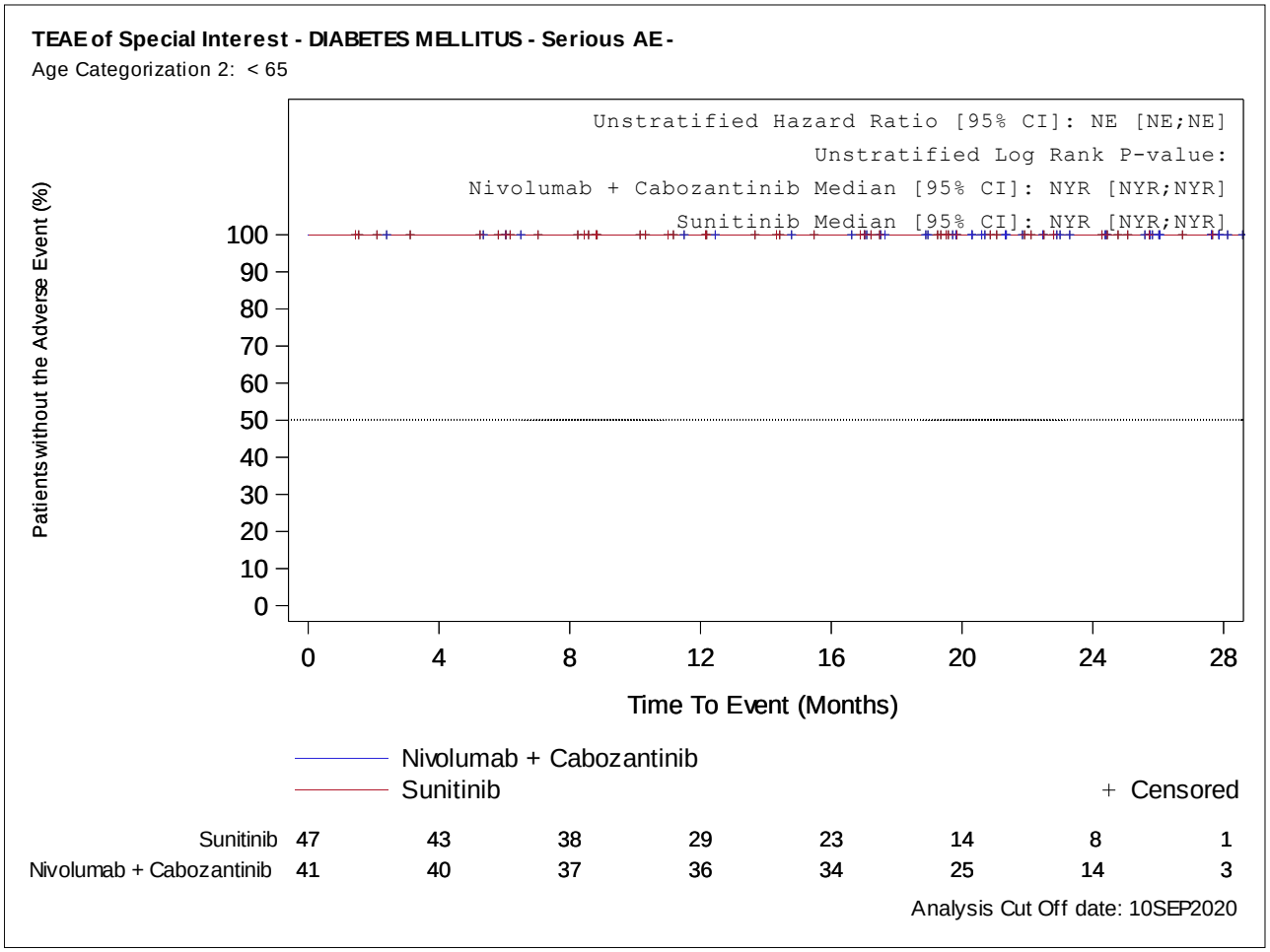

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:02:53

FIGURE 3.69.2.2: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



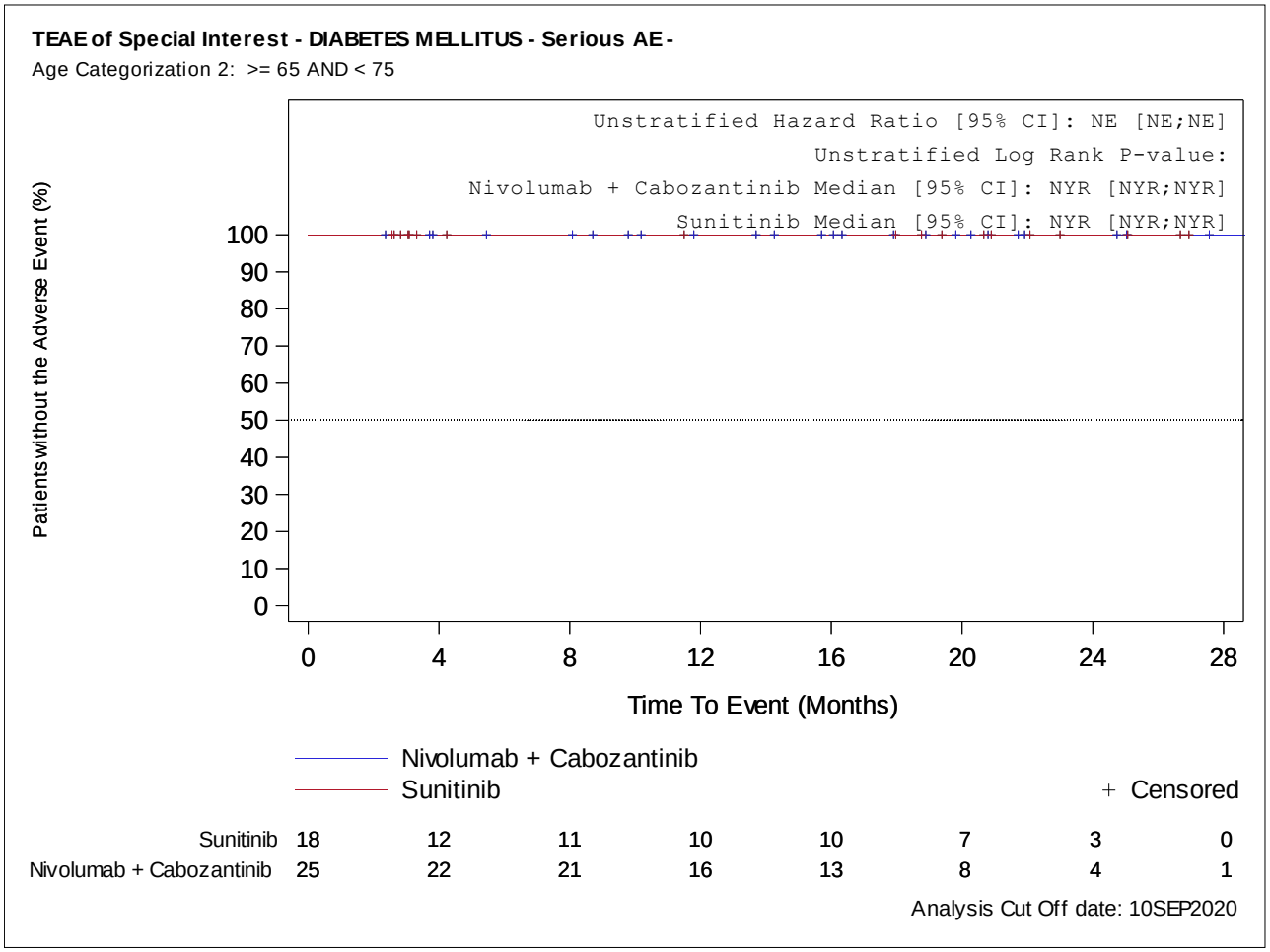

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:02:59

FIGURE 3.69.2.3: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



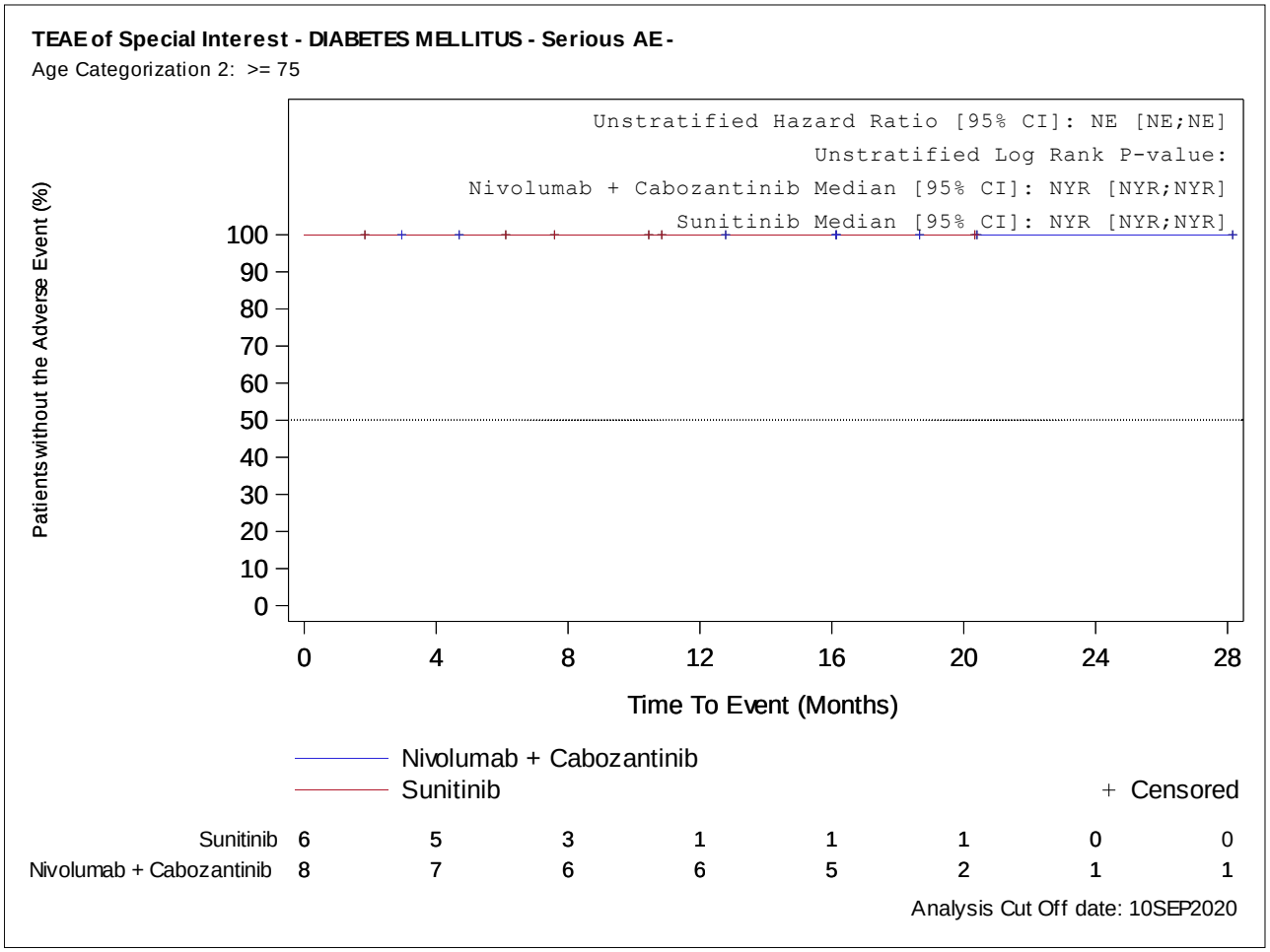

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:05

FIGURE 3.69.2.4: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



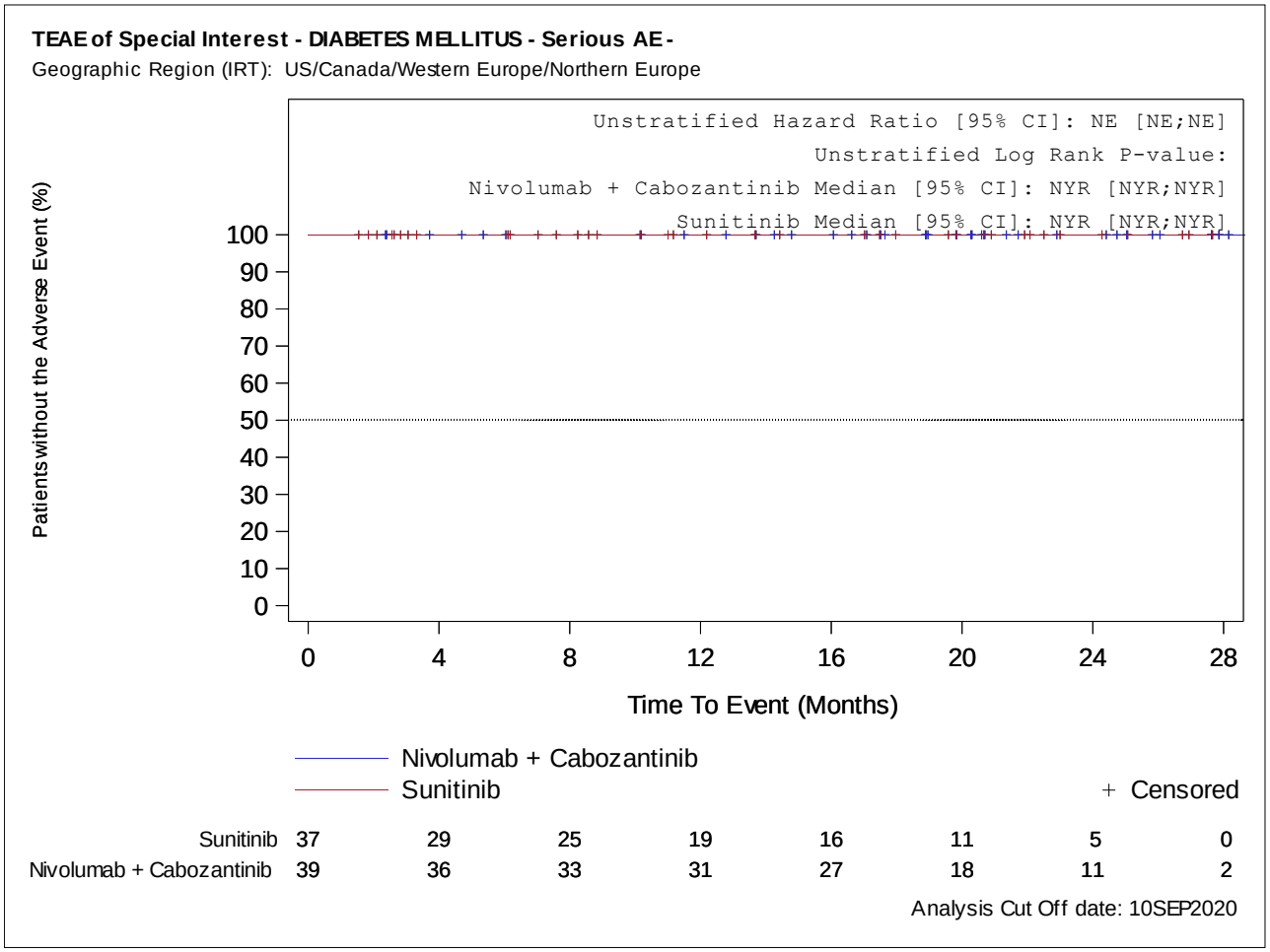

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:11

FIGURE 3.69.2.5: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



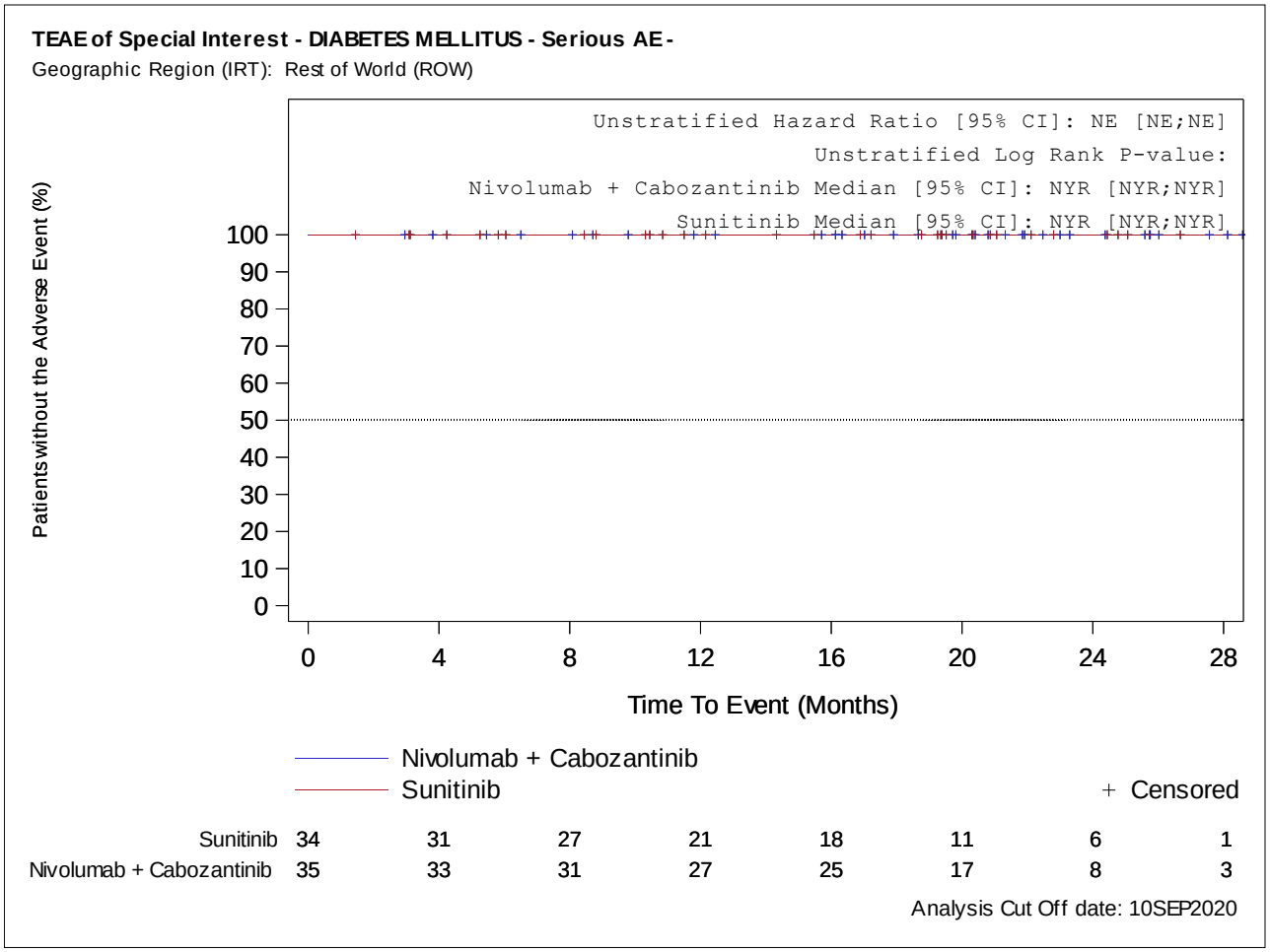

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:17

FIGURE 3.69.2.6: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



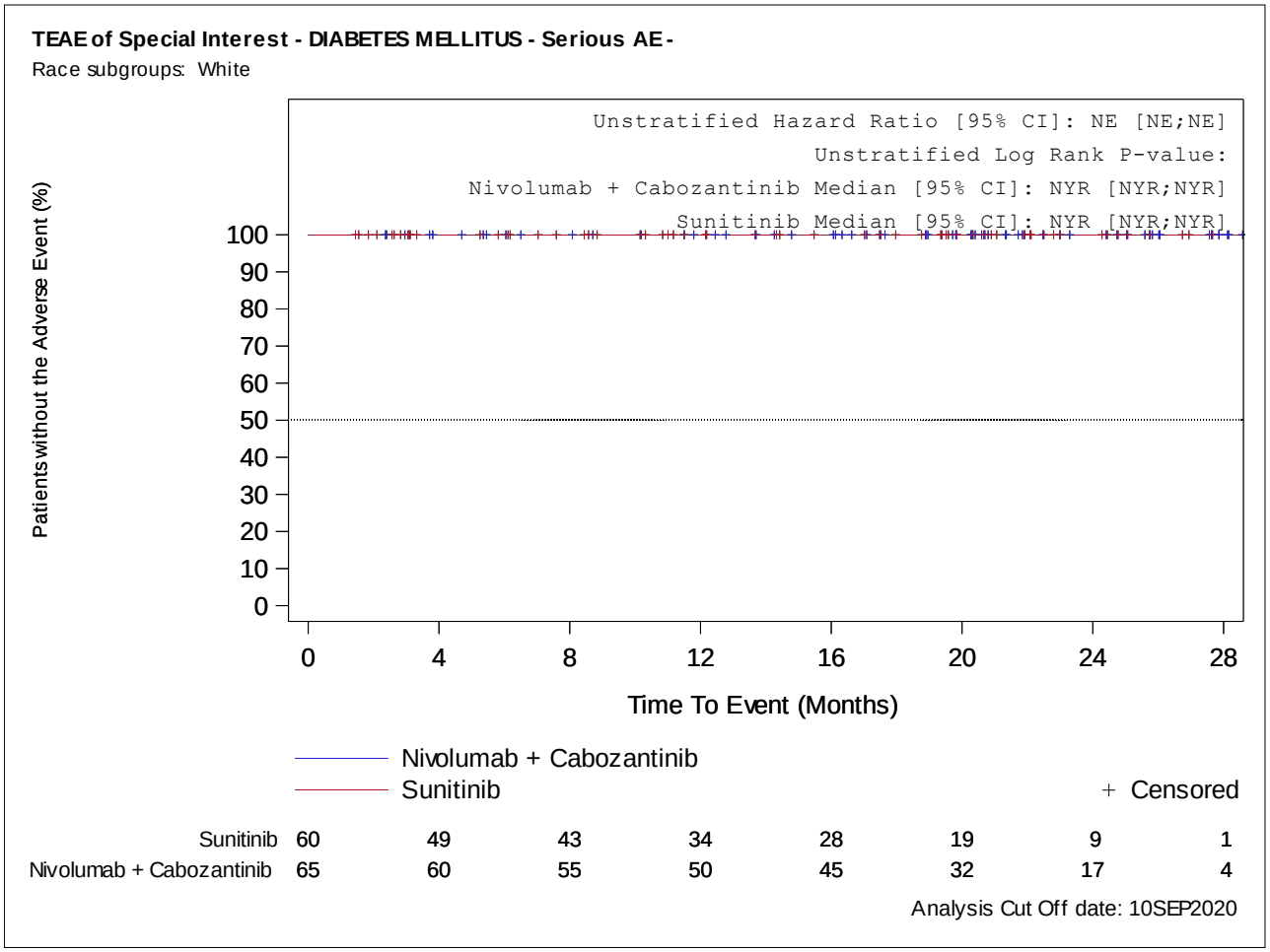

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:23

FIGURE 3.69.2.7: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



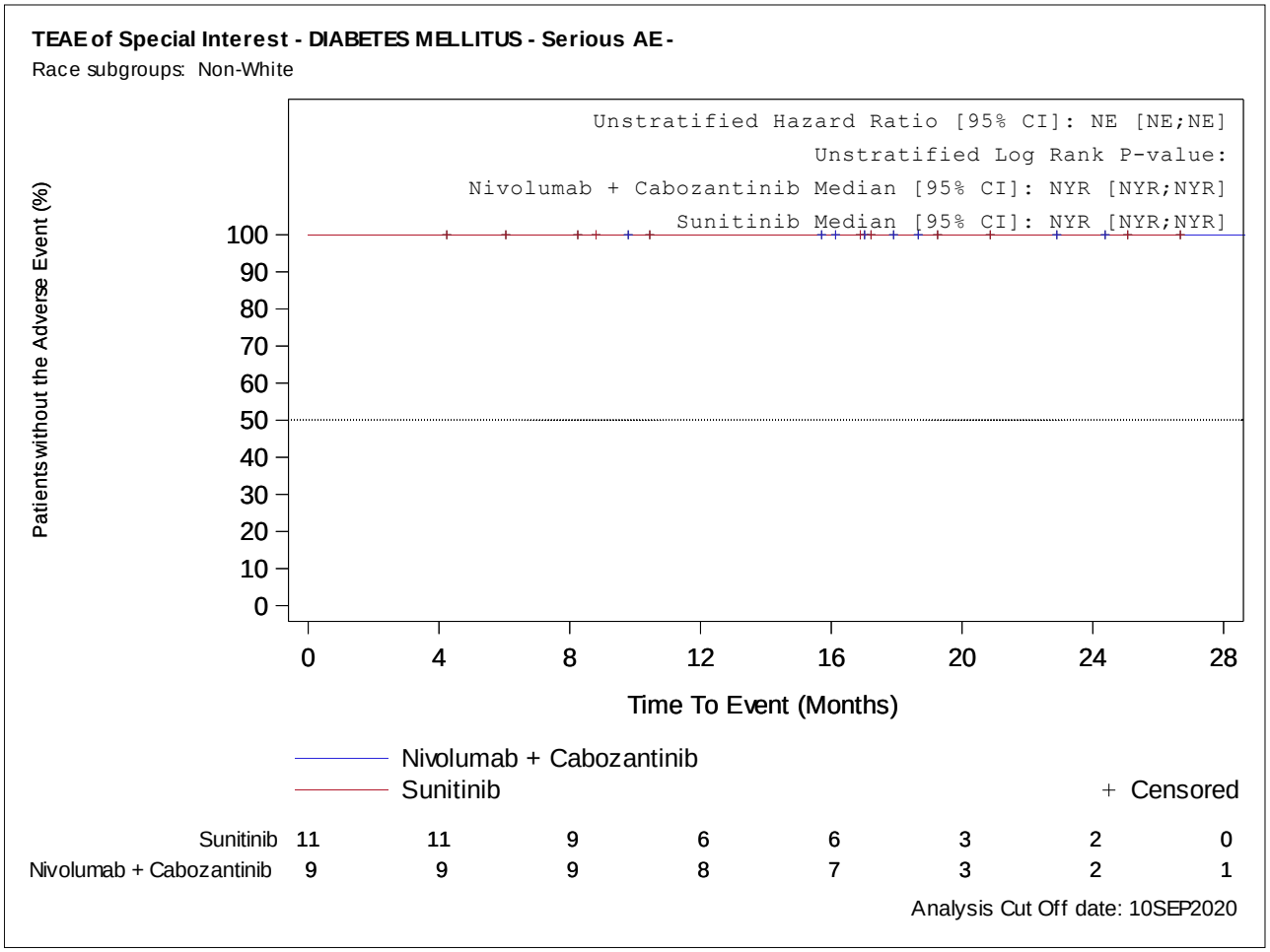

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:28

FIGURE 3.69.2.8: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



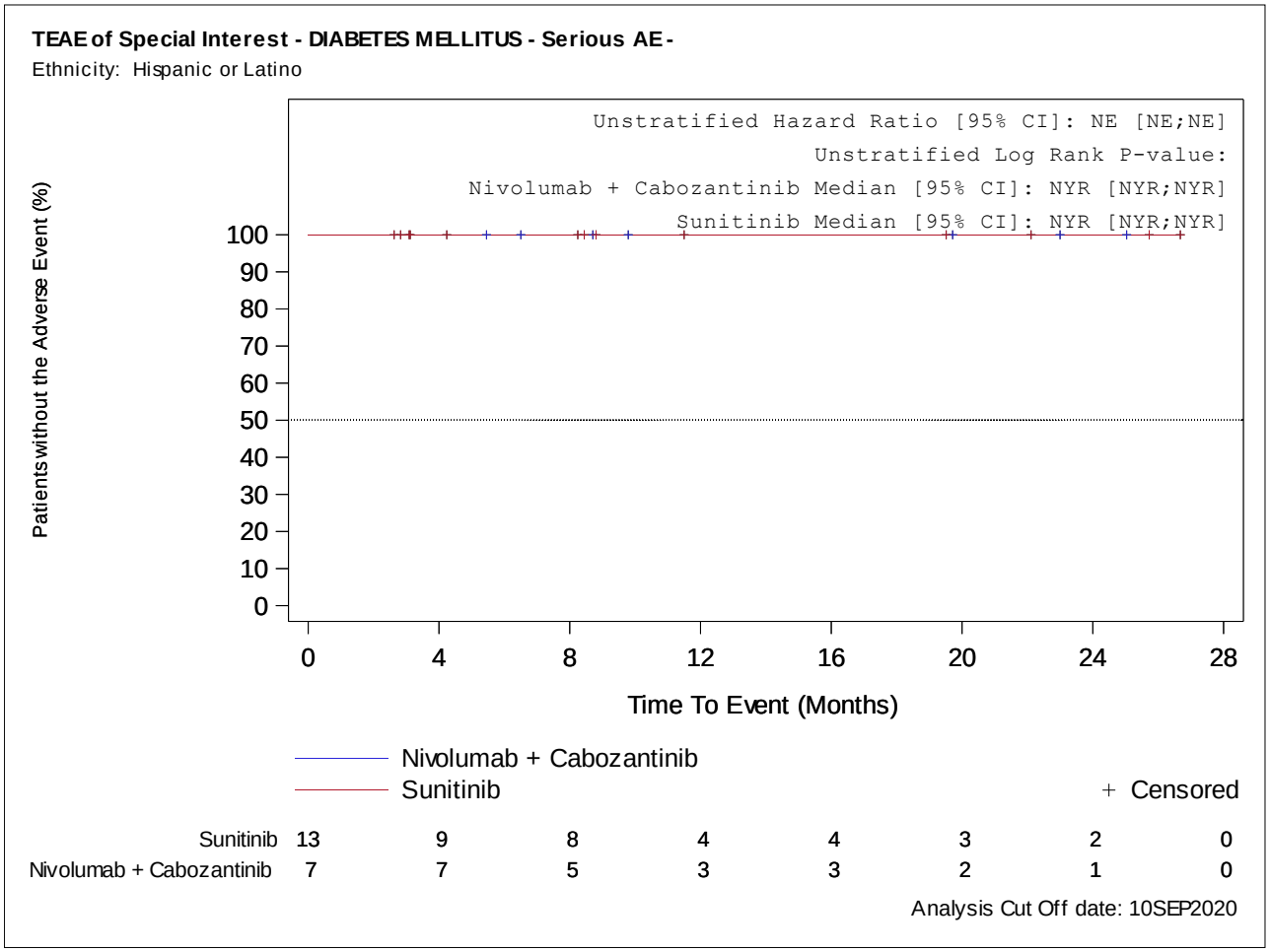

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:34

FIGURE 3.69.2.9: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



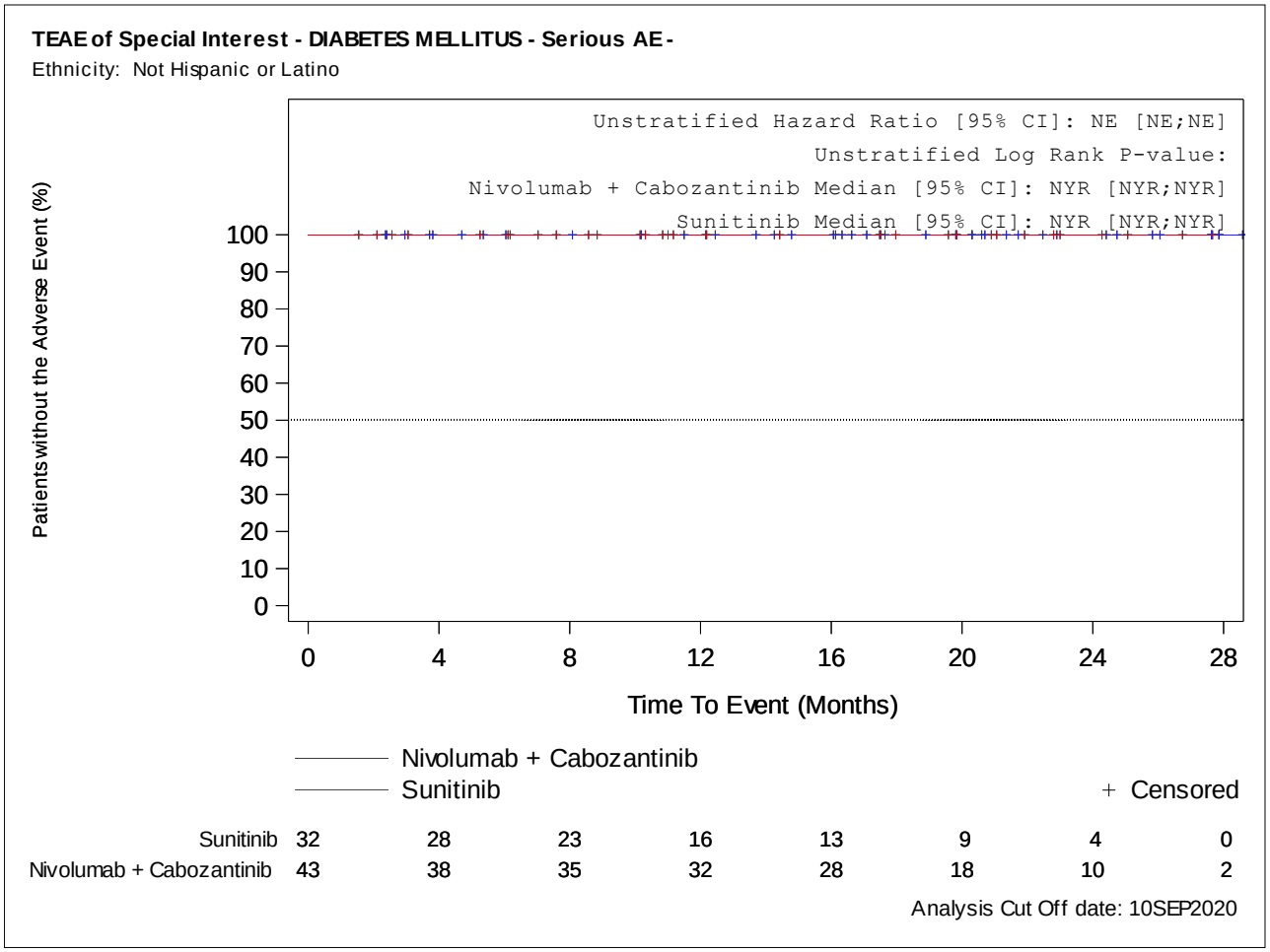

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:40

FIGURE 3.69.2.10: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



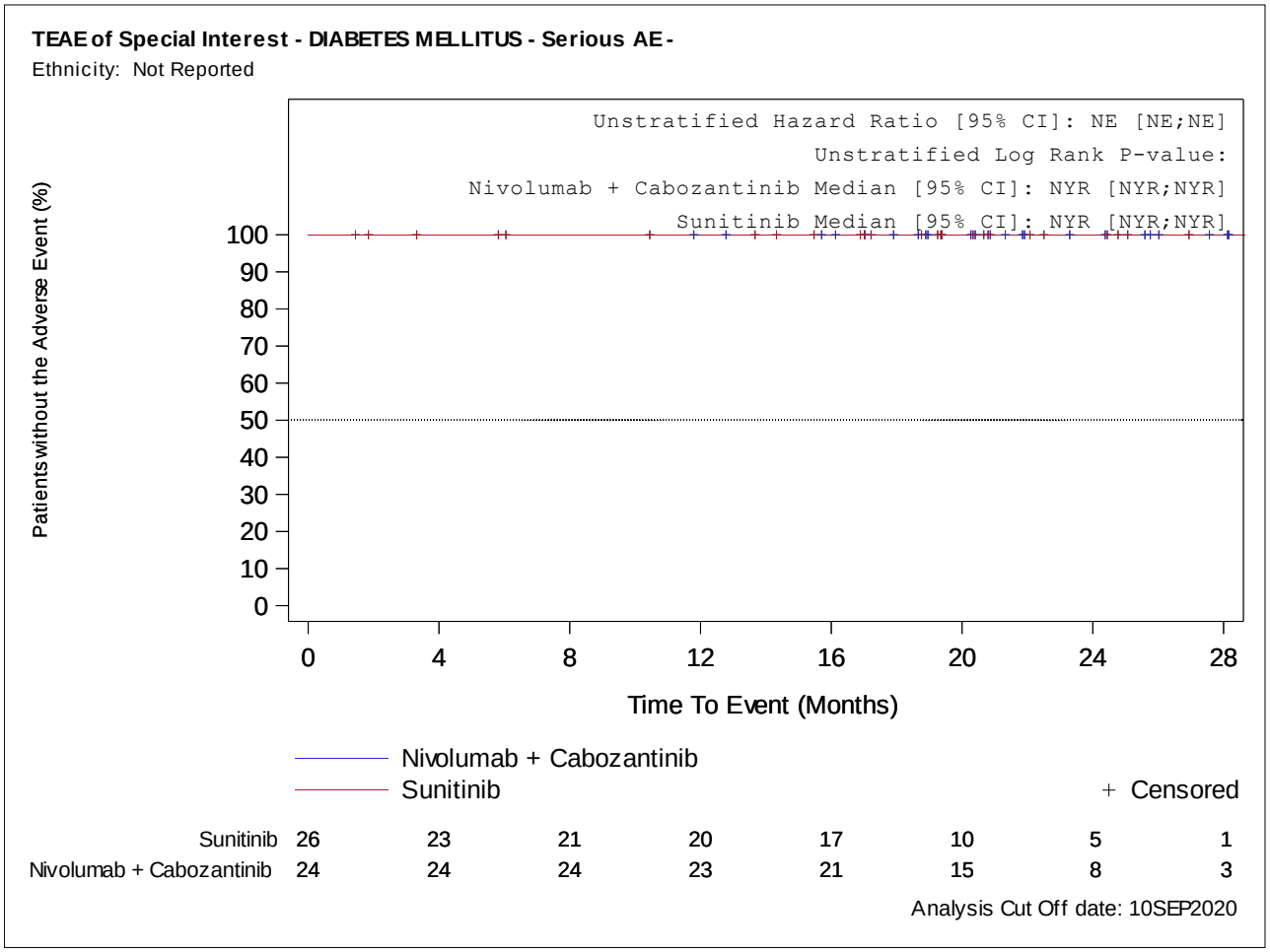

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:45

FIGURE 3.69.2.11: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



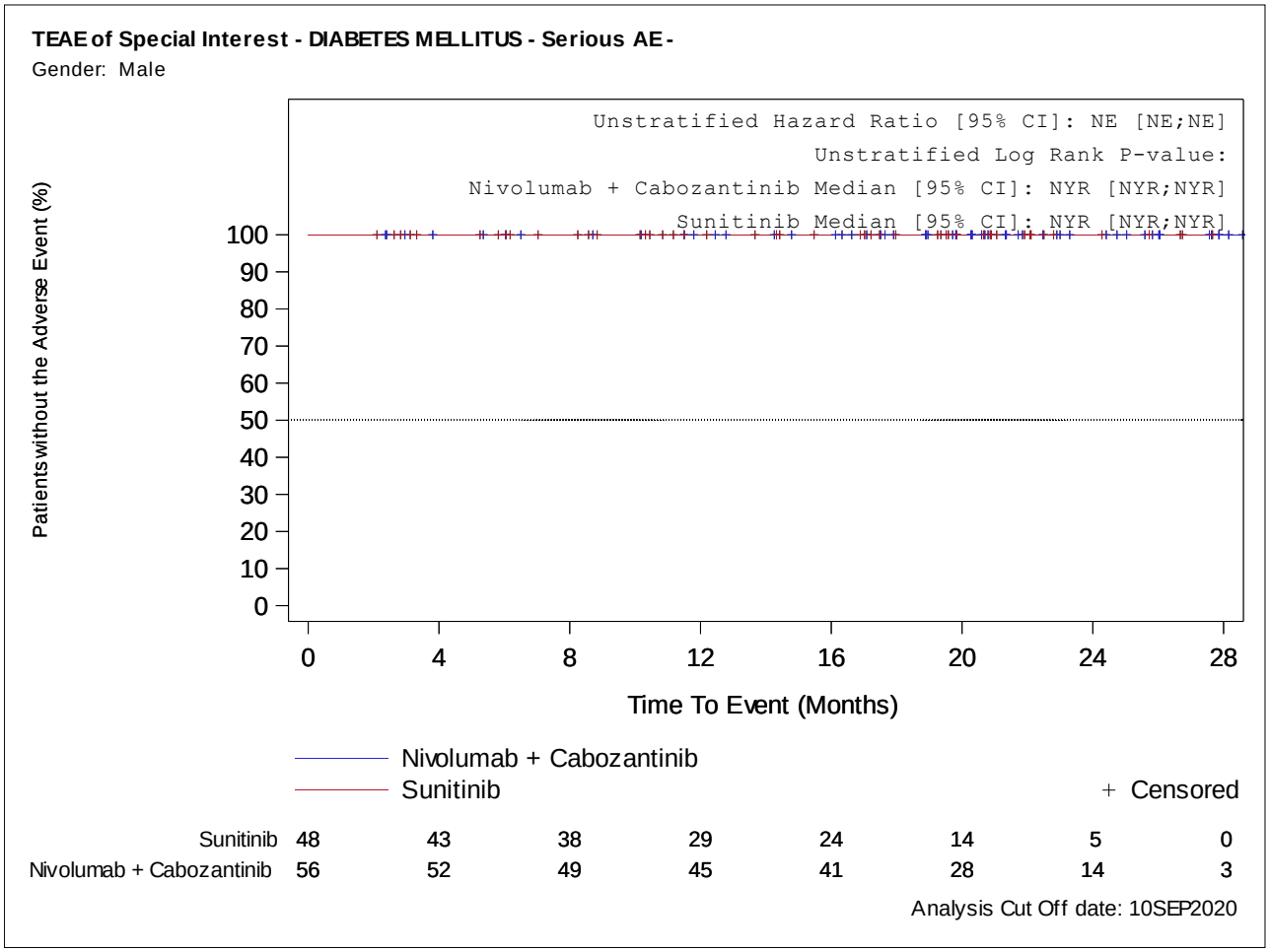

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:51

FIGURE 3.69.2.12: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



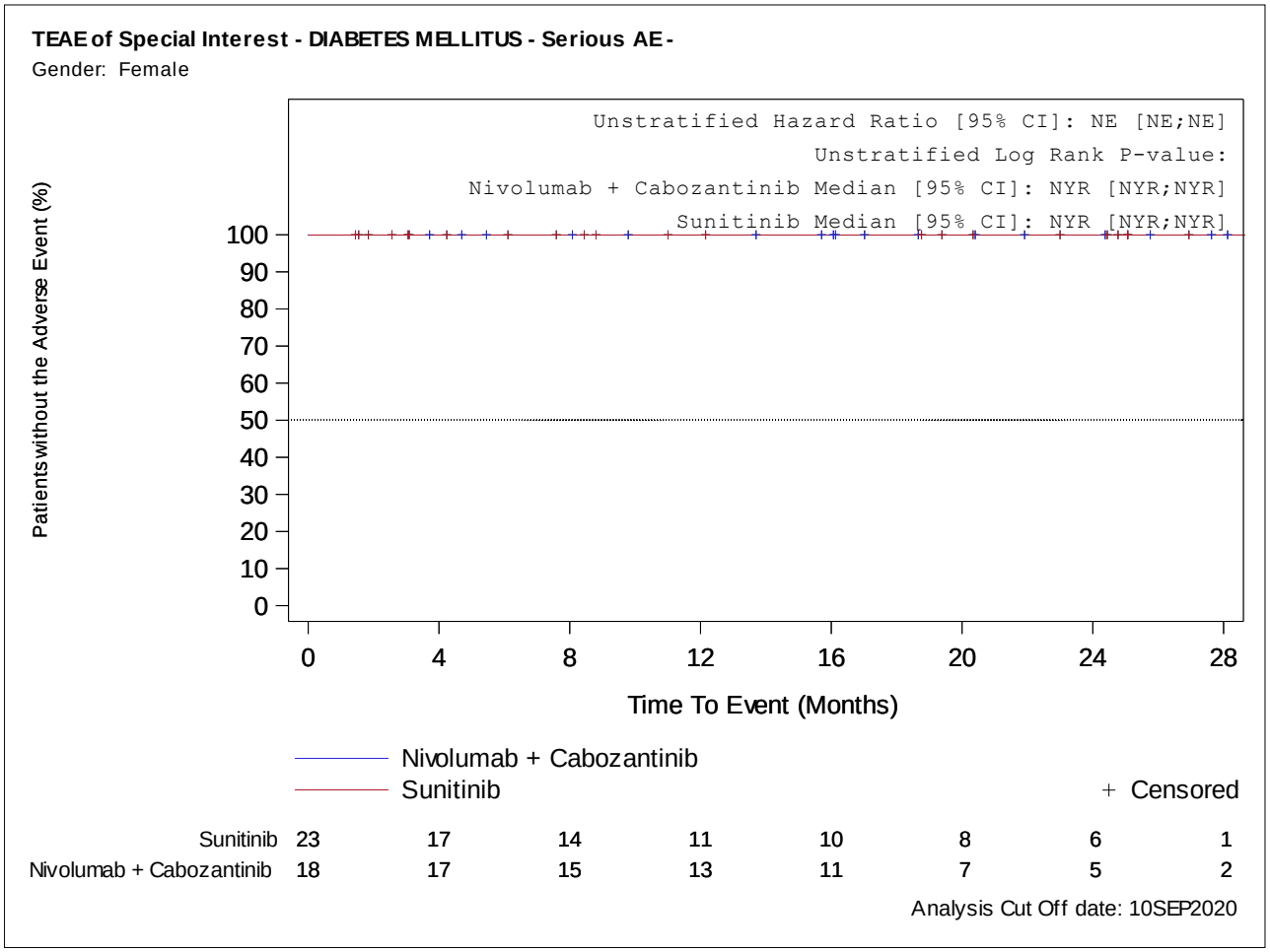

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:03:58

FIGURE 3.69.2.13: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



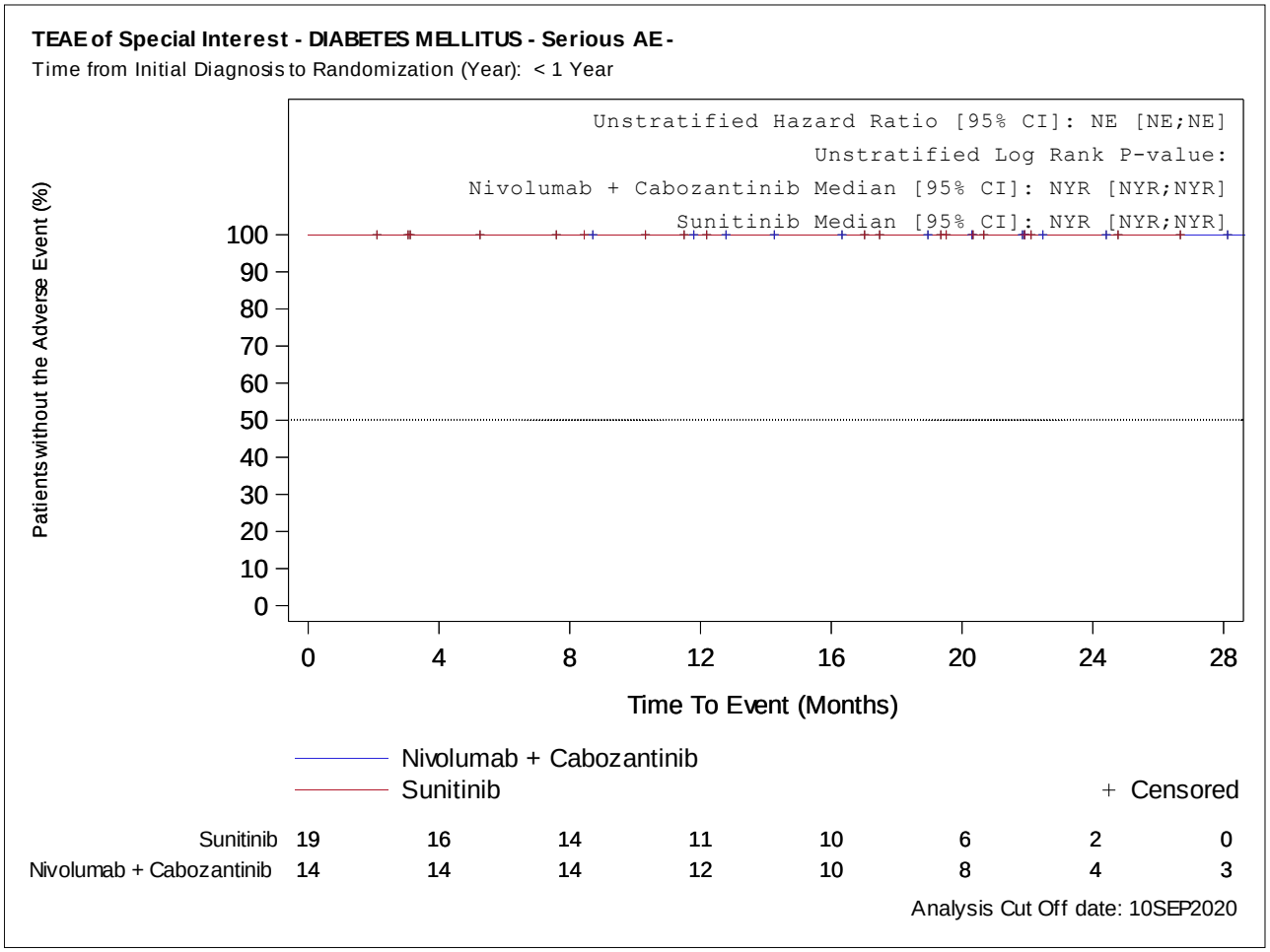

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:04:04

FIGURE 3.69.2.14: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



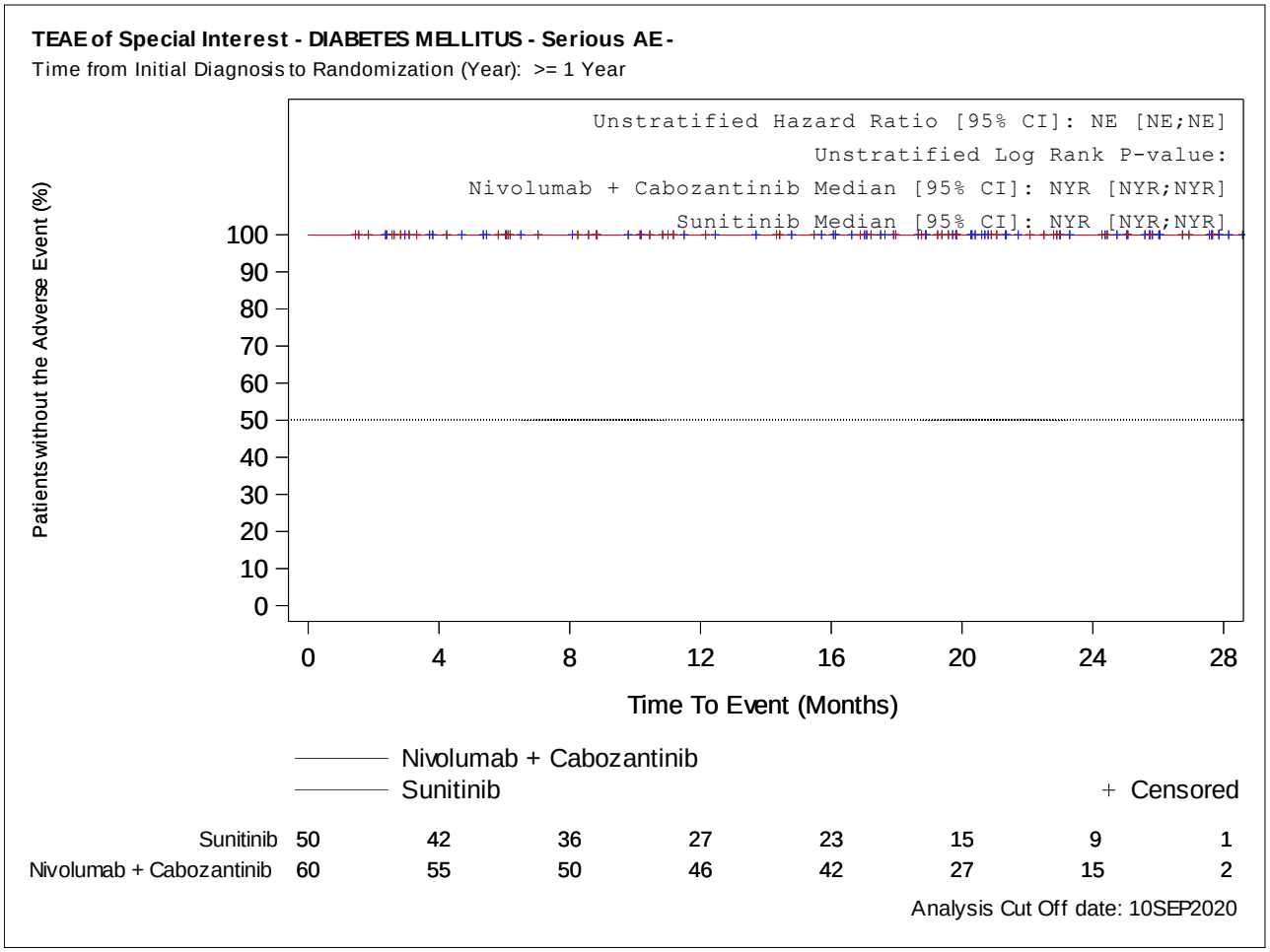

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:04:10

FIGURE 3.69.2.15: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



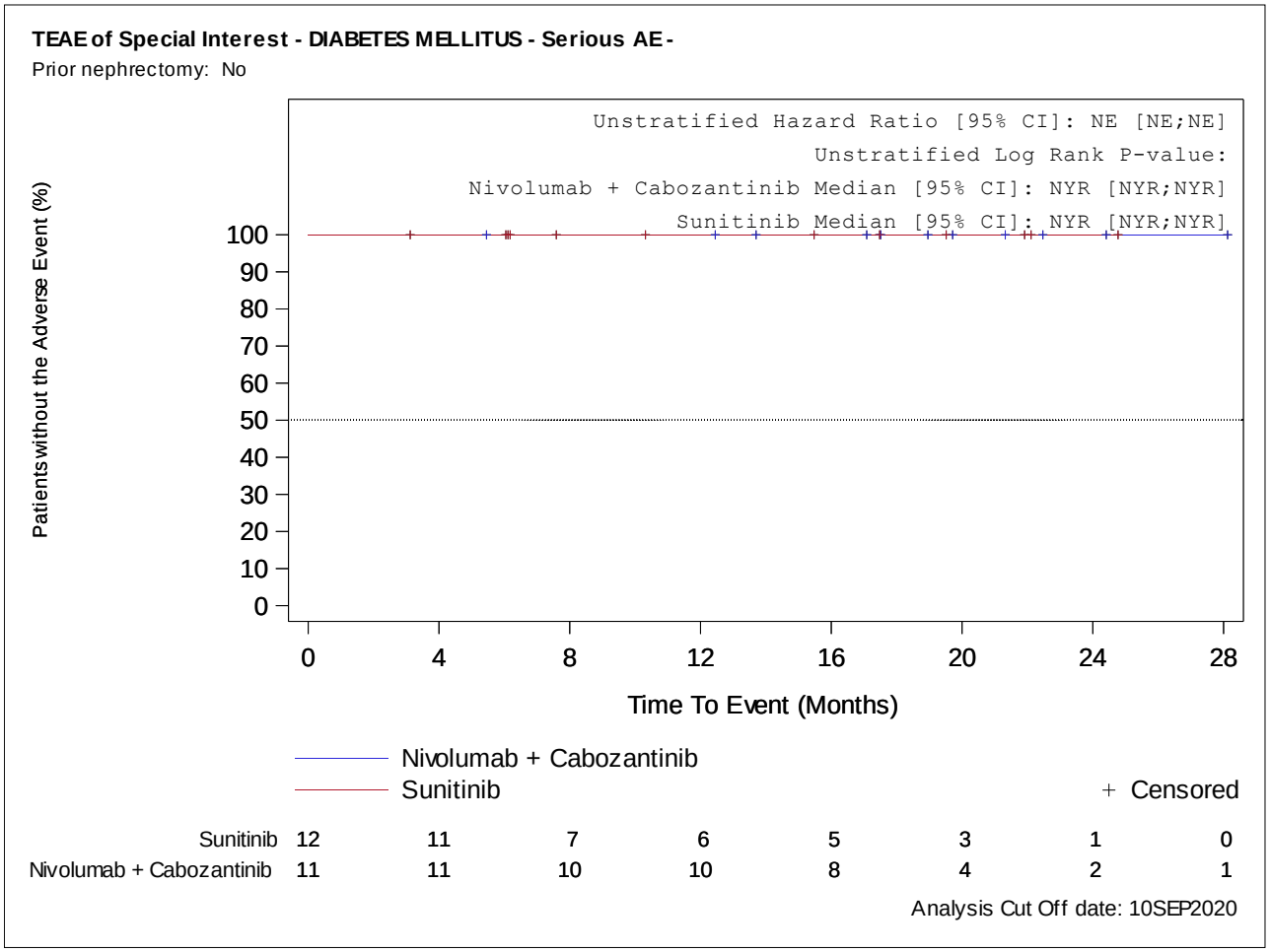

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:04:28

FIGURE 3.69.2.16: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:04:34

FIGURE 3.69.2.17: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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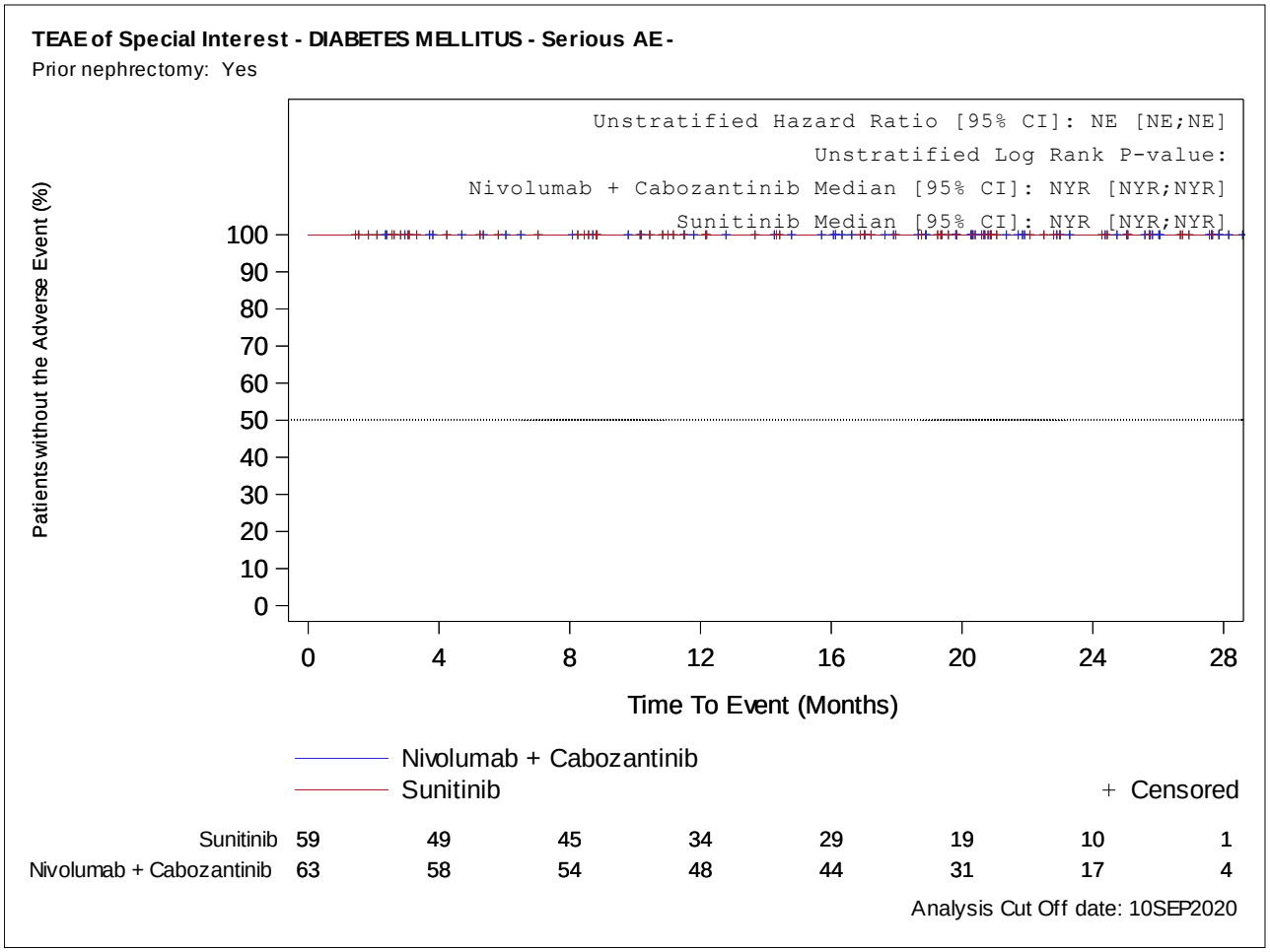
FIGURE 3.69.2.18: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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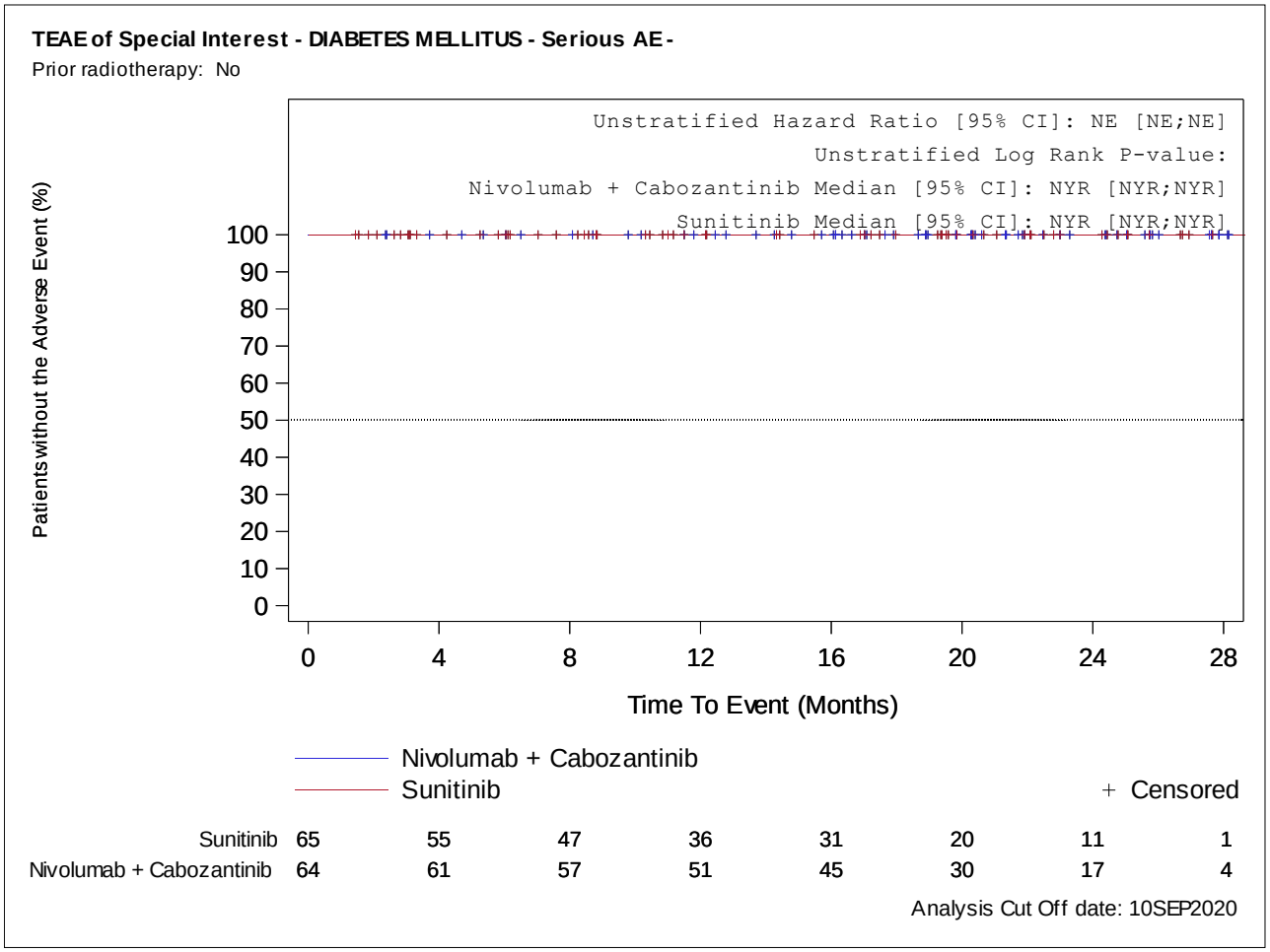
FIGURE 3.69.2.19: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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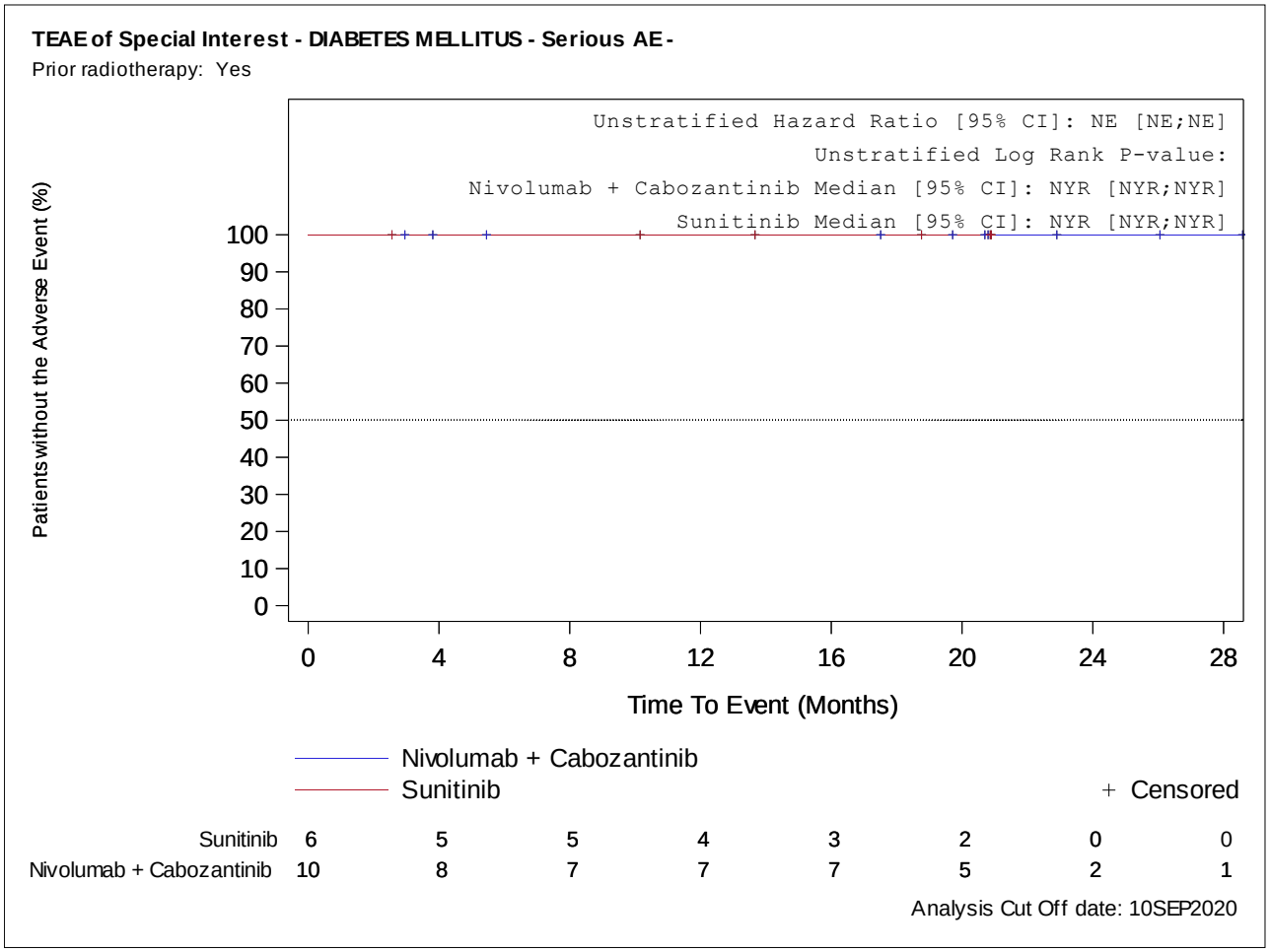
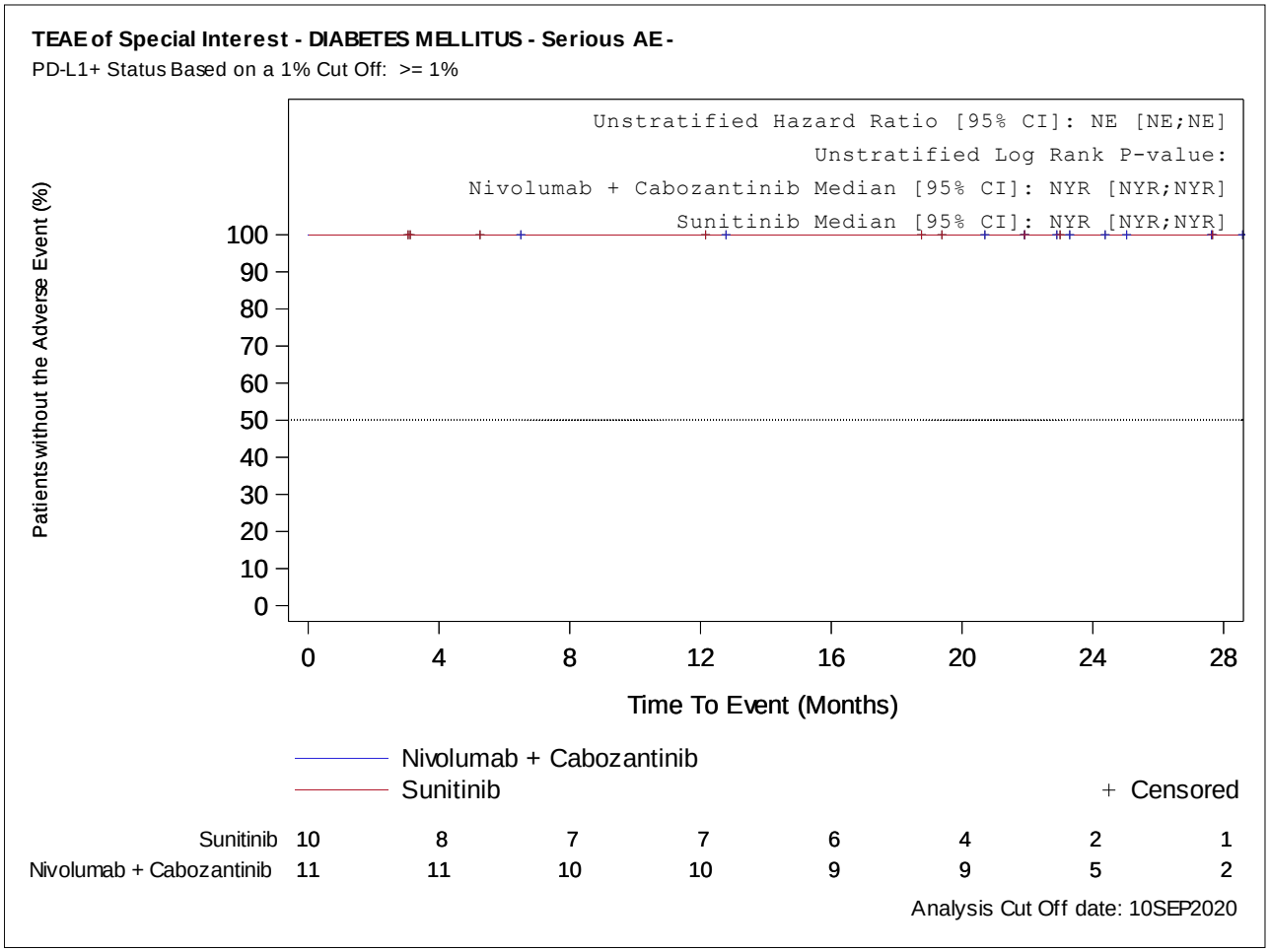
FIGURE 3.69.2.20: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy:  Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:05:43

FIGURE 3.69.2.21: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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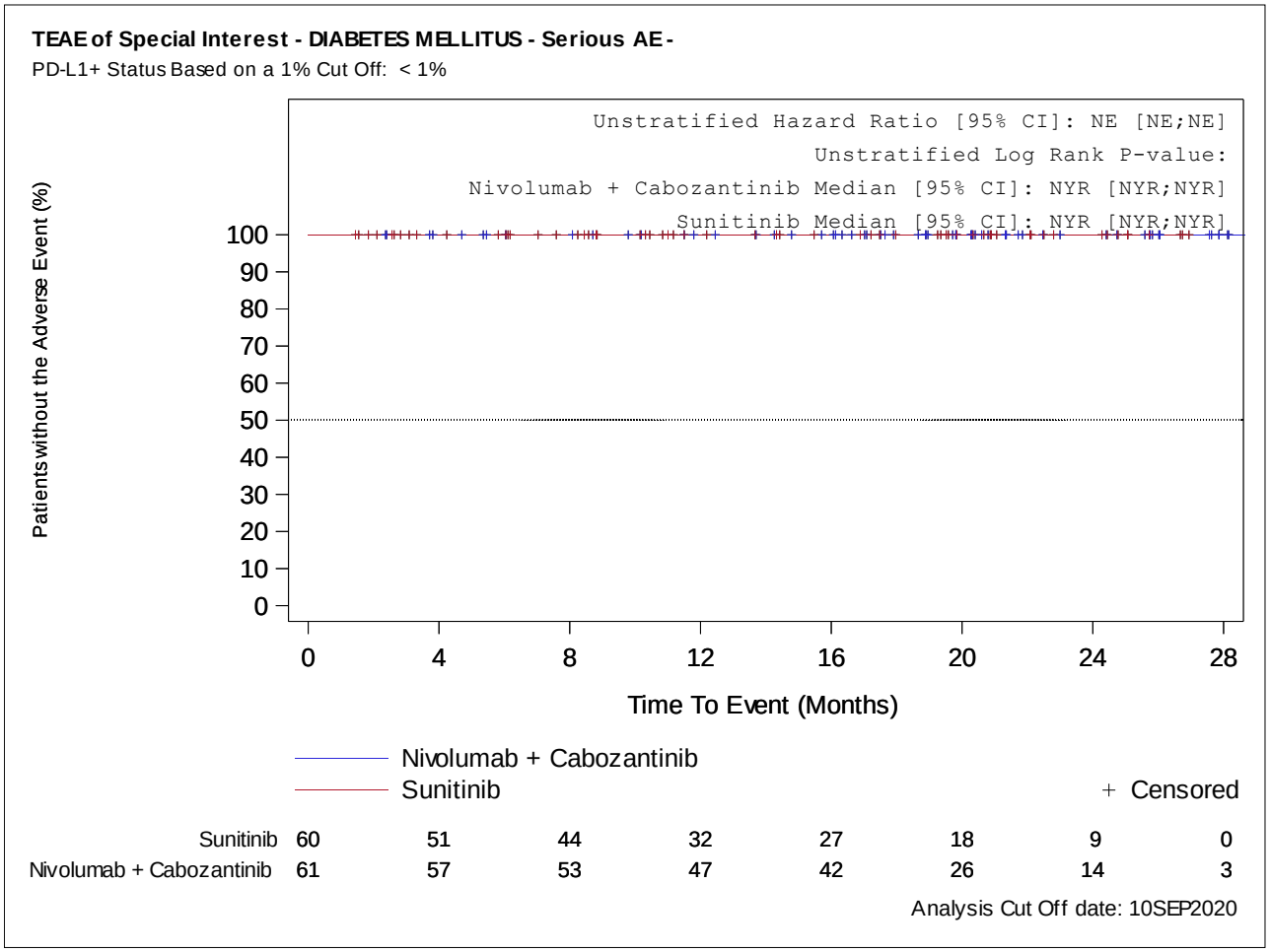
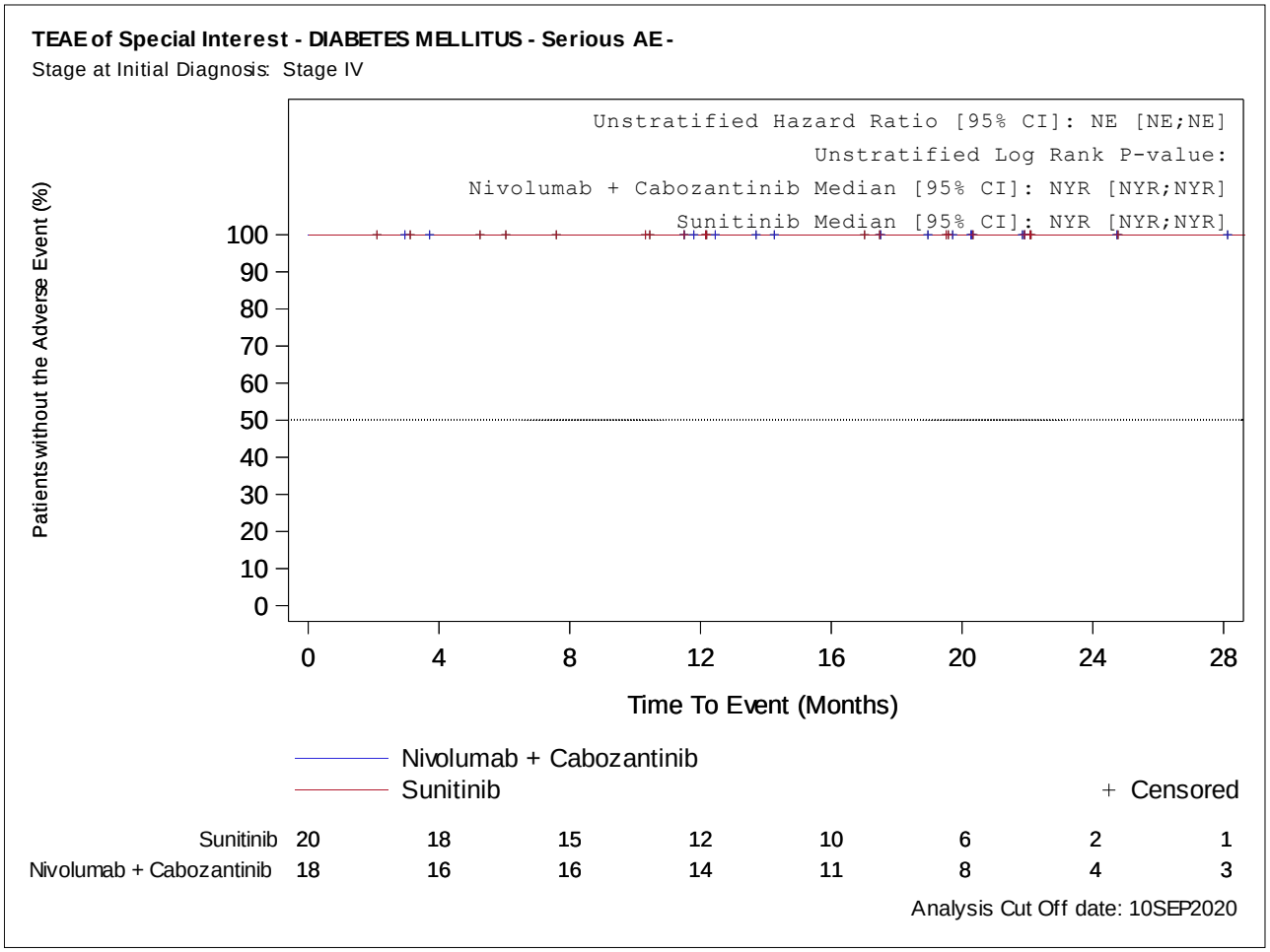
FIGURE 3.69.2.22: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



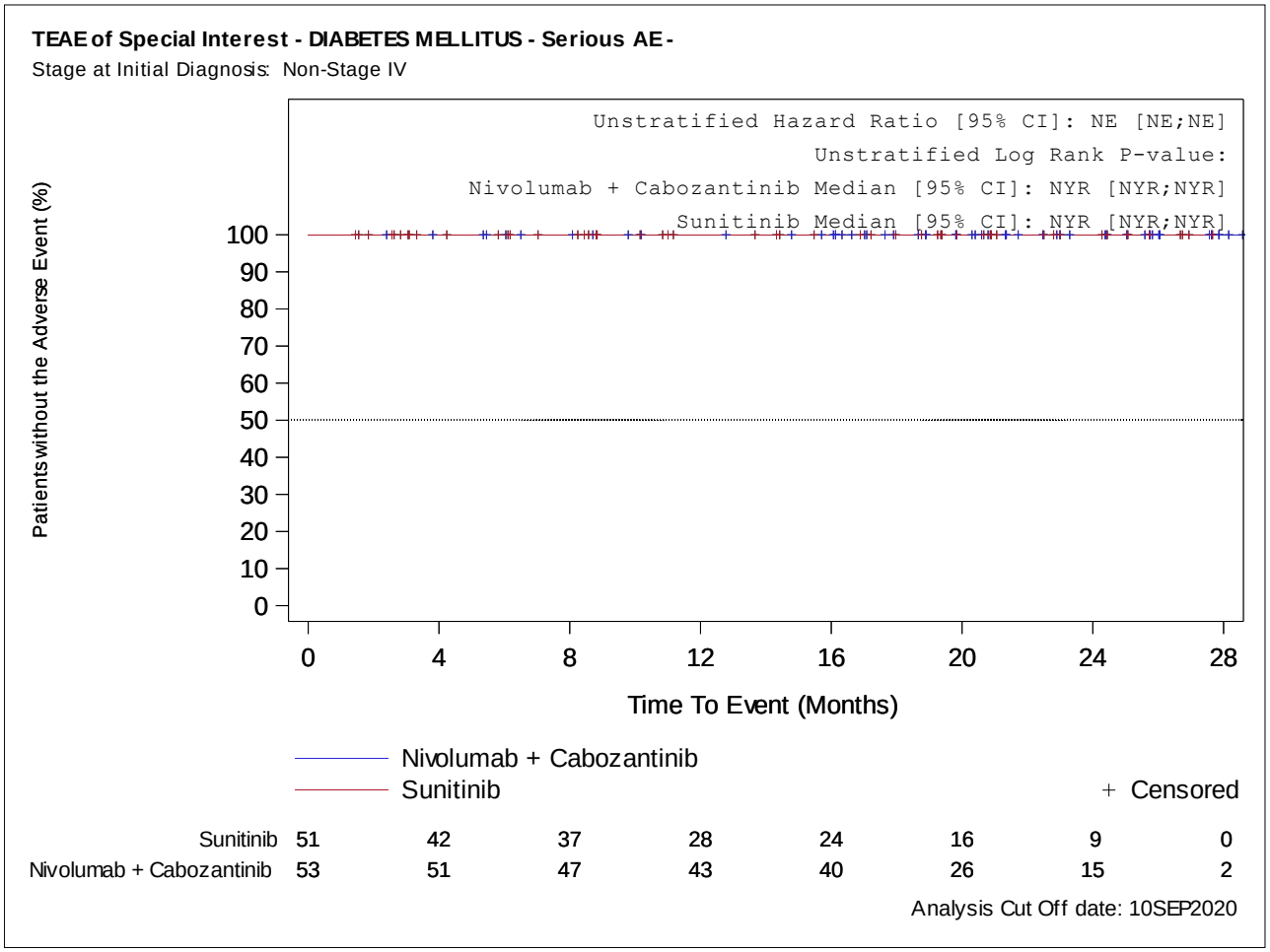

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:05:55

FIGURE 3.69.2.23: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



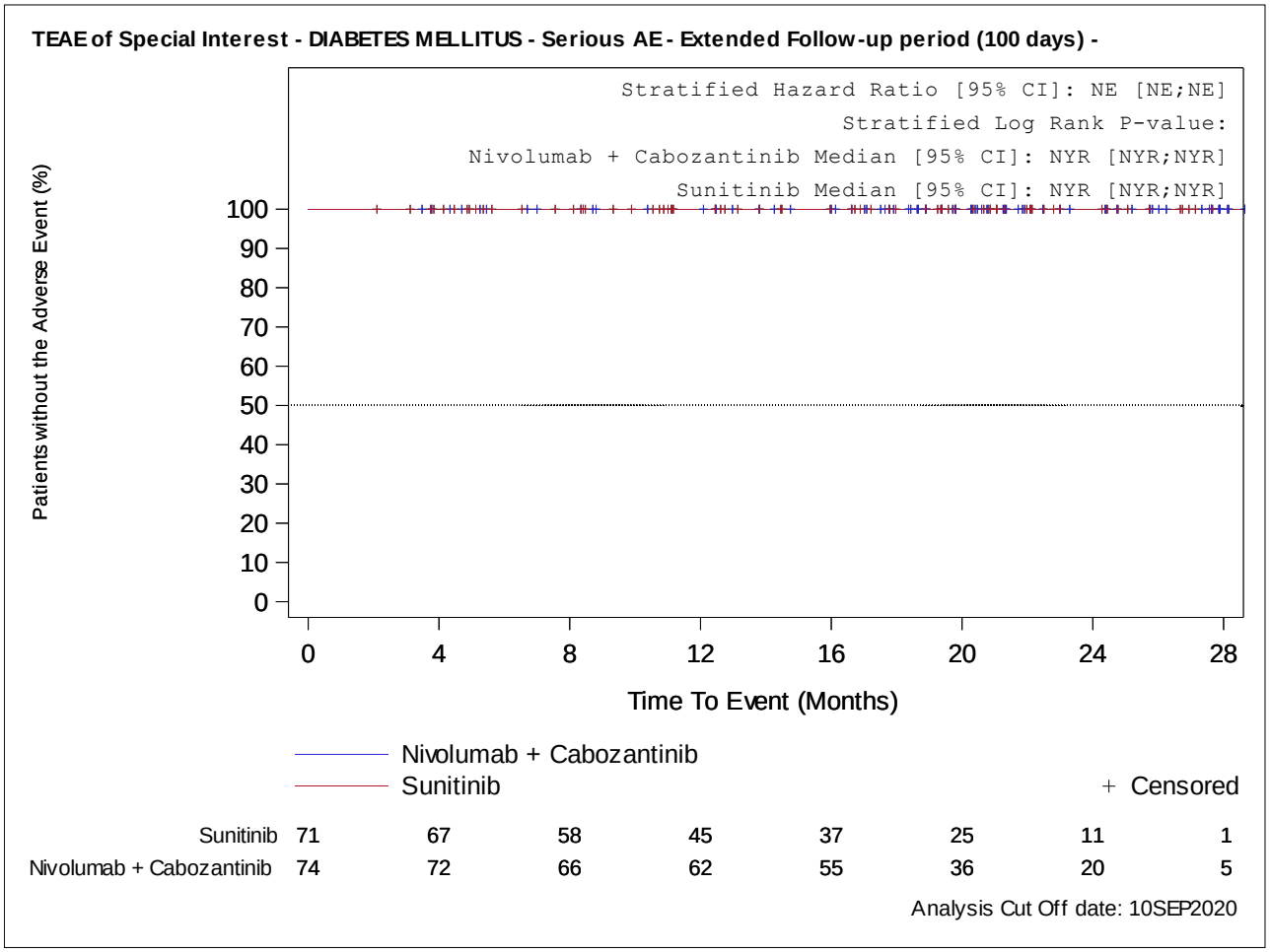

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:06:22

FIGURE 3.69.2.24: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



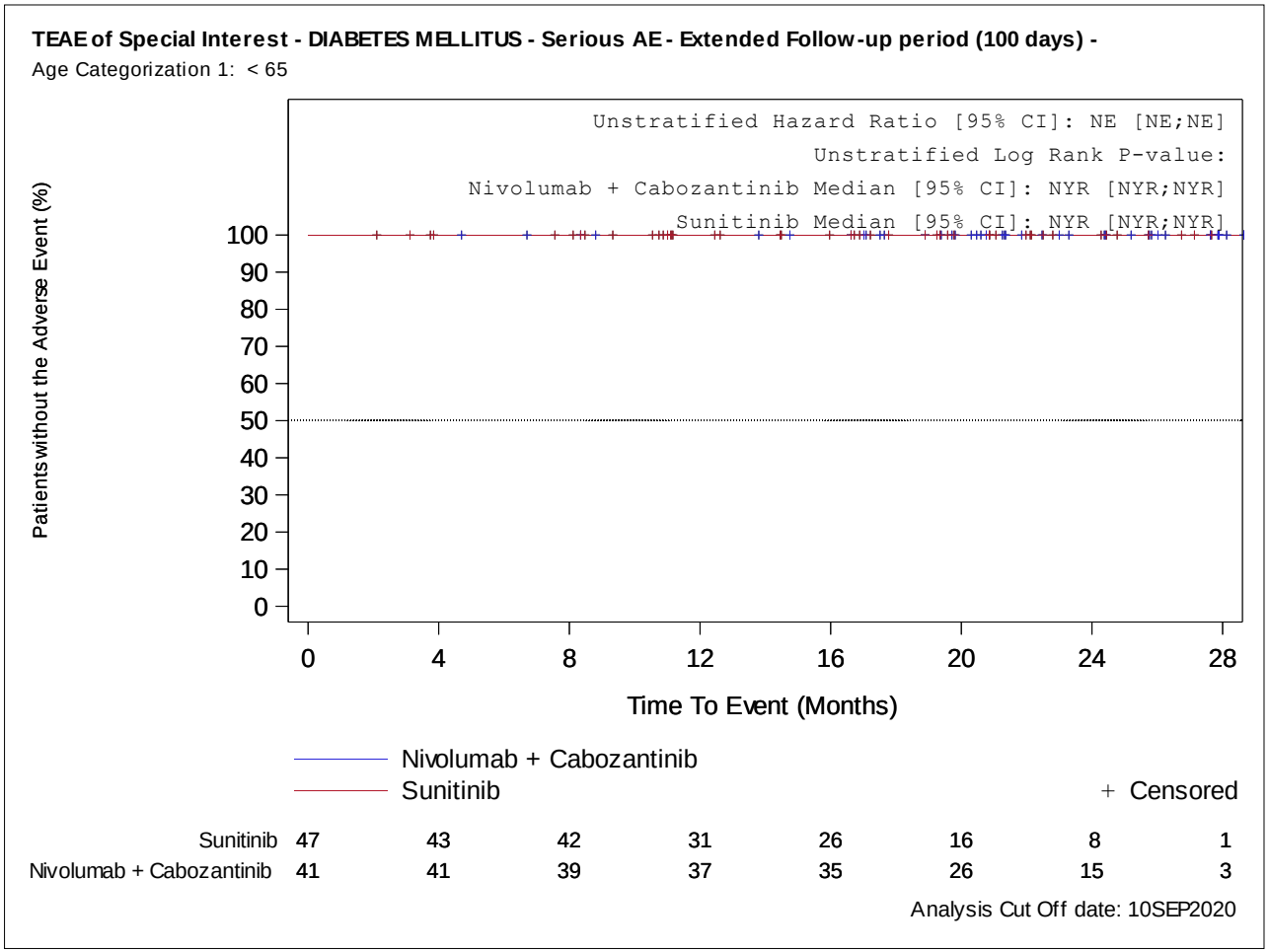

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:06:28

FIGURE 3.70.1: TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:09:49

FIGURE 3.70.2.1: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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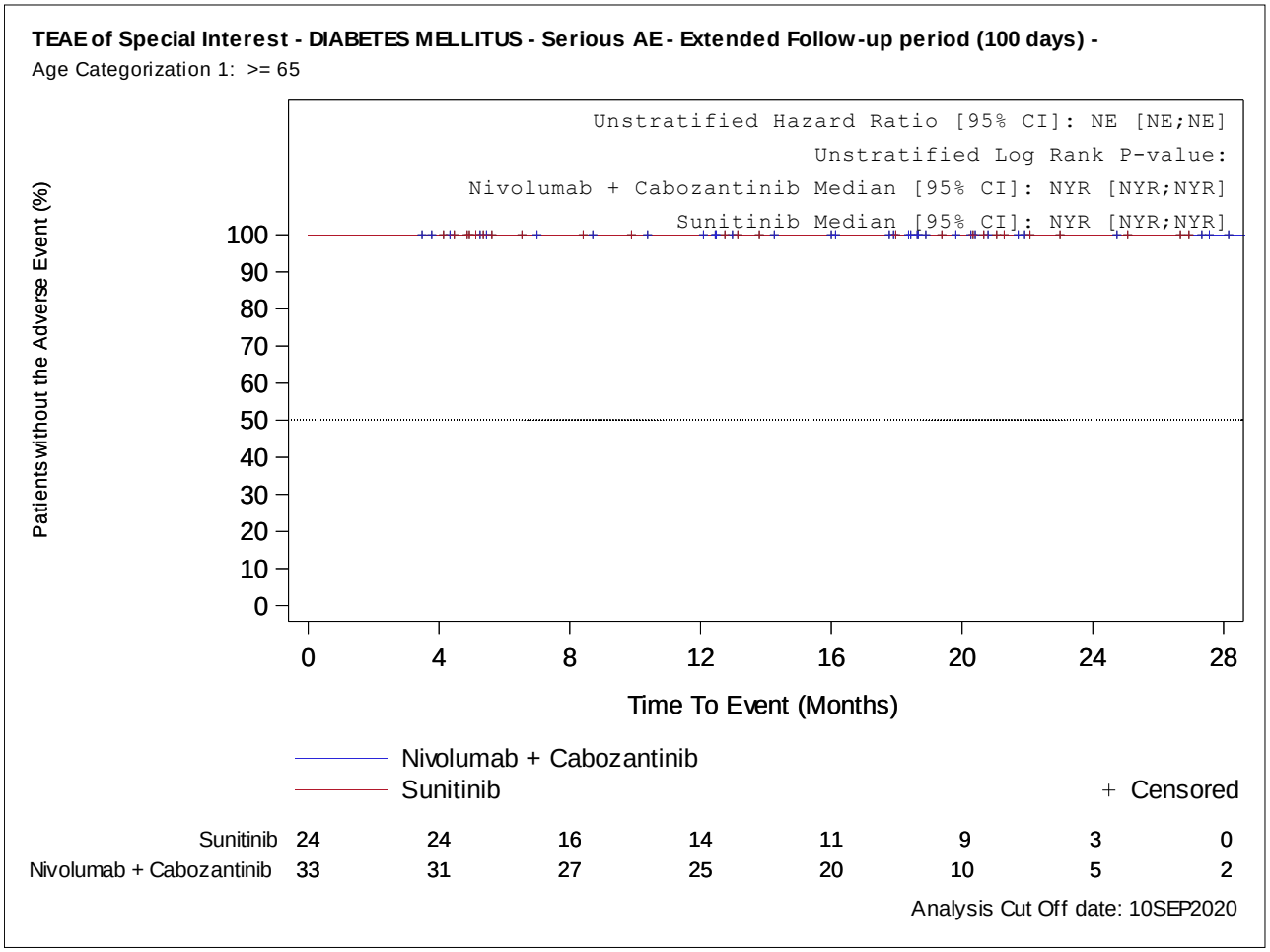
FIGURE 3.70.2.2: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
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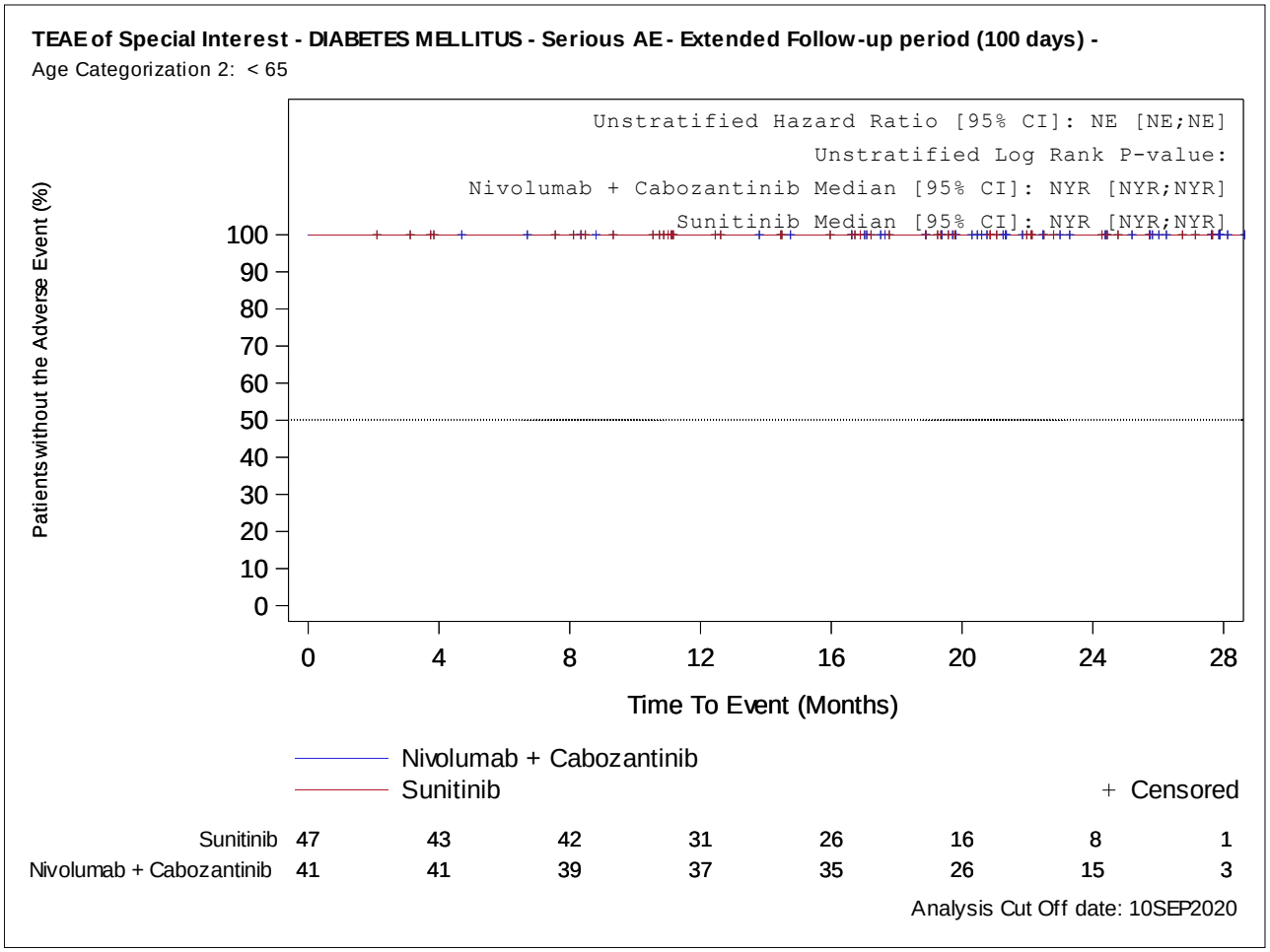
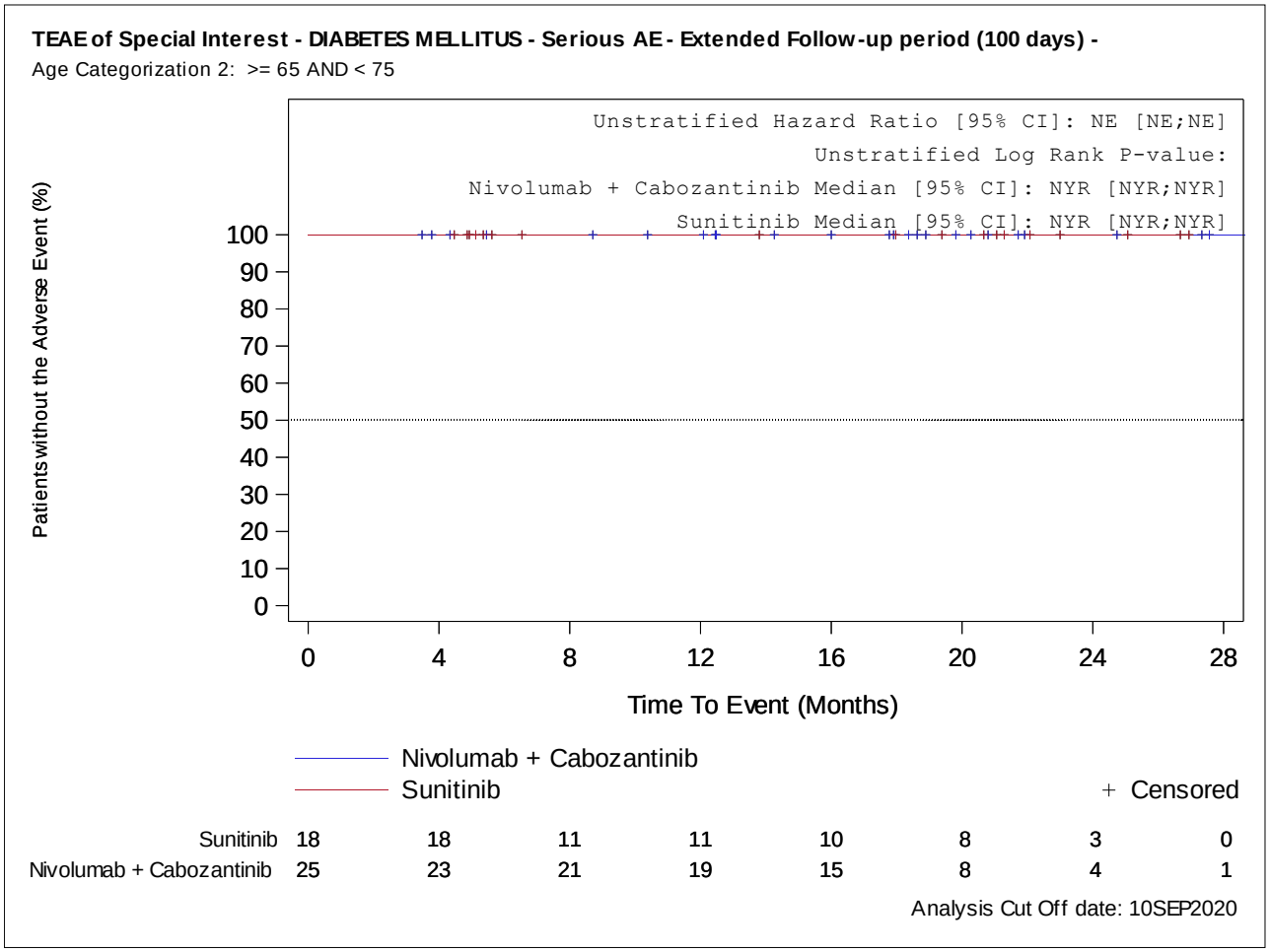
FIGURE 3.70.2.3: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:10:03

FIGURE 3.70.2.4: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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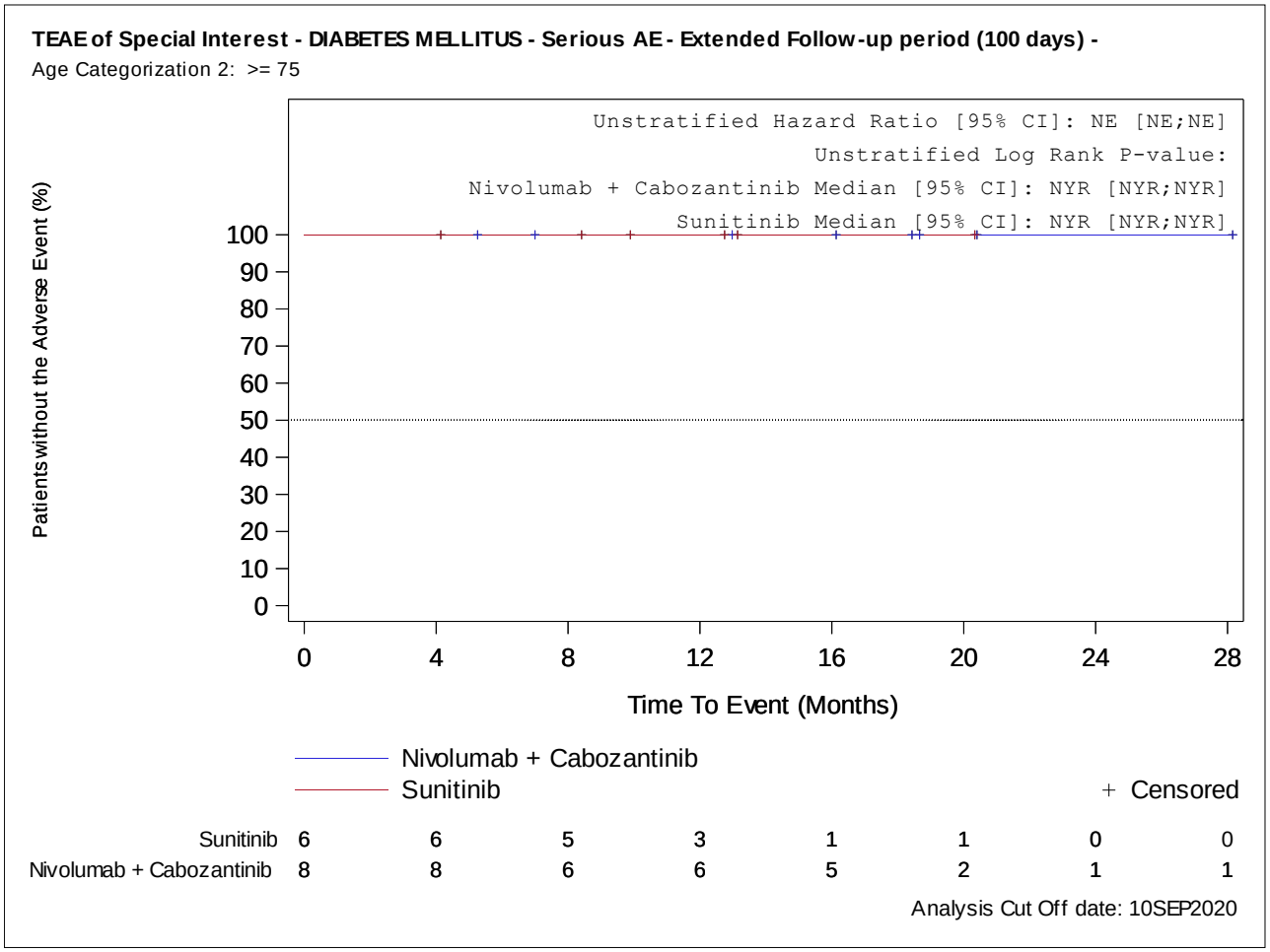
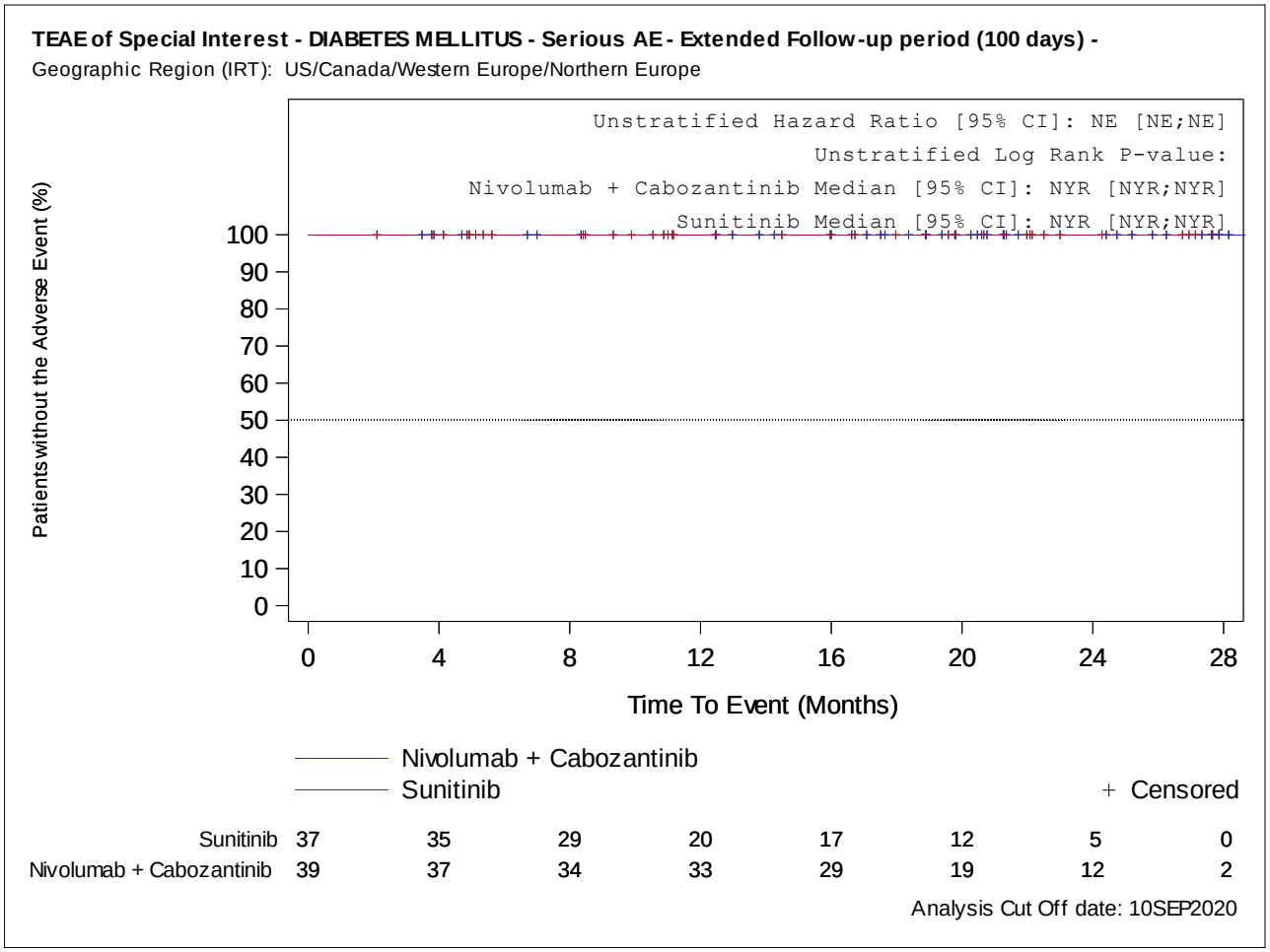
FIGURE 3.70.2.5: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



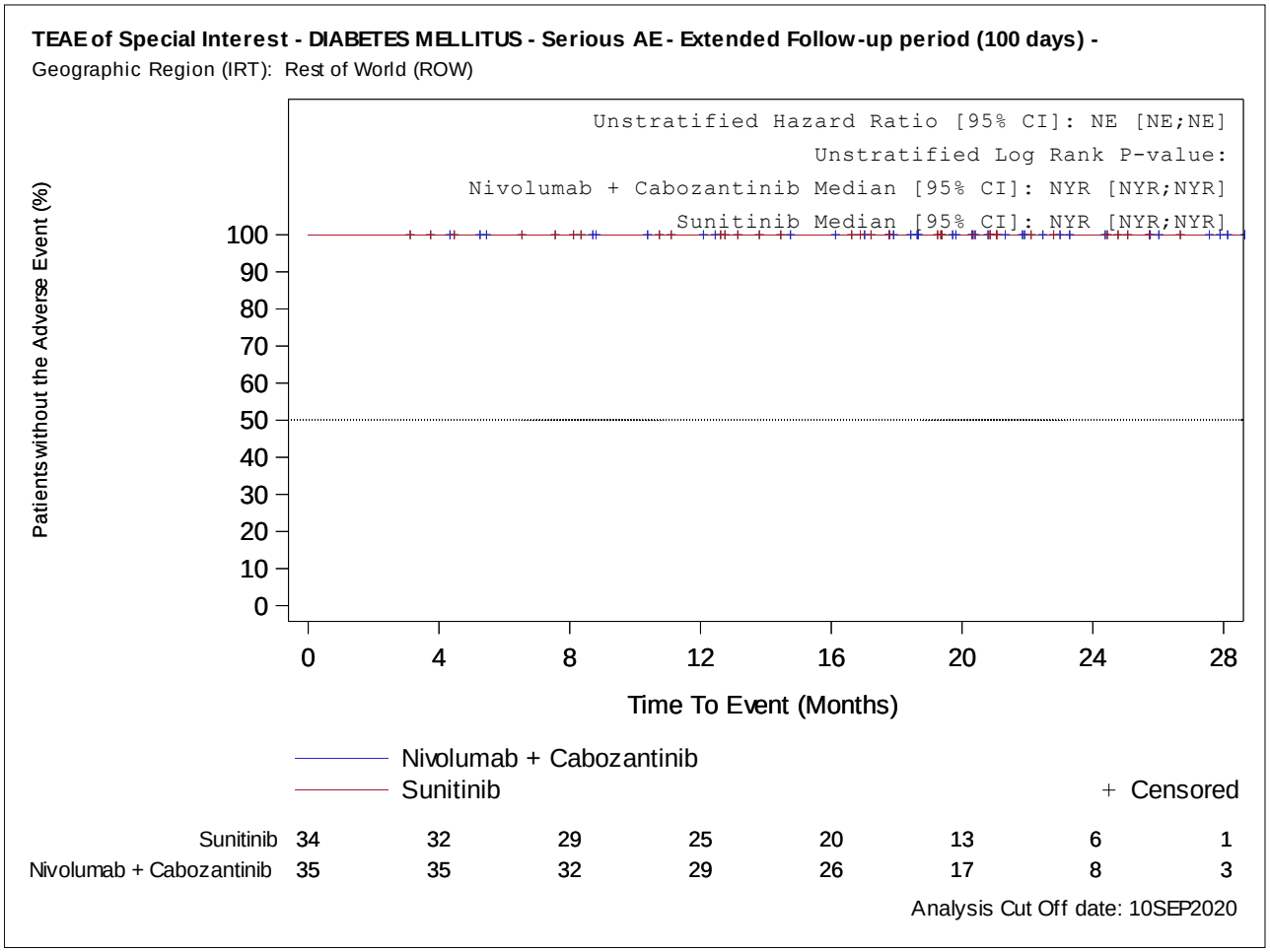

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:10:15

FIGURE 3.70.2.6: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



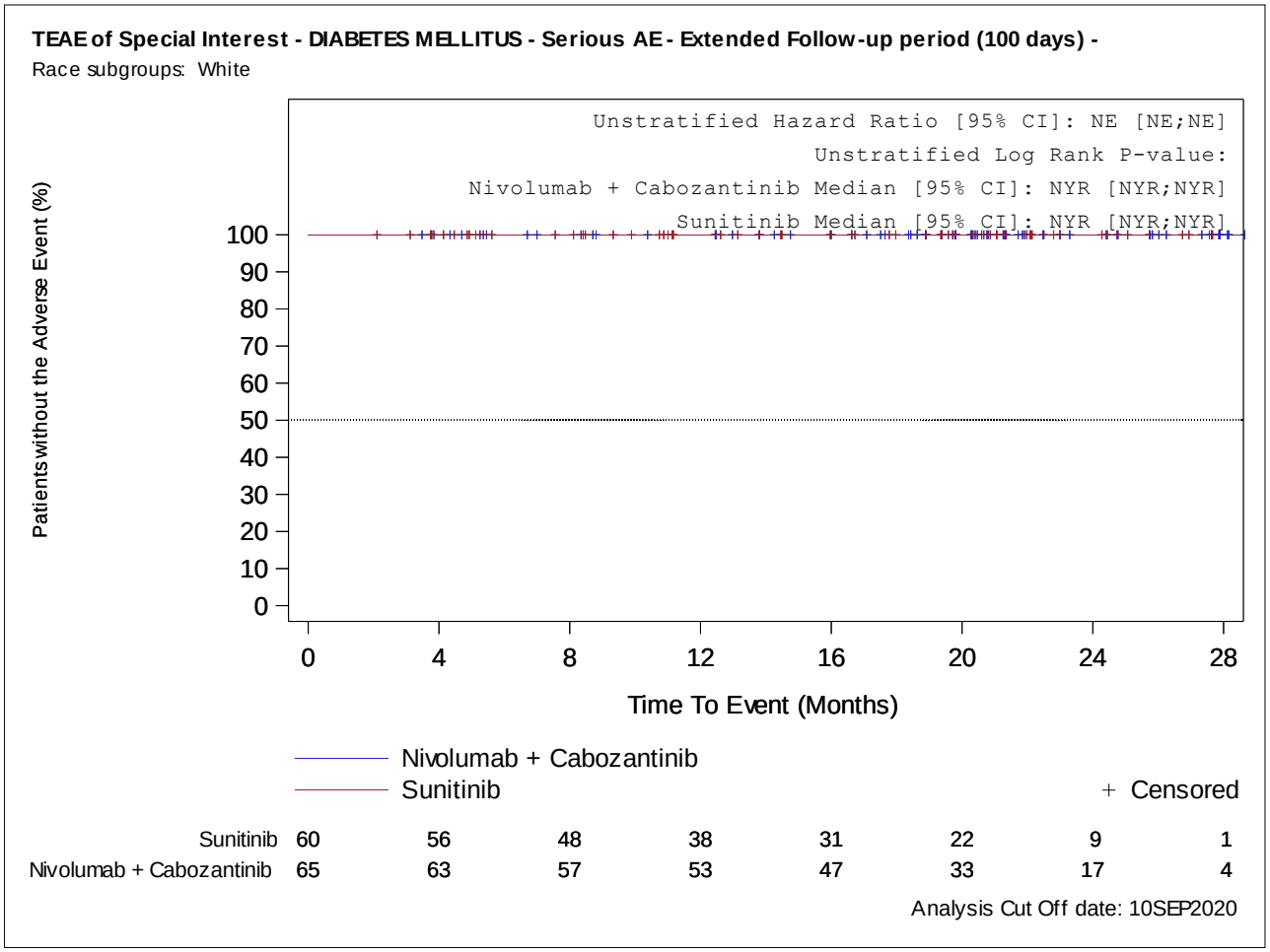

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:10:20

FIGURE 3.70.2.7: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



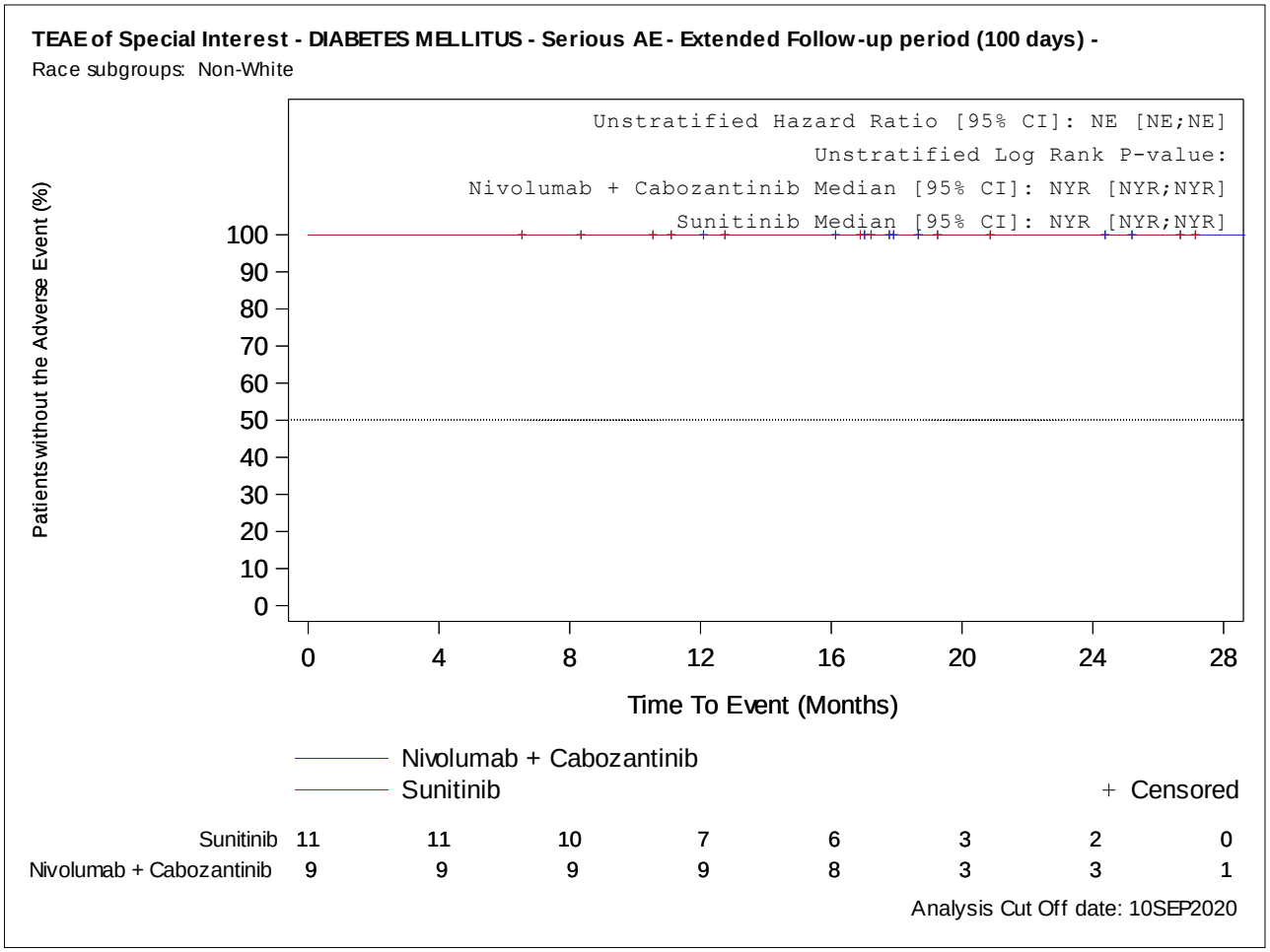

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:10:26

FIGURE 3.70.2.8: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



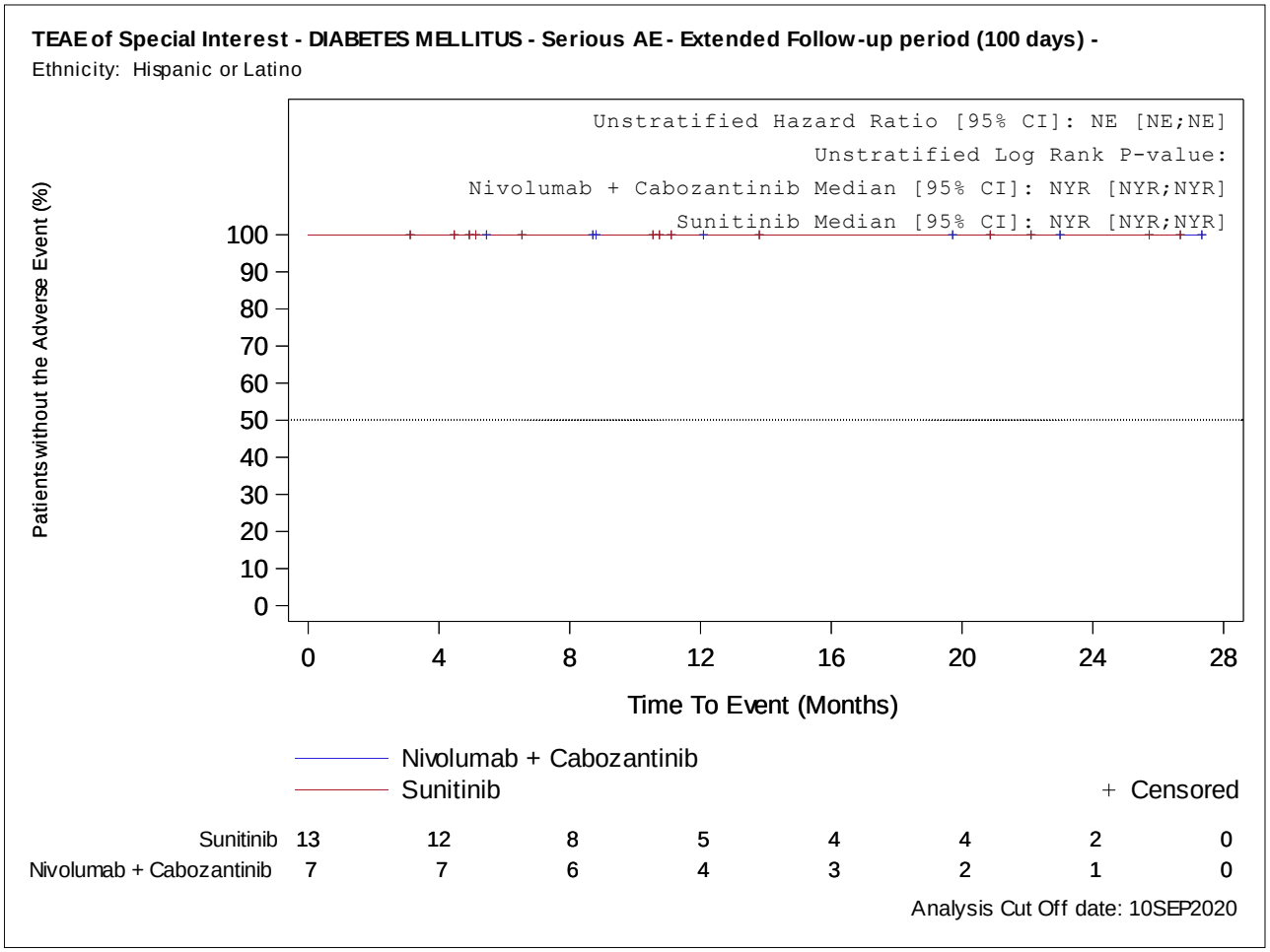

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:10:32

FIGURE 3.70.2.9: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:10:37

FIGURE 3.70.2.10: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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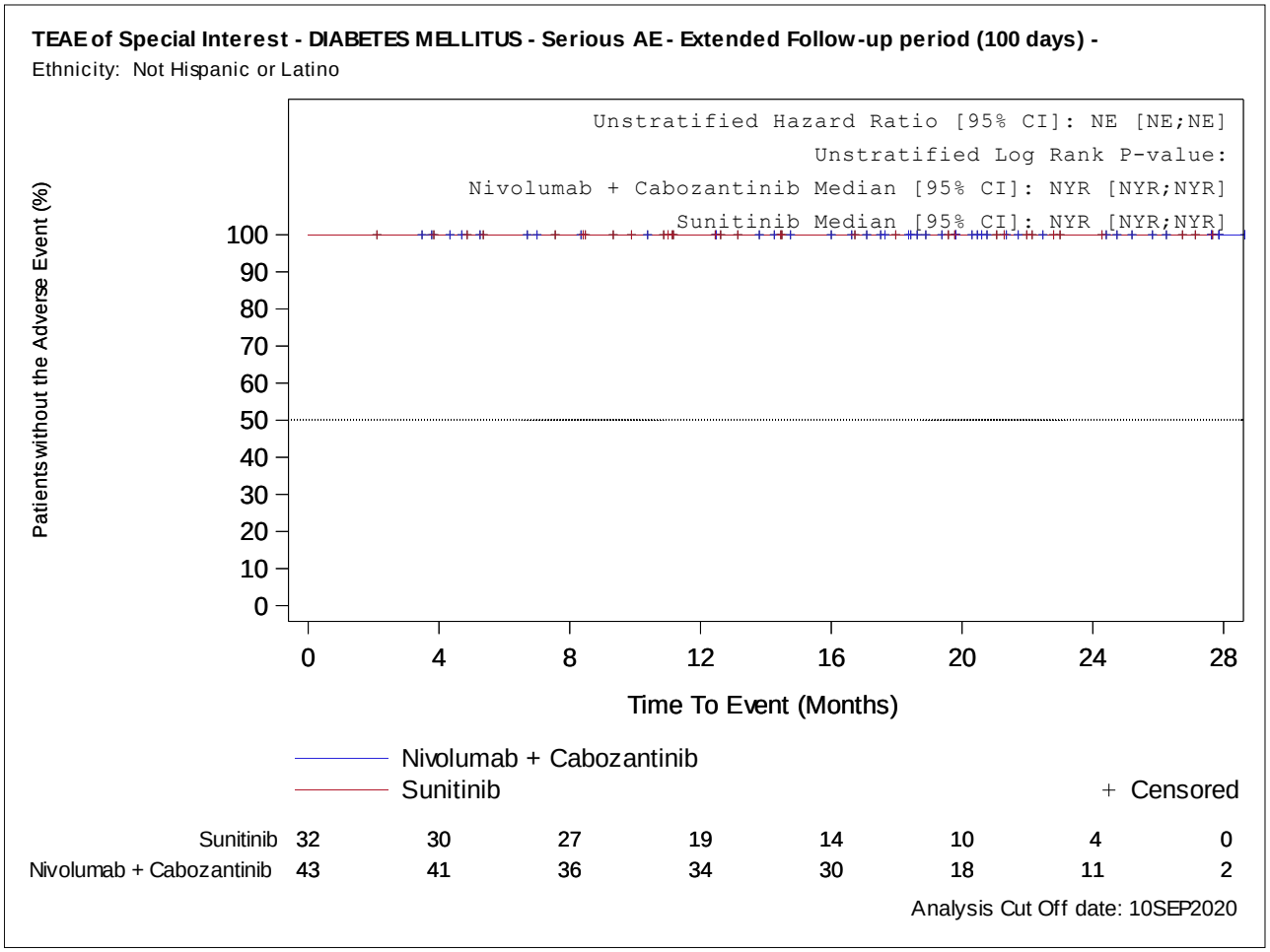
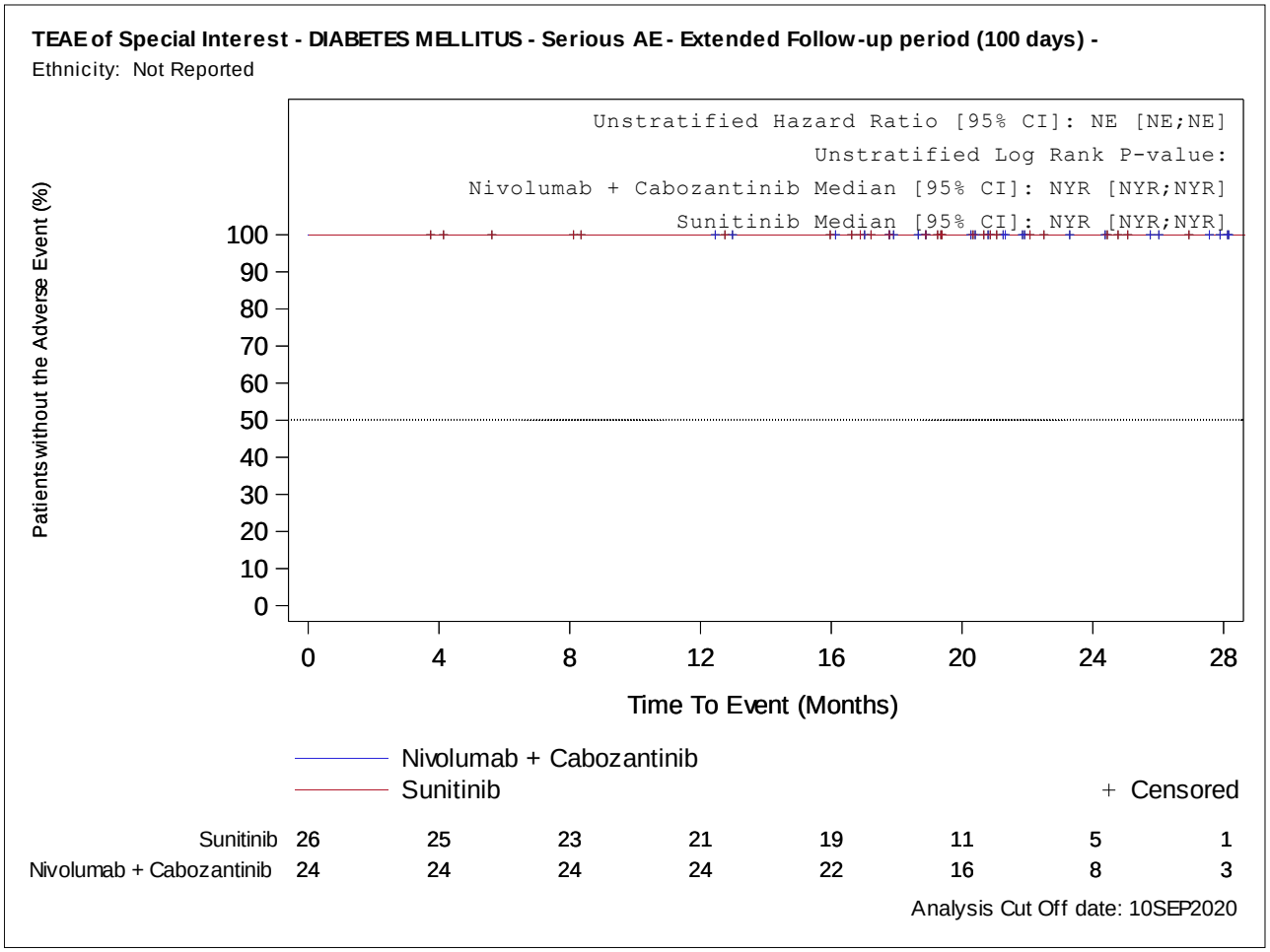
FIGURE 3.70.2.11: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



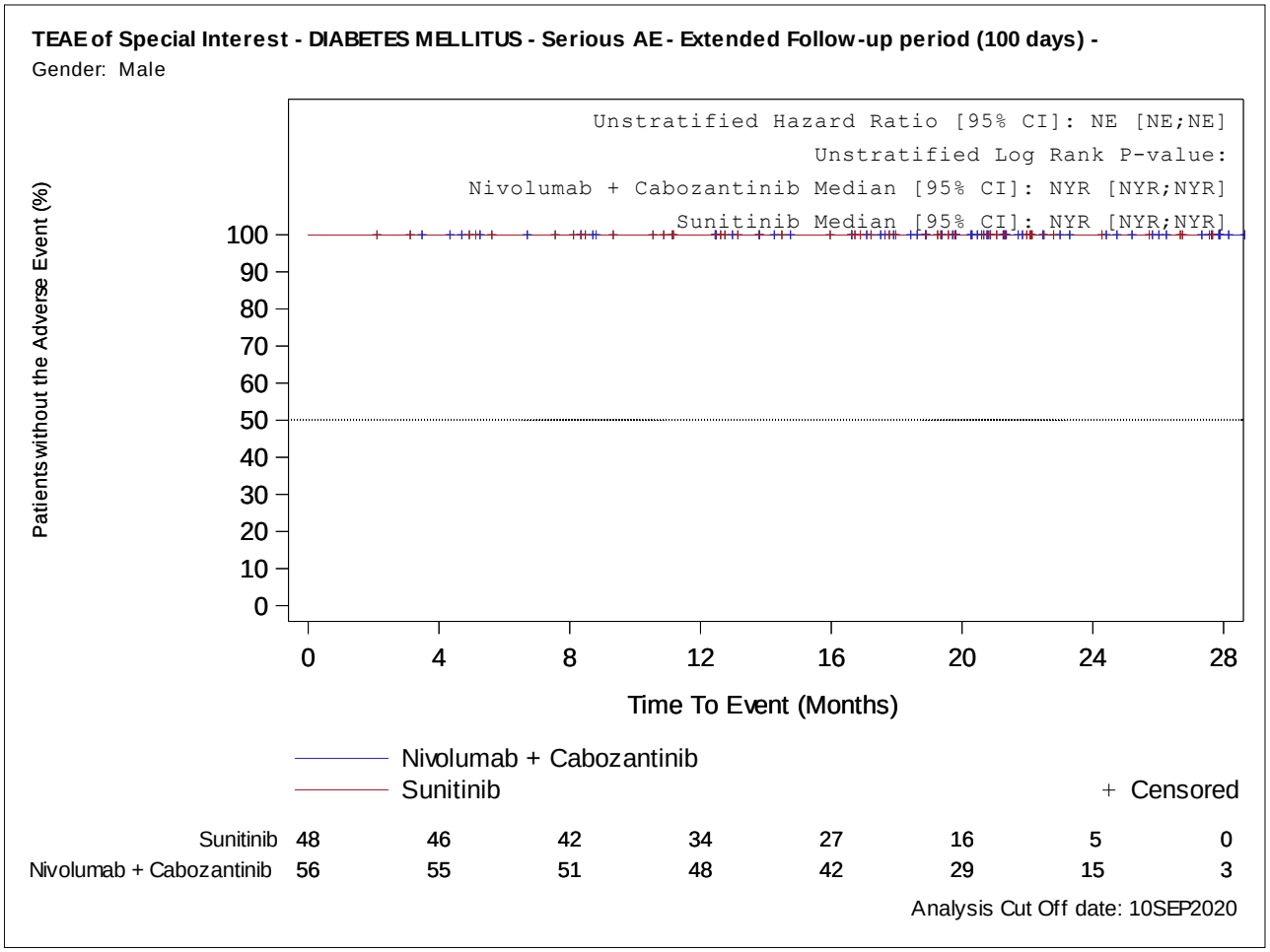

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:10:49

FIGURE 3.70.2.12: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:10:55

FIGURE 3.70.2.13: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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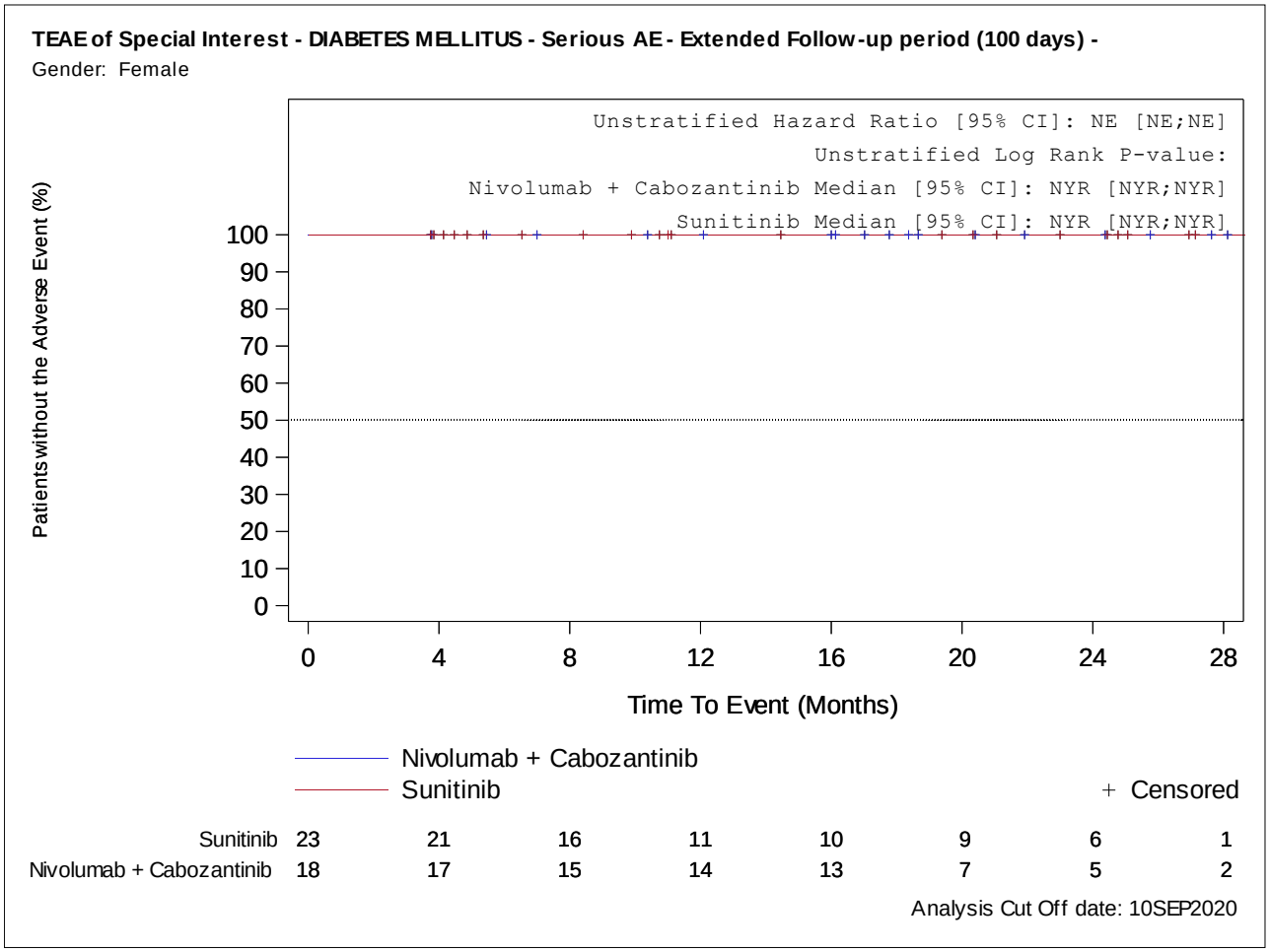
FIGURE 3.70.2.14: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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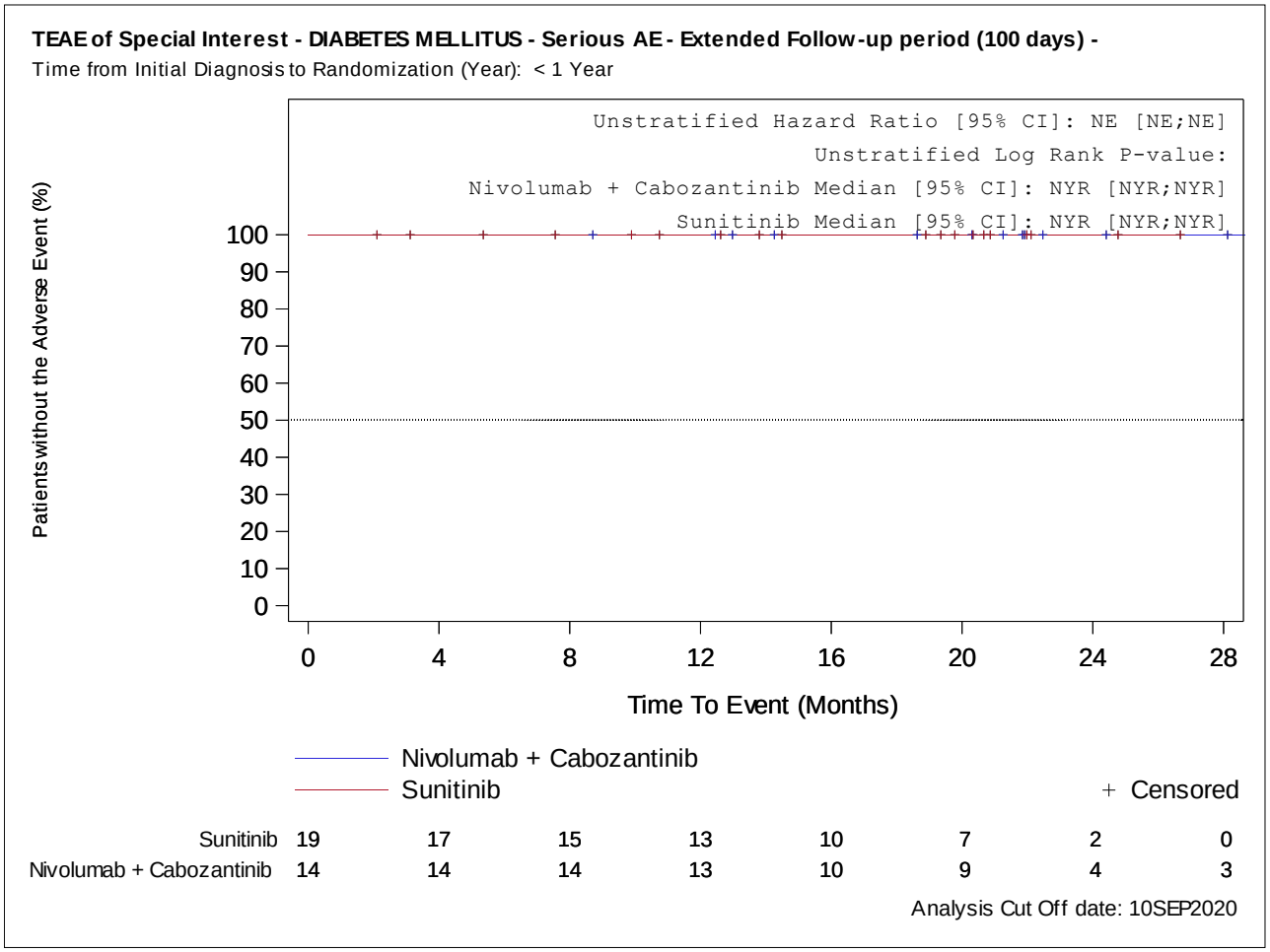
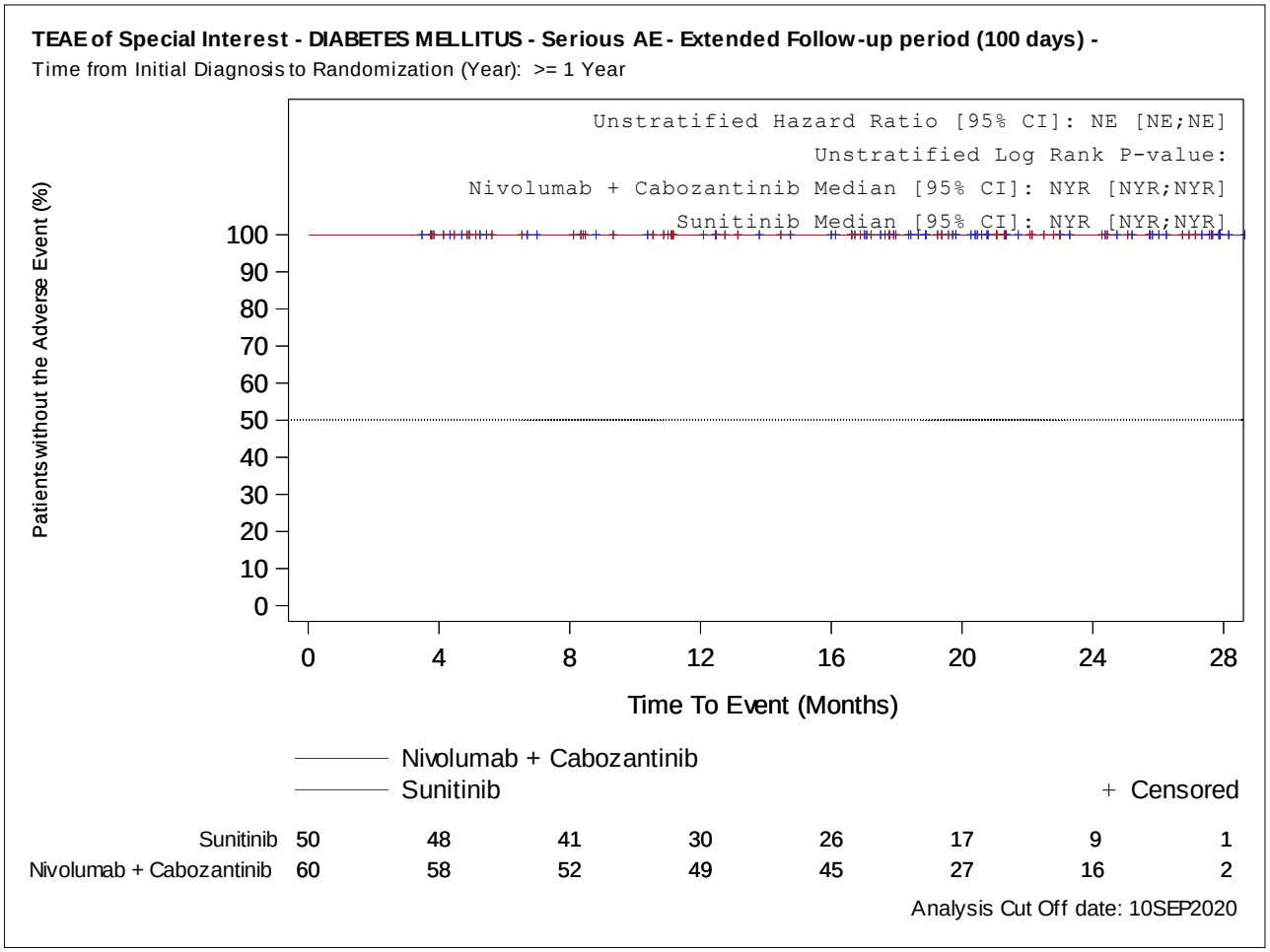
FIGURE 3.70.2.15: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



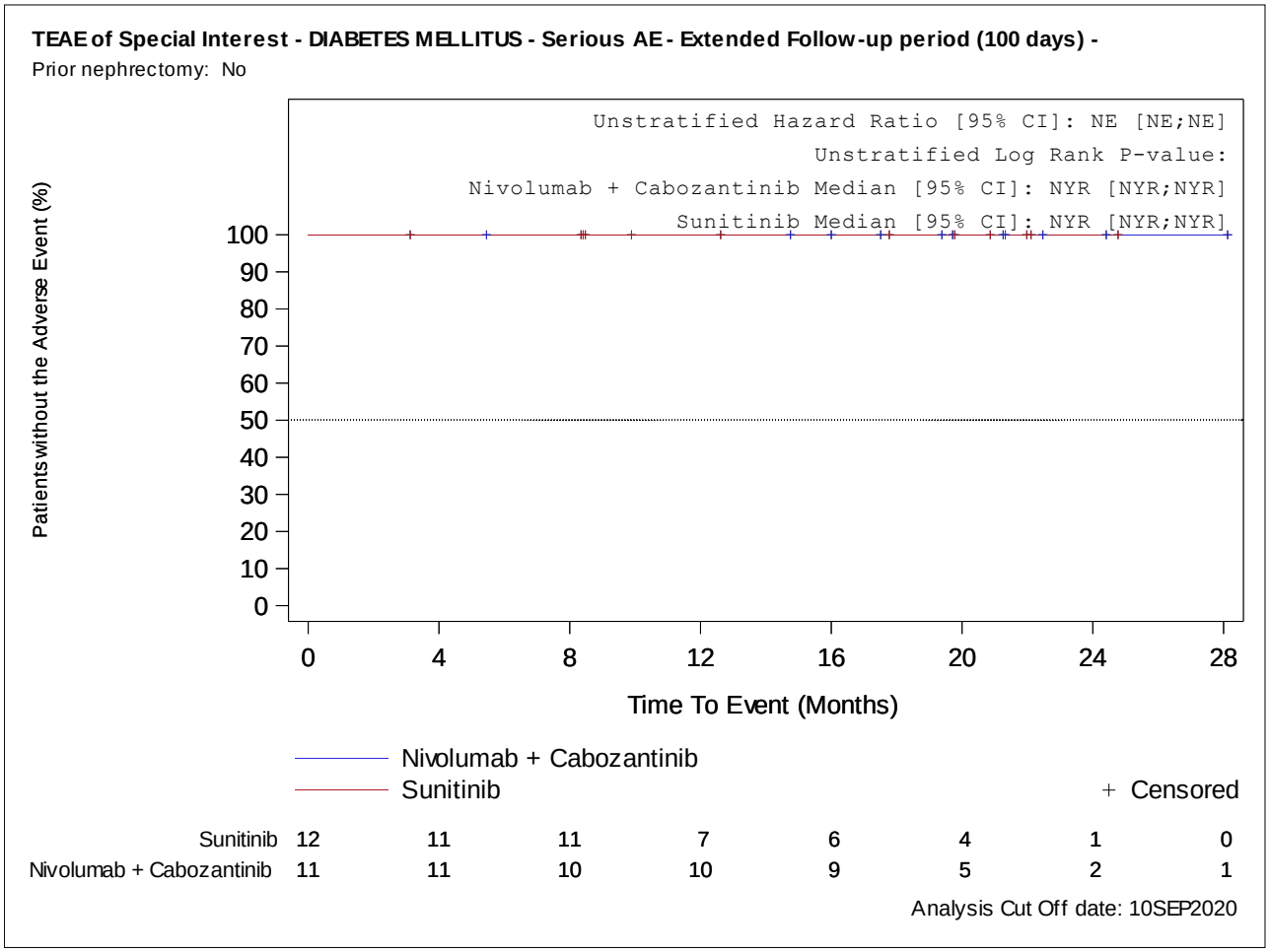

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:11:24

FIGURE 3.70.2.16: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



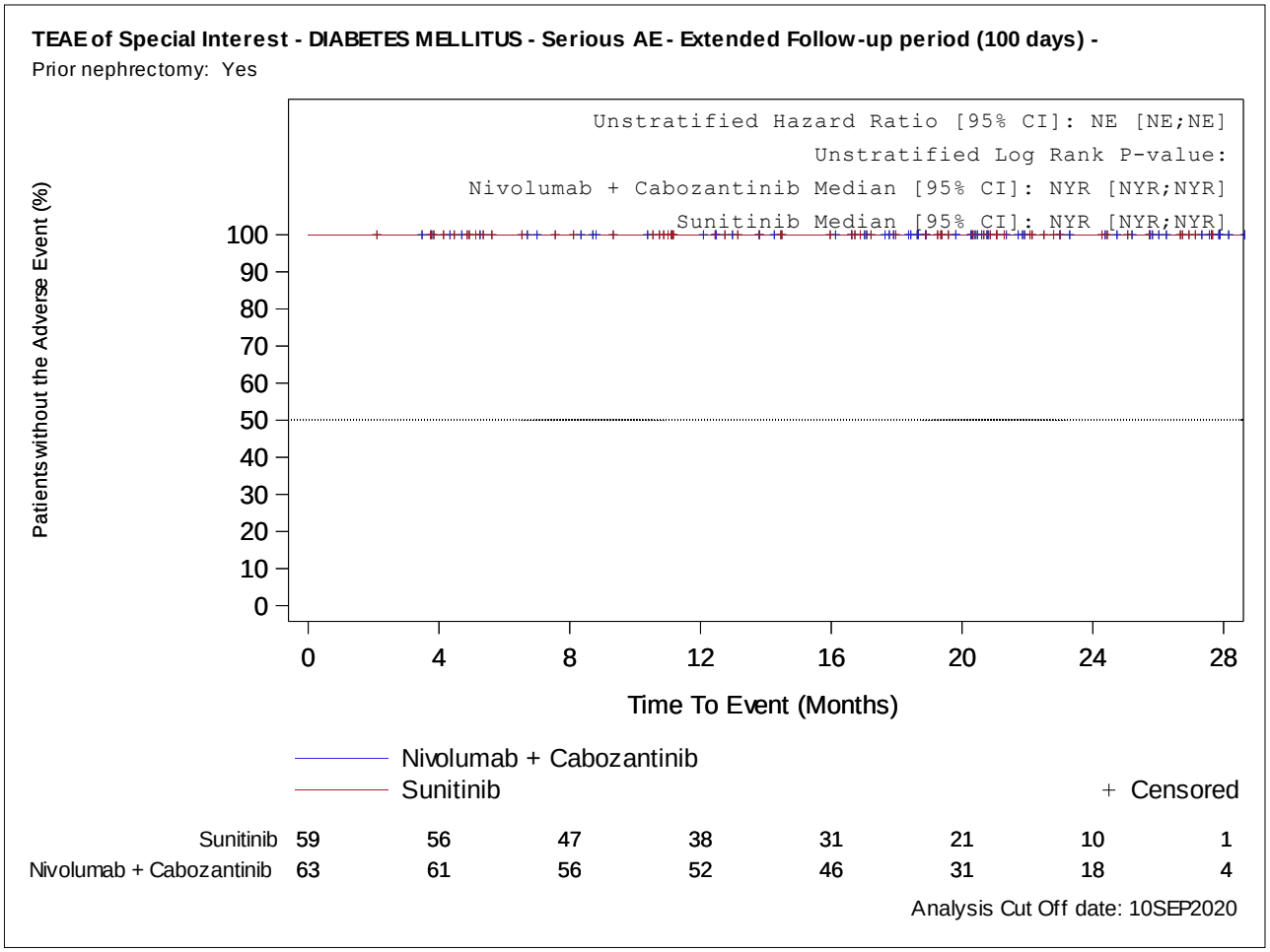

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:11:30

FIGURE 3.70.2.17: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



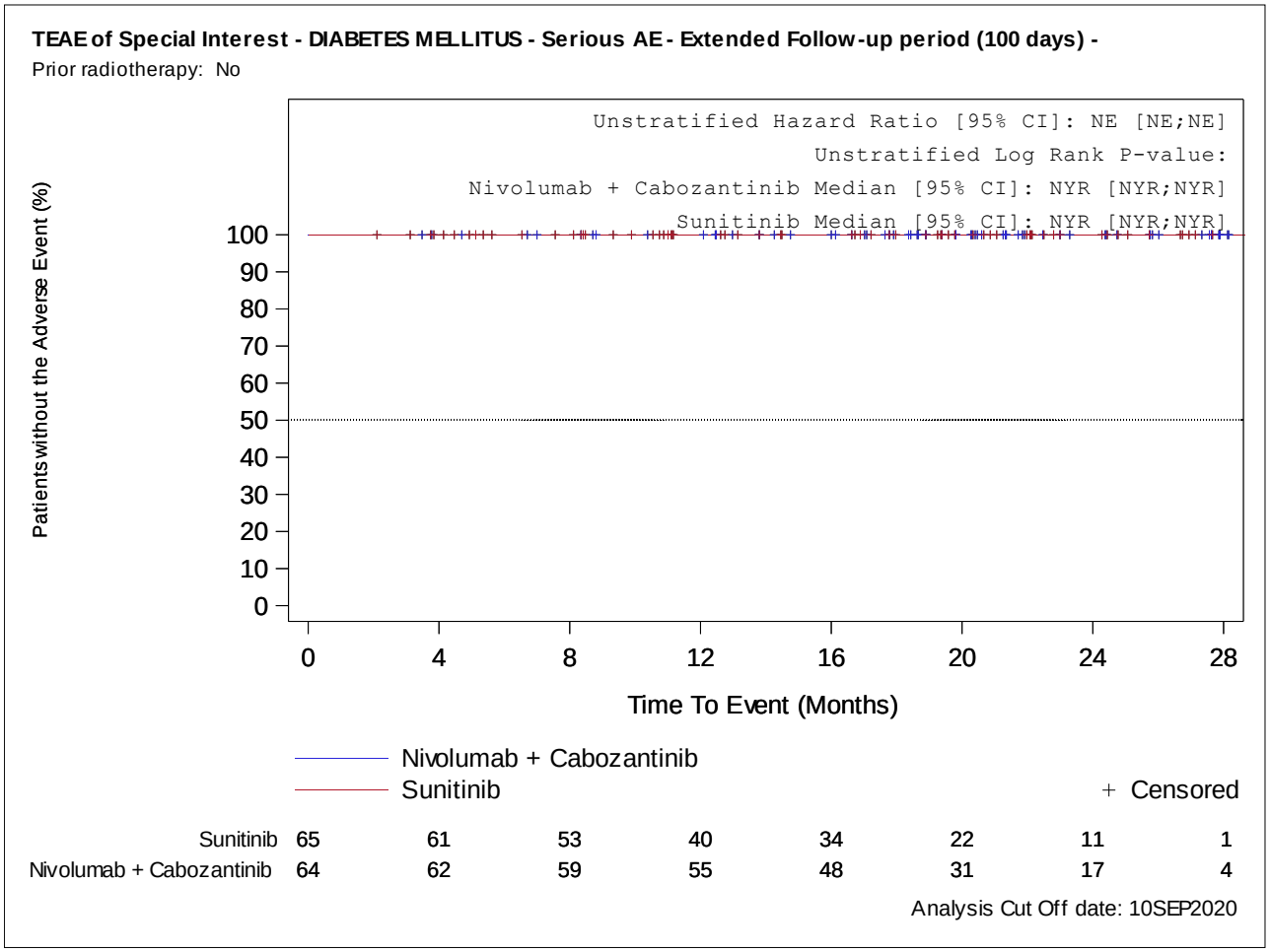

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:12:22

FIGURE 3.70.2.18: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:12:28

FIGURE 3.70.2.19: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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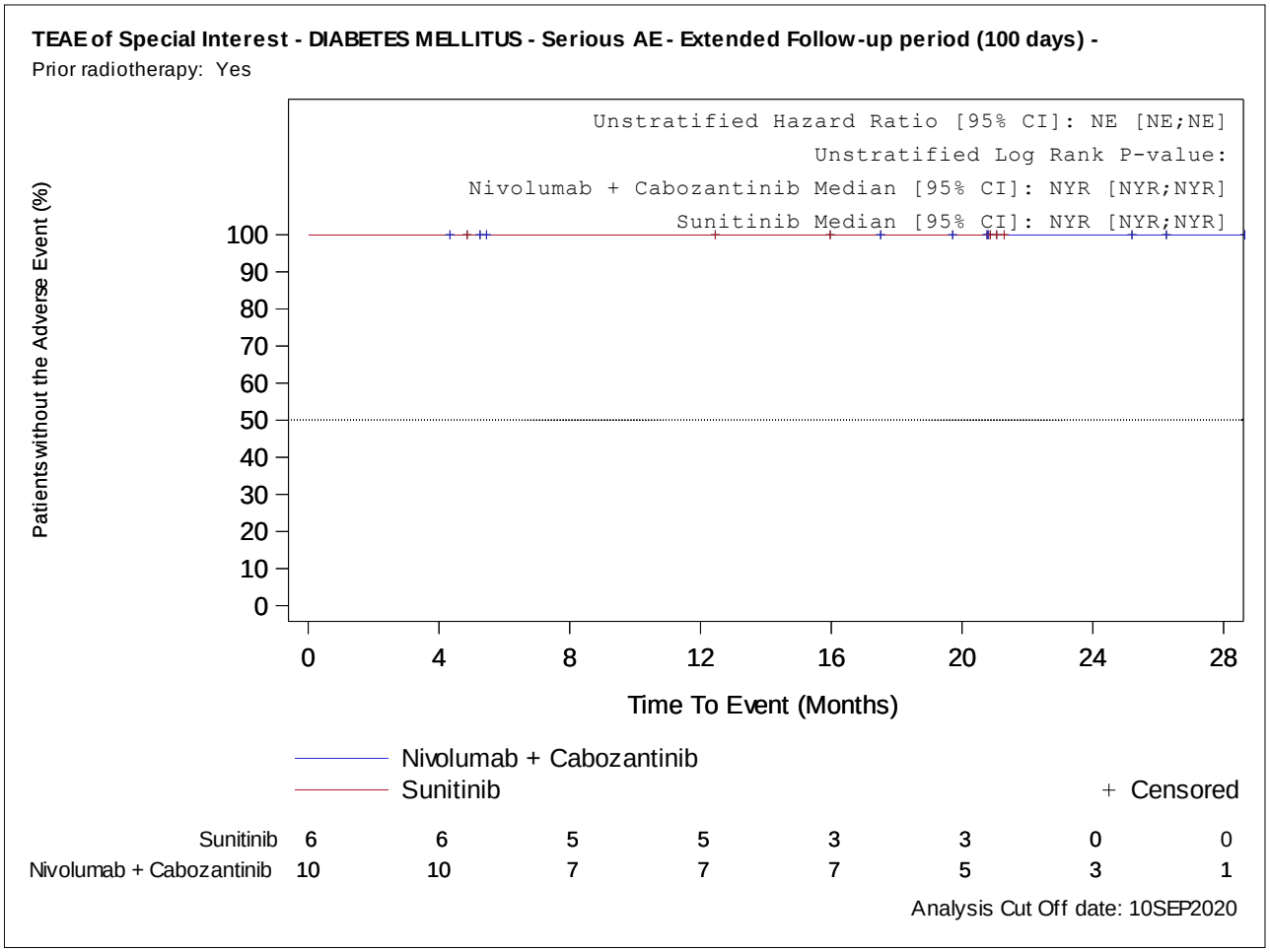
FIGURE 3.70.2.20: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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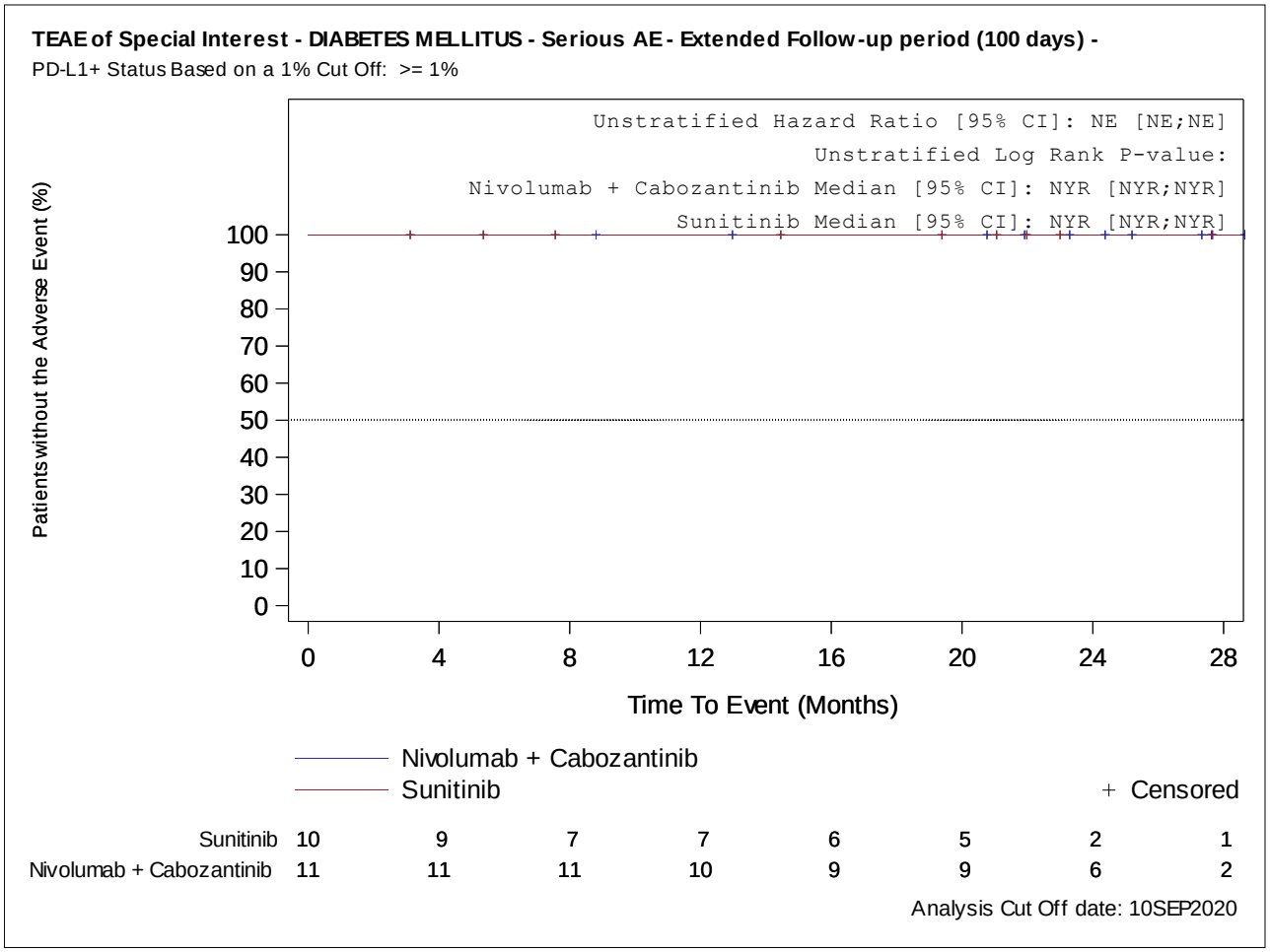
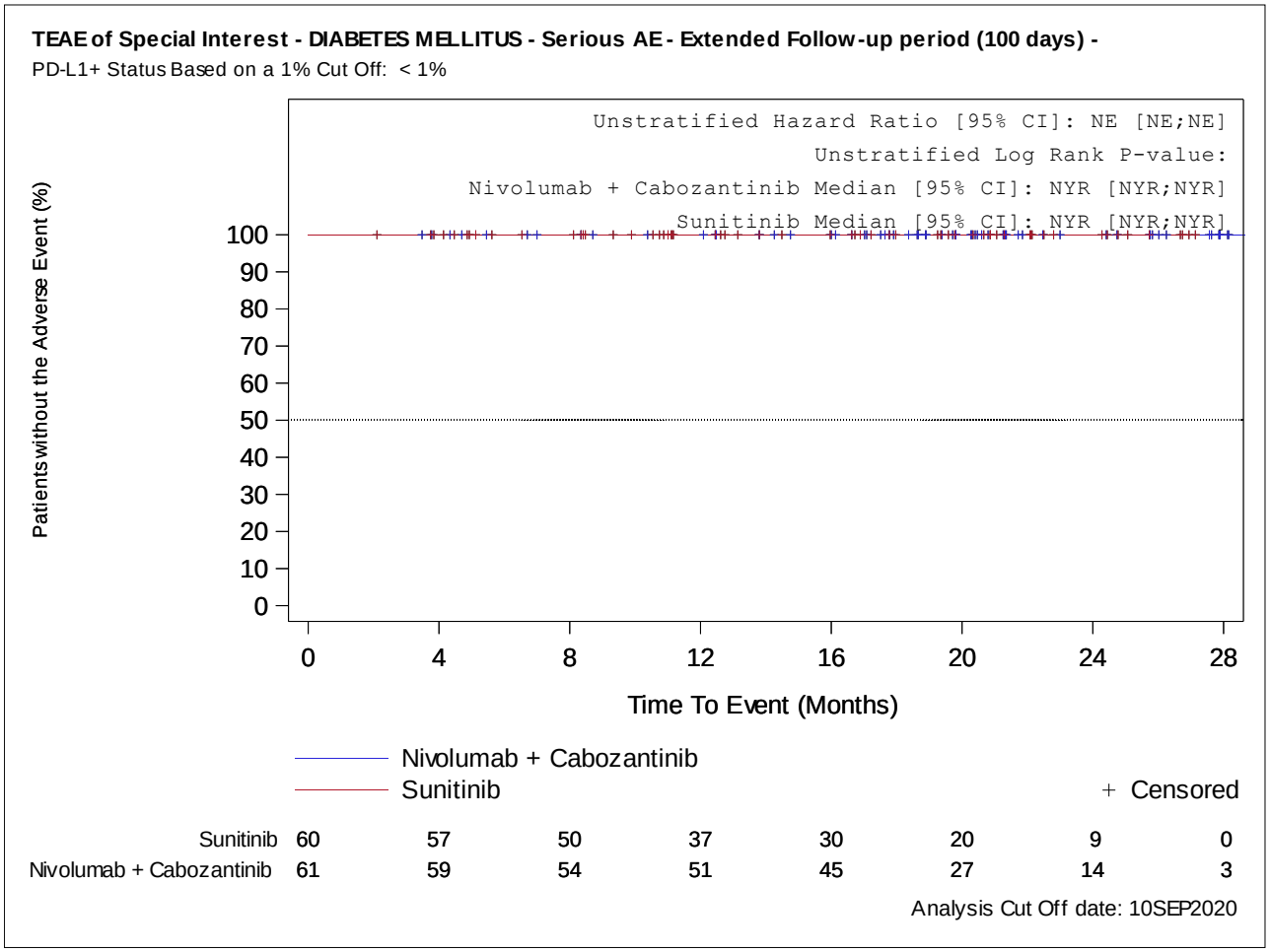
FIGURE 3.70.2.21: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



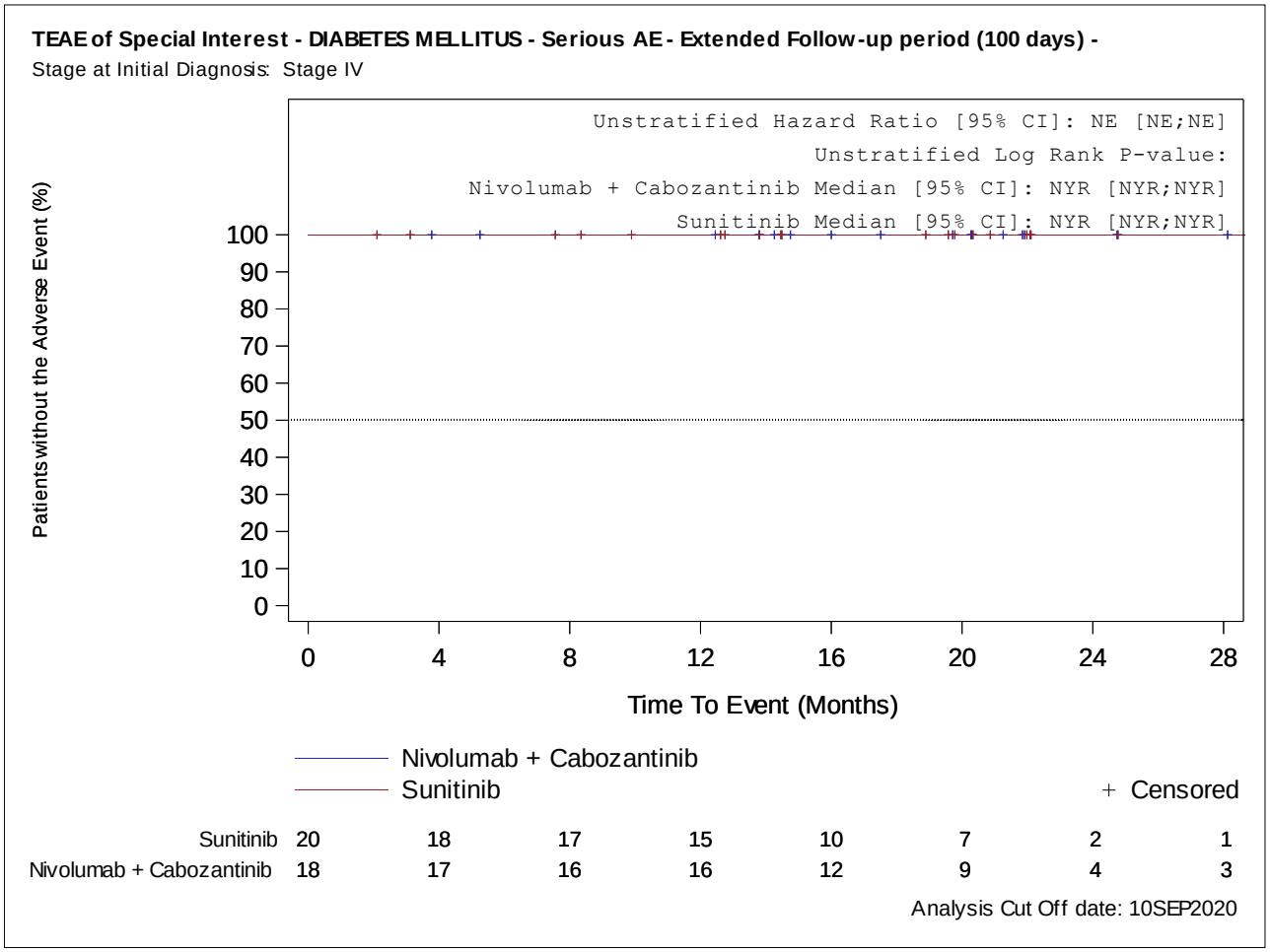

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:12:46

FIGURE 3.70.2.22: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



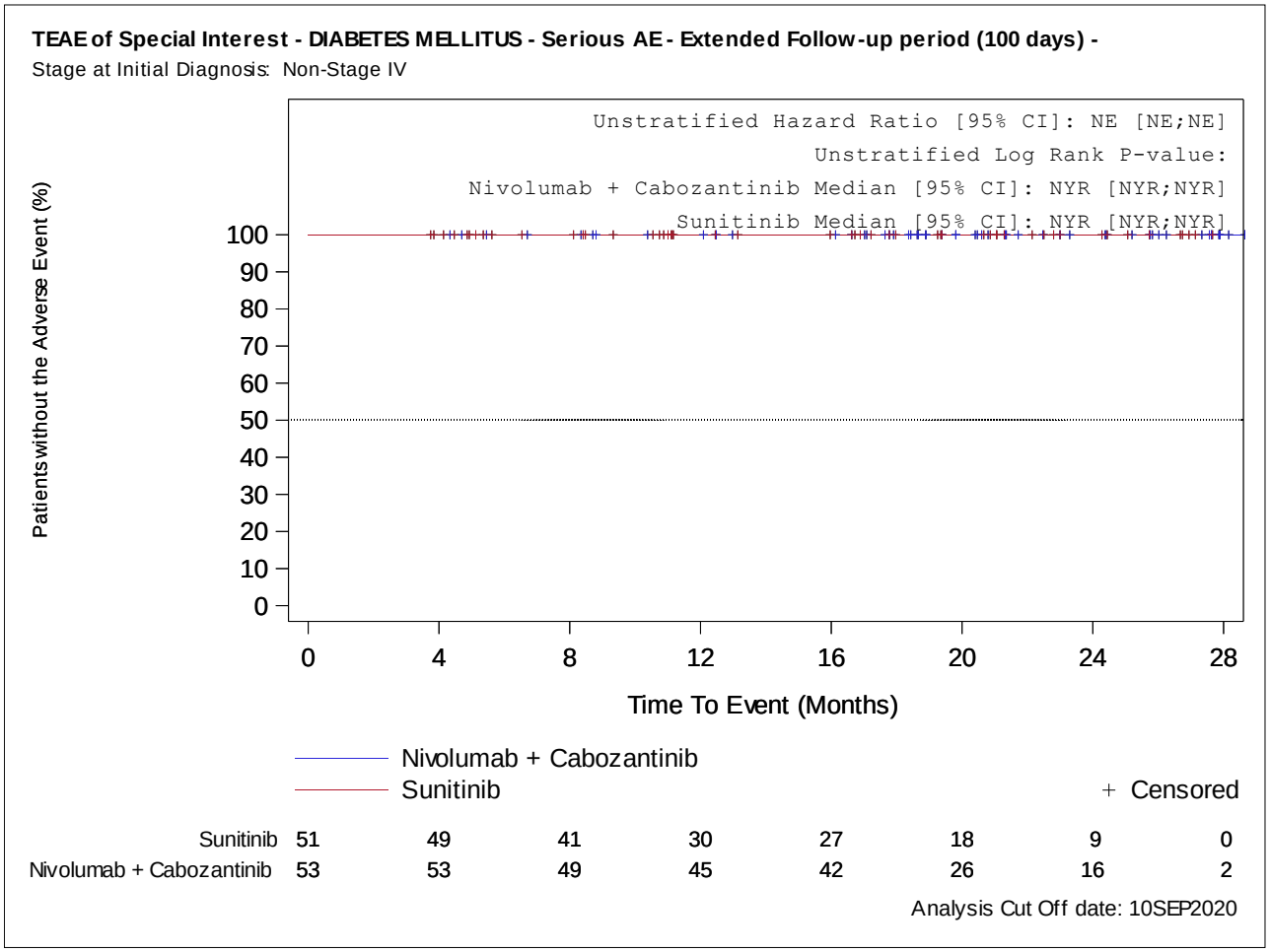

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:12:52

FIGURE 3.70.2.23: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



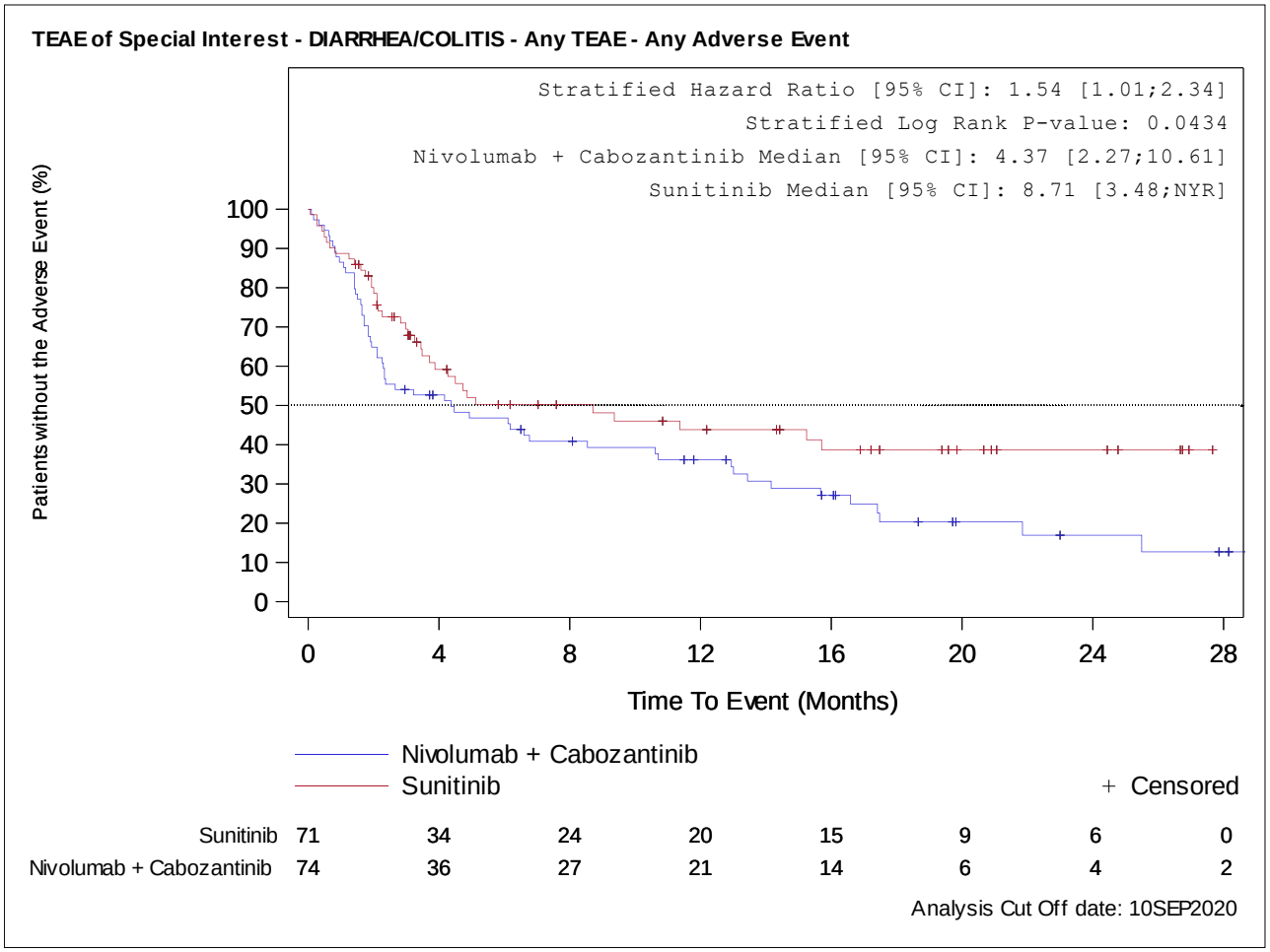

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:13:21

FIGURE 3.70.2.24: Kaplan-Meier curve - TEAE of Special Interest - DIABETES MELLITUS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



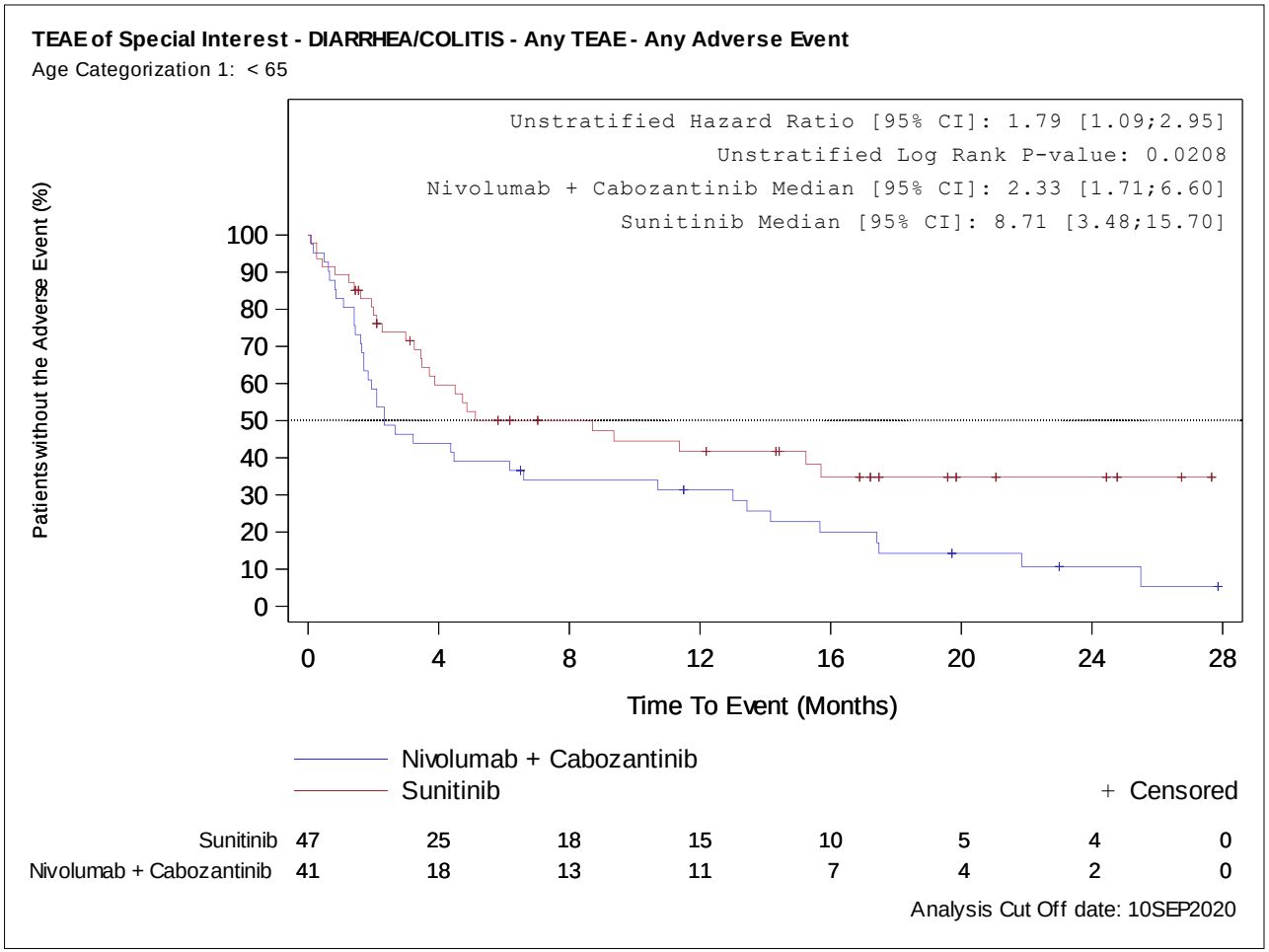

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:13:26

FIGURE 3.71.1: TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



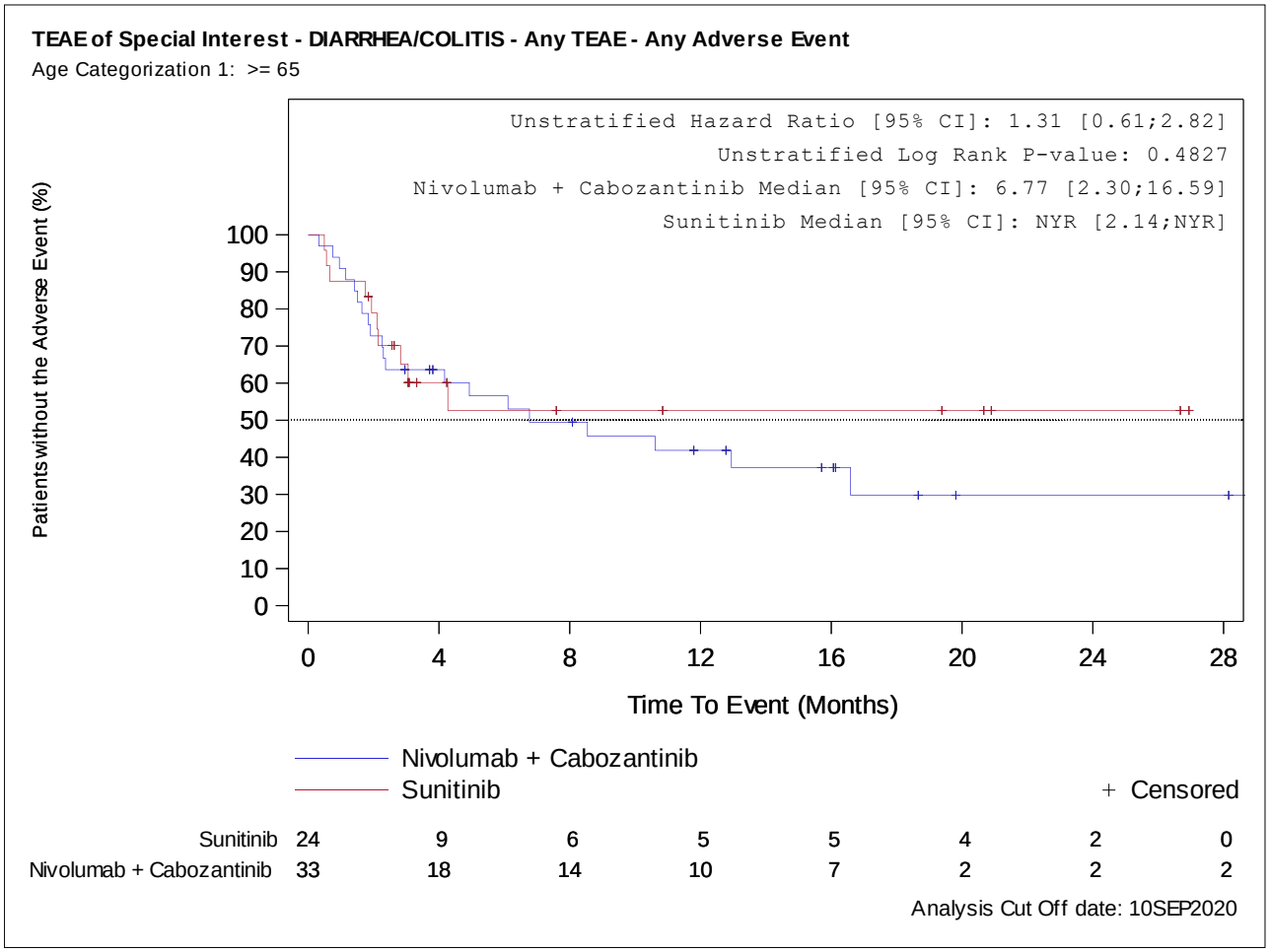

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:16:46

FIGURE 3.71.2.1: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



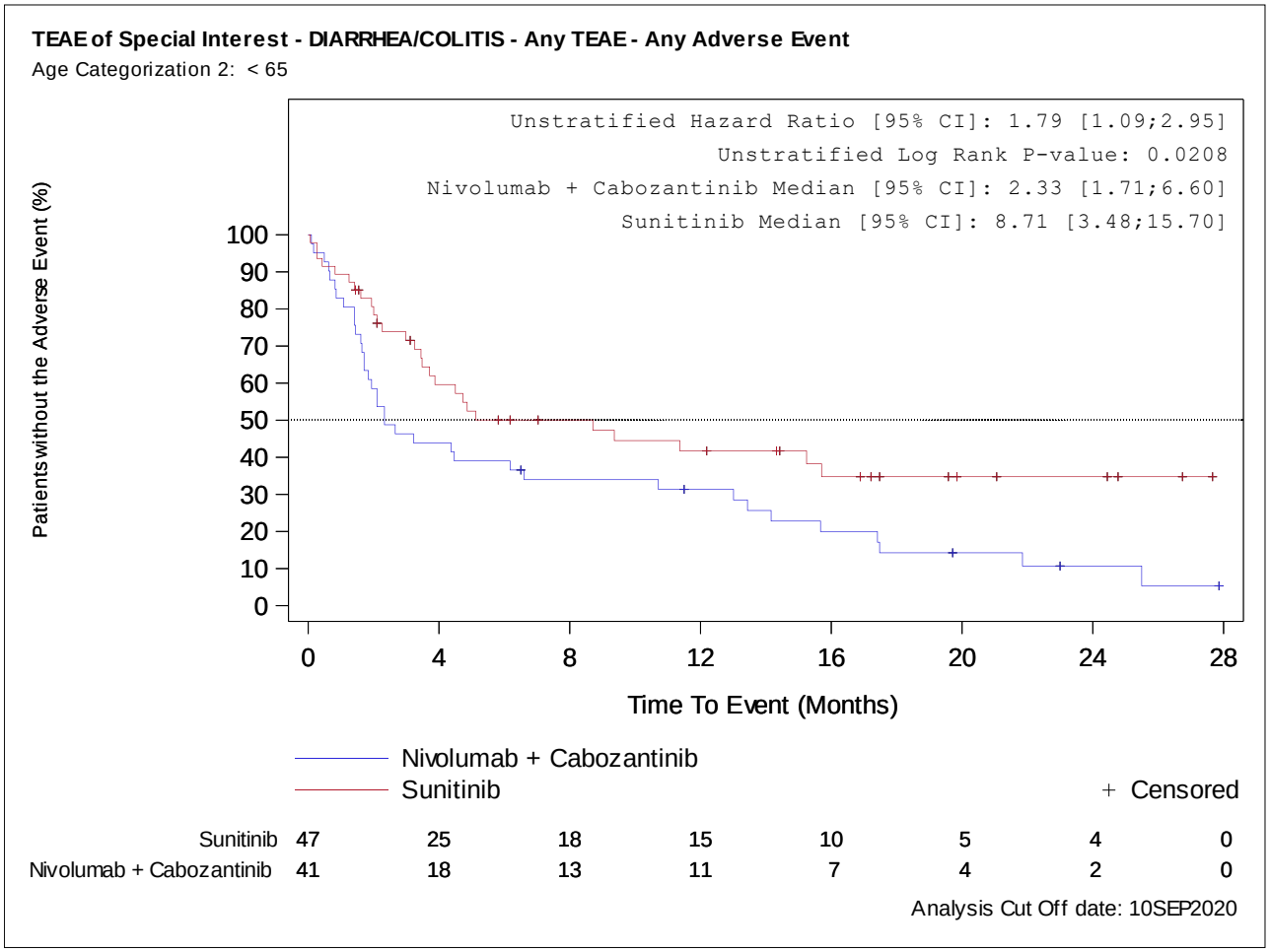

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:16:49

FIGURE 3.71.2.2: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



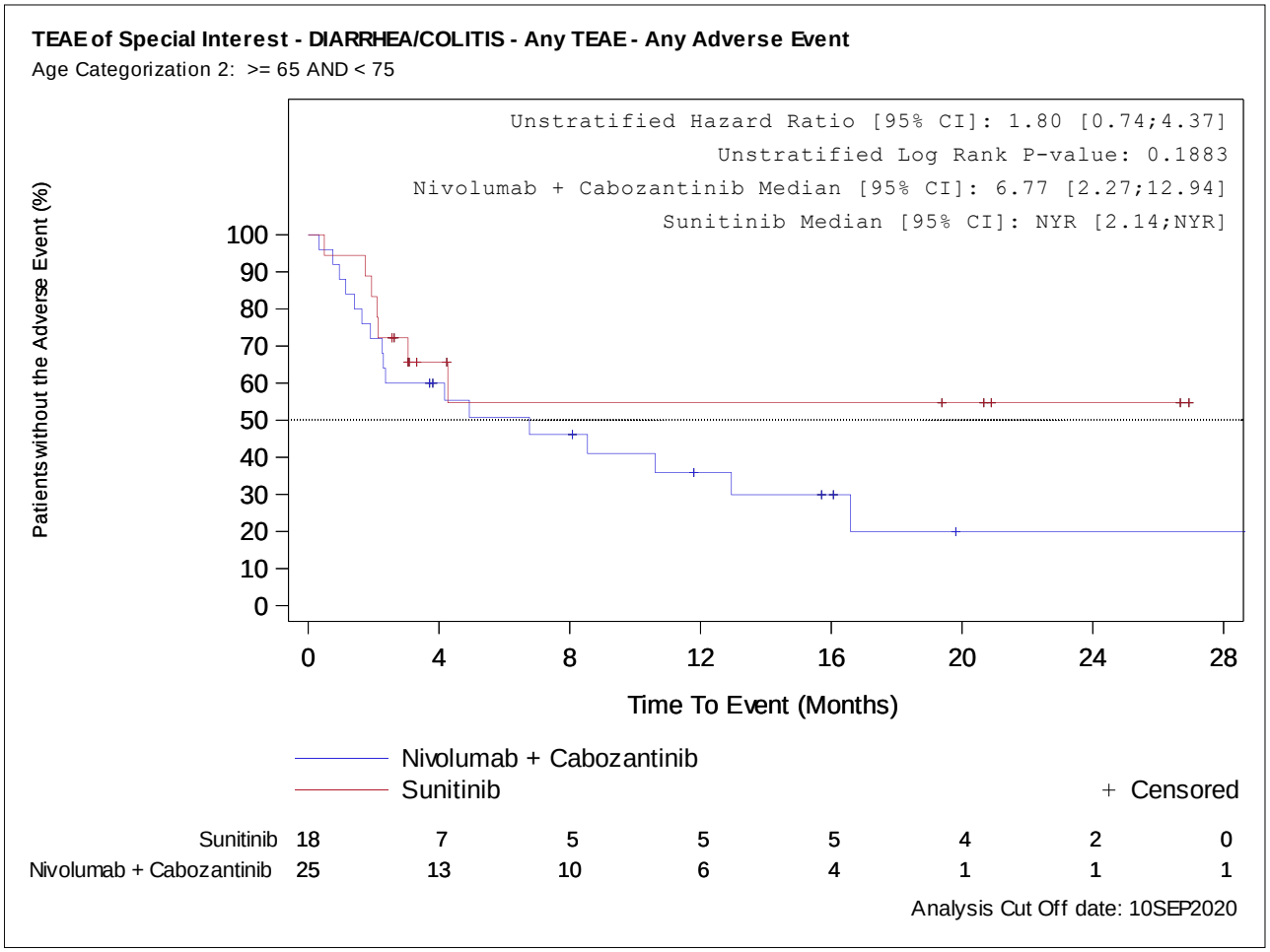

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:16:55

FIGURE 3.71.2.3: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



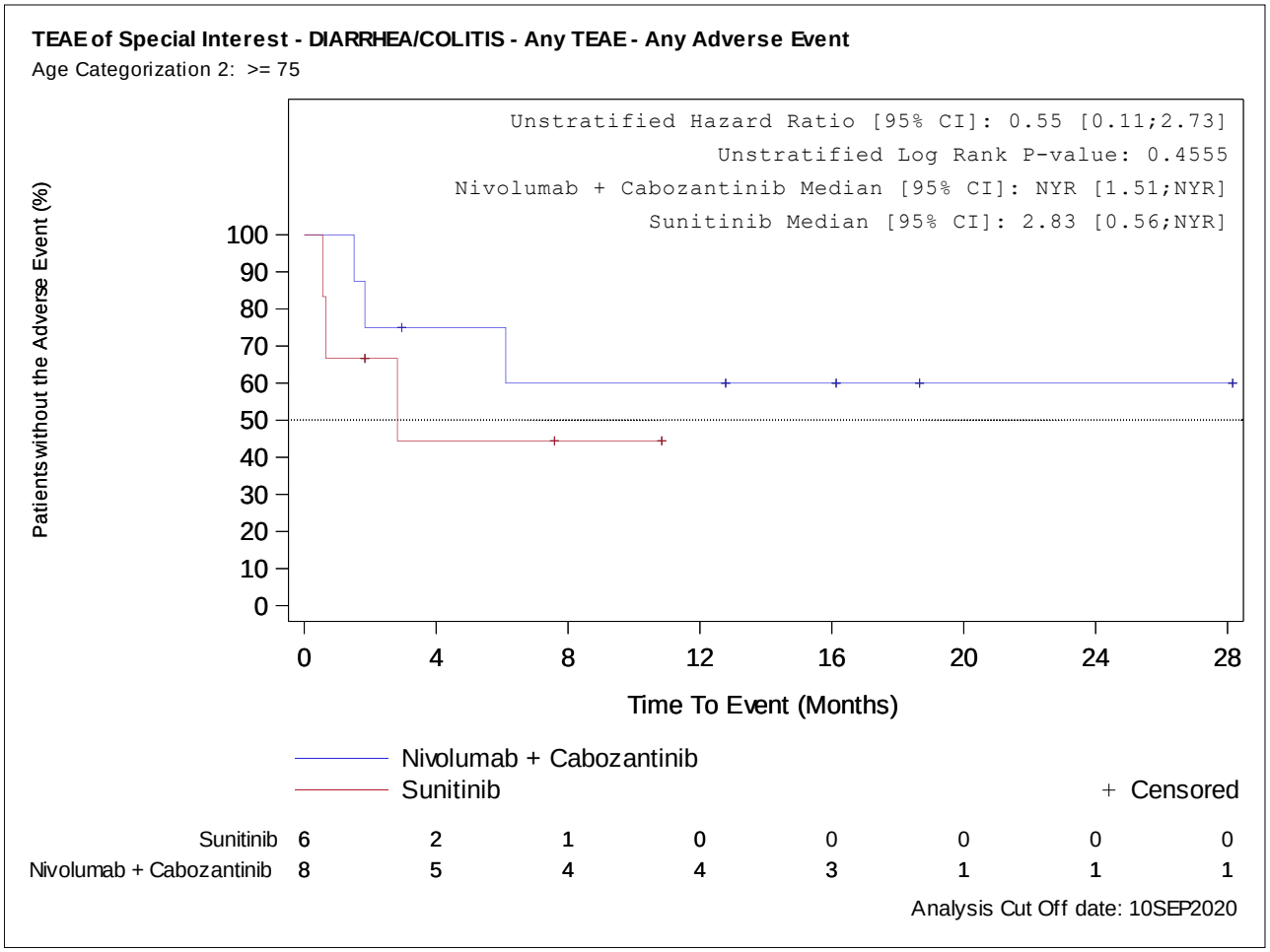

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:01

FIGURE 3.71.2.4: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



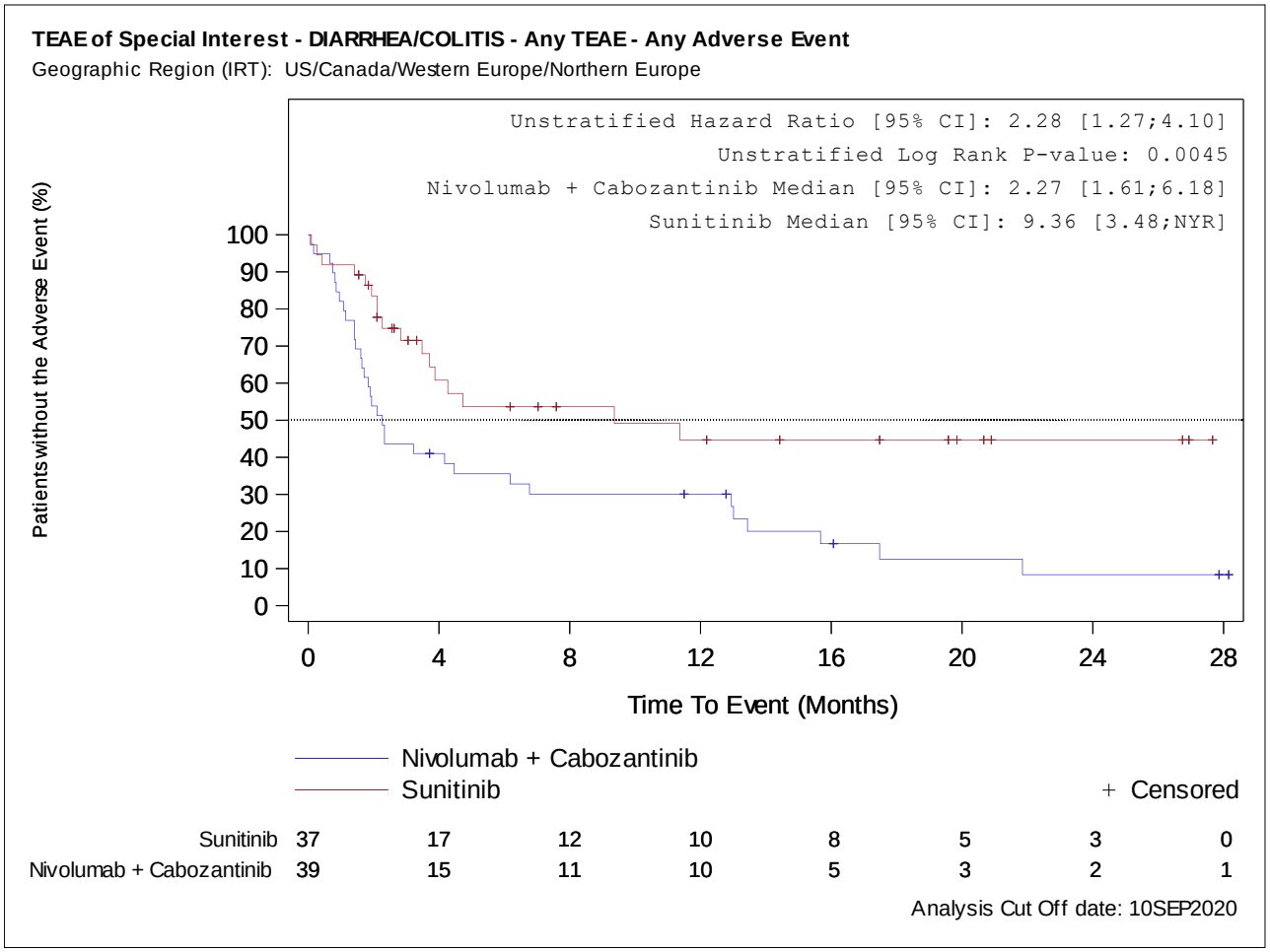

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:07

FIGURE 3.71.2.5: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



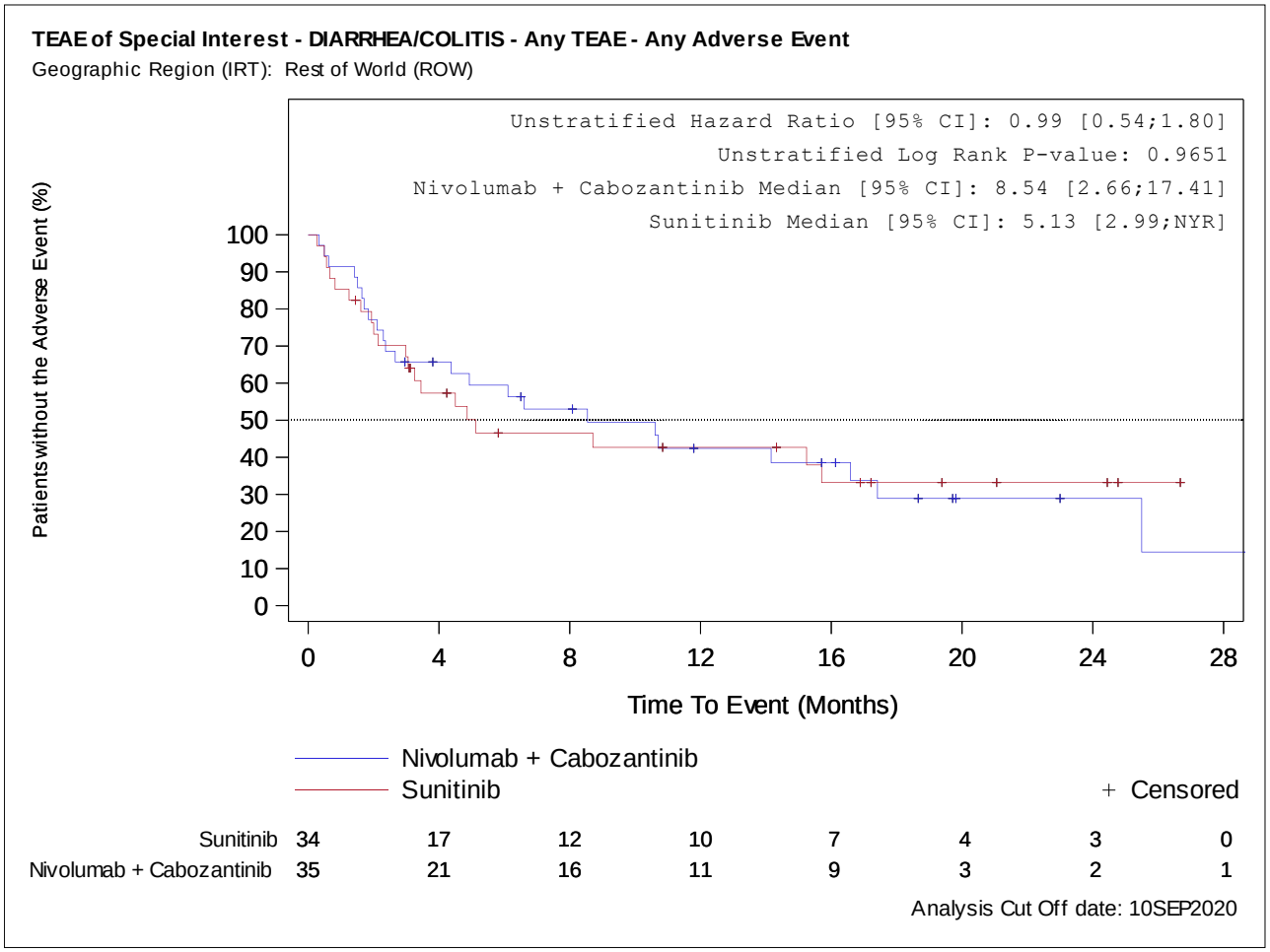

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:13

FIGURE 3.71.2.6: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



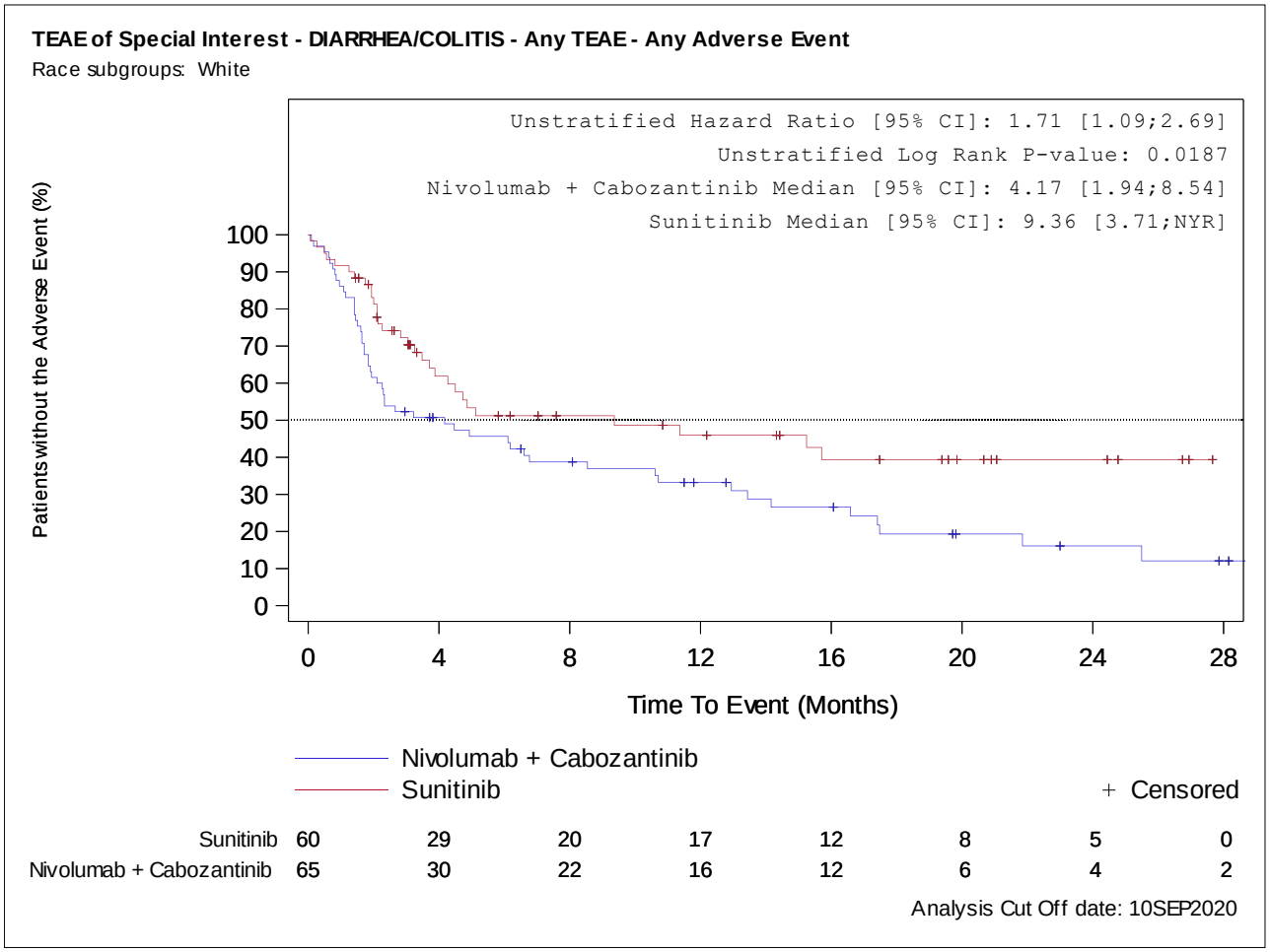

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:19

FIGURE 3.71.2.7: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



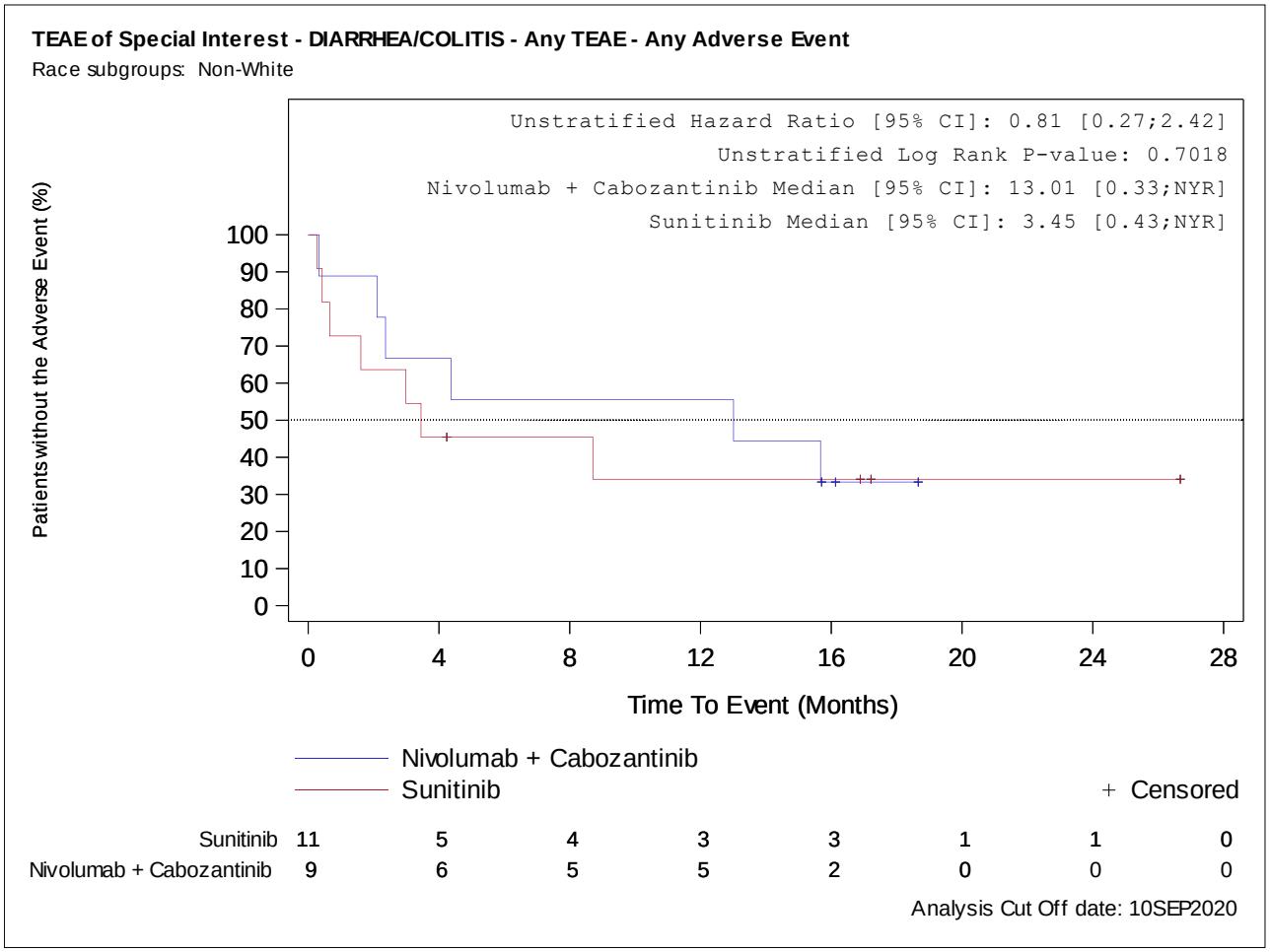

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:25

FIGURE 3.71.2.8: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



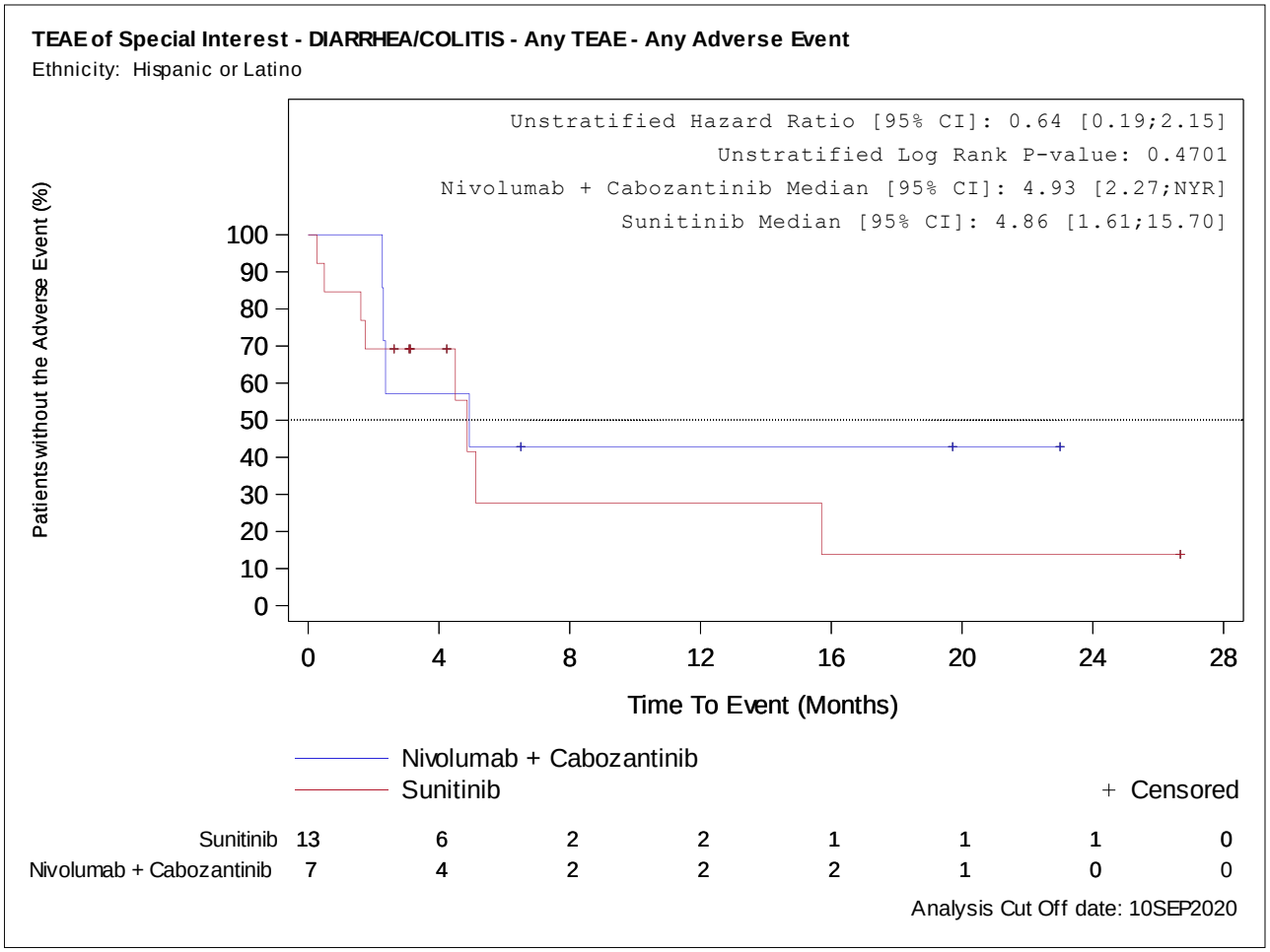

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:31

FIGURE 3.71.2.9: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



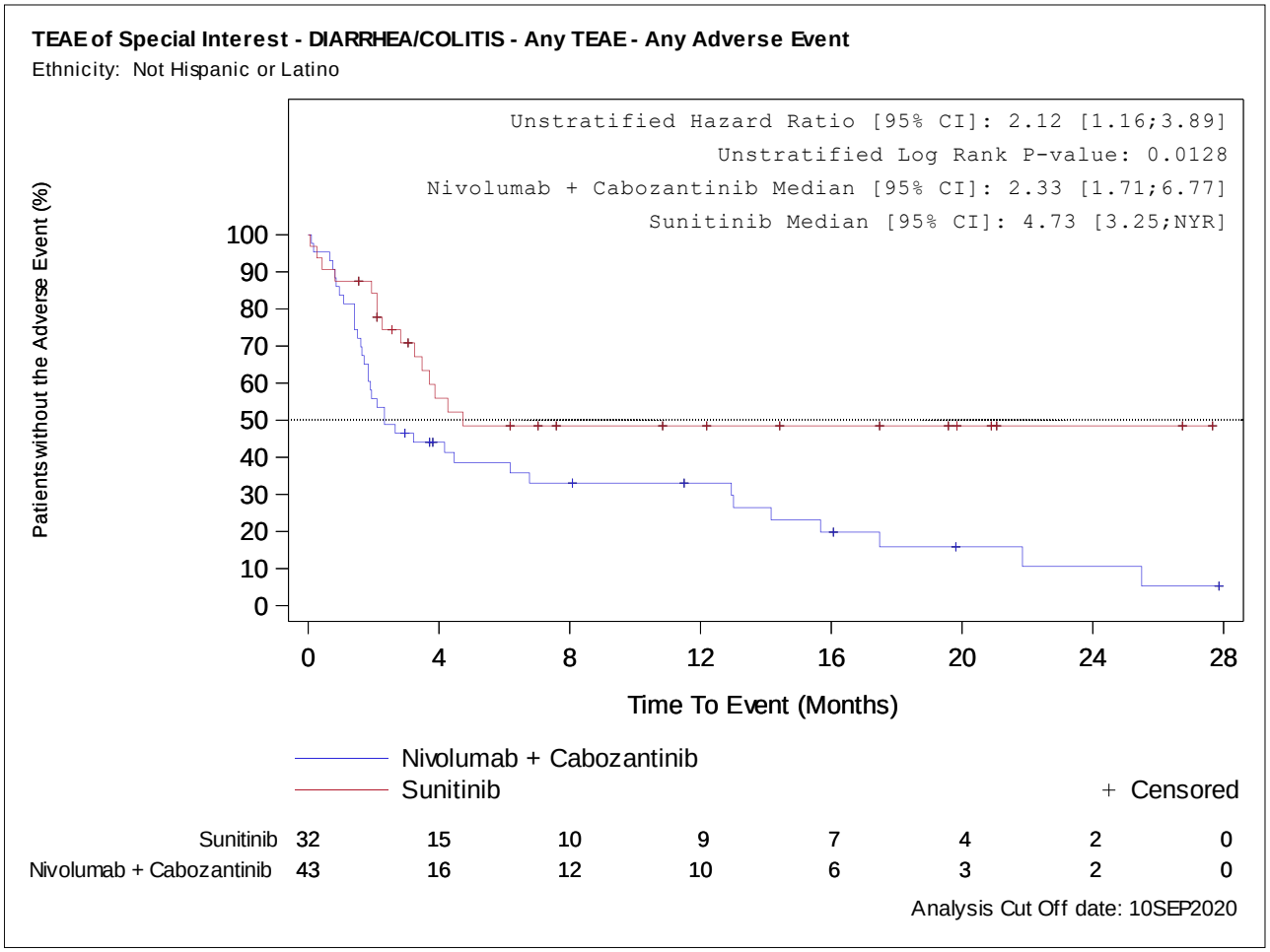

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:37

FIGURE 3.71.2.10: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



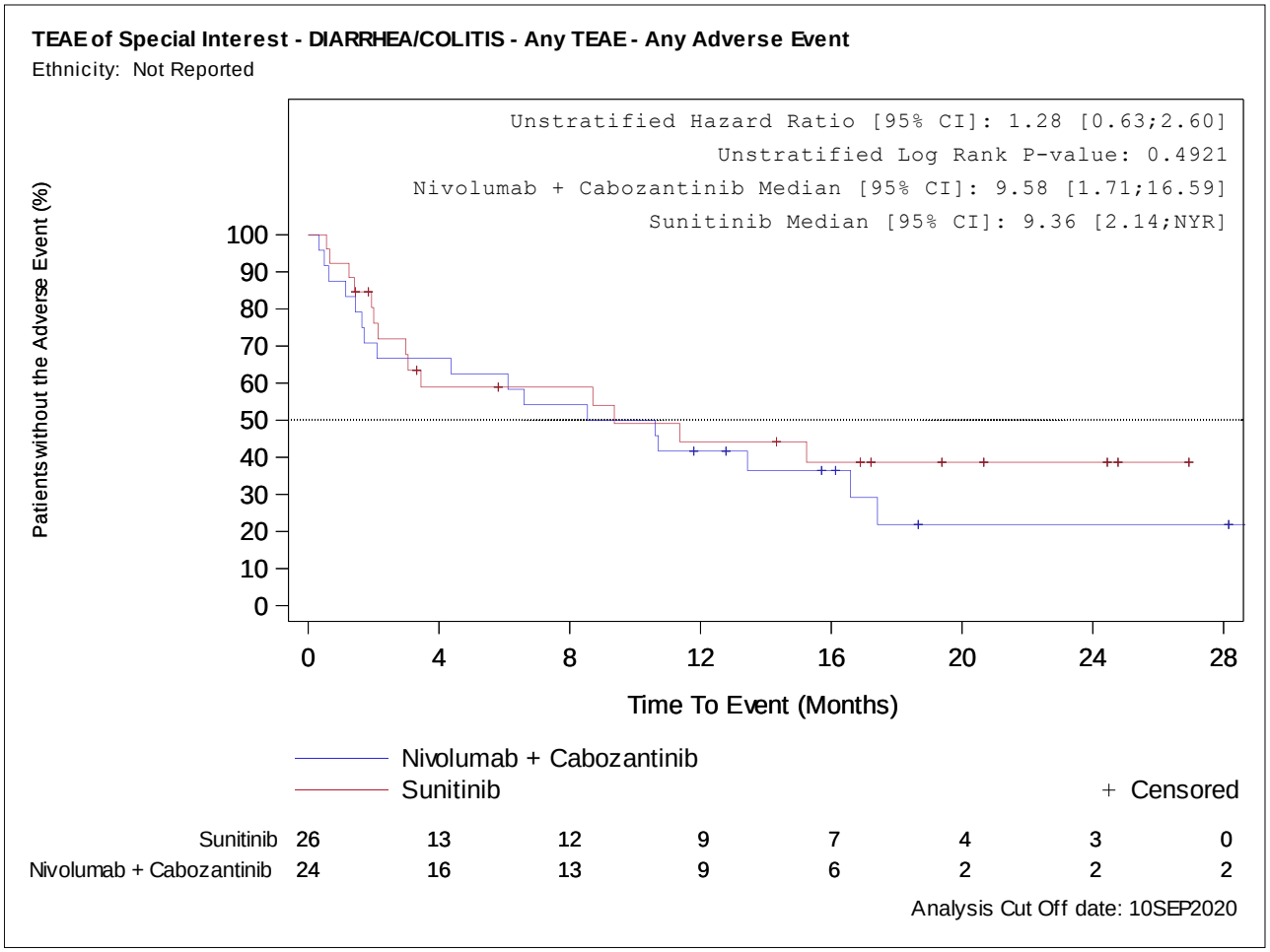

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:43

FIGURE 3.71.2.11: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



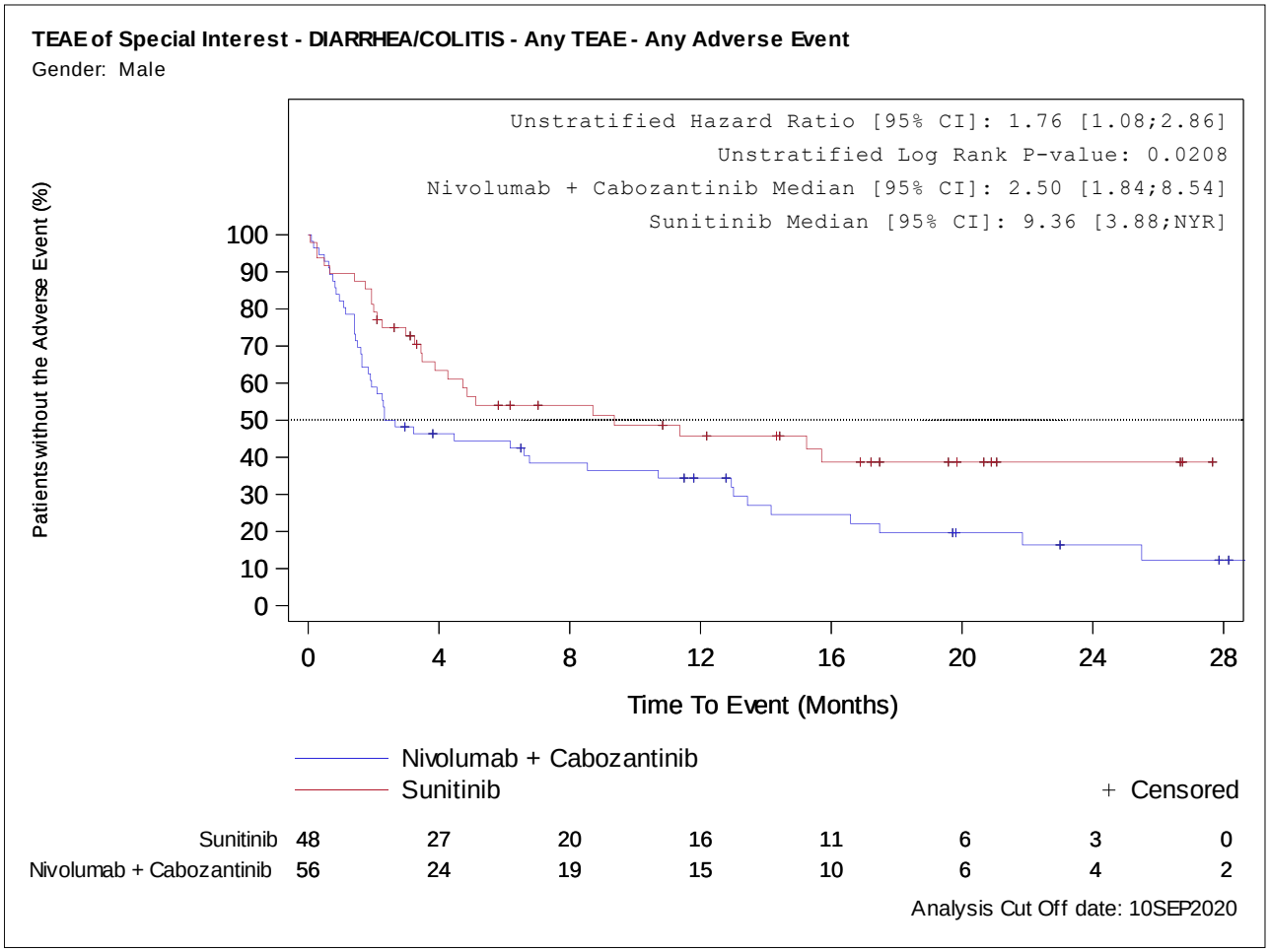

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:49

FIGURE 3.71.2.12: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



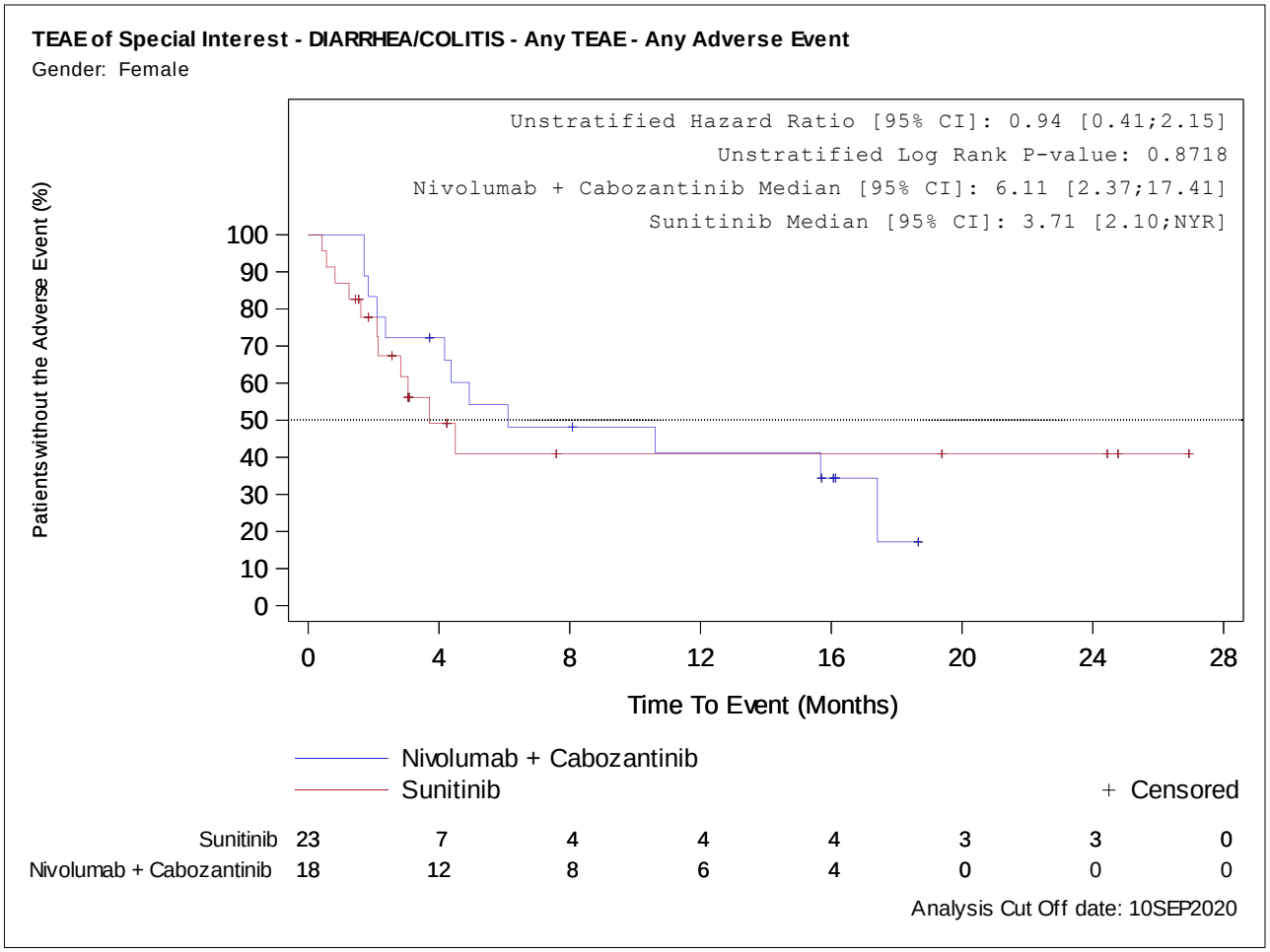

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:17:55

FIGURE 3.71.2.13: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



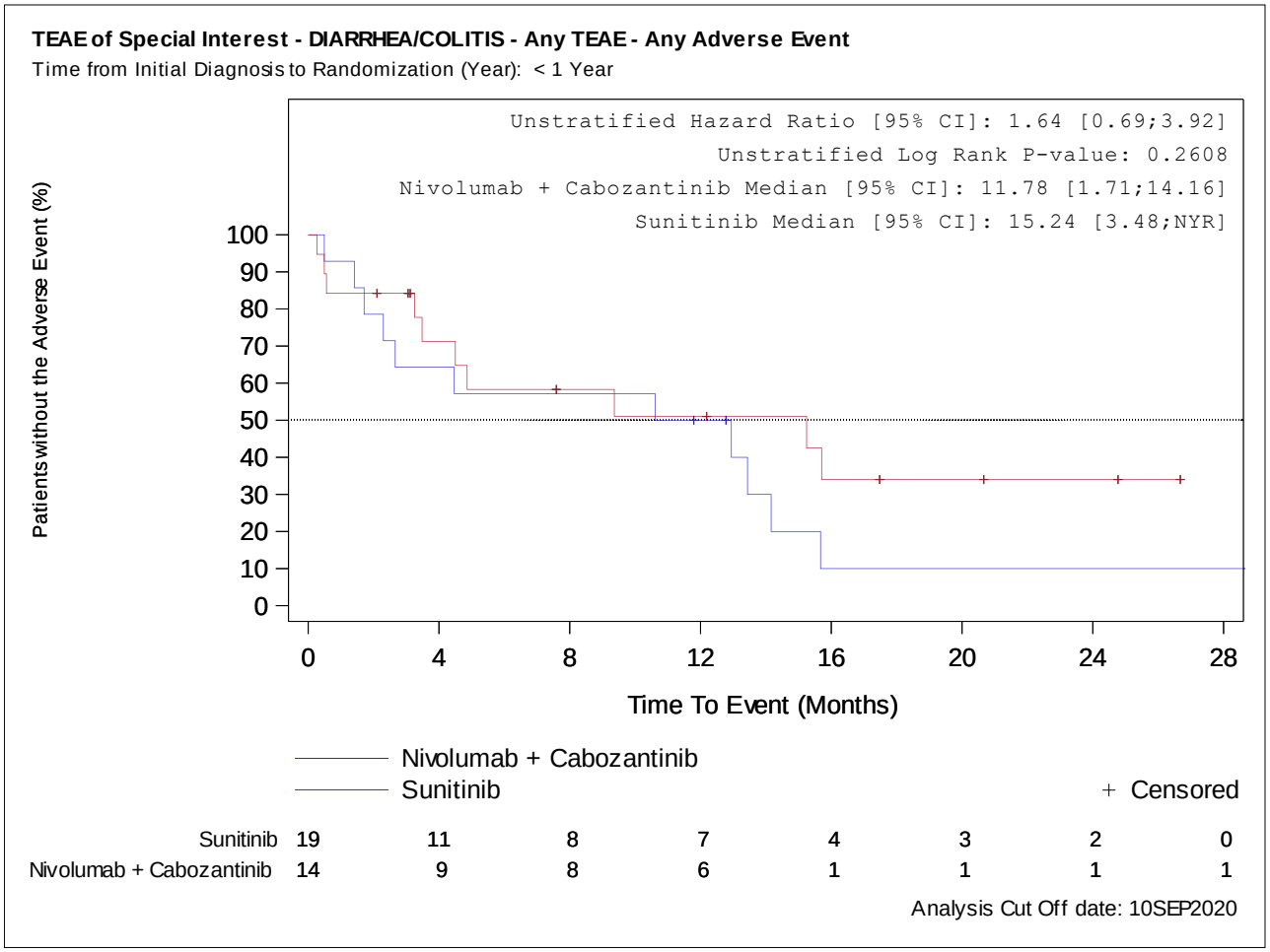

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:18:01

FIGURE 3.71.2.14: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



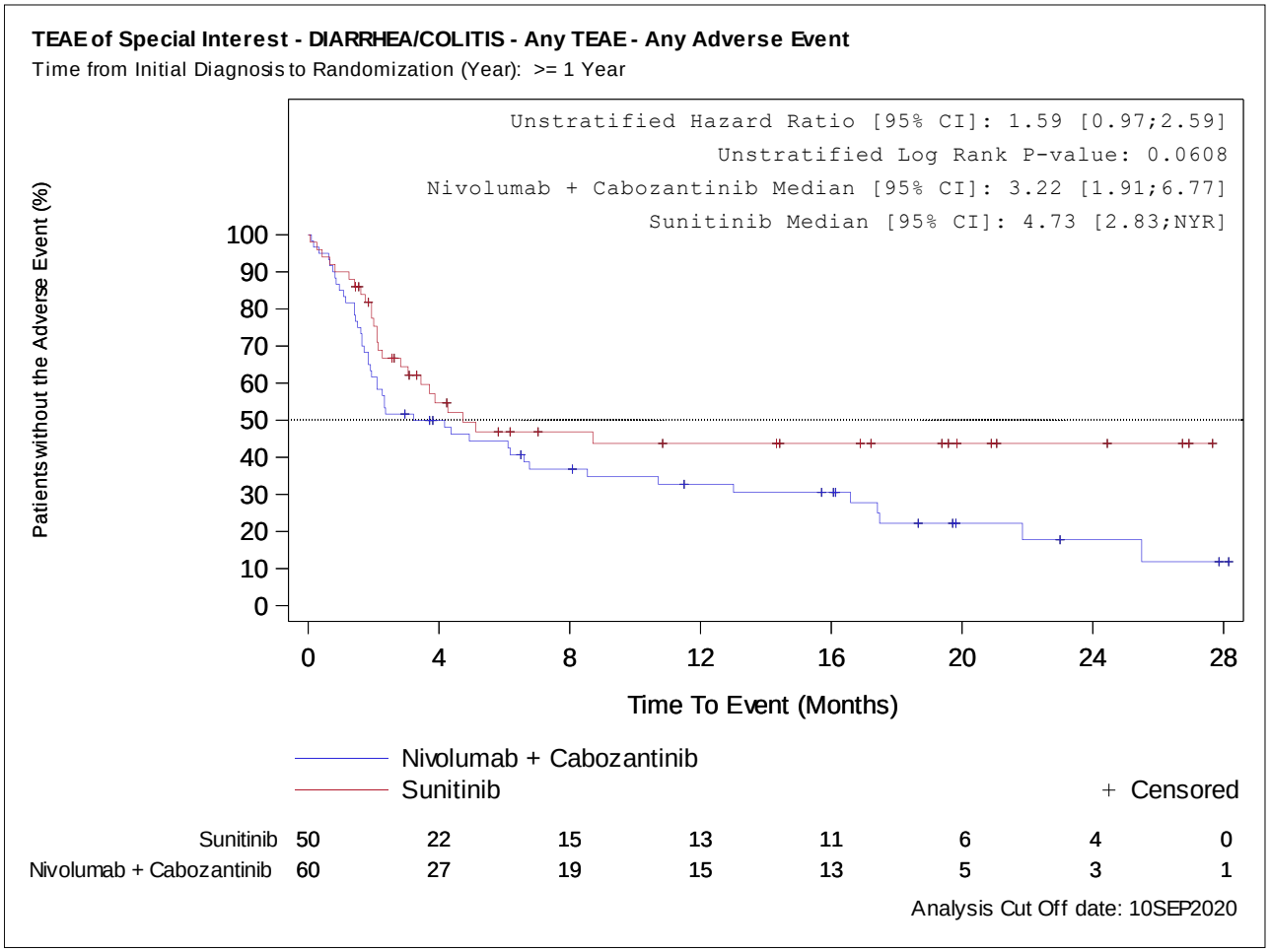

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:18:07

FIGURE 3.71.2.15: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



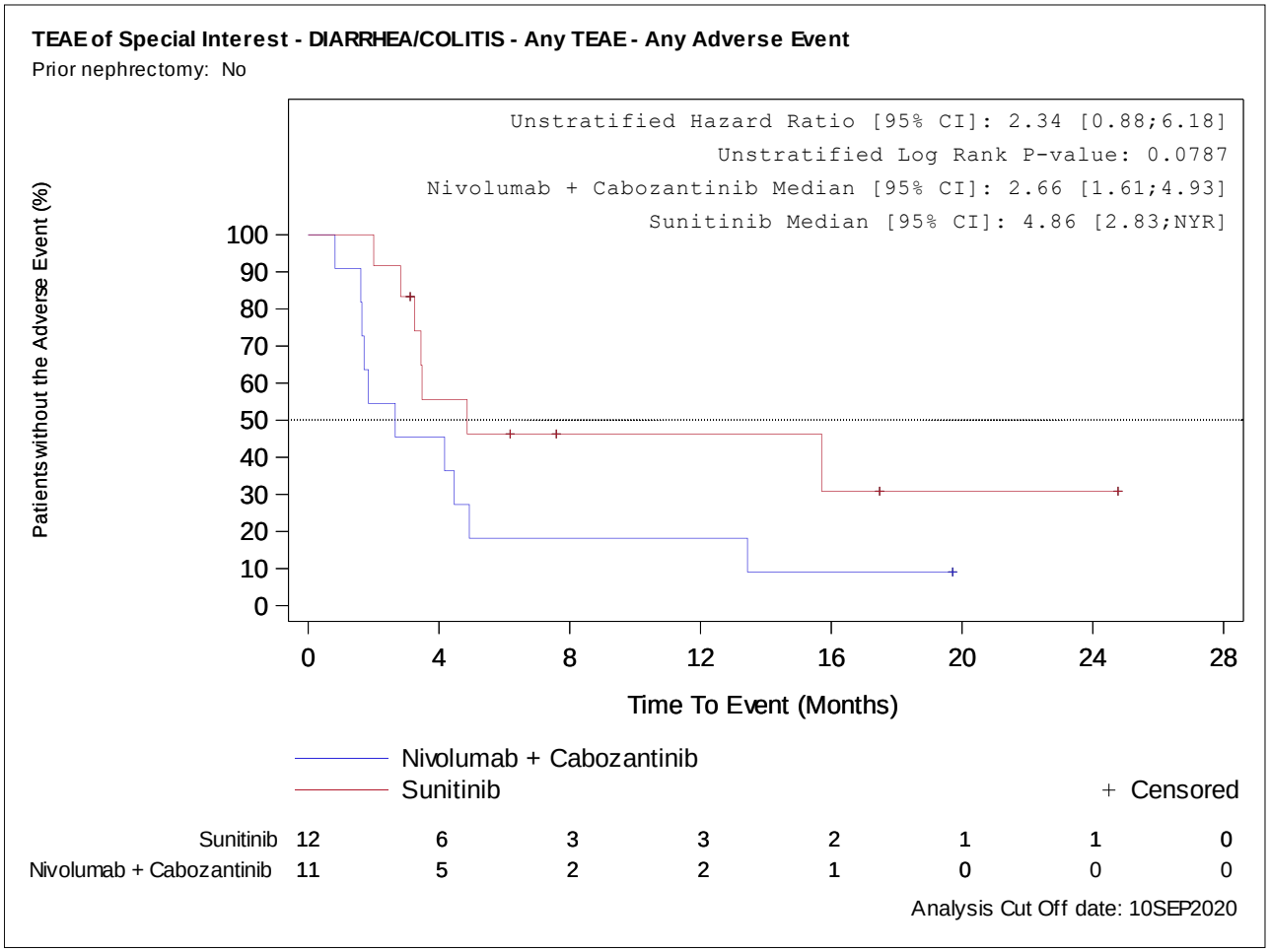

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:18:25

FIGURE 3.71.2.16: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



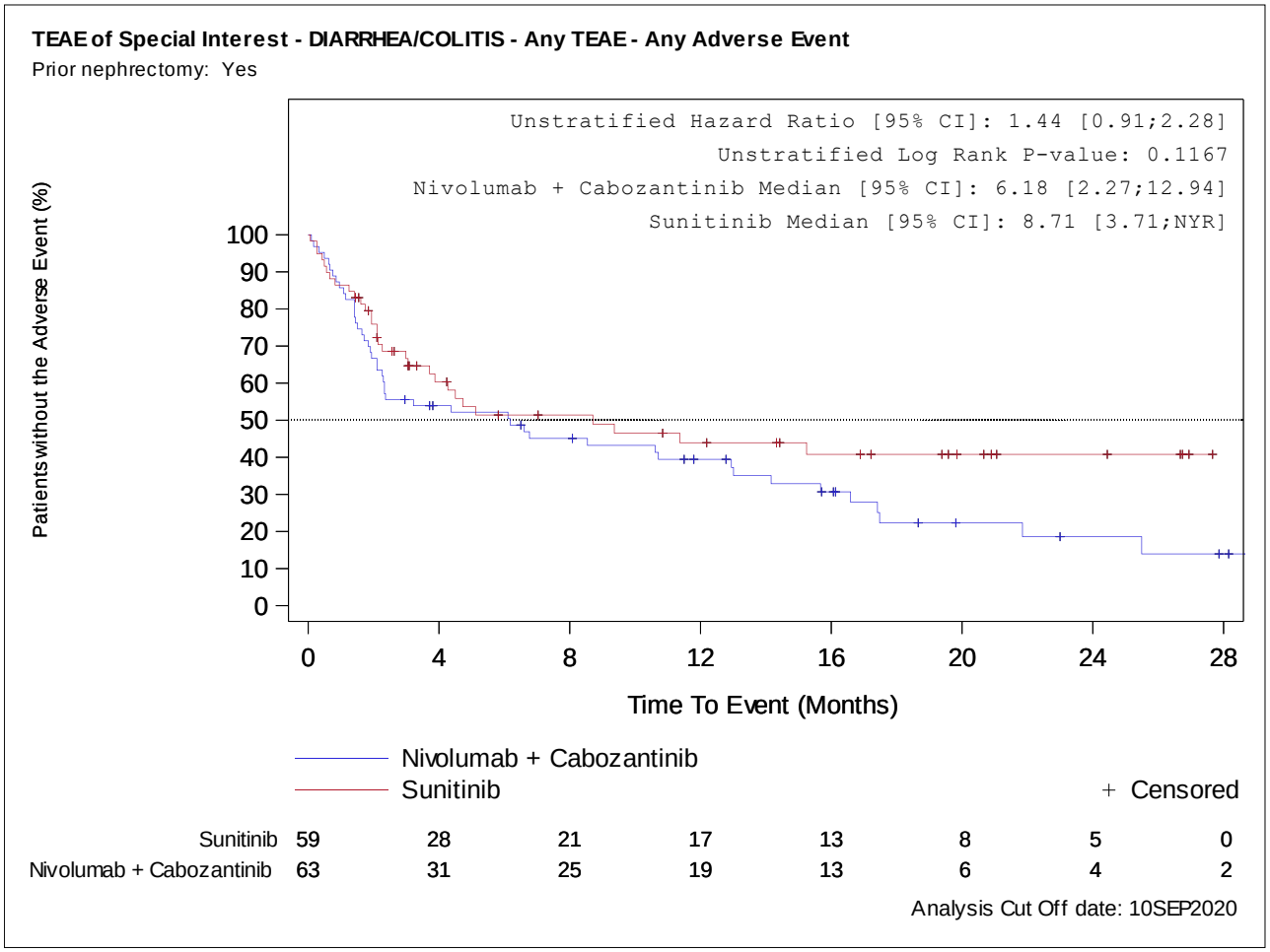

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:18:30

FIGURE 3.71.2.17: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:19:24

FIGURE 3.71.2.18: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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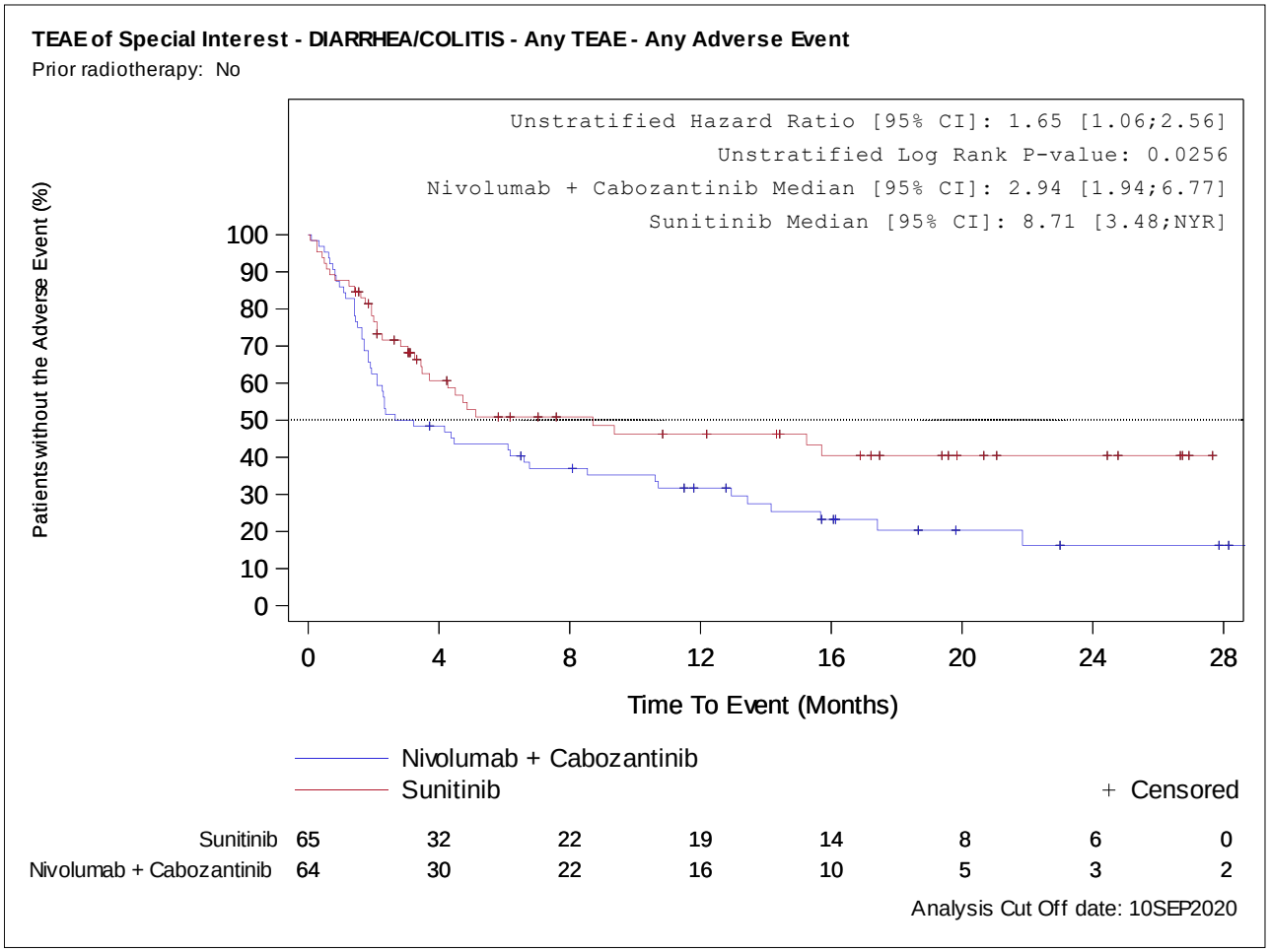
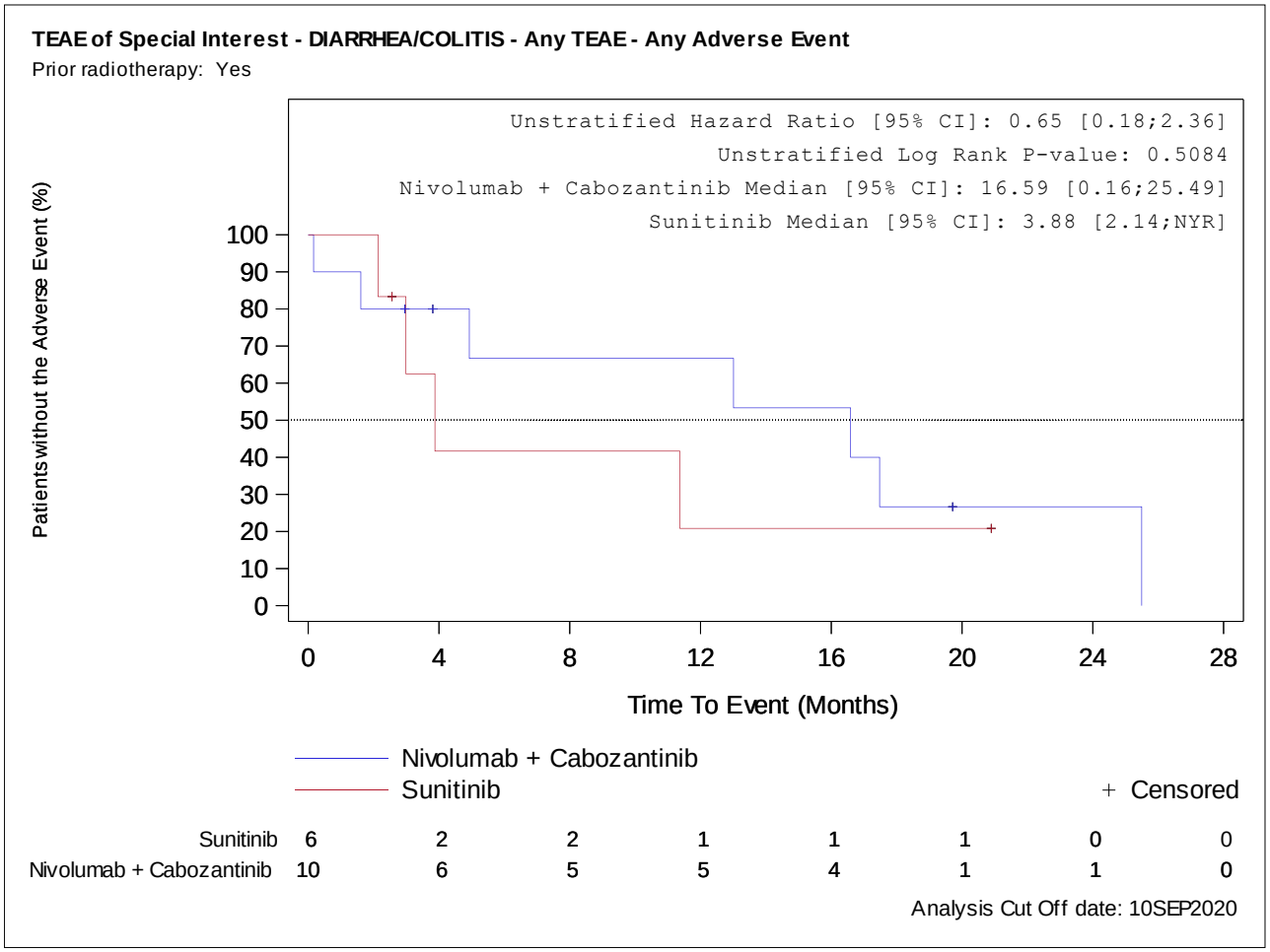
FIGURE 3.71.2.19: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



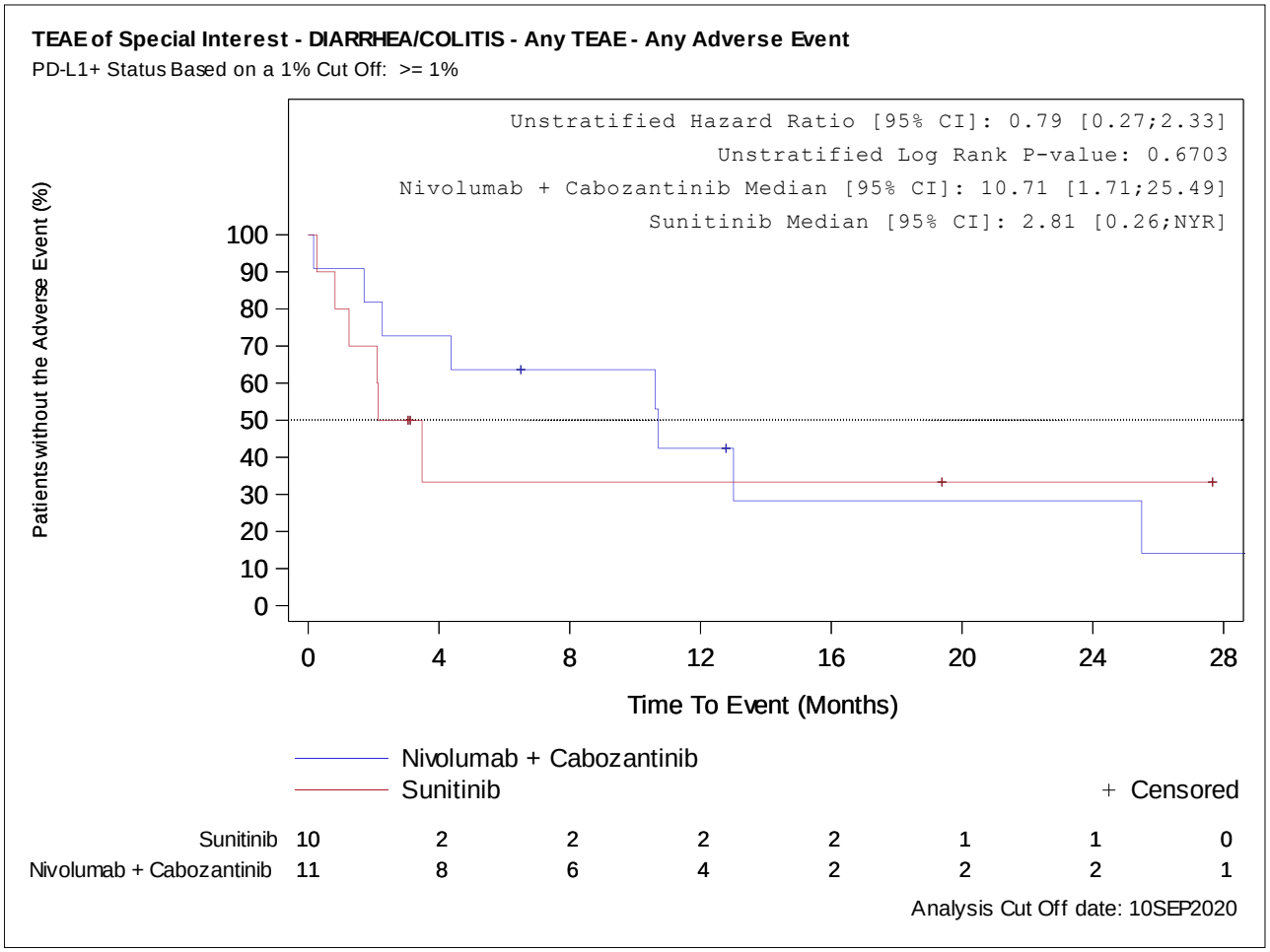

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:19:36

FIGURE 3.71.2.20: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



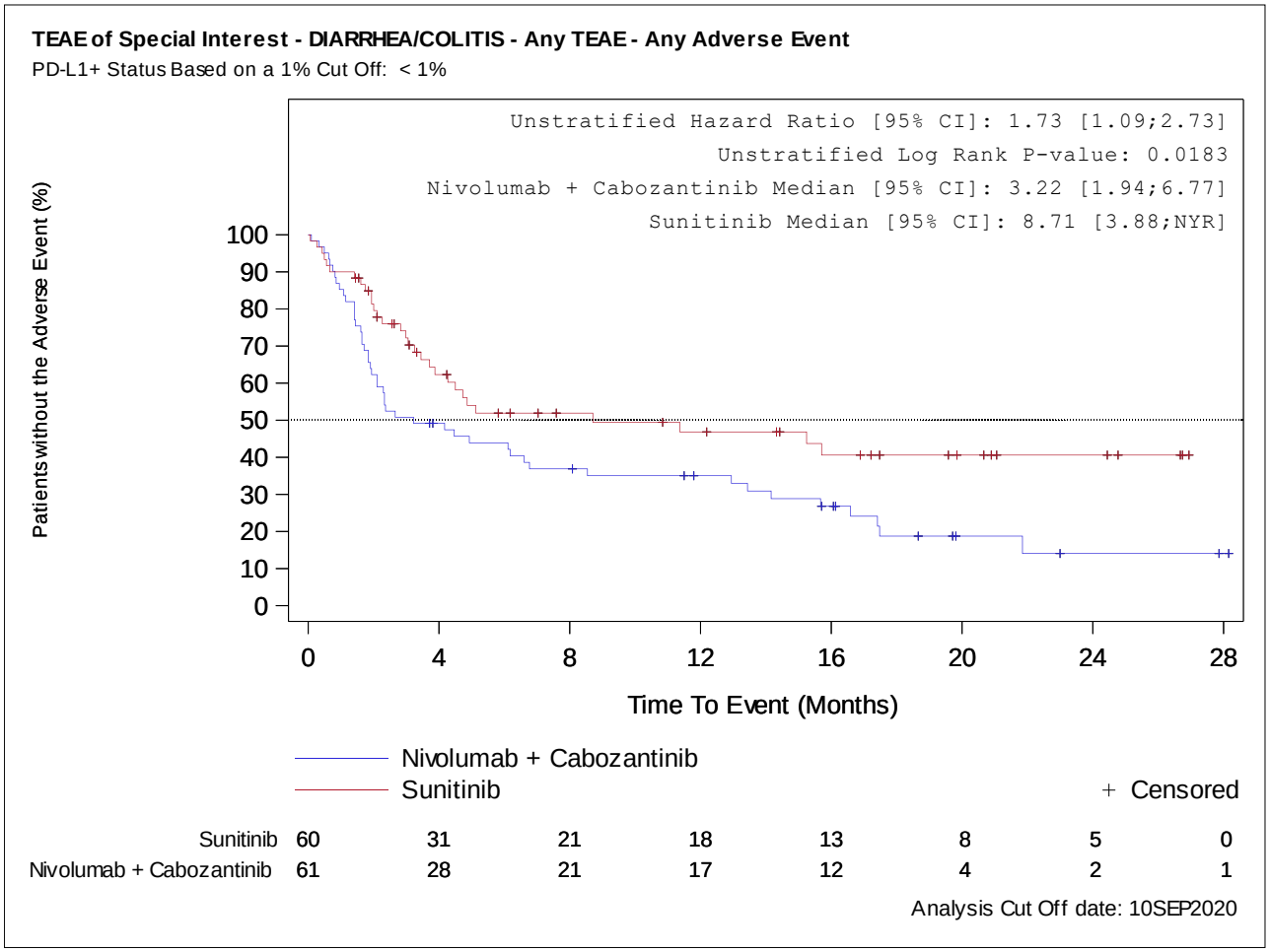

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:19:42

FIGURE 3.71.2.21: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



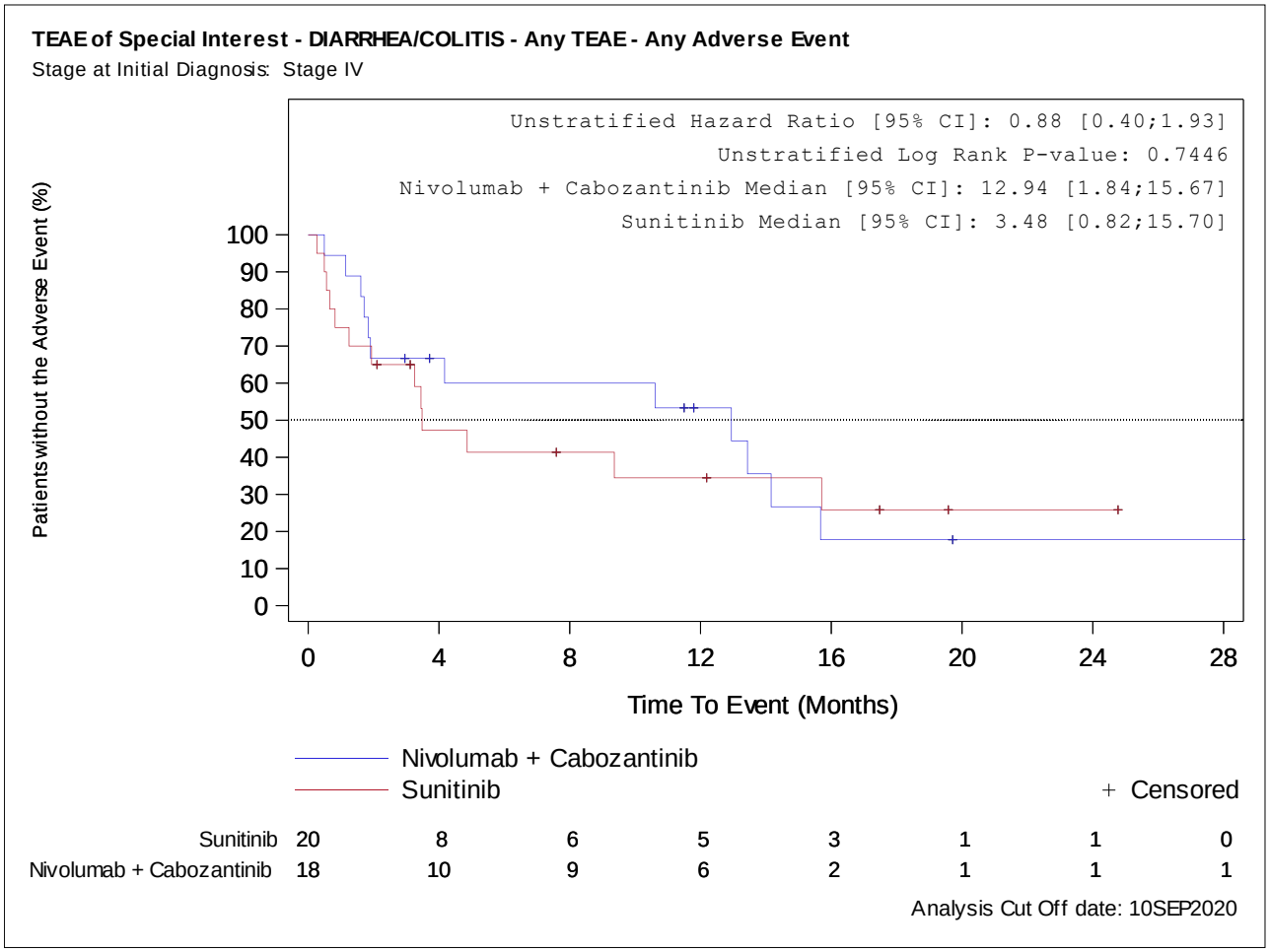

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:19:49

FIGURE 3.71.2.22: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



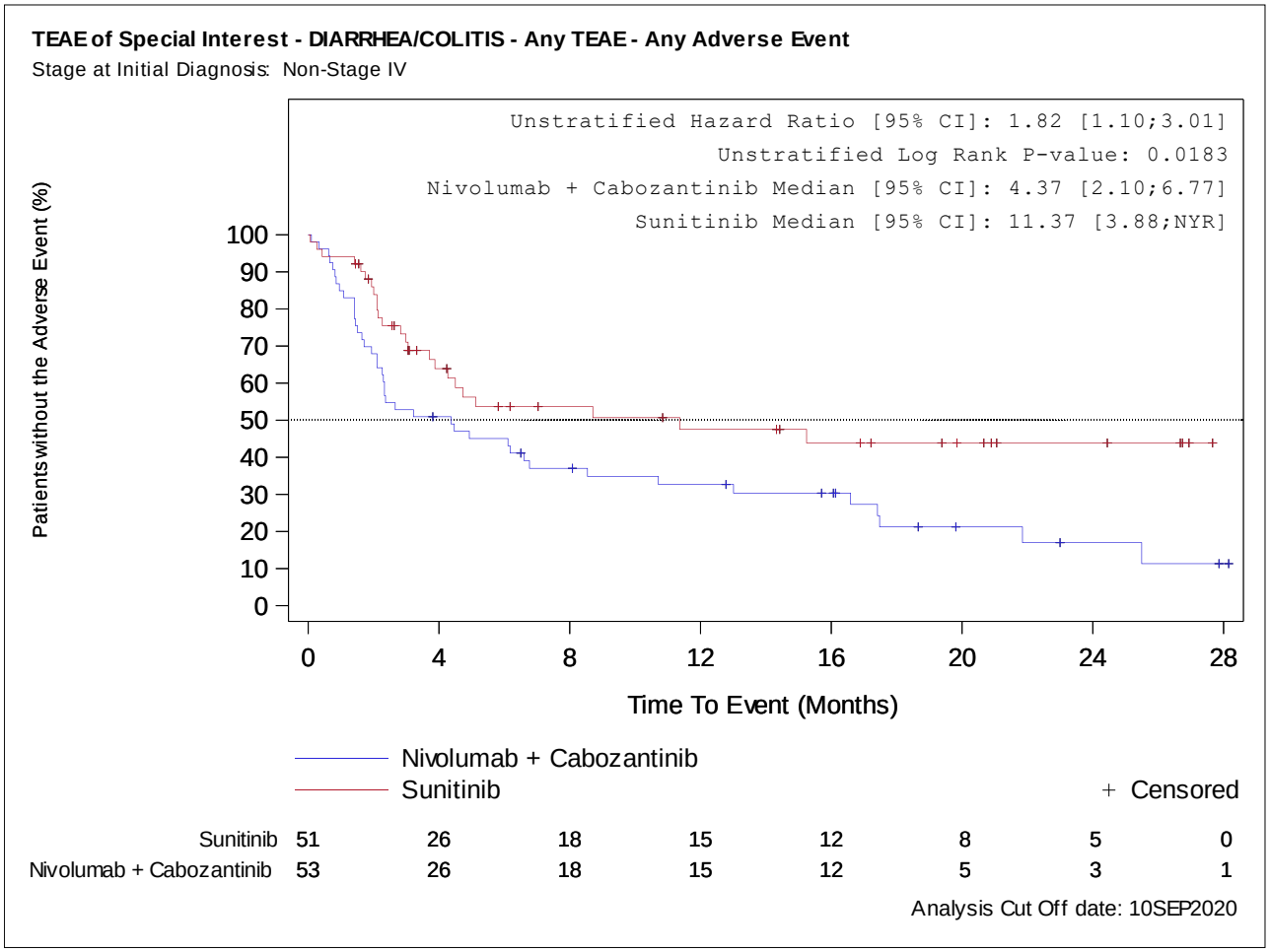

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:19:54

FIGURE 3.71.2.23: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



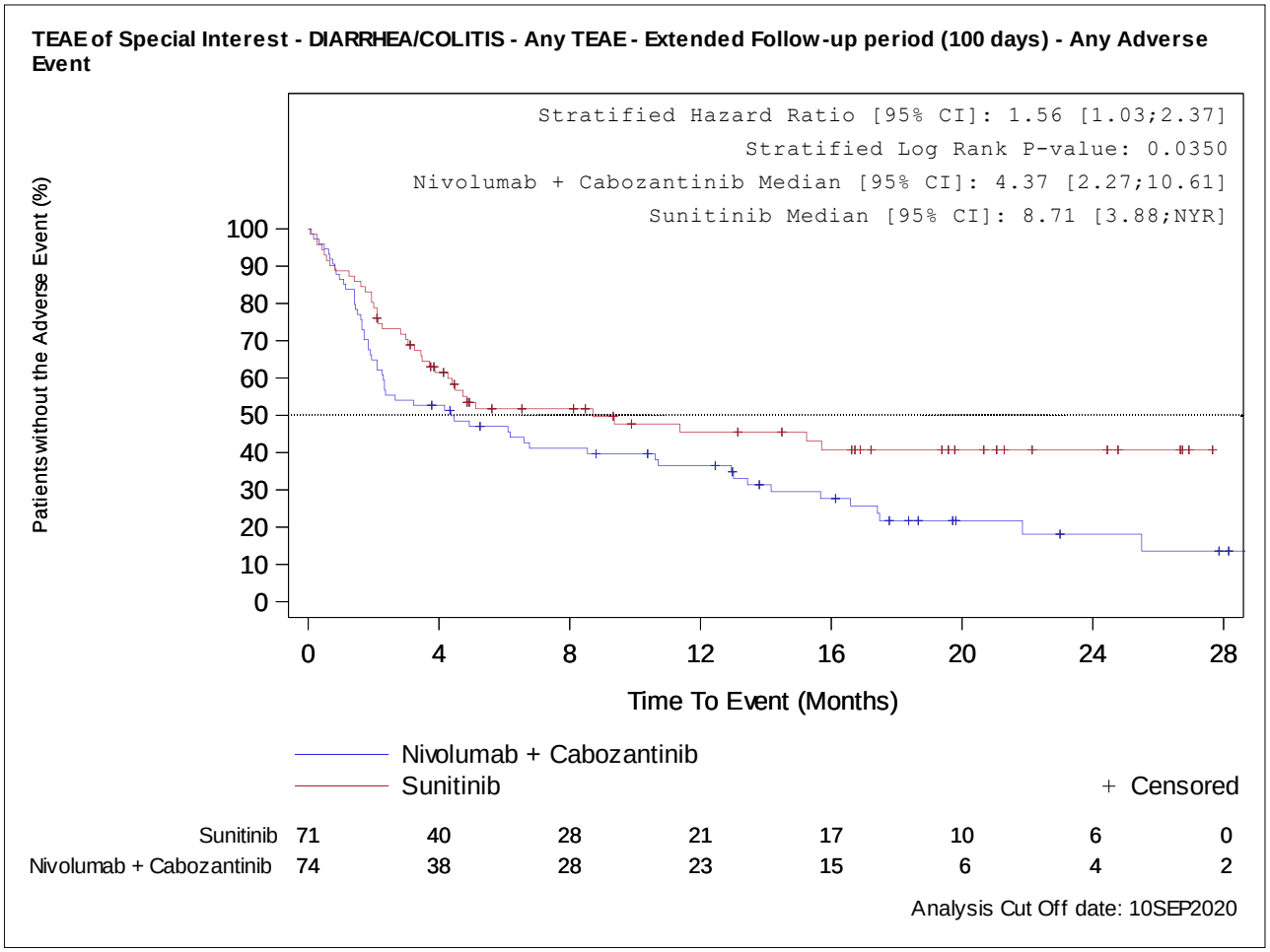

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:20:23

FIGURE 3.71.2.24: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



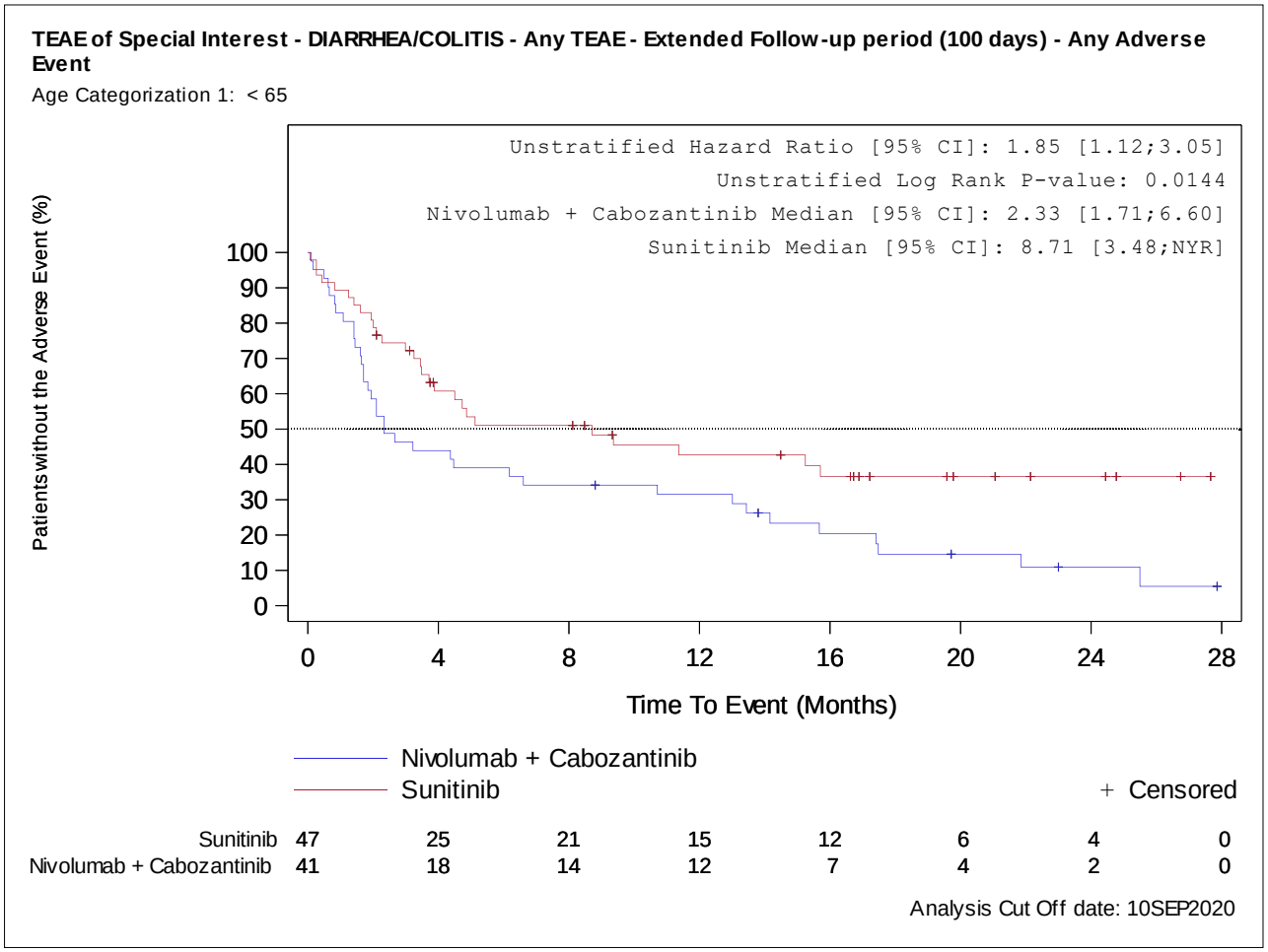

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:20:29

FIGURE 3.72.1: TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



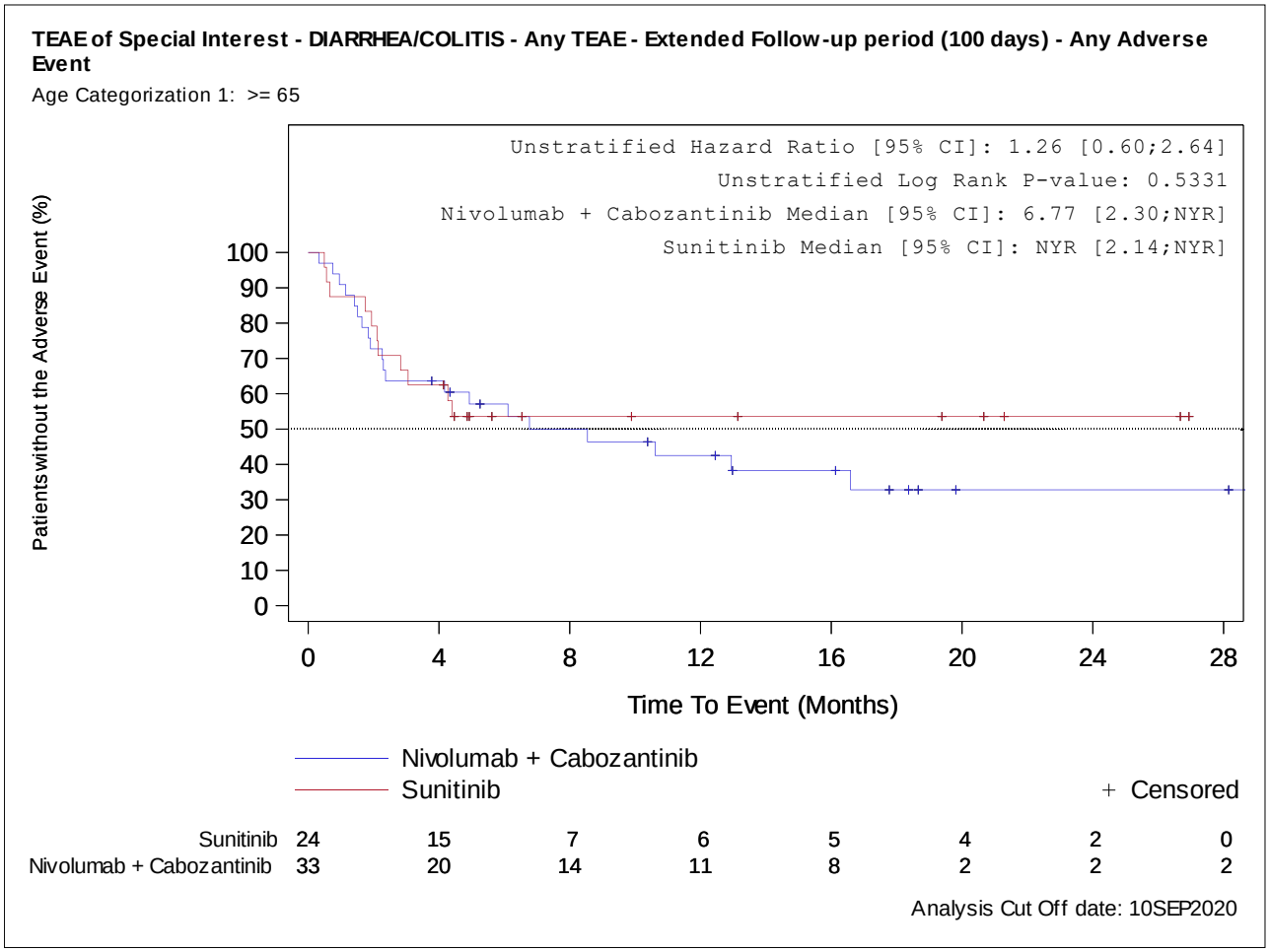

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:23:44

FIGURE 3.72.2.1: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



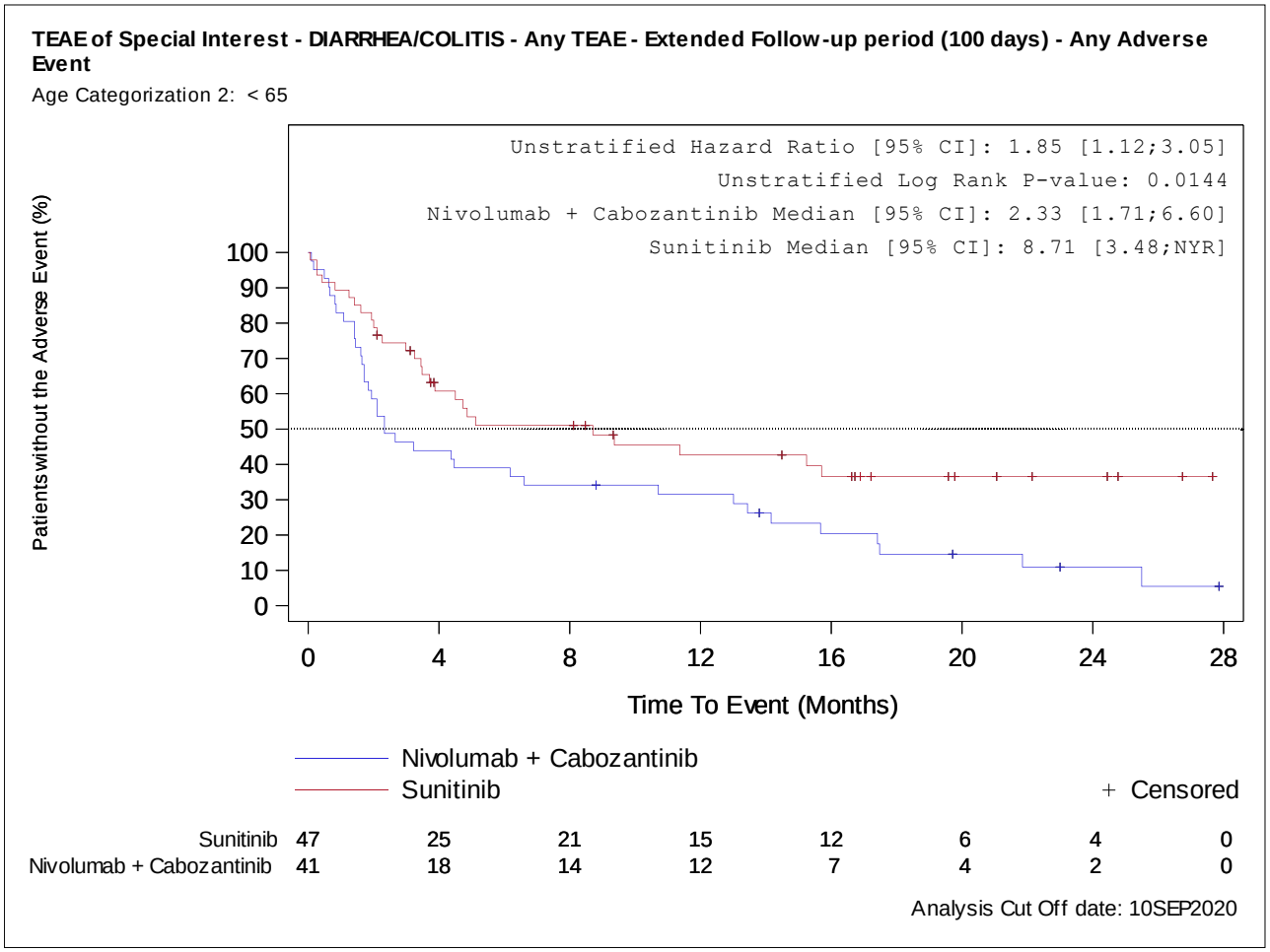

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:23:47

FIGURE 3.72.2.2: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



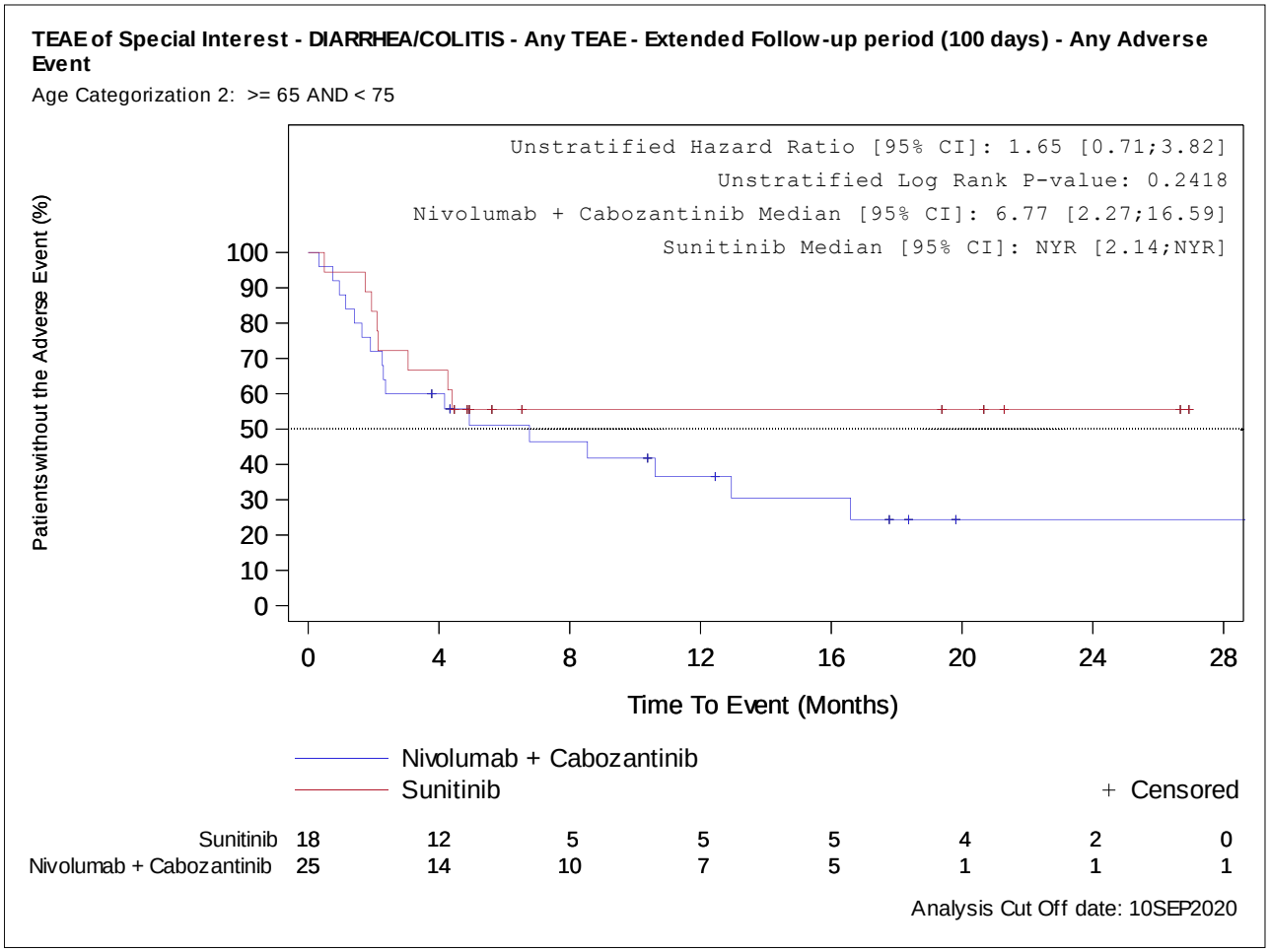

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:23:54

FIGURE 3.72.2.3: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



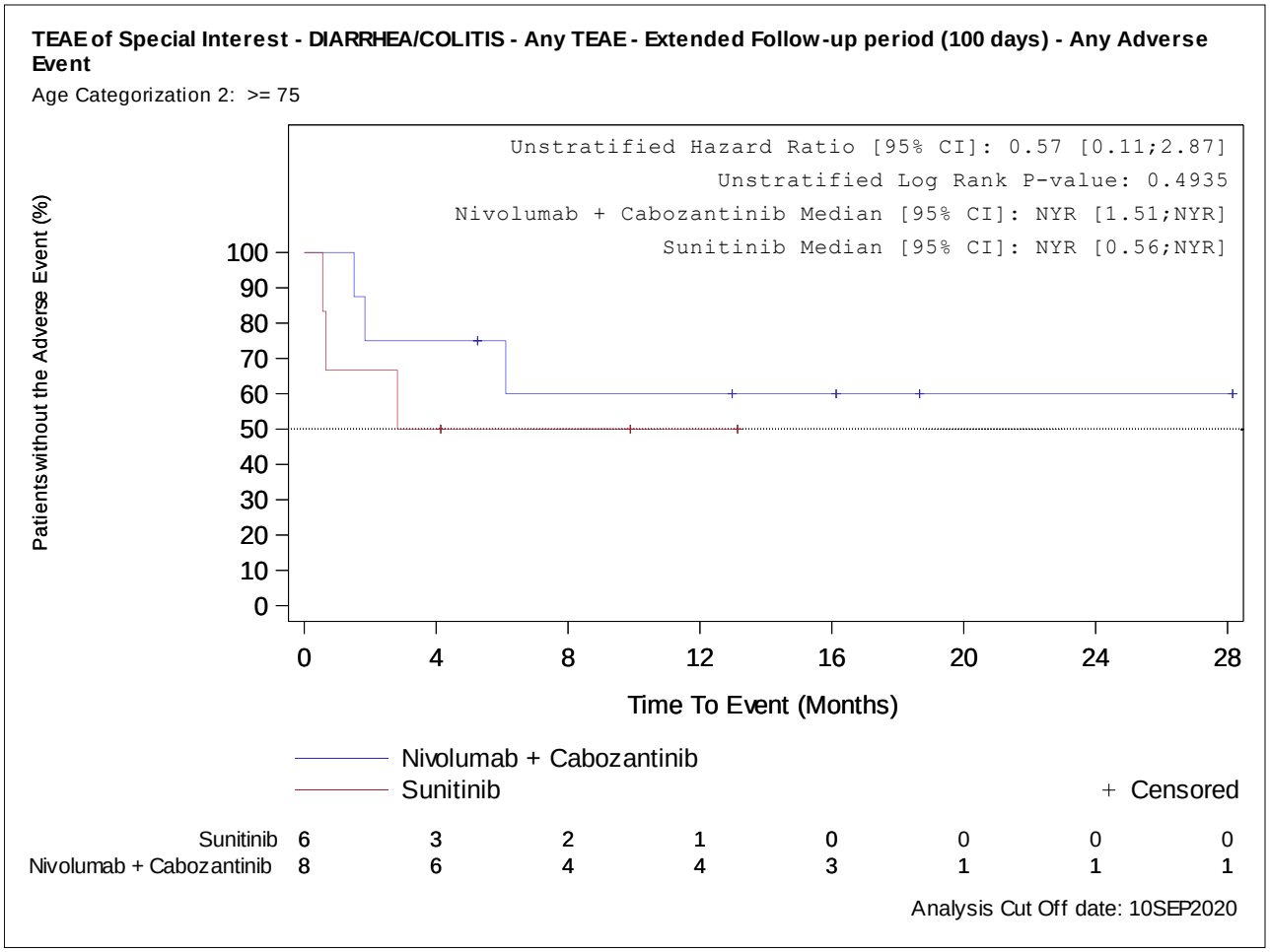

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:24:00

FIGURE 3.72.2.4: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



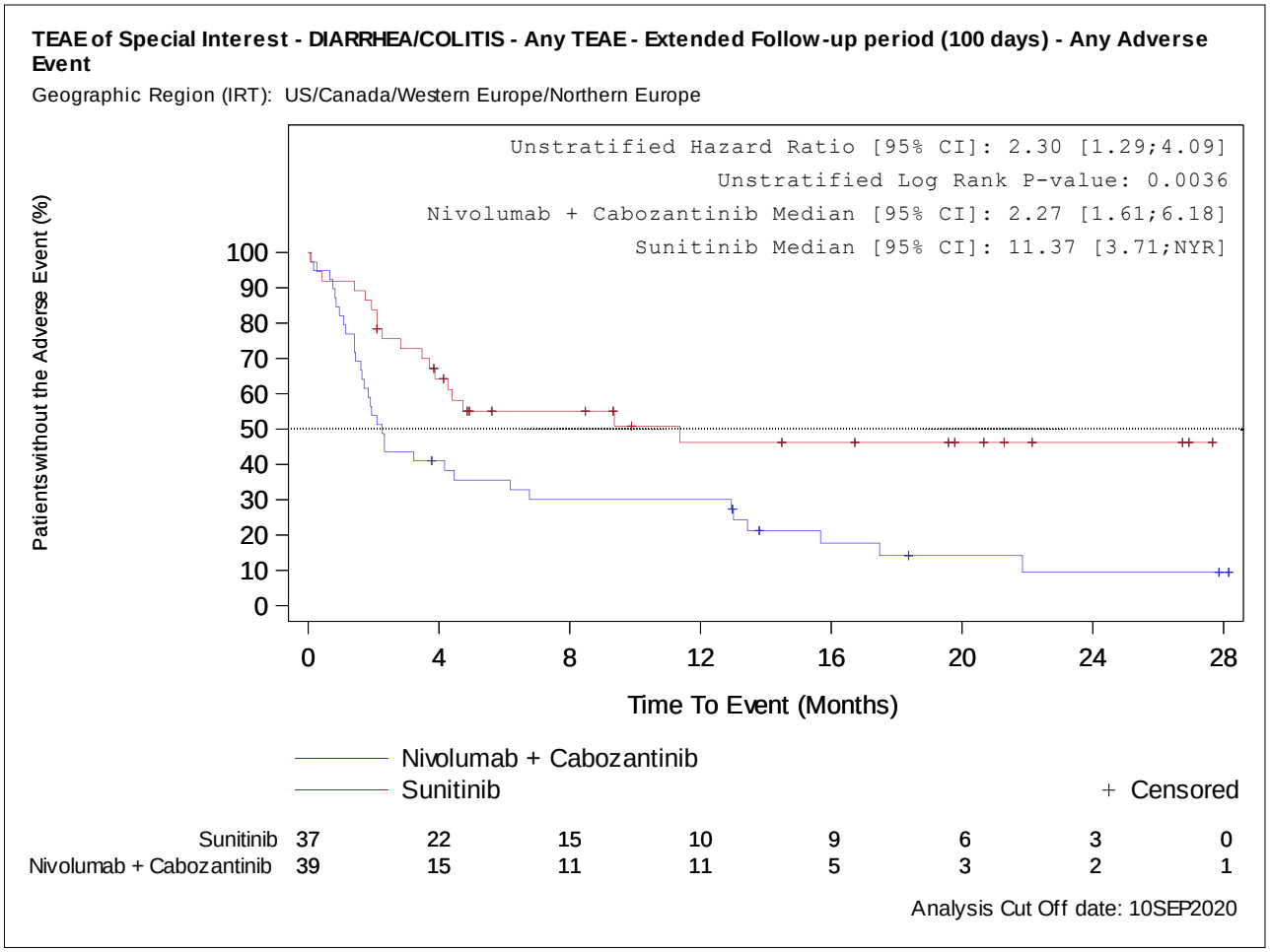

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:24:06

FIGURE 3.72.2.5: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



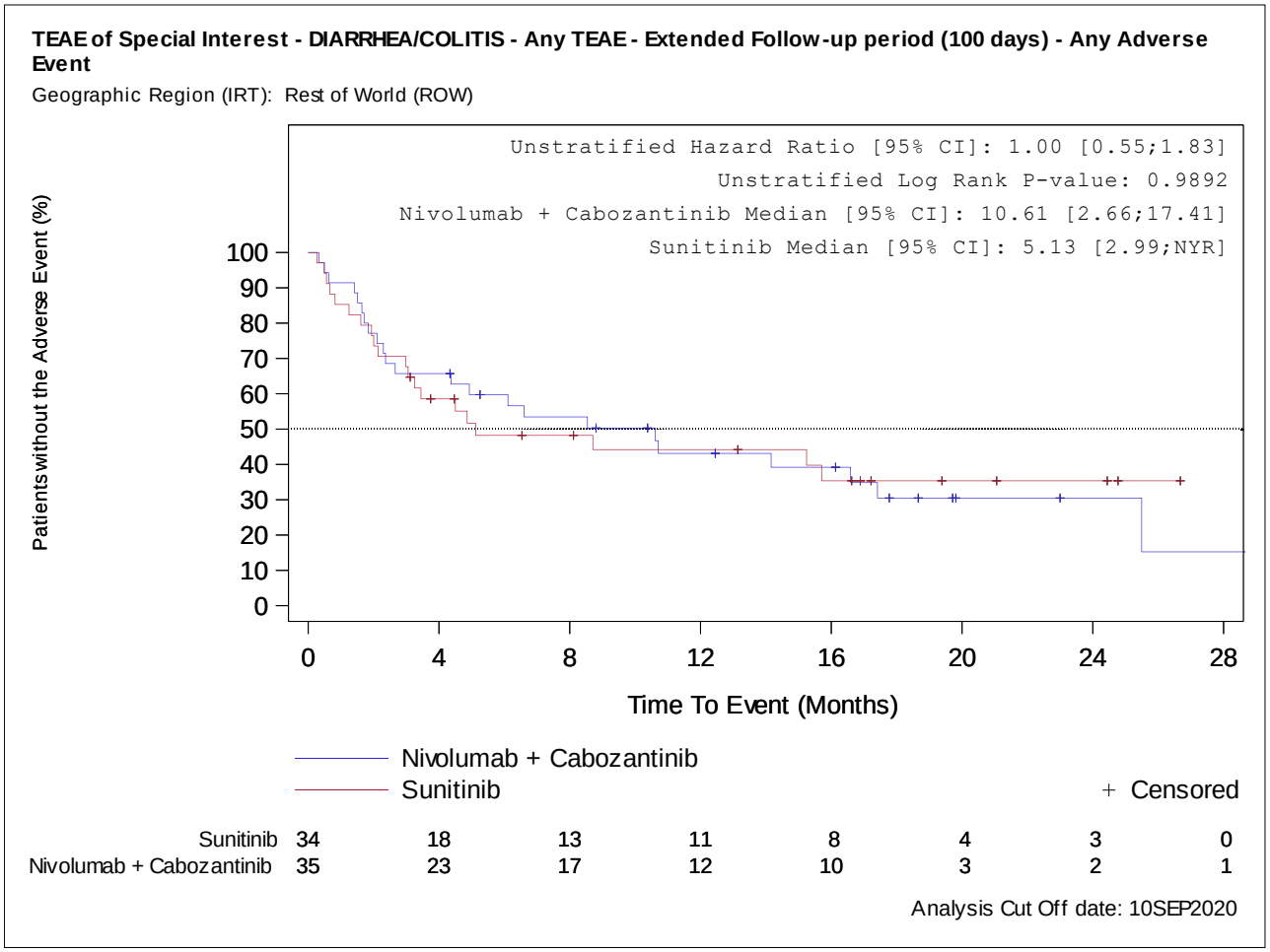

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:24:11

FIGURE 3.72.2.6: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



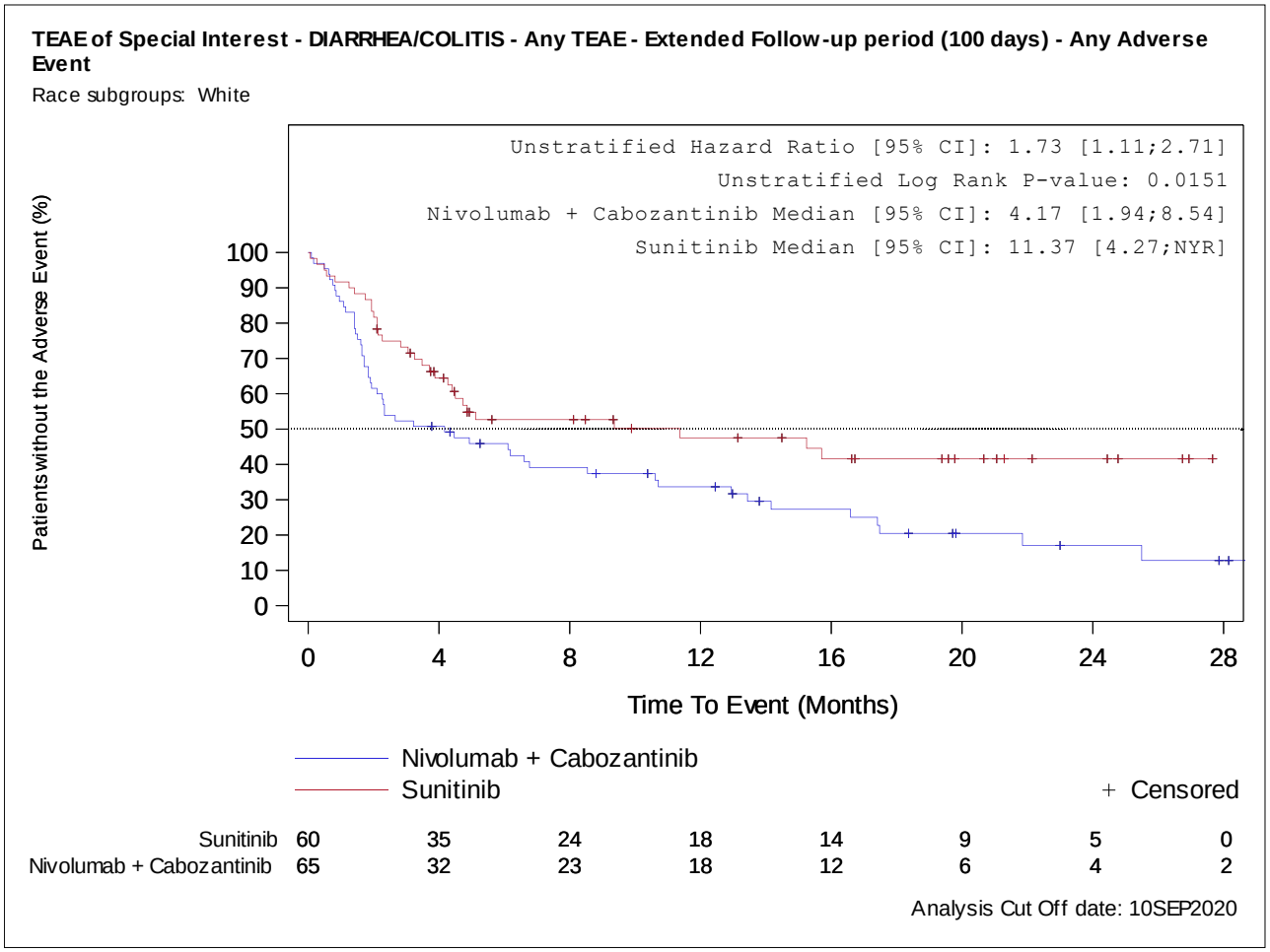

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:24:17

FIGURE 3.72.2.7: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



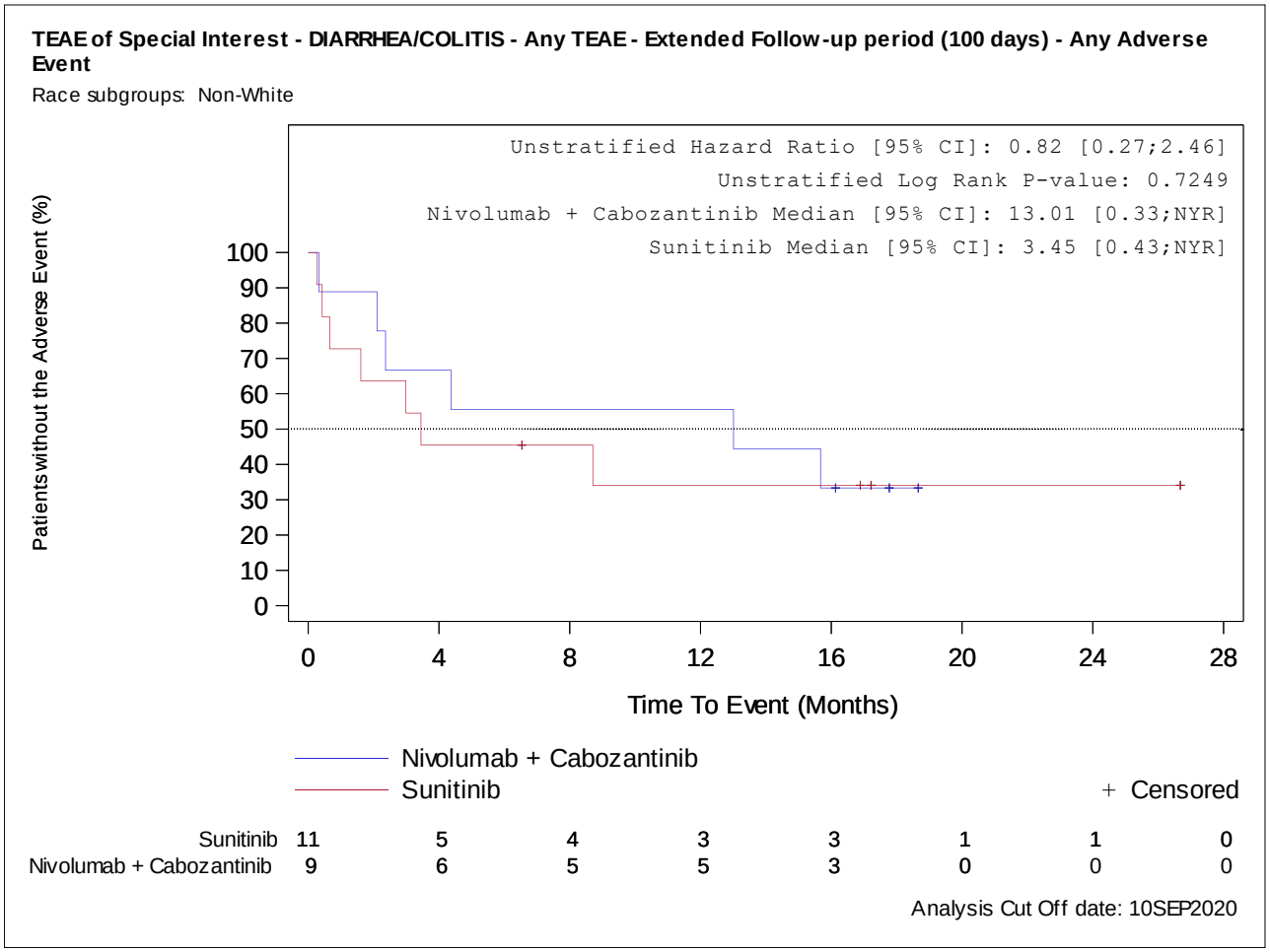

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:24:23

FIGURE 3.72.2.8: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



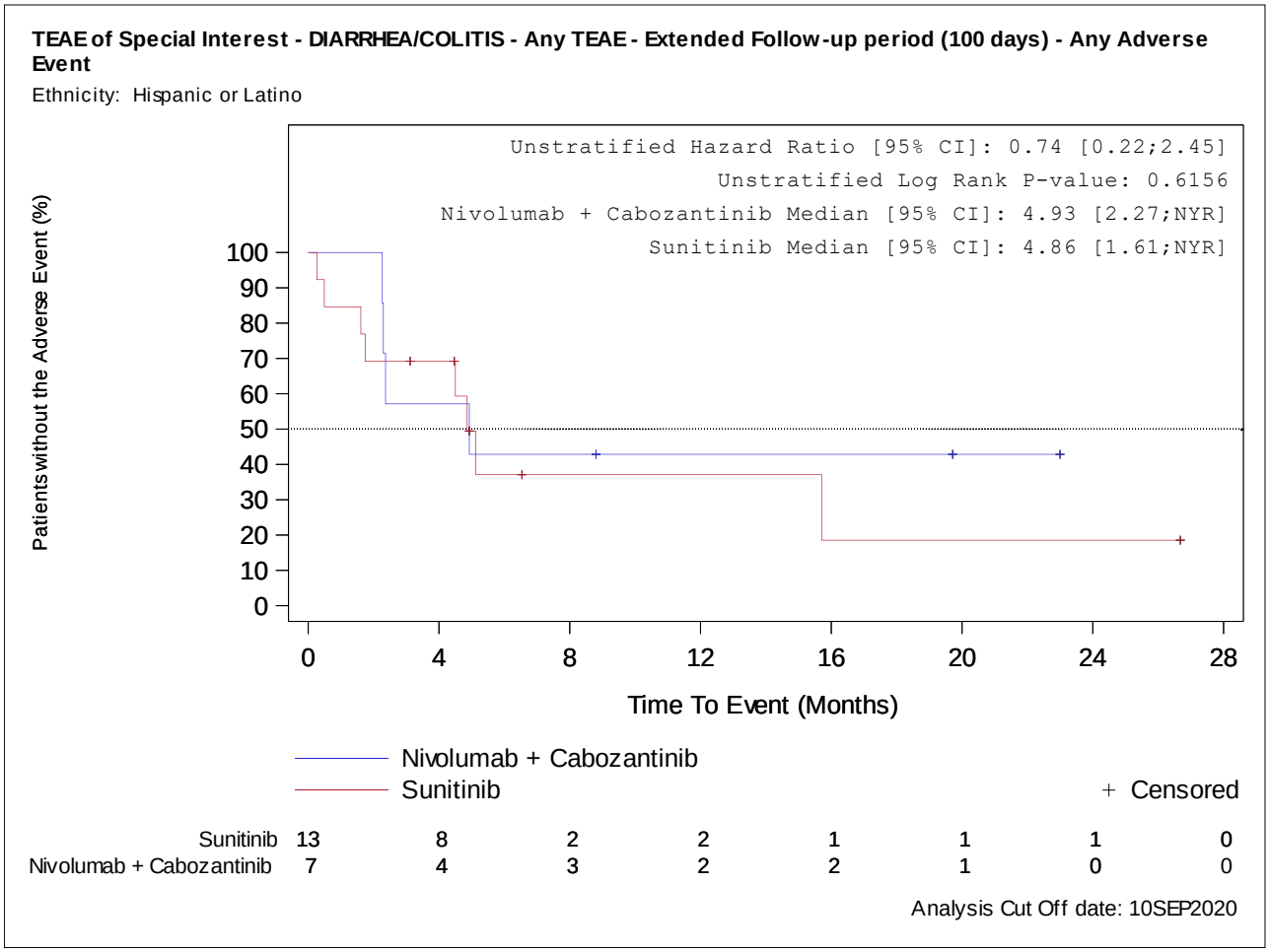

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:24:29

FIGURE 3.72.2.9: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



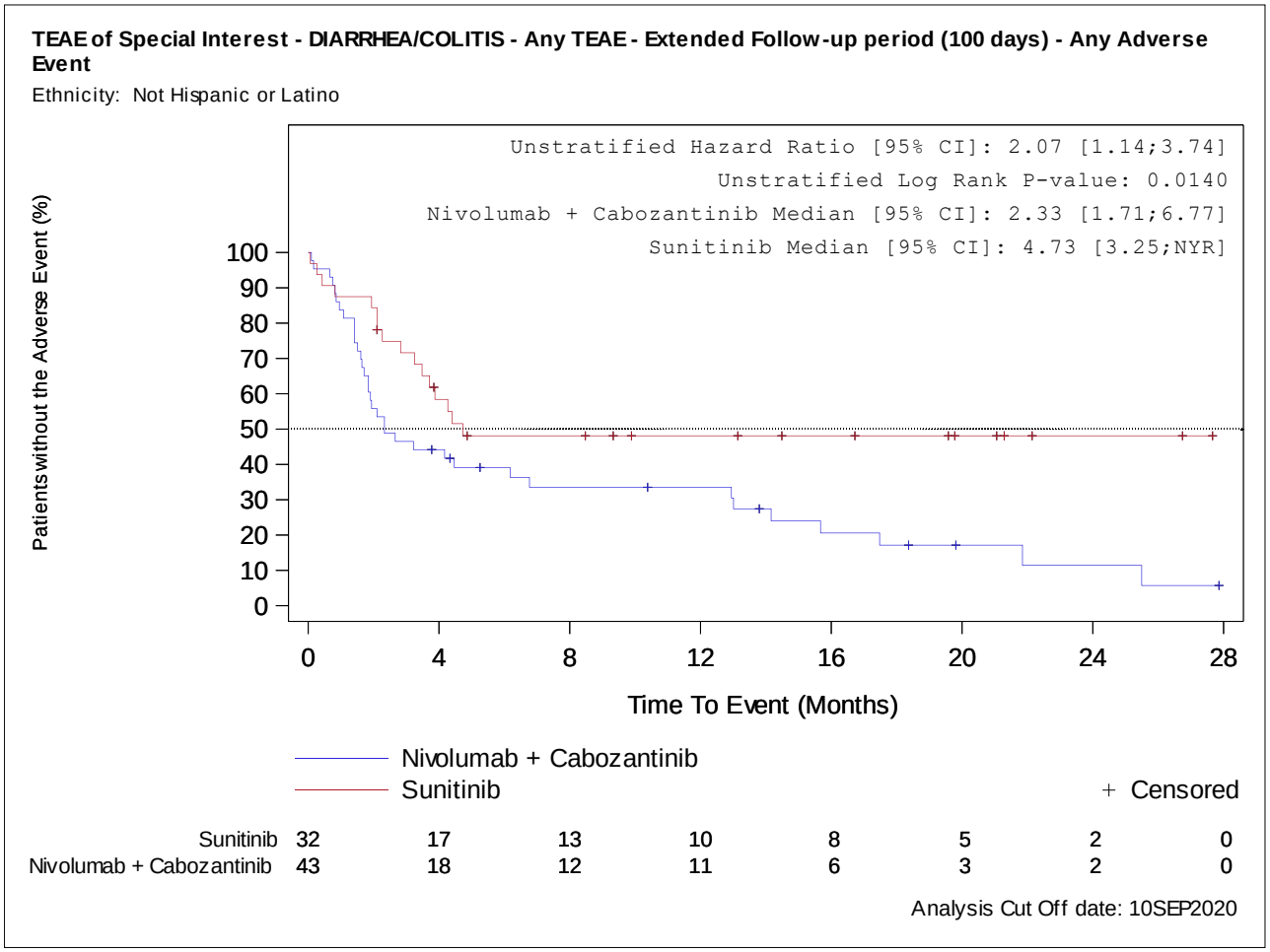

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:24:35

FIGURE 3.72.2.10: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



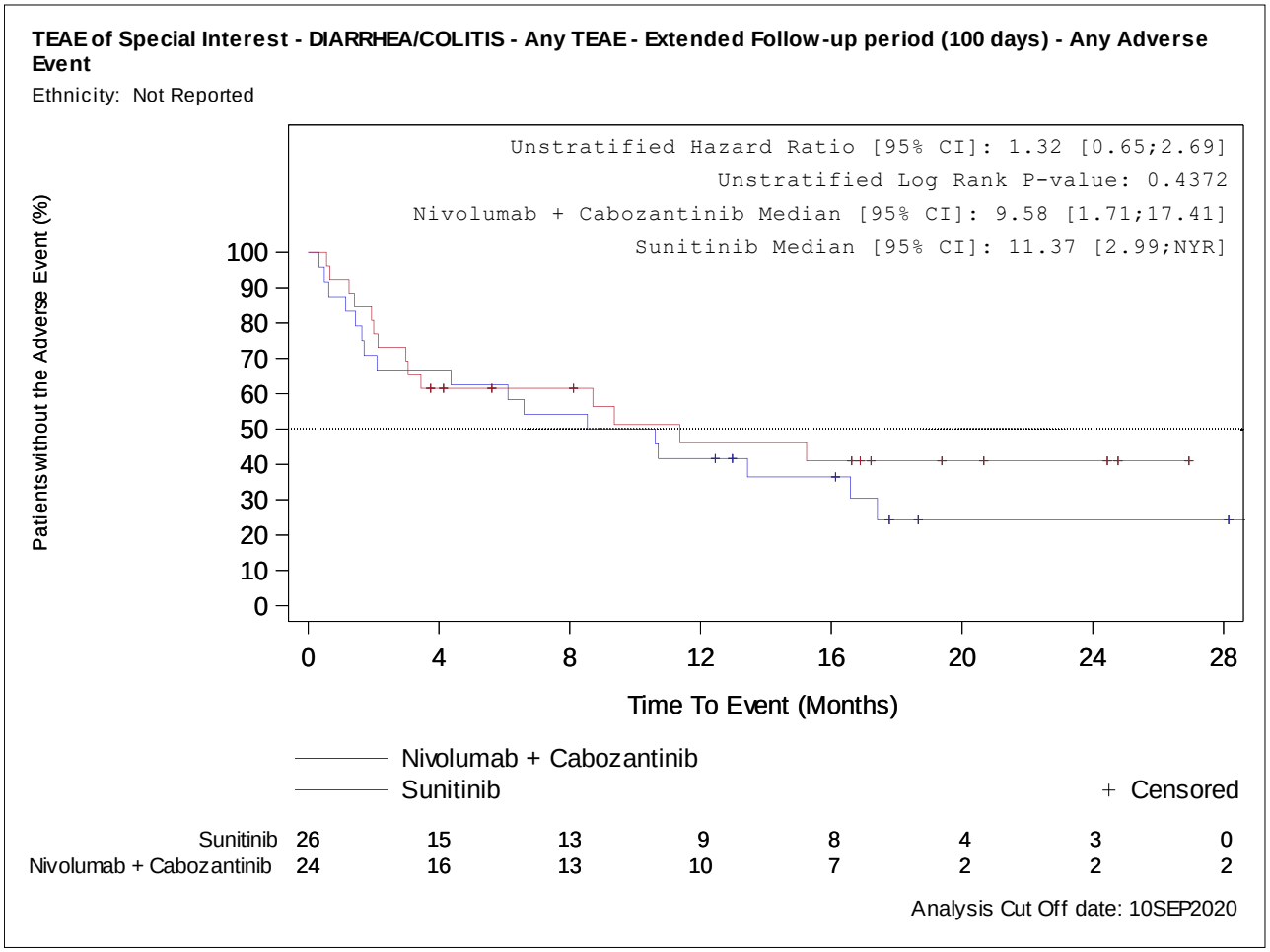

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:24:41

FIGURE 3.72.2.11: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:24:47

FIGURE 3.72.2.12: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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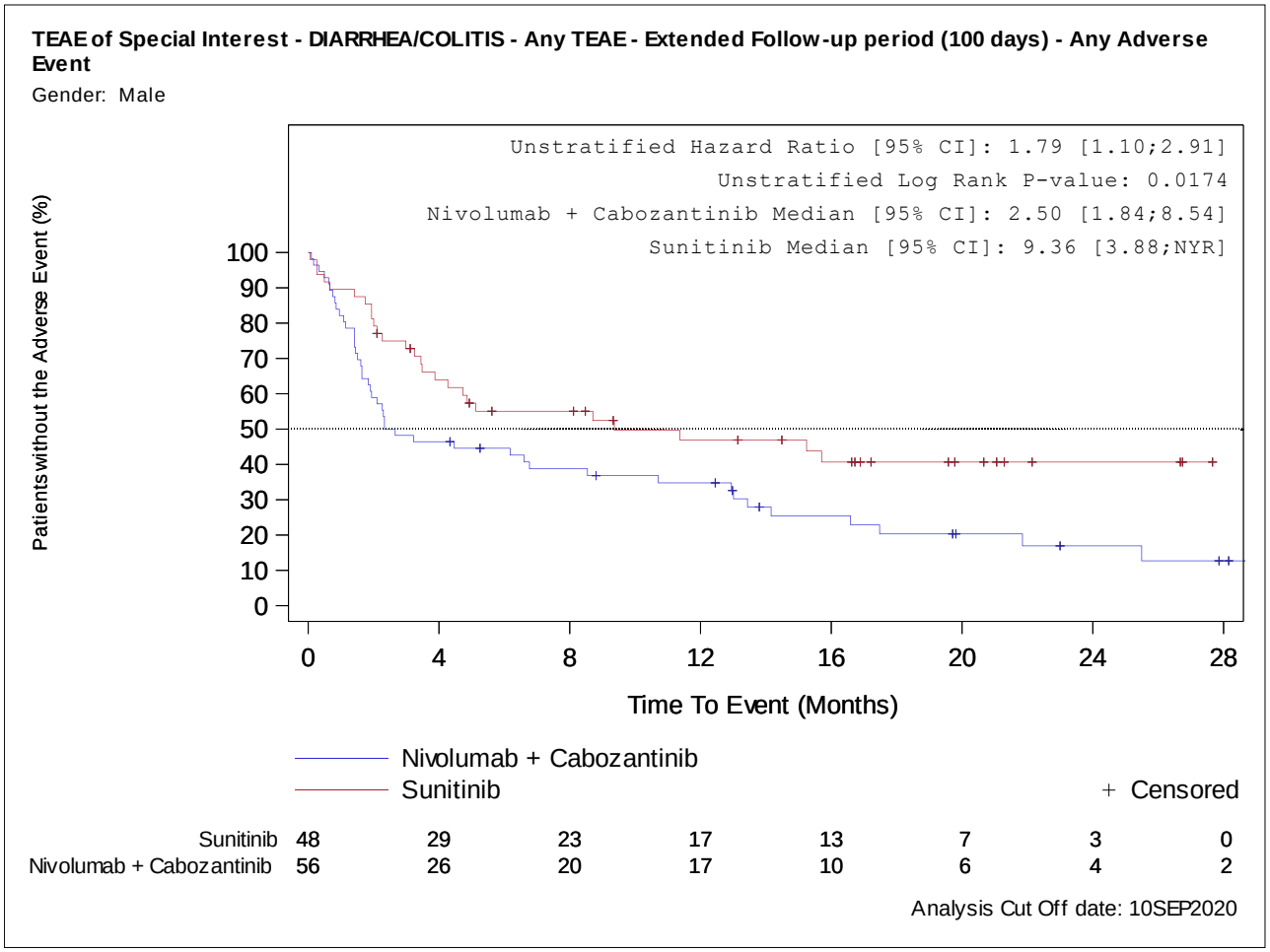
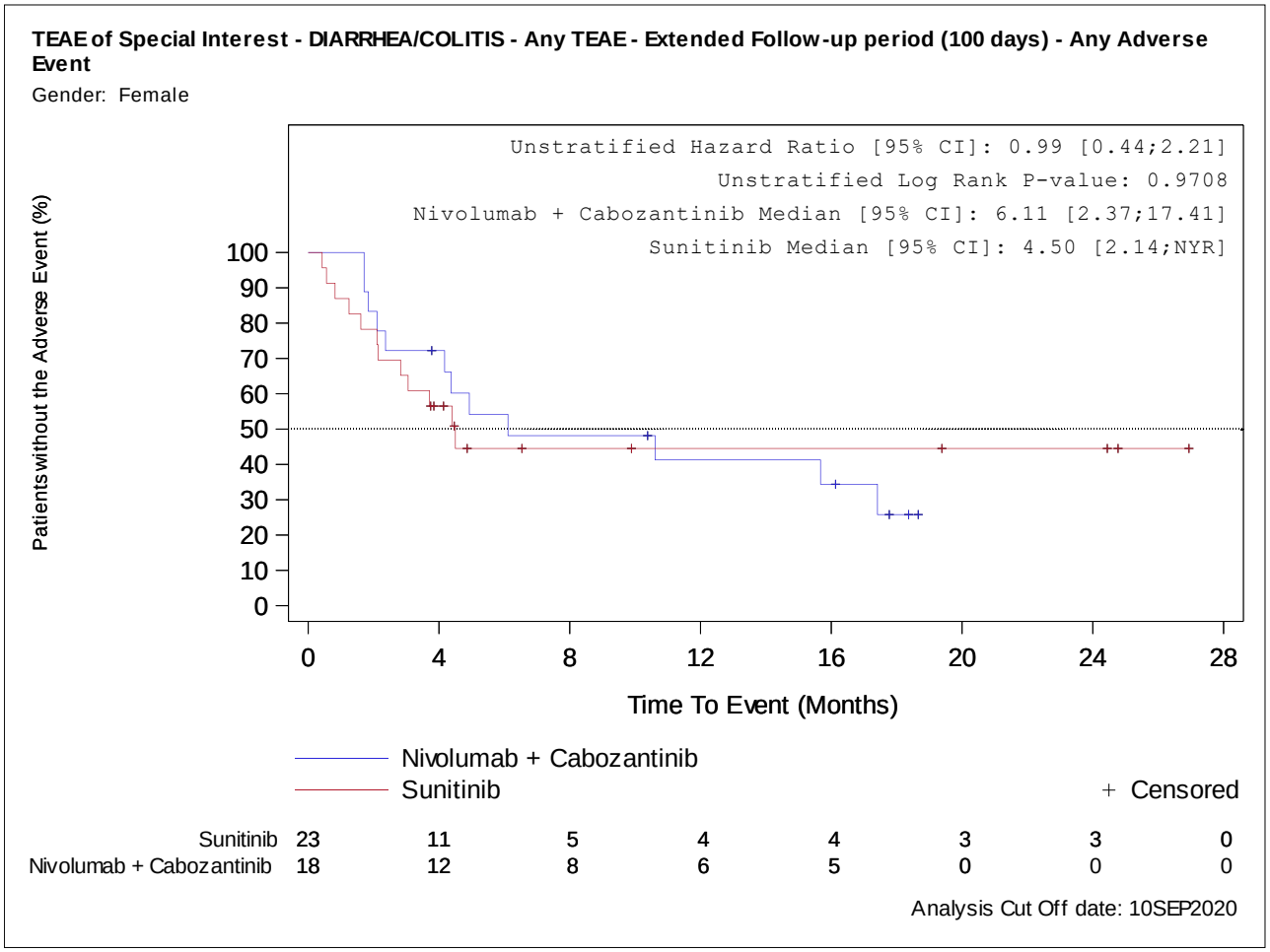
FIGURE 3.72.2.13: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



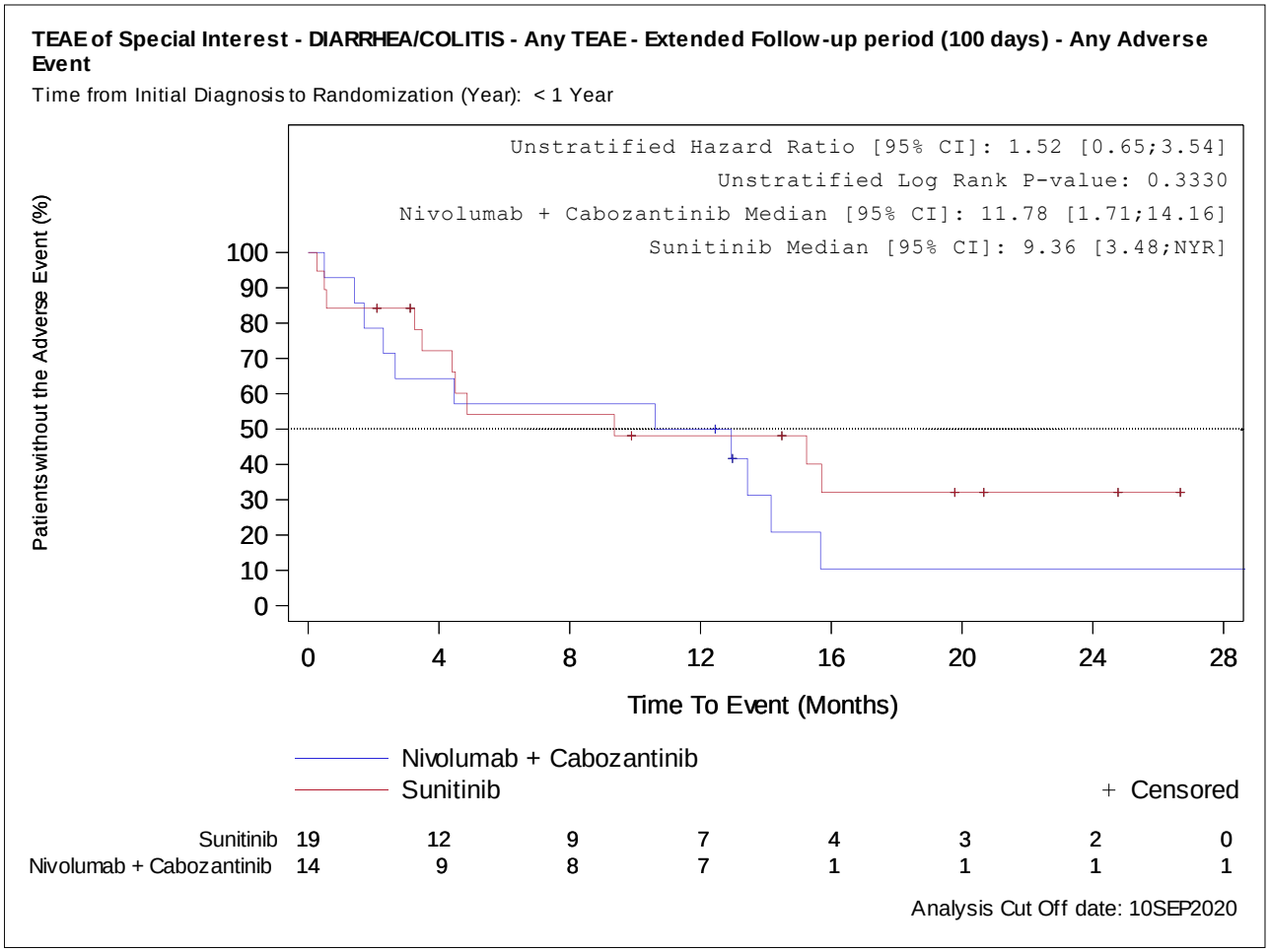

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:25:00

FIGURE 3.72.2.14: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



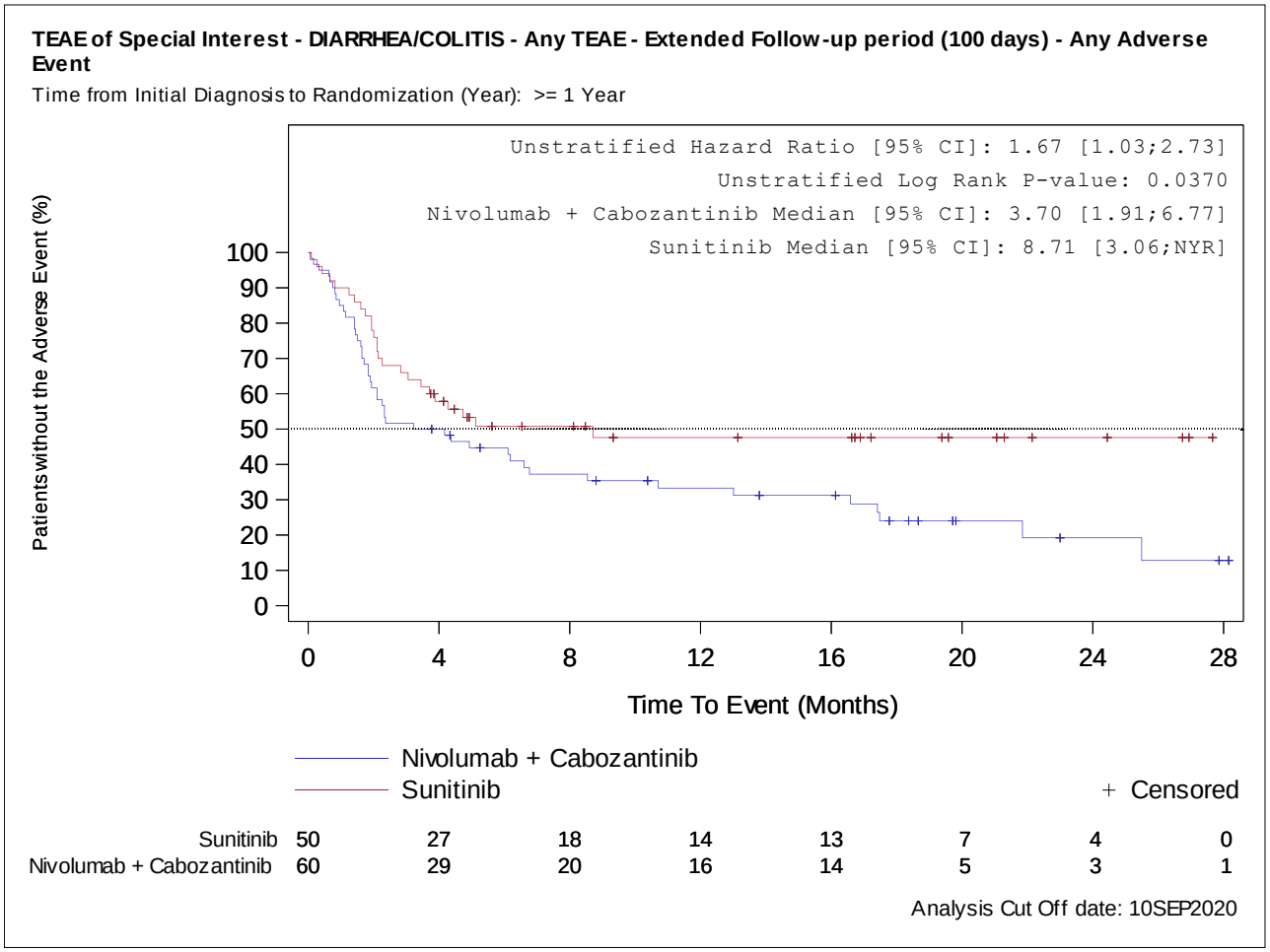

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:25:06

FIGURE 3.72.2.15: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



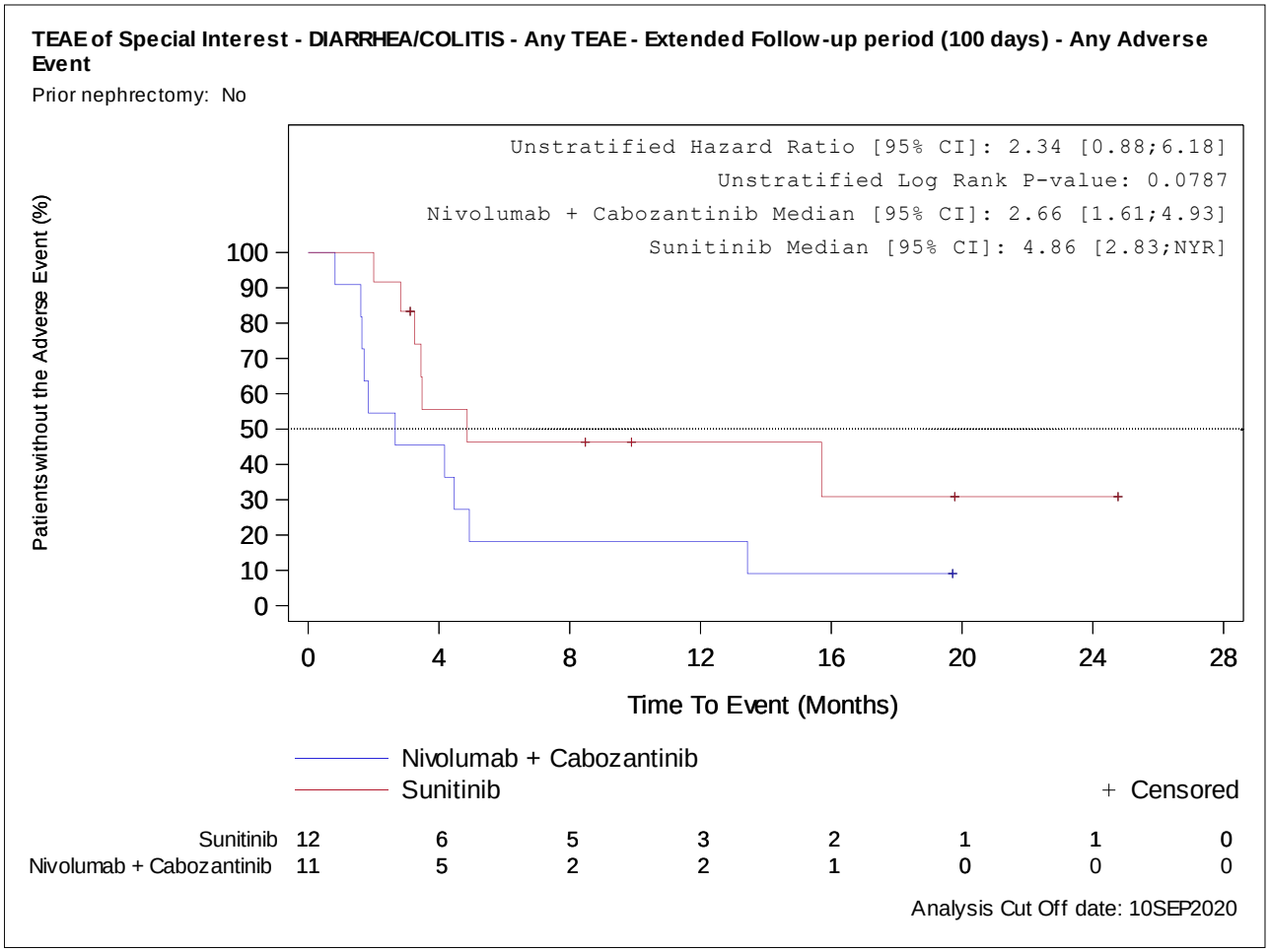

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:25:24

FIGURE 3.72.2.16: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



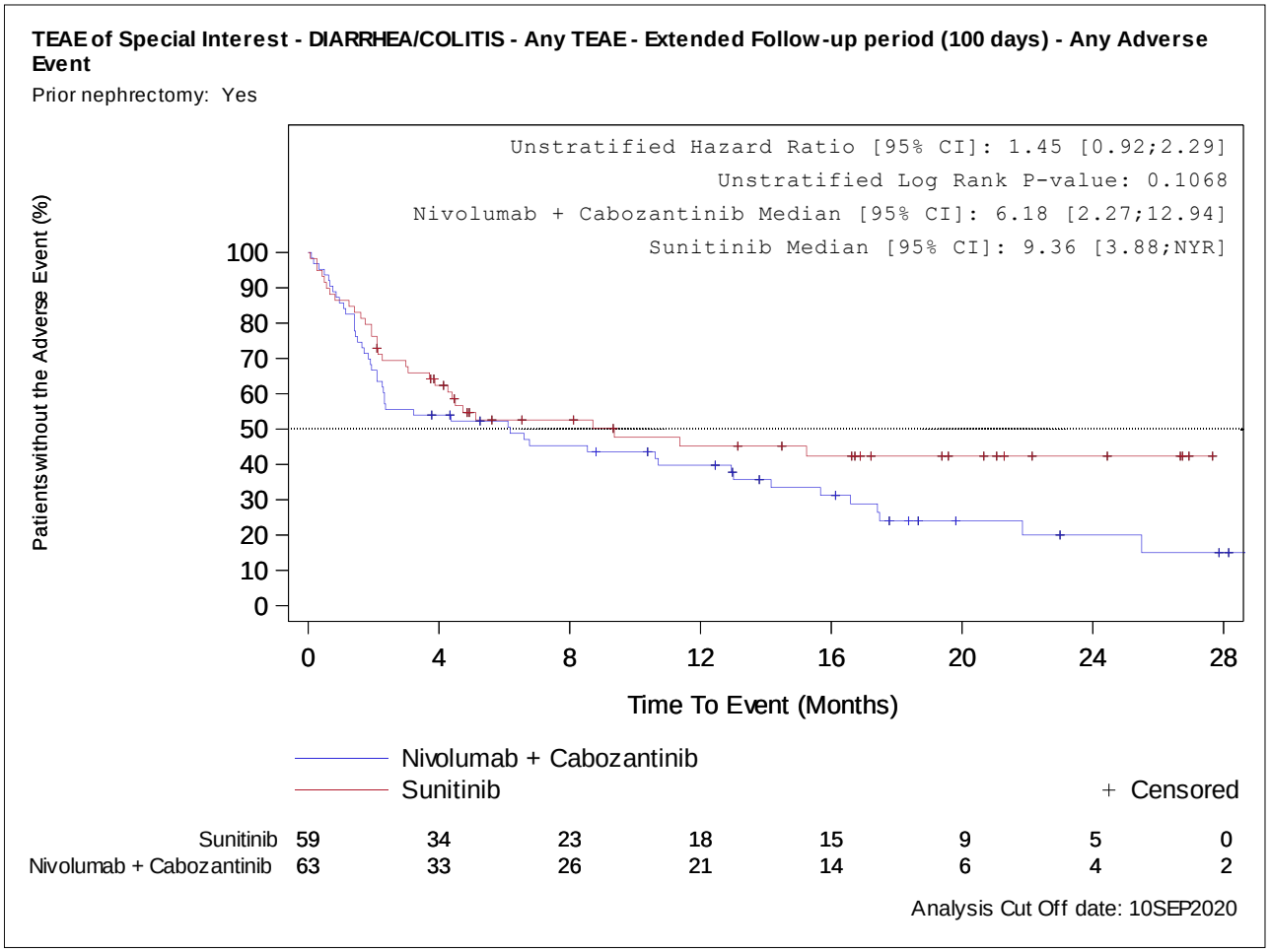

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:25:29

FIGURE 3.72.2.17: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



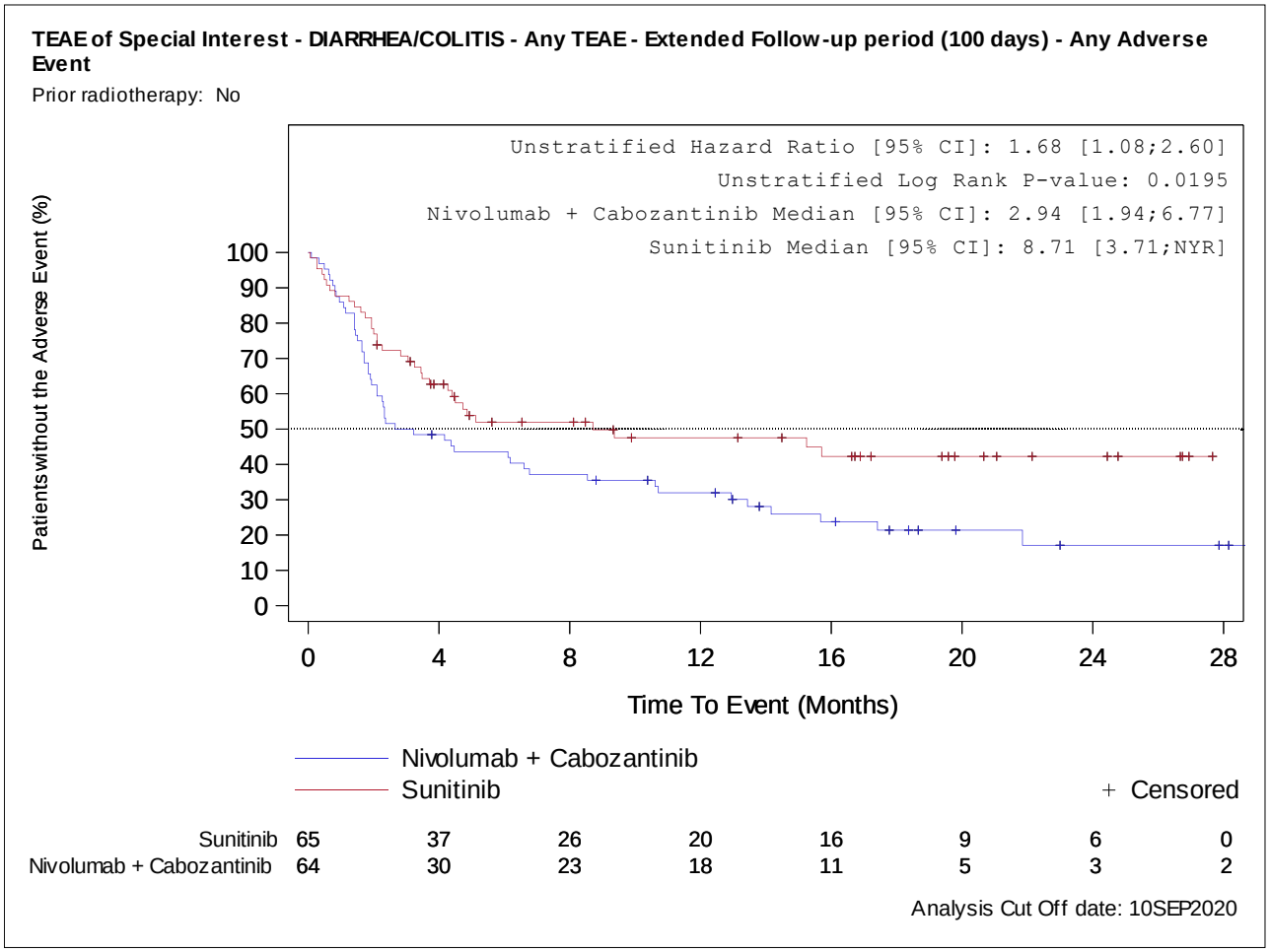

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:26:21

FIGURE 3.72.2.18: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



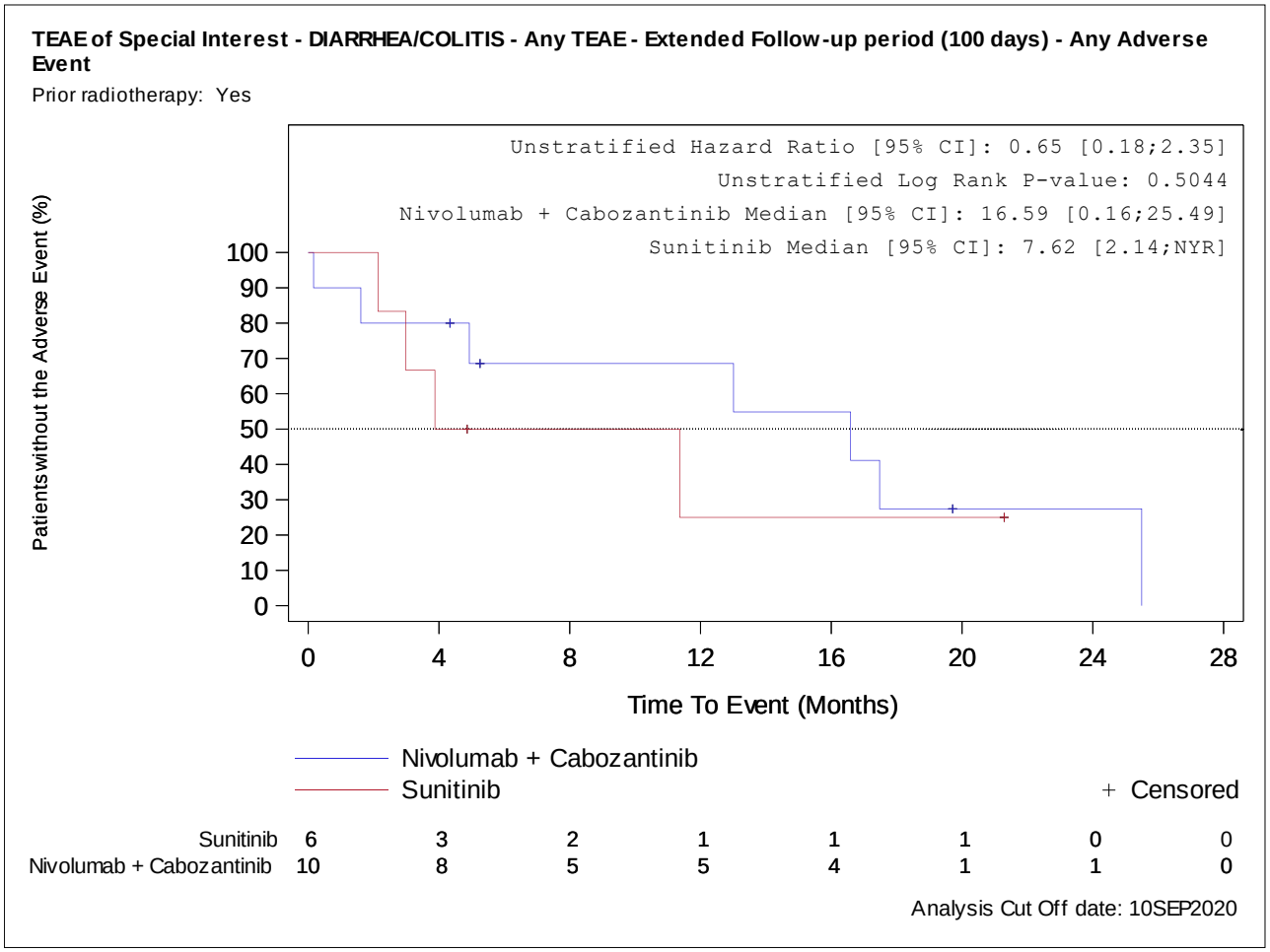

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:26:27

FIGURE 3.72.2.19: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



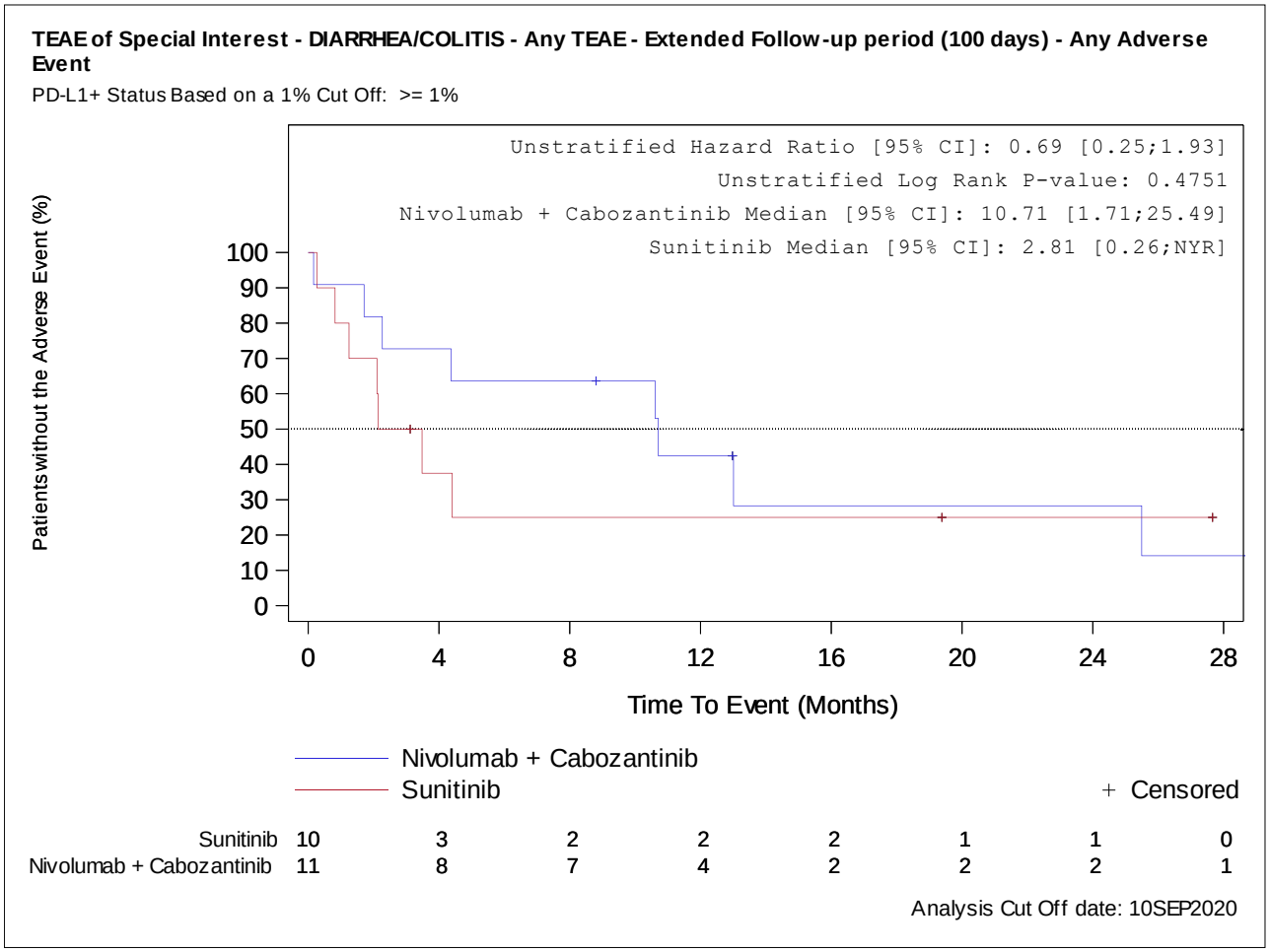

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:26:32

FIGURE 3.72.2.20: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



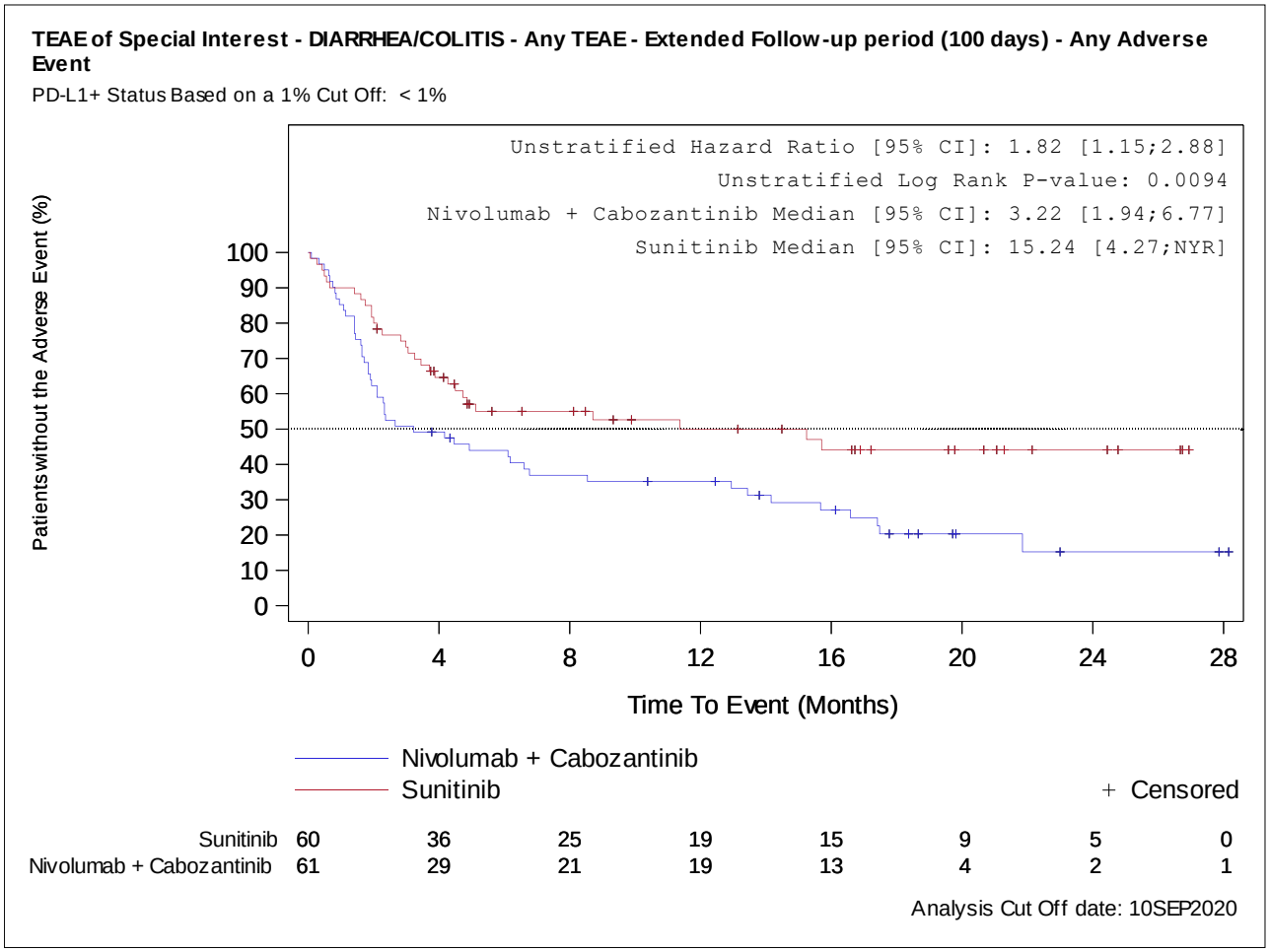

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:26:38

FIGURE 3.72.2.21: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



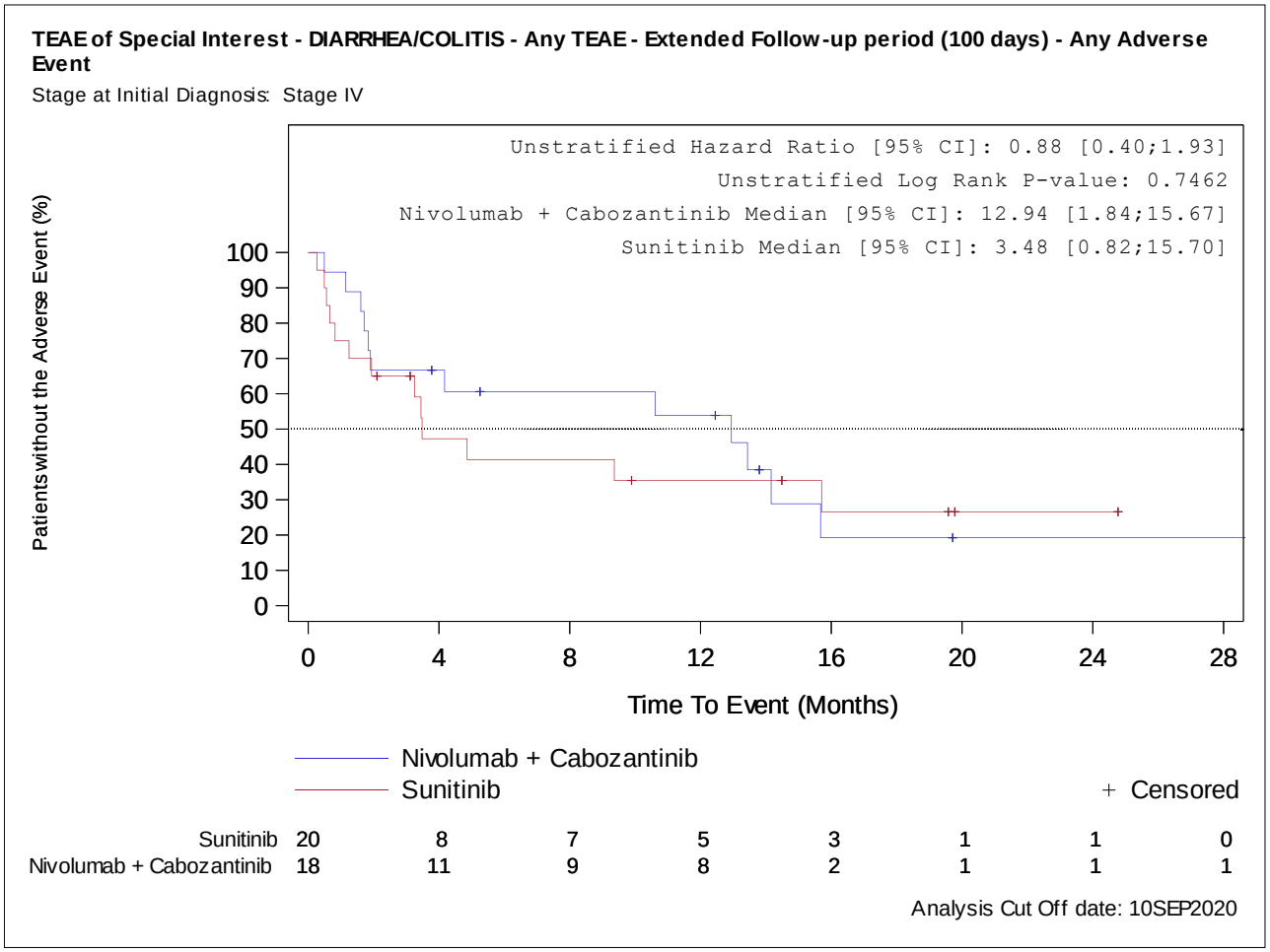

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:26:44

FIGURE 3.72.2.22: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



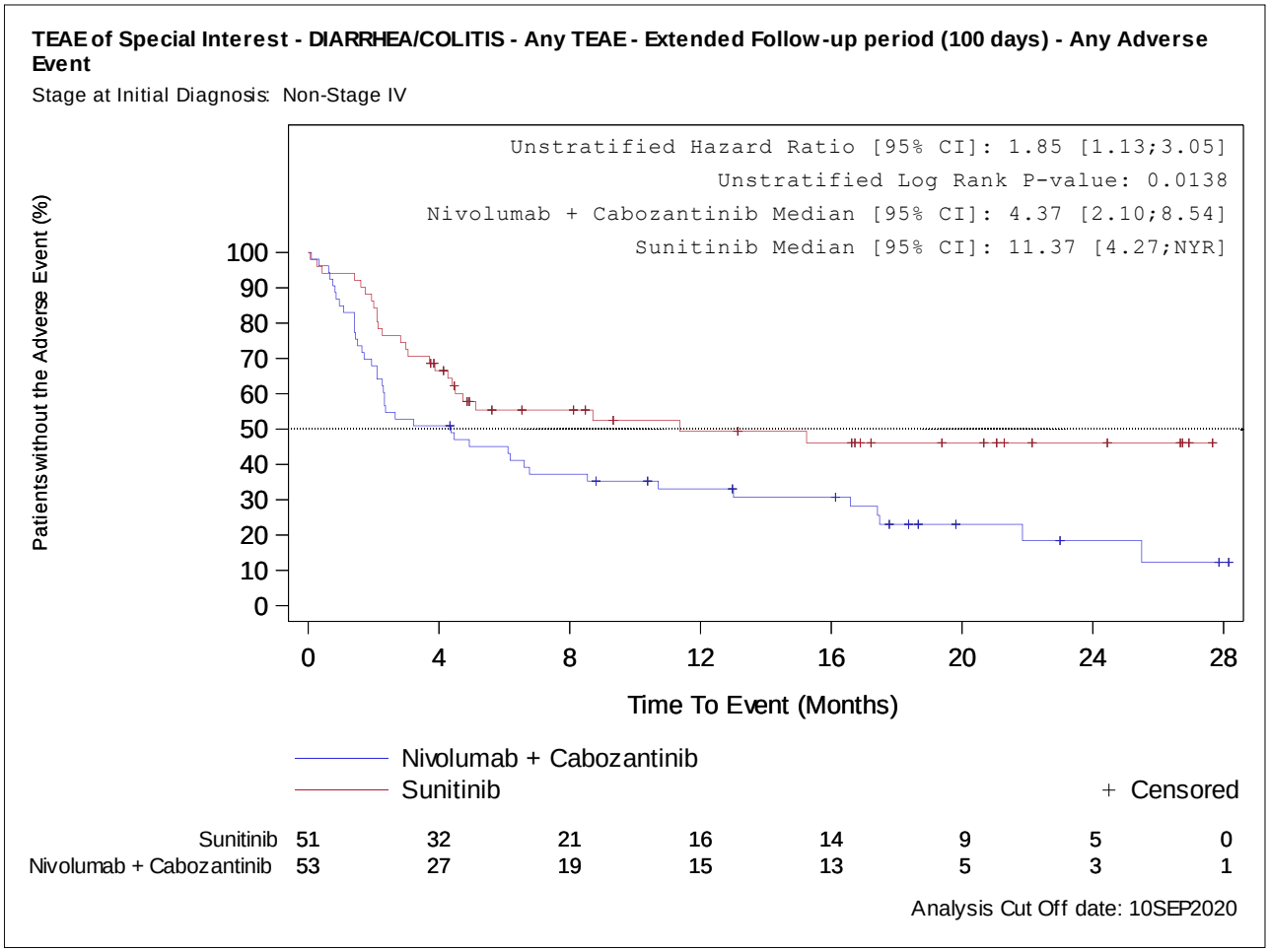

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:26:51

FIGURE 3.72.2.23: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



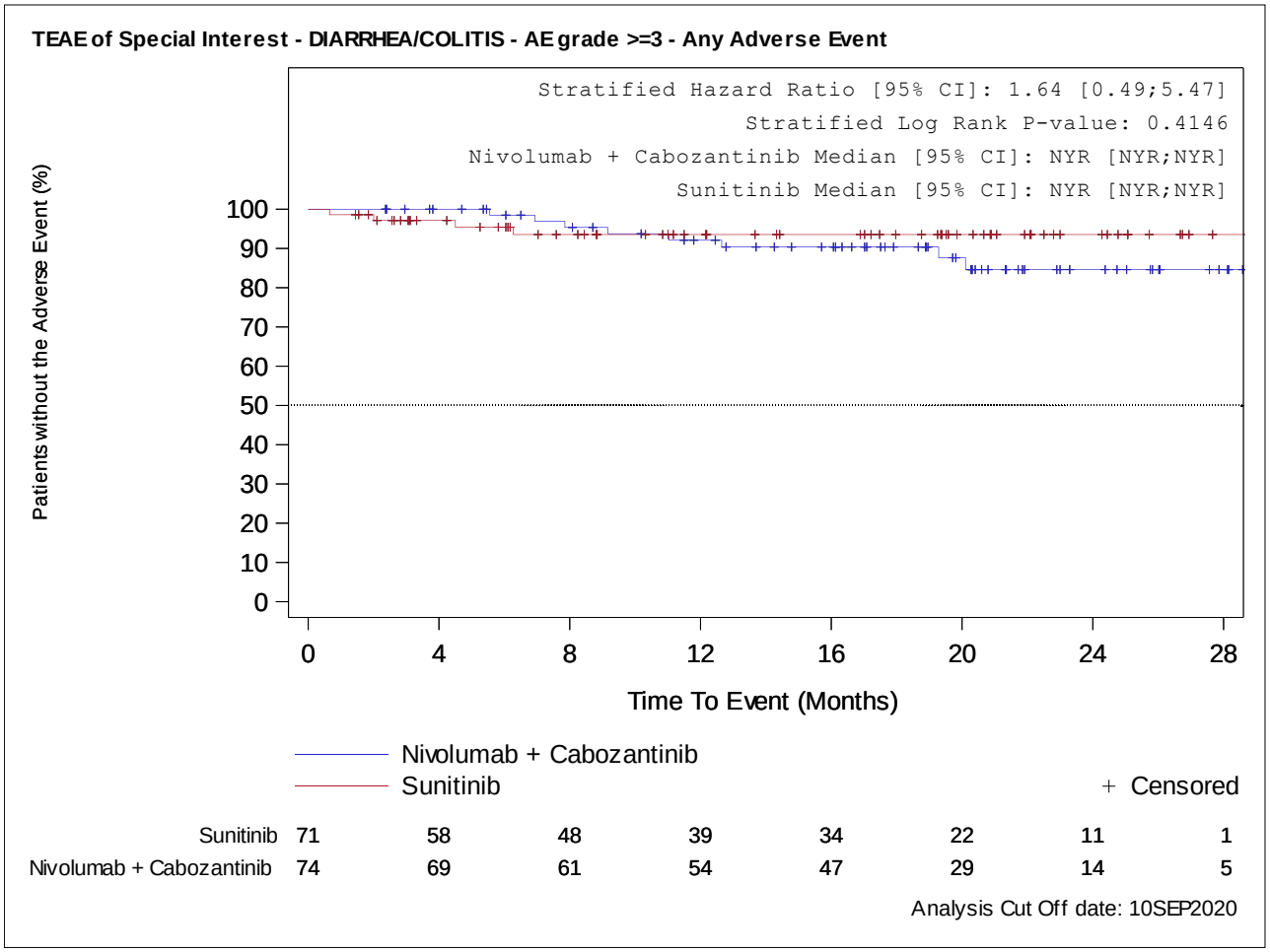

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:27:20

FIGURE 3.72.2.24: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



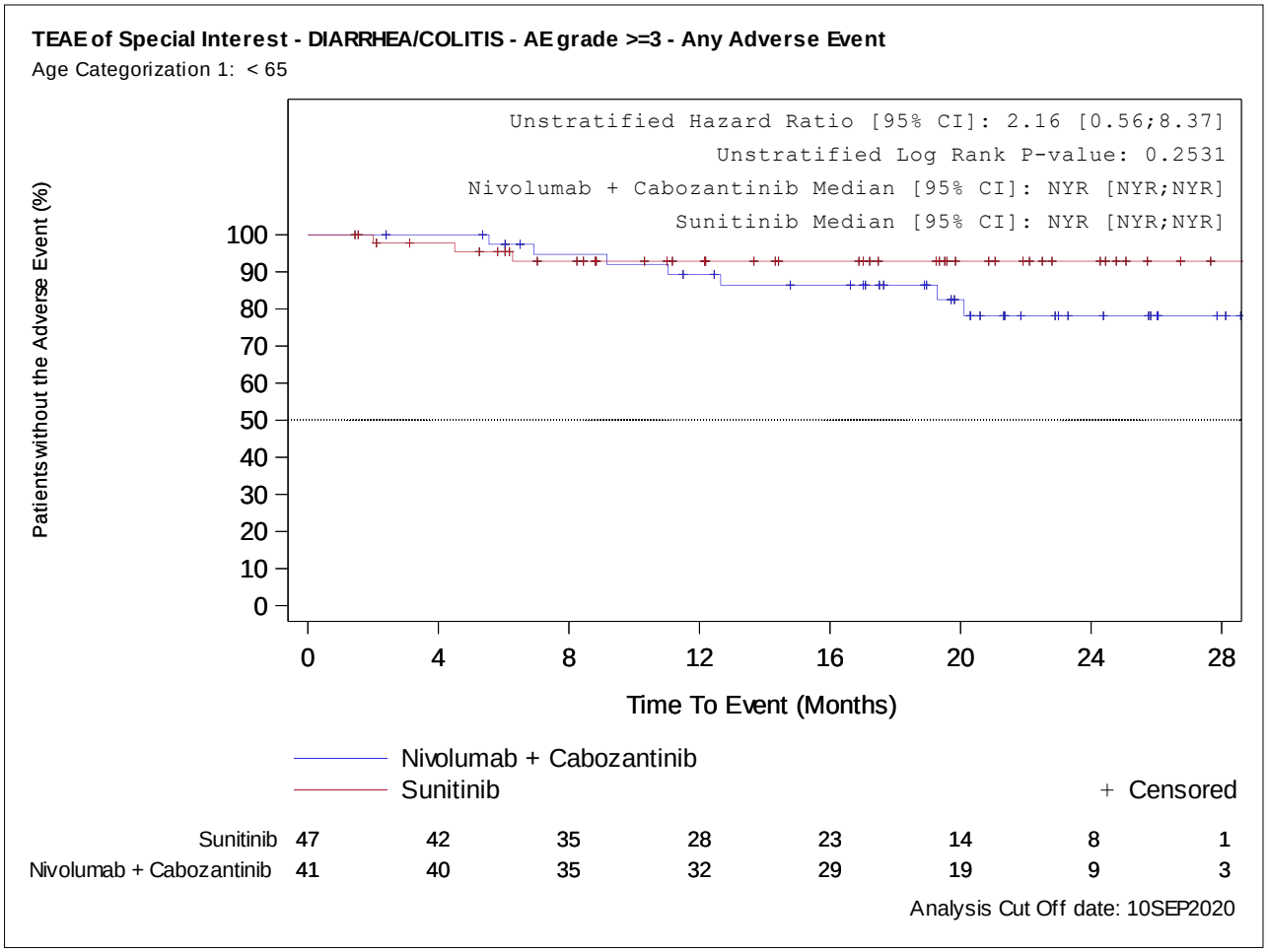

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:27:25

FIGURE 3.73.1: TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



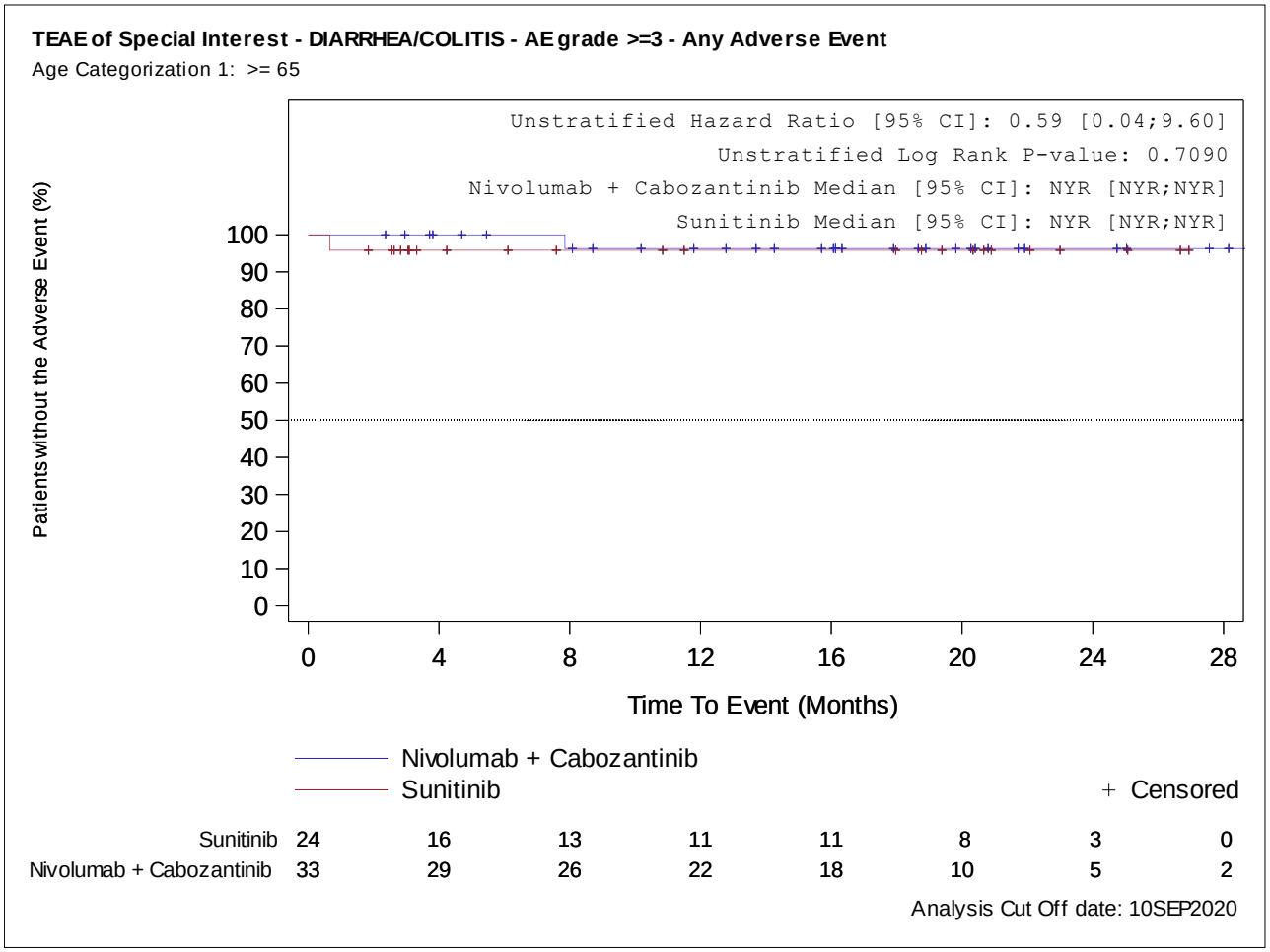

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:30:39

FIGURE 3.73.2.1: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



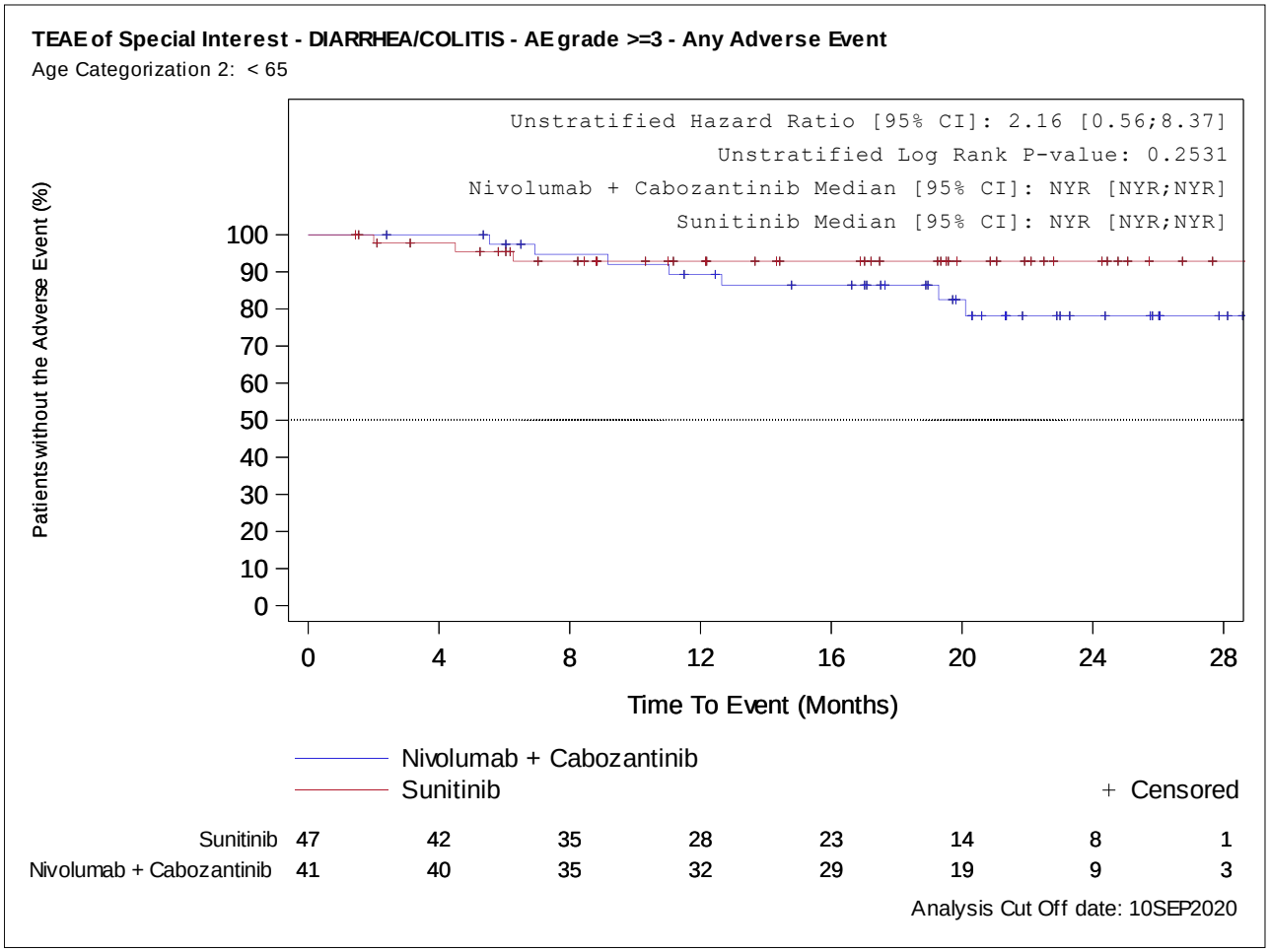

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:30:43

FIGURE 3.73.2.2: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



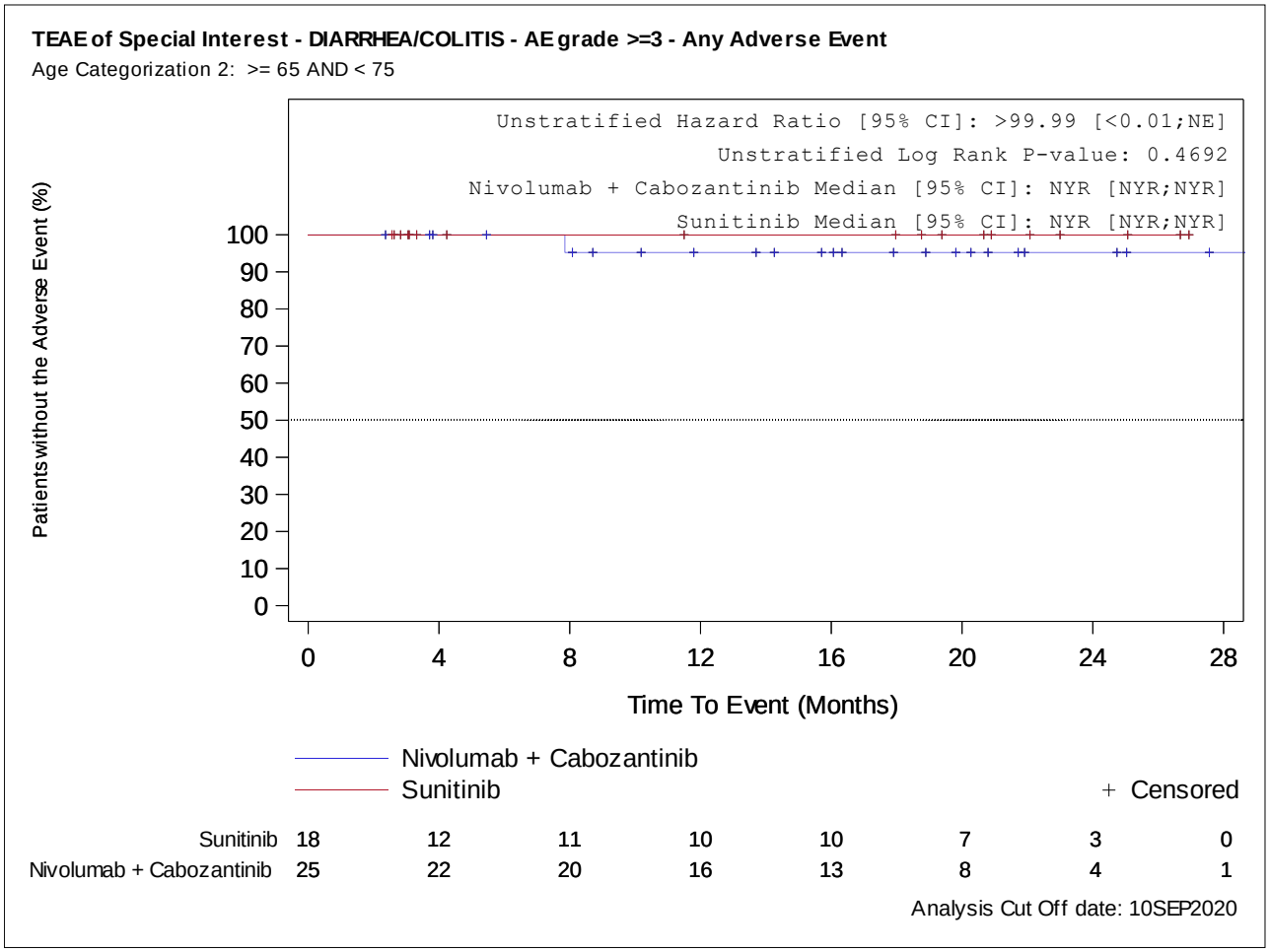

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:30:49

FIGURE 3.73.2.3: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



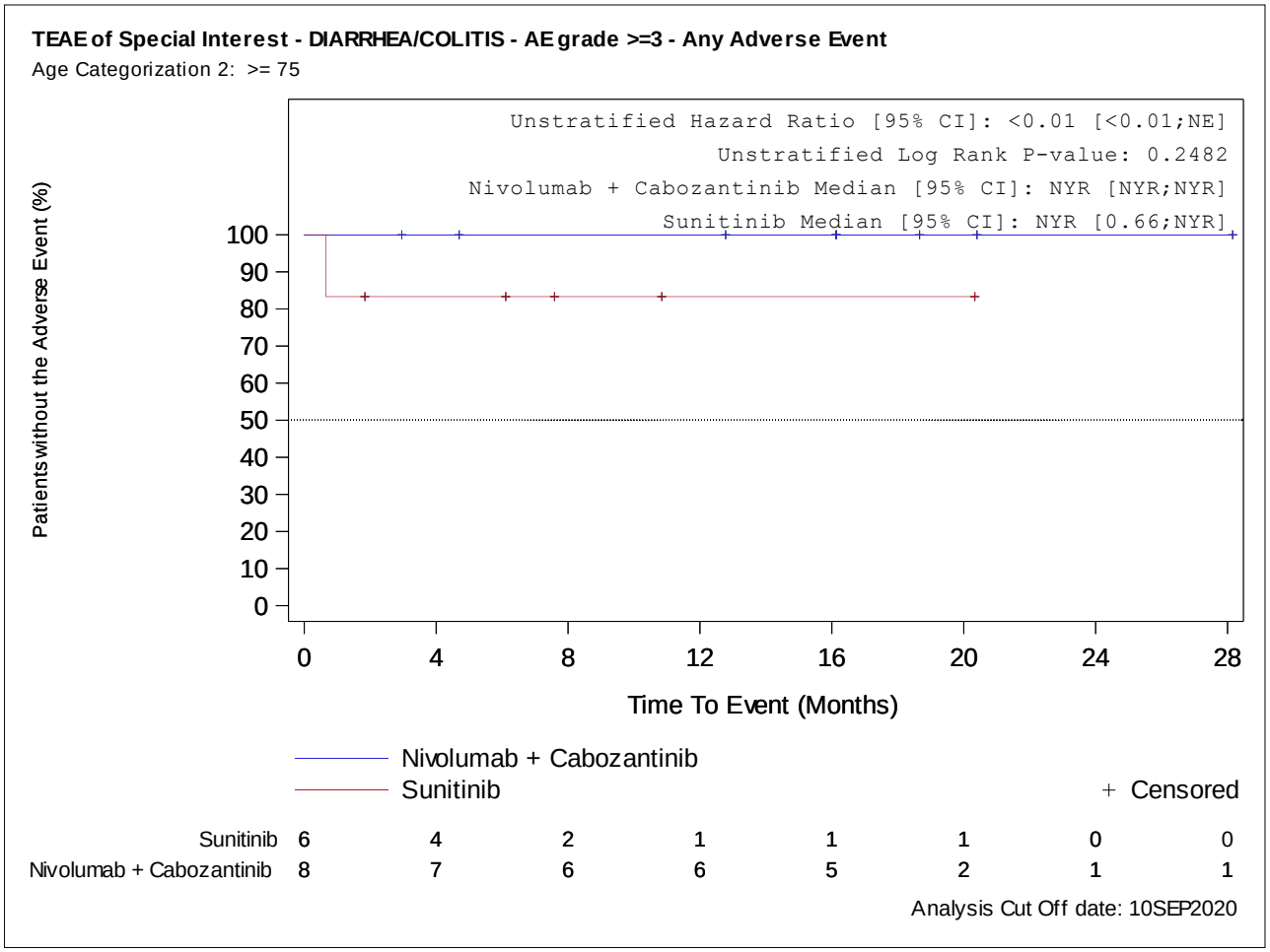

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:30:55

FIGURE 3.73.2.4: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



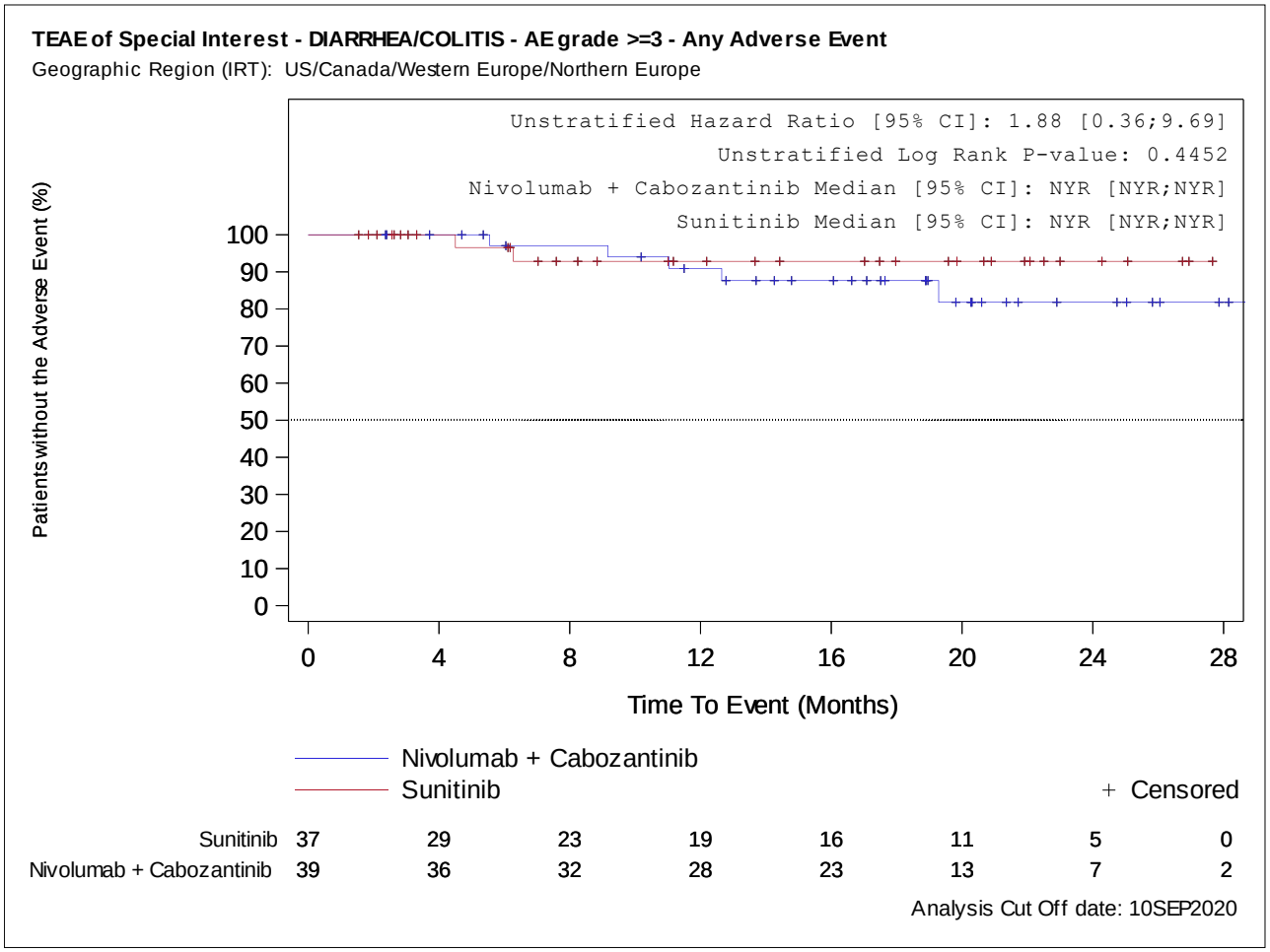

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:31:01

FIGURE 3.73.2.5: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



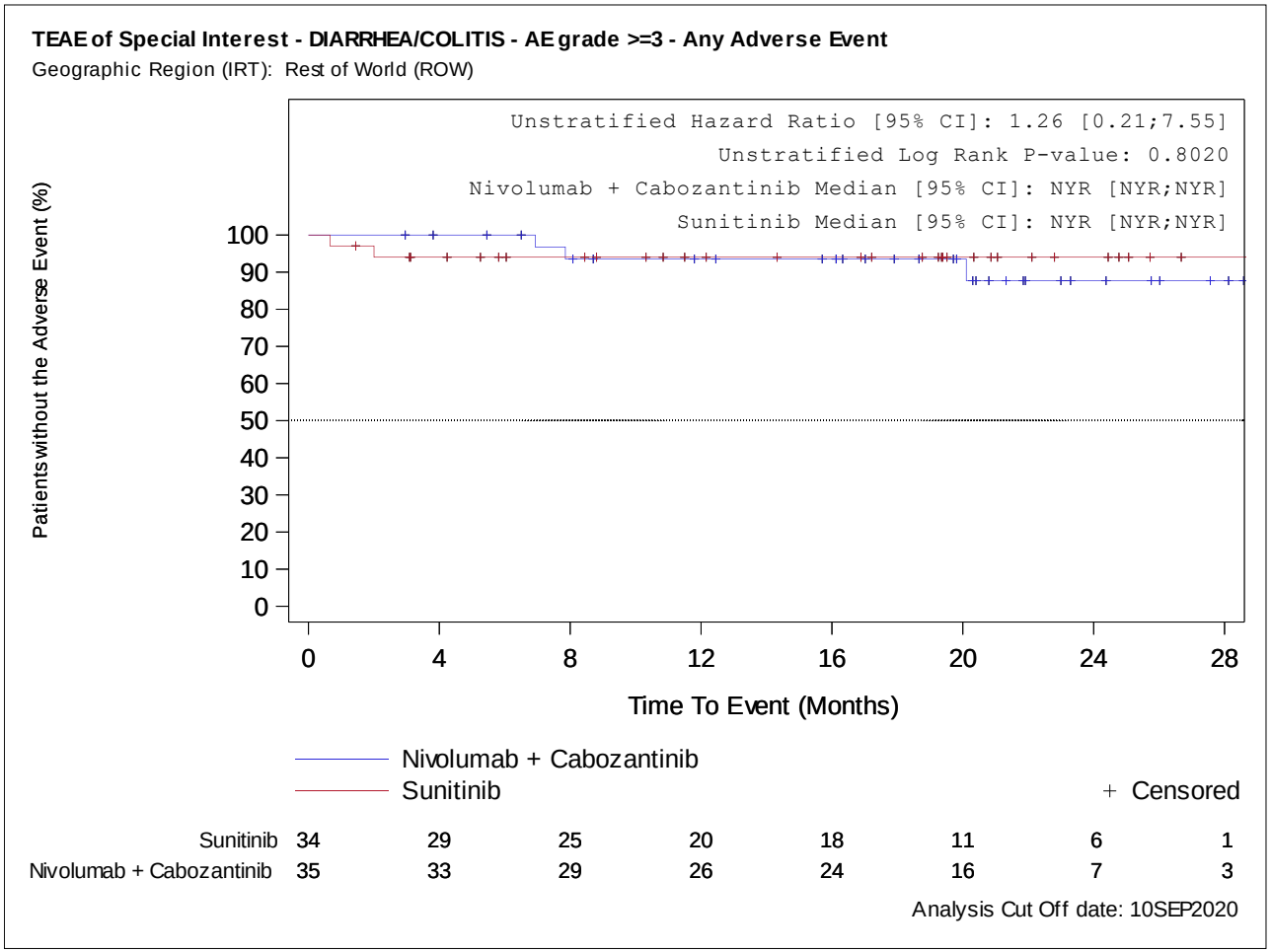

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:31:06

FIGURE 3.73.2.6: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



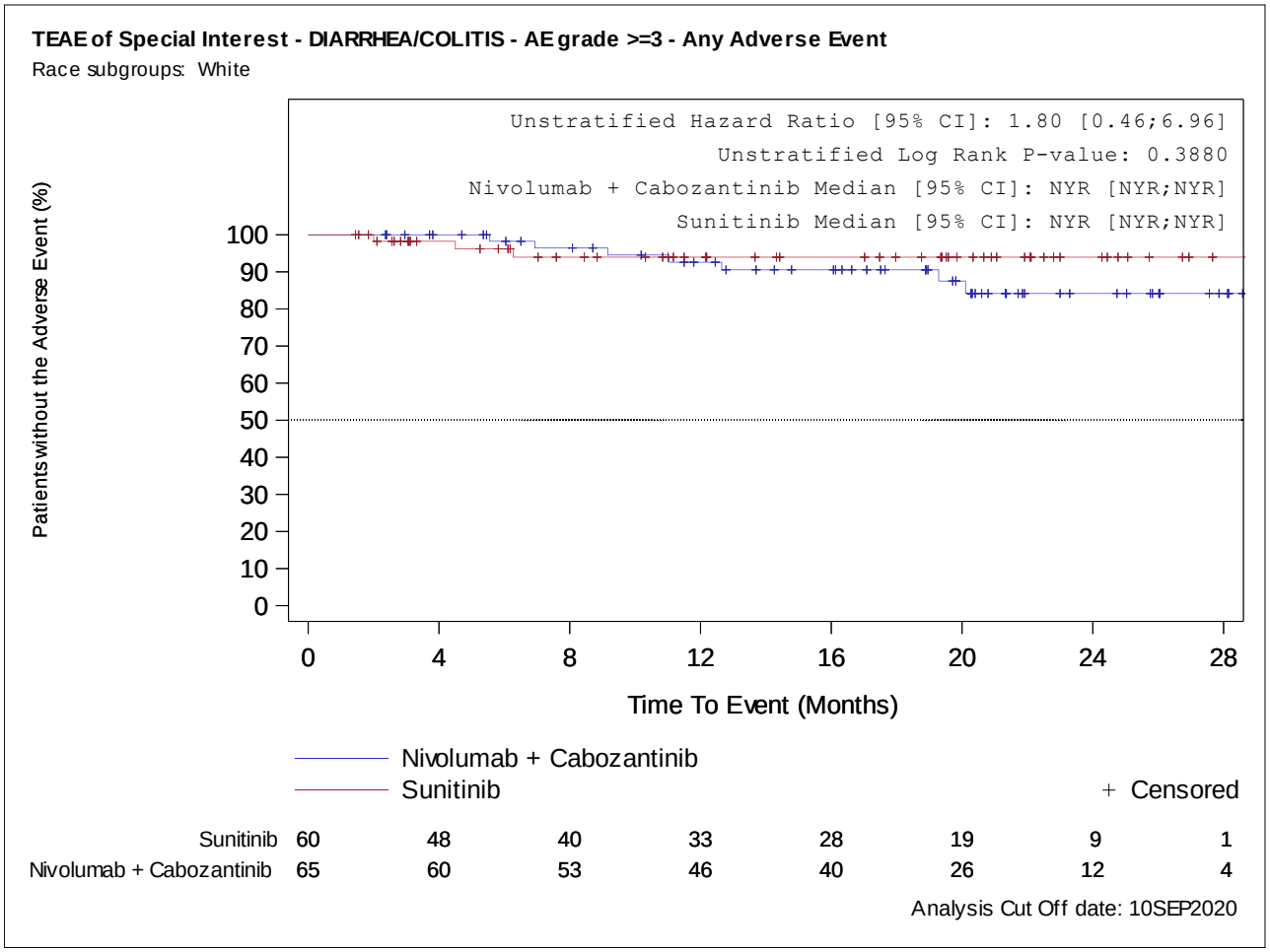

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:31:11

FIGURE 3.73.2.7: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



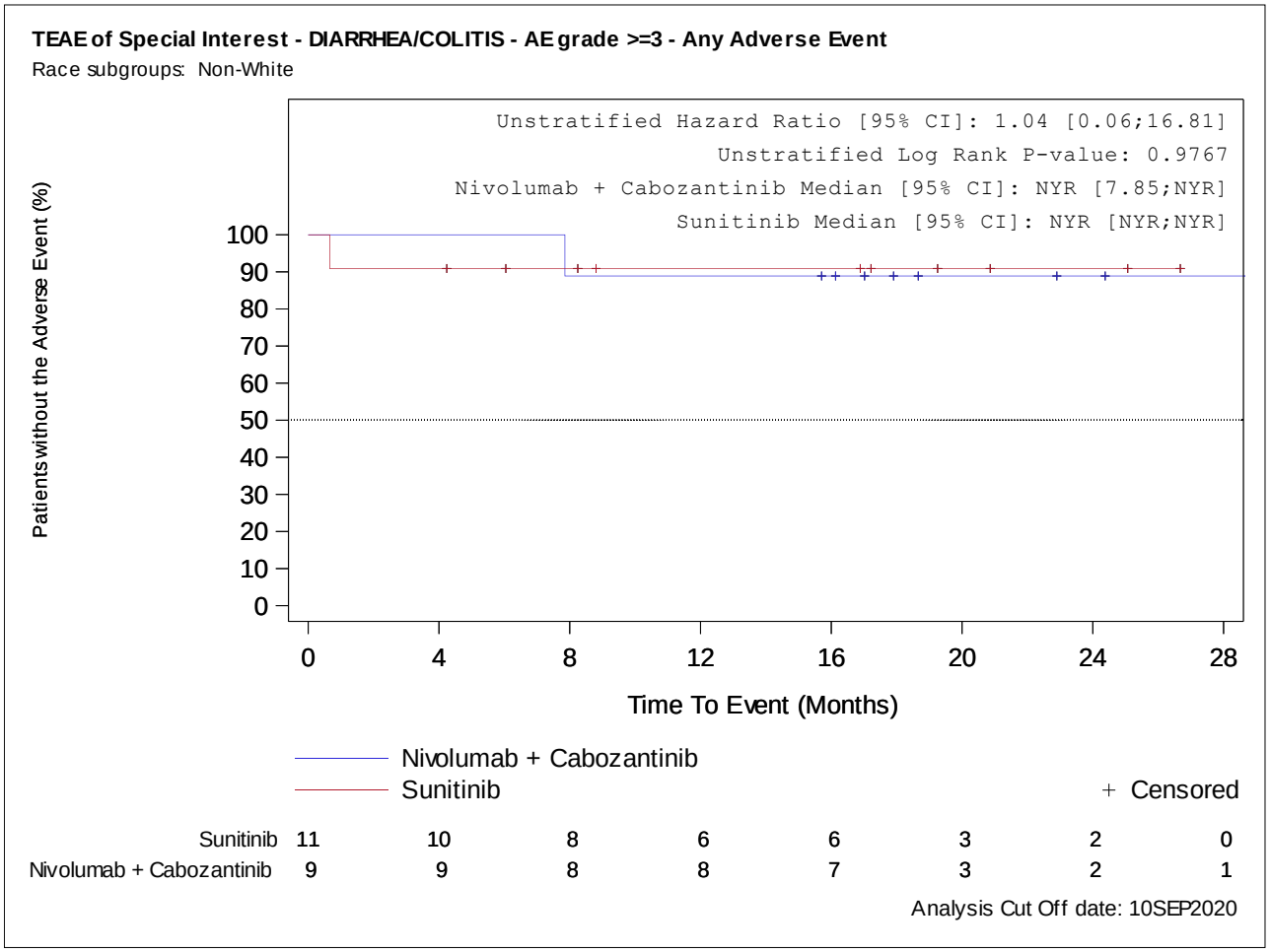

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:31:16

FIGURE 3.73.2.8: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



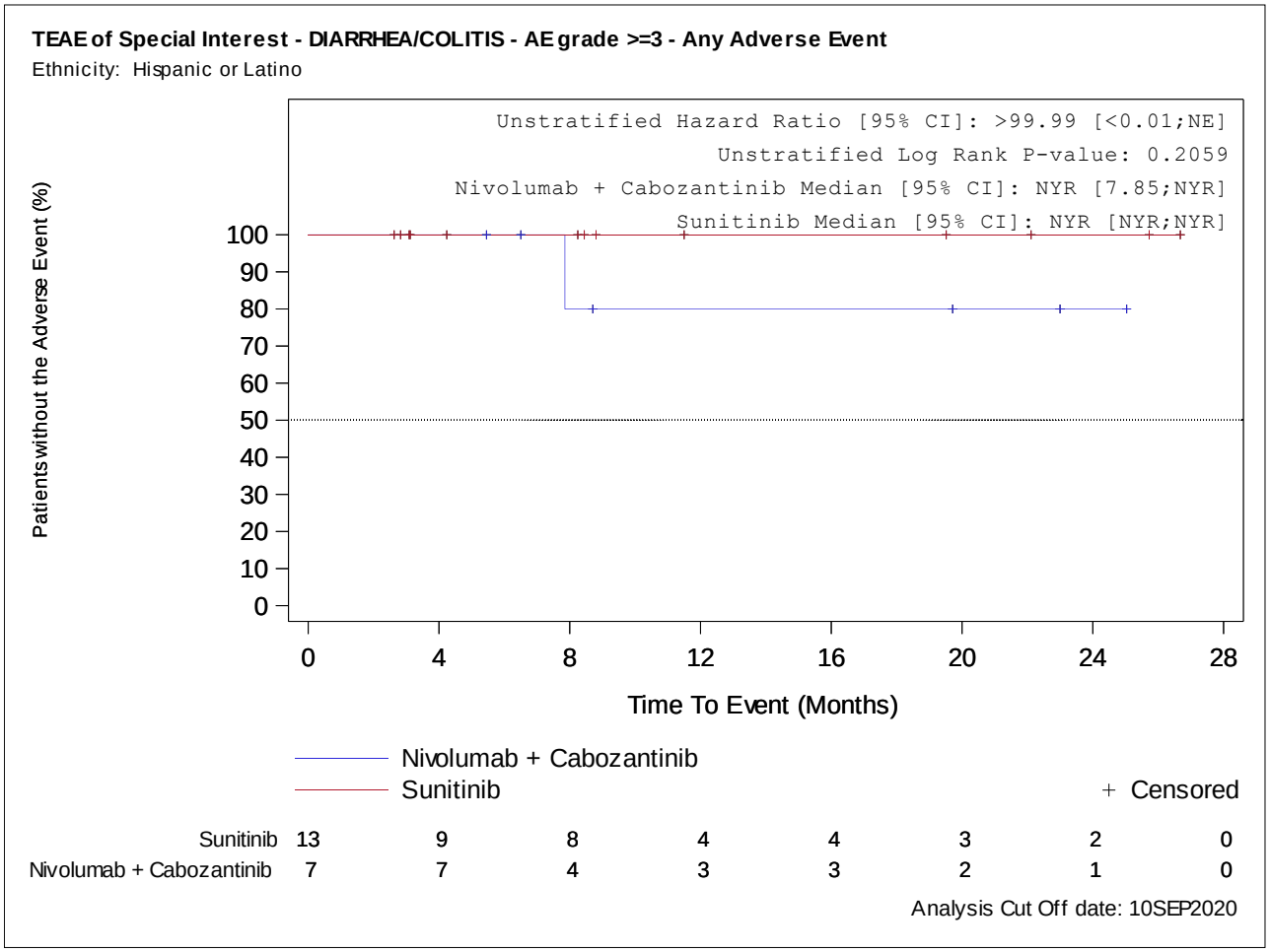

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:31:22

FIGURE 3.73.2.9: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



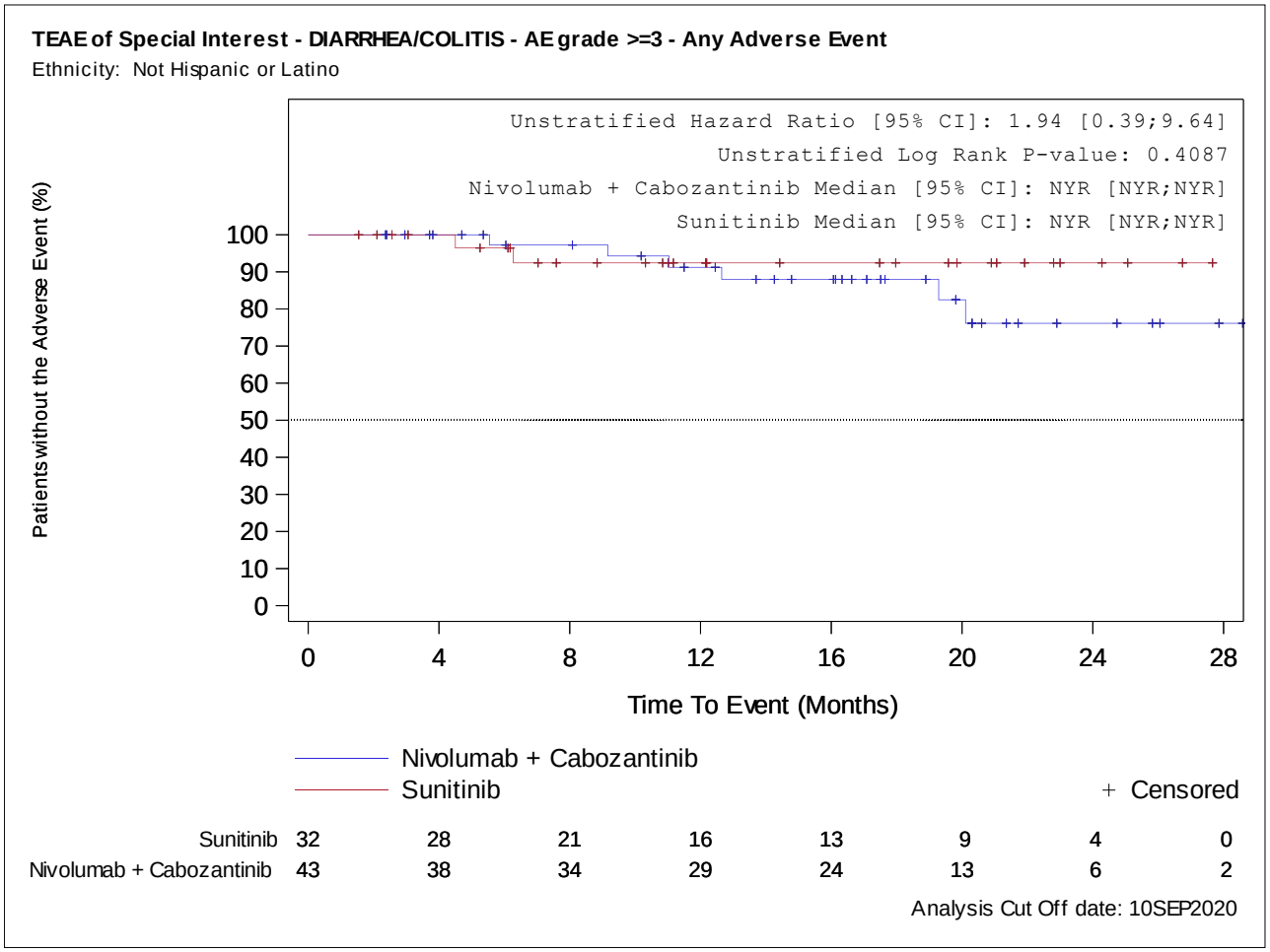

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:31:28

FIGURE 3.73.2.10: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



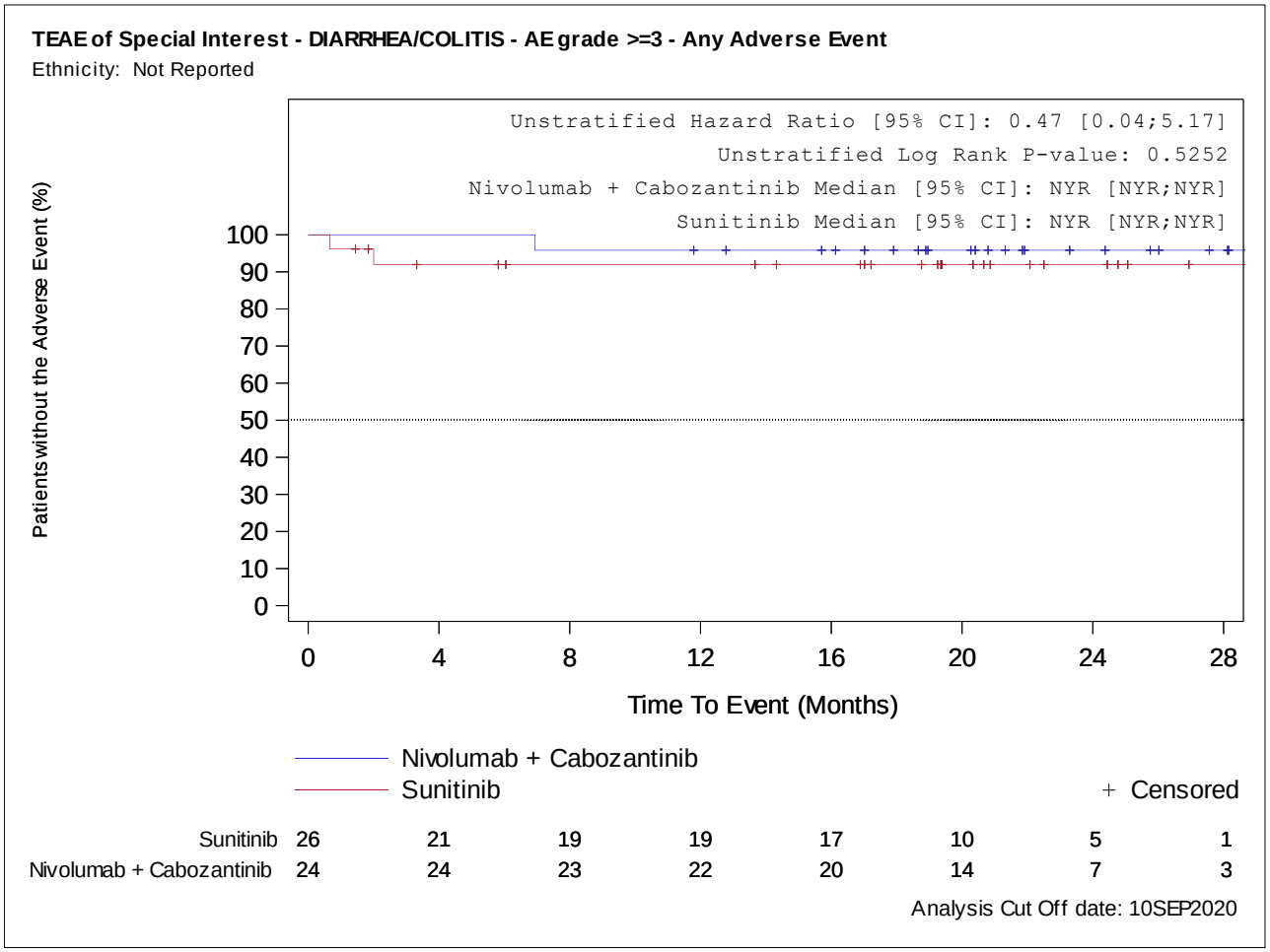

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:31:34

FIGURE 3.73.2.11: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



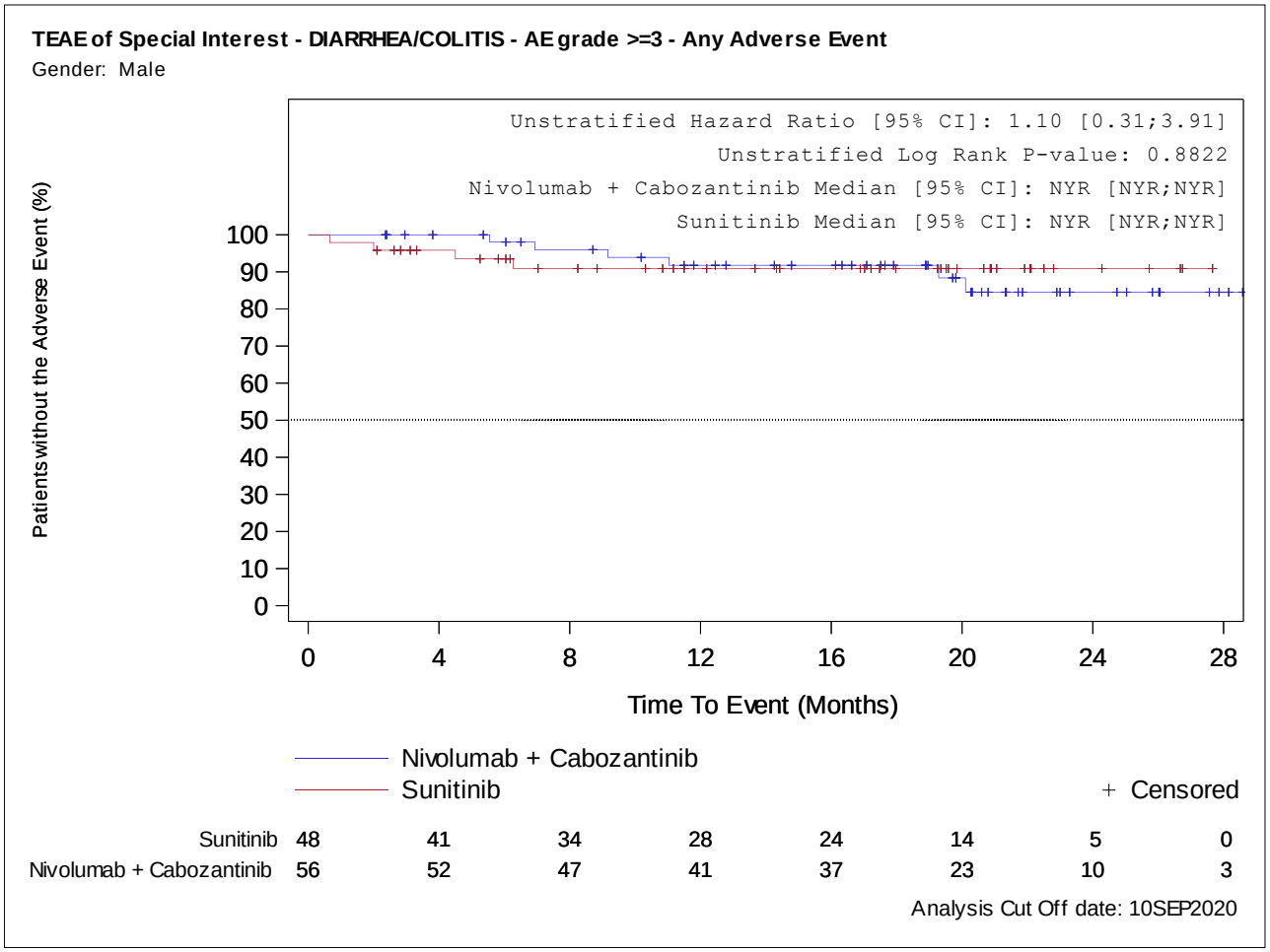

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:31:41

FIGURE 3.73.2.12: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



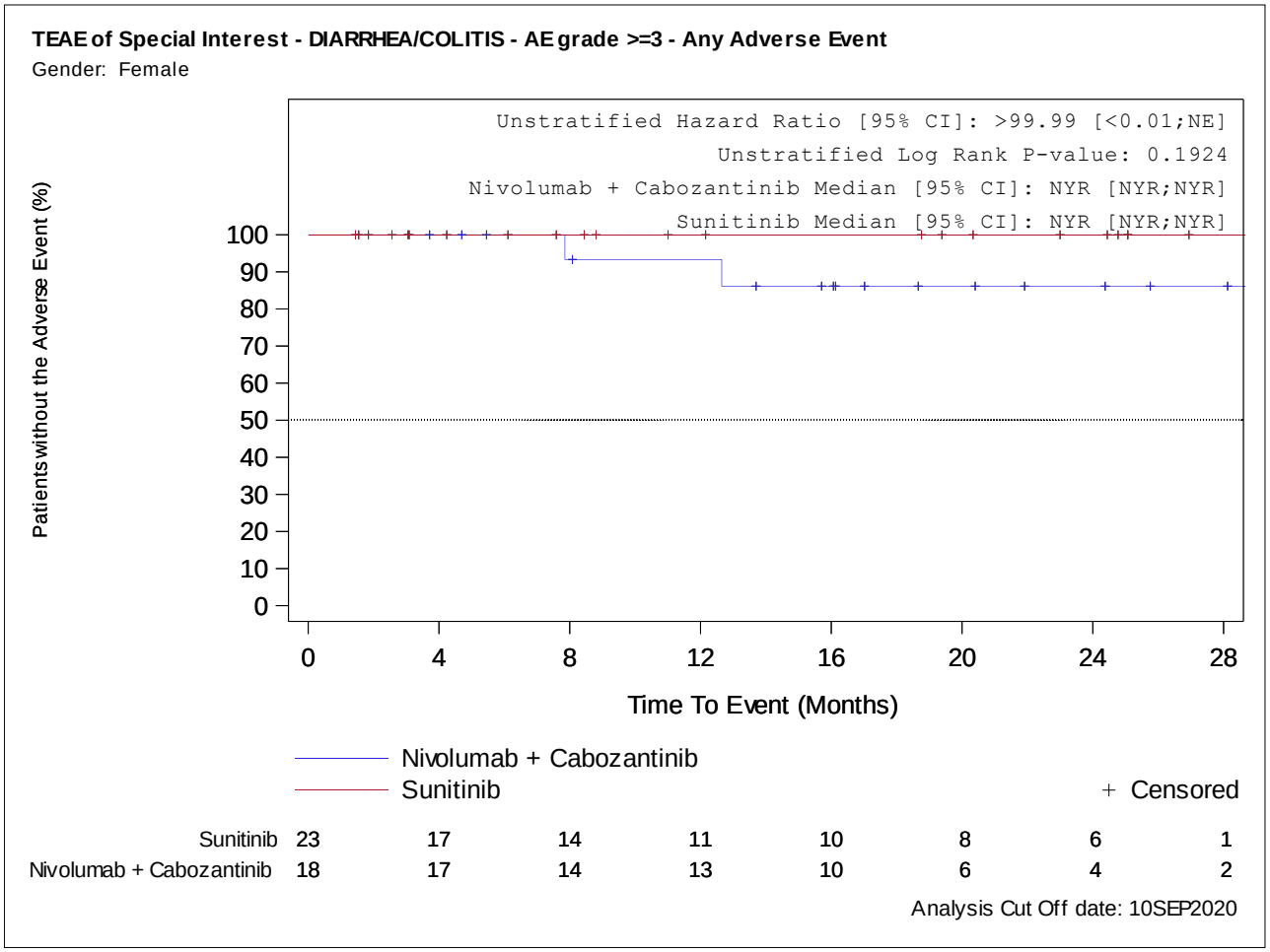

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:31:47

FIGURE 3.73.2.13: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



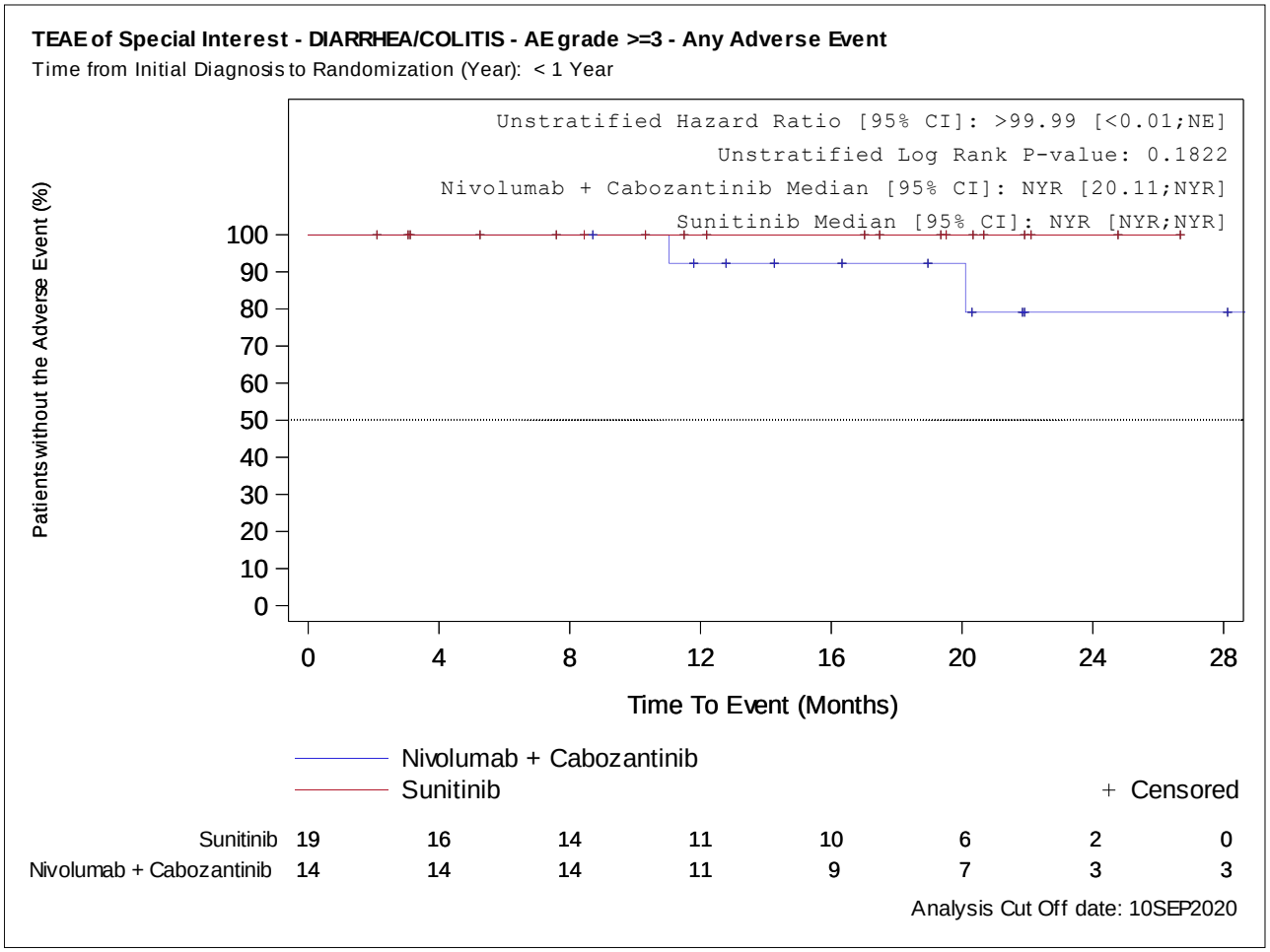

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:31:53

FIGURE 3.73.2.14: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



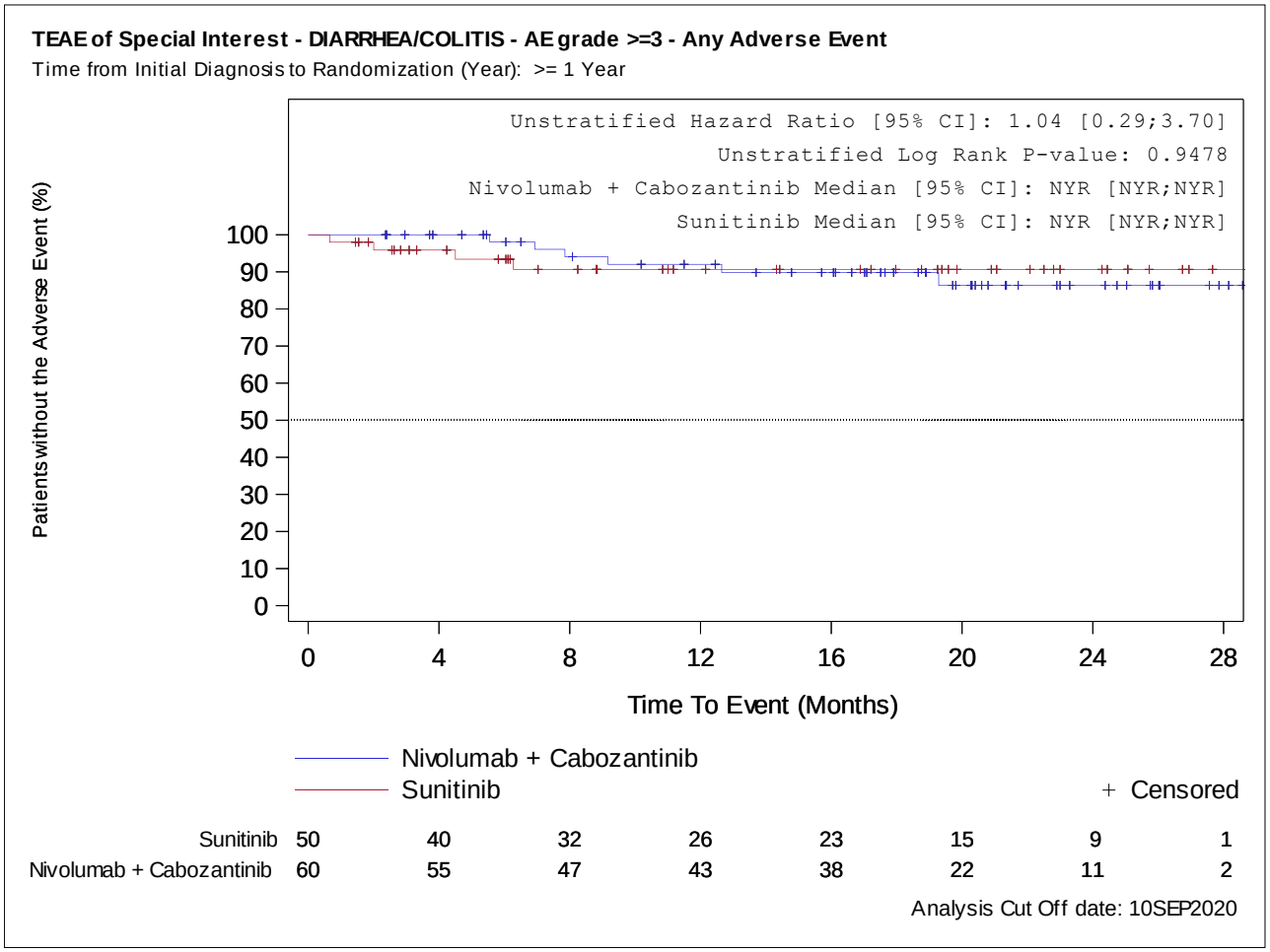

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:31:59

FIGURE 3.73.2.15: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



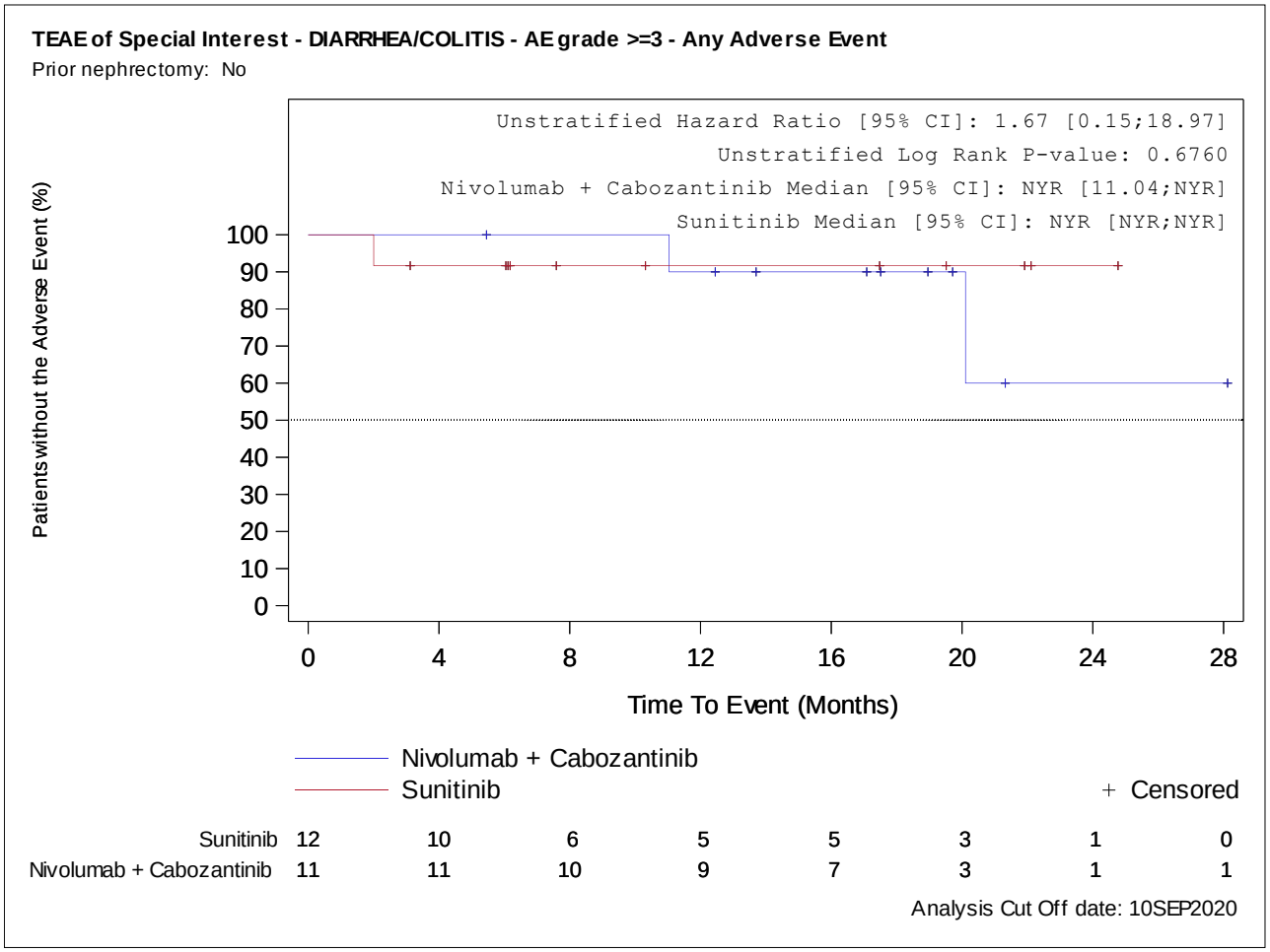

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:32:17

FIGURE 3.73.2.16: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



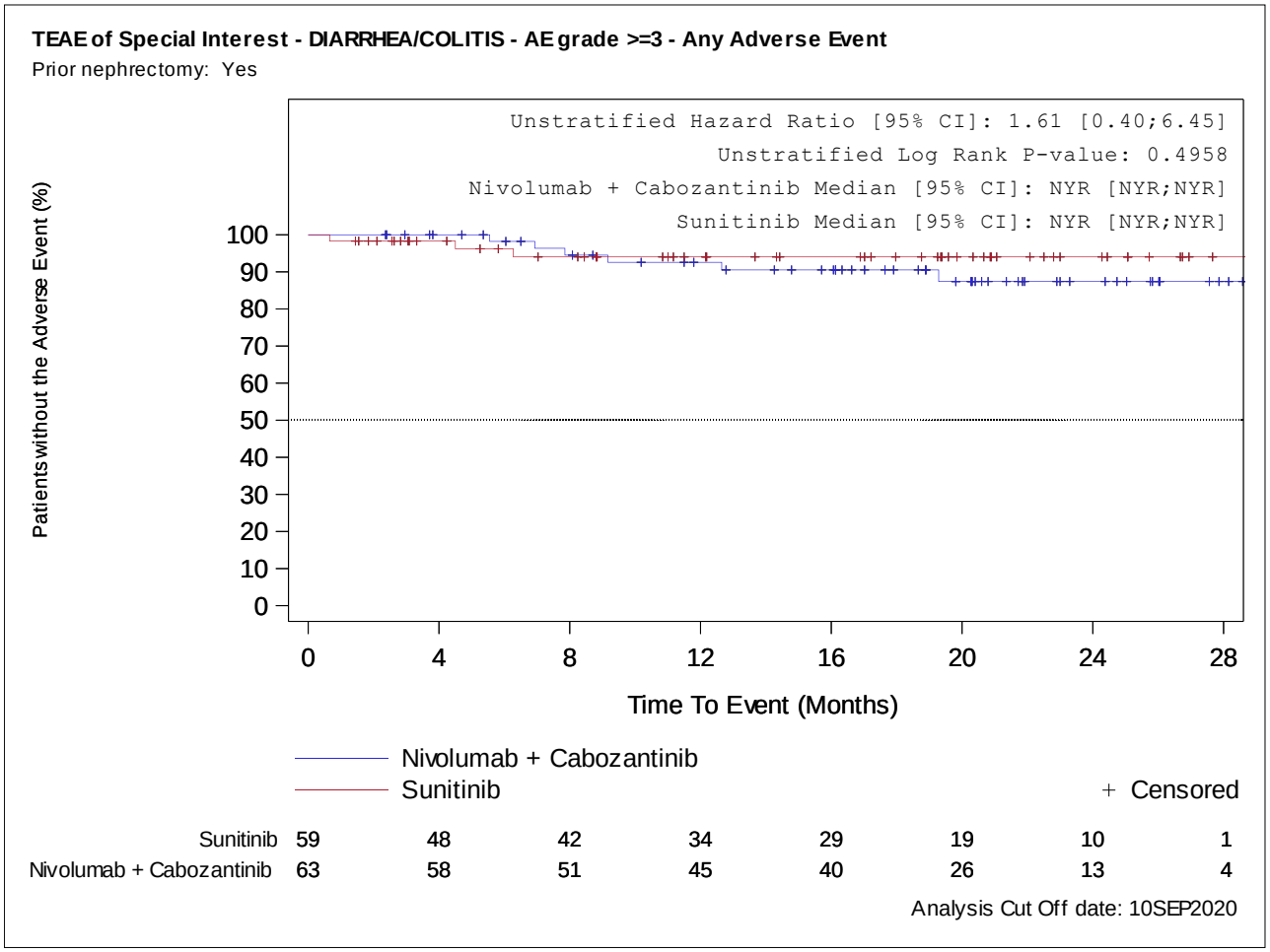

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:32:23

FIGURE 3.73.2.17: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



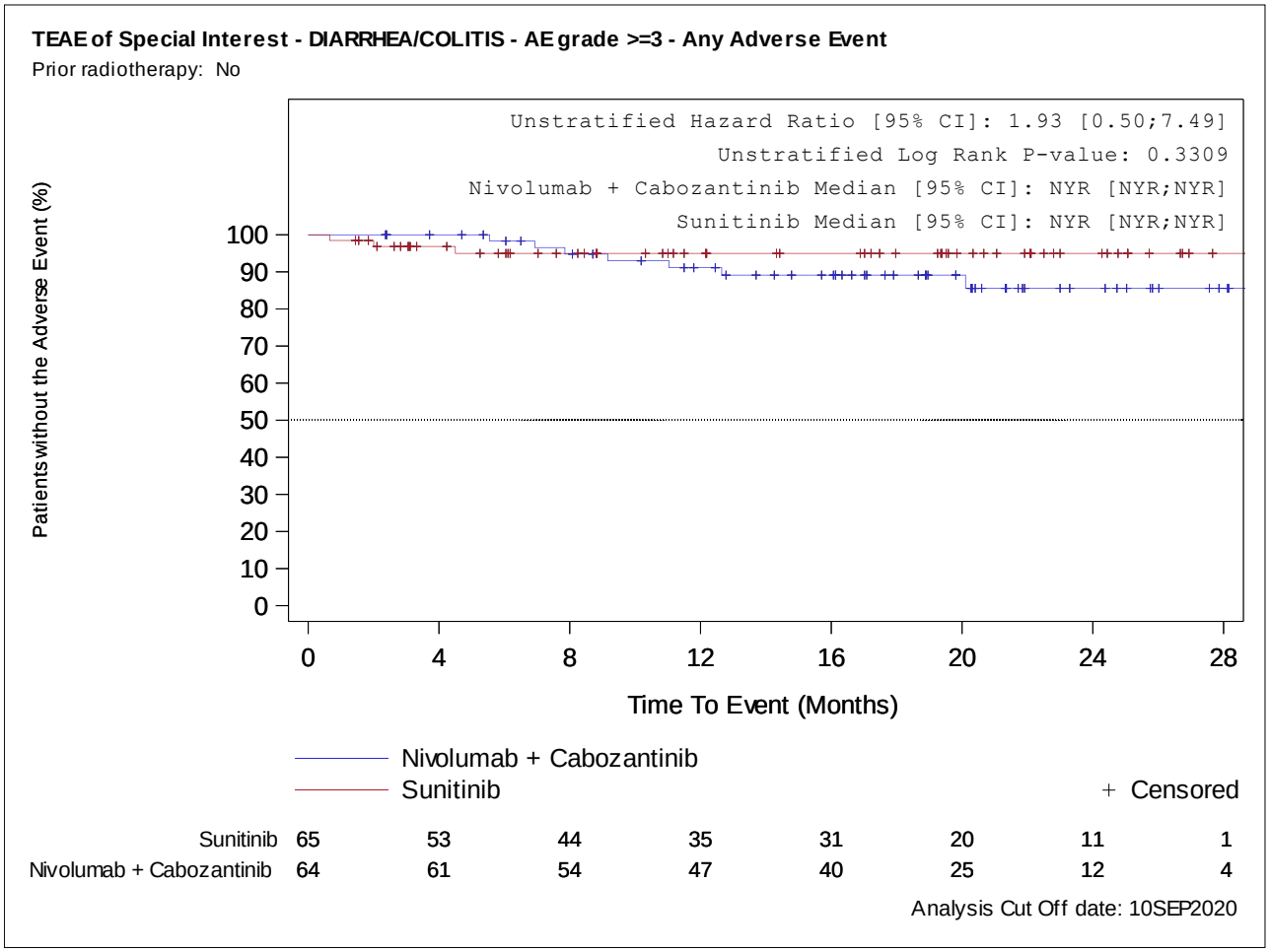

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:33:14

FIGURE 3.73.2.18: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:33:20

FIGURE 3.73.2.19: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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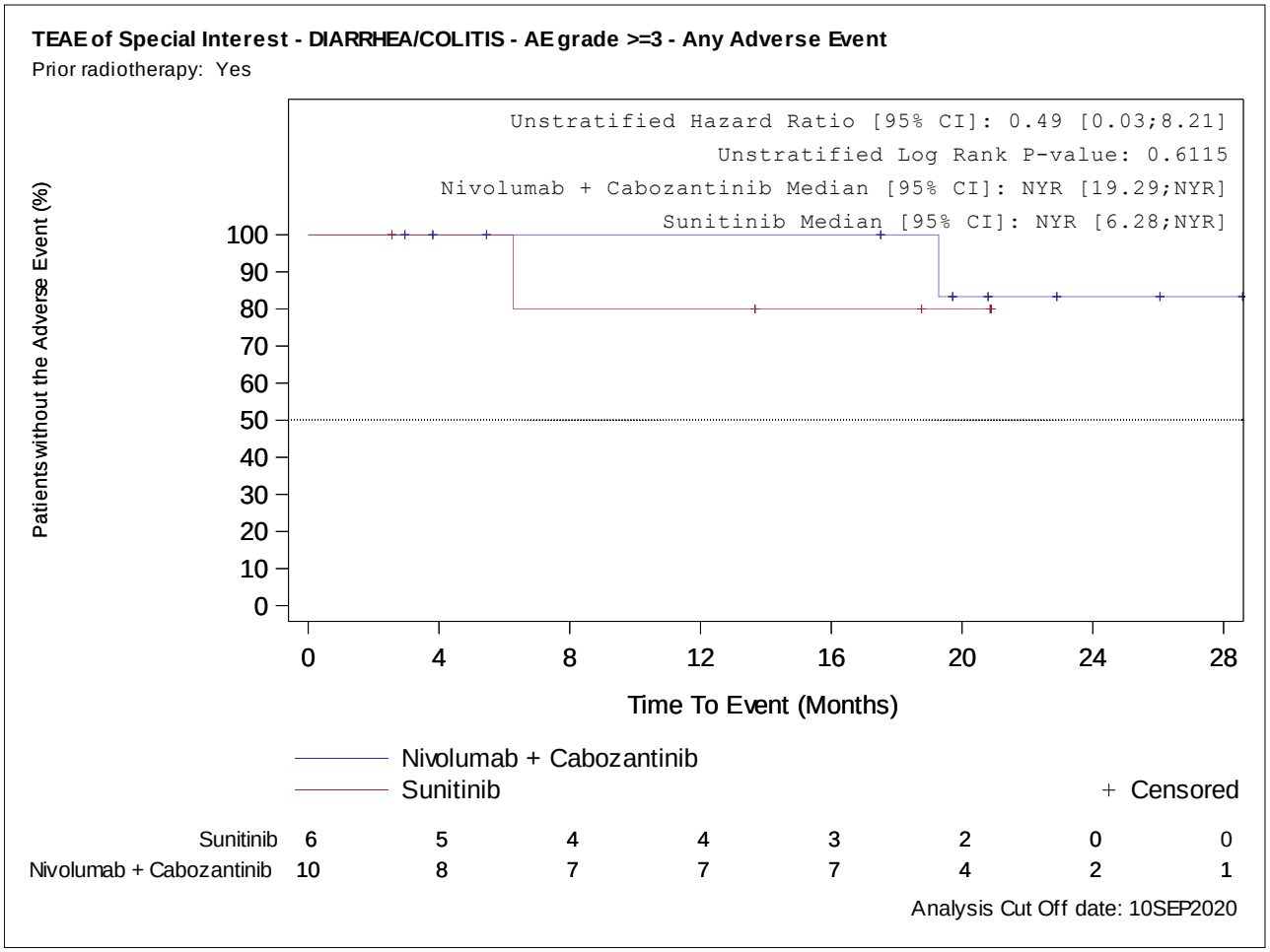
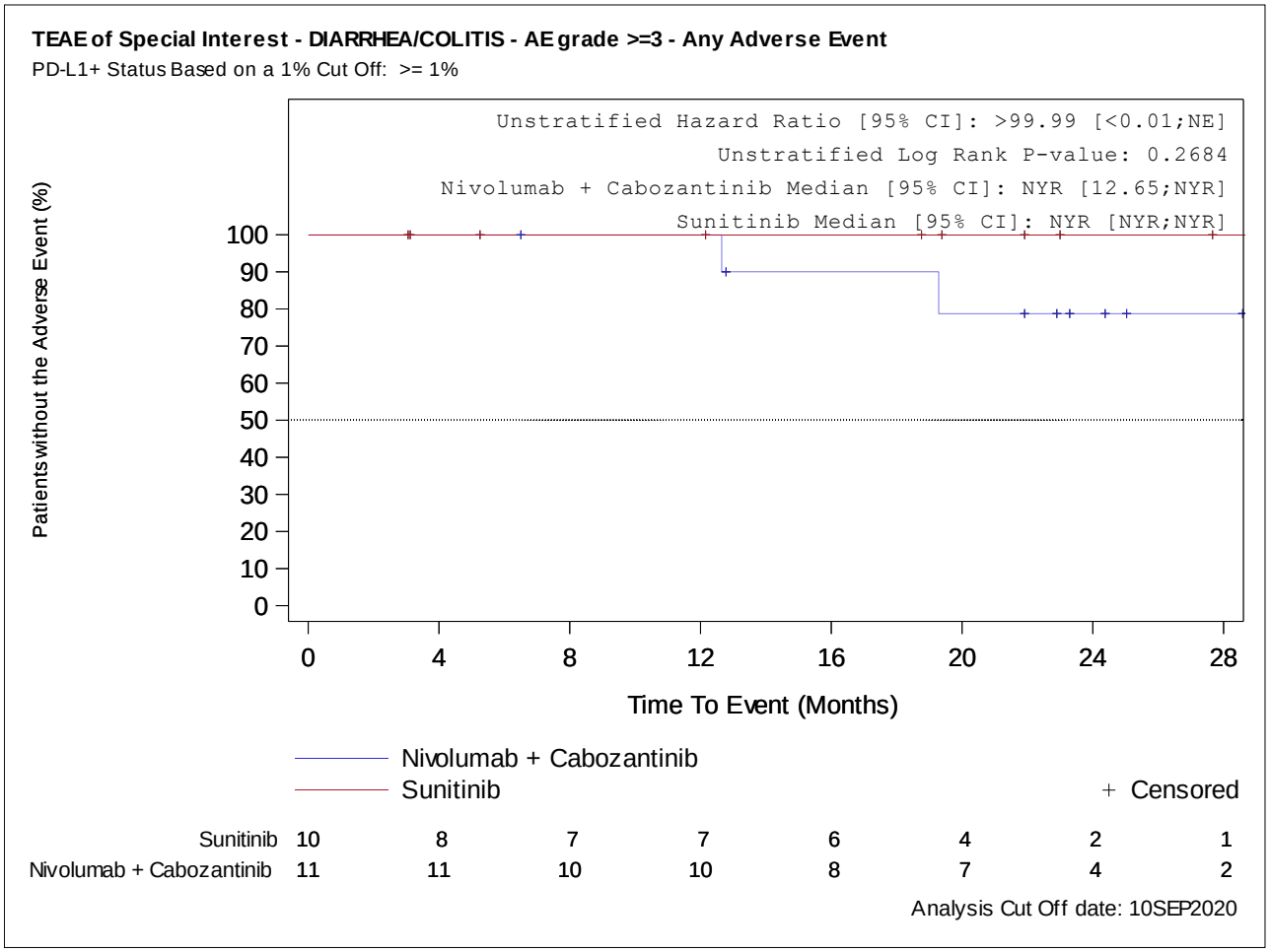
FIGURE 3.73.2.20: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



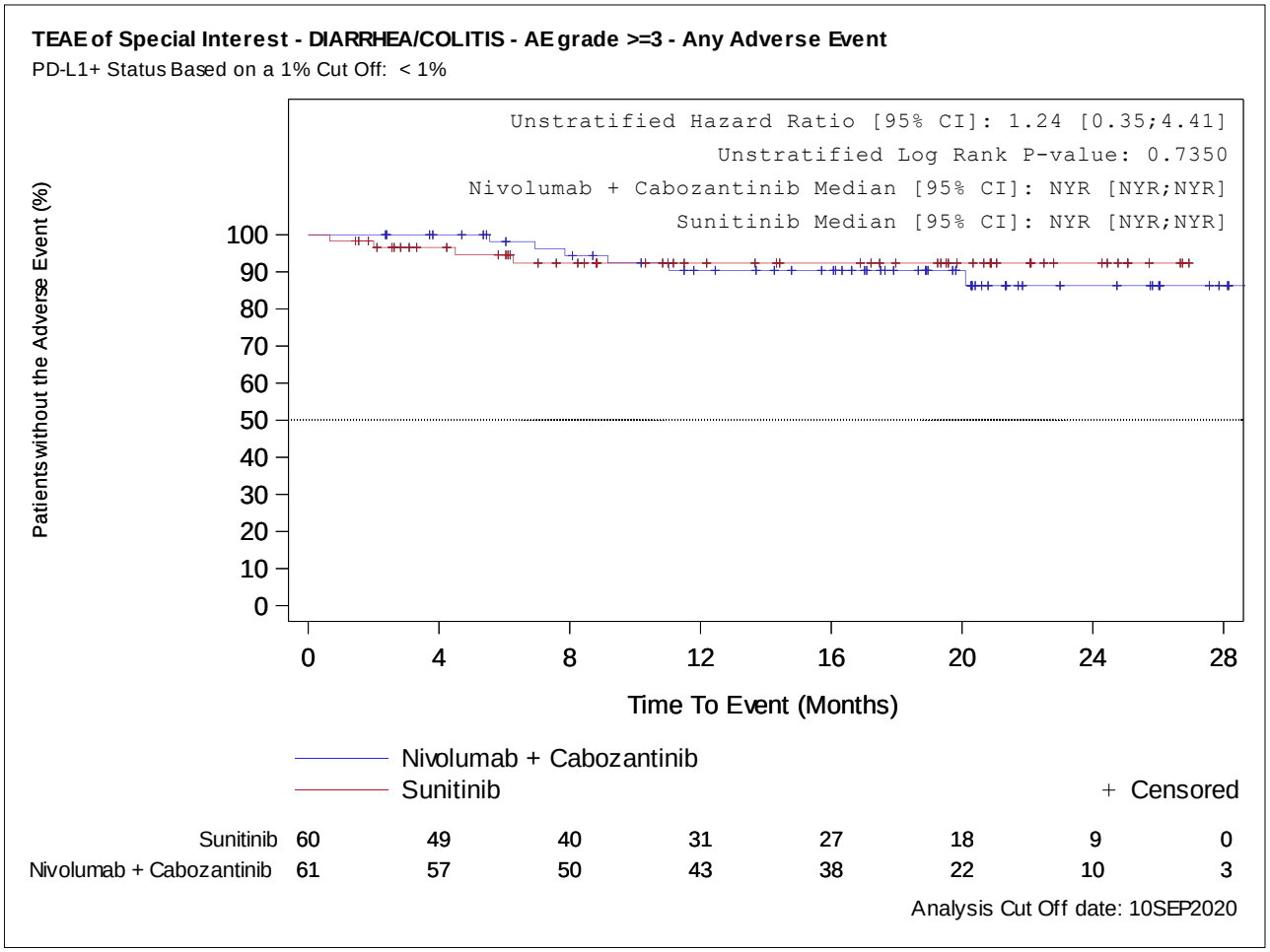

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:33:32

FIGURE 3.73.2.21: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off:  >= 1%



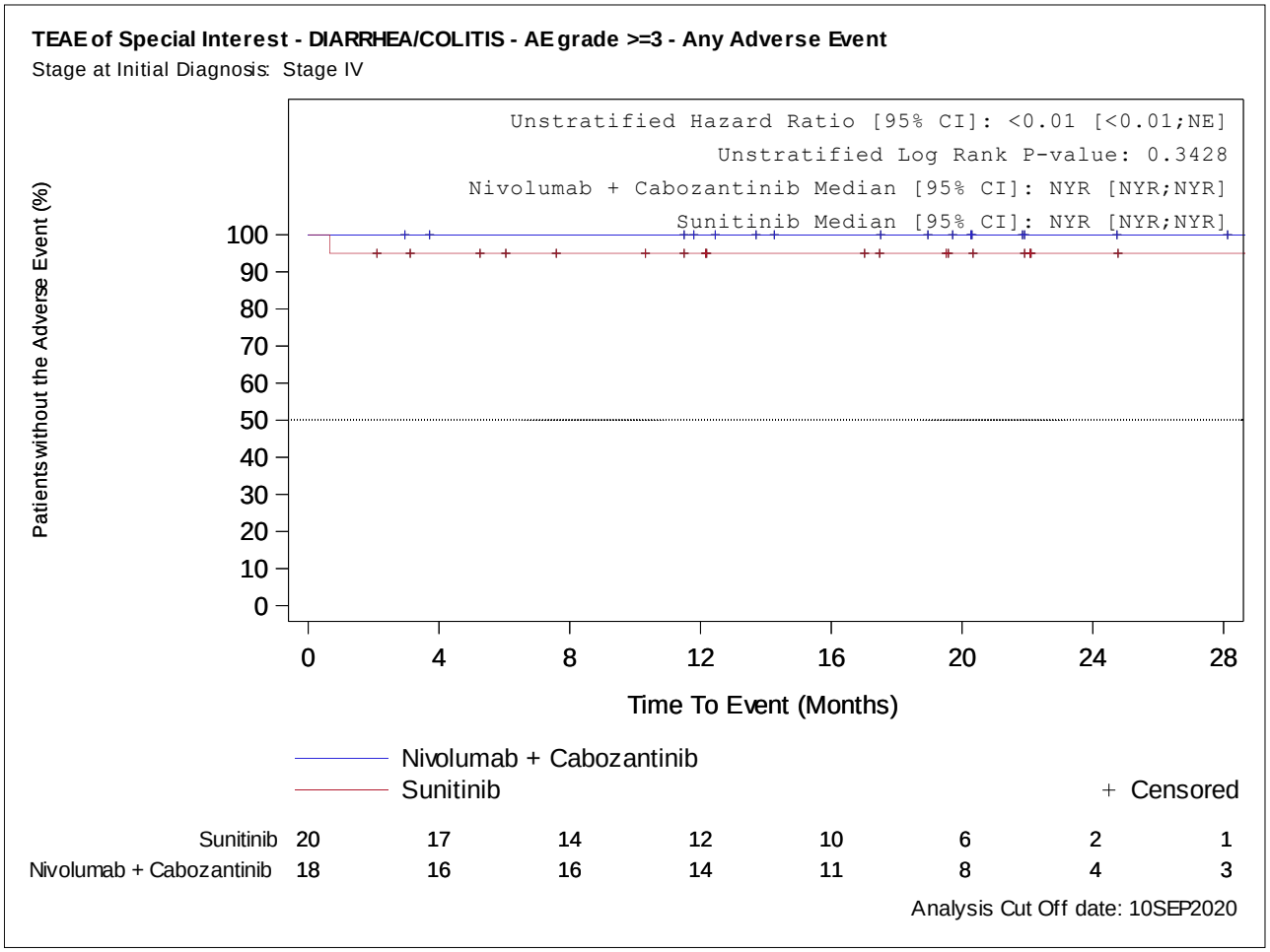

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:33:37

FIGURE 3.73.2.22: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



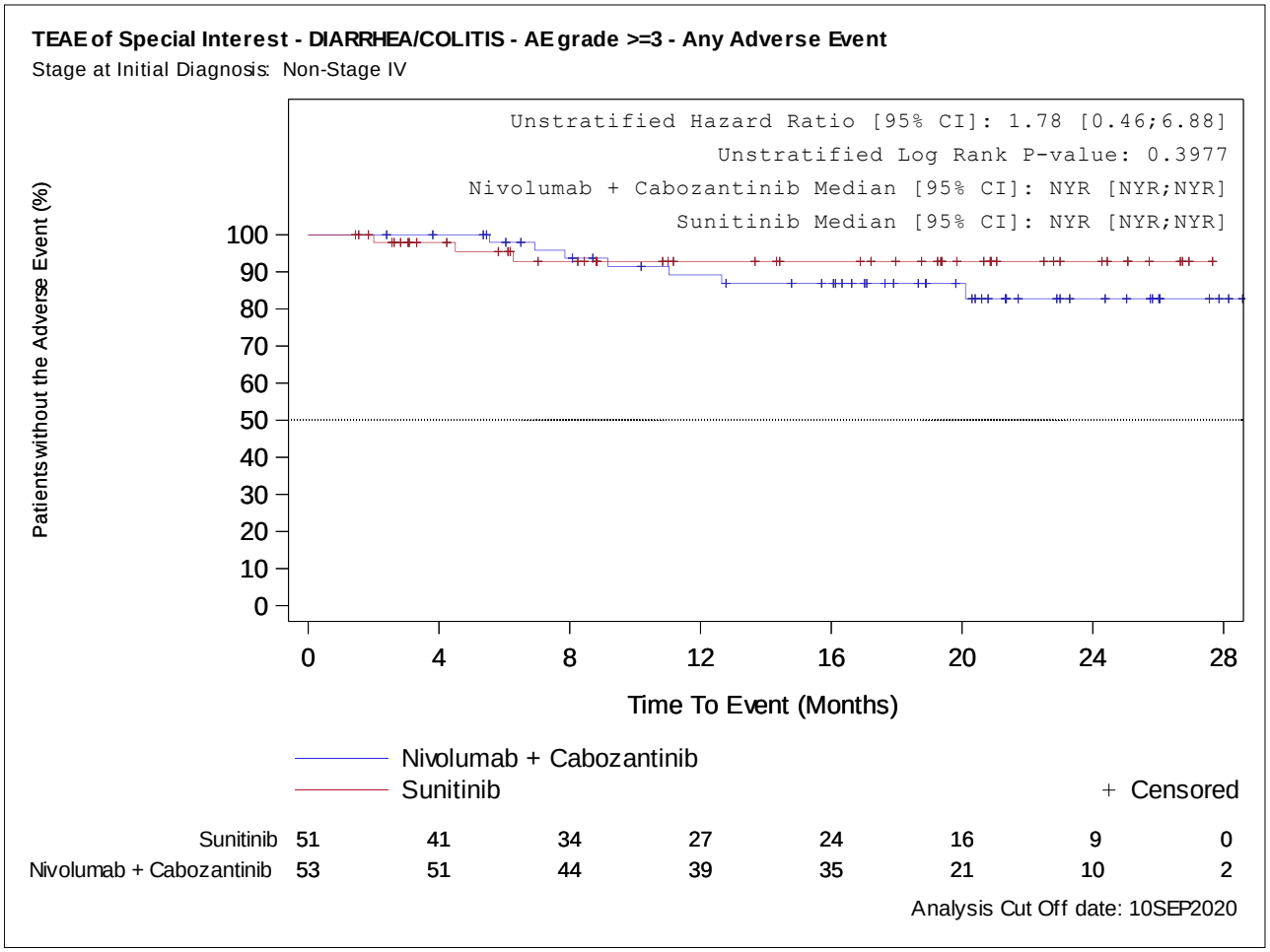

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:33:43

FIGURE 3.73.2.23: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



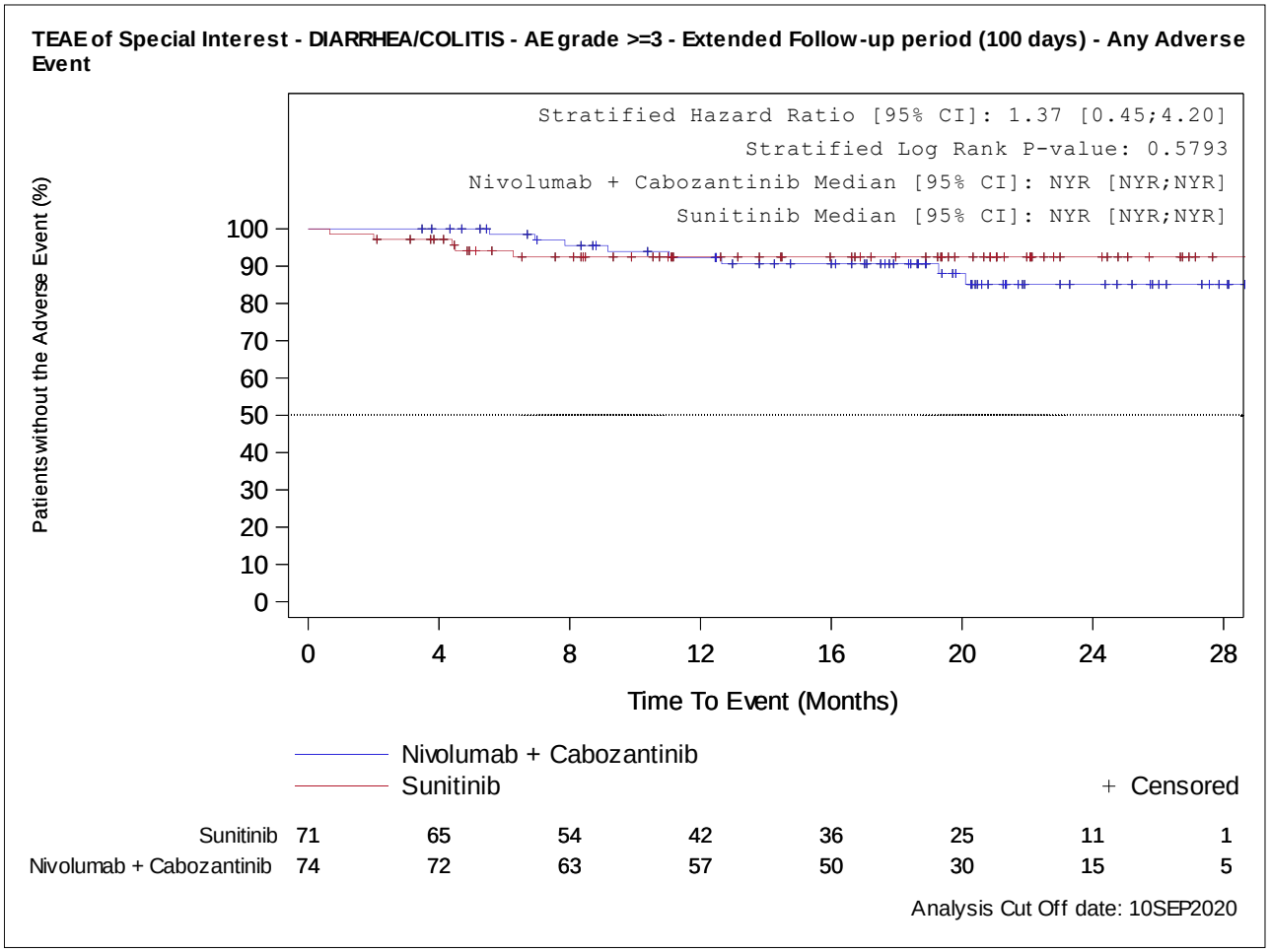

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:34:13

FIGURE 3.73.2.24: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



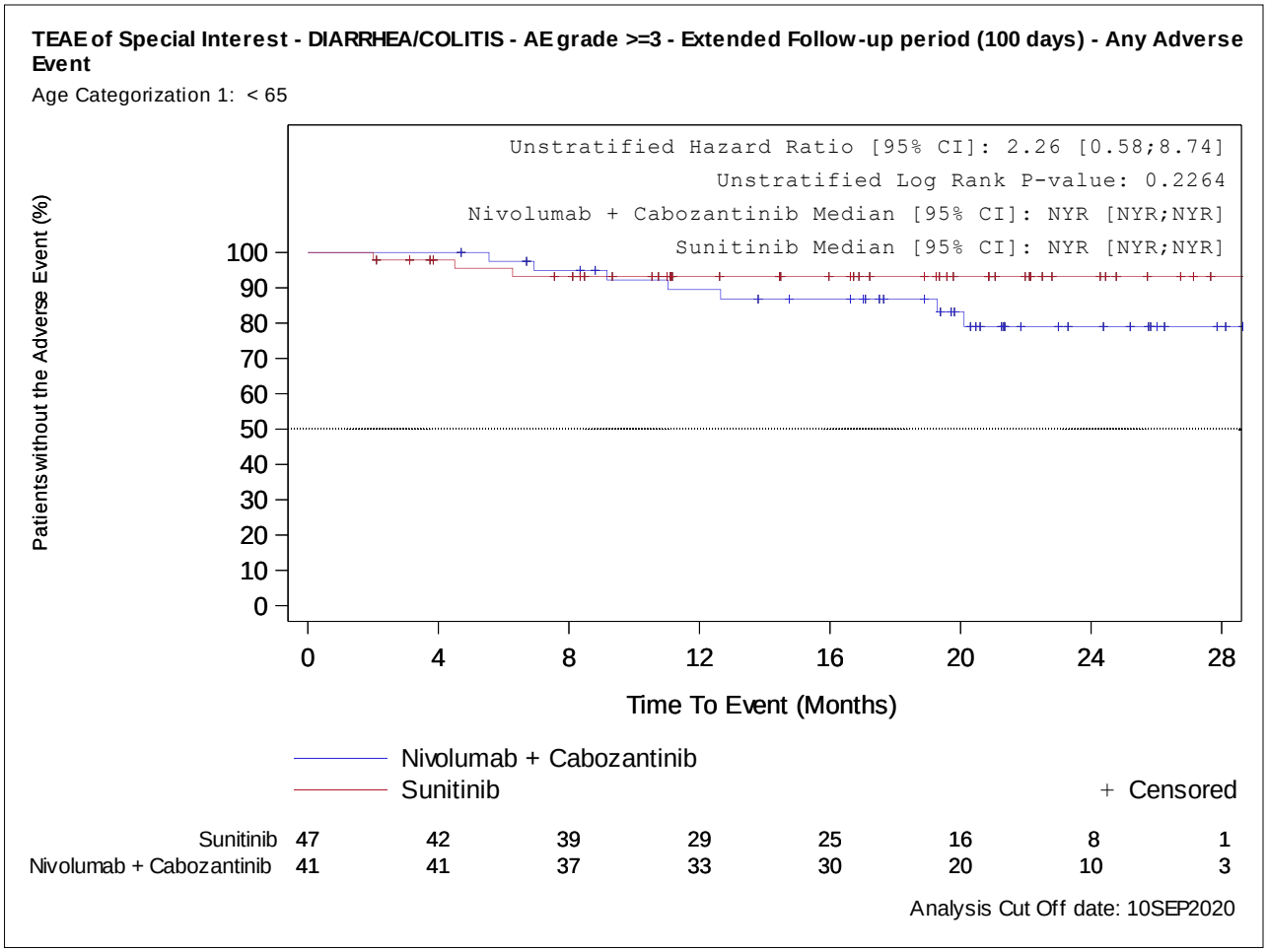

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:34:19

FIGURE 3.74.1: TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



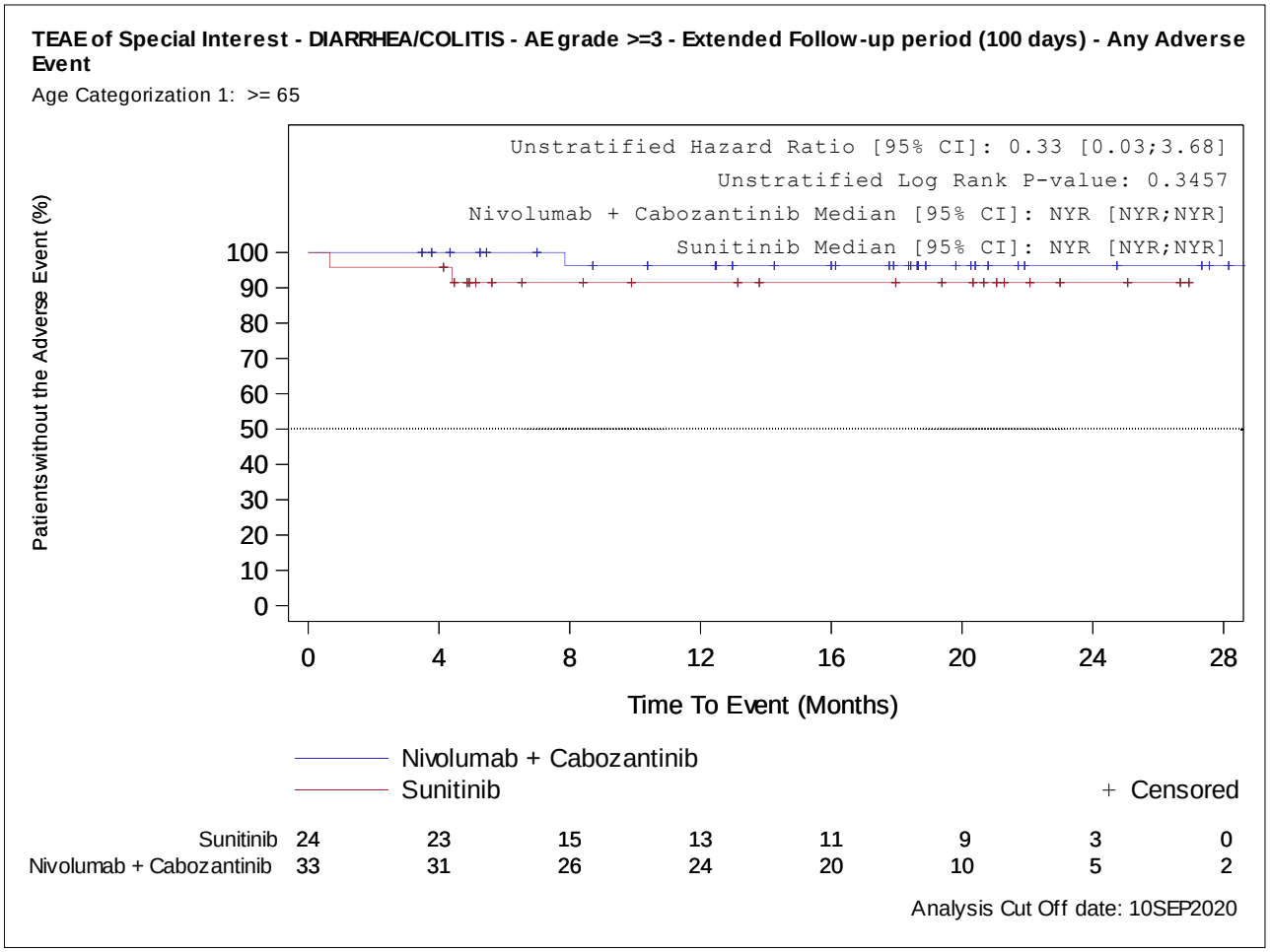

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:37:31

FIGURE 3.74.2.1: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



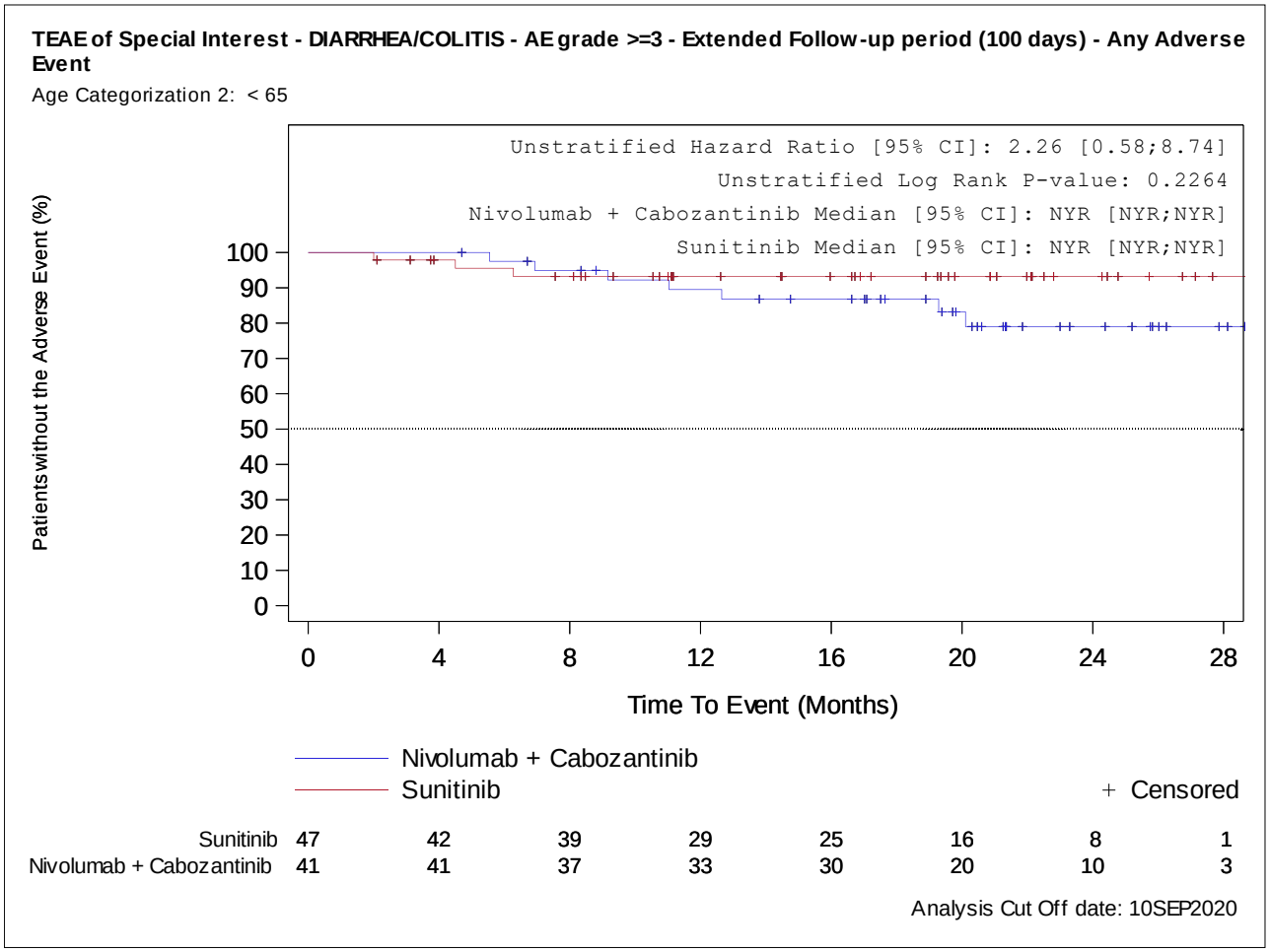

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:37:34

FIGURE 3.74.2.2: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:37:41

FIGURE 3.74.2.3: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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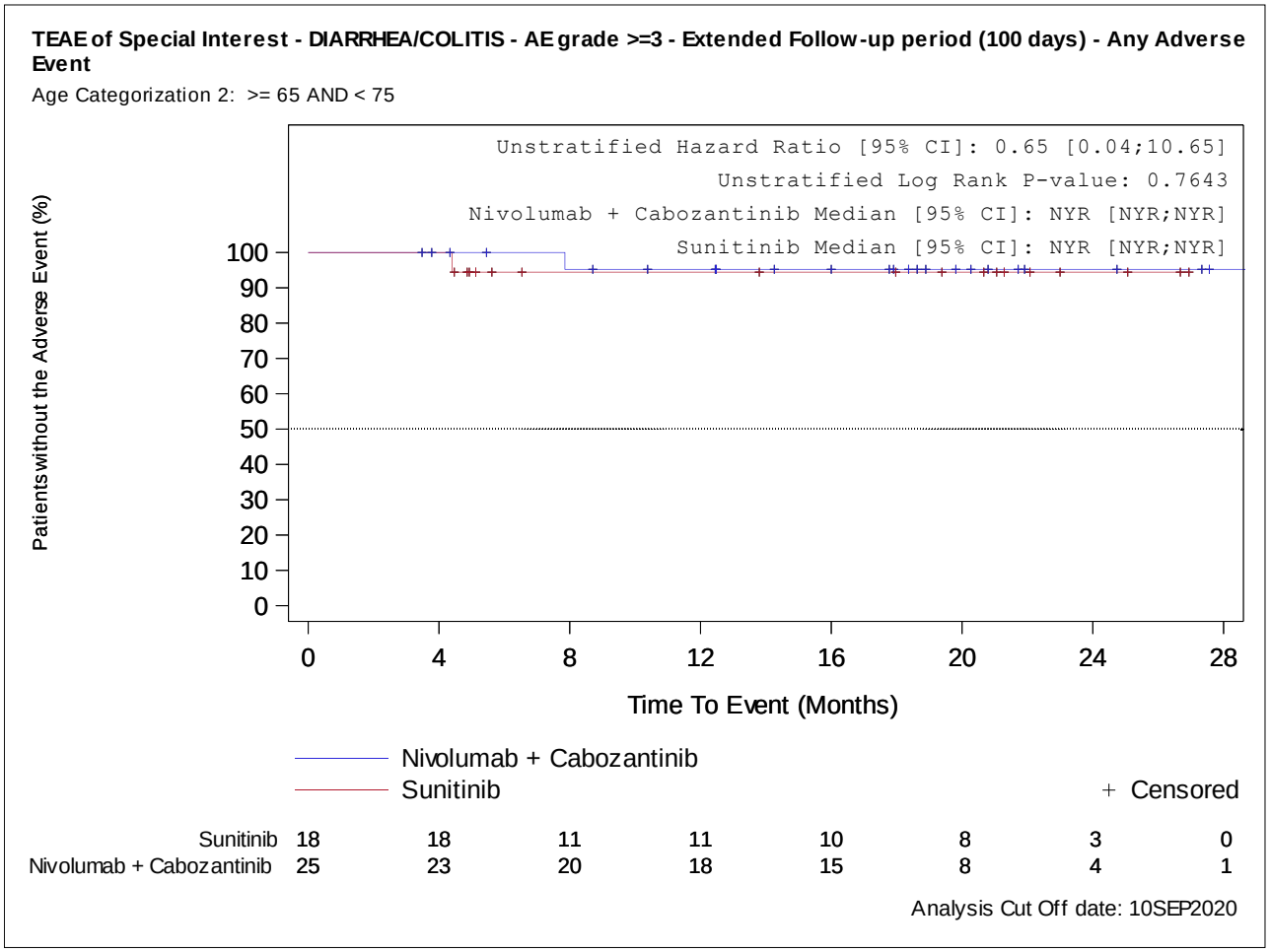
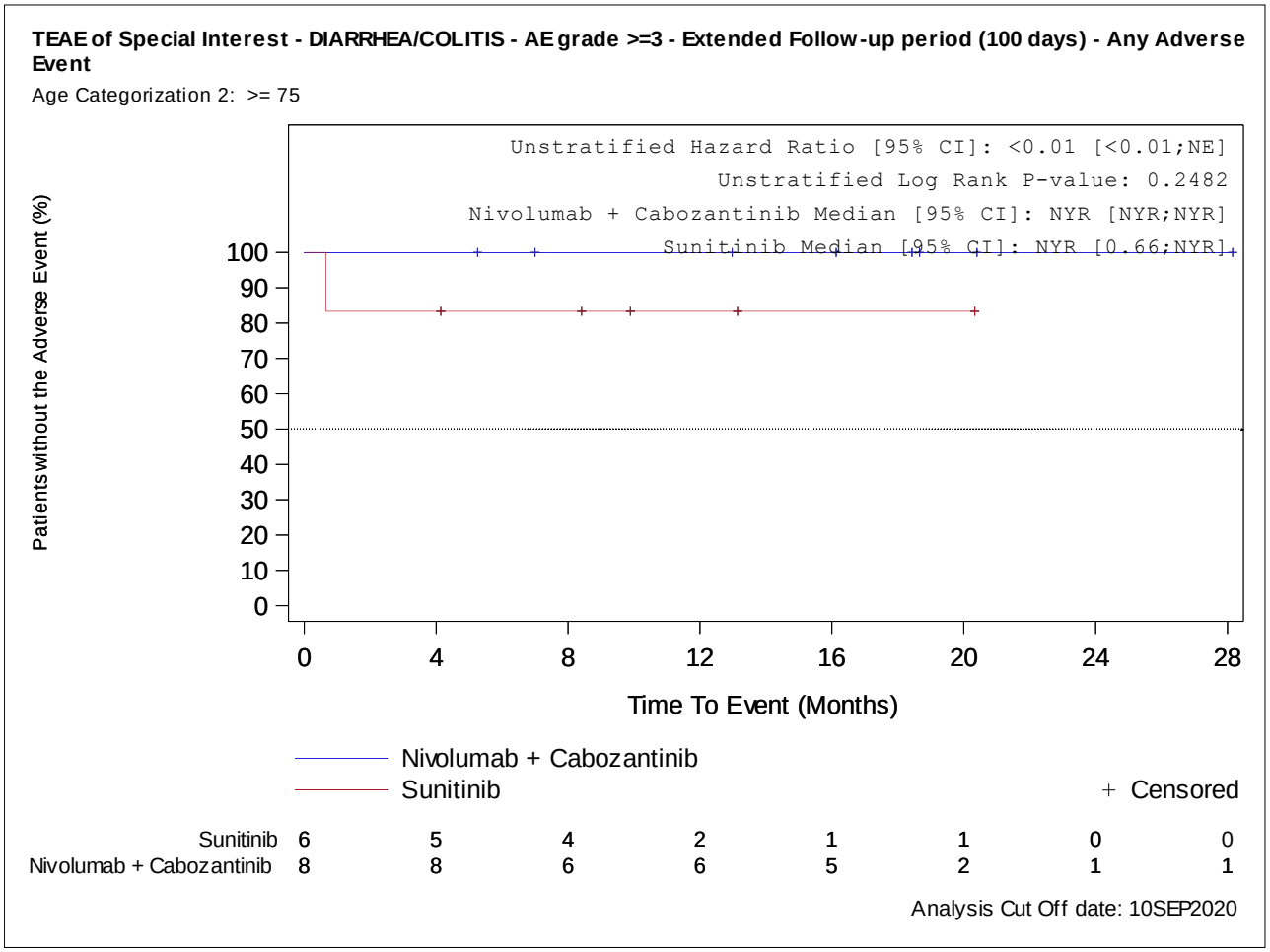
FIGURE 3.74.2.4: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



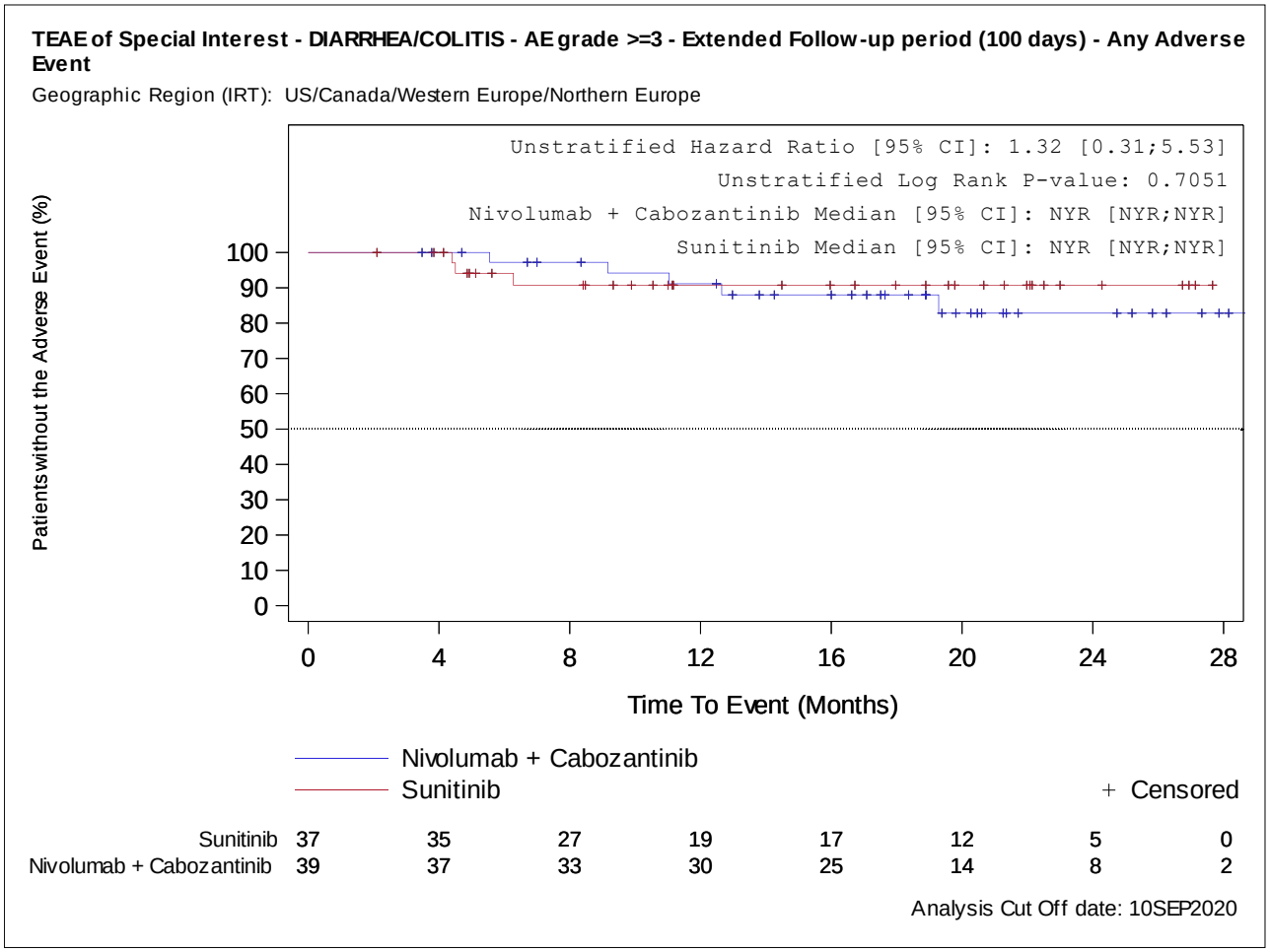

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:37:53

FIGURE 3.74.2.5: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



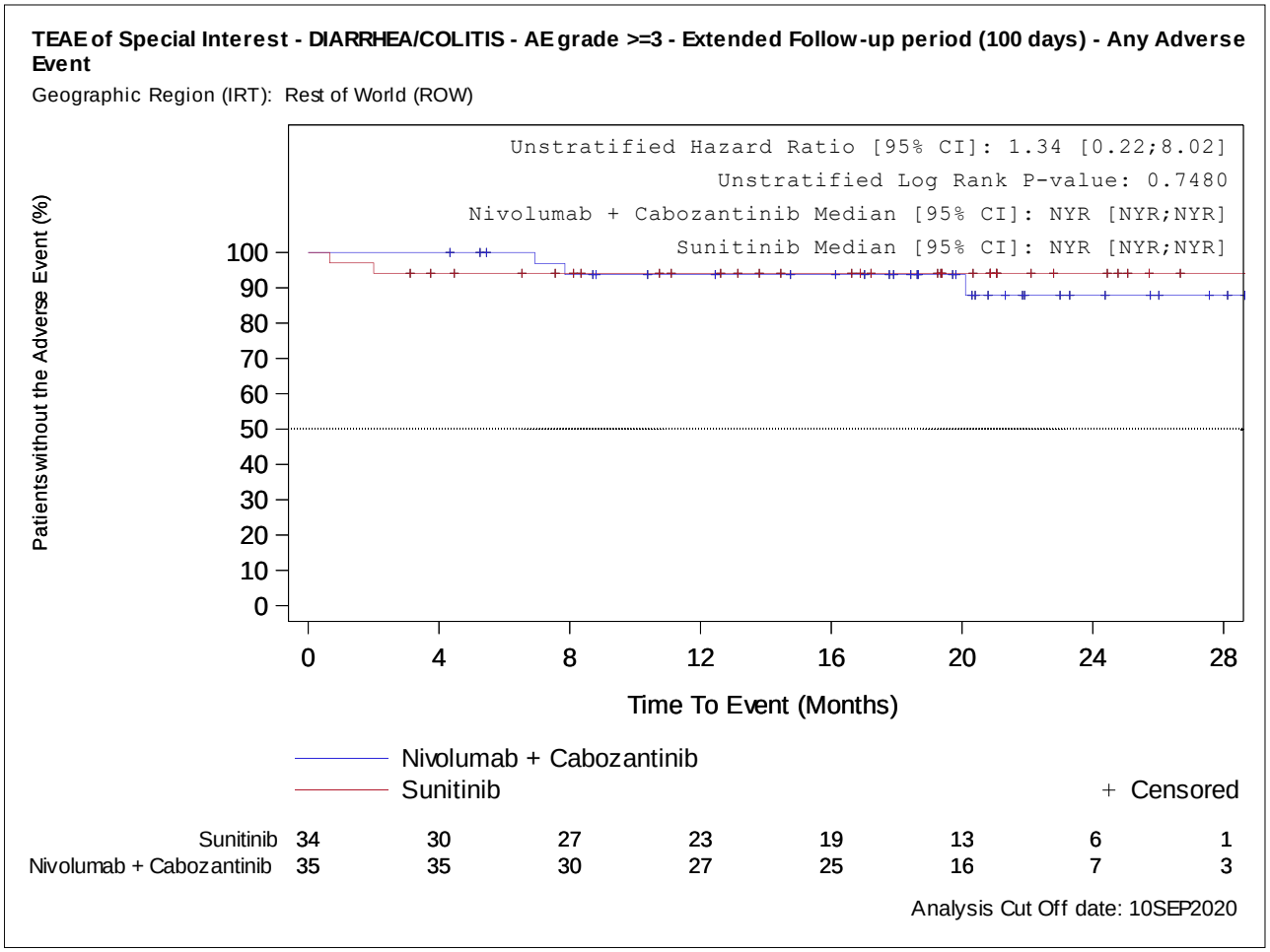

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:37:59

FIGURE 3.74.2.6: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



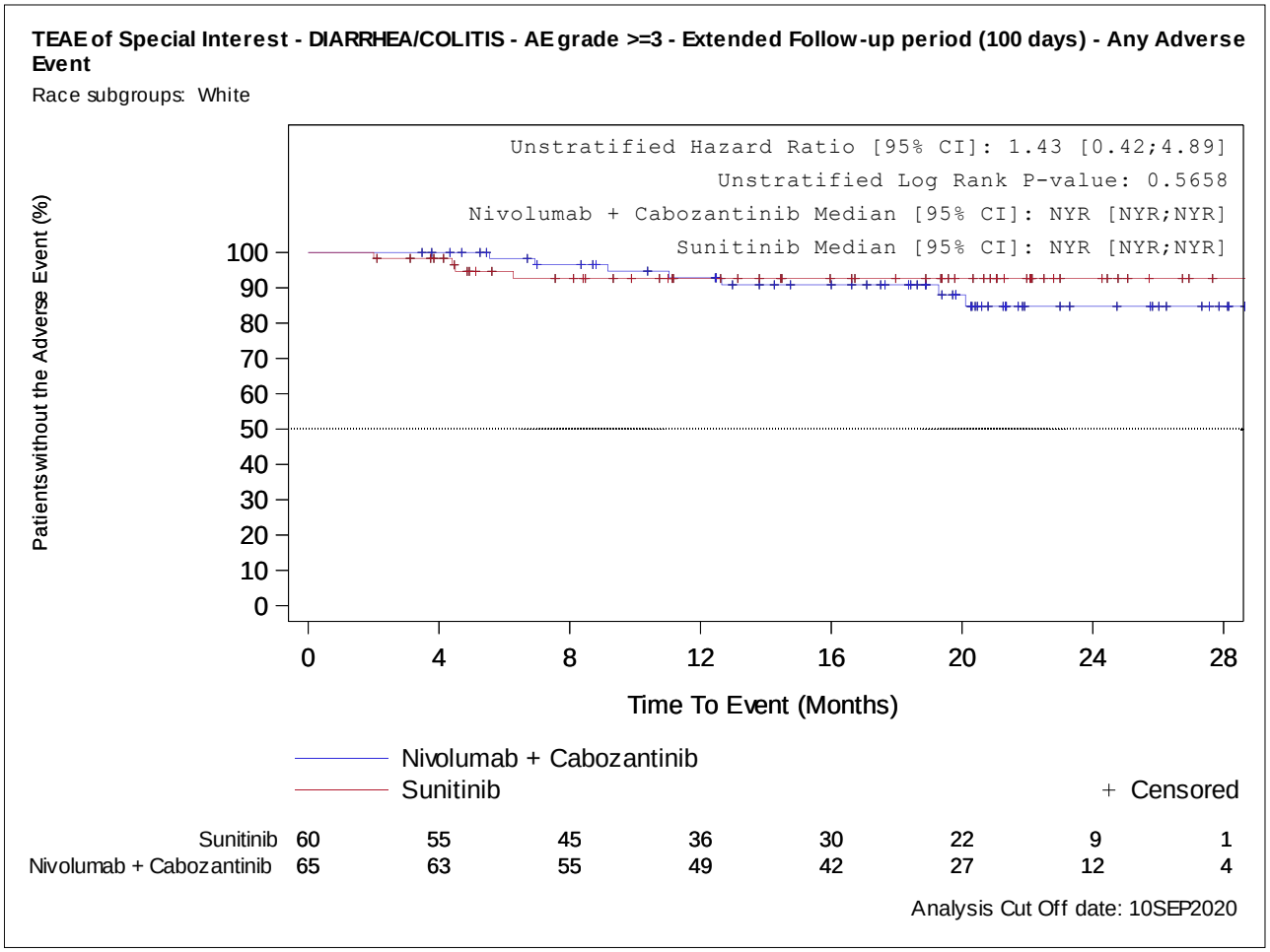

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:38:04

FIGURE 3.74.2.7: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



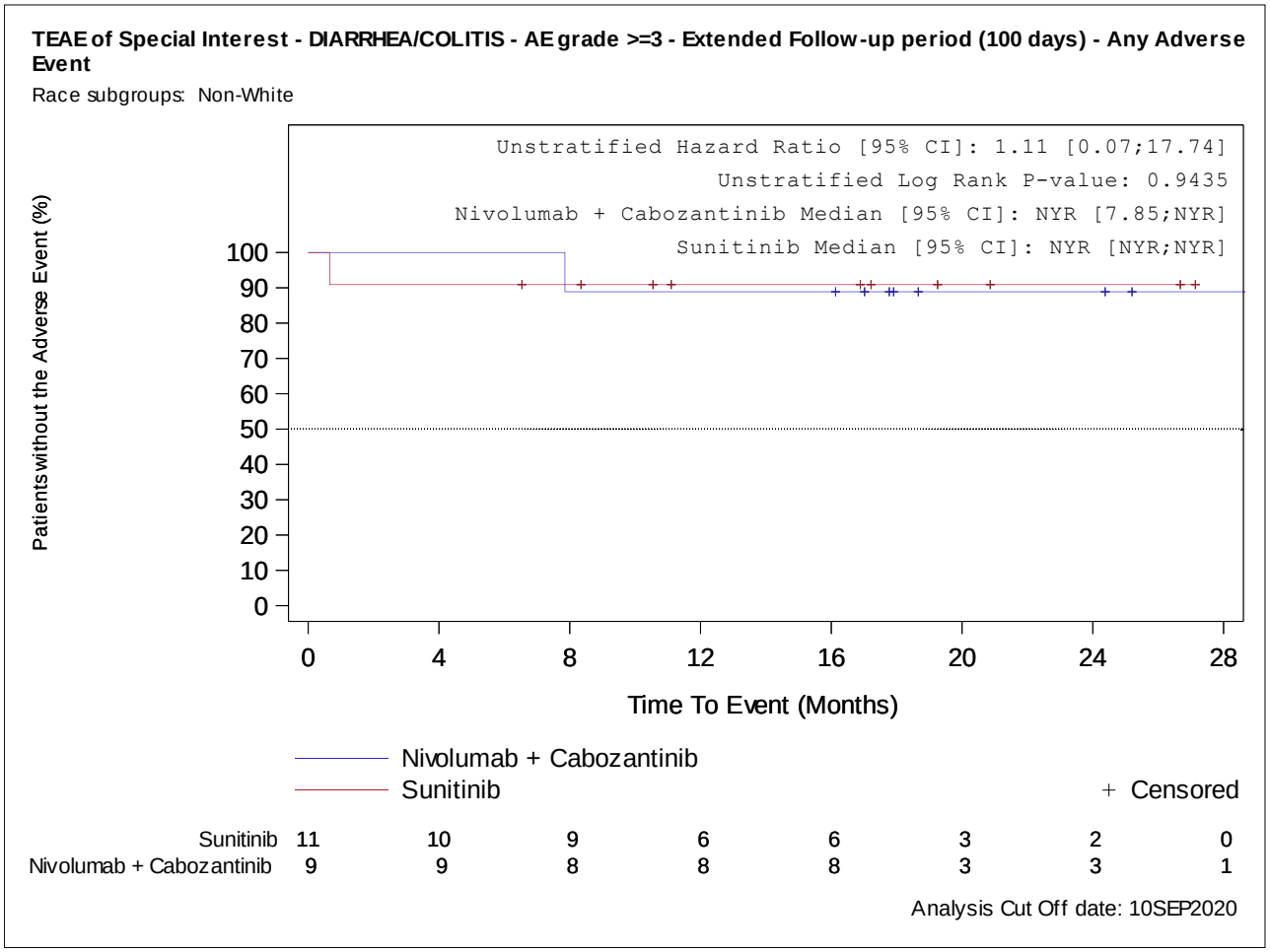

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:38:11

FIGURE 3.74.2.8: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



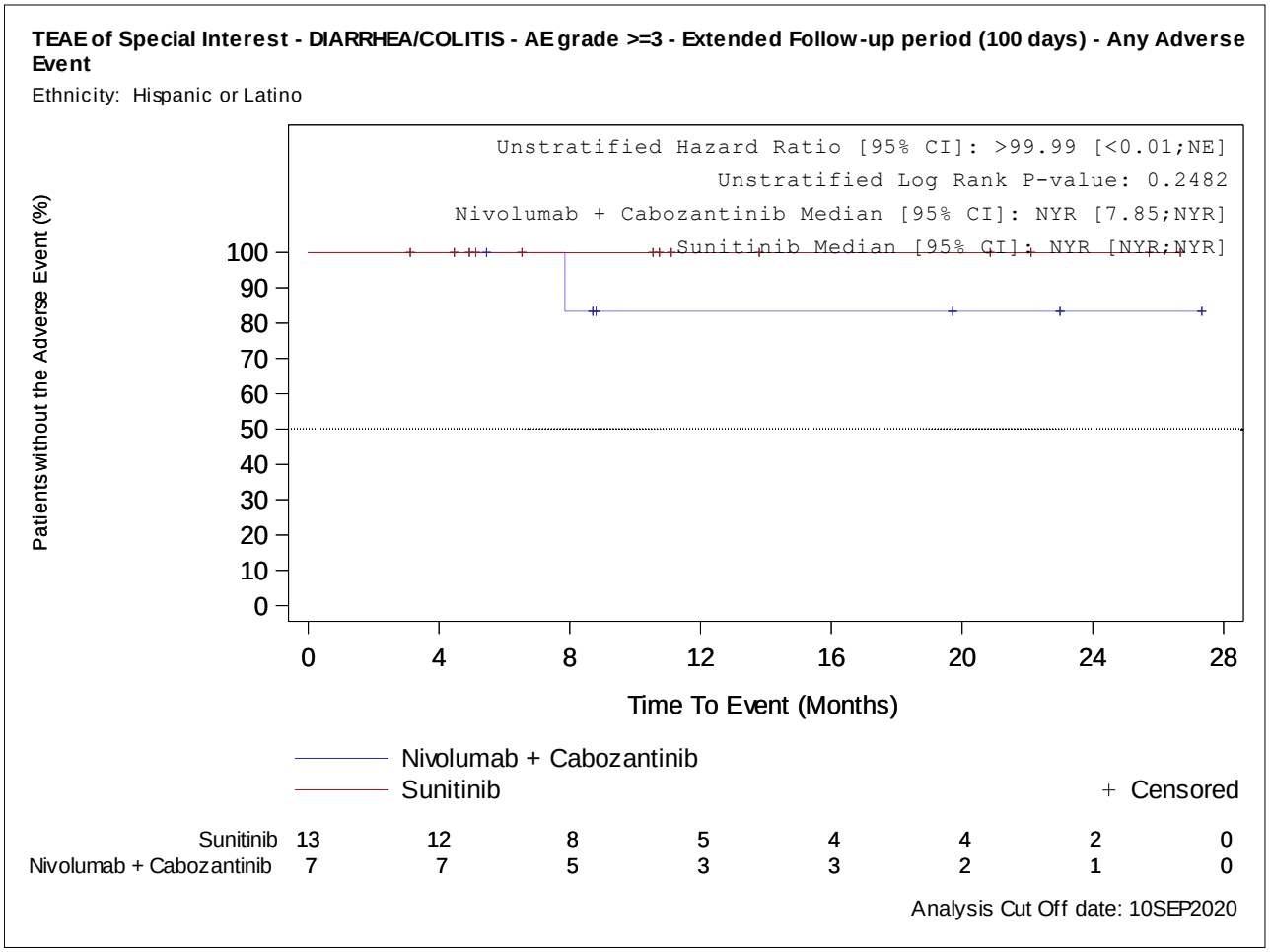

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:38:17

FIGURE 3.74.2.9: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



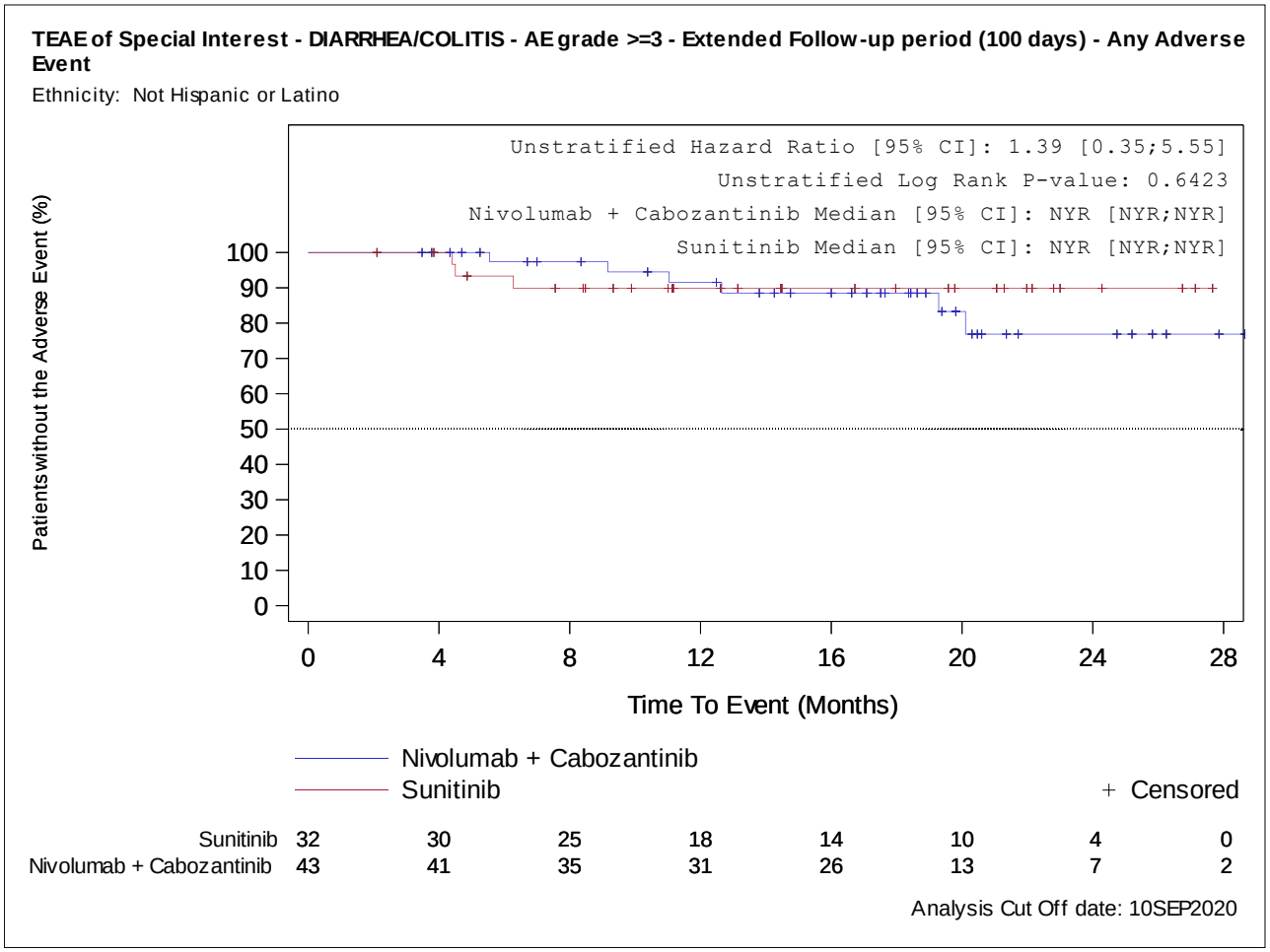

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:38:22

FIGURE 3.74.2.10: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



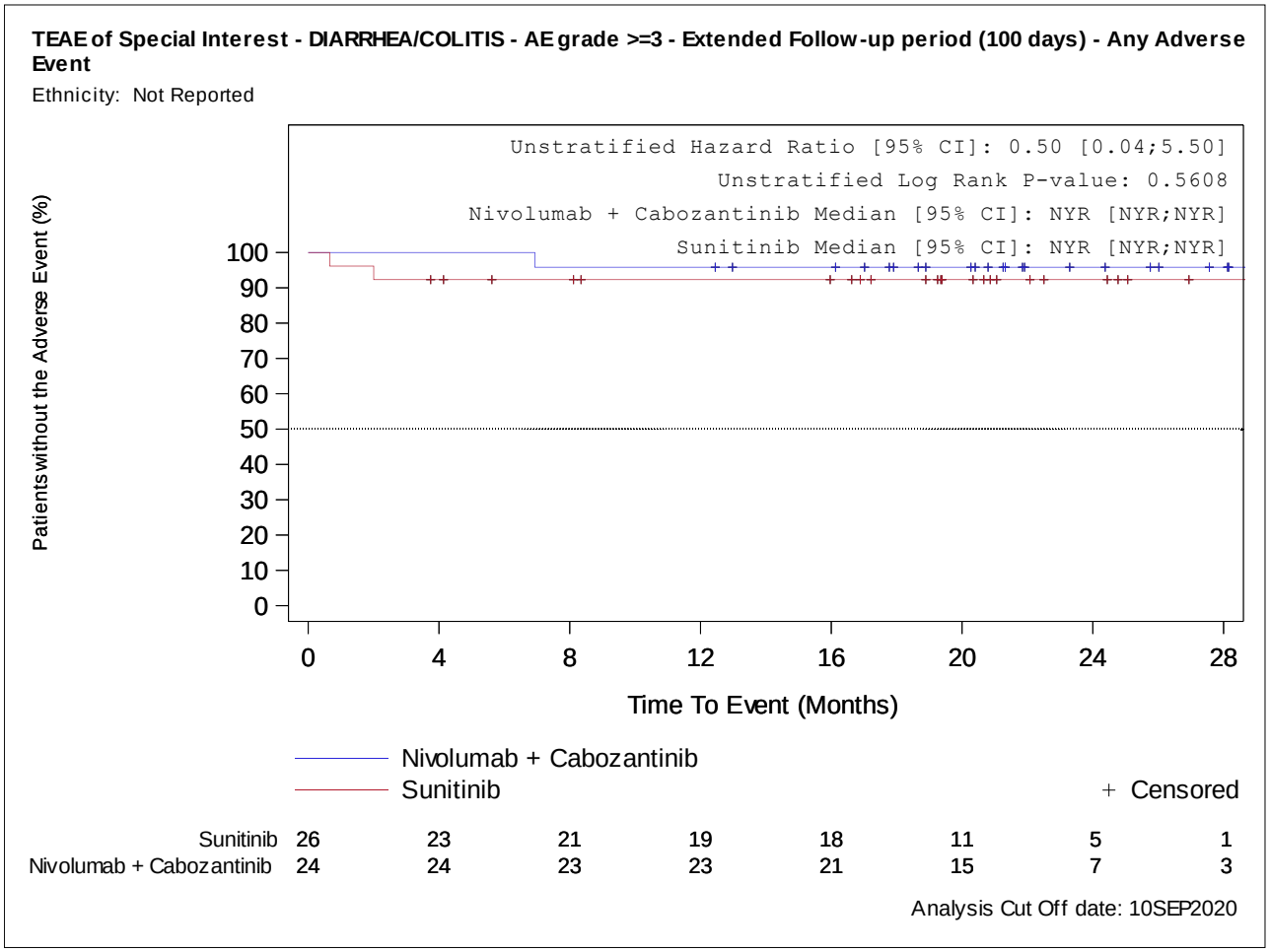

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:38:28

FIGURE 3.74.2.11: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:38:34

FIGURE 3.74.2.12: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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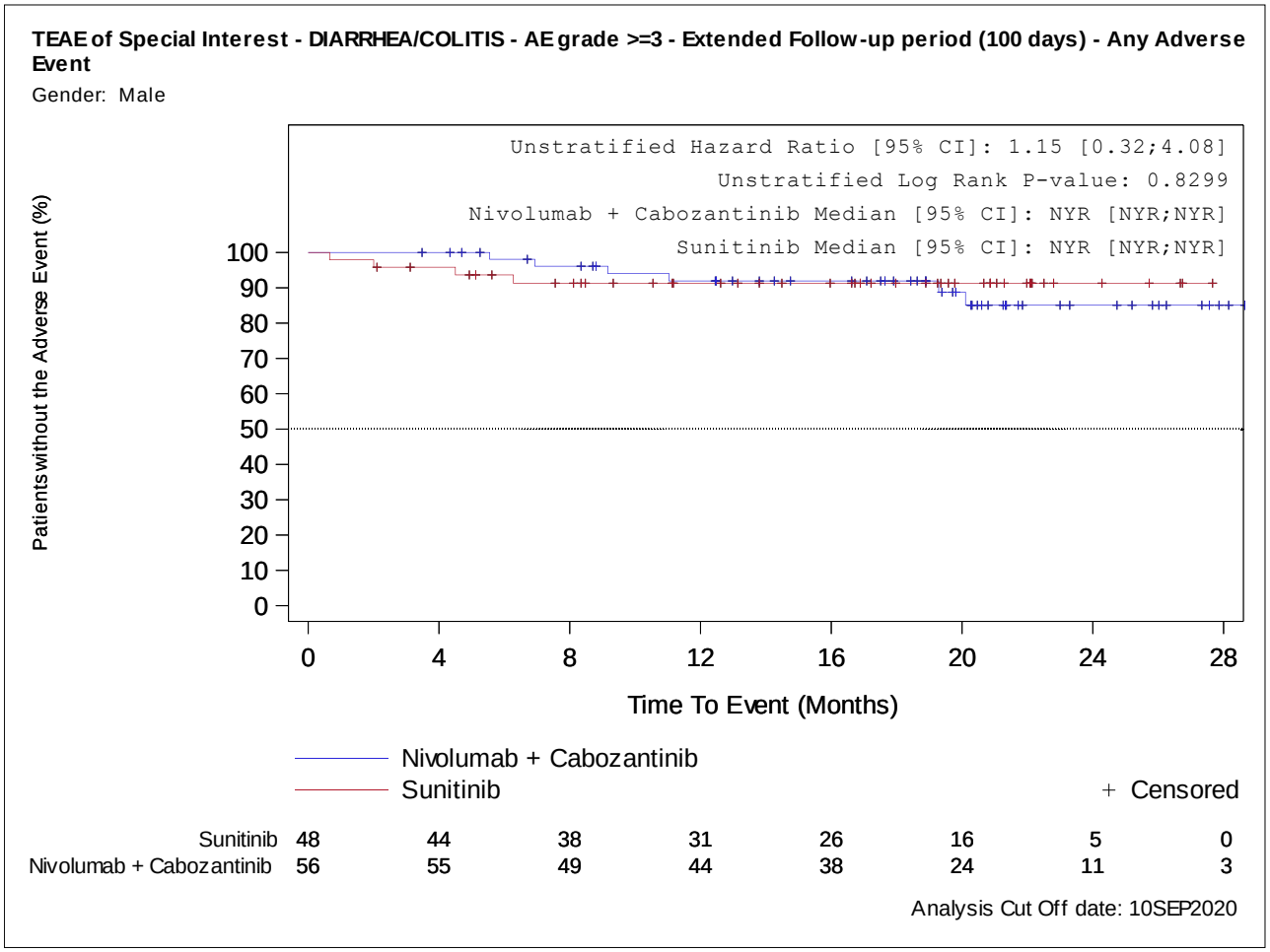
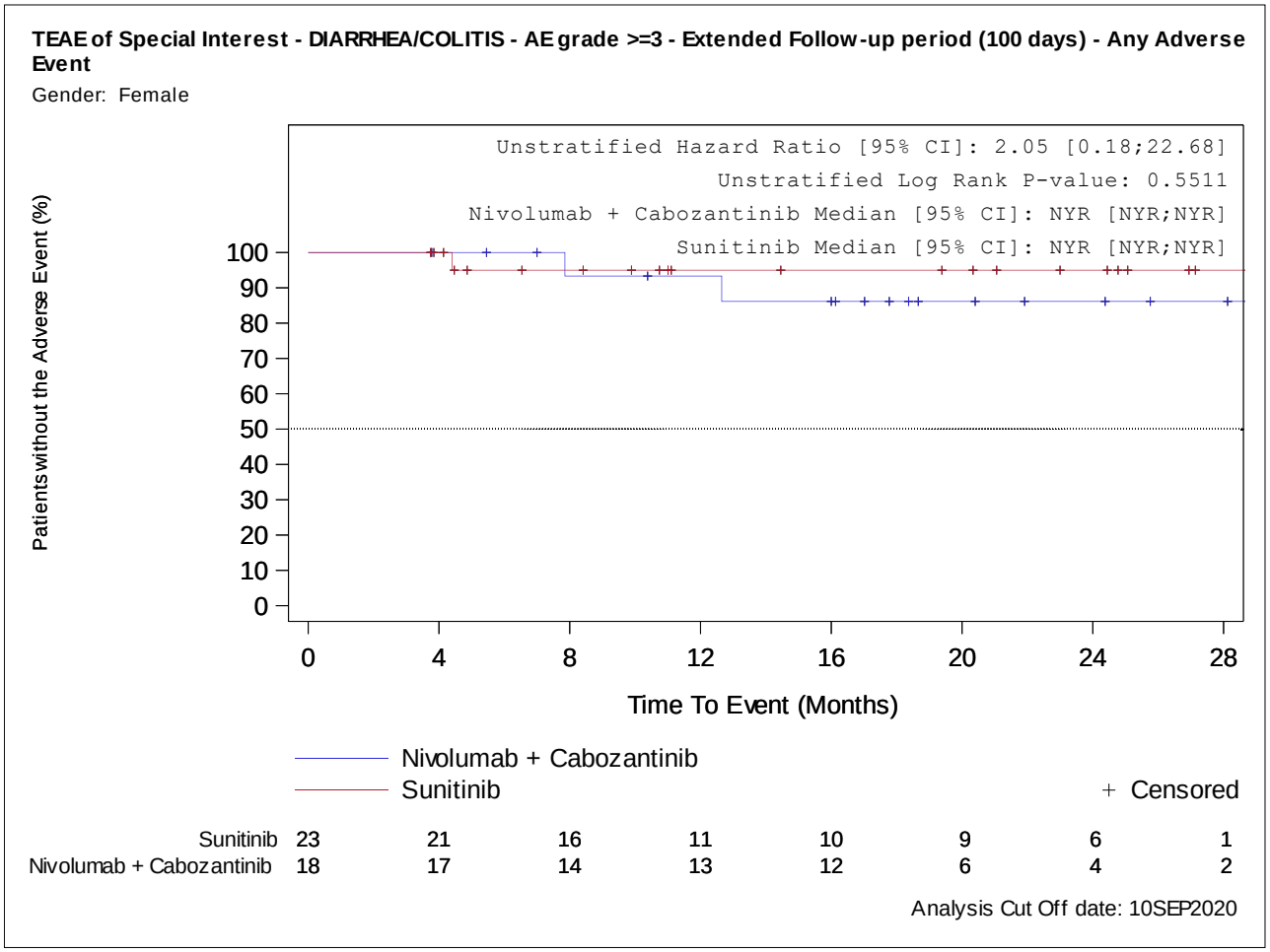
FIGURE 3.74.2.13: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



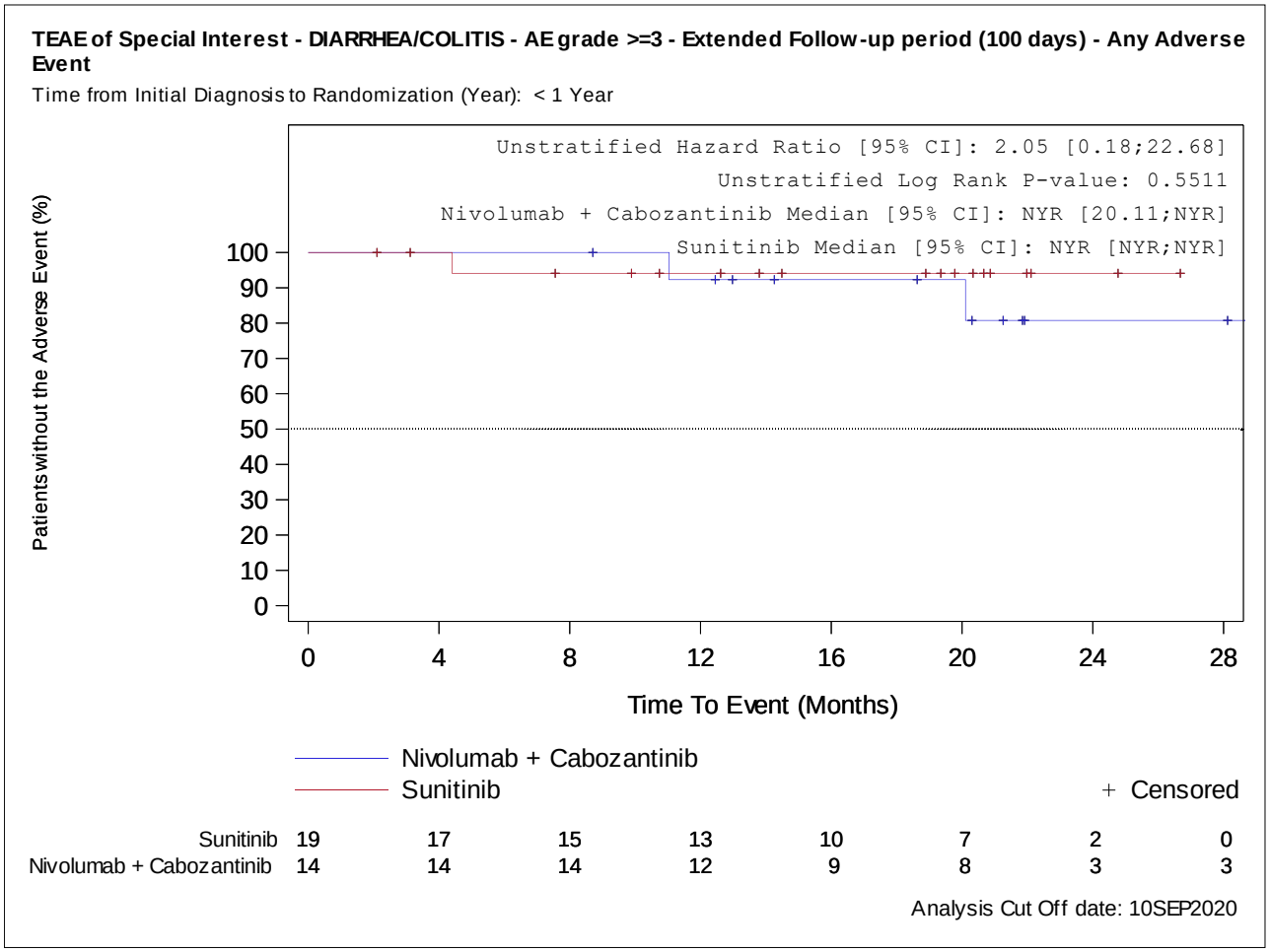

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:38:46

FIGURE 3.74.2.14: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



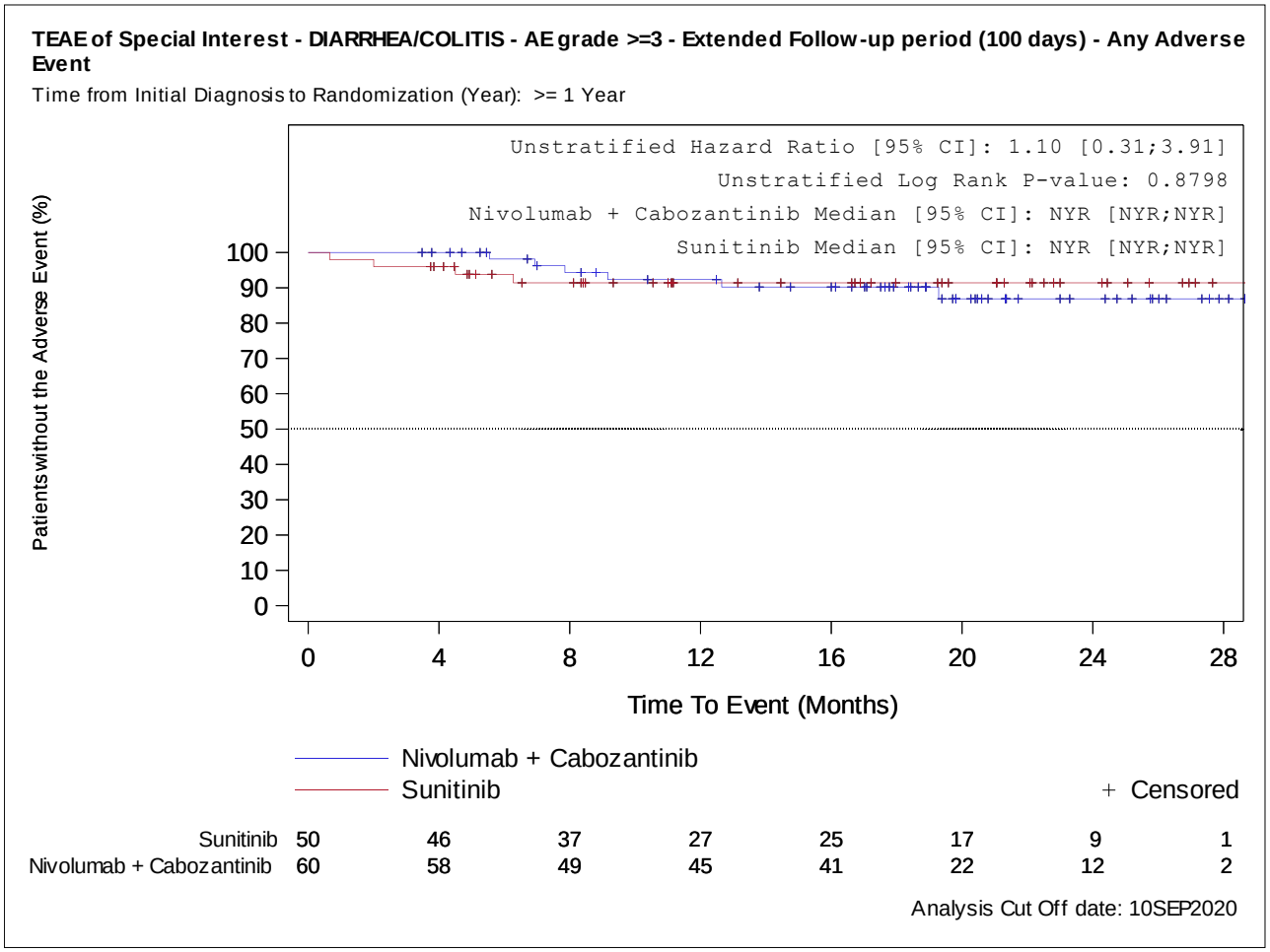

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:38:52

FIGURE 3.74.2.15: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:39:09

FIGURE 3.74.2.16: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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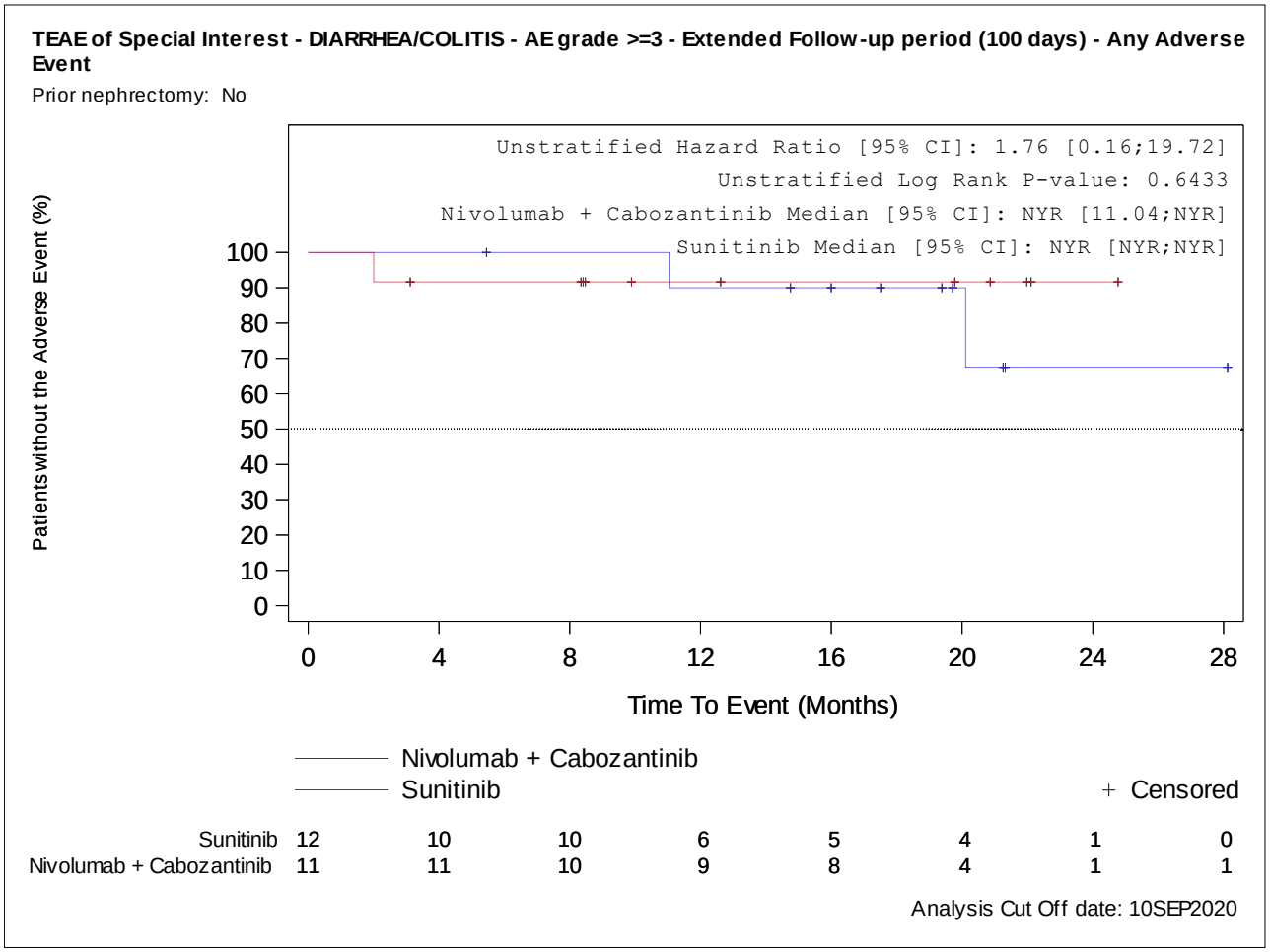
FIGURE 3.74.2.17: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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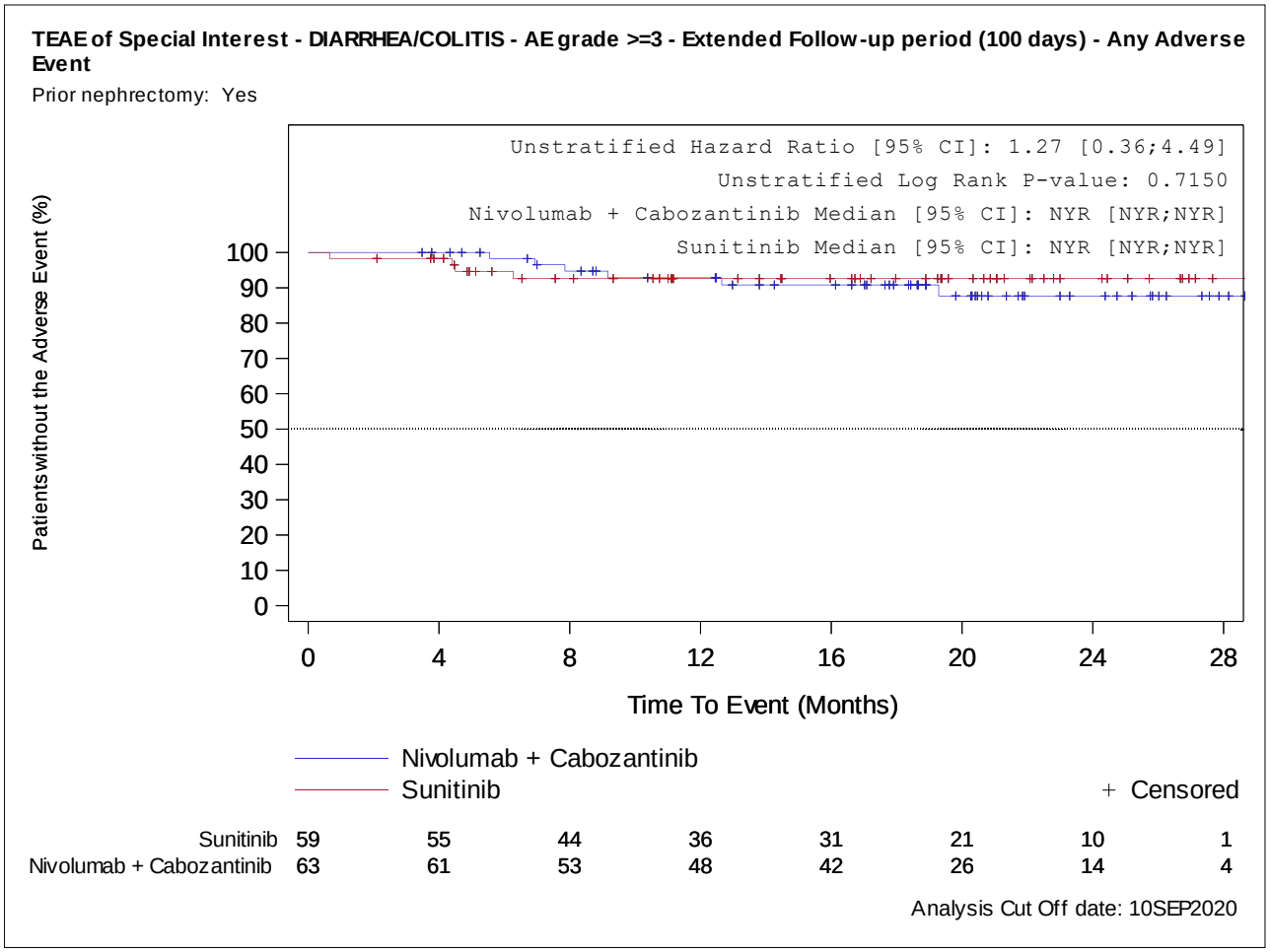
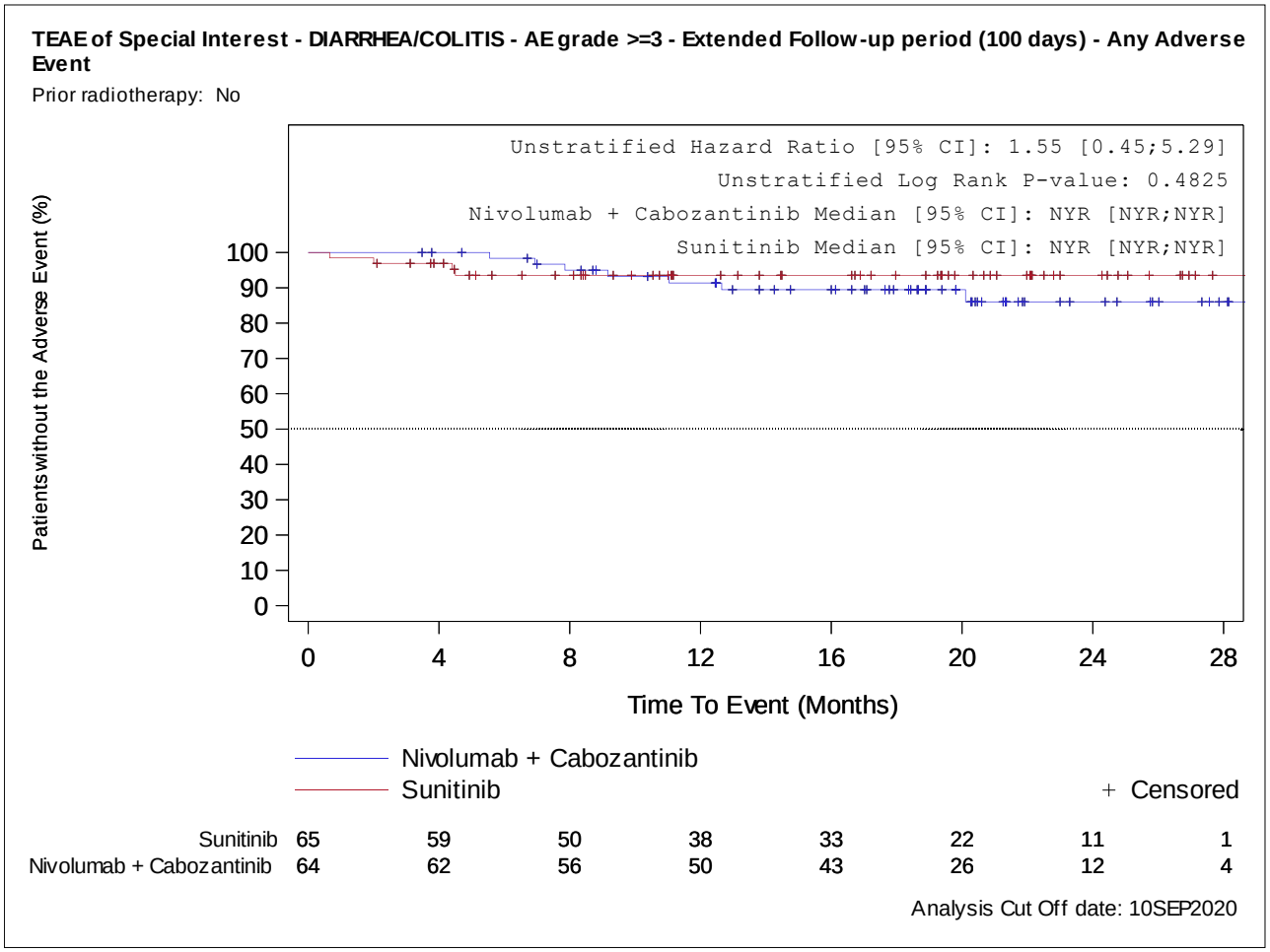
FIGURE 3.74.2.18: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:40:13

FIGURE 3.74.2.19: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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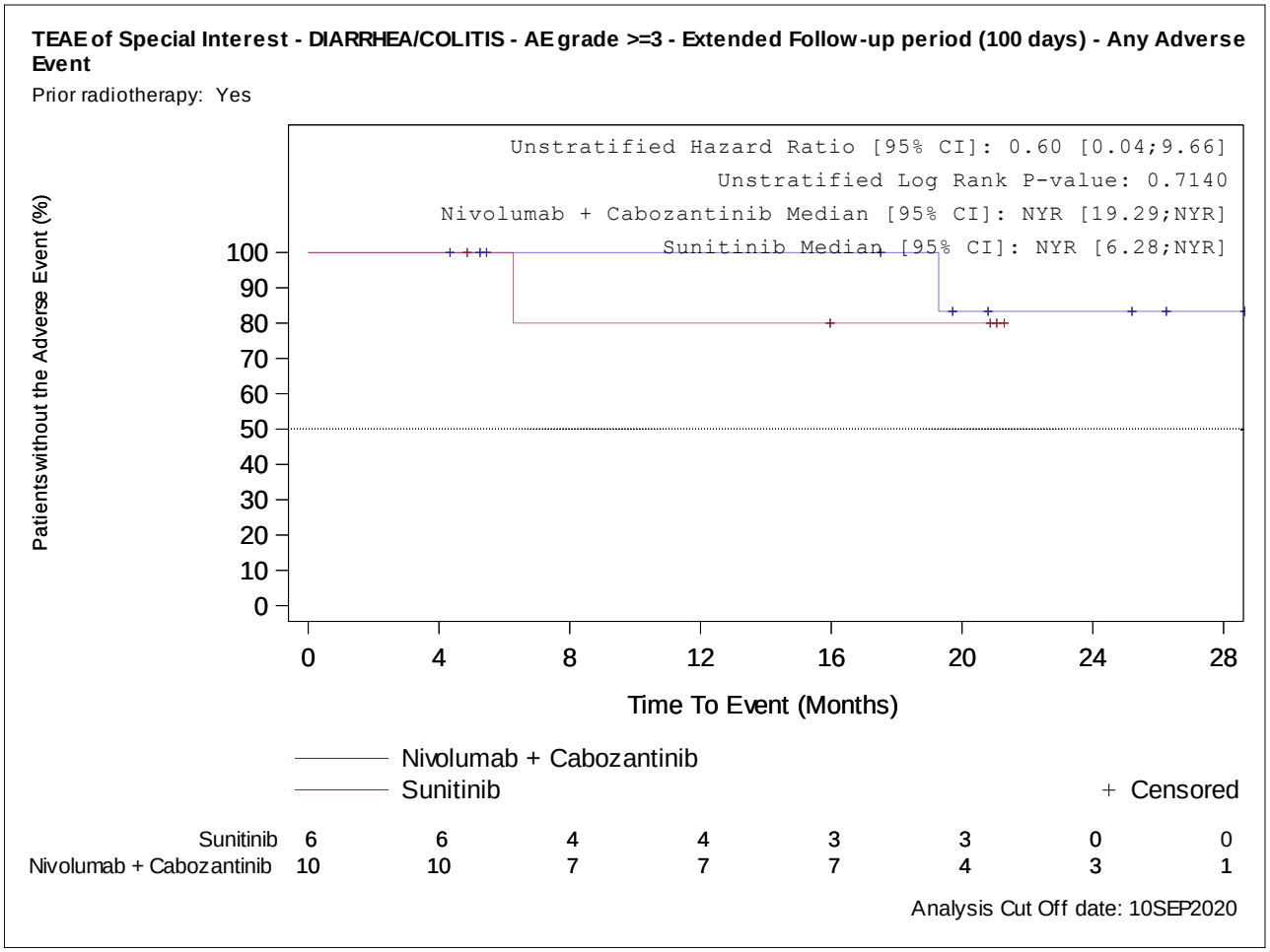
FIGURE 3.74.2.20: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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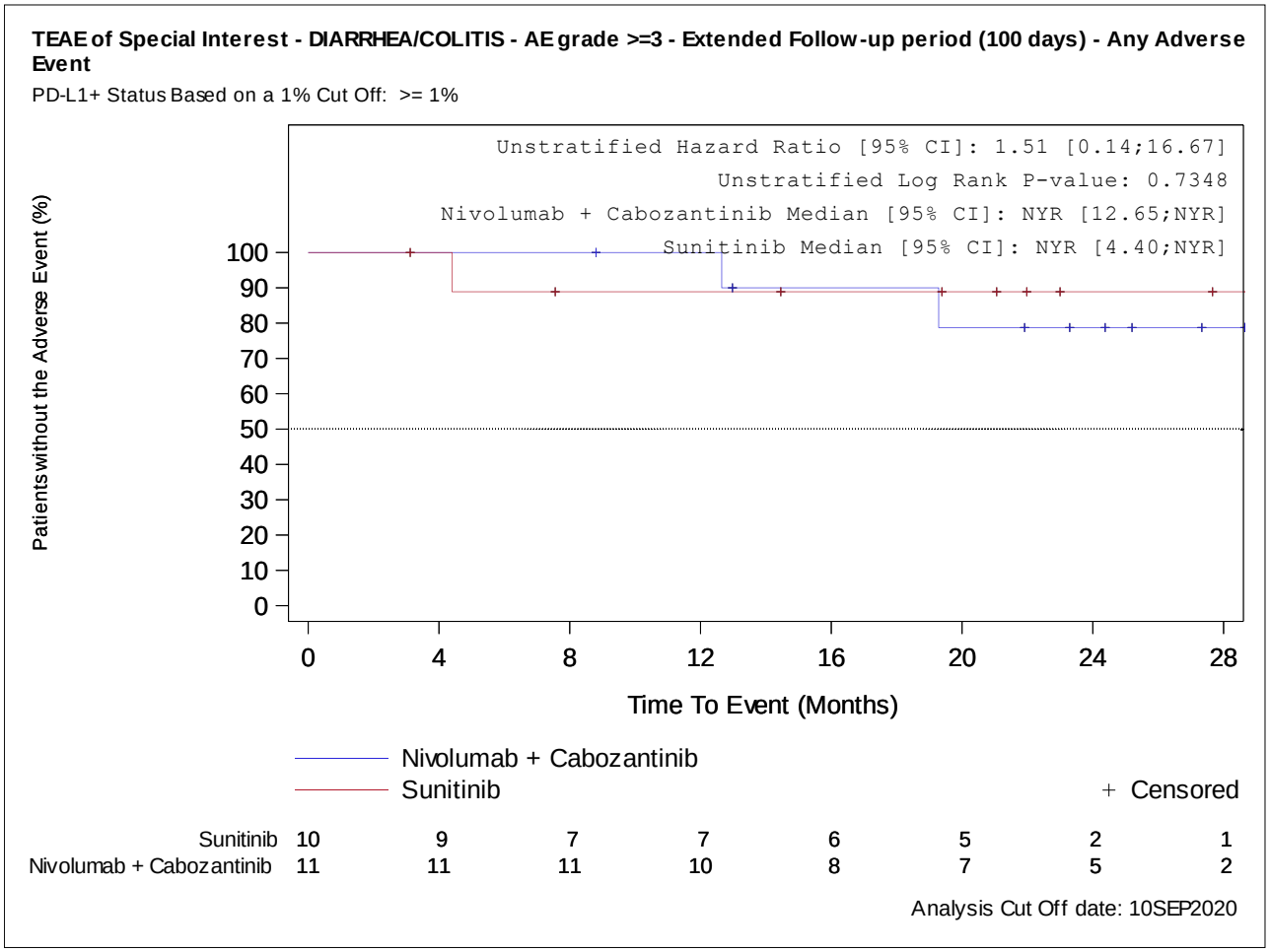
FIGURE 3.74.2.21: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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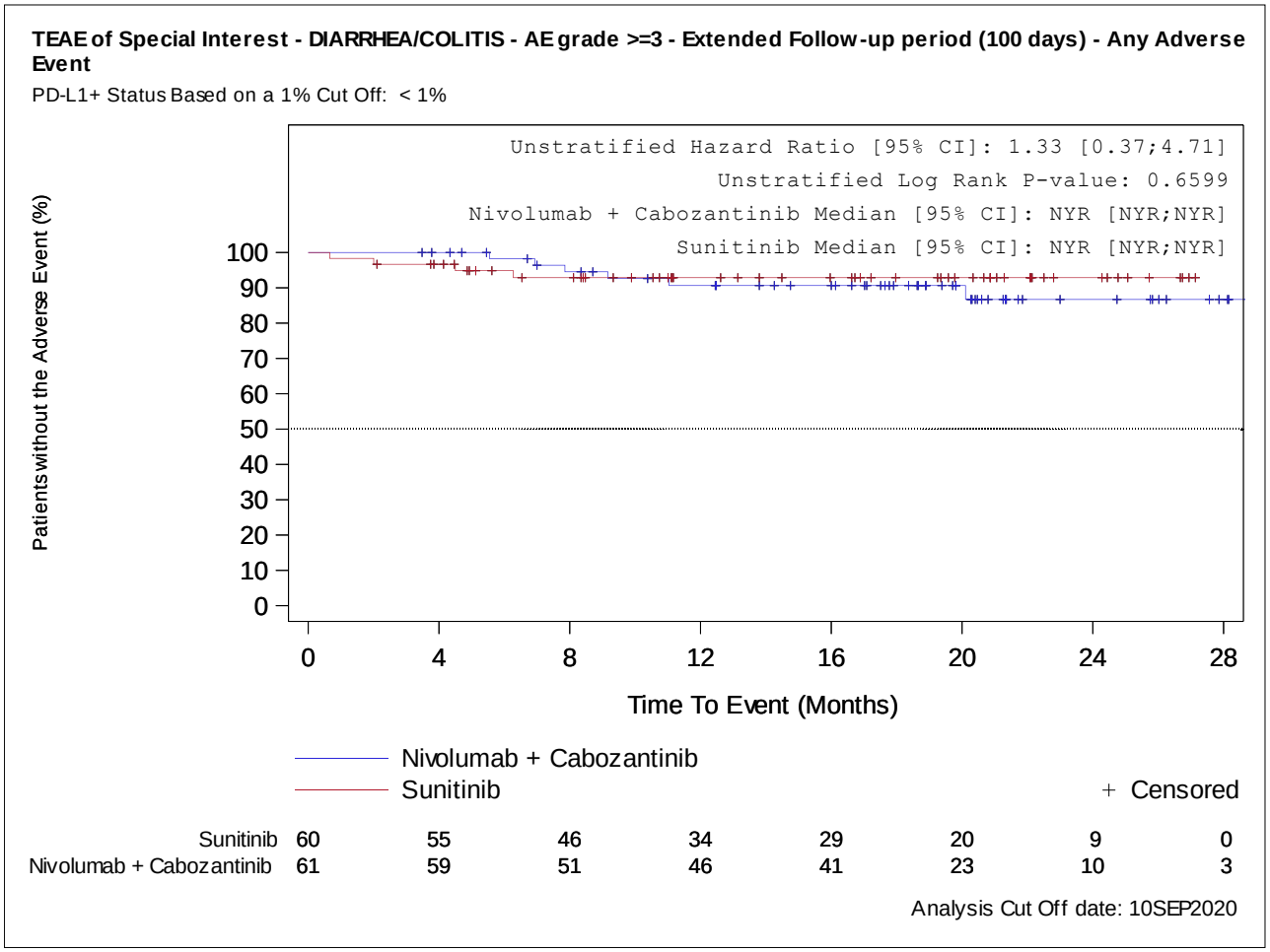
FIGURE 3.74.2.22: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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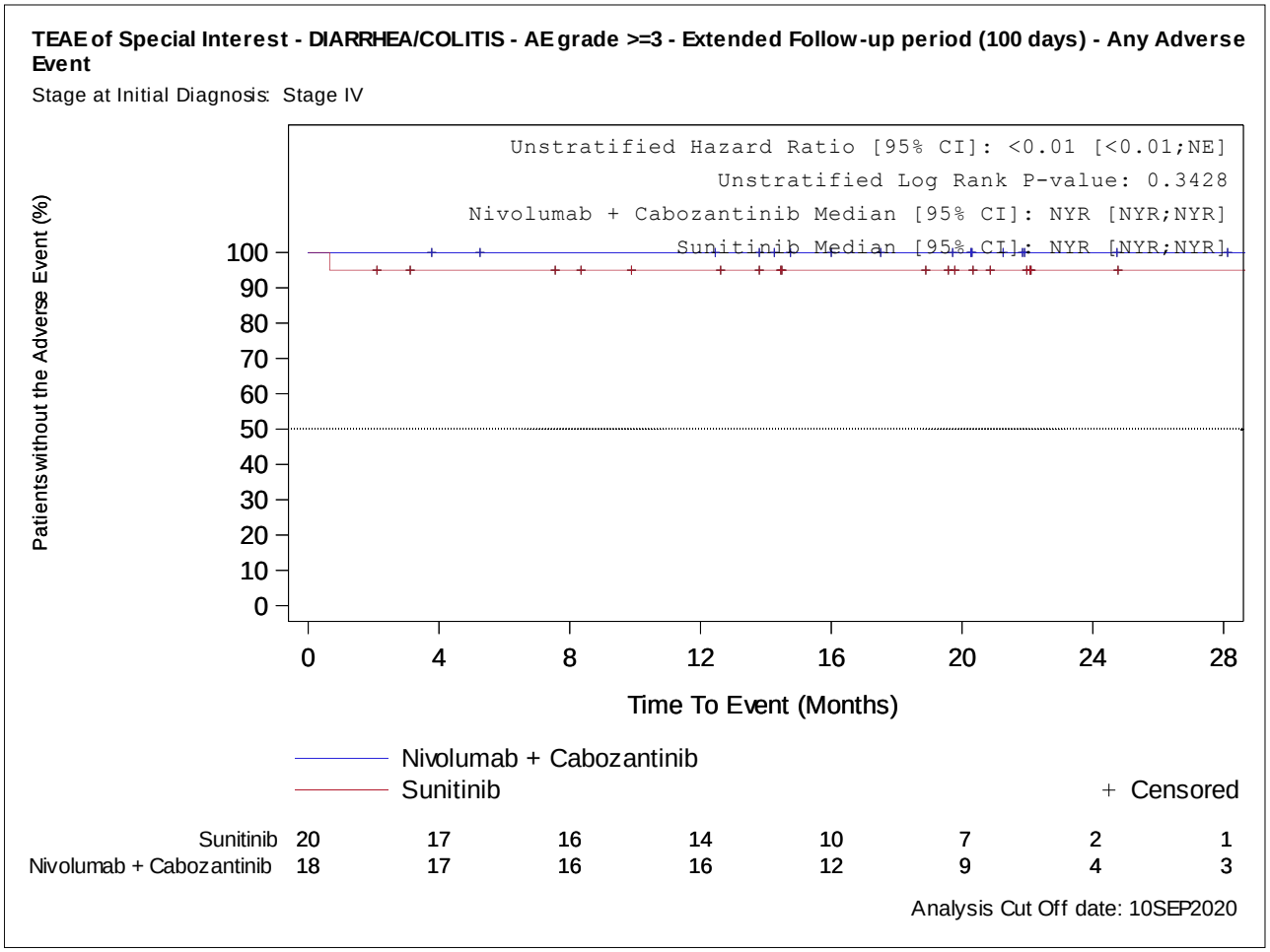
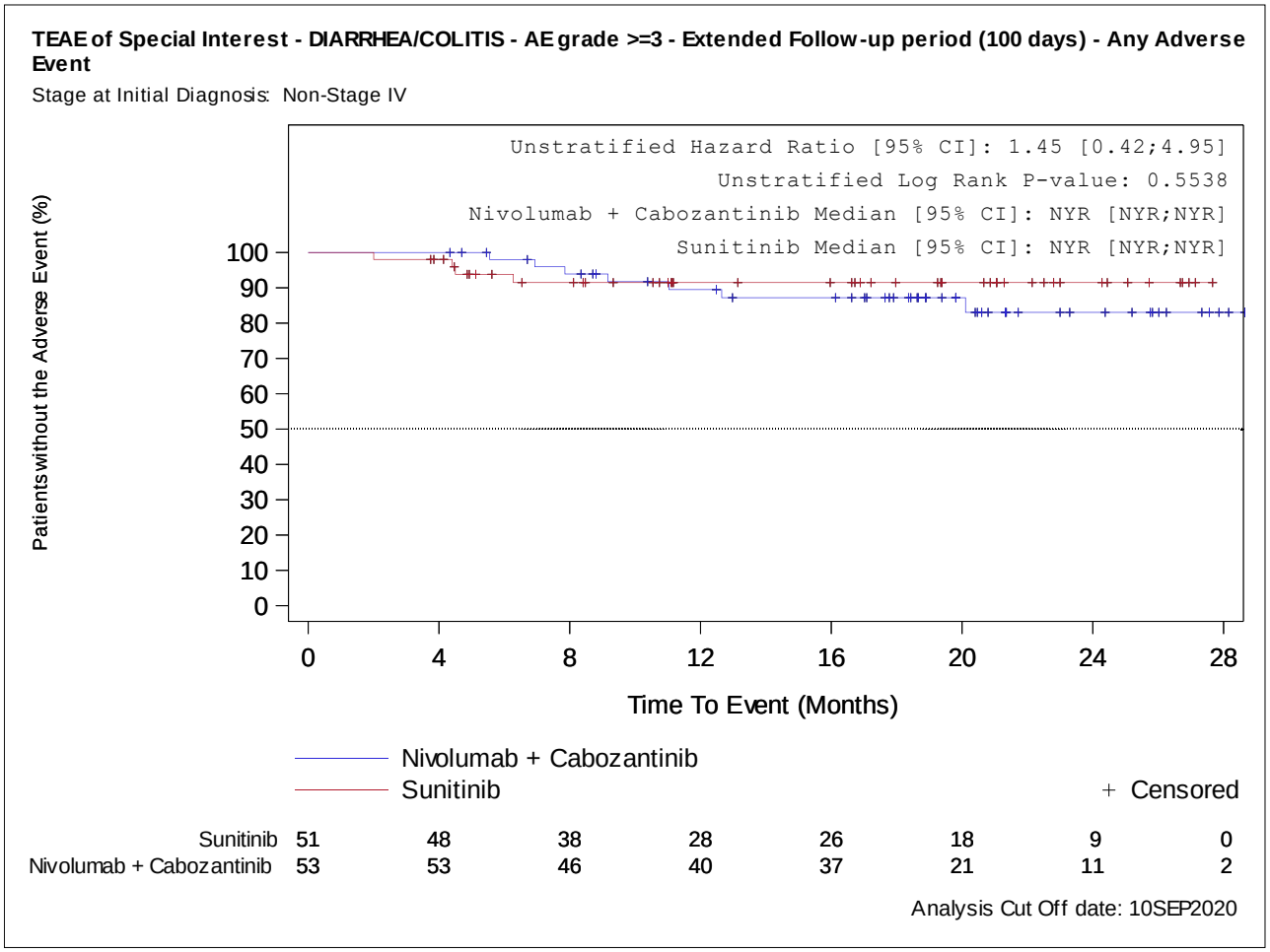
FIGURE 3.74.2.23: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



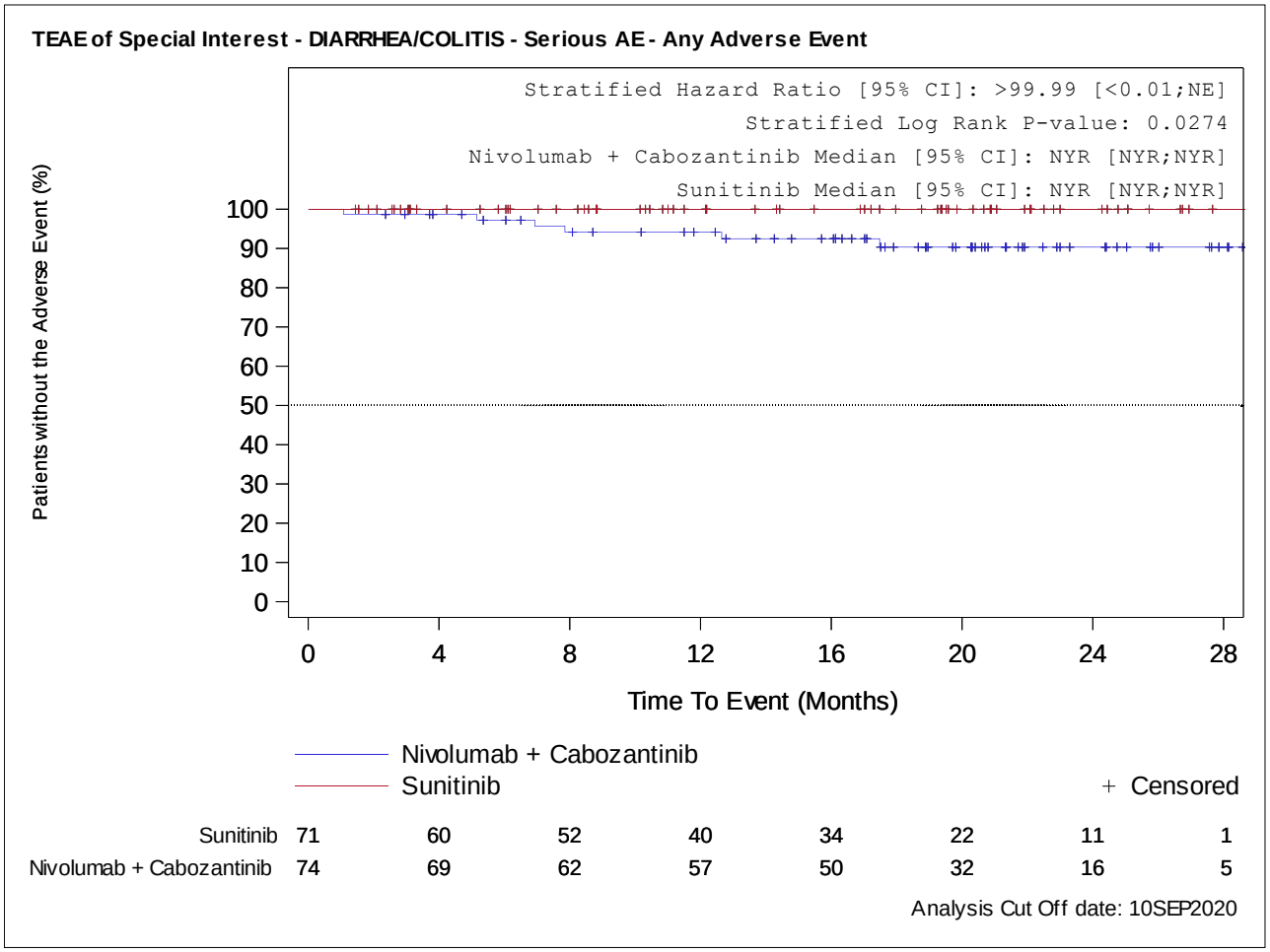

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:41:05

FIGURE 3.74.2.24: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:41:11

FIGURE 3.75.1: TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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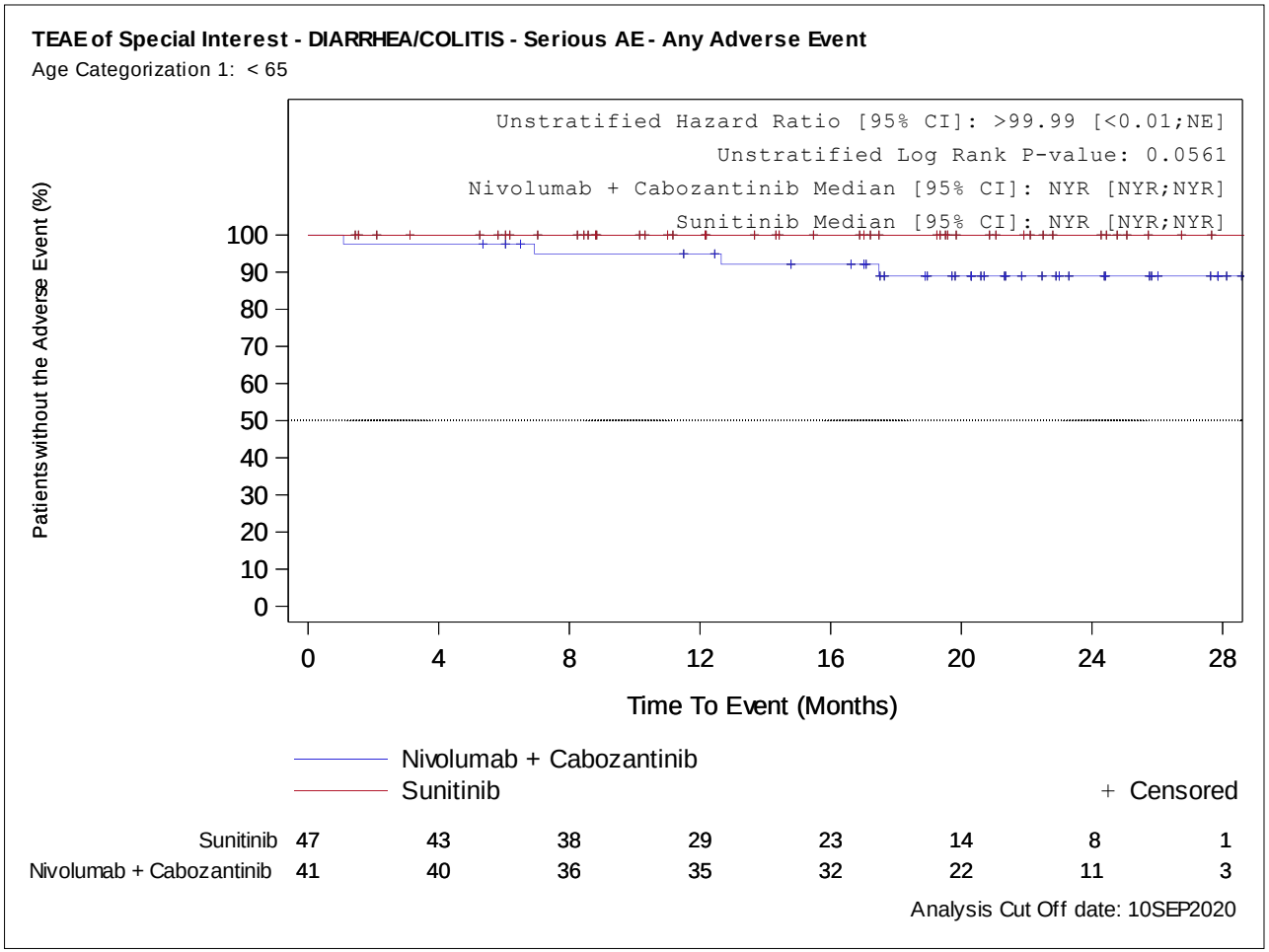
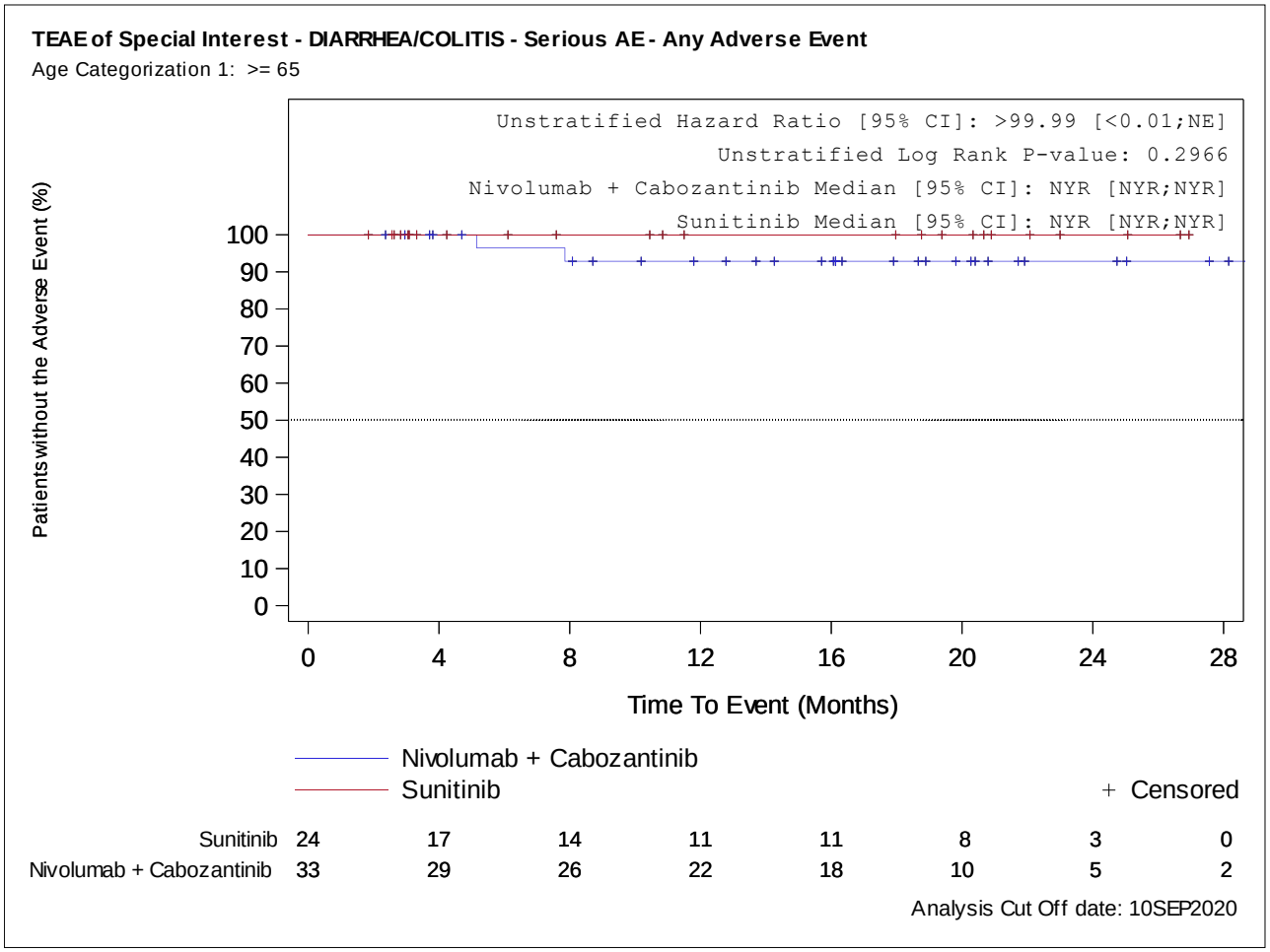
FIGURE 3.75.2.1: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



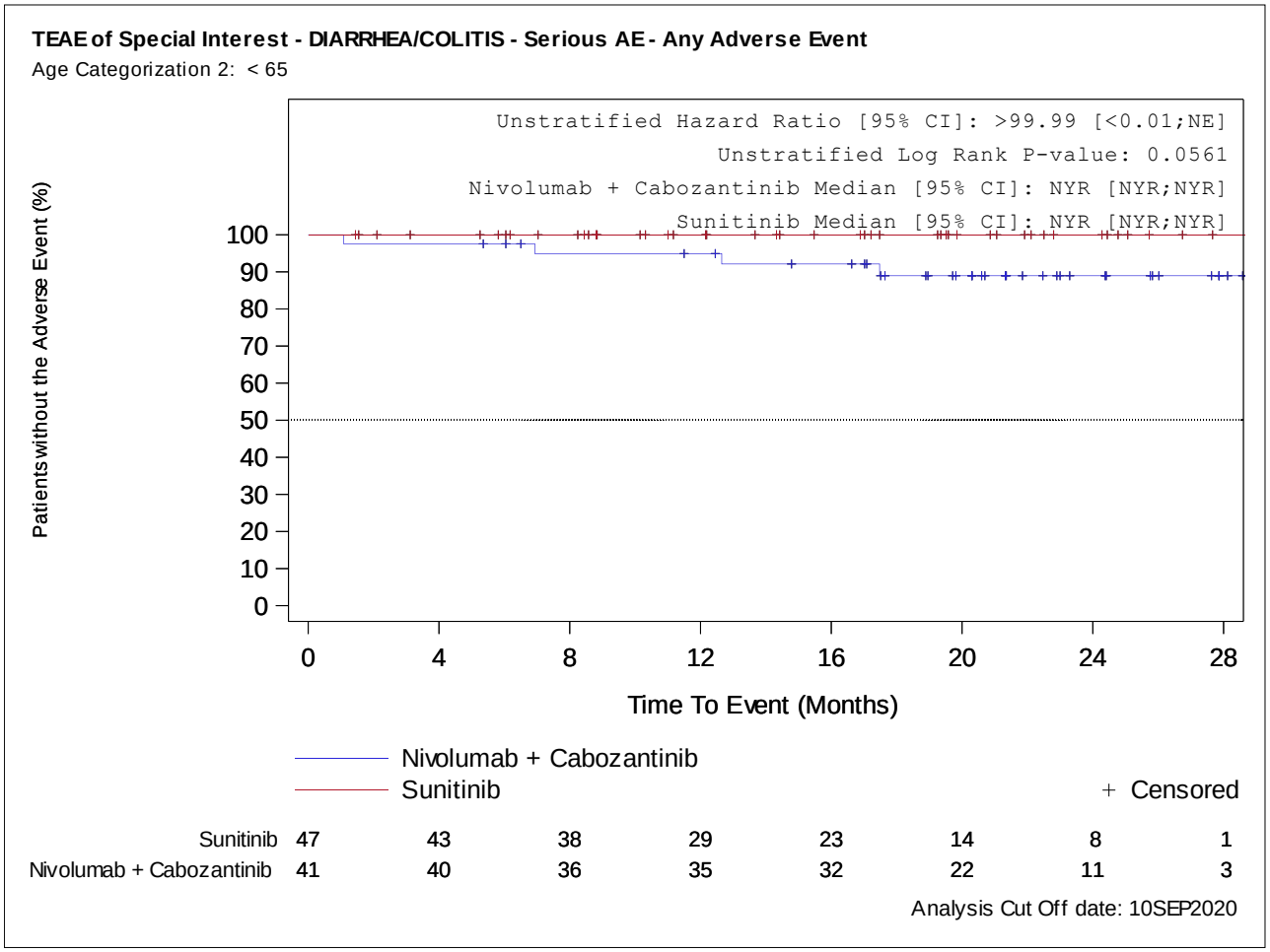

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:44:33

FIGURE 3.75.2.2: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



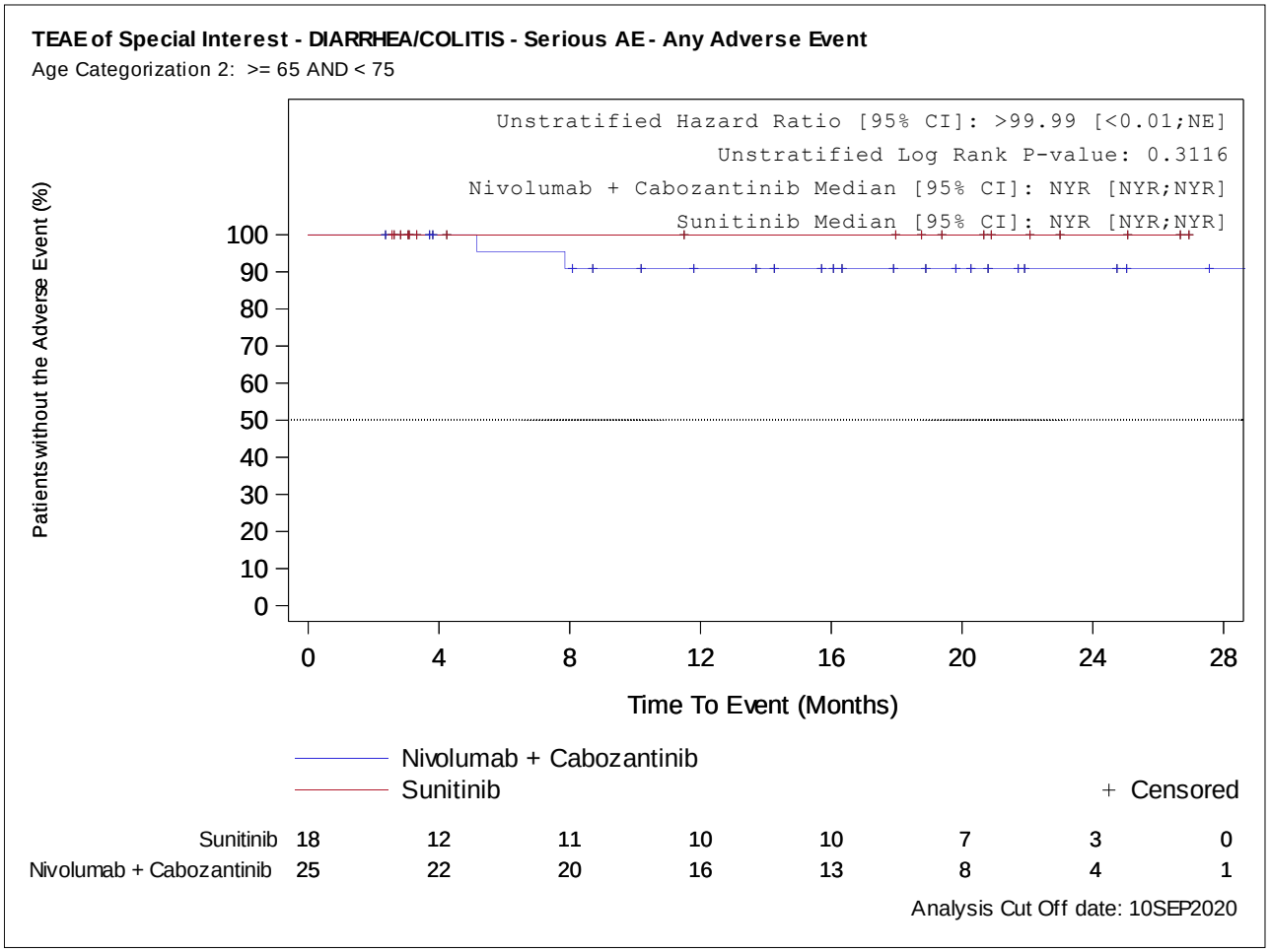

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:44:39

FIGURE 3.75.2.3: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



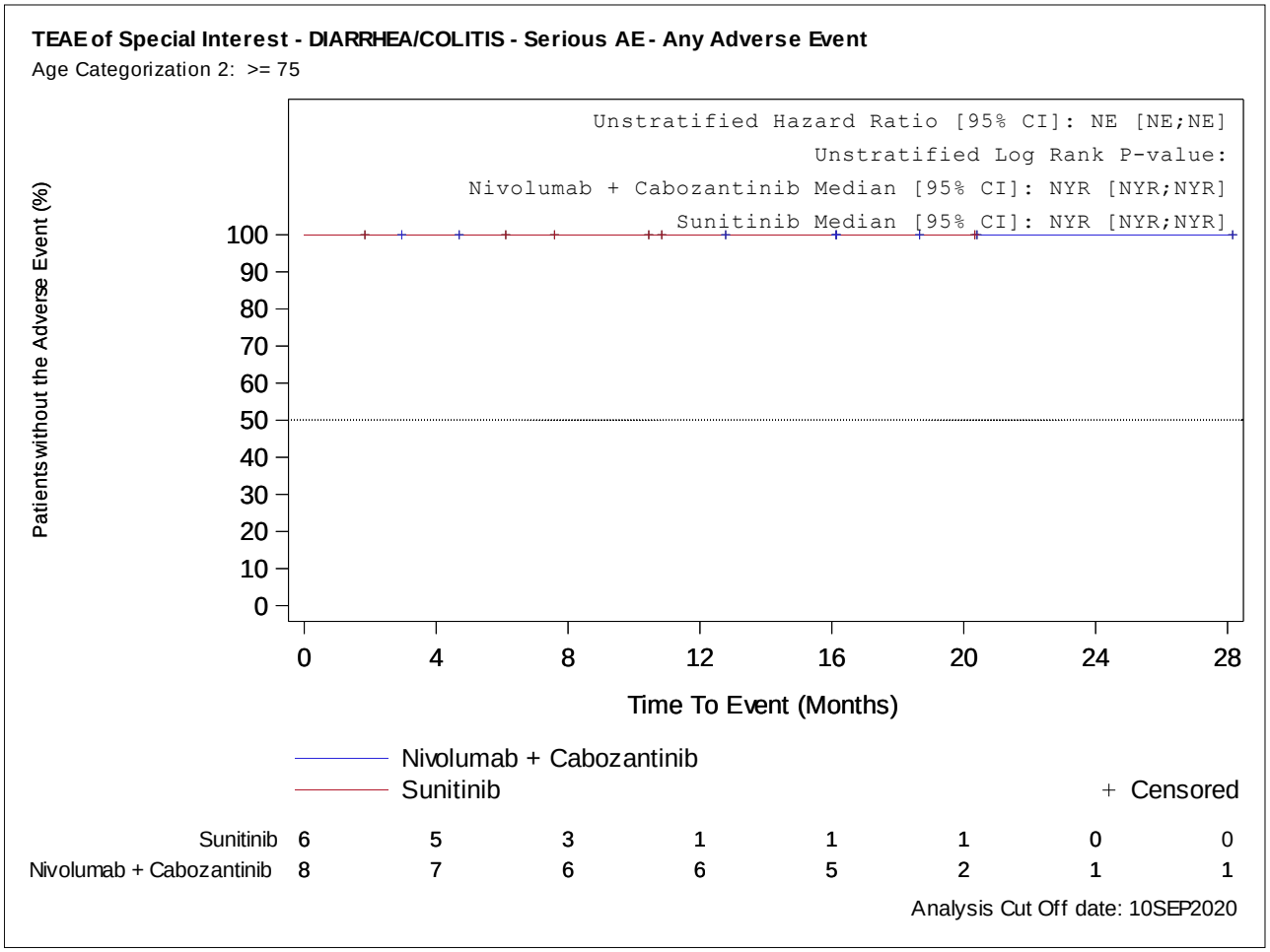

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:44:44

FIGURE 3.75.2.4: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



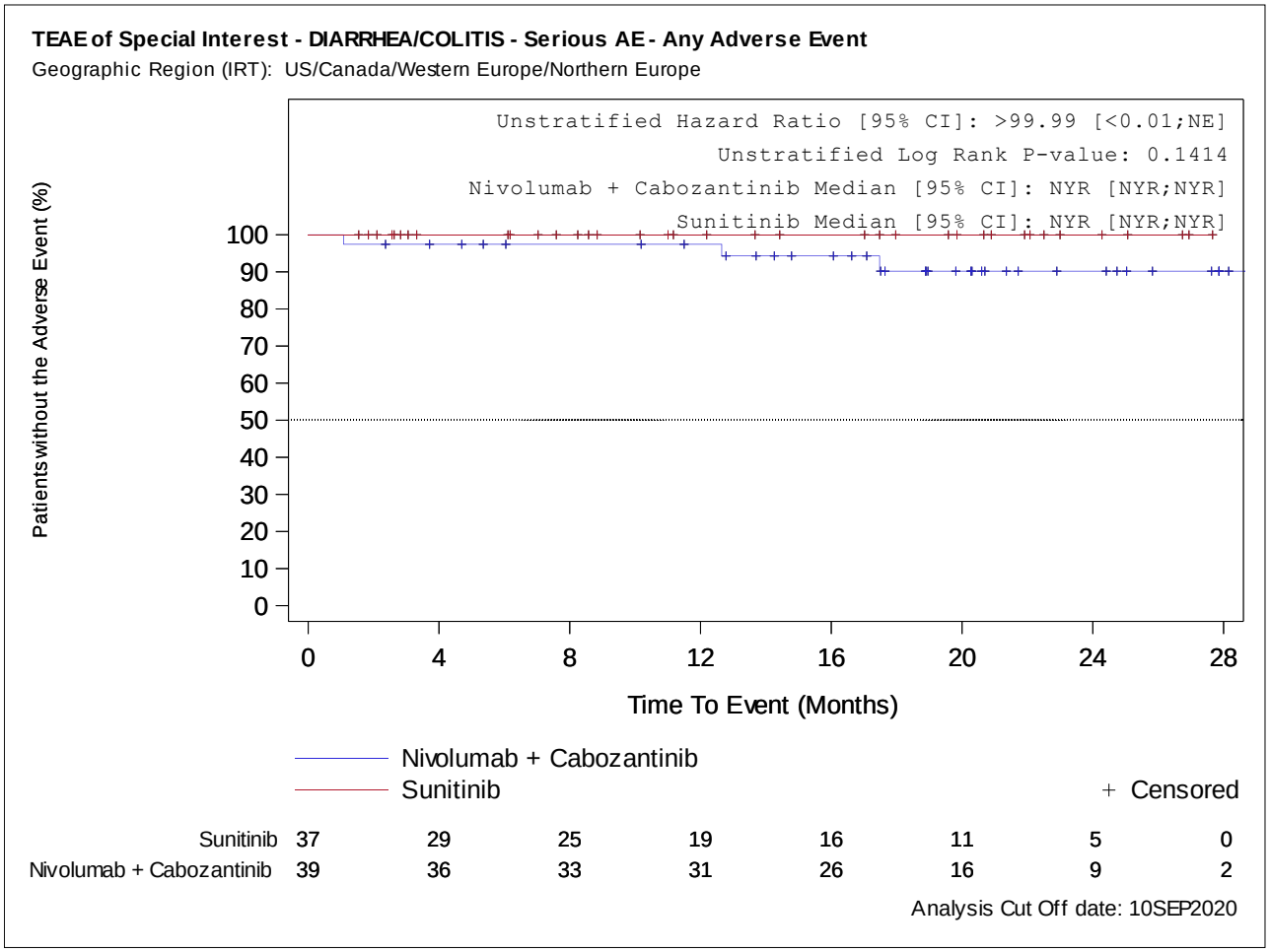

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:44:50

FIGURE 3.75.2.5: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



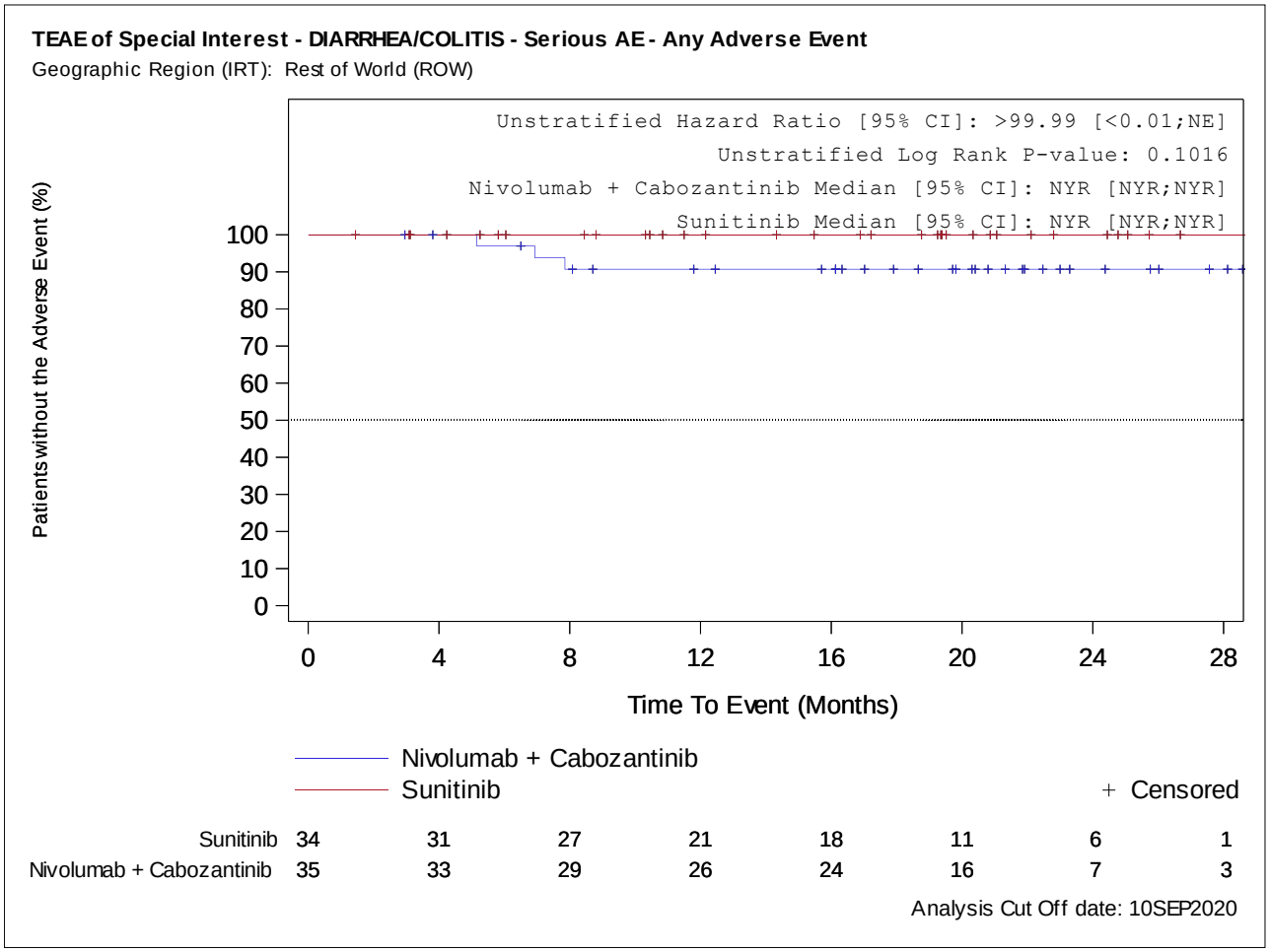

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:44:56

FIGURE 3.75.2.6: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



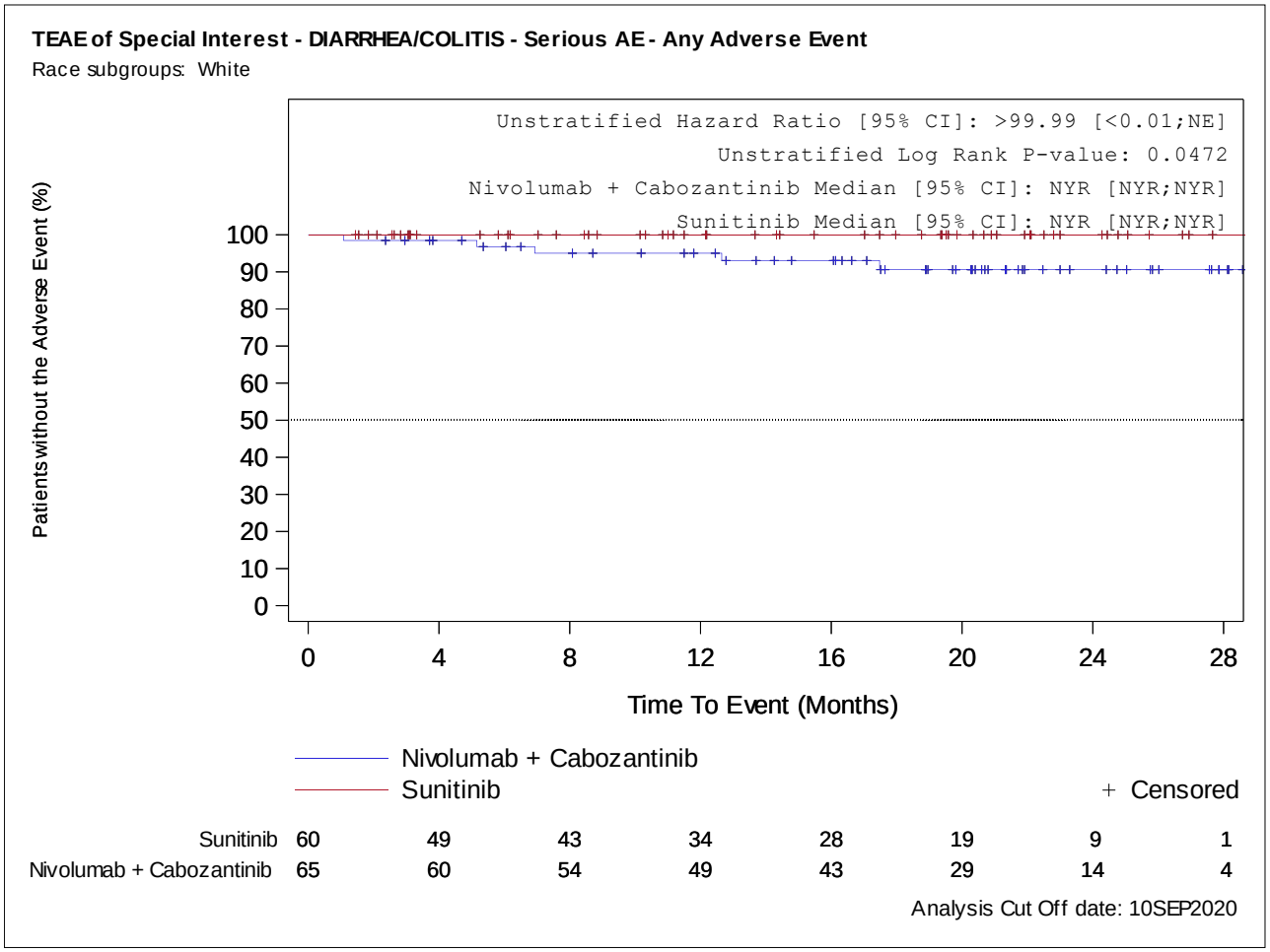

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:45:02

FIGURE 3.75.2.7: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



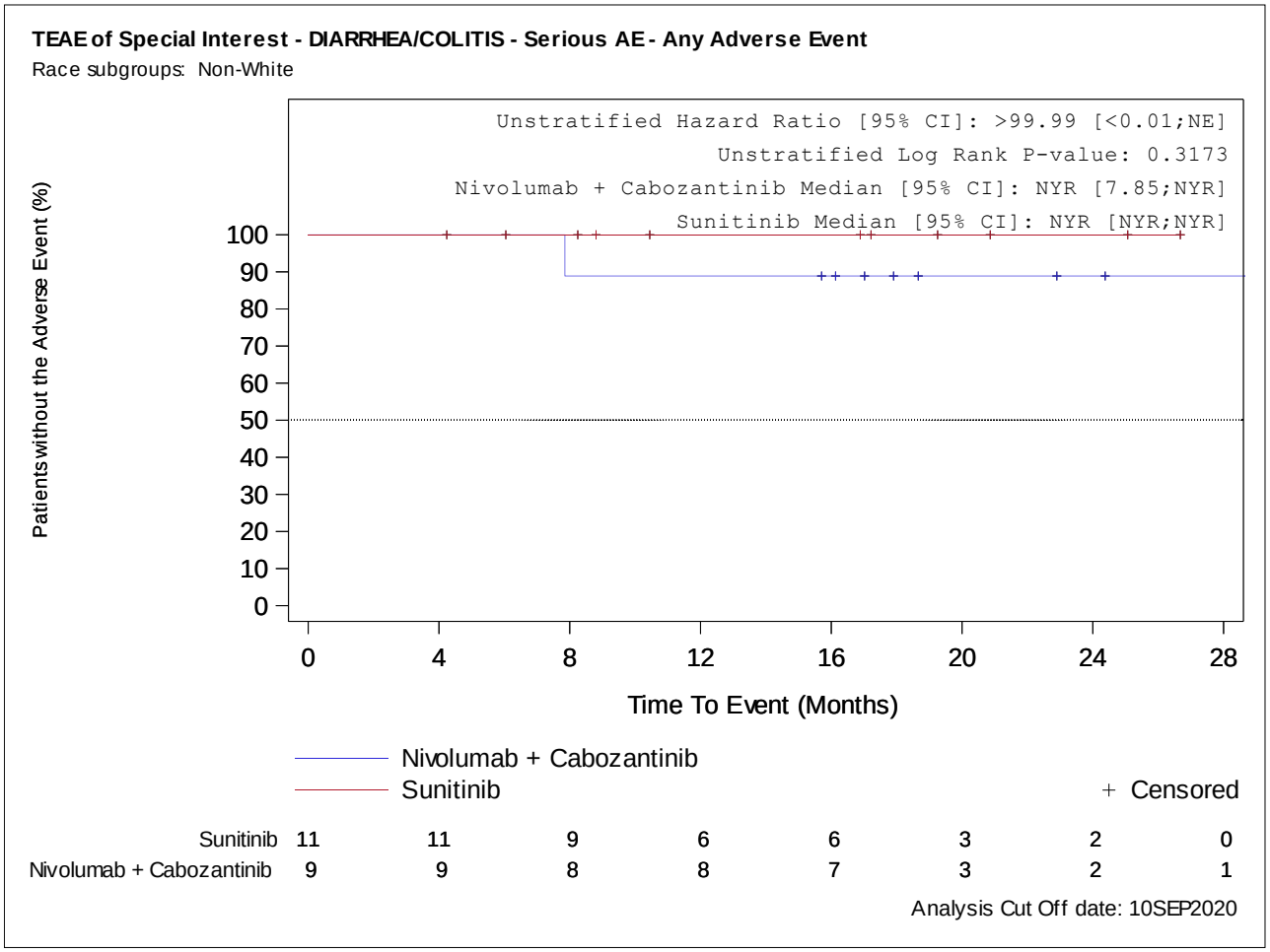

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:45:07

FIGURE 3.75.2.8: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



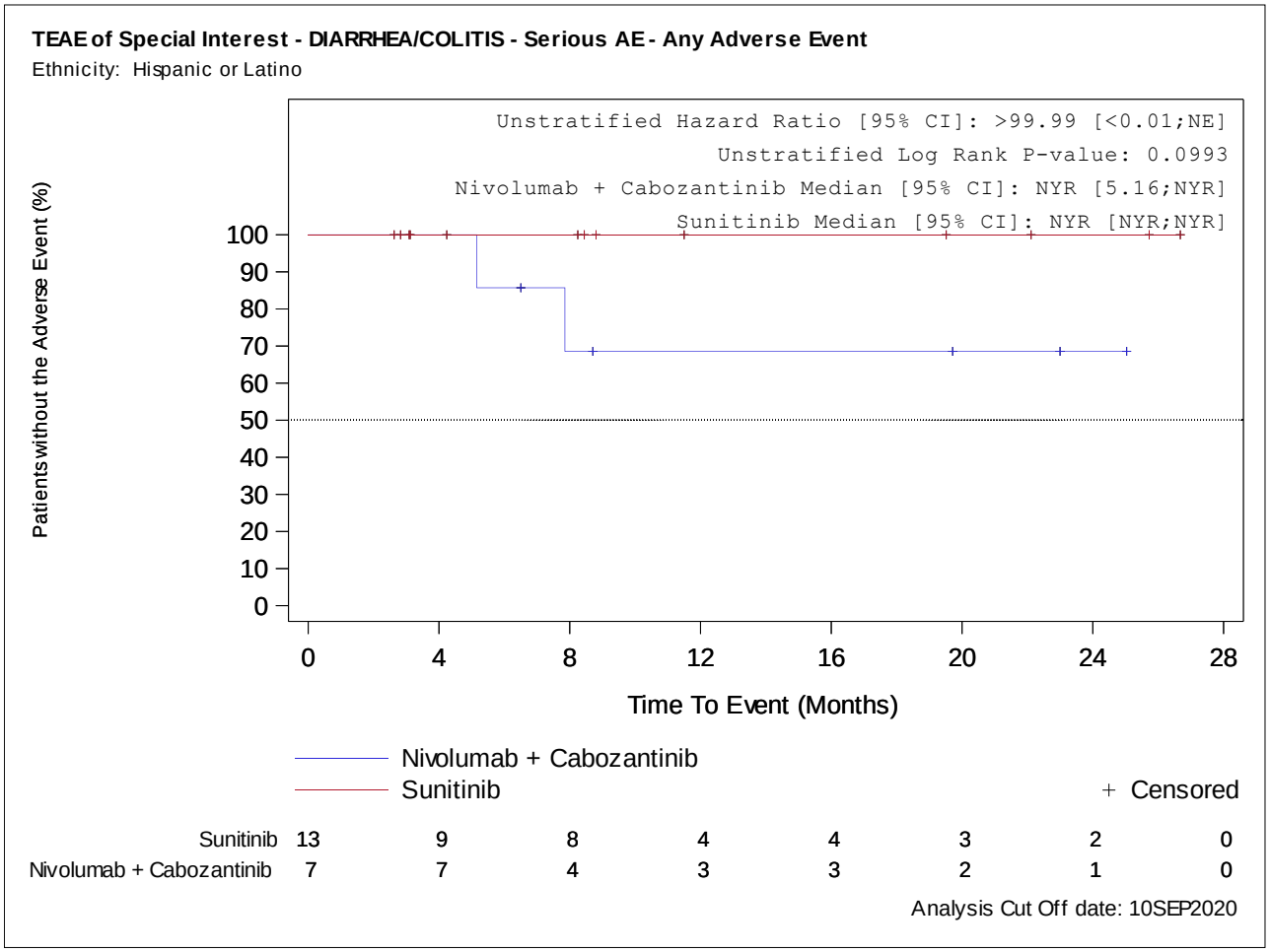

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:45:13

FIGURE 3.75.2.9: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



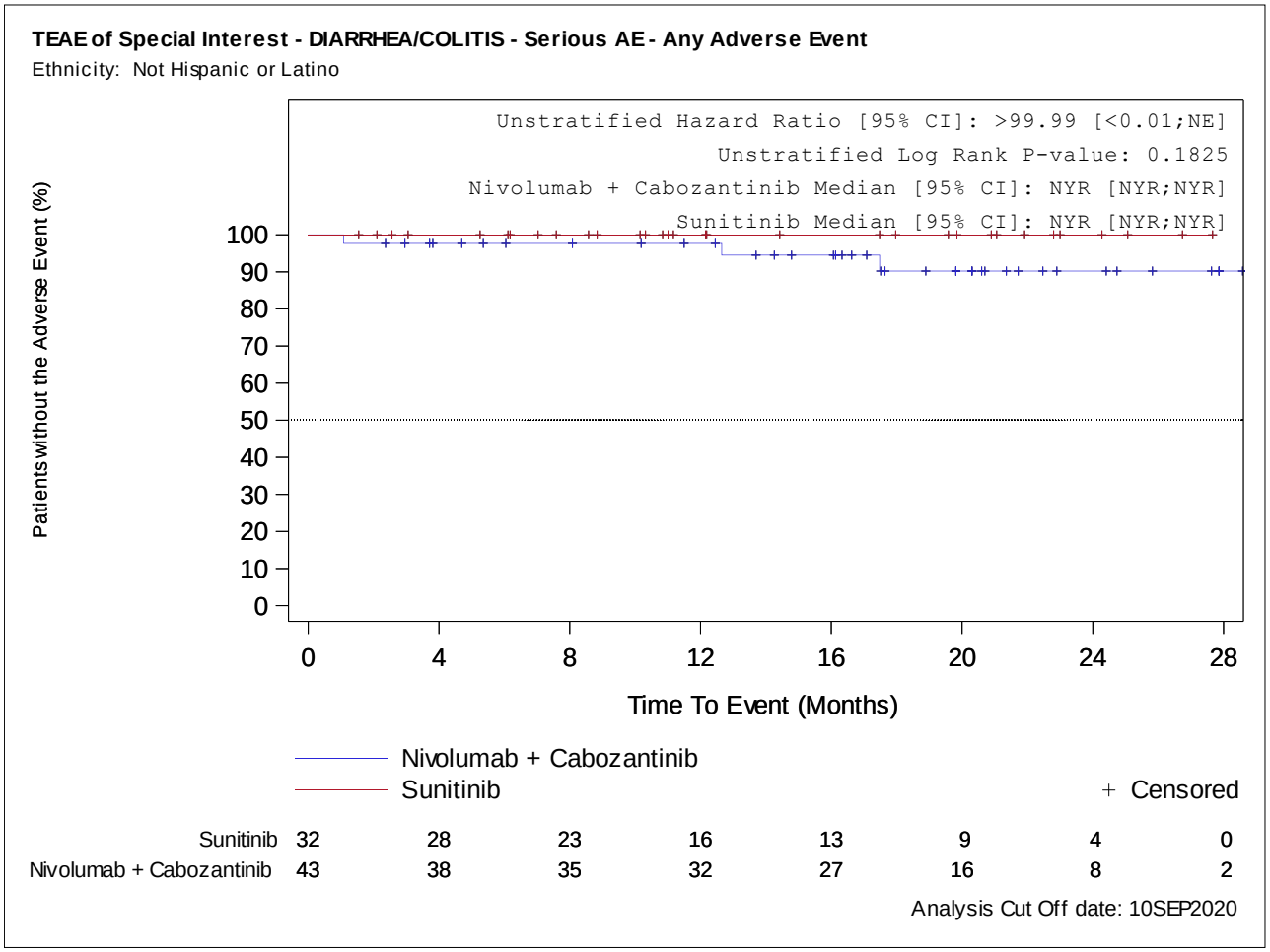

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:45:19

FIGURE 3.75.2.10: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



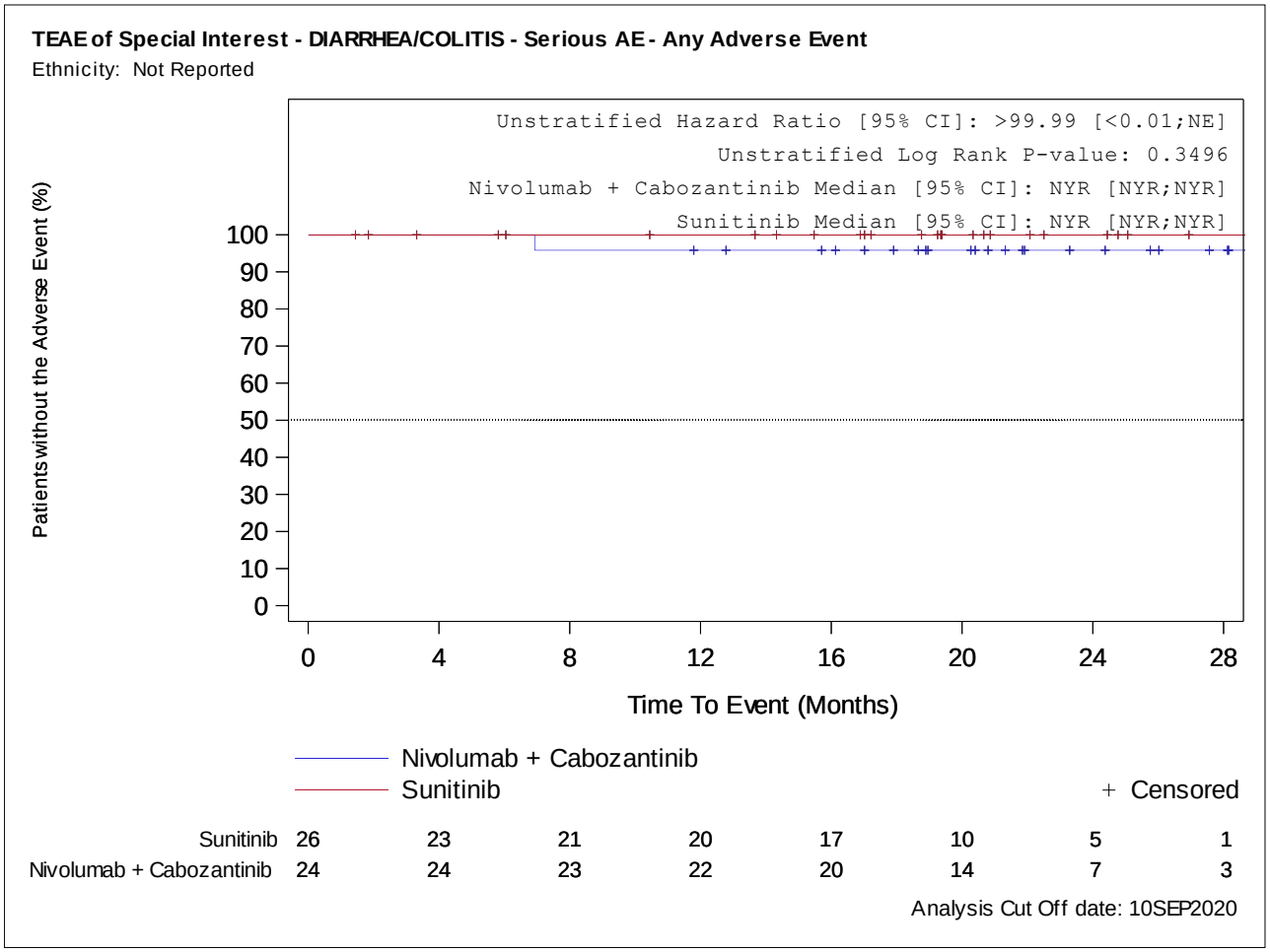

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:45:25

FIGURE 3.75.2.11: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



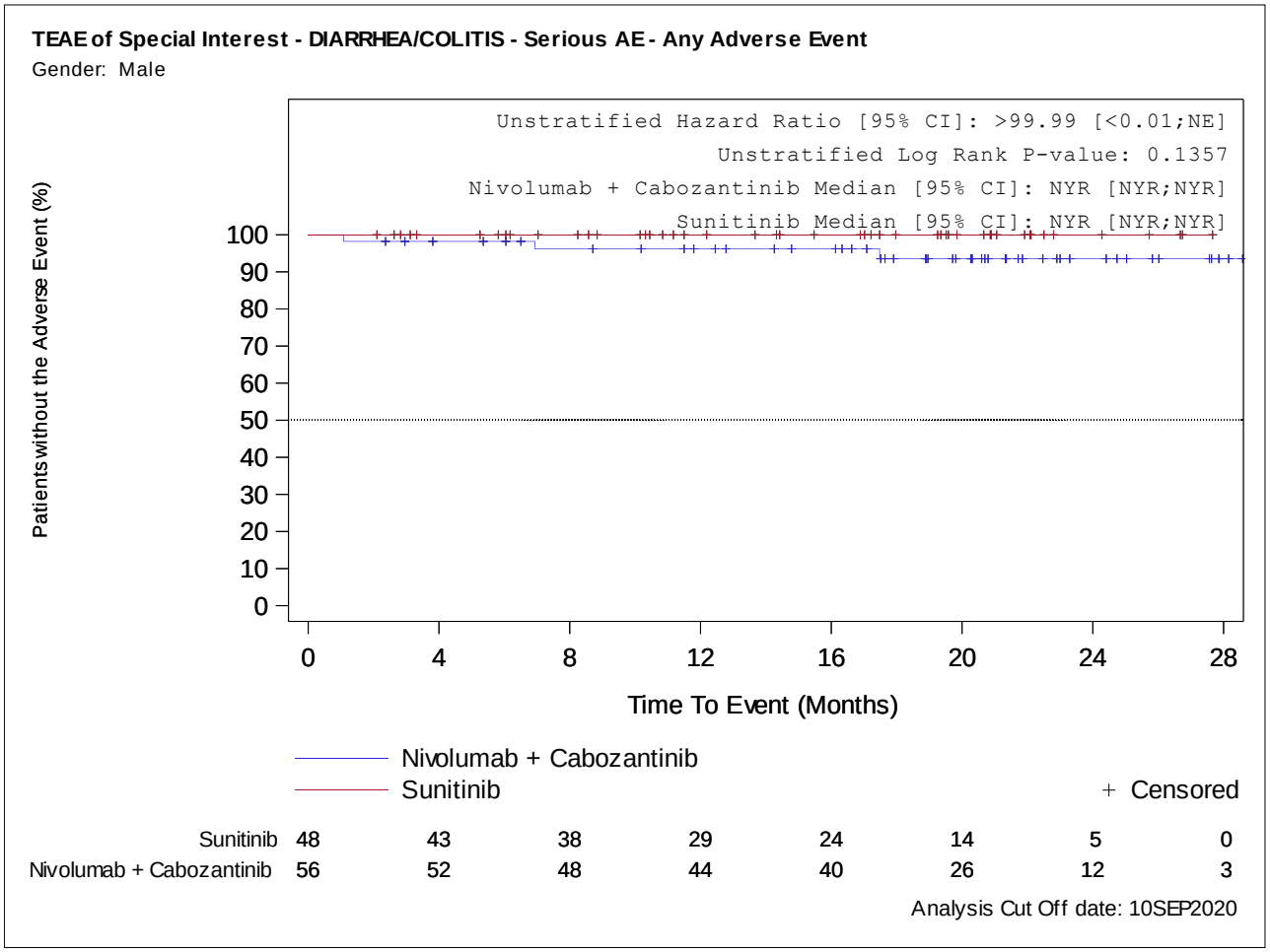

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:45:31

FIGURE 3.75.2.12: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



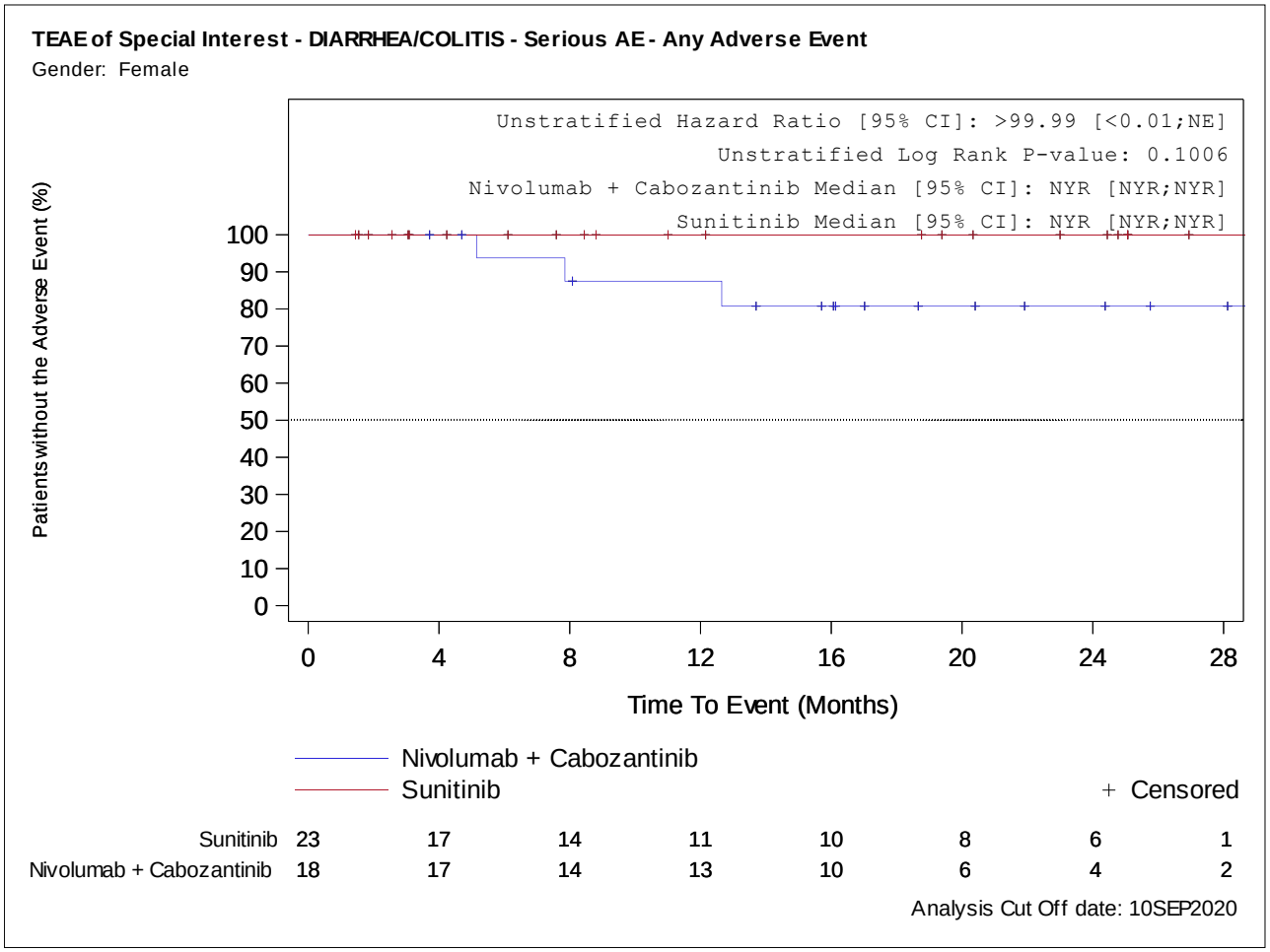

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:45:37

FIGURE 3.75.2.13: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



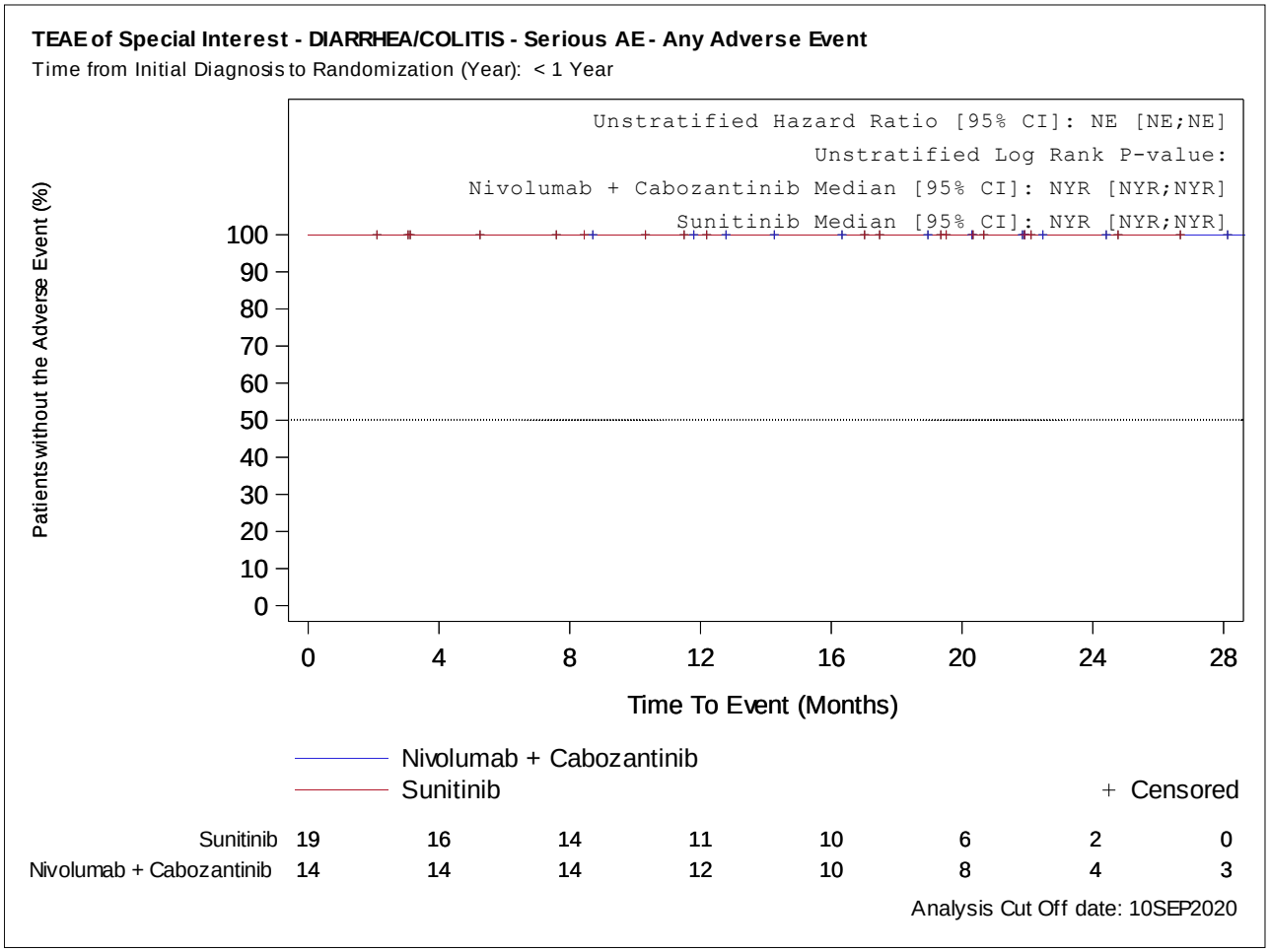

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:45:43

FIGURE 3.75.2.14: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



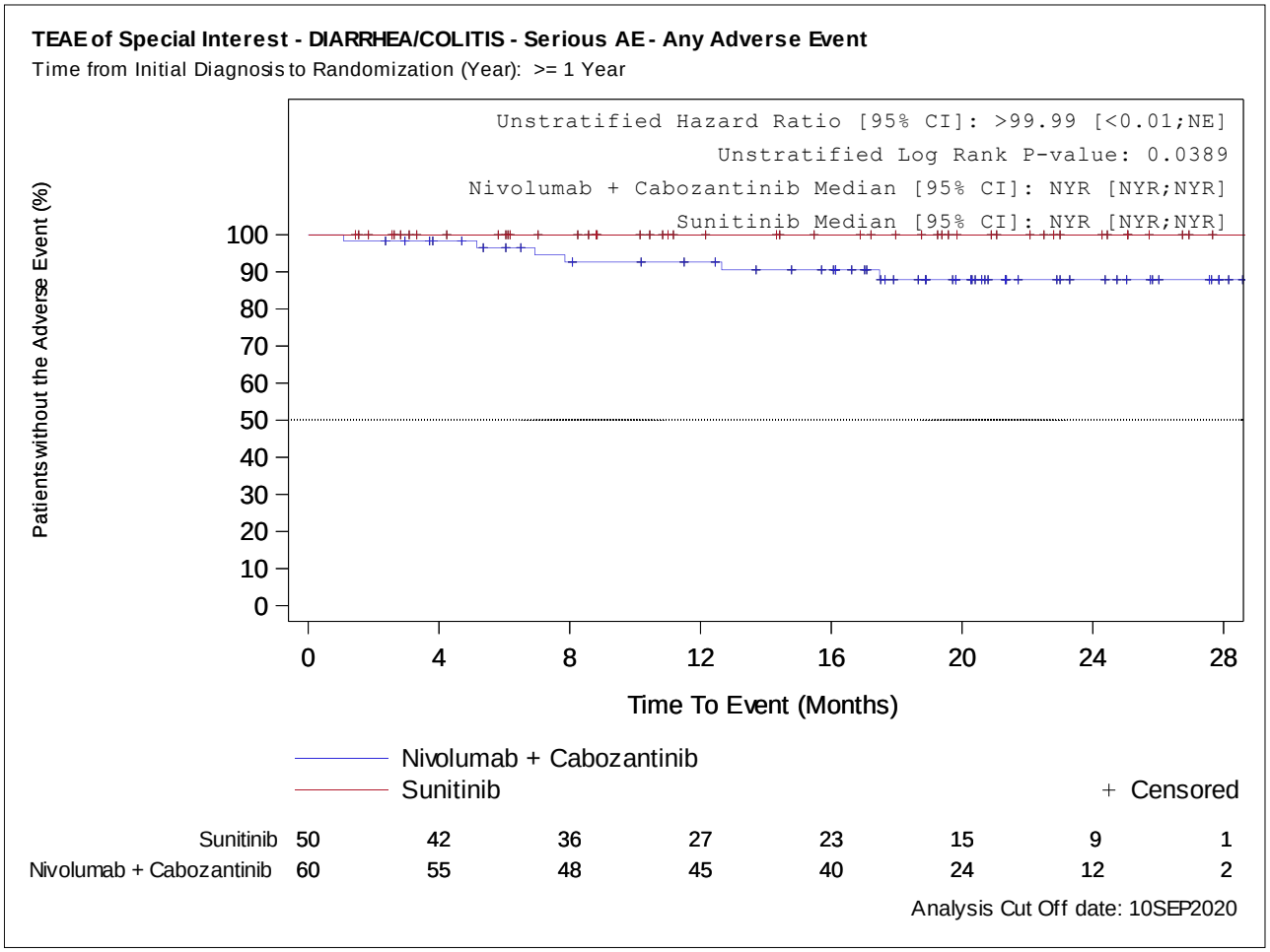

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:45:48

FIGURE 3.75.2.15: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



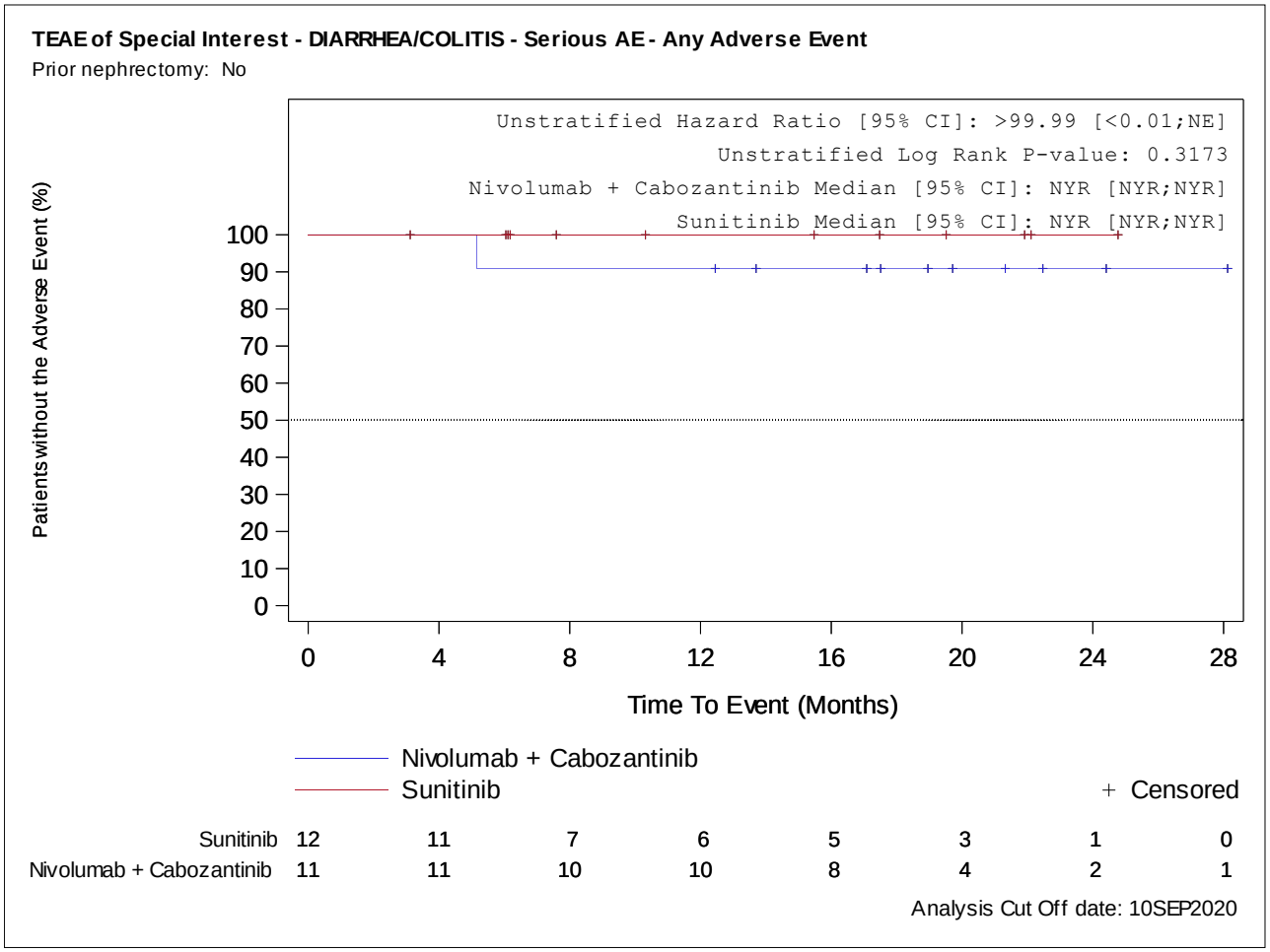

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:46:06

FIGURE 3.75.2.16: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



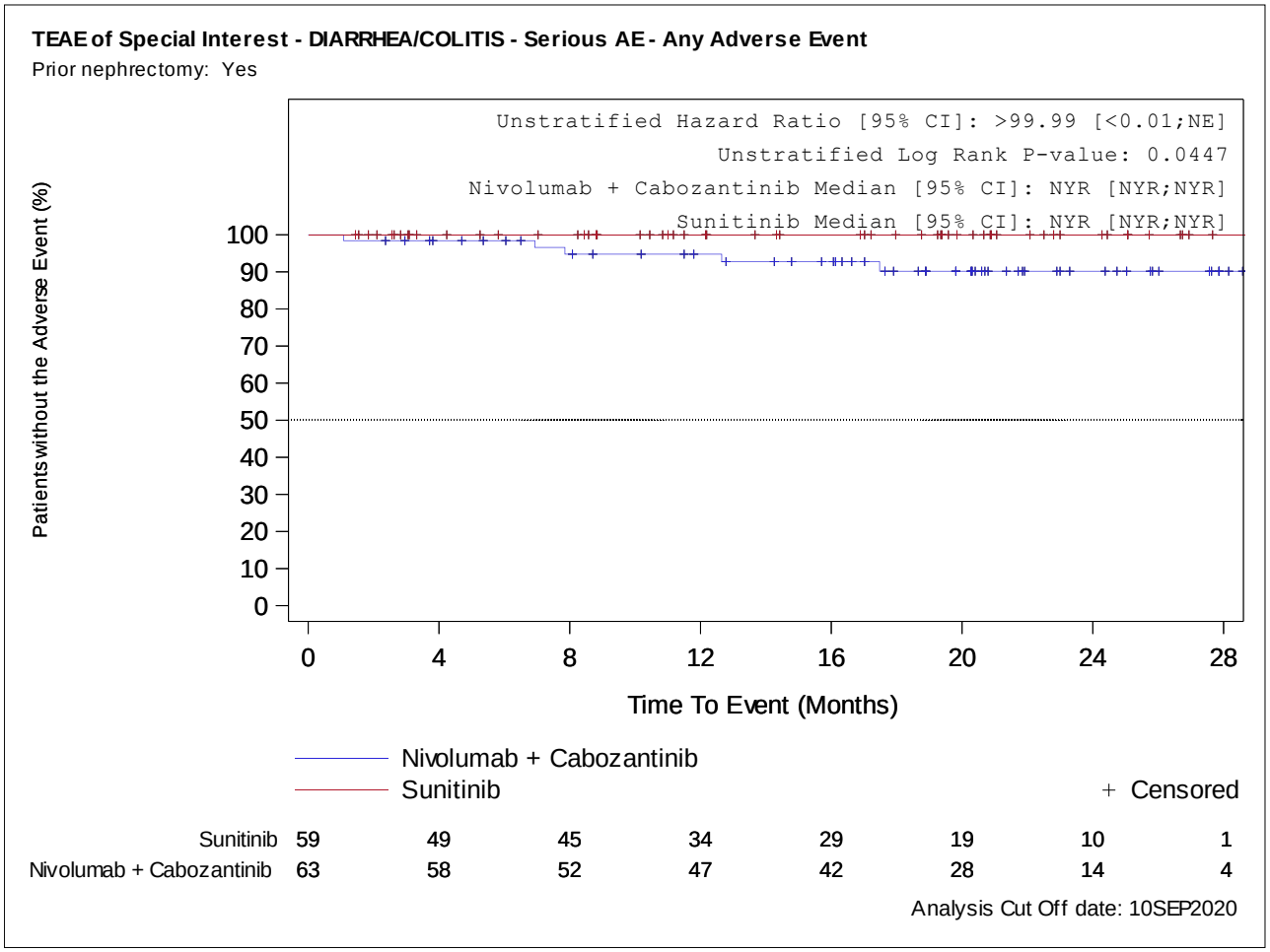

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:46:12

FIGURE 3.75.2.17: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



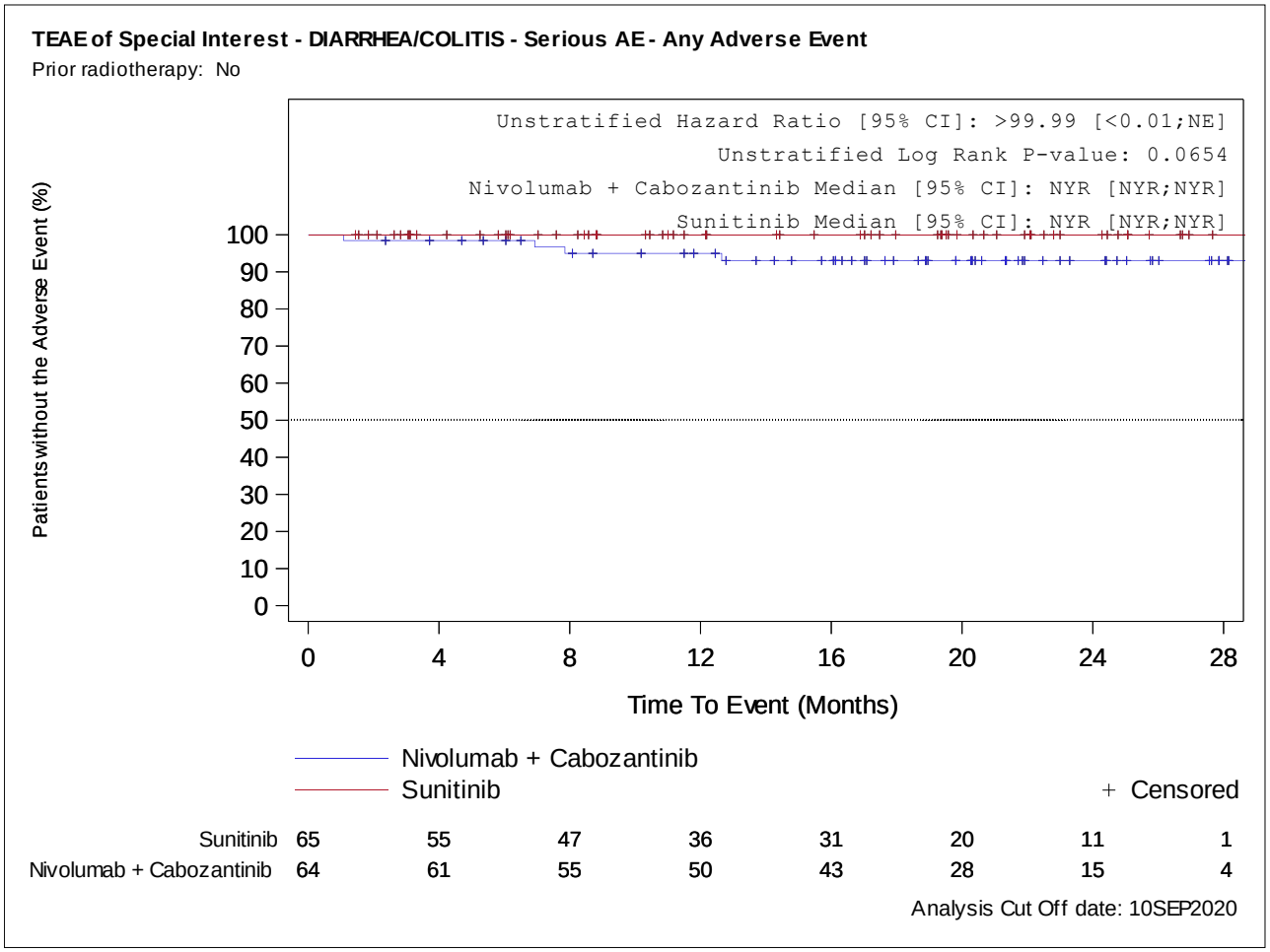

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:47:06

FIGURE 3.75.2.18: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



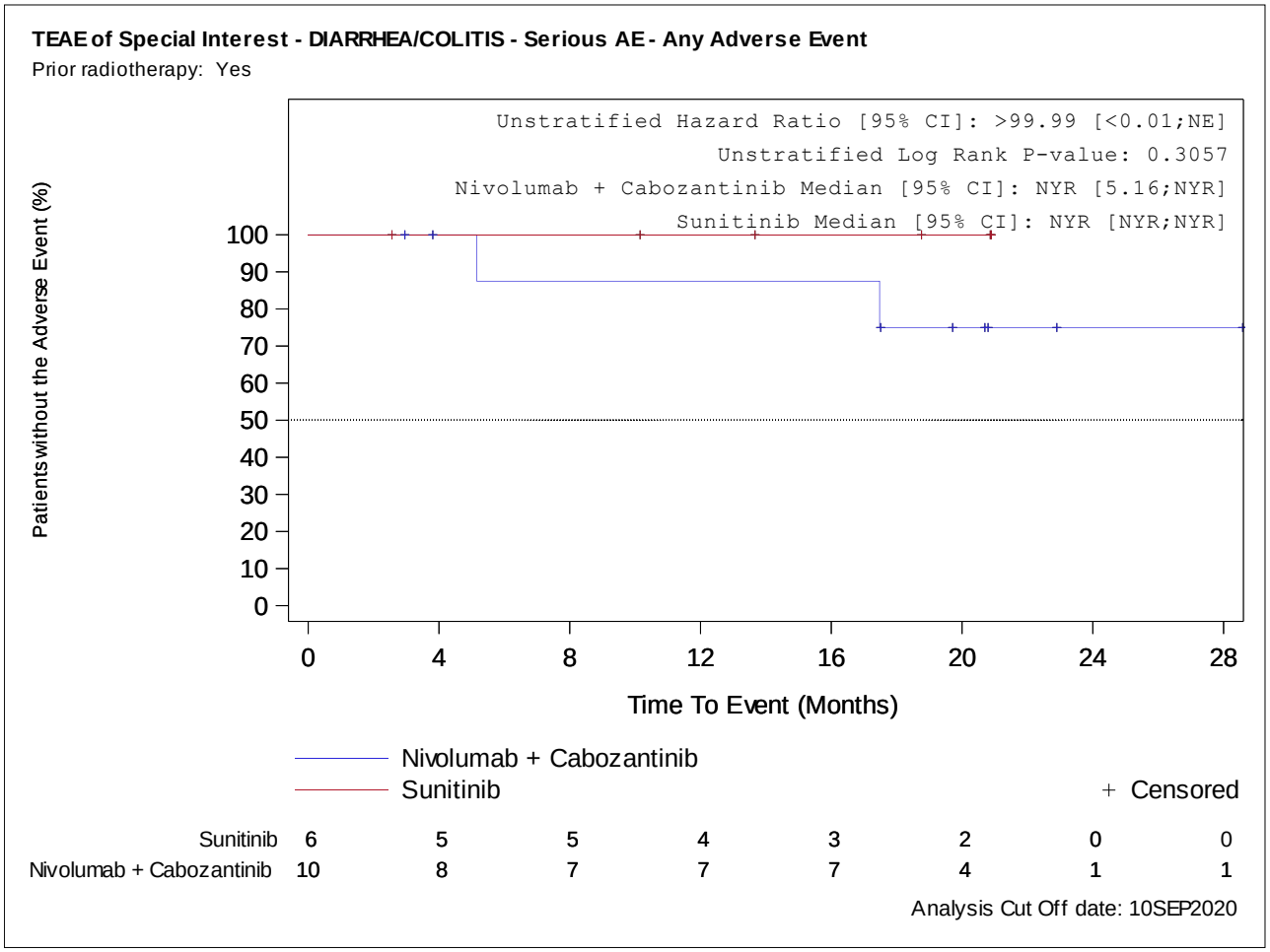

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:47:11

FIGURE 3.75.2.19: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



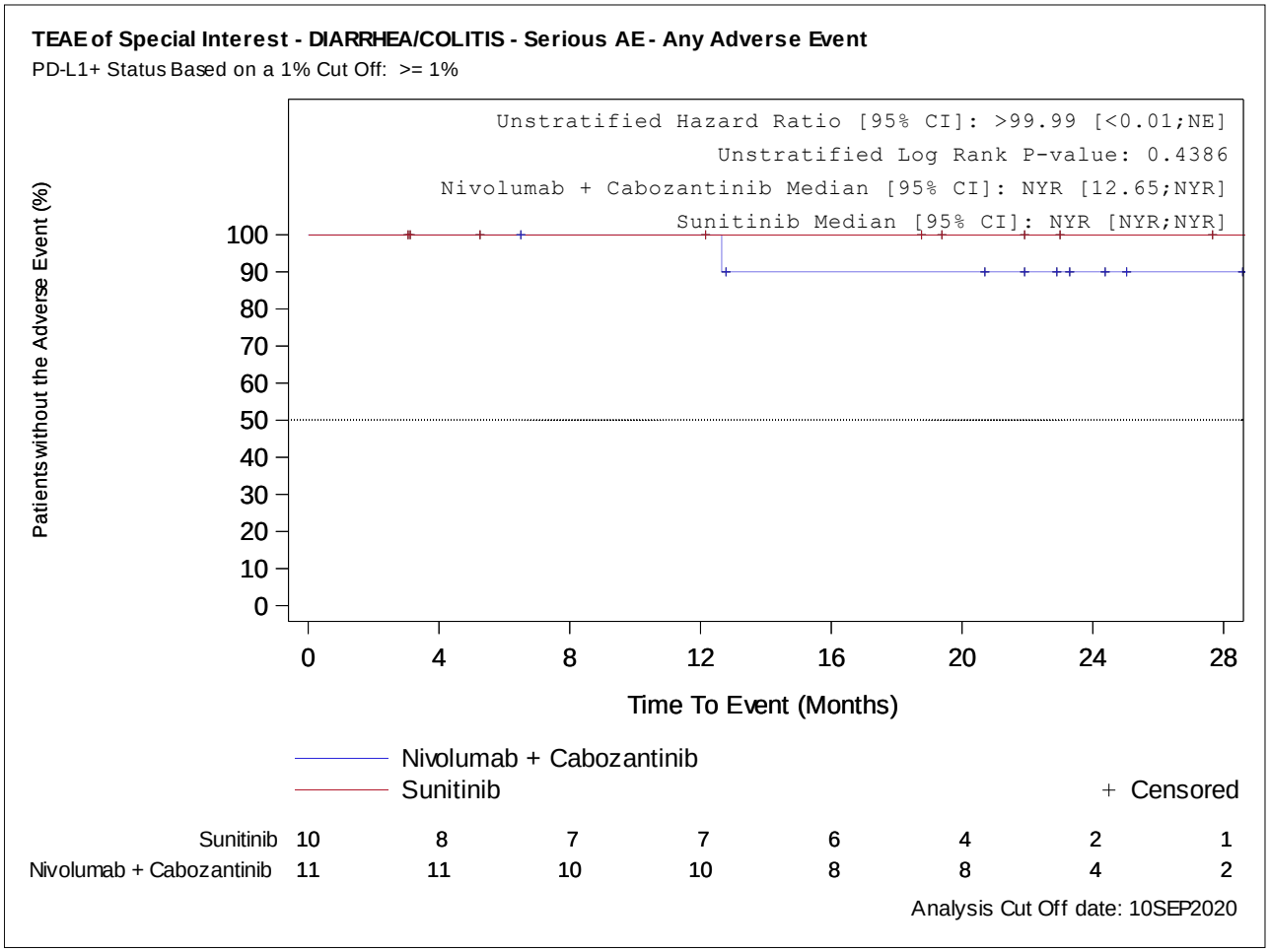

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:47:17

FIGURE 3.75.2.20: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



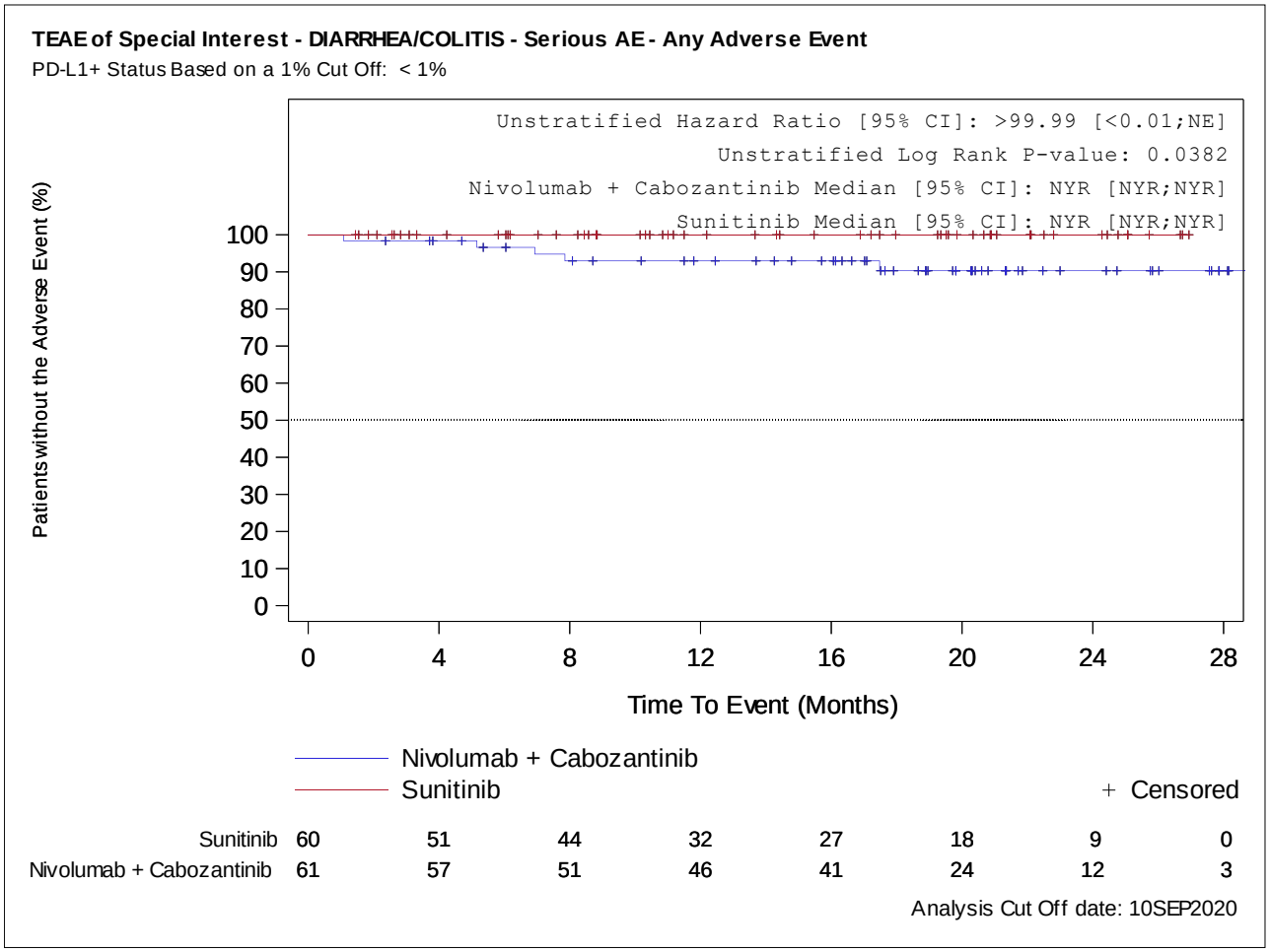

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:47:23

FIGURE 3.75.2.21: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



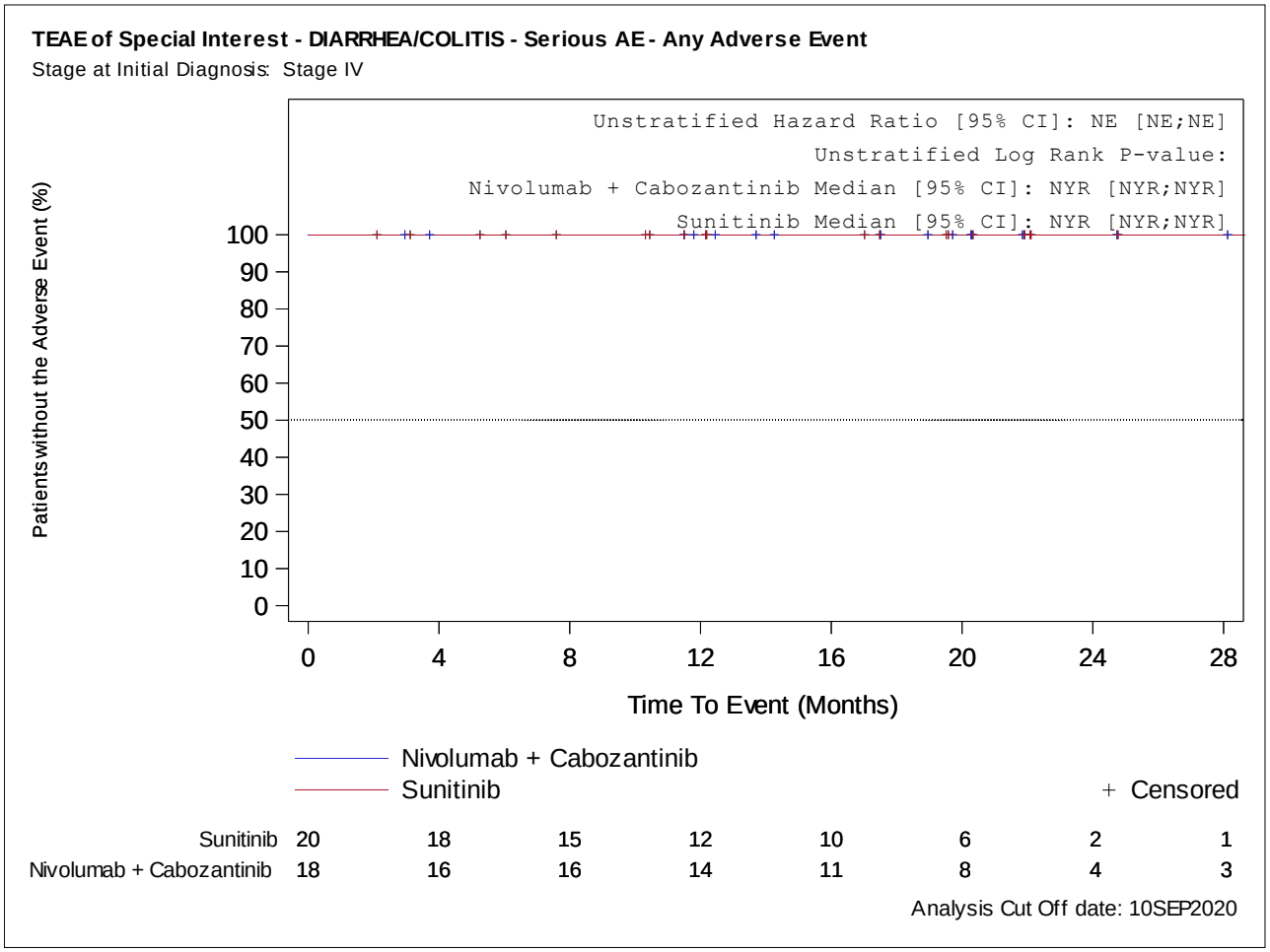

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:47:28

FIGURE 3.75.2.22: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



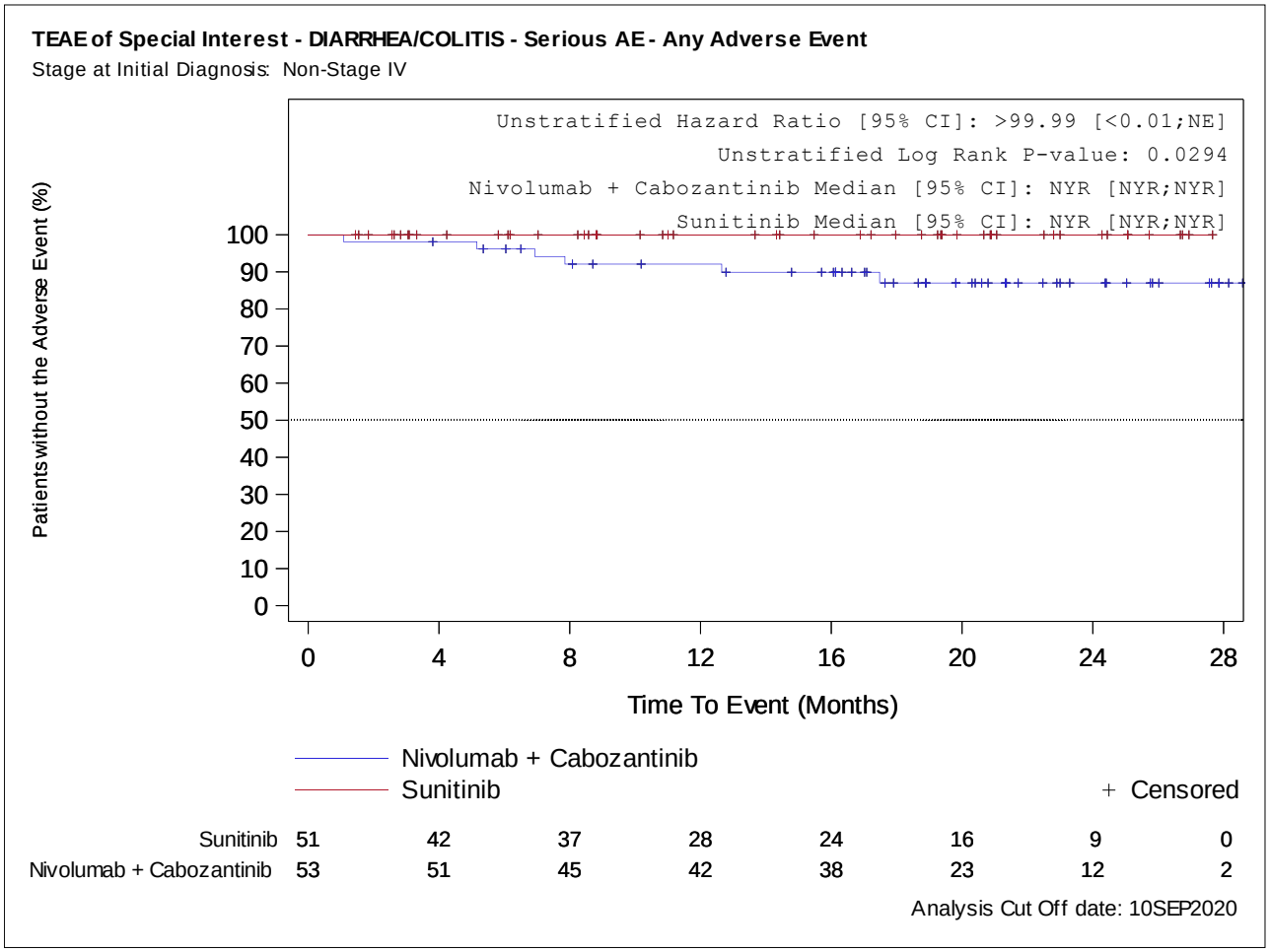

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:47:34

FIGURE 3.75.2.23: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



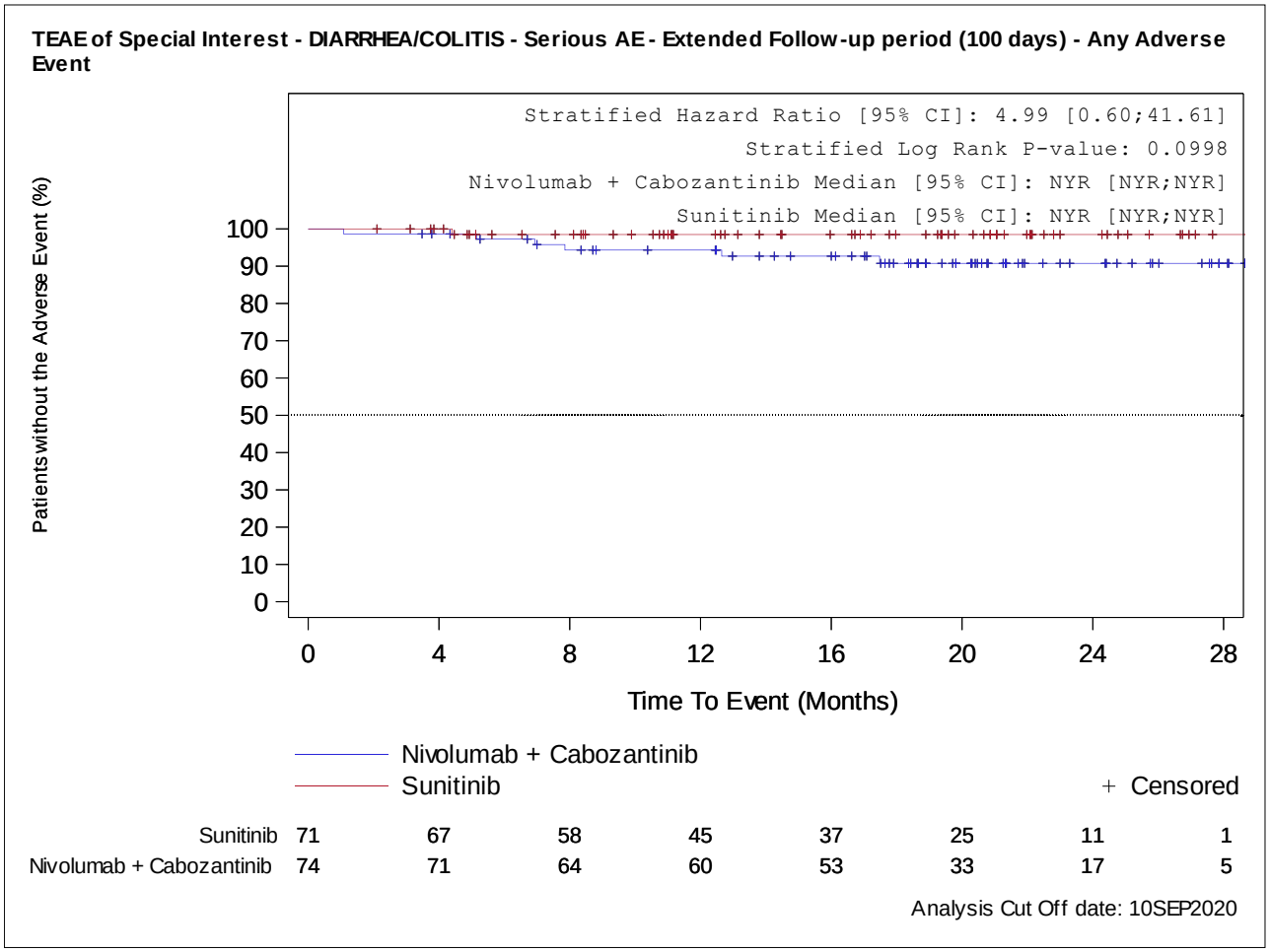

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:48:03

FIGURE 3.75.2.24: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



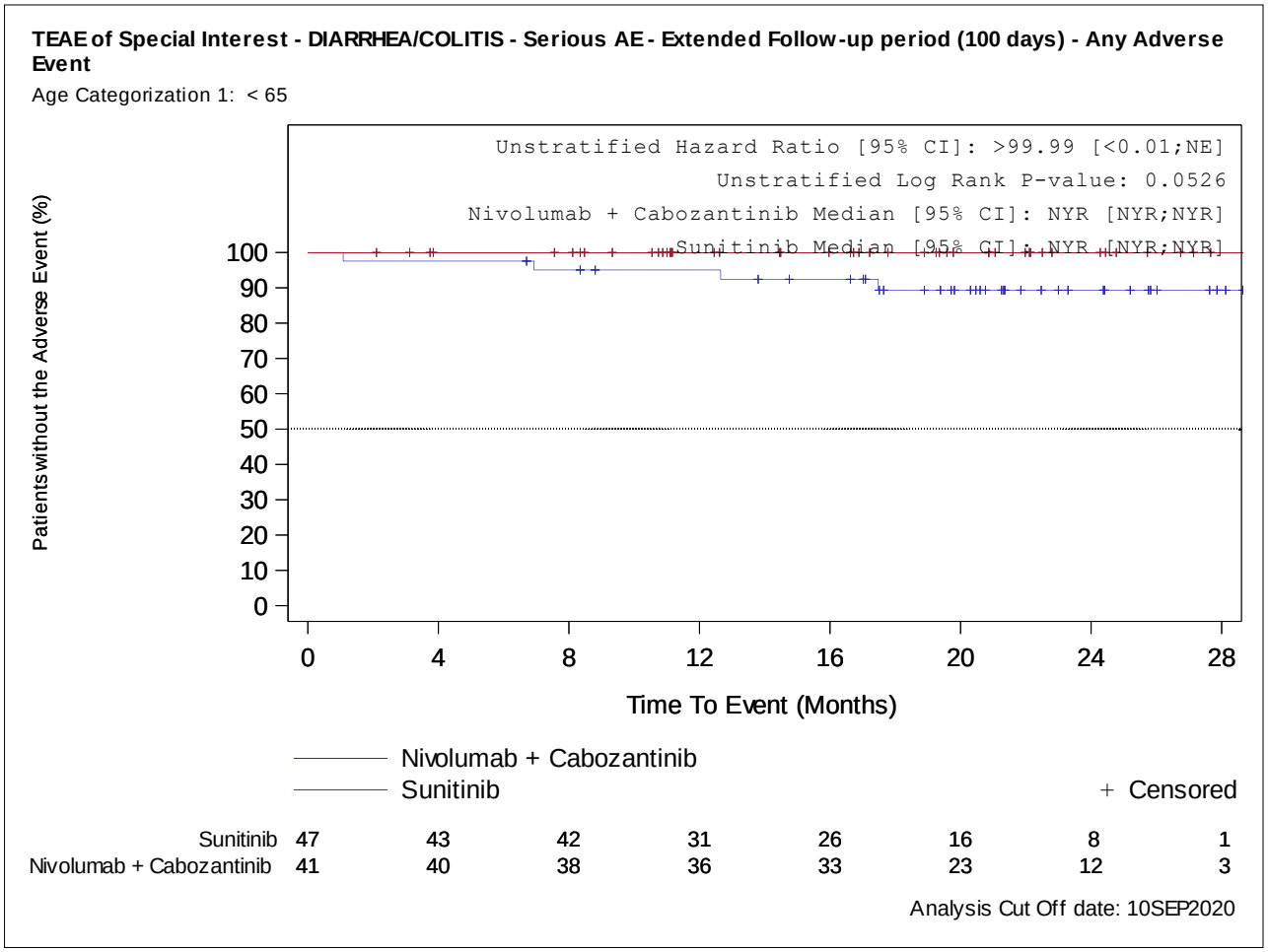

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:48:08

FIGURE 3.76.1: TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



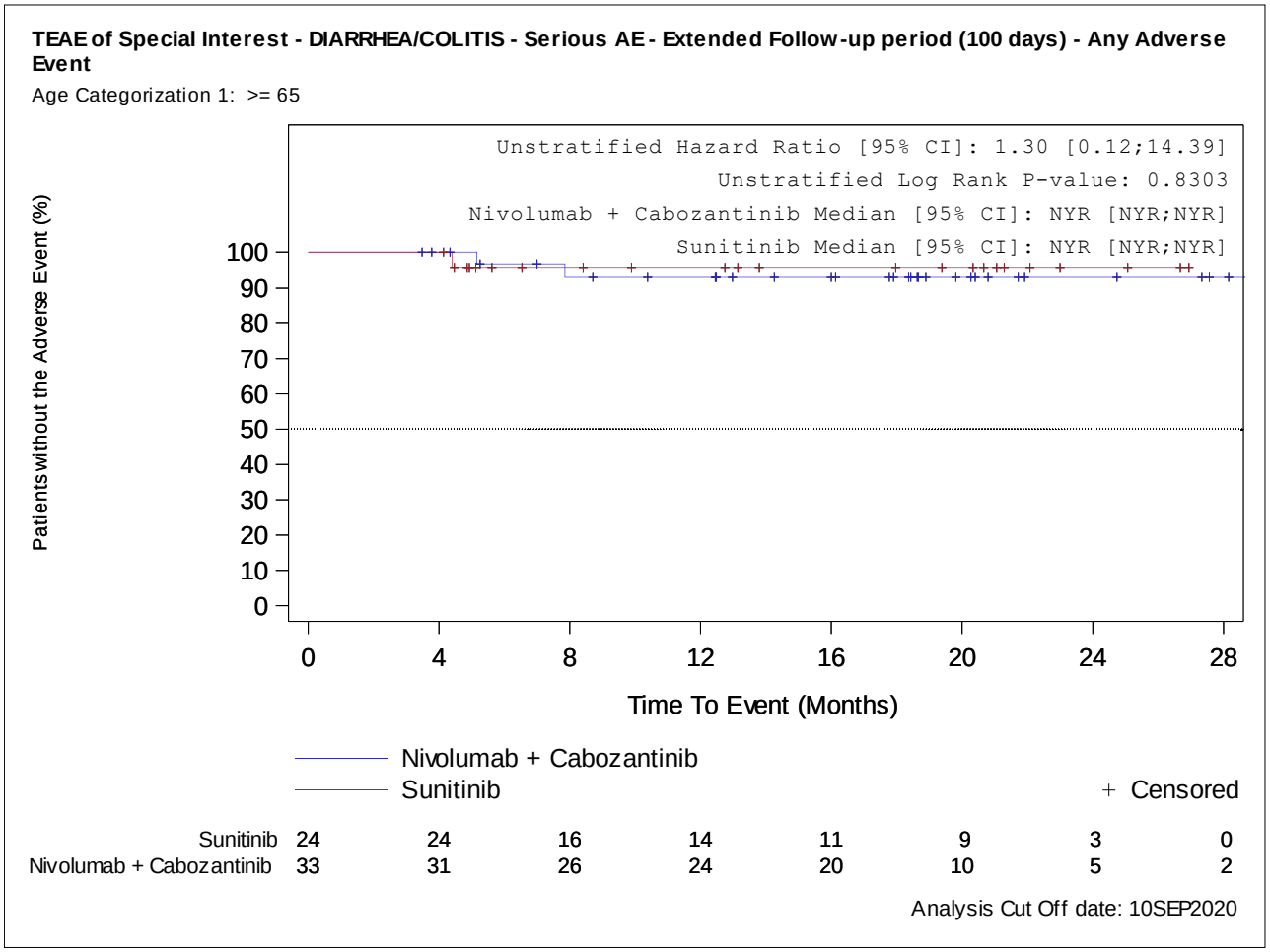

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:51:27

FIGURE 3.76.2.1: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



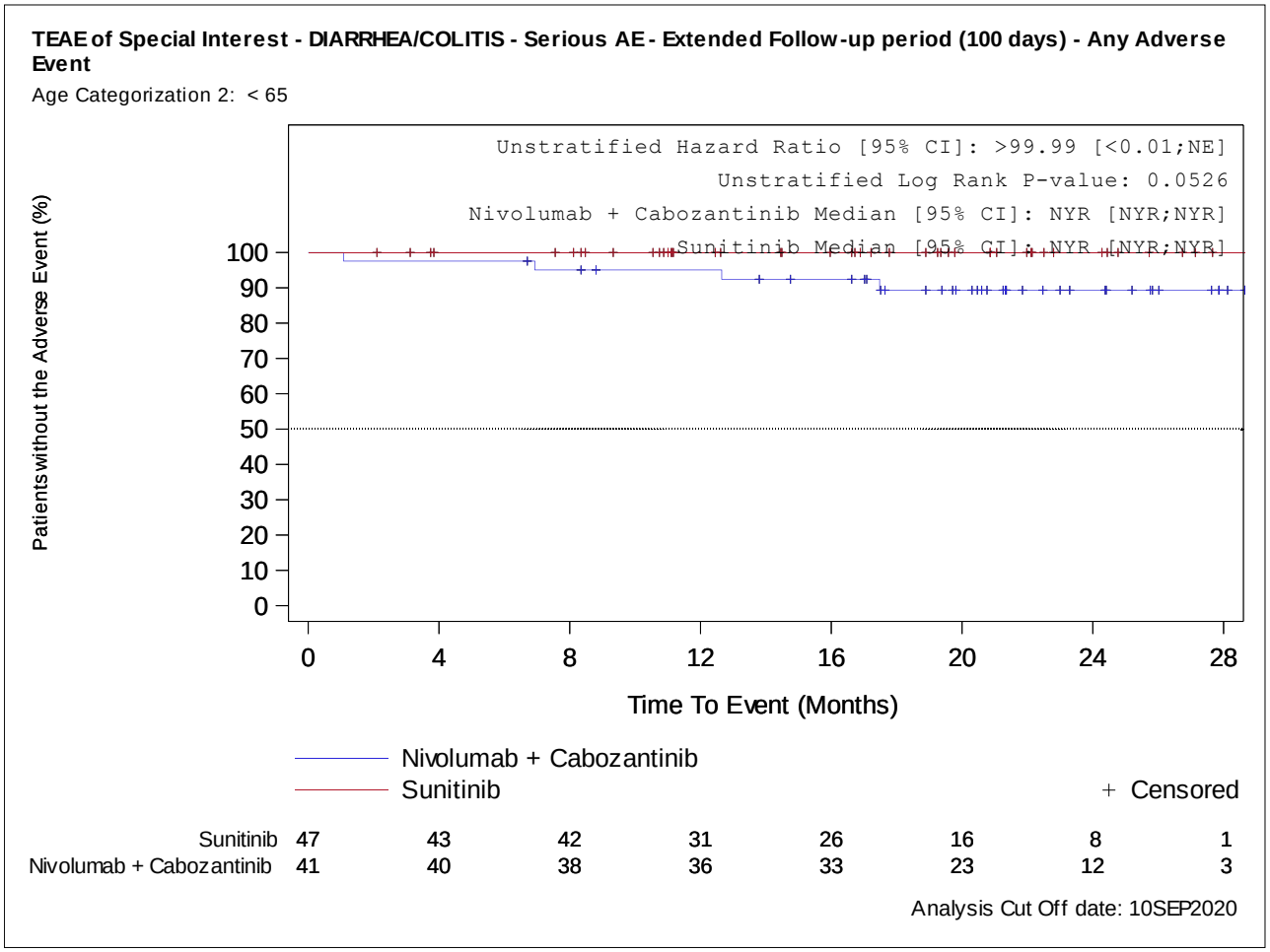

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:51:30

FIGURE 3.76.2.2: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



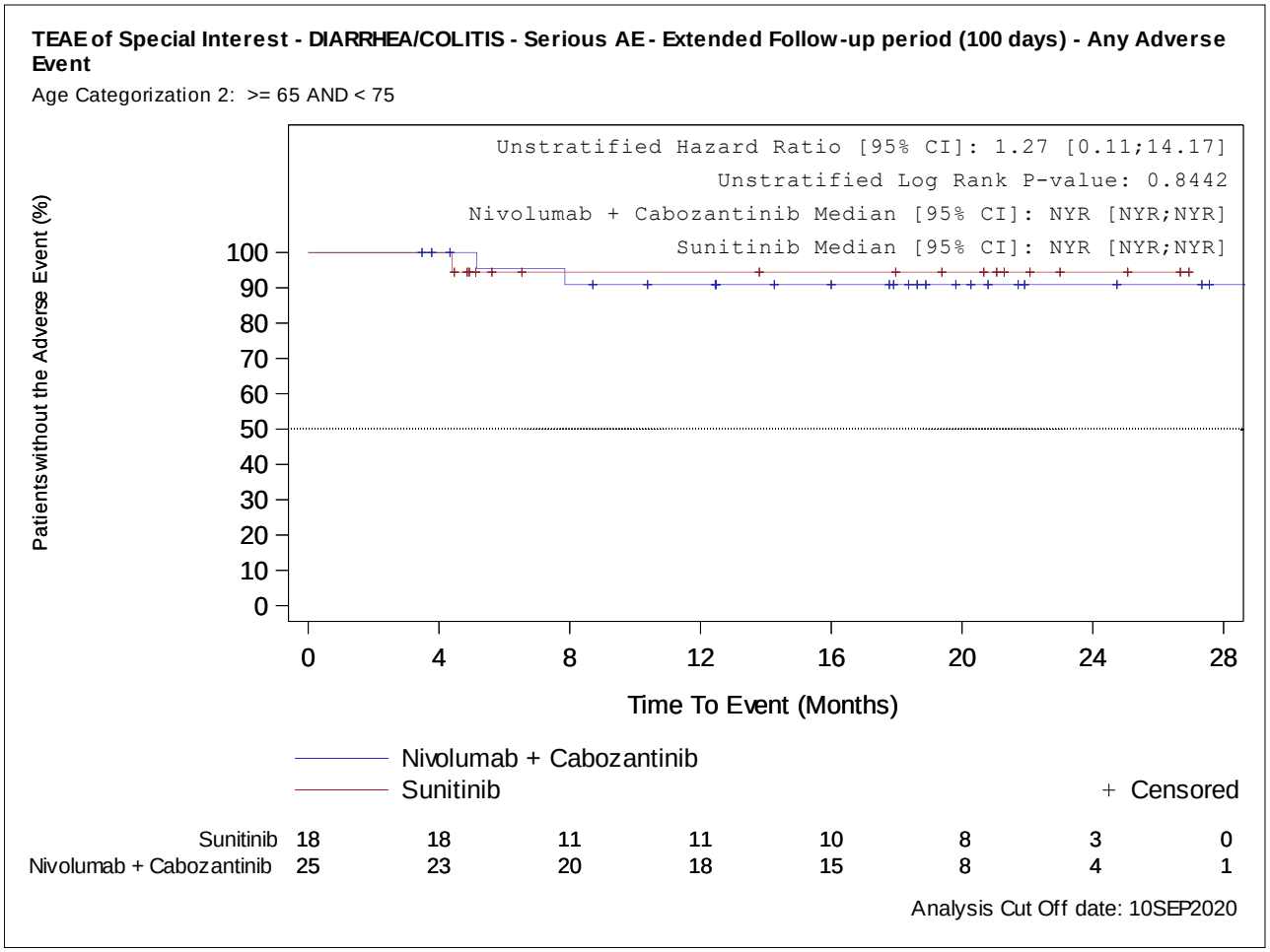

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:51:36

FIGURE 3.76.2.3: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



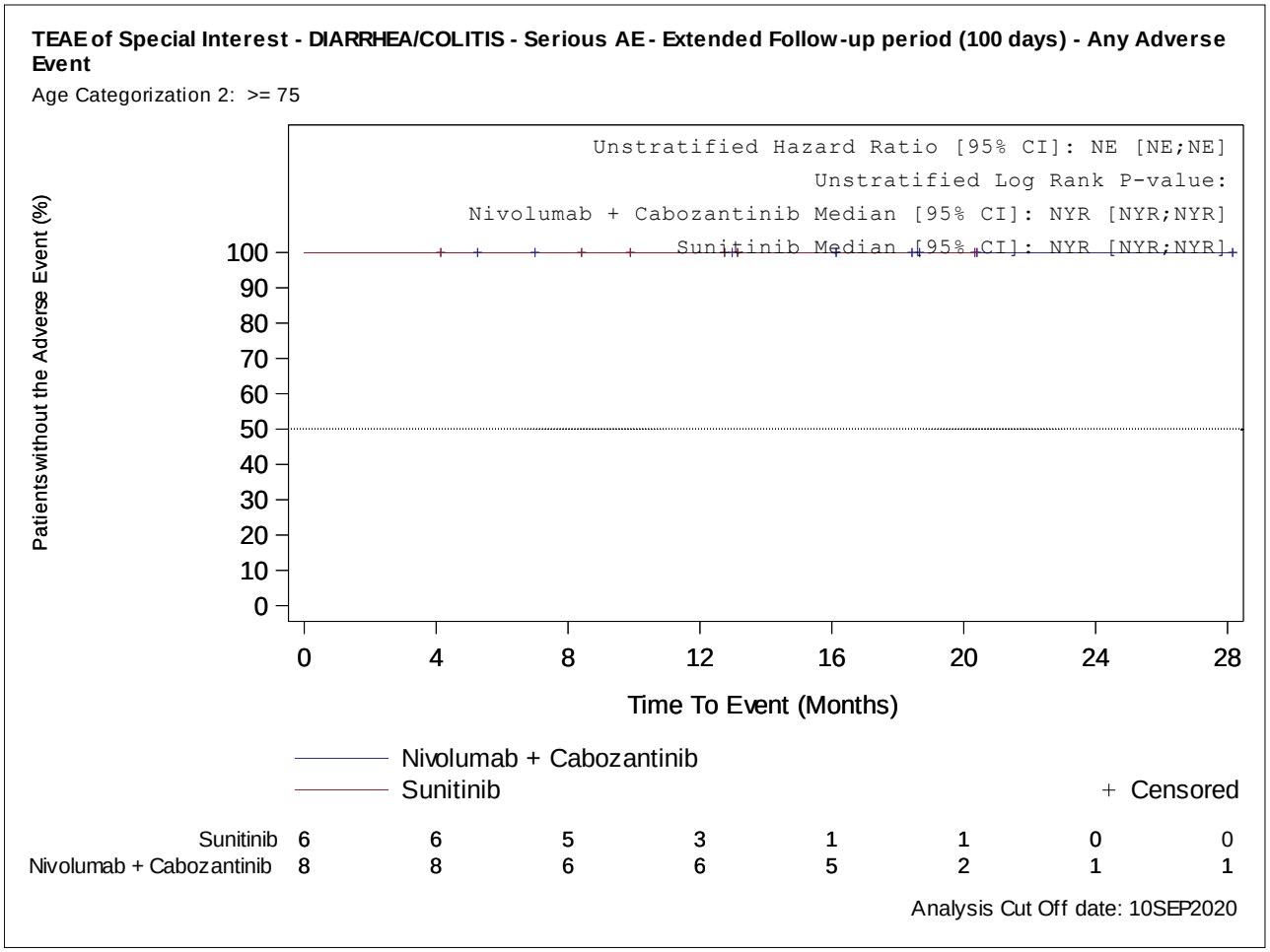

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:51:43

FIGURE 3.76.2.4: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



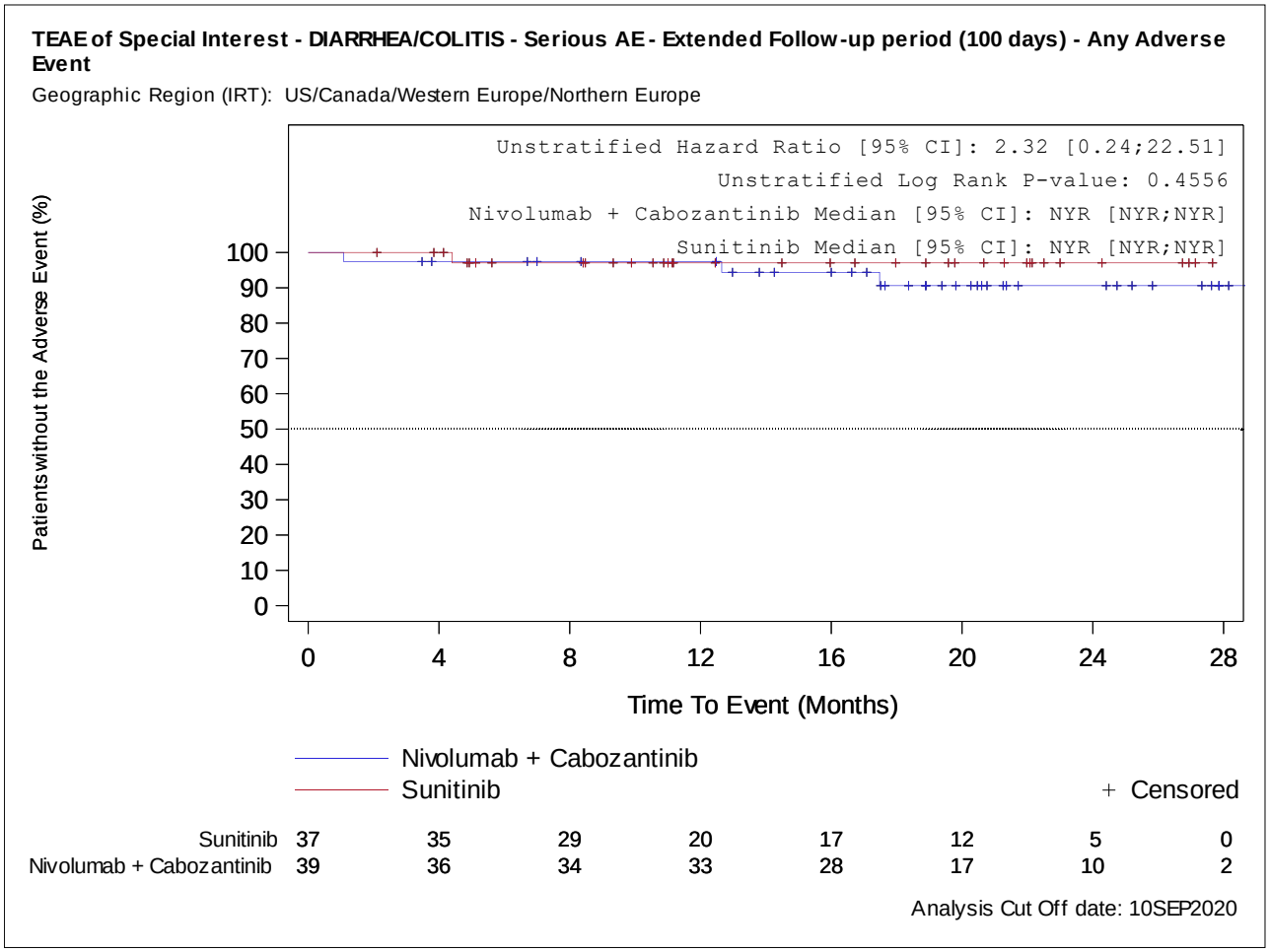

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:51:48

FIGURE 3.76.2.5: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



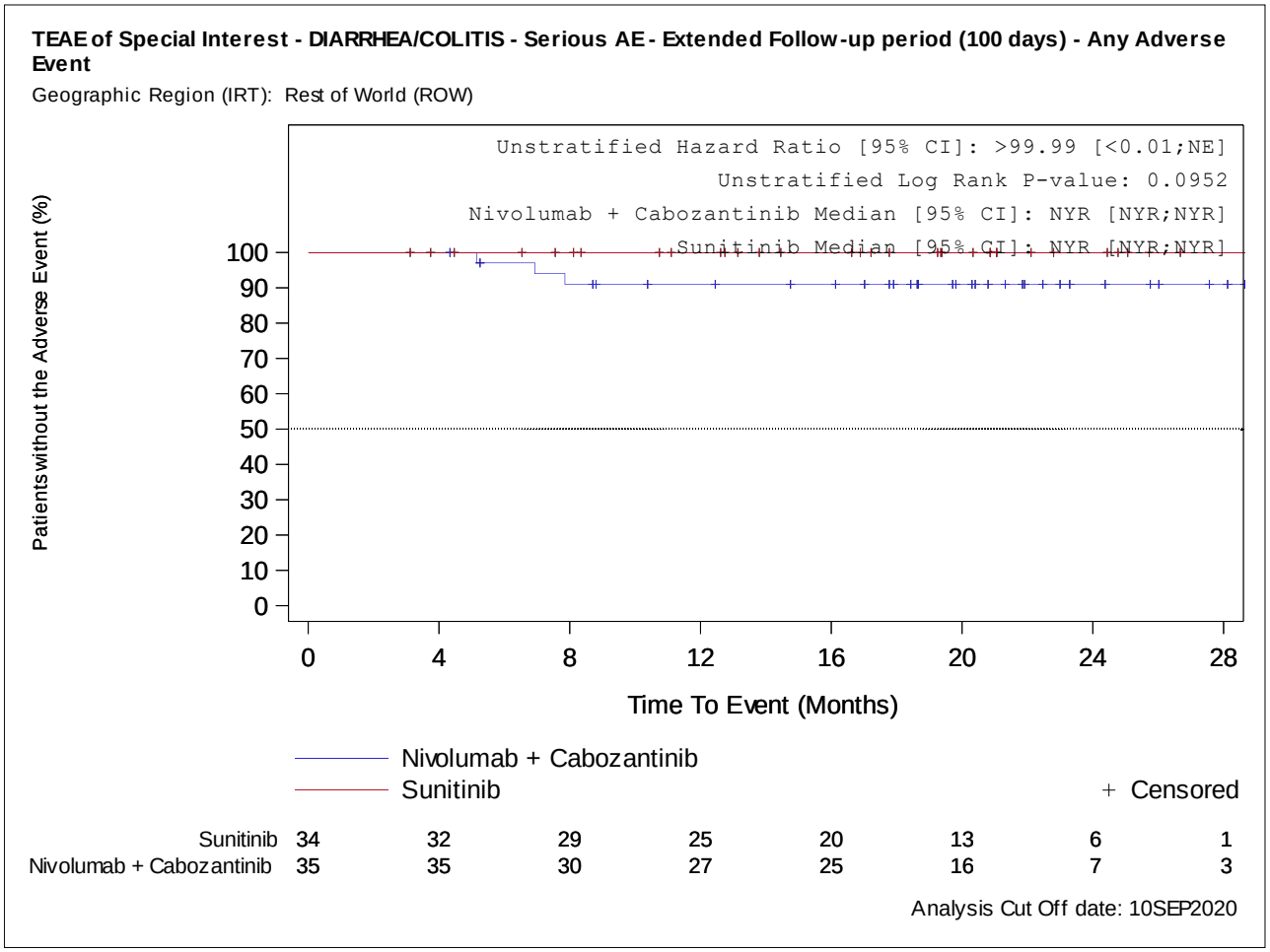

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:51:55

FIGURE 3.76.2.6: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



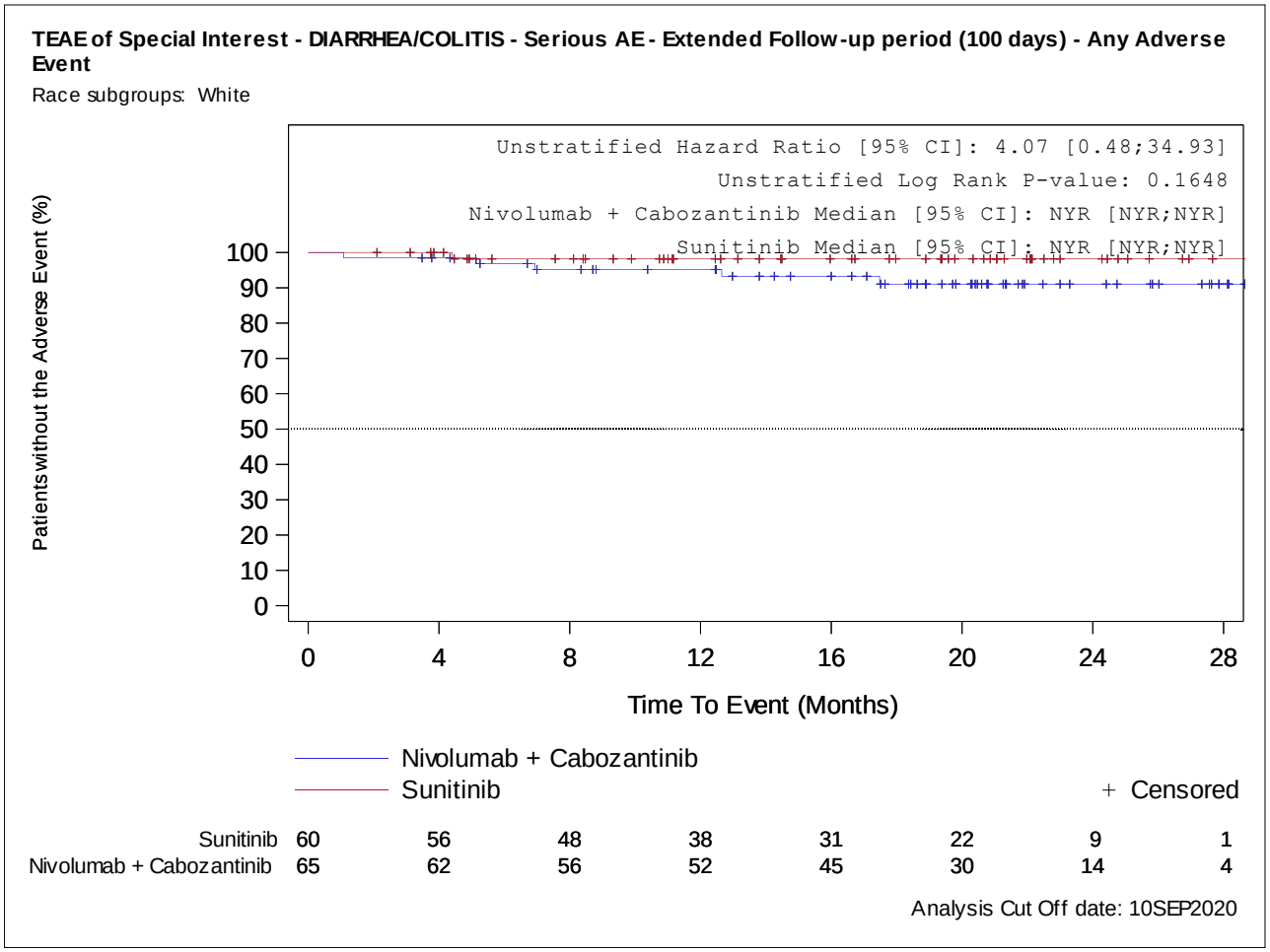

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:52:01

FIGURE 3.76.2.7: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



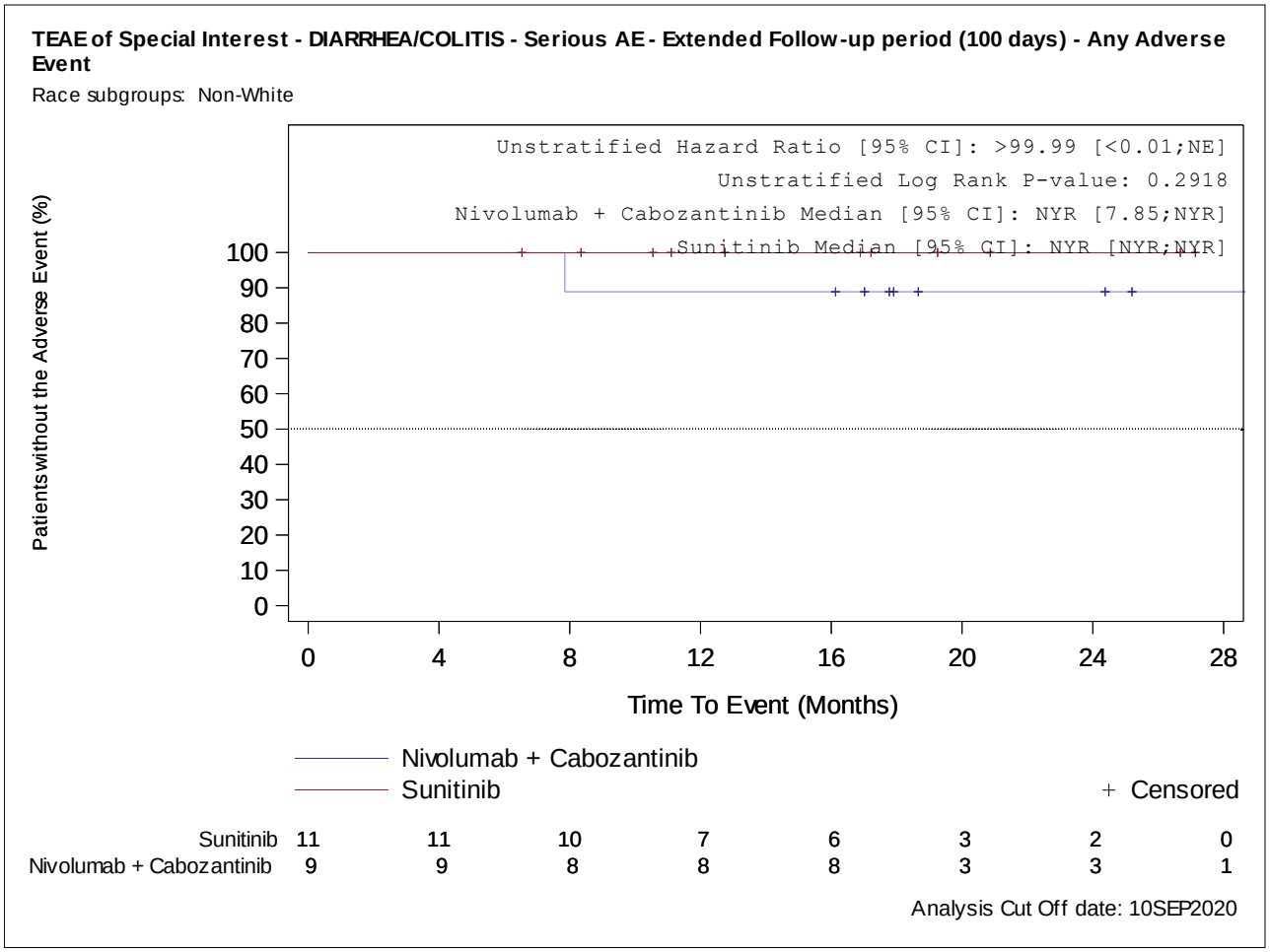

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:52:08

FIGURE 3.76.2.8: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



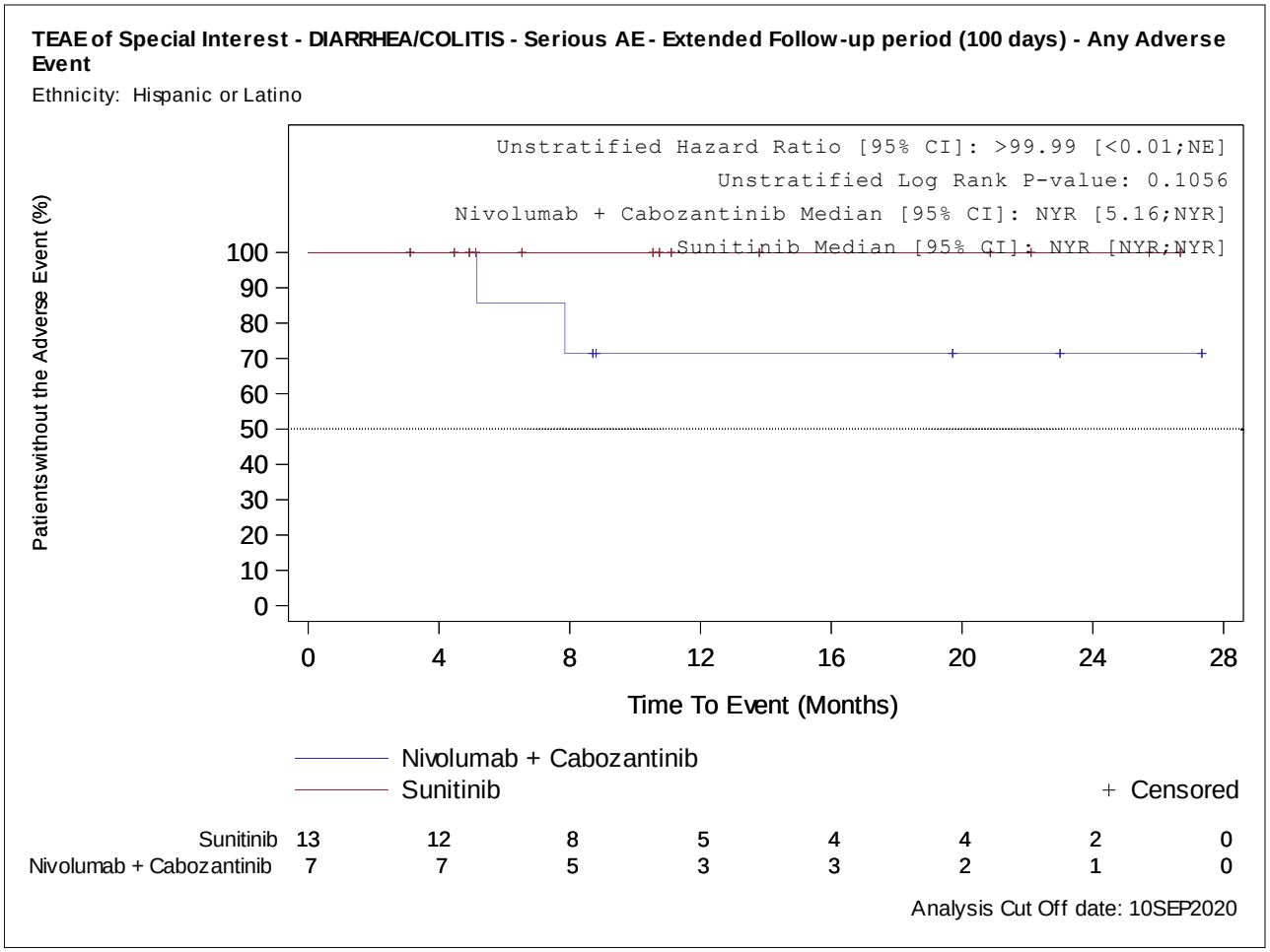

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:52:13

FIGURE 3.76.2.9: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



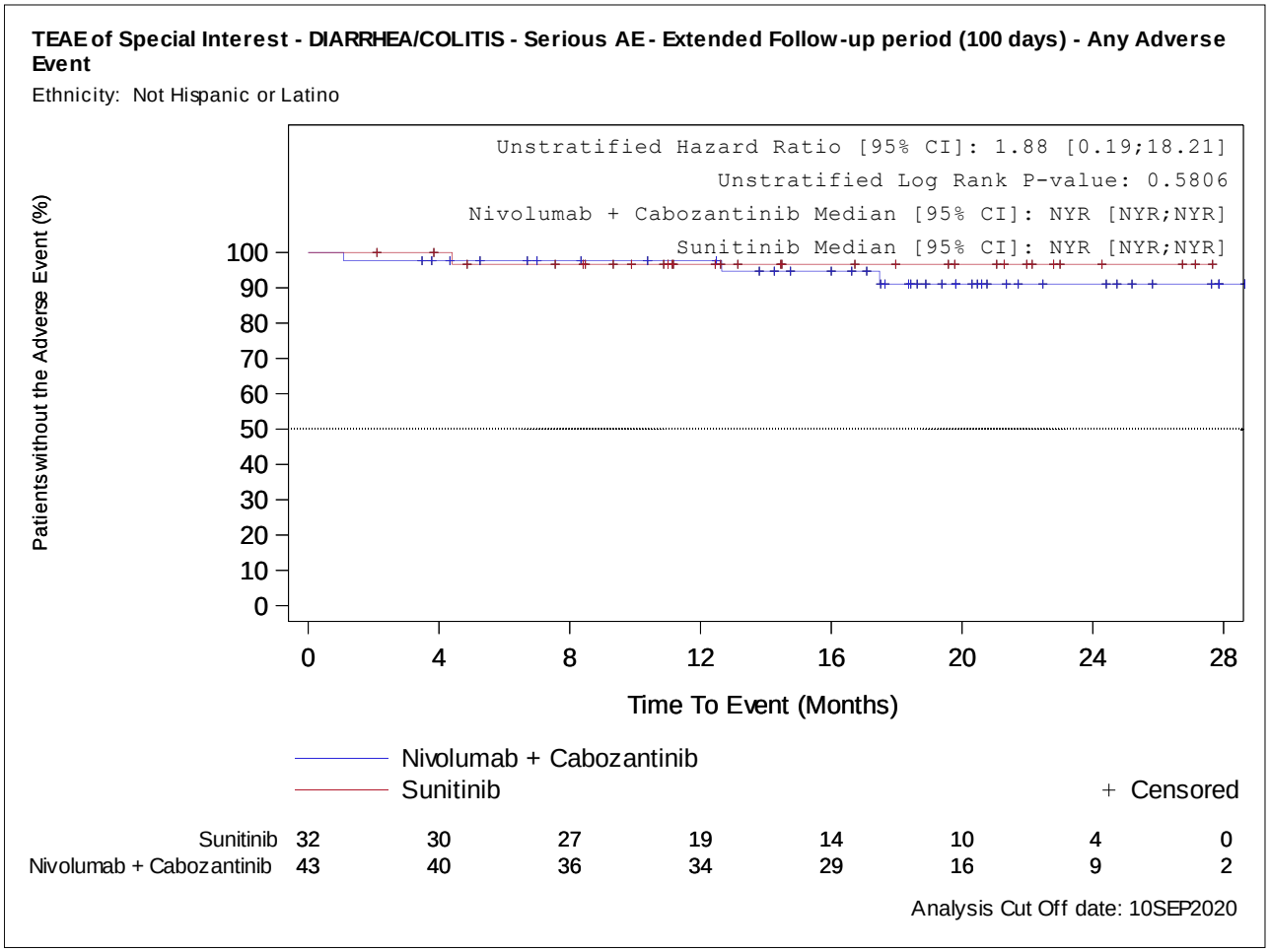

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:52:19

FIGURE 3.76.2.10: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



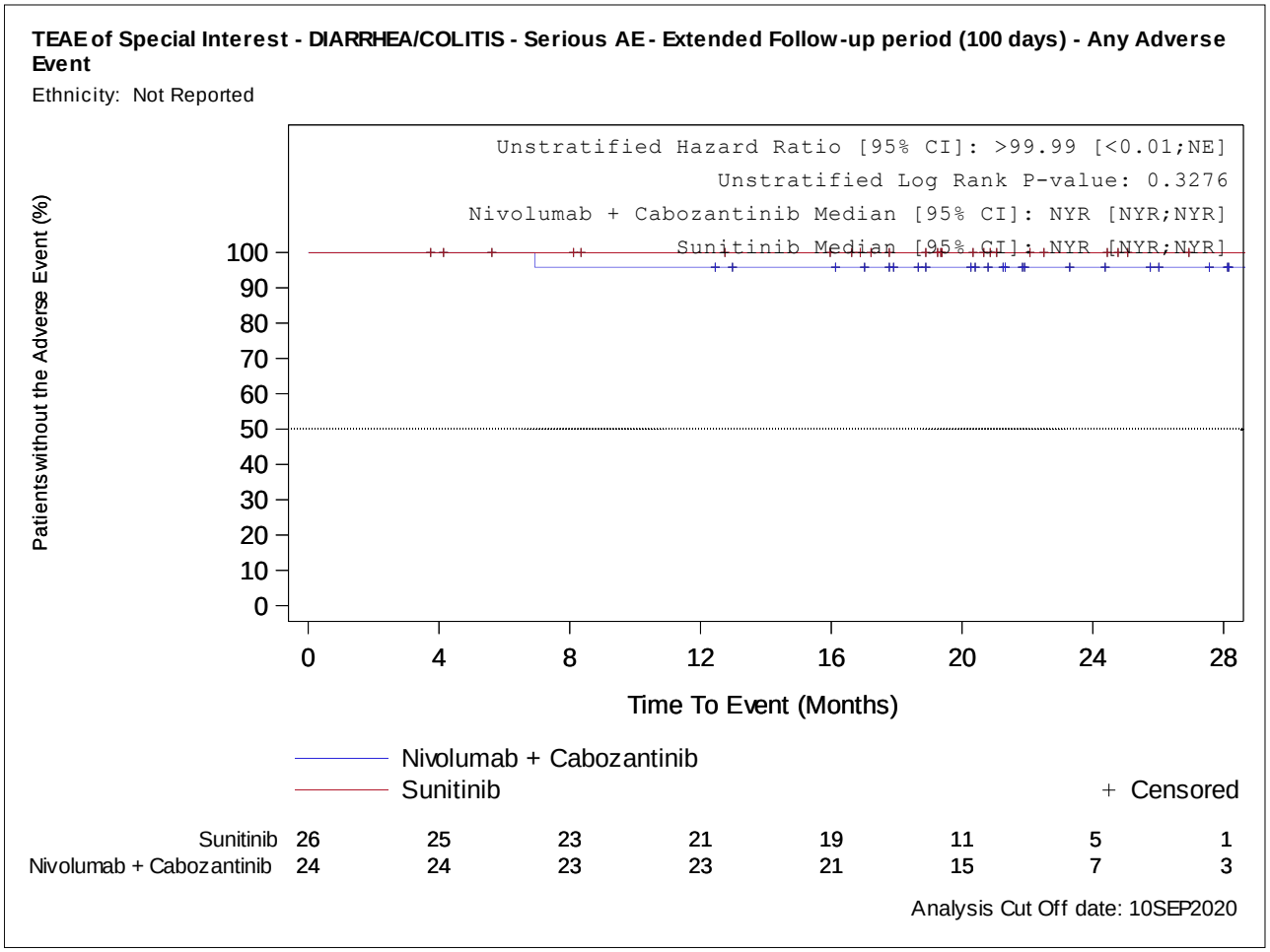

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:52:26

FIGURE 3.76.2.11: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



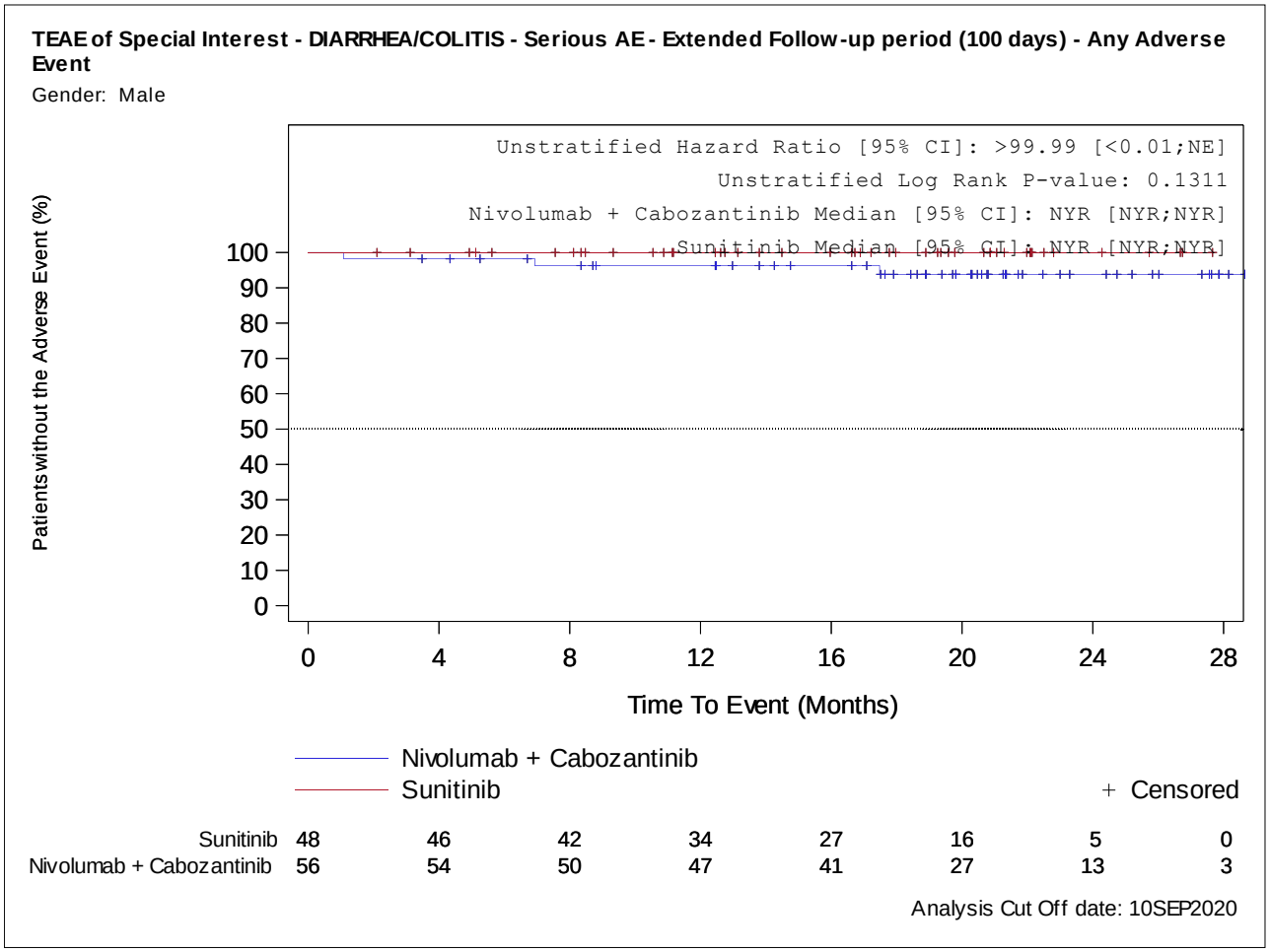

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:52:31

FIGURE 3.76.2.12: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



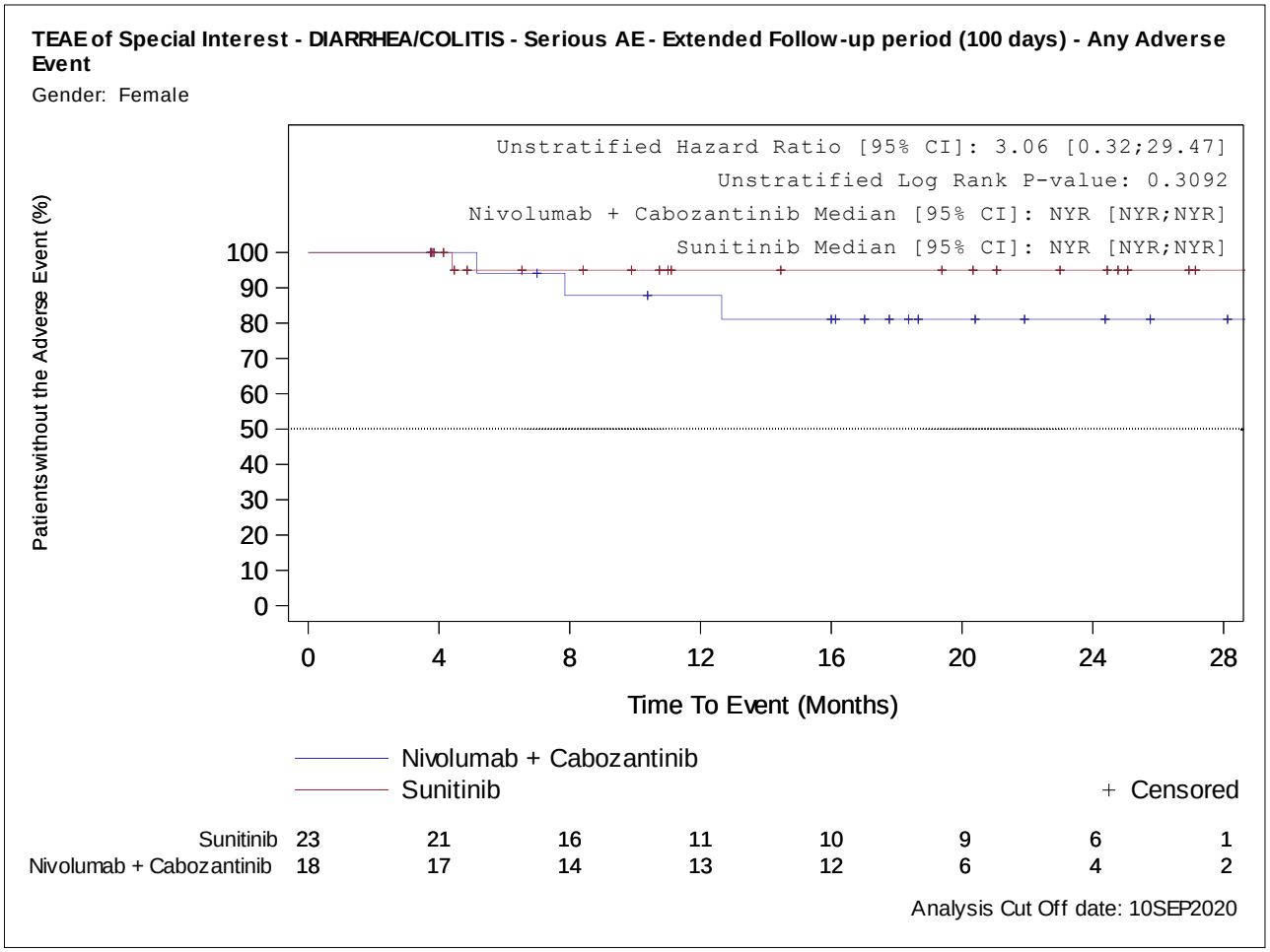

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:52:37

FIGURE 3.76.2.13: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



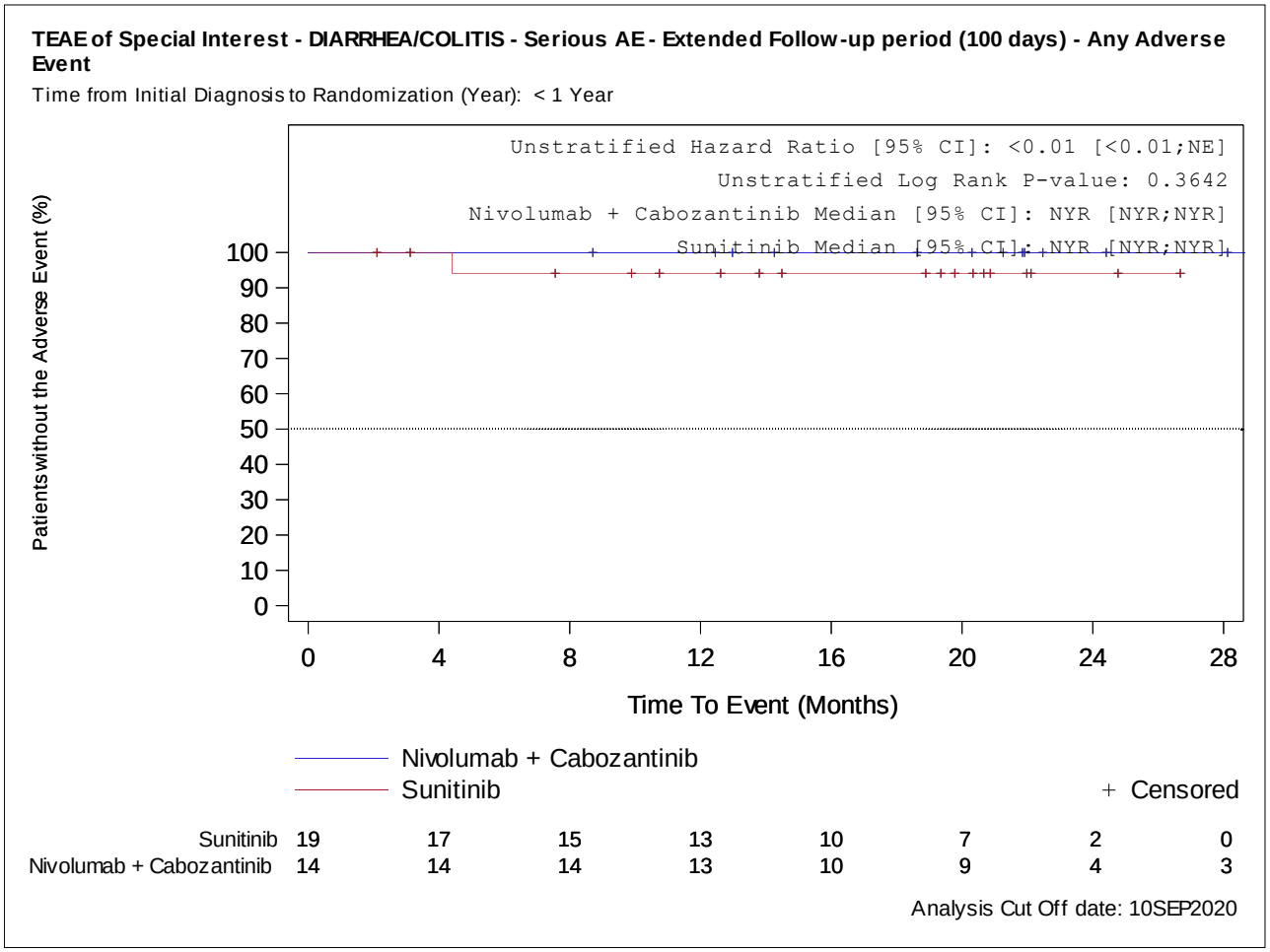

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:52:43

FIGURE 3.76.2.14: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



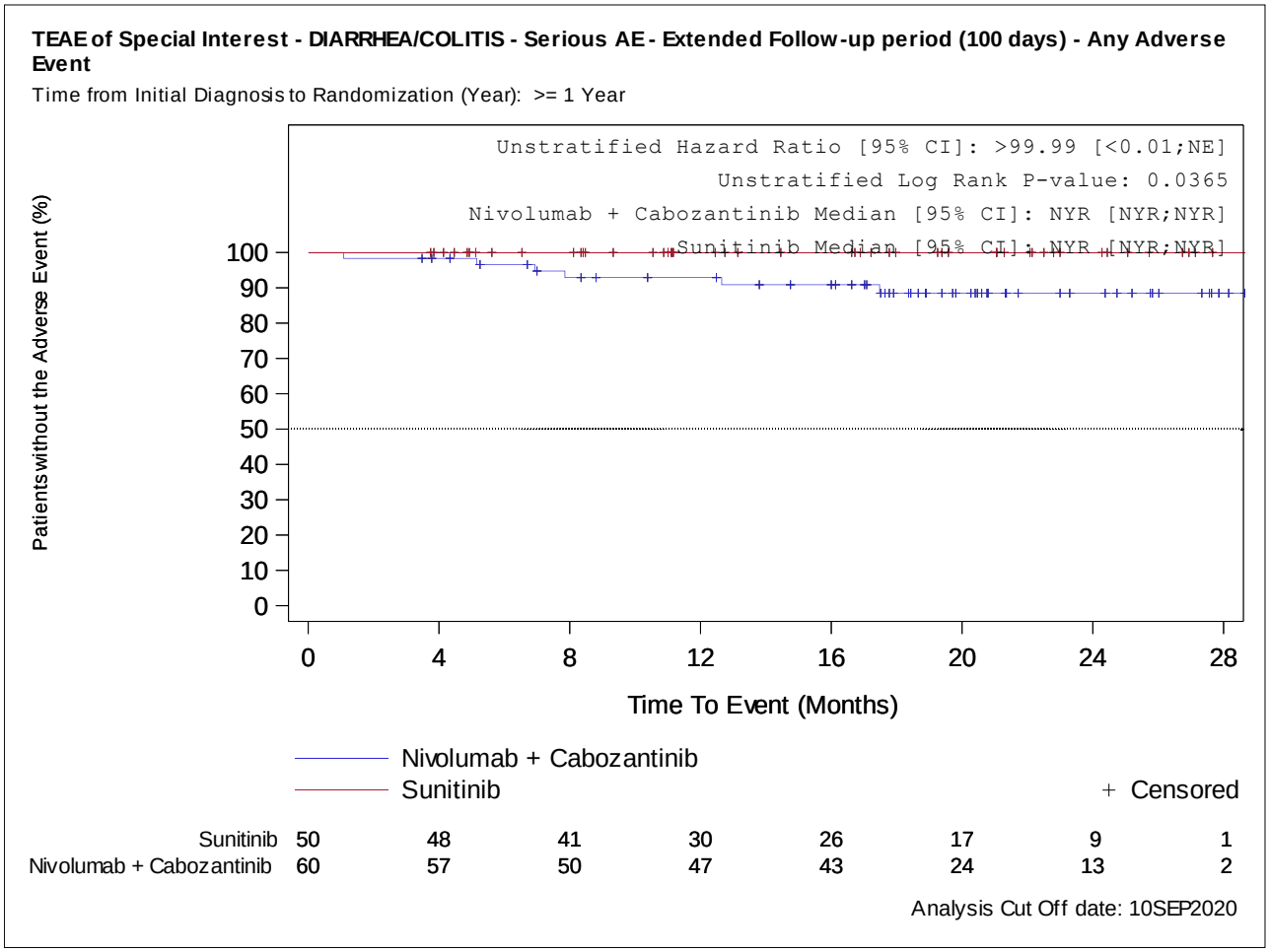

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:52:49

FIGURE 3.76.2.15: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



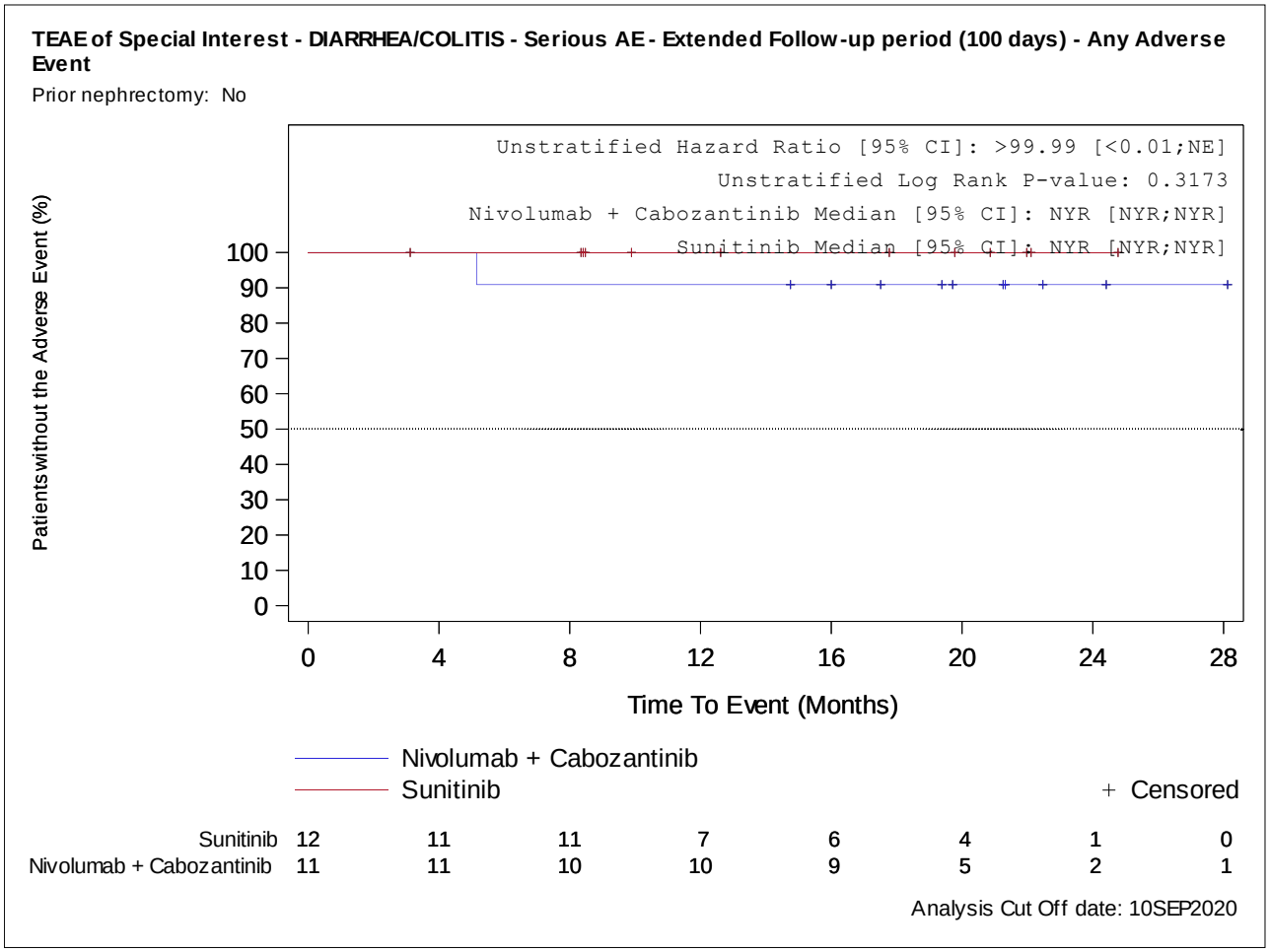

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:53:06

FIGURE 3.76.2.16: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



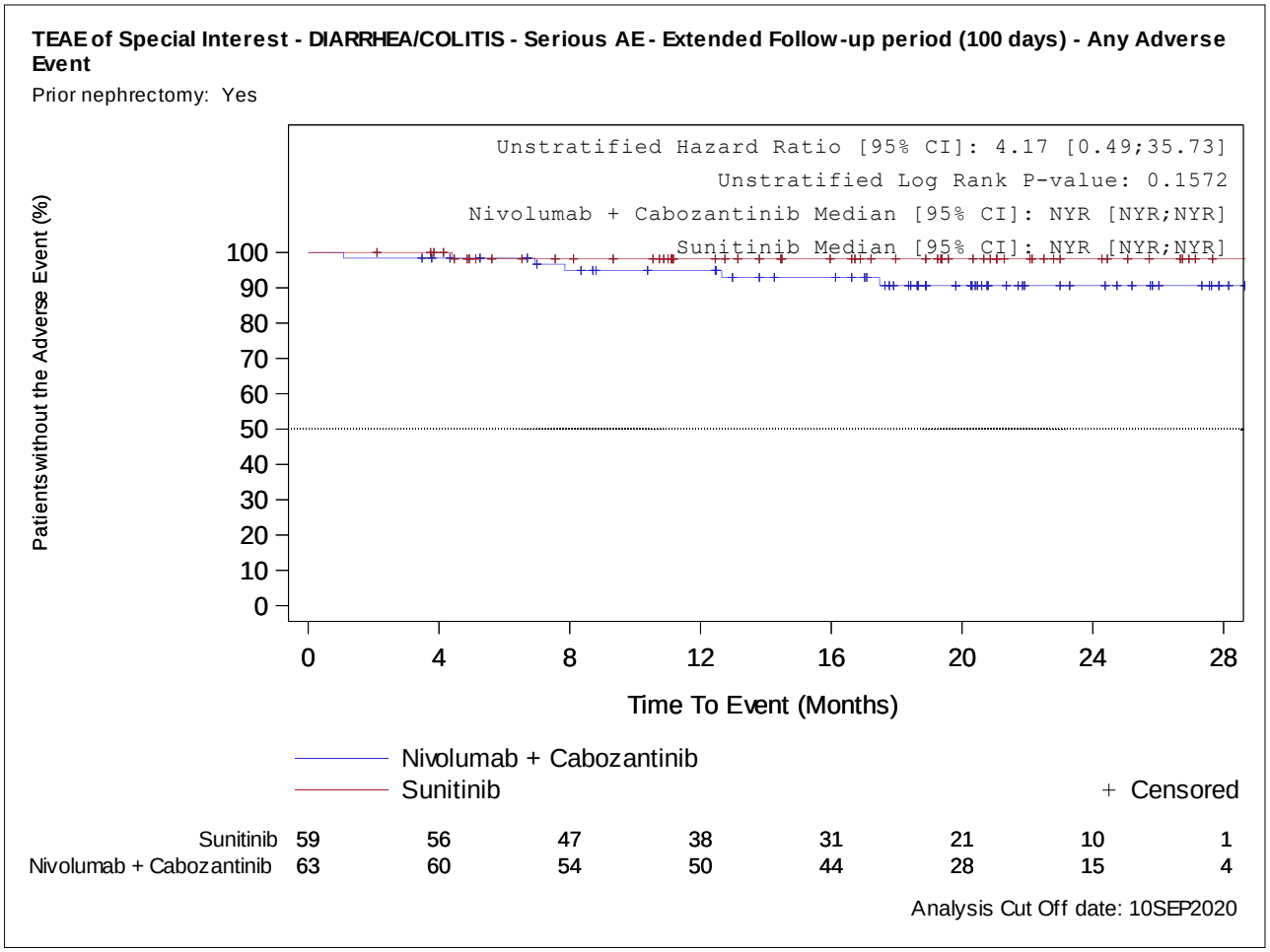

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:53:13

FIGURE 3.76.2.17: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



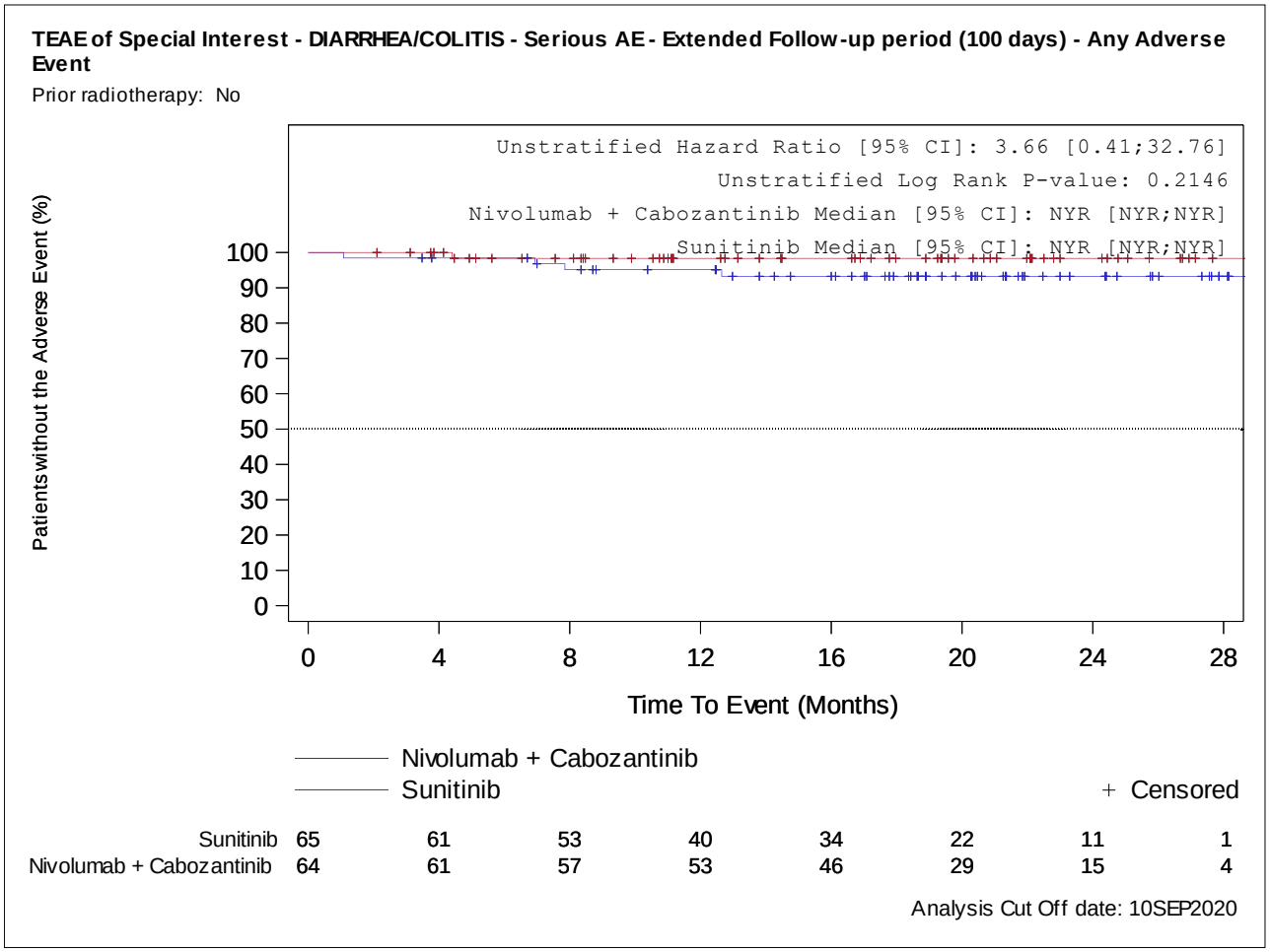

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:54:06

FIGURE 3.76.2.18: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



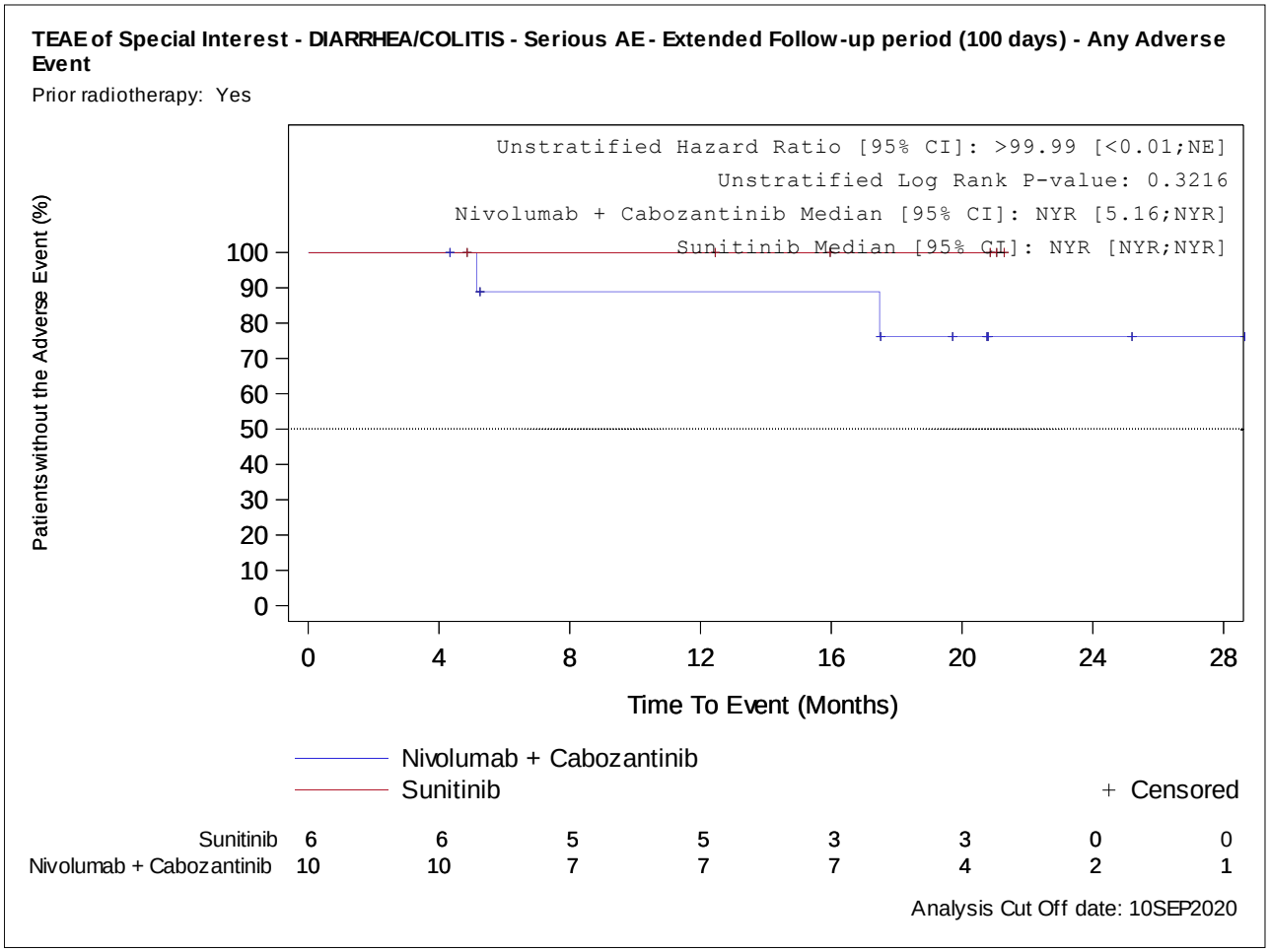

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:54:12

FIGURE 3.76.2.19: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



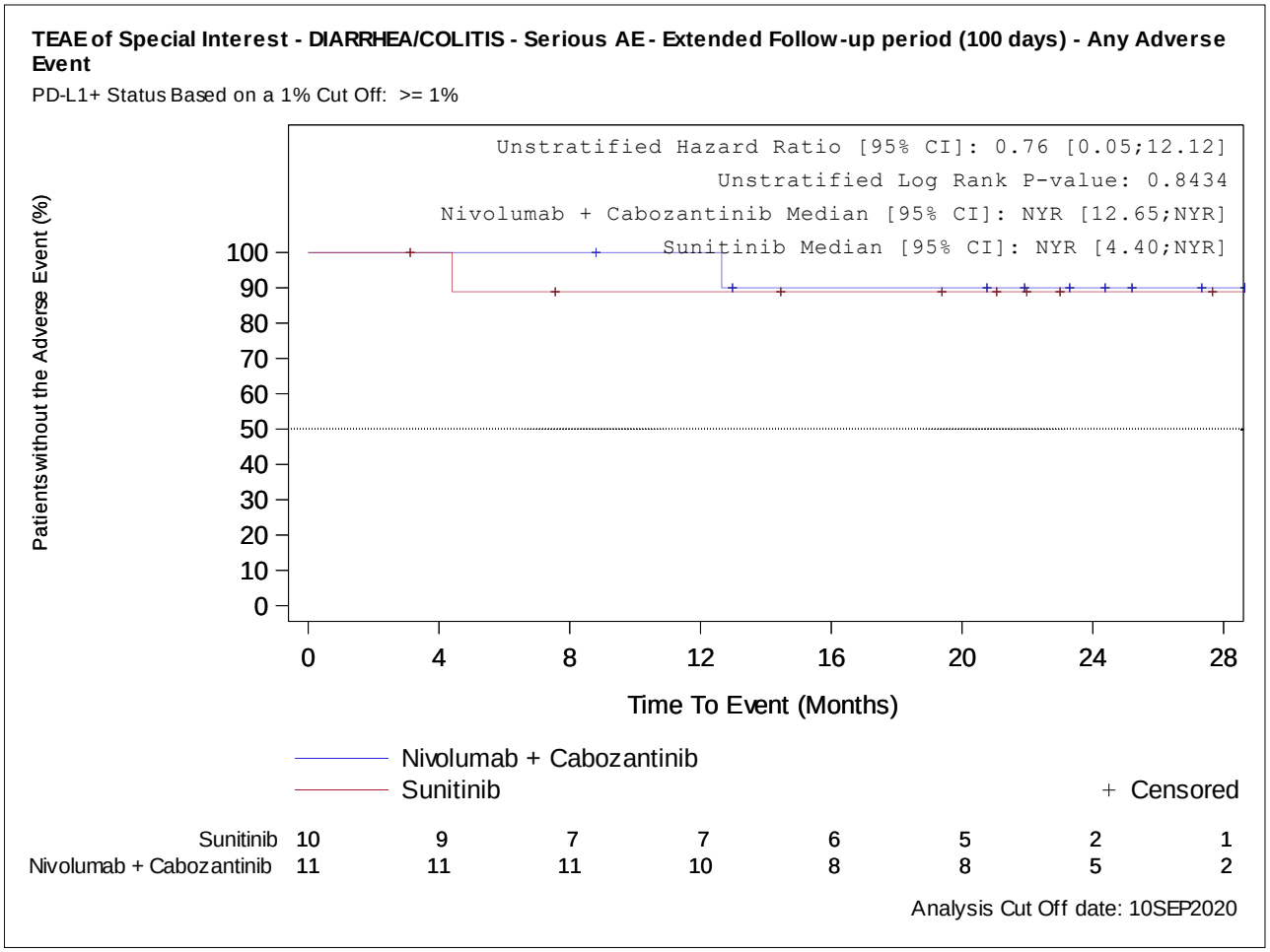

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:54:18

FIGURE 3.76.2.20: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



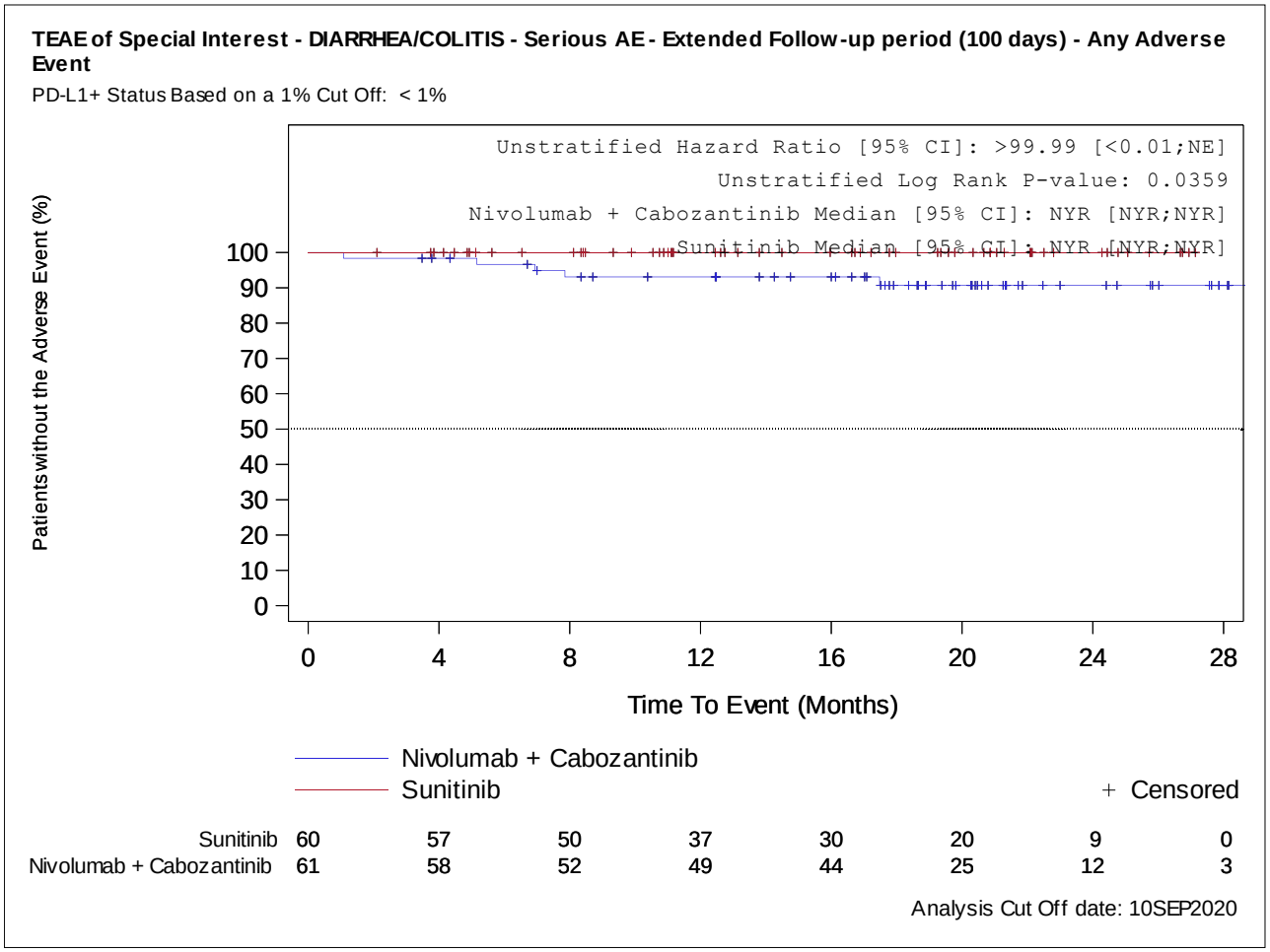

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:54:24

FIGURE 3.76.2.21: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



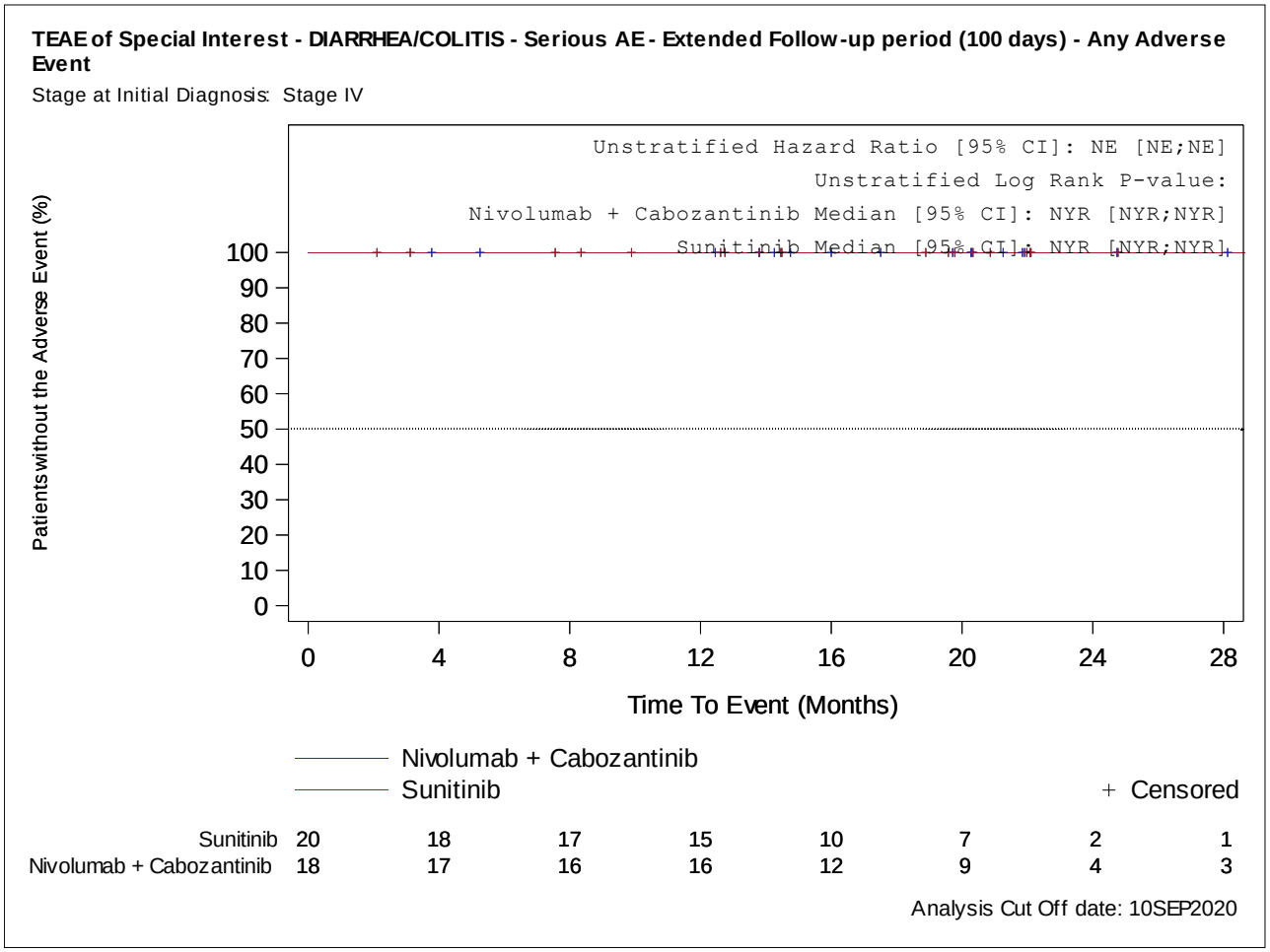

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:54:30

FIGURE 3.76.2.22: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



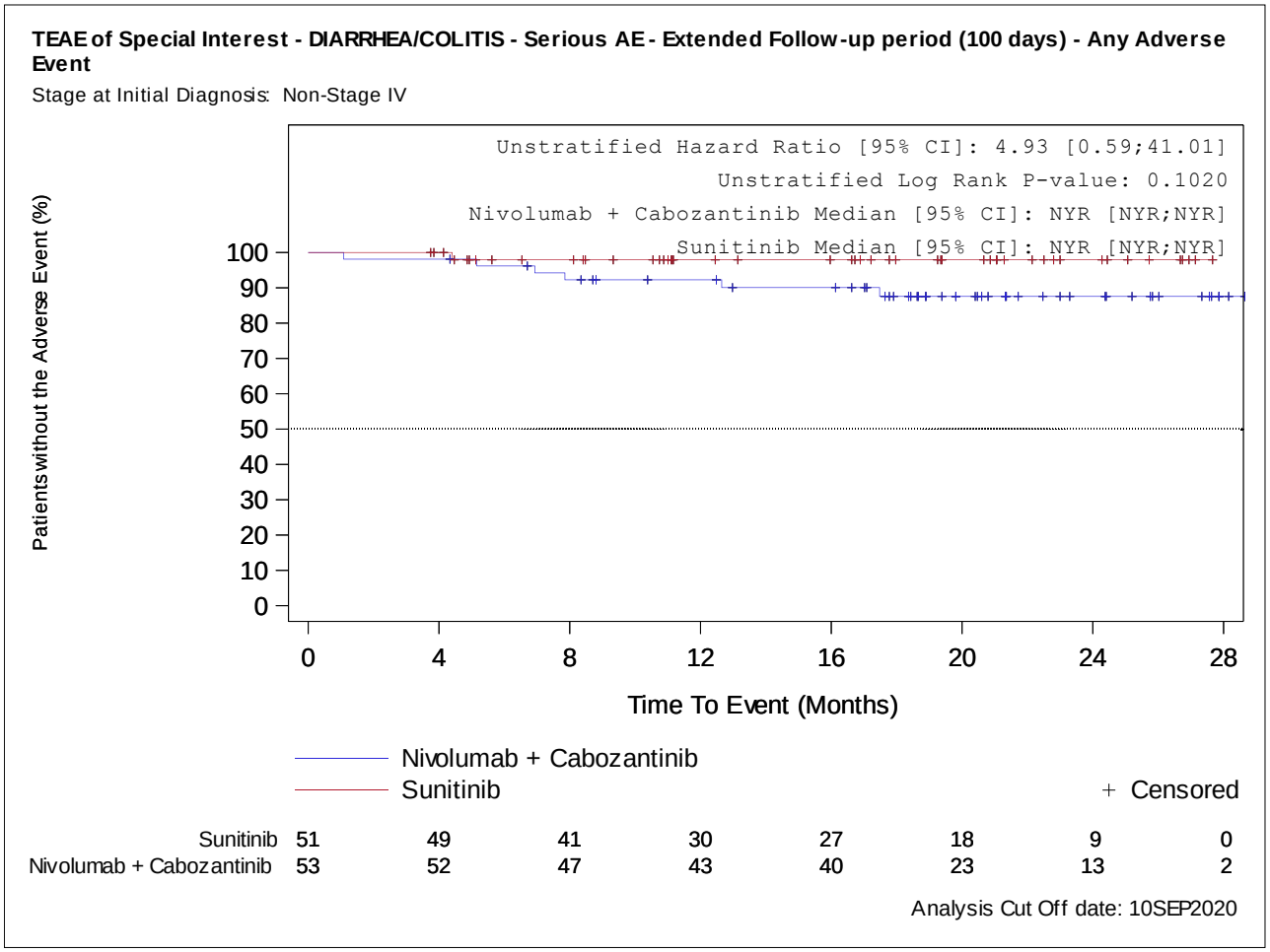

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:54:36

FIGURE 3.76.2.23: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



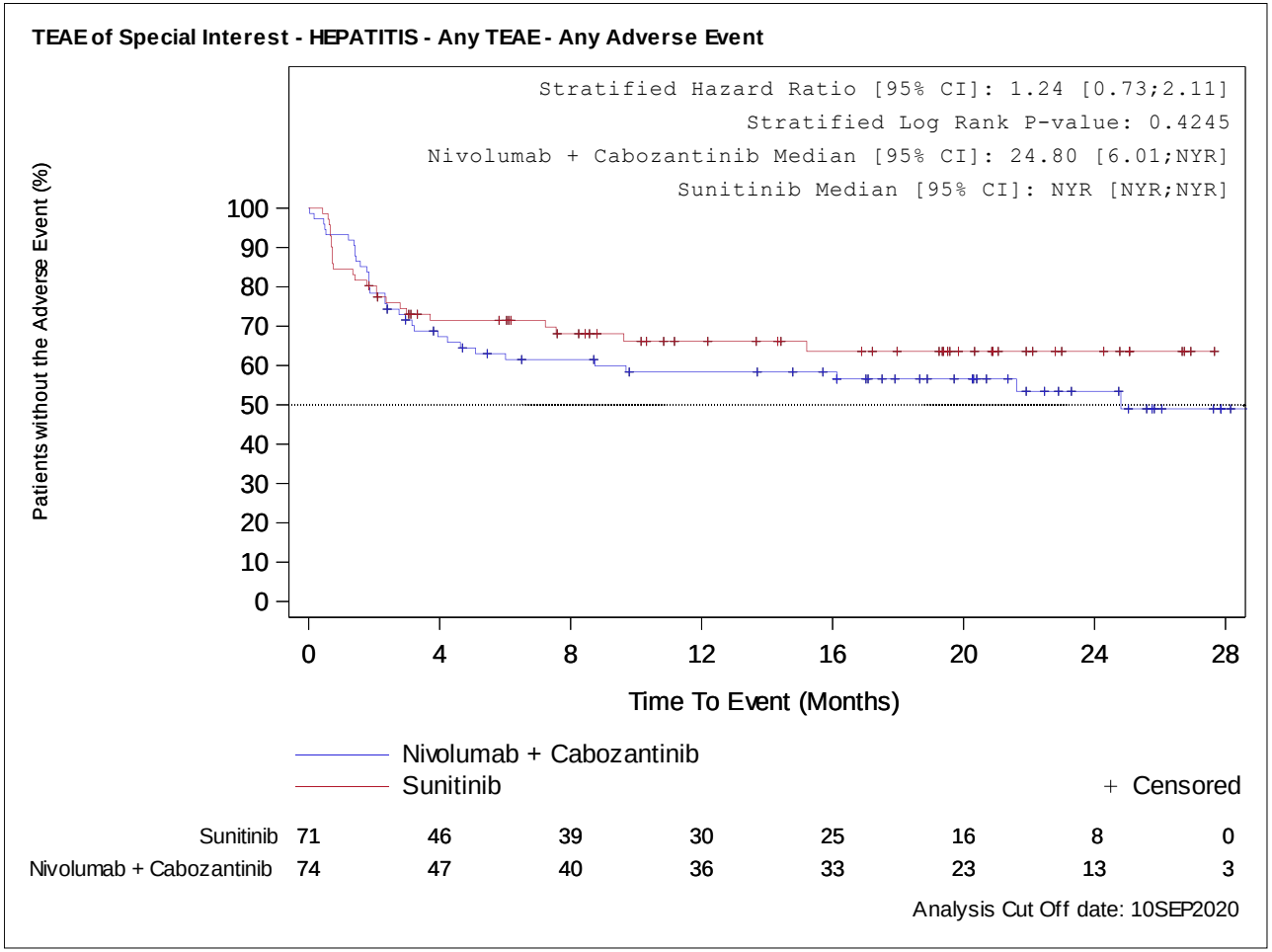

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:55:05

FIGURE 3.76.2.24: Kaplan-Meier curve - TEAE of Special Interest - DIARRHEA/COLITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



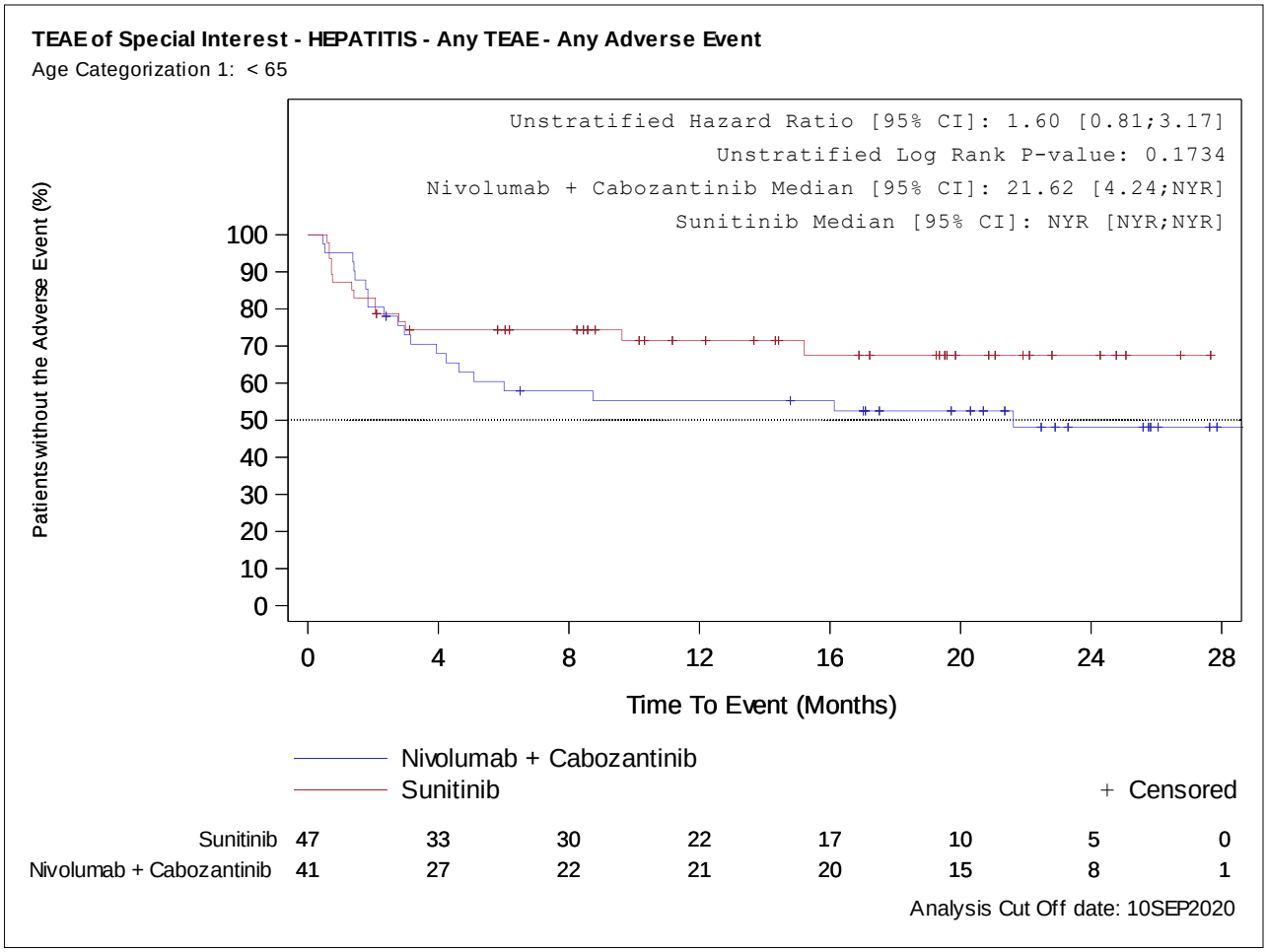

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:55:11

FIGURE 3.77.1: TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



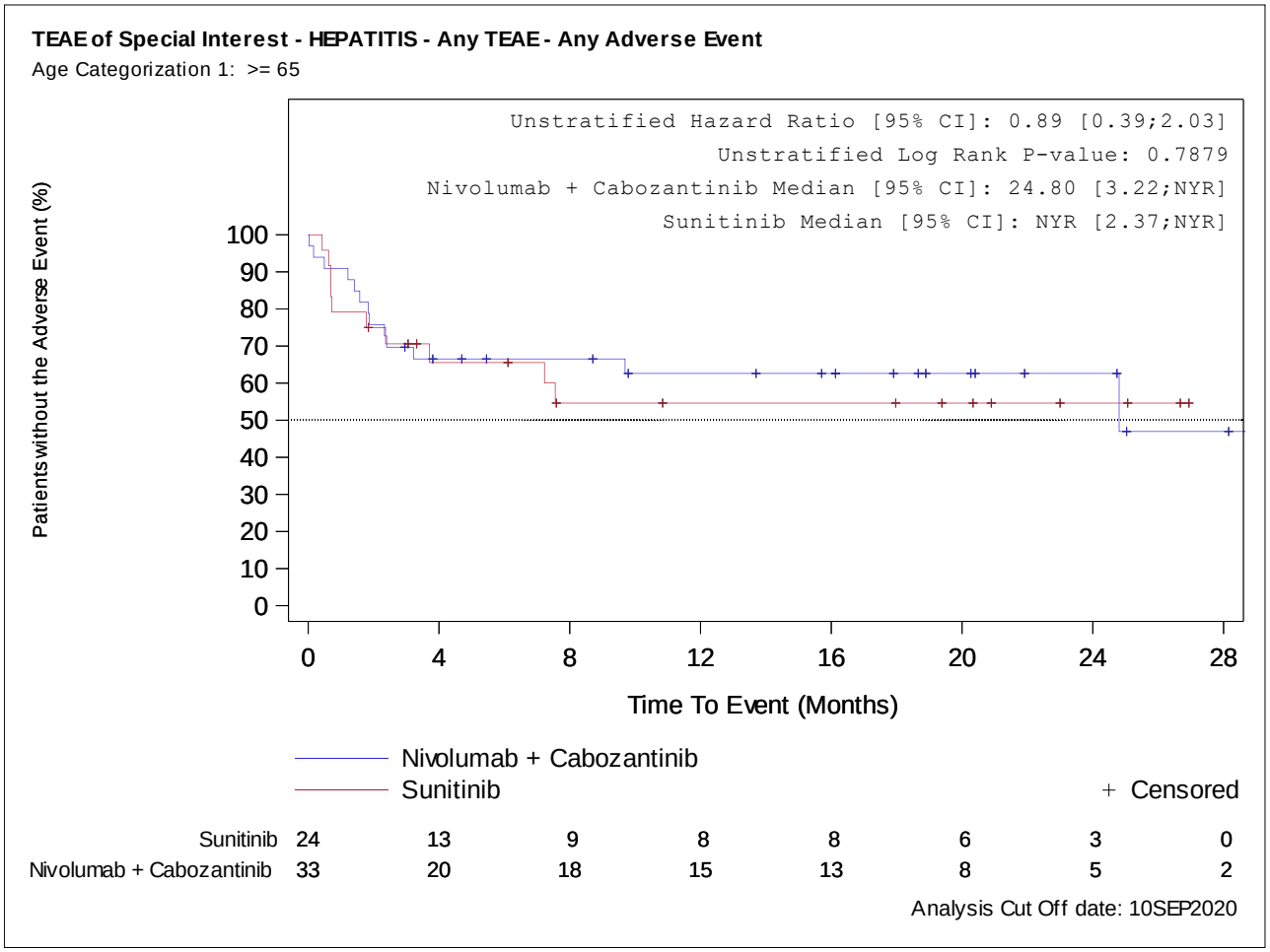

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:58:27

FIGURE 3.77.2.1: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:58:30

FIGURE 3.77.2.2: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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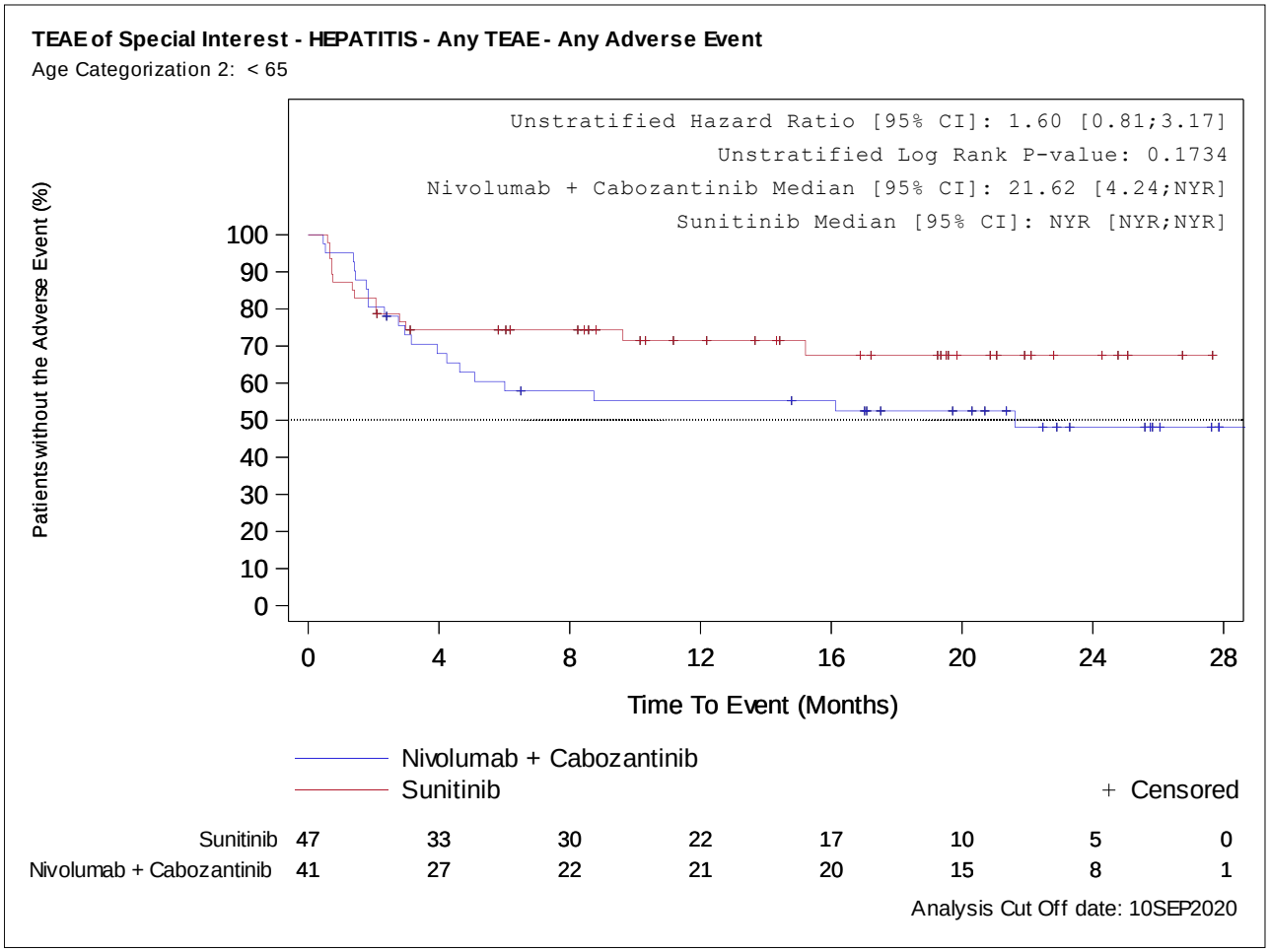
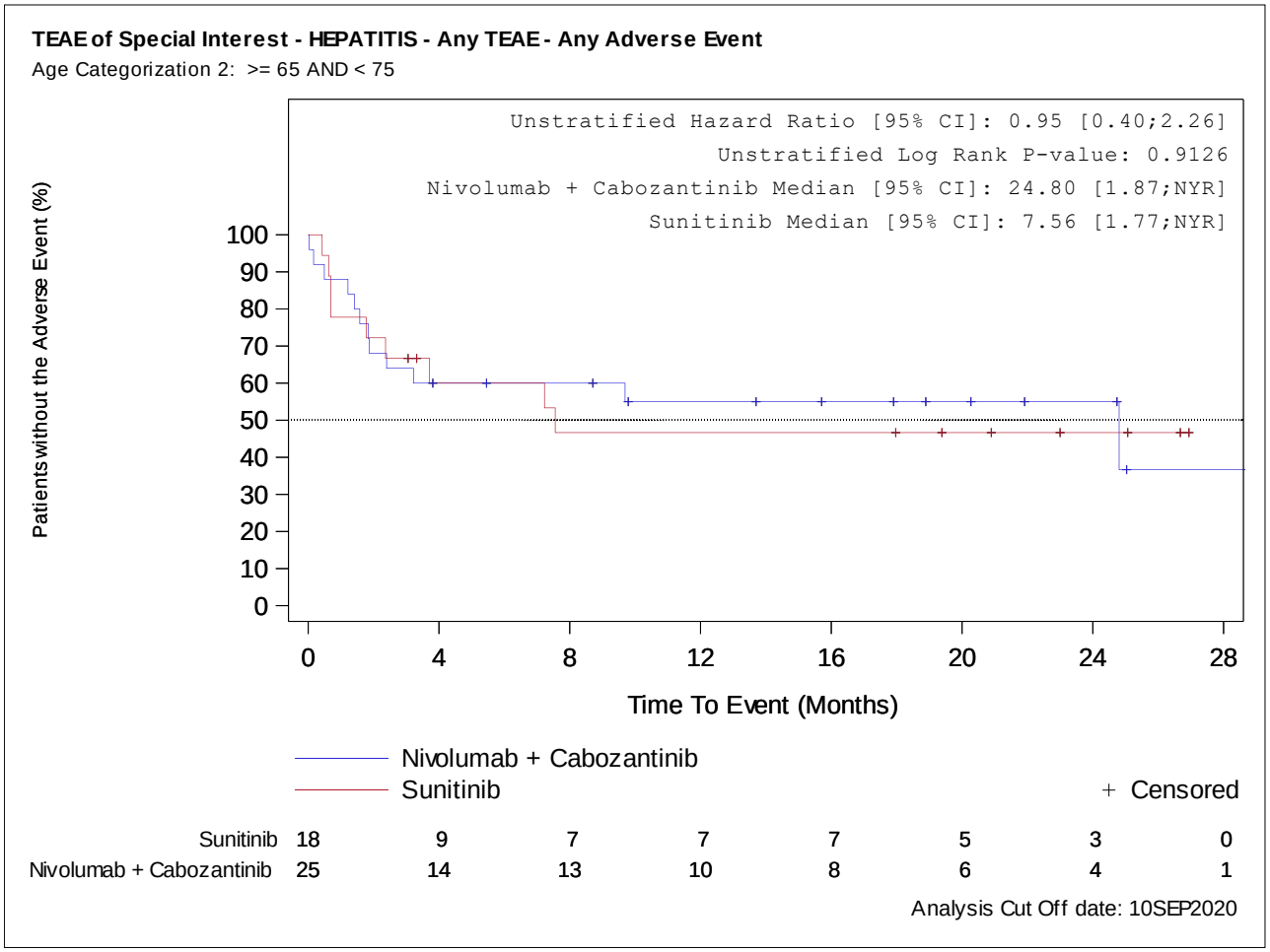
FIGURE 3.77.2.3: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



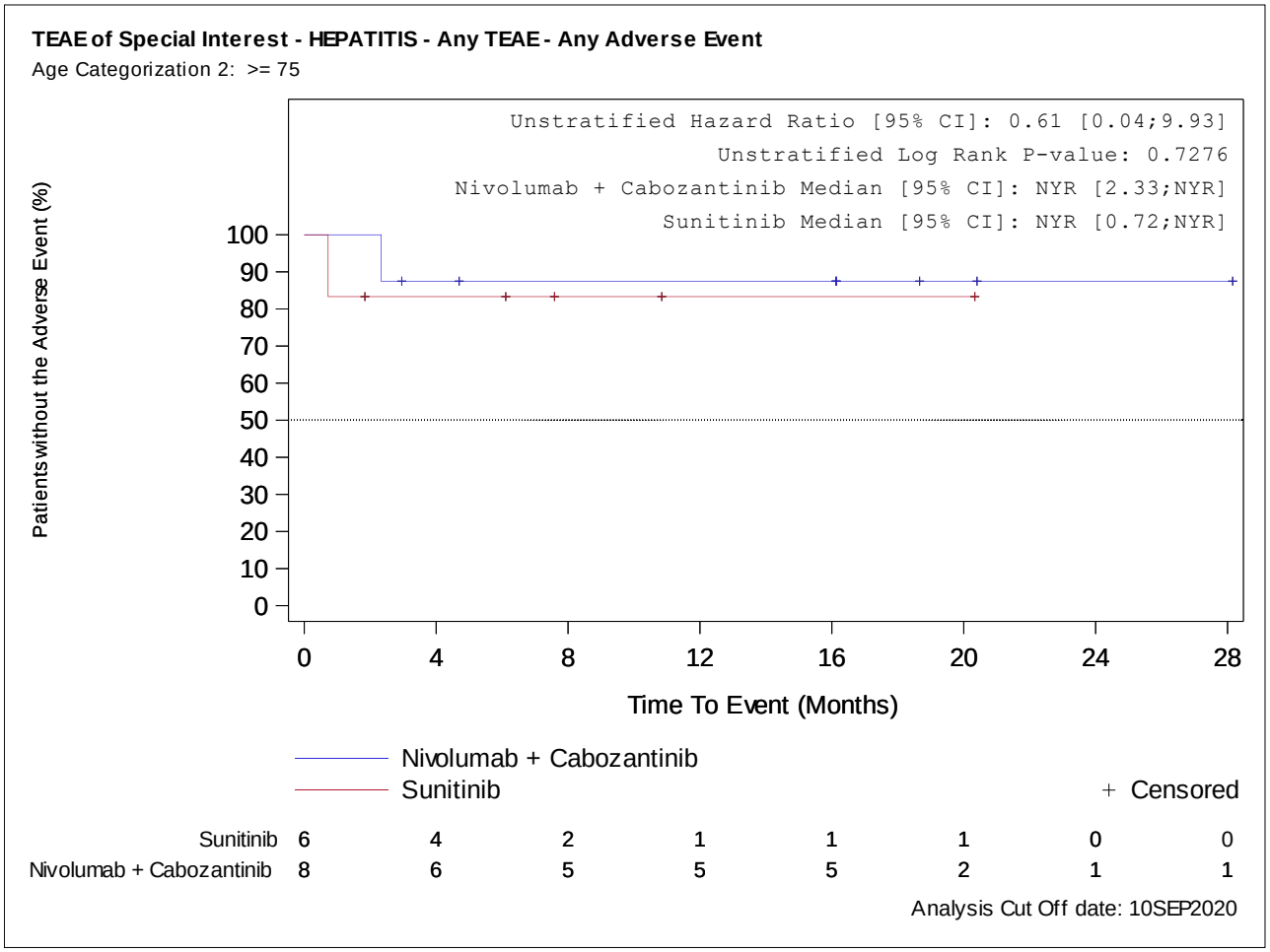

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:58:42

FIGURE 3.77.2.4: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



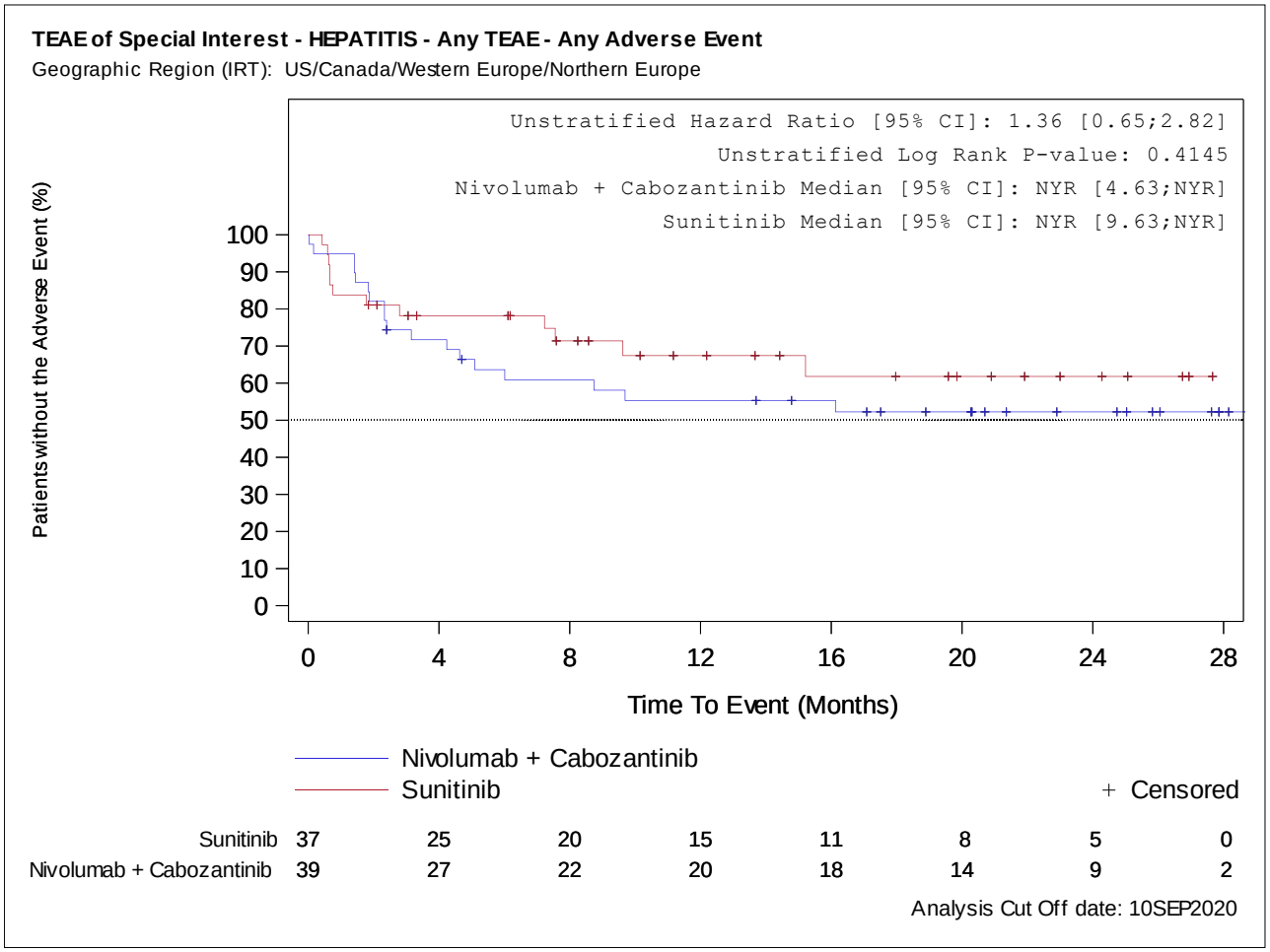

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:58:47

FIGURE 3.77.2.5: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



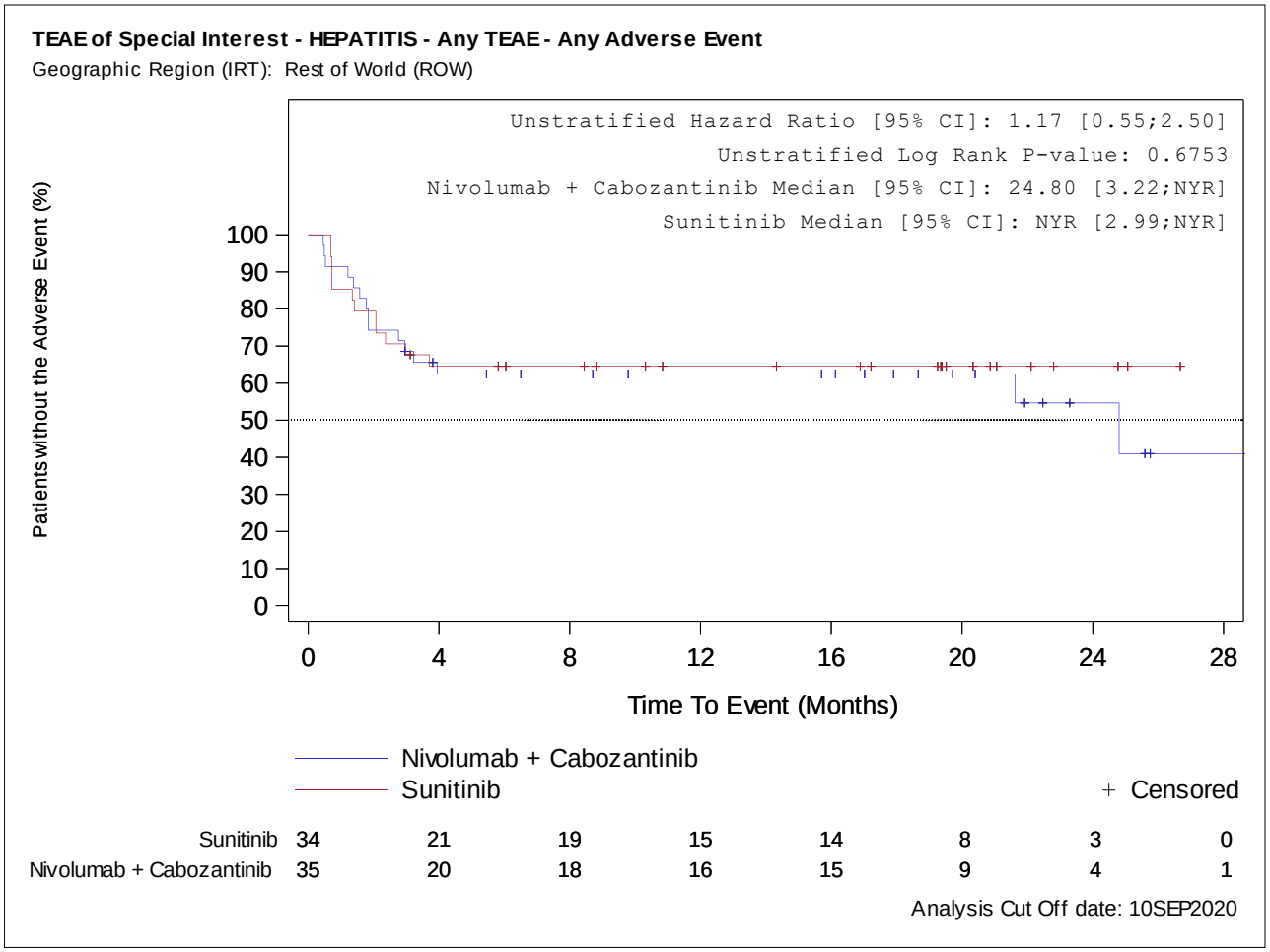

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:58:54

FIGURE 3.77.2.6: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



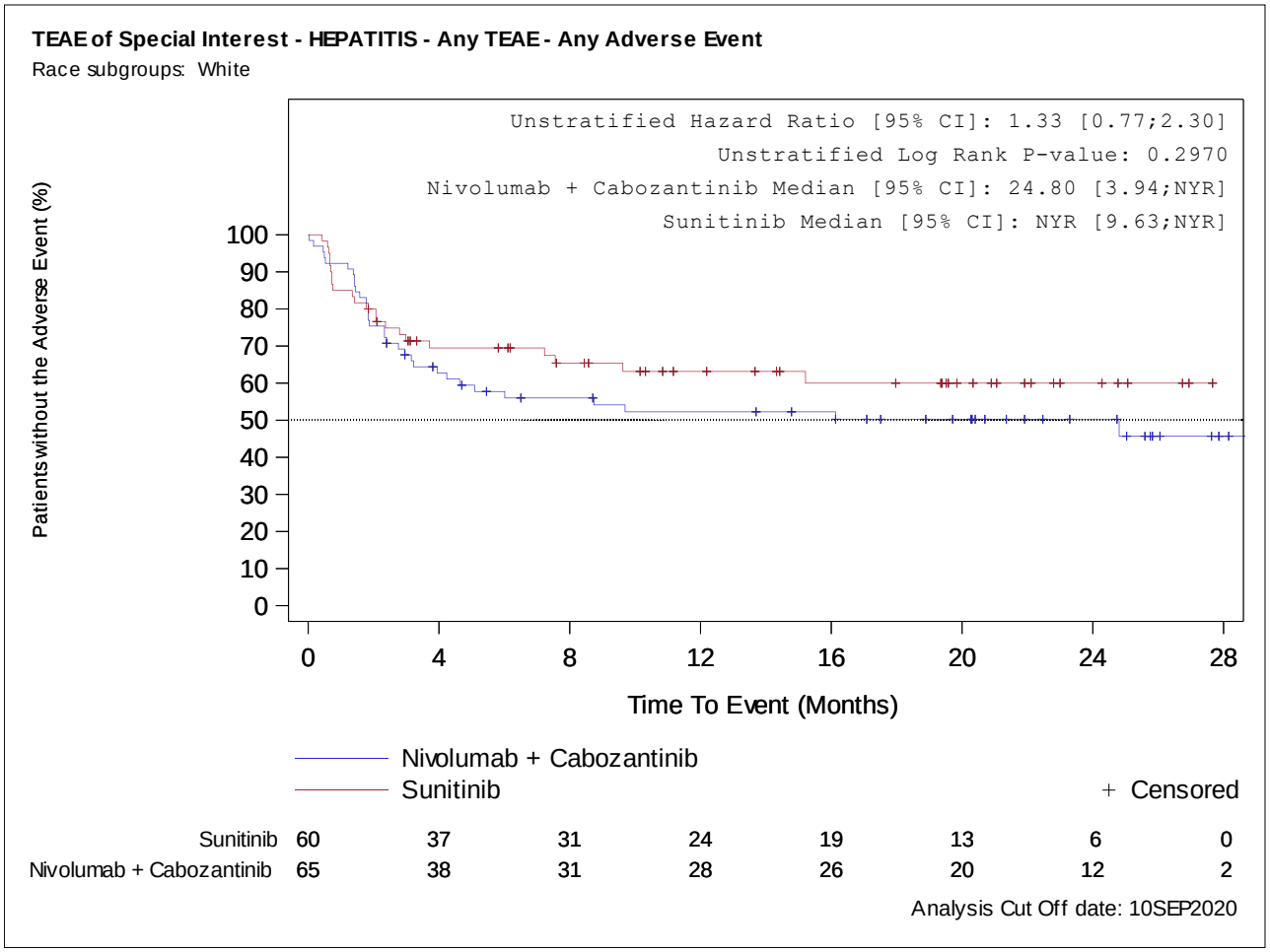

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:58:59

FIGURE 3.77.2.7: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



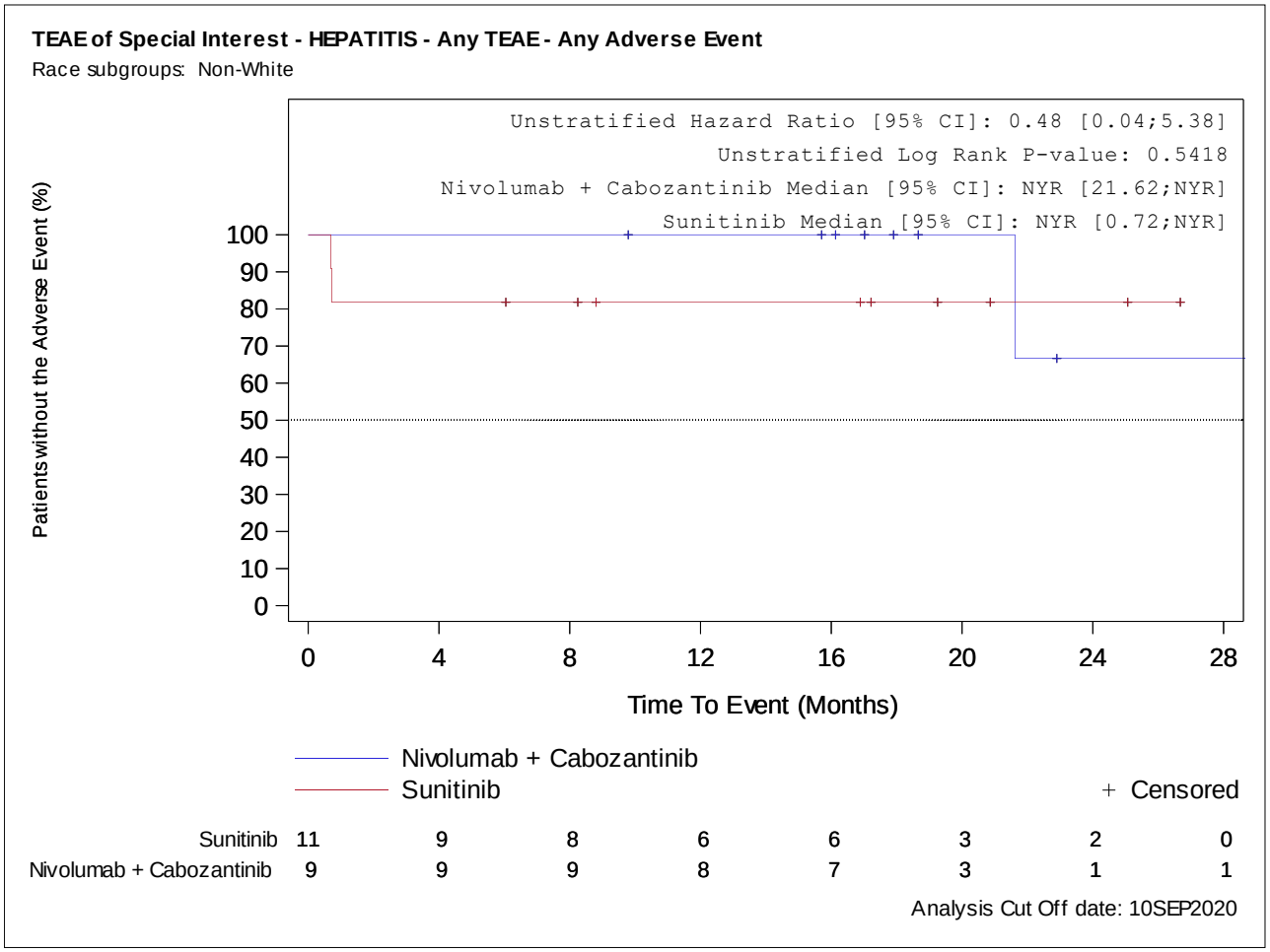

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:59:05

FIGURE 3.77.2.8: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



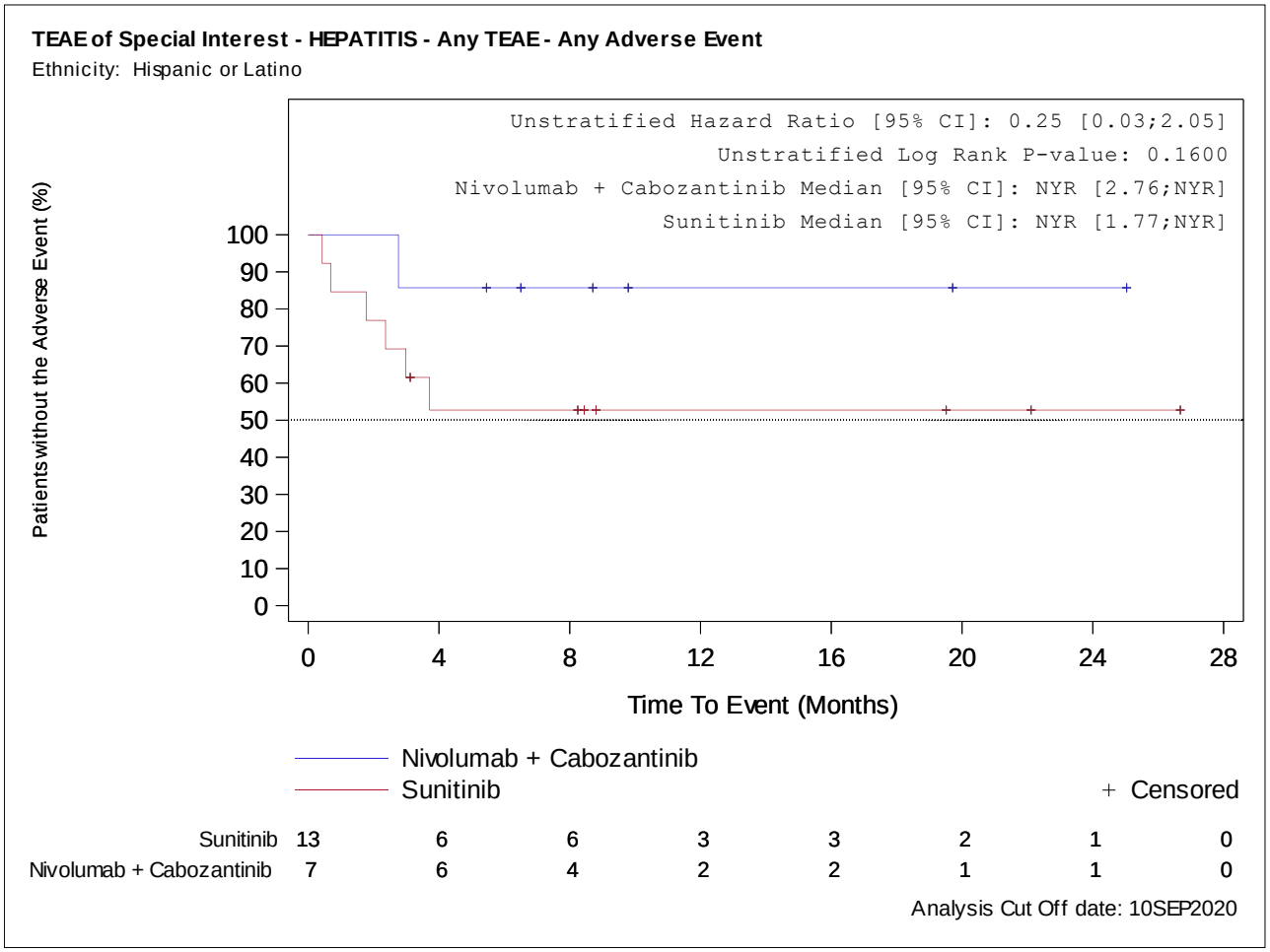

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:59:11

FIGURE 3.77.2.9: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



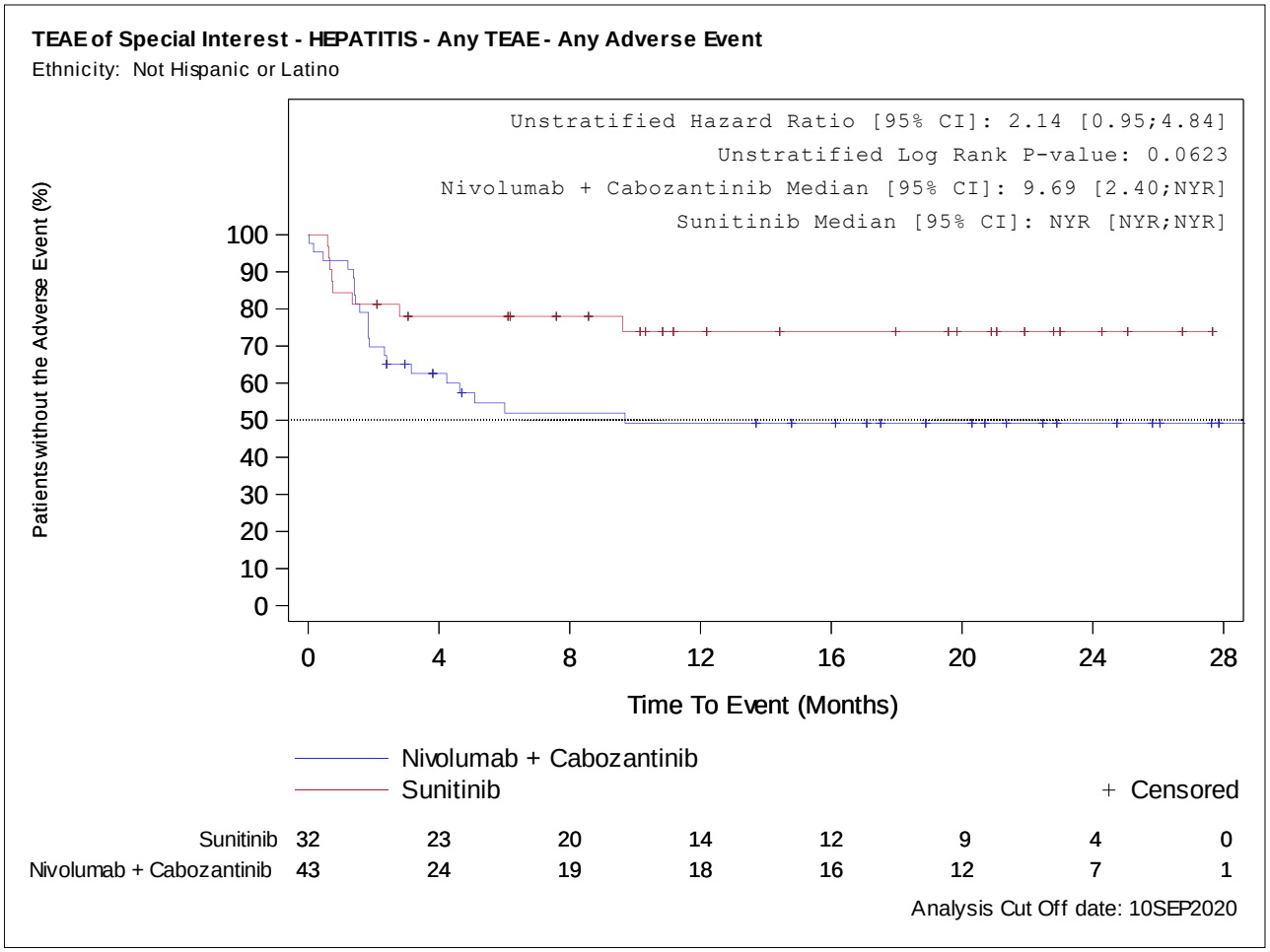

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:59:17

FIGURE 3.77.2.10: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



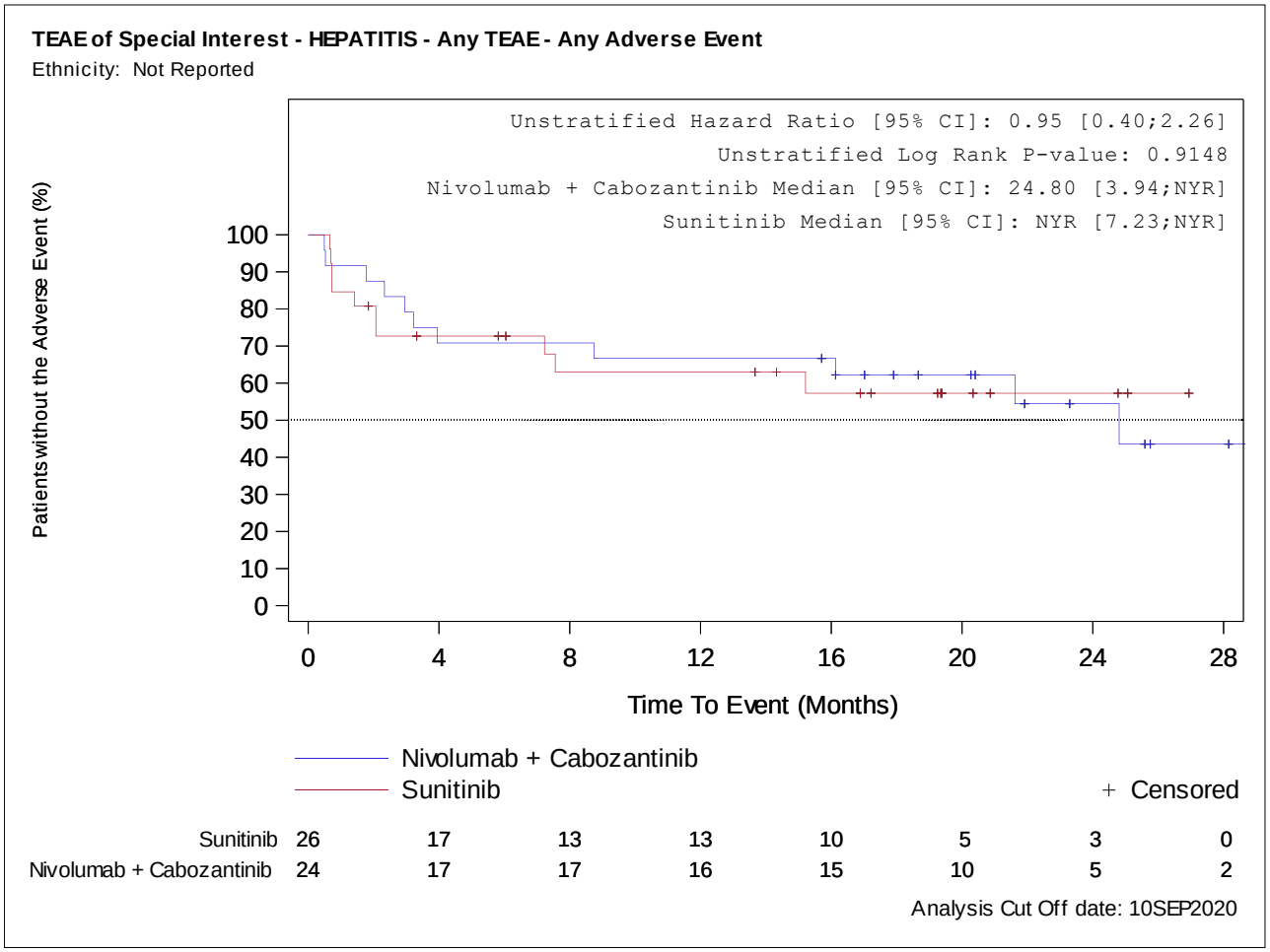

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:59:22

FIGURE 3.77.2.11: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



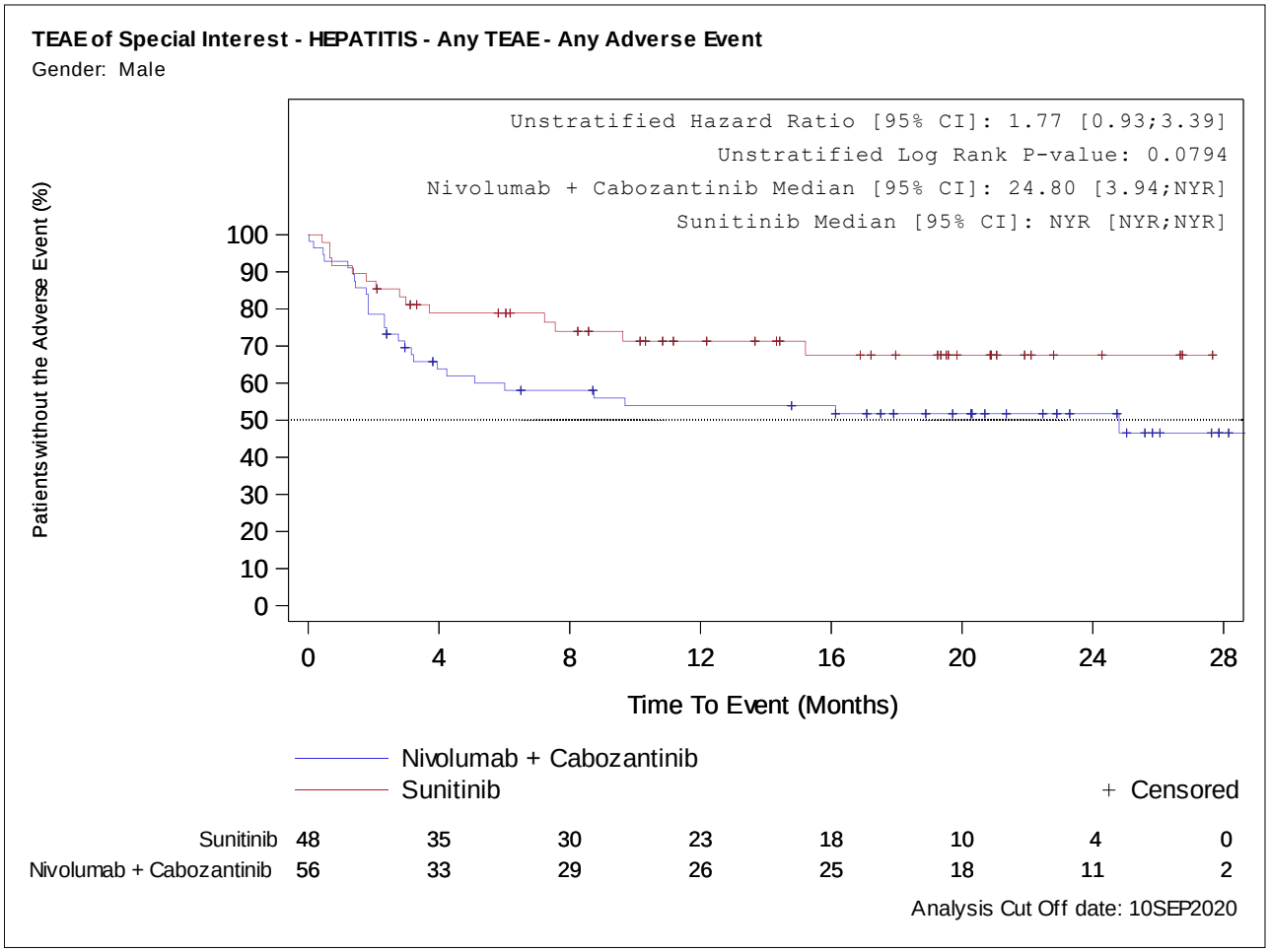

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:59:28

FIGURE 3.77.2.12: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



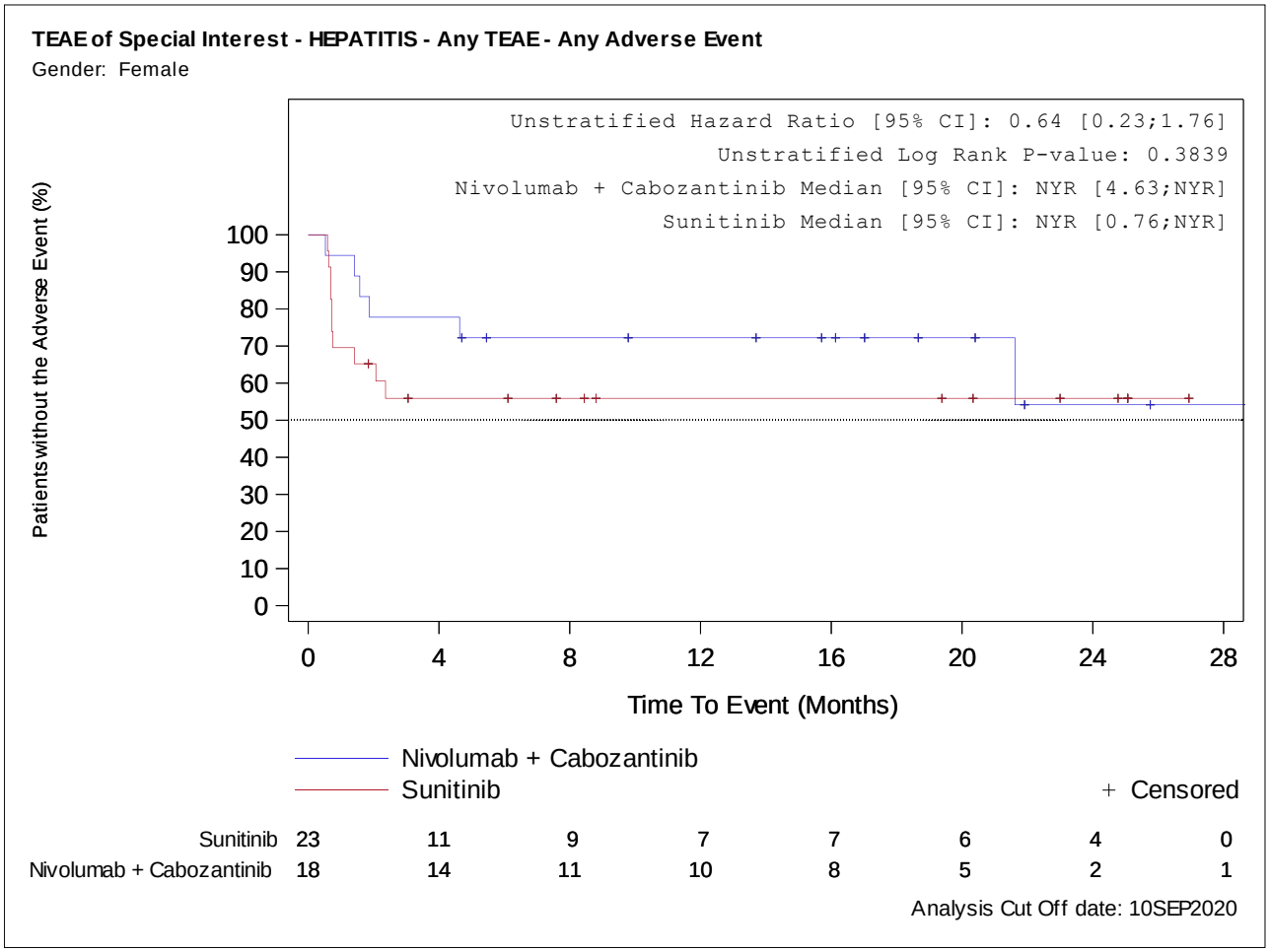

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:59:34

FIGURE 3.77.2.13: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 20:59:40

FIGURE 3.77.2.14: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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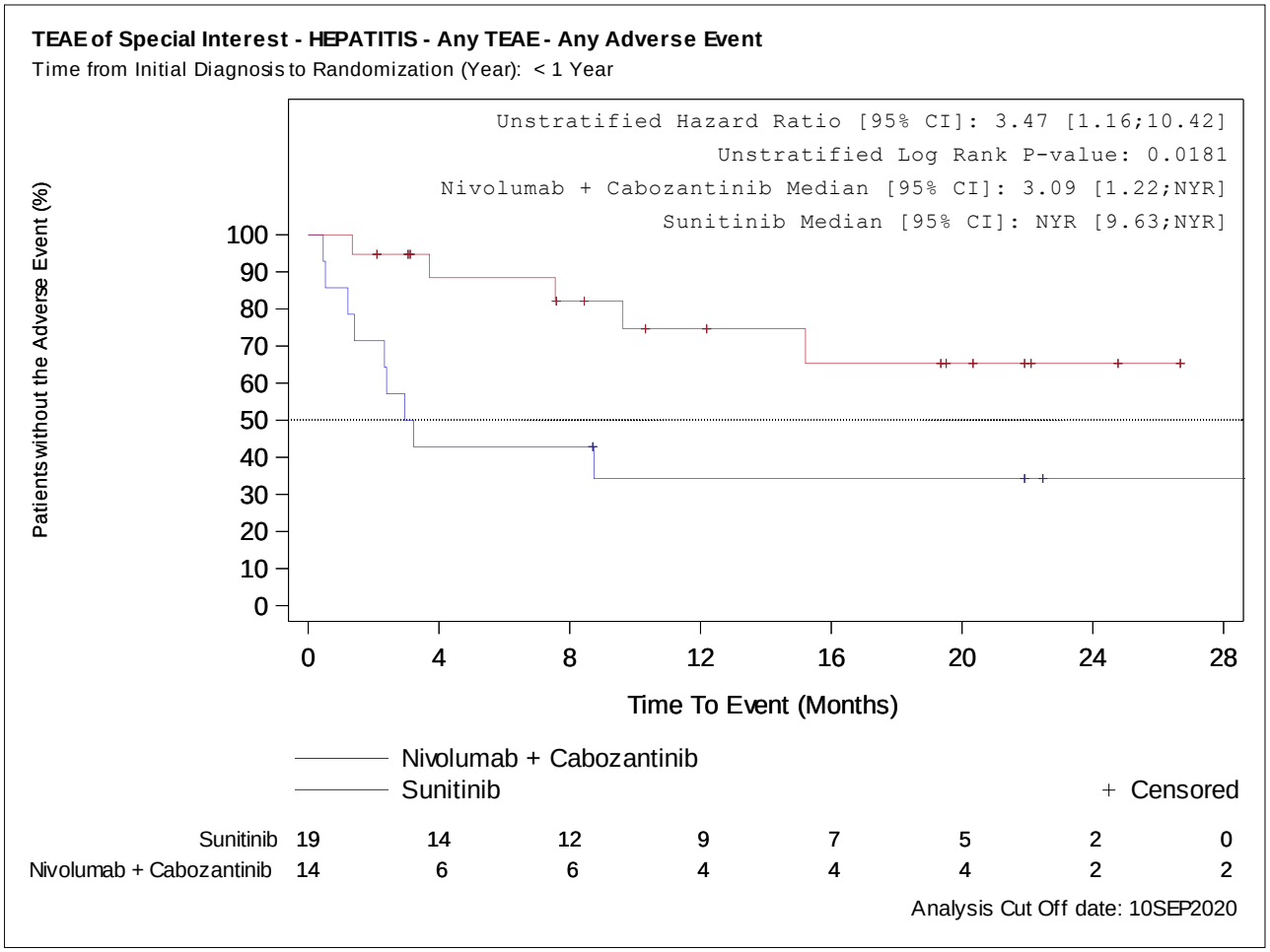
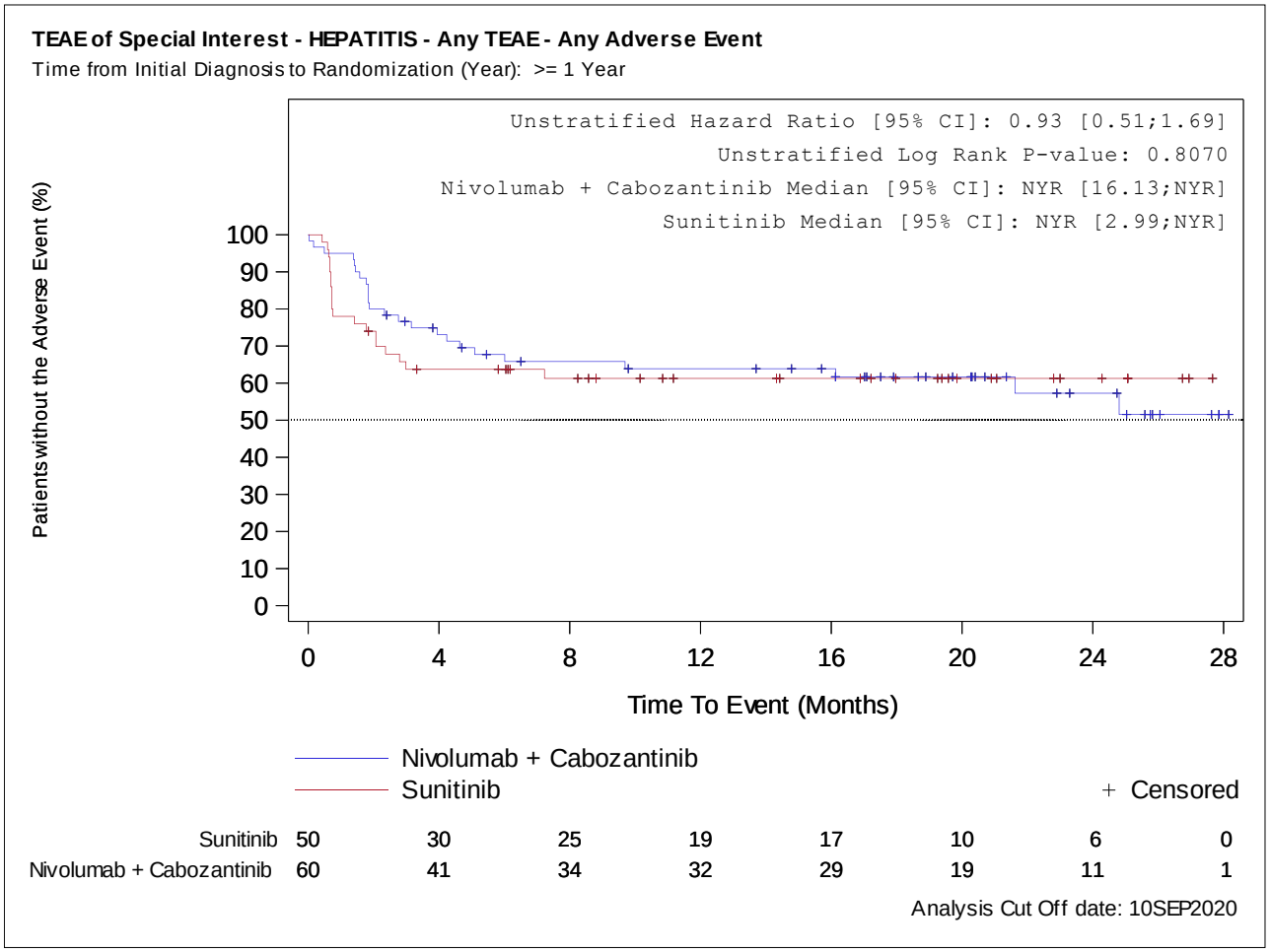
FIGURE 3.77.2.15: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



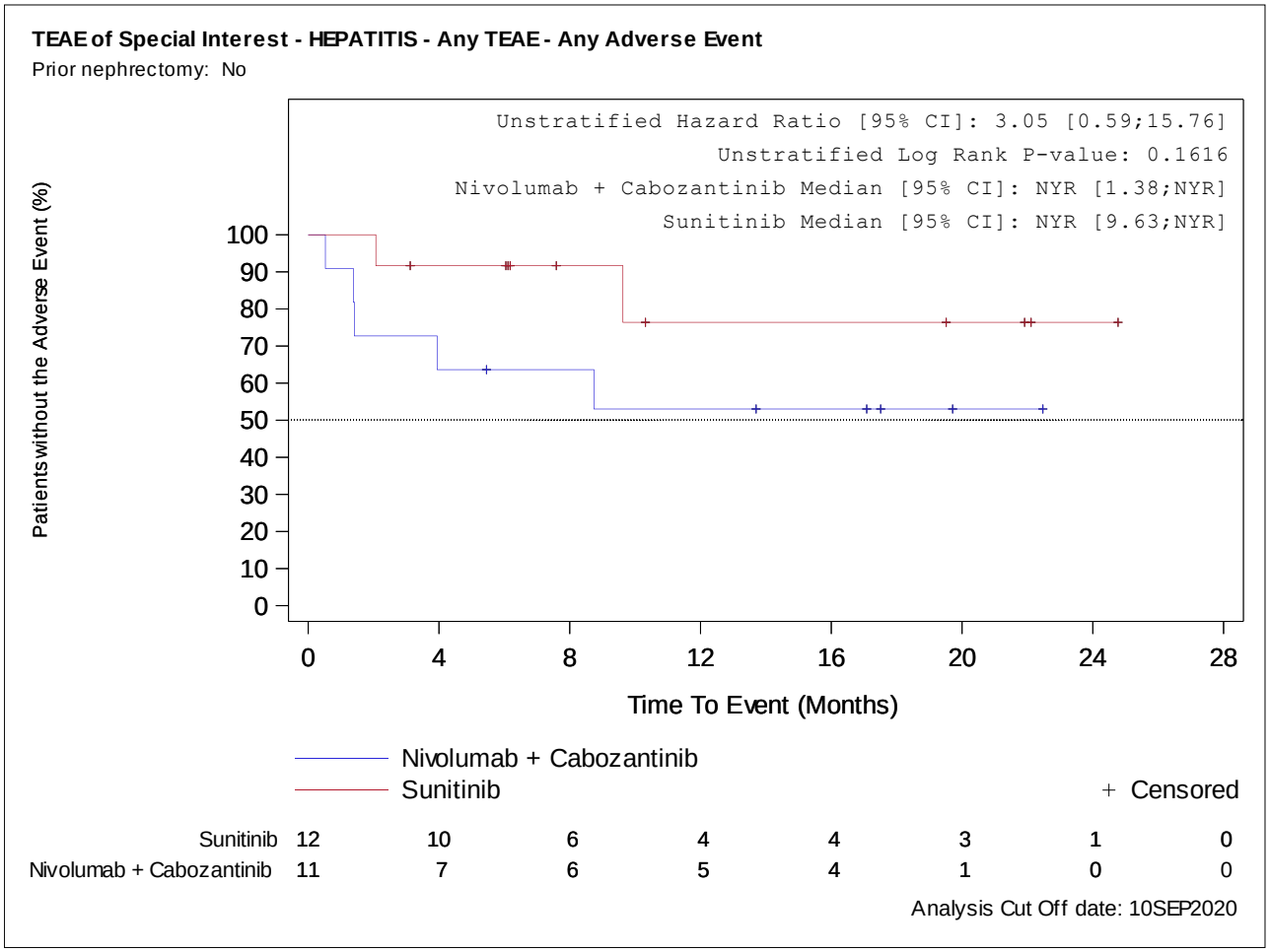

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:00:03

FIGURE 3.77.2.16: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



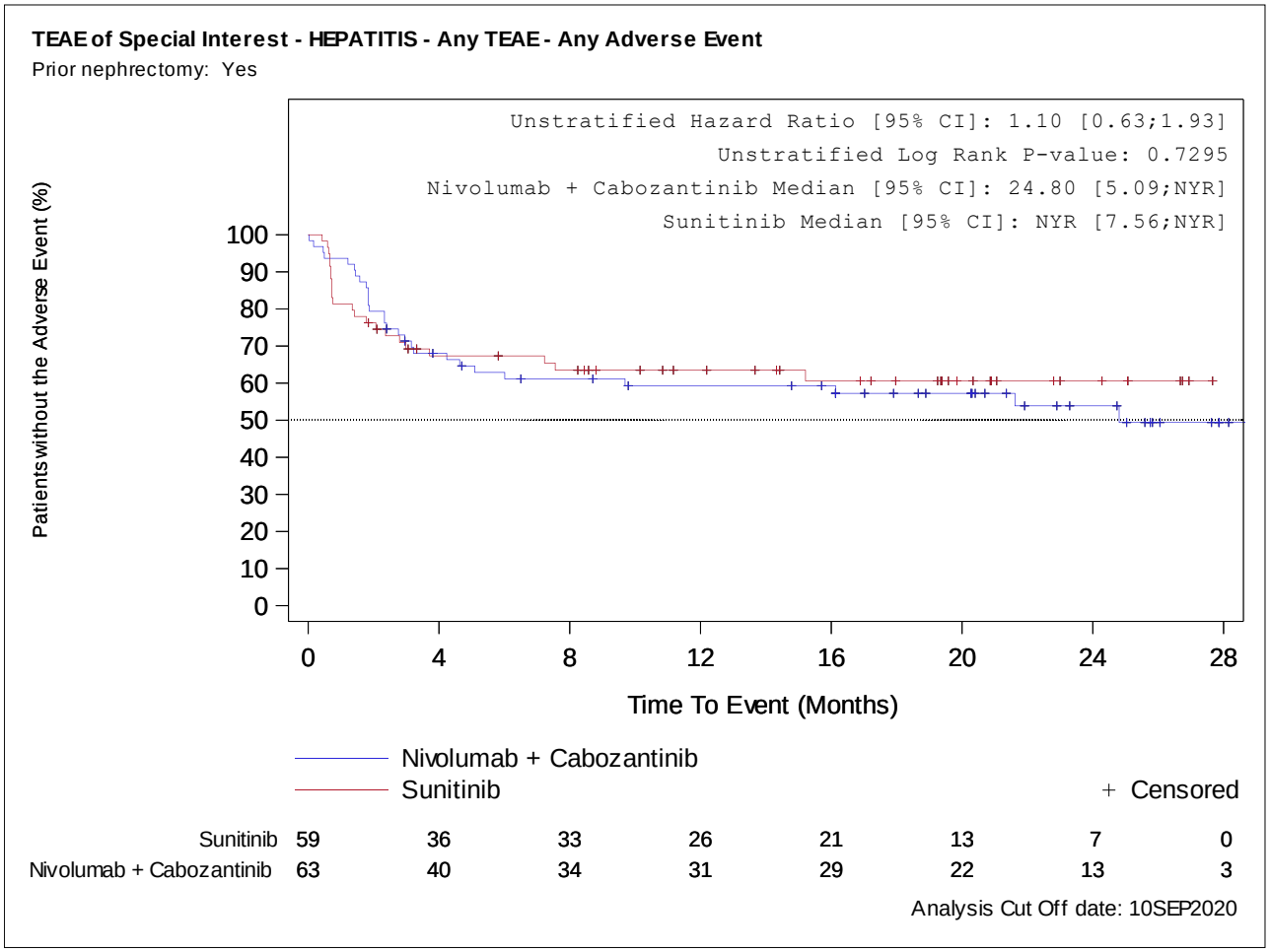

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:00:09

FIGURE 3.77.2.17: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



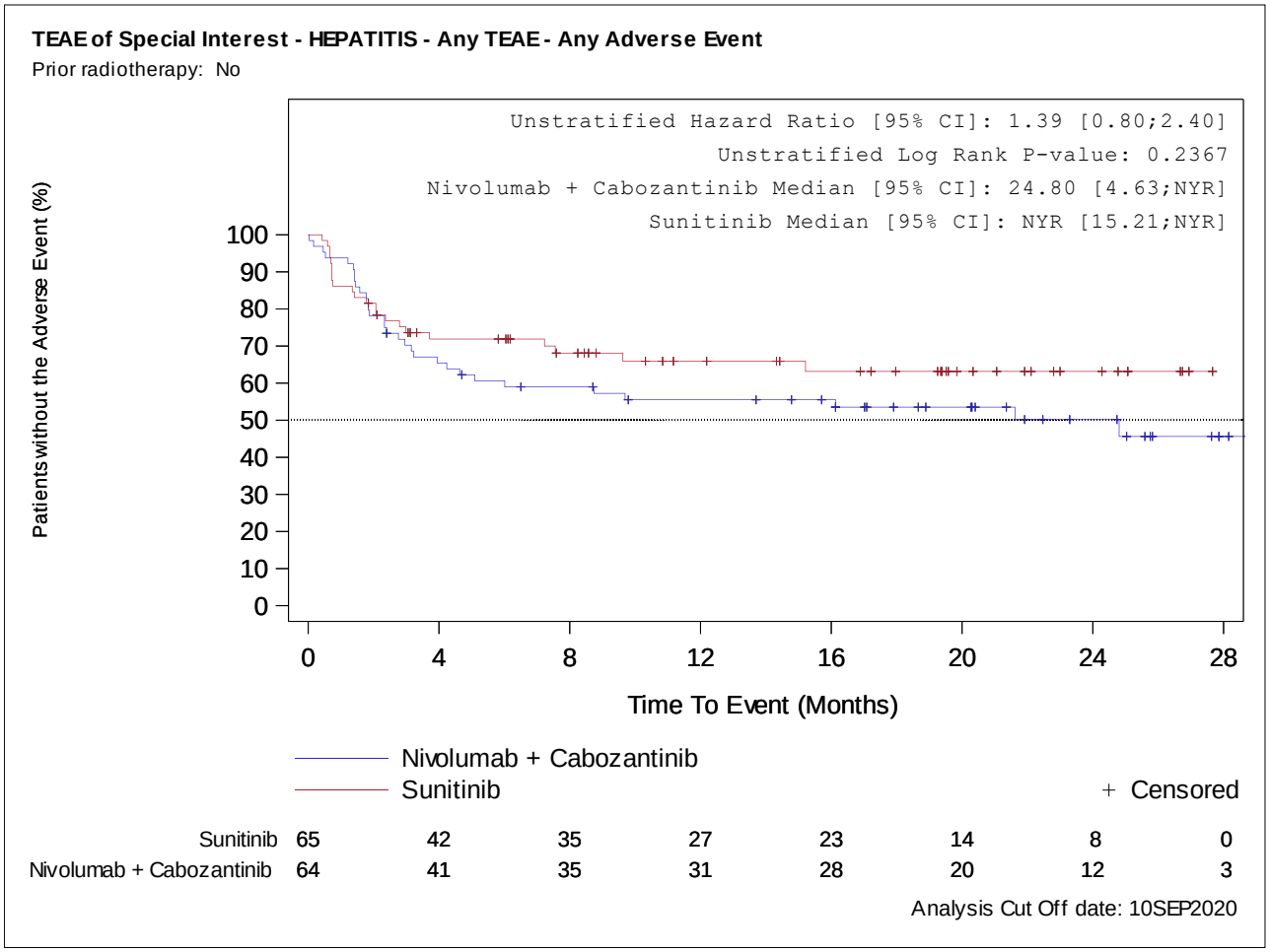

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:01:02

FIGURE 3.77.2.18: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



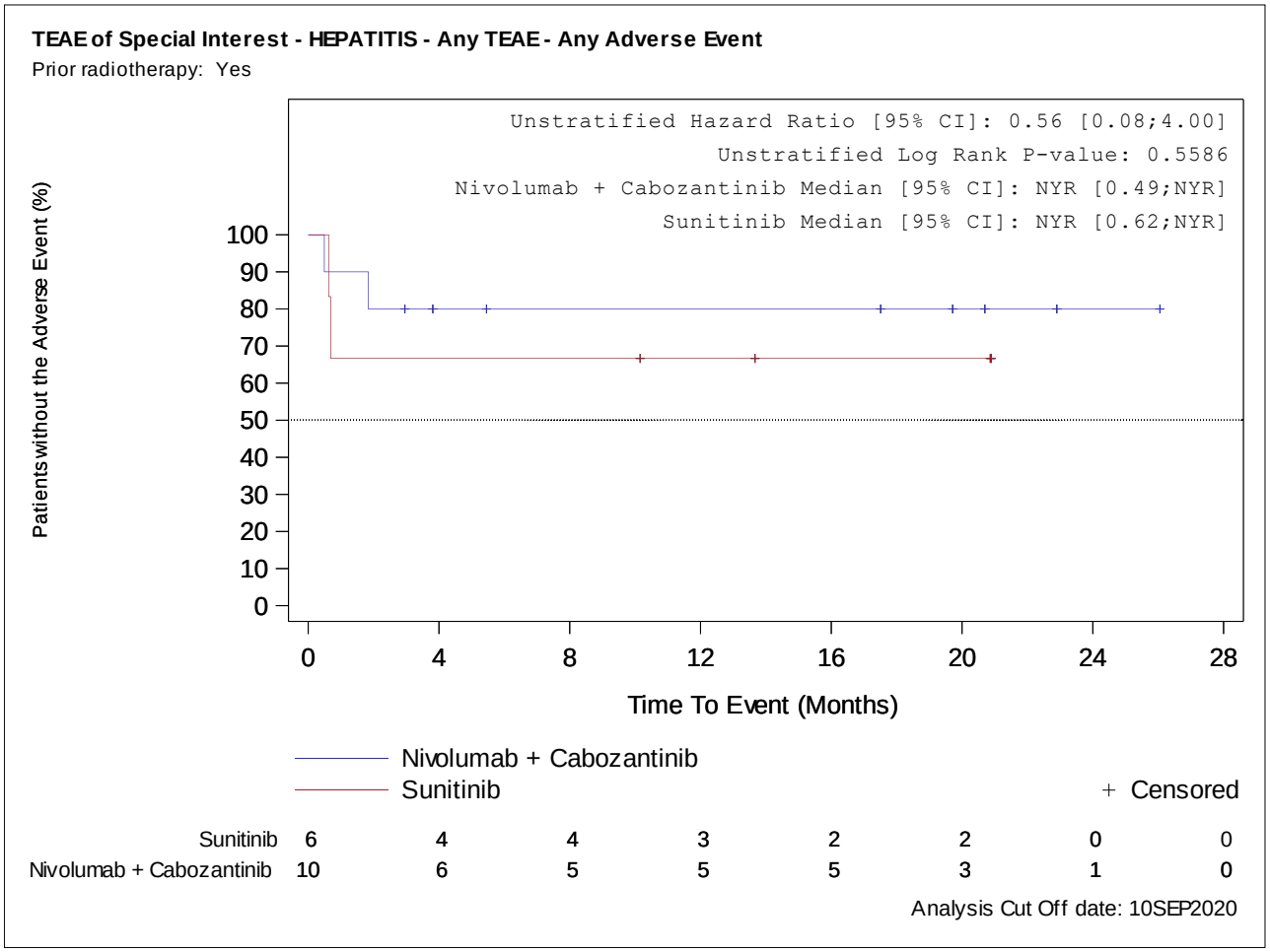

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:01:07

FIGURE 3.77.2.19: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



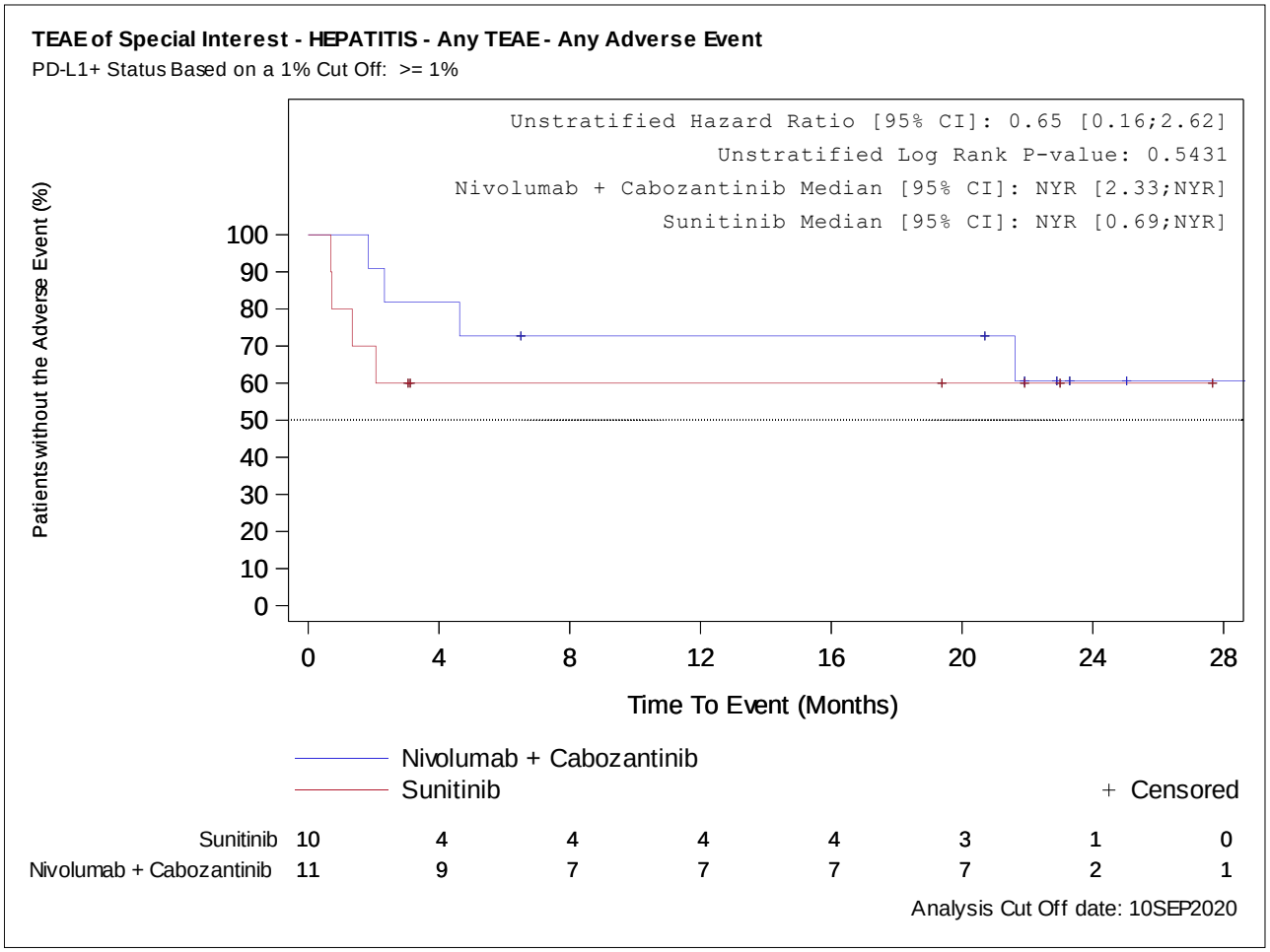

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:01:13

FIGURE 3.77.2.20: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



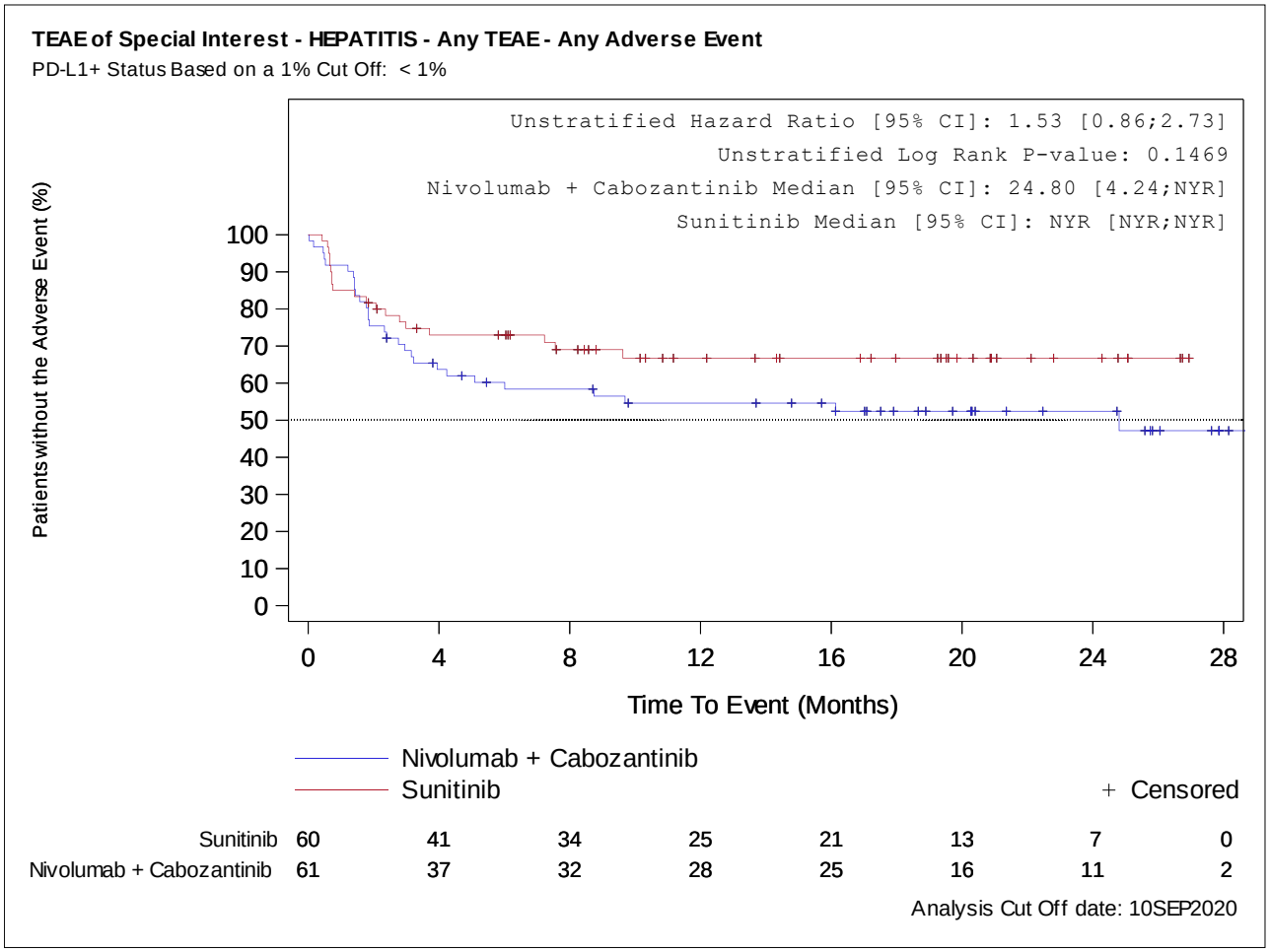

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:01:18

FIGURE 3.77.2.21: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



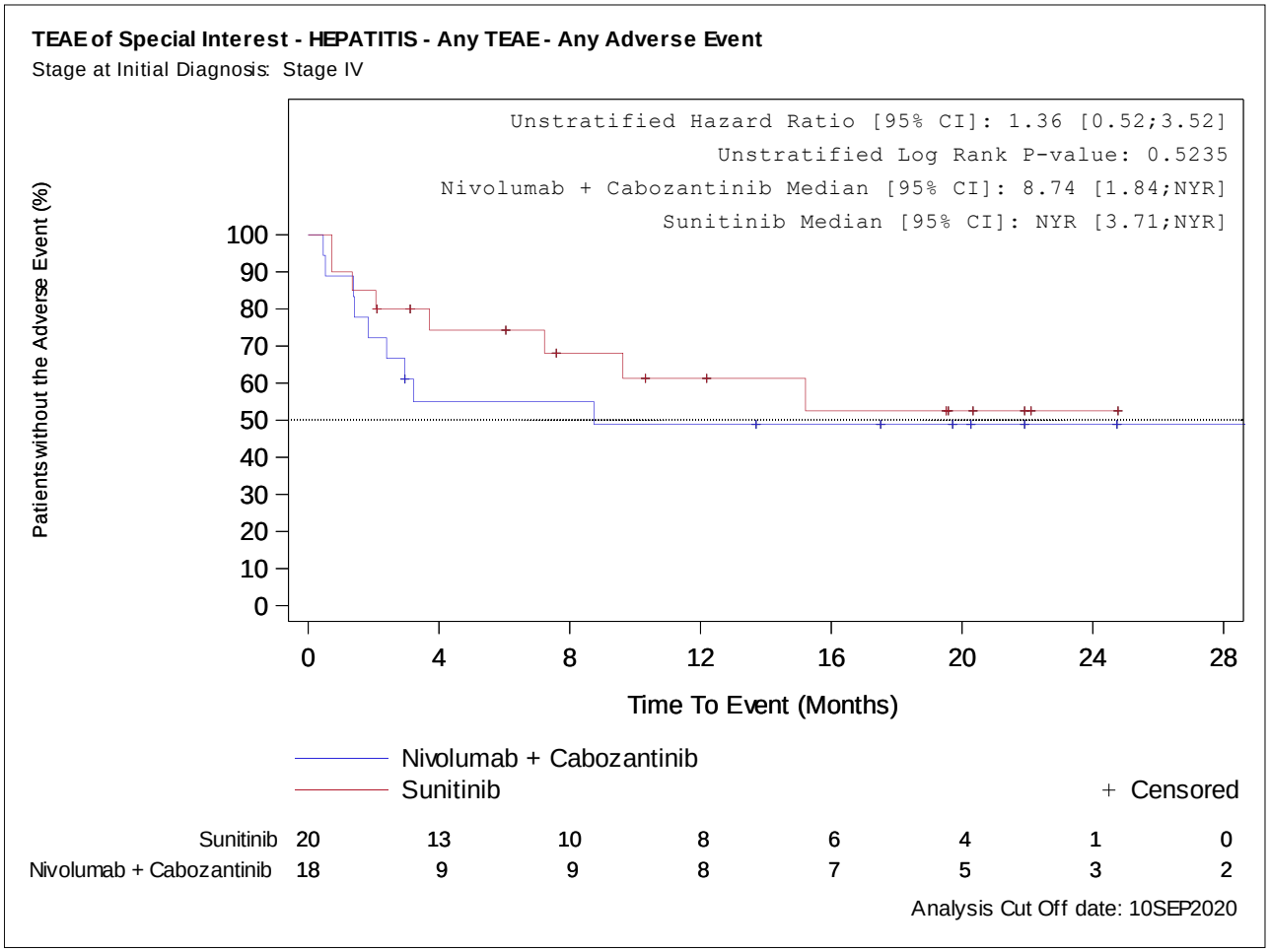

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:01:25

FIGURE 3.77.2.22: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



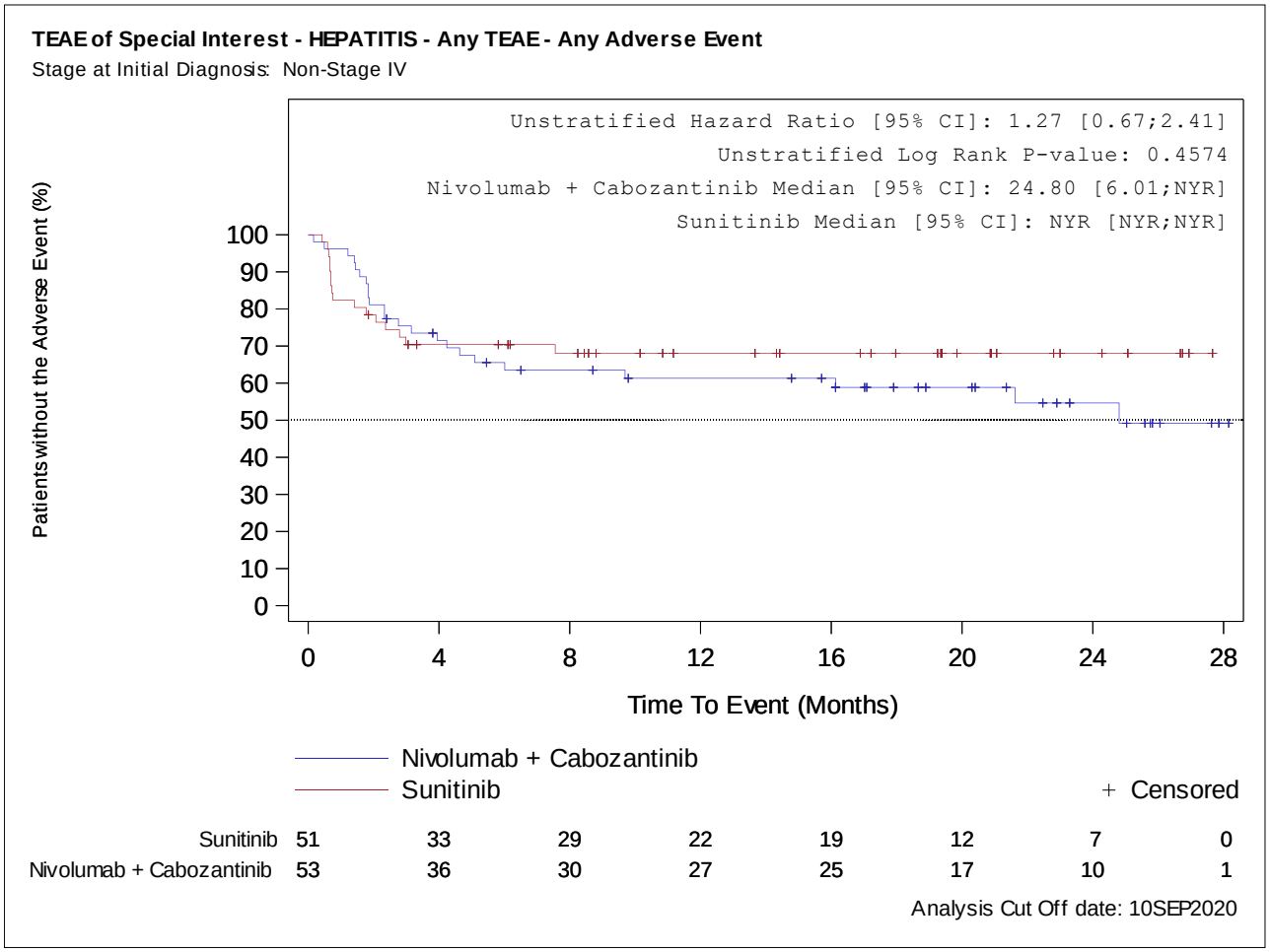

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:01:30

FIGURE 3.77.2.23: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



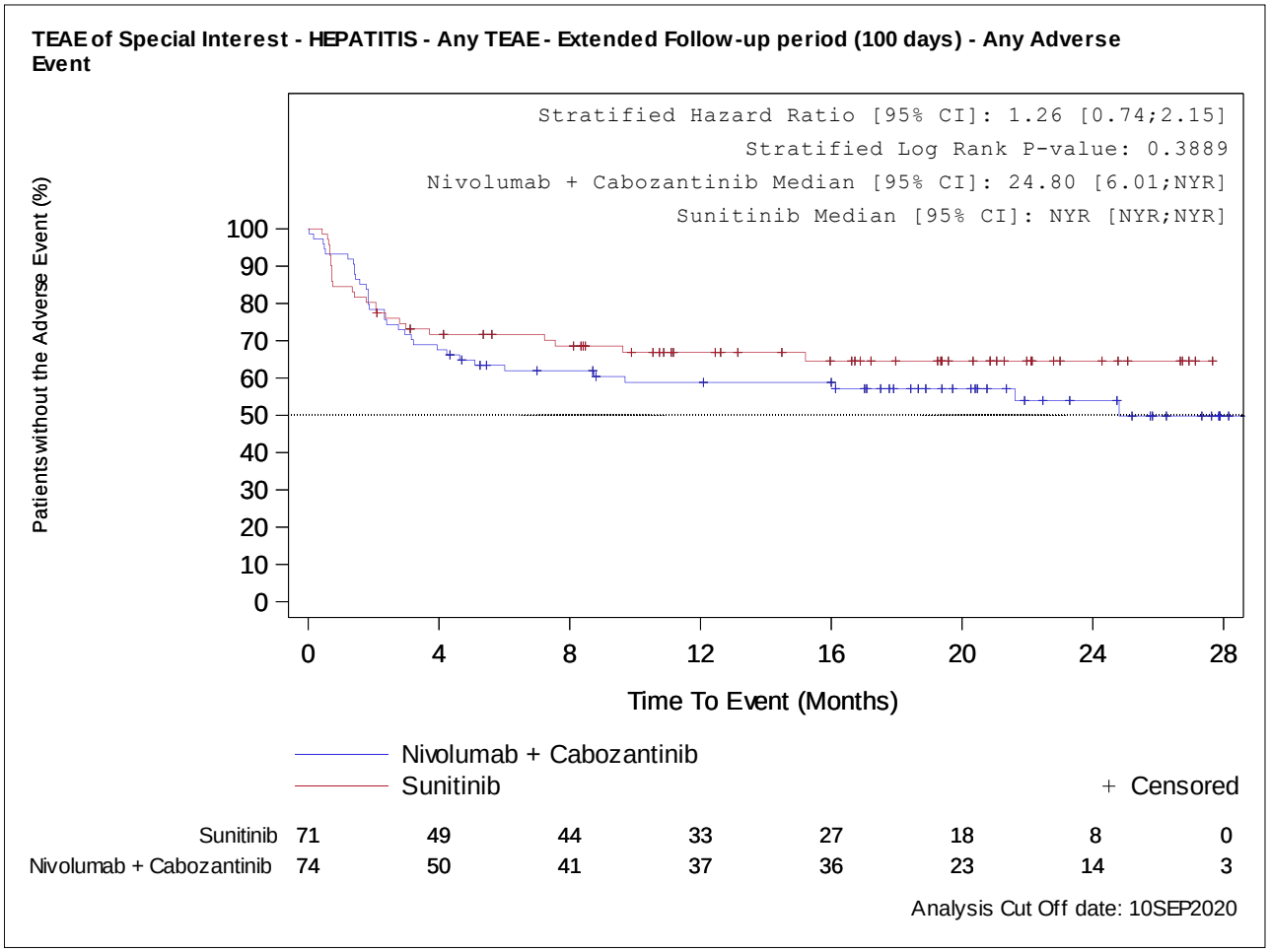

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:02:00

FIGURE 3.77.2.24: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



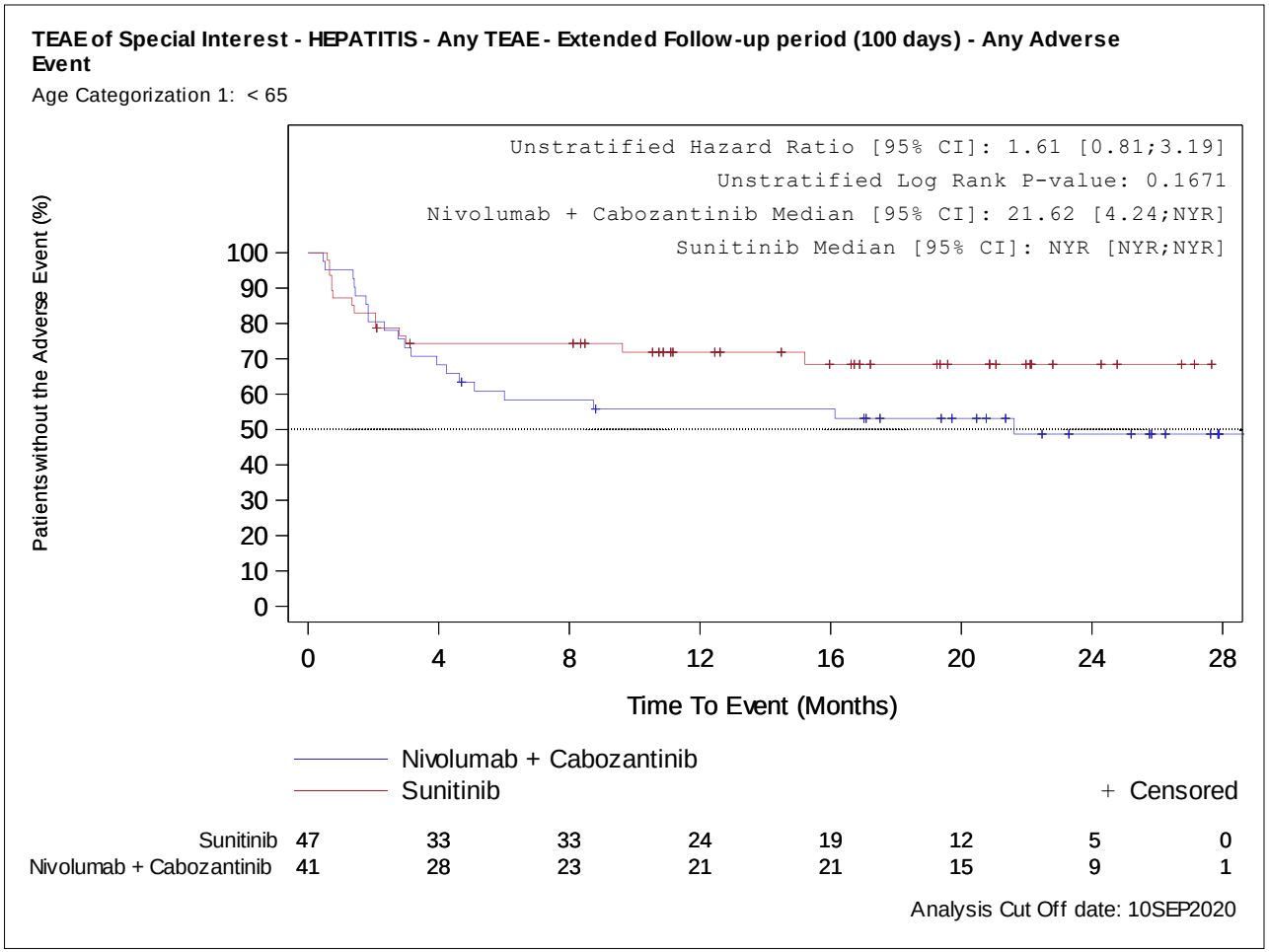

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:02:05

FIGURE 3.78.1: TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



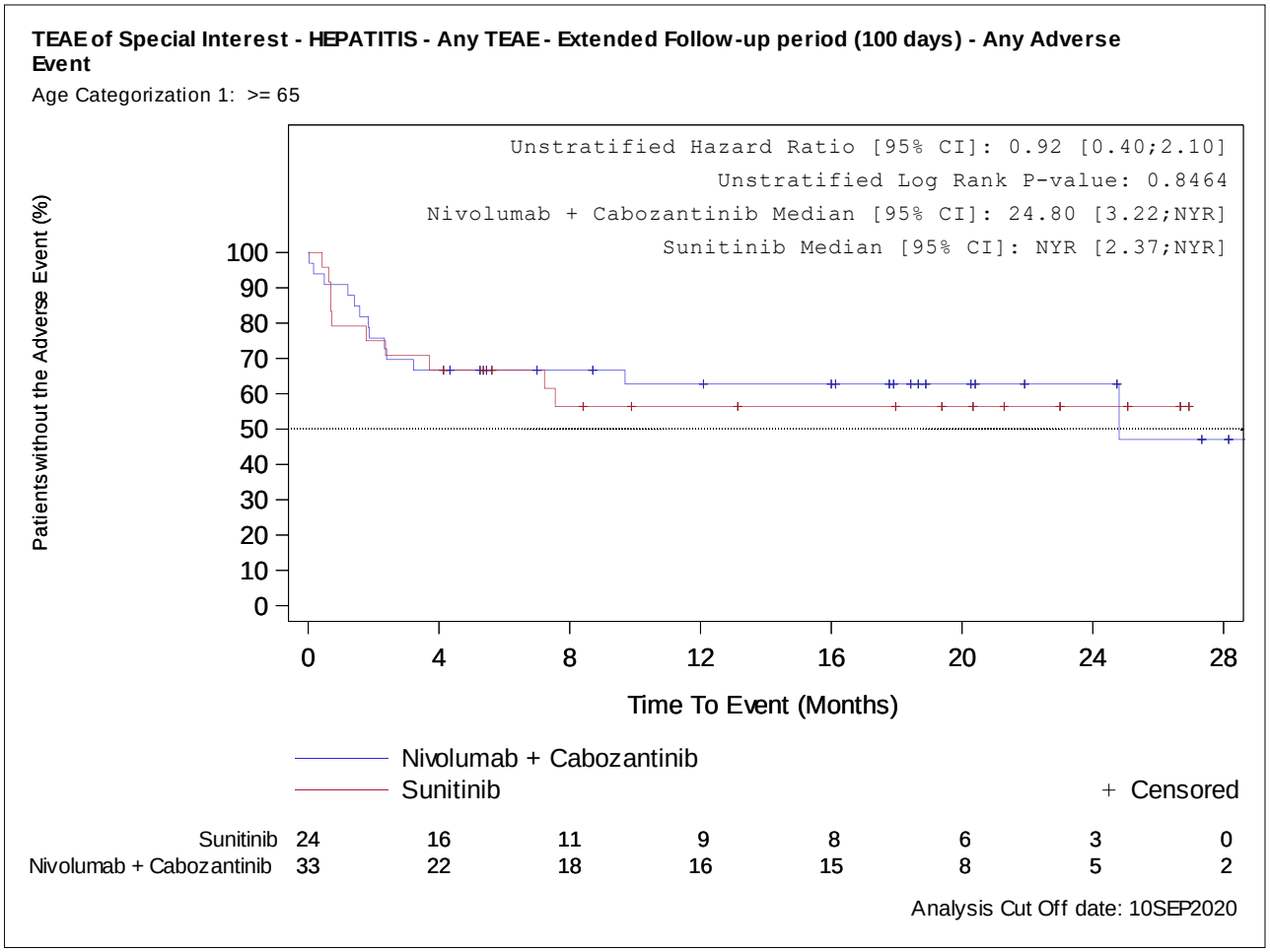

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:05:22

FIGURE 3.78.2.1: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



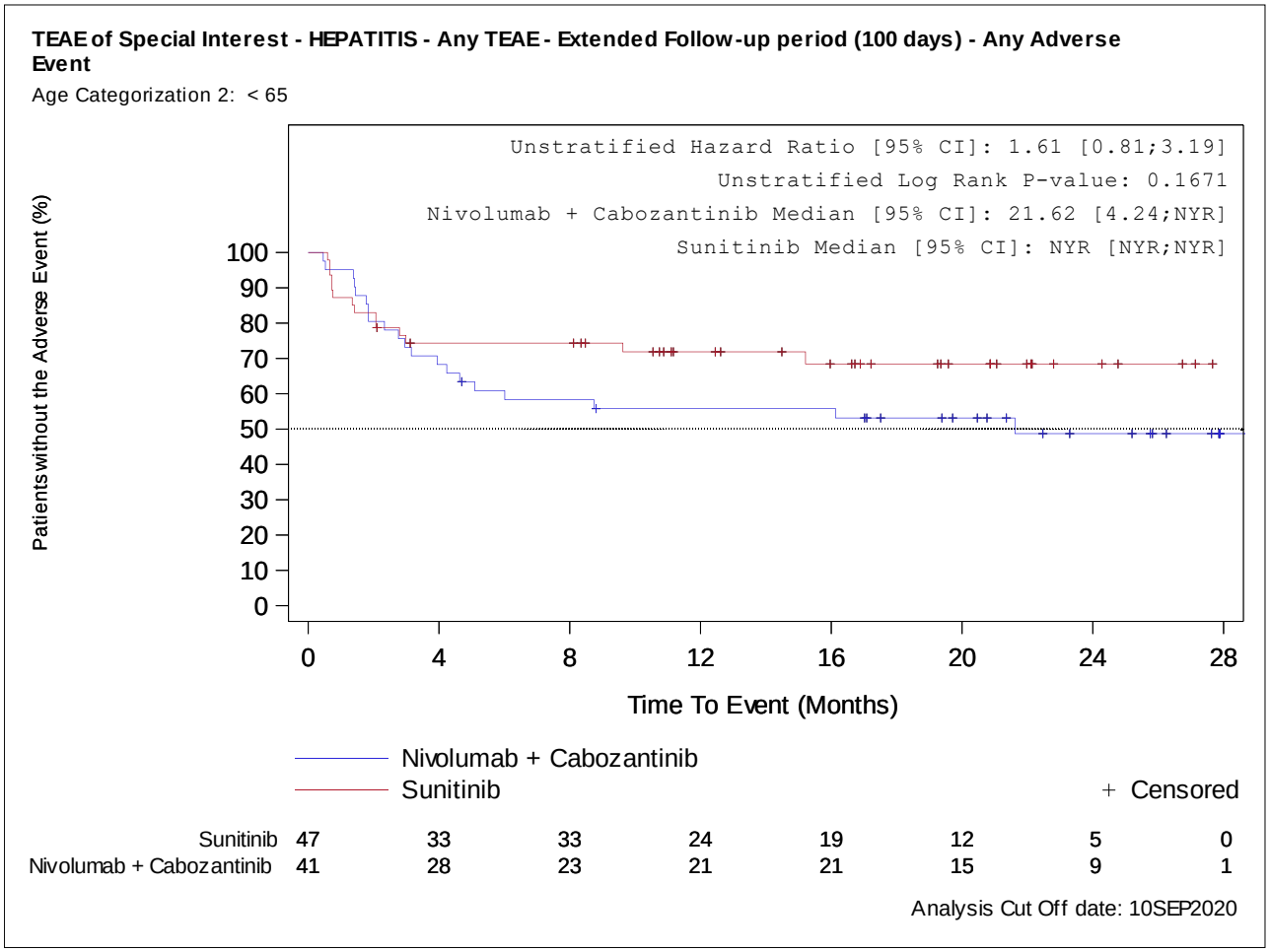

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:05:25

FIGURE 3.78.2.2: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



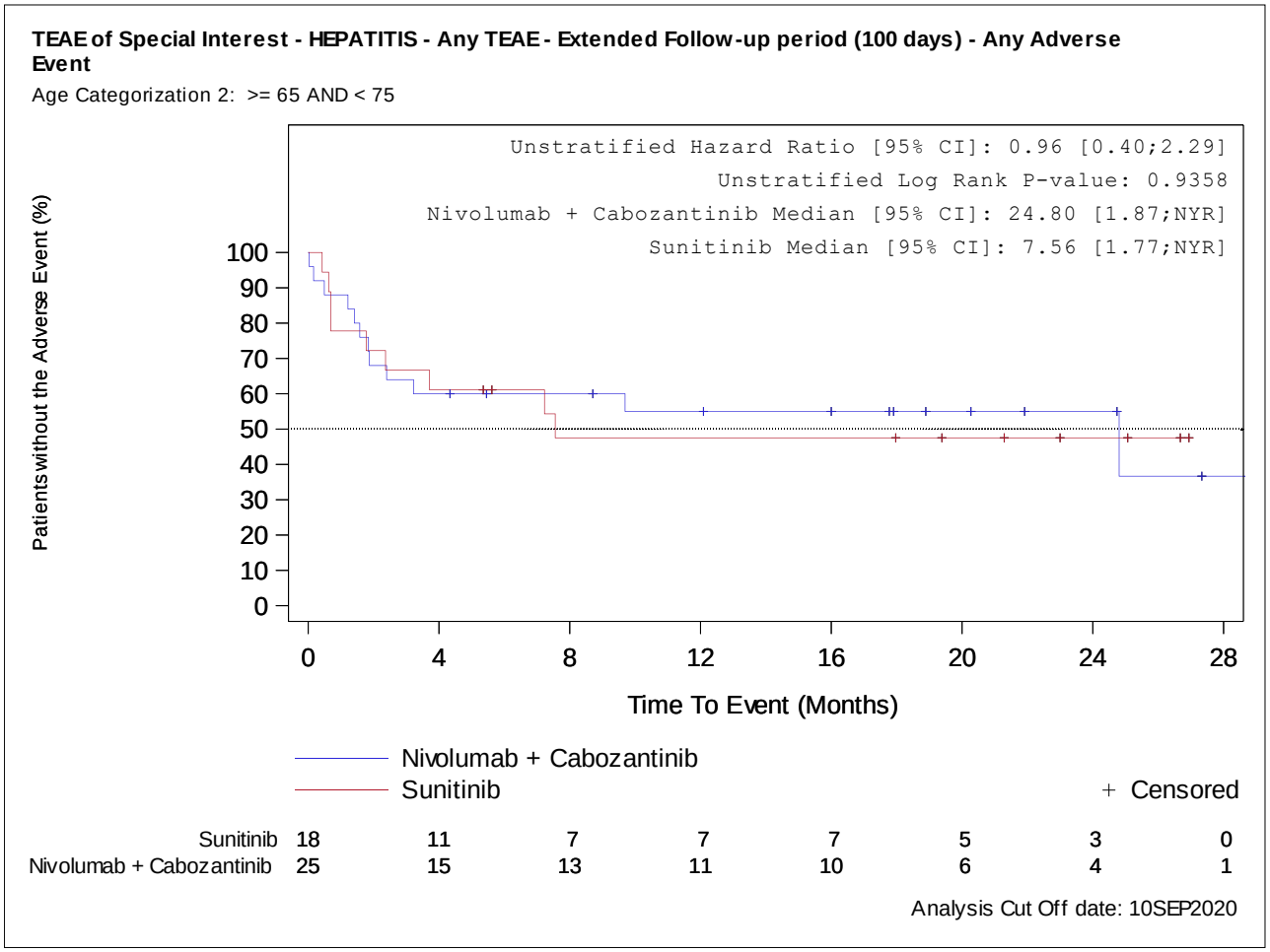

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:05:31

FIGURE 3.78.2.3: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



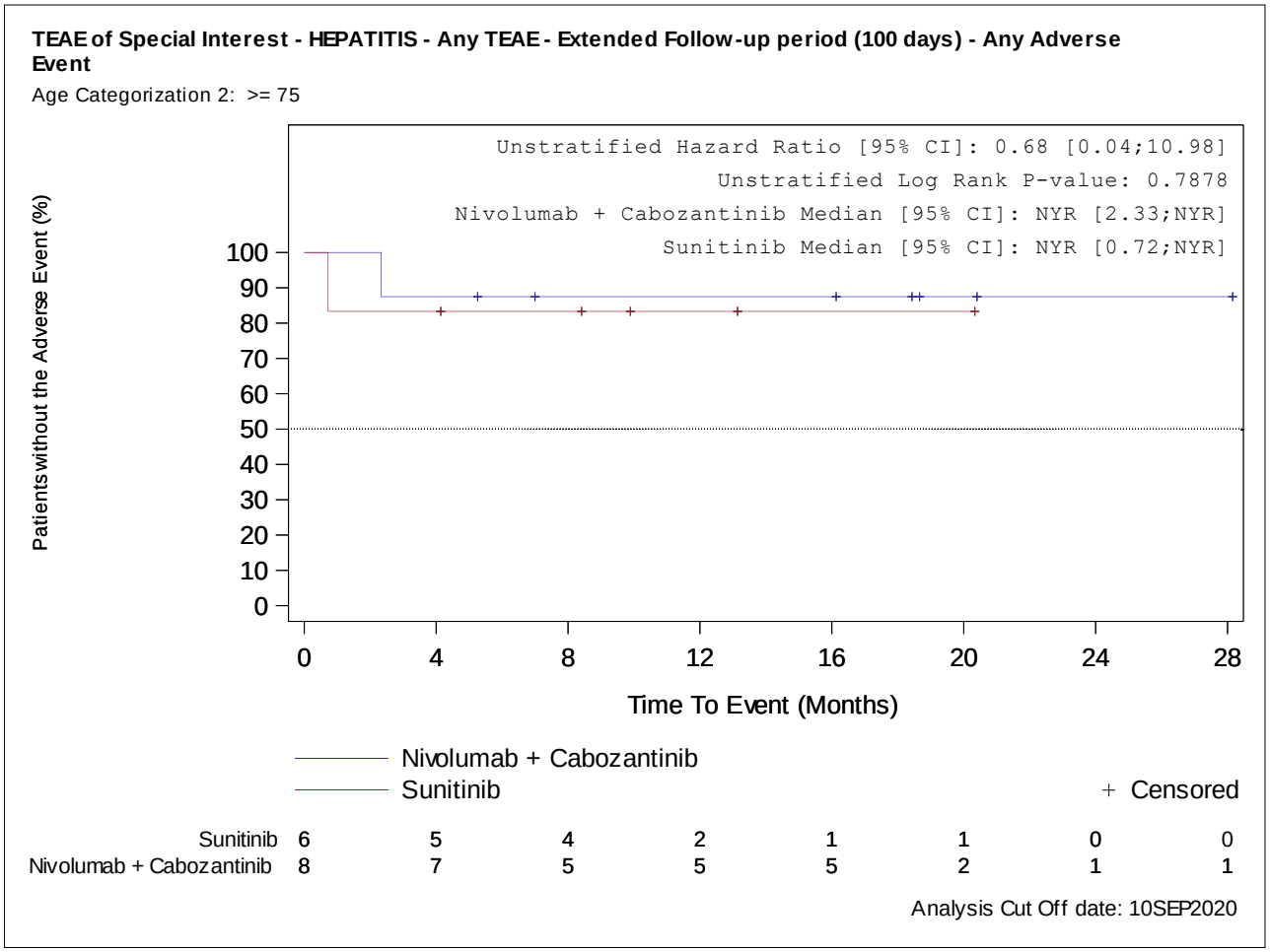

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:05:37

FIGURE 3.78.2.4: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



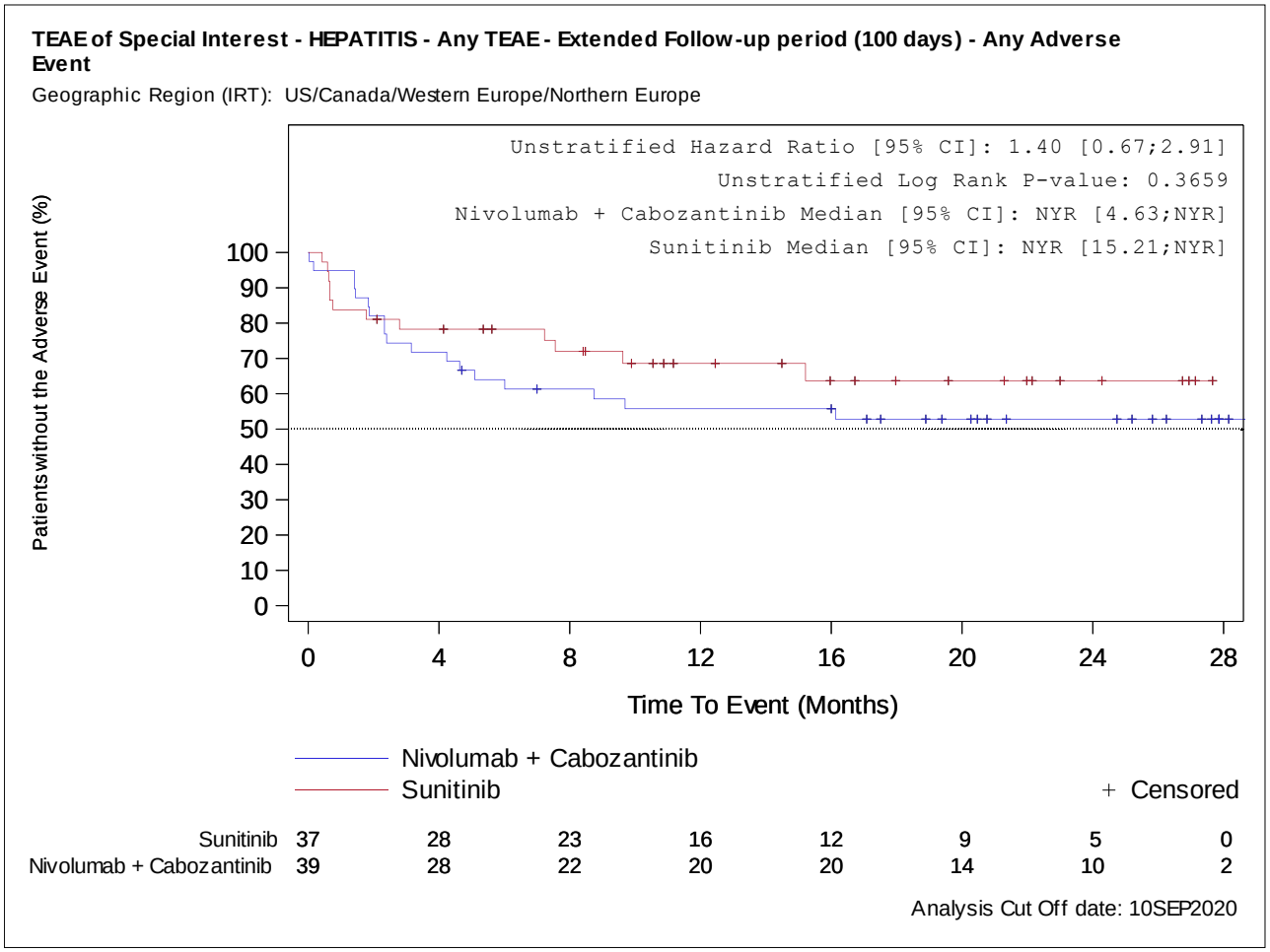

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:05:43

FIGURE 3.78.2.5: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



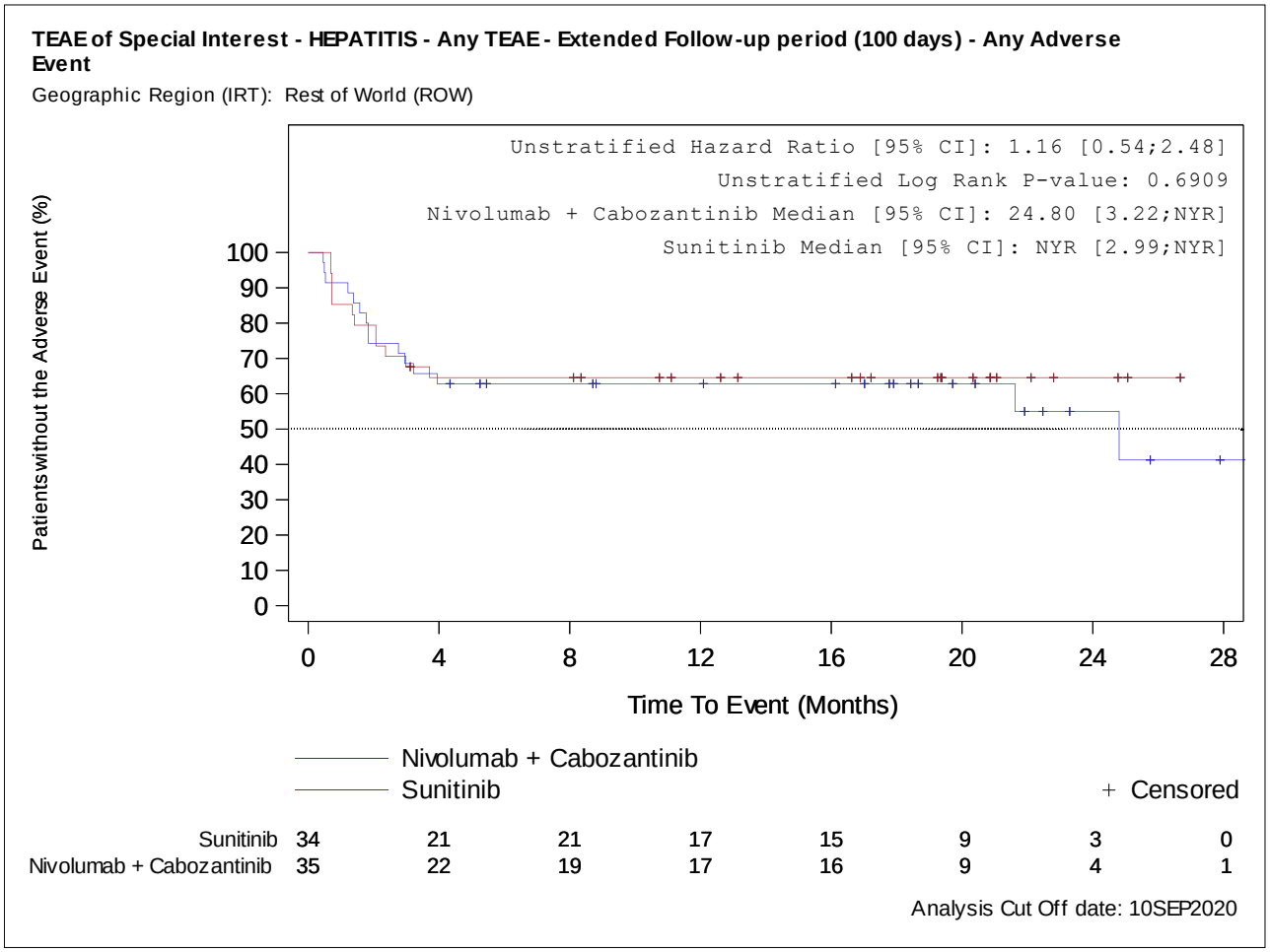

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:05:49

FIGURE 3.78.2.6: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



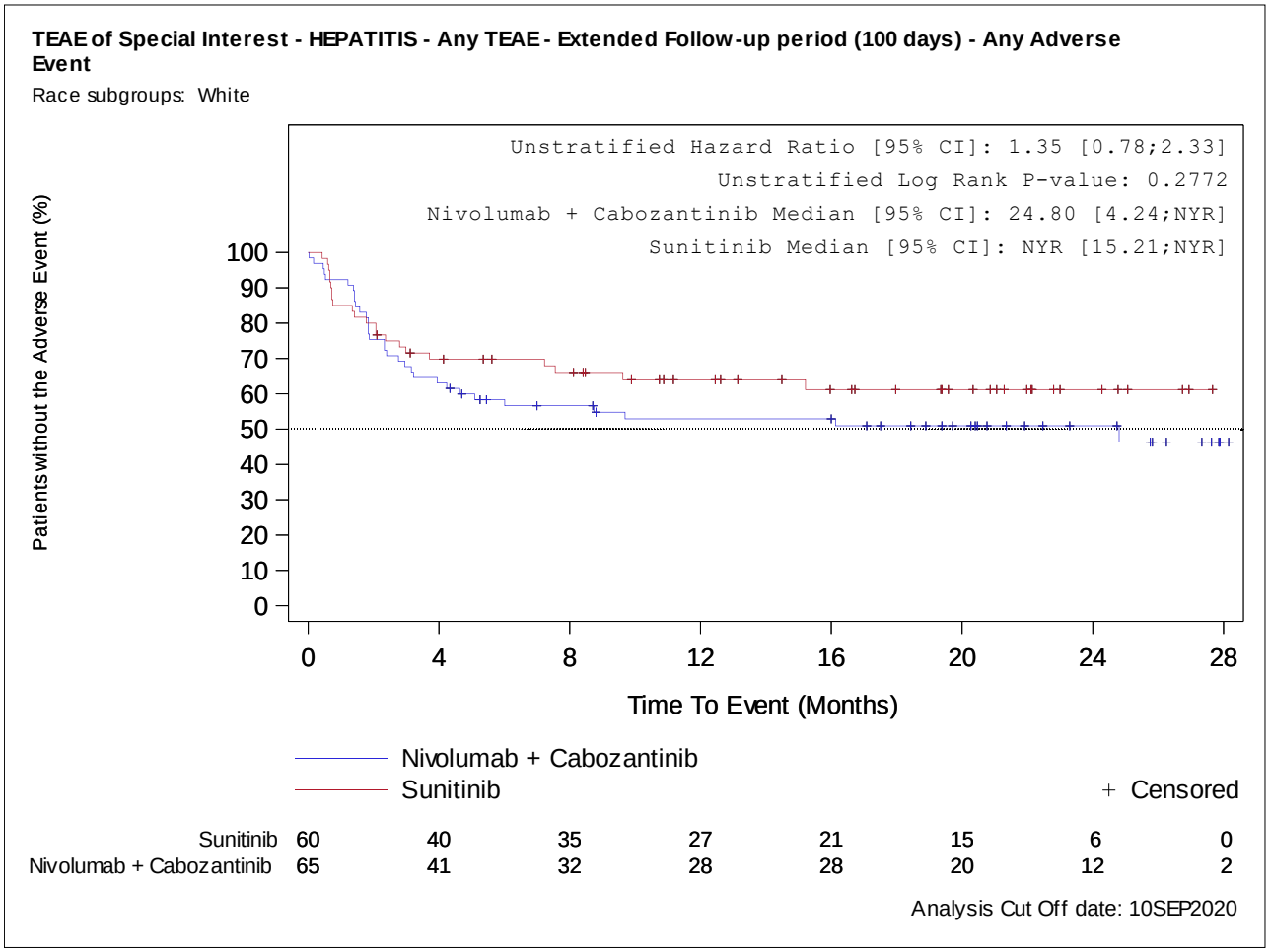

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:05:55

FIGURE 3.78.2.7: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



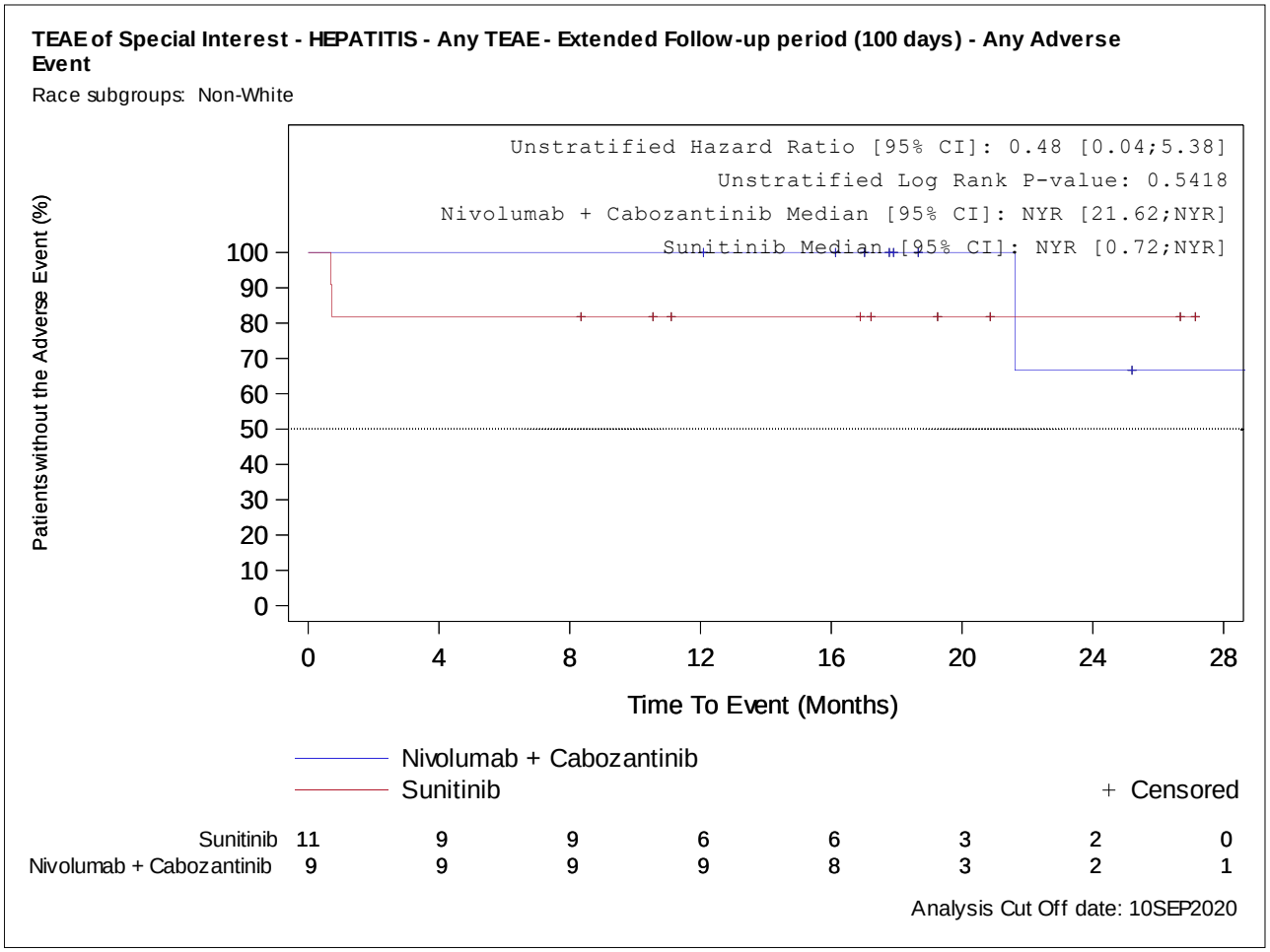

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:06:01

FIGURE 3.78.2.8: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



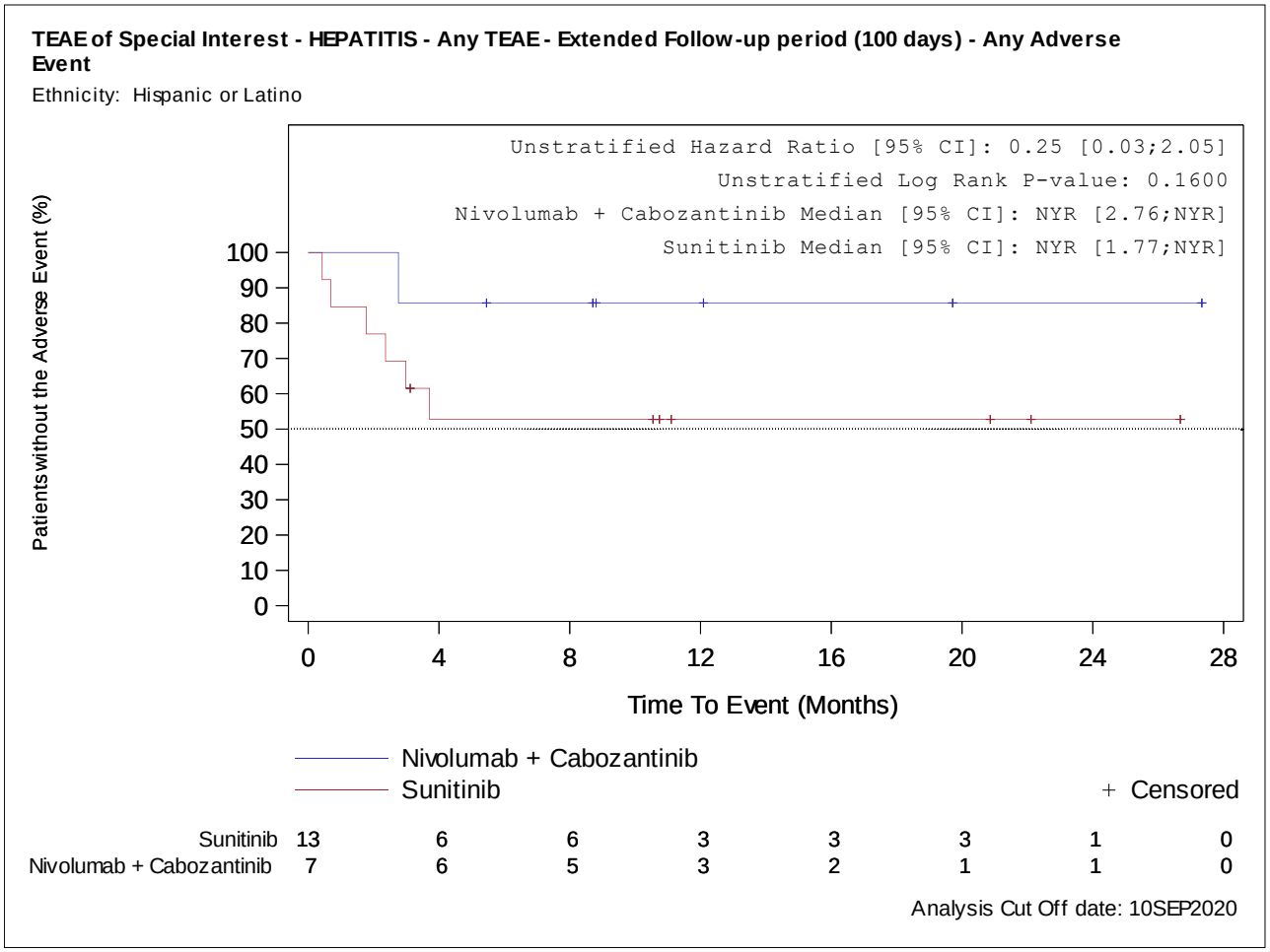

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:06:06

FIGURE 3.78.2.9: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



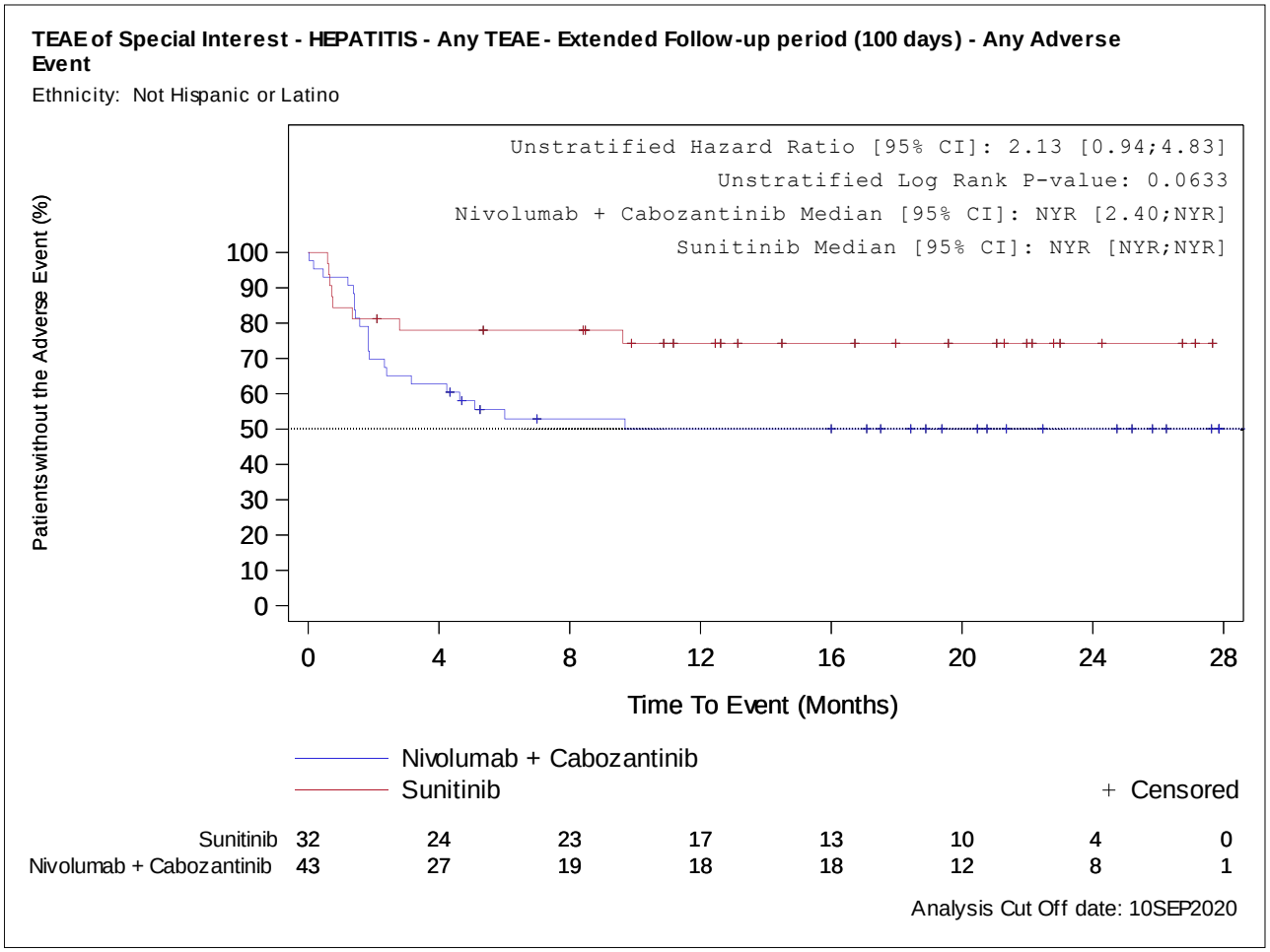

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:06:12

FIGURE 3.78.2.10: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



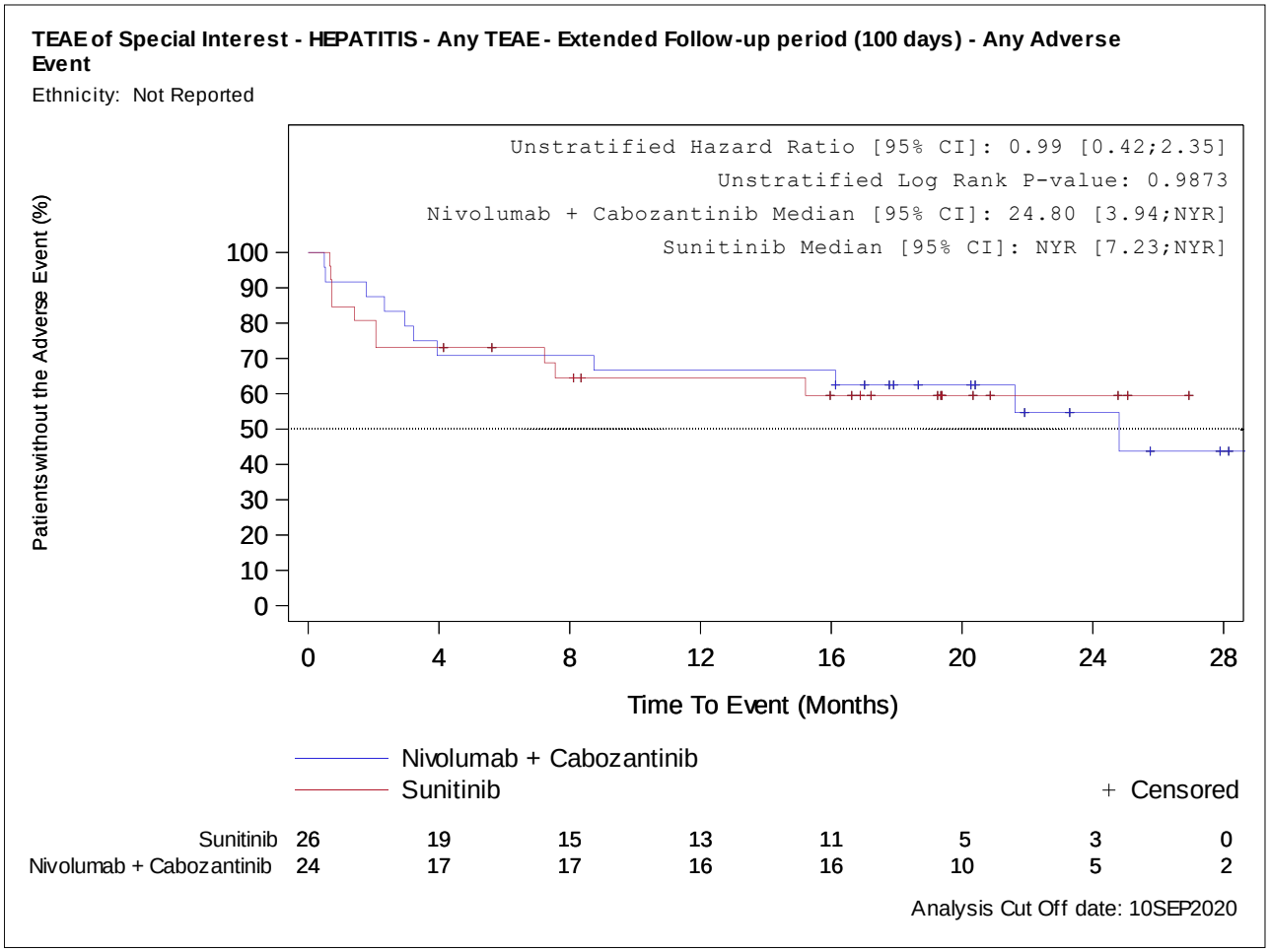

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:06:18

FIGURE 3.78.2.11: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



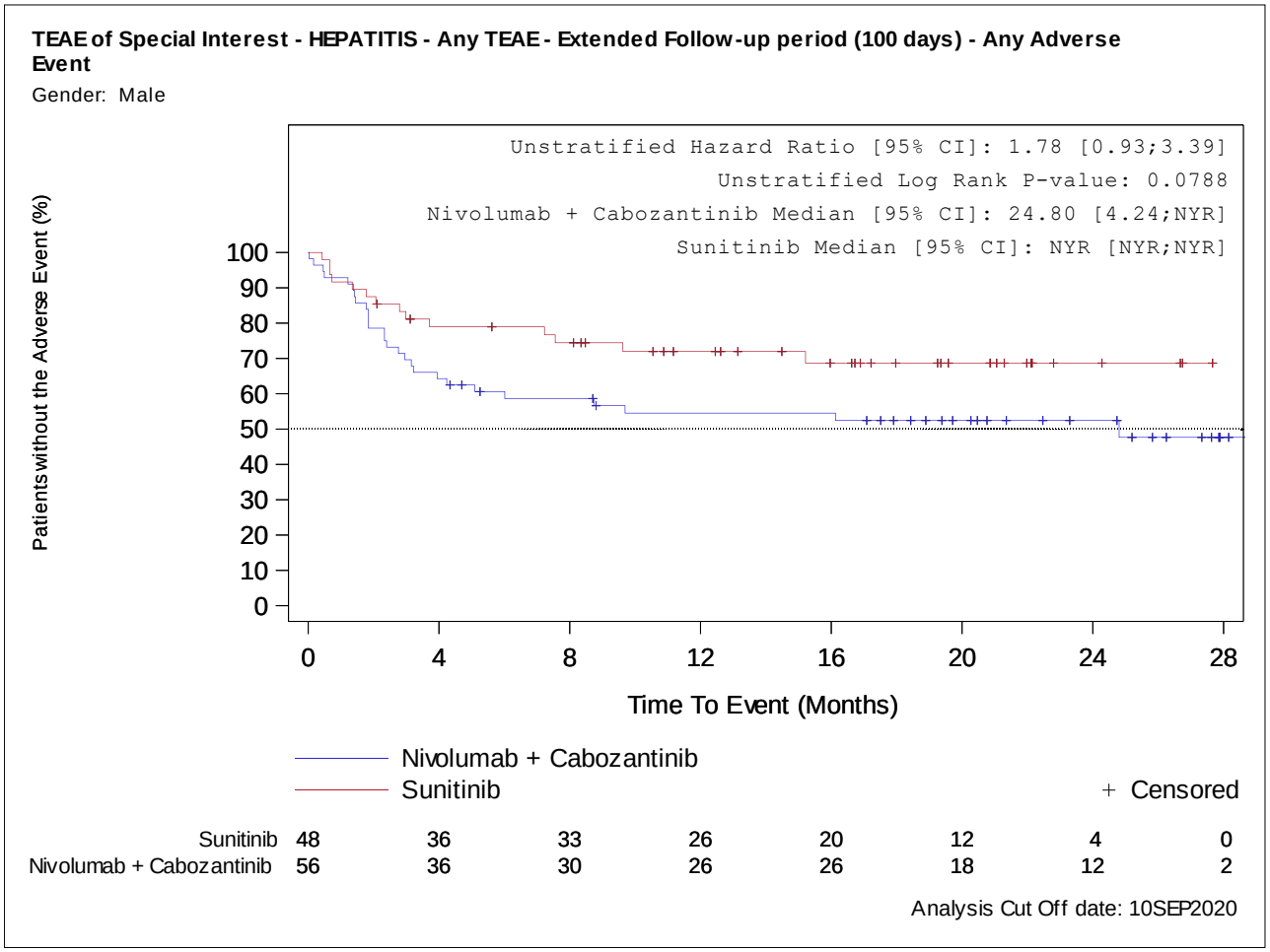

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:06:24

FIGURE 3.78.2.12: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



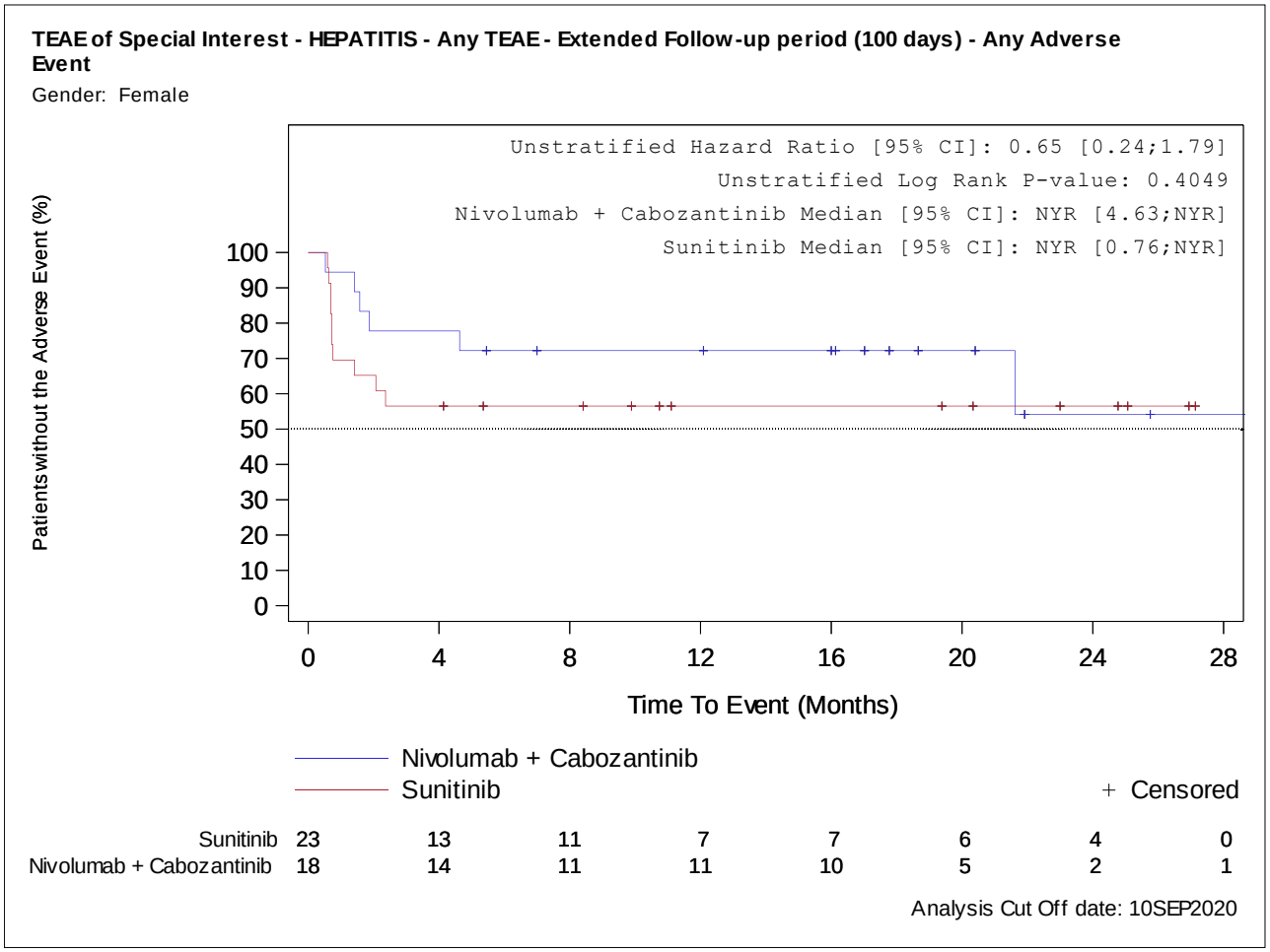

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:06:30

FIGURE 3.78.2.13: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



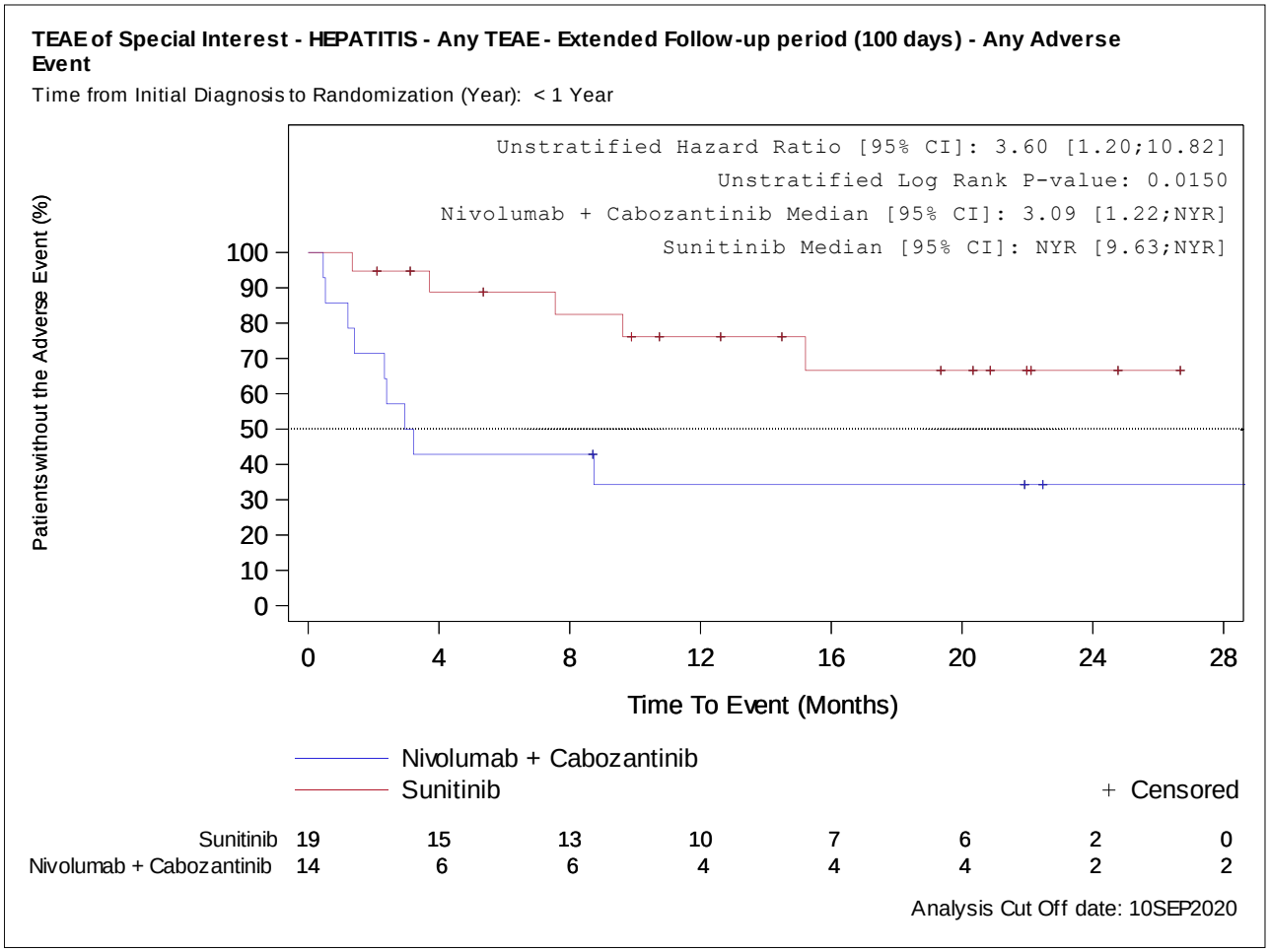

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:06:36

FIGURE 3.78.2.14: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



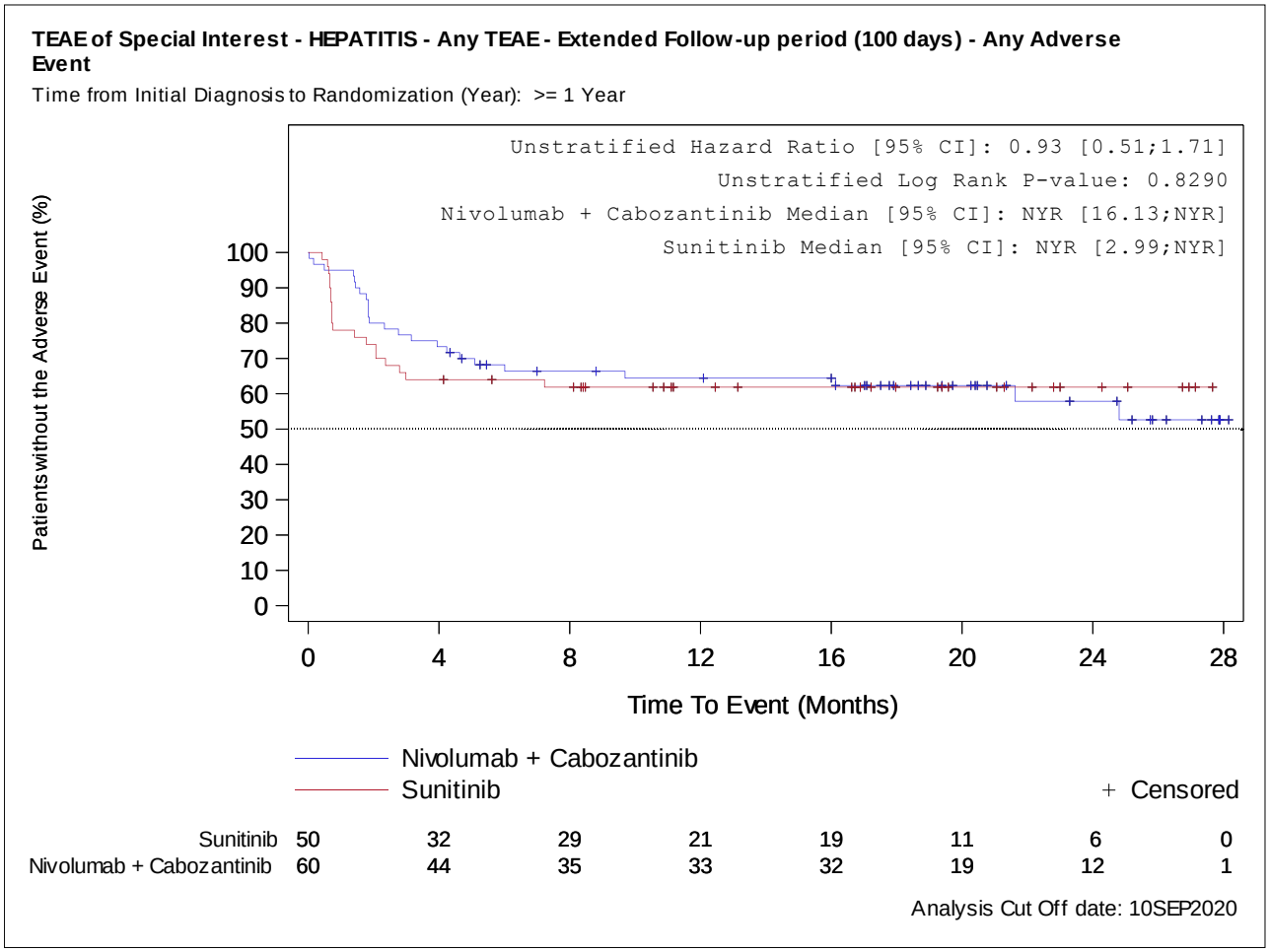

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:06:42

FIGURE 3.78.2.15: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



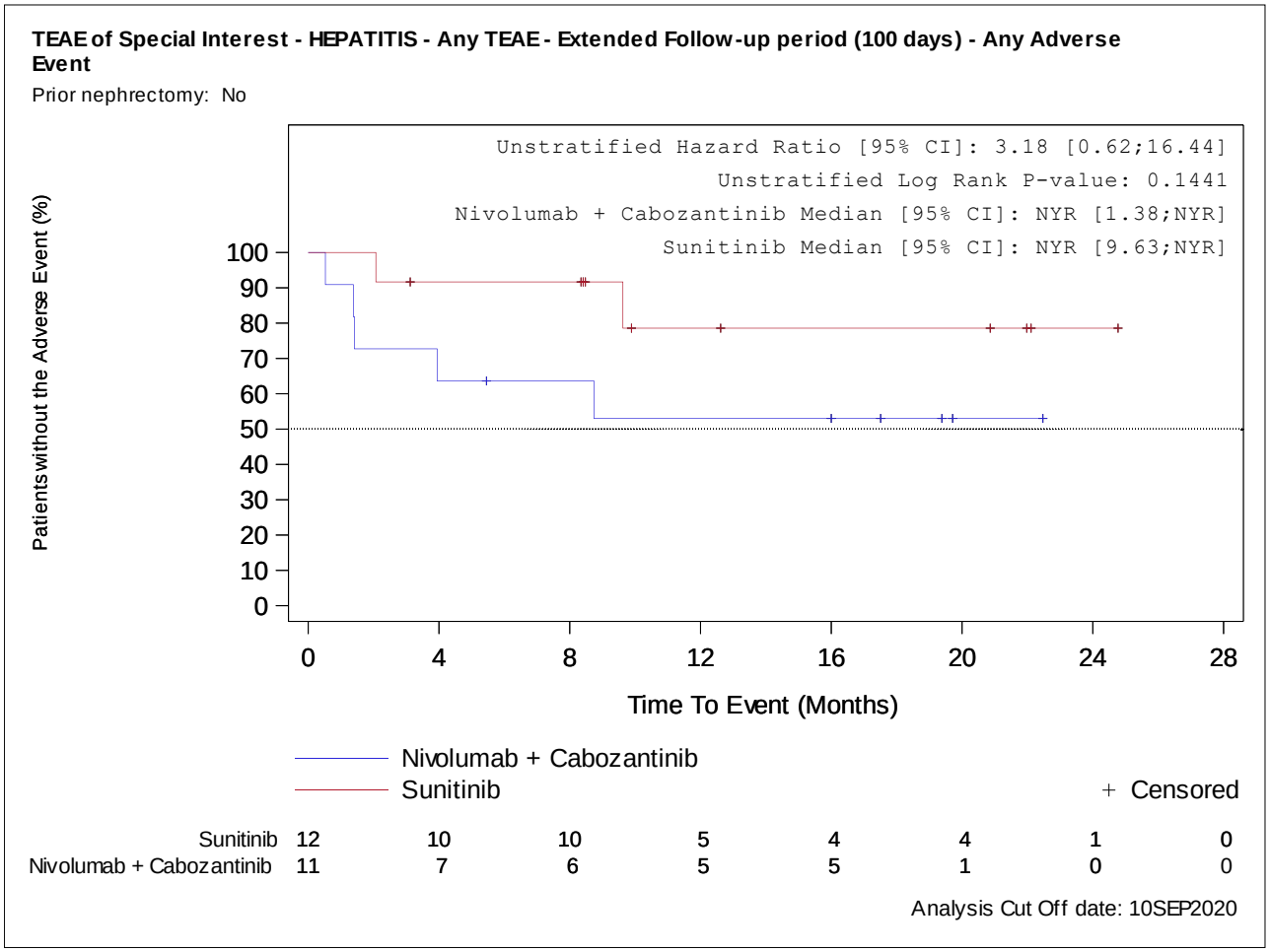

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:07:00

FIGURE 3.78.2.16: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



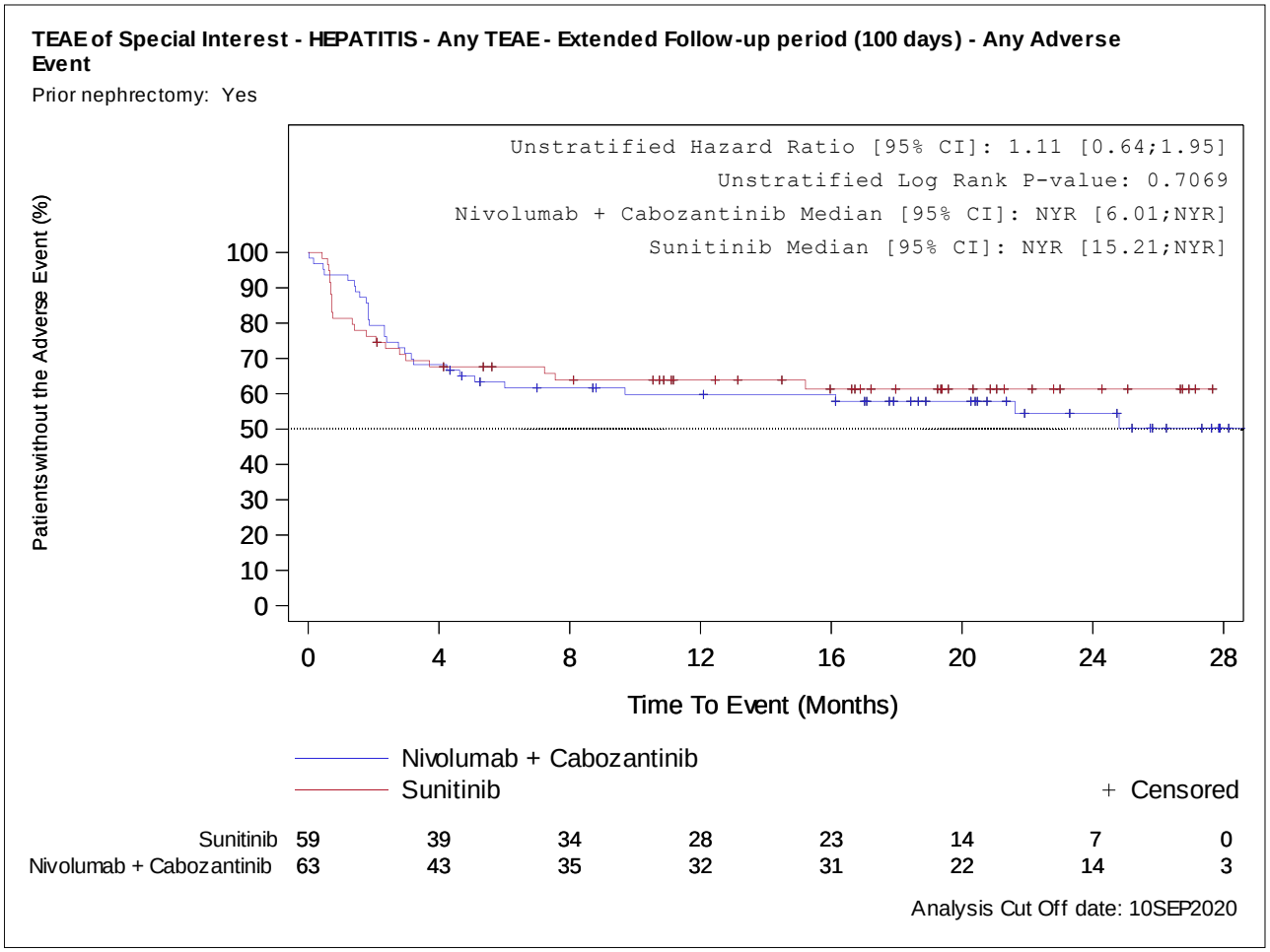

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:07:06

FIGURE 3.78.2.17: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



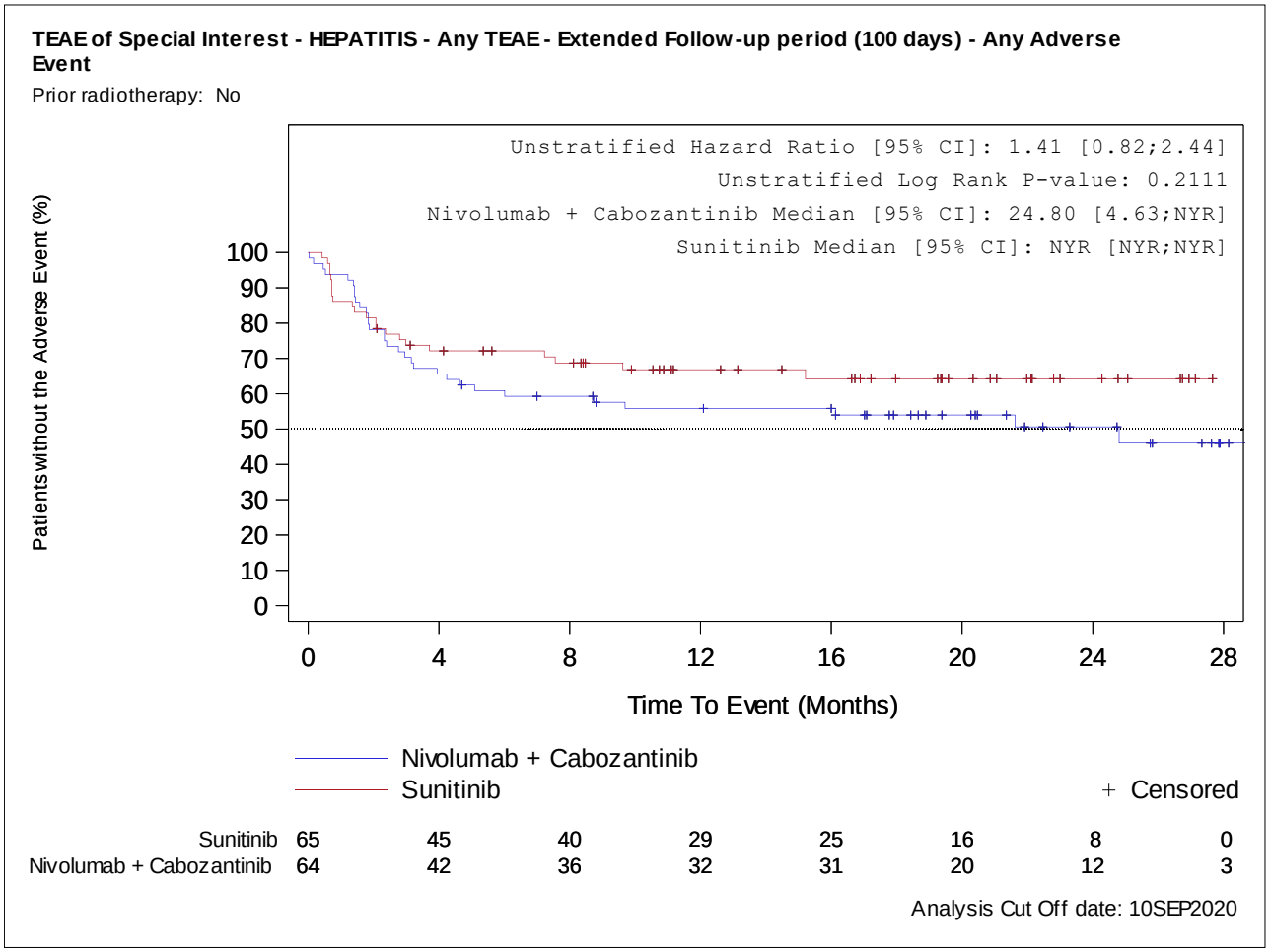

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:07:58

FIGURE 3.78.2.18: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



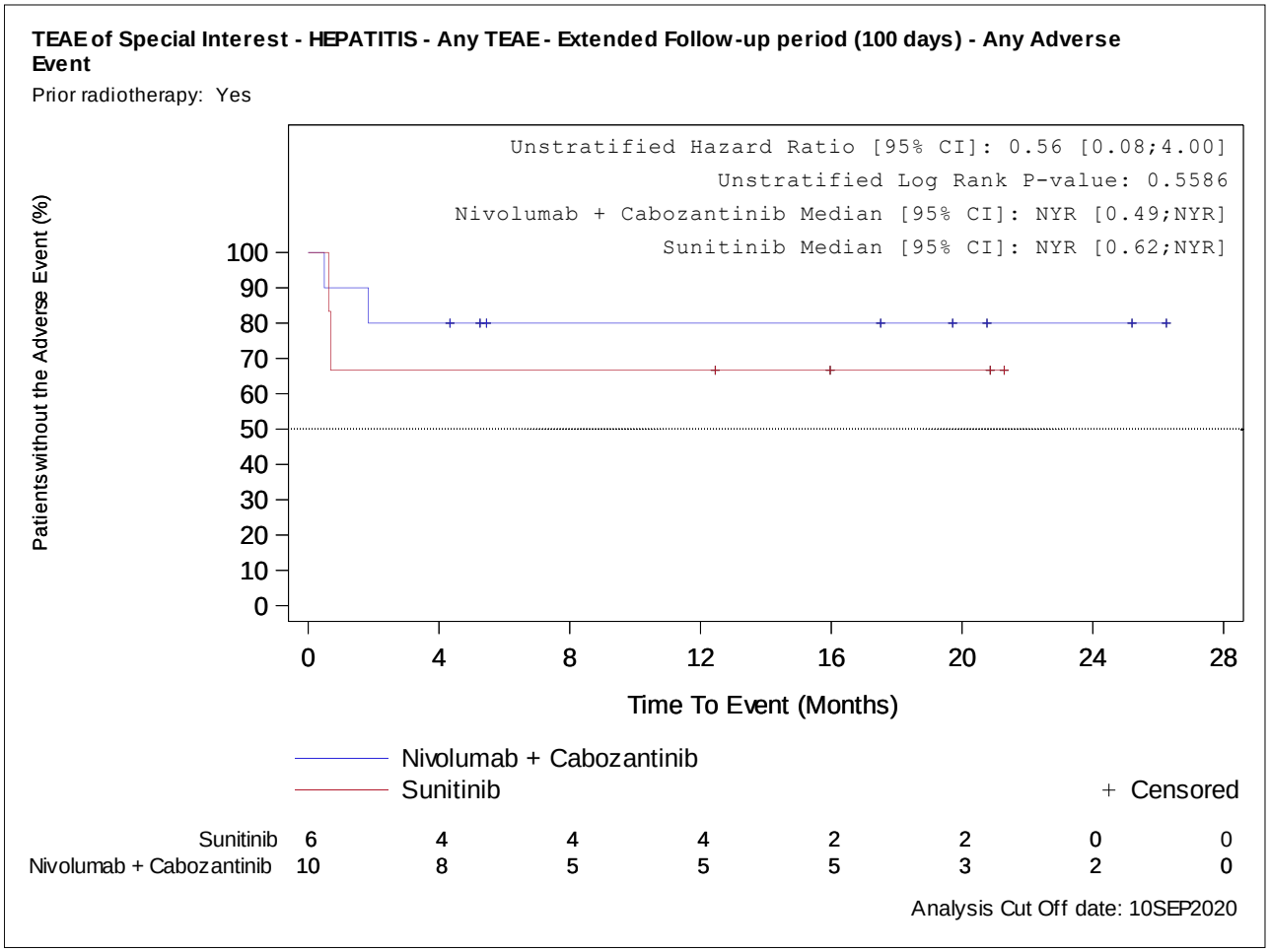

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:08:03

FIGURE 3.78.2.19: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



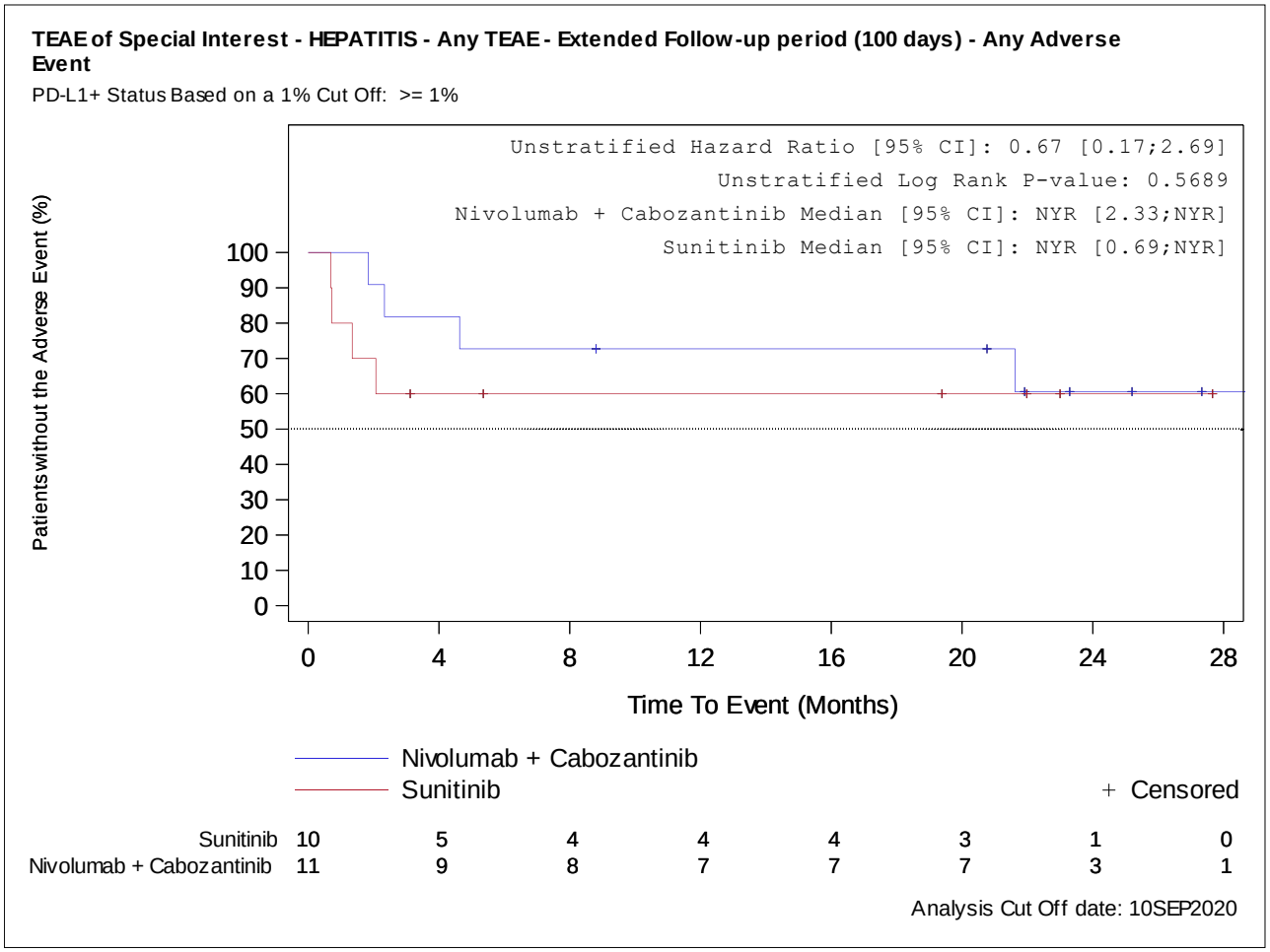

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:08:09

FIGURE 3.78.2.20: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



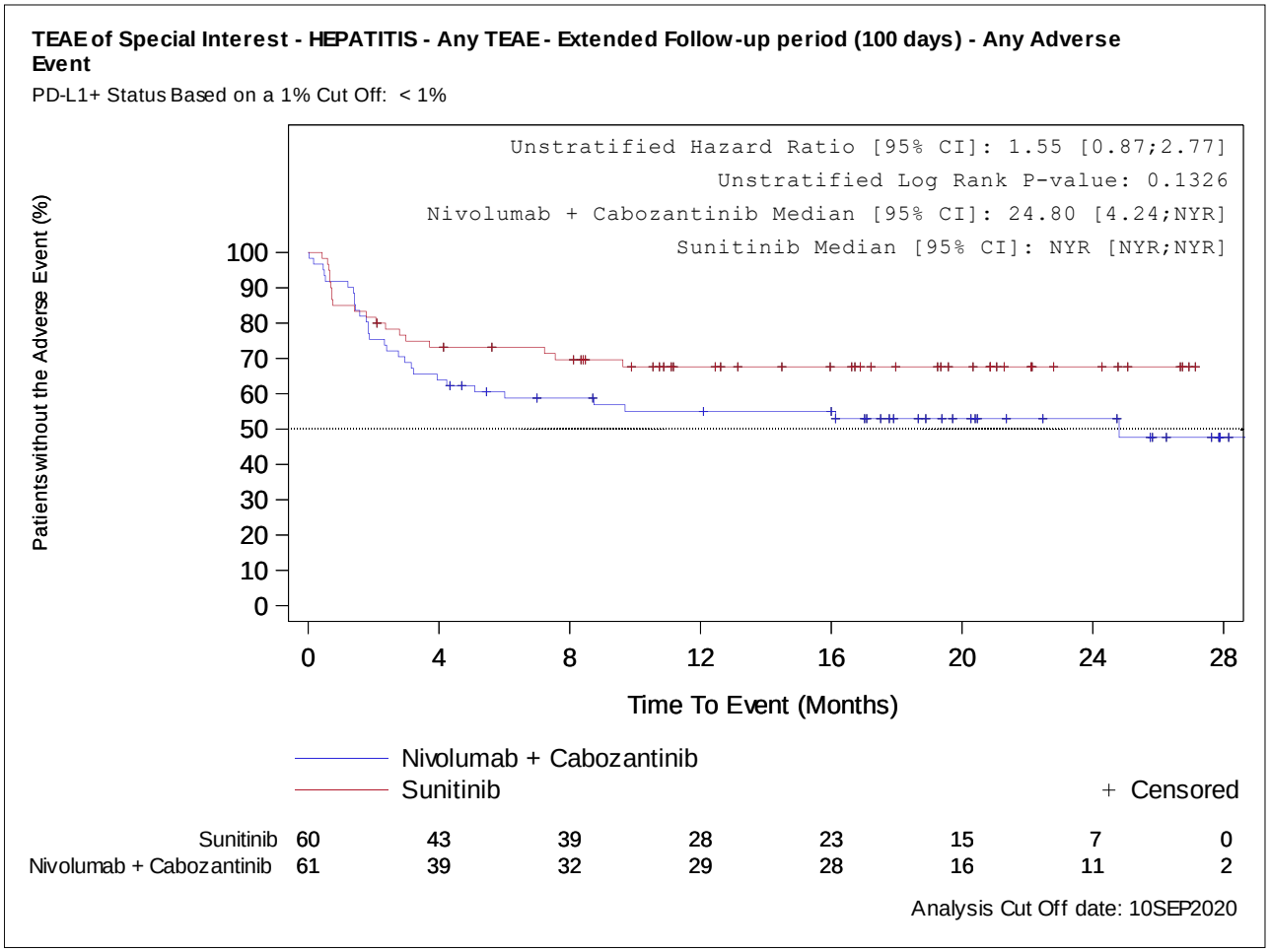

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:08:15

FIGURE 3.78.2.21: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



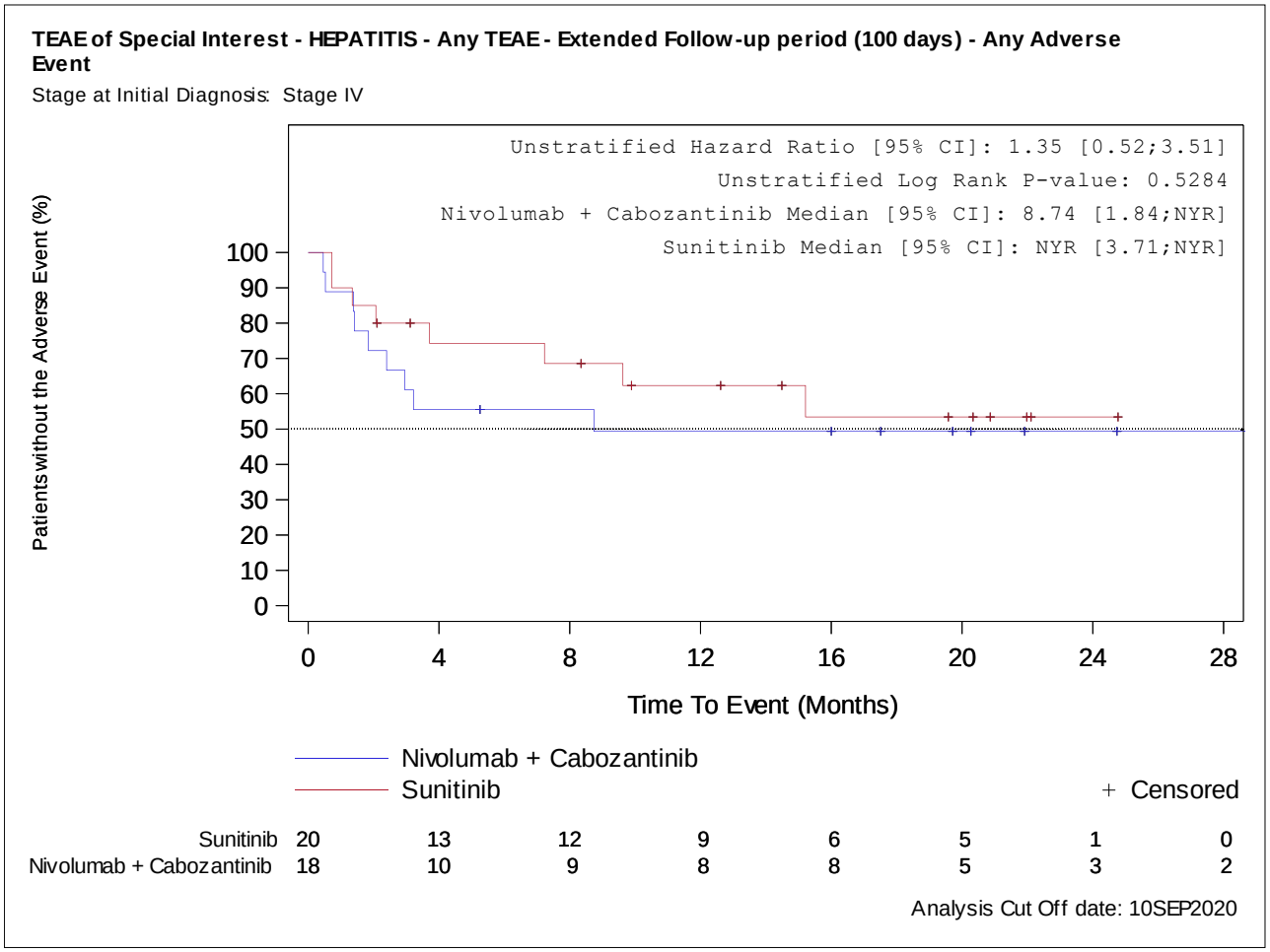

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:08:21

FIGURE 3.78.2.22: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



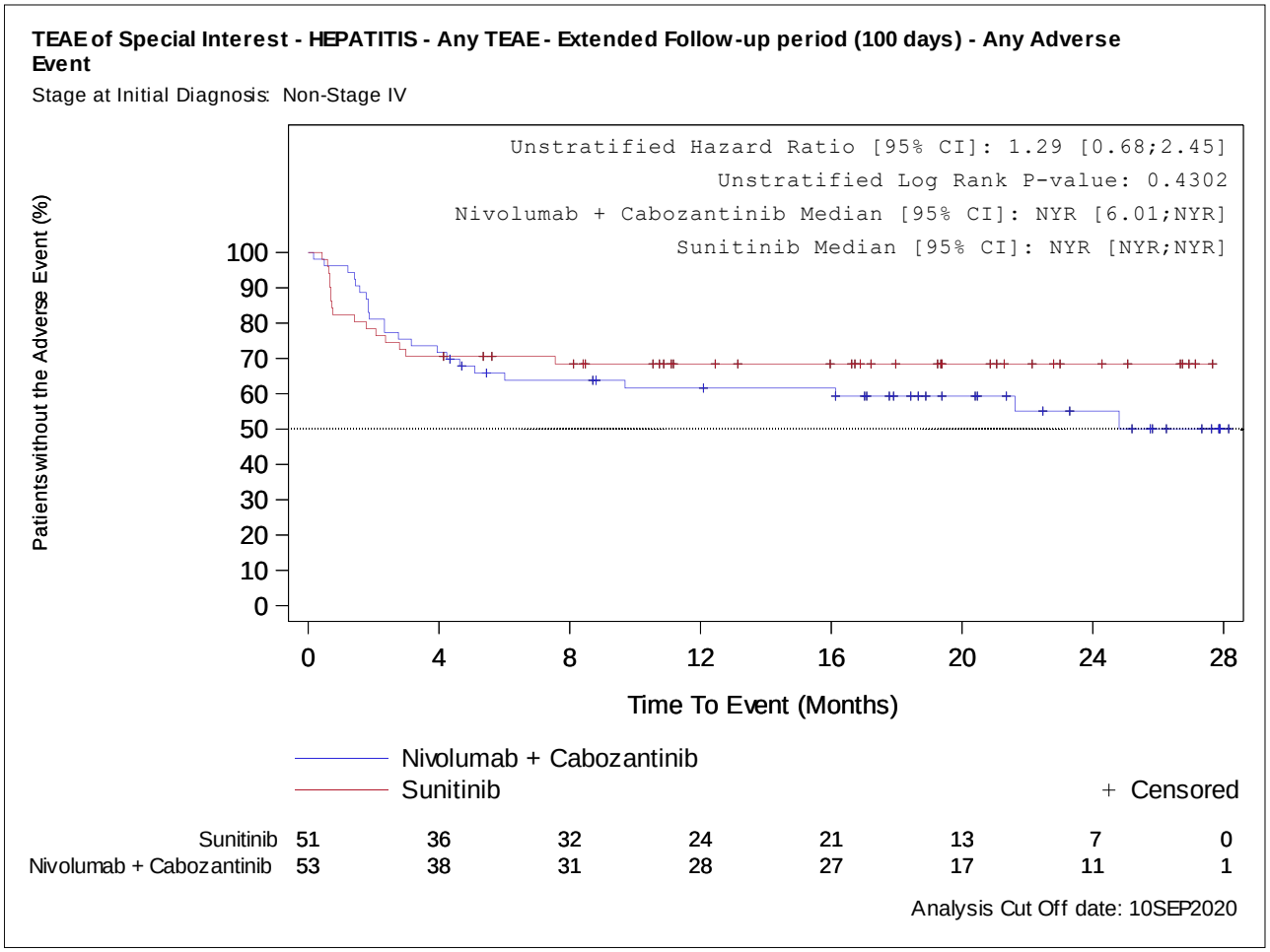

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:08:26

FIGURE 3.78.2.23: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



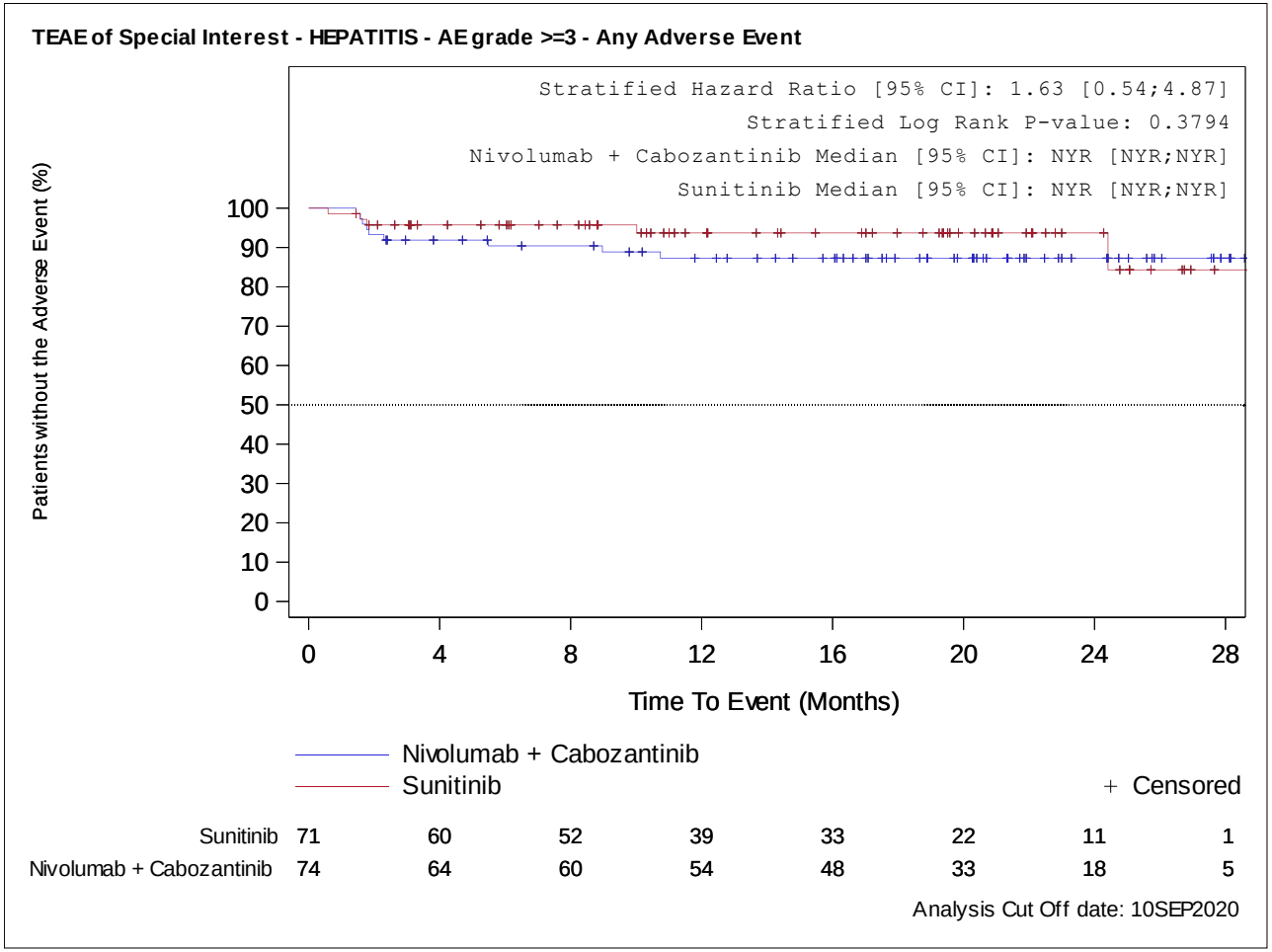

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:08:56

FIGURE 3.78.2.24: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



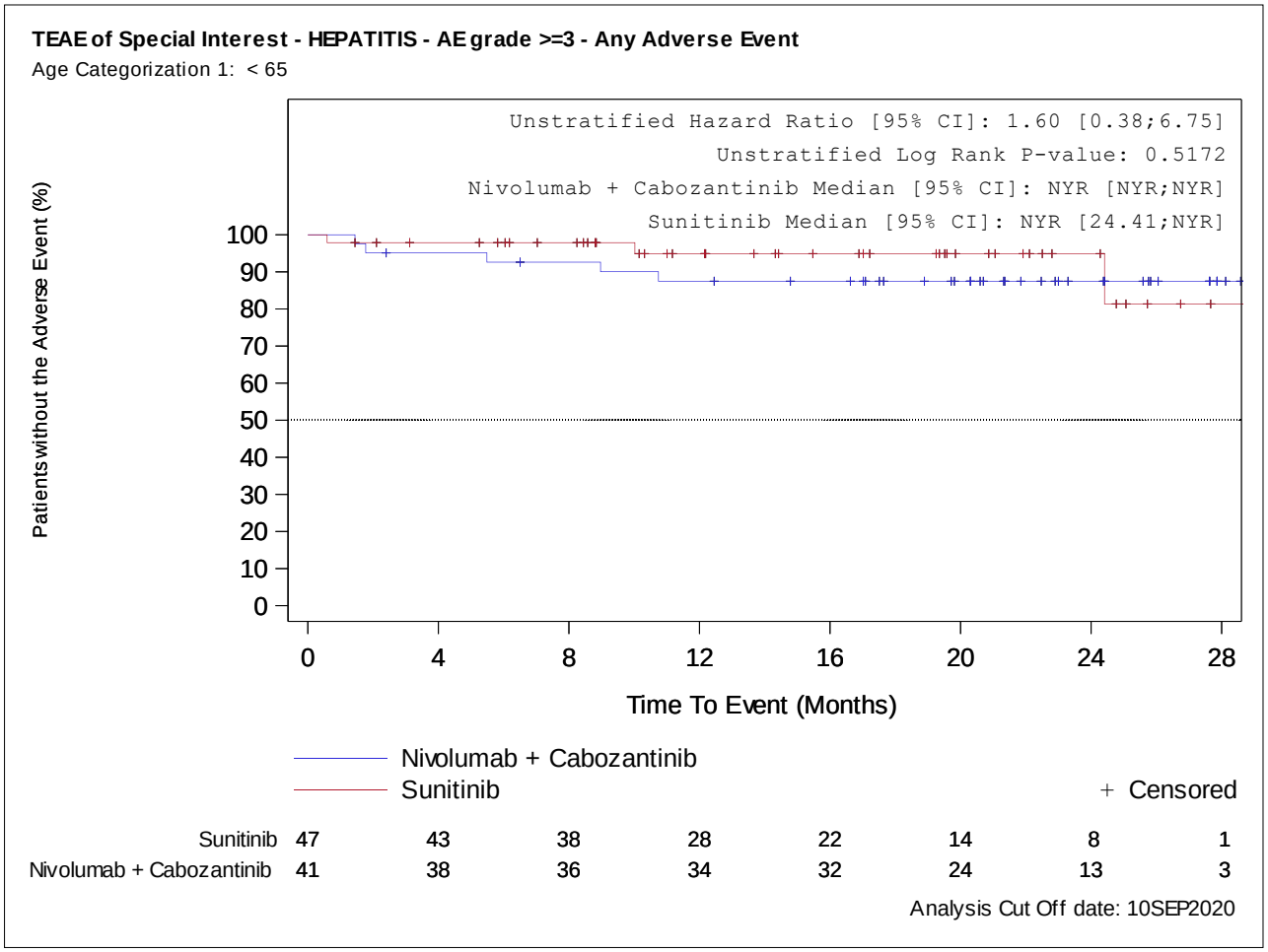

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:09:02

FIGURE 3.79.1: TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



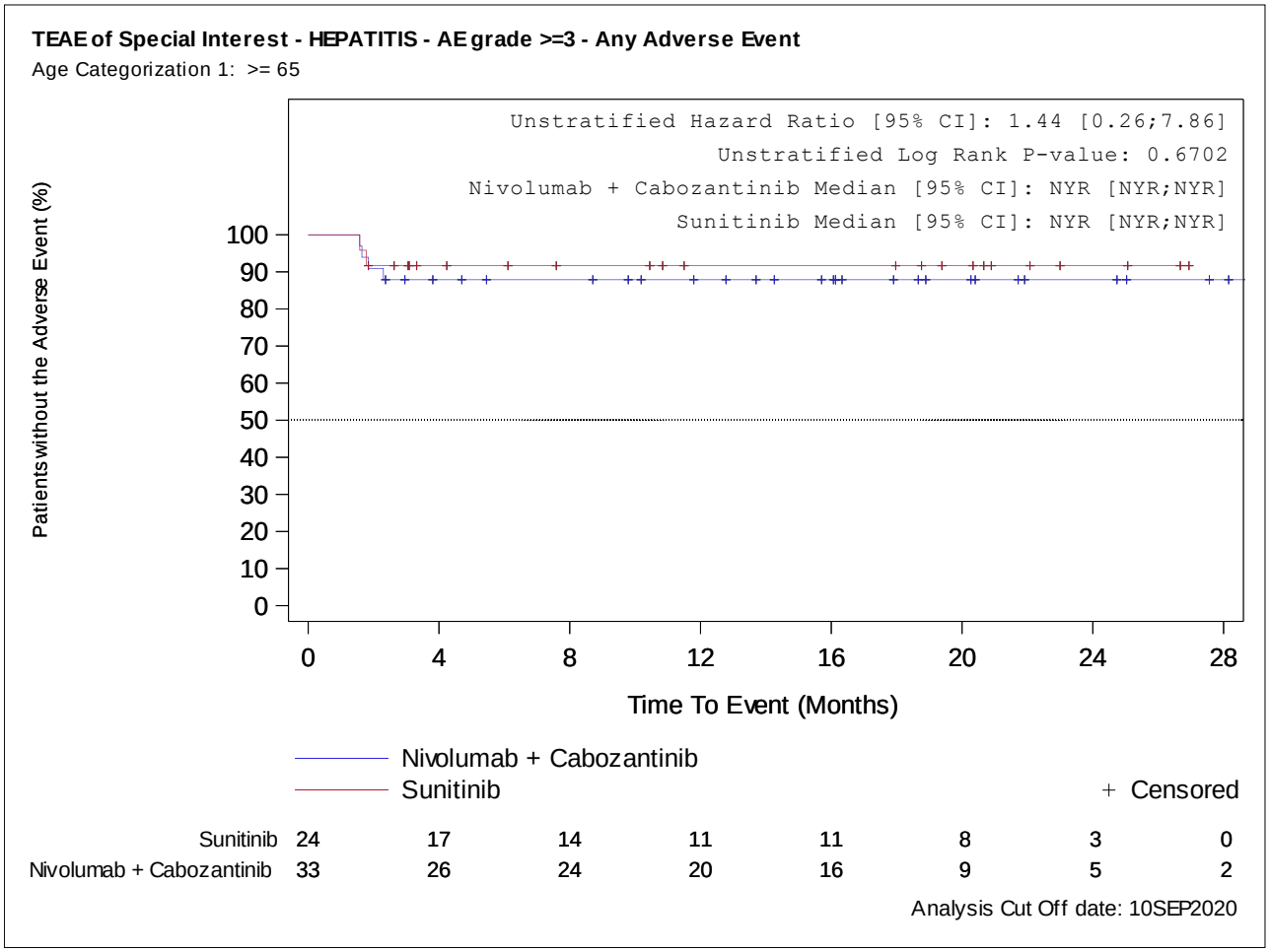

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:12:18

FIGURE 3.79.2.1: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



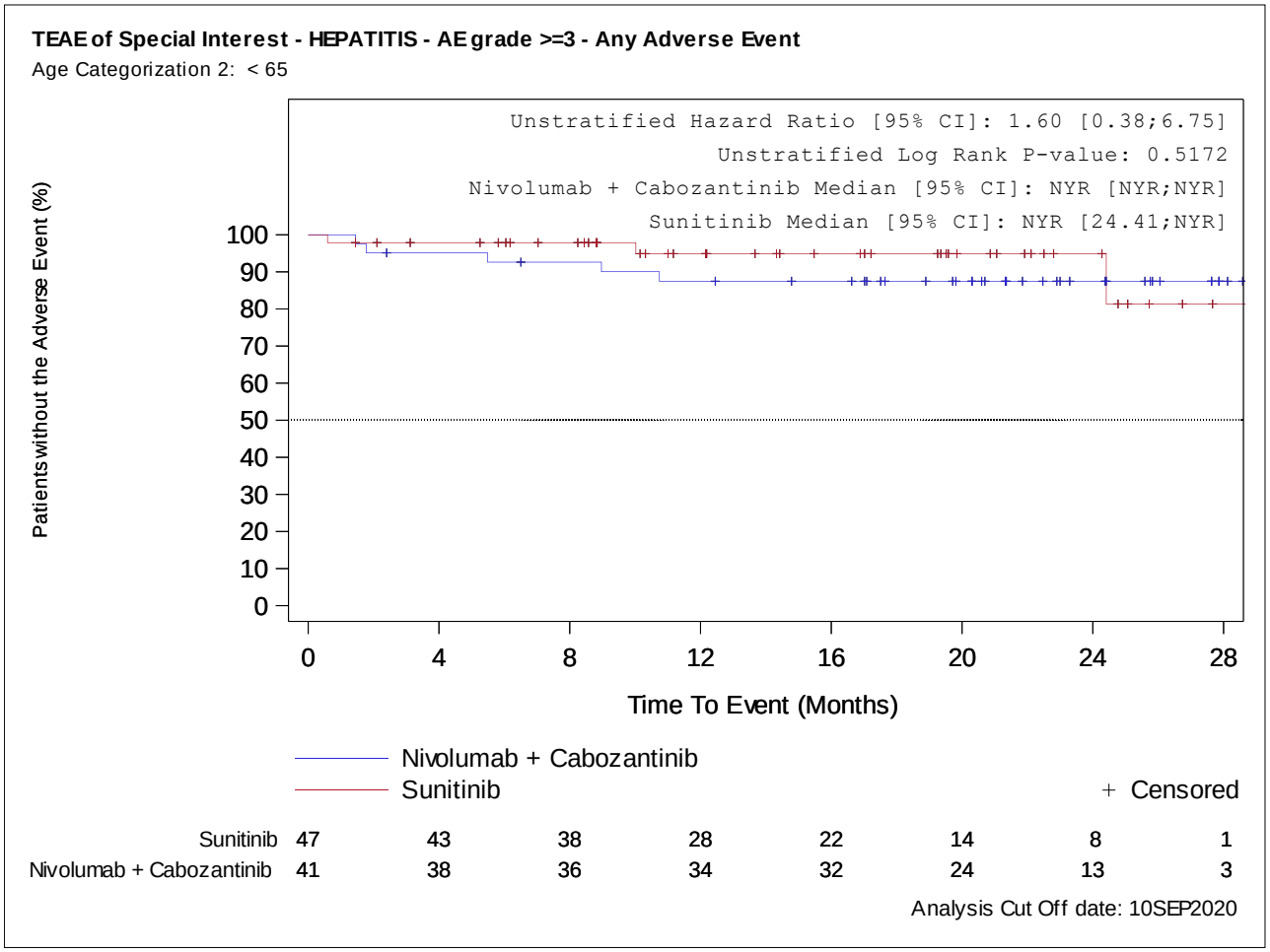

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:12:21

FIGURE 3.79.2.2: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:12:28

FIGURE 3.79.2.3: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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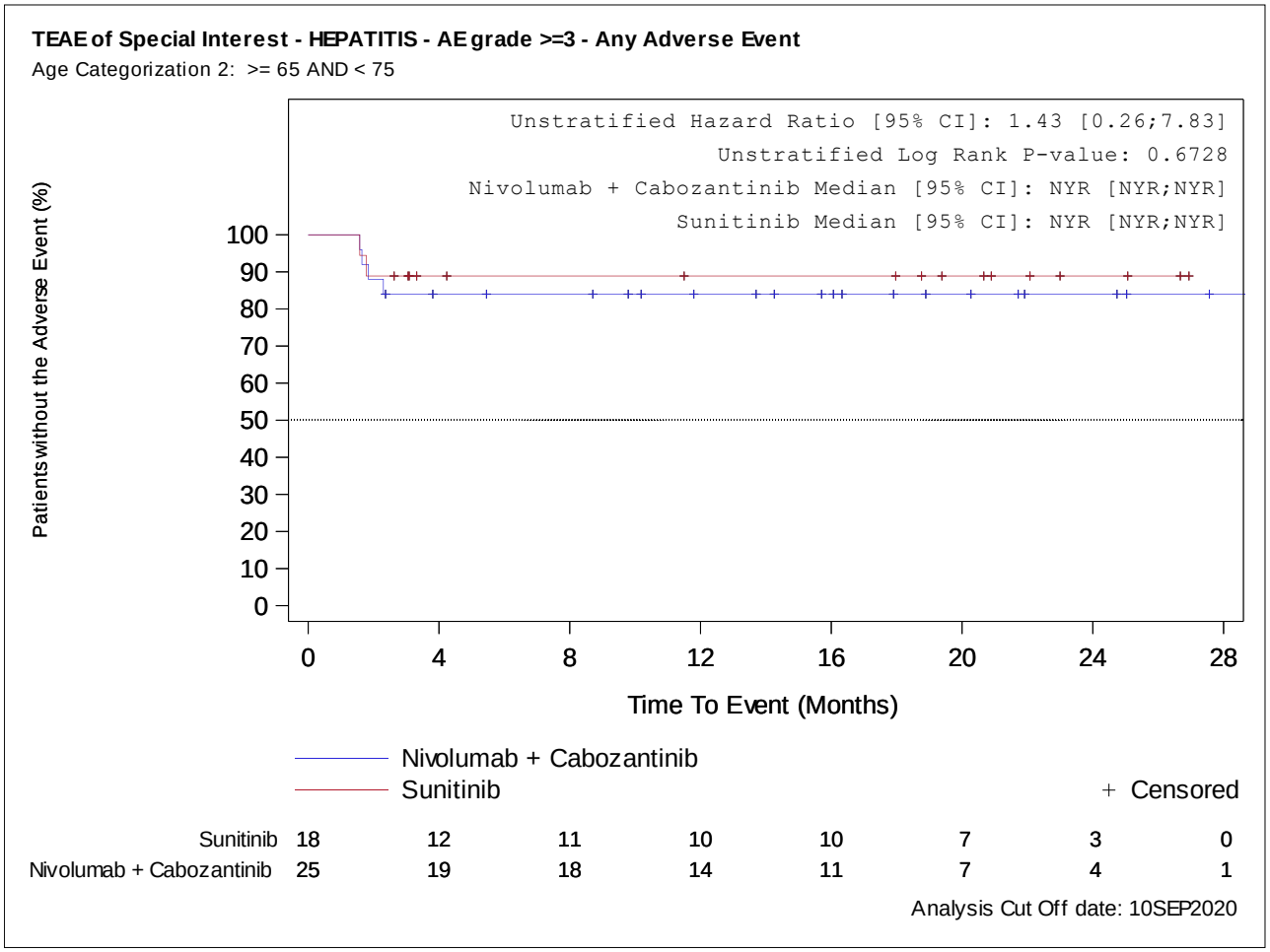
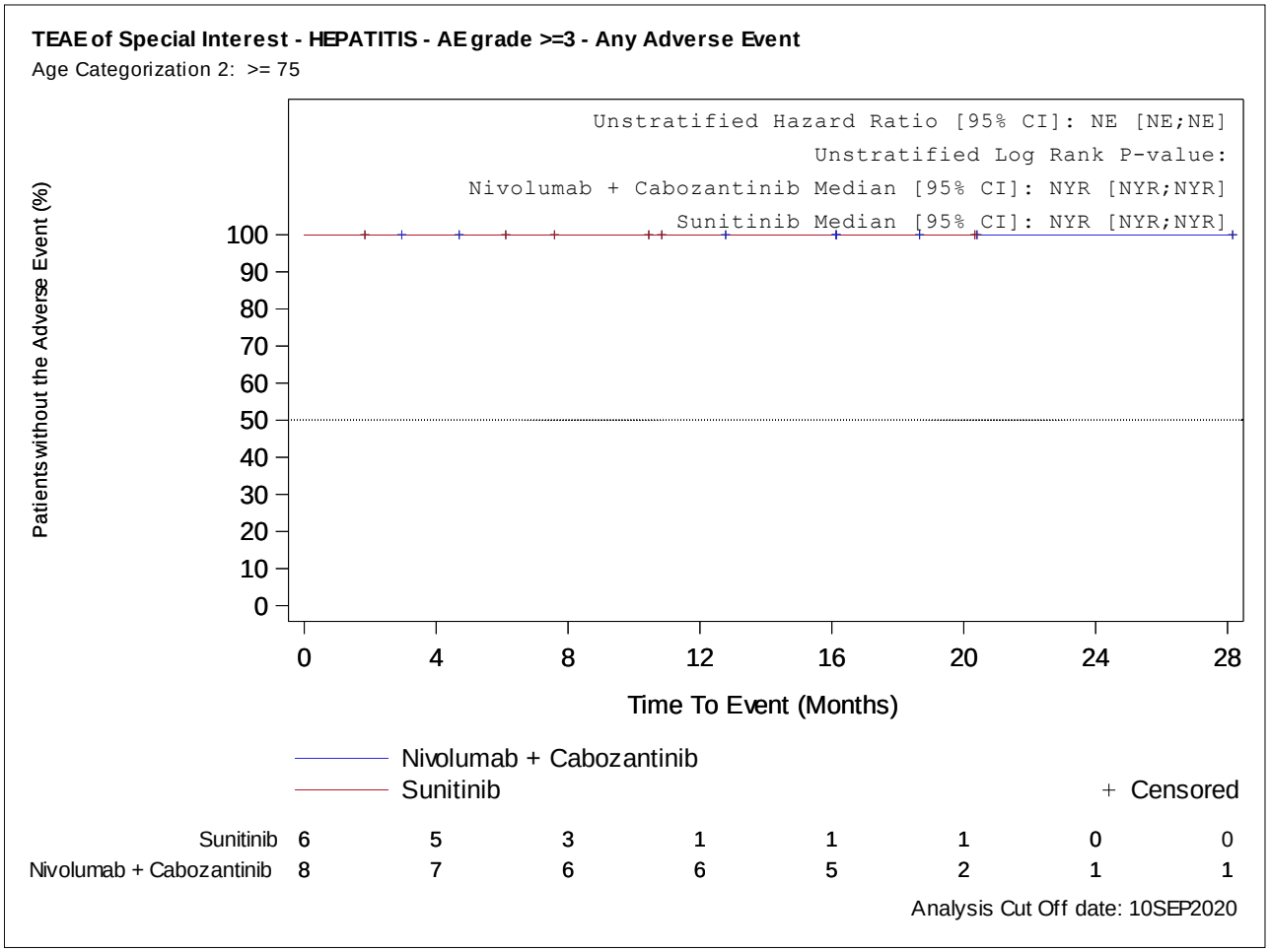
FIGURE 3.79.2.4: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



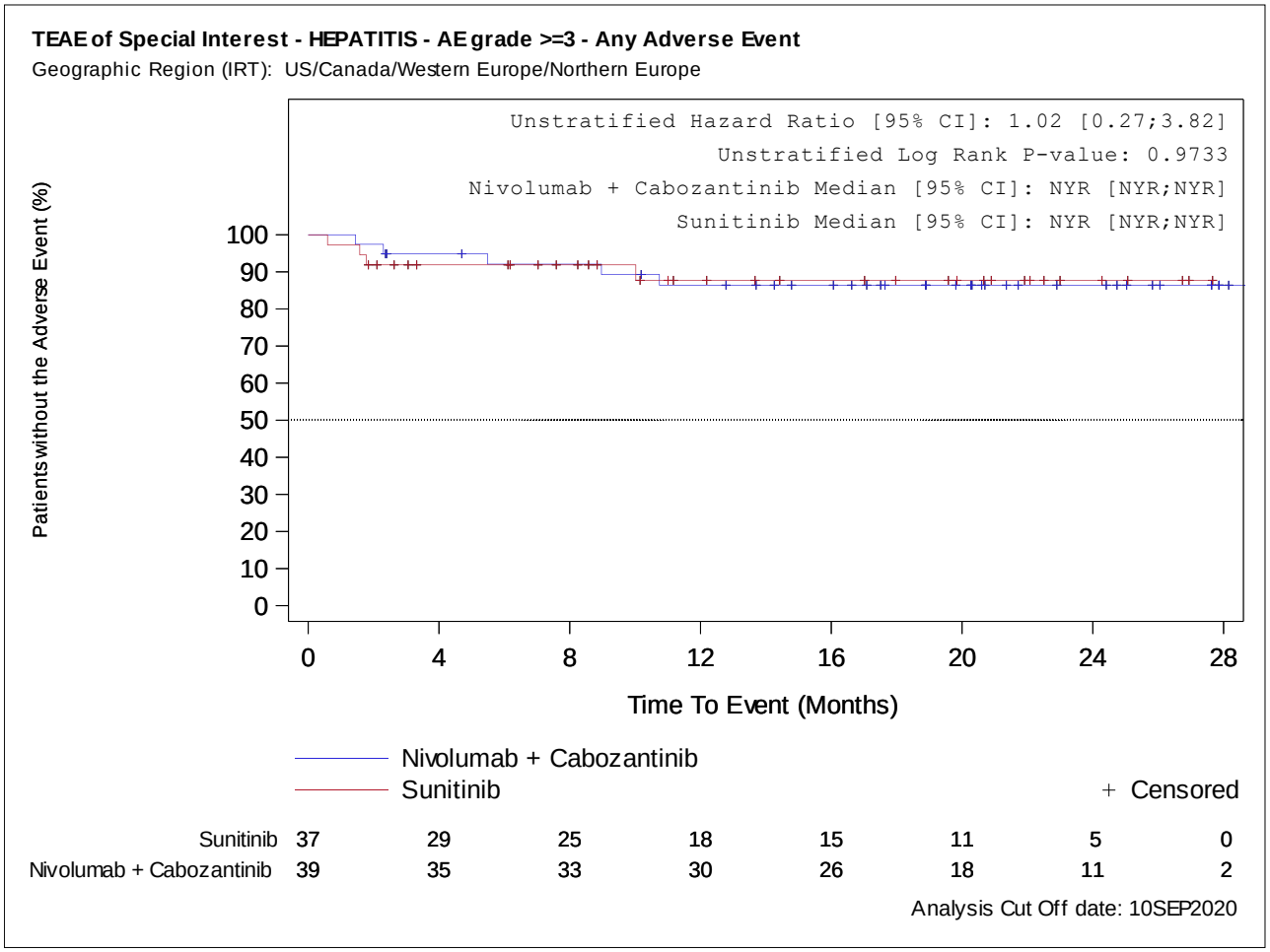

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:12:39

FIGURE 3.79.2.5: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



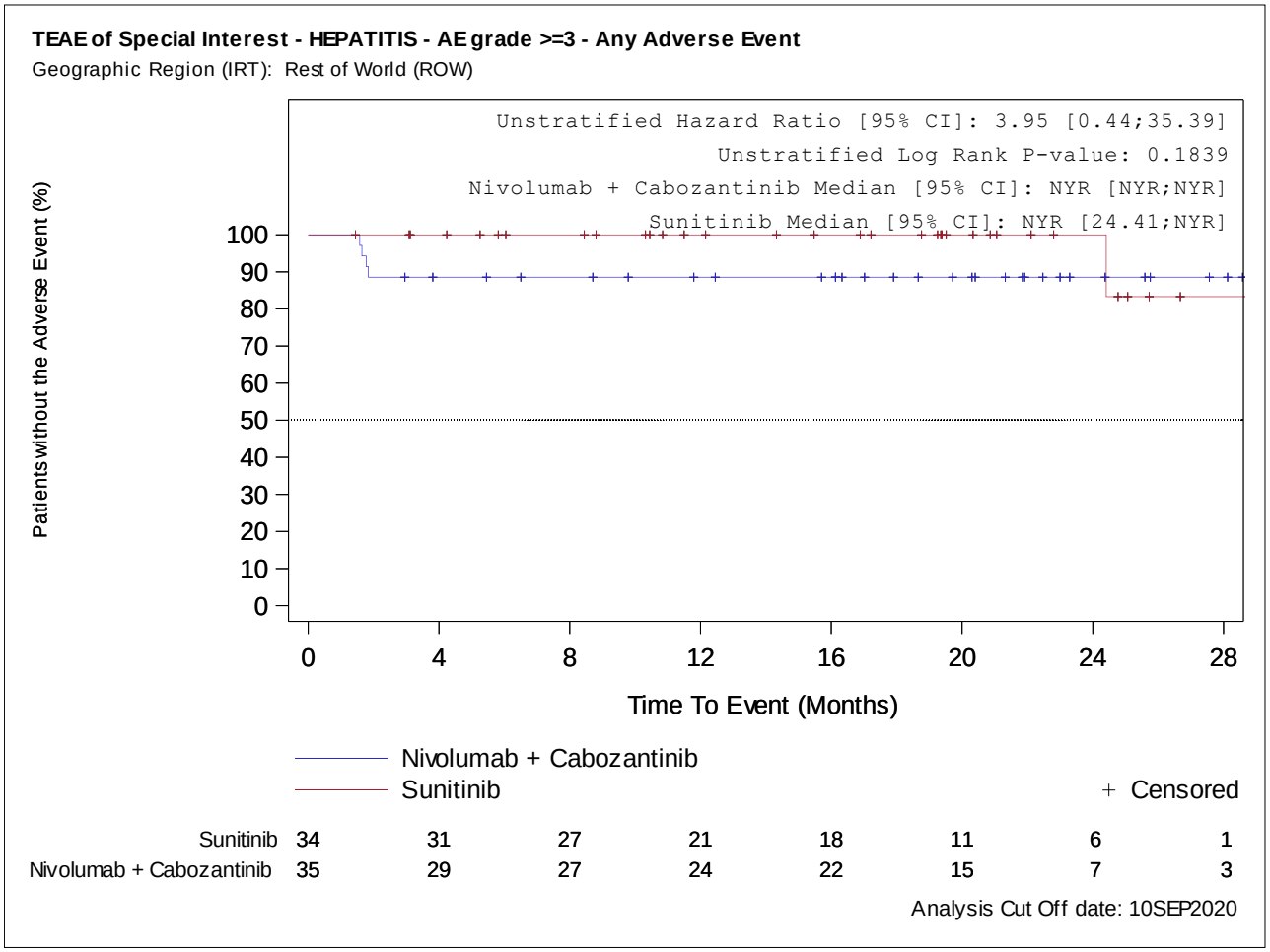

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:12:45

FIGURE 3.79.2.6: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



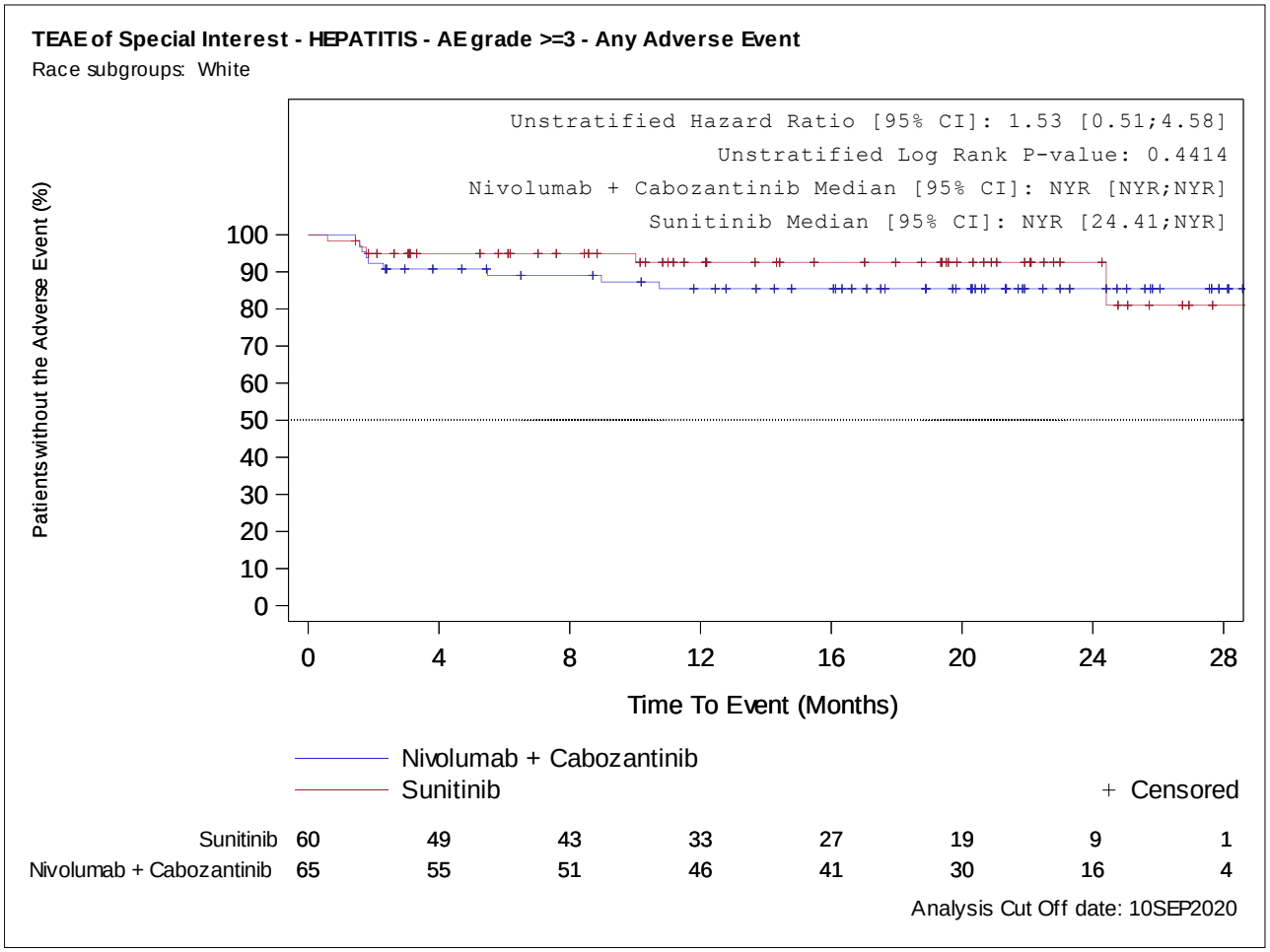

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:12:51

FIGURE 3.79.2.7: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



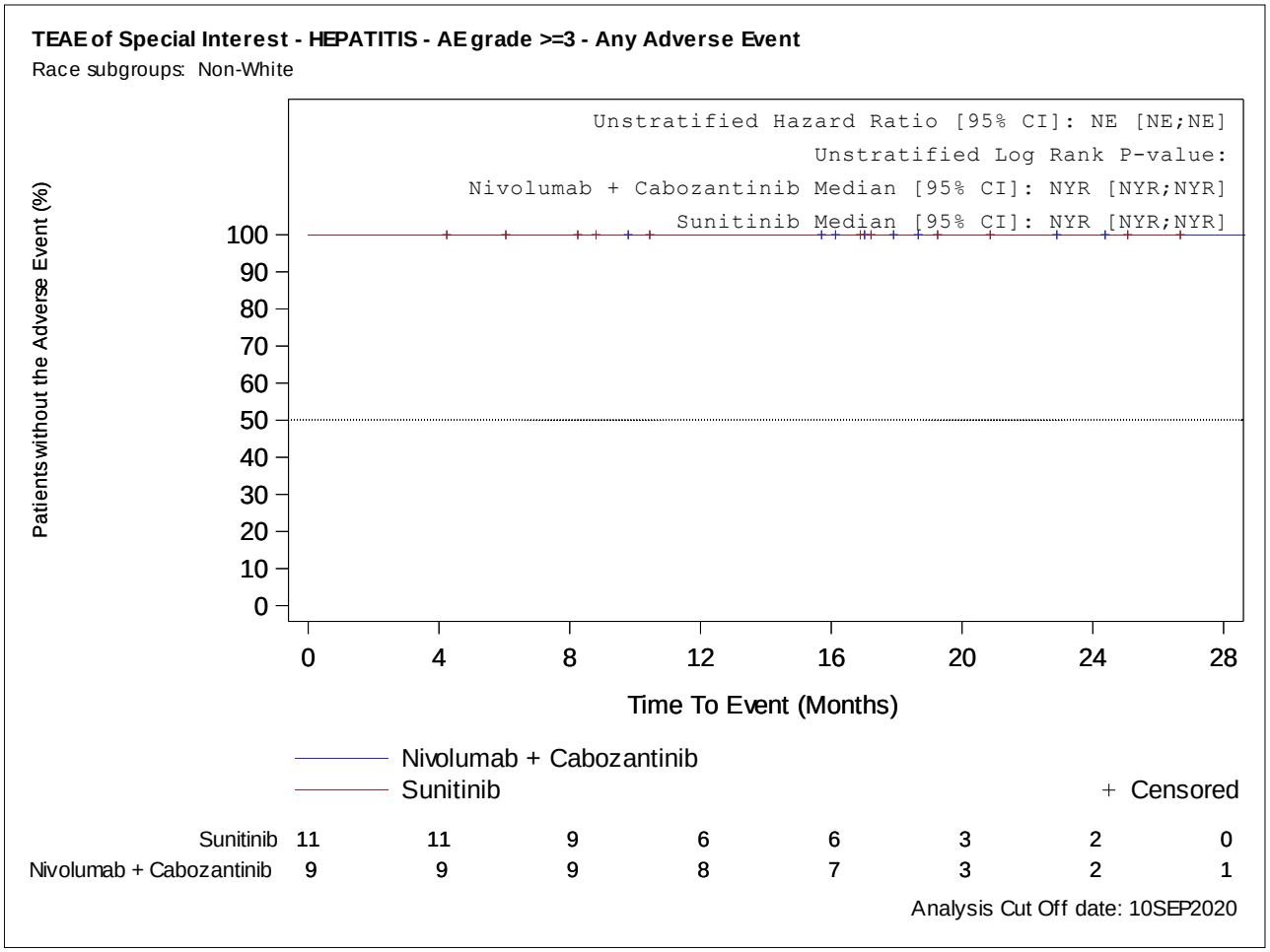

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:12:56

FIGURE 3.79.2.8: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



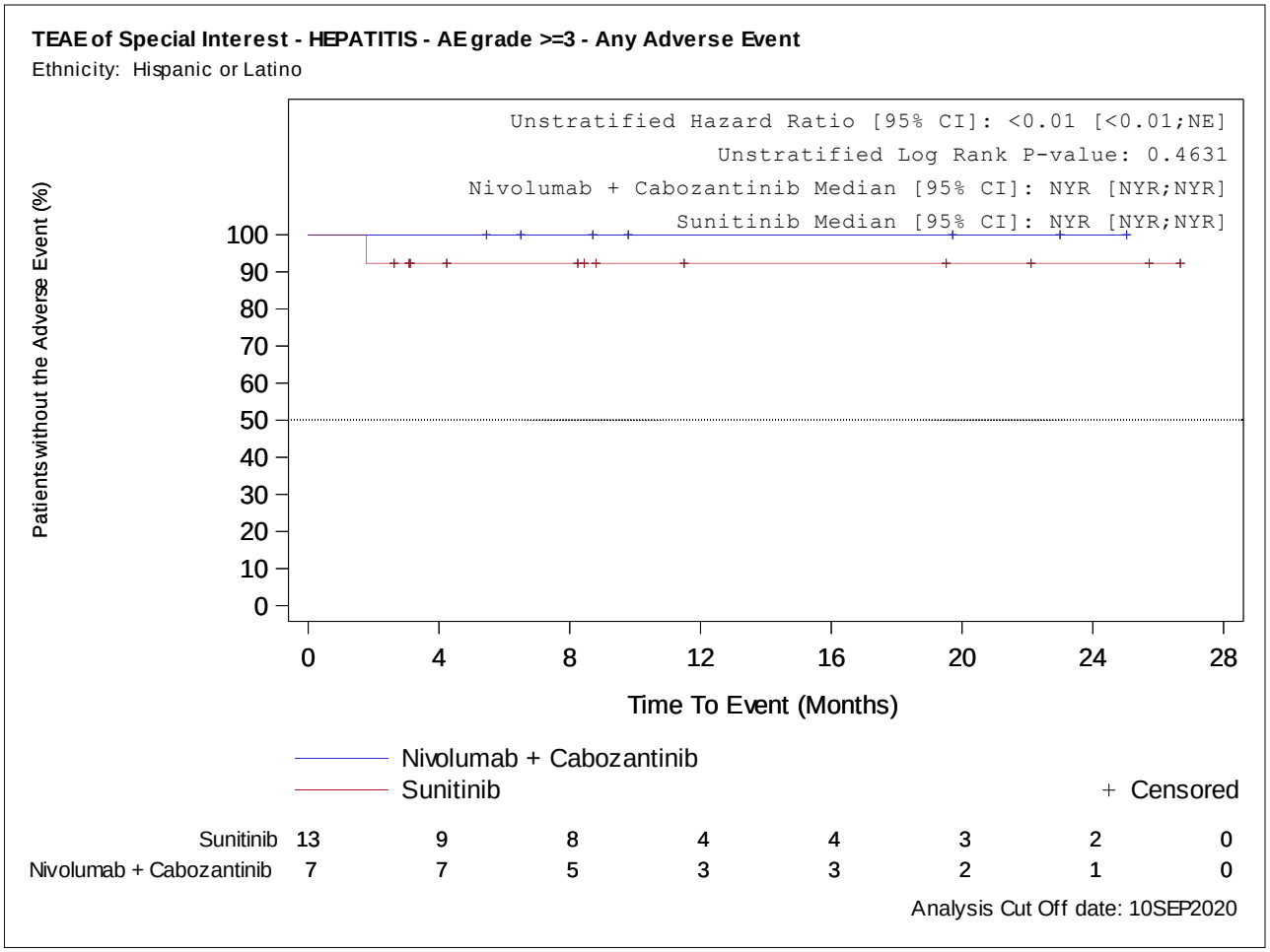

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:13:02

FIGURE 3.79.2.9: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



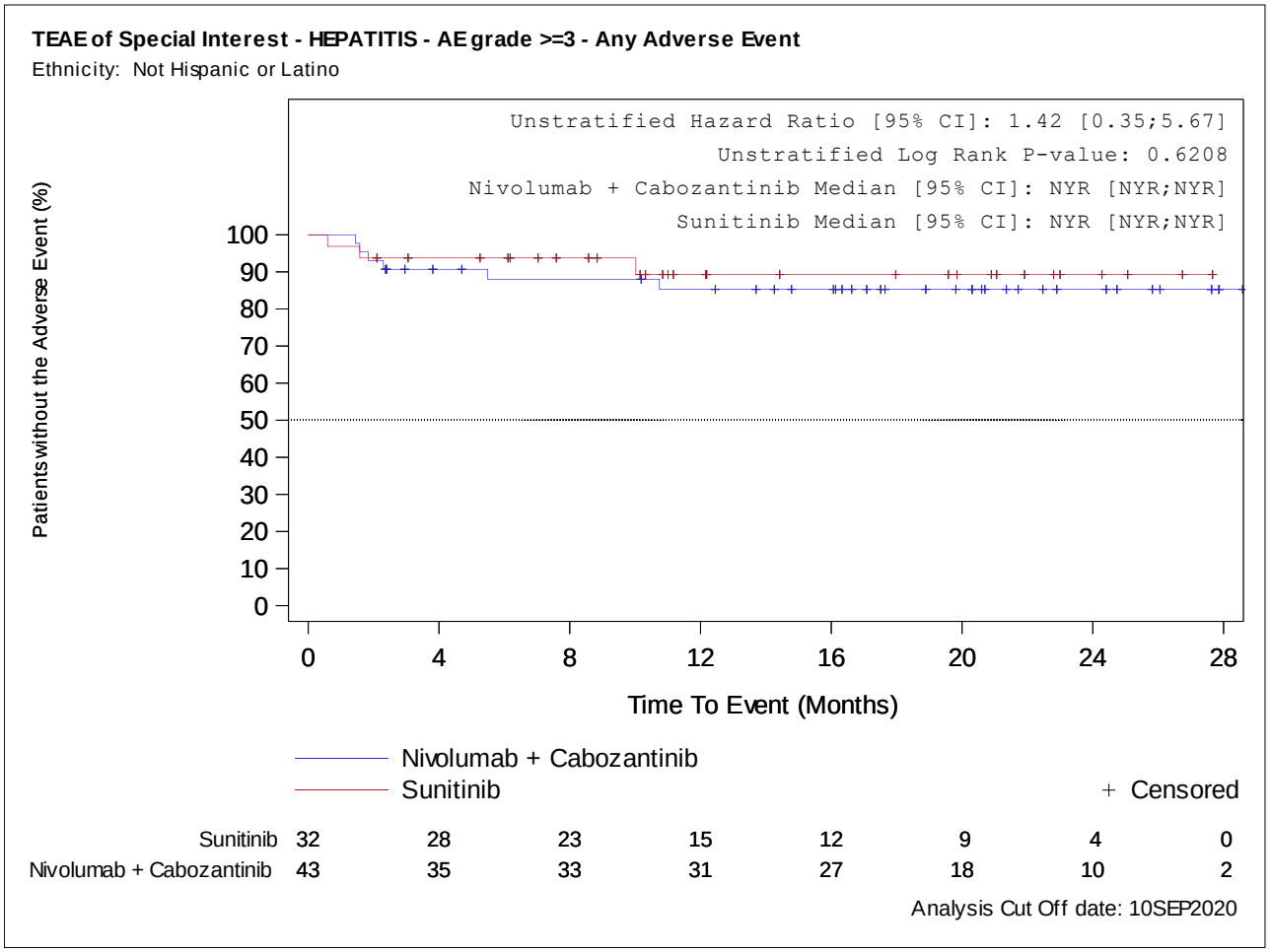

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:13:08

FIGURE 3.79.2.10: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



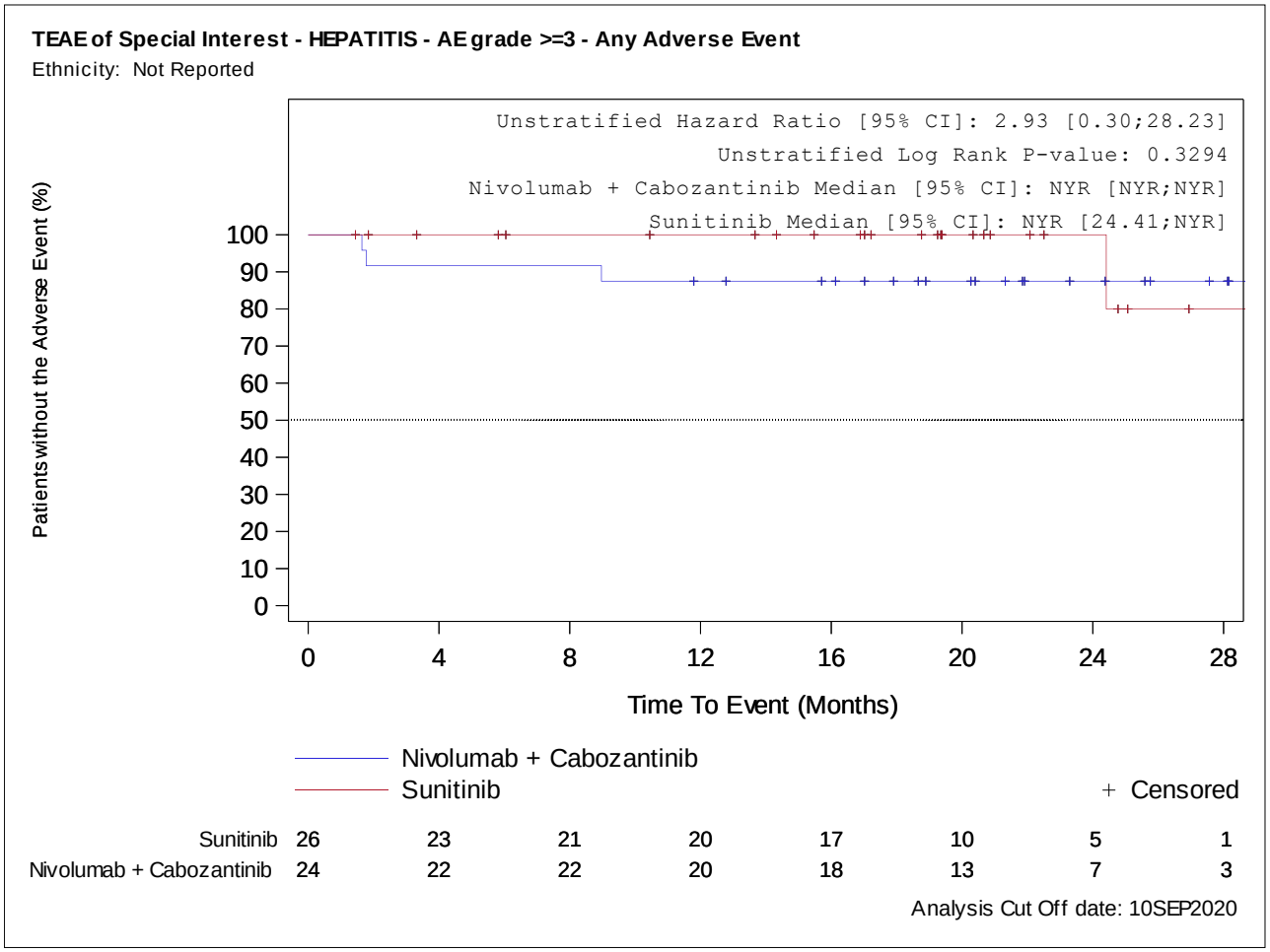

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:13:14

FIGURE 3.79.2.11: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



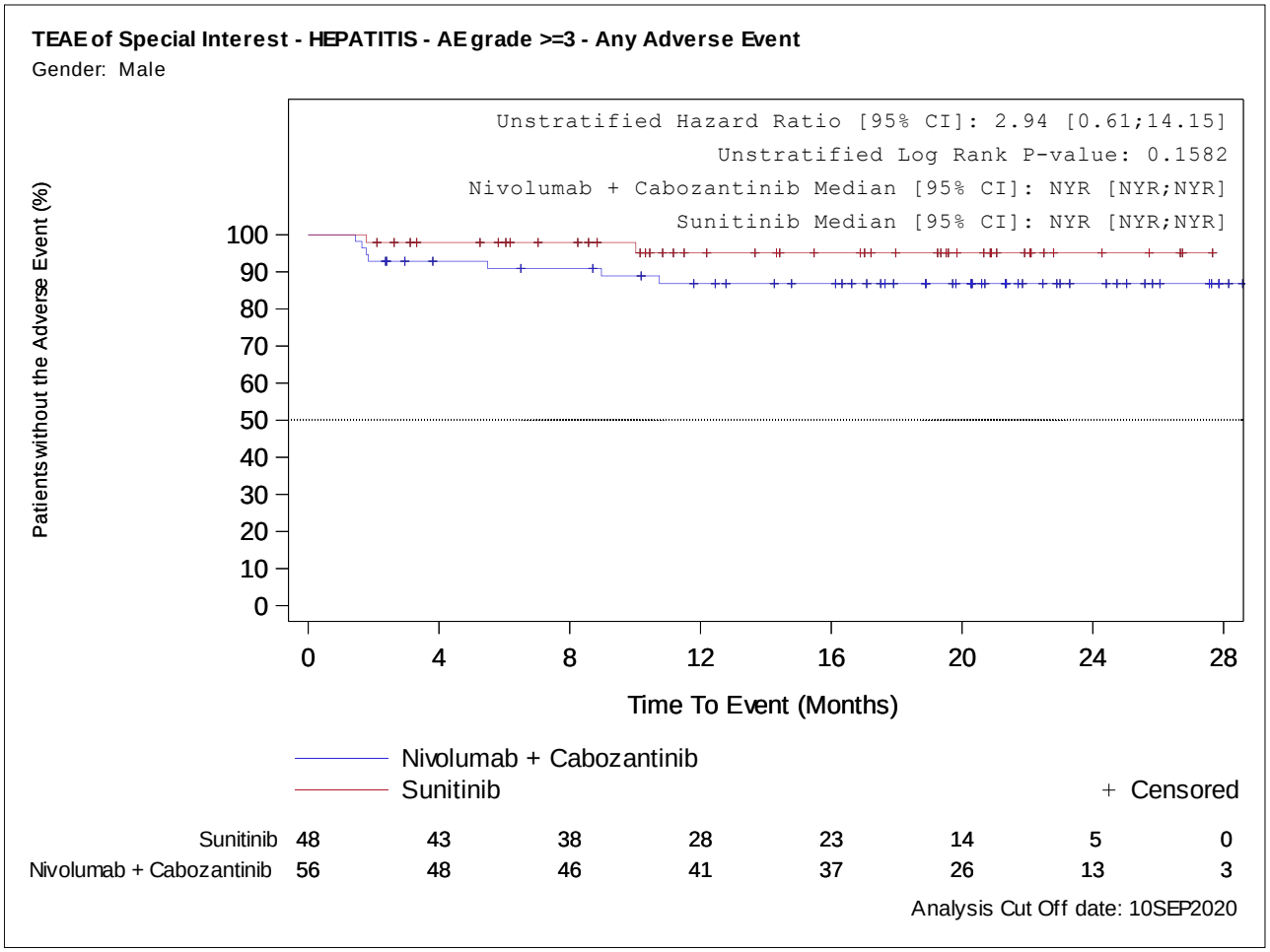

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:13:20

FIGURE 3.79.2.12: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



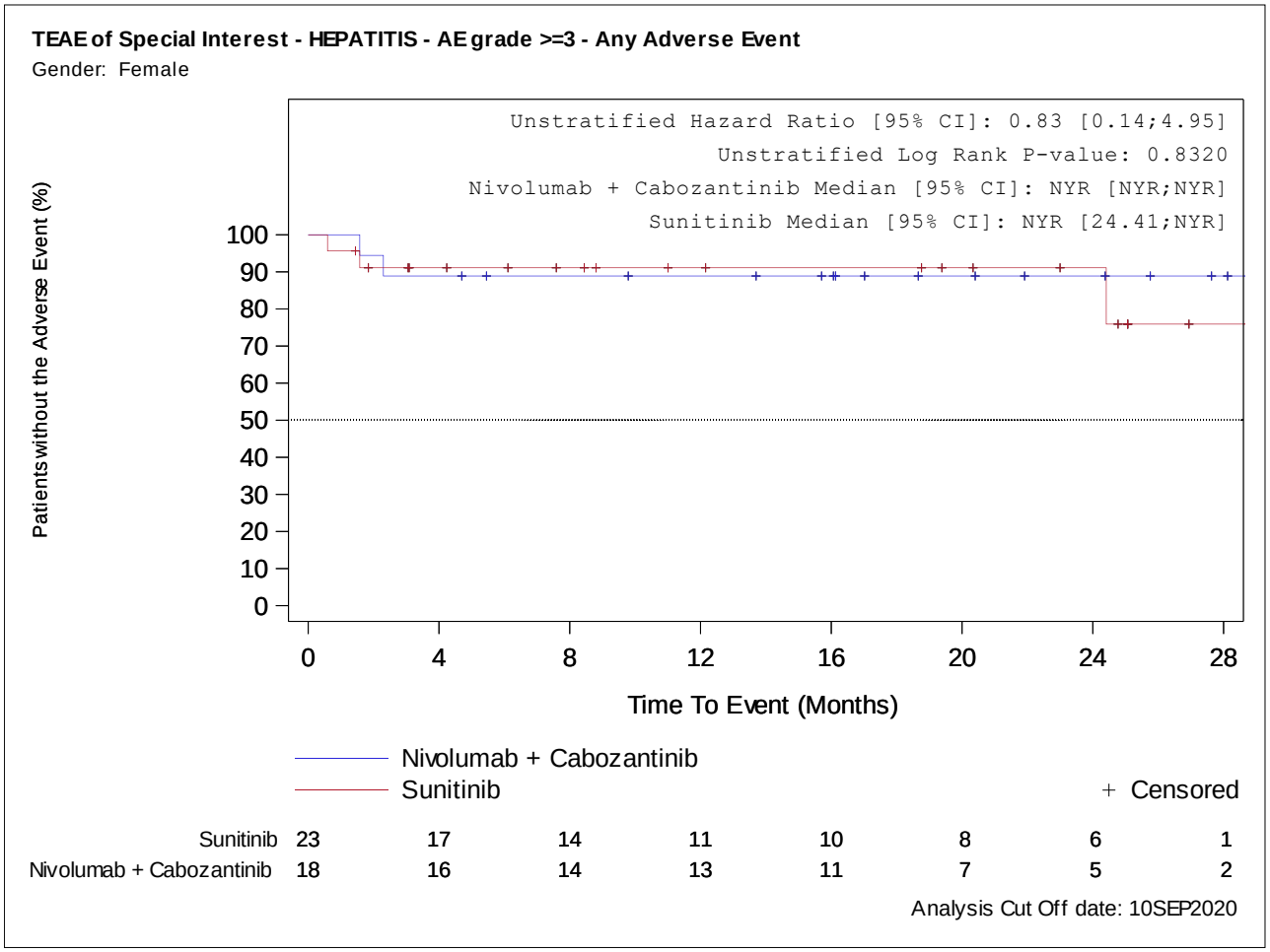

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:13:25

FIGURE 3.79.2.13: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



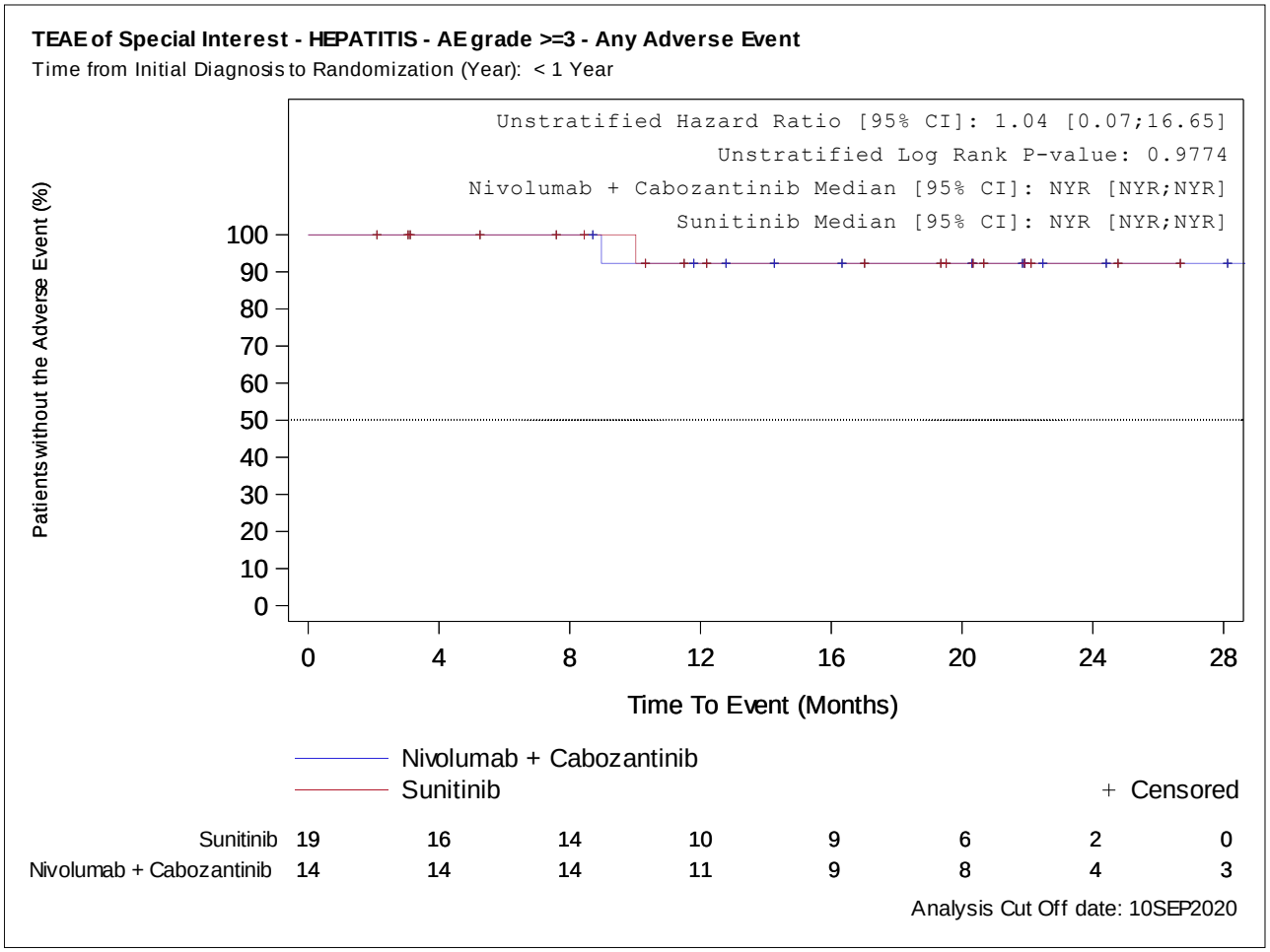

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:13:31

FIGURE 3.79.2.14: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



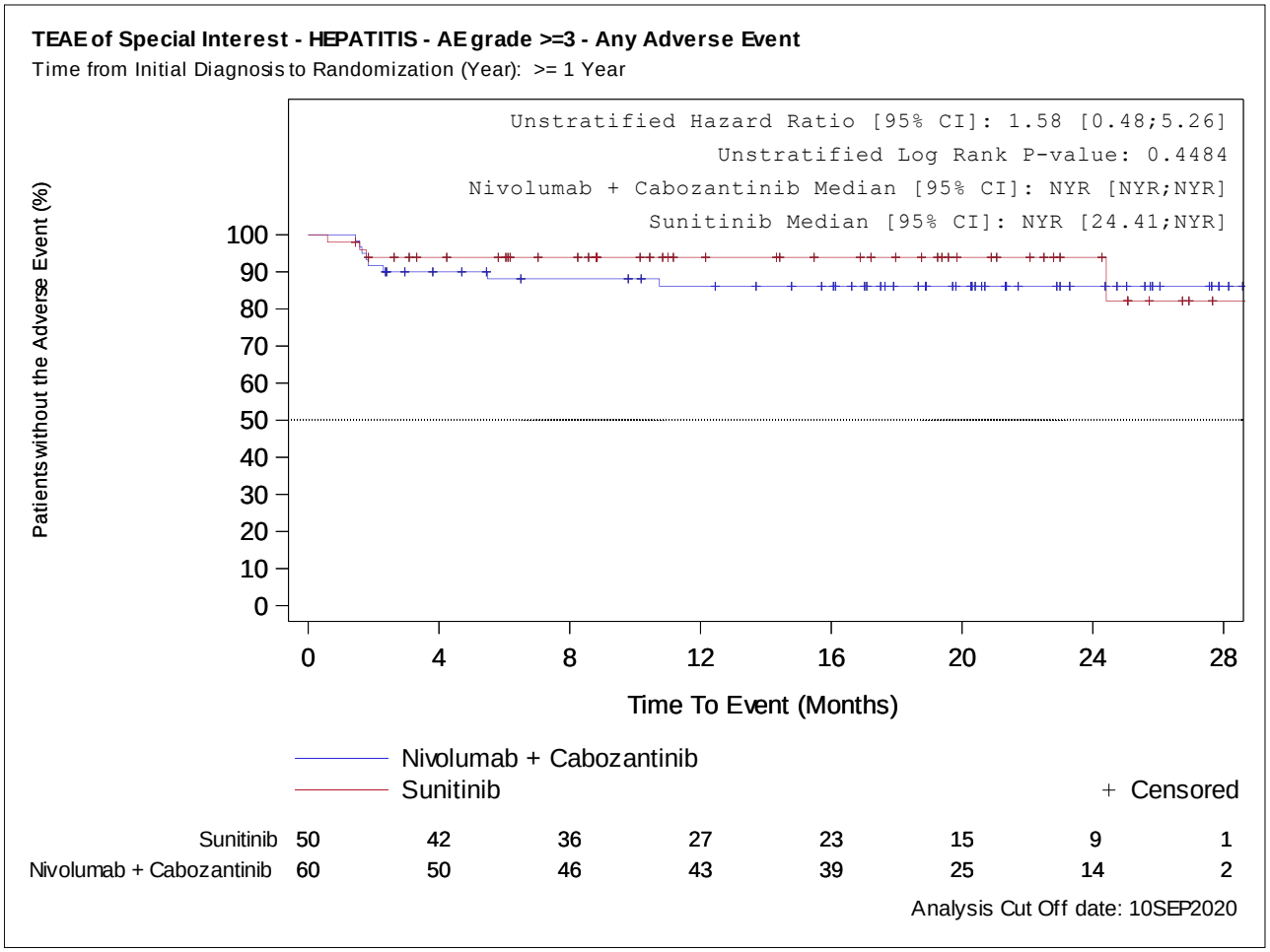

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:13:37

FIGURE 3.79.2.15: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



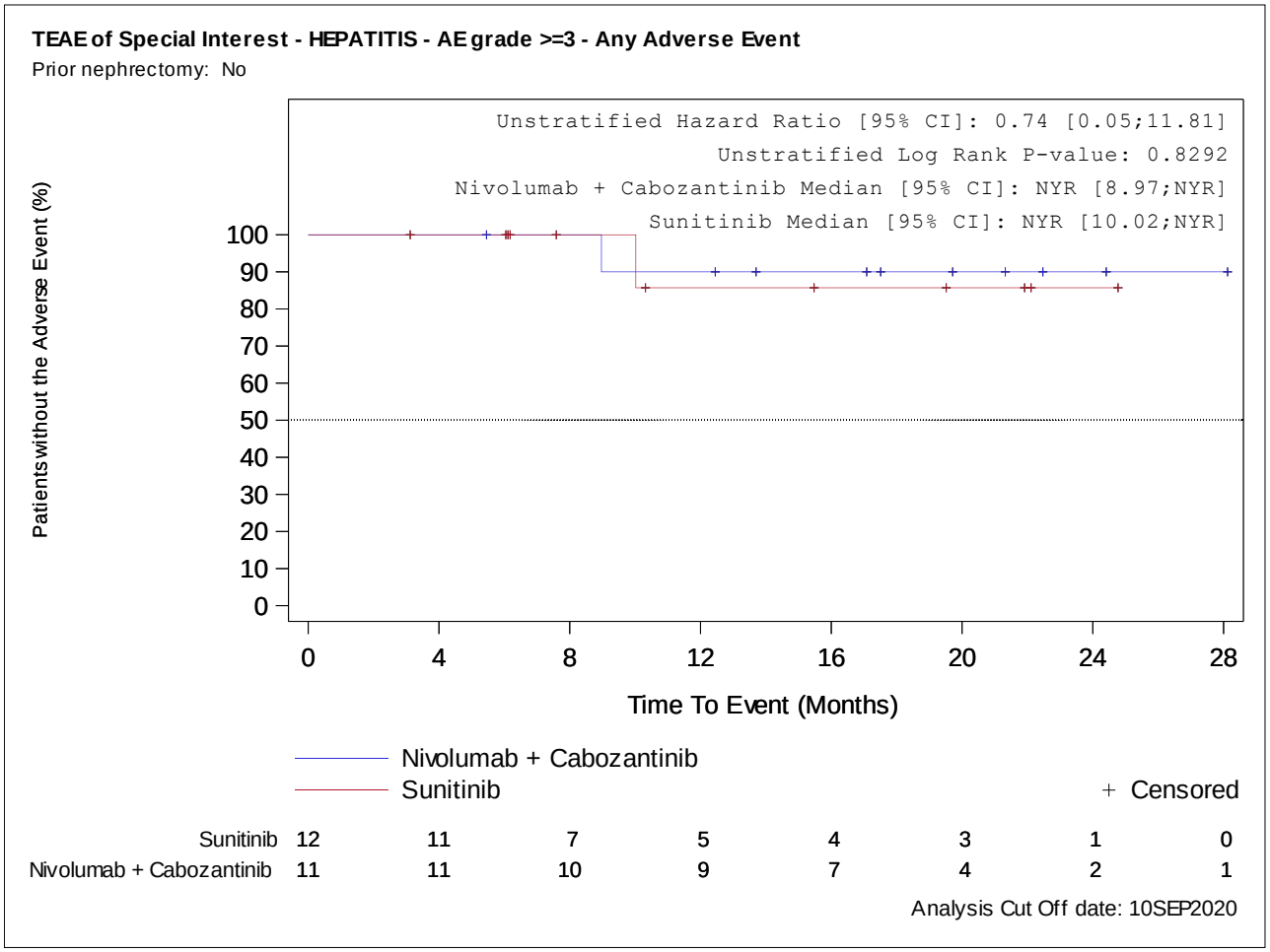

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:13:56

FIGURE 3.79.2.16: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:14:02

FIGURE 3.79.2.17: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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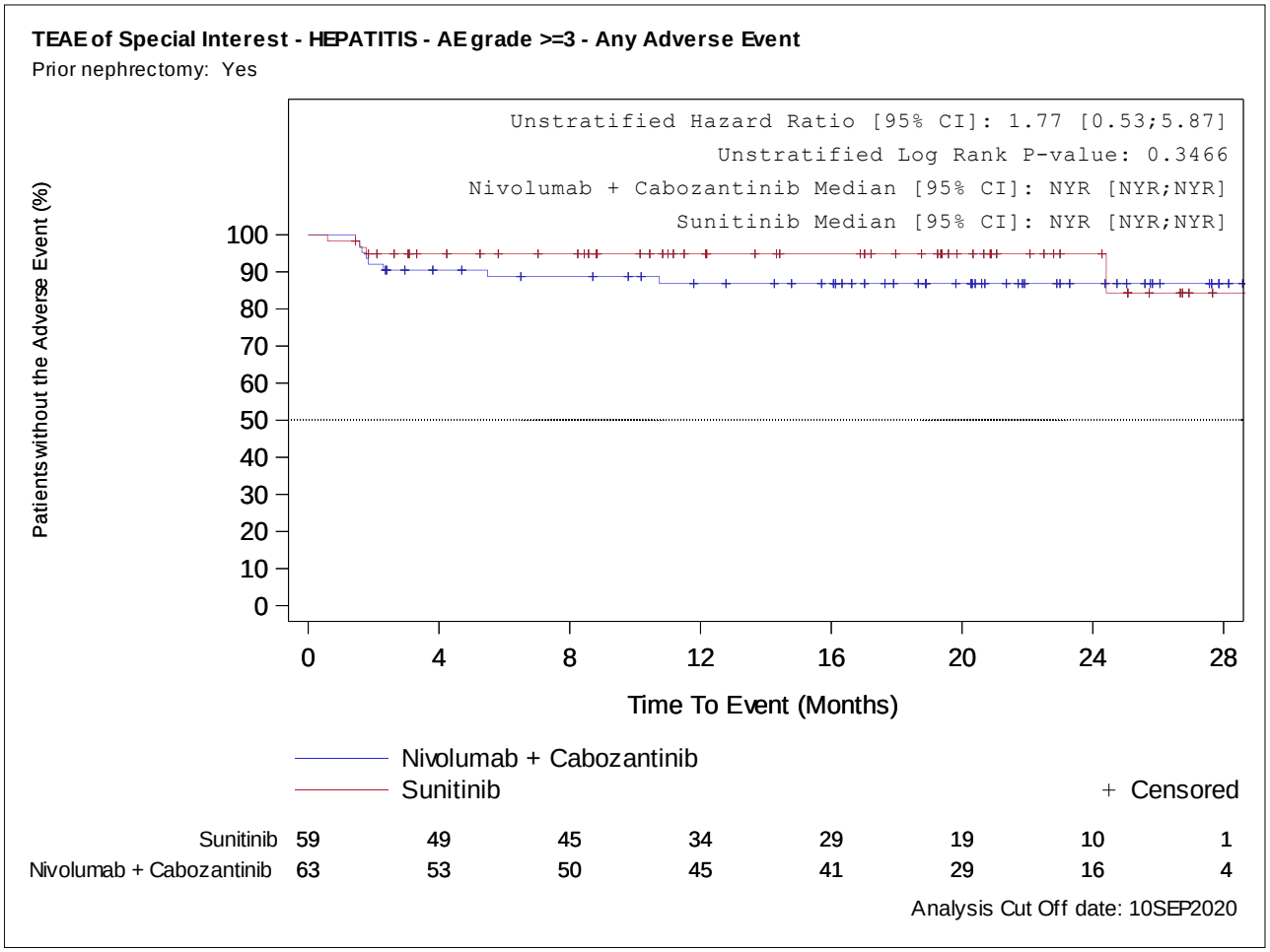
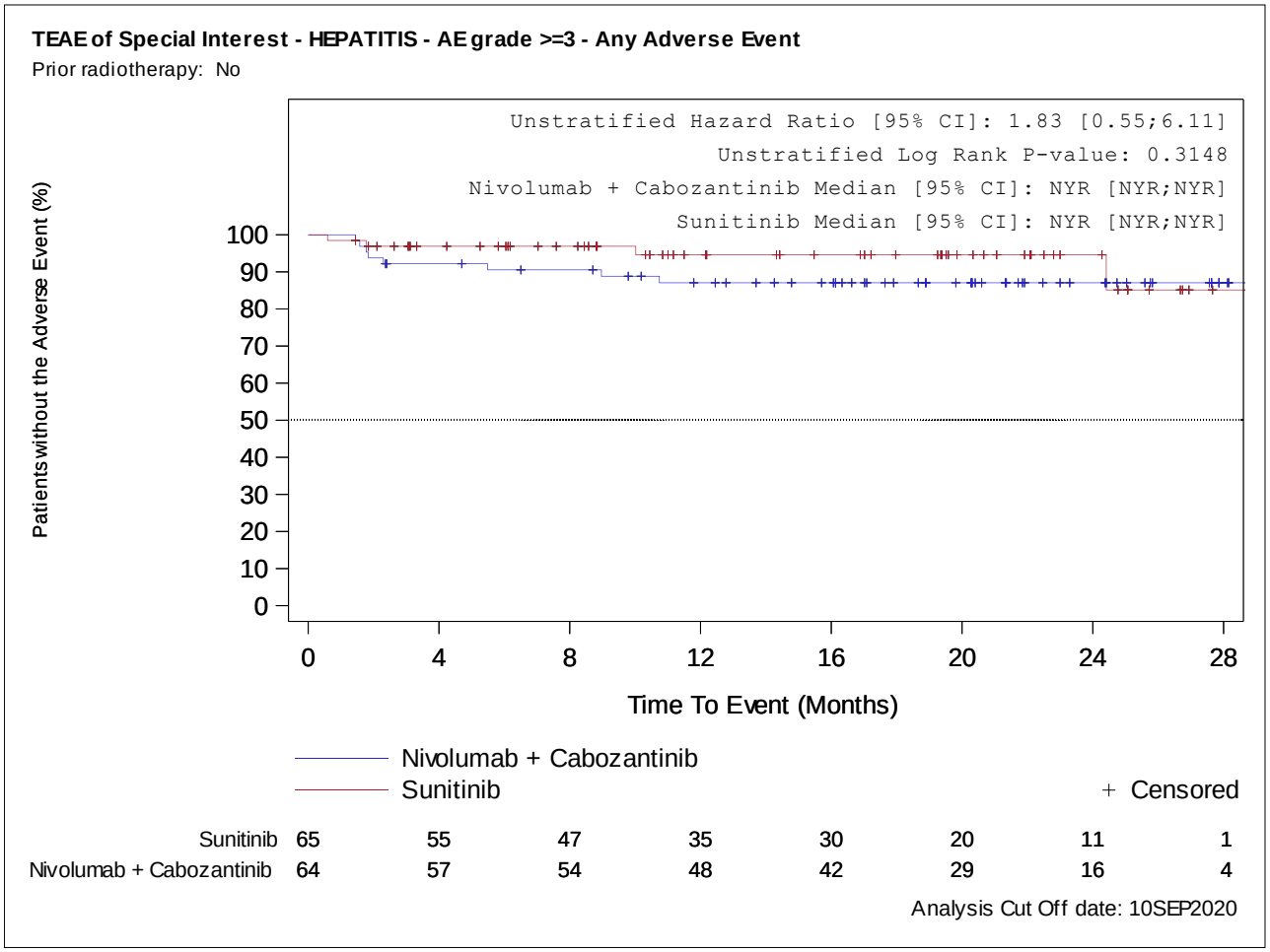
FIGURE 3.79.2.18: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



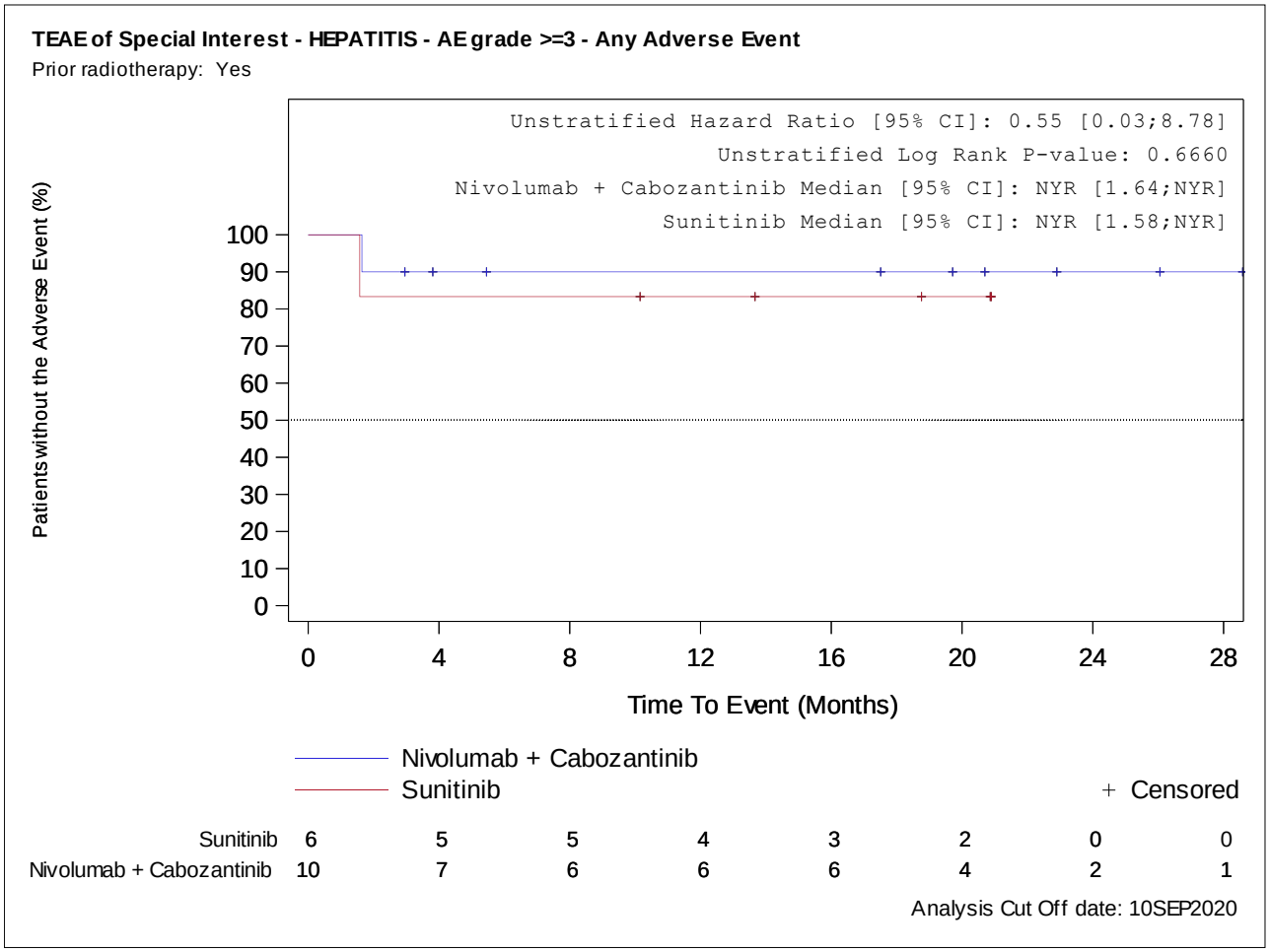

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:15:02

FIGURE 3.79.2.19: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



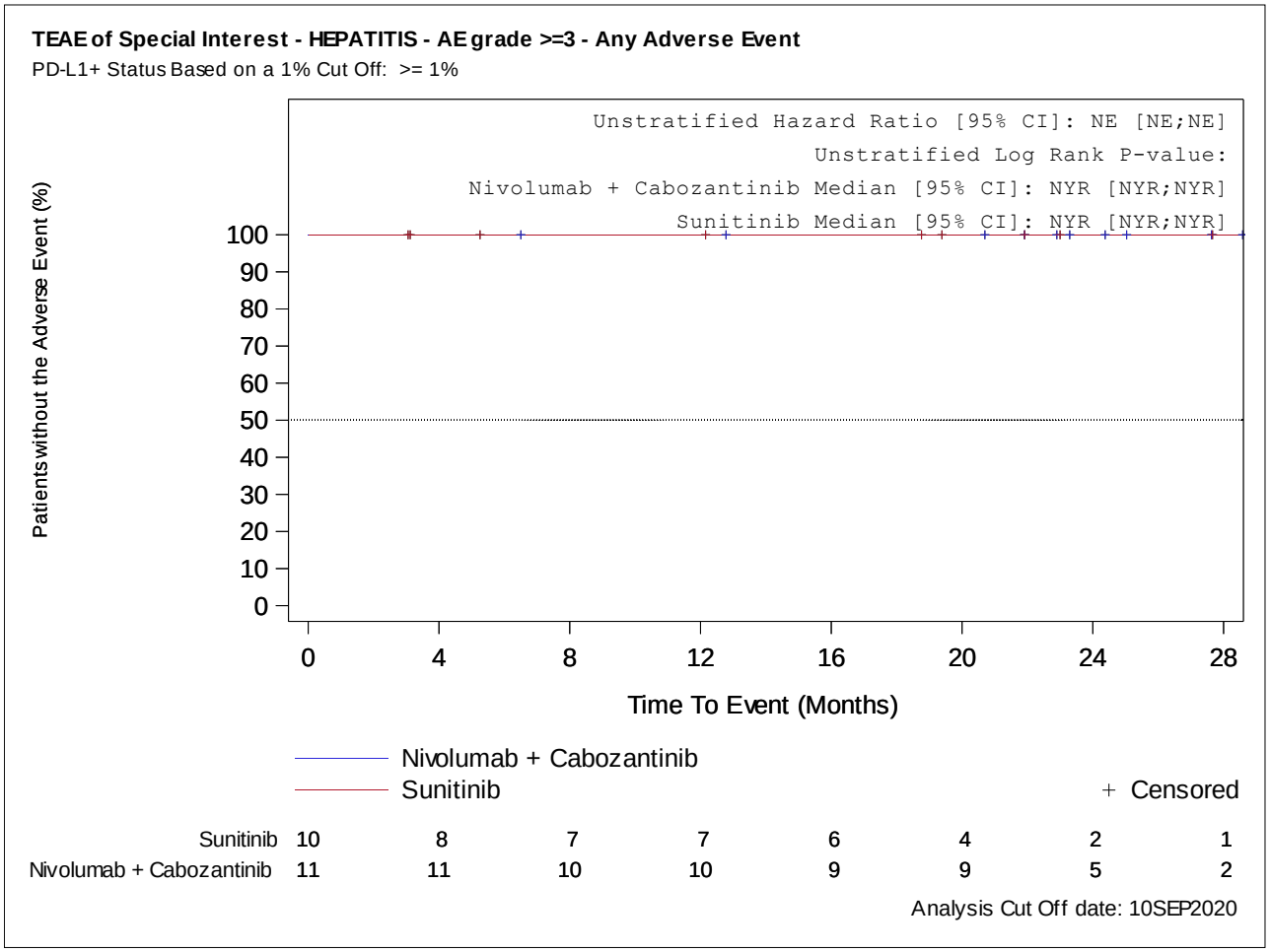

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:15:08

FIGURE 3.79.2.20: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



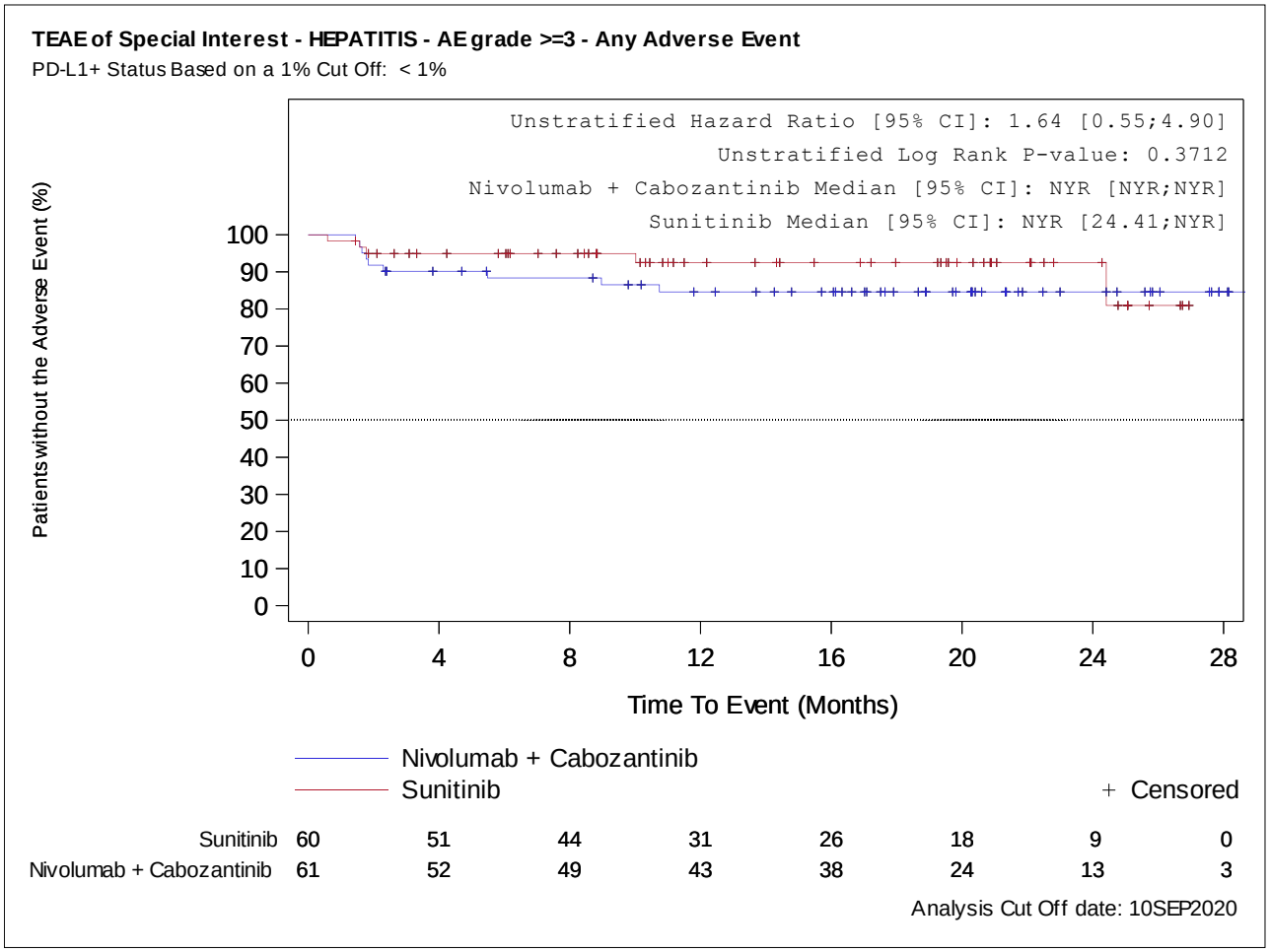

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:15:14

FIGURE 3.79.2.21: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



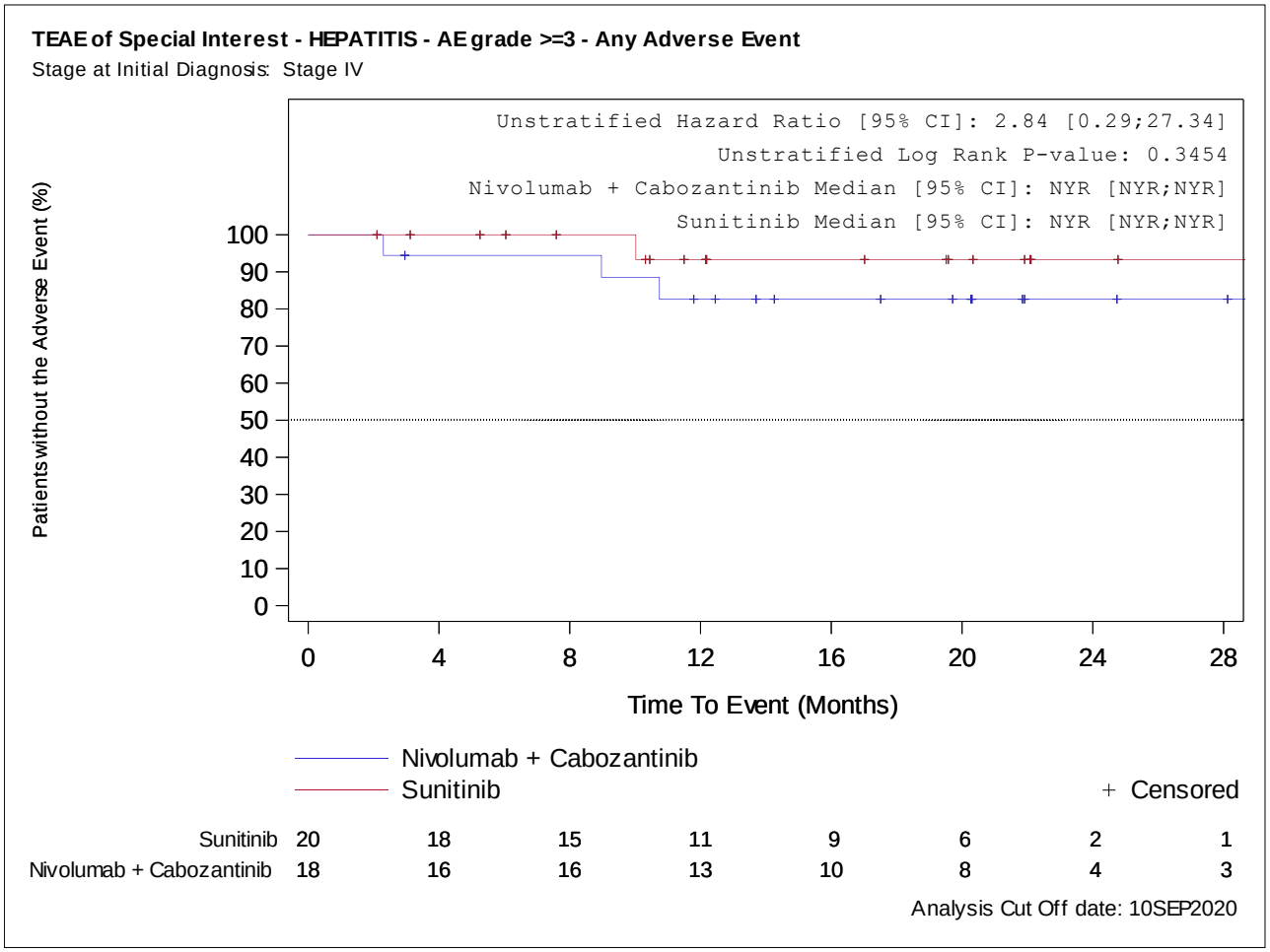

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:15:19

FIGURE 3.79.2.22: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



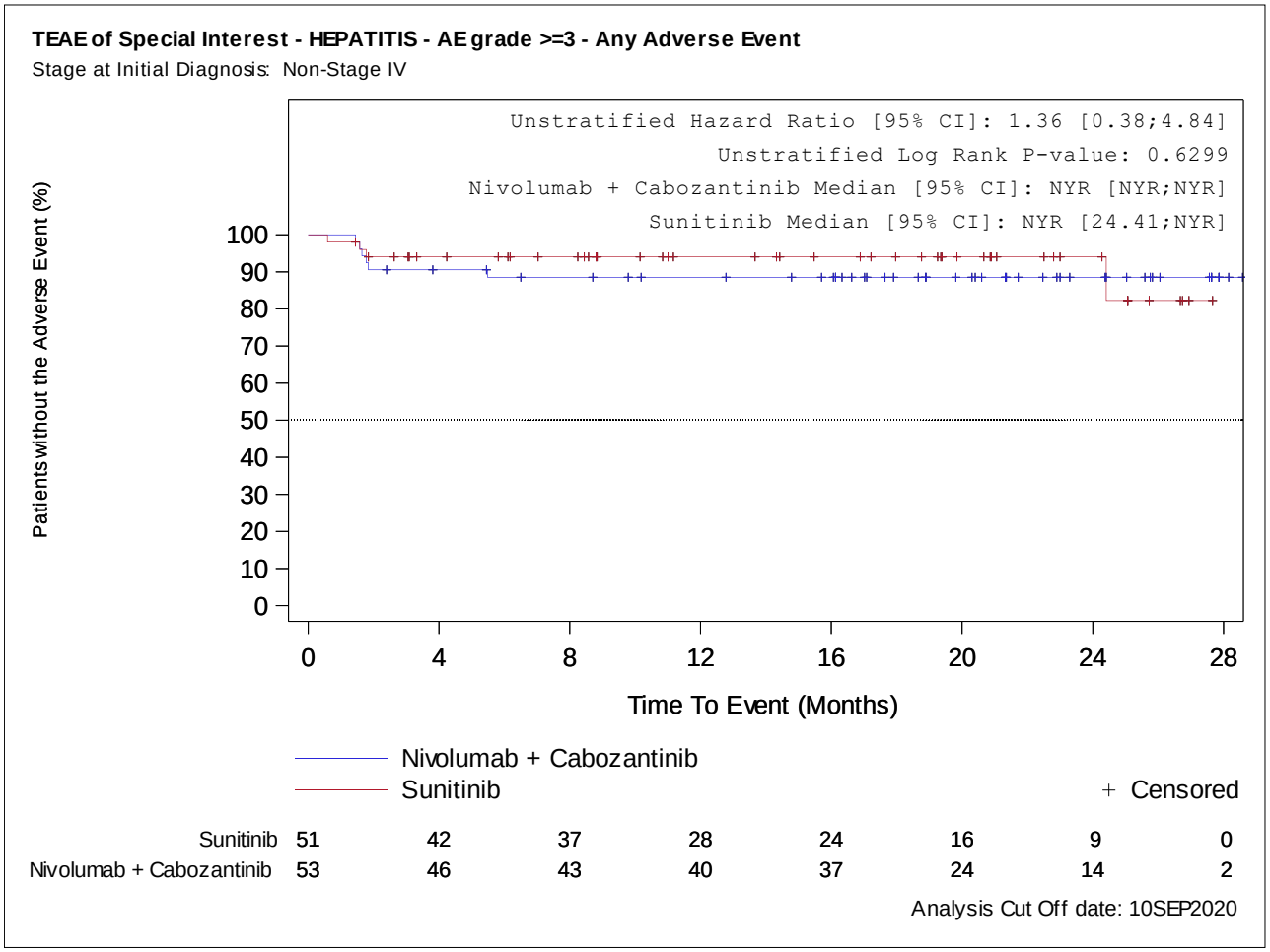

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:15:25

FIGURE 3.79.2.23: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



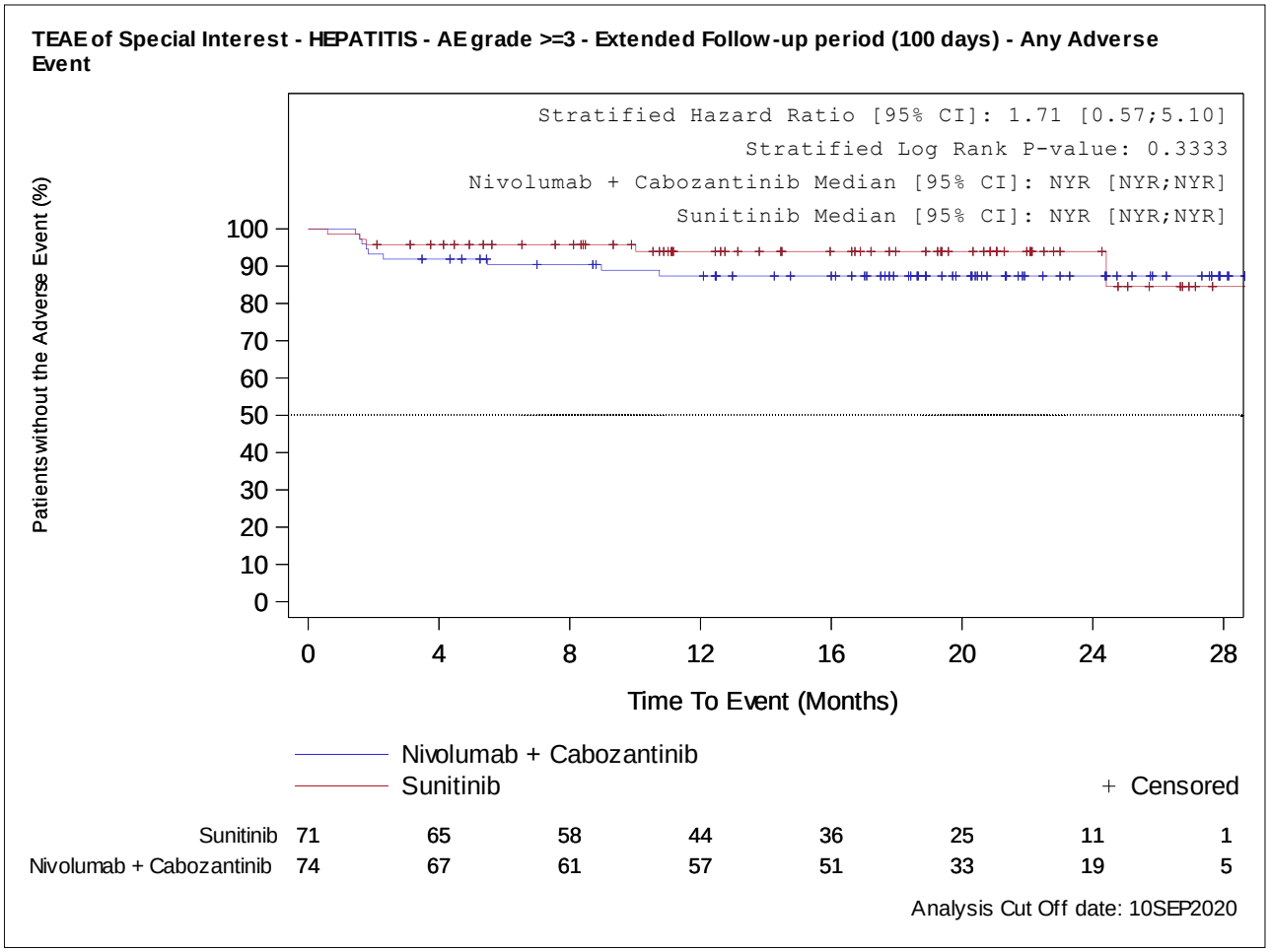

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:15:55

FIGURE 3.79.2.24: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



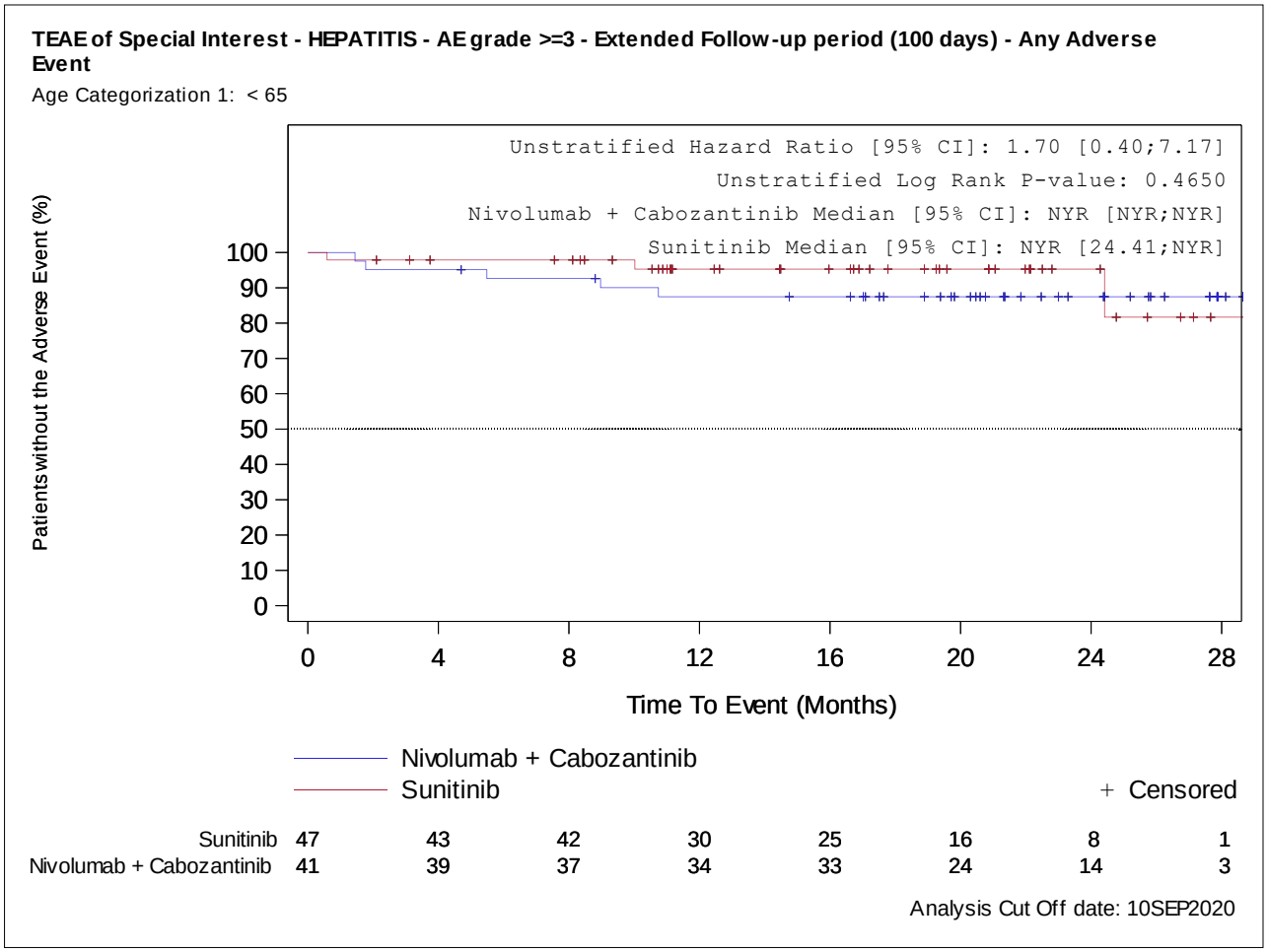

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:16:01

FIGURE 3.80.1: TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



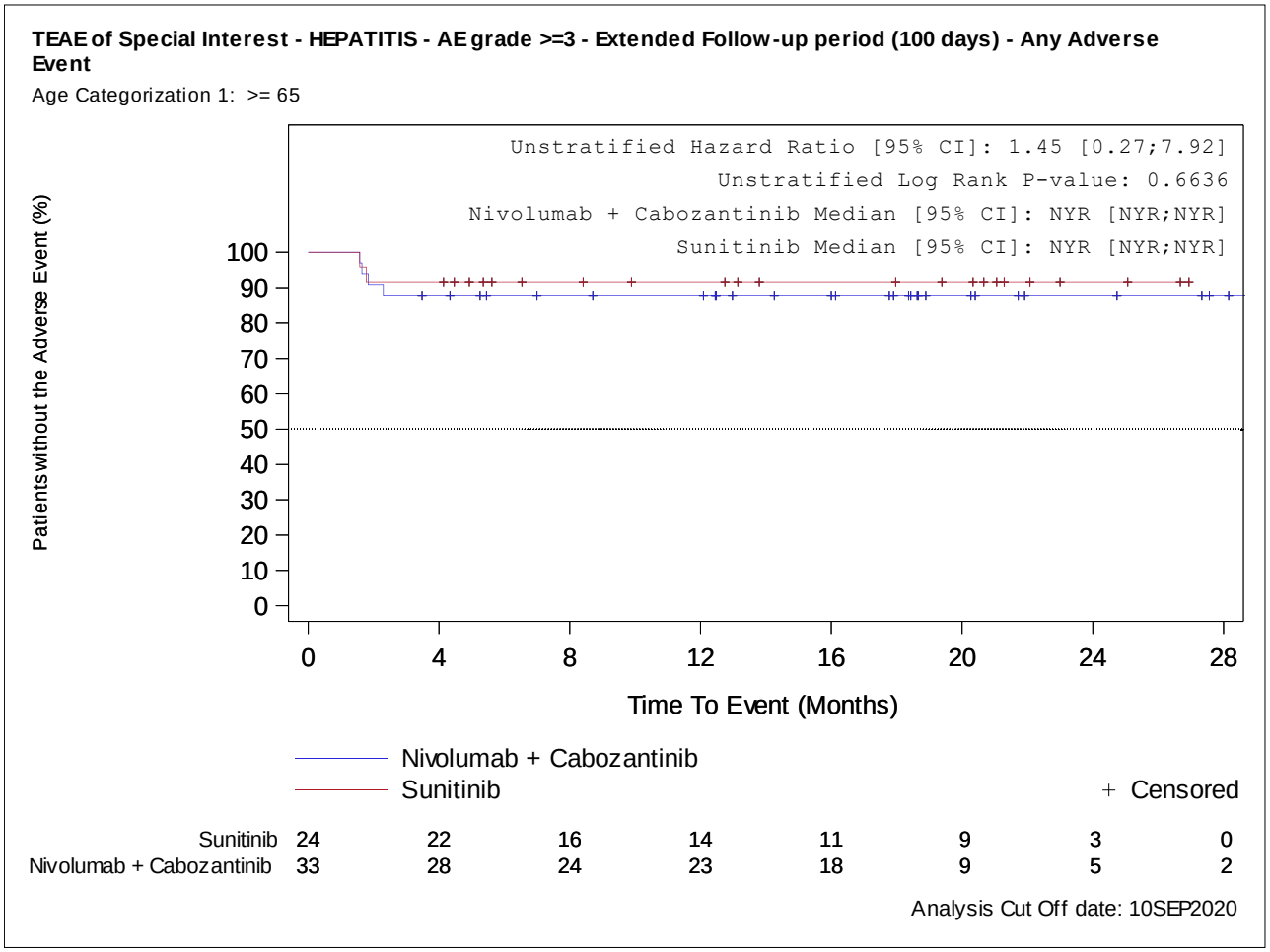

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:19:18

FIGURE 3.80.2.1: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



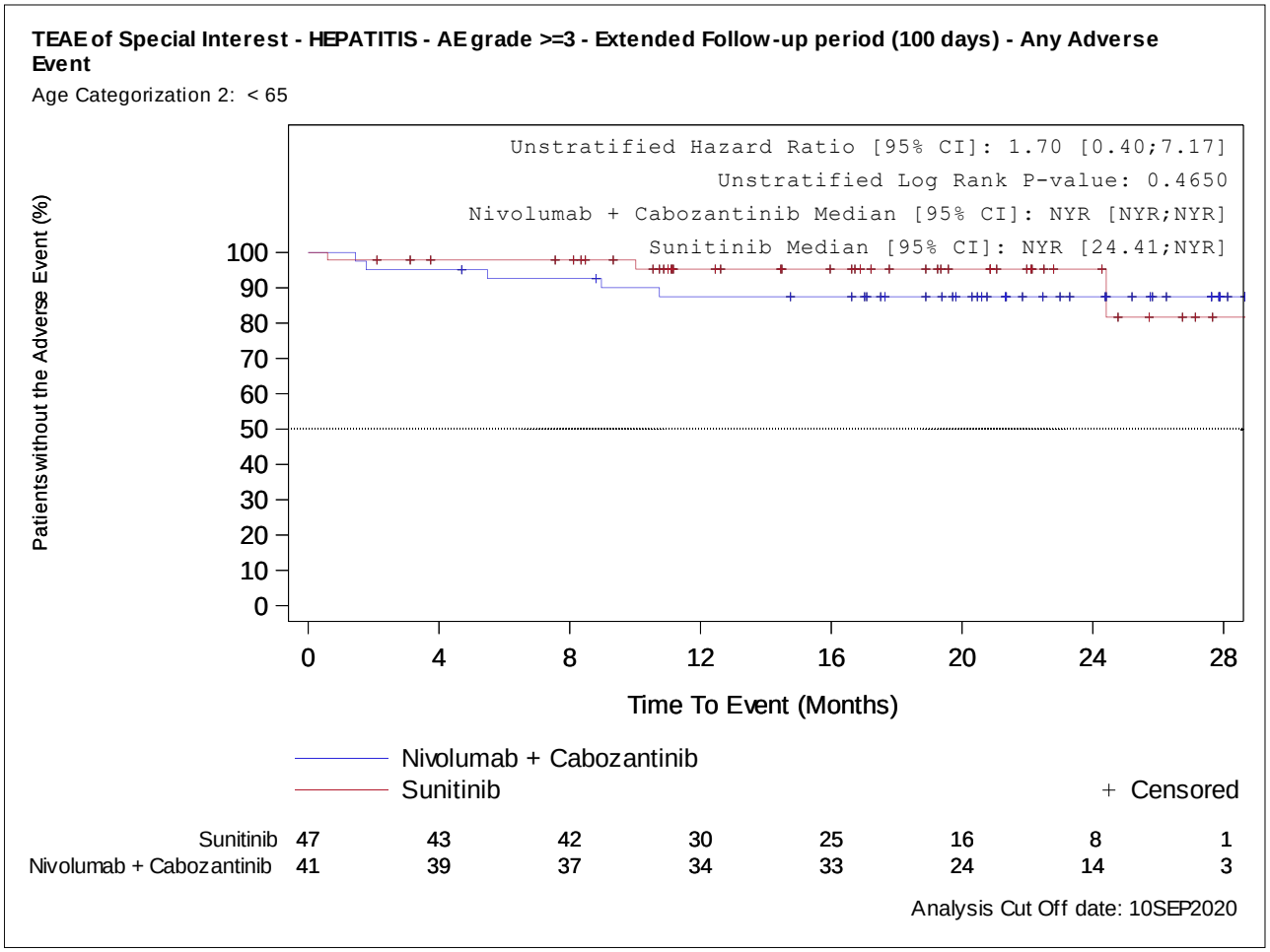

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:19:22

FIGURE 3.80.2.2: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



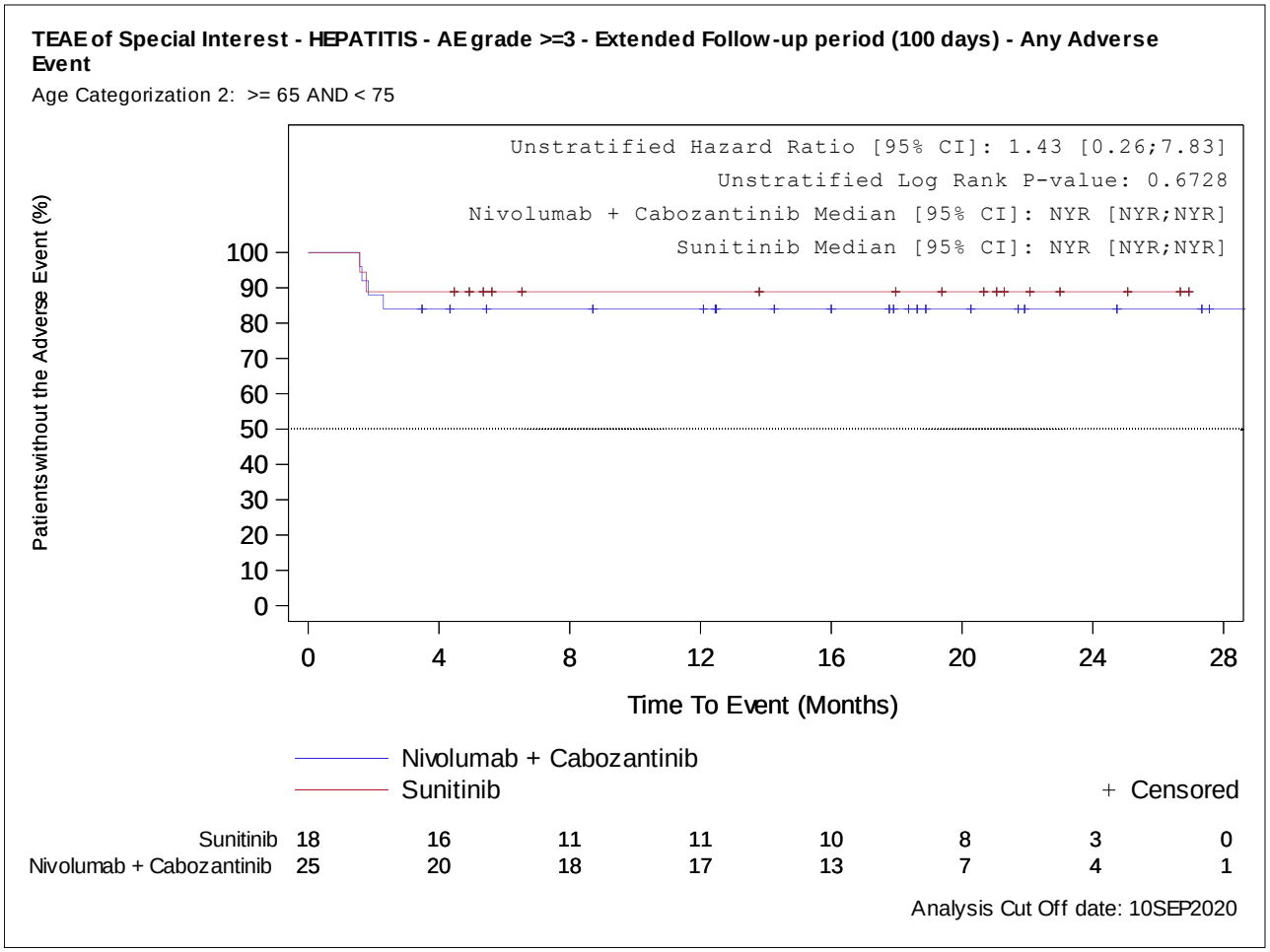

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:19:27

FIGURE 3.80.2.3: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



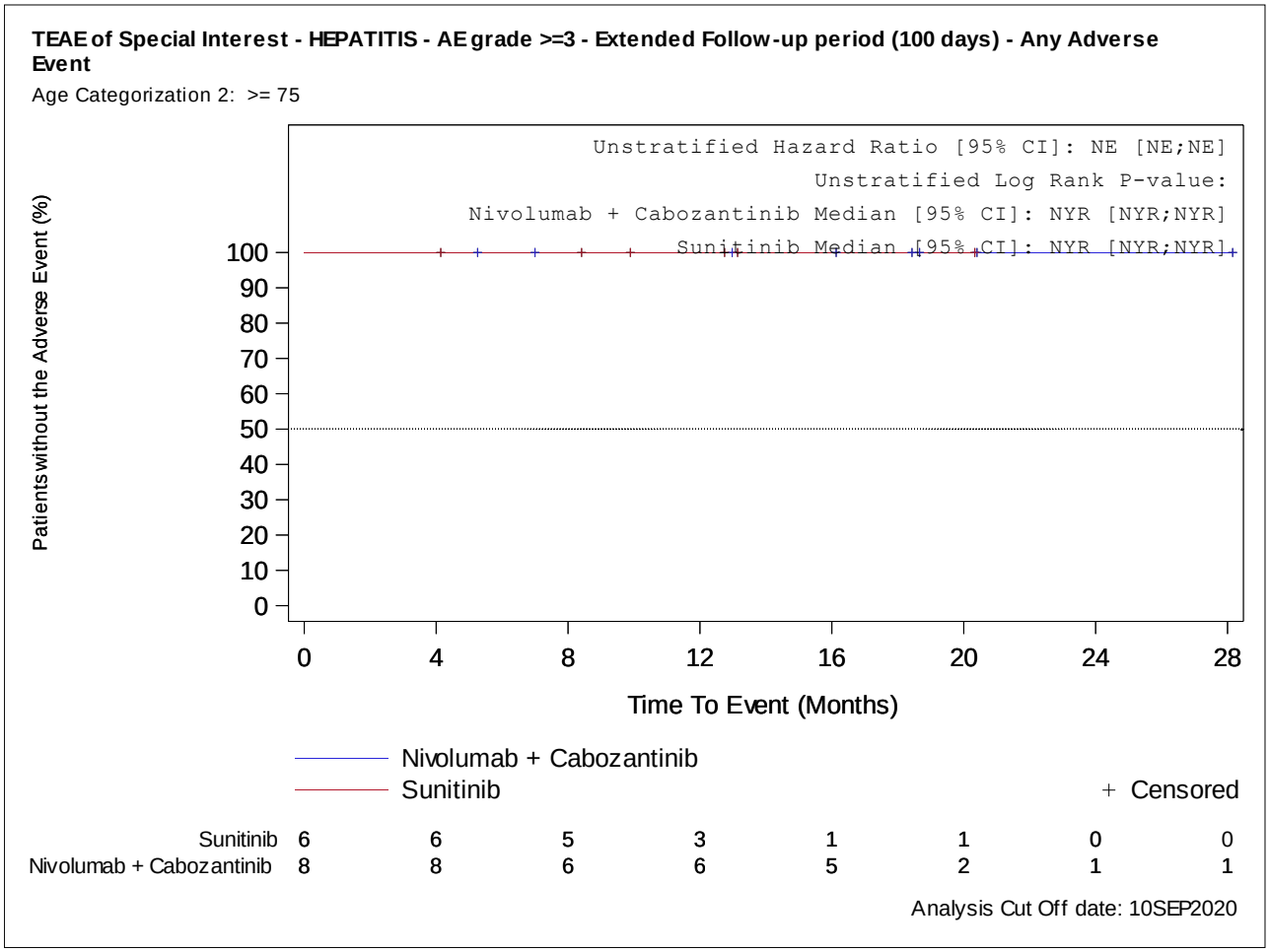

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:19:33

FIGURE 3.80.2.4: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



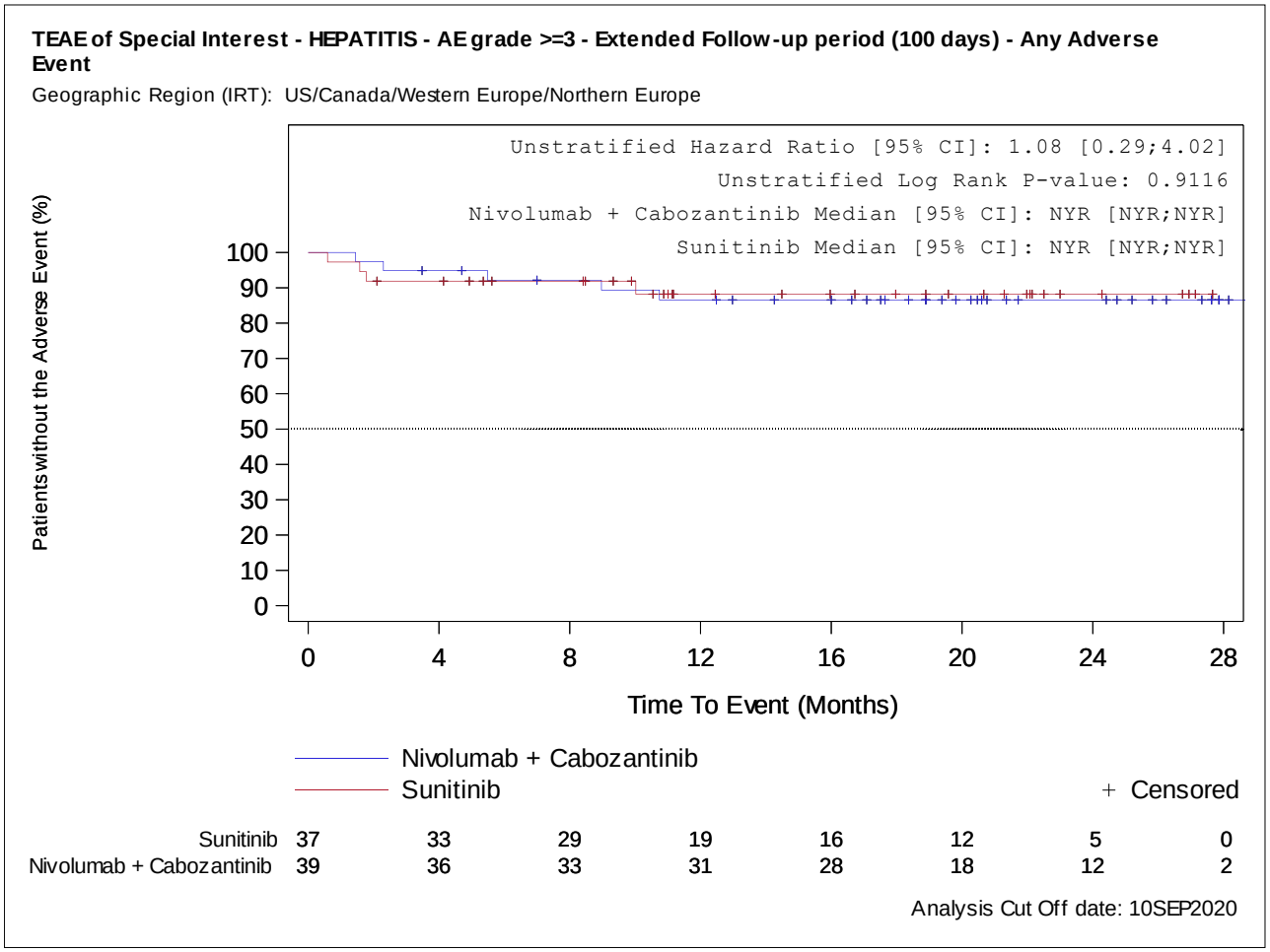

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:19:39

FIGURE 3.80.2.5: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:19:45

FIGURE 3.80.2.6: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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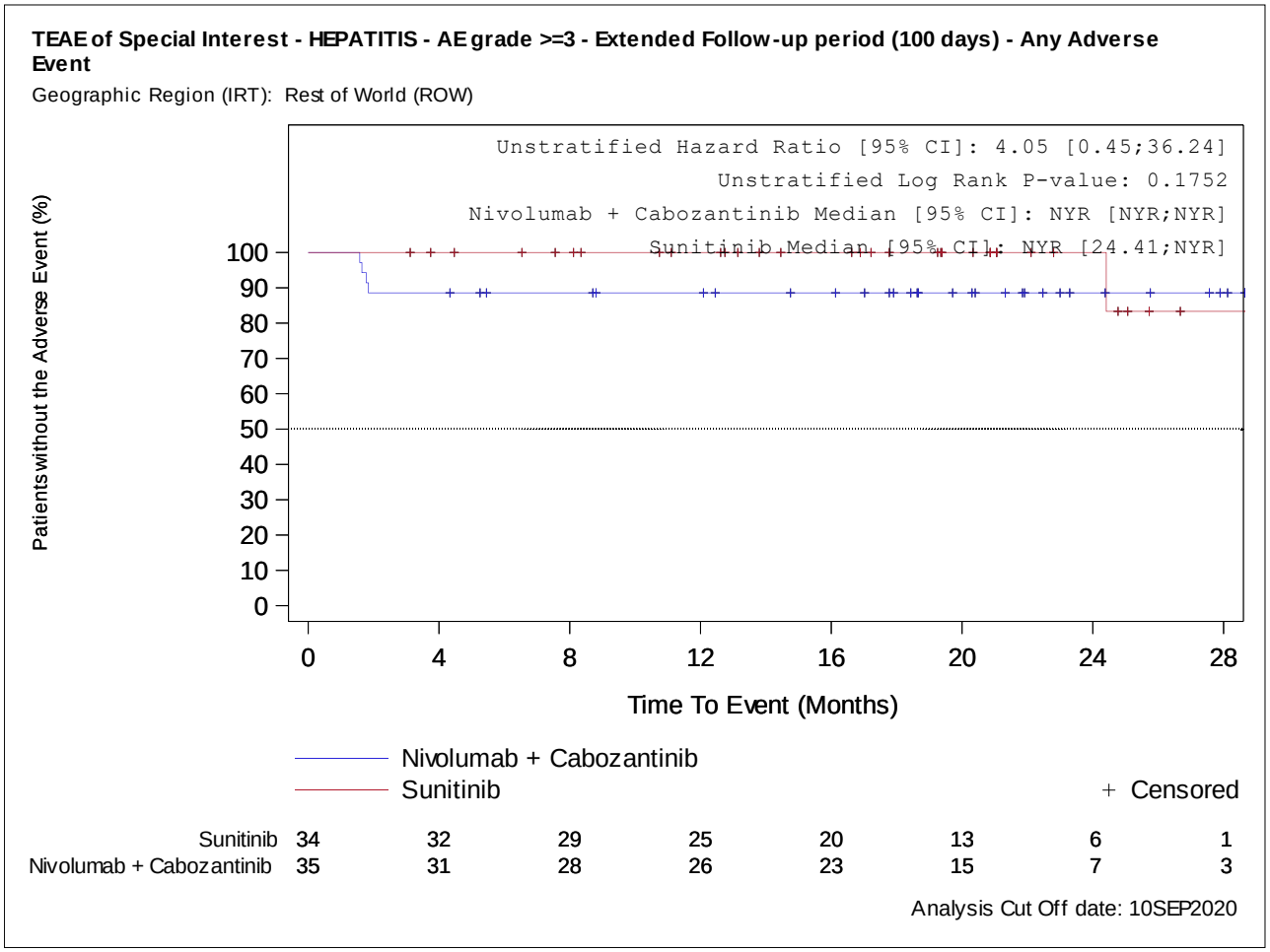
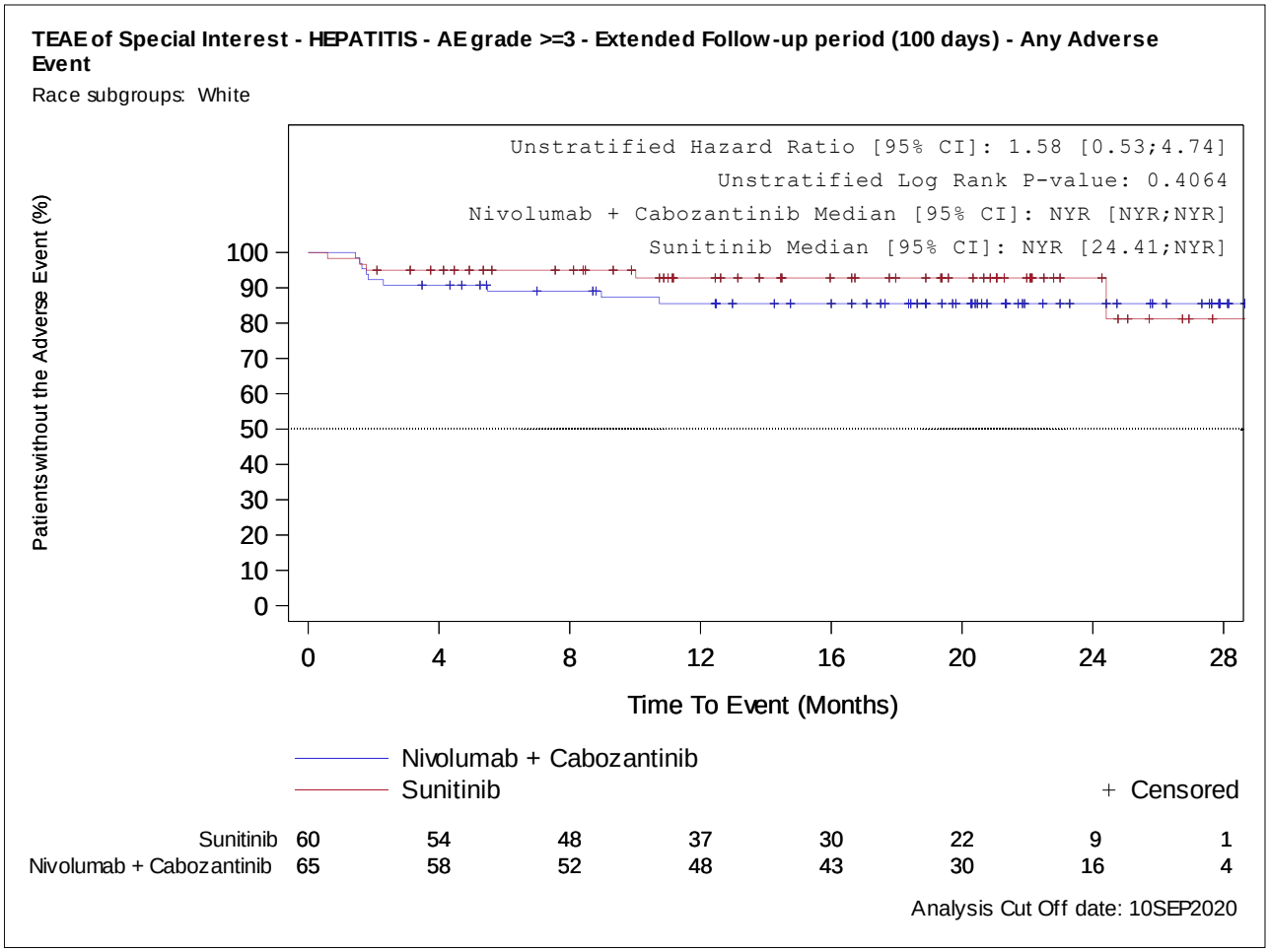
FIGURE 3.80.2.7: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:19:56

FIGURE 3.80.2.8: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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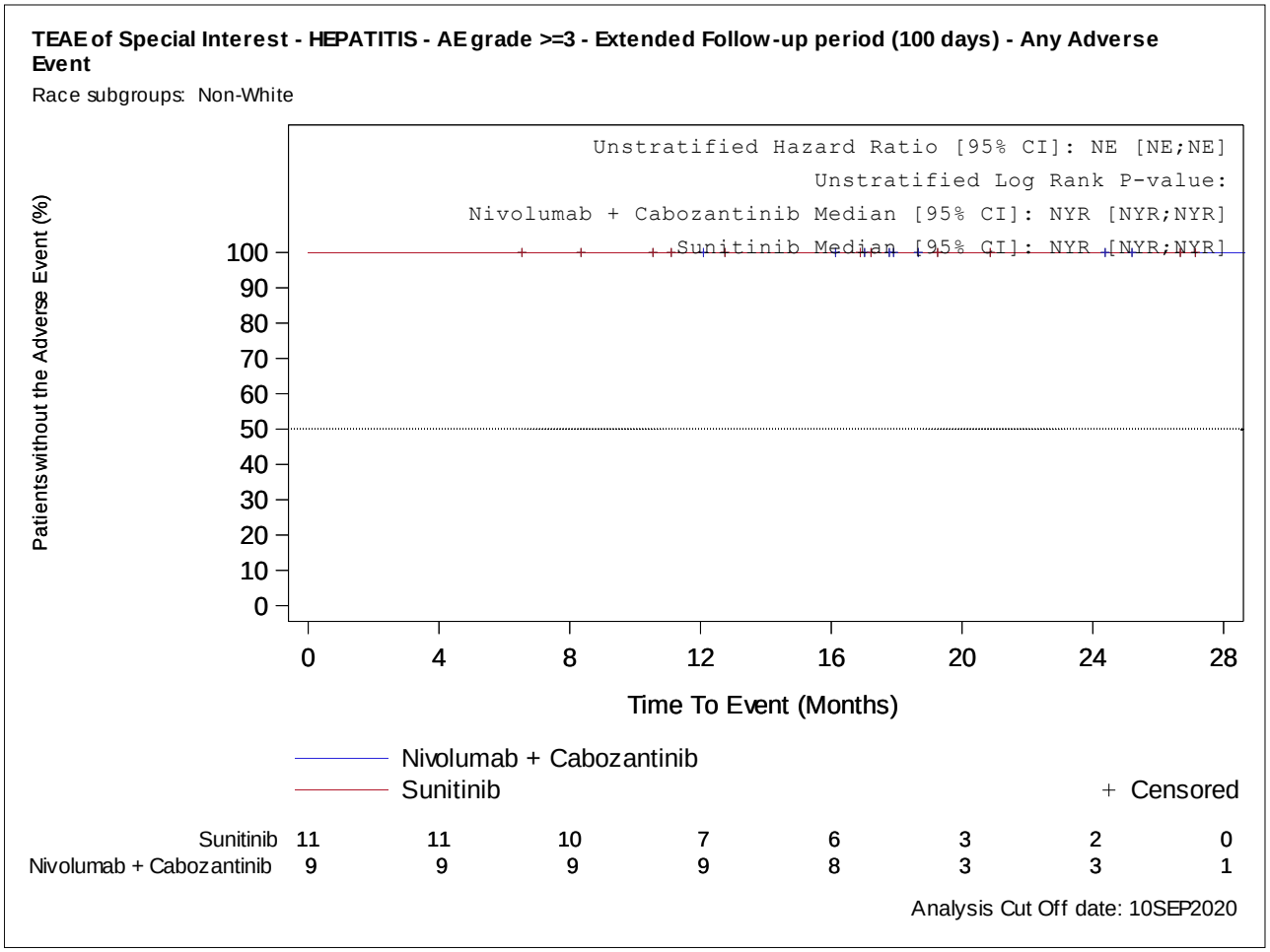
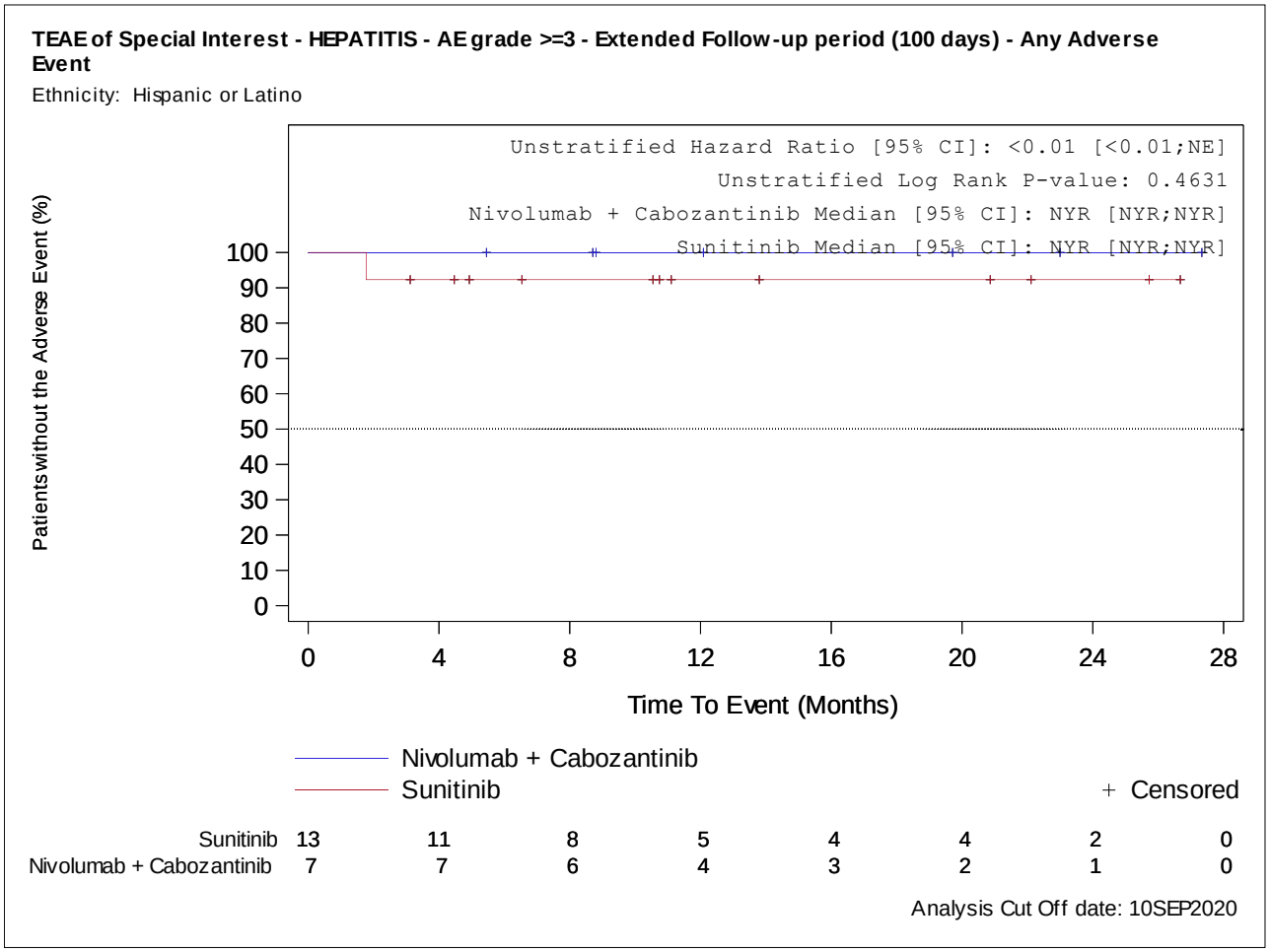
FIGURE 3.80.2.9: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



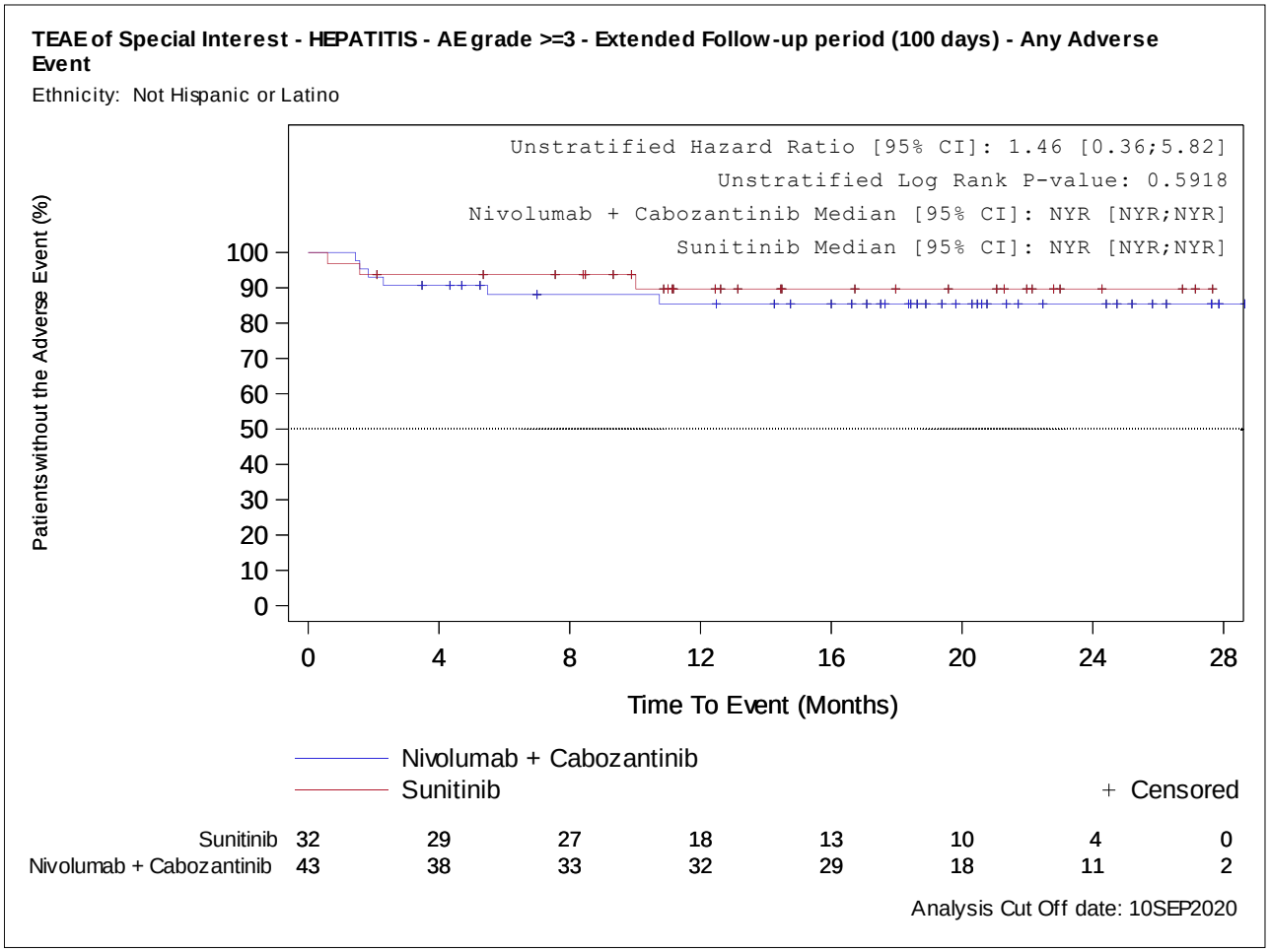

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:20:08

FIGURE 3.80.2.10: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



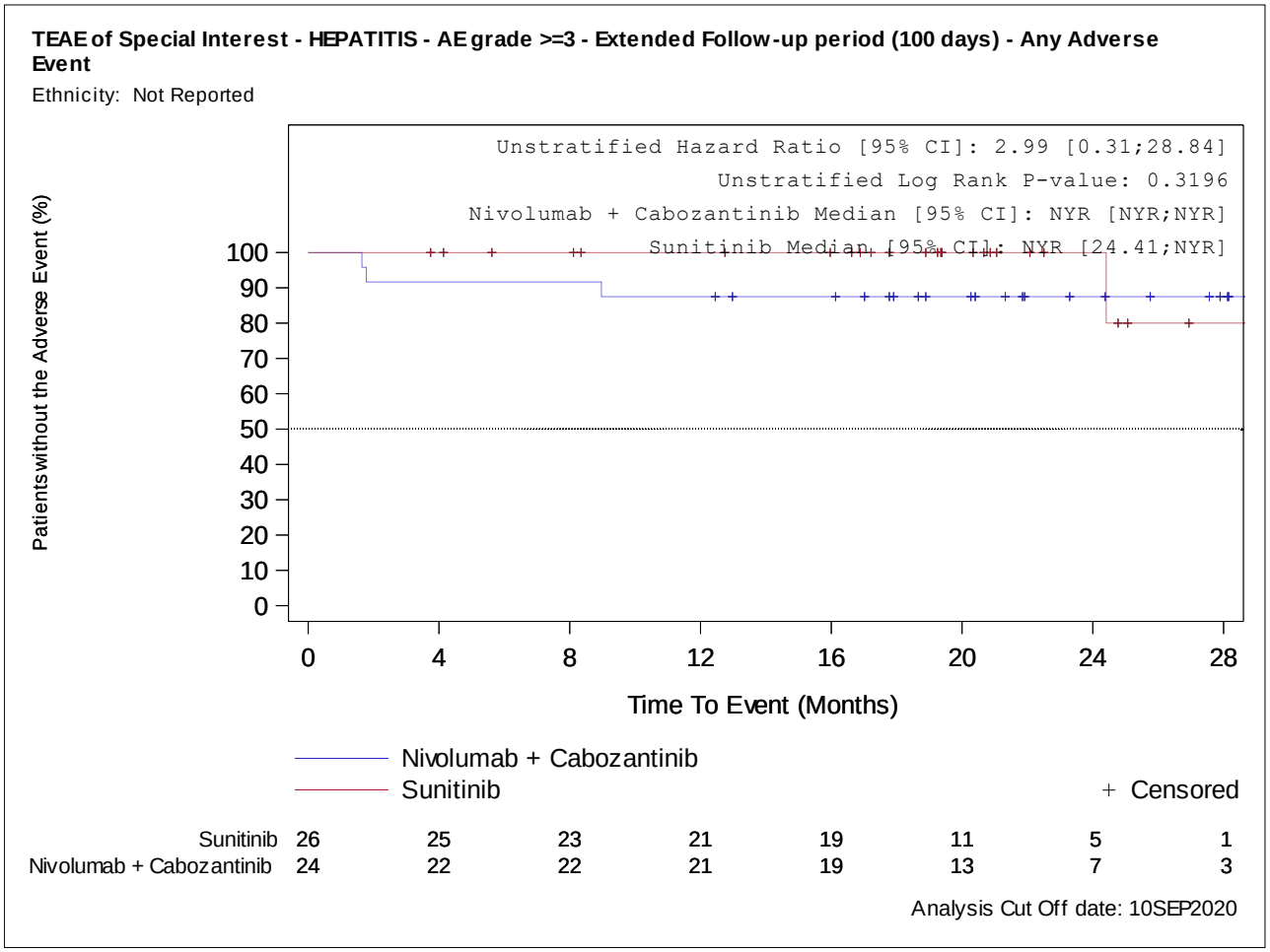

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:20:14

FIGURE 3.80.2.11: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



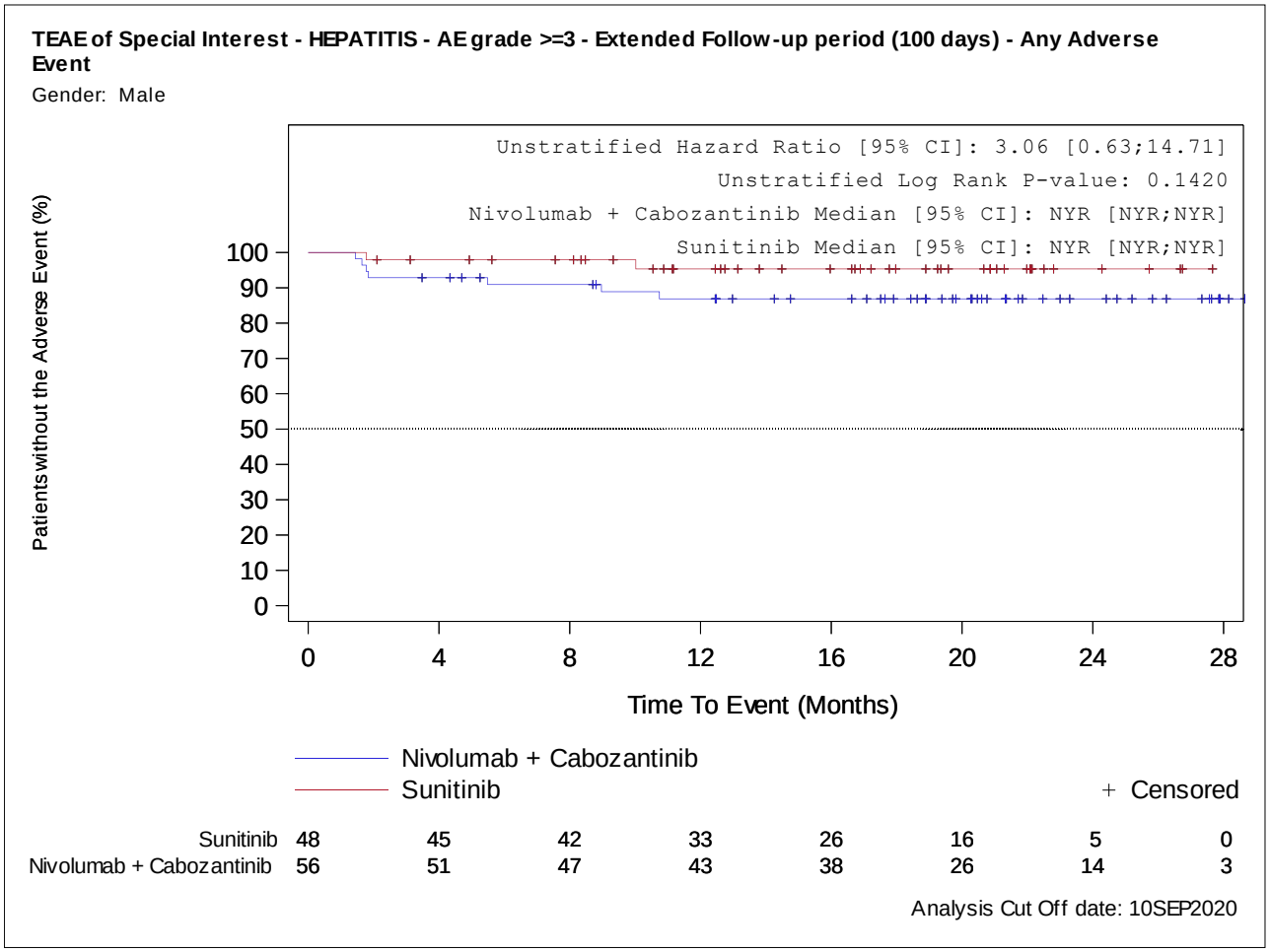

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:20:20

FIGURE 3.80.2.12: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



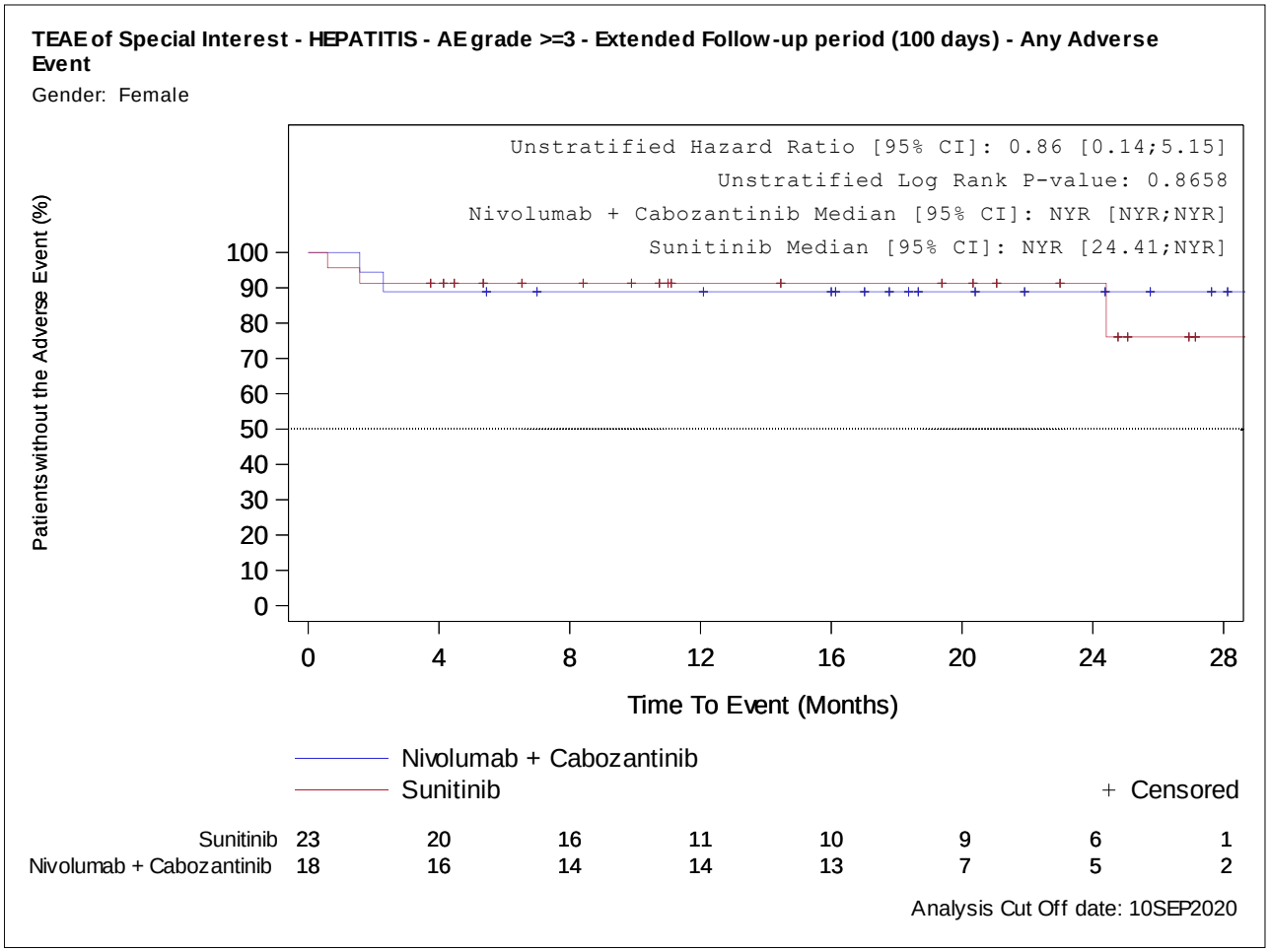

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:20:26

FIGURE 3.80.2.13: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:20:32

FIGURE 3.80.2.14: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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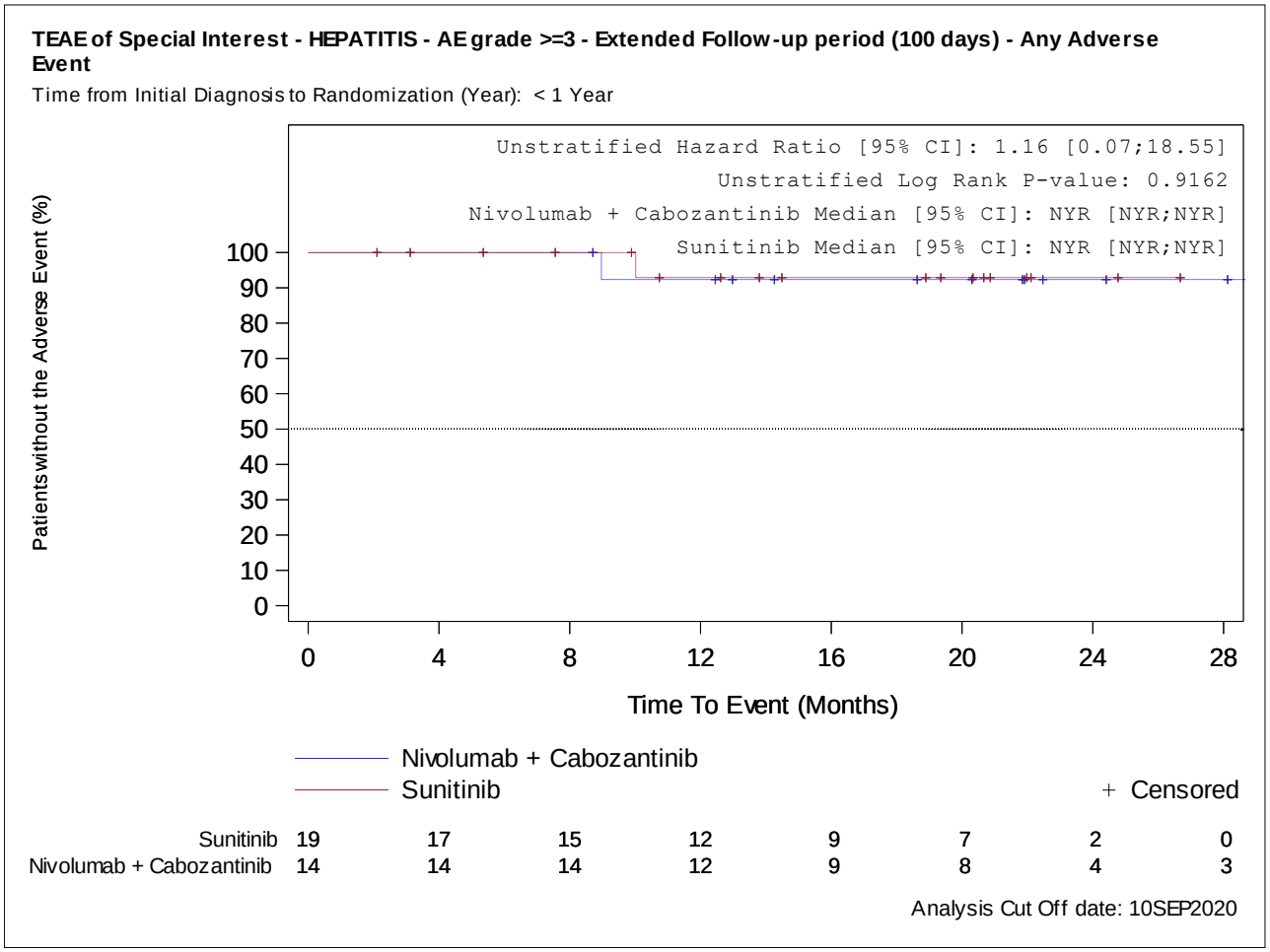
FIGURE 3.80.2.15: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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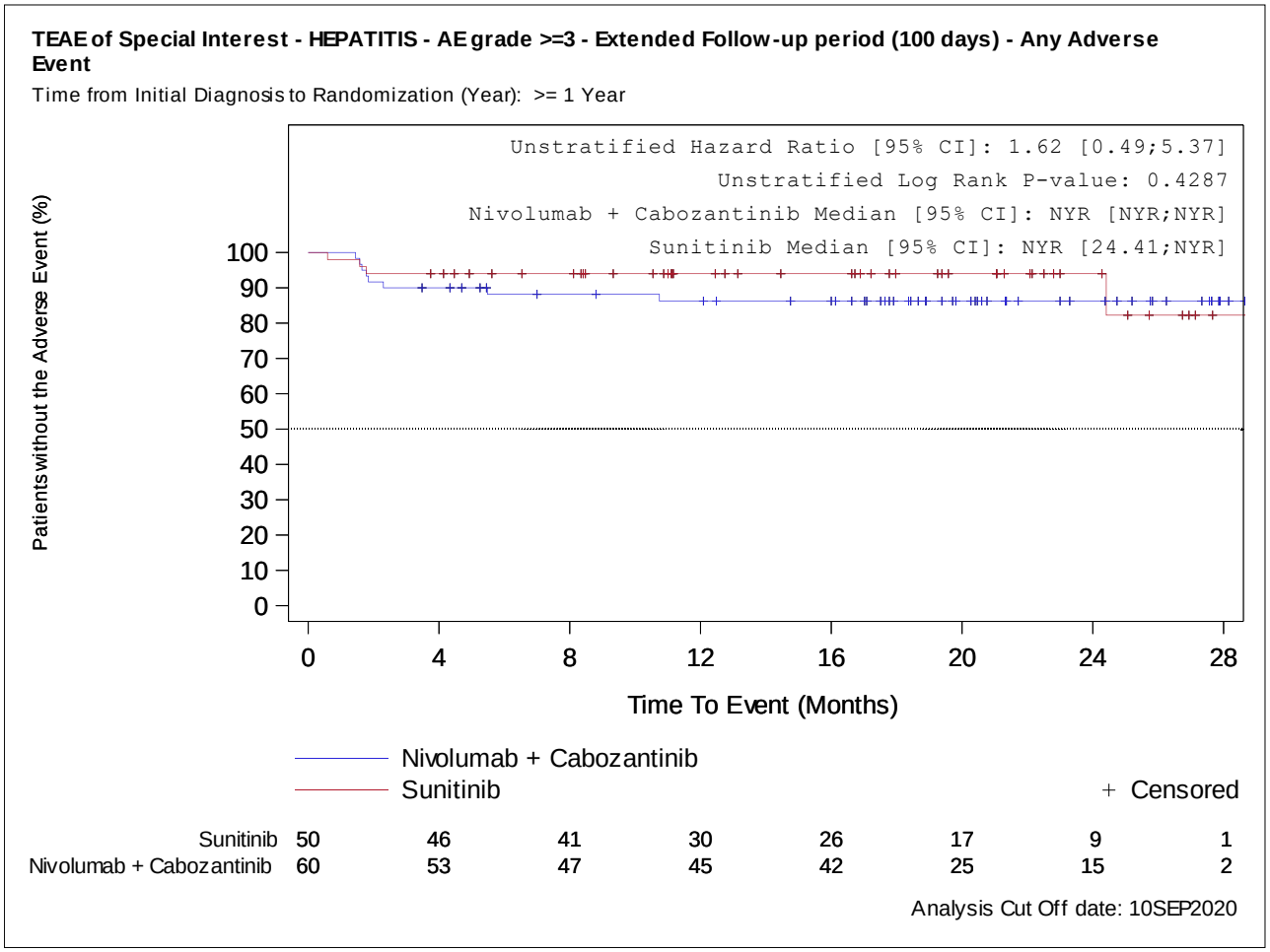
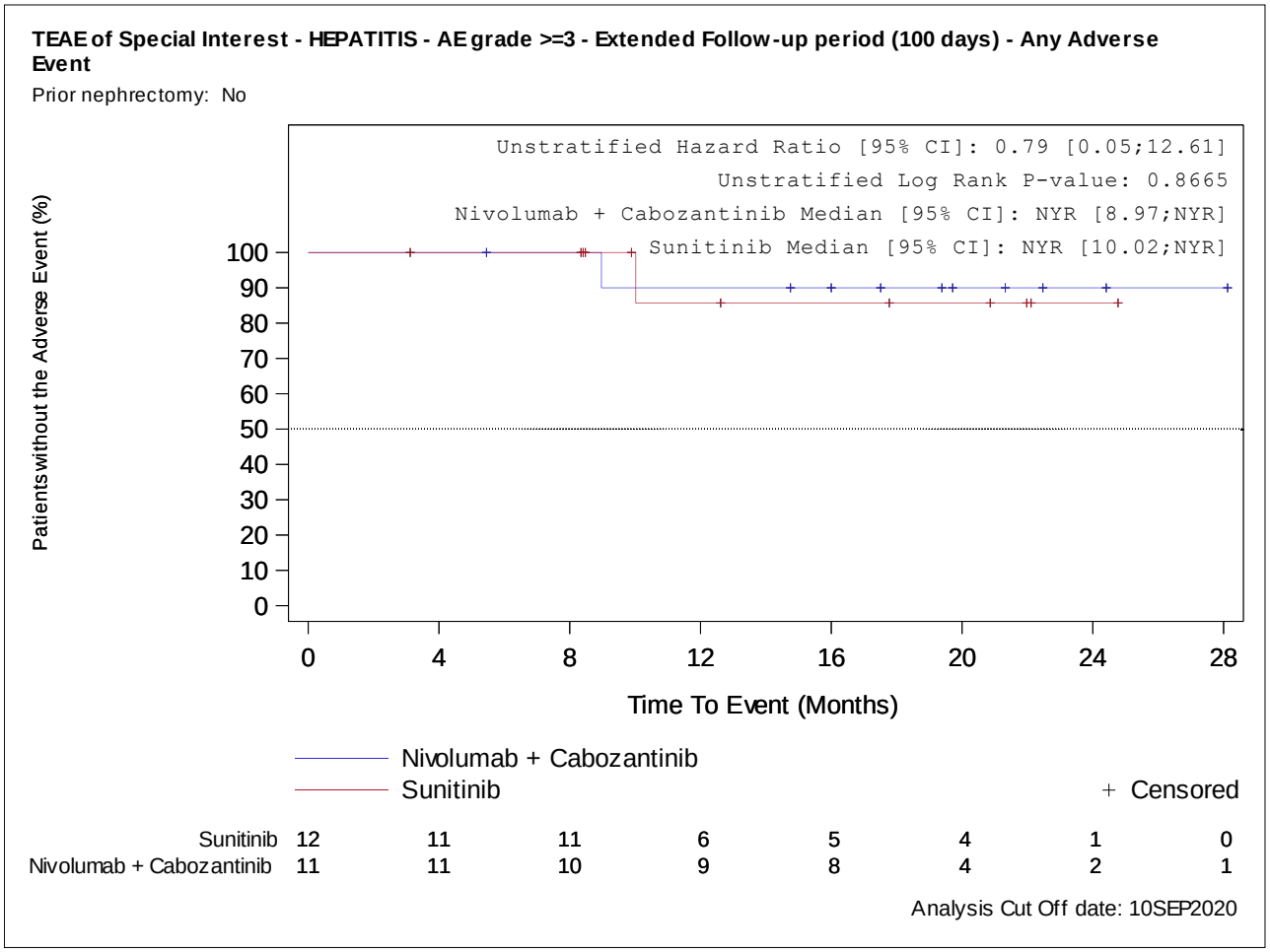
FIGURE 3.80.2.16: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



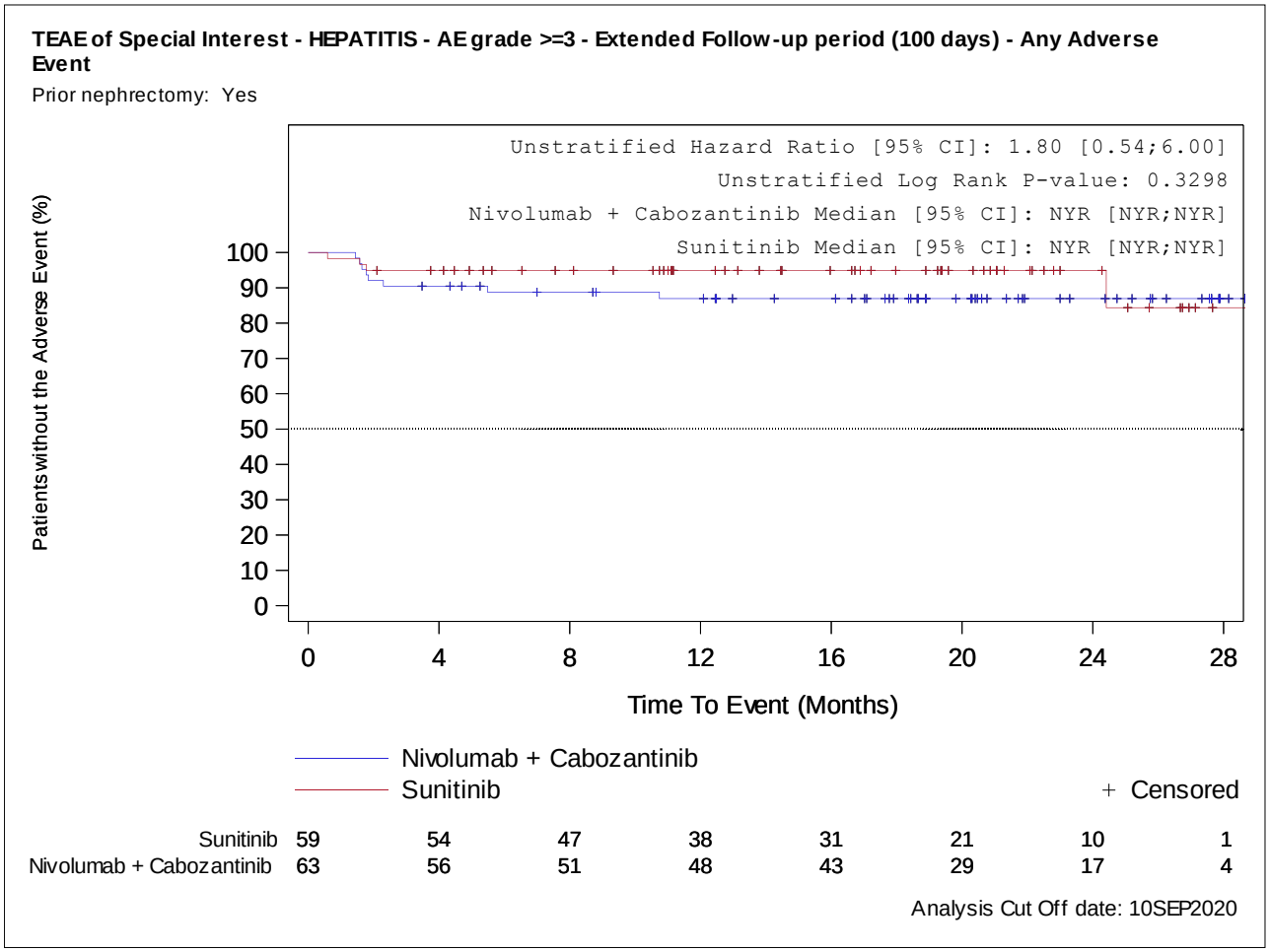

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:21:01

FIGURE 3.80.2.17: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



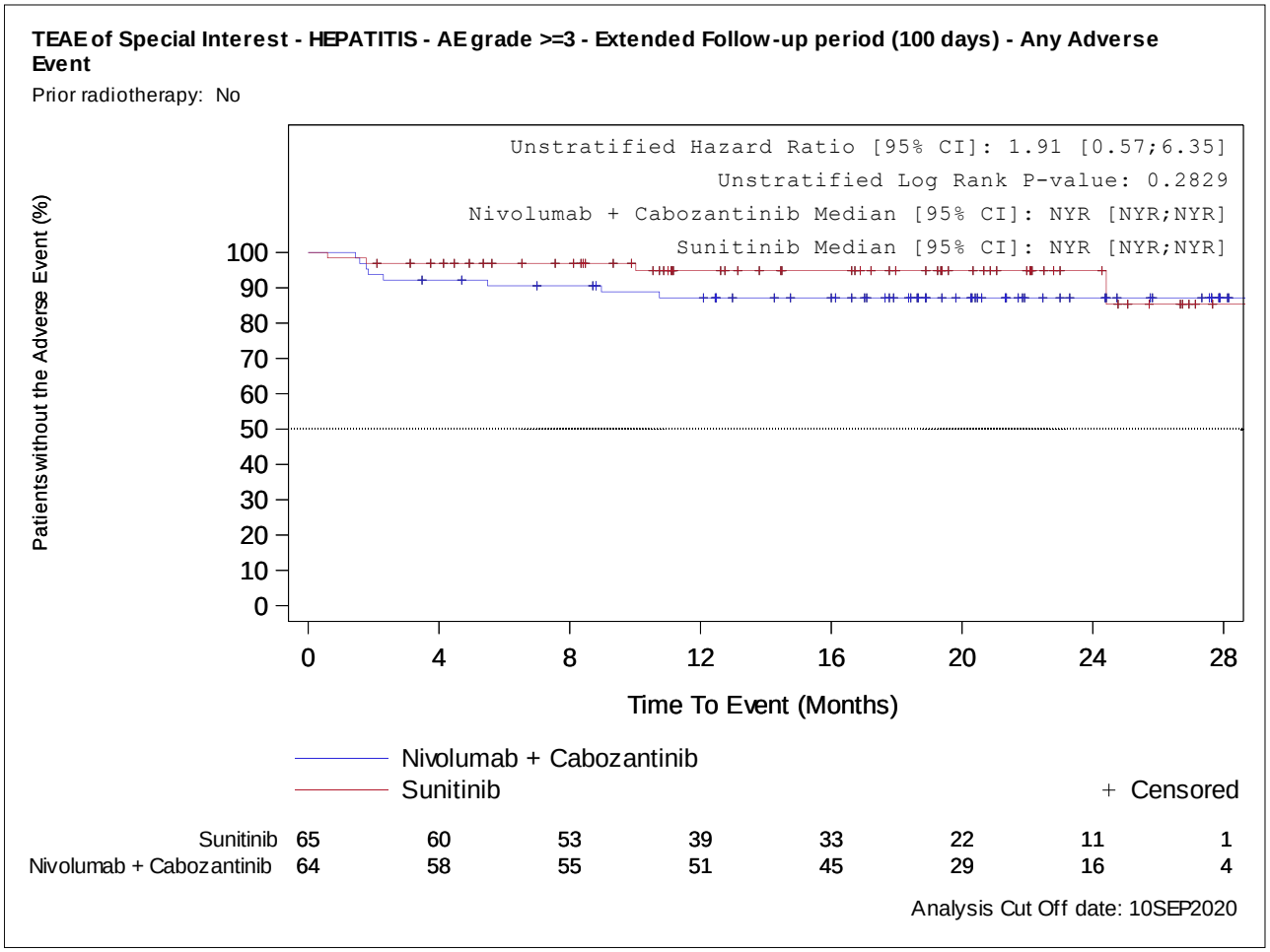

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:21:55

FIGURE 3.80.2.18: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:22:00

FIGURE 3.80.2.19: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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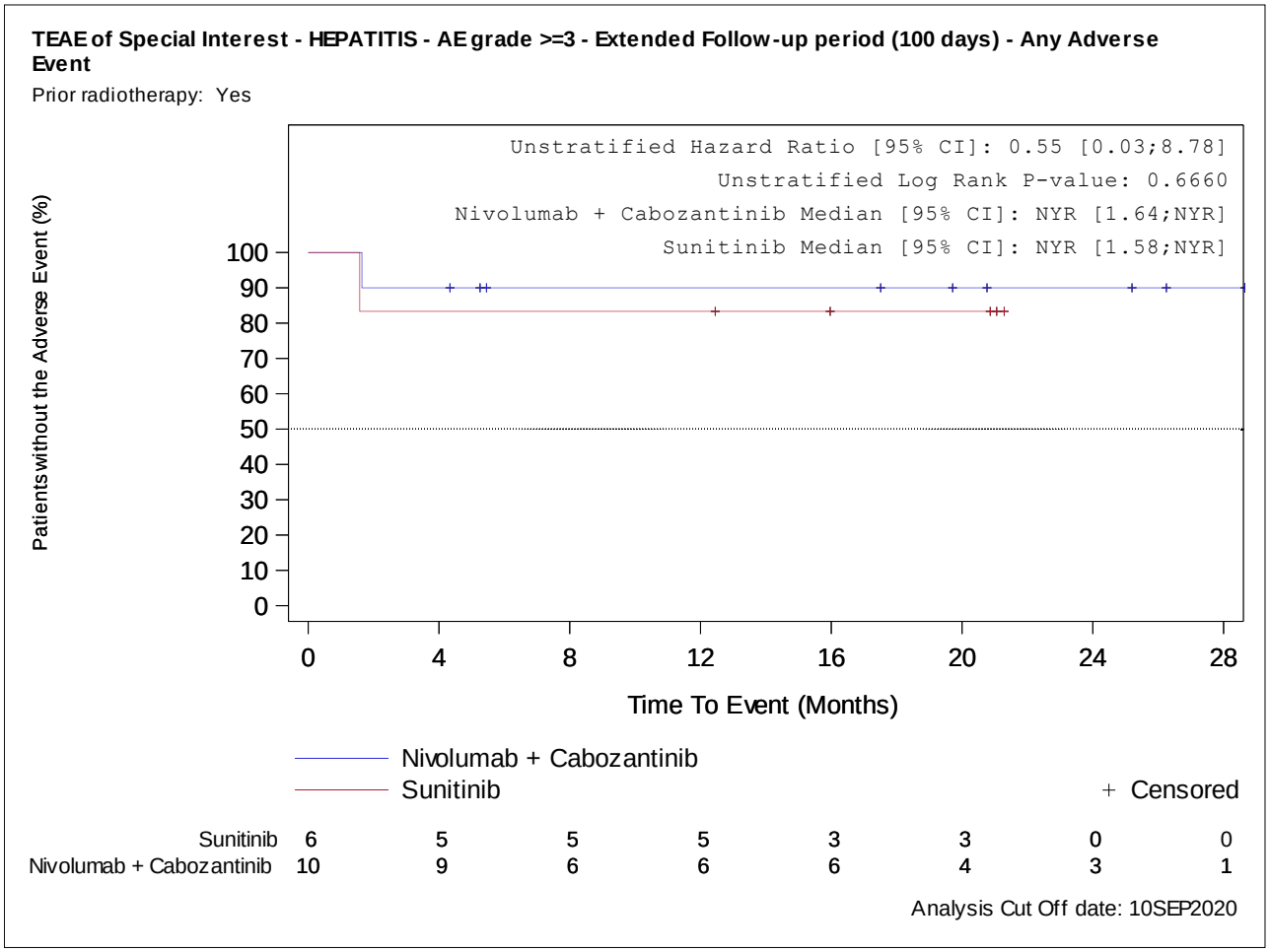
FIGURE 3.80.2.20: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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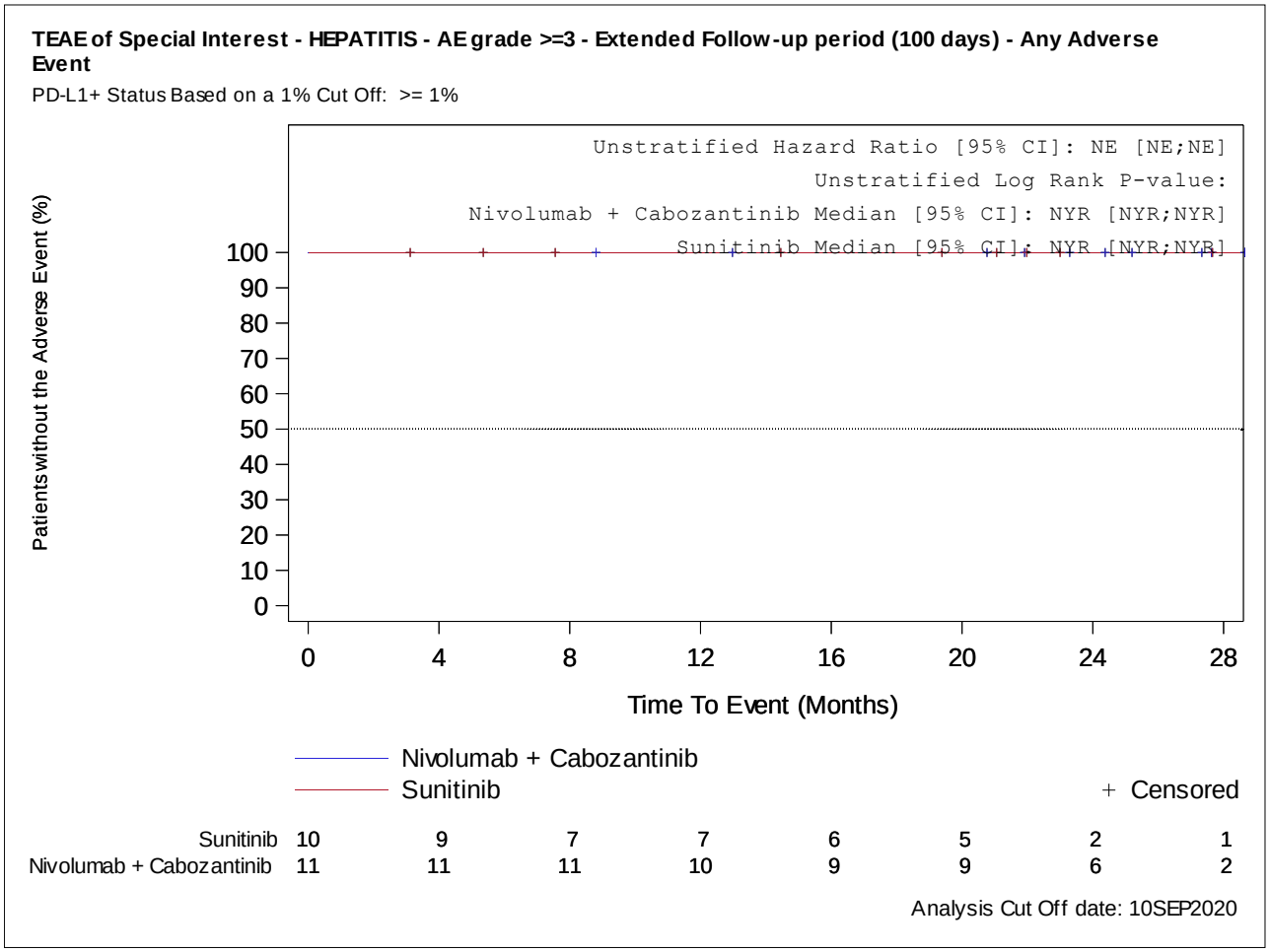
FIGURE 3.80.2.21: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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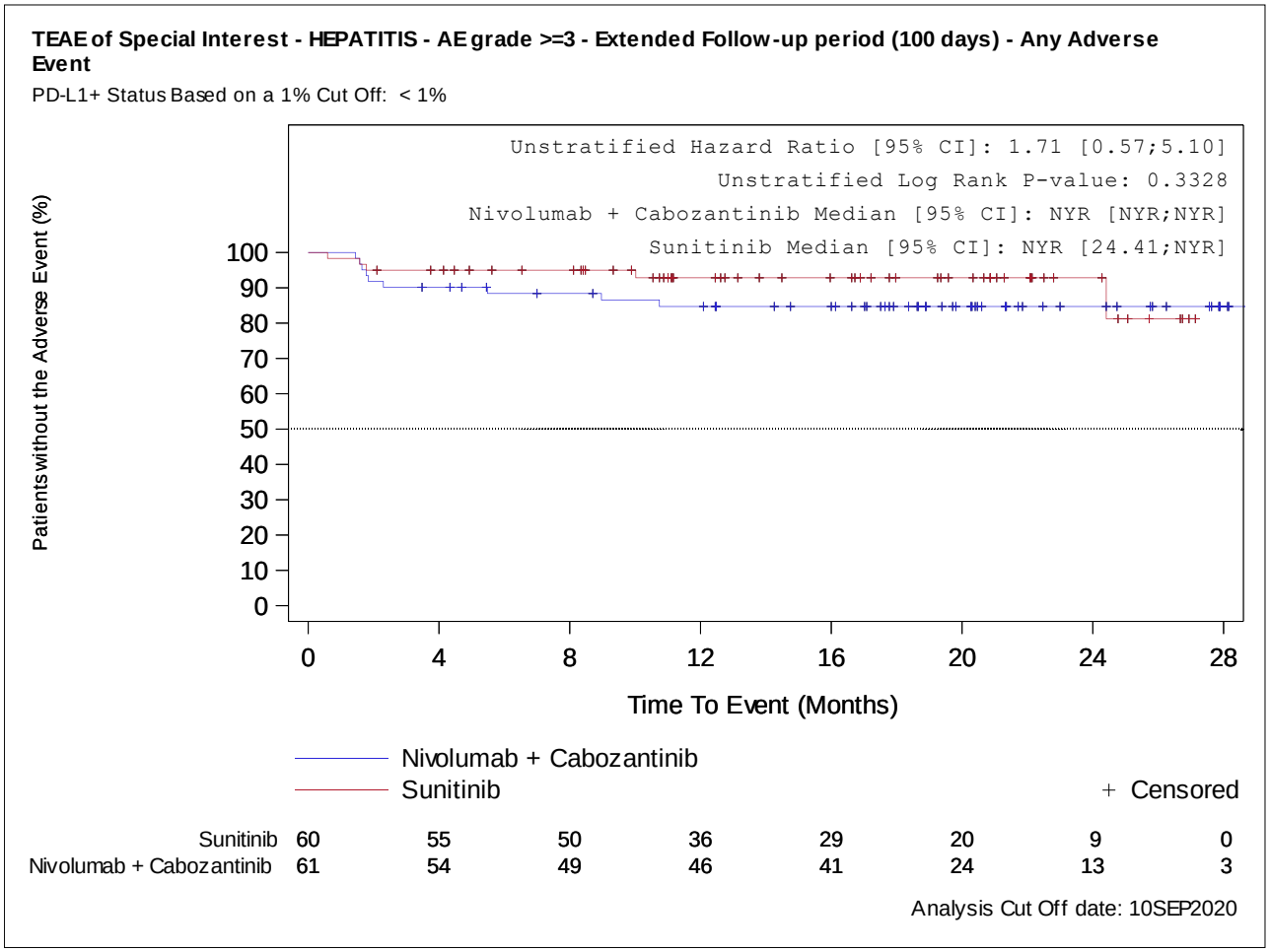
FIGURE 3.80.2.22: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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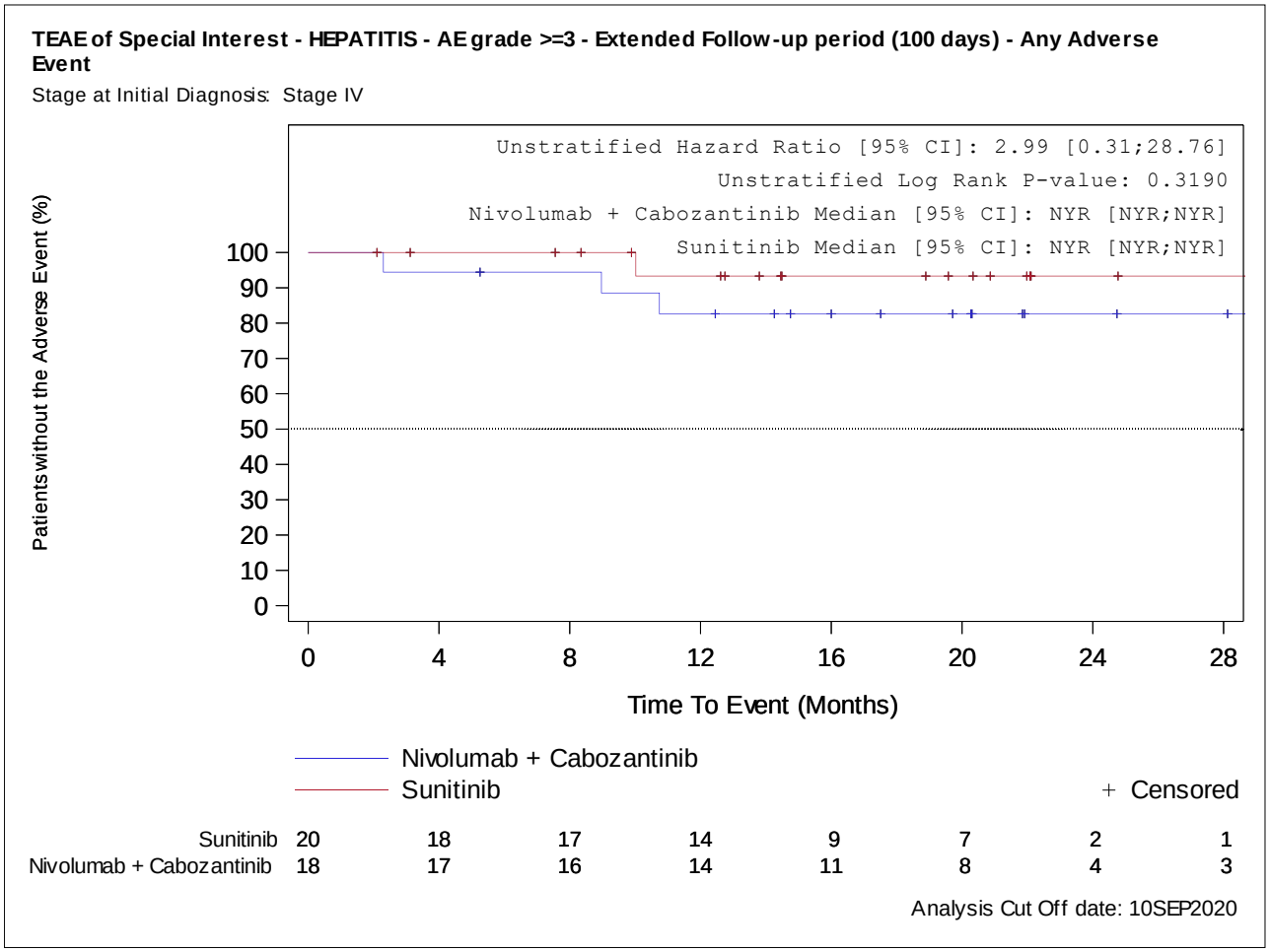
FIGURE 3.80.2.23: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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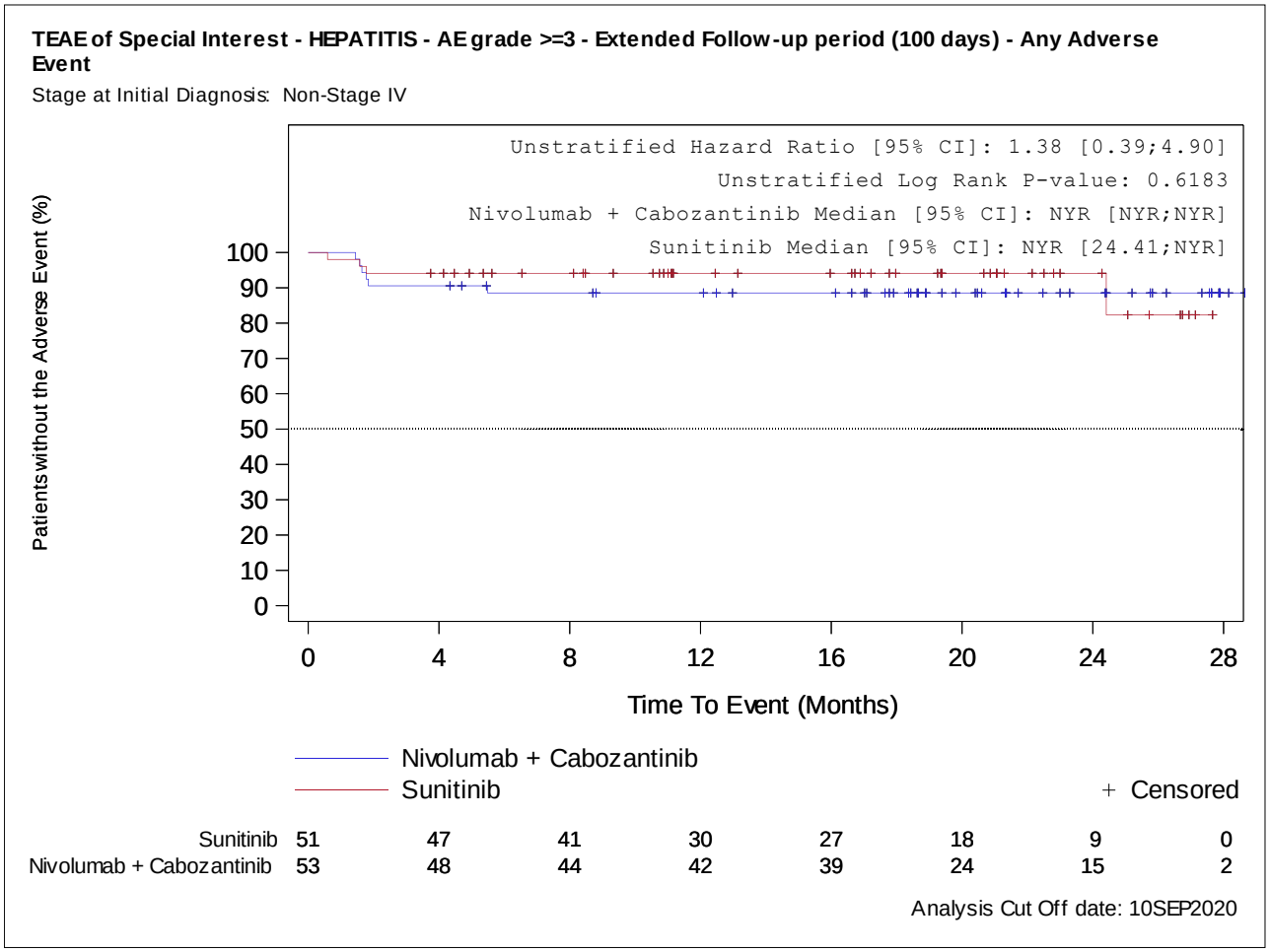
FIGURE 3.80.2.24: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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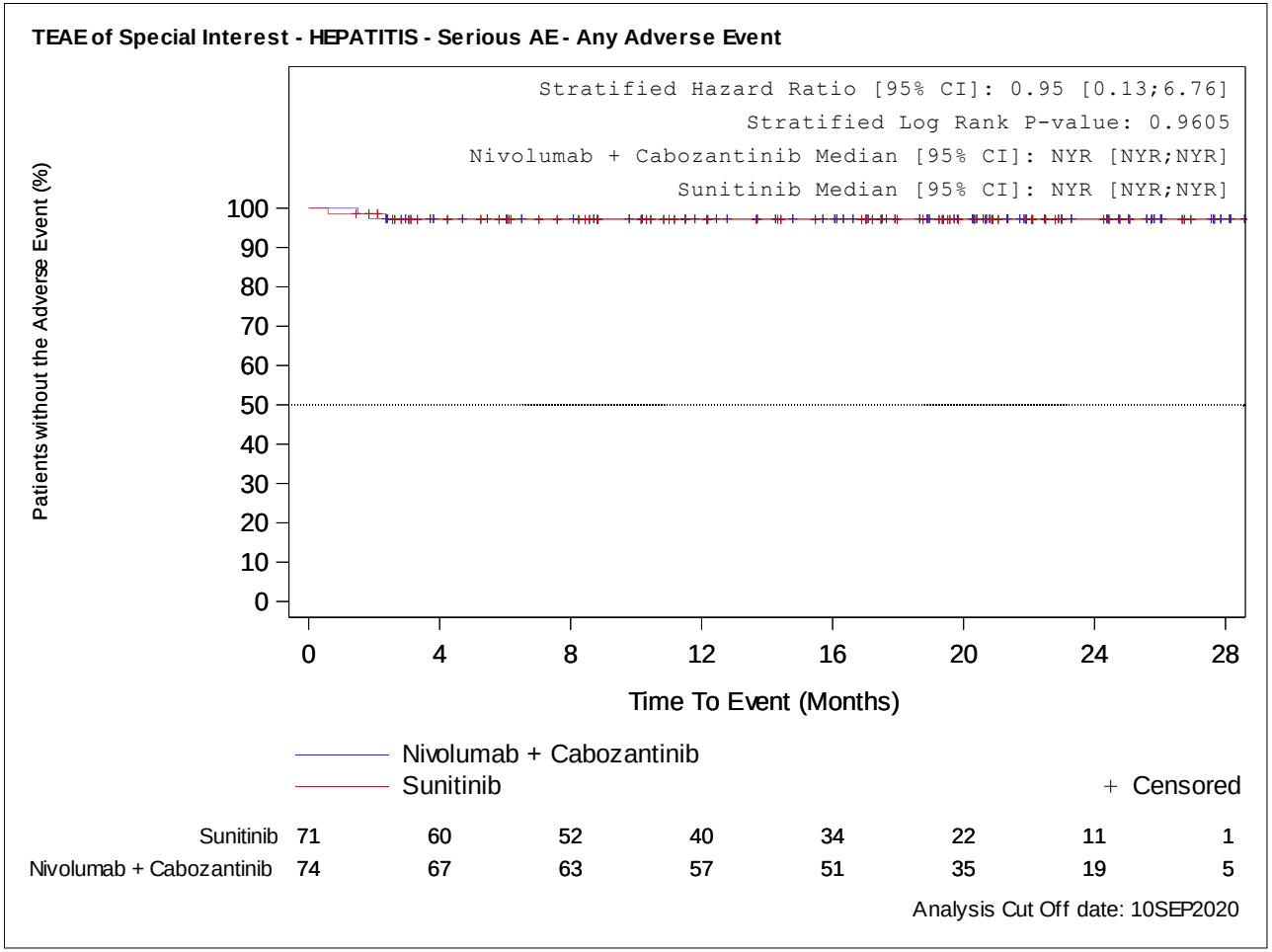
FIGURE 3.81.1: TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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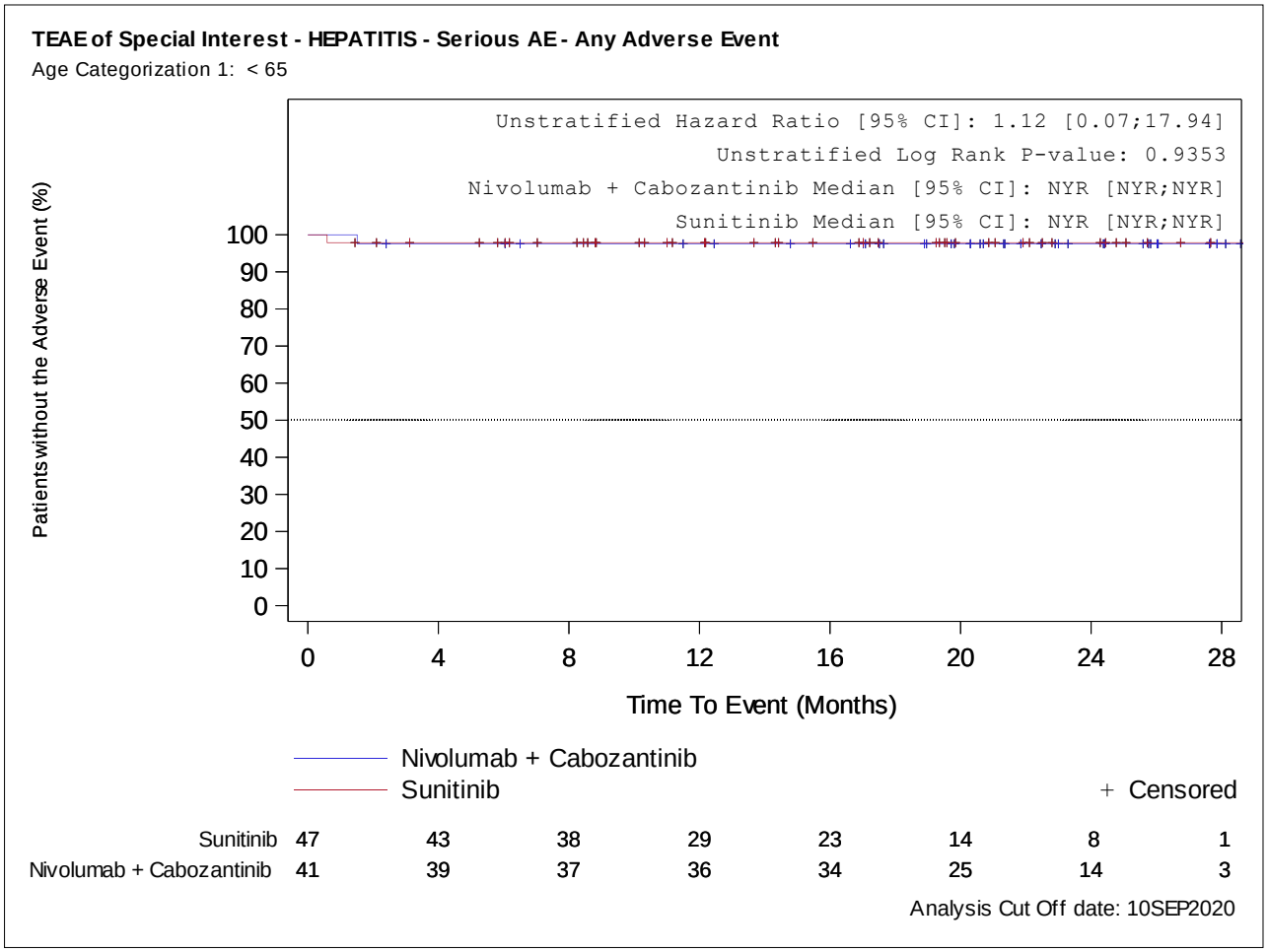
FIGURE 3.81.2.1: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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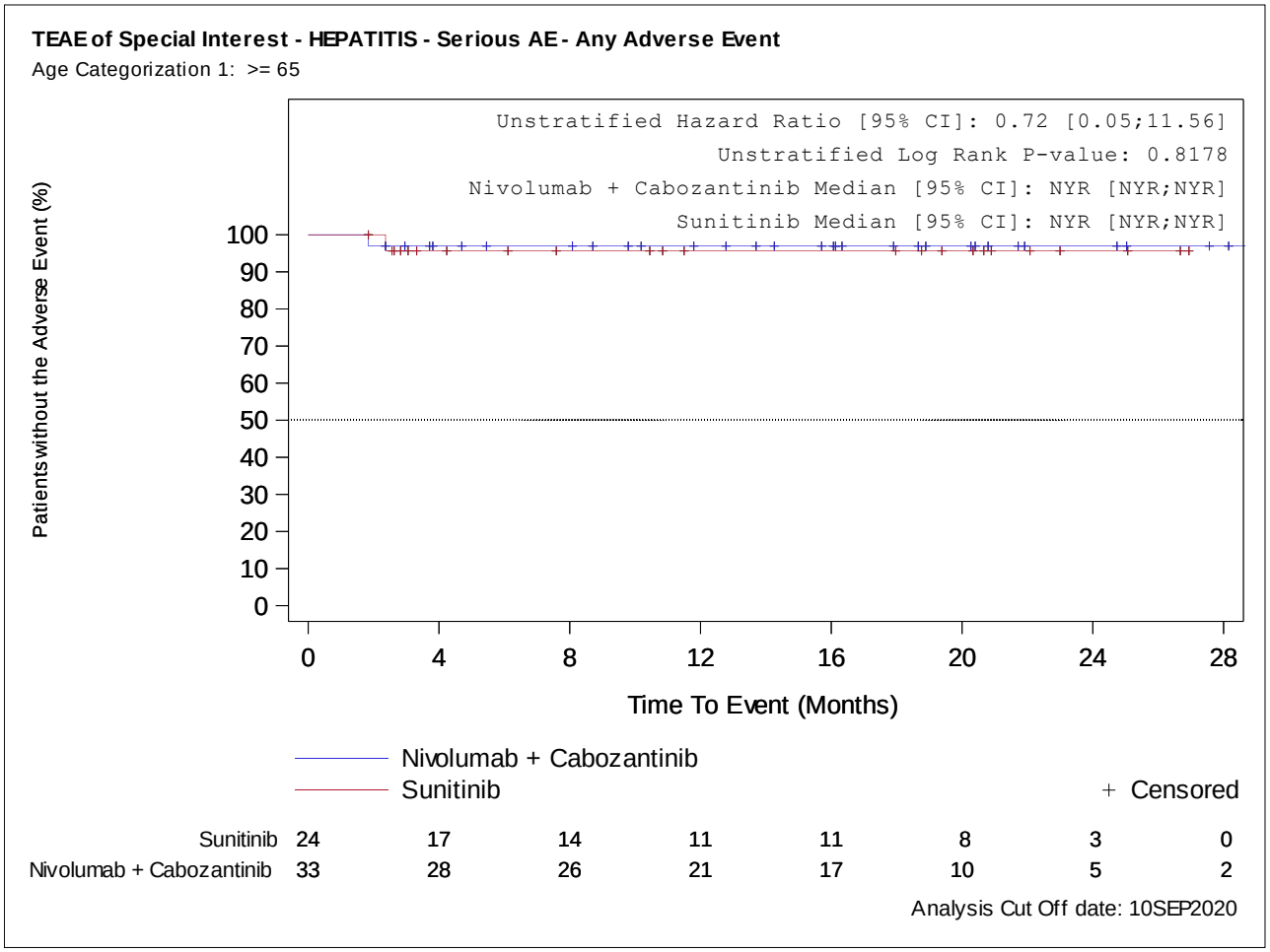
FIGURE 3.81.2.2: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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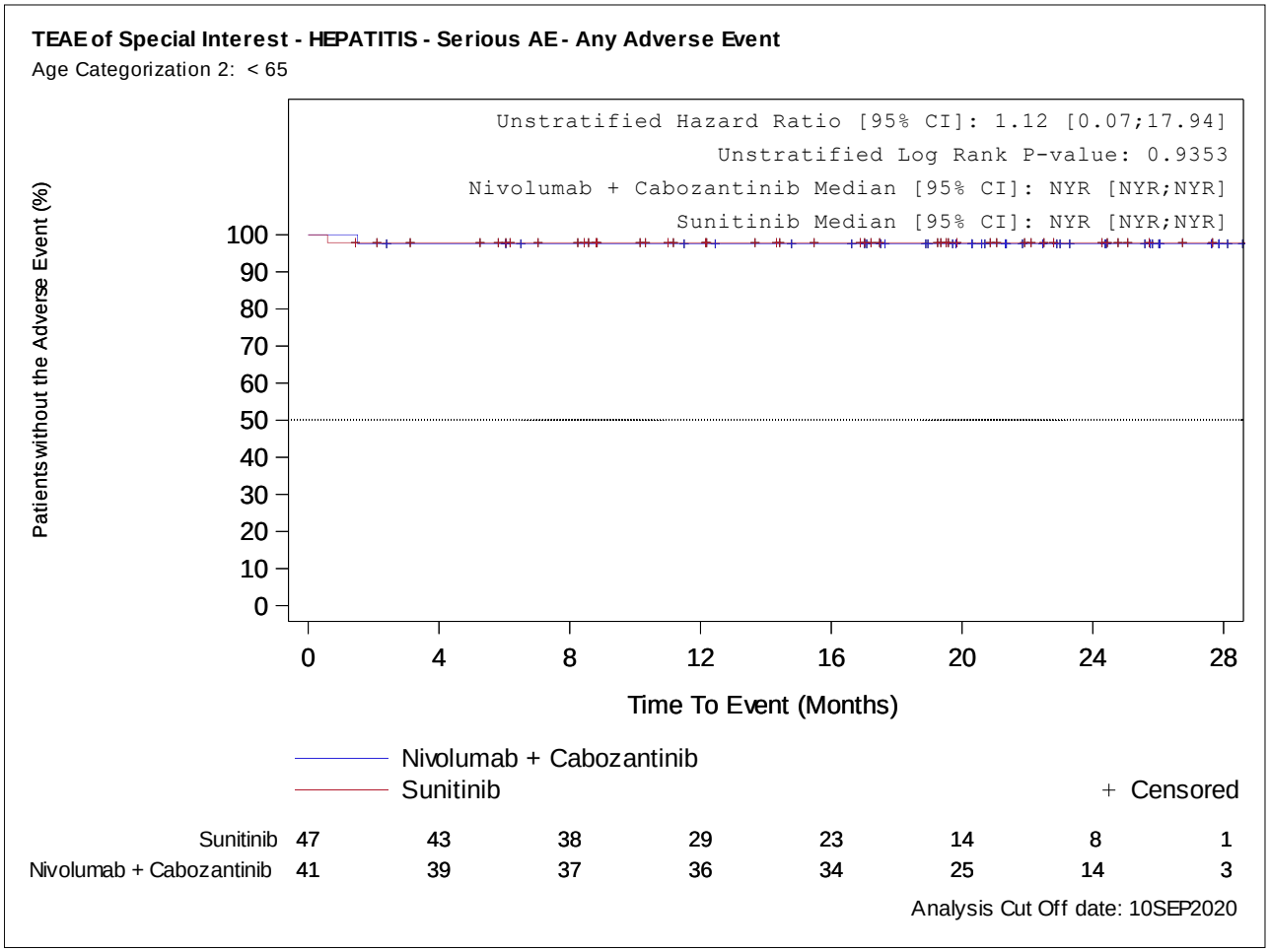
FIGURE 3.81.2.3: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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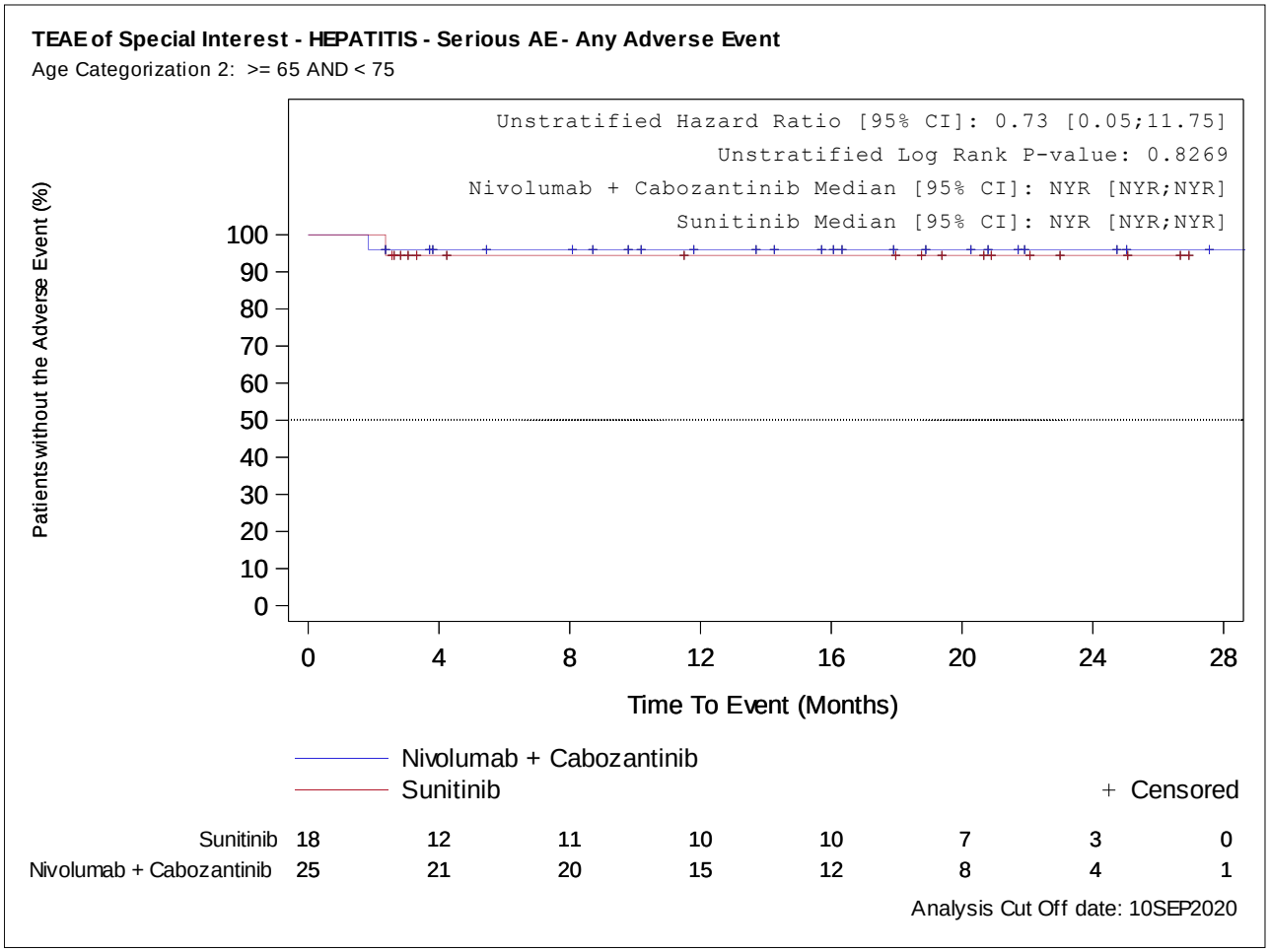
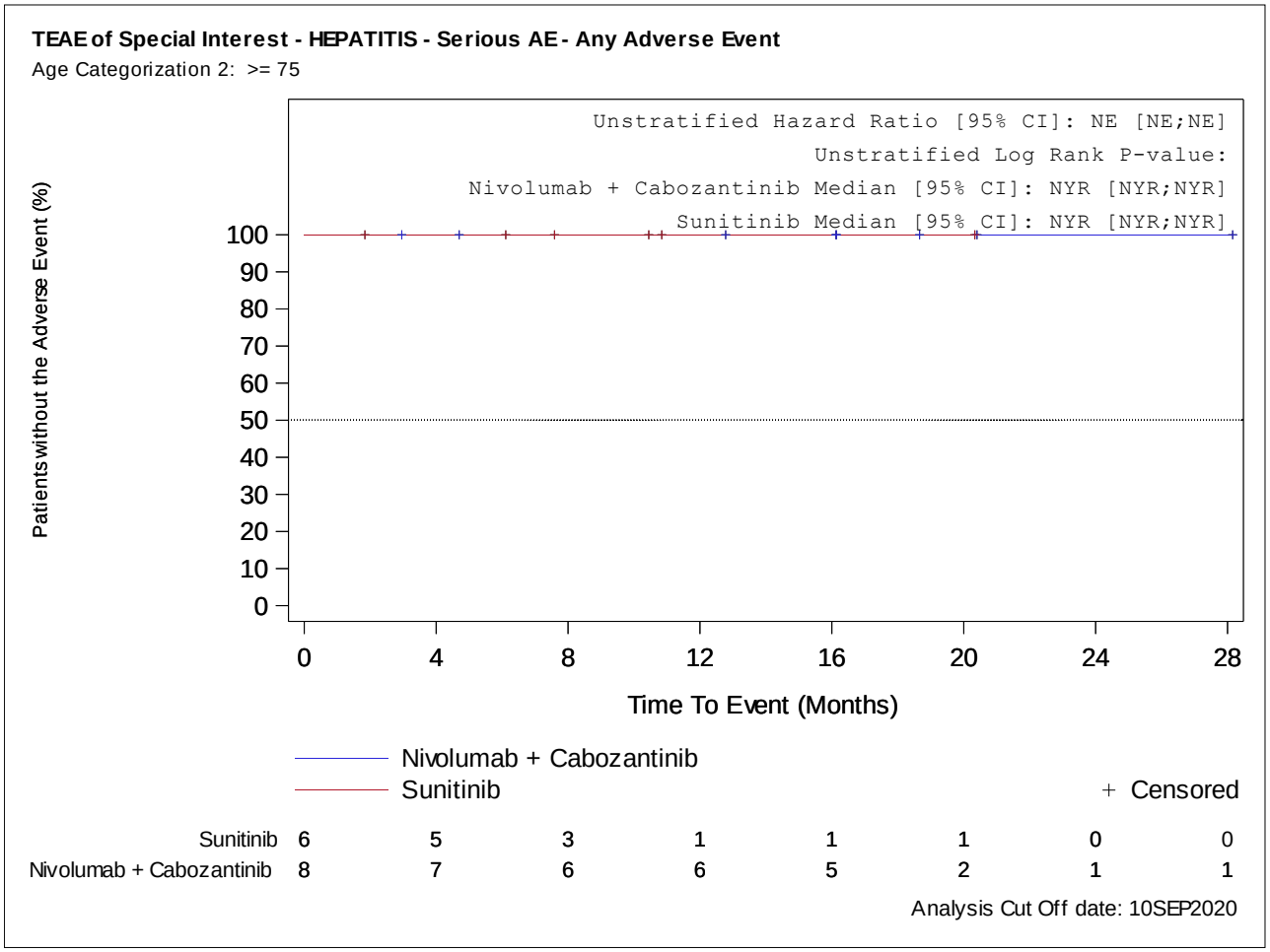
FIGURE 3.81.2.4: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



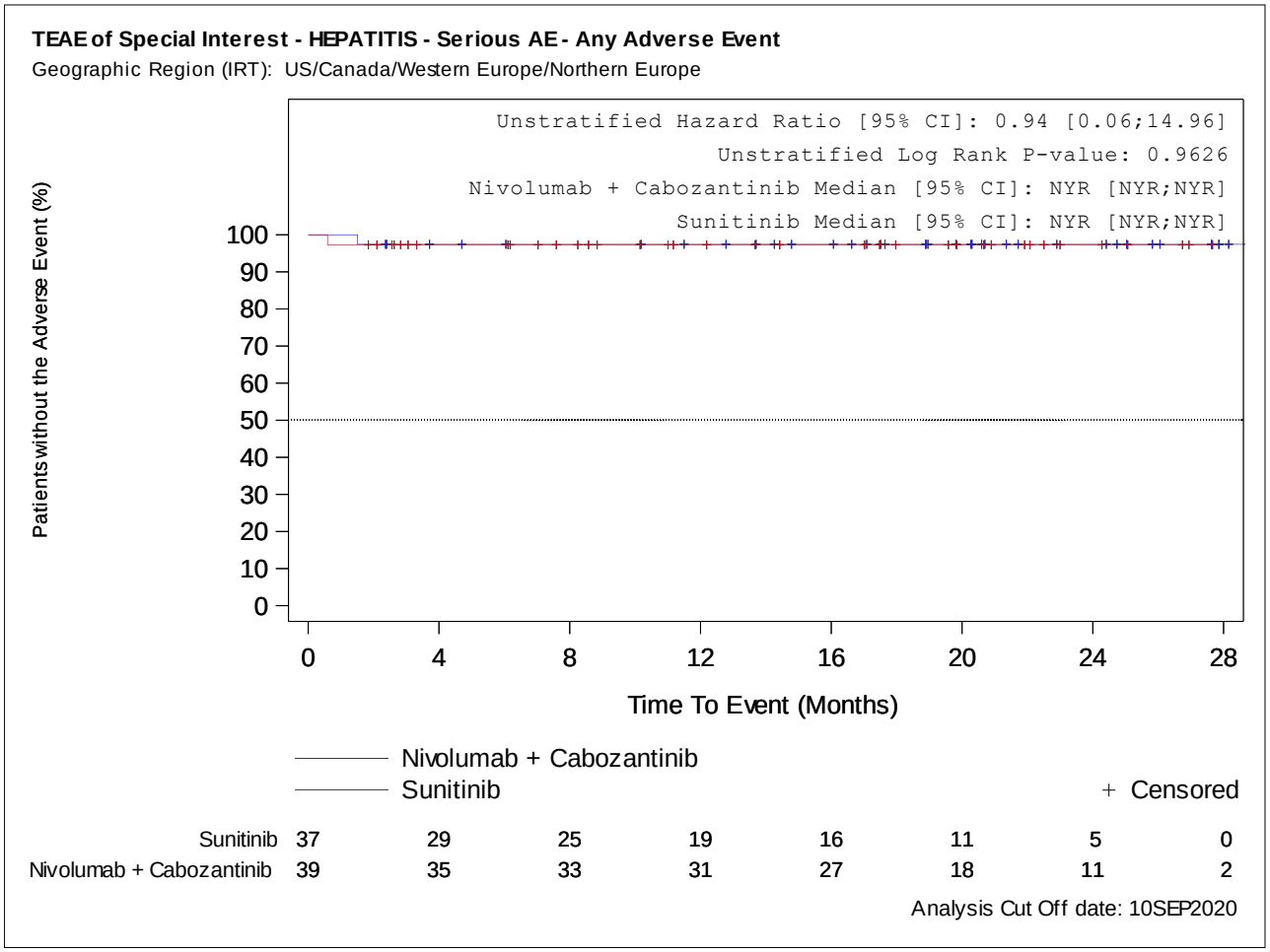

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:26:38

FIGURE 3.81.2.5: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:26:44

FIGURE 3.81.2.6: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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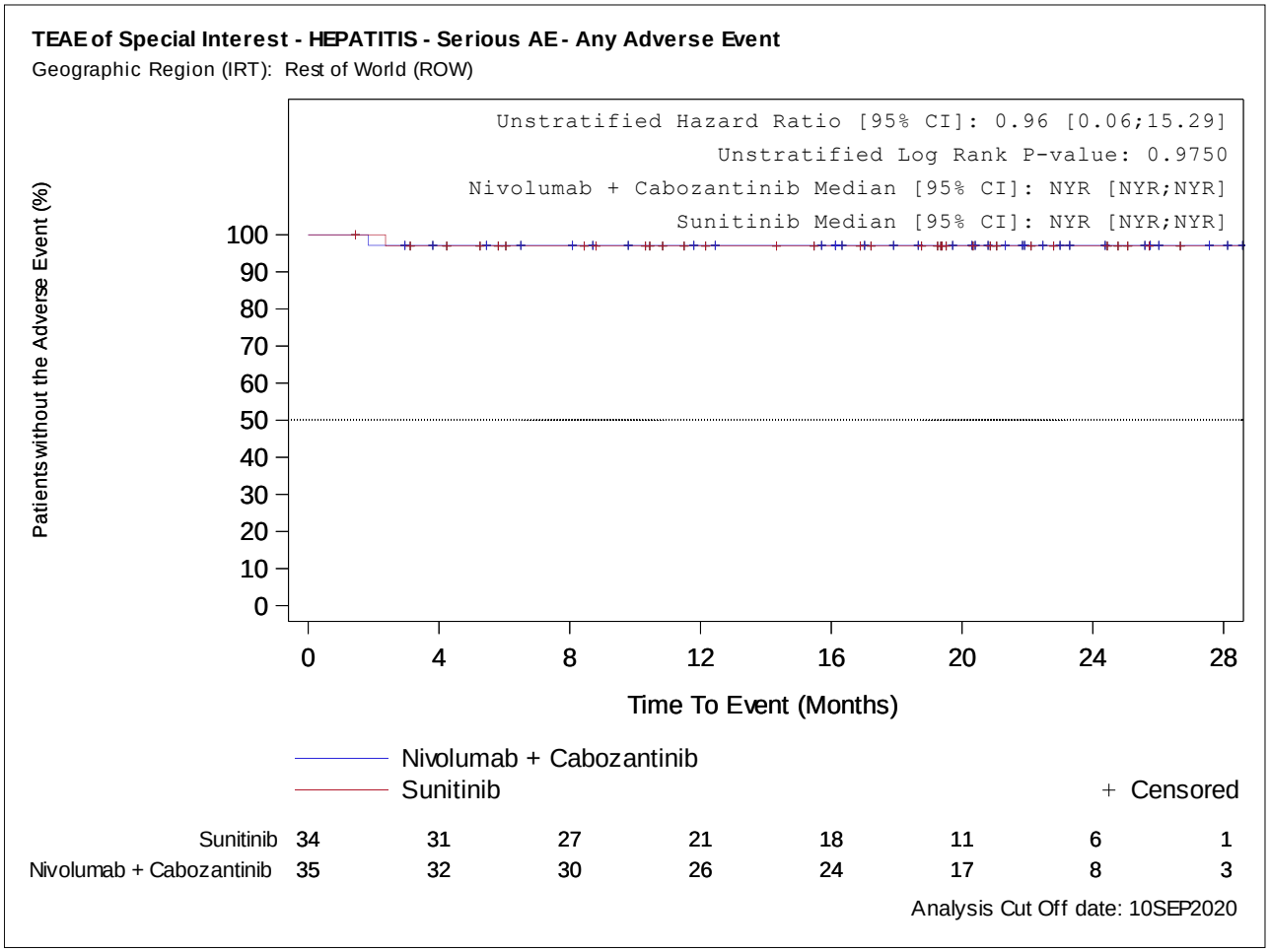
FIGURE 3.81.2.7: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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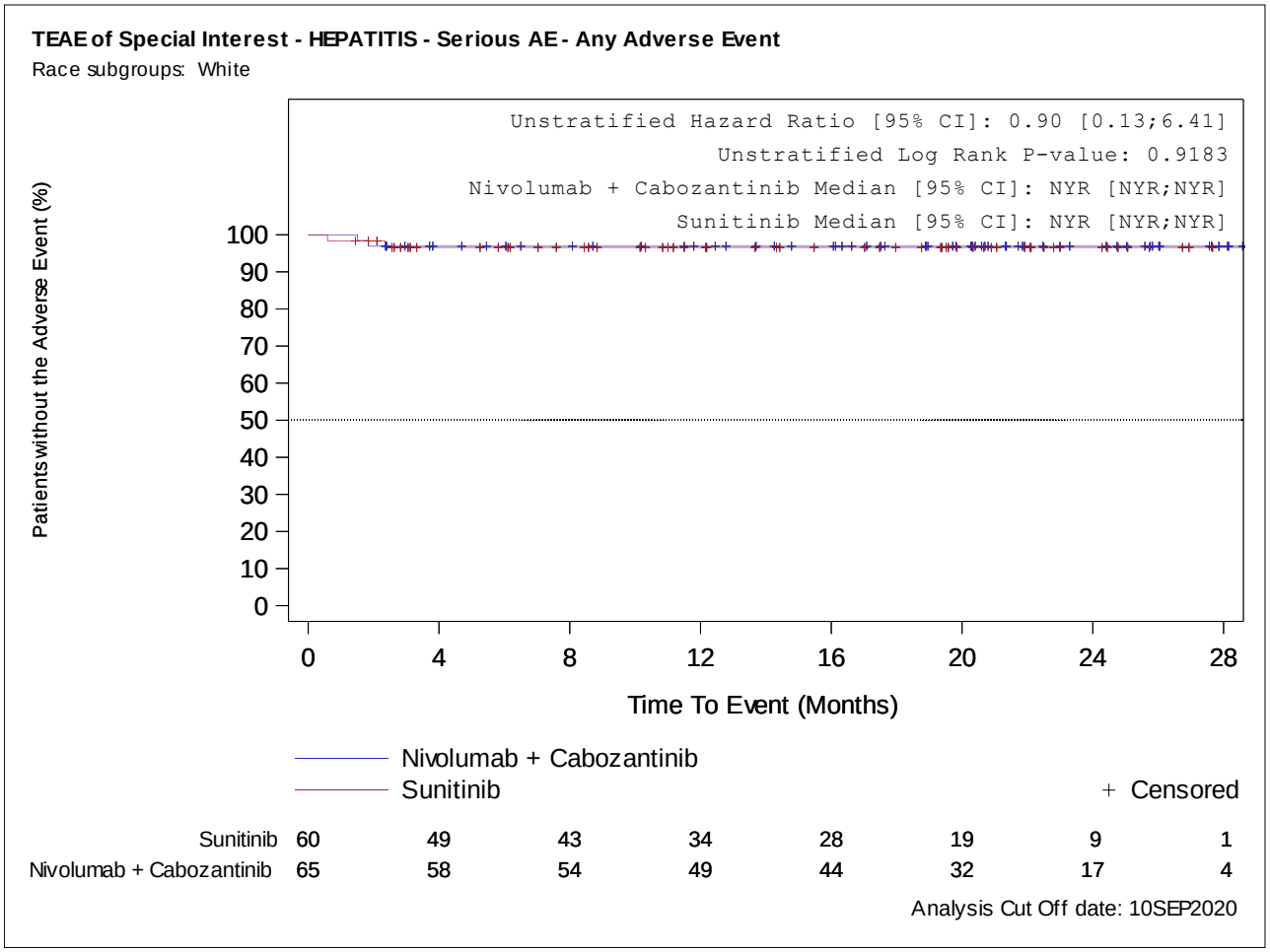
FIGURE 3.81.2.8: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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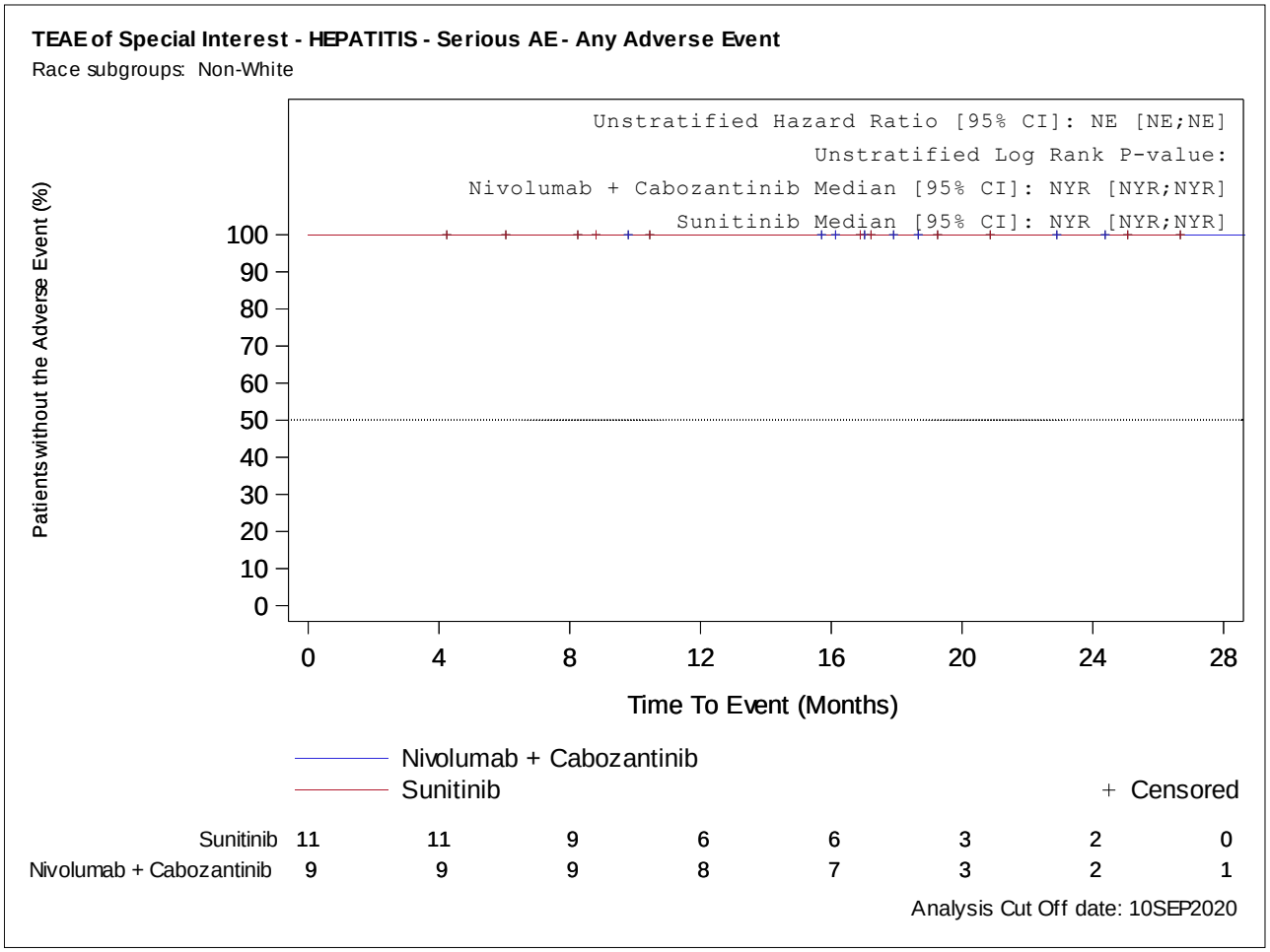
FIGURE 3.81.2.9: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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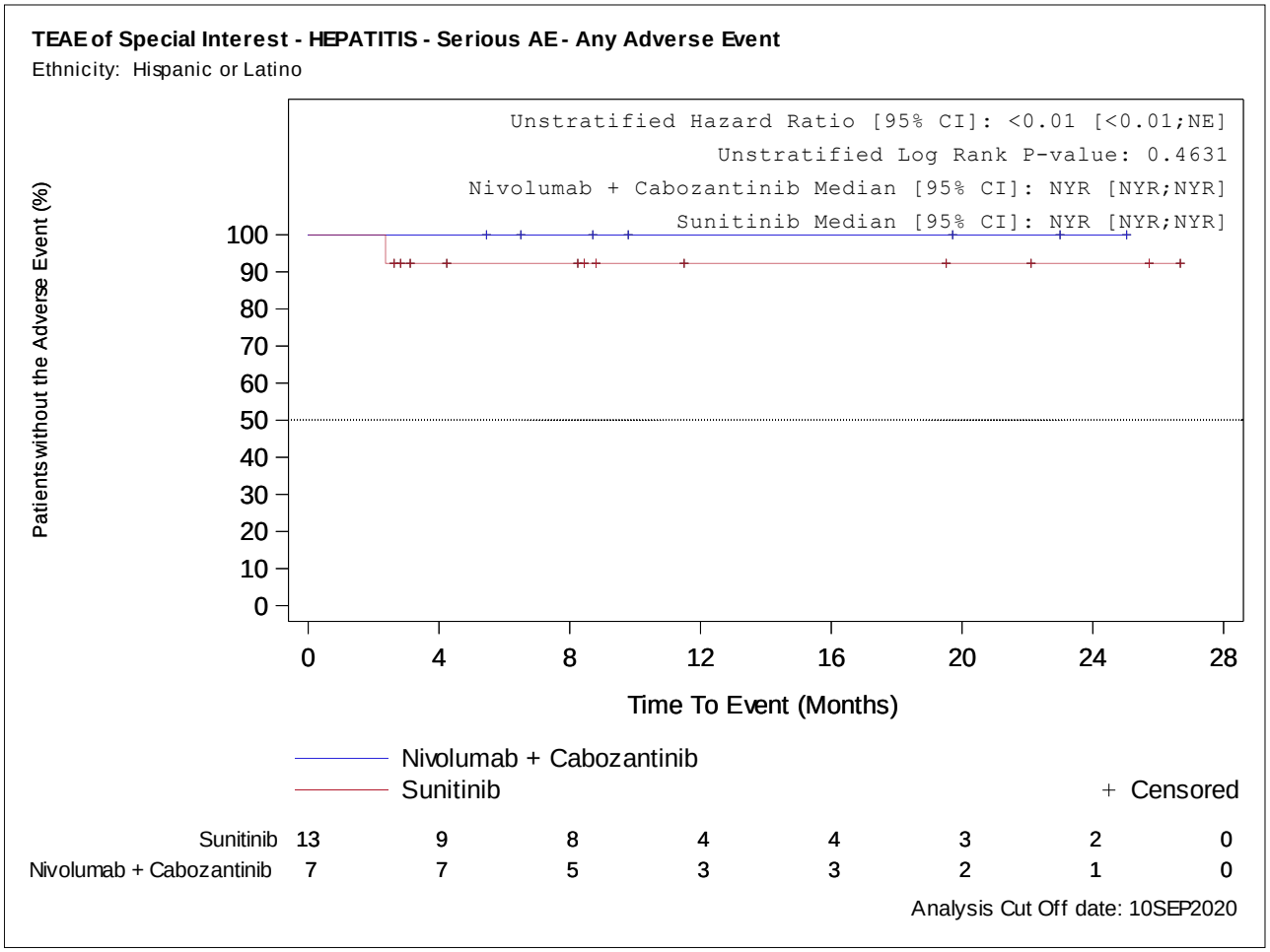
FIGURE 3.81.2.10: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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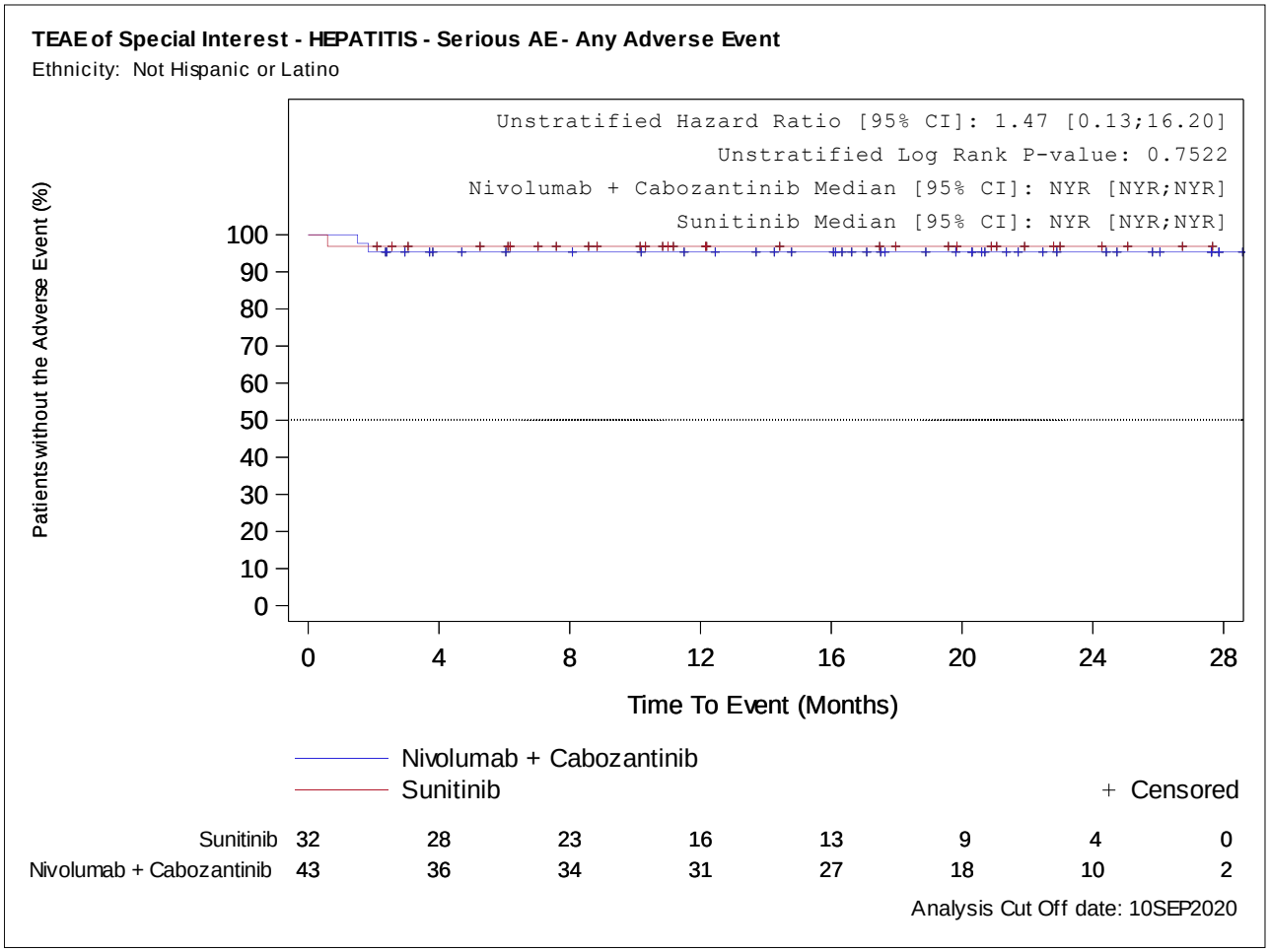
FIGURE 3.81.2.11: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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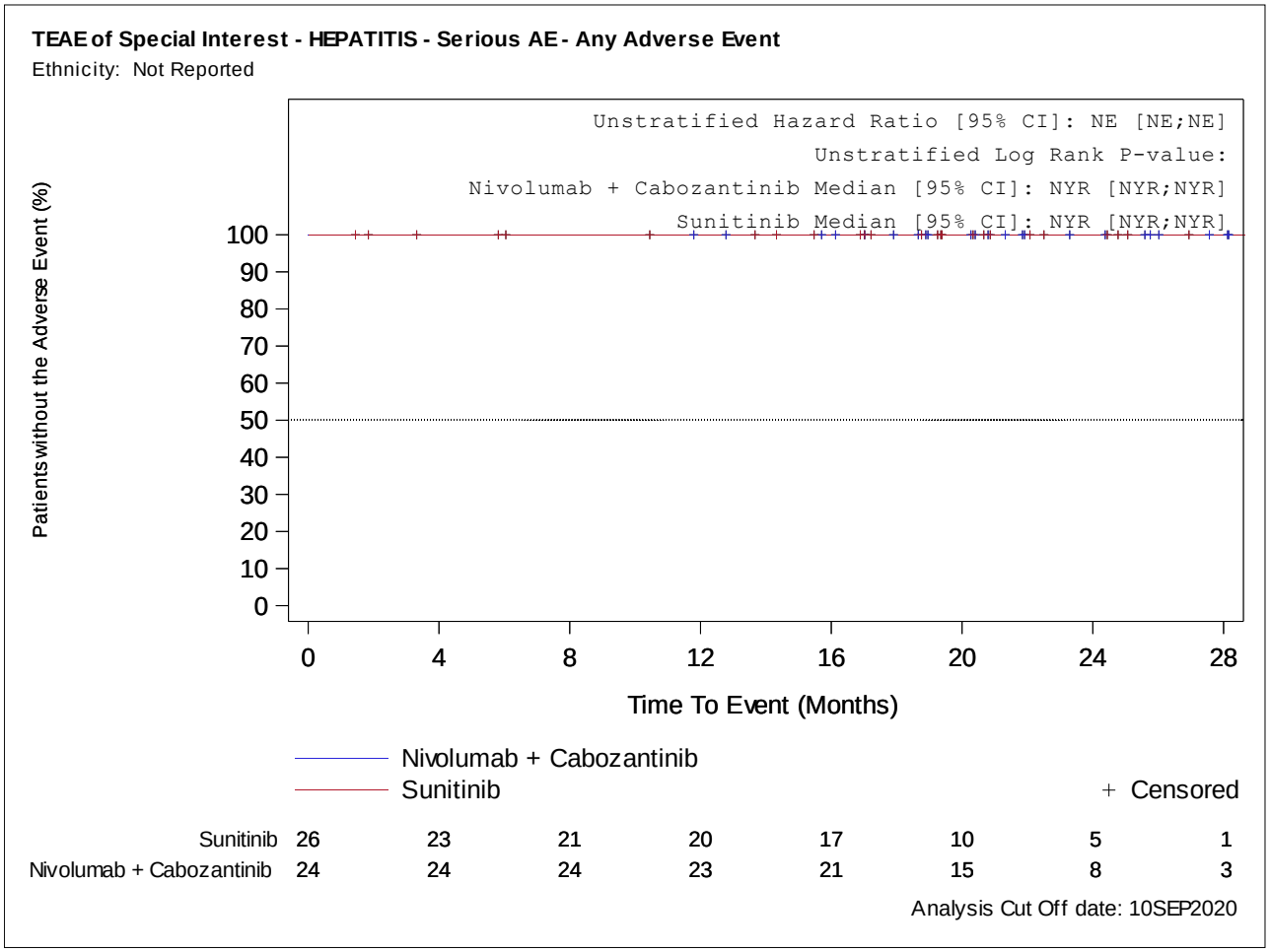
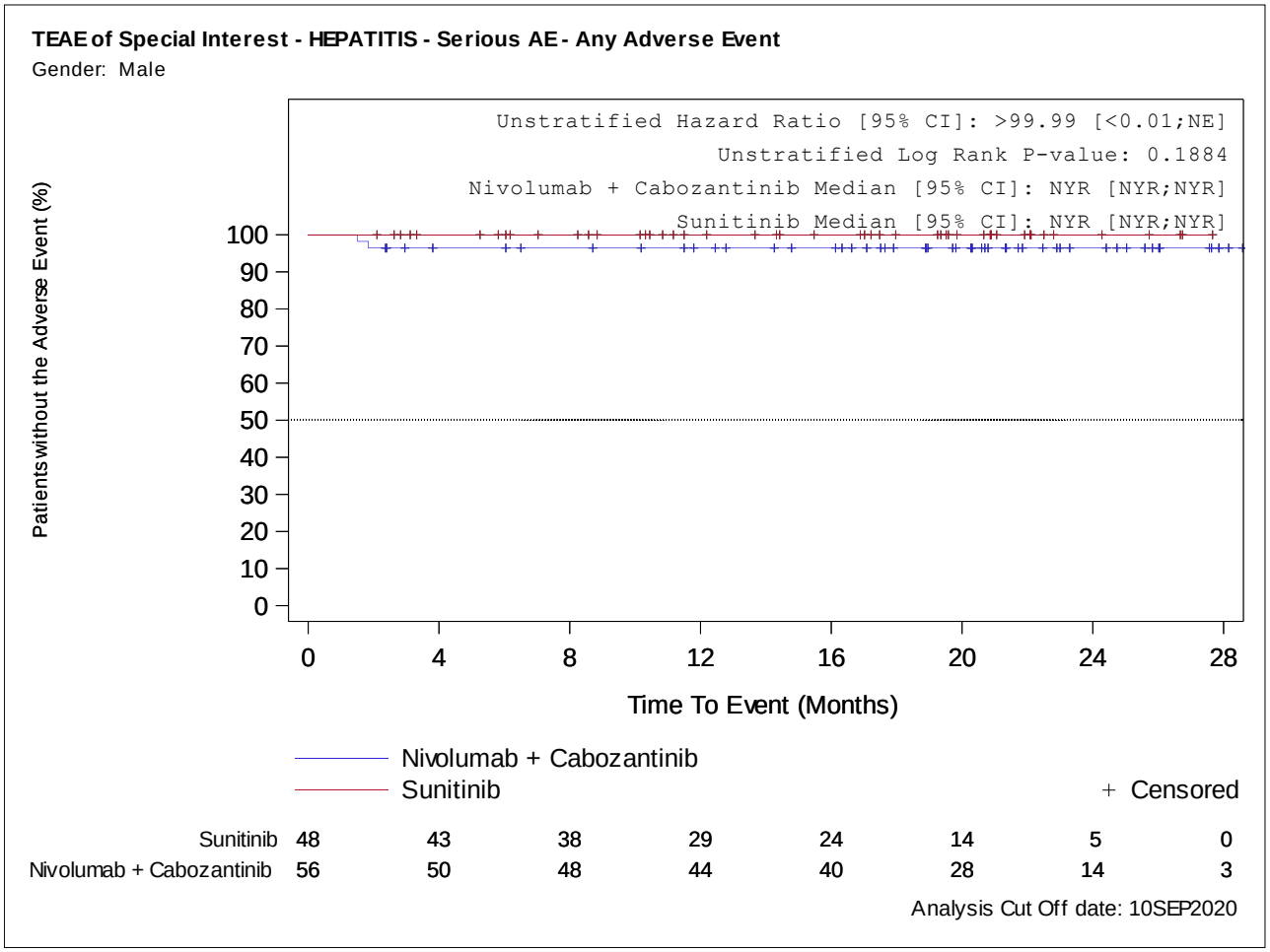
FIGURE 3.81.2.12: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



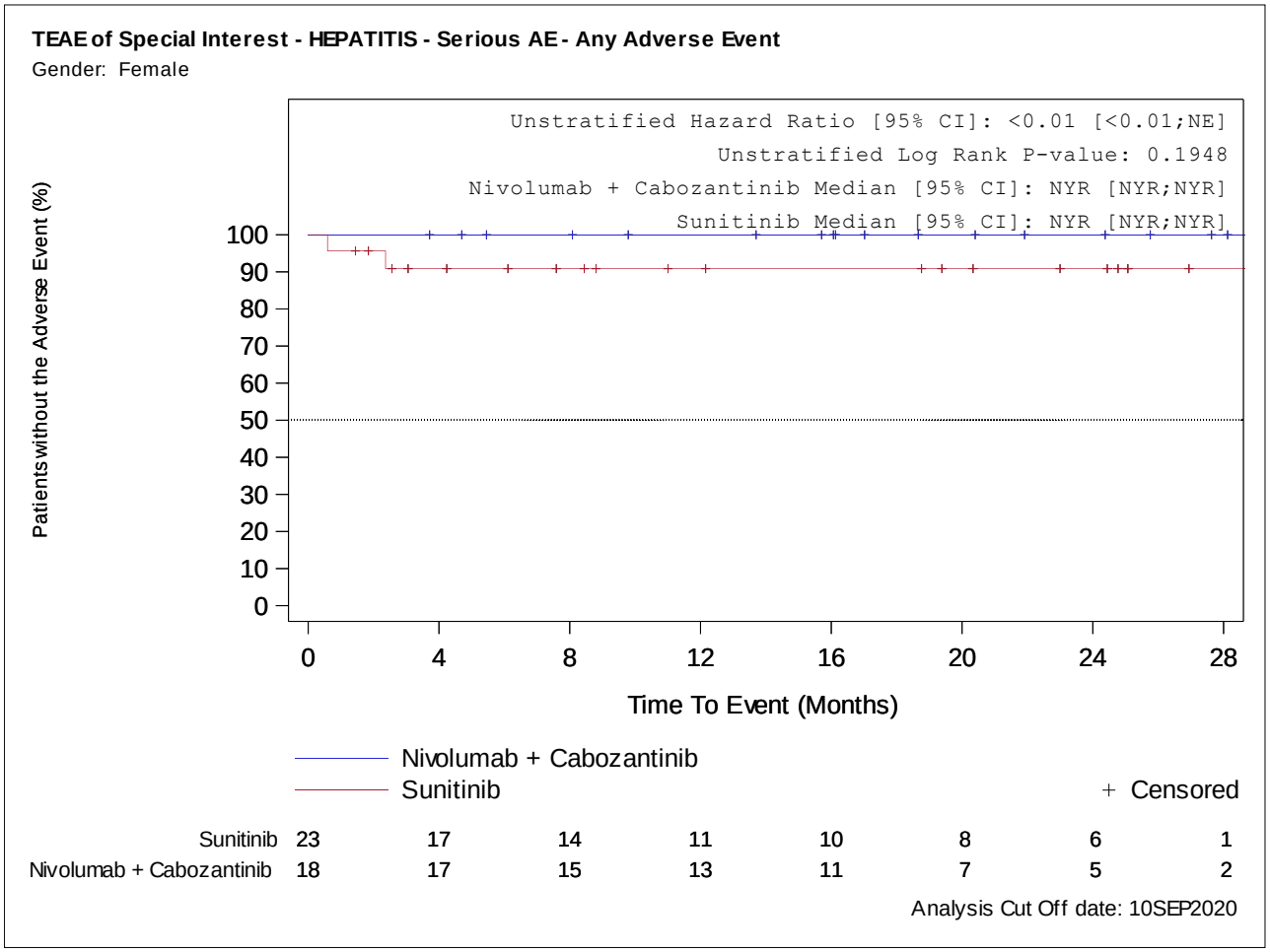

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:27:26

FIGURE 3.81.2.13: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



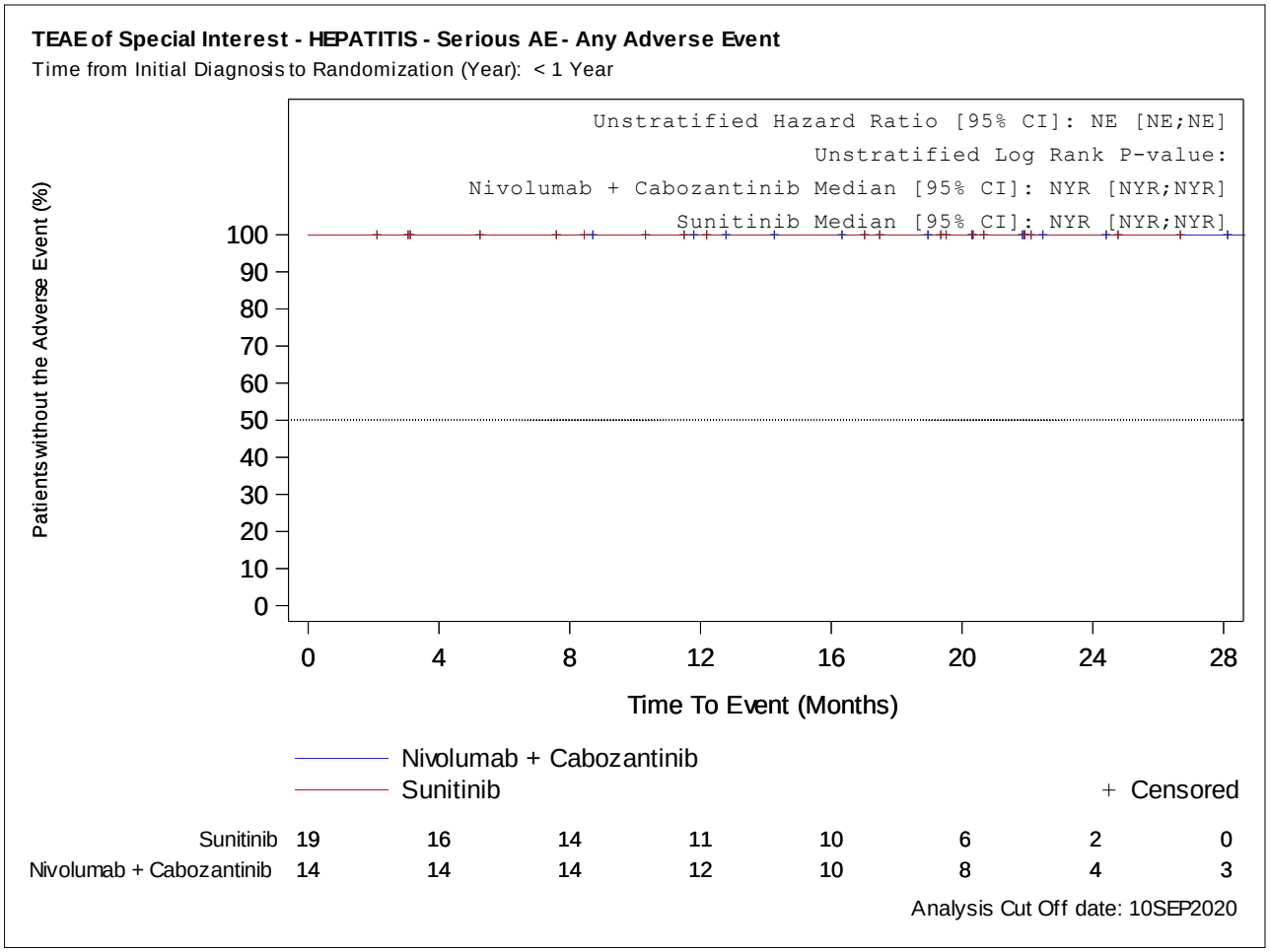

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:27:32

FIGURE 3.81.2.14: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



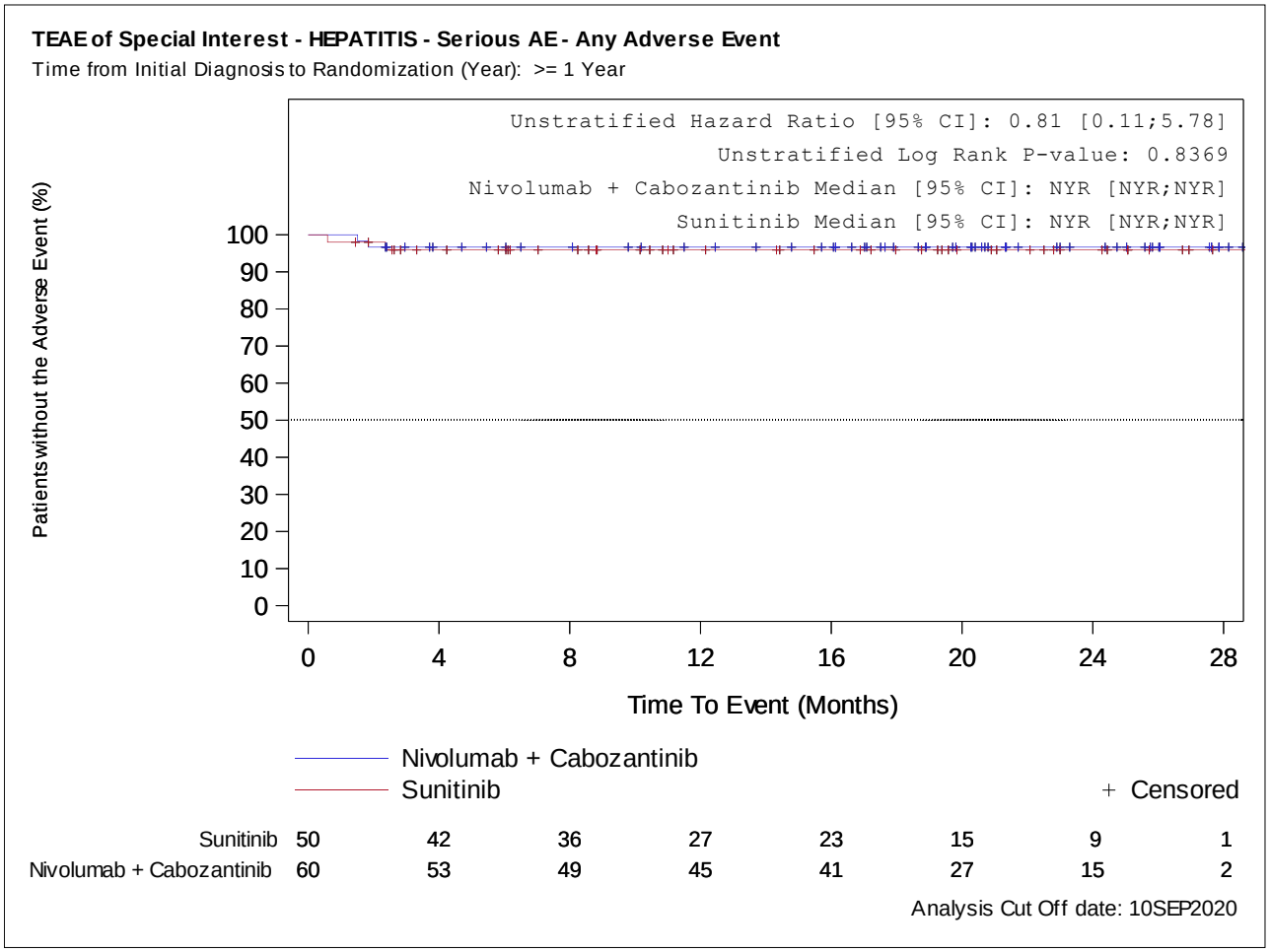

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:27:37

FIGURE 3.81.2.15: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



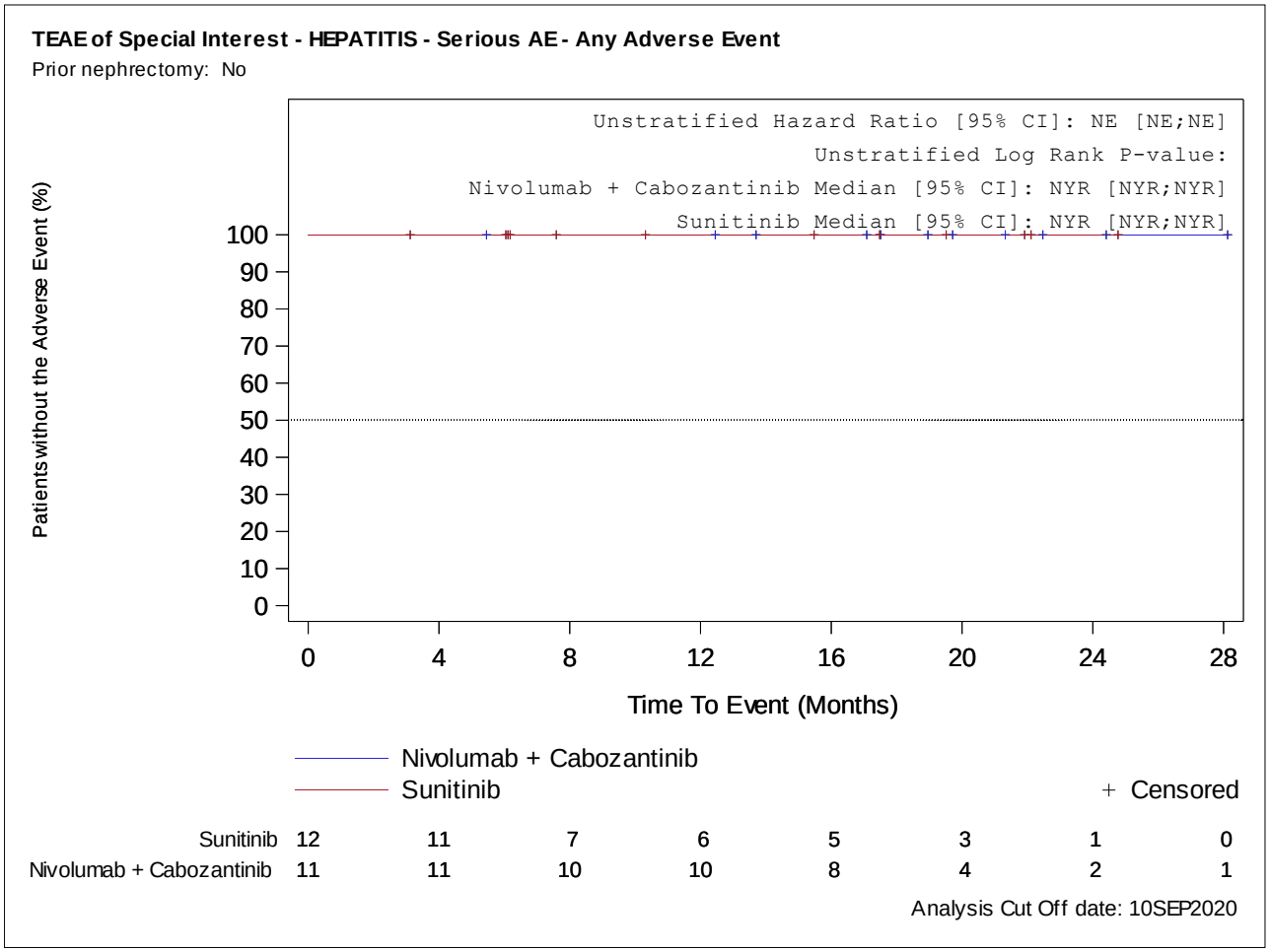

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:27:55

FIGURE 3.81.2.16: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



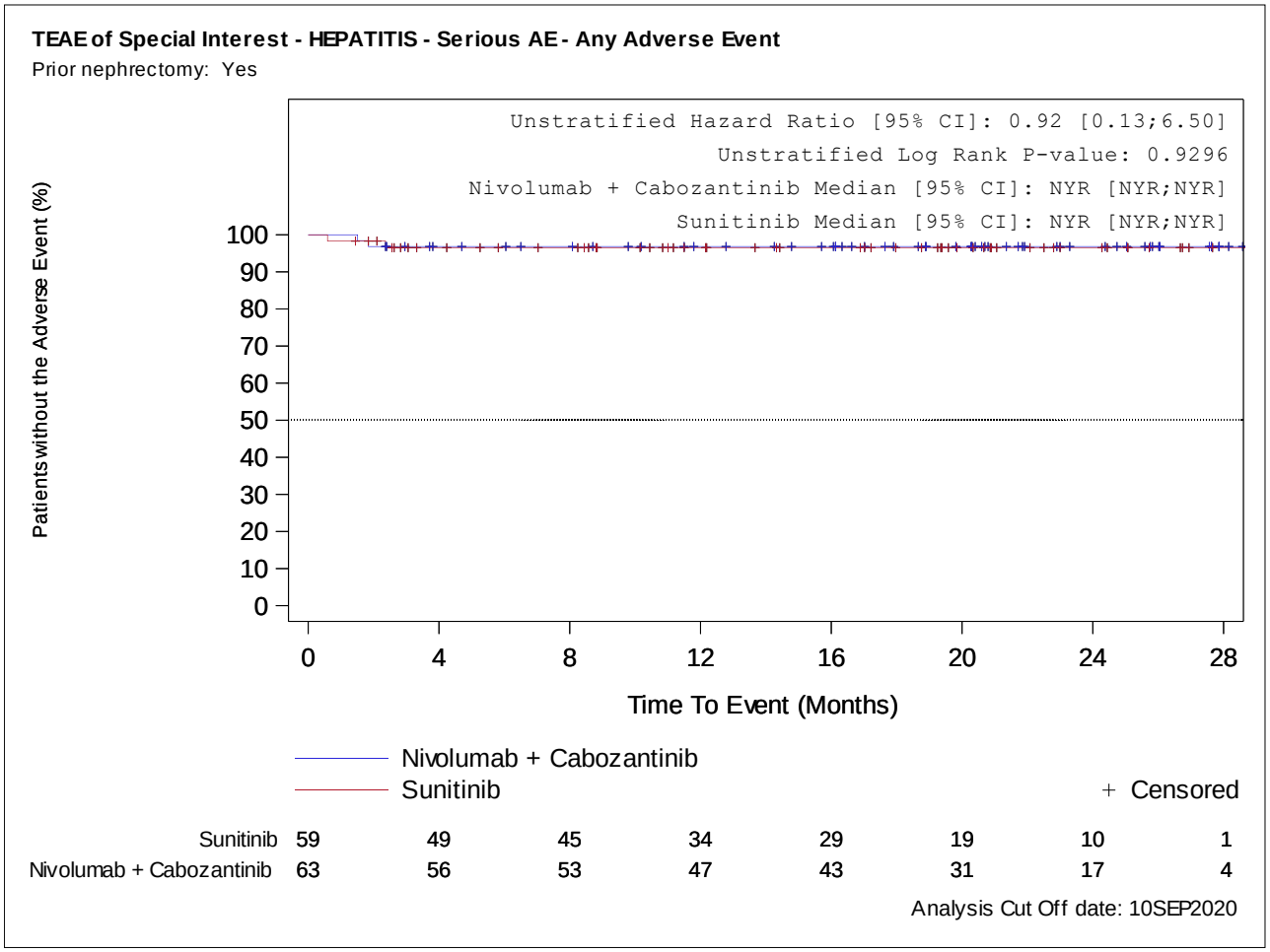

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:28:01

FIGURE 3.81.2.17: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



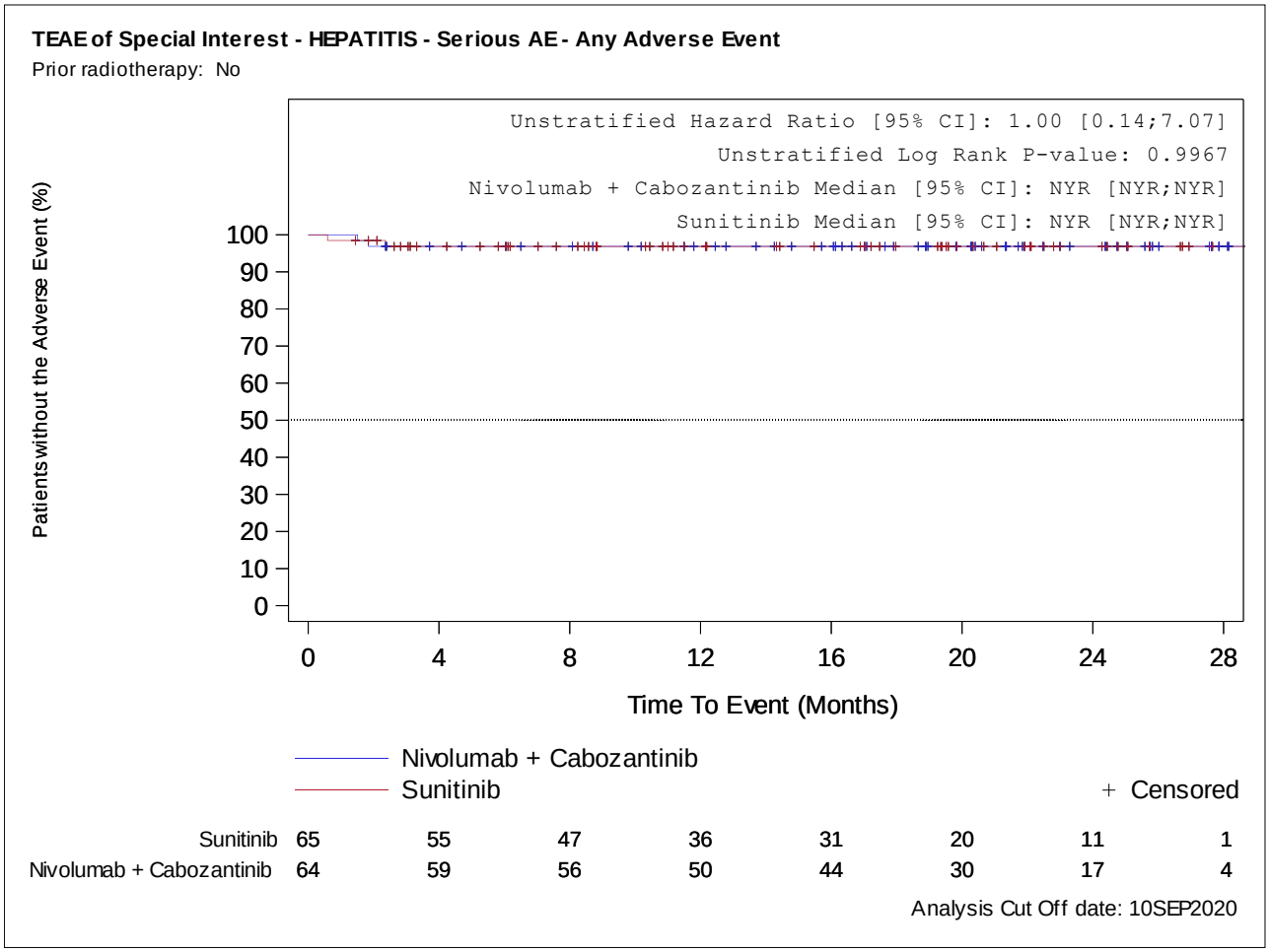

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:28:53

FIGURE 3.81.2.18: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



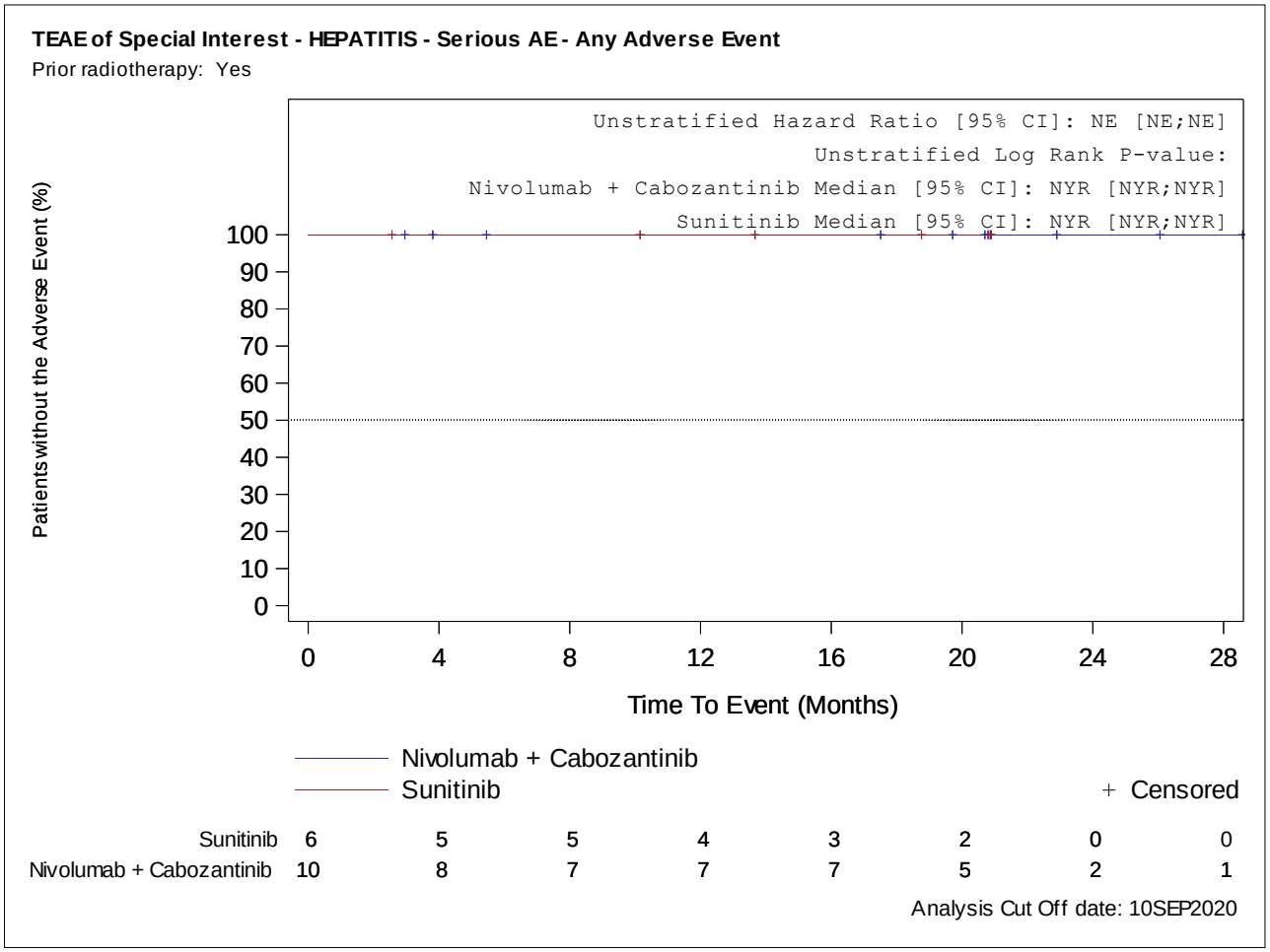

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:28:59

FIGURE 3.81.2.19: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



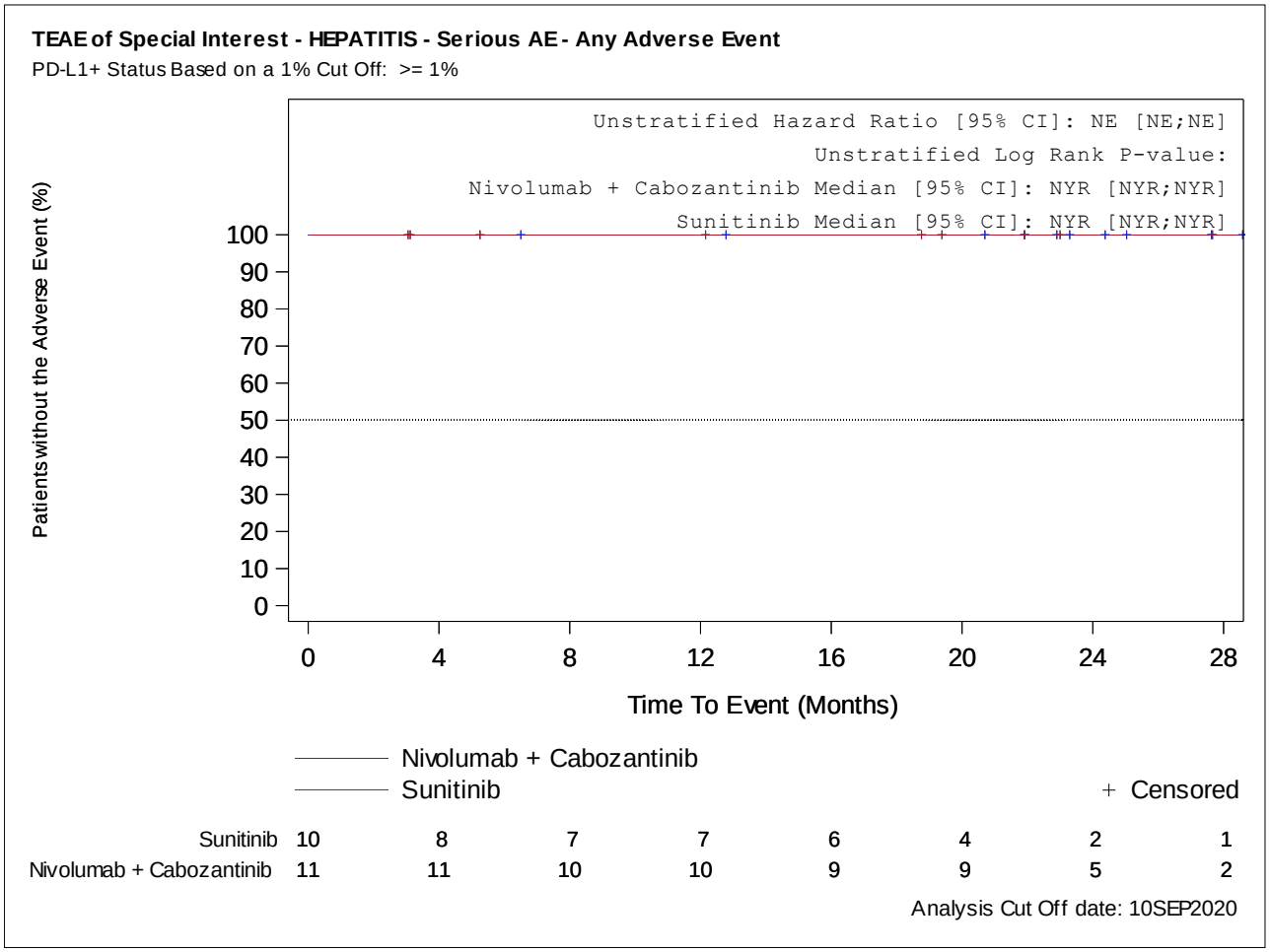

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:29:04

FIGURE 3.81.2.20: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



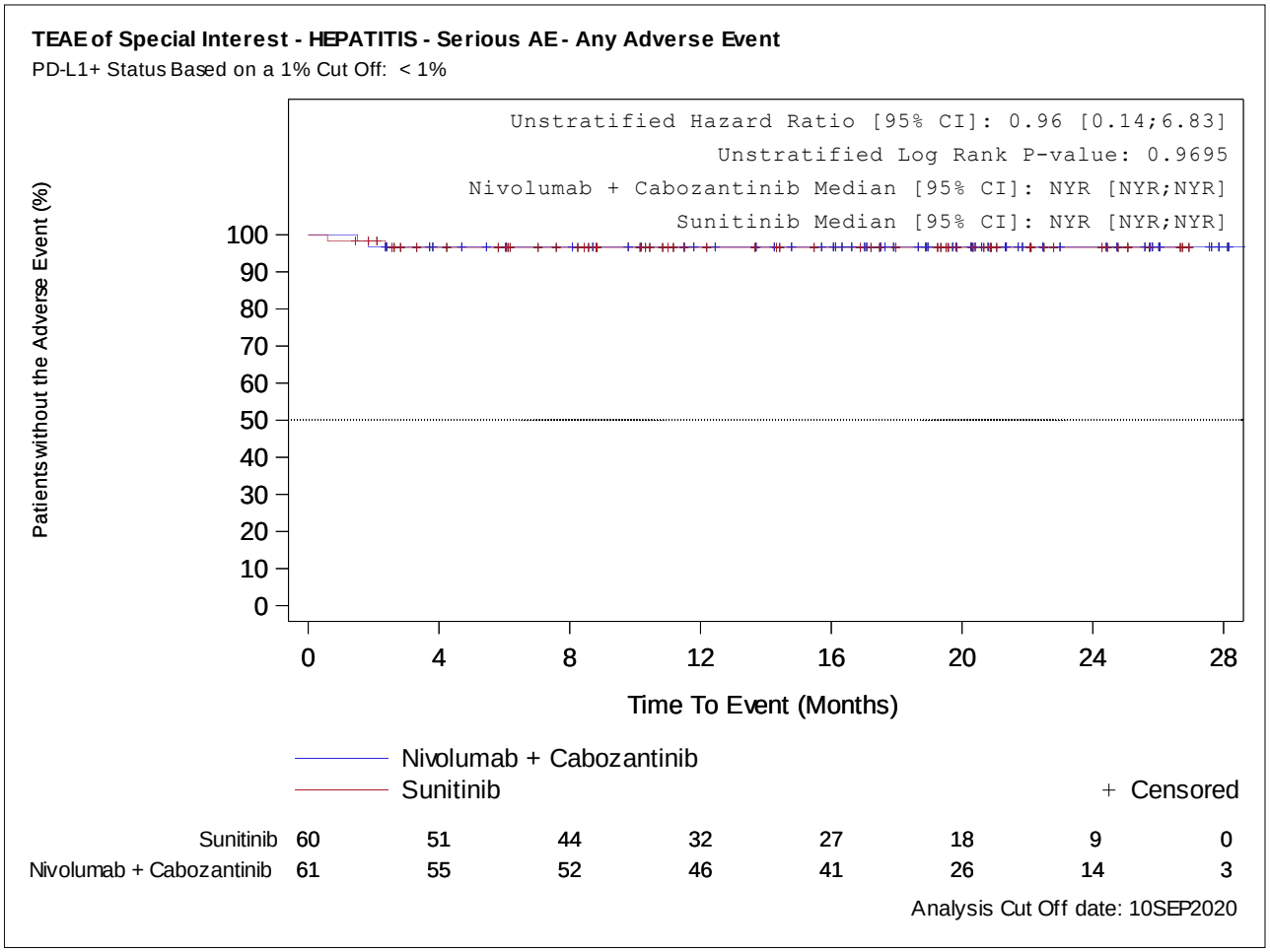

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:29:09

FIGURE 3.81.2.21: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



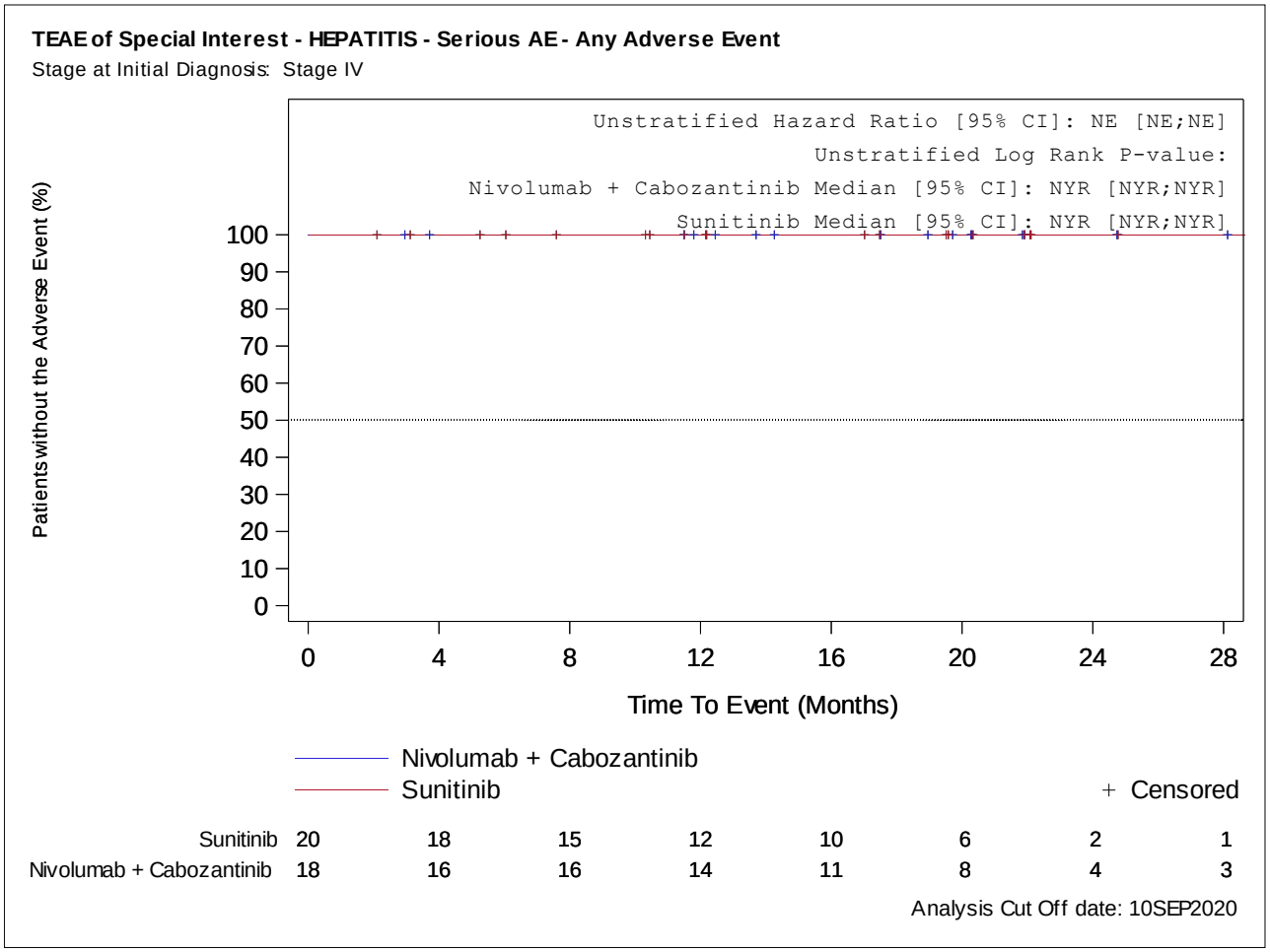

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:29:15

FIGURE 3.81.2.22: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



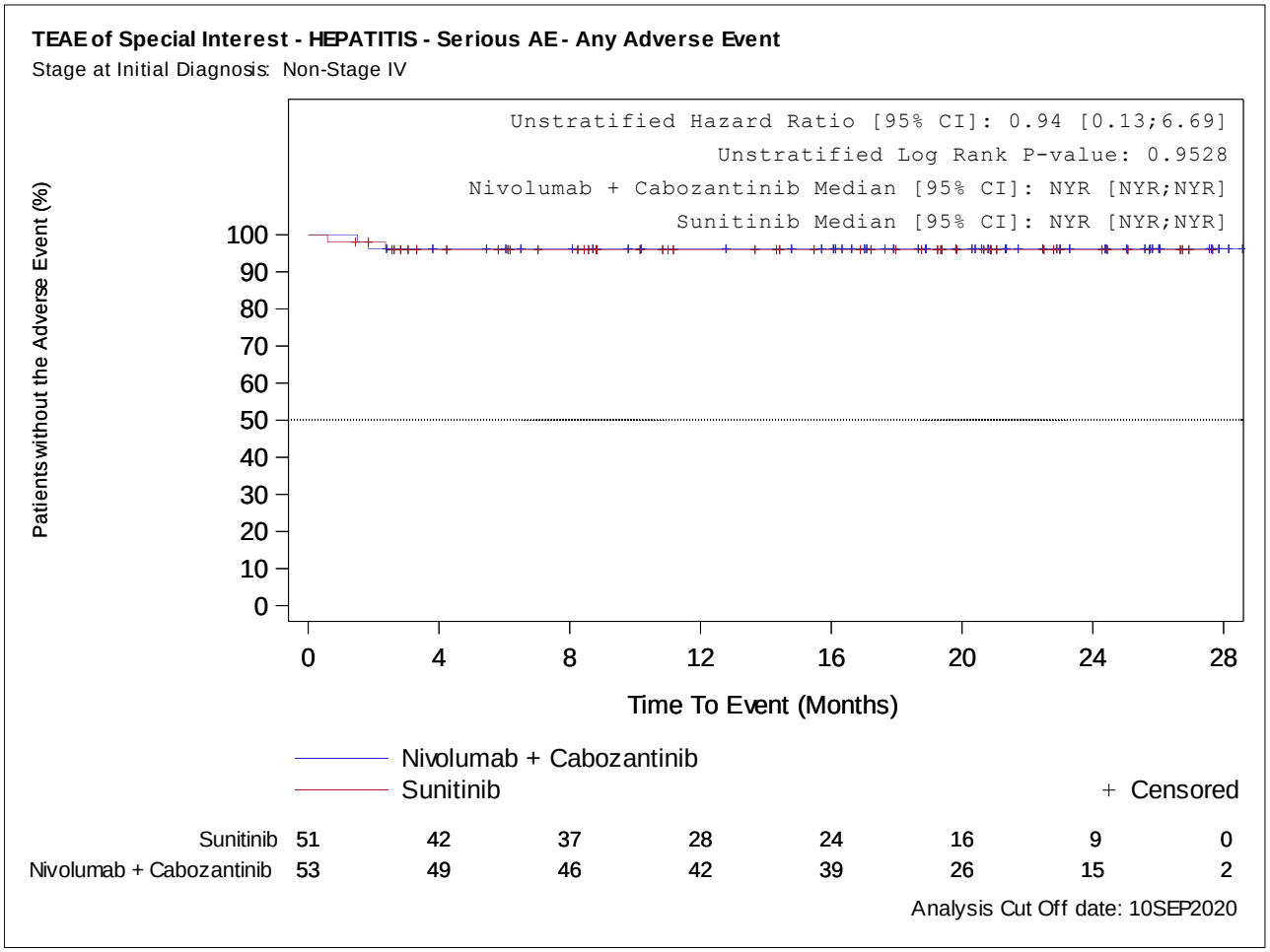

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:29:21

FIGURE 3.81.2.23: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



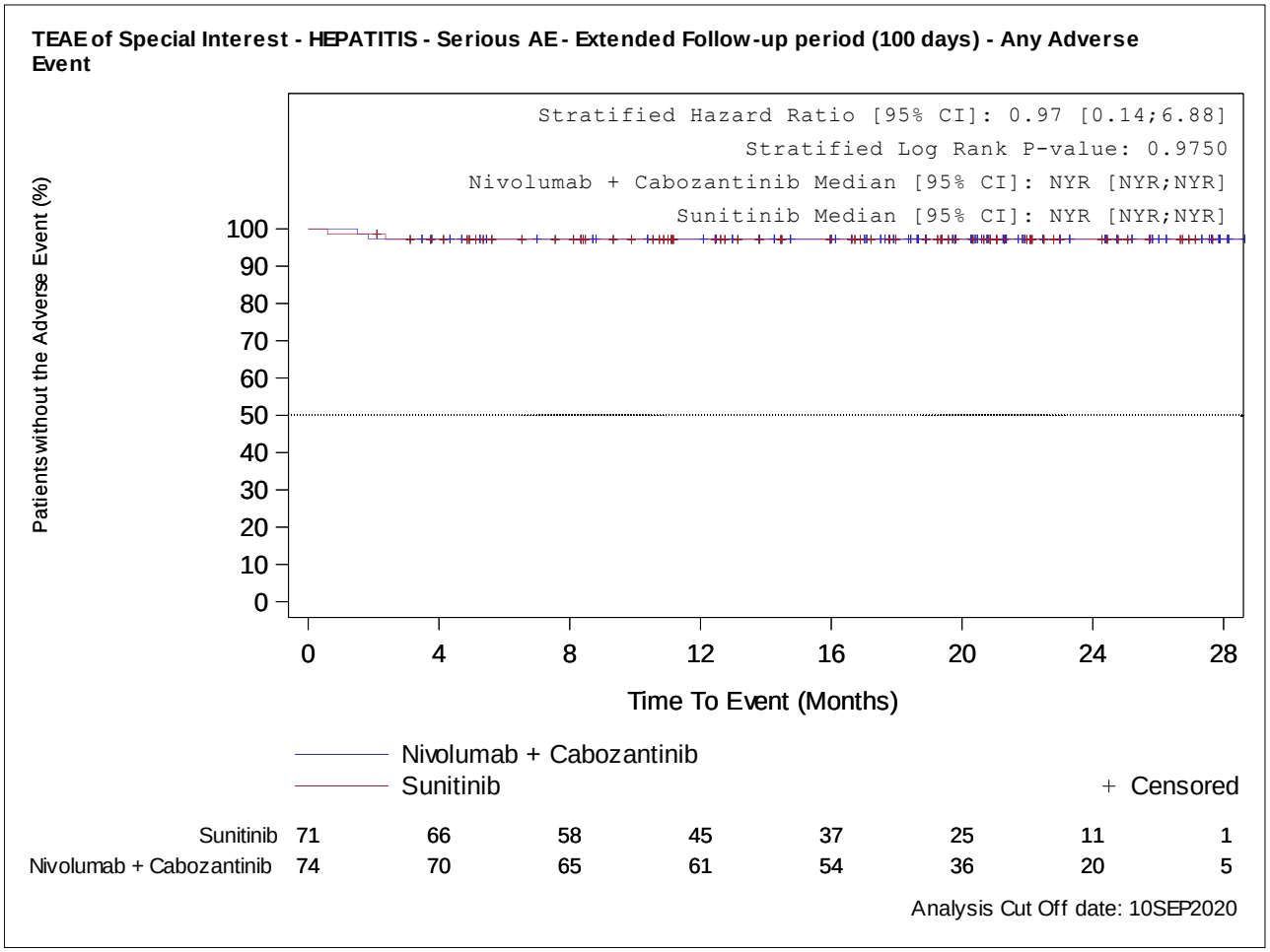

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:29:50

FIGURE 3.81.2.24: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



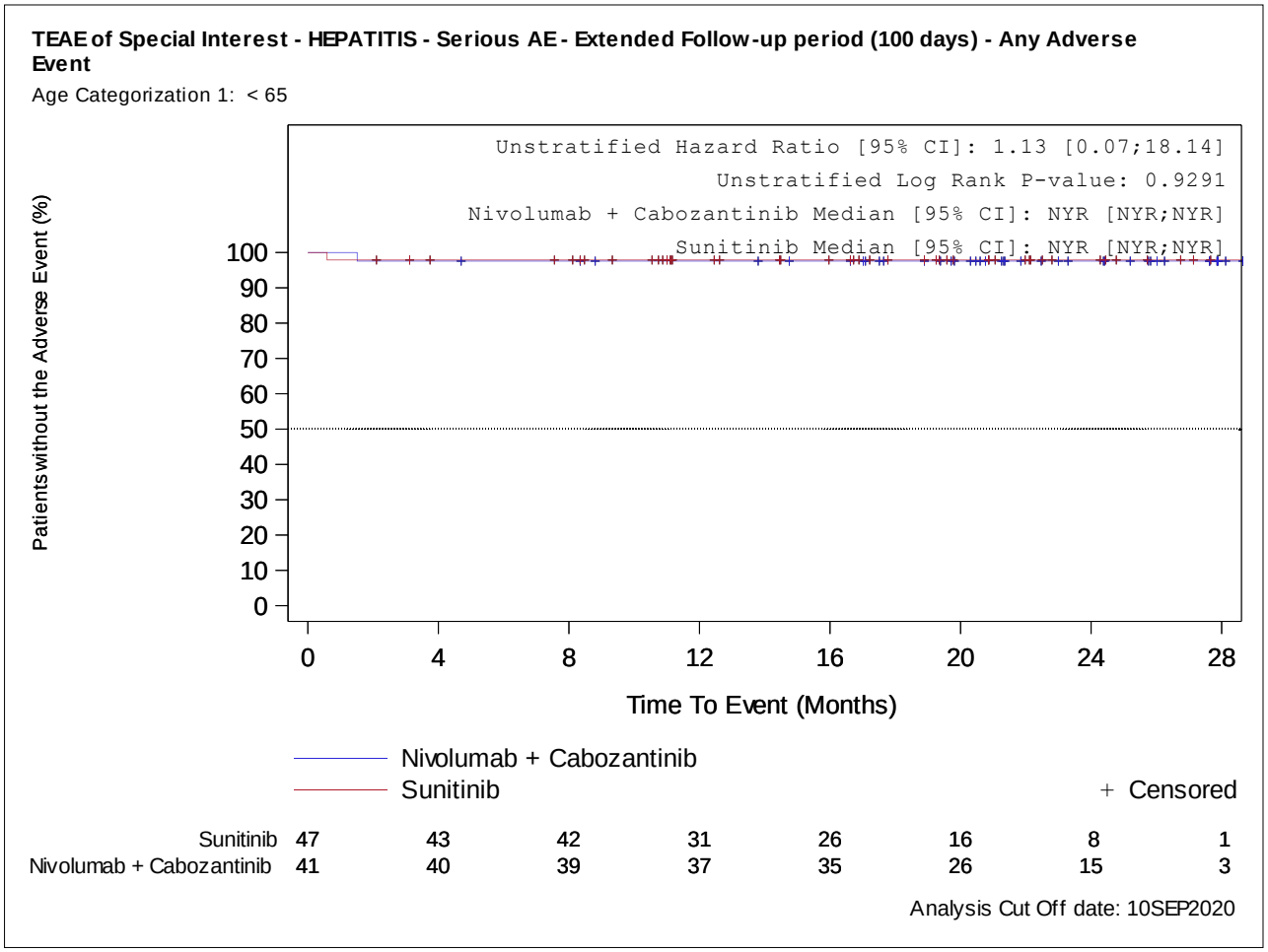

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:29:56

FIGURE 3.82.1: TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



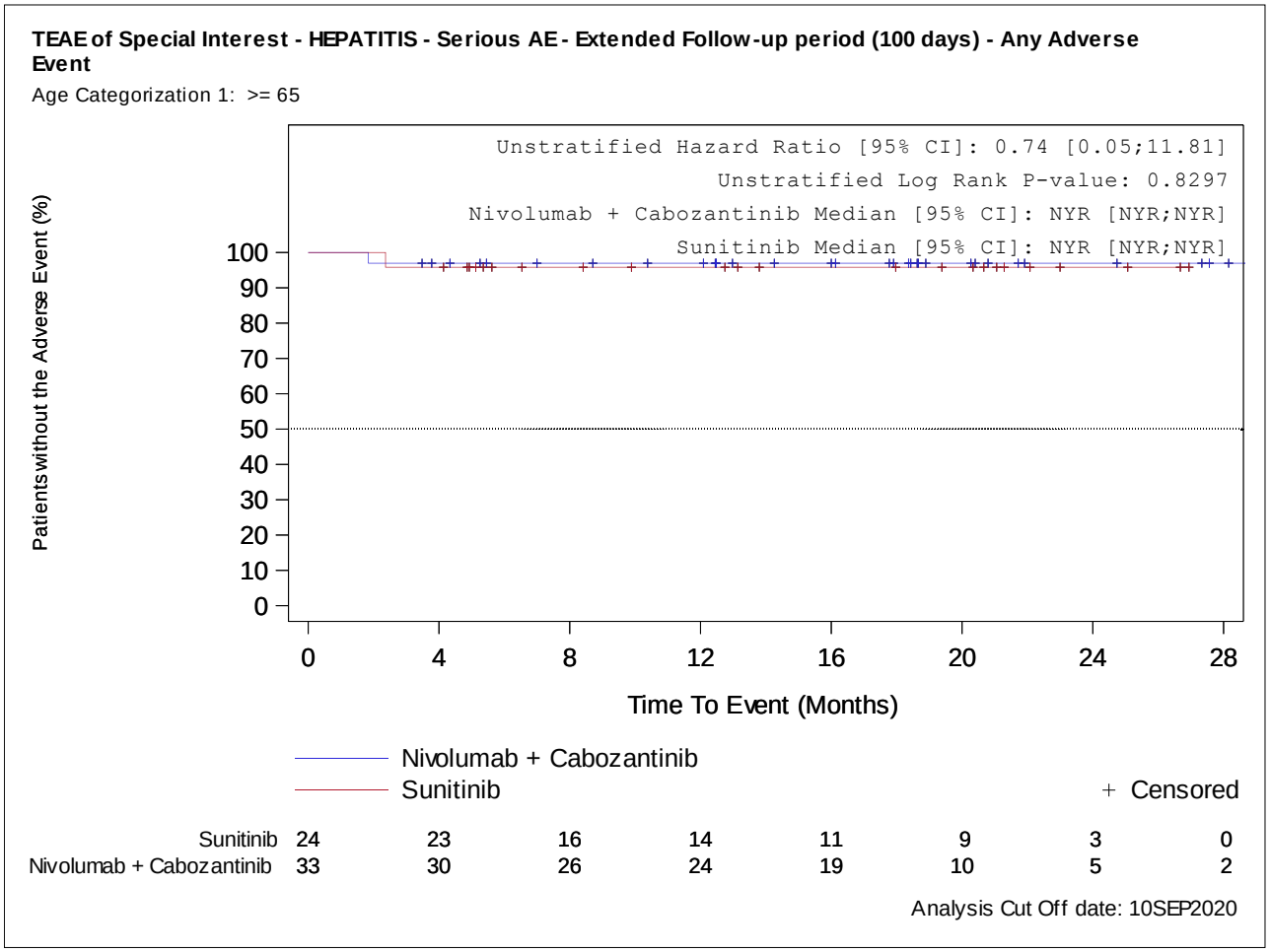

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:33:15

FIGURE 3.82.2.1: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



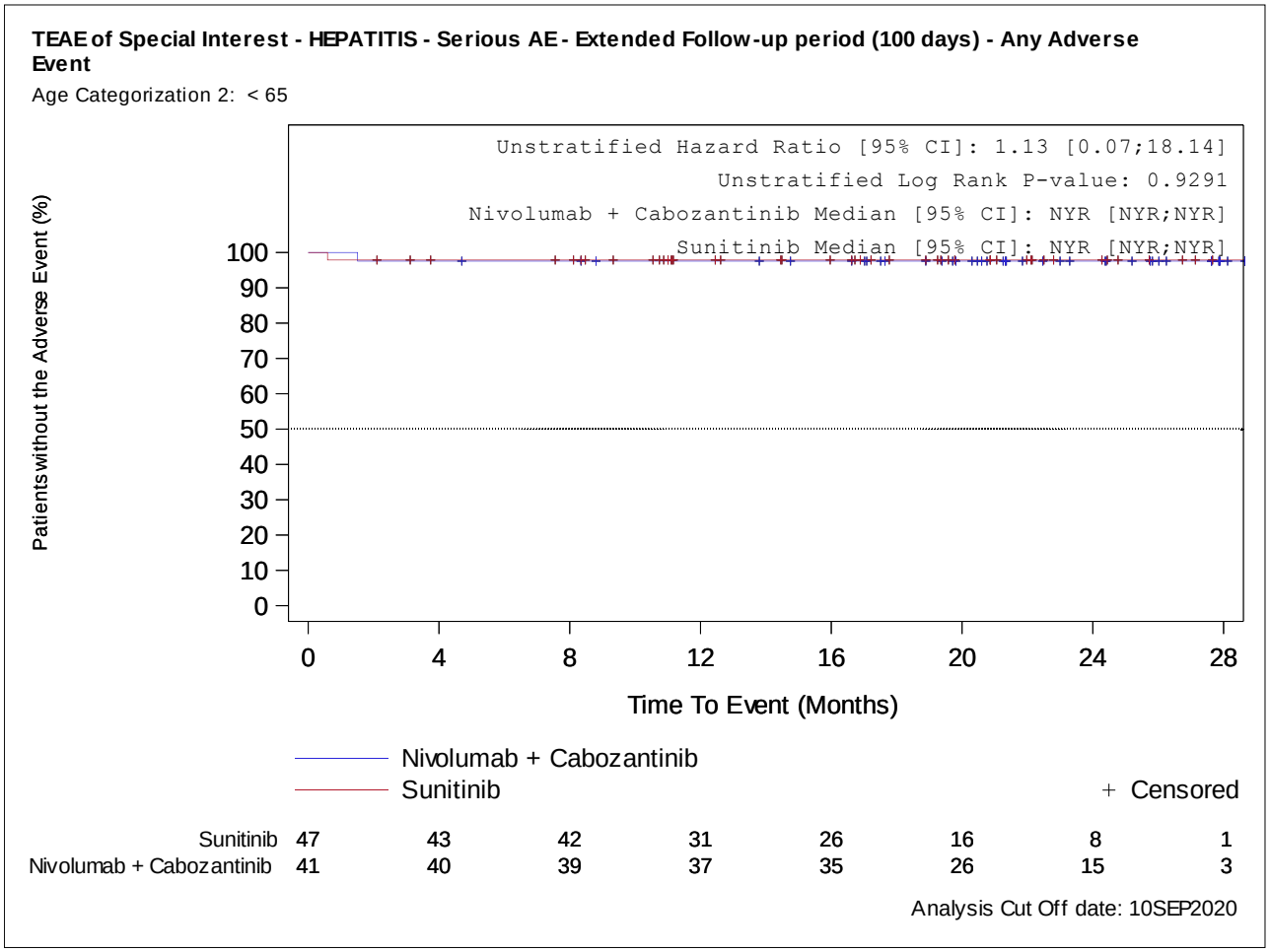

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:33:18

FIGURE 3.82.2.2: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



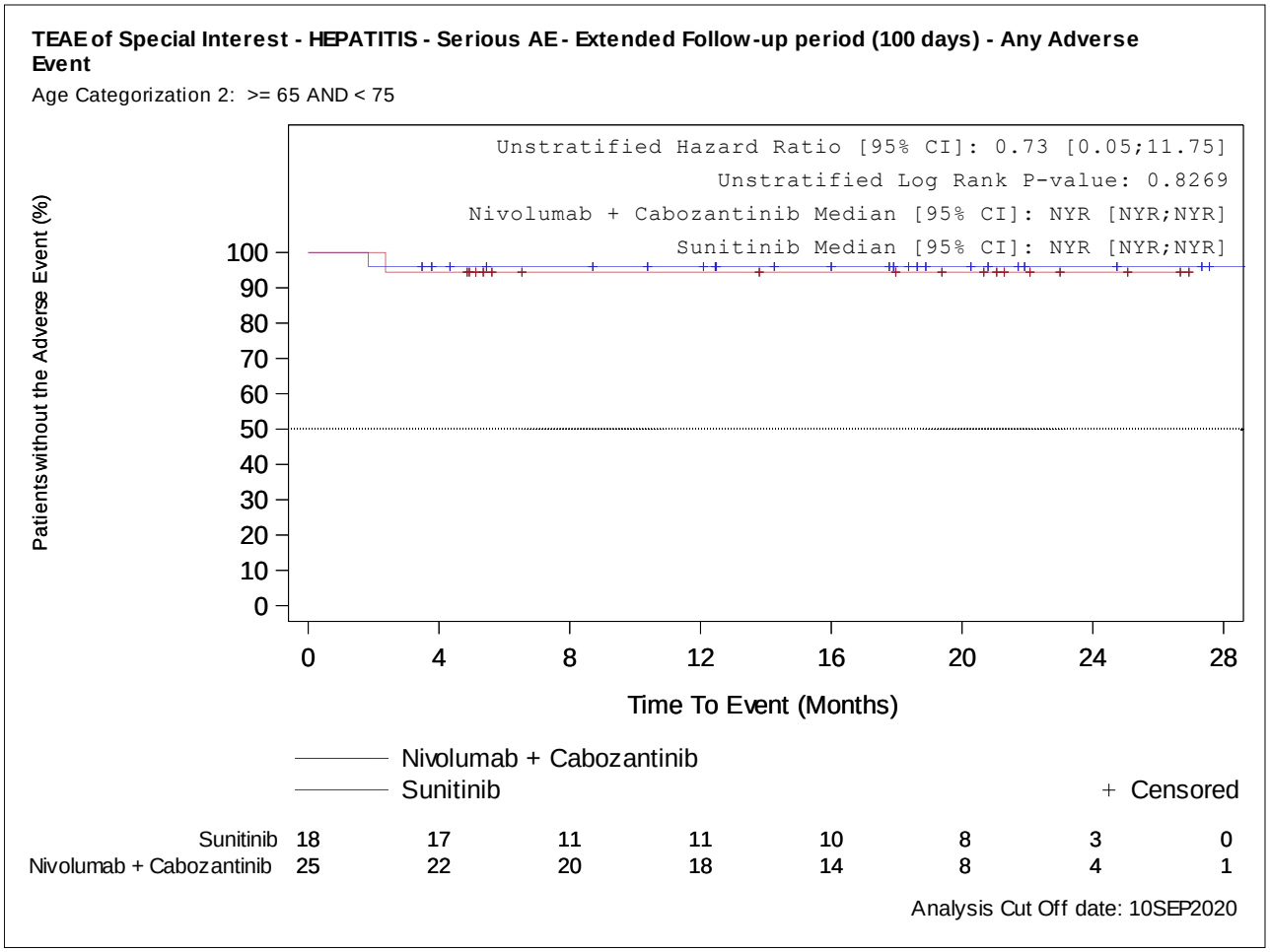

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:33:24

FIGURE 3.82.2.3: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



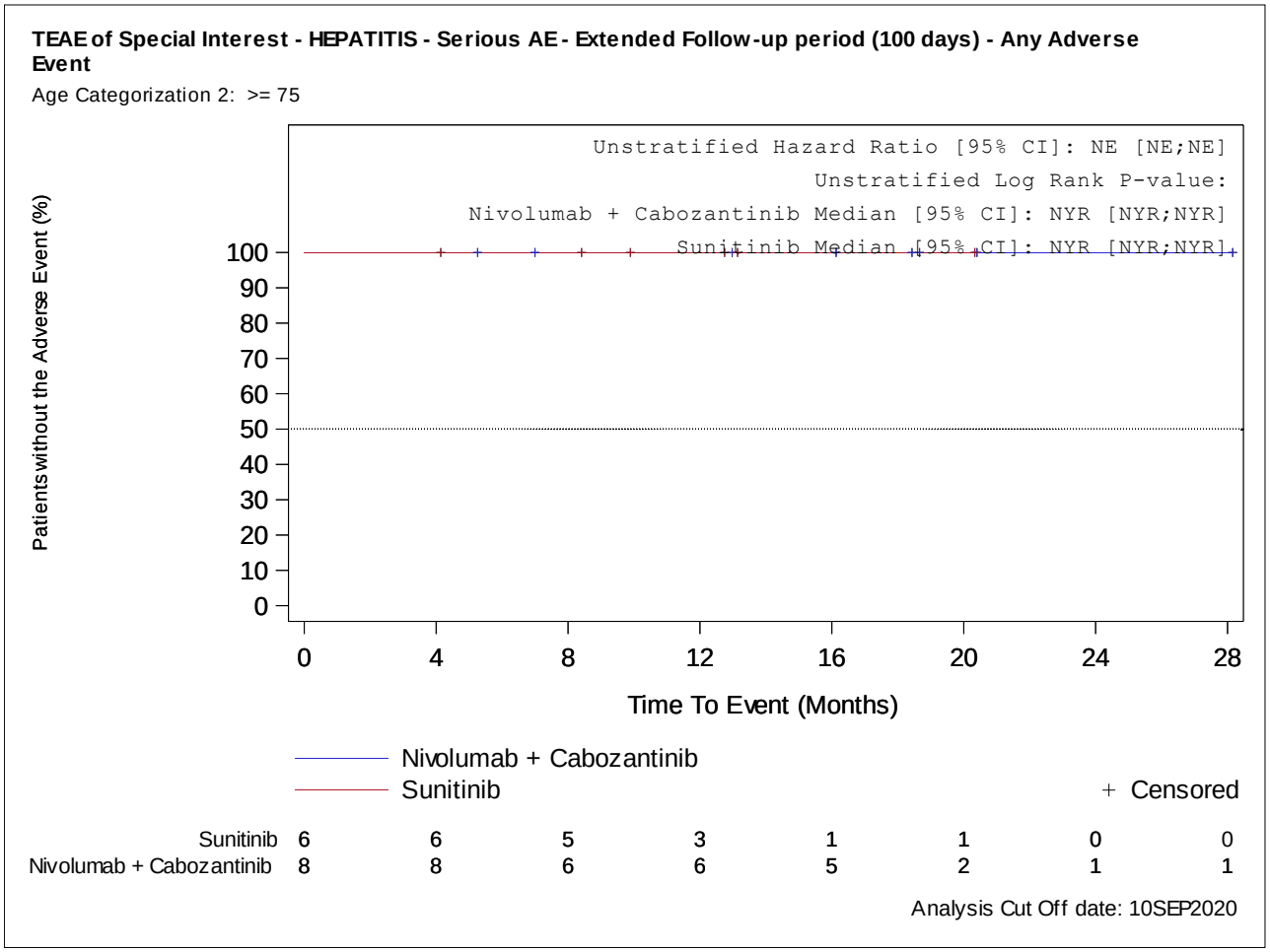

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:33:30

FIGURE 3.82.2.4: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



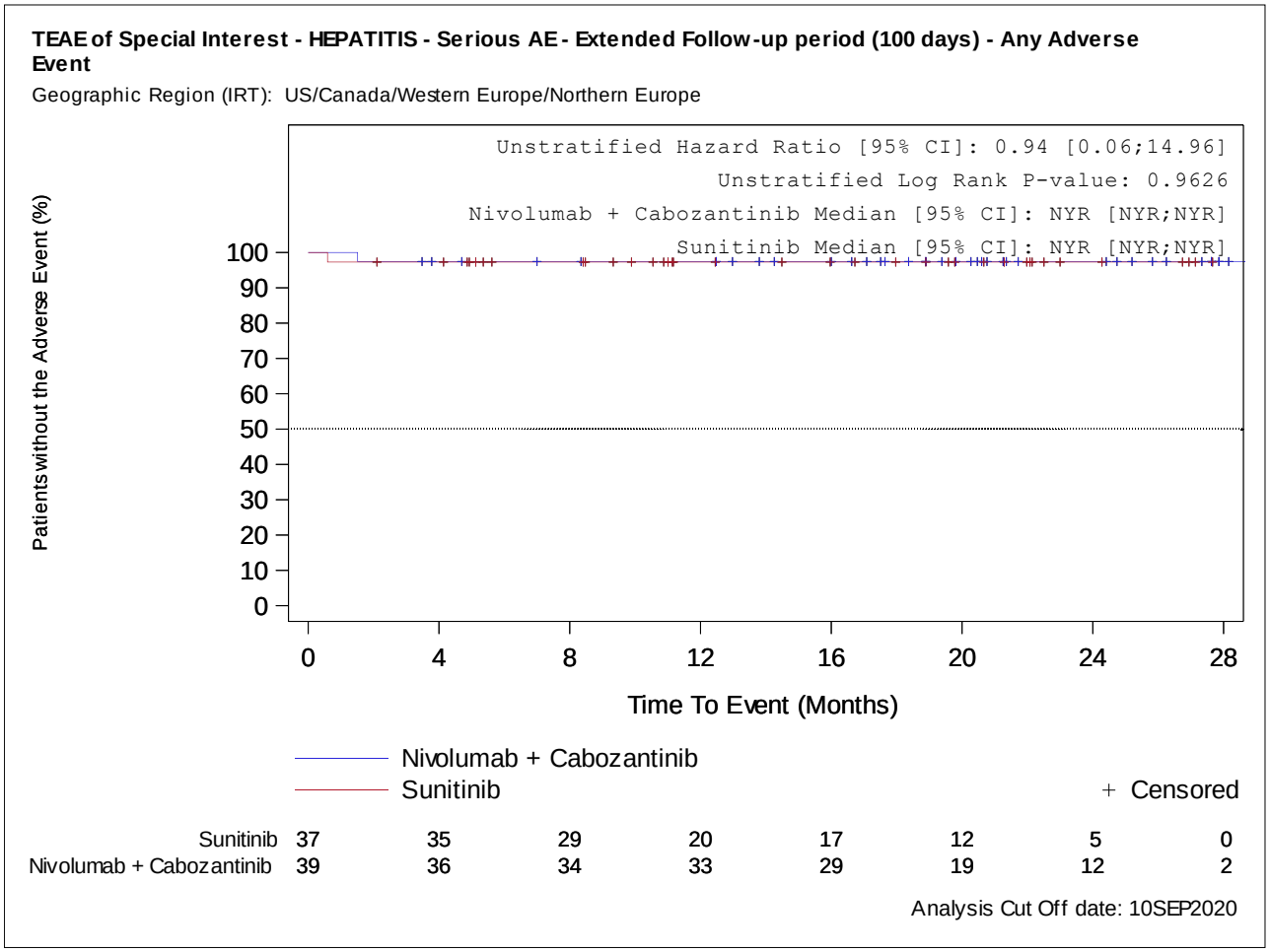

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:33:36

FIGURE 3.82.2.5: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



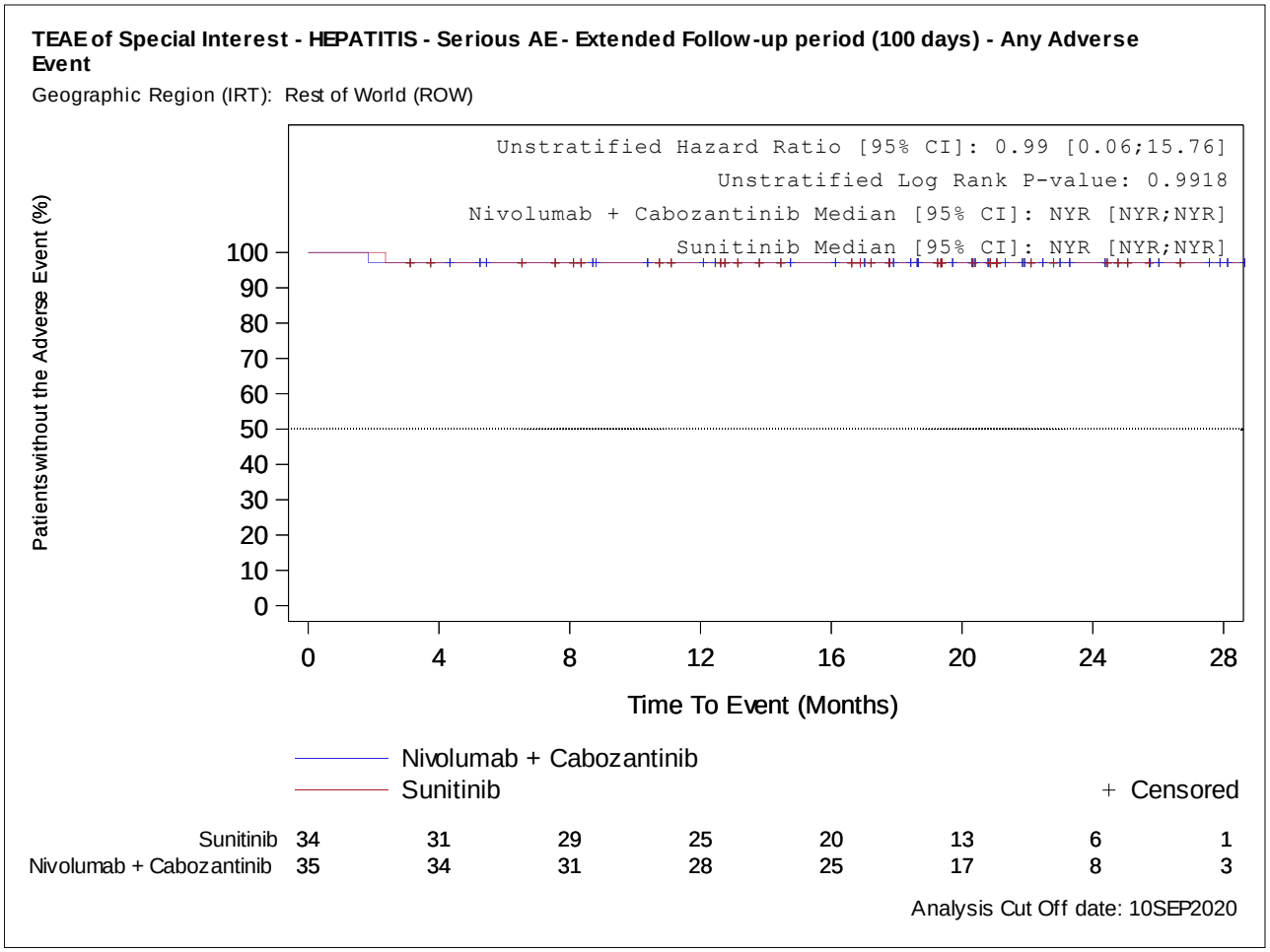

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:33:41

FIGURE 3.82.2.6: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



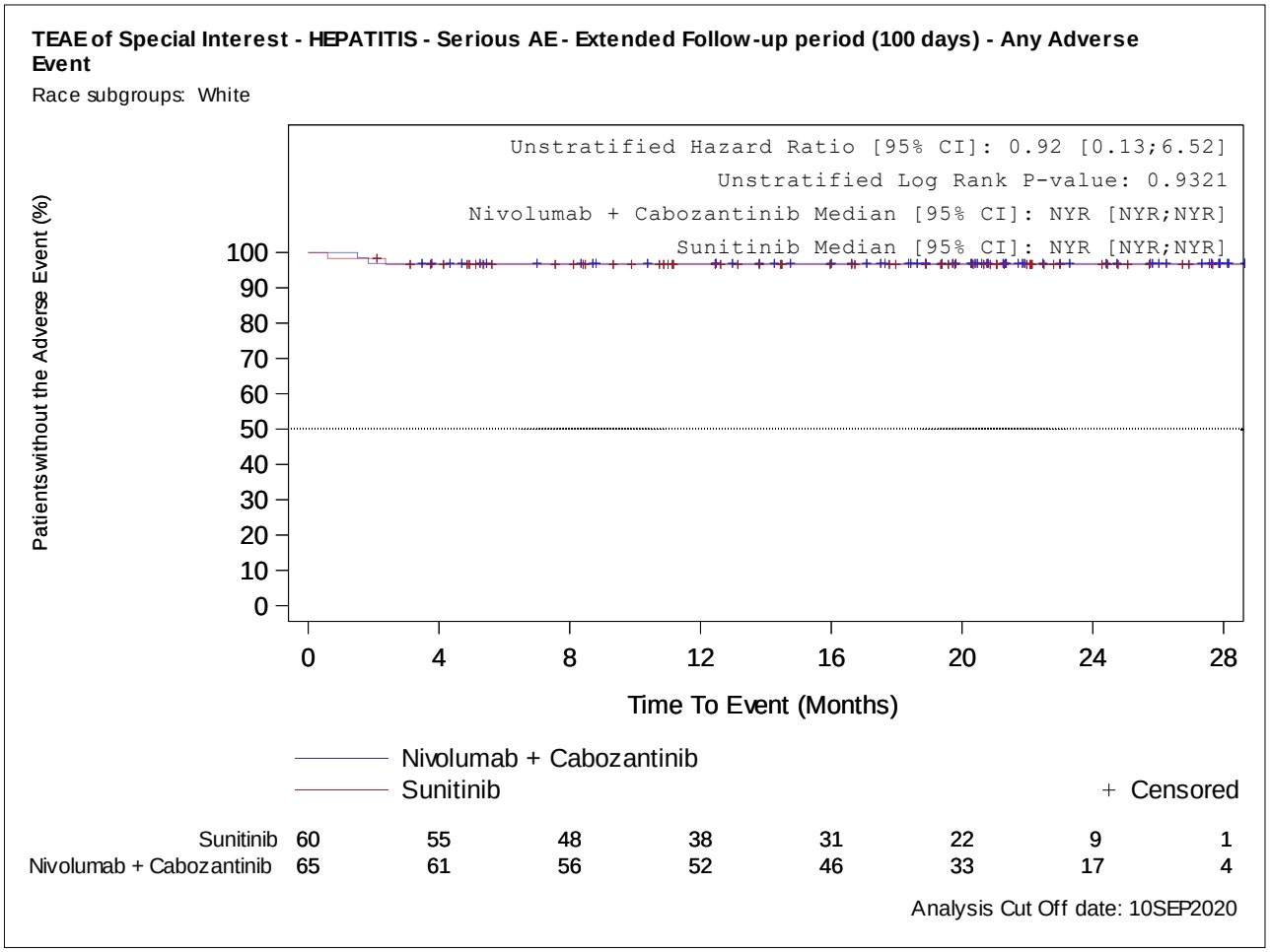

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:33:47

FIGURE 3.82.2.7: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



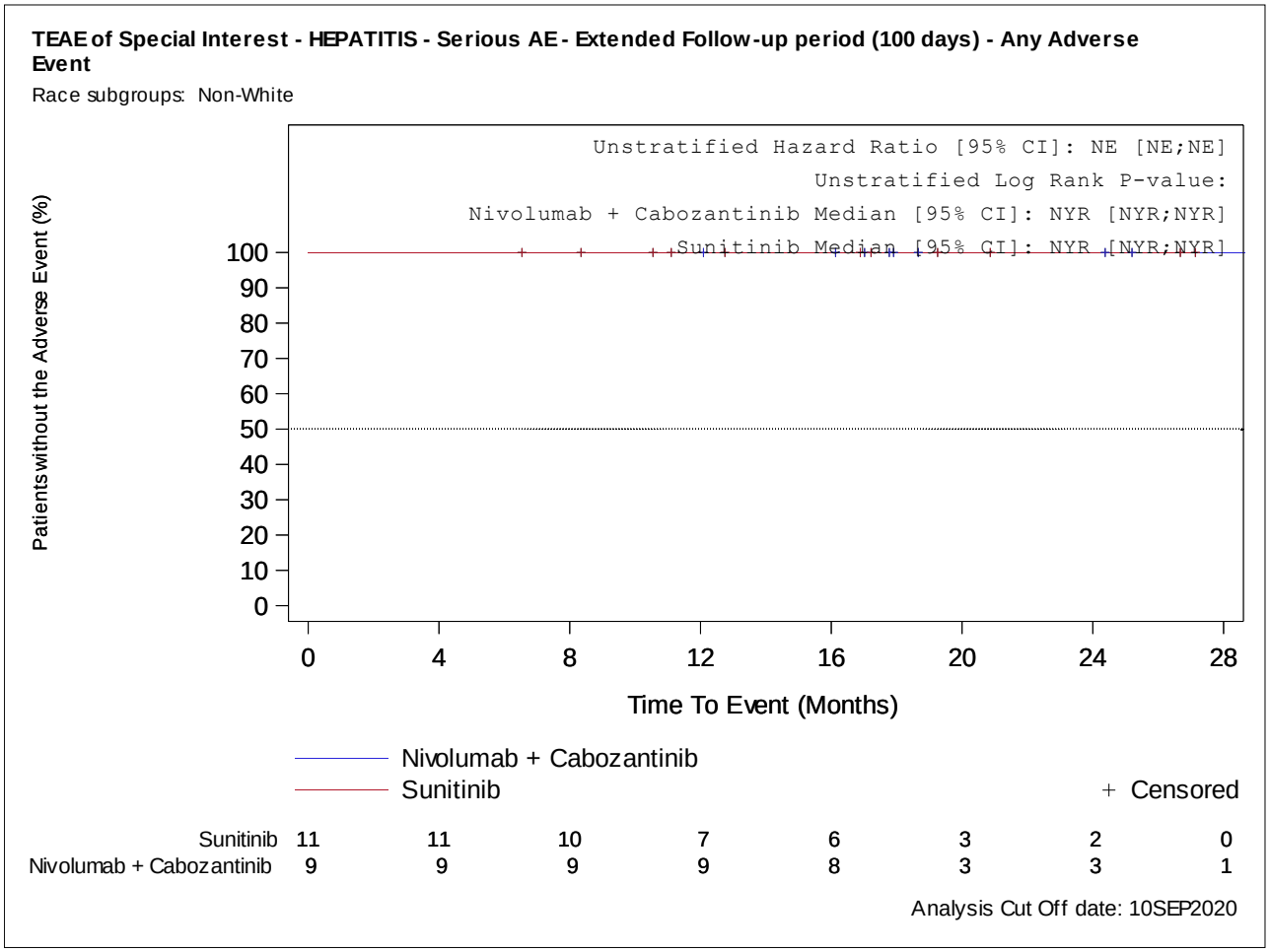

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:33:53

FIGURE 3.82.2.8: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



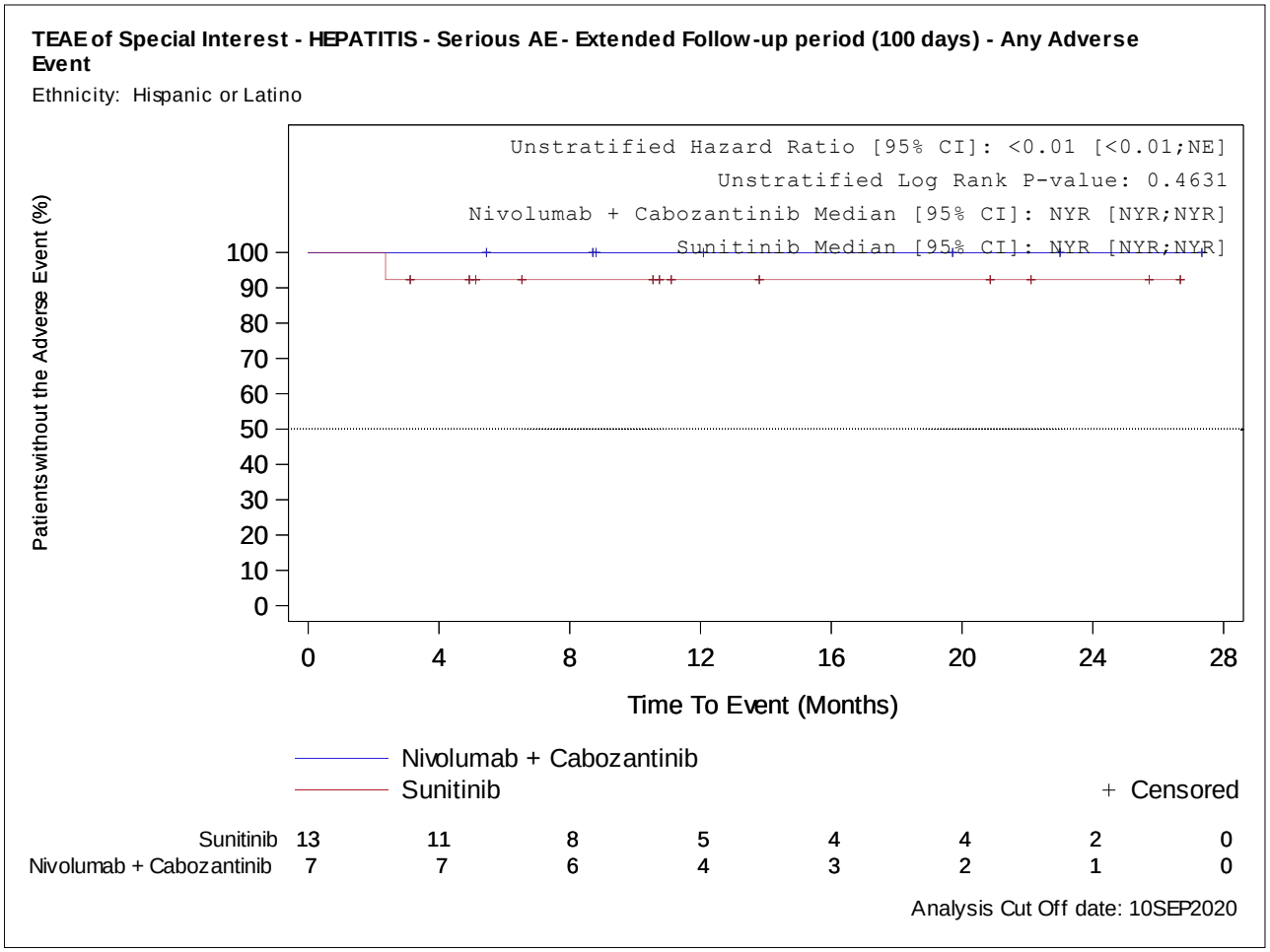

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:33:59

FIGURE 3.82.2.9: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



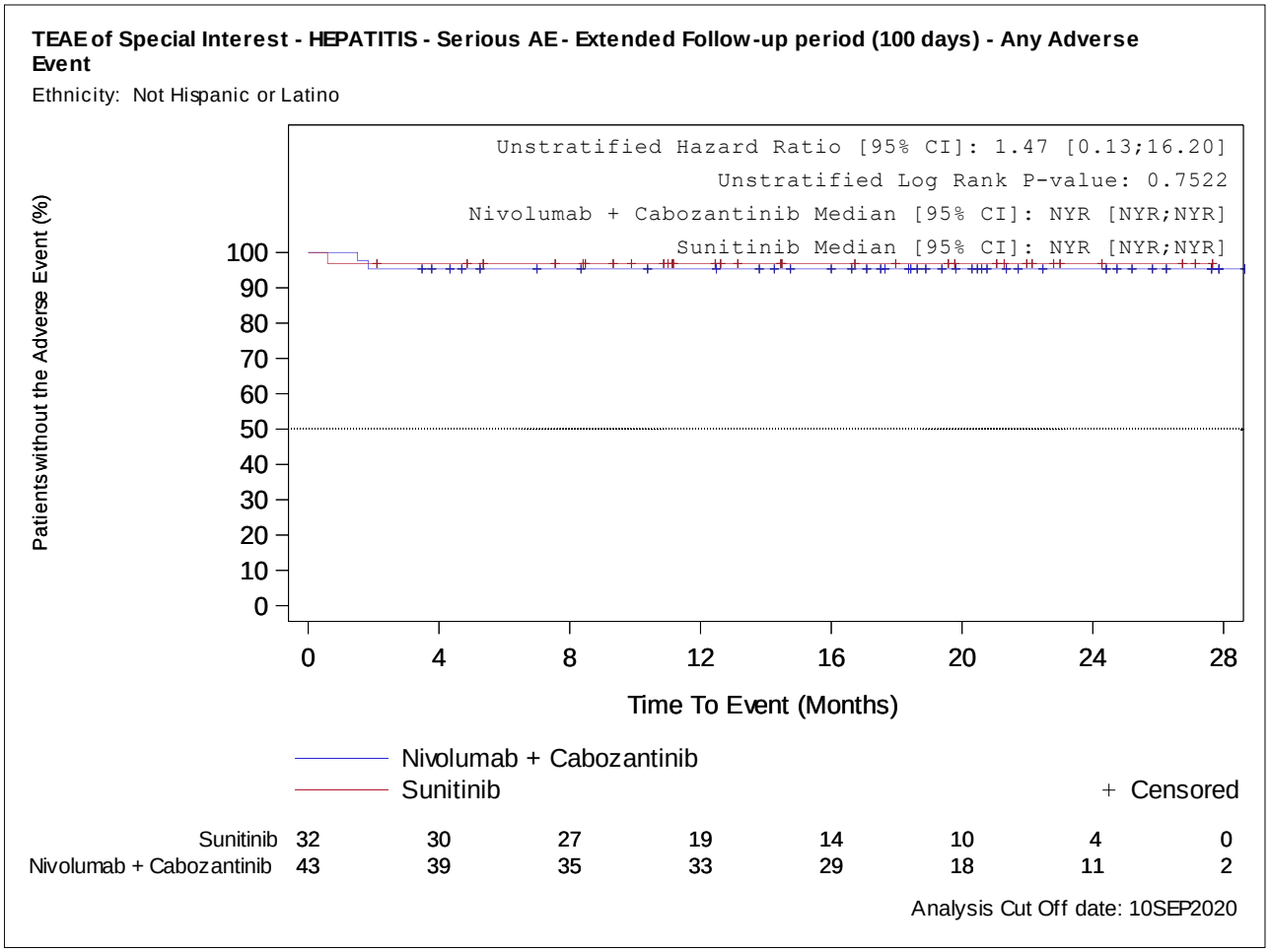

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:34:05

FIGURE 3.82.2.10: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



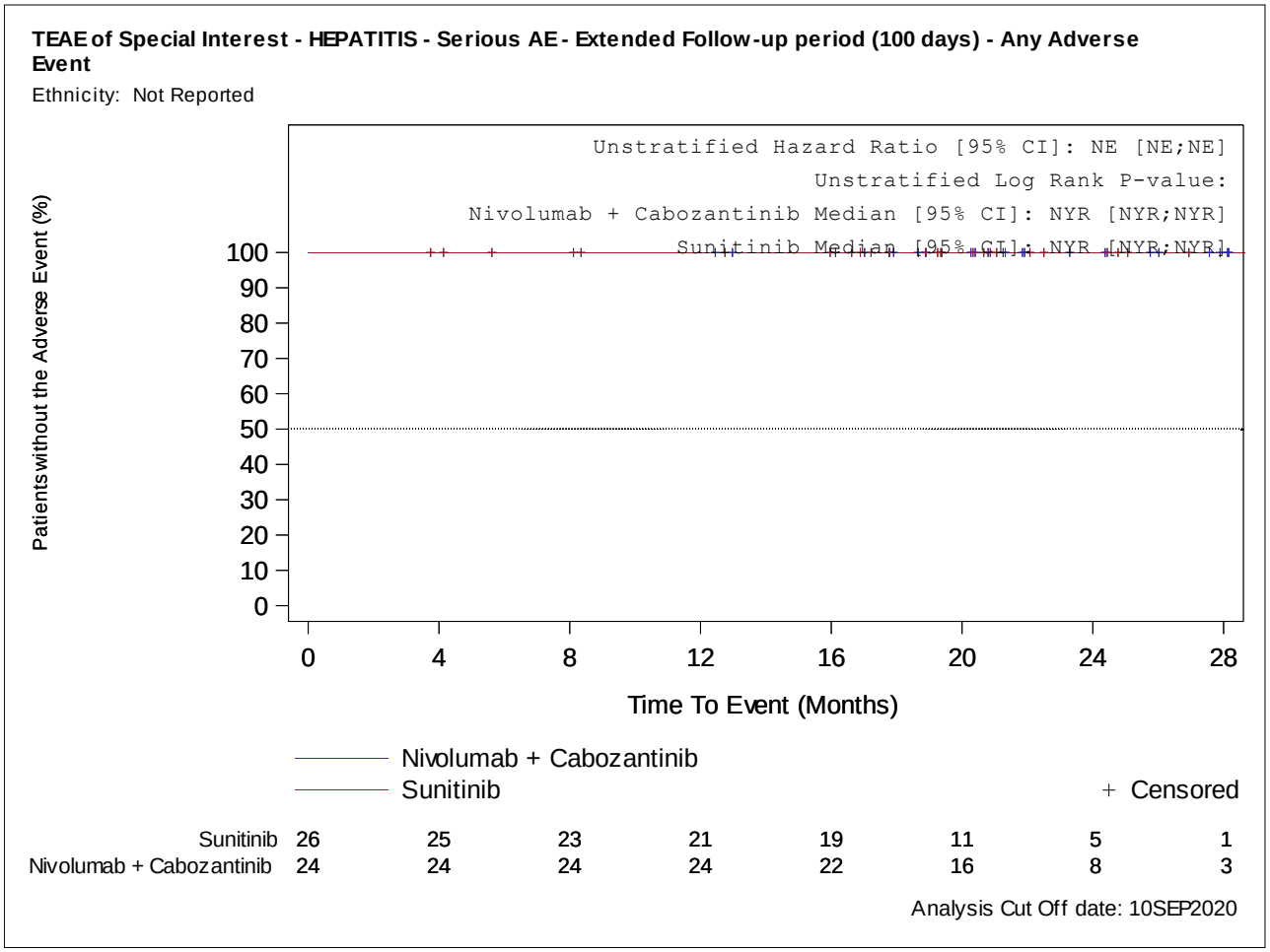

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:34:10

FIGURE 3.82.2.11: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



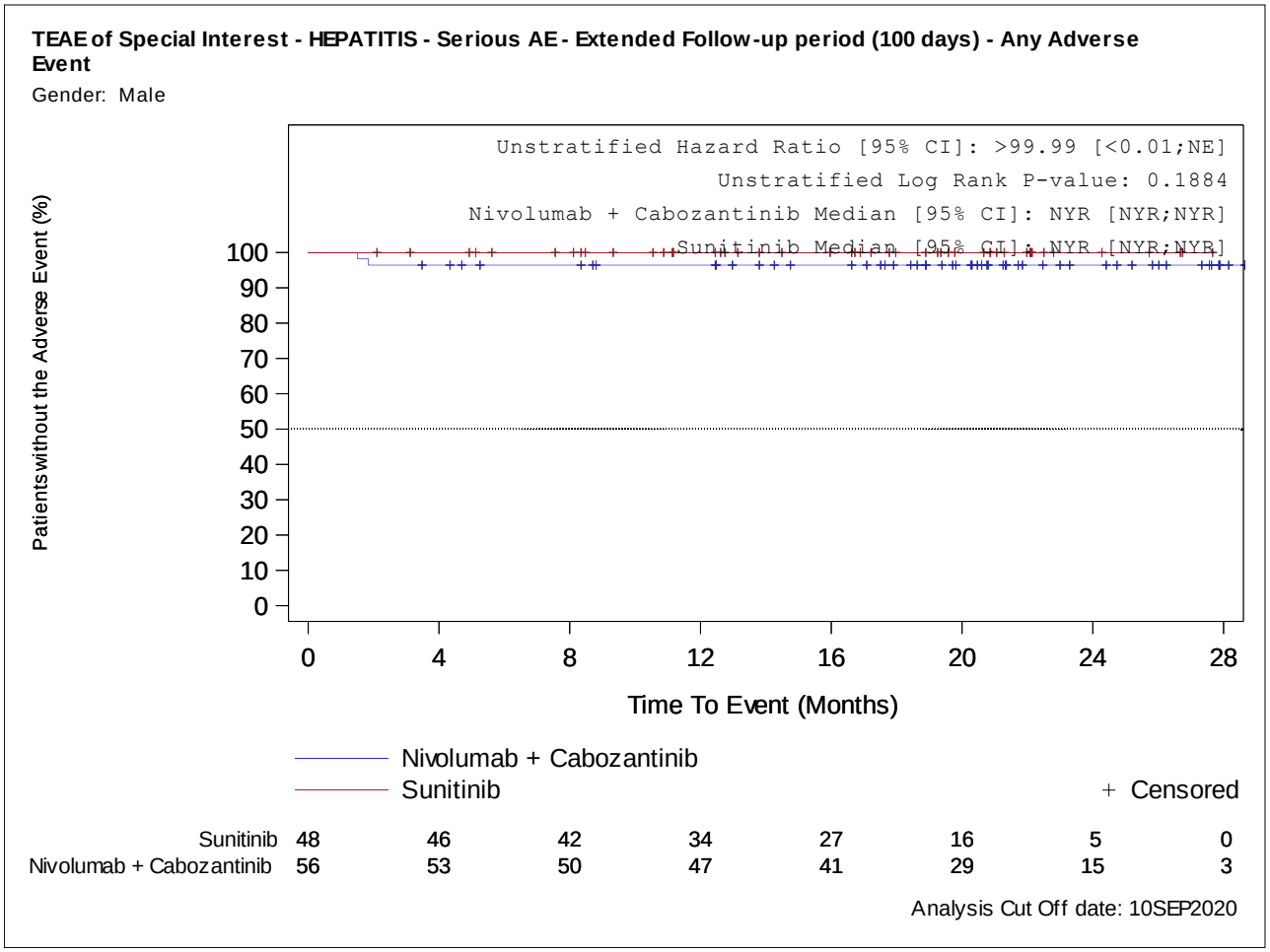

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:34:16

FIGURE 3.82.2.12: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



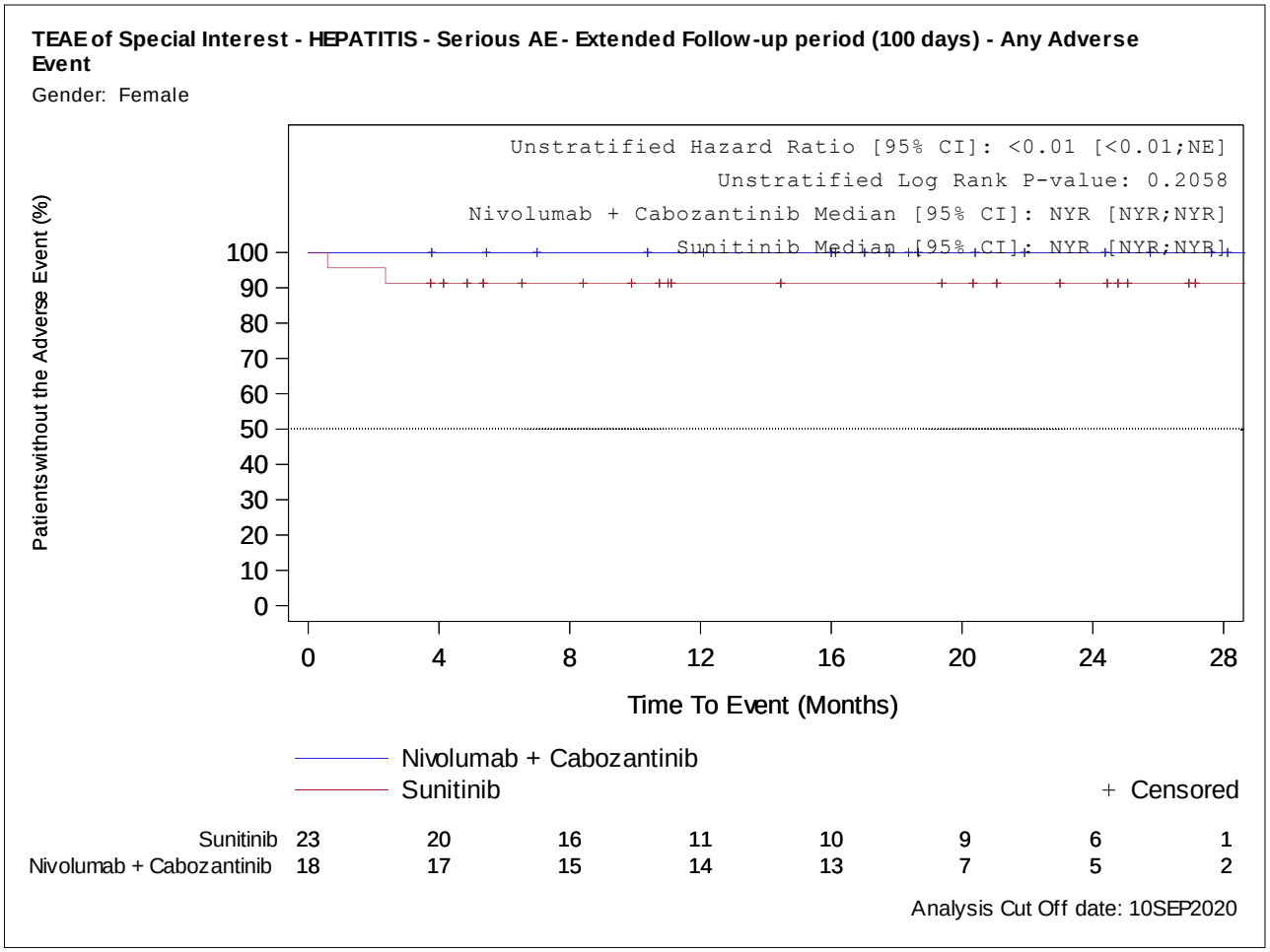

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:34:22

FIGURE 3.82.2.13: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:34:28

FIGURE 3.82.2.14: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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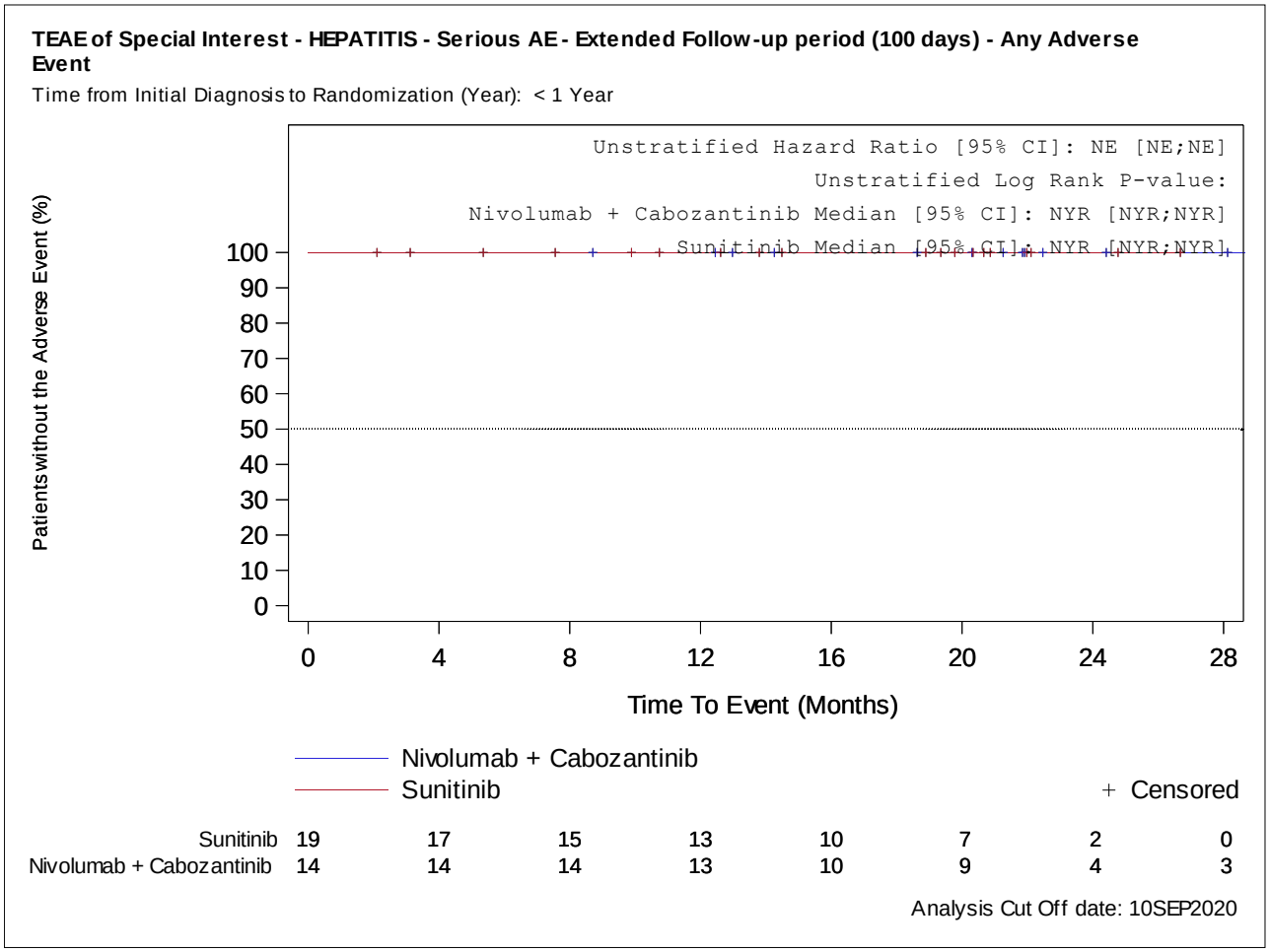
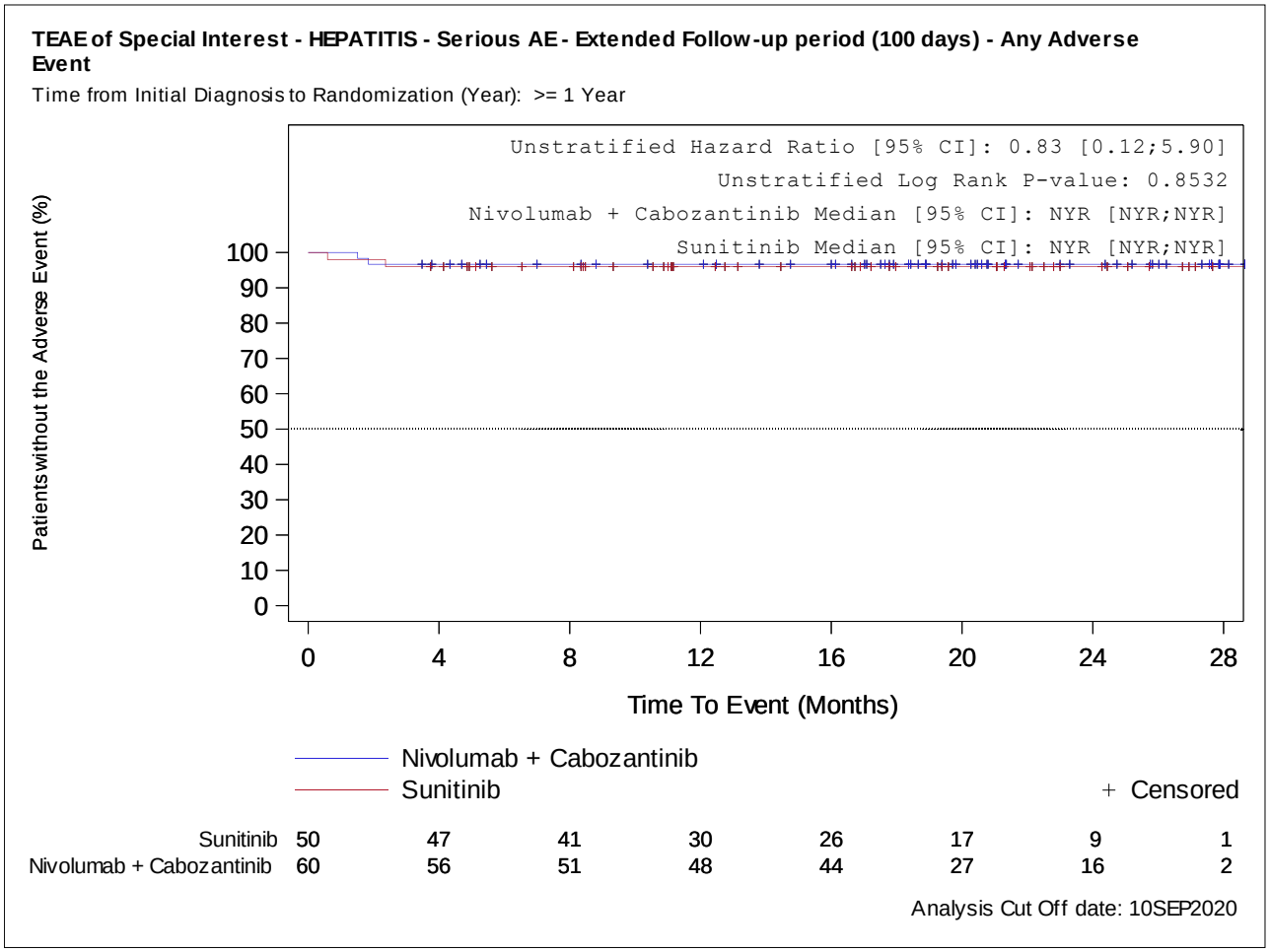
FIGURE 3.82.2.15: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:34:52

FIGURE 3.82.2.16: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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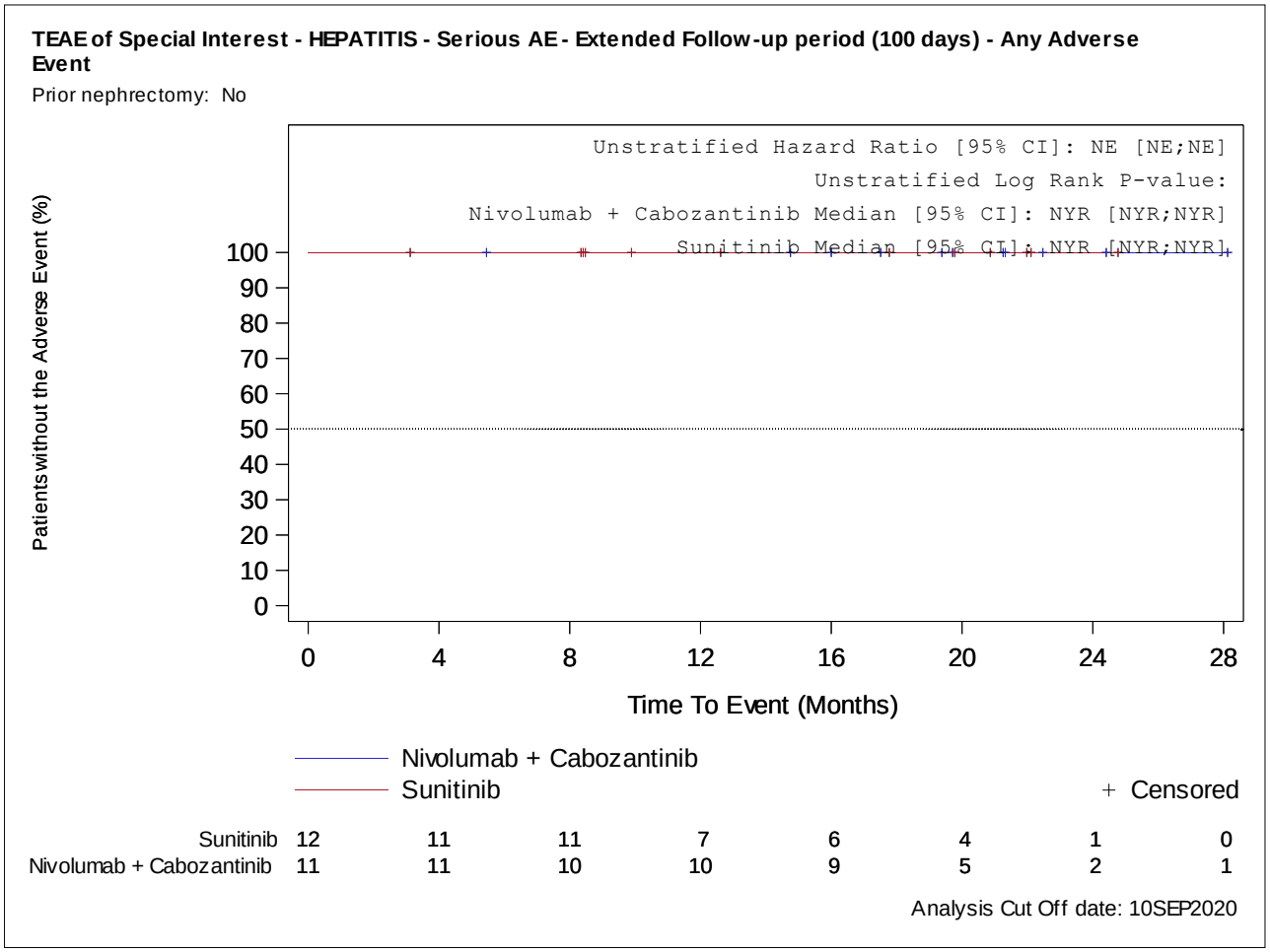
FIGURE 3.82.2.17: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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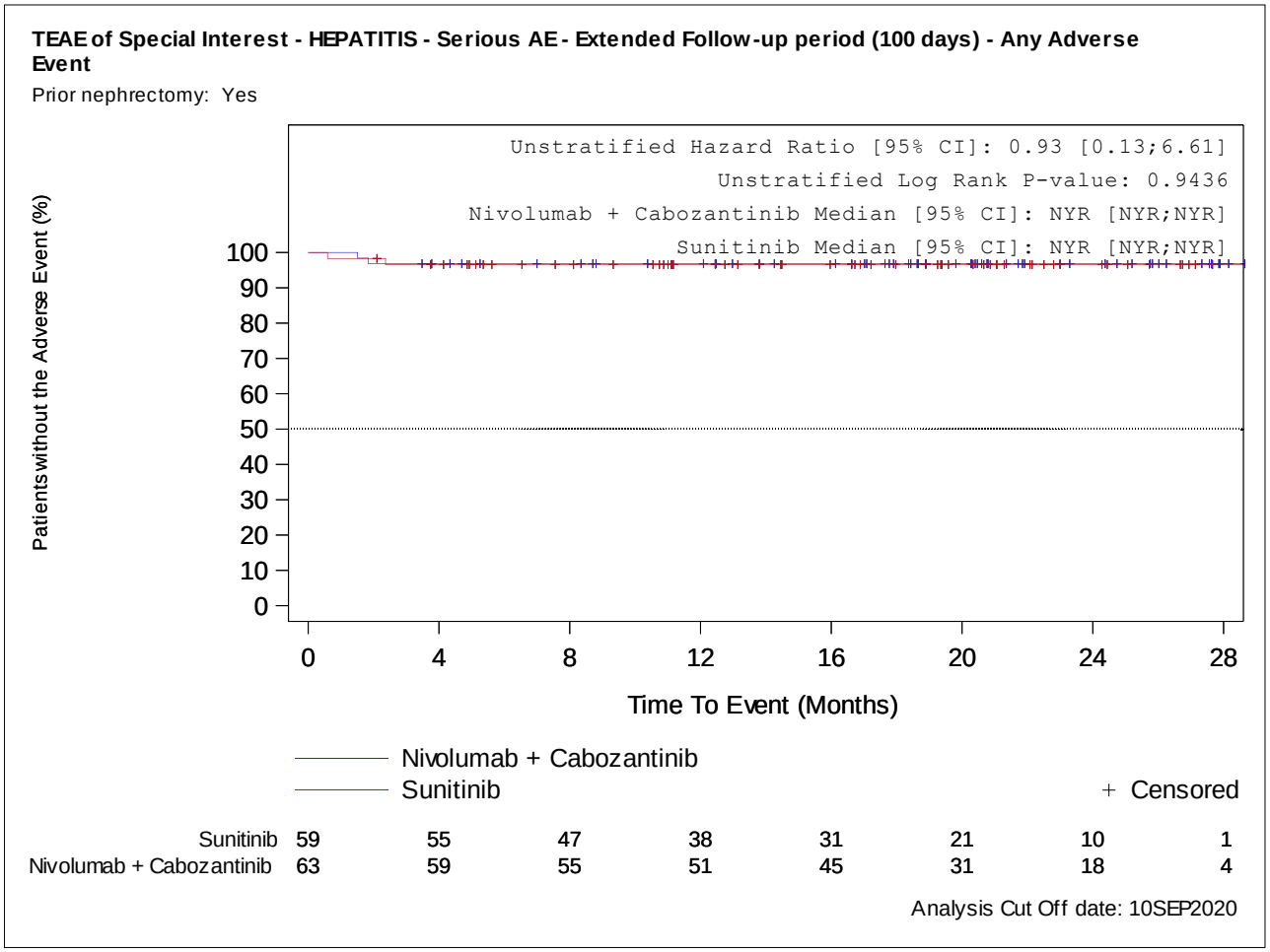
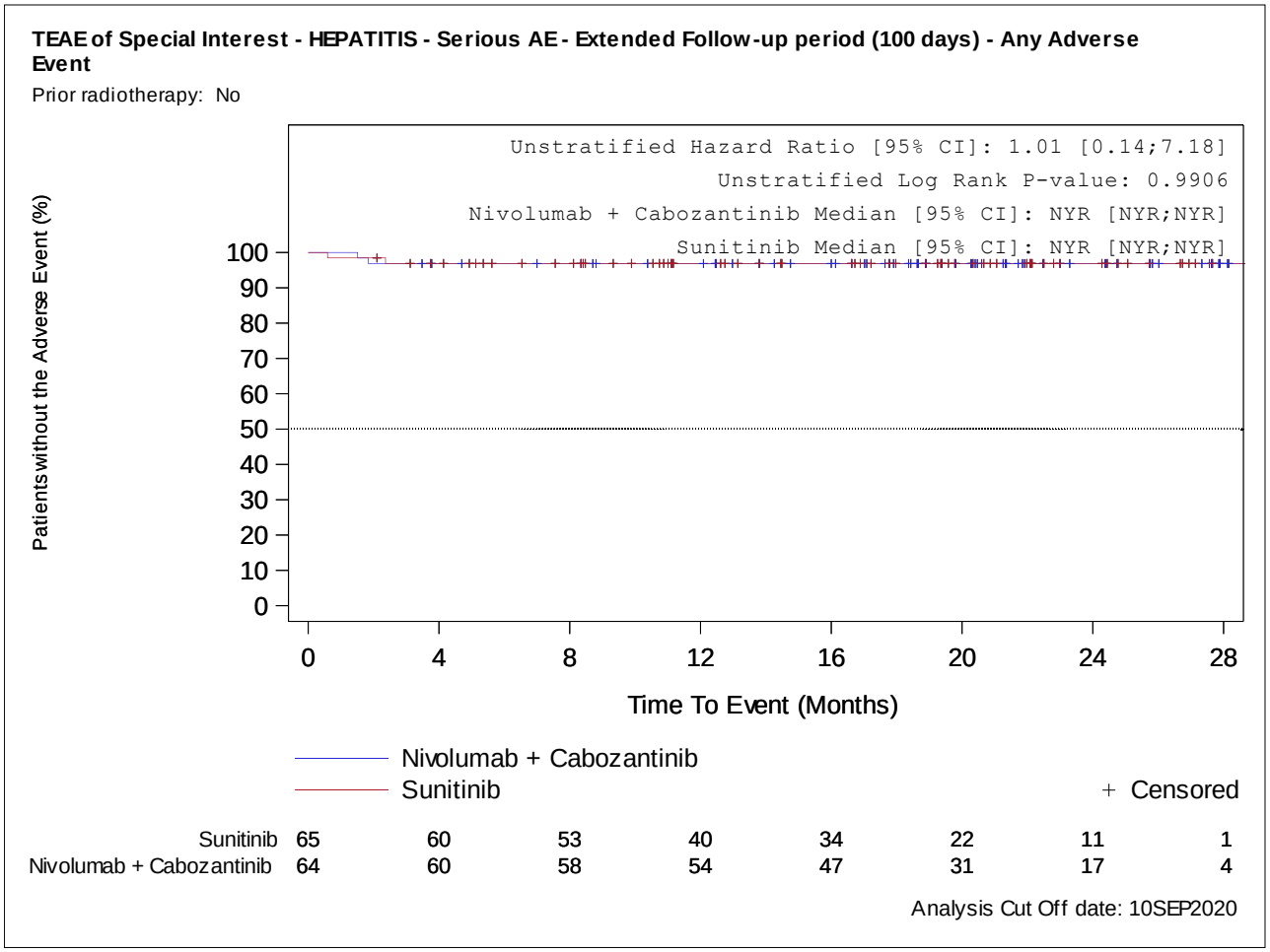
FIGURE 3.82.2.18: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



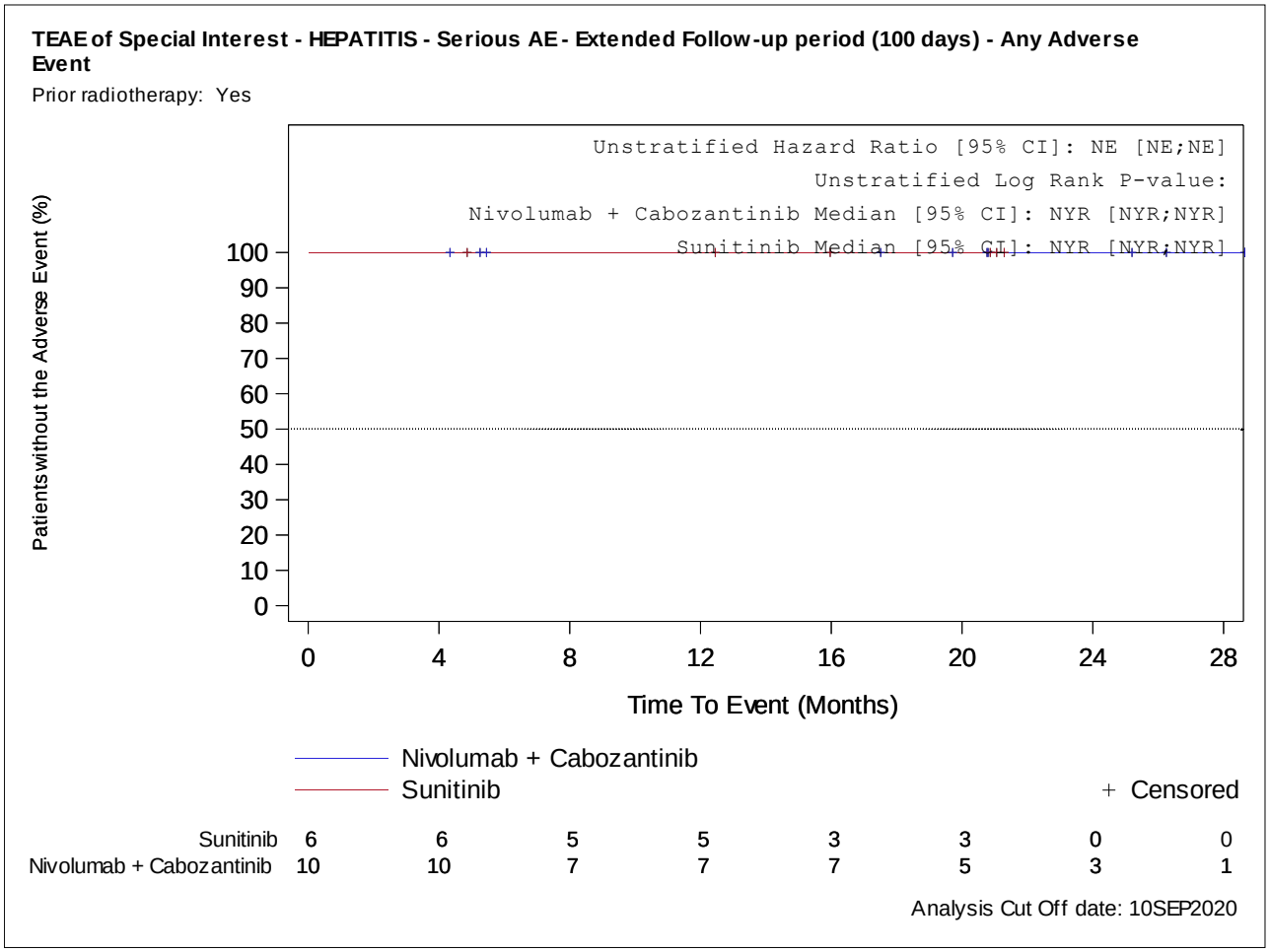

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:35:58

FIGURE 3.82.2.19: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



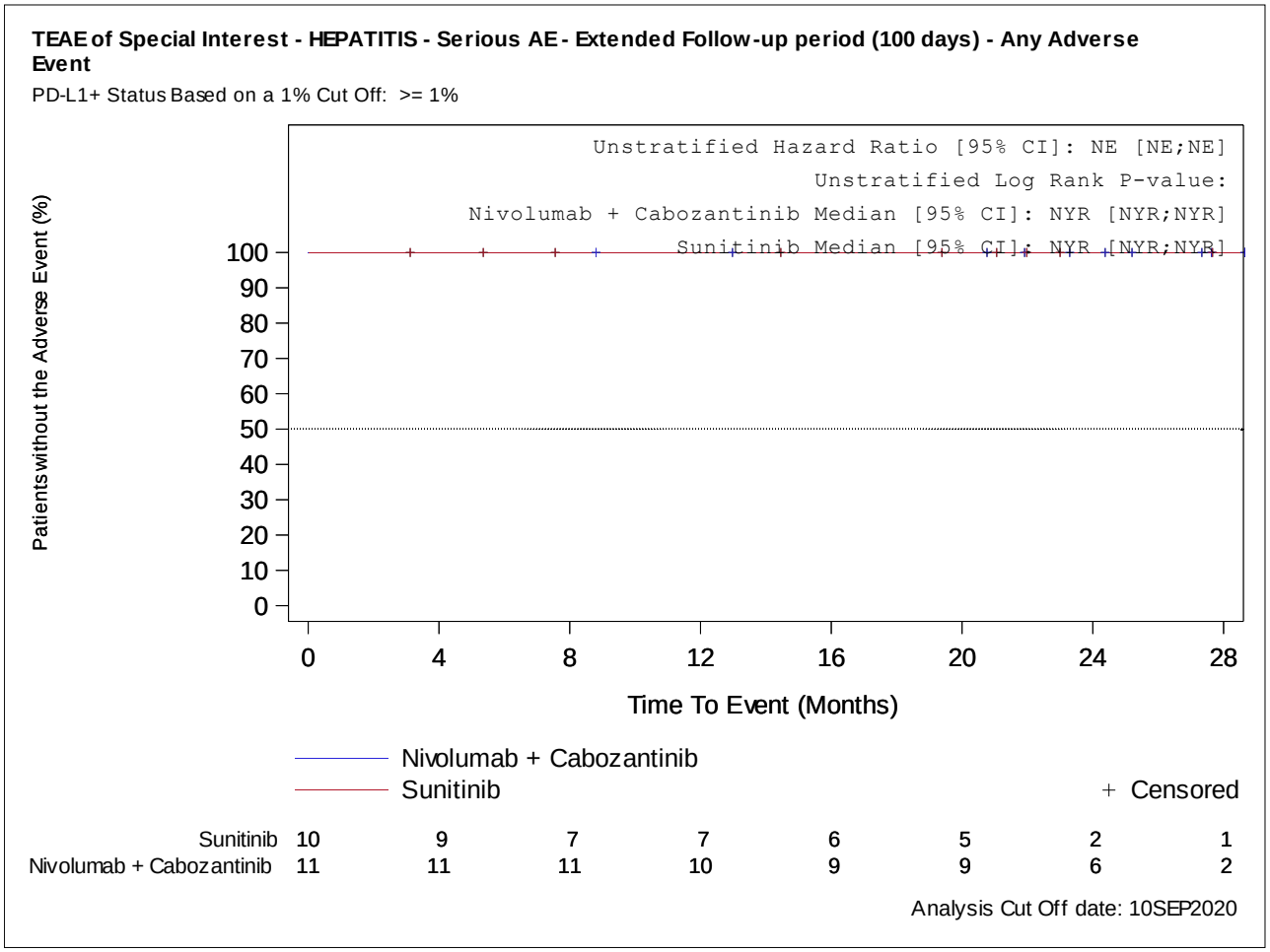

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:36:04

FIGURE 3.82.2.20: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



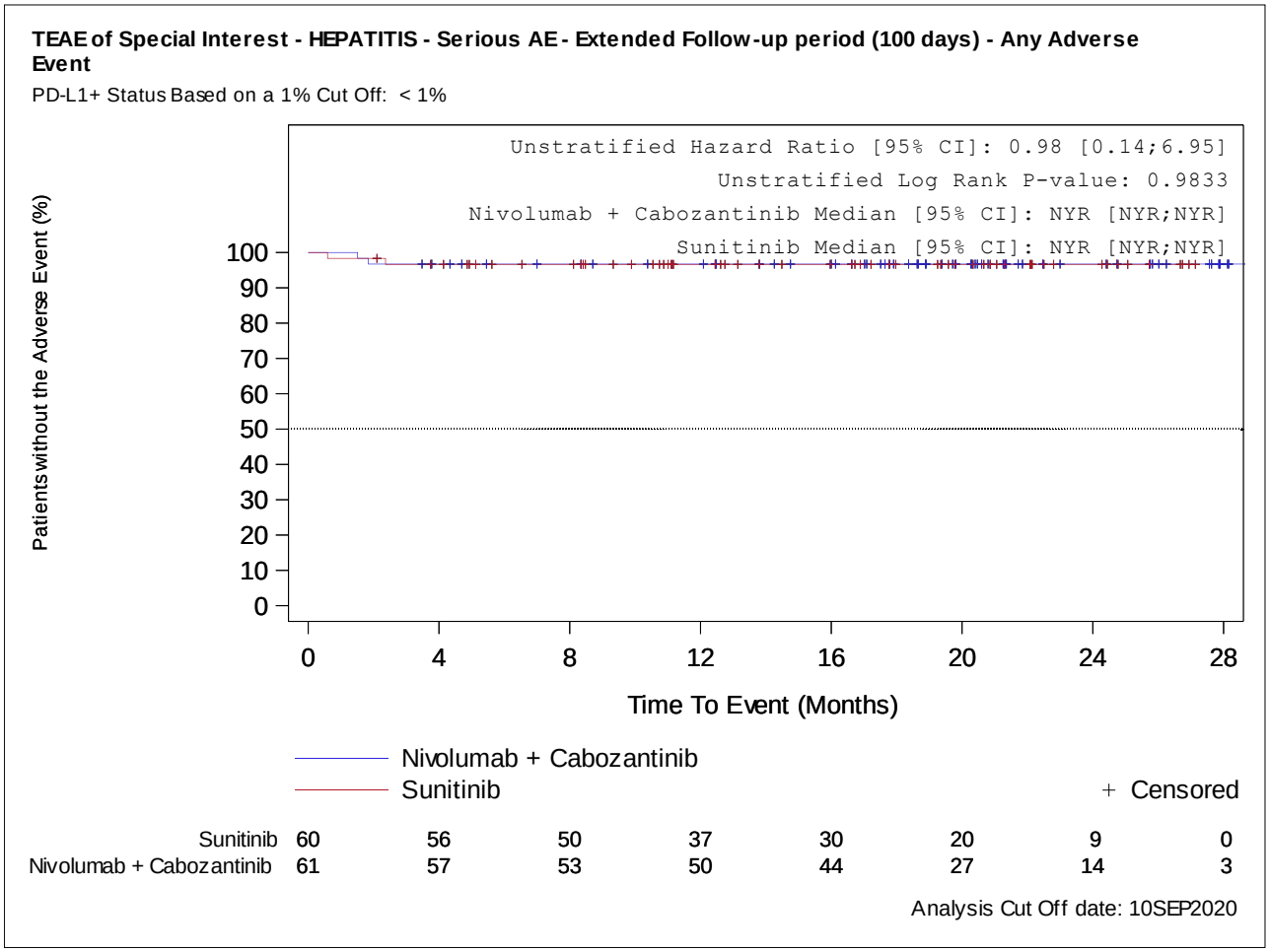

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:36:10

FIGURE 3.82.2.21: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



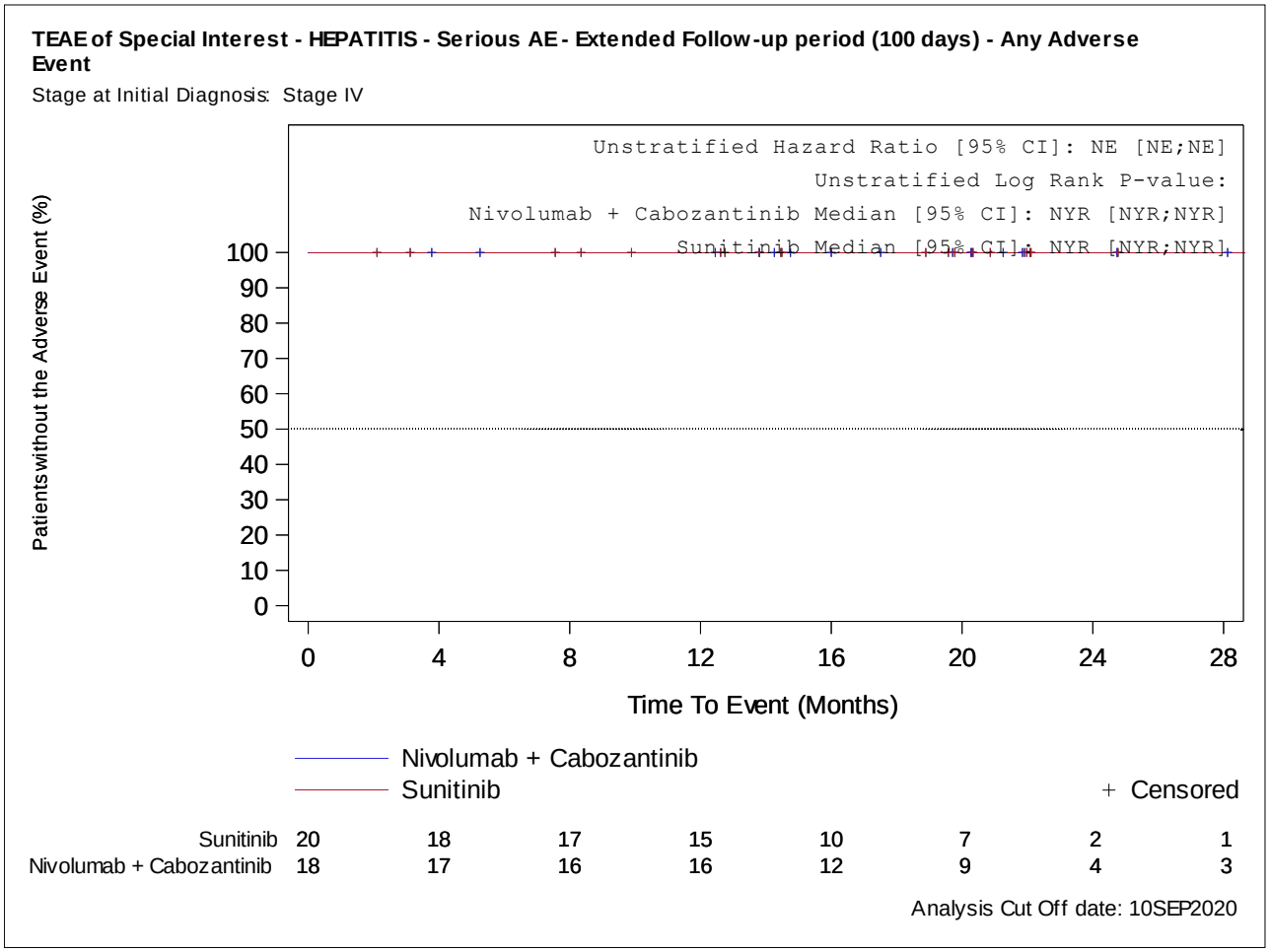

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:36:16

FIGURE 3.82.2.22: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



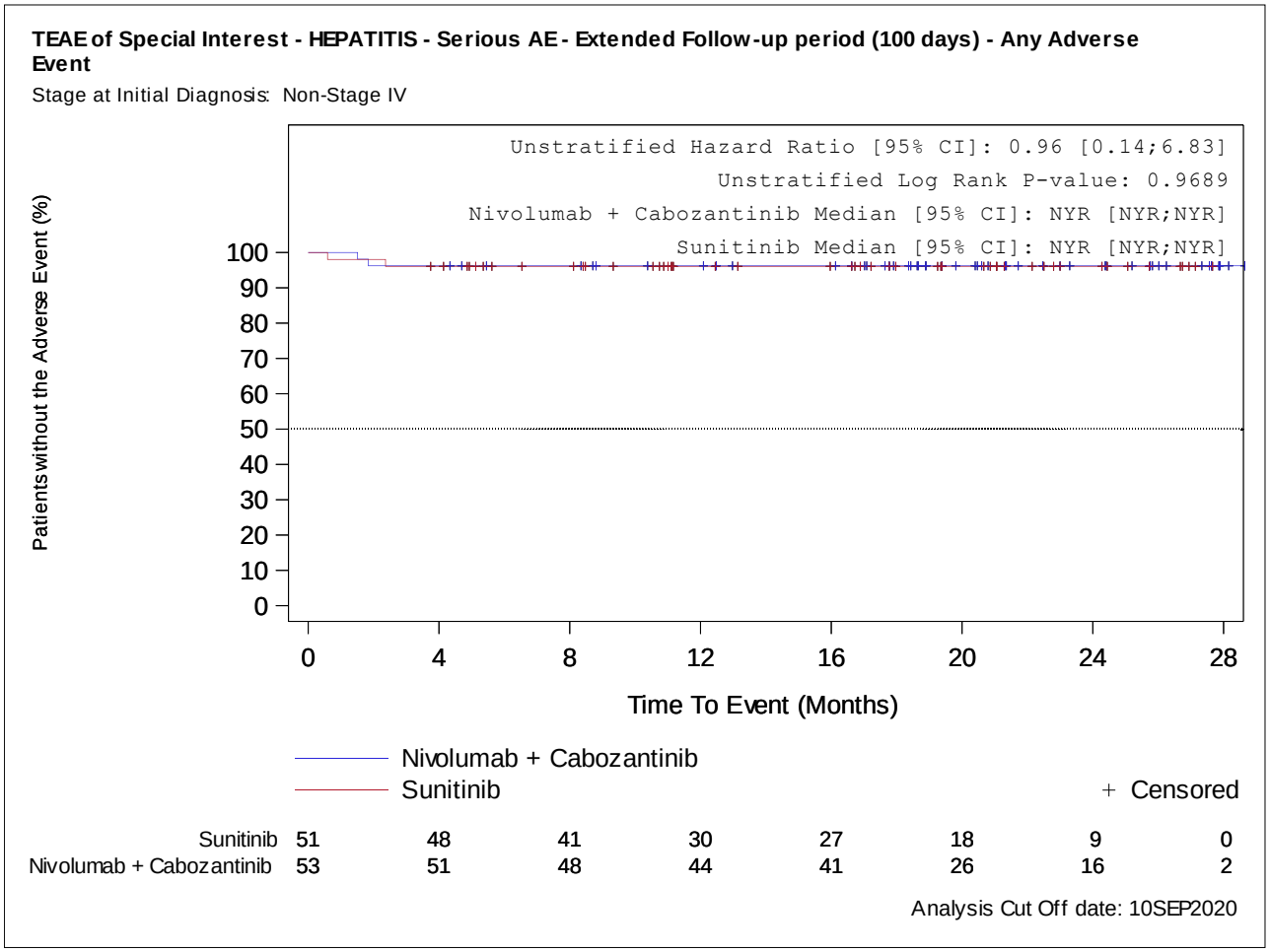

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:36:22

FIGURE 3.82.2.23: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



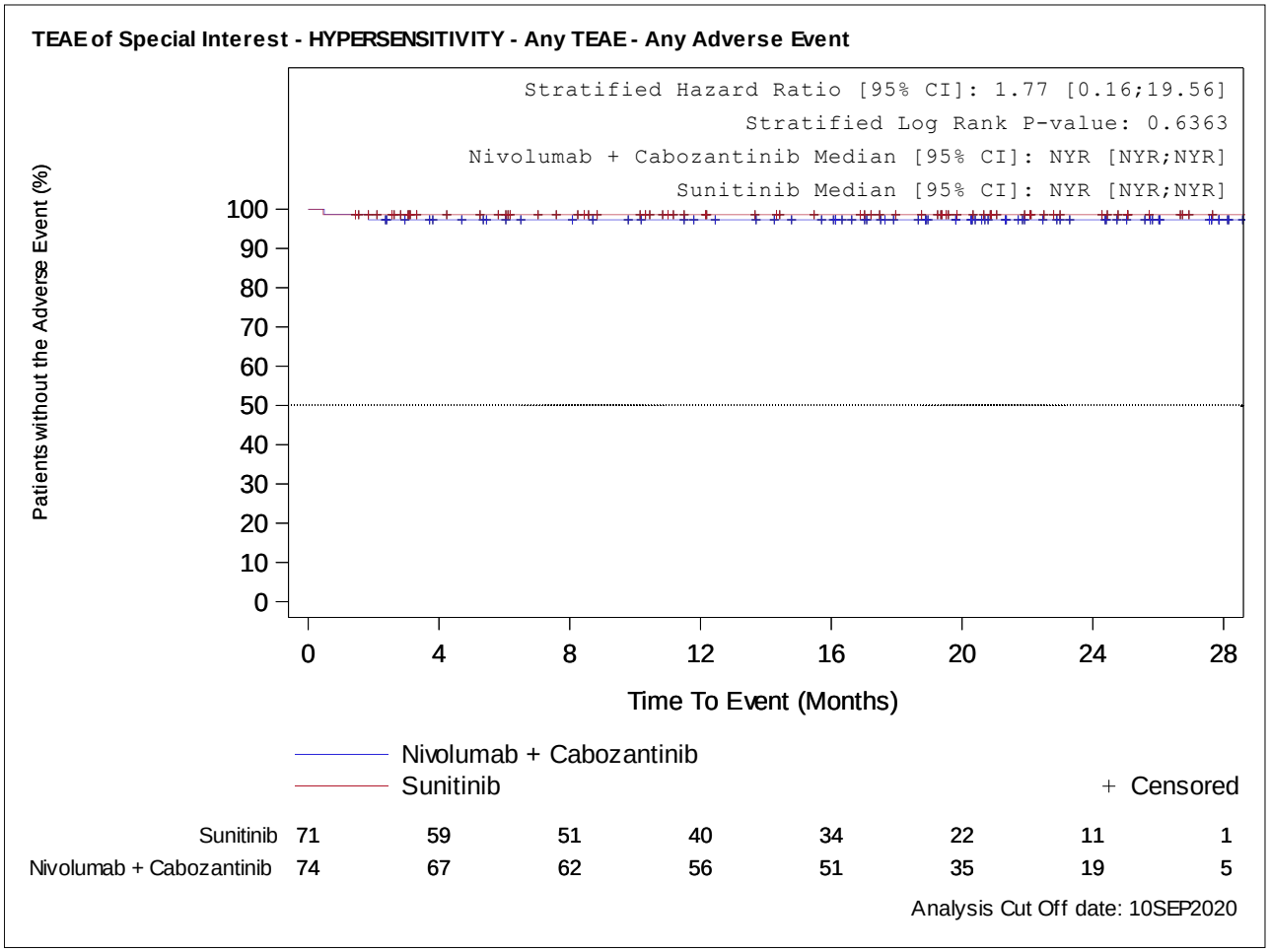

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:36:49

FIGURE 3.82.2.24: Kaplan-Meier curve - TEAE of Special Interest - HEPATITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



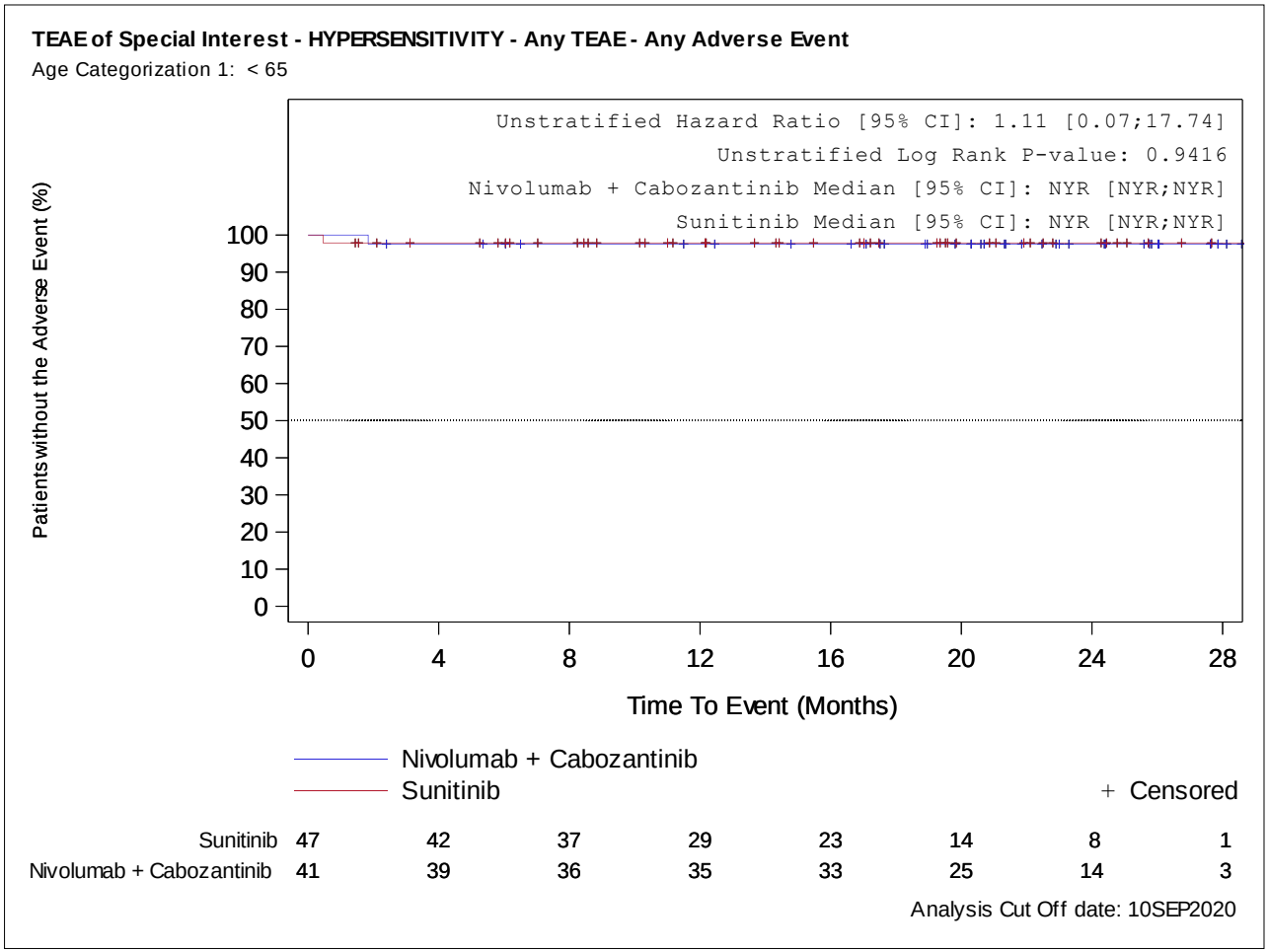

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:36:55

FIGURE 3.83.1: TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



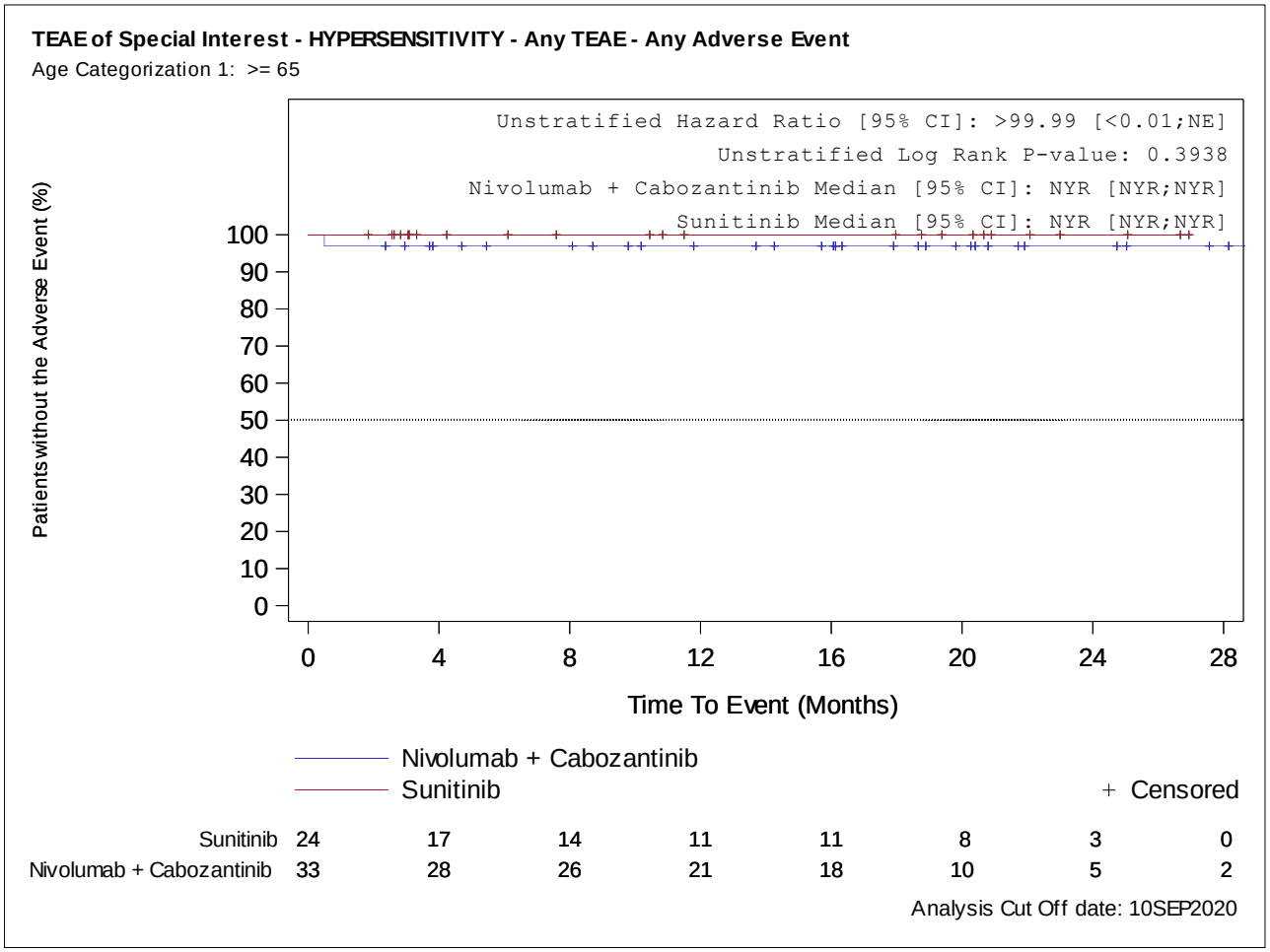

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:40:08

FIGURE 3.83.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



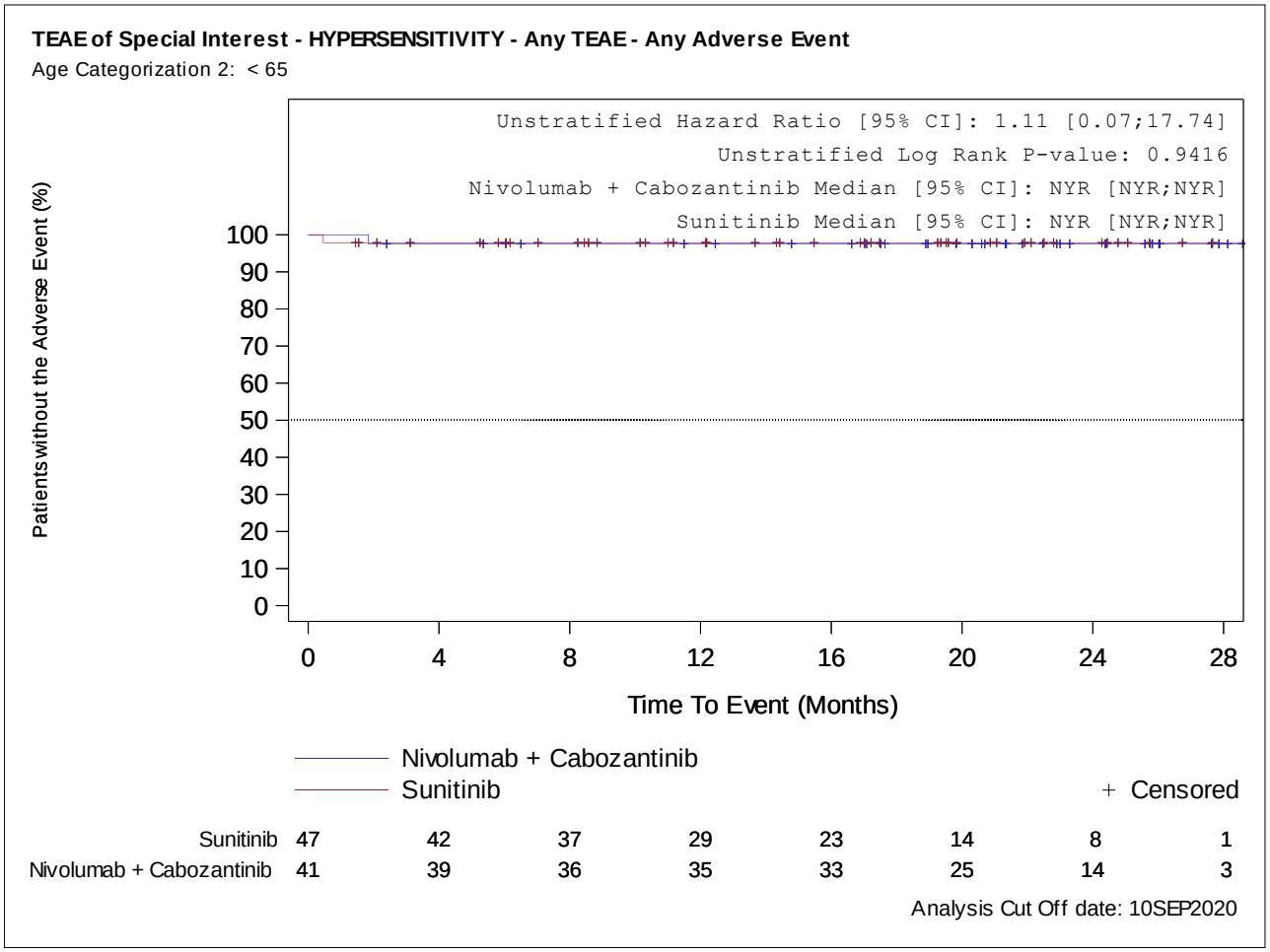

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:40:11

FIGURE 3.83.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



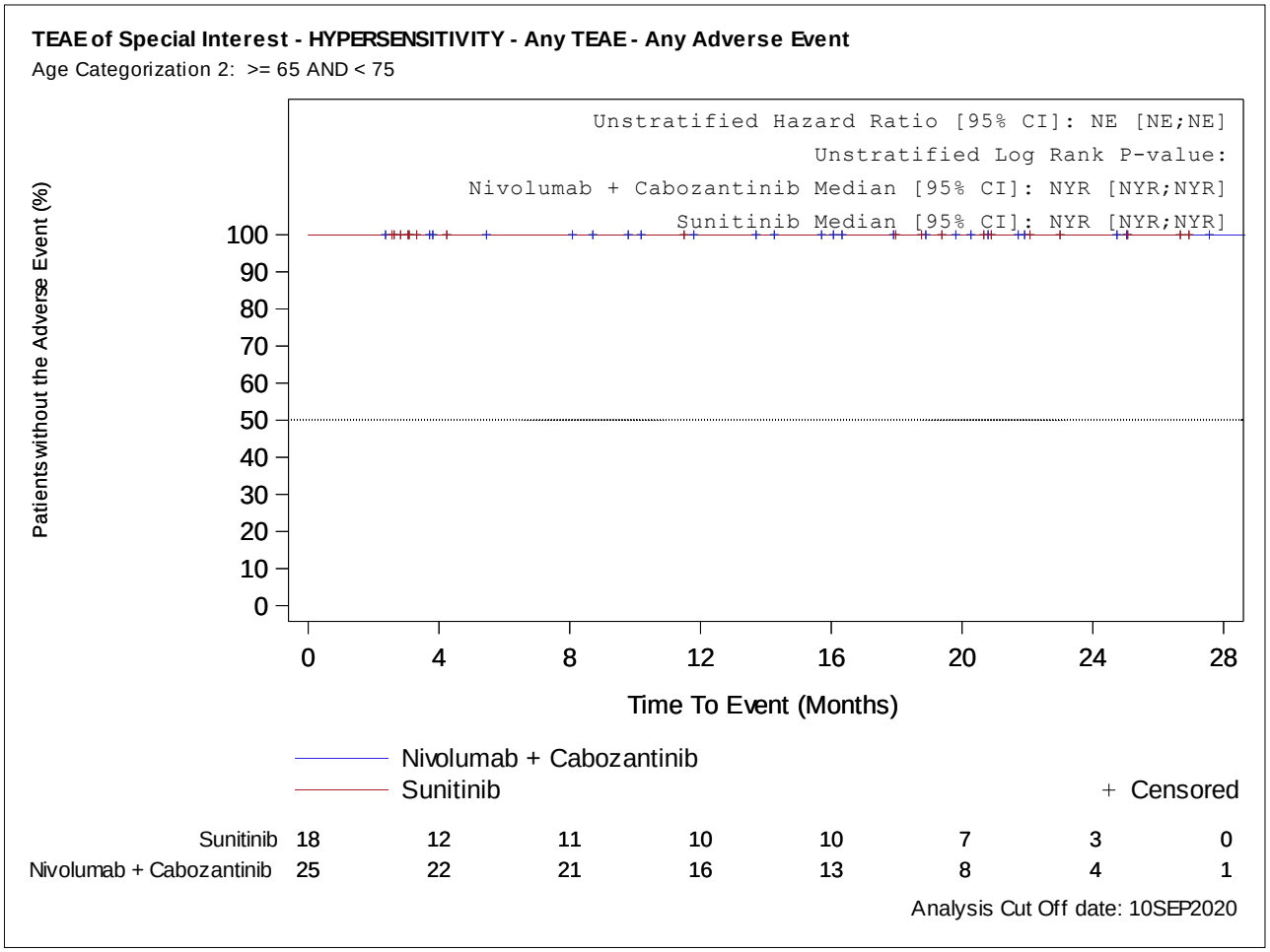

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:40:17

FIGURE 3.83.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



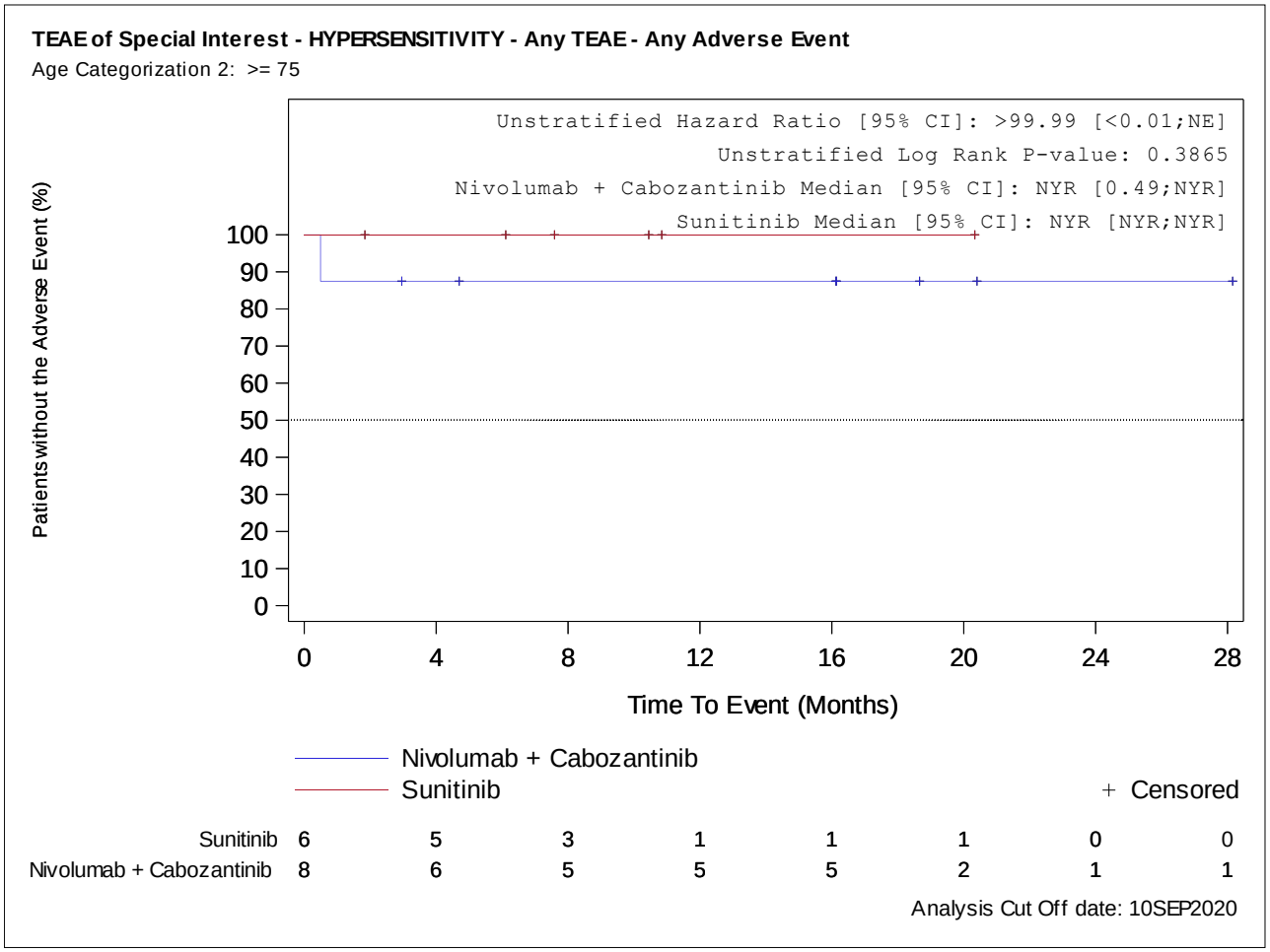

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:40:22

FIGURE 3.83.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



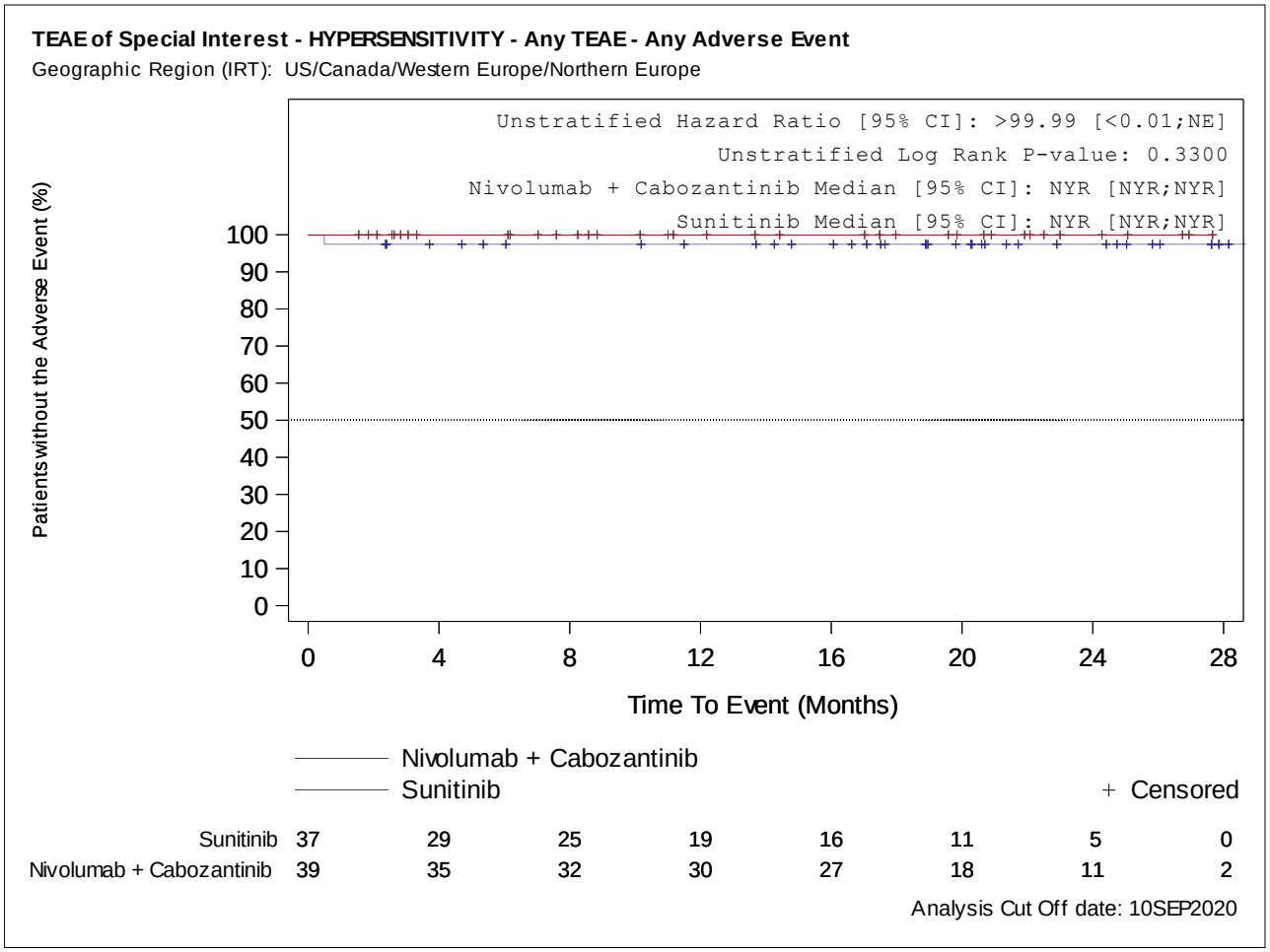

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:40:28

FIGURE 3.83.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



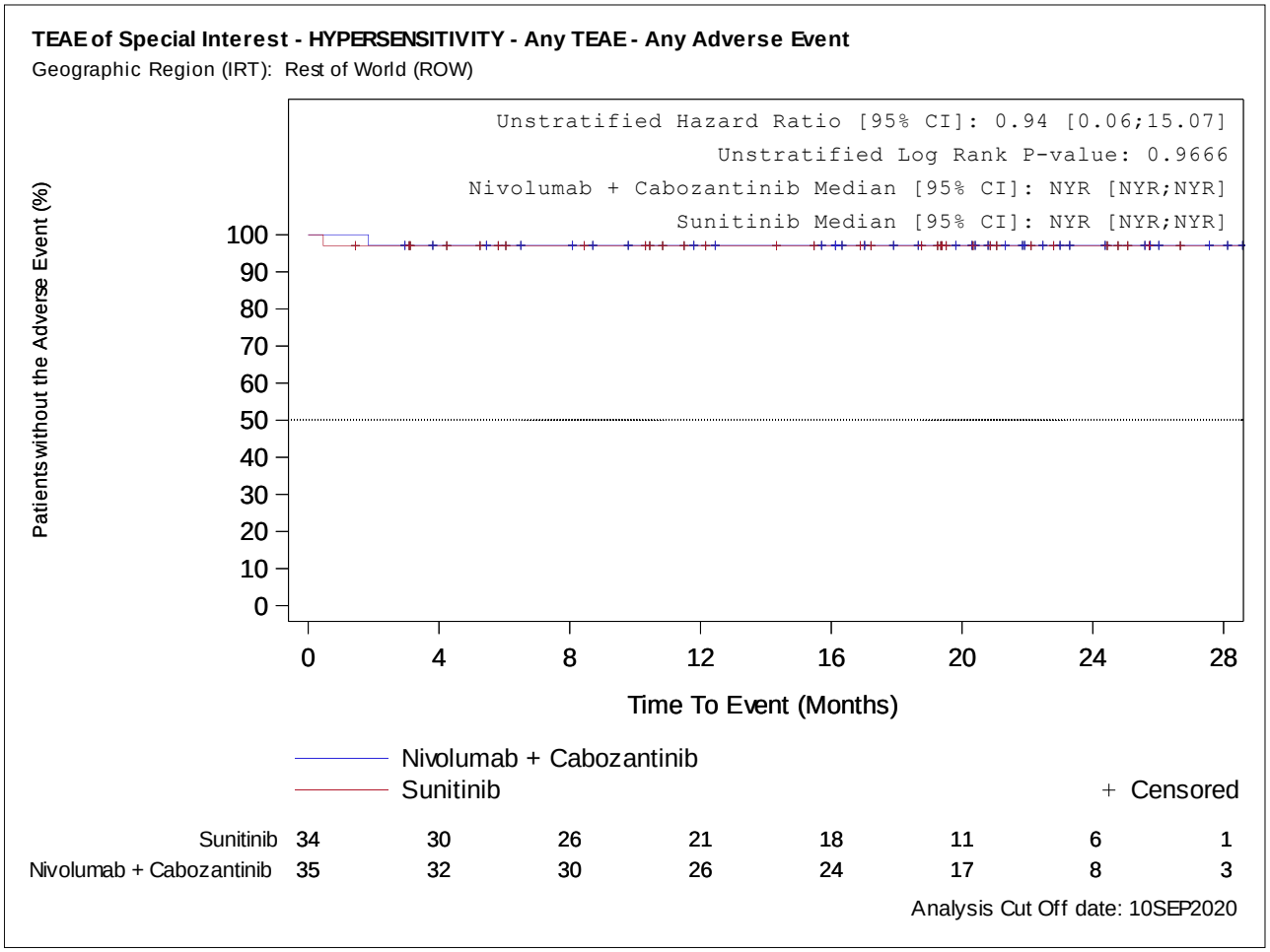

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:40:34

FIGURE 3.83.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



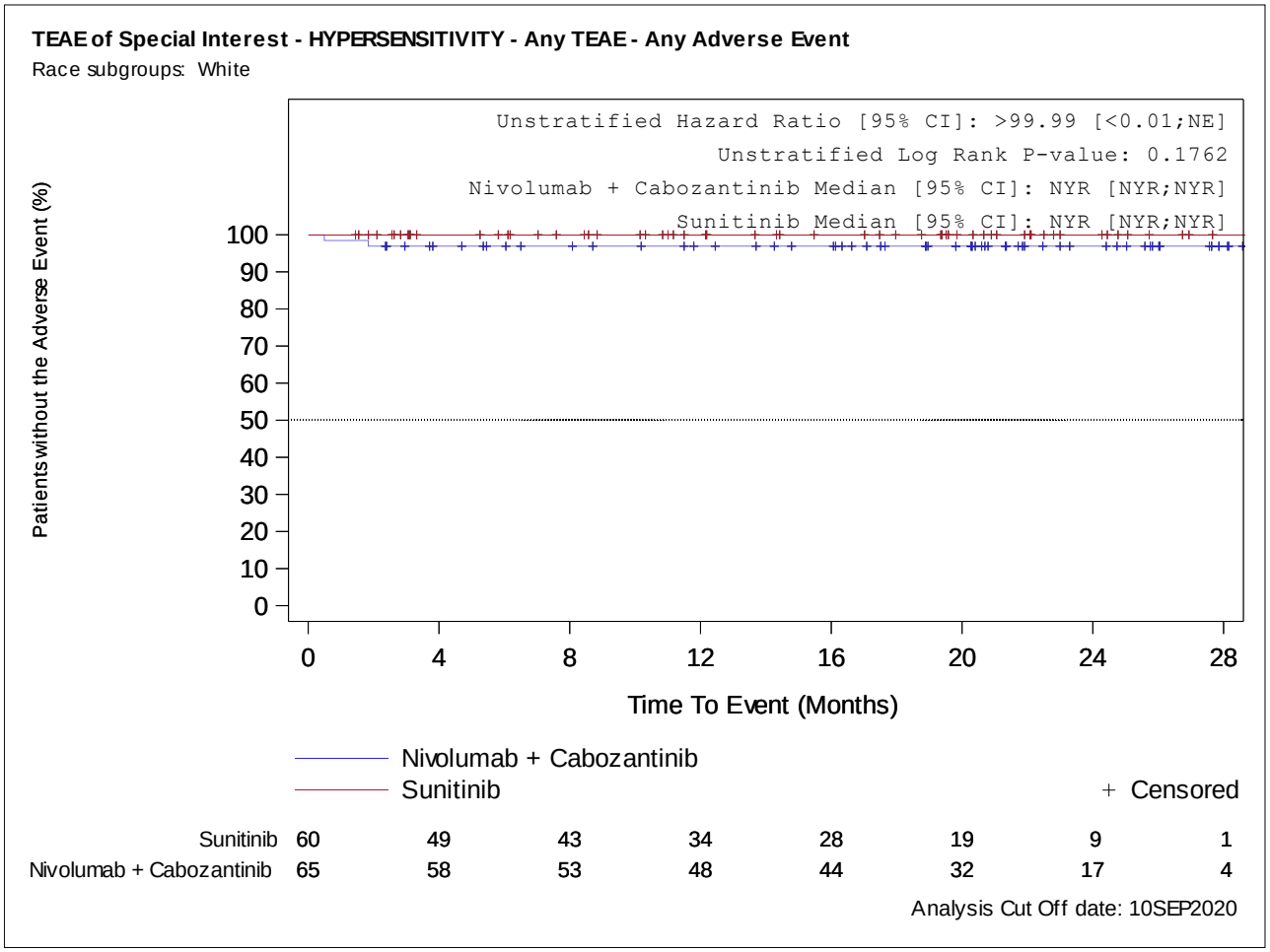

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:40:40

FIGURE 3.83.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



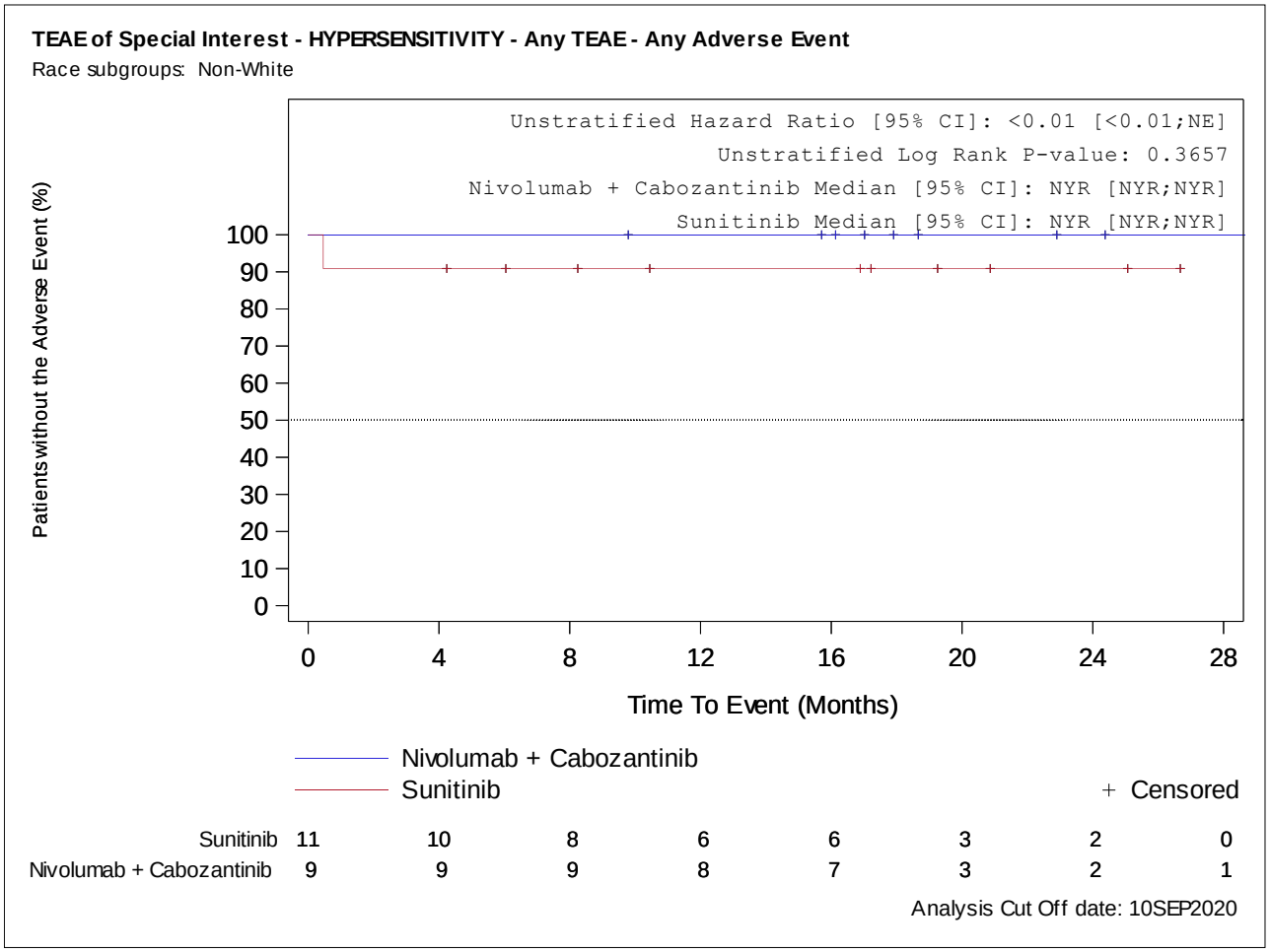

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:40:46

FIGURE 3.83.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



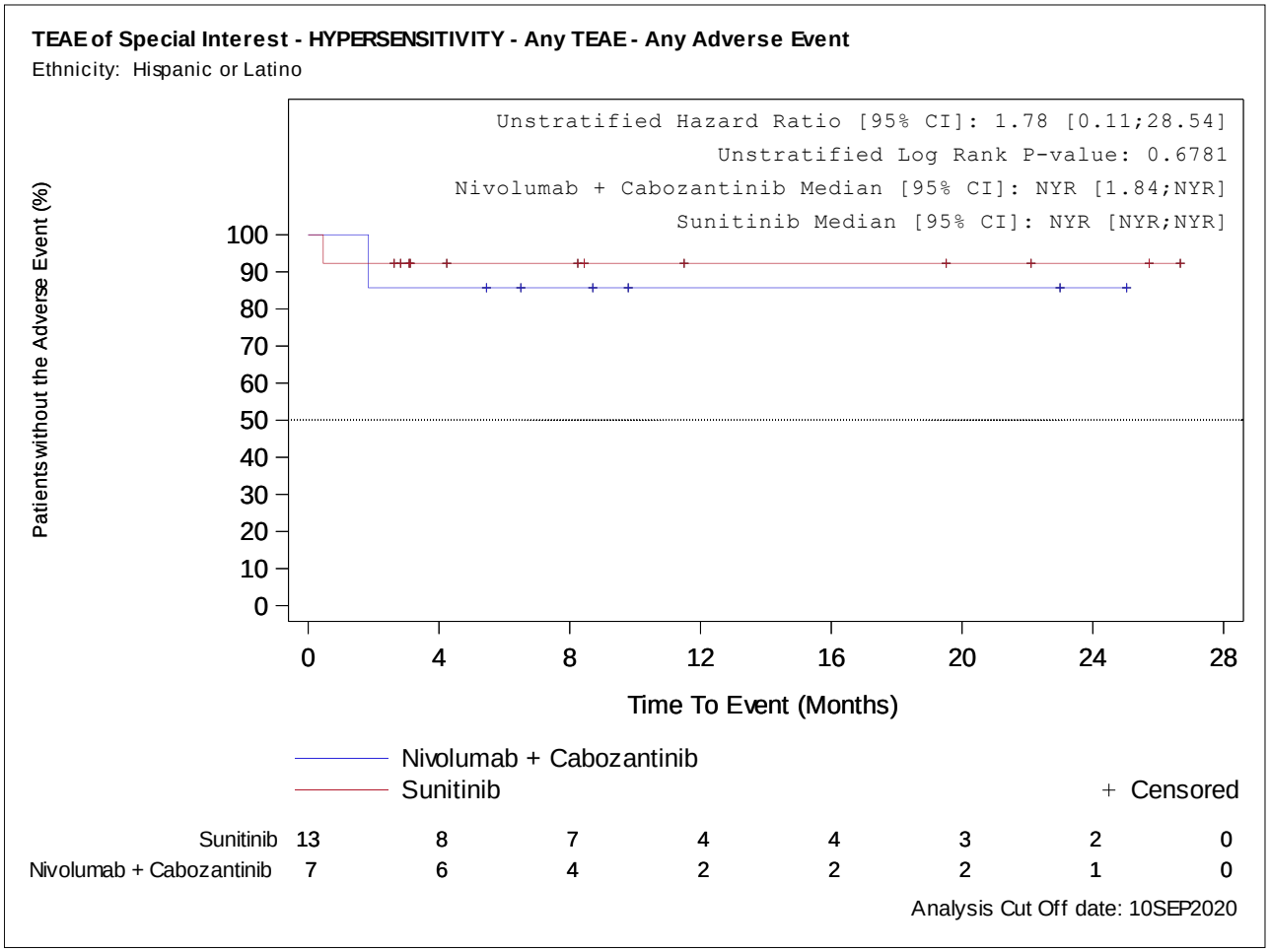

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:40:52

FIGURE 3.83.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



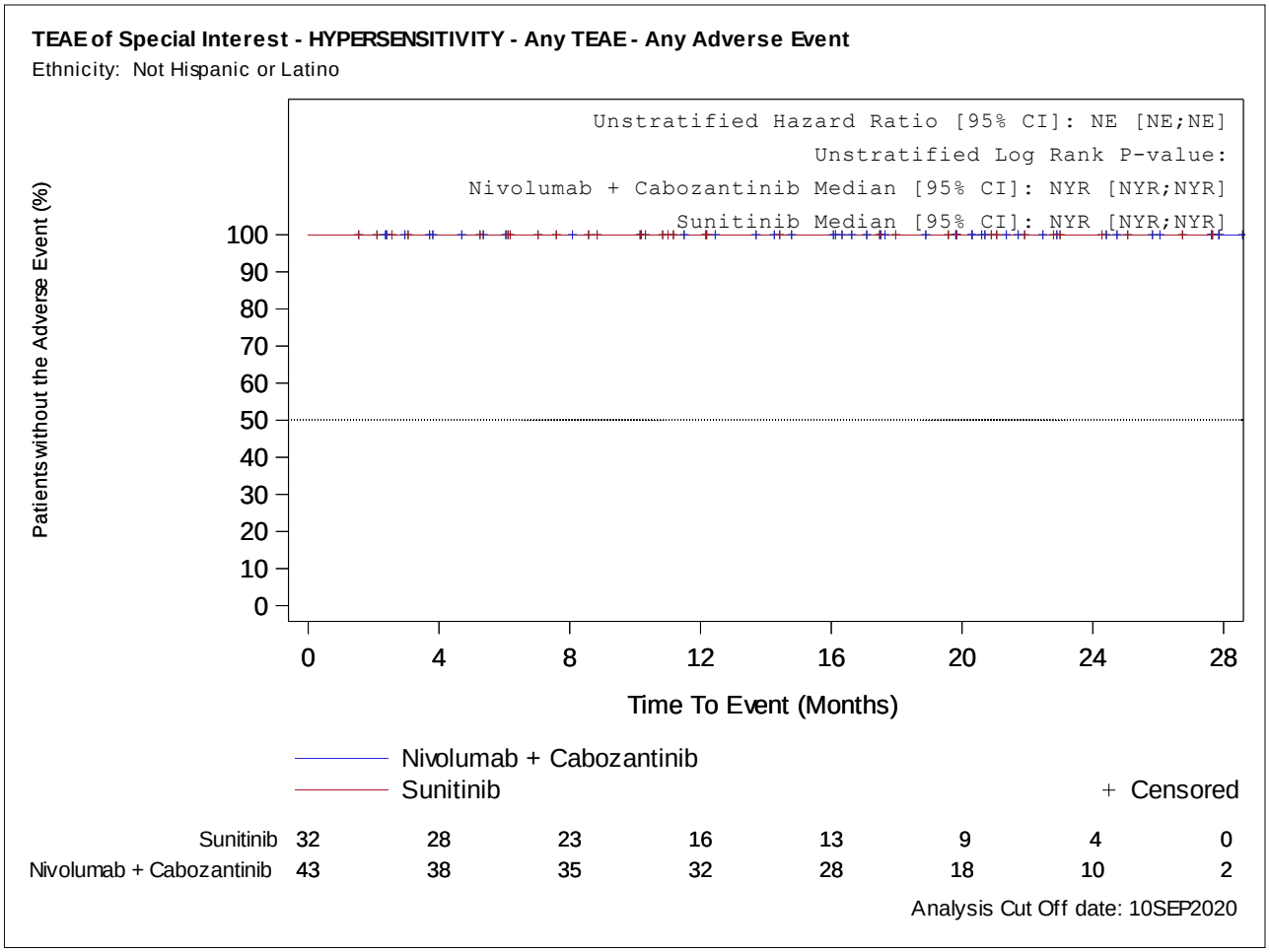

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:40:58

FIGURE 3.83.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



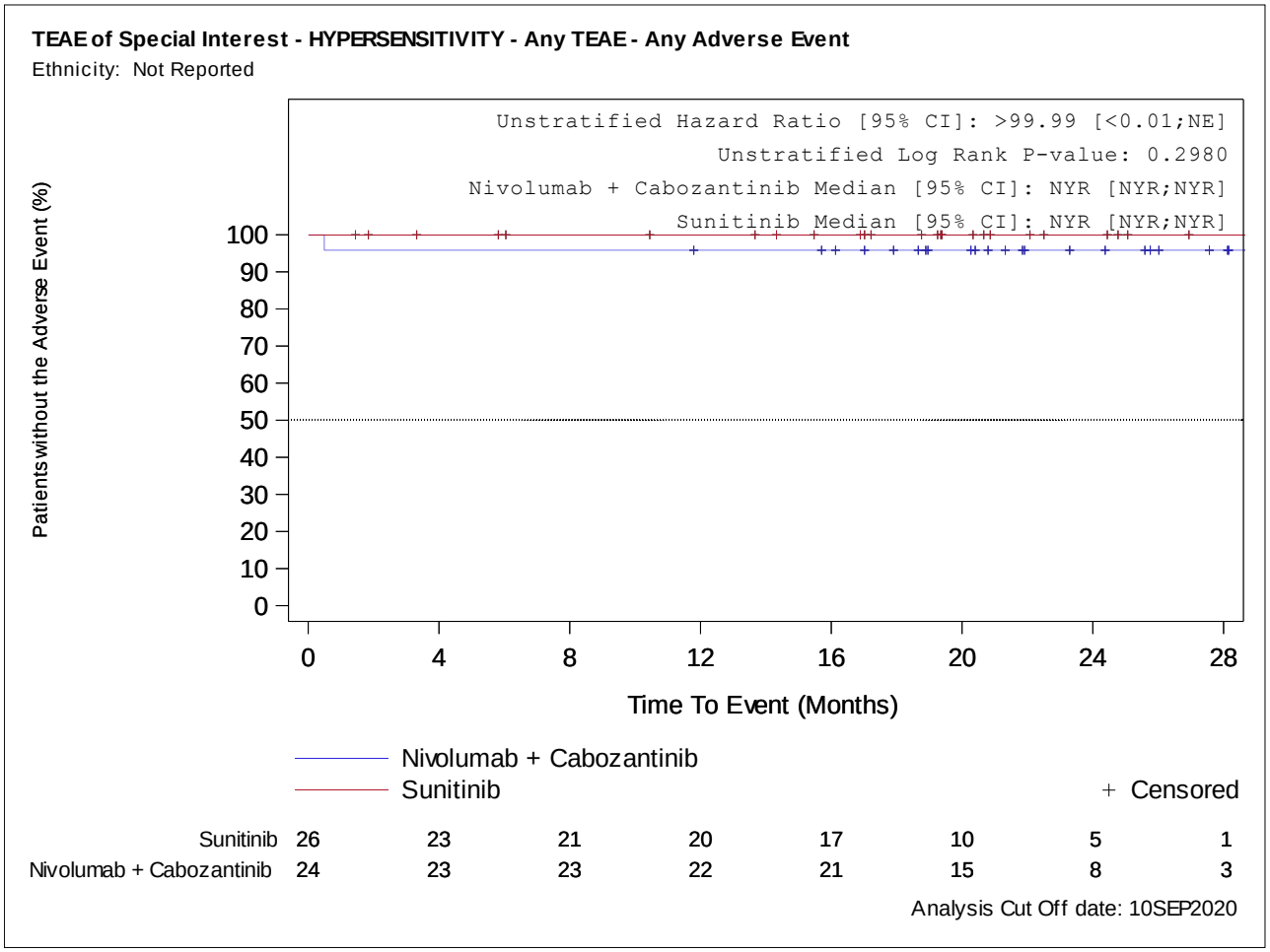

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:41:03

FIGURE 3.83.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



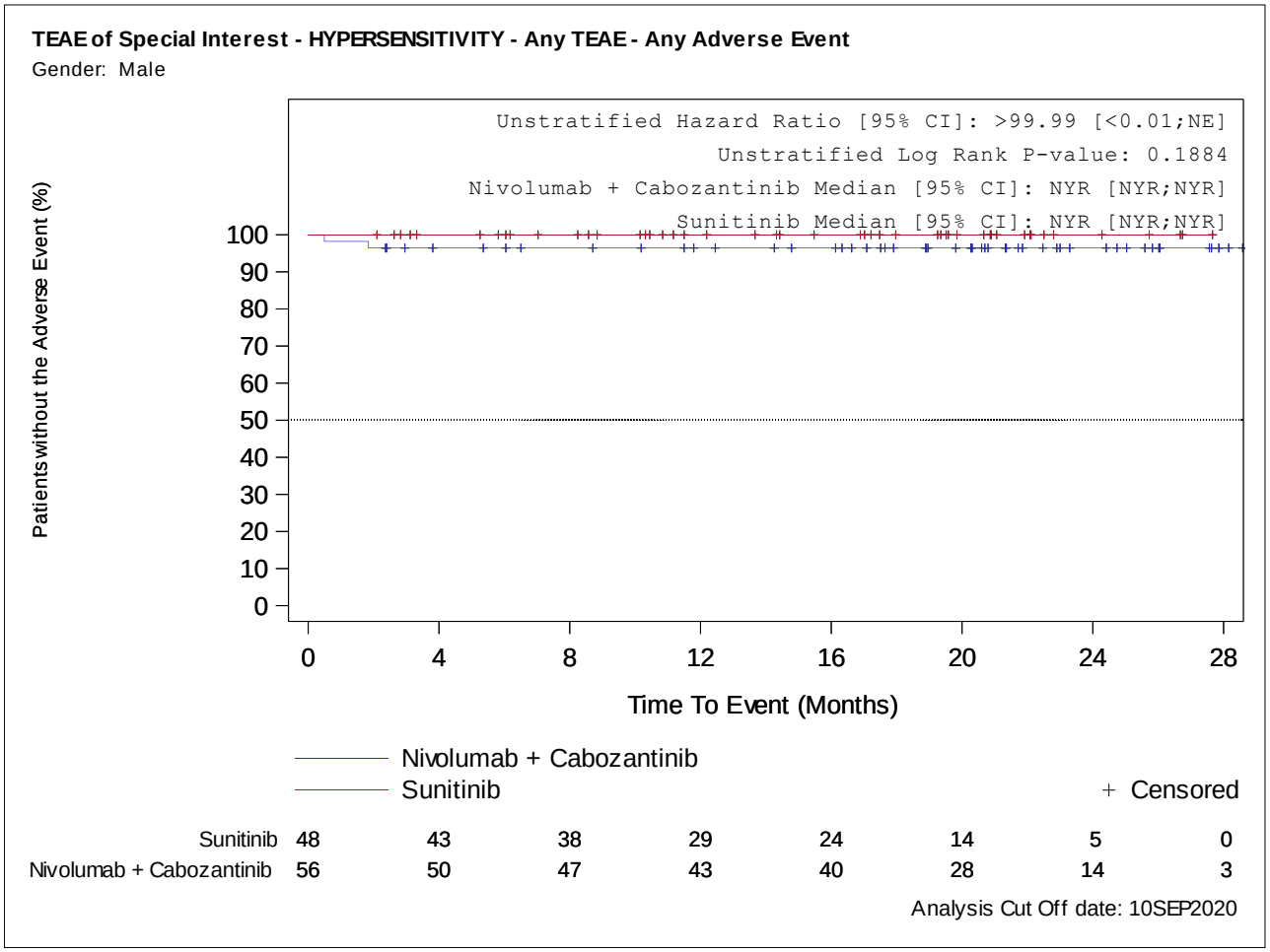

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:41:10

FIGURE 3.83.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



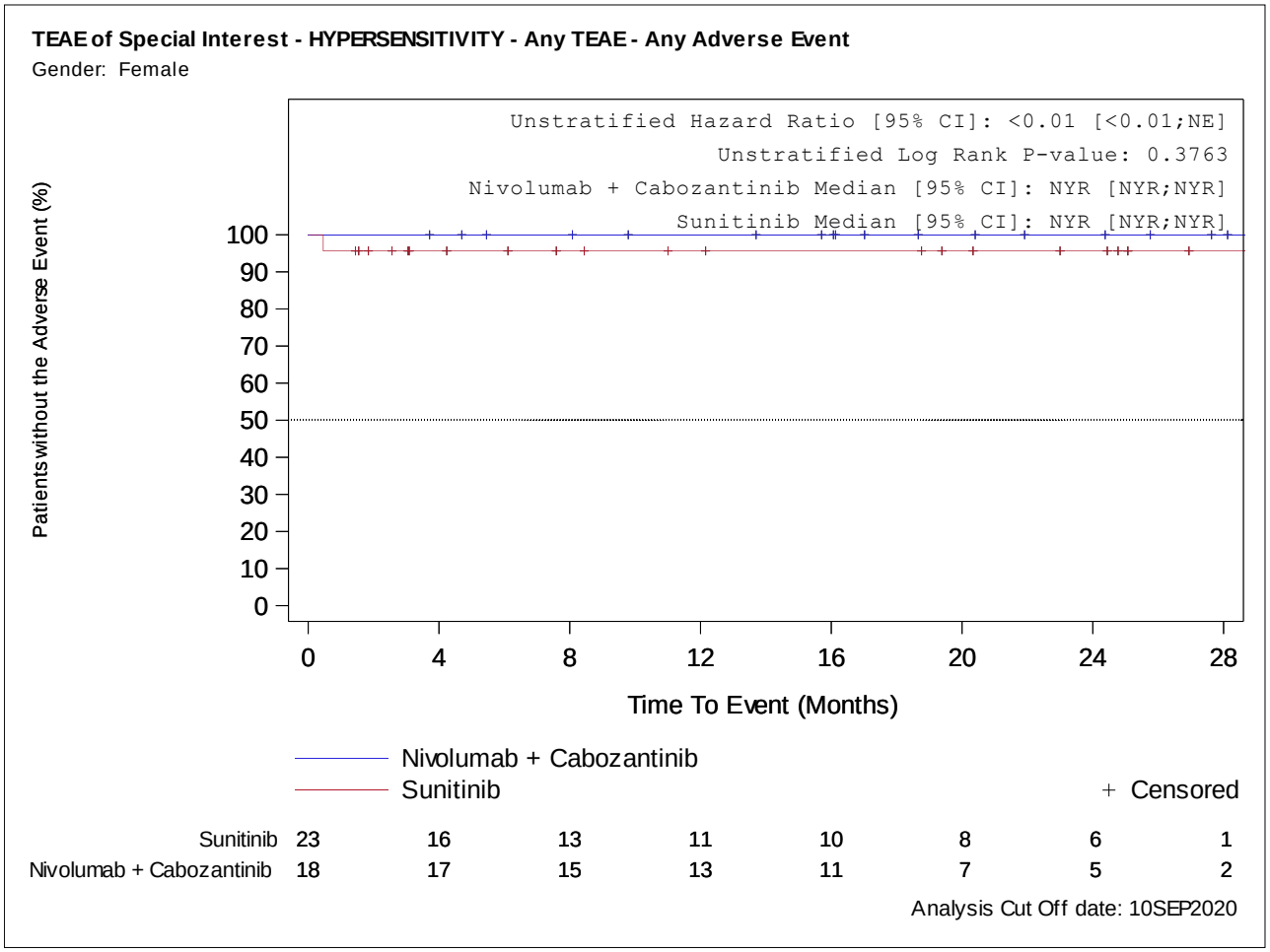

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:41:16

FIGURE 3.83.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



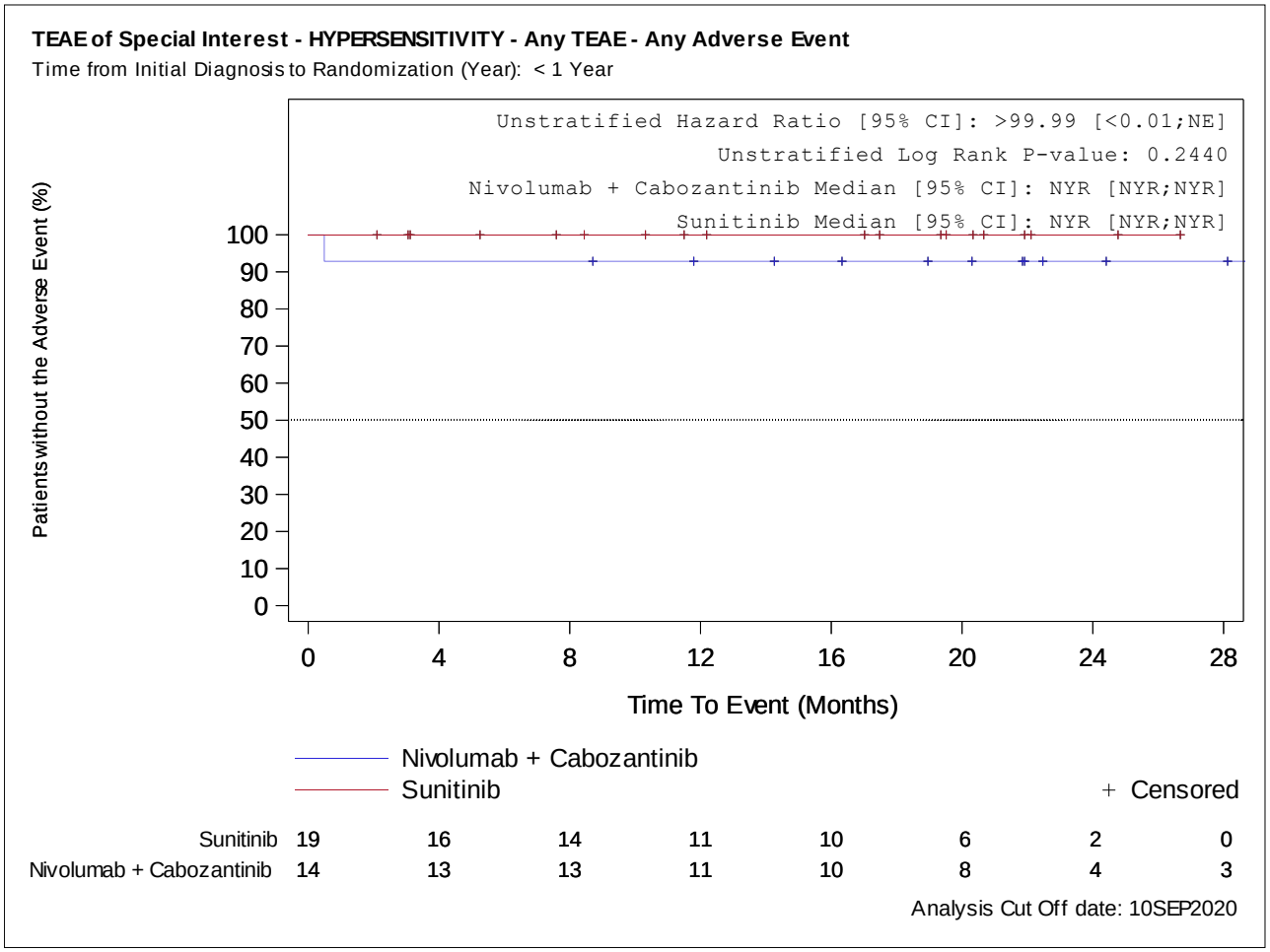

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:41:22

FIGURE 3.83.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



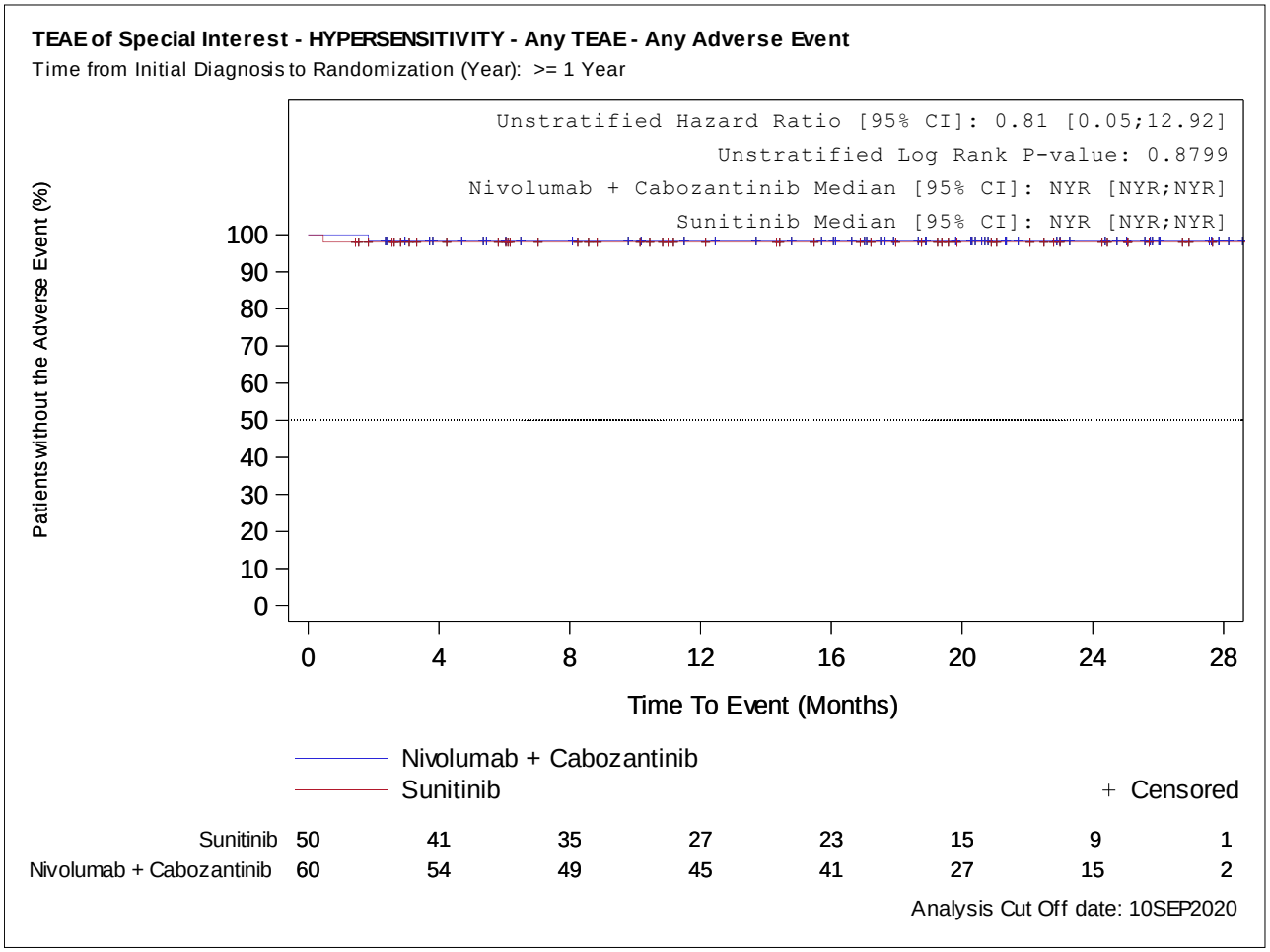

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:41:28

FIGURE 3.83.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



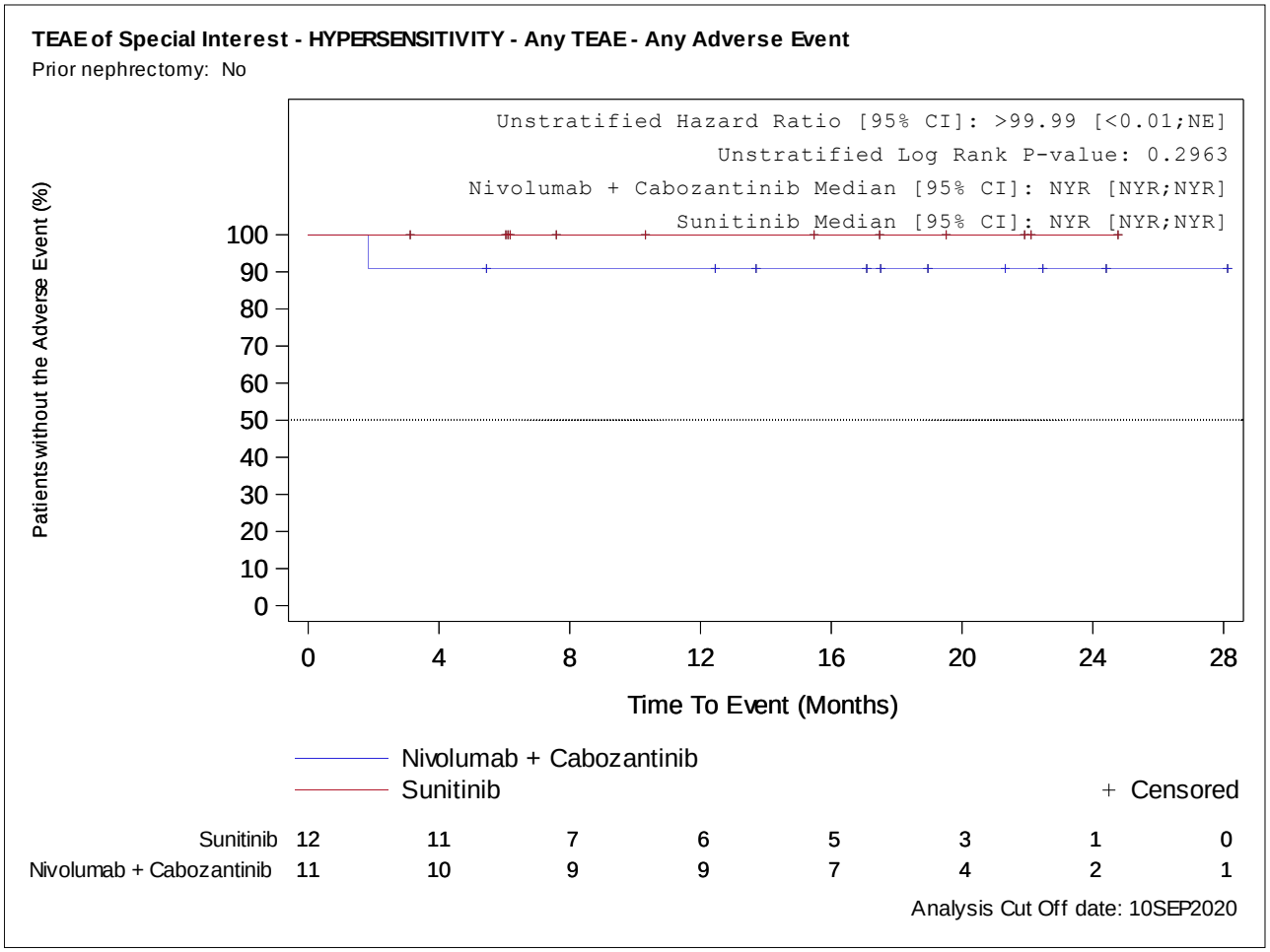

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:41:45

FIGURE 3.83.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



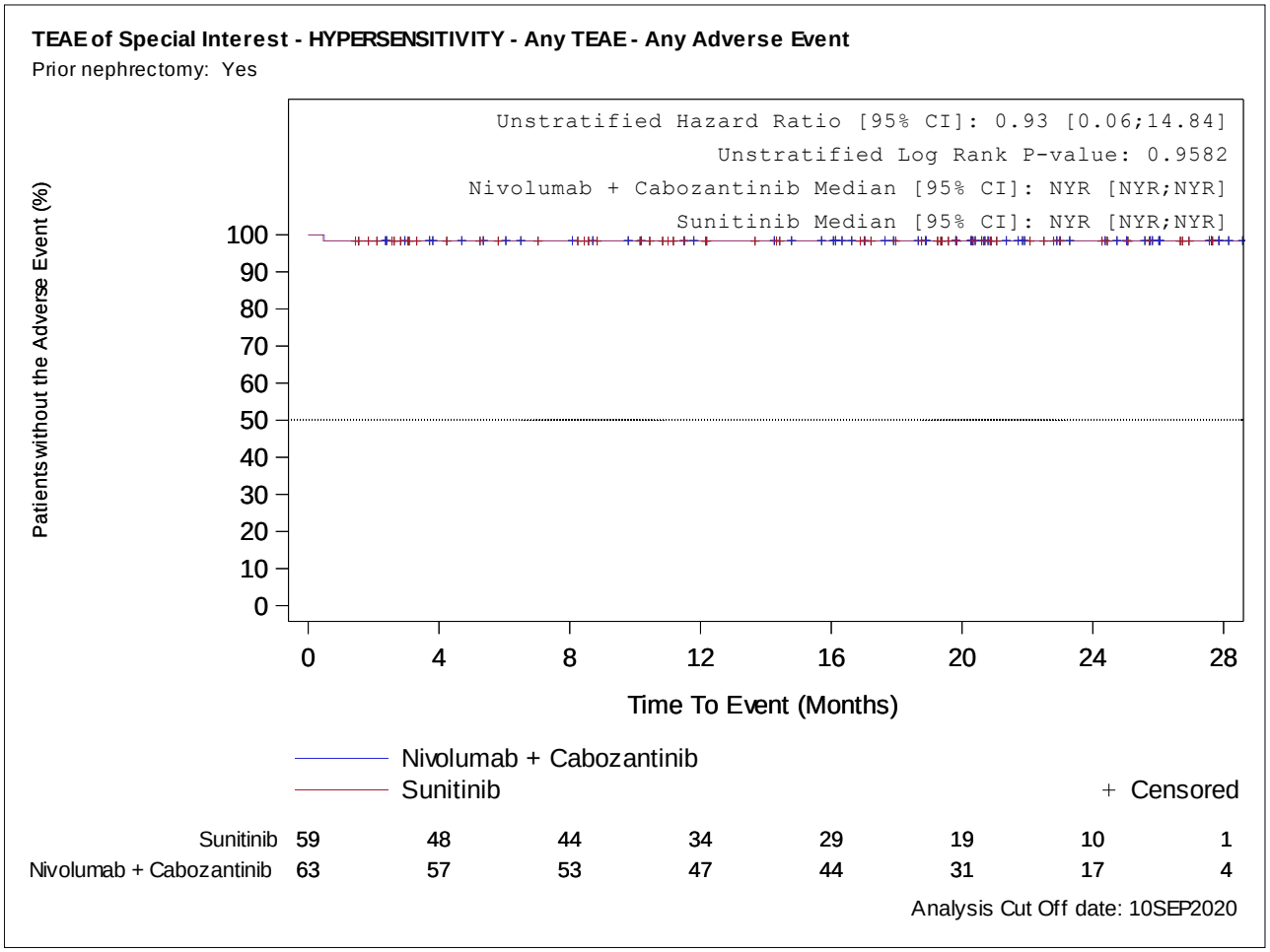

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:41:51

FIGURE 3.83.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



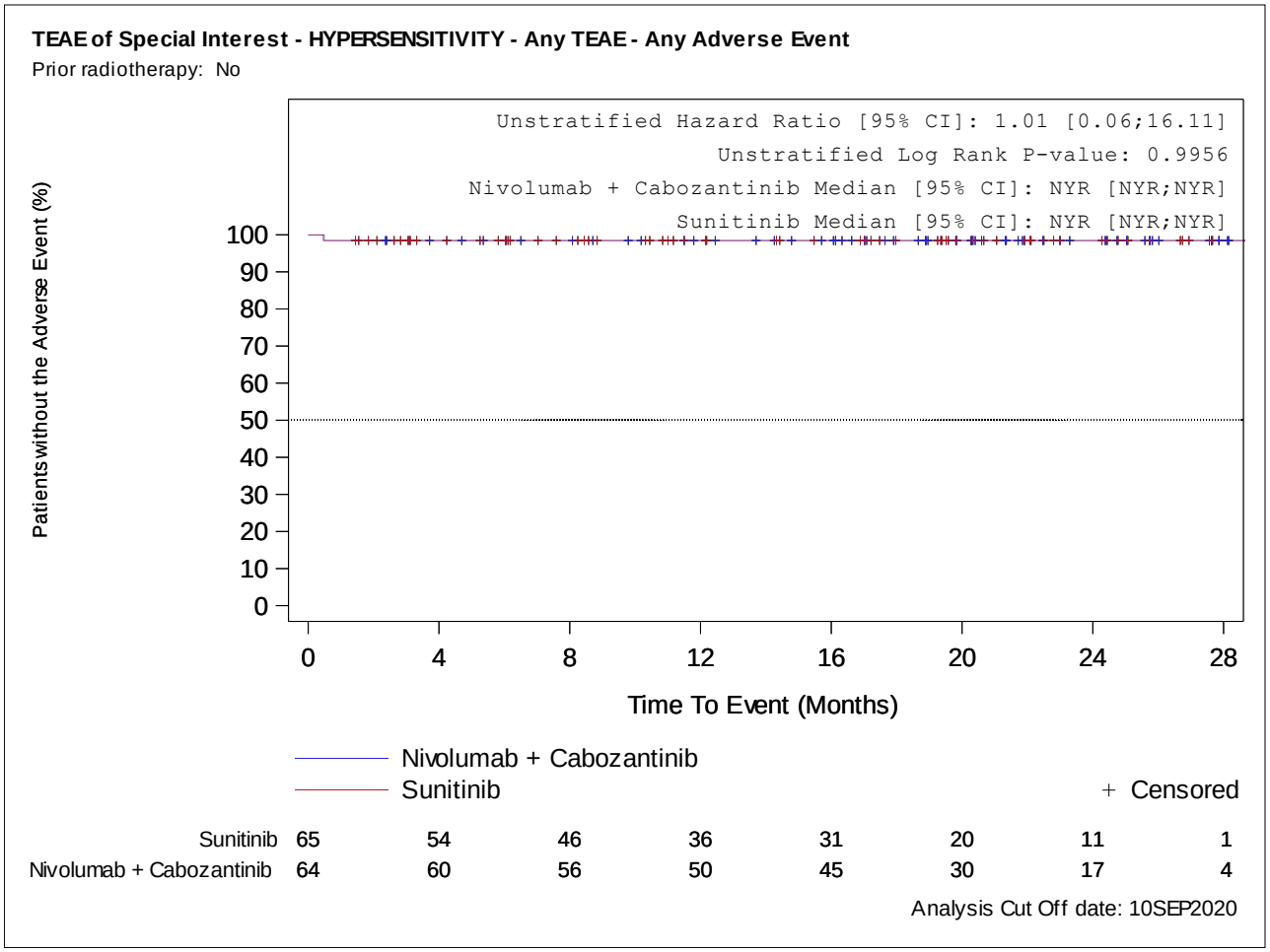

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:42:44

FIGURE 3.83.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:42:49

FIGURE 3.83.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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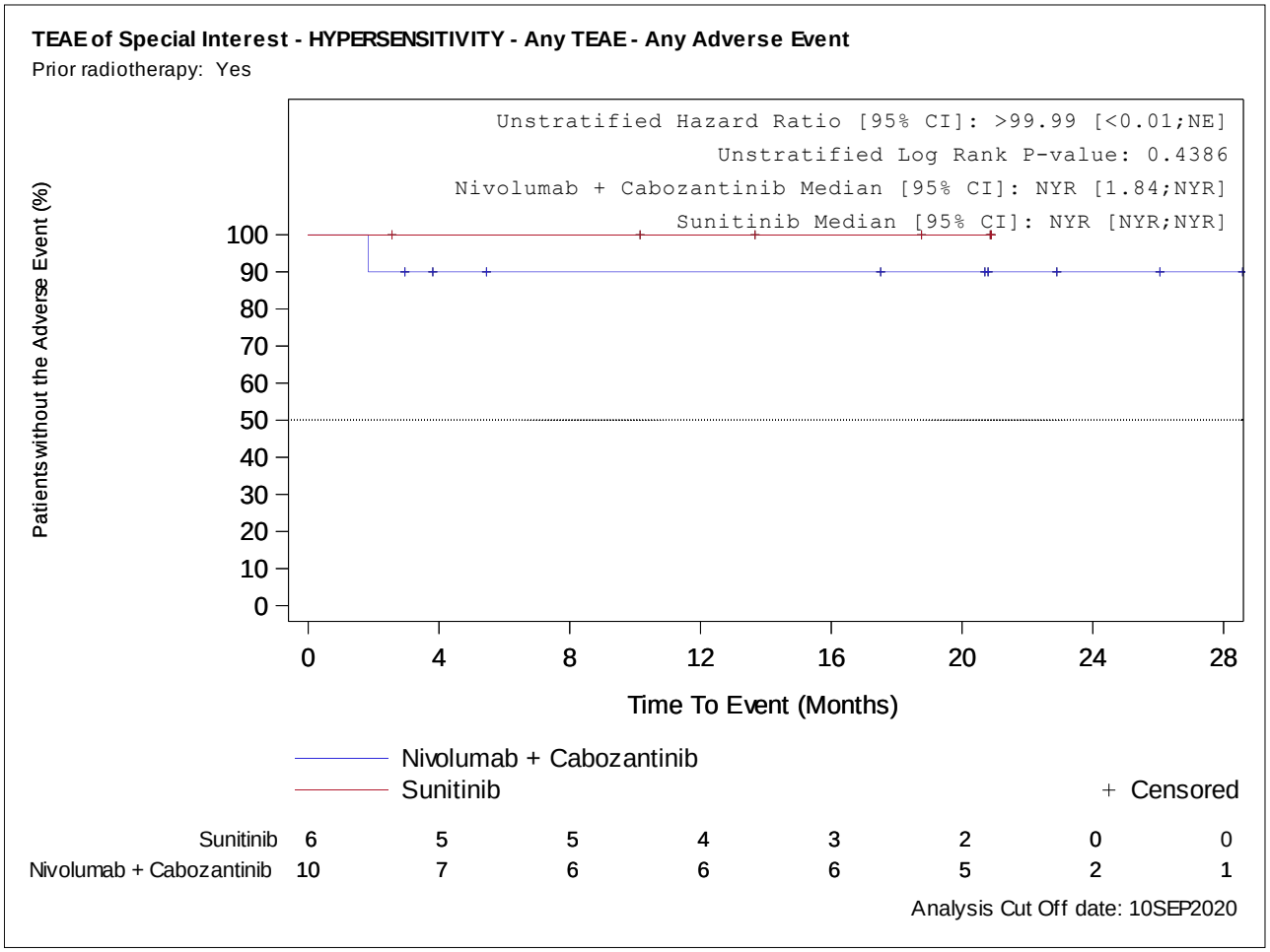
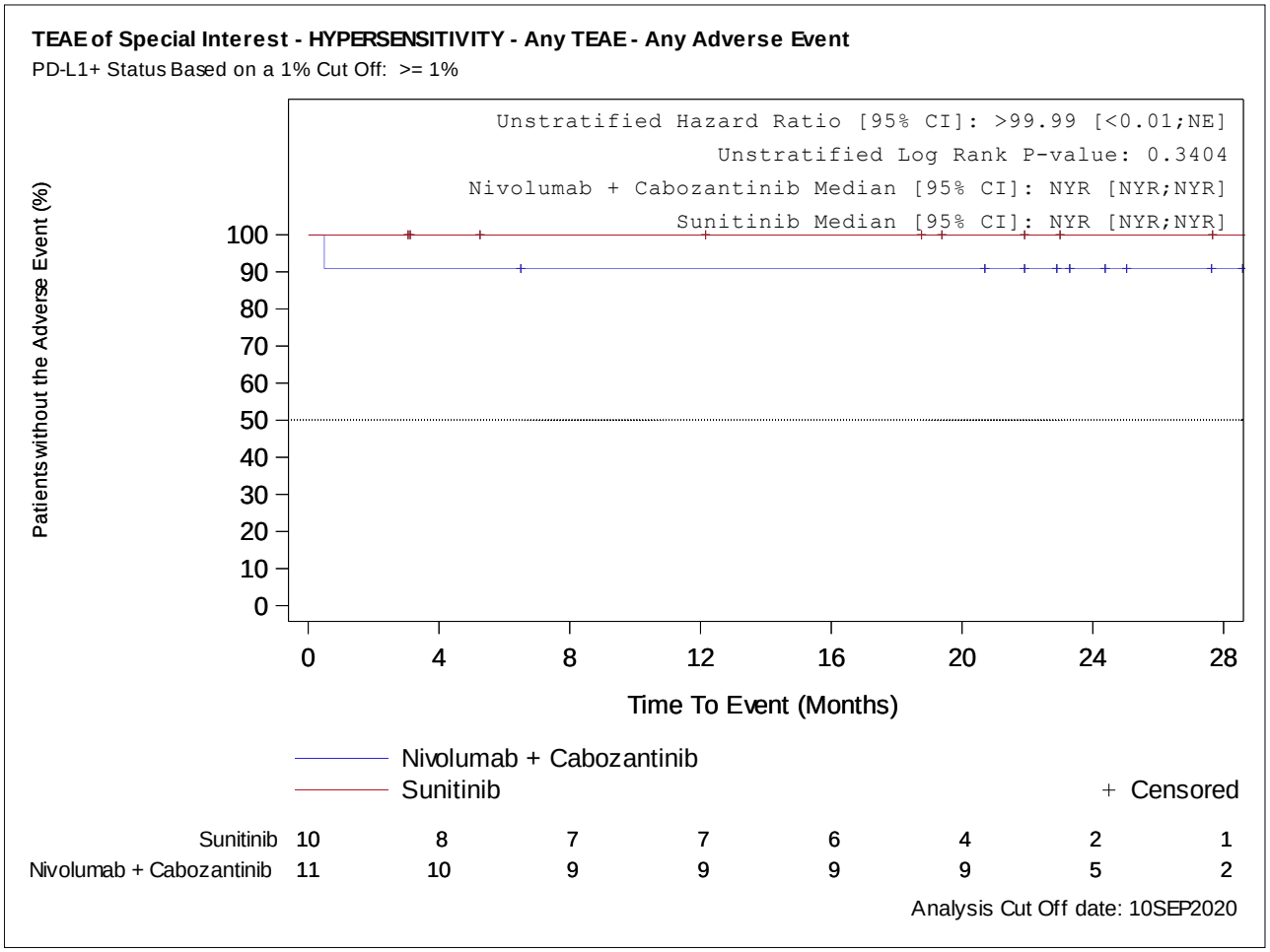
FIGURE 3.83.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:43:00

FIGURE 3.83.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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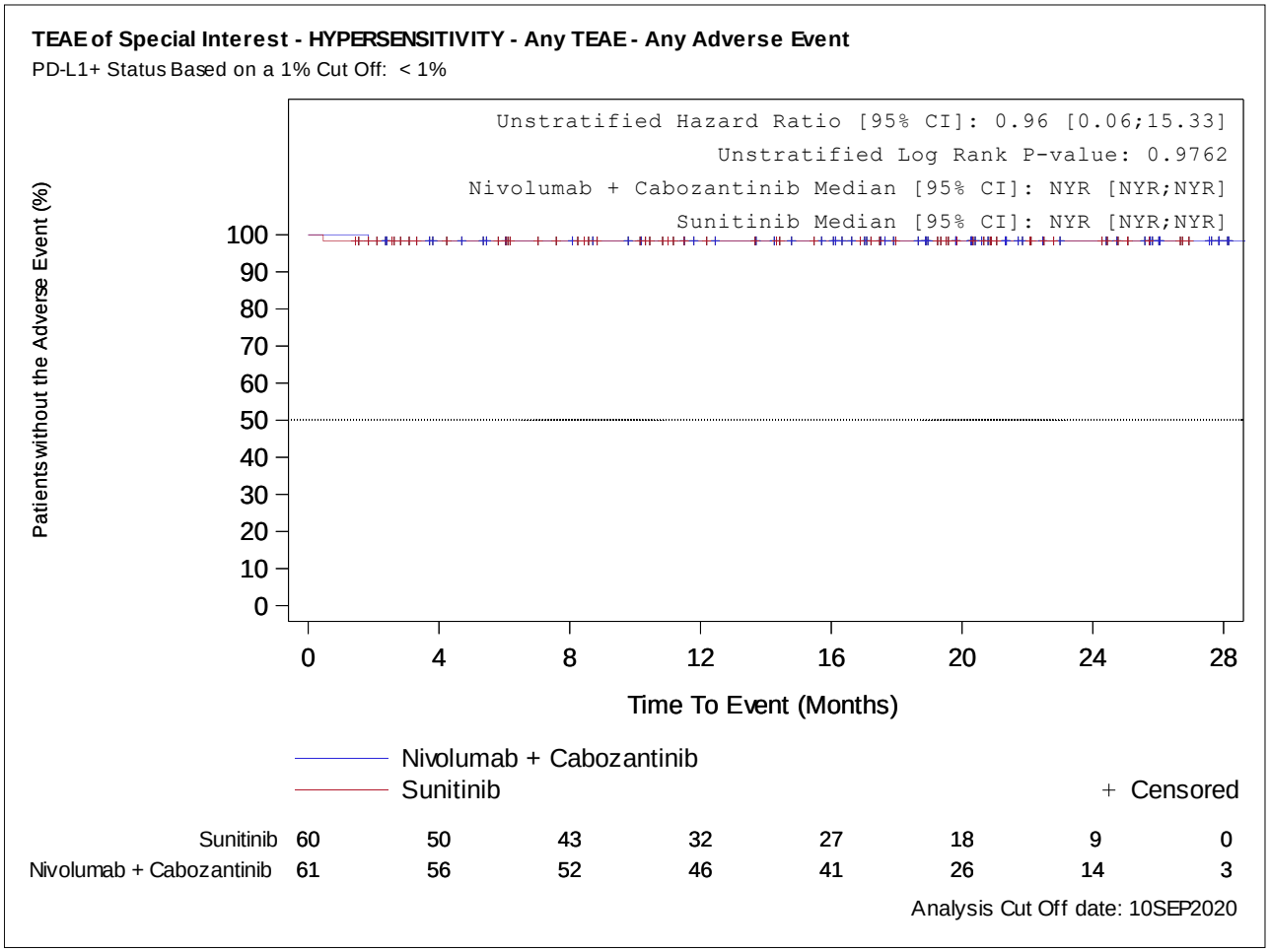
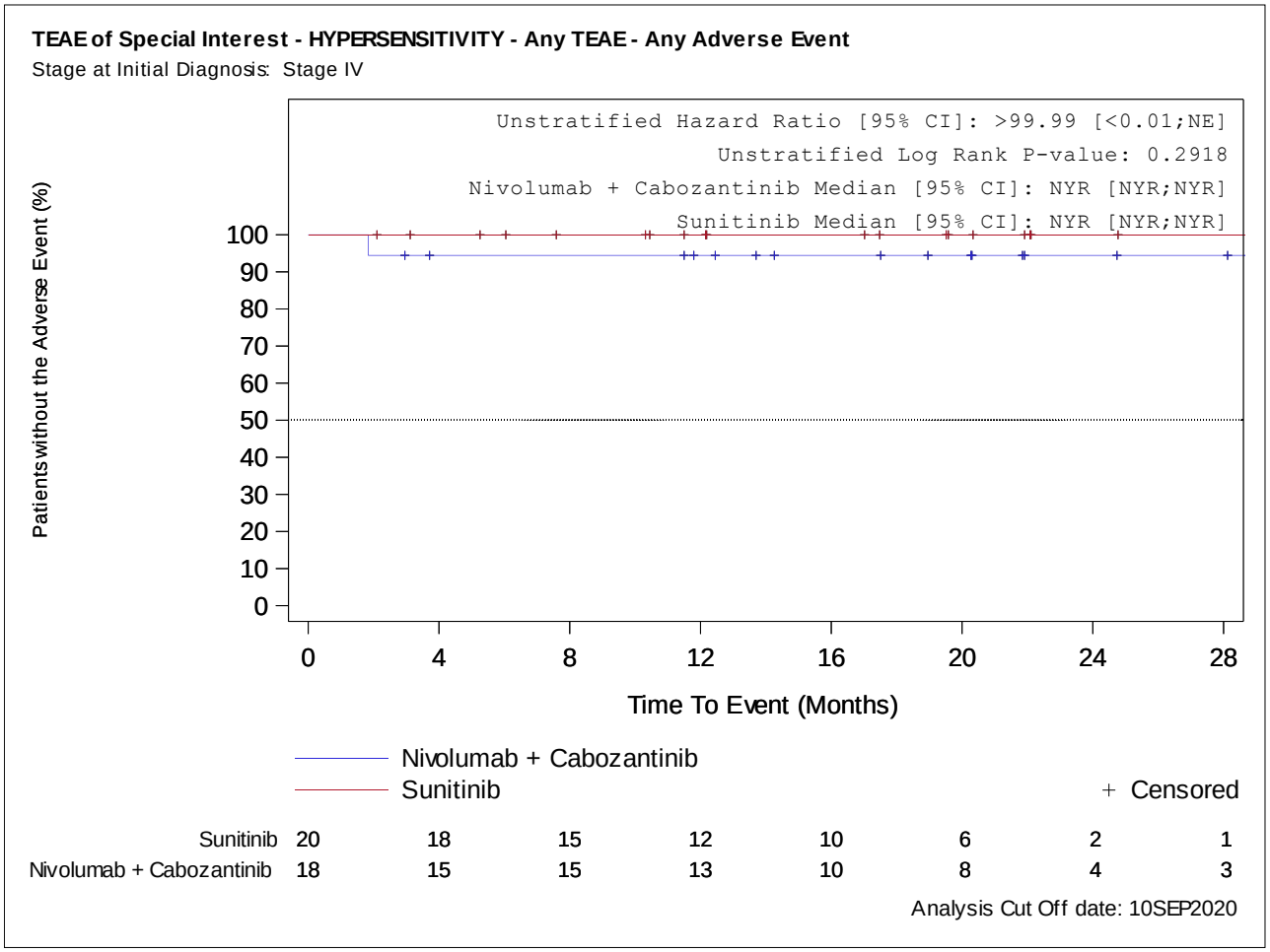
FIGURE 3.83.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



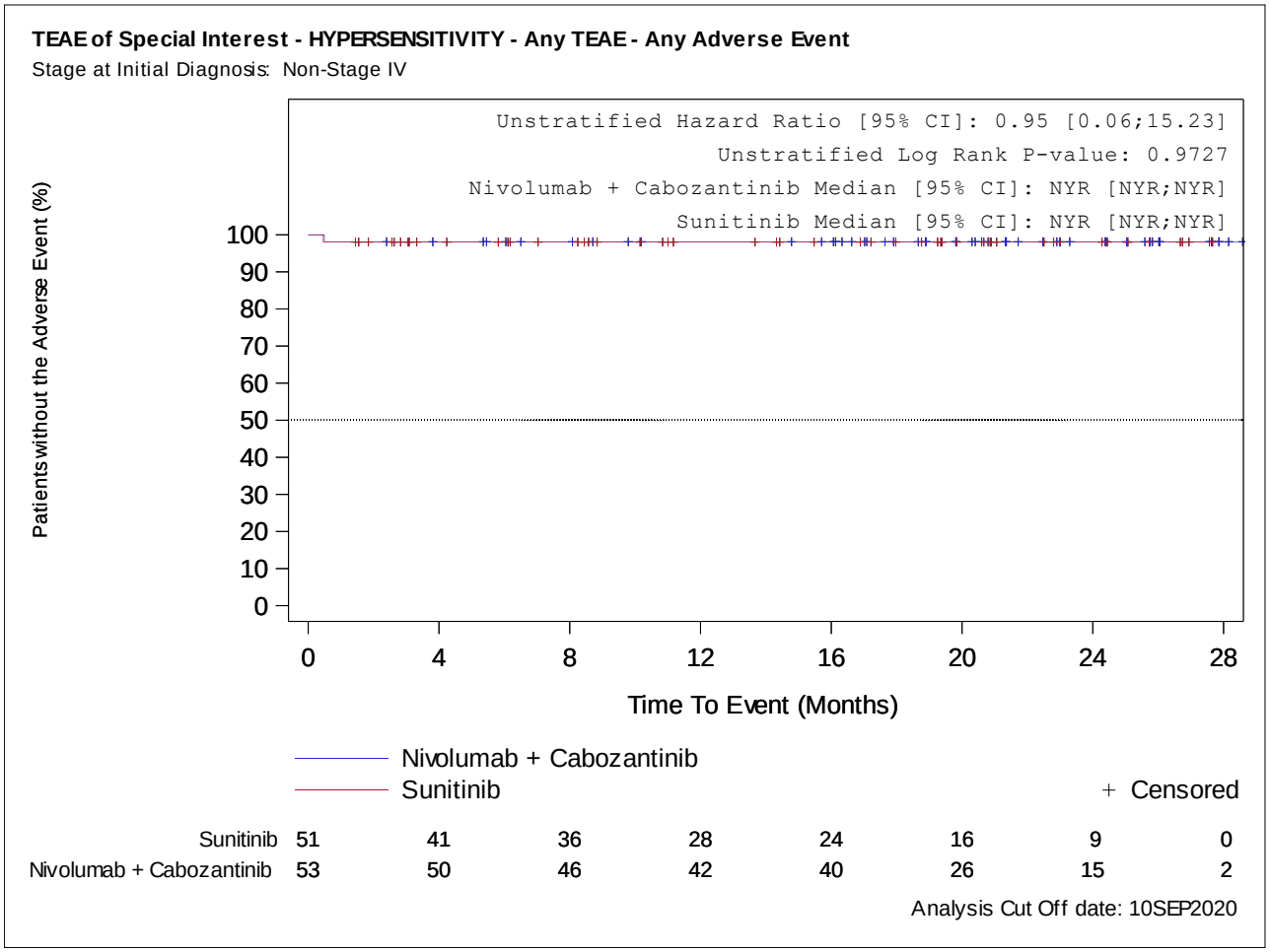

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:43:12

FIGURE 3.83.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



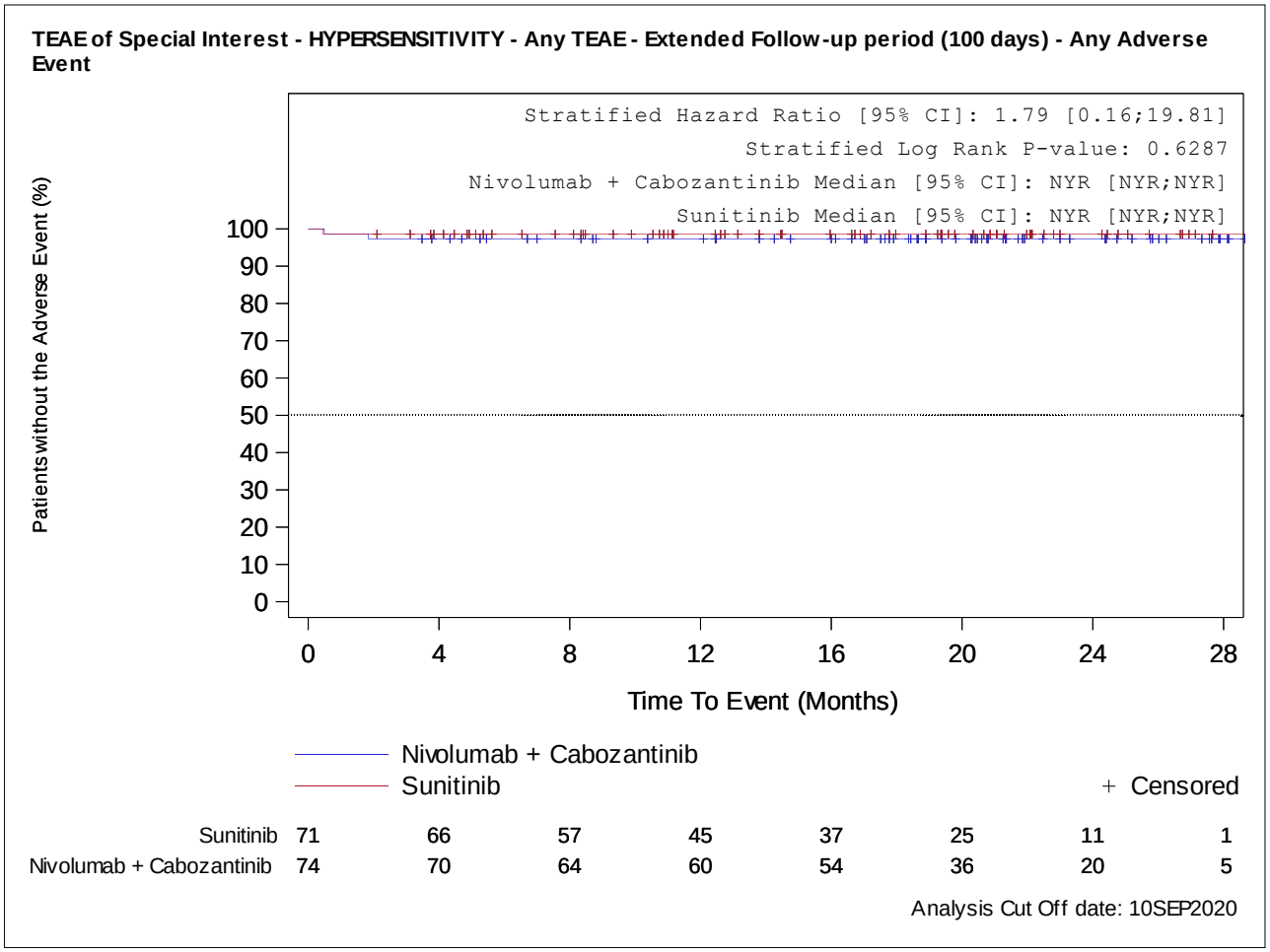

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:43:42

FIGURE 3.83.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



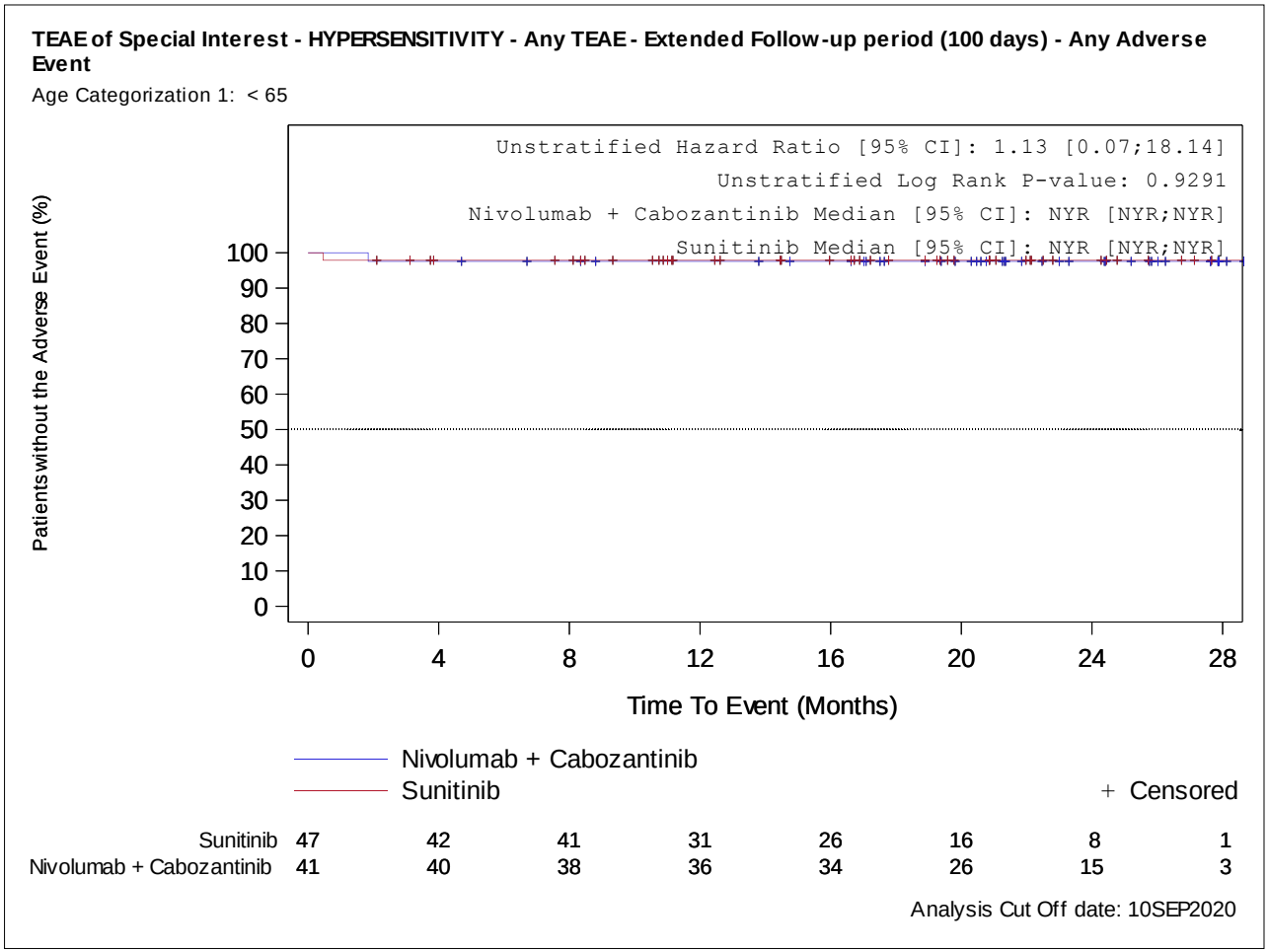

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:43:48

FIGURE 3.84.1: TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



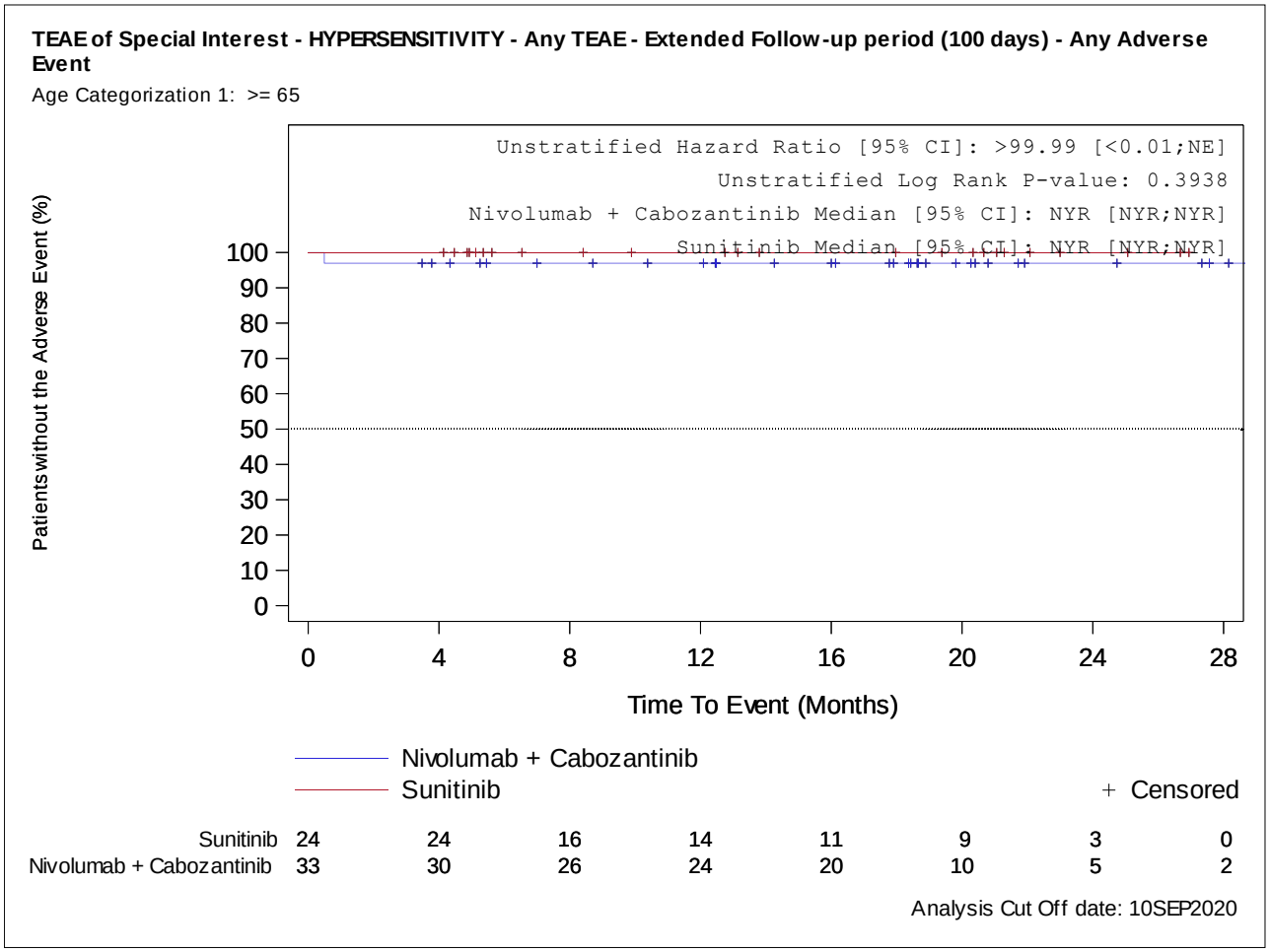

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:47:07

FIGURE 3.84.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



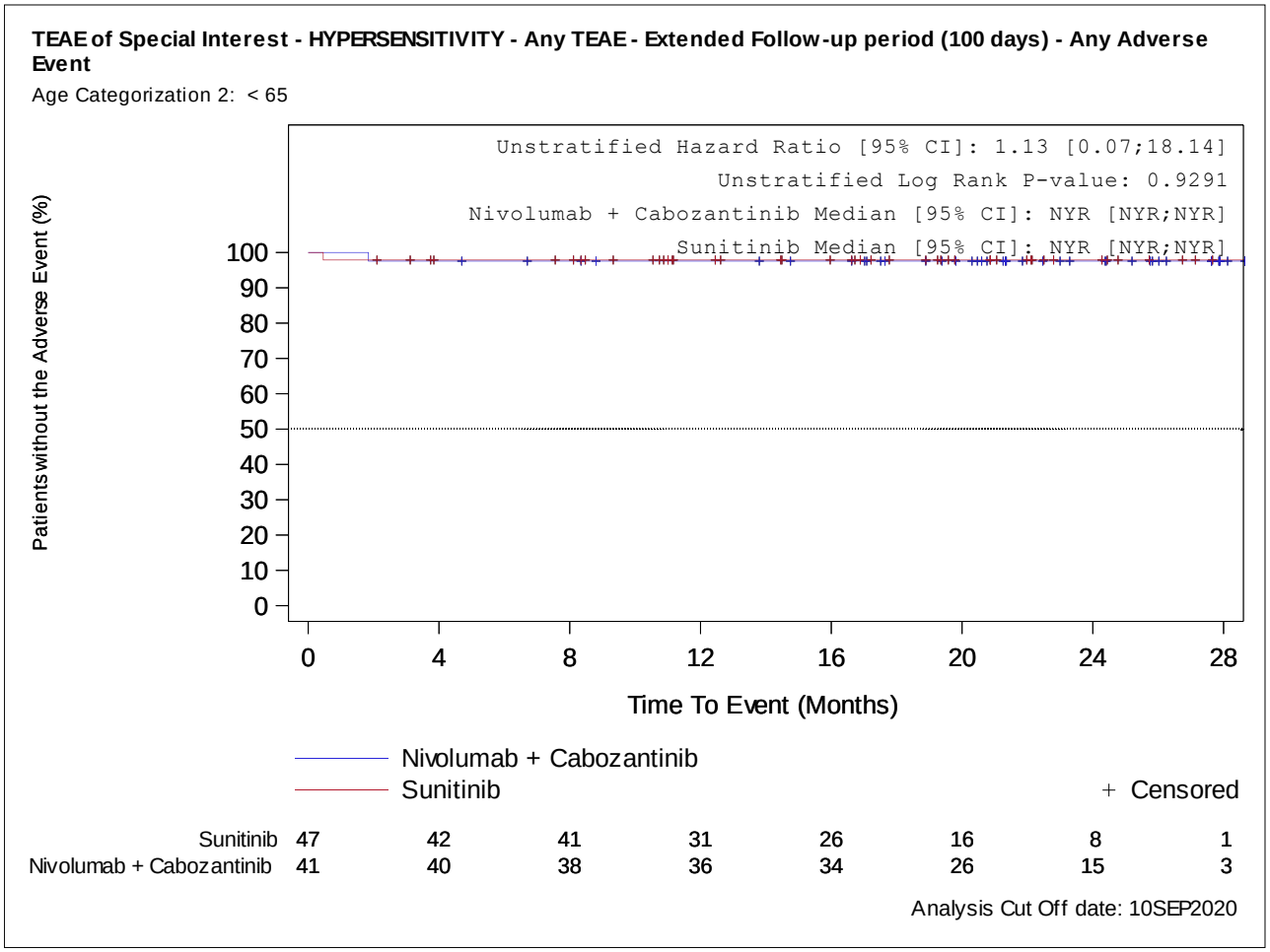

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:47:10

FIGURE 3.84.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



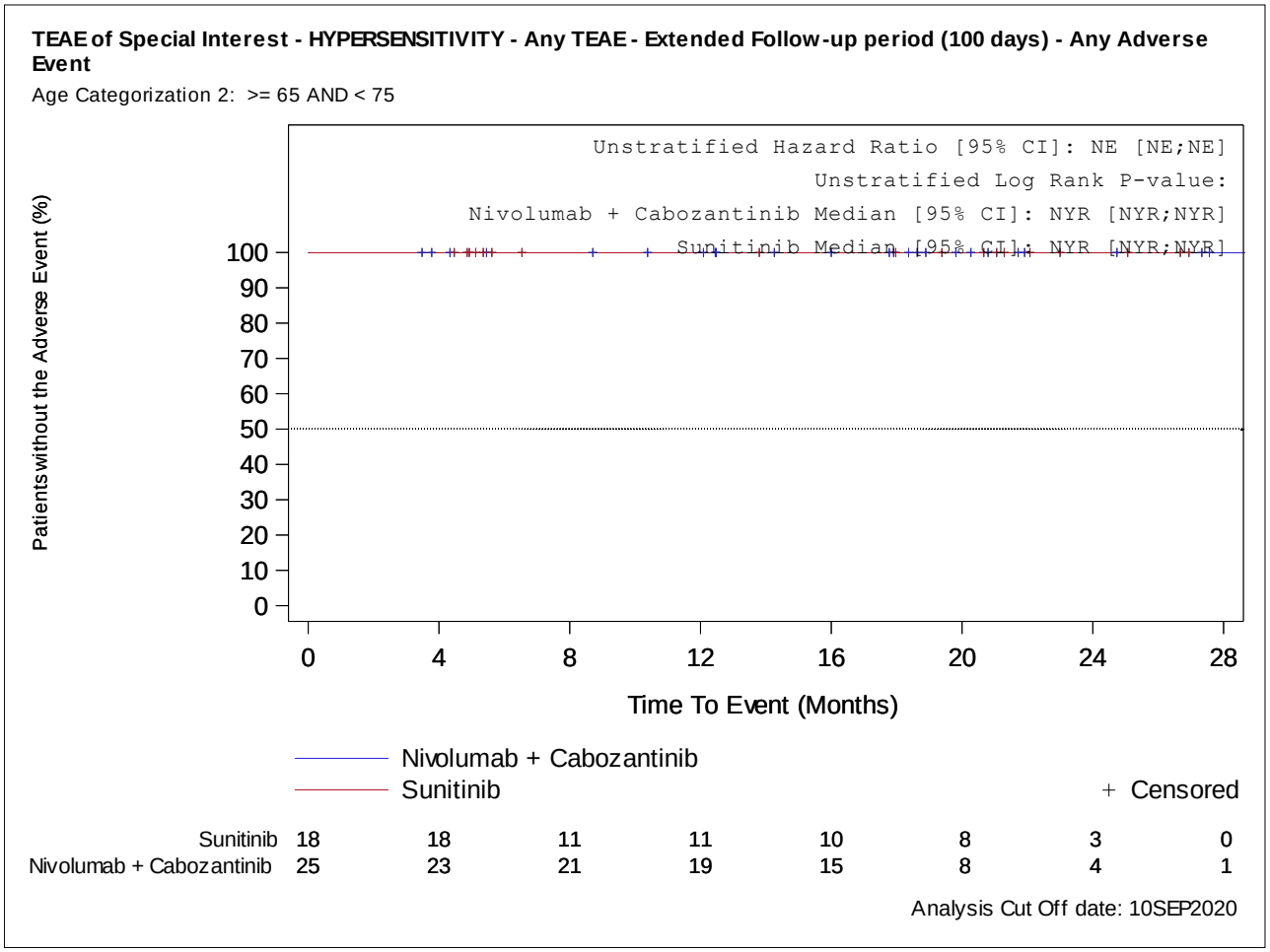

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:47:16

FIGURE 3.84.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



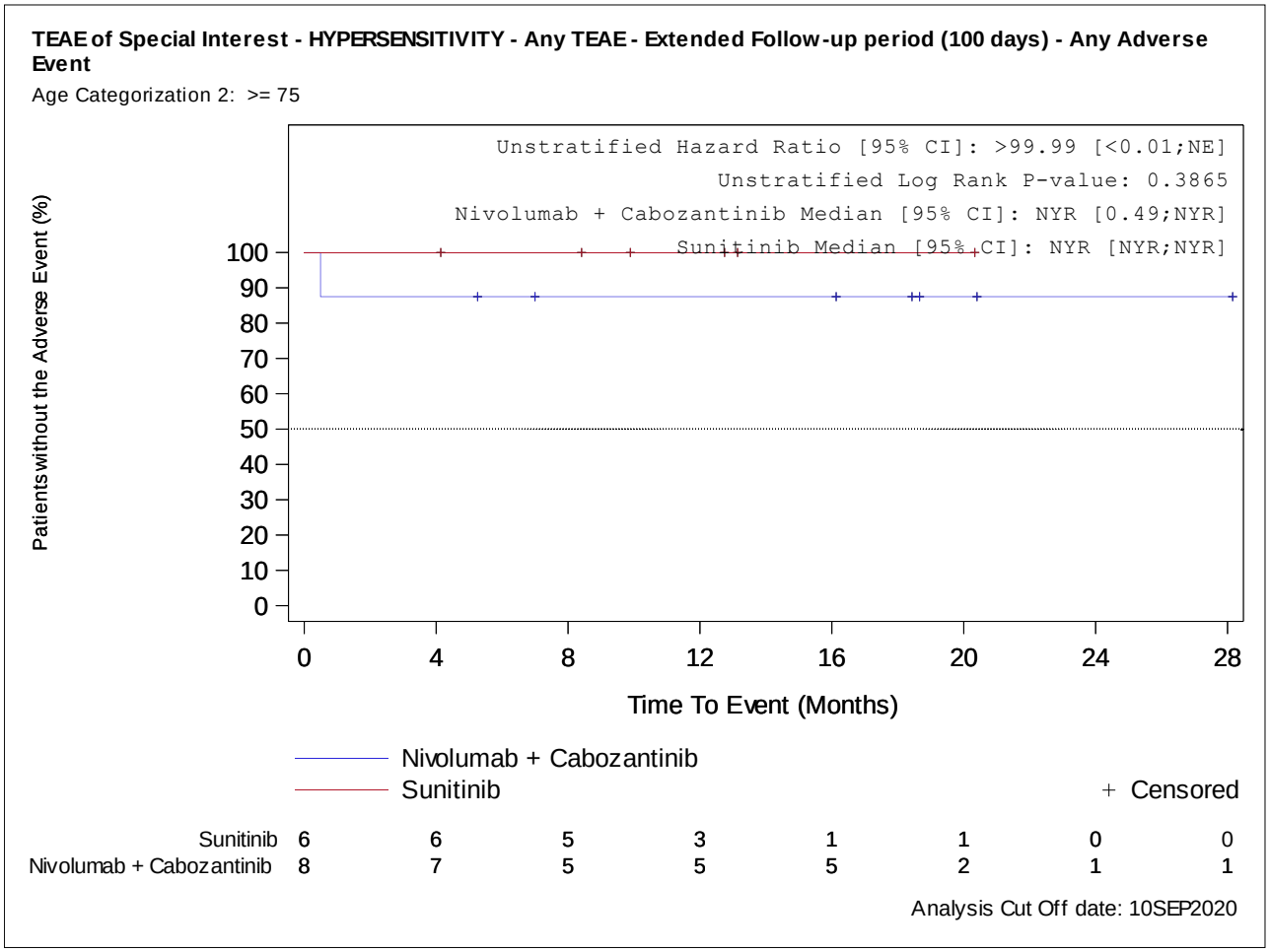

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:47:22

FIGURE 3.84.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



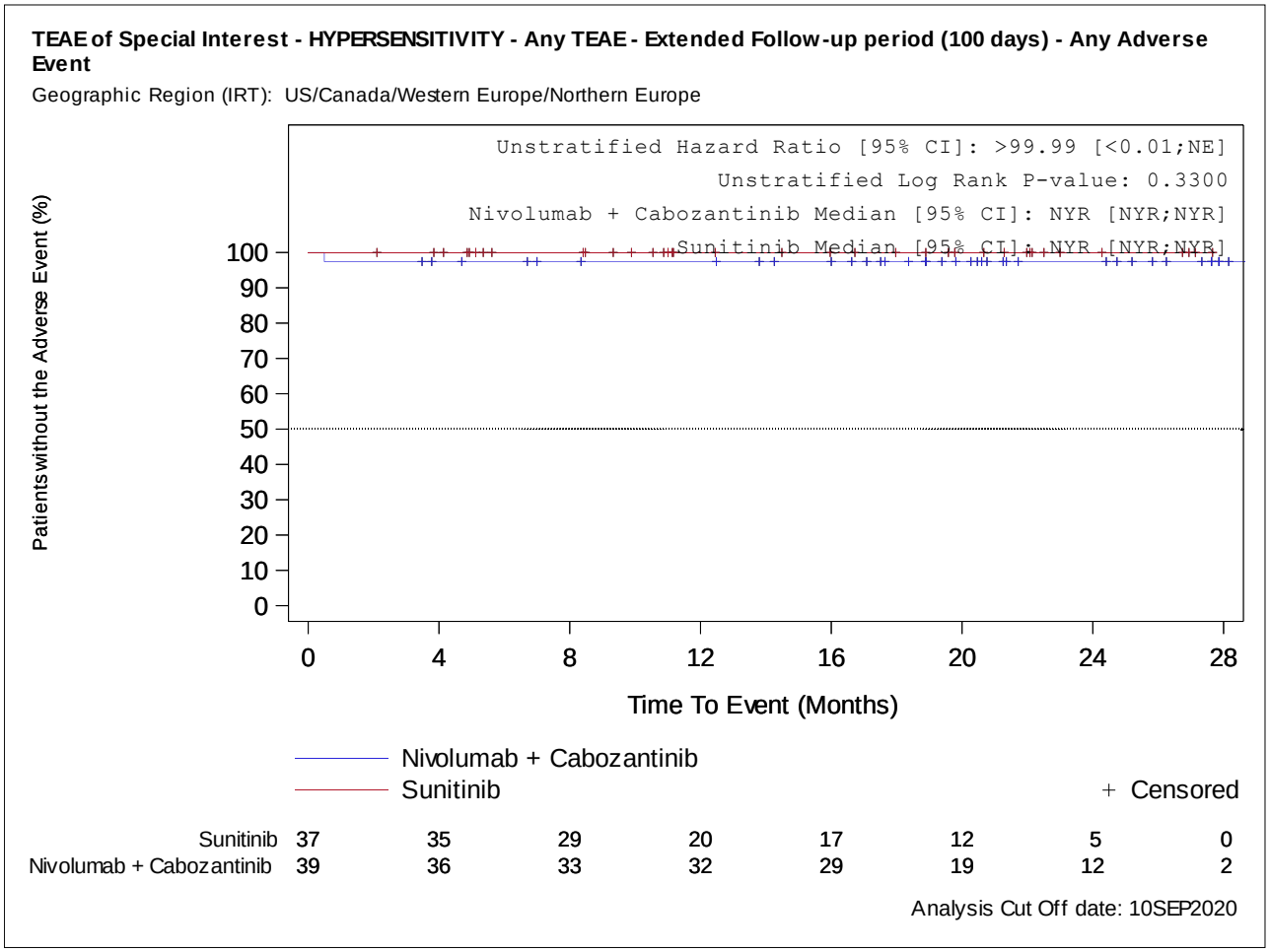

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:47:27

FIGURE 3.84.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



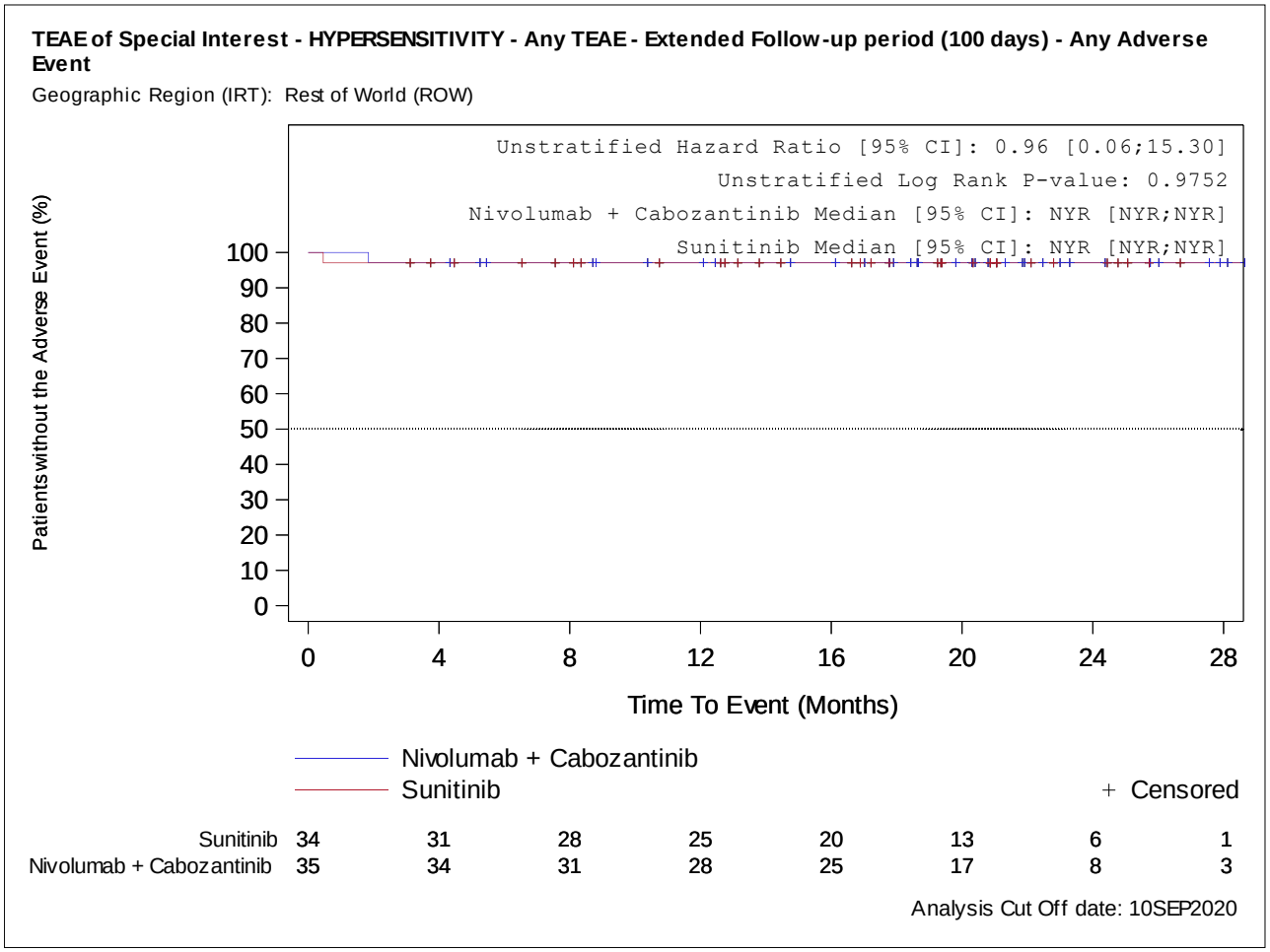

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:47:33

FIGURE 3.84.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



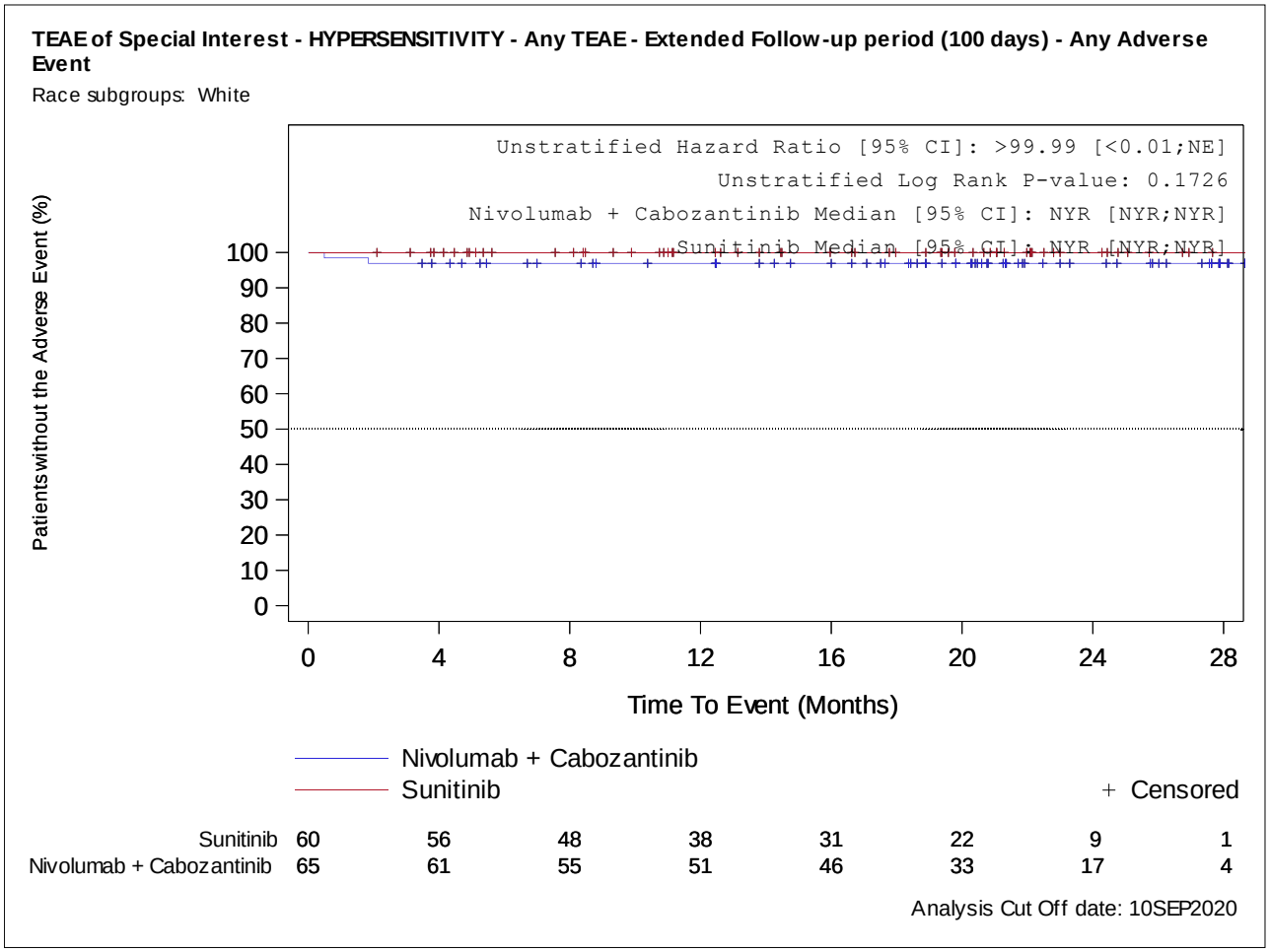

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:47:39

FIGURE 3.84.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



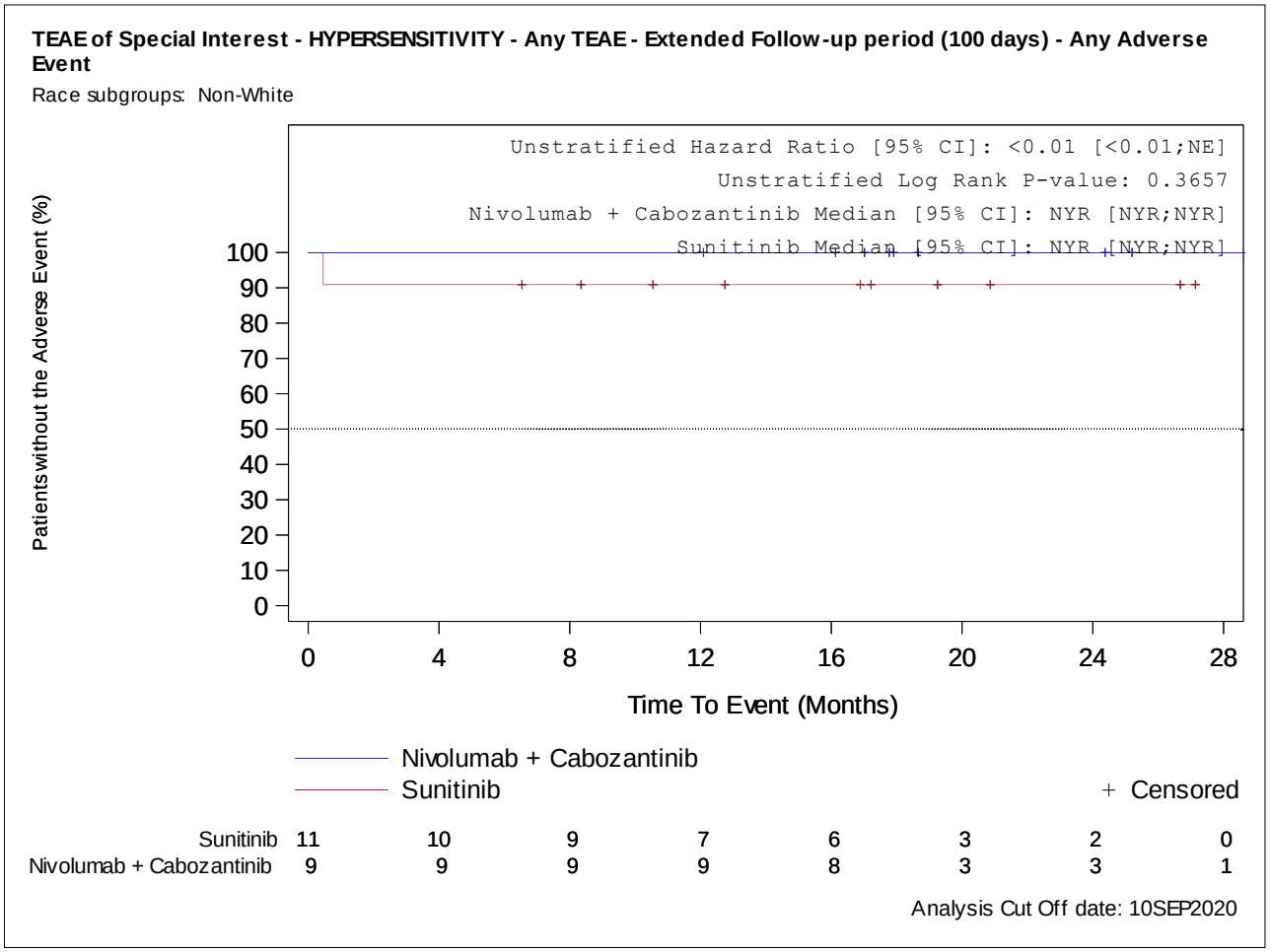

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:47:44

FIGURE 3.84.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



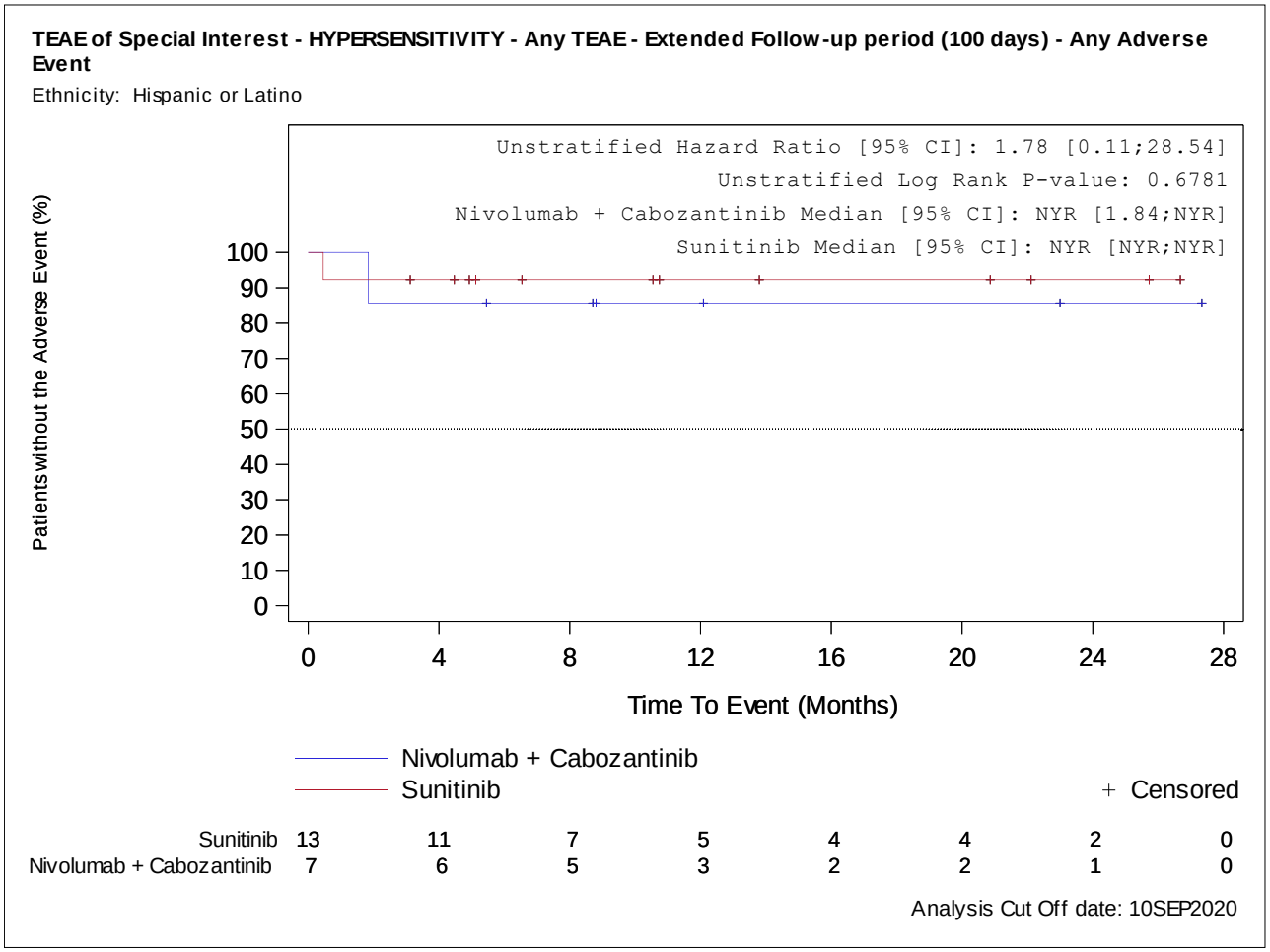

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:47:50

FIGURE 3.84.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



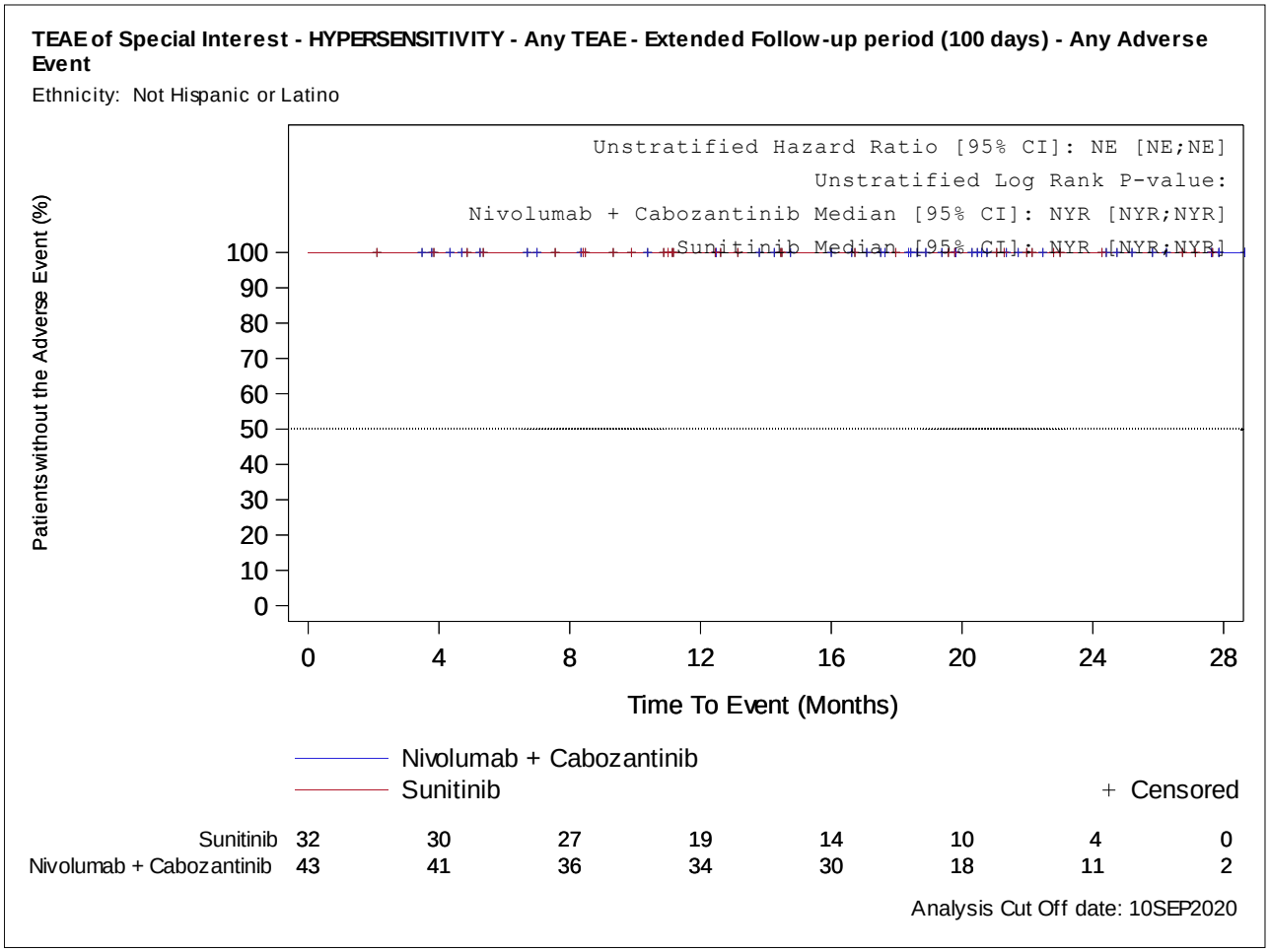

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:47:56

FIGURE 3.84.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



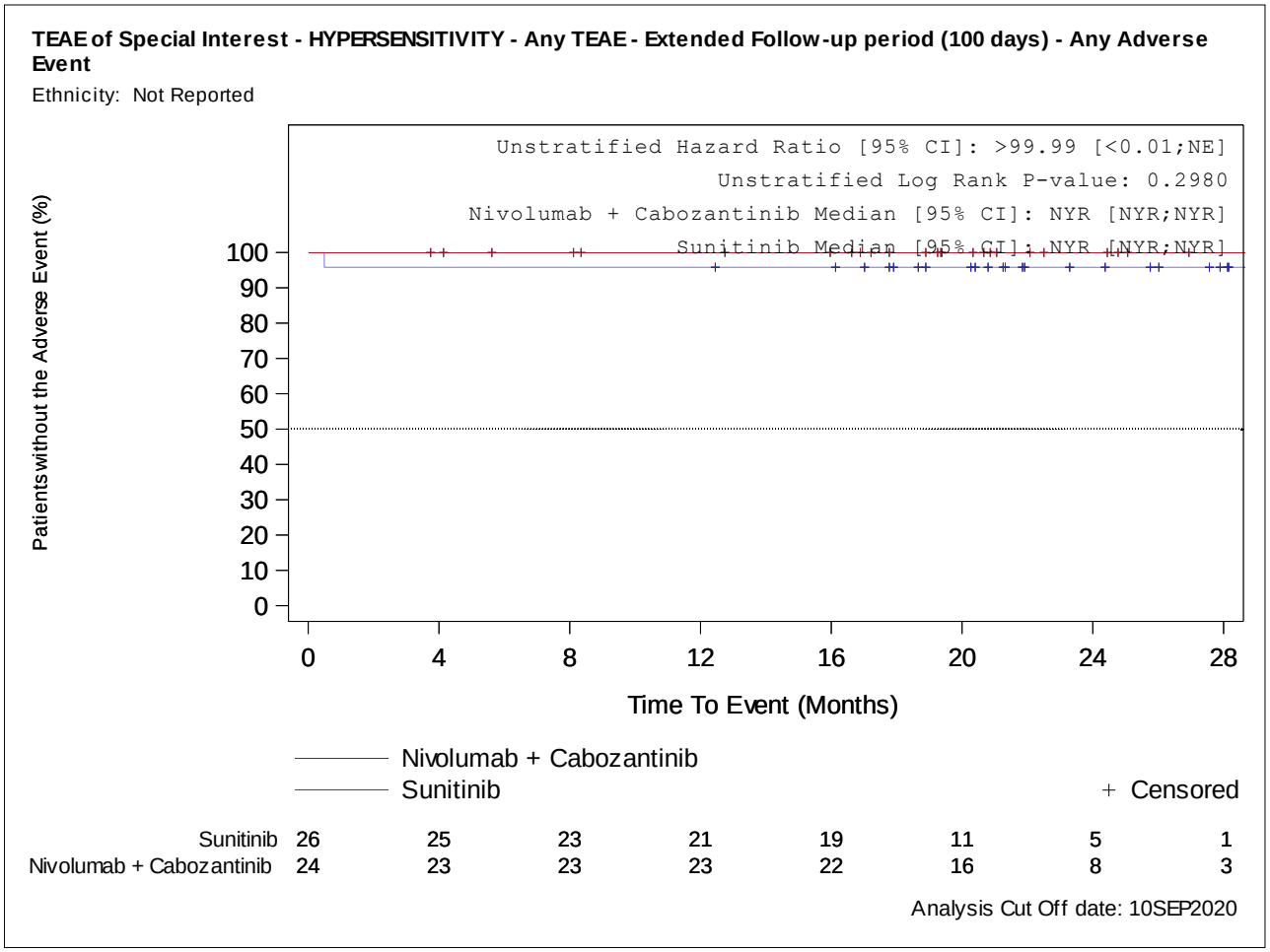

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:48:02

FIGURE 3.84.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



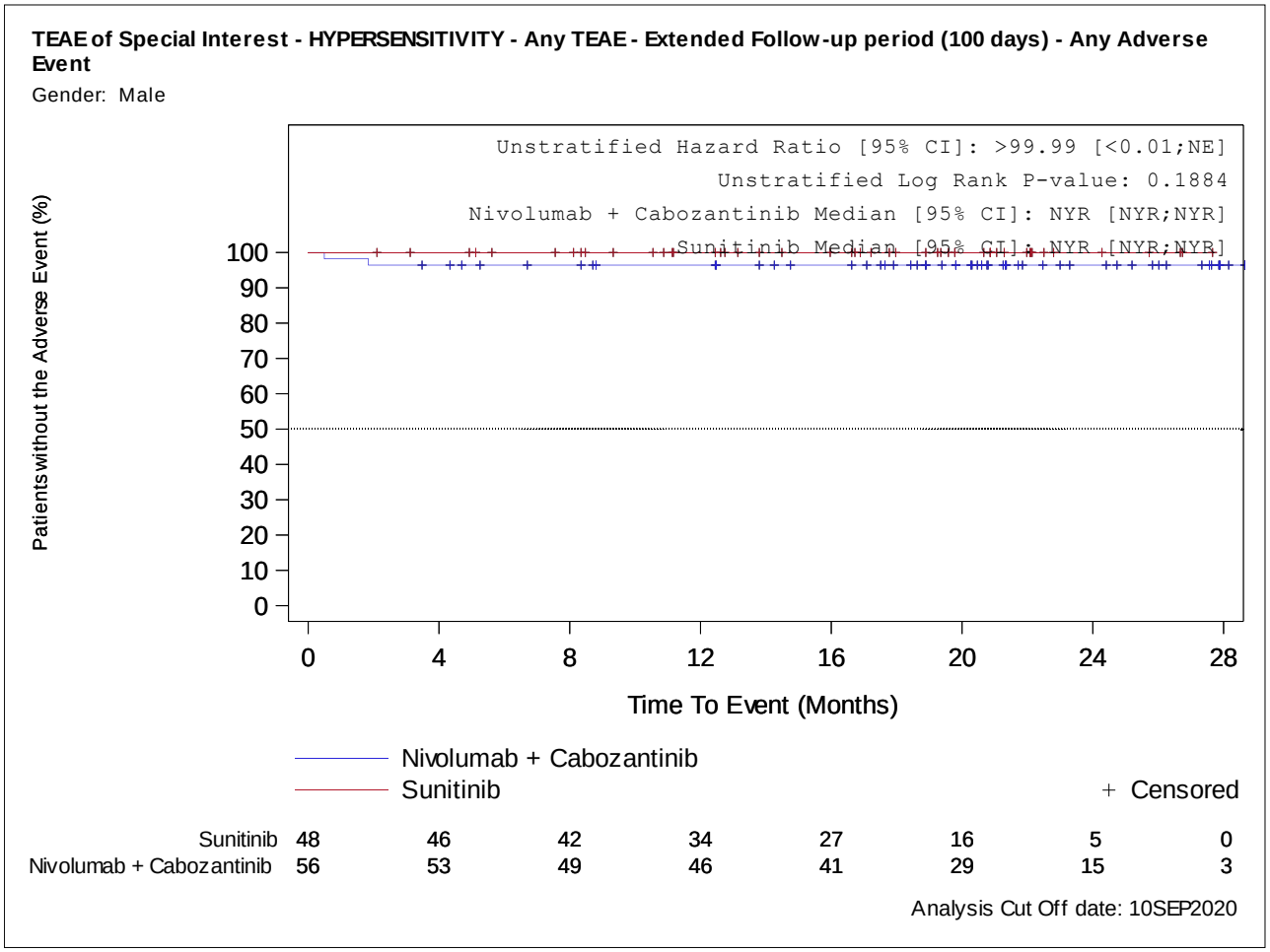

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:48:08

FIGURE 3.84.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



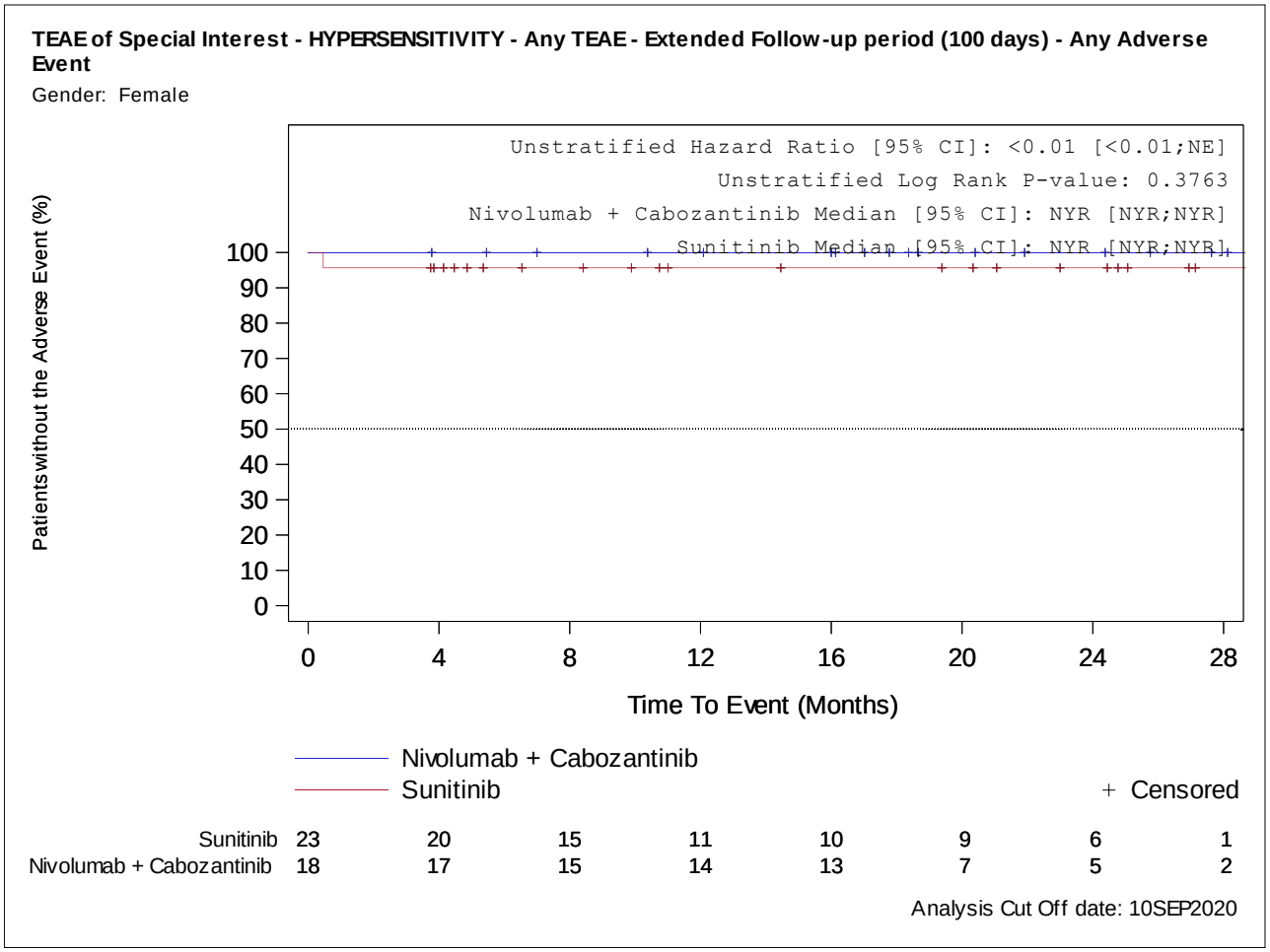

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:48:14

FIGURE 3.84.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



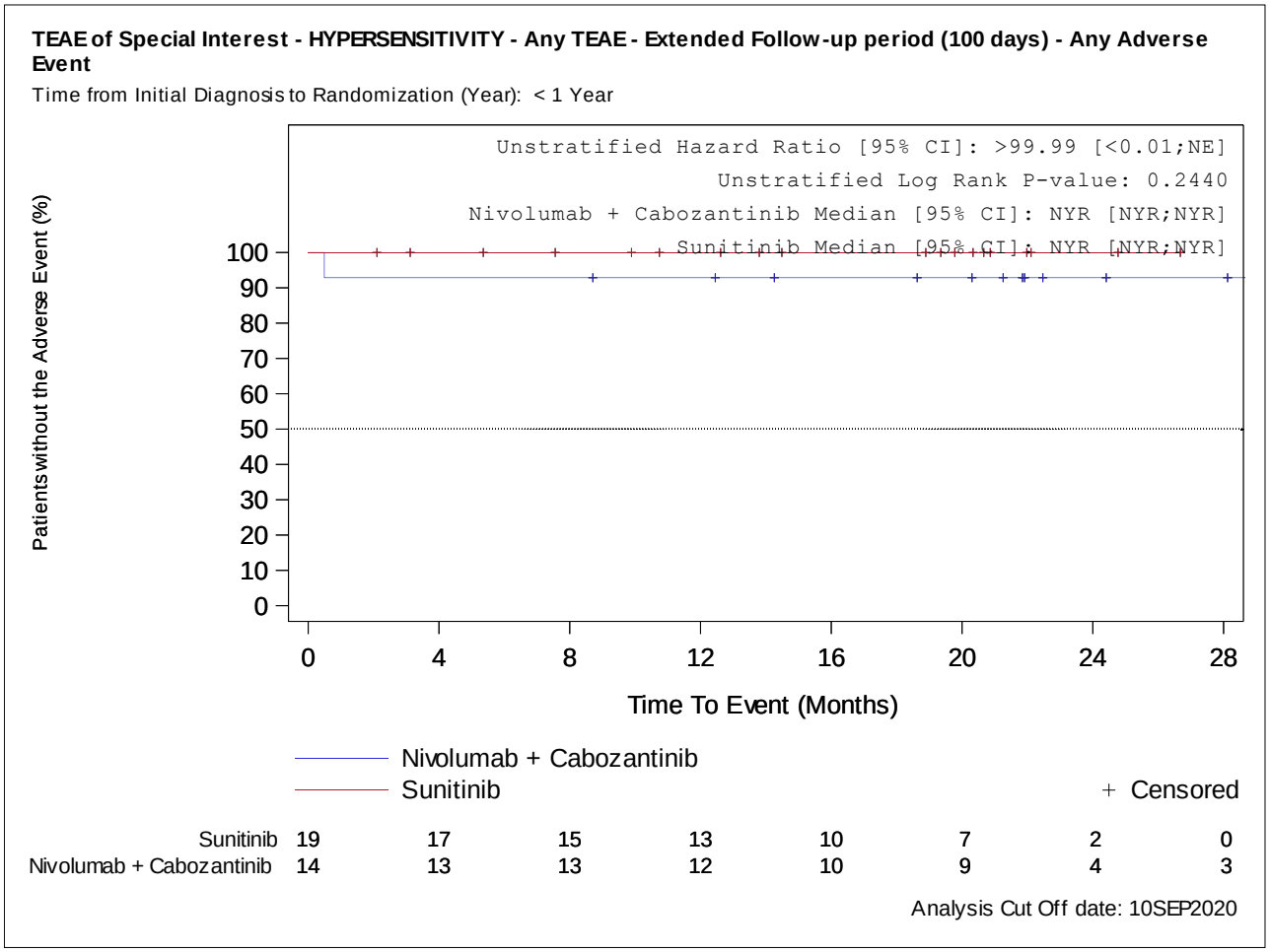

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:48:20

FIGURE 3.84.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



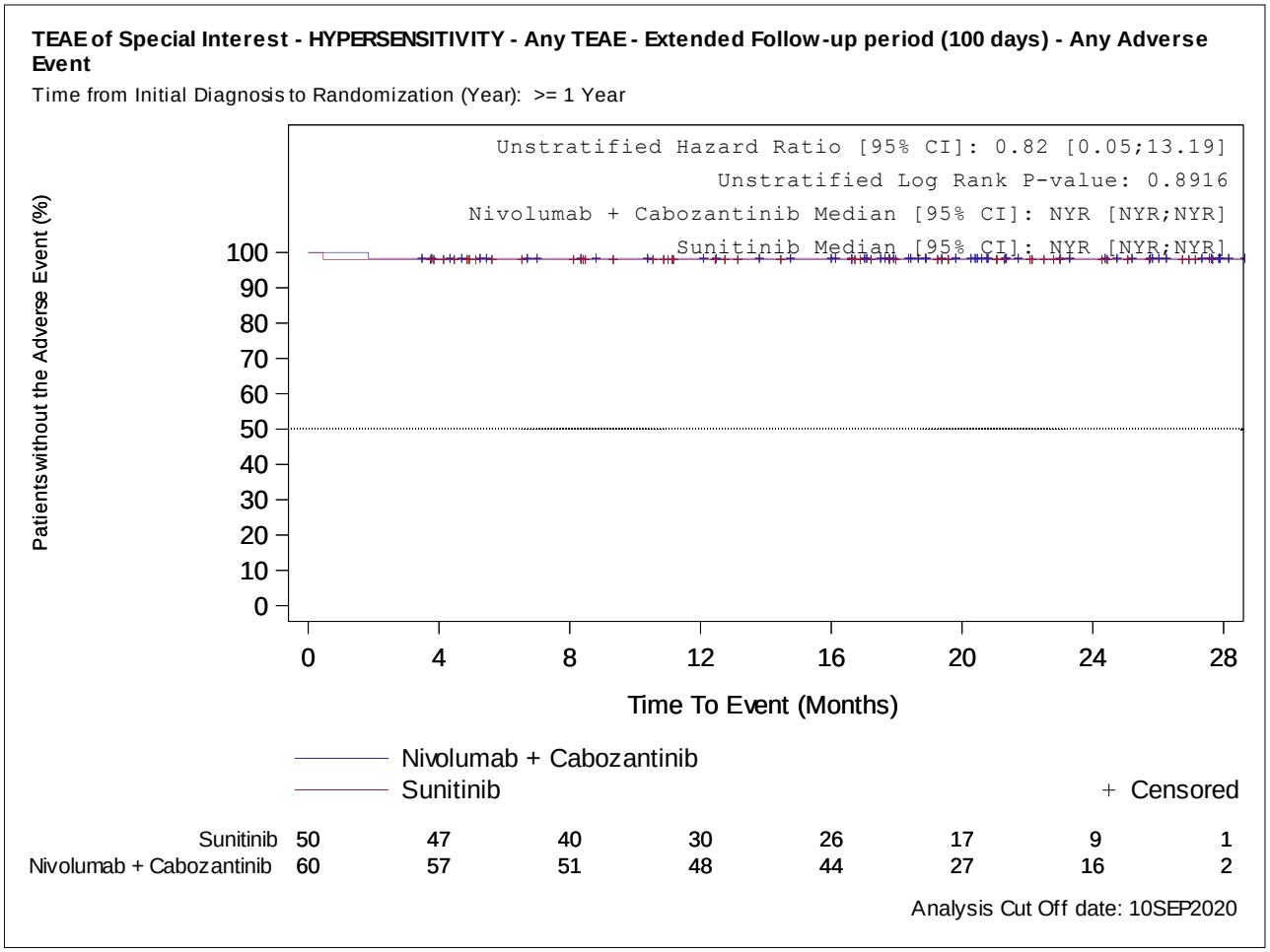

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:48:26

FIGURE 3.84.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



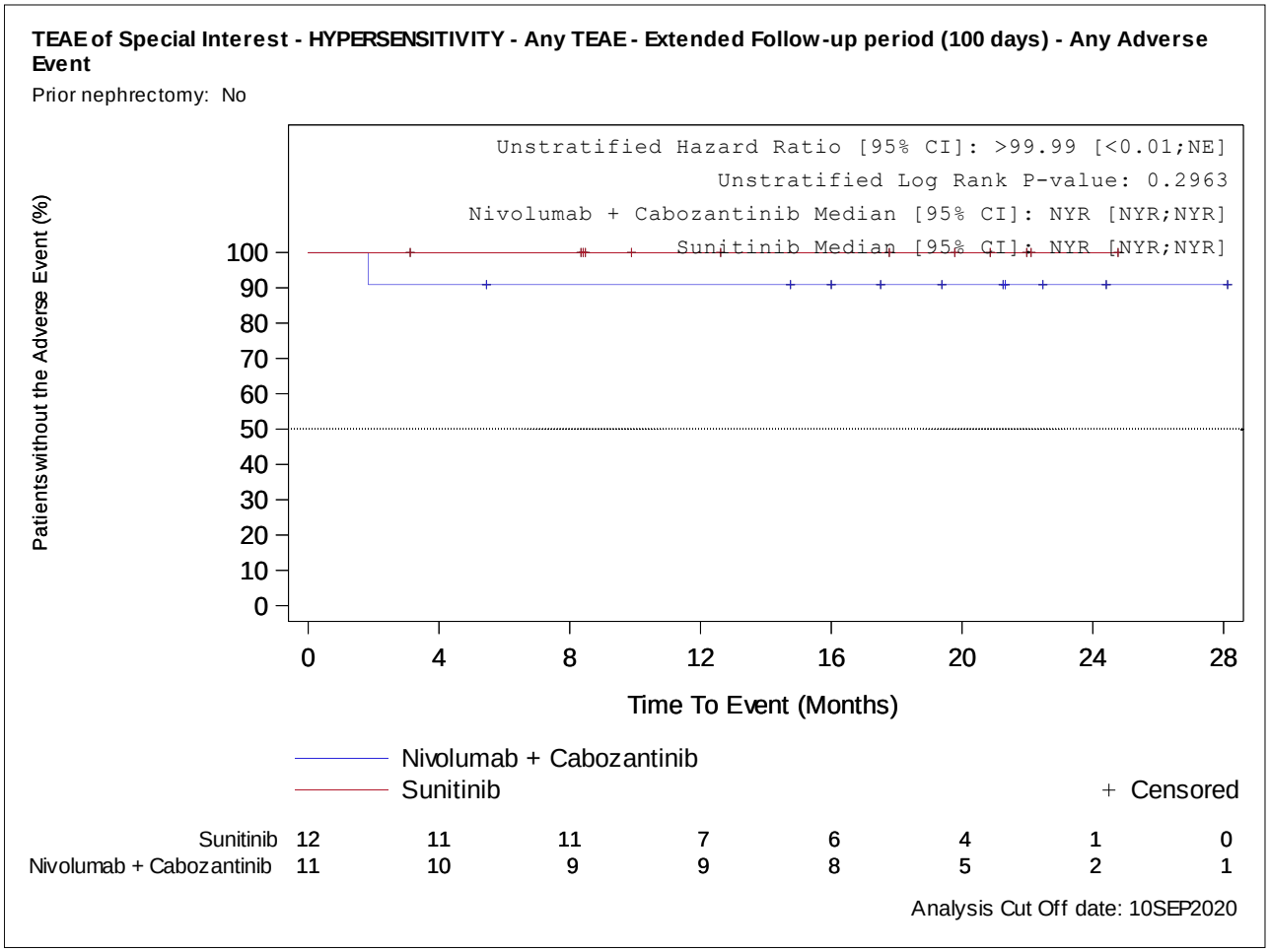

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:48:43

FIGURE 3.84.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



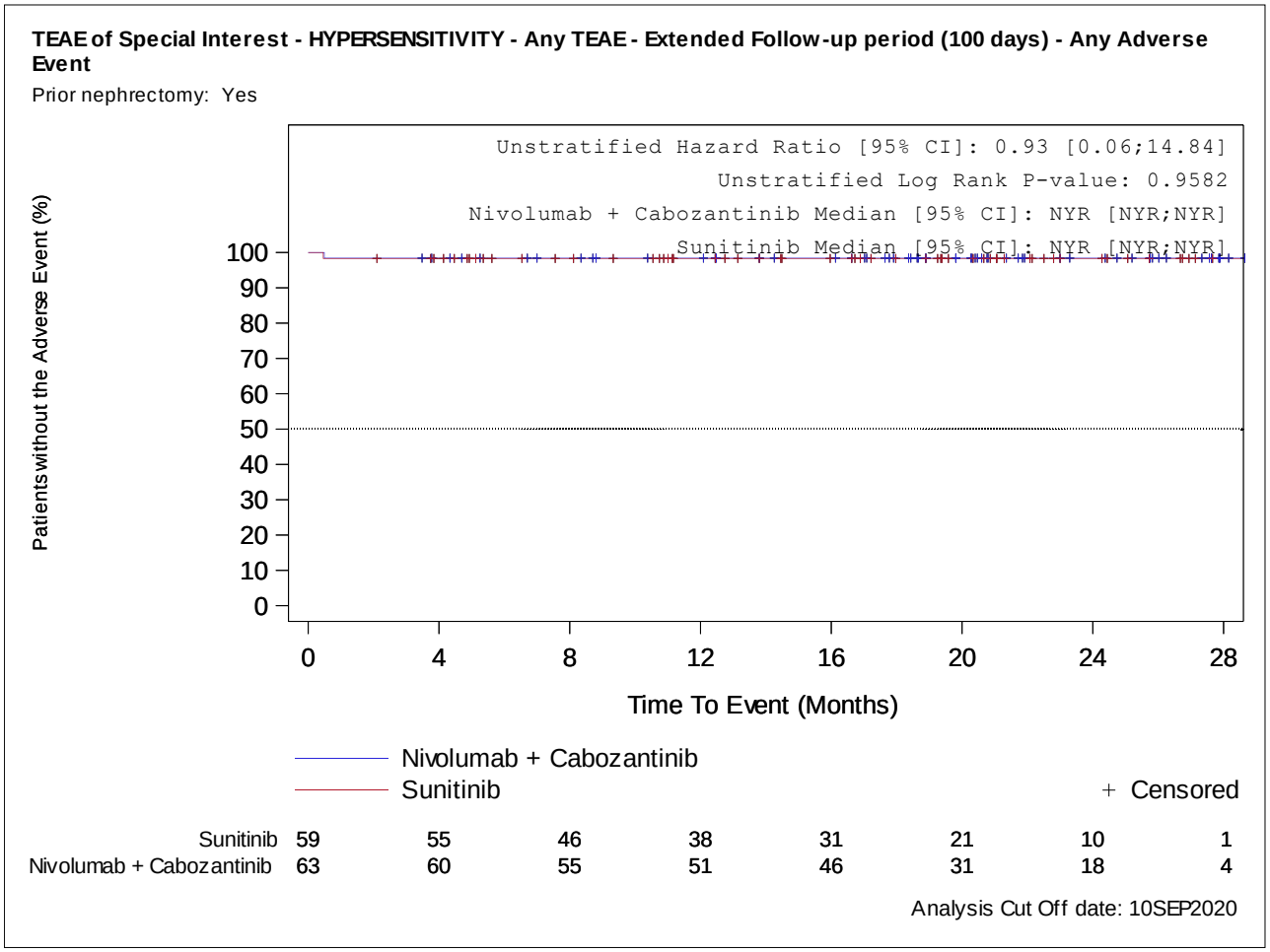

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:48:49

FIGURE 3.84.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



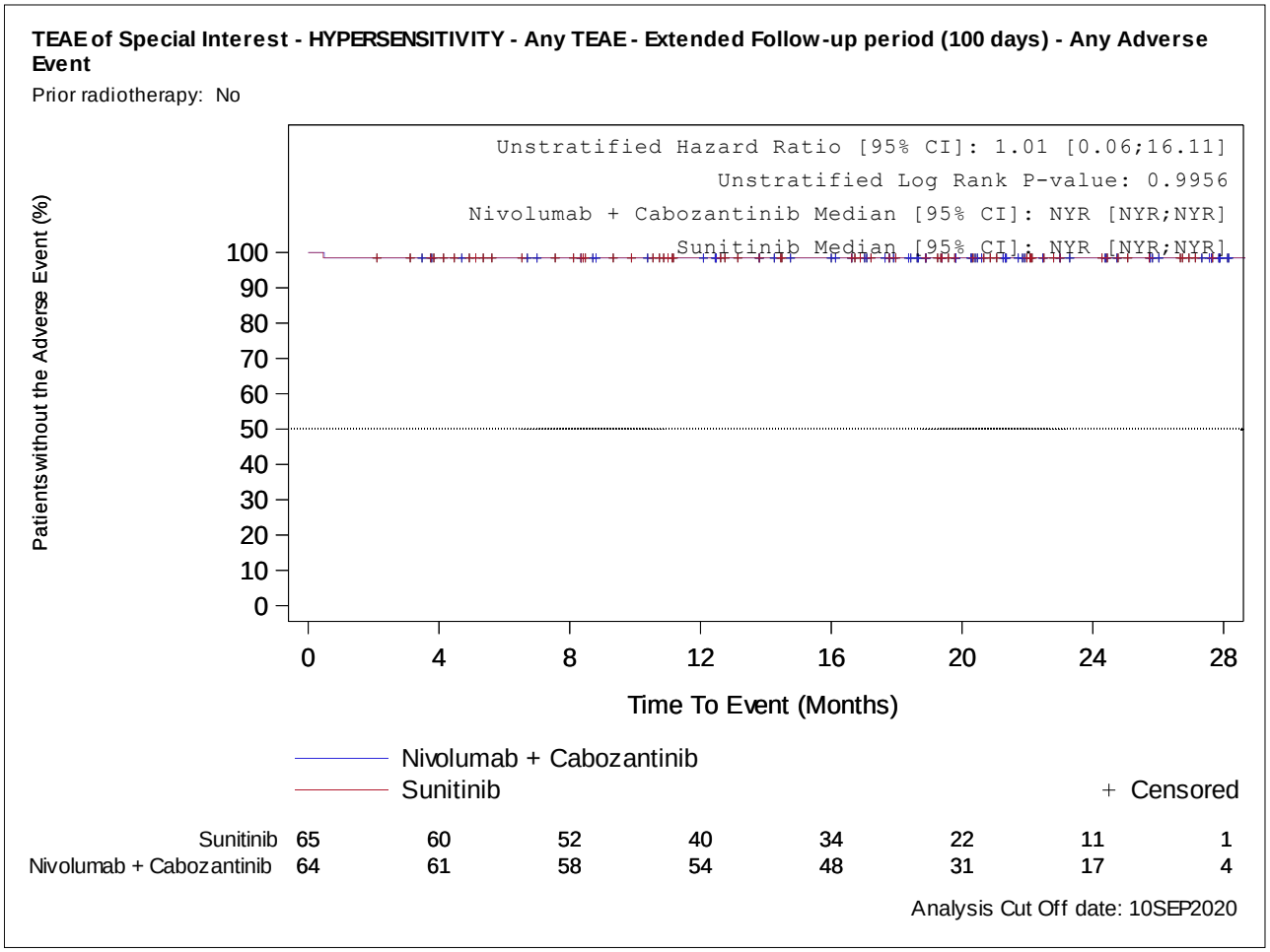

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:49:41

FIGURE 3.84.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



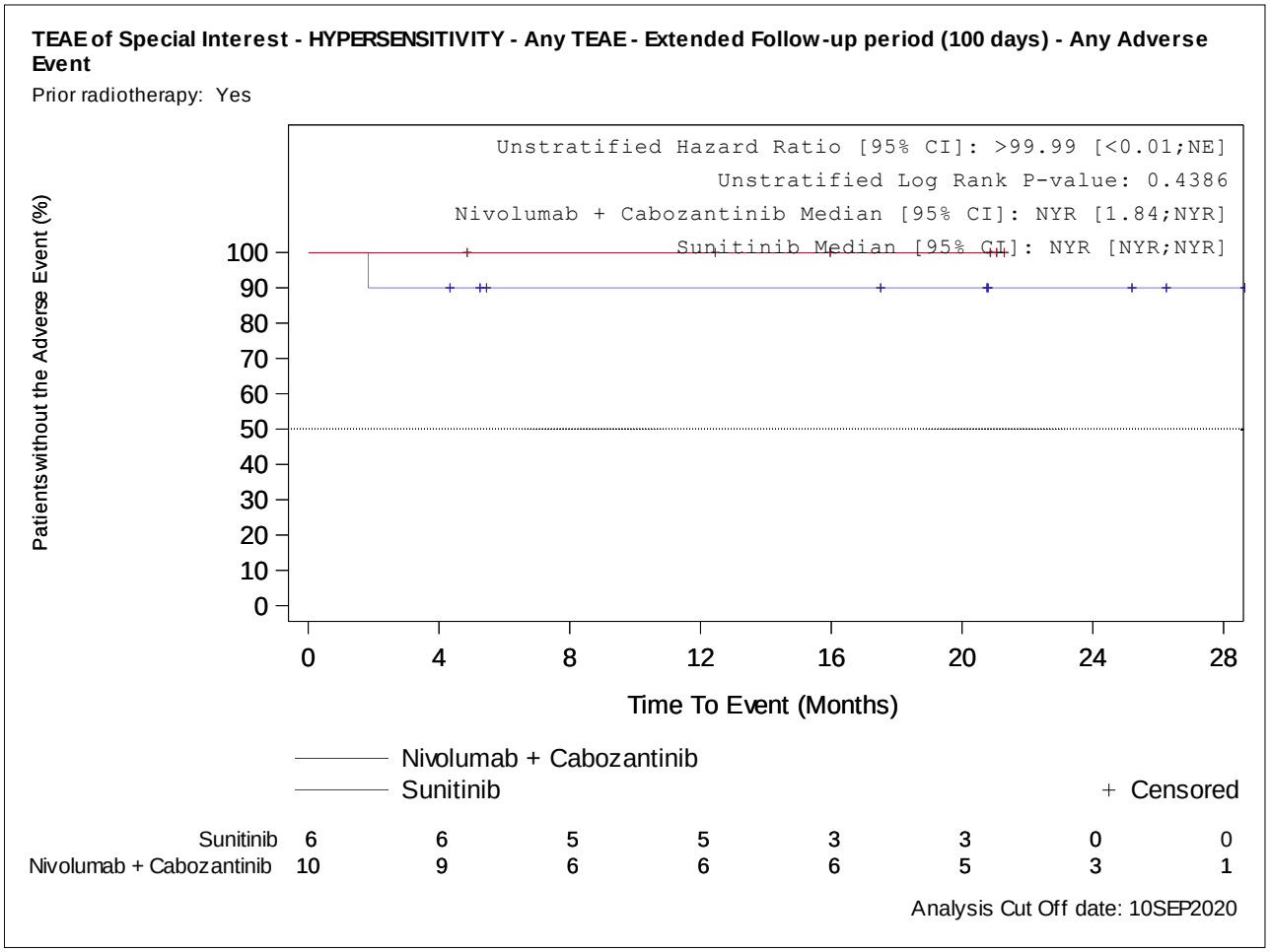

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:49:47

FIGURE 3.84.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



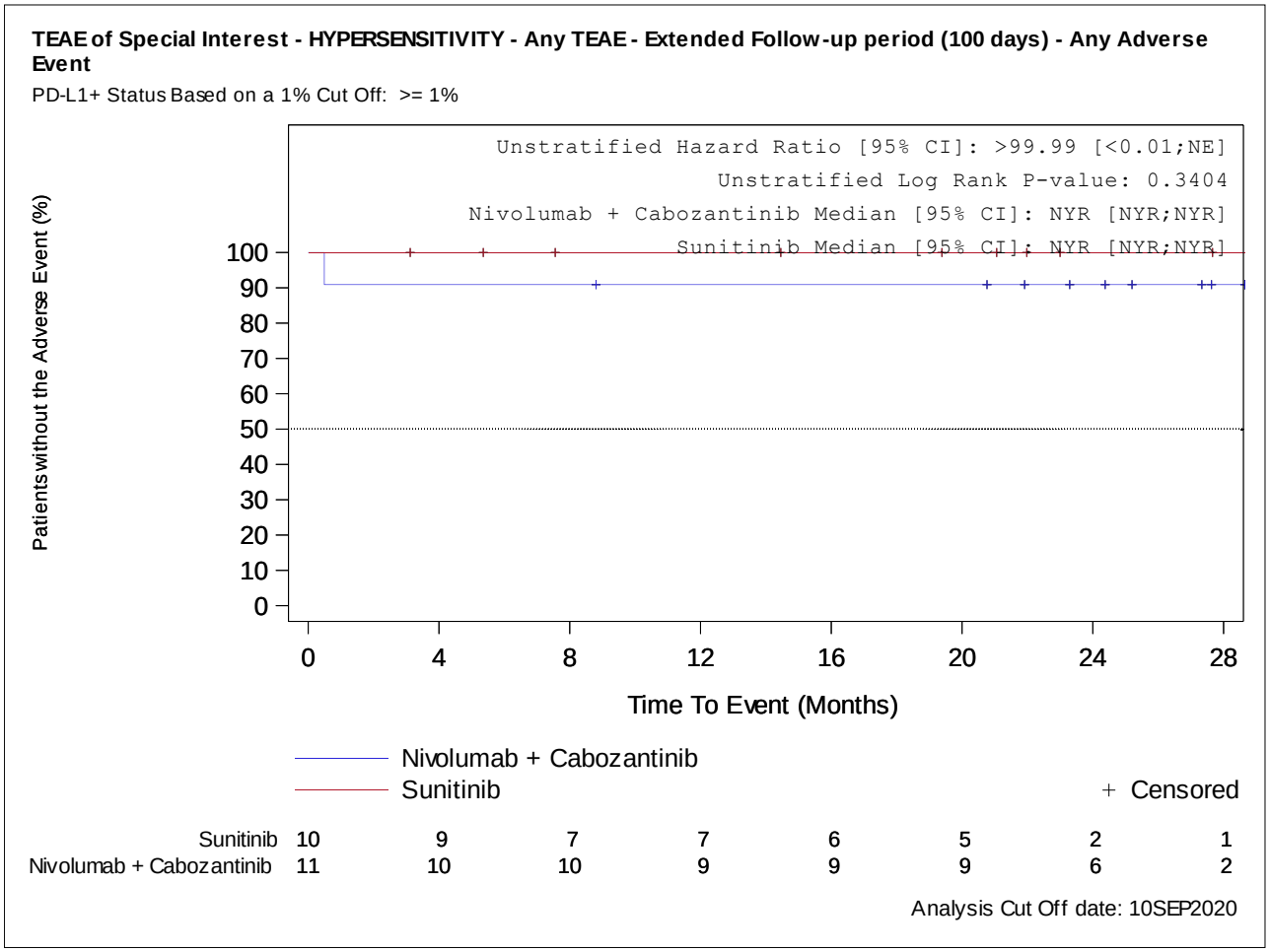

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:49:52

FIGURE 3.84.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



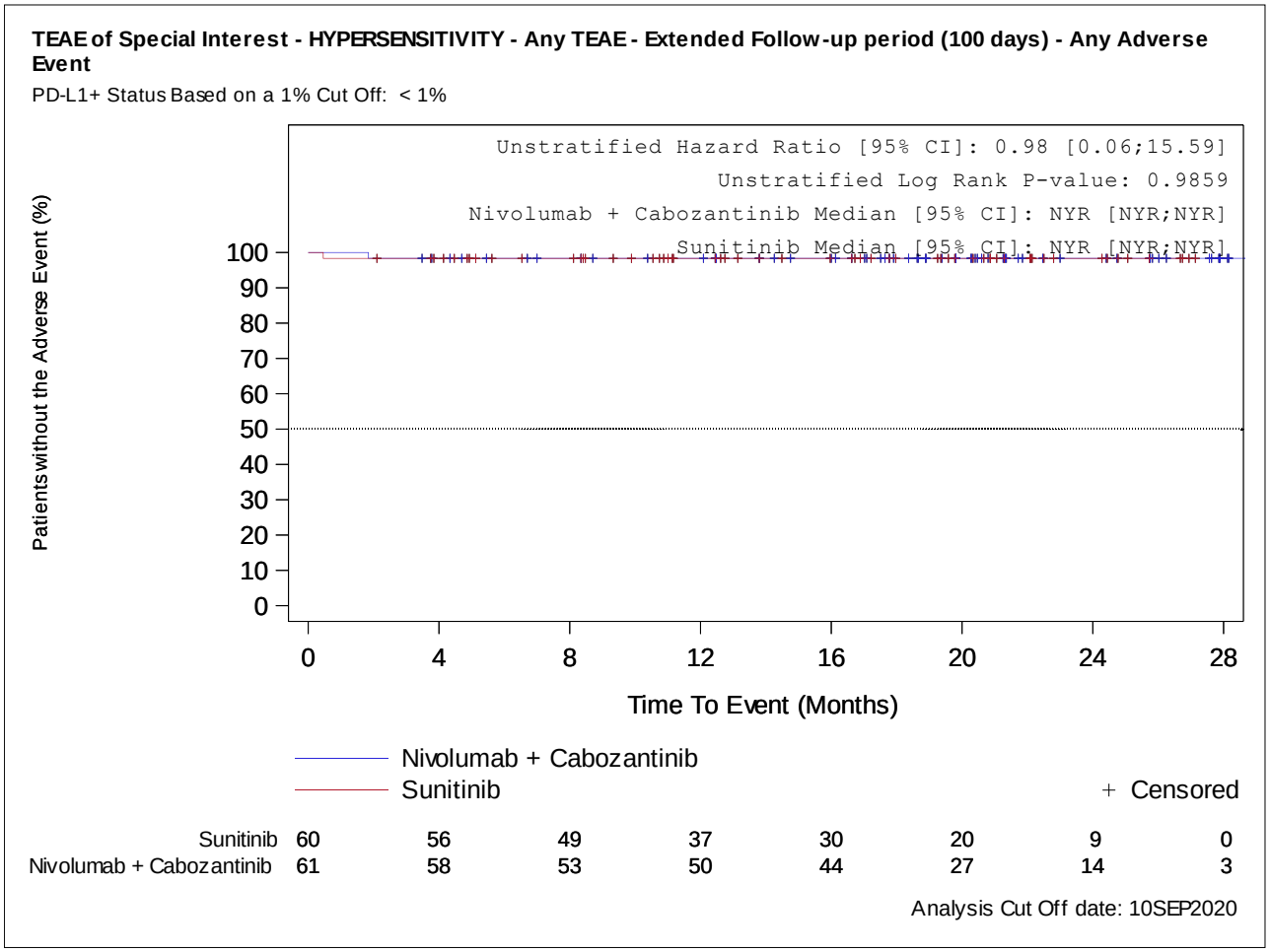

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:49:58

FIGURE 3.84.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



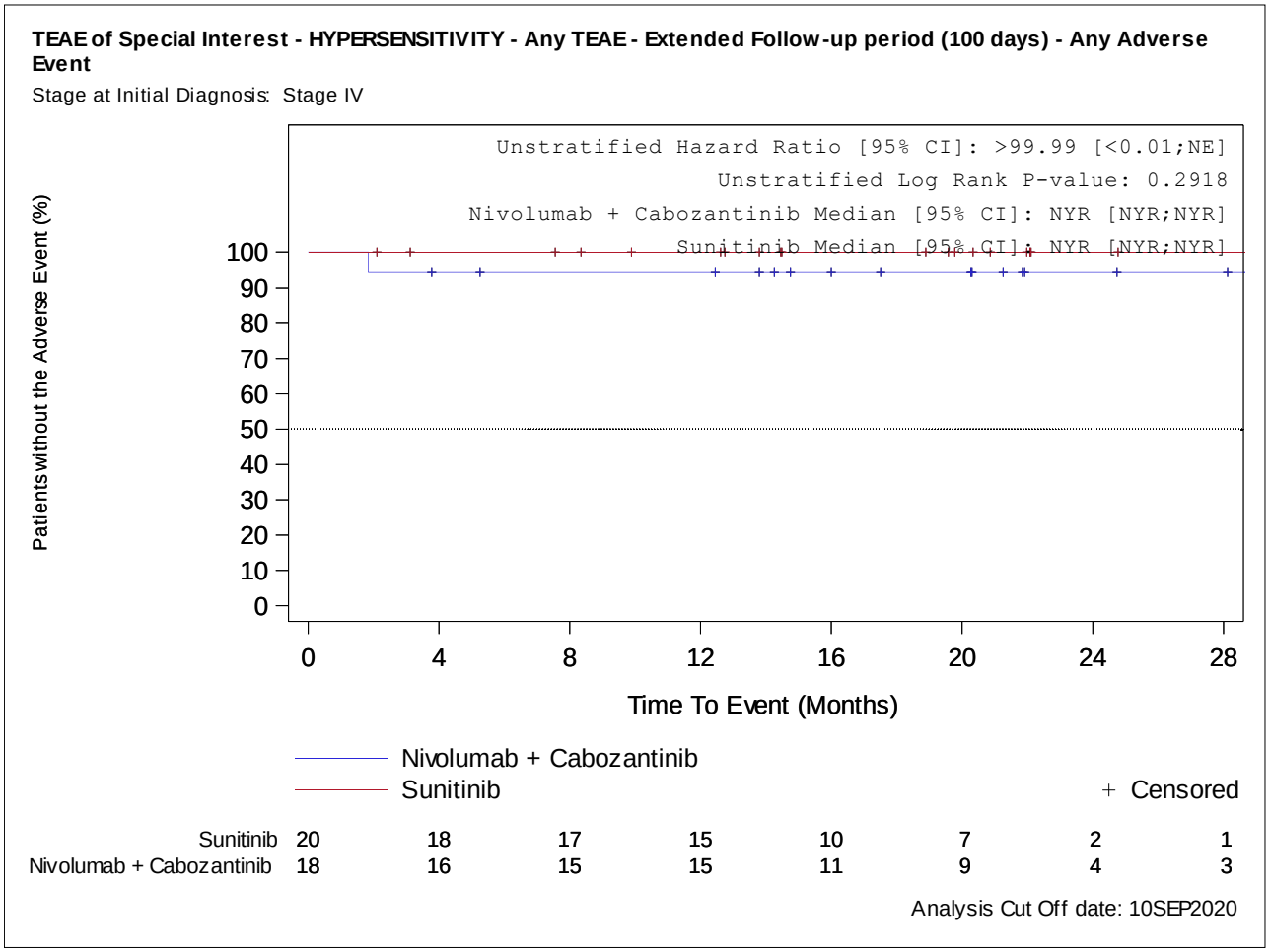

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:50:04

FIGURE 3.84.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



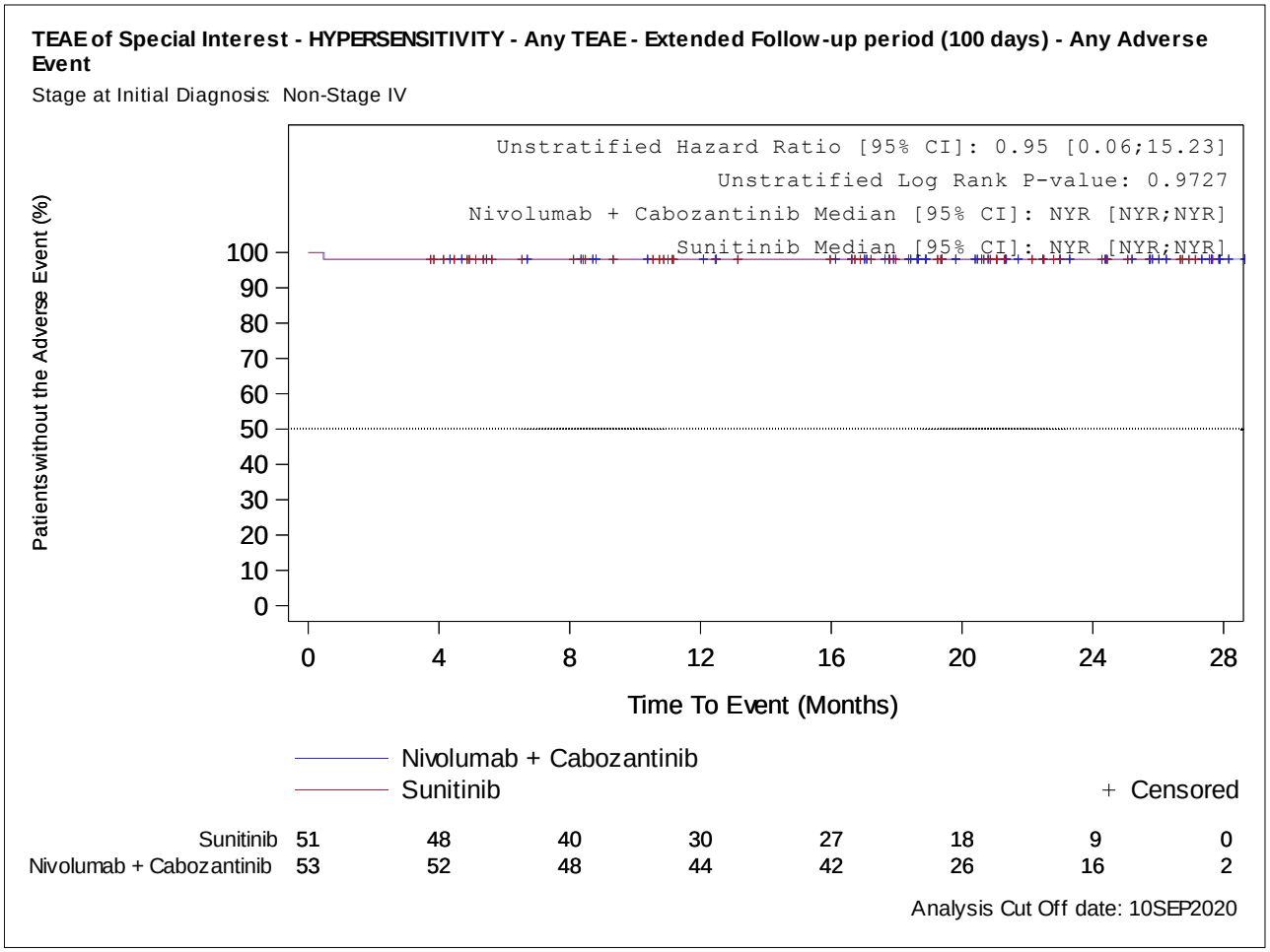

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:50:10

FIGURE 3.84.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



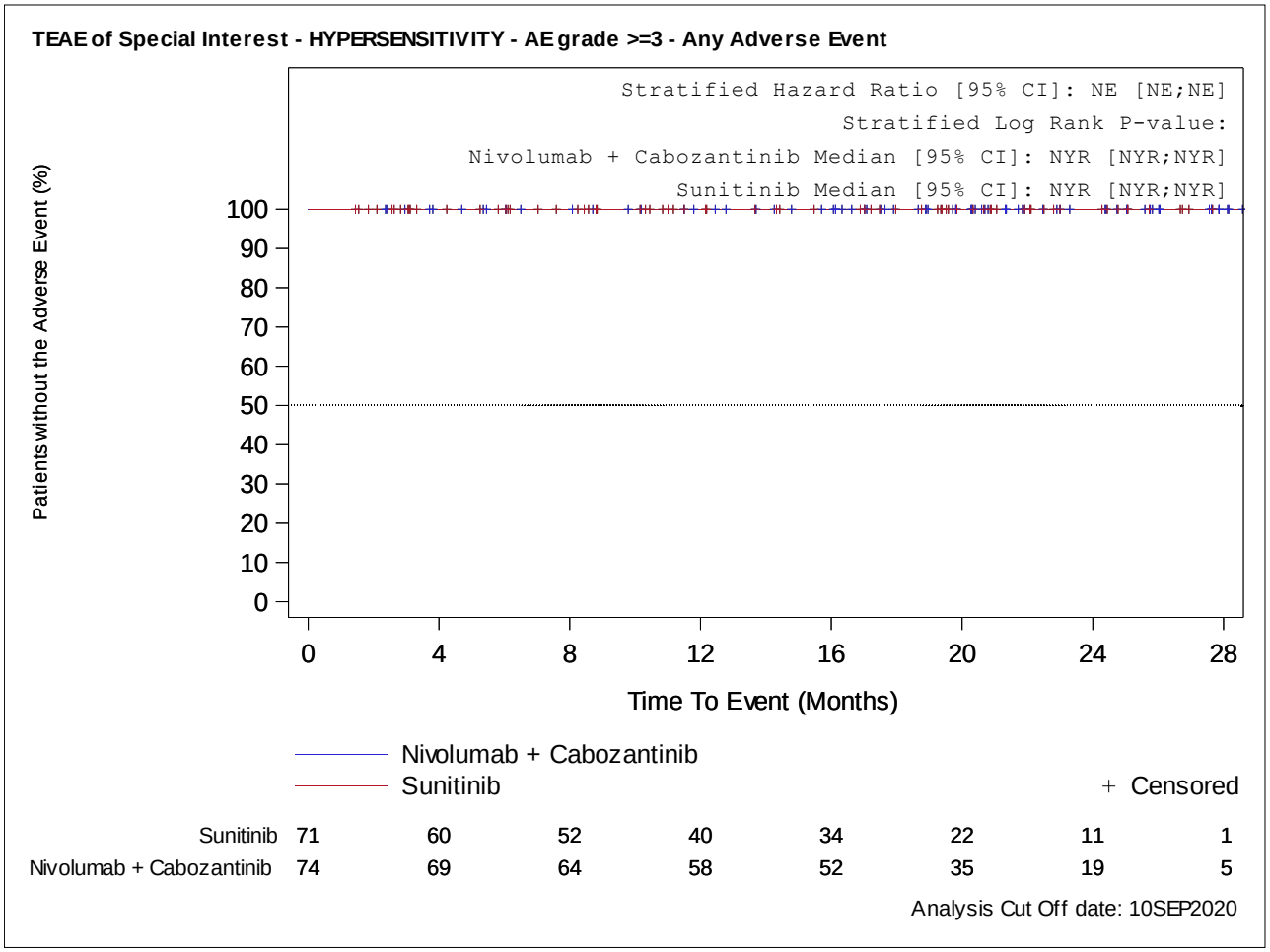

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:50:40

FIGURE 3.84.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



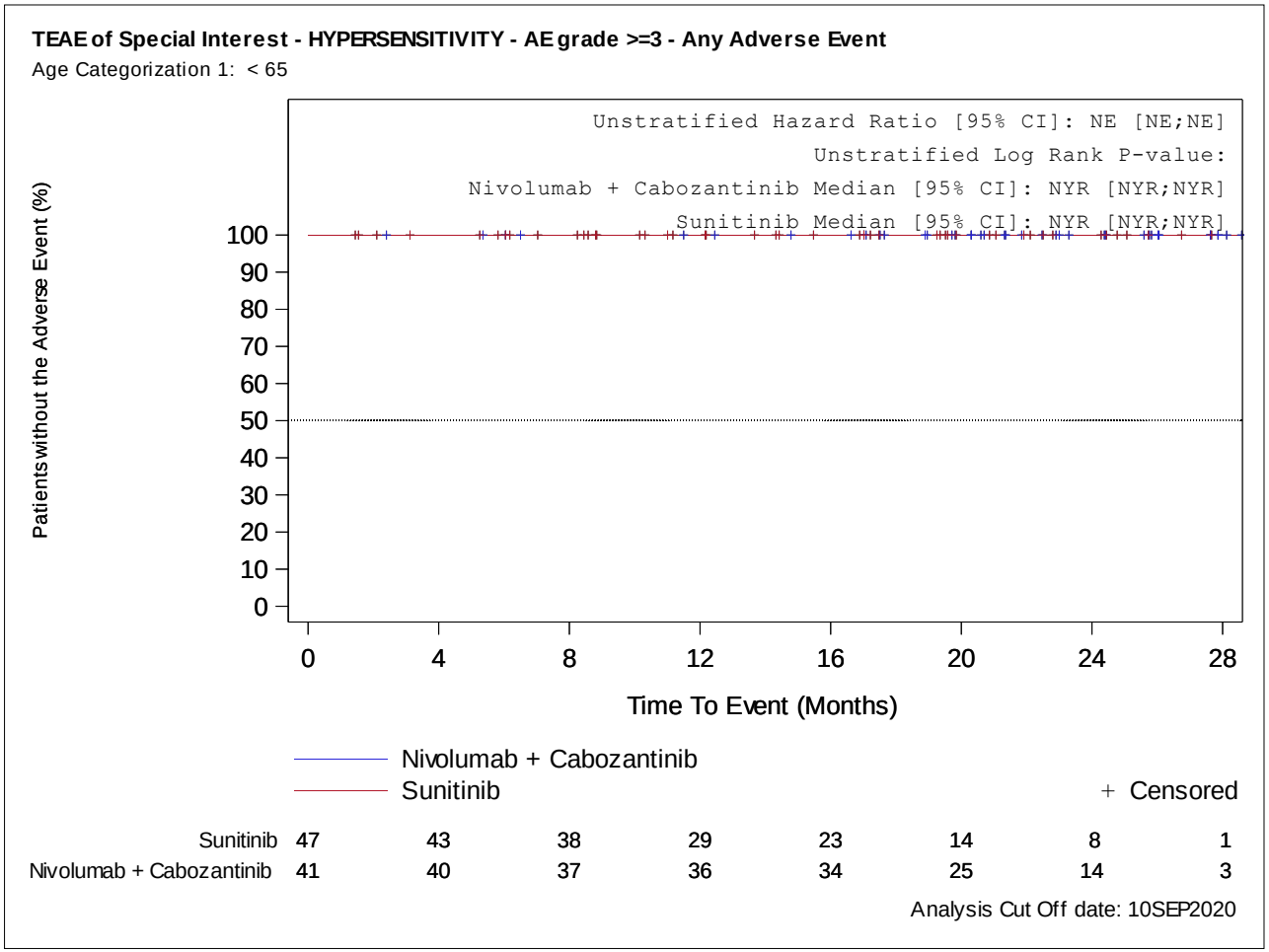

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:50:45

FIGURE 3.85.1: TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



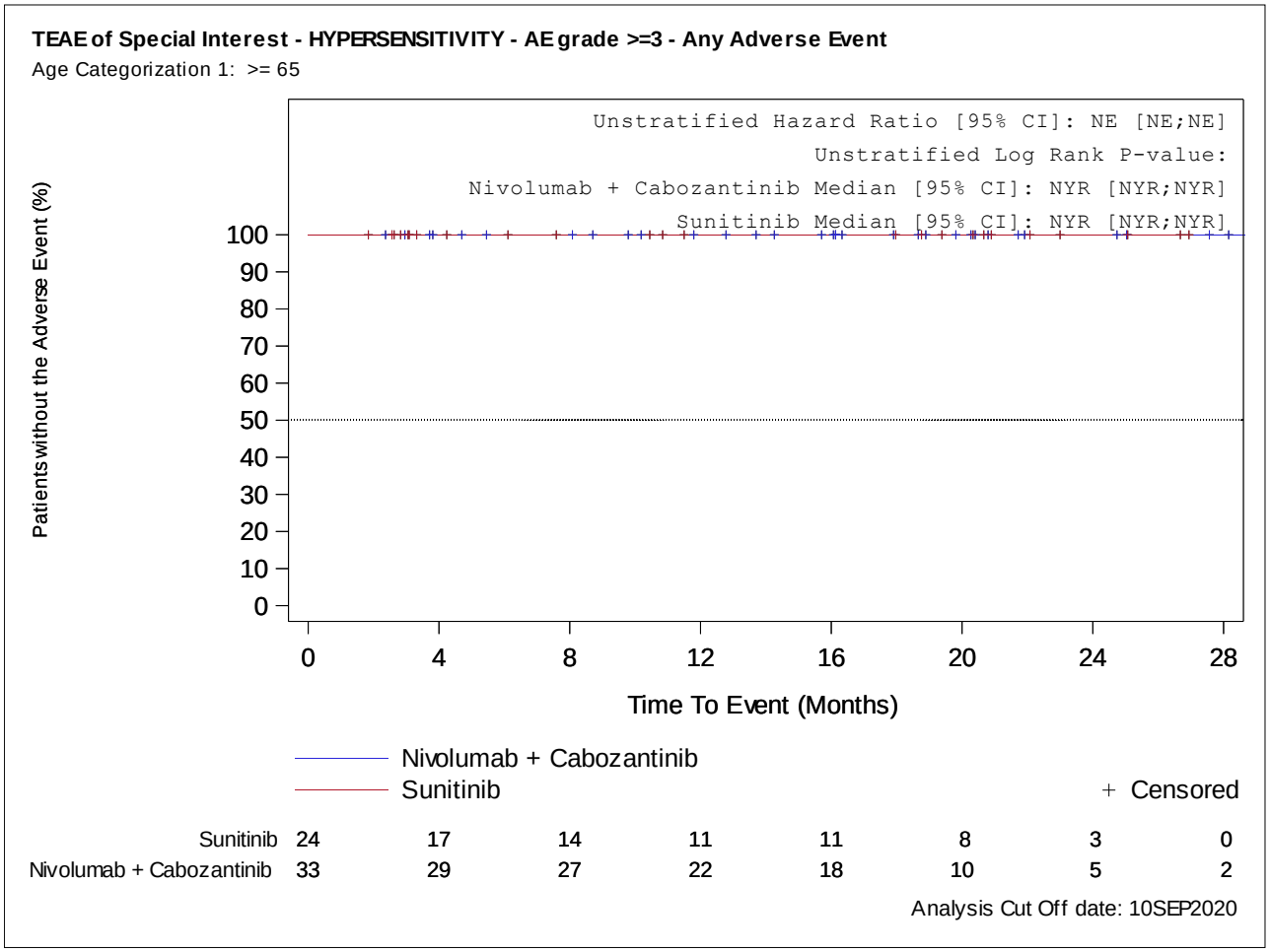

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:54:01

FIGURE 3.85.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



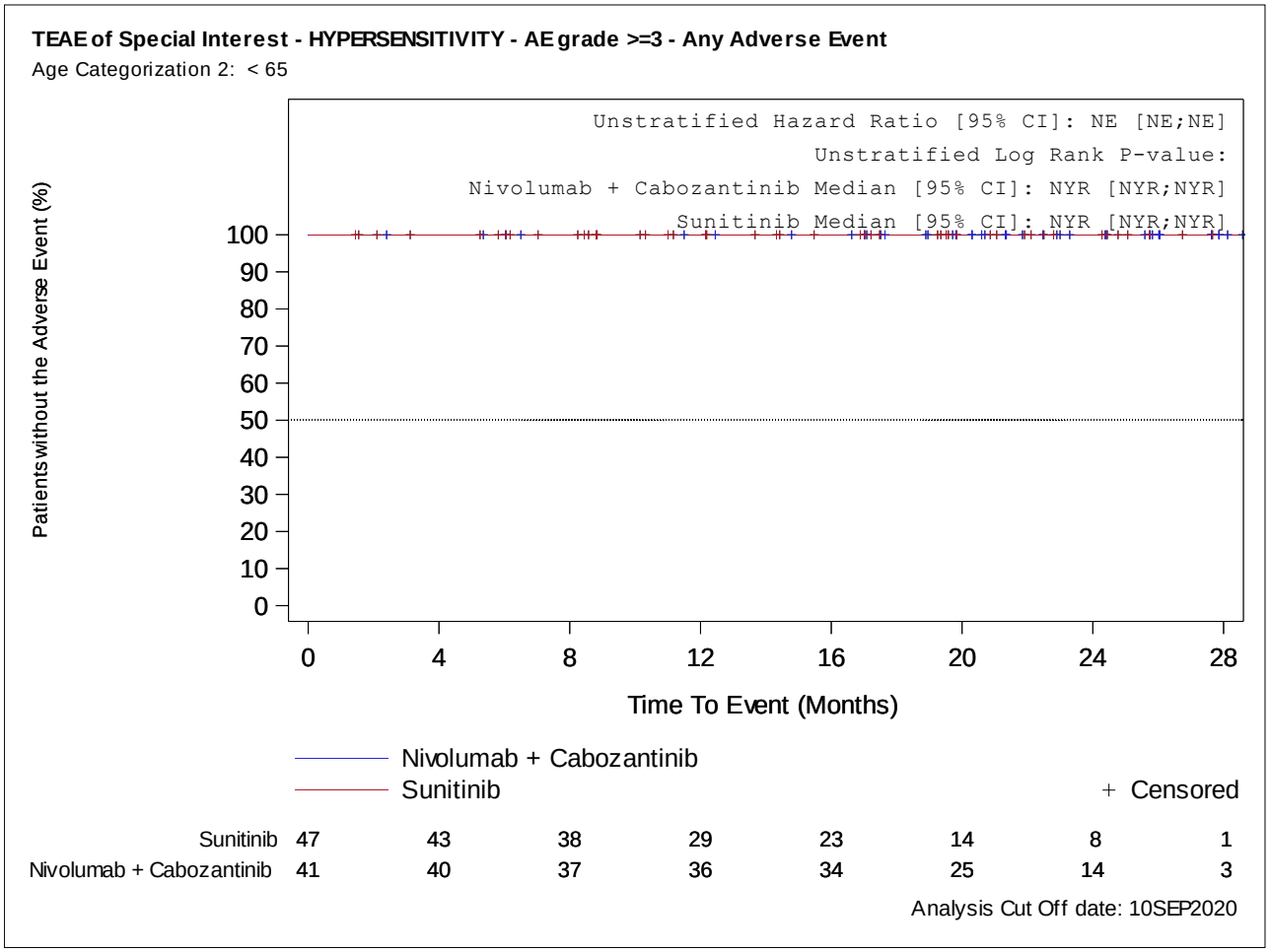

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:54:04

FIGURE 3.85.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



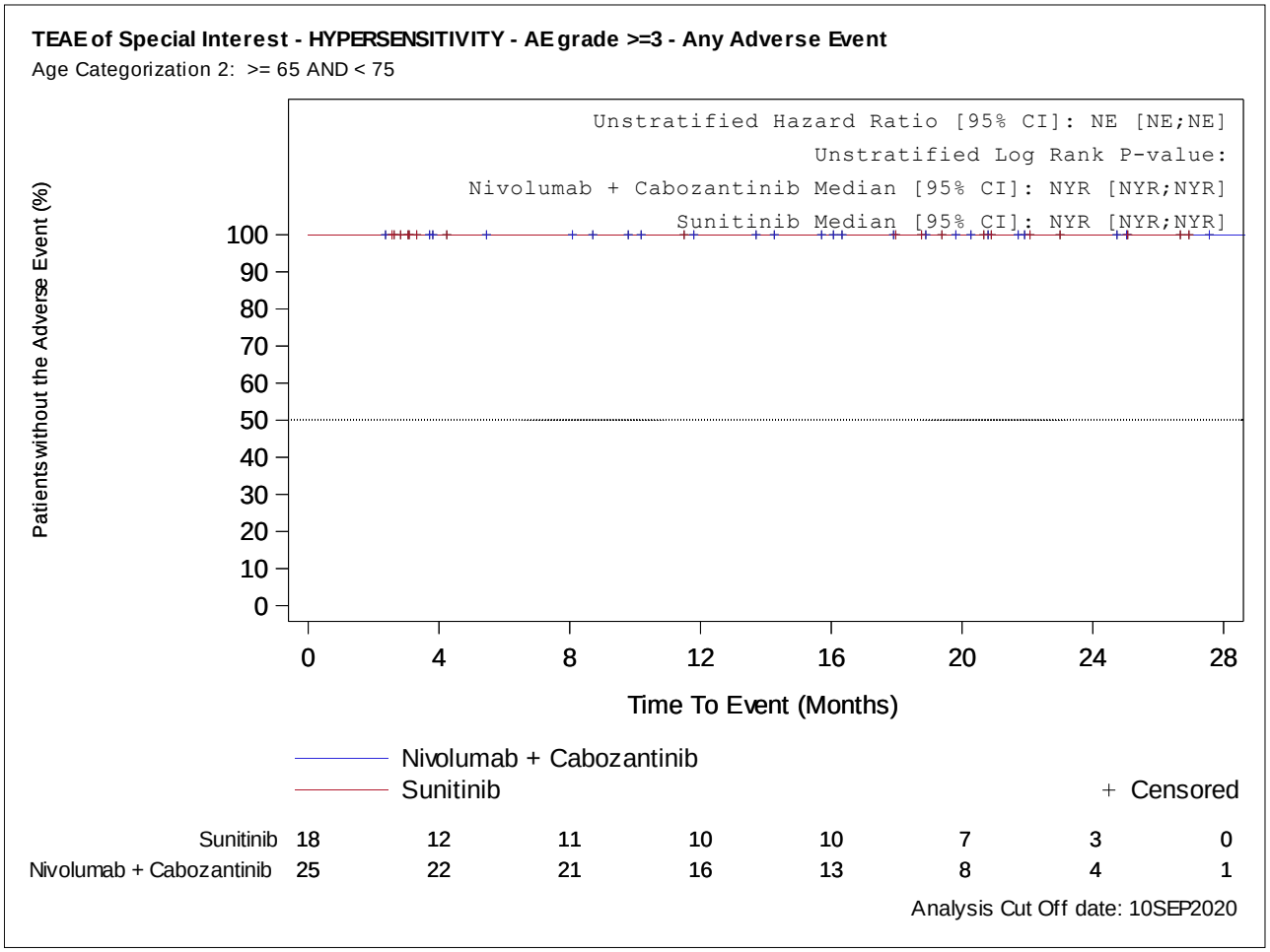

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:54:10

FIGURE 3.85.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



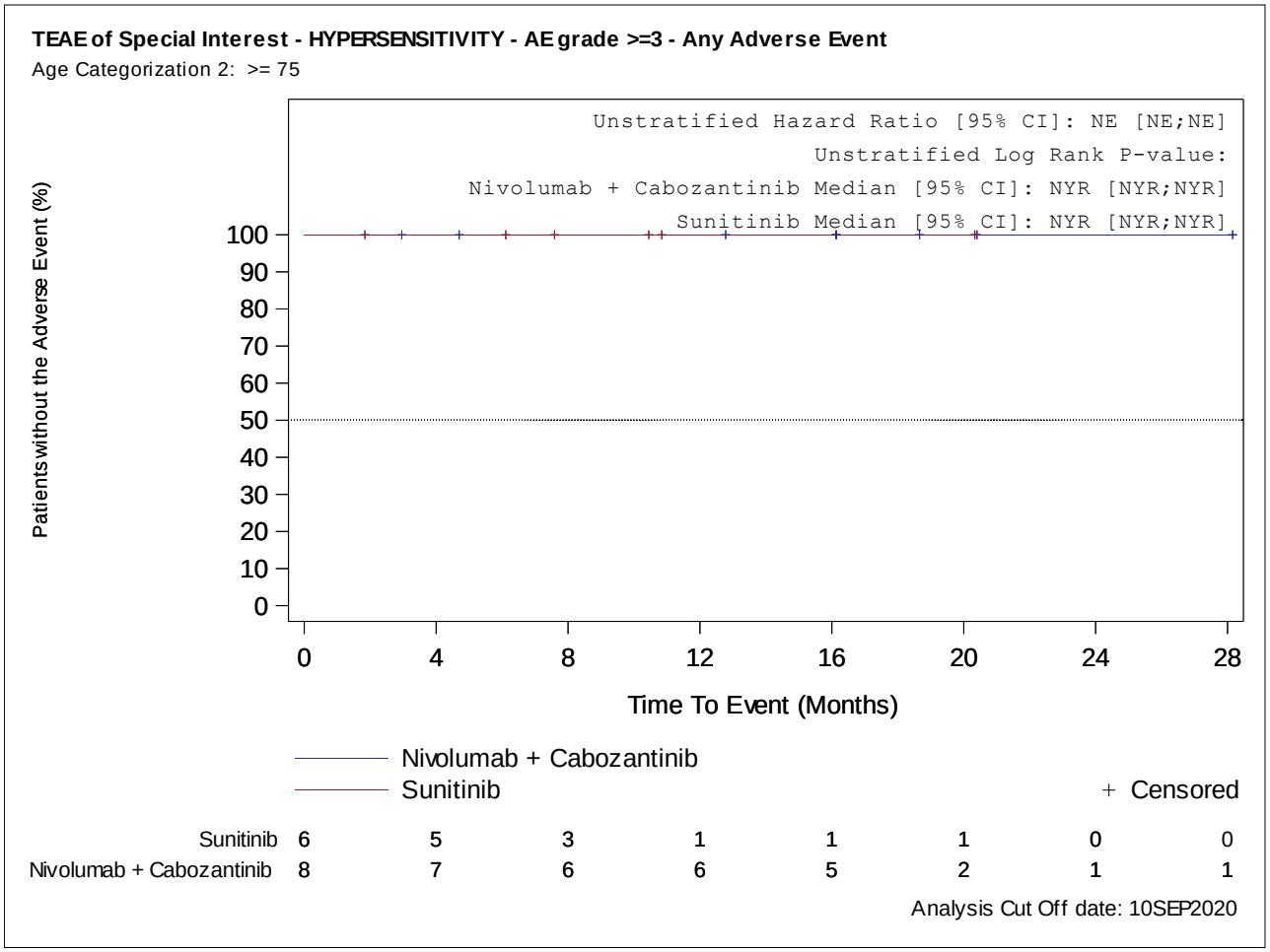

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:54:16

FIGURE 3.85.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



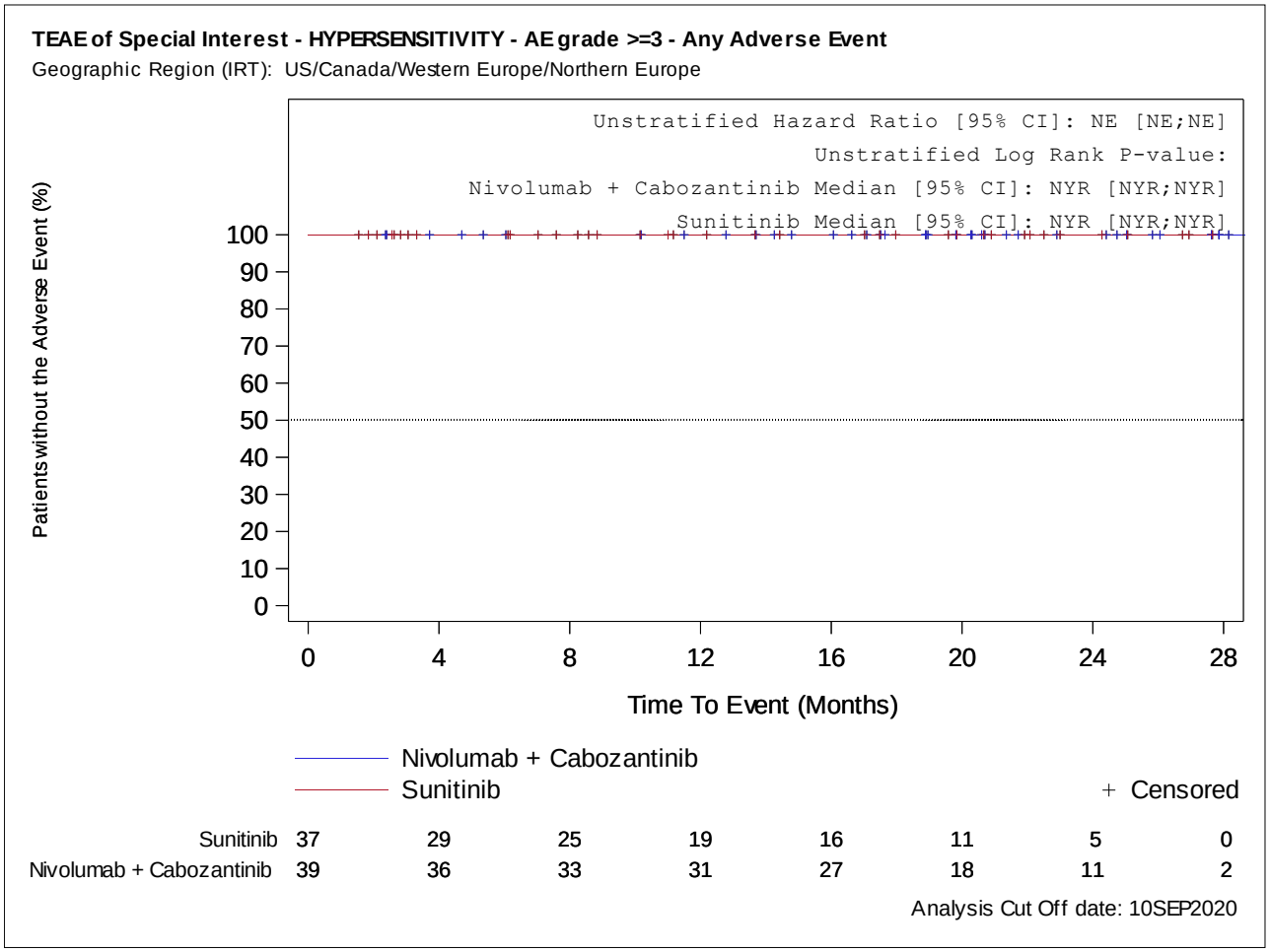

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:54:22

FIGURE 3.85.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



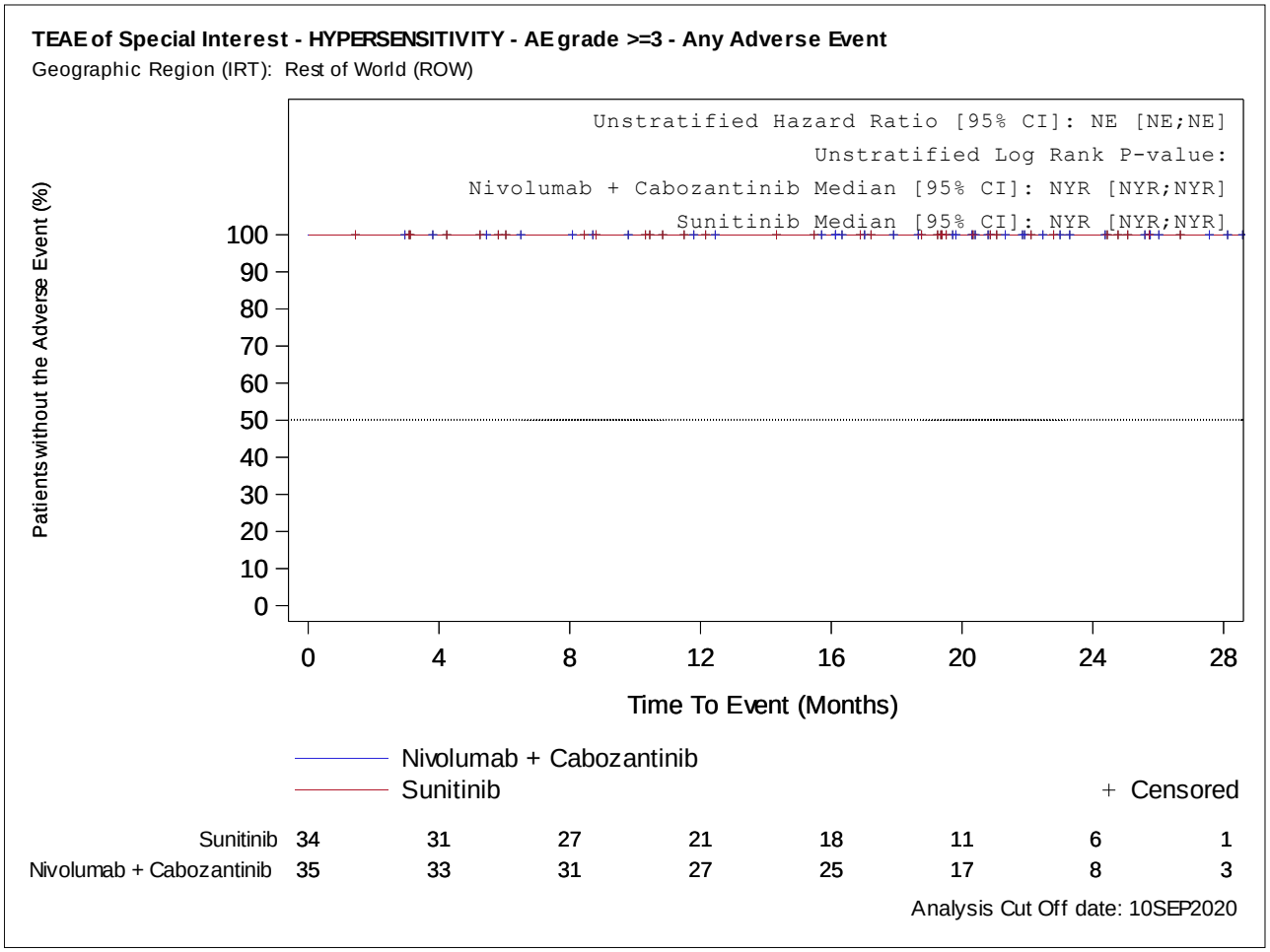

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:54:28

FIGURE 3.85.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



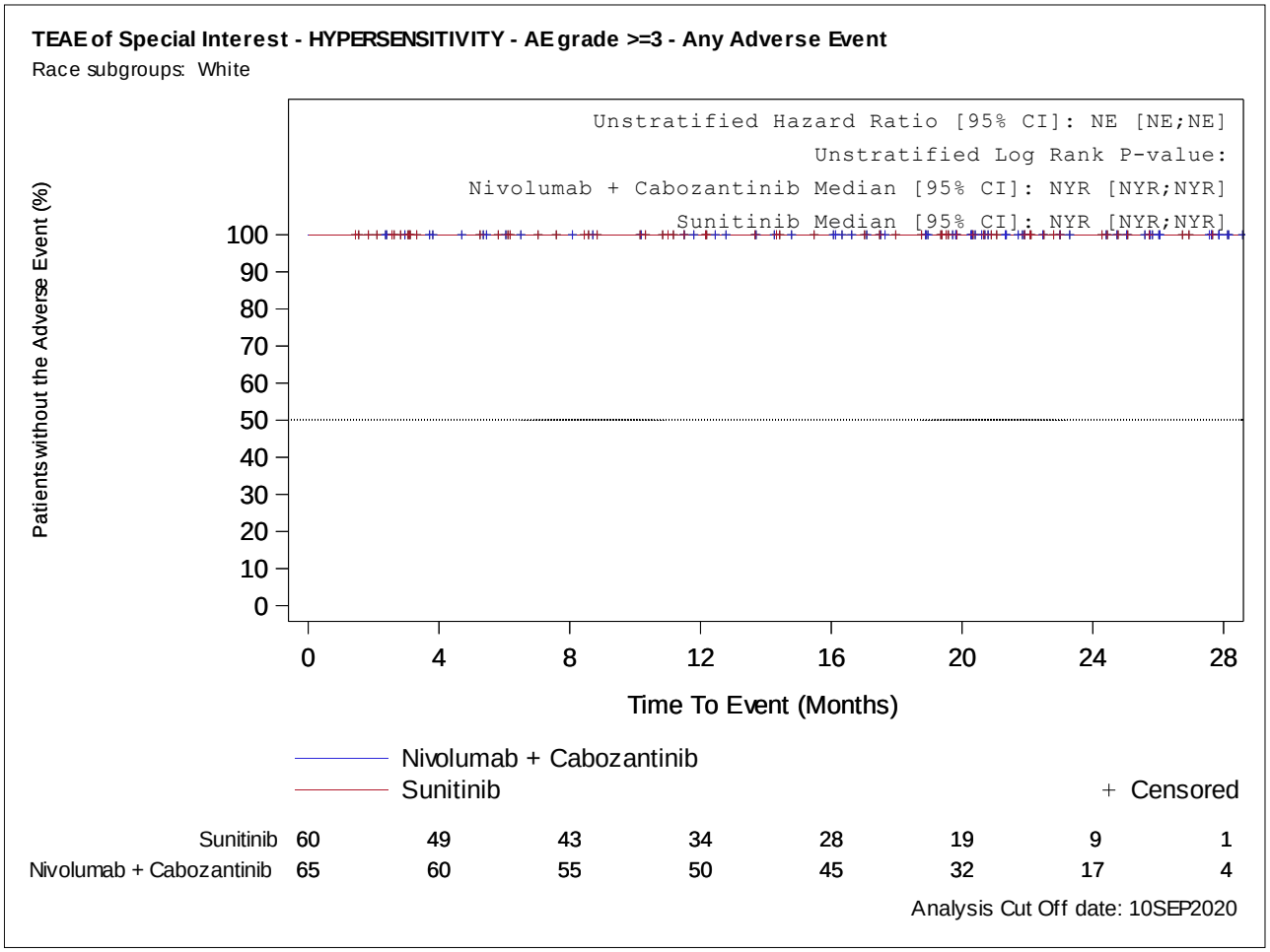

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:54:34

FIGURE 3.85.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



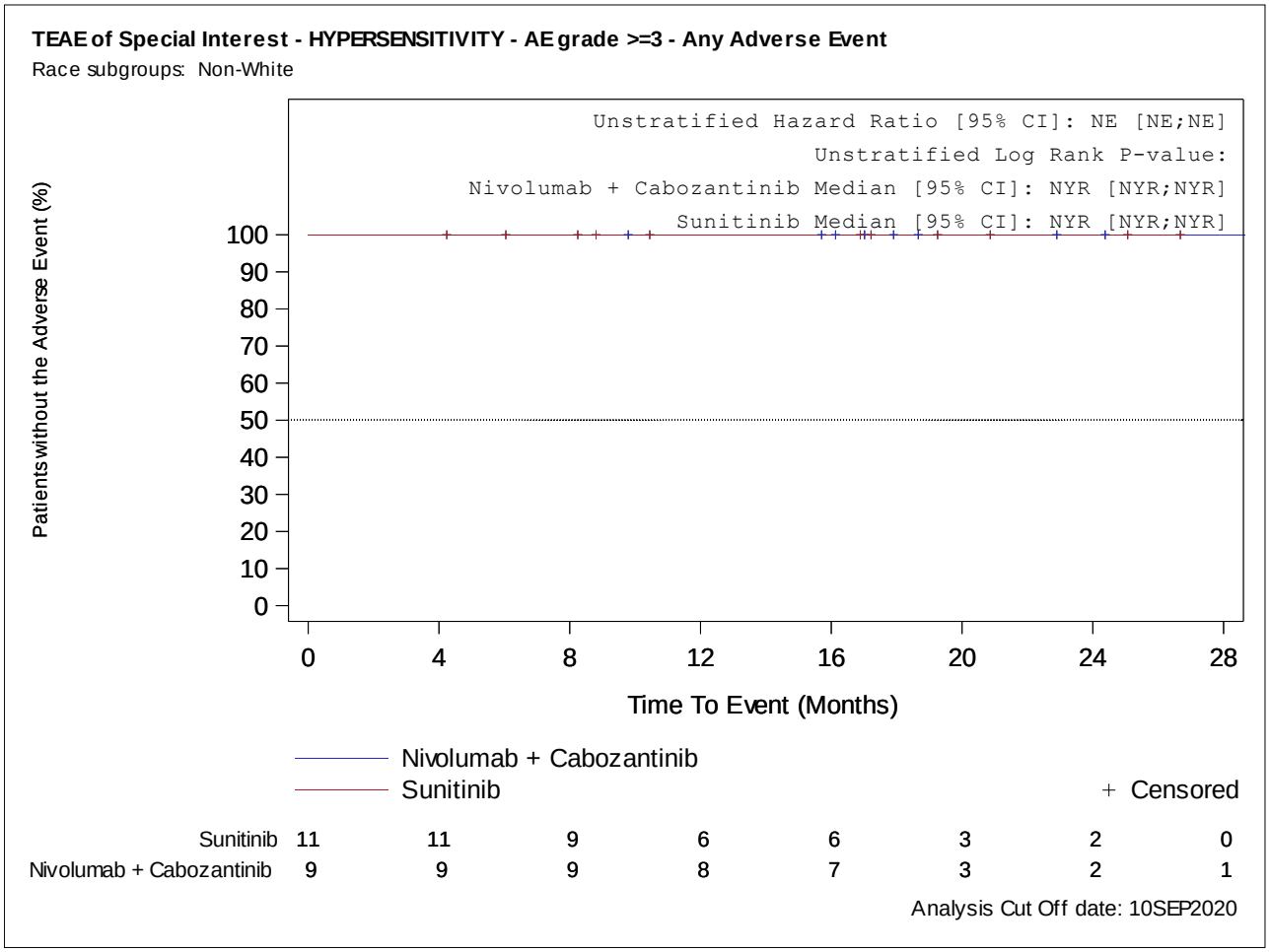

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:54:40

FIGURE 3.85.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



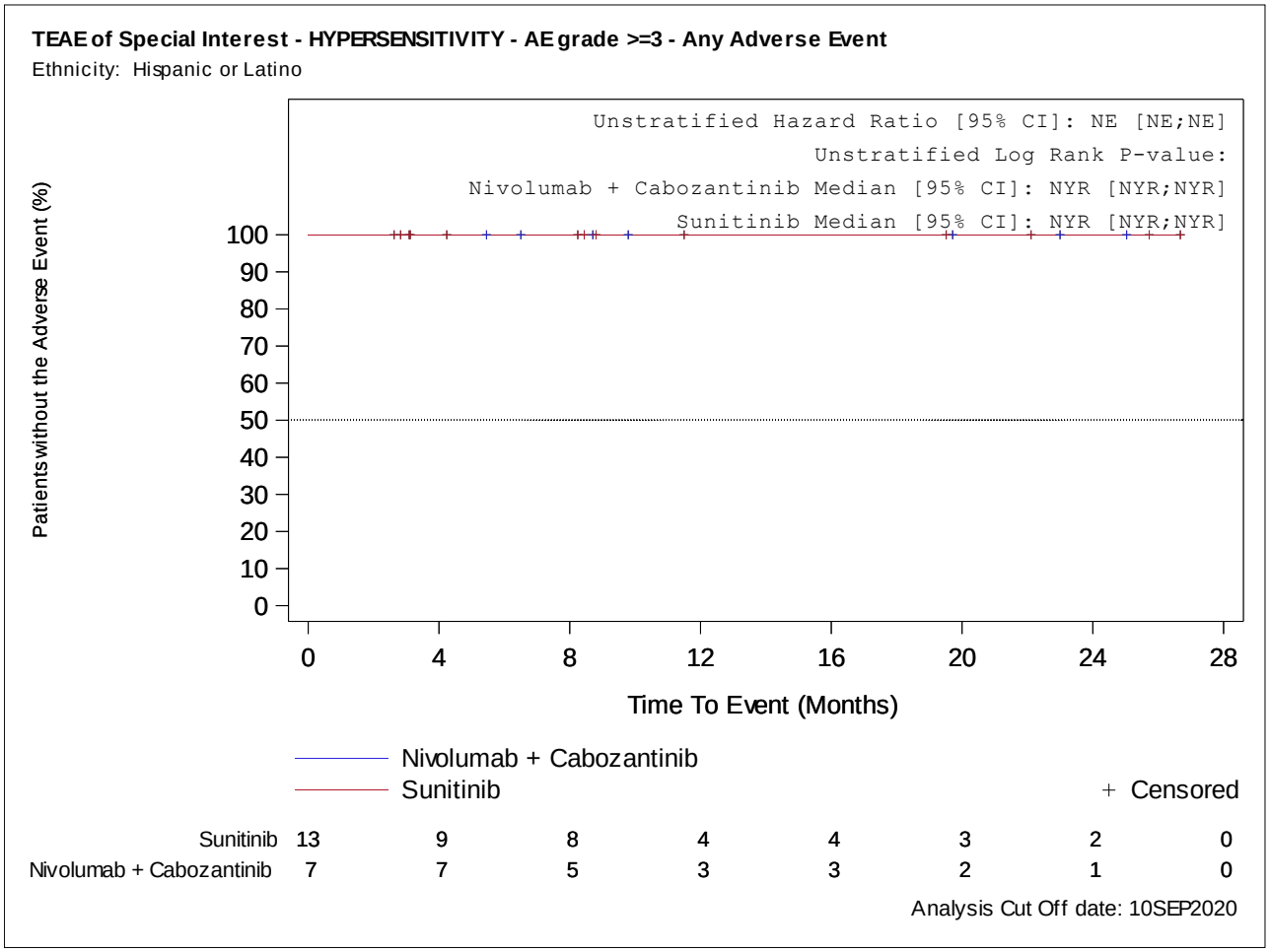

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:54:46

FIGURE 3.85.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



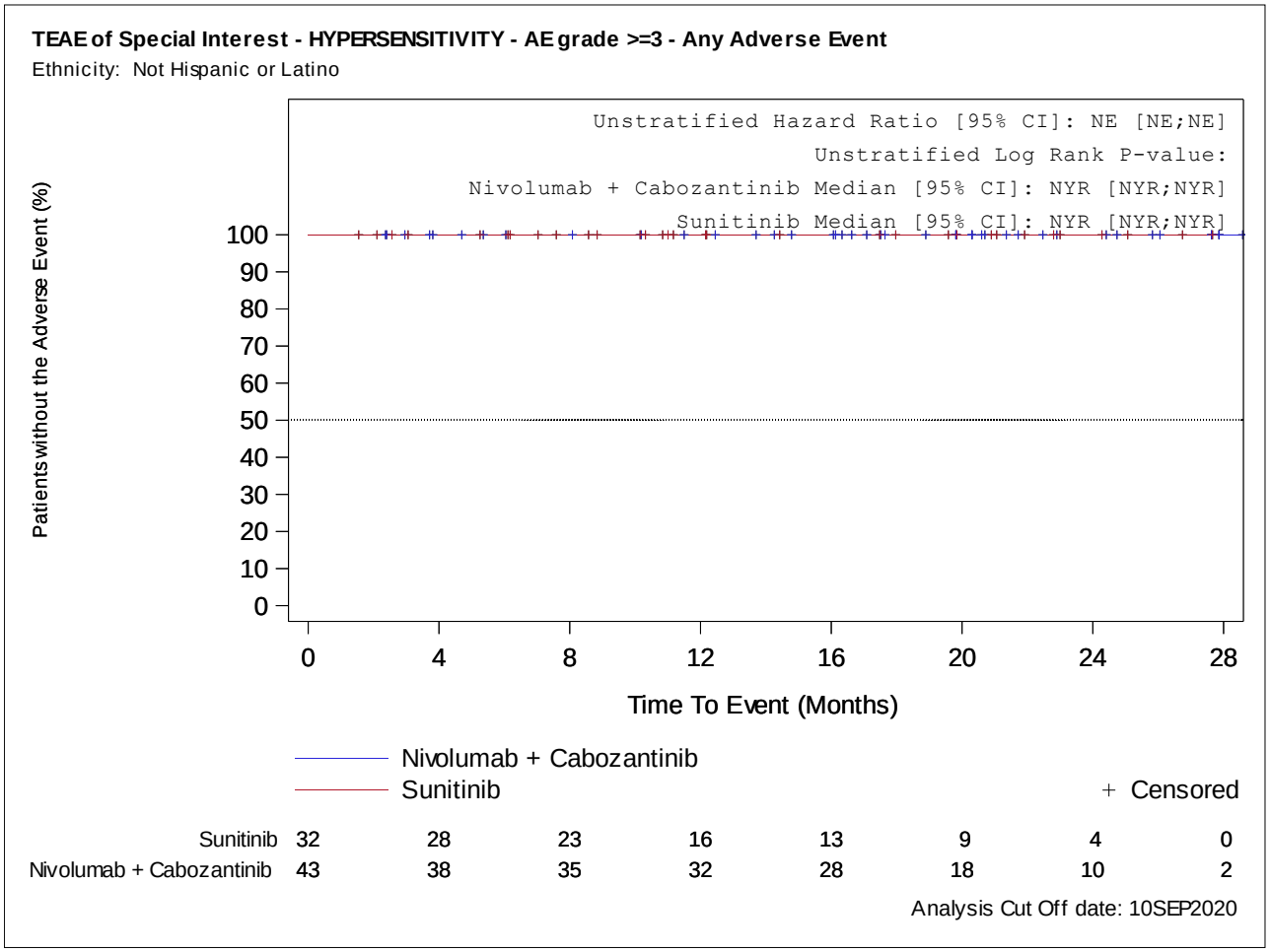

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:54:52

FIGURE 3.85.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



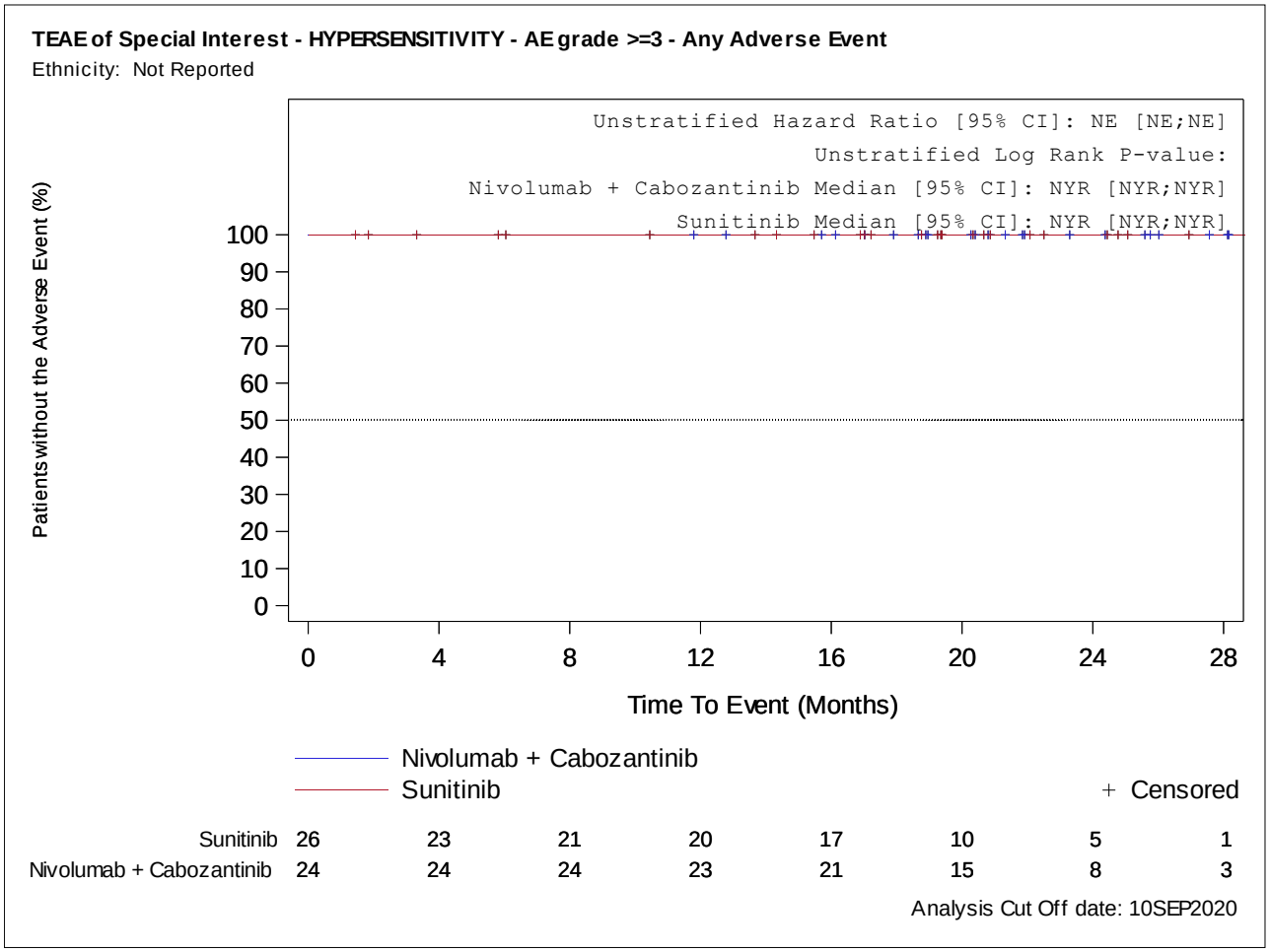

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:54:58

FIGURE 3.85.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



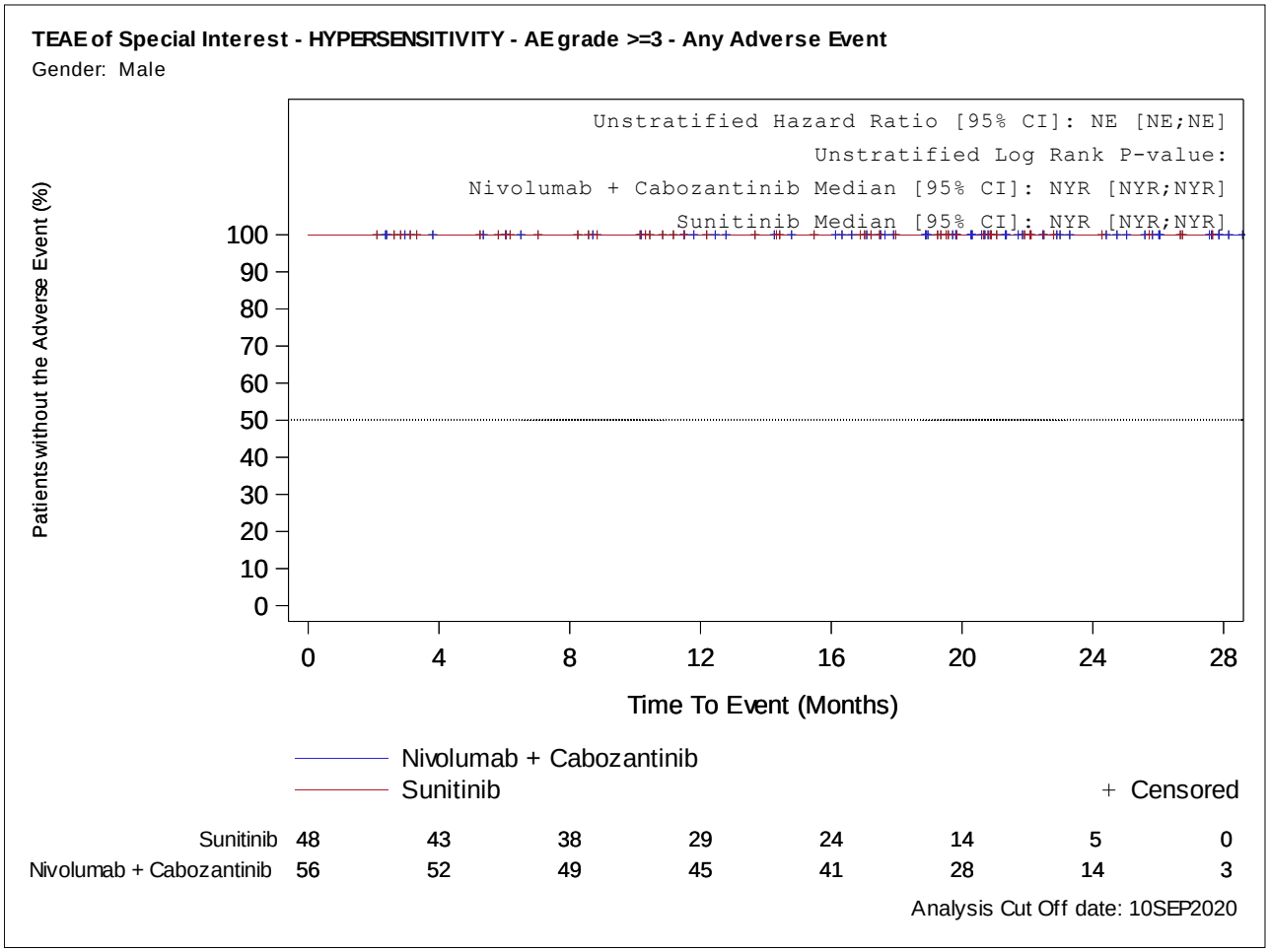

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:55:04

FIGURE 3.85.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



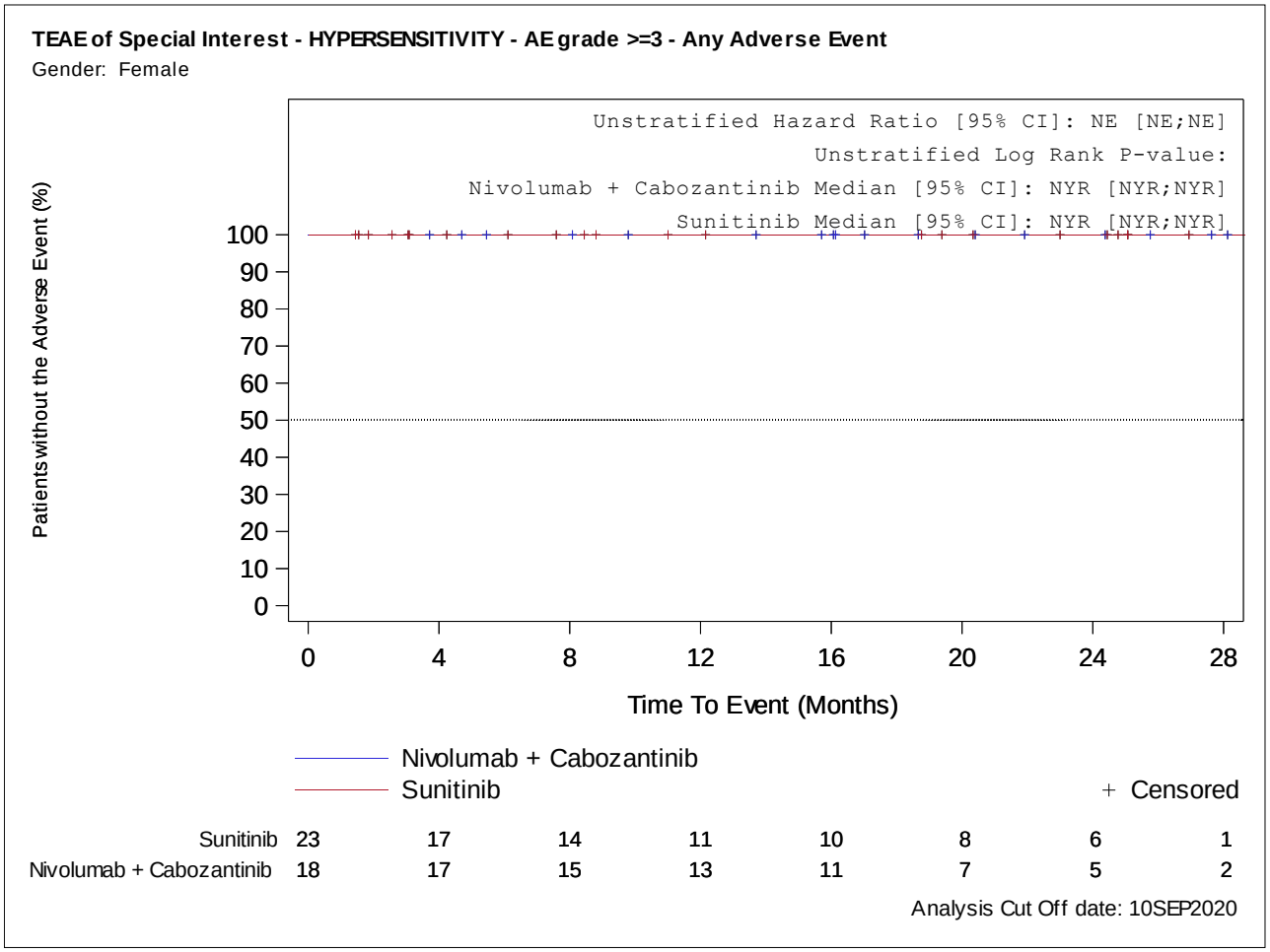

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:55:10

FIGURE 3.85.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



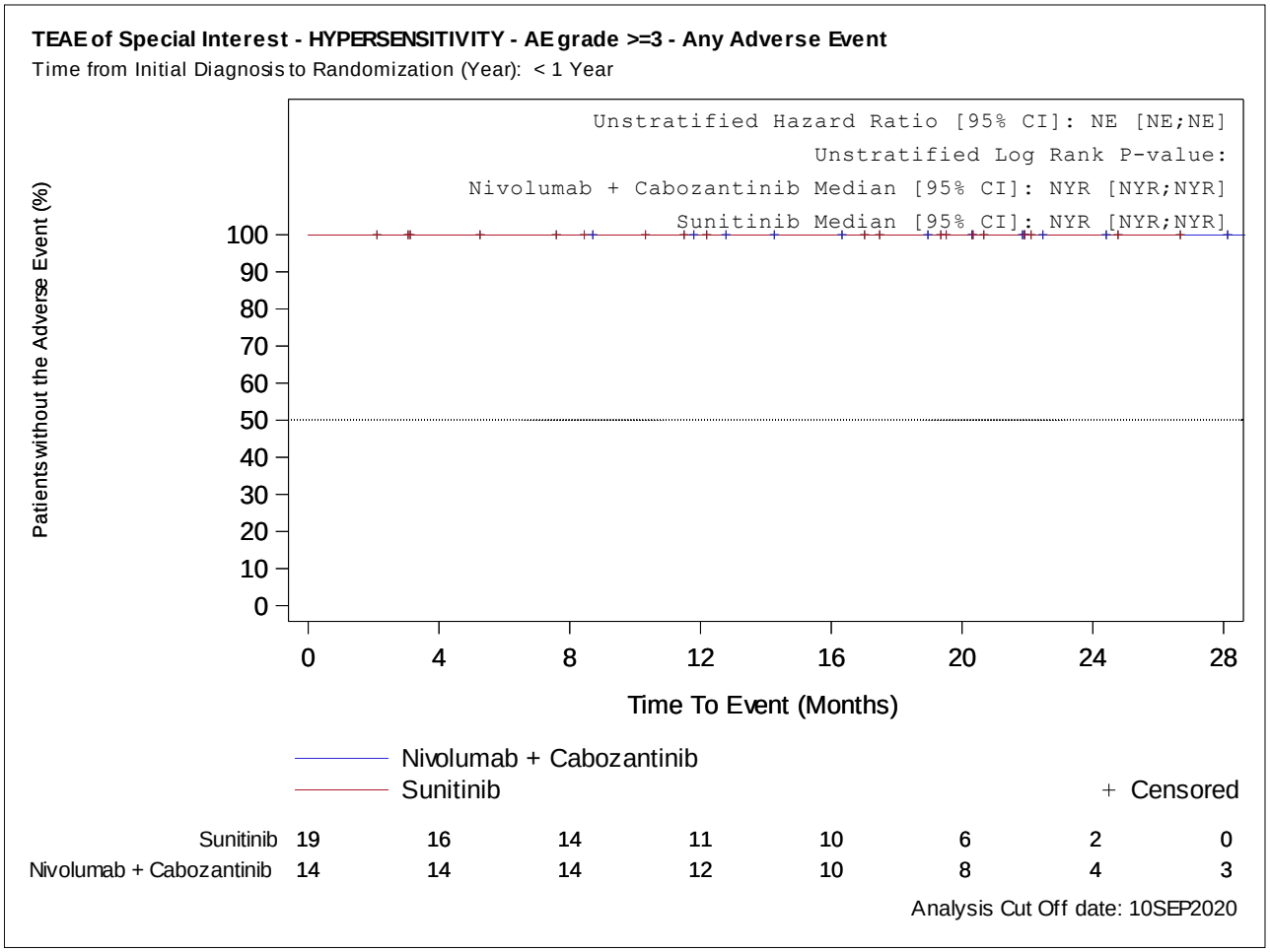

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:55:16

FIGURE 3.85.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



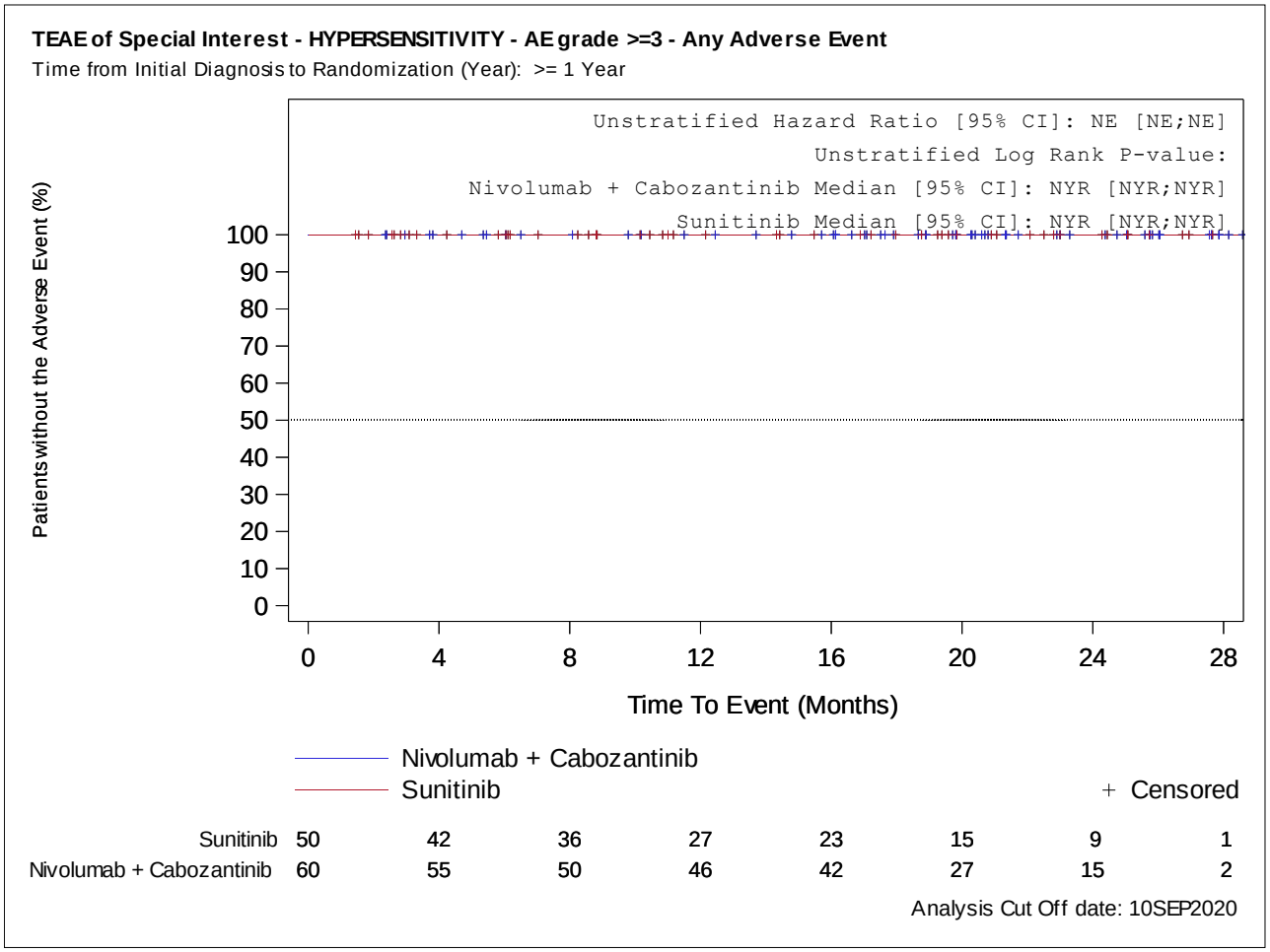

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:55:21

FIGURE 3.85.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



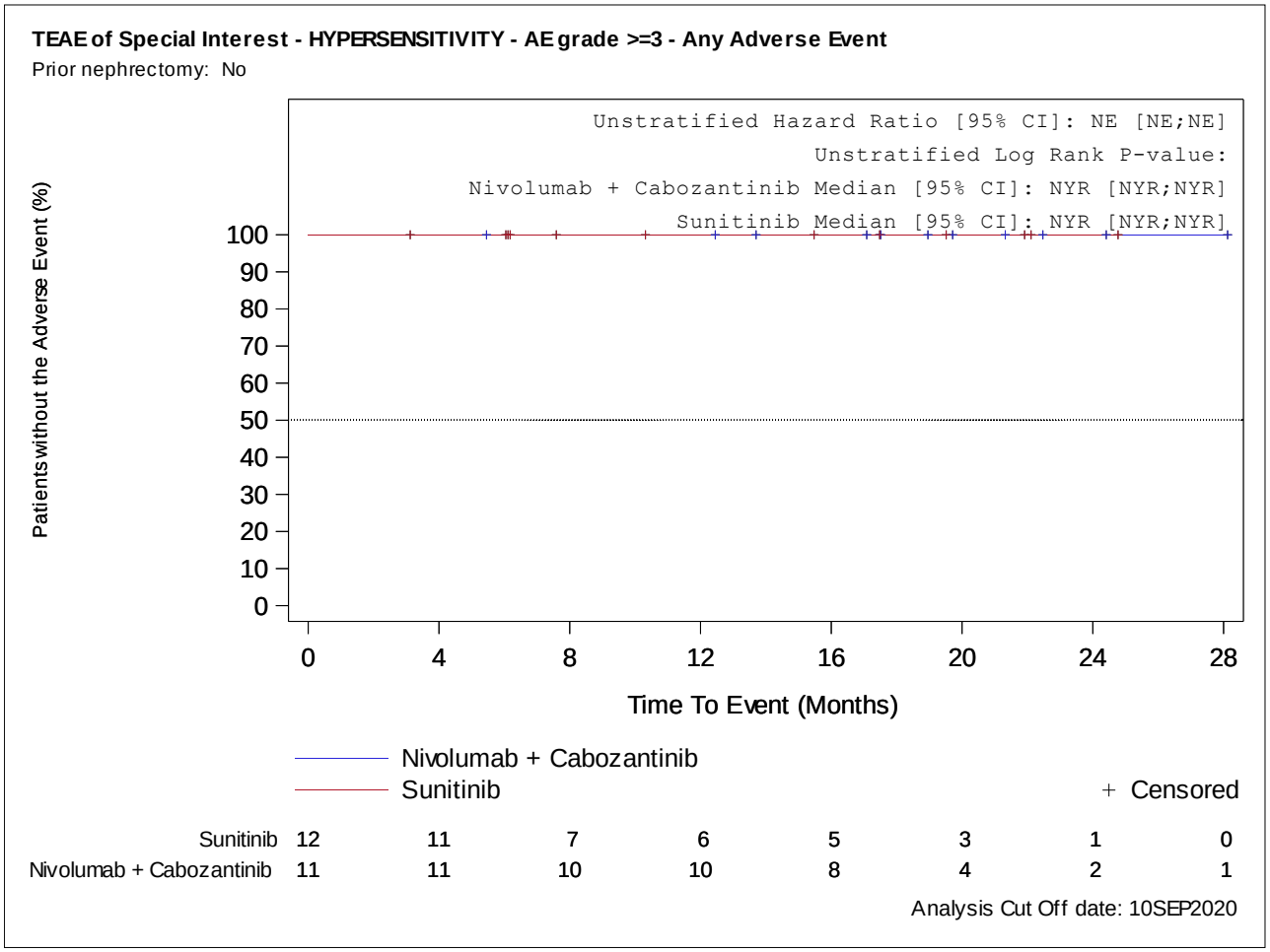

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:55:38

FIGURE 3.85.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



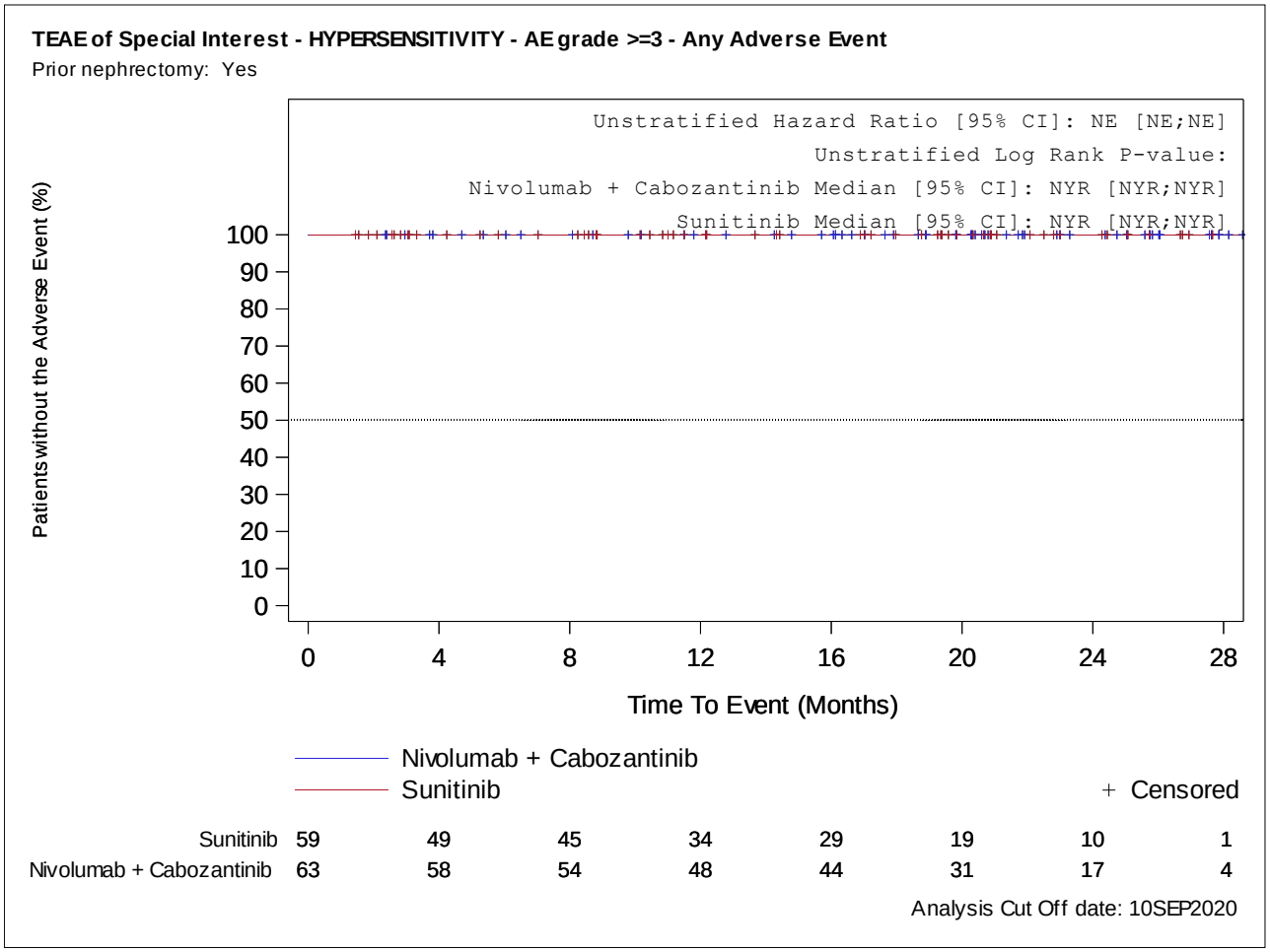

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:55:44

FIGURE 3.85.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:56:37

FIGURE 3.85.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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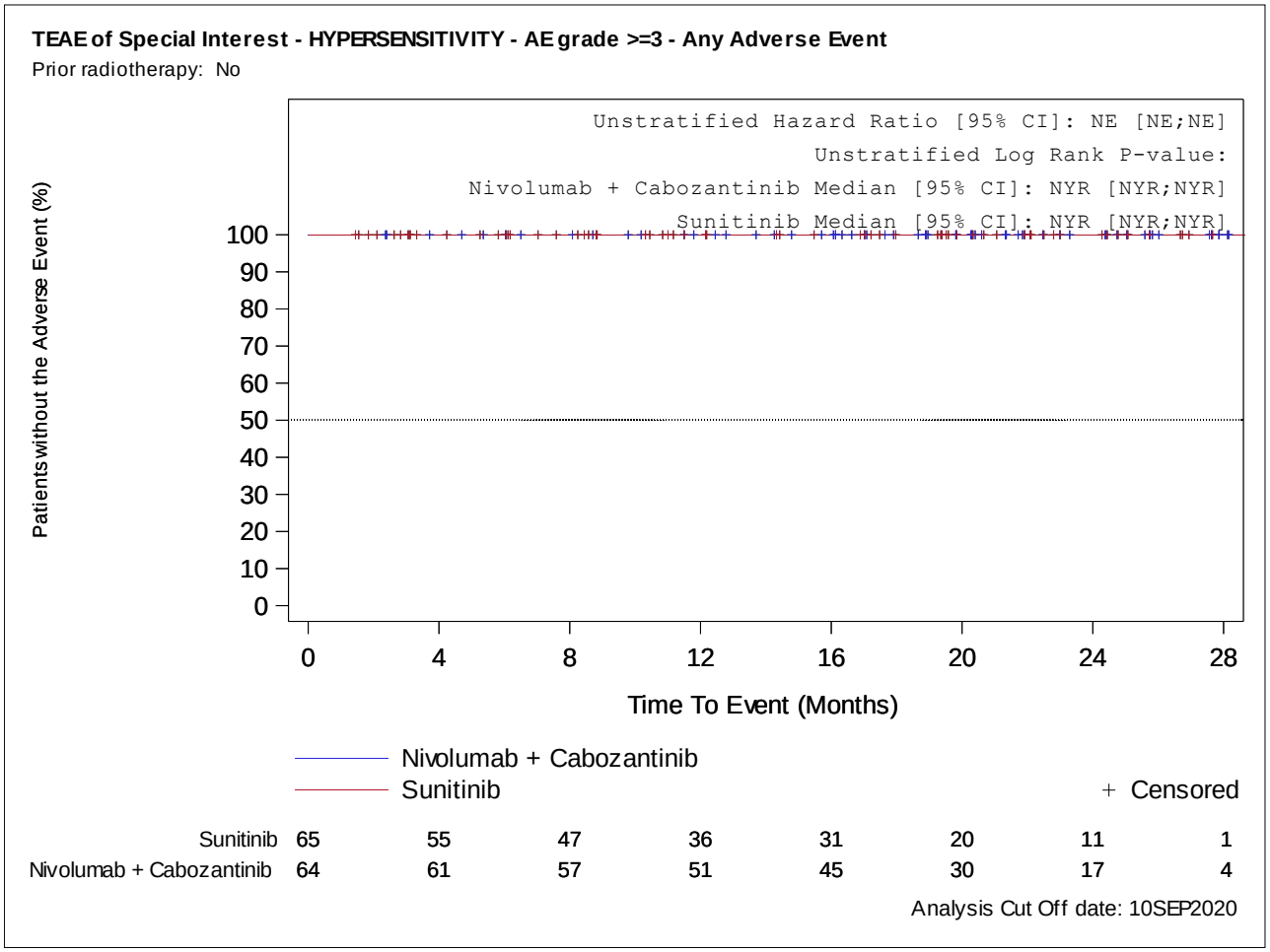
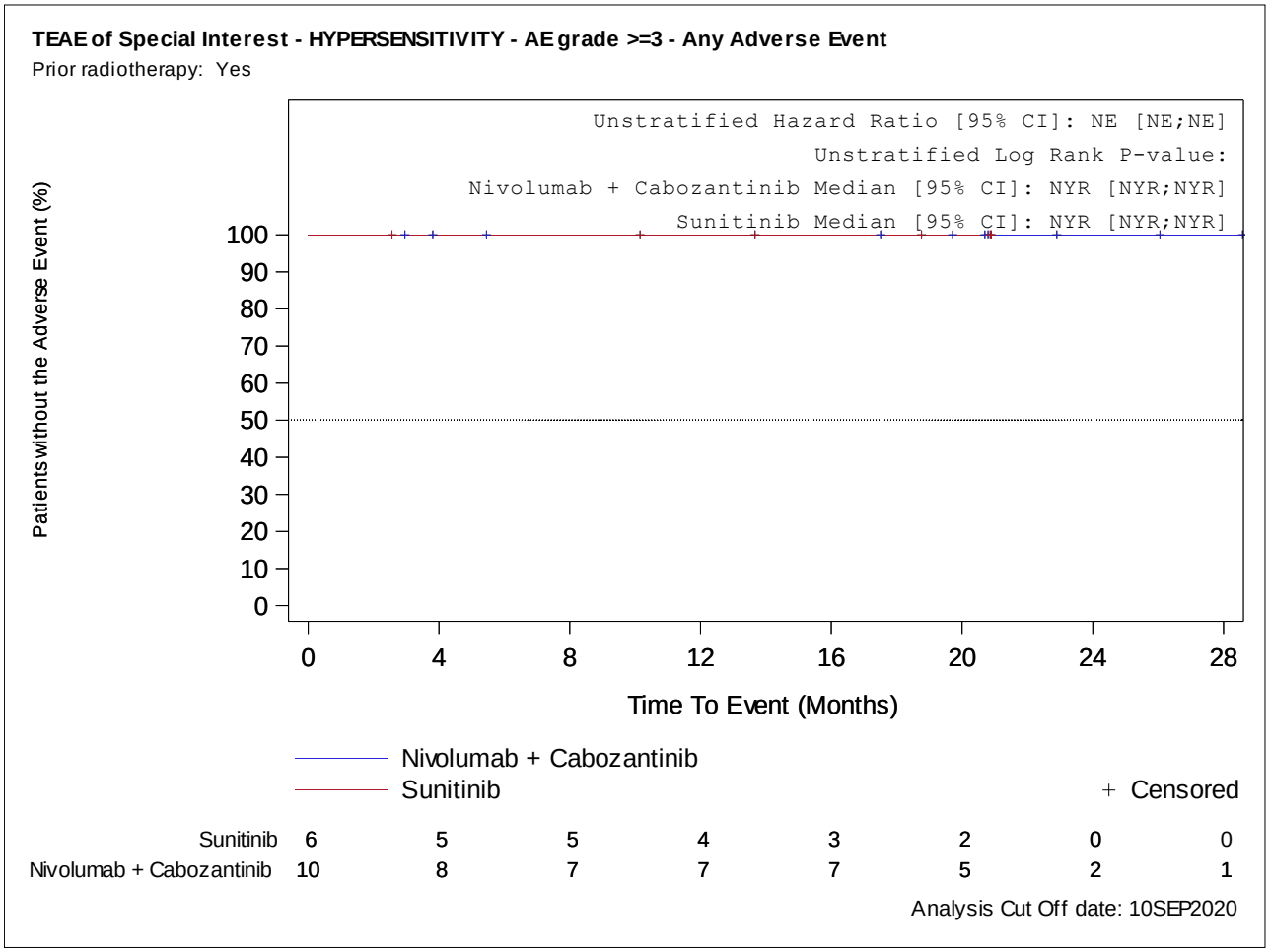
FIGURE 3.85.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



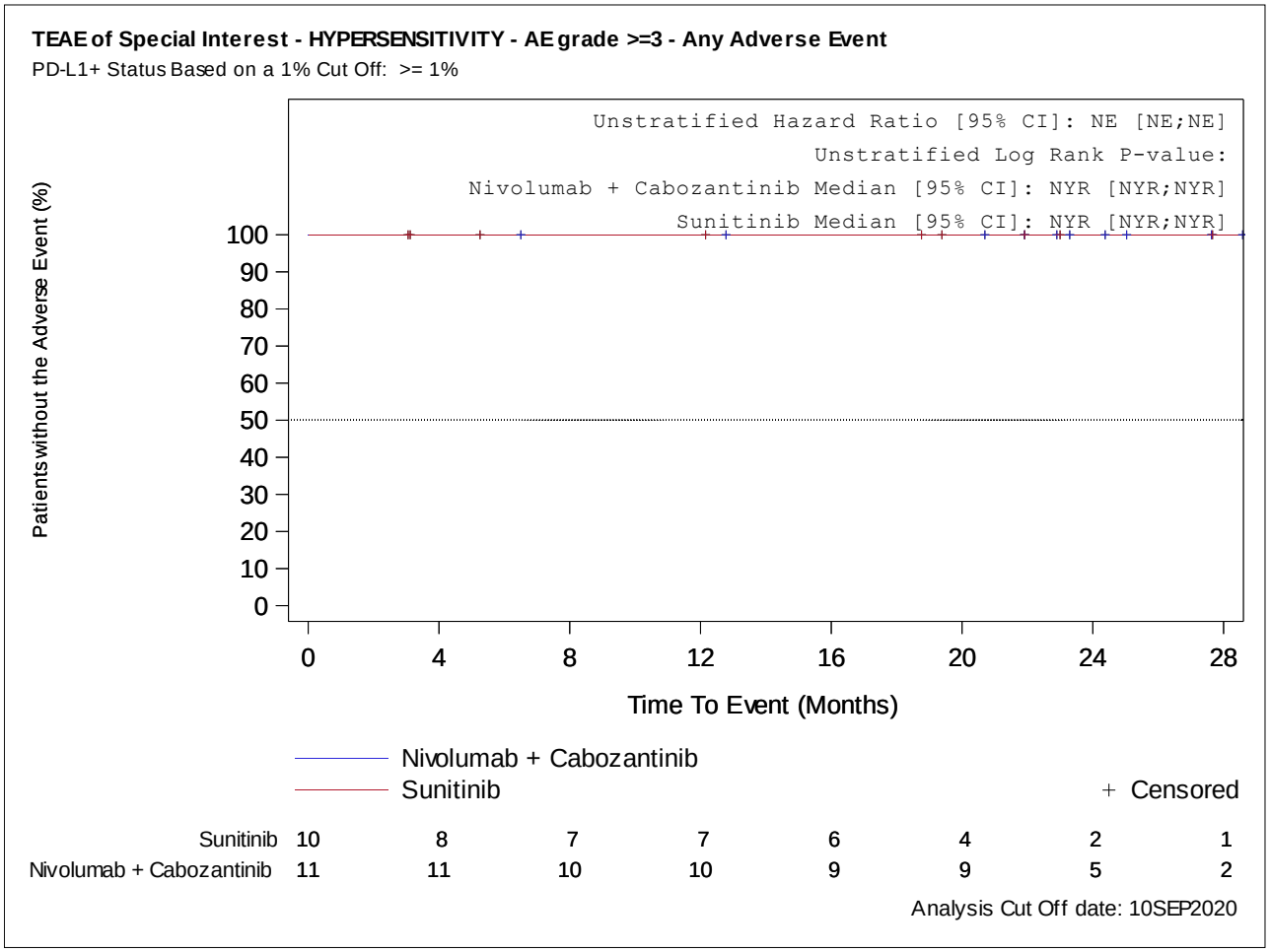

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:56:50

FIGURE 3.85.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



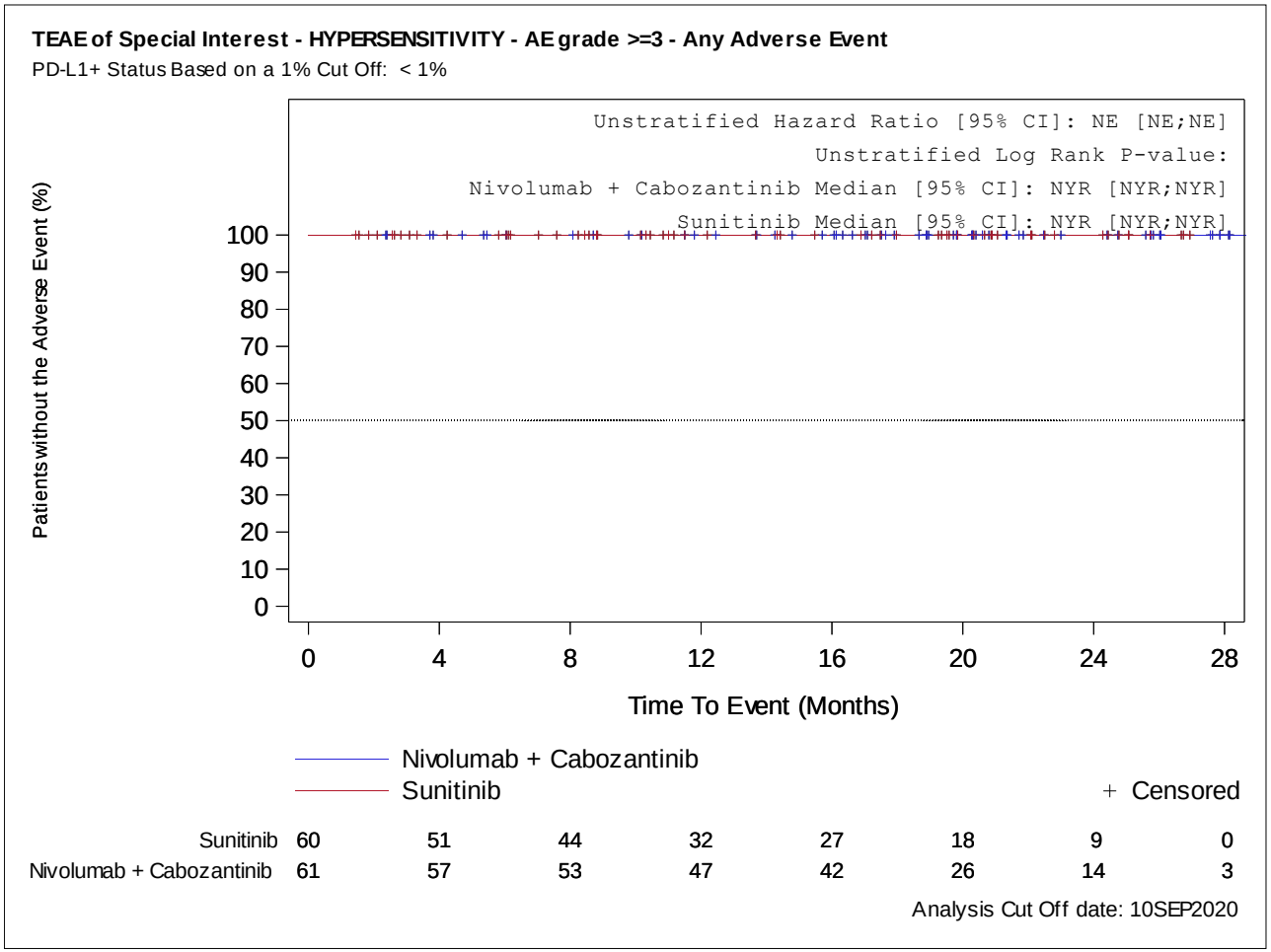

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:56:55

FIGURE 3.85.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



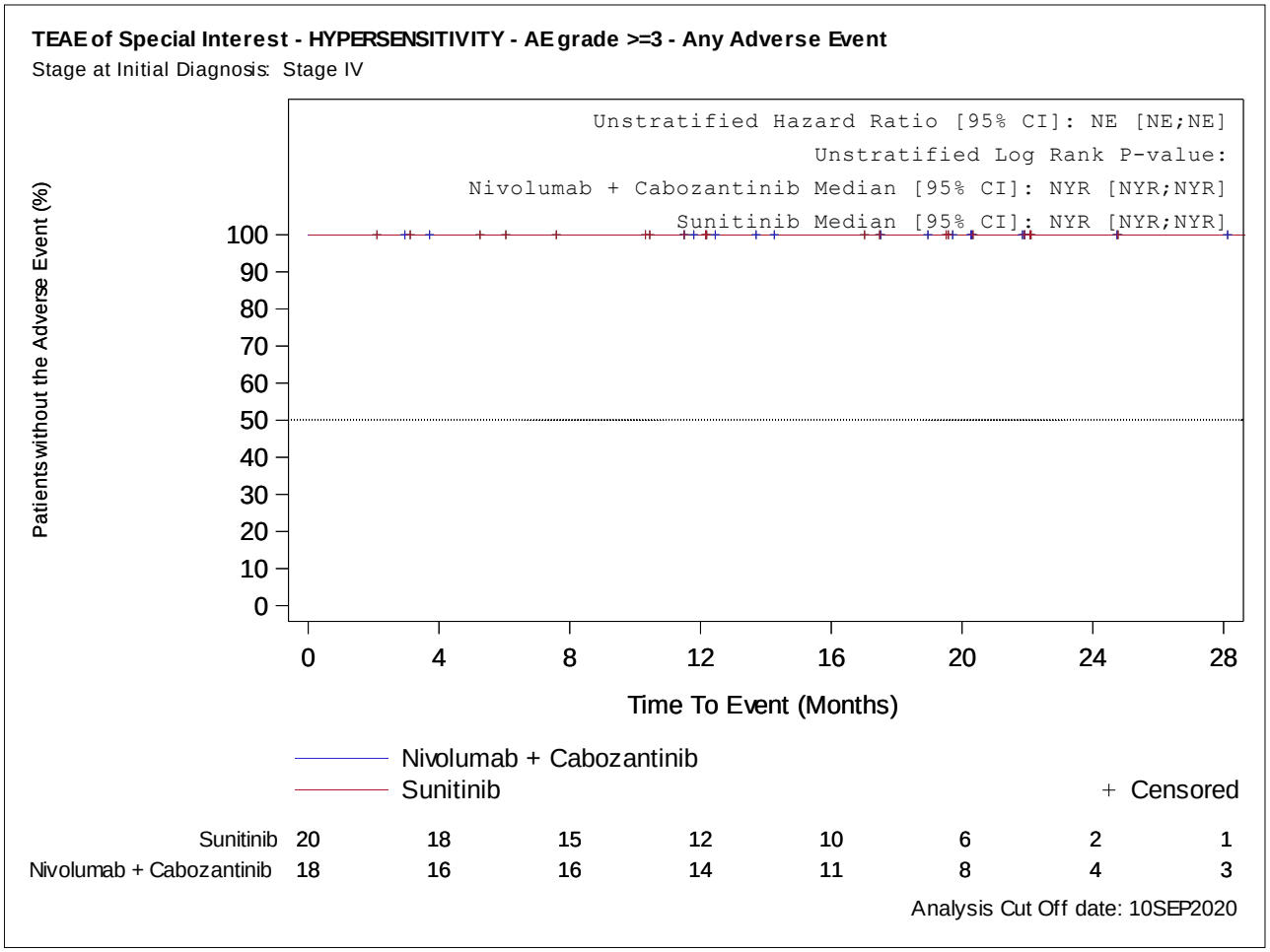

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:57:01

FIGURE 3.85.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



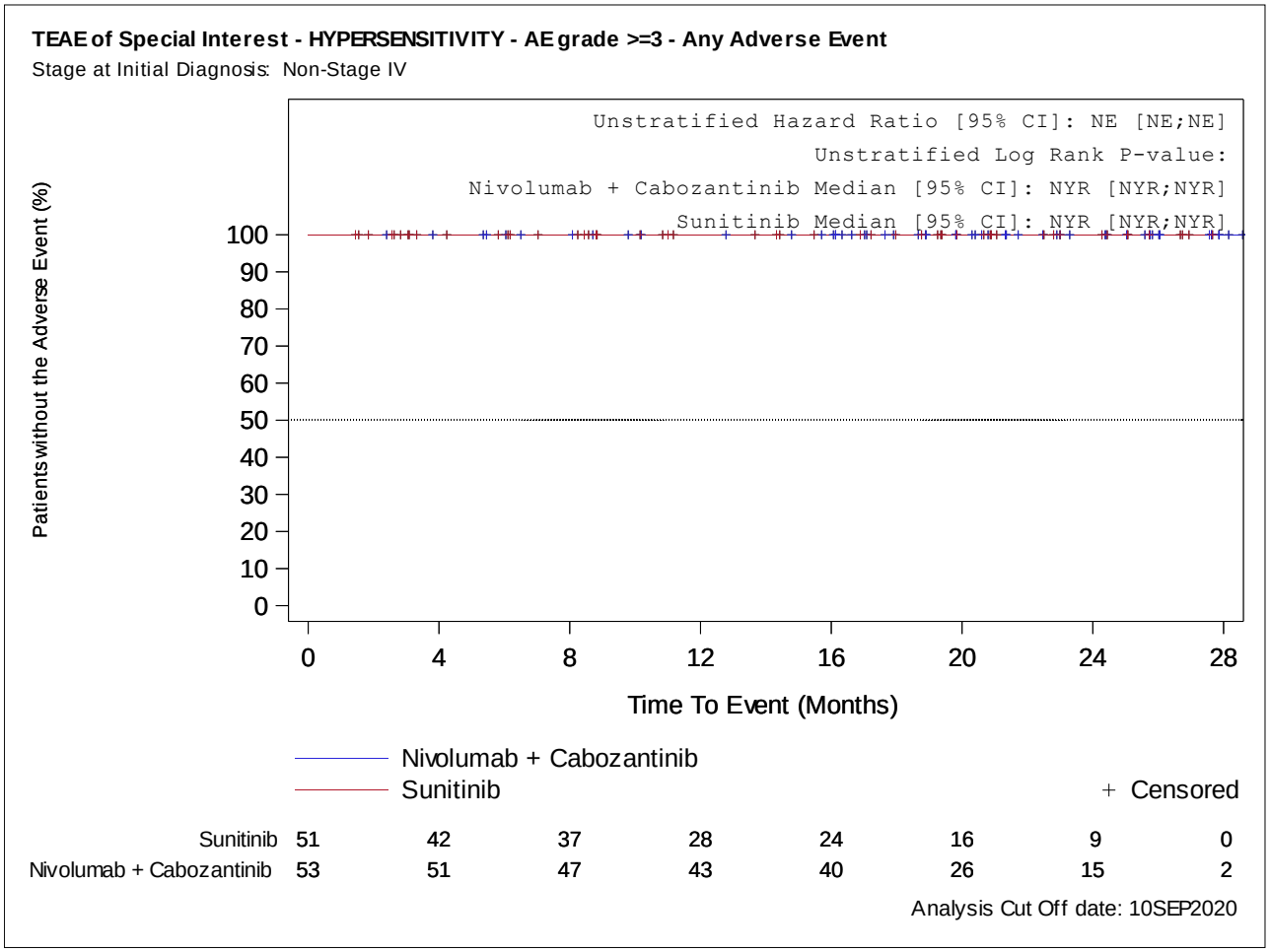

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:57:07

FIGURE 3.85.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



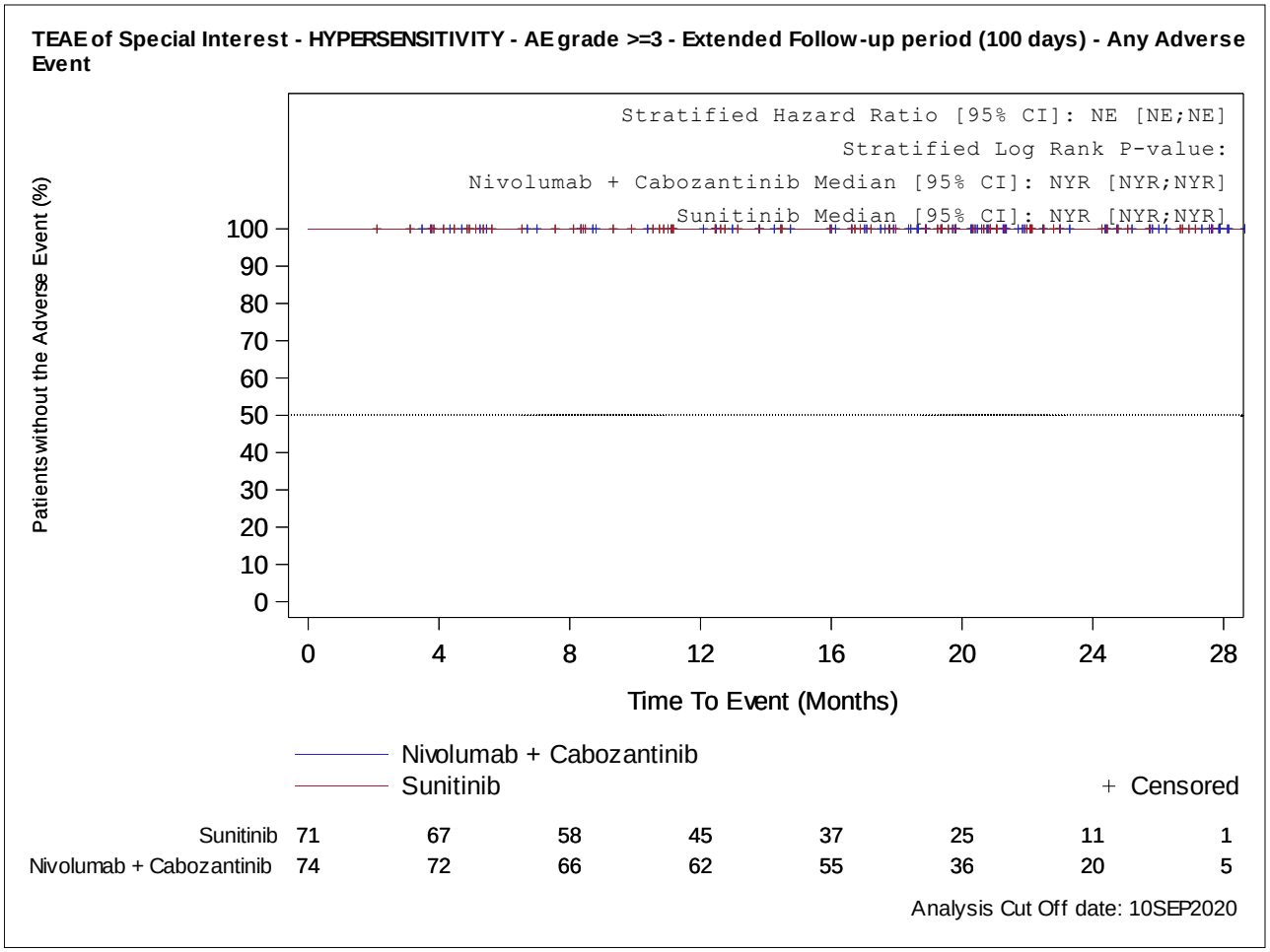

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:57:37

FIGURE 3.85.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



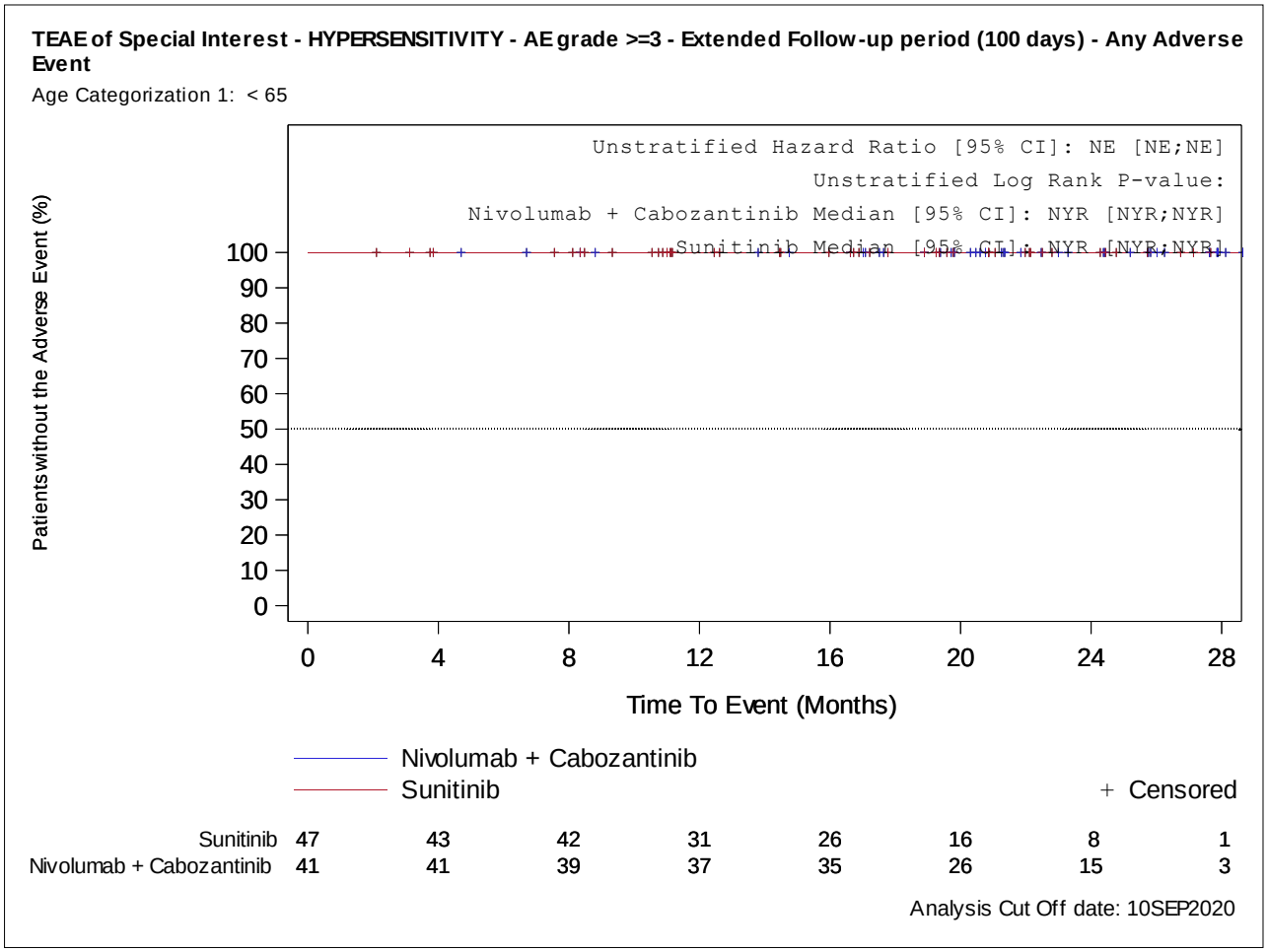

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 21:57:42

FIGURE 3.86.1: TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



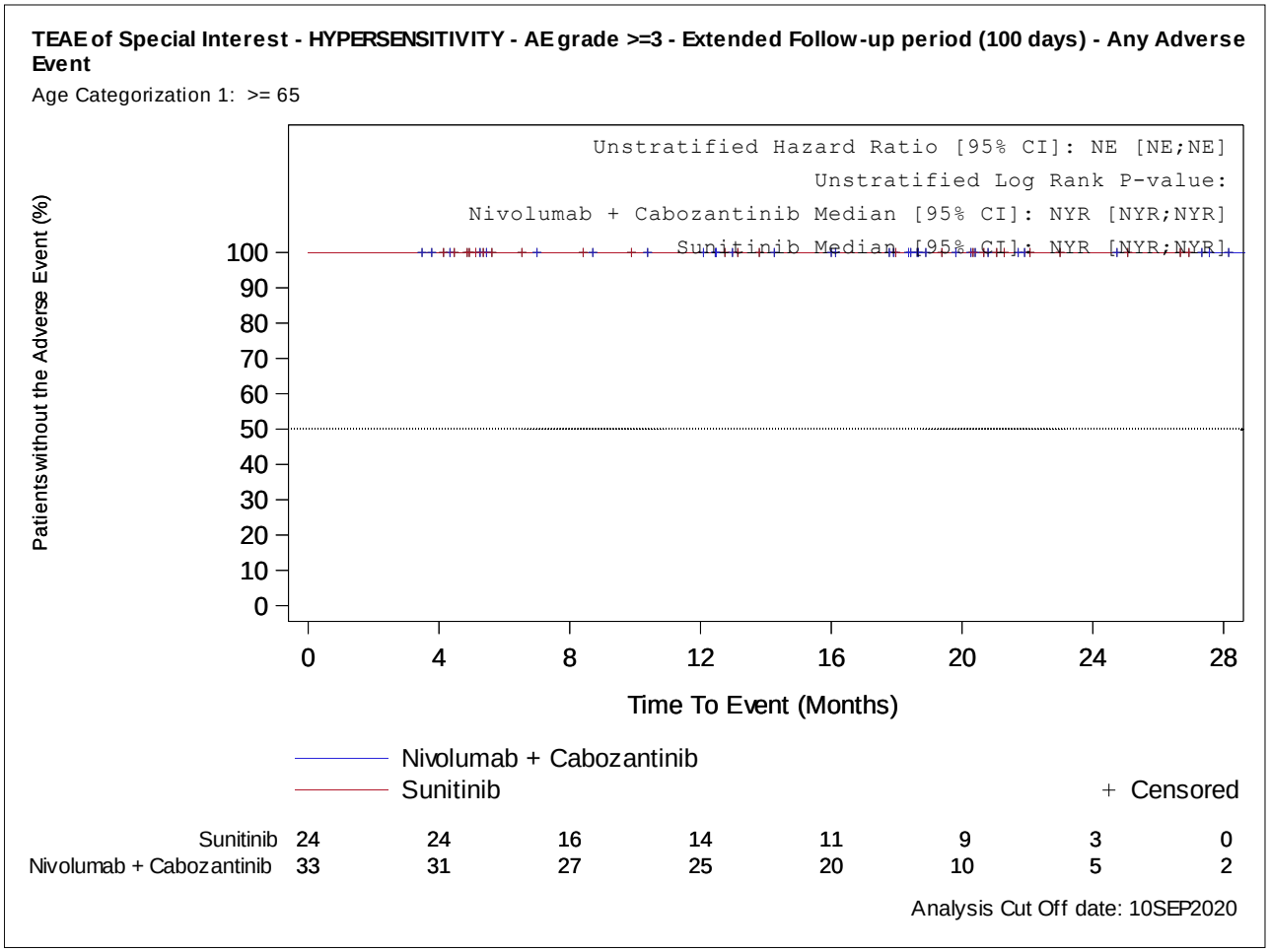

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:00:55

FIGURE 3.86.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



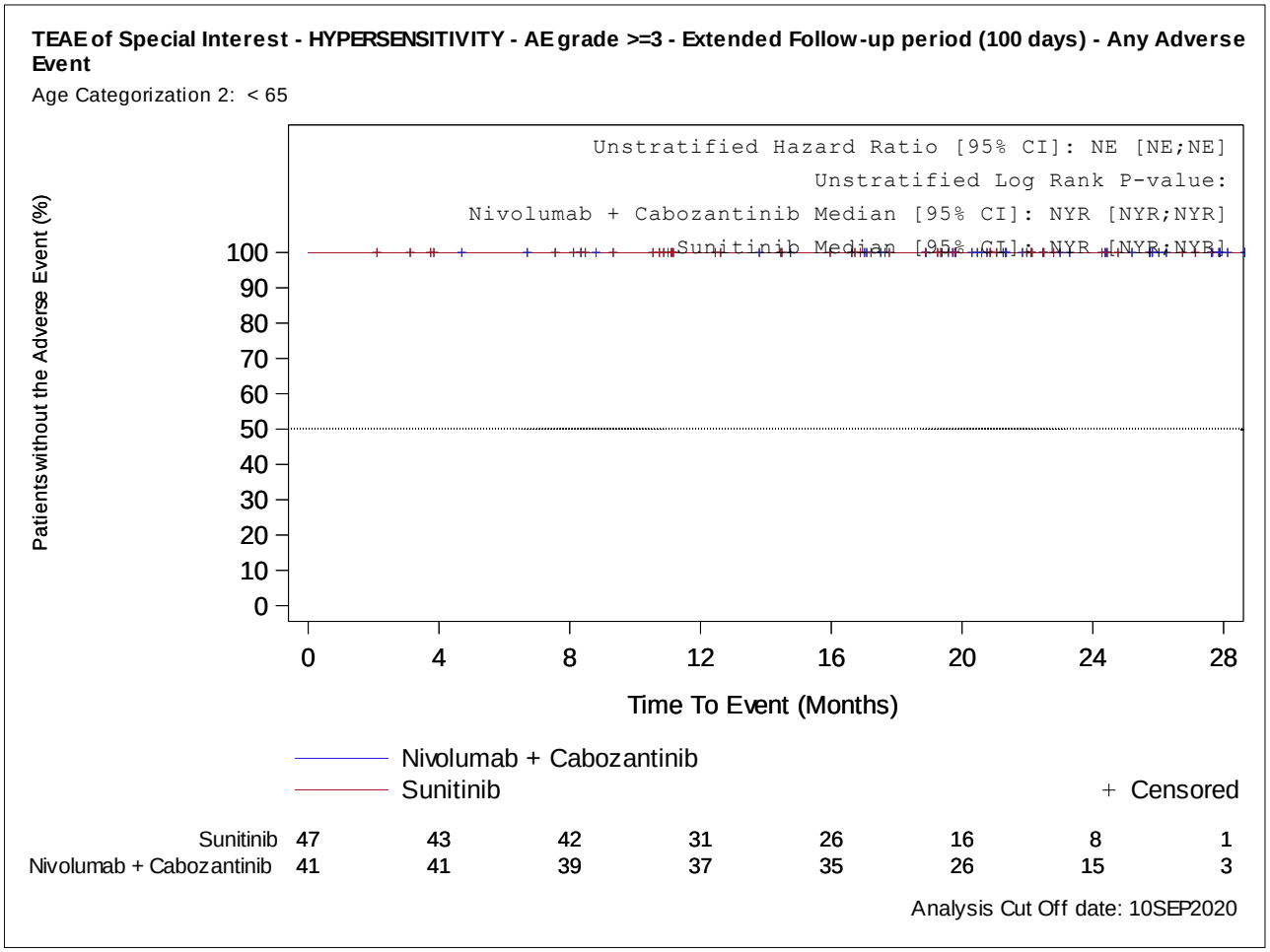

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:00:58

FIGURE 3.86.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



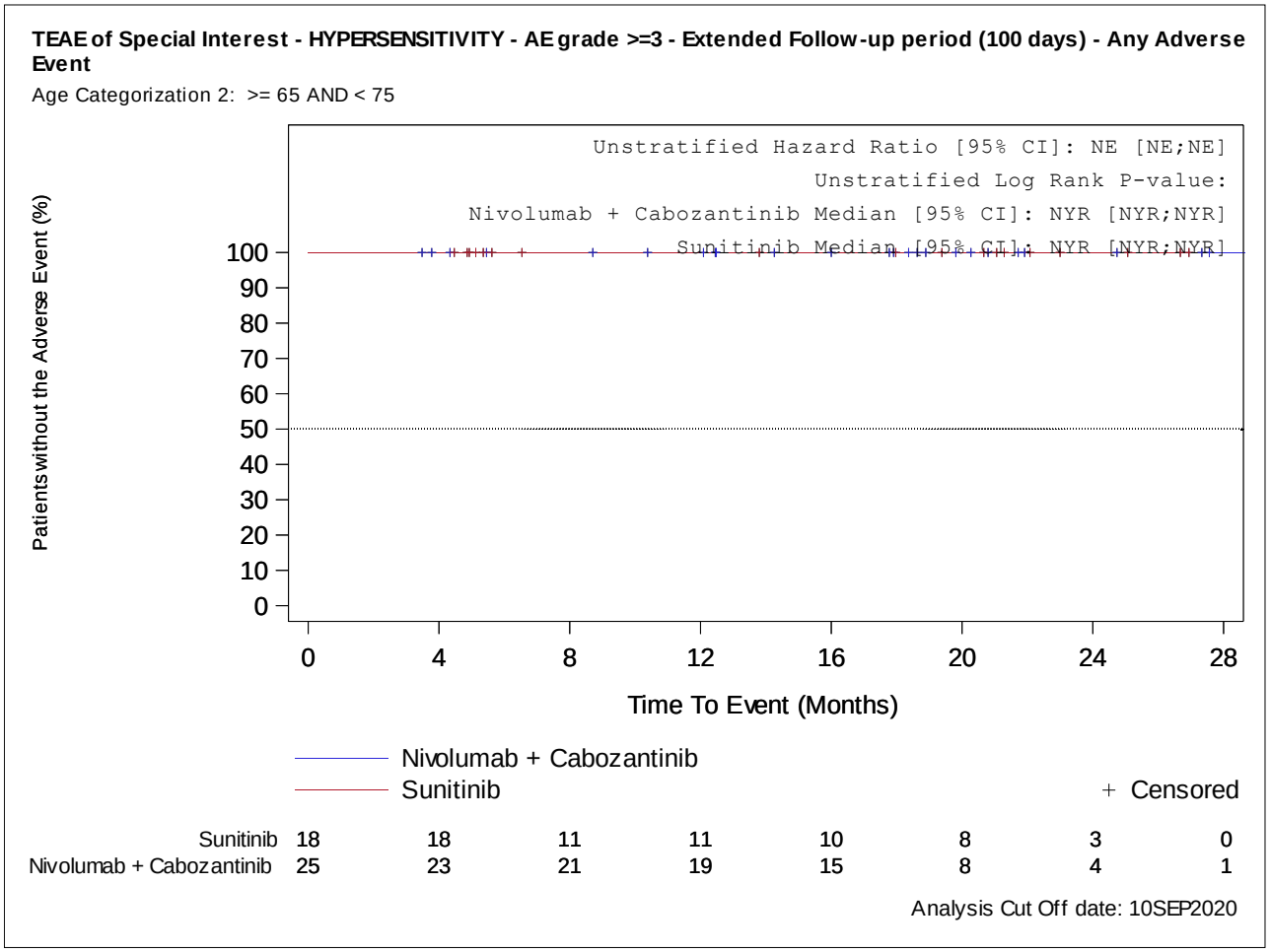

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:01:04

FIGURE 3.86.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



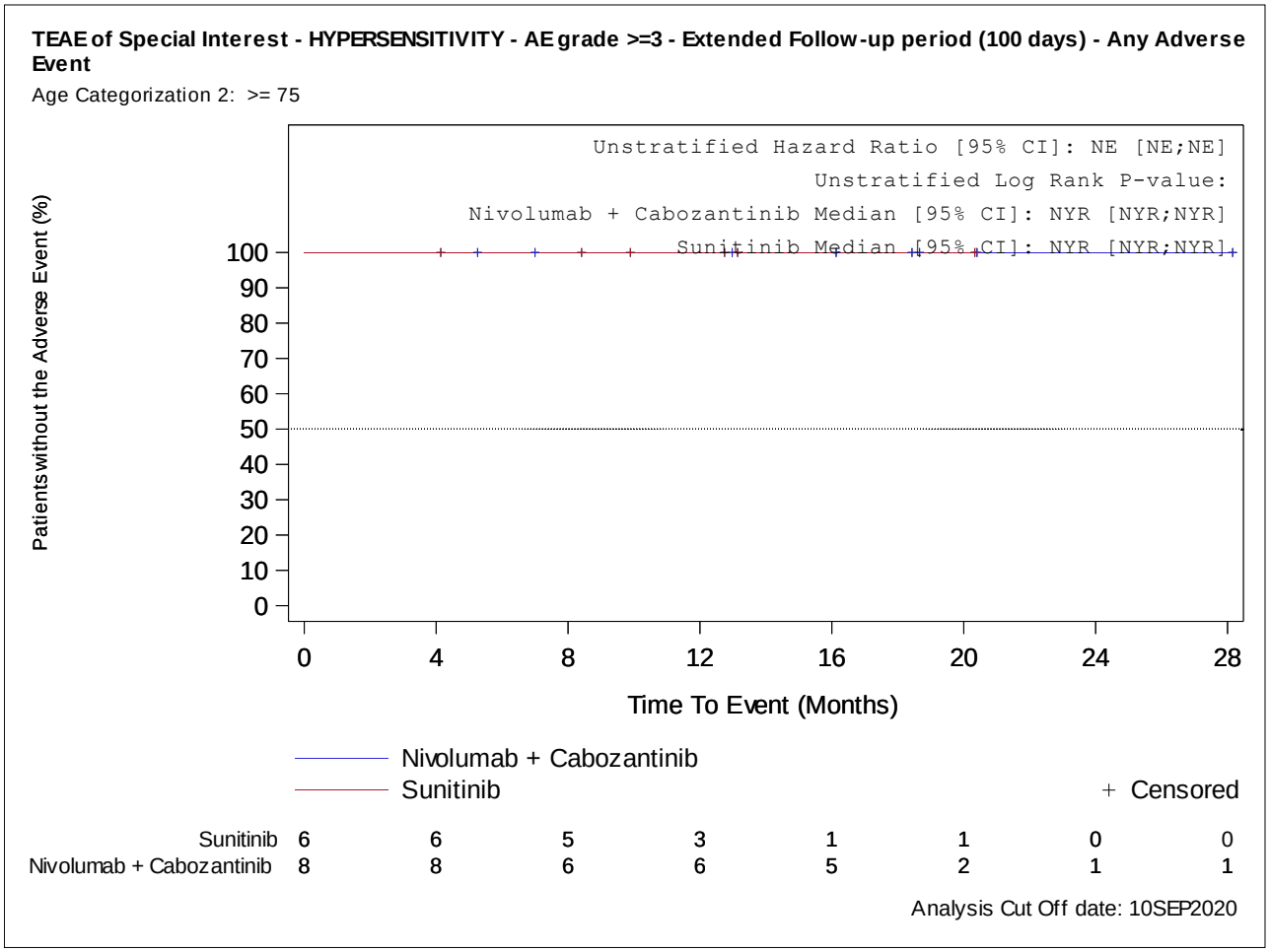

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:01:10

FIGURE 3.86.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



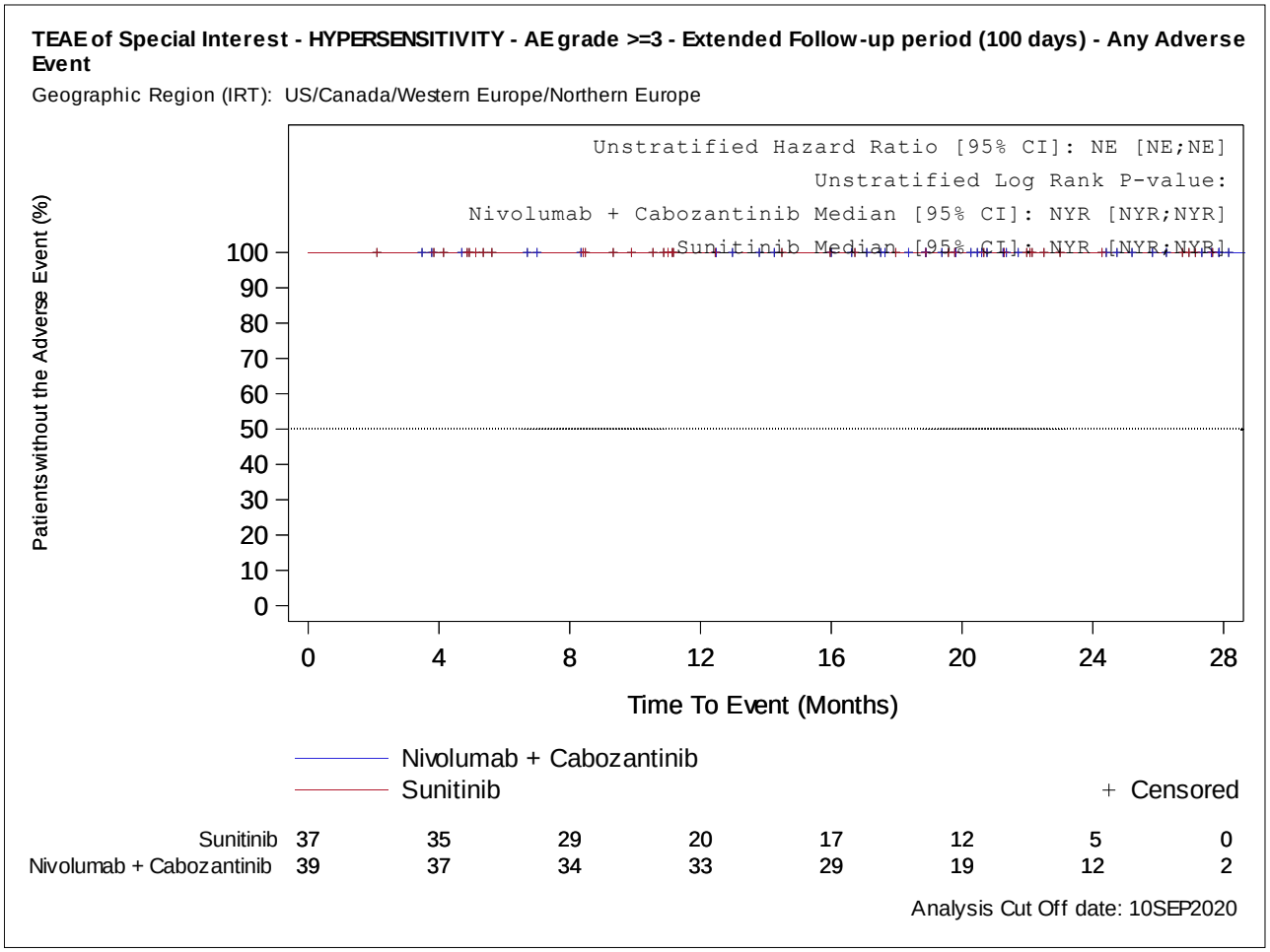

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:01:16

FIGURE 3.86.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



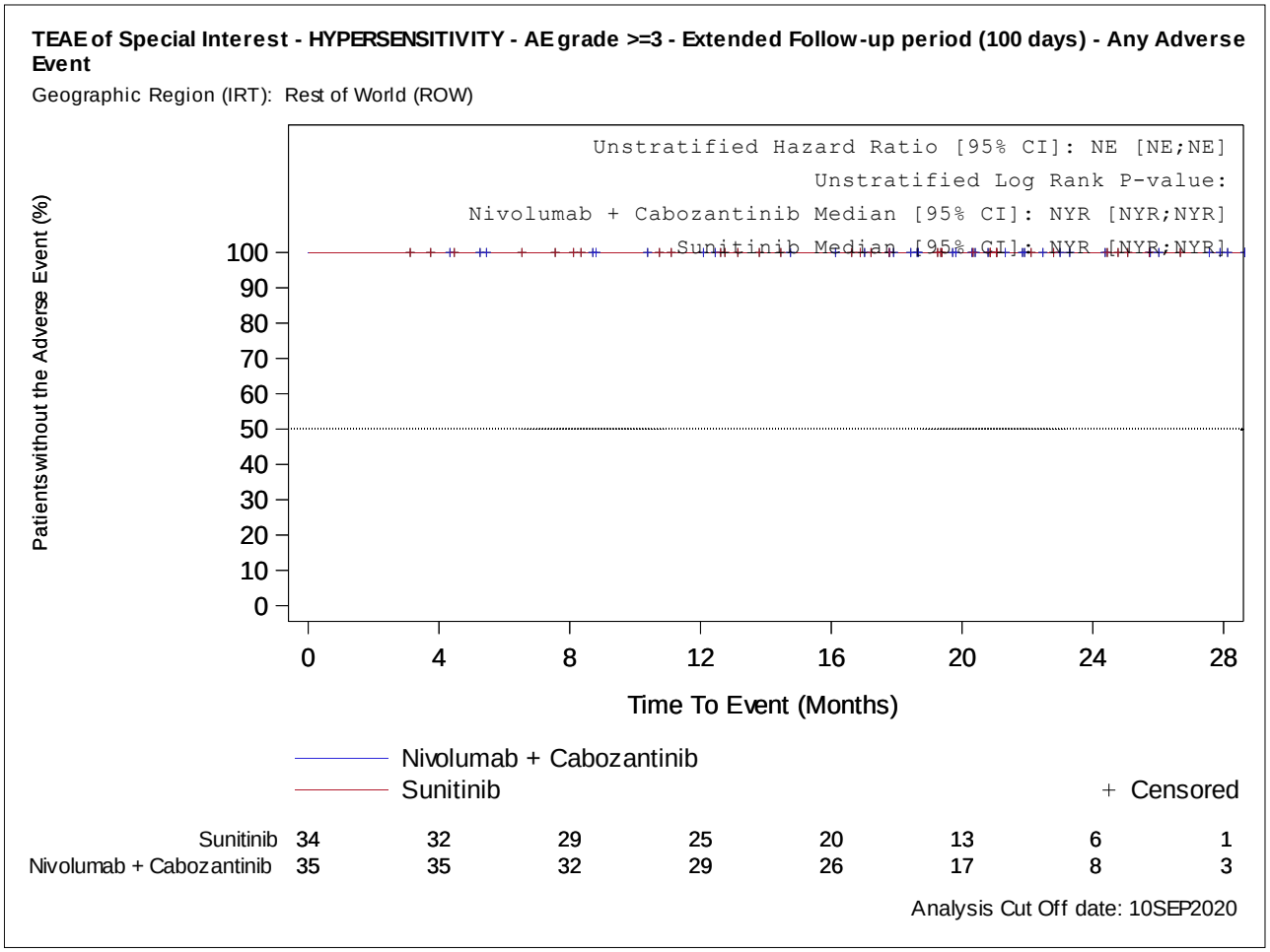

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:01:21

FIGURE 3.86.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



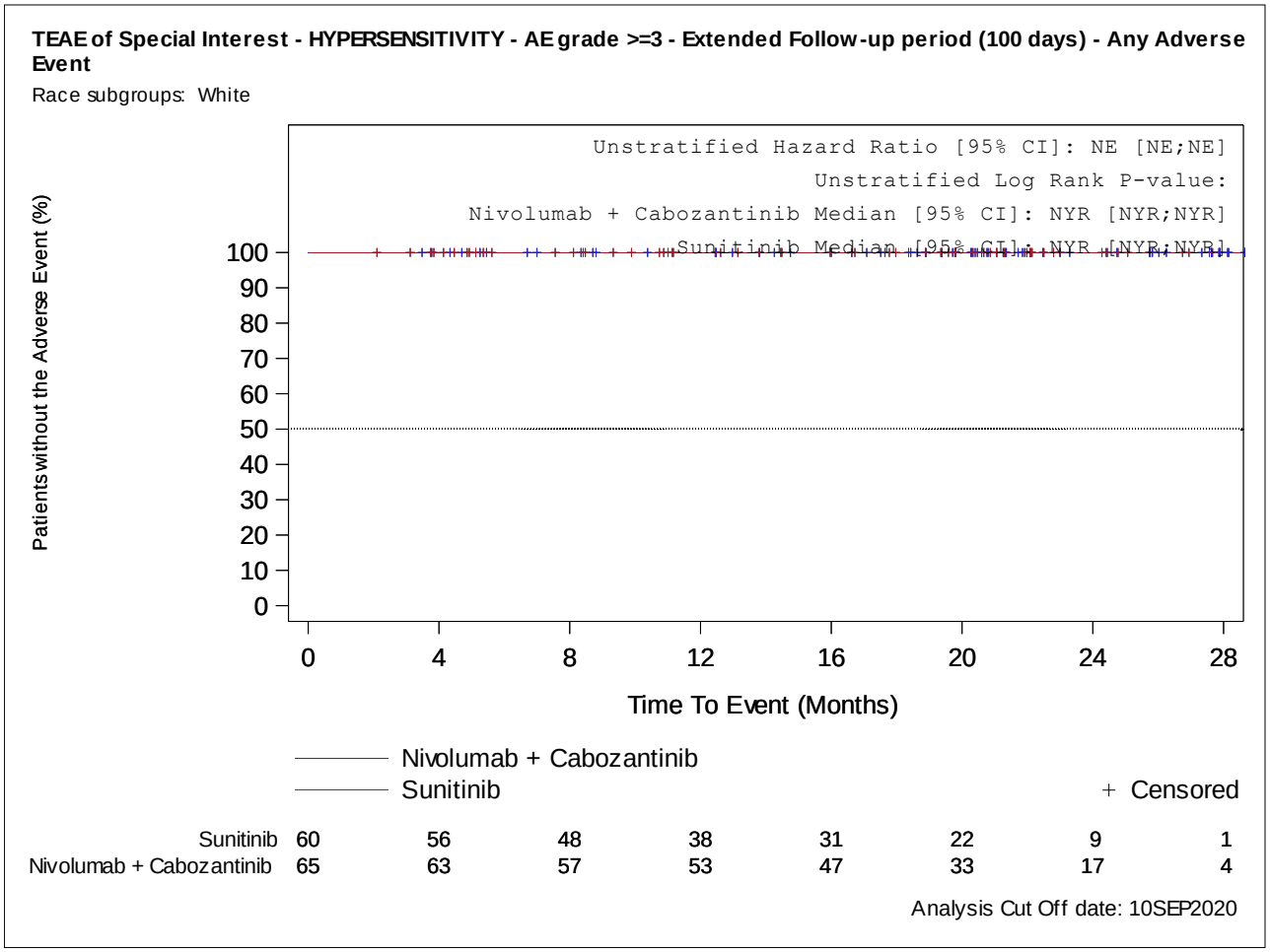

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:01:27

FIGURE 3.86.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



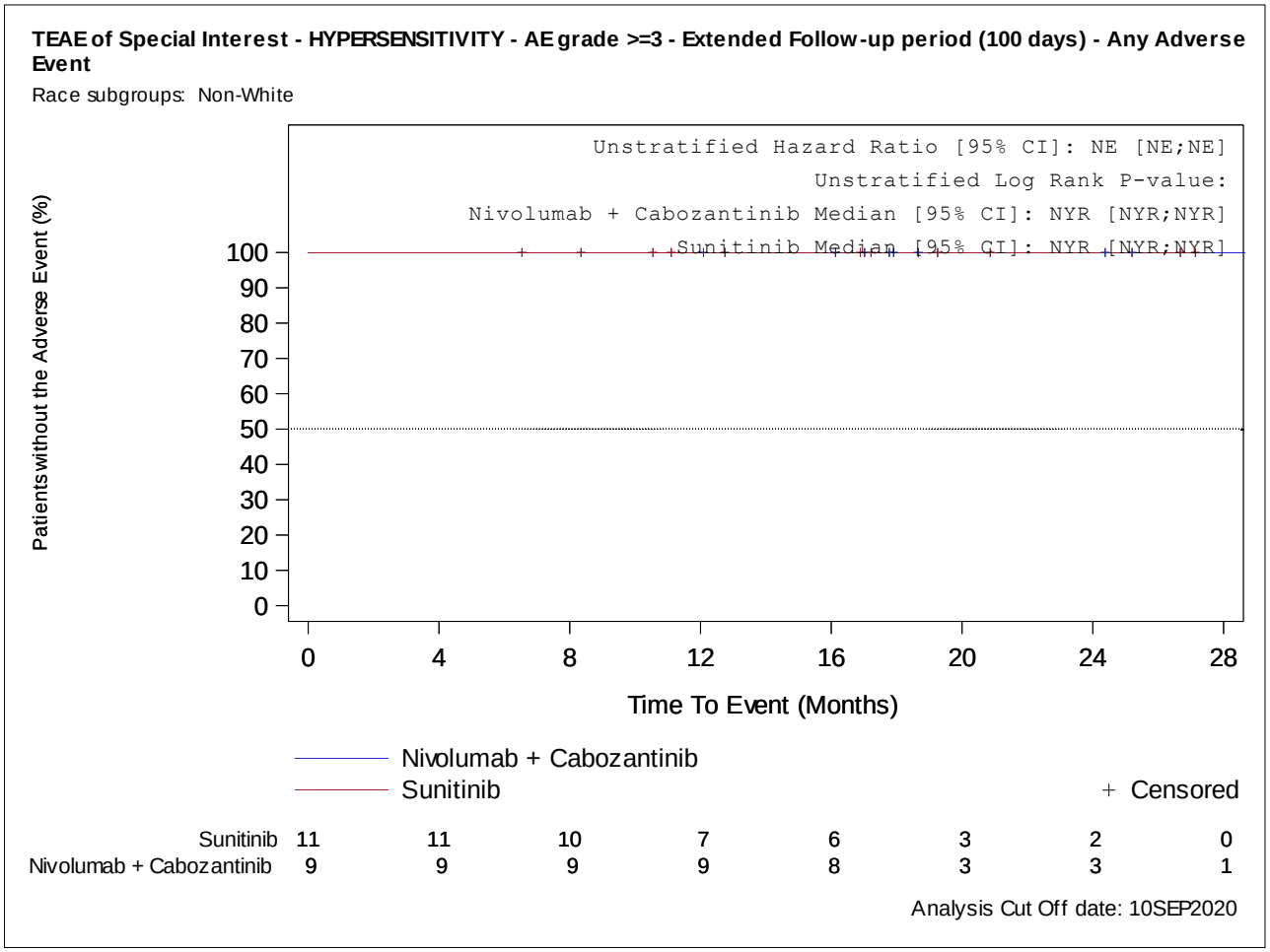

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:01:32

FIGURE 3.86.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



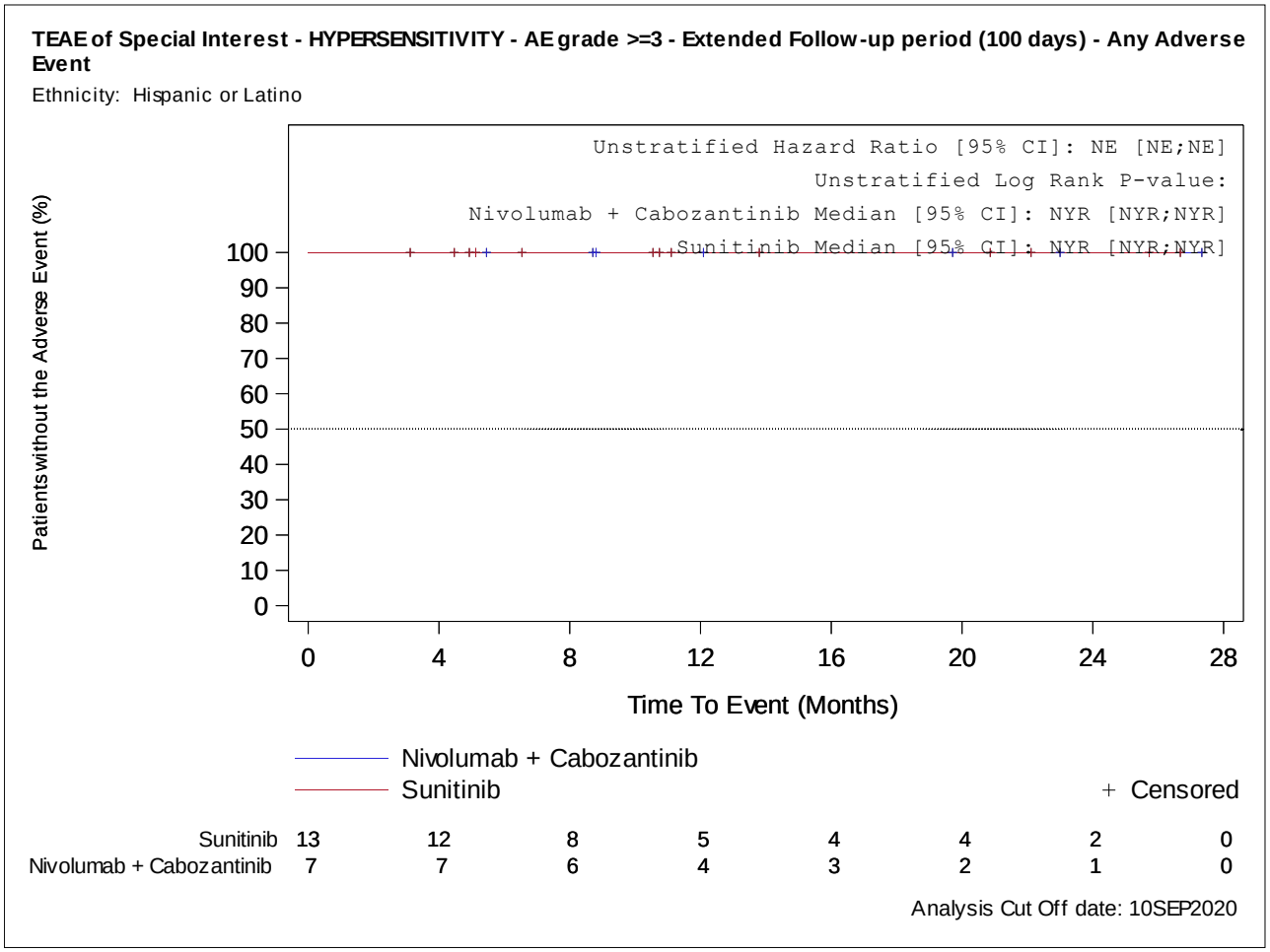

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:01:38

FIGURE 3.86.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



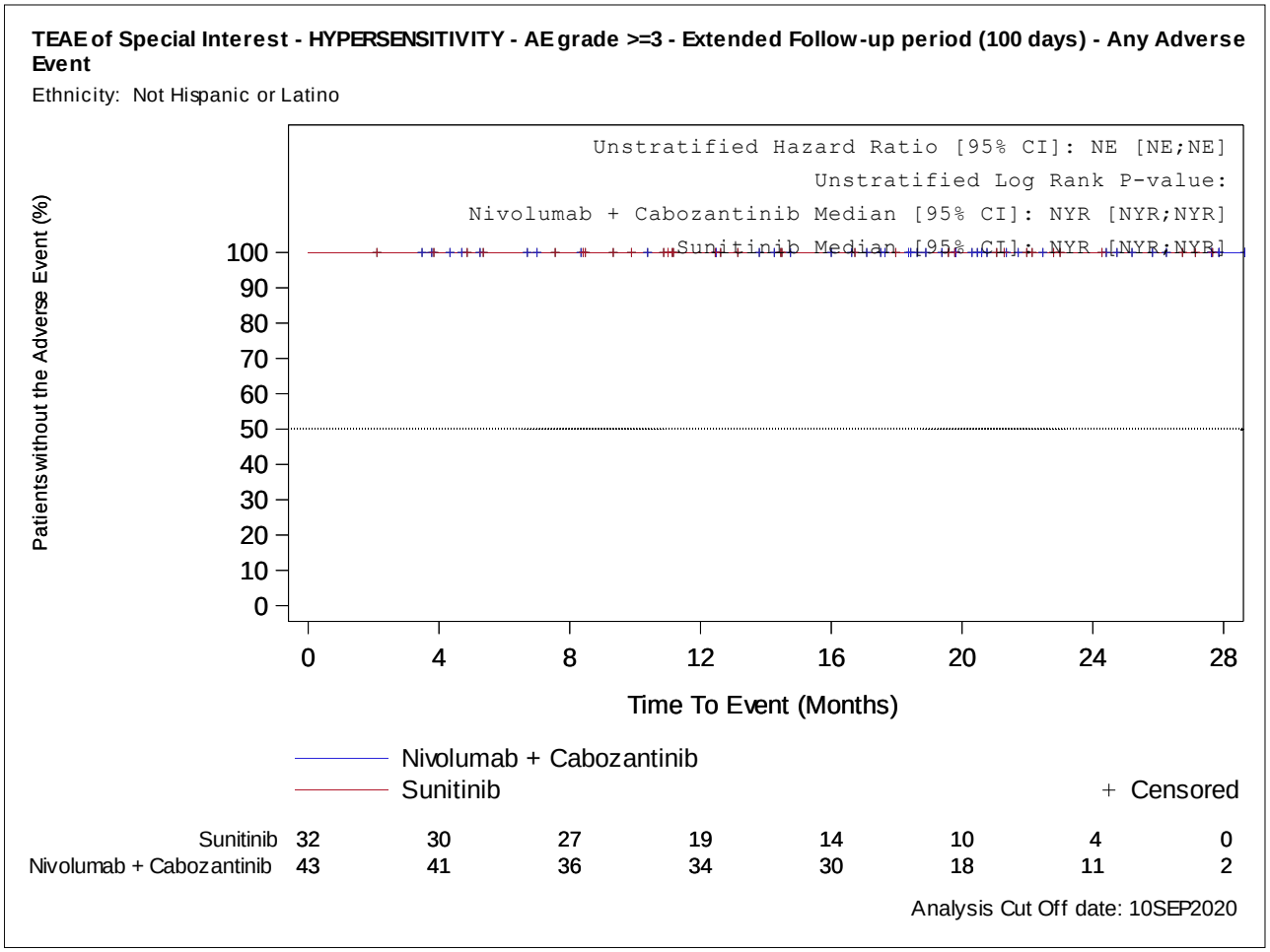

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:01:44

FIGURE 3.86.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:01:50

FIGURE 3.86.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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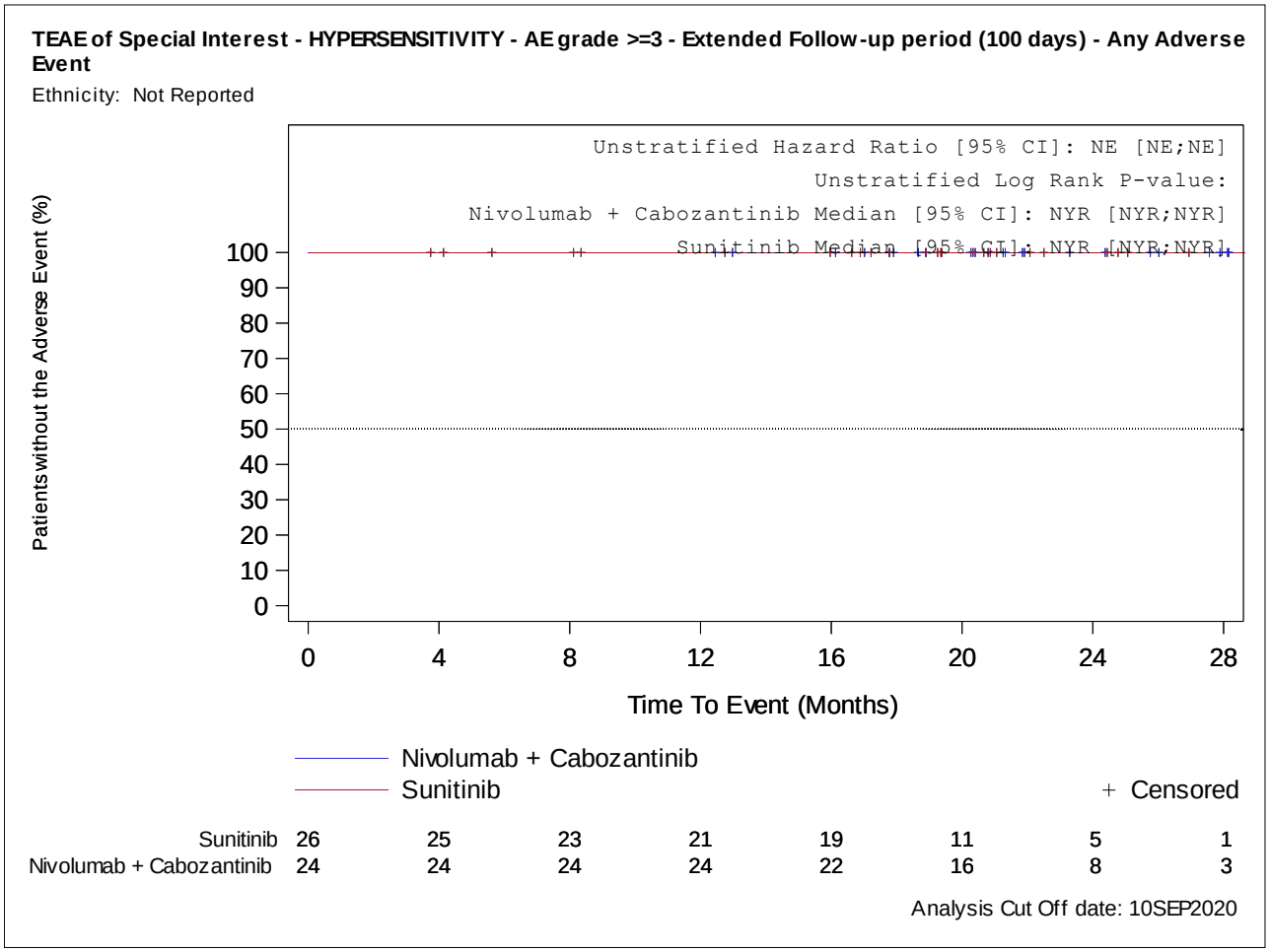
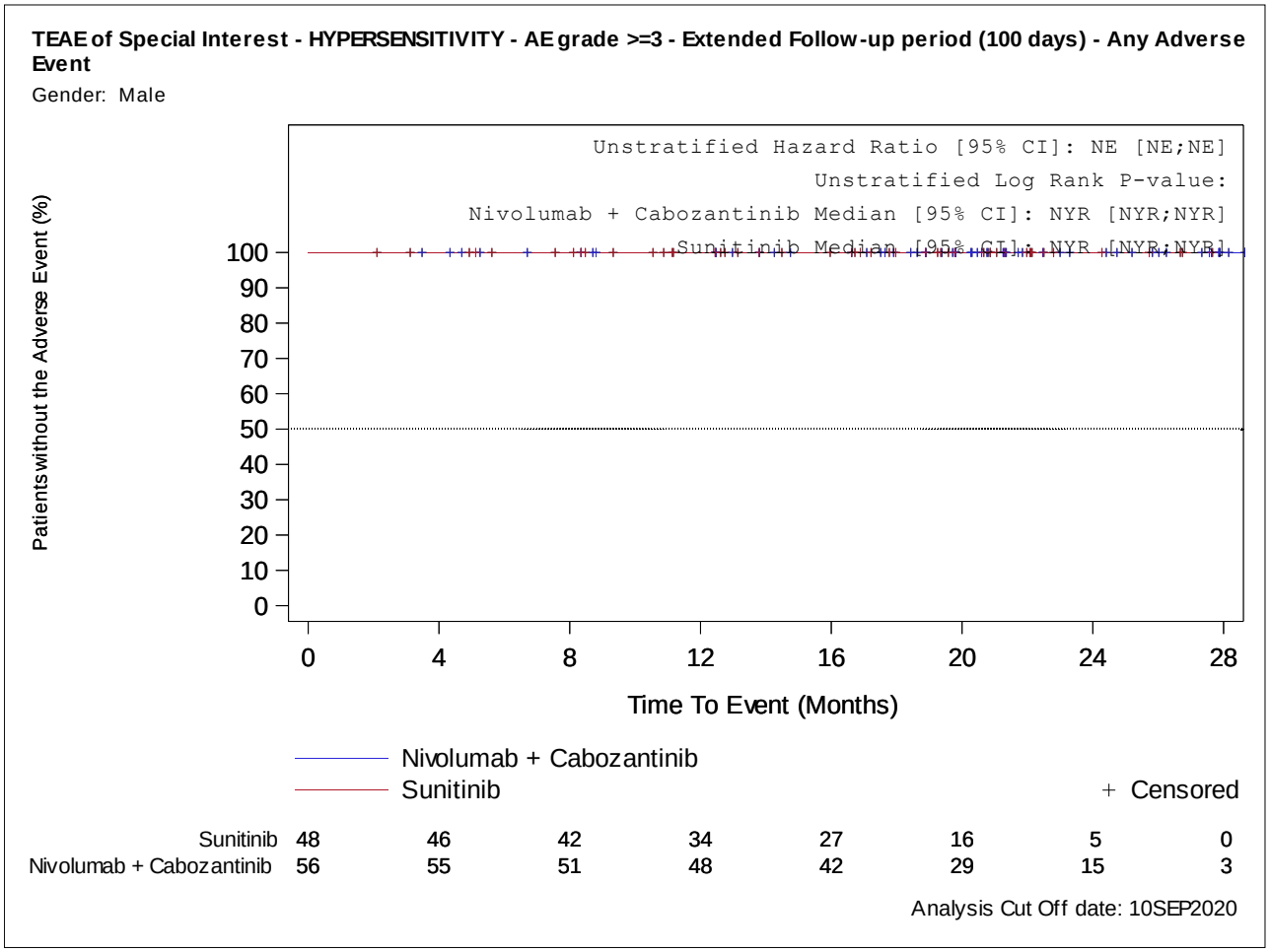
FIGURE 3.86.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



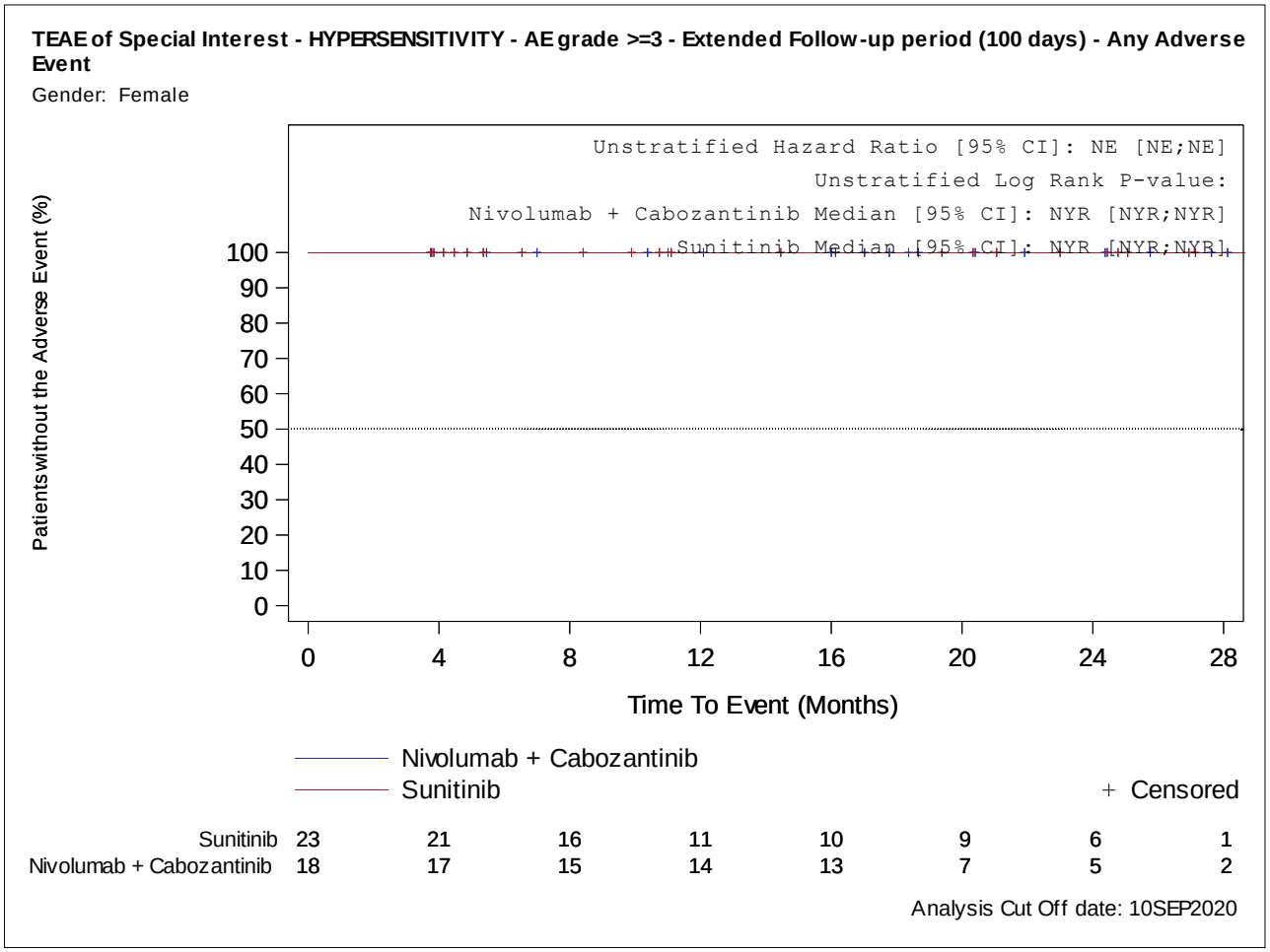

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:02:02

FIGURE 3.86.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



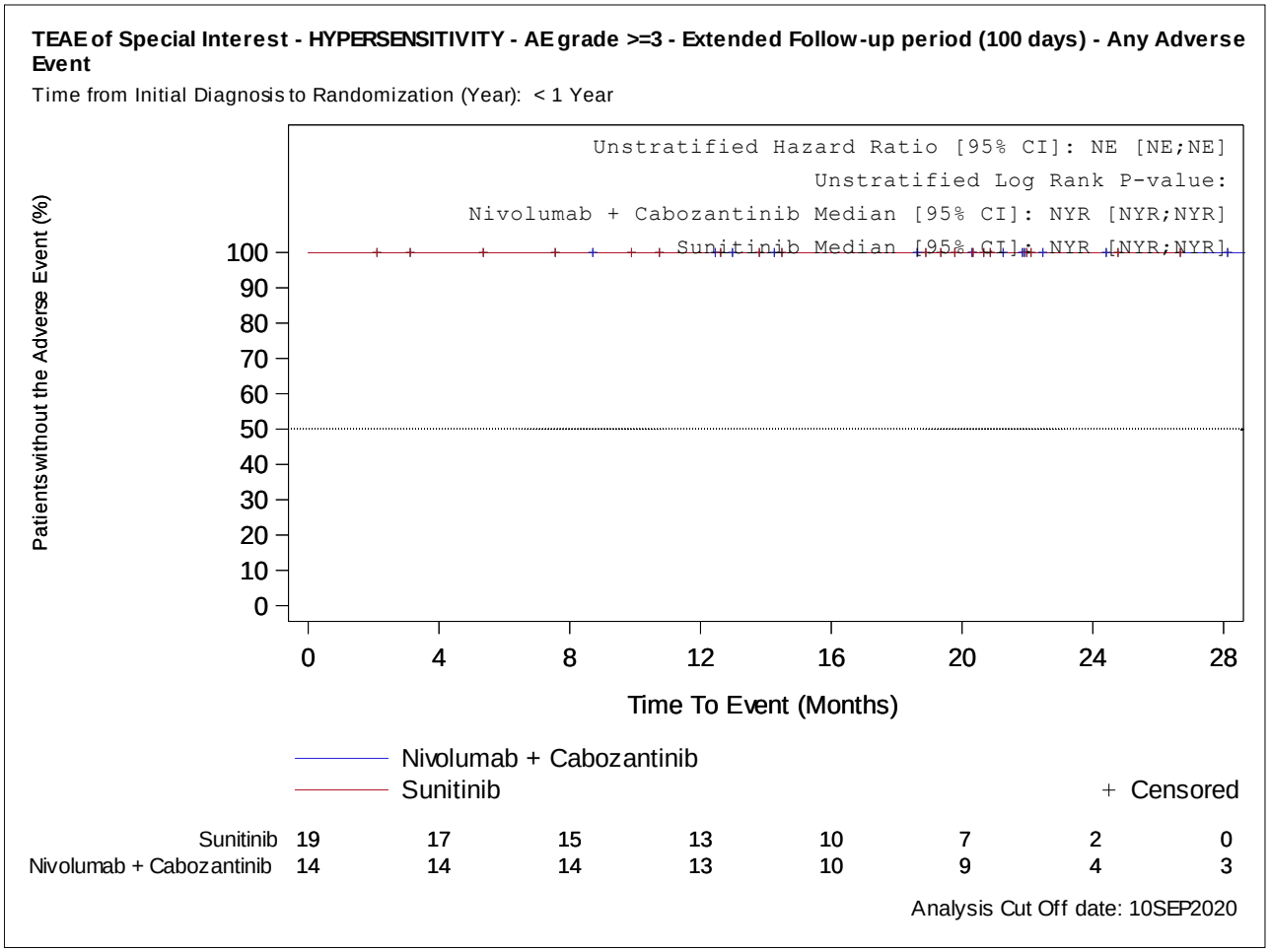

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:02:07

FIGURE 3.86.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



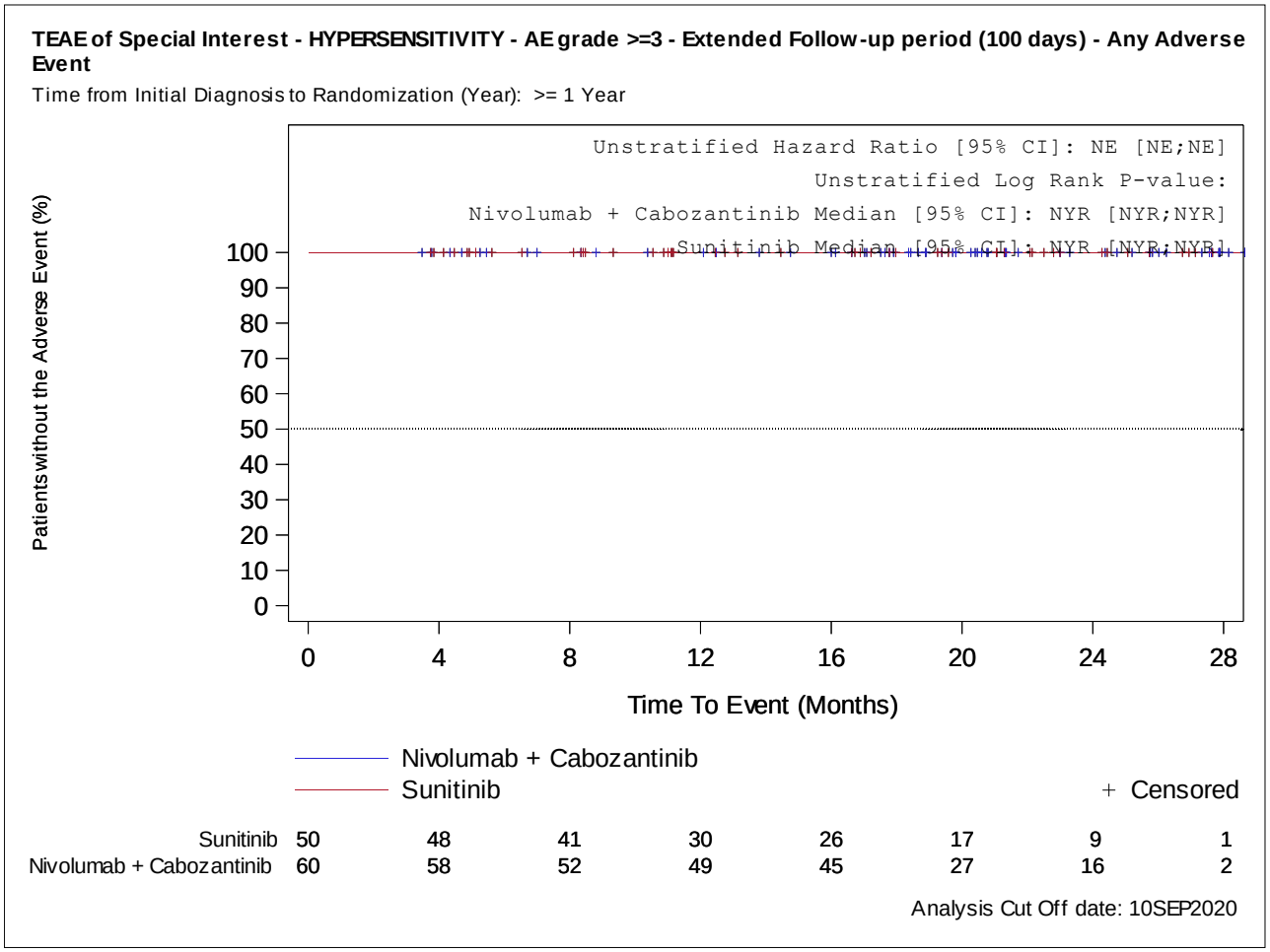

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:02:12

FIGURE 3.86.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



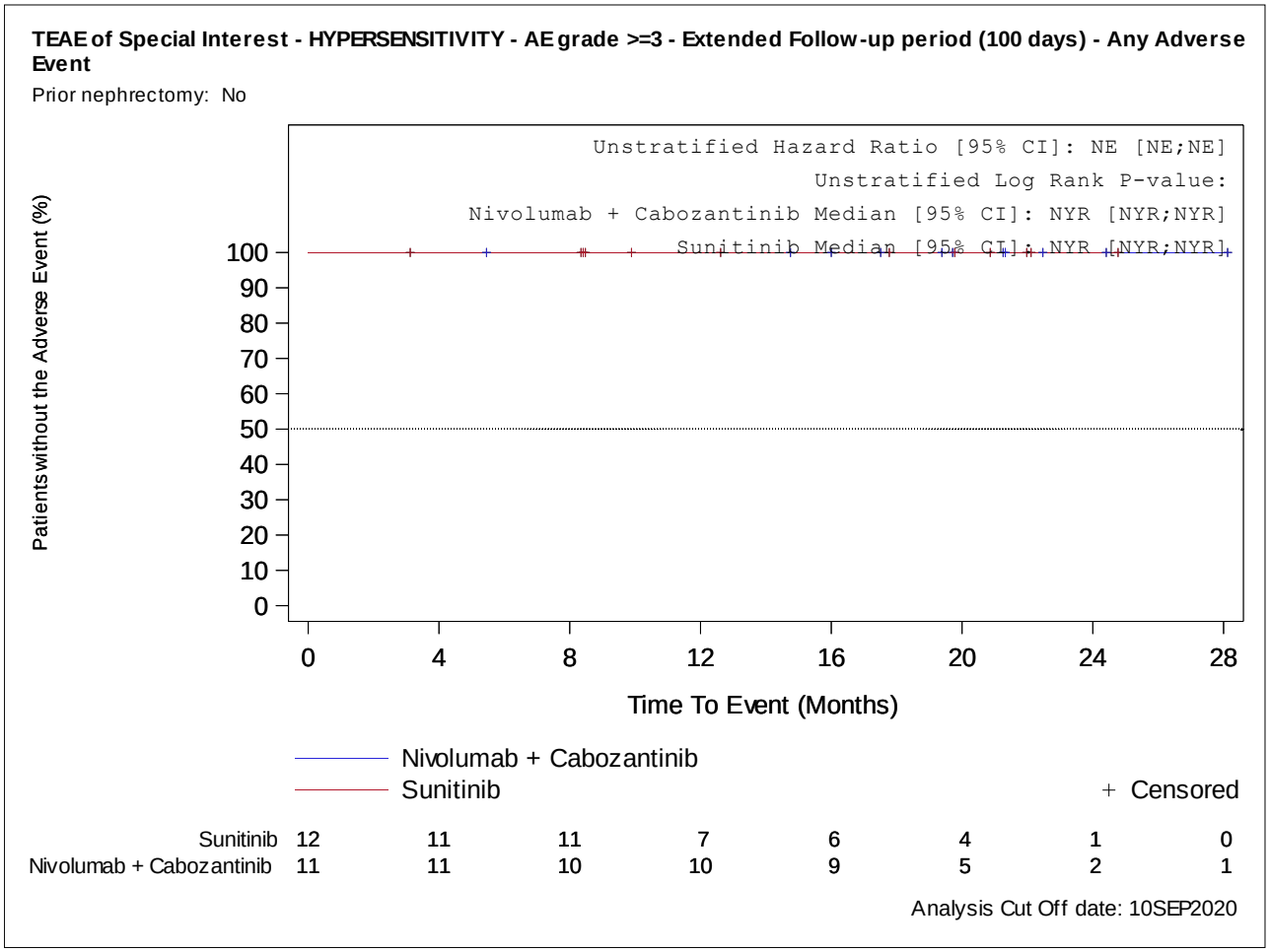

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:02:28

FIGURE 3.86.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



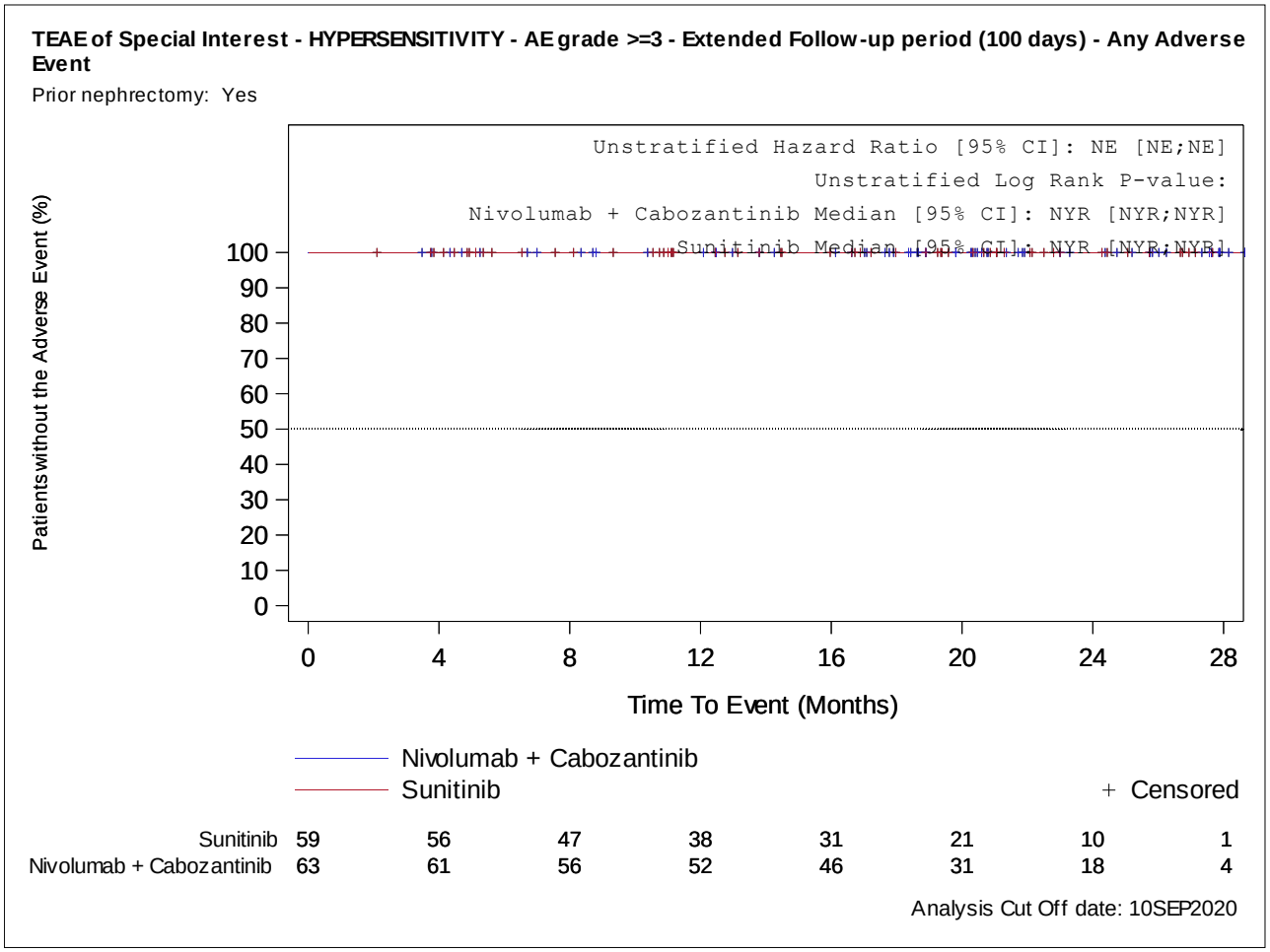

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:02:33

FIGURE 3.86.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



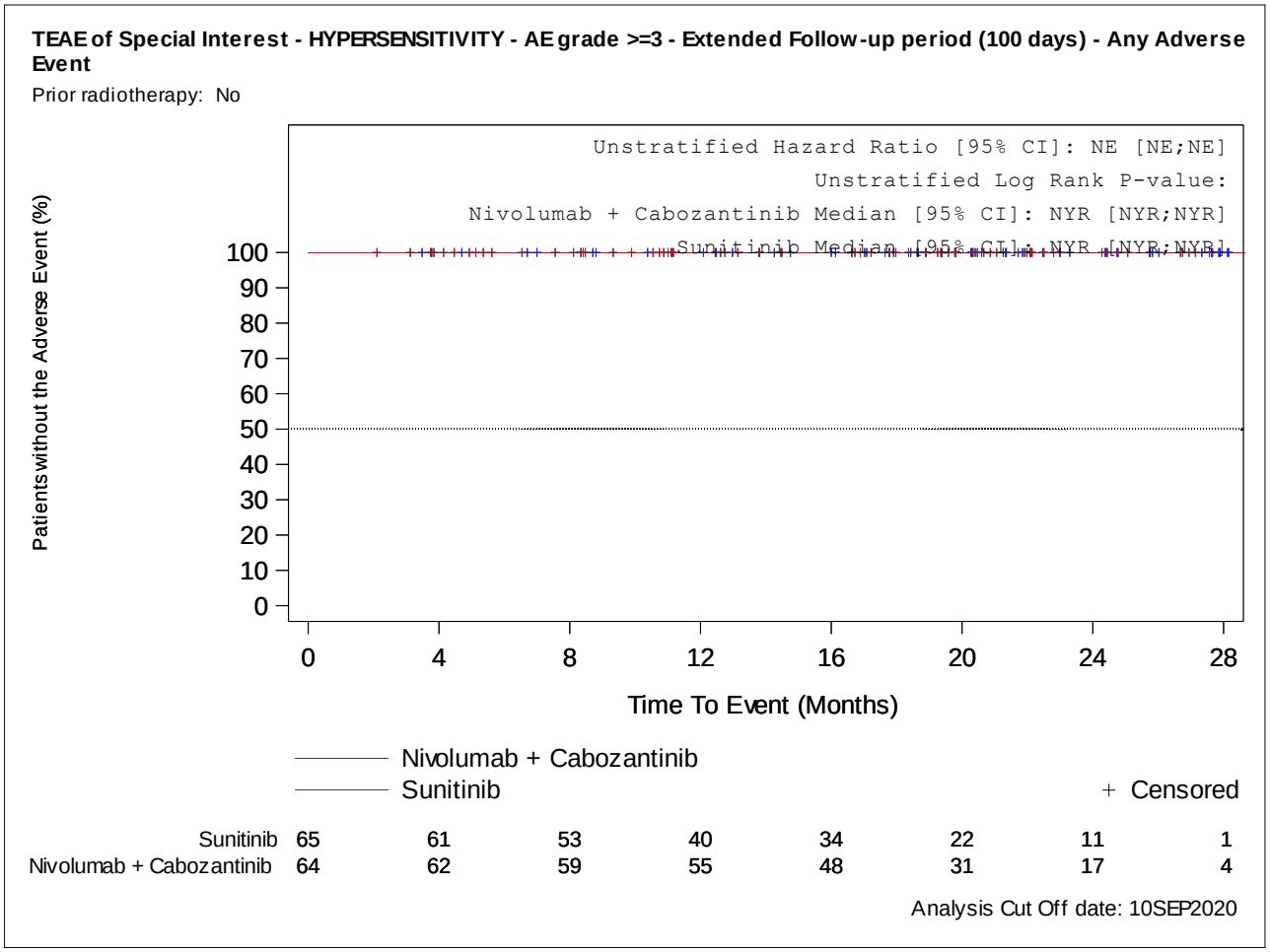

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:03:21

FIGURE 3.86.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



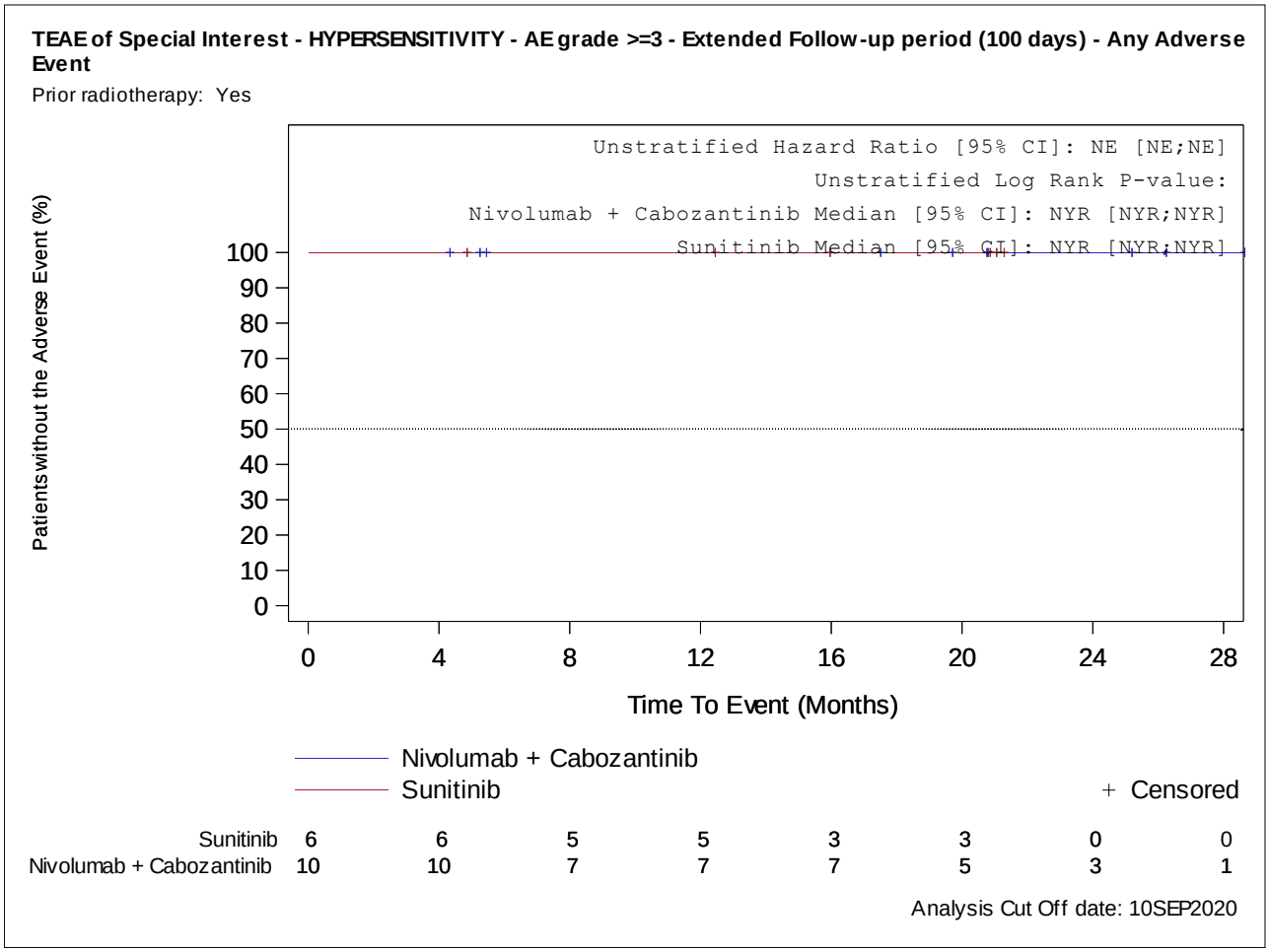

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:03:26

FIGURE 3.86.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



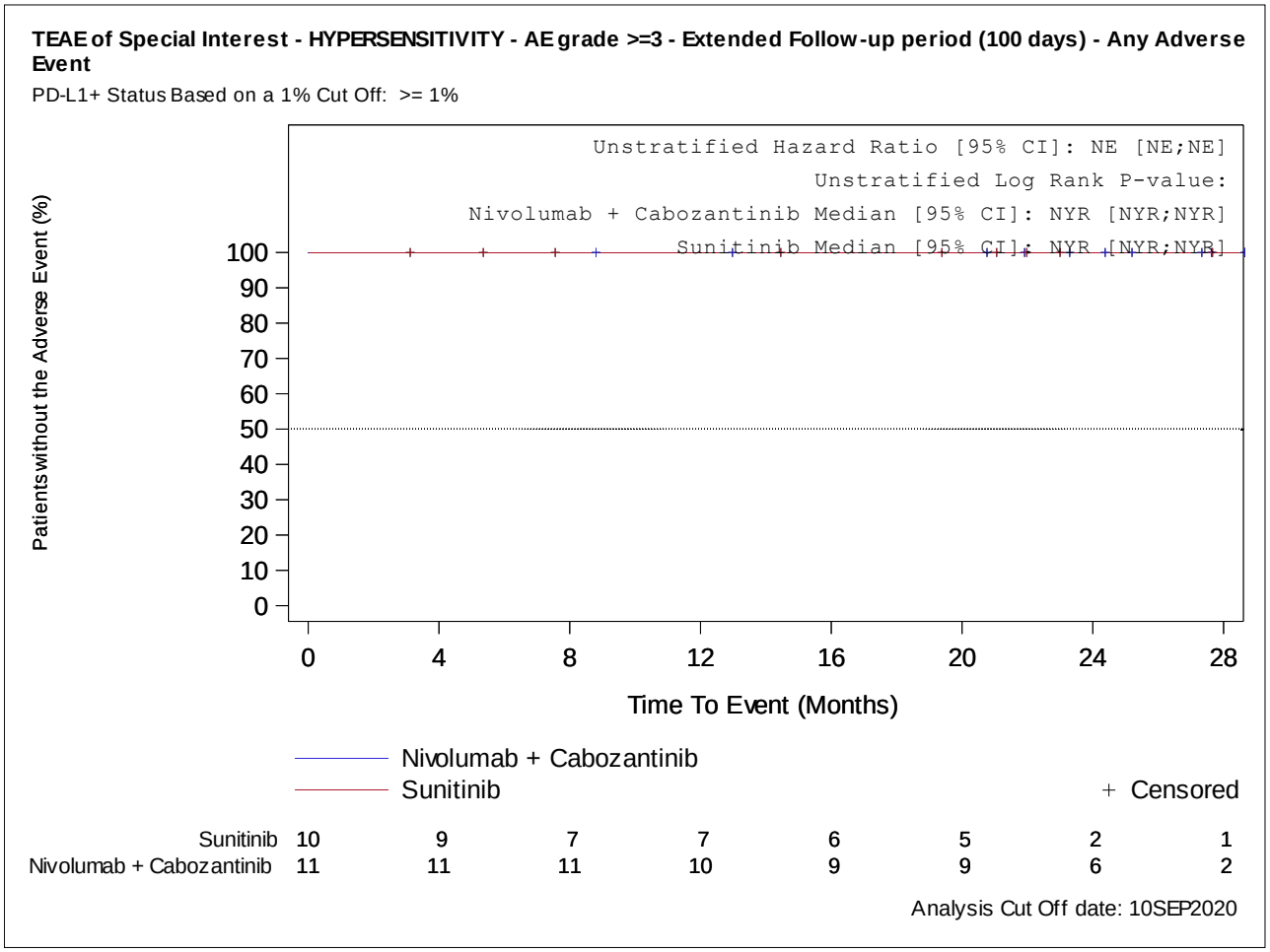

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:03:31

FIGURE 3.86.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



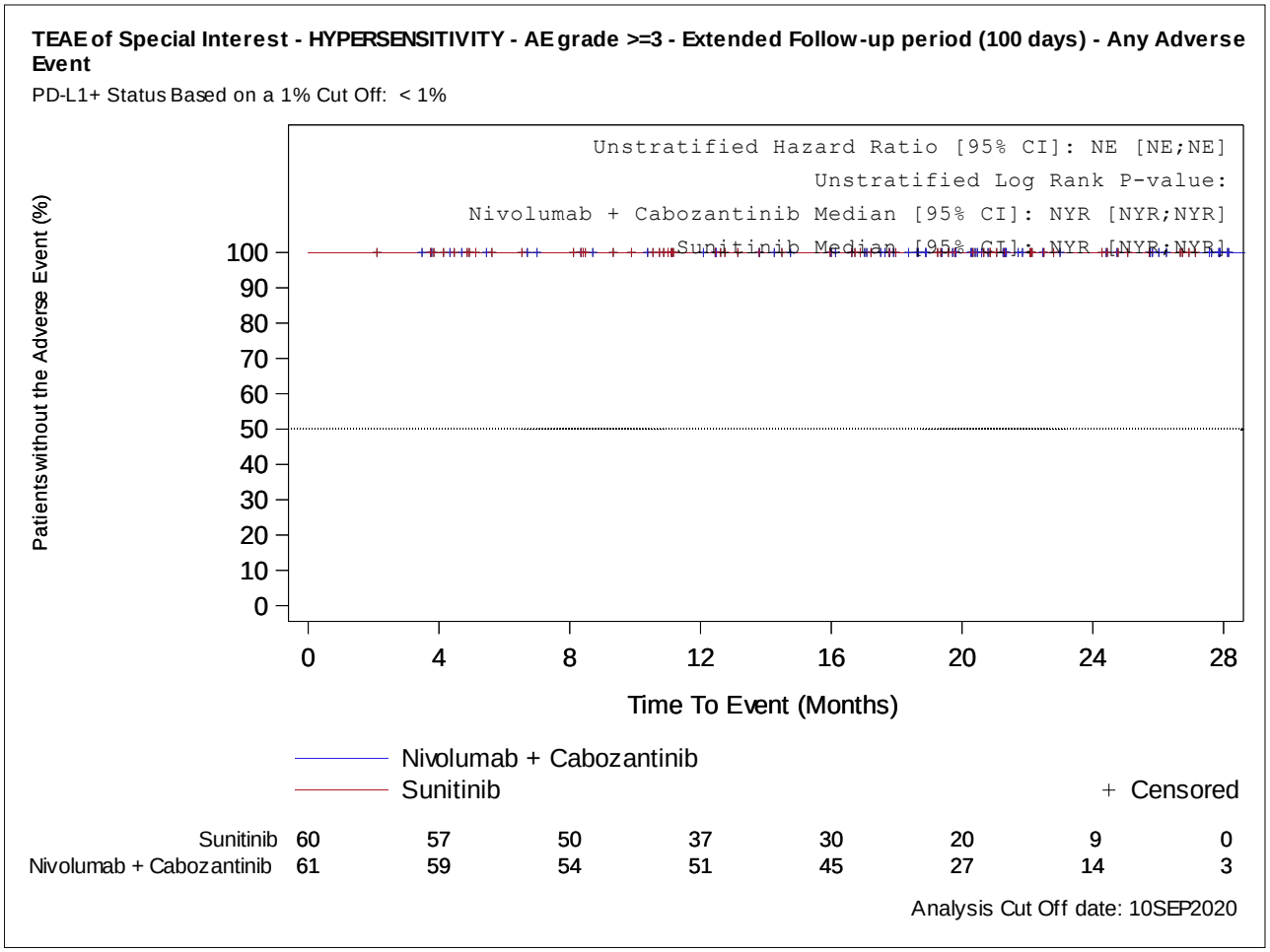

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:03:37

FIGURE 3.86.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



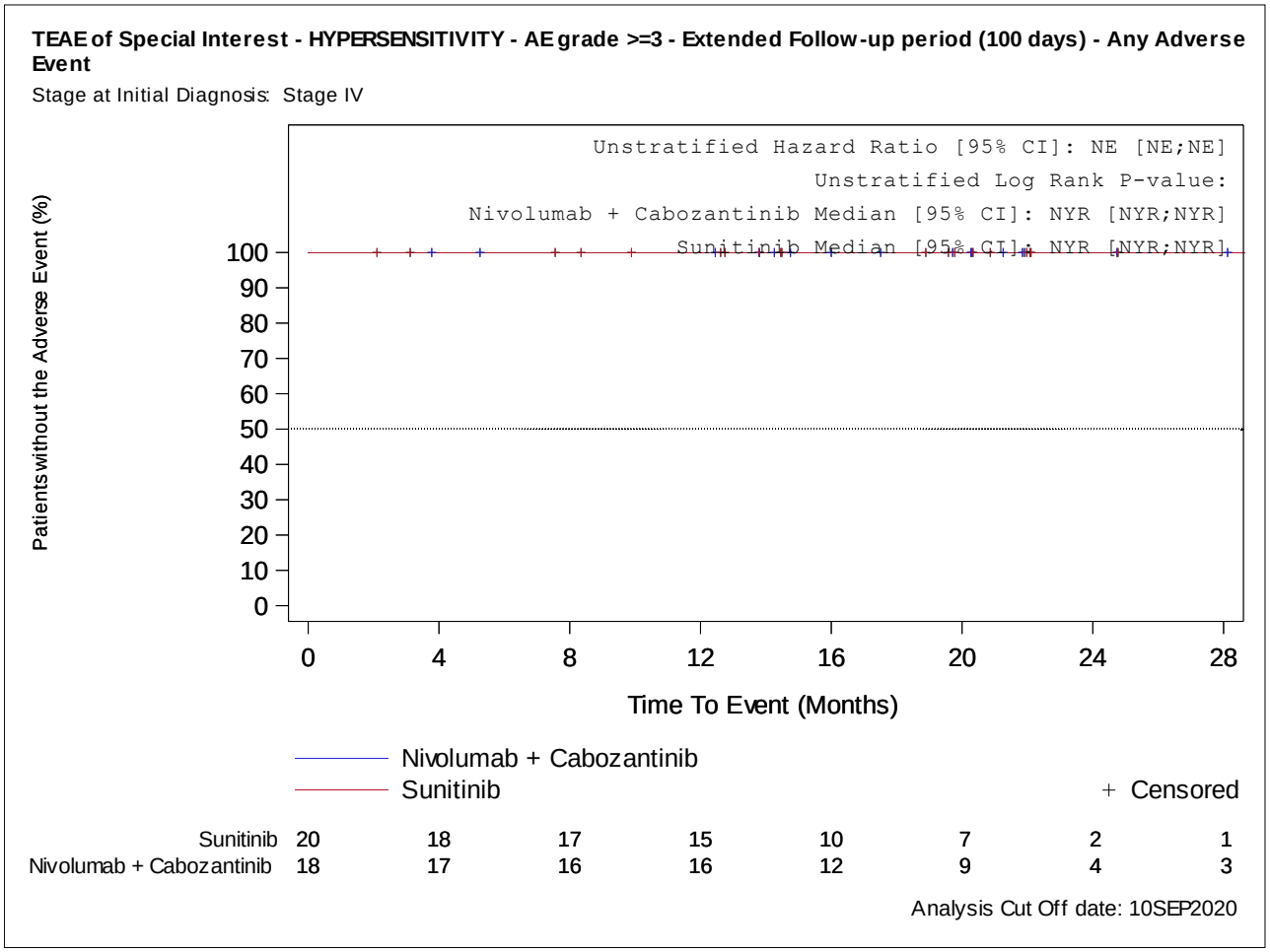

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:03:41

FIGURE 3.86.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



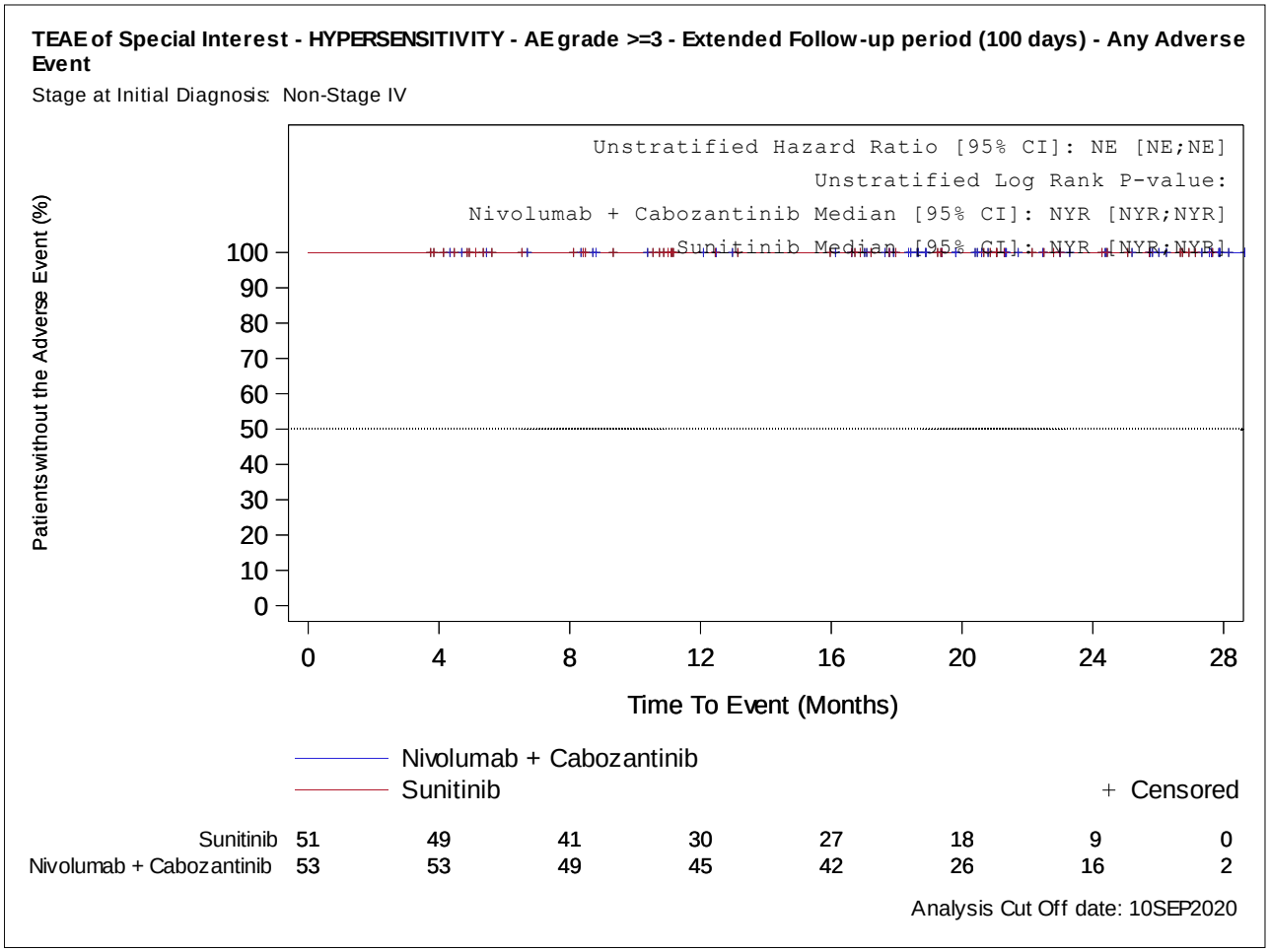

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:03:47

FIGURE 3.86.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



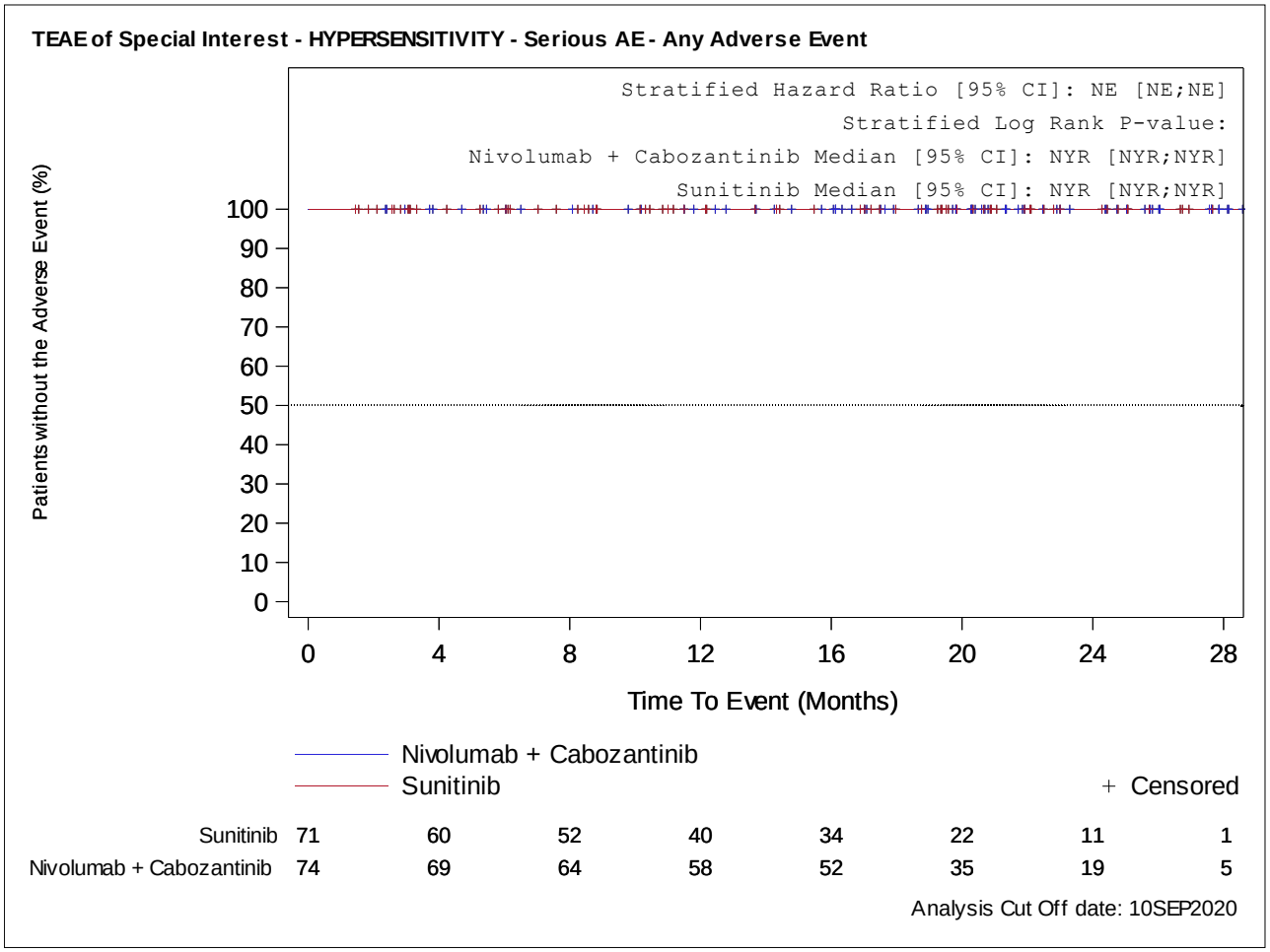

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:04:12

FIGURE 3.86.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



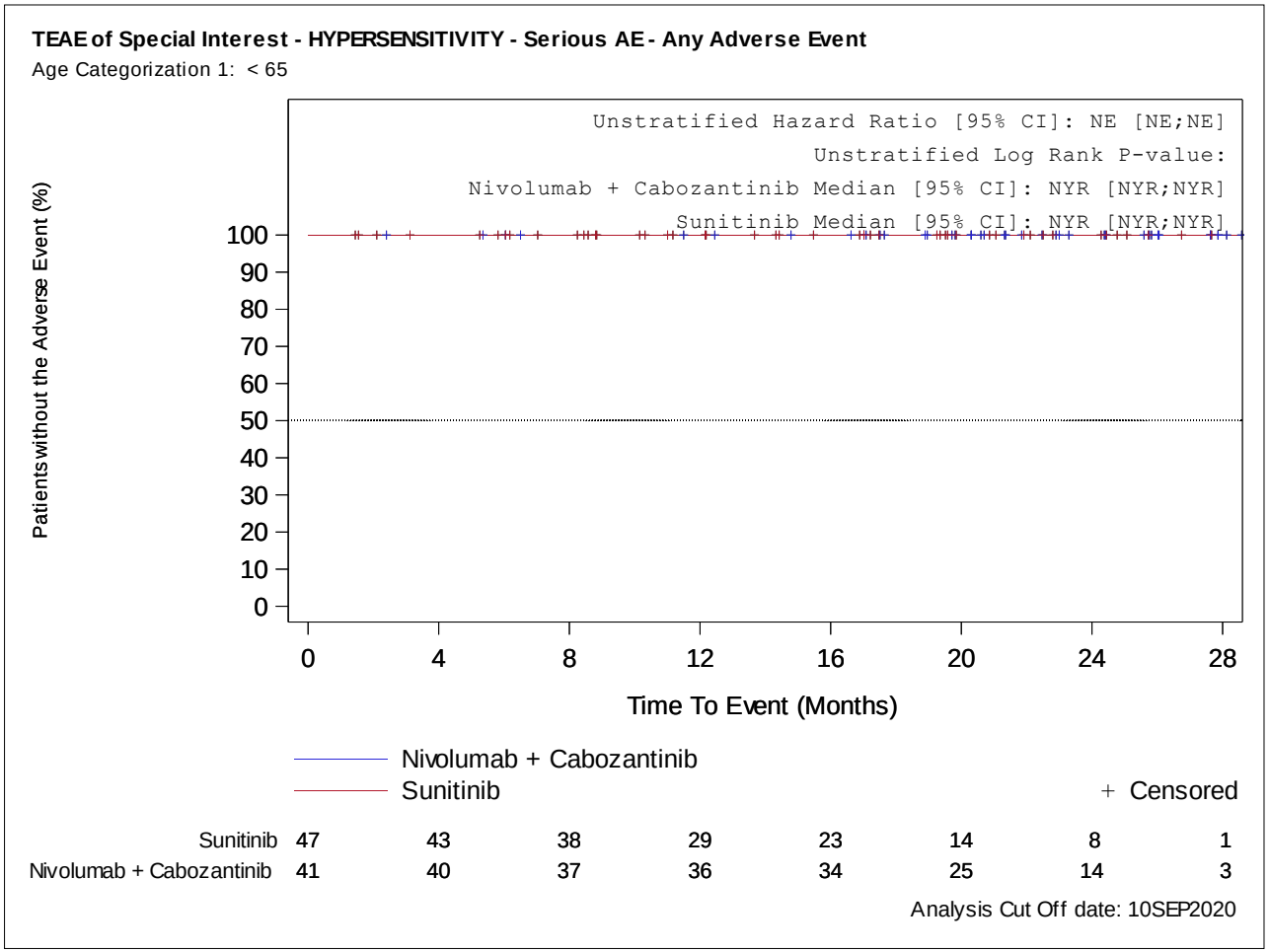

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:04:18

FIGURE 3.87.1: TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



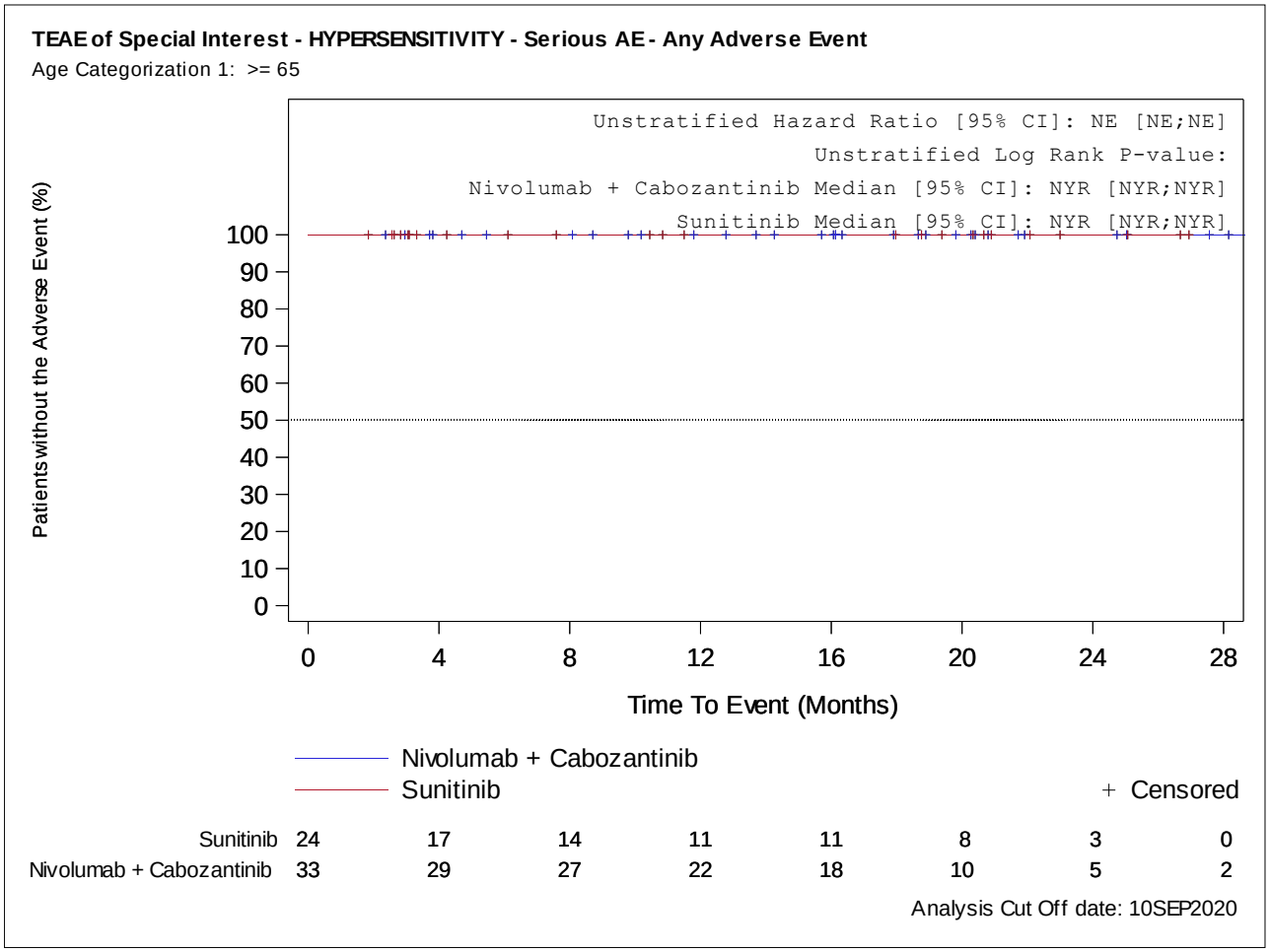

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:07:15

FIGURE 3.87.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:07:18

FIGURE 3.87.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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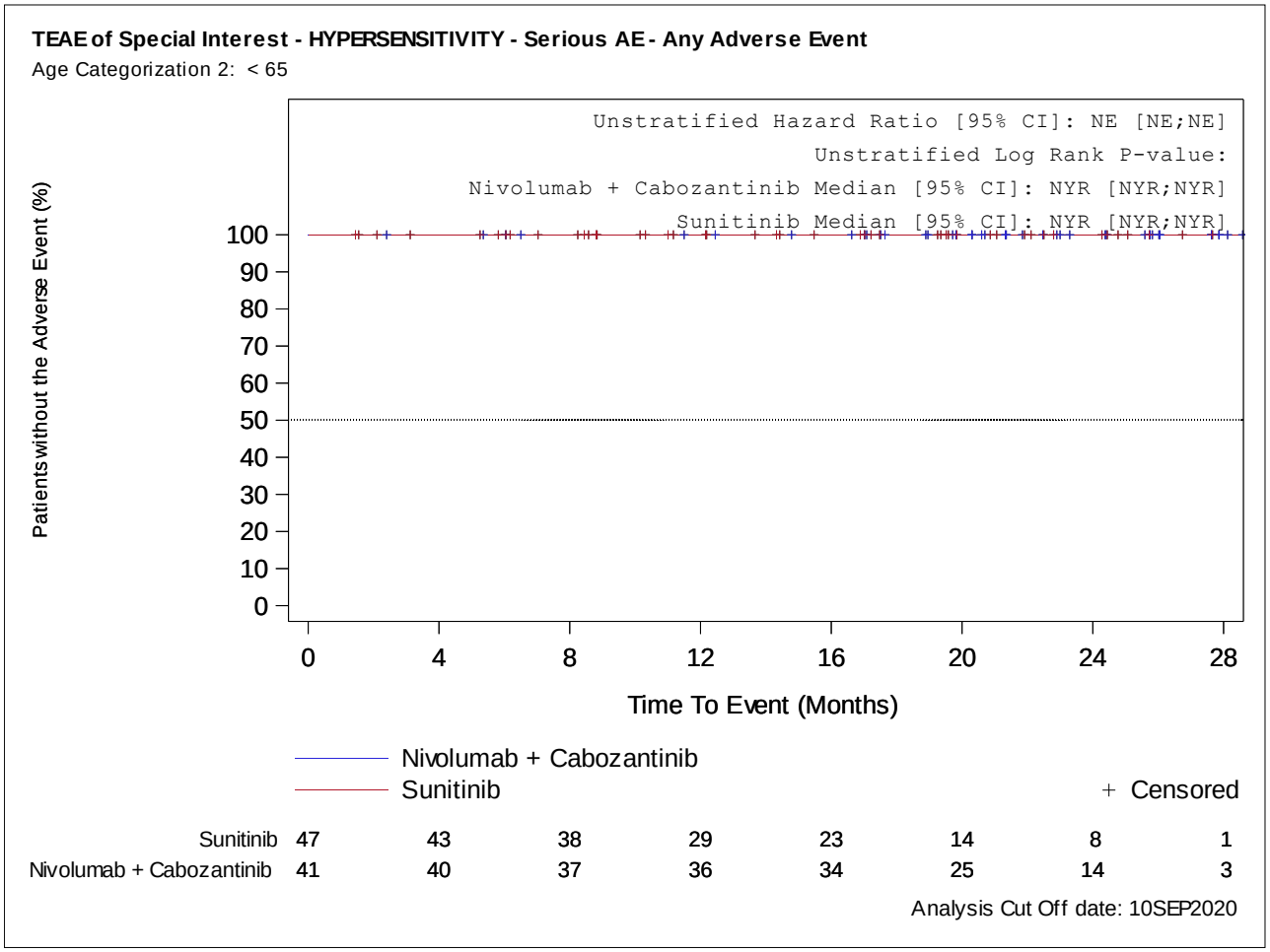
FIGURE 3.87.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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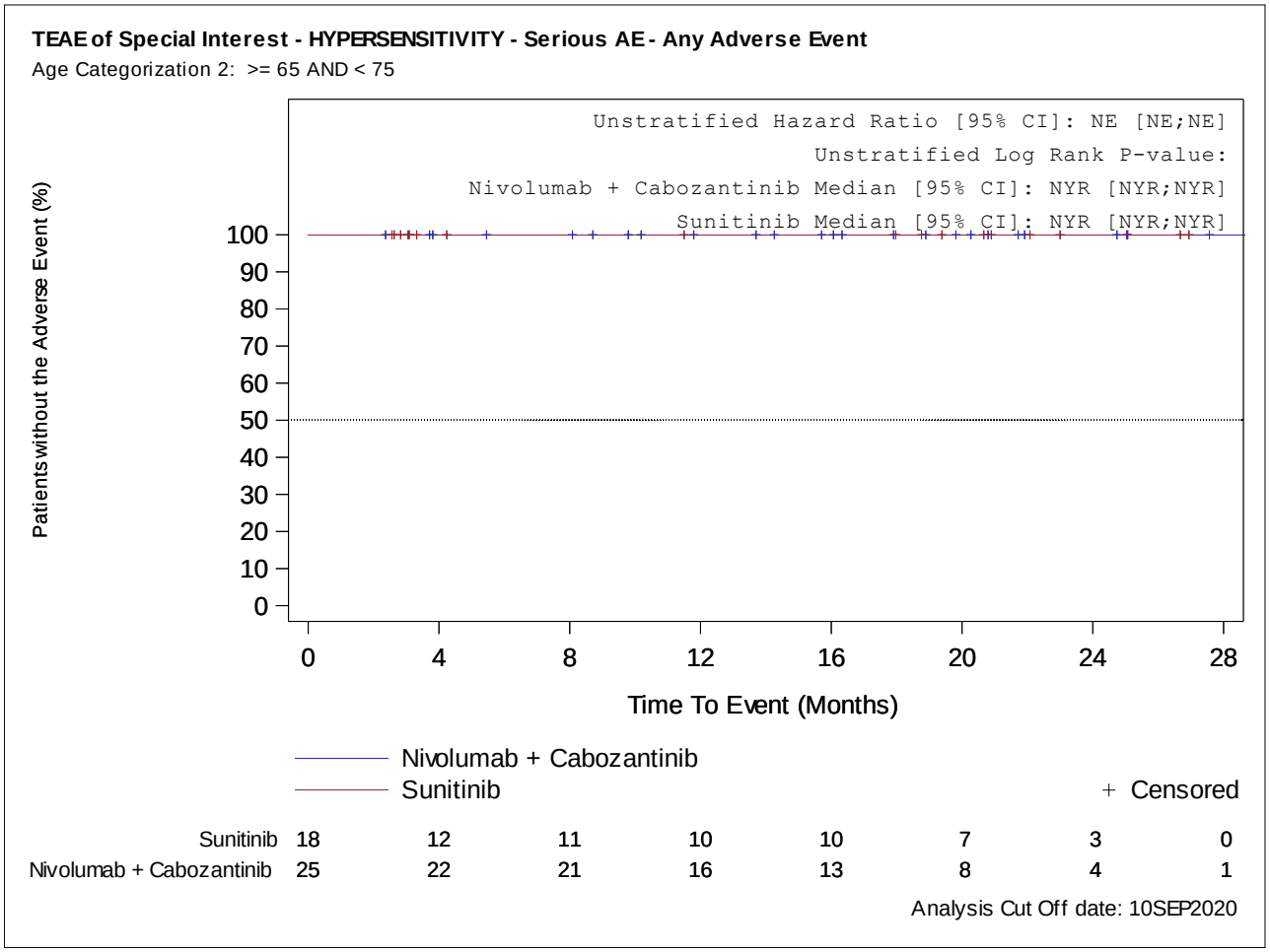
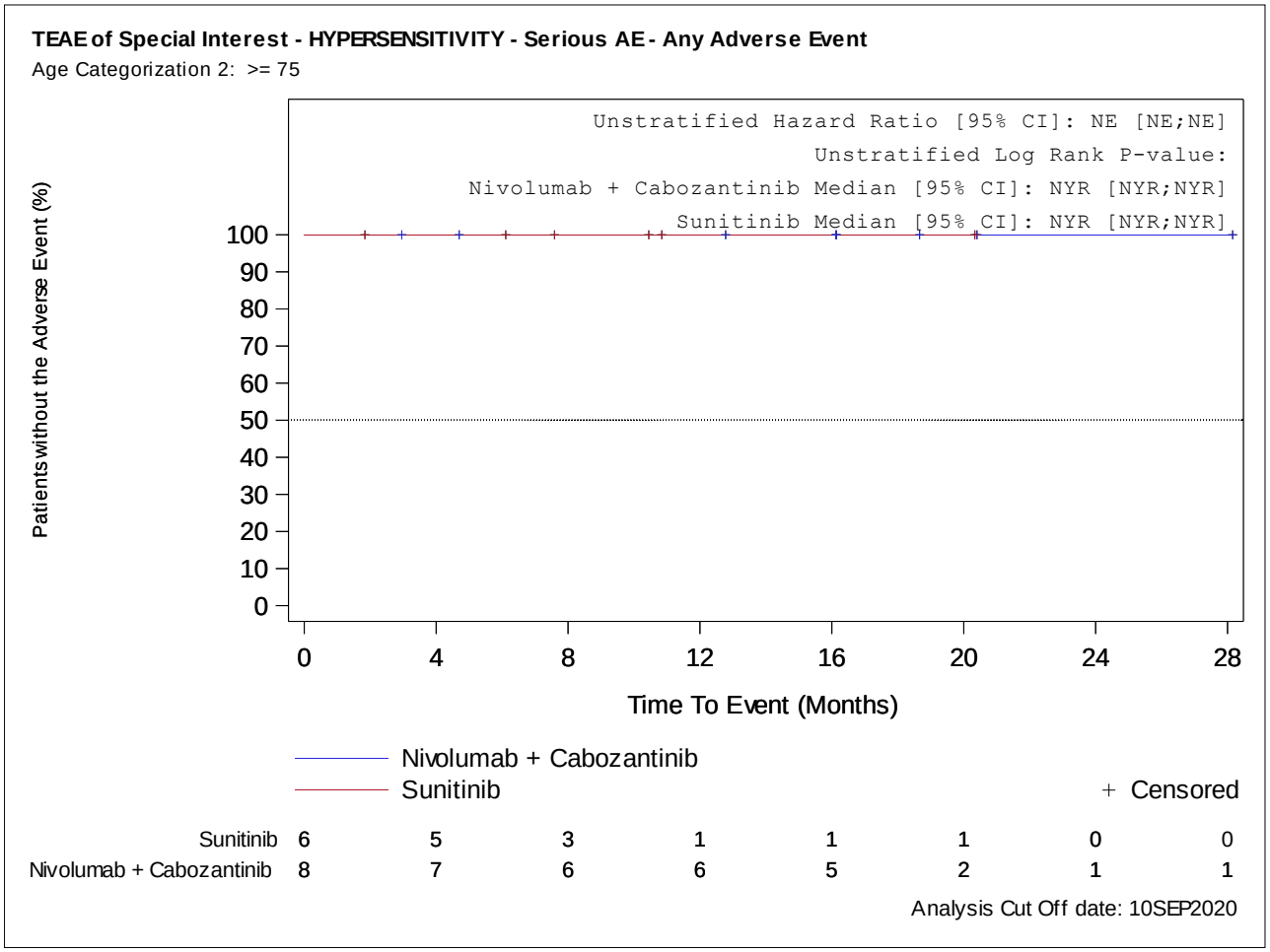
FIGURE 3.87.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



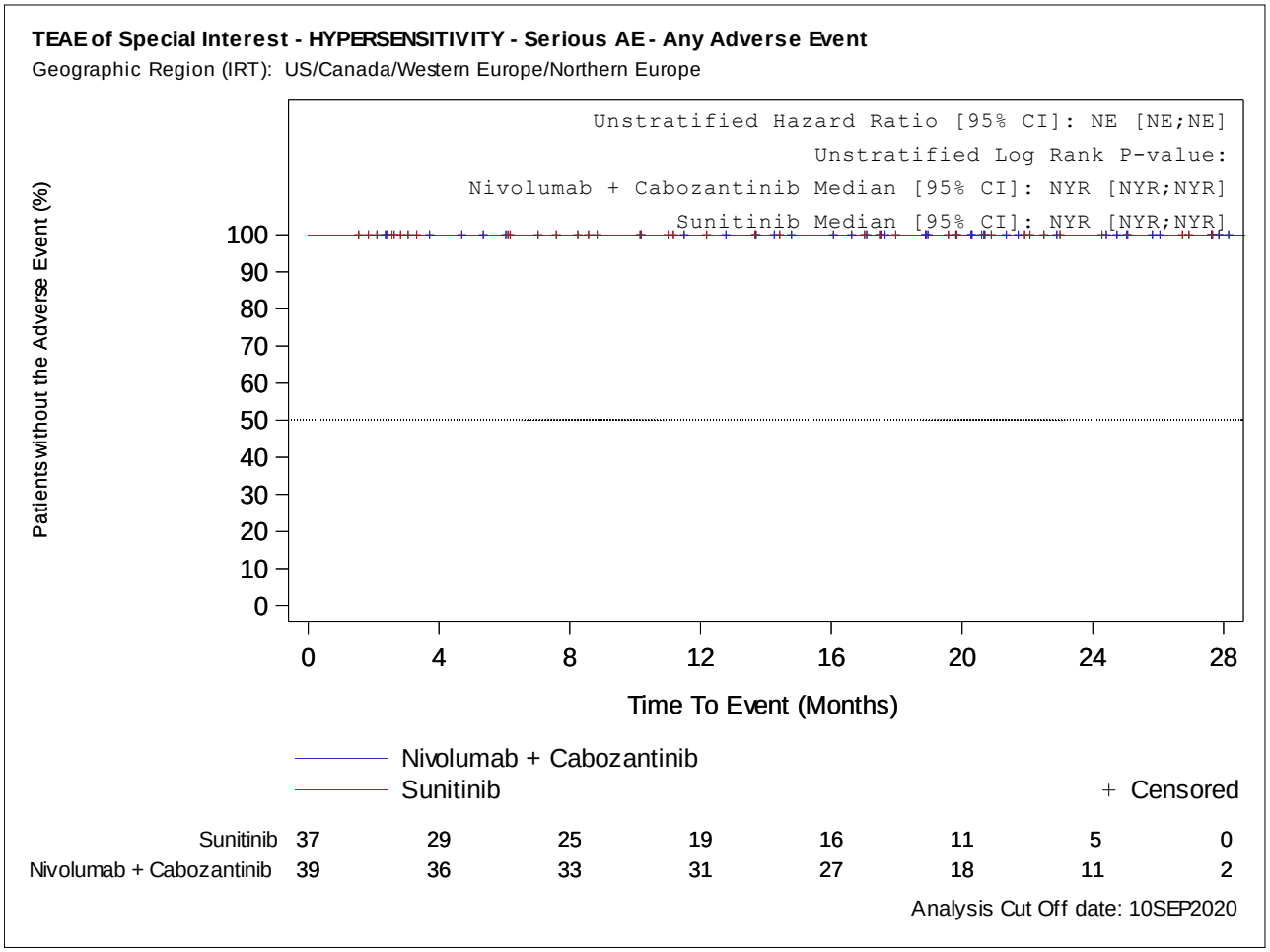

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:07:33

FIGURE 3.87.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



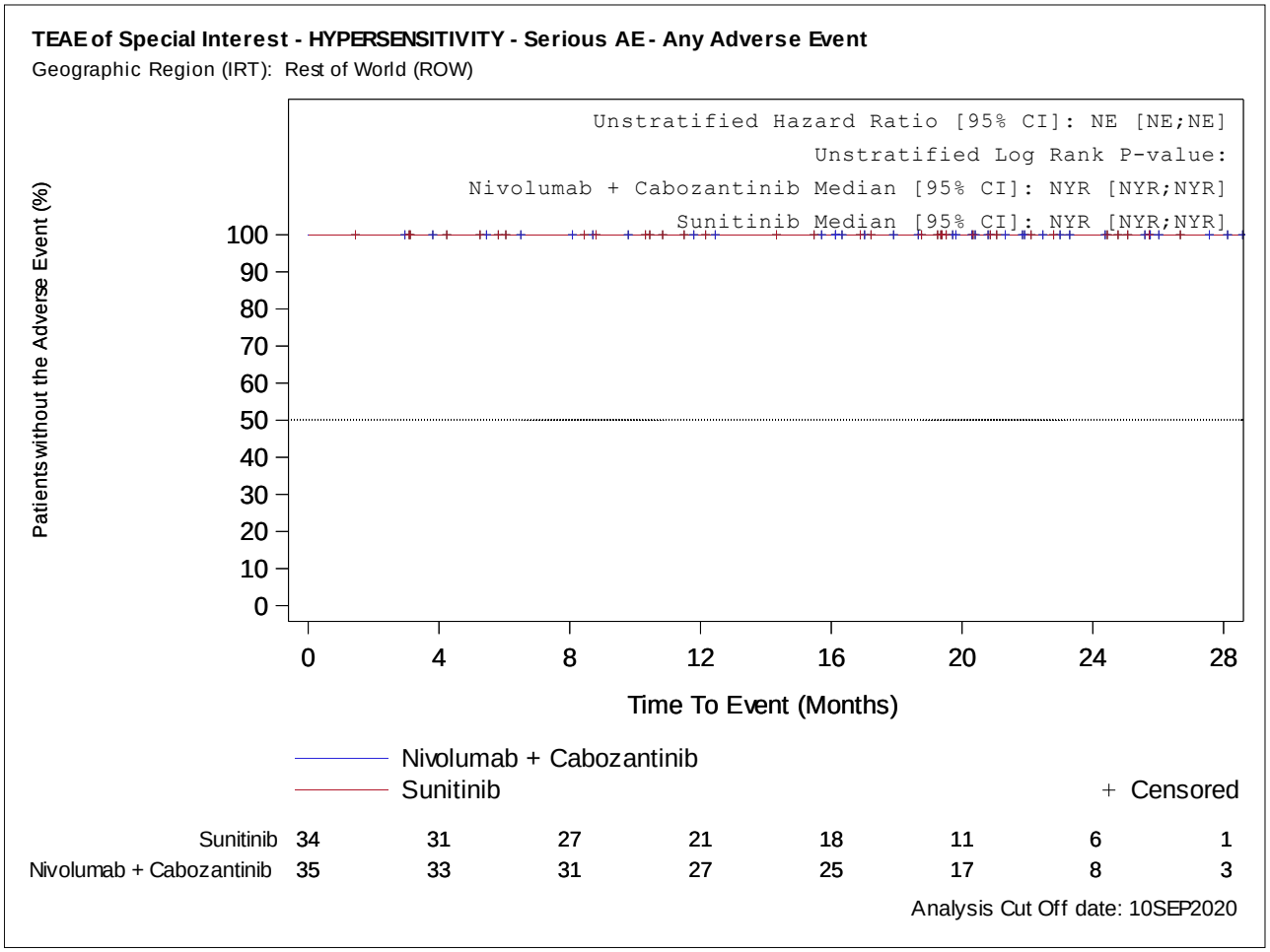

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:07:39

FIGURE 3.87.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



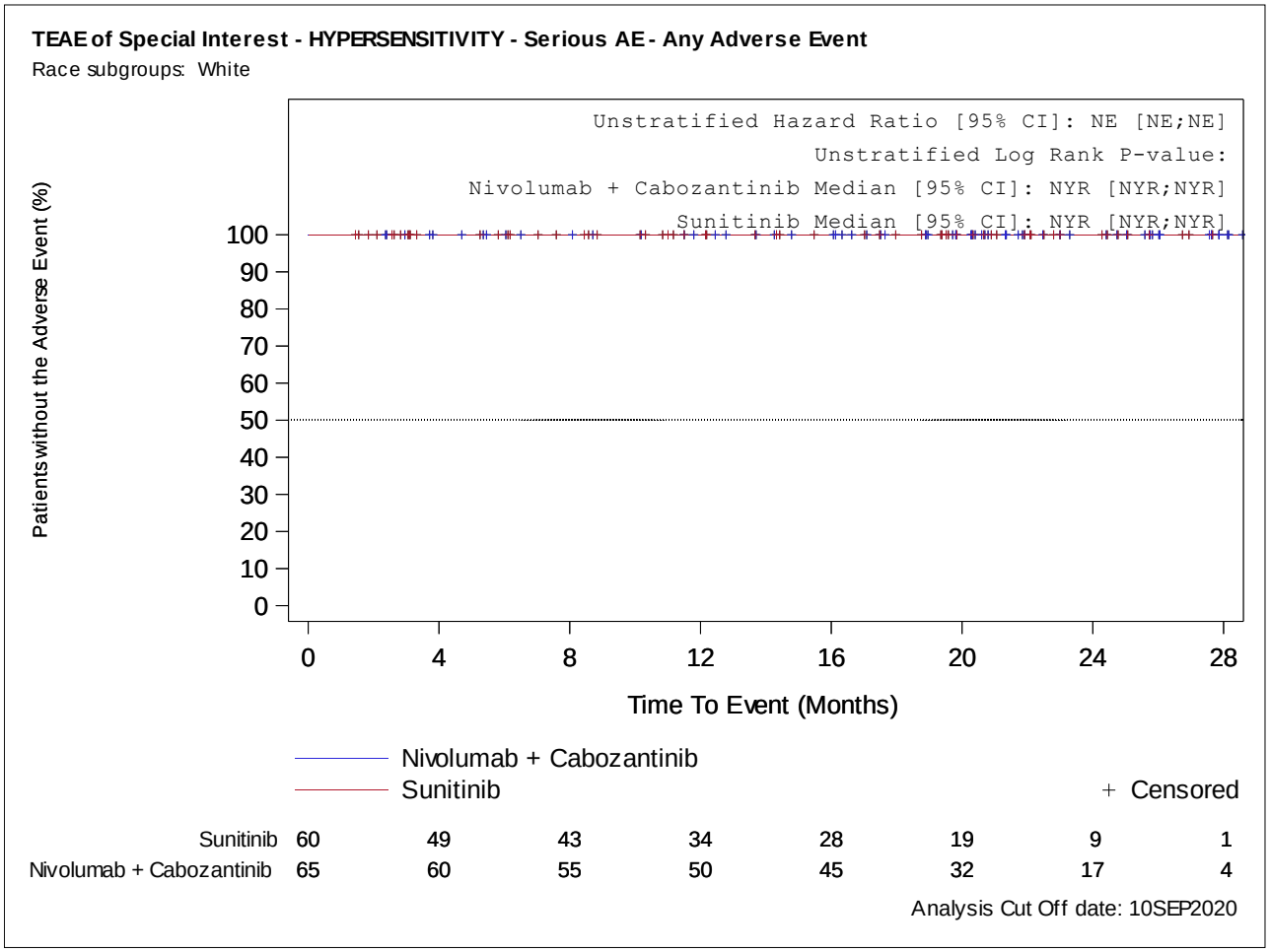

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:07:44

FIGURE 3.87.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



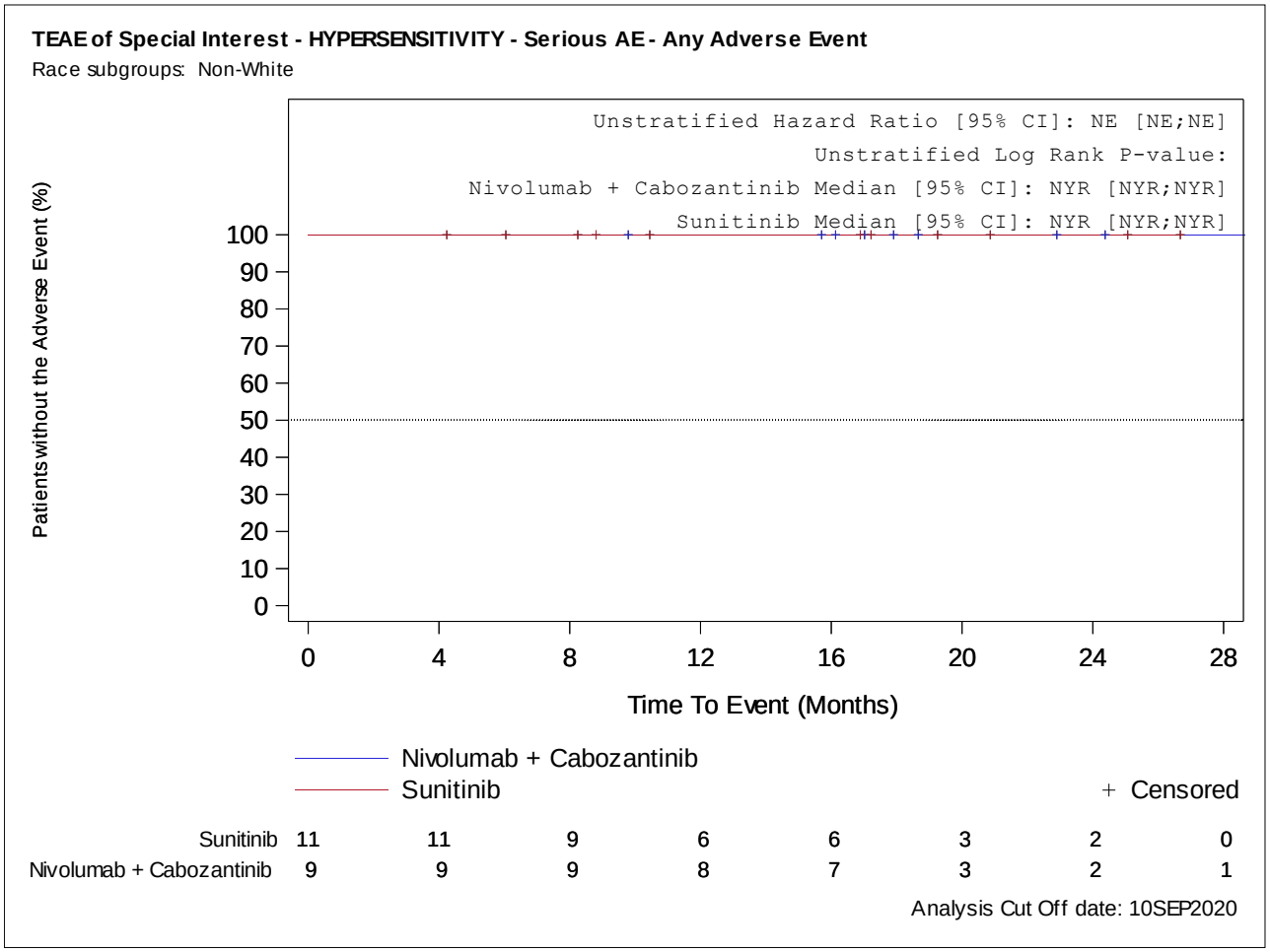

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:07:49

FIGURE 3.87.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



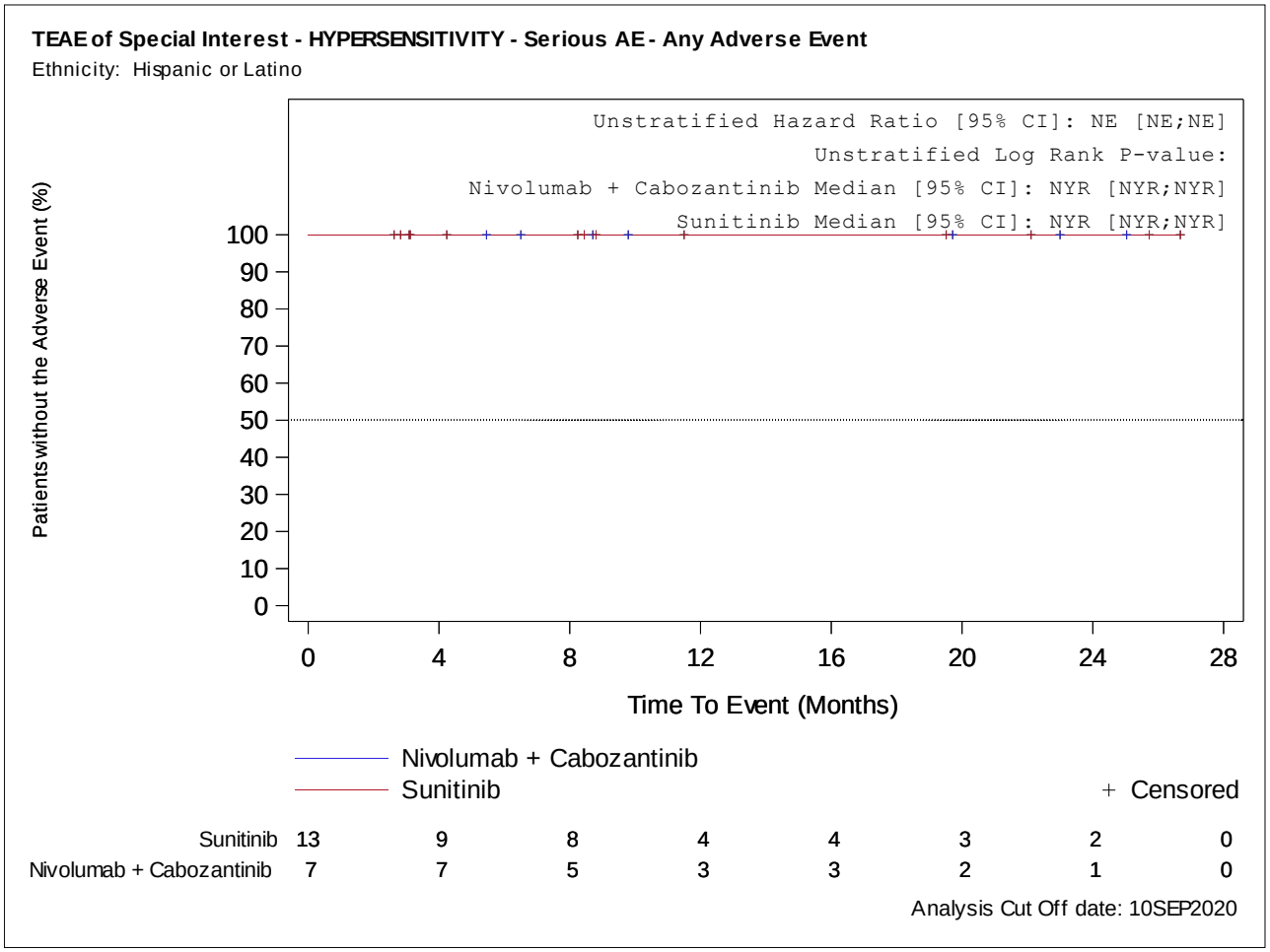

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:07:54

FIGURE 3.87.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



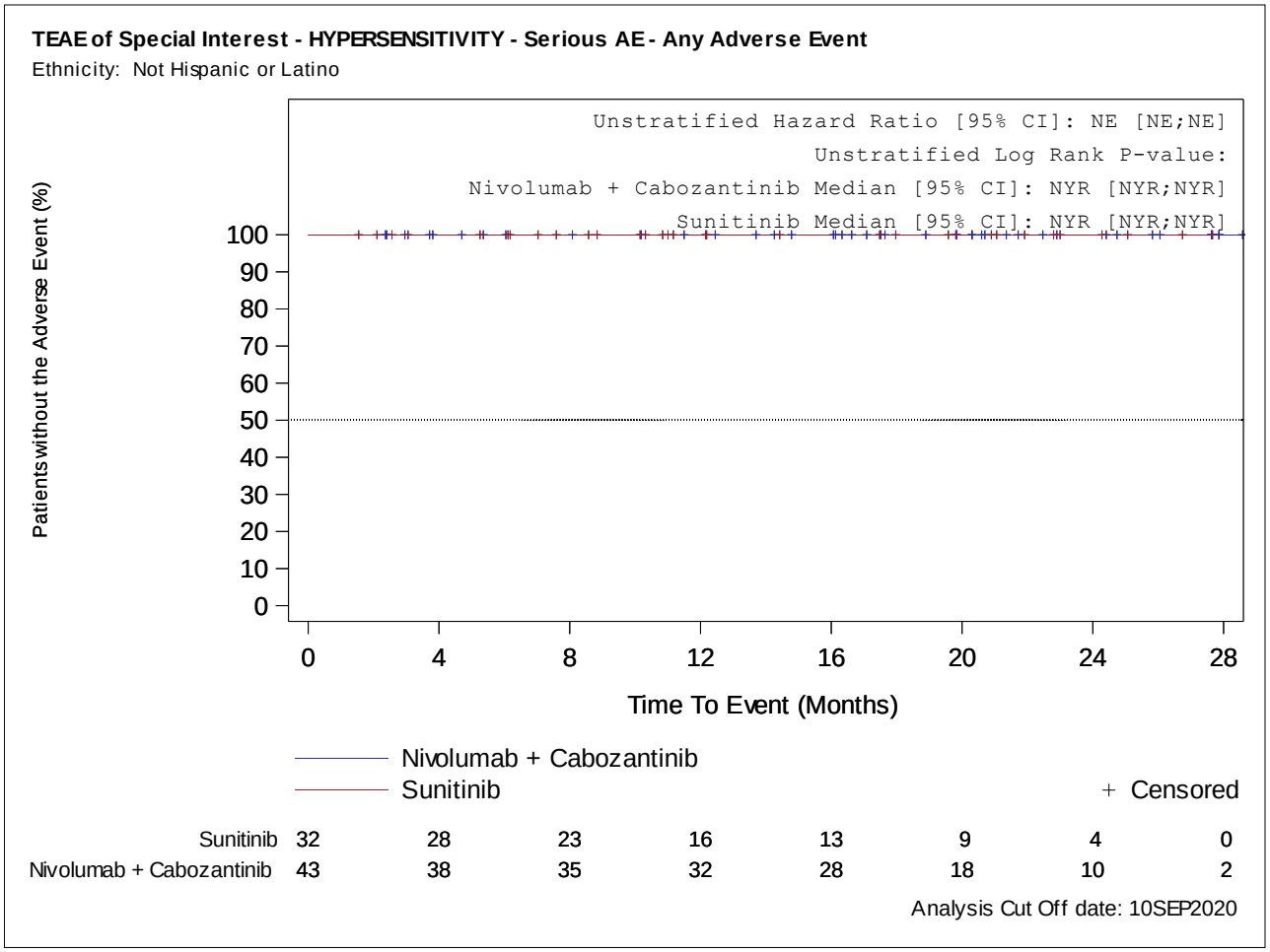

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:08:00

FIGURE 3.87.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



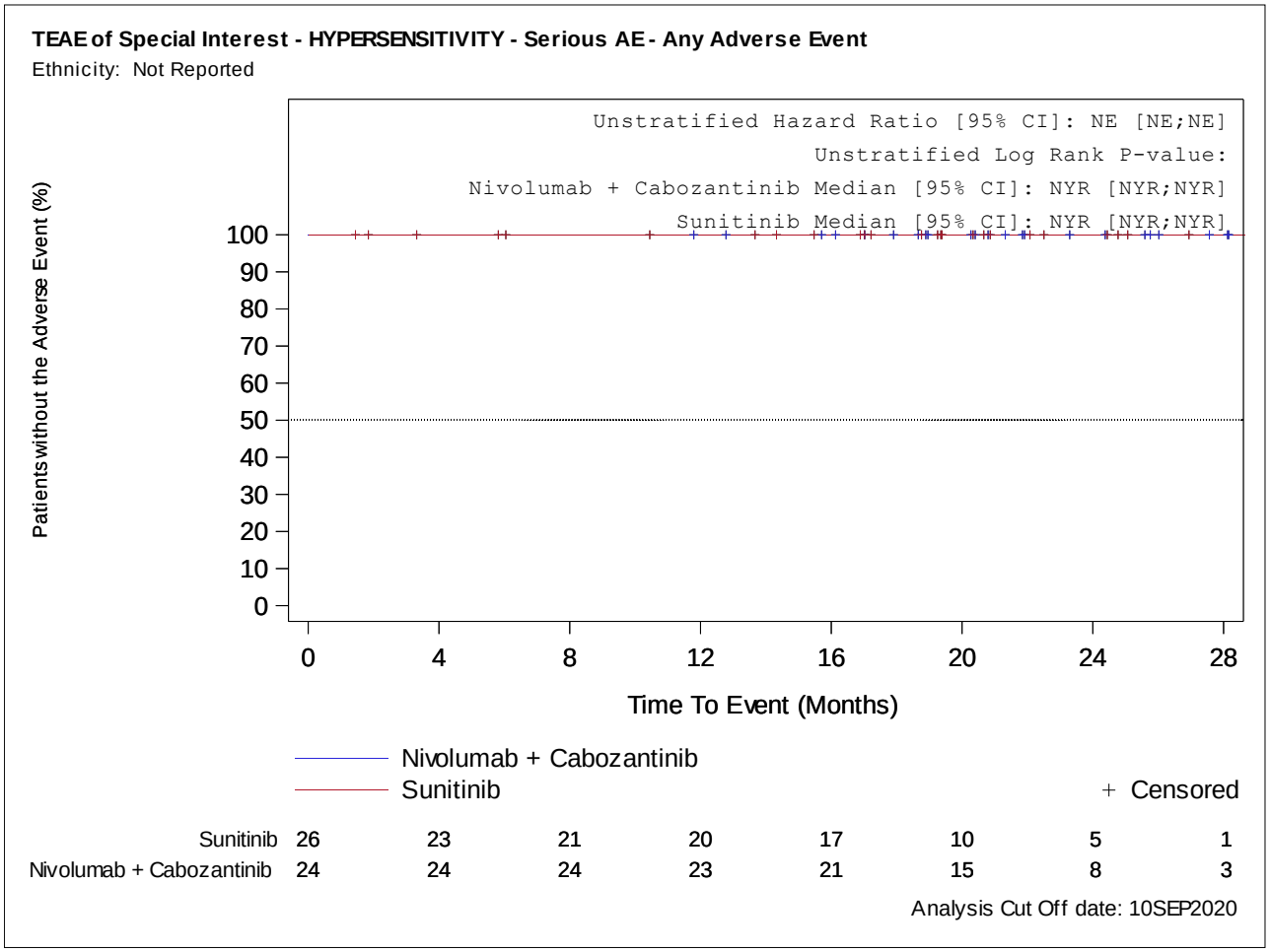

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:08:05

FIGURE 3.87.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



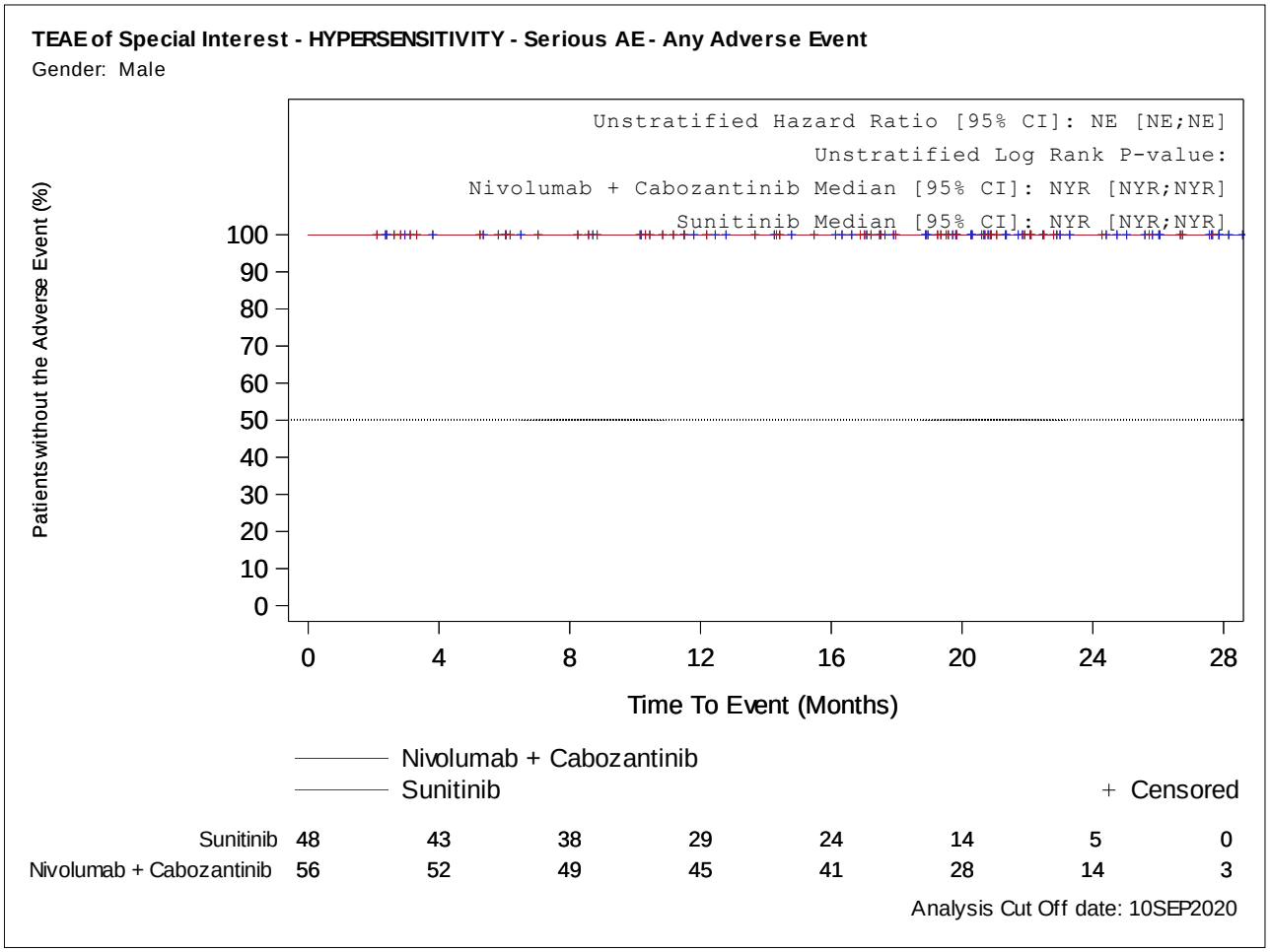

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:08:10

FIGURE 3.87.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



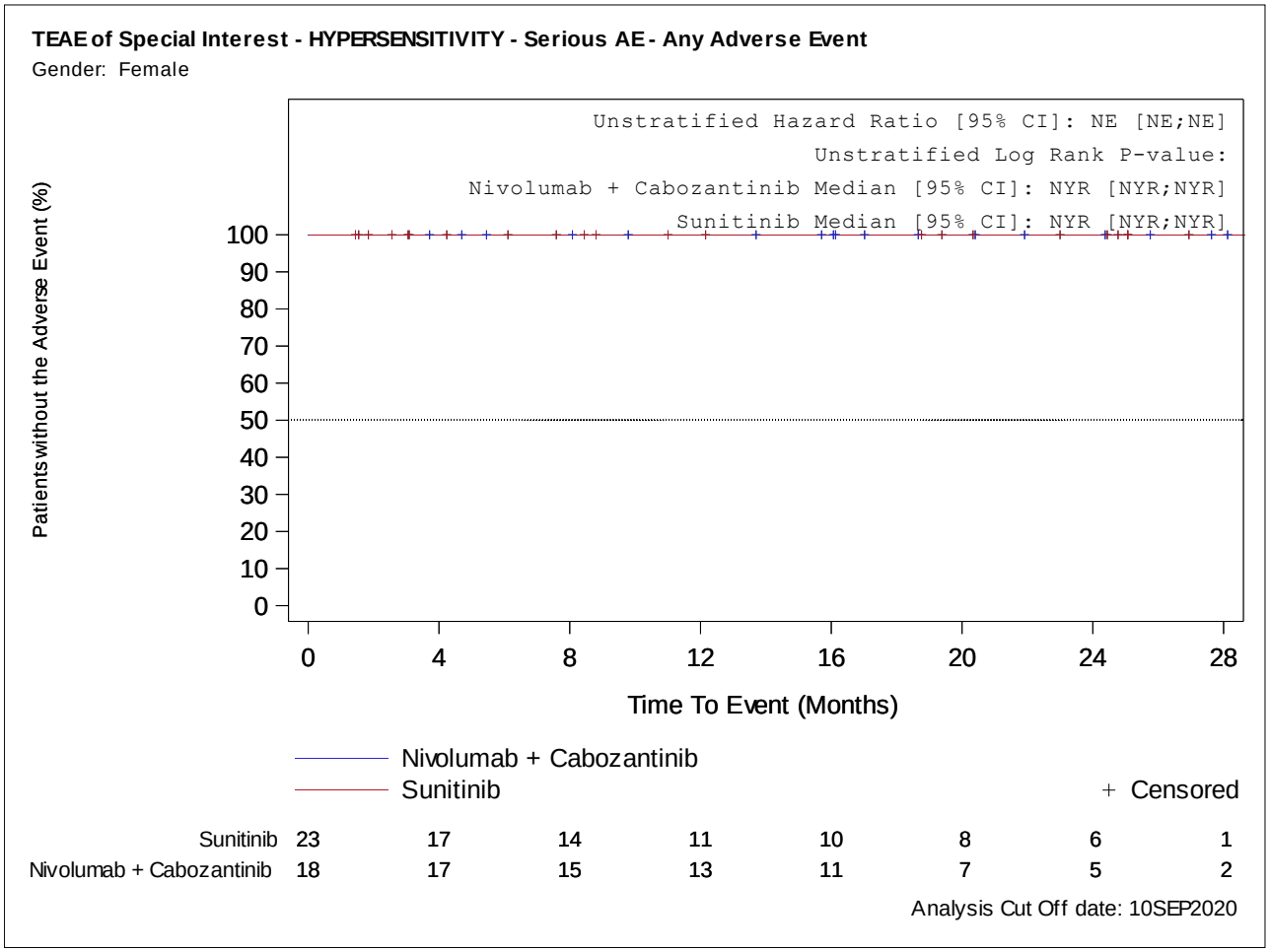

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:08:15

FIGURE 3.87.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:08:21

FIGURE 3.87.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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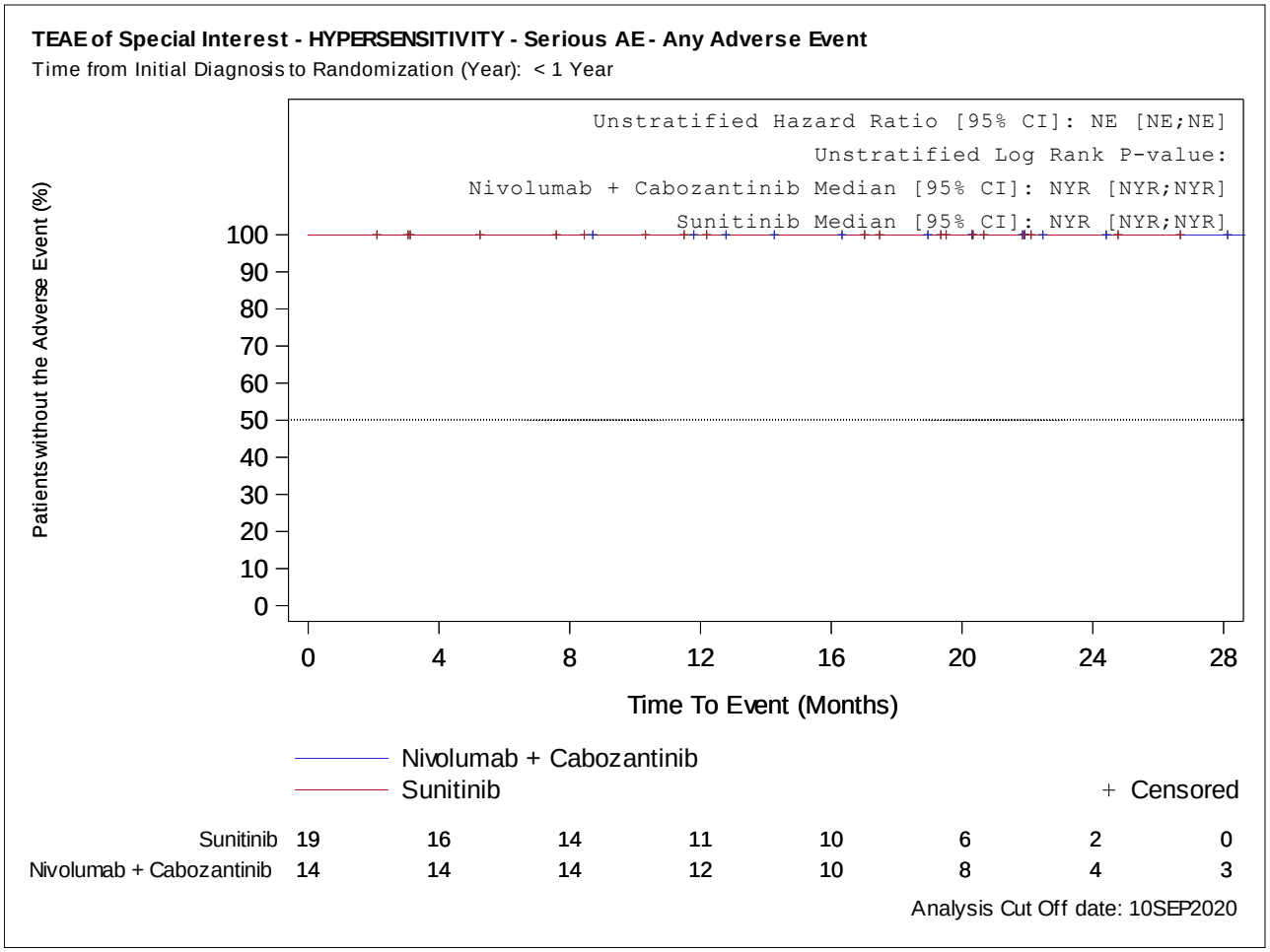
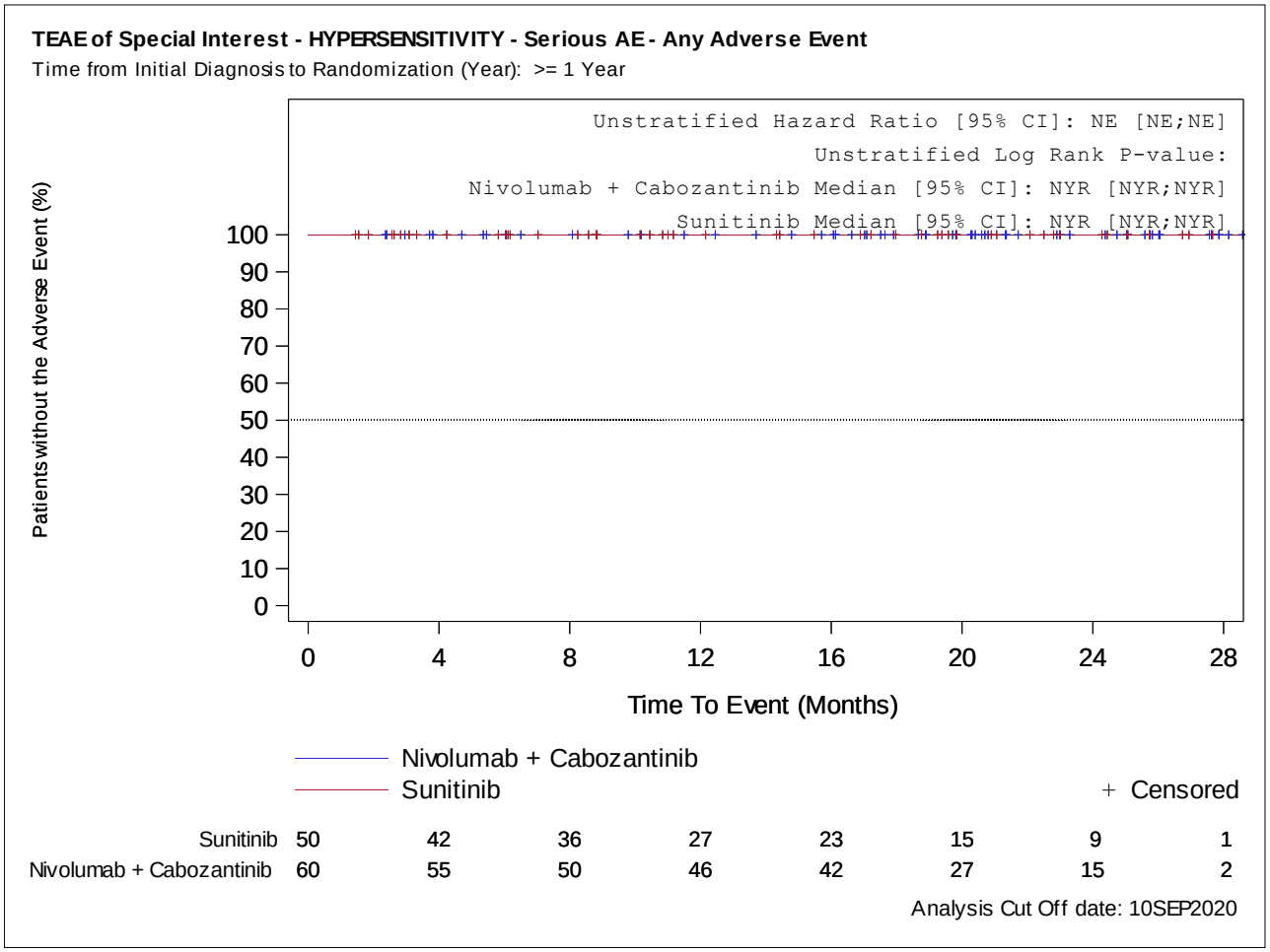
FIGURE 3.87.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:08:42

FIGURE 3.87.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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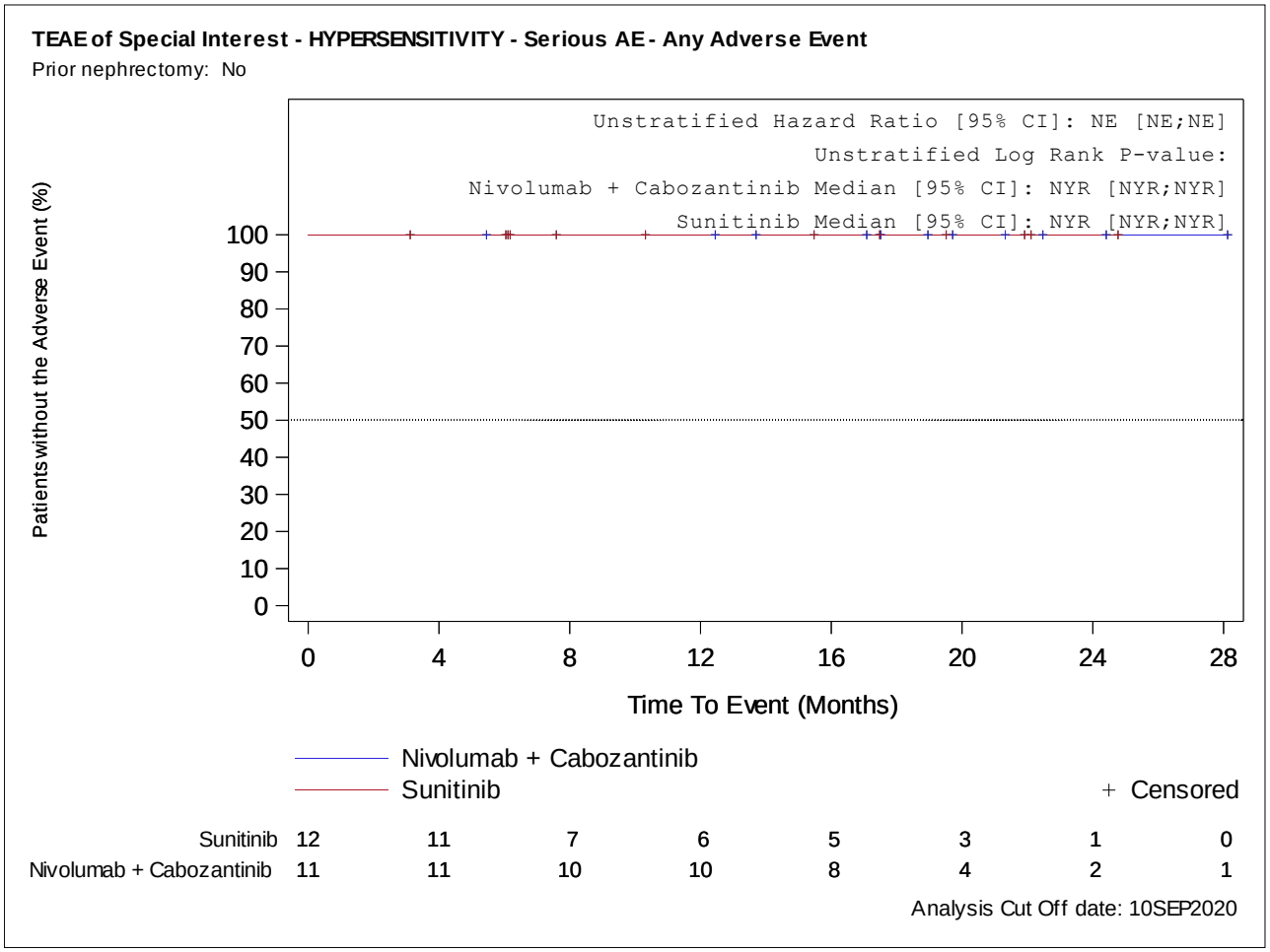
FIGURE 3.87.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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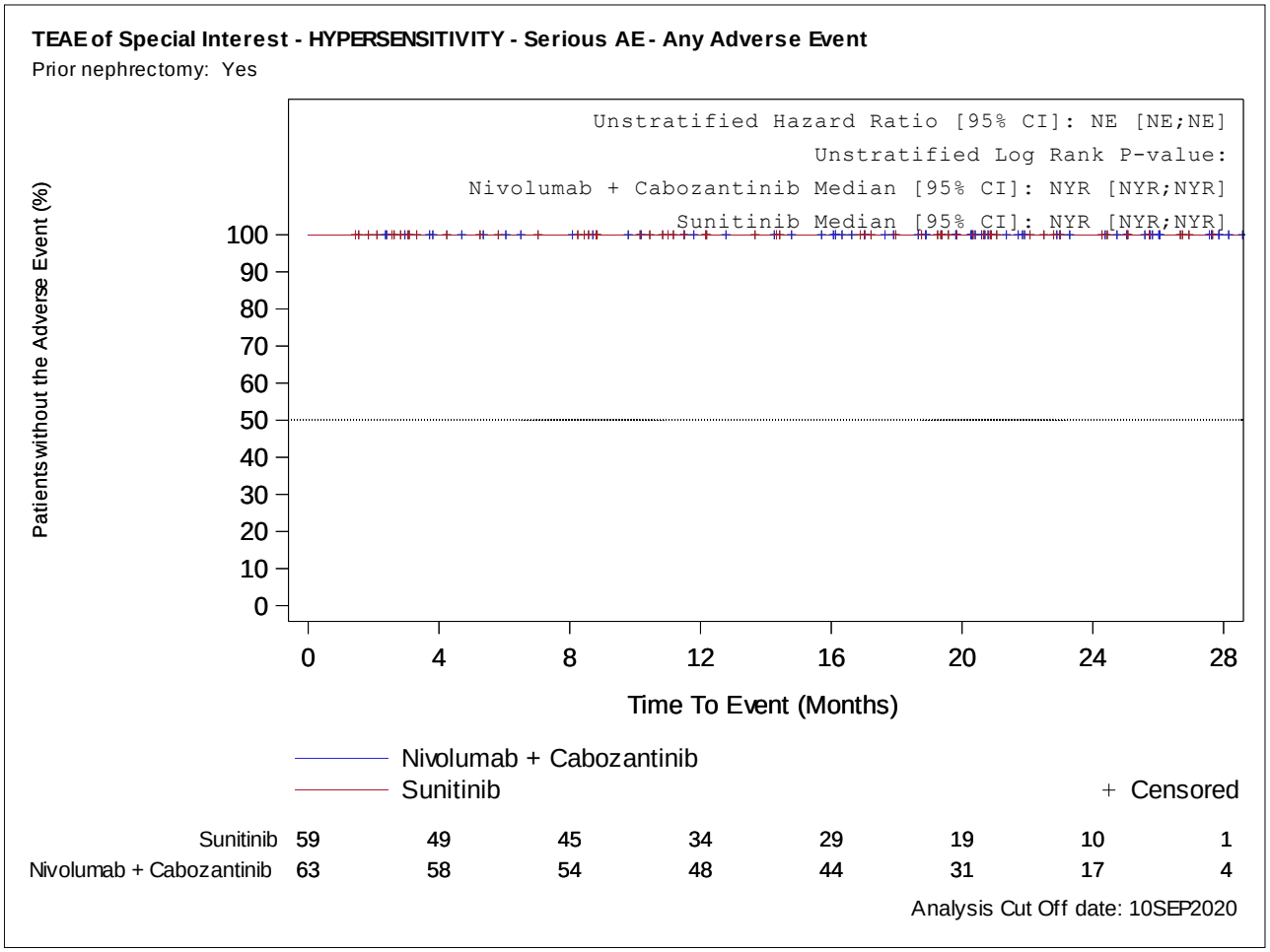
FIGURE 3.87.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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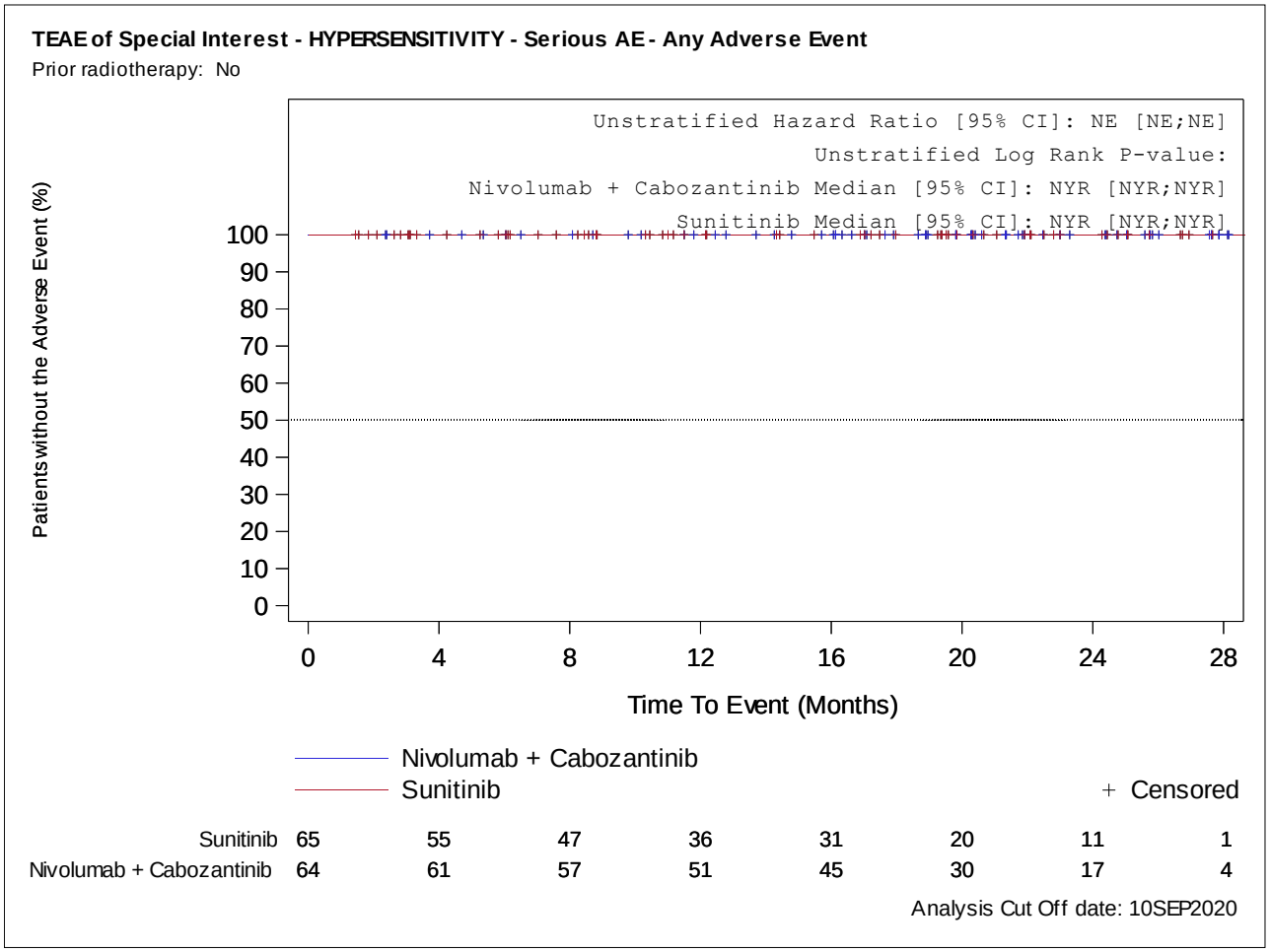
FIGURE 3.87.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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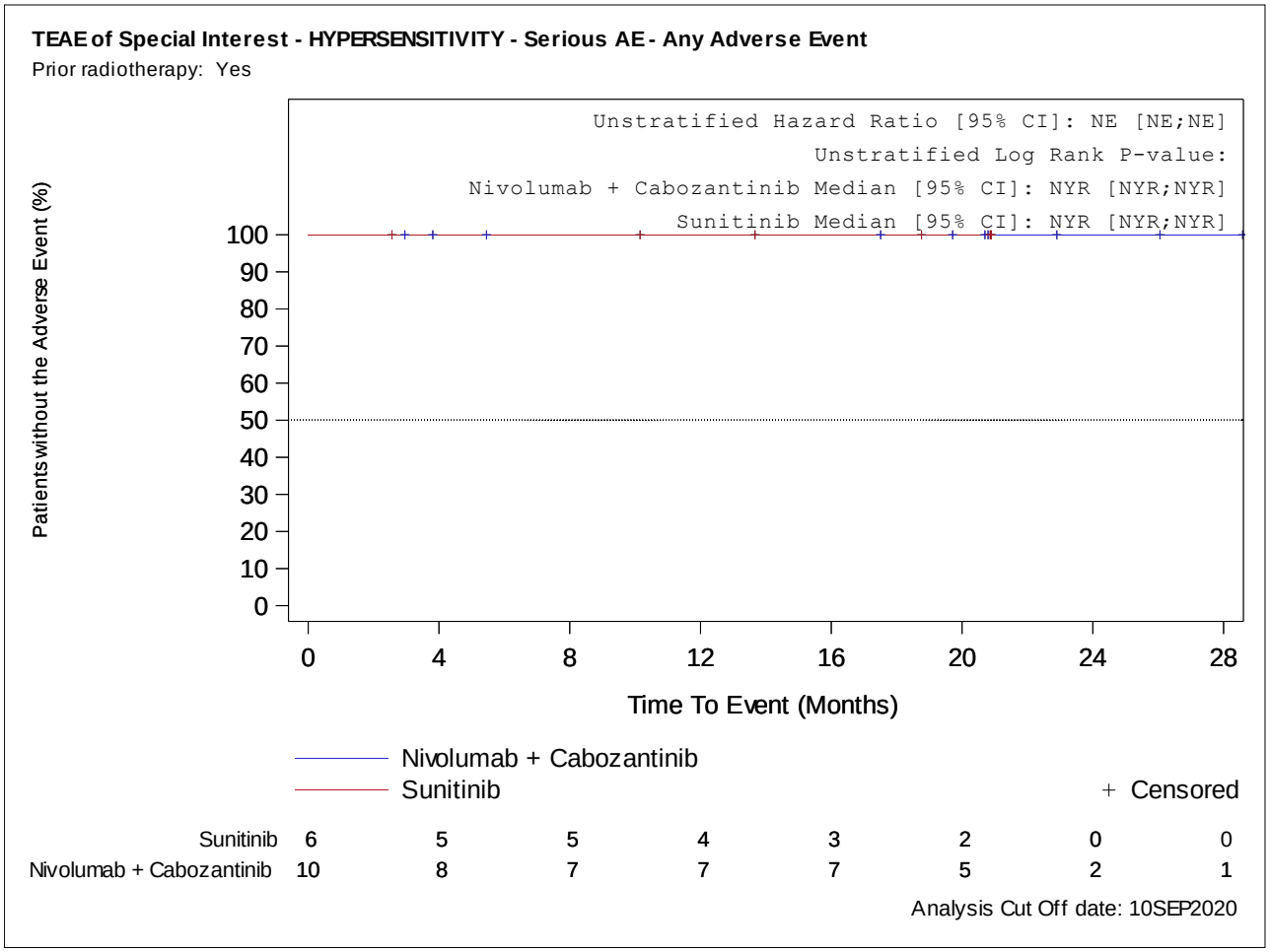
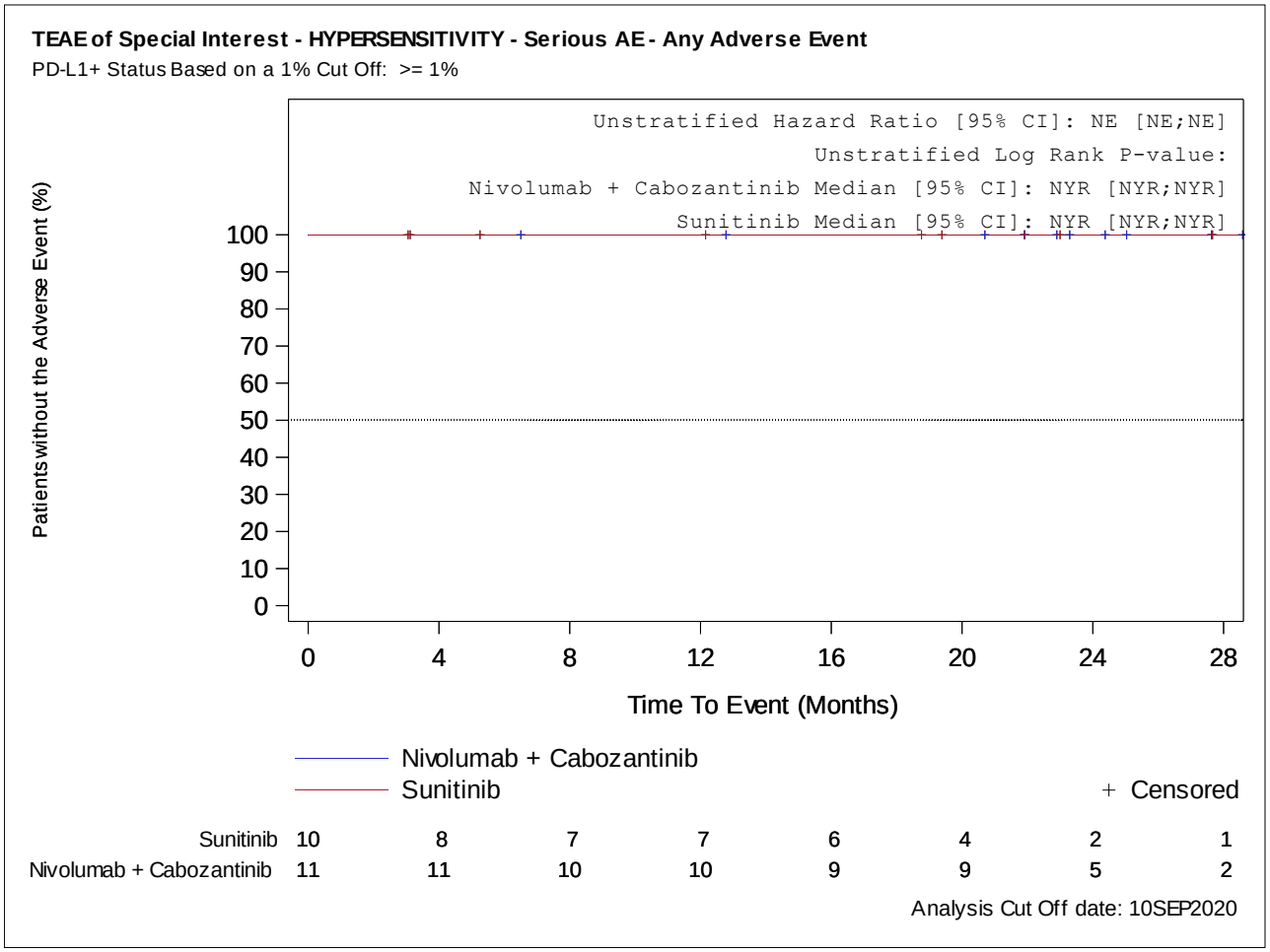
FIGURE 3.87.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



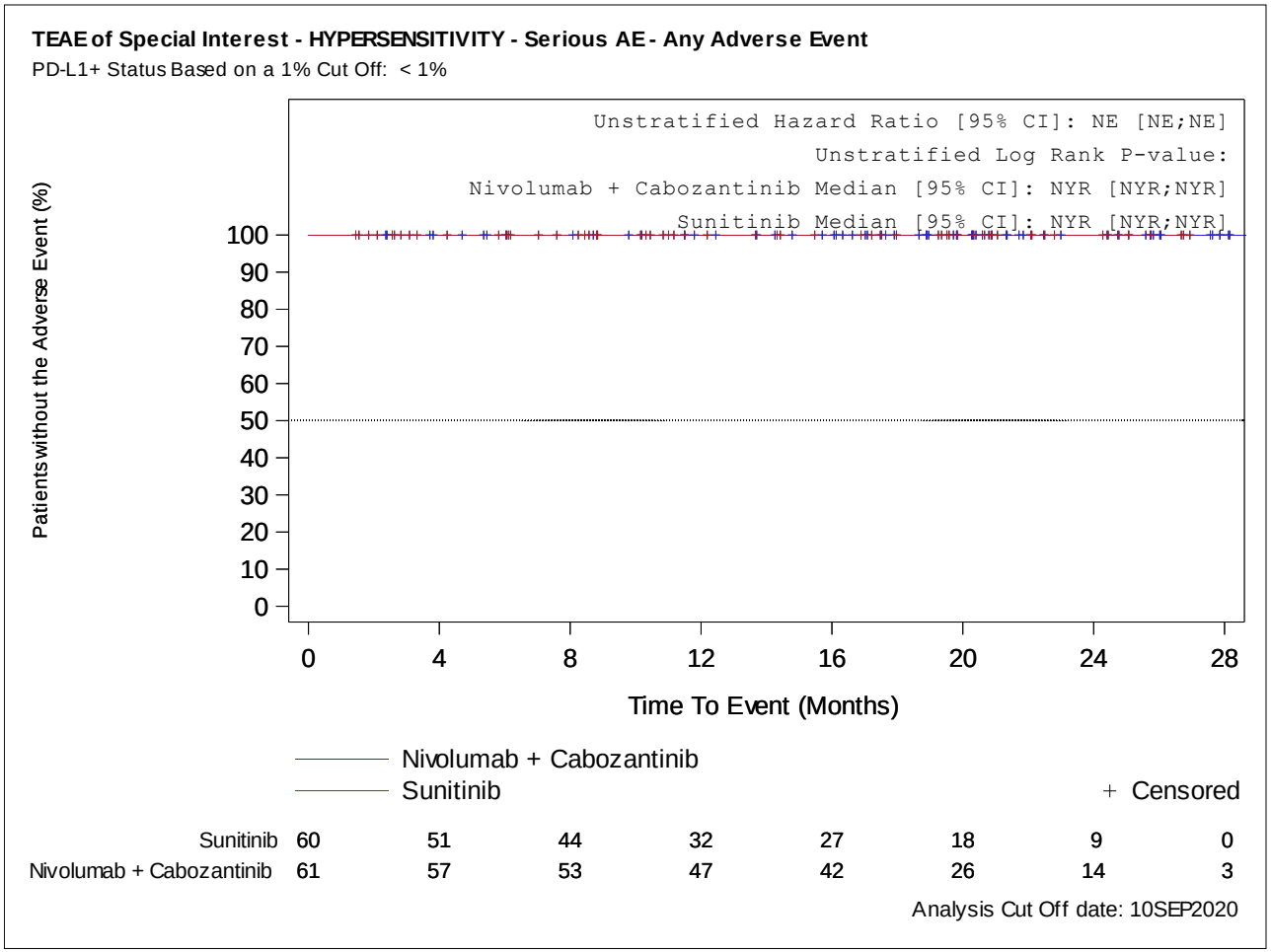

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:09:51

FIGURE 3.87.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



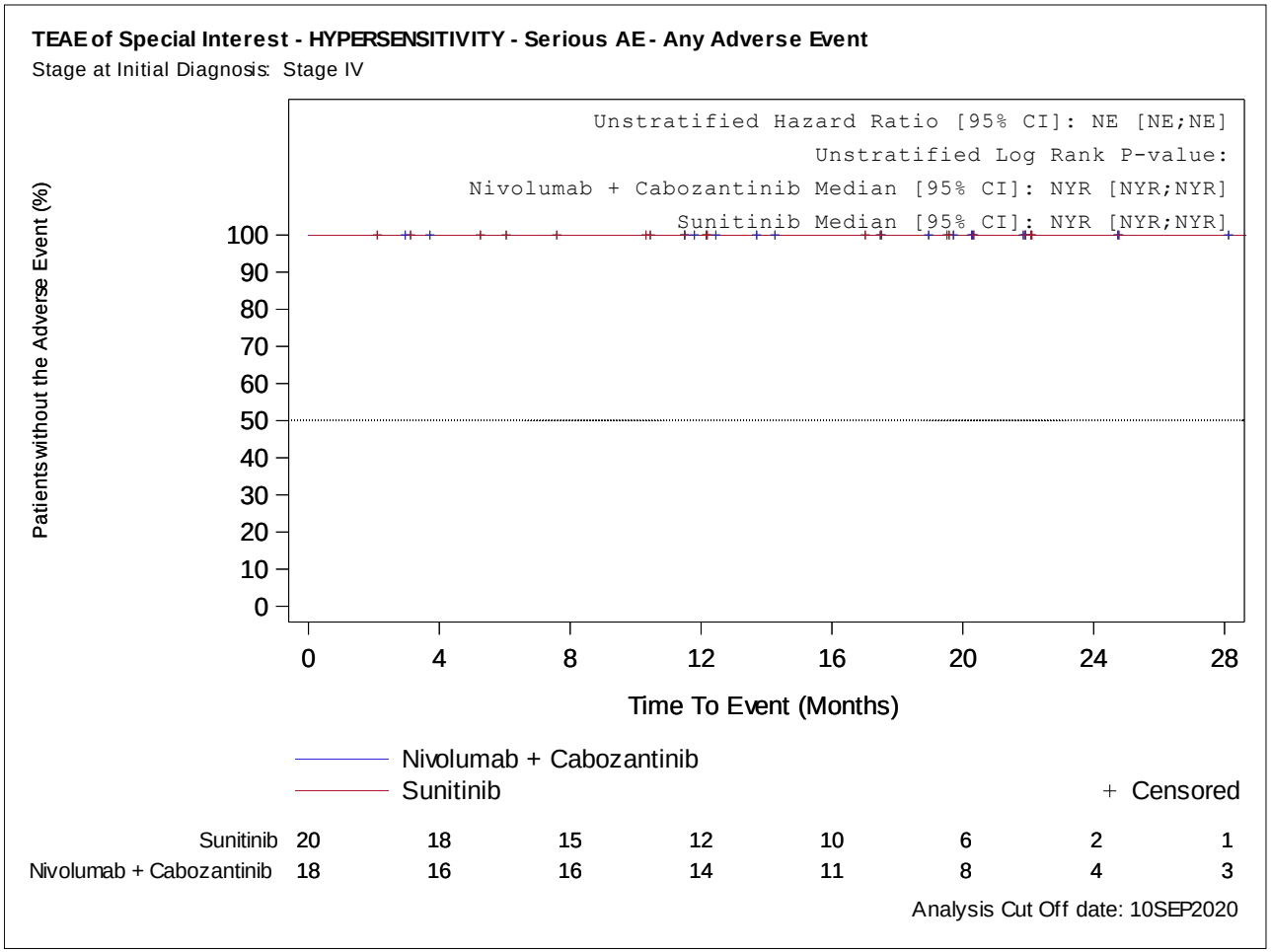

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:09:56

FIGURE 3.87.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



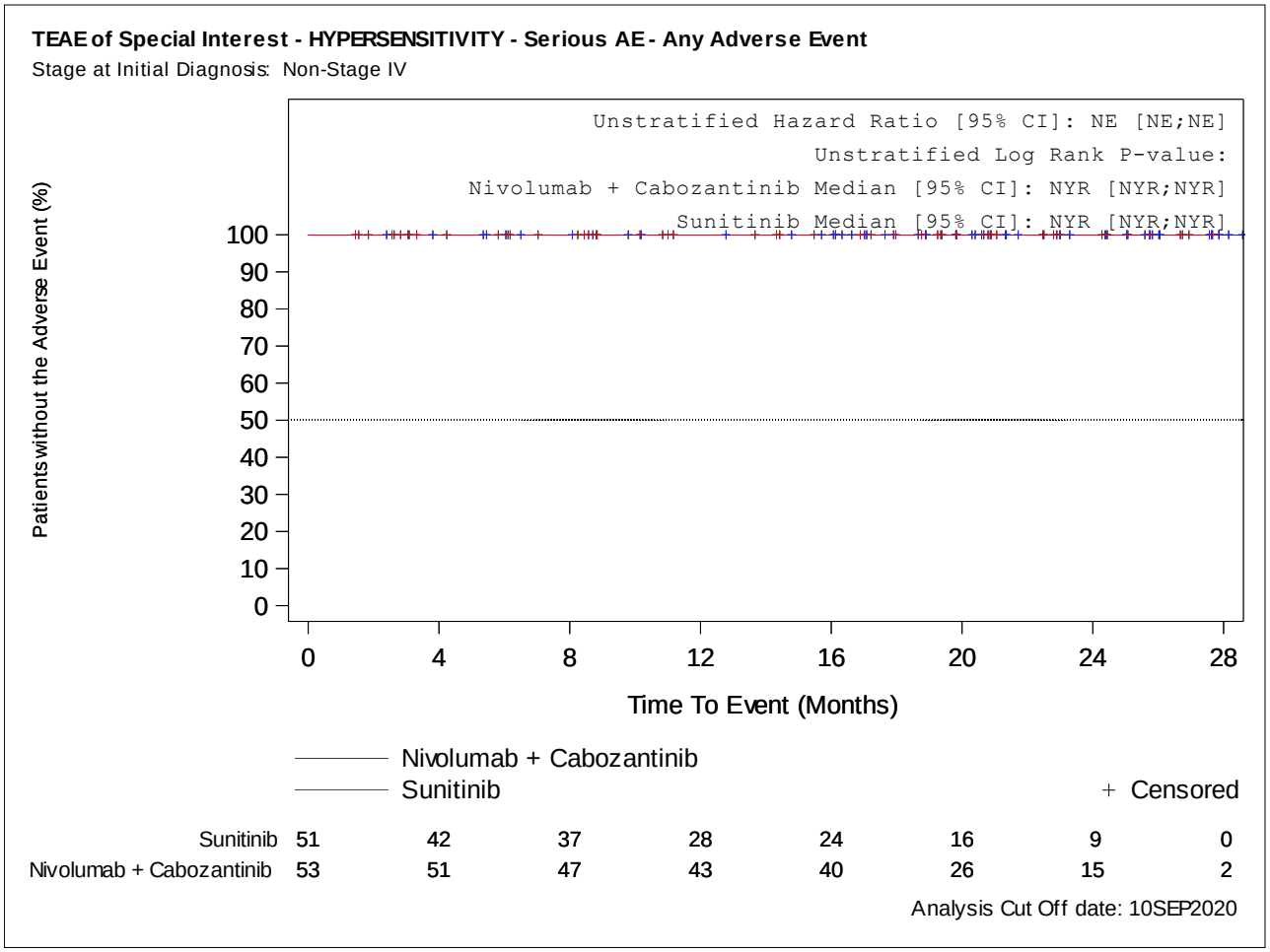

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:10:02

FIGURE 3.87.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:10:27

FIGURE 3.87.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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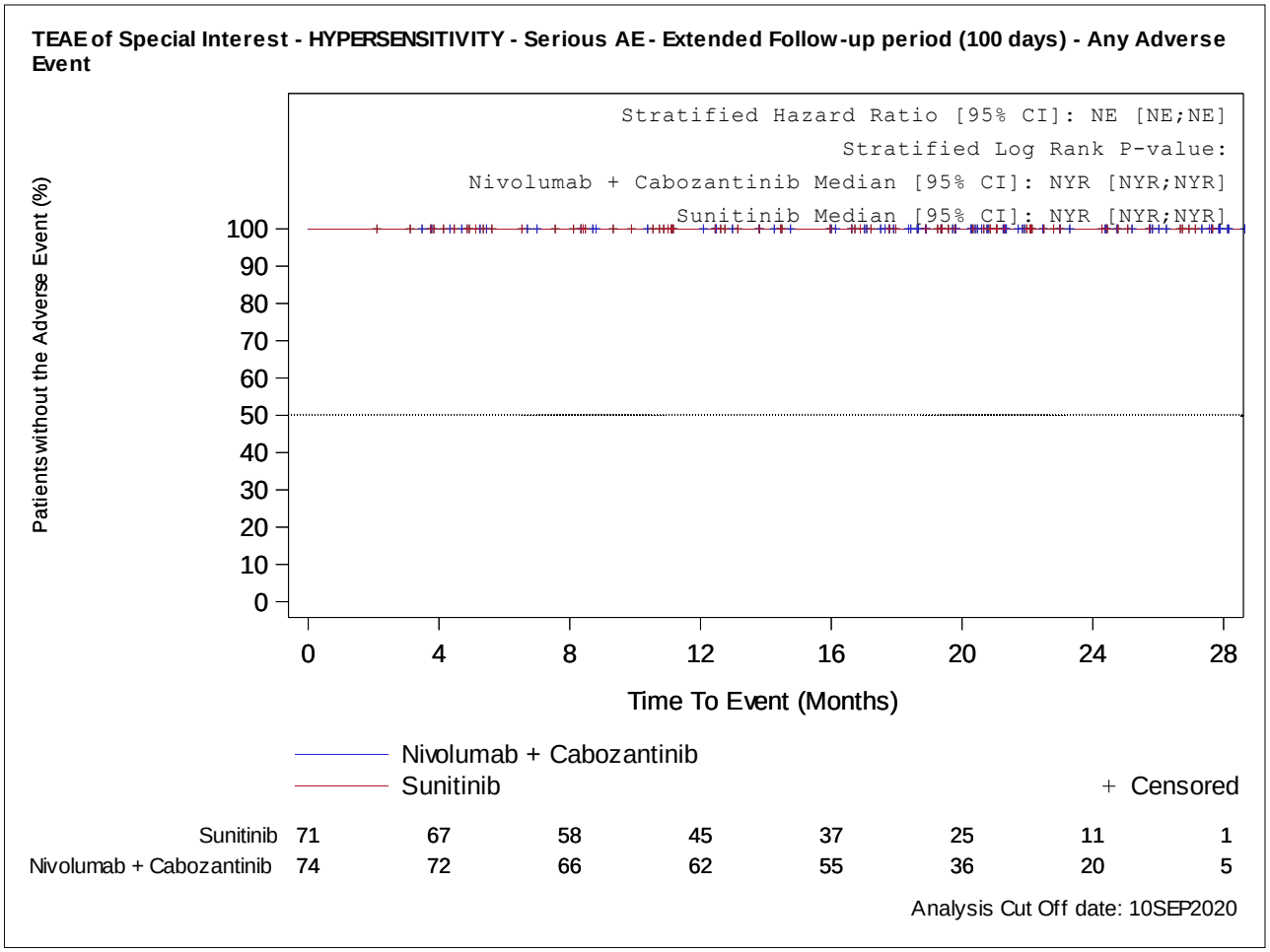
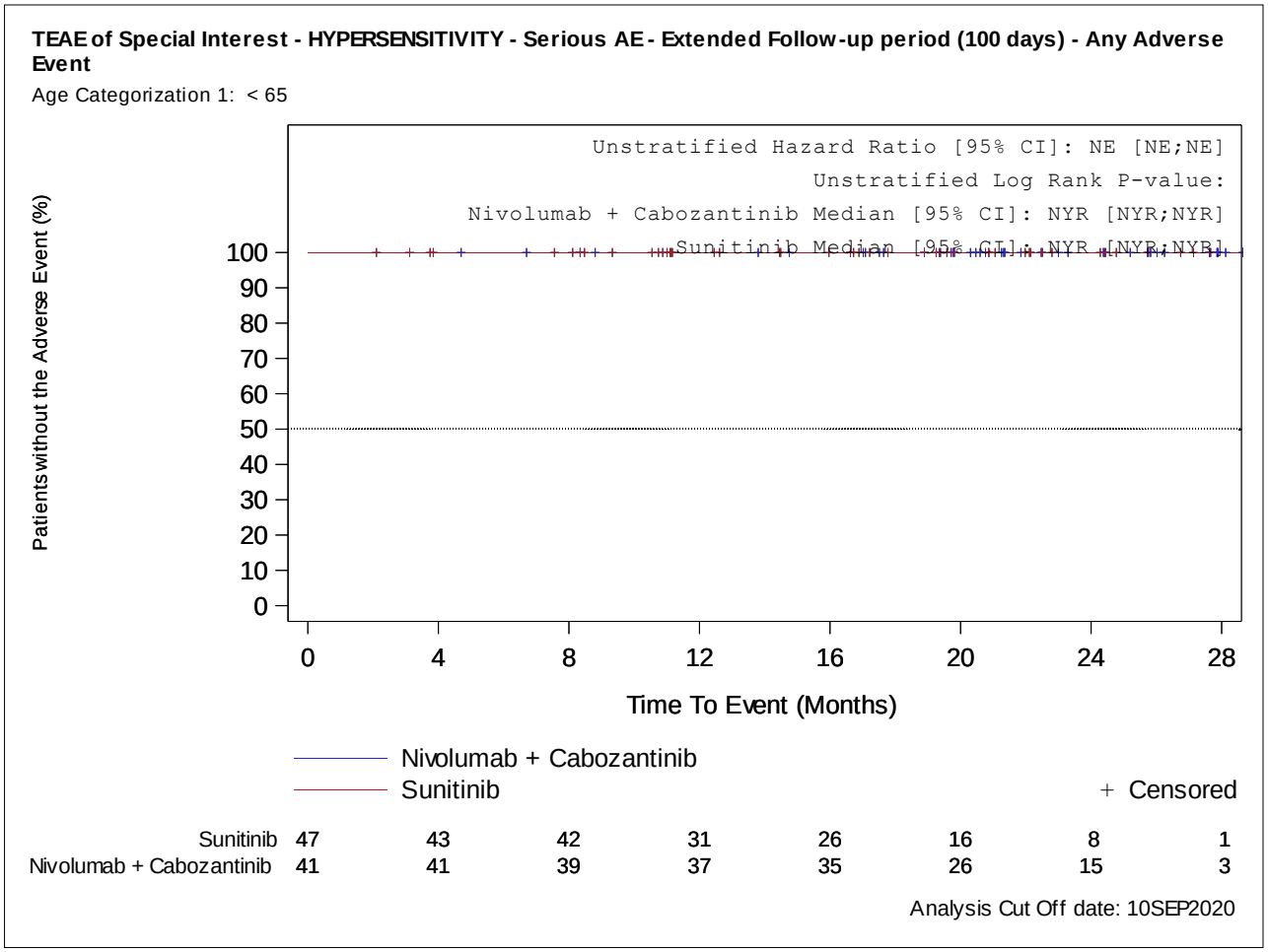
FIGURE 3.88.1: TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



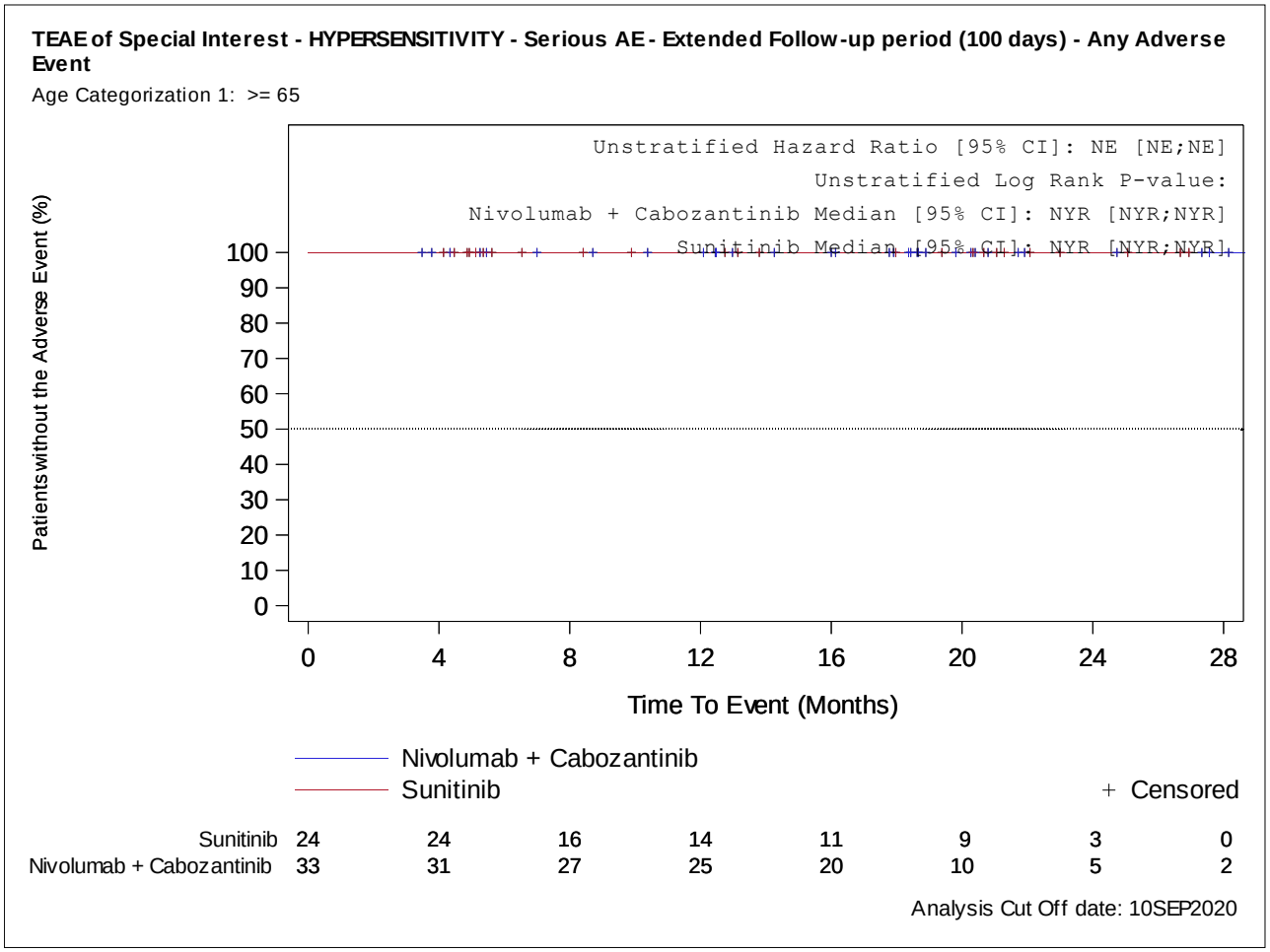

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:13:28

FIGURE 3.88.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



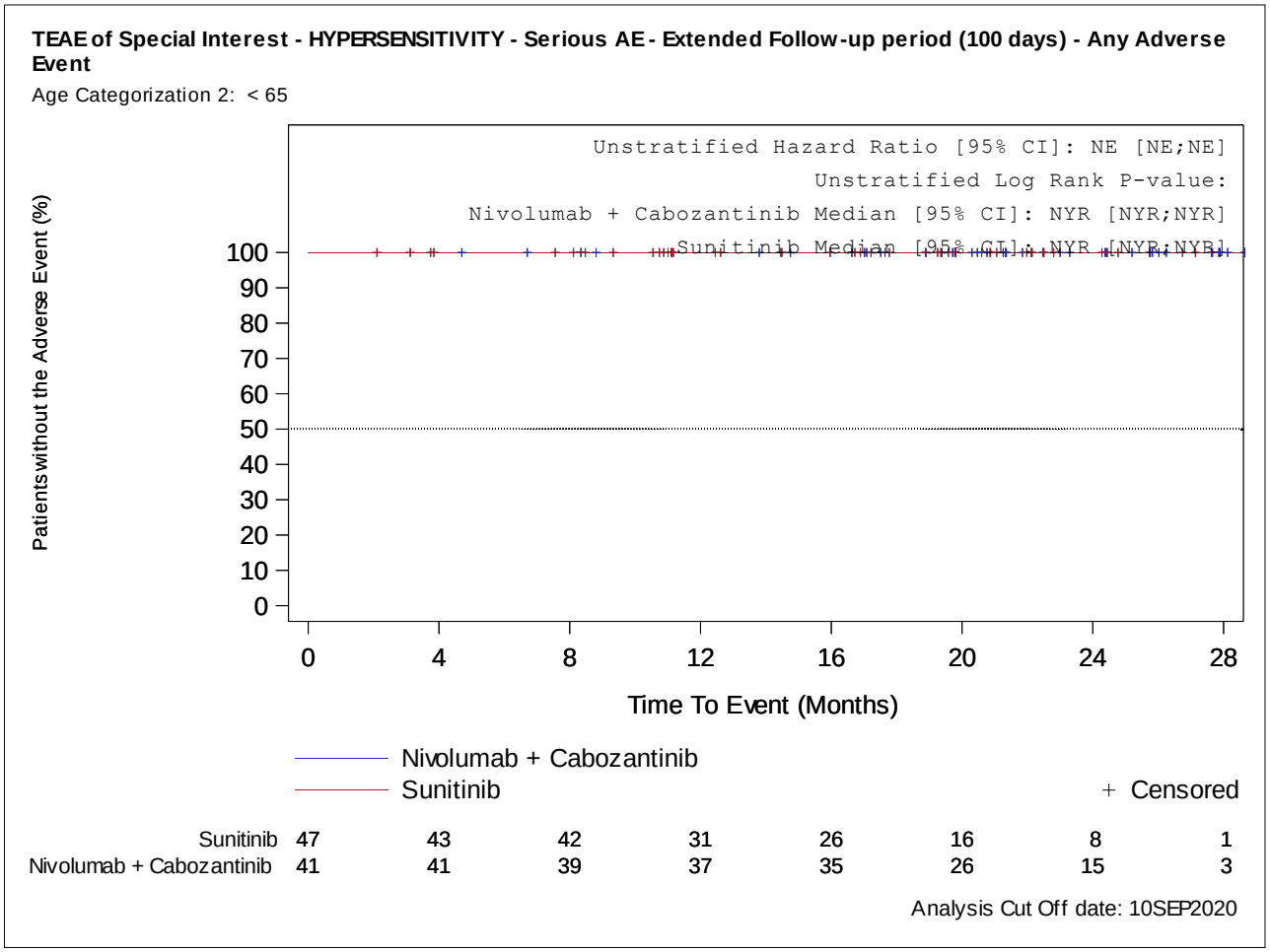

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:13:31

FIGURE 3.88.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



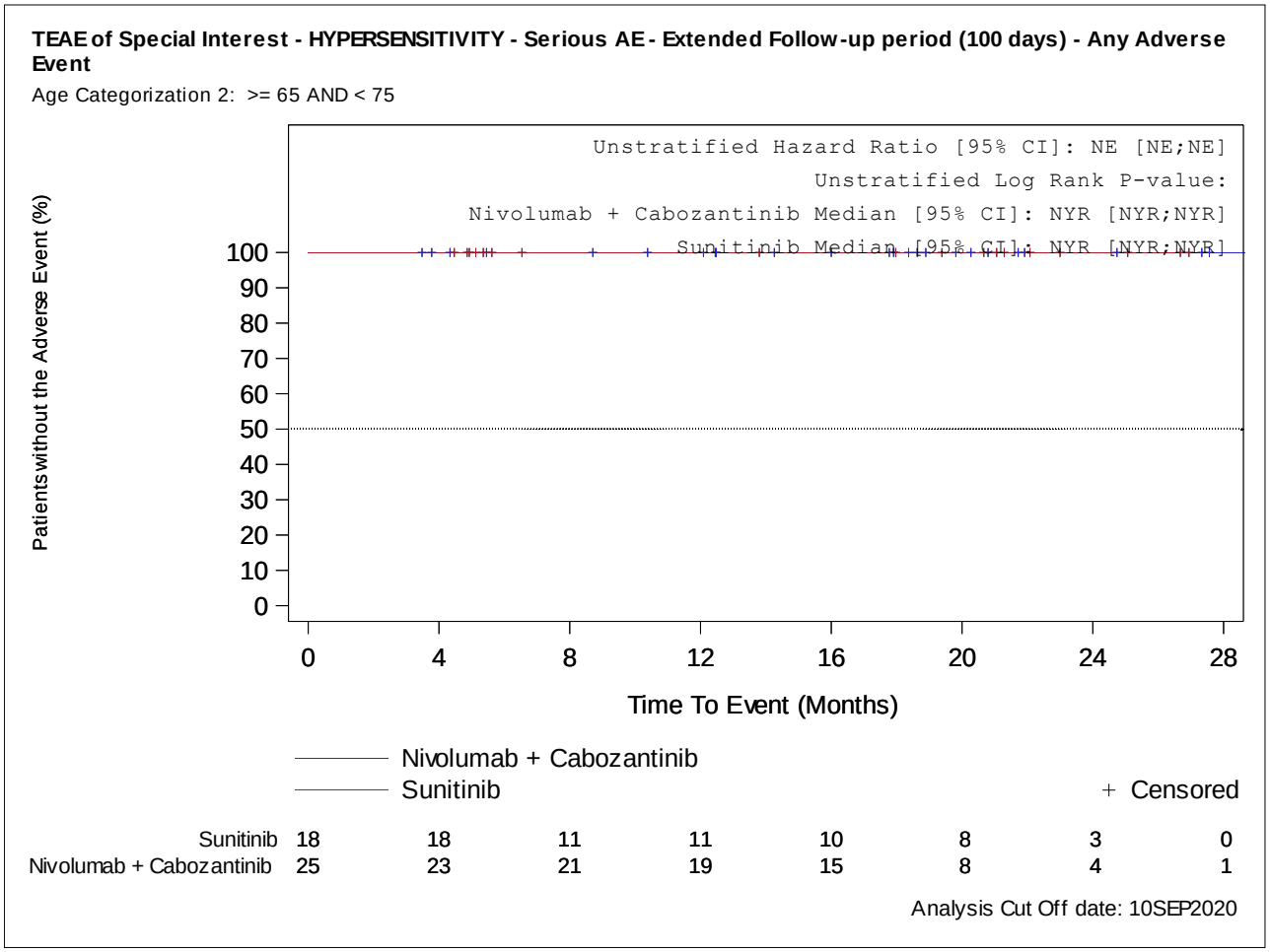

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:13:37

FIGURE 3.88.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



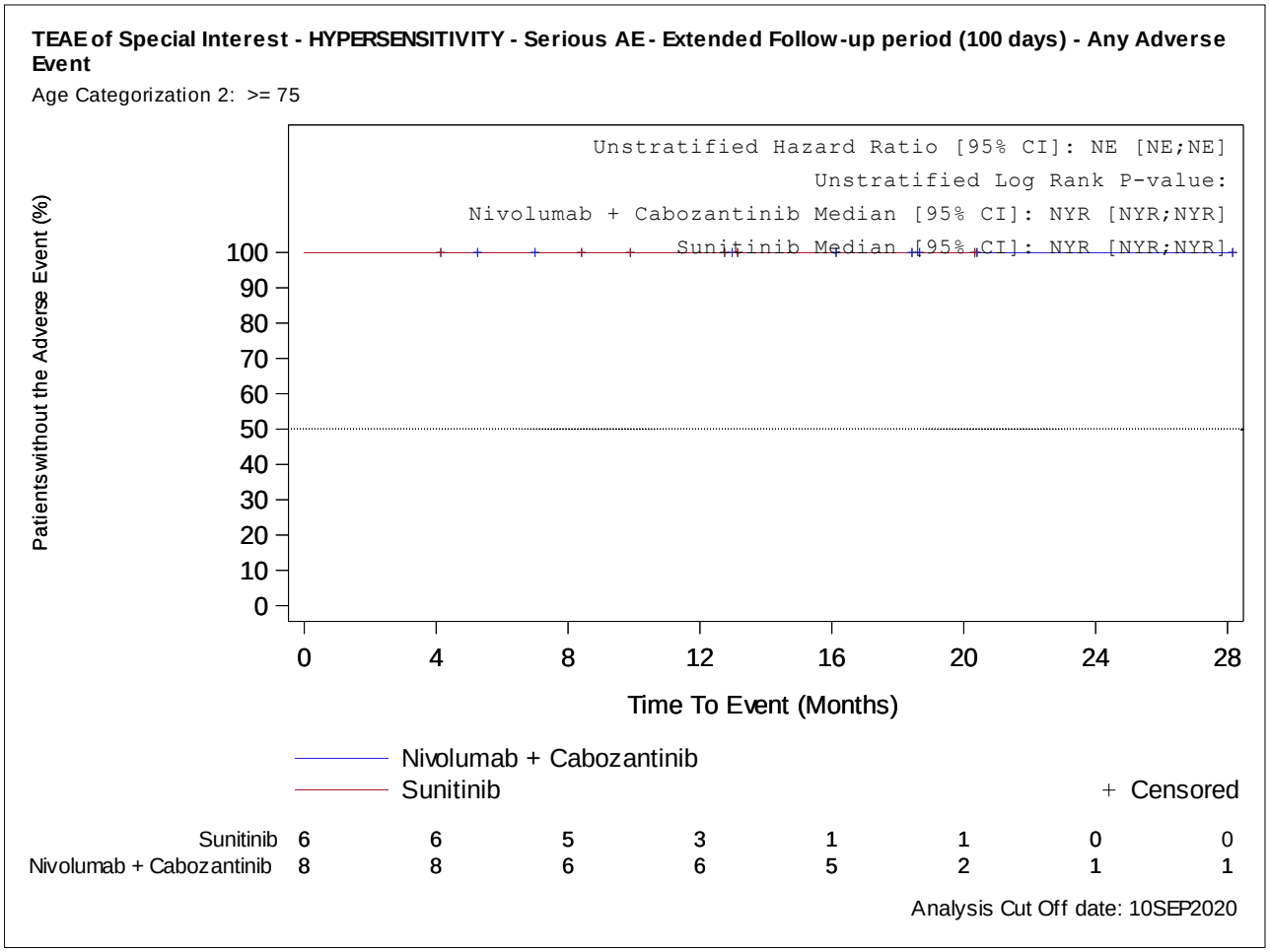

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:13:42

FIGURE 3.88.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



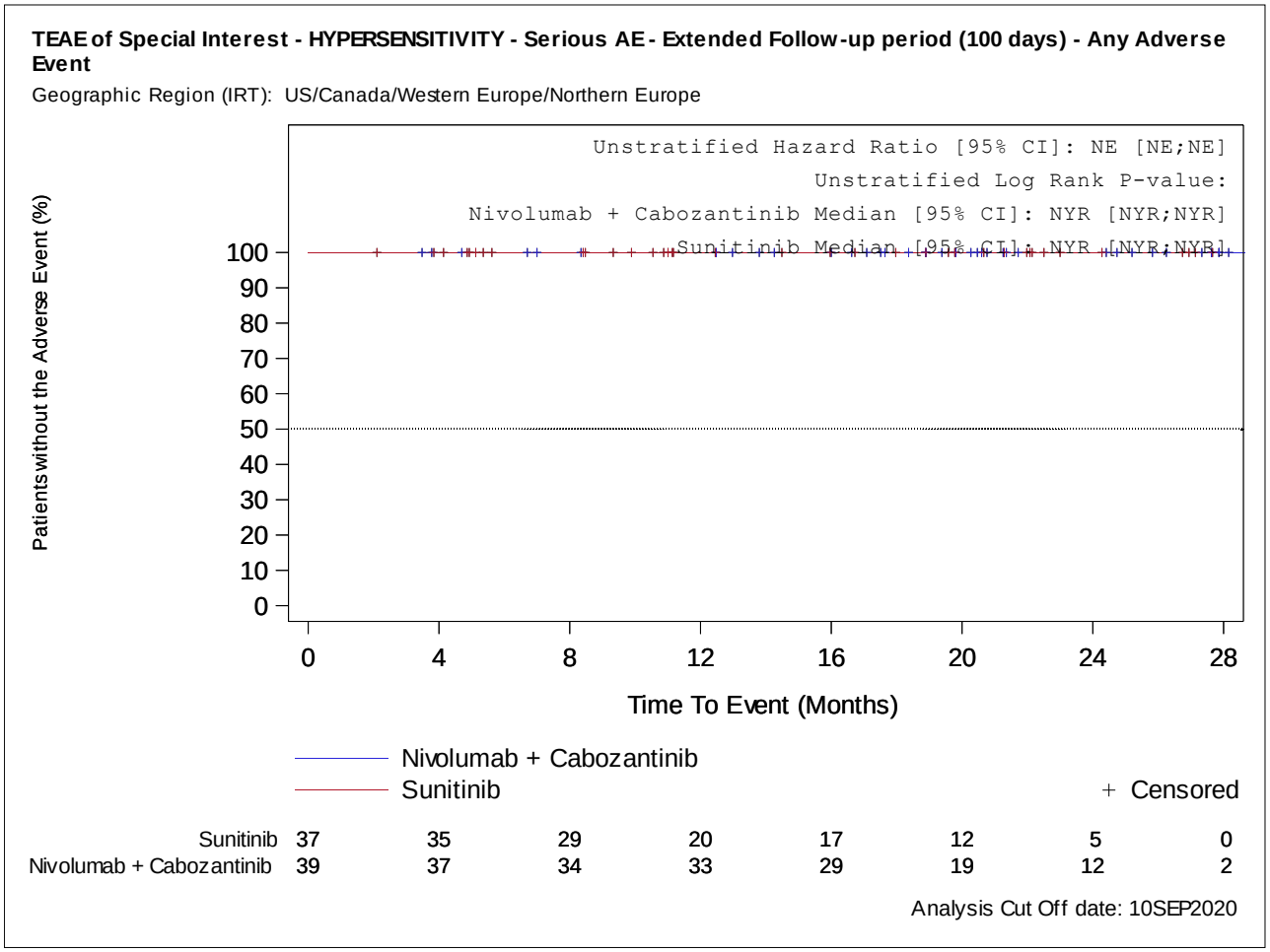

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:13:47

FIGURE 3.88.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



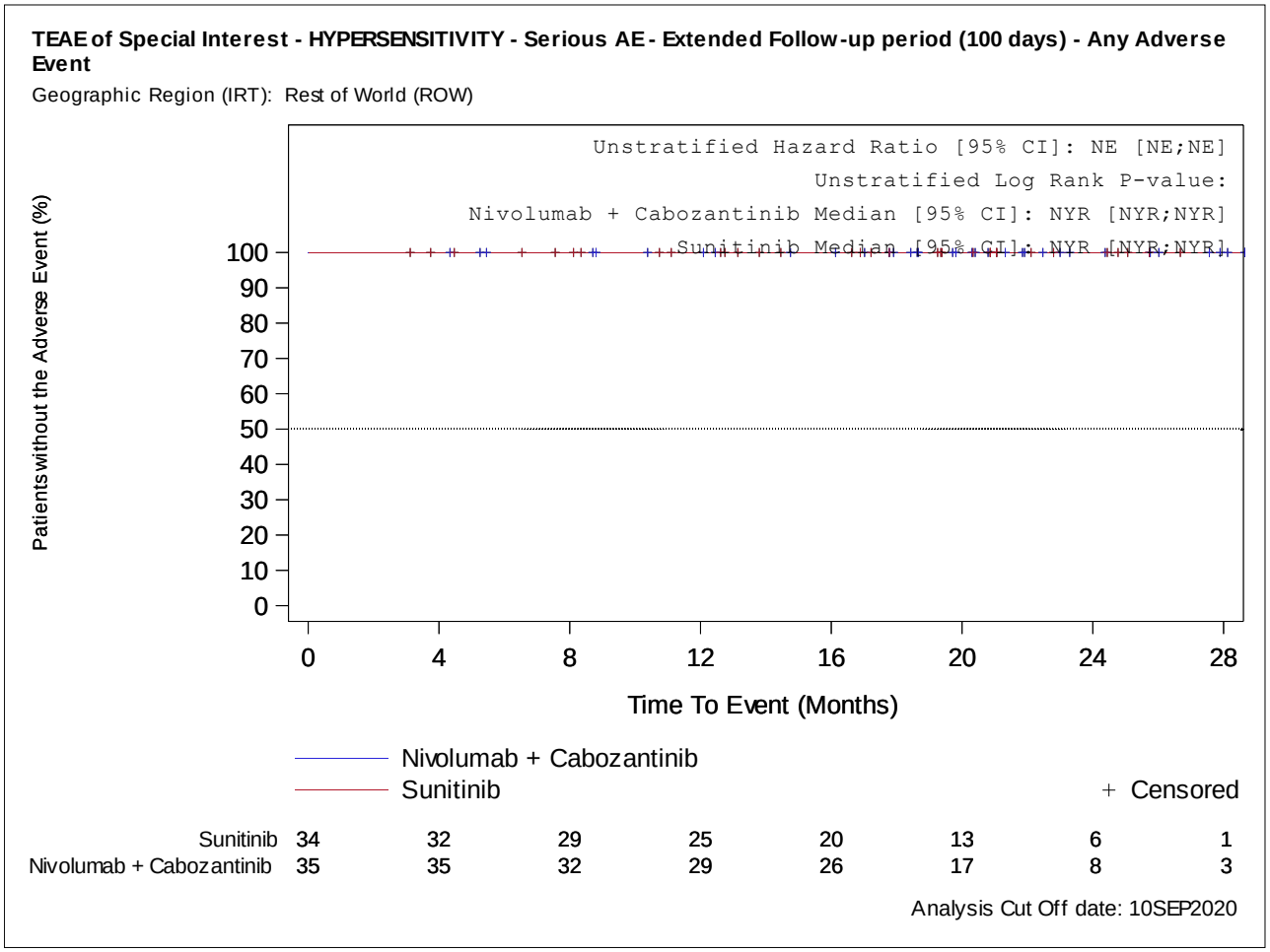

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:13:52

FIGURE 3.88.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



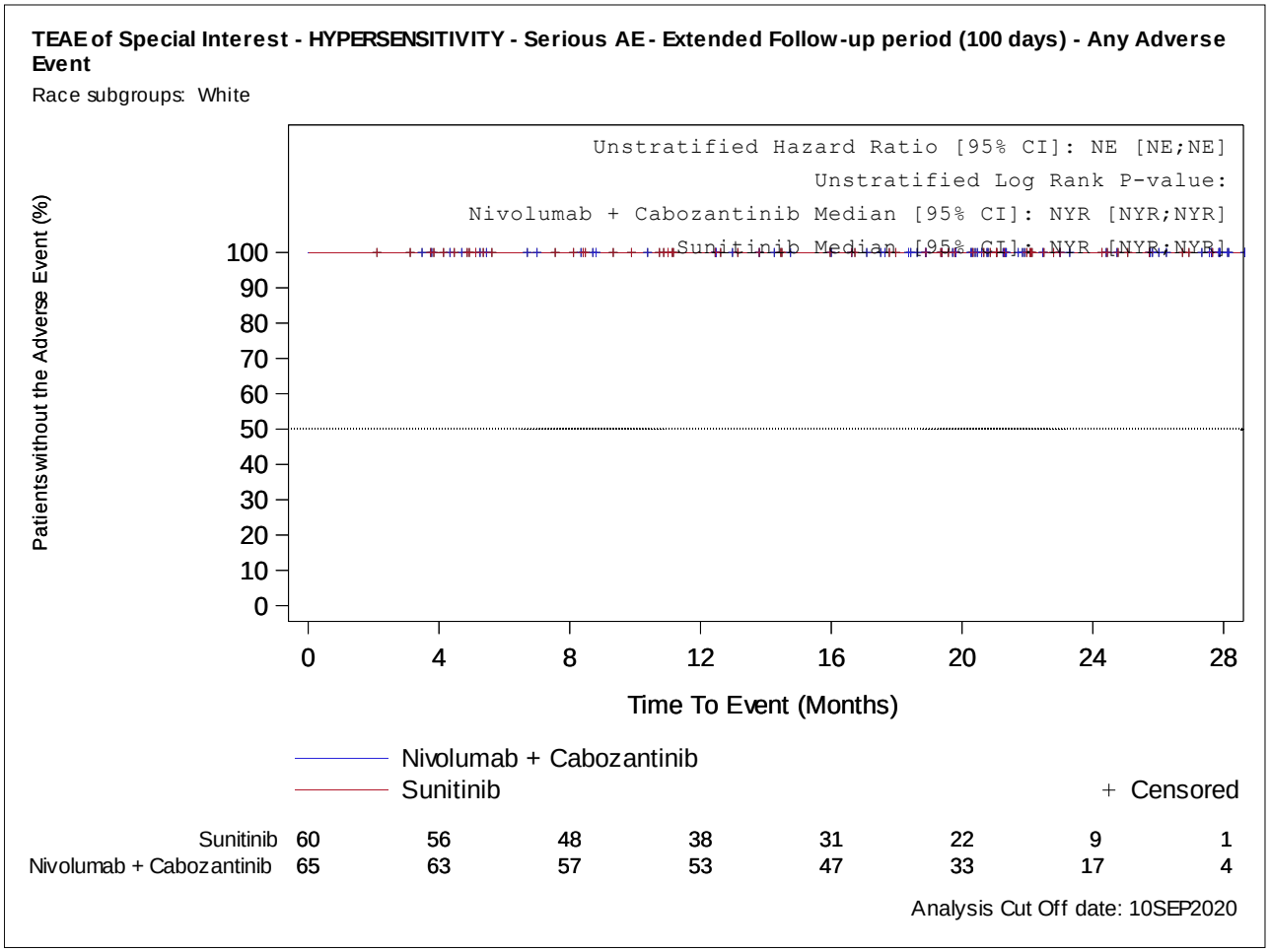

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:13:58

FIGURE 3.88.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



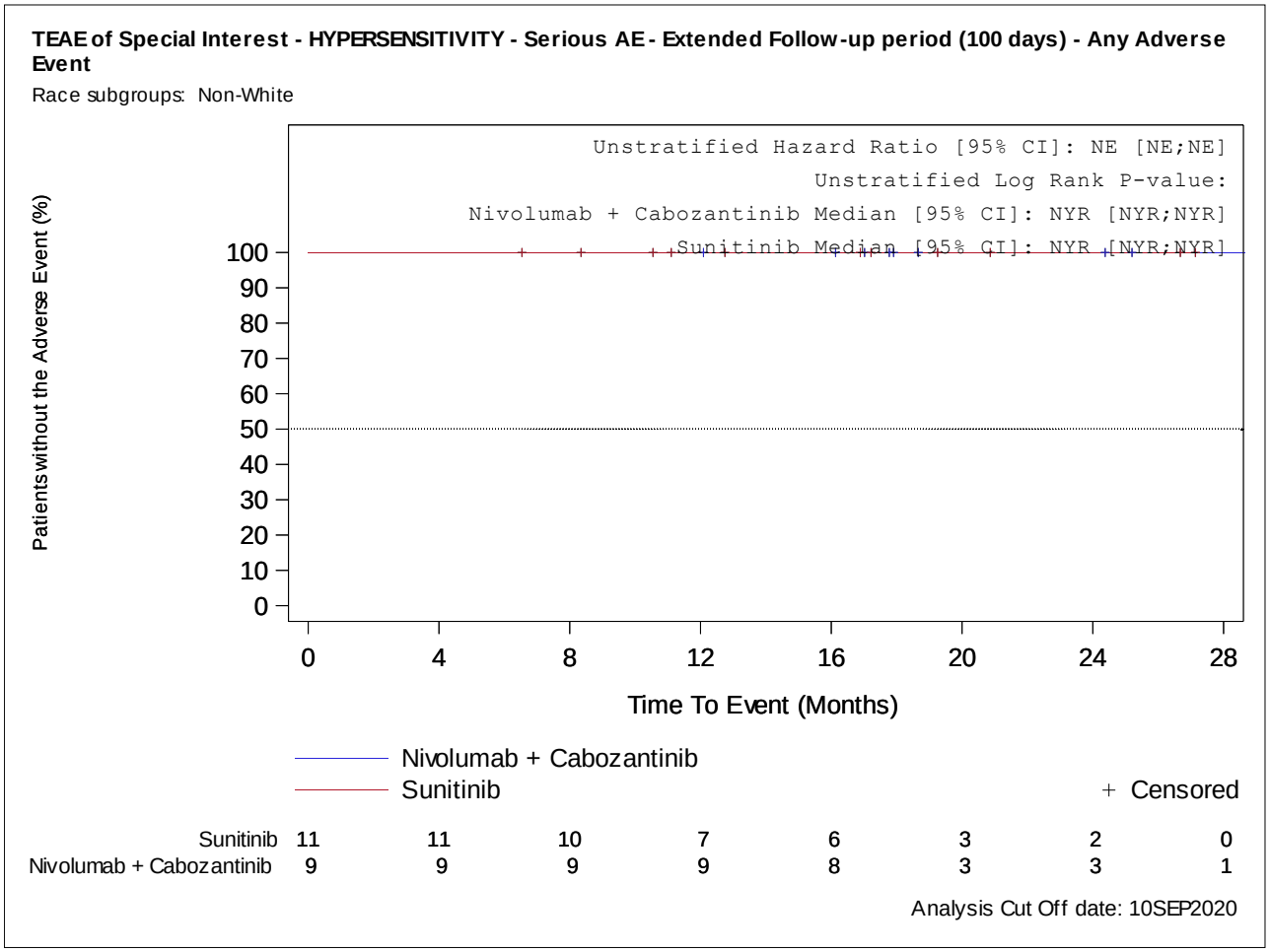

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:14:03

FIGURE 3.88.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



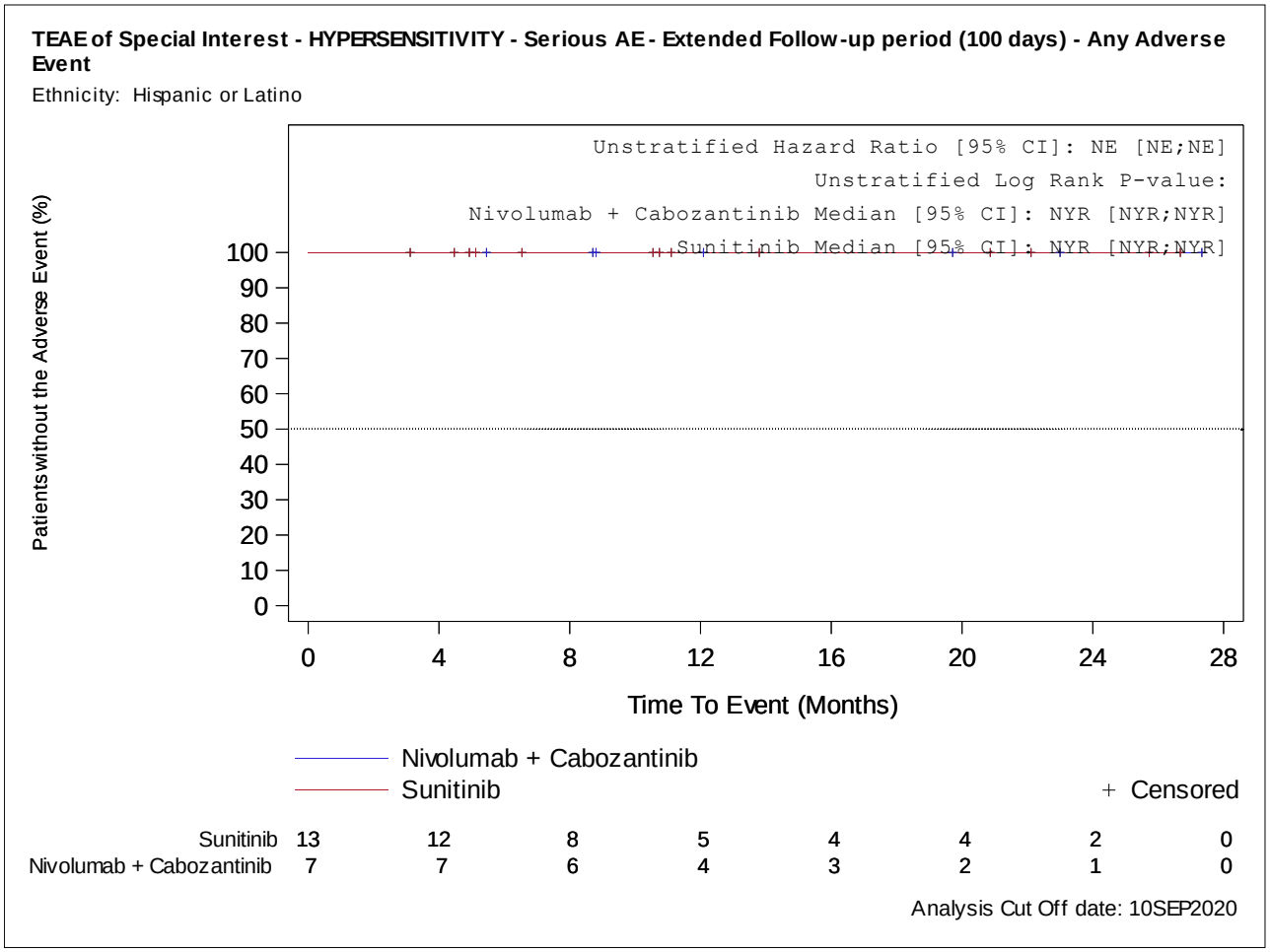

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:14:08

FIGURE 3.88.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



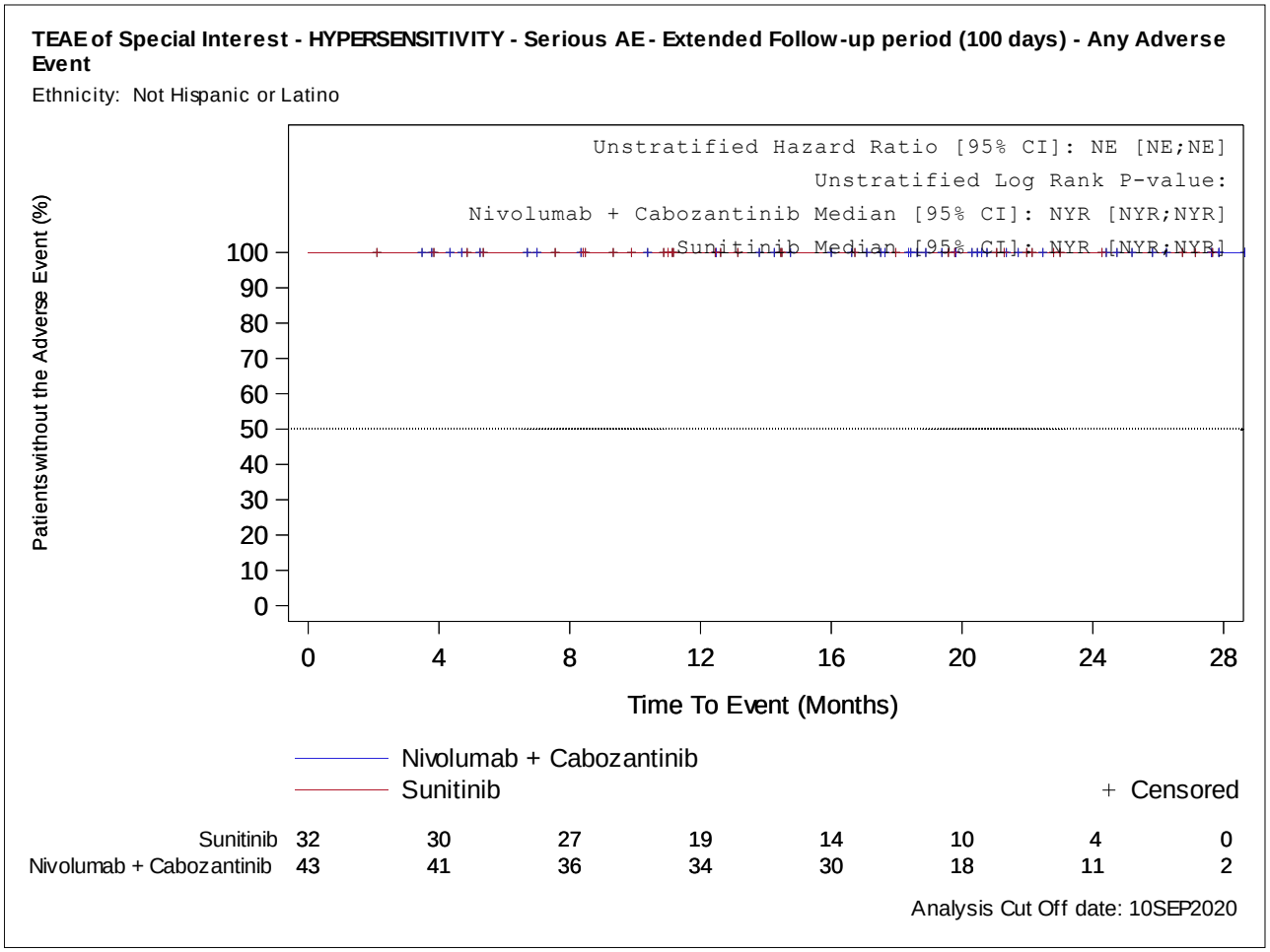

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:14:13

FIGURE 3.88.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



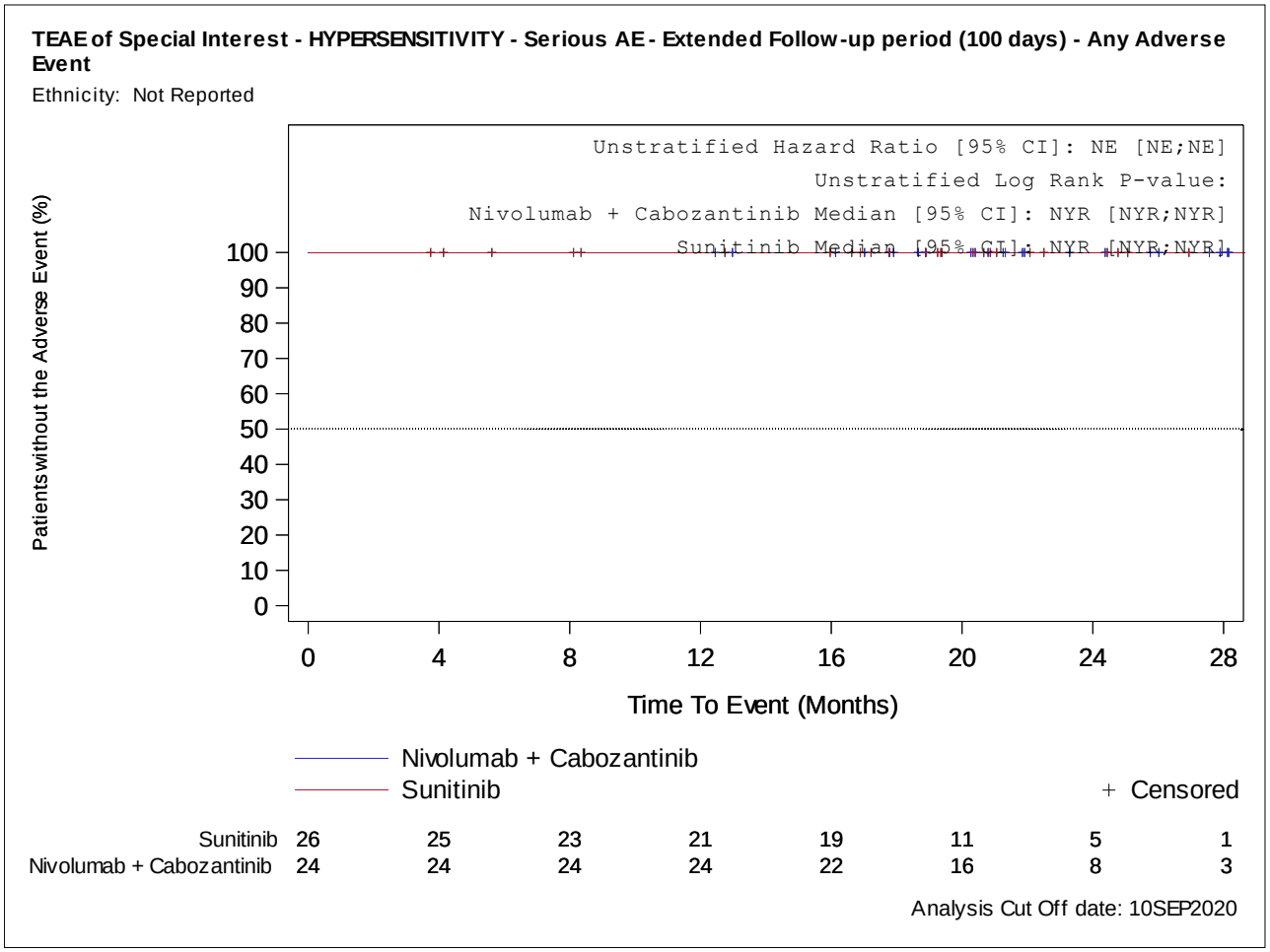

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:14:18

FIGURE 3.88.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



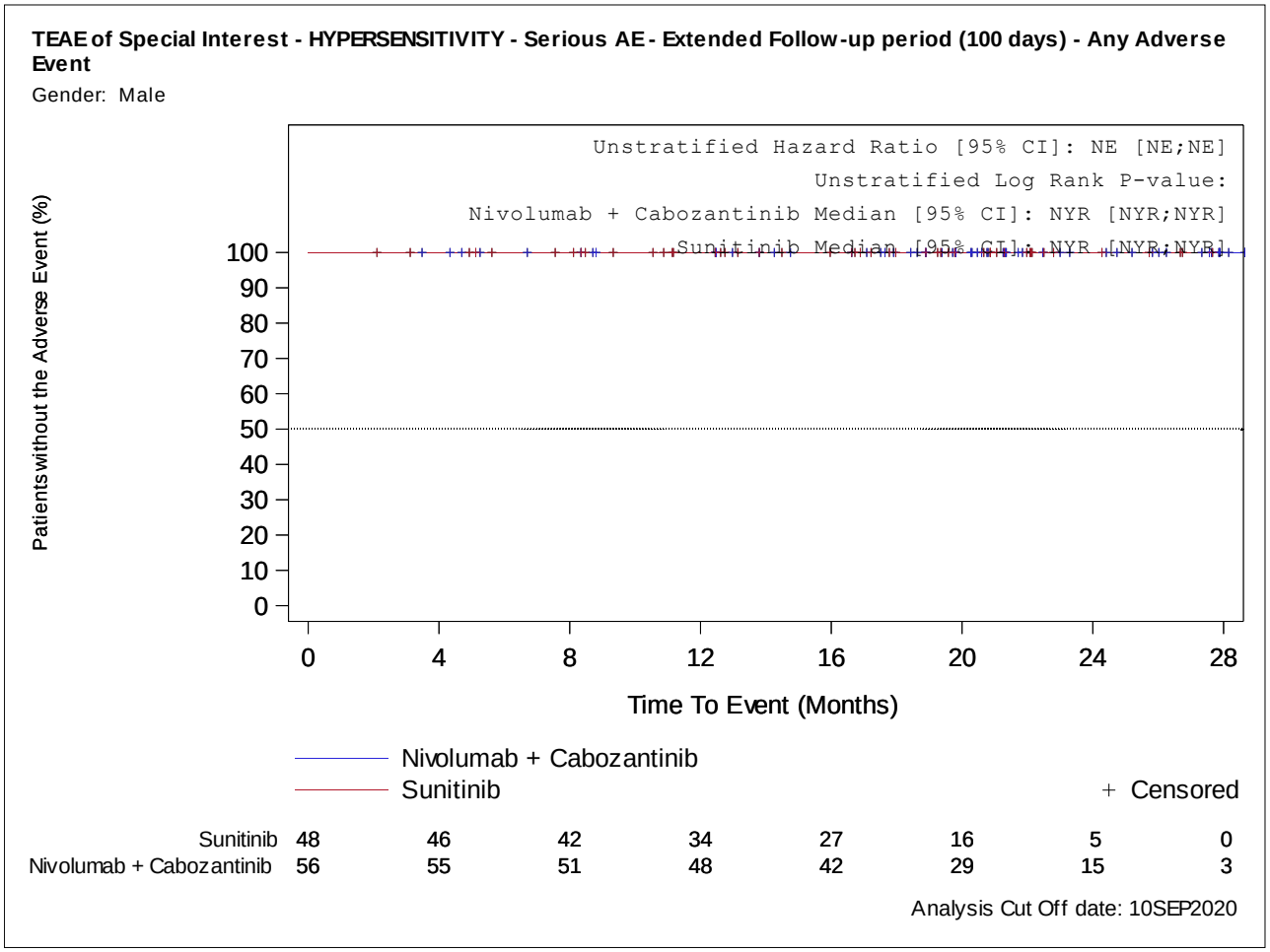

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:14:23

FIGURE 3.88.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



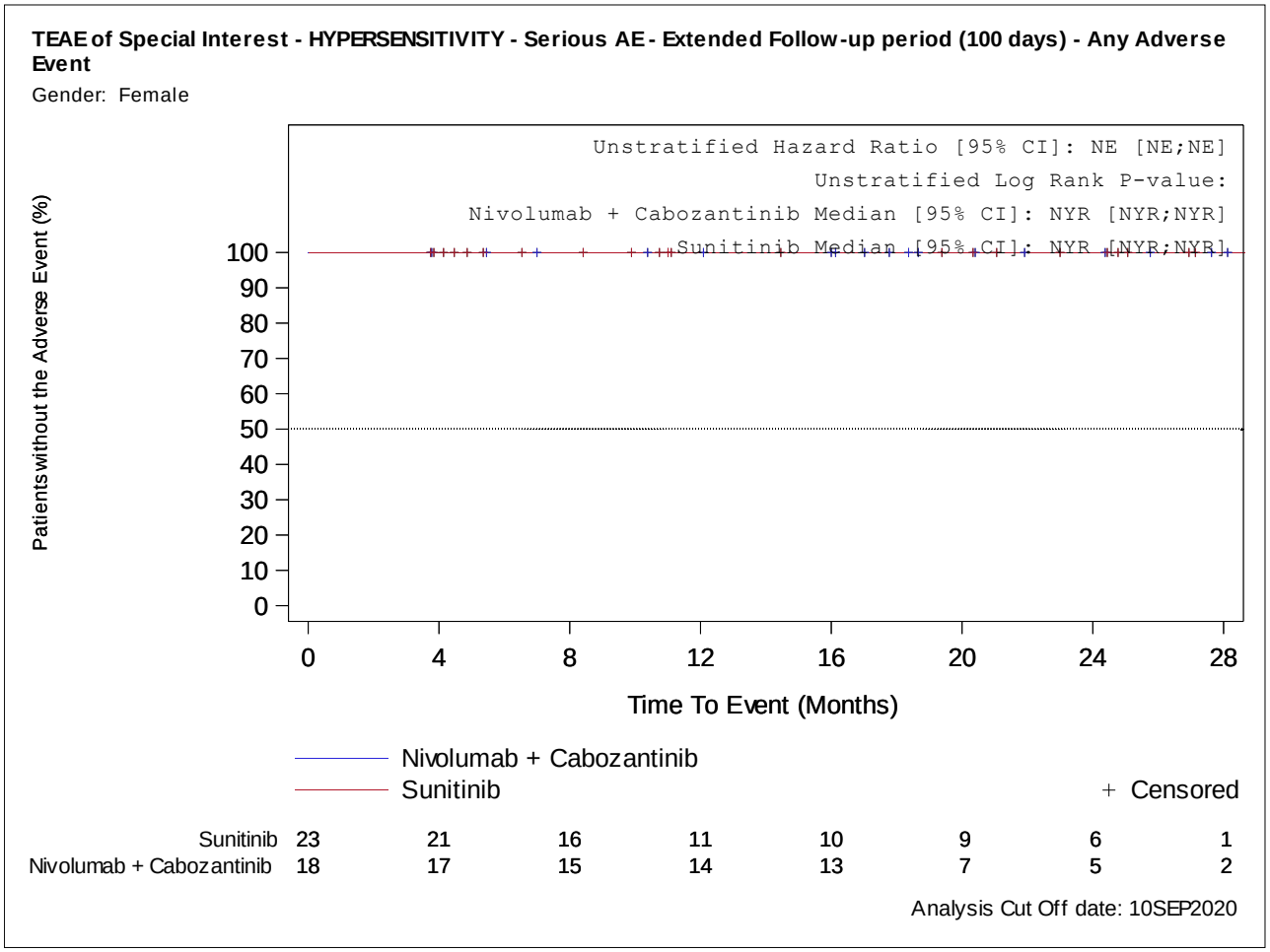

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:14:29

FIGURE 3.88.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



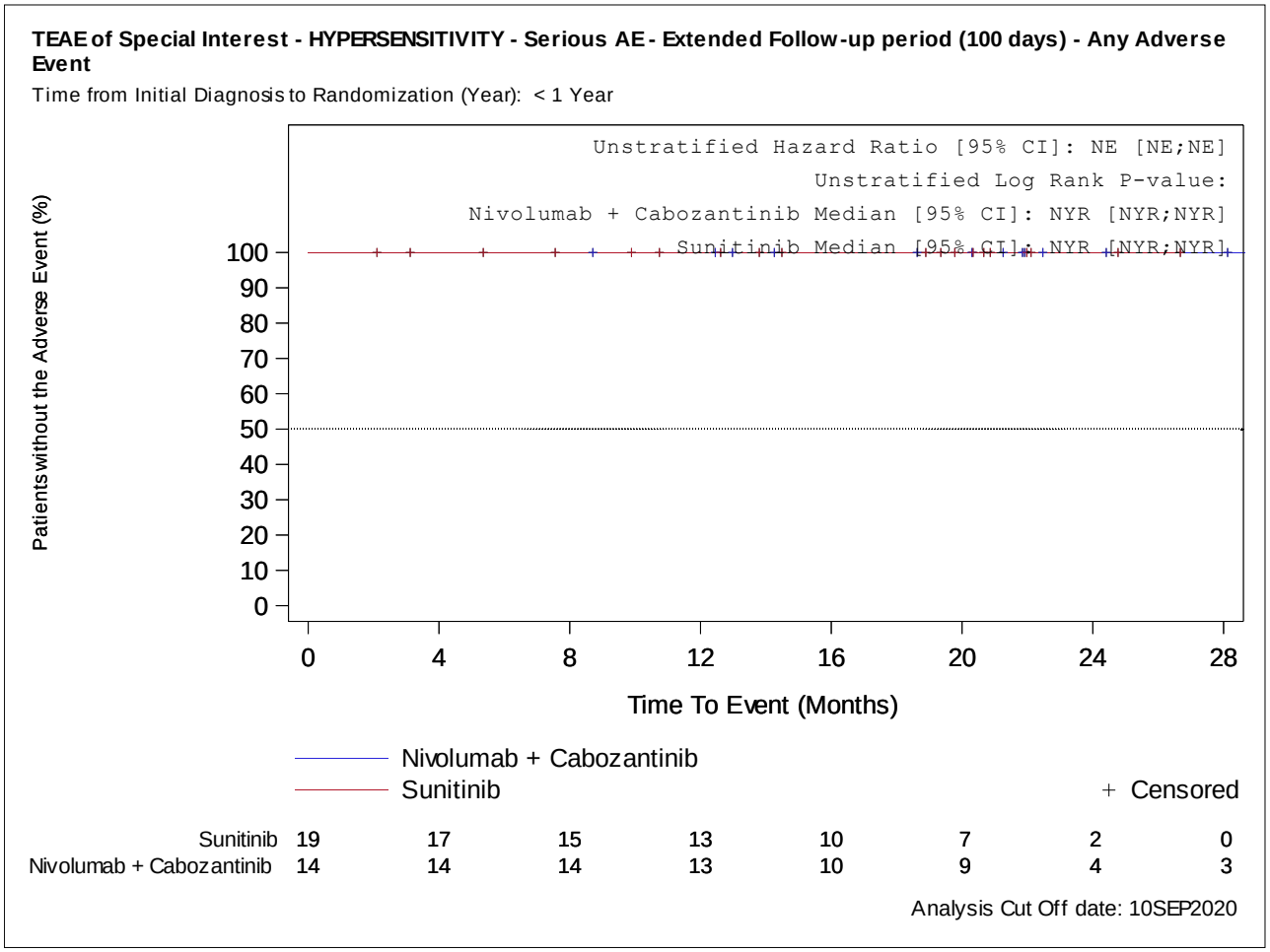

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:14:34

FIGURE 3.88.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



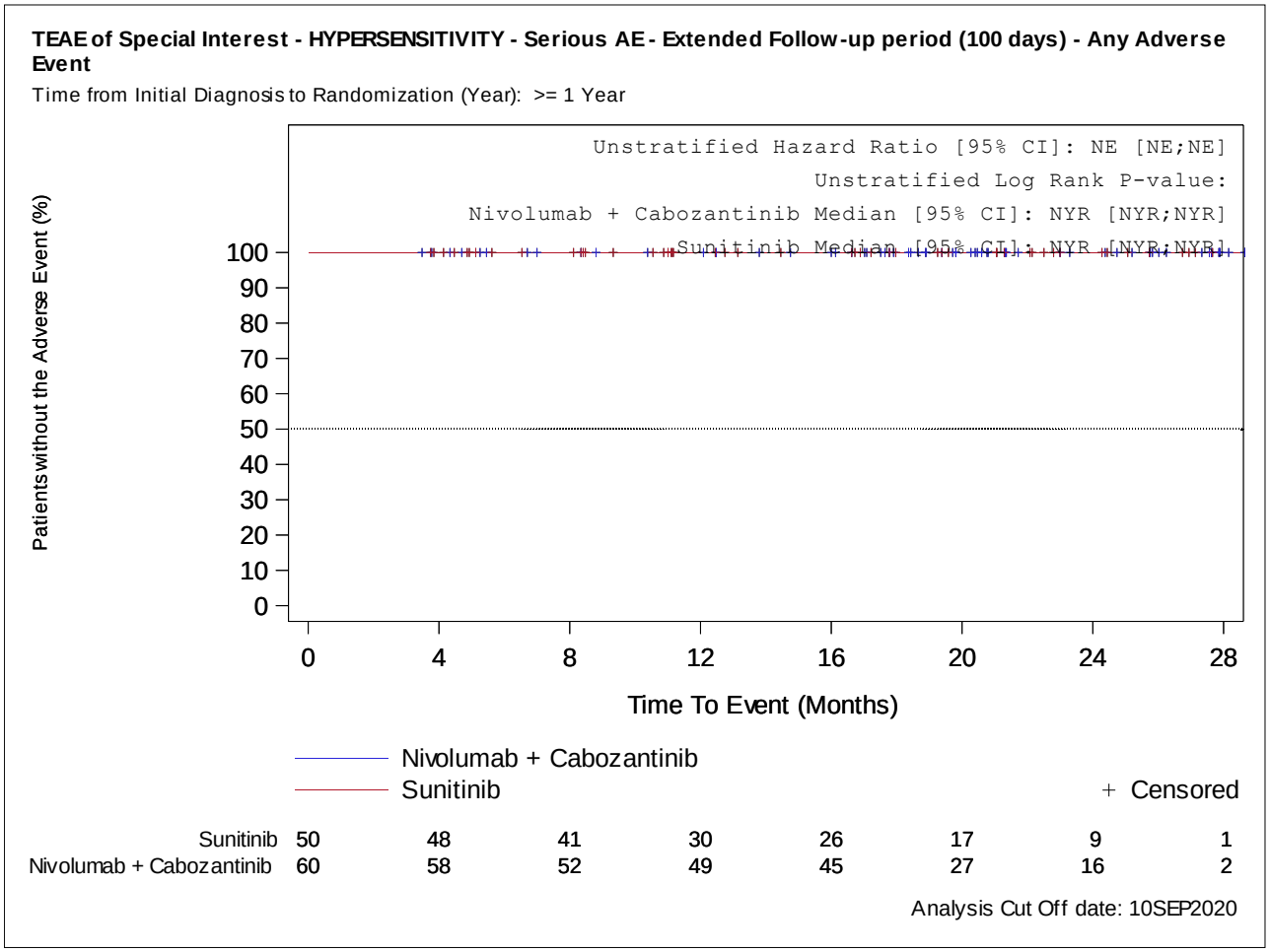

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:14:39

FIGURE 3.88.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



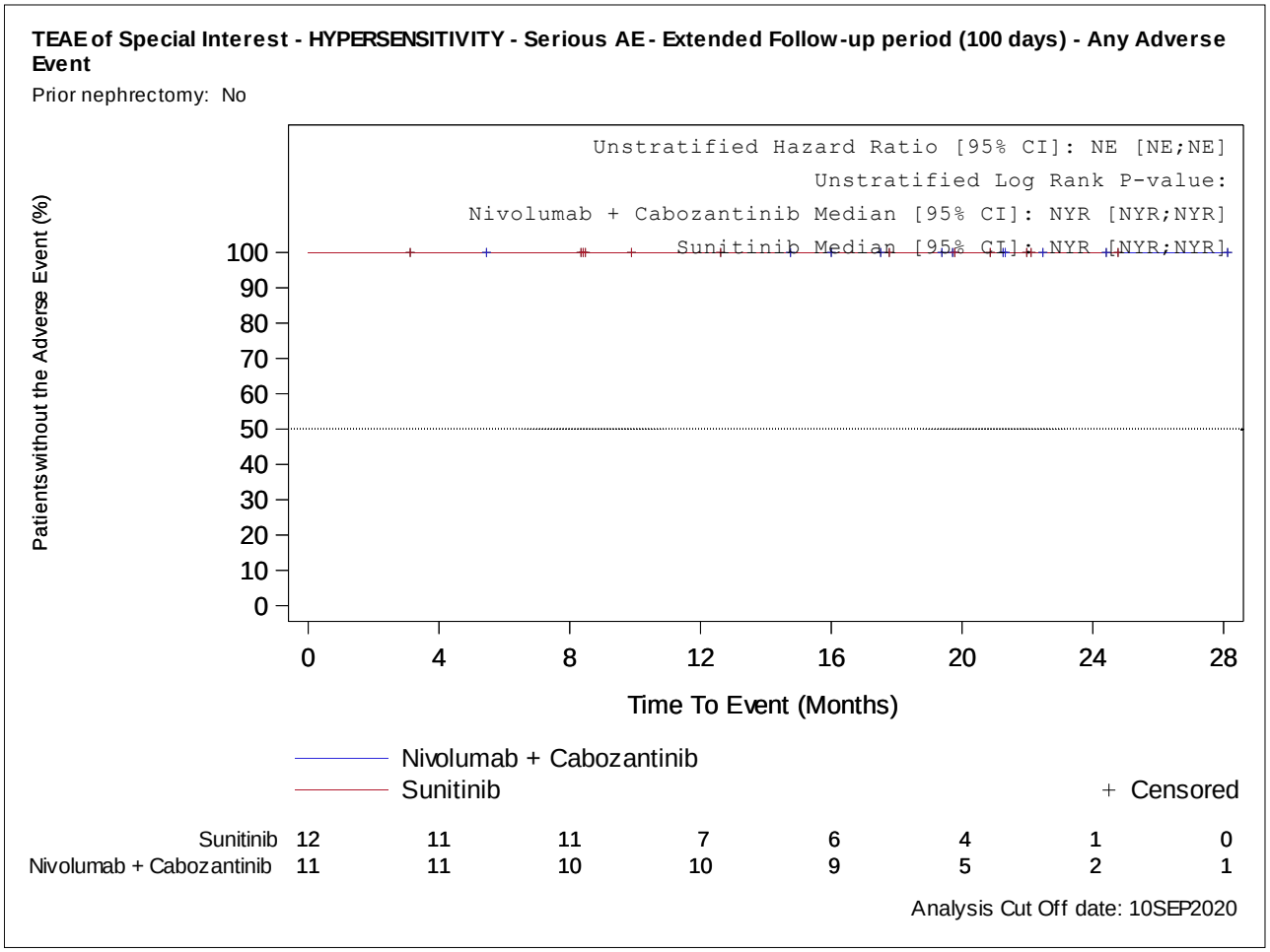

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:14:54

FIGURE 3.88.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



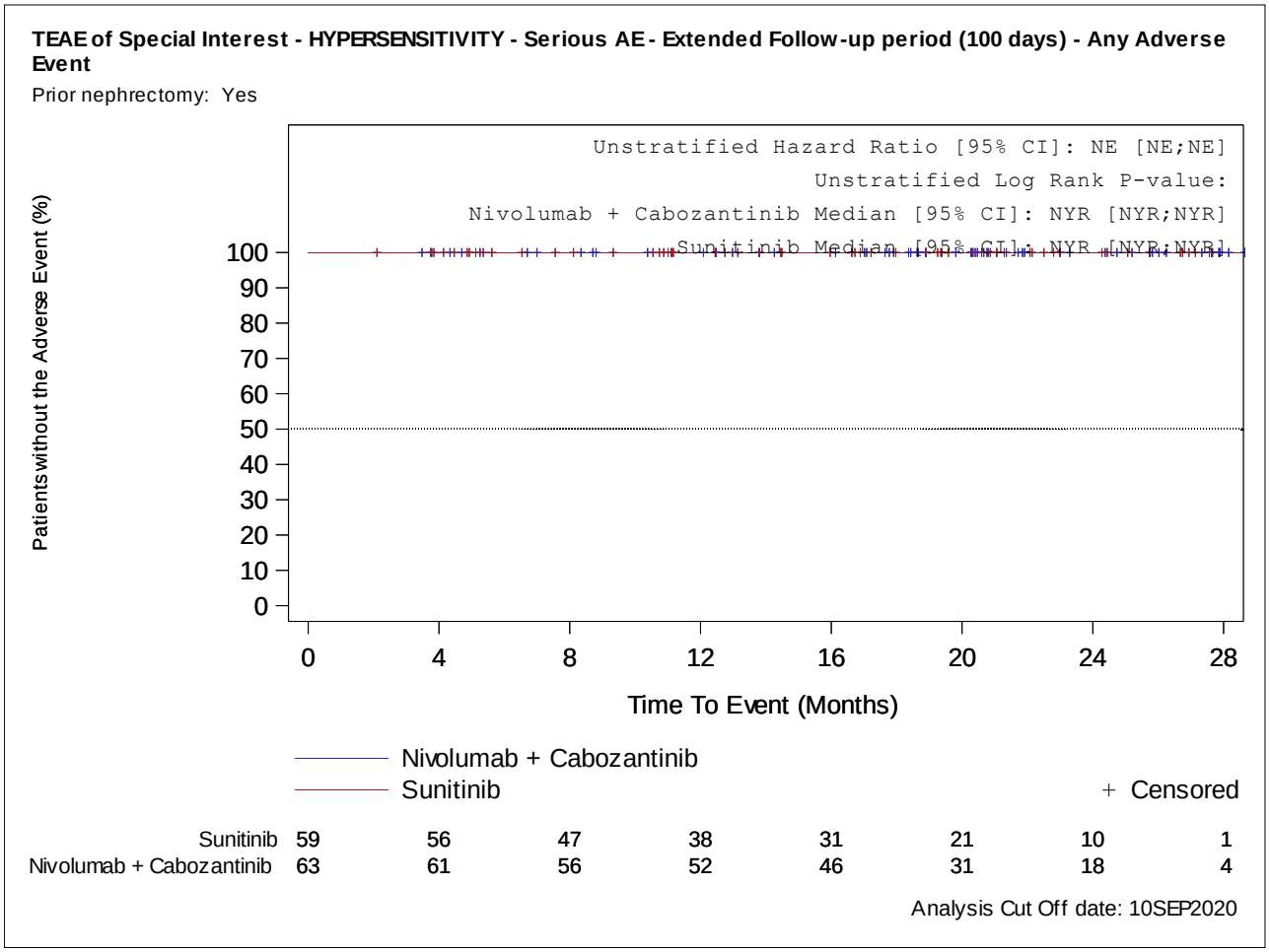

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:14:59

FIGURE 3.88.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:15:46

FIGURE 3.88.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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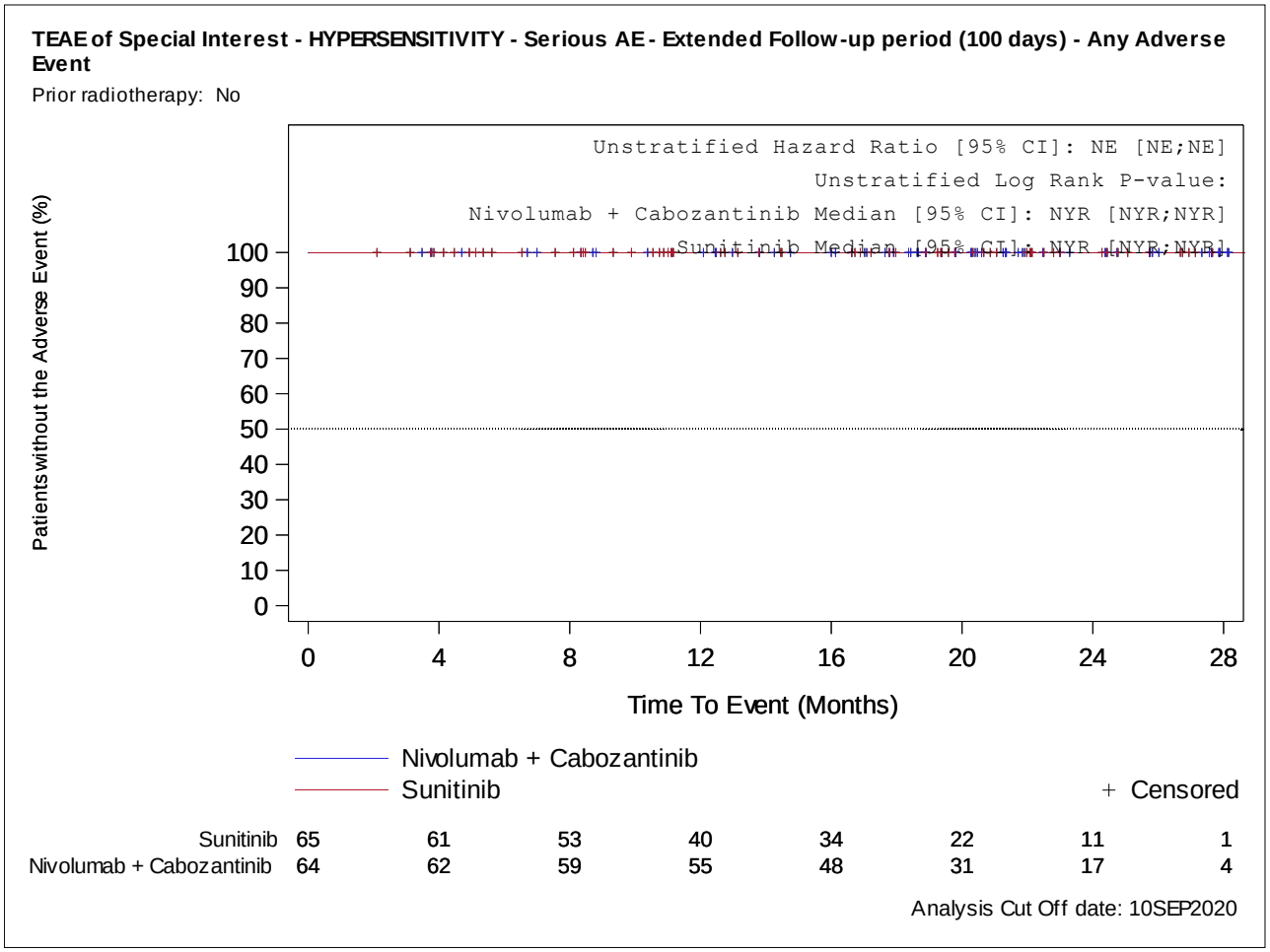
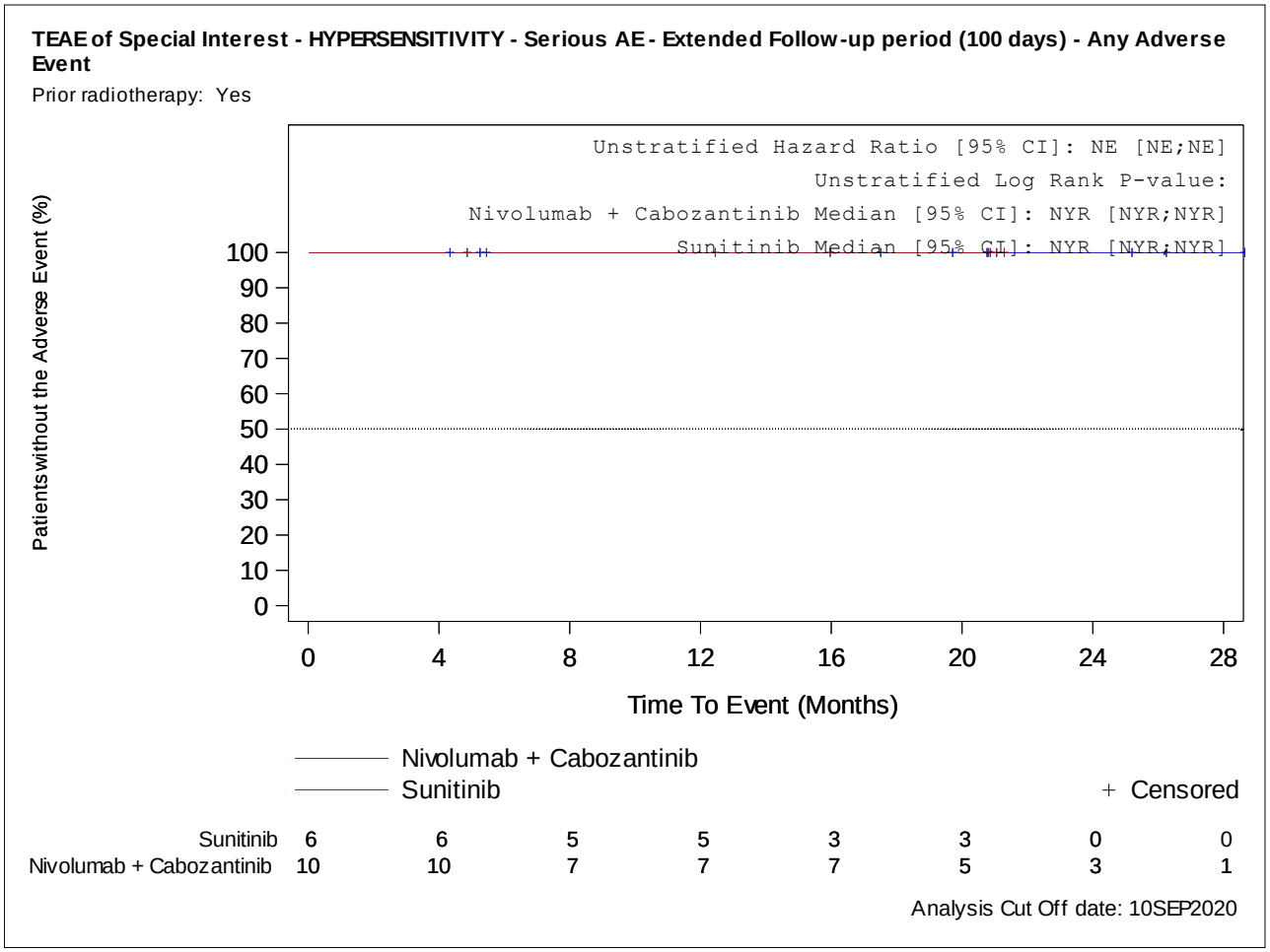
FIGURE 3.88.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



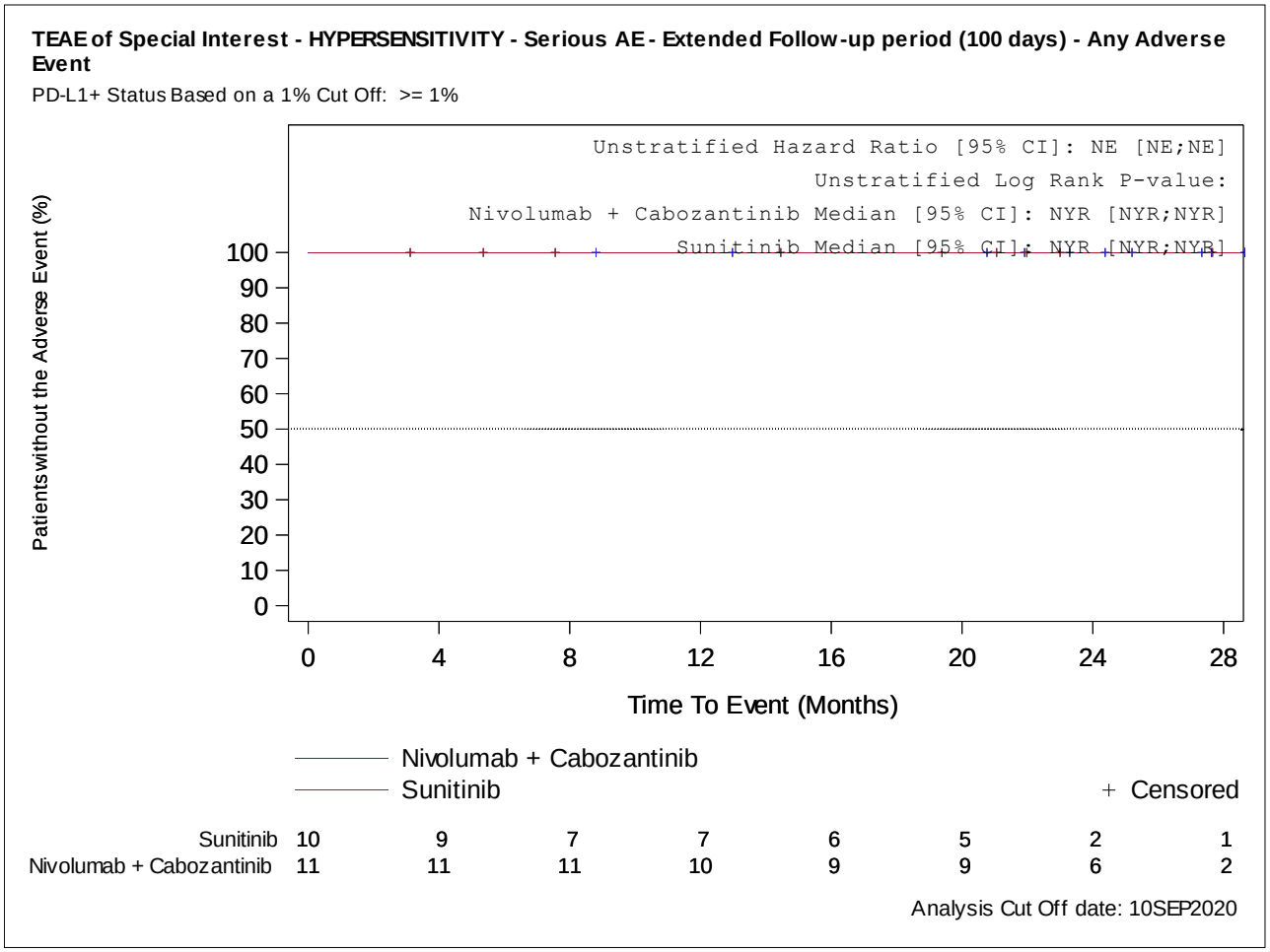

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:15:56

FIGURE 3.88.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:16:02

FIGURE 3.88.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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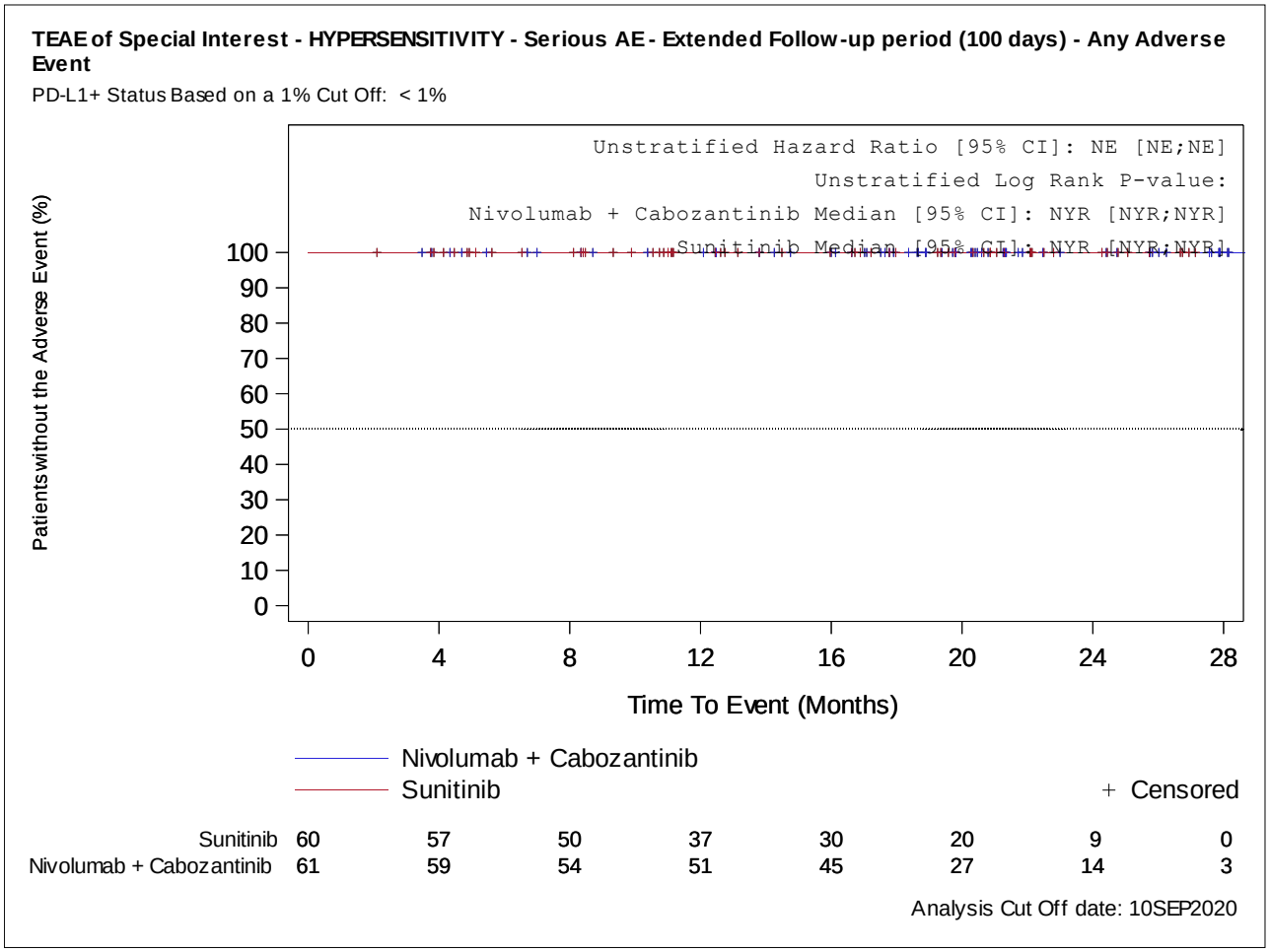
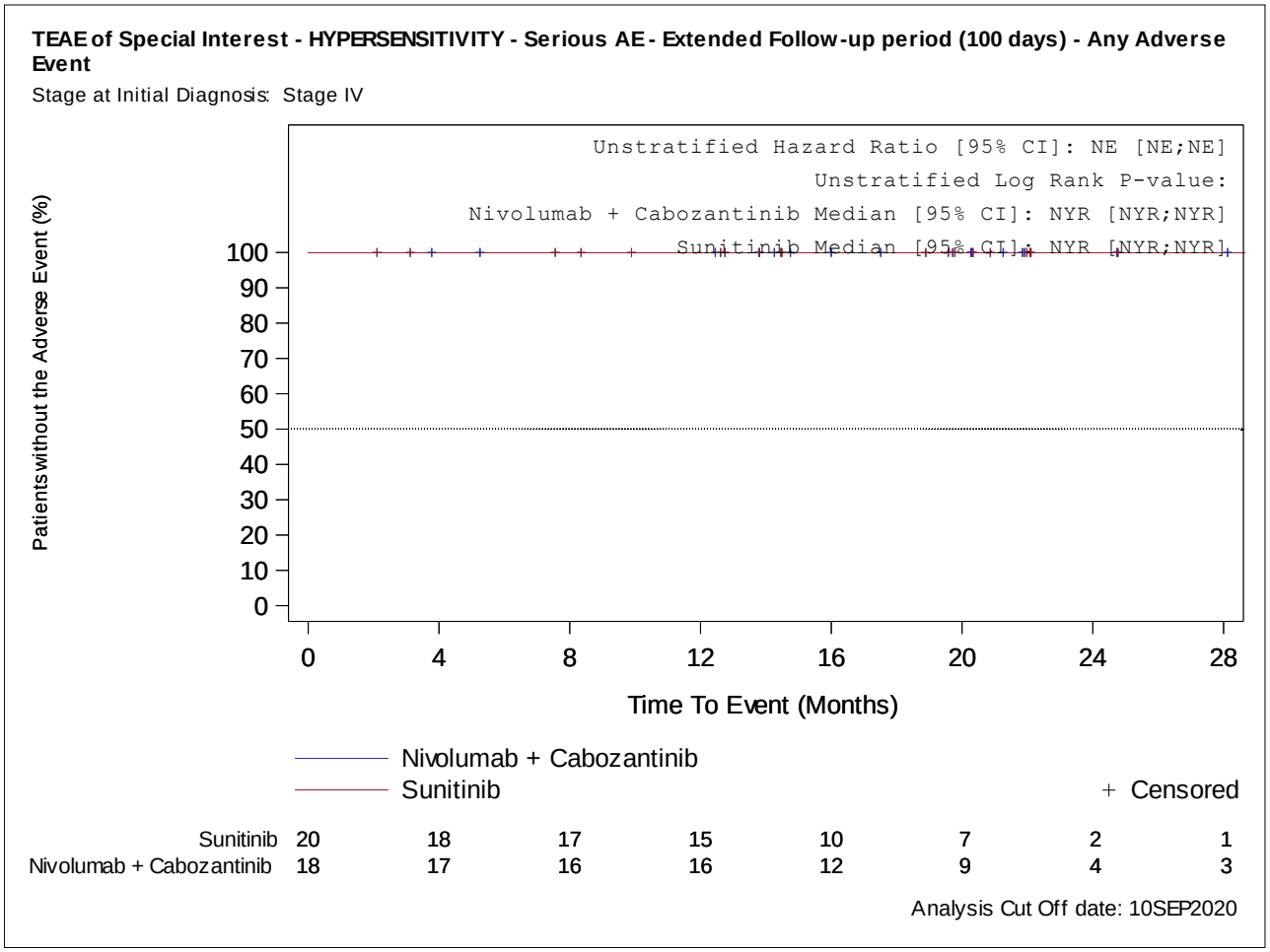
FIGURE 3.88.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



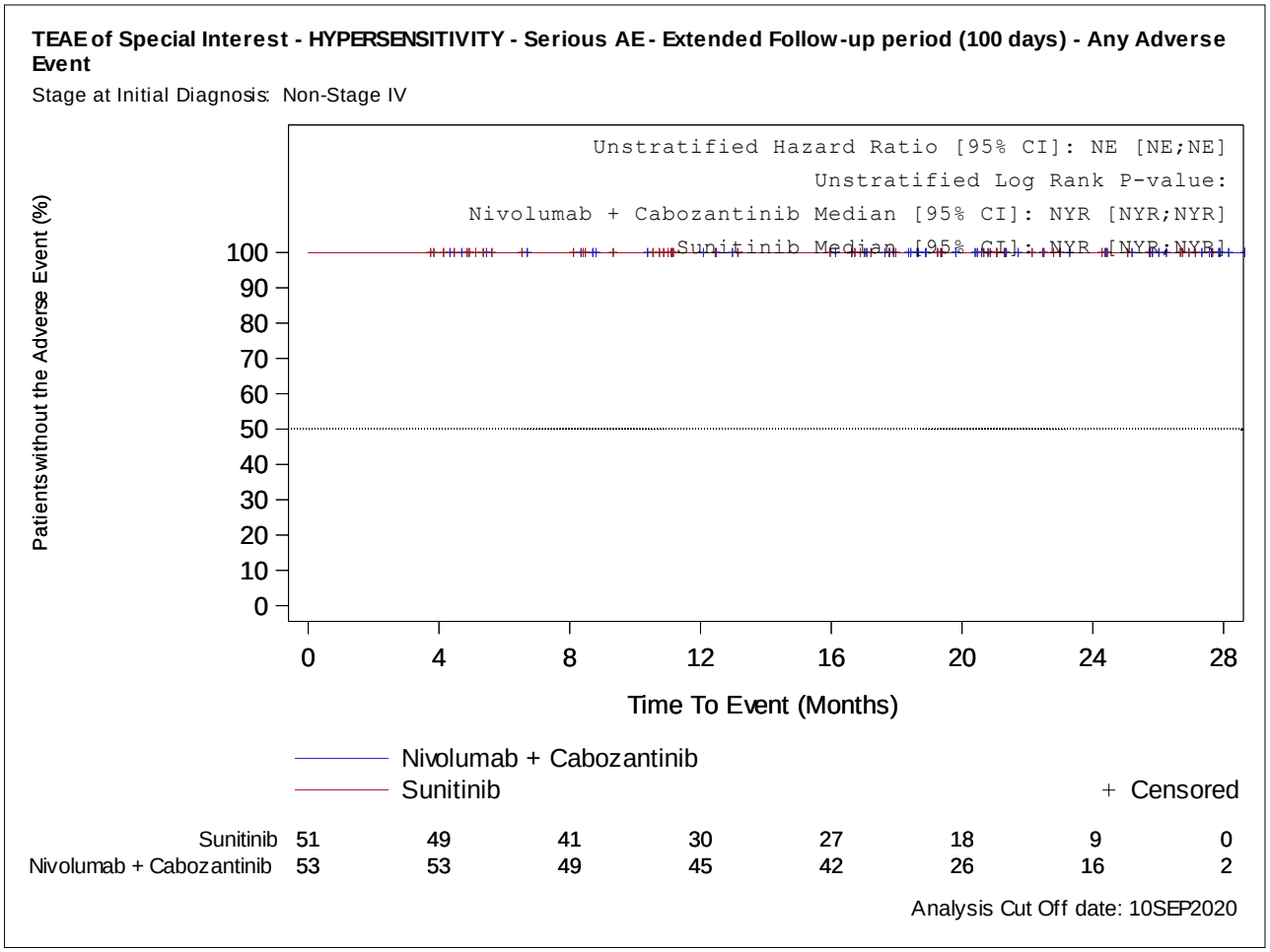

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:16:12

FIGURE 3.88.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



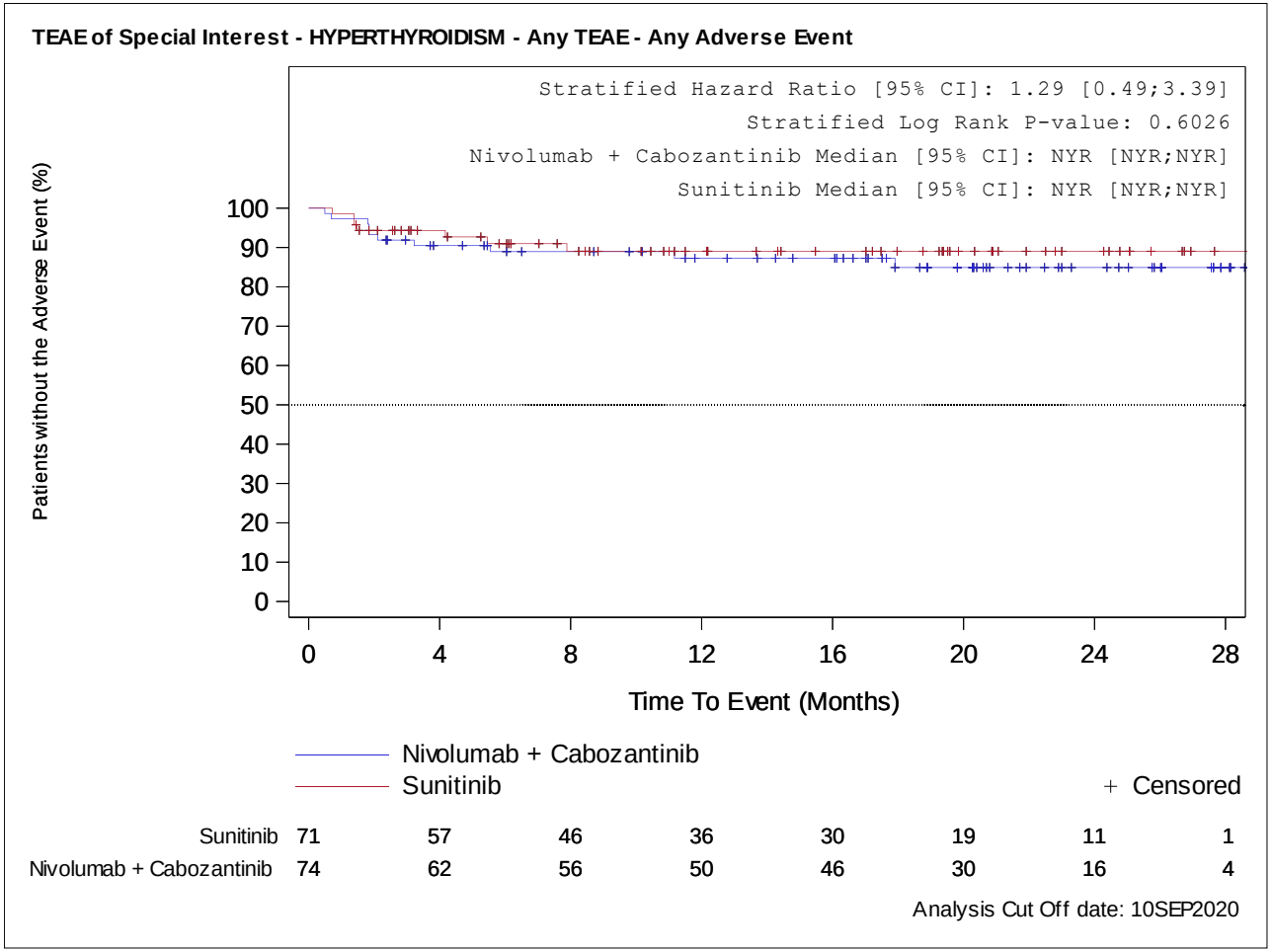

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:16:37

FIGURE 3.88.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERSENSITIVITY - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



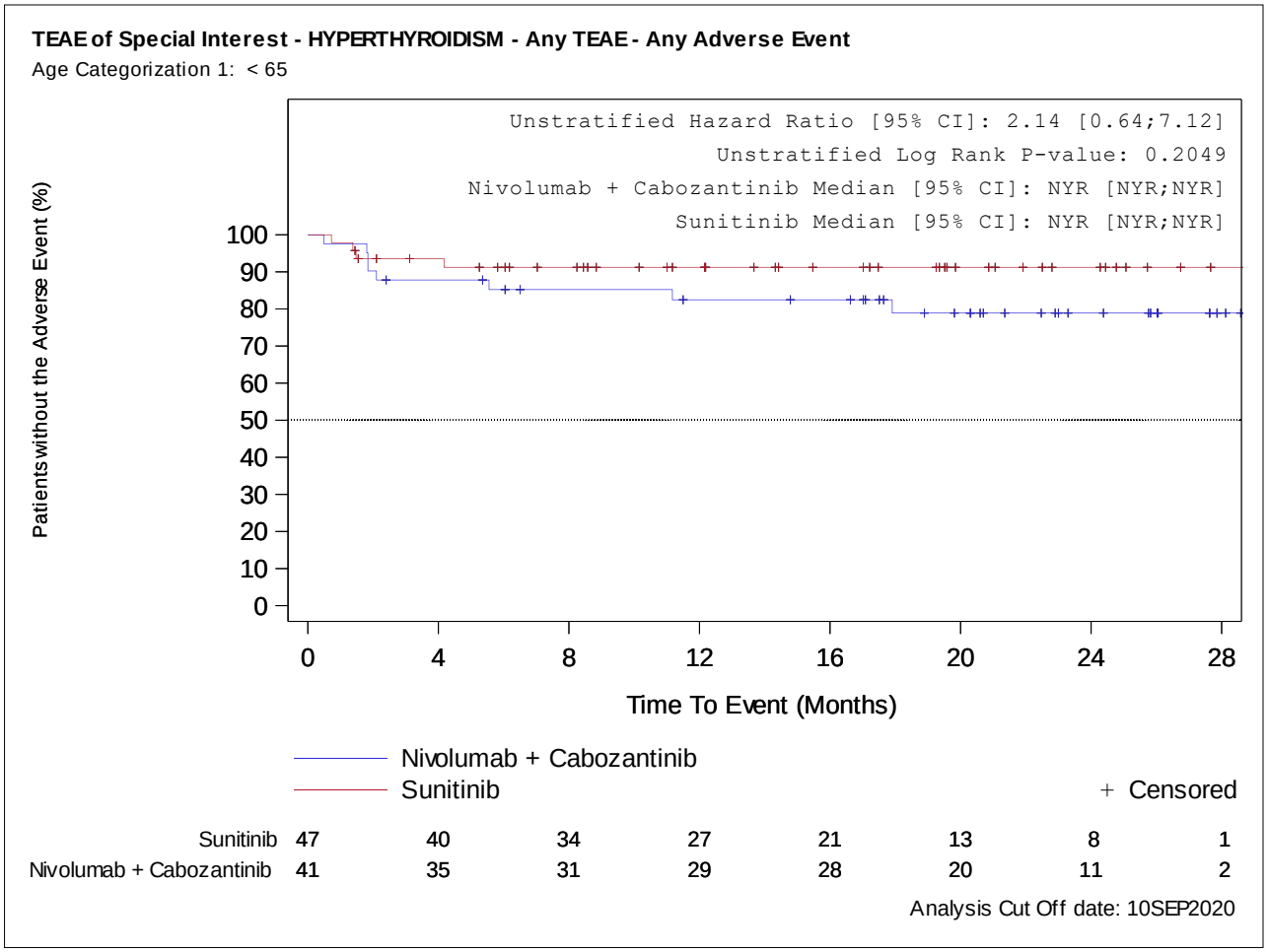

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:16:42

FIGURE 3.89.1: TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



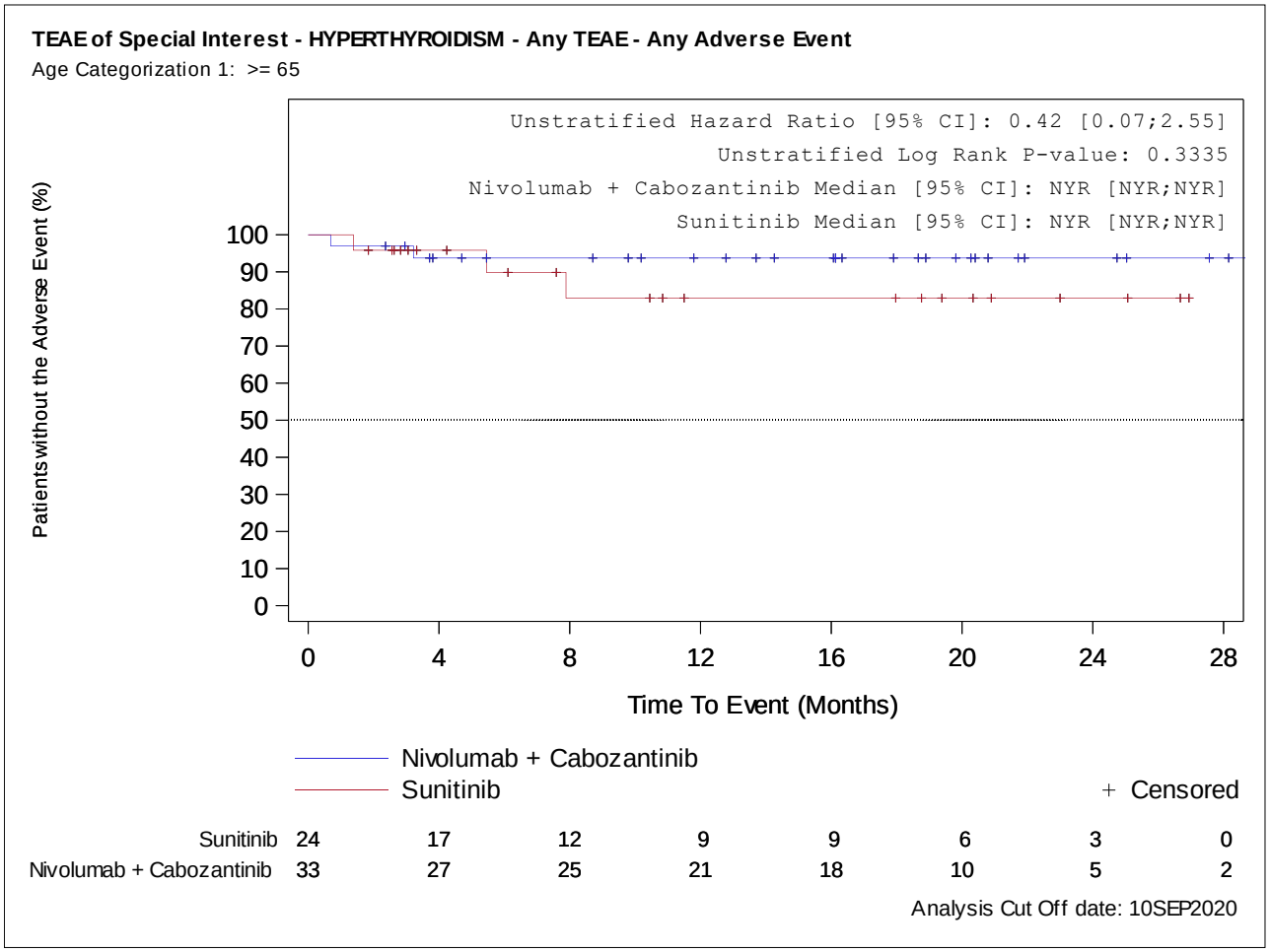

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:19:43

FIGURE 3.89.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



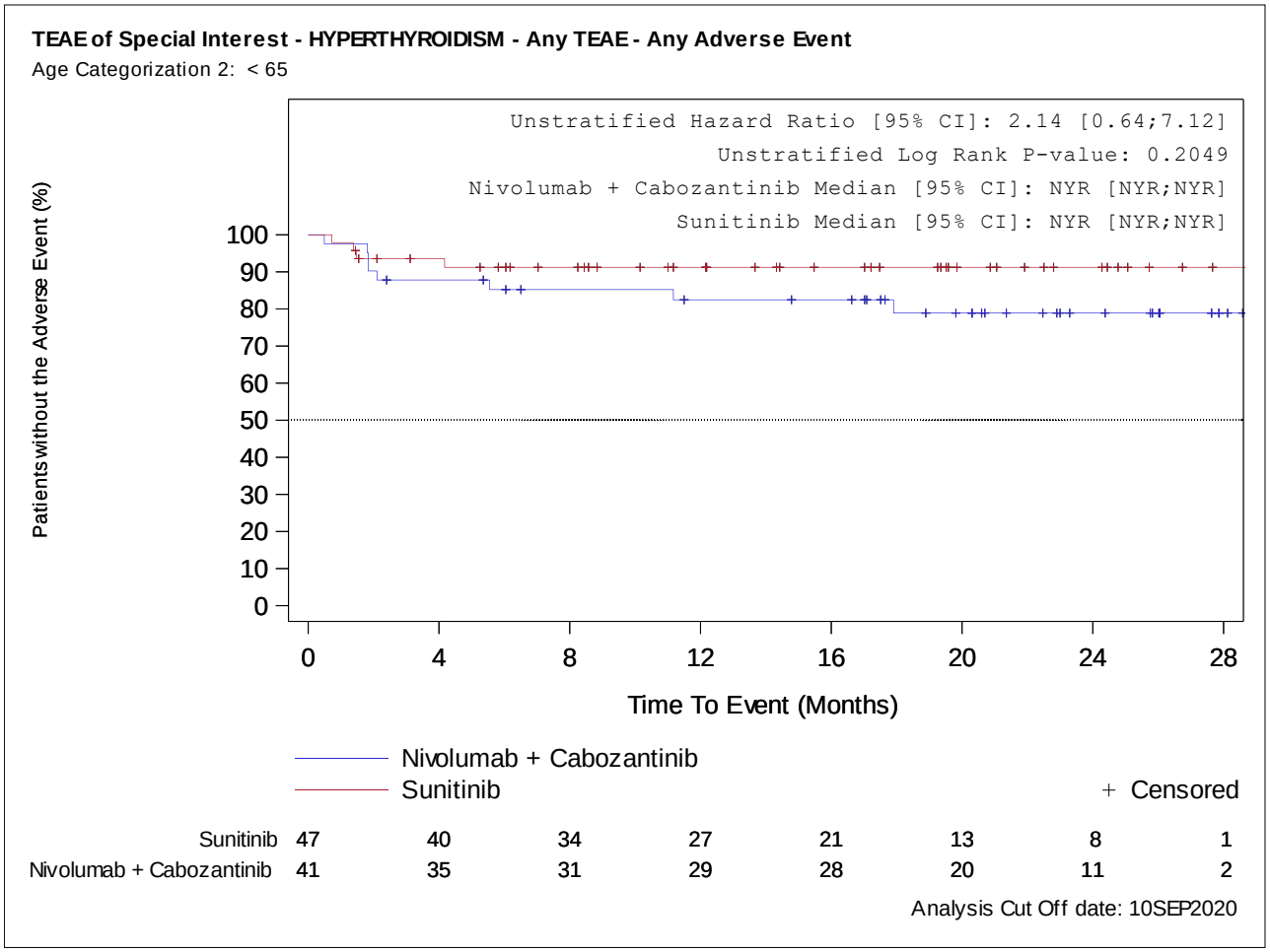

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:19:46

FIGURE 3.89.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:19:52

FIGURE 3.89.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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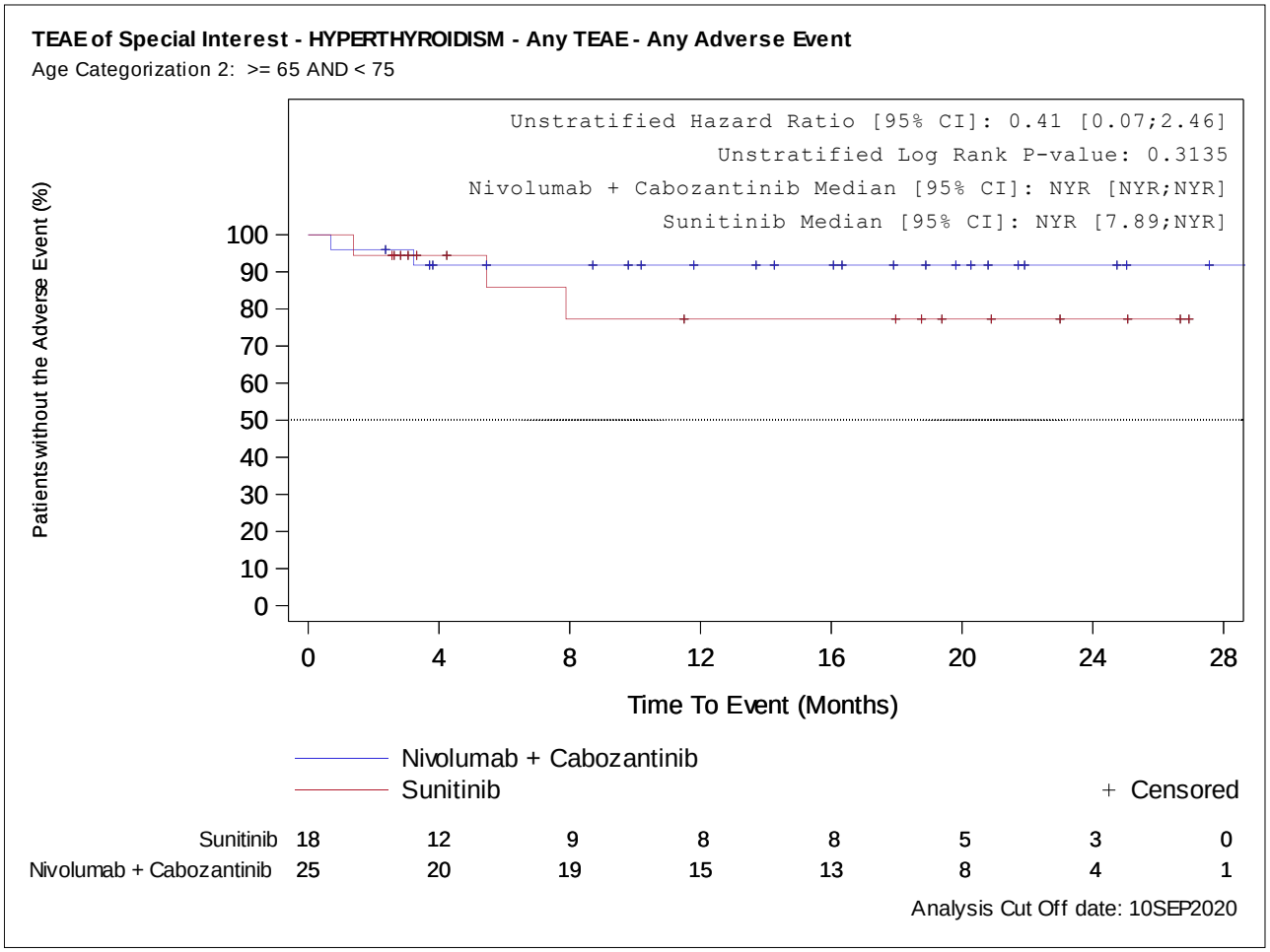
FIGURE 3.89.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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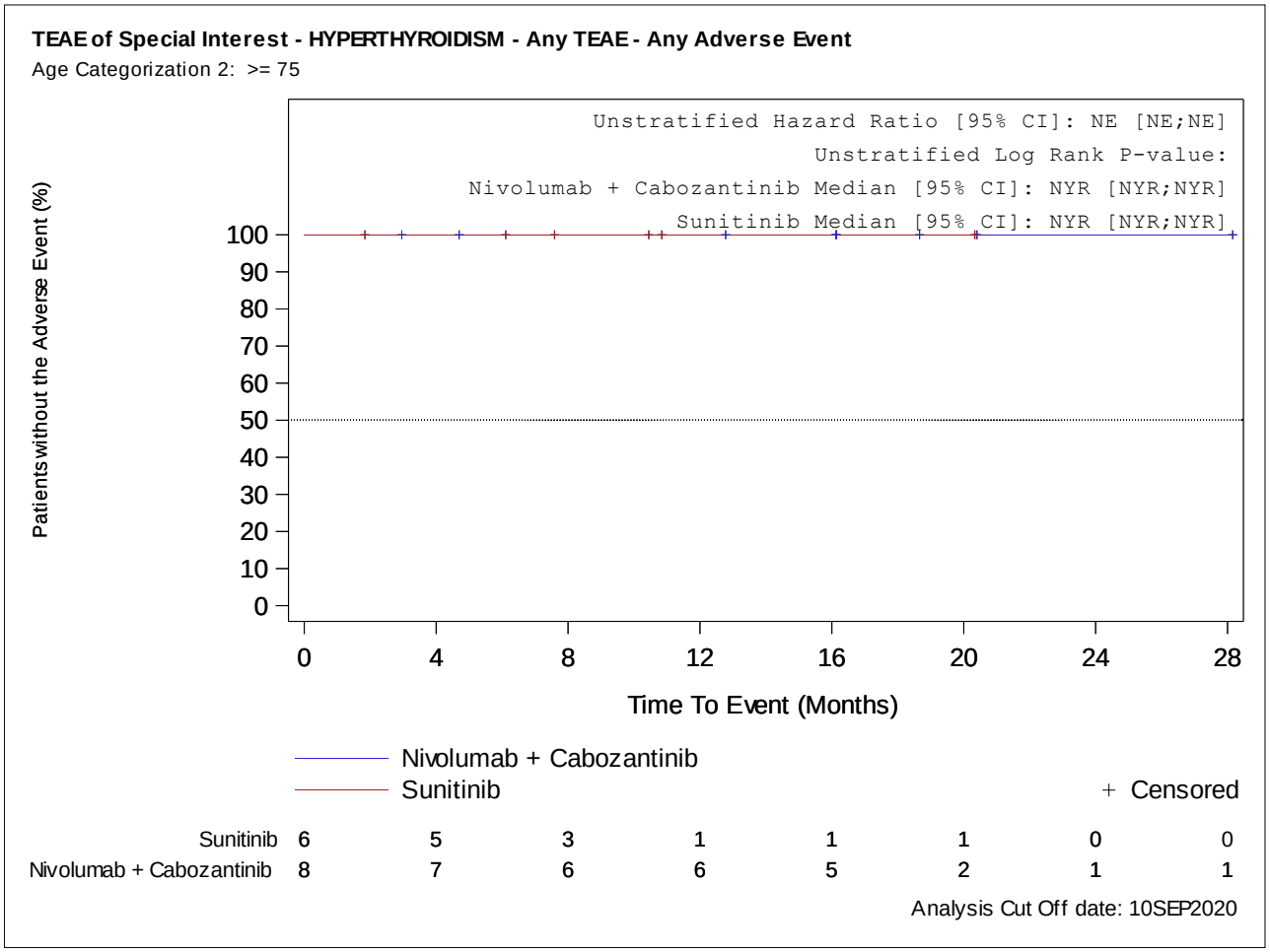
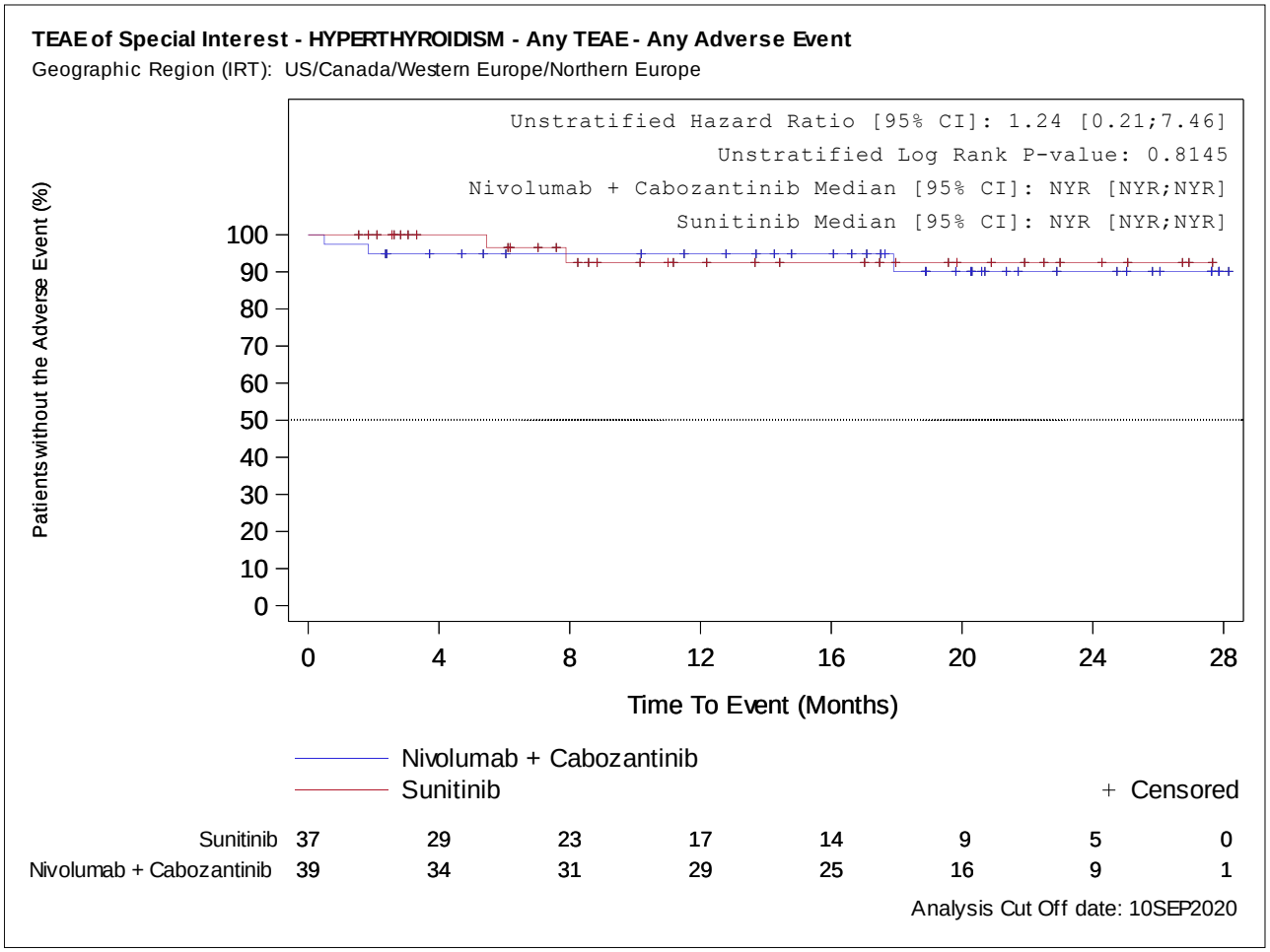
FIGURE 3.89.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



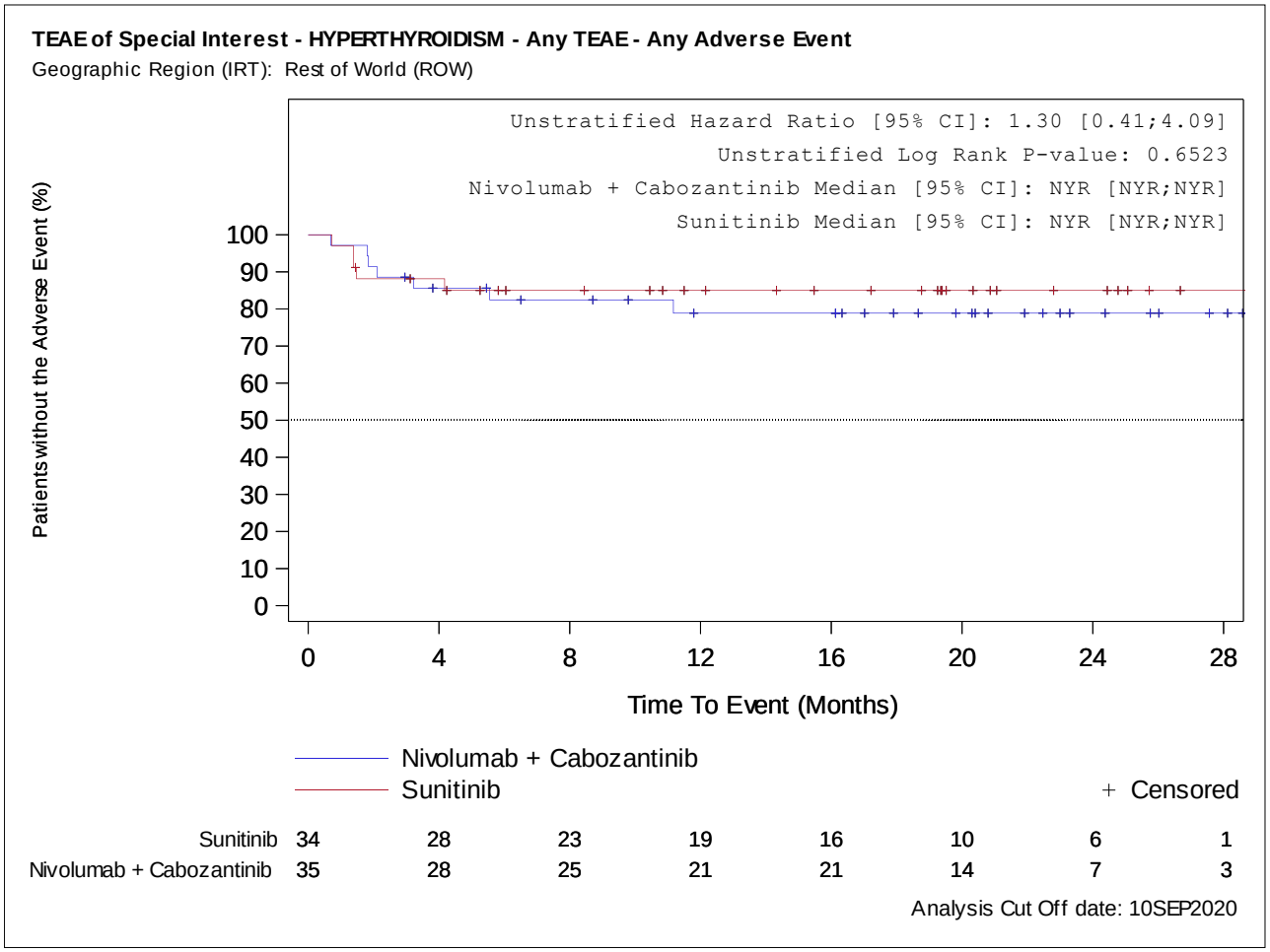

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:20:07

FIGURE 3.89.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



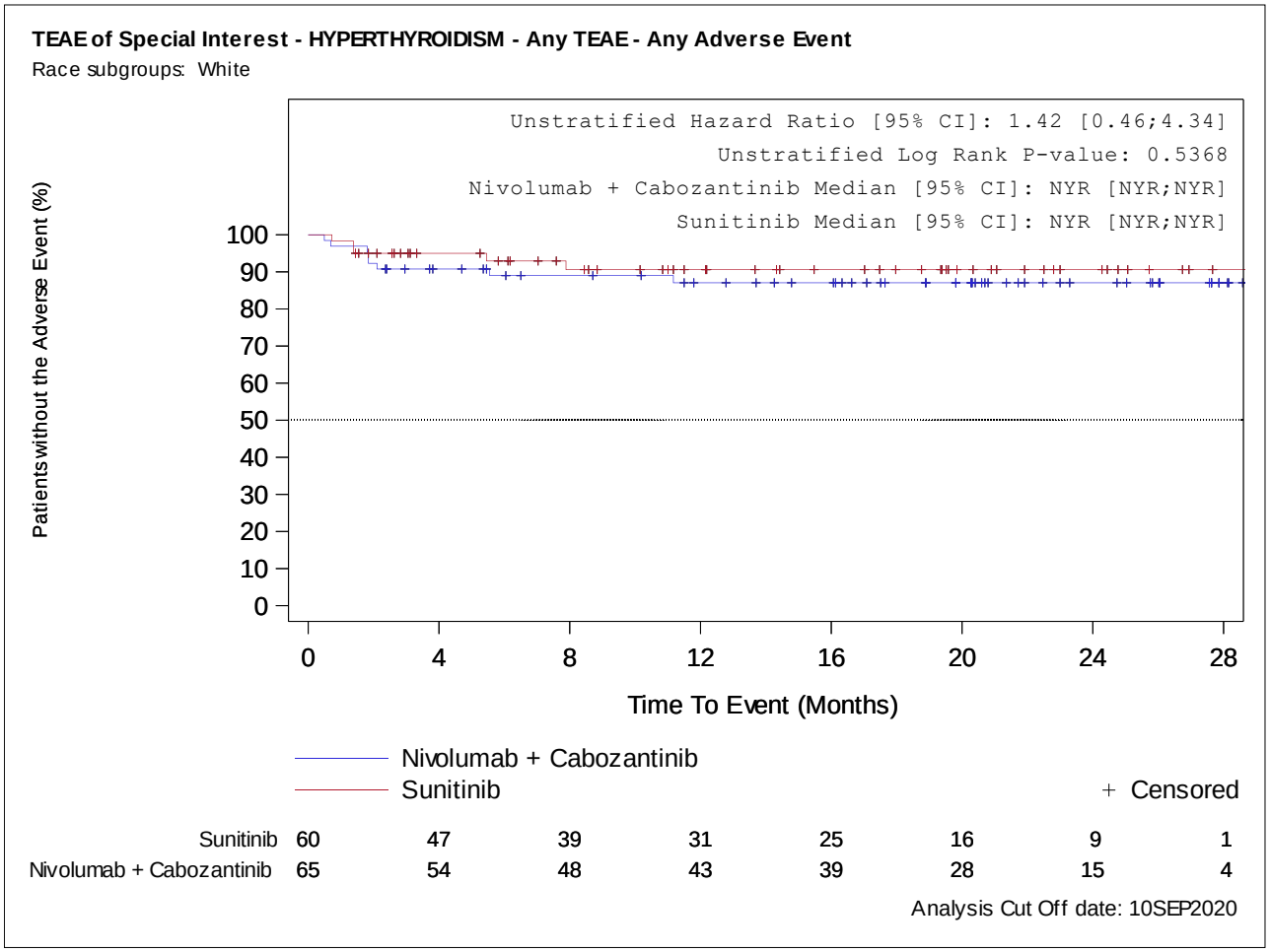

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:20:13

FIGURE 3.89.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:20:18

FIGURE 3.89.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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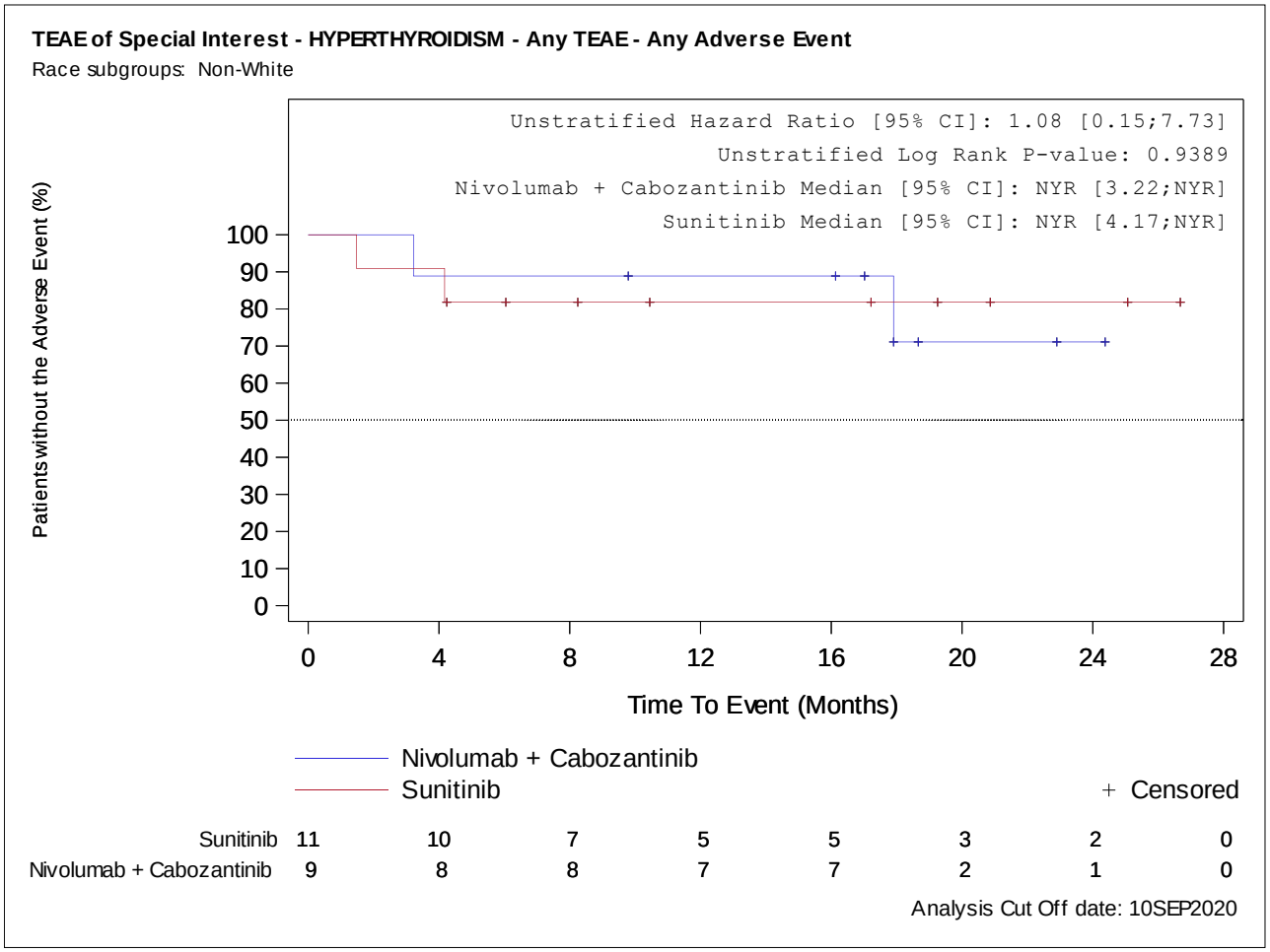
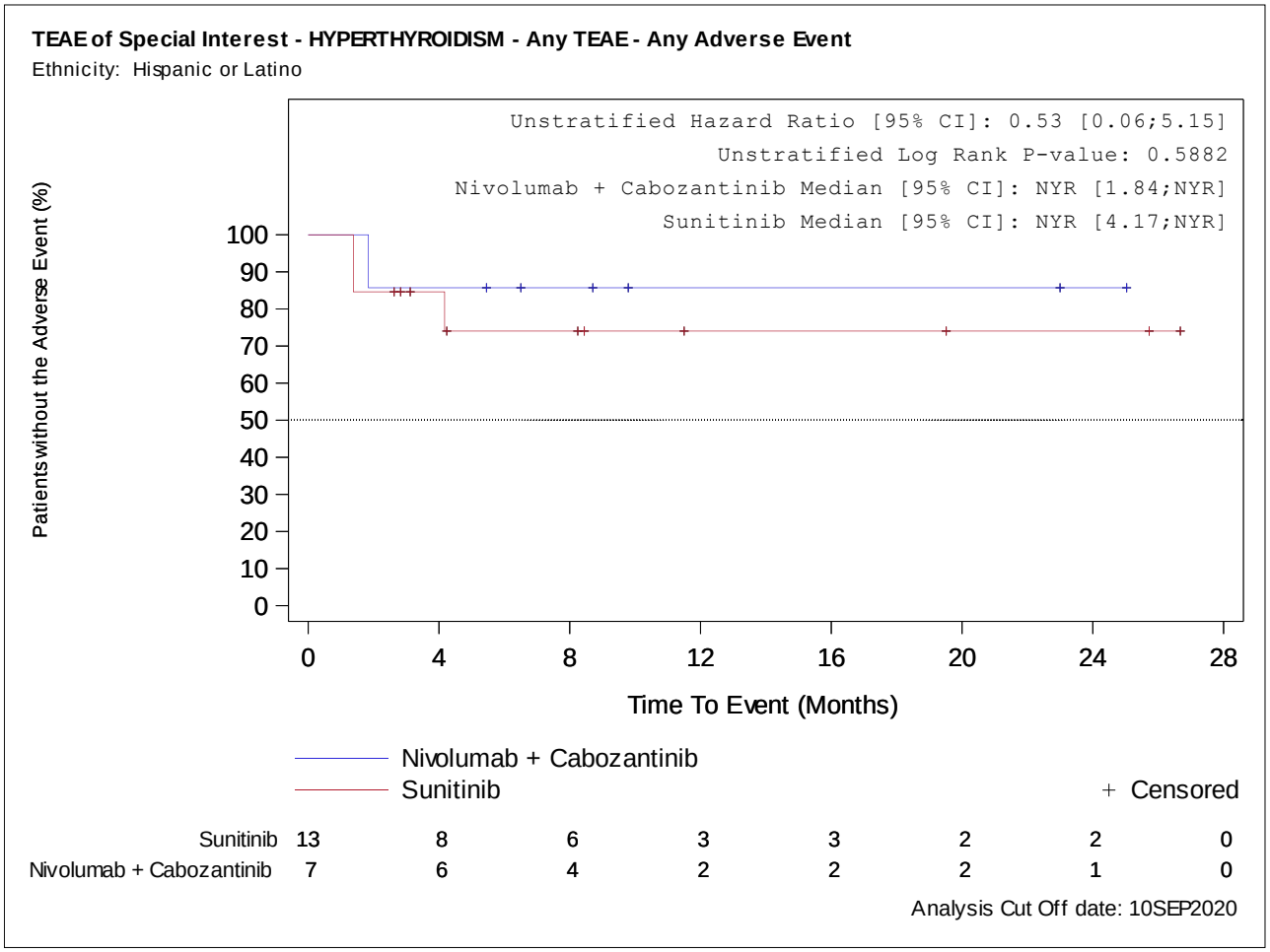
FIGURE 3.89.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



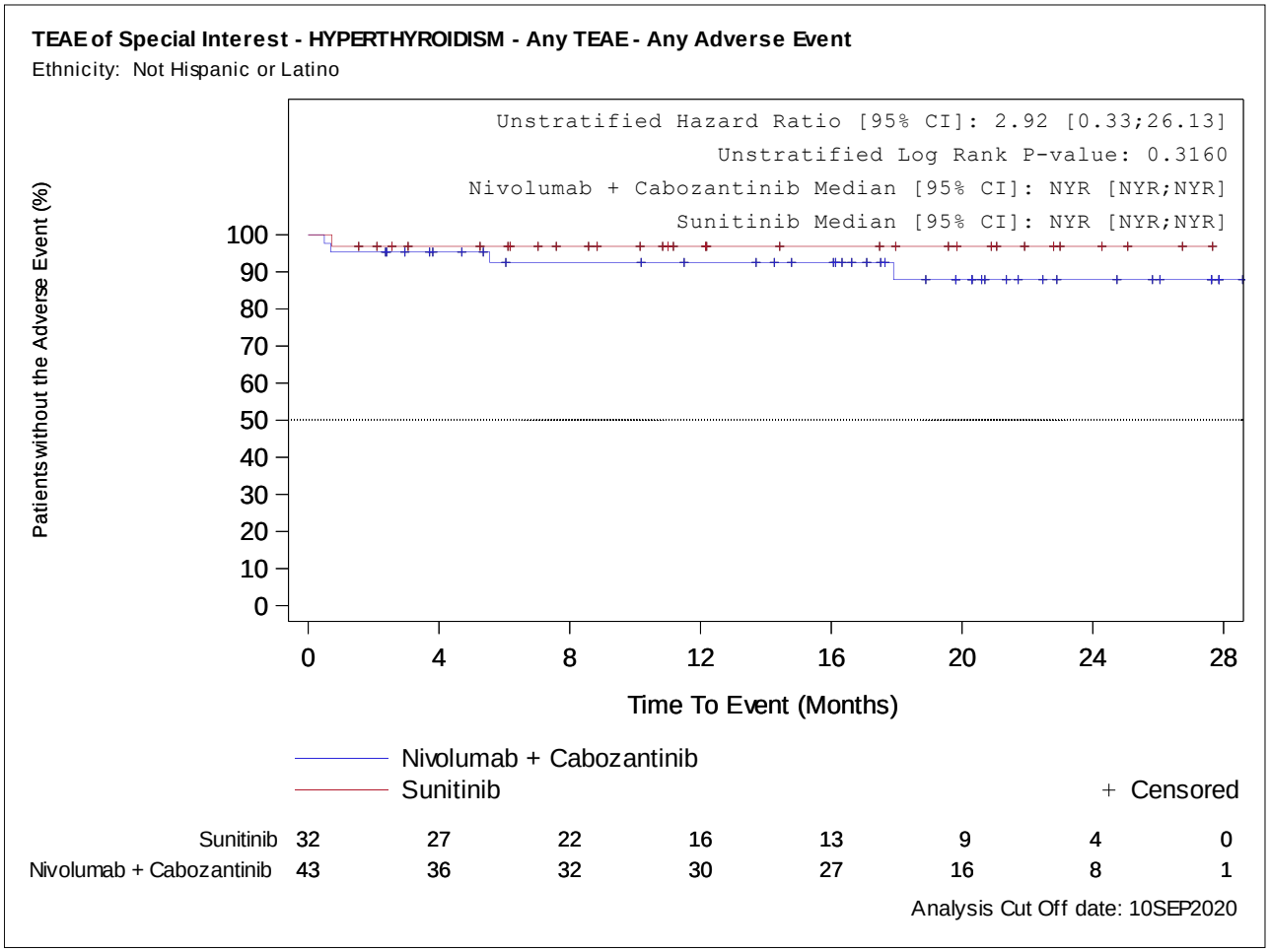

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:20:28

FIGURE 3.89.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



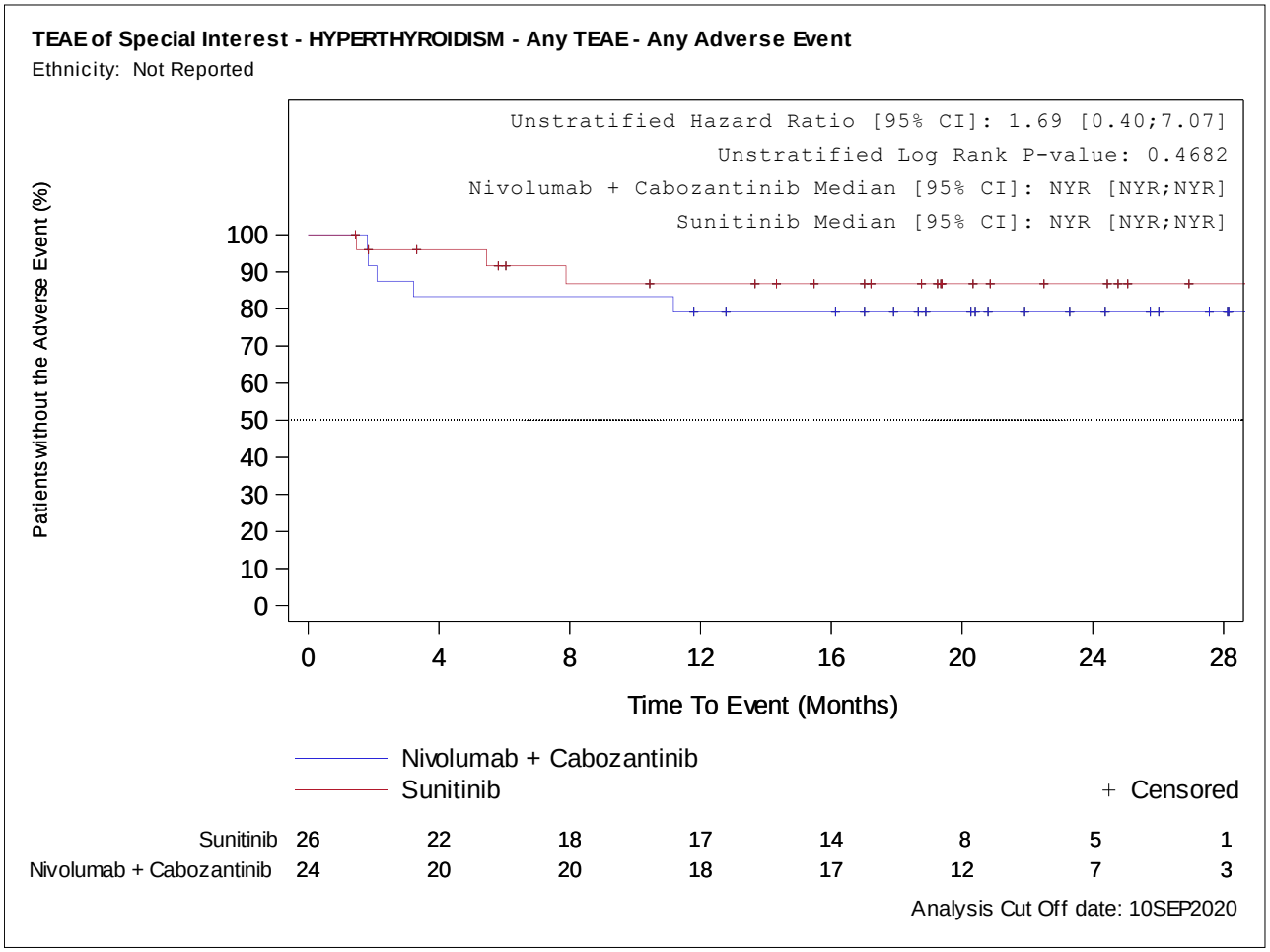

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:20:33

FIGURE 3.89.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



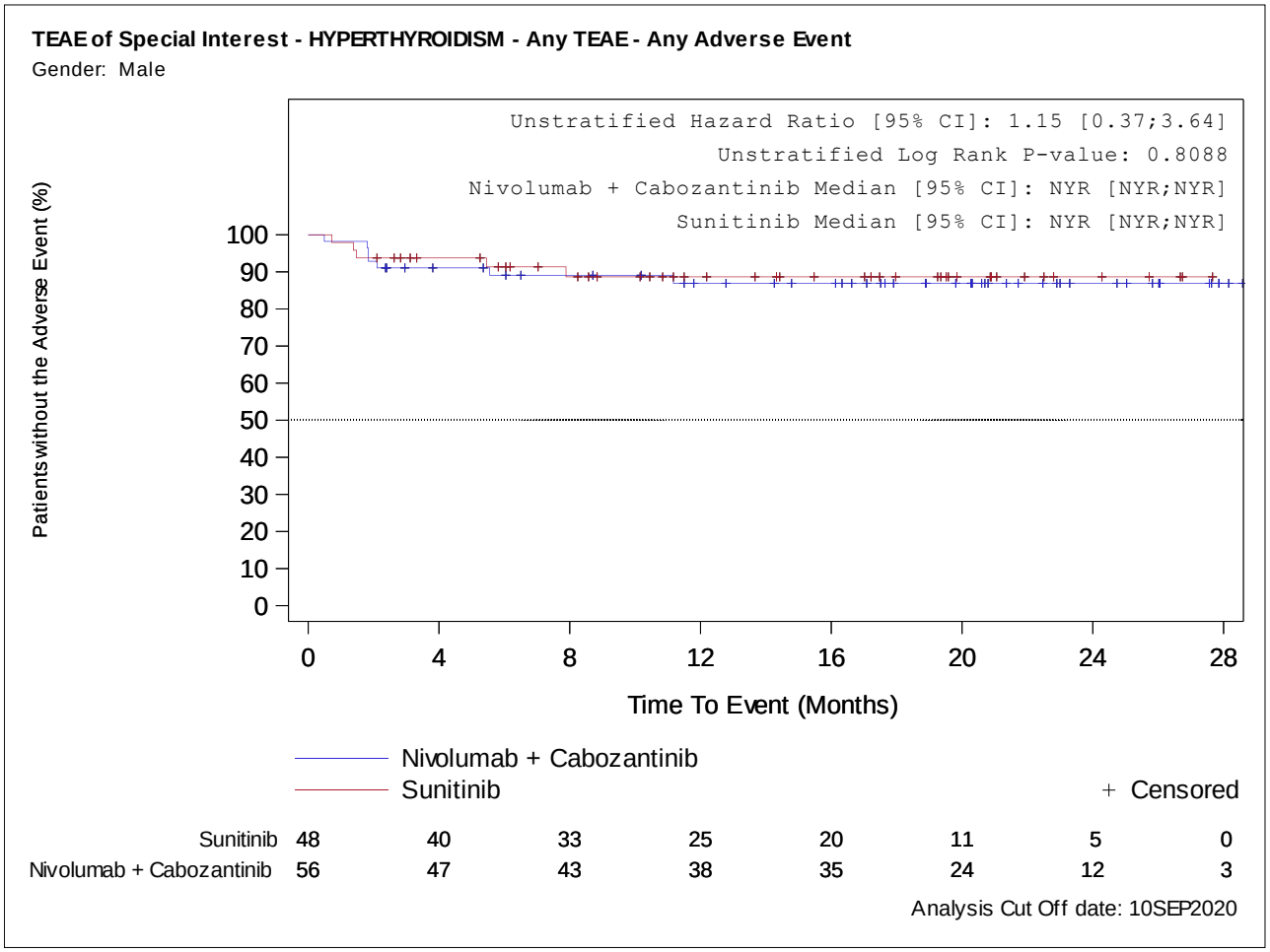

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:20:38

FIGURE 3.89.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:20:43

FIGURE 3.89.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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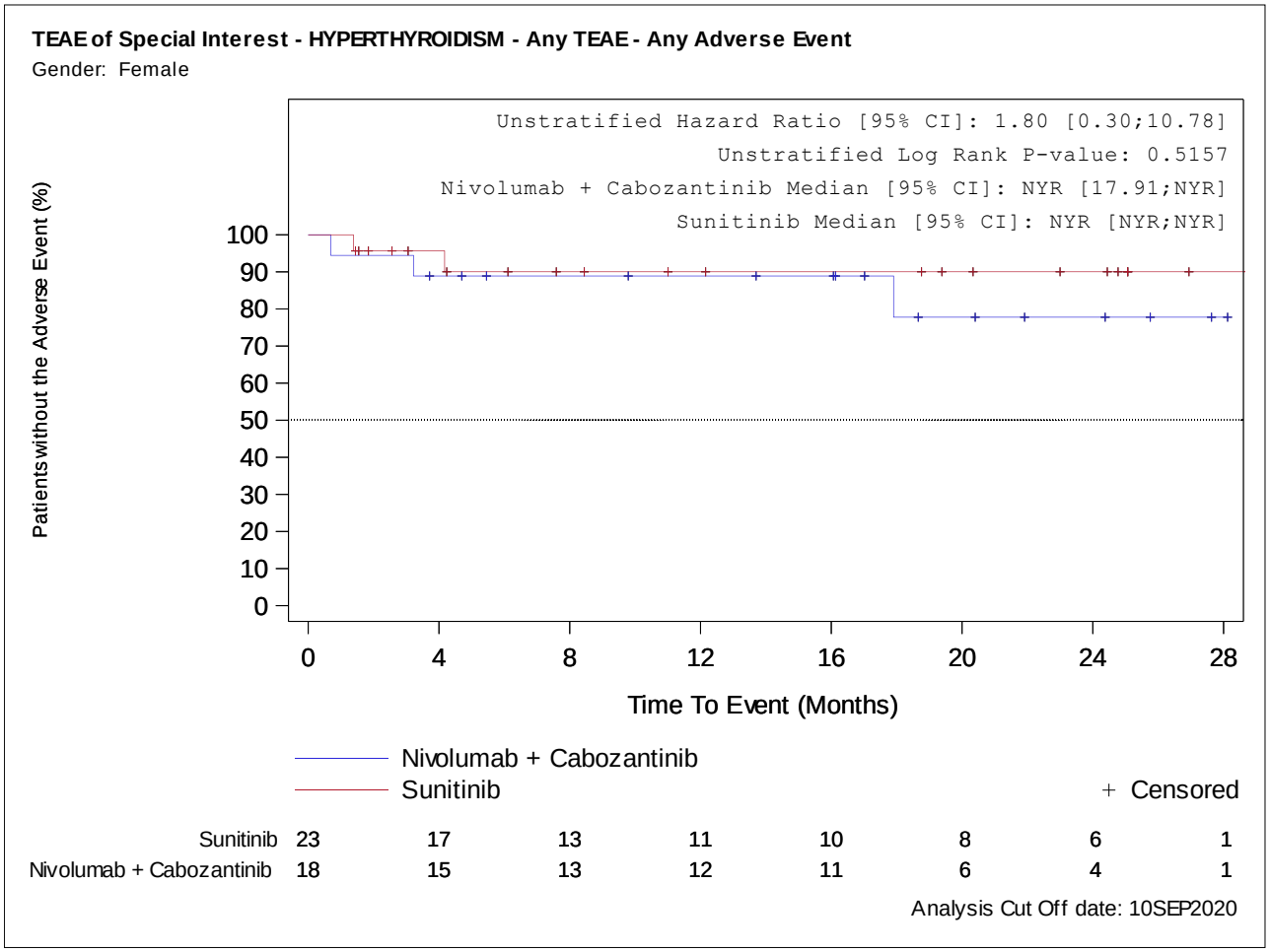
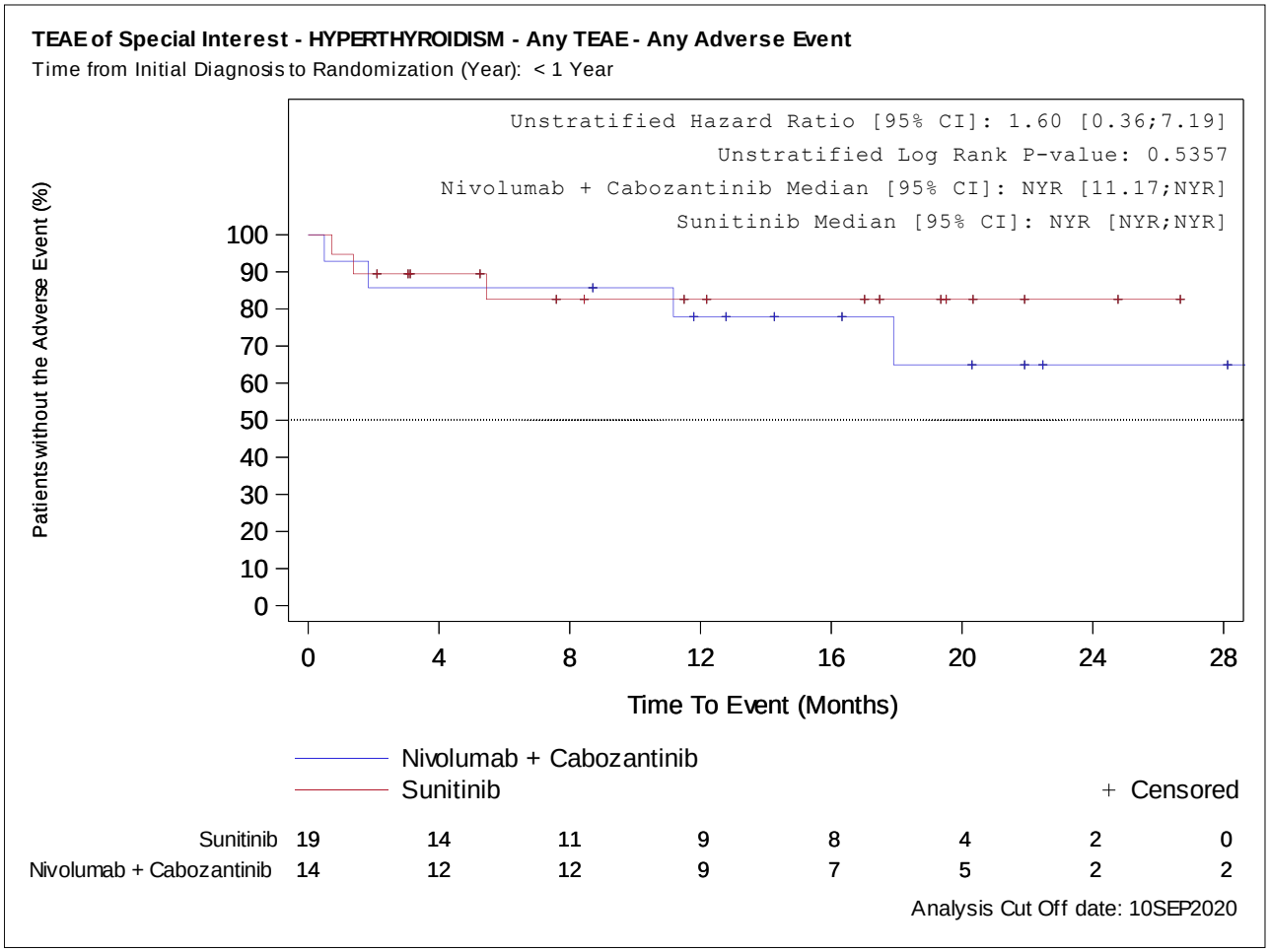
FIGURE 3.89.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



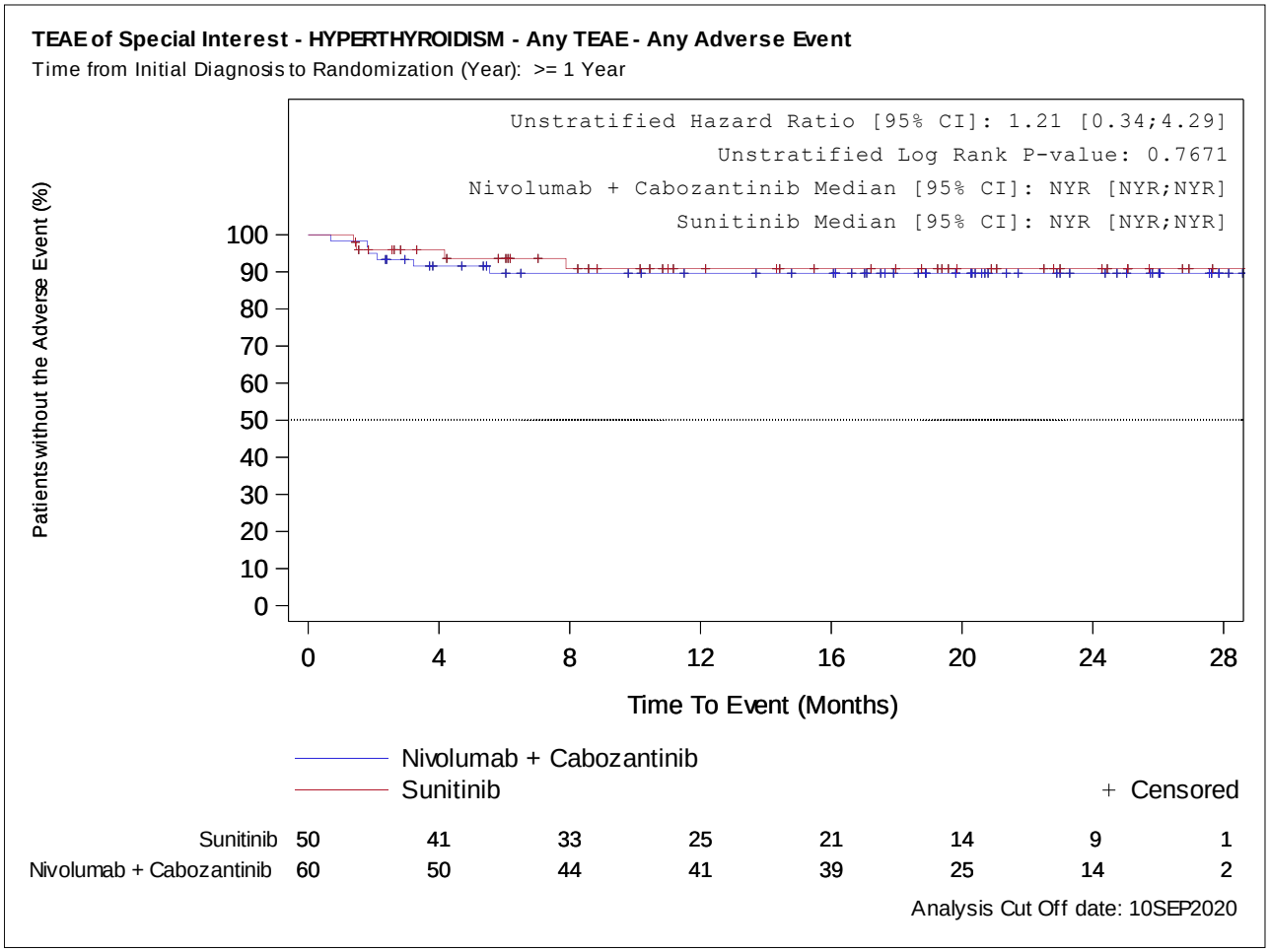

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:20:54

FIGURE 3.89.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



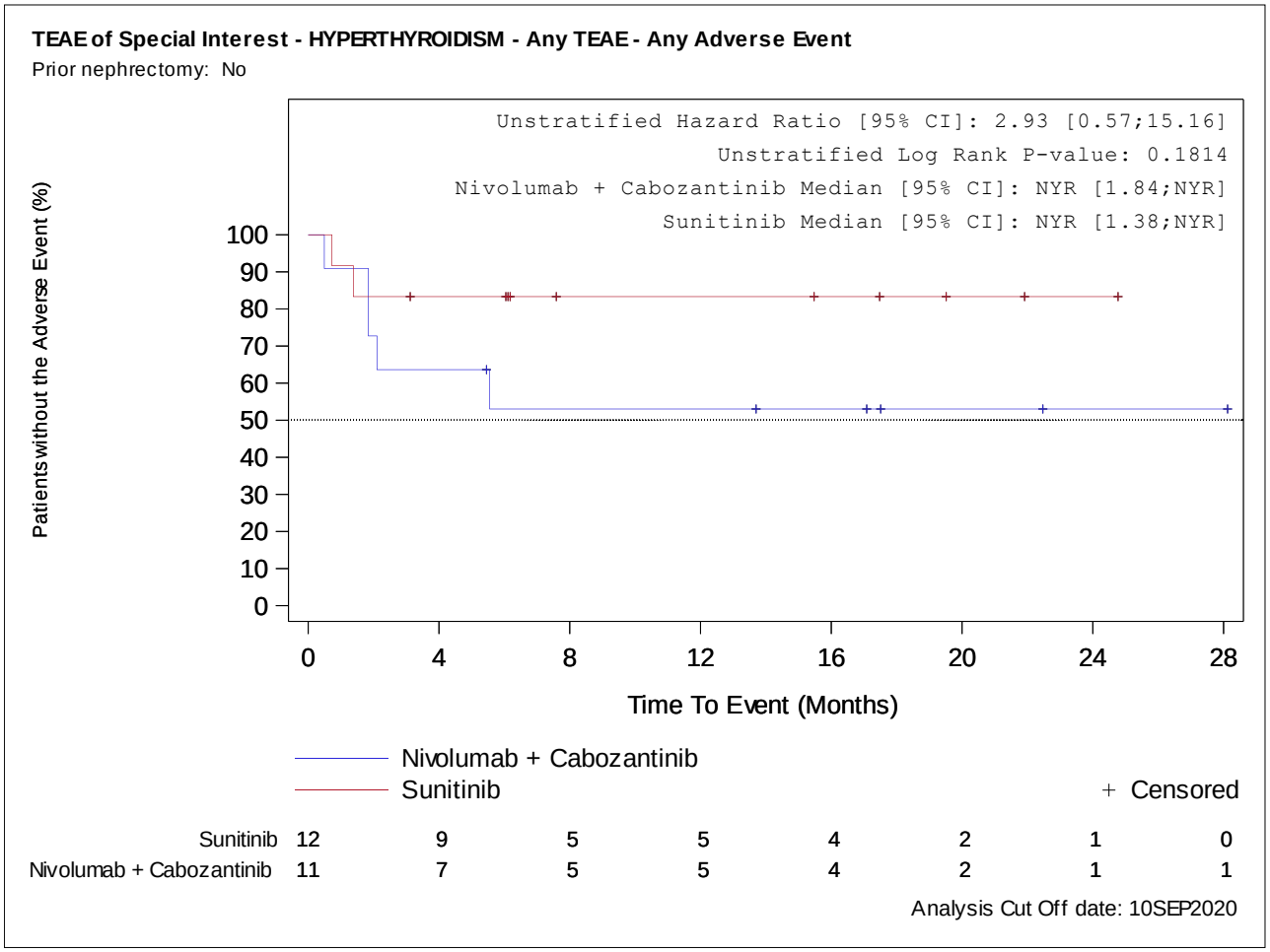

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:21:09

FIGURE 3.89.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



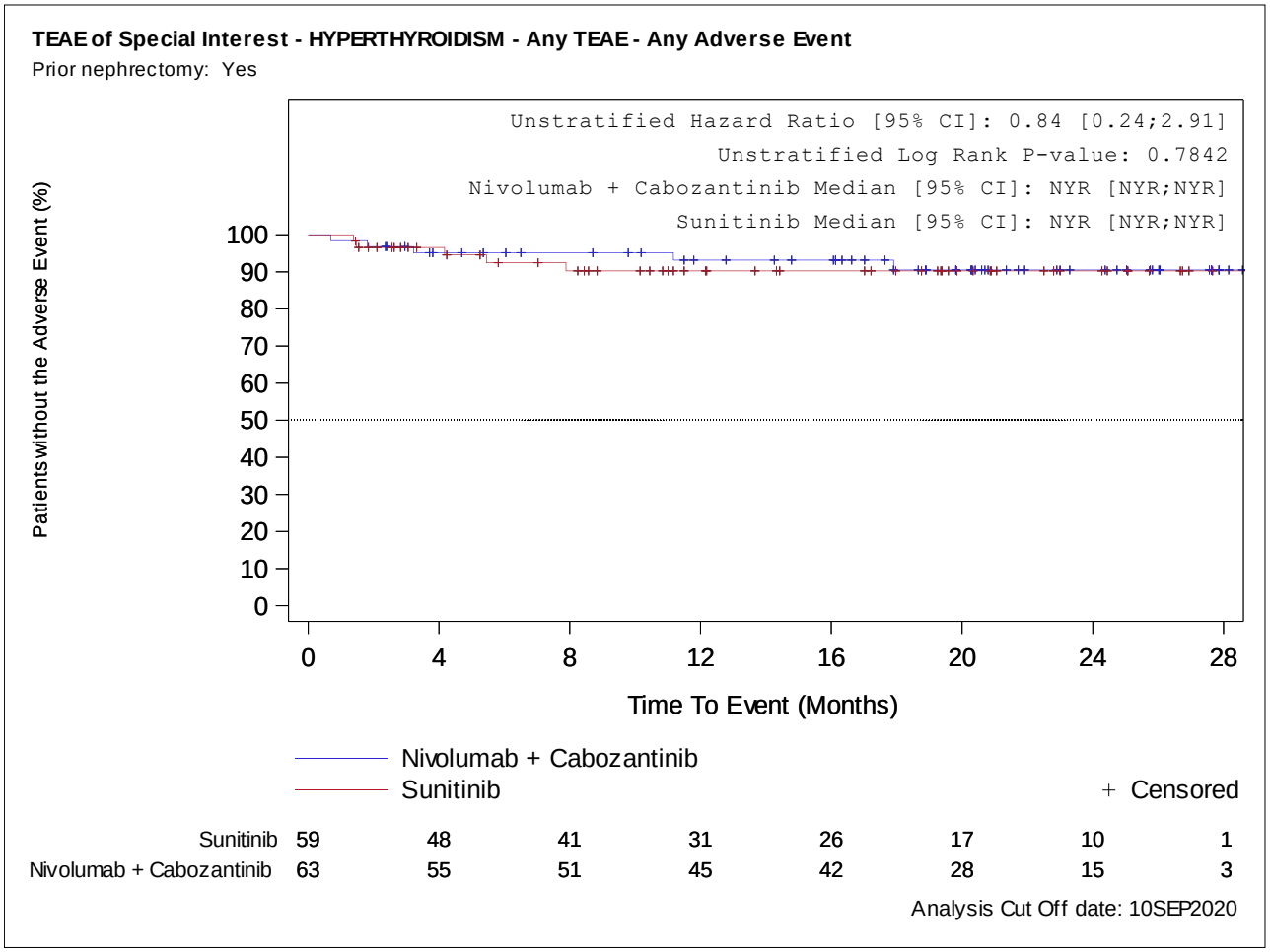

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:21:14

FIGURE 3.89.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



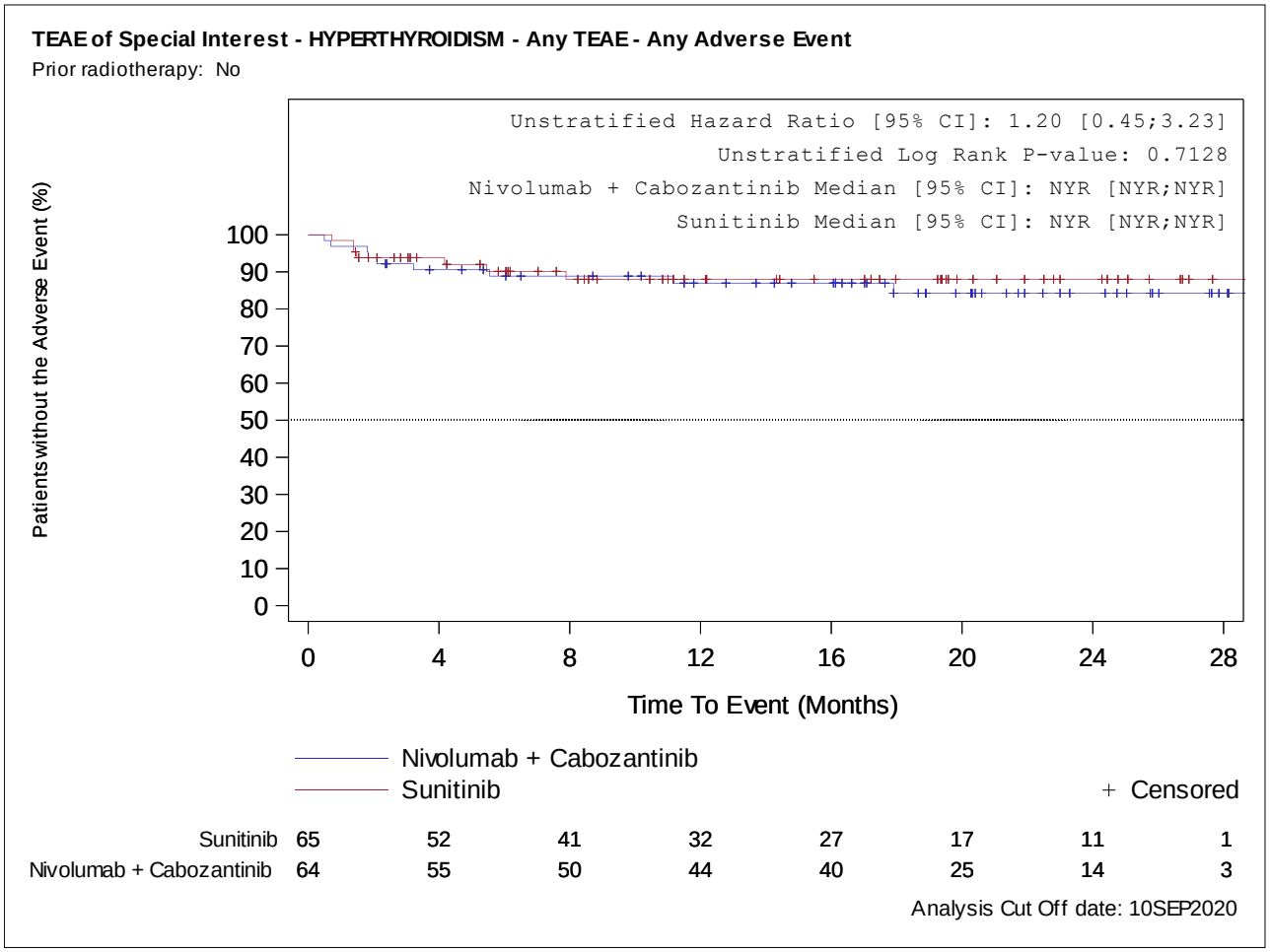

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:22:00

FIGURE 3.89.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



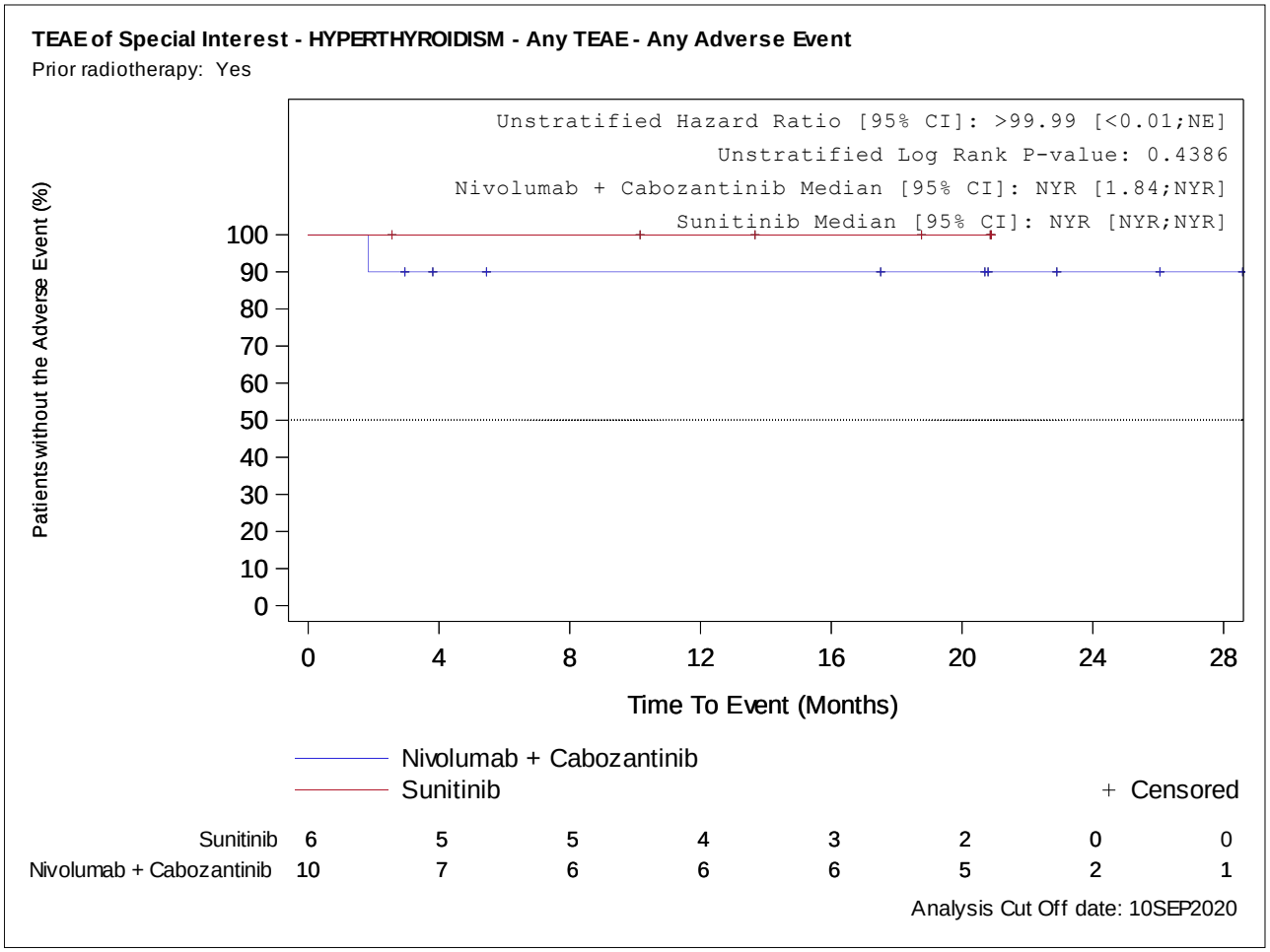

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:22:06

FIGURE 3.89.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



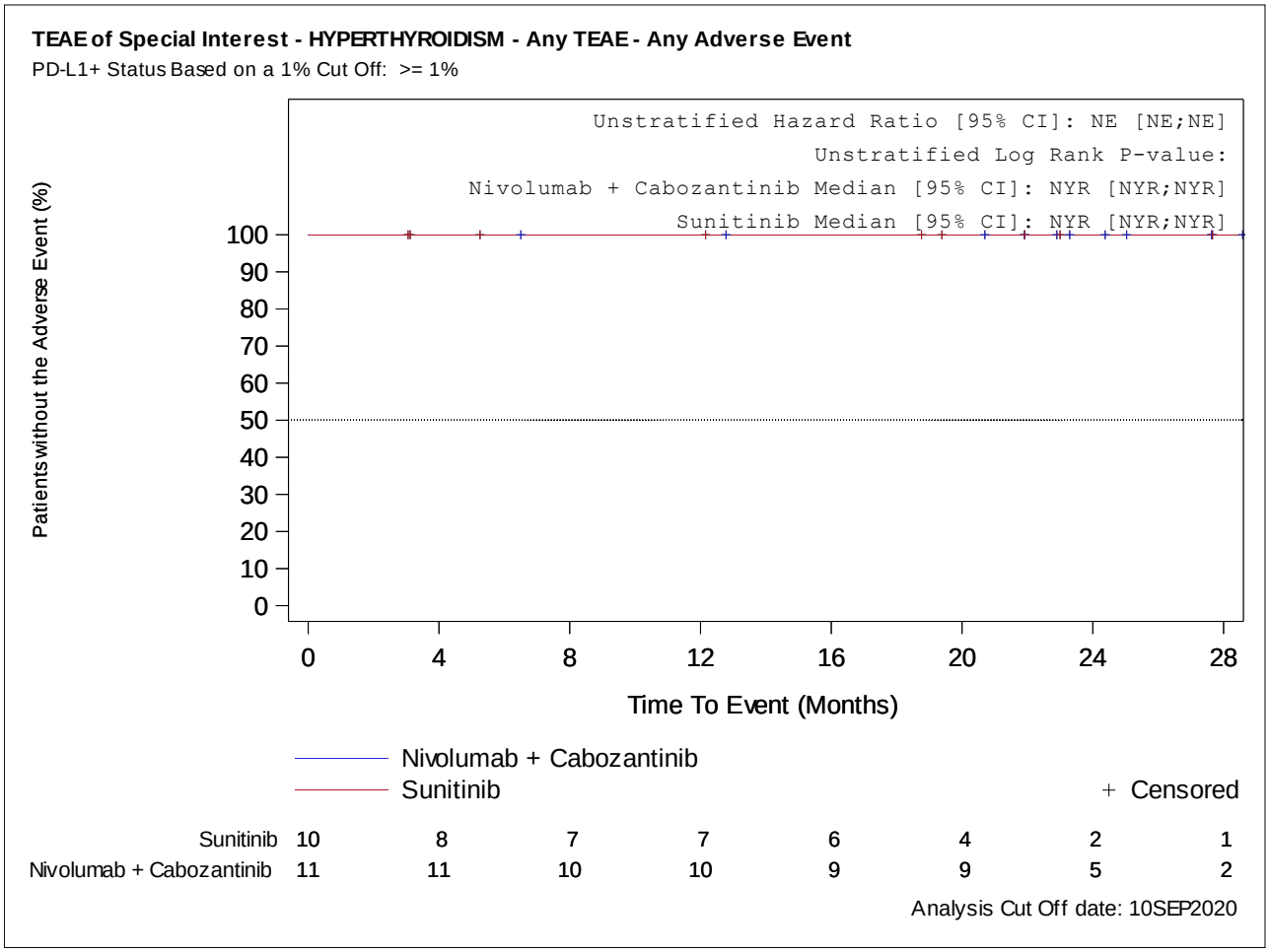

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:22:11

FIGURE 3.89.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



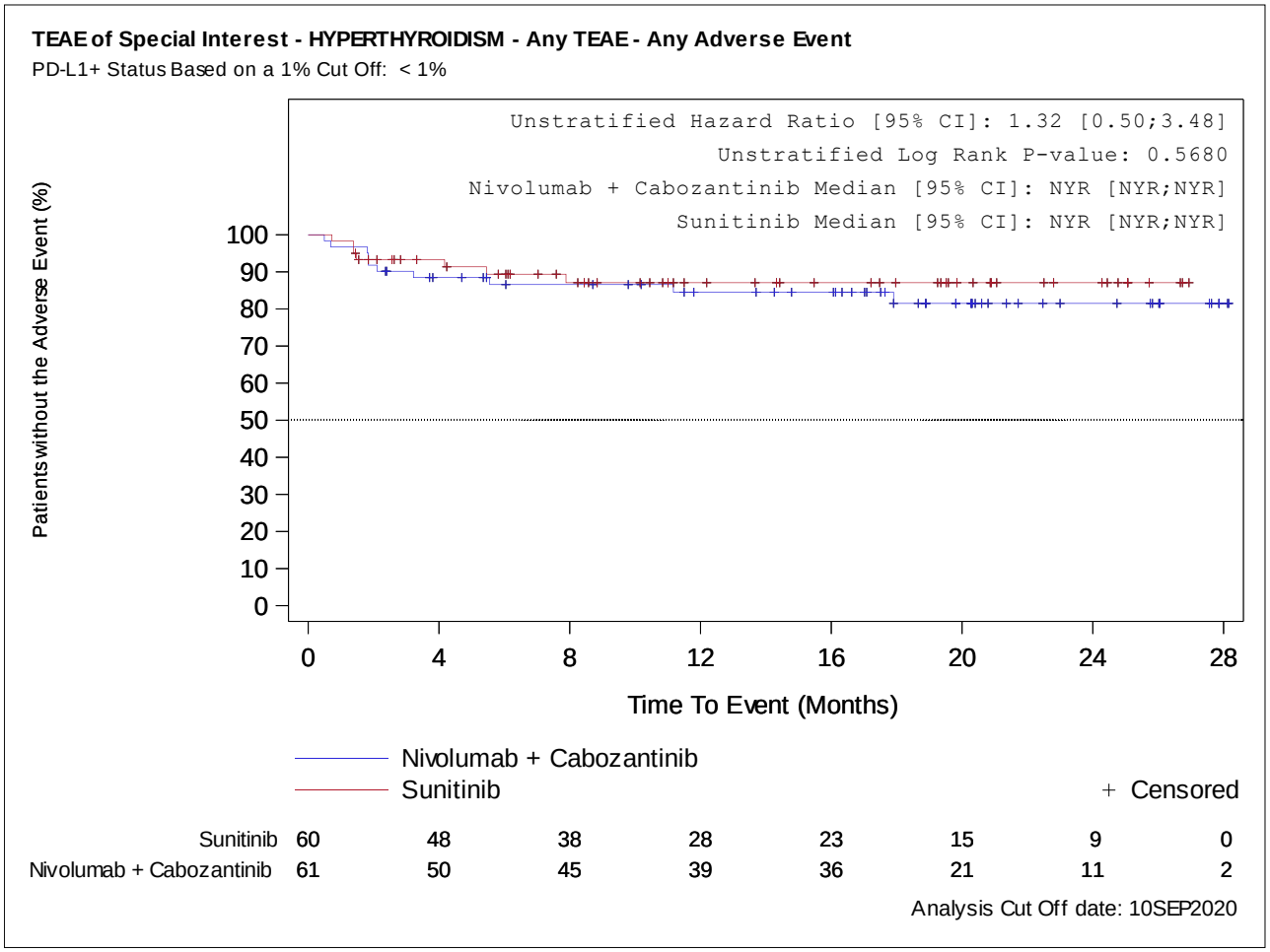

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:22:16

FIGURE 3.89.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



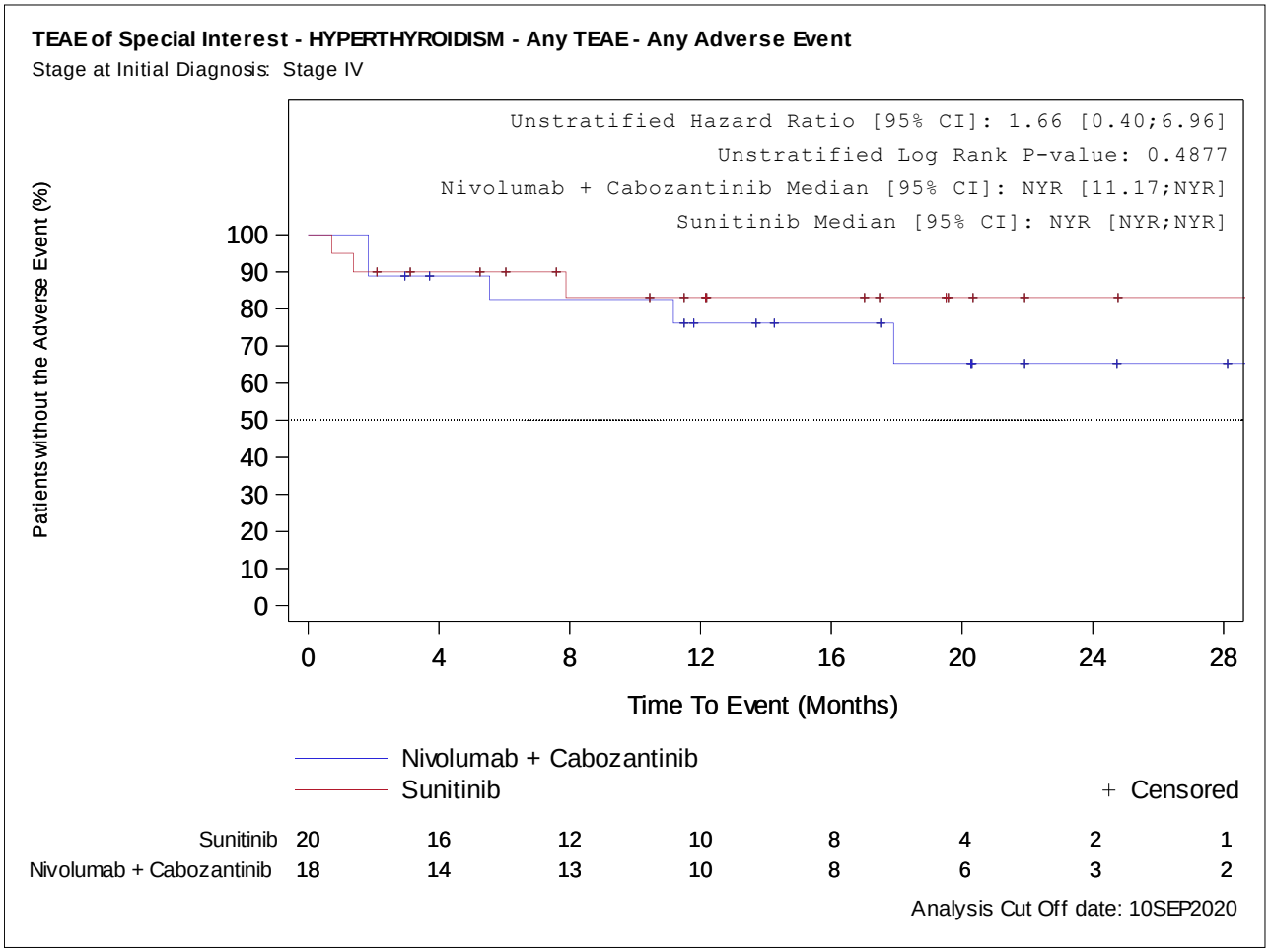

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:22:22

FIGURE 3.89.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



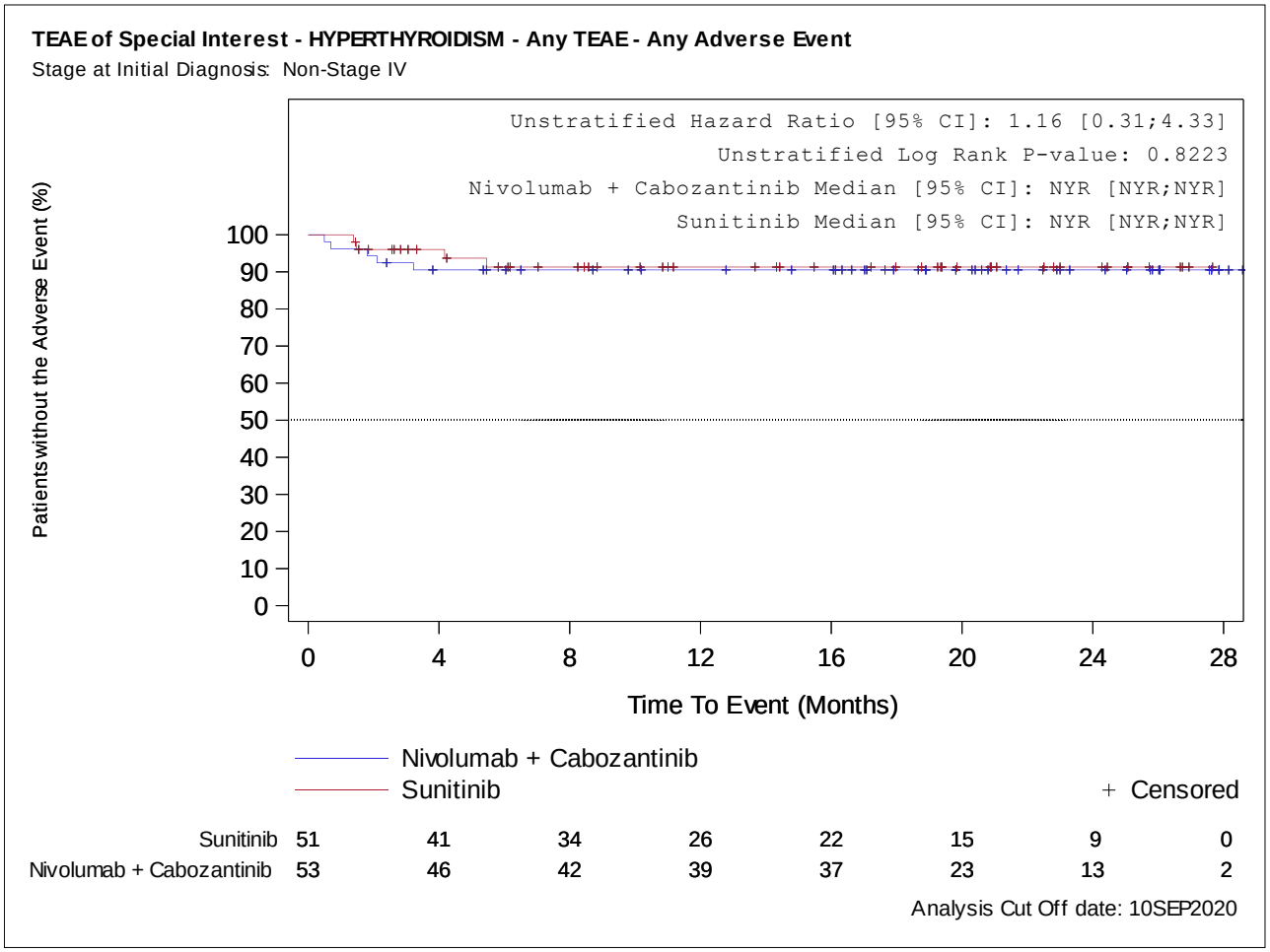

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:22:27

FIGURE 3.89.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



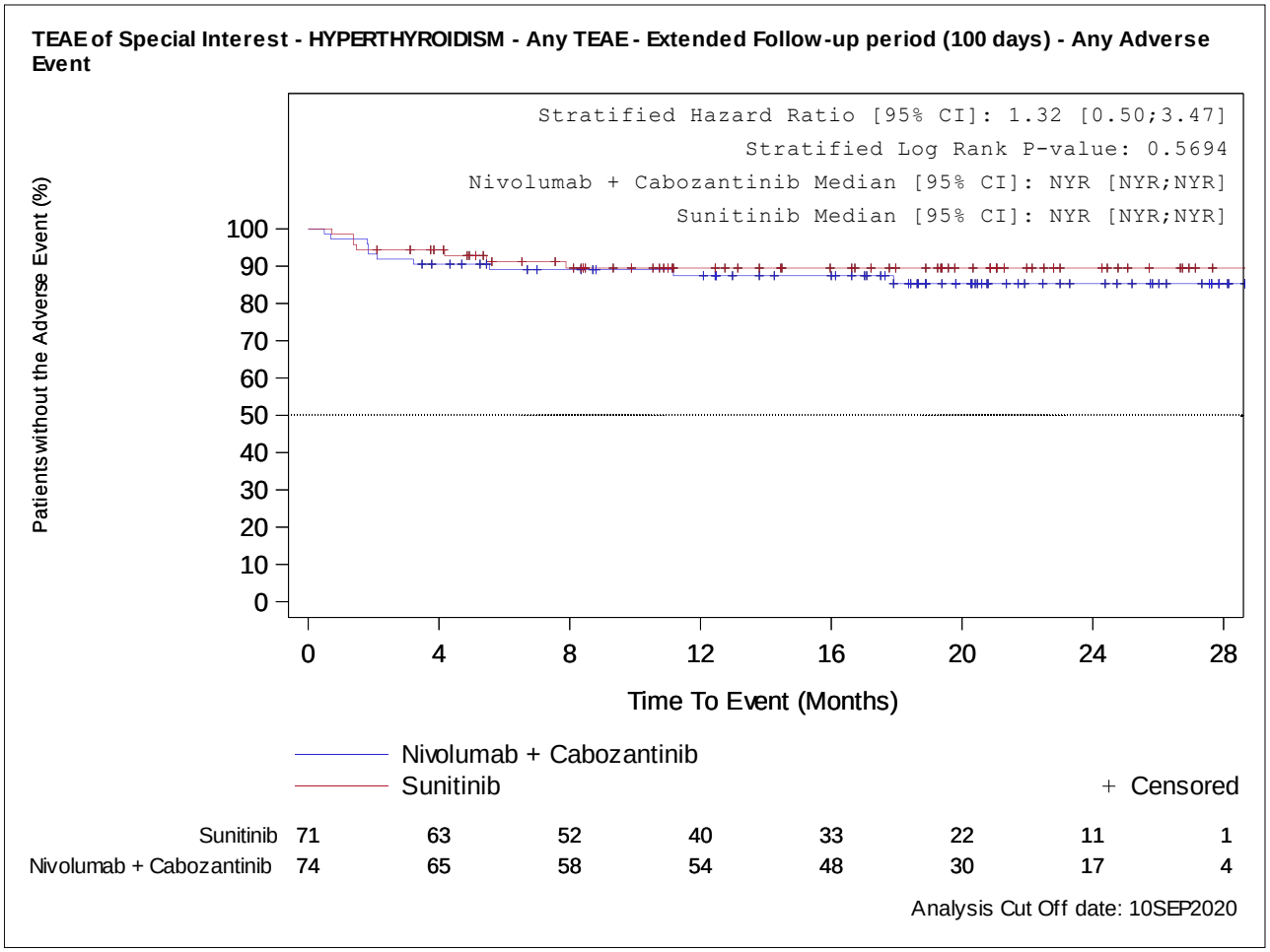

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:22:52

FIGURE 3.89.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



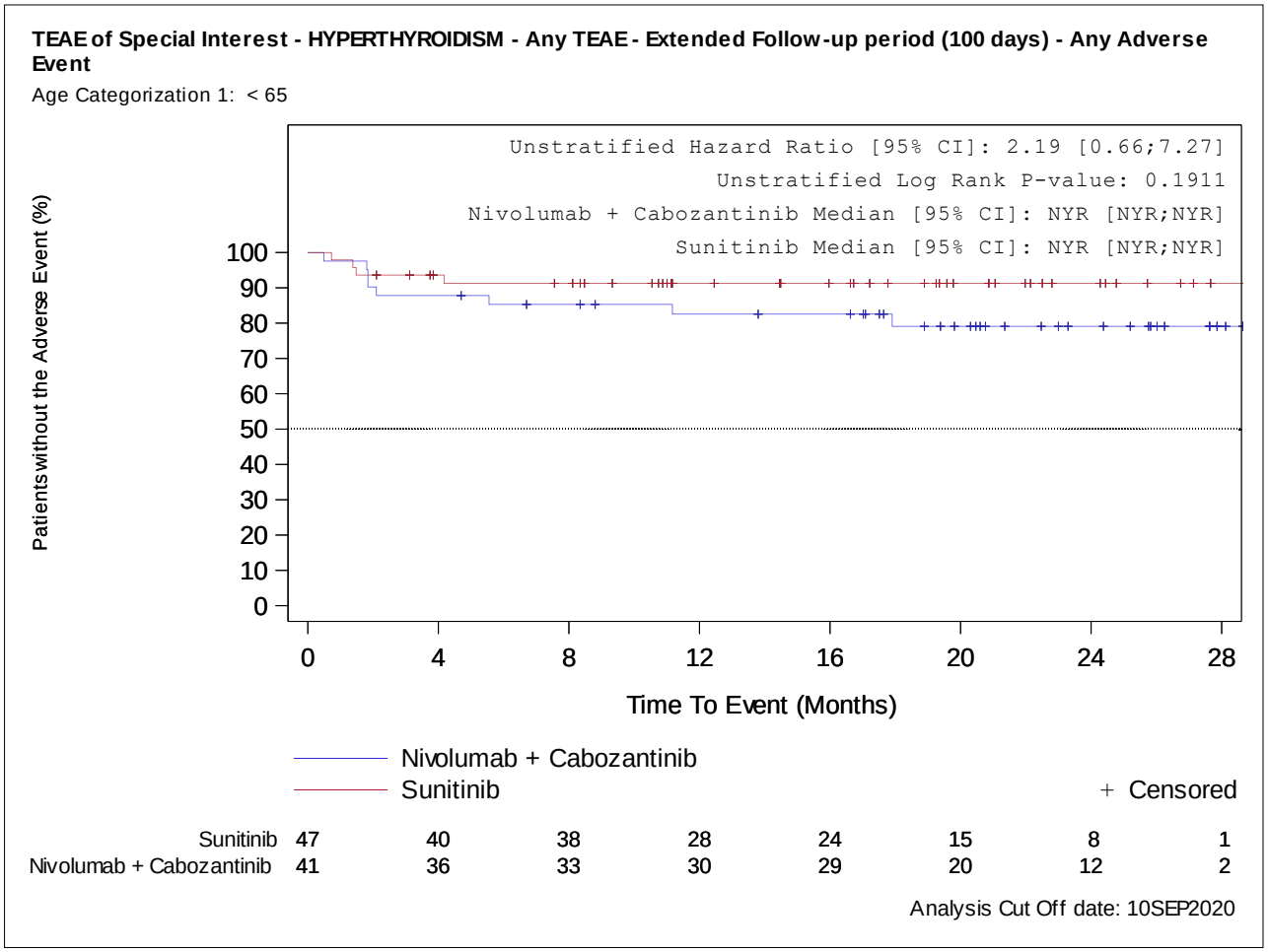

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:22:58

FIGURE 3.90.1: TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



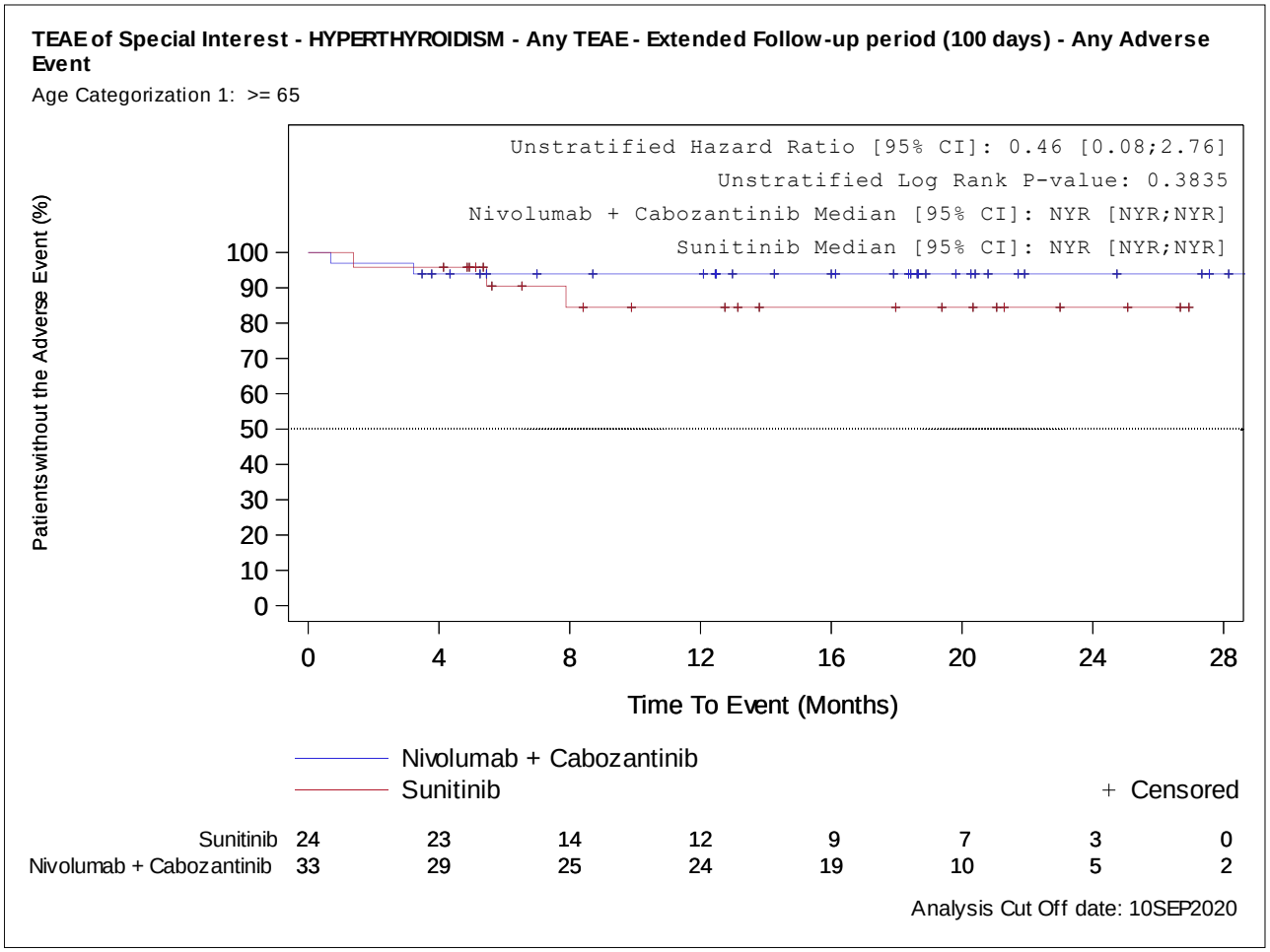

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:25:56

FIGURE 3.90.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



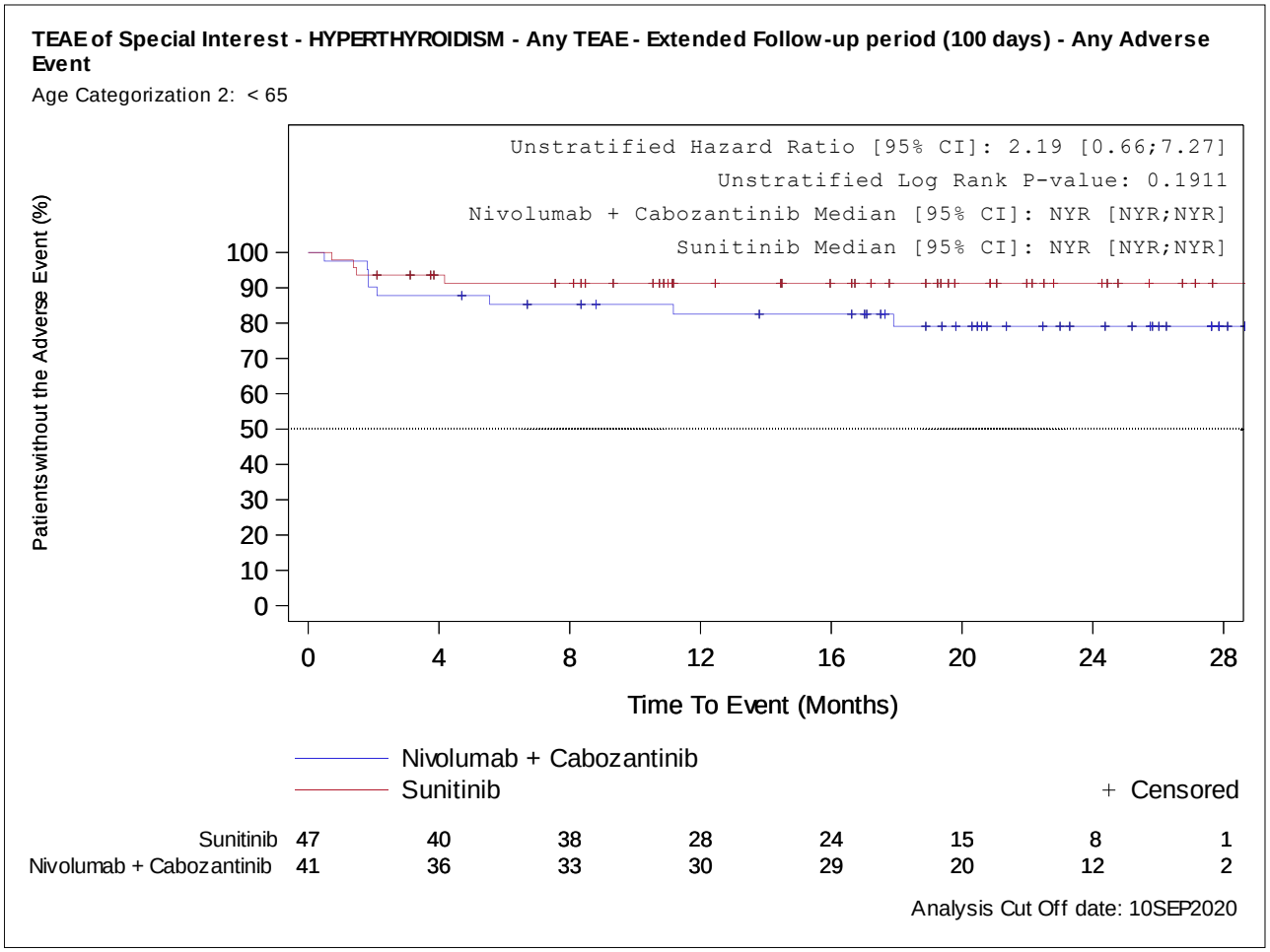

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:25:59

FIGURE 3.90.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



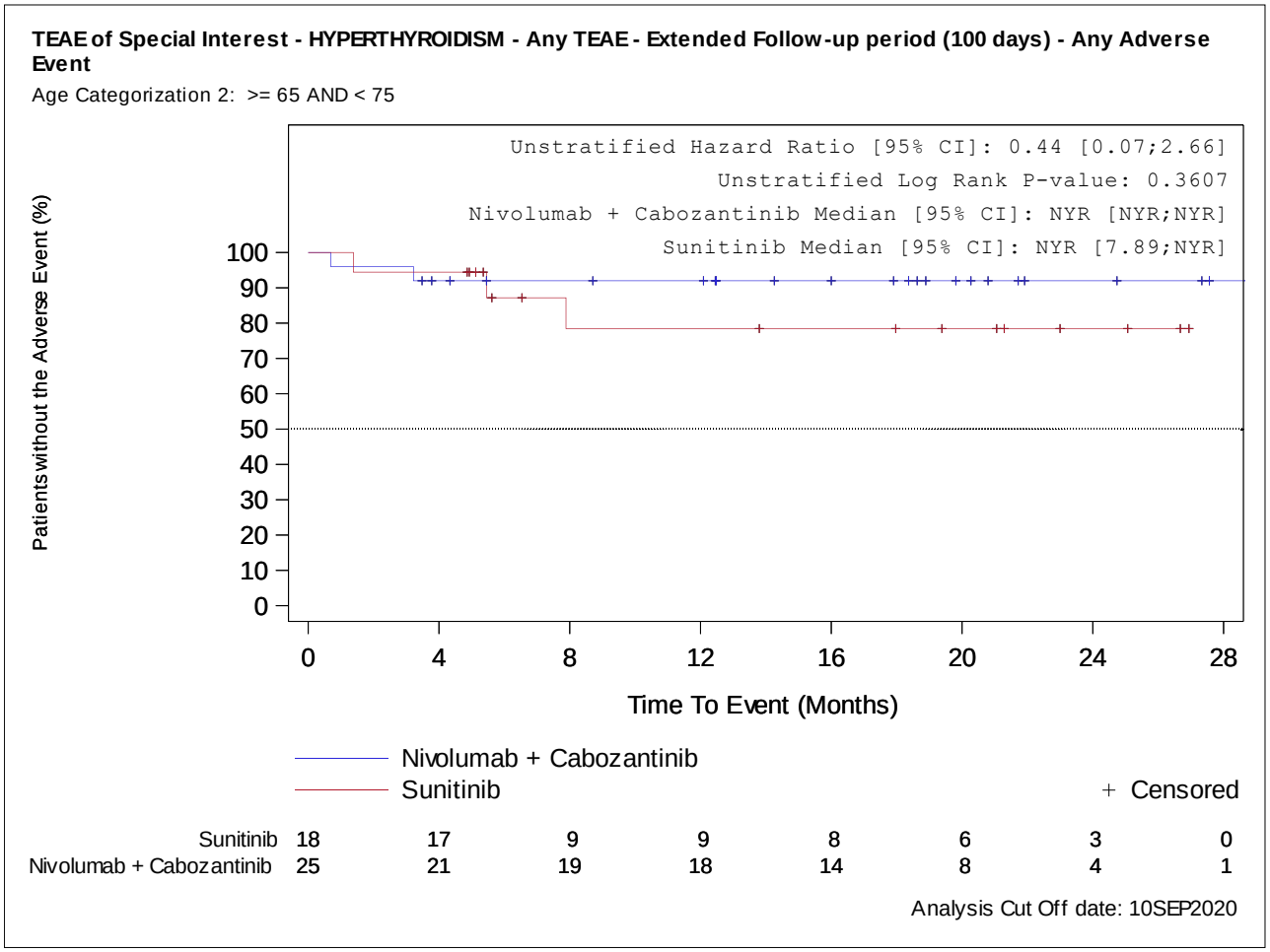

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:04

FIGURE 3.90.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



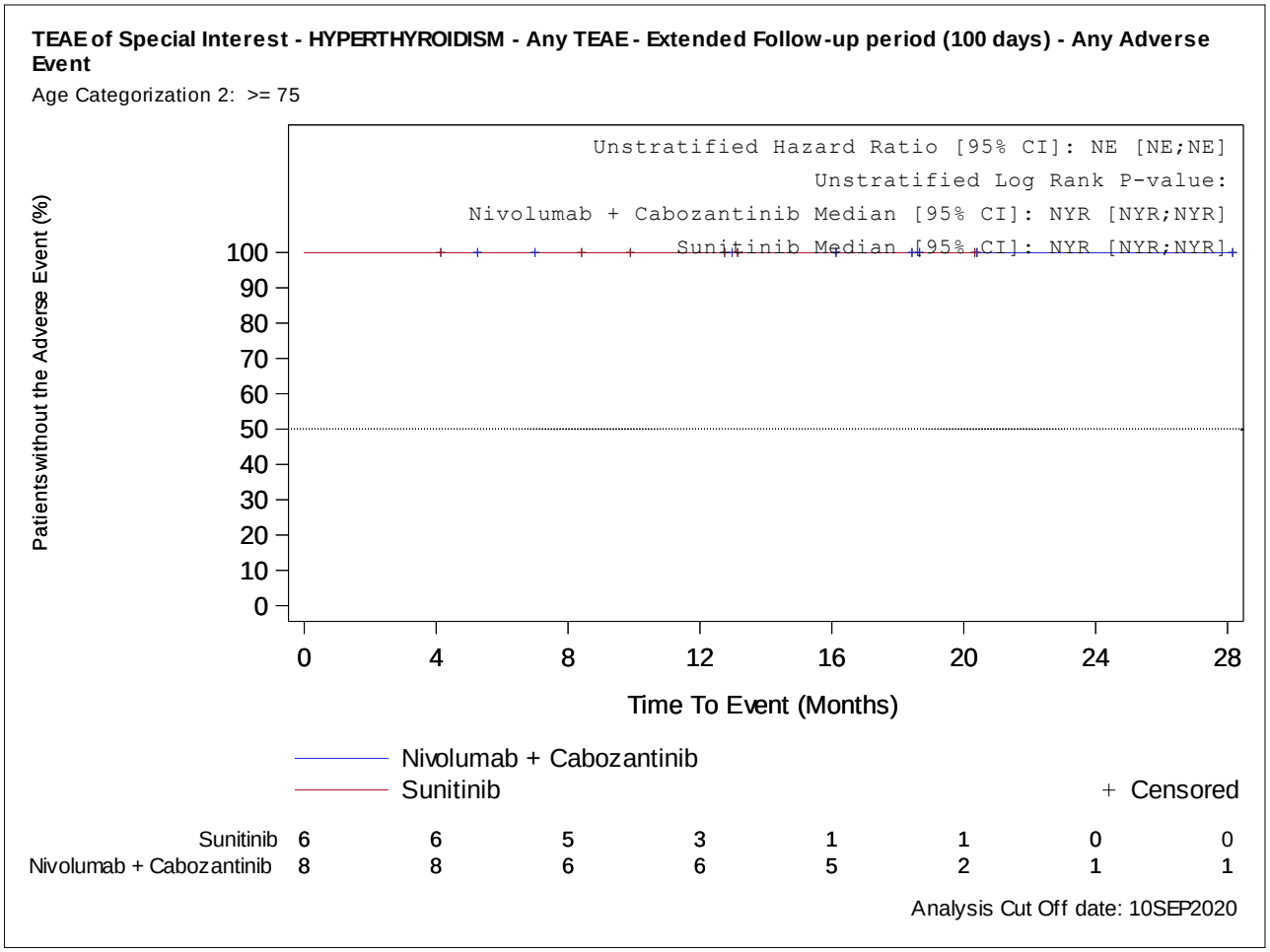

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:10

FIGURE 3.90.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



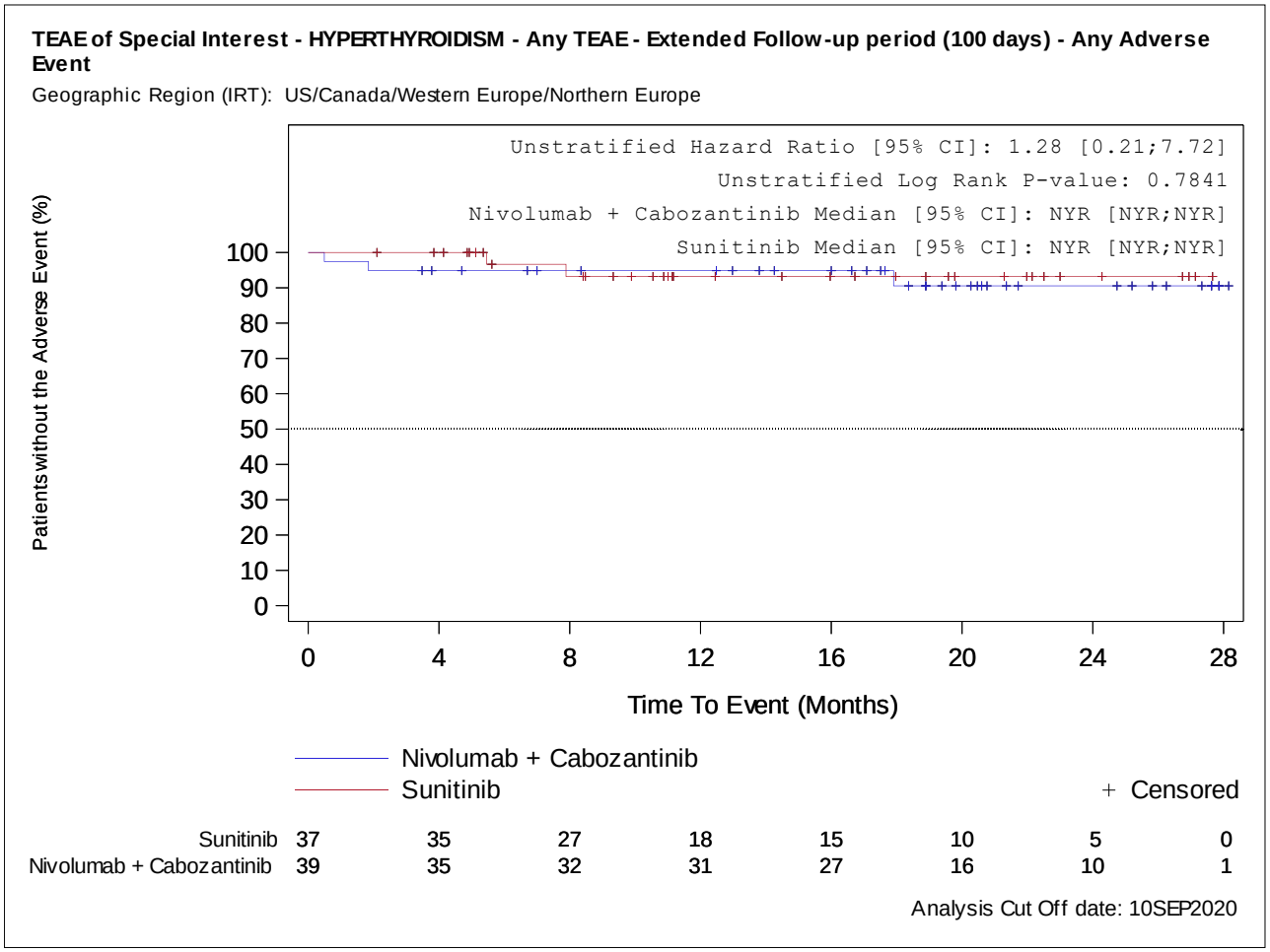

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:15

FIGURE 3.90.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



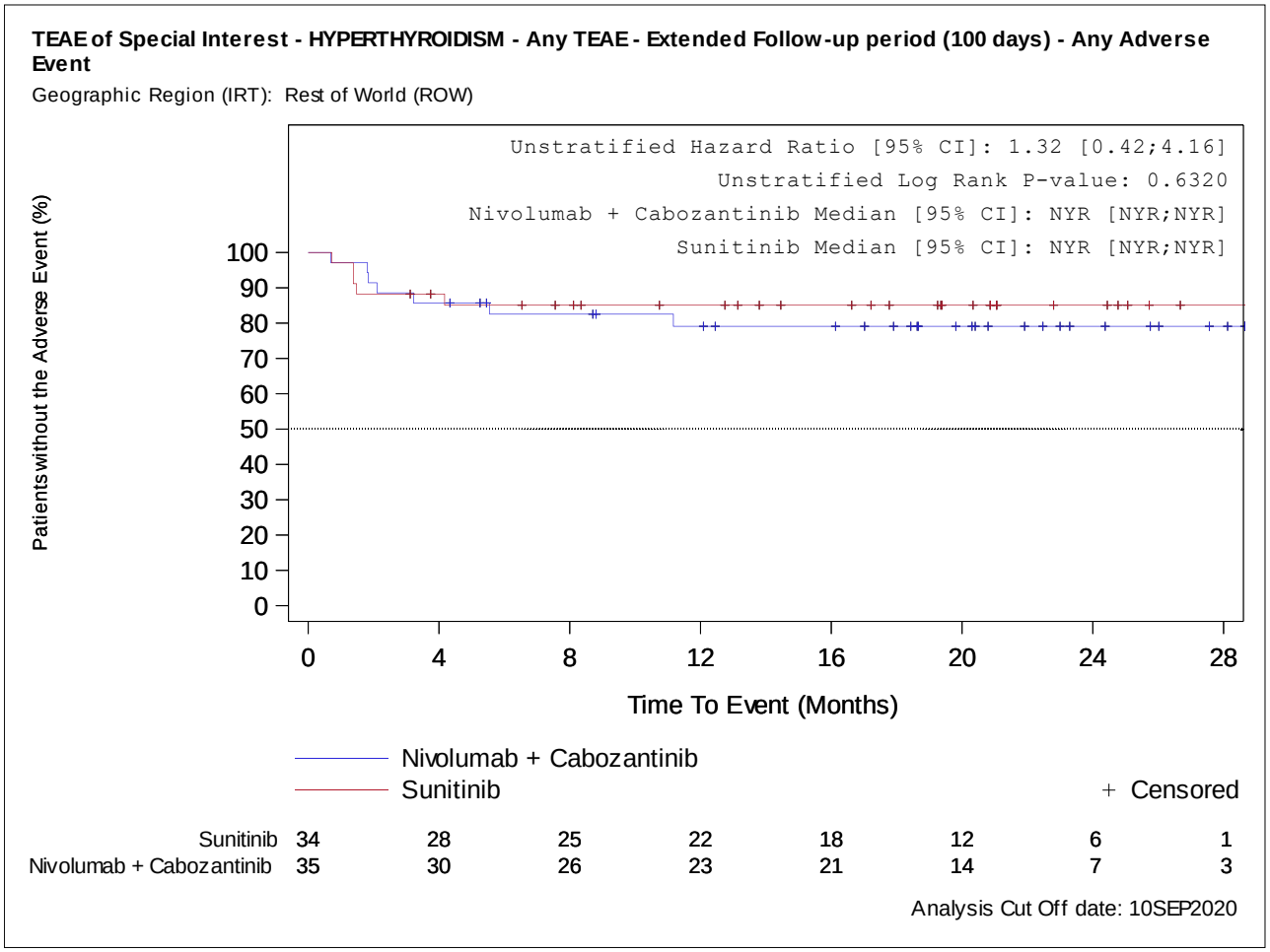

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:20

FIGURE 3.90.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



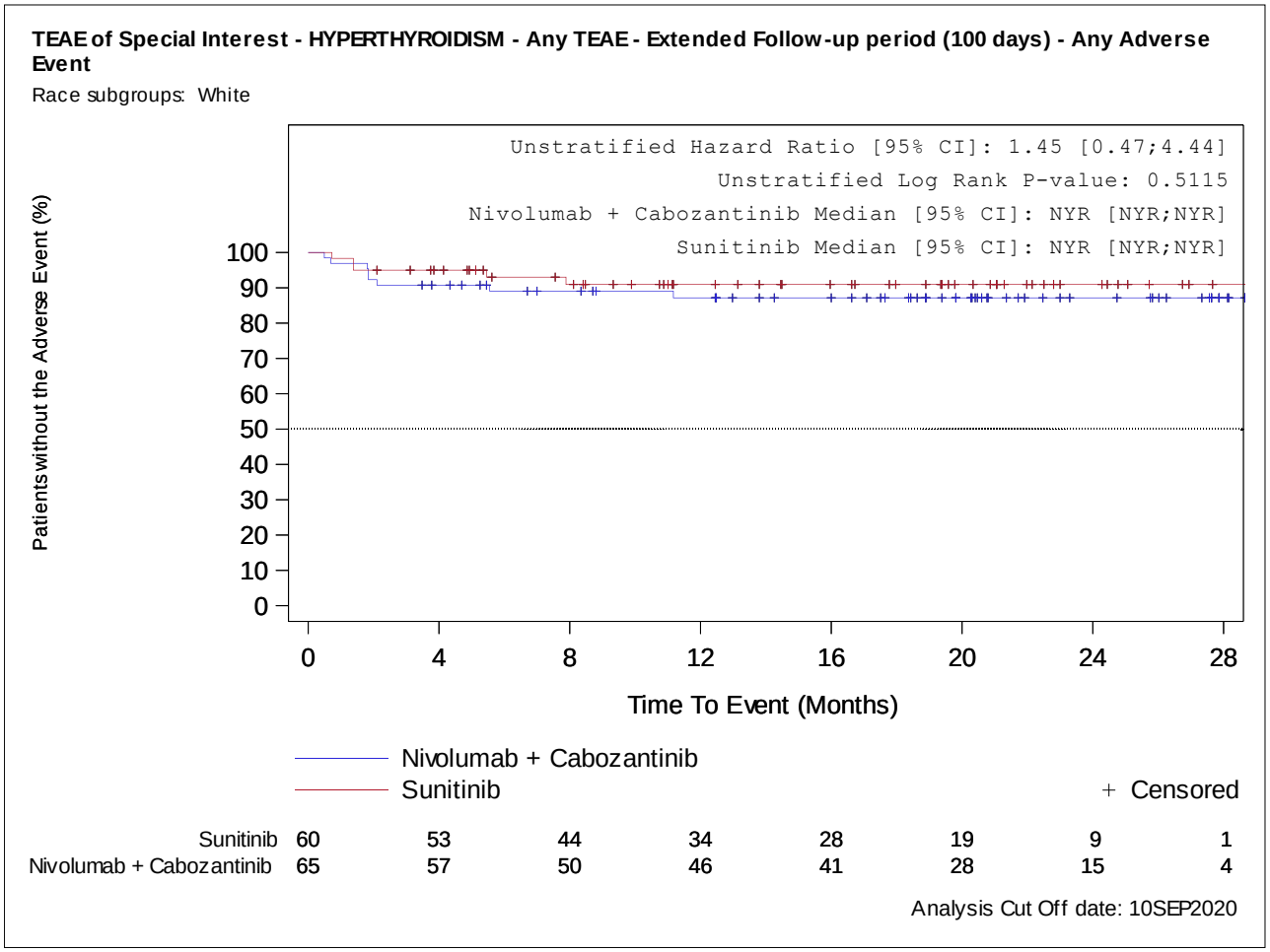

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:26

FIGURE 3.90.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



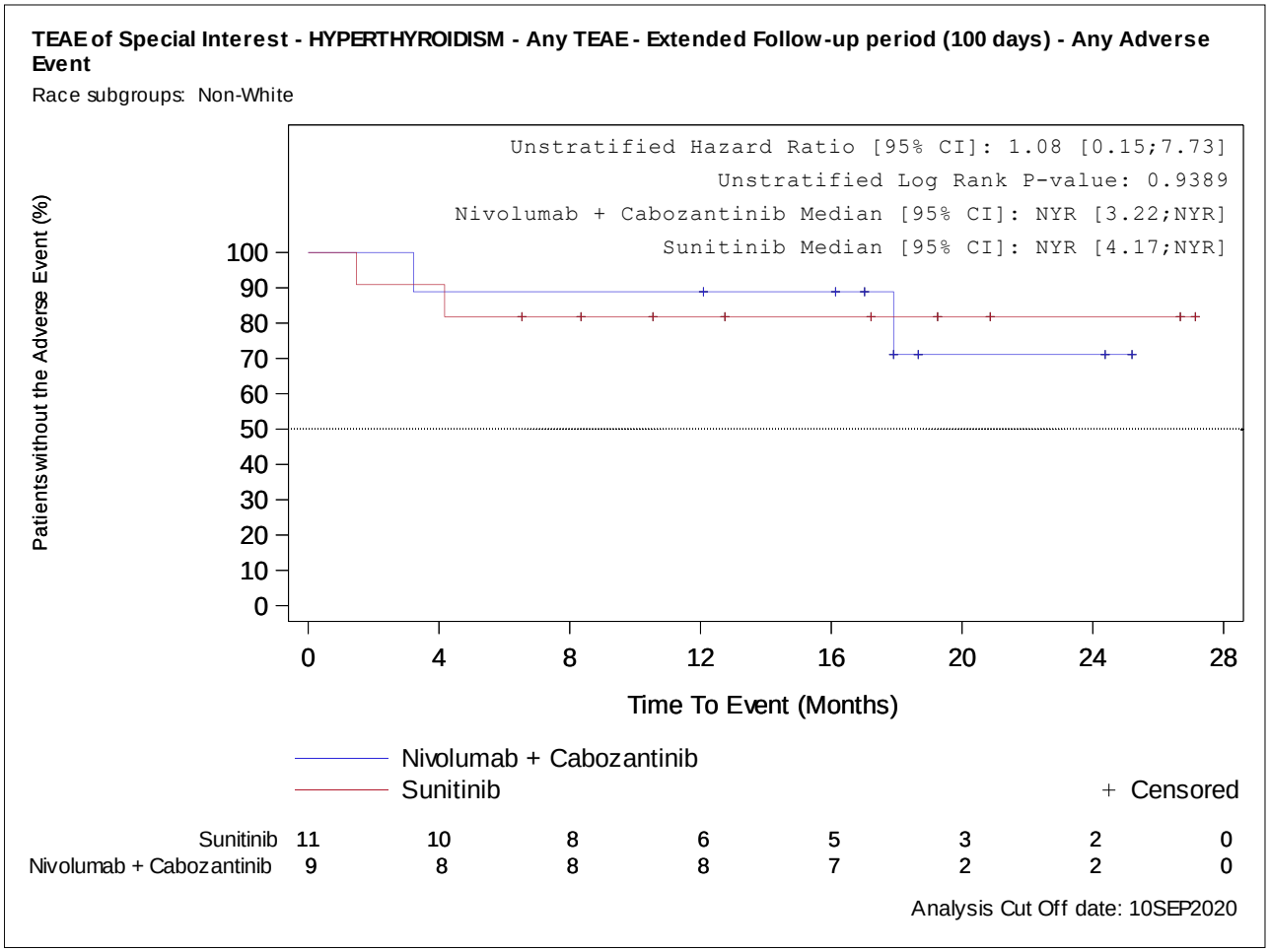

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:31

FIGURE 3.90.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



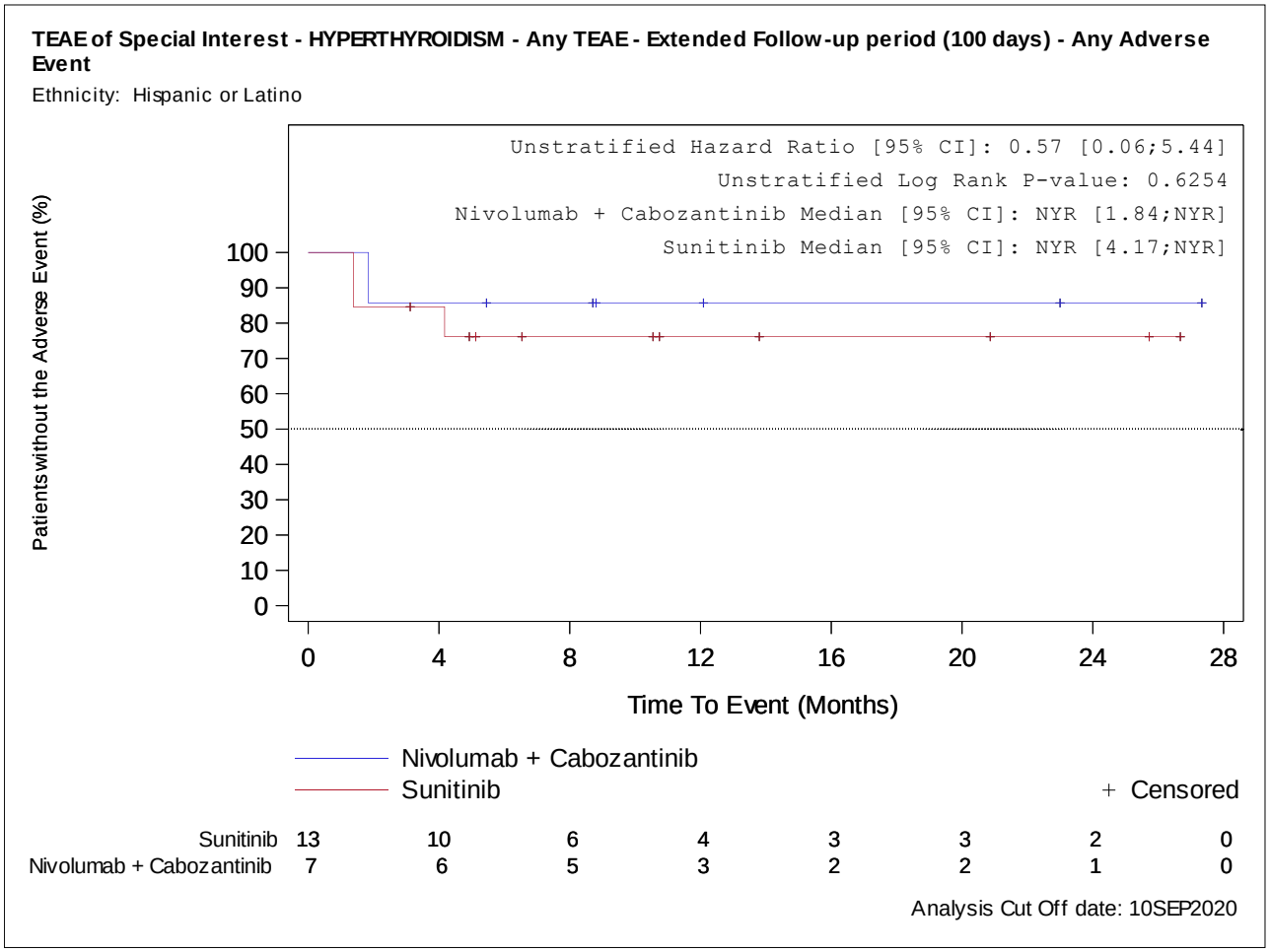

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:36

FIGURE 3.90.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



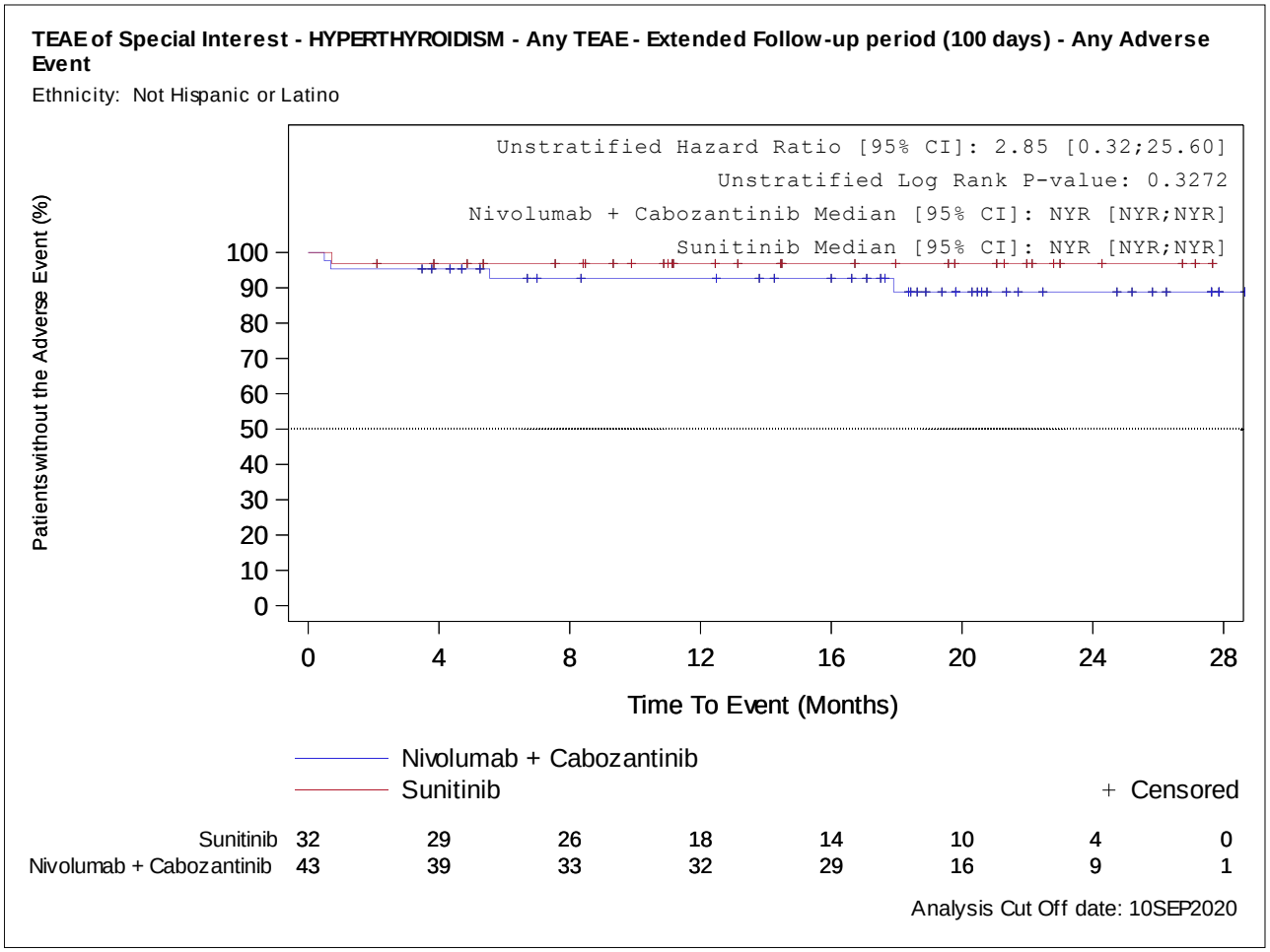

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:42

FIGURE 3.90.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



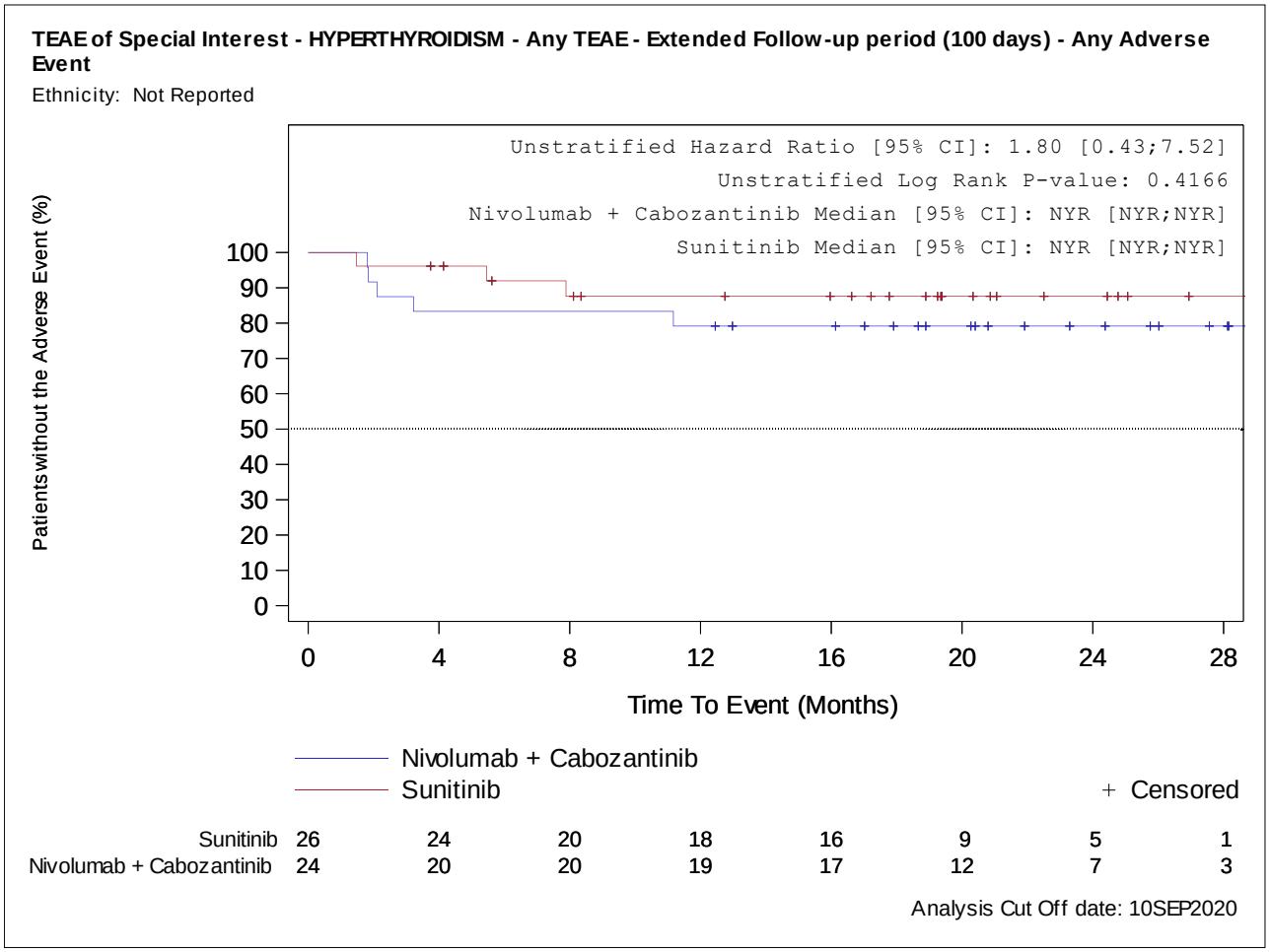

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:47

FIGURE 3.90.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



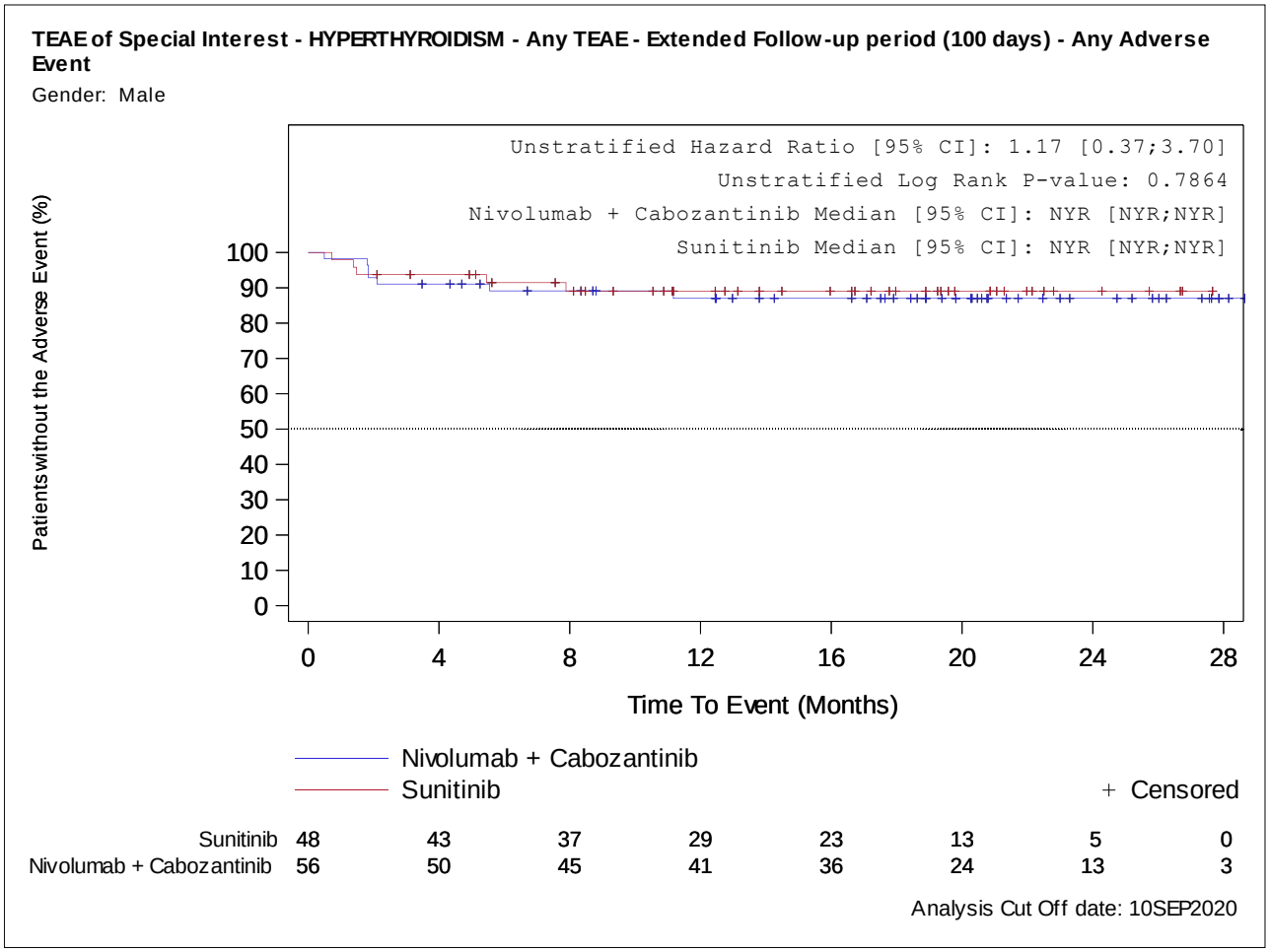

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:52

FIGURE 3.90.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



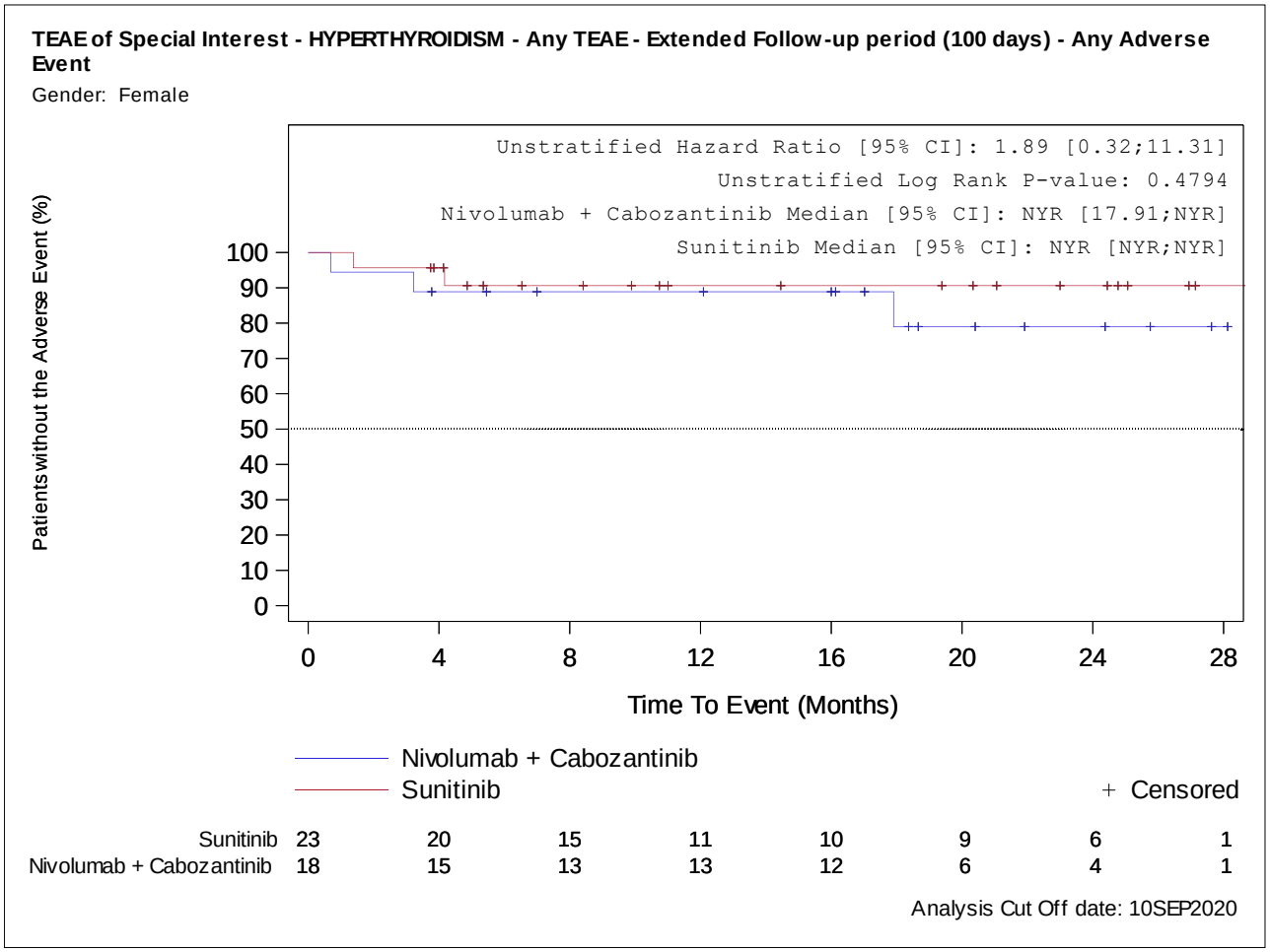

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:26:58

FIGURE 3.90.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



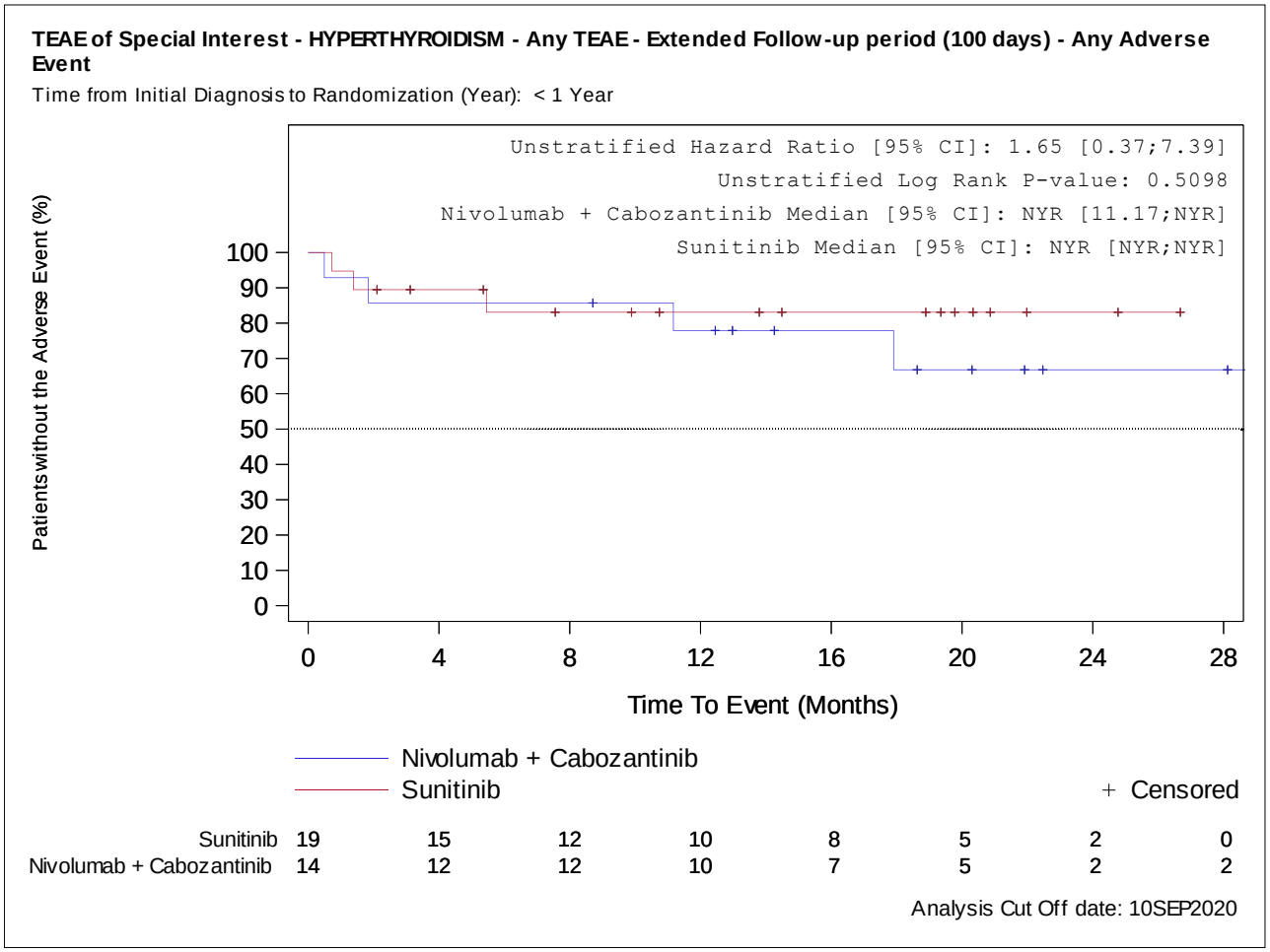

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:27:03

FIGURE 3.90.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



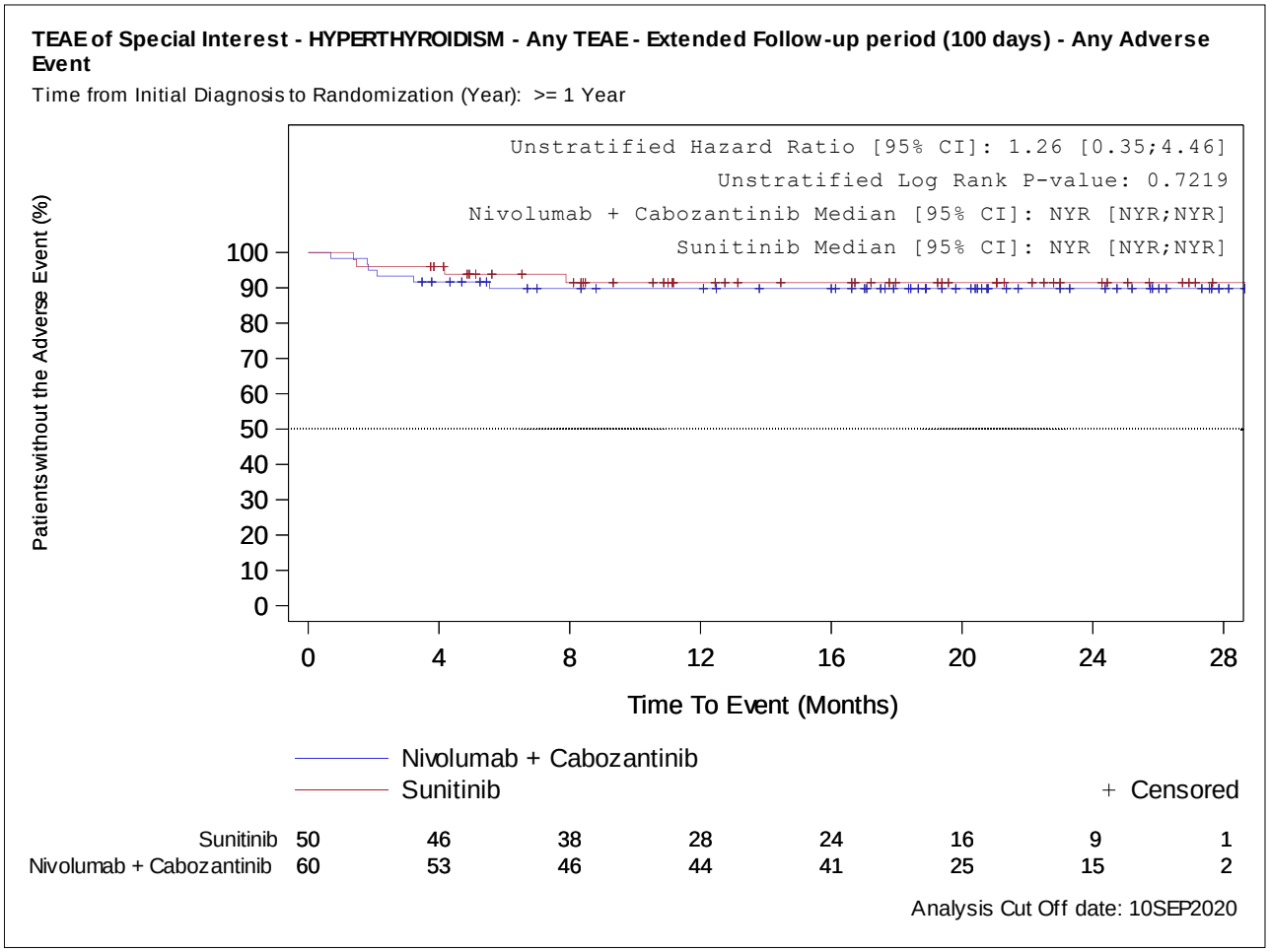

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:27:08

FIGURE 3.90.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



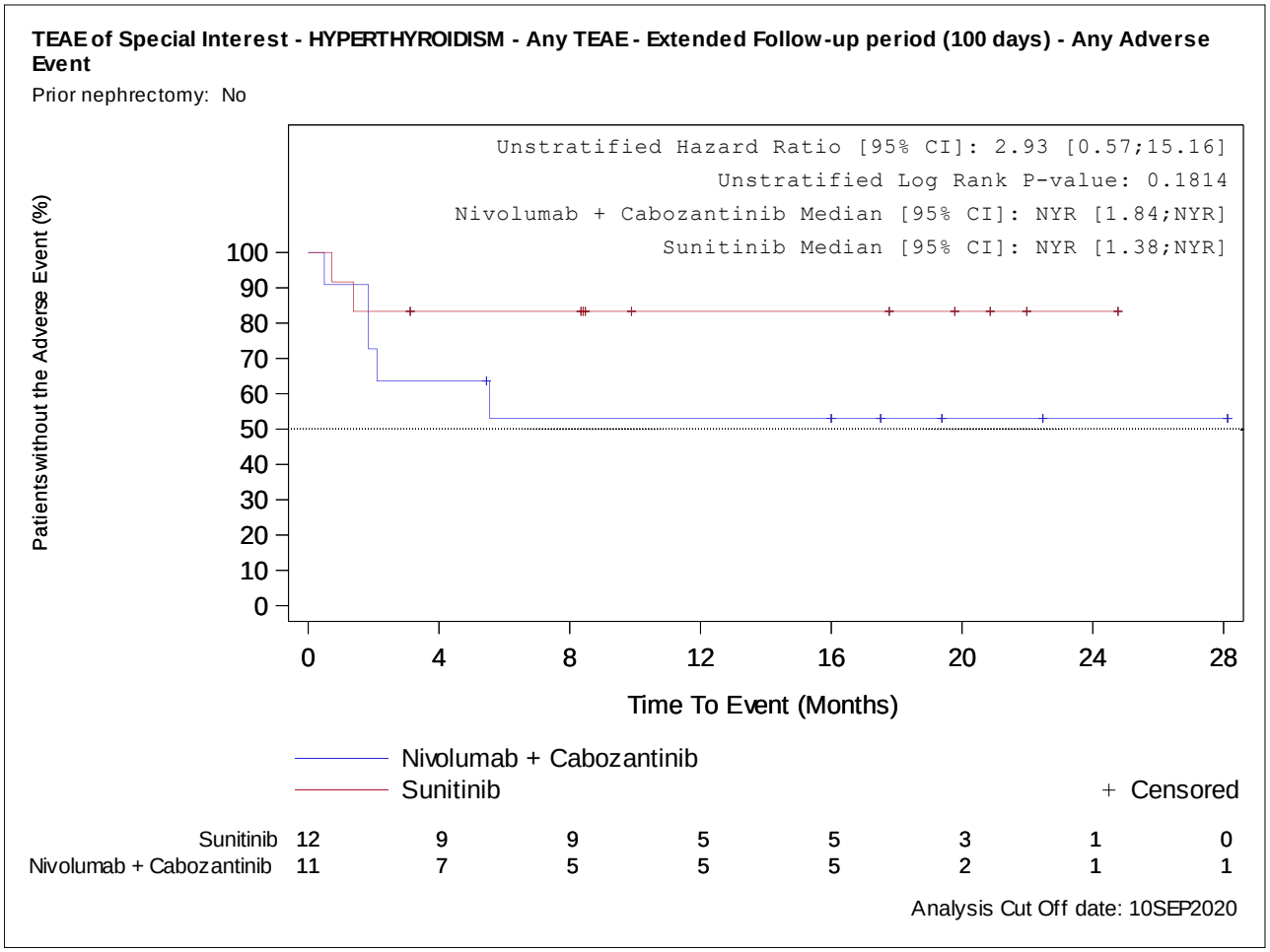

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:27:24

FIGURE 3.90.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



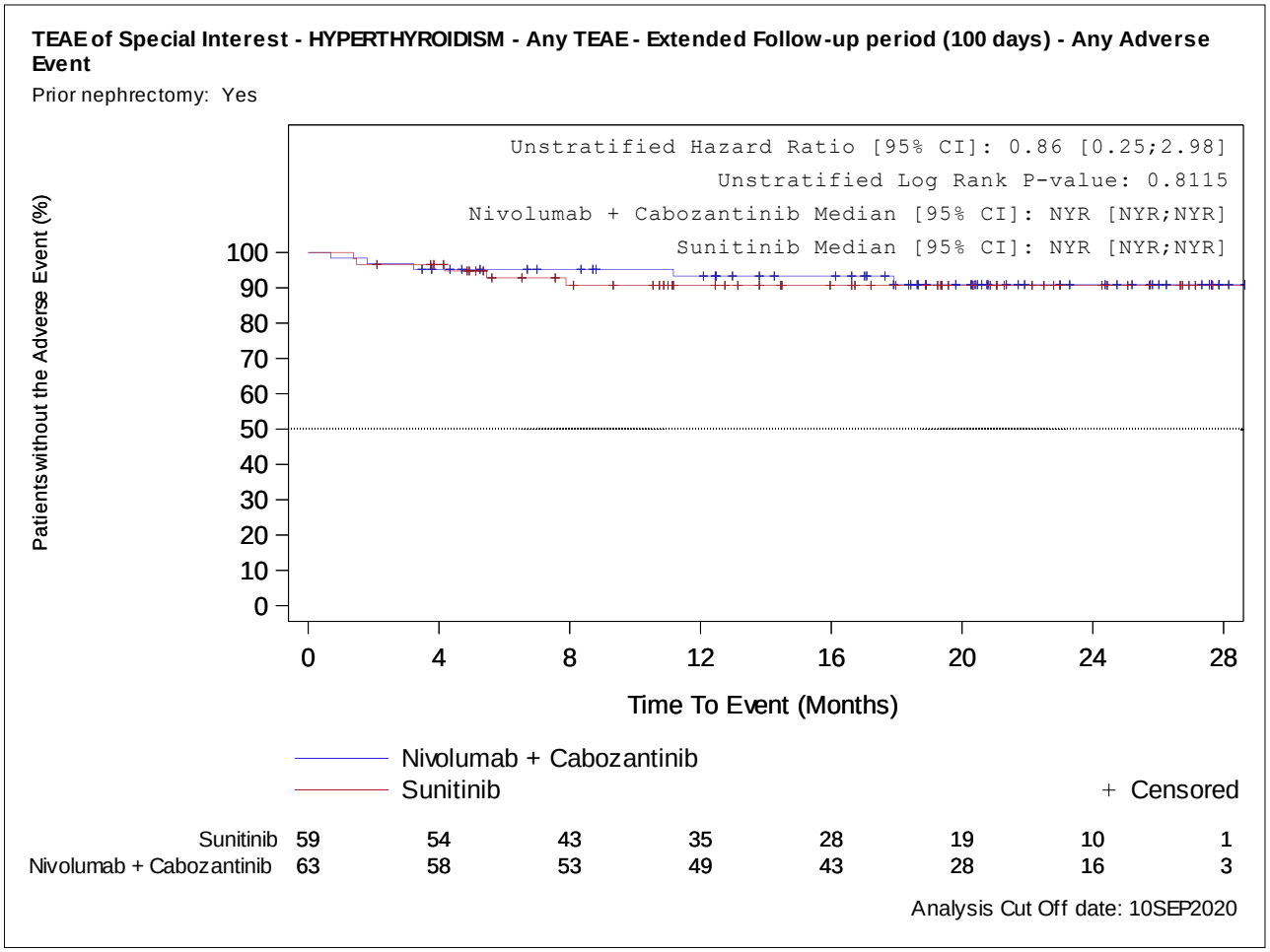

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:27:30

FIGURE 3.90.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



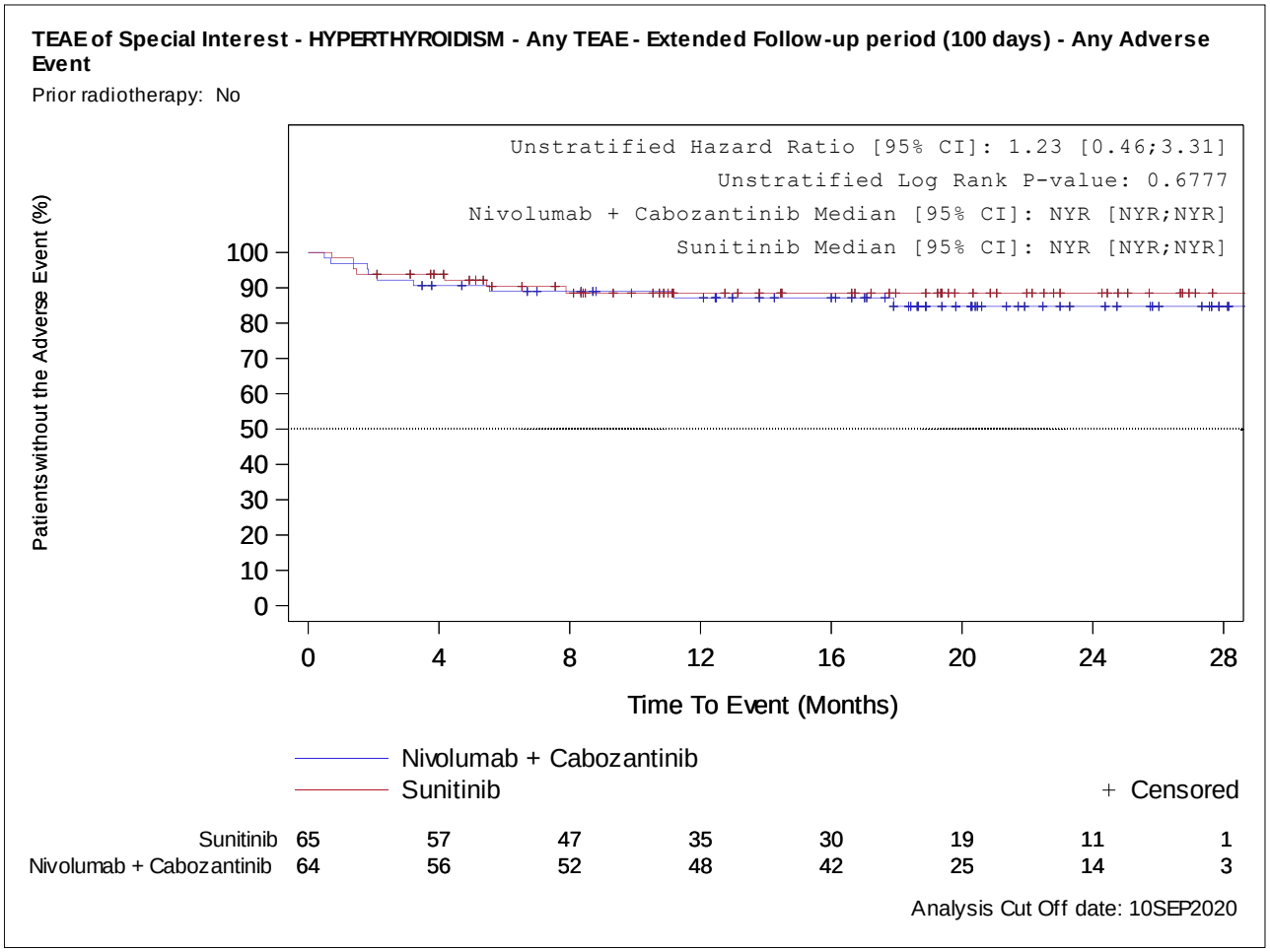

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:28:17

FIGURE 3.90.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



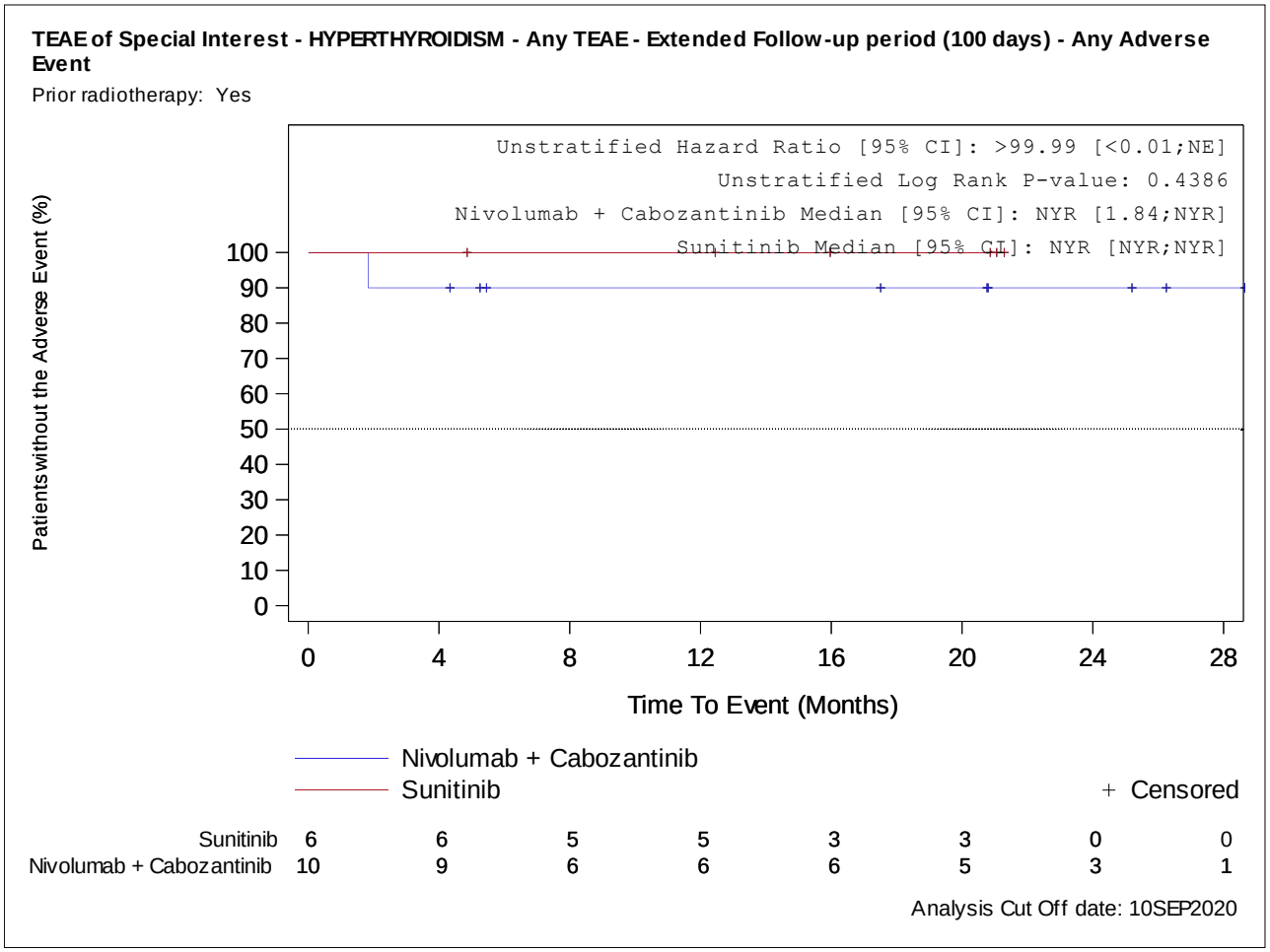

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:28:23

FIGURE 3.90.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



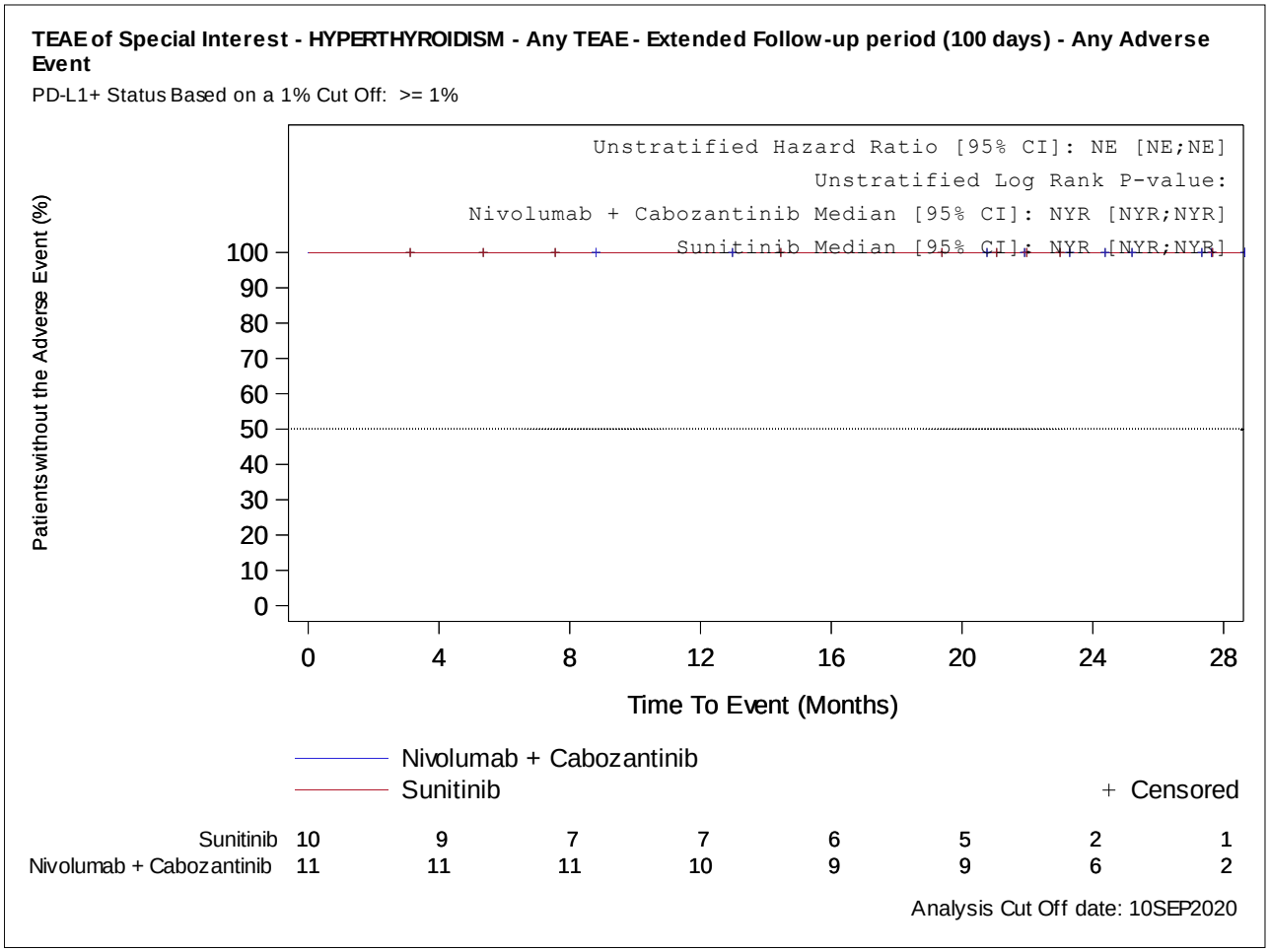

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:28:28

FIGURE 3.90.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



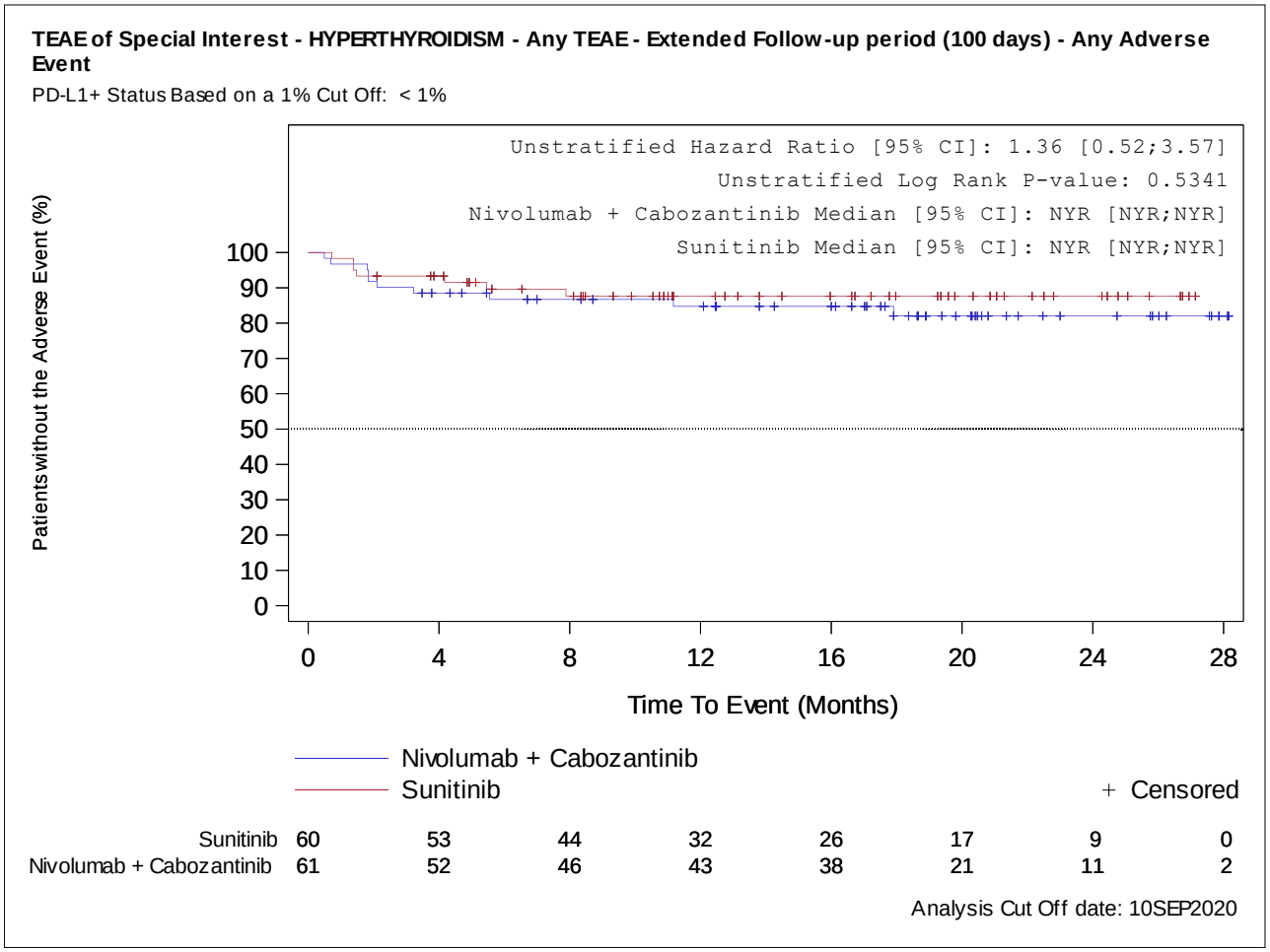

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:28:34

FIGURE 3.90.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:28:39

FIGURE 3.90.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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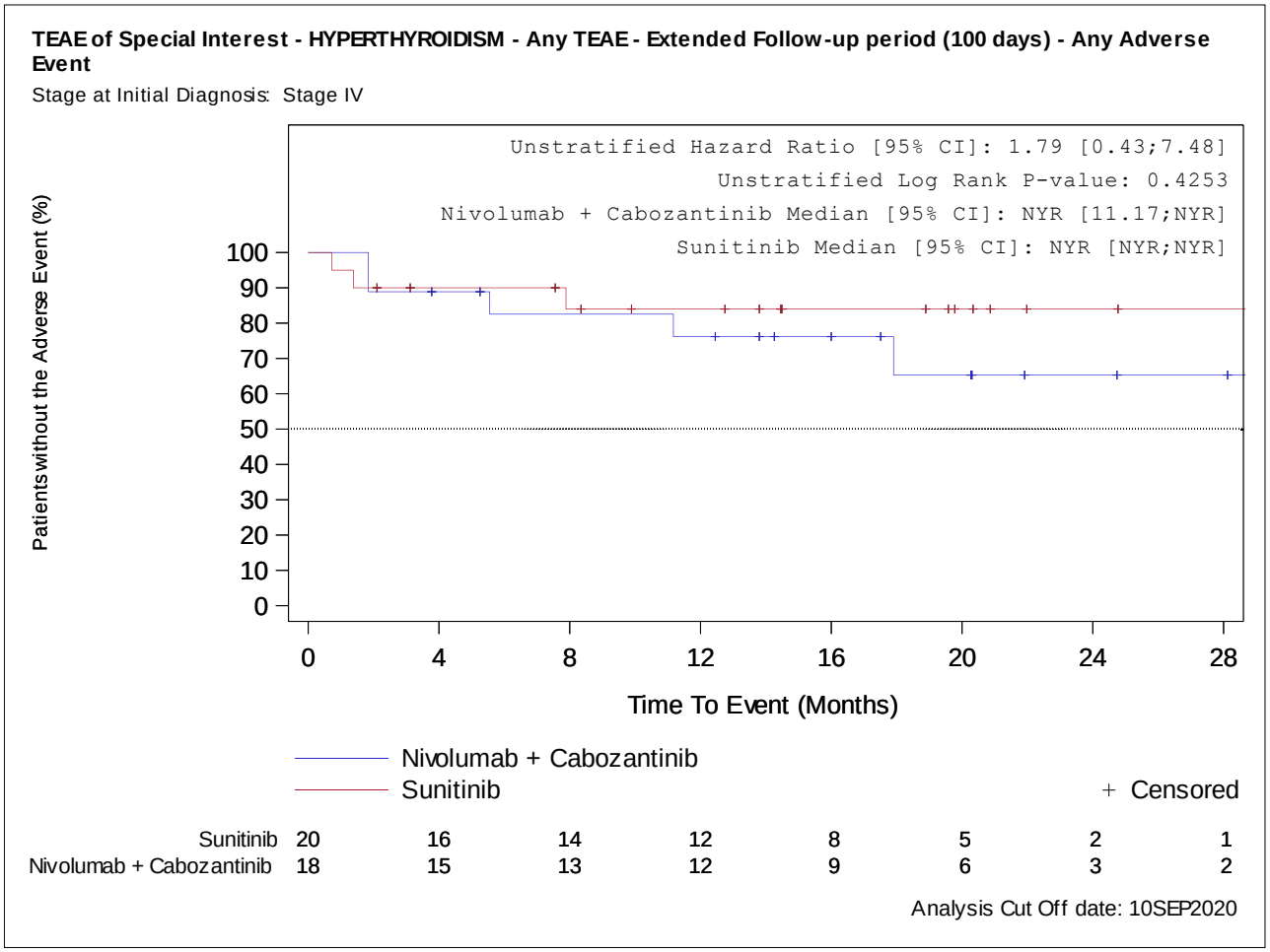
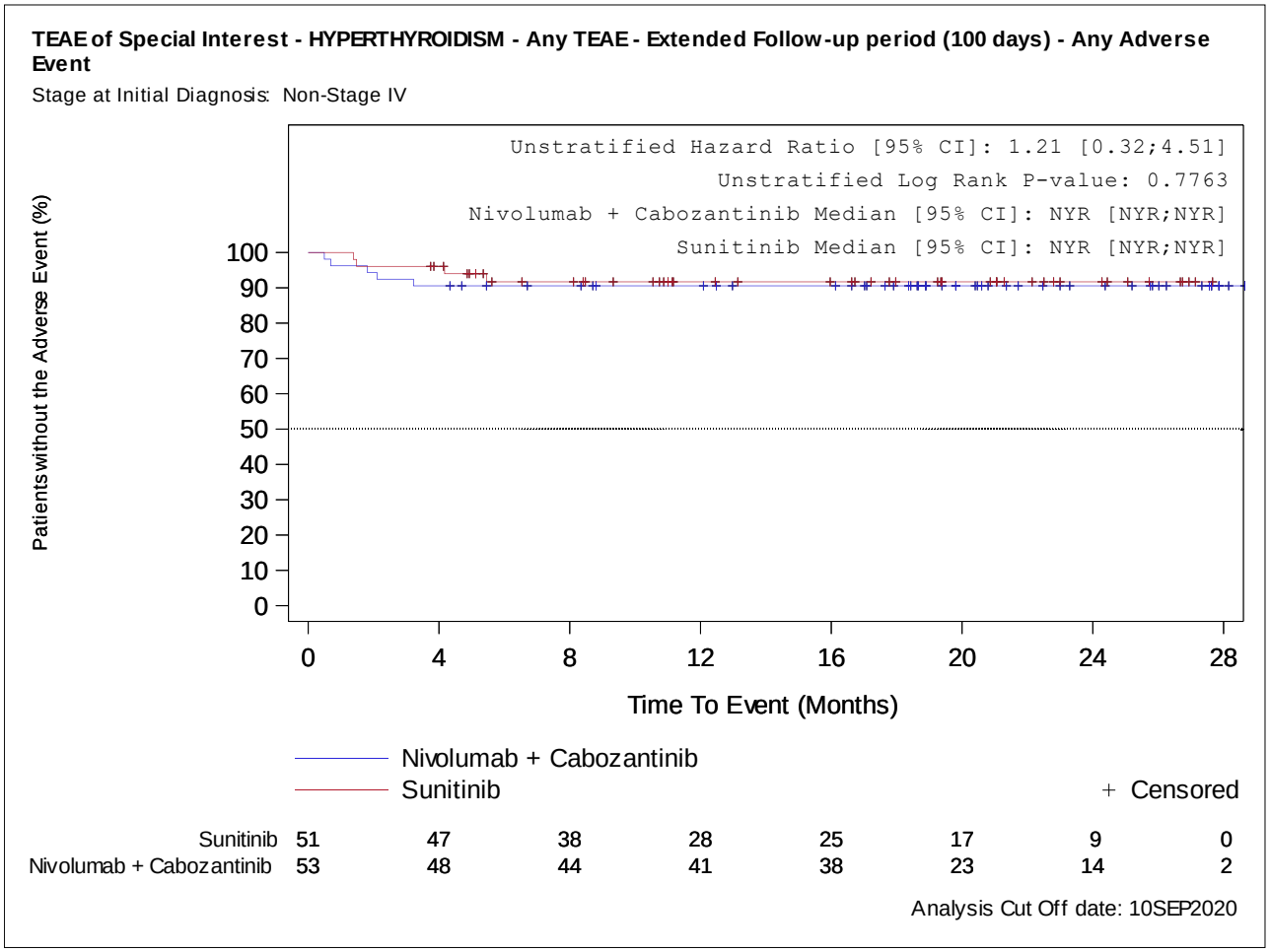
FIGURE 3.90.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



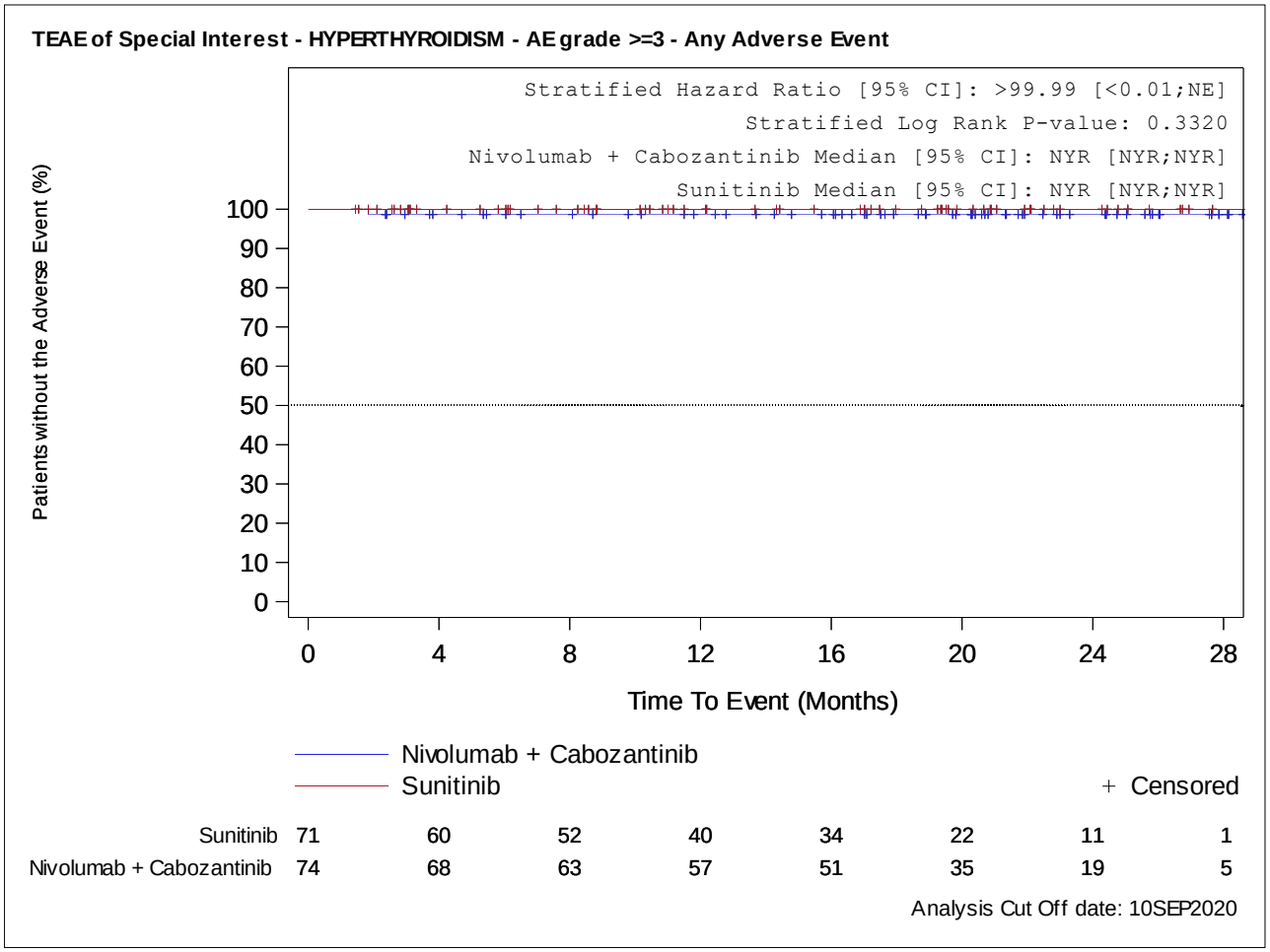

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:29:09

FIGURE 3.90.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



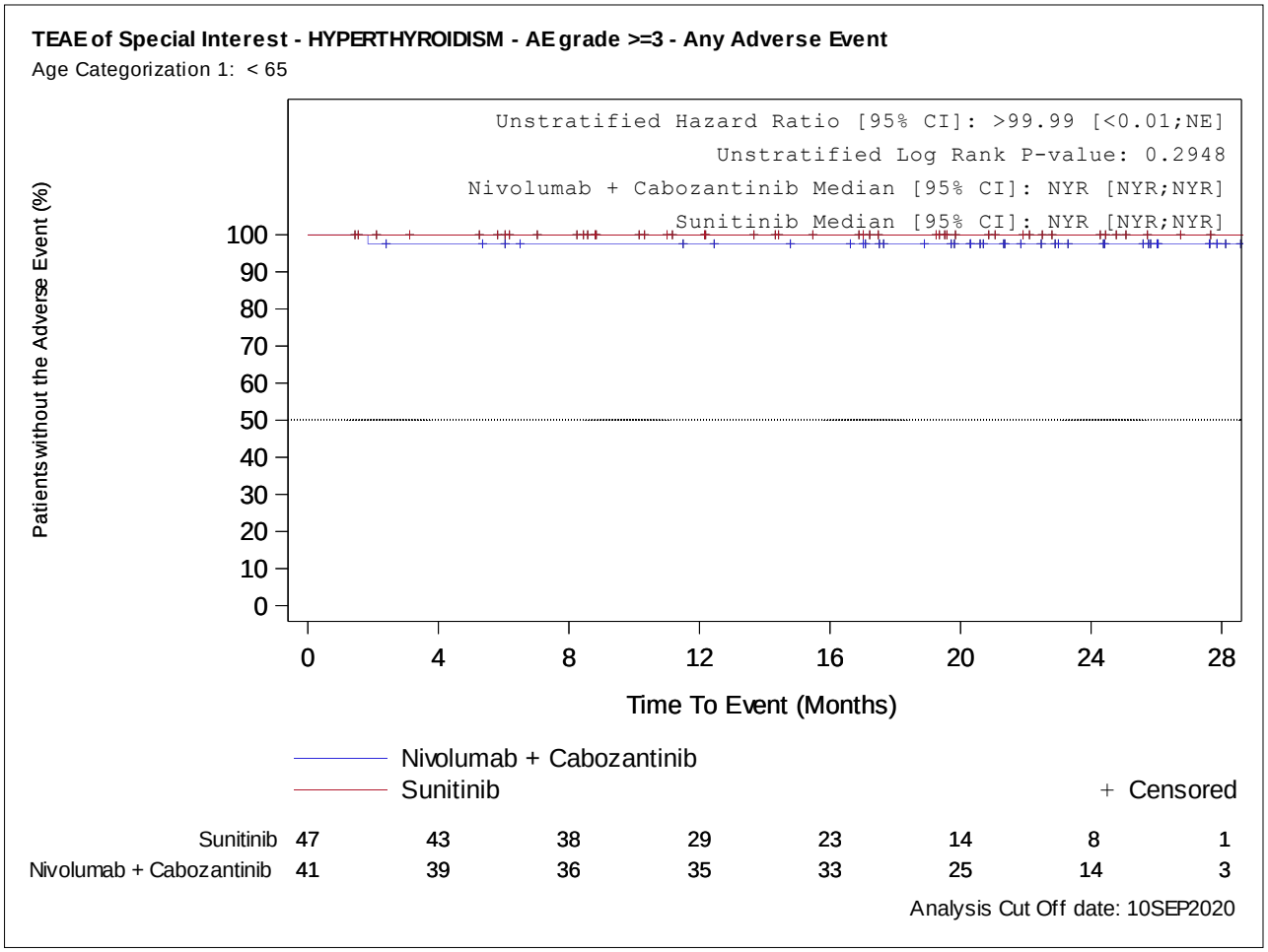

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:29:15

FIGURE 3.91.1: TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



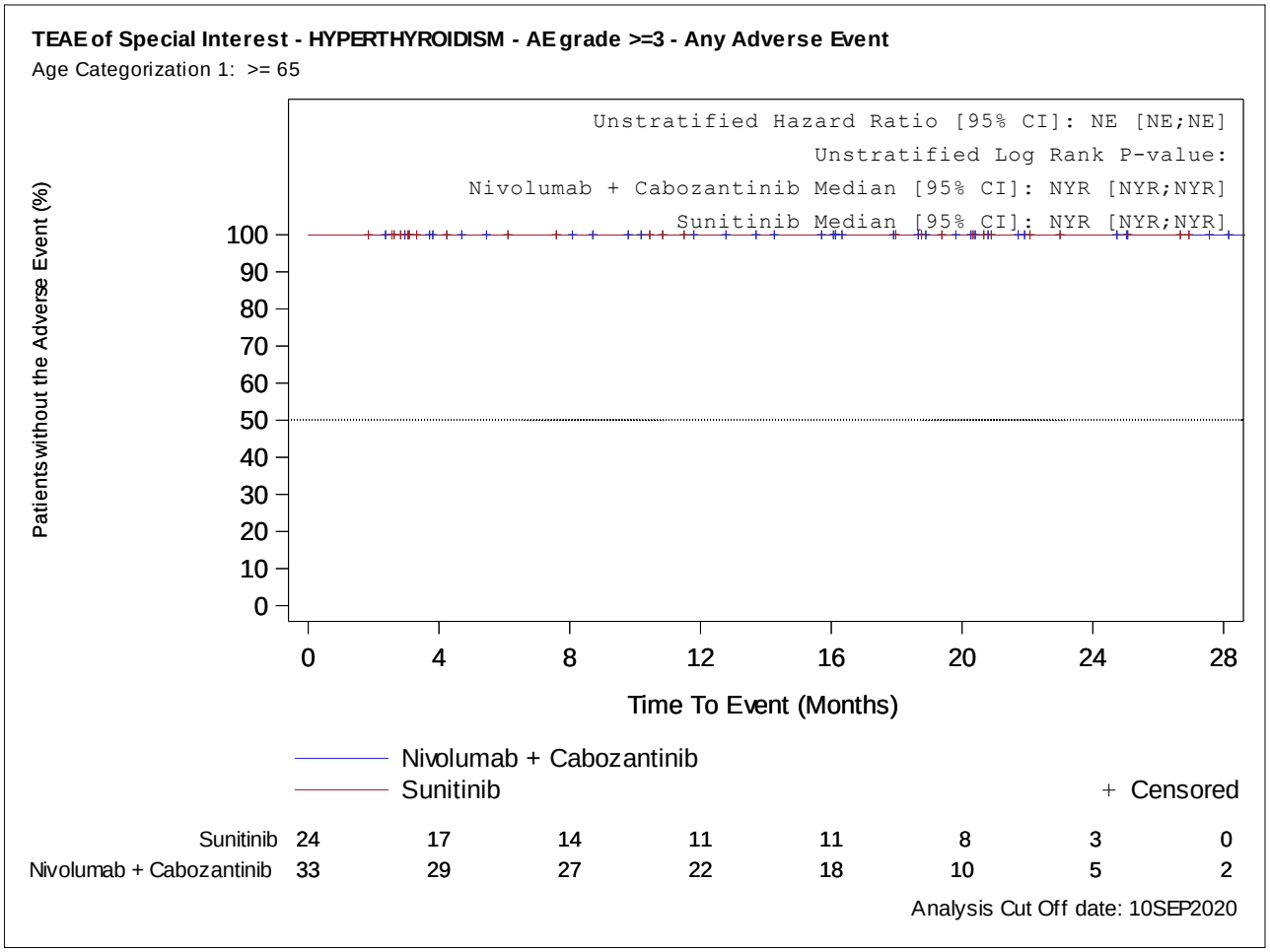

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:32:10

FIGURE 3.91.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



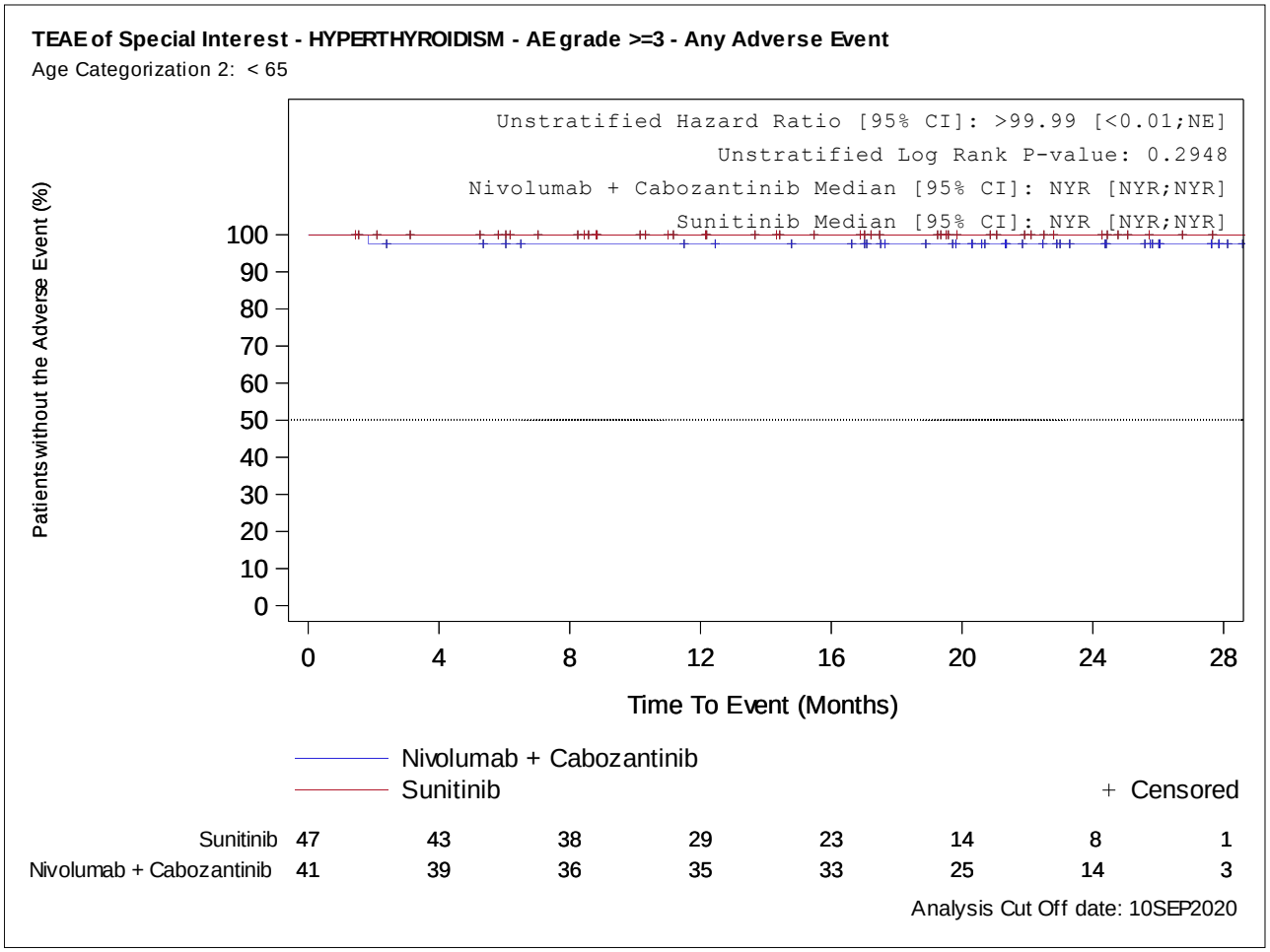

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:32:13

FIGURE 3.91.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



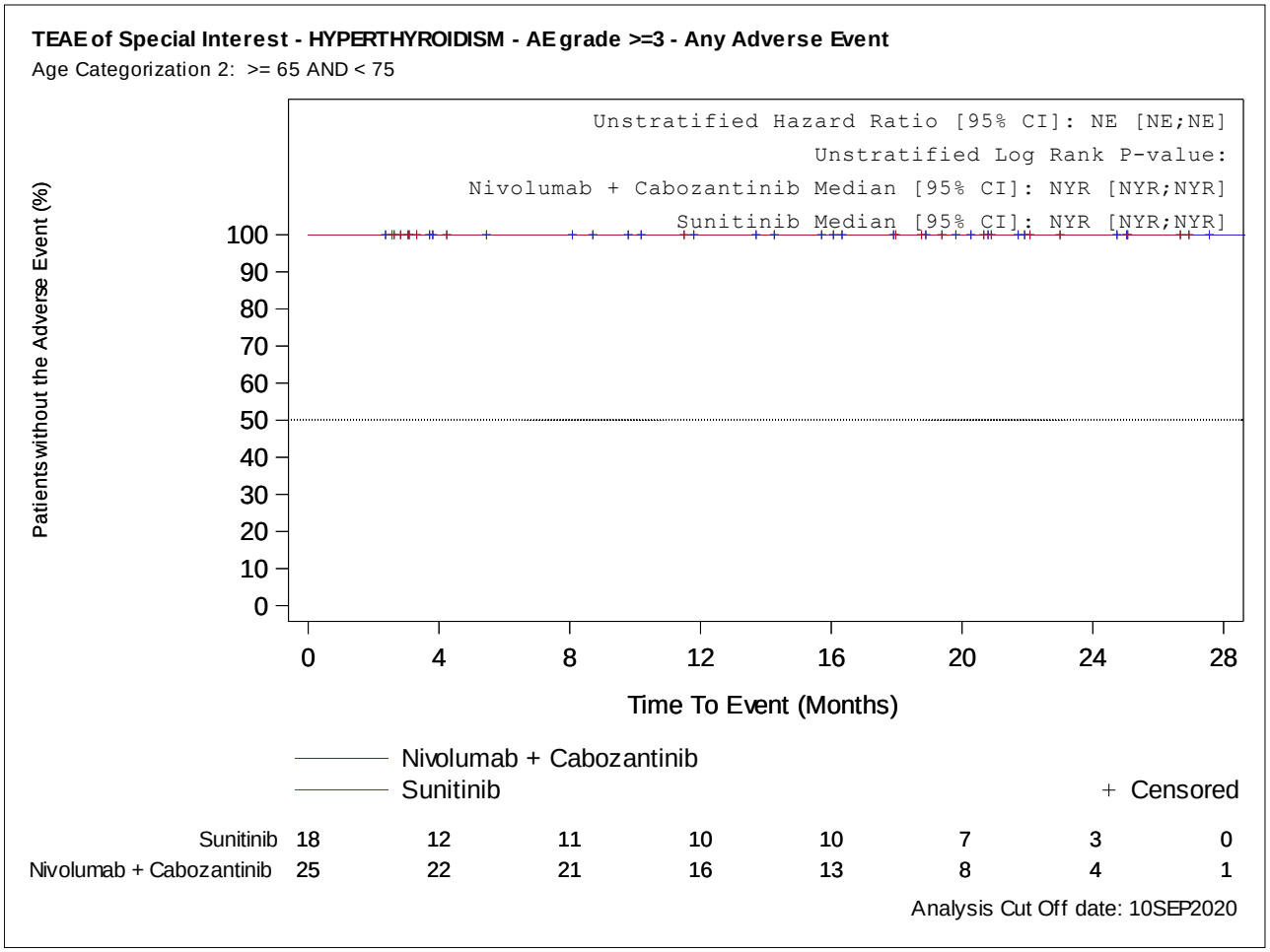

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:32:19

FIGURE 3.91.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



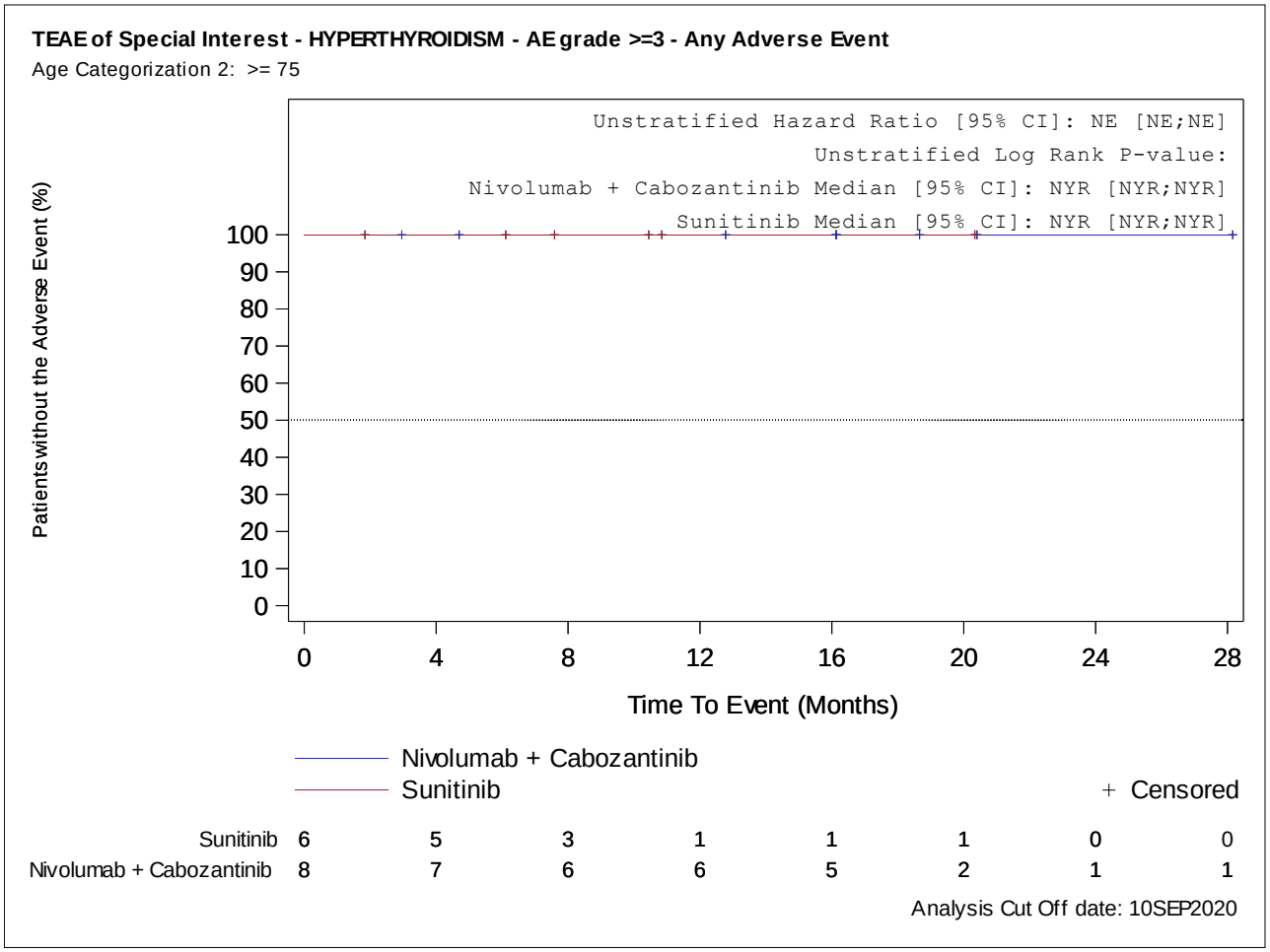

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:32:24

FIGURE 3.91.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



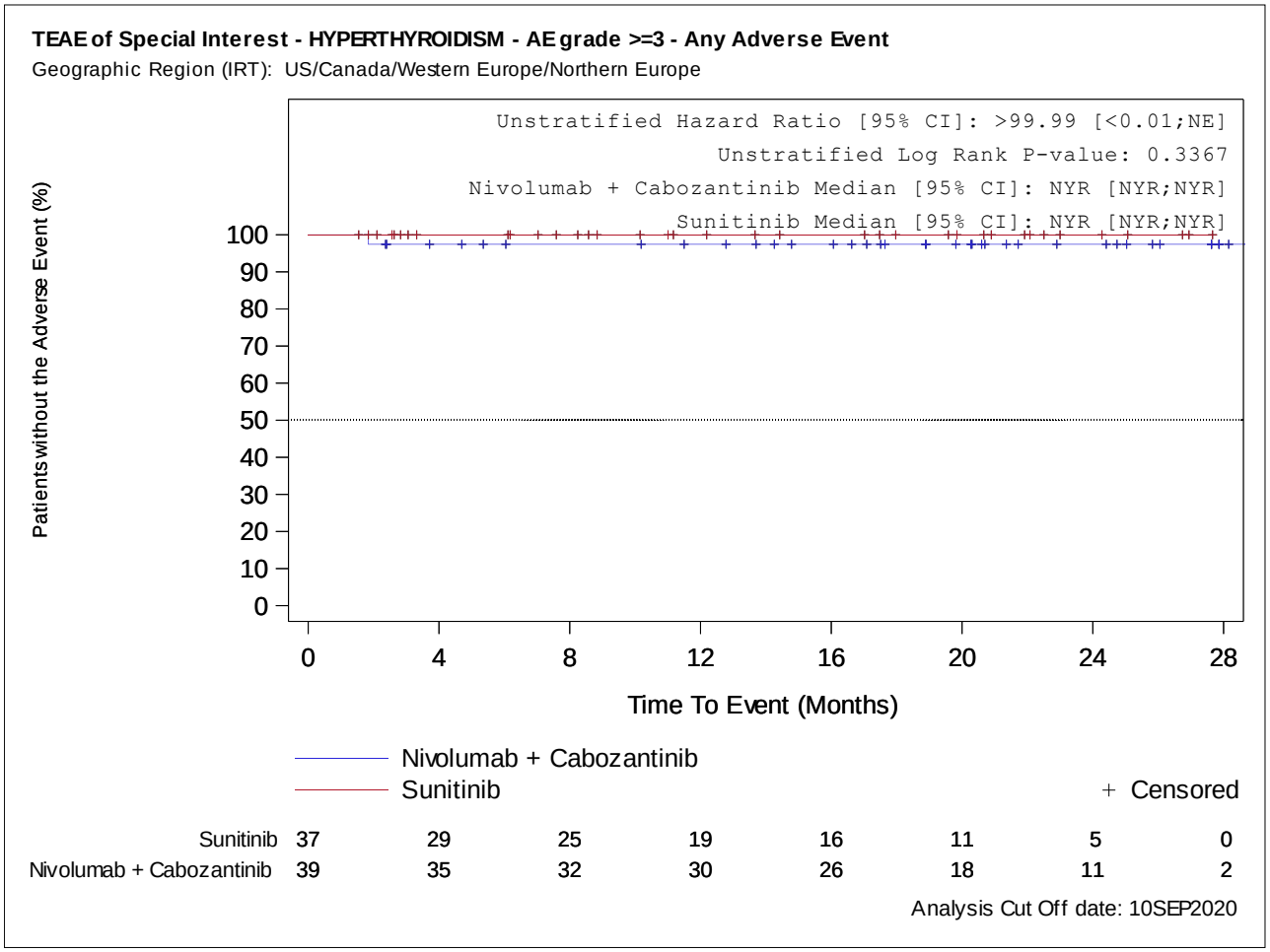

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:32:29

FIGURE 3.91.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



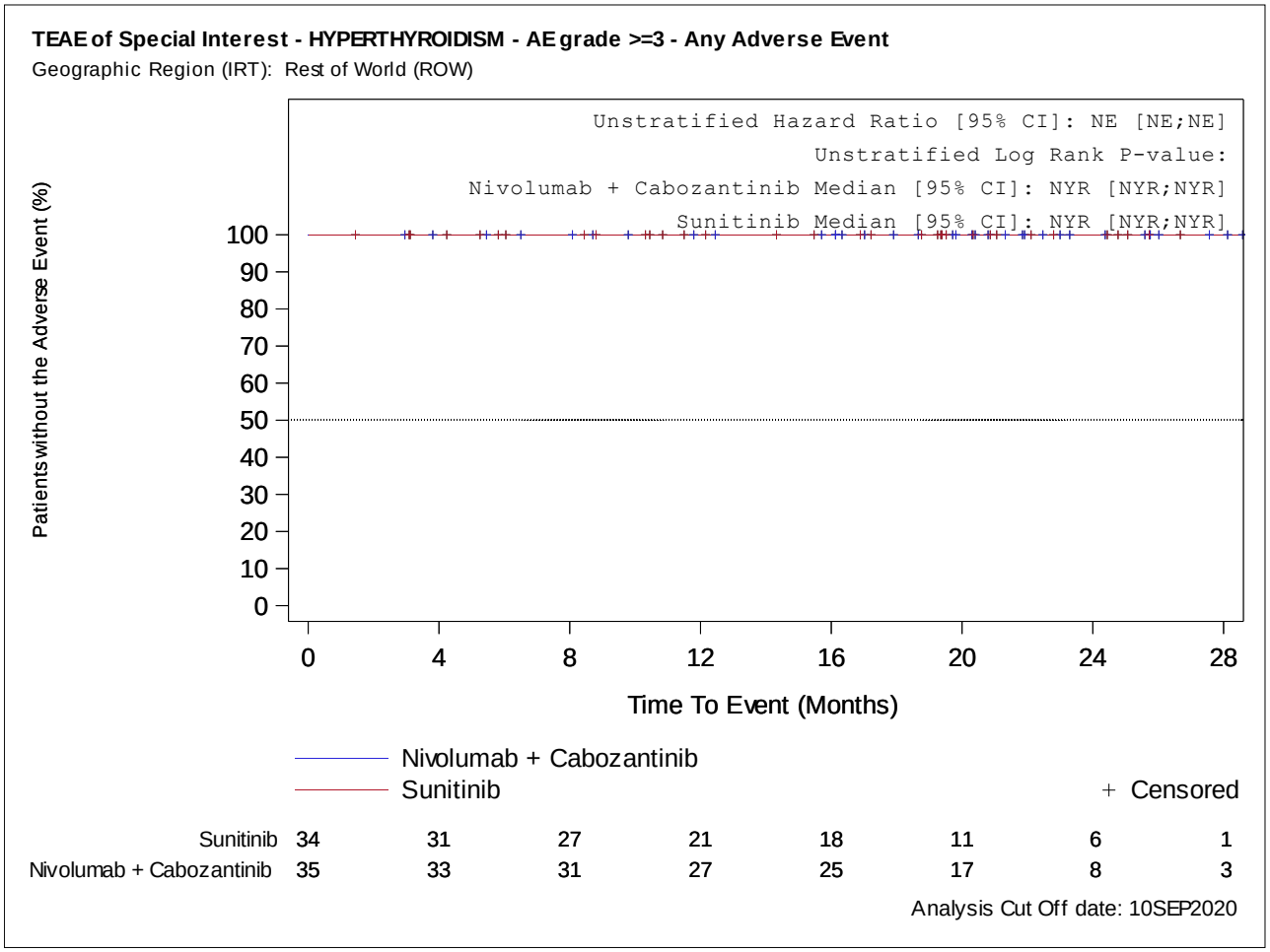

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:32:34

FIGURE 3.91.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:32:39

FIGURE 3.91.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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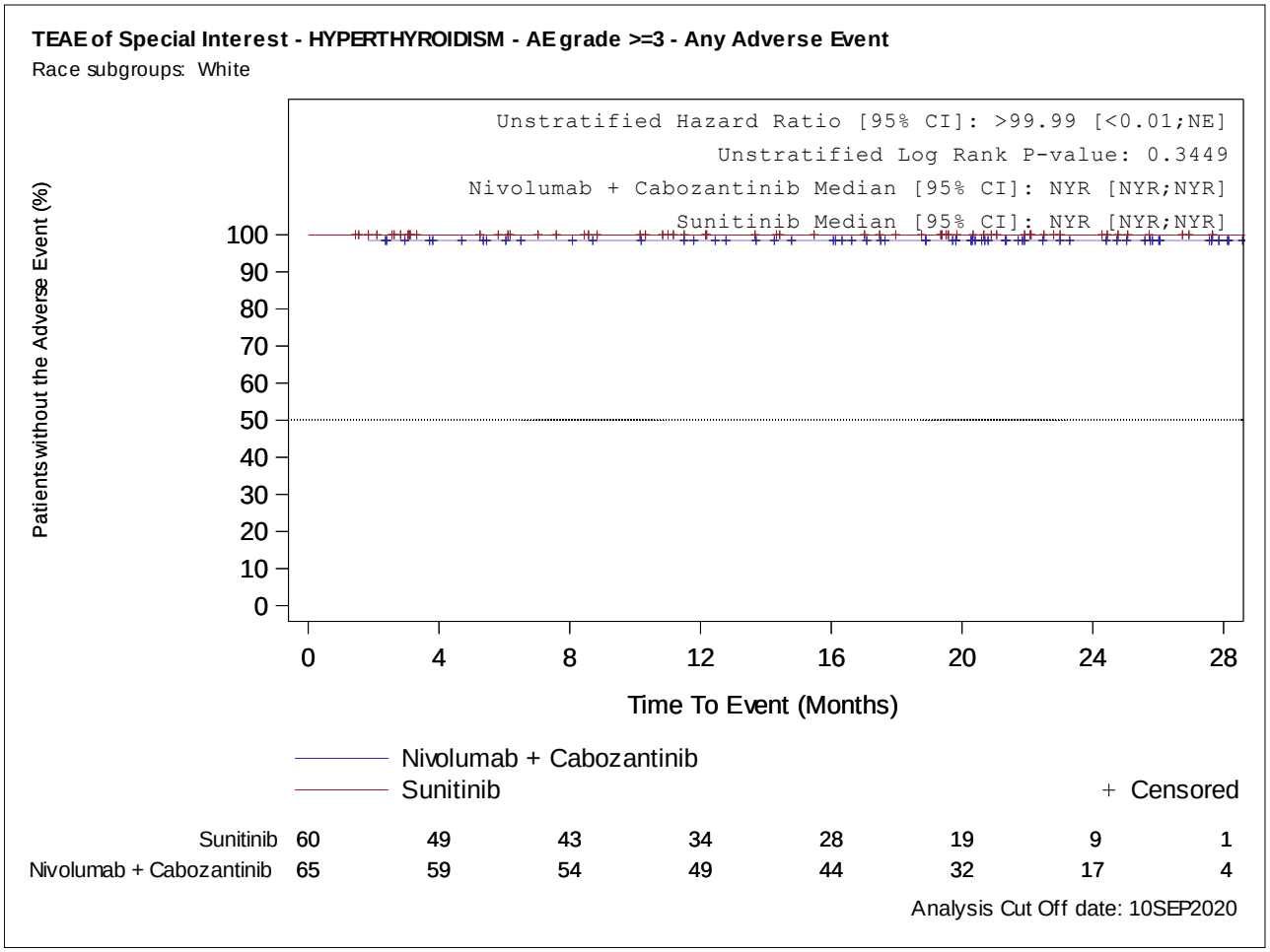
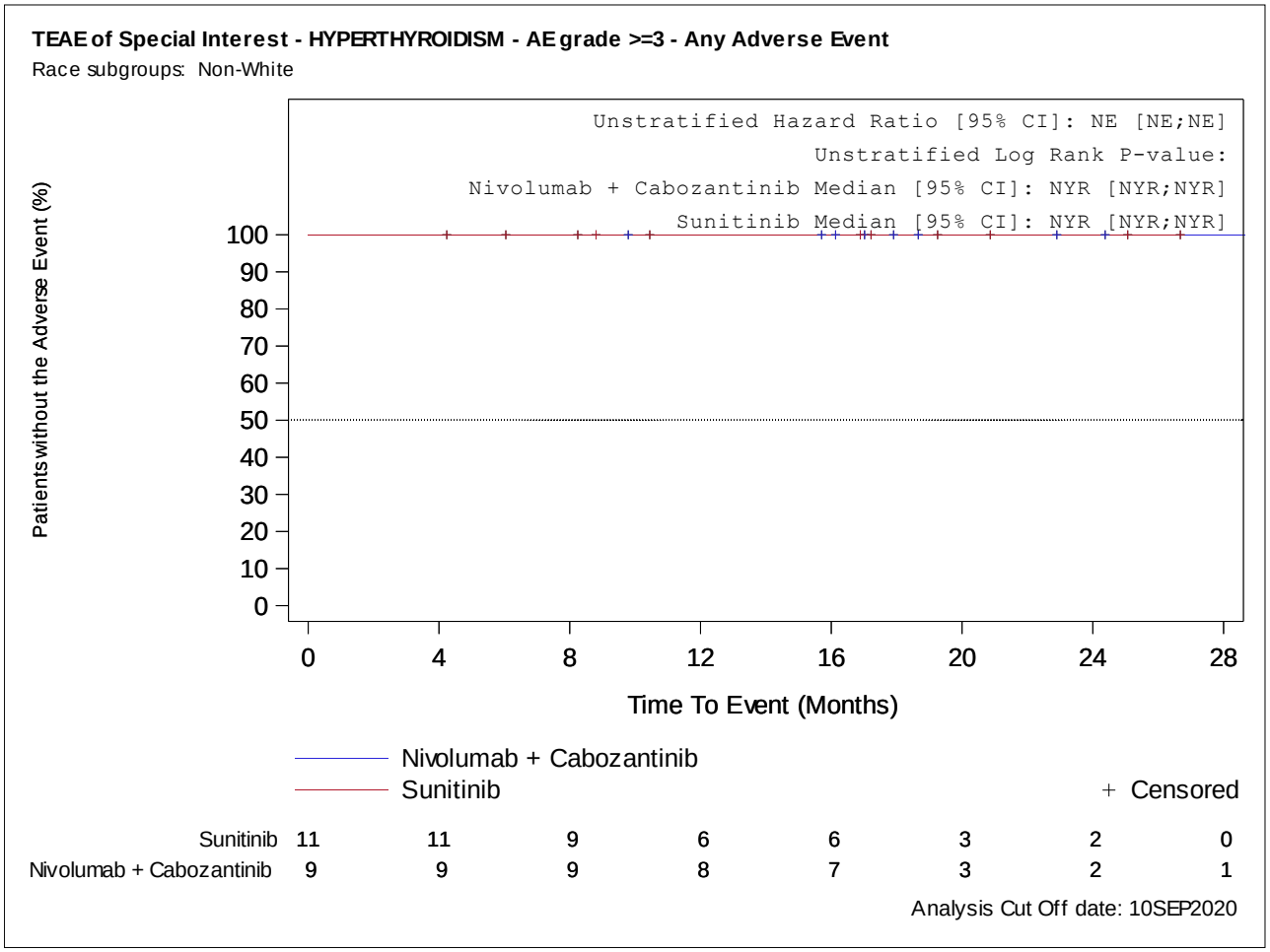
FIGURE 3.91.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



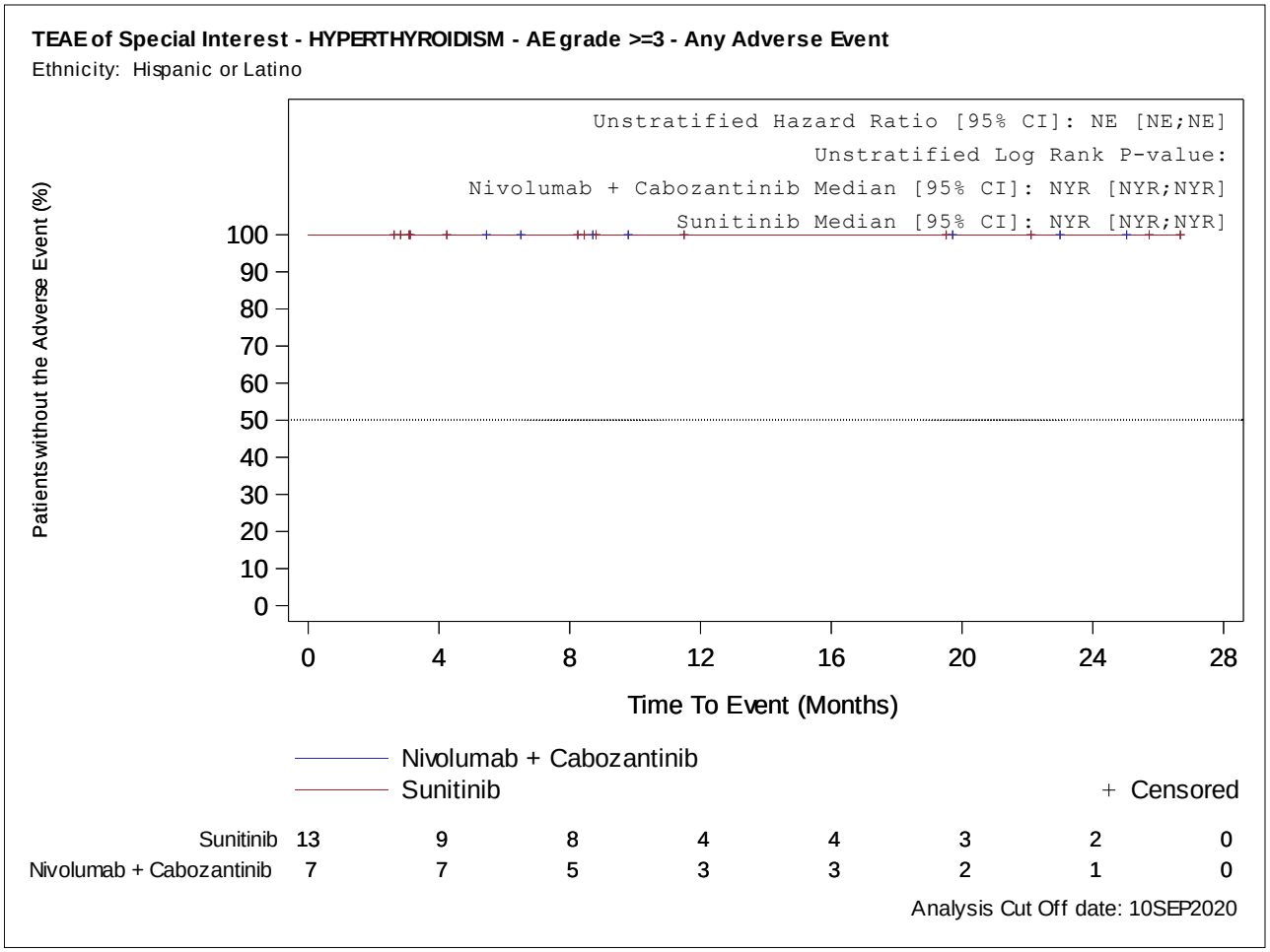

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:32:50

FIGURE 3.91.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



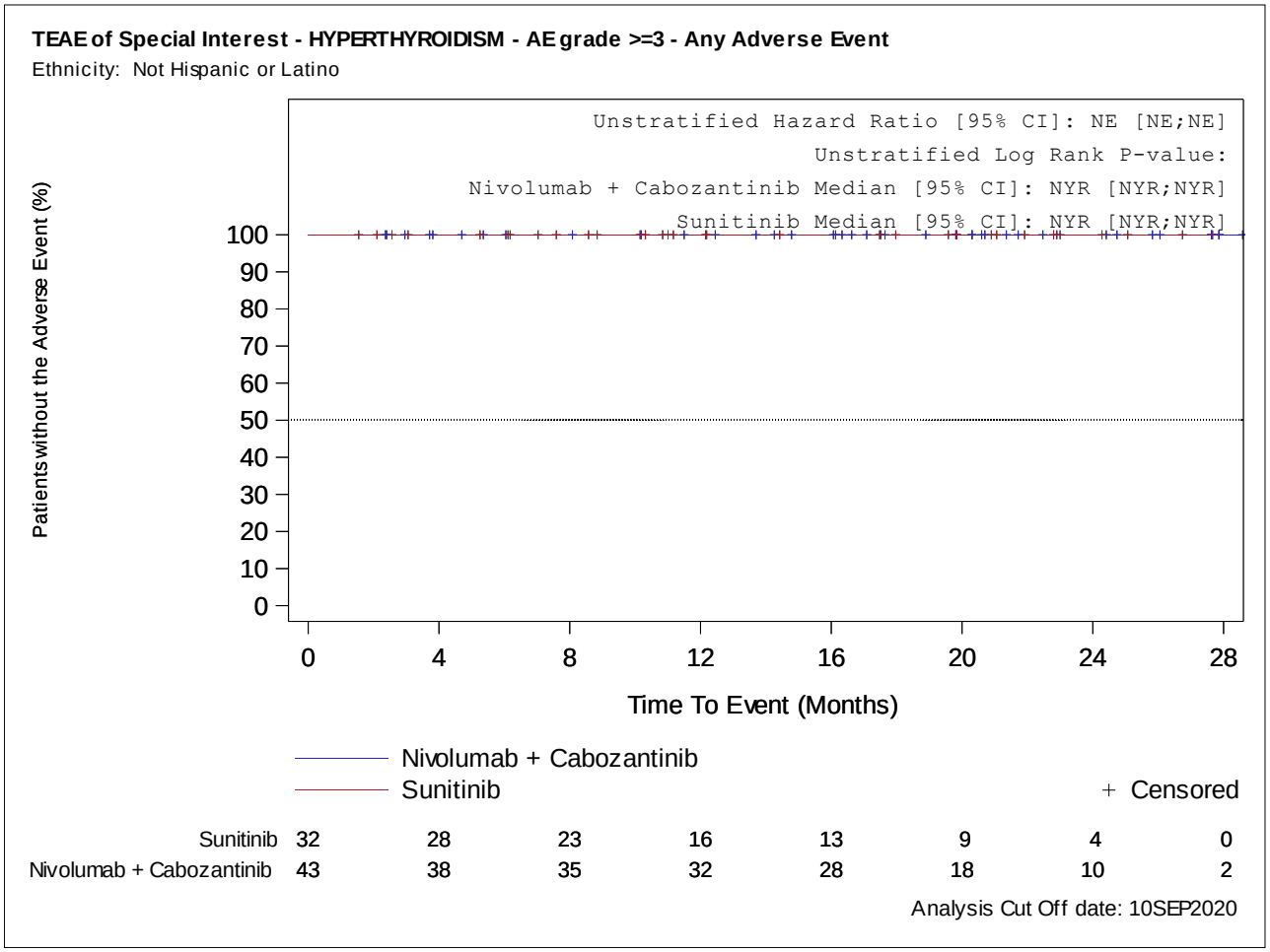

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:32:55

FIGURE 3.91.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



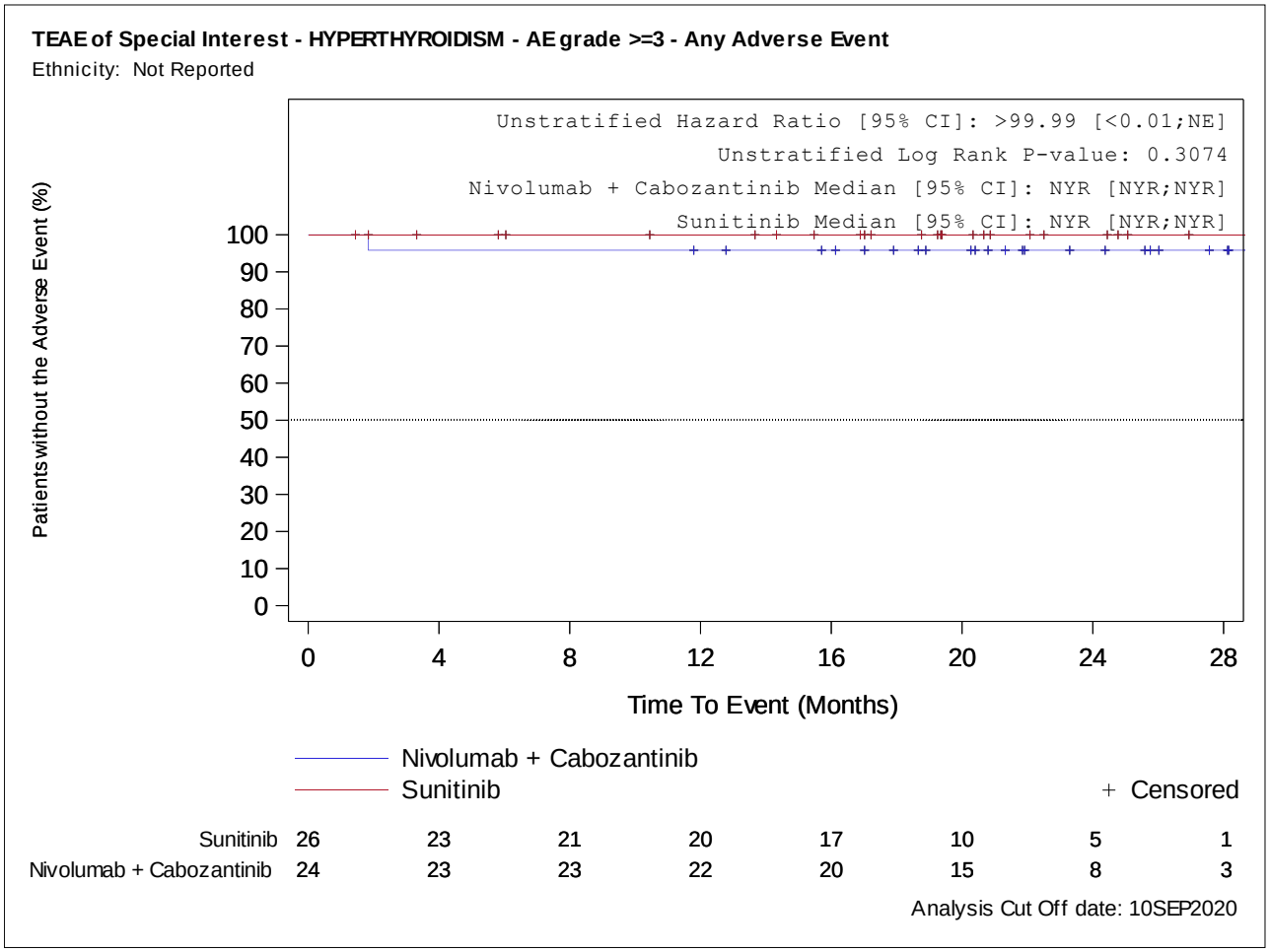

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:33:00

FIGURE 3.91.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



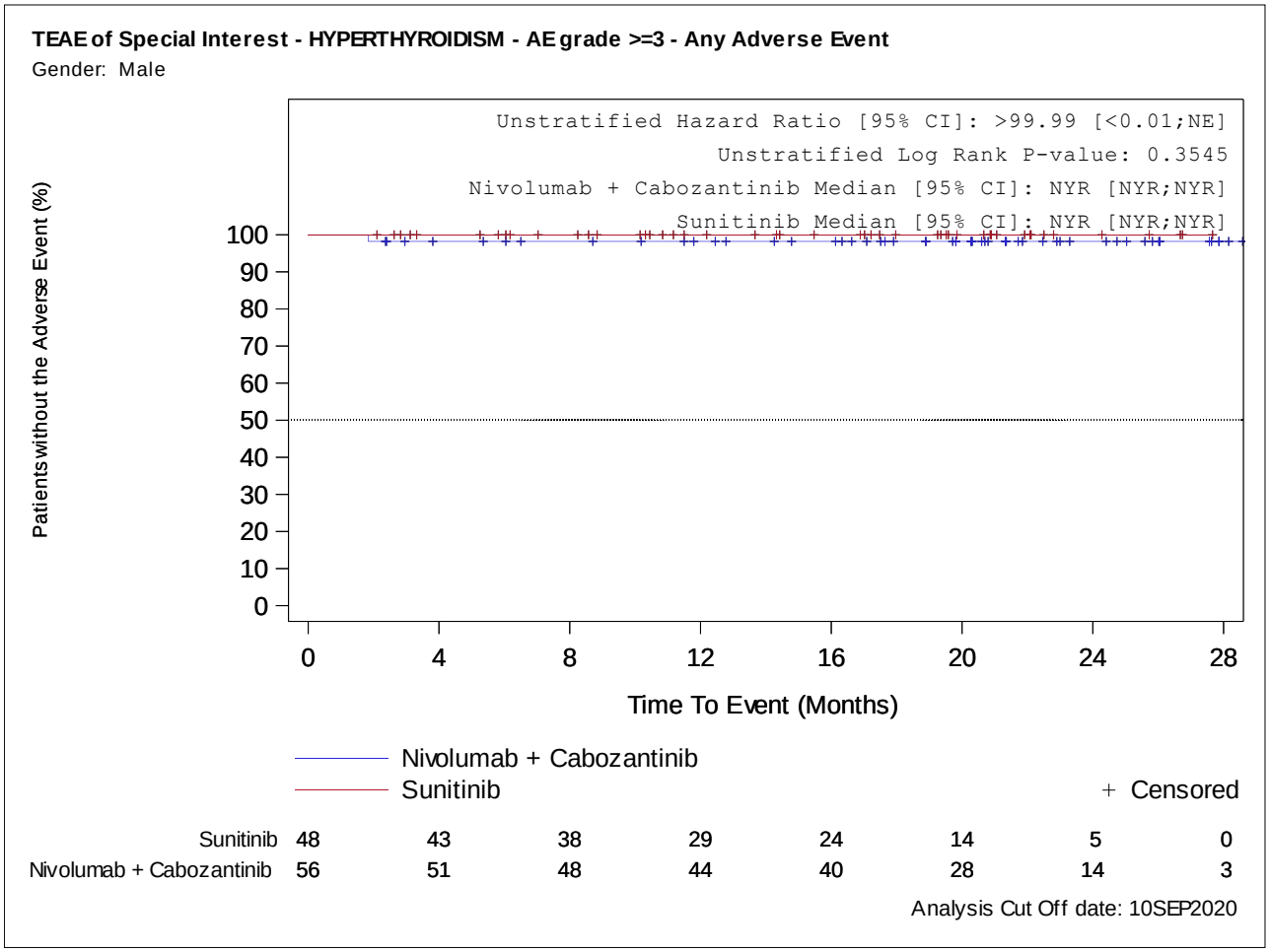

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:33:05

FIGURE 3.91.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



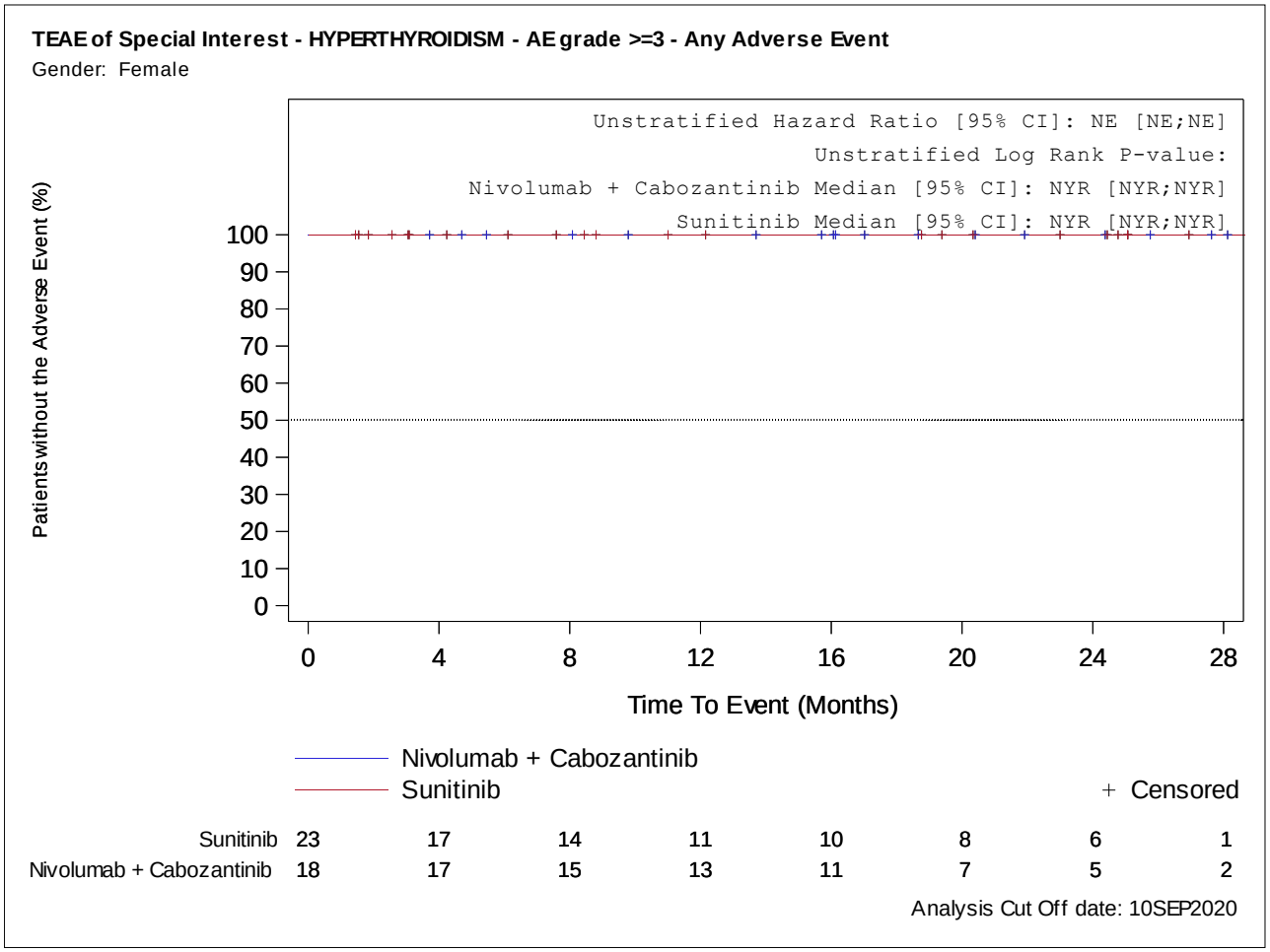

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:33:11

FIGURE 3.91.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:33:16

FIGURE 3.91.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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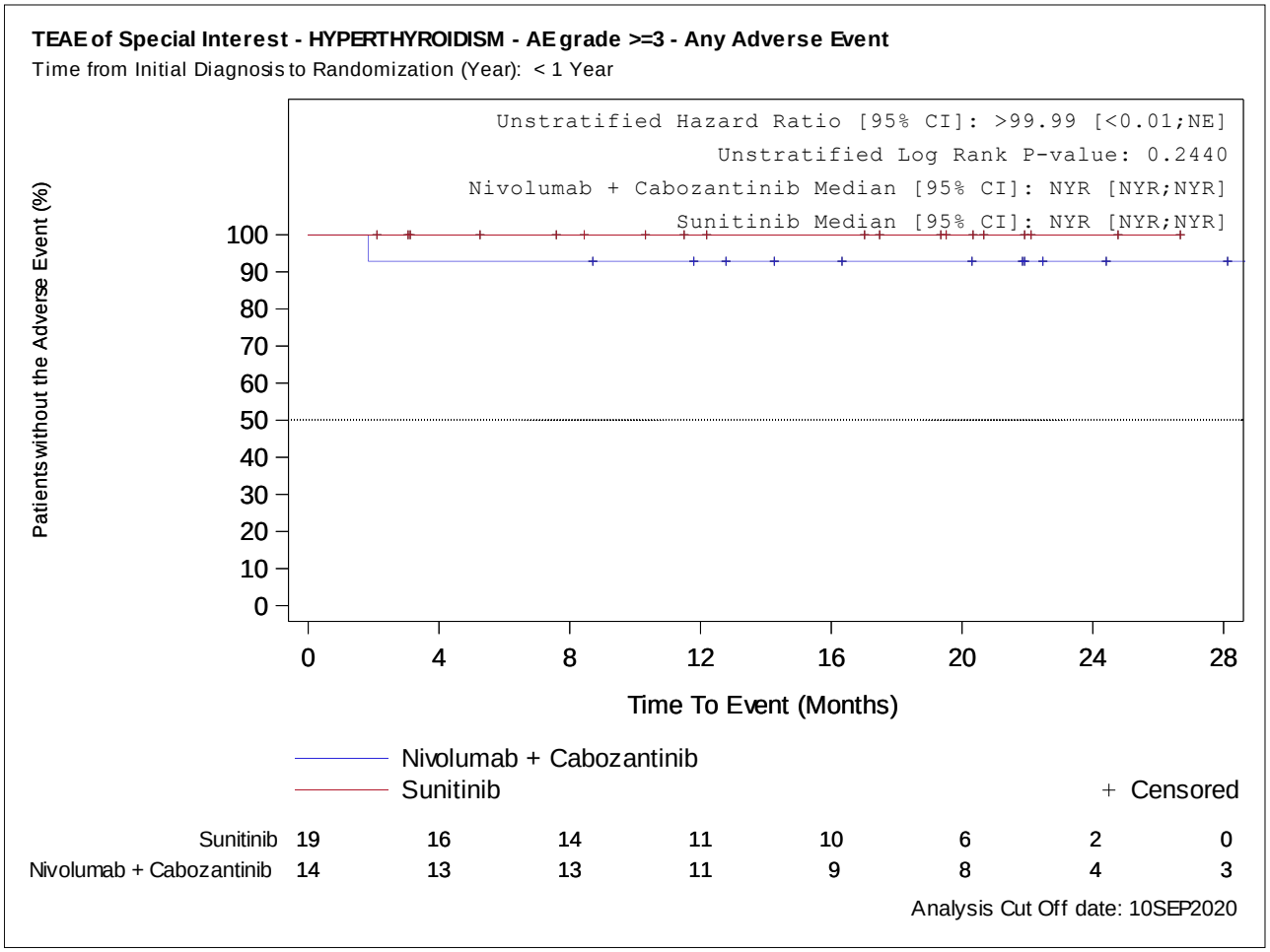
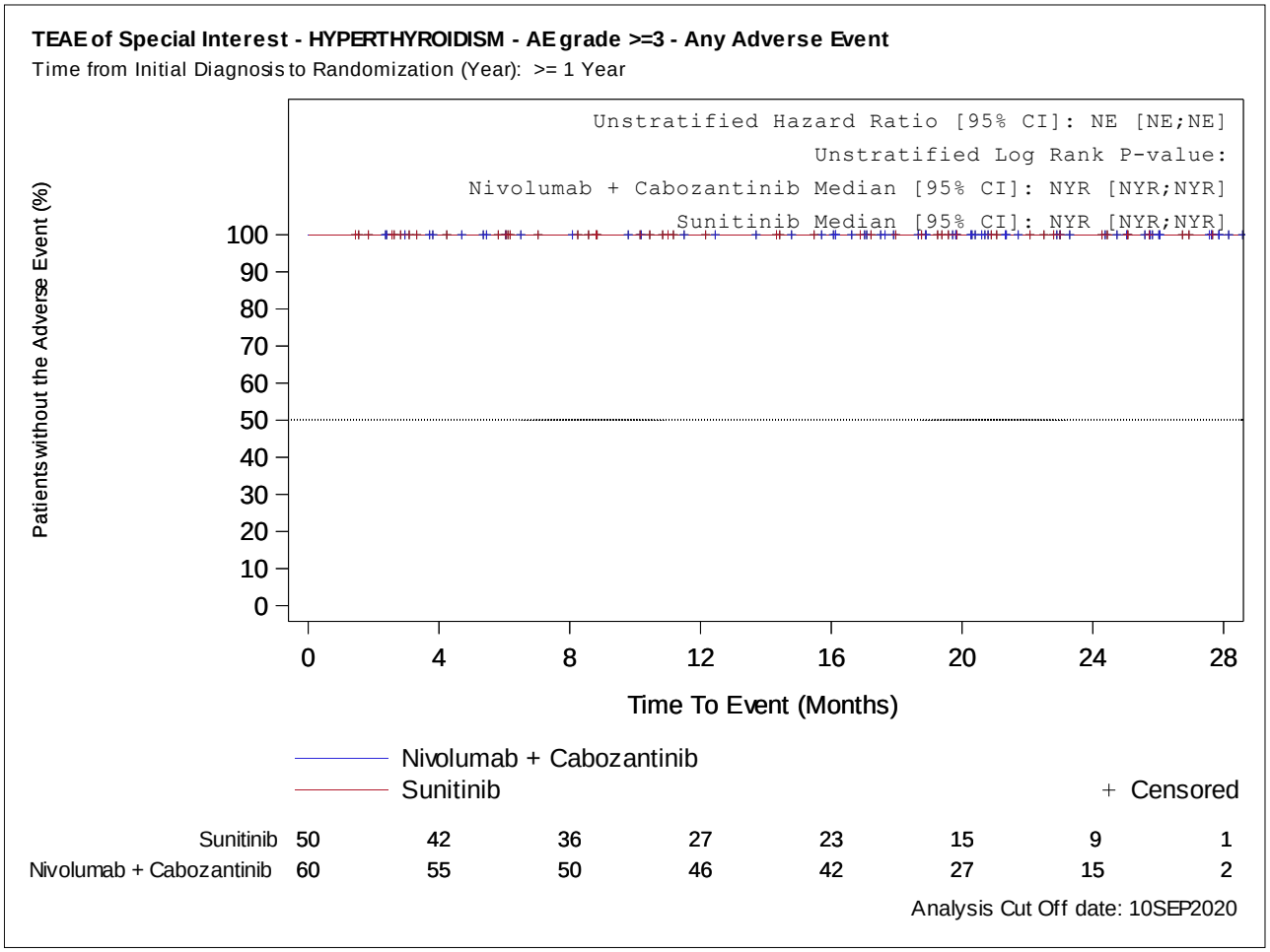
FIGURE 3.91.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



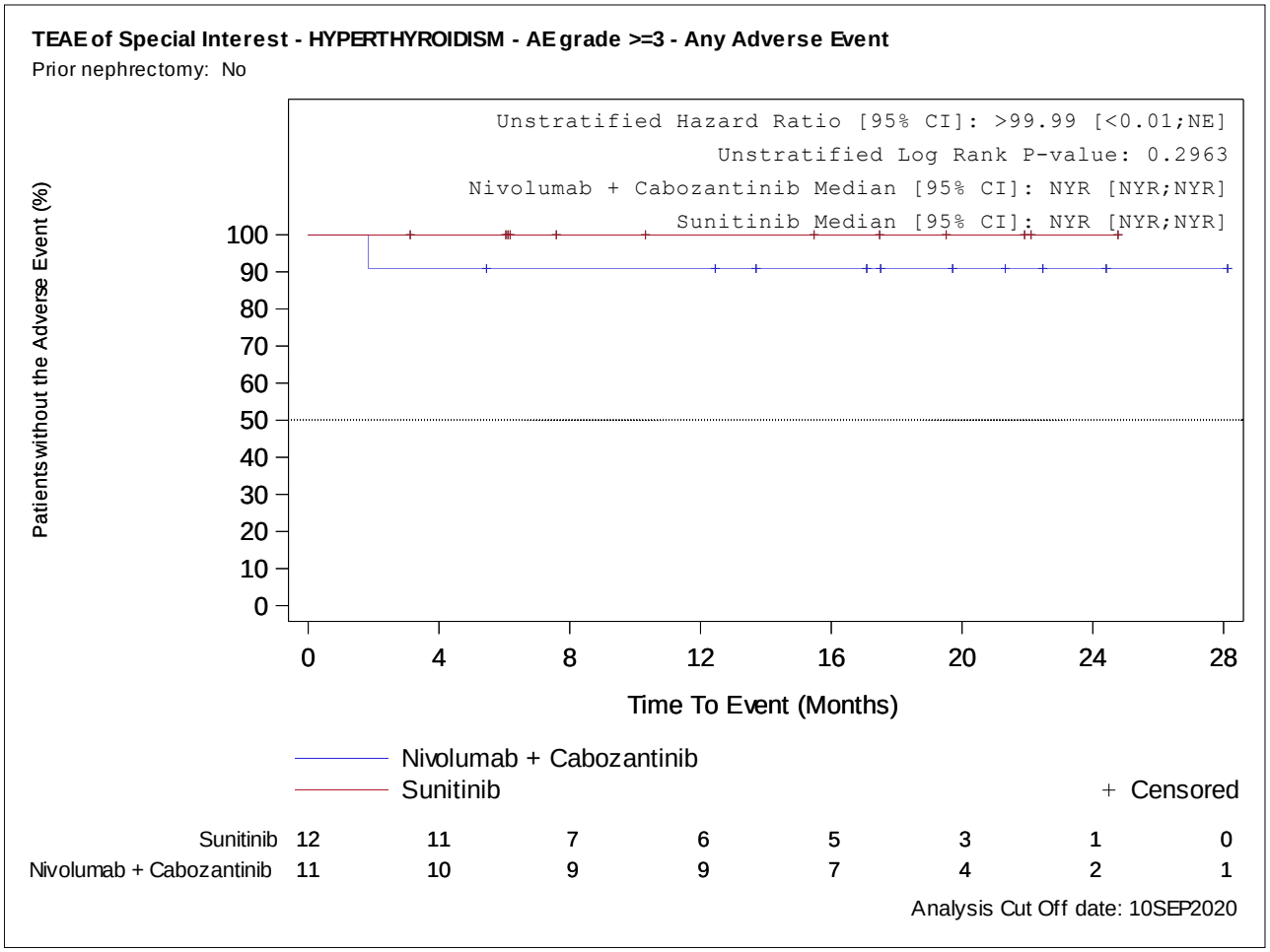

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:33:36

FIGURE 3.91.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



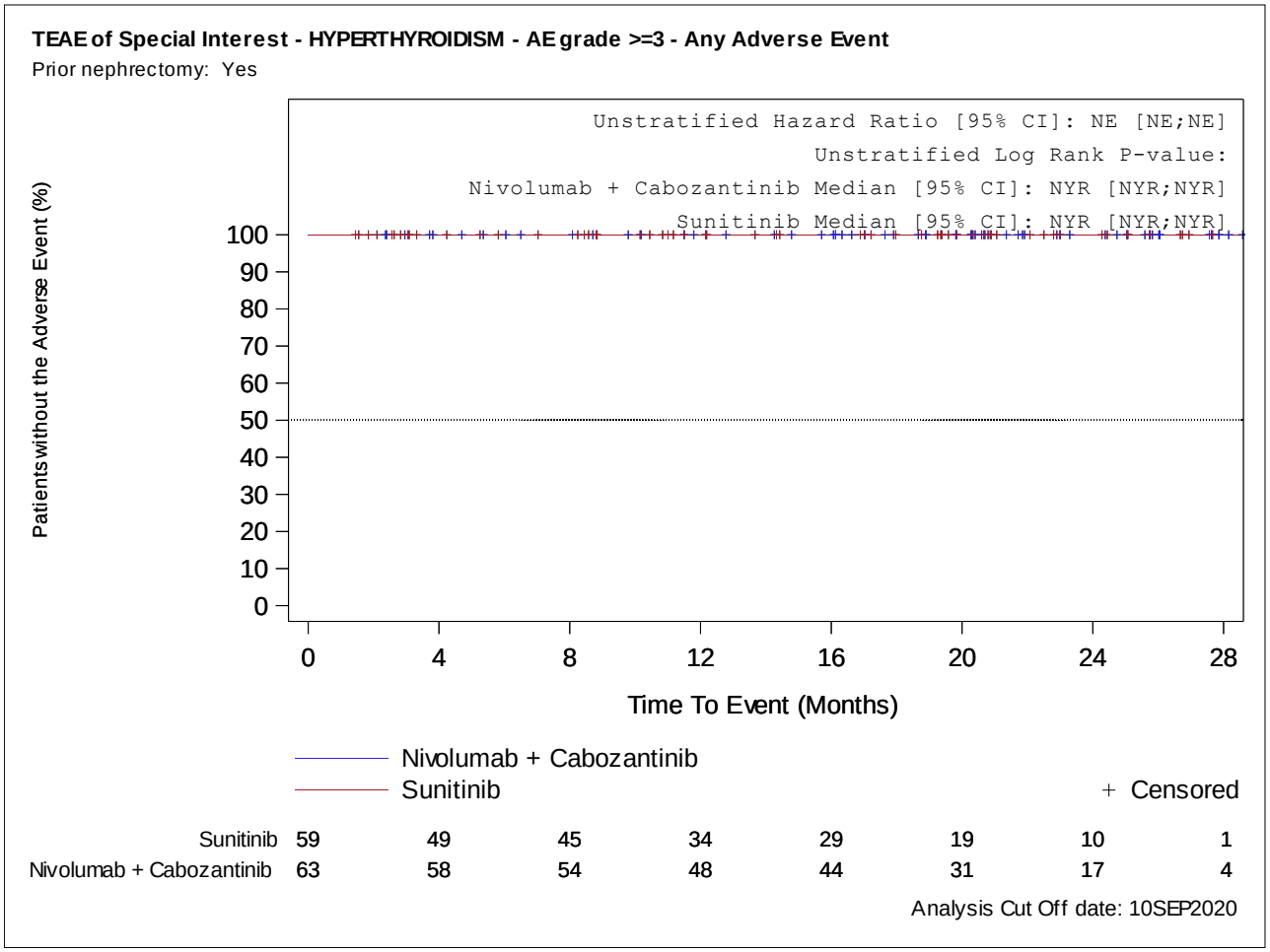

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:33:41

FIGURE 3.91.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:34:28

FIGURE 3.91.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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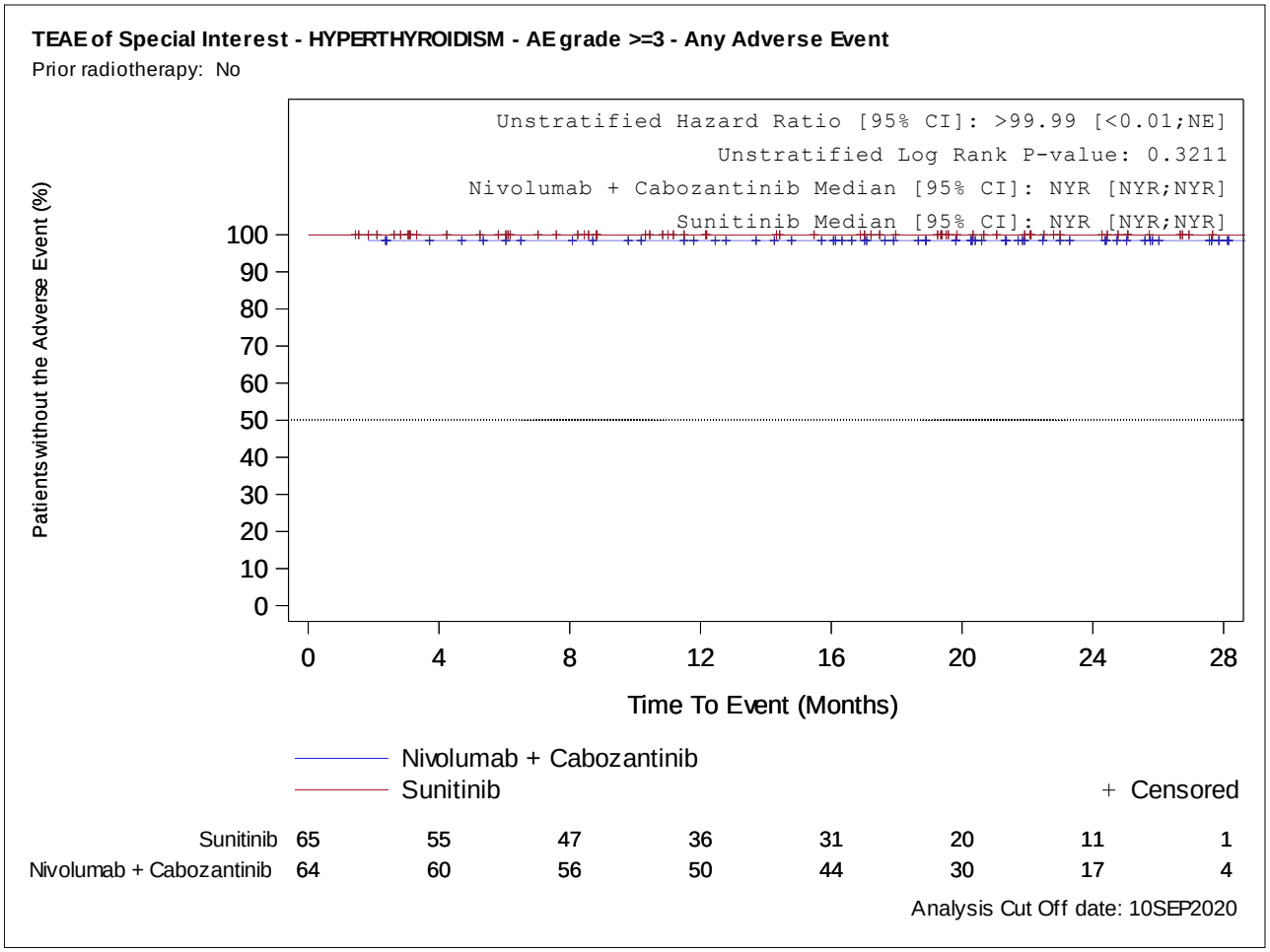
FIGURE 3.91.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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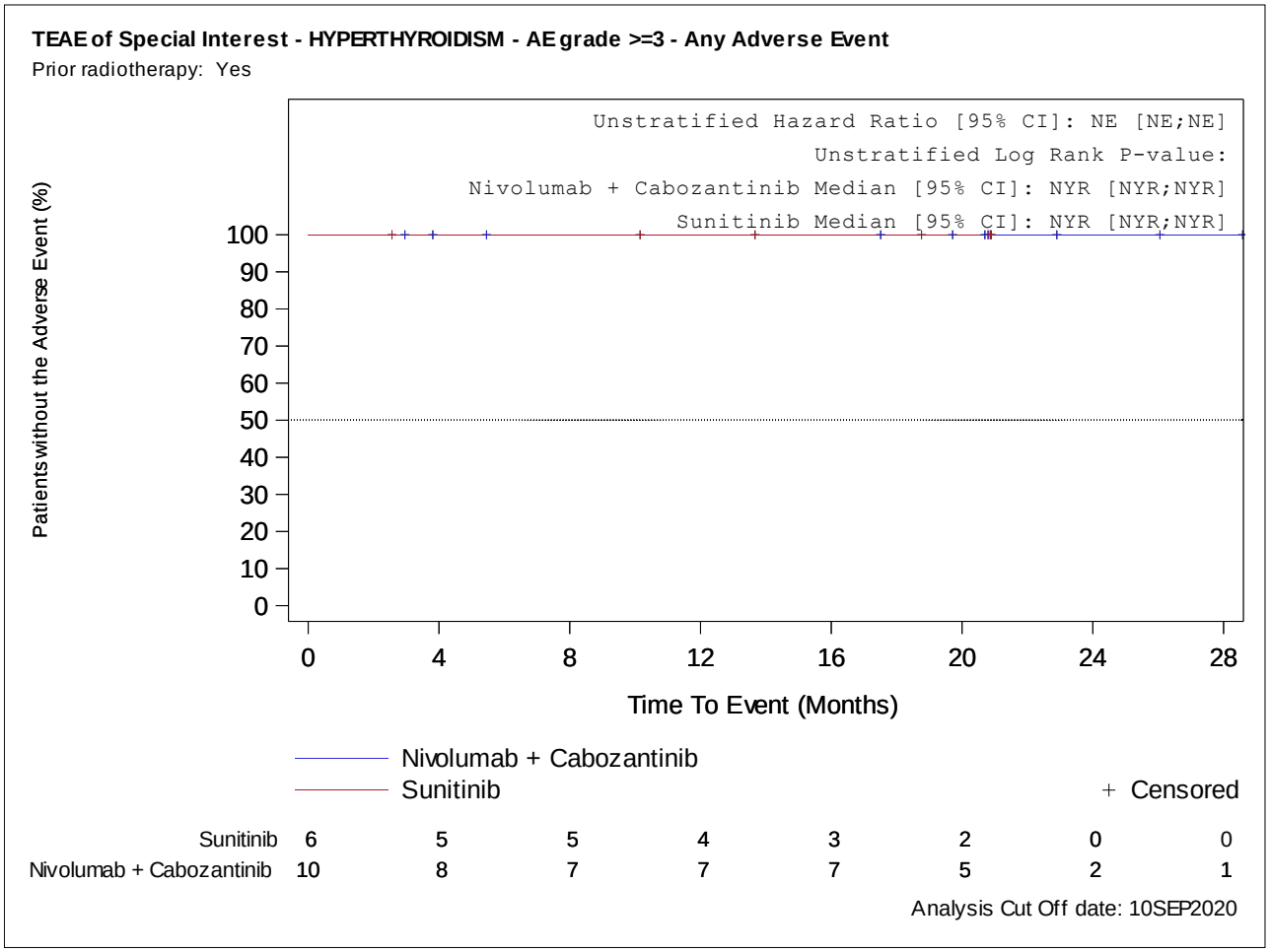
FIGURE 3.91.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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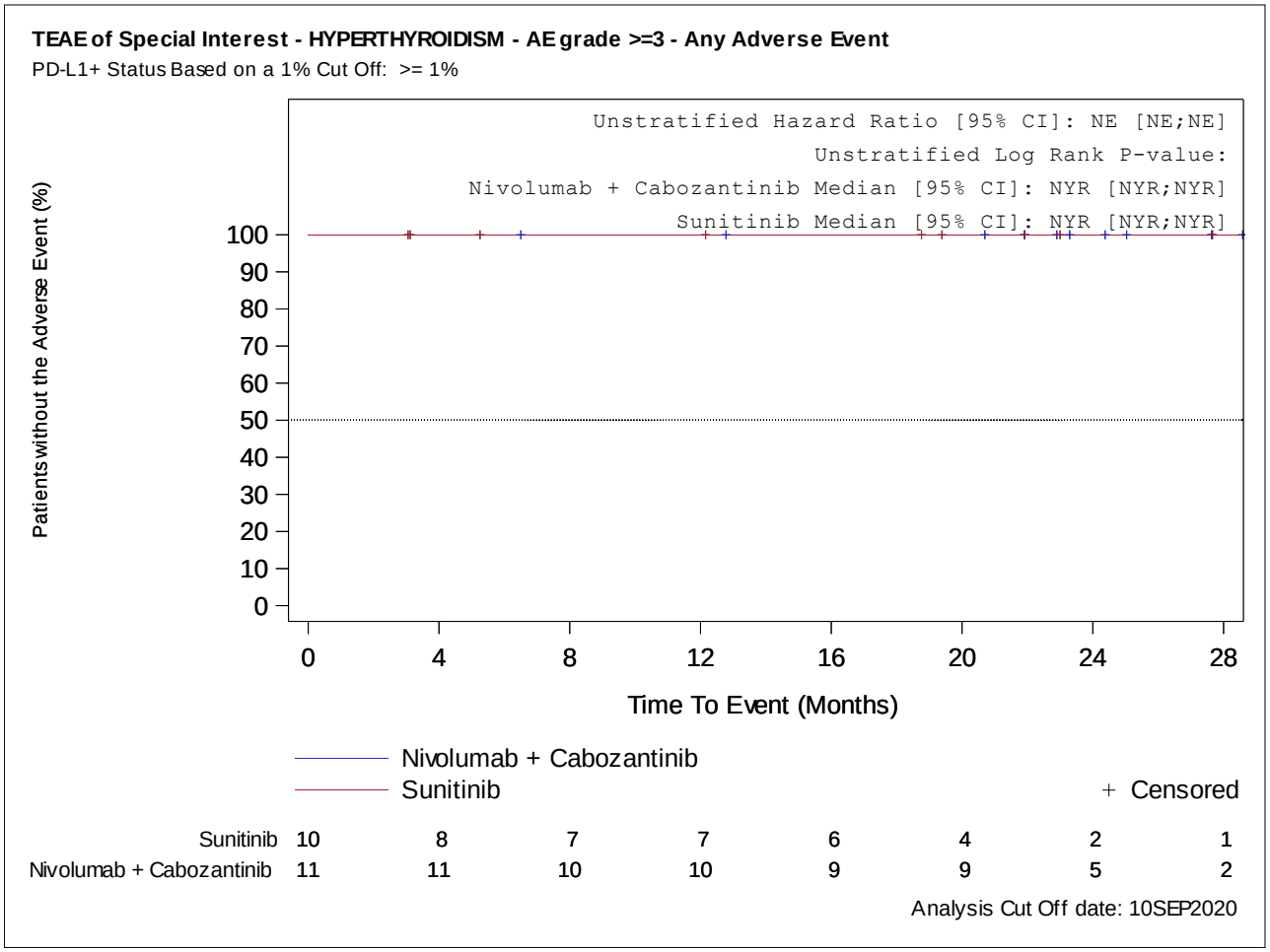
FIGURE 3.91.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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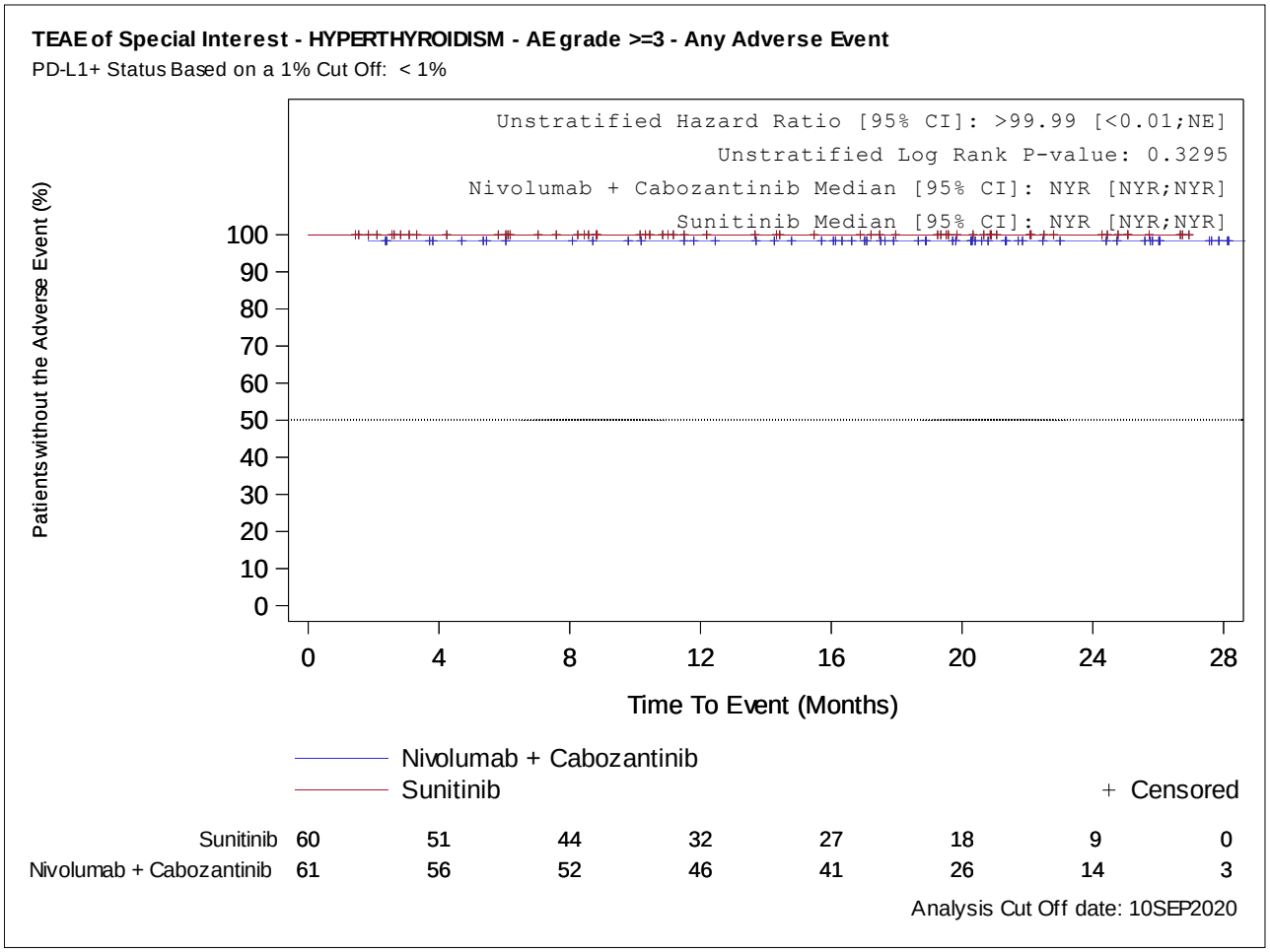
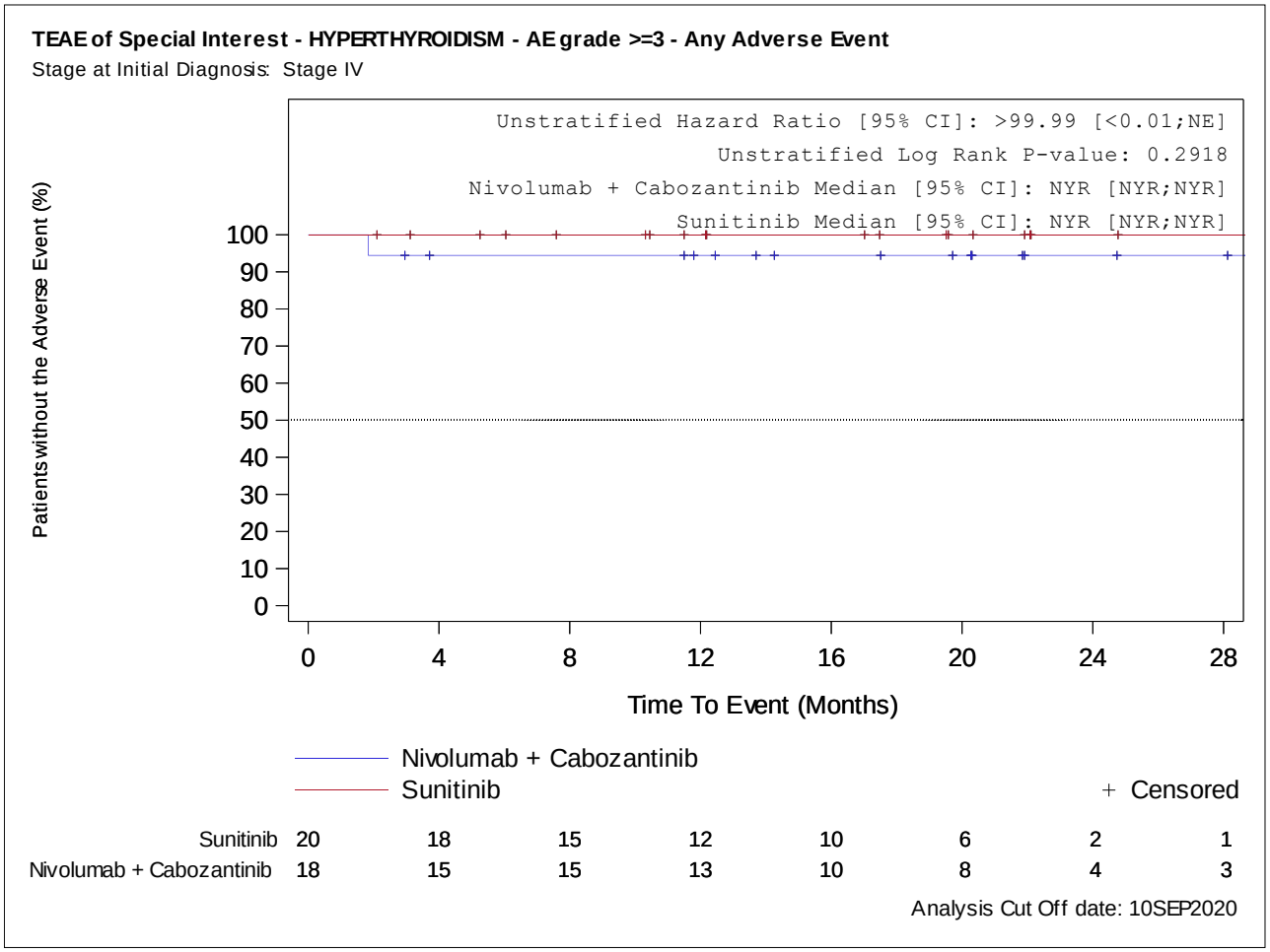
FIGURE 3.91.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



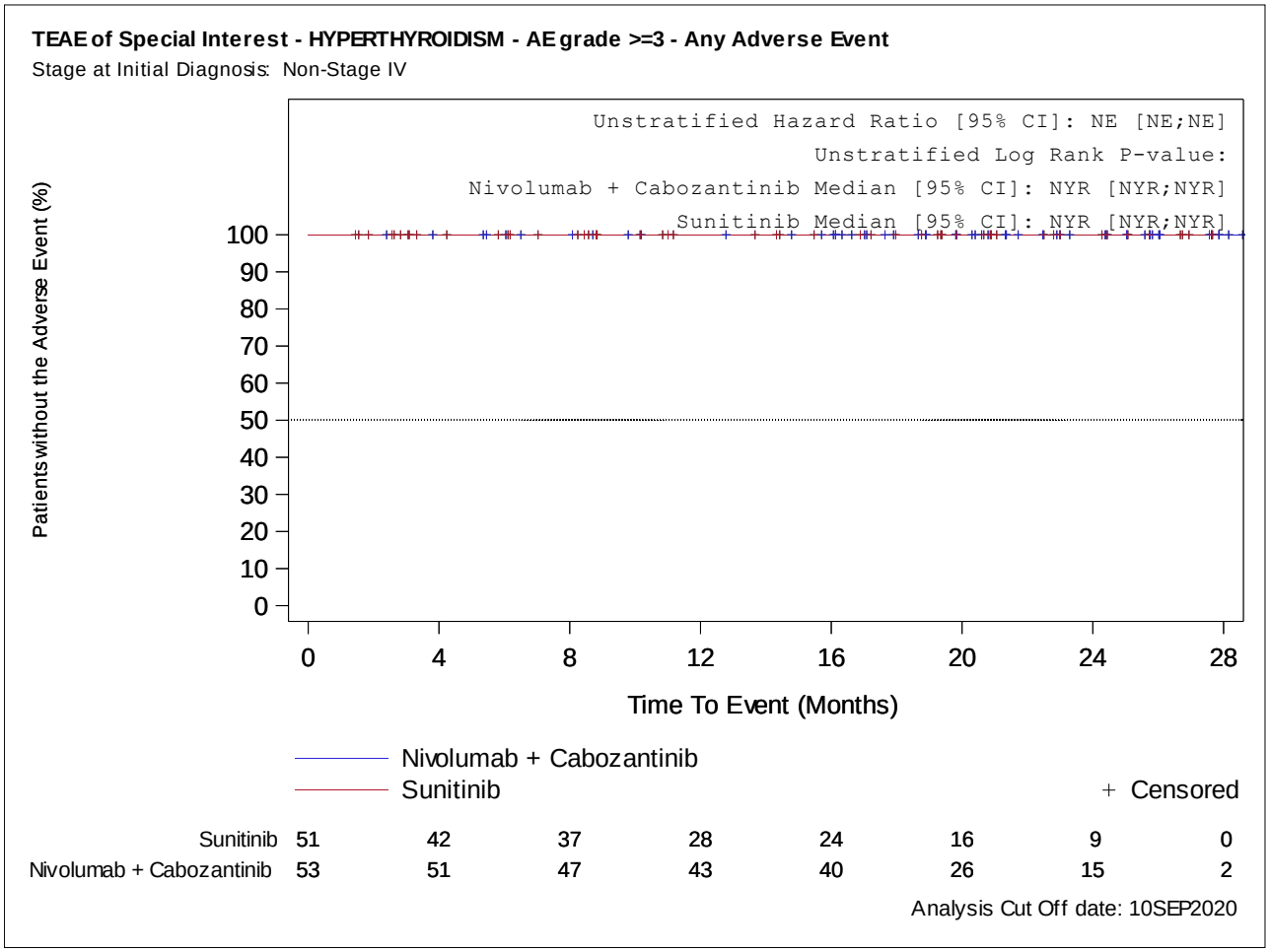

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:34:55

FIGURE 3.91.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



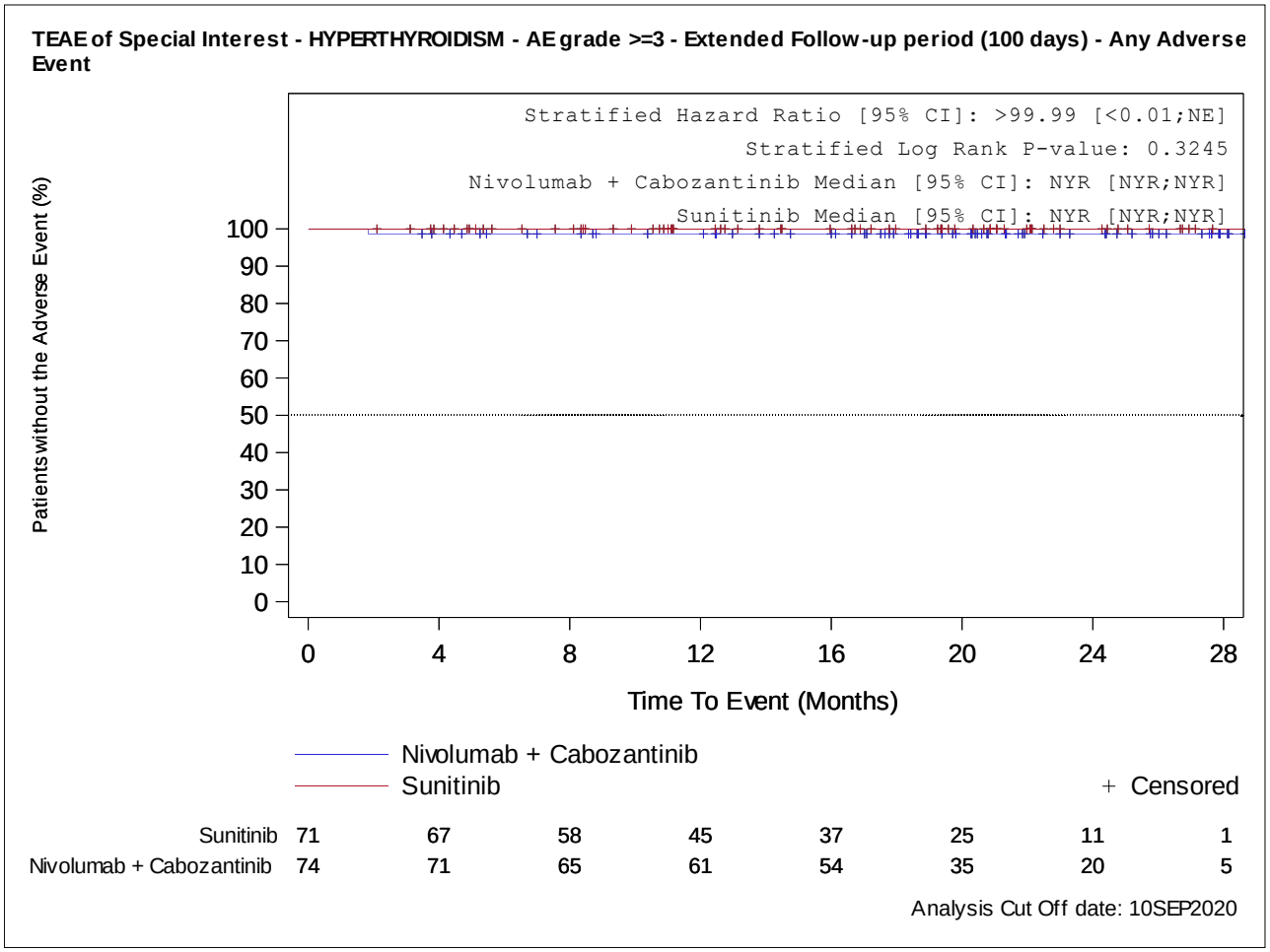

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:35:21

FIGURE 3.91.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



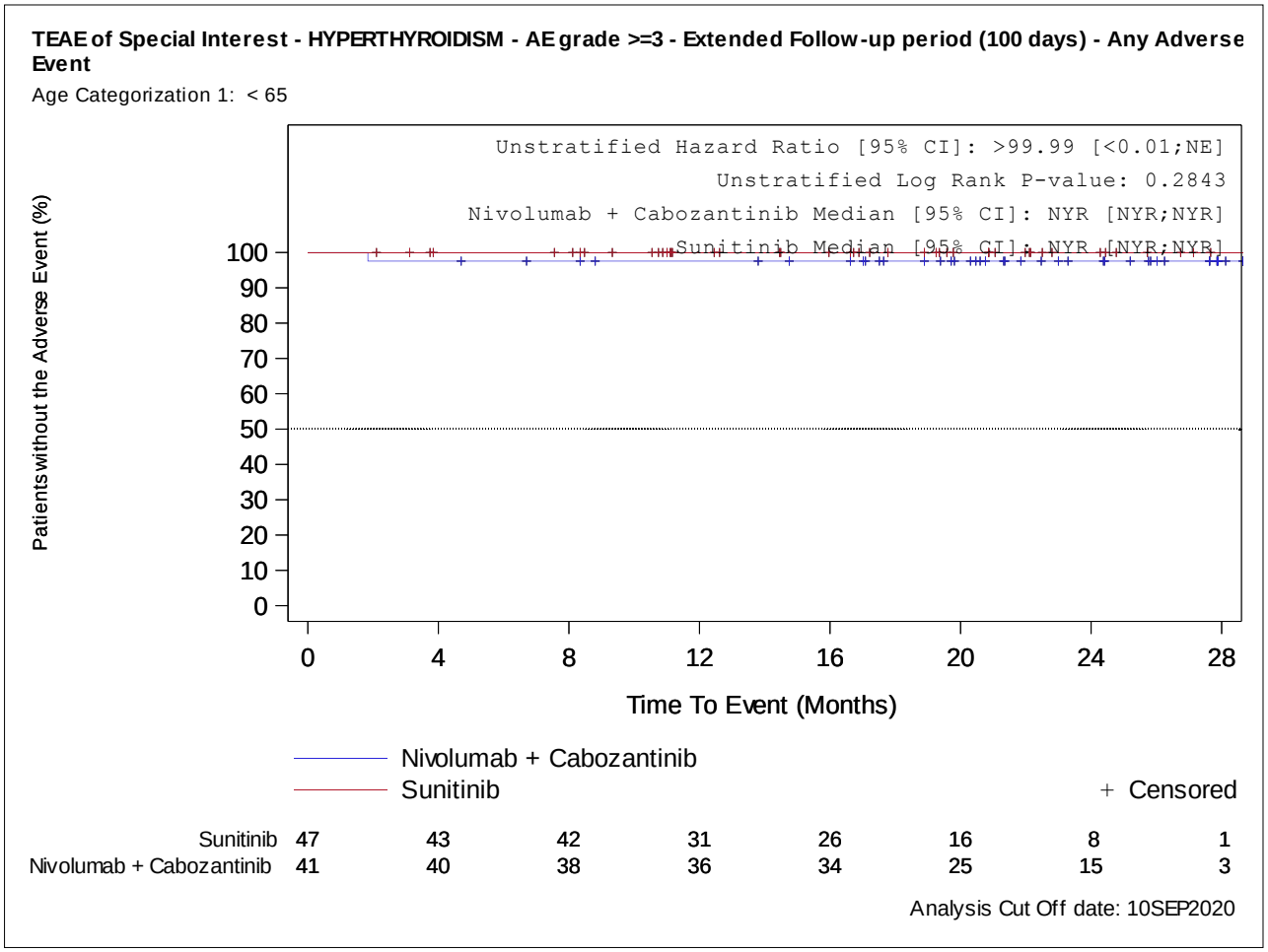

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:35:26

FIGURE 3.92.1: TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



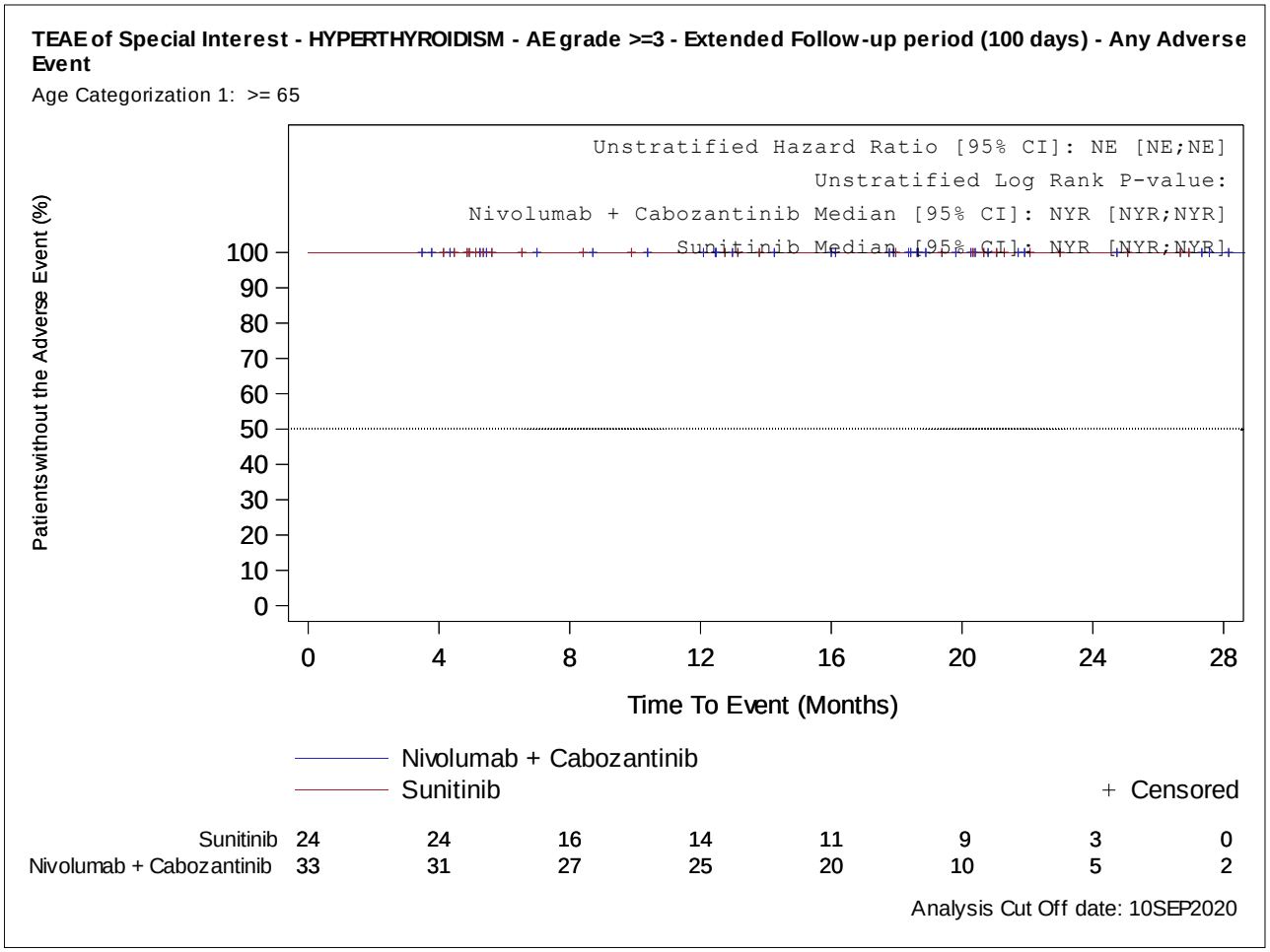

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:38:22

FIGURE 3.92.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



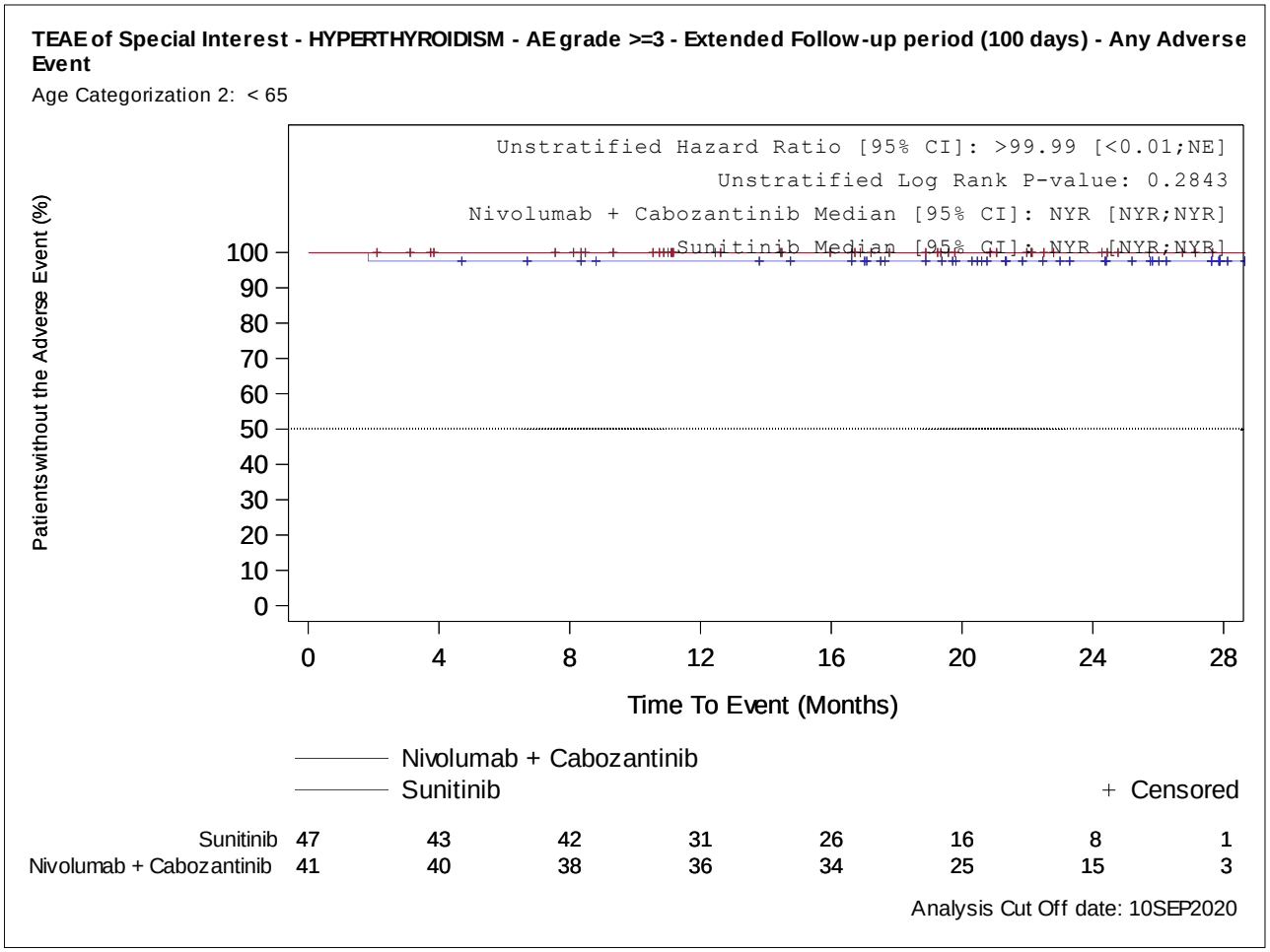

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:38:26

FIGURE 3.92.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



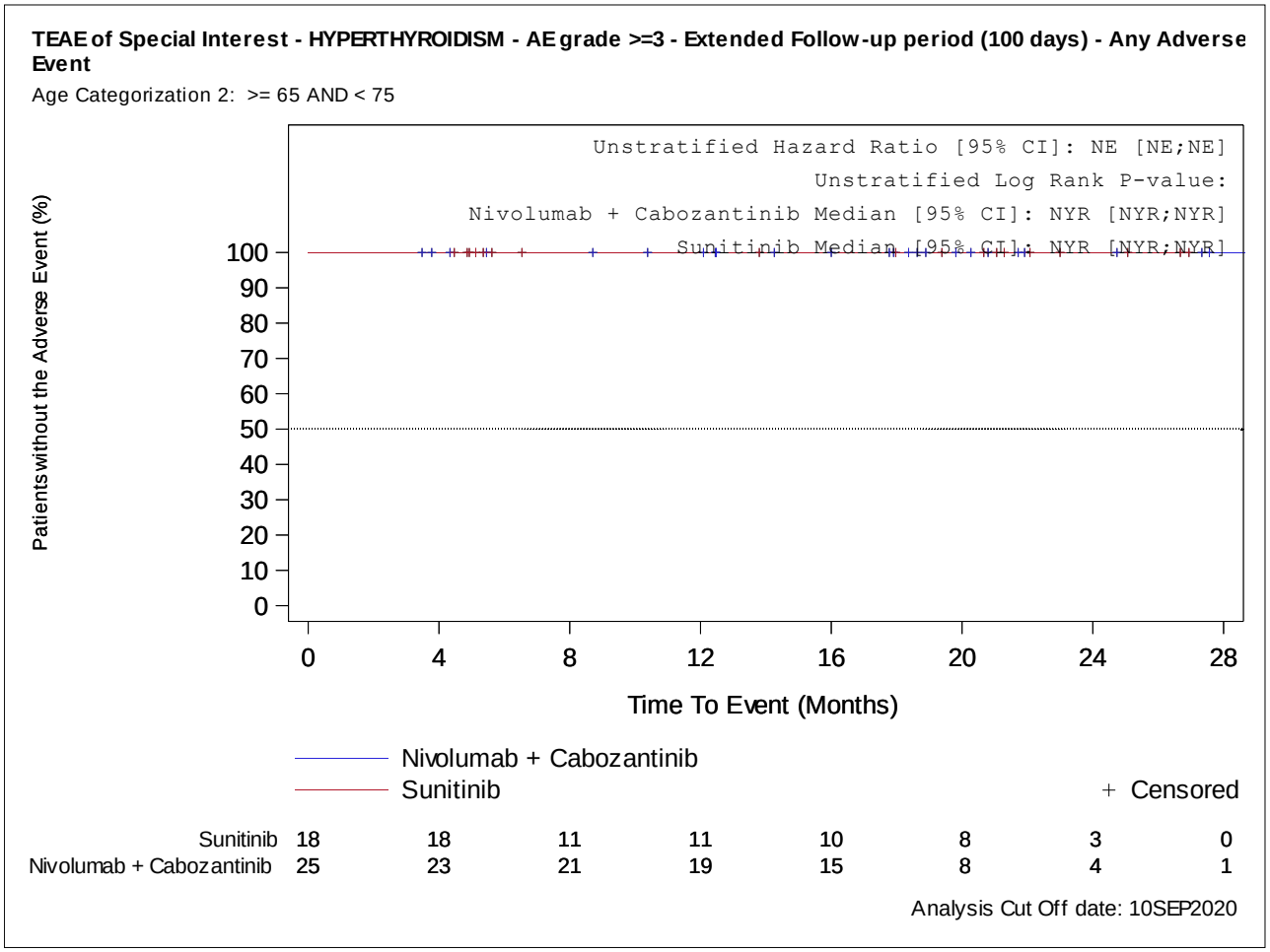

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:38:31

FIGURE 3.92.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:38:36

FIGURE 3.92.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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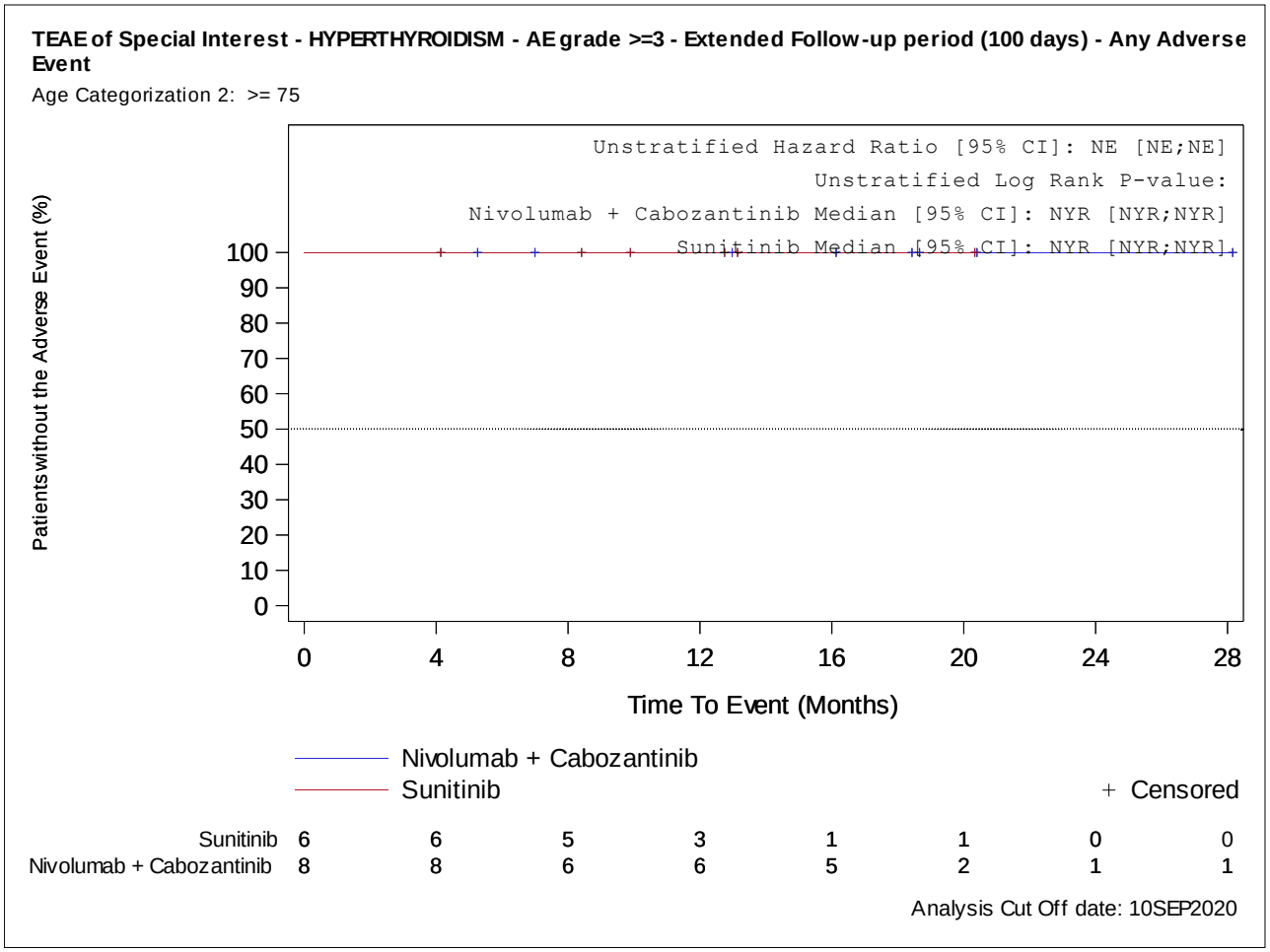
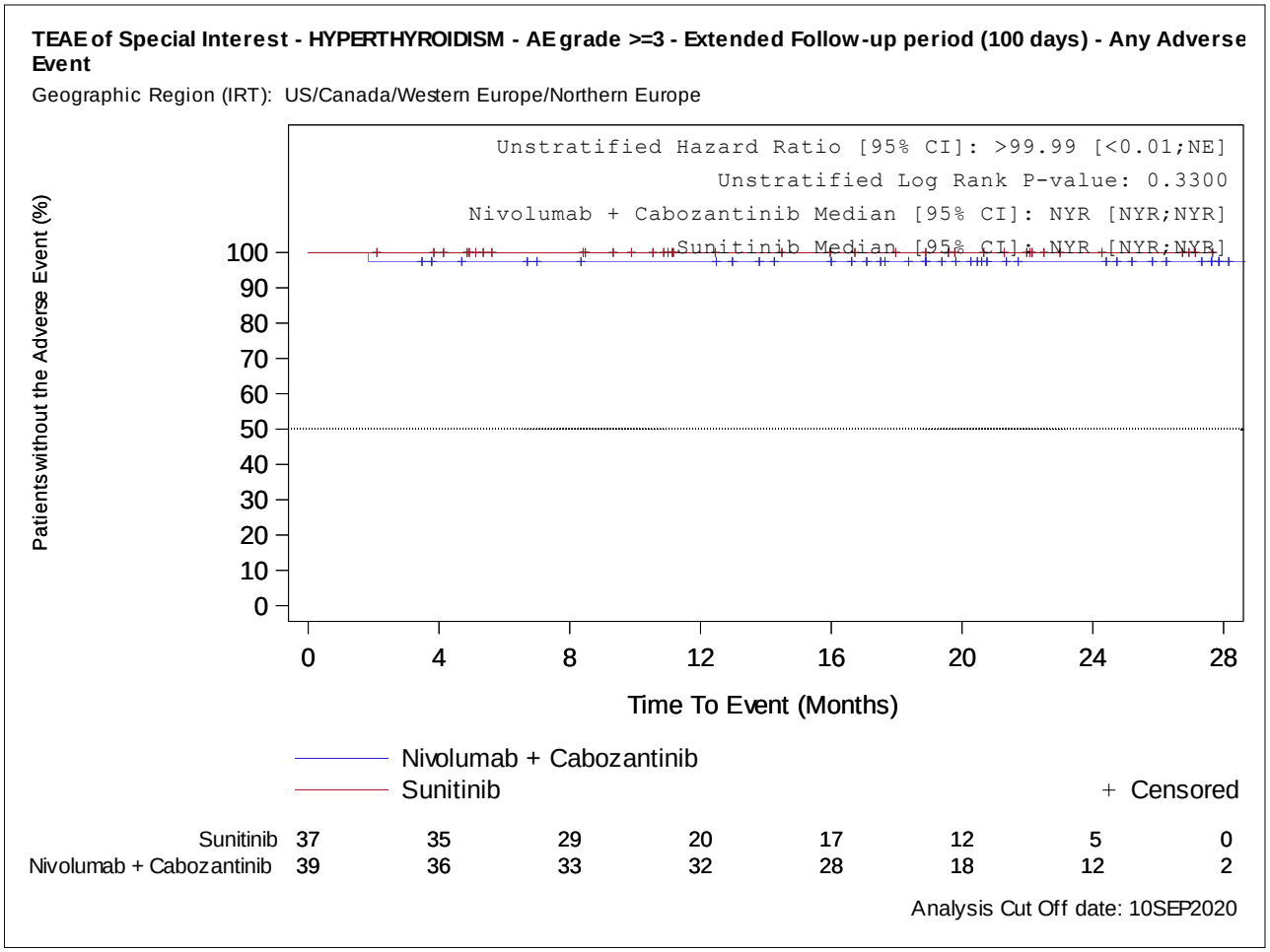
FIGURE 3.92.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



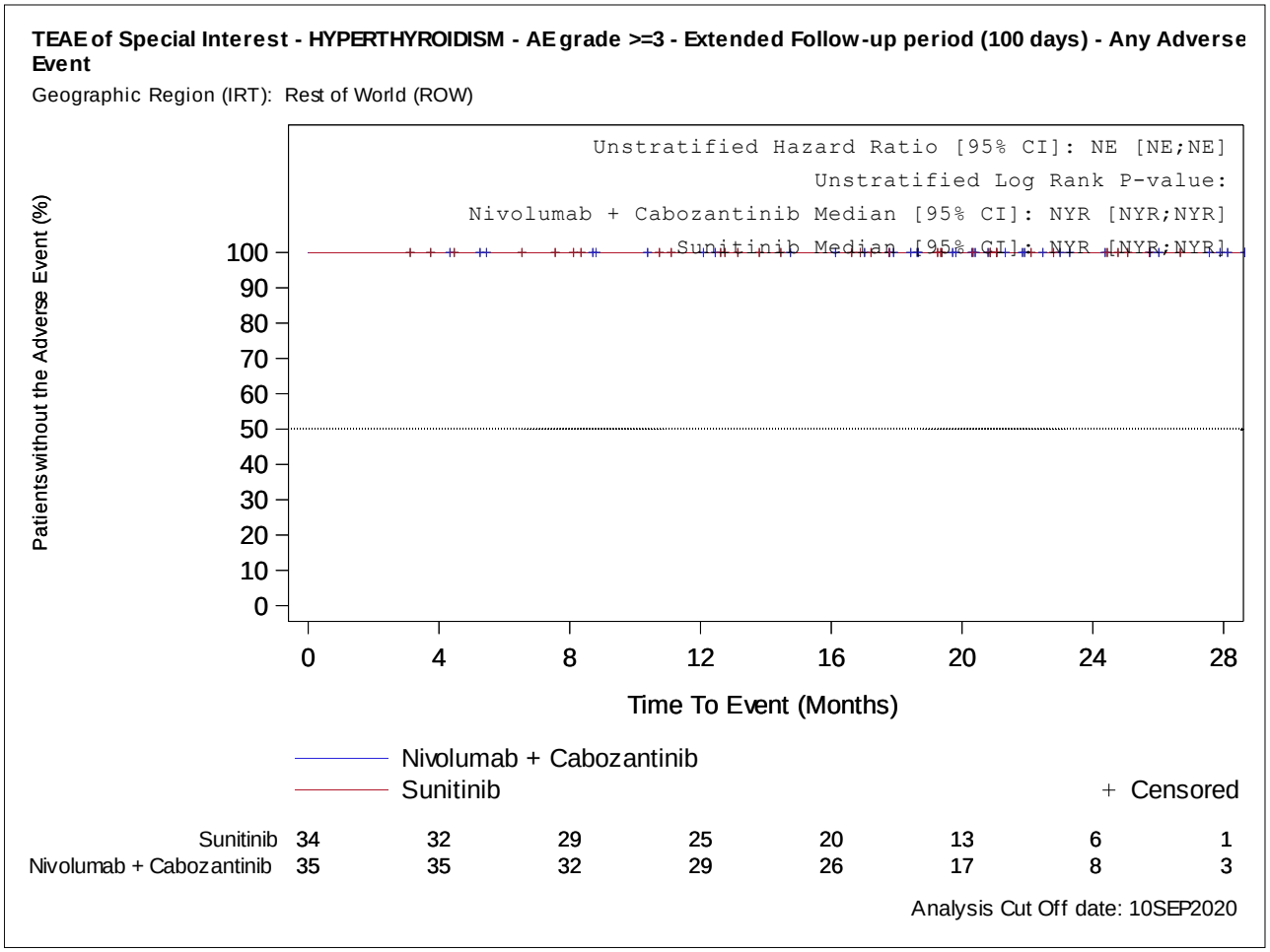

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:38:47

FIGURE 3.92.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



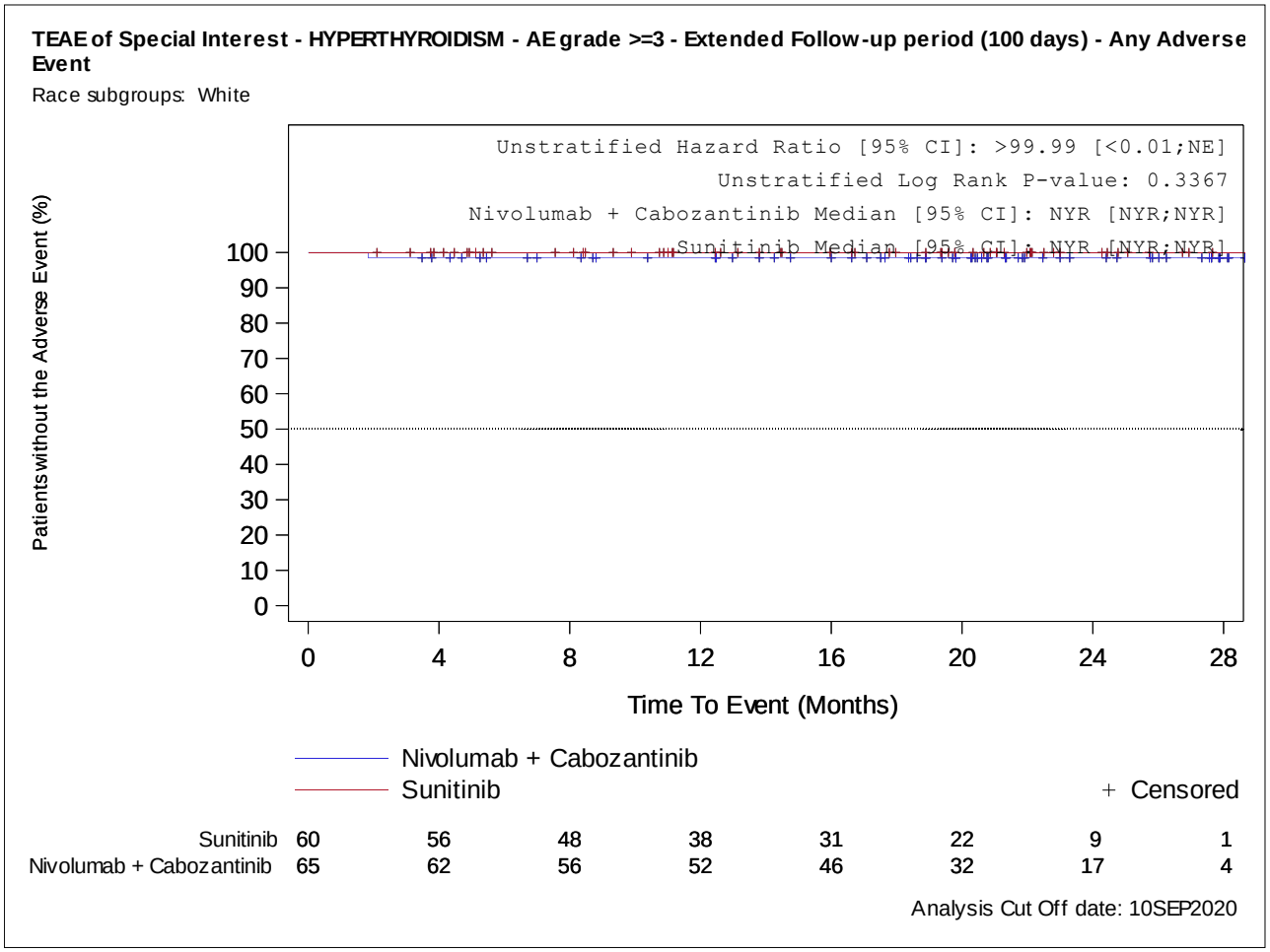

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:38:53

FIGURE 3.92.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



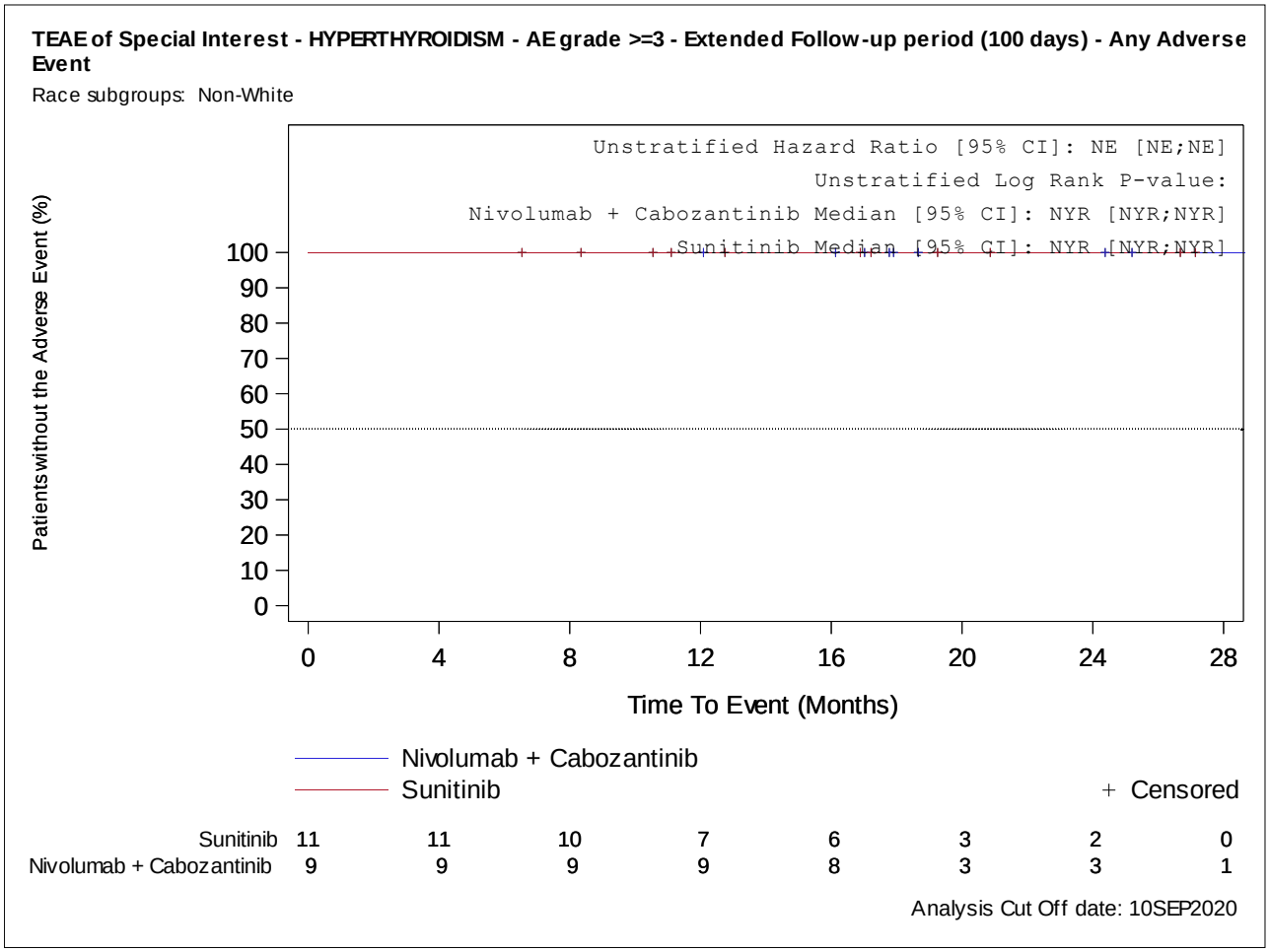

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:38:58

FIGURE 3.92.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



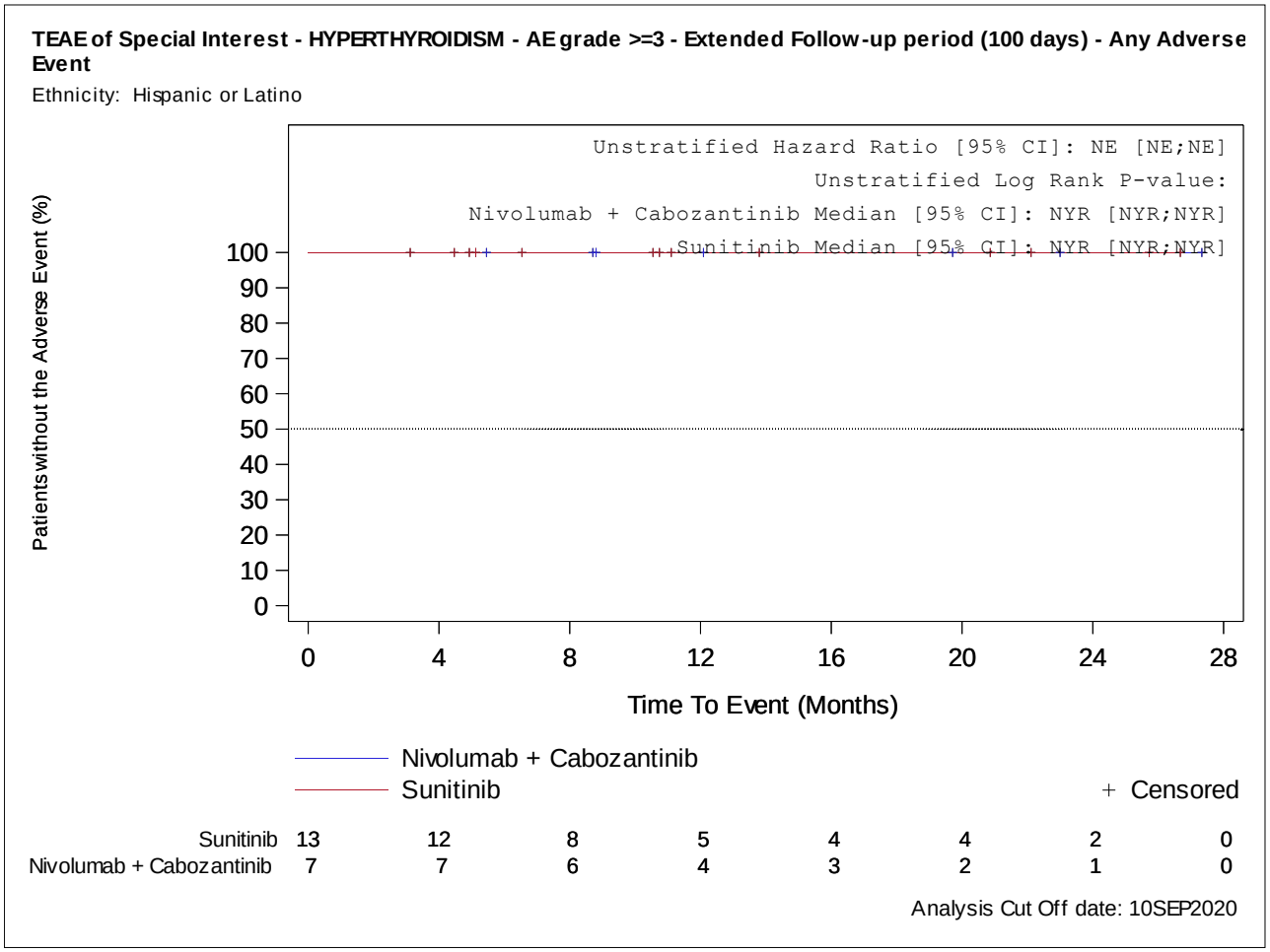

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:39:03

FIGURE 3.92.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



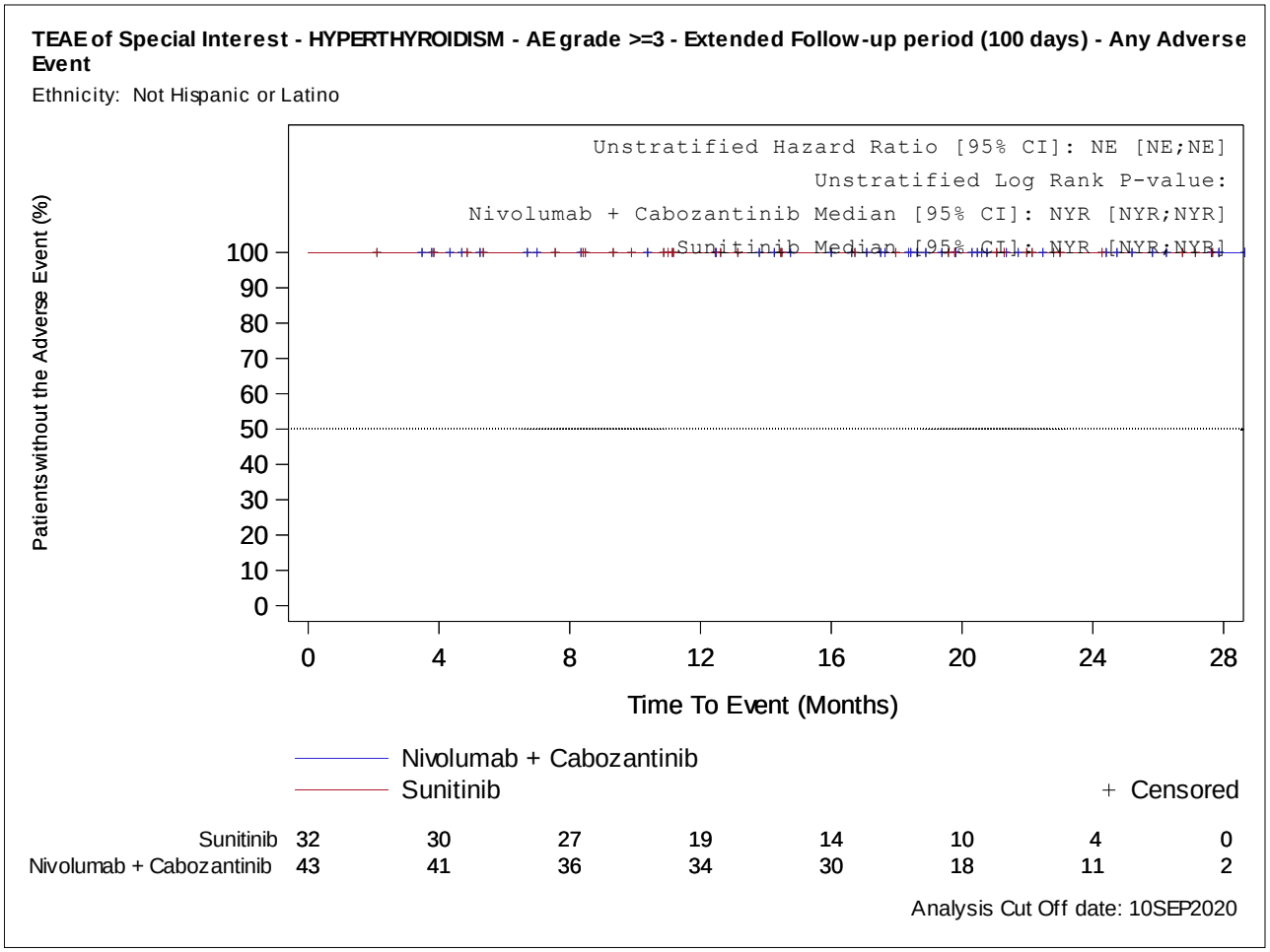

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:39:08

FIGURE 3.92.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



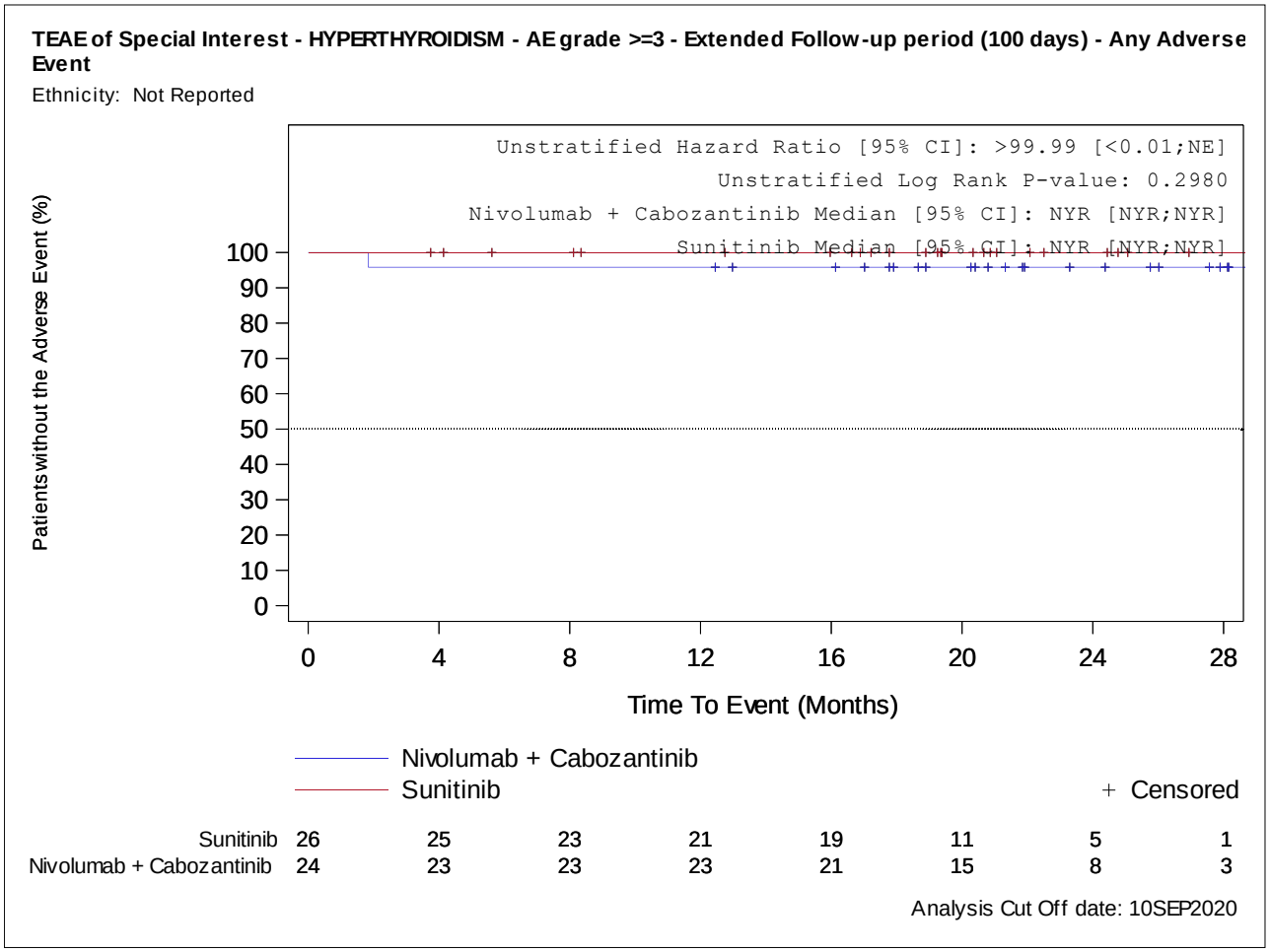

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:39:14

FIGURE 3.92.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



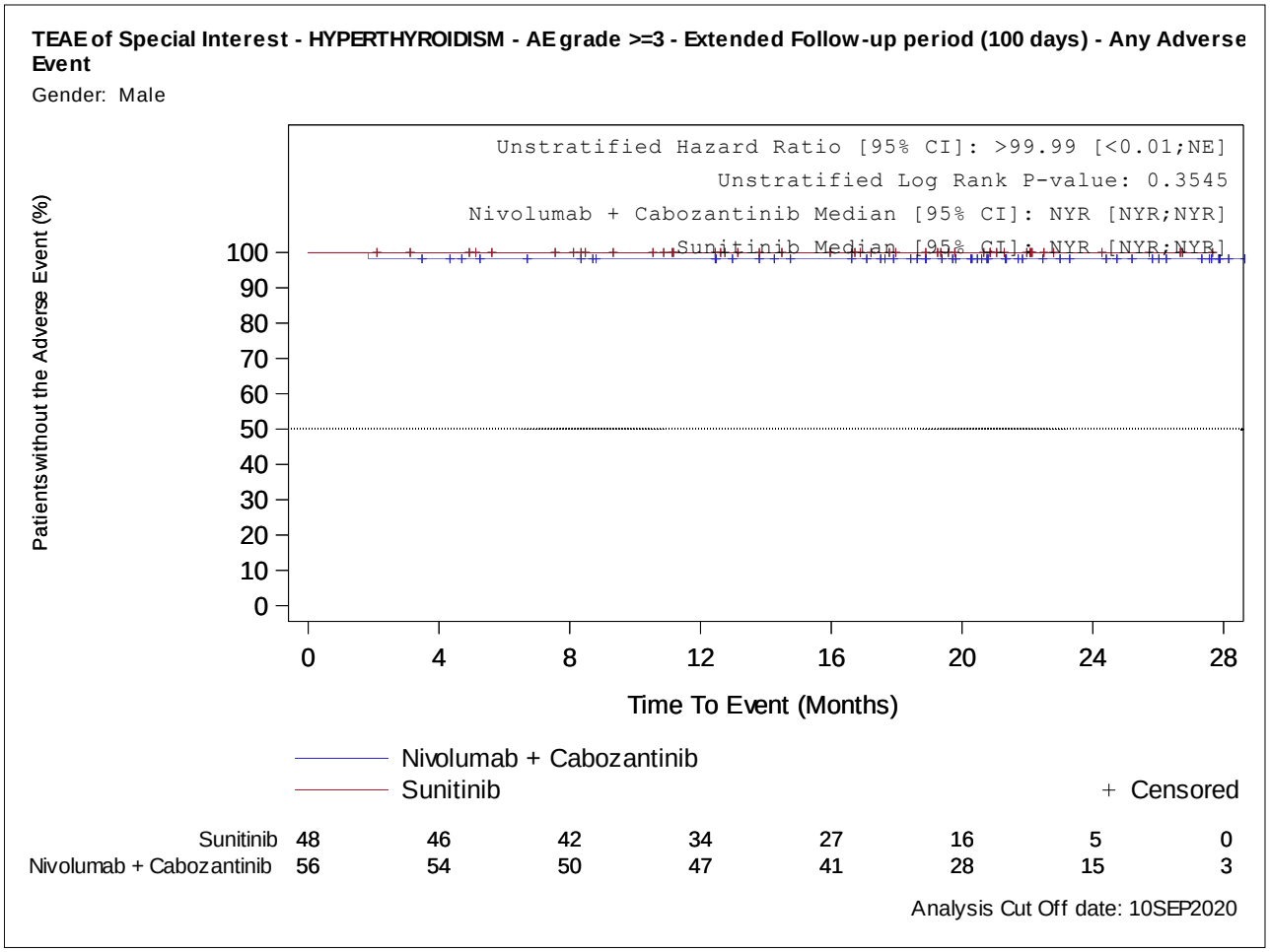

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:39:19

FIGURE 3.92.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:39:25

FIGURE 3.92.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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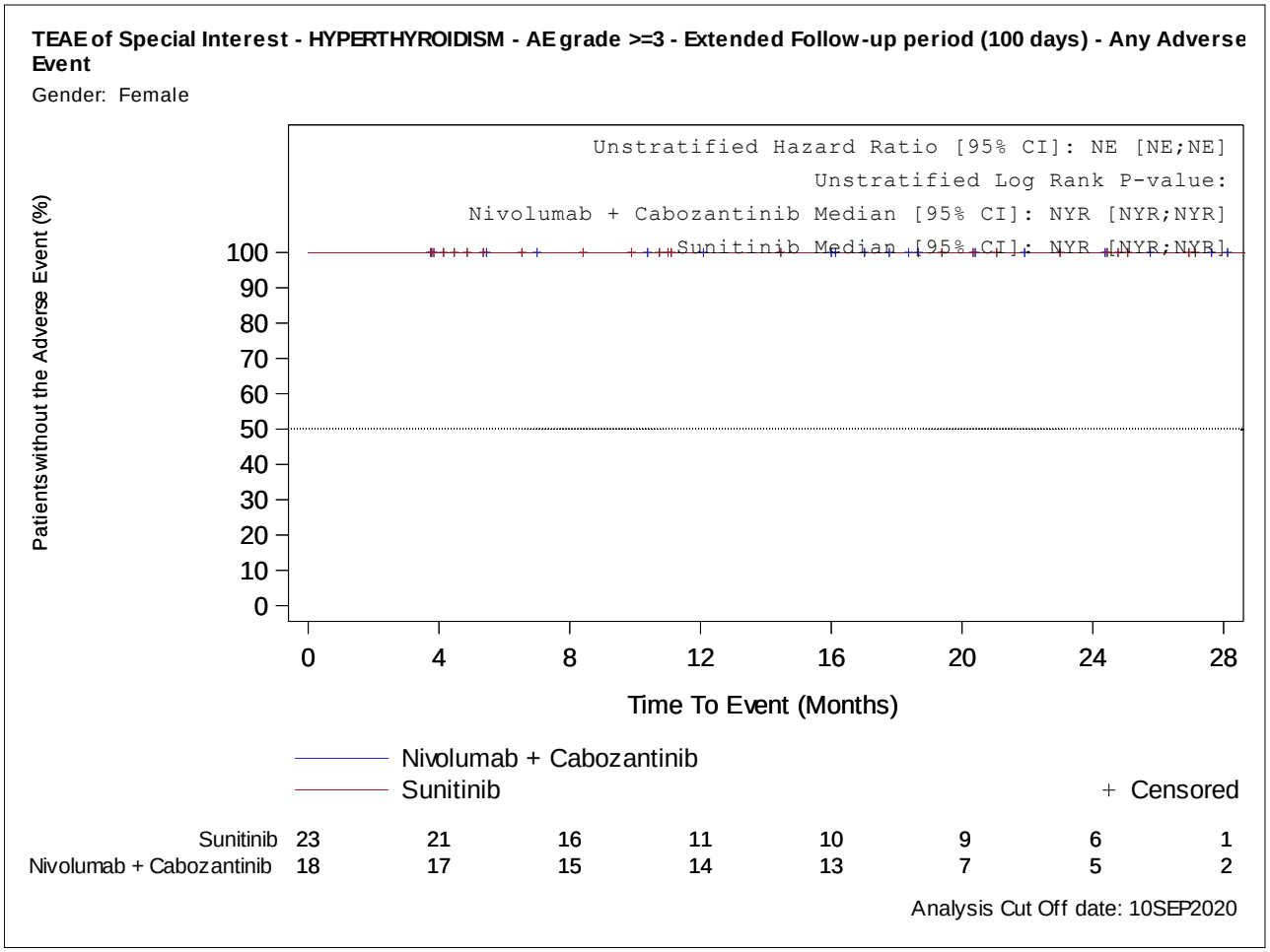
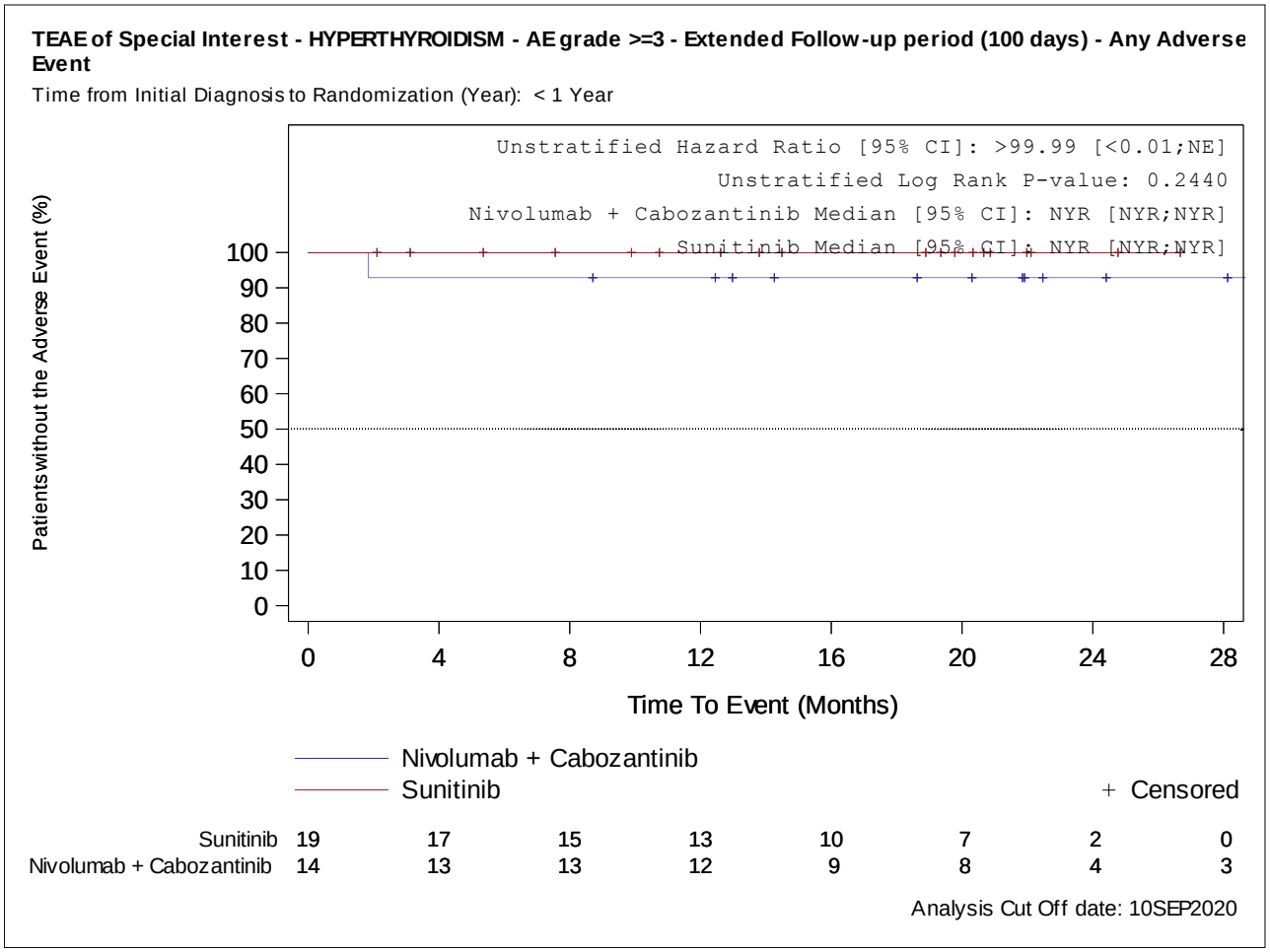
FIGURE 3.92.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:39:35

FIGURE 3.92.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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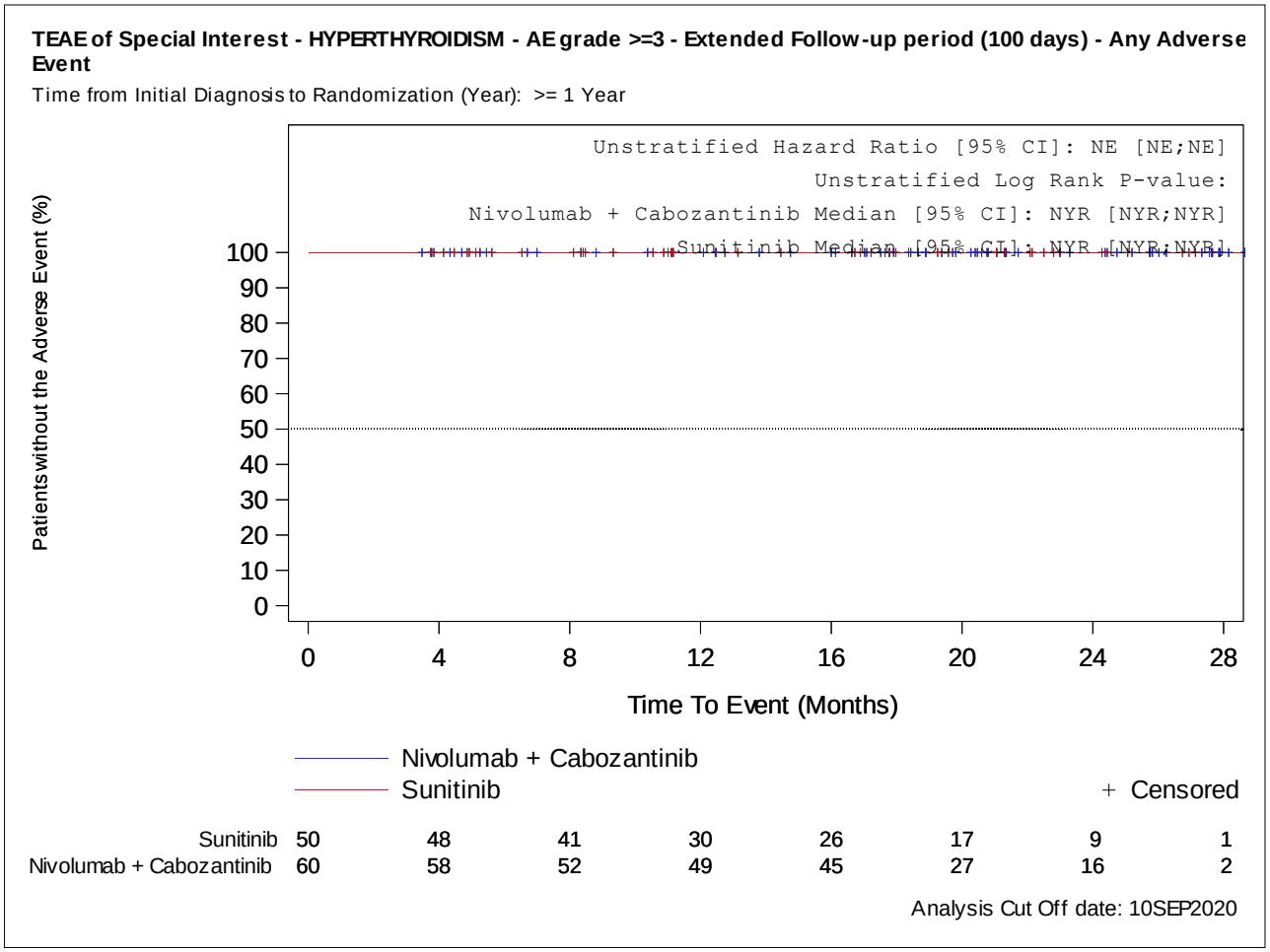
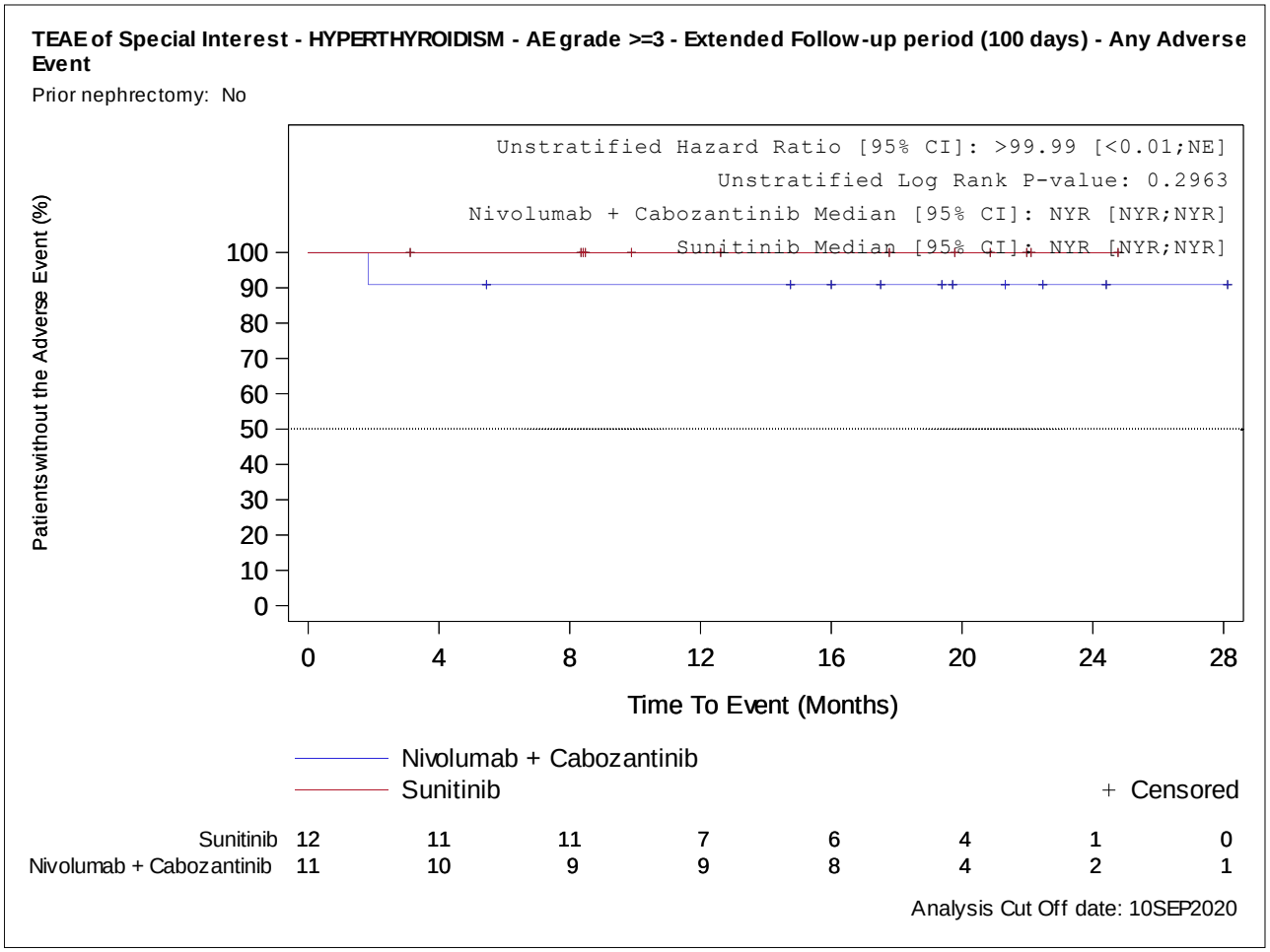
FIGURE 3.92.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



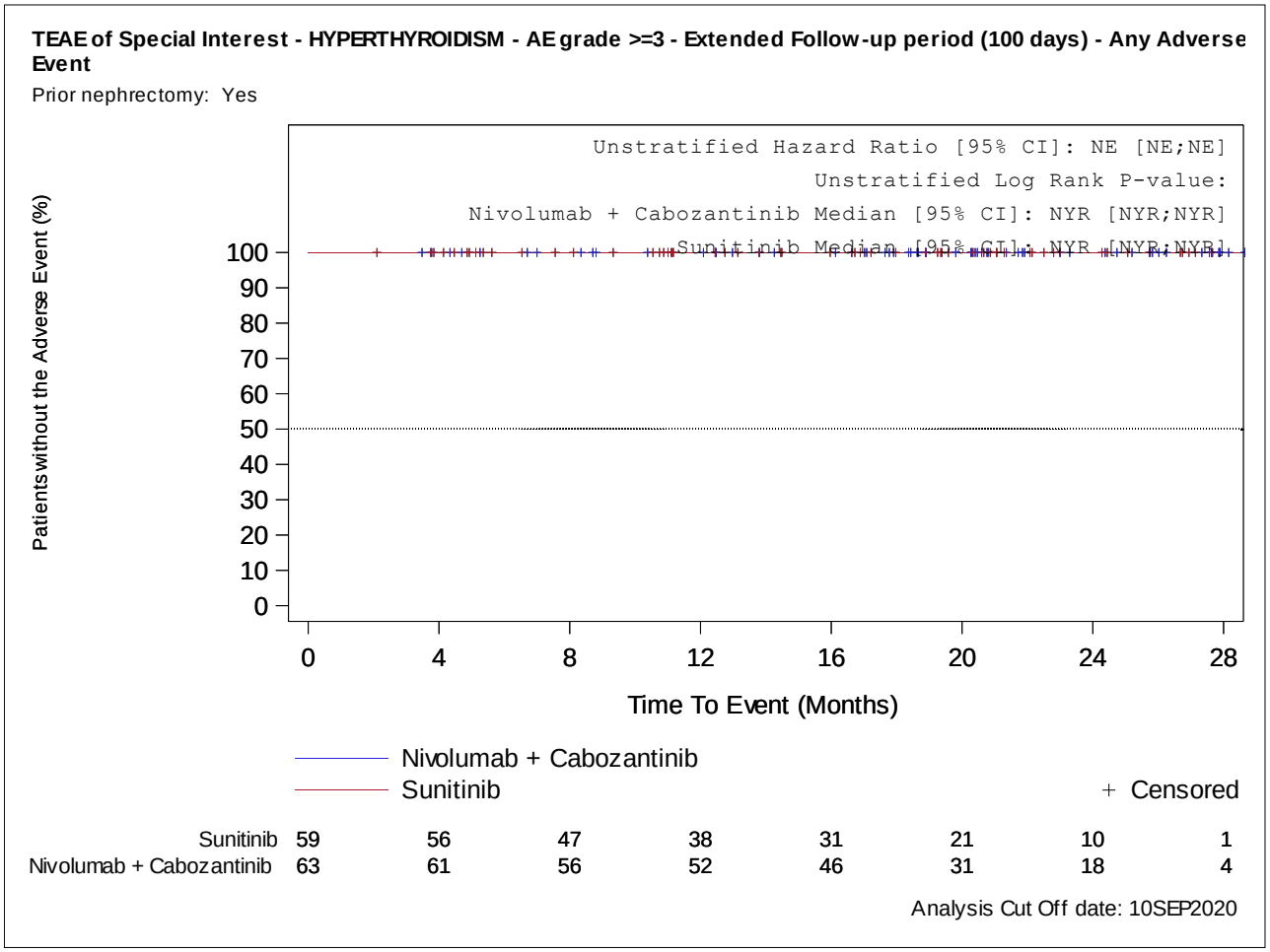

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:39:57

FIGURE 3.92.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



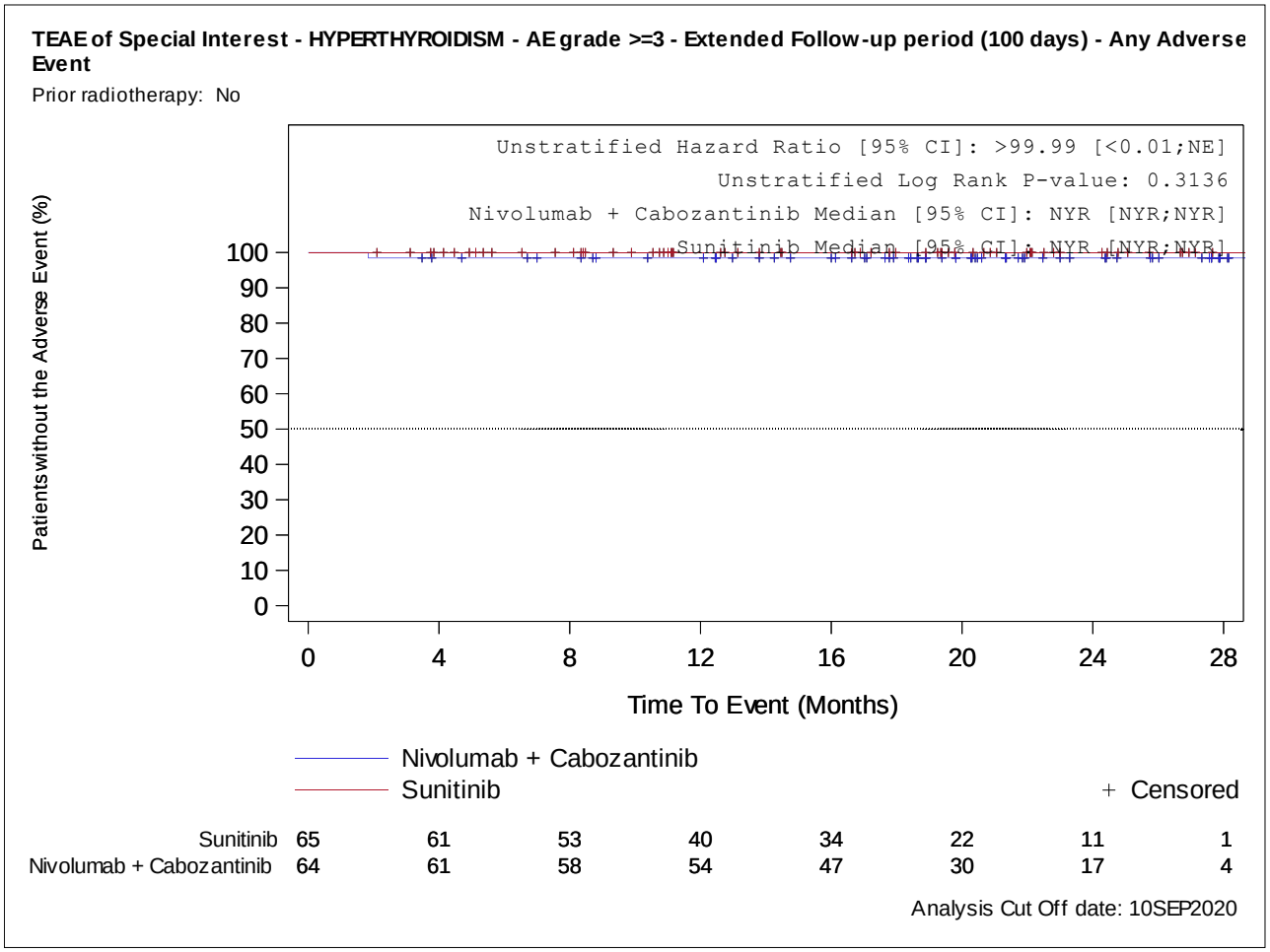

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:40:44

FIGURE 3.92.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:40:50

FIGURE 3.92.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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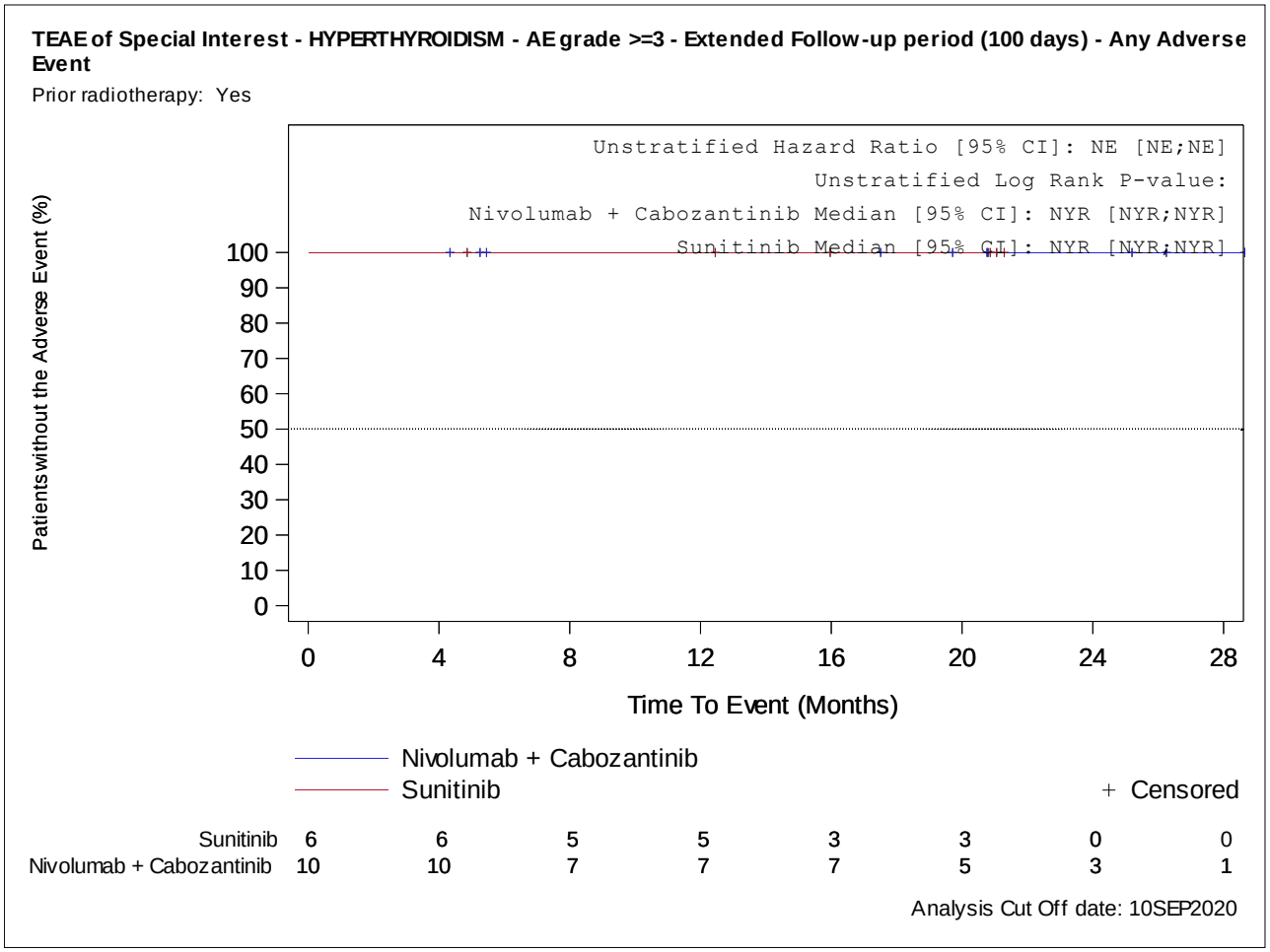
FIGURE 3.92.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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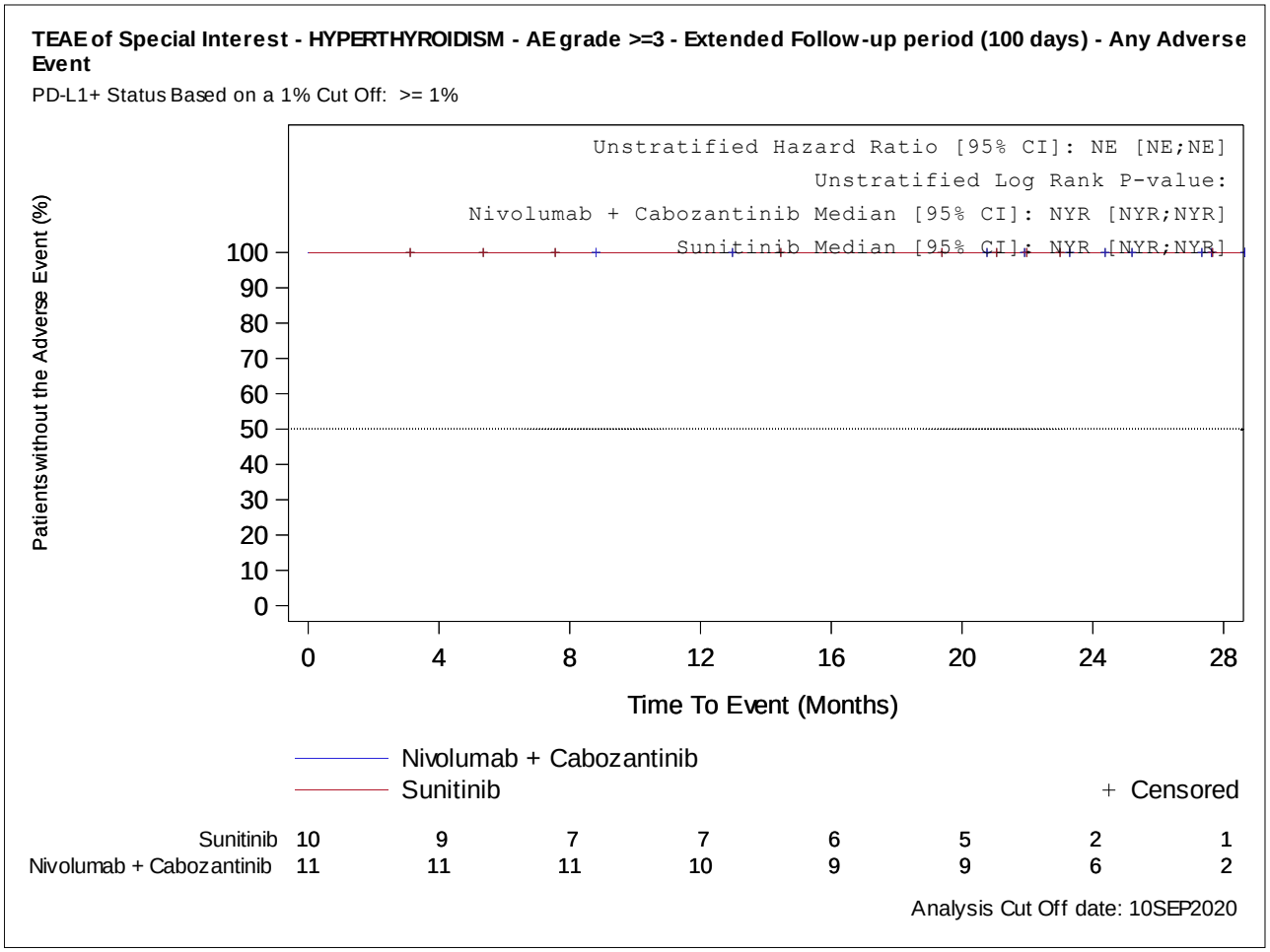
FIGURE 3.92.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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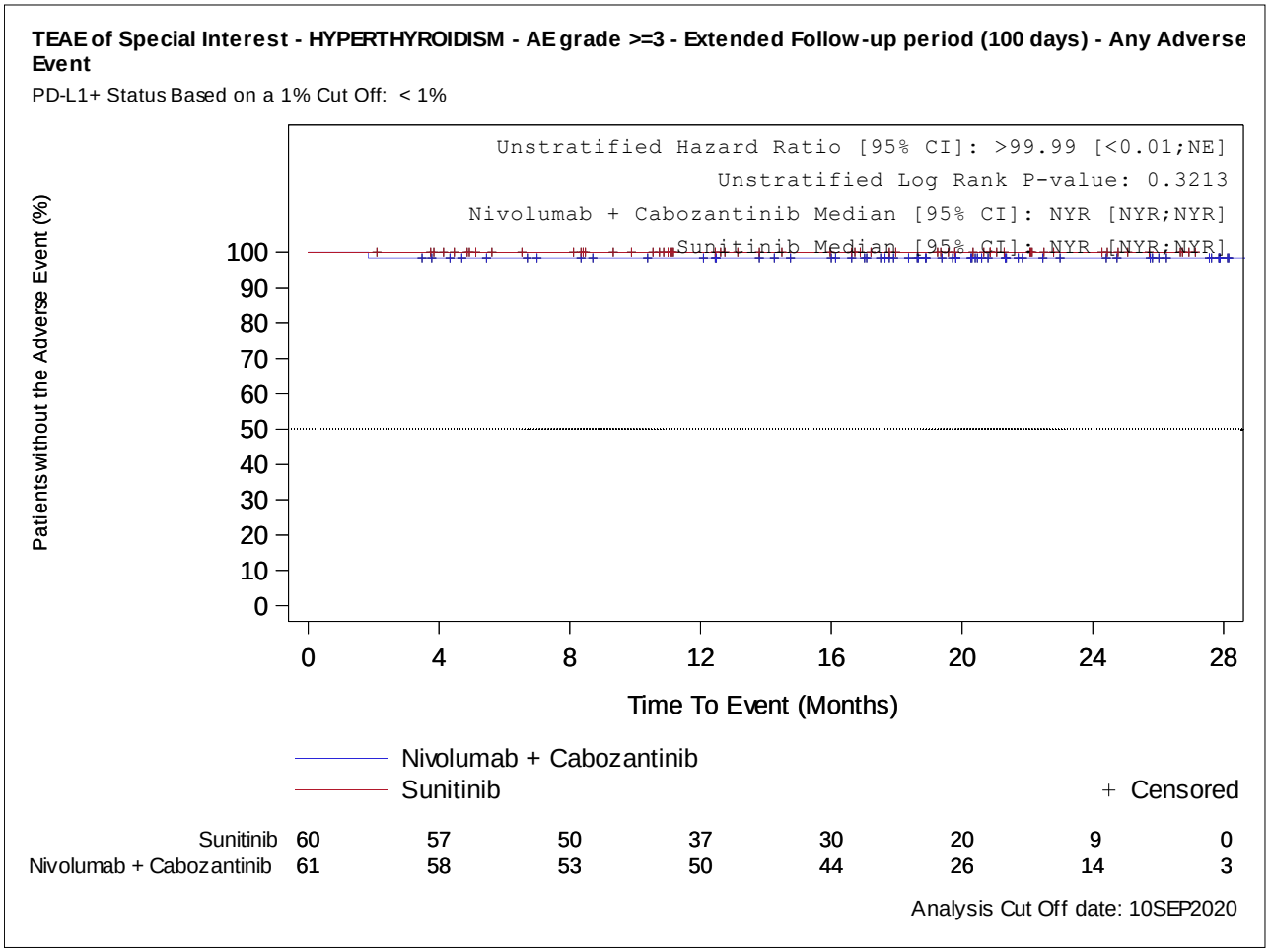
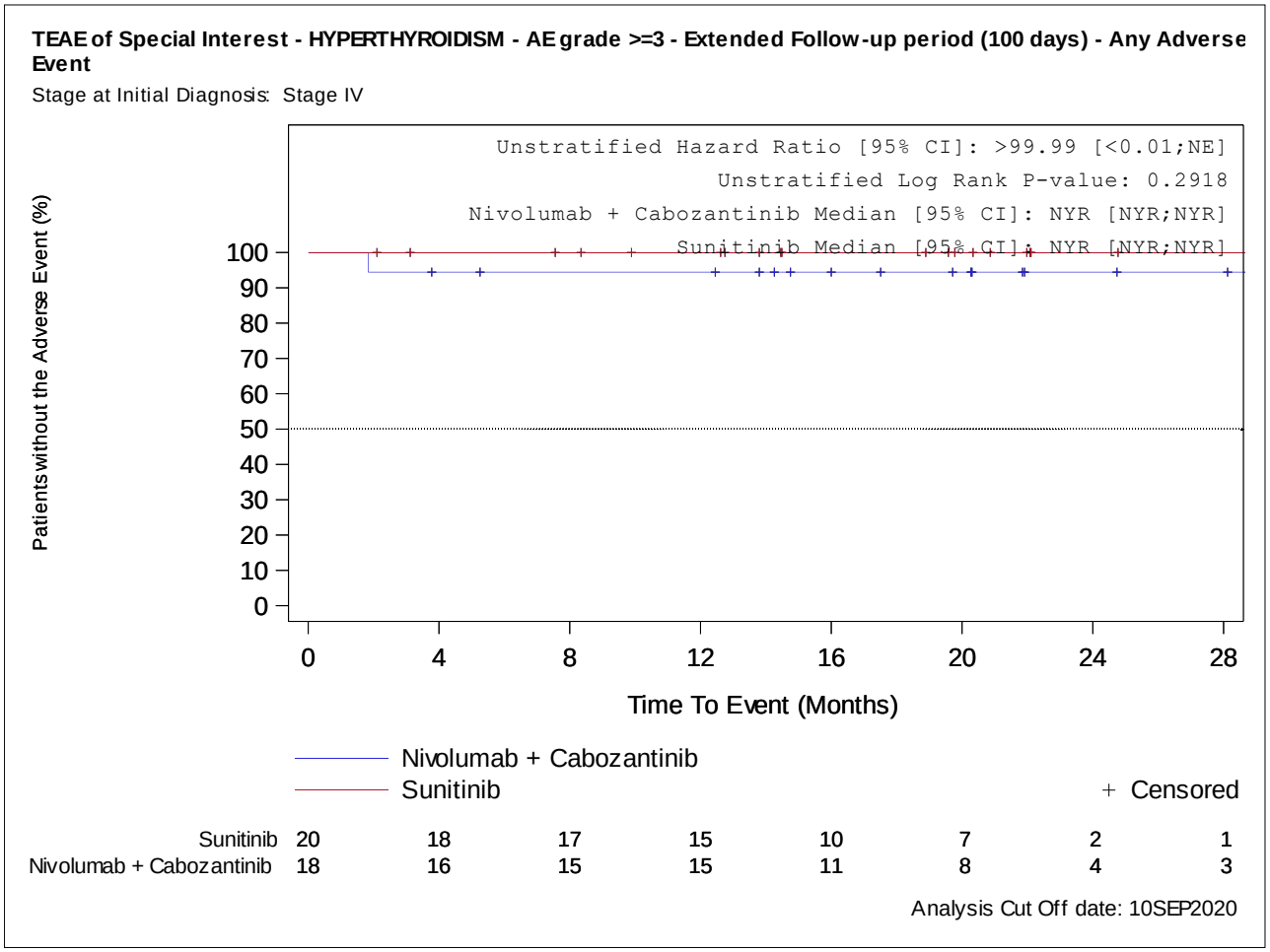
FIGURE 3.92.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



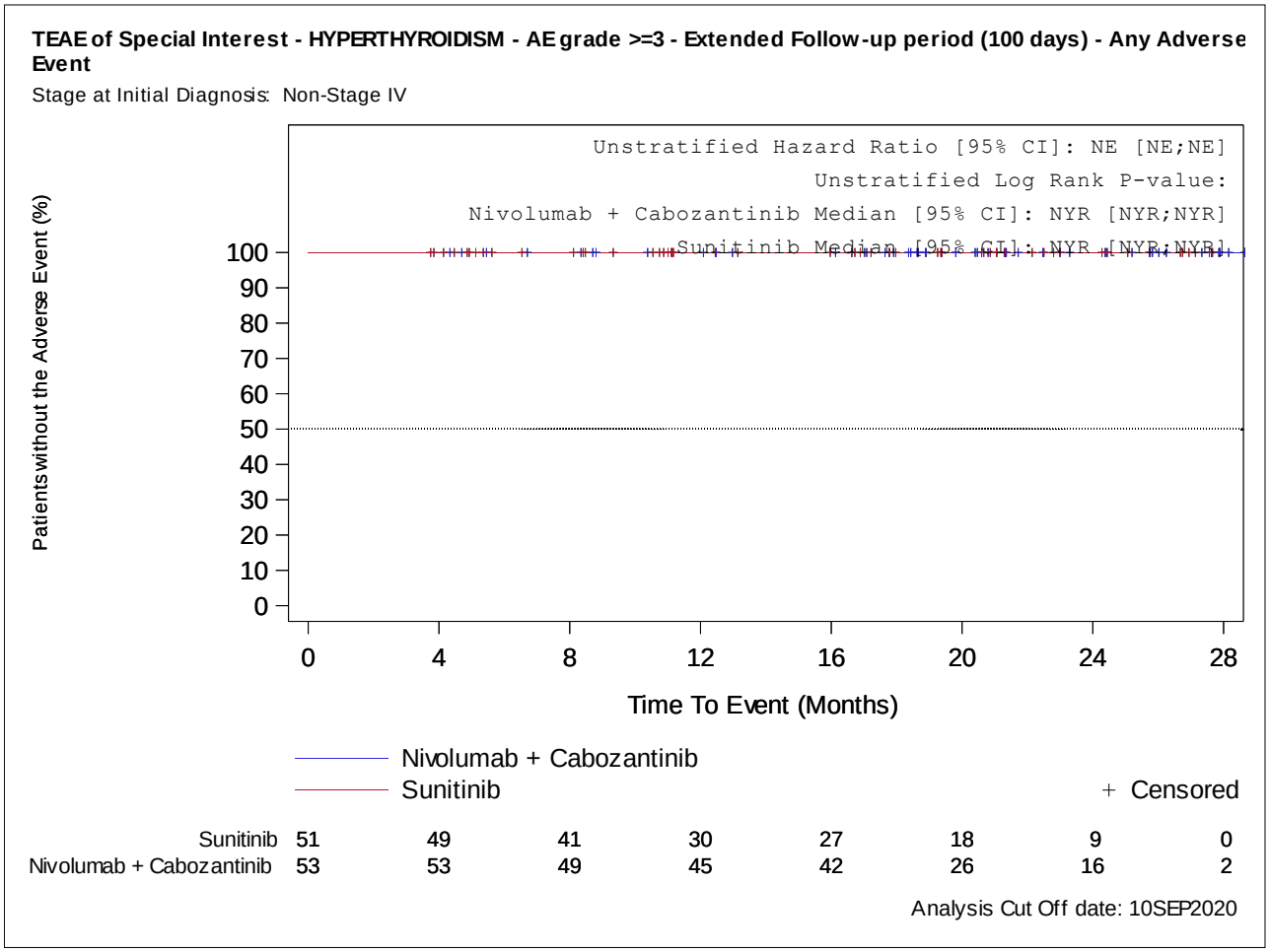

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:41:11

FIGURE 3.92.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



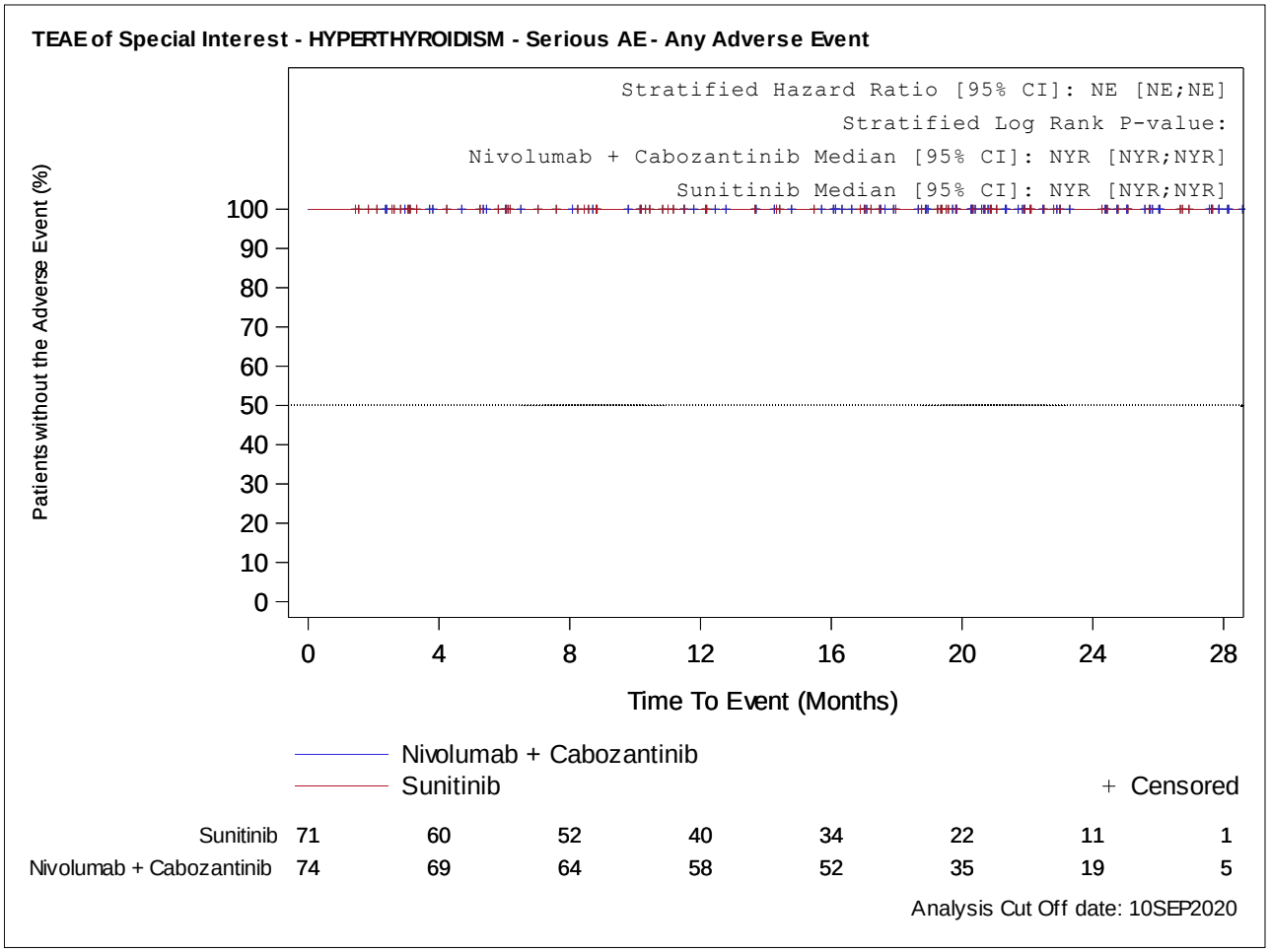

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:41:37

FIGURE 3.92.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



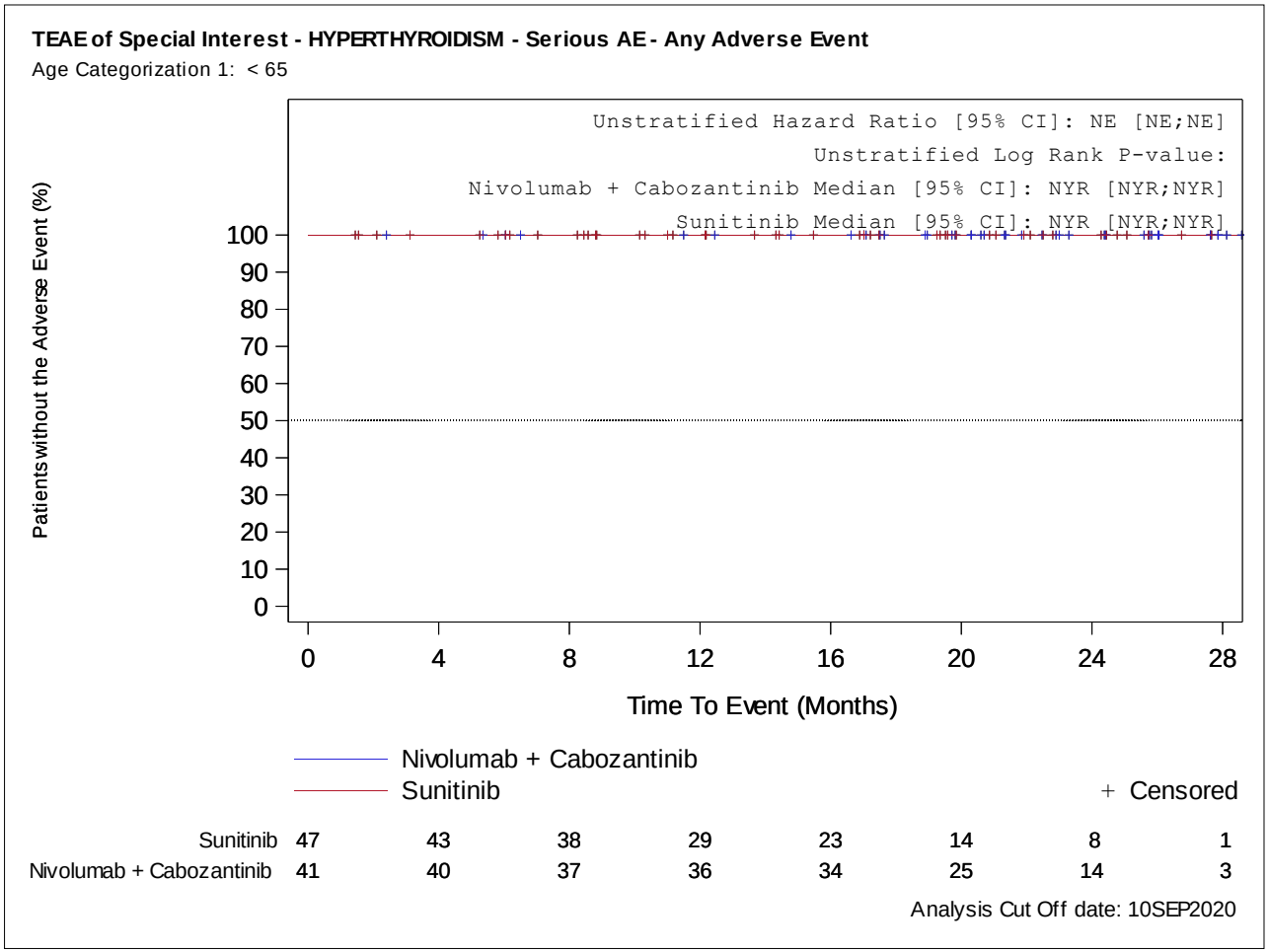

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:41:43

FIGURE 3.93.1: TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



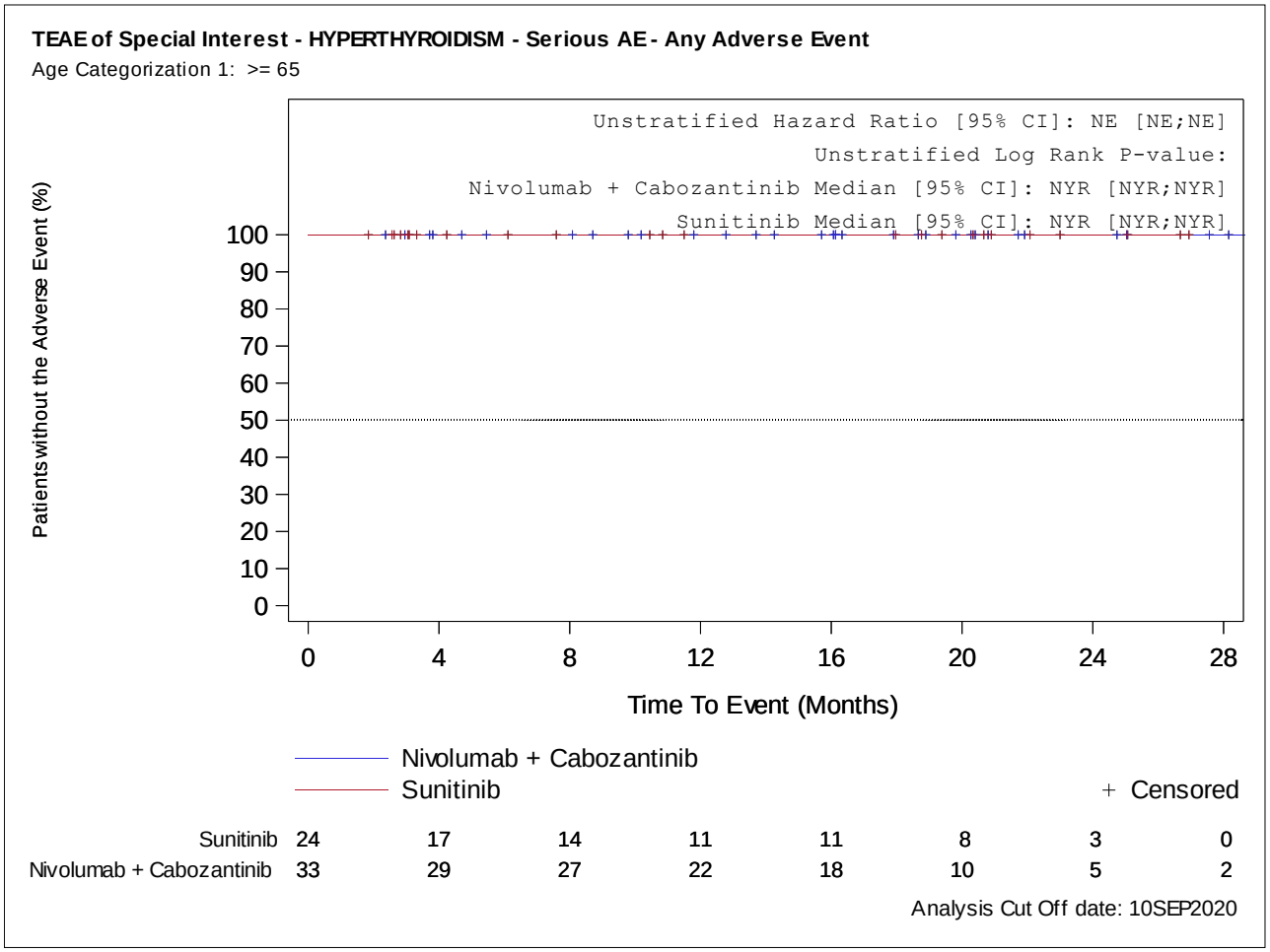

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:44:41

FIGURE 3.93.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



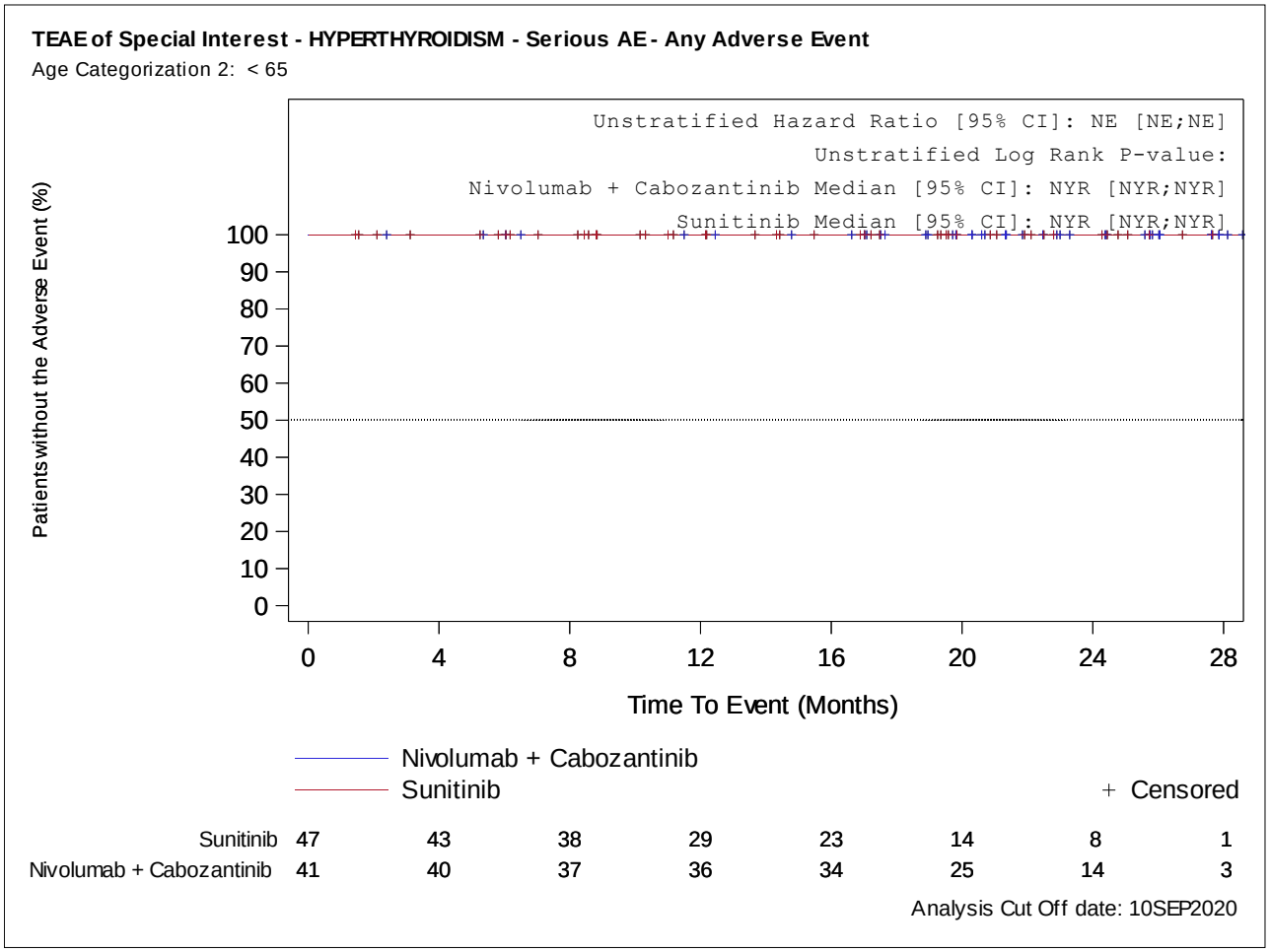

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:44:44

FIGURE 3.93.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



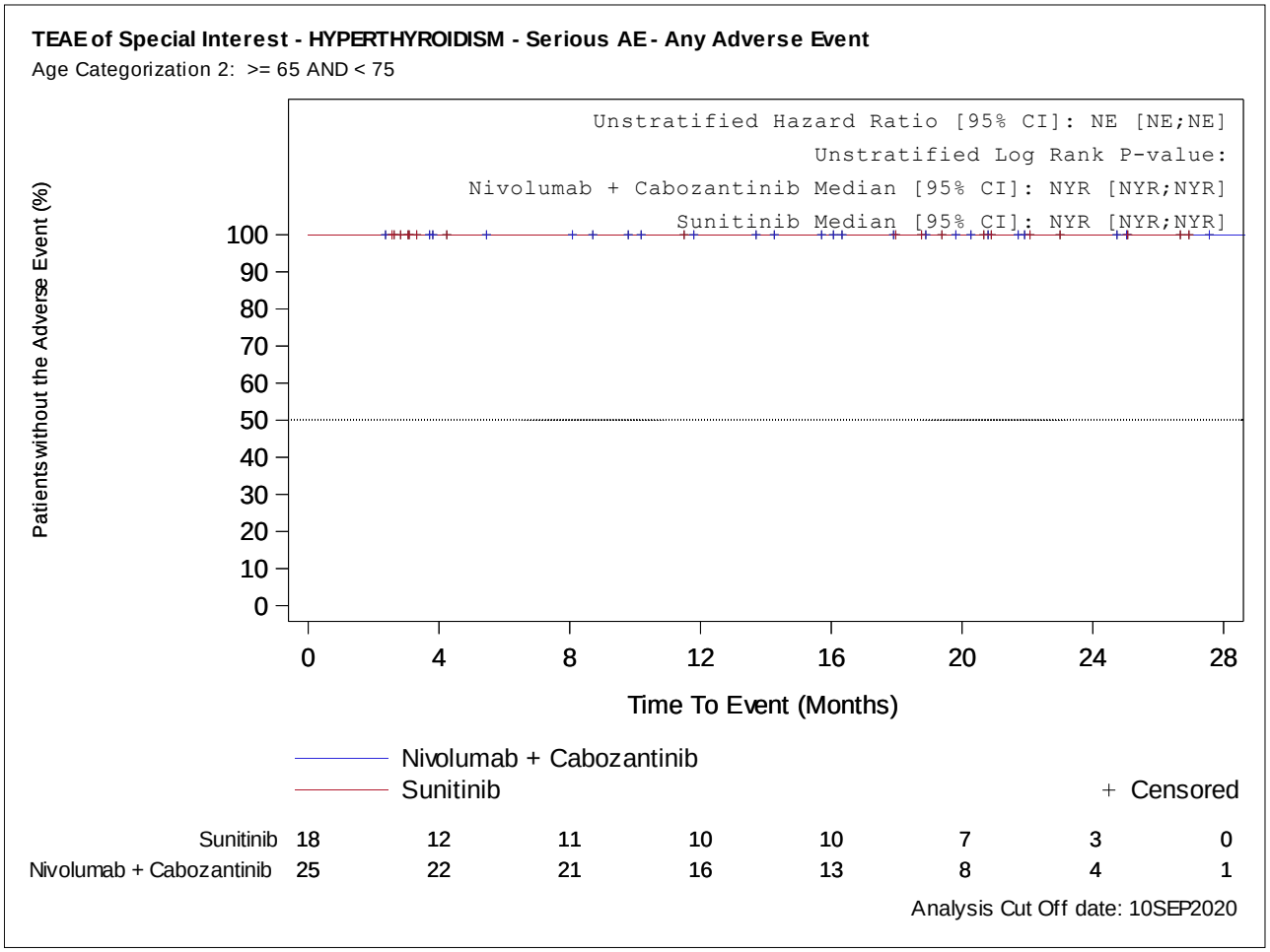

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:44:49

FIGURE 3.93.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



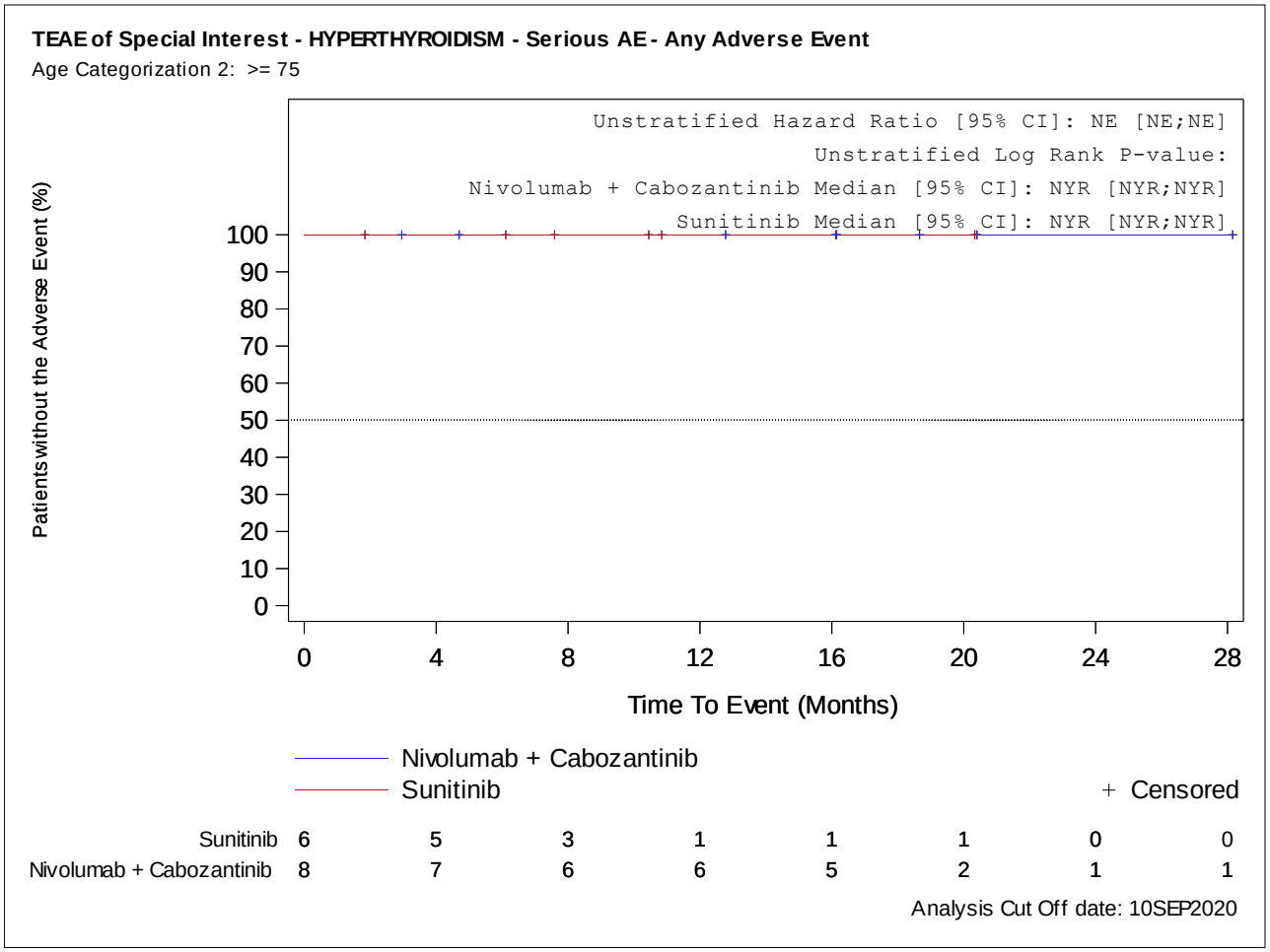

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:44:54

FIGURE 3.93.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



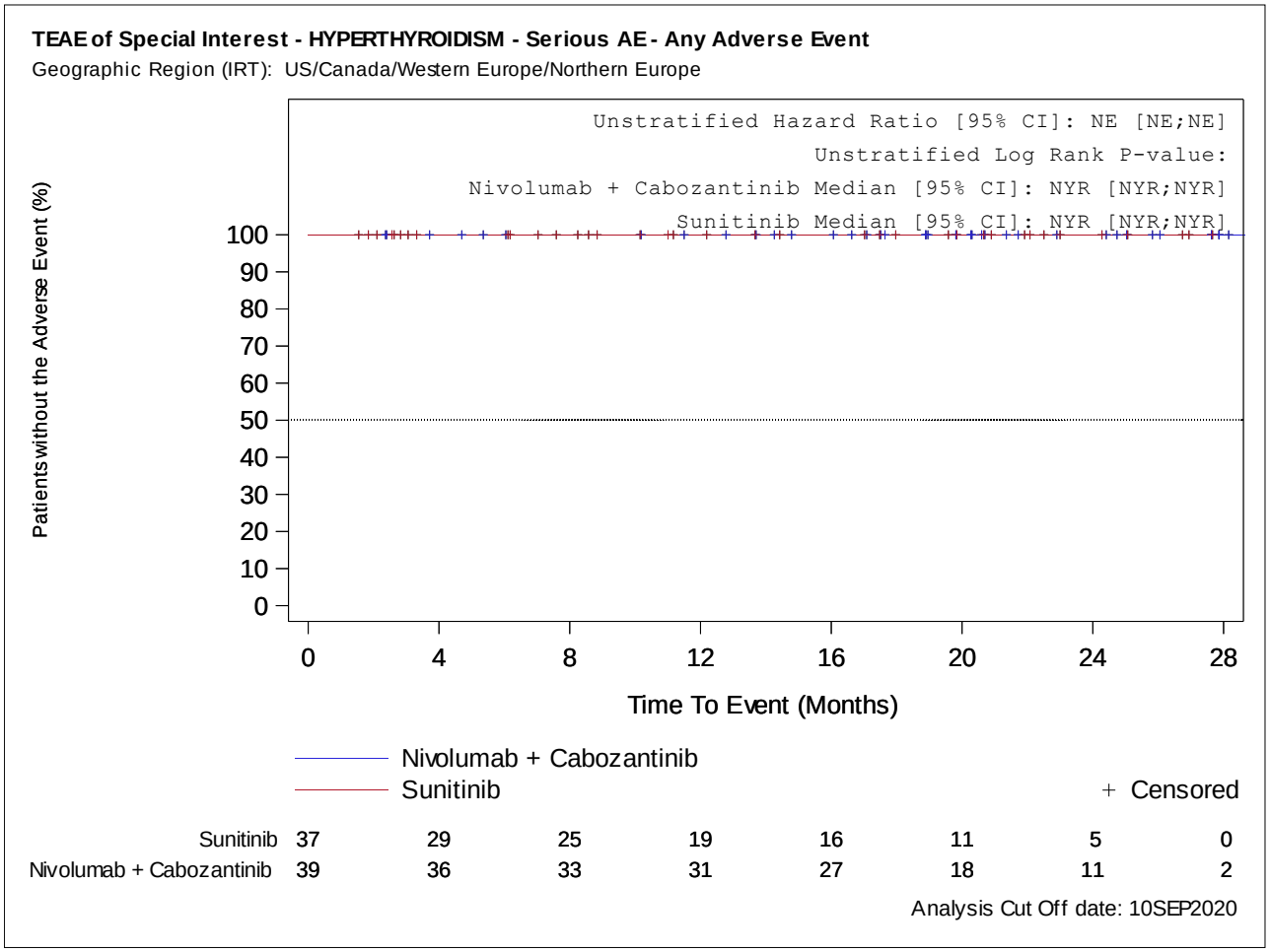

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:00

FIGURE 3.93.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



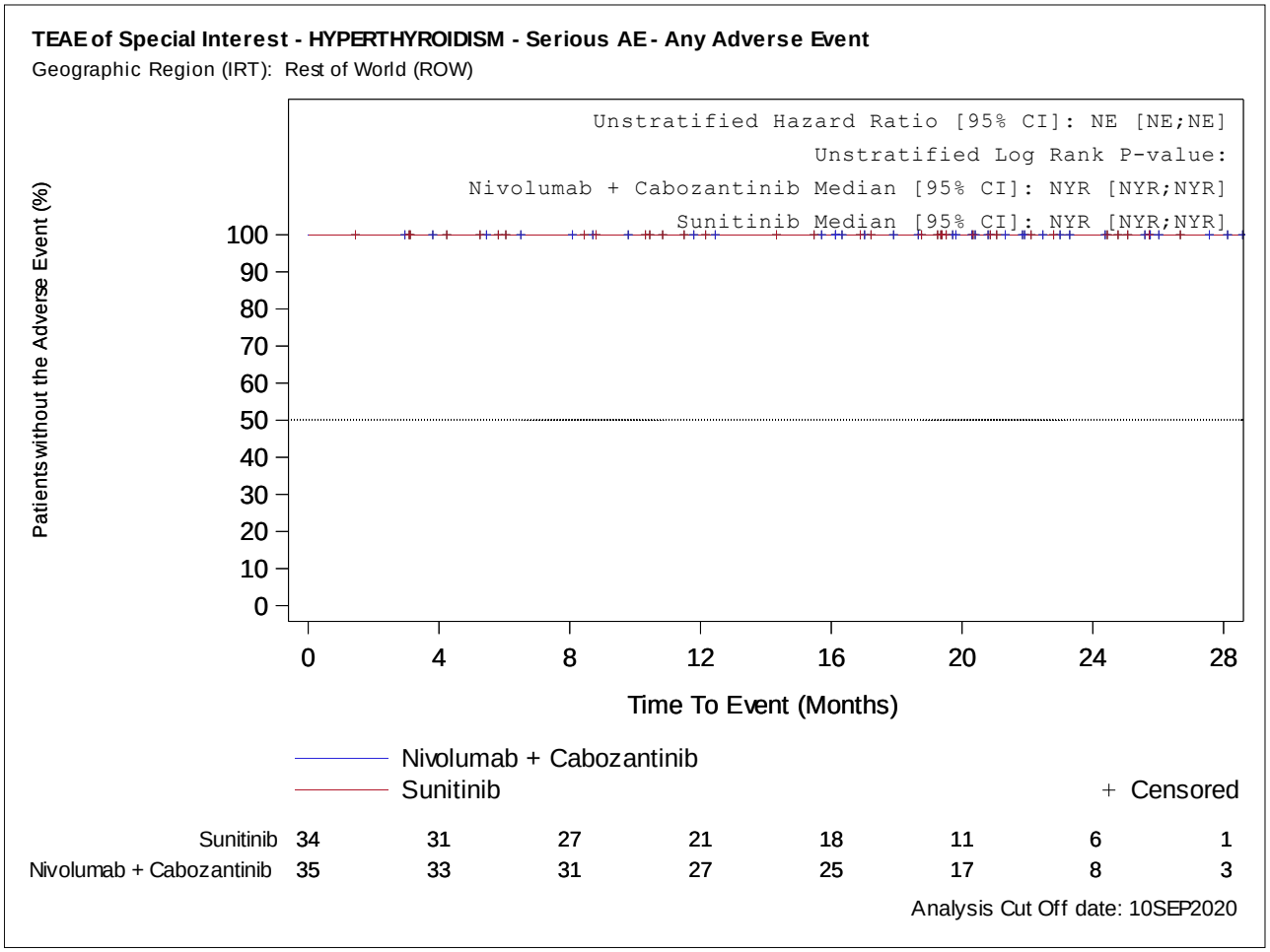

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:05

FIGURE 3.93.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



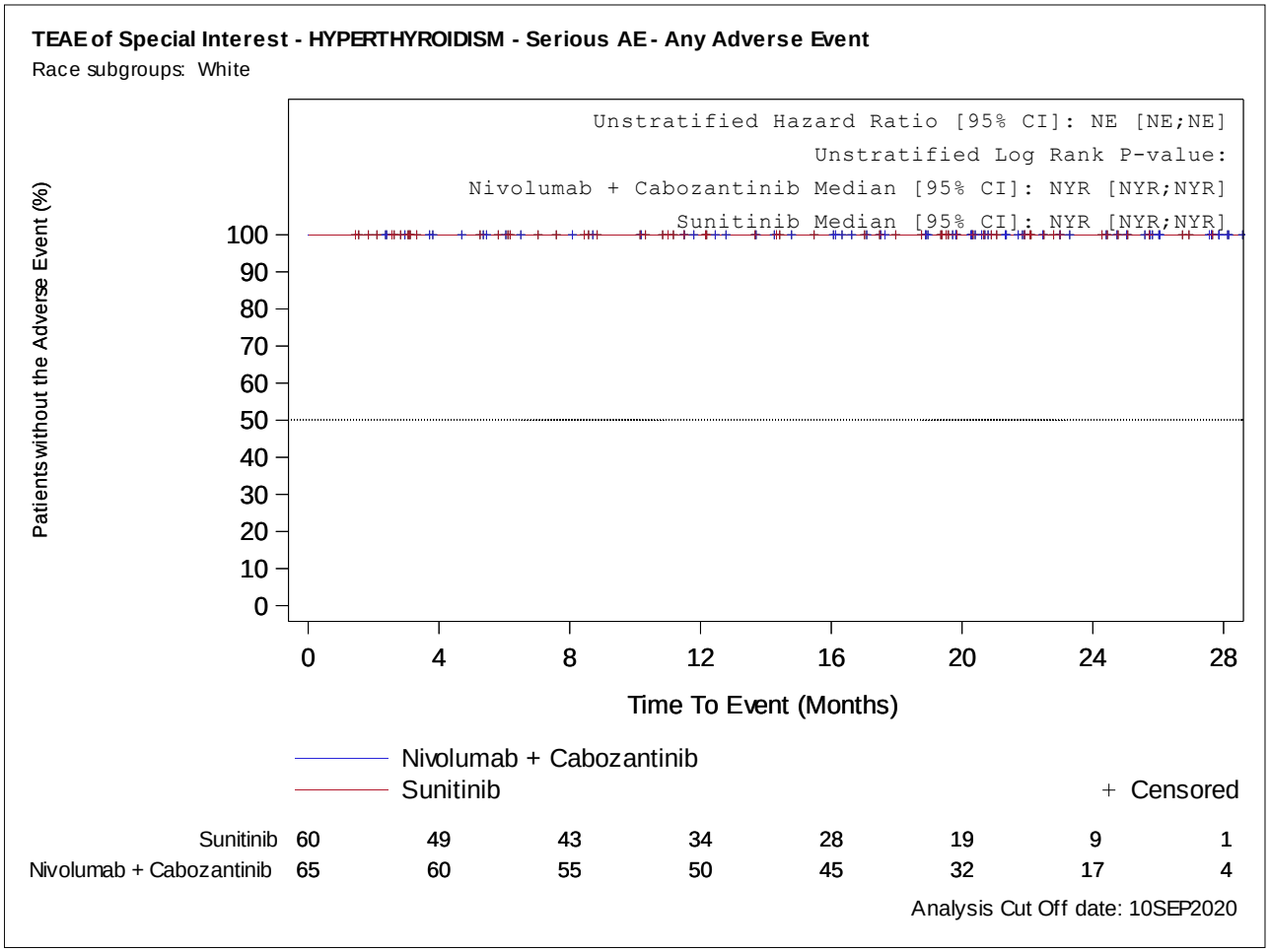

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:10

FIGURE 3.93.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



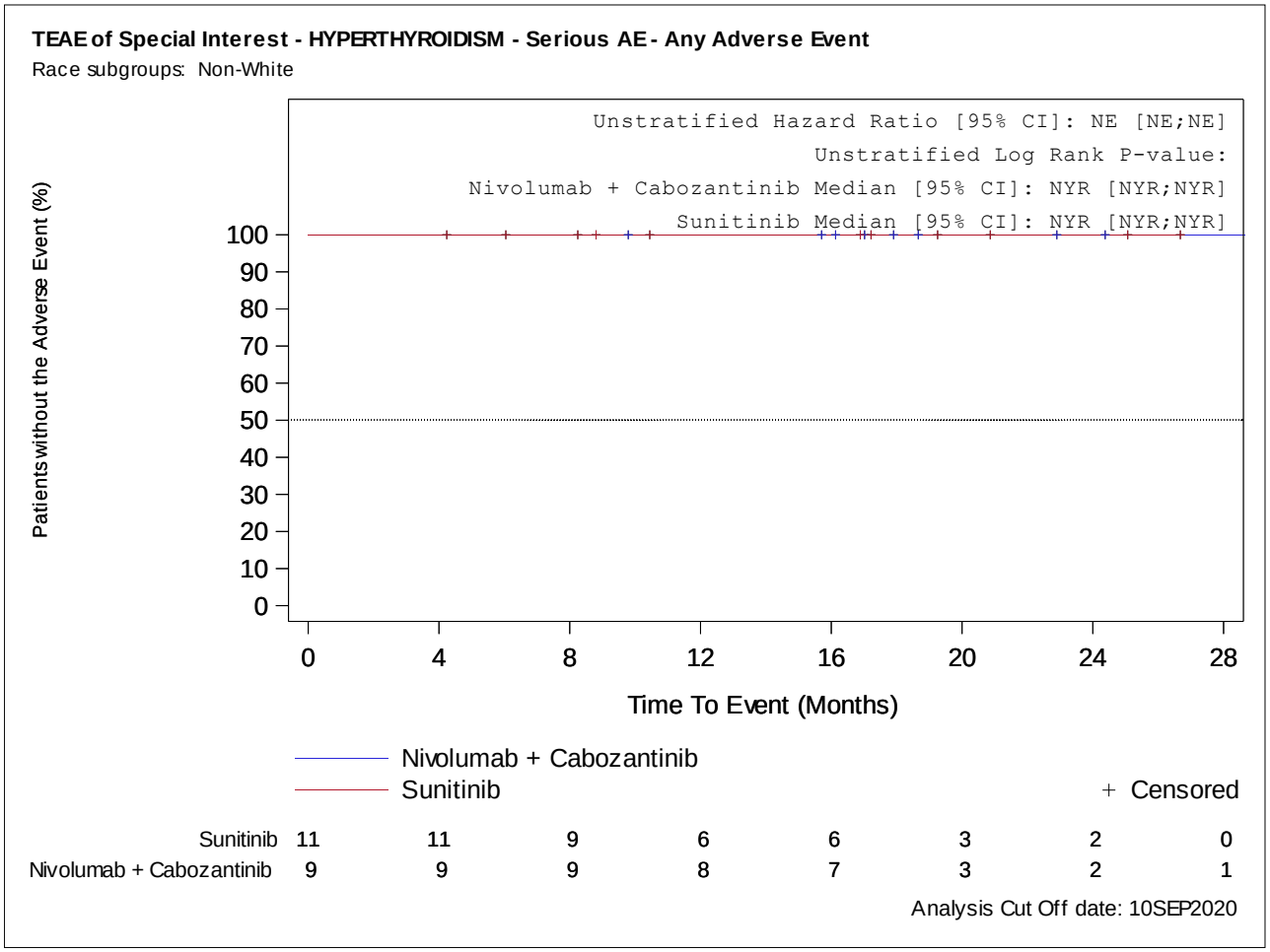

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:15

FIGURE 3.93.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



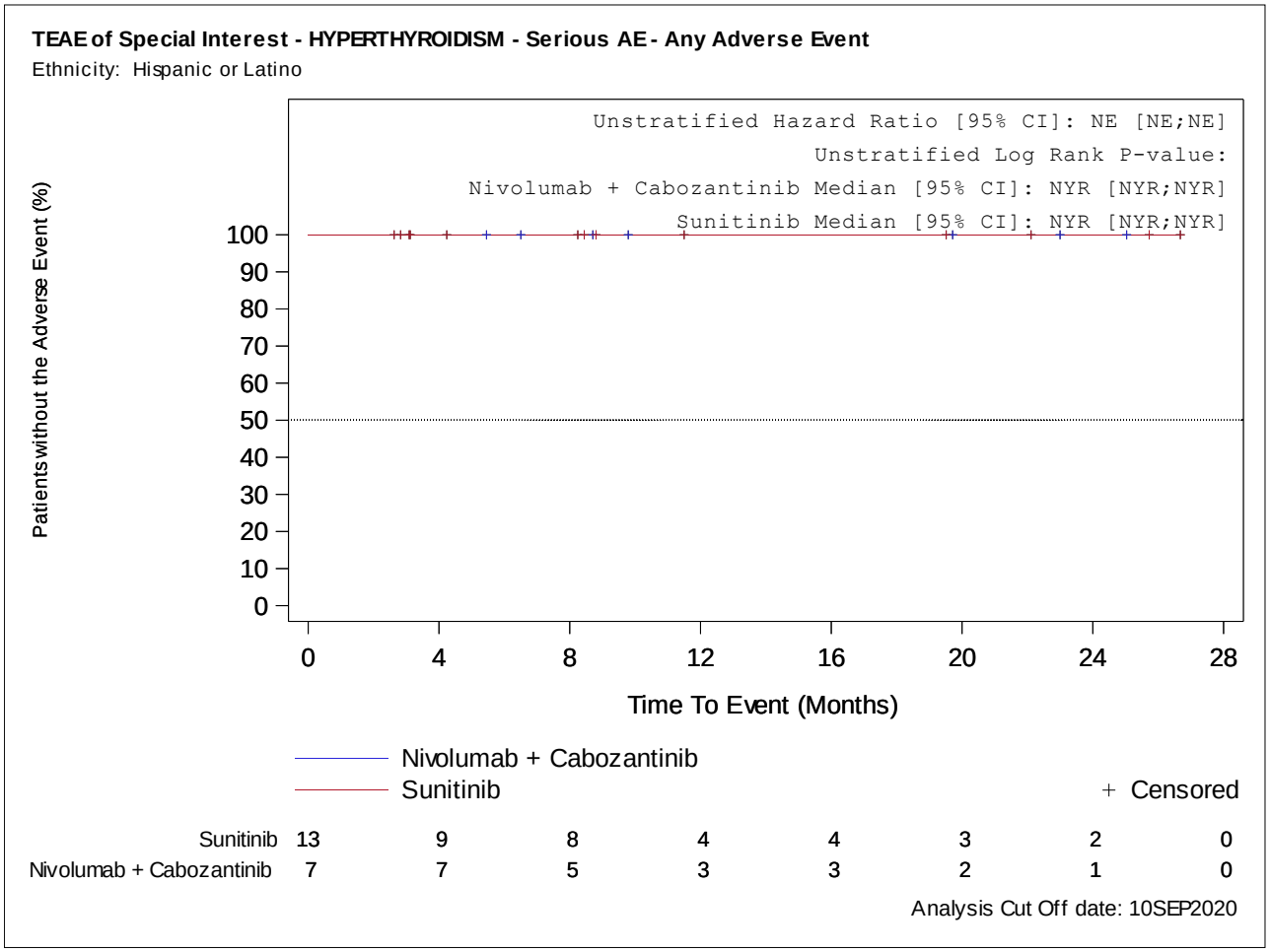

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:20

FIGURE 3.93.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



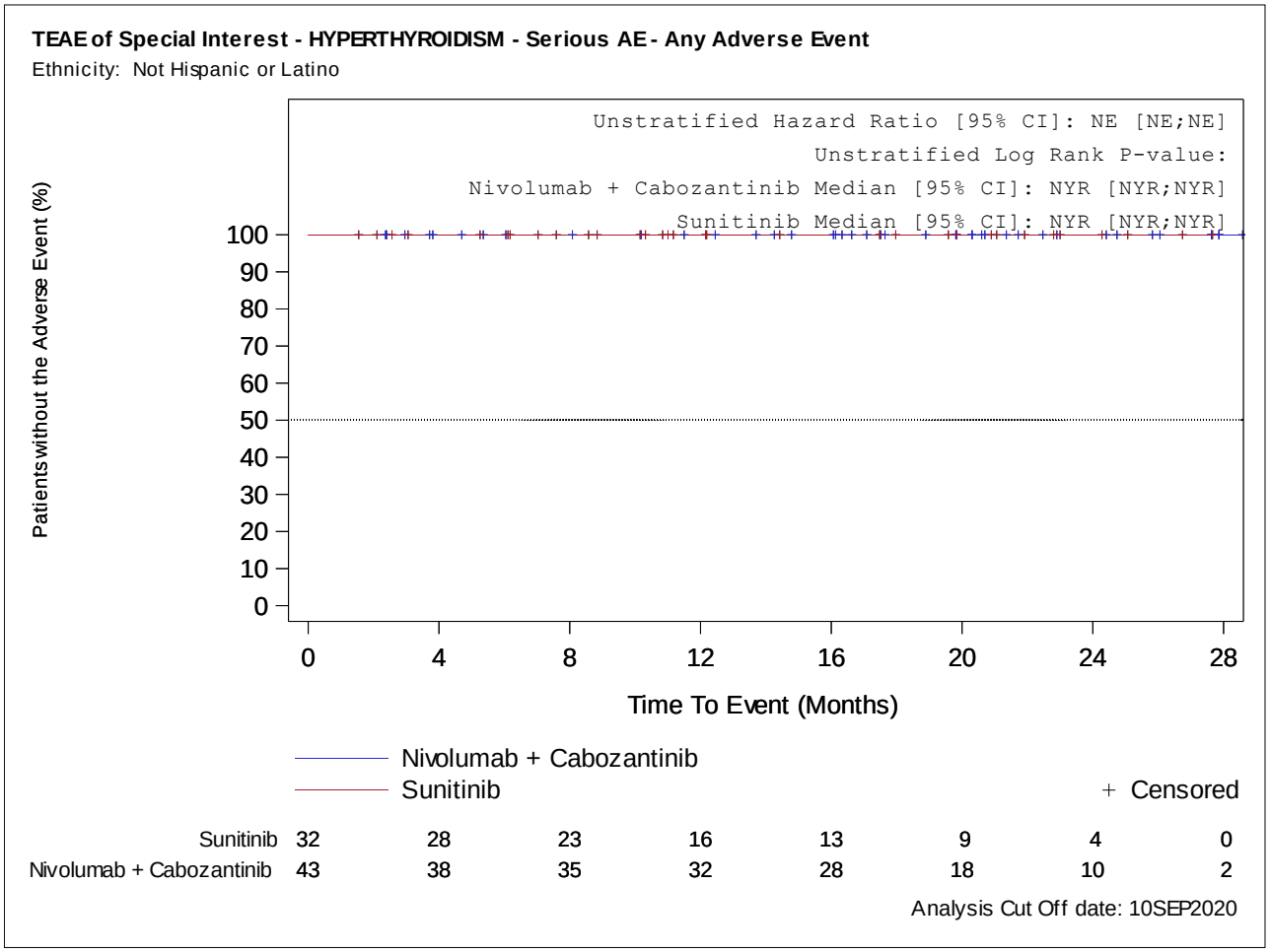

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:26

FIGURE 3.93.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



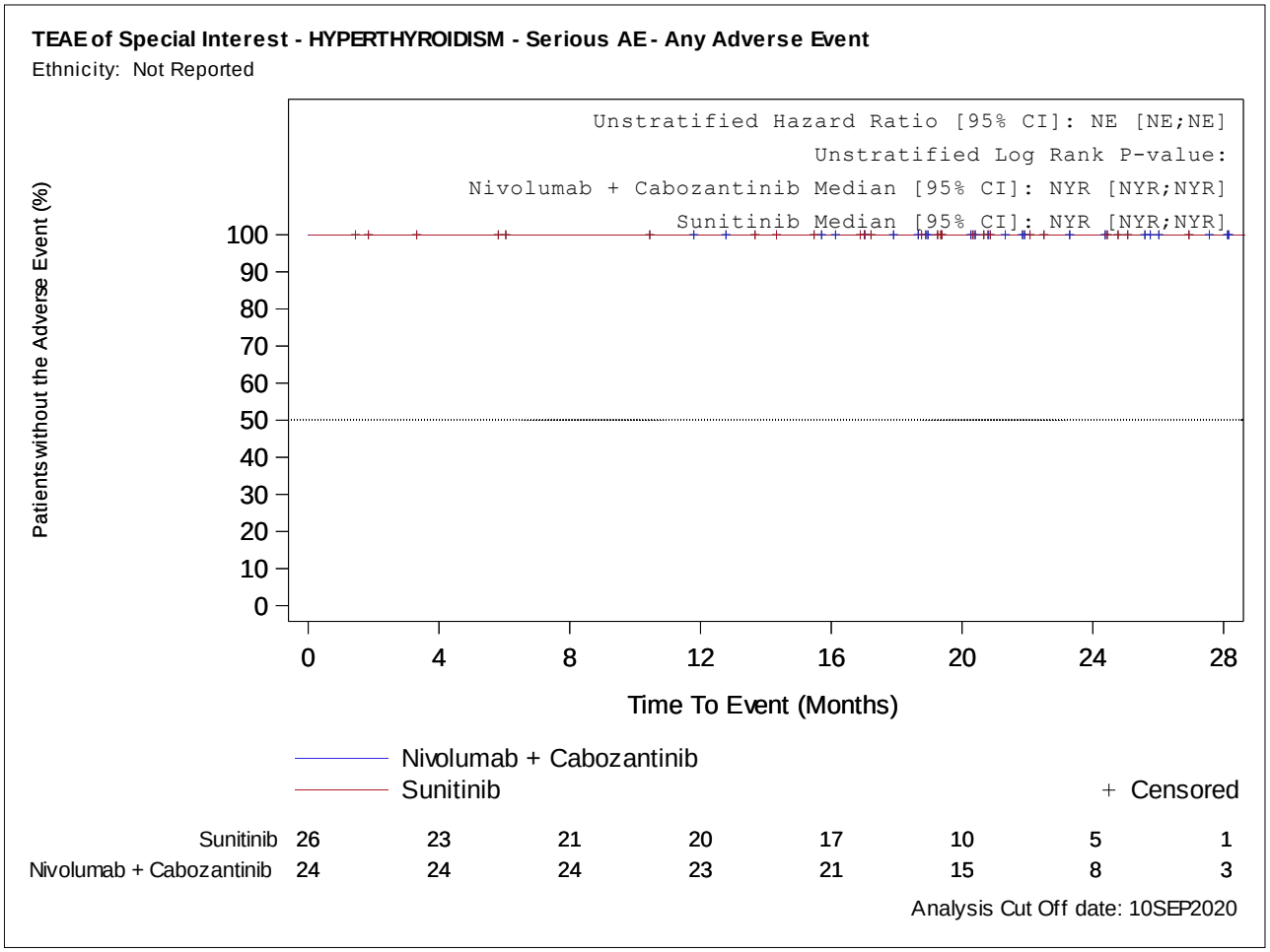

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:31

FIGURE 3.93.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



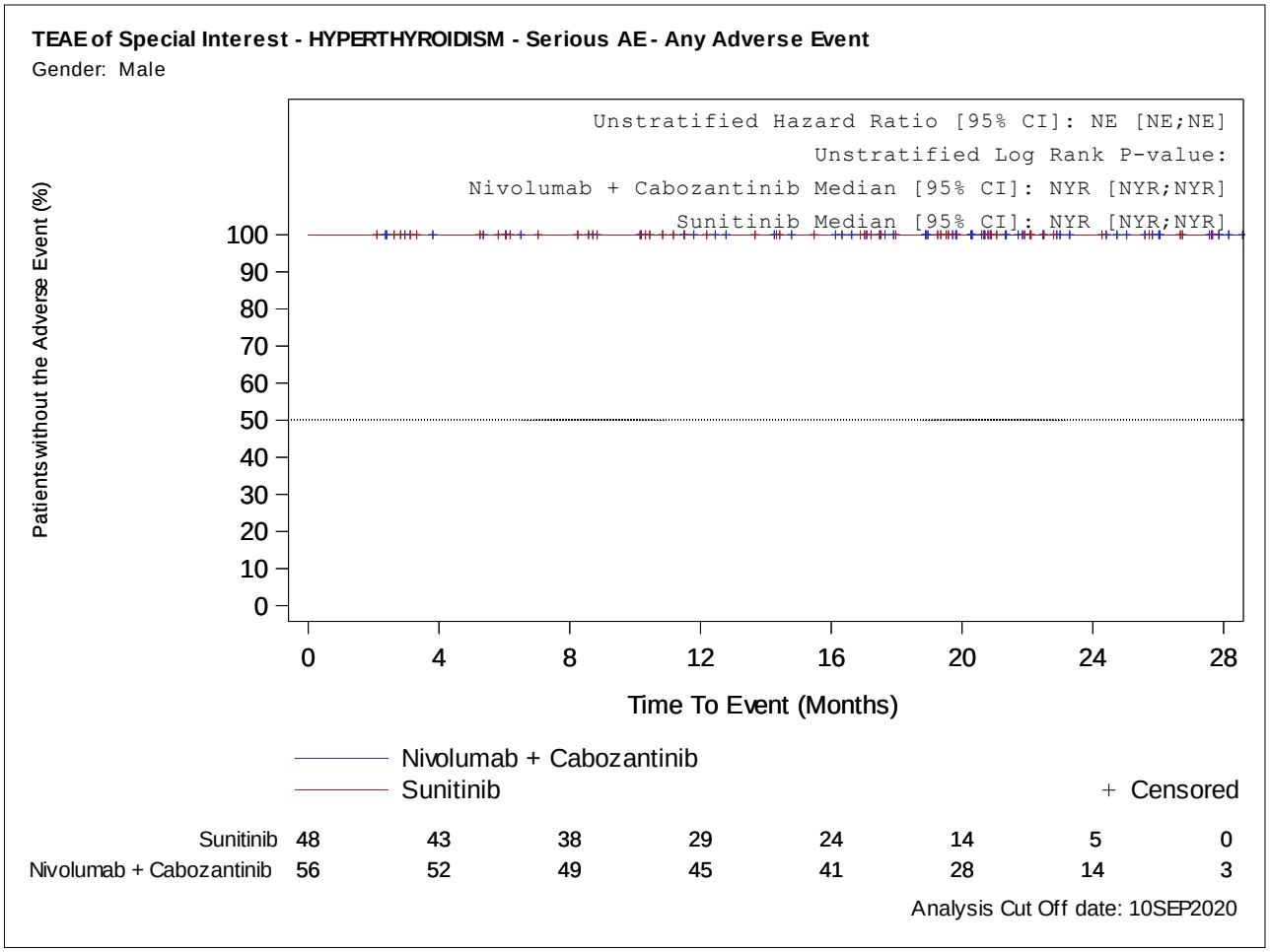

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:36

FIGURE 3.93.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:41

FIGURE 3.93.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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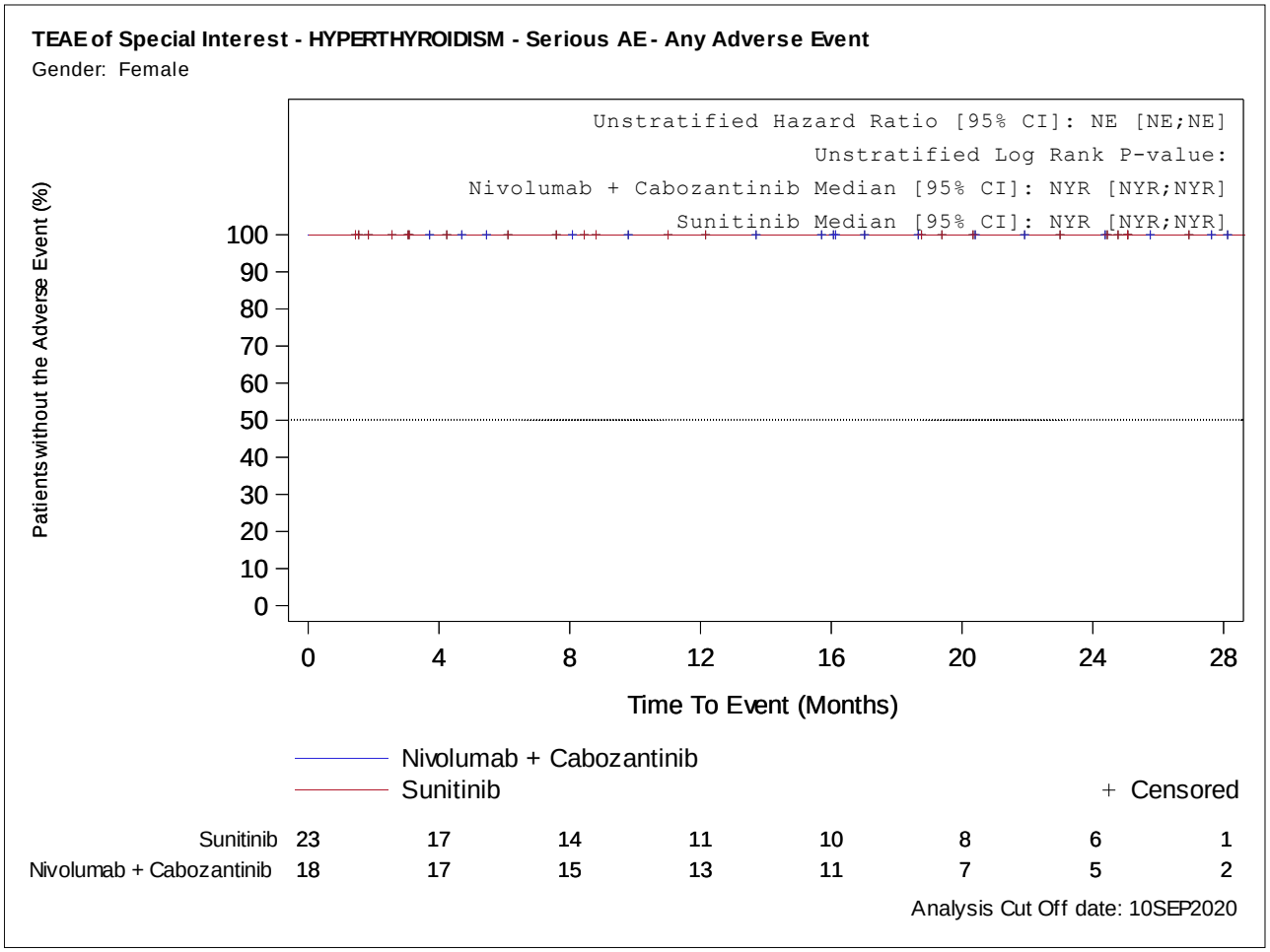
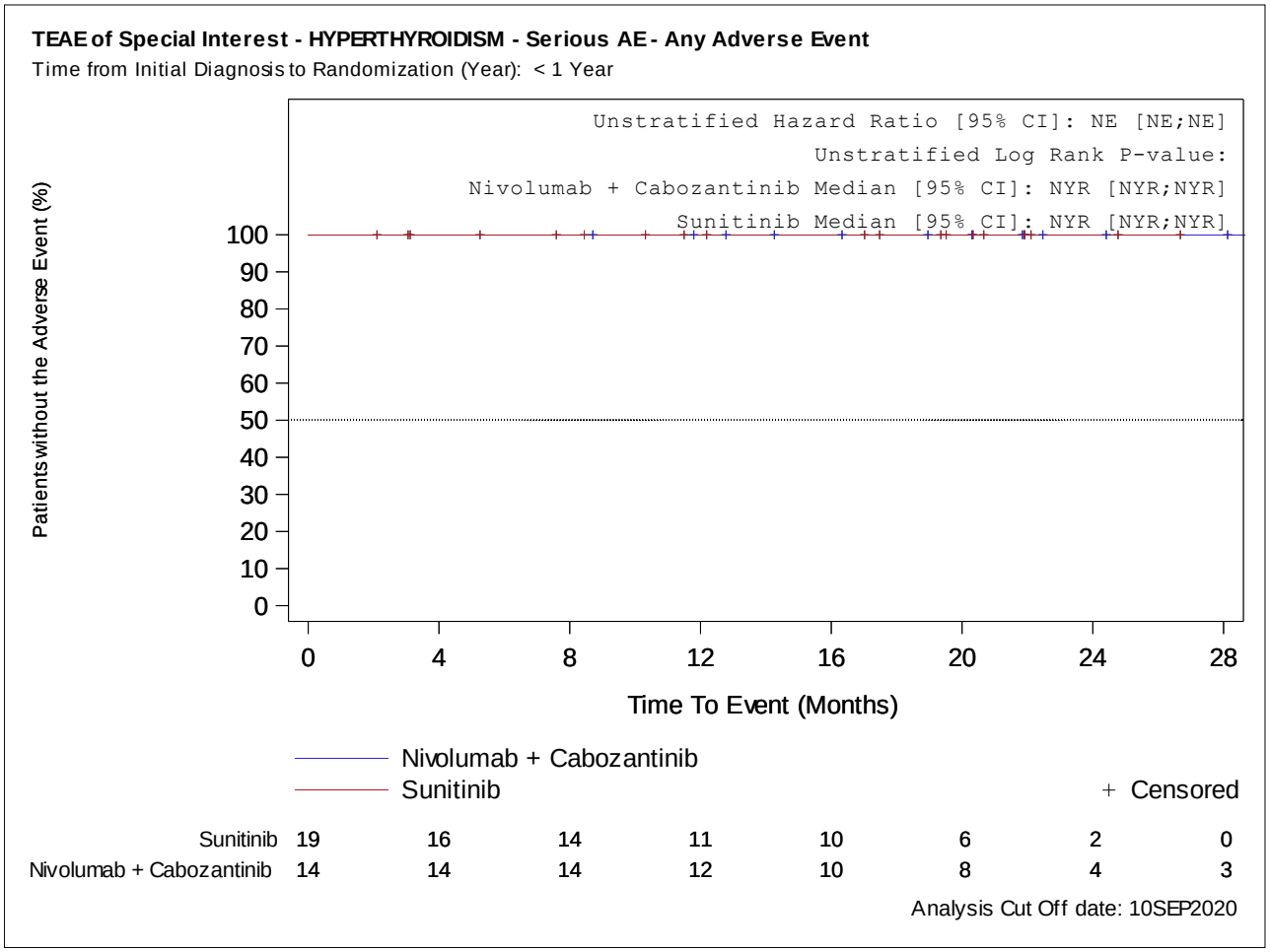
FIGURE 3.93.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



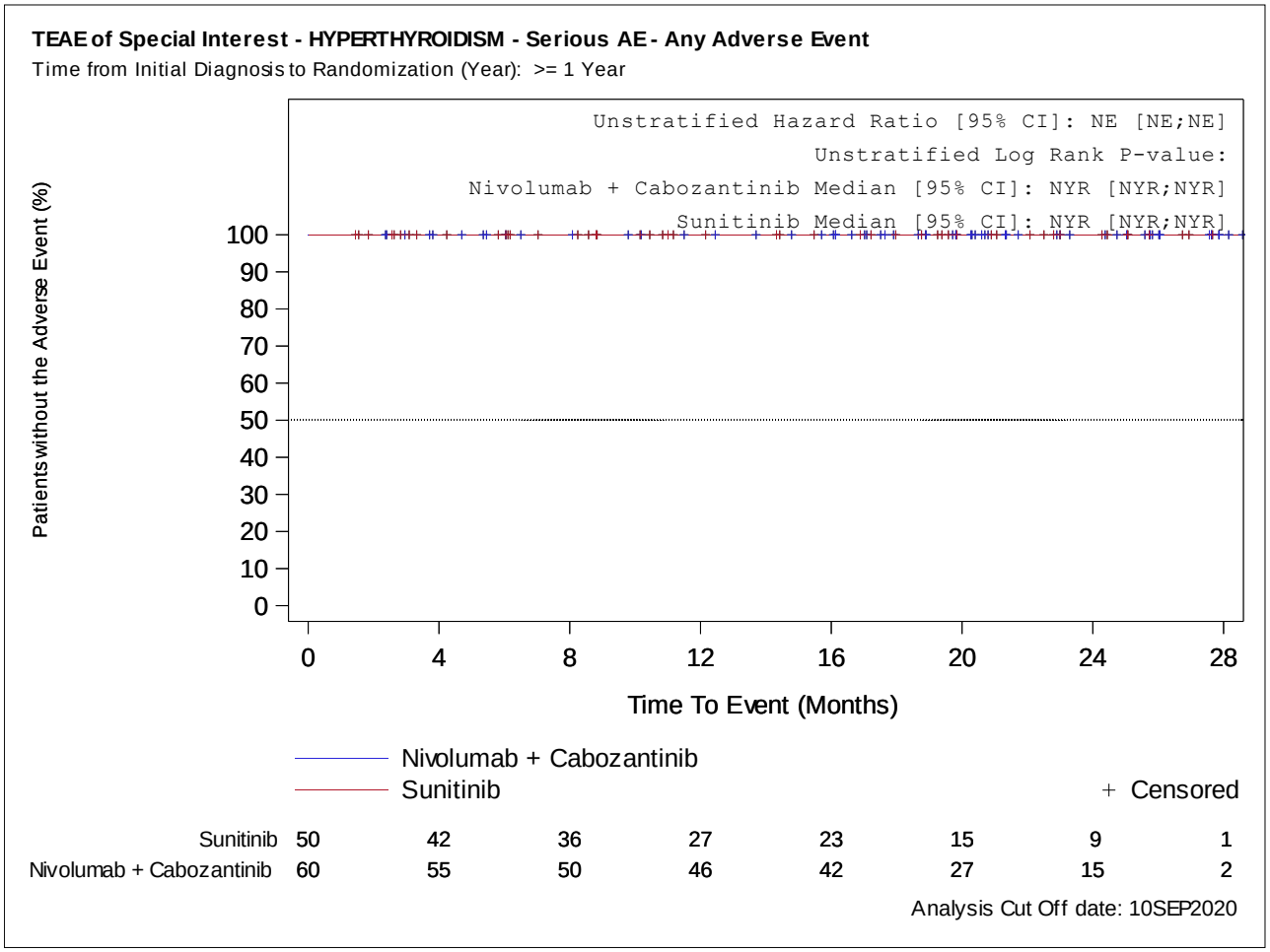

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:45:52

FIGURE 3.93.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



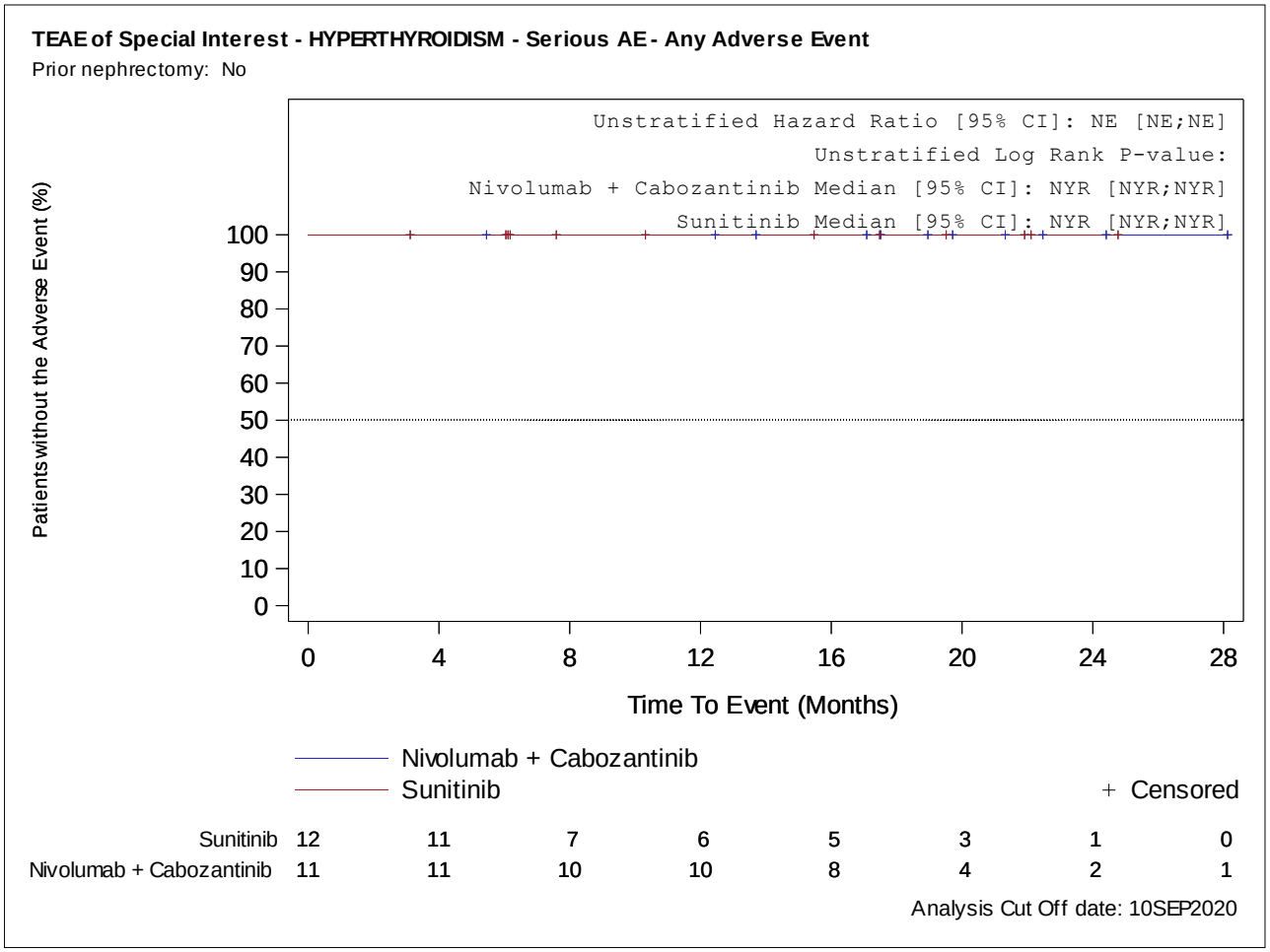

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:46:07

FIGURE 3.93.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



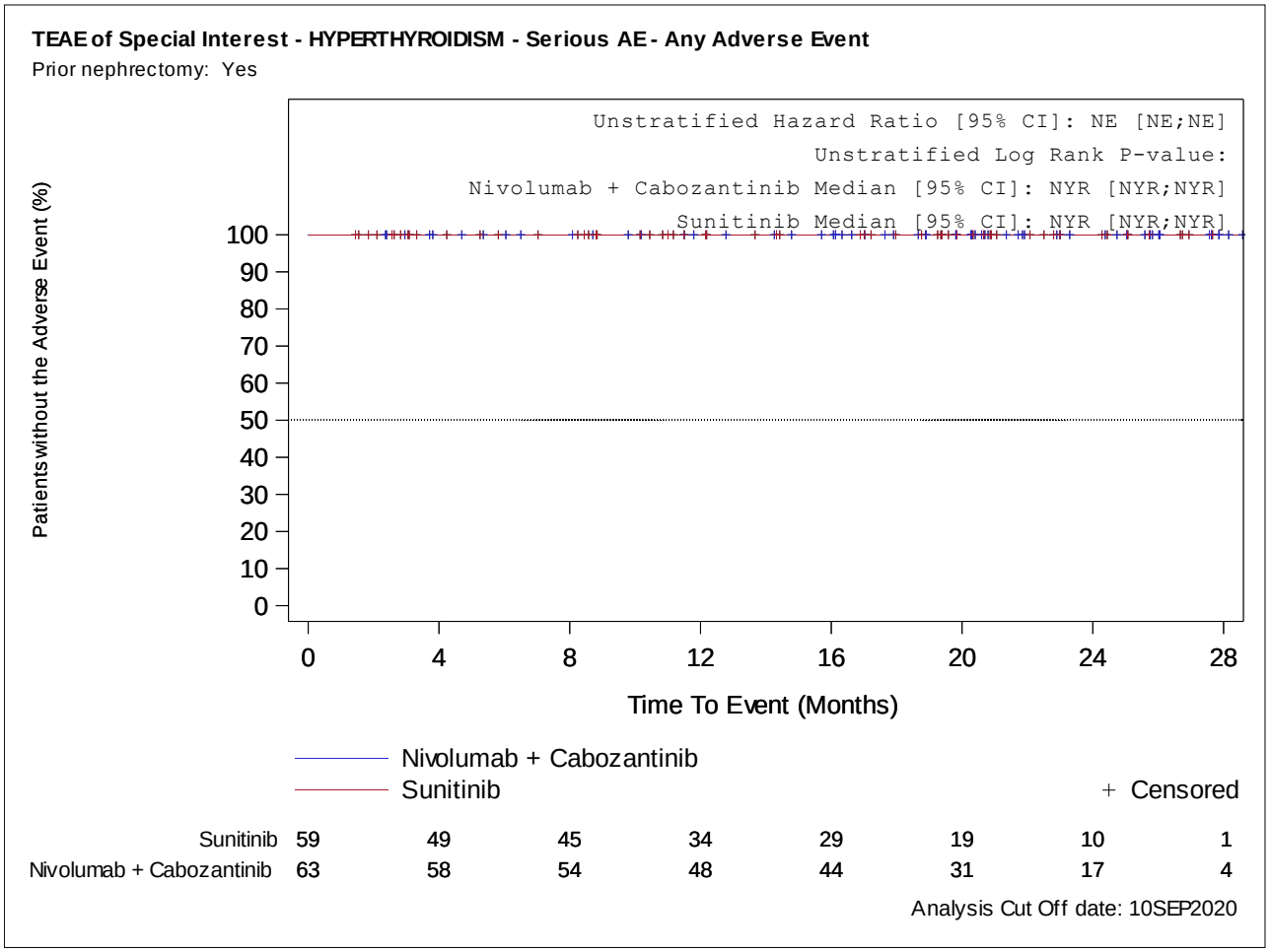

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:46:13

FIGURE 3.93.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



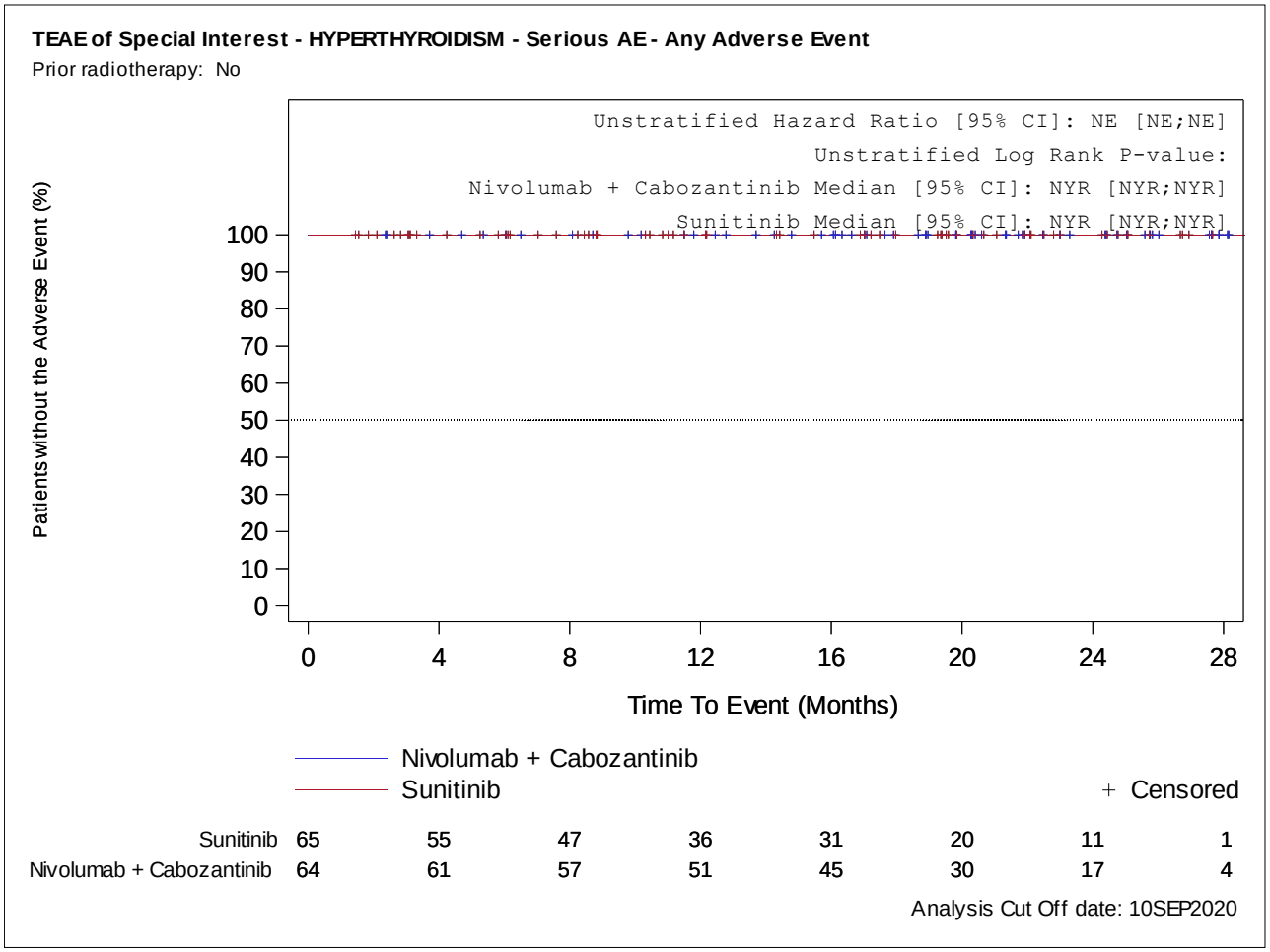

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:47:01

FIGURE 3.93.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



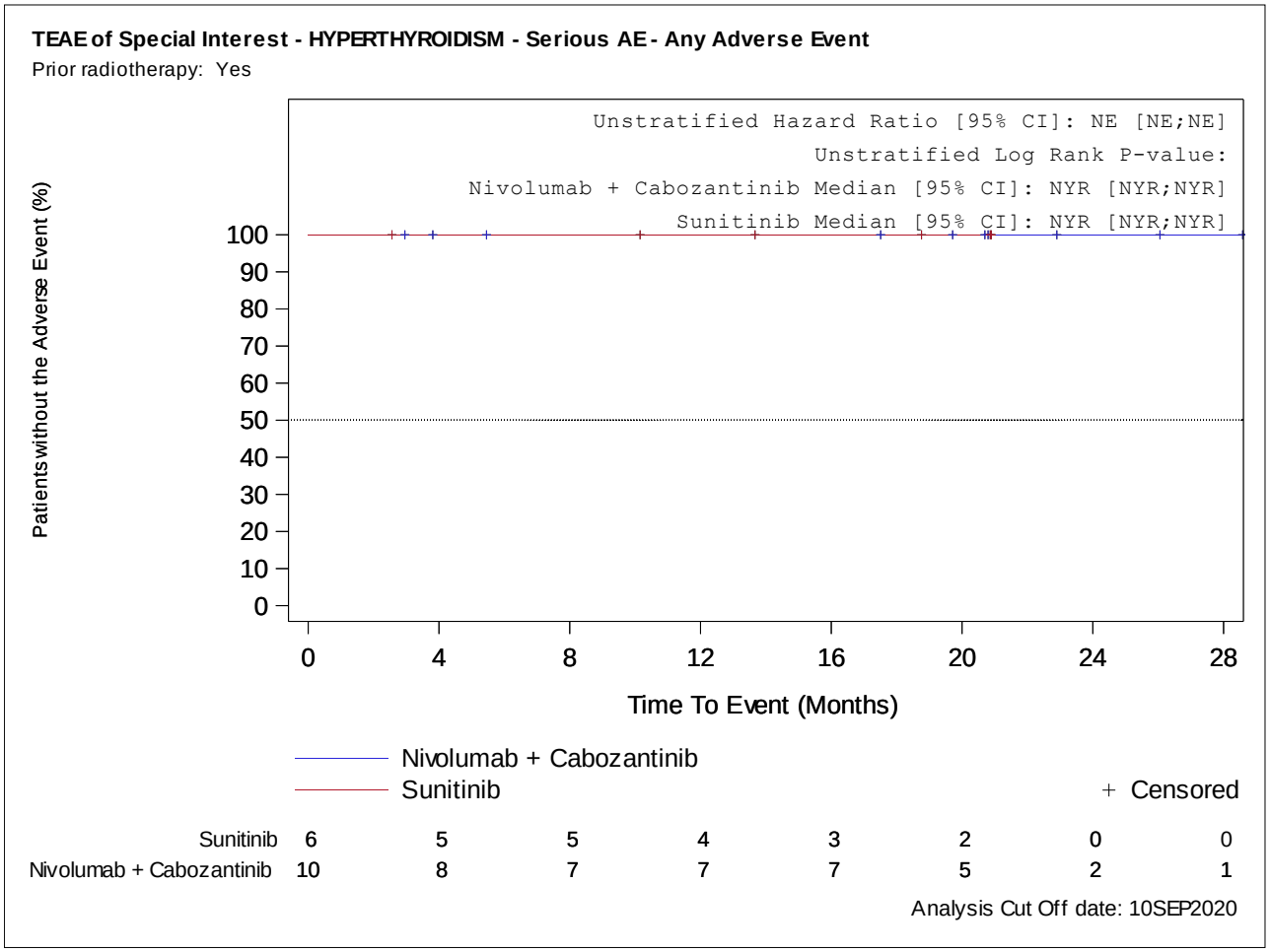

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:47:06

FIGURE 3.93.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



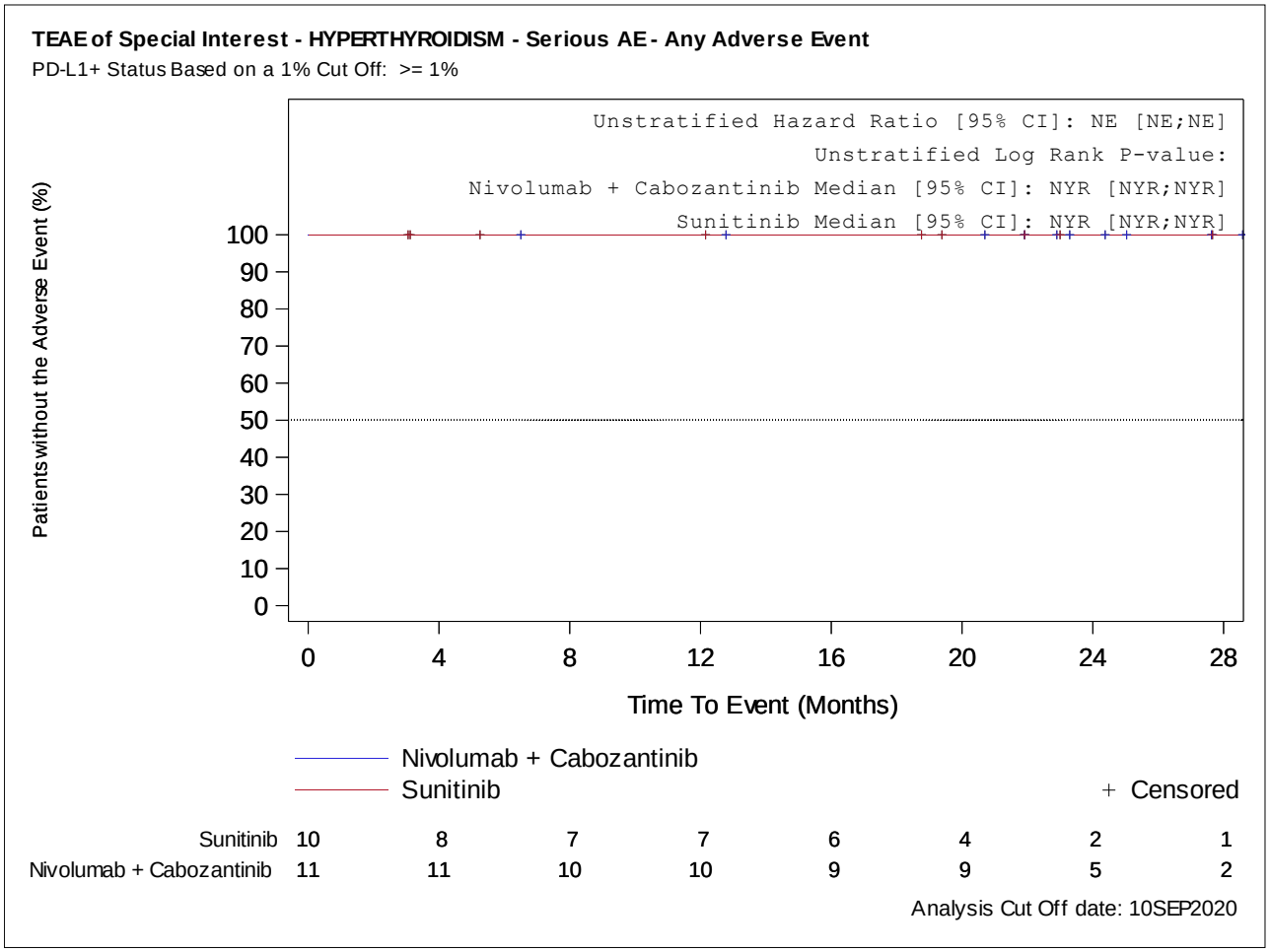

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:47:11

FIGURE 3.93.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:47:17

FIGURE 3.93.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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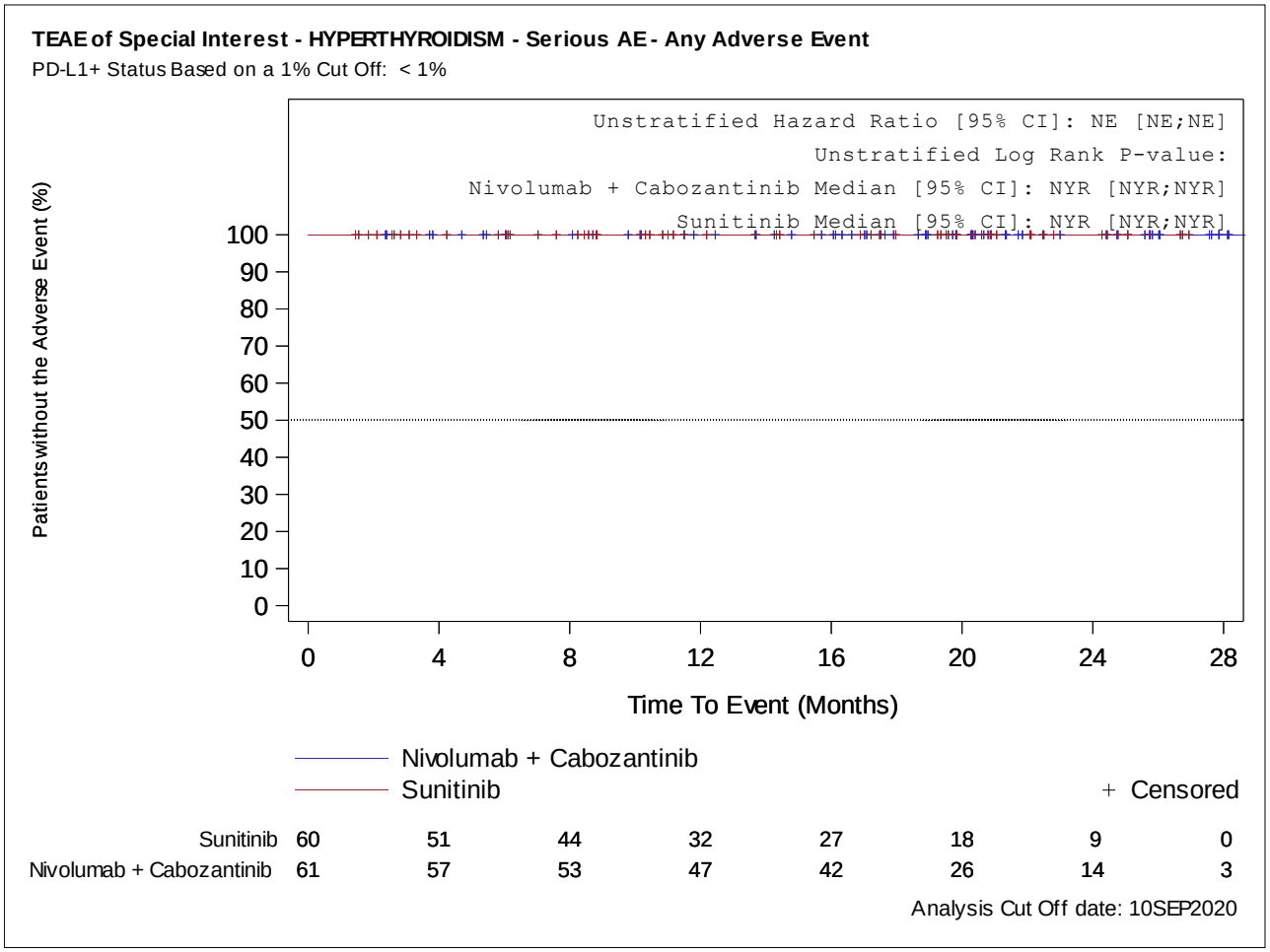
FIGURE 3.93.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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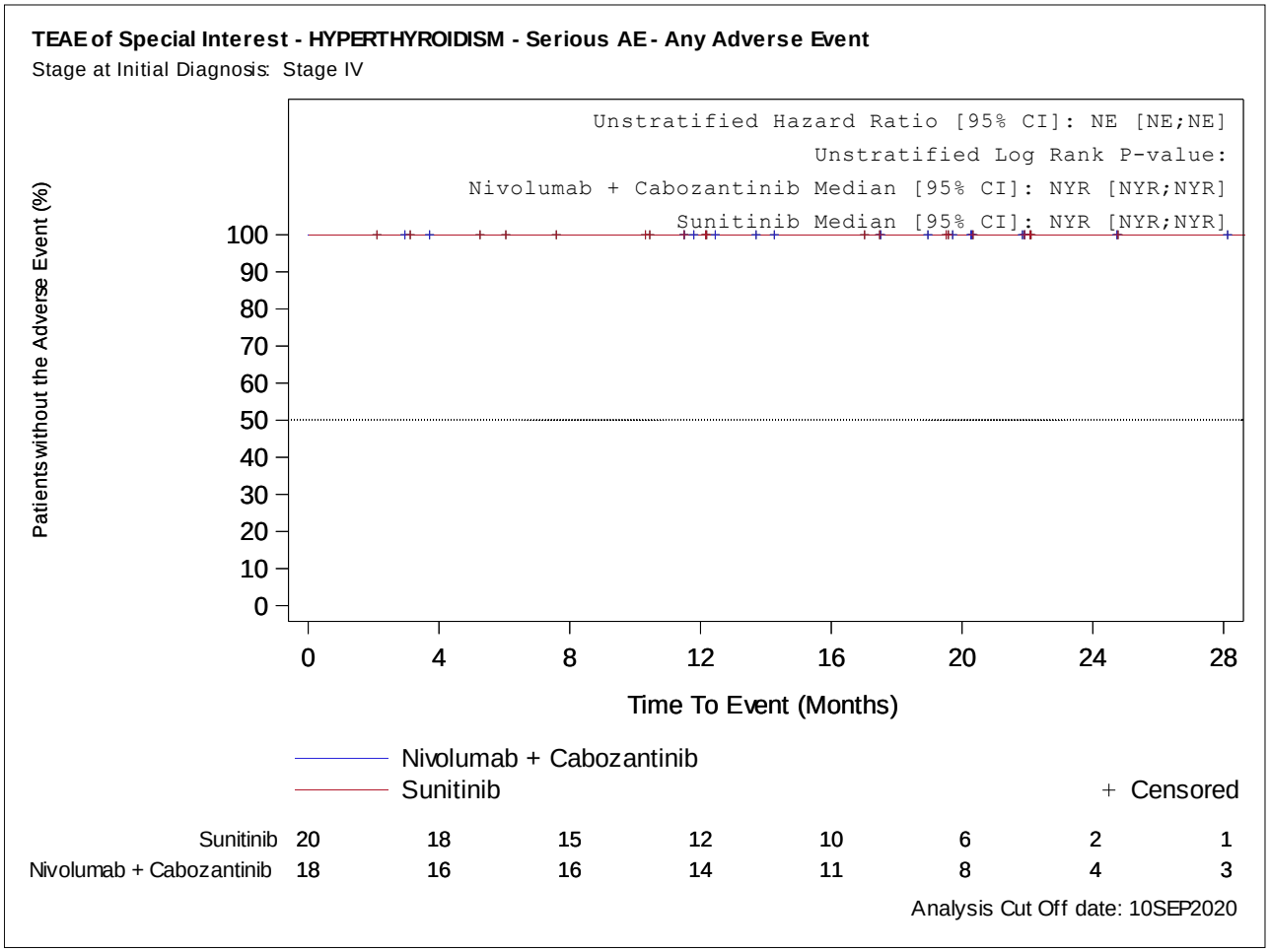
FIGURE 3.93.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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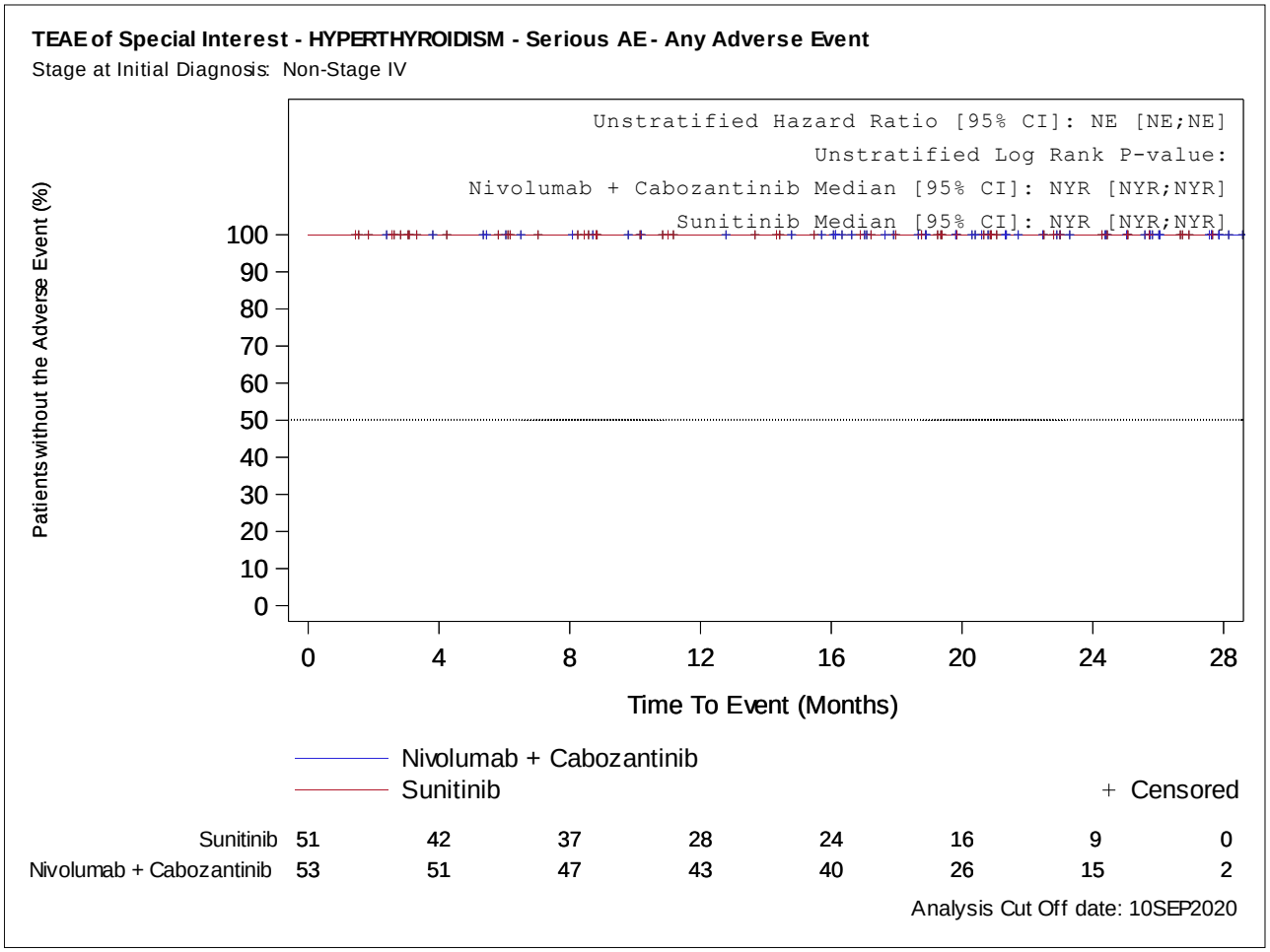
FIGURE 3.93.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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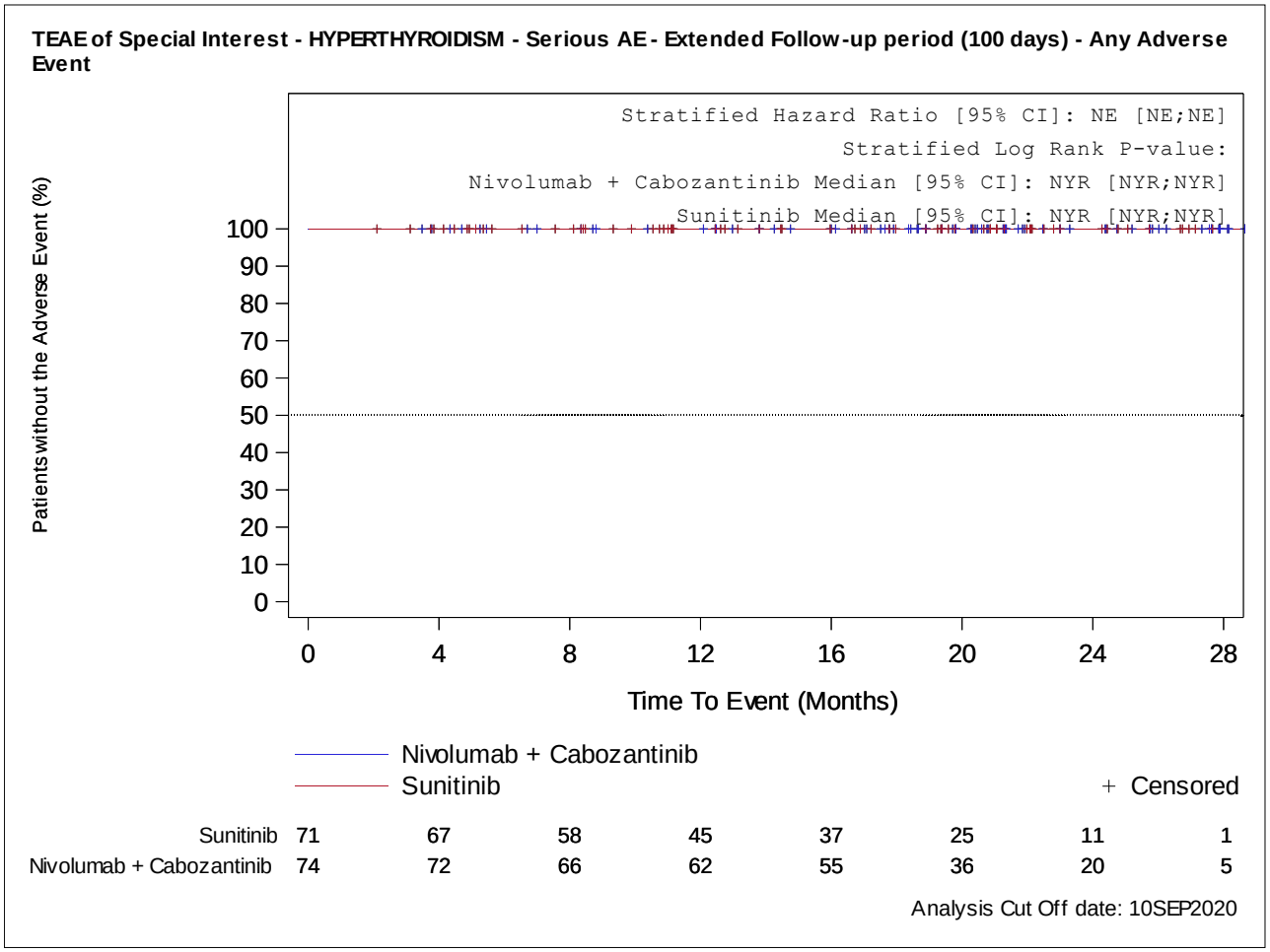
FIGURE 3.94.1: TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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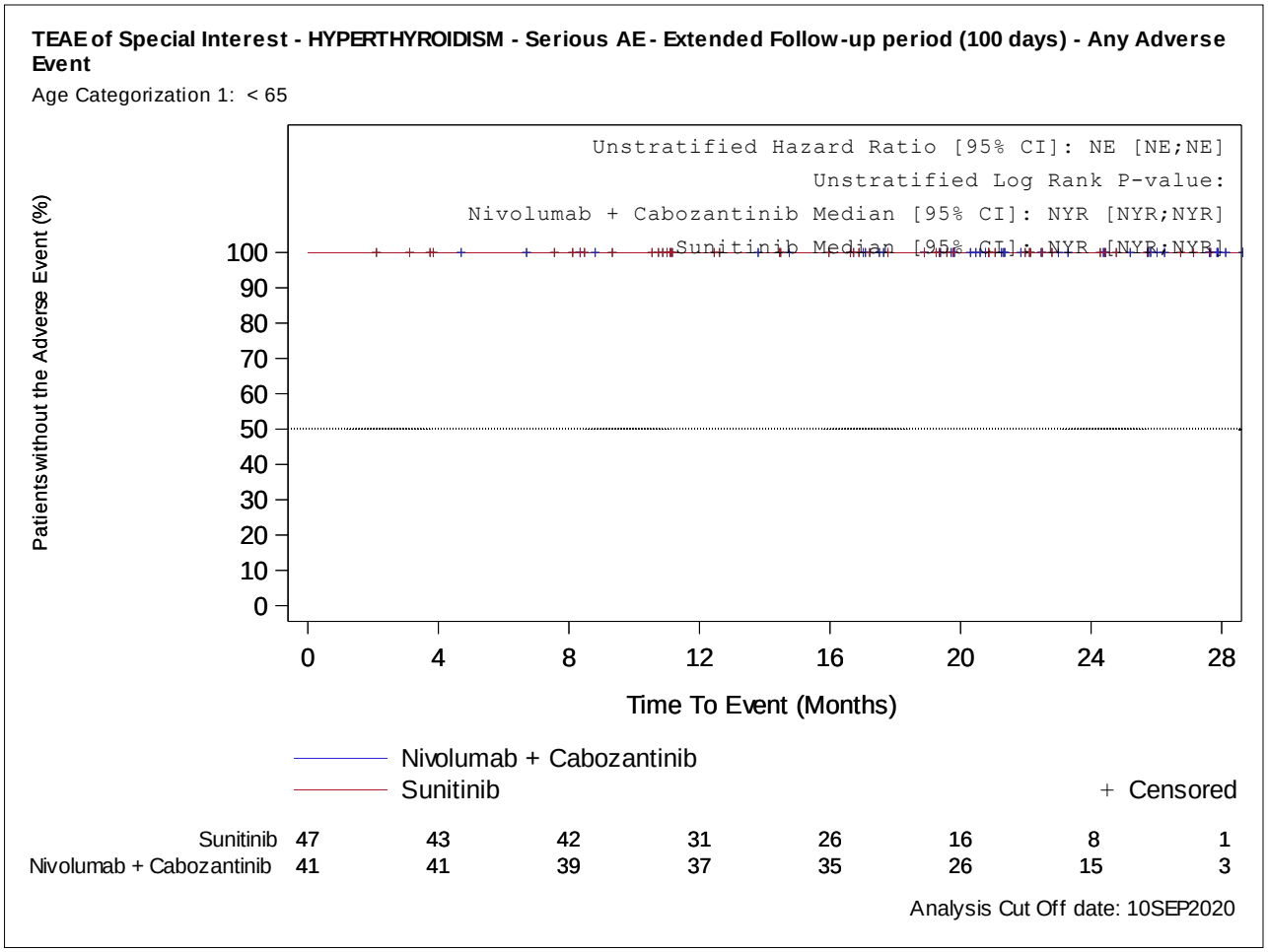
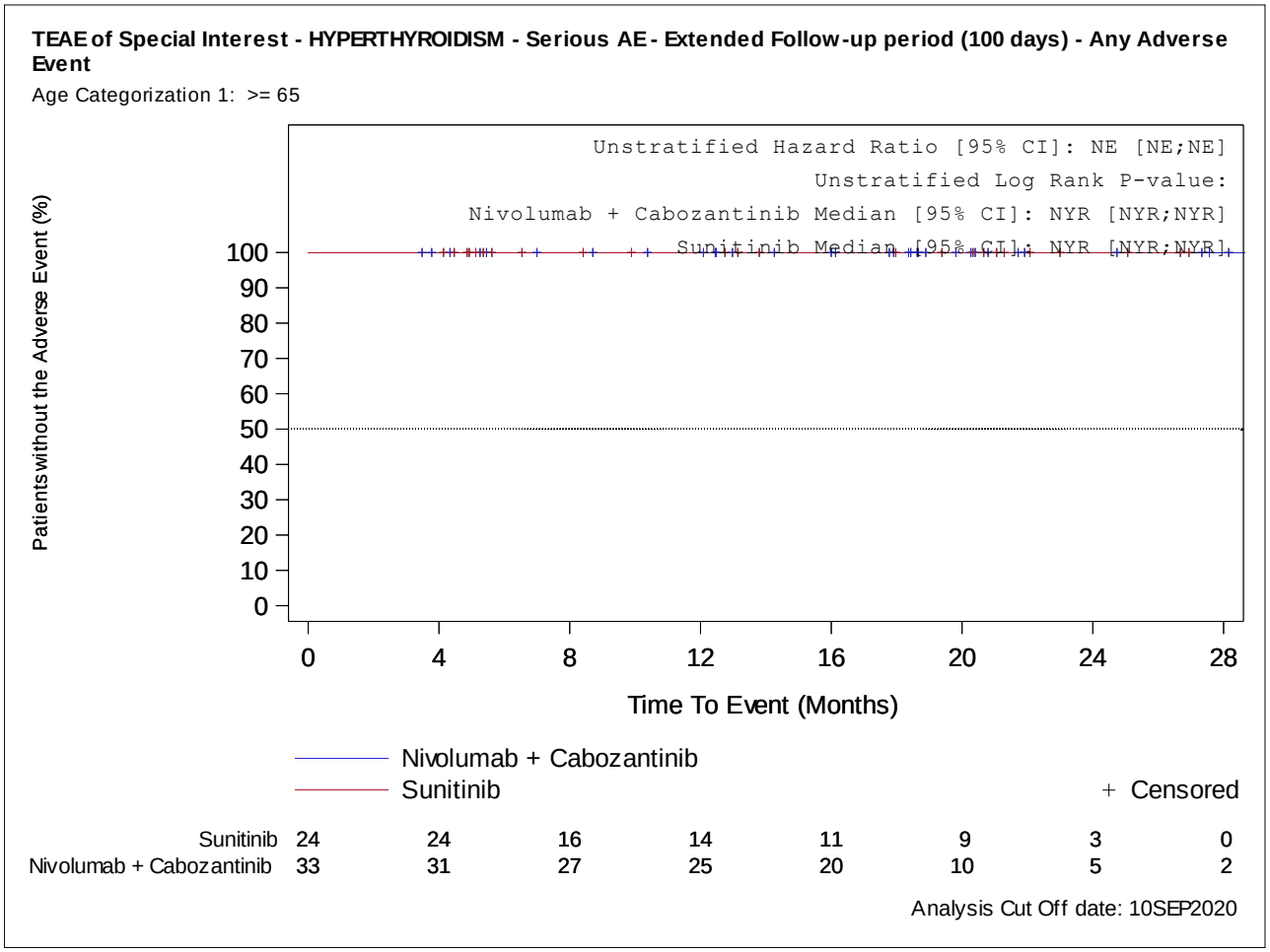
FIGURE 3.94.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



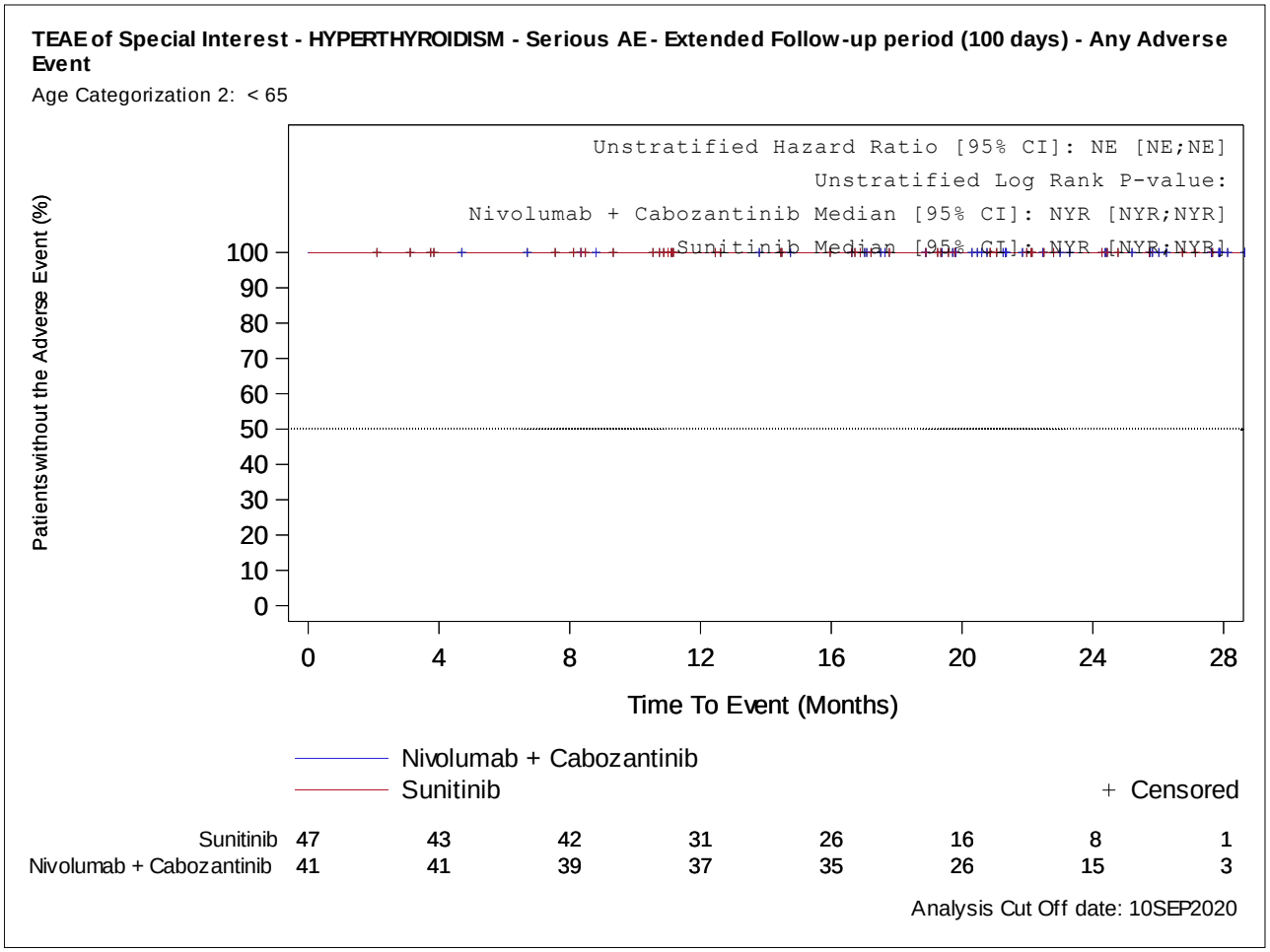

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:51:00

FIGURE 3.94.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



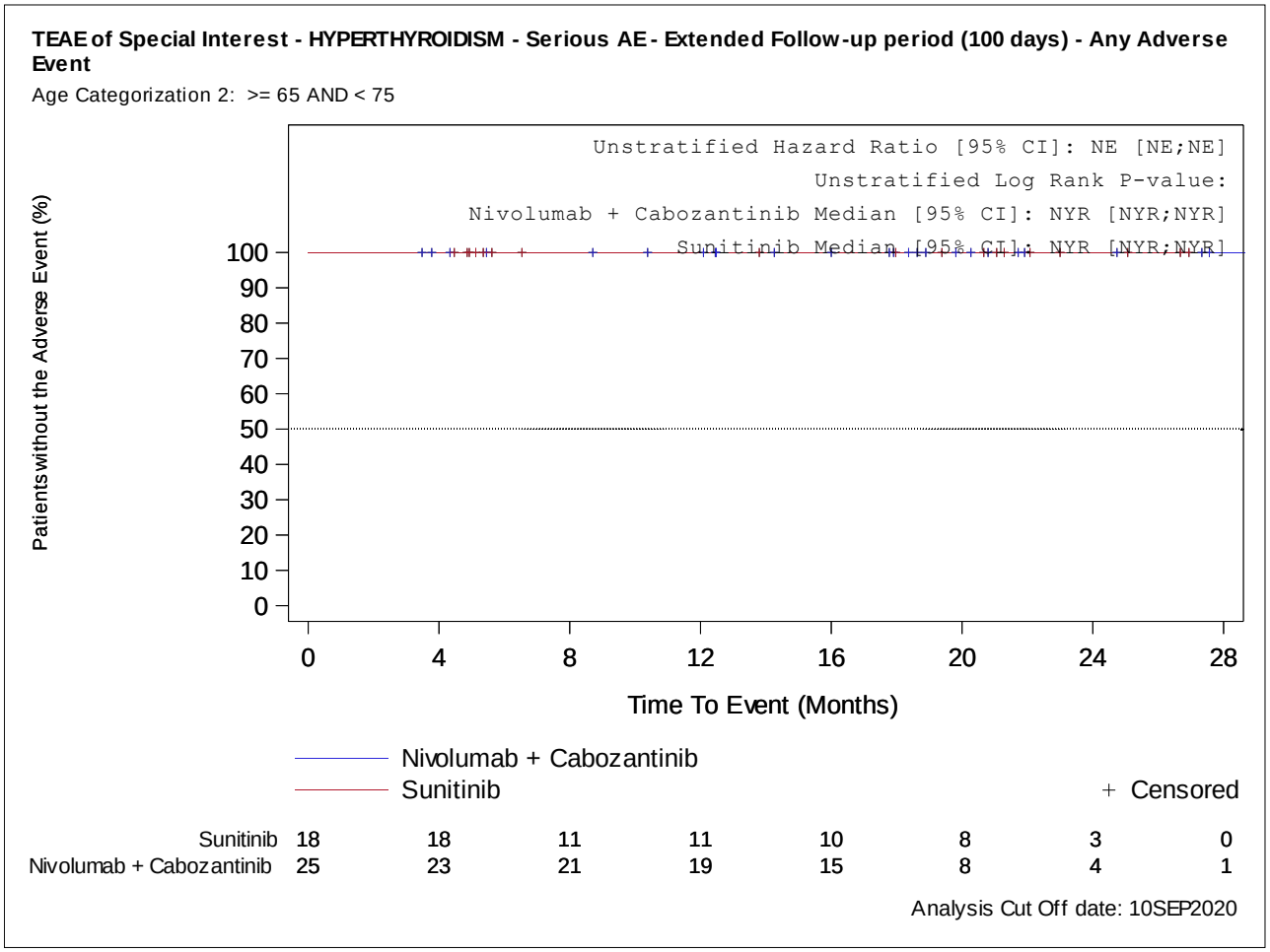

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:51:05

FIGURE 3.94.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



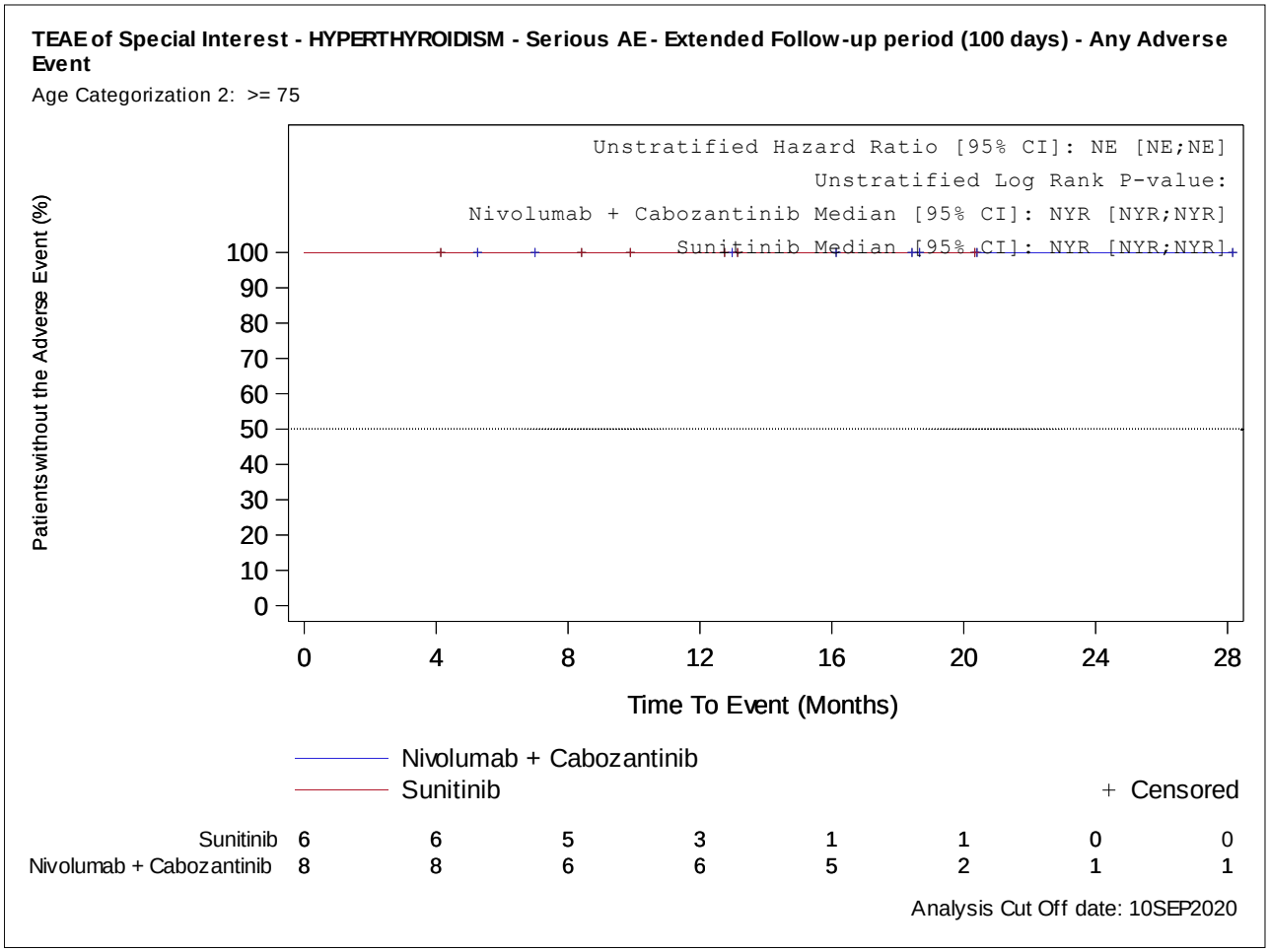

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:51:11

FIGURE 3.94.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:51:16

FIGURE 3.94.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75




Analysis Cut Off date: 10SEP2020
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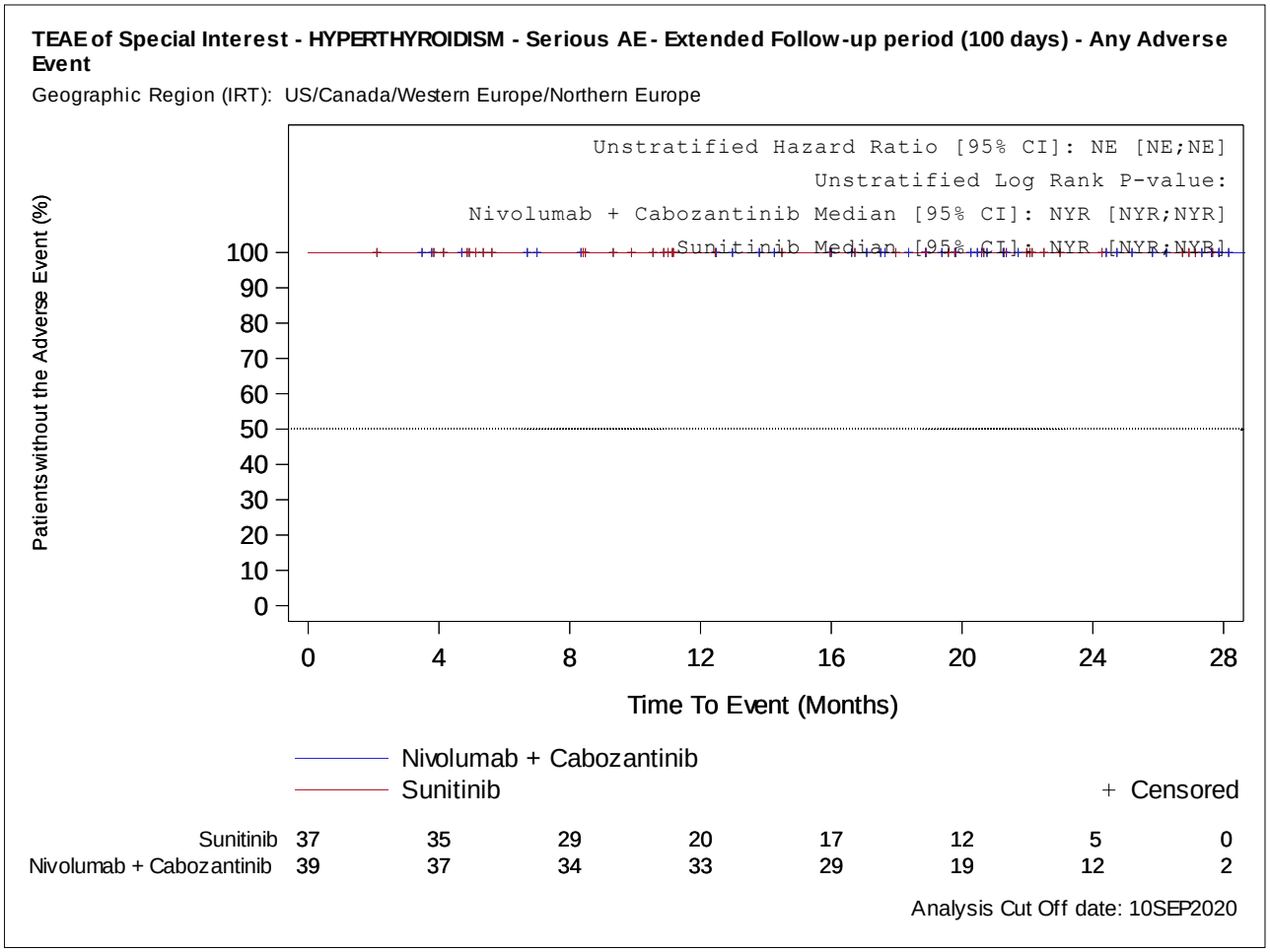
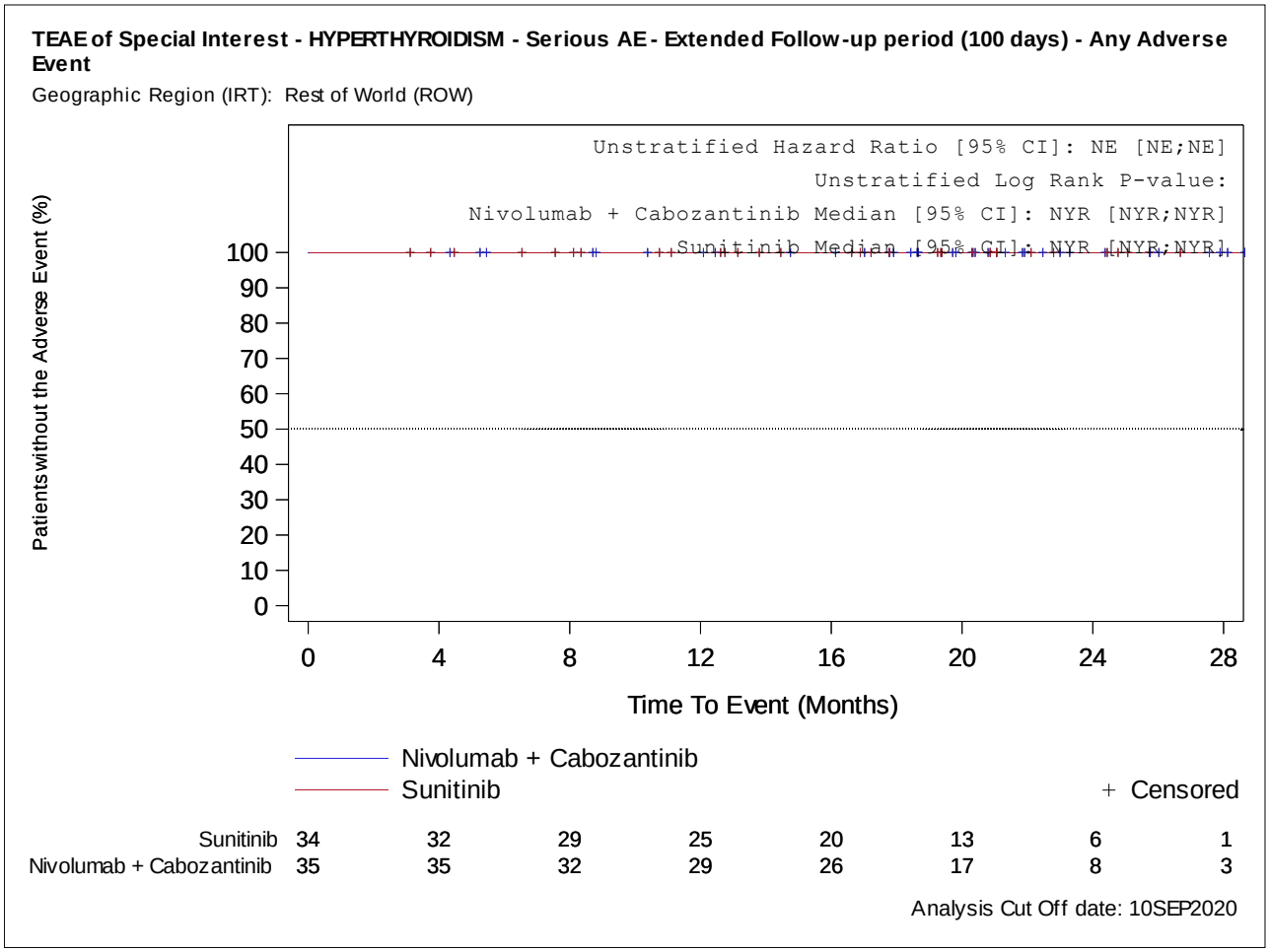
FIGURE 3.94.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



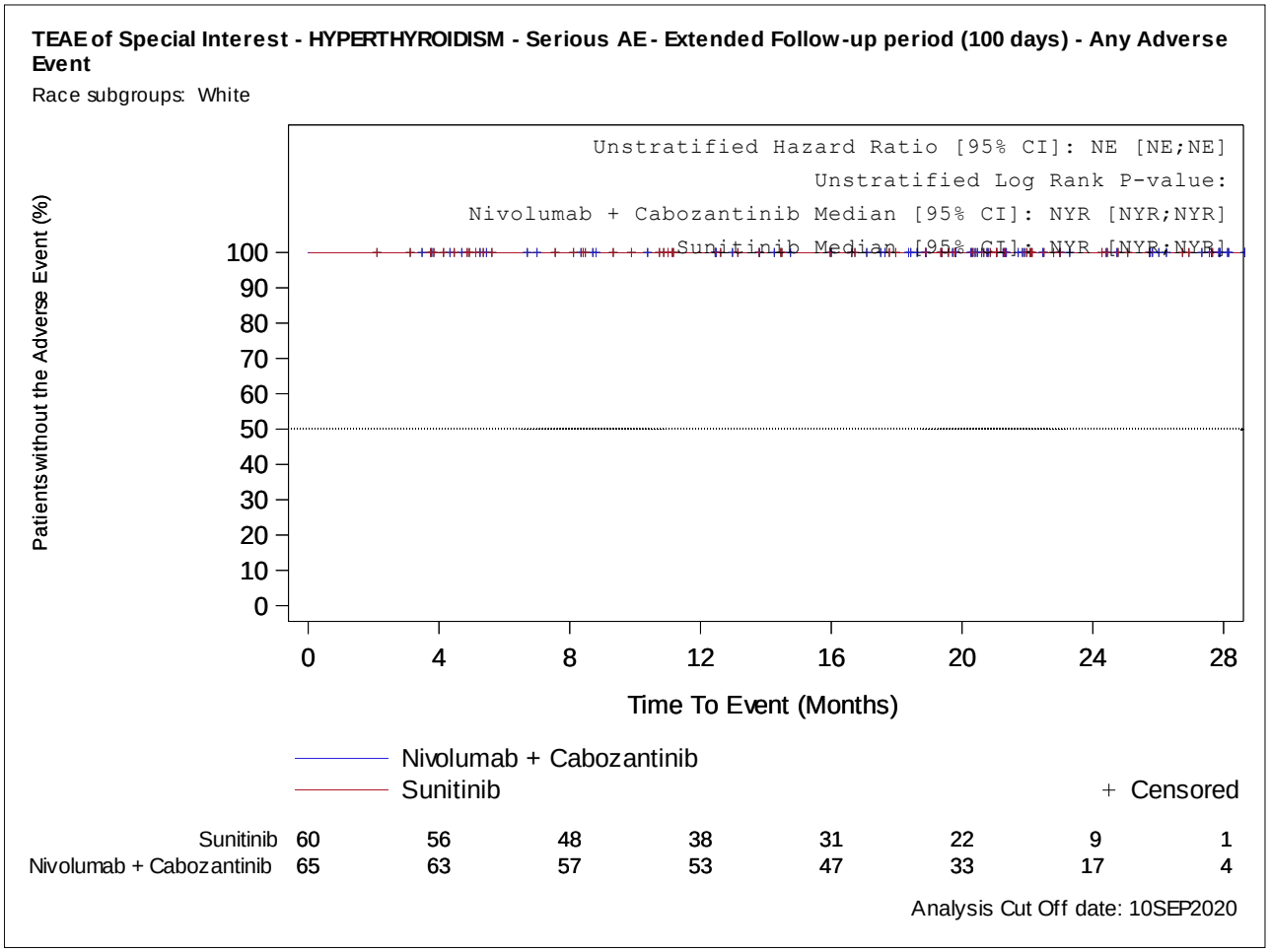

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:51:26

FIGURE 3.94.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



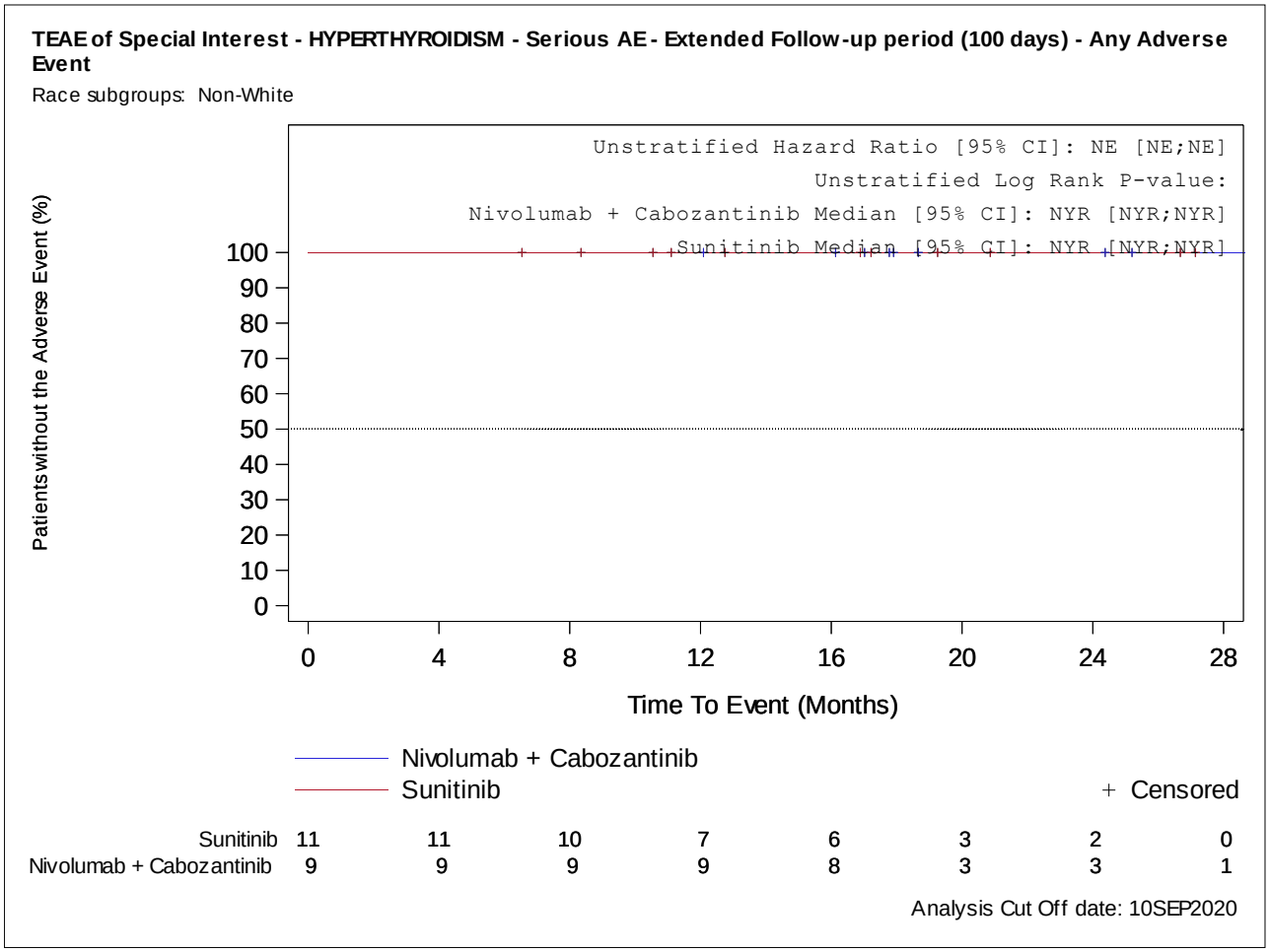

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:51:31

FIGURE 3.94.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:51:37

FIGURE 3.94.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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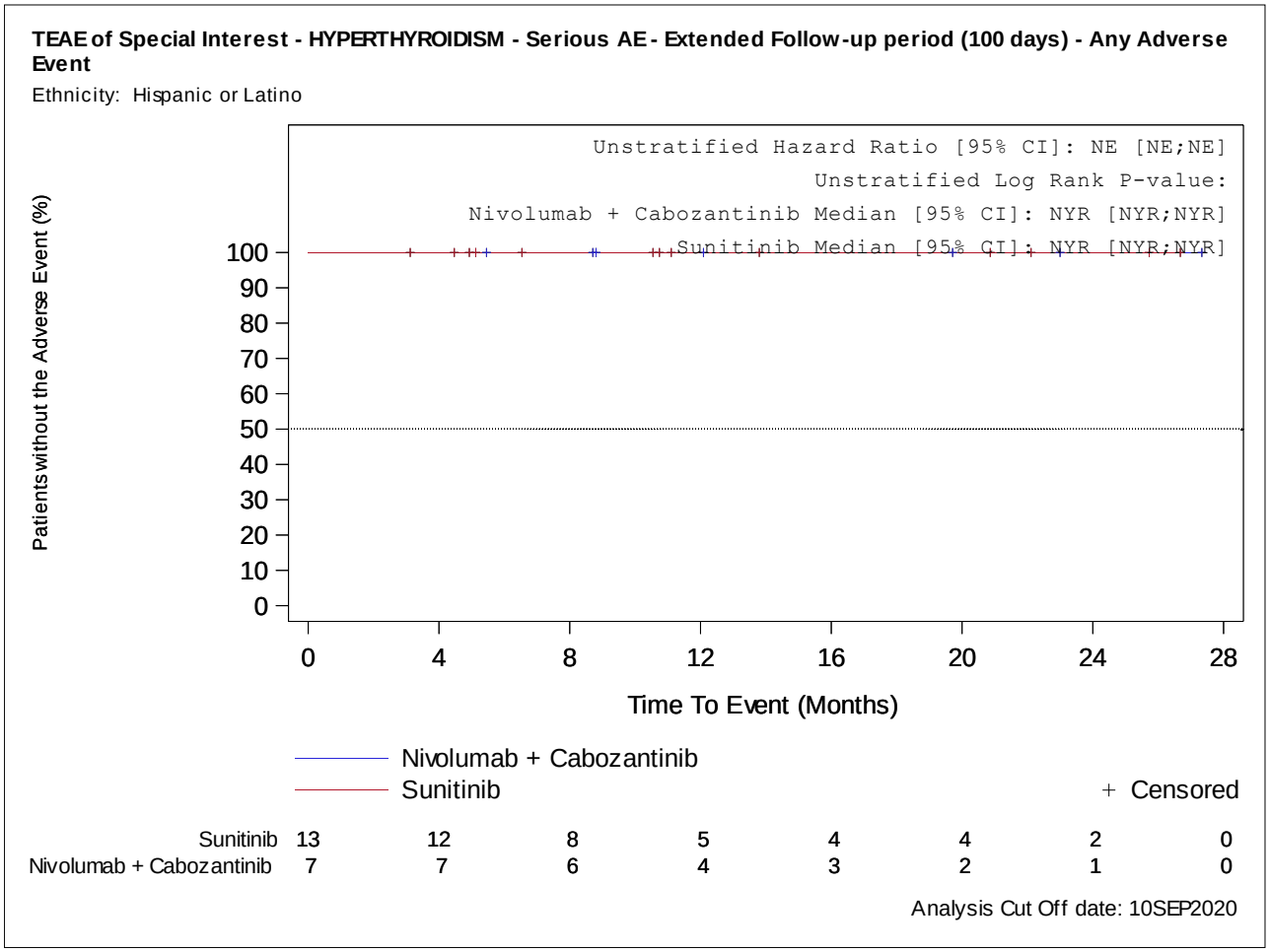
FIGURE 3.94.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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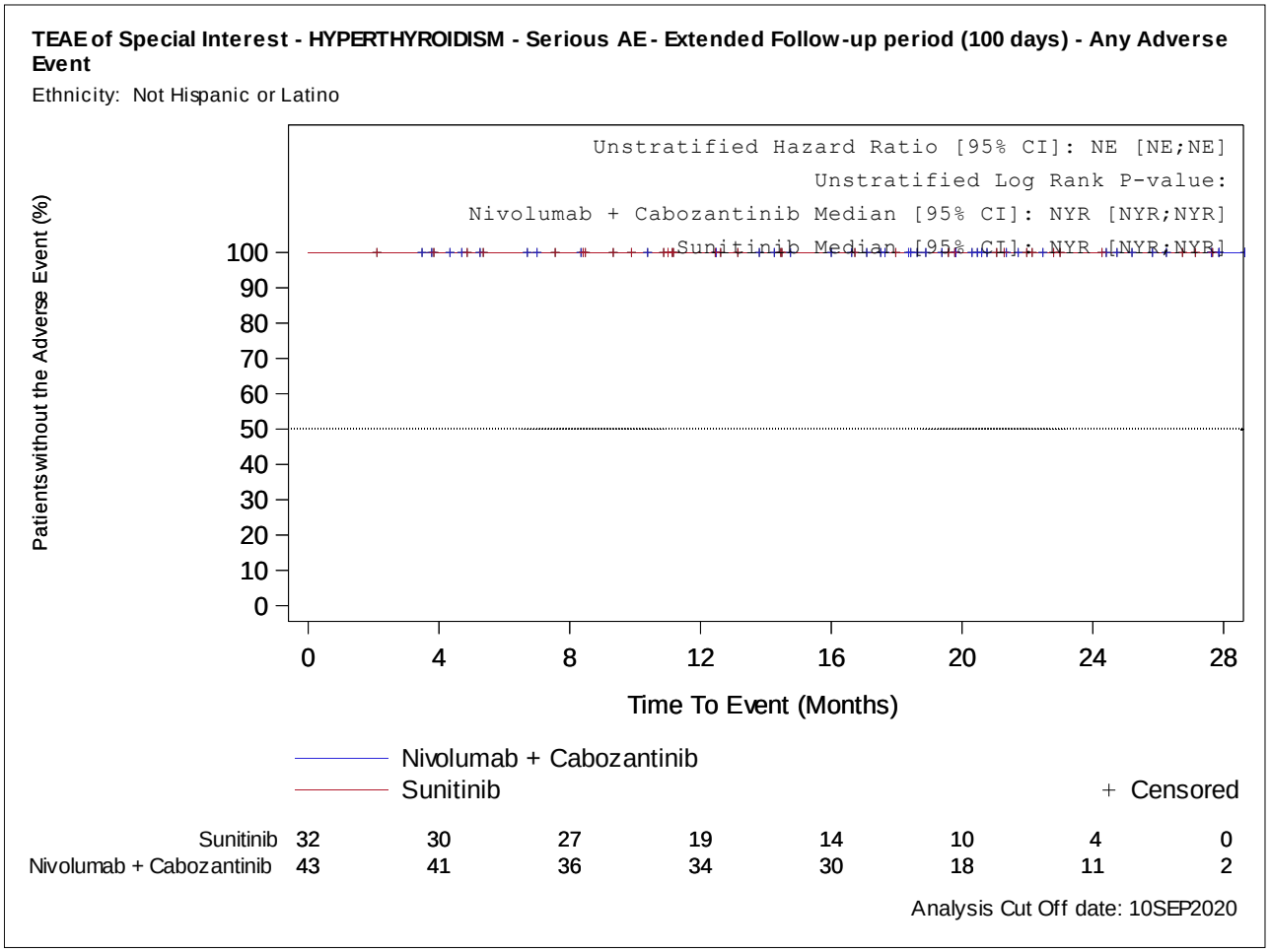
FIGURE 3.94.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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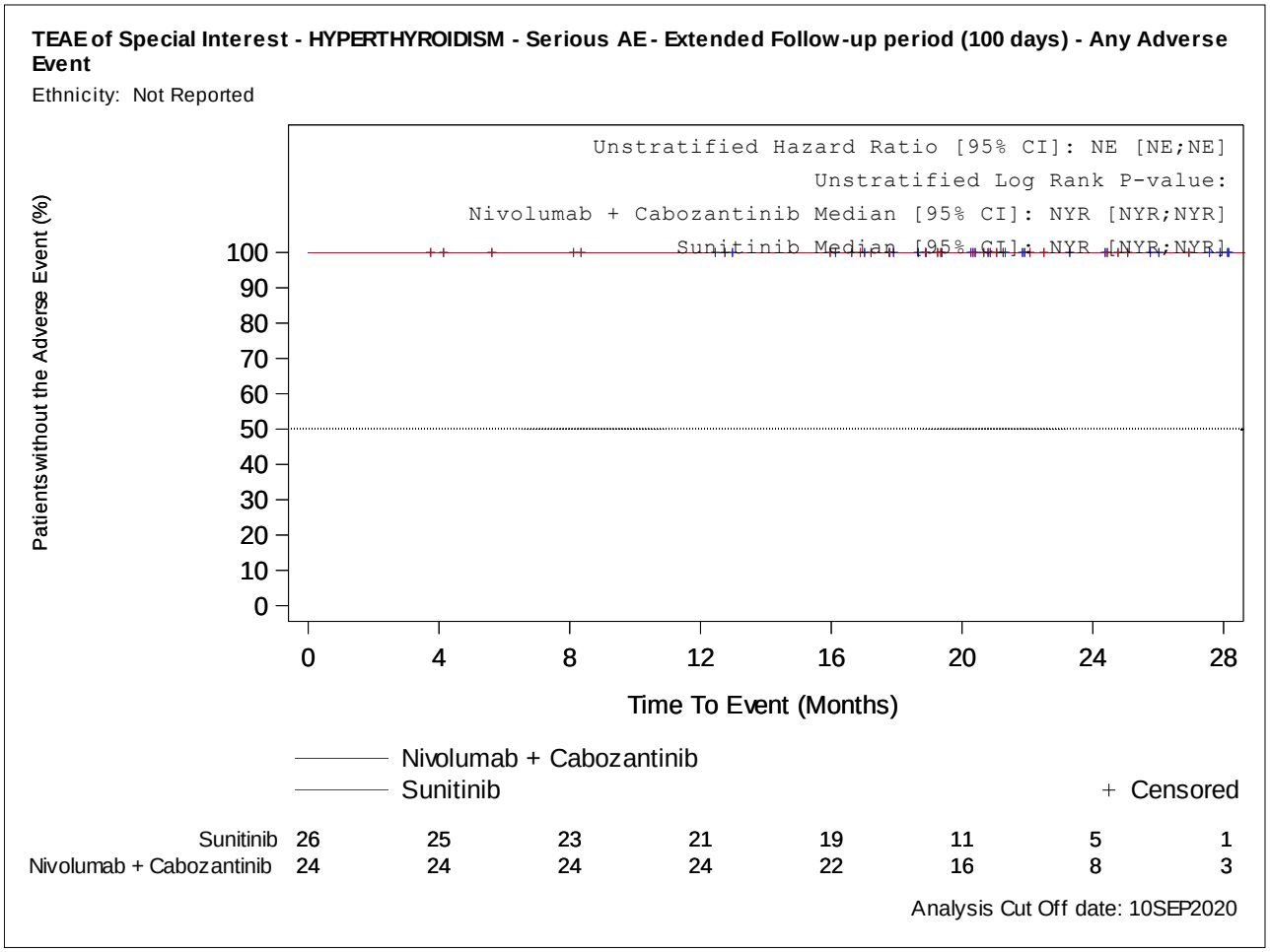
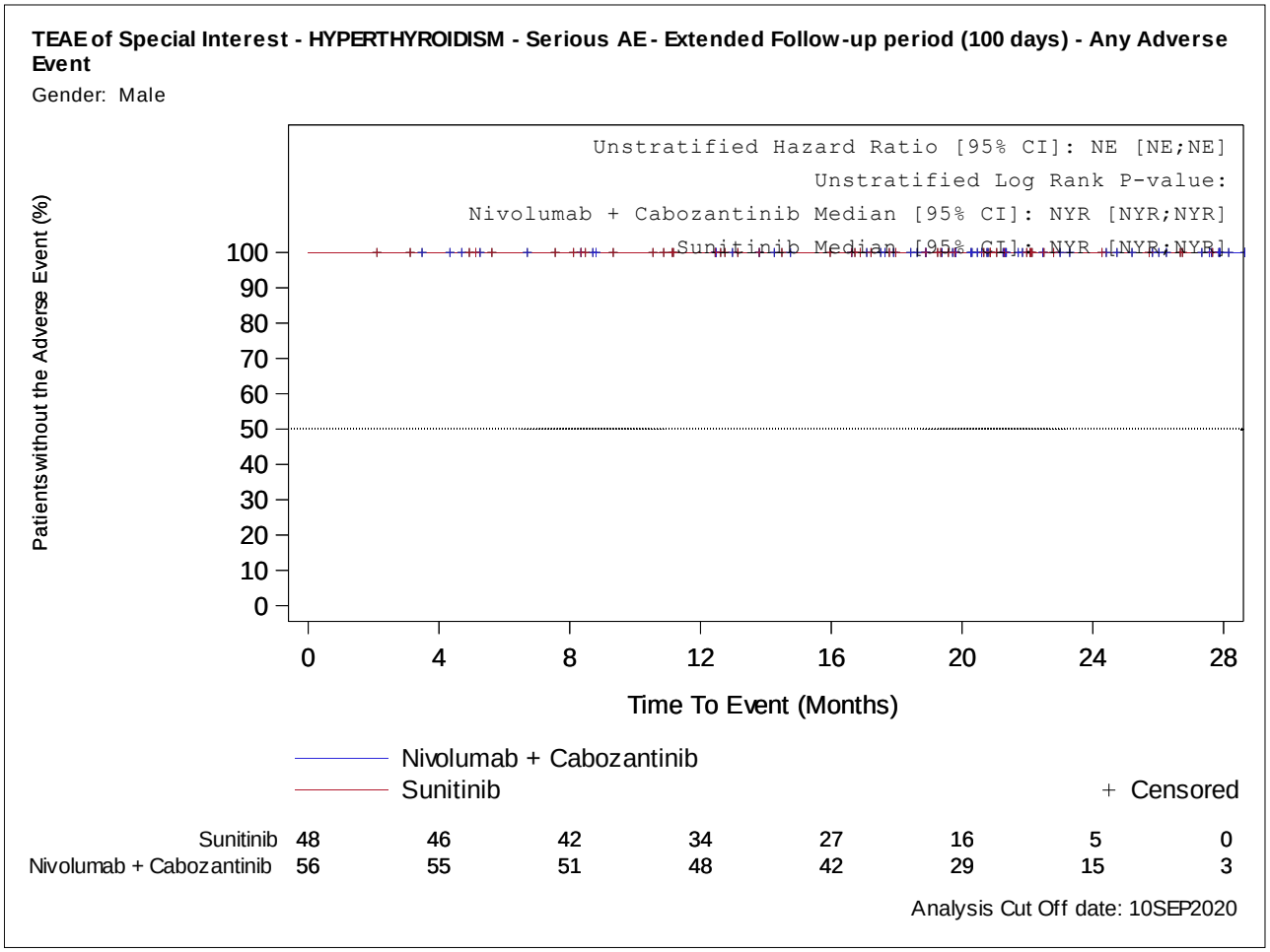
FIGURE 3.94.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



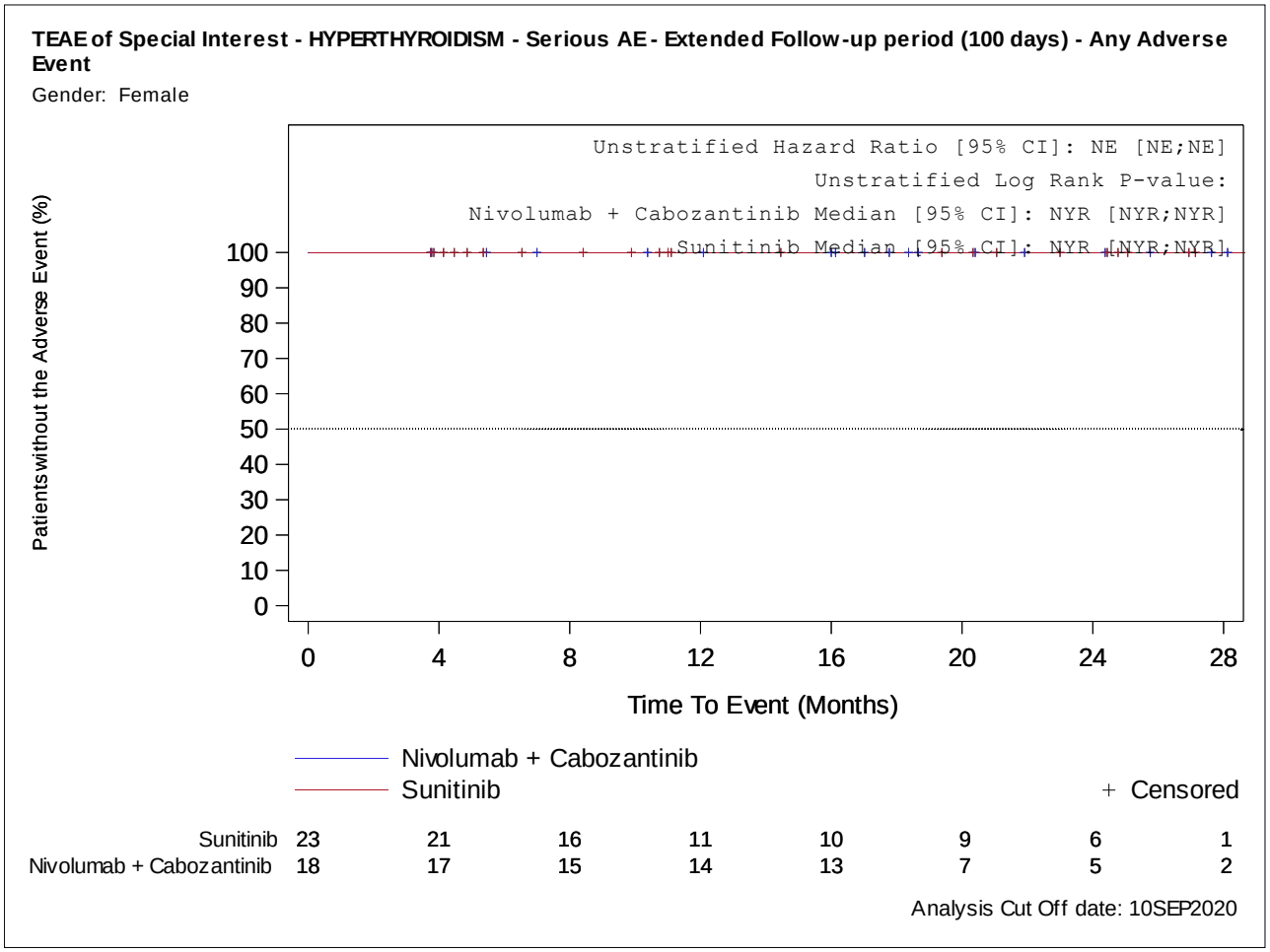

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:51:58

FIGURE 3.94.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



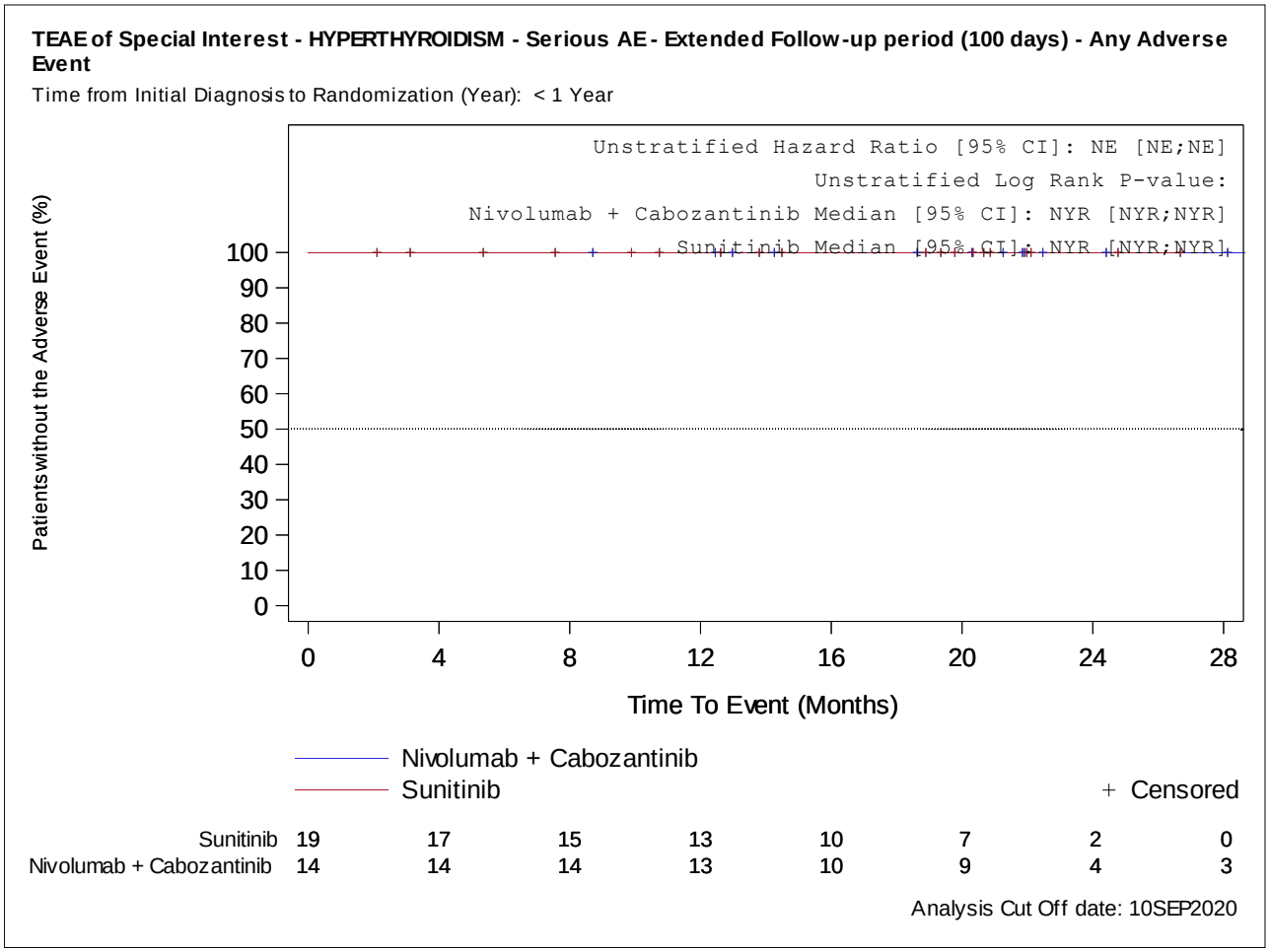

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:52:03

FIGURE 3.94.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:52:08

FIGURE 3.94.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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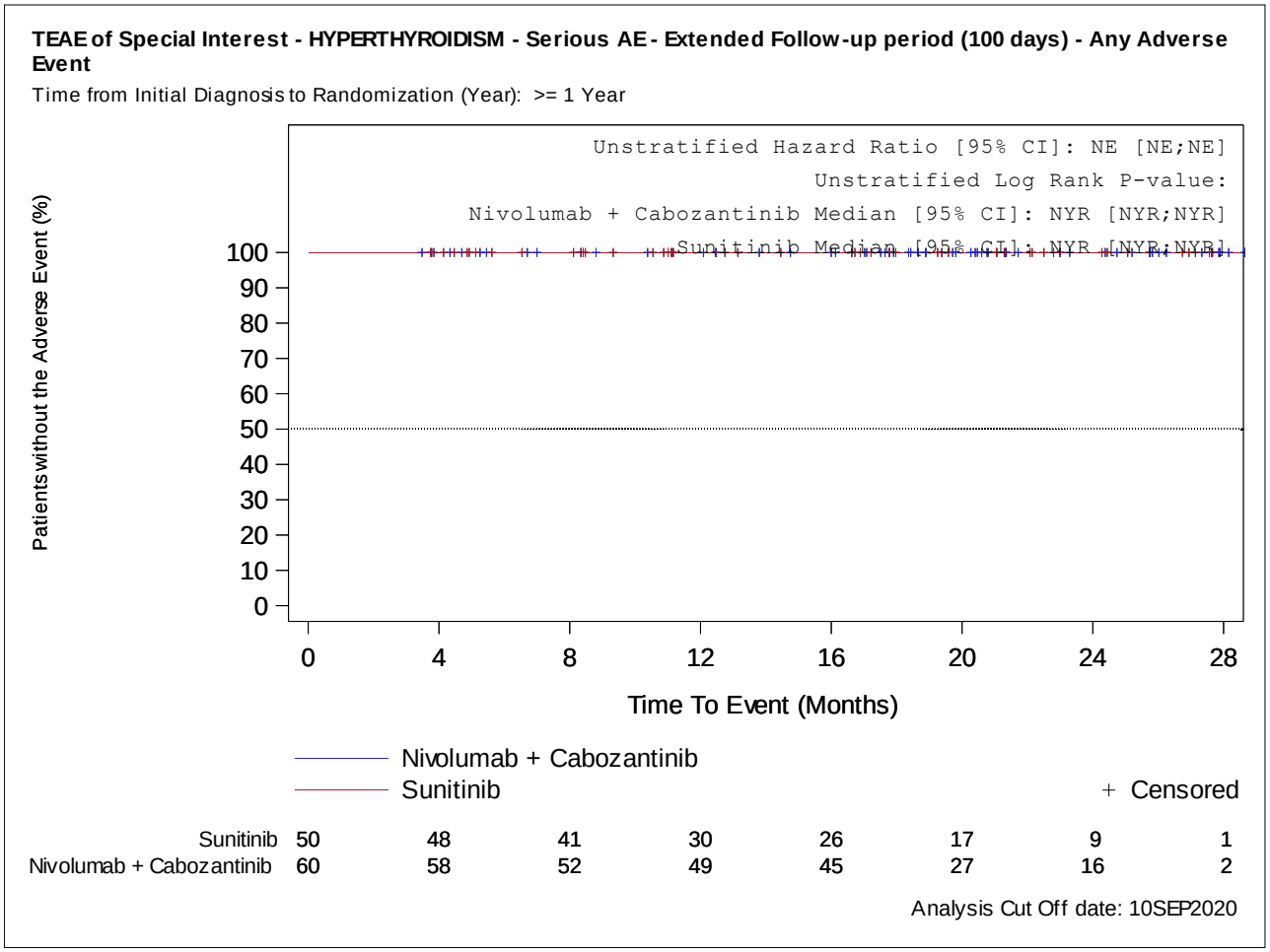
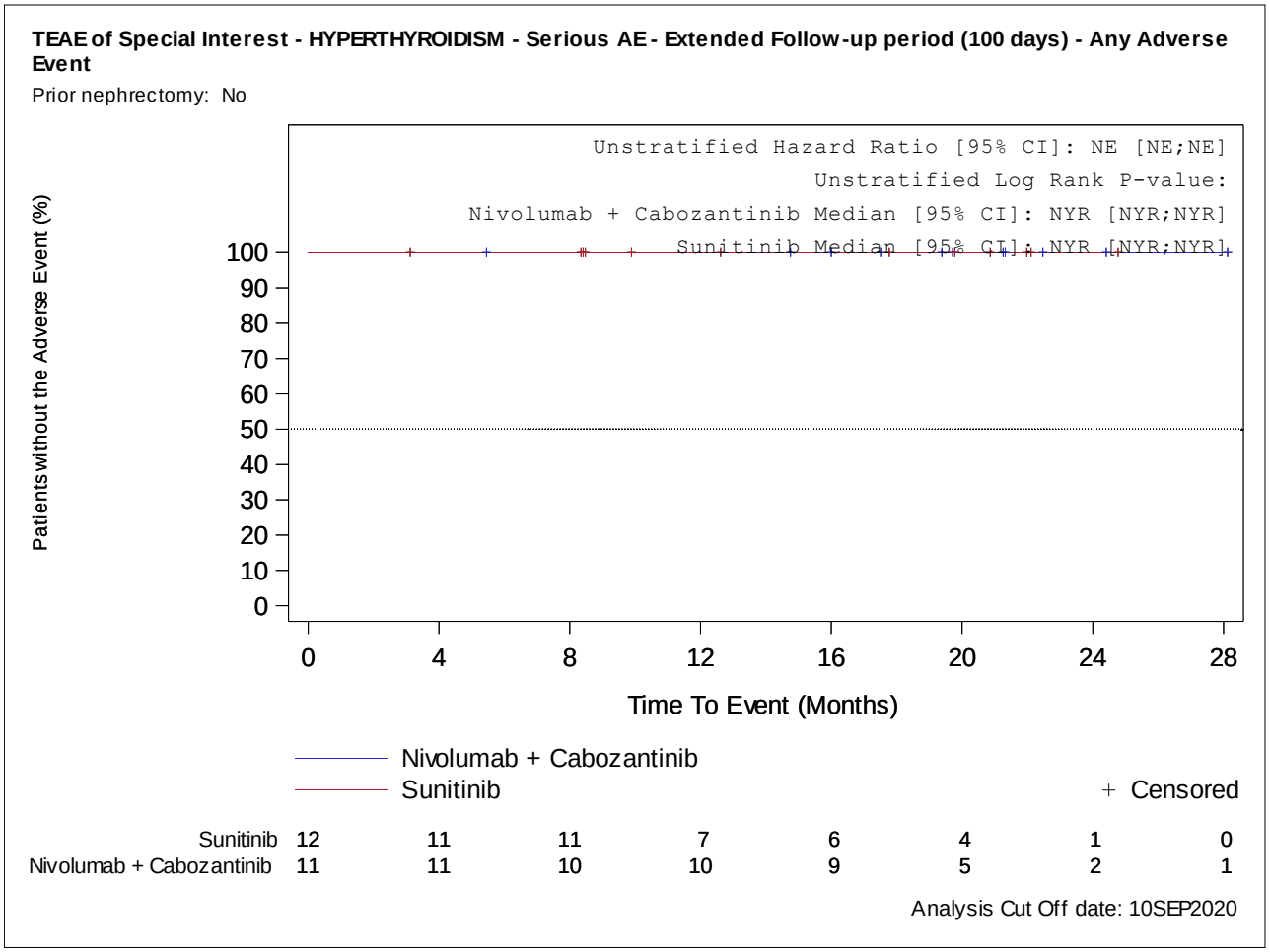
FIGURE 3.94.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



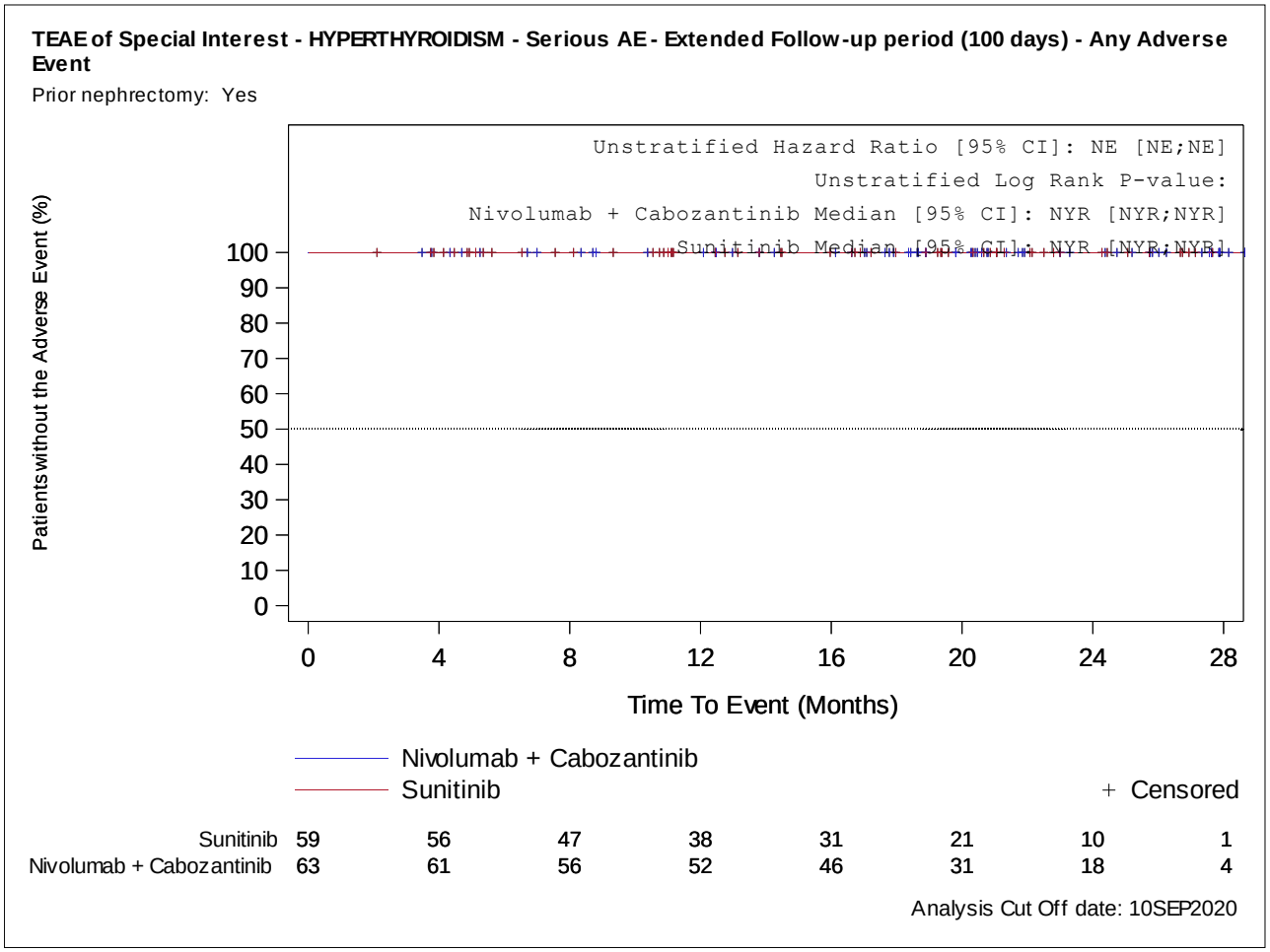

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:52:29

FIGURE 3.94.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



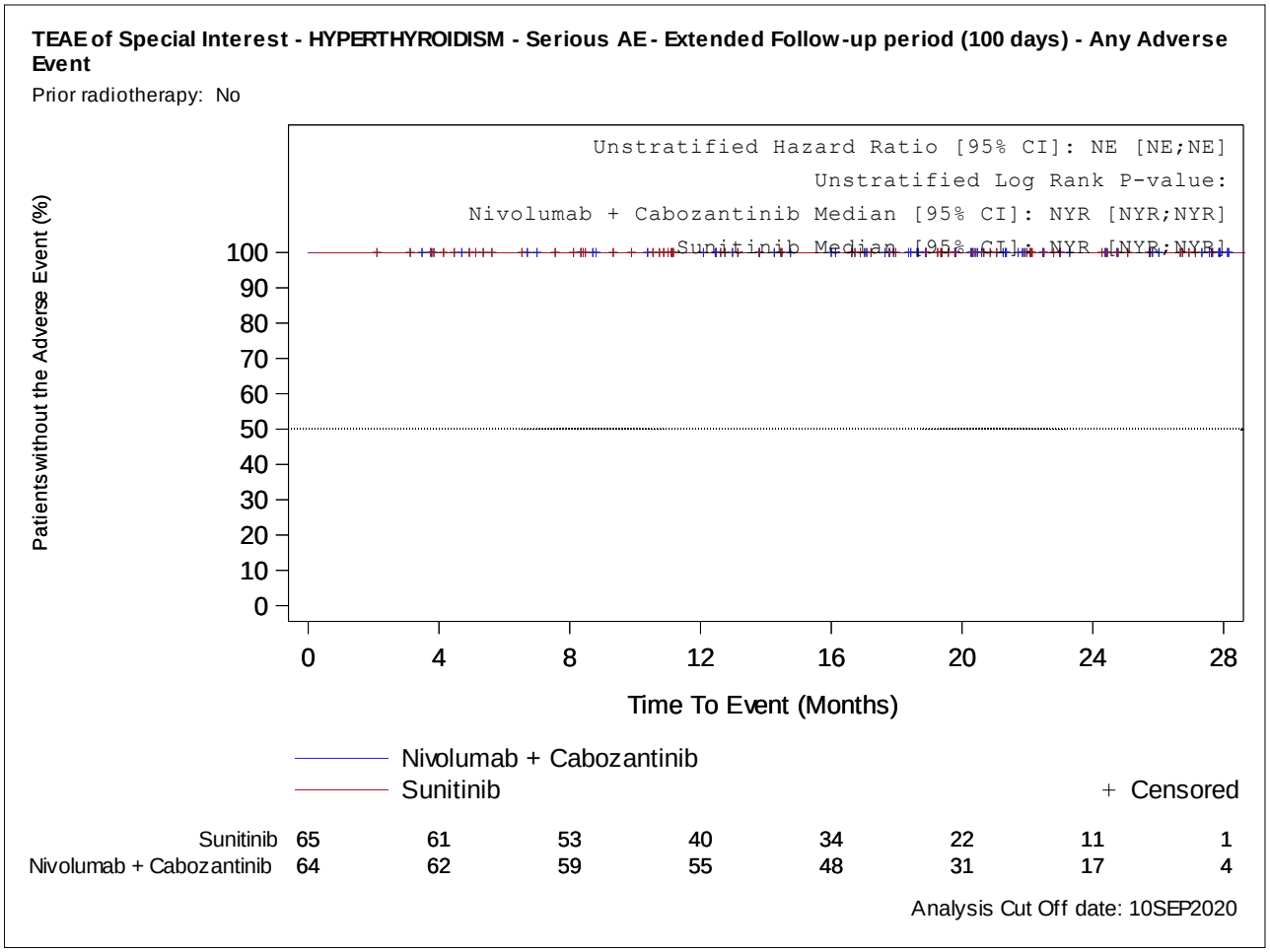

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:53:15

FIGURE 3.94.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



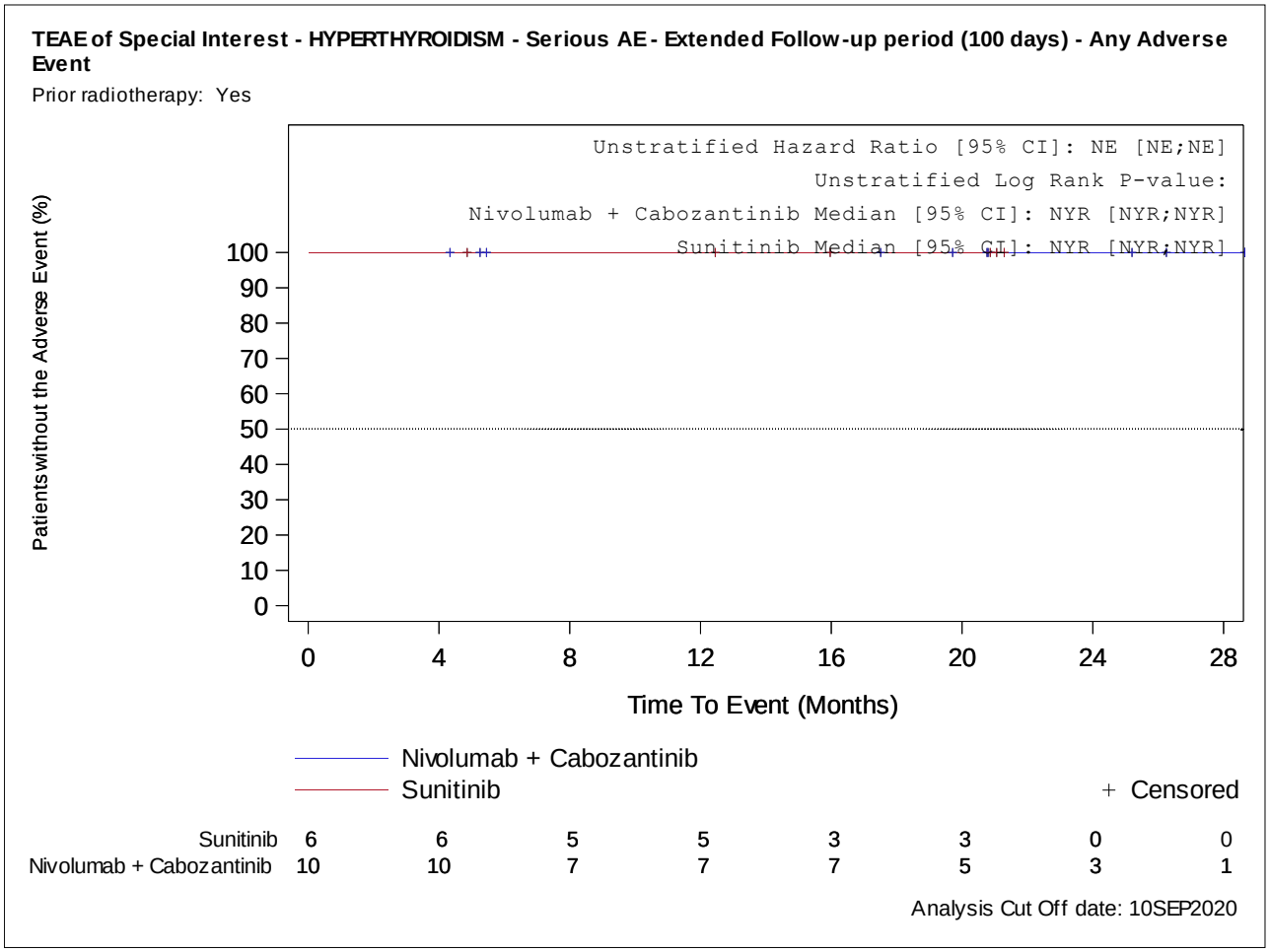

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:53:21

FIGURE 3.94.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



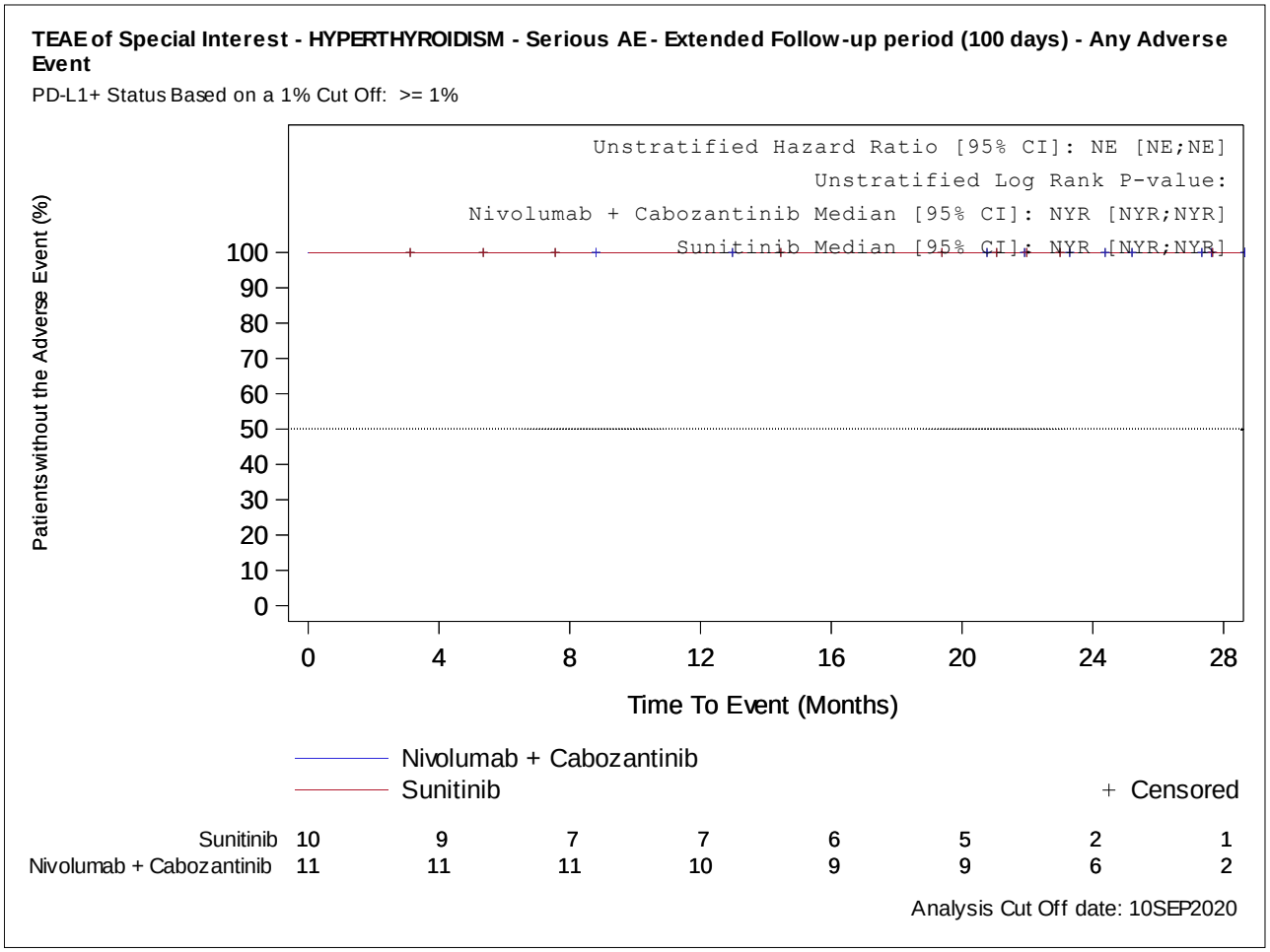

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:53:26

FIGURE 3.94.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



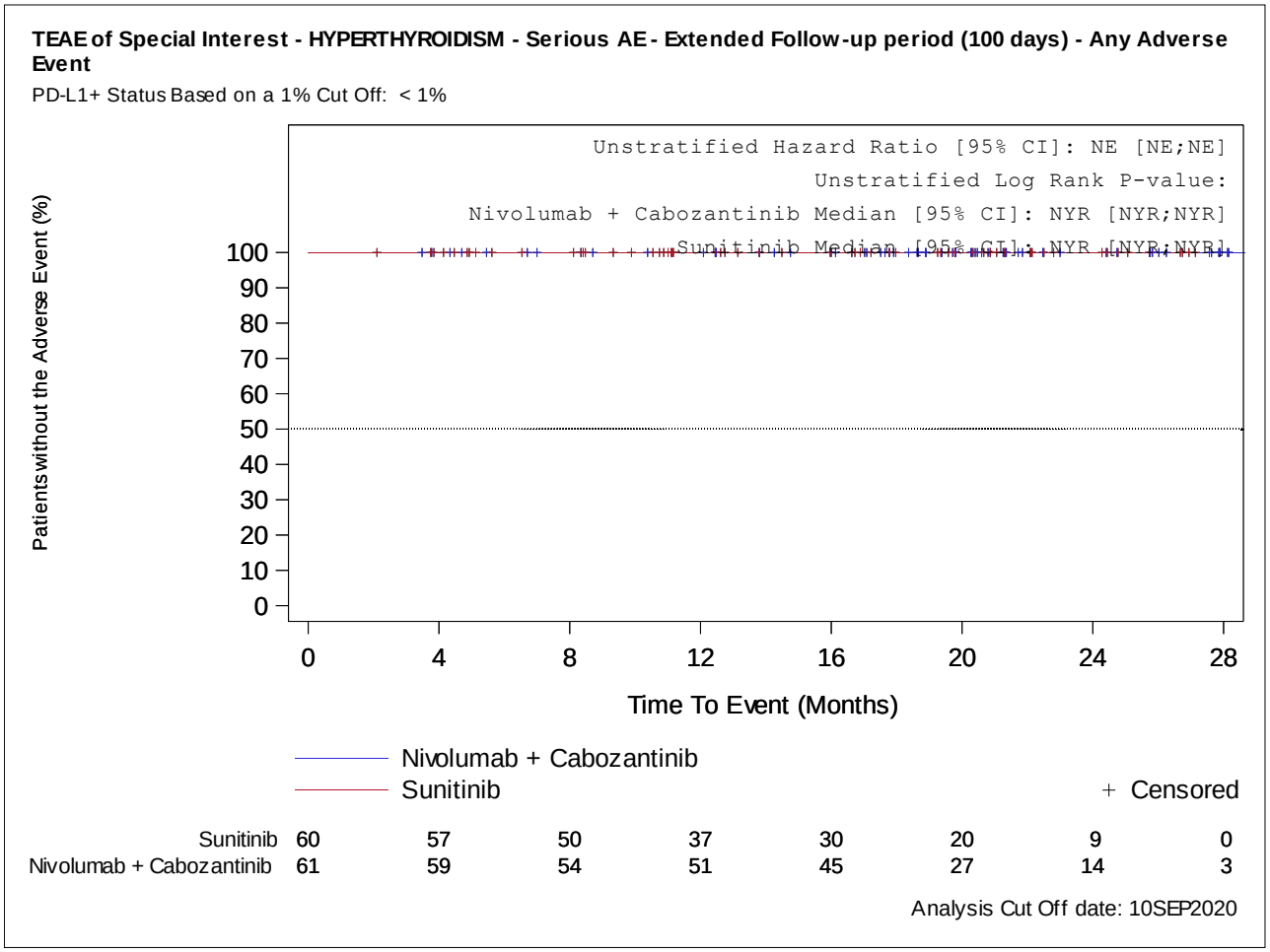

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:53:31

FIGURE 3.94.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



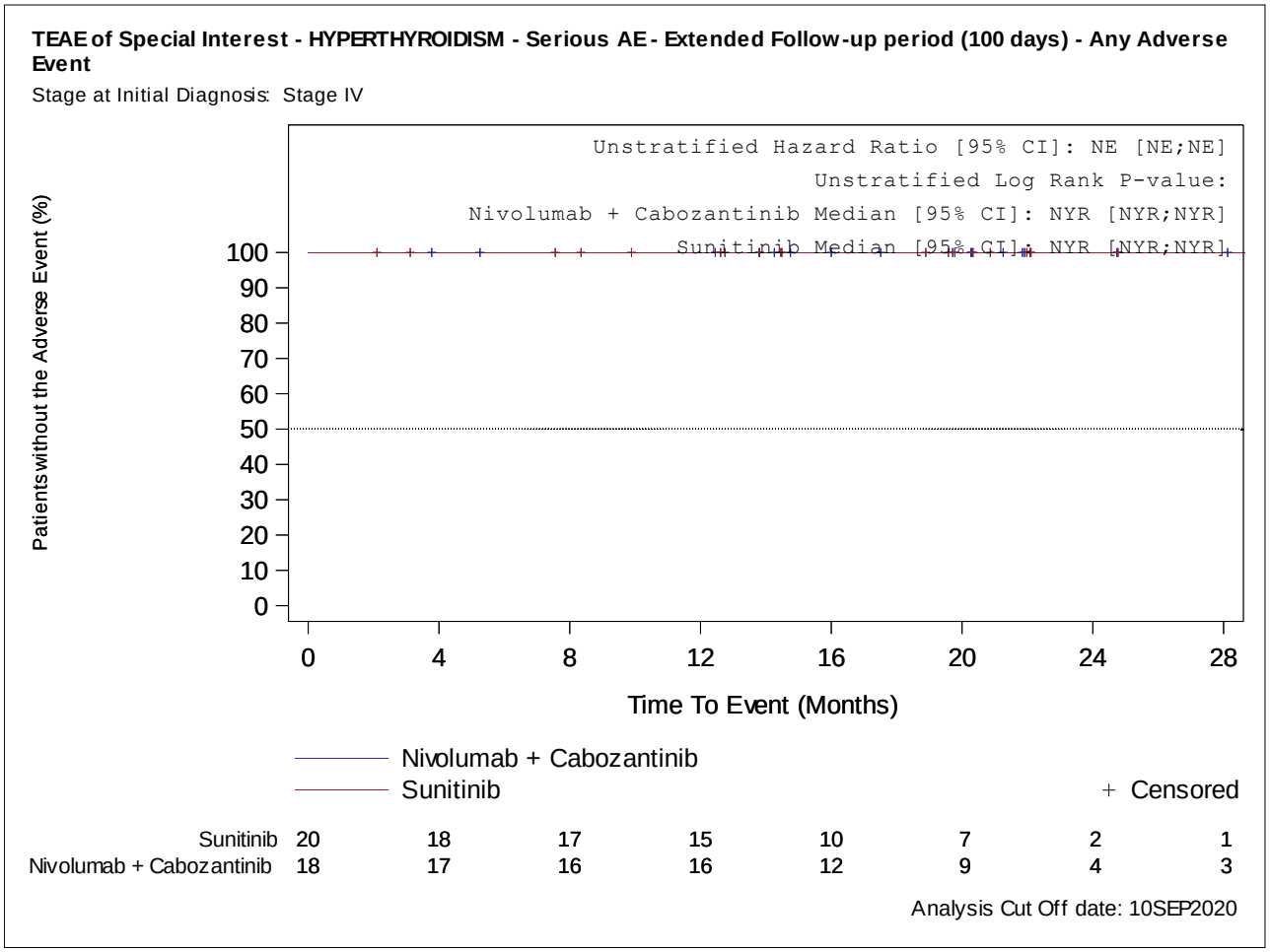

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:53:37

FIGURE 3.94.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:53:41

FIGURE 3.94.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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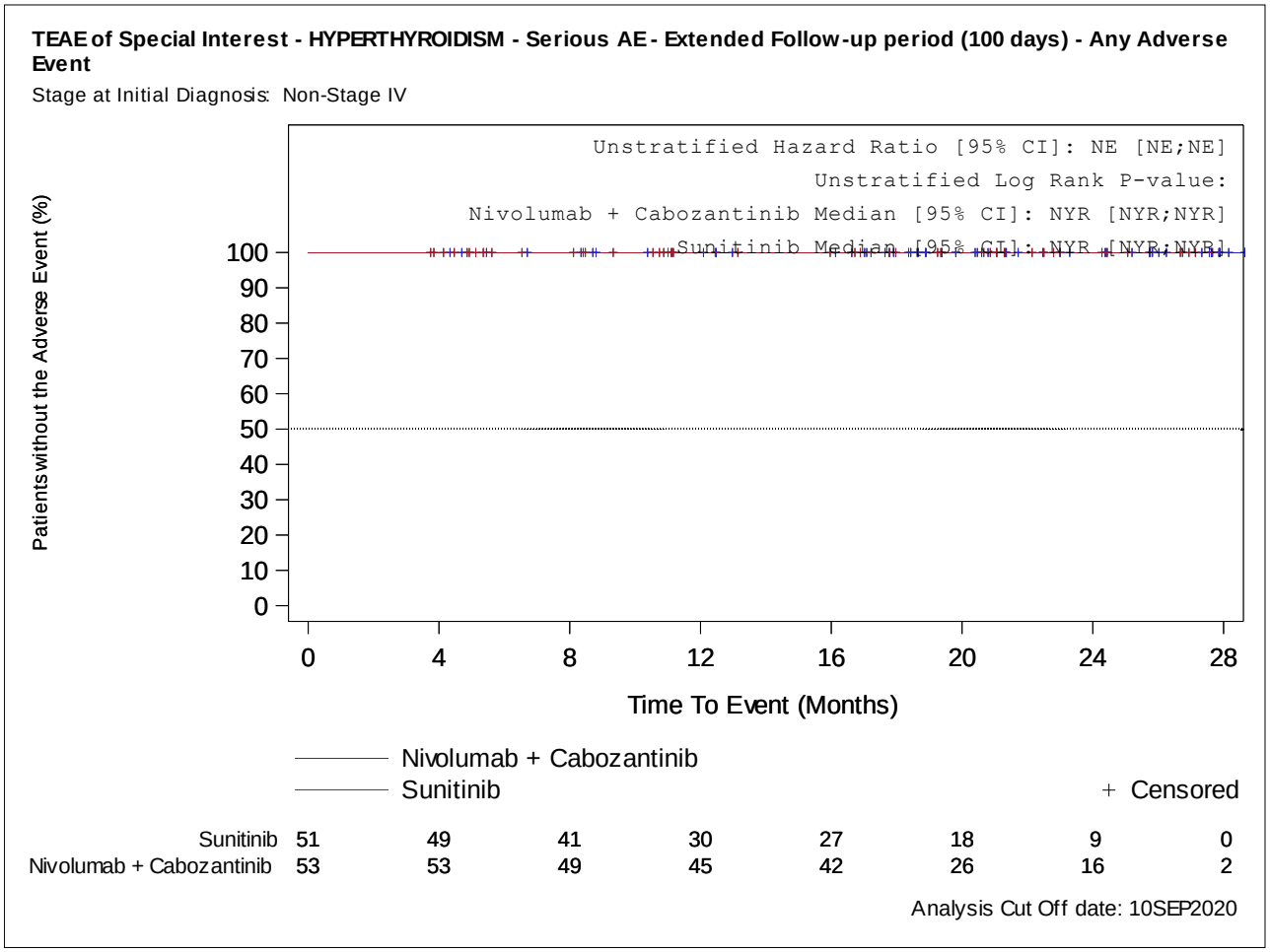
FIGURE 3.94.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPERTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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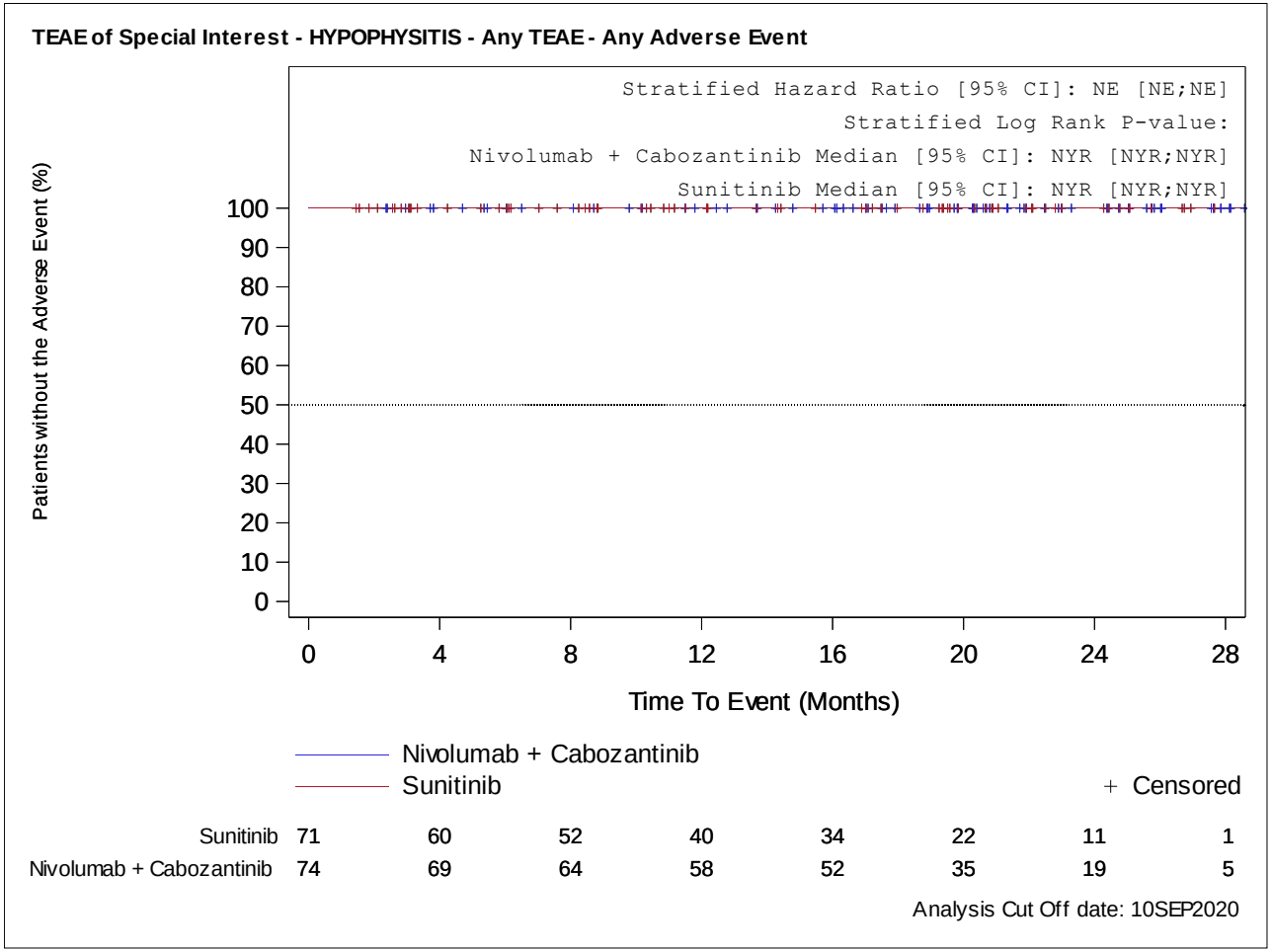
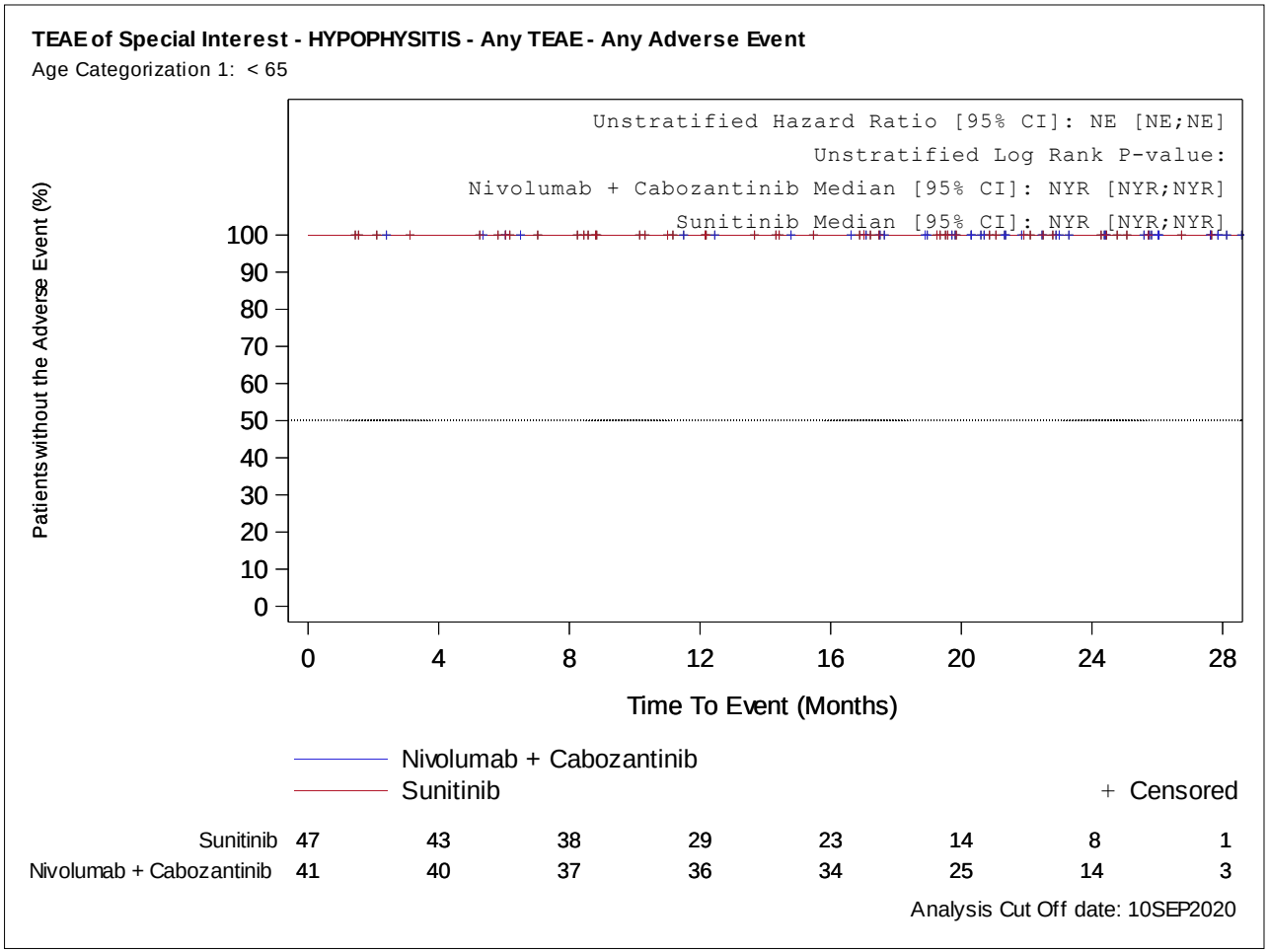
FIGURE 3.95.1: TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:57:09

FIGURE 3.95.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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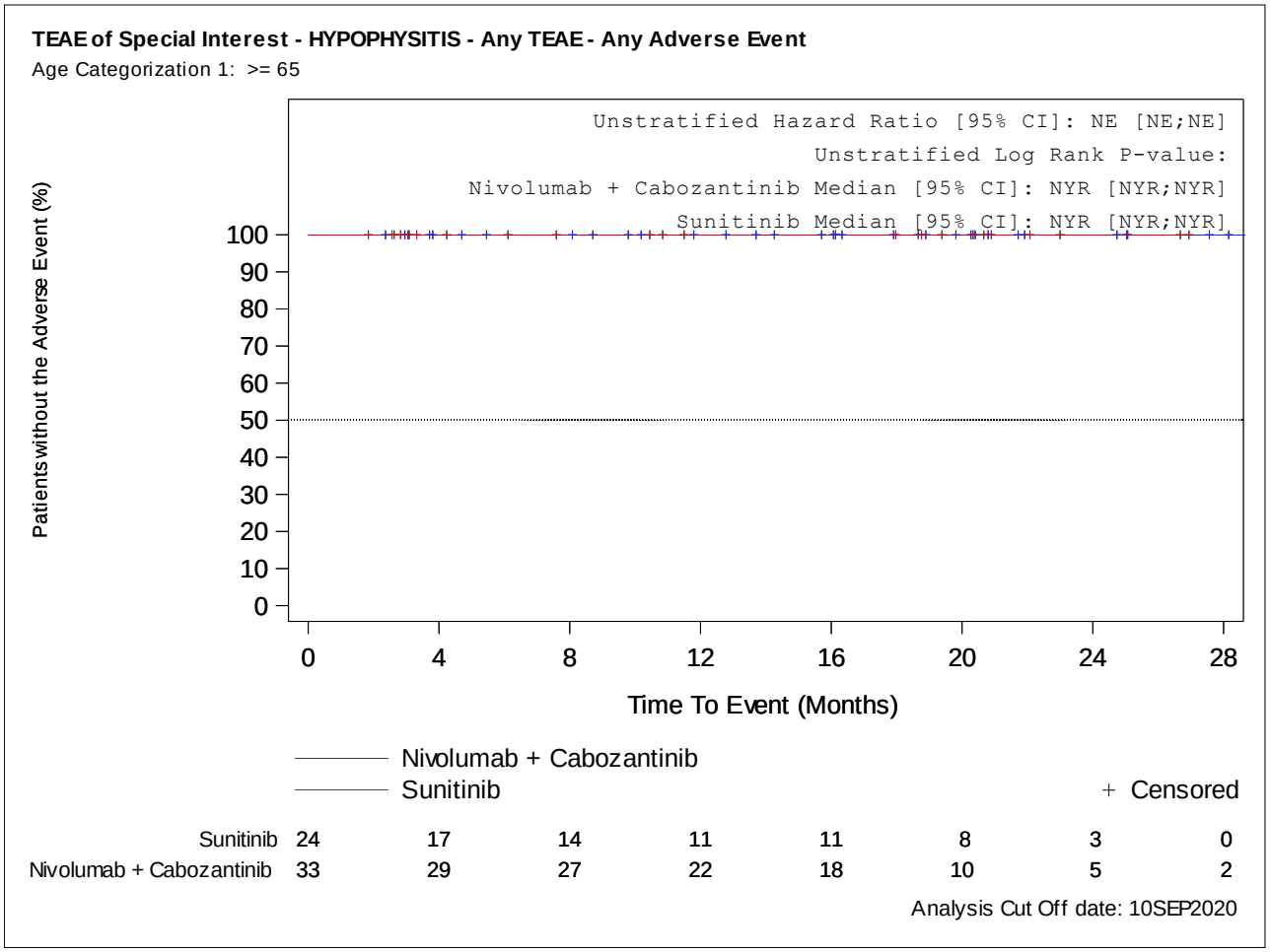
FIGURE 3.95.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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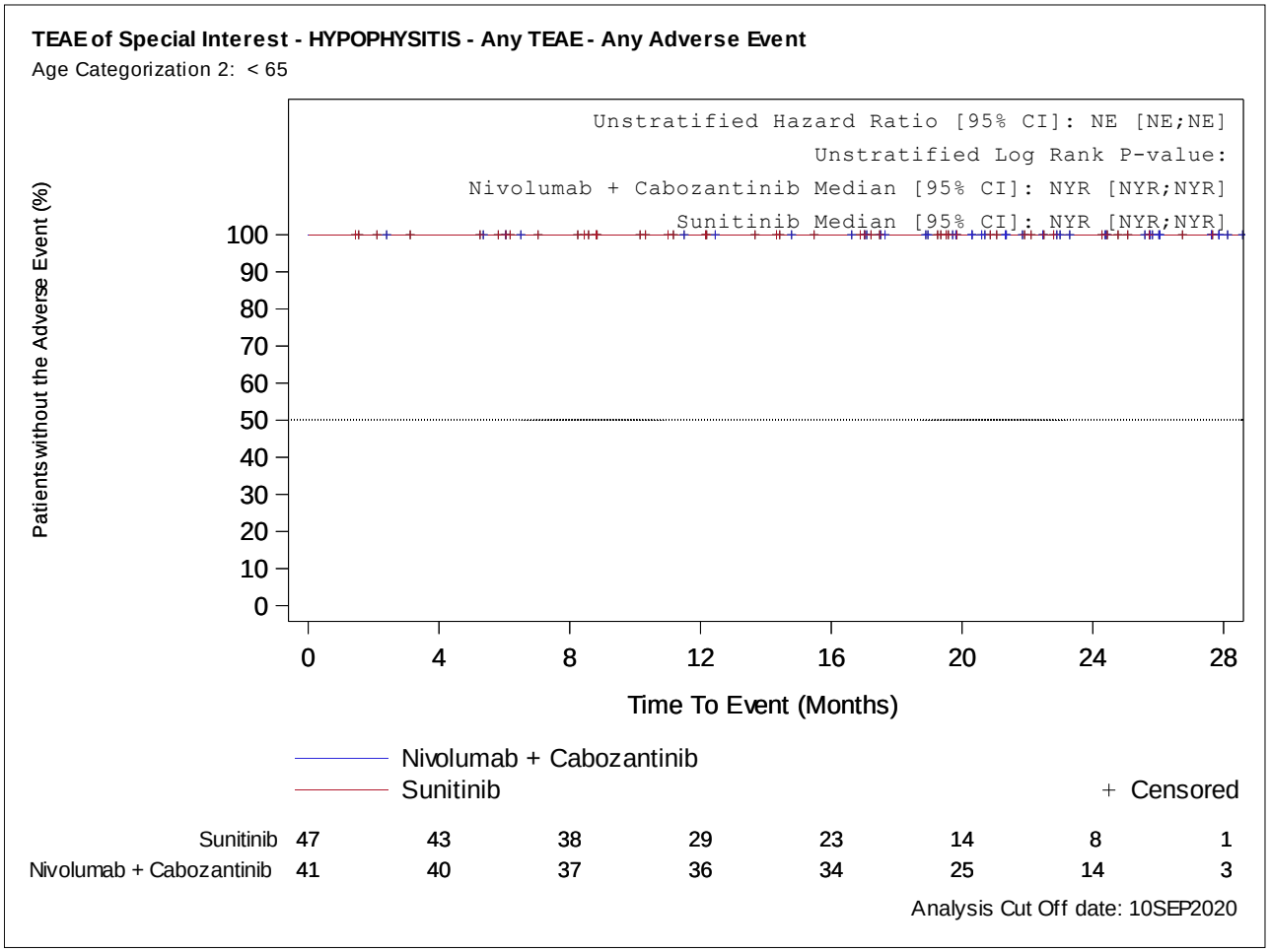
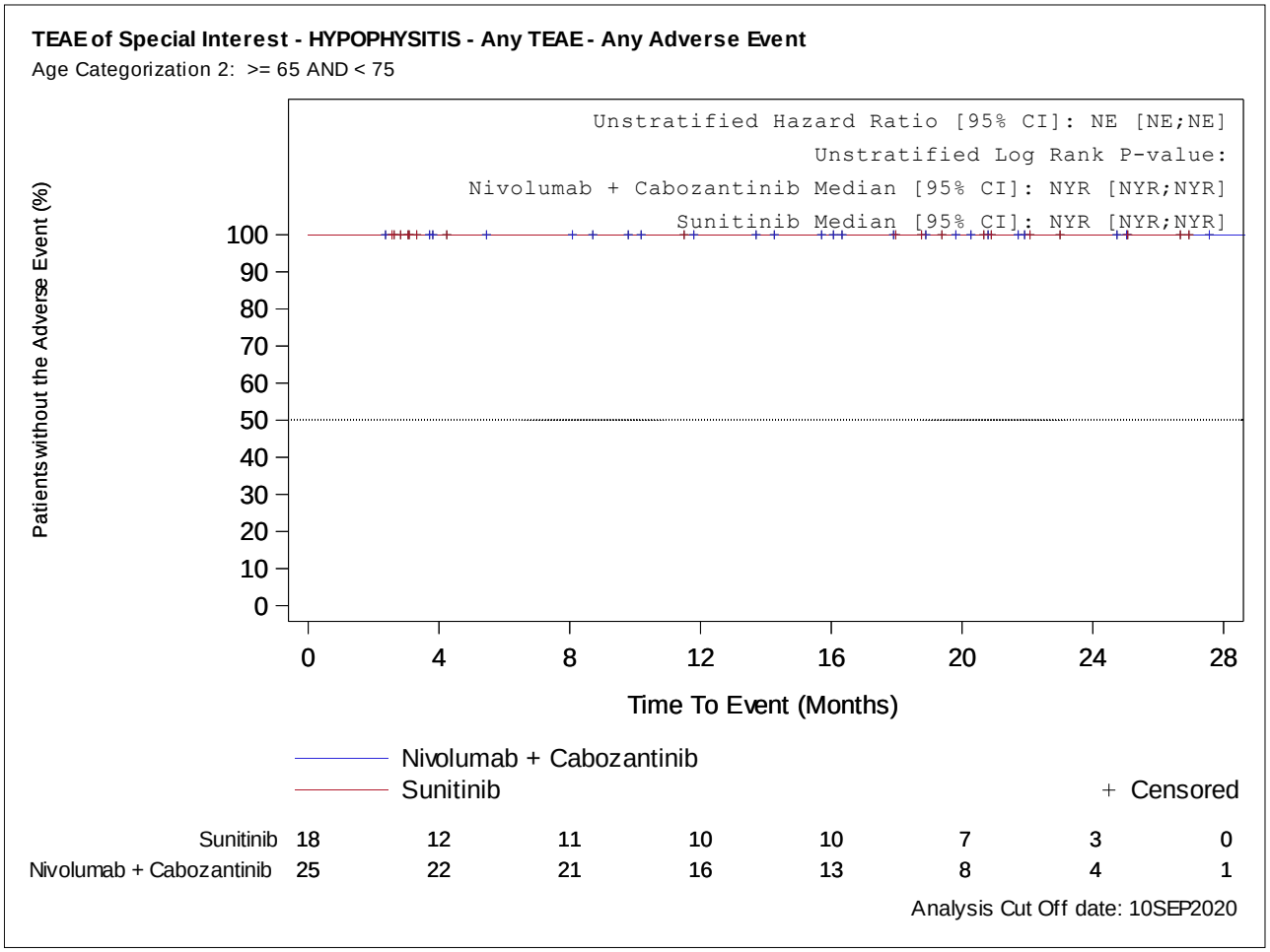
FIGURE 3.95.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



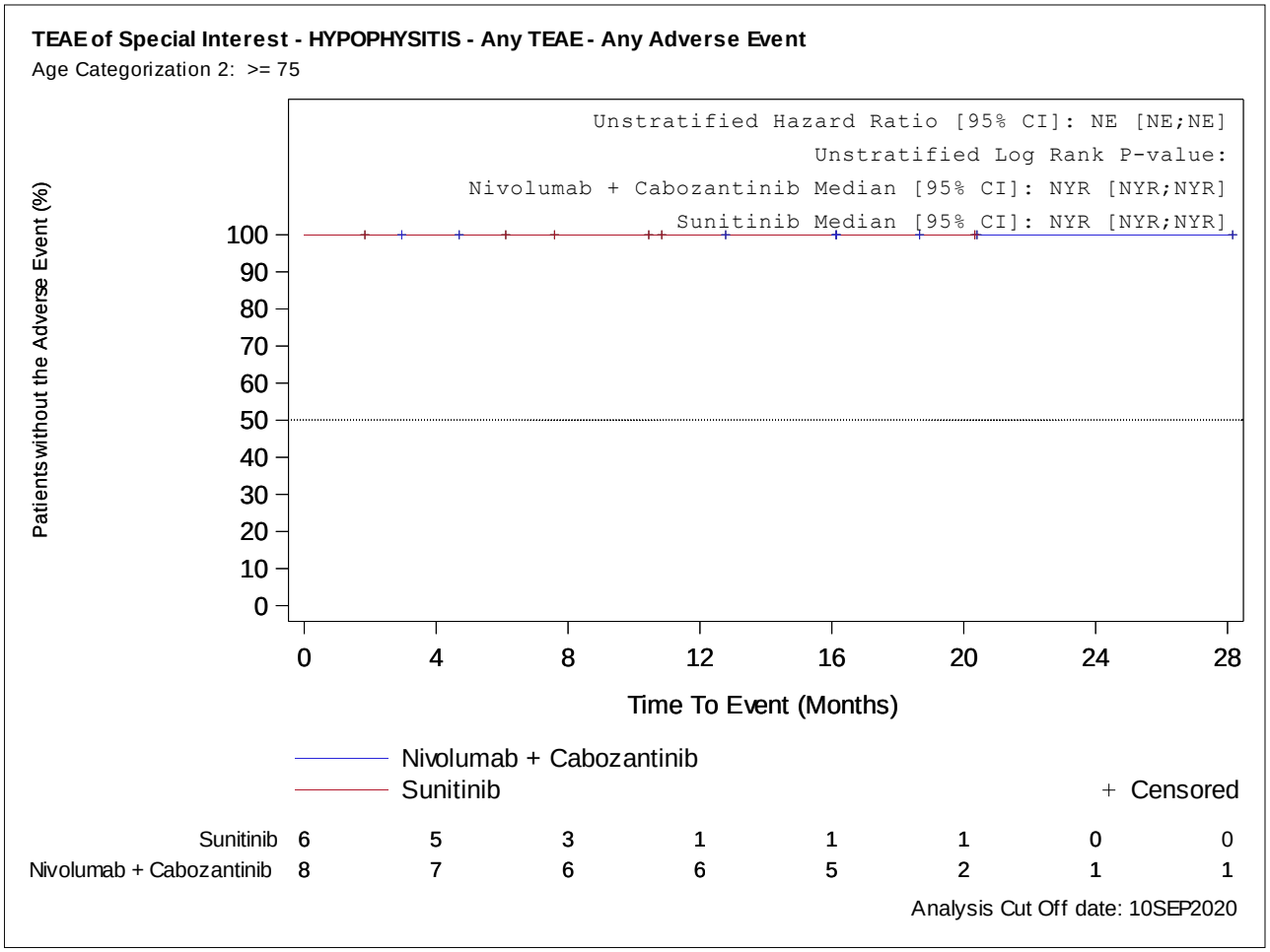

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:57:23

FIGURE 3.95.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



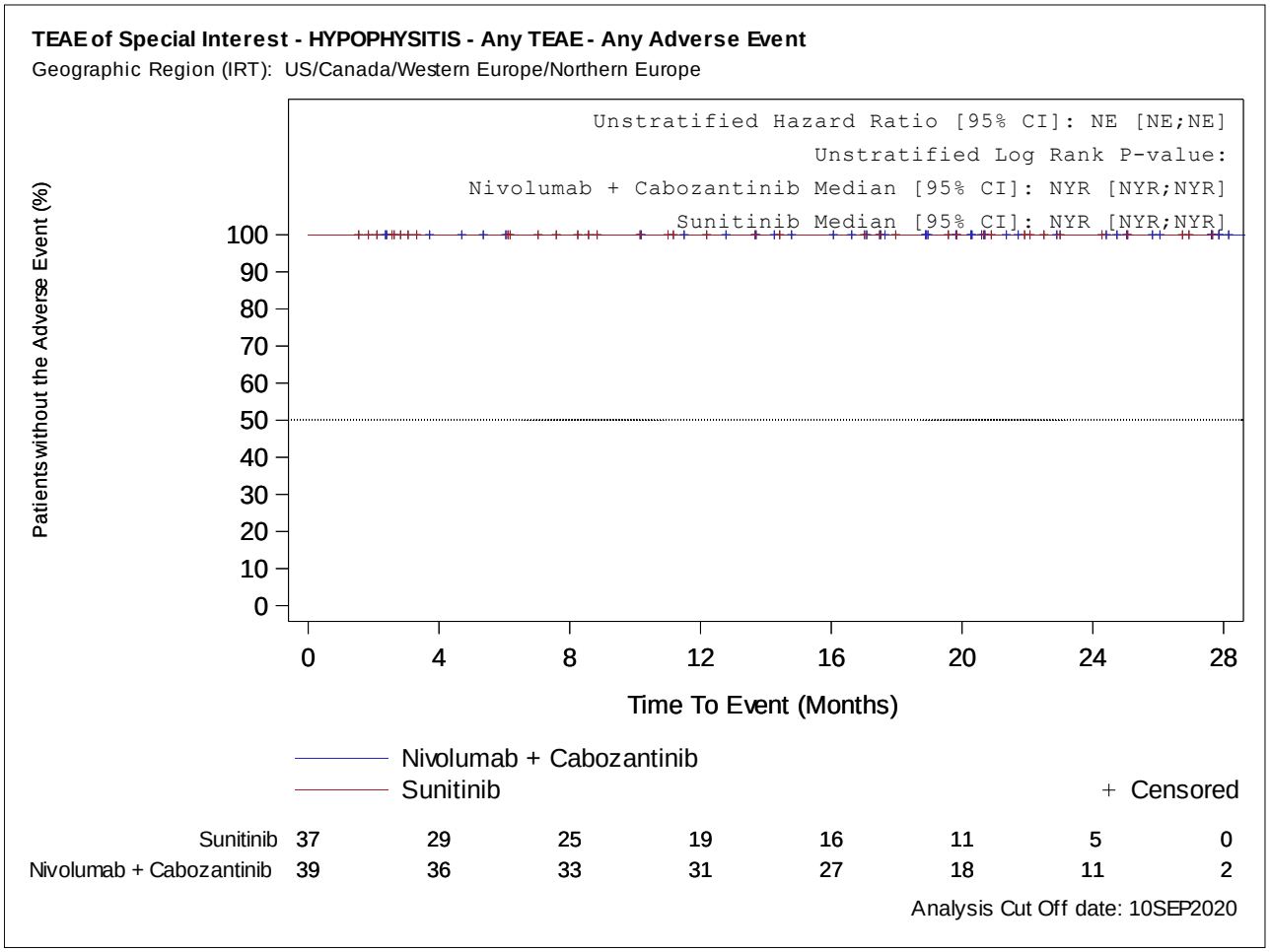

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:57:28

FIGURE 3.95.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



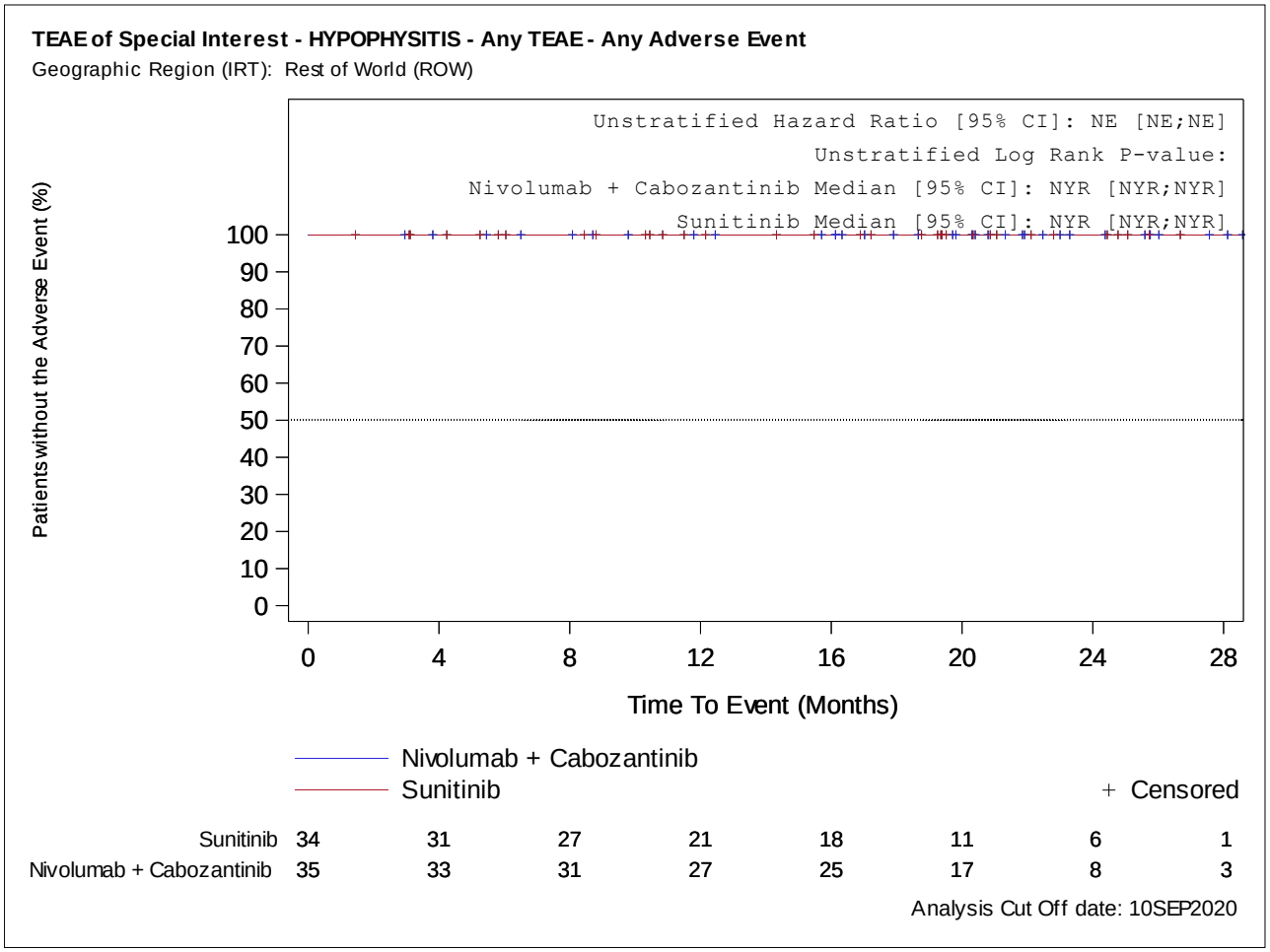

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:57:34

FIGURE 3.95.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



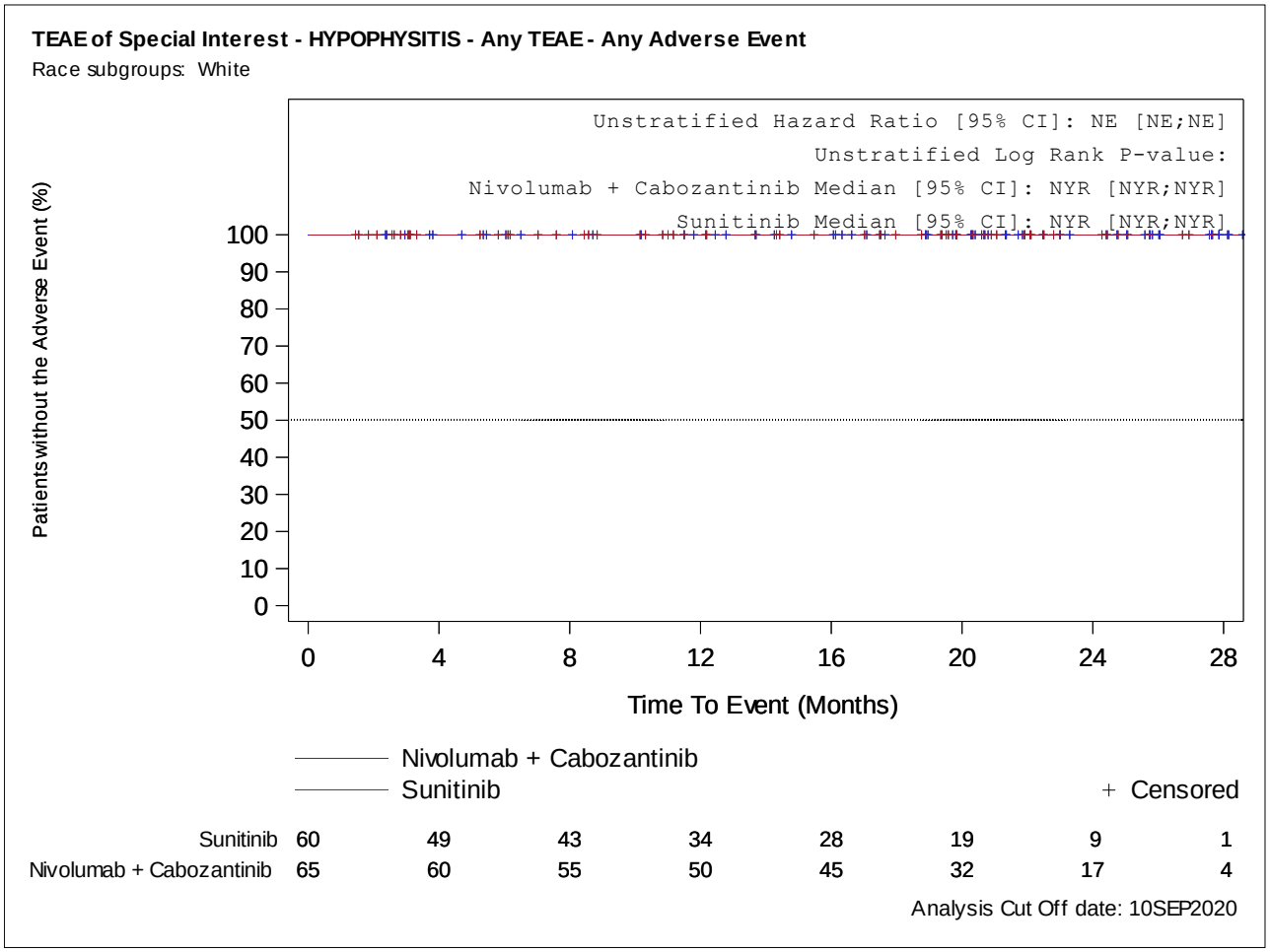

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:57:39

FIGURE 3.95.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:57:44

FIGURE 3.95.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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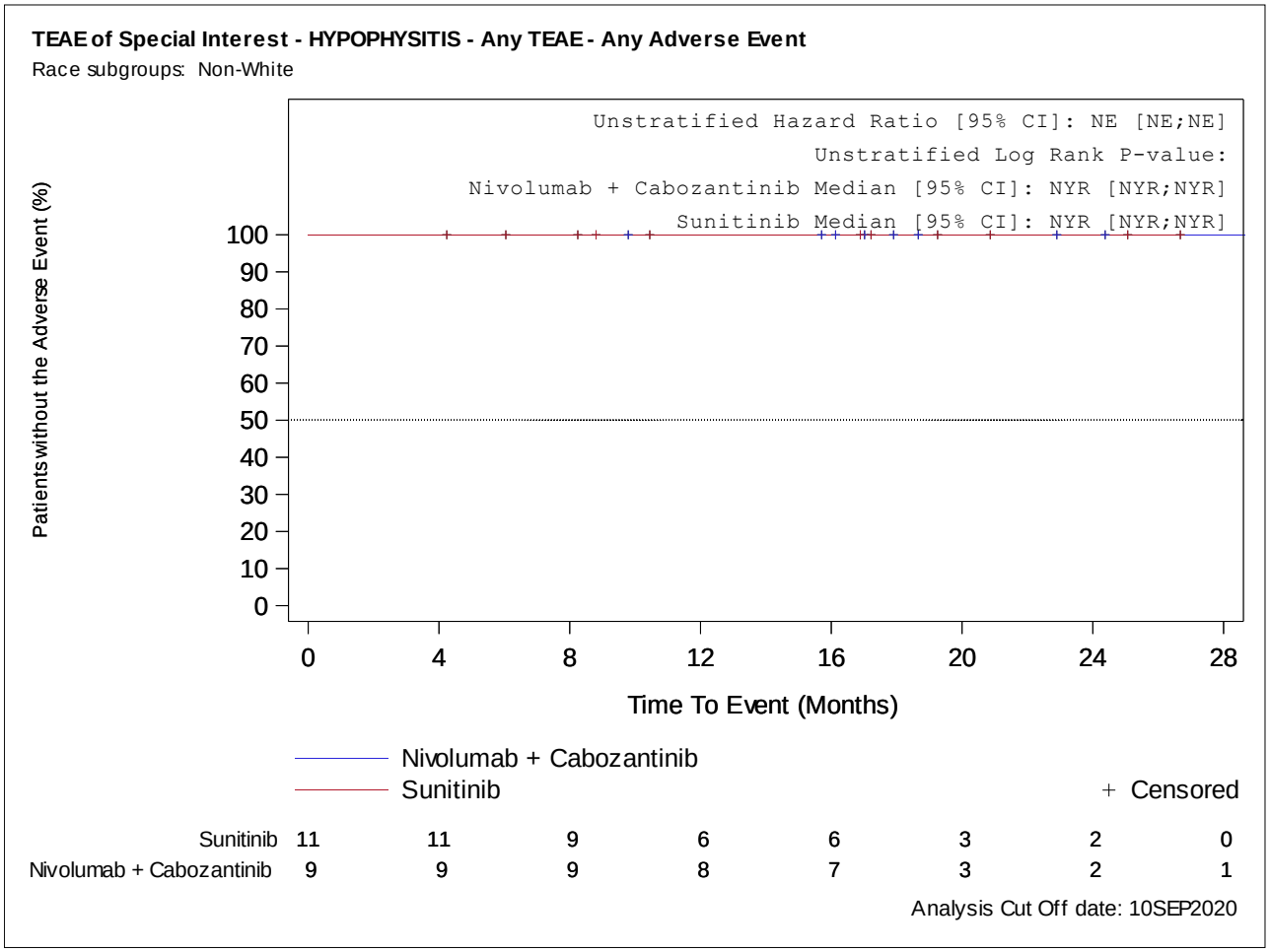
FIGURE 3.95.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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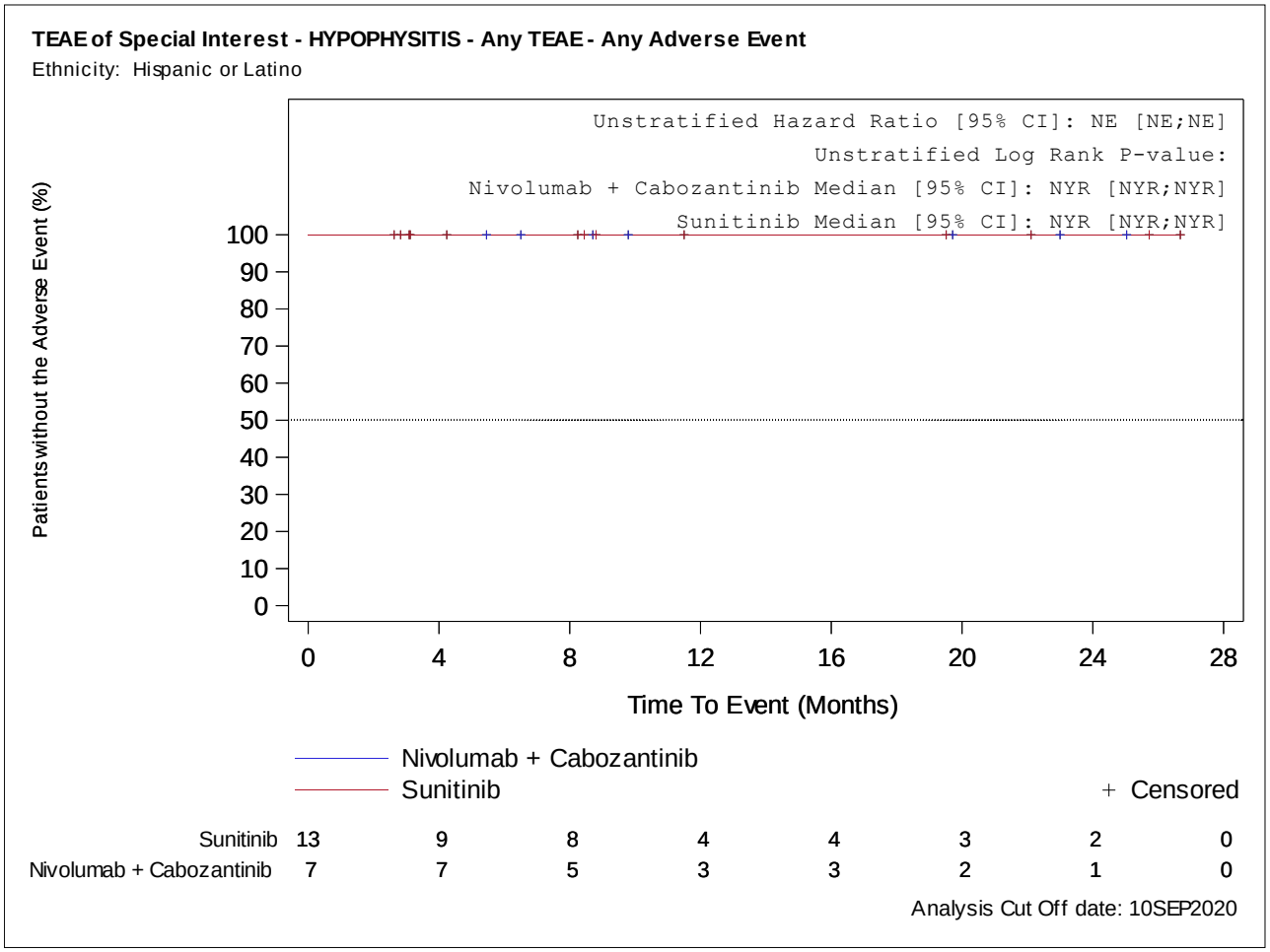
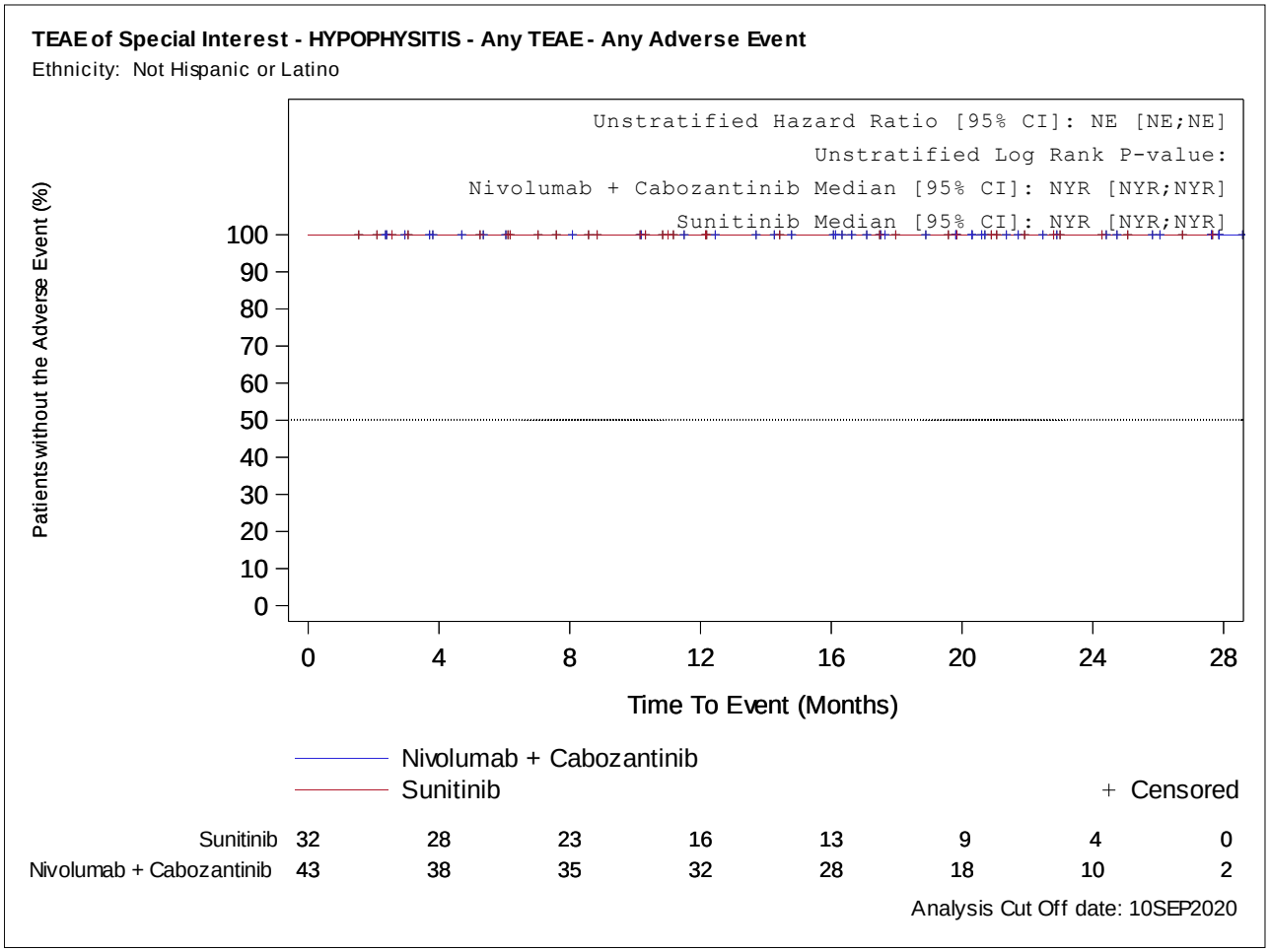
FIGURE 3.95.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



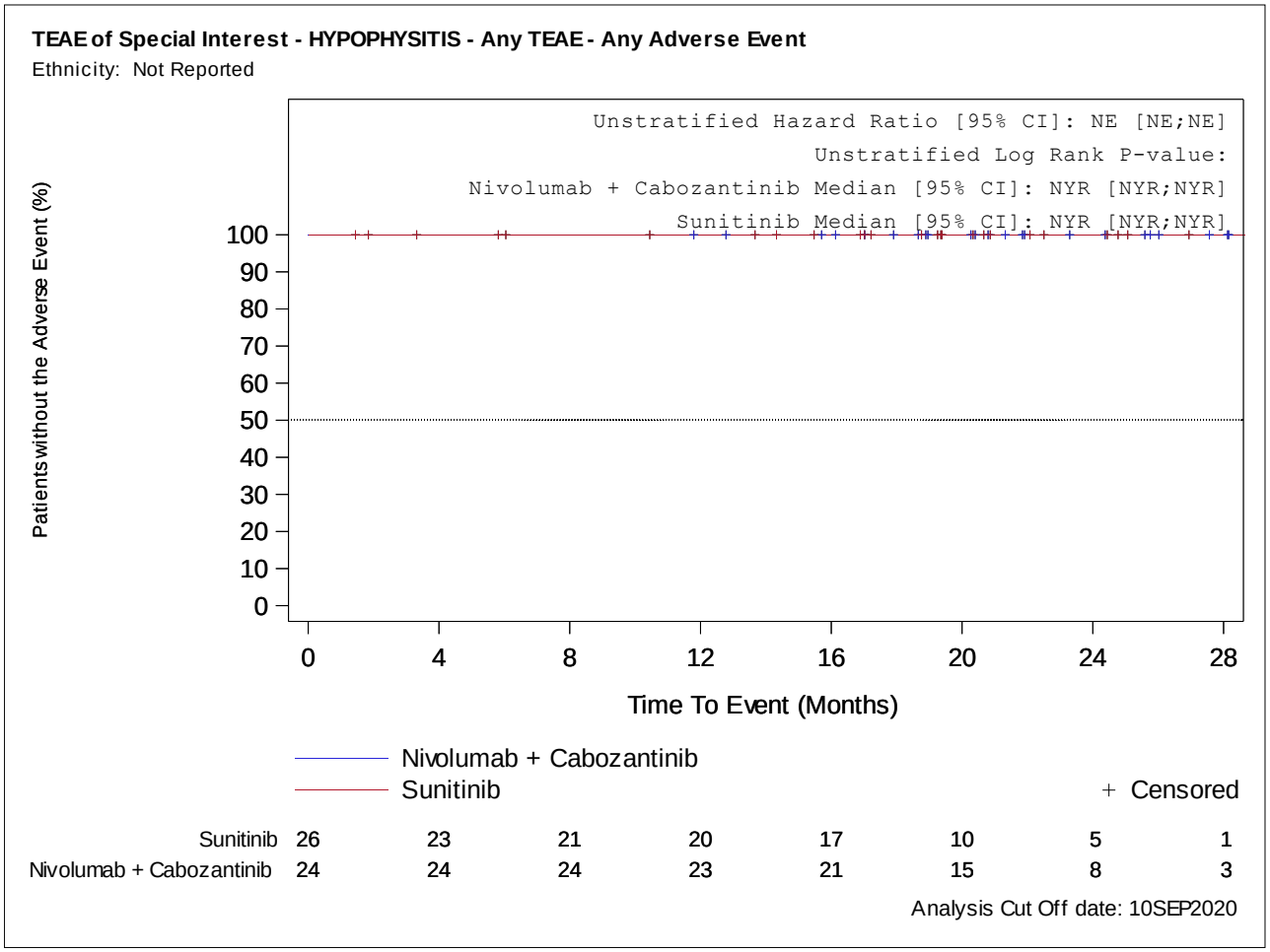

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:58:00

FIGURE 3.95.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



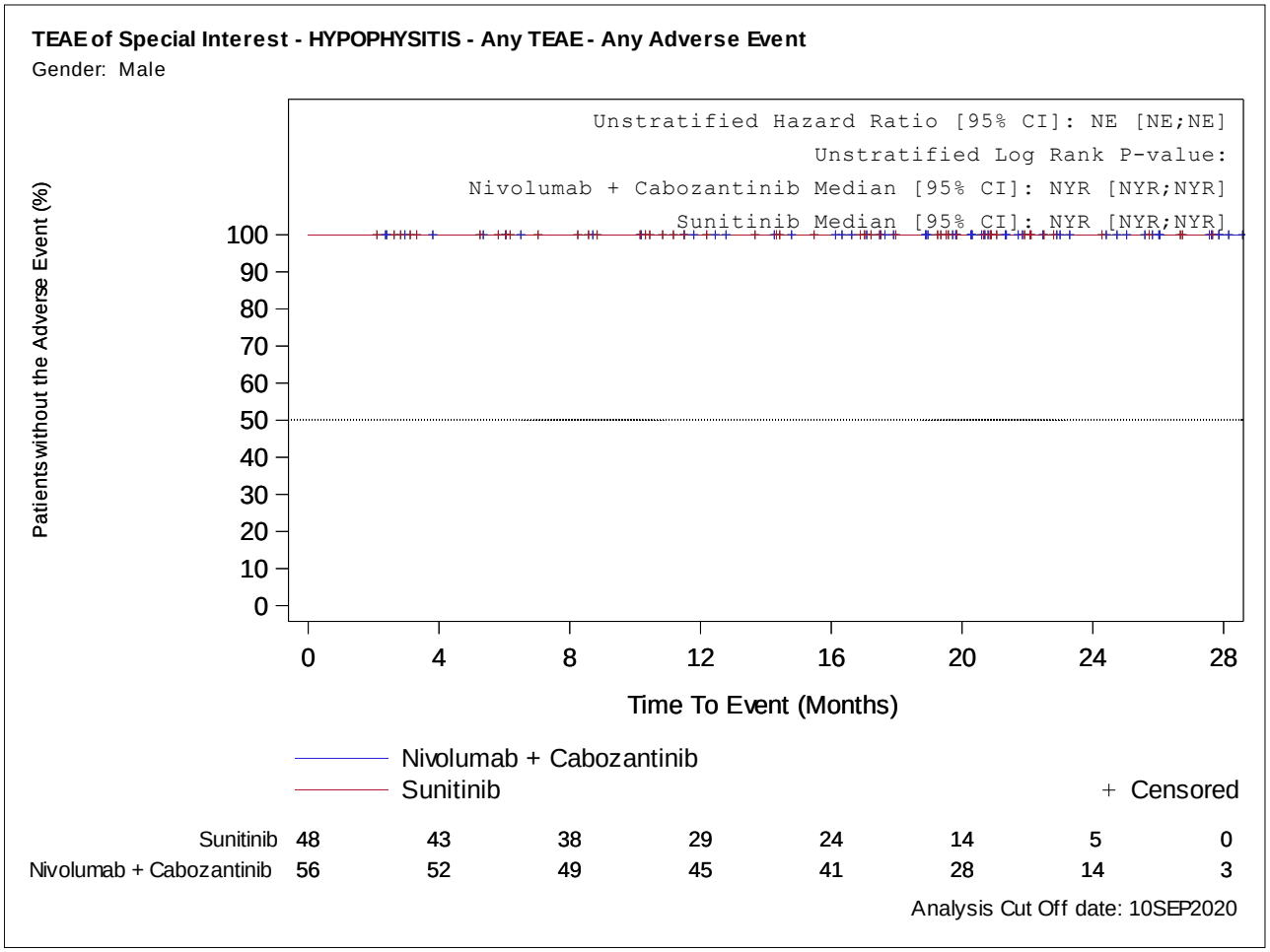

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:58:05

FIGURE 3.95.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



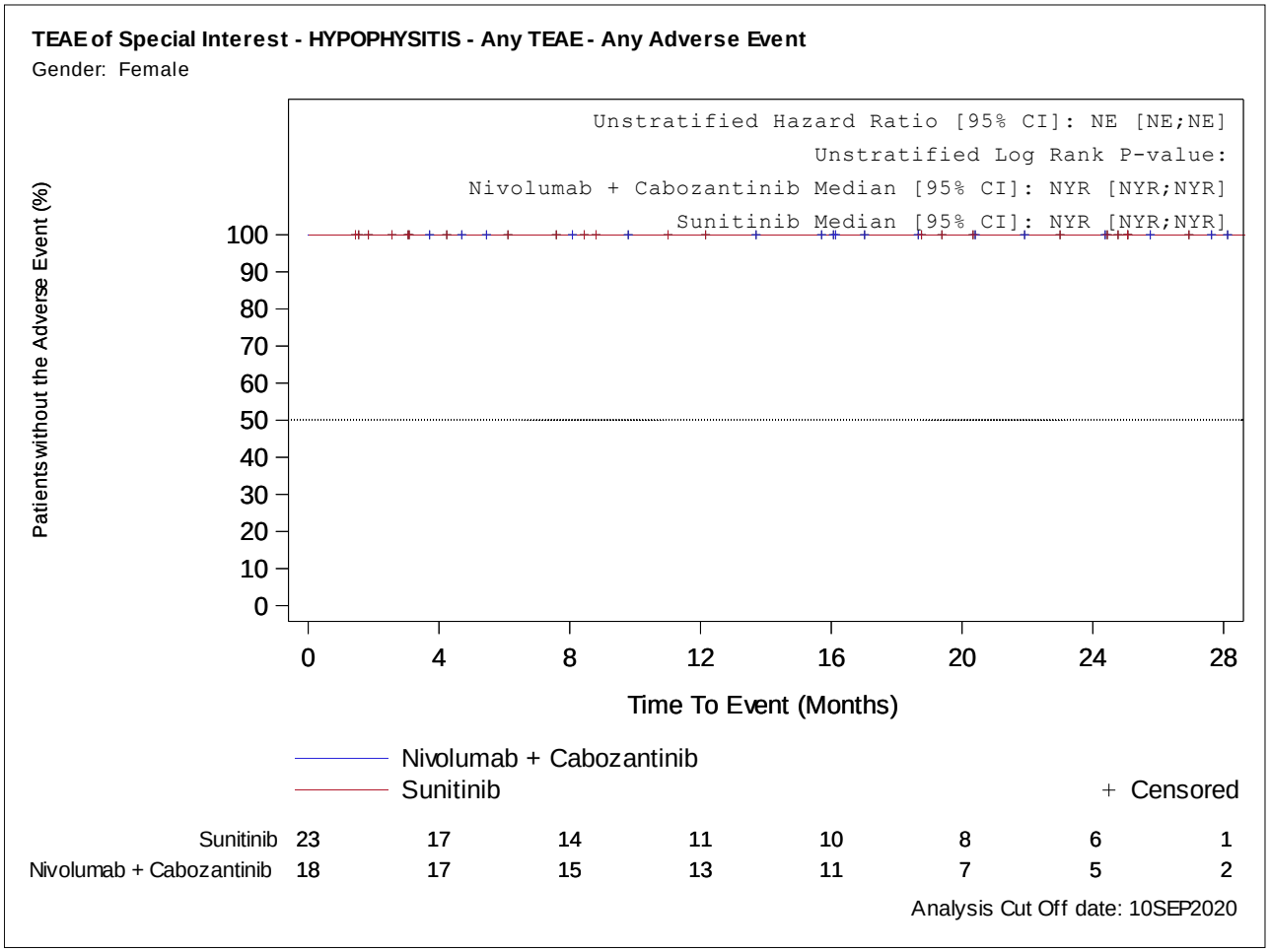

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:58:11

FIGURE 3.95.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



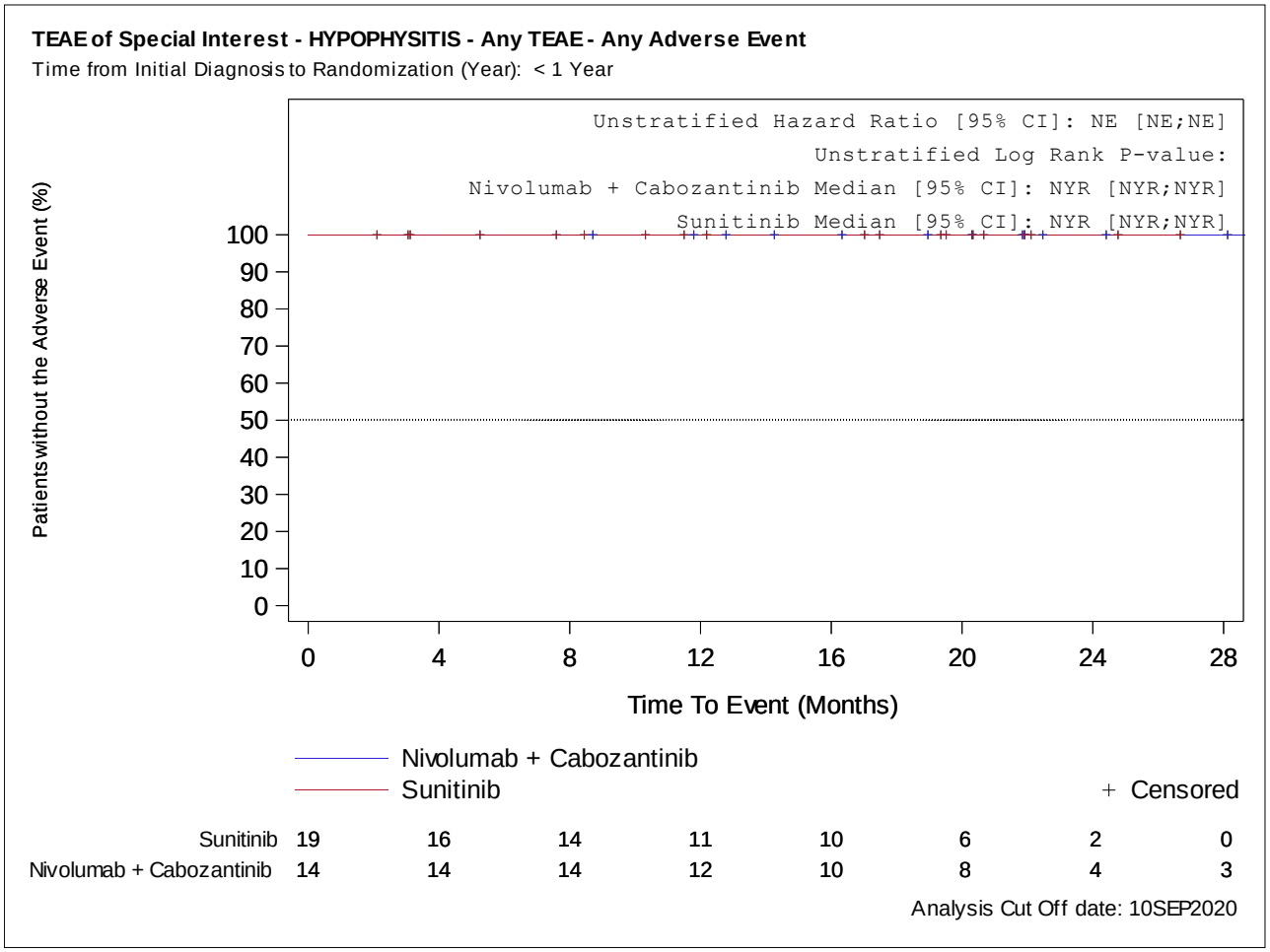

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:58:16

FIGURE 3.95.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



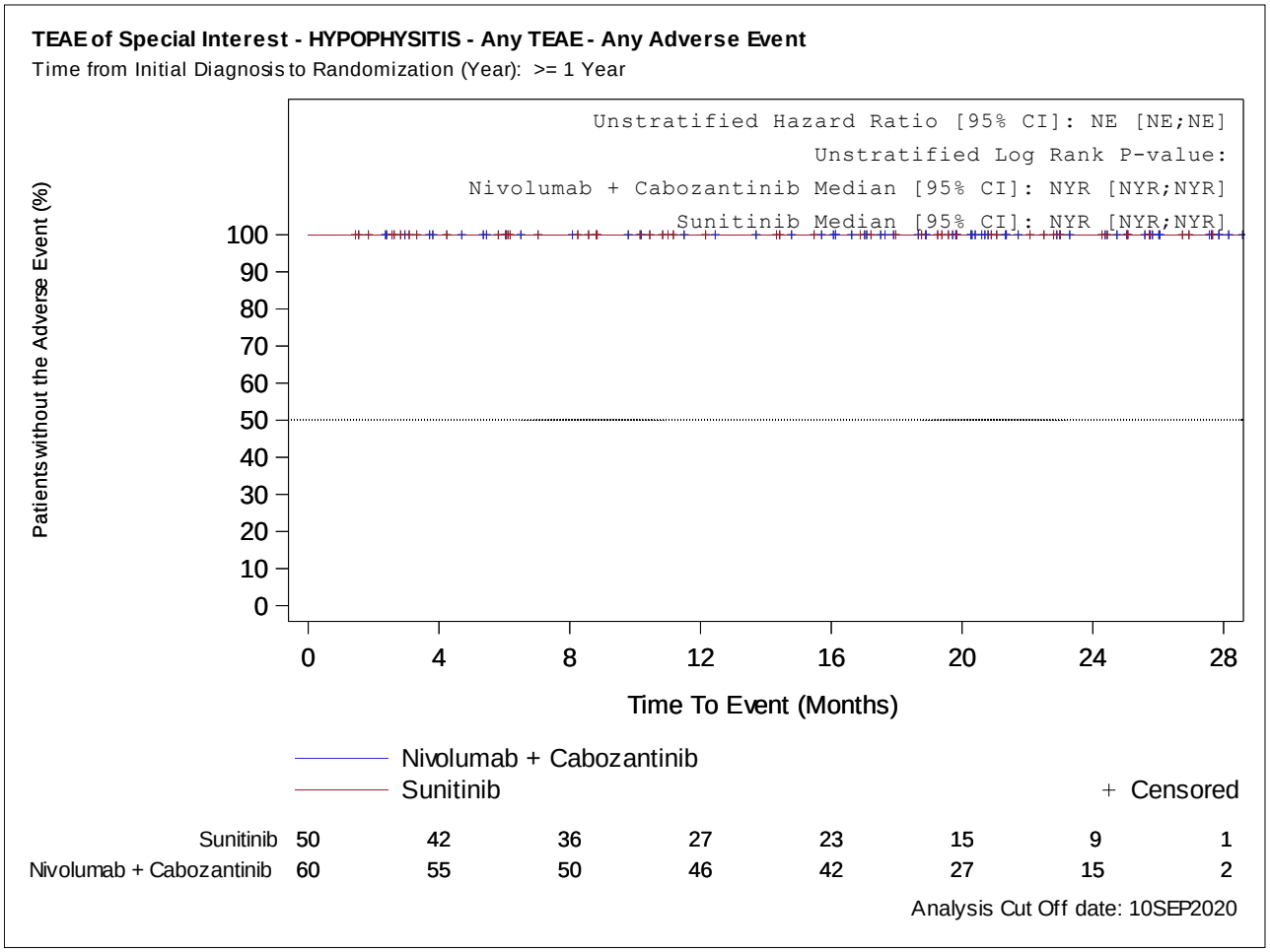

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:58:21

FIGURE 3.95.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



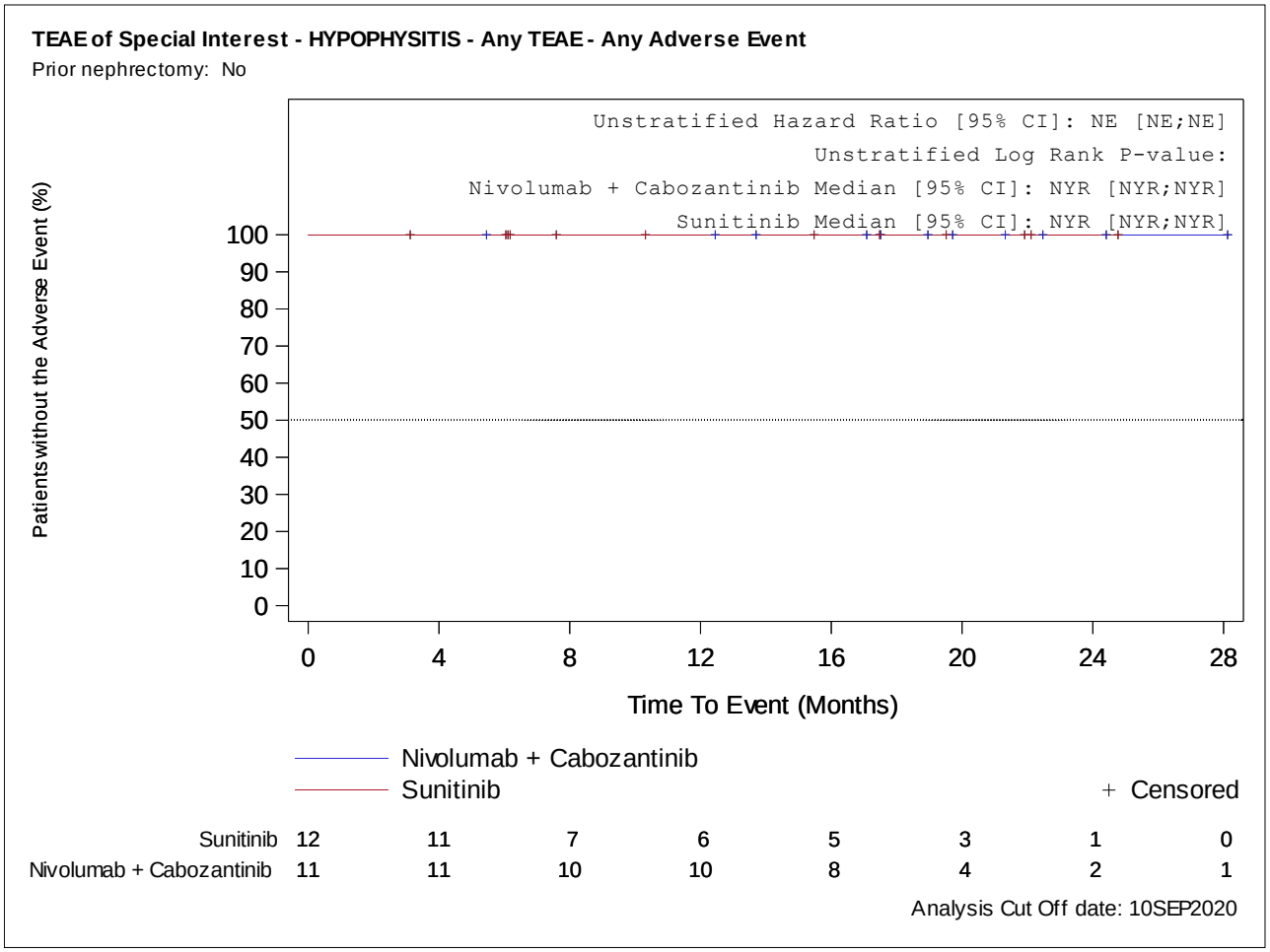

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:58:37

FIGURE 3.95.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



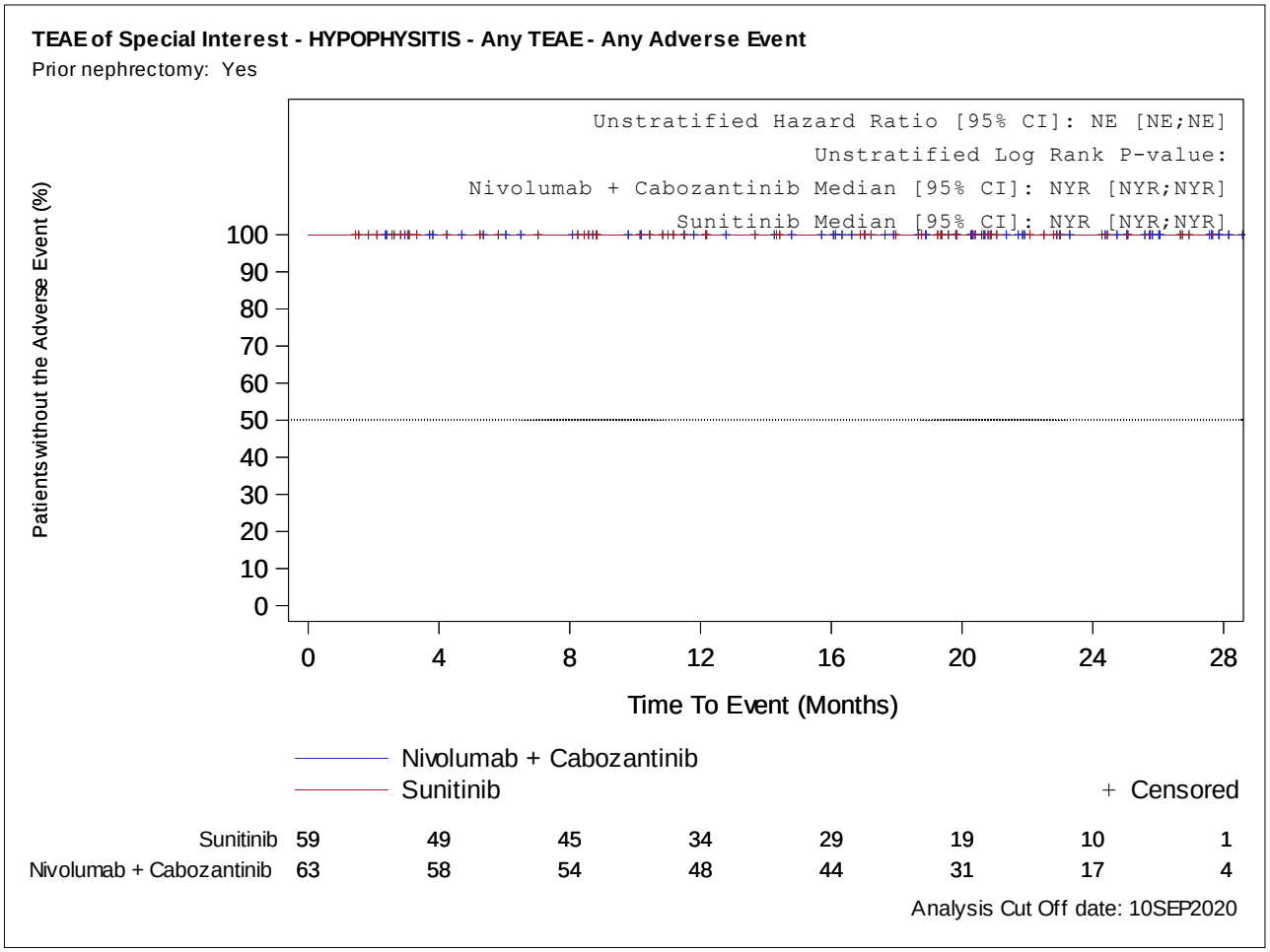

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:58:42

FIGURE 3.95.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



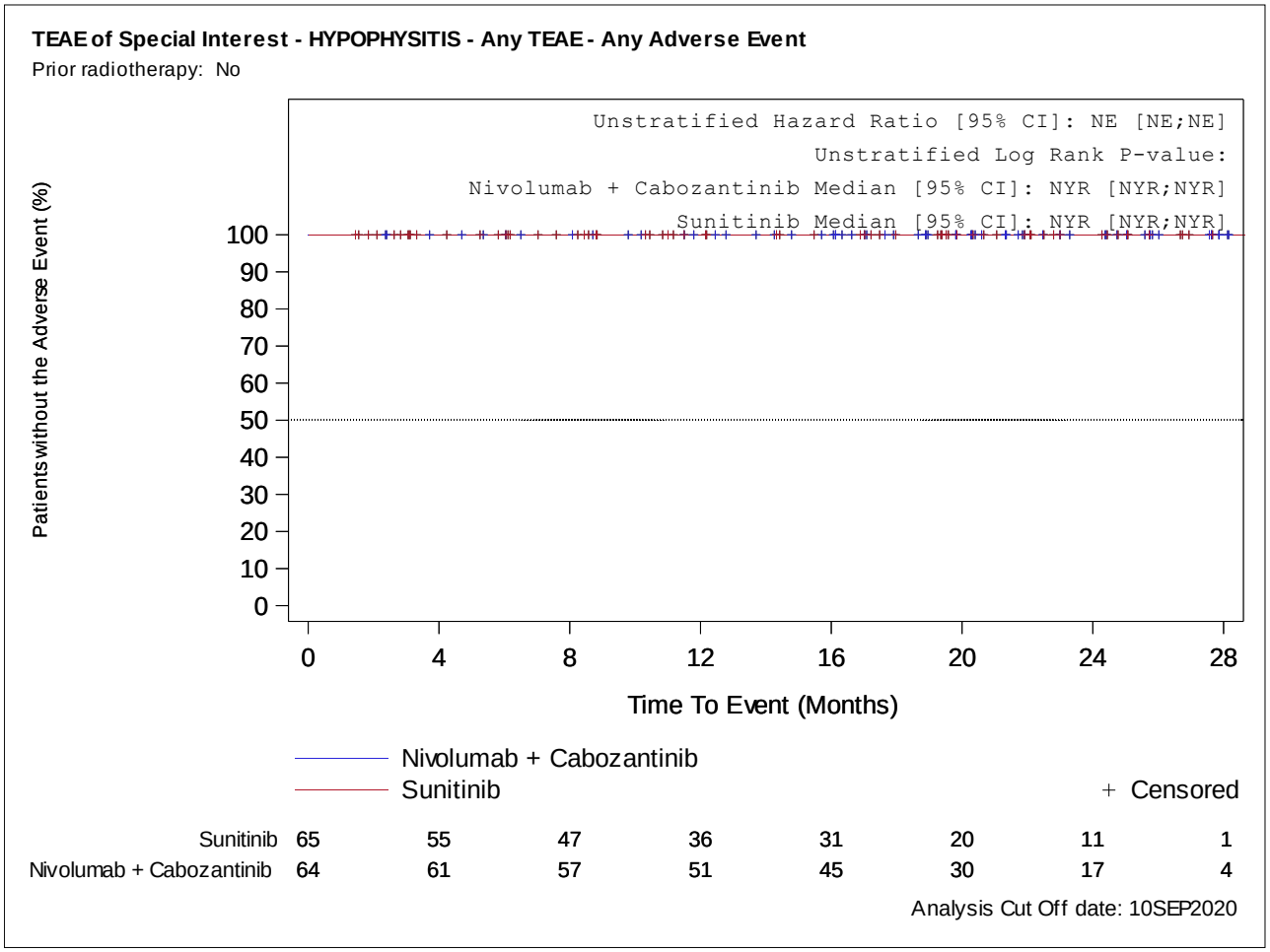

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:59:29

FIGURE 3.95.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



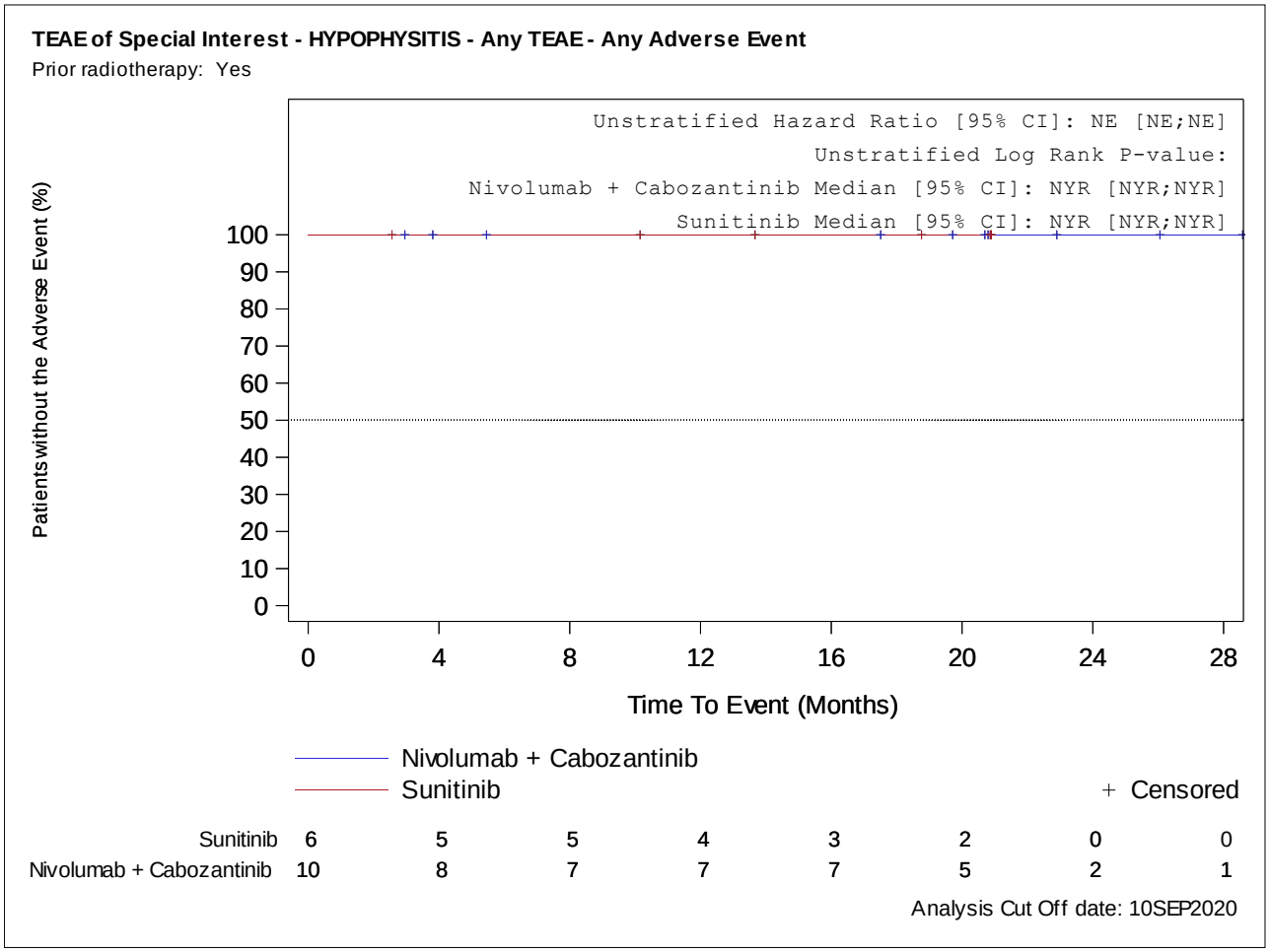

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:59:35

FIGURE 3.95.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



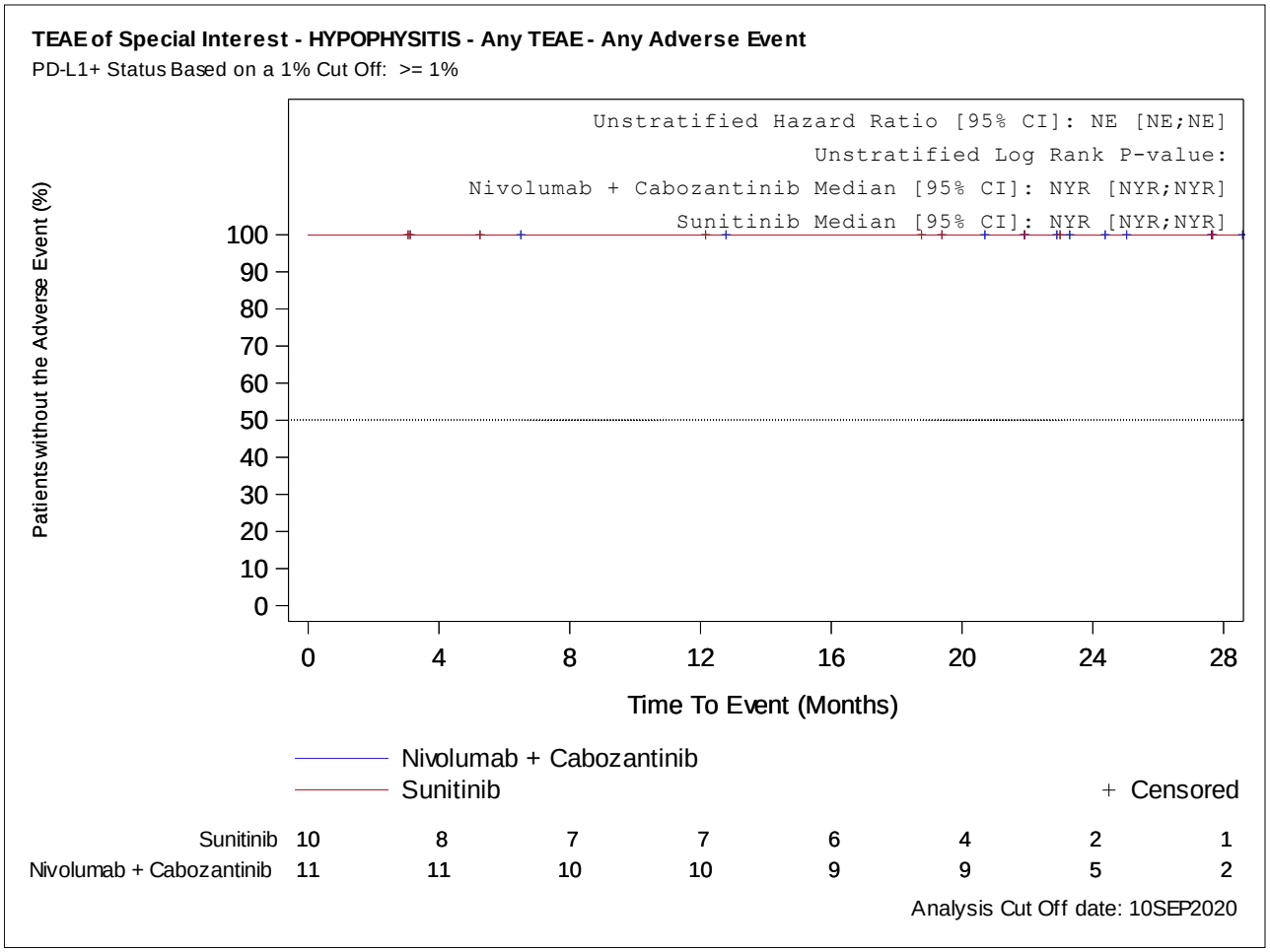

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:59:40

FIGURE 3.95.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



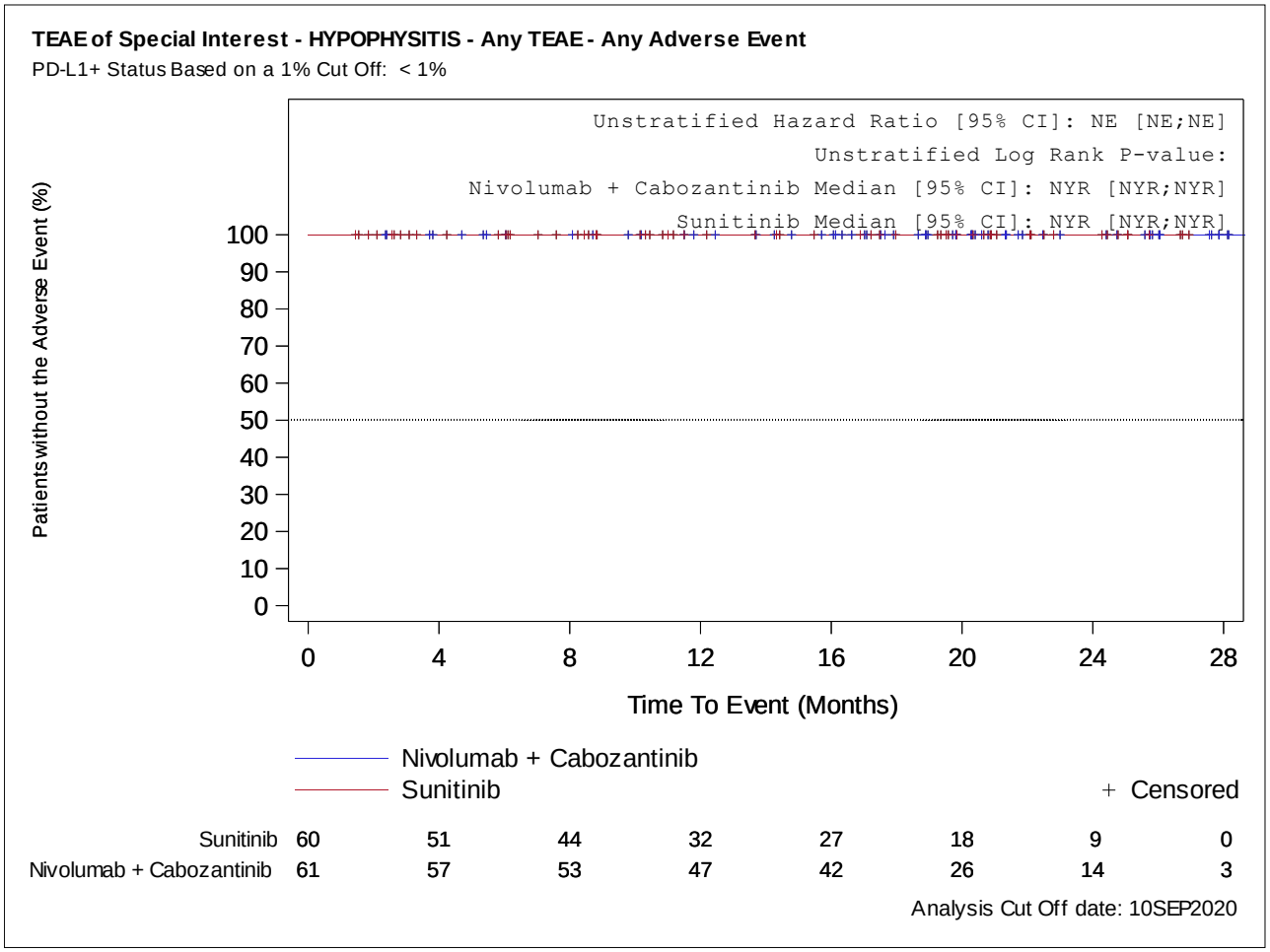

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:59:45

FIGURE 3.95.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



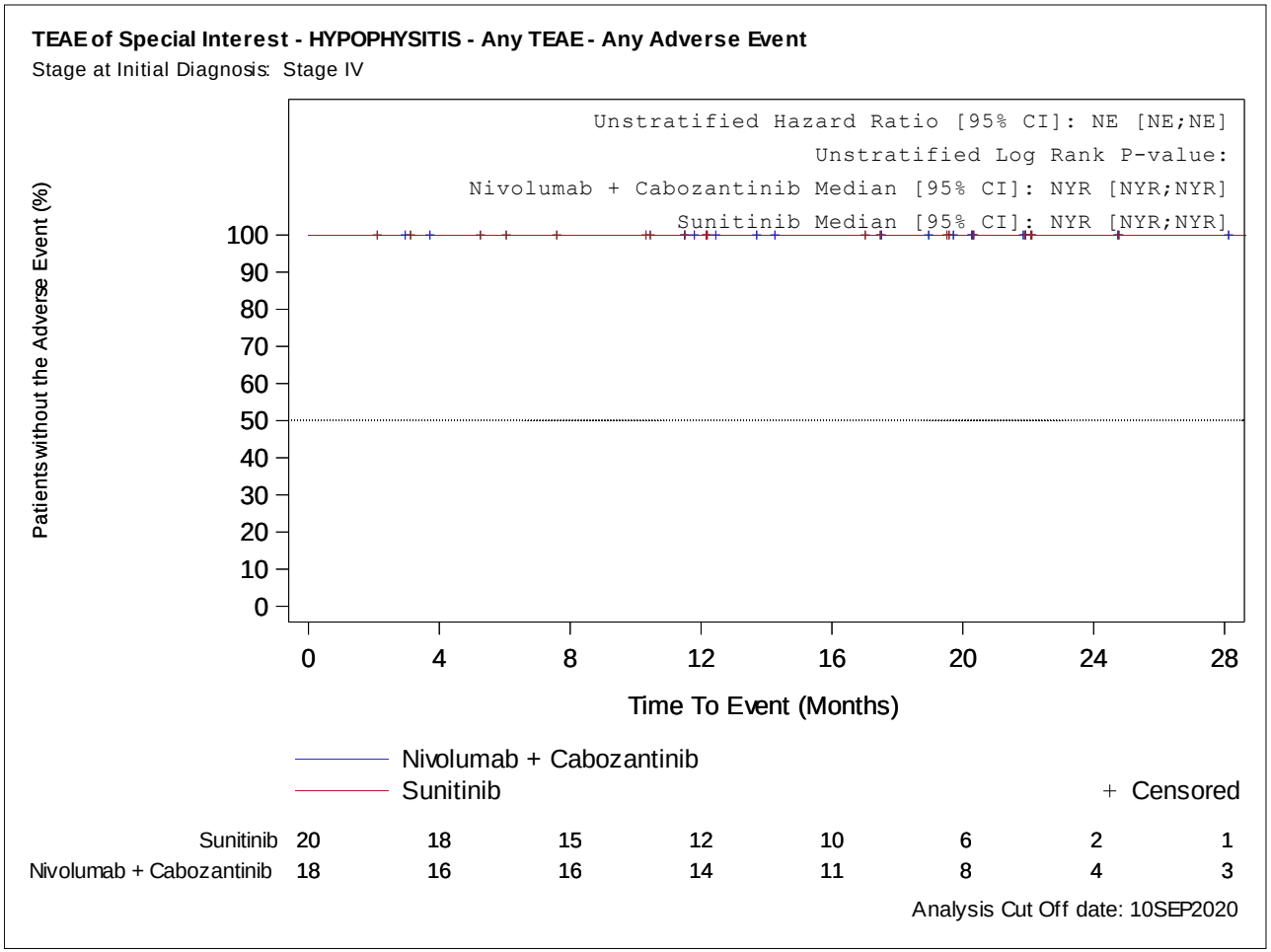

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:59:51

FIGURE 3.95.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



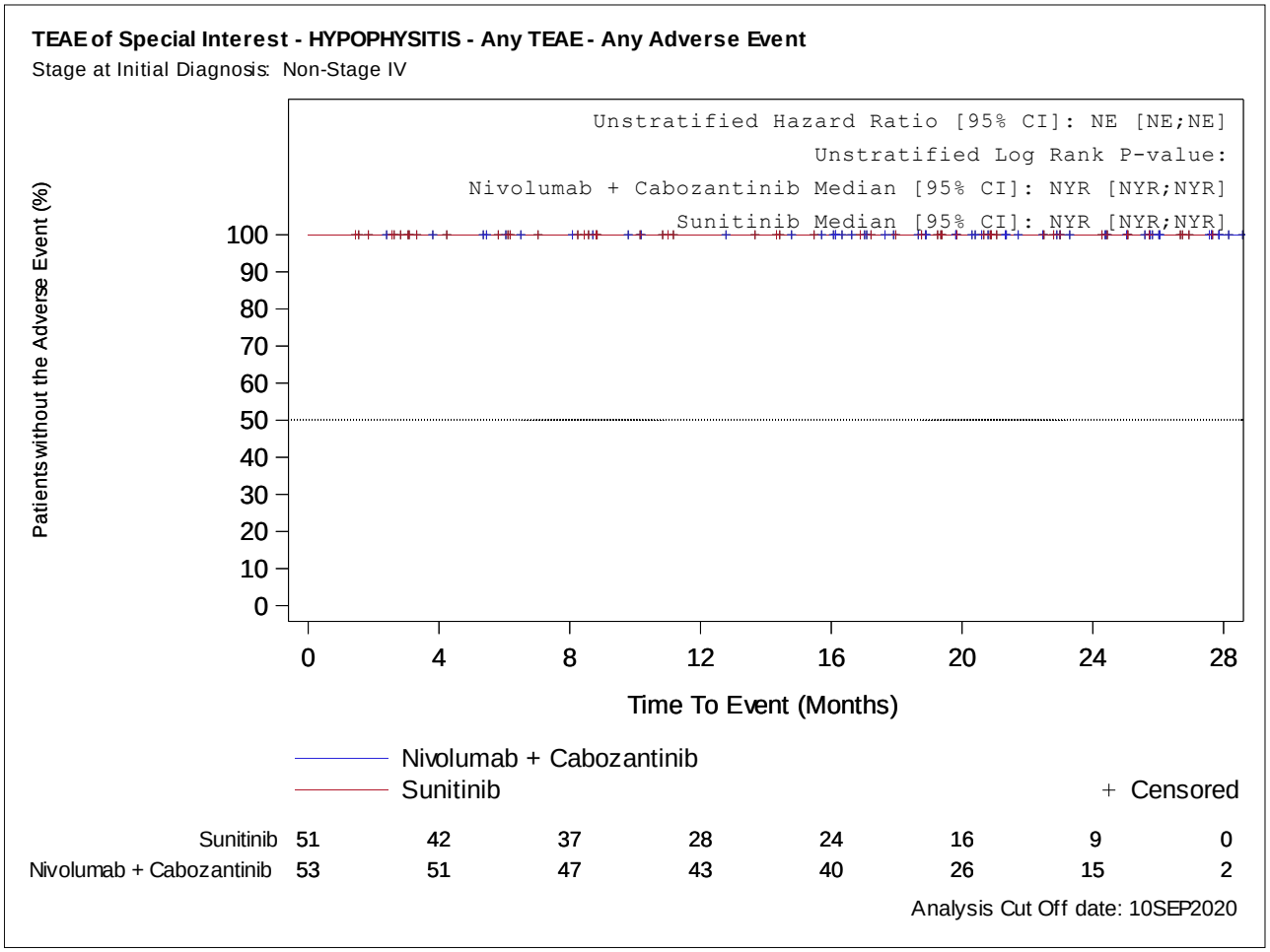

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 22:59:56

FIGURE 3.95.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



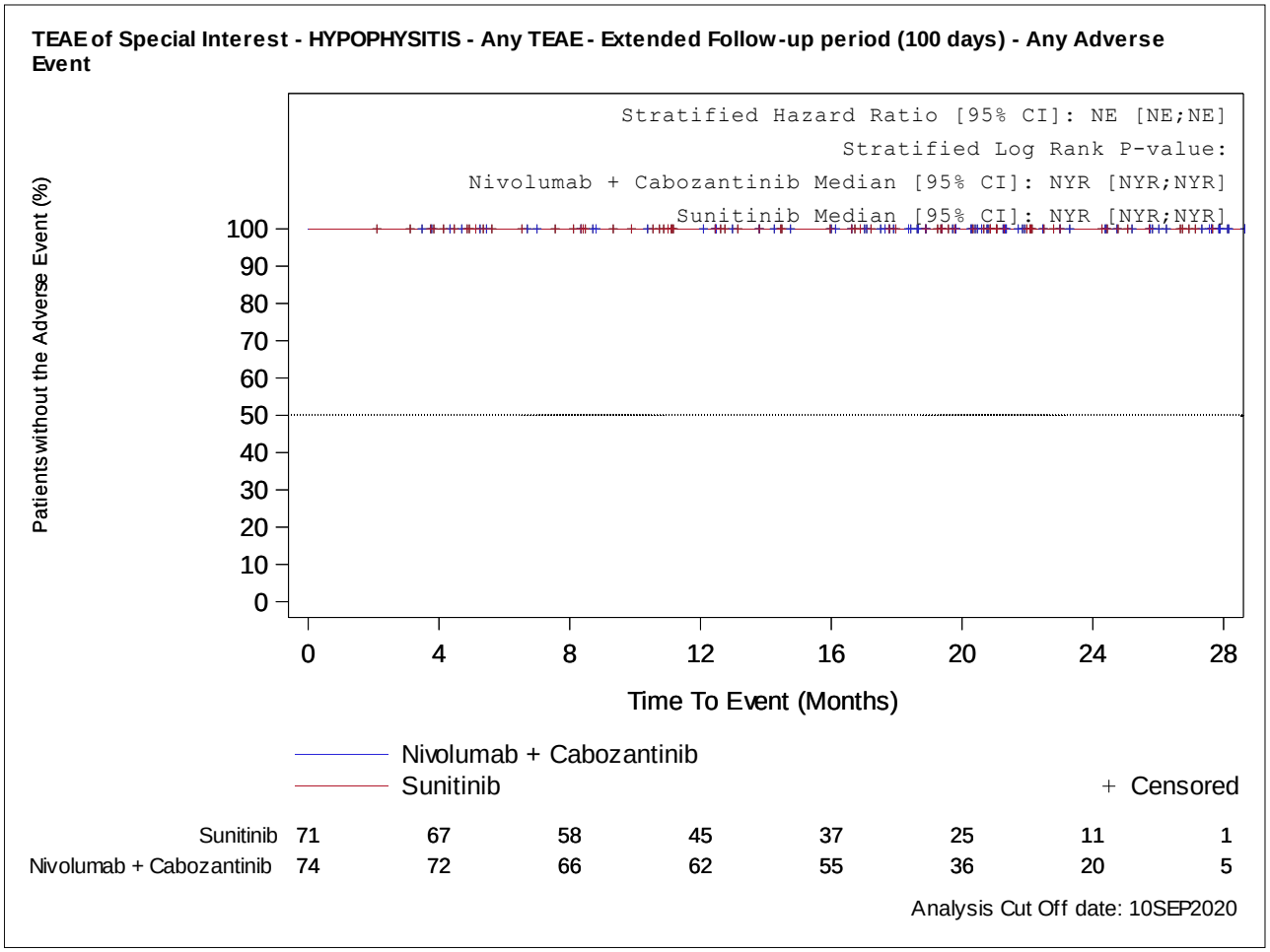

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:00:22

FIGURE 3.95.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



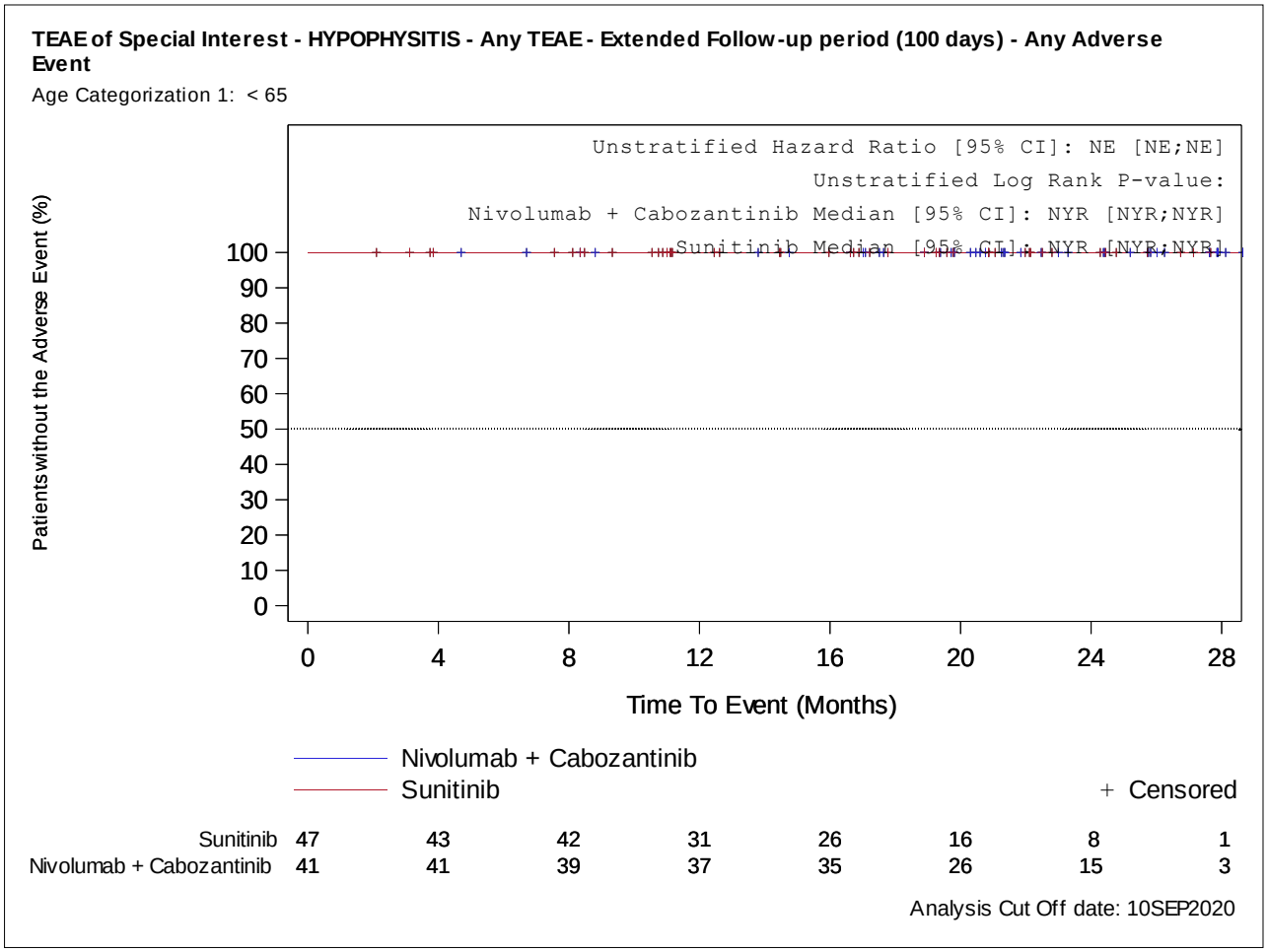

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:00:27

FIGURE 3.96.1: TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



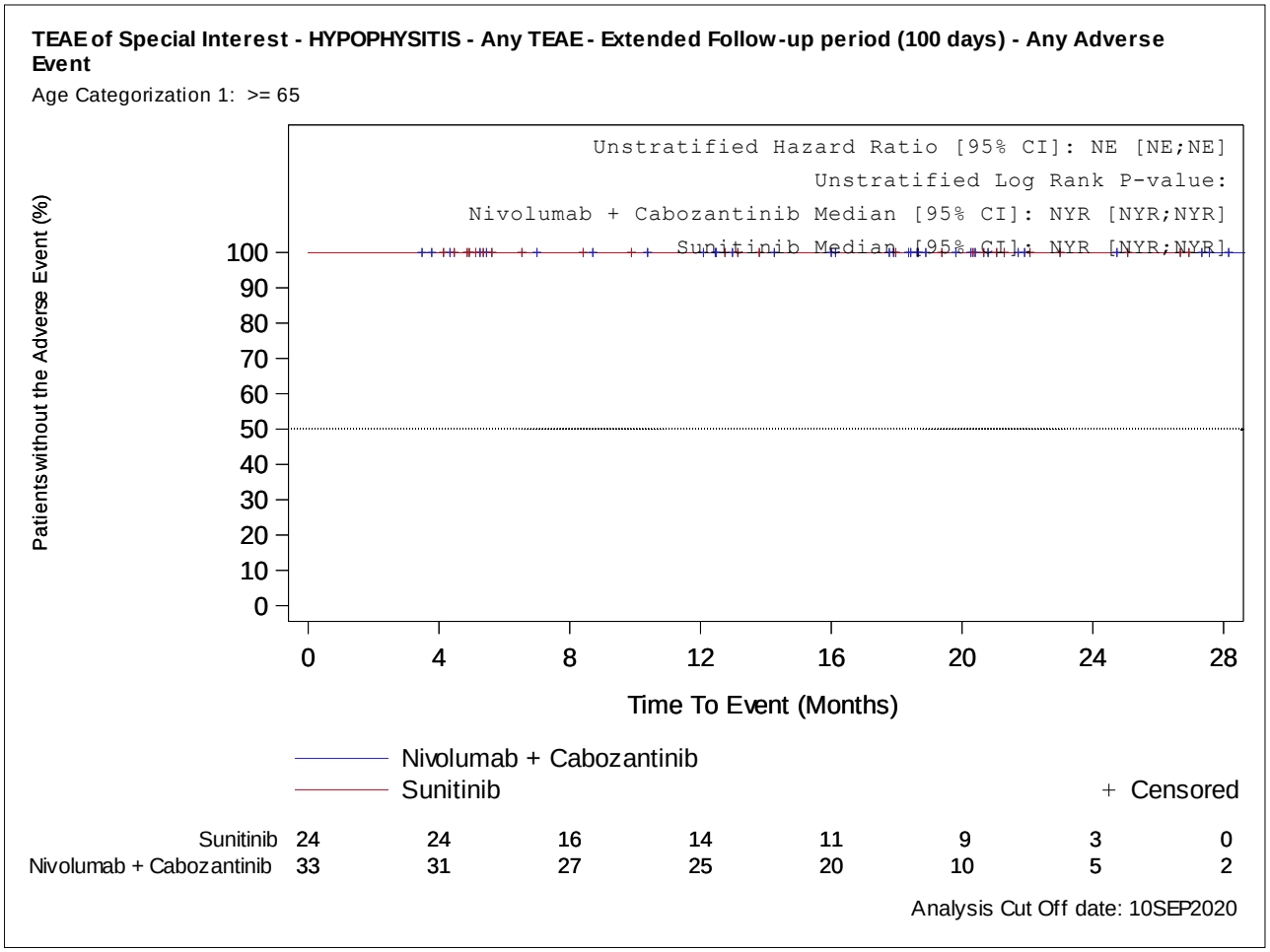

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:03:28

FIGURE 3.96.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



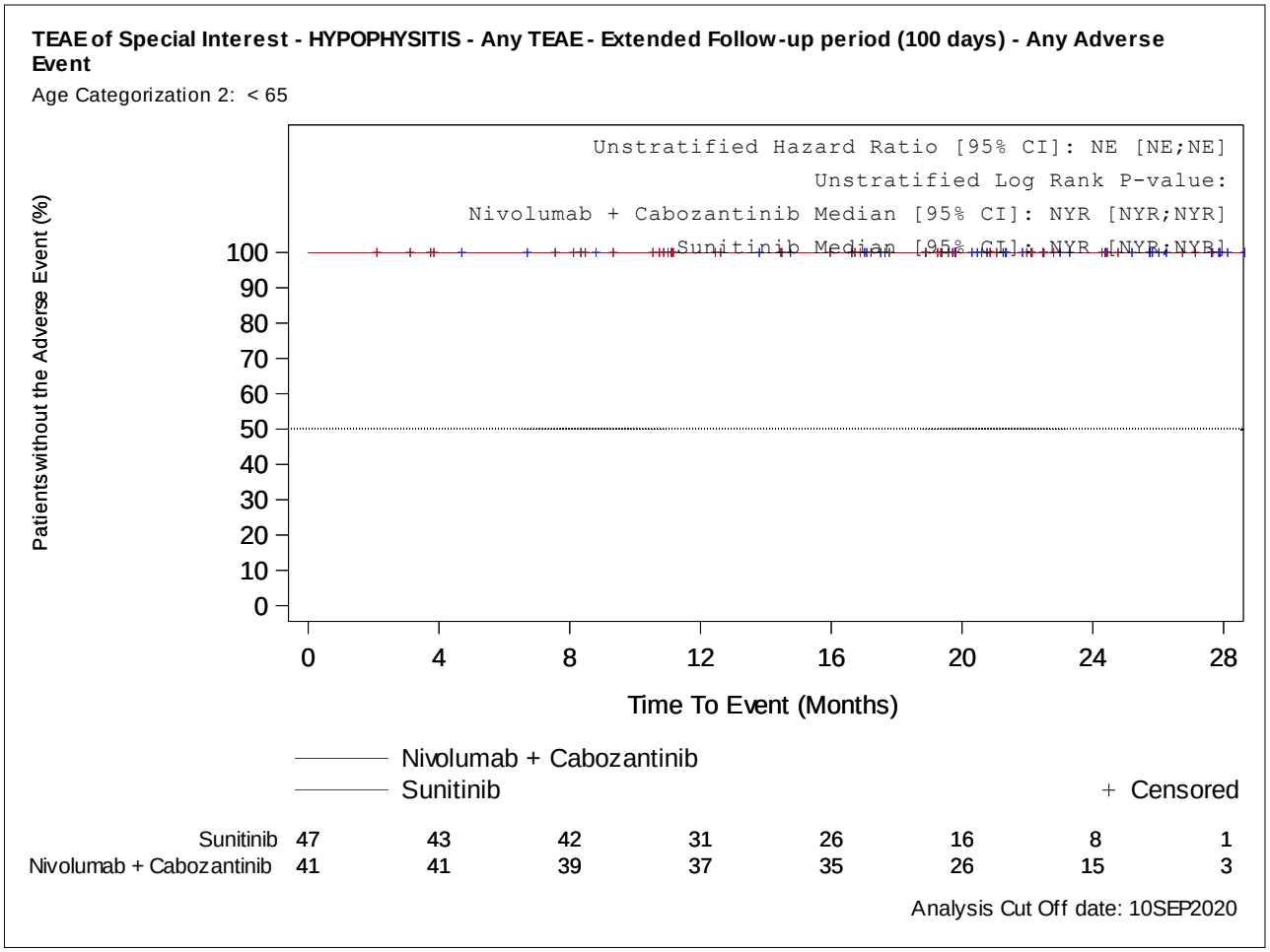

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:03:30

FIGURE 3.96.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



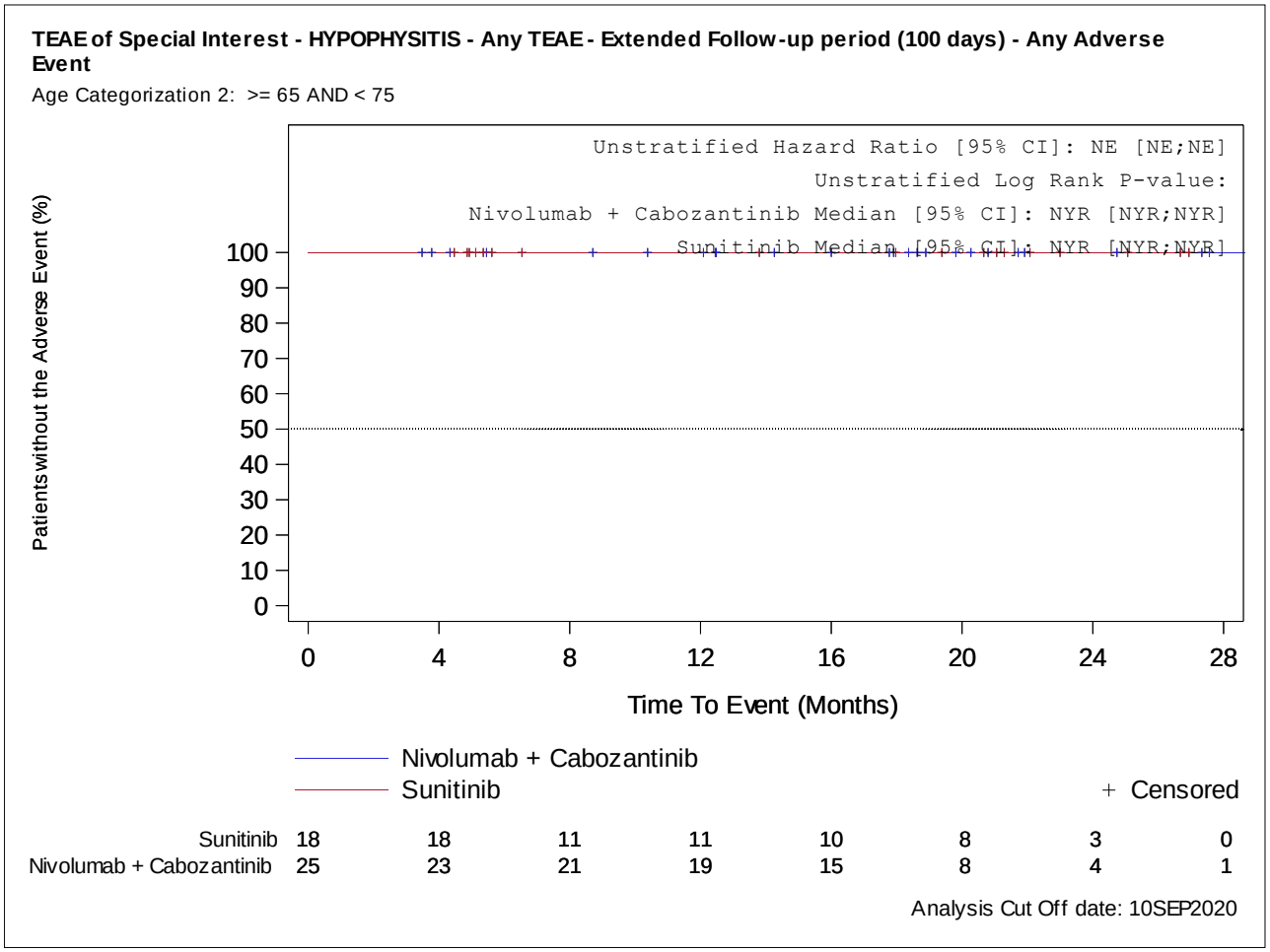

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:03:36

FIGURE 3.96.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



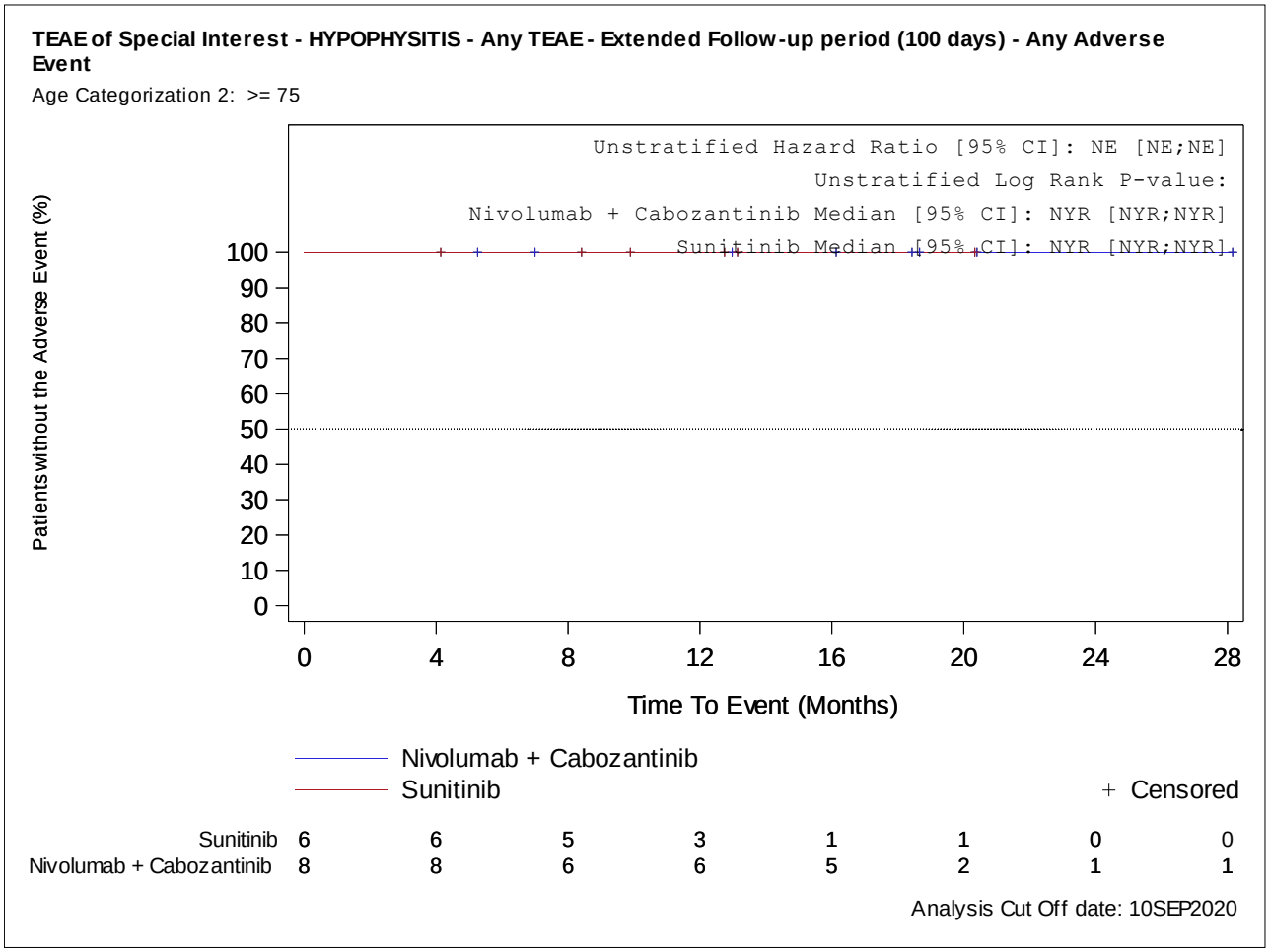

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:03:41

FIGURE 3.96.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



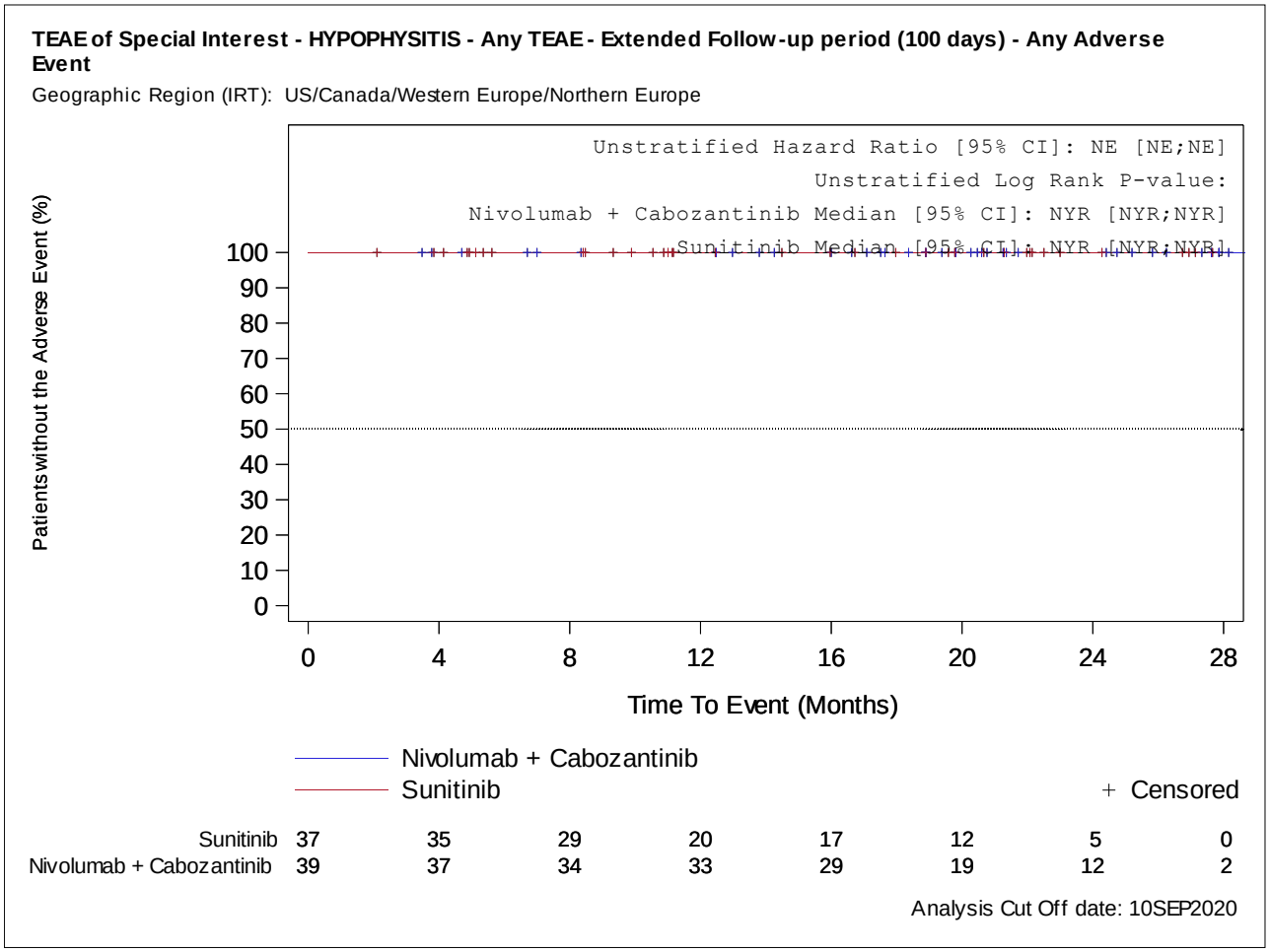

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:03:46

FIGURE 3.96.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



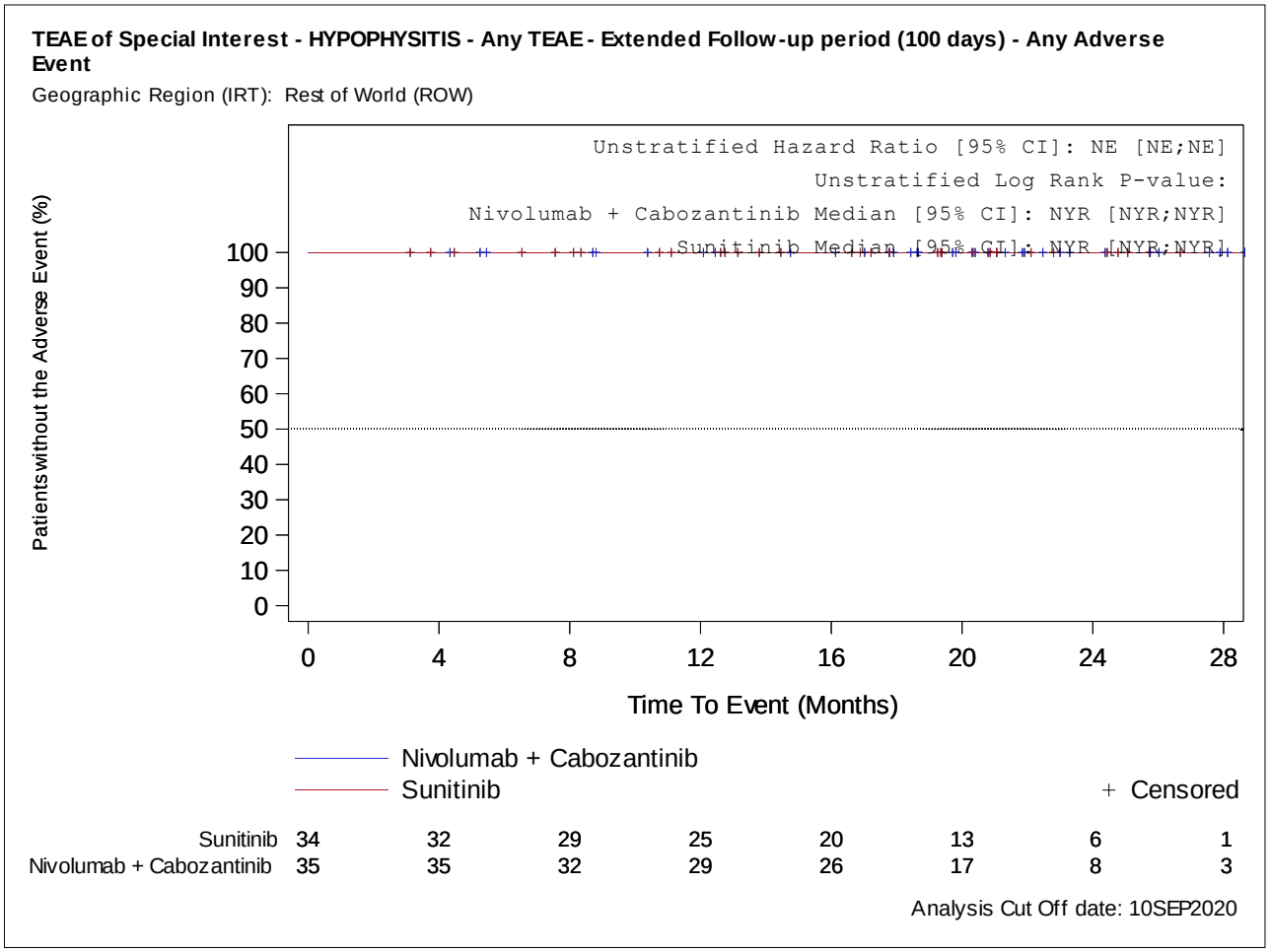

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:03:51

FIGURE 3.96.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



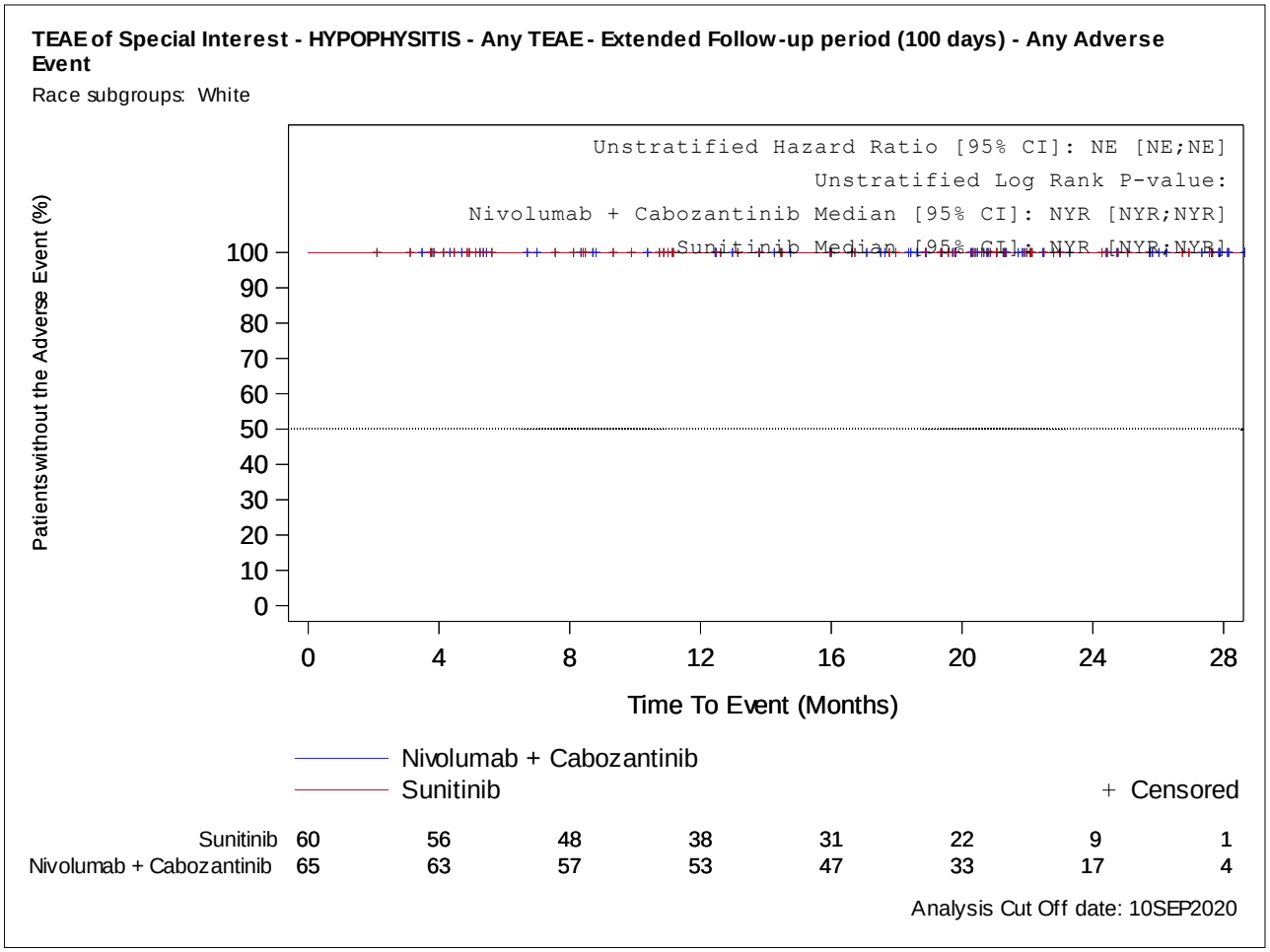

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:03:56

FIGURE 3.96.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



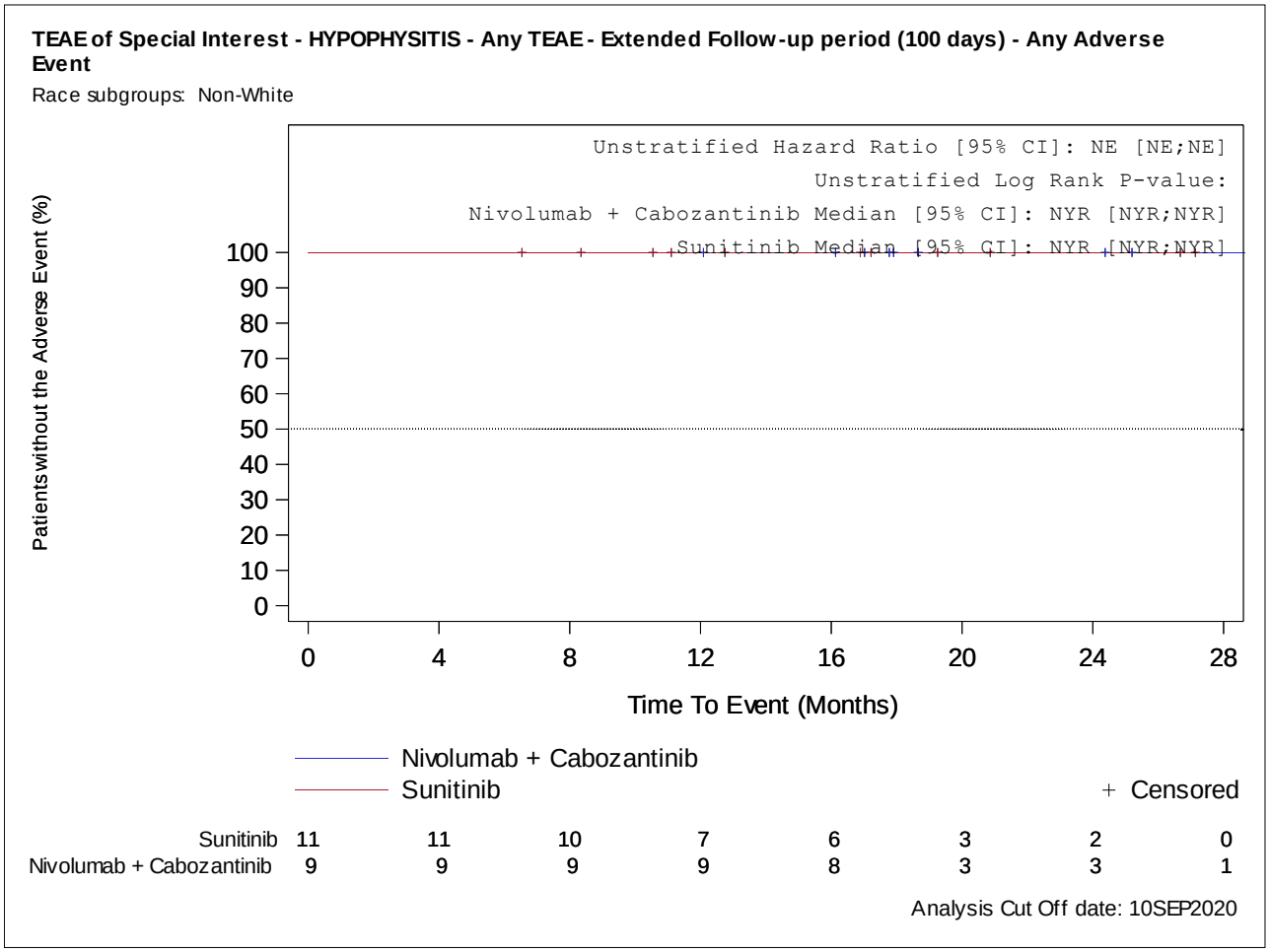

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:02

FIGURE 3.96.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



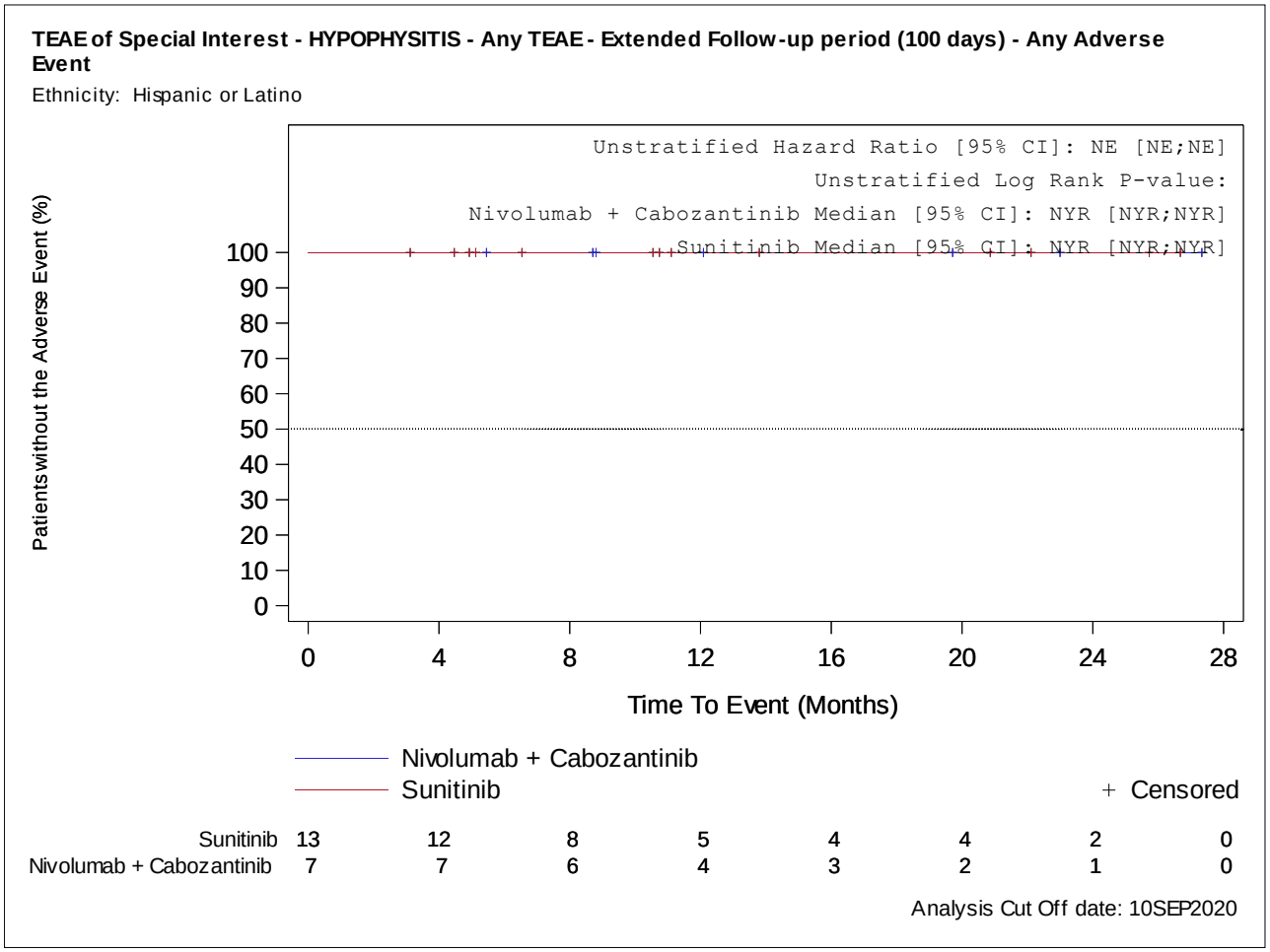

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:07

FIGURE 3.96.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



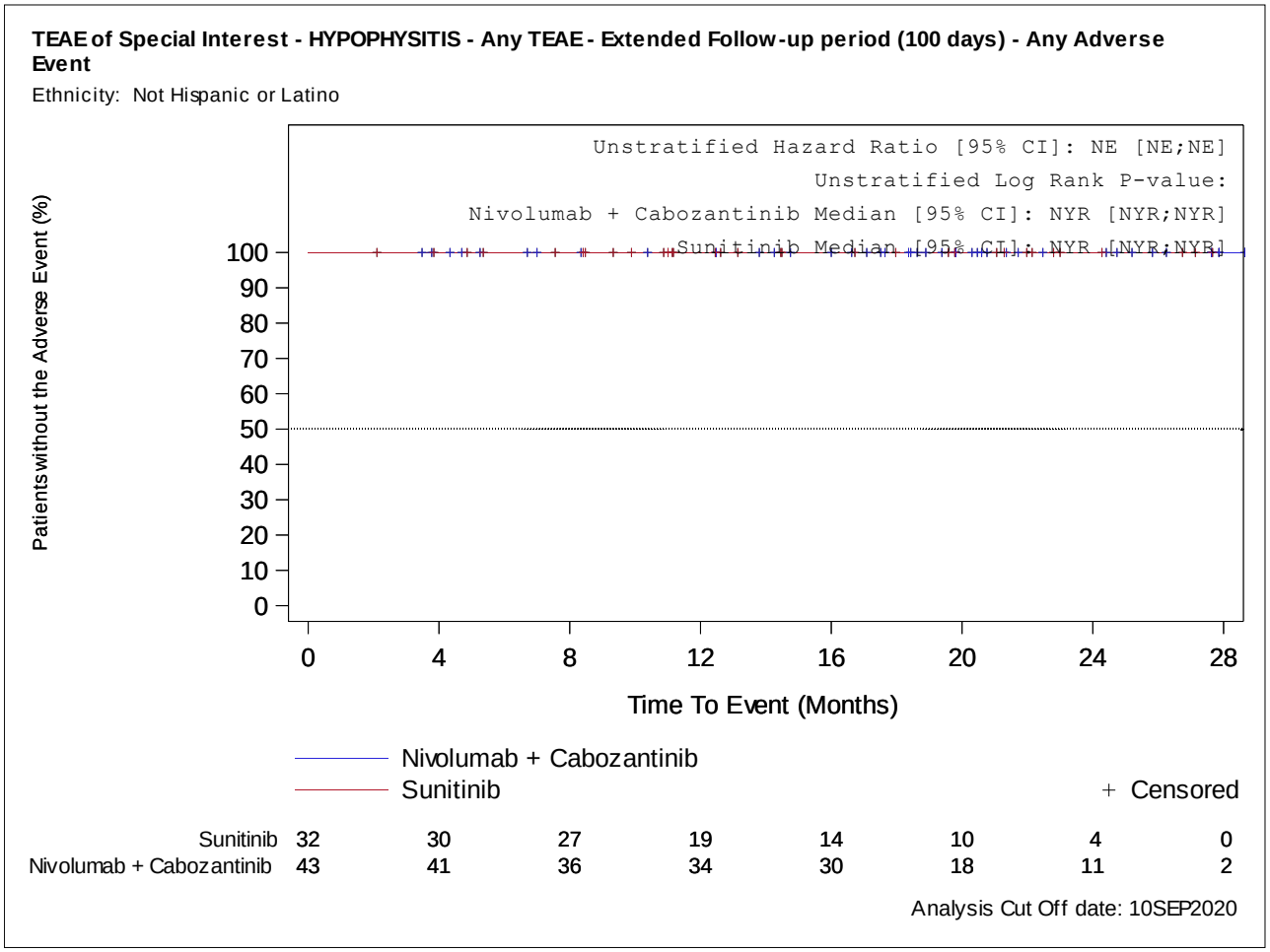

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:12

FIGURE 3.96.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



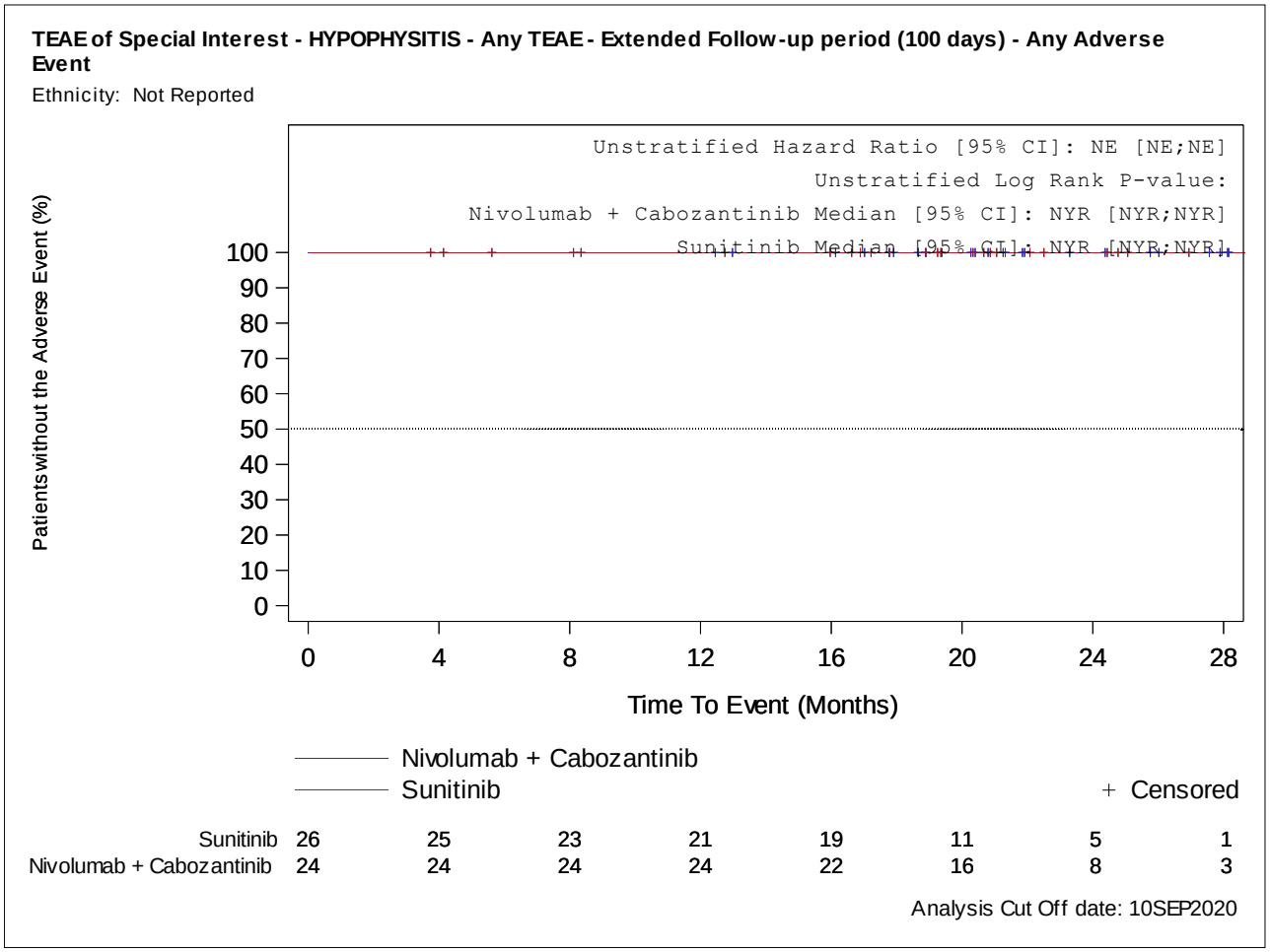

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:17

FIGURE 3.96.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



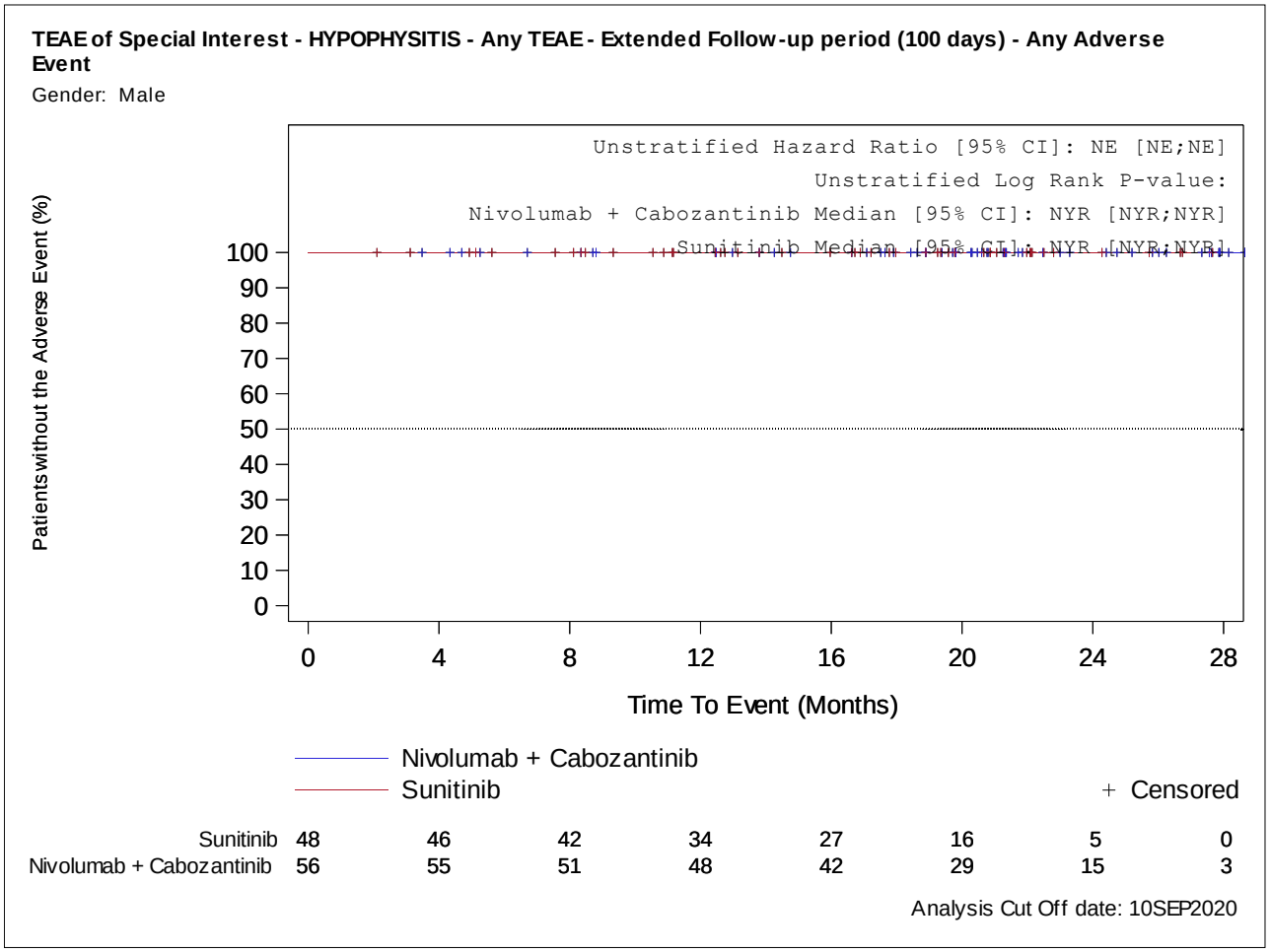

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:22

FIGURE 3.96.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



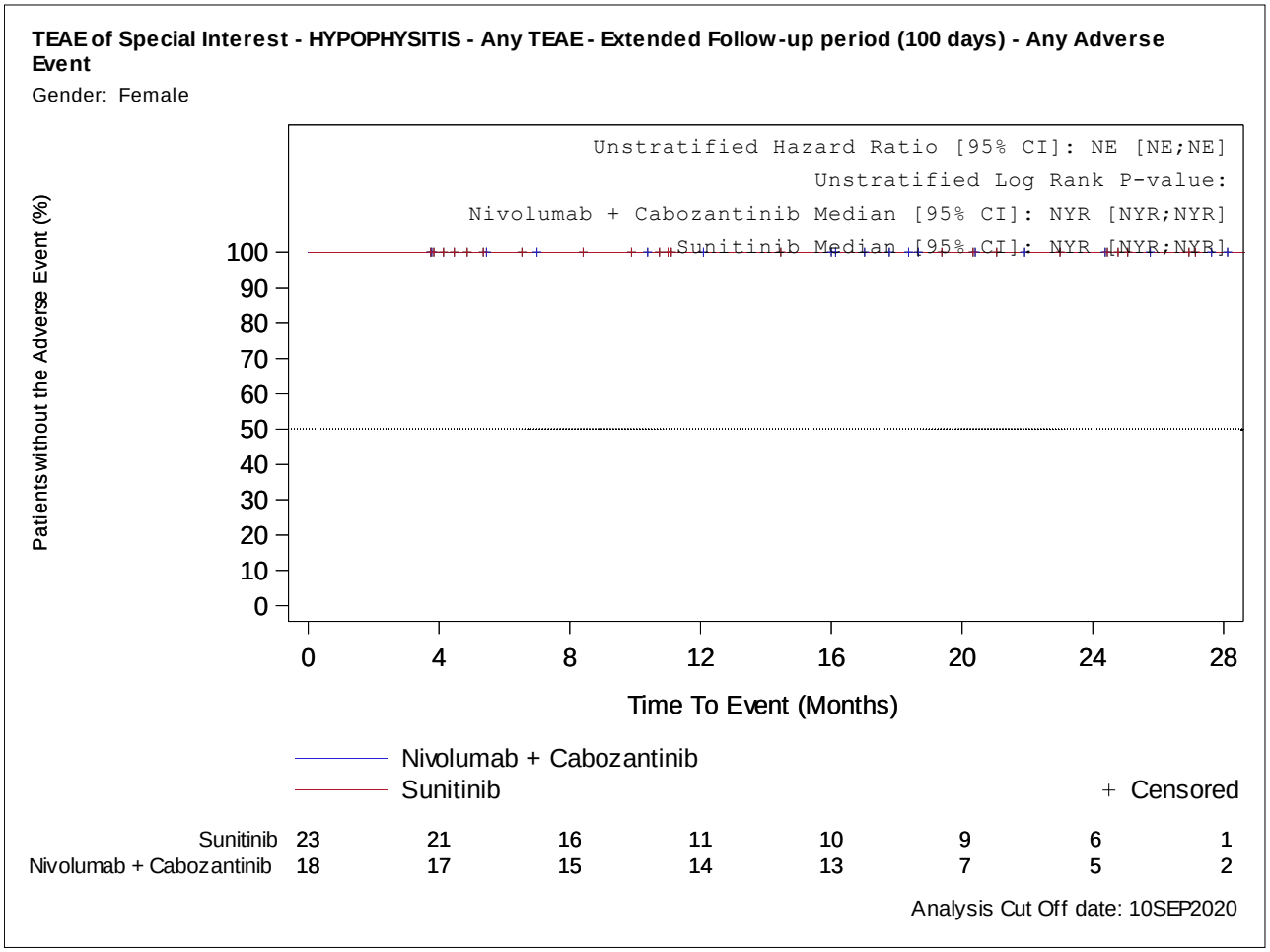

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:27

FIGURE 3.96.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



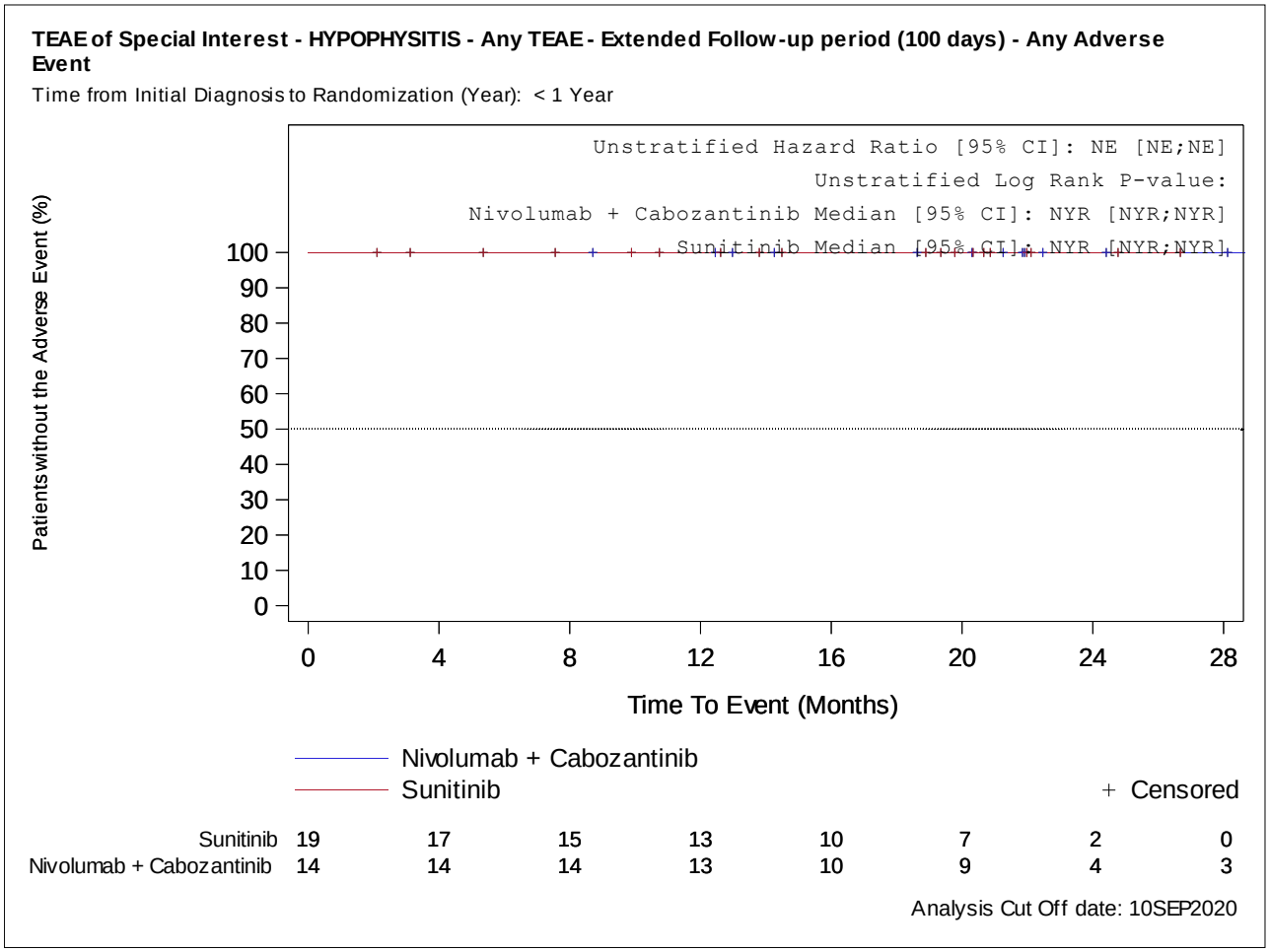

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:32

FIGURE 3.96.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



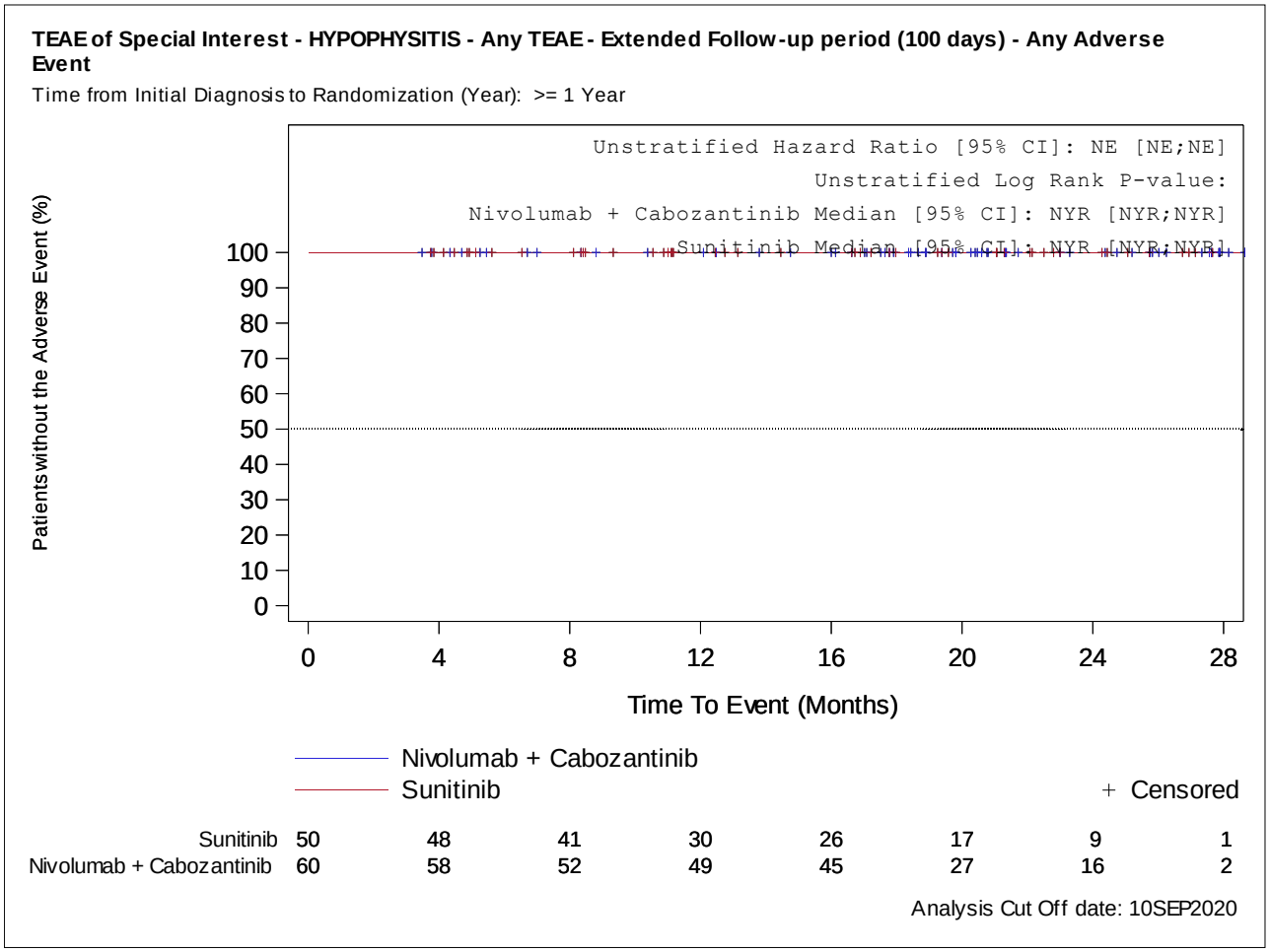

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:38

FIGURE 3.96.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



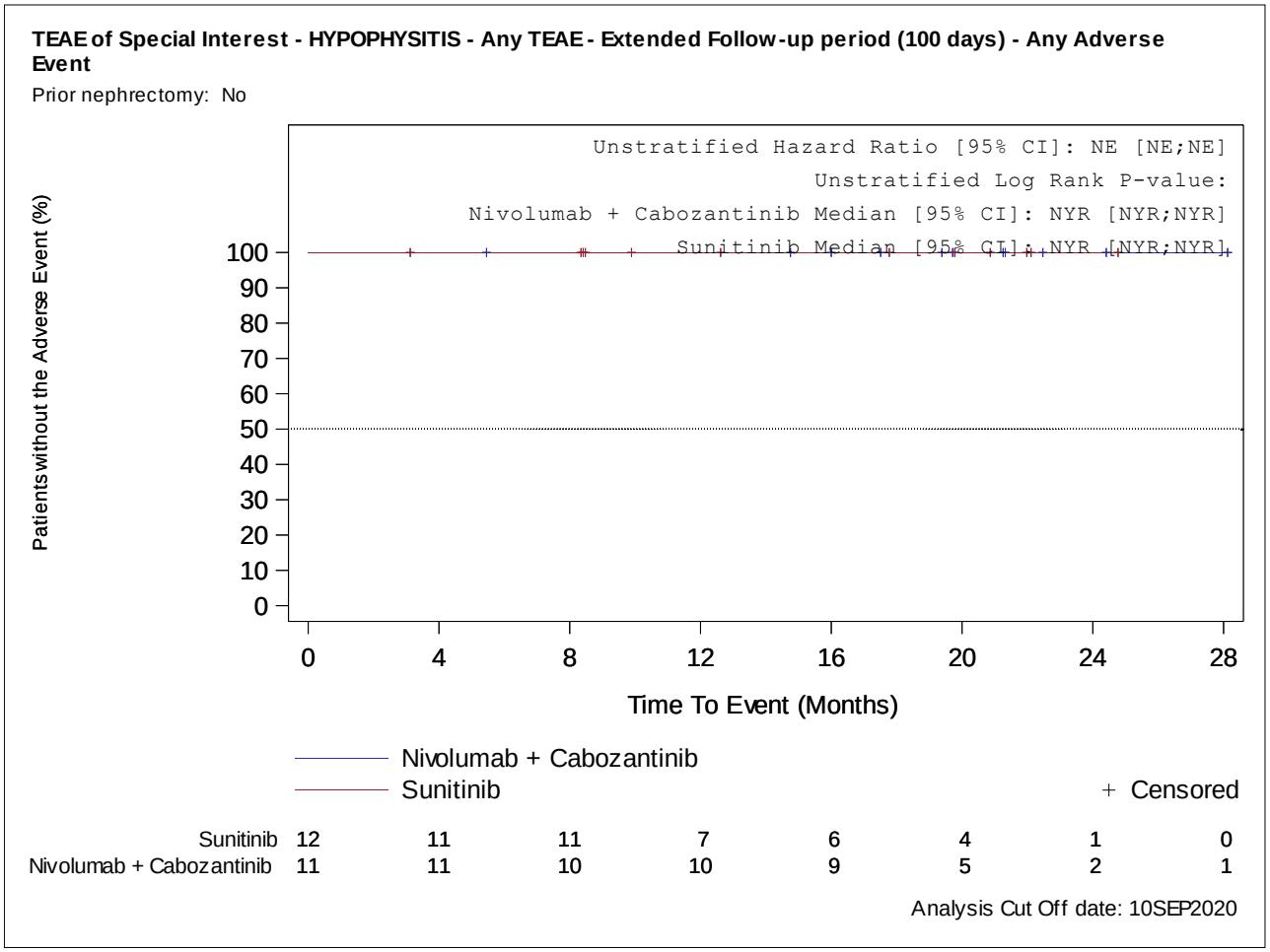

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:53

FIGURE 3.96.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



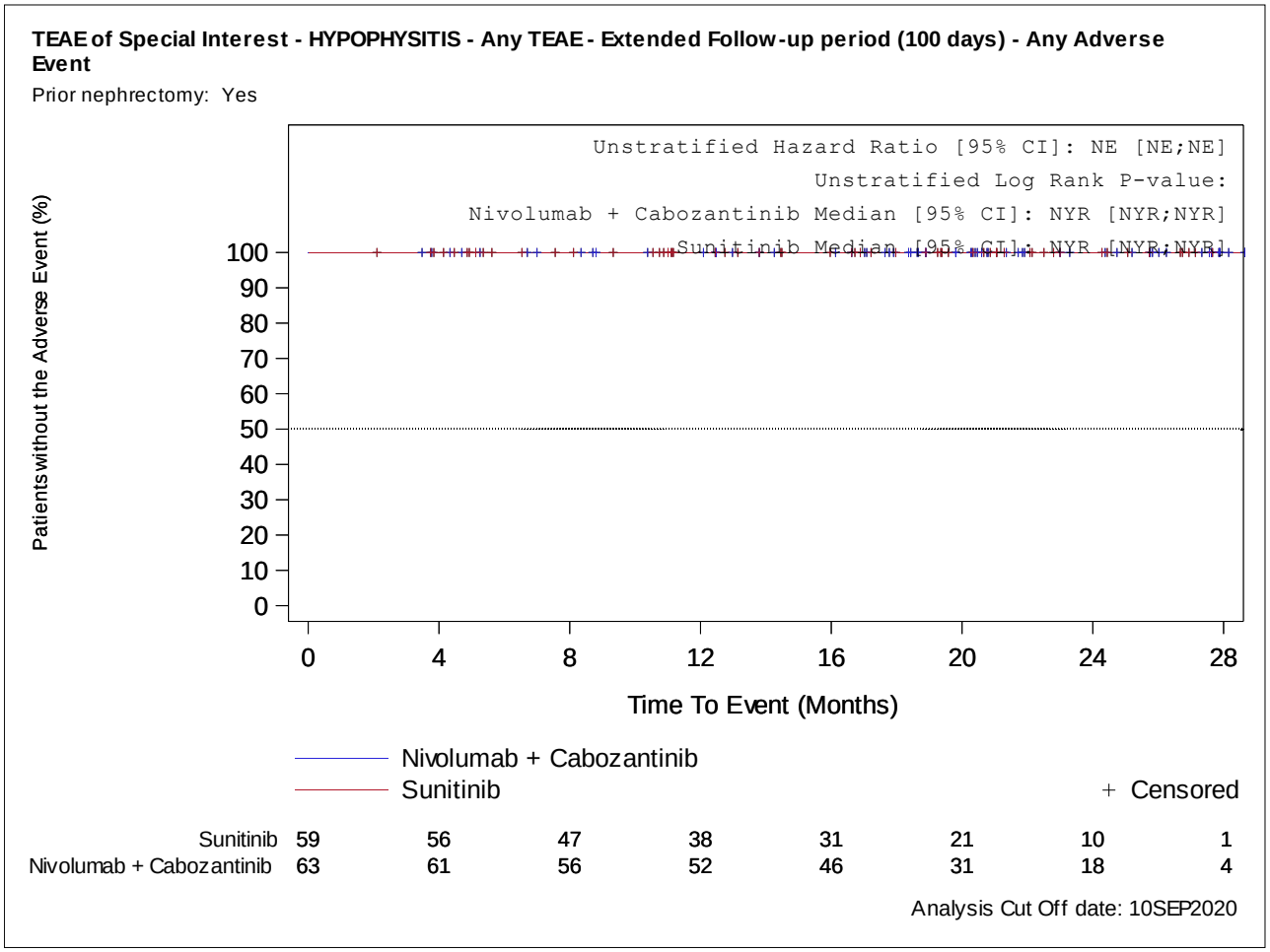

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:04:58

FIGURE 3.96.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



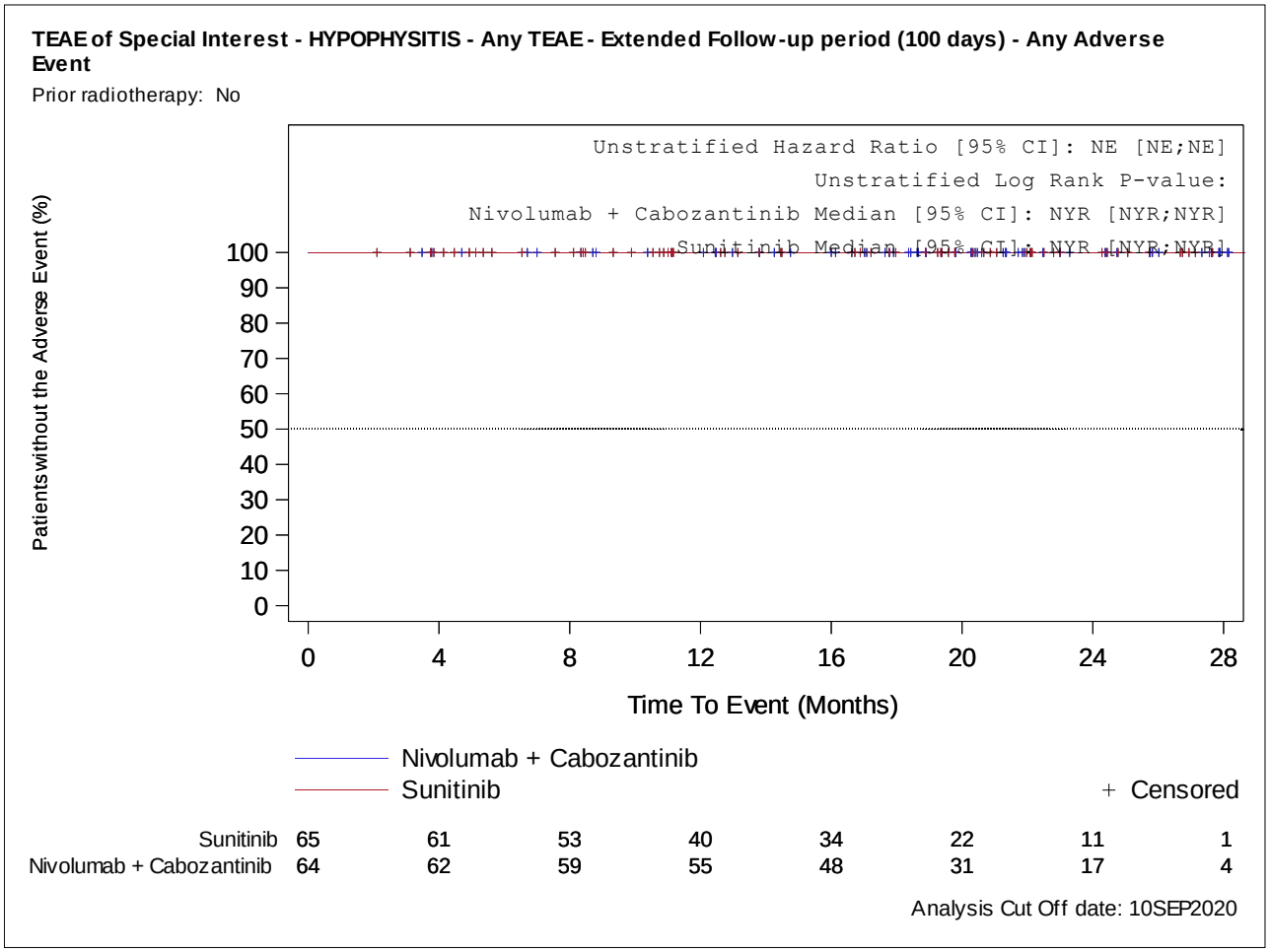

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:05:45

FIGURE 3.96.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



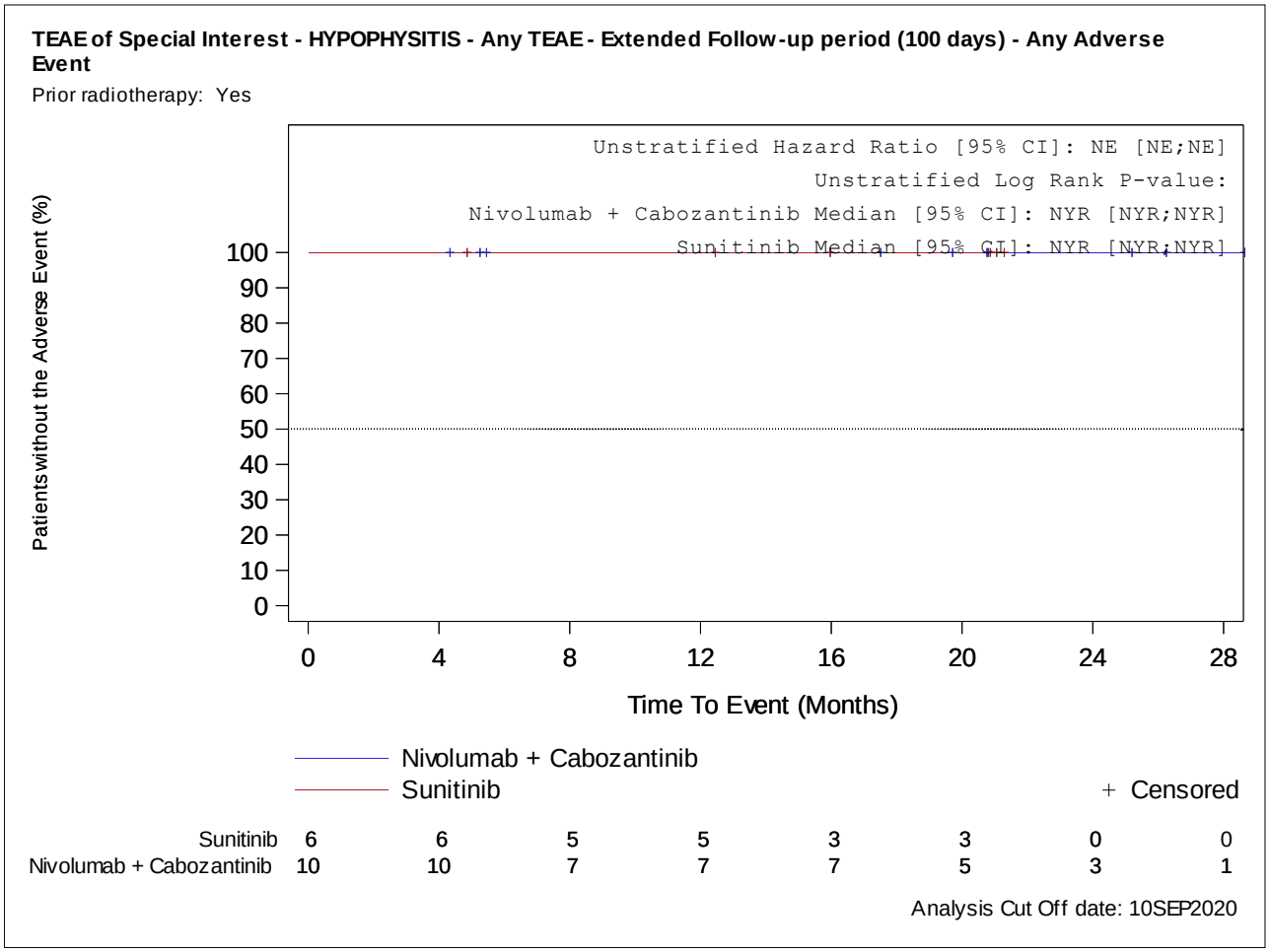

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:05:50

FIGURE 3.96.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



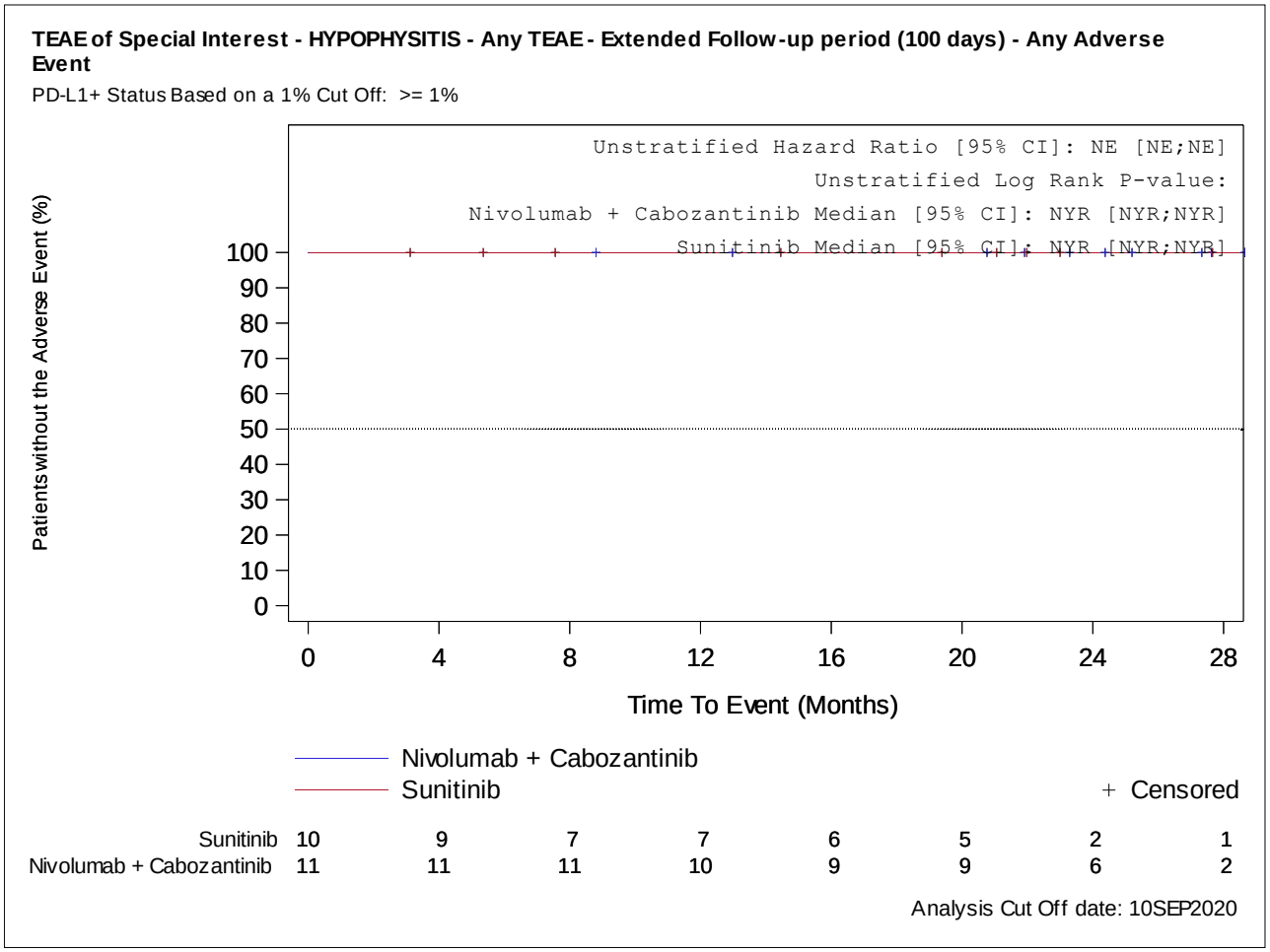

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:05:55

FIGURE 3.96.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



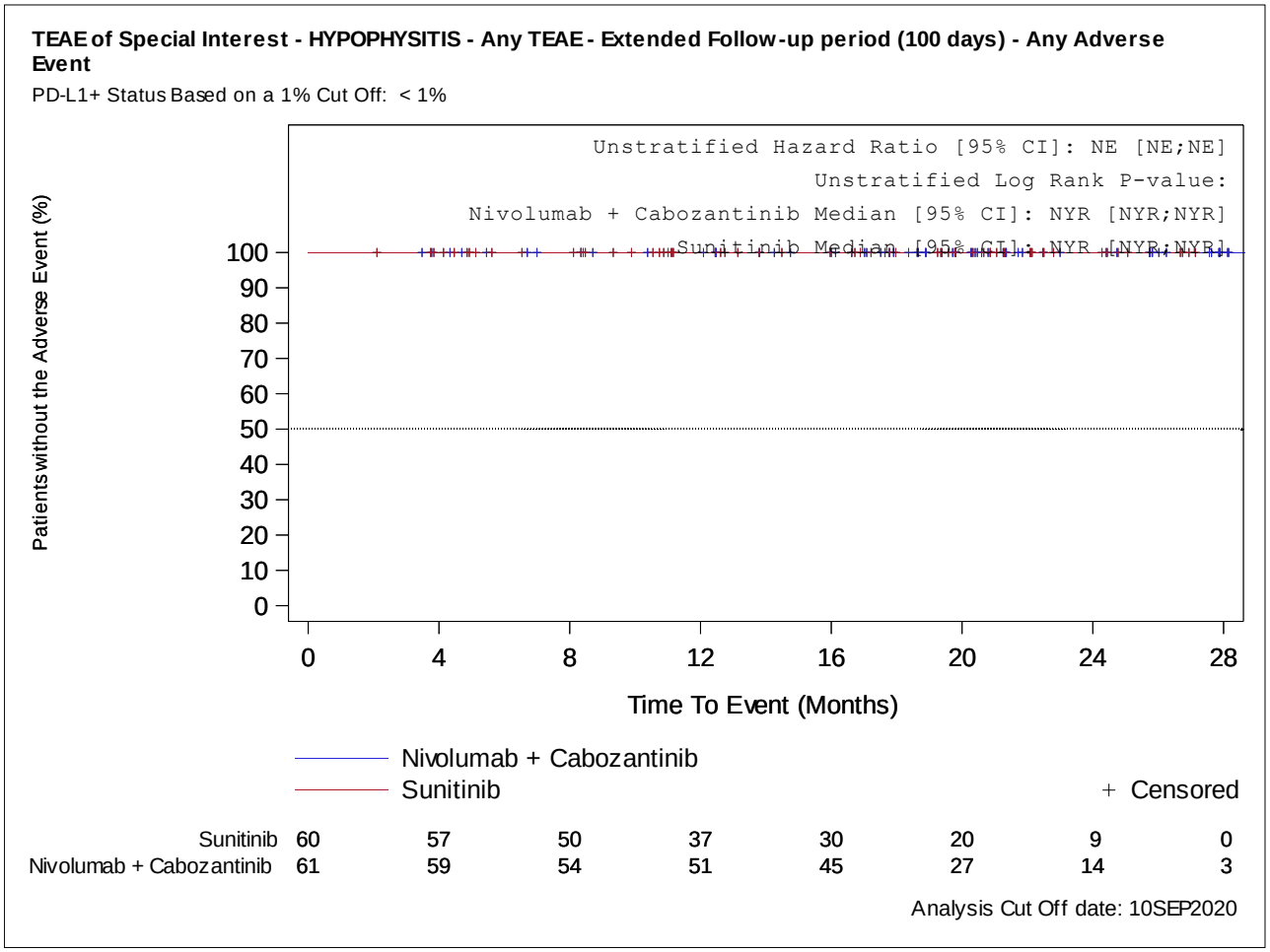

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:06:00

FIGURE 3.96.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



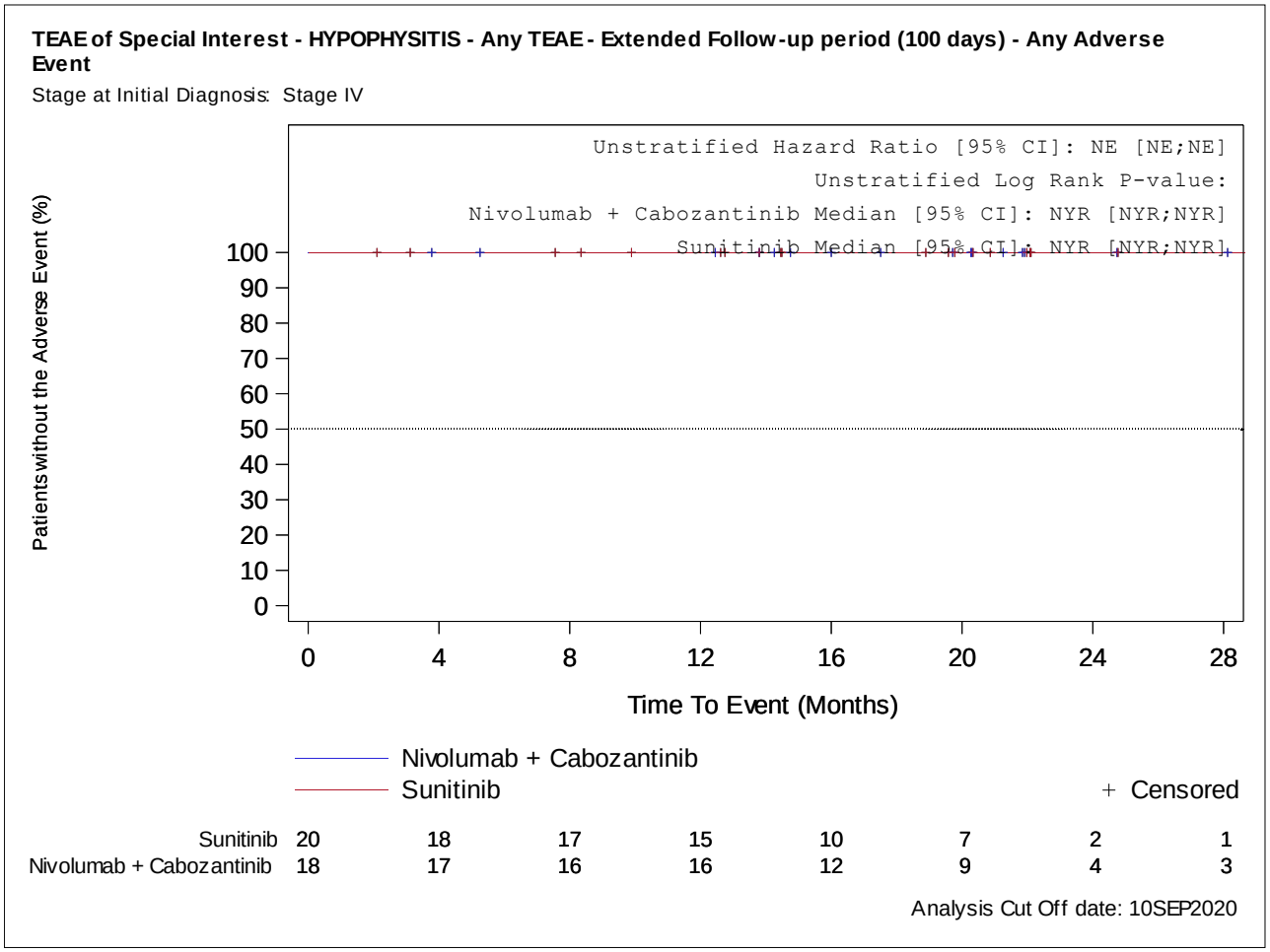

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:06:05

FIGURE 3.96.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



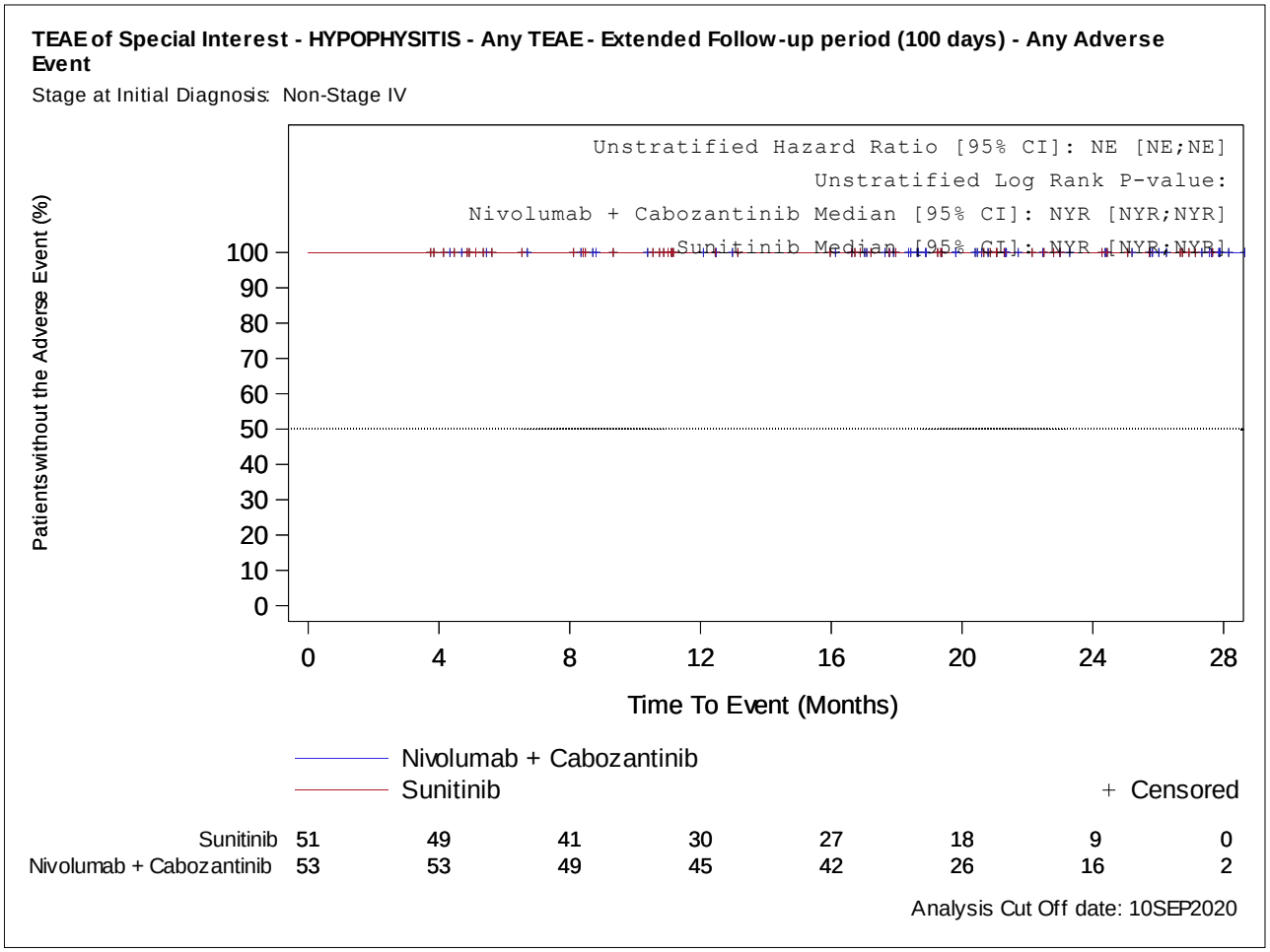

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:06:11

FIGURE 3.96.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



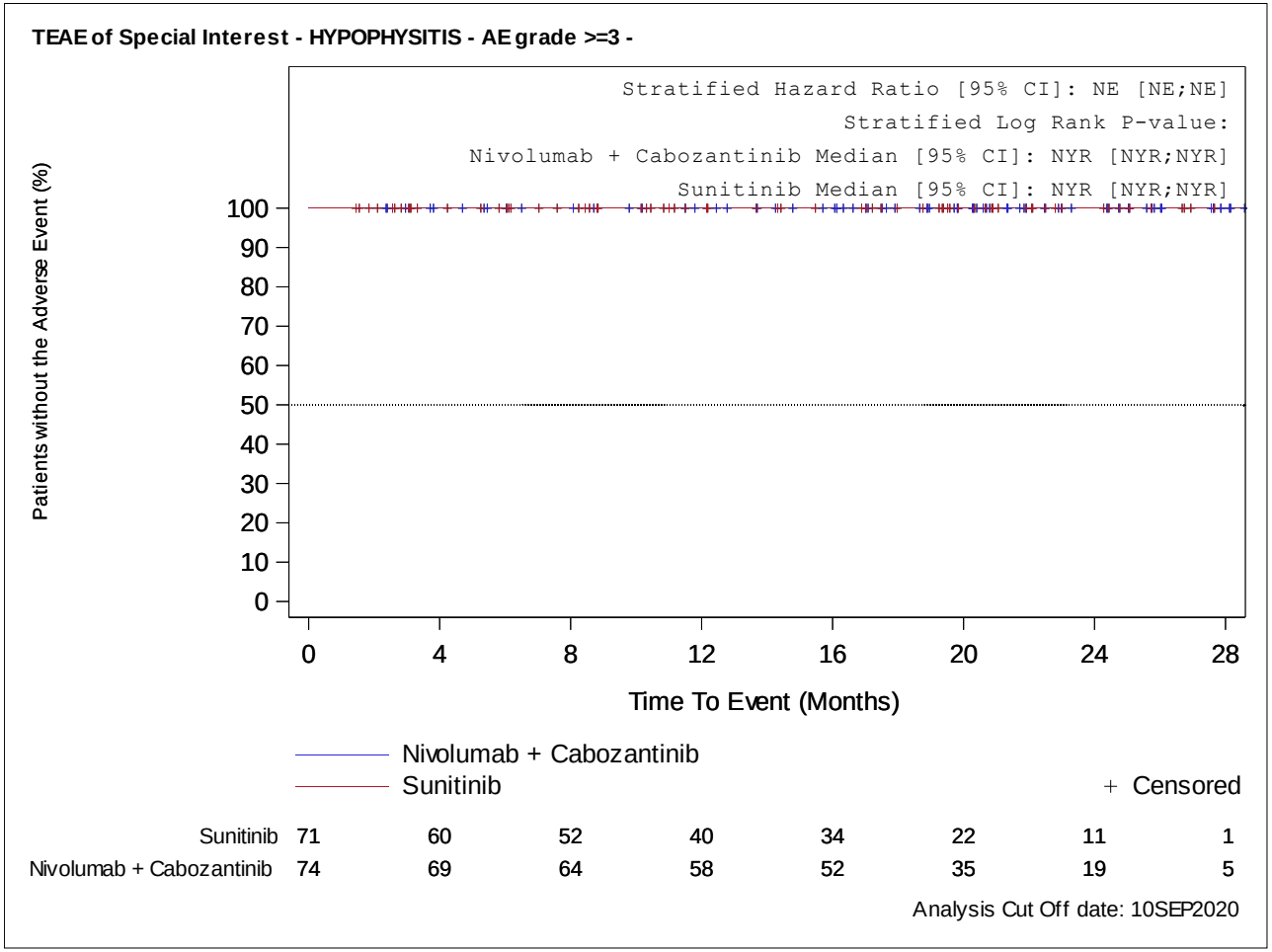

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:06:37

FIGURE 3.96.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



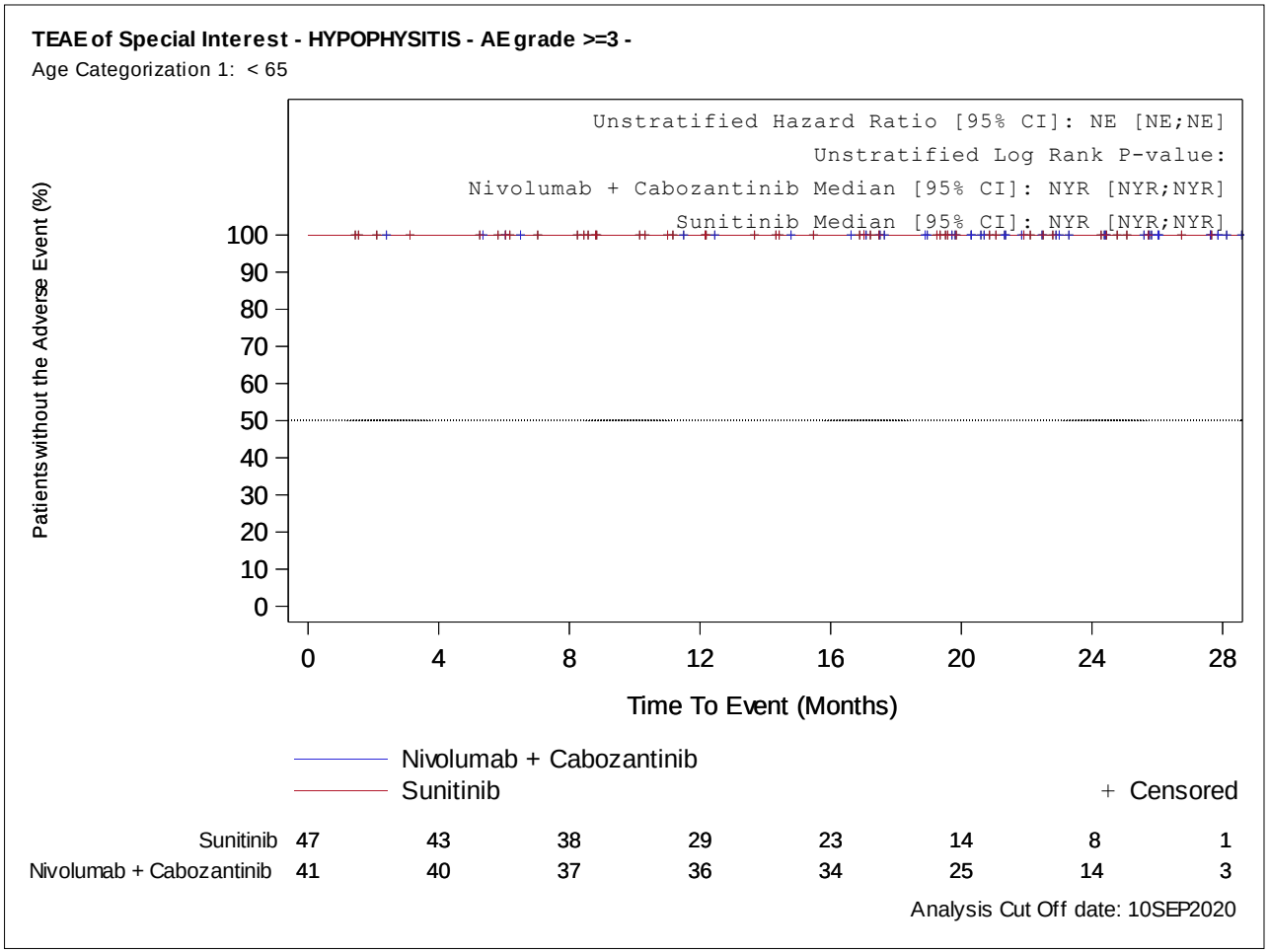

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:06:42

FIGURE 3.97.1: TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



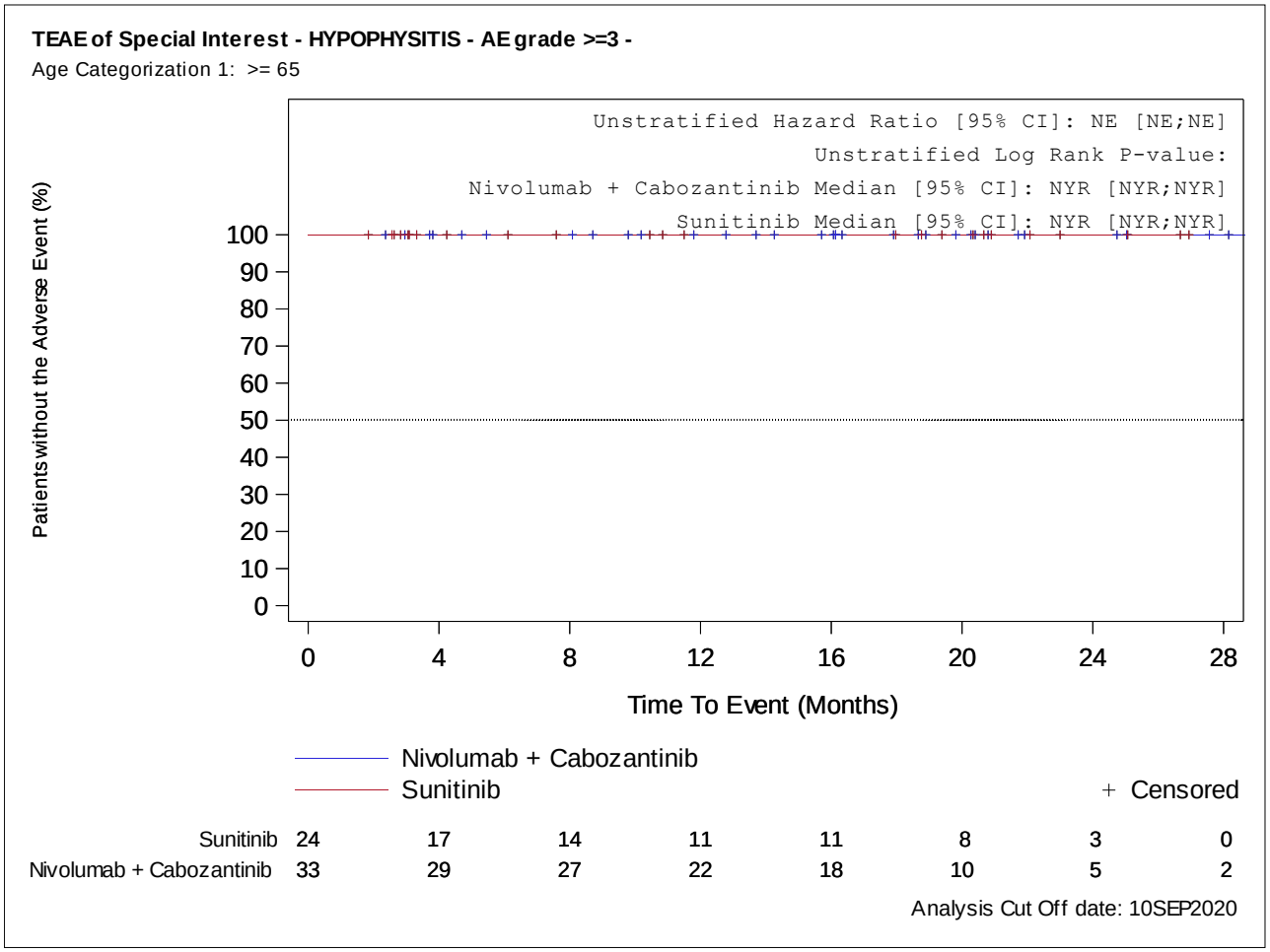

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:09:39

FIGURE 3.97.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:09:42

FIGURE 3.97.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
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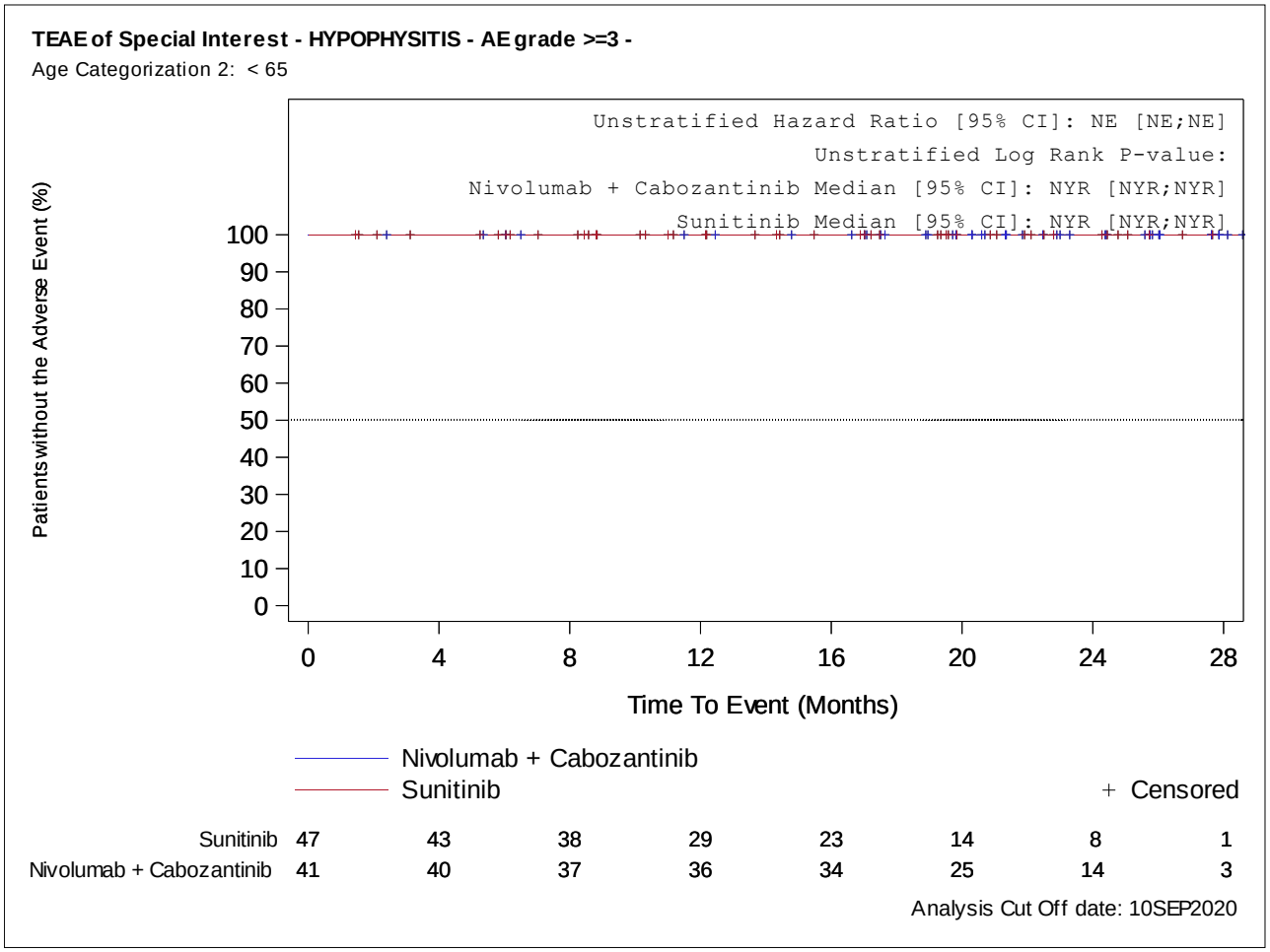
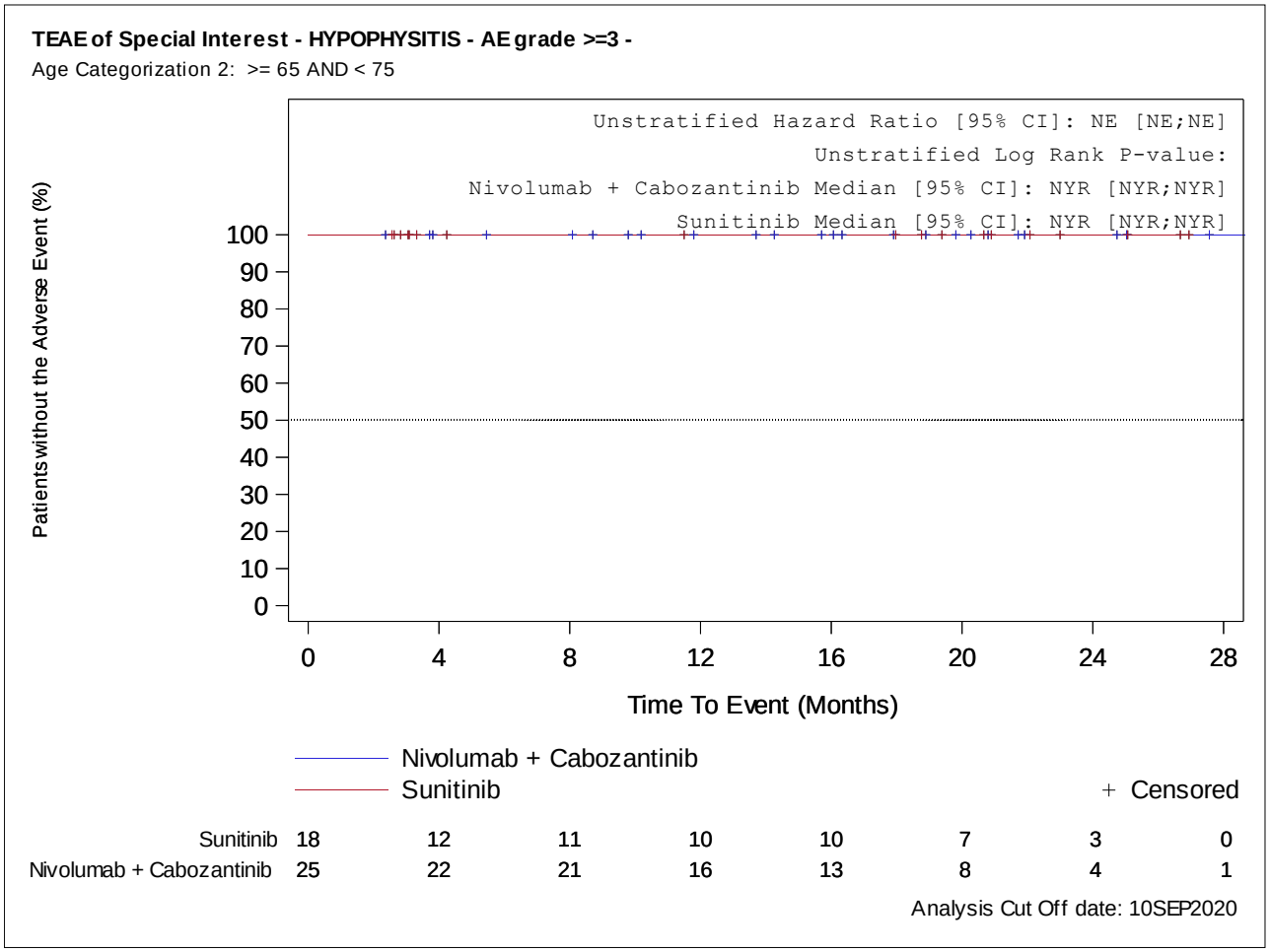
FIGURE 3.97.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  < 65



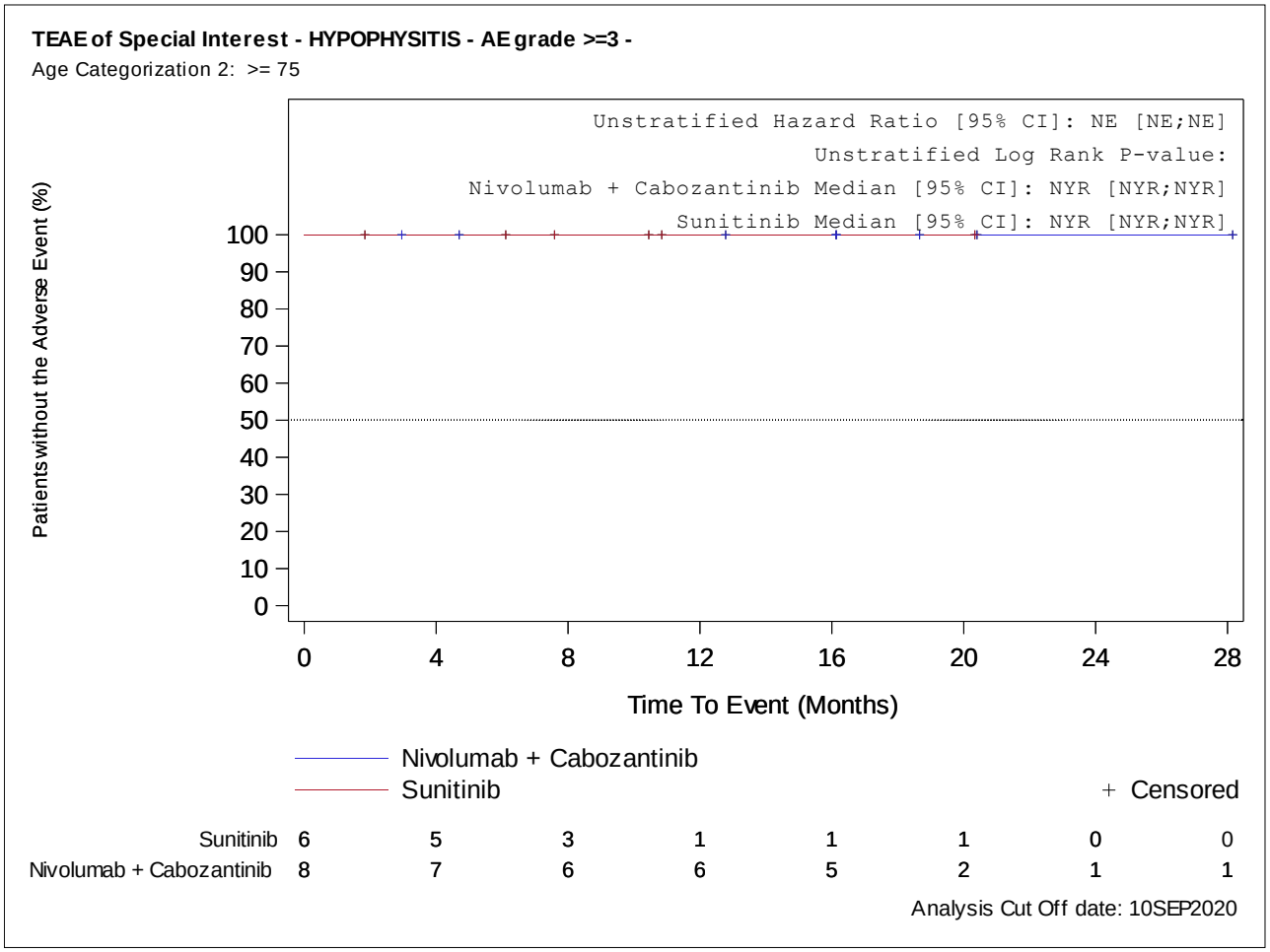

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:09:53

FIGURE 3.97.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



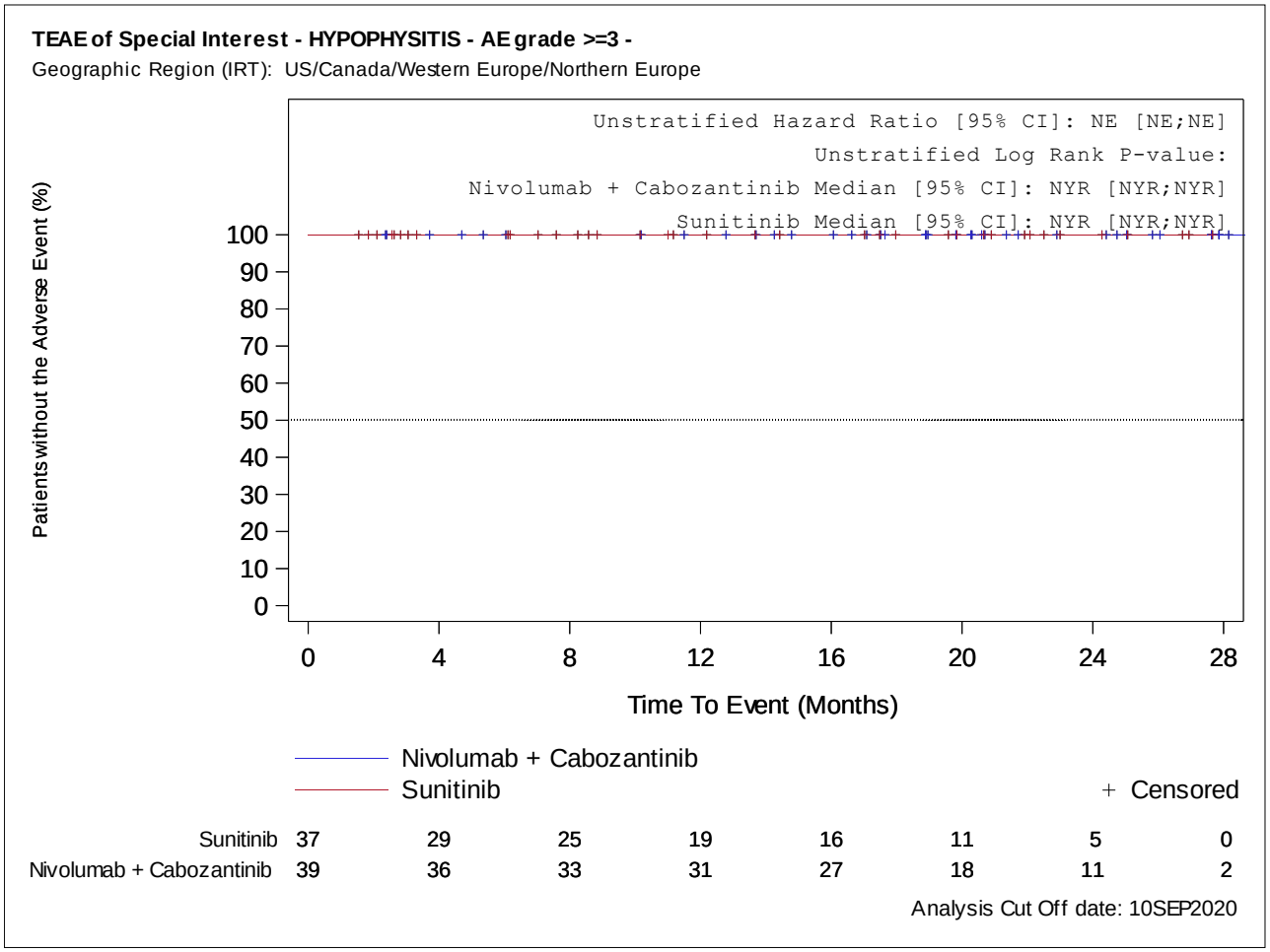

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:09:58

FIGURE 3.97.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



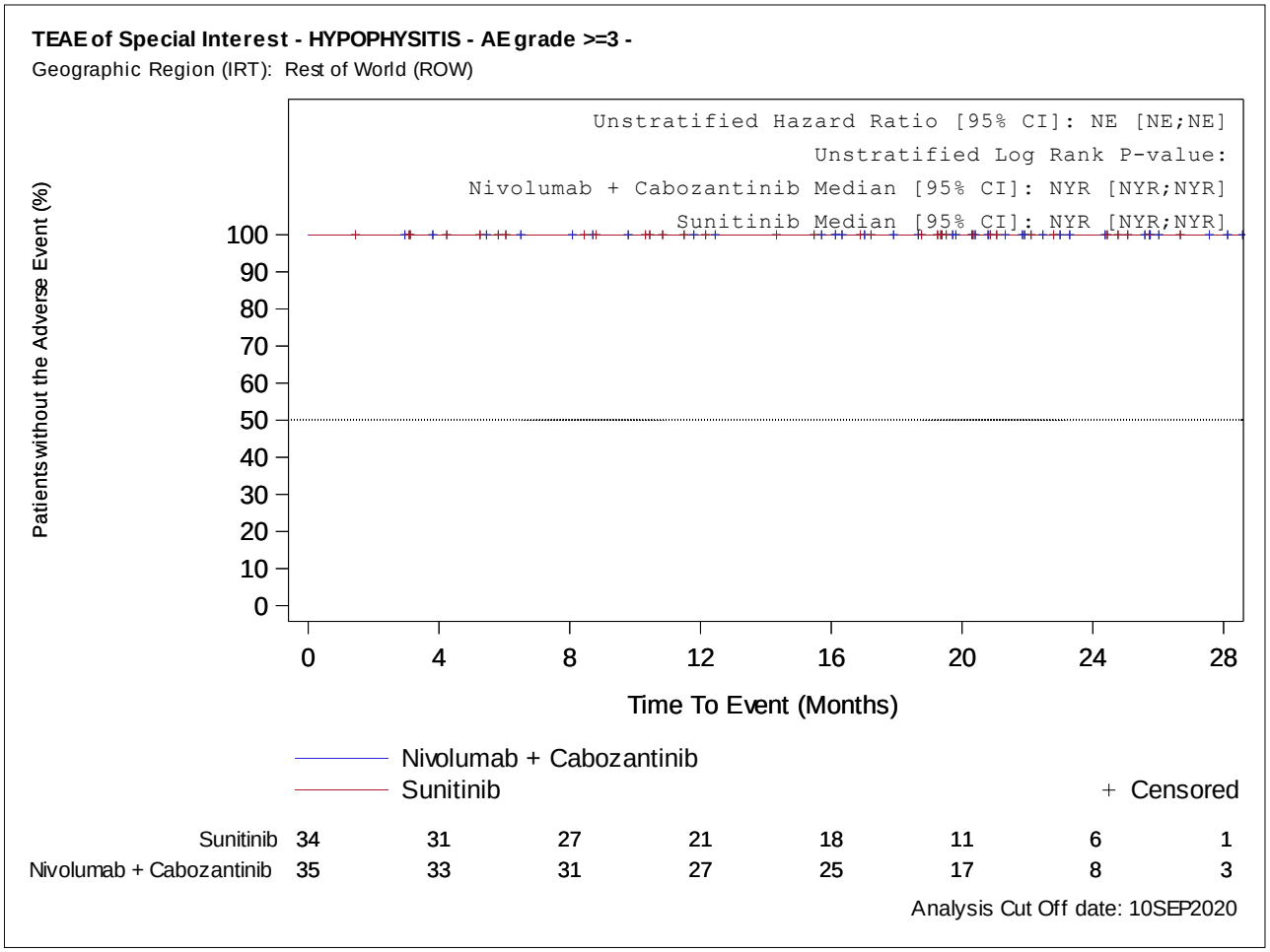

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:03

FIGURE 3.97.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



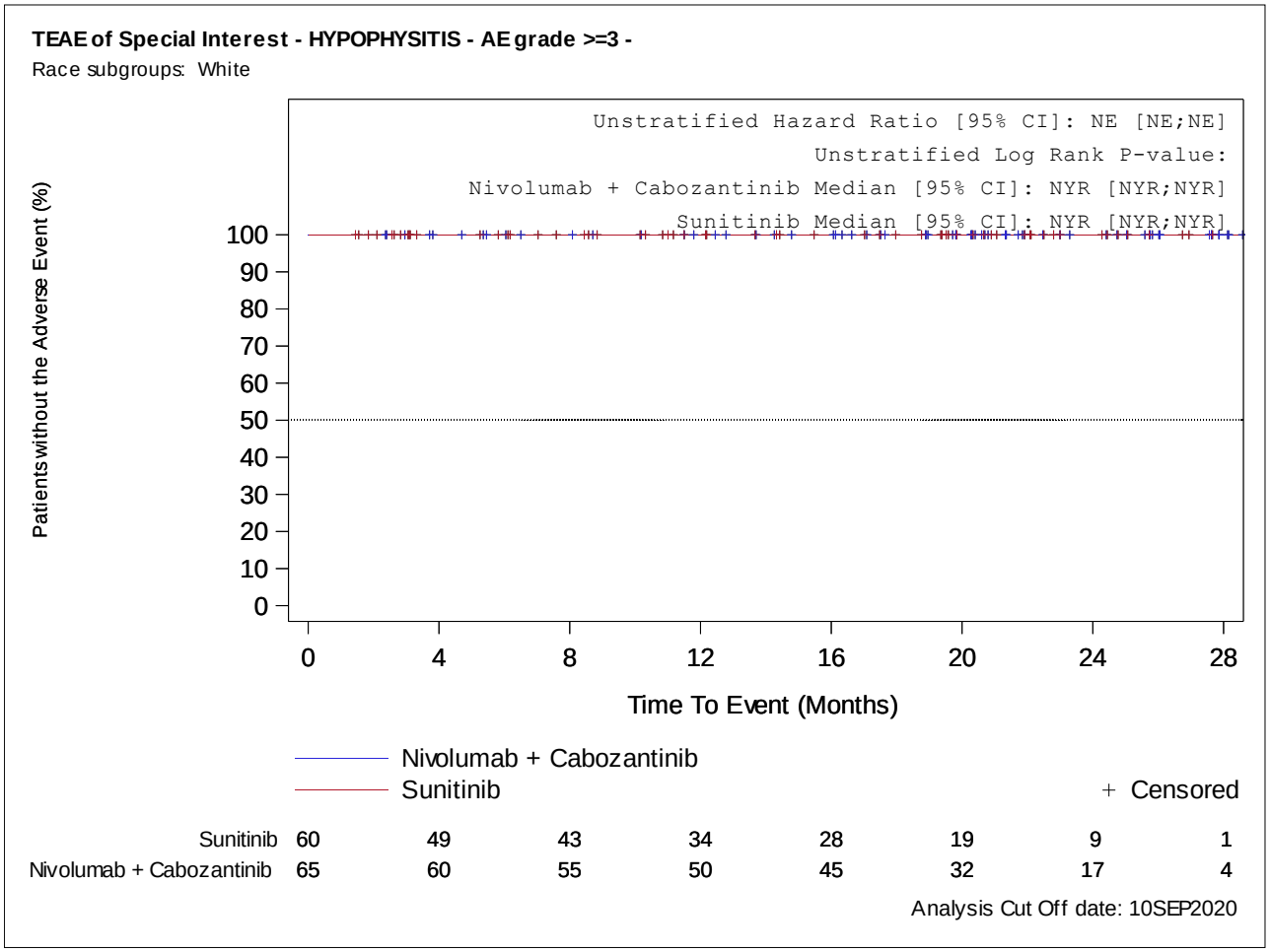

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:08

FIGURE 3.97.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



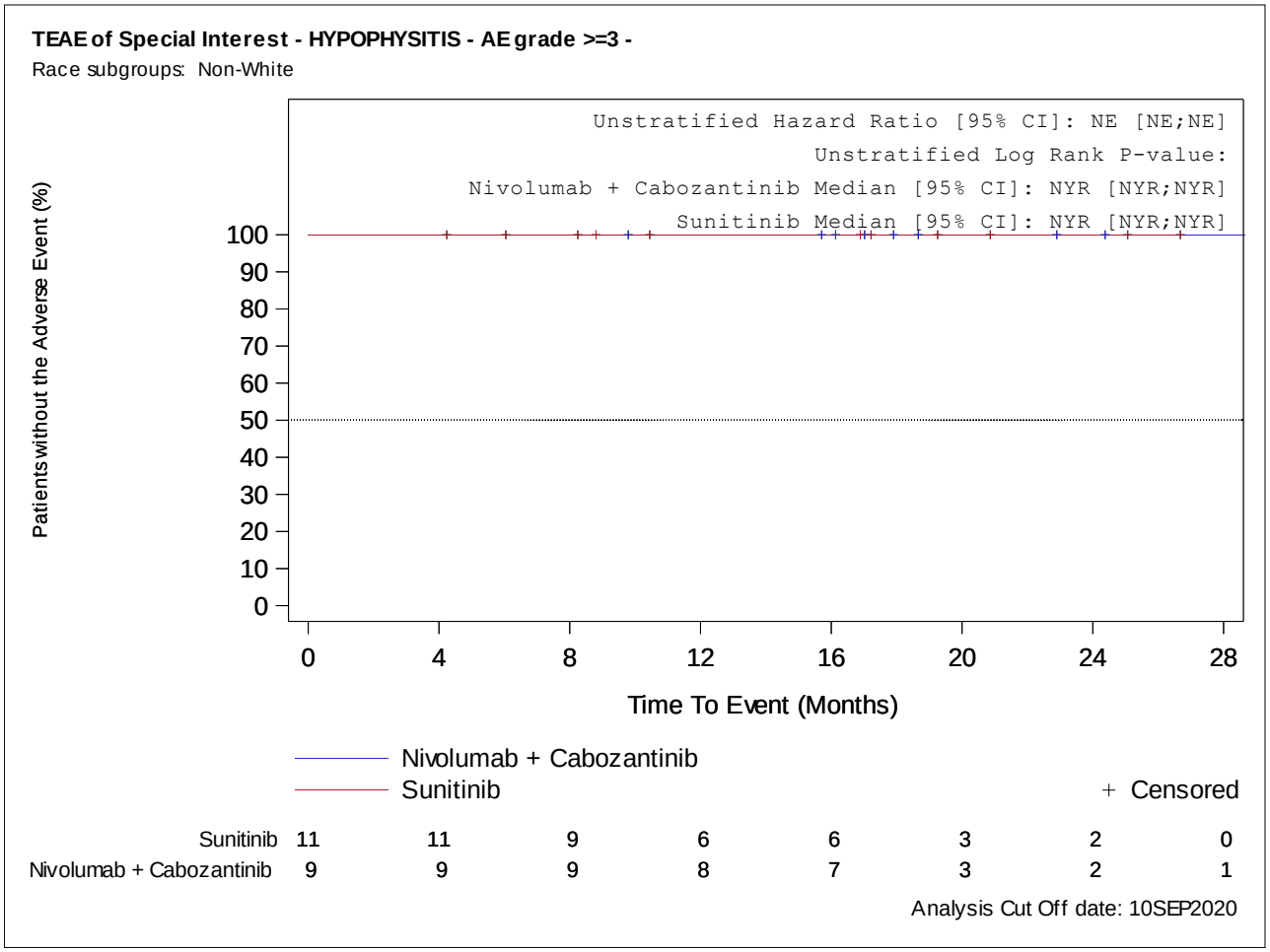

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:13

FIGURE 3.97.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



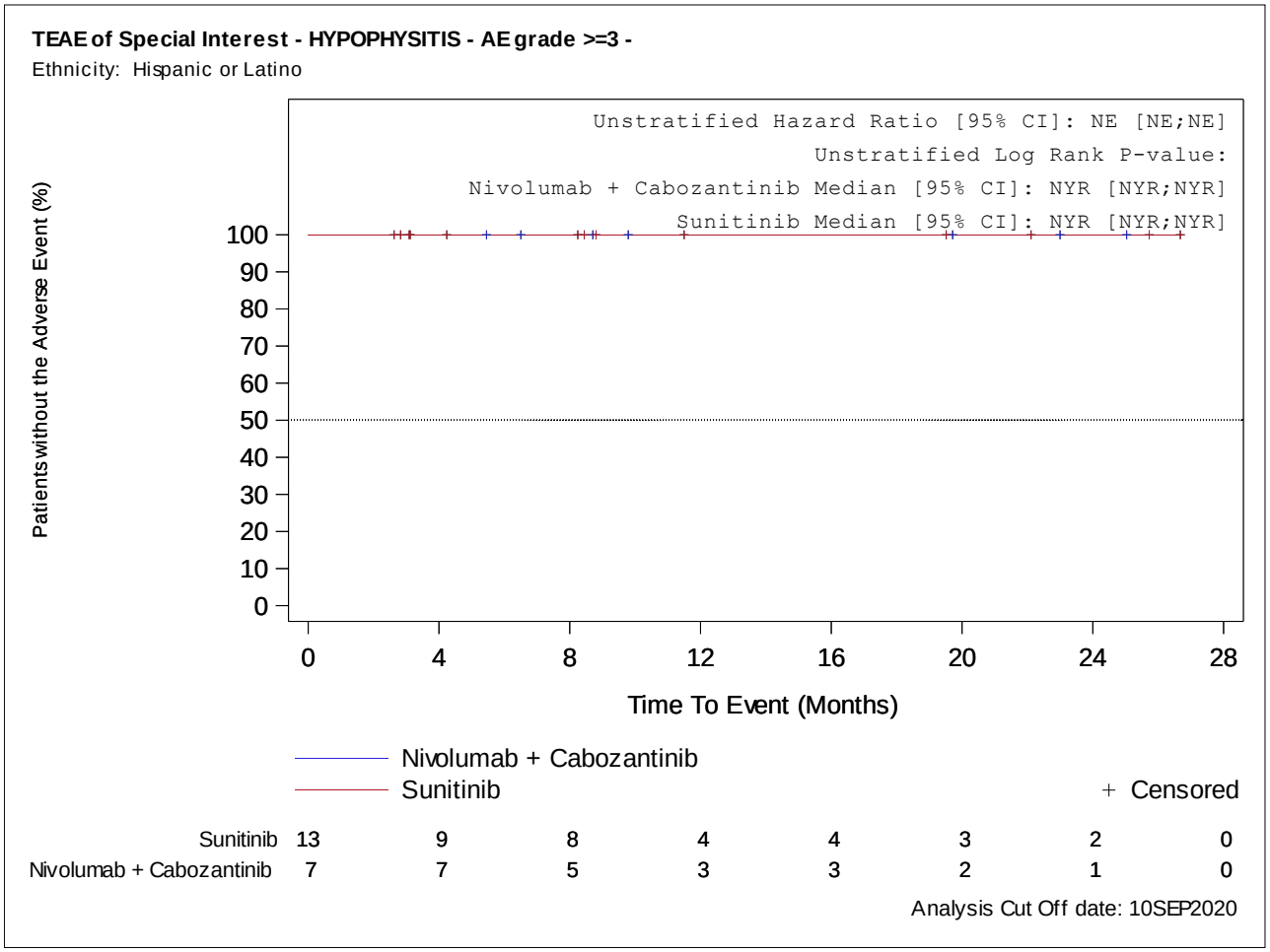

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:18

FIGURE 3.97.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



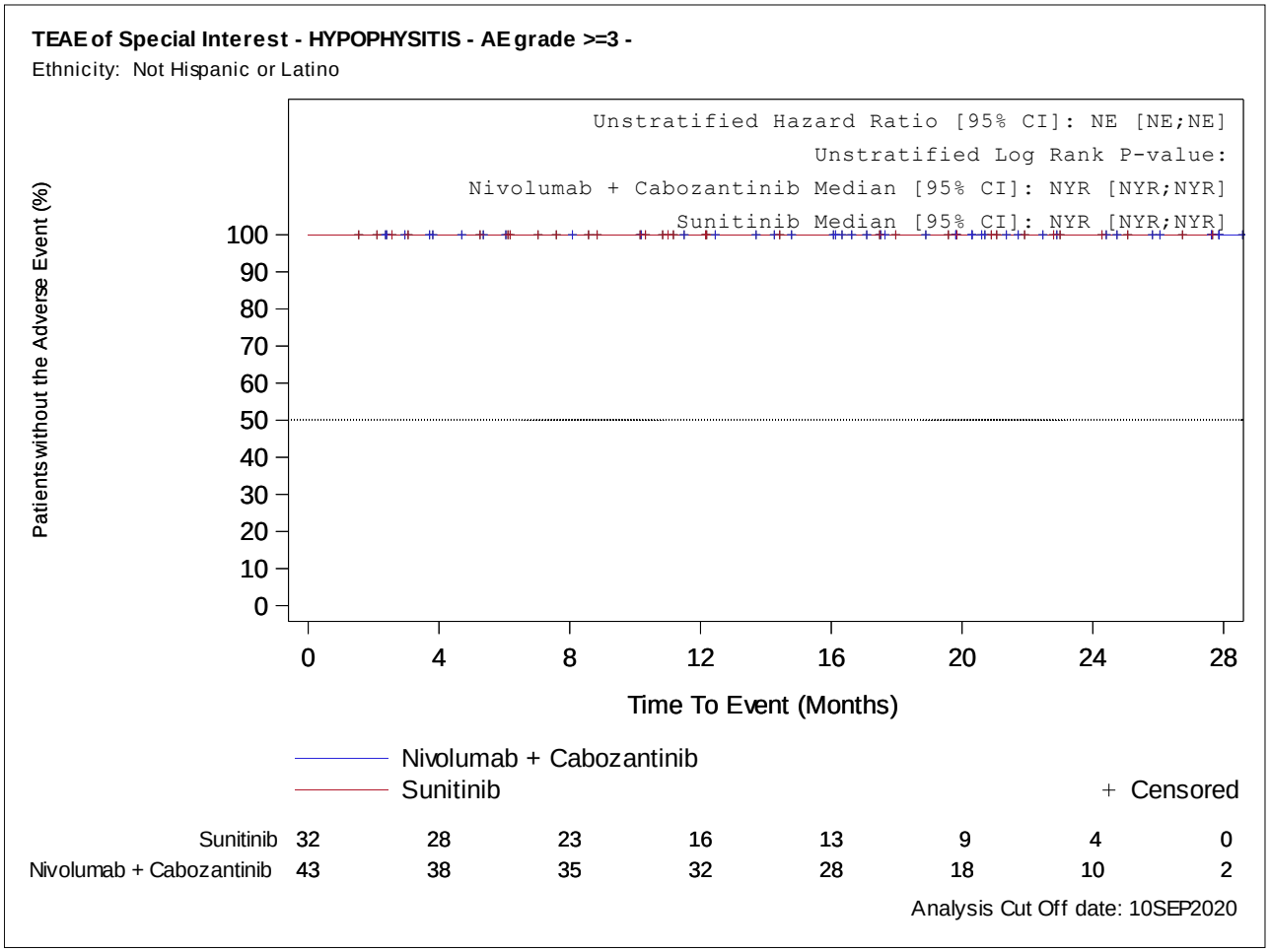

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:23

FIGURE 3.97.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



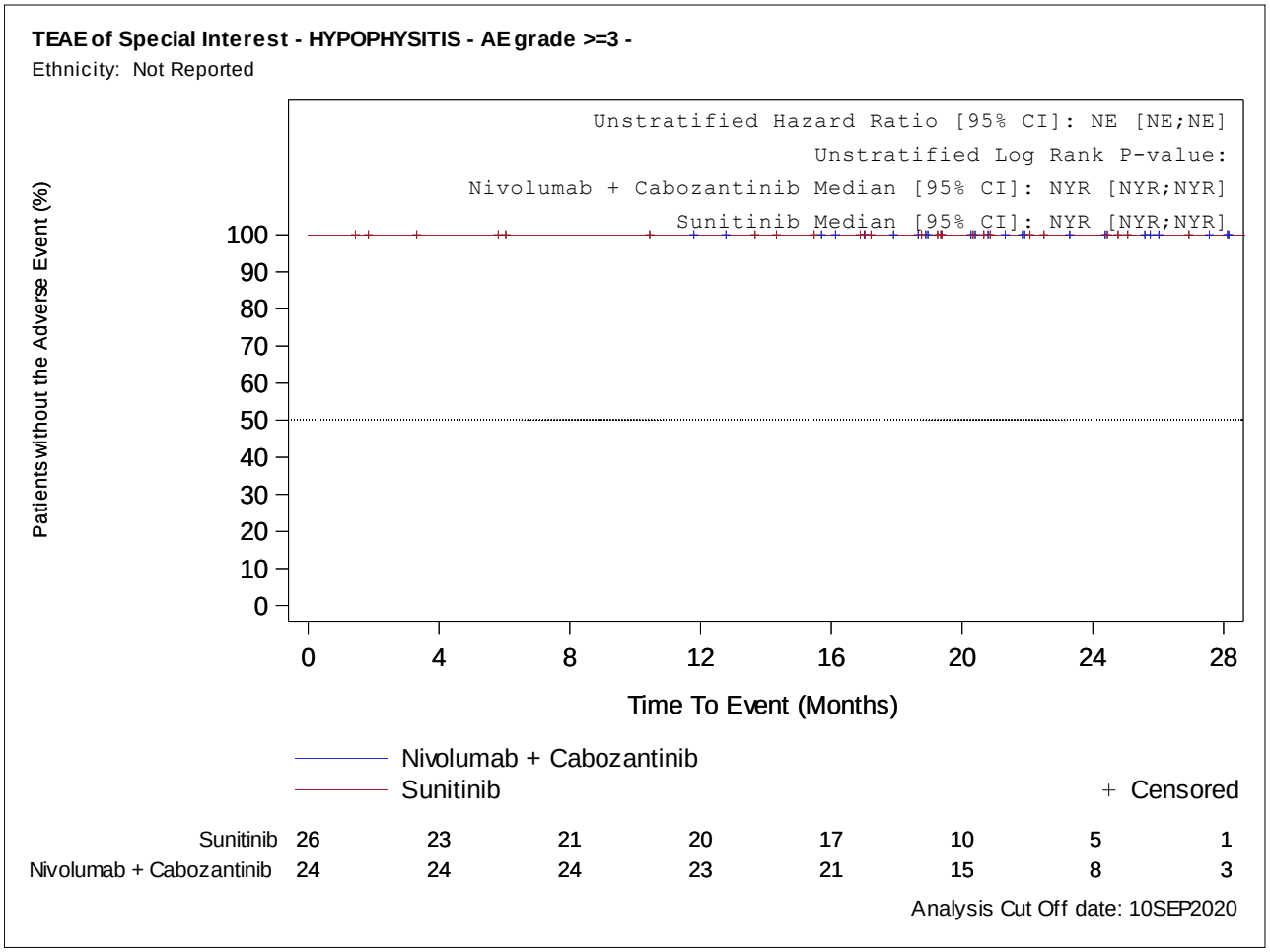

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:29

FIGURE 3.97.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



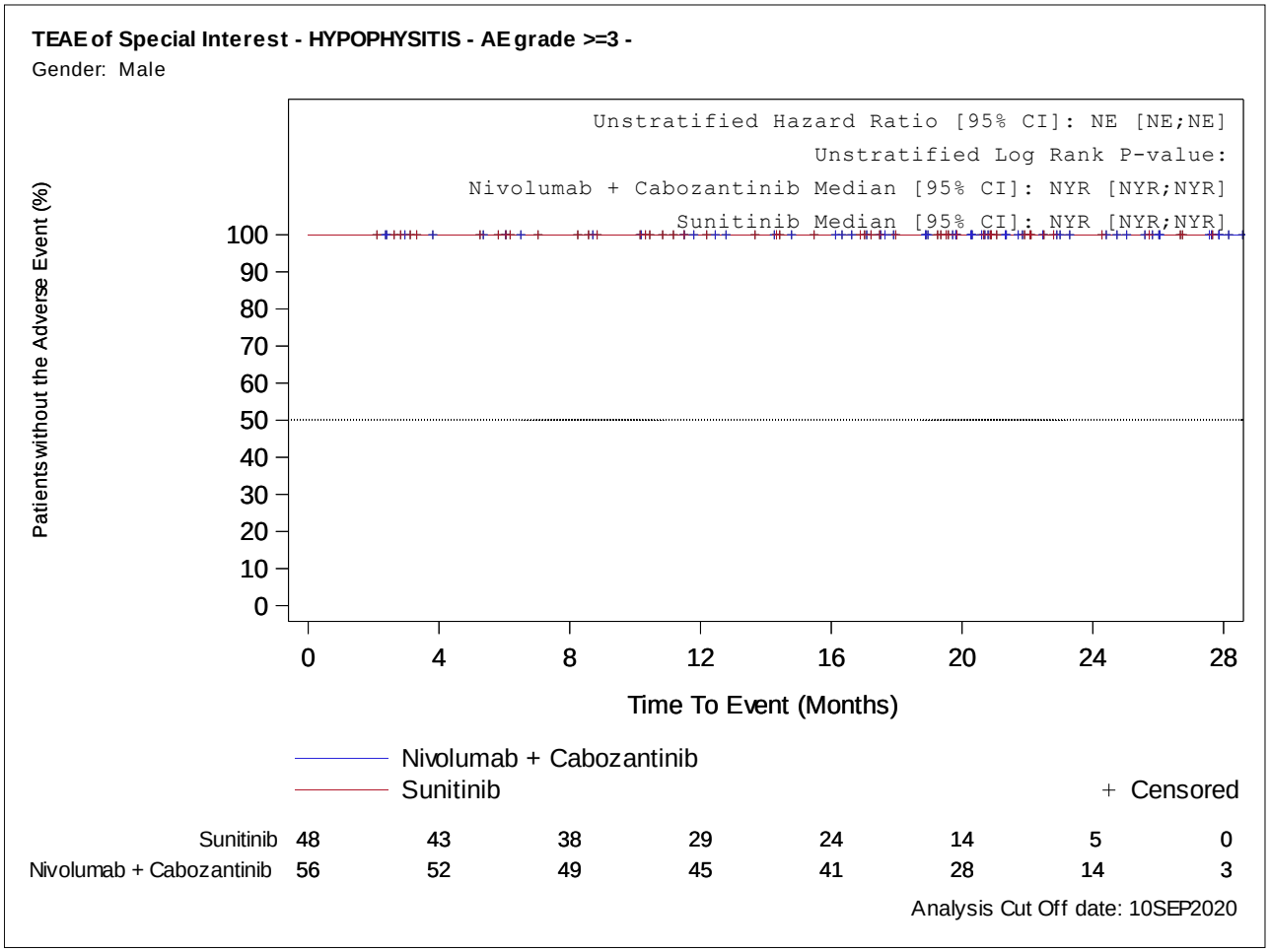

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:34

FIGURE 3.97.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



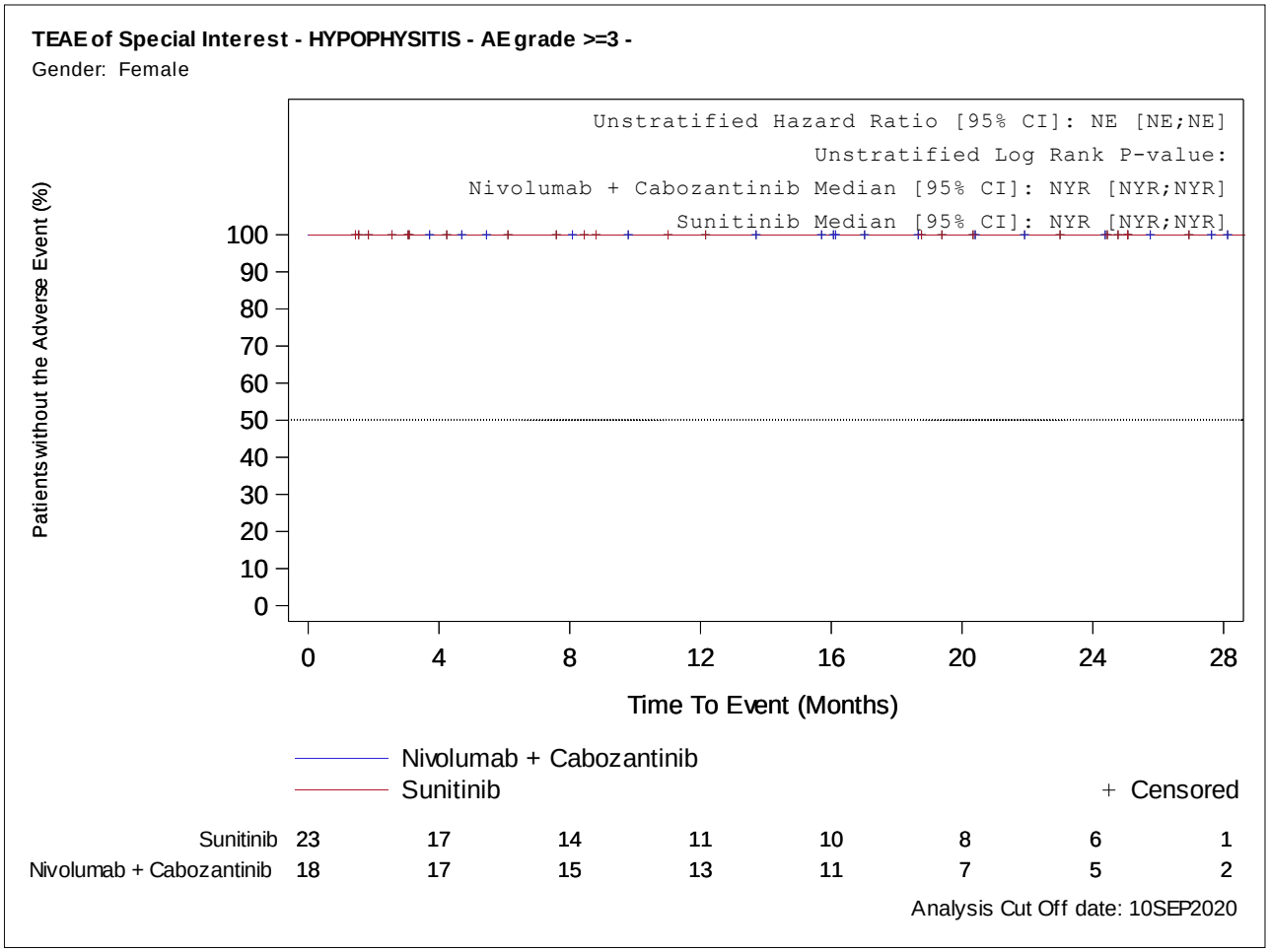

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:39

FIGURE 3.97.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



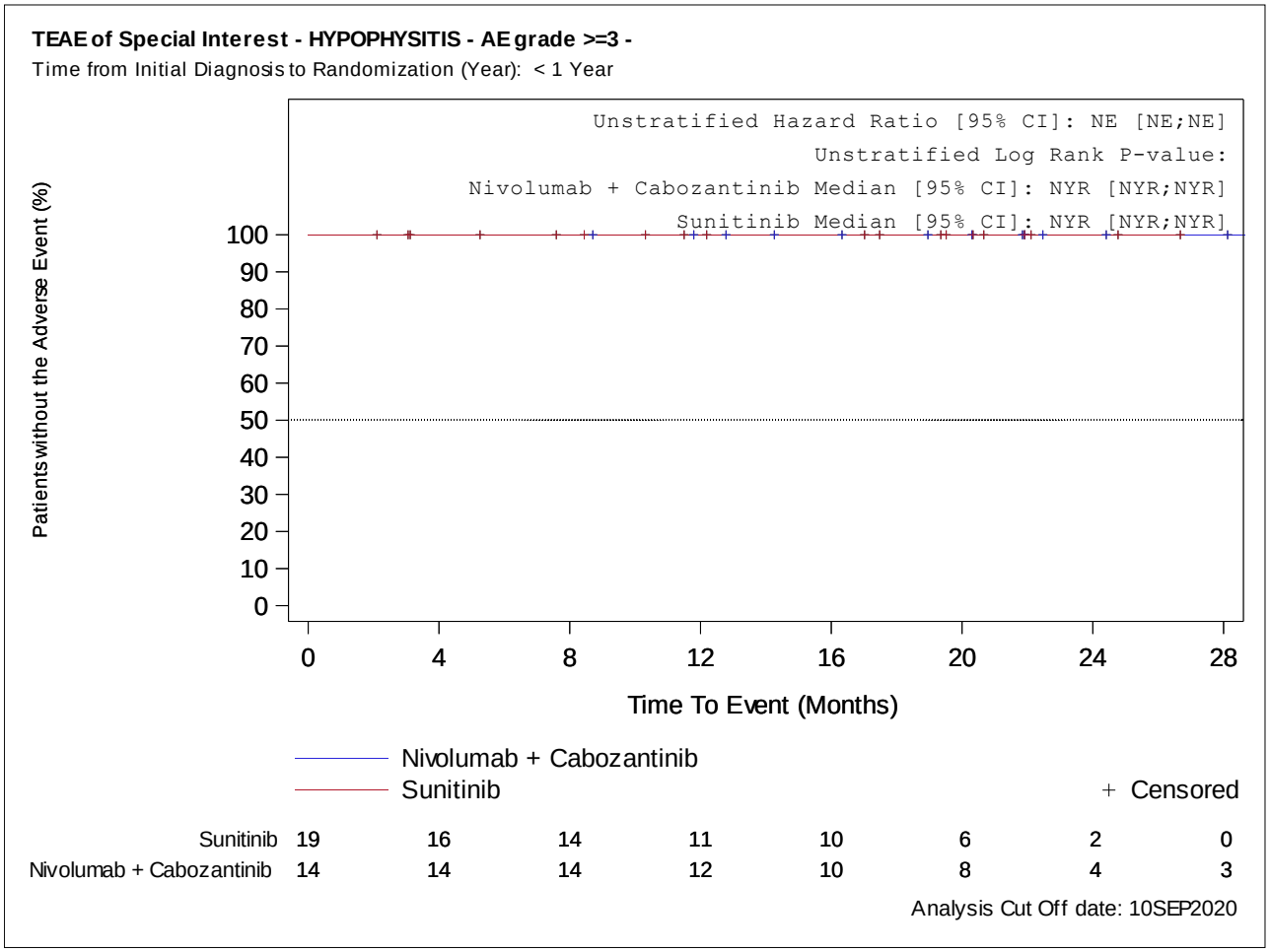

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:44

FIGURE 3.97.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



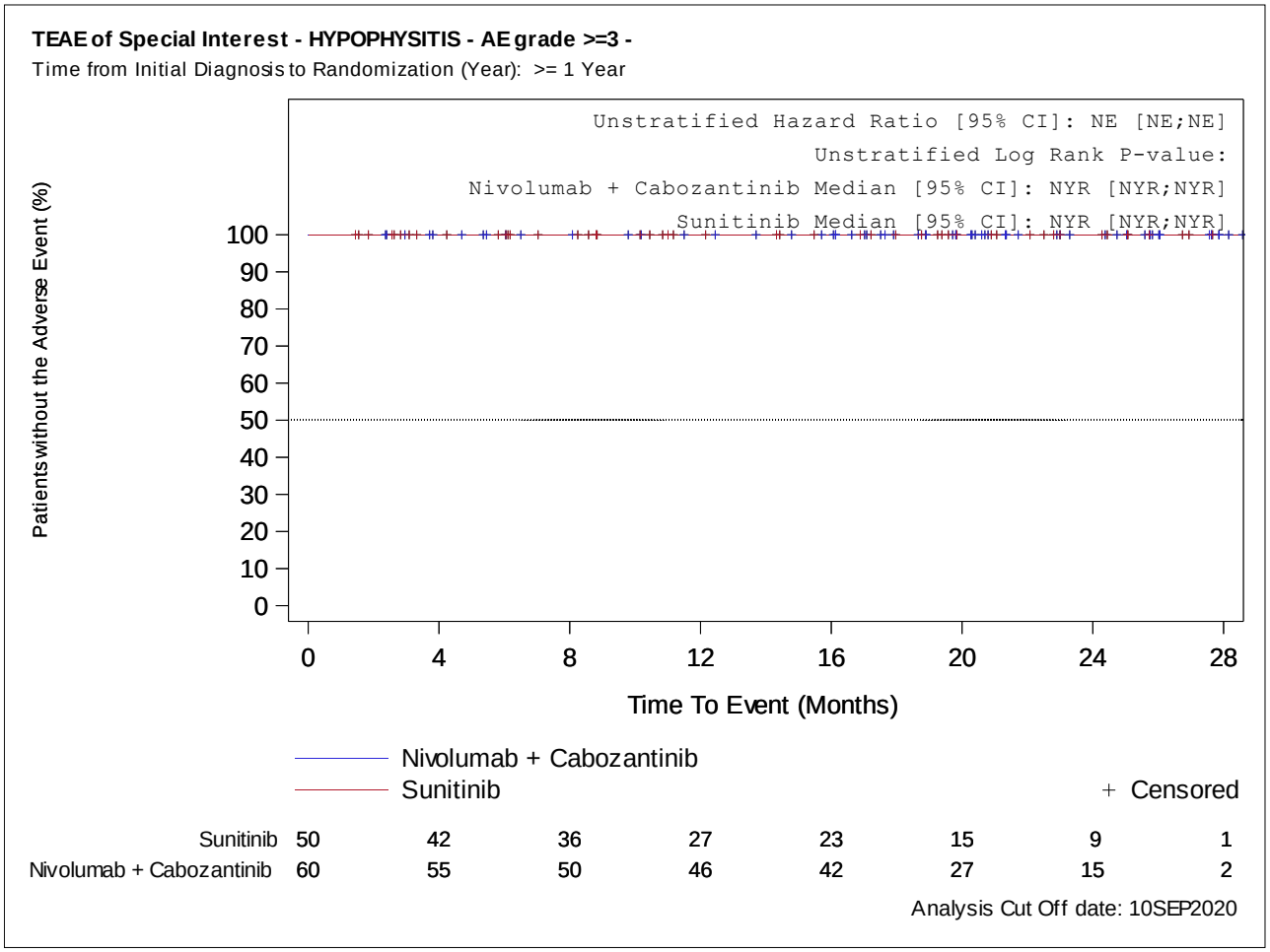

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:10:49

FIGURE 3.97.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:11:05

FIGURE 3.97.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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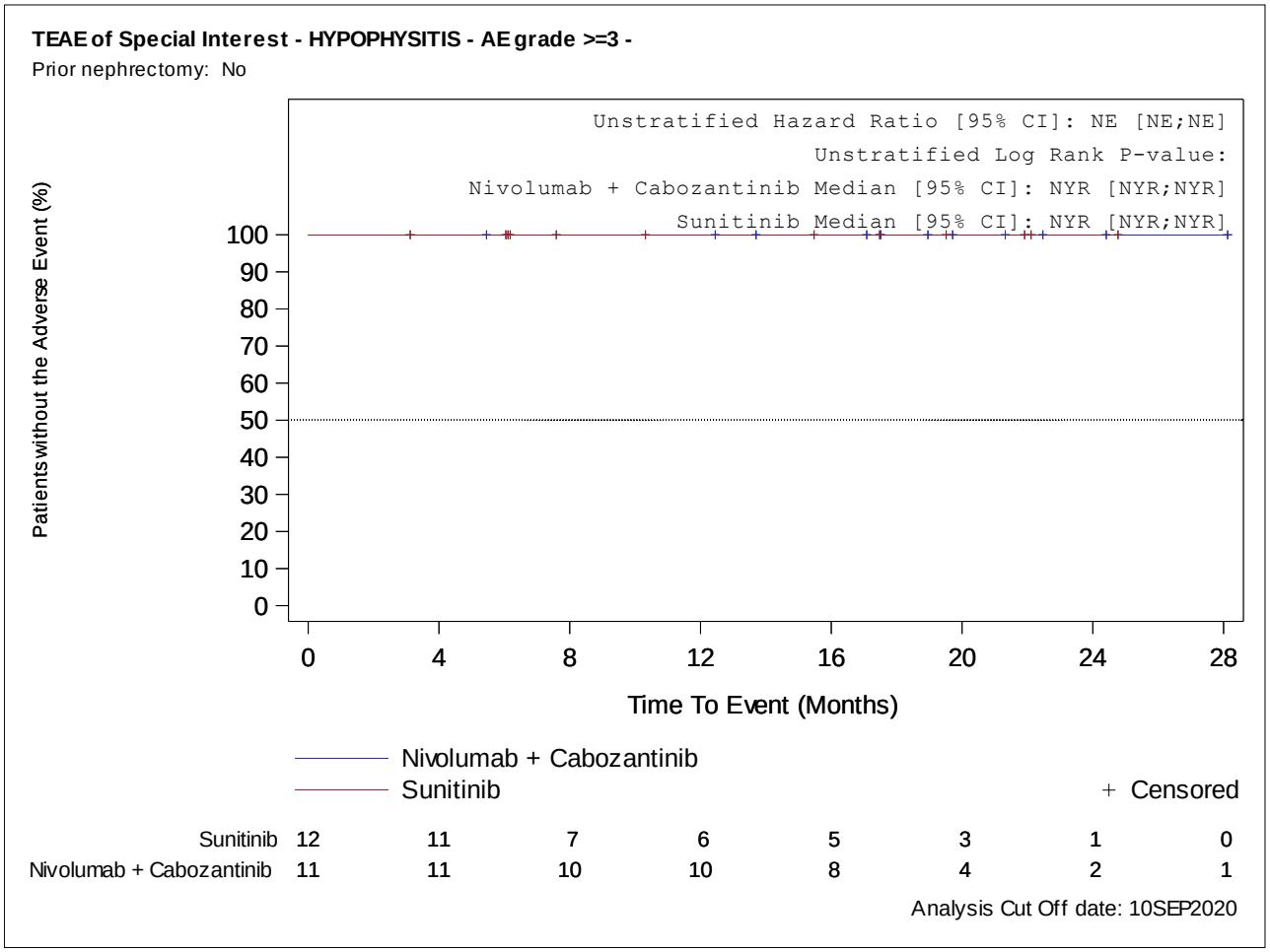
FIGURE 3.97.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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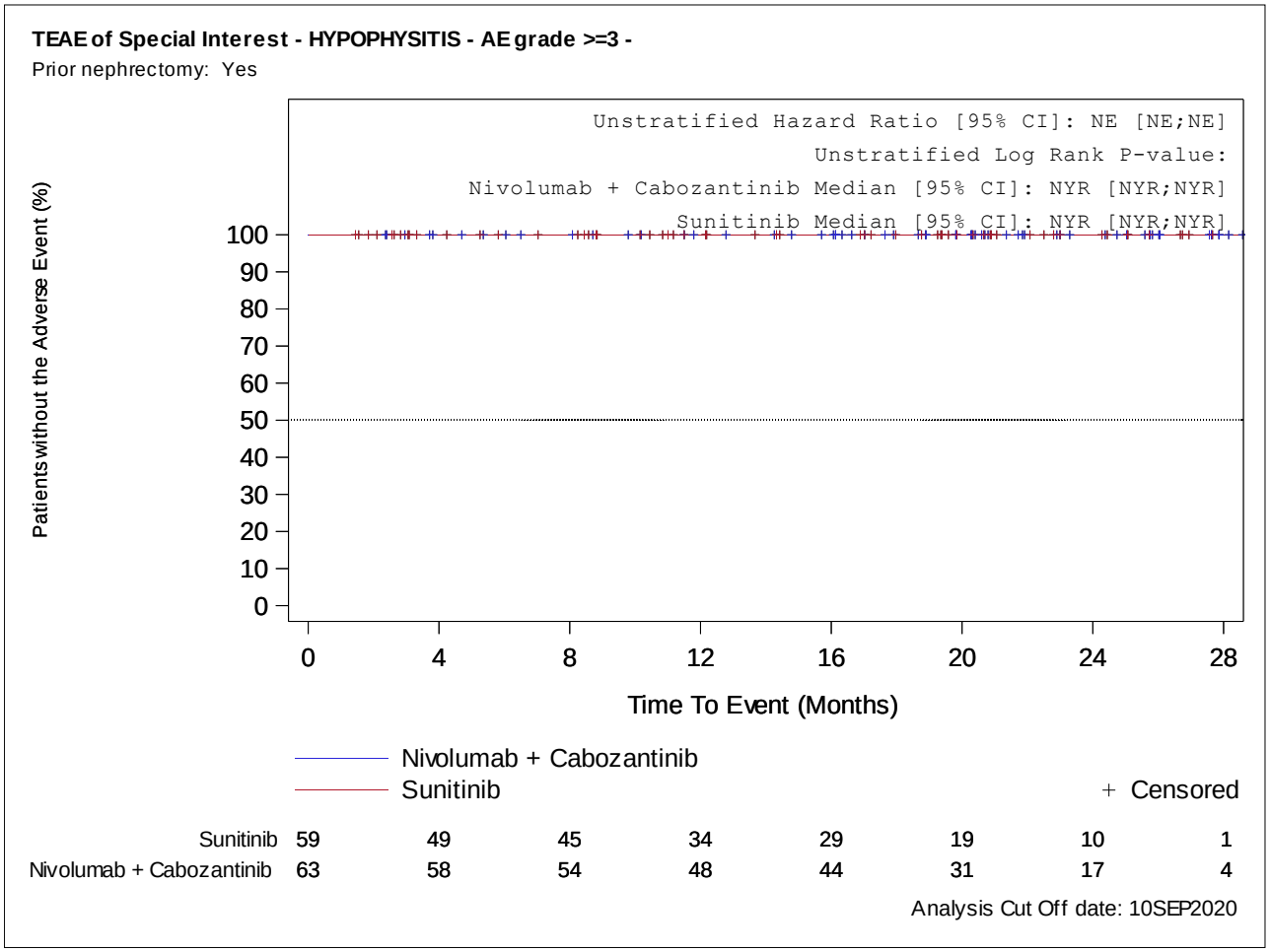
FIGURE 3.97.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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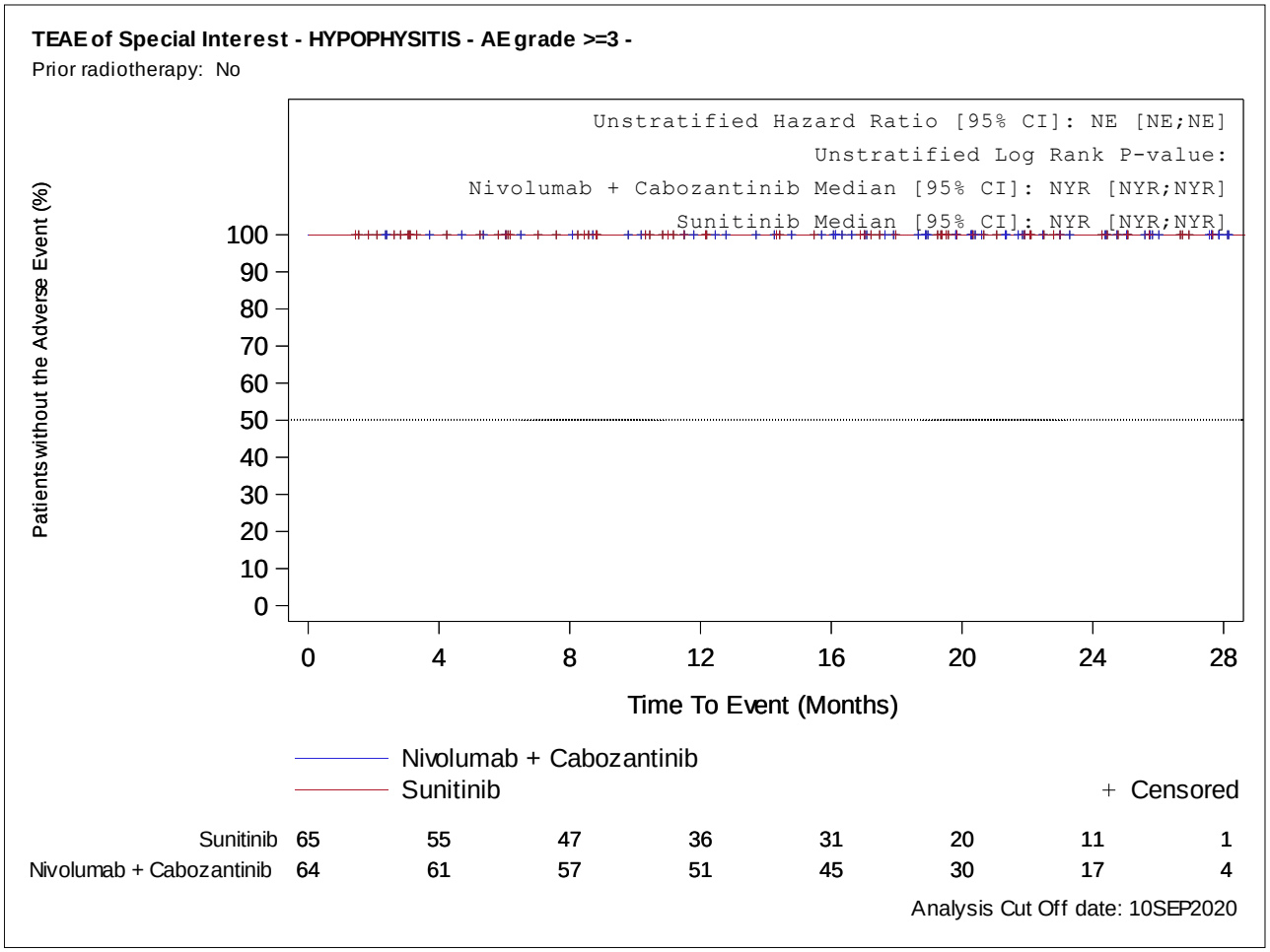
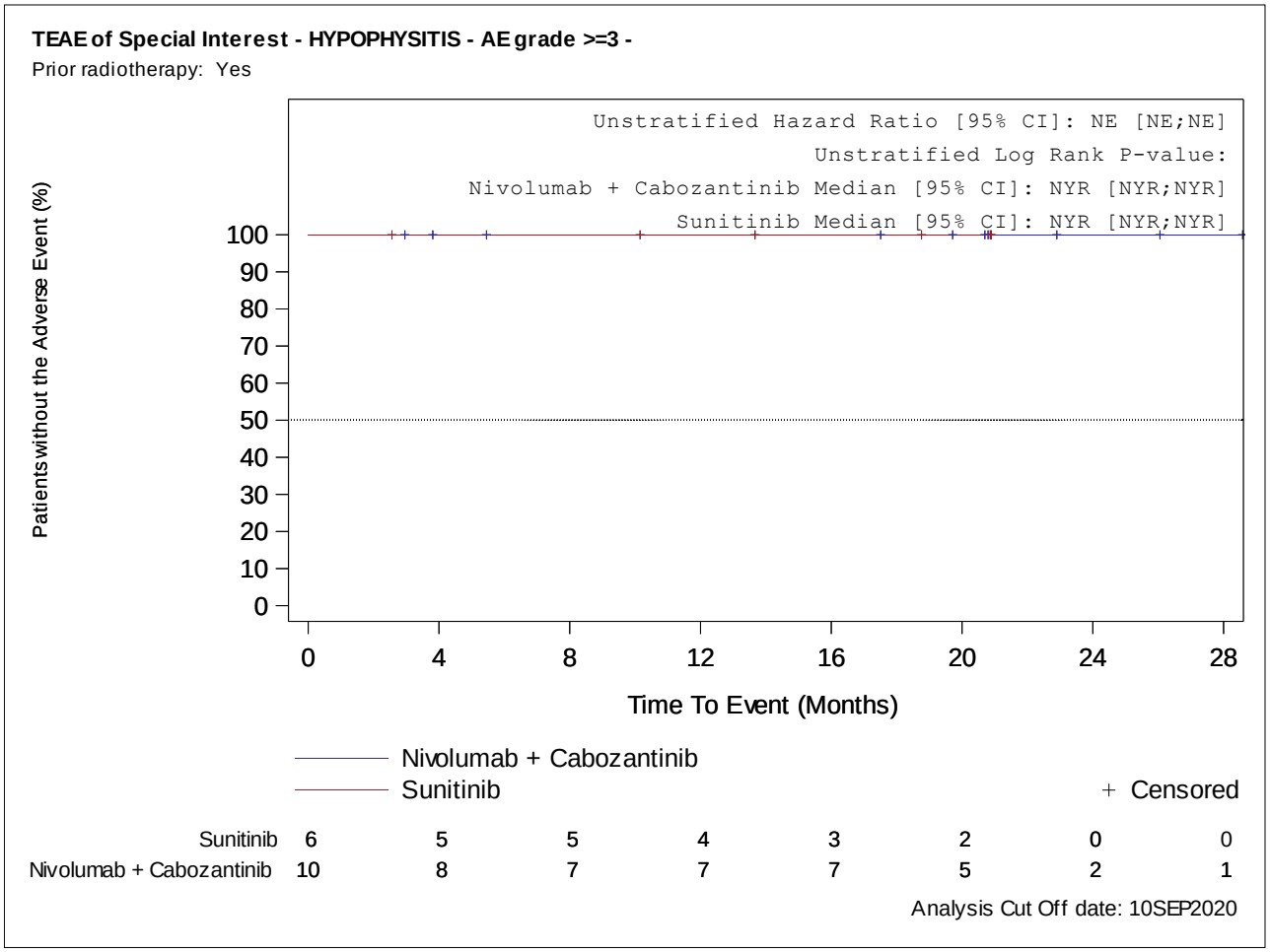
FIGURE 3.97.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:12:05

FIGURE 3.97.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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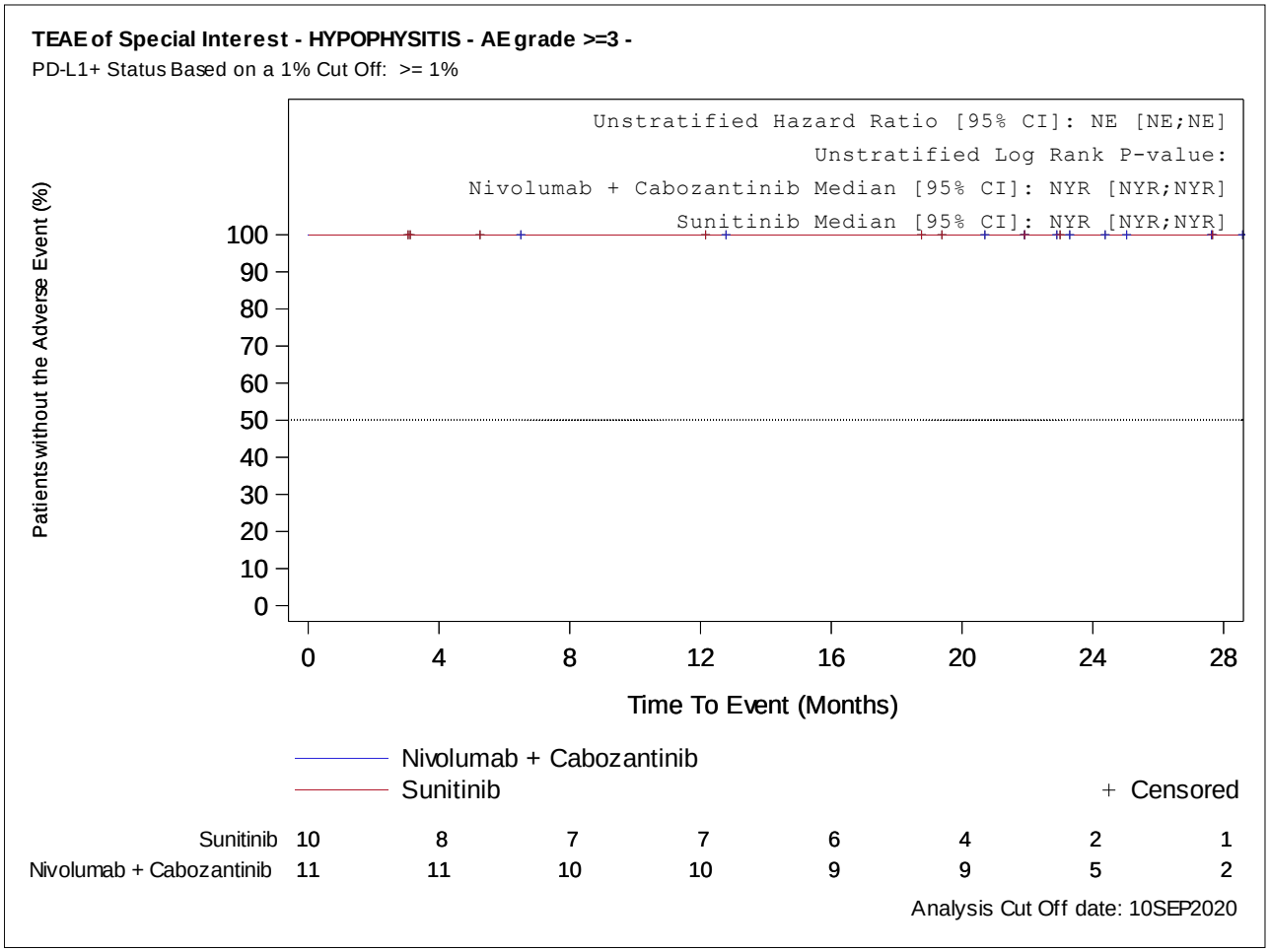
FIGURE 3.97.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off:  >= 1%




Analysis Cut Off date: 10SEP2020
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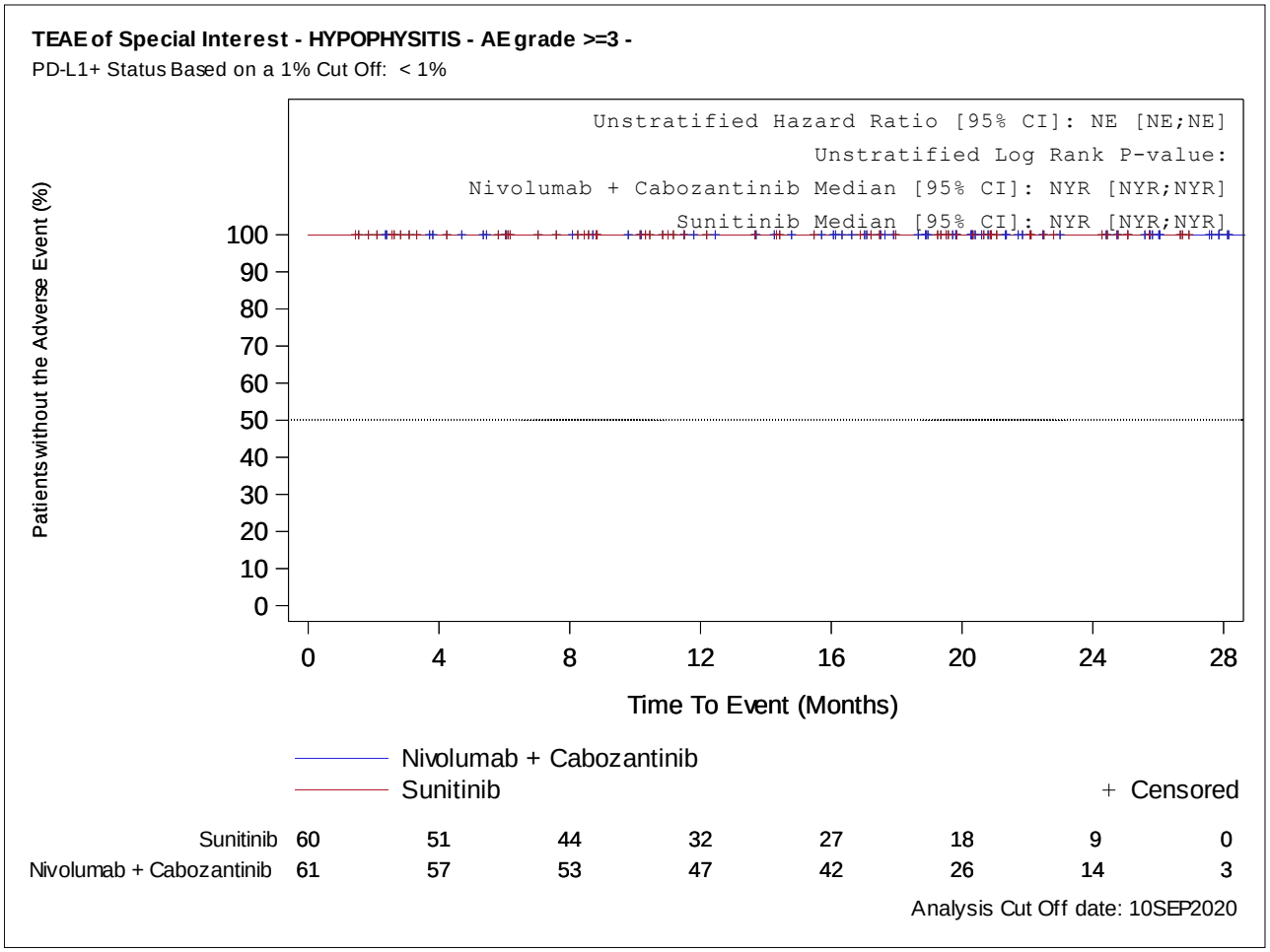
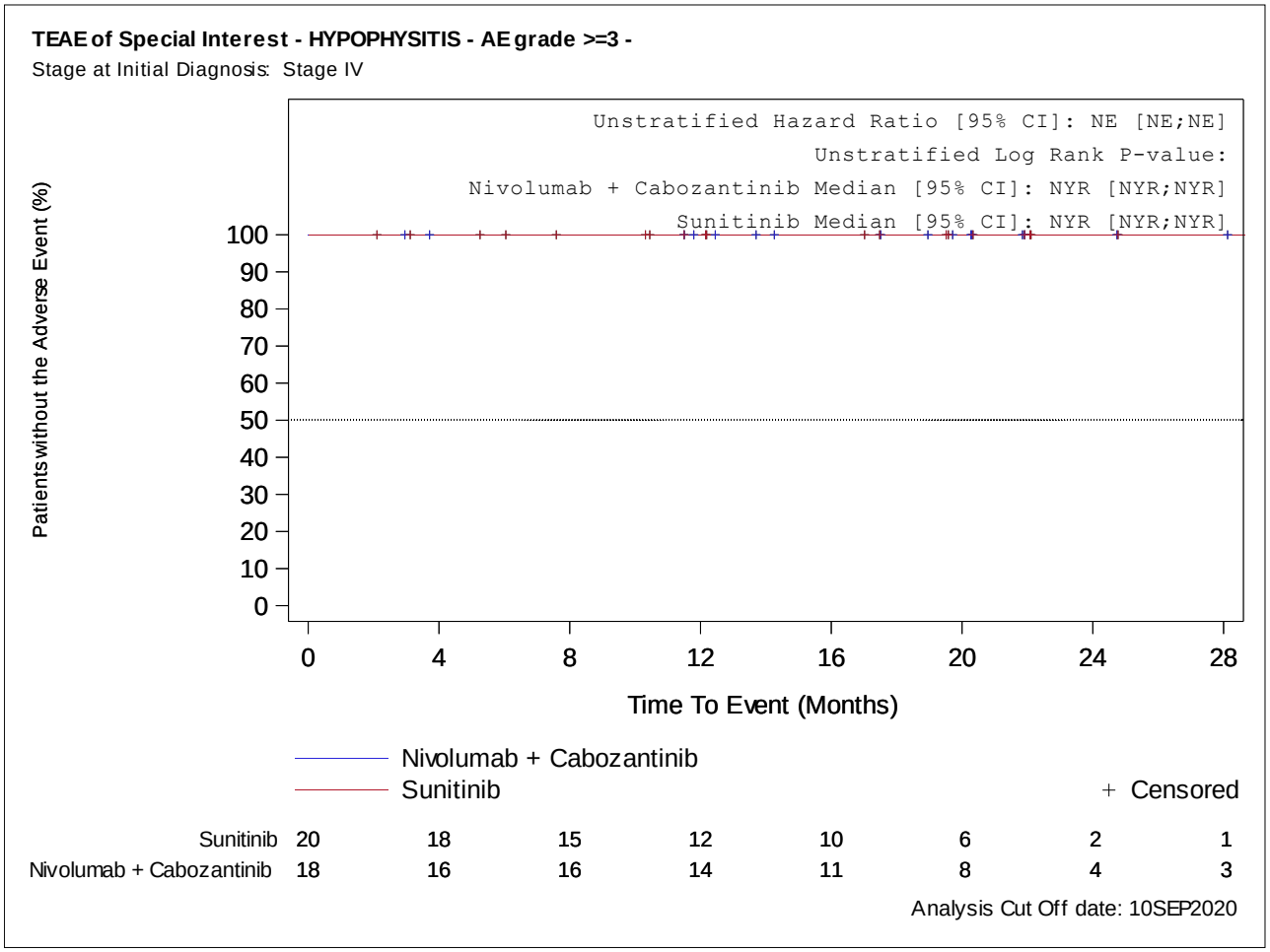
FIGURE 3.97.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



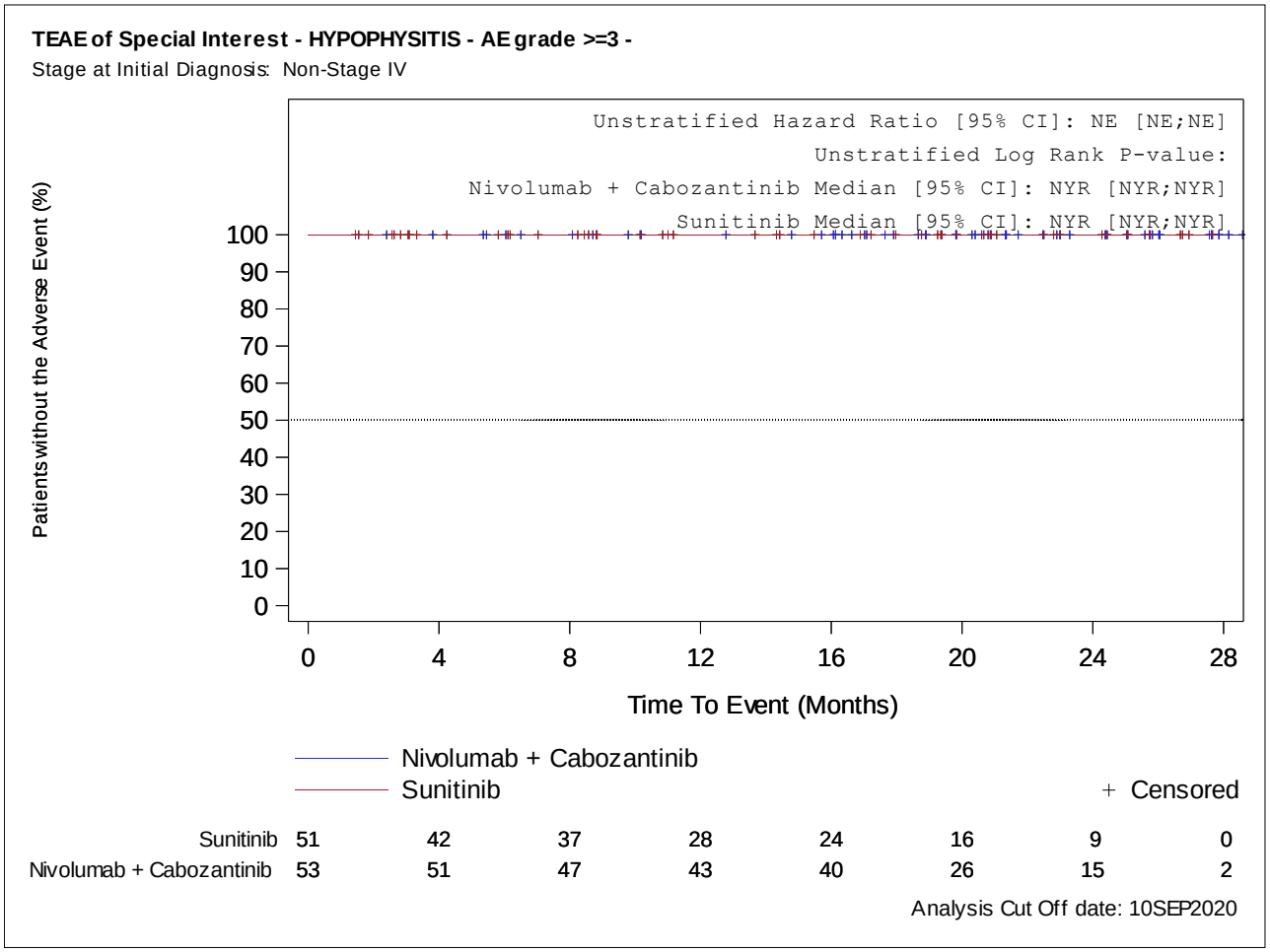

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:12:21

FIGURE 3.97.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



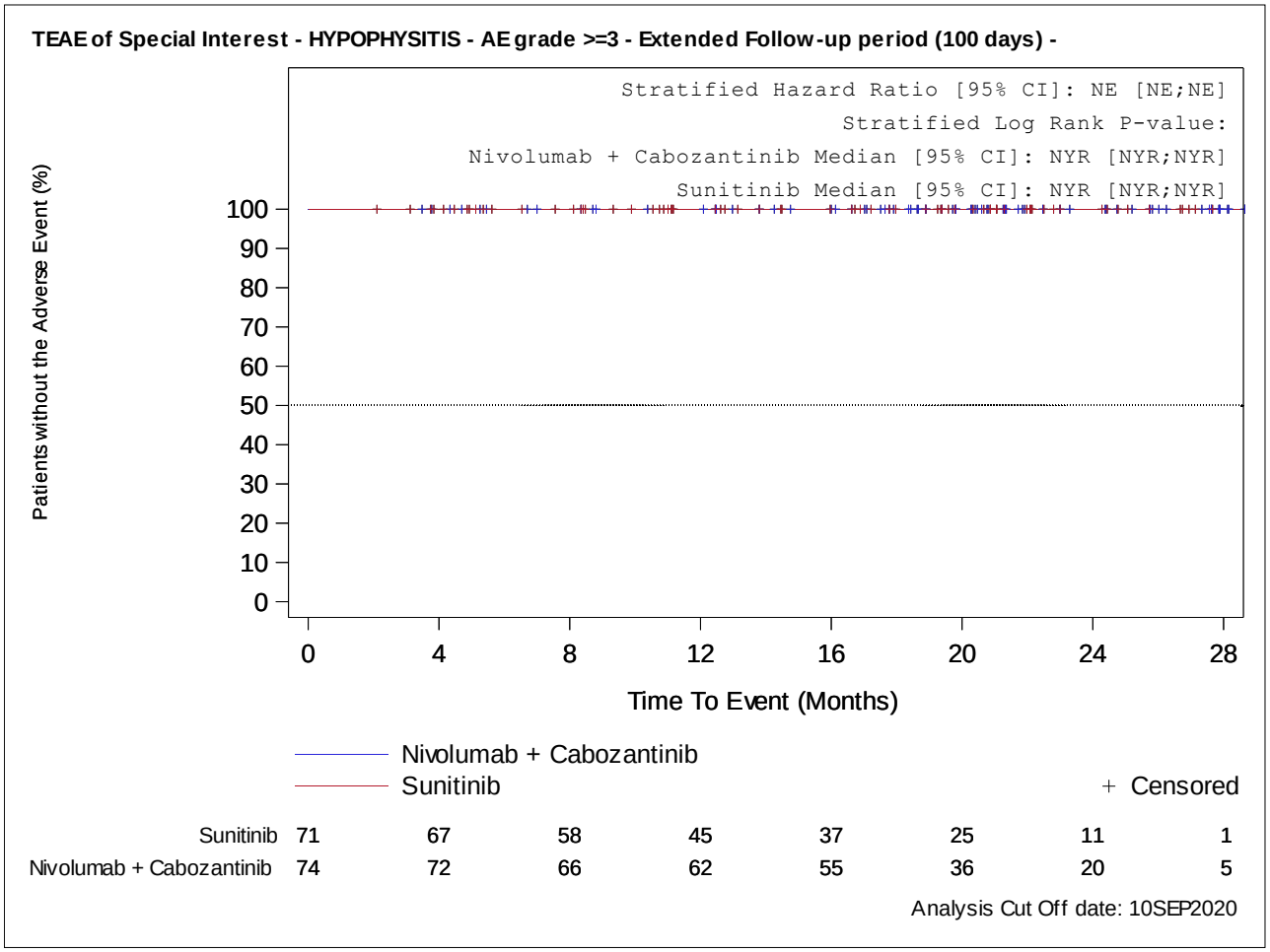

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:12:48

FIGURE 3.97.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



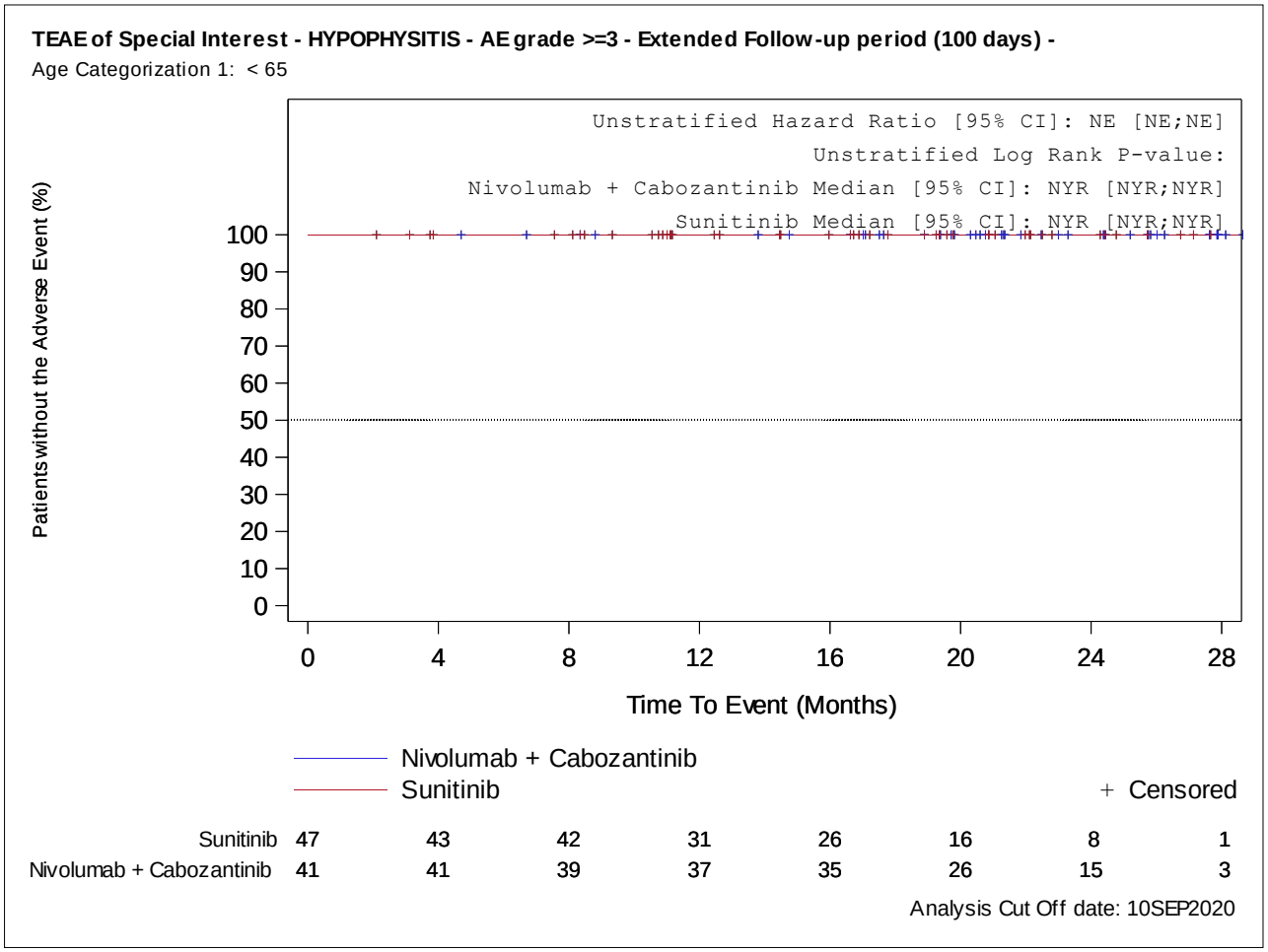

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:12:53

FIGURE 3.98.1: TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:15:49

FIGURE 3.98.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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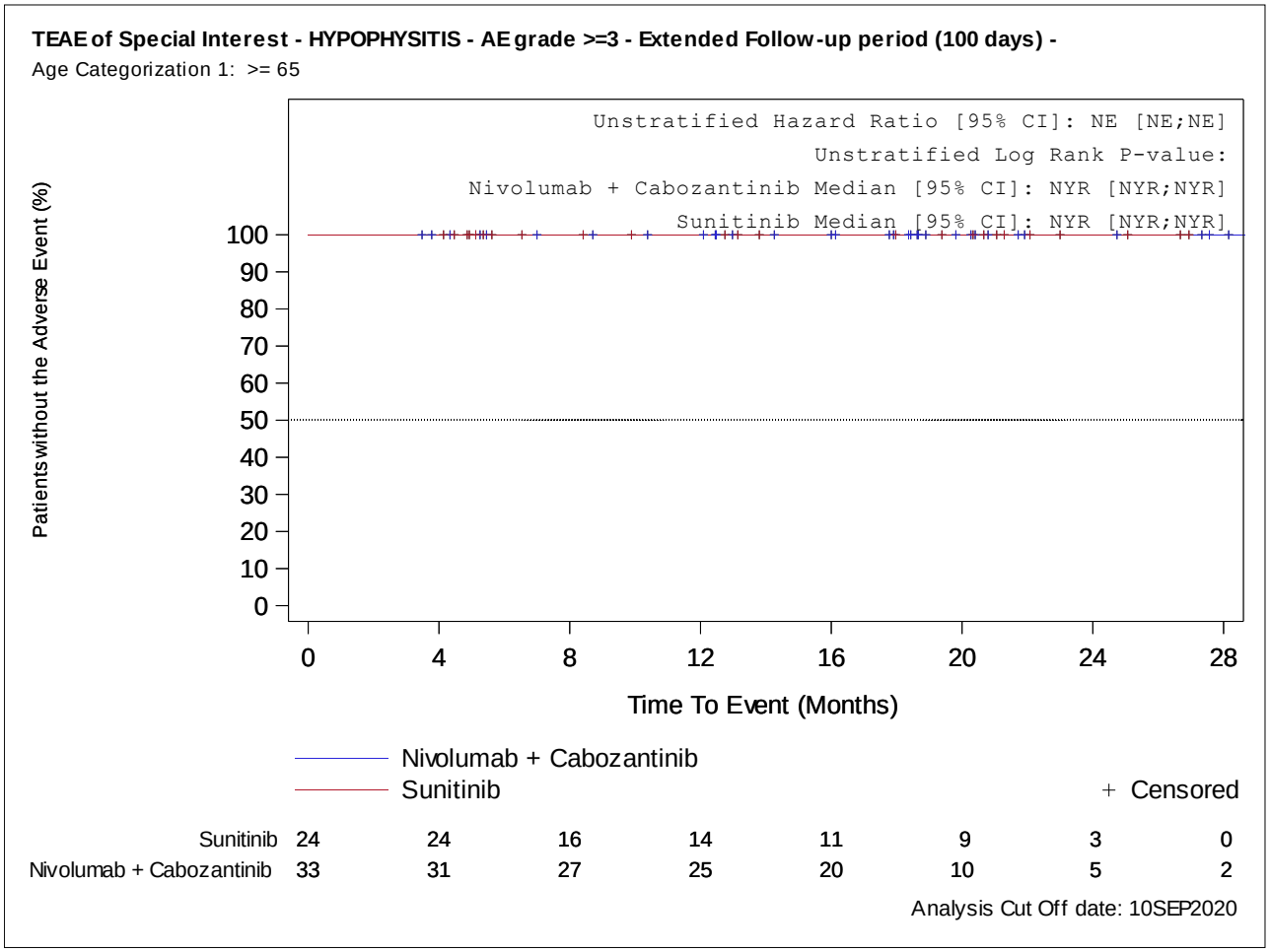
FIGURE 3.98.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
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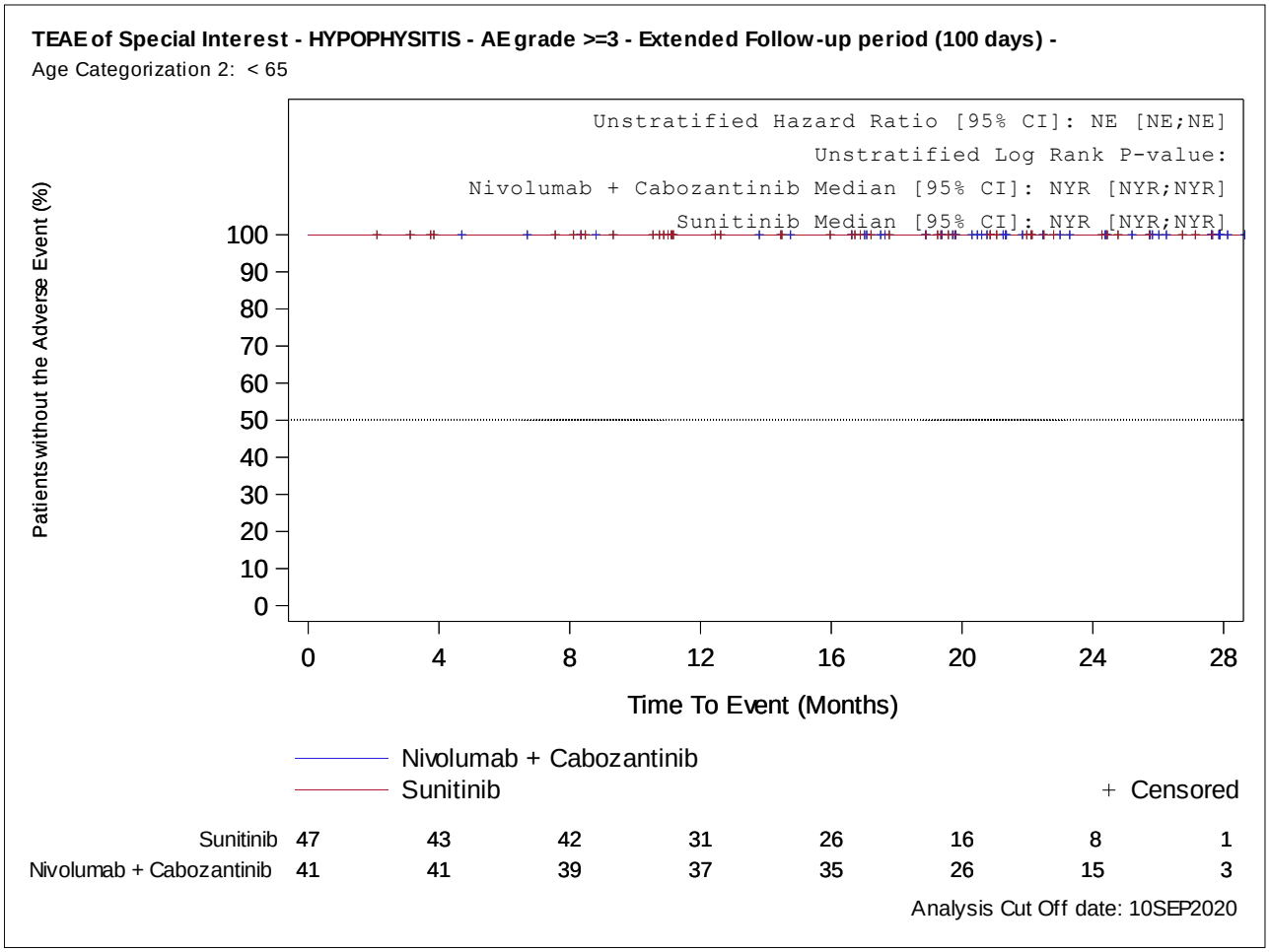
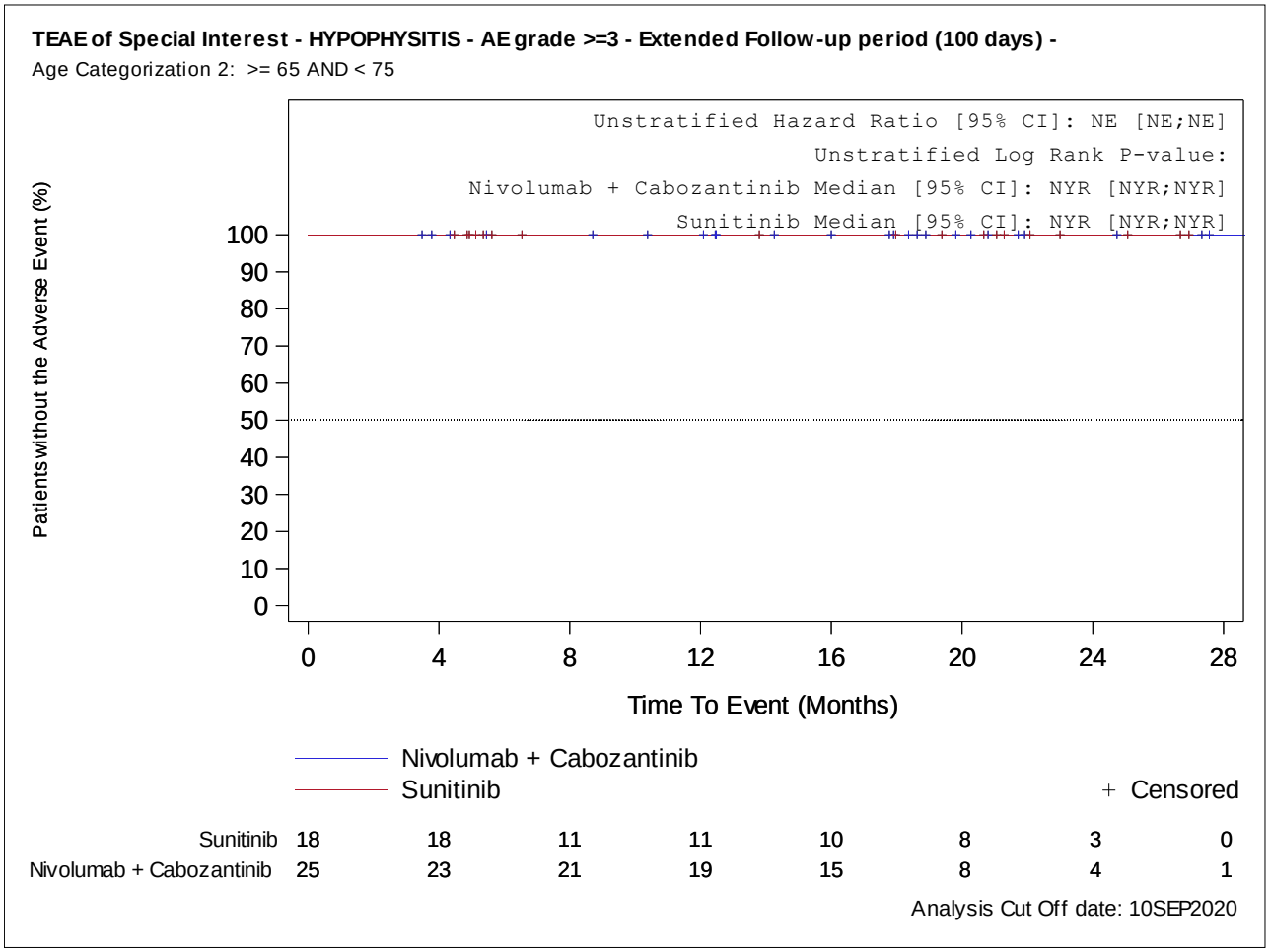
FIGURE 3.98.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:16:03

FIGURE 3.98.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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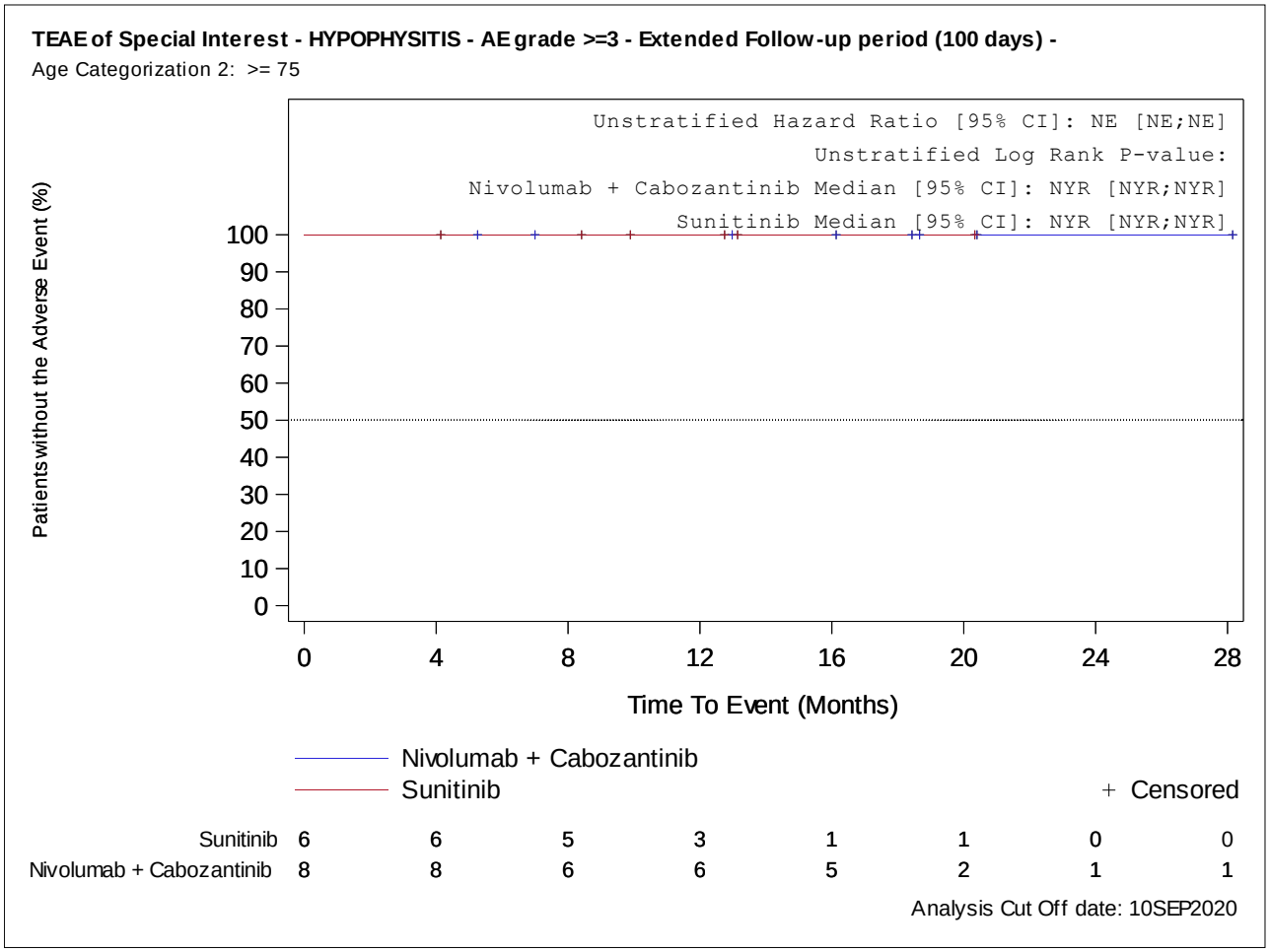
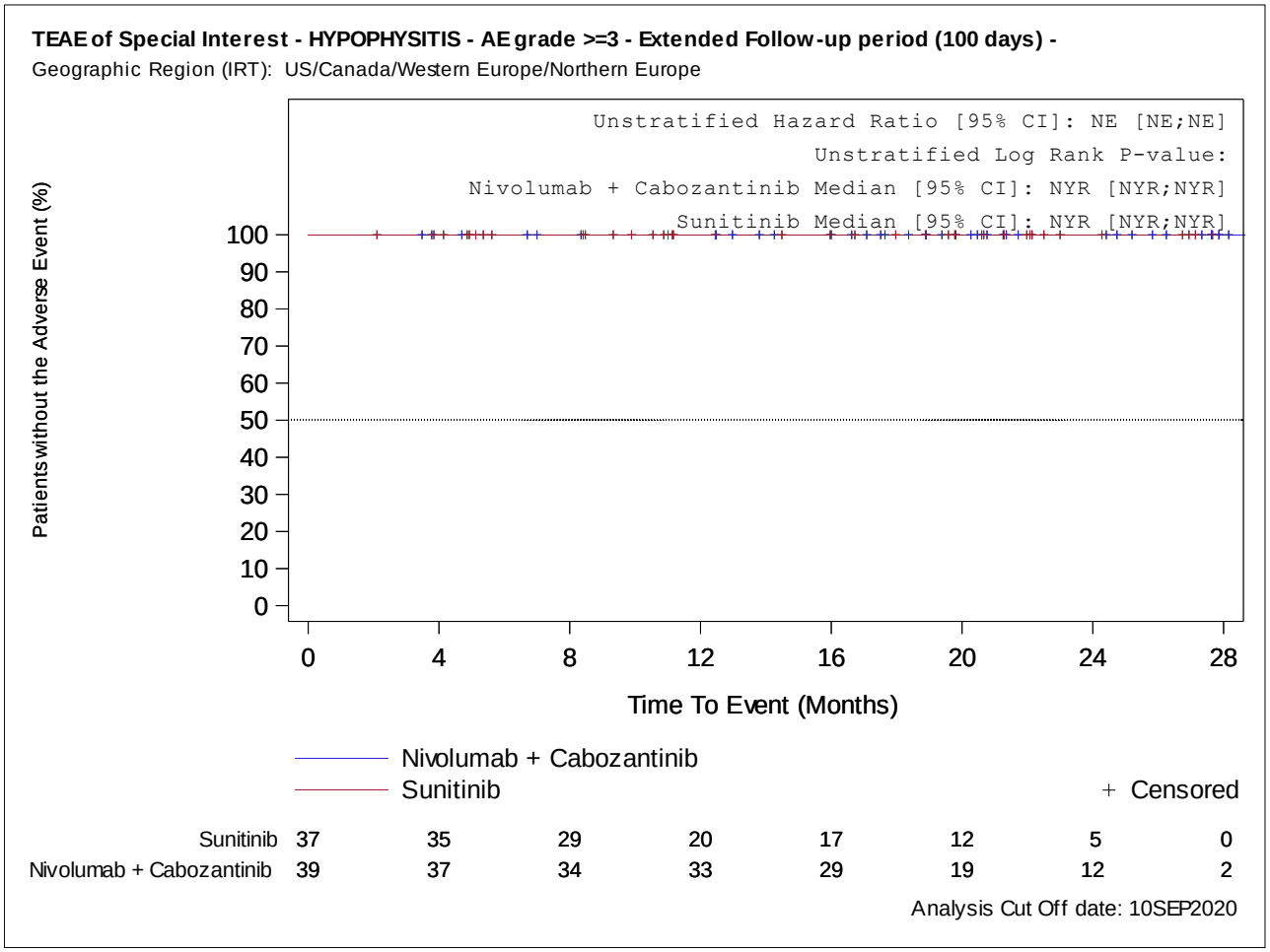
FIGURE 3.98.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



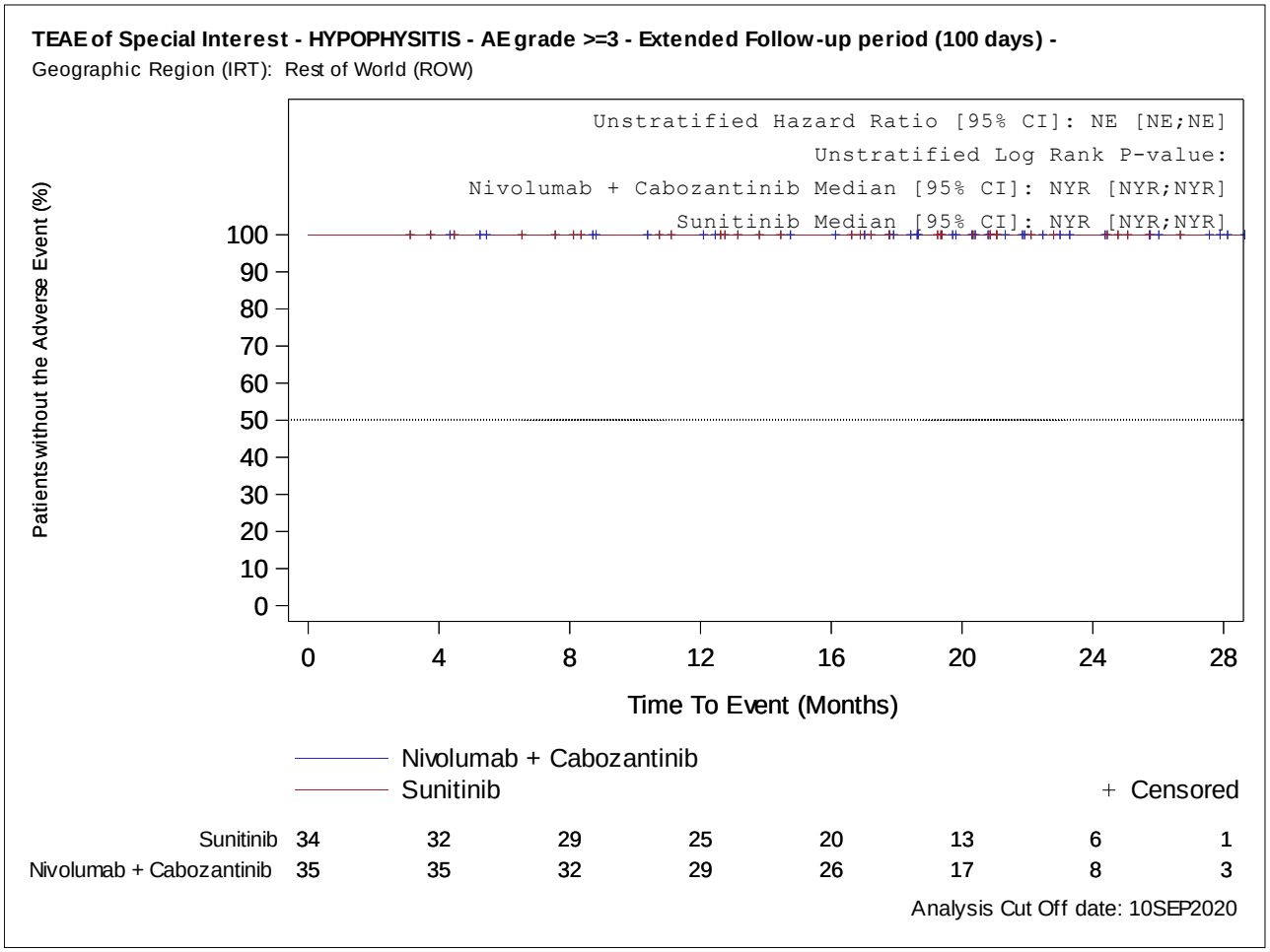

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:16:13

FIGURE 3.98.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



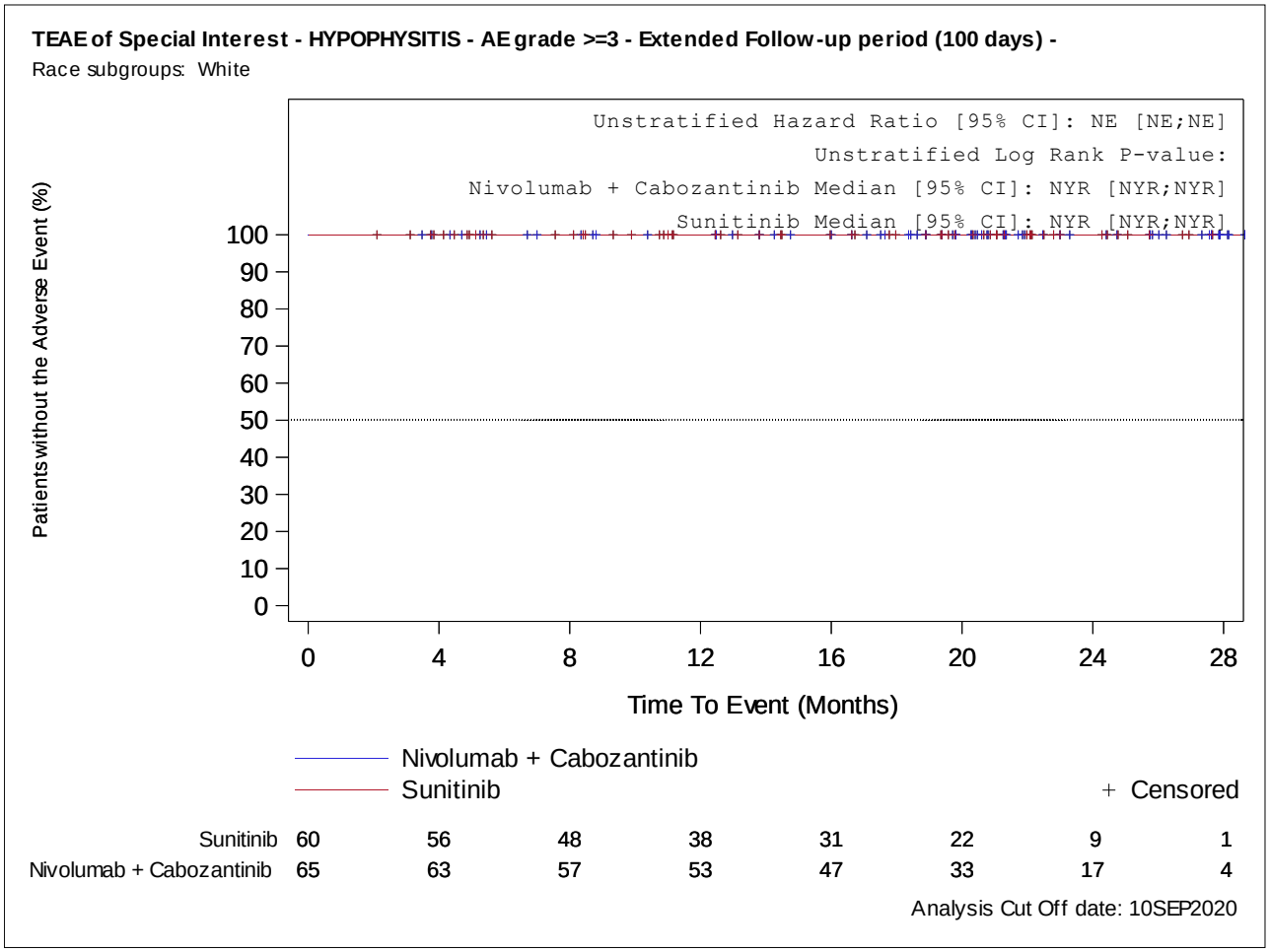

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:16:18

FIGURE 3.98.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



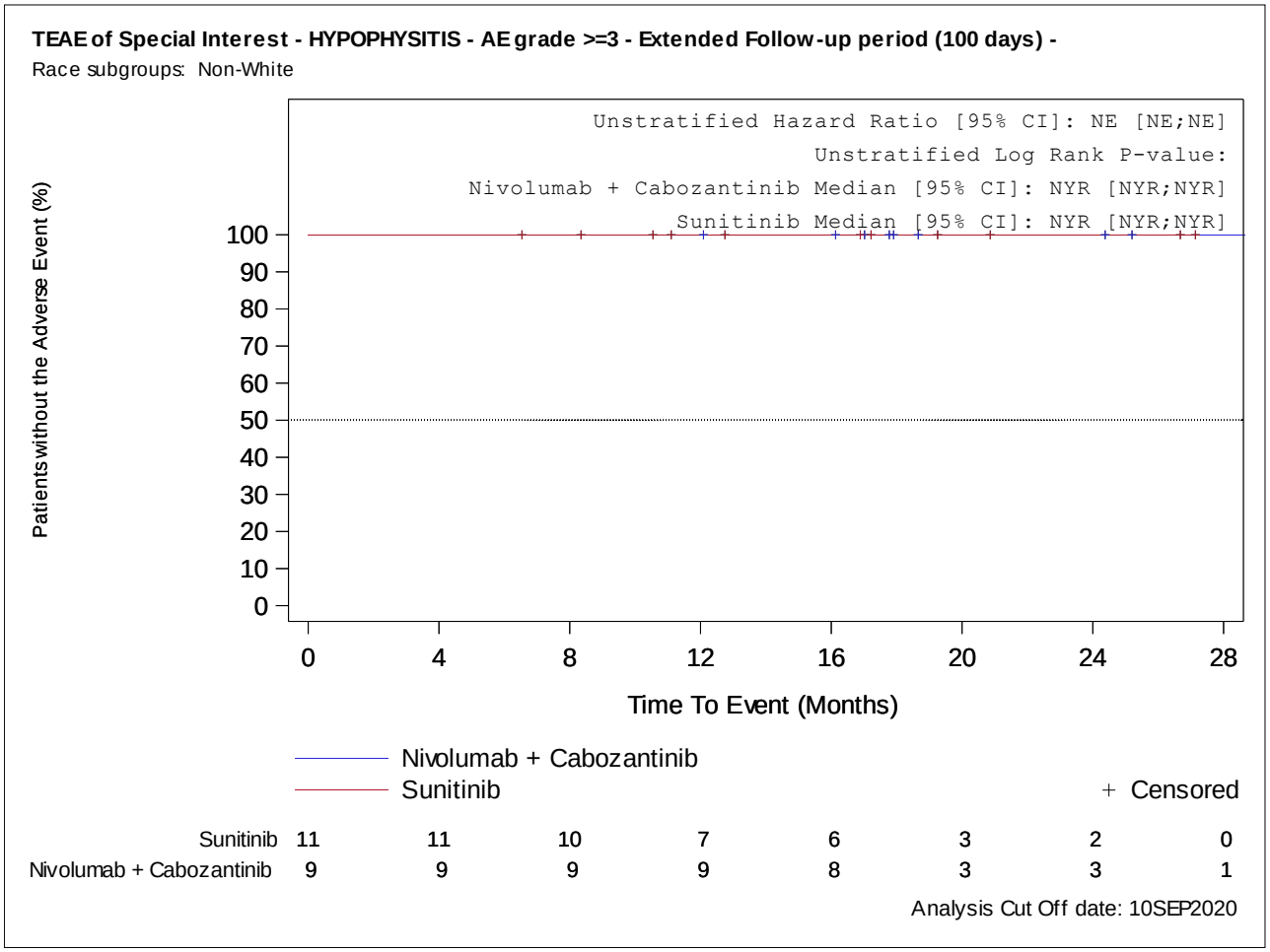

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:16:23

FIGURE 3.98.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



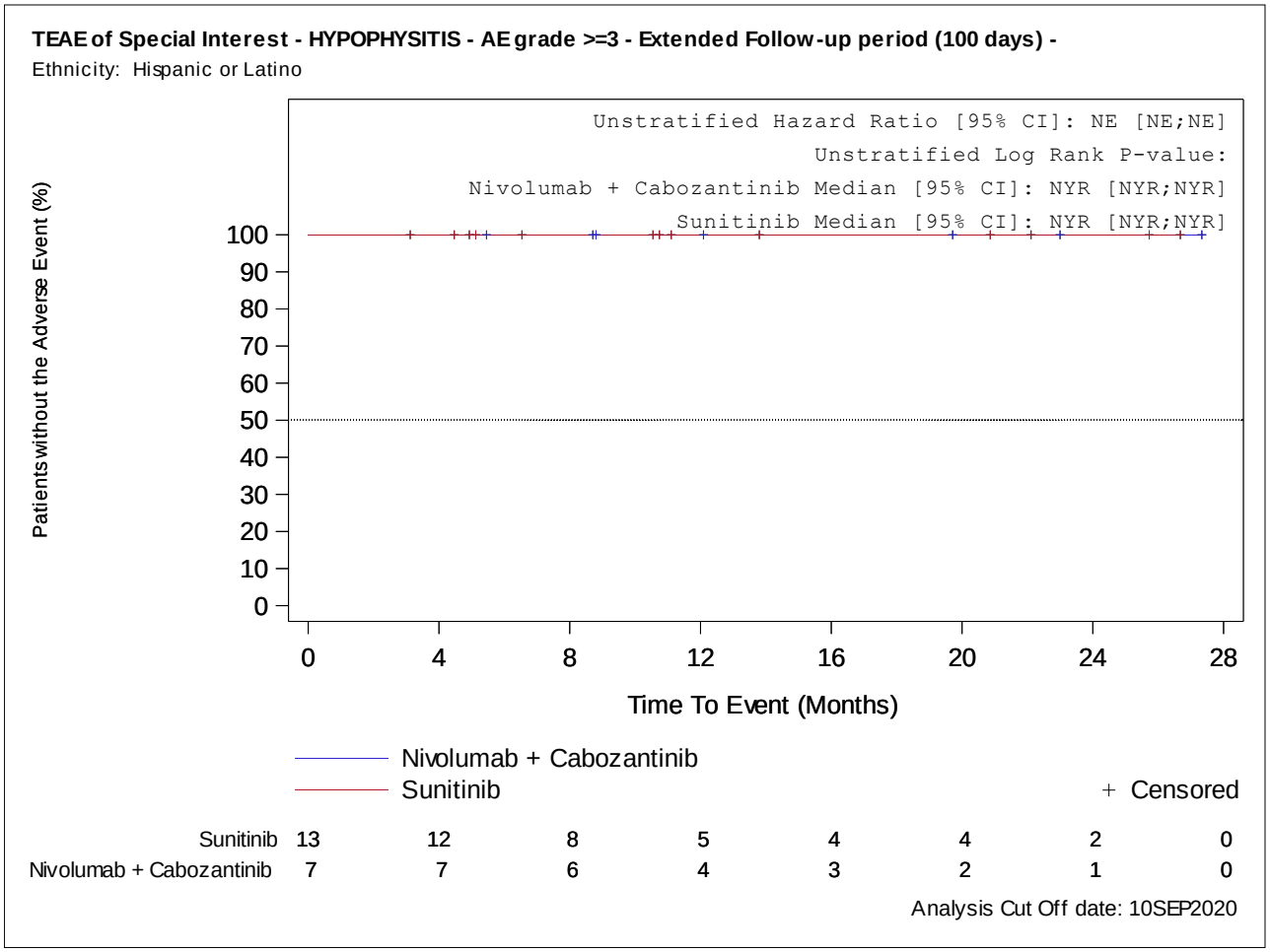

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:16:29

FIGURE 3.98.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:16:34

FIGURE 3.98.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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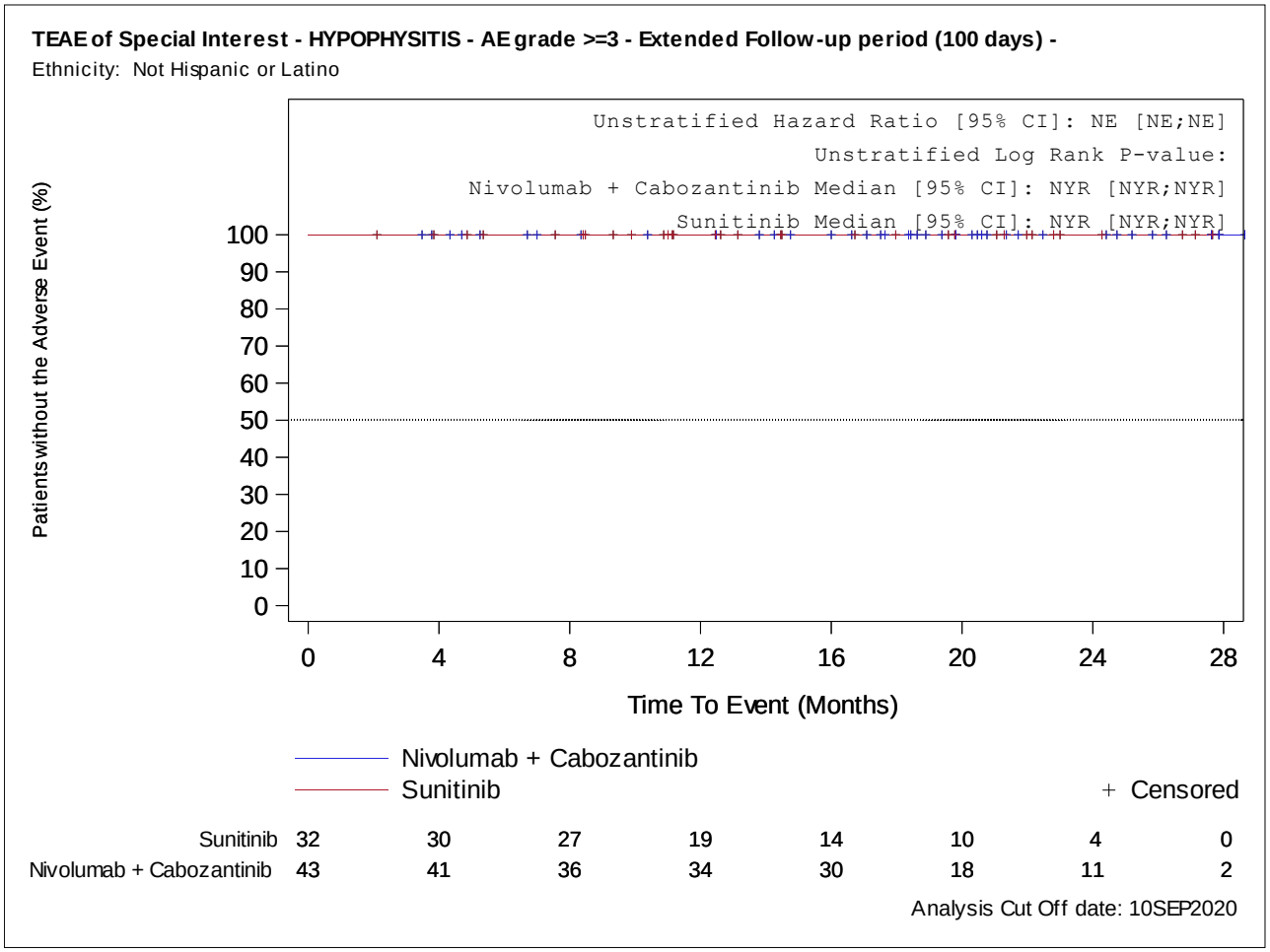
FIGURE 3.98.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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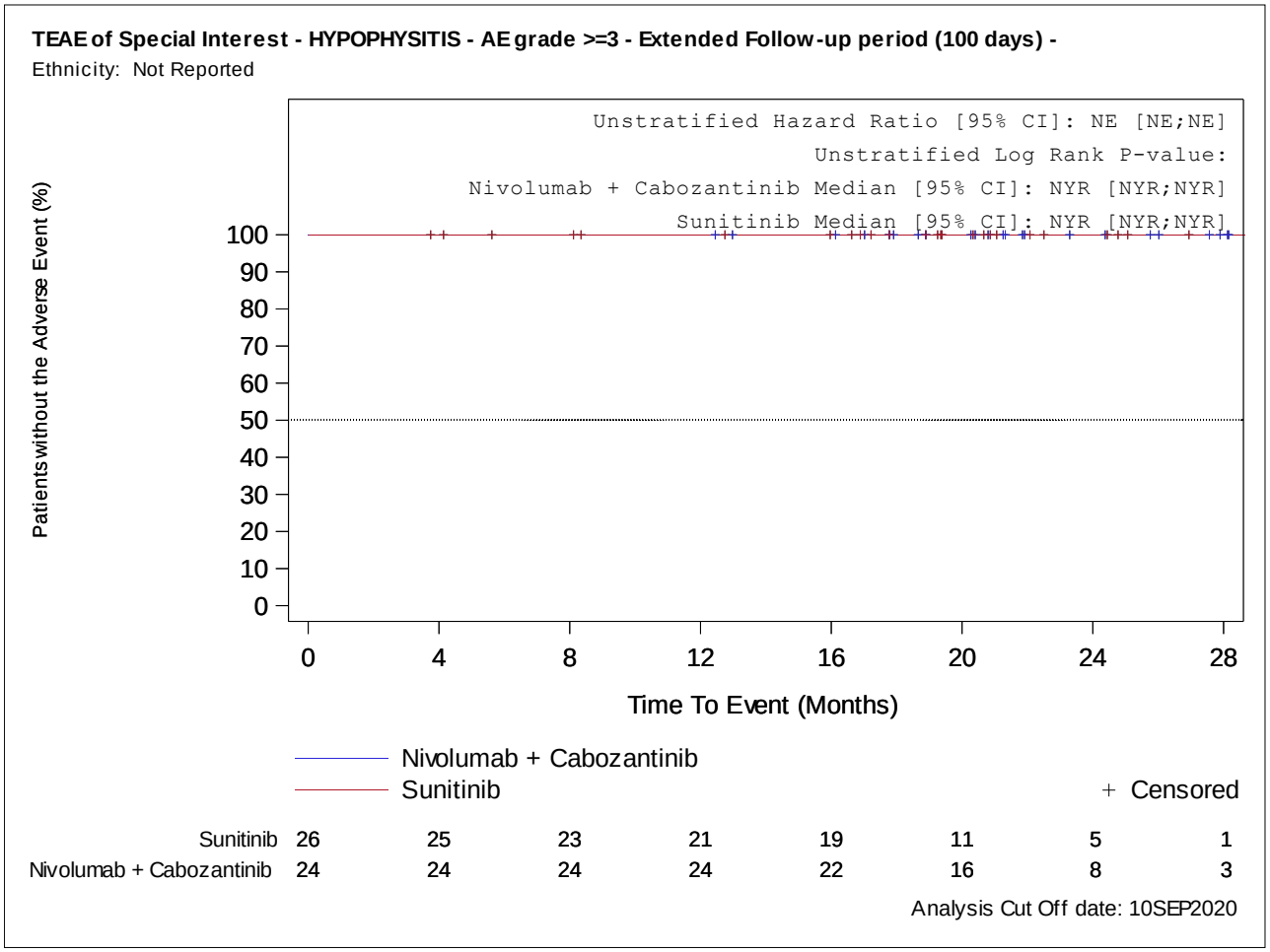
FIGURE 3.98.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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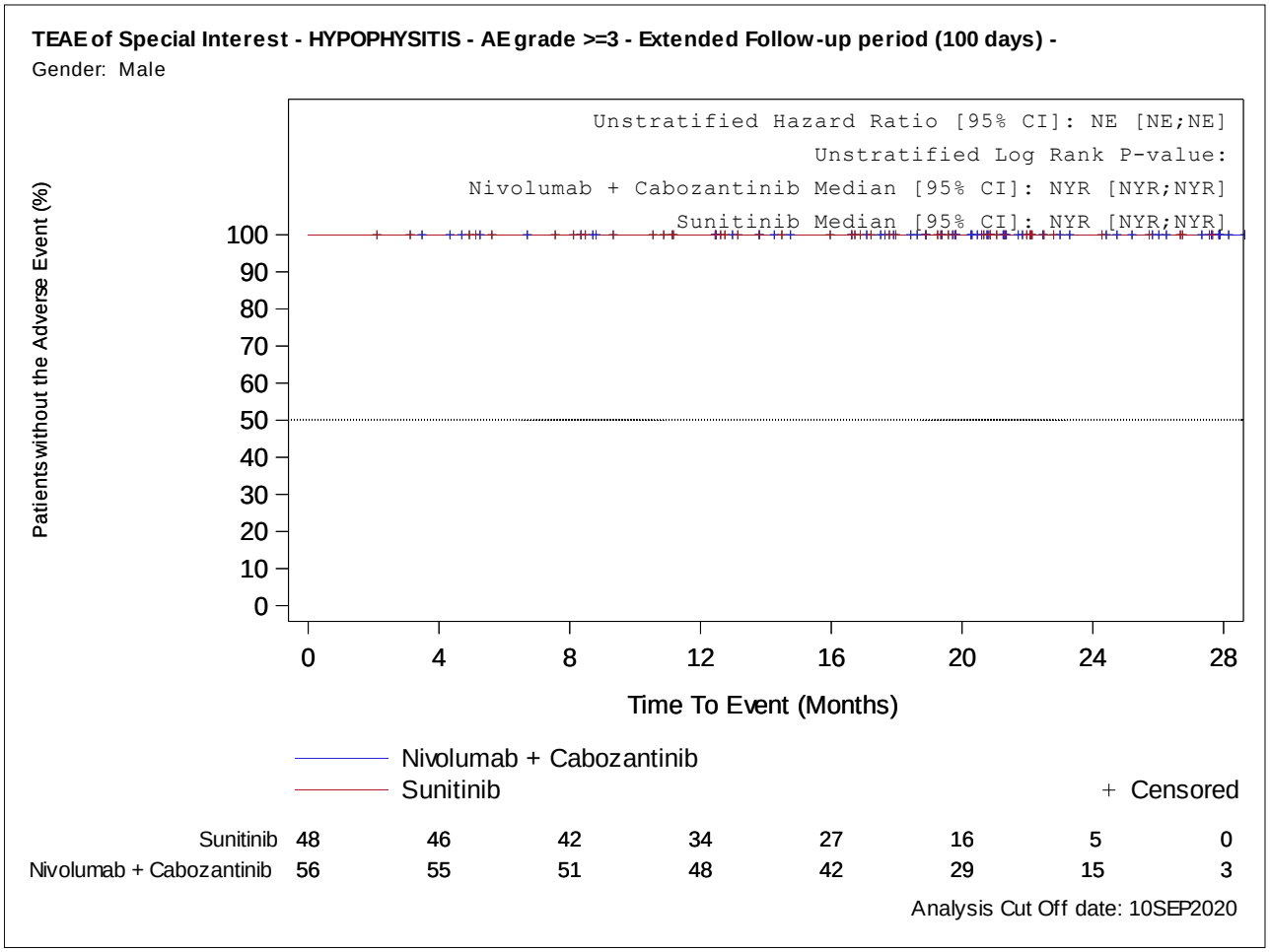
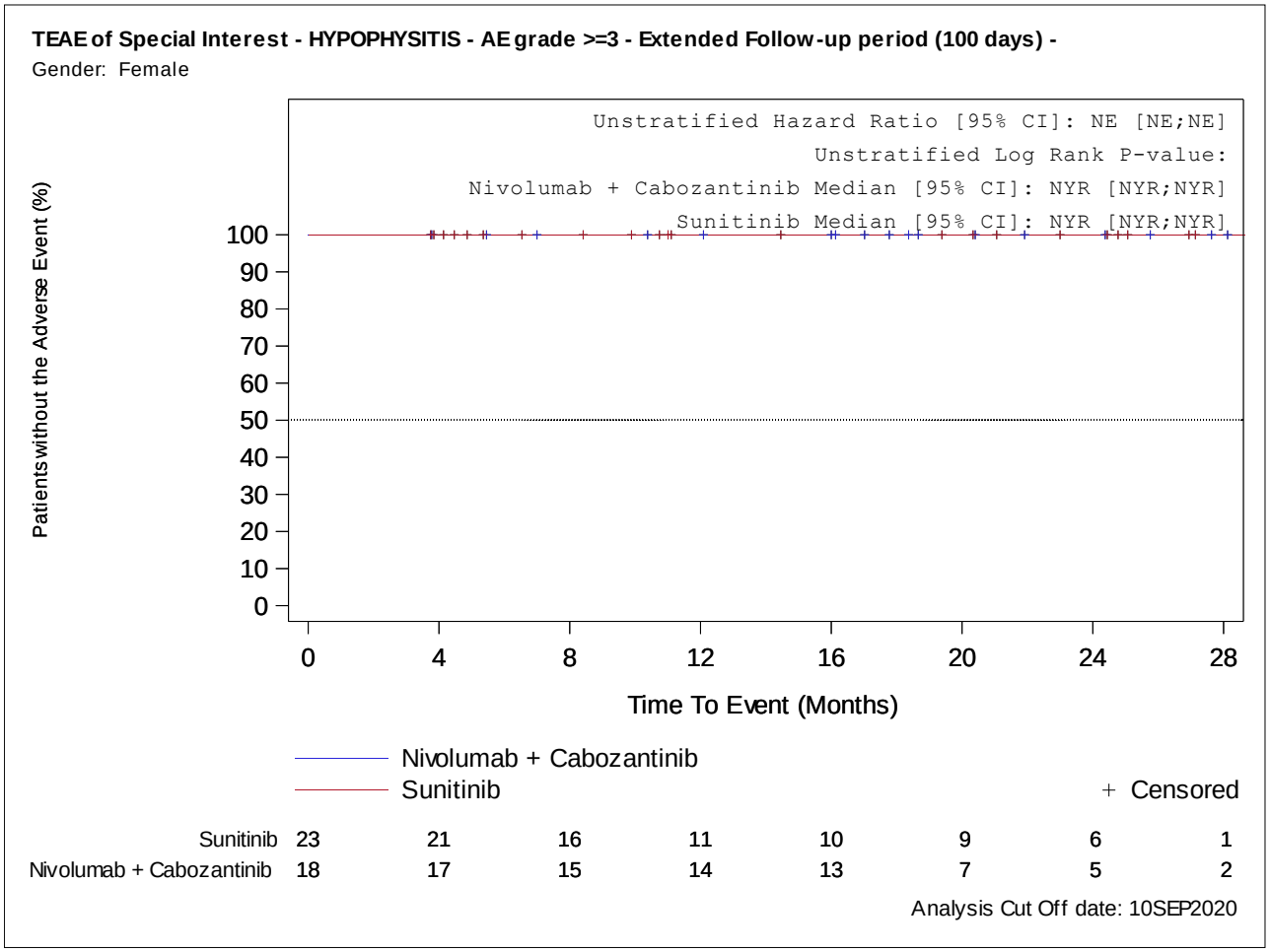
FIGURE 3.98.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



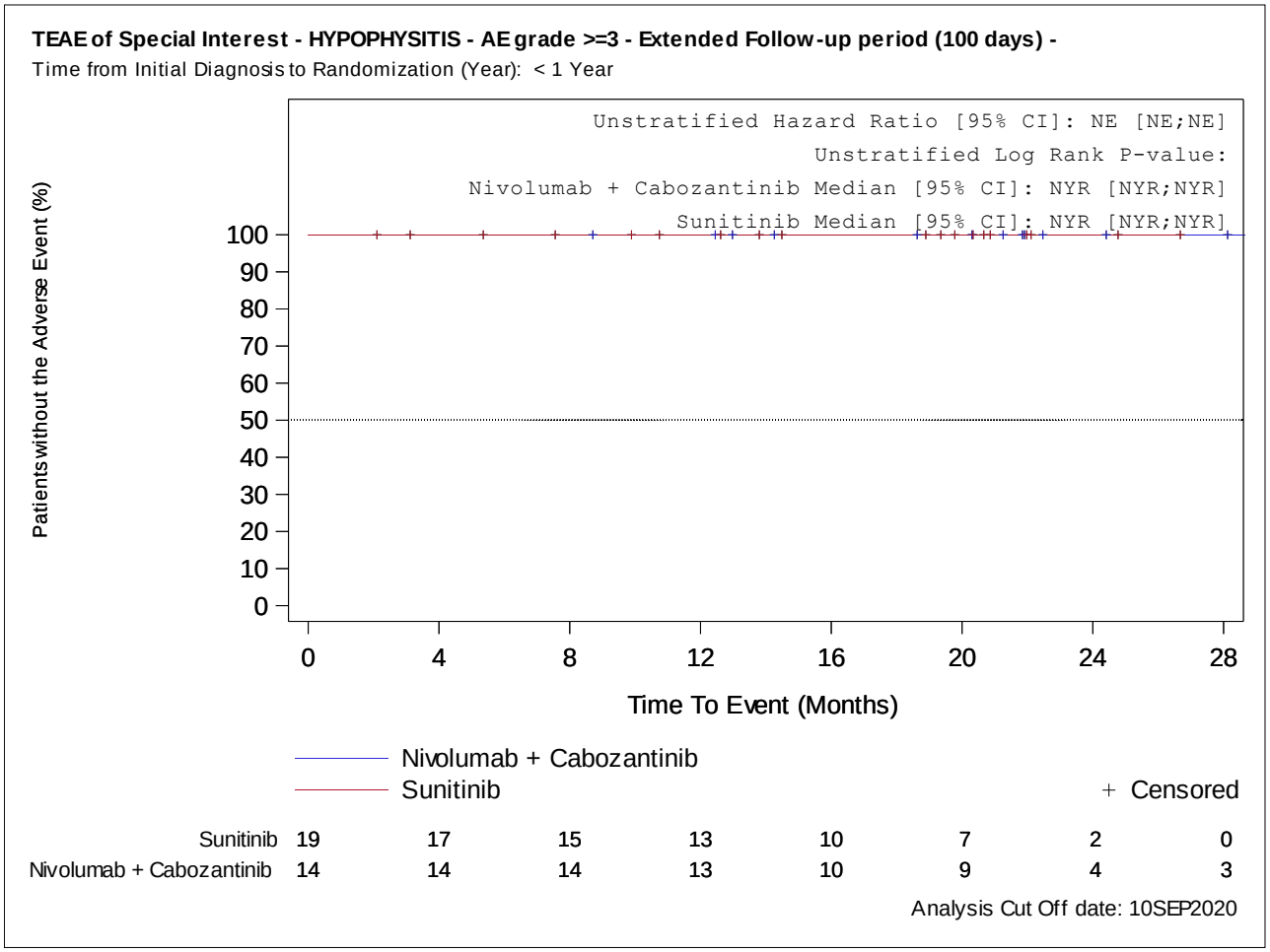

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:16:54

FIGURE 3.98.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:16:59

FIGURE 3.98.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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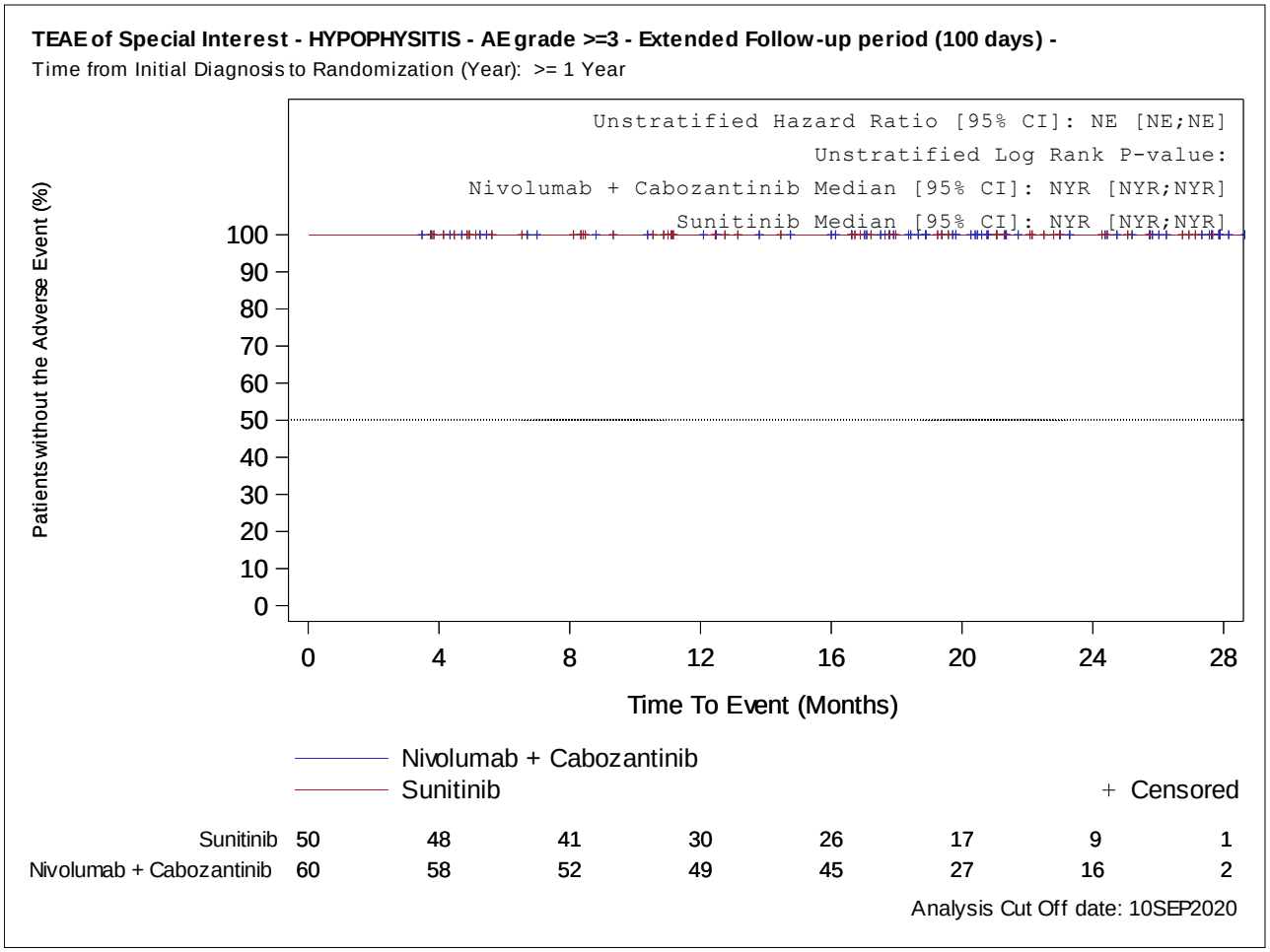
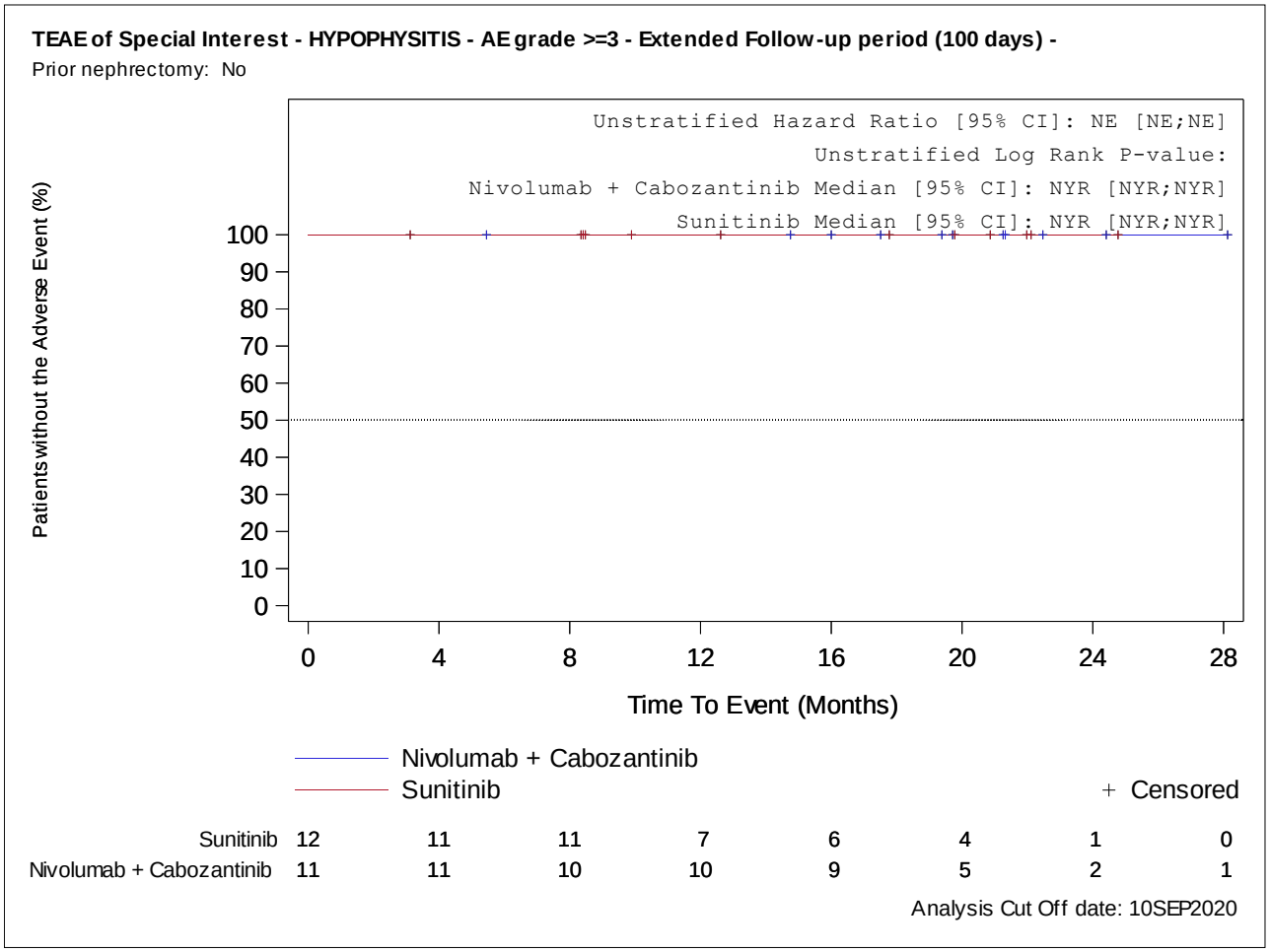
FIGURE 3.98.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



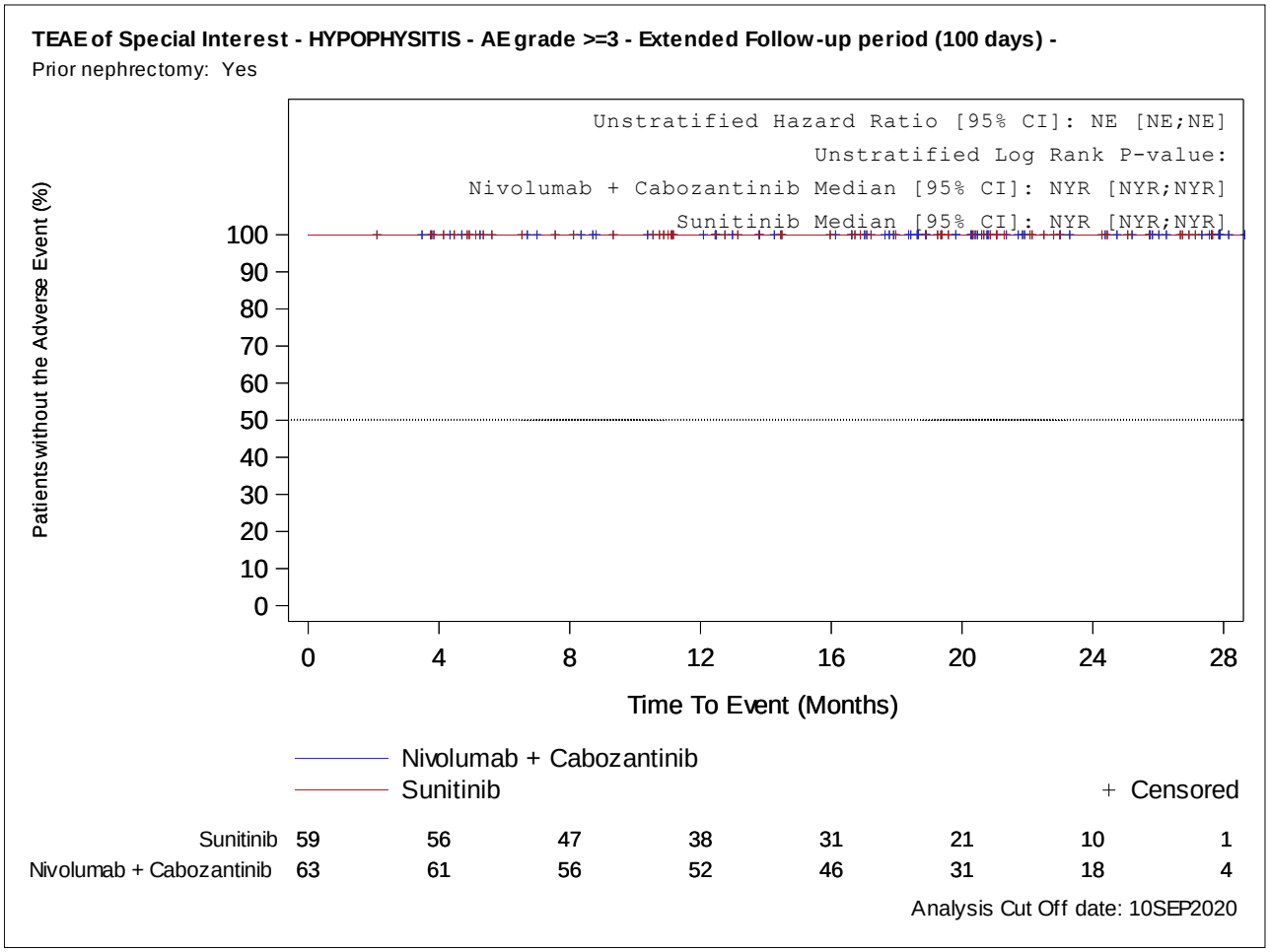

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:17:20

FIGURE 3.98.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



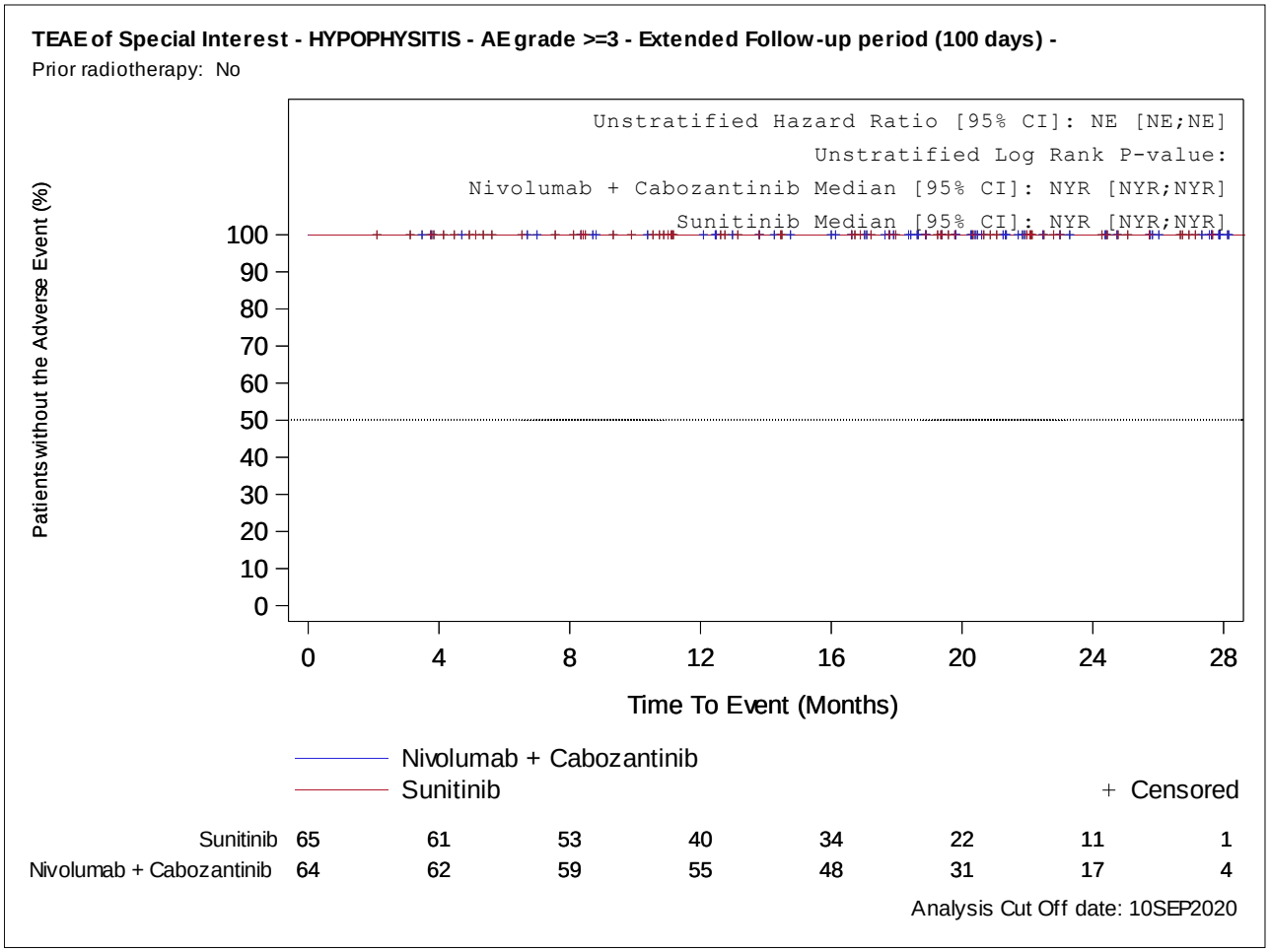

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:18:07

FIGURE 3.98.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



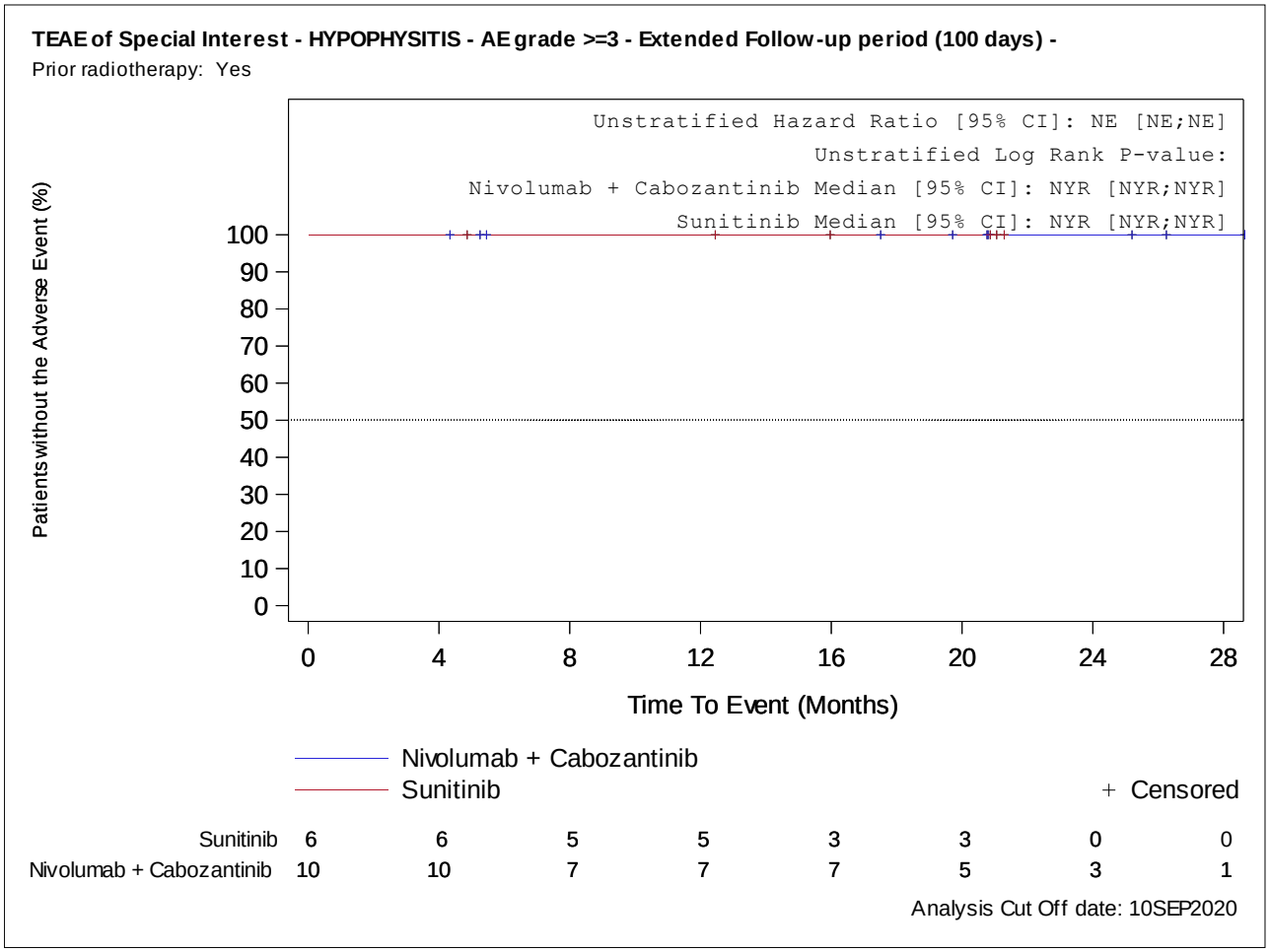

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:18:12

FIGURE 3.98.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



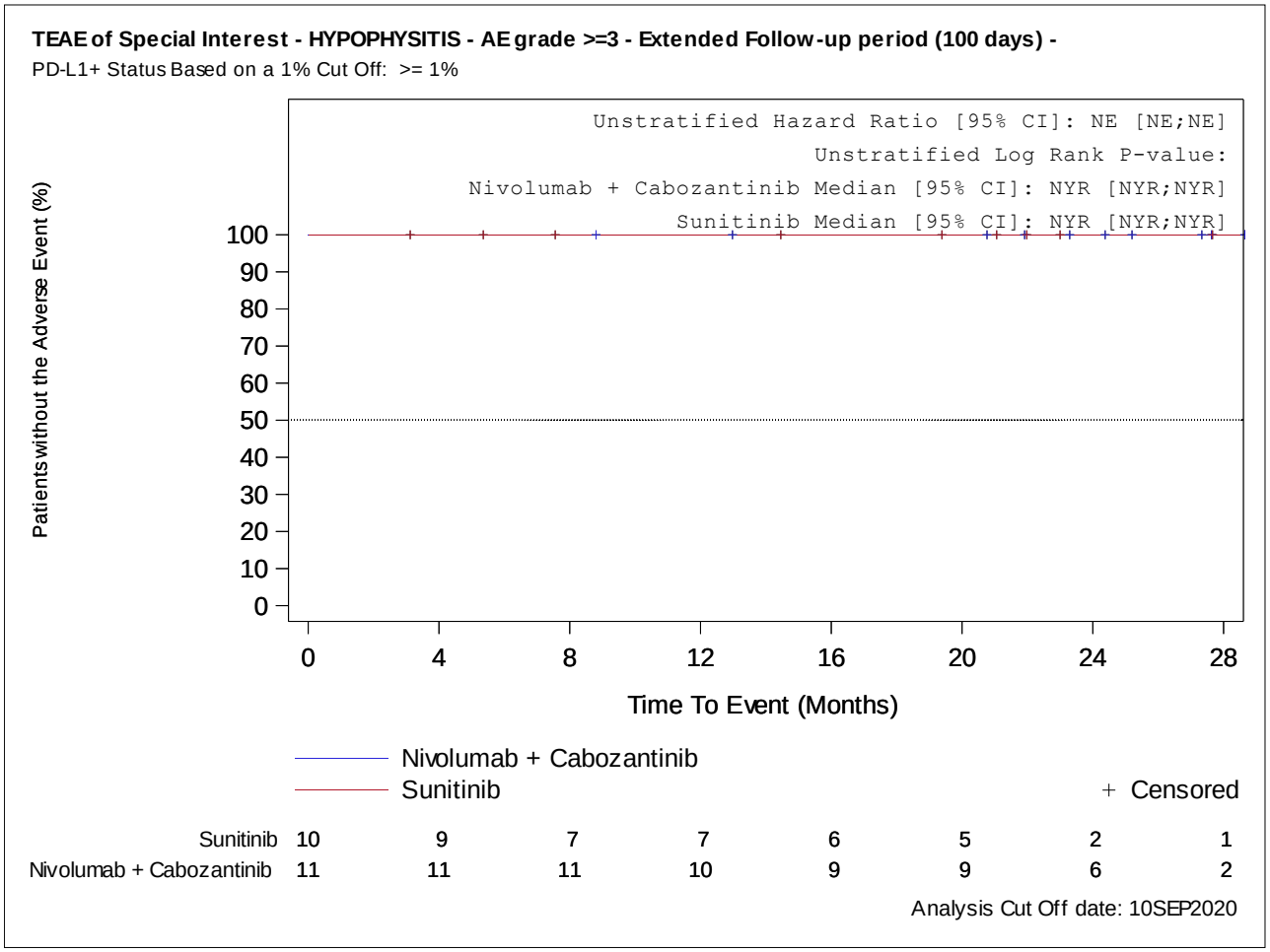

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:18:18

FIGURE 3.98.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



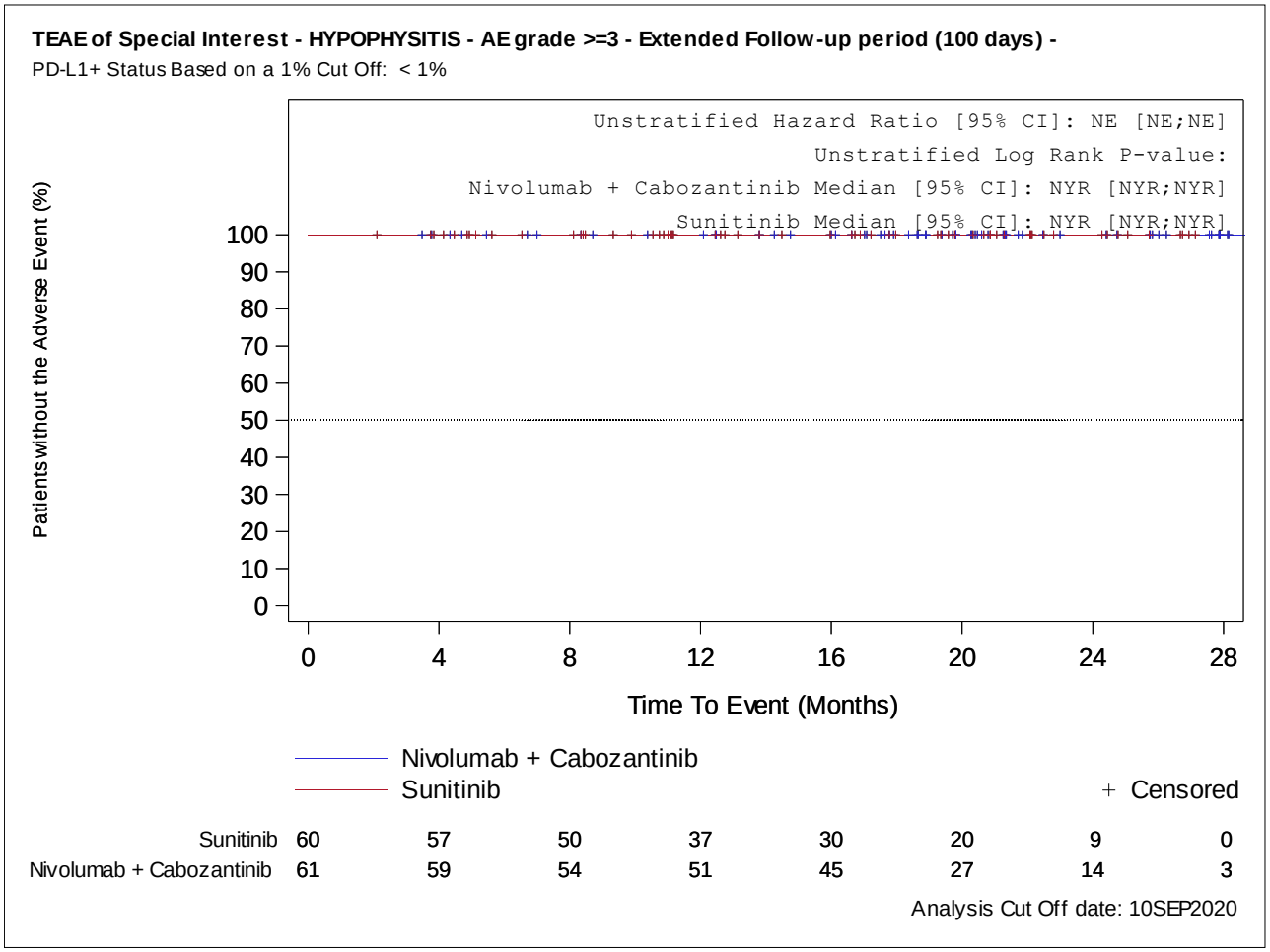

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:18:23

FIGURE 3.98.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



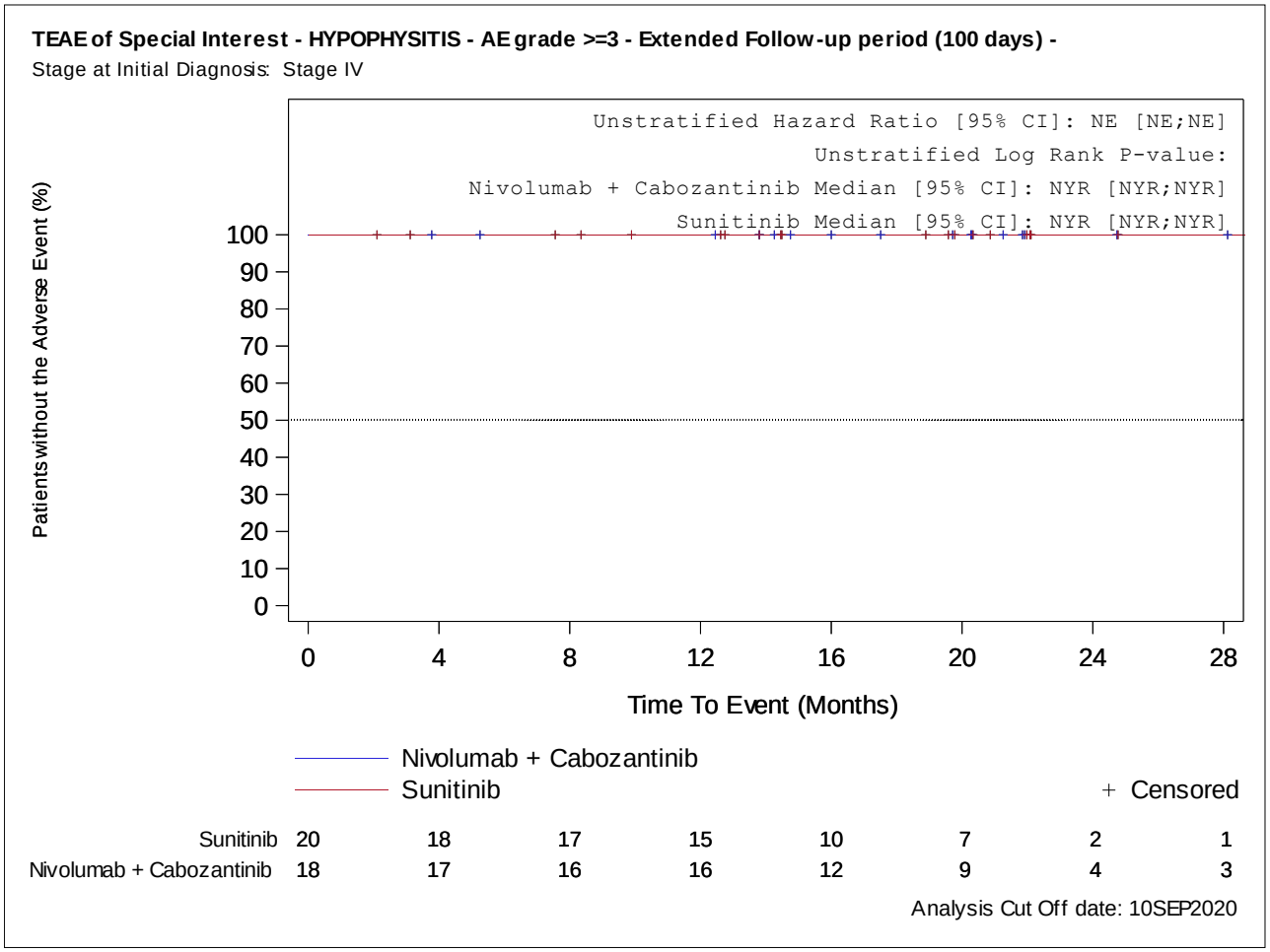

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:18:29

FIGURE 3.98.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



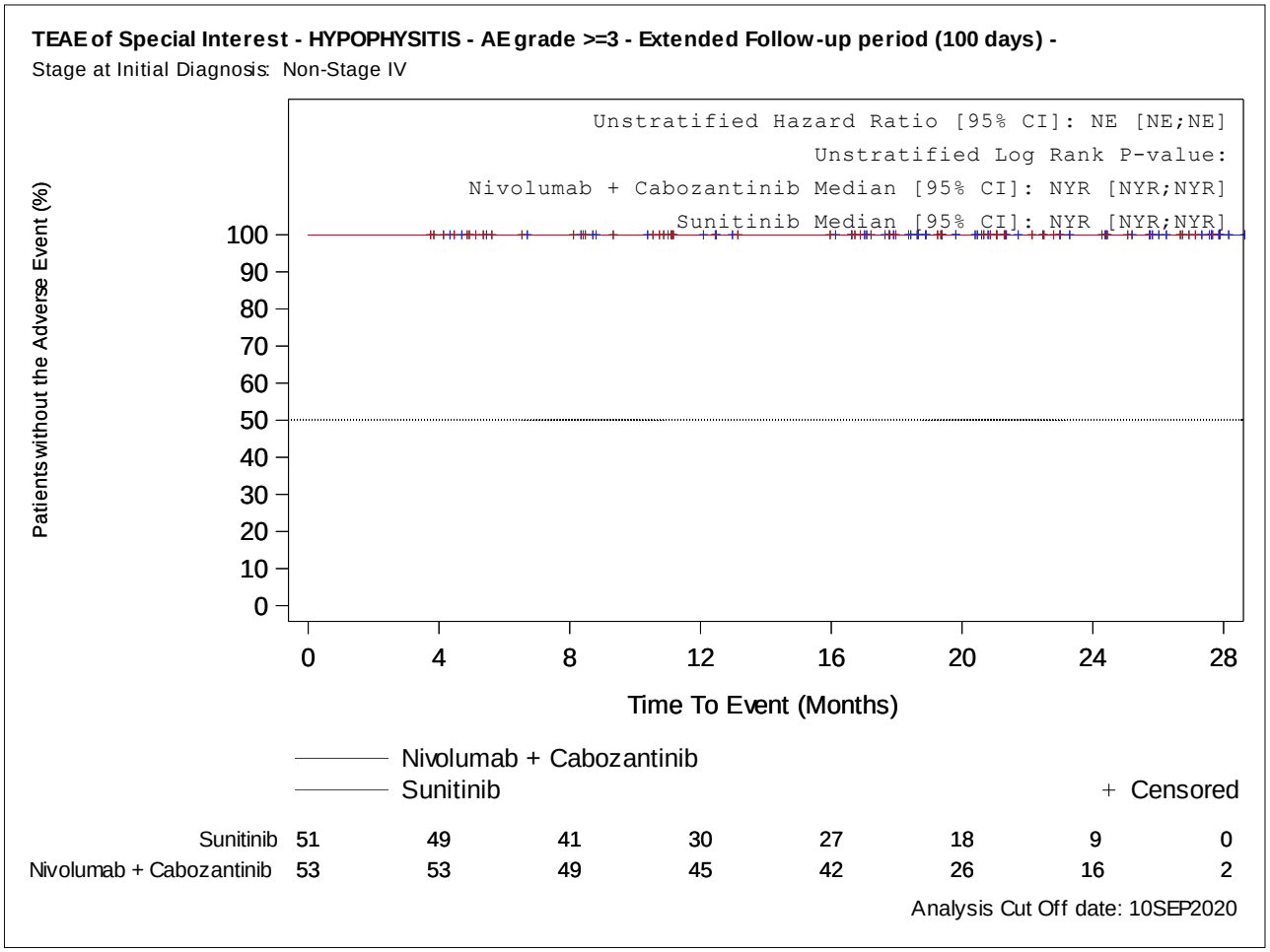

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:18:34

FIGURE 3.98.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



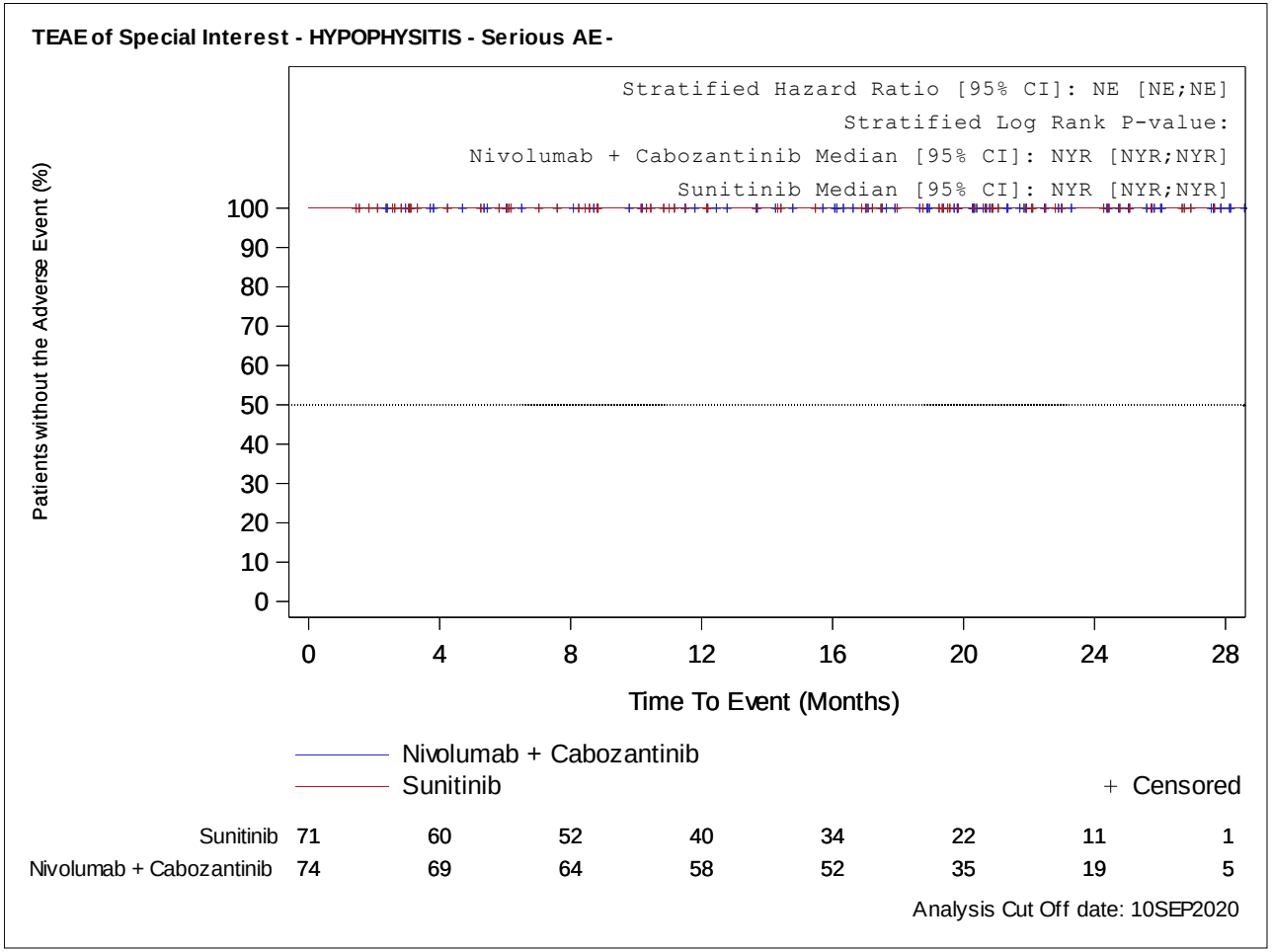

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:18:59

FIGURE 3.98.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - AE grade >=3 - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



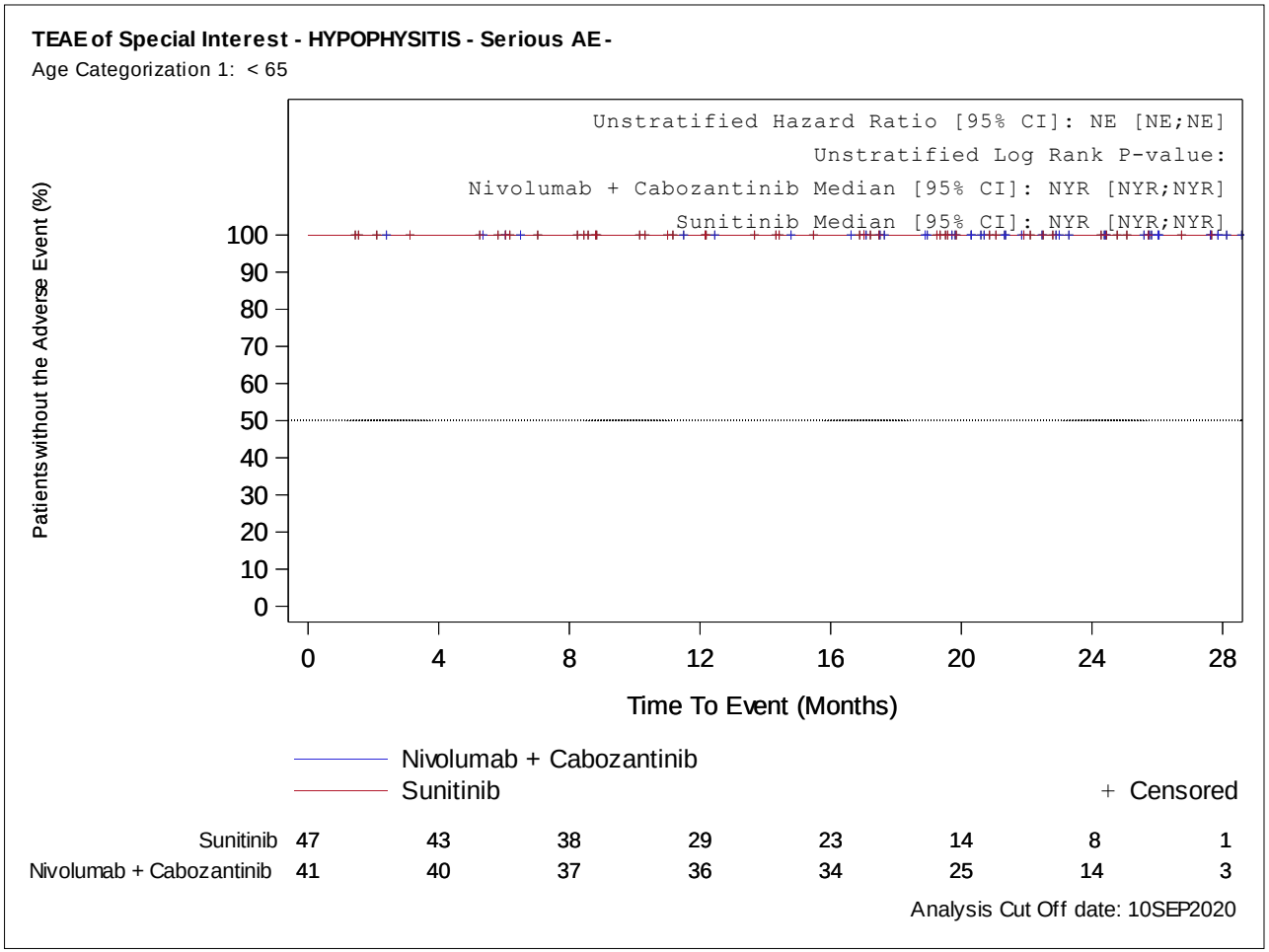

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:19:05

FIGURE 3.99.1: TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



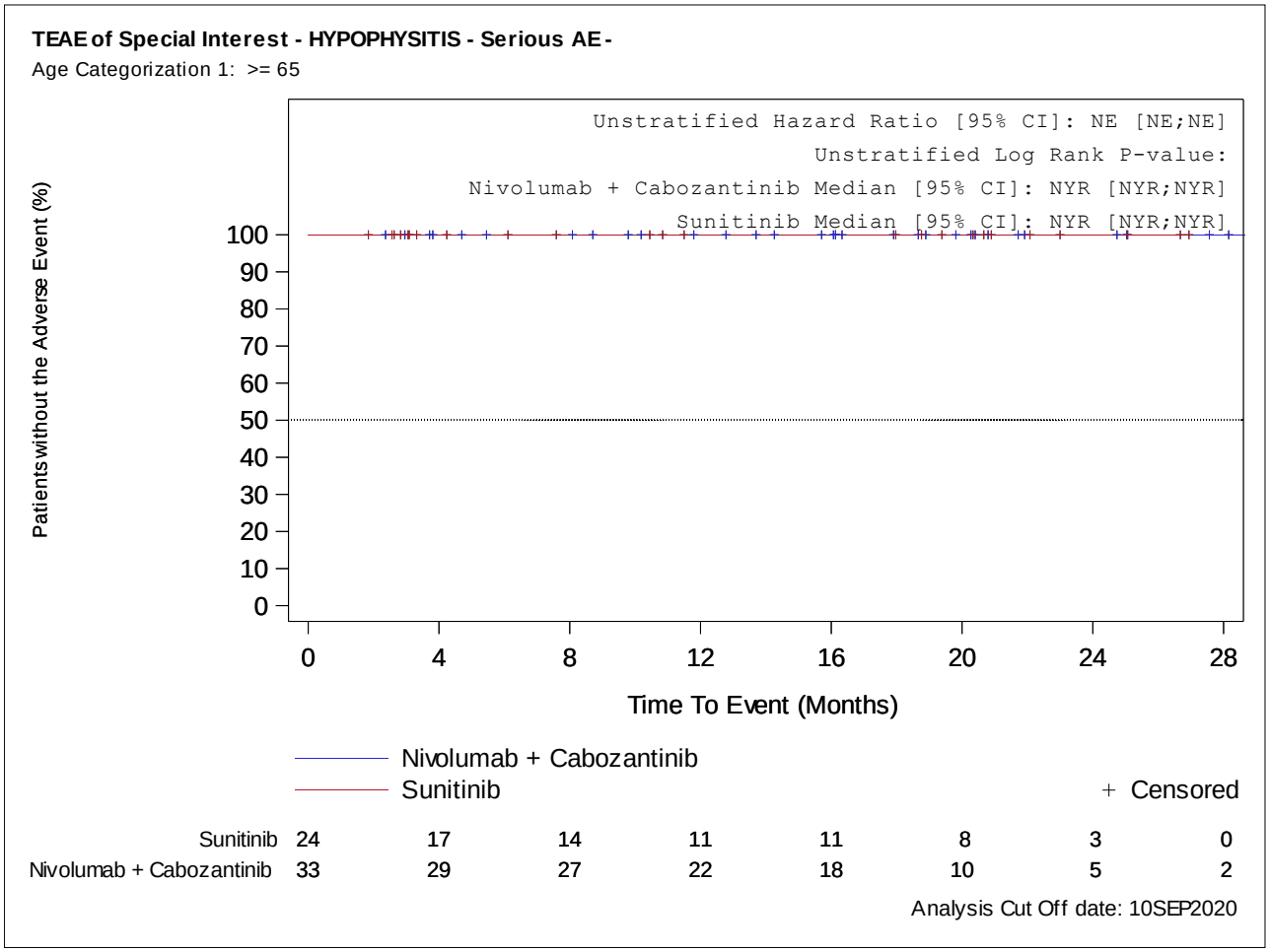

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:01

FIGURE 3.99.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



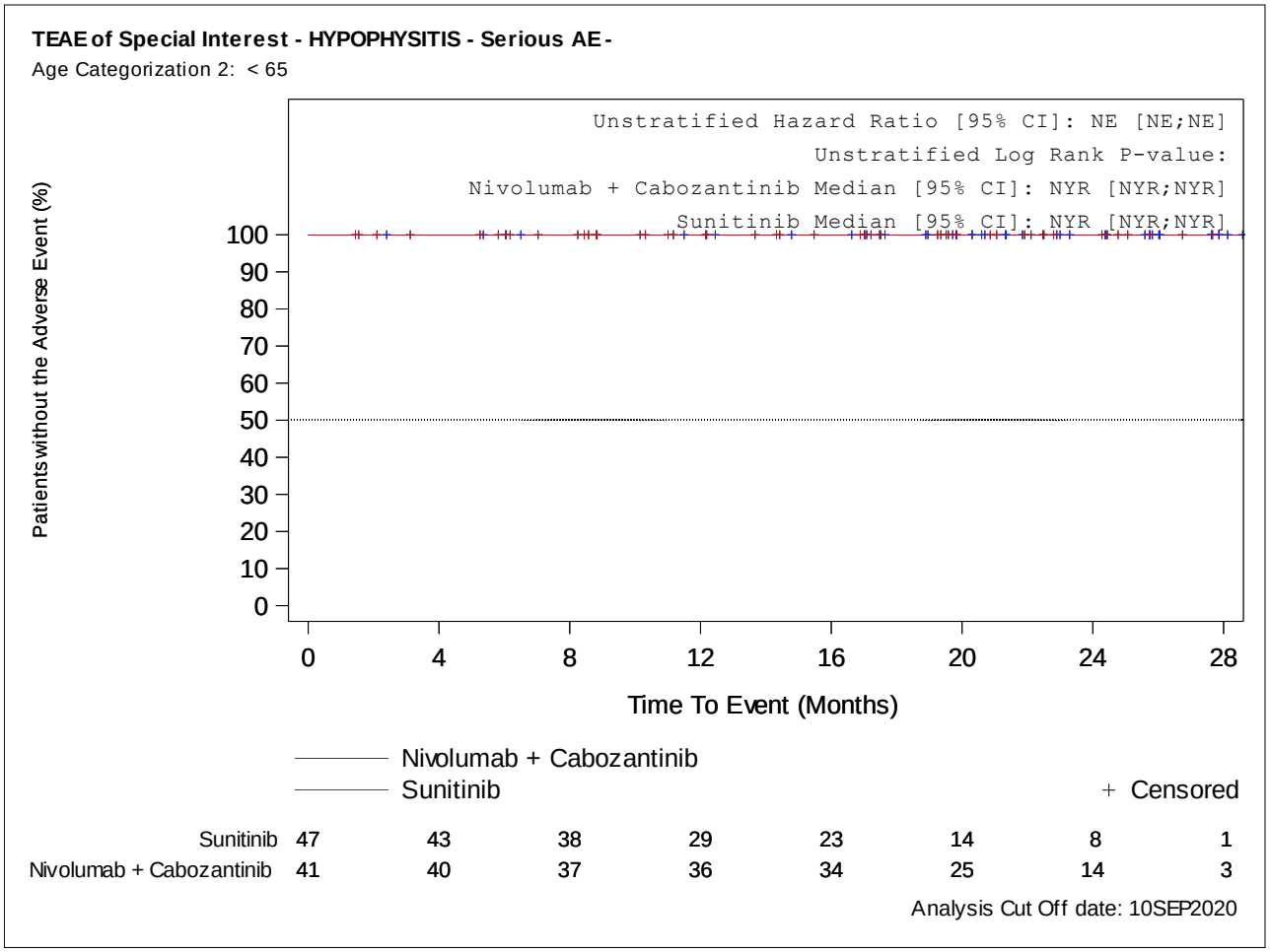

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:04

FIGURE 3.99.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



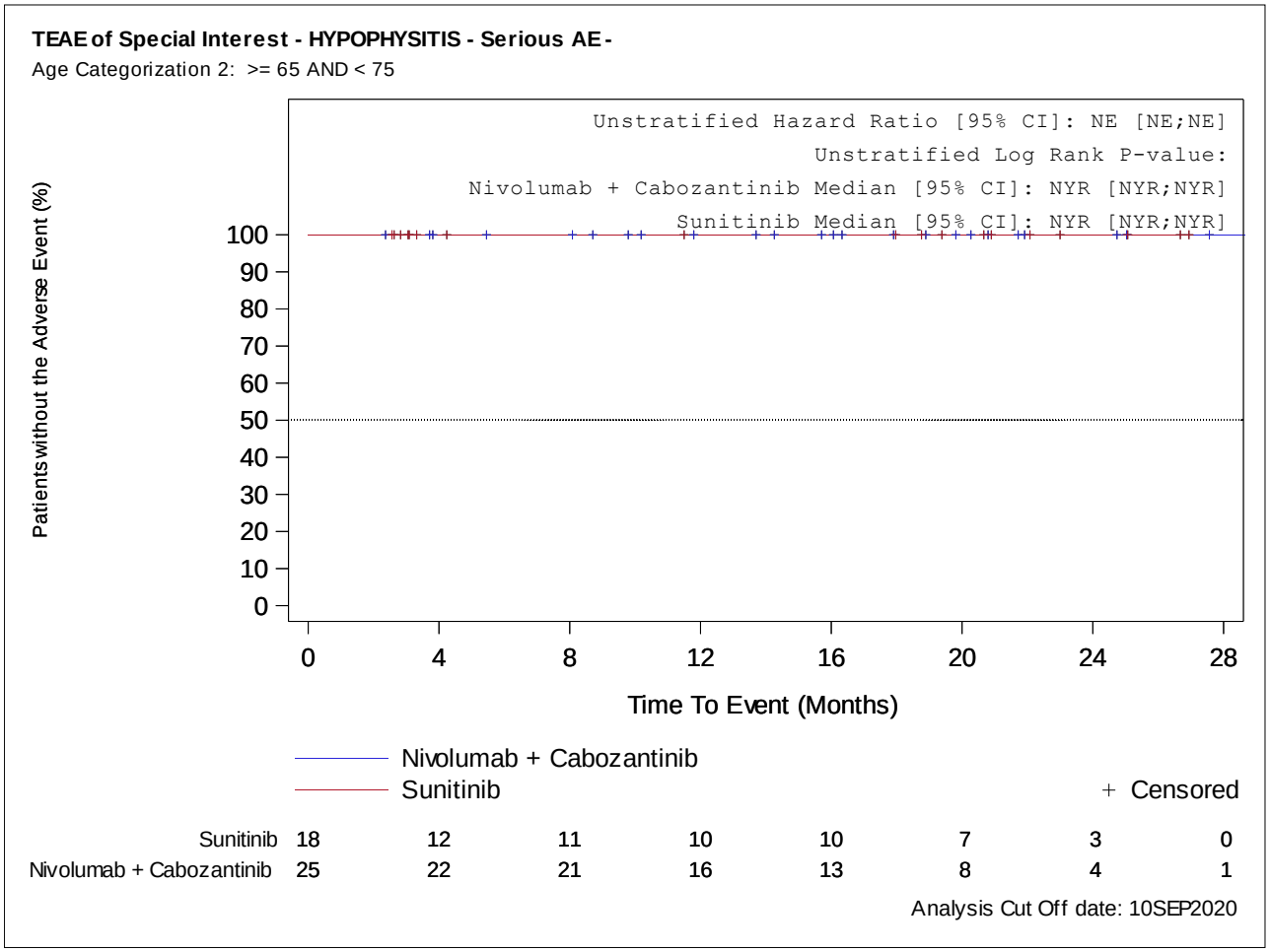

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:09

FIGURE 3.99.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



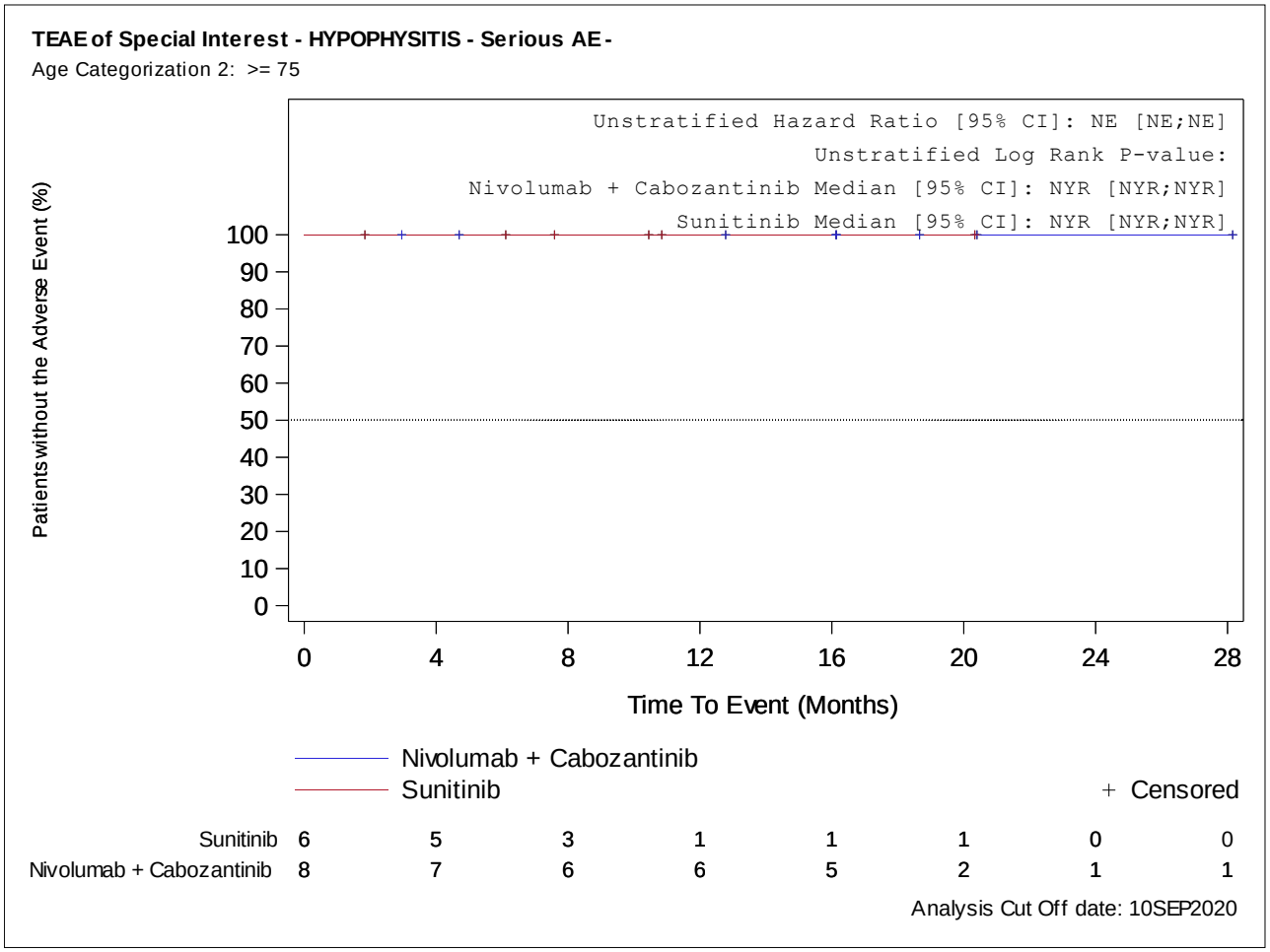

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:15

FIGURE 3.99.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



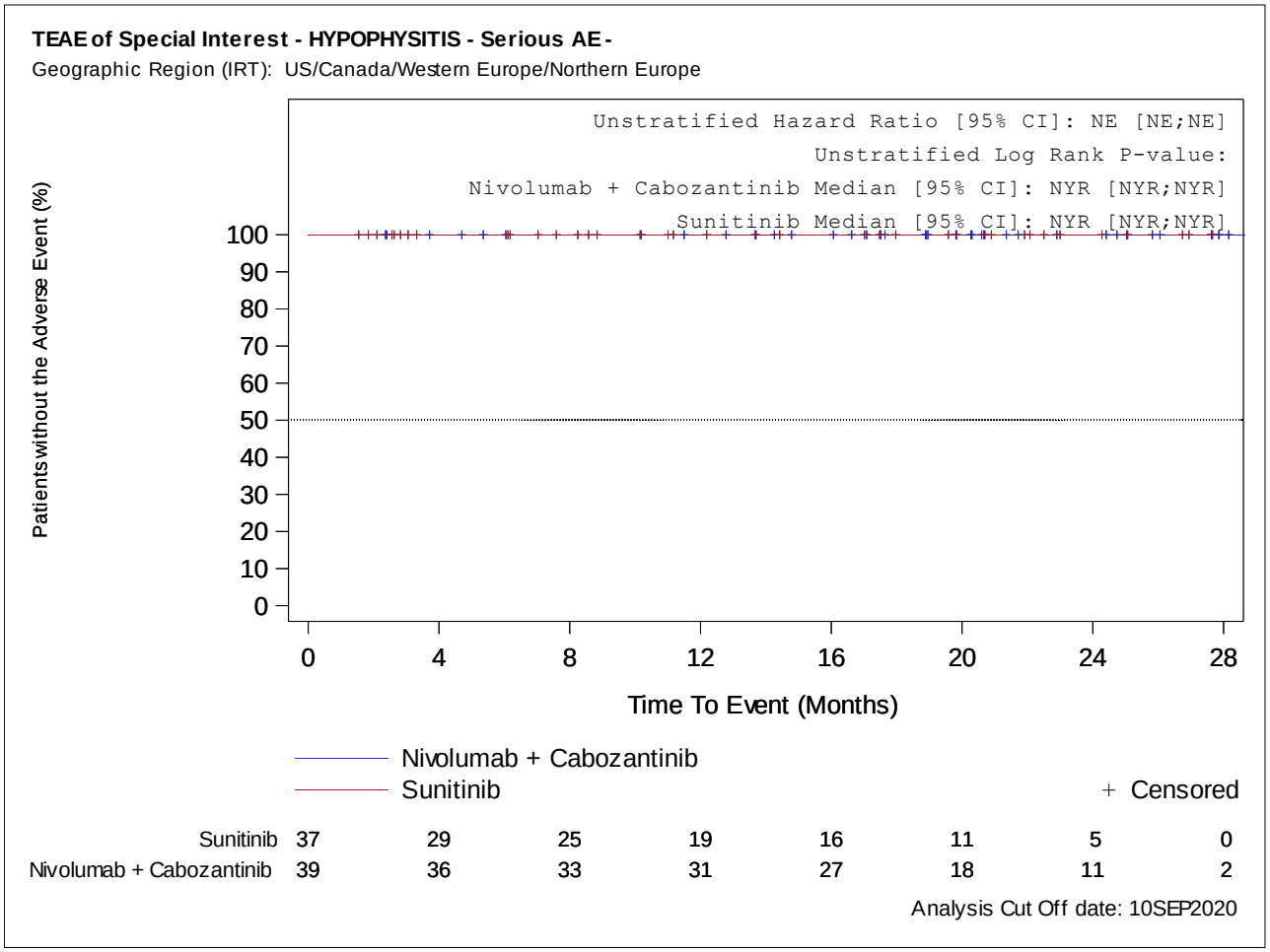

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:20

FIGURE 3.99.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



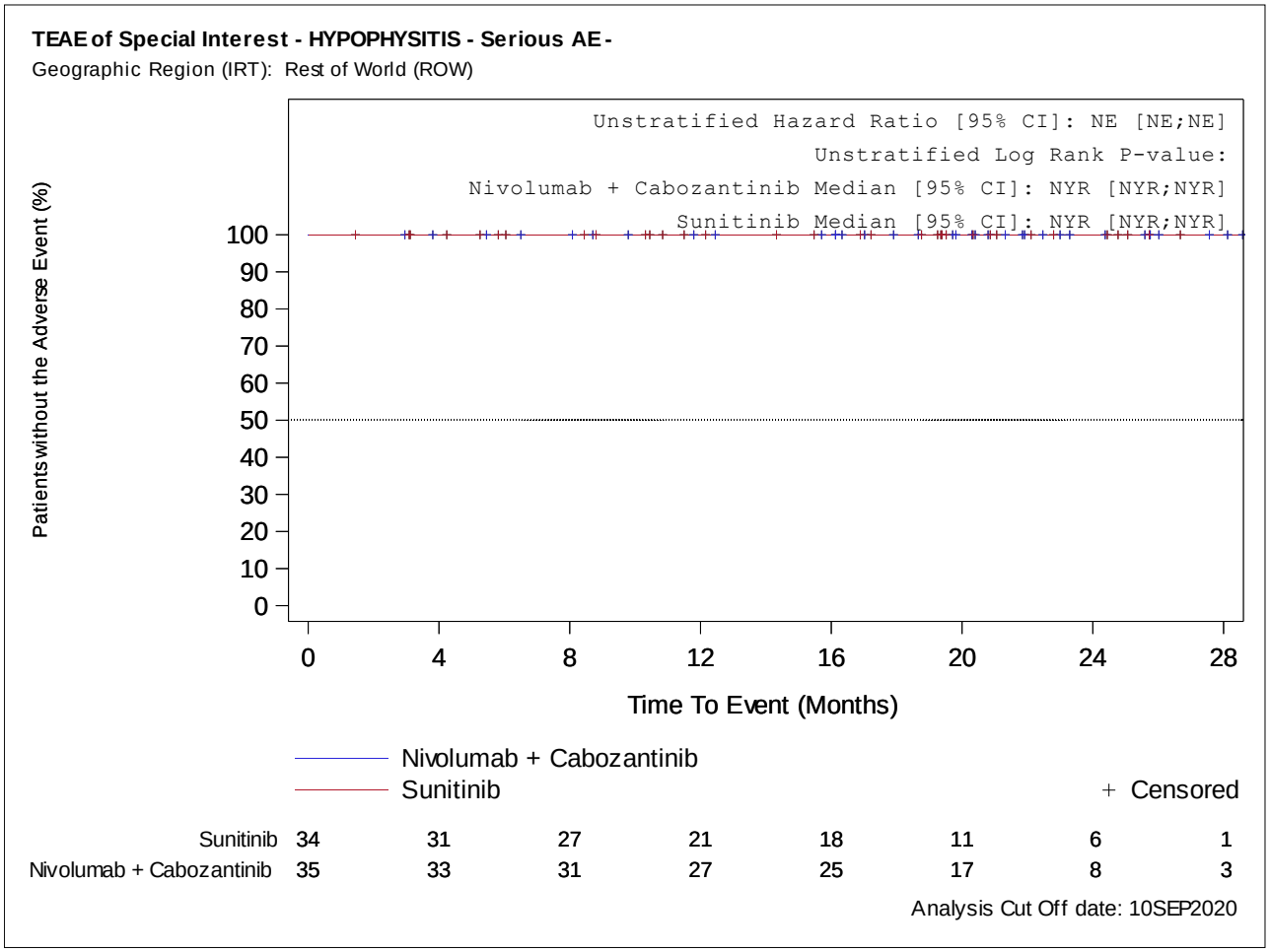

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:25

FIGURE 3.99.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



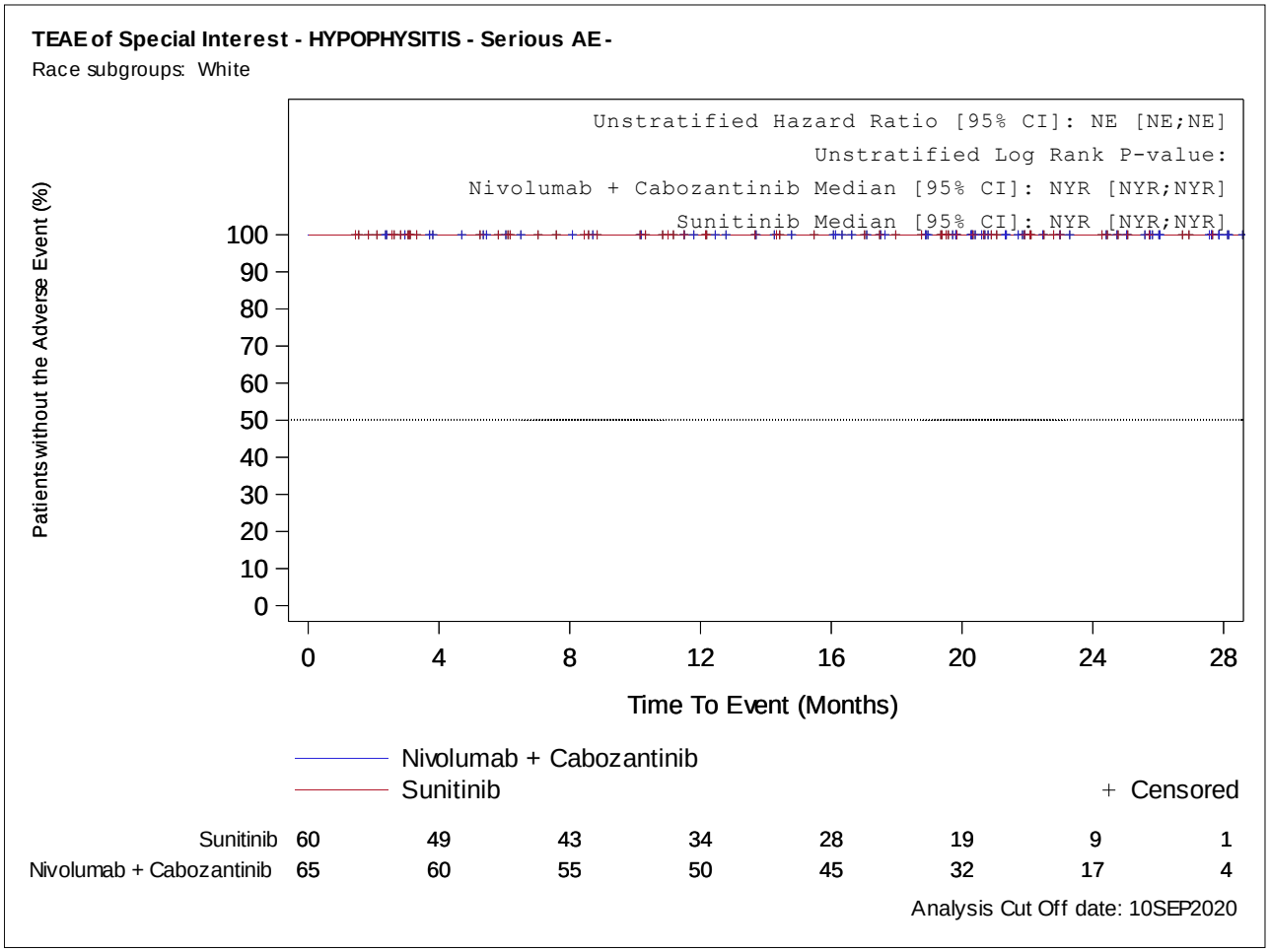

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:31

FIGURE 3.99.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



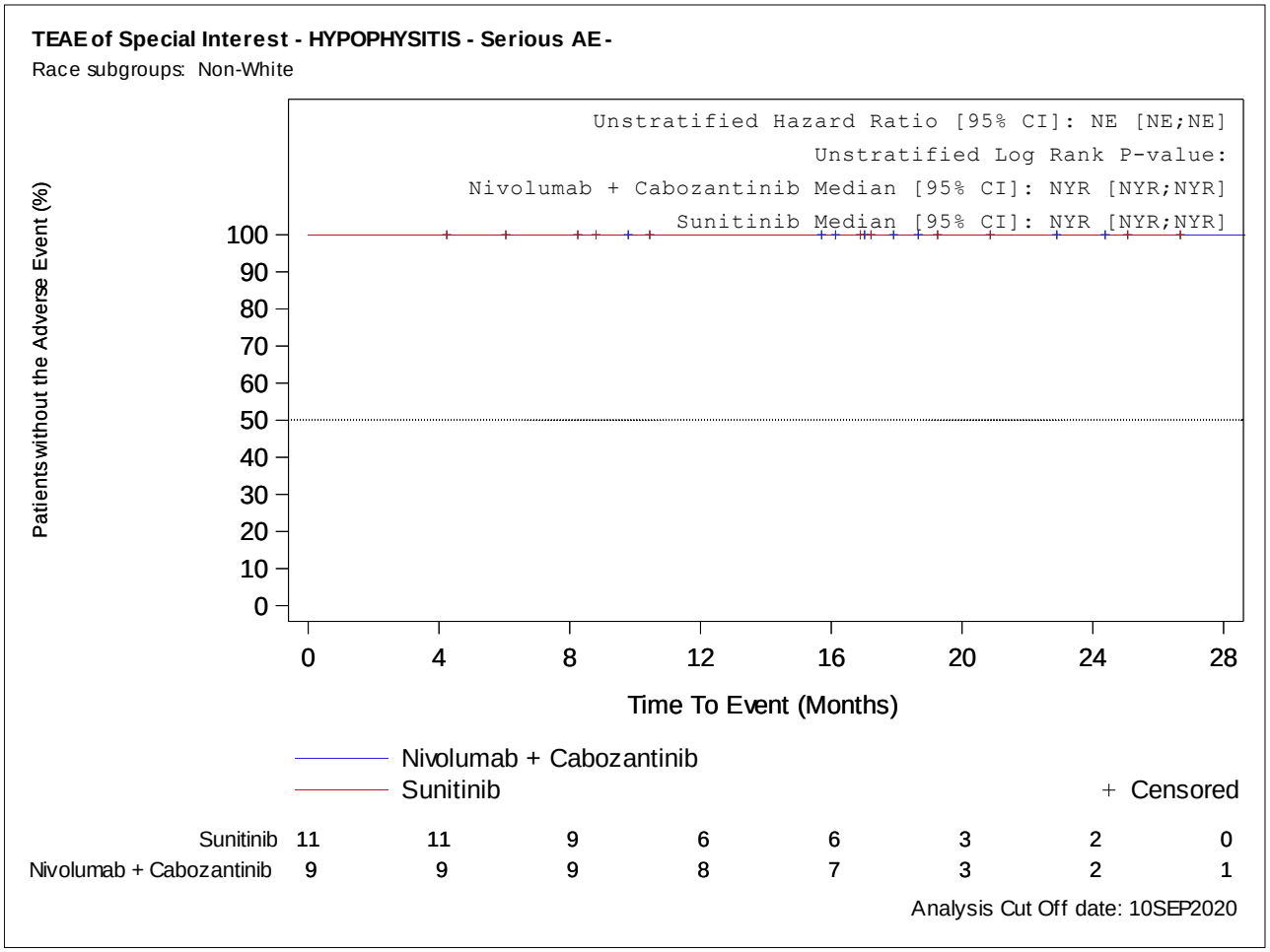

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:36

FIGURE 3.99.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



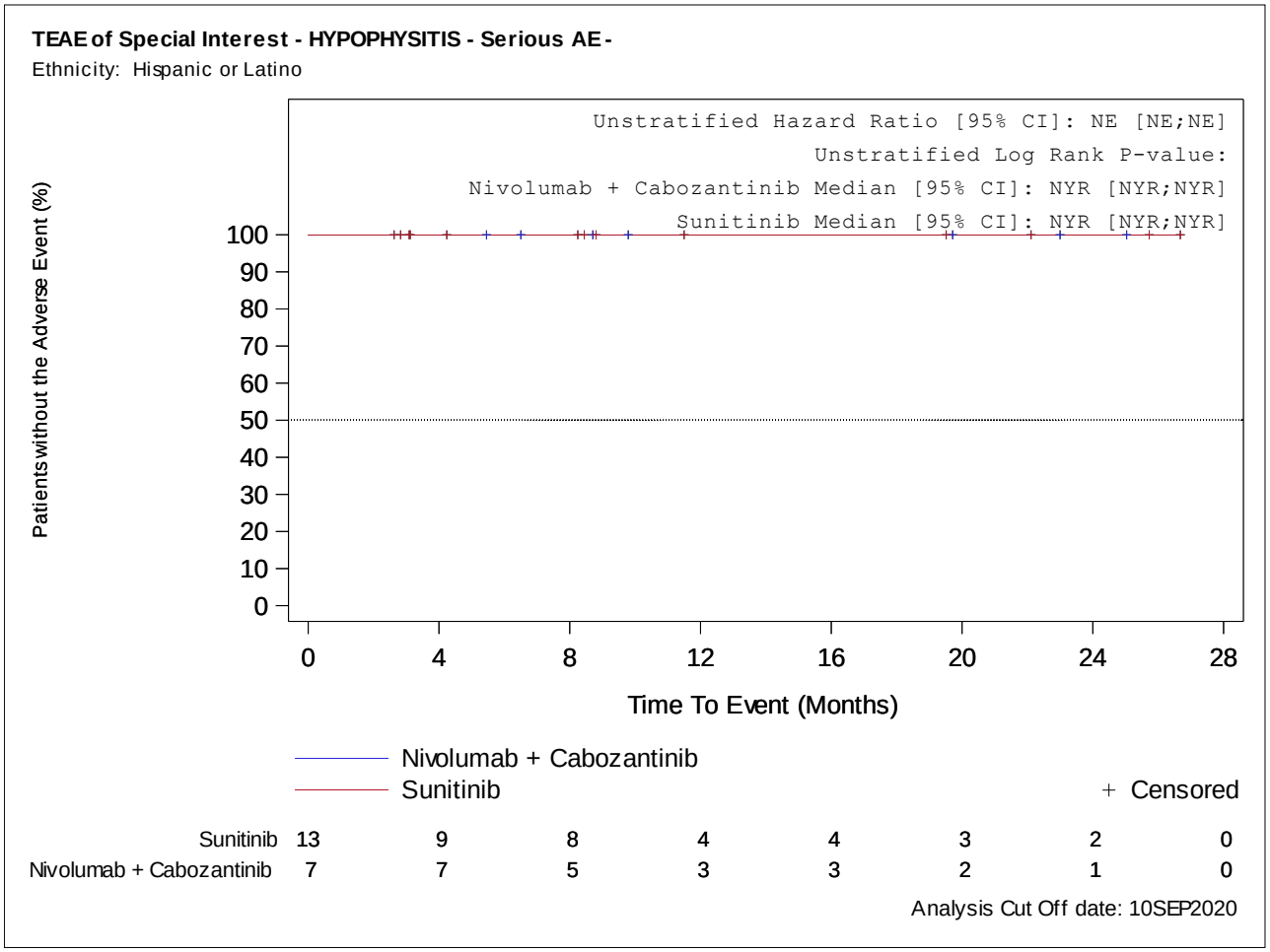

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:41

FIGURE 3.99.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:22:47

FIGURE 3.99.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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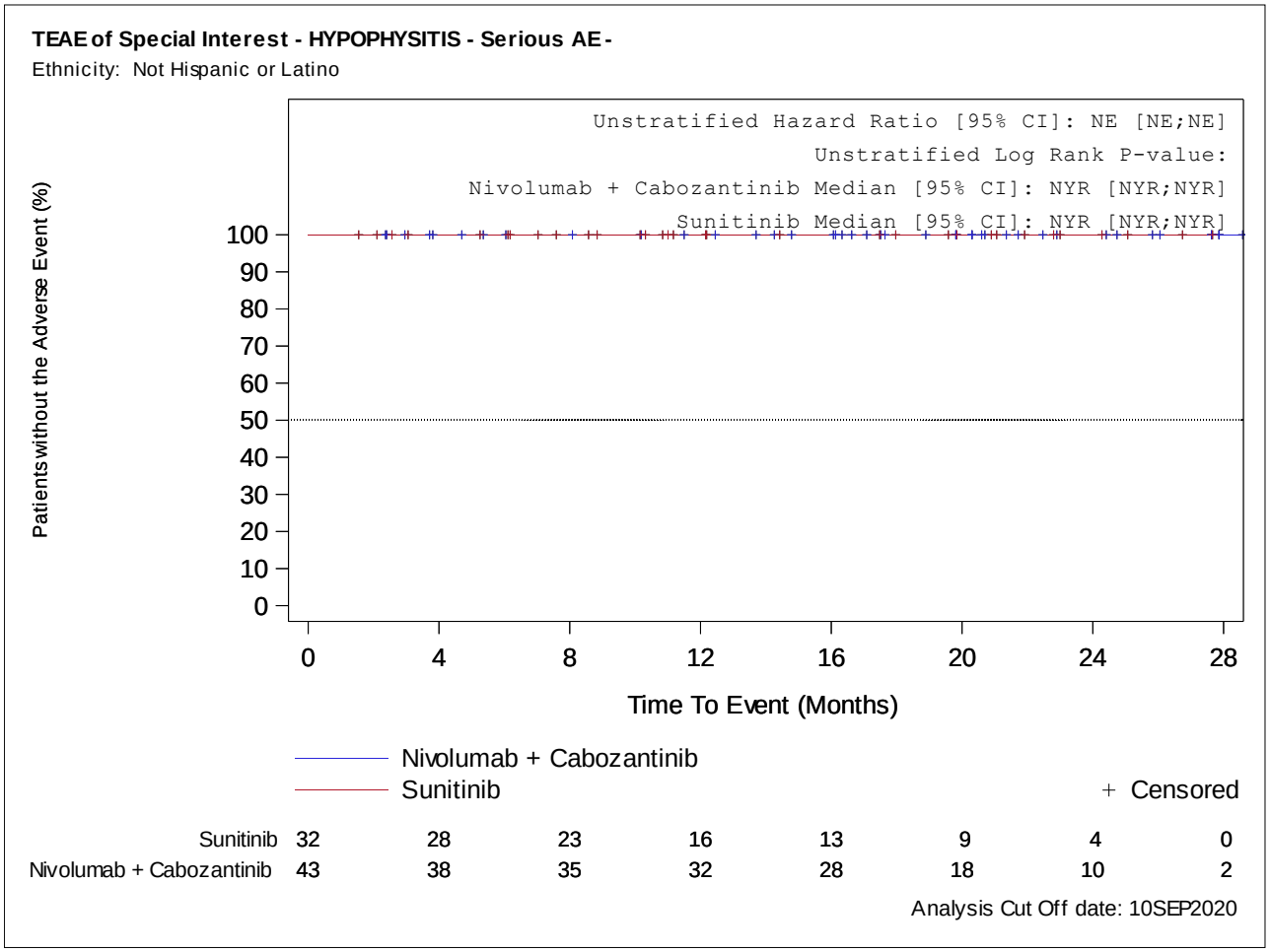
FIGURE 3.99.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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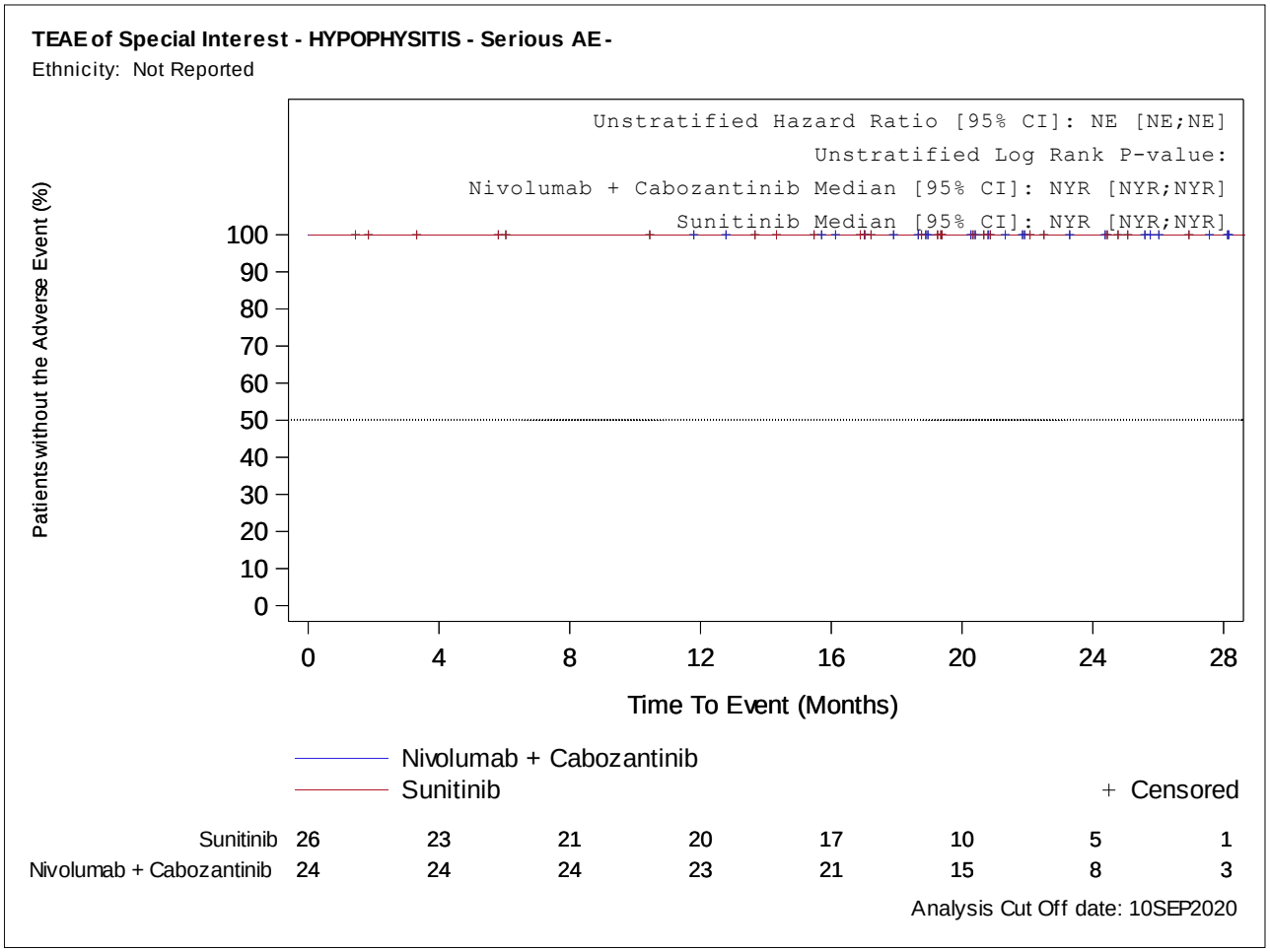
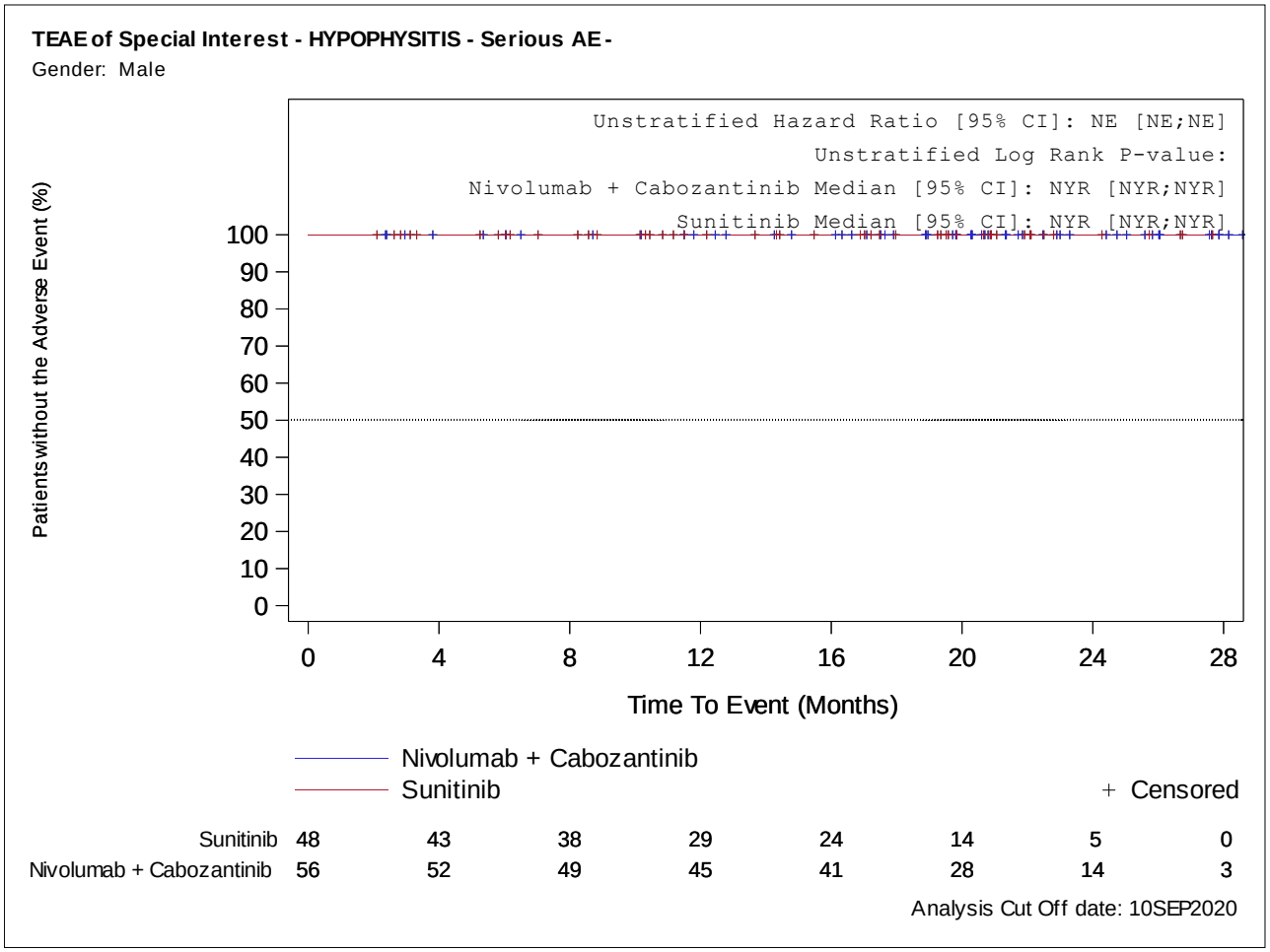
FIGURE 3.99.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



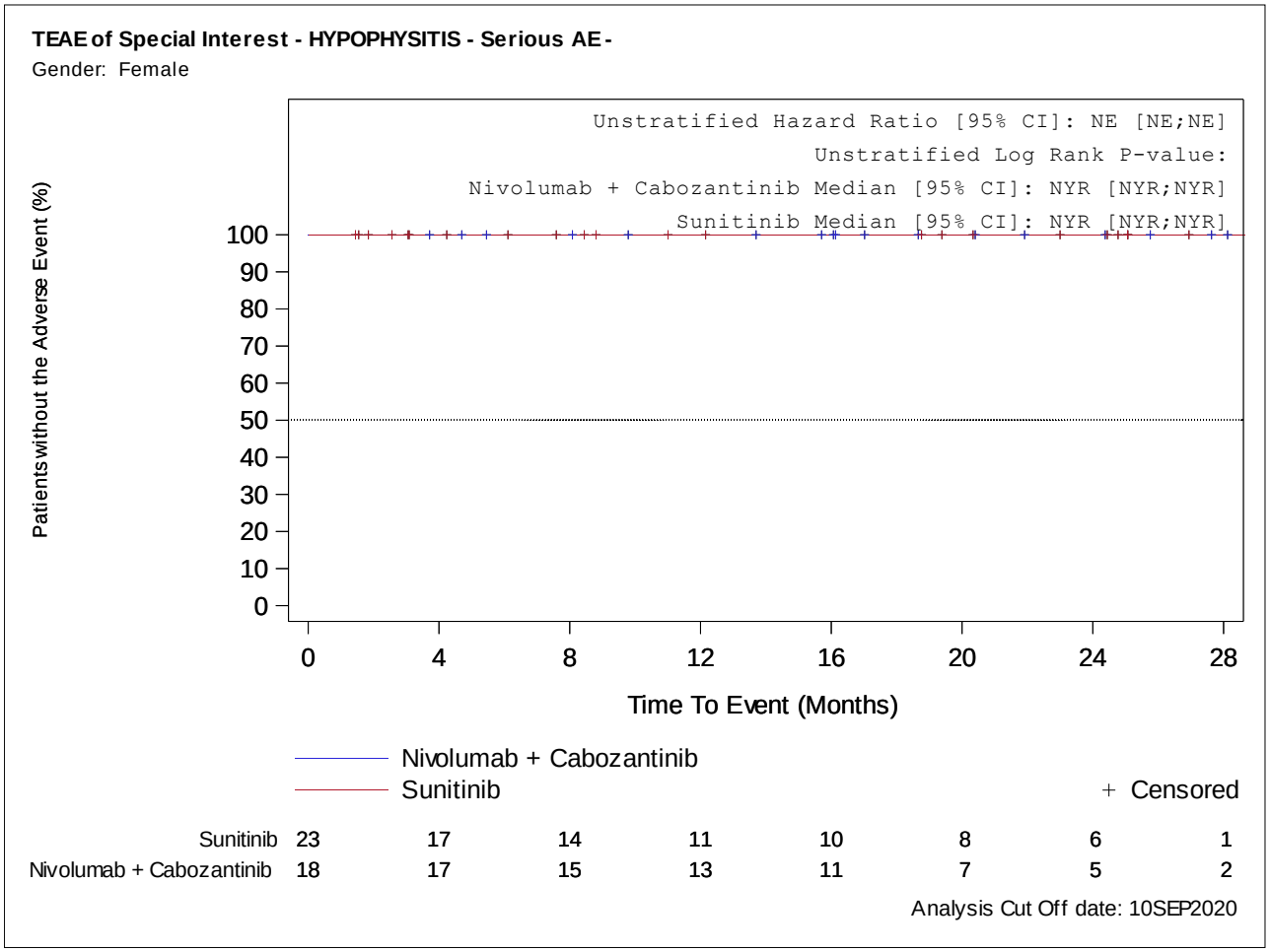

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:23:02

FIGURE 3.99.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



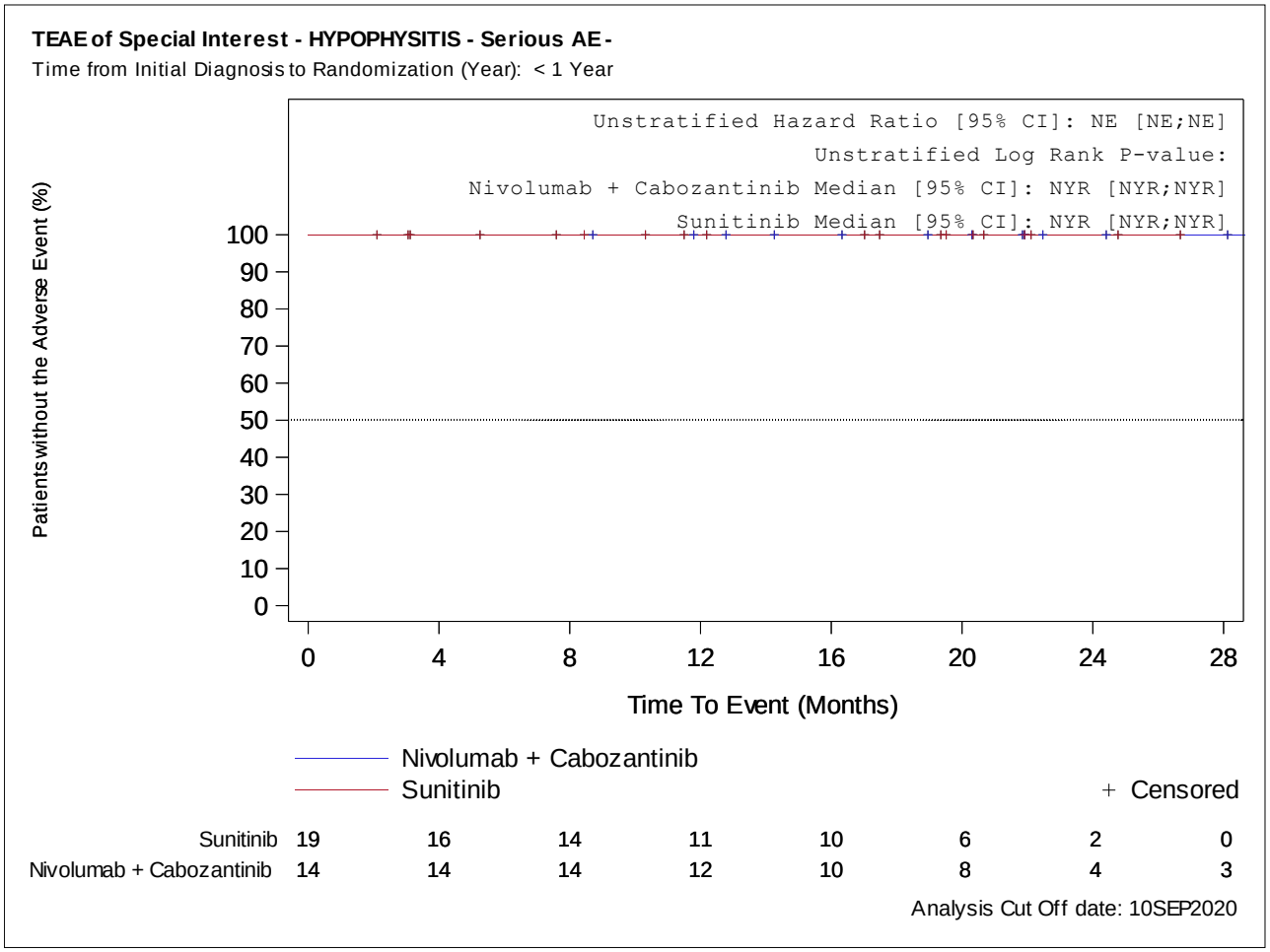

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:23:08

FIGURE 3.99.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



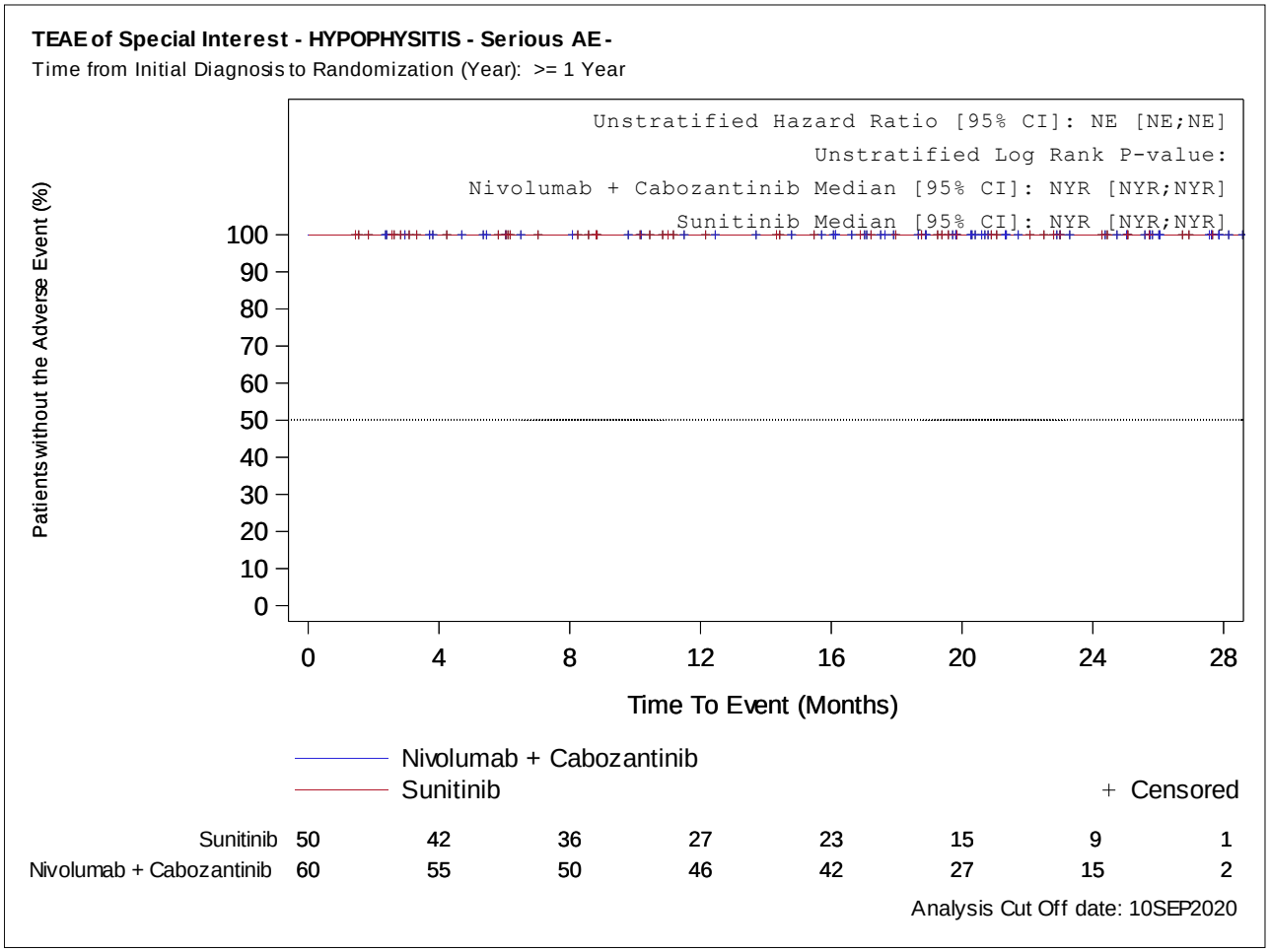

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:23:13

FIGURE 3.99.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



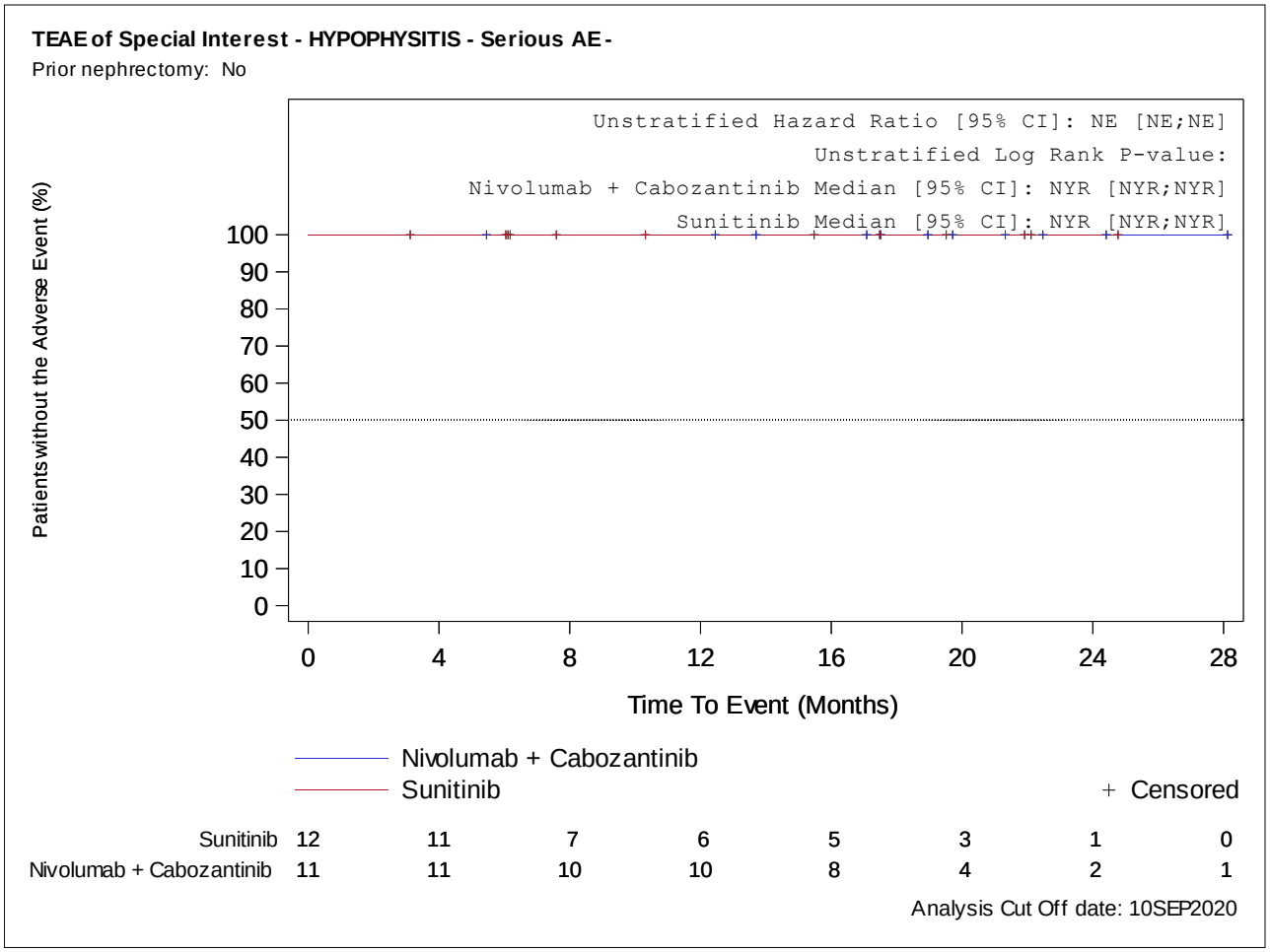

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:23:29

FIGURE 3.99.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



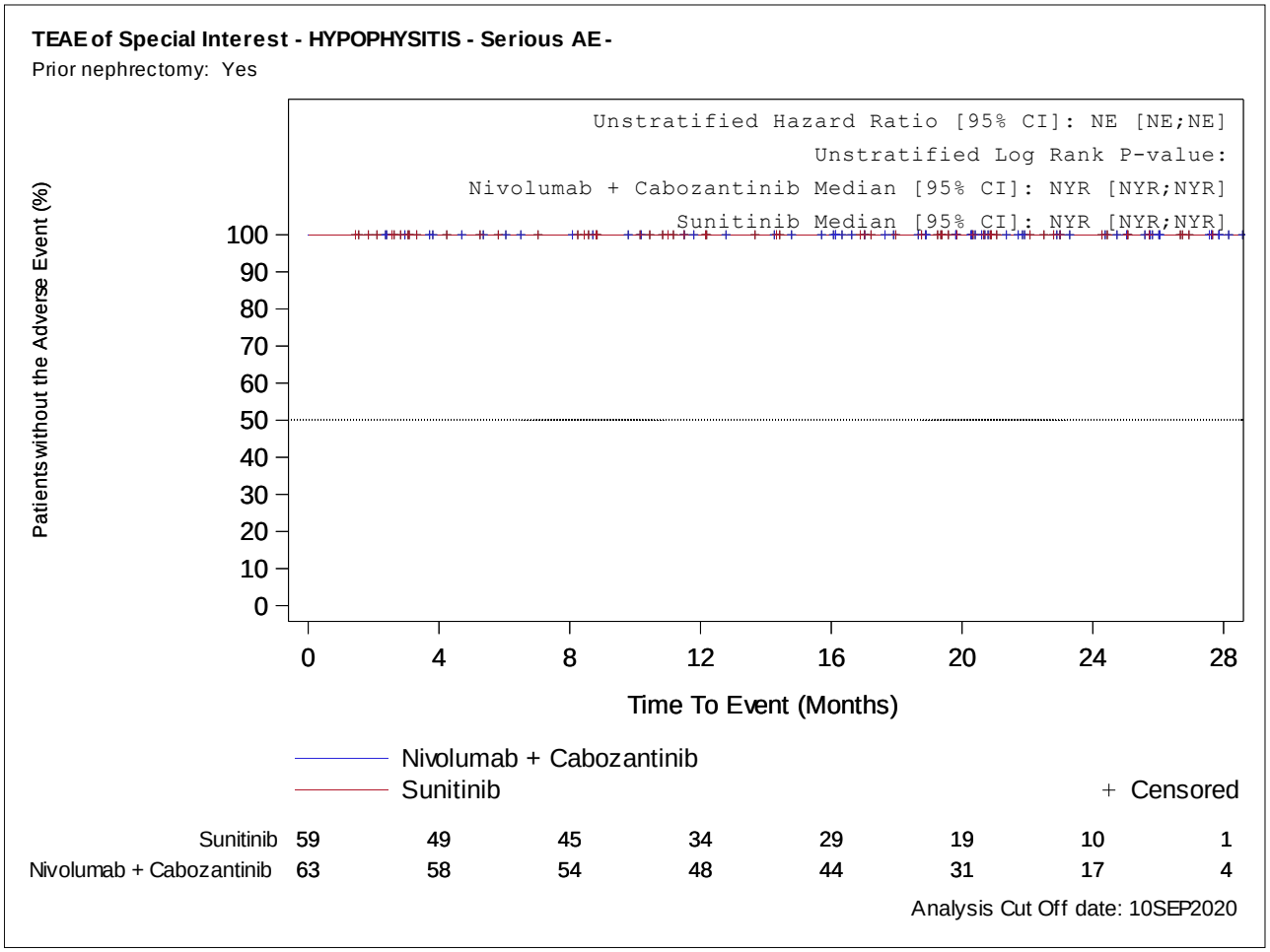

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:23:34

FIGURE 3.99.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



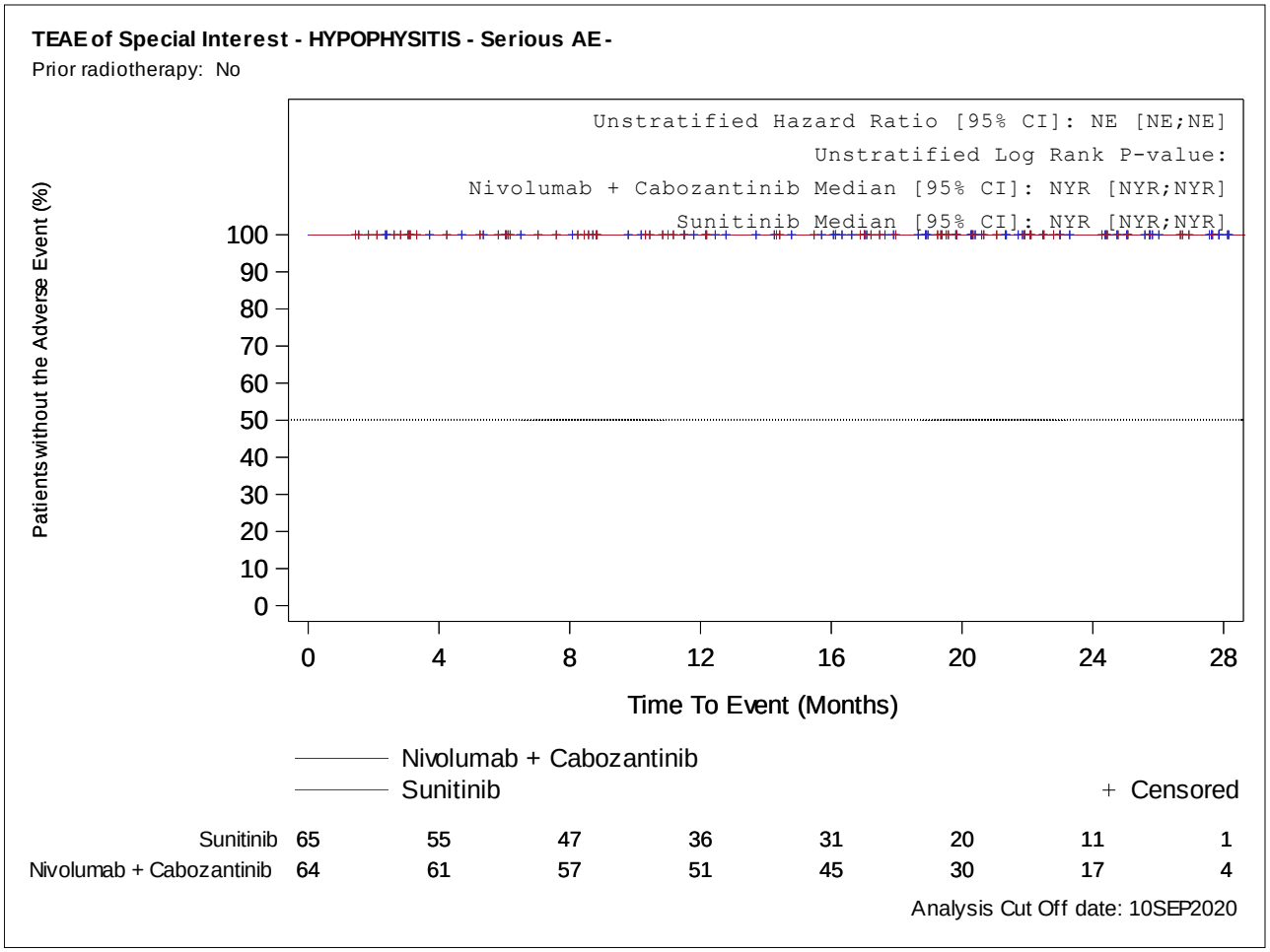

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:24:21

FIGURE 3.99.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



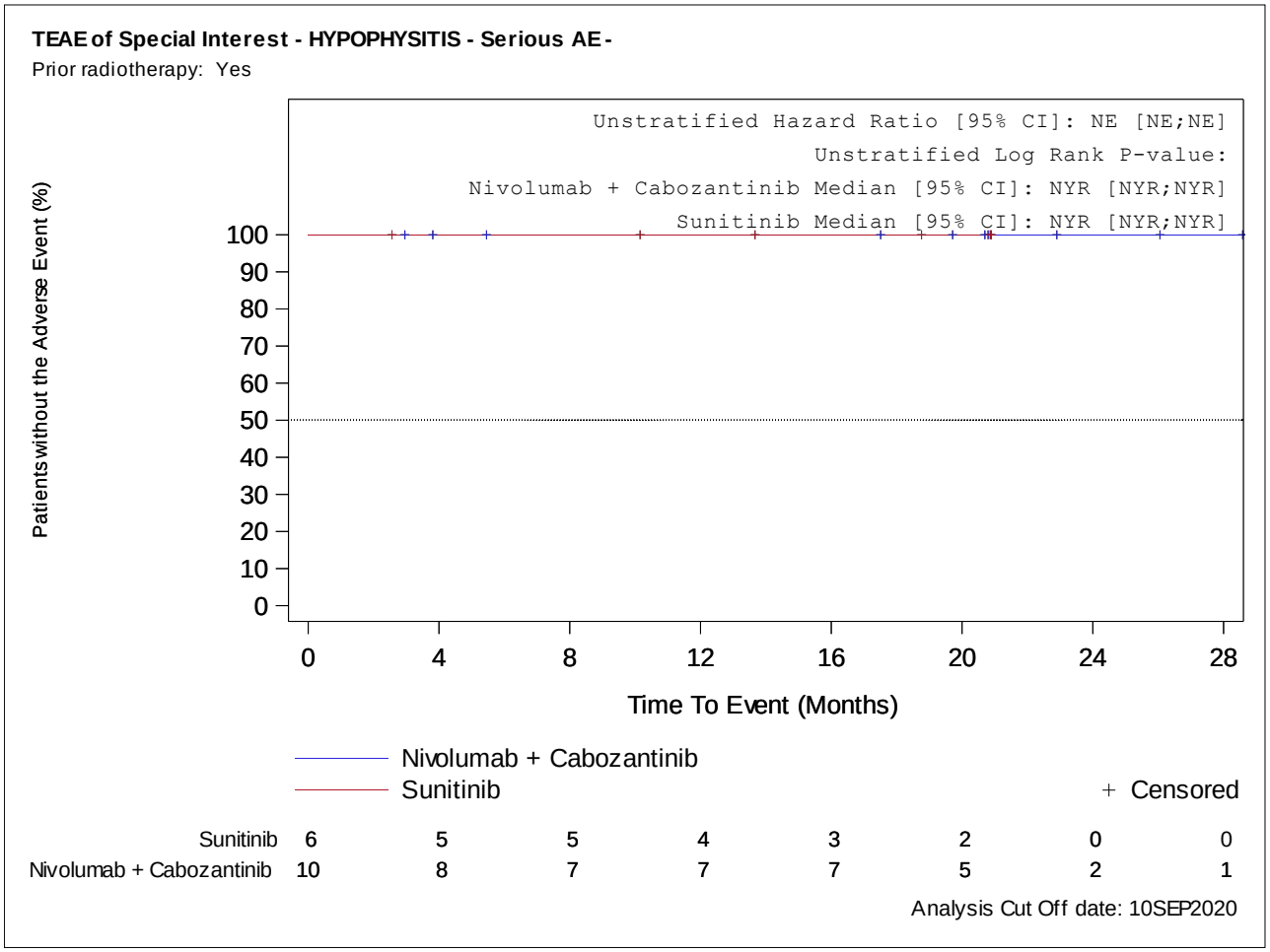

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:24:26

FIGURE 3.99.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



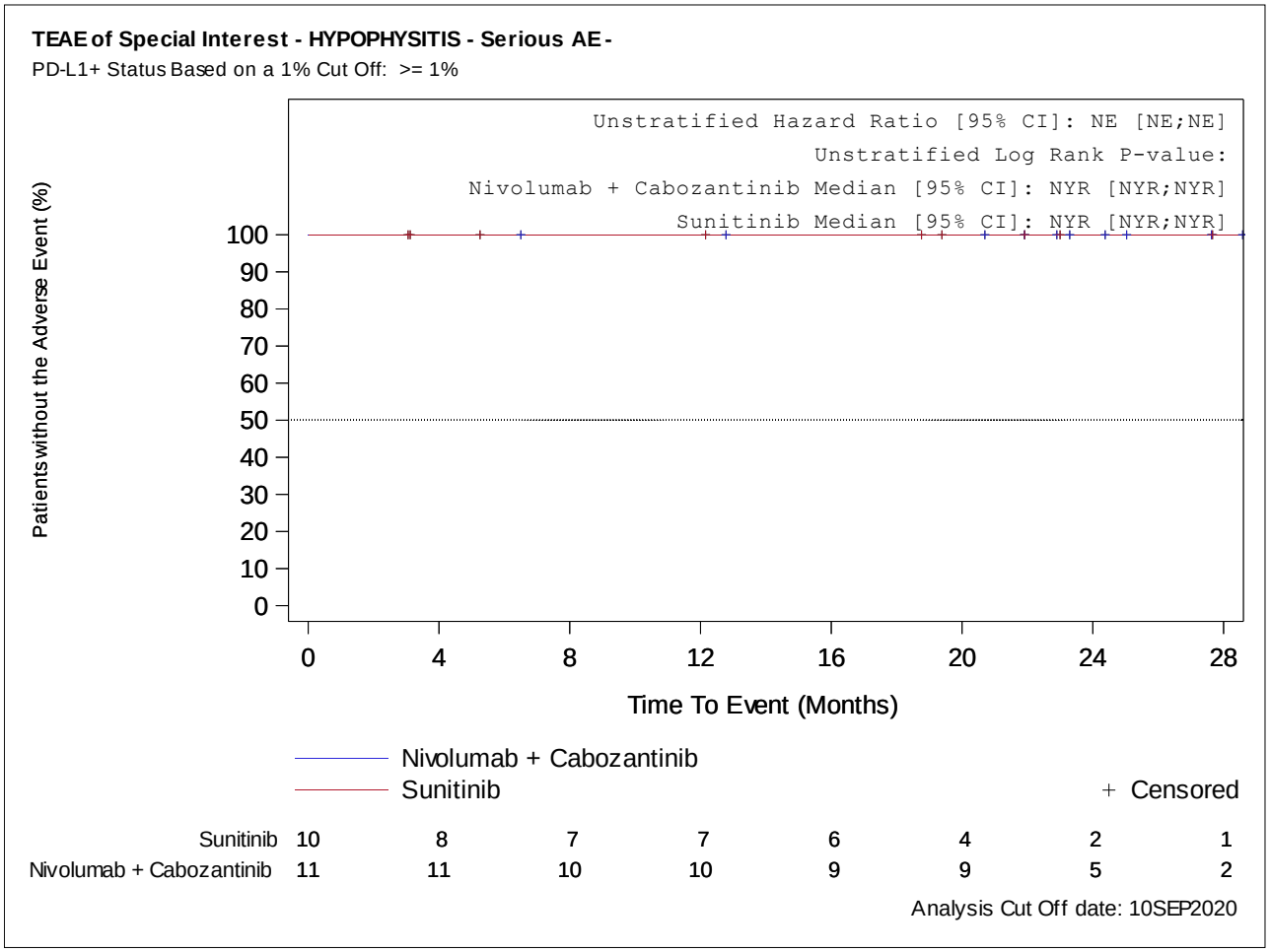

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:24:32

FIGURE 3.99.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



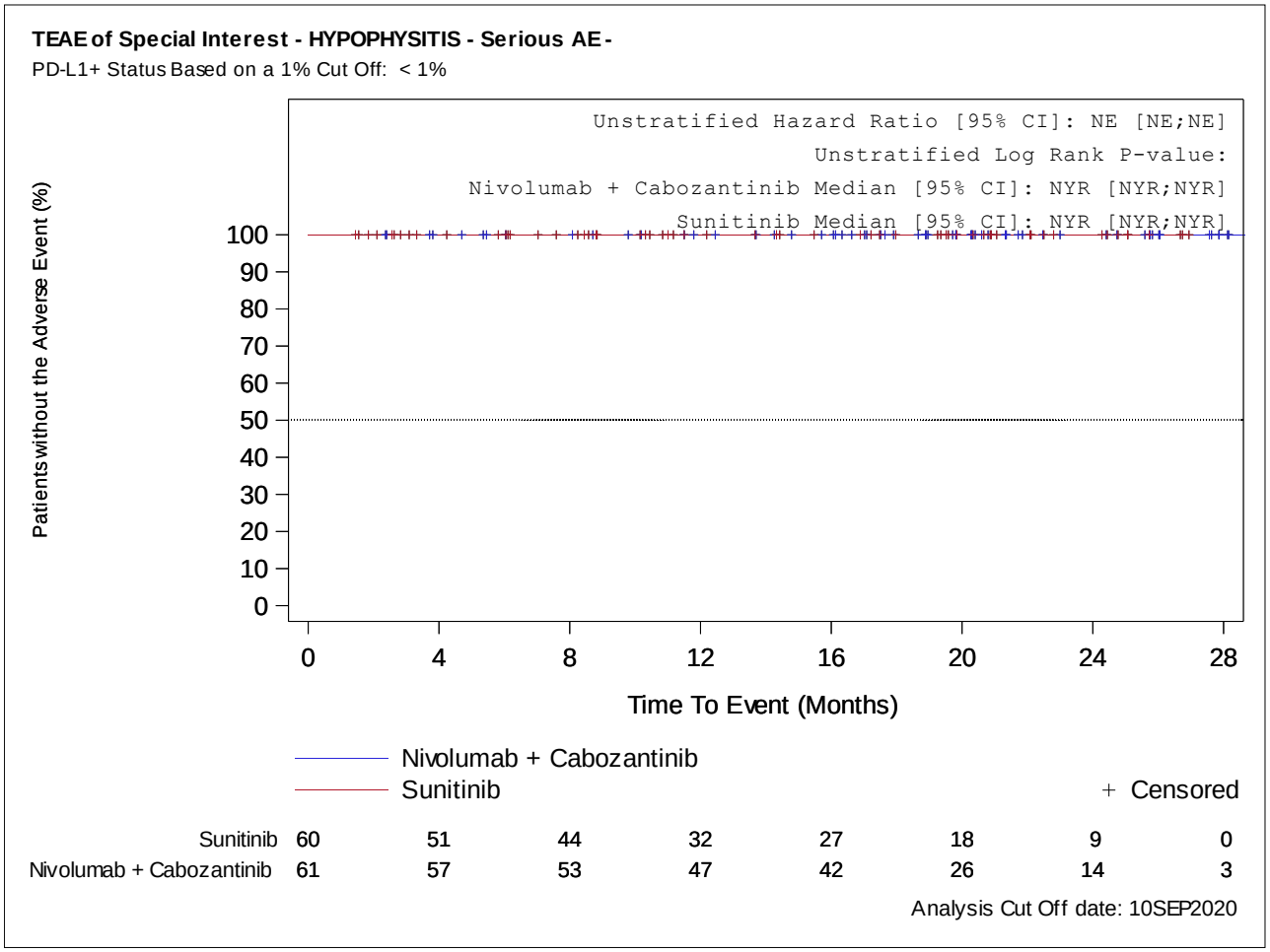

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:24:37

FIGURE 3.99.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



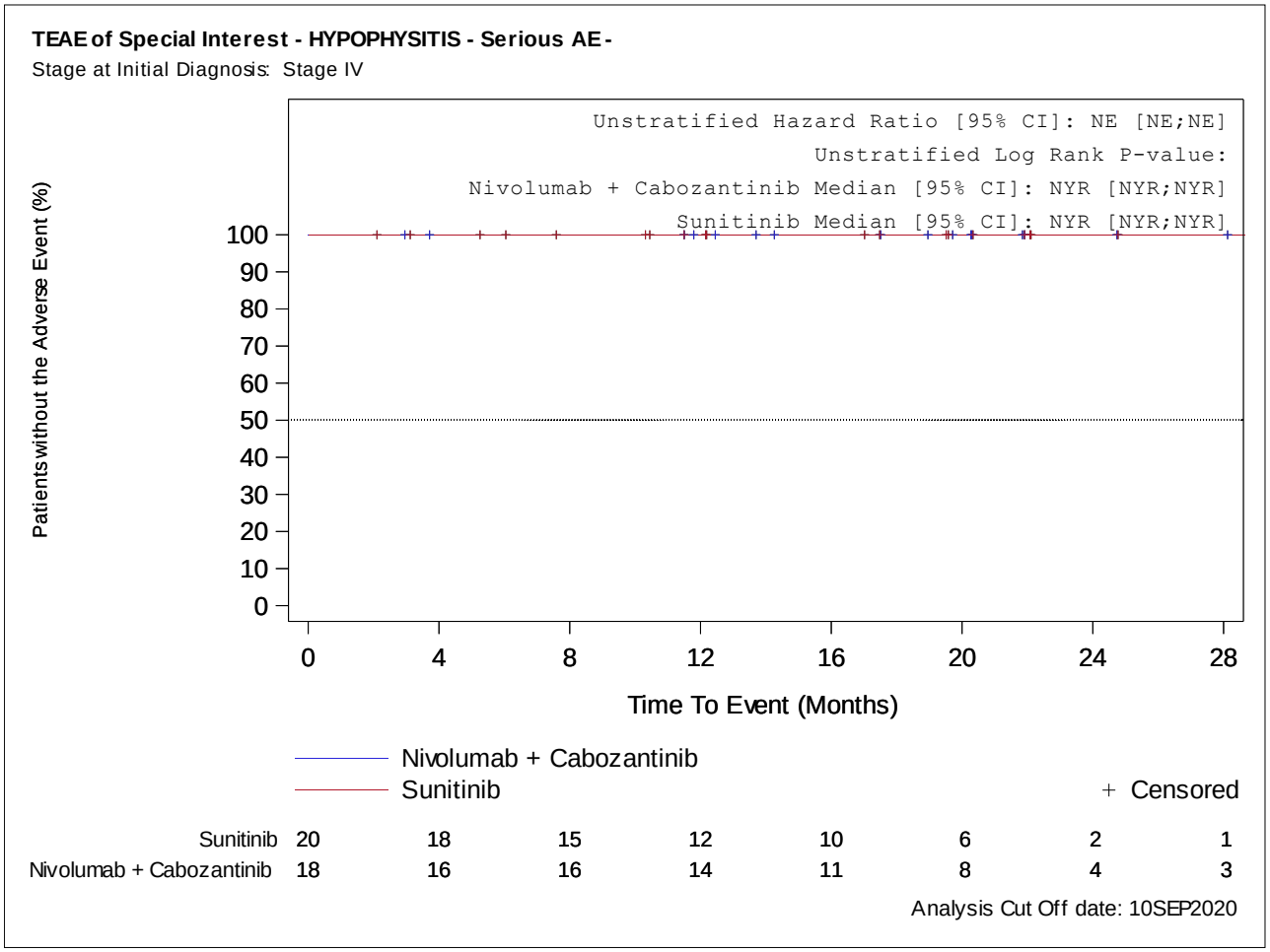

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:24:42

FIGURE 3.99.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



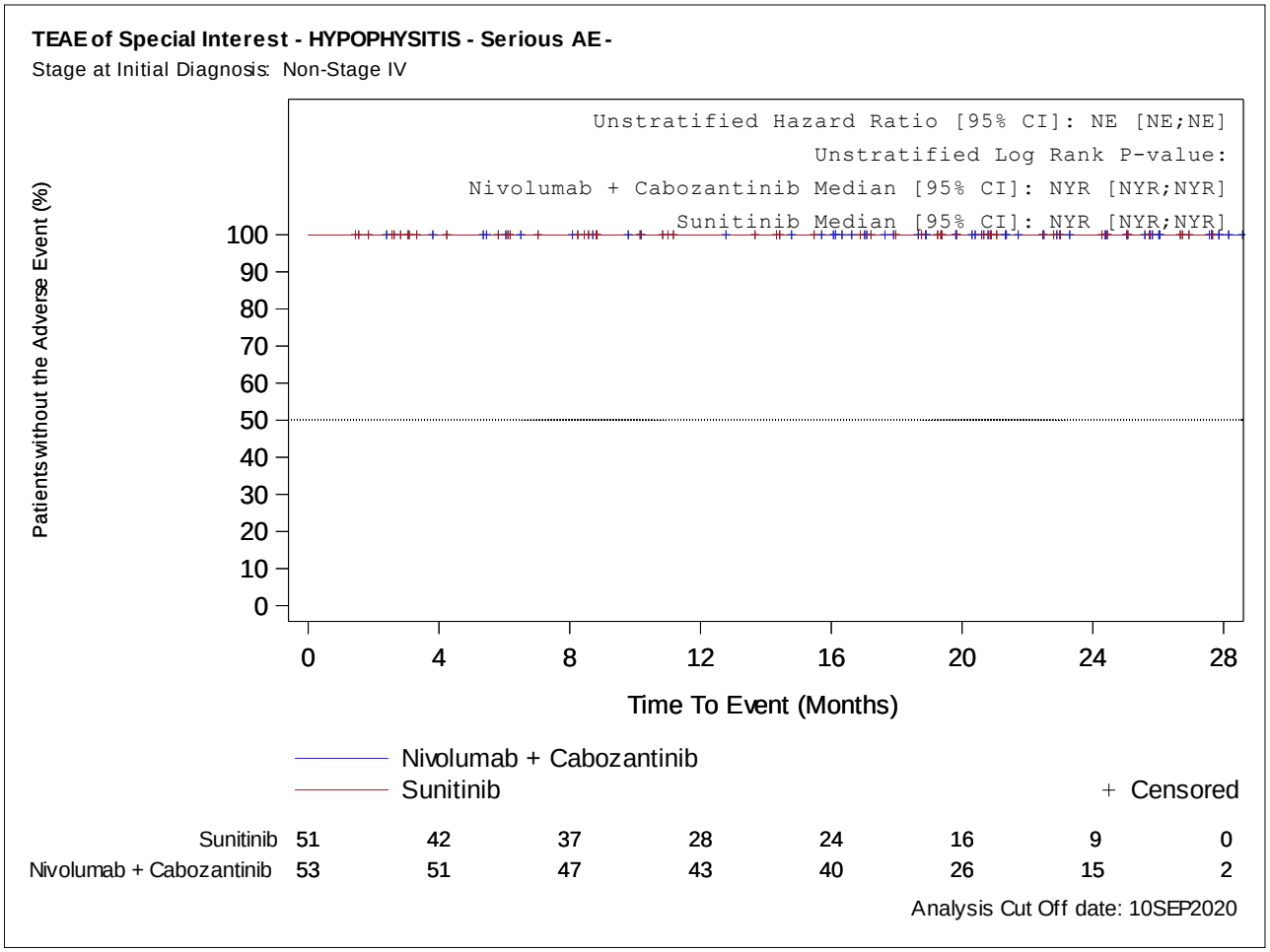

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:24:47

FIGURE 3.99.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



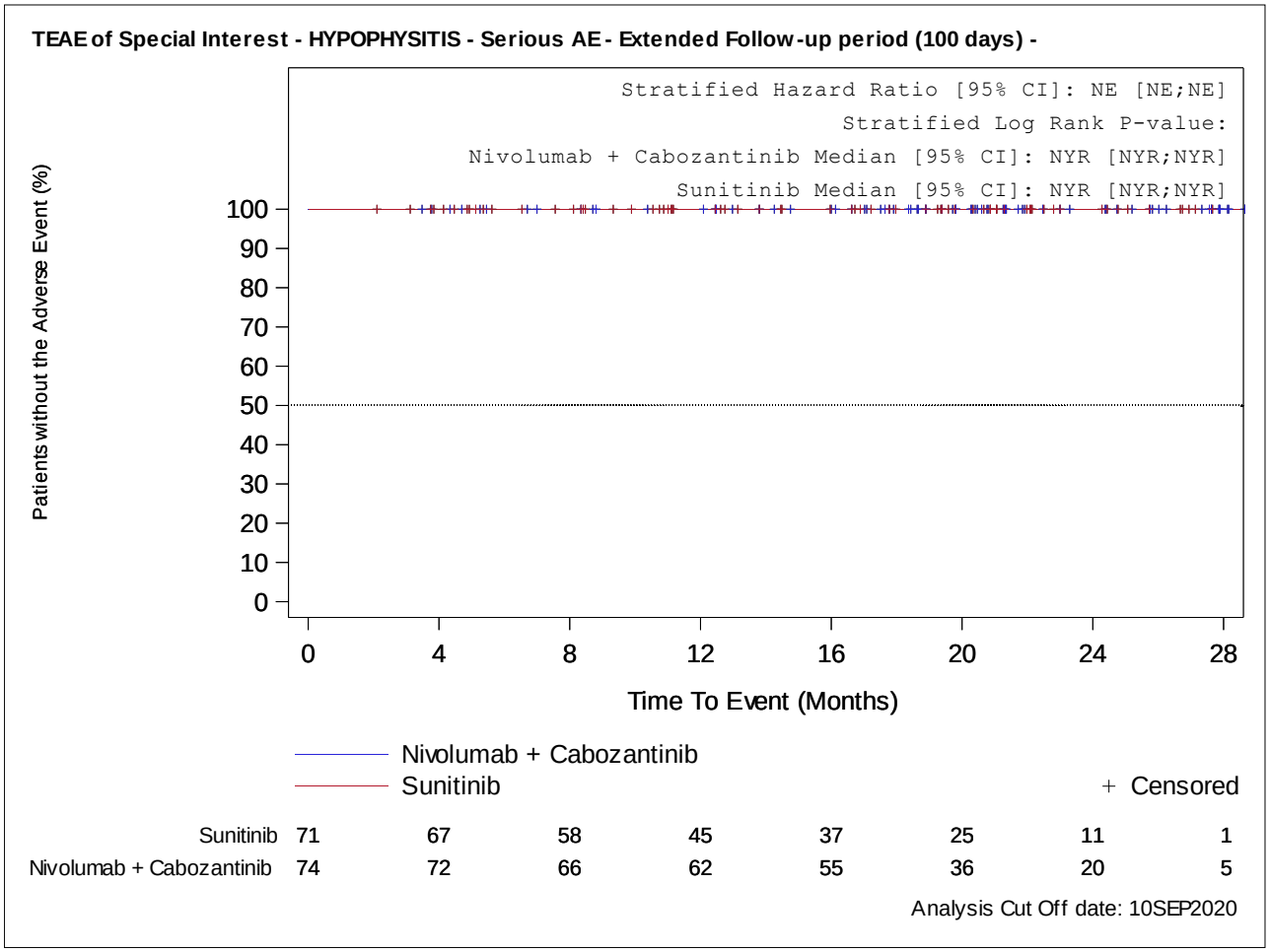

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:25:13

FIGURE 3.99.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



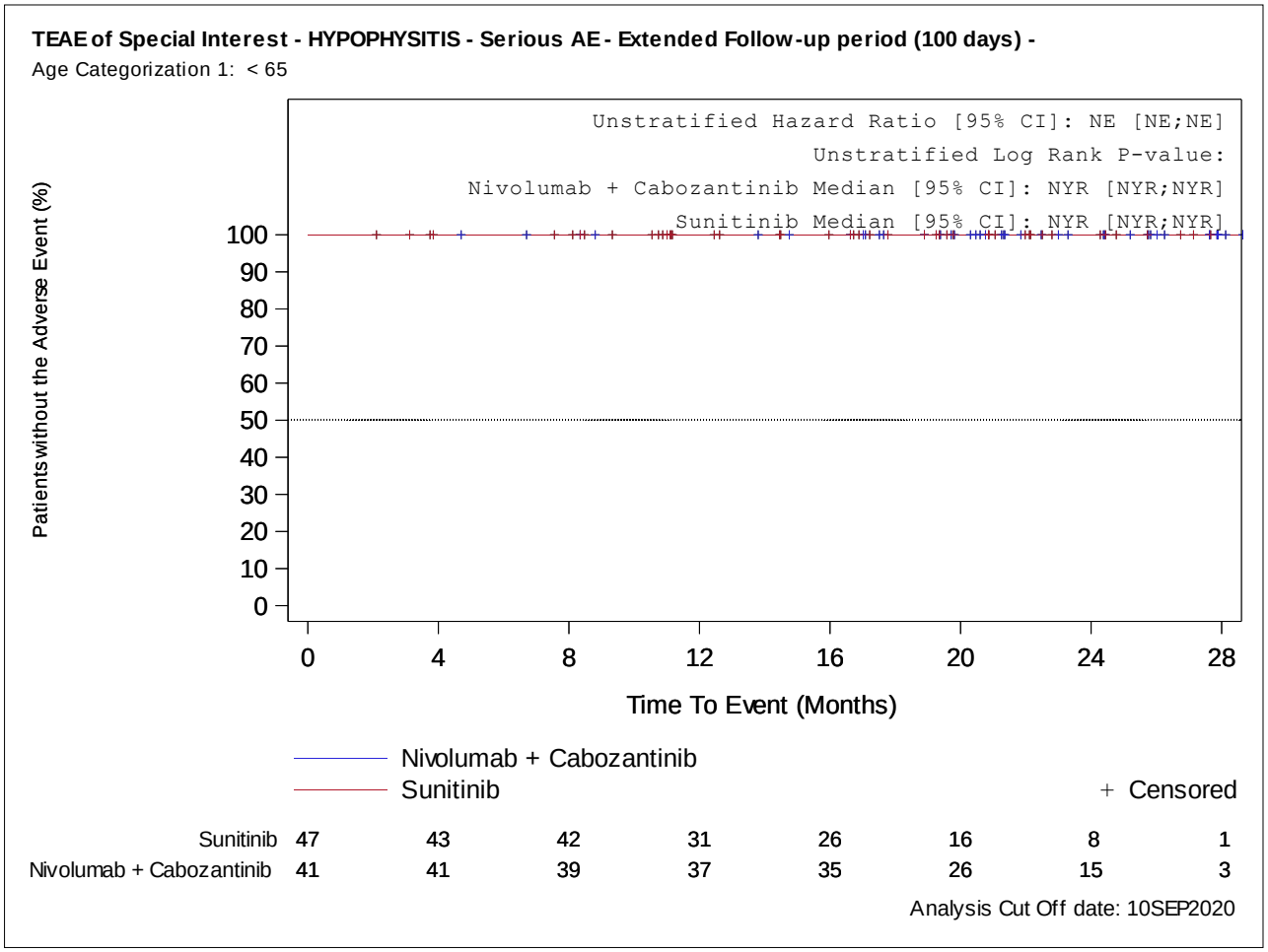

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:25:18

FIGURE 3.100.1: TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



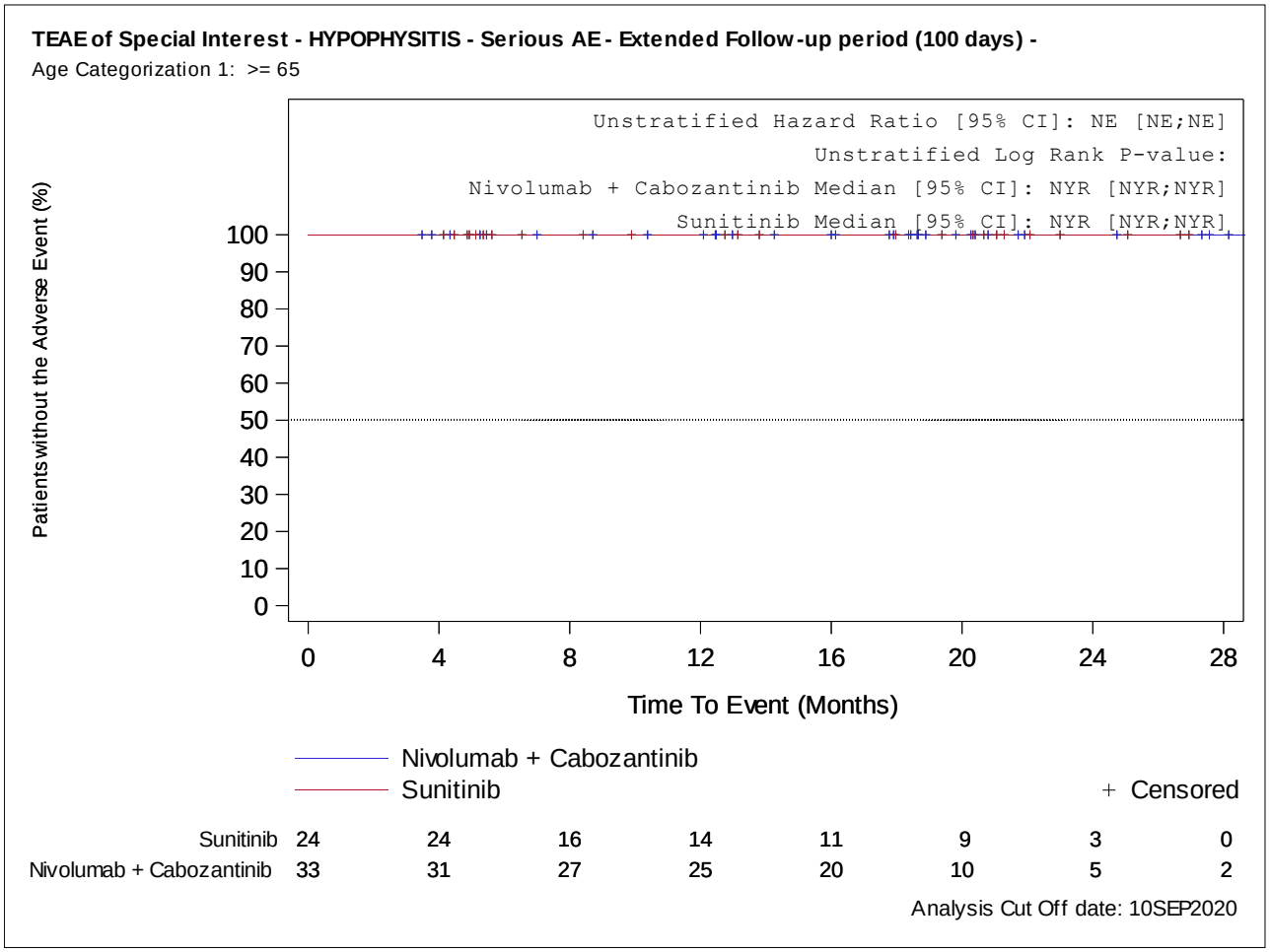

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:14

FIGURE 3.100.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



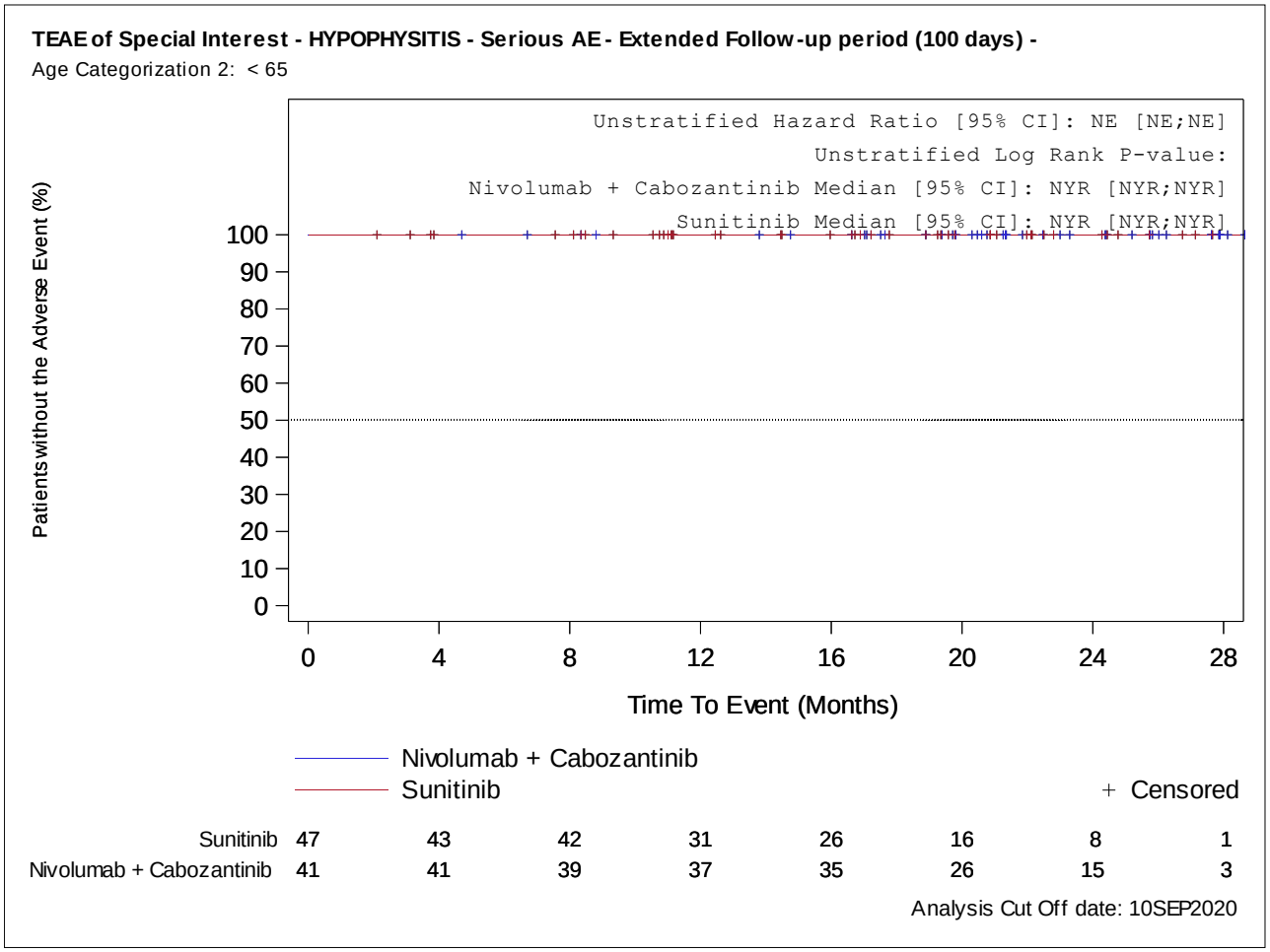

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:16

FIGURE 3.100.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



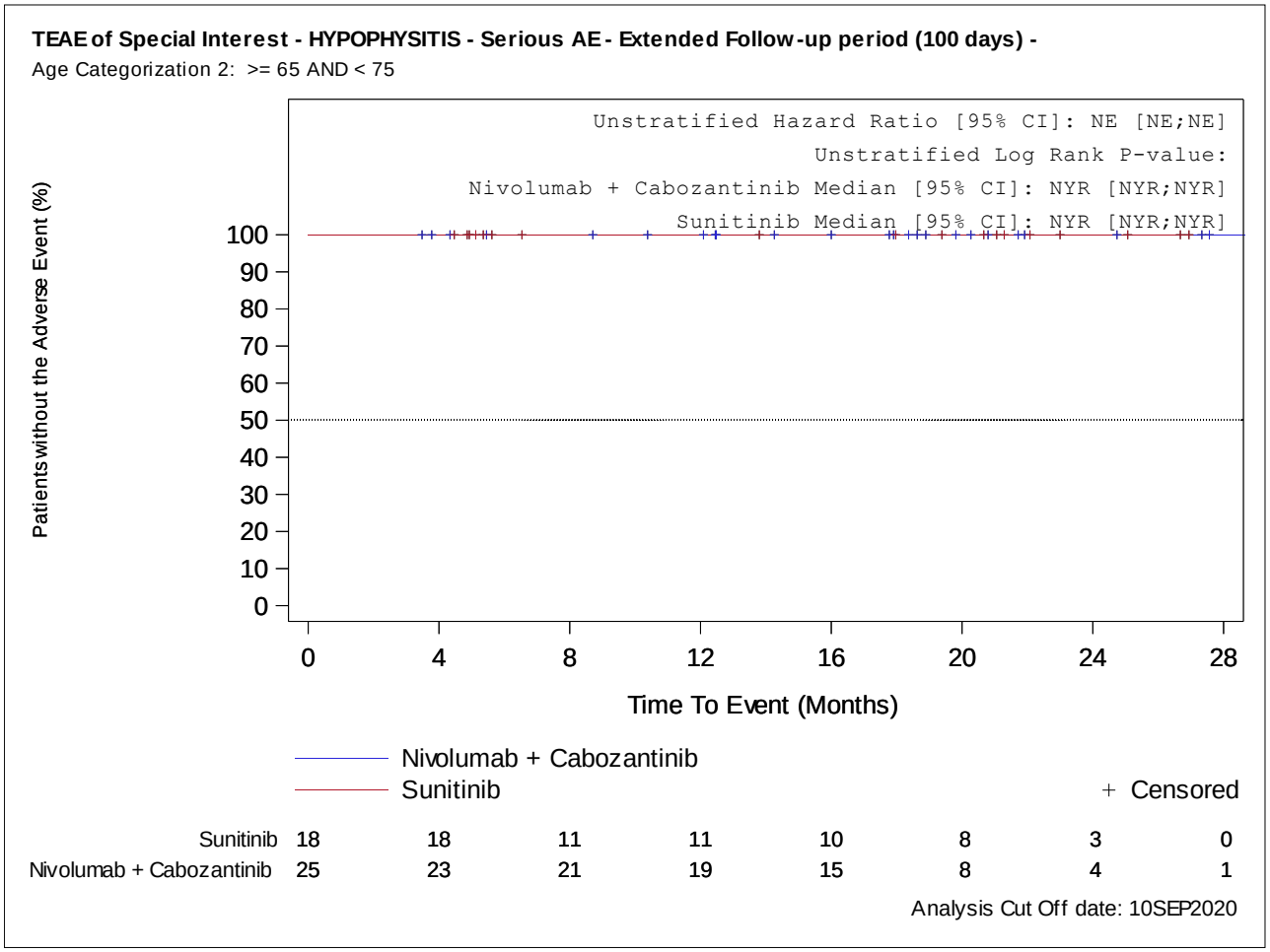

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:22

FIGURE 3.100.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



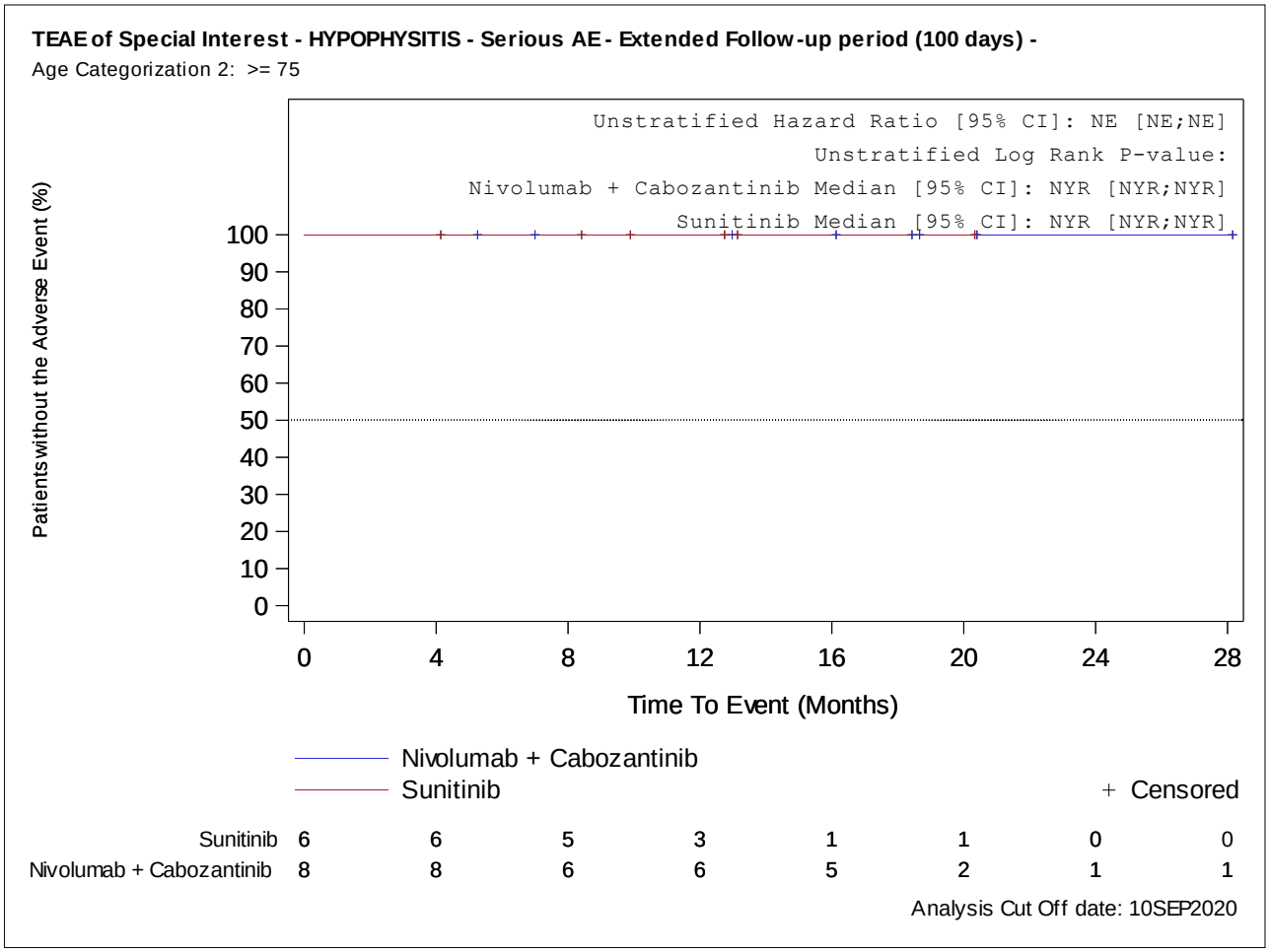

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:27

FIGURE 3.100.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



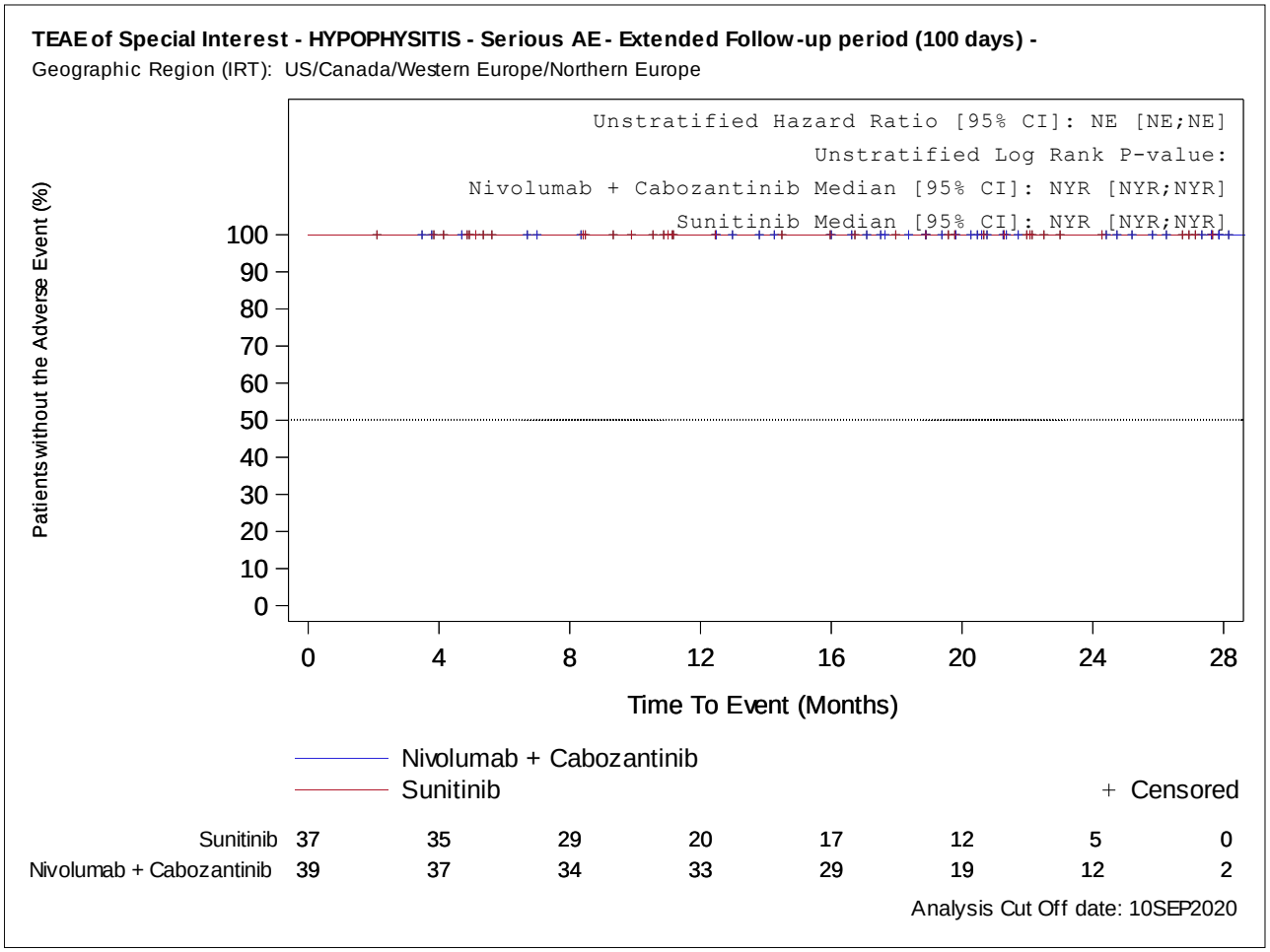

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:32

FIGURE 3.100.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



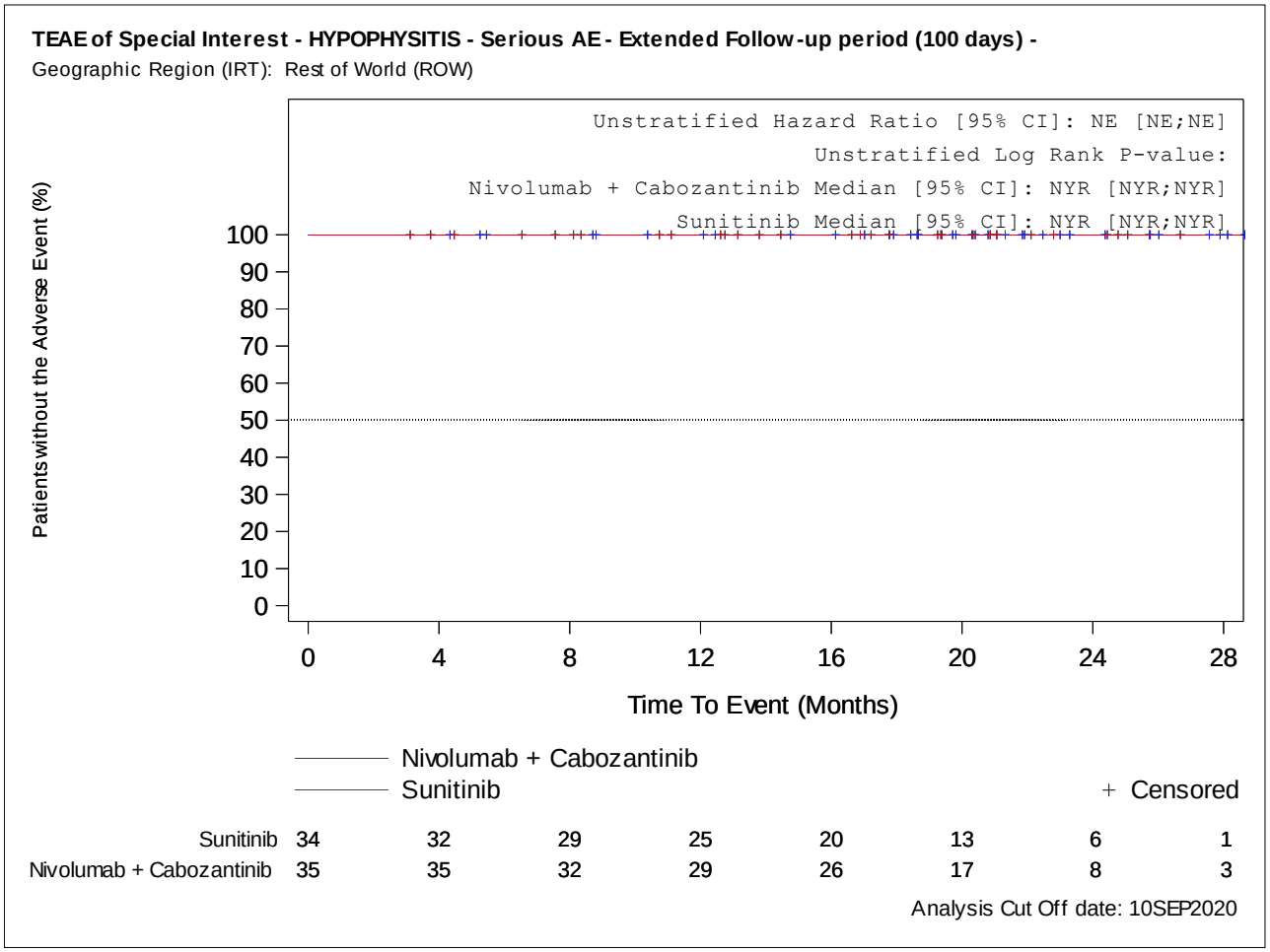

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:37

FIGURE 3.100.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



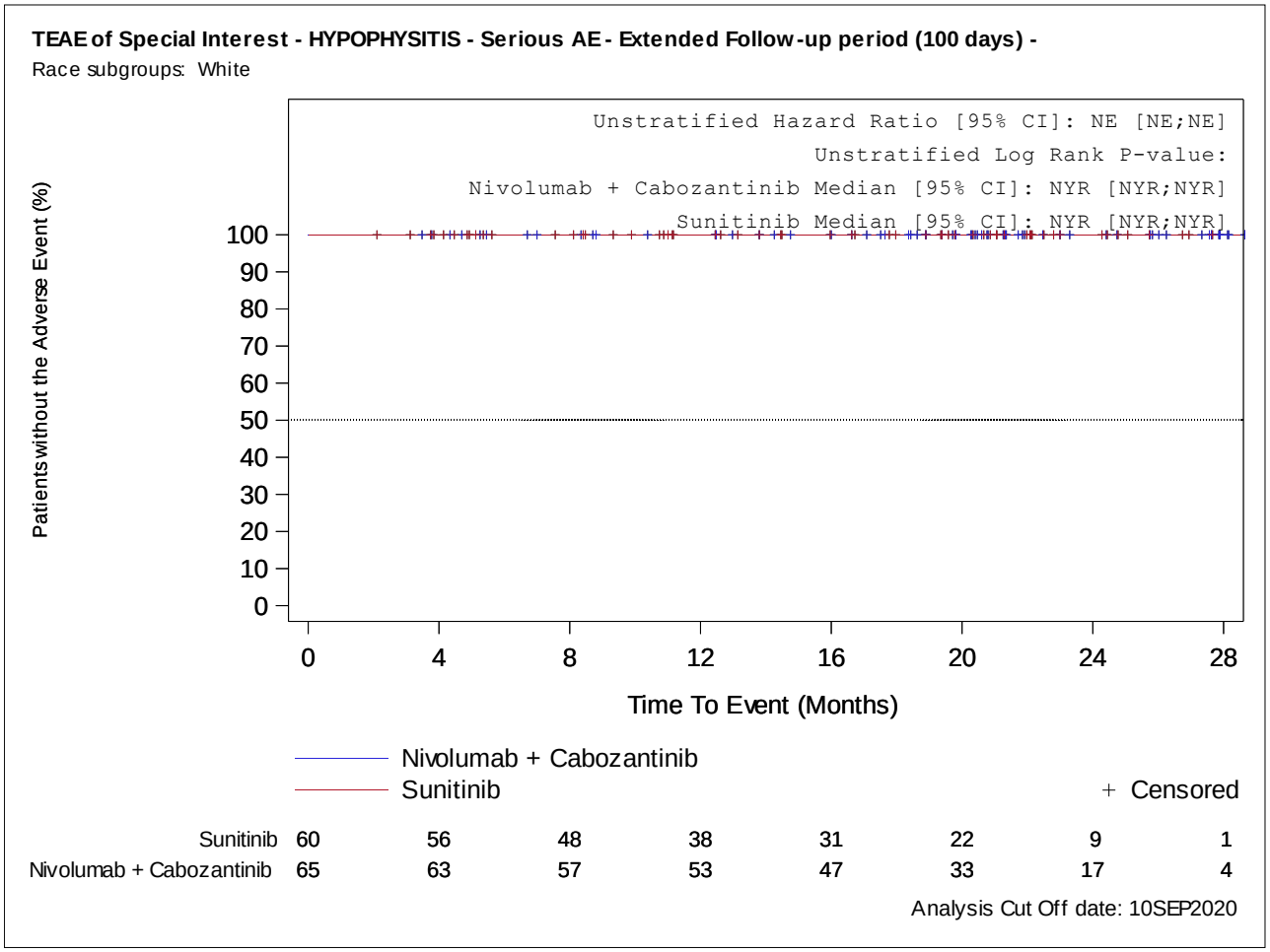

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:42

FIGURE 3.100.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



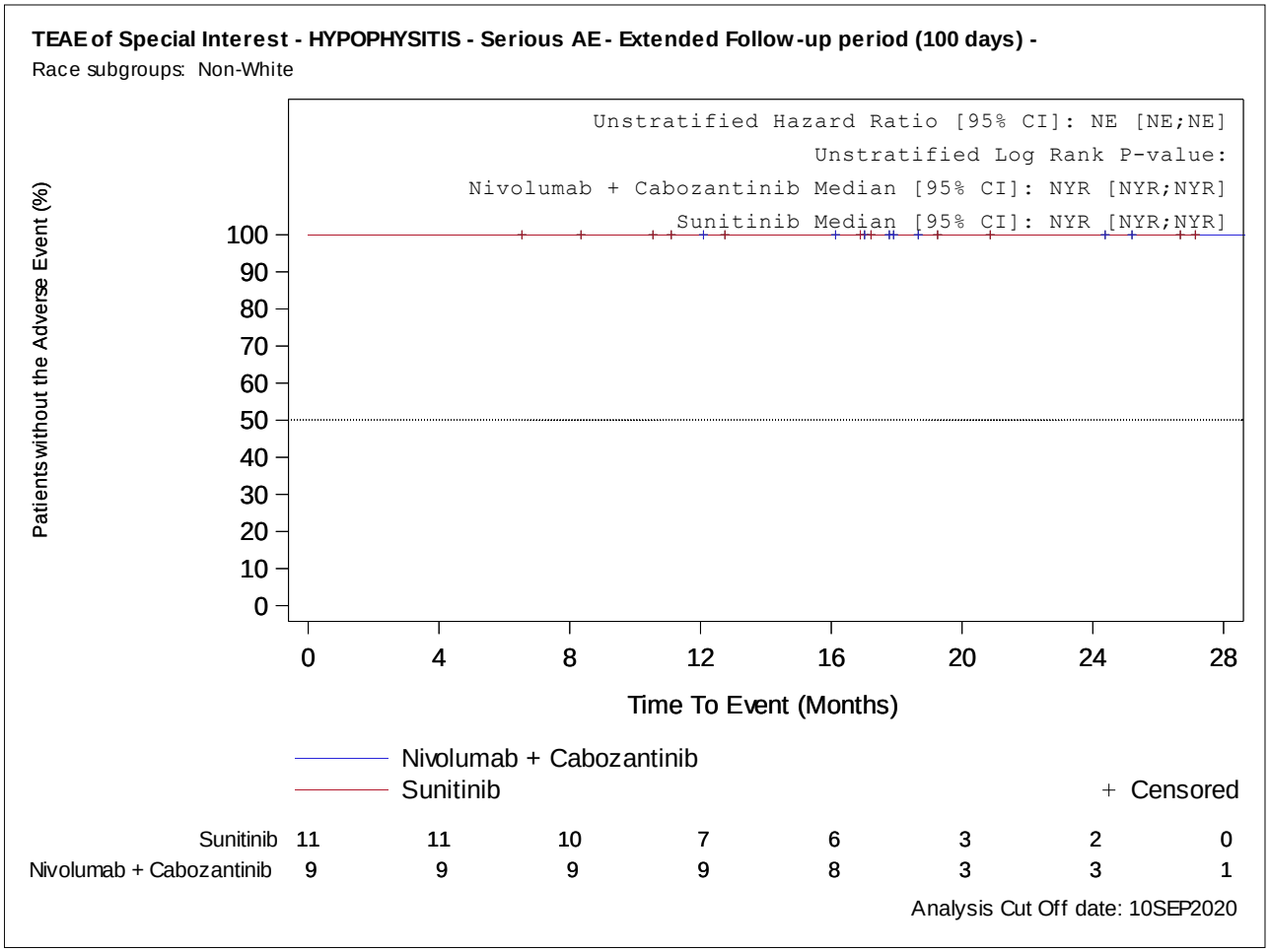

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:47

FIGURE 3.100.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



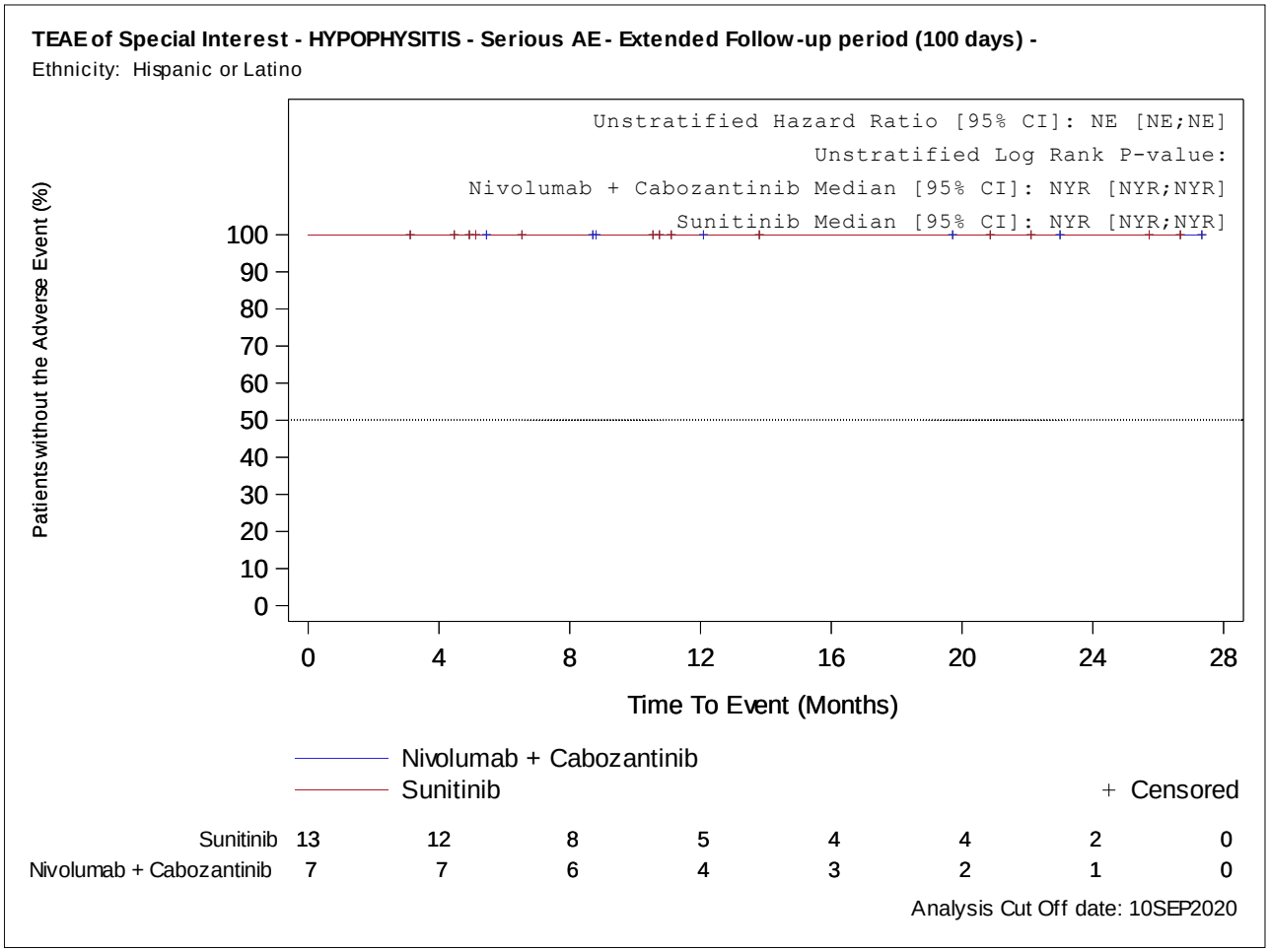

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:53

FIGURE 3.100.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



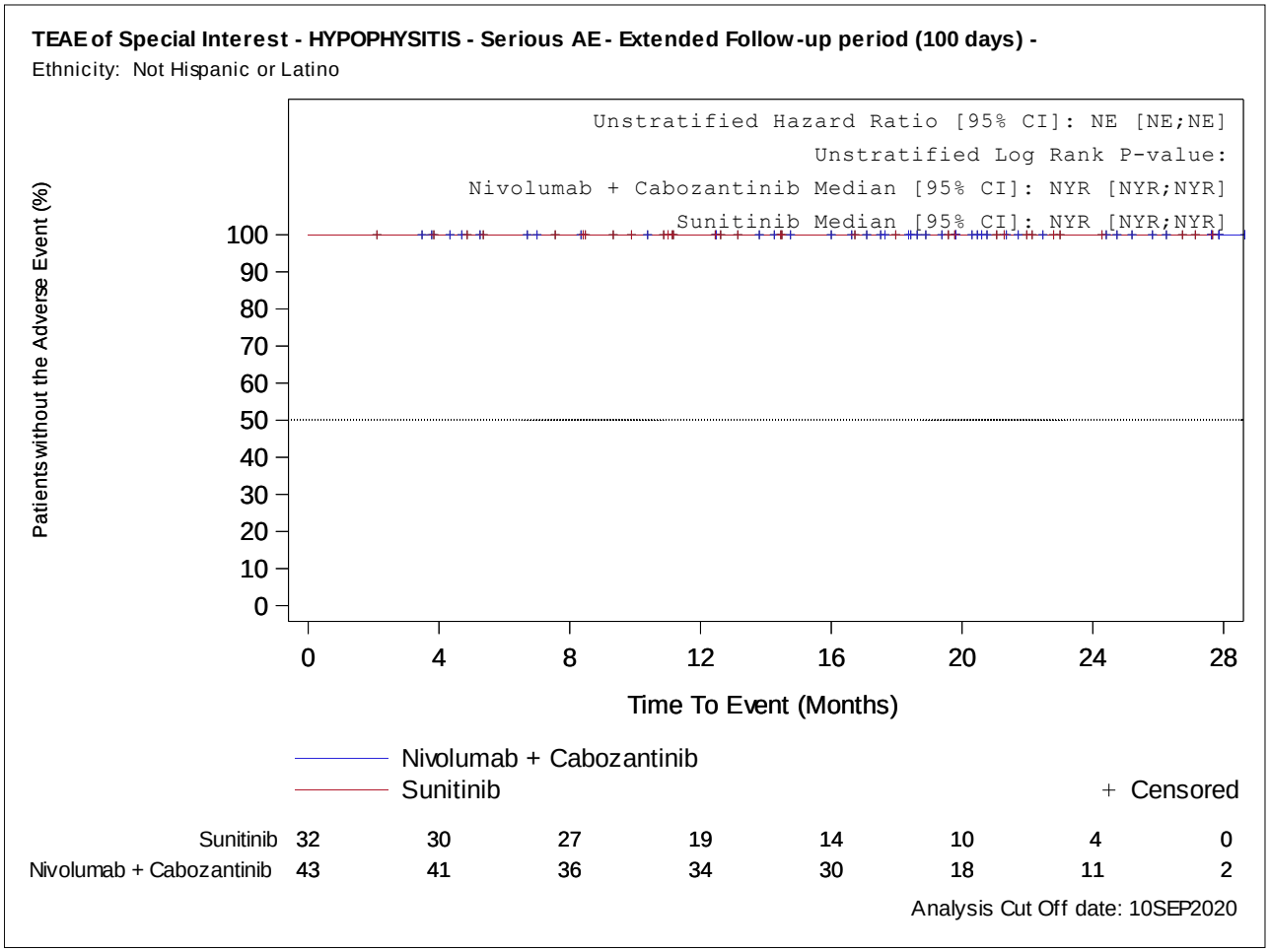

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:28:58

FIGURE 3.100.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



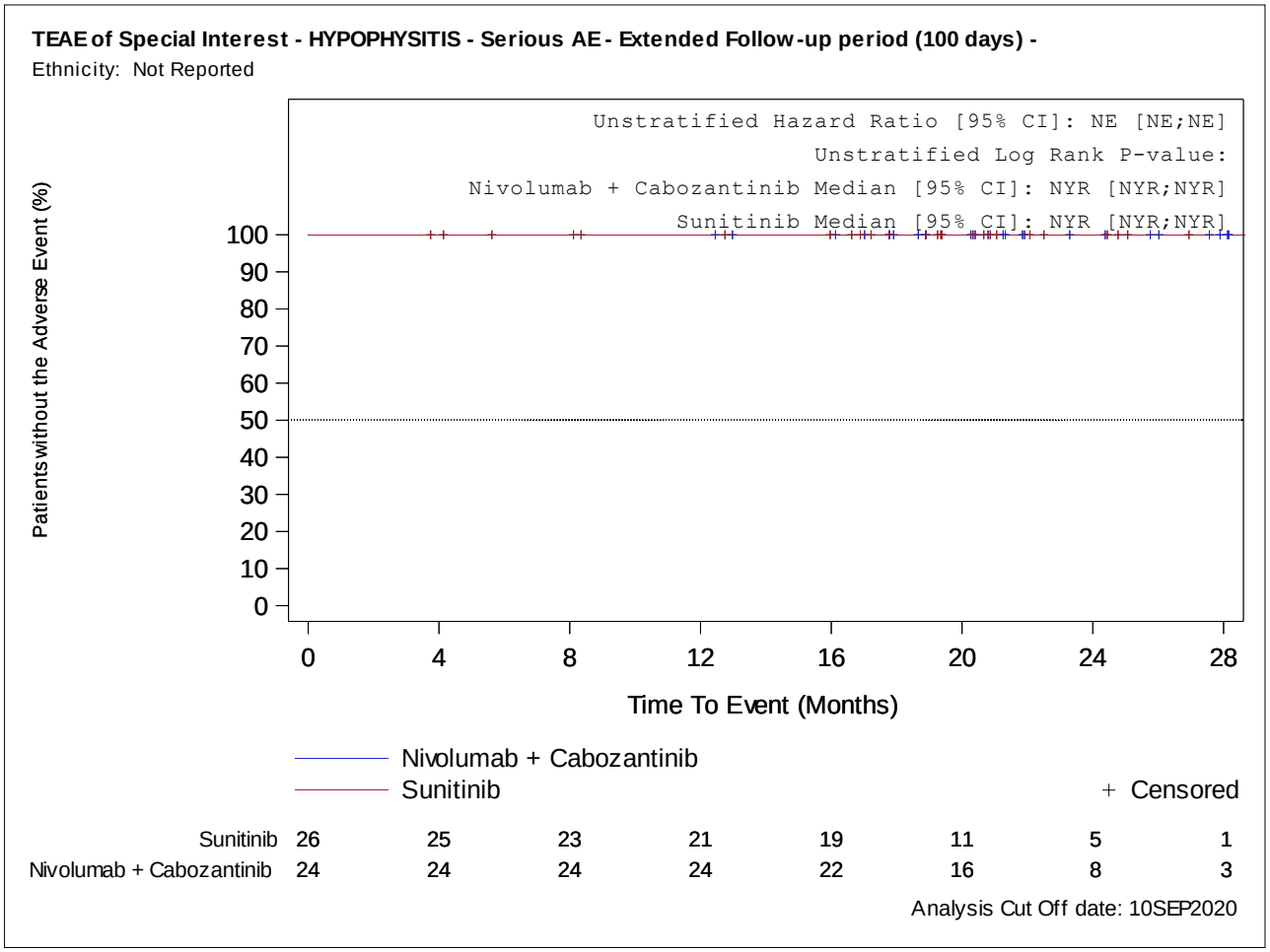

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:29:03

FIGURE 3.100.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:29:08

FIGURE 3.100.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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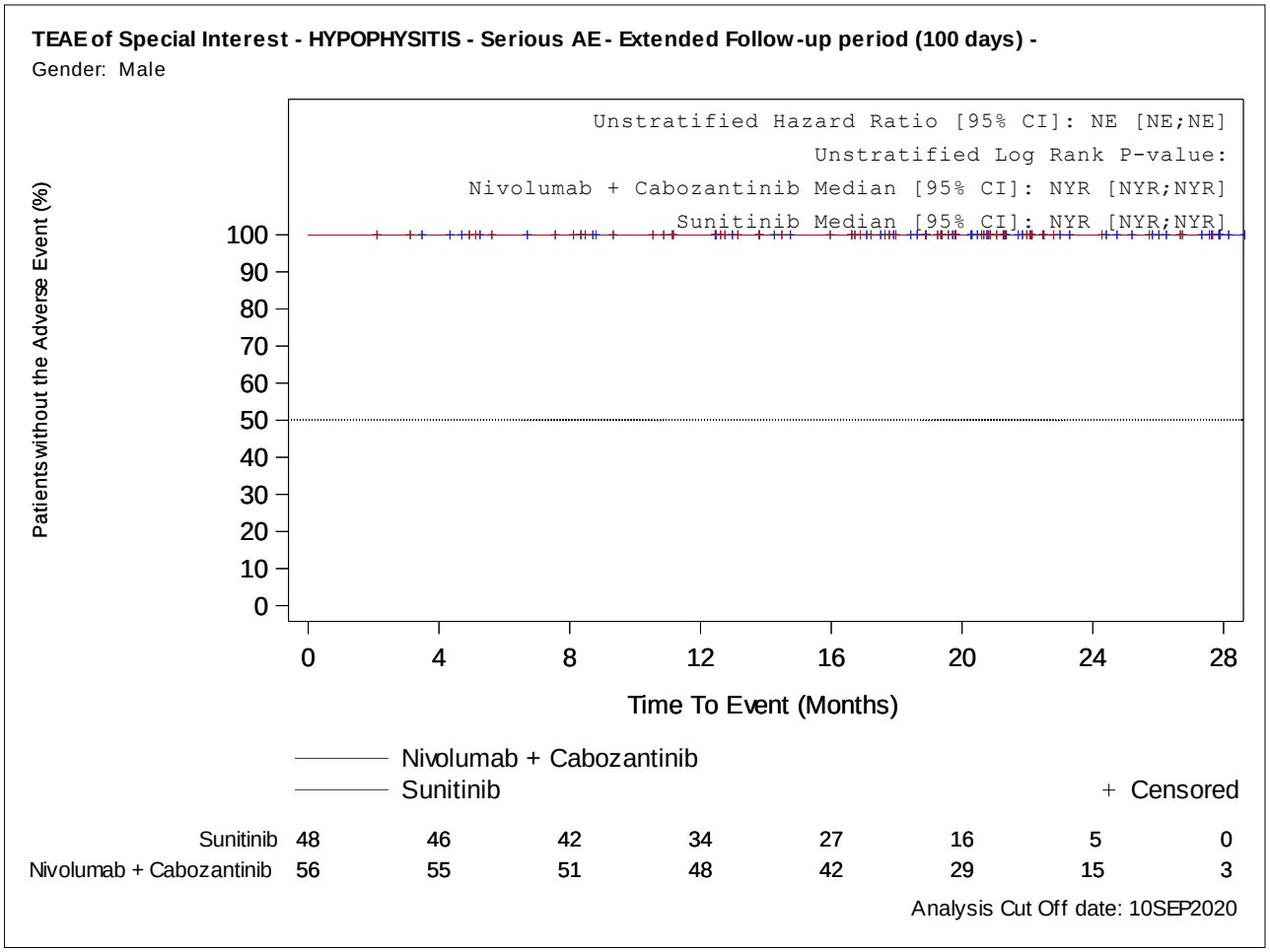
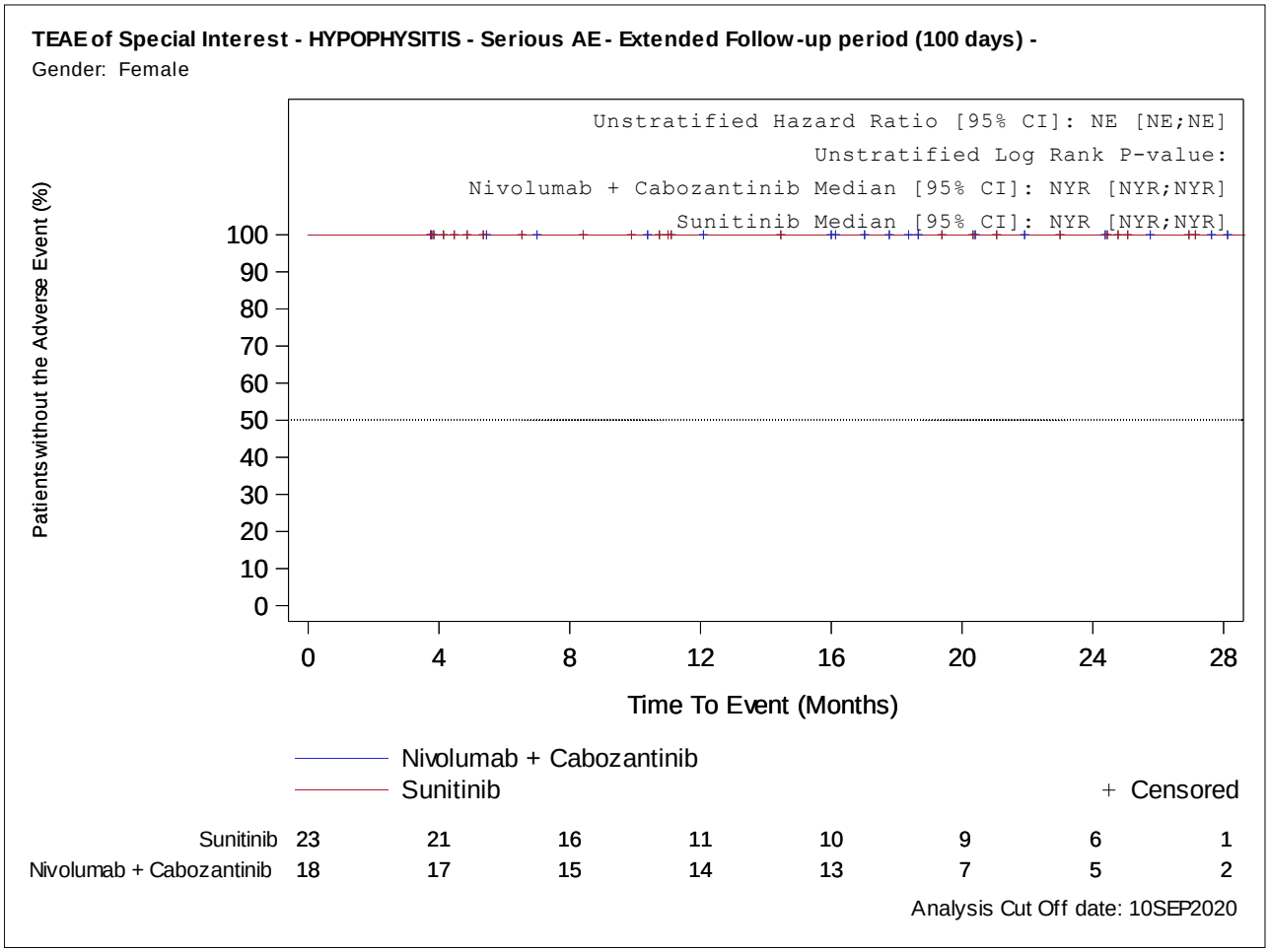
FIGURE 3.100.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



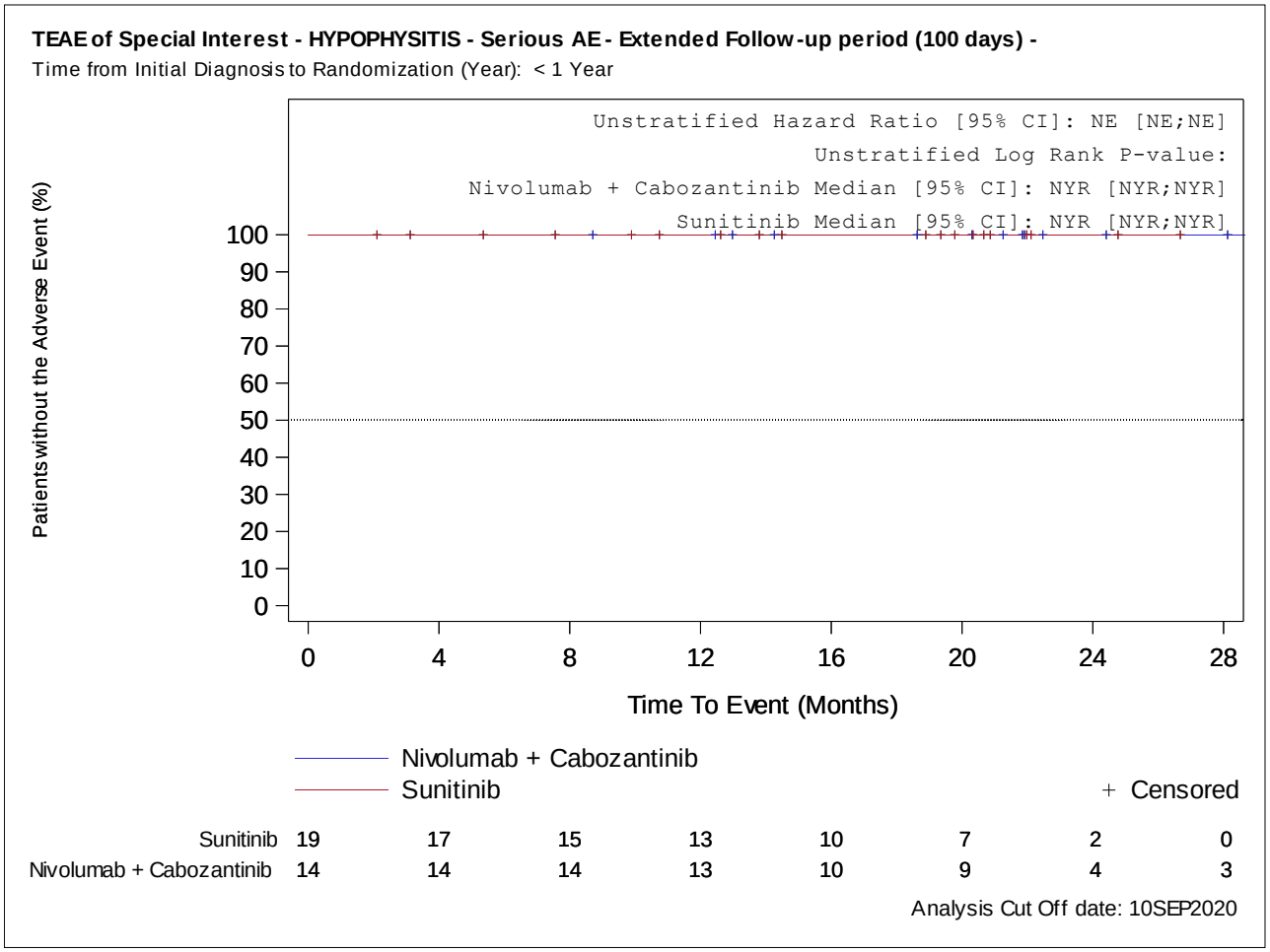

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:29:18

FIGURE 3.100.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



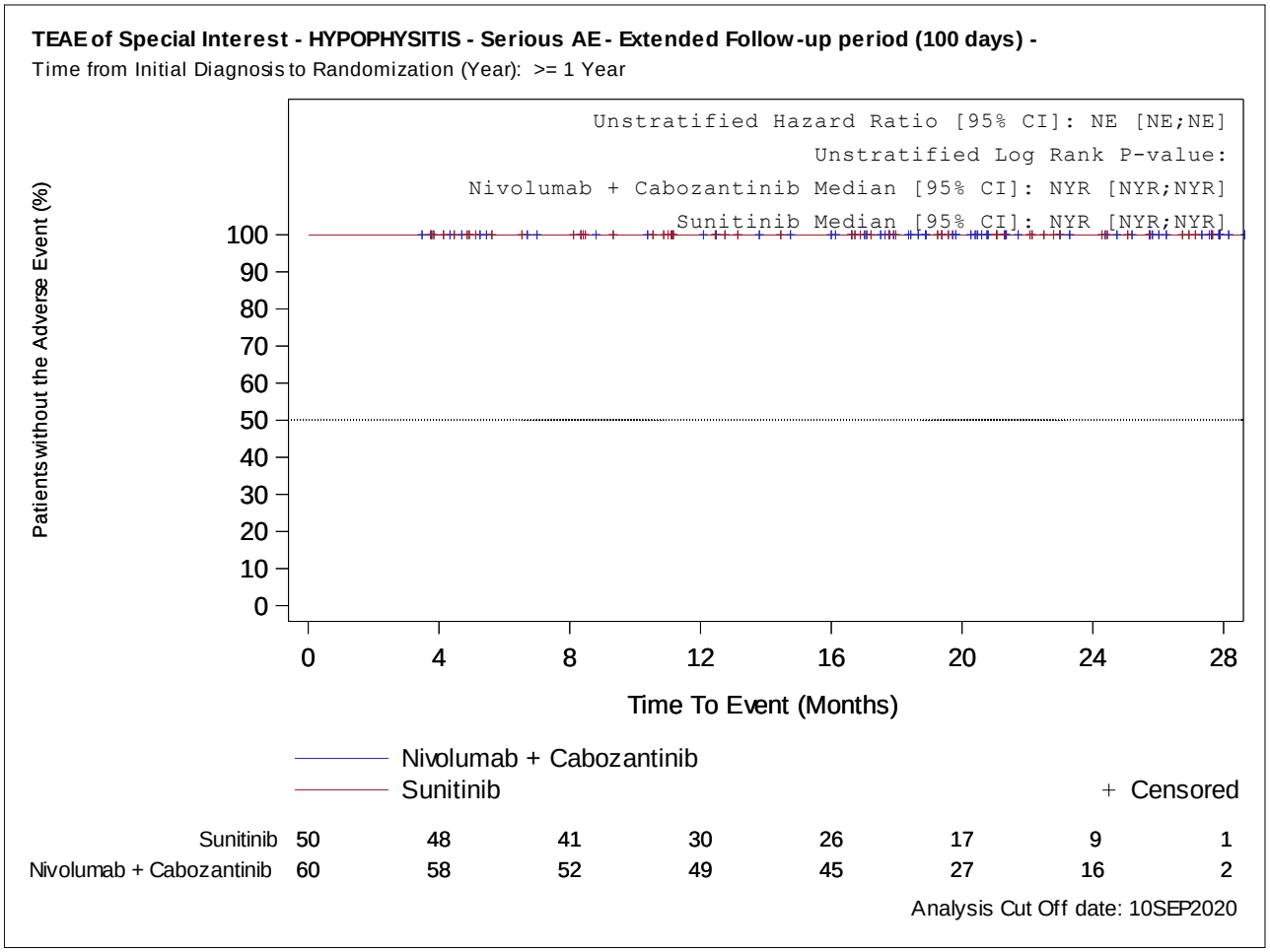

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:29:24

FIGURE 3.100.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



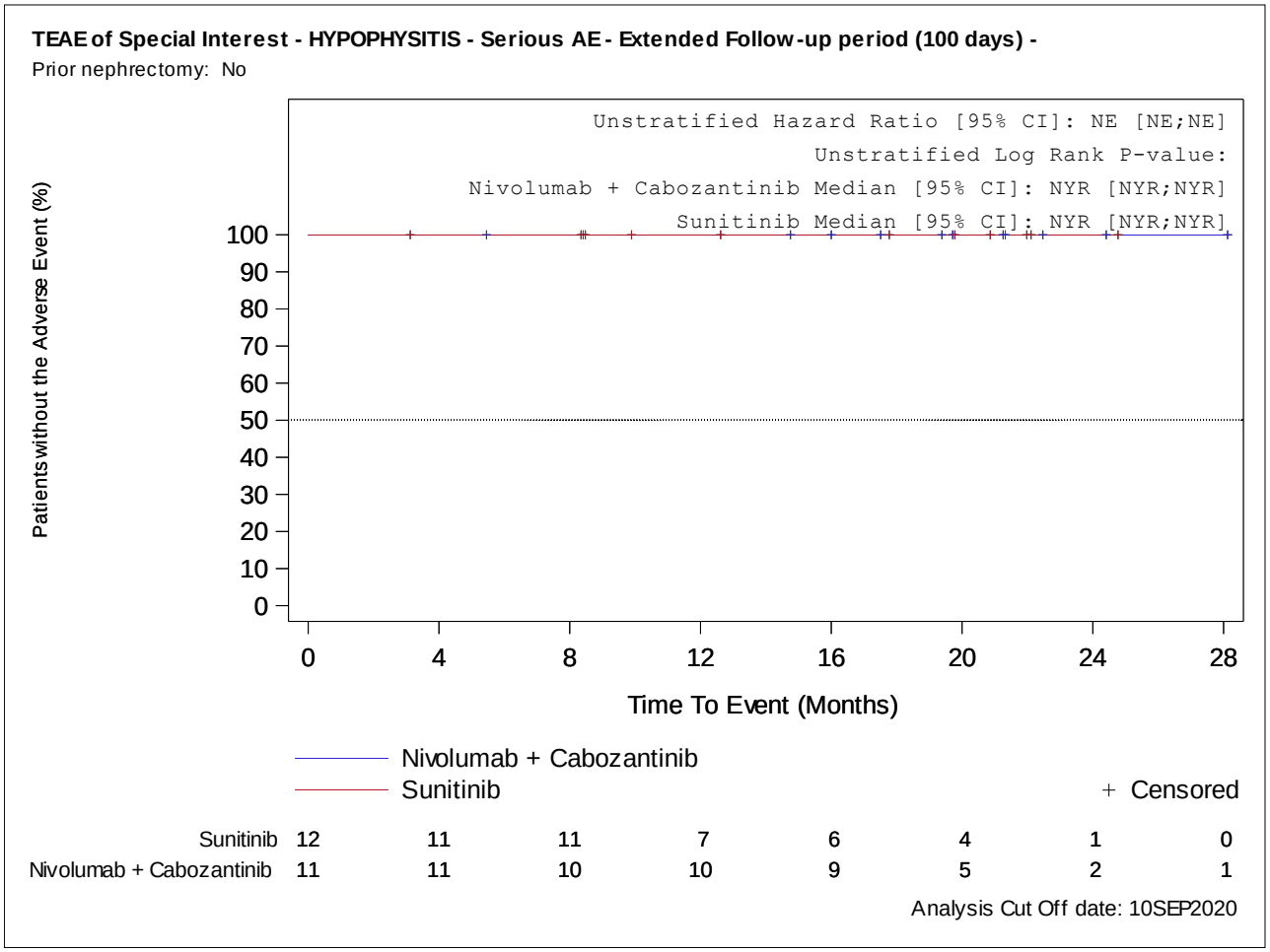

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:29:40

FIGURE 3.100.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



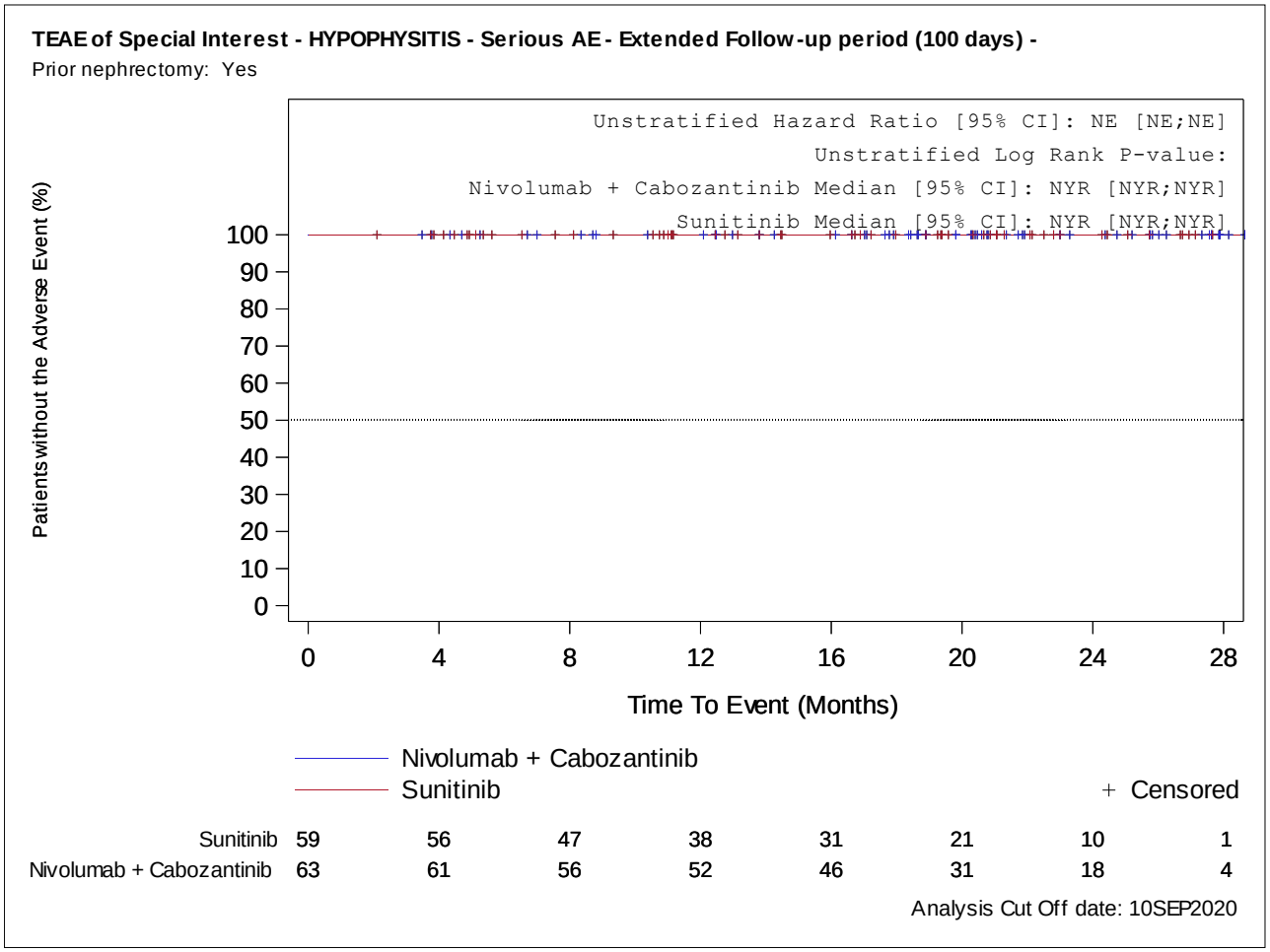

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:29:46

FIGURE 3.100.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



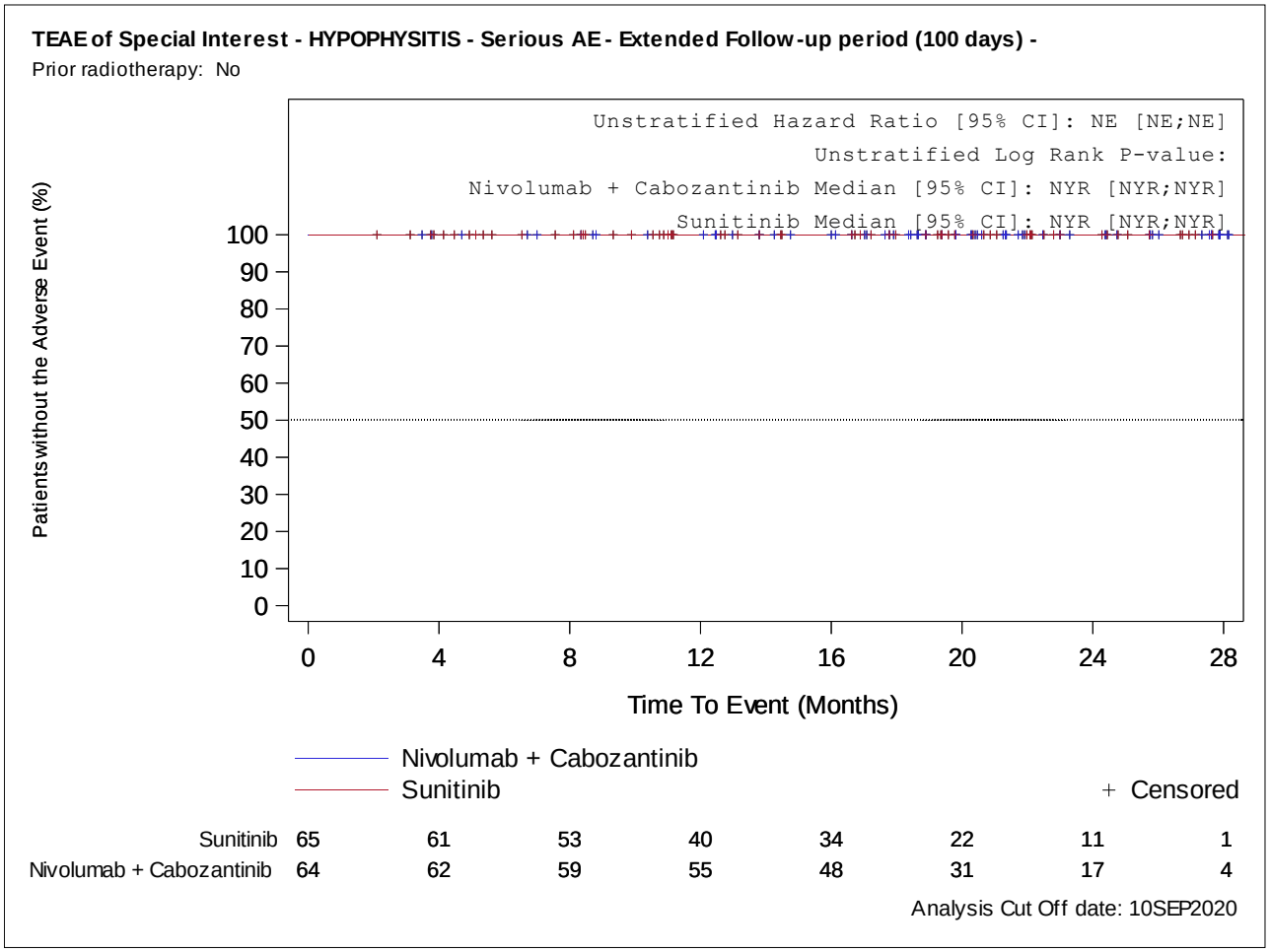

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:30:32

FIGURE 3.100.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



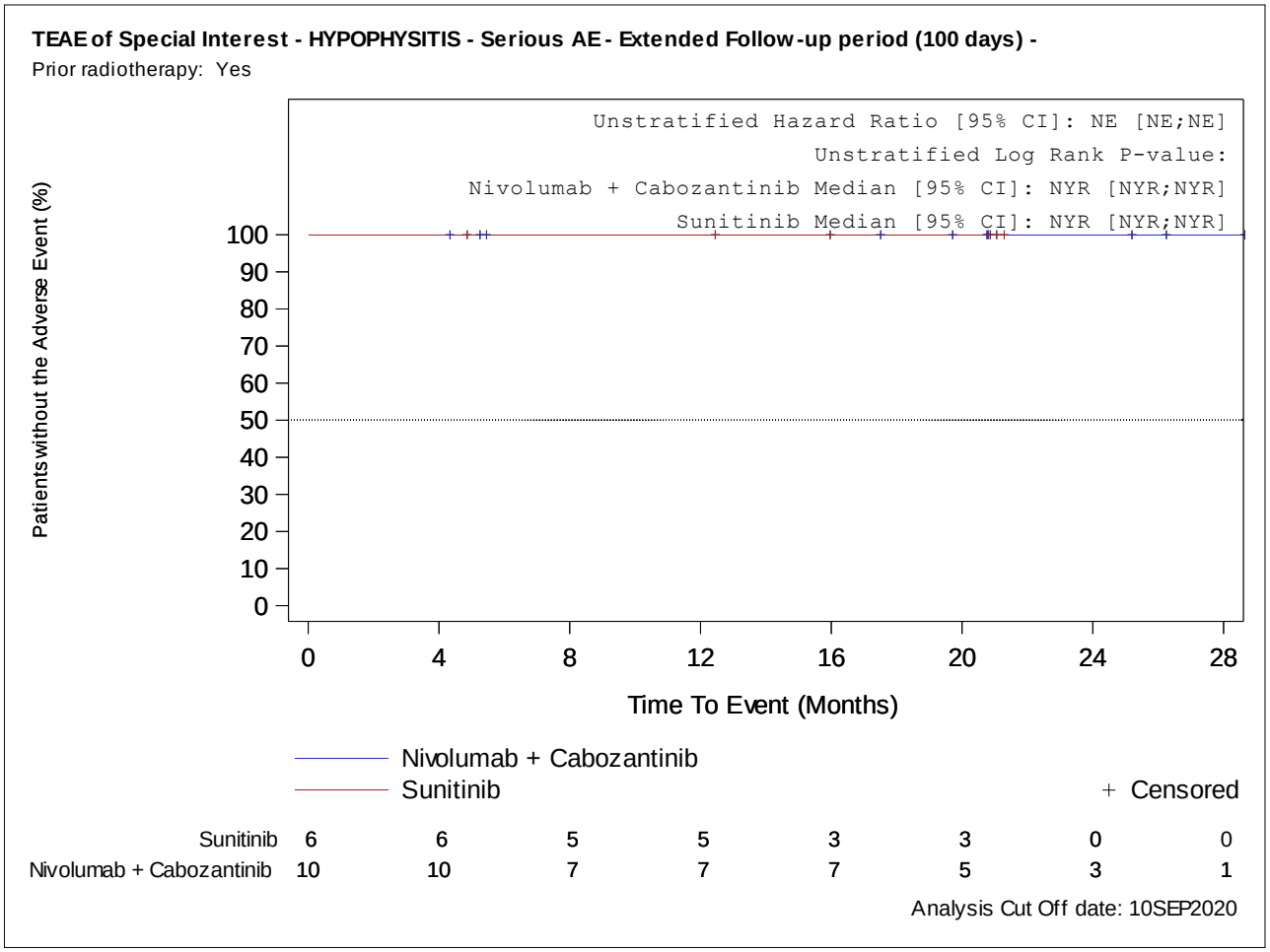

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:30:36

FIGURE 3.100.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



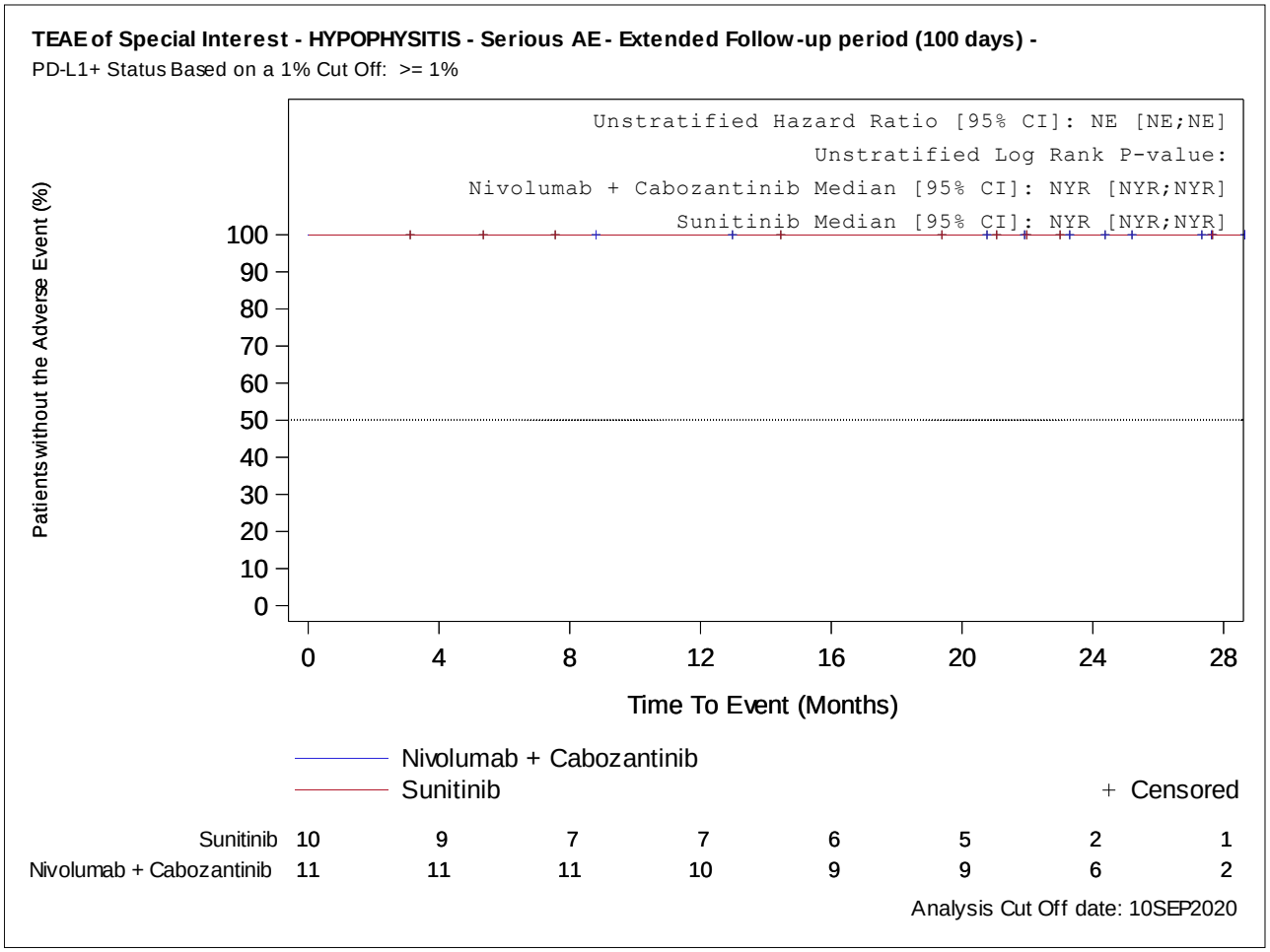

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:30:42

FIGURE 3.100.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



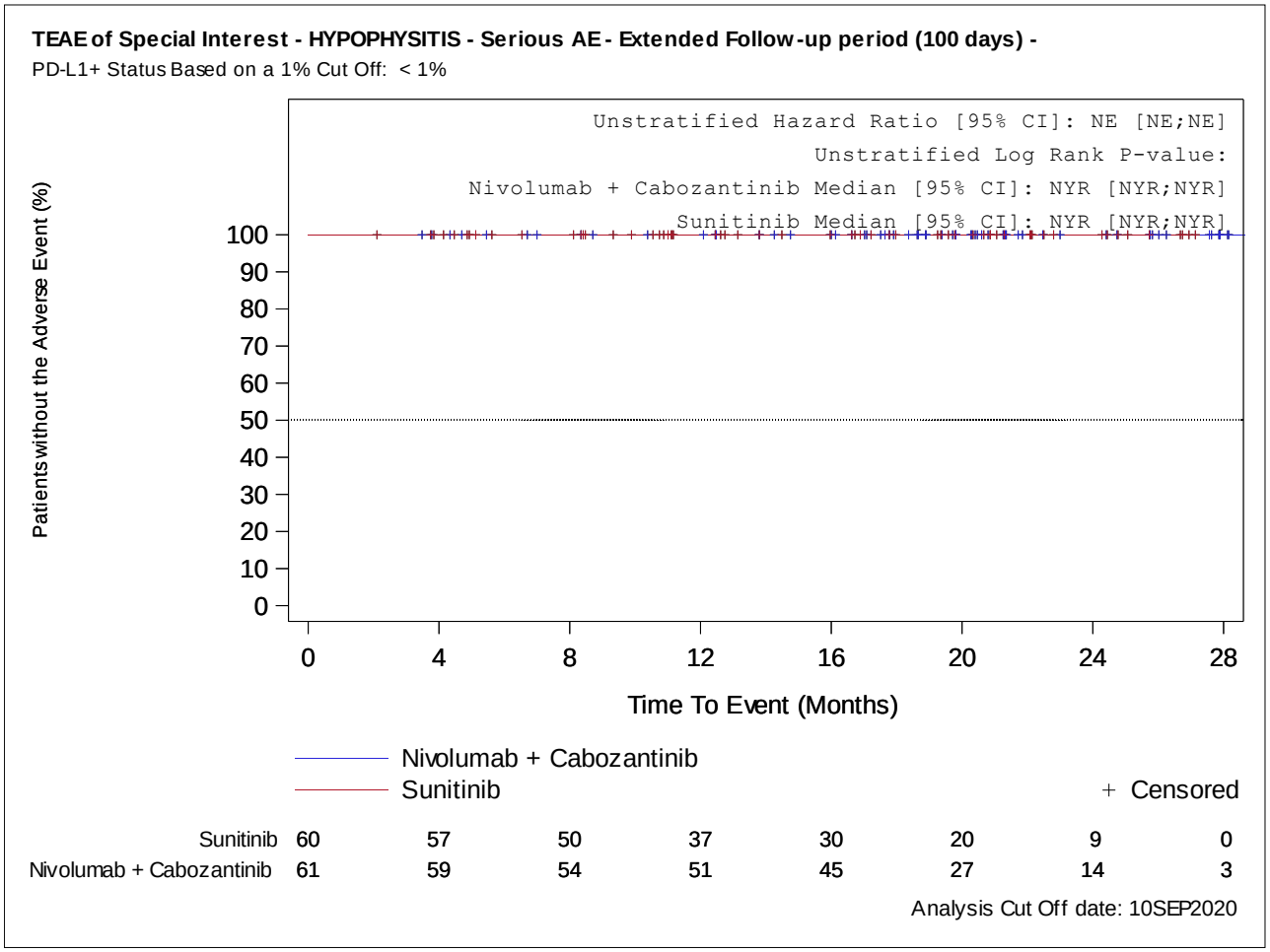

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:30:47

FIGURE 3.100.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



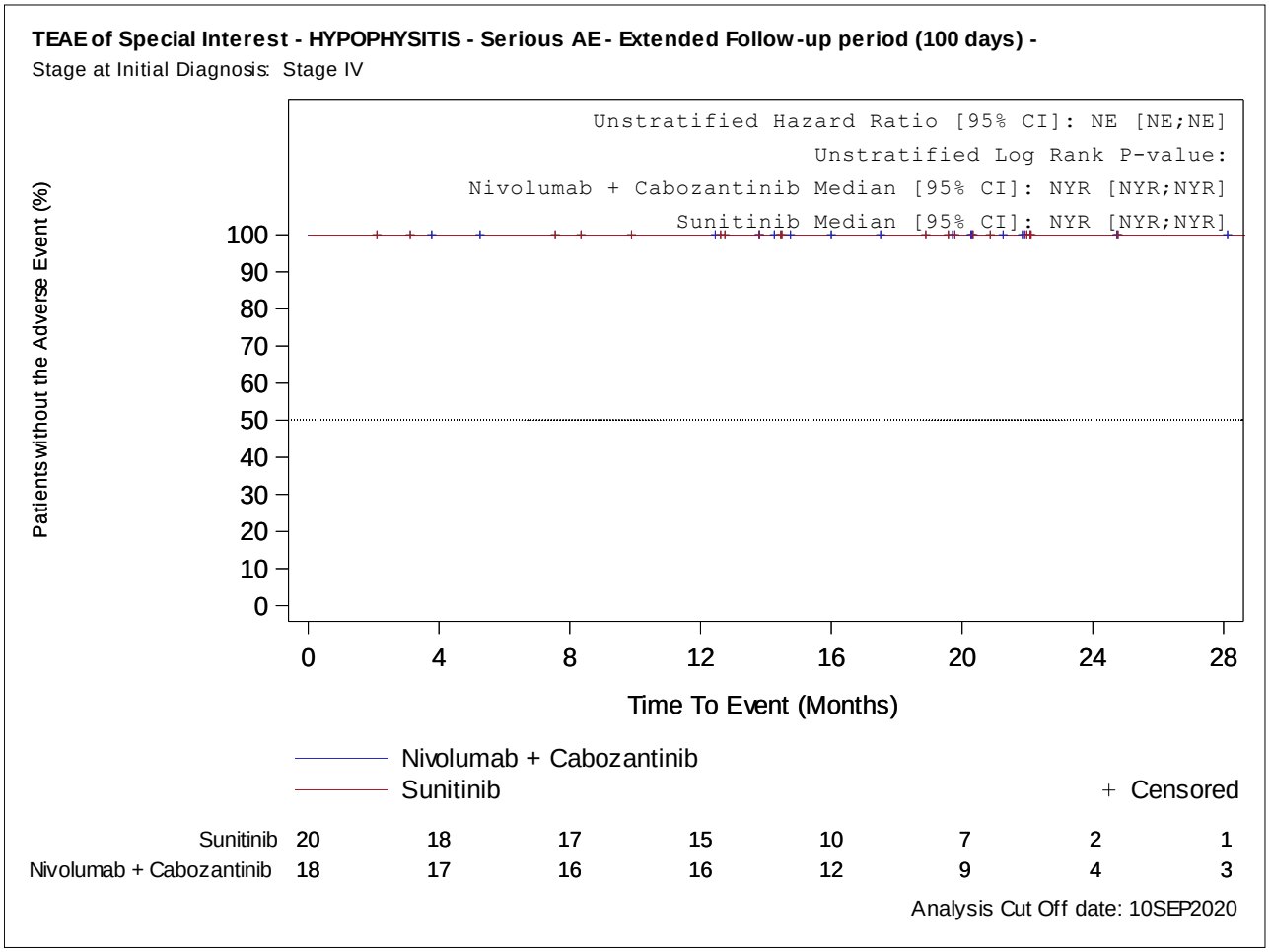

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:30:52

FIGURE 3.100.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



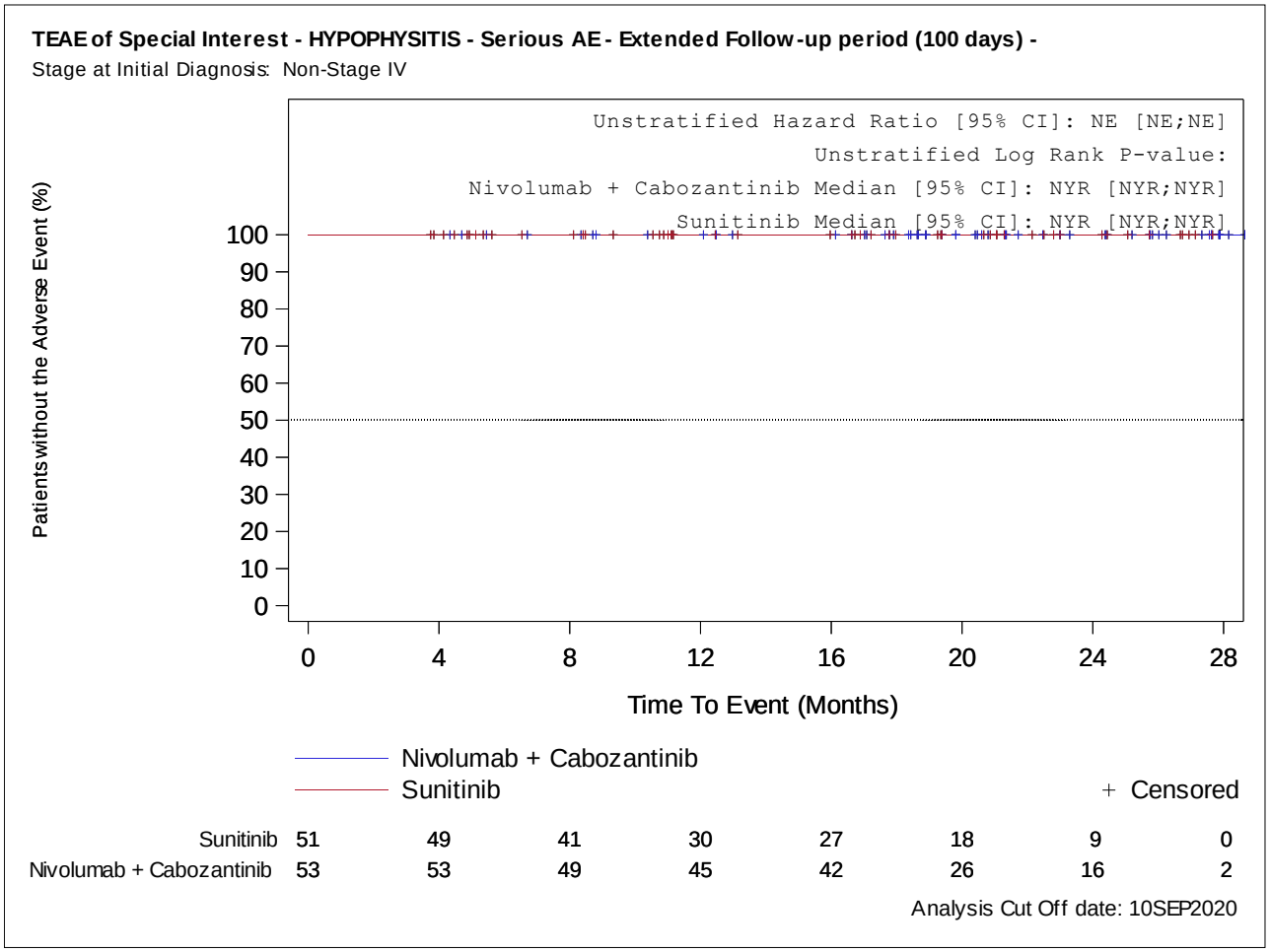

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:30:57

FIGURE 3.100.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



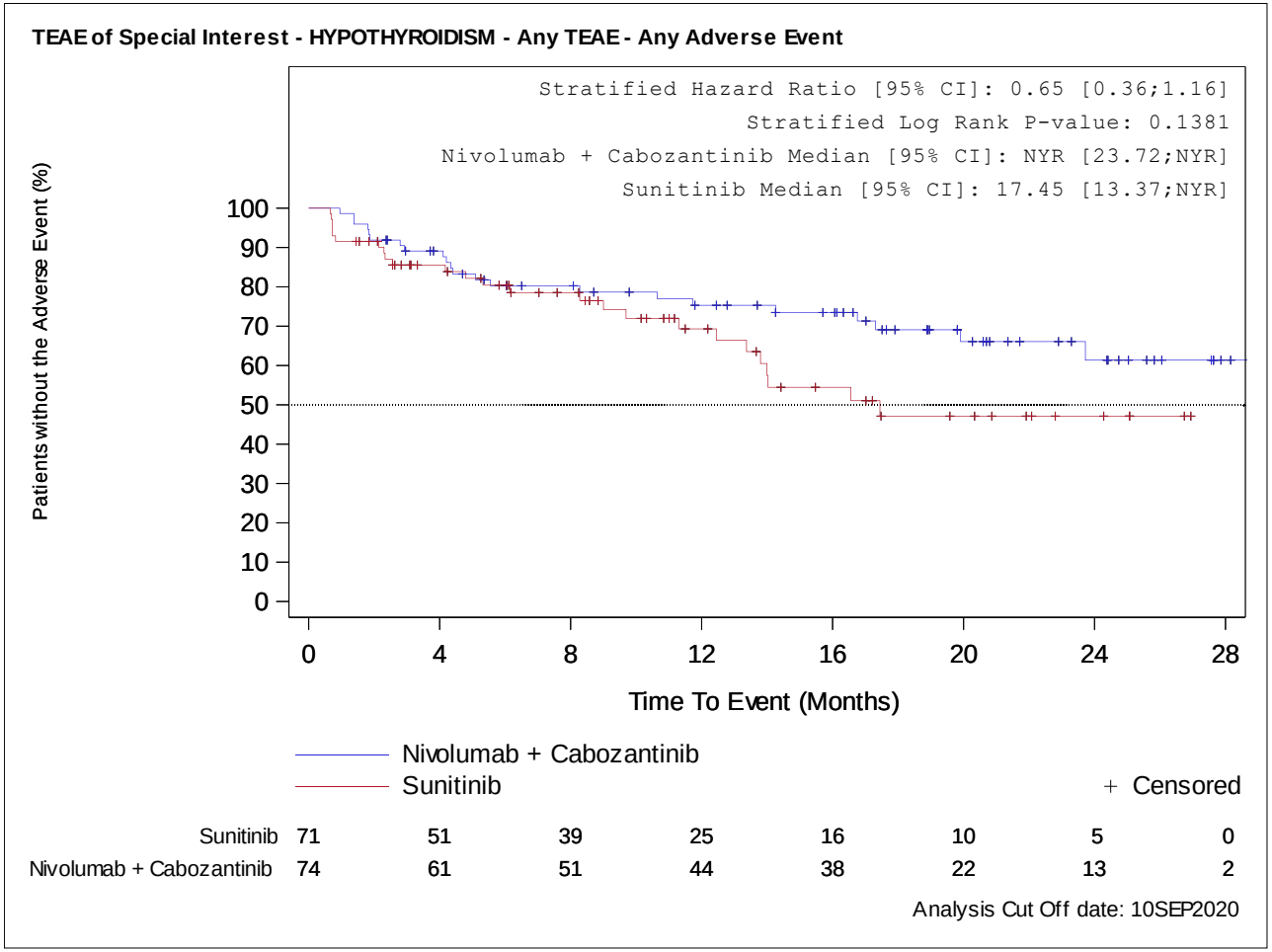

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:31:23

FIGURE 3.100.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOPHYSITIS - Serious AE - Extended Follow-up period (100 days) - - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



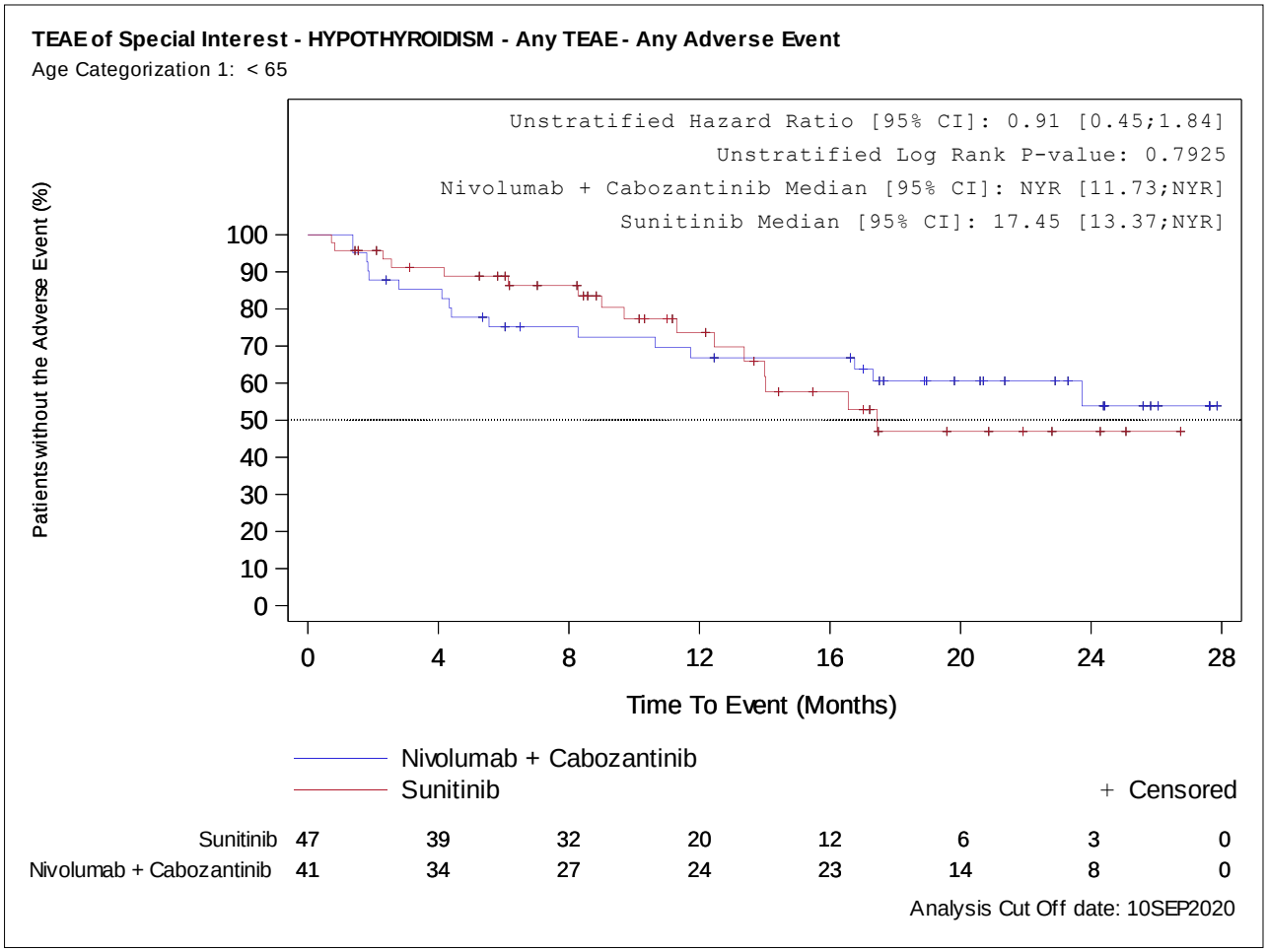

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:31:28

FIGURE 3.101.1: TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



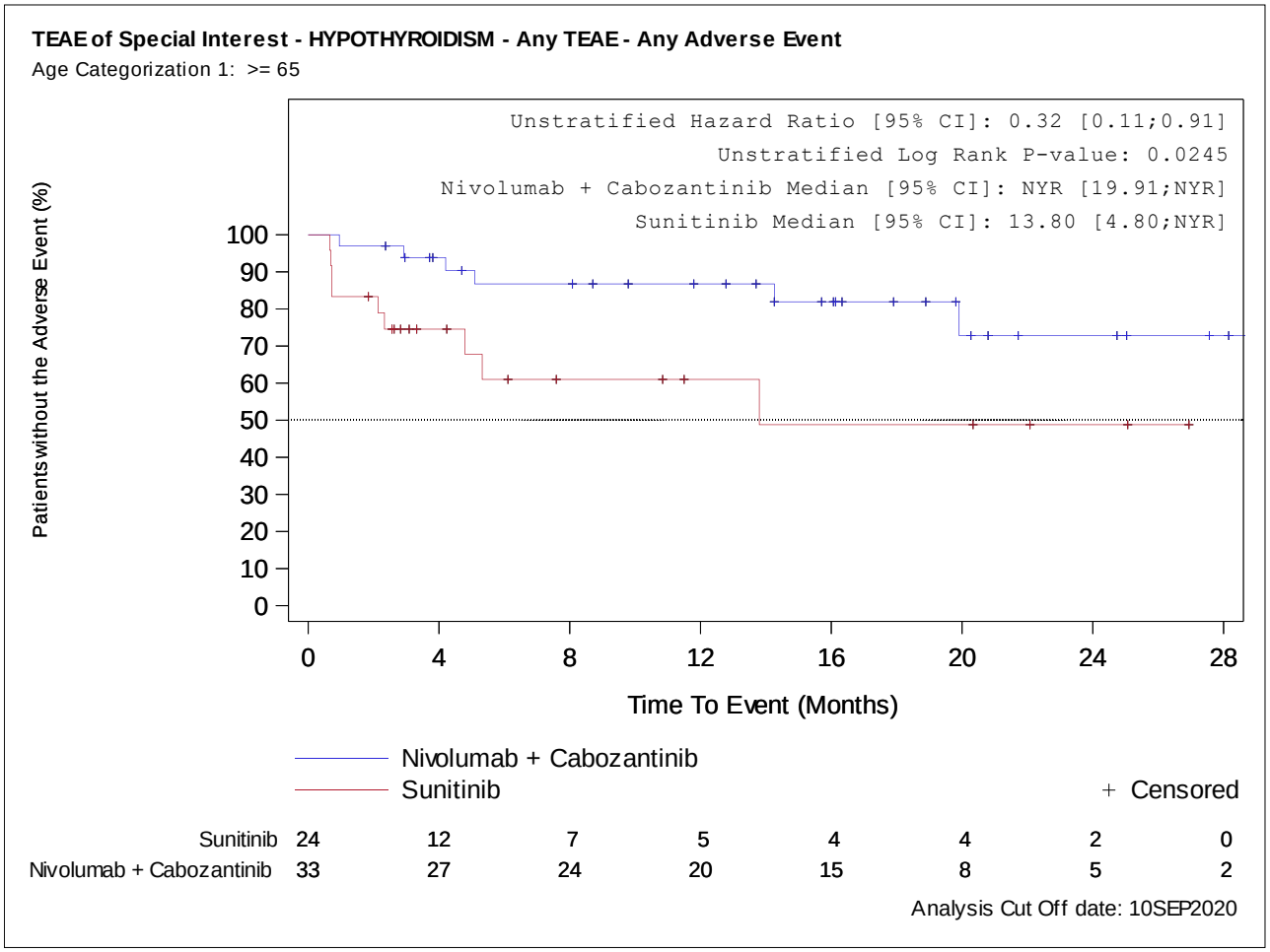

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:34:23

FIGURE 3.101.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



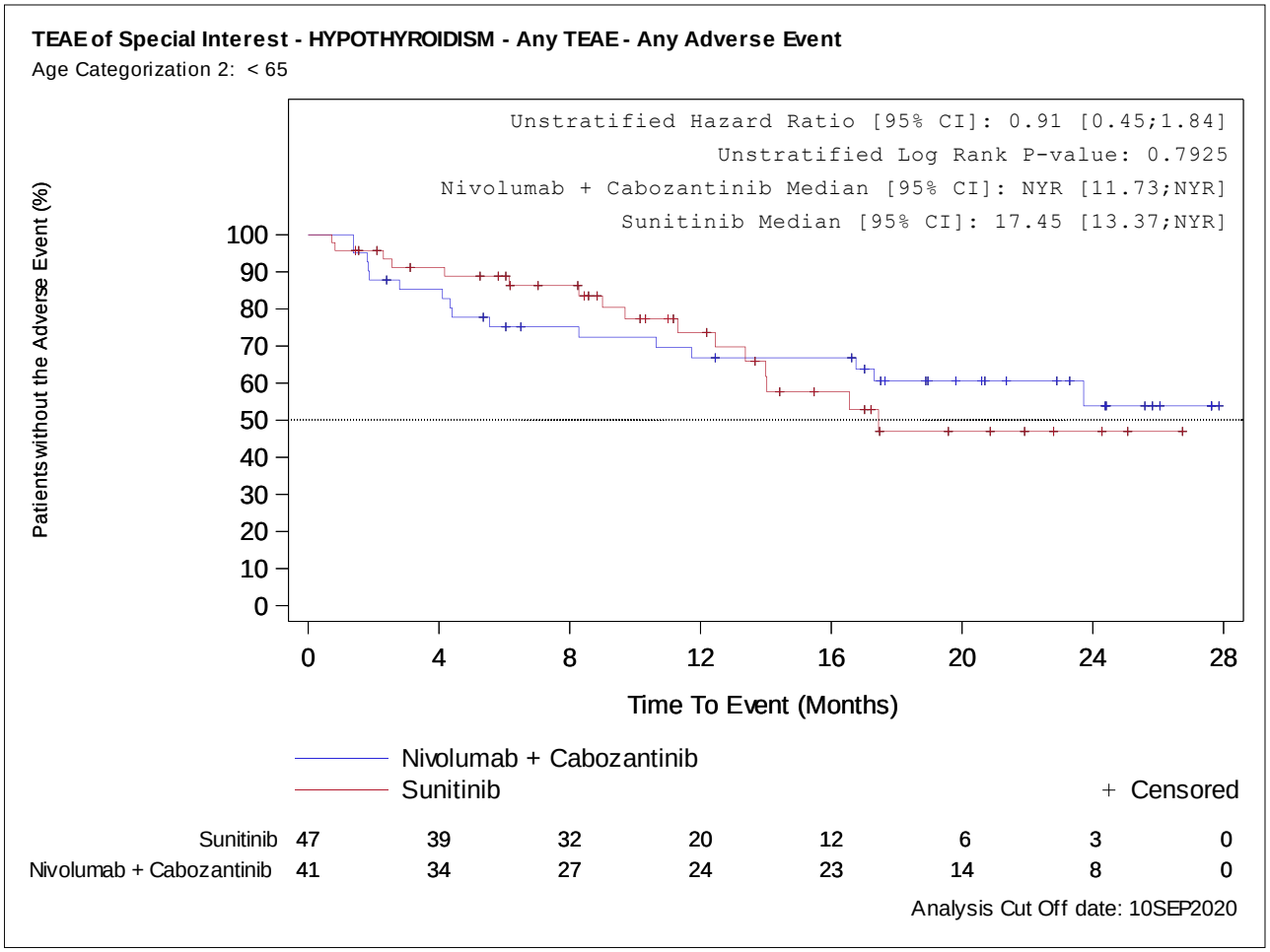

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:34:26

FIGURE 3.101.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



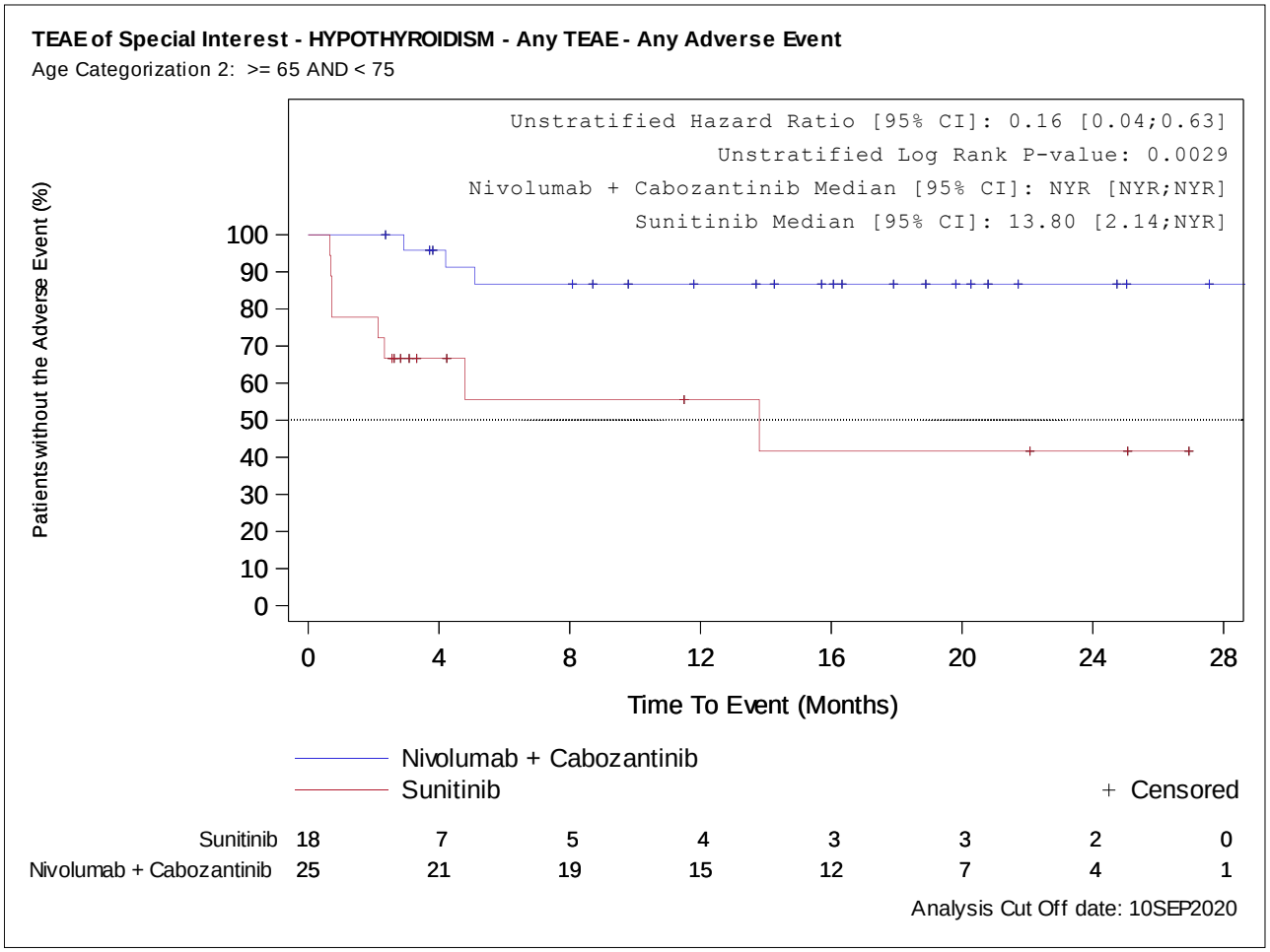

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:34:31

FIGURE 3.101.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



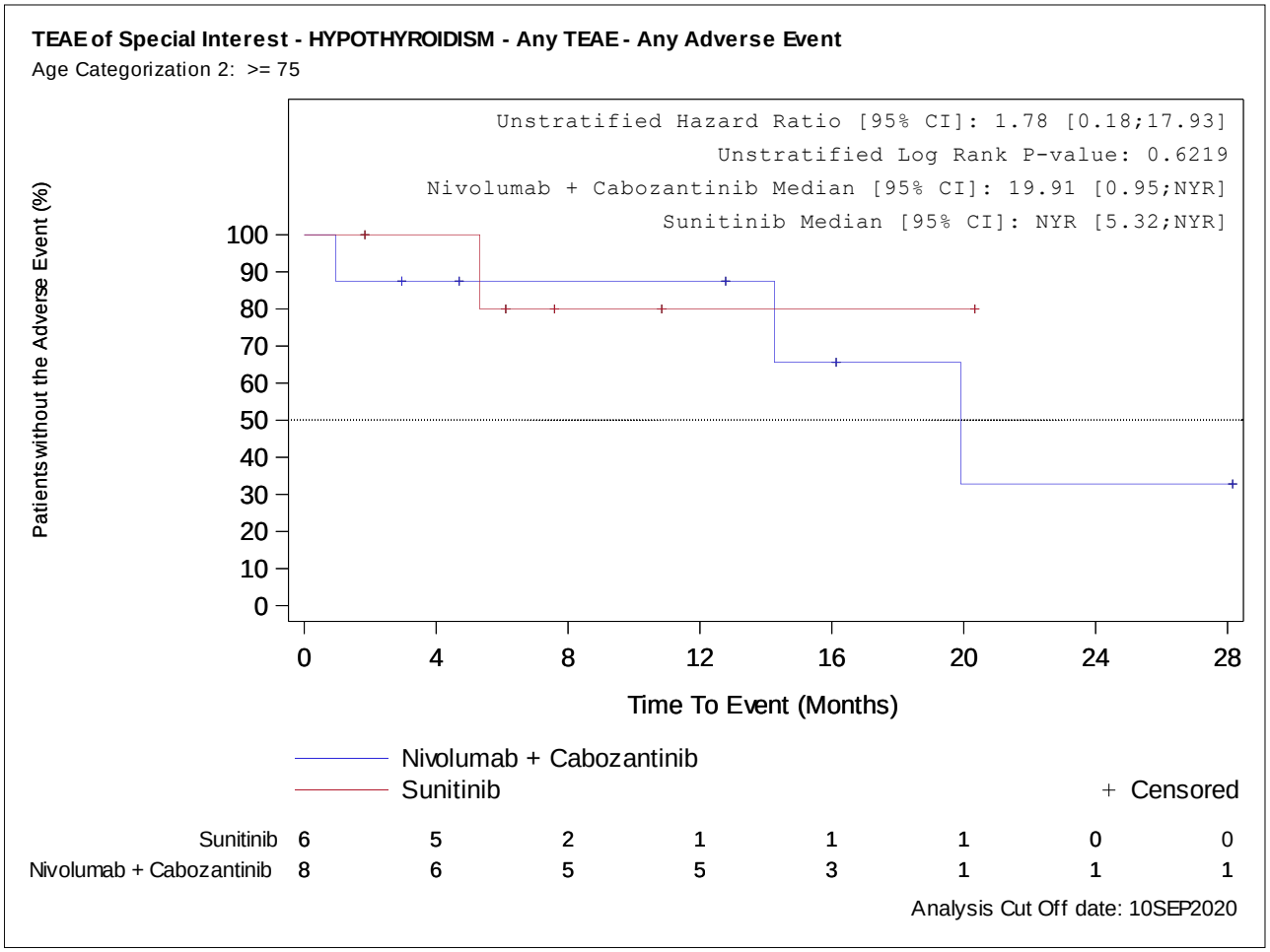

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:34:37

FIGURE 3.101.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



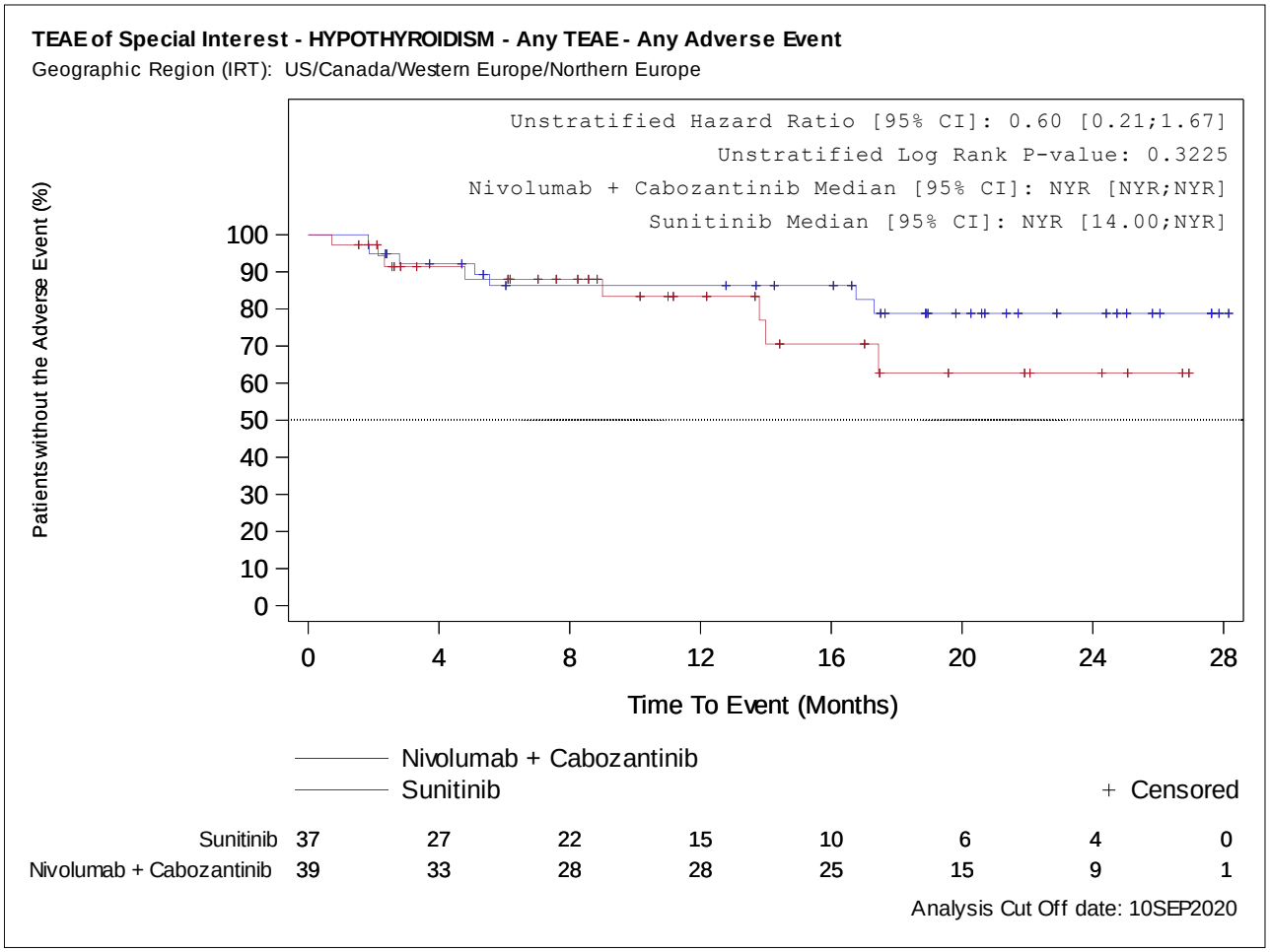

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:34:42

FIGURE 3.101.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



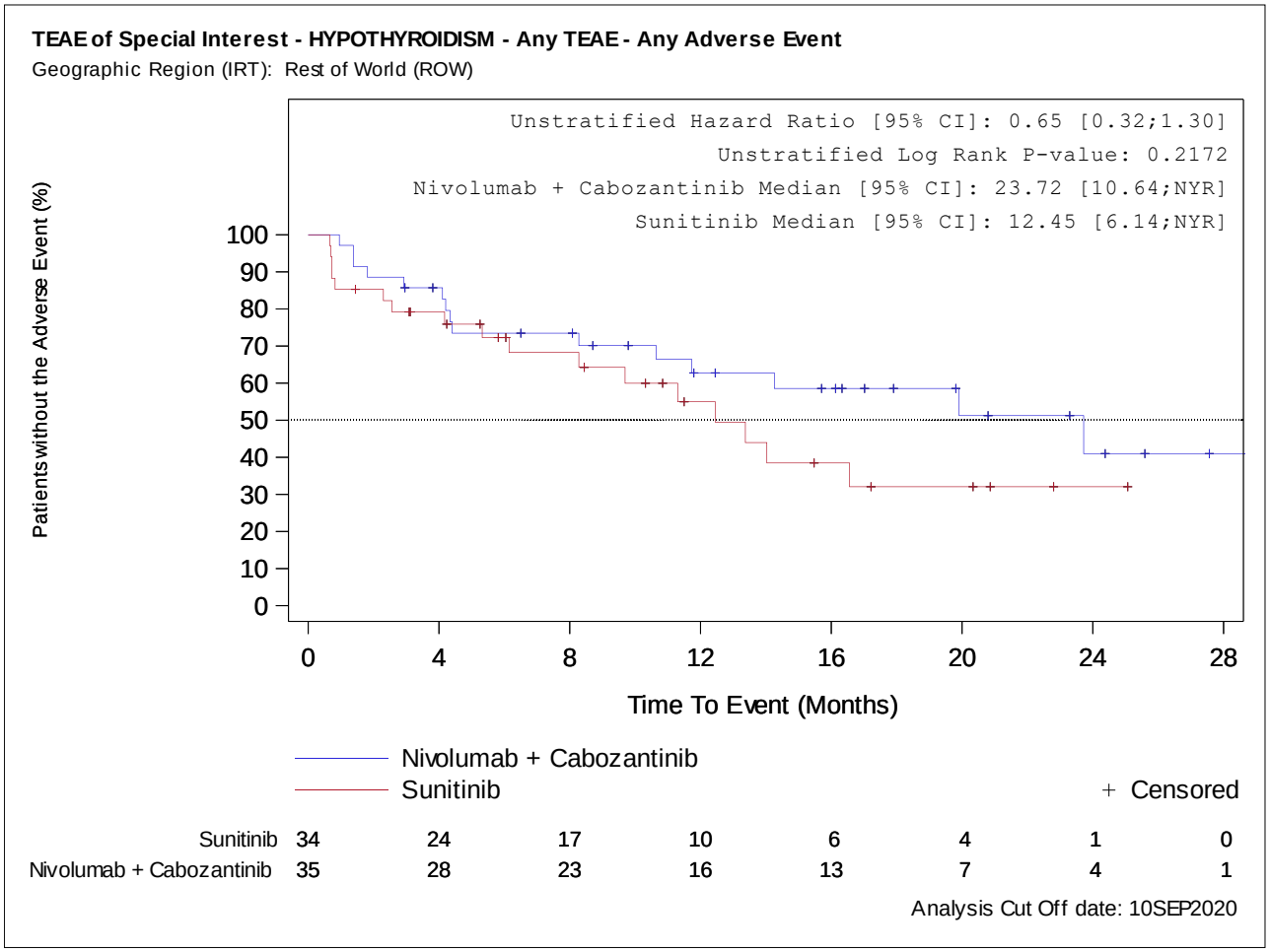

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:34:47

FIGURE 3.101.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



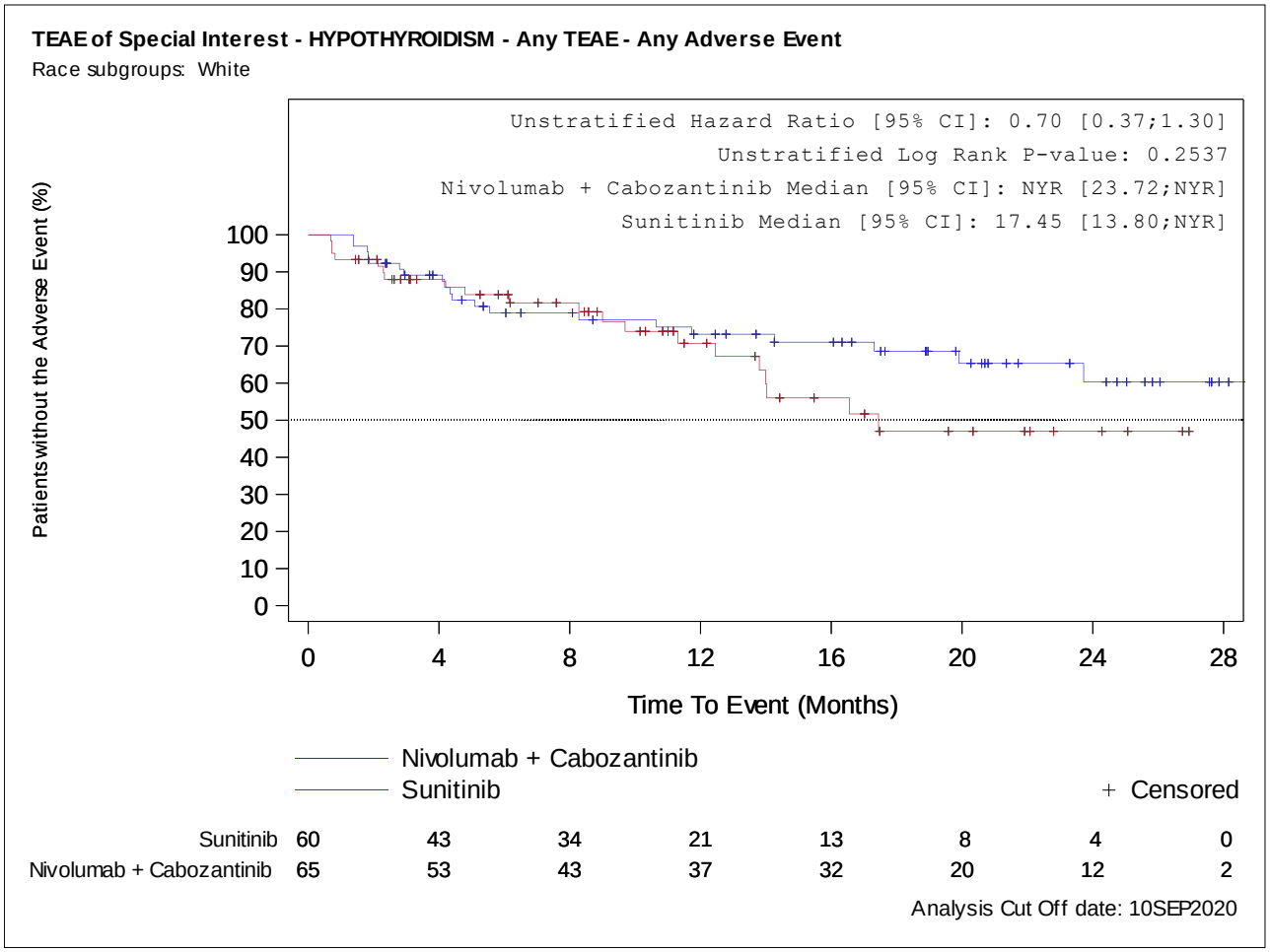

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:34:52

FIGURE 3.101.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



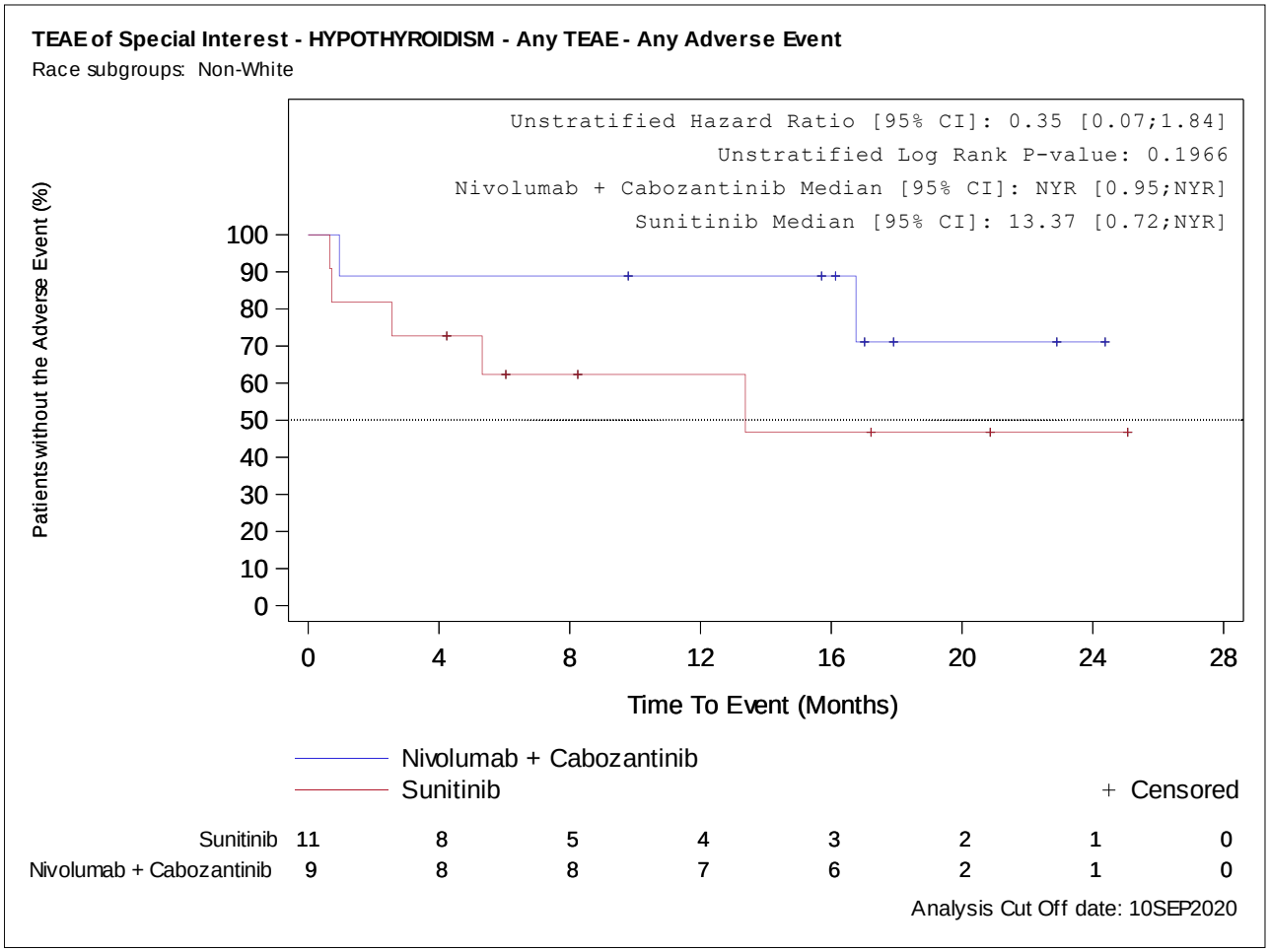

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:34:58

FIGURE 3.101.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



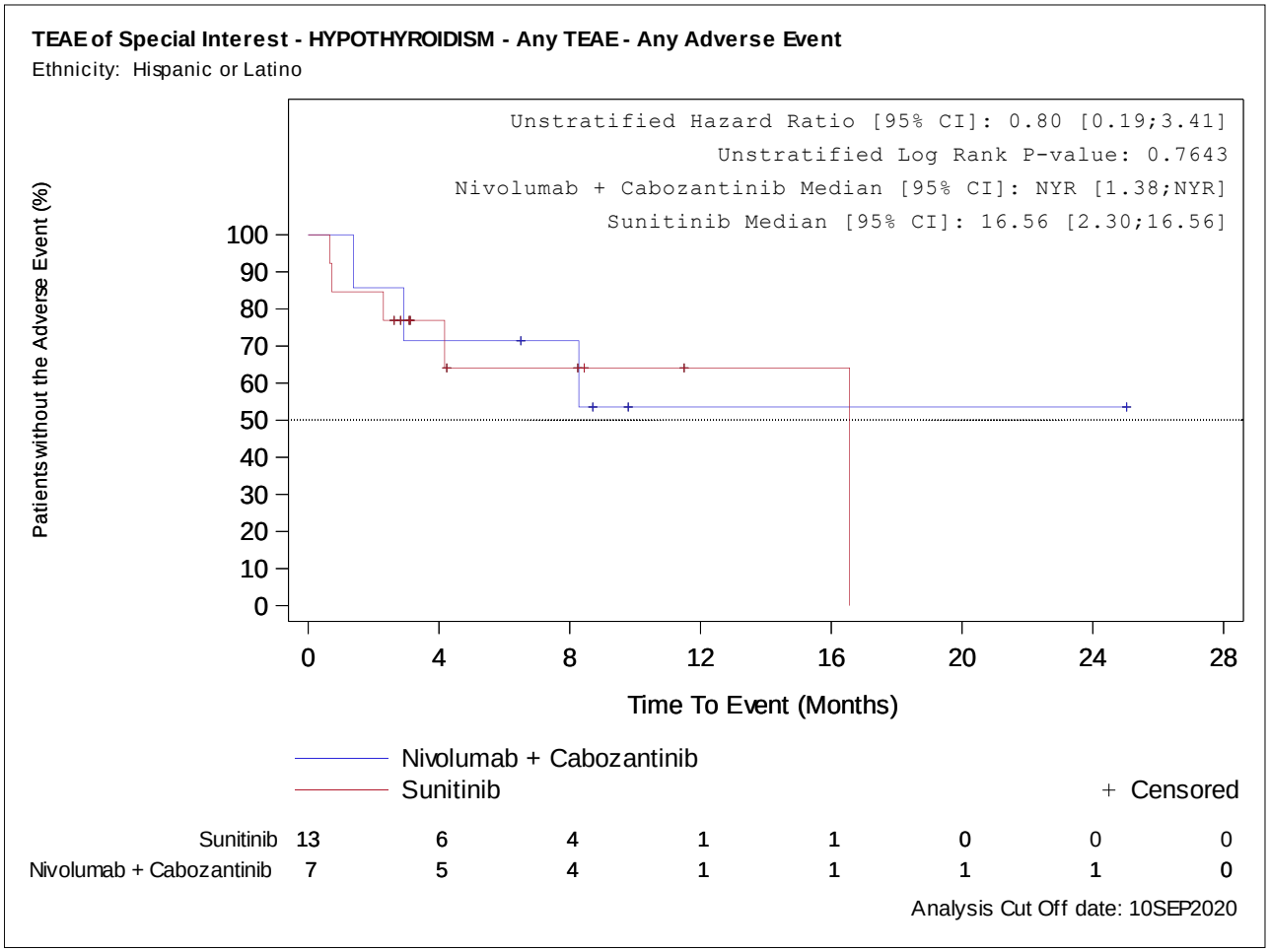

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:35:03

FIGURE 3.101.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



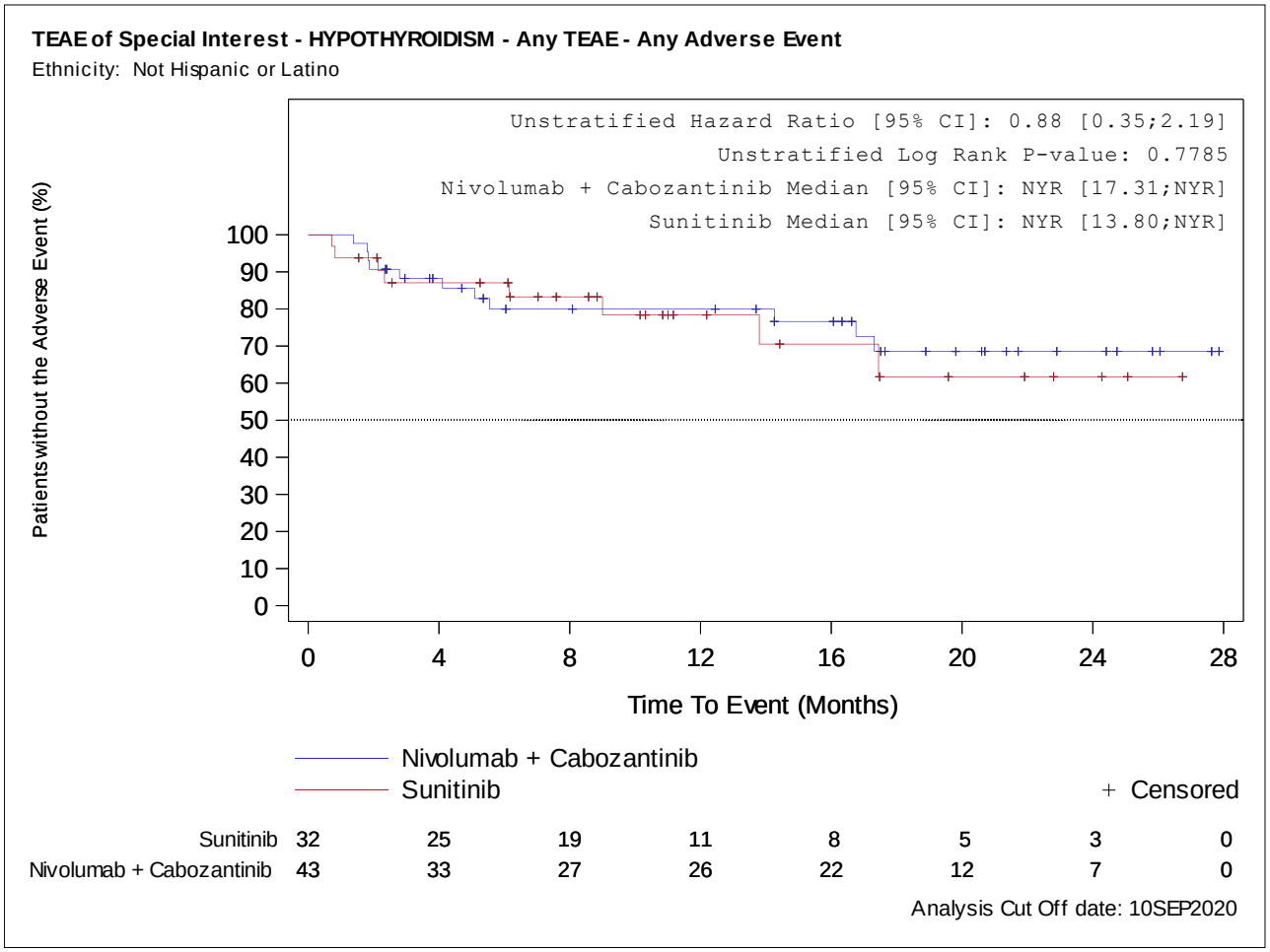

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:35:08

FIGURE 3.101.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



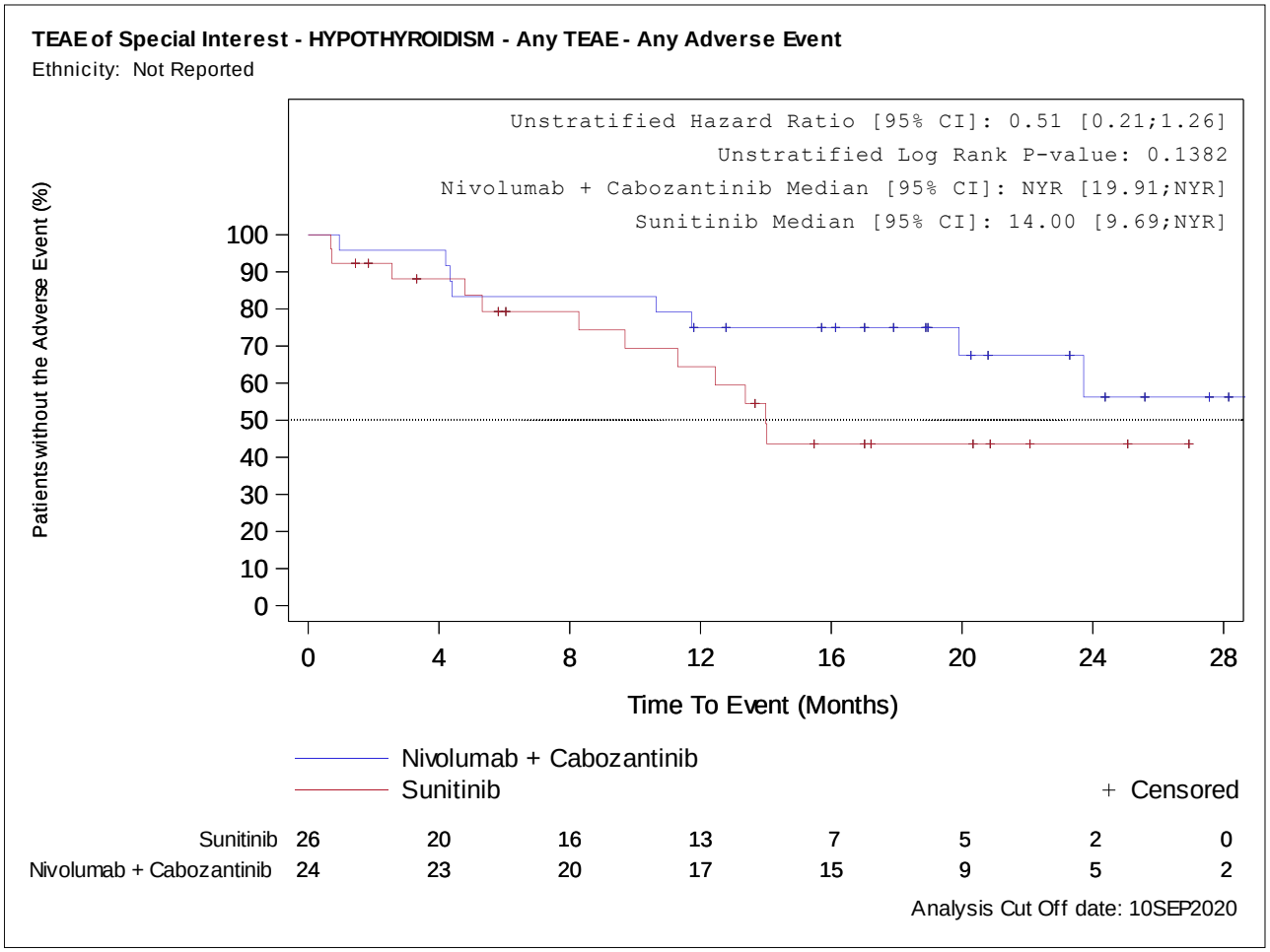

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:35:14

FIGURE 3.101.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



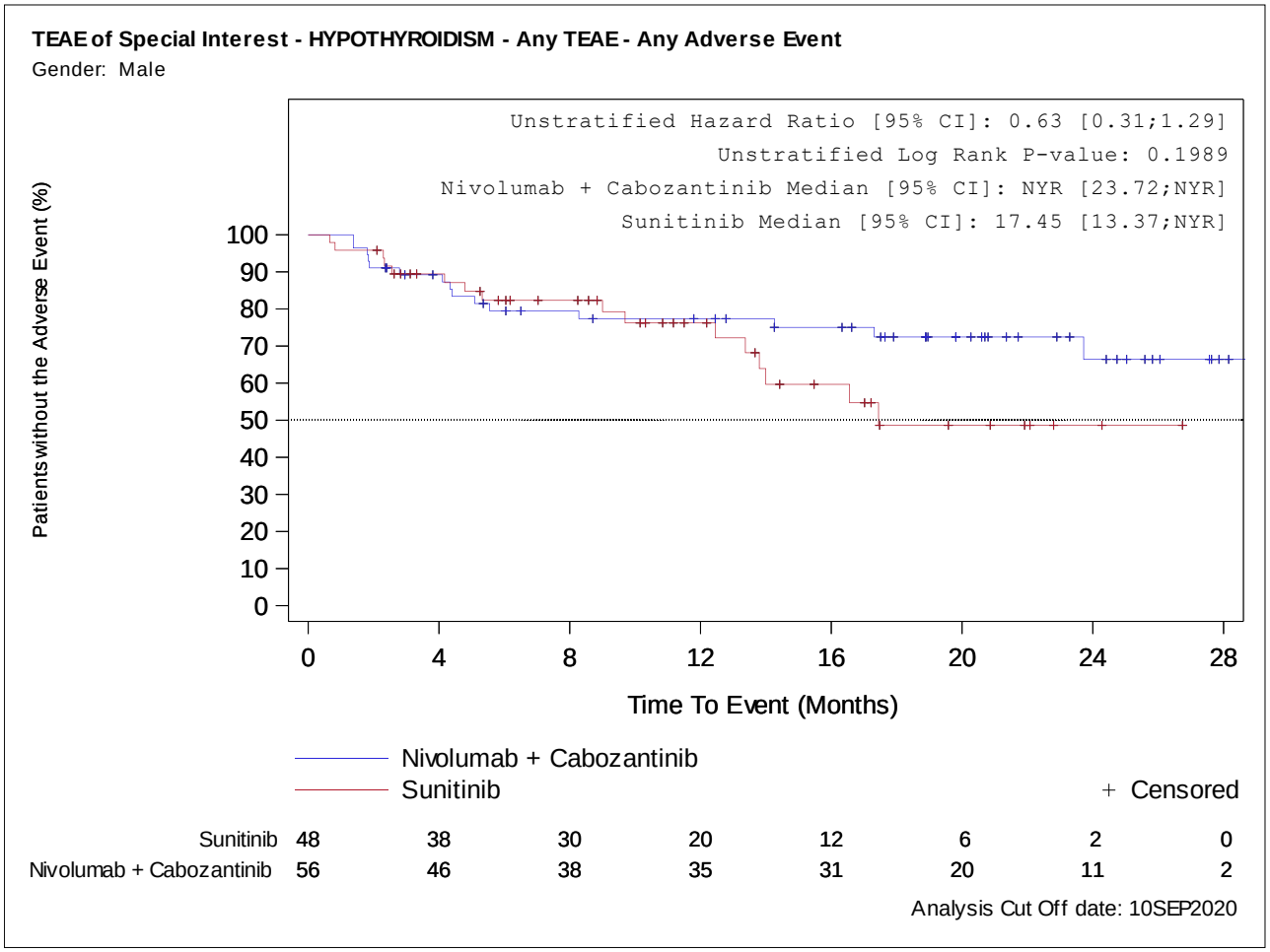

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:35:19

FIGURE 3.101.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



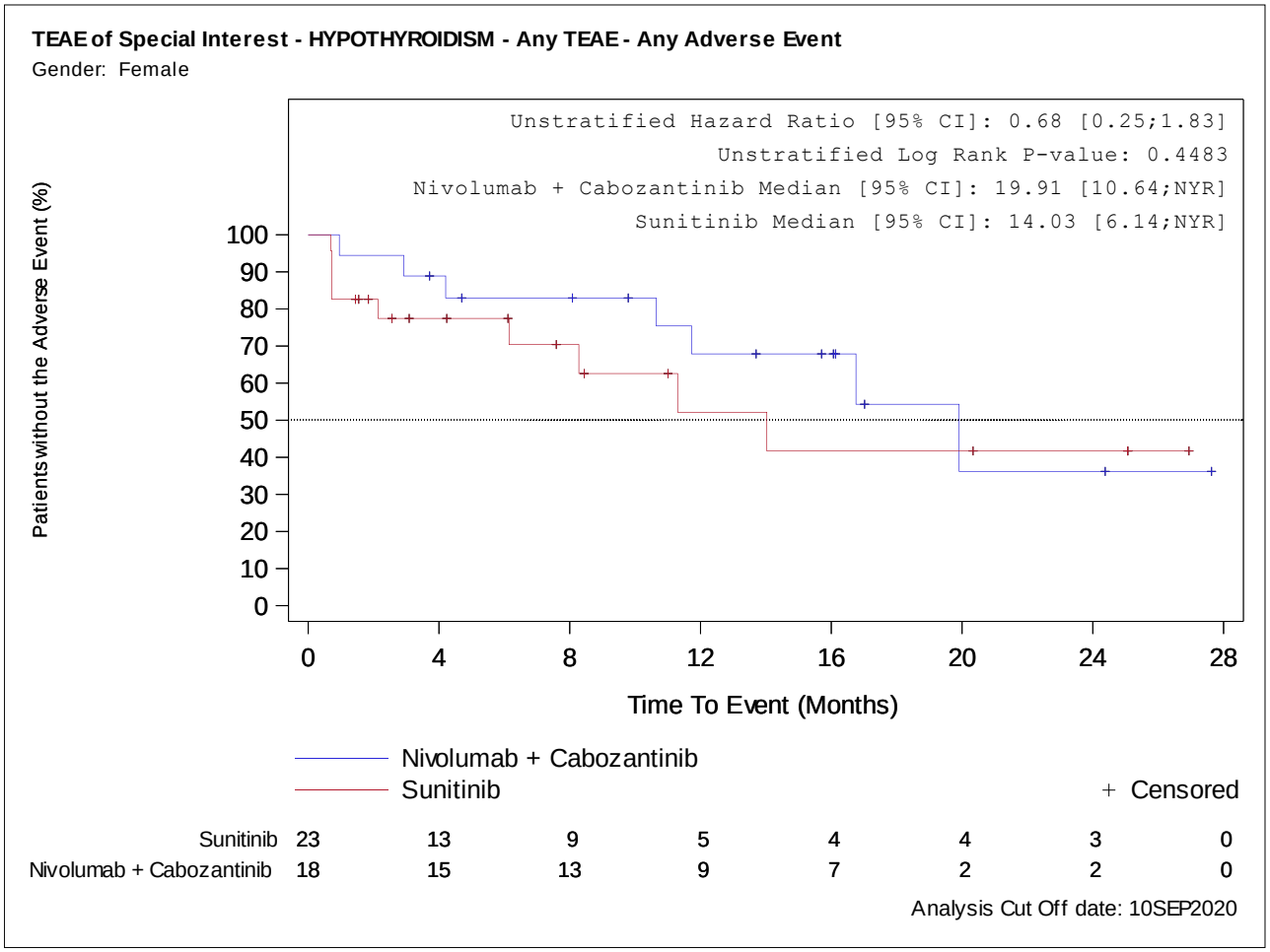

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:35:24

FIGURE 3.101.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:35:30

FIGURE 3.101.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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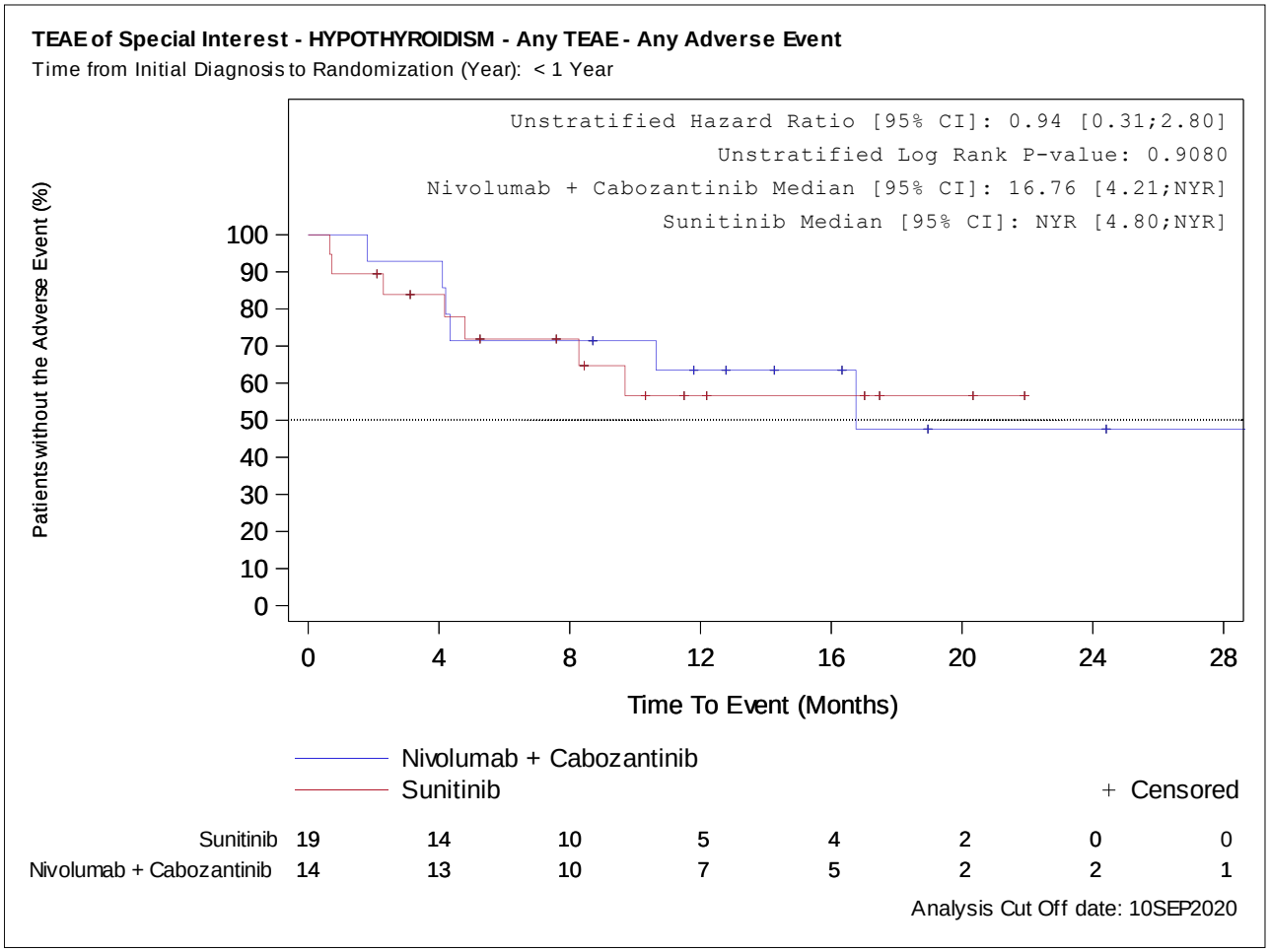
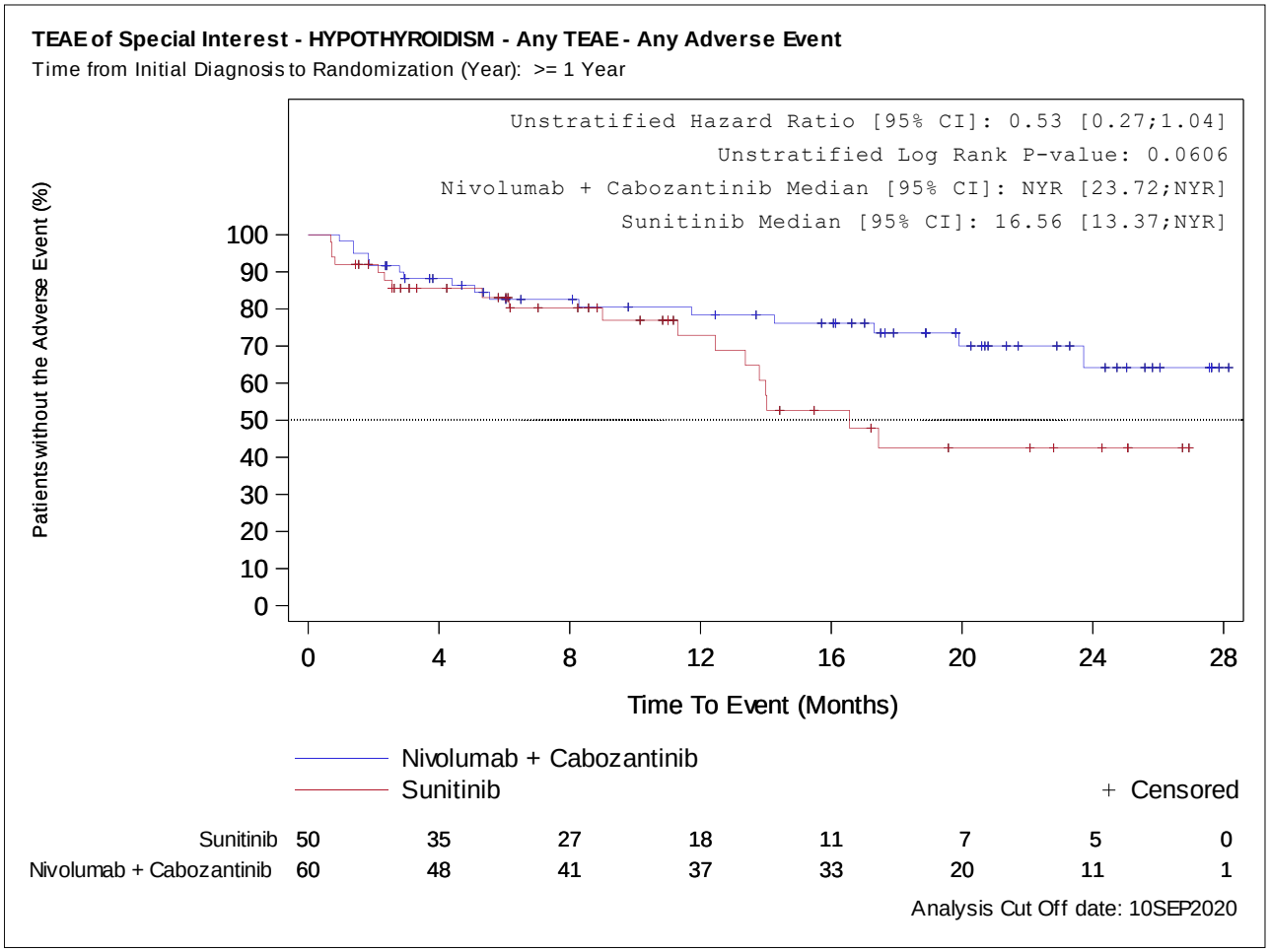
FIGURE 3.101.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:35:51

FIGURE 3.101.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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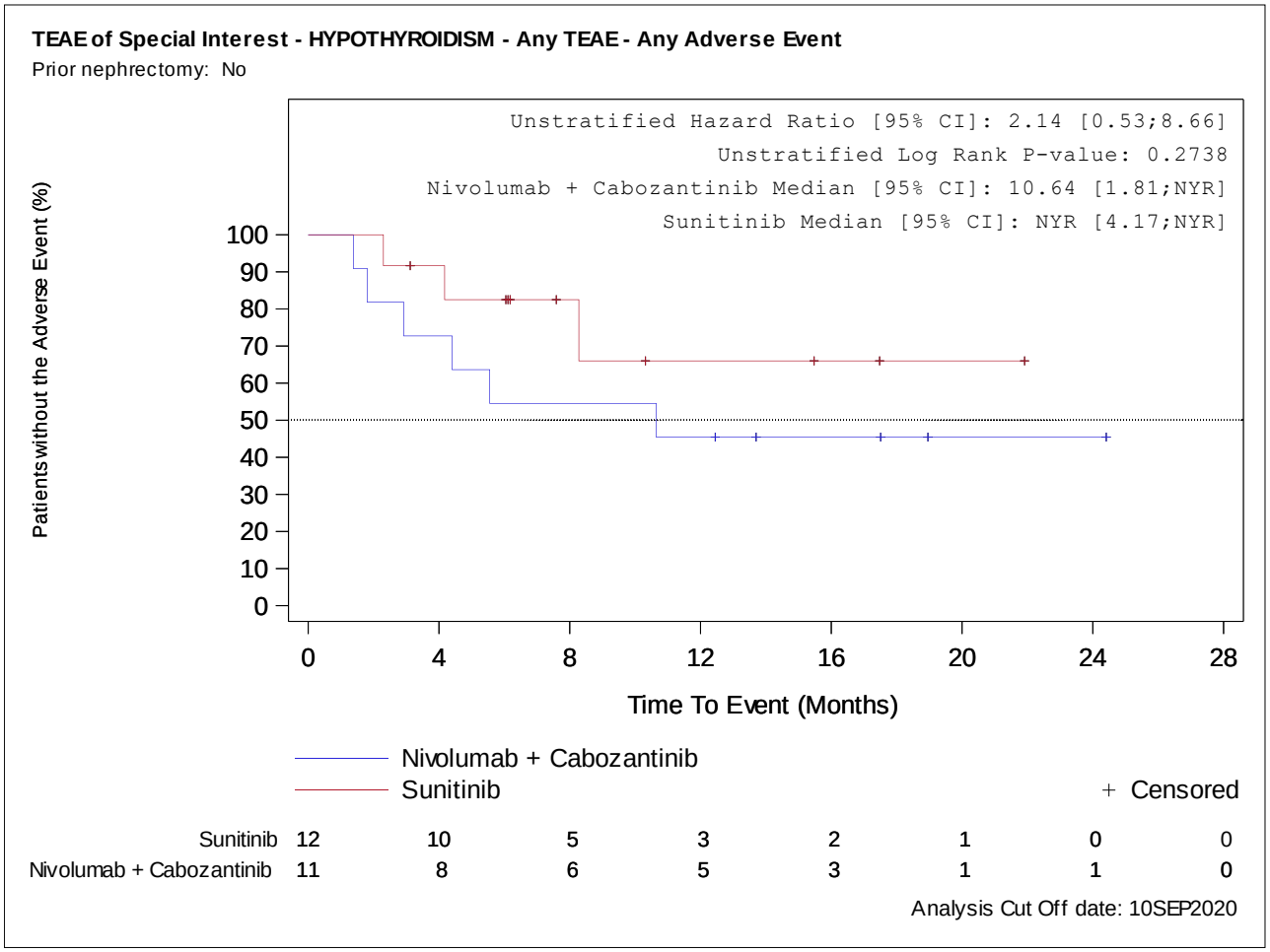
FIGURE 3.101.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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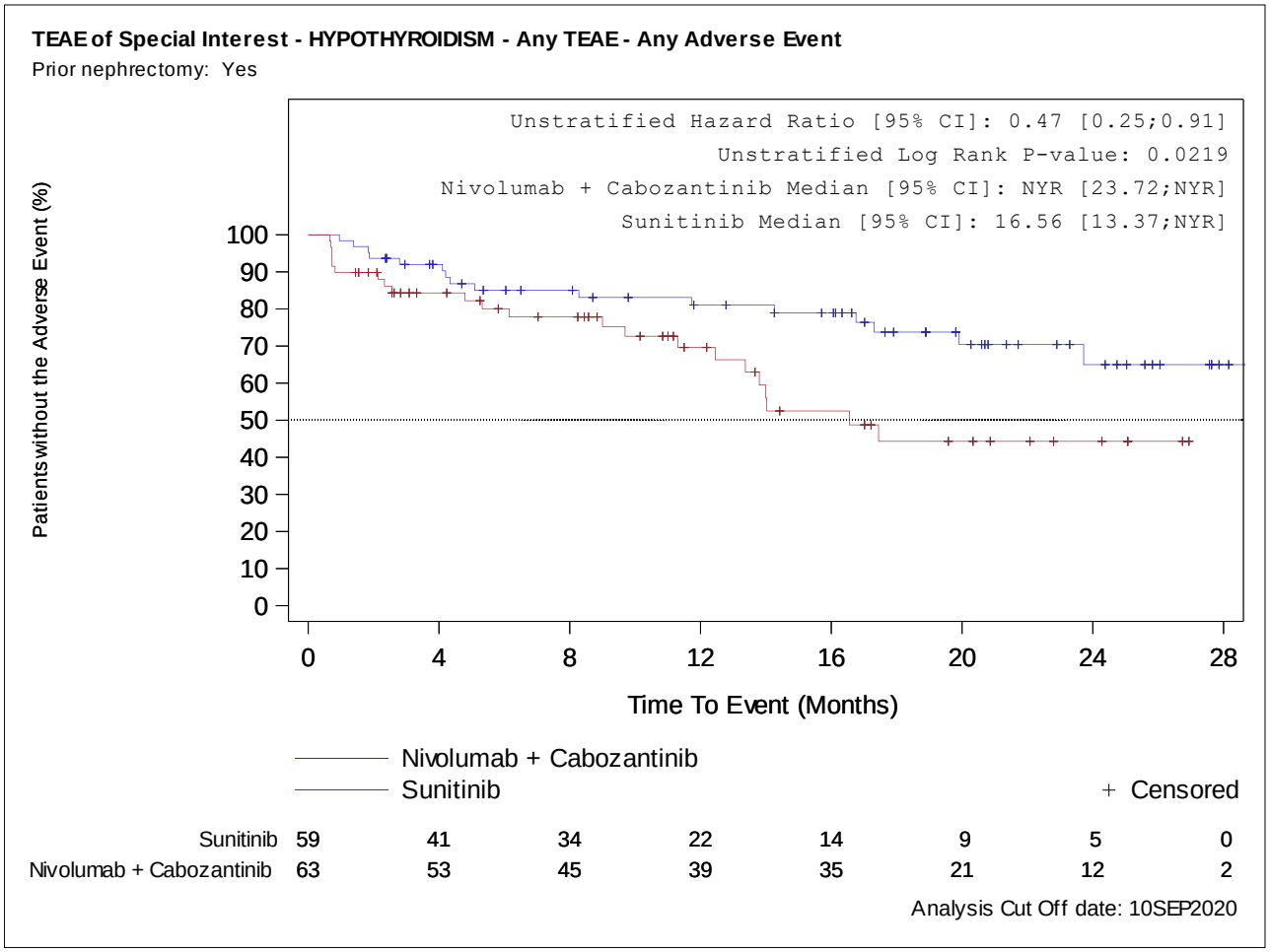
FIGURE 3.101.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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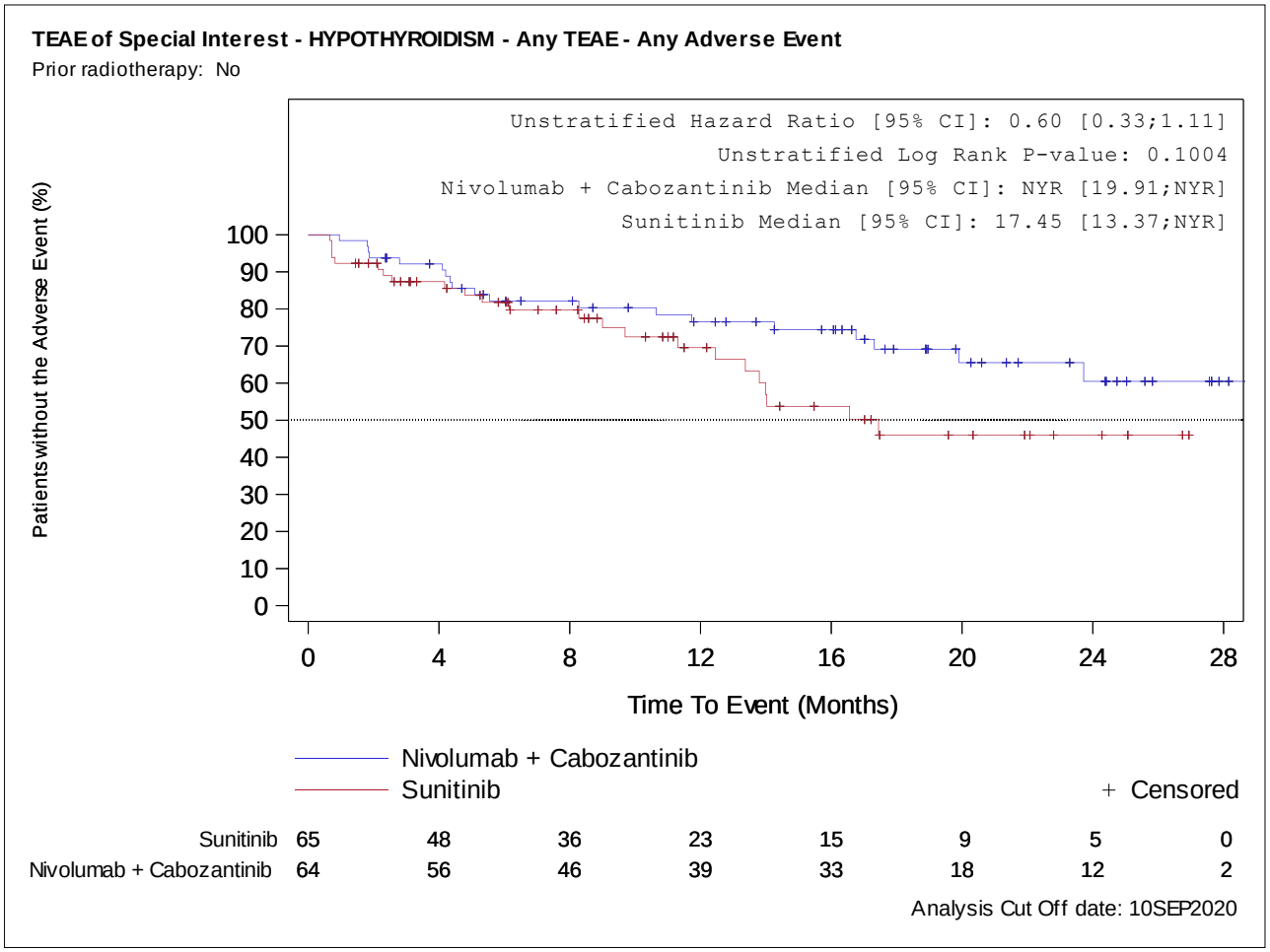
FIGURE 3.101.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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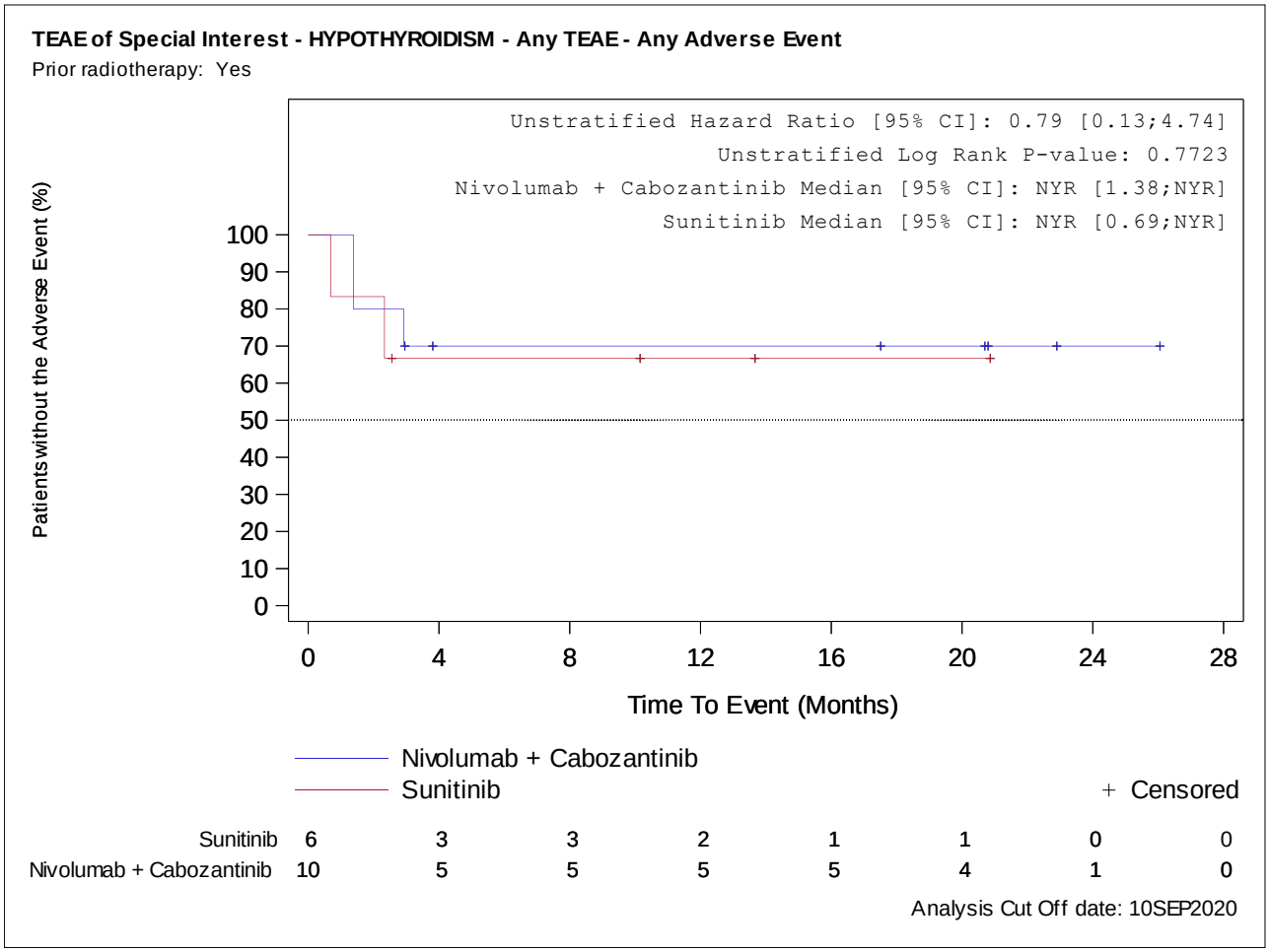
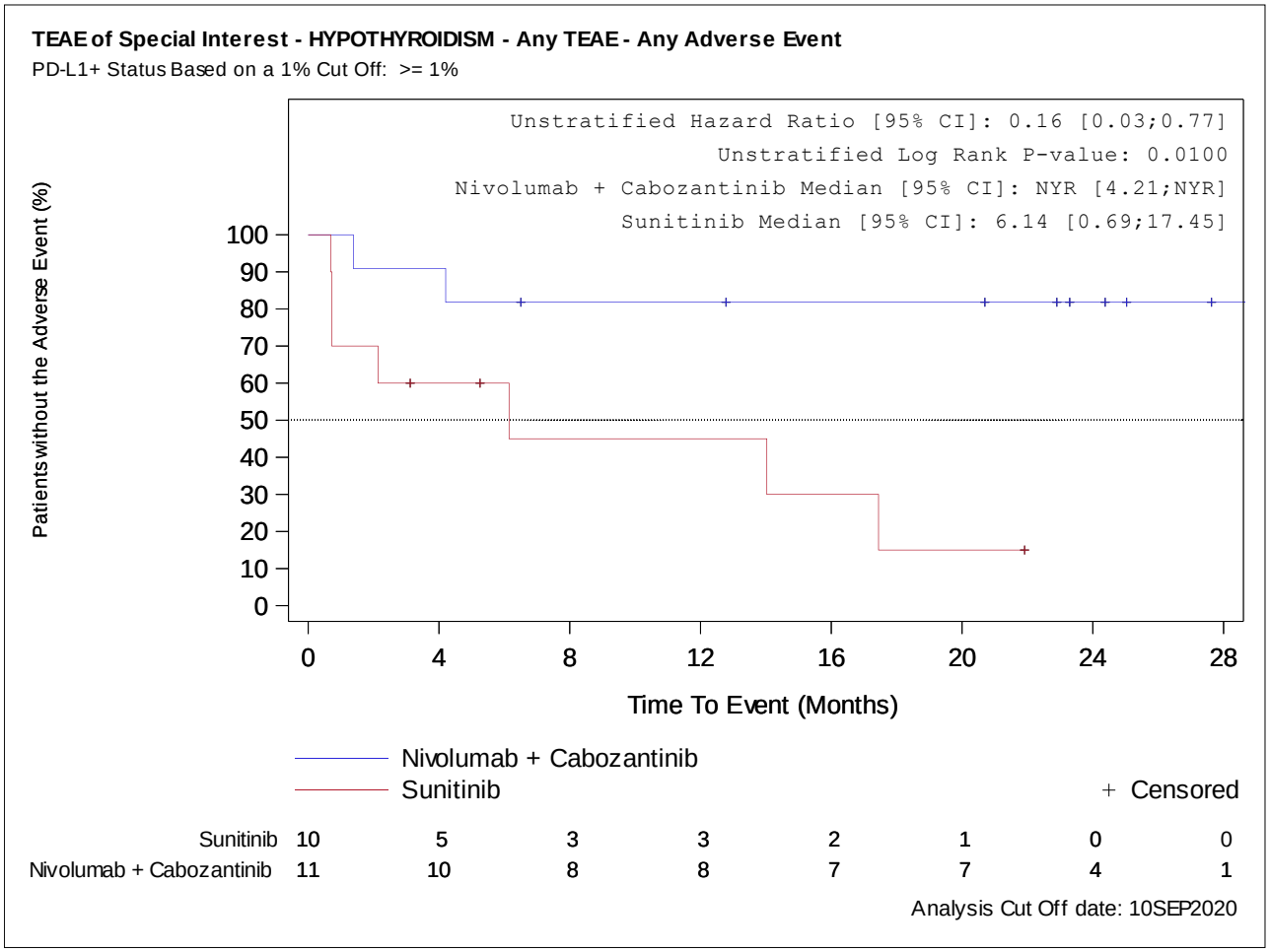
FIGURE 3.101.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



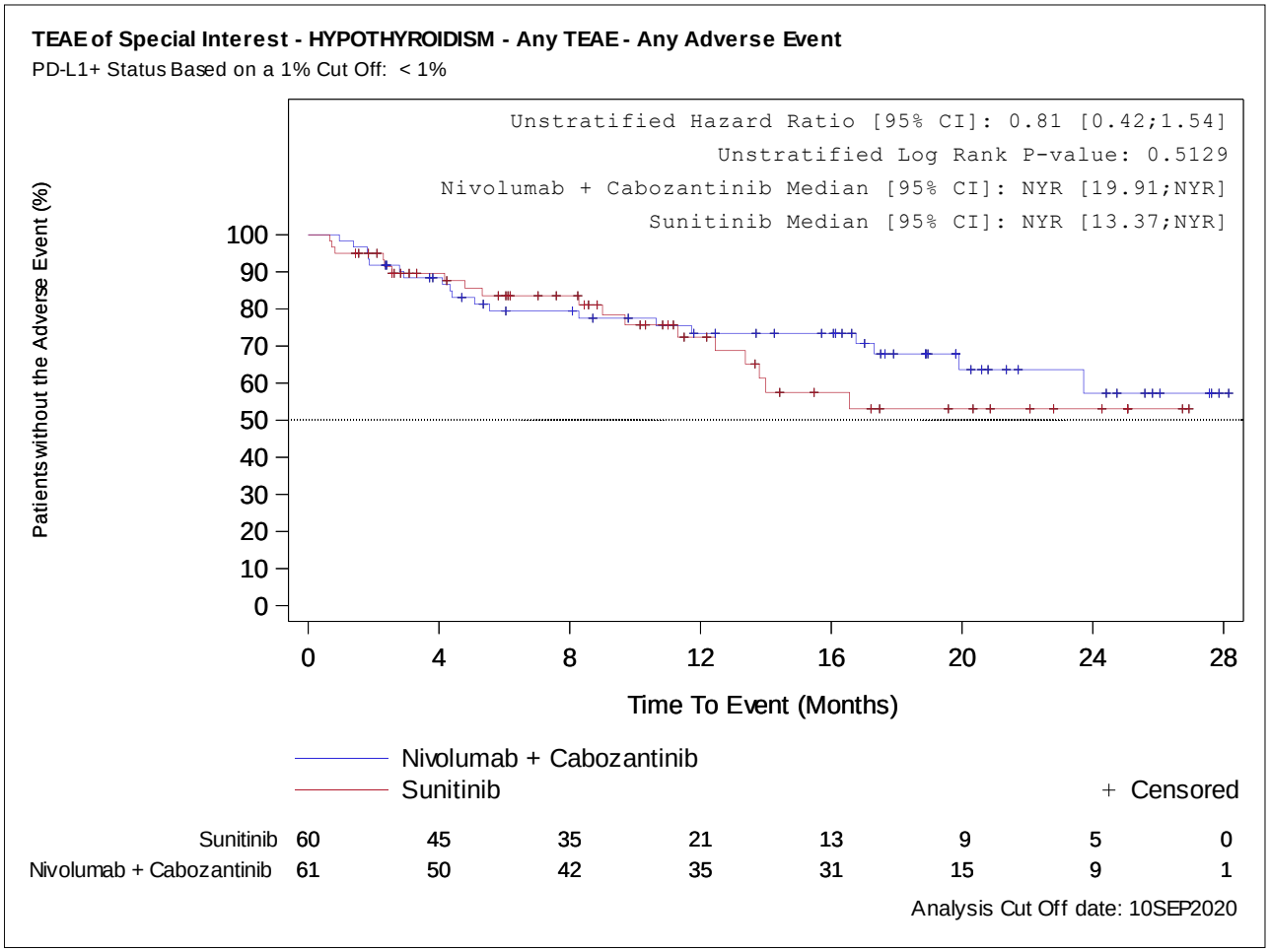

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:36:59

FIGURE 3.101.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



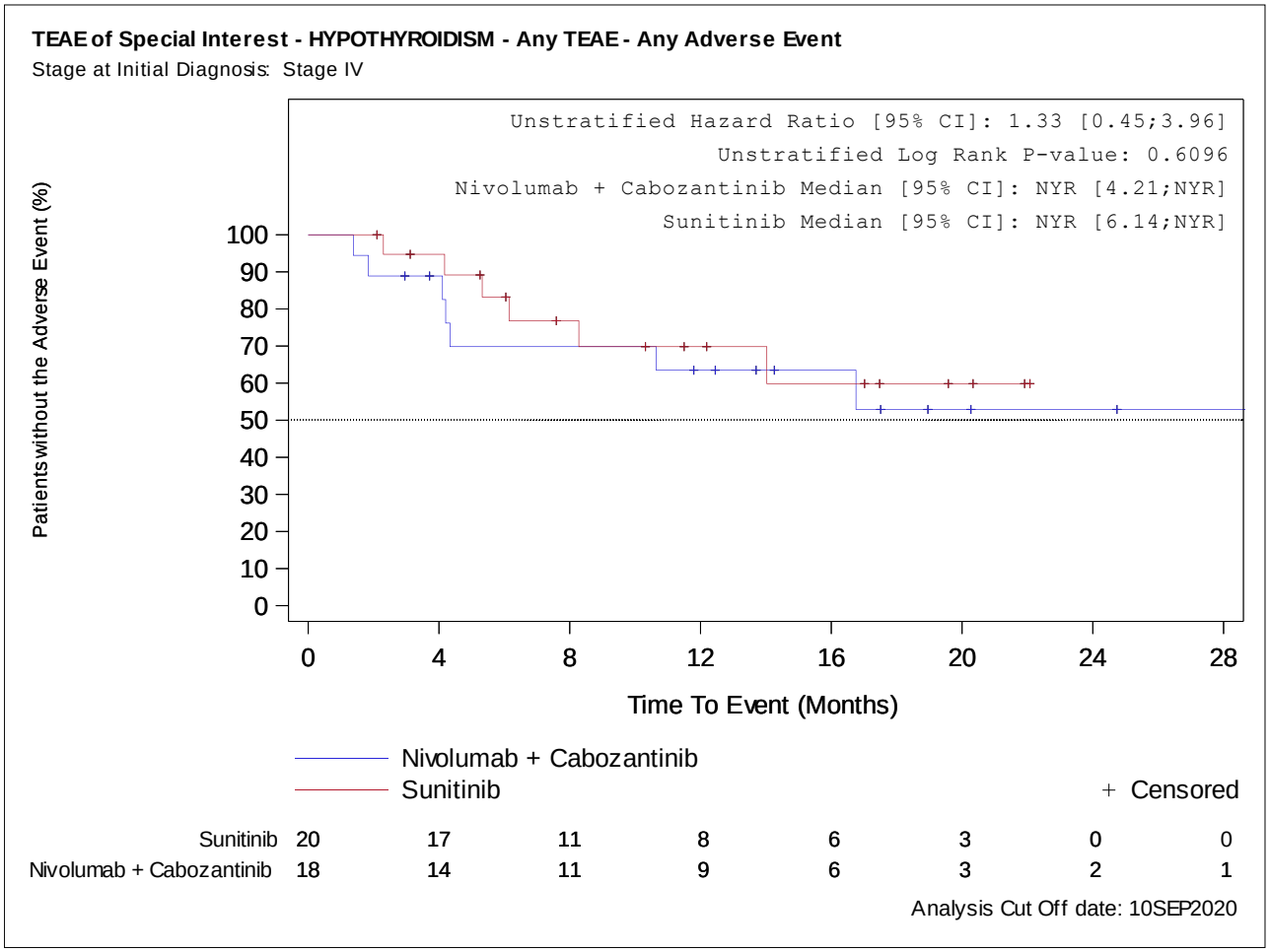

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:37:04

FIGURE 3.101.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



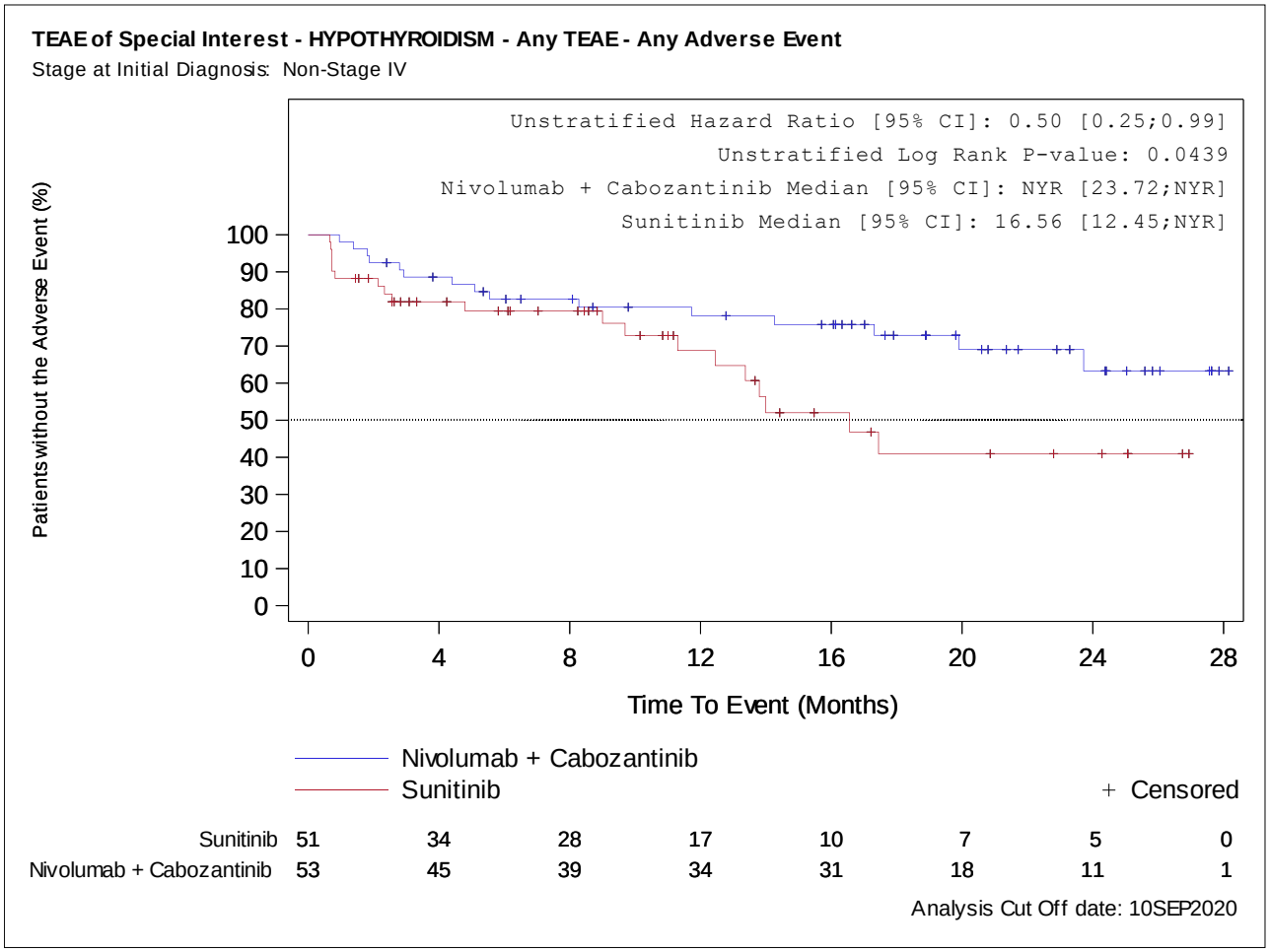

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:37:09

FIGURE 3.101.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



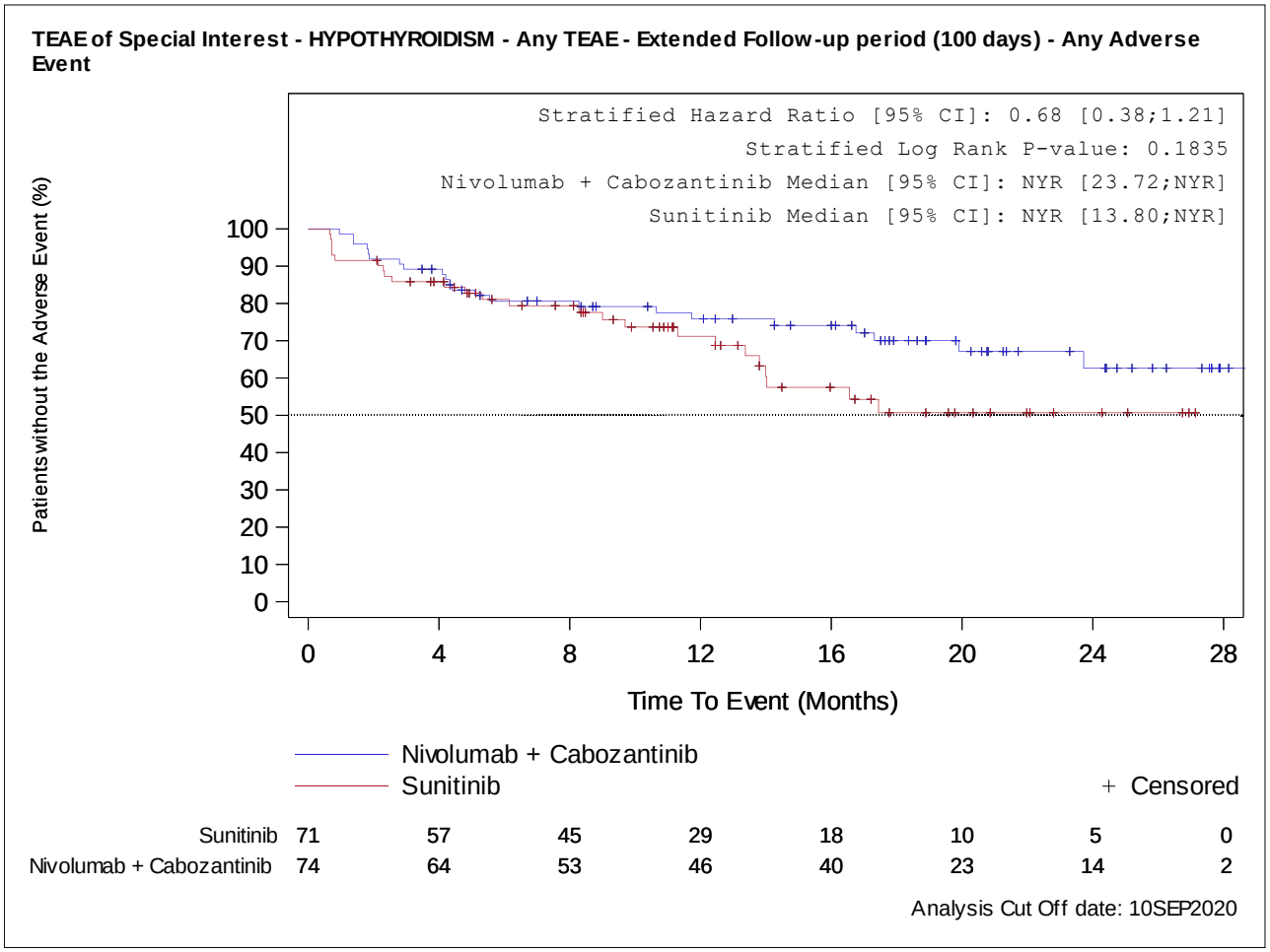

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:37:35

FIGURE 3.101.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



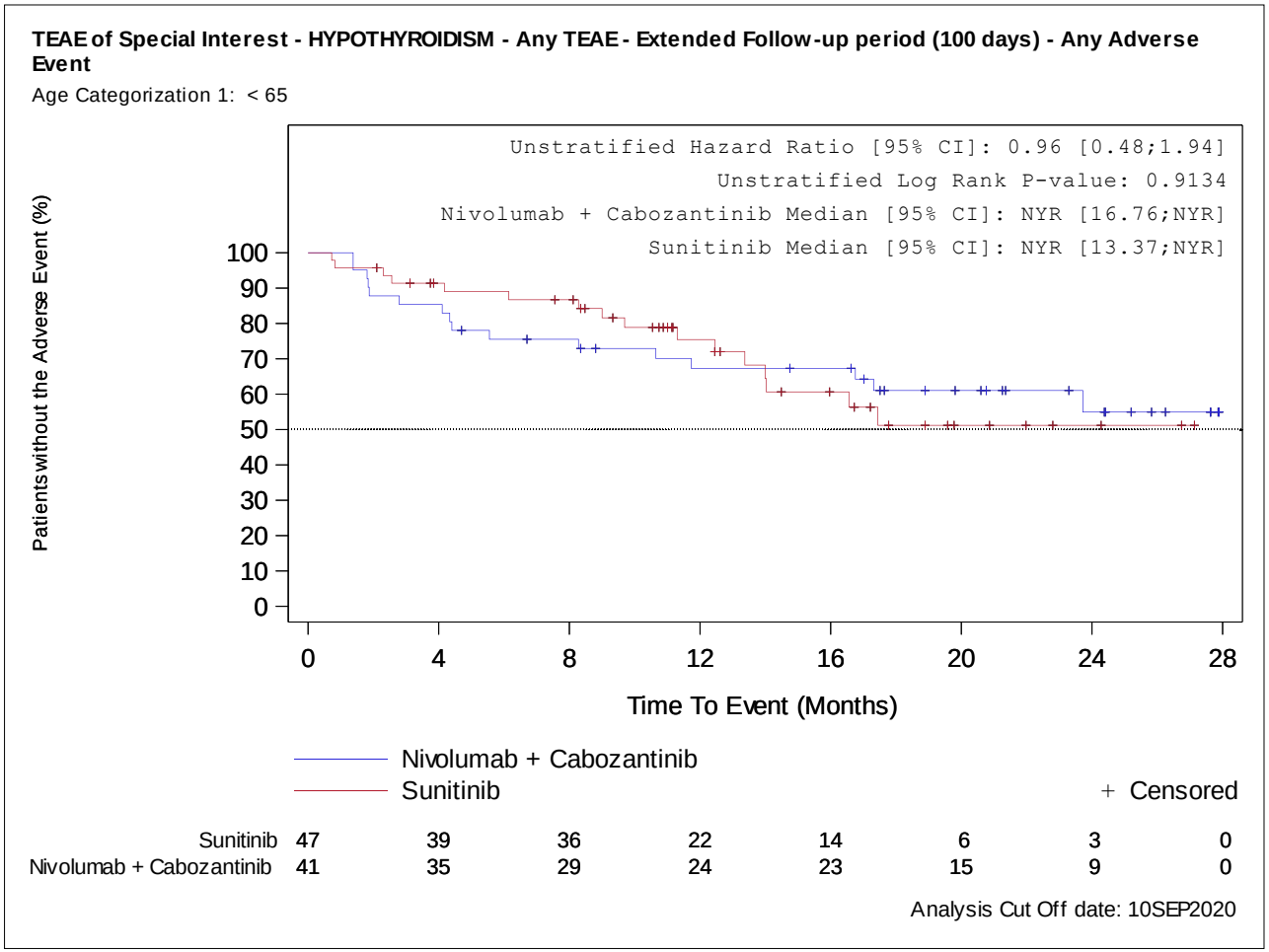

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:37:40

FIGURE 3.102.1: TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



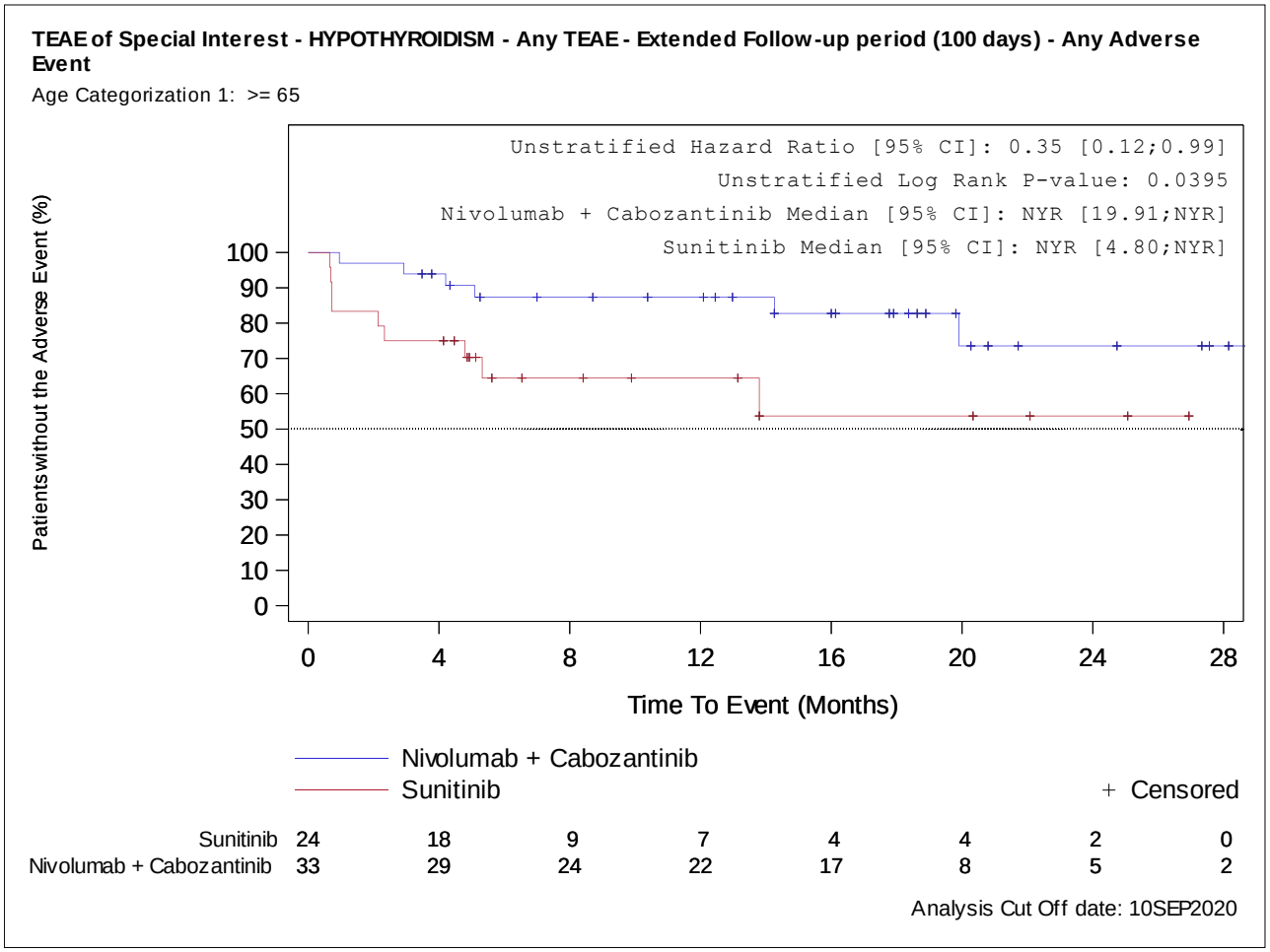

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:40:36

FIGURE 3.102.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



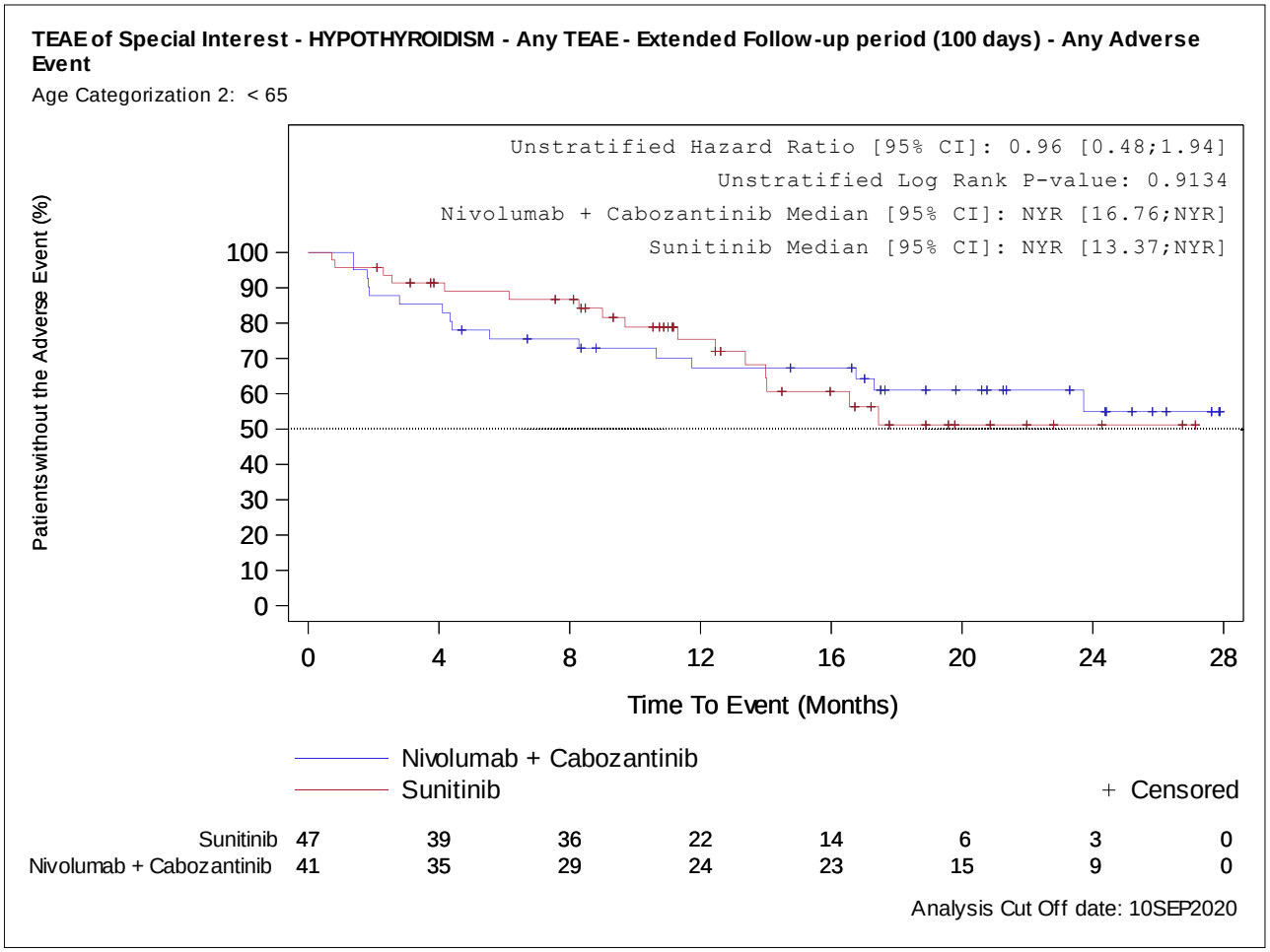

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:40:40

FIGURE 3.102.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



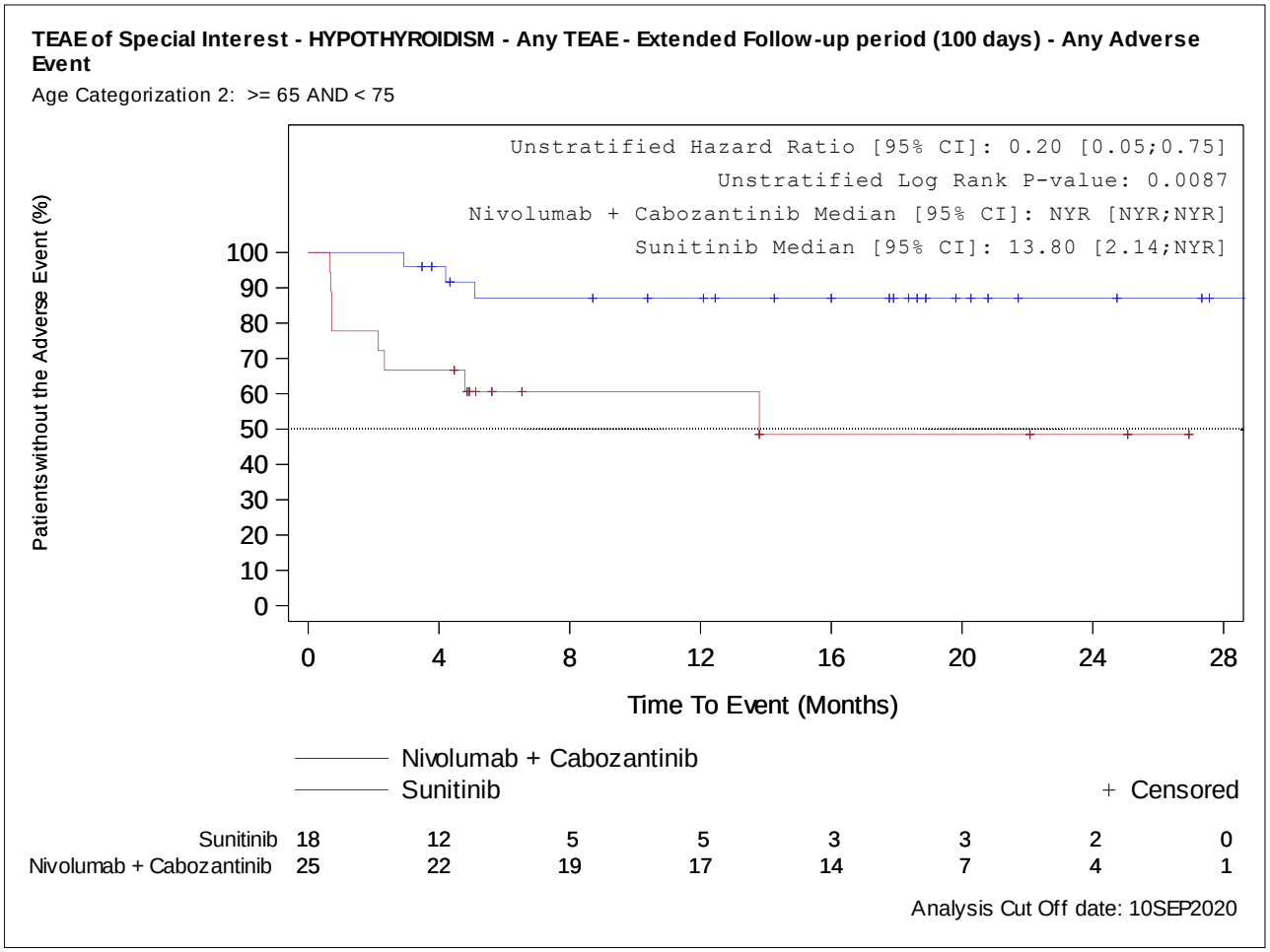

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:40:45

FIGURE 3.102.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



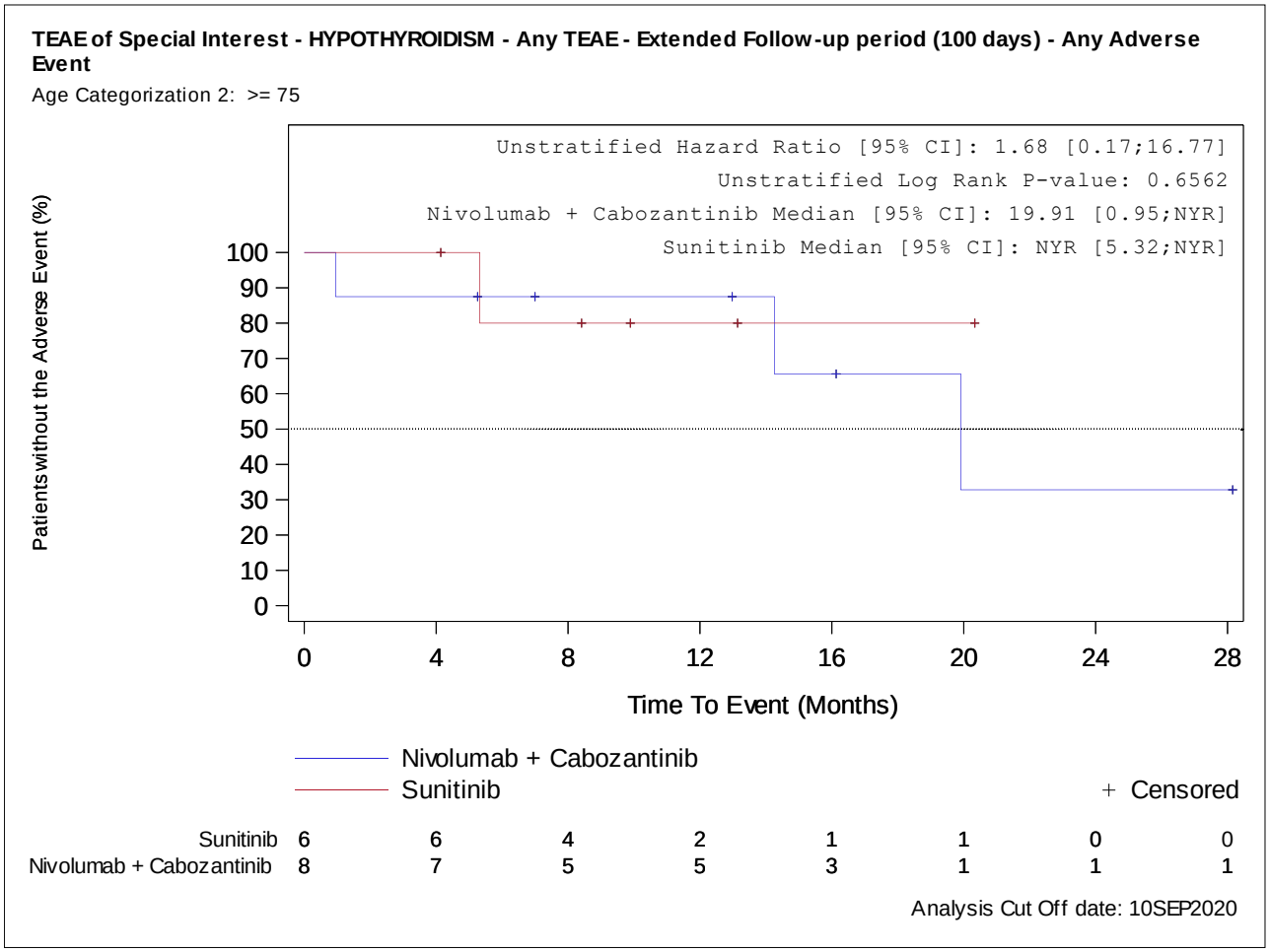

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:40:50

FIGURE 3.102.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



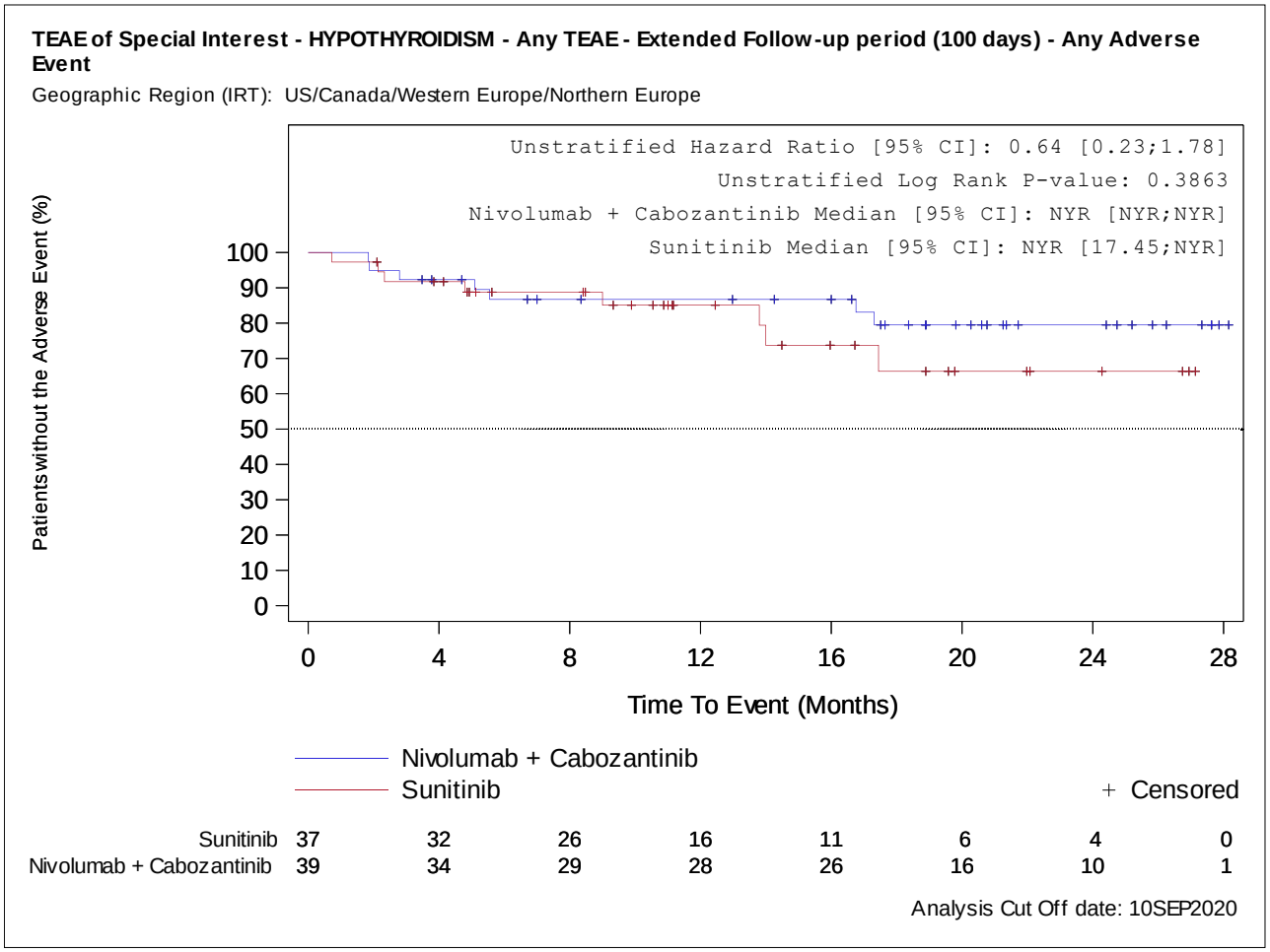

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:40:55

FIGURE 3.102.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



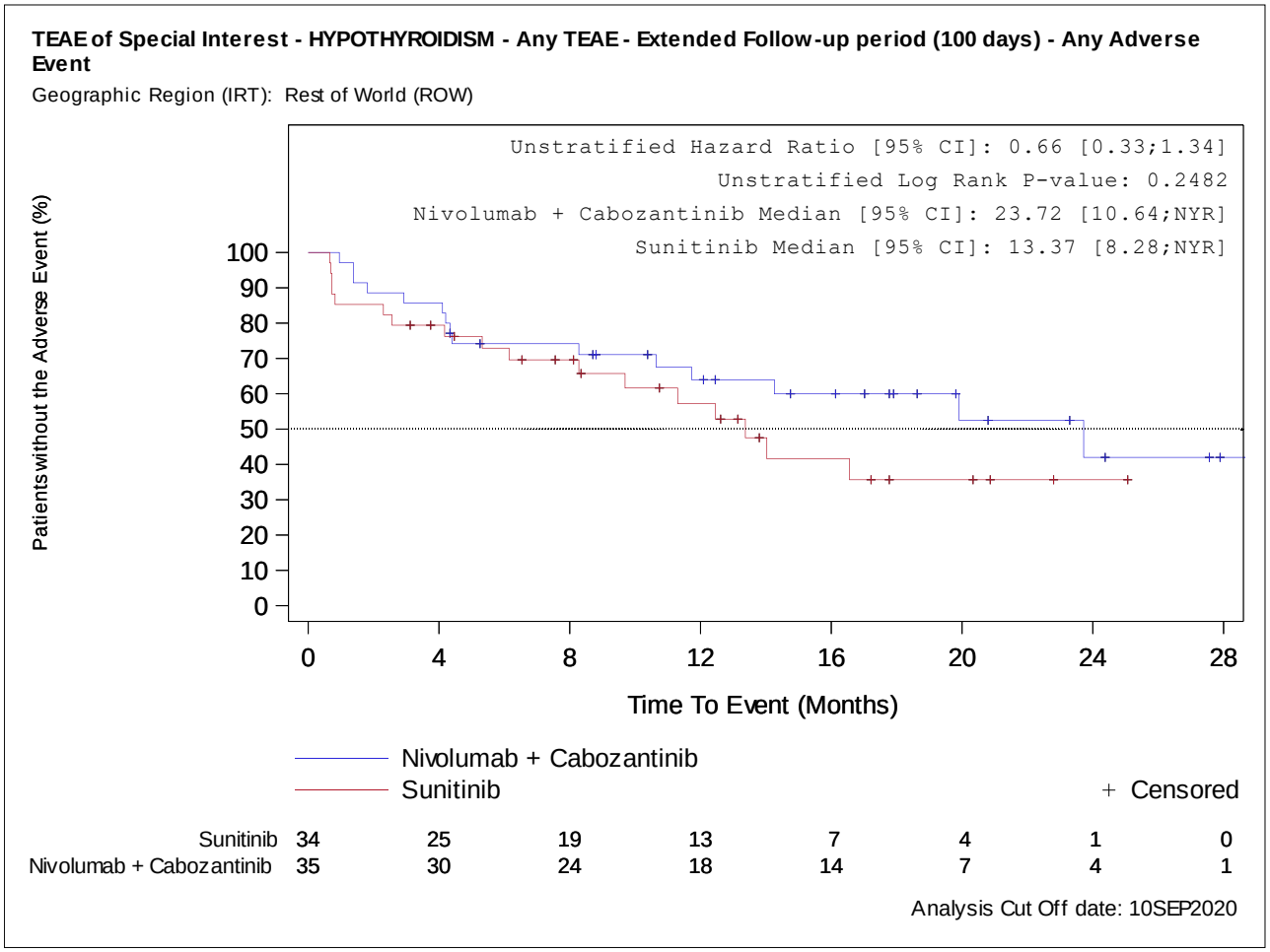

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:00

FIGURE 3.102.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



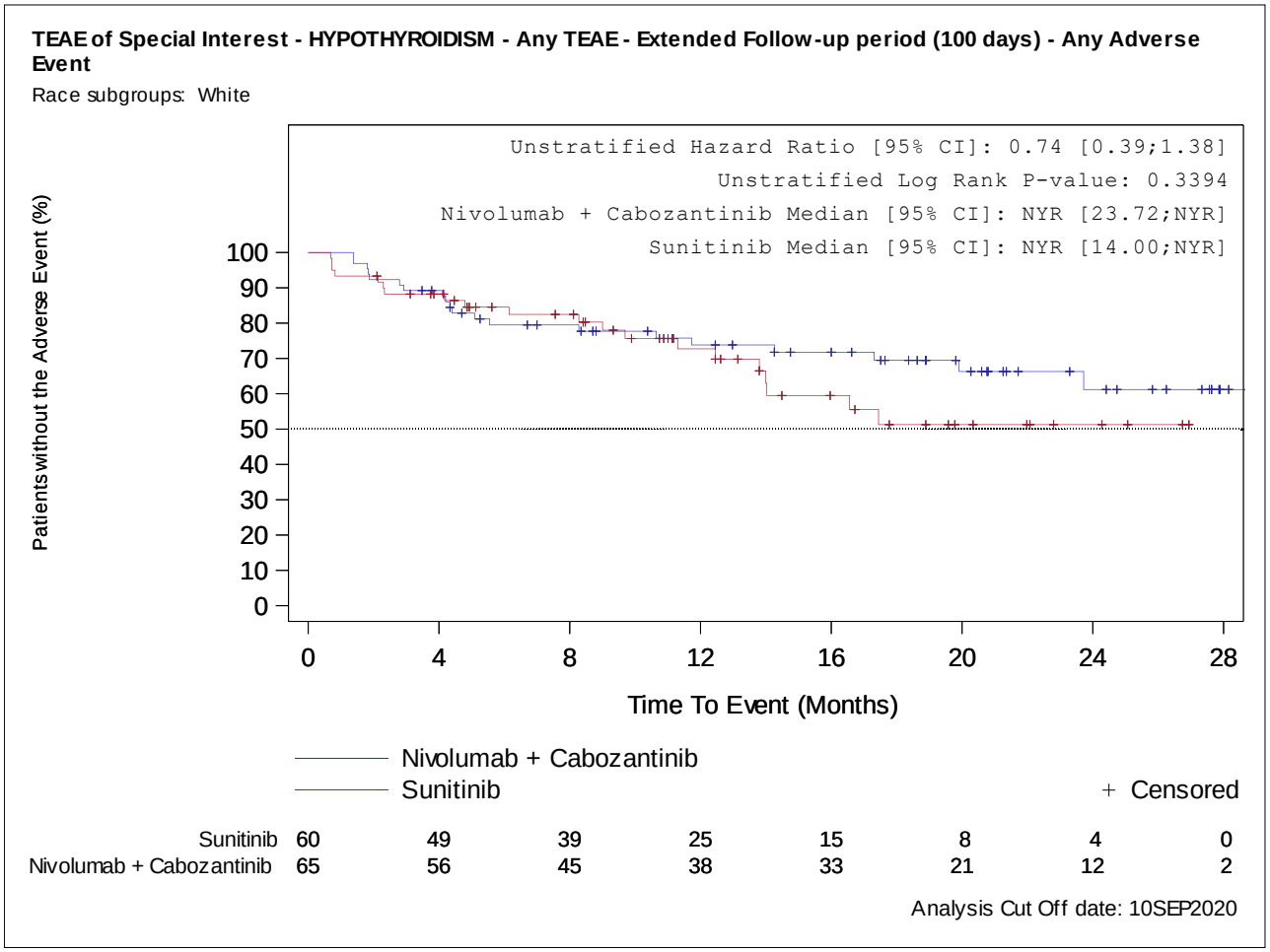

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:05

FIGURE 3.102.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



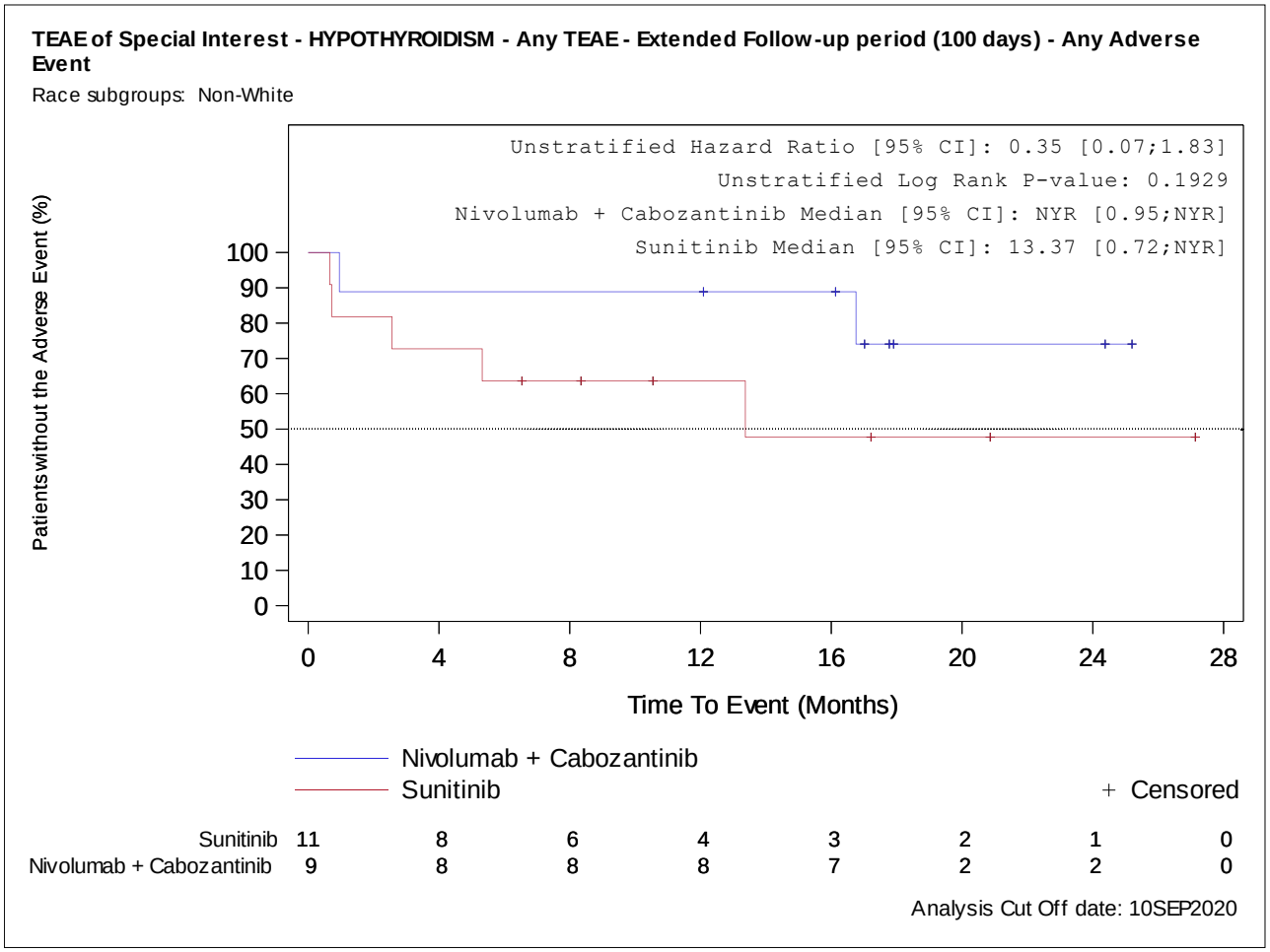

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:11

FIGURE 3.102.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



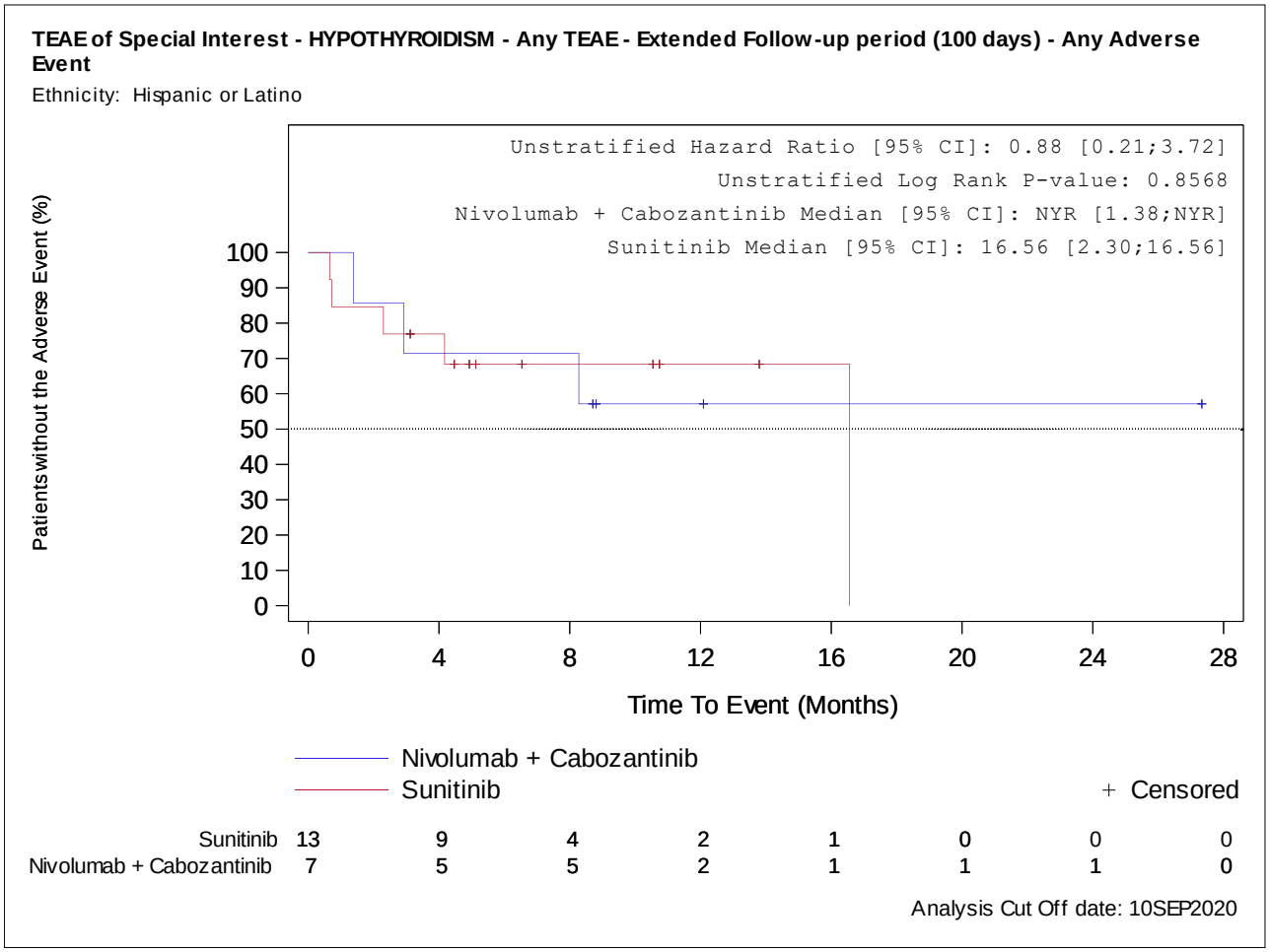

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:16

FIGURE 3.102.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



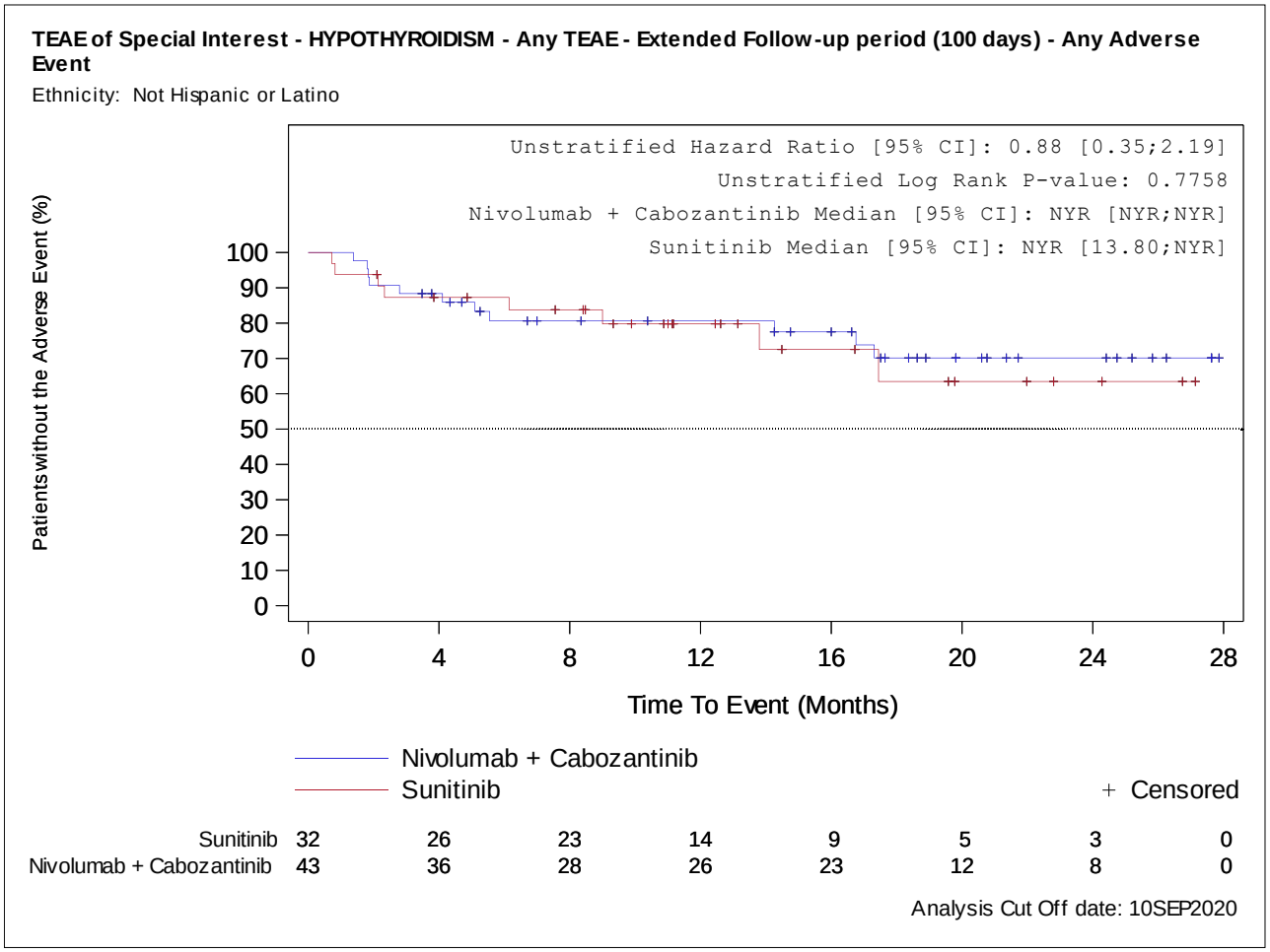

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:21

FIGURE 3.102.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



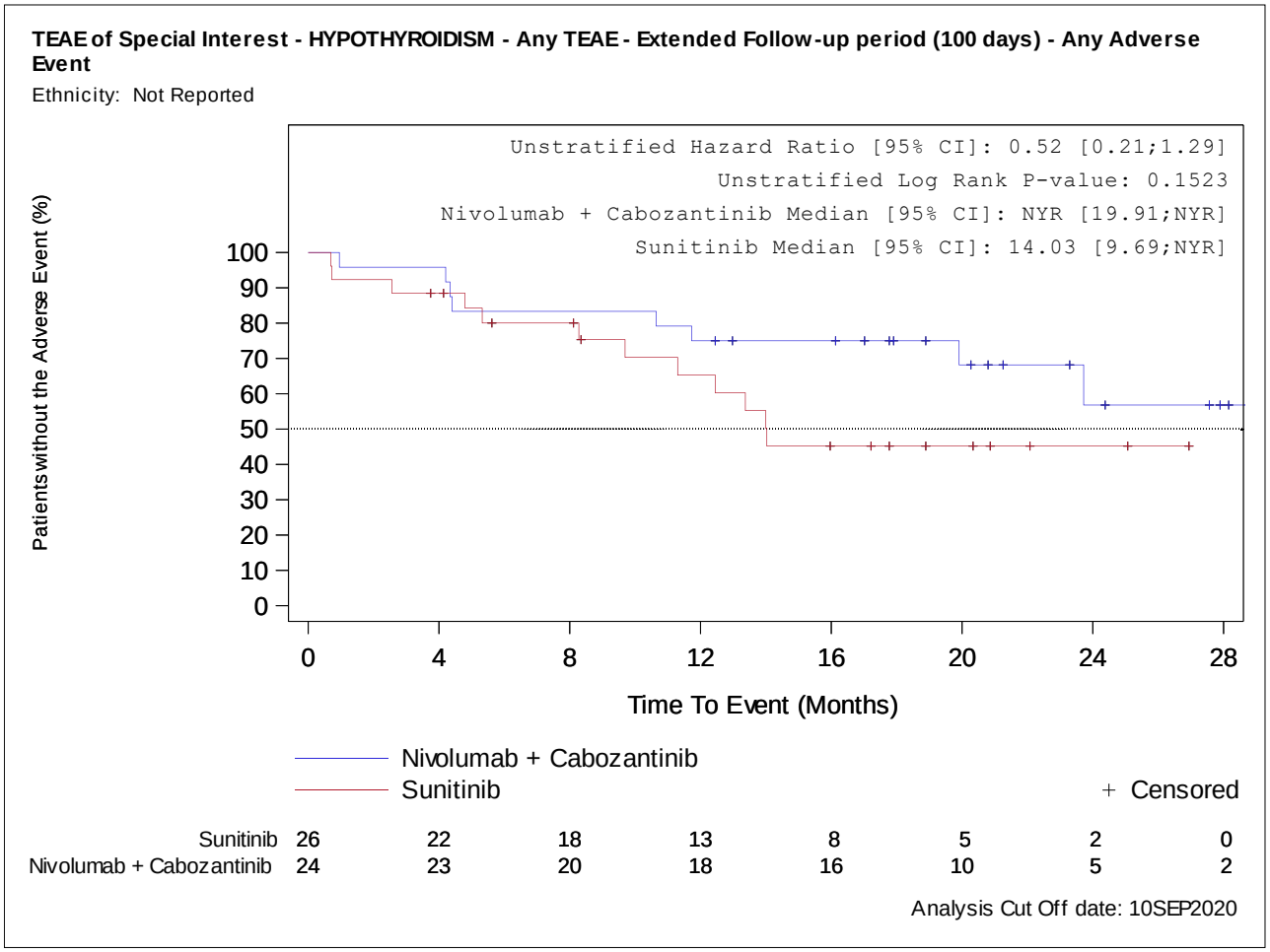

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:27

FIGURE 3.102.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



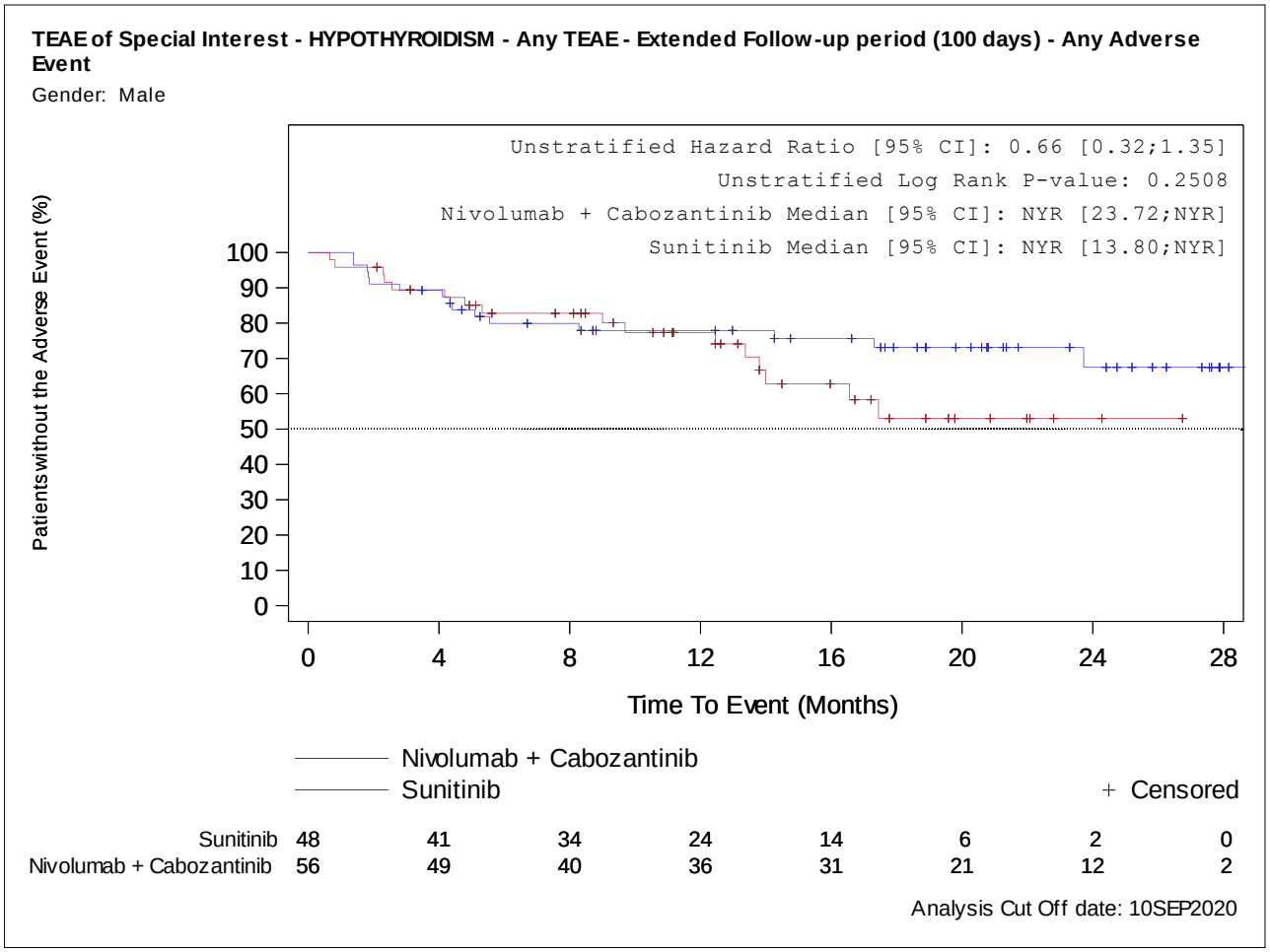

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:32

FIGURE 3.102.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



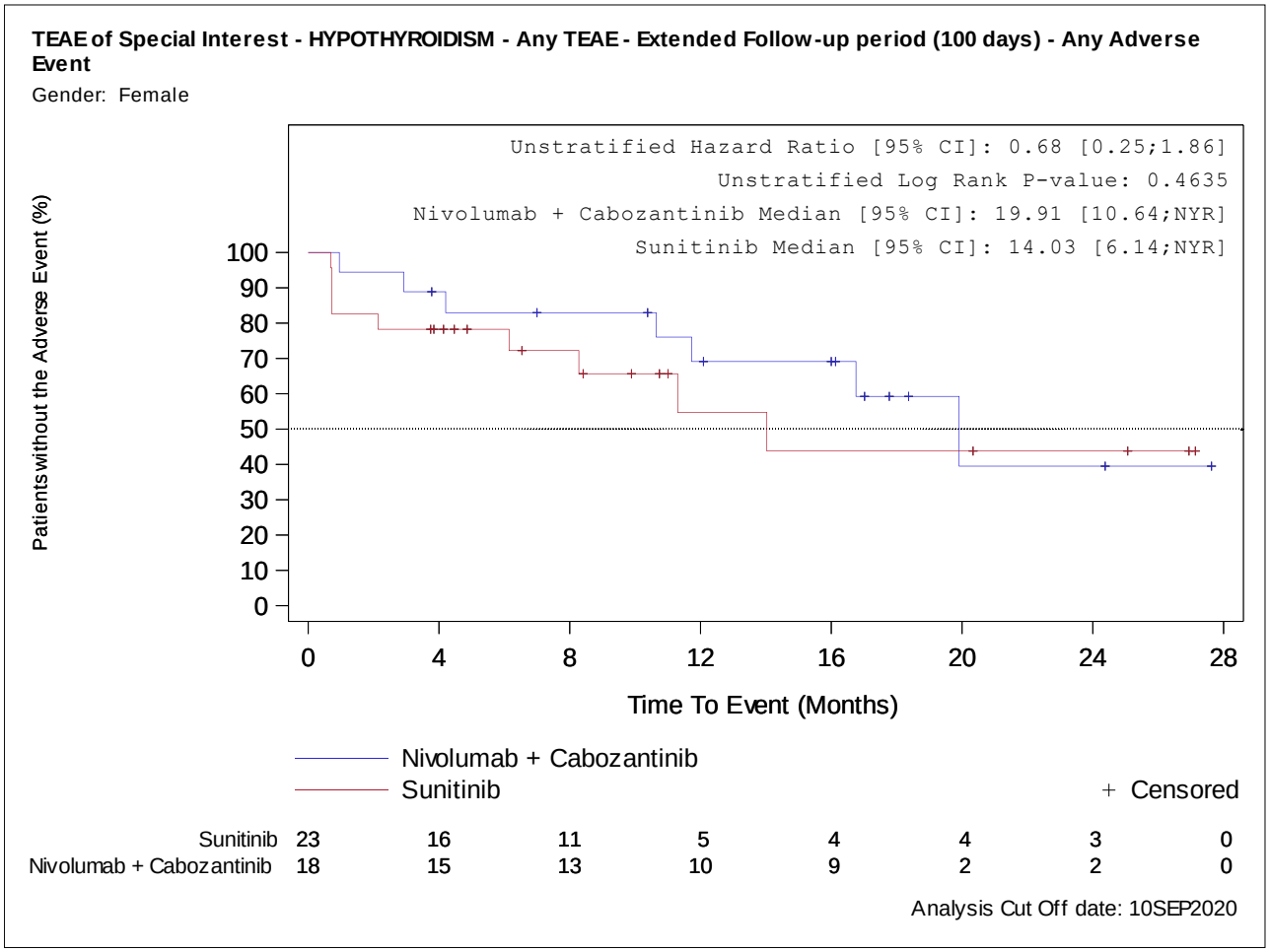

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:37

FIGURE 3.102.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



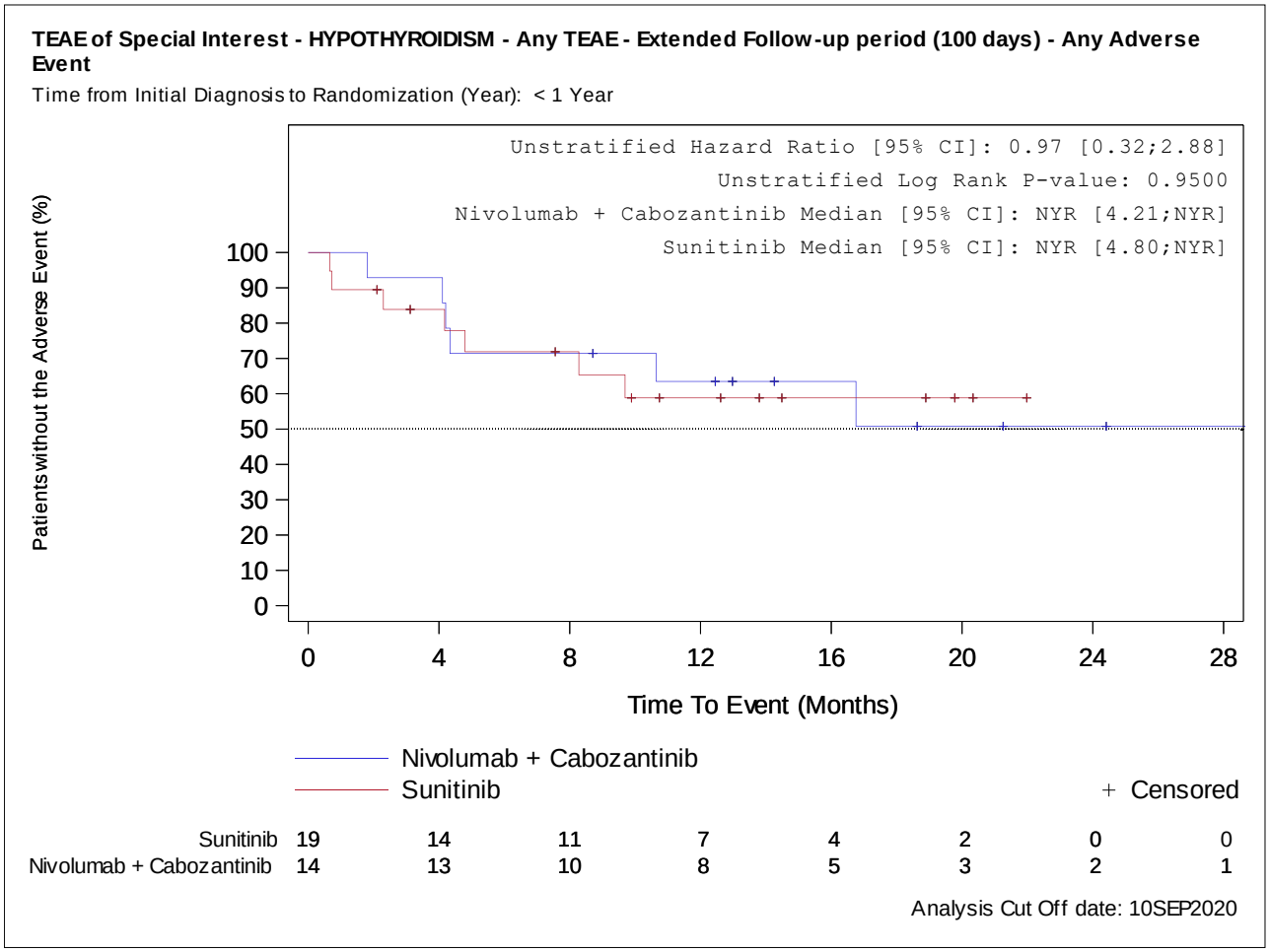

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:42

FIGURE 3.102.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



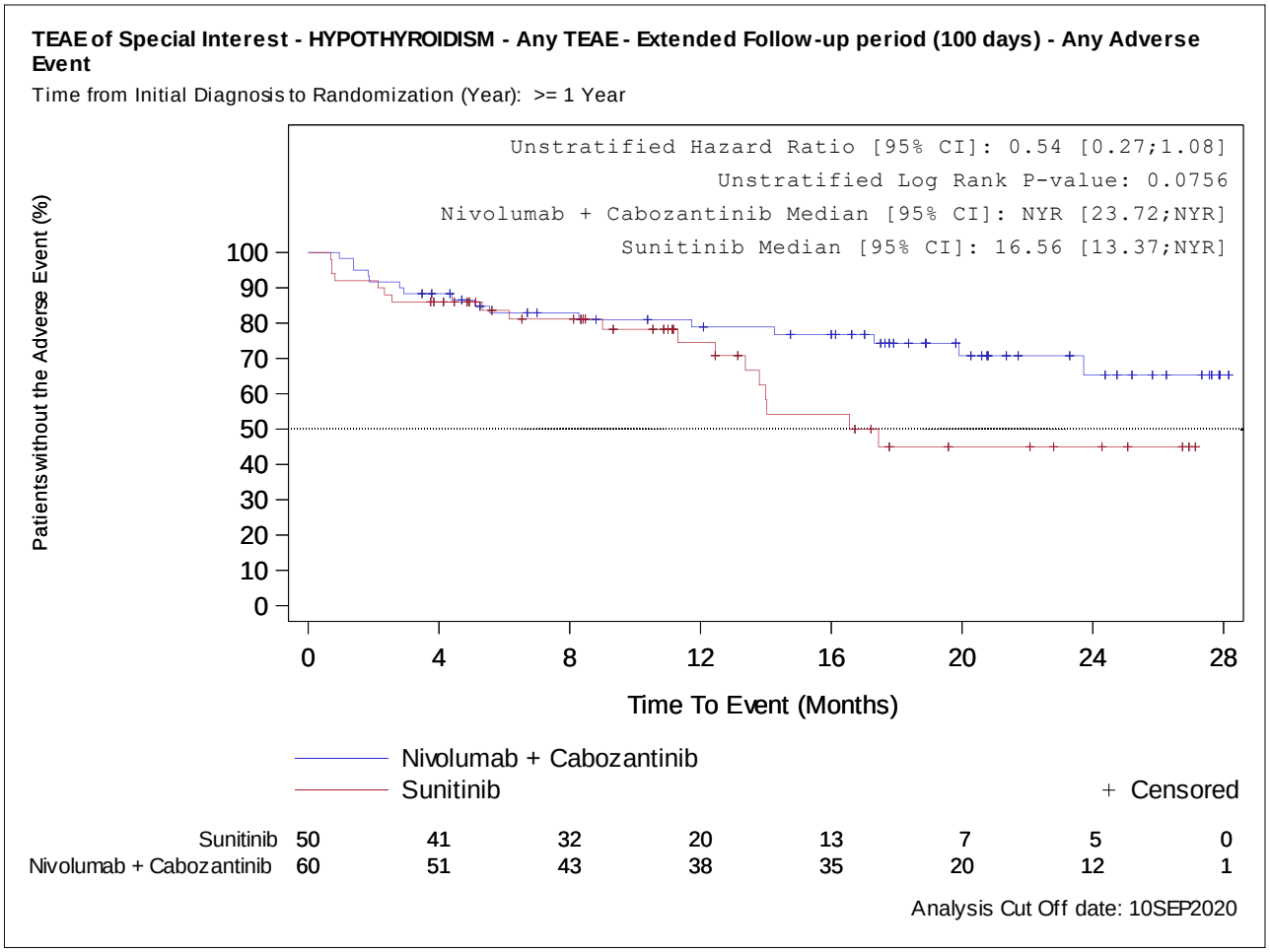

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:41:47

FIGURE 3.102.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



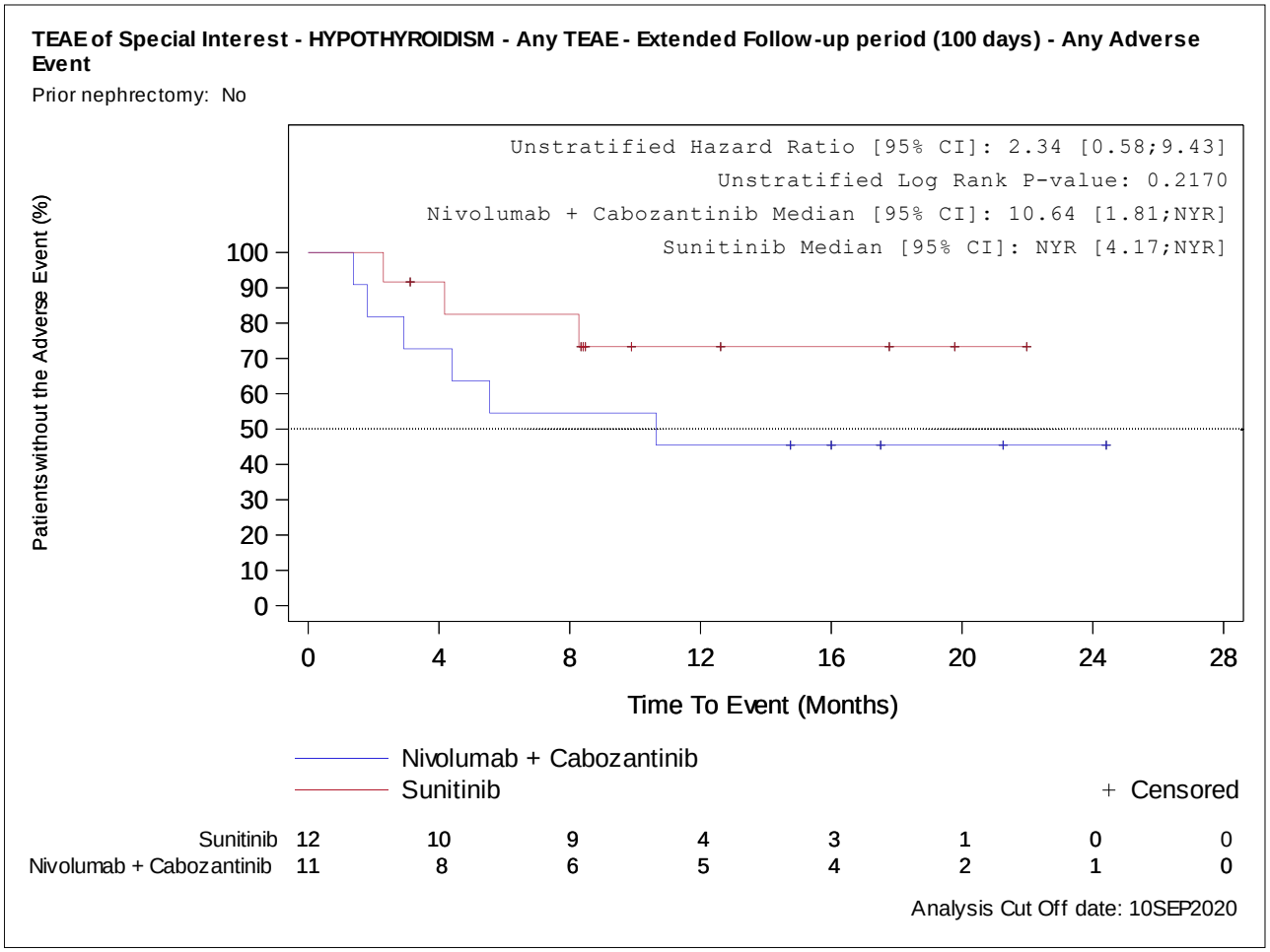

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:42:03

FIGURE 3.102.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



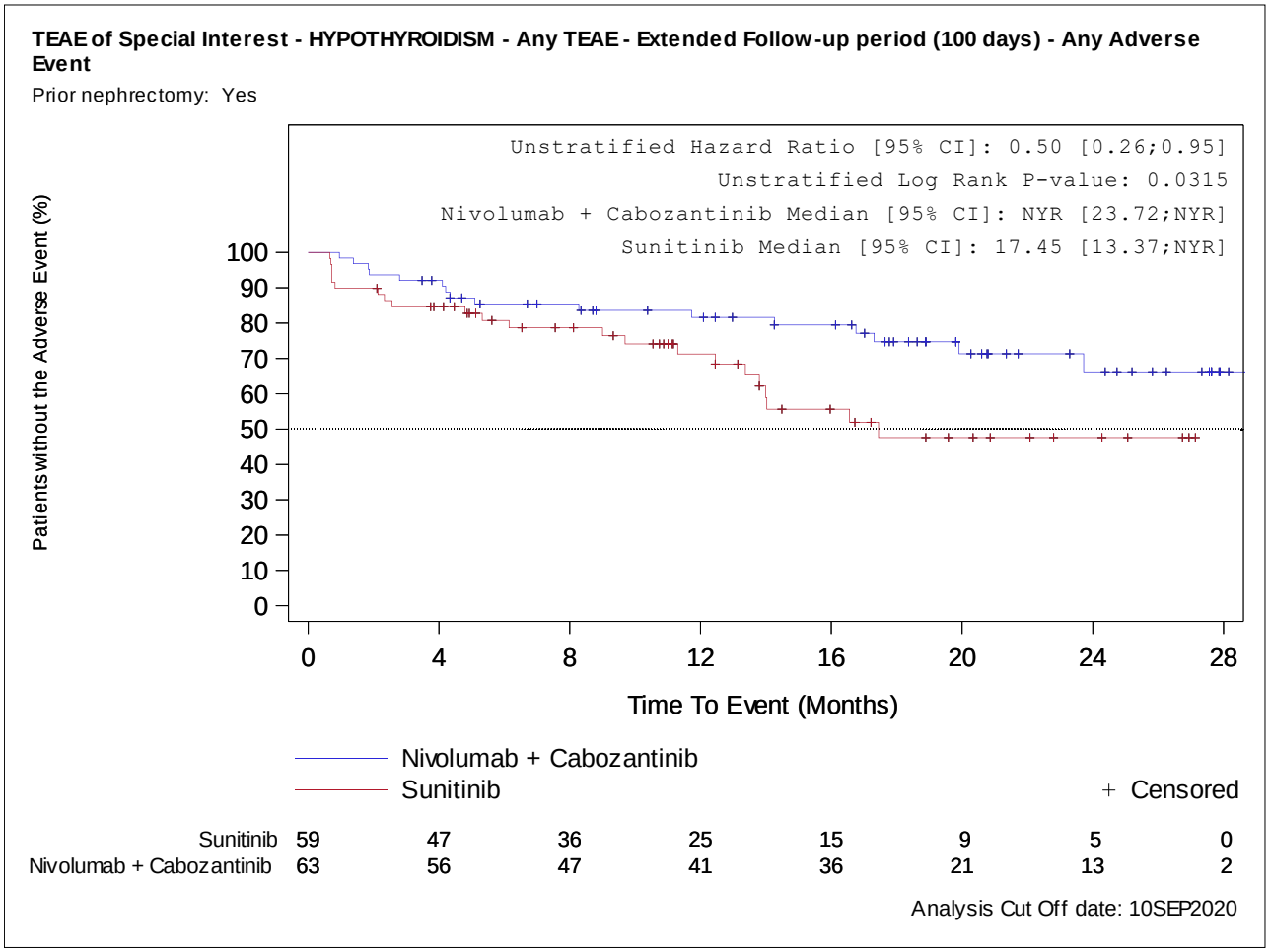

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:42:08

FIGURE 3.102.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



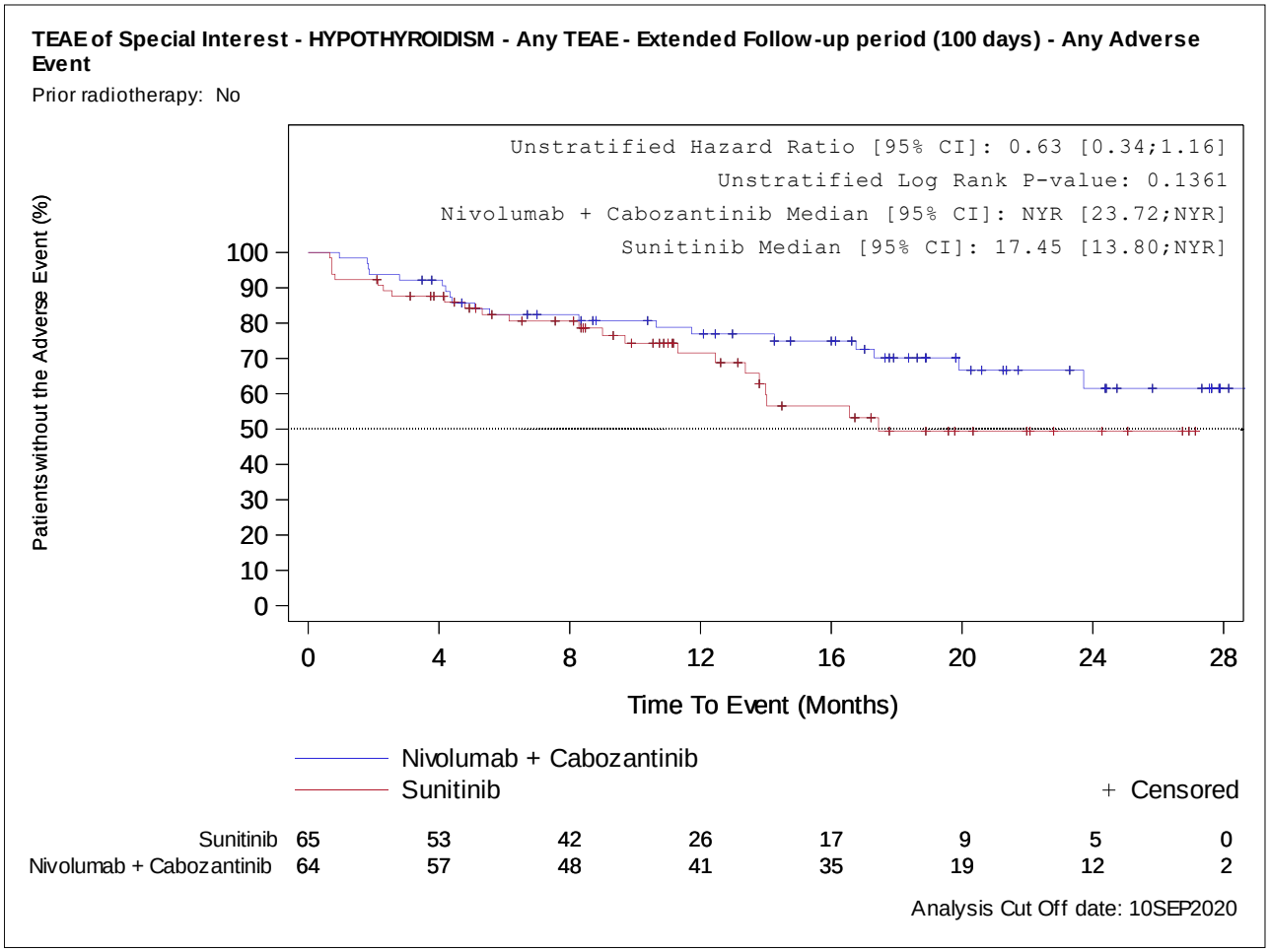

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:42:57

FIGURE 3.102.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



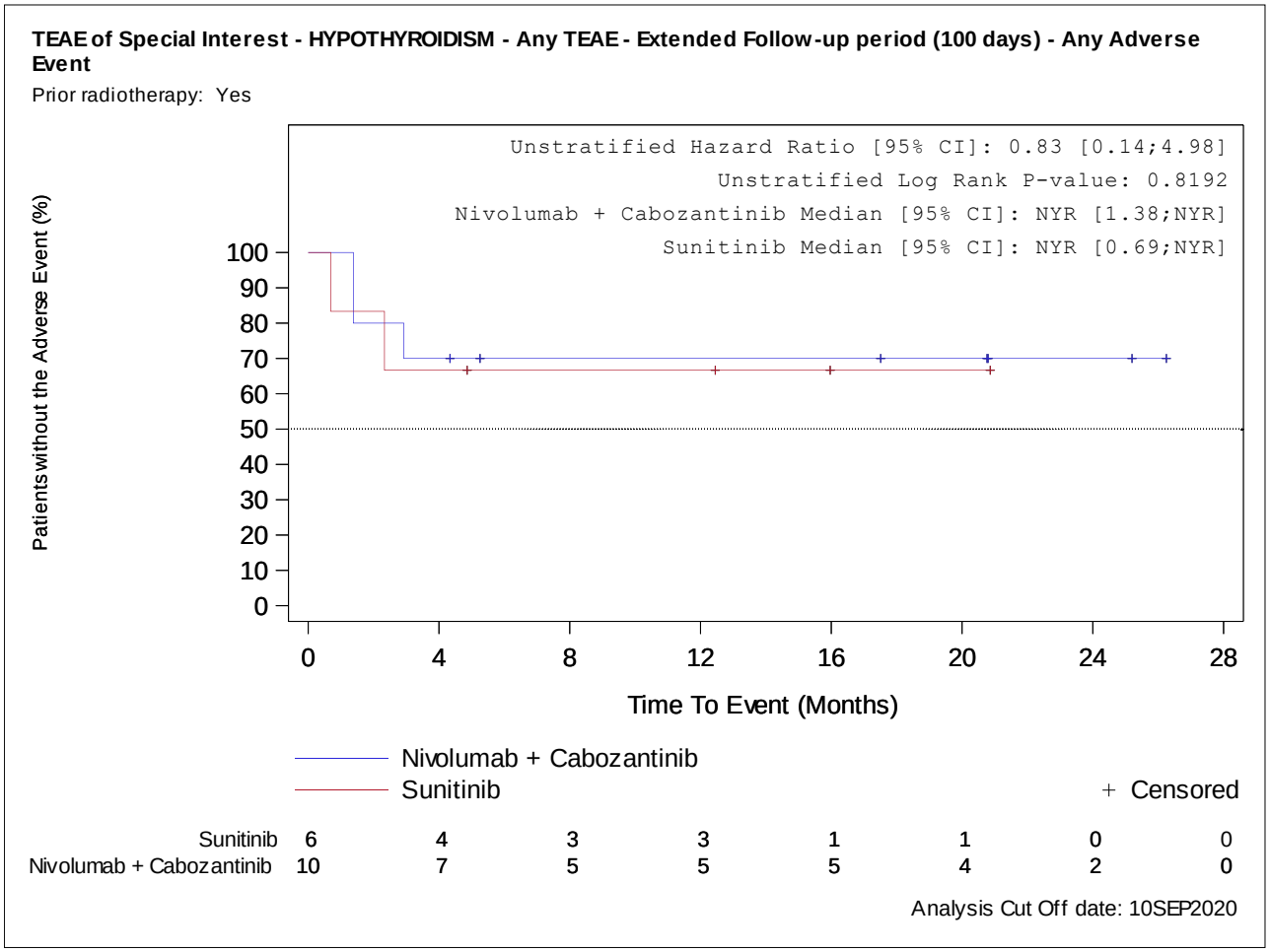

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:43:02

FIGURE 3.102.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



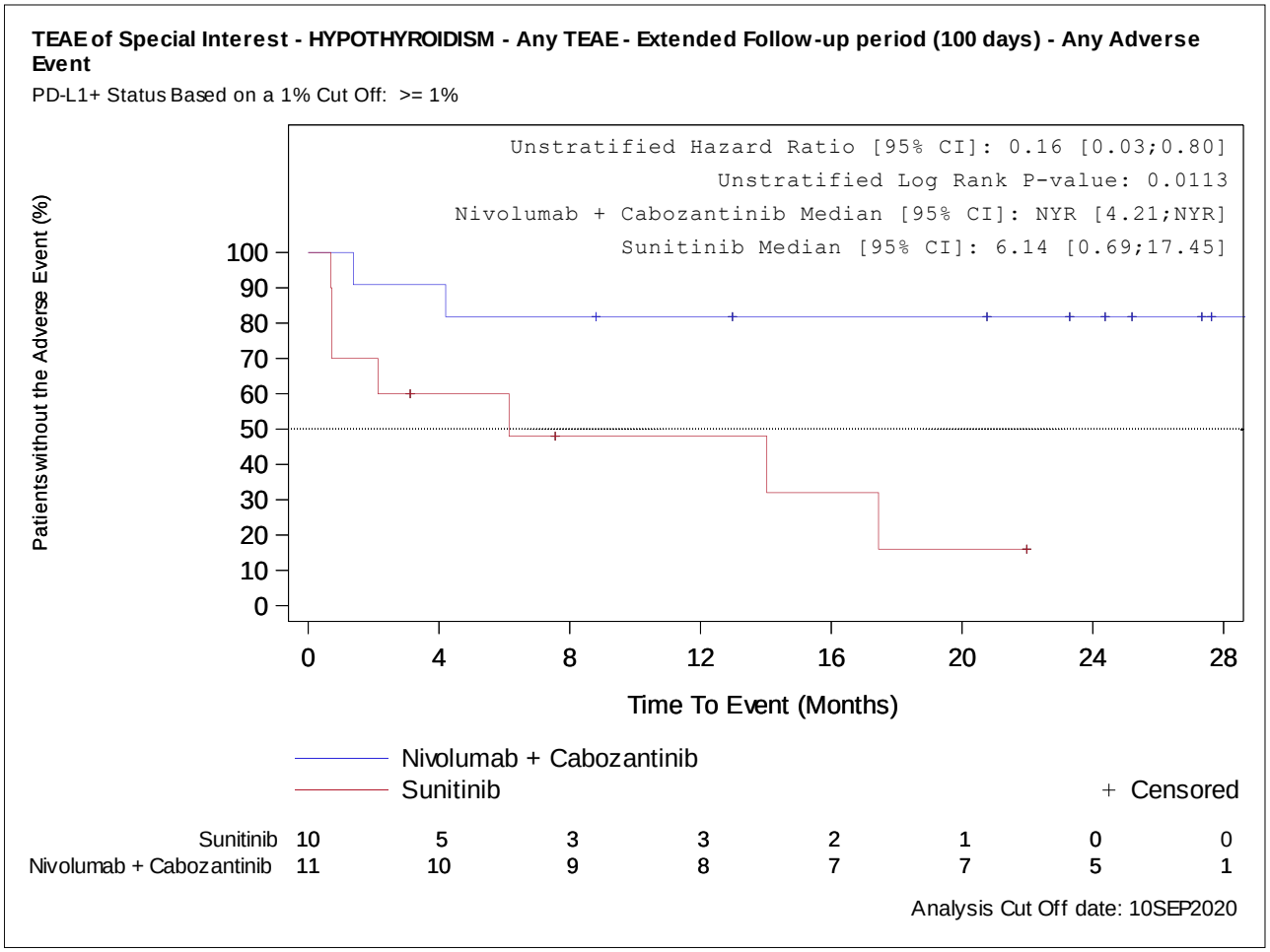

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:43:07

FIGURE 3.102.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



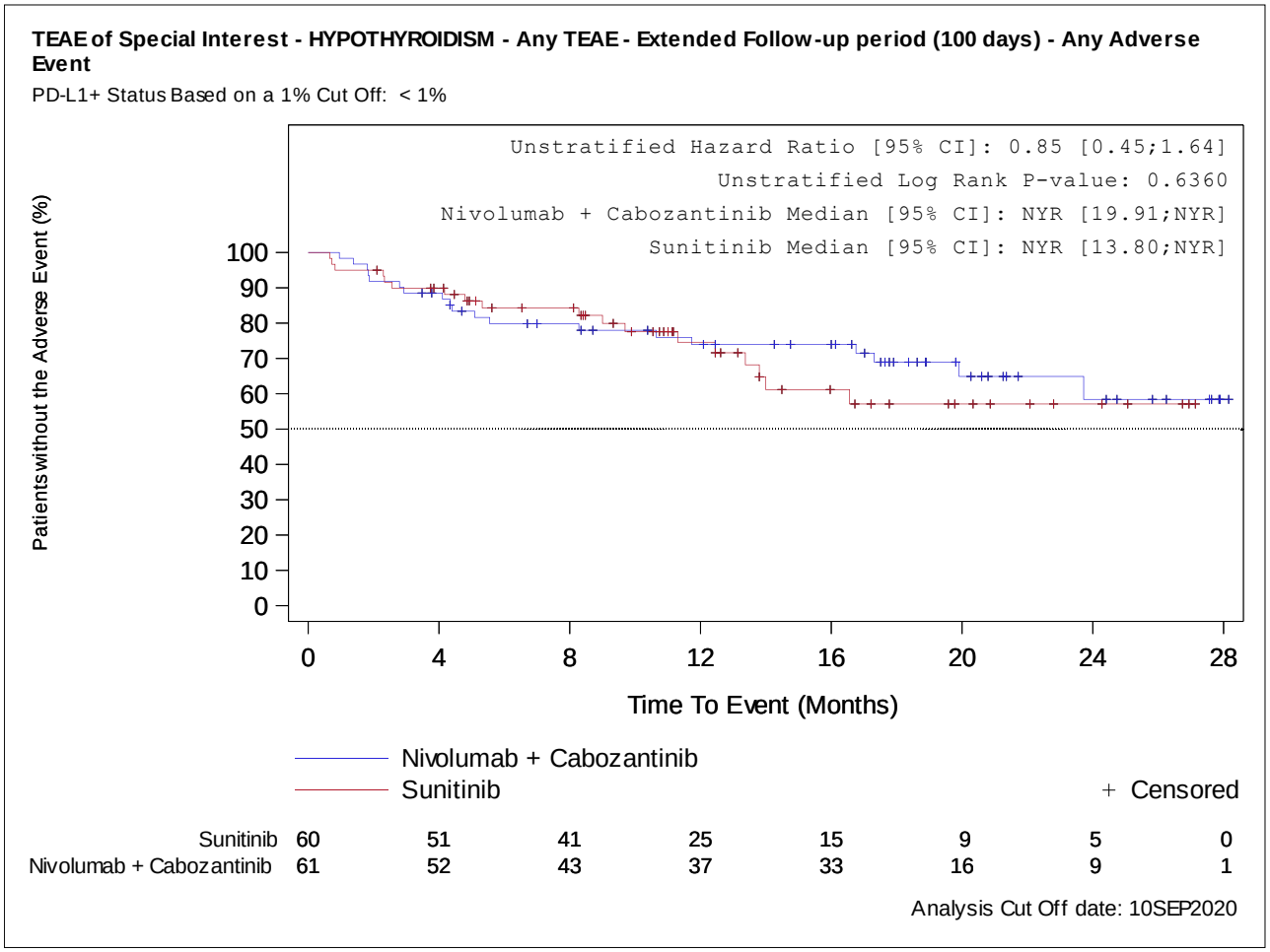

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:43:13

FIGURE 3.102.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



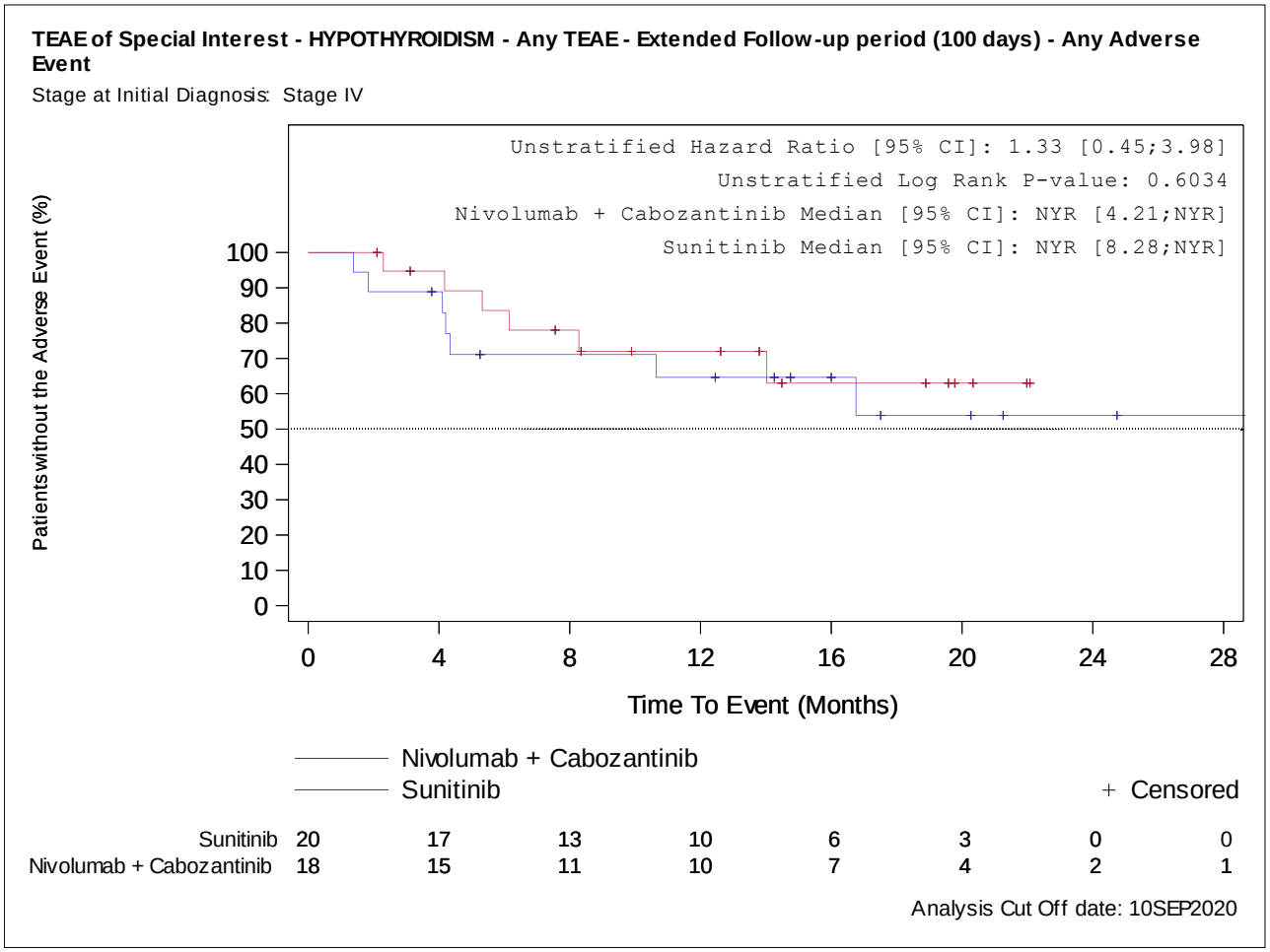

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:43:18

FIGURE 3.102.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



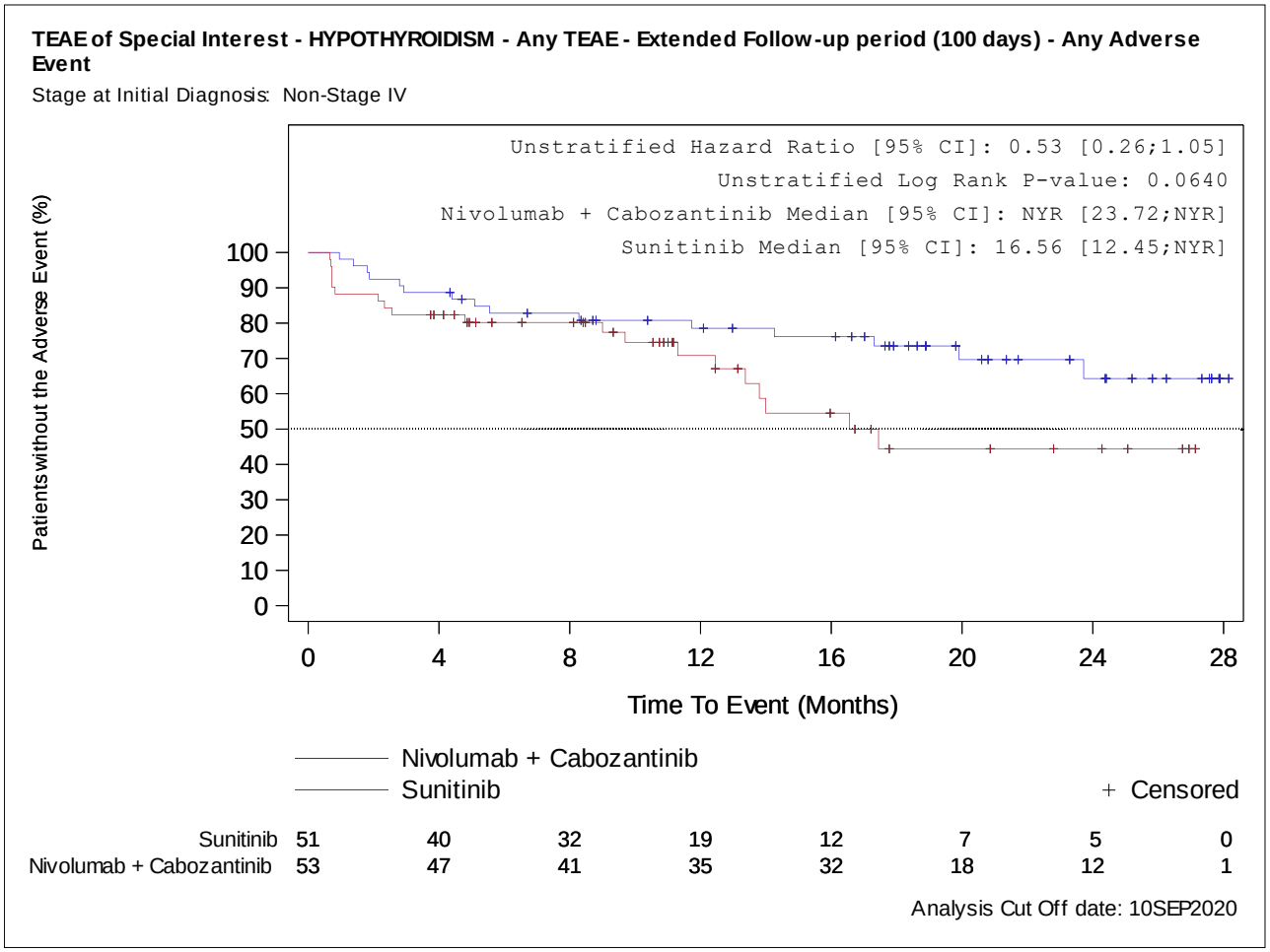

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:43:23

FIGURE 3.102.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



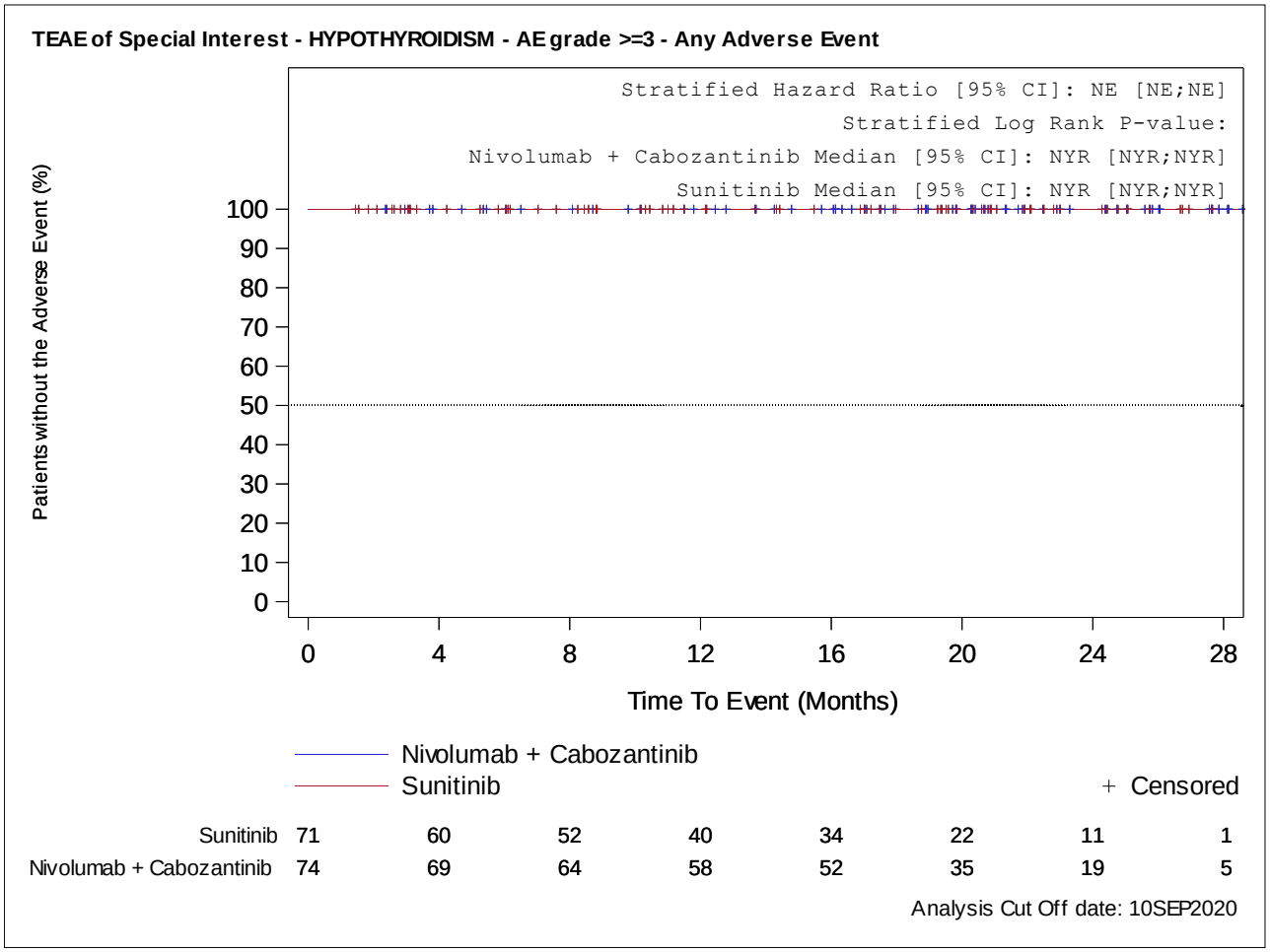

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:43:48

FIGURE 3.102.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



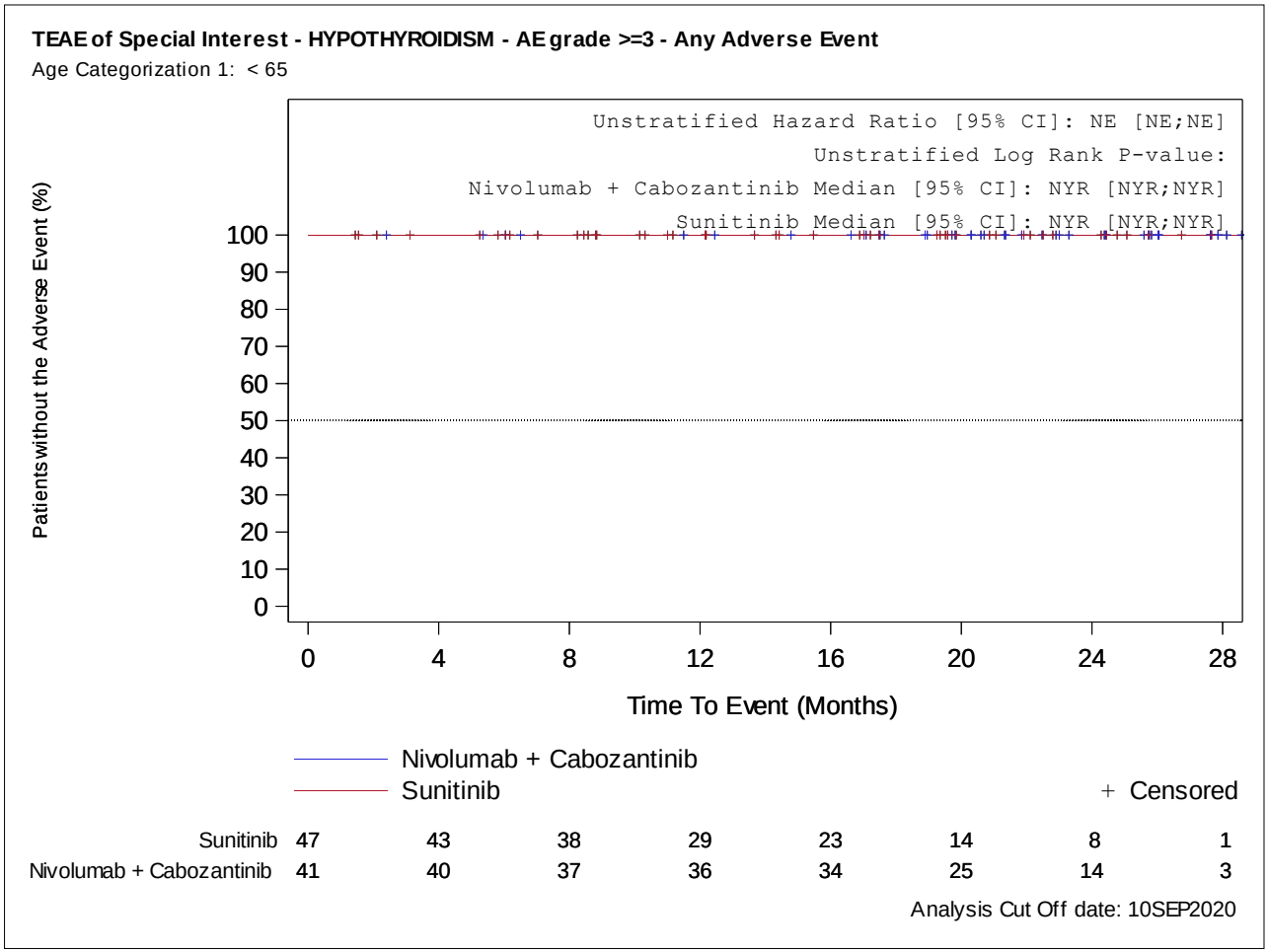

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:43:53

FIGURE 3.103.1: TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



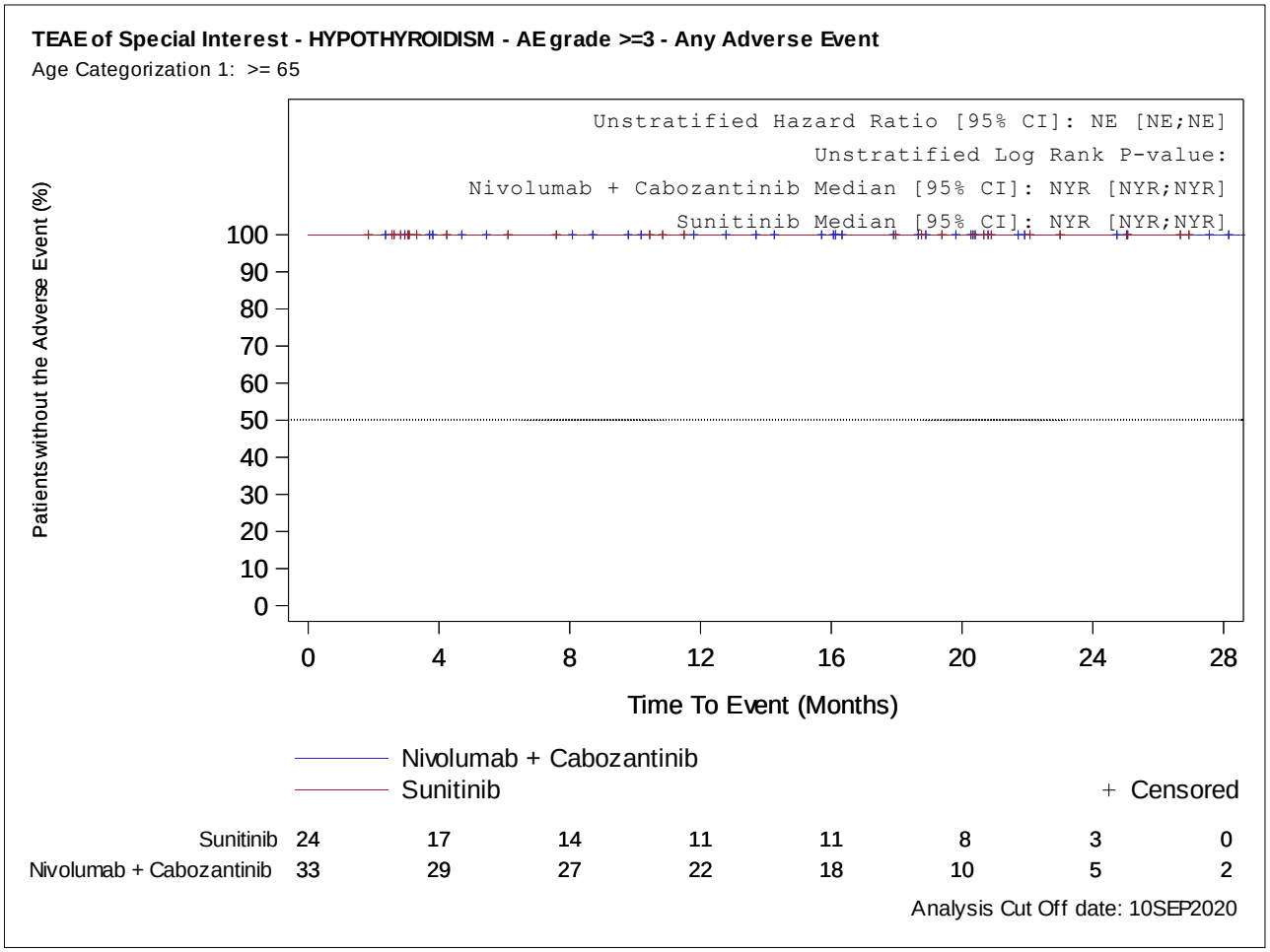

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:46:51

FIGURE 3.103.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:46:54

FIGURE 3.103.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
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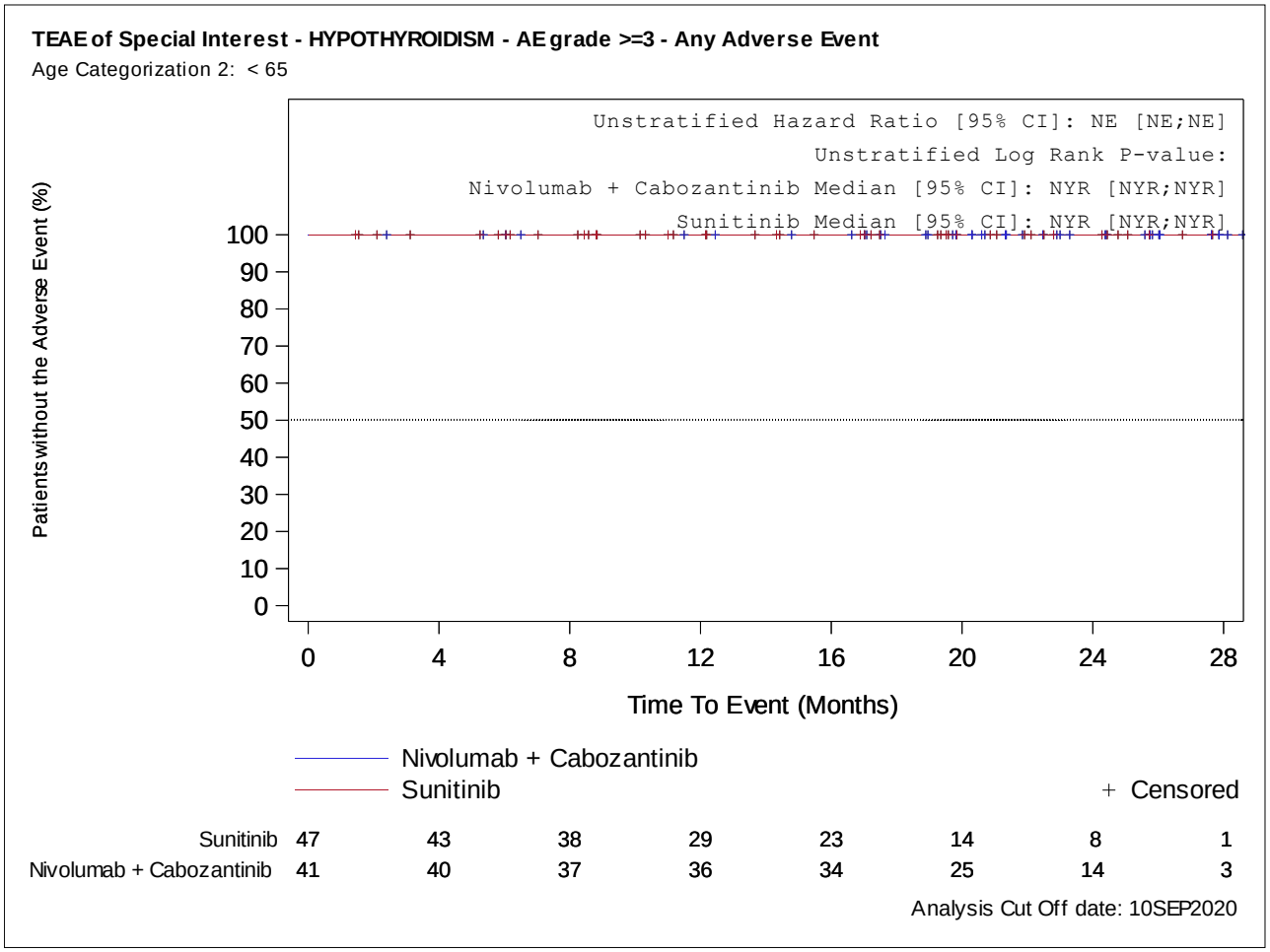
FIGURE 3.103.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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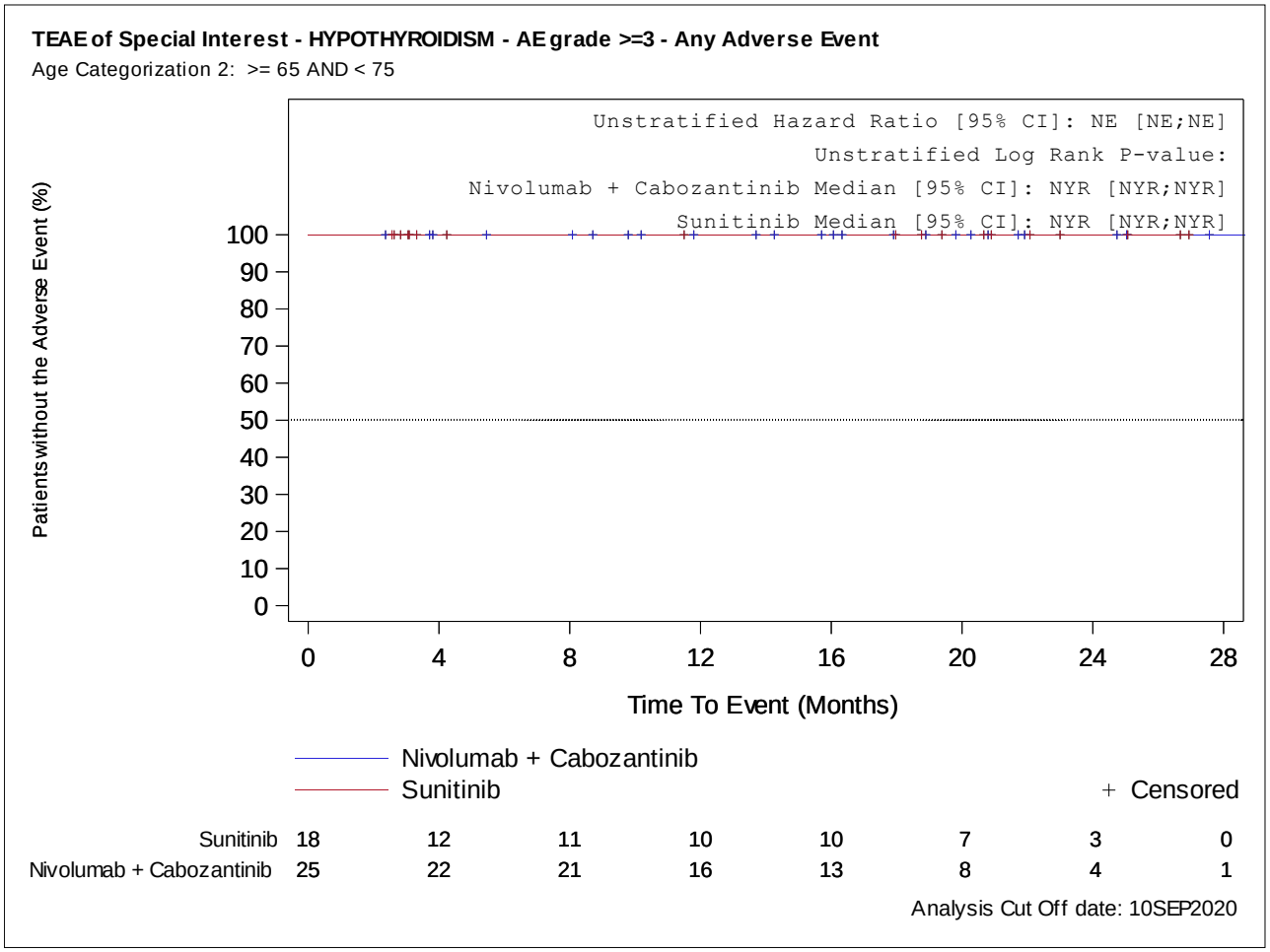
FIGURE 3.103.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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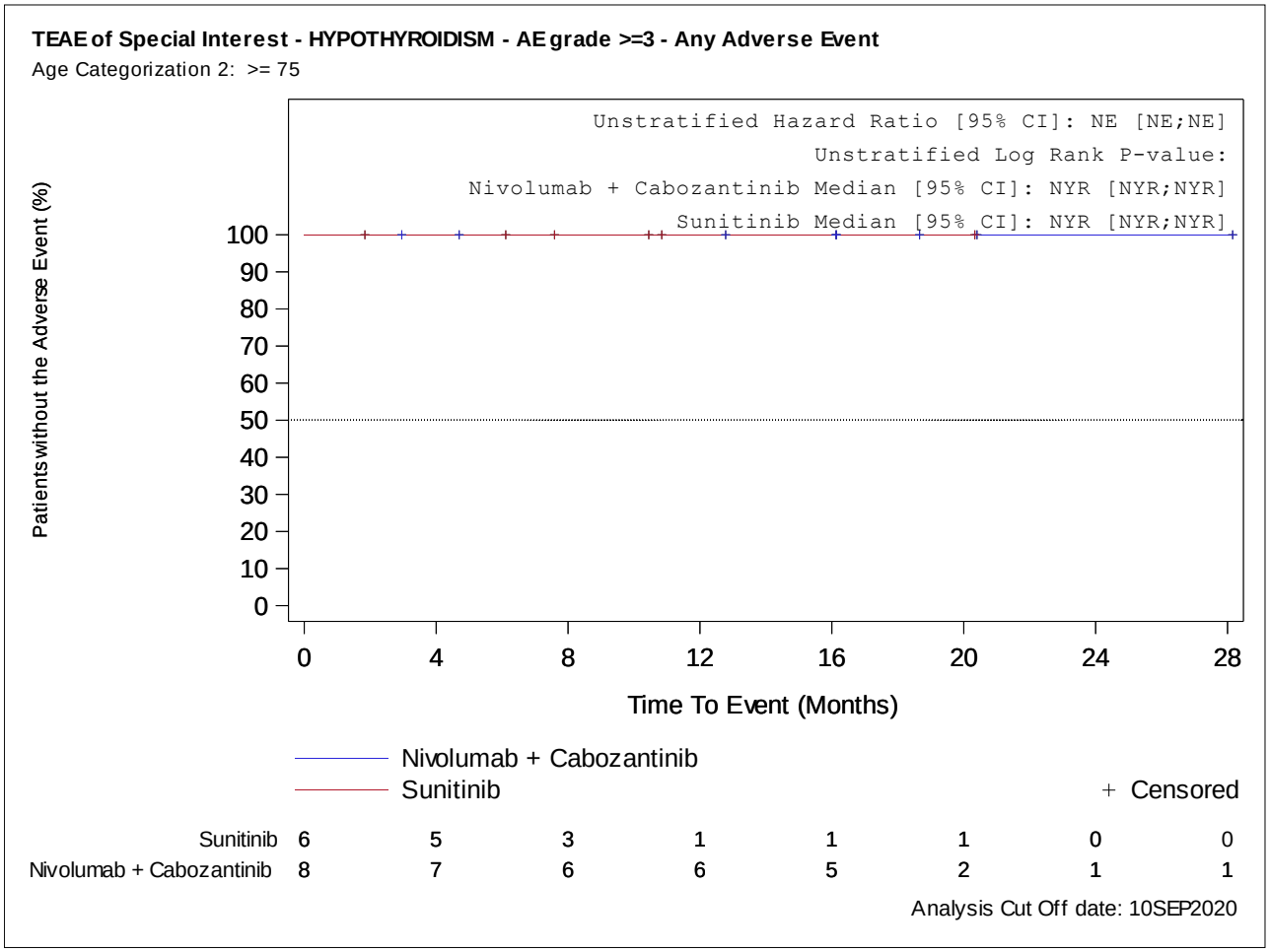
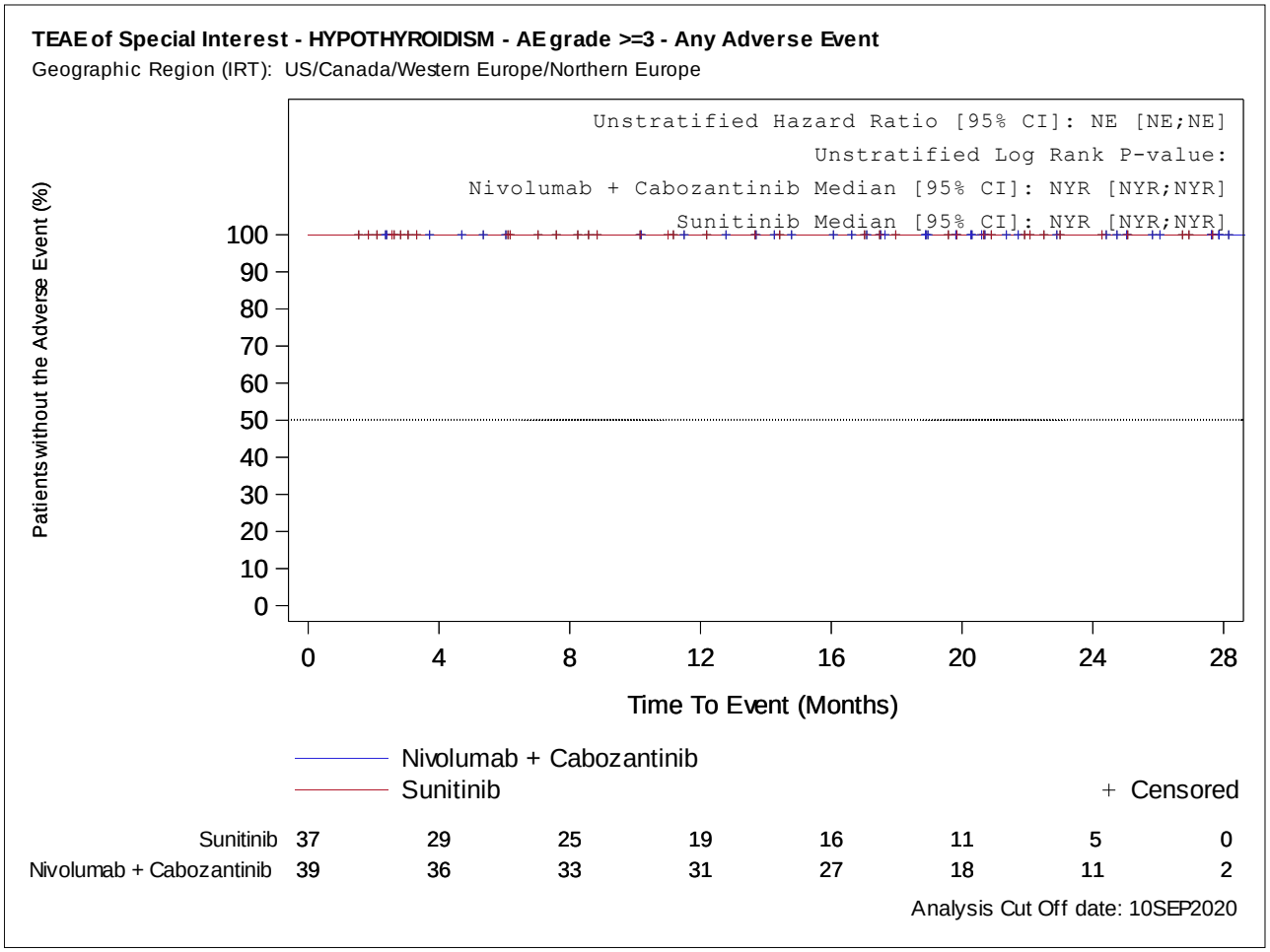
FIGURE 3.103.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



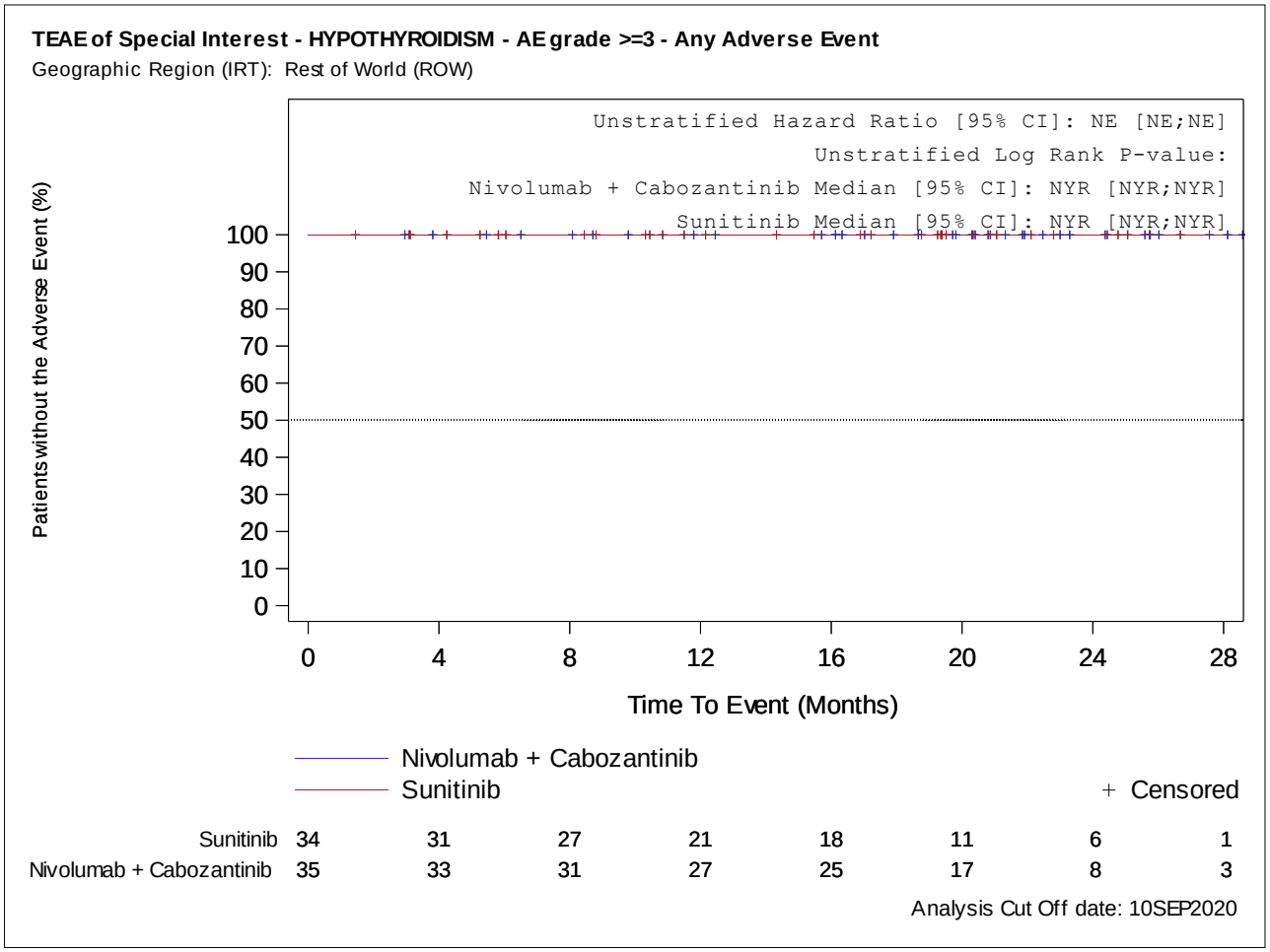

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:47:15

FIGURE 3.103.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



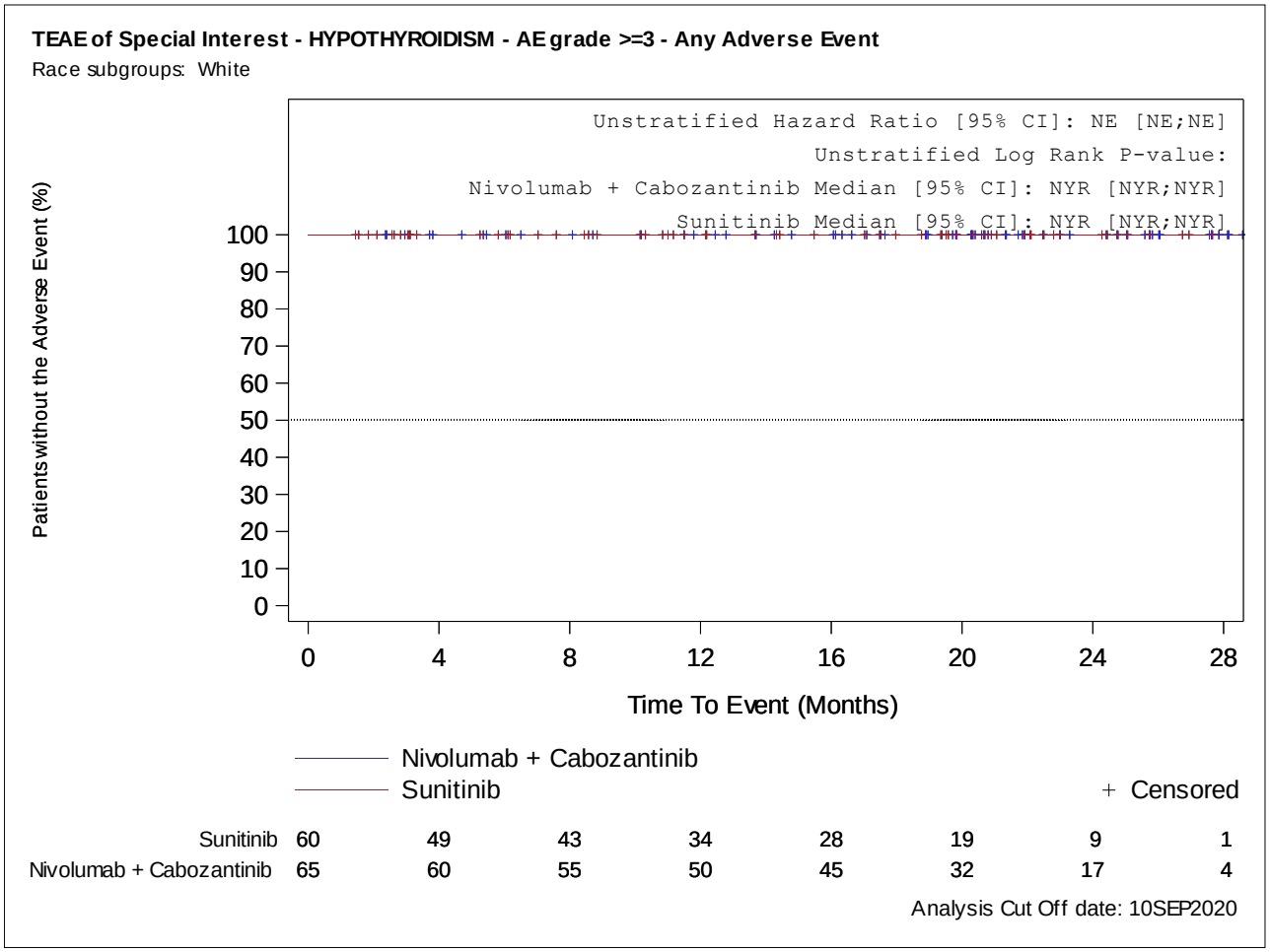

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:47:20

FIGURE 3.103.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:47:25

FIGURE 3.103.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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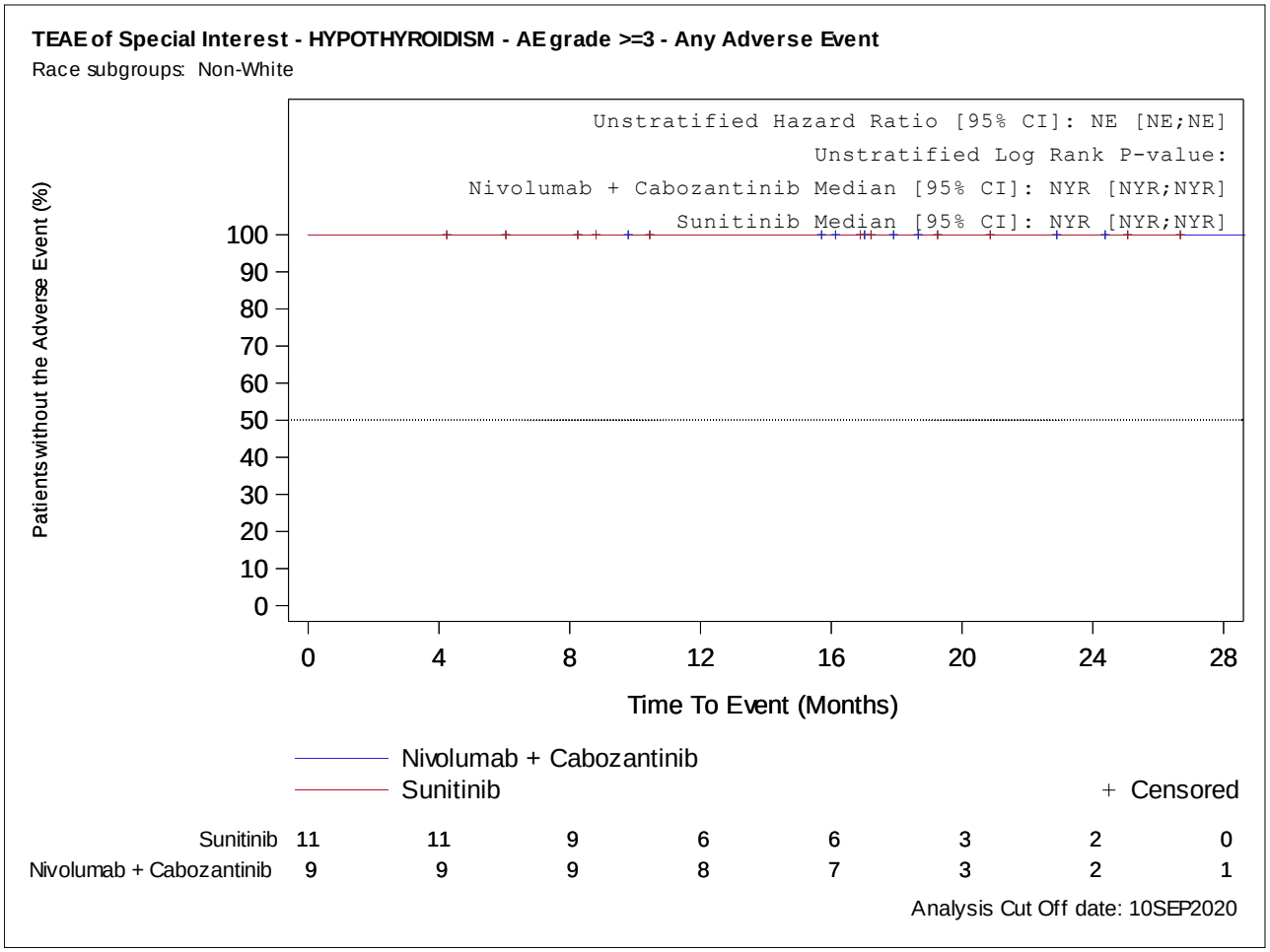
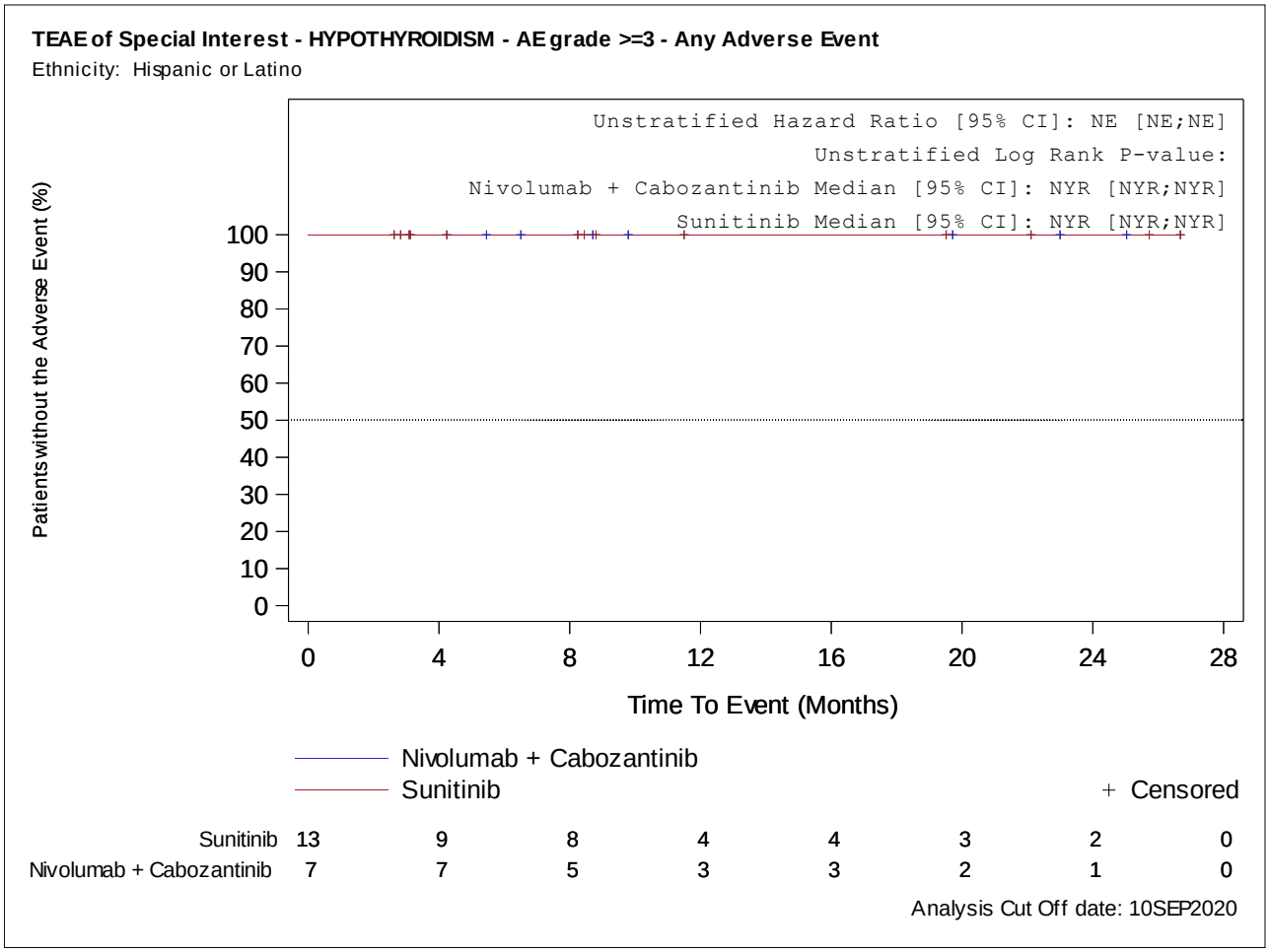
FIGURE 3.103.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



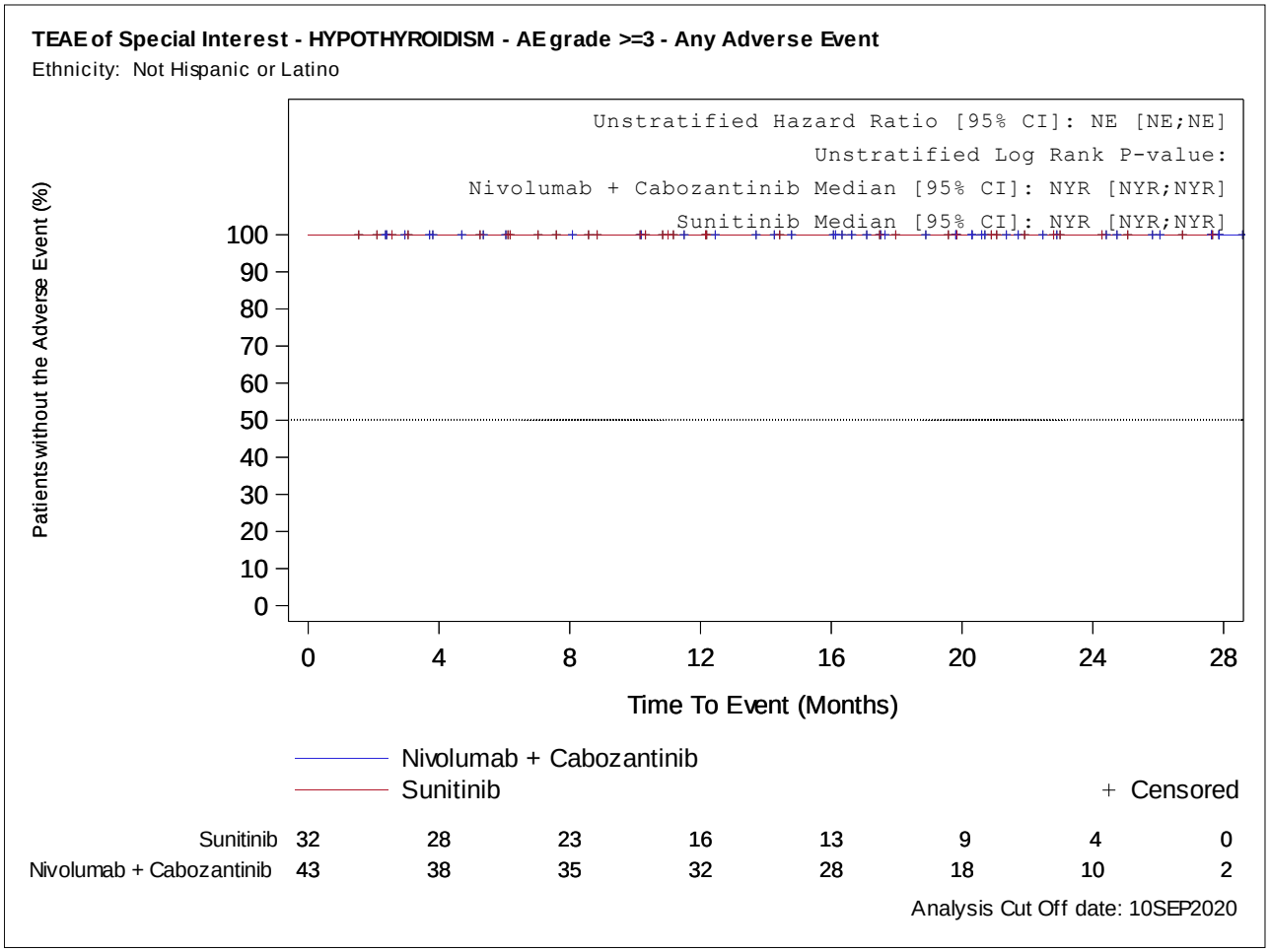

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:47:36

FIGURE 3.103.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



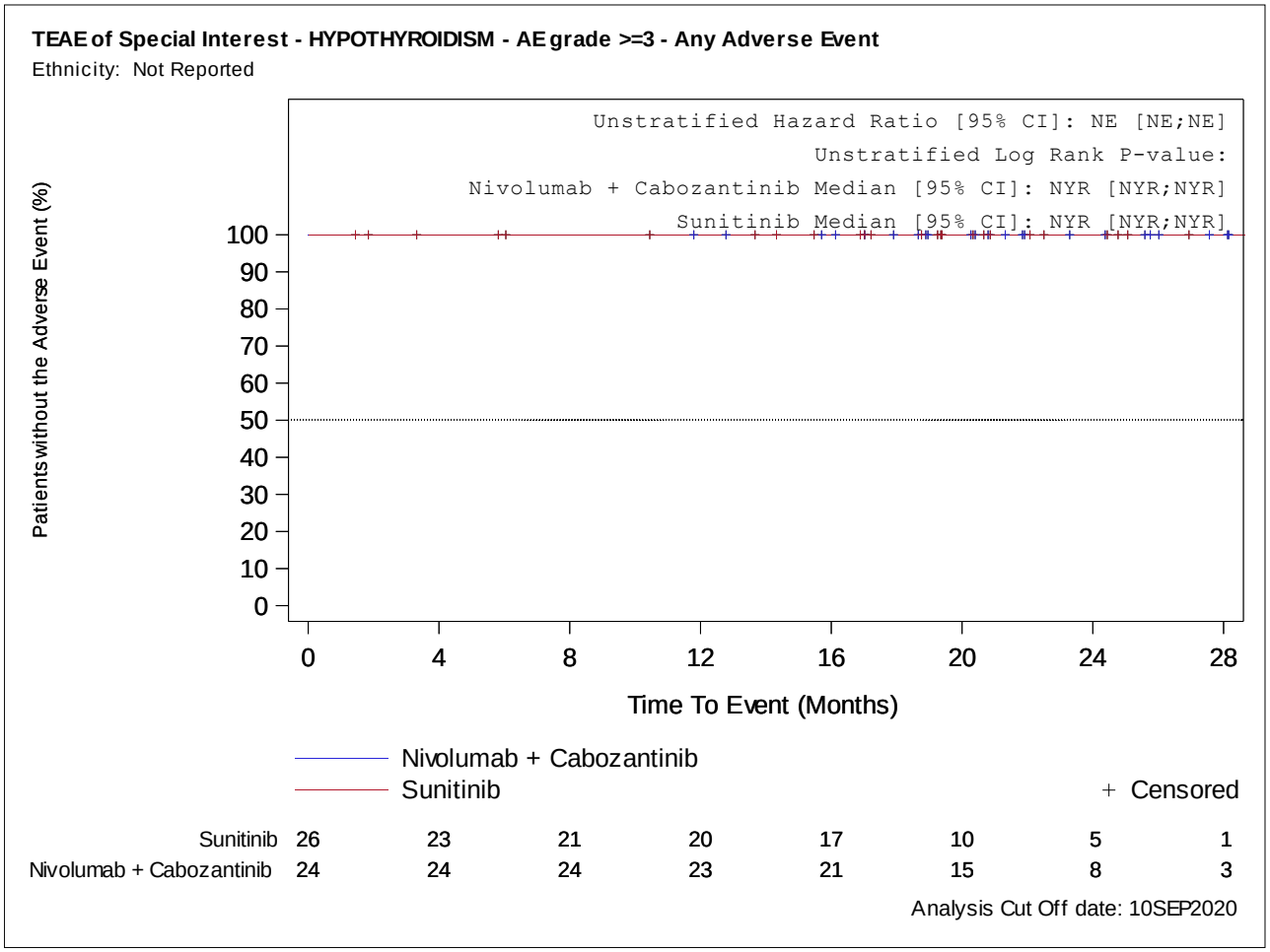

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:47:41

FIGURE 3.103.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



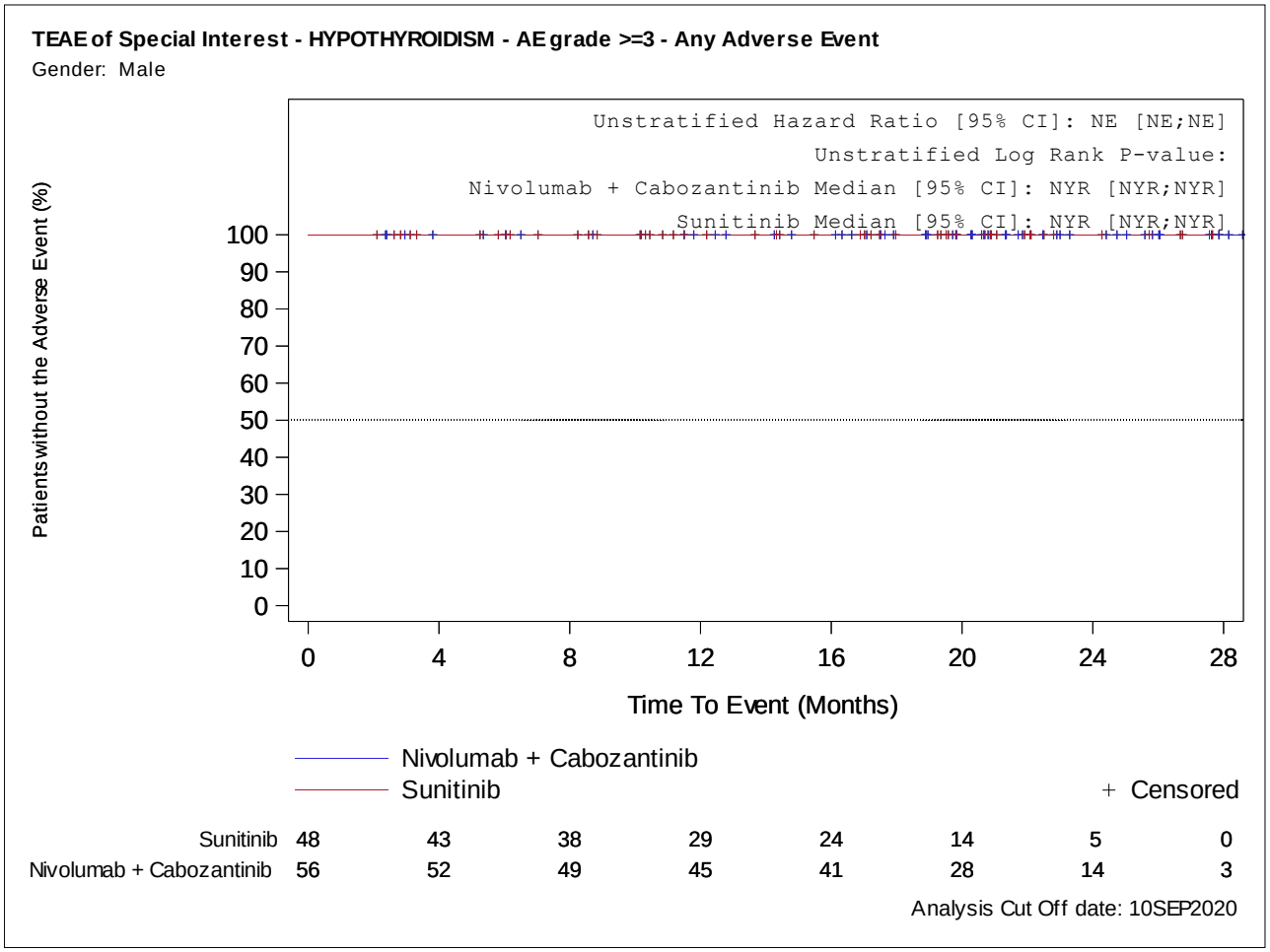

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:47:46

FIGURE 3.103.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:47:51

FIGURE 3.103.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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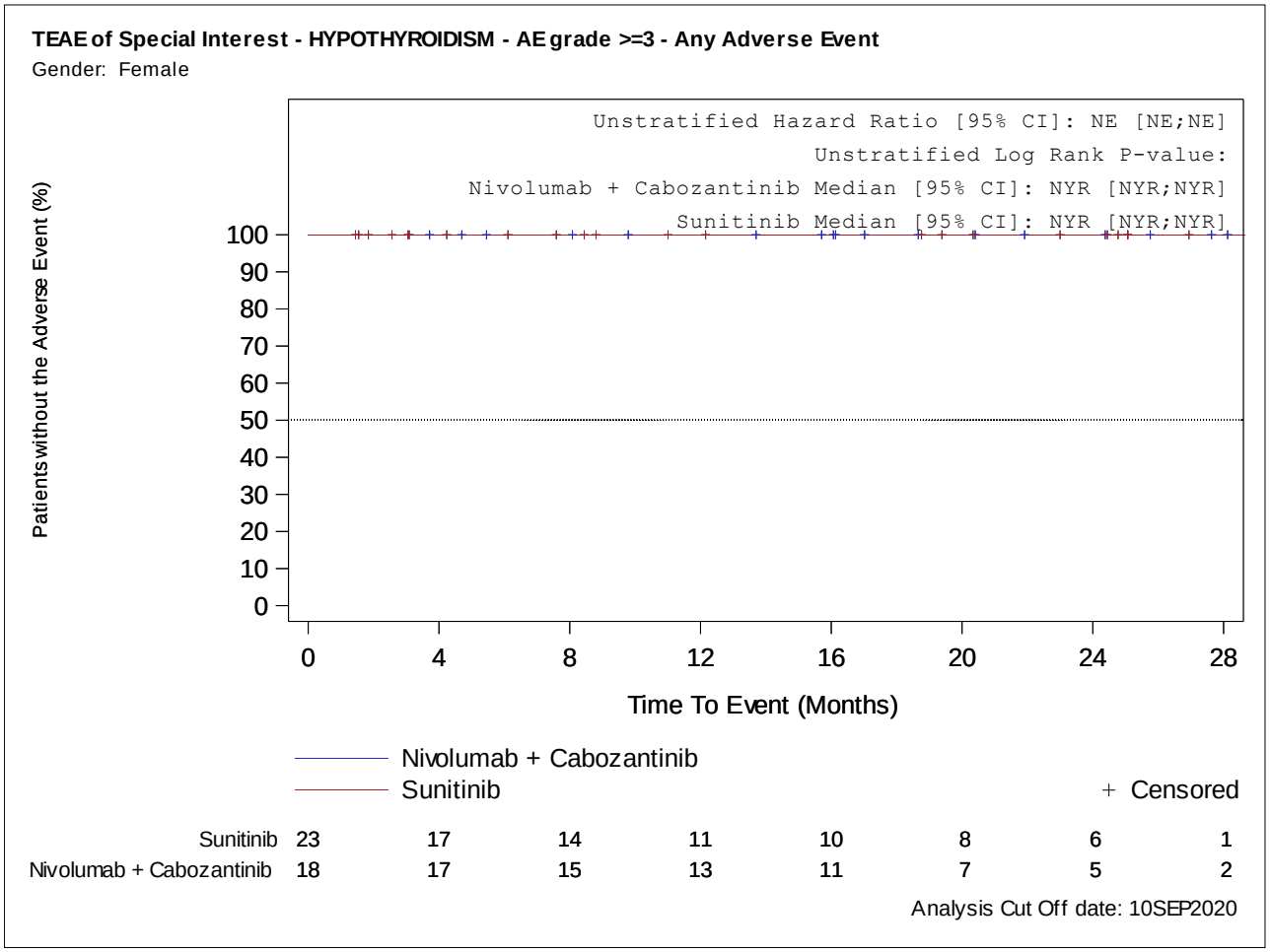
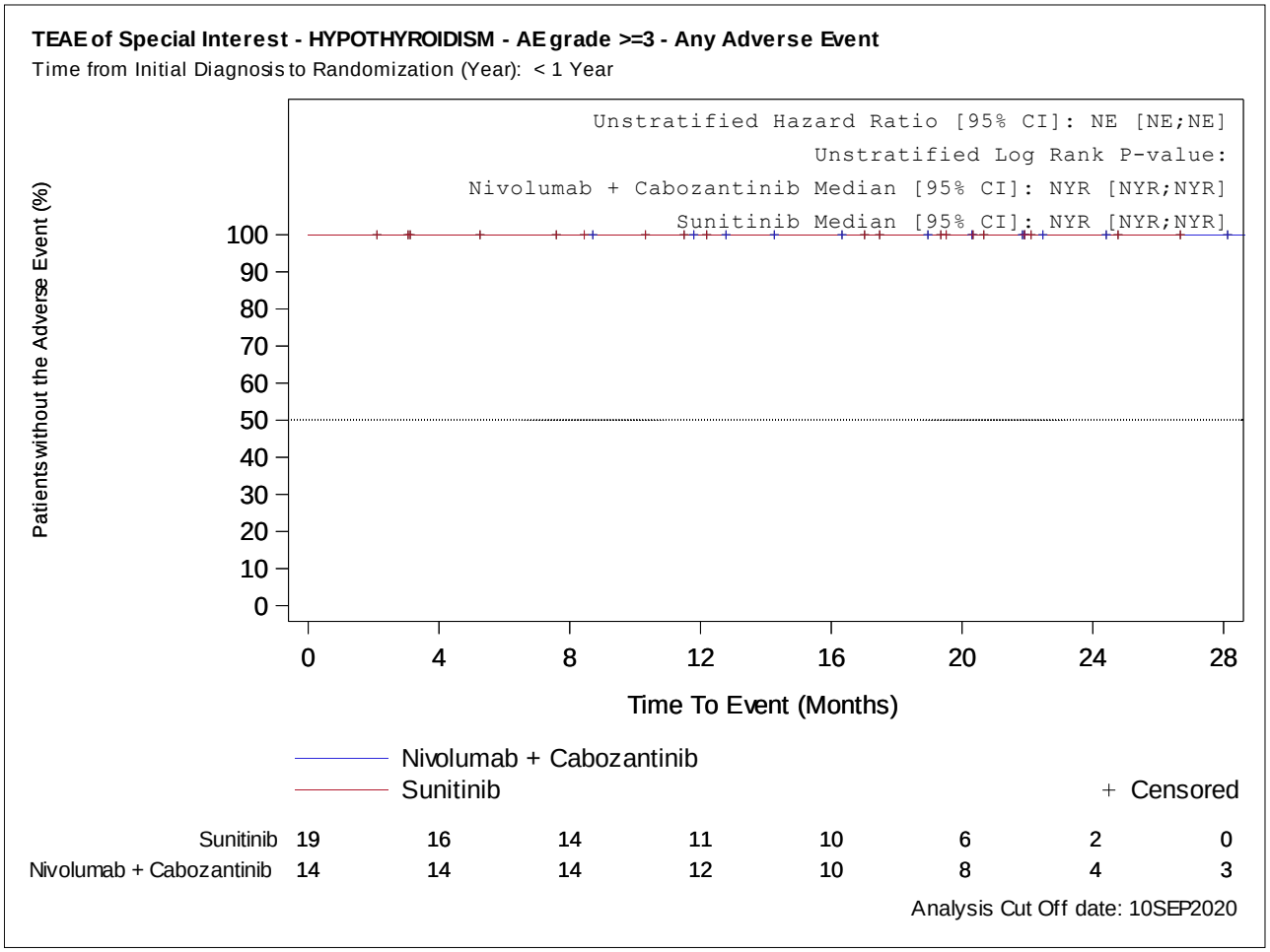
FIGURE 3.103.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:48:02

FIGURE 3.103.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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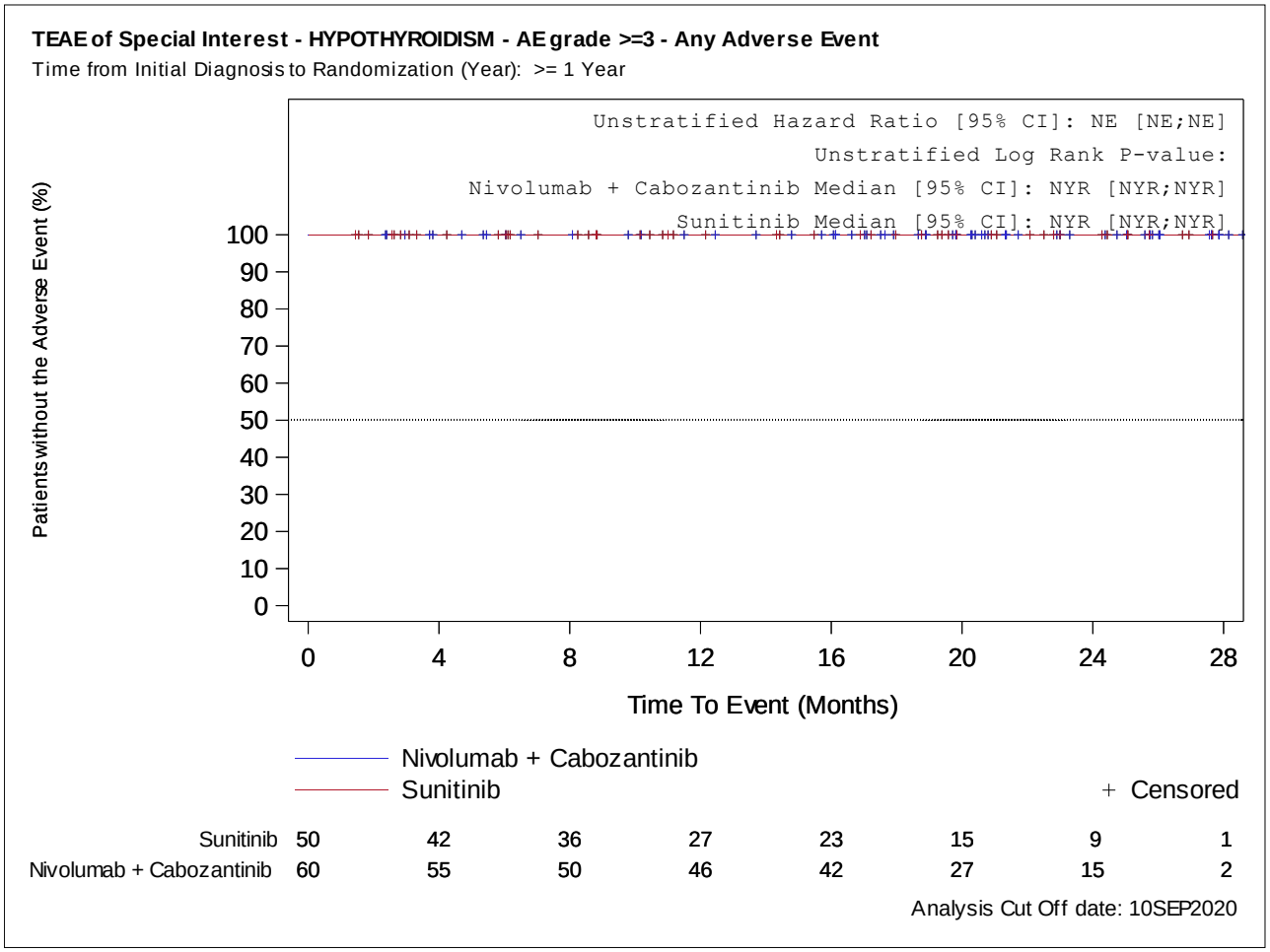
FIGURE 3.103.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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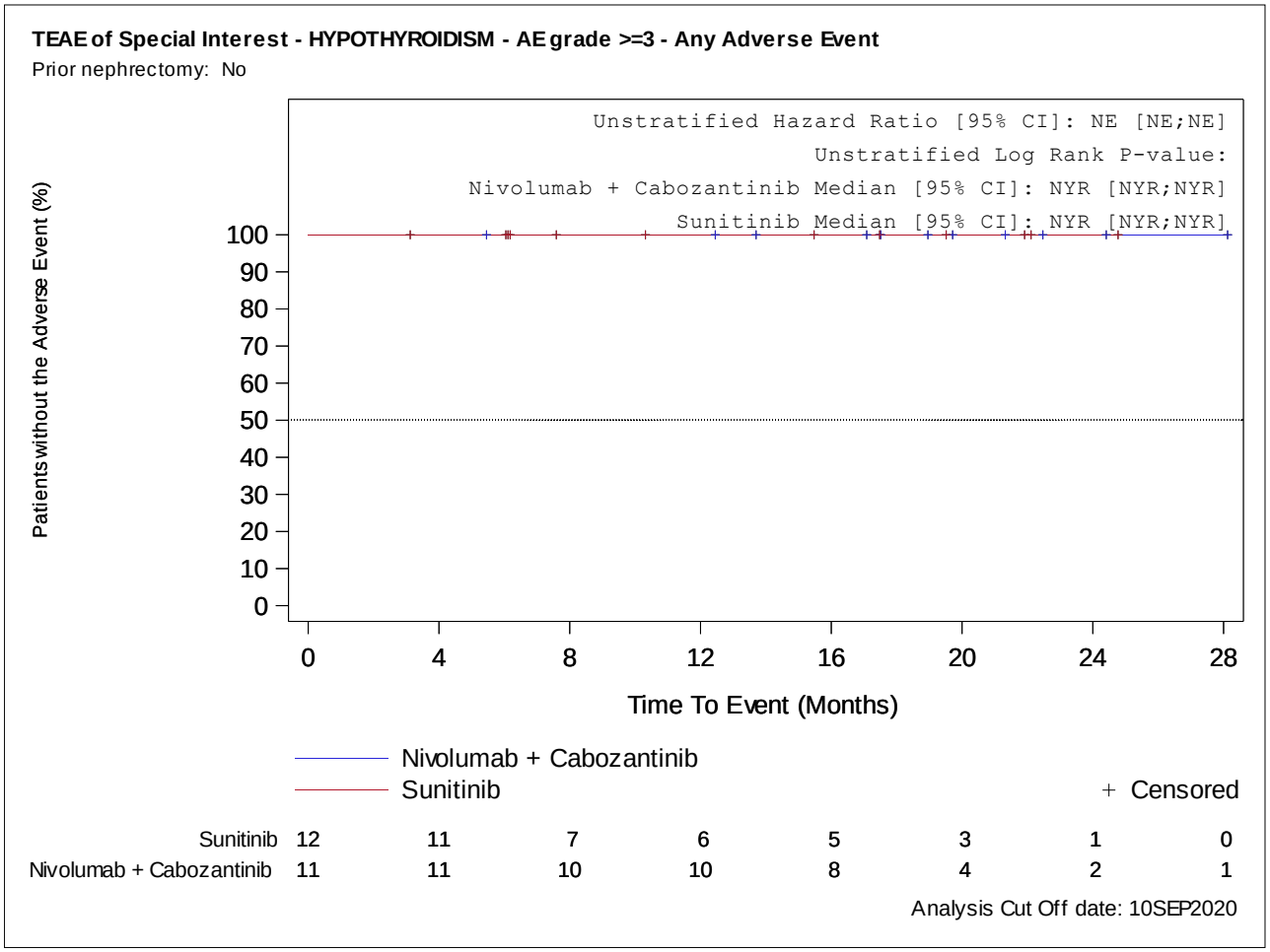
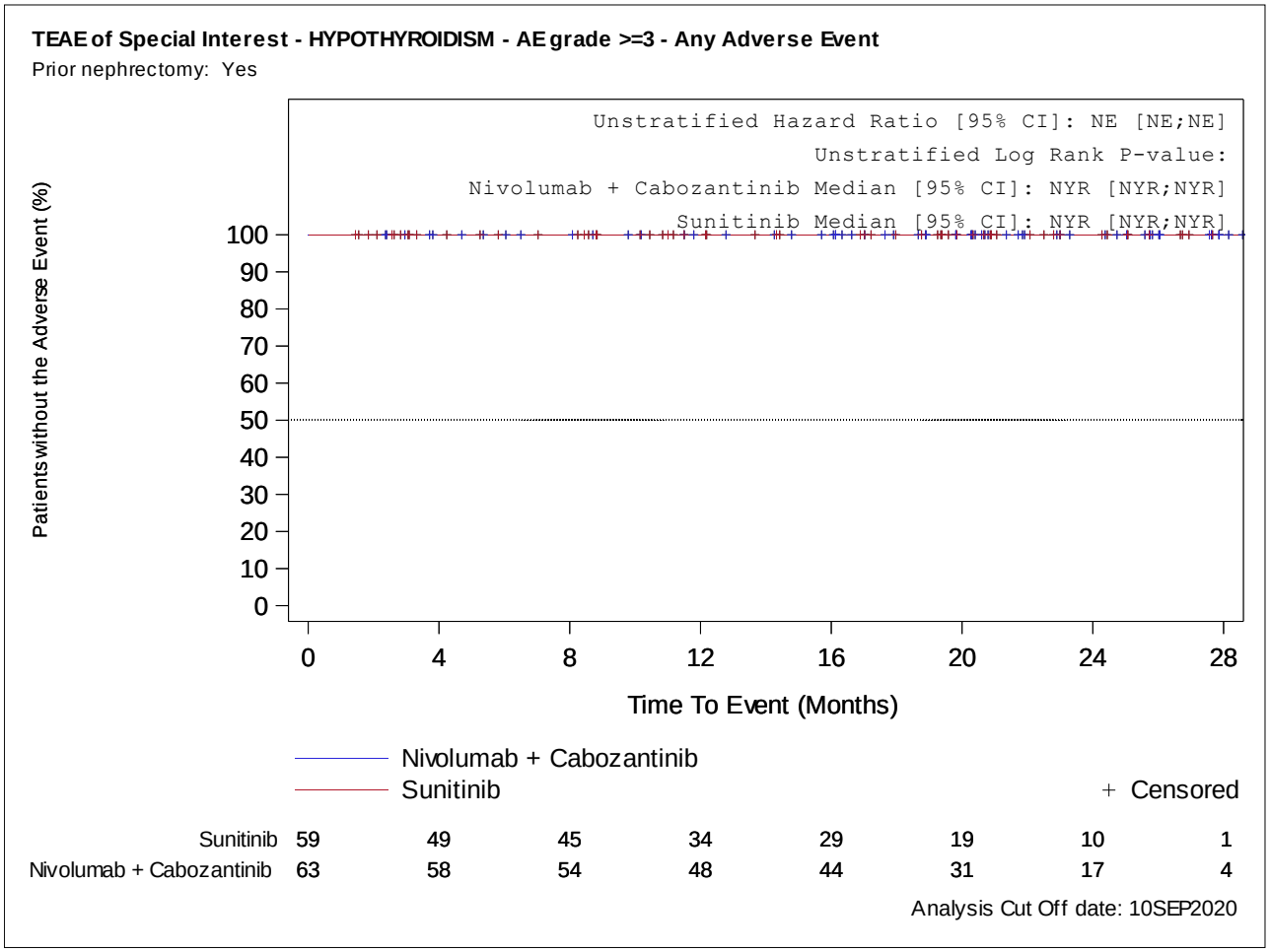
FIGURE 3.103.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:49:09

FIGURE 3.103.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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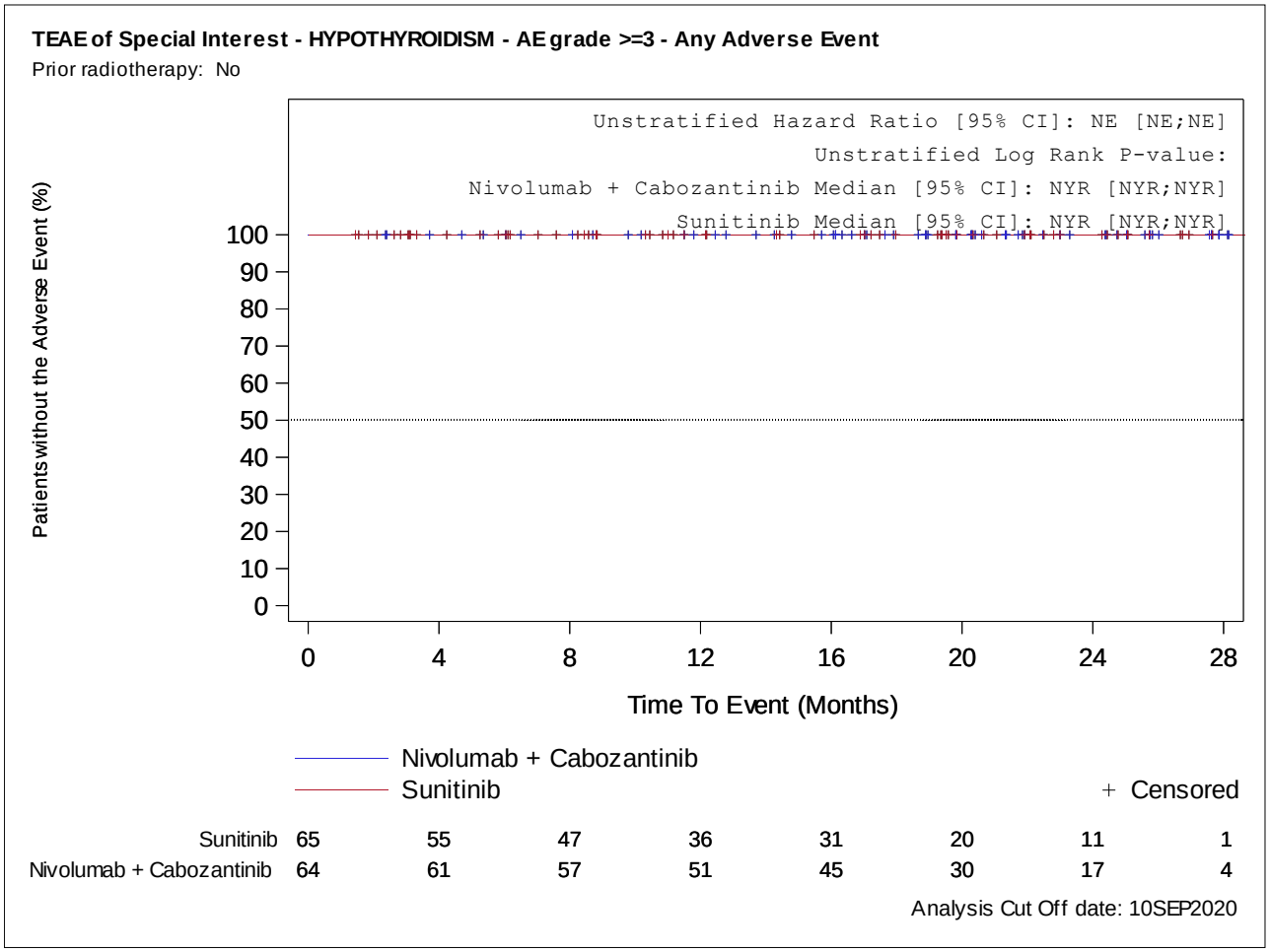
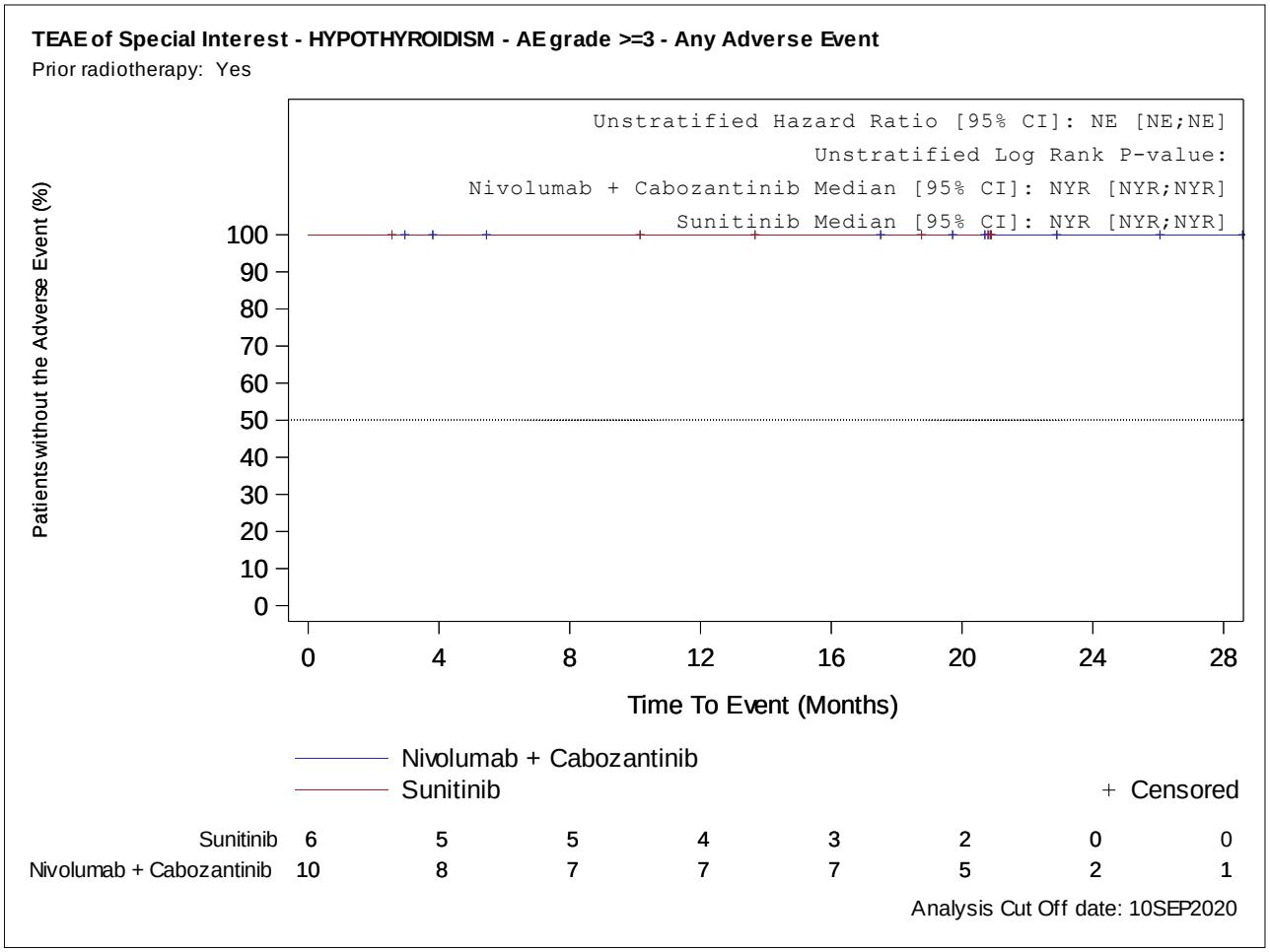
FIGURE 3.103.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



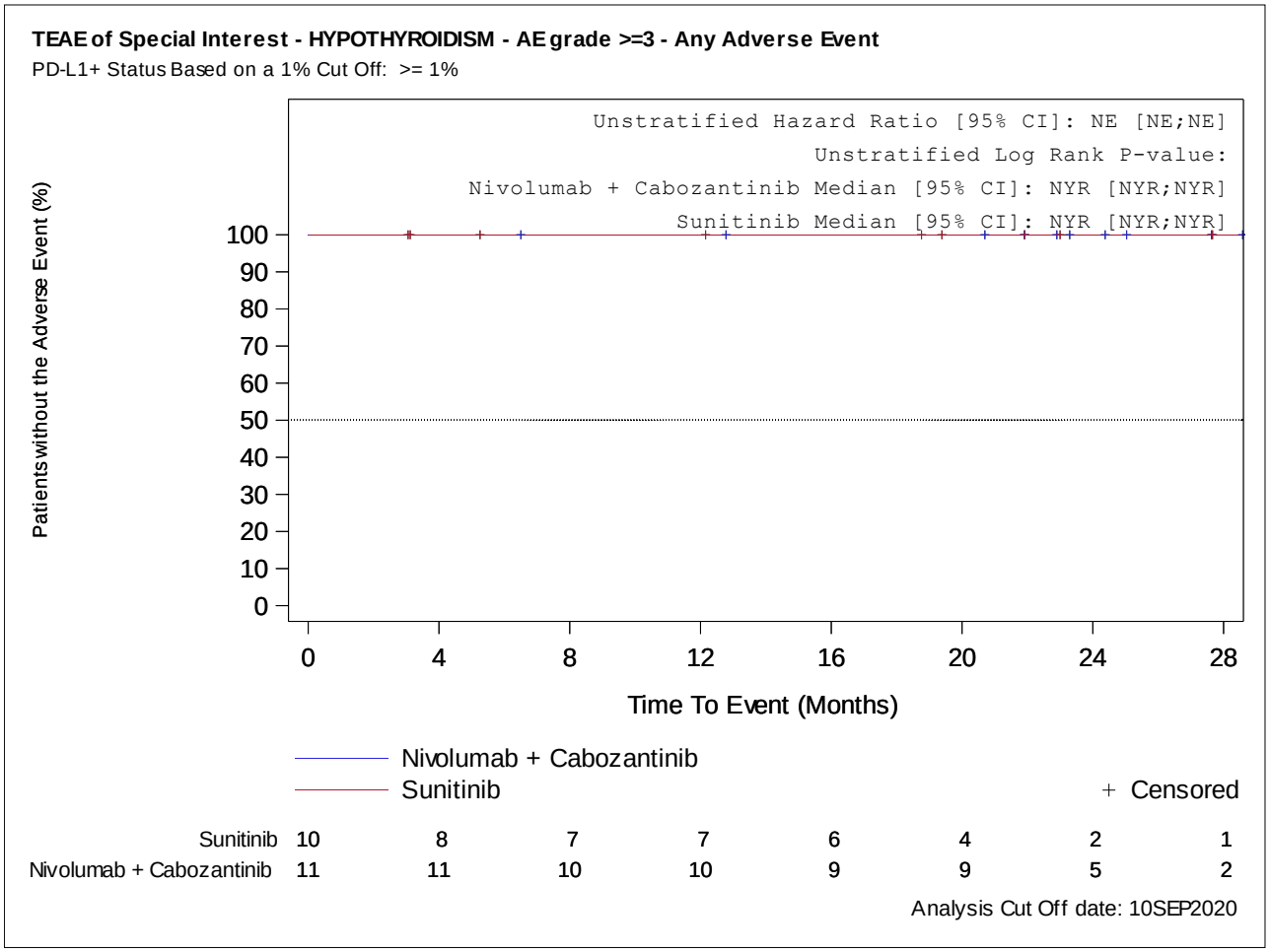

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:49:20

FIGURE 3.103.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:49:25

FIGURE 3.103.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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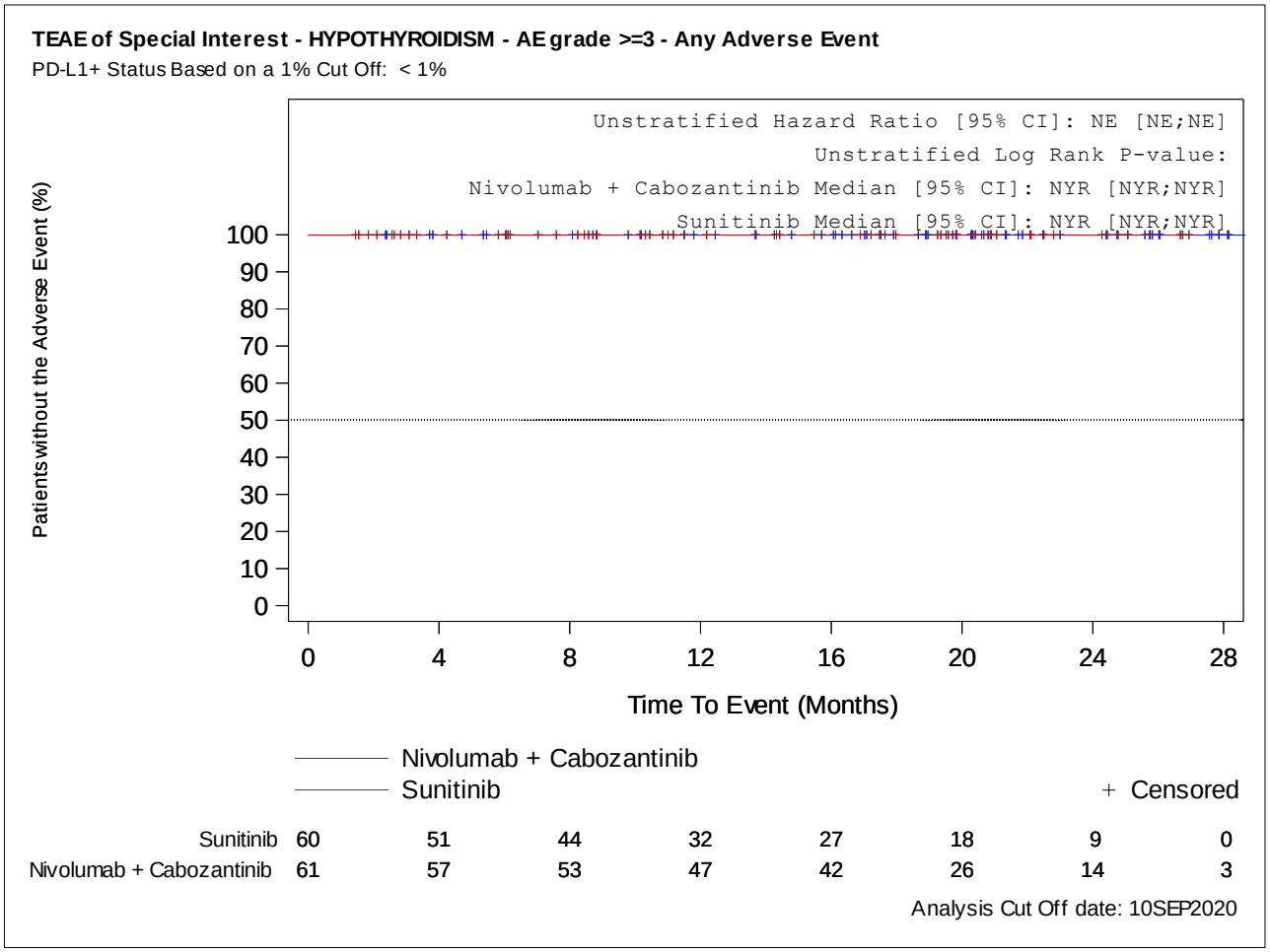
FIGURE 3.103.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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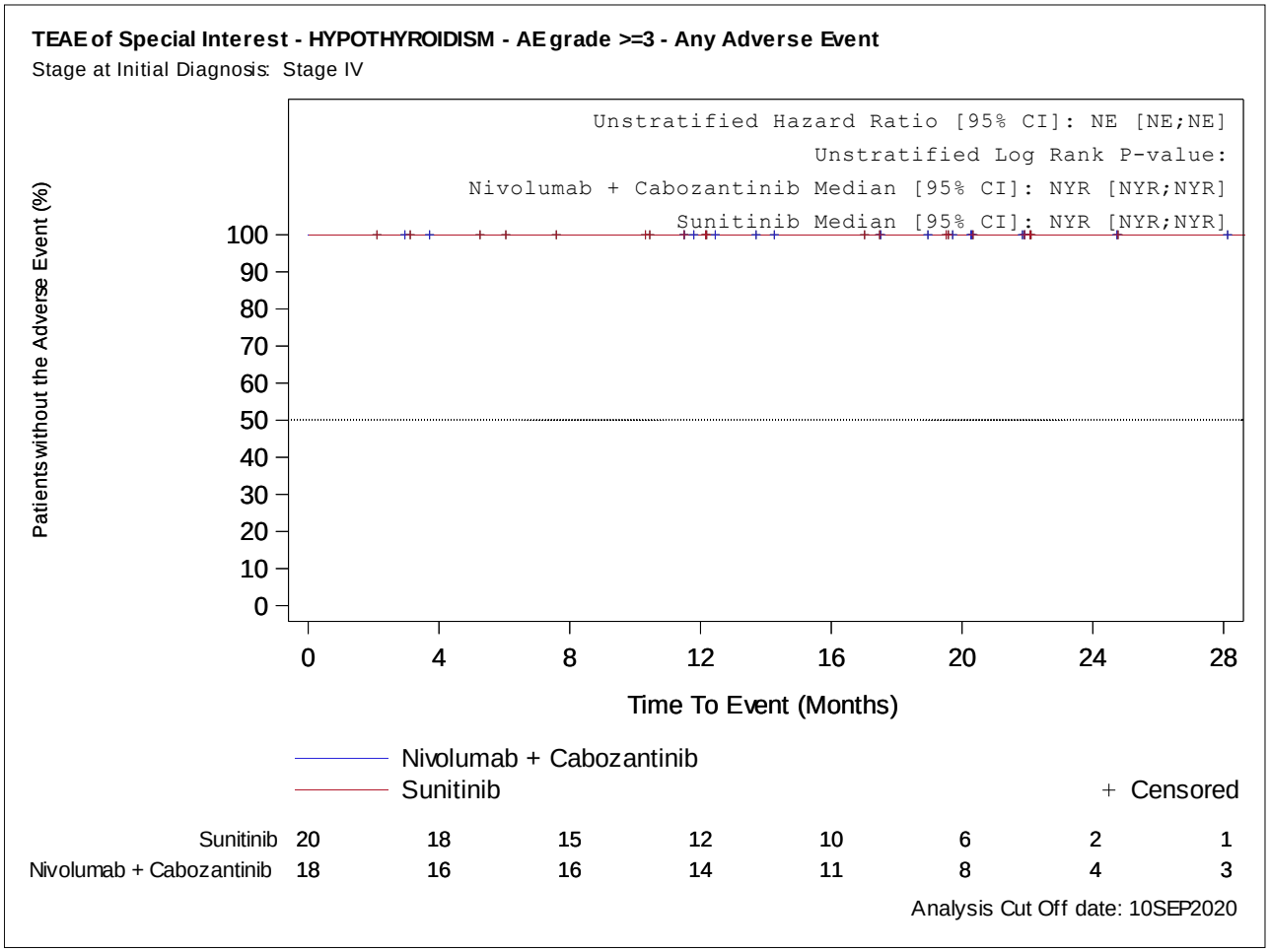
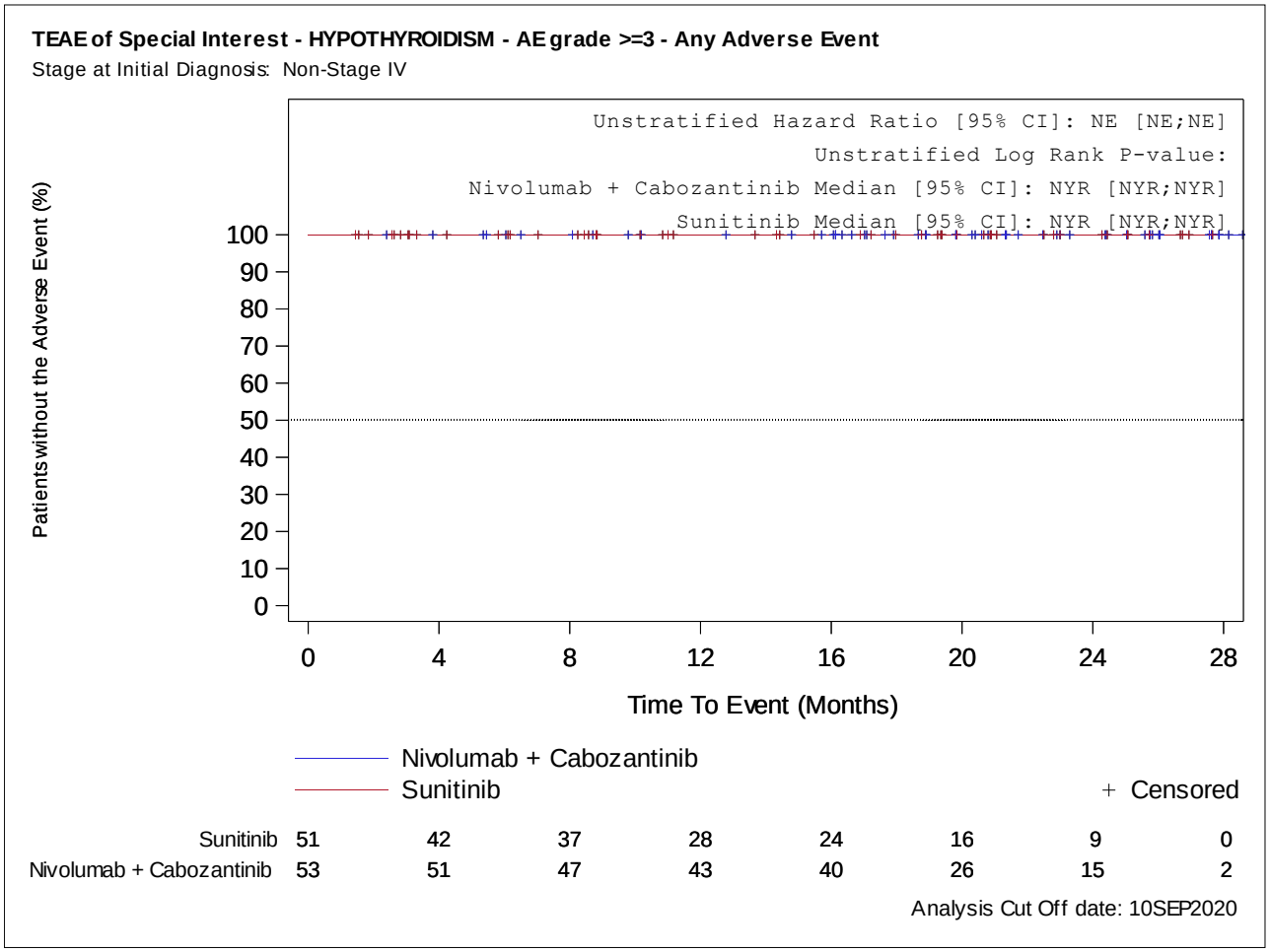
FIGURE 3.103.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:50:01

FIGURE 3.103.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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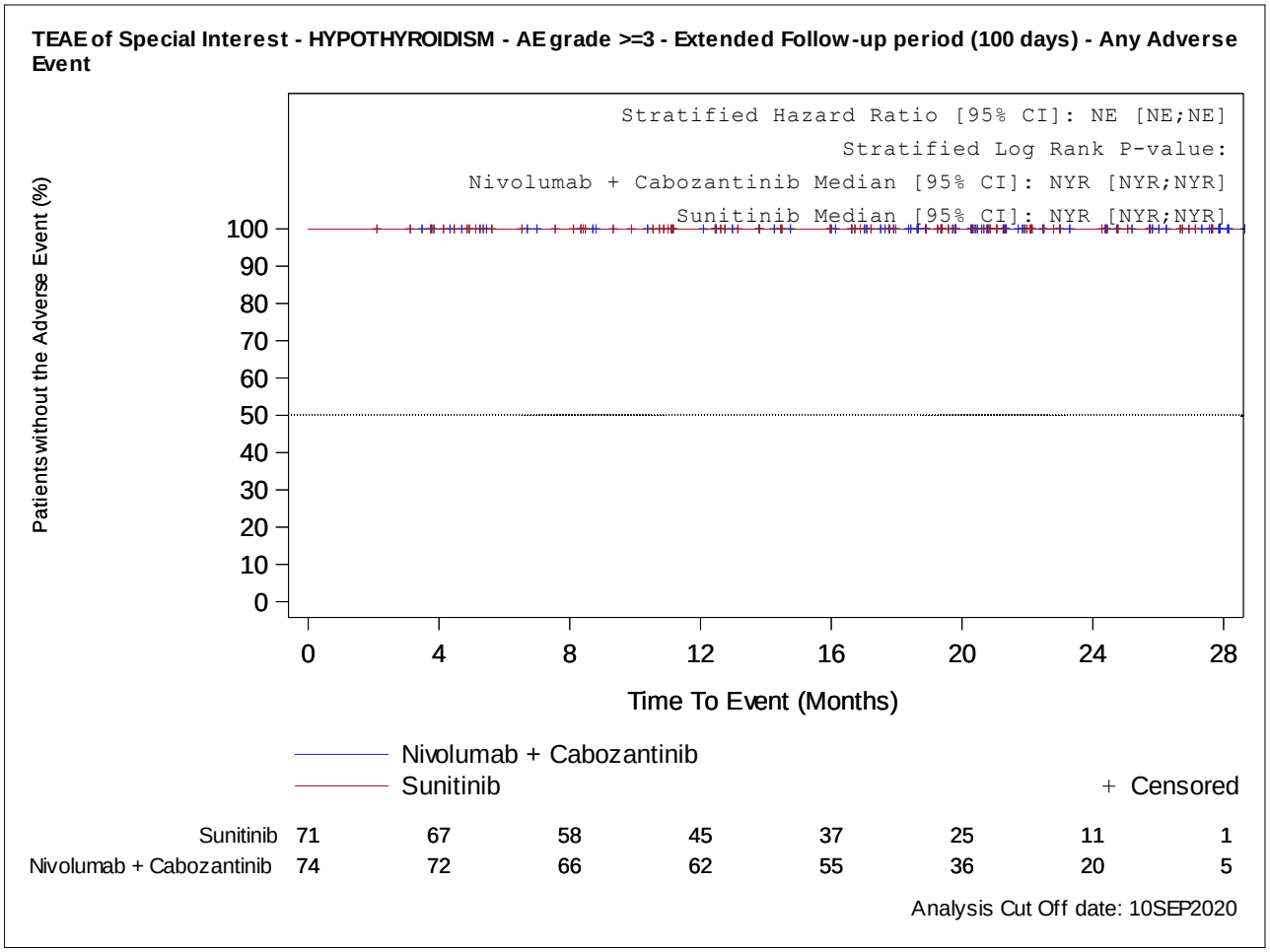
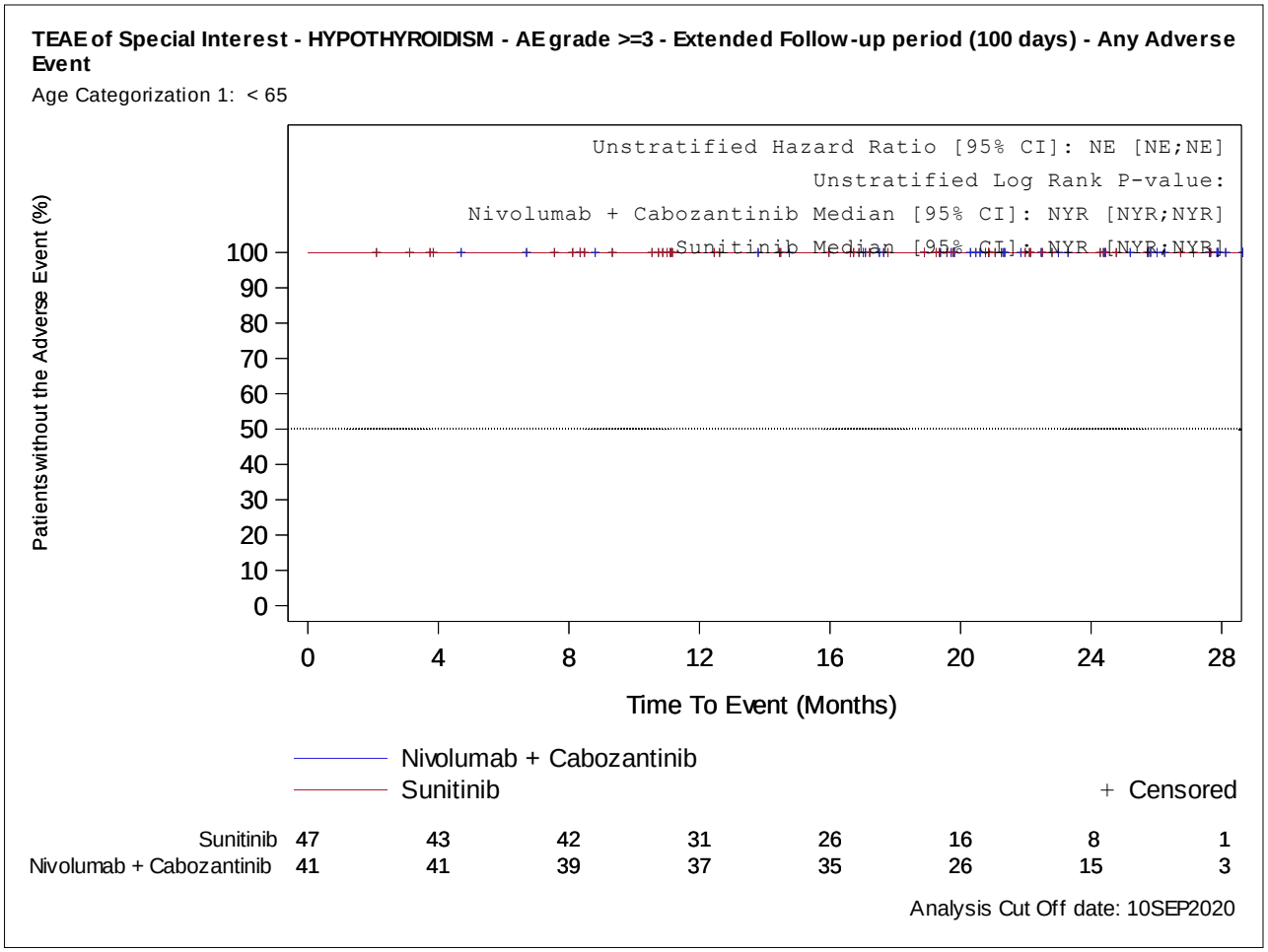
FIGURE 3.104.1: TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



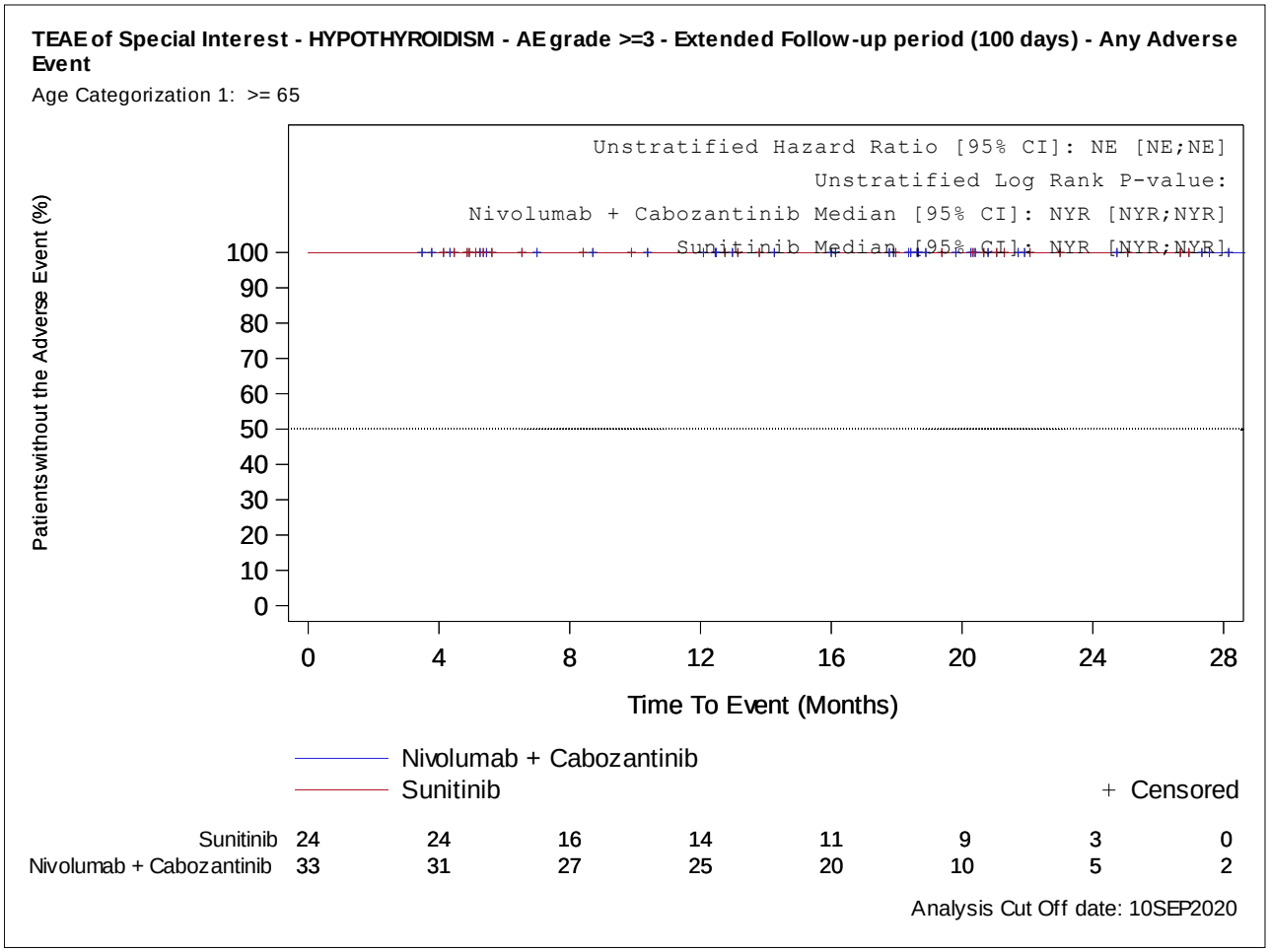

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:53:02

FIGURE 3.104.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



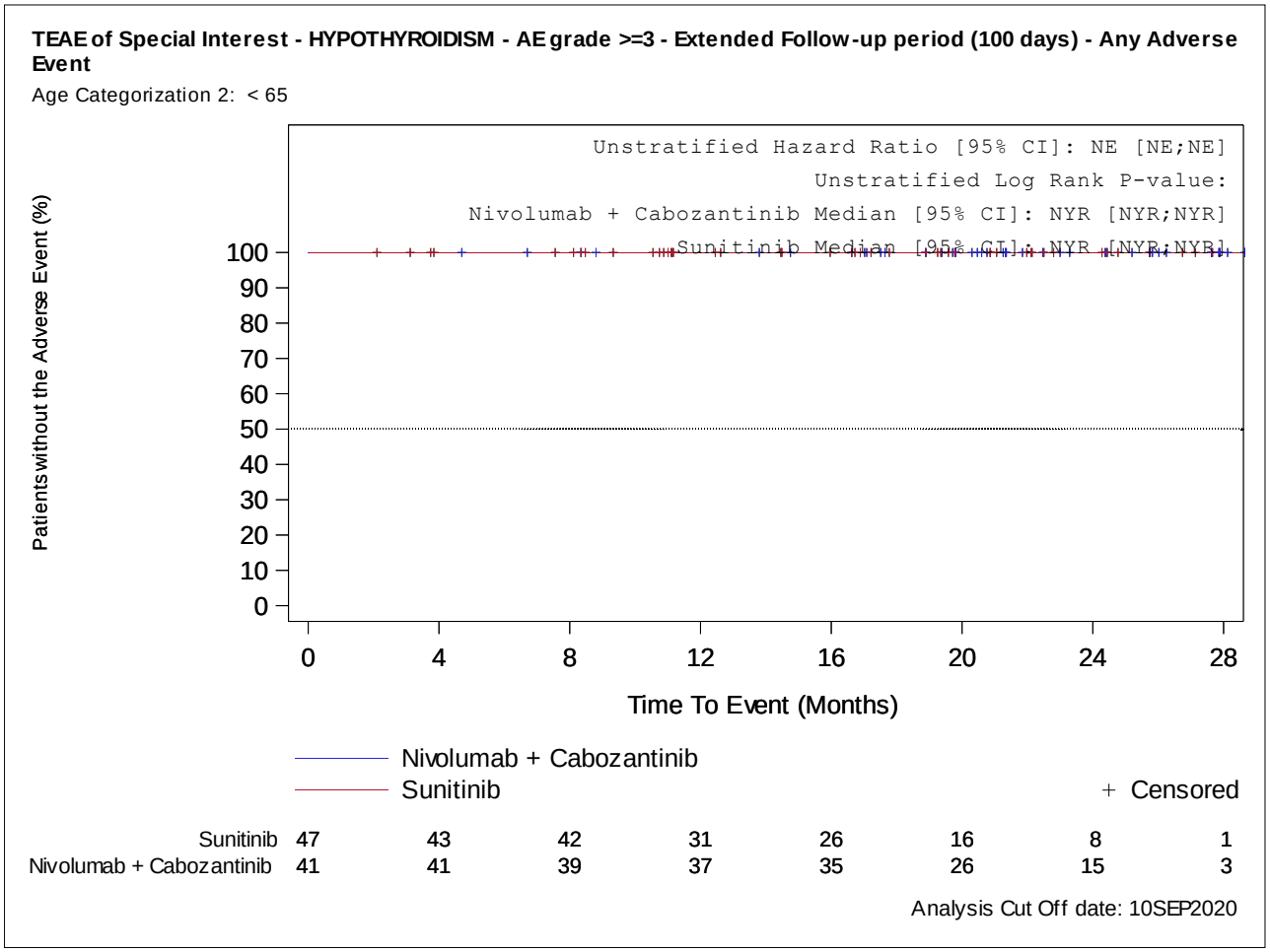

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:53:05

FIGURE 3.104.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:53:10

FIGURE 3.104.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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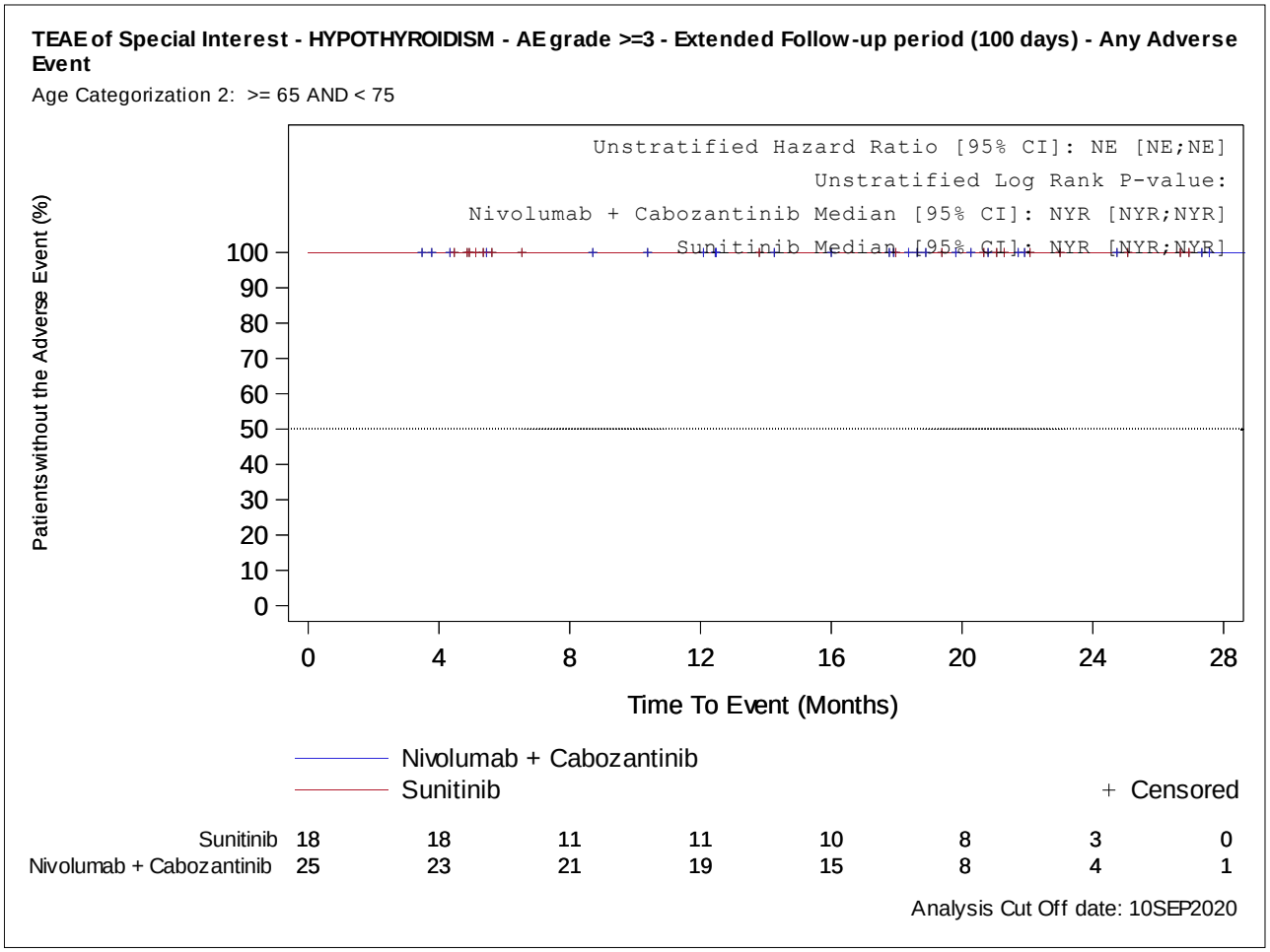
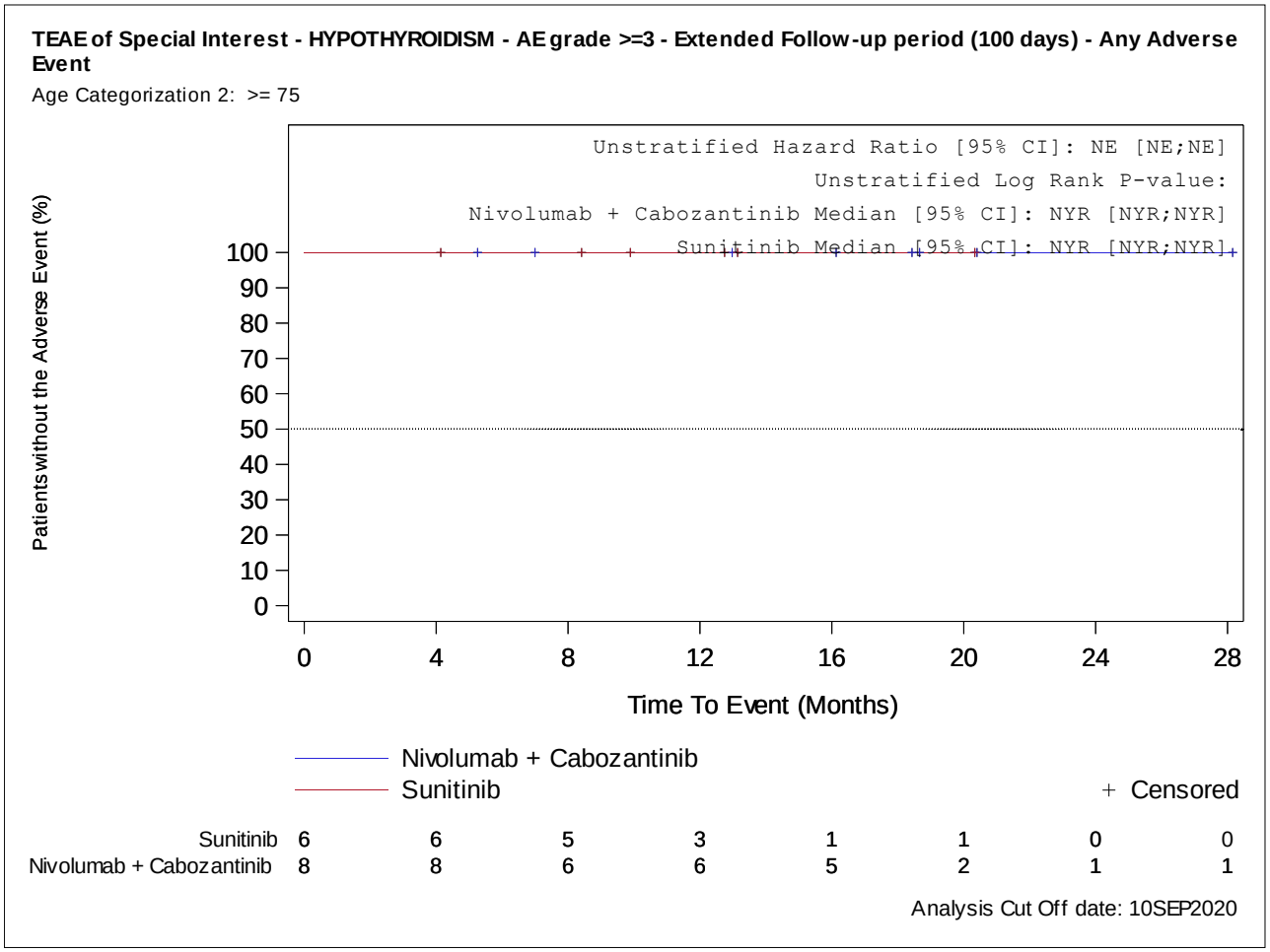
FIGURE 3.104.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



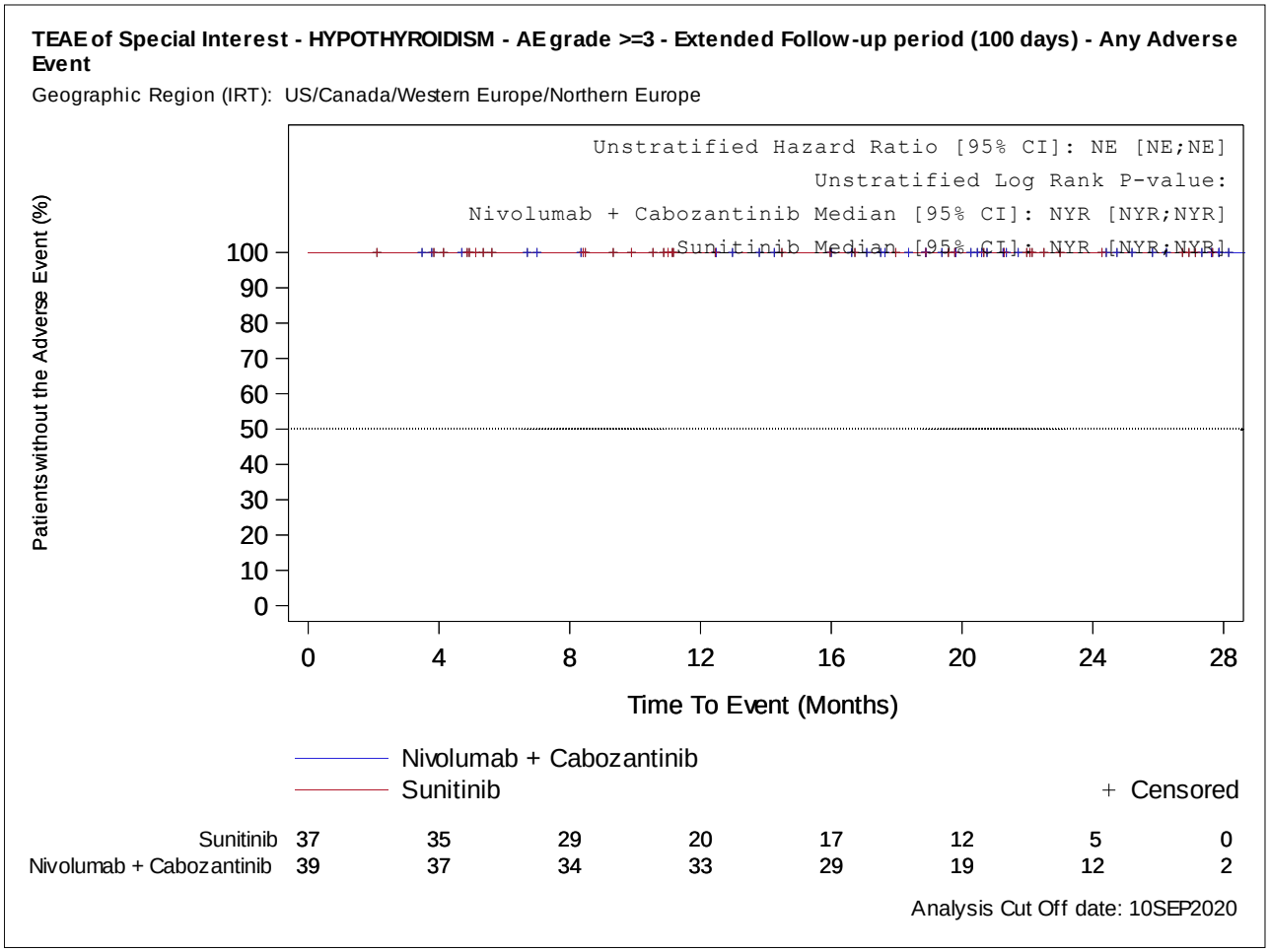

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:53:21

FIGURE 3.104.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:53:26

FIGURE 3.104.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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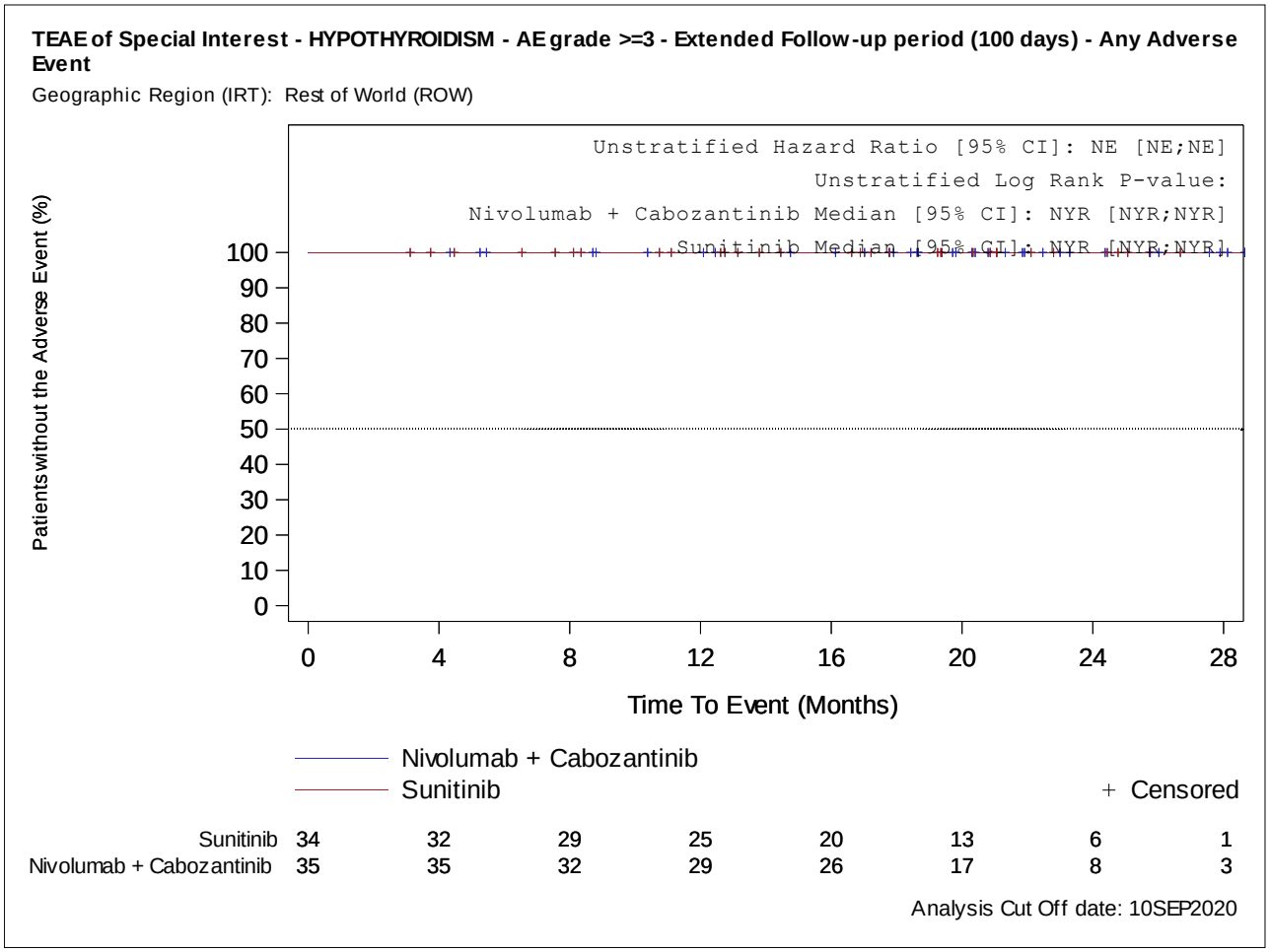
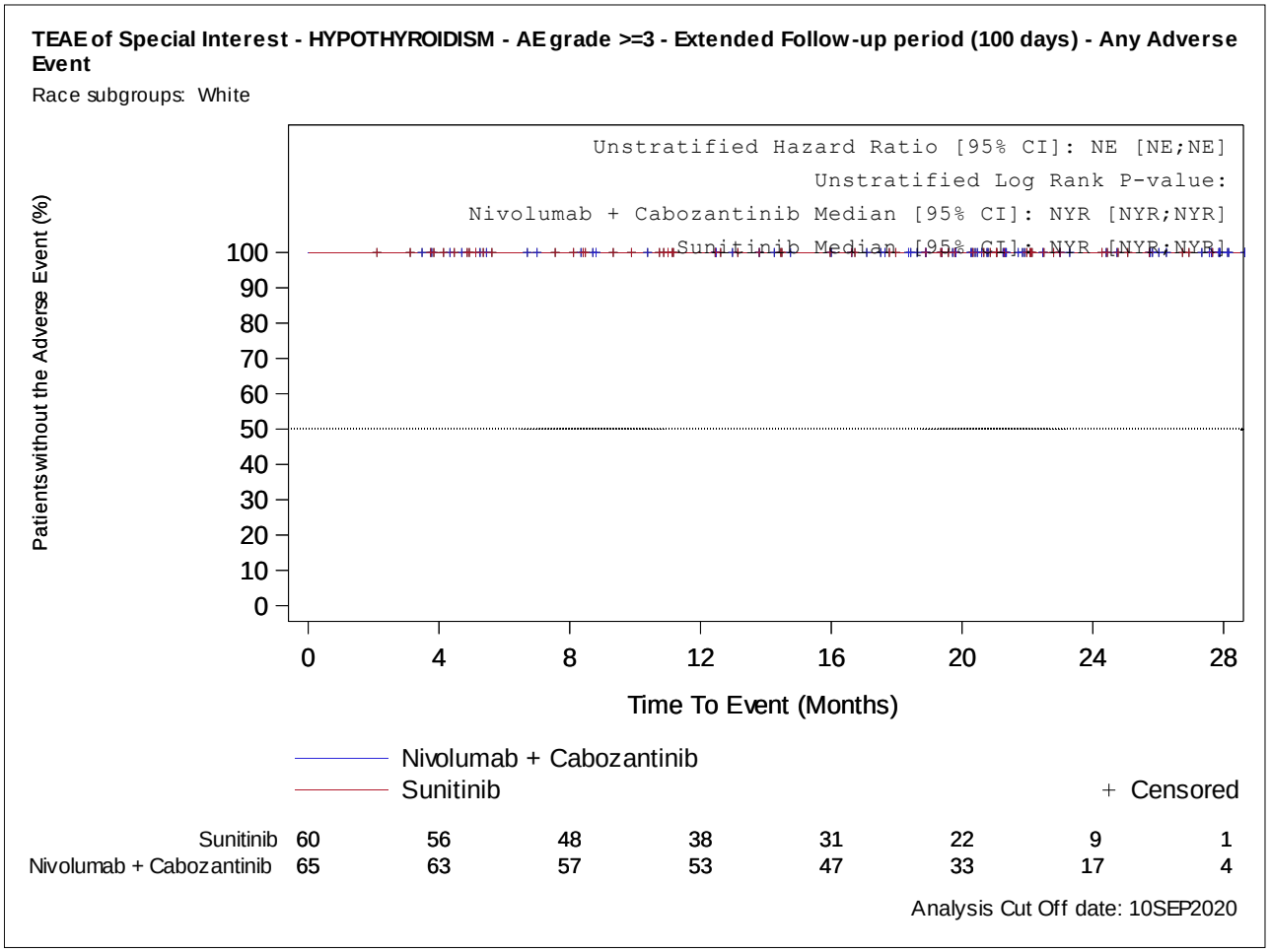
FIGURE 3.104.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



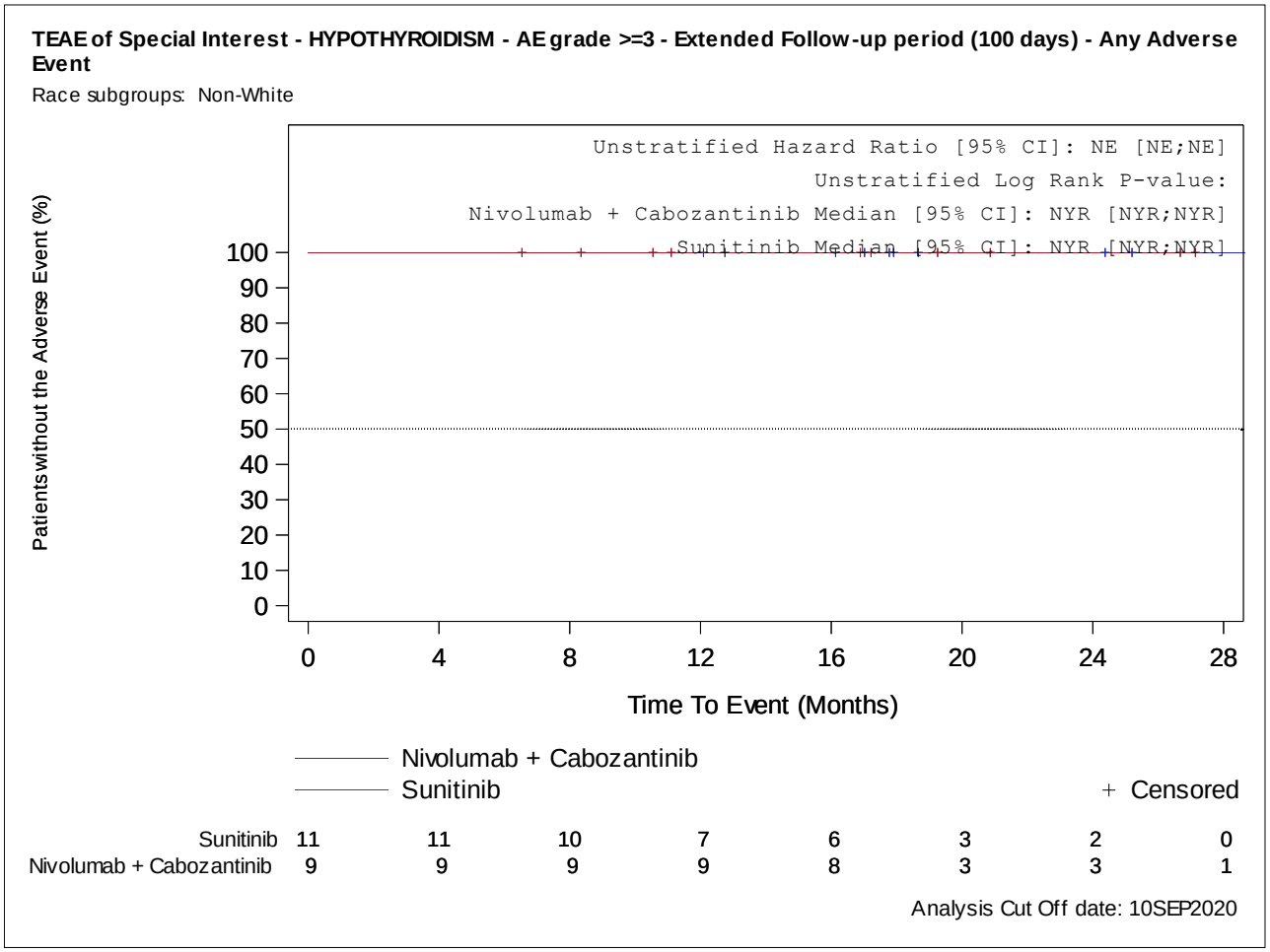

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:53:37

FIGURE 3.104.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



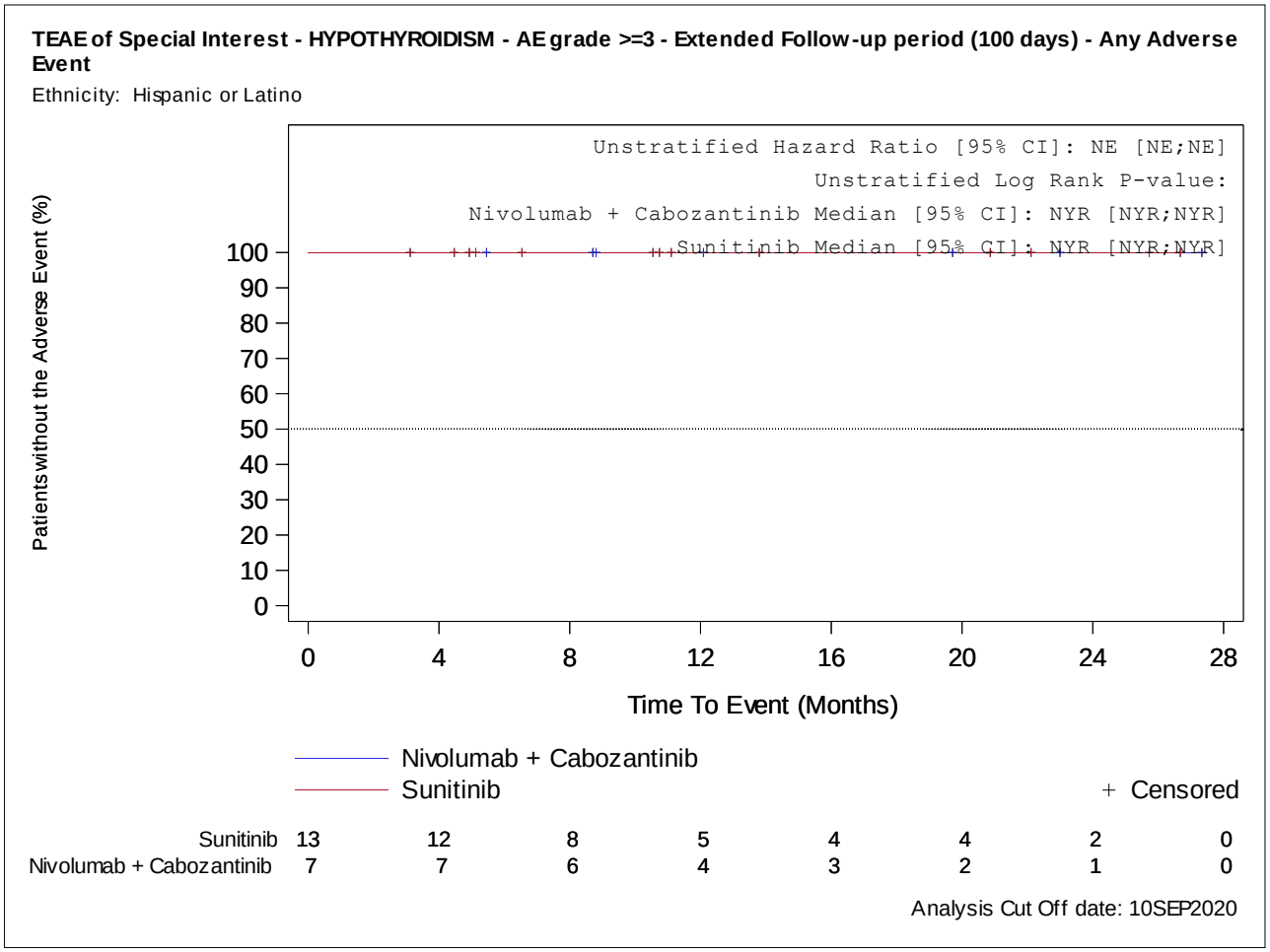

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:53:42

FIGURE 3.104.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:53:47

FIGURE 3.104.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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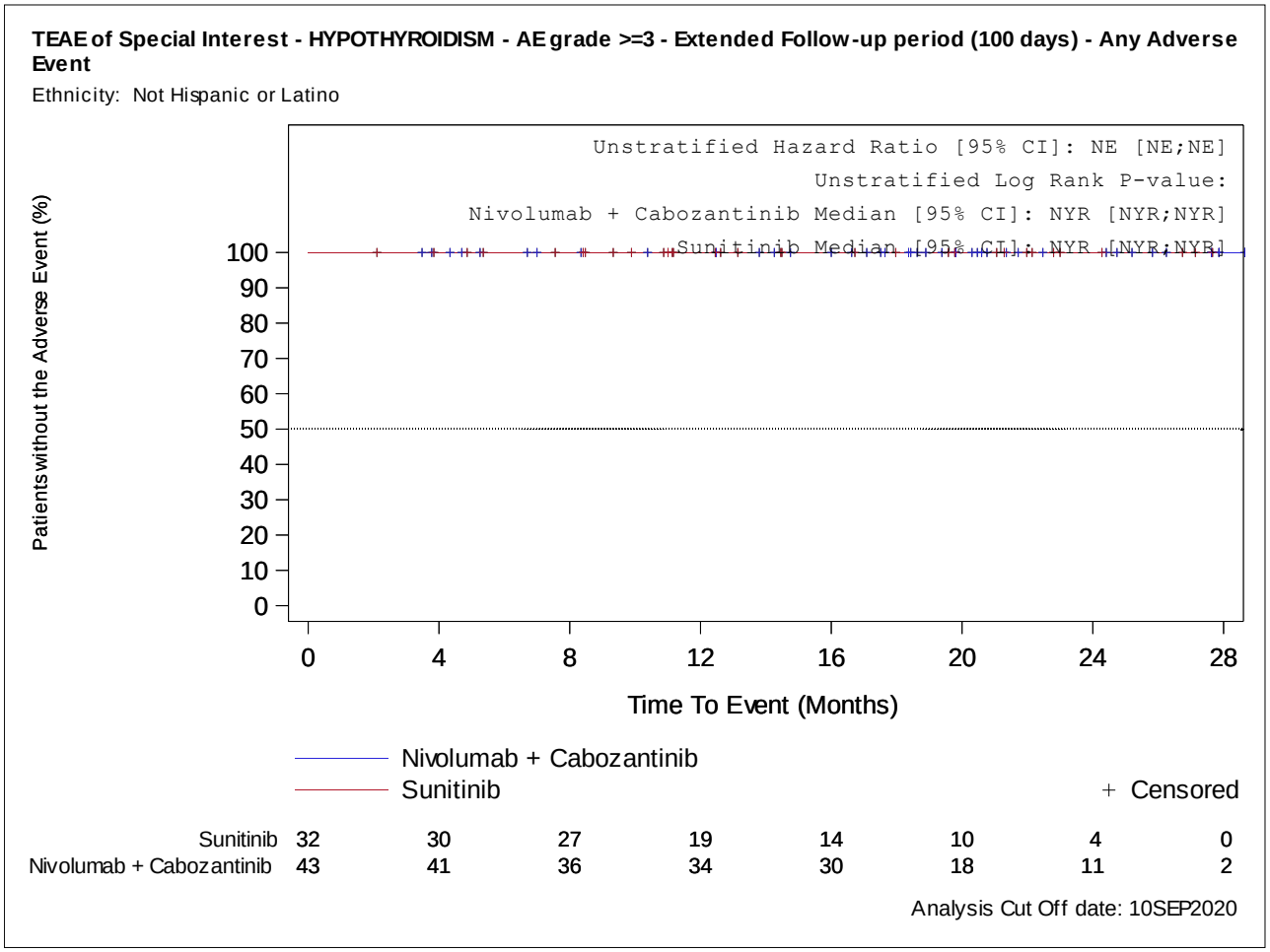
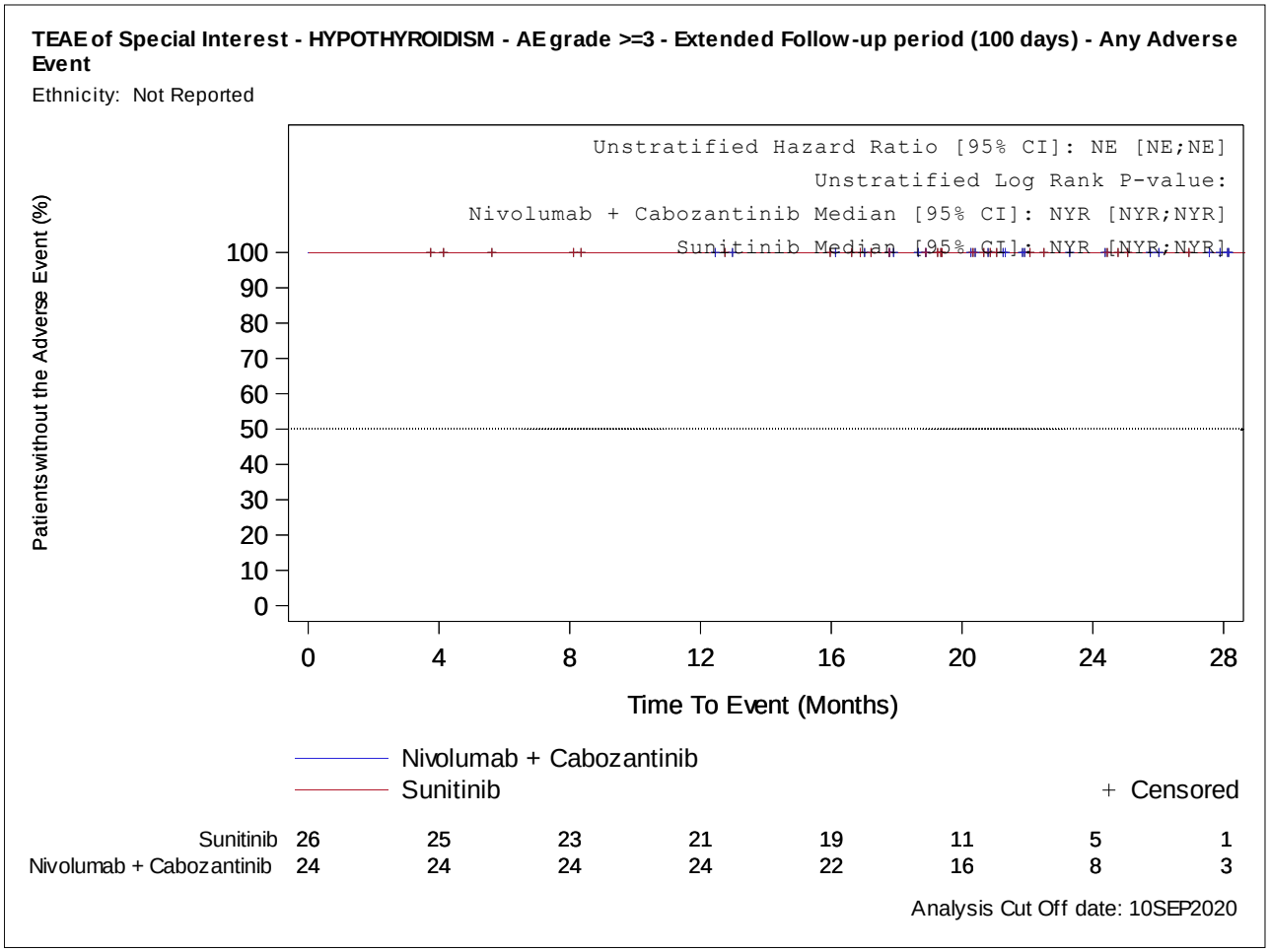
FIGURE 3.104.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



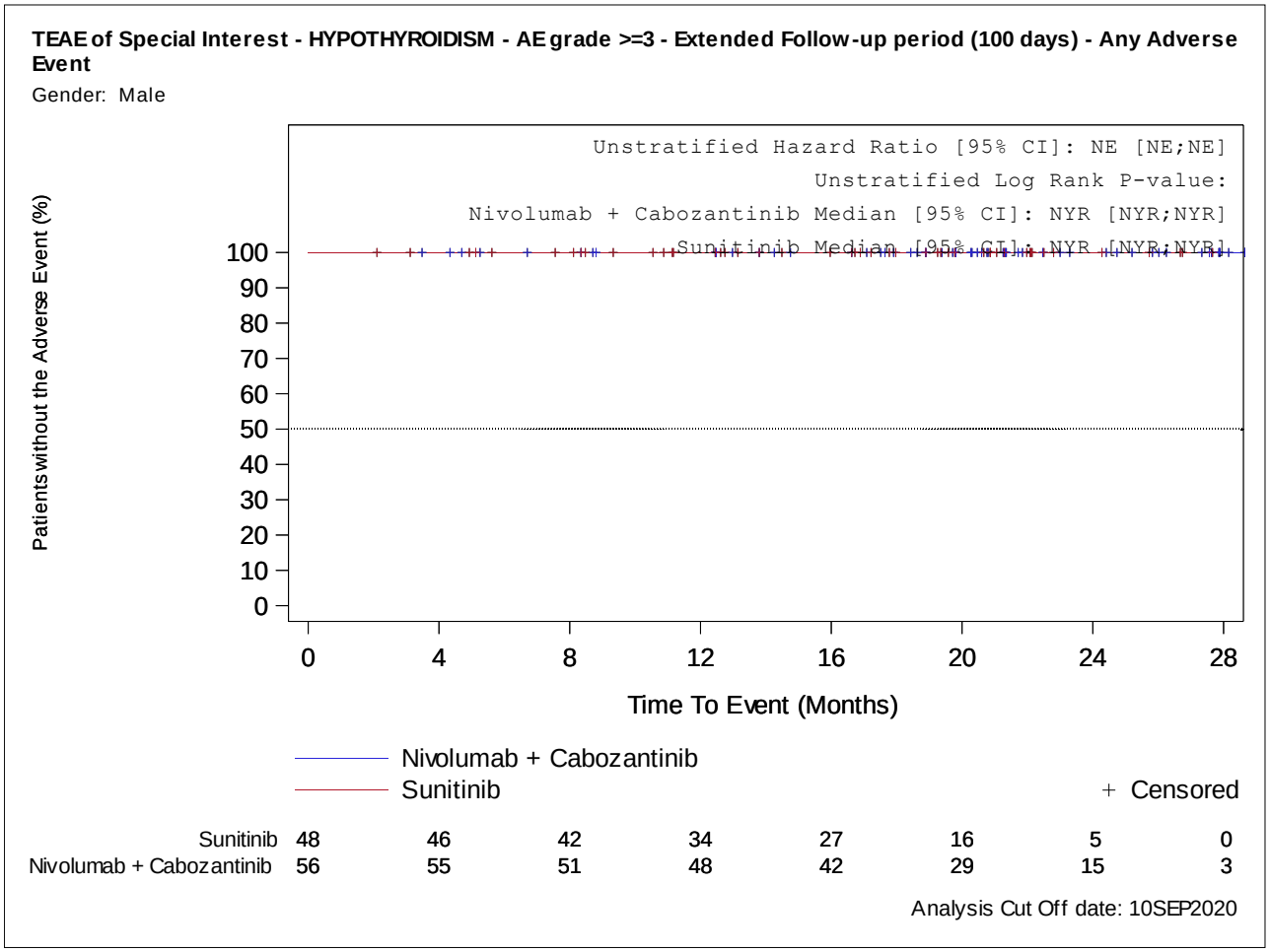

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:53:58

FIGURE 3.104.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



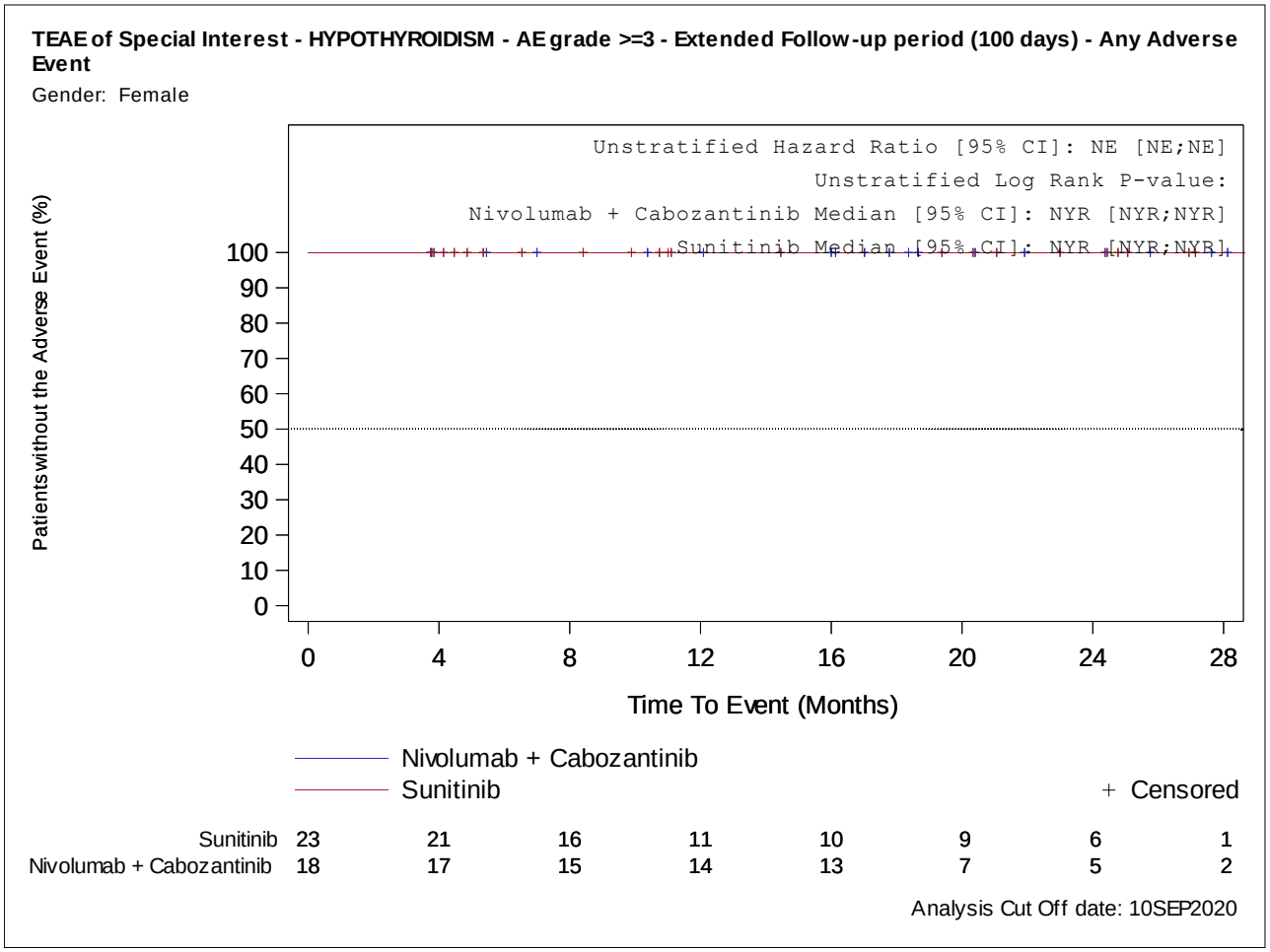

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:54:03

FIGURE 3.104.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



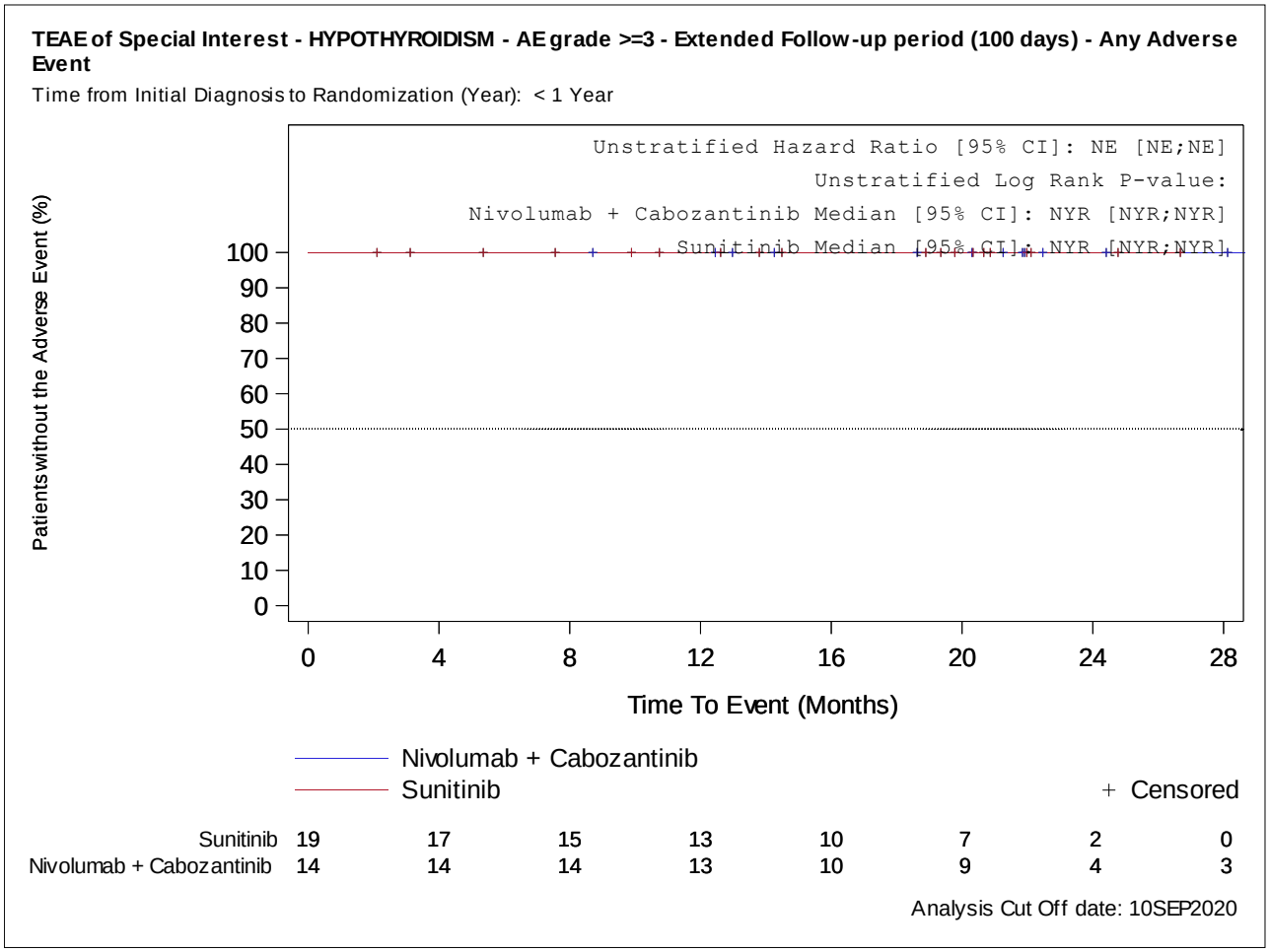

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:54:08

FIGURE 3.104.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



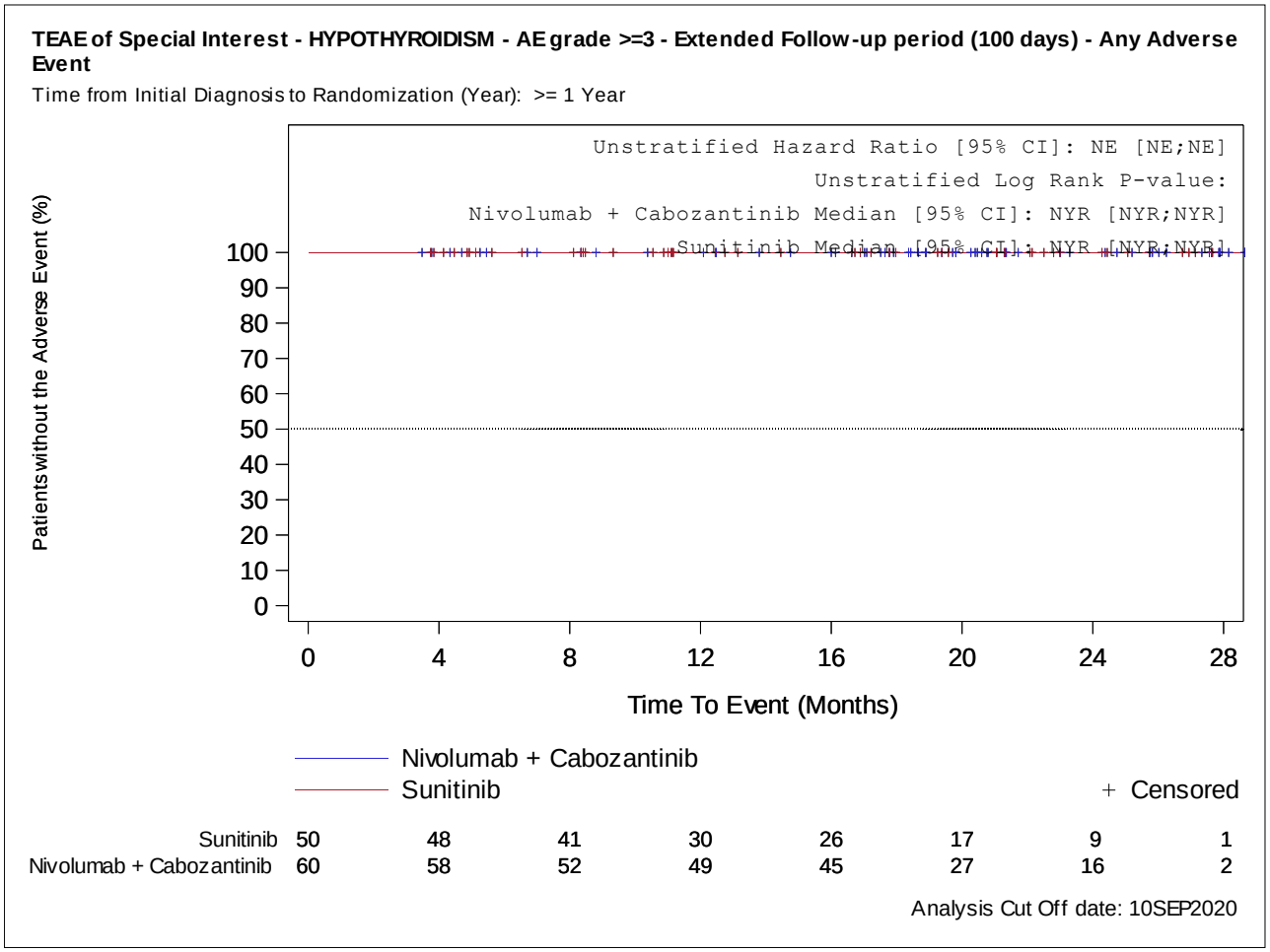

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:54:13

FIGURE 3.104.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



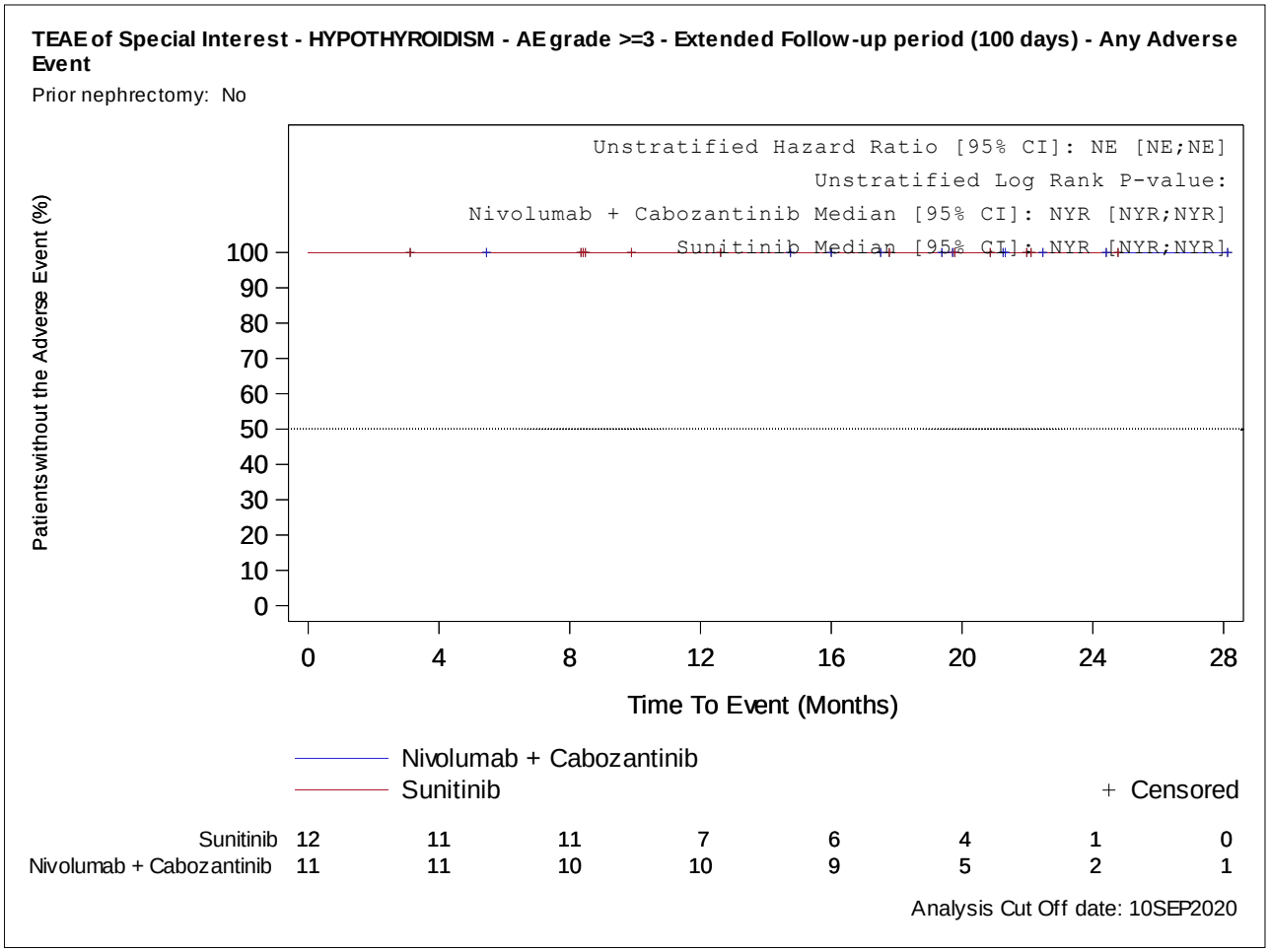

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:54:29

FIGURE 3.104.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



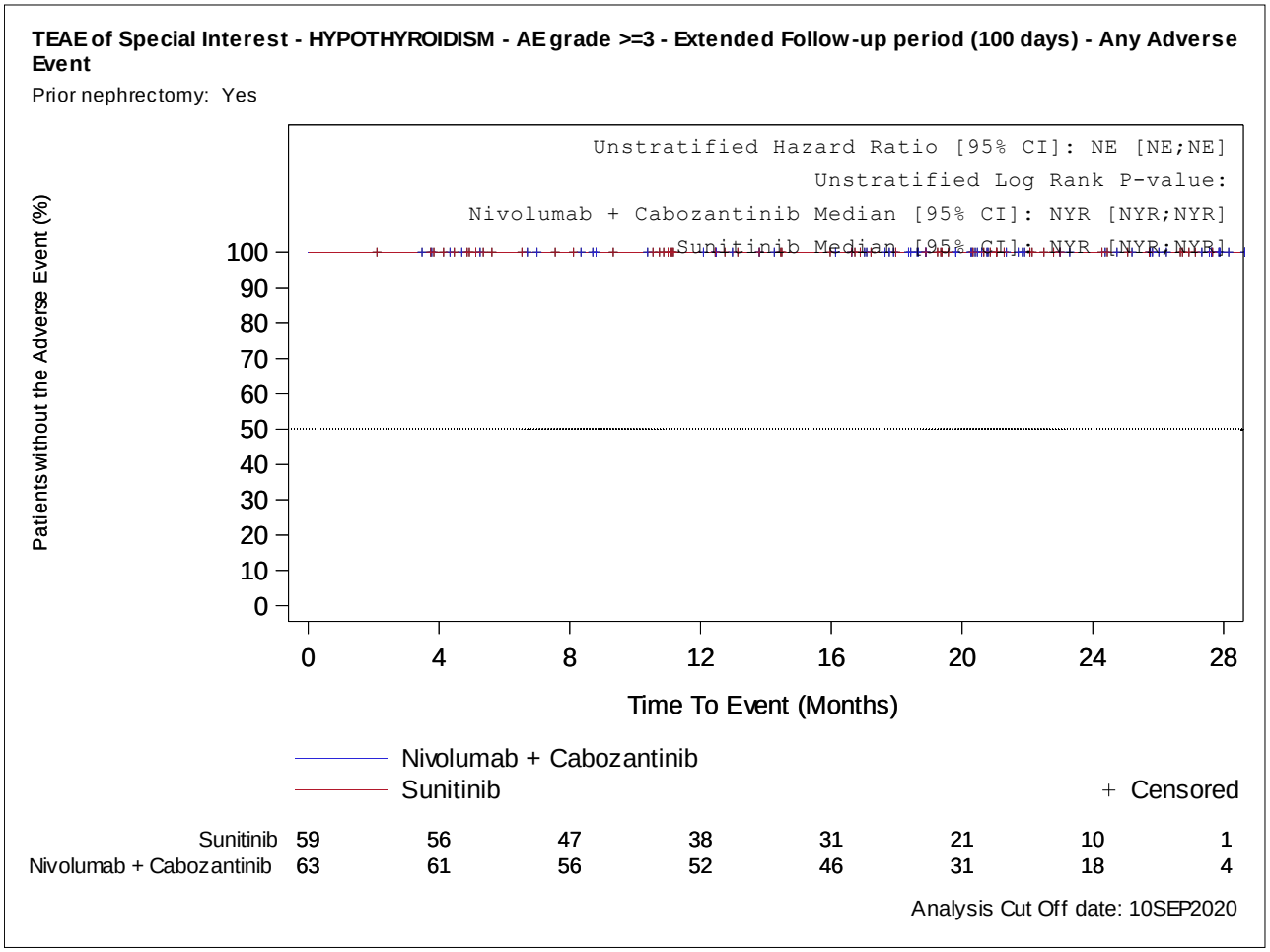

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:54:34

FIGURE 3.104.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:55:22

FIGURE 3.104.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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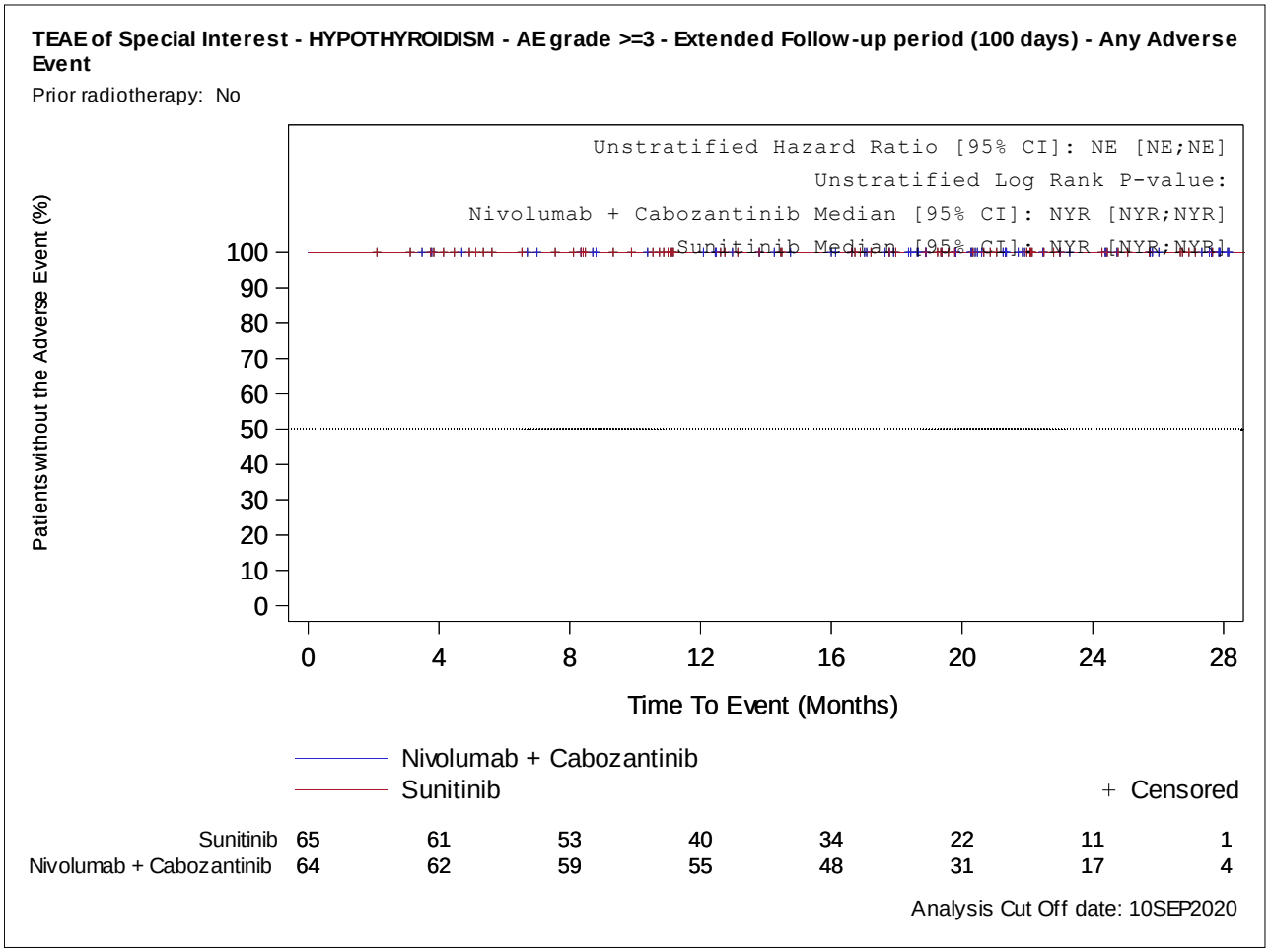
FIGURE 3.104.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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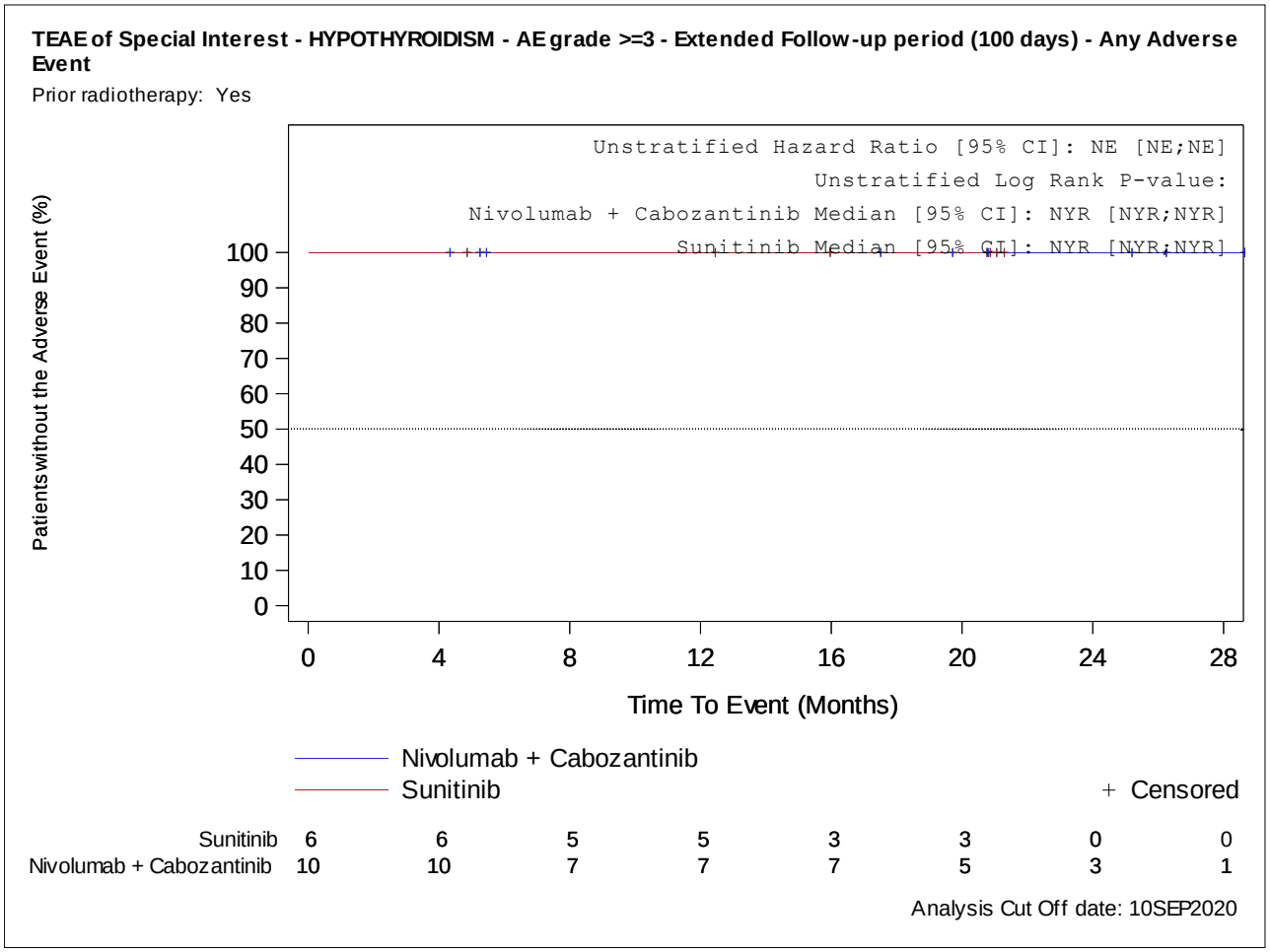
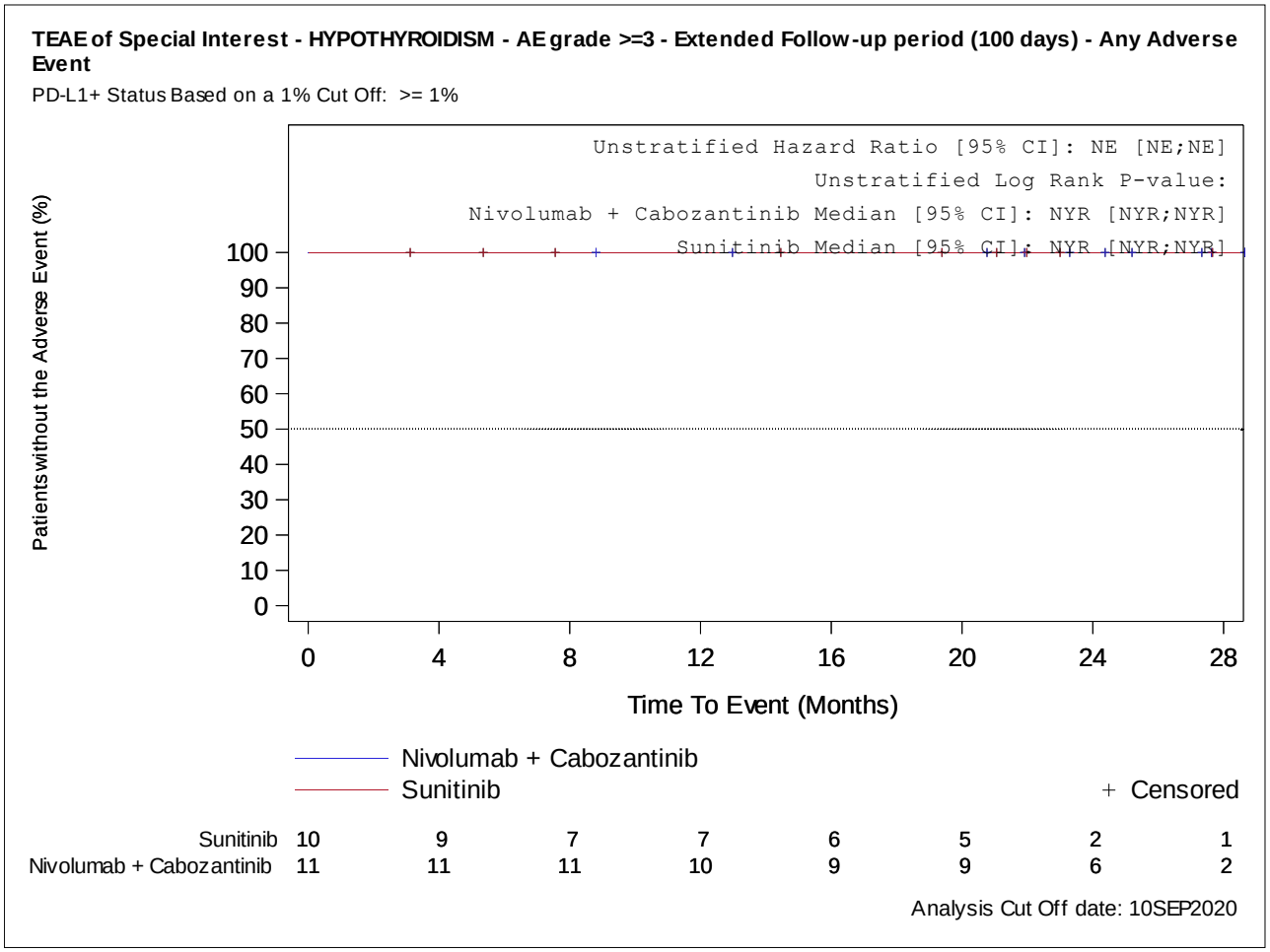
FIGURE 3.104.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



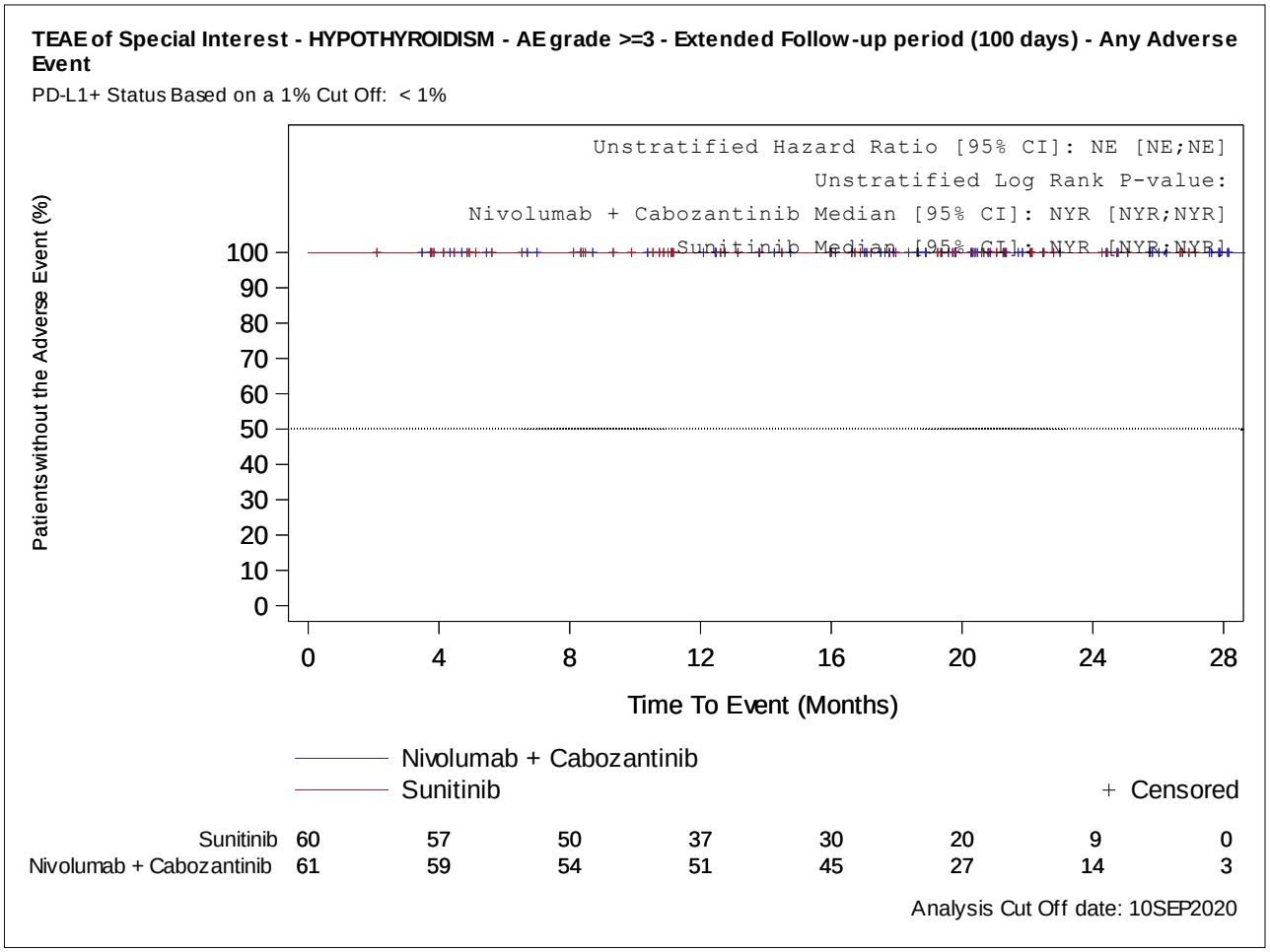

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:55:37

FIGURE 3.104.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



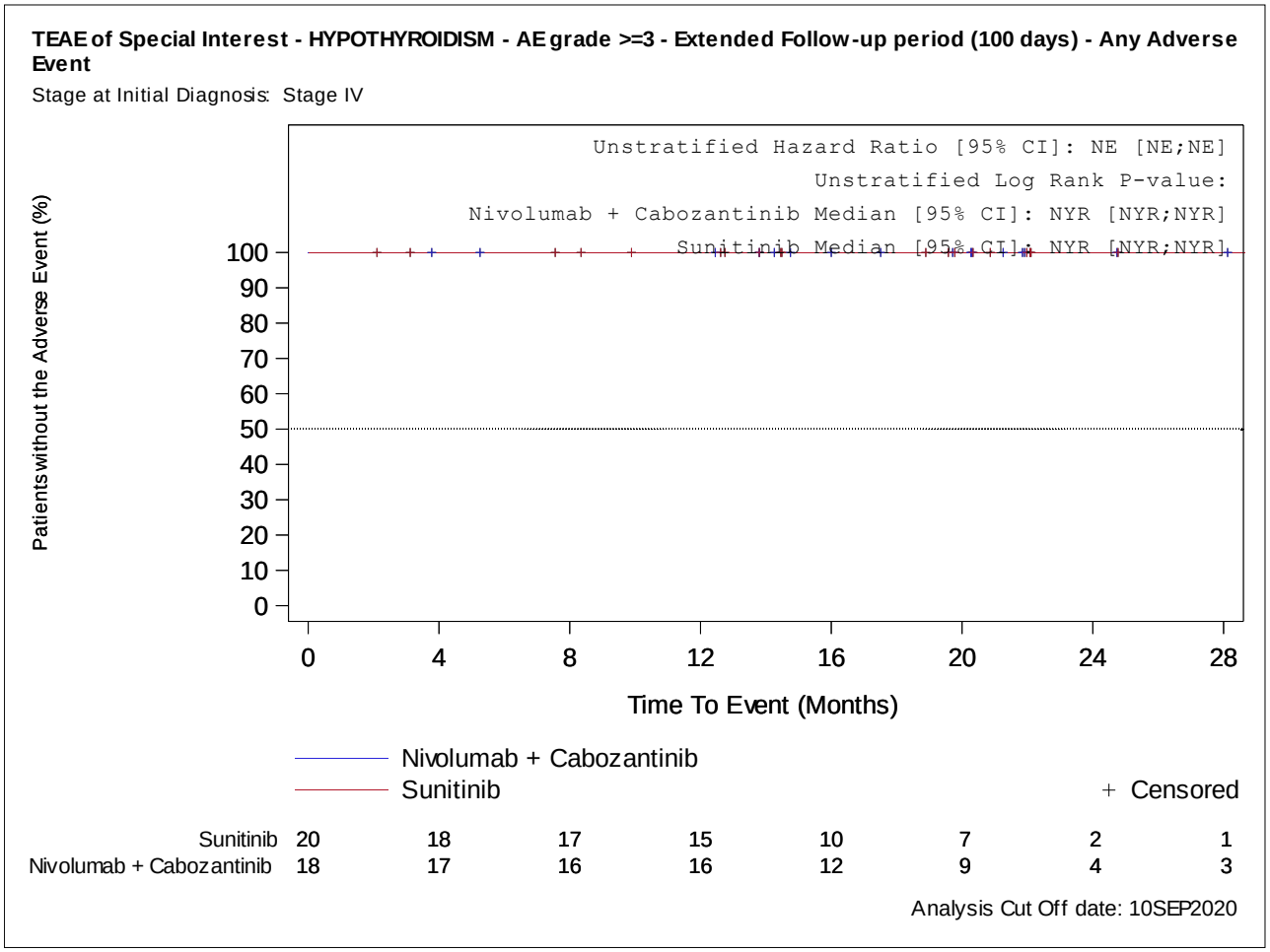

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:55:42

FIGURE 3.104.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



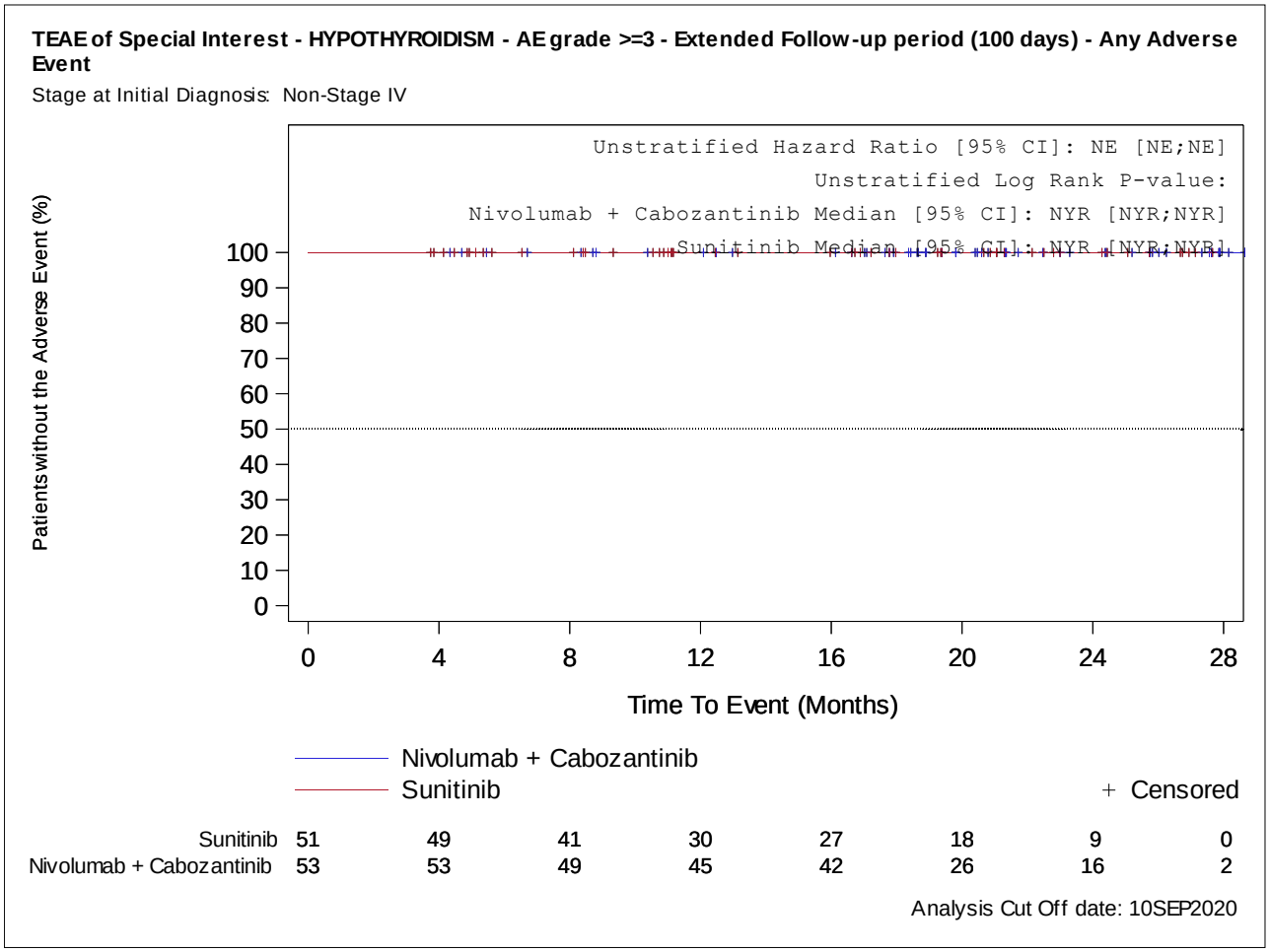

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:55:47

FIGURE 3.104.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:56:13

FIGURE 3.104.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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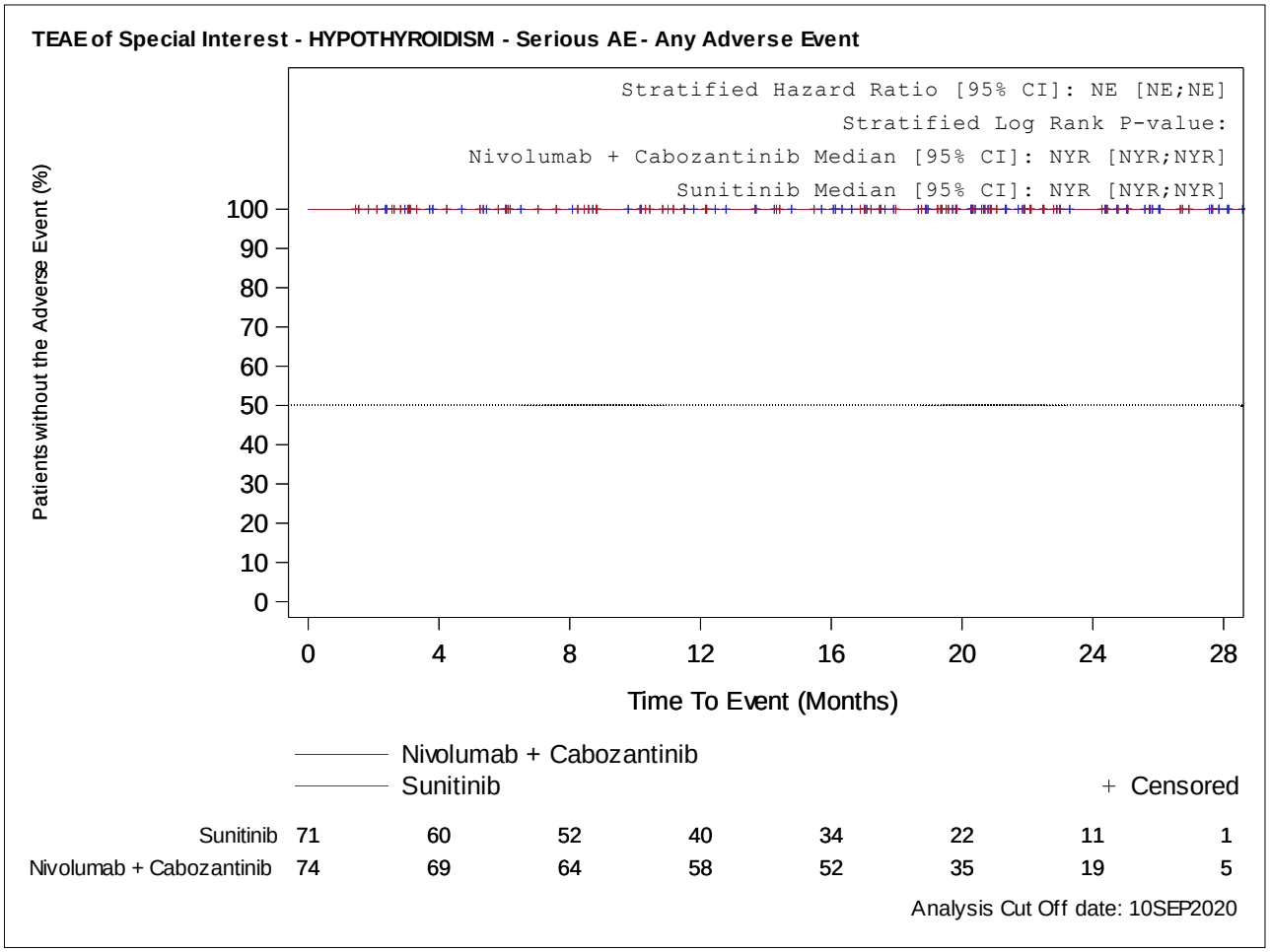
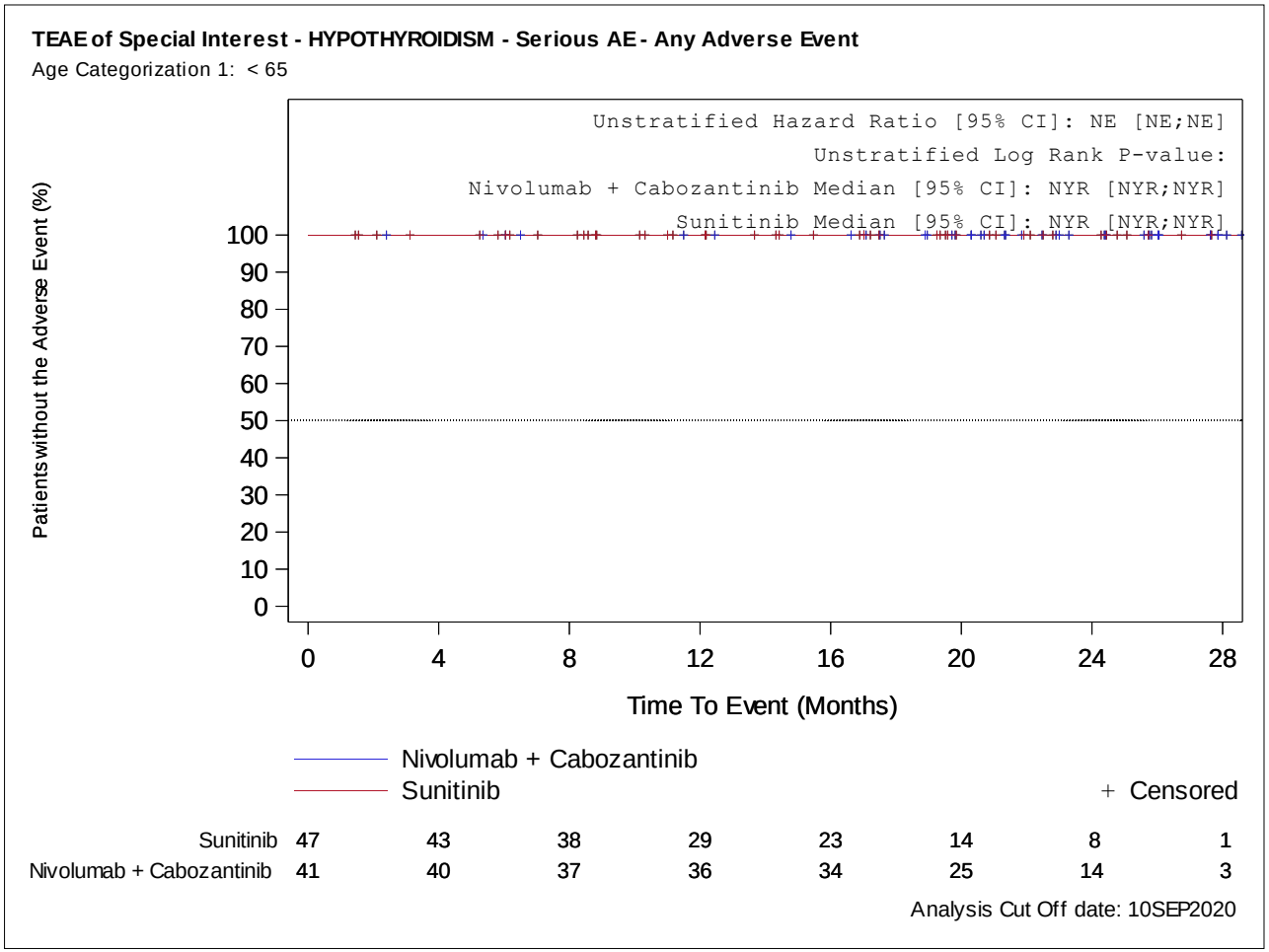
FIGURE 3.105.1: TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



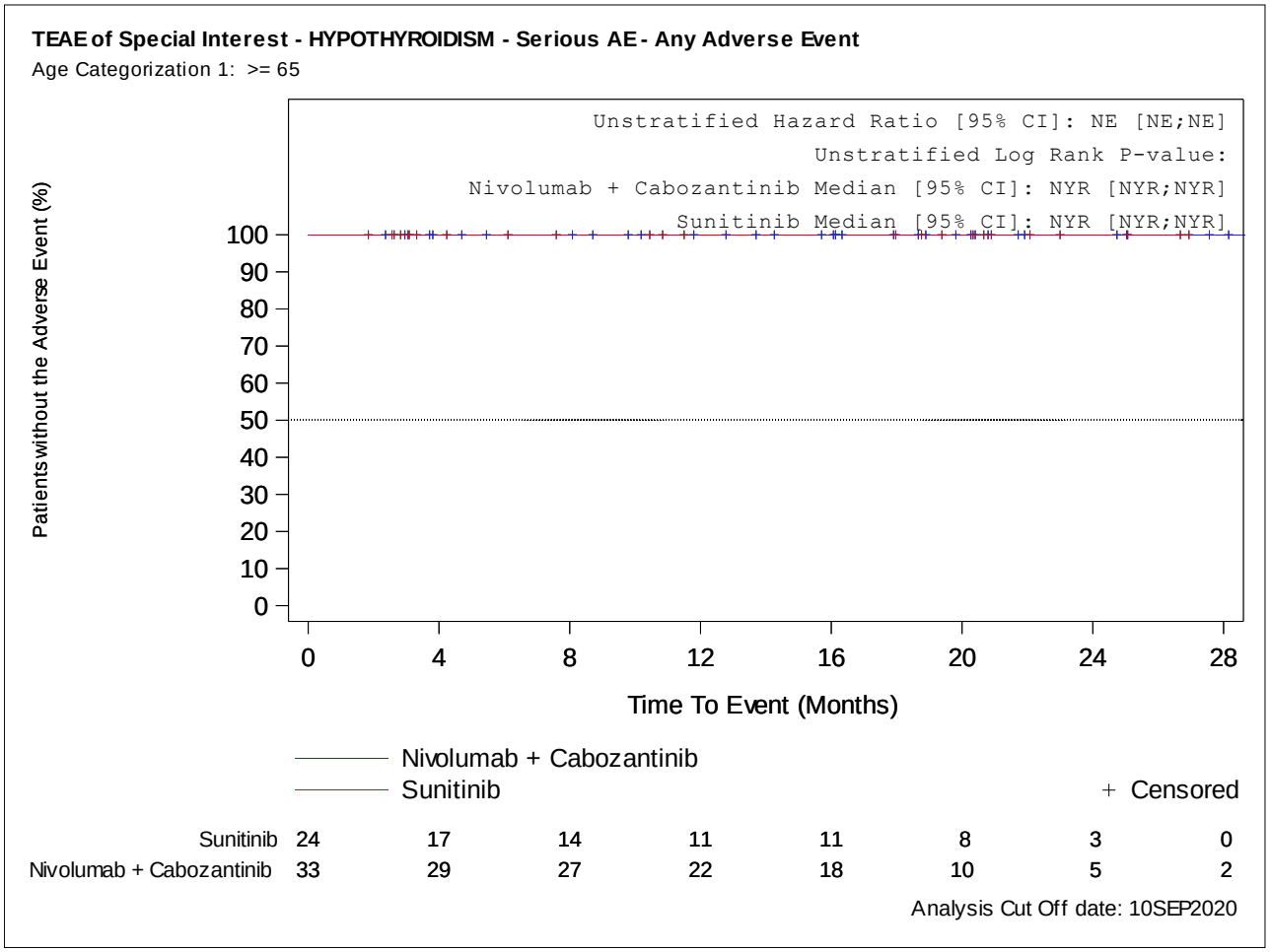

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:59:14

FIGURE 3.105.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:59:17

FIGURE 3.105.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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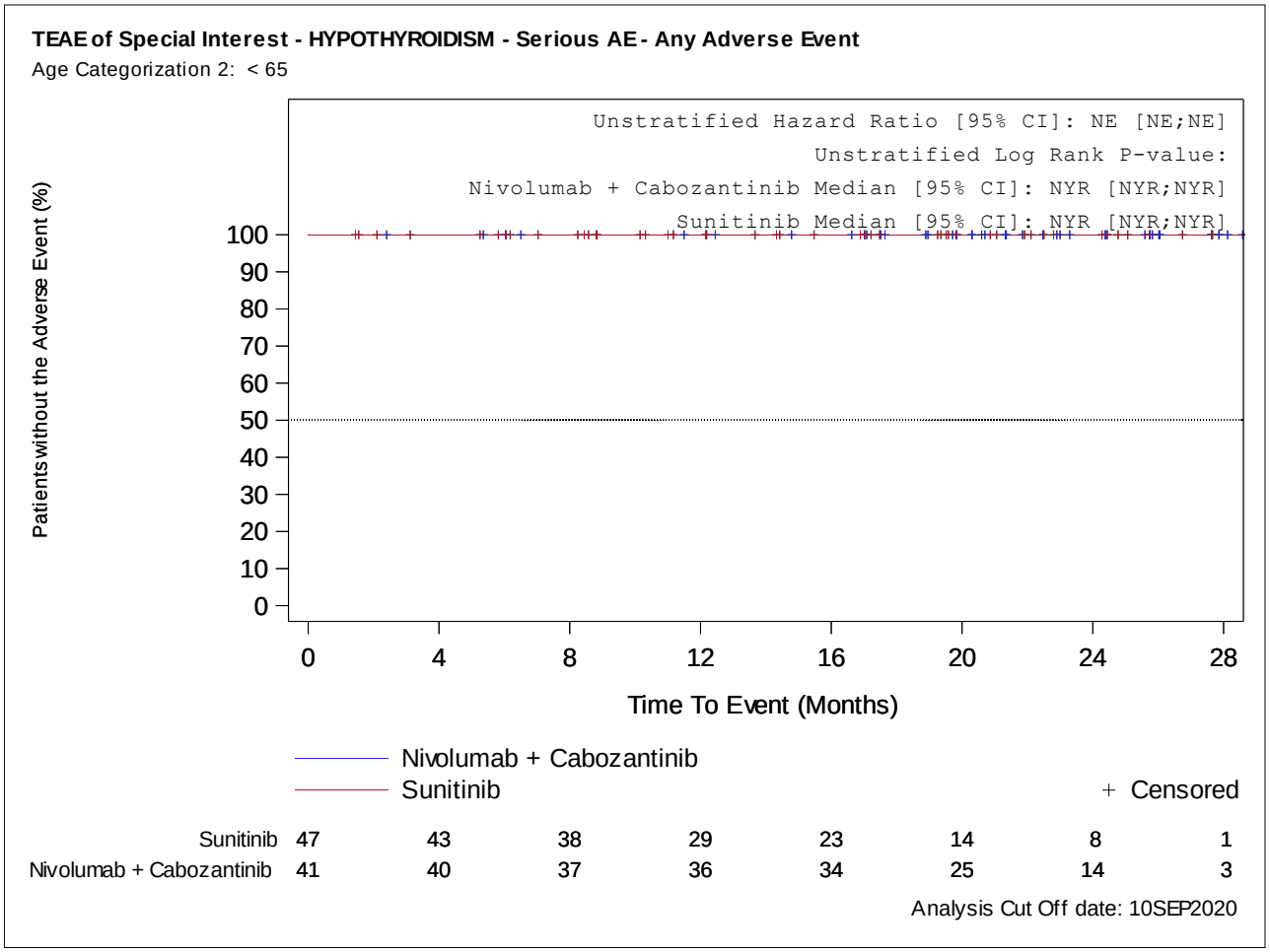
FIGURE 3.105.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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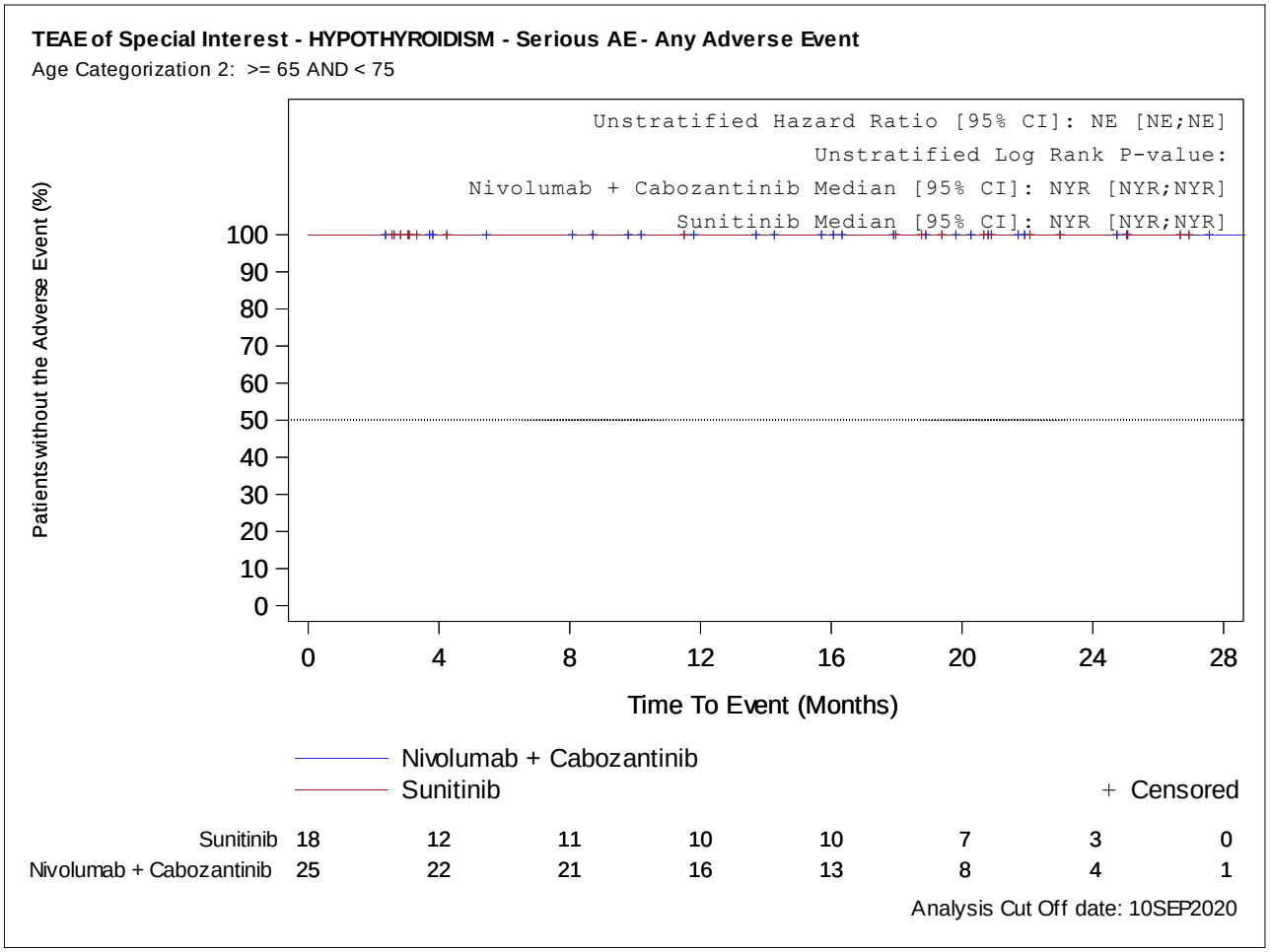
FIGURE 3.105.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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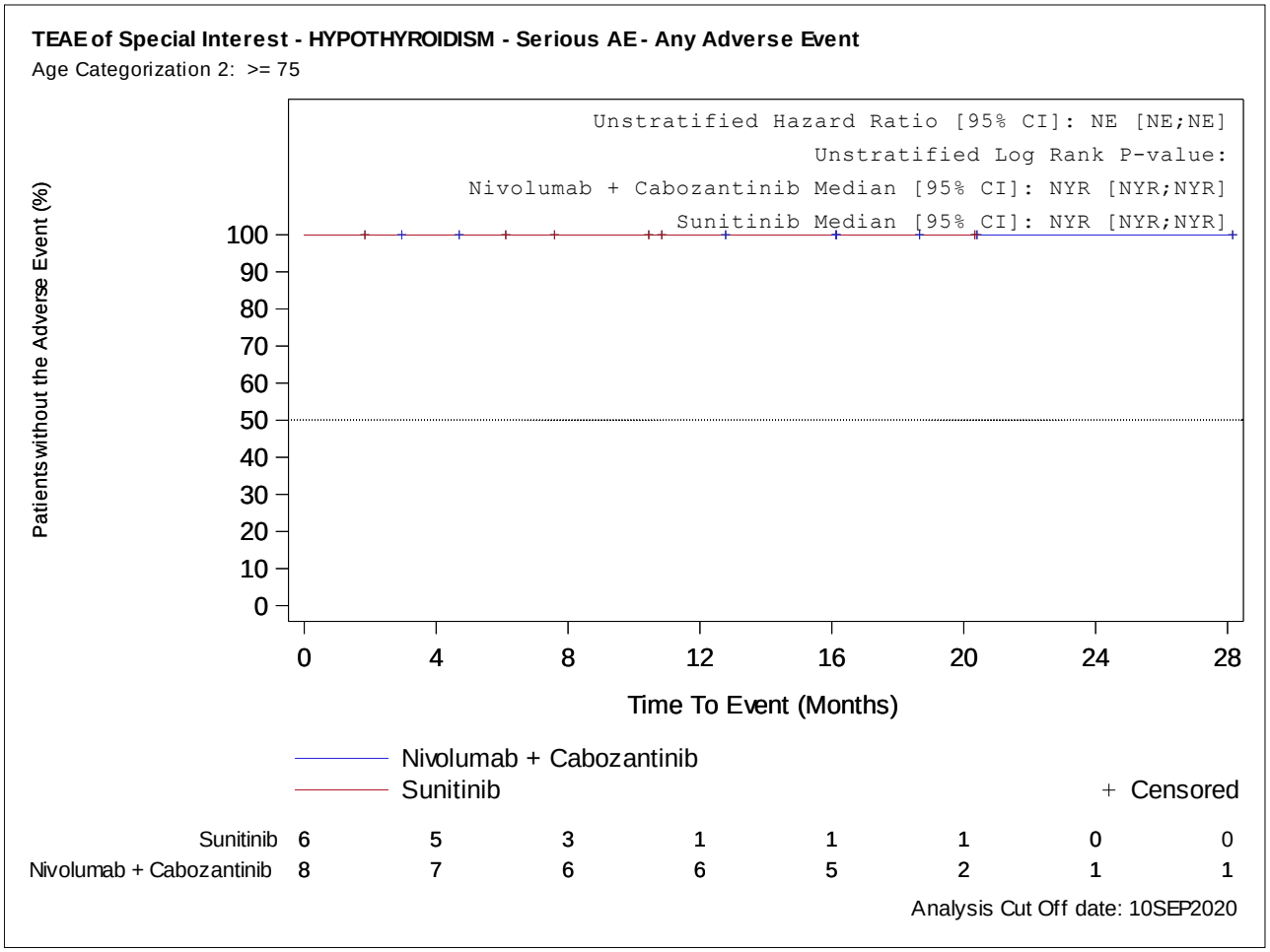
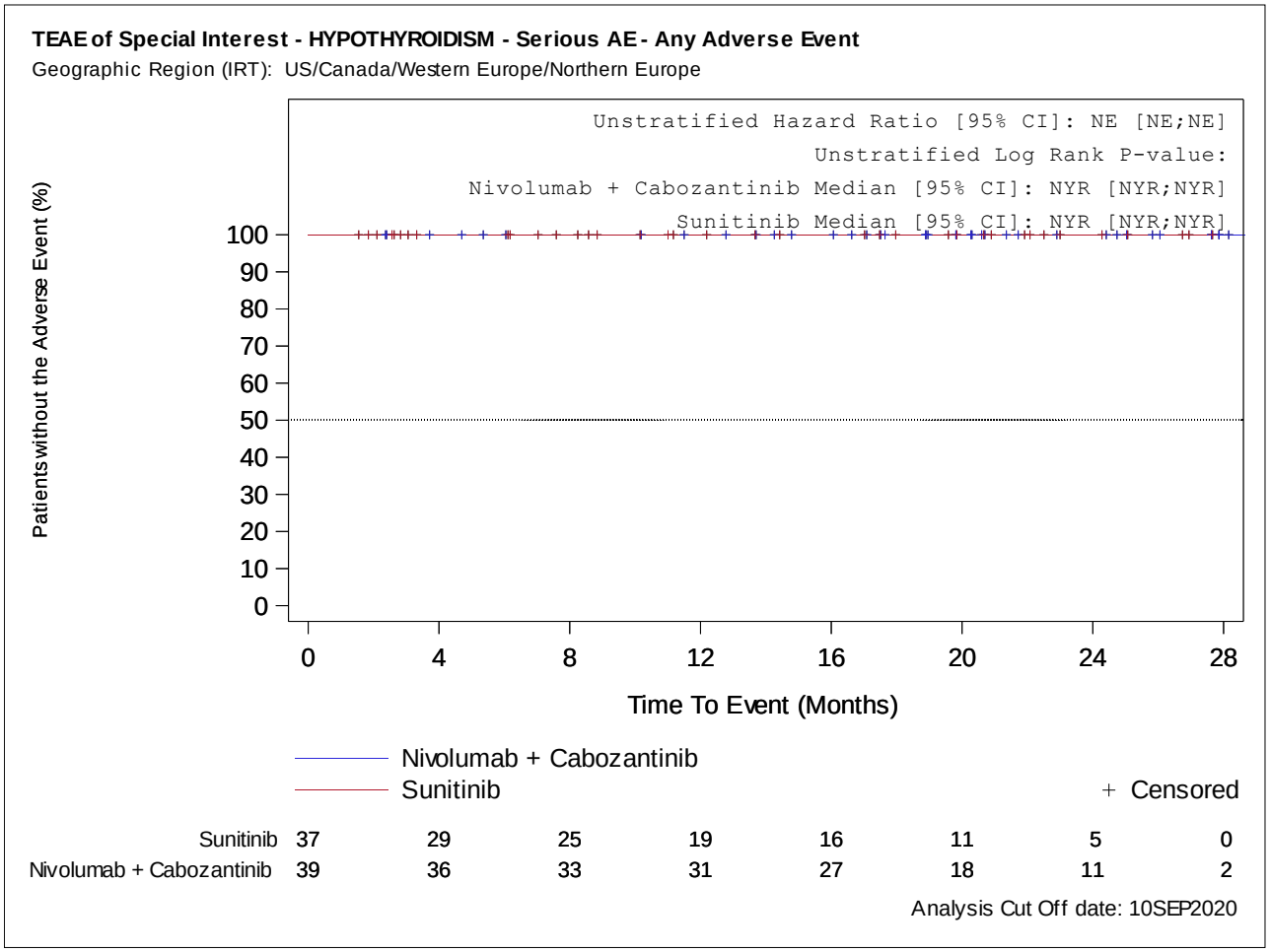
FIGURE 3.105.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



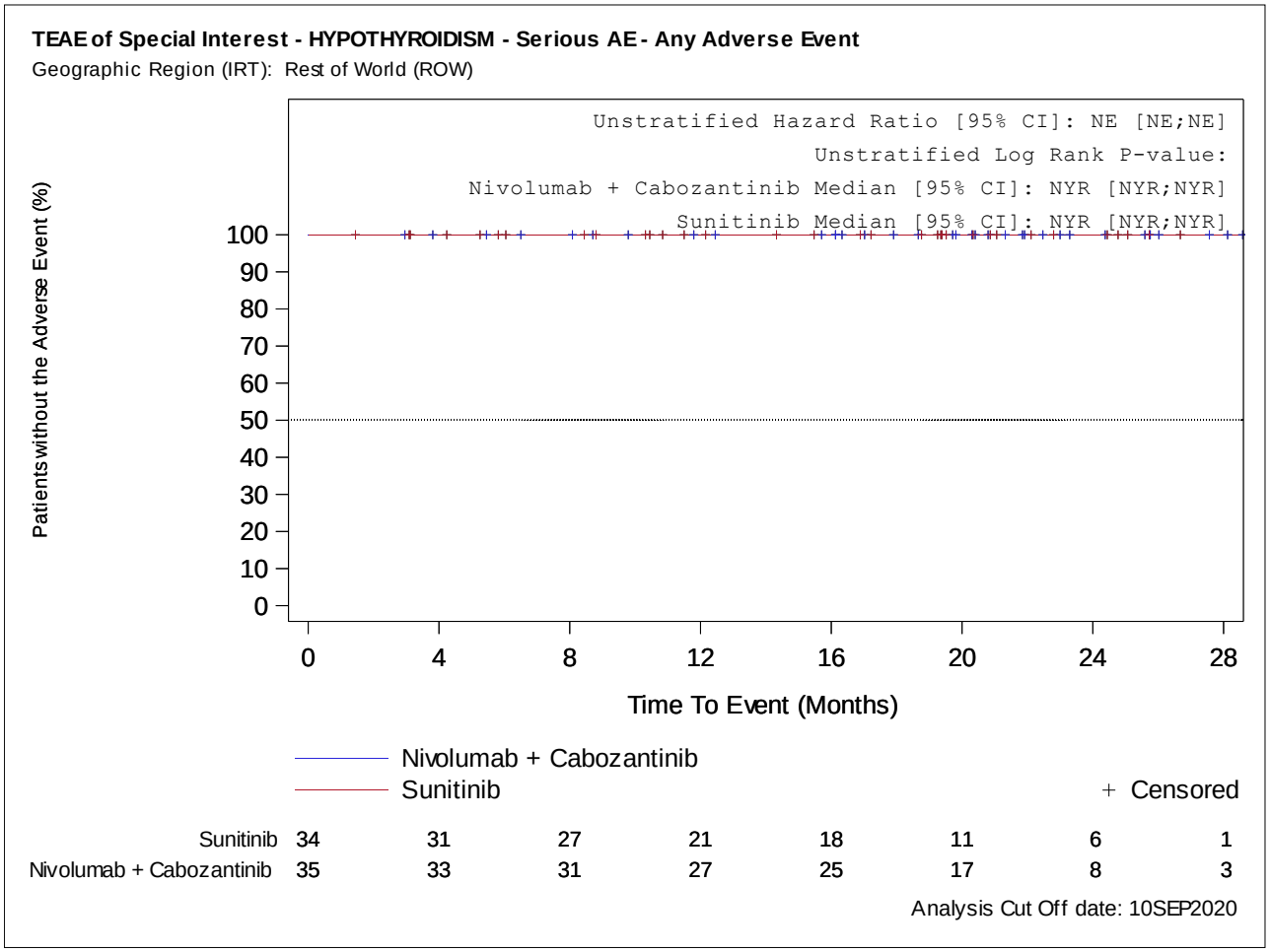

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:59:38

FIGURE 3.105.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



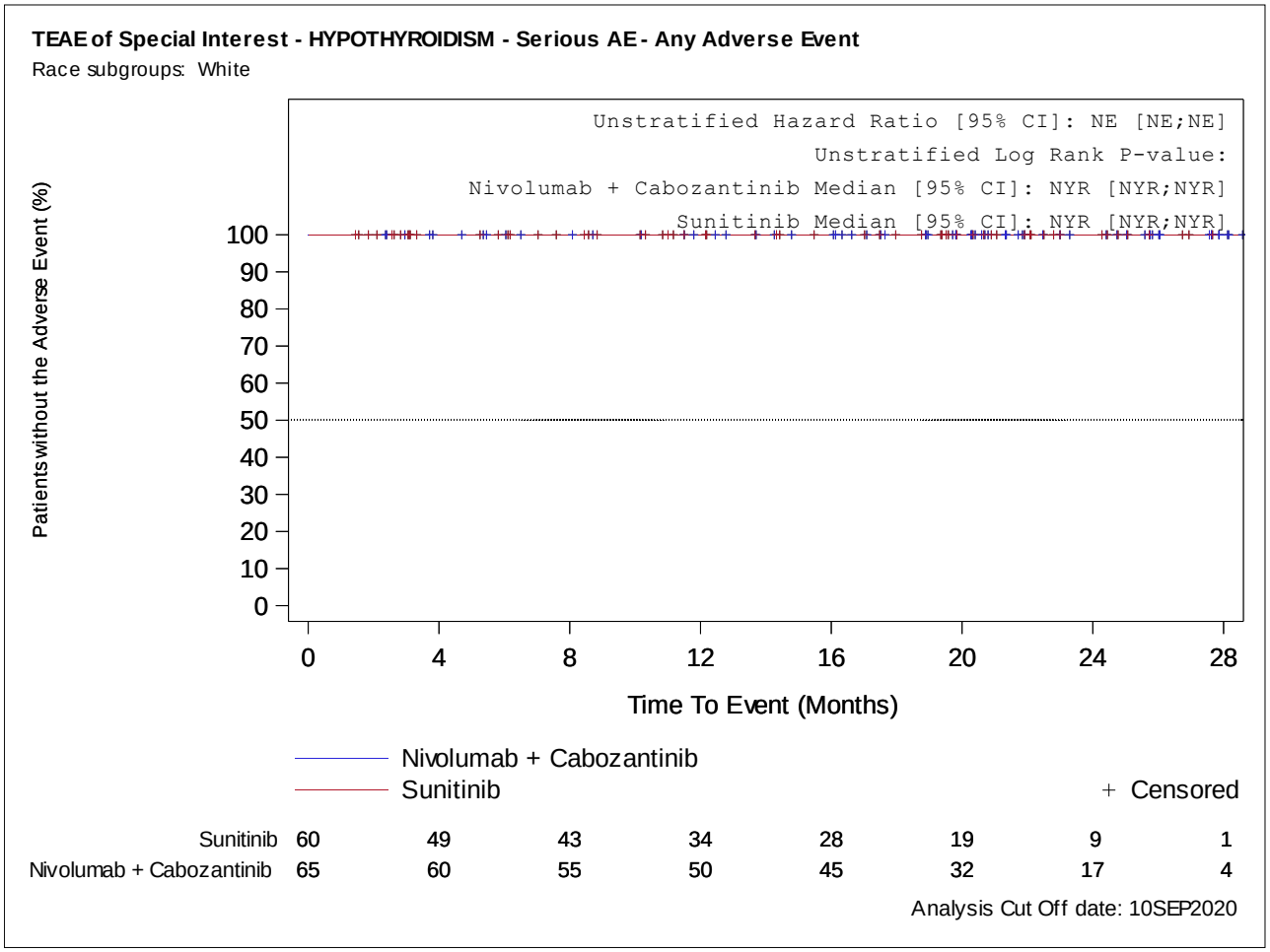

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:59:43

FIGURE 3.105.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:59:48

FIGURE 3.105.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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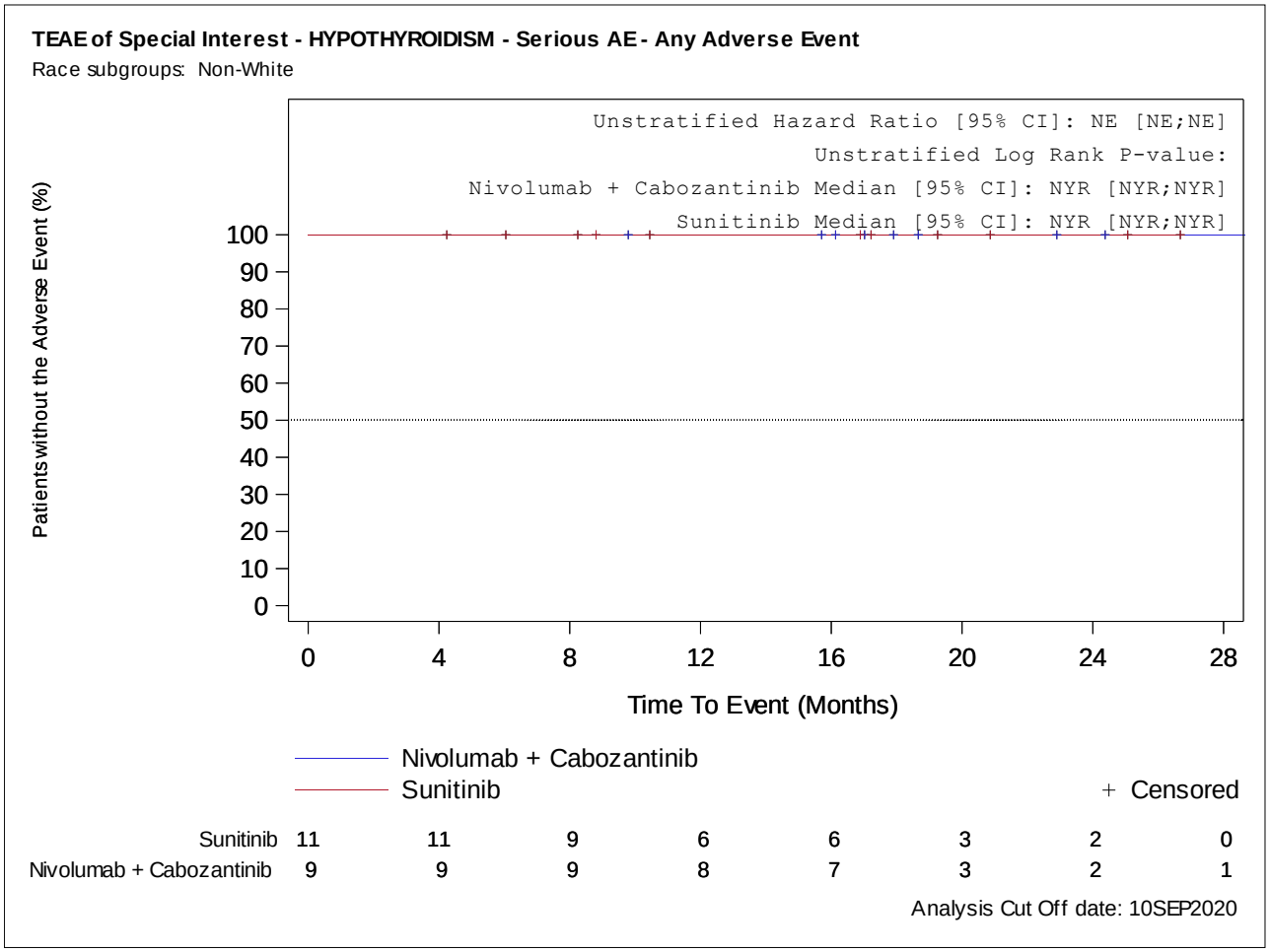
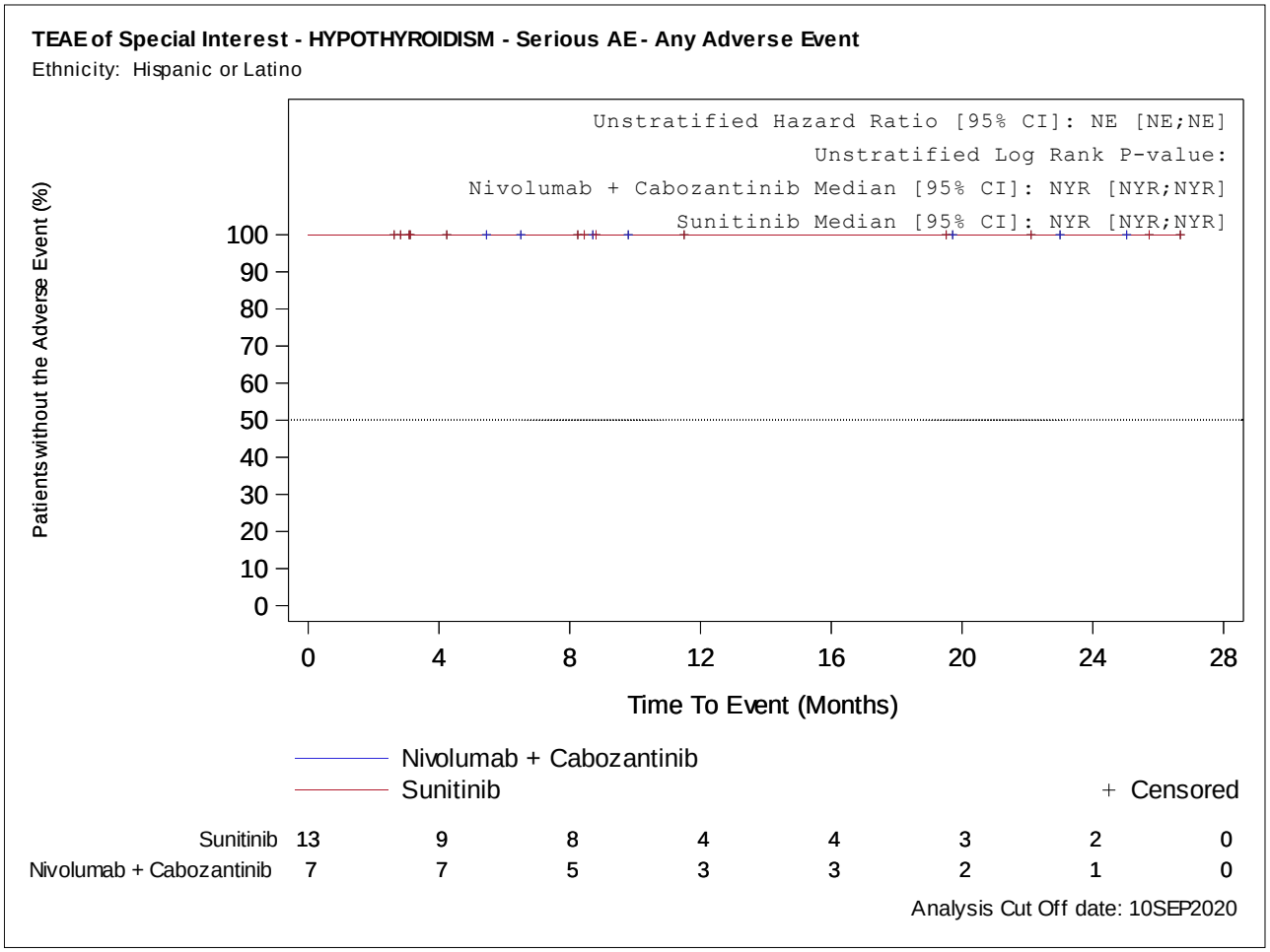
FIGURE 3.105.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



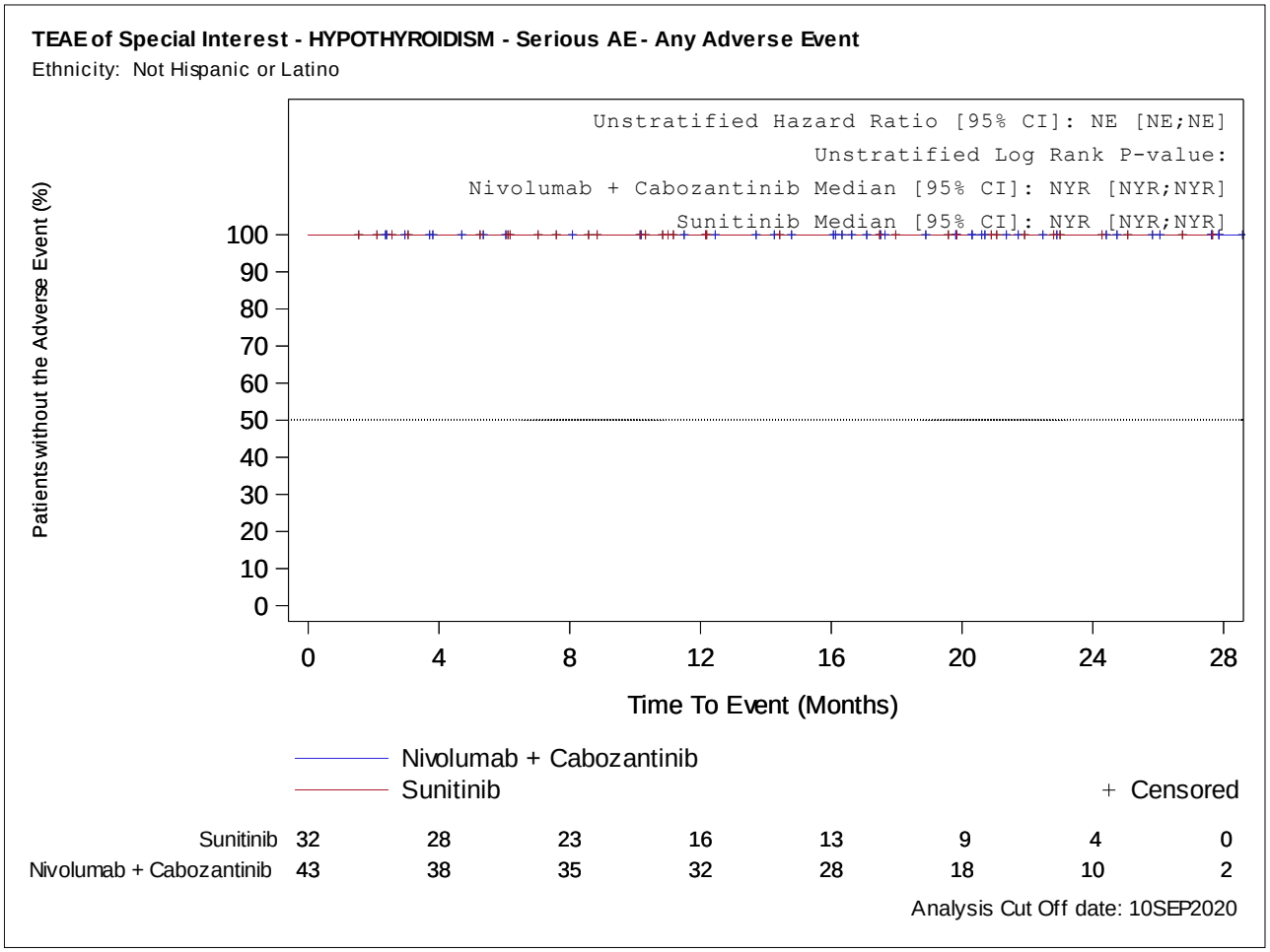

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 23:59:59

FIGURE 3.105.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



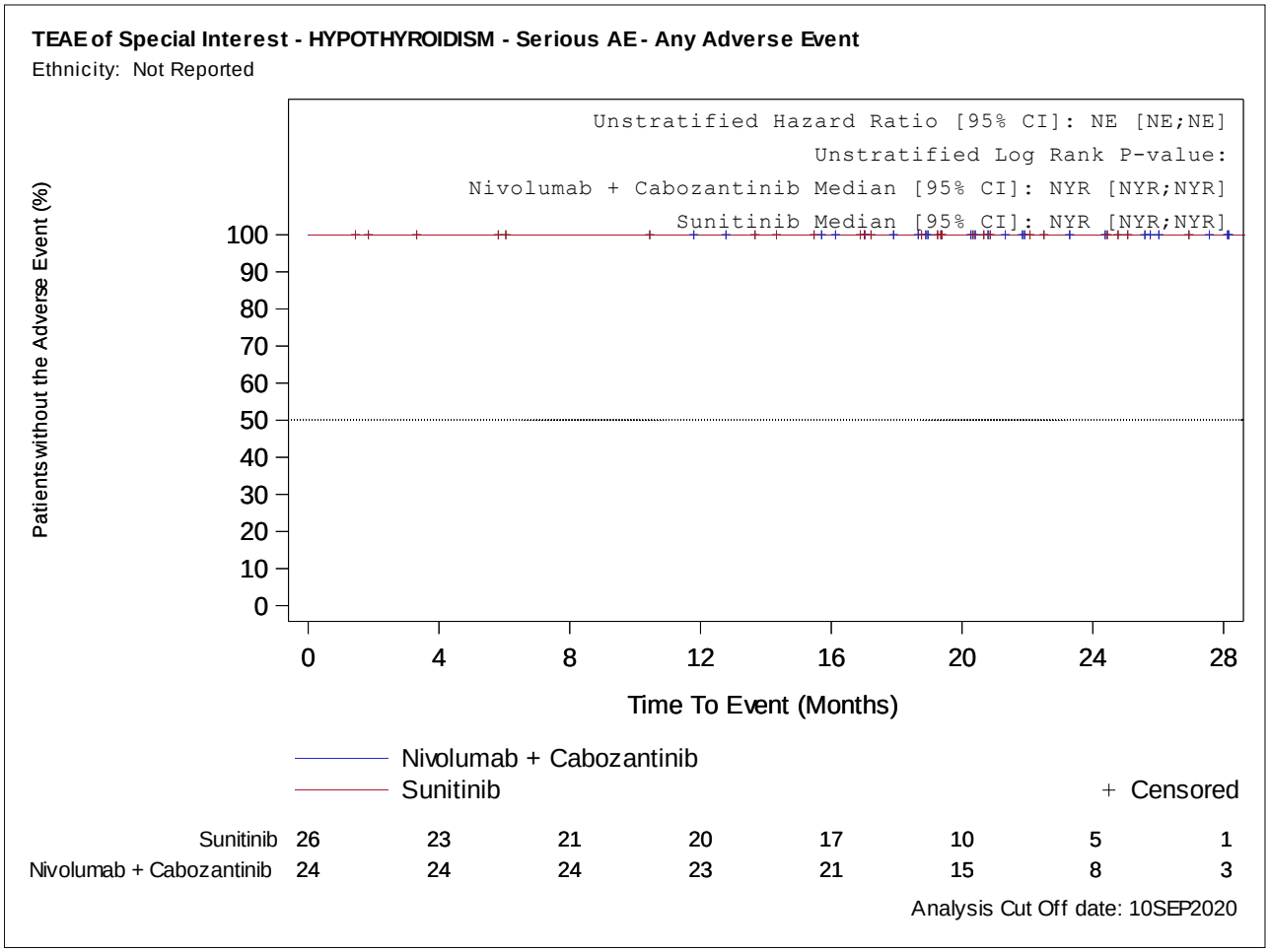

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:00:04

FIGURE 3.105.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:00:10

FIGURE 3.105.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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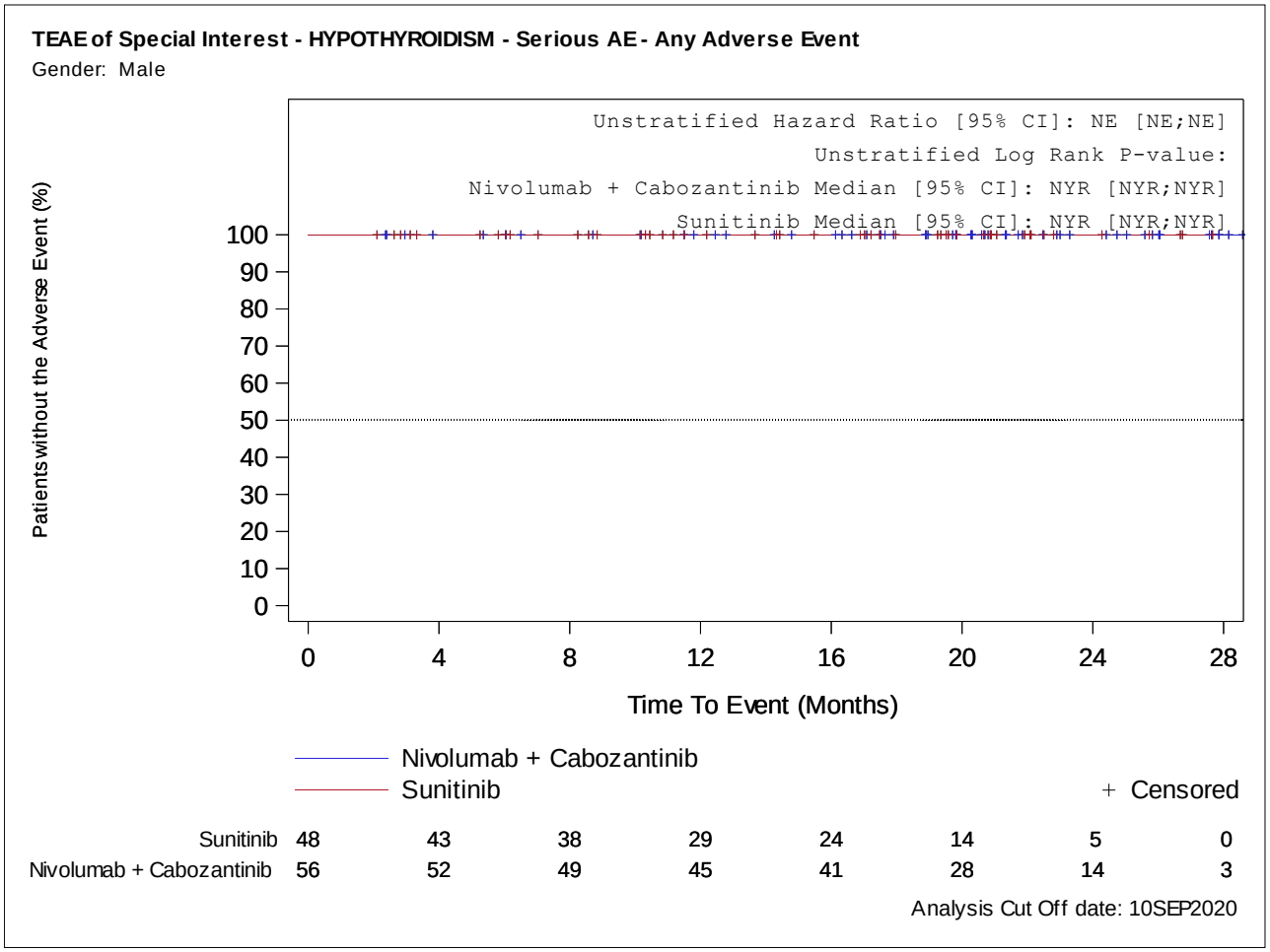
FIGURE 3.105.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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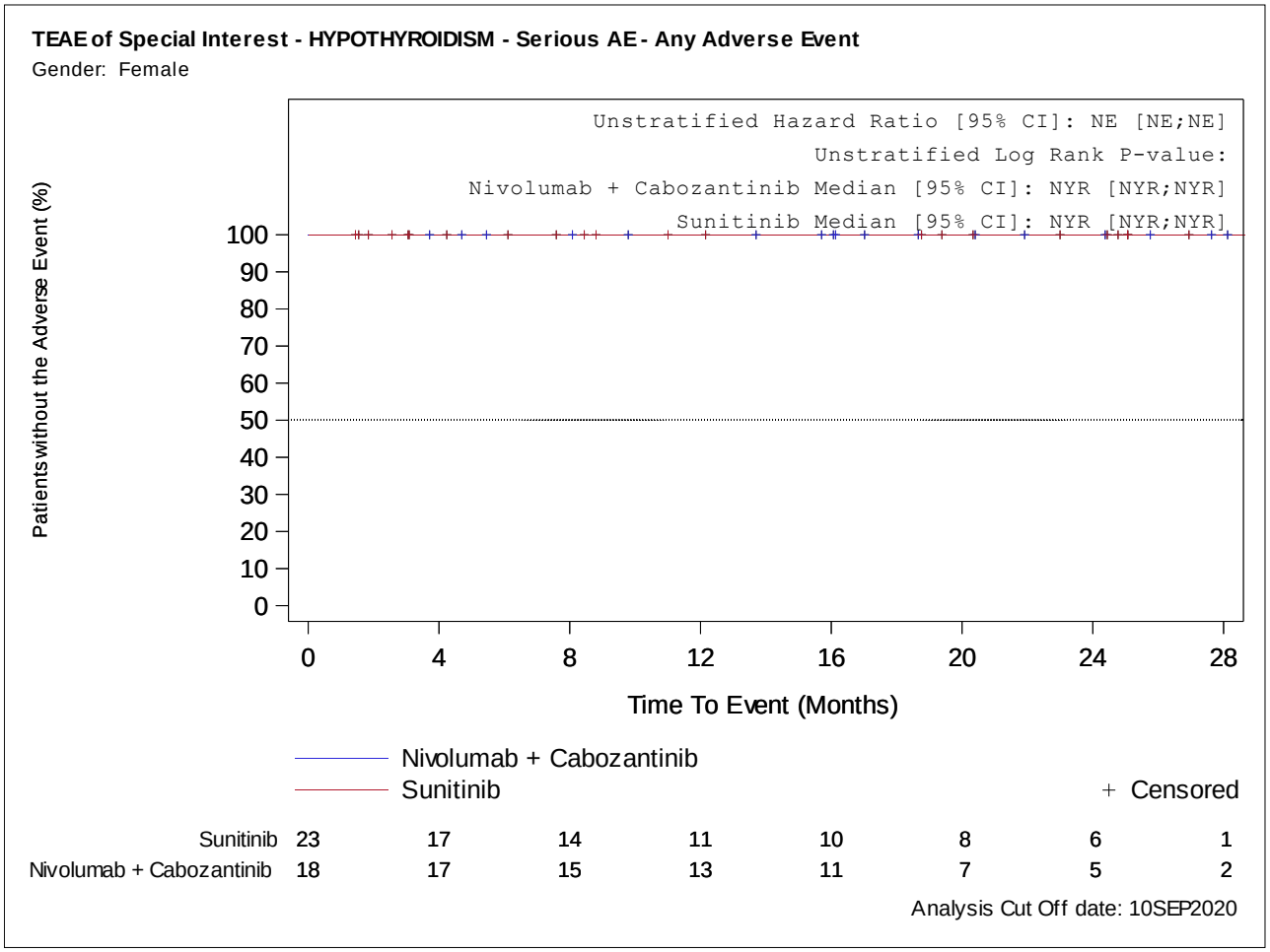
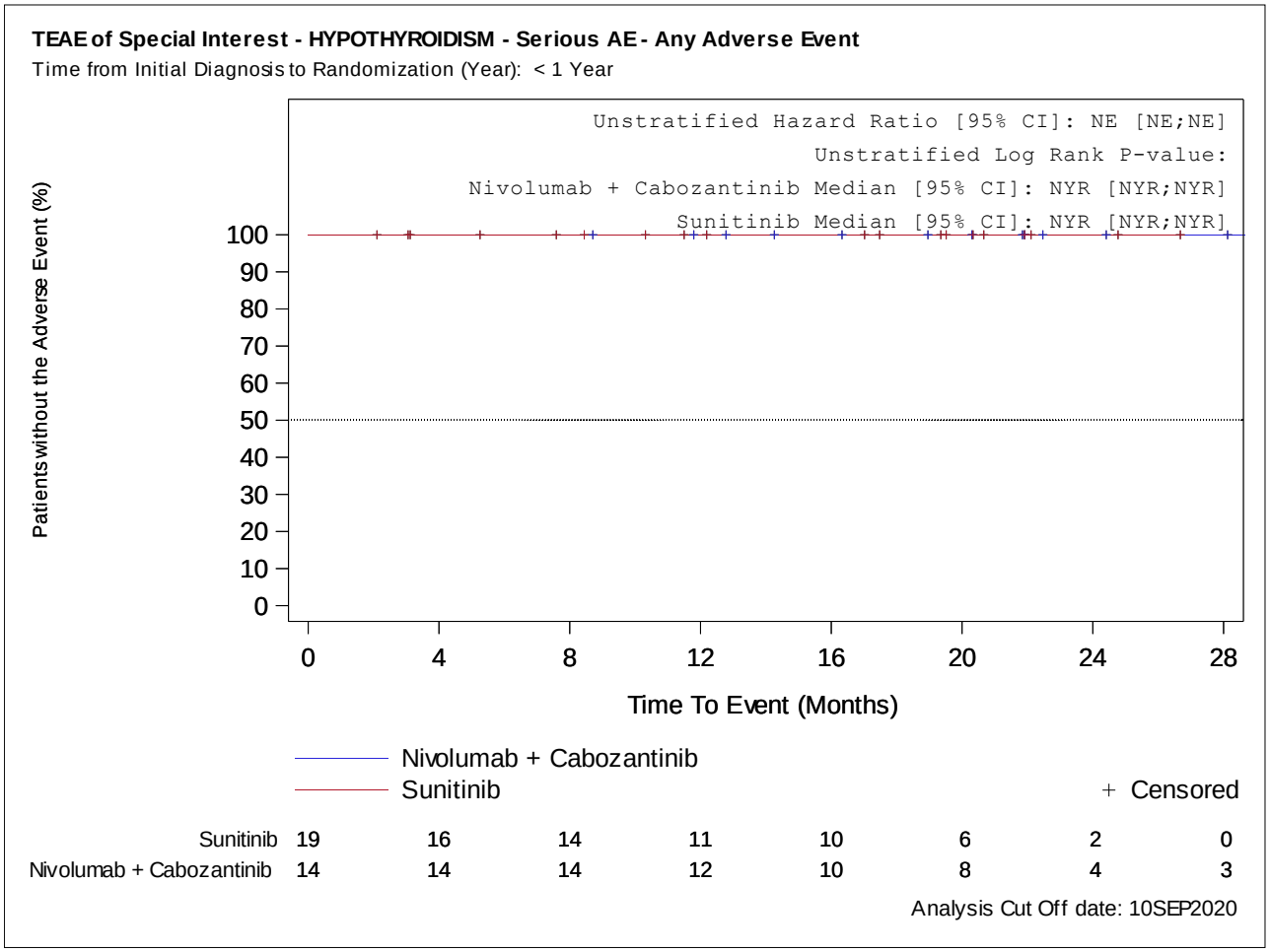
FIGURE 3.105.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



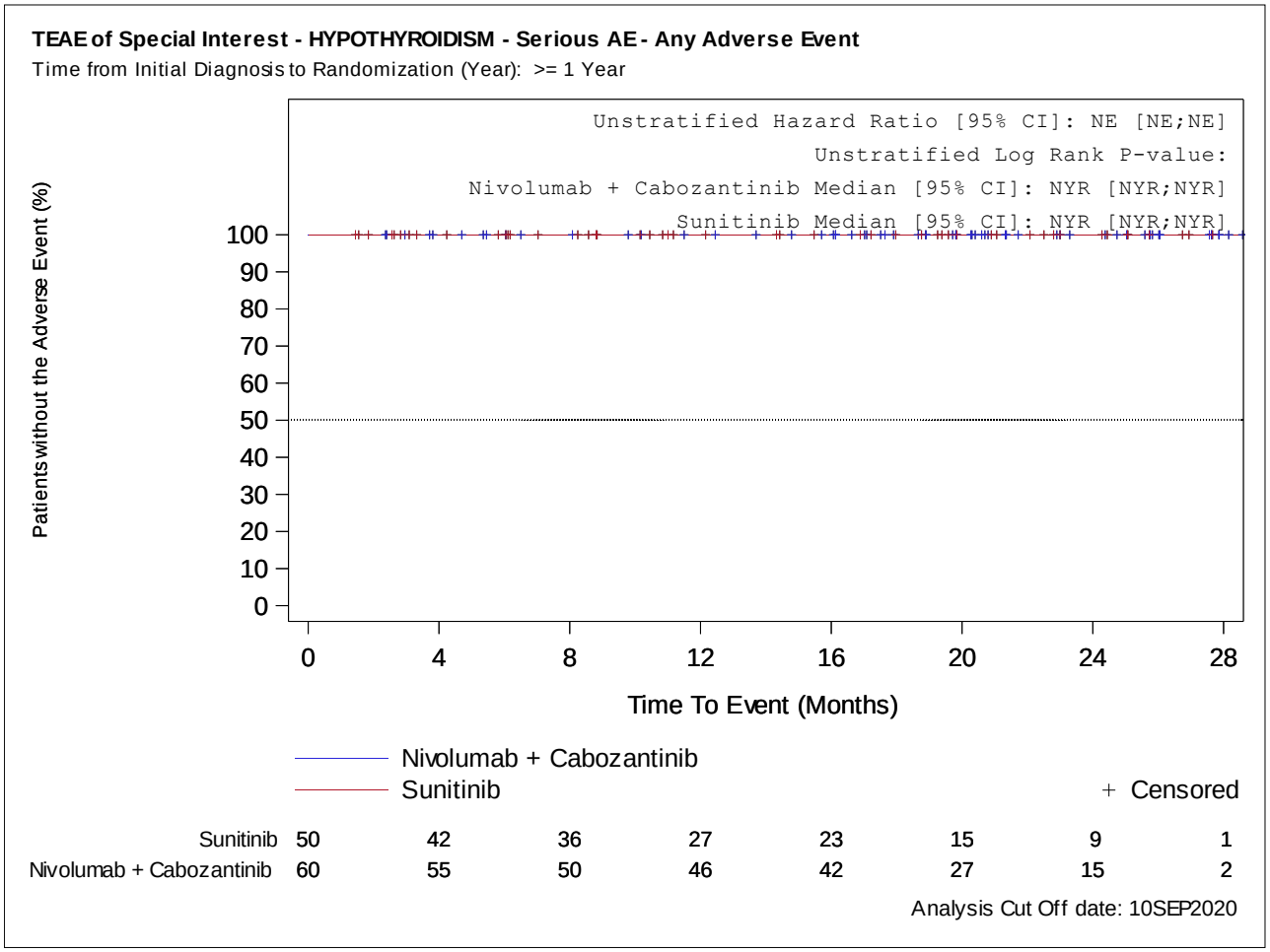

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:00:25

FIGURE 3.105.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



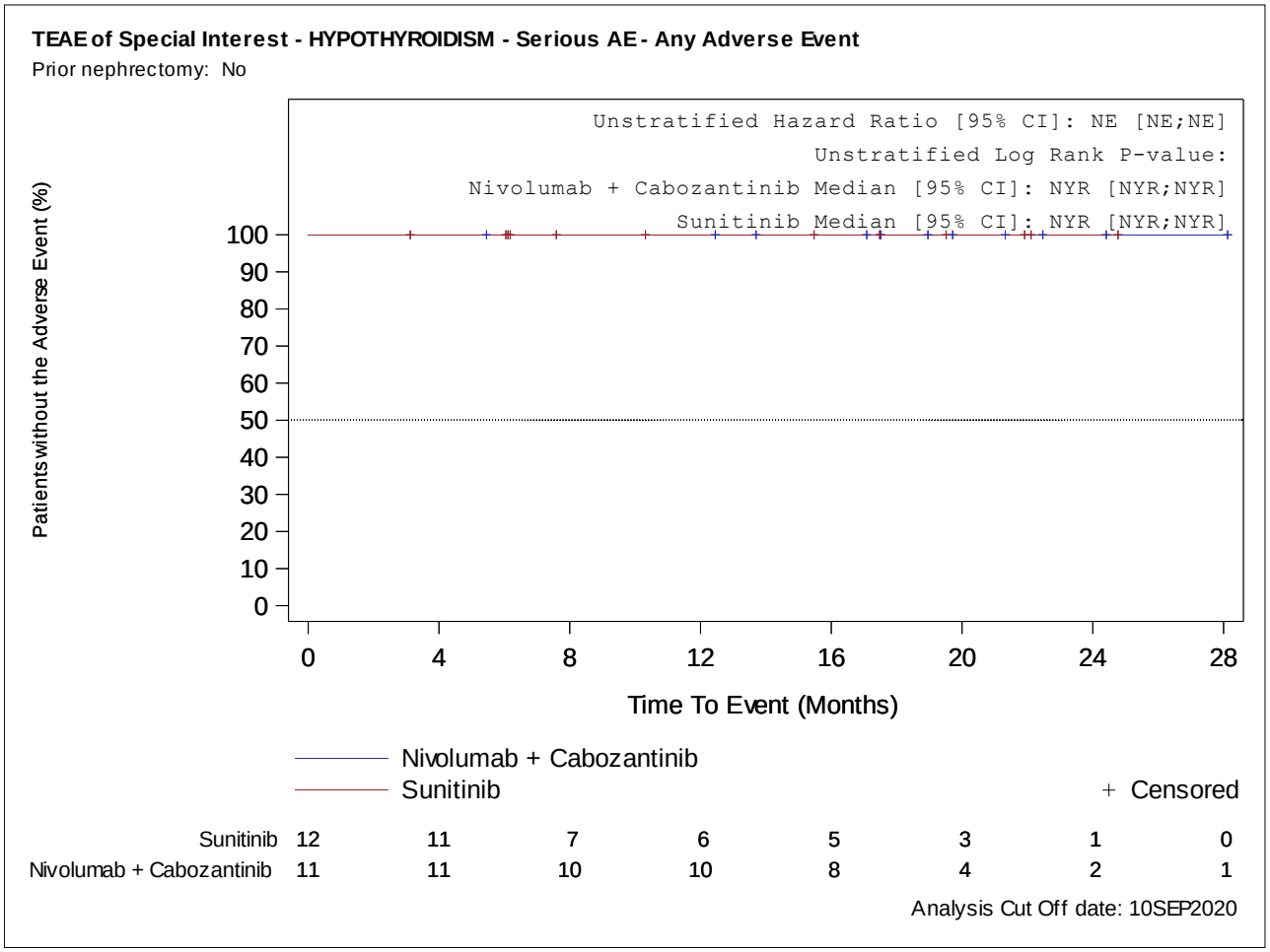

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:00:41

FIGURE 3.105.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



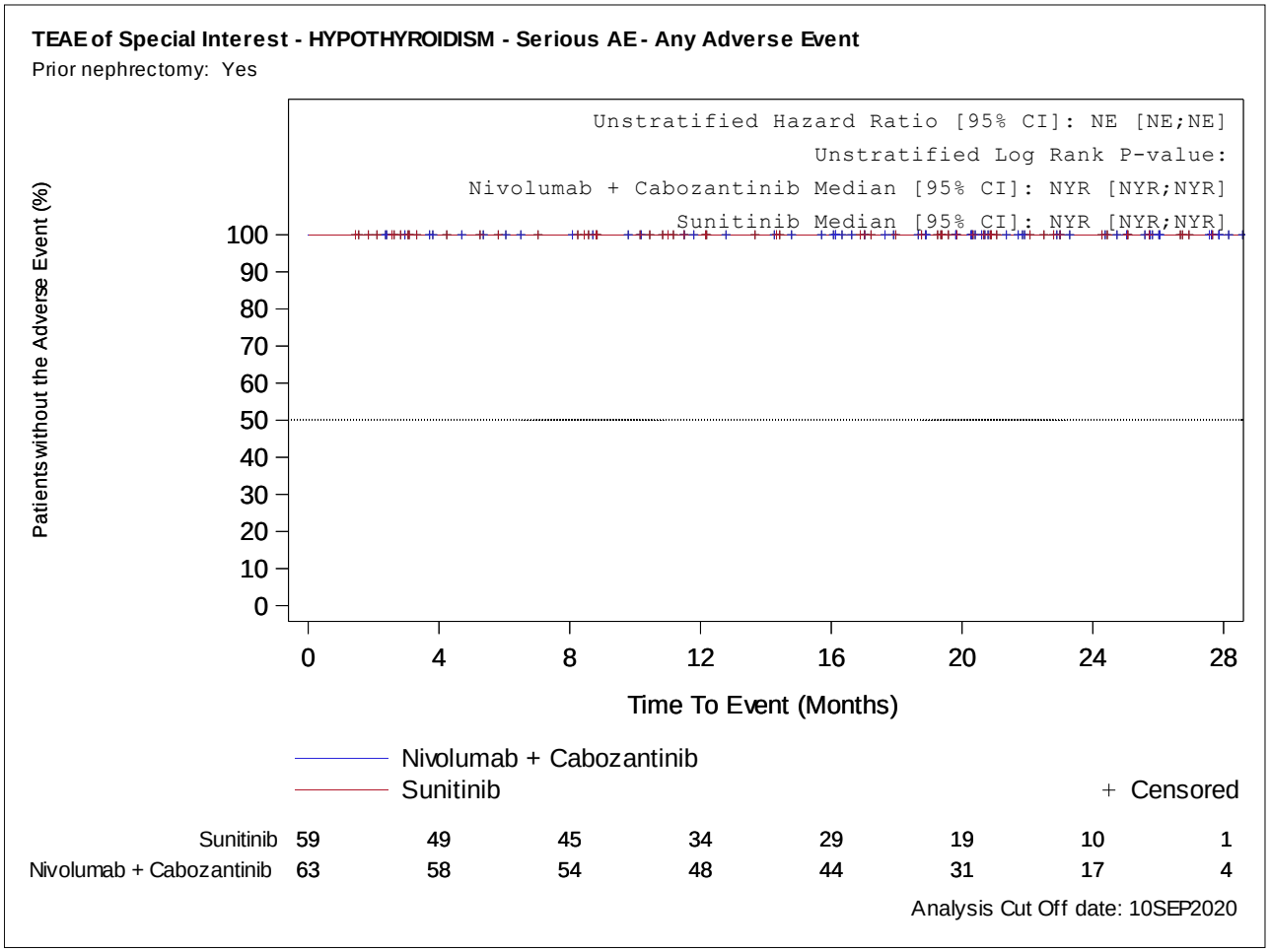

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:00:46

FIGURE 3.105.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



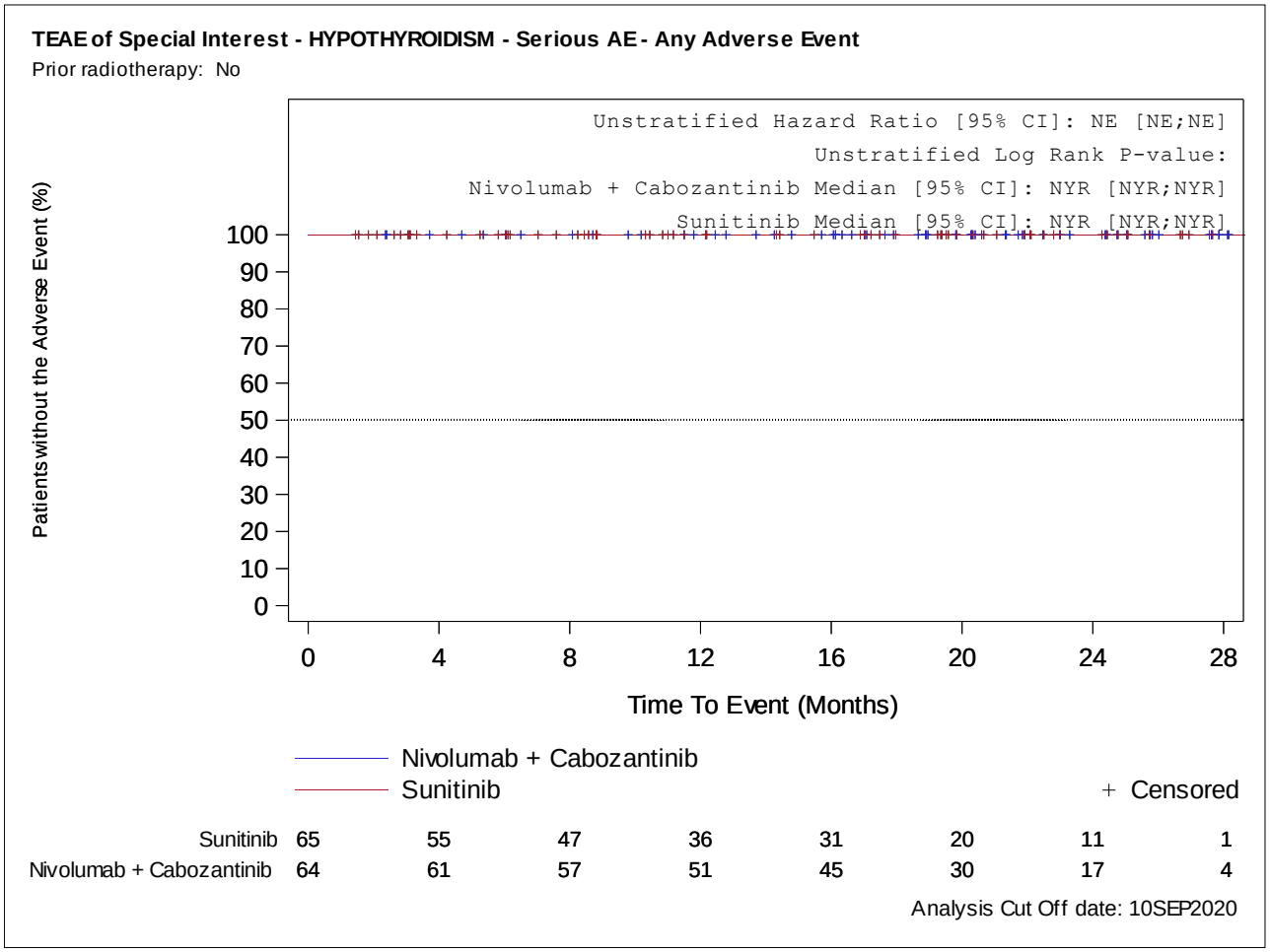

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:01:32

FIGURE 3.105.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:01:38

FIGURE 3.105.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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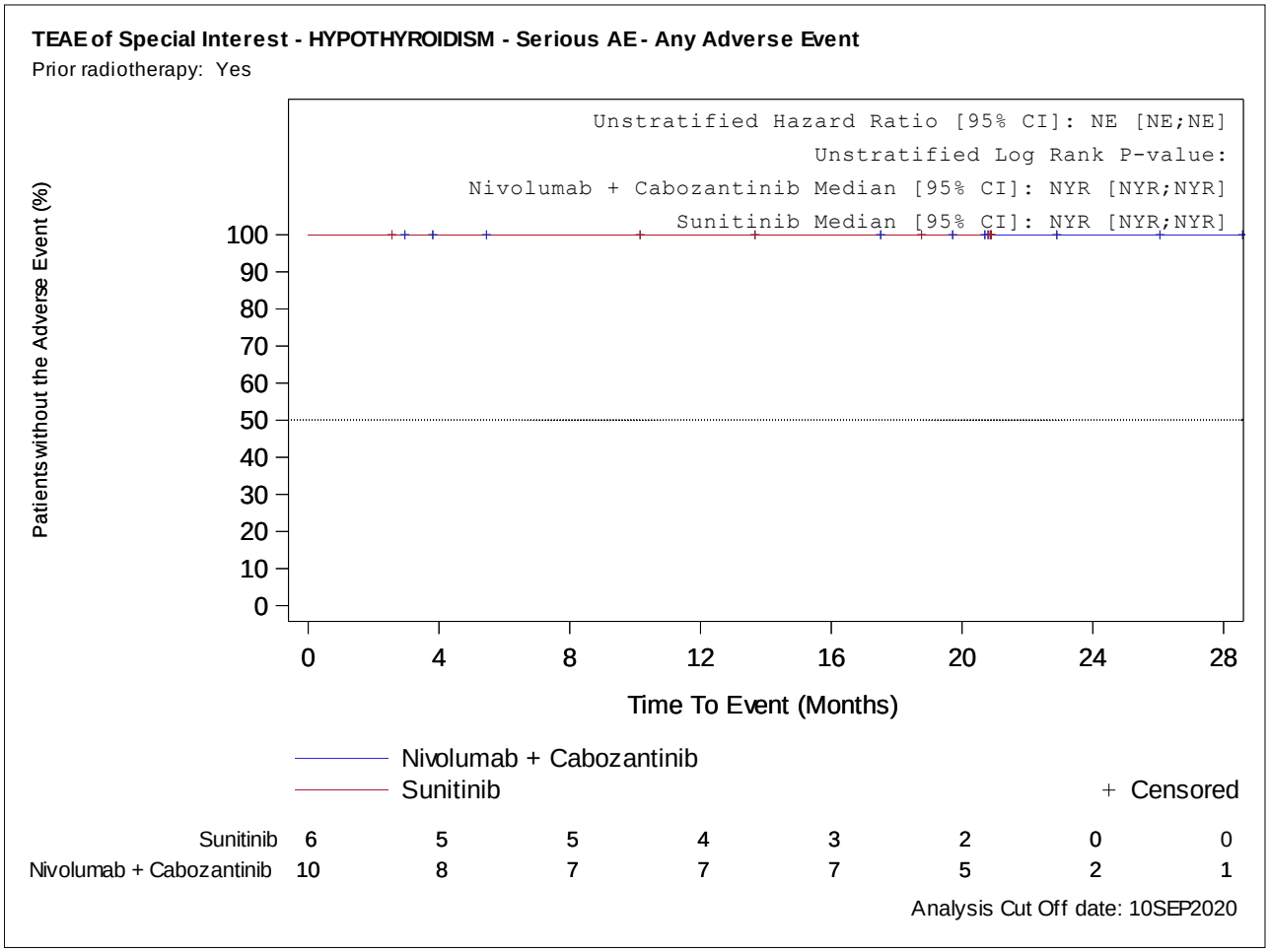
FIGURE 3.105.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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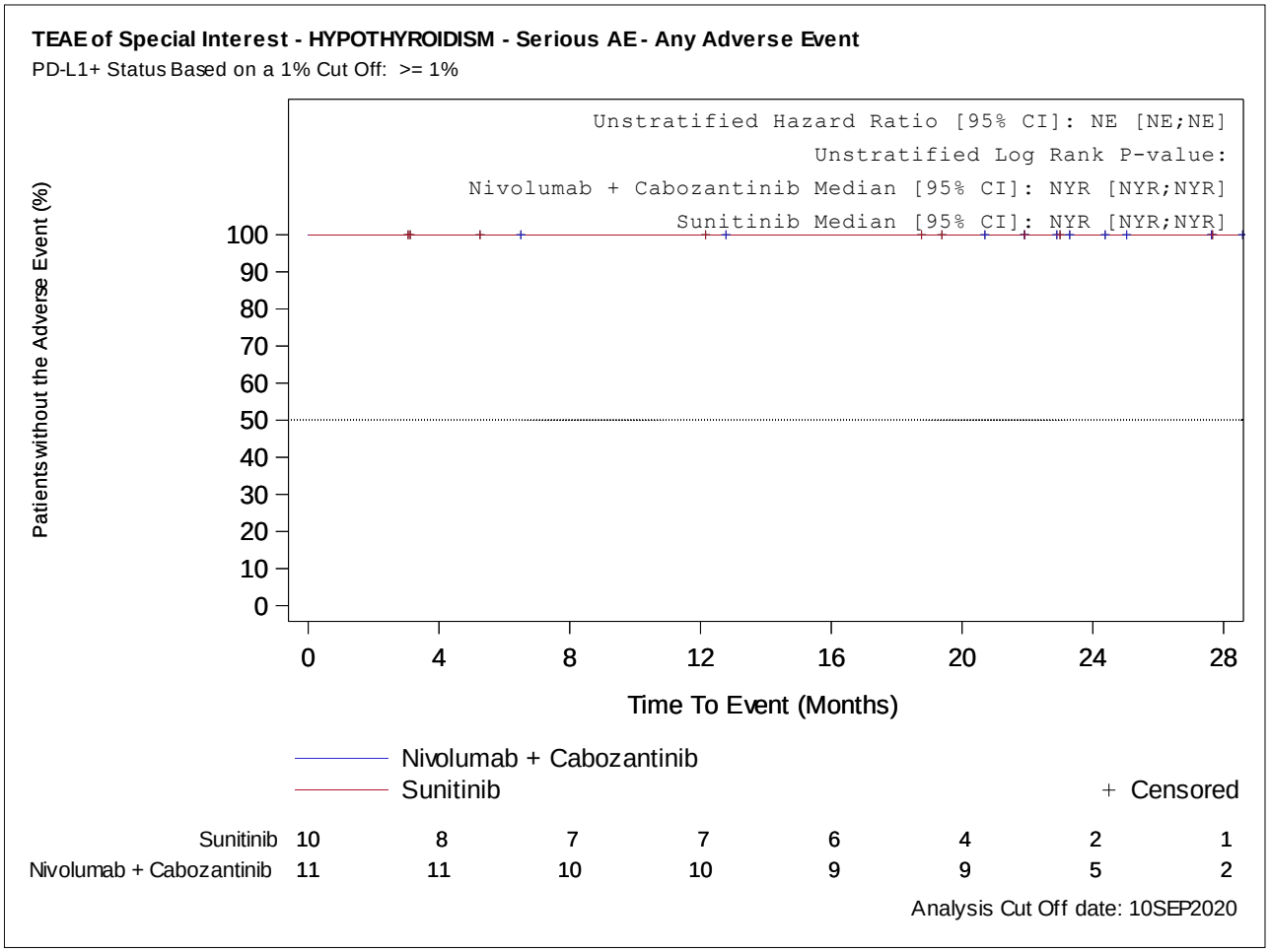
FIGURE 3.105.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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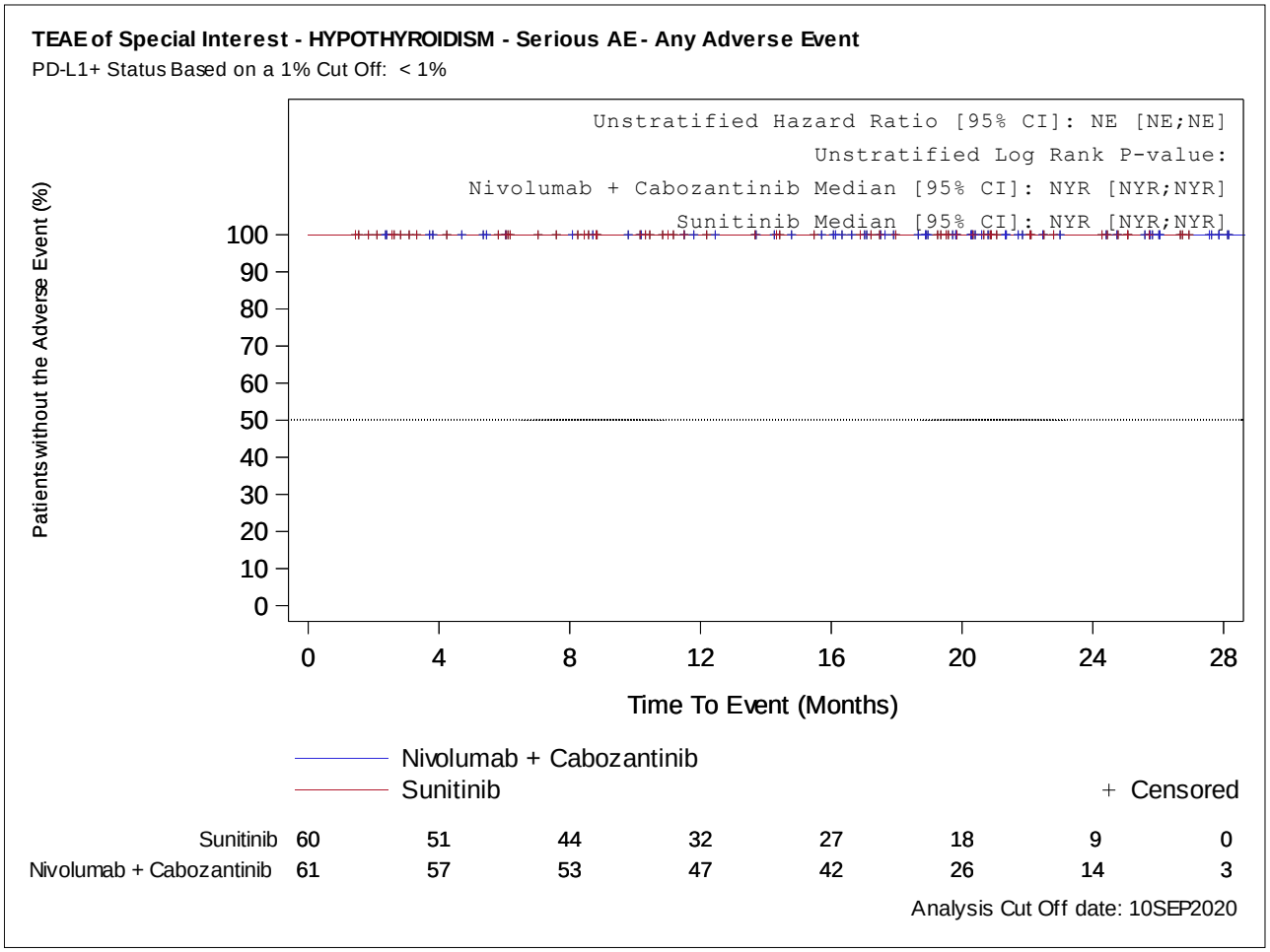
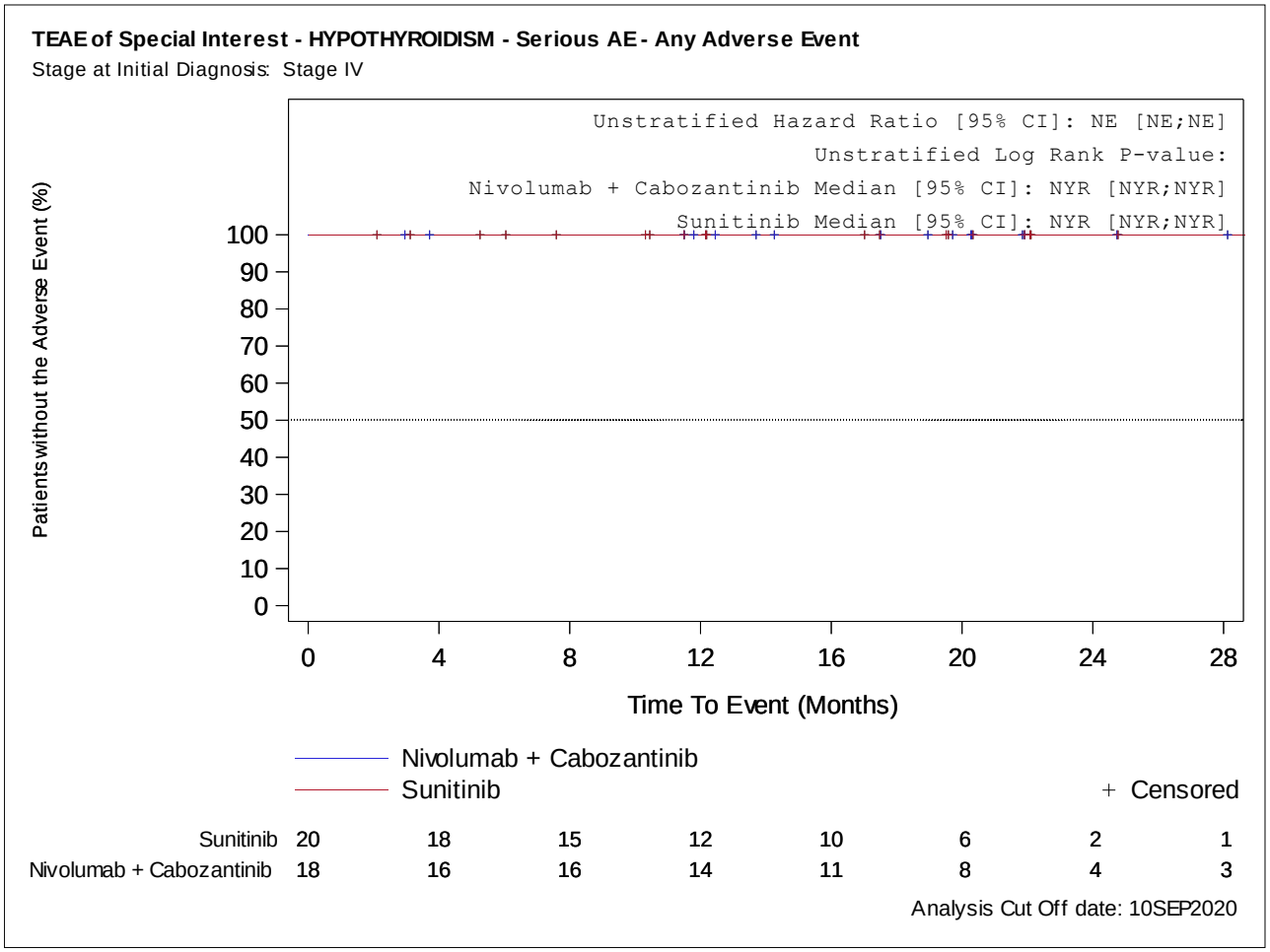
FIGURE 3.105.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



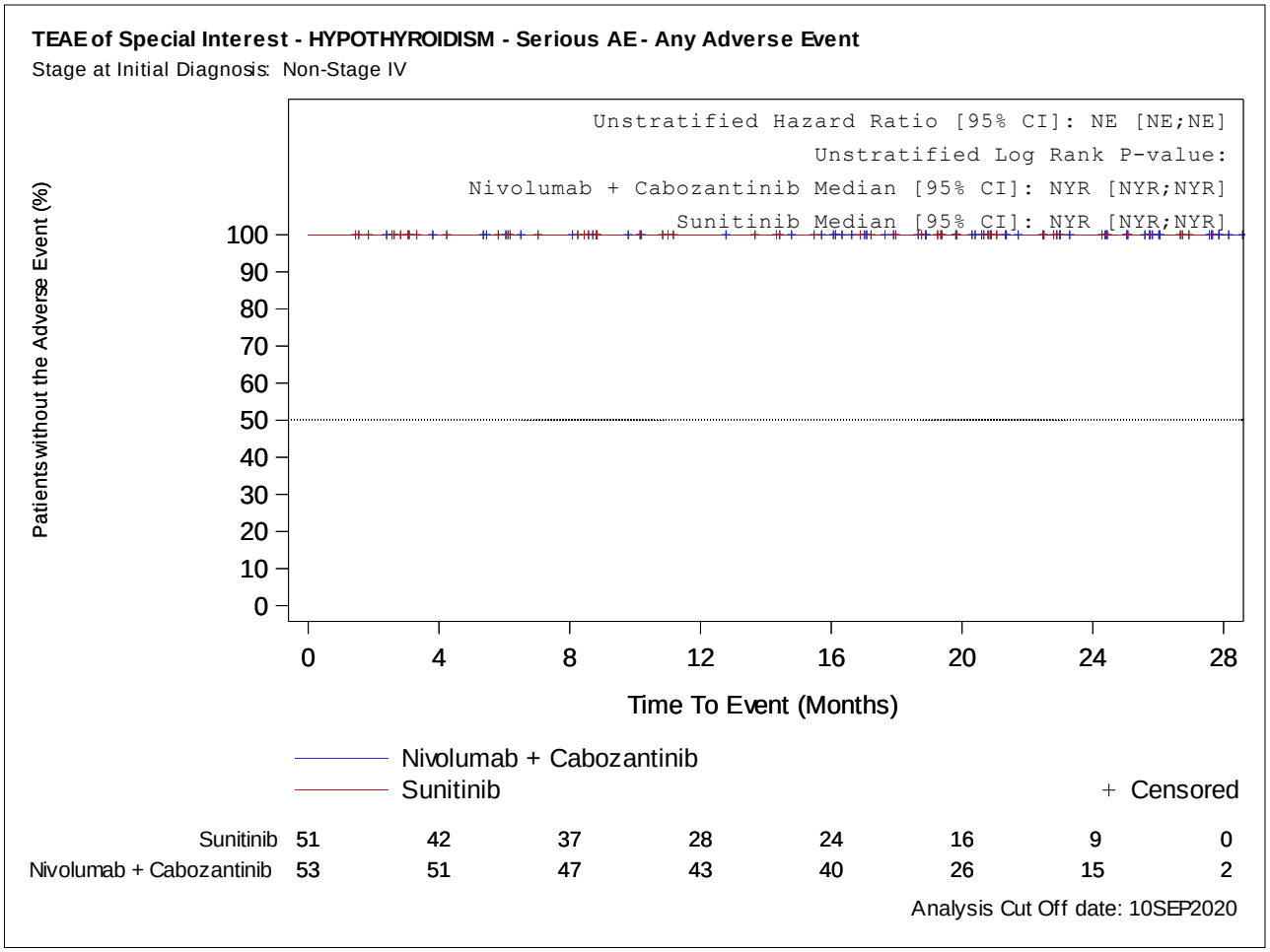

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:01:59

FIGURE 3.105.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



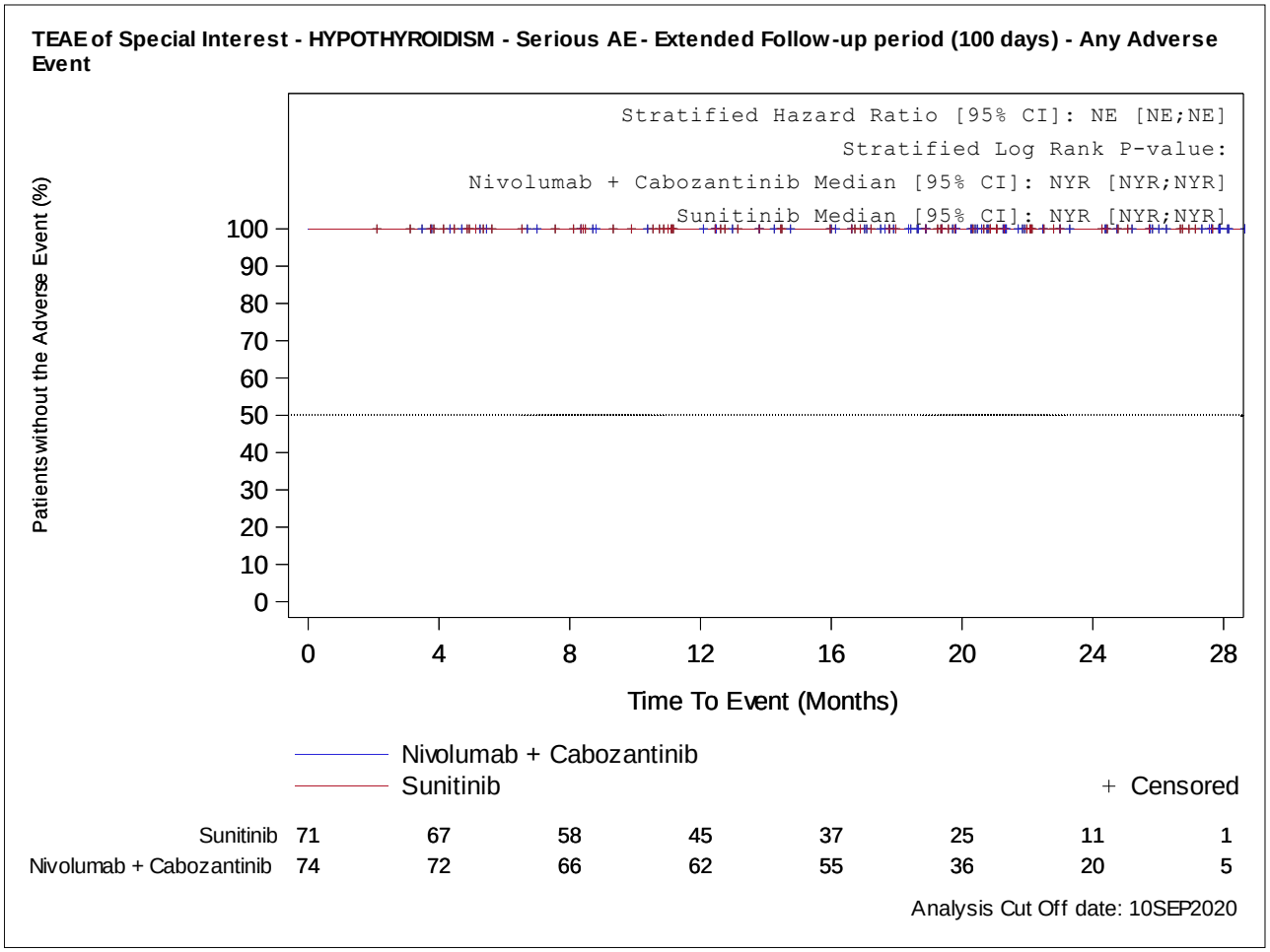

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:02:26

FIGURE 3.105.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



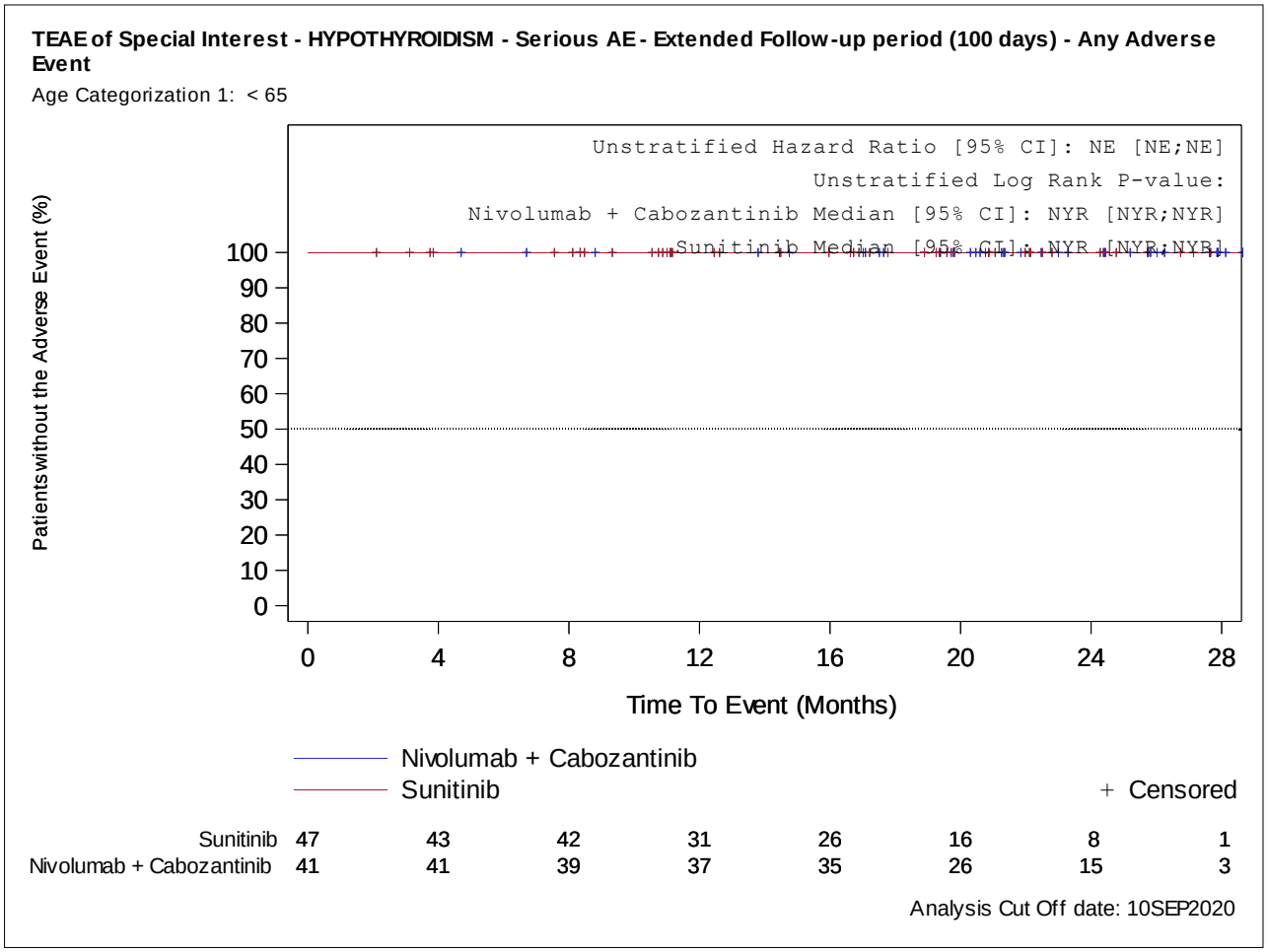

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:02:31

FIGURE 3.106.1: TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



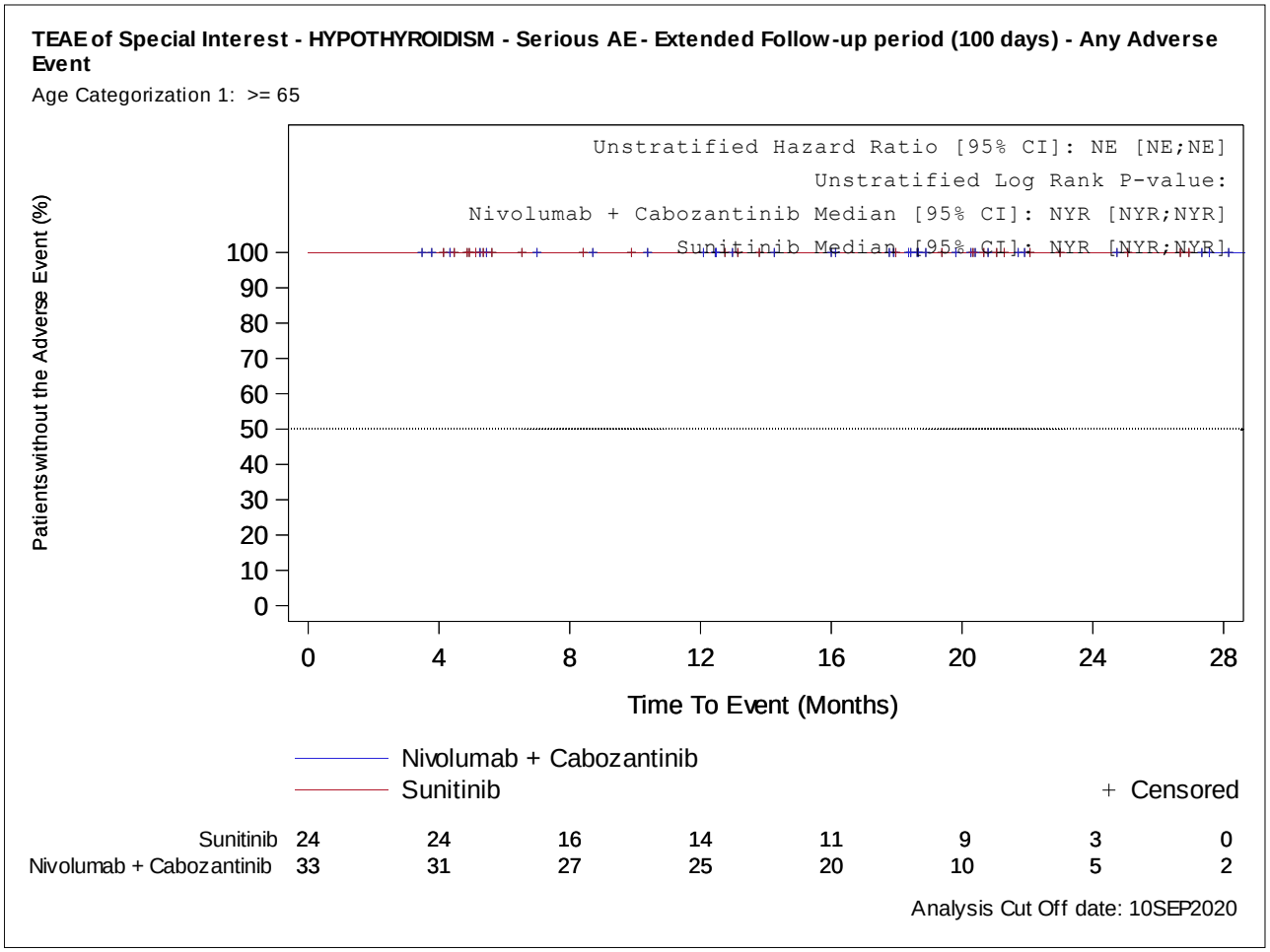

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:05:26

FIGURE 3.106.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:05:29

FIGURE 3.106.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
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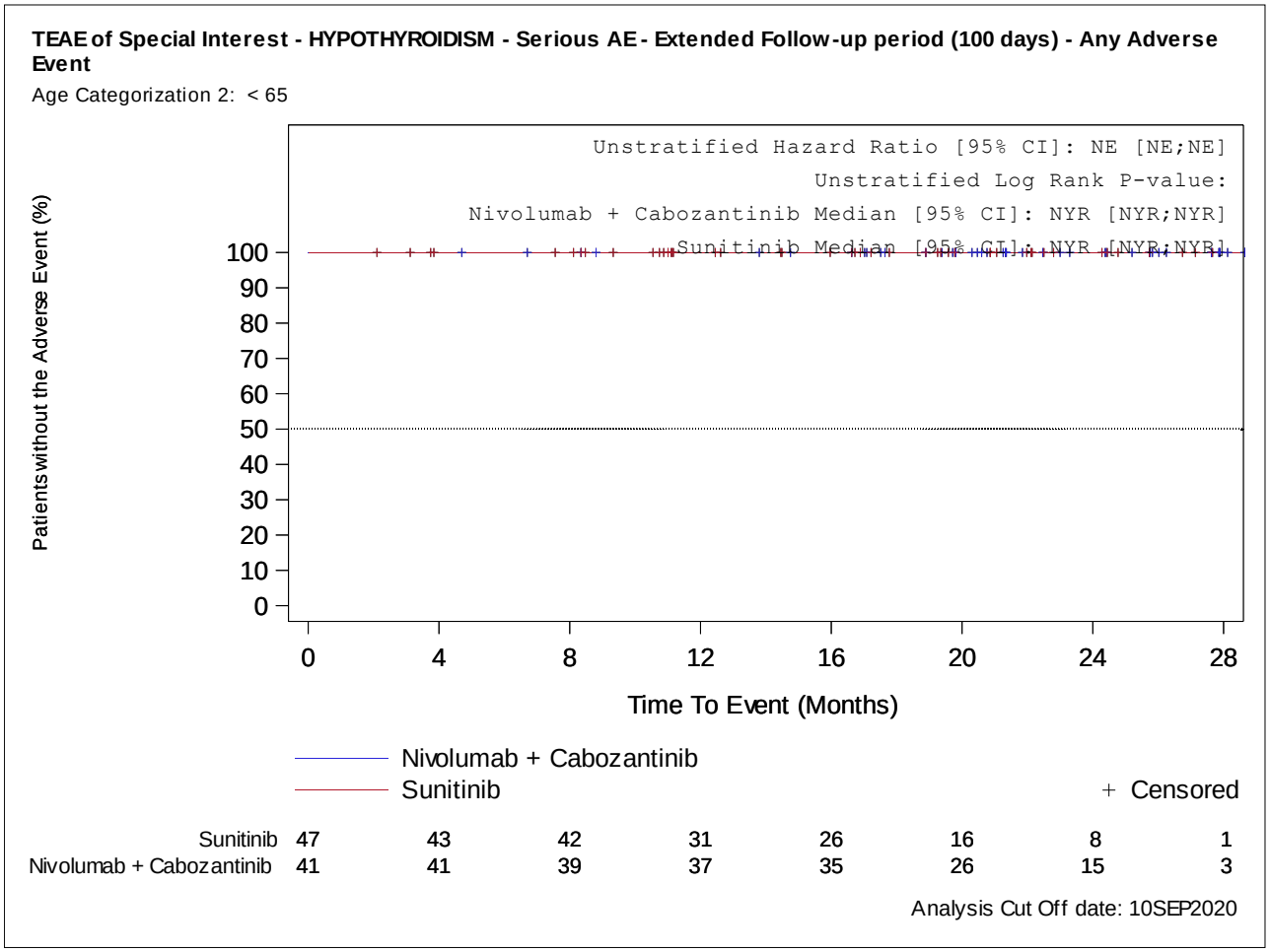
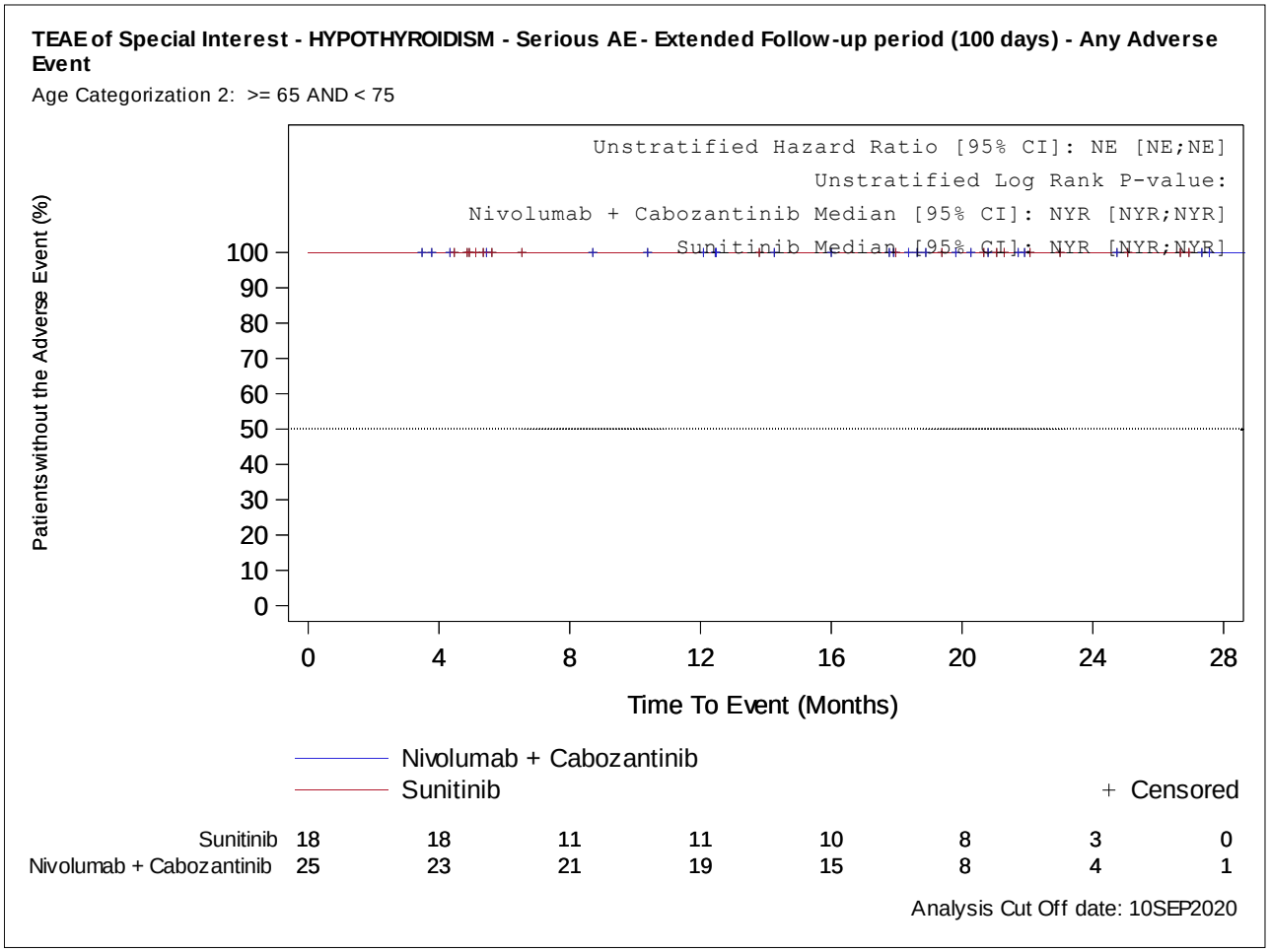
FIGURE 3.106.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



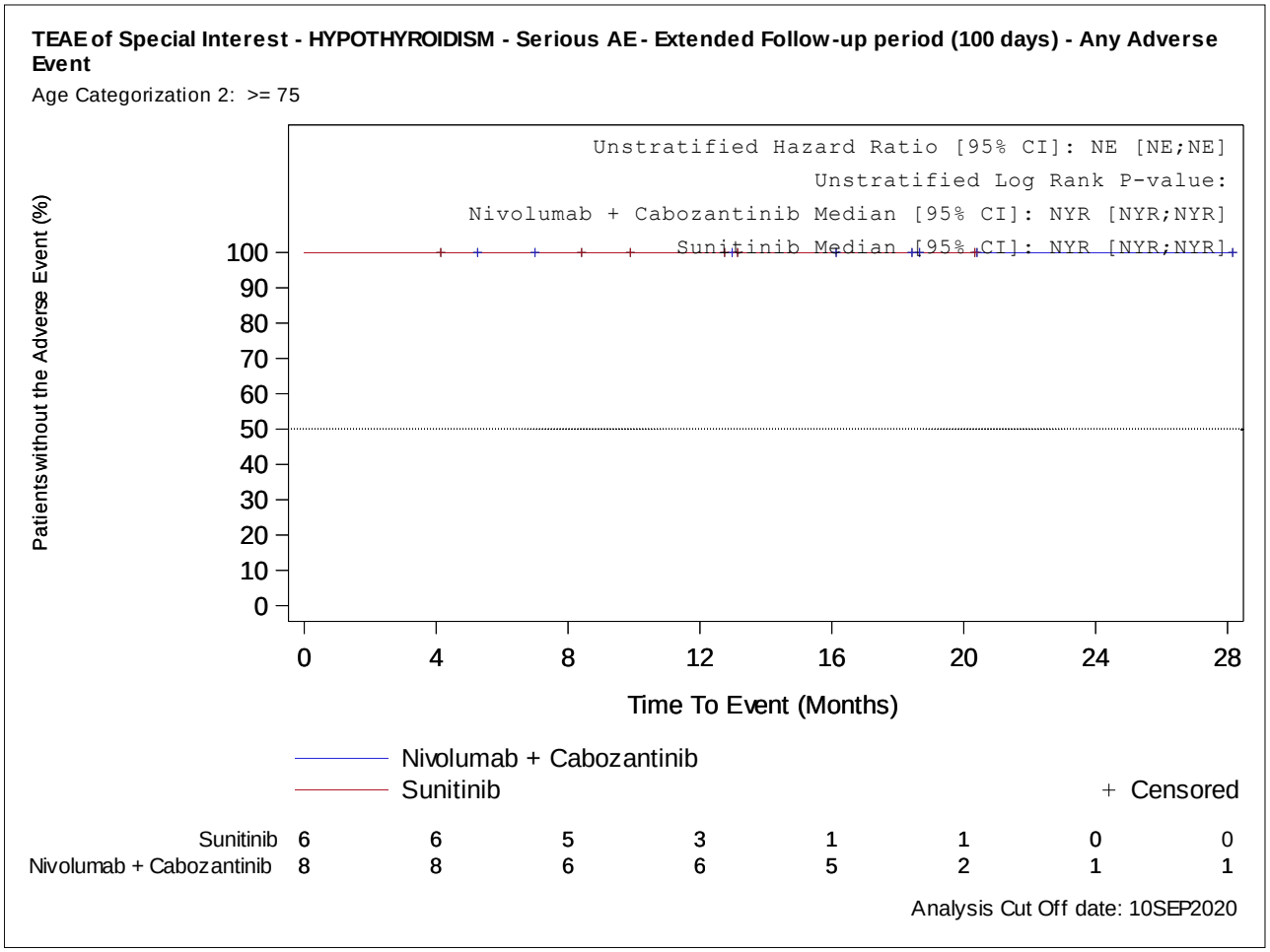

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:05:40

FIGURE 3.106.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



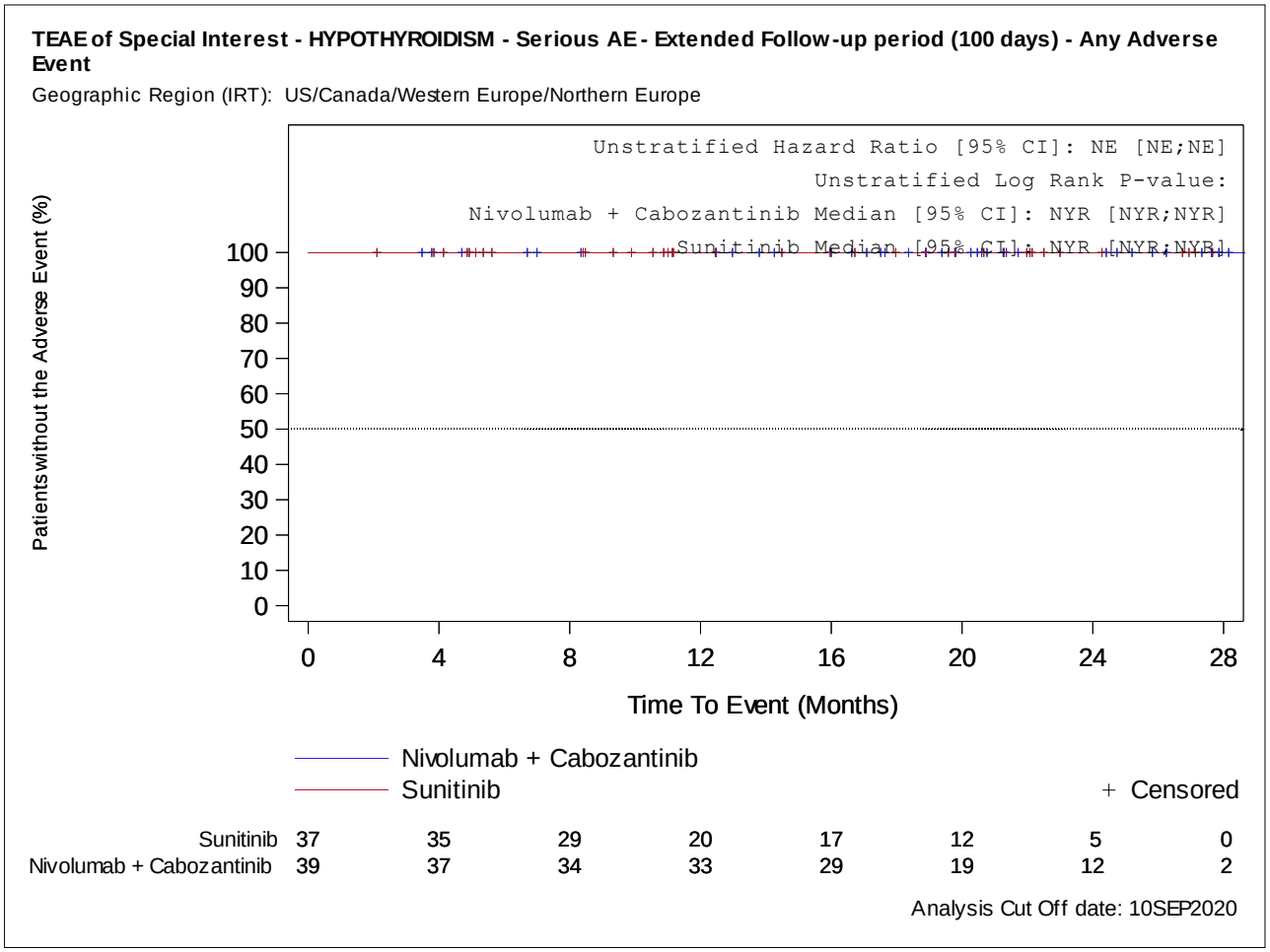

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:05:45

FIGURE 3.106.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



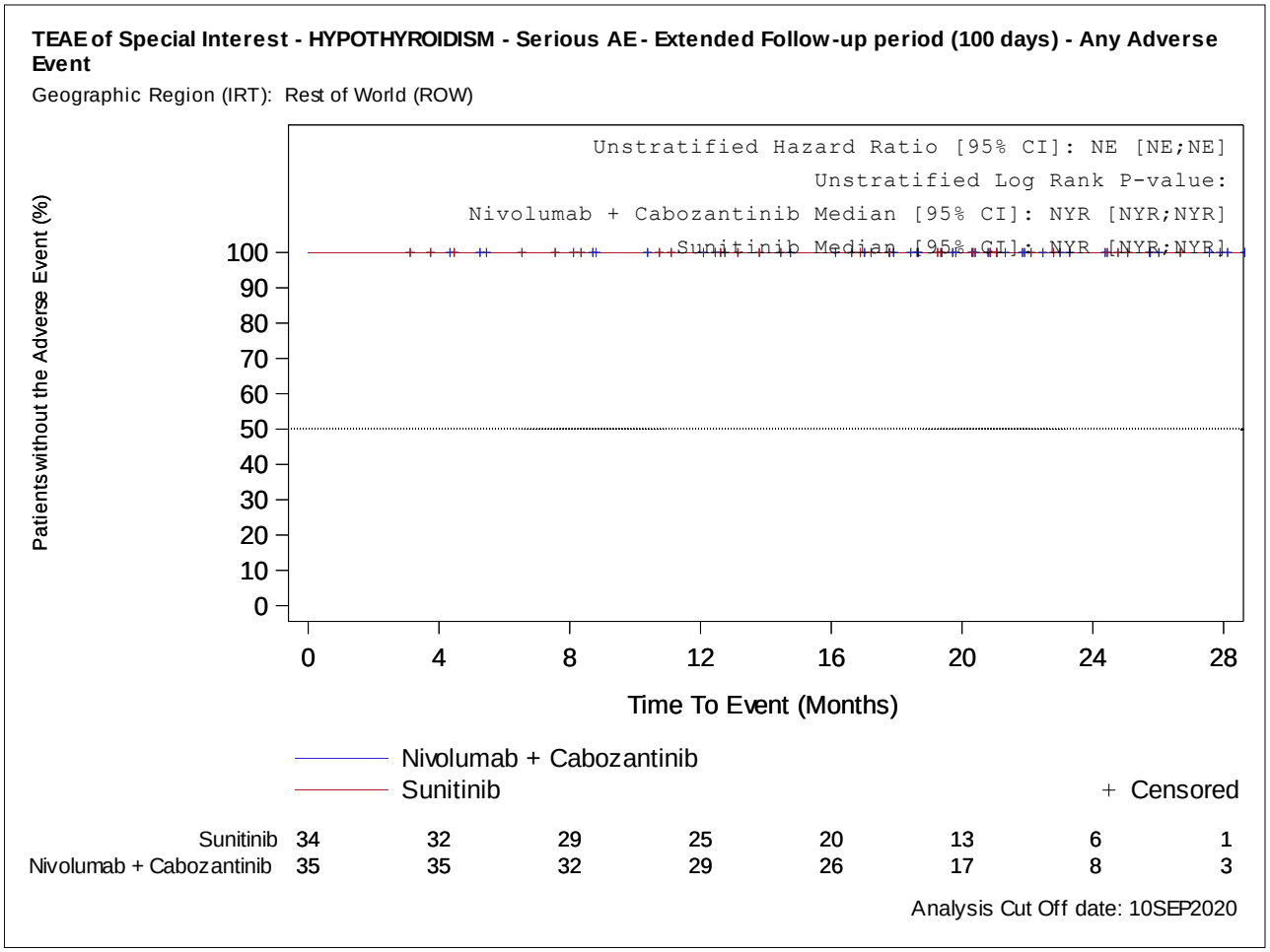

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:05:50

FIGURE 3.106.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



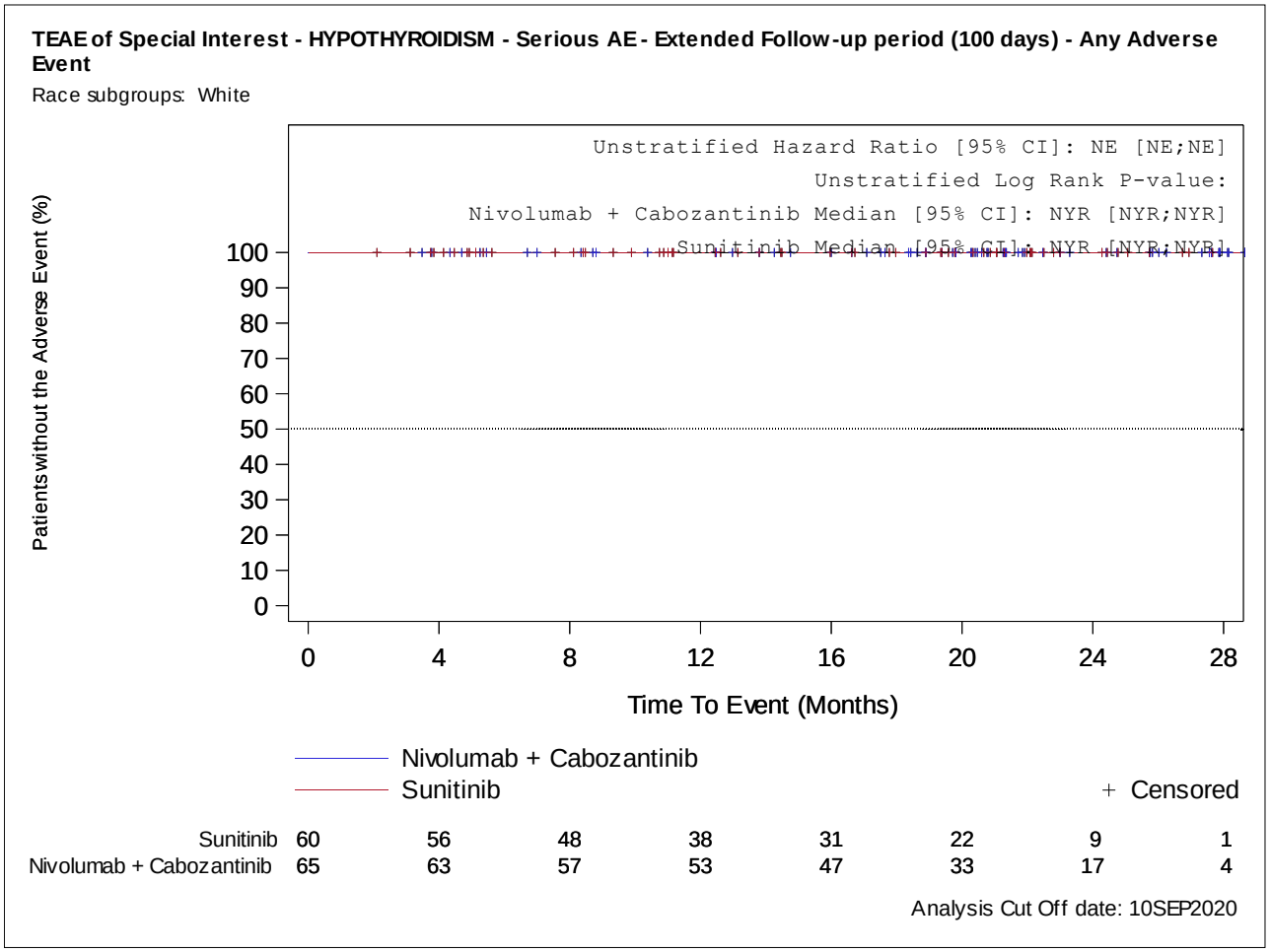

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:05:55

FIGURE 3.106.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



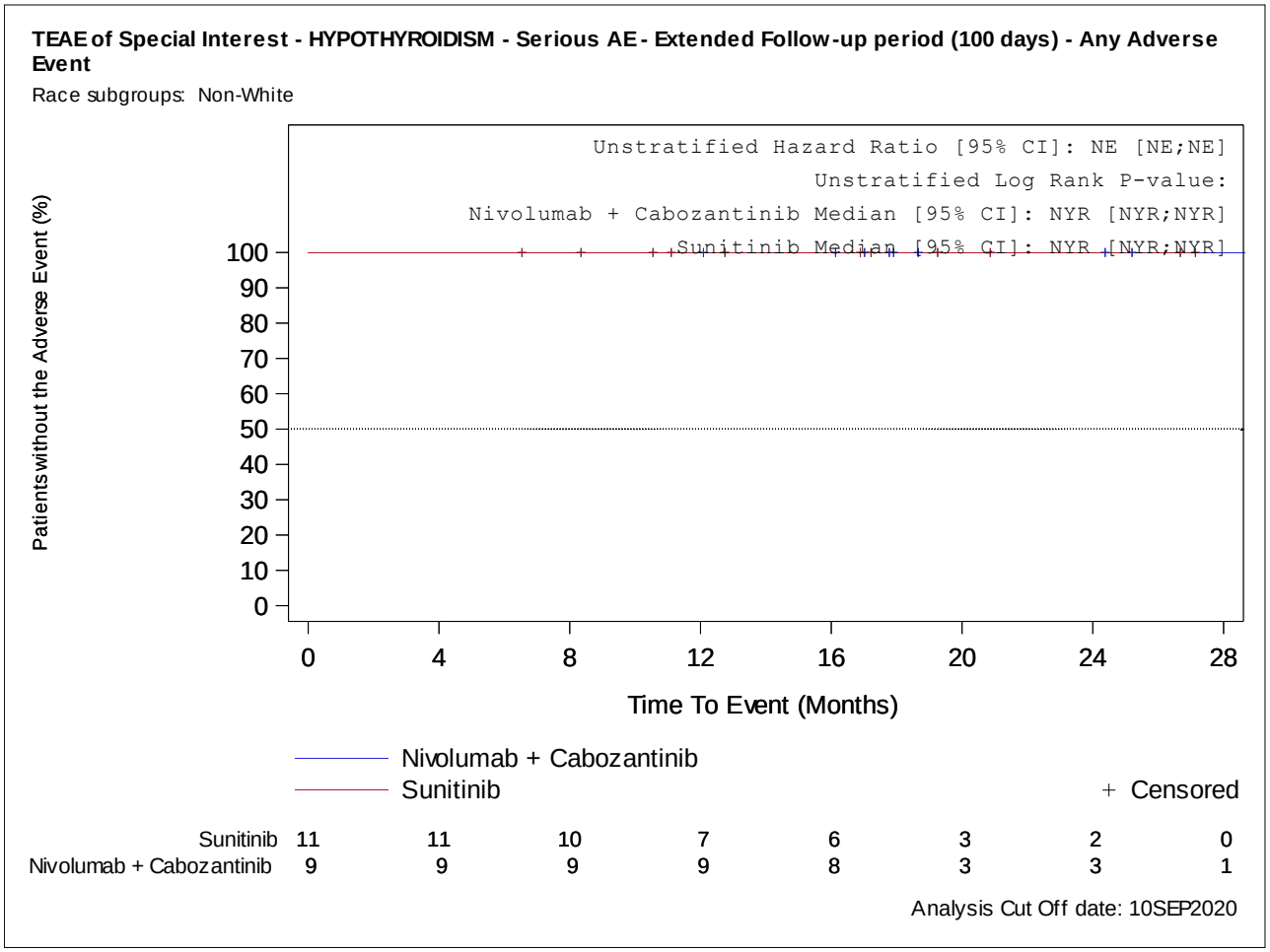

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:06:01

FIGURE 3.106.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



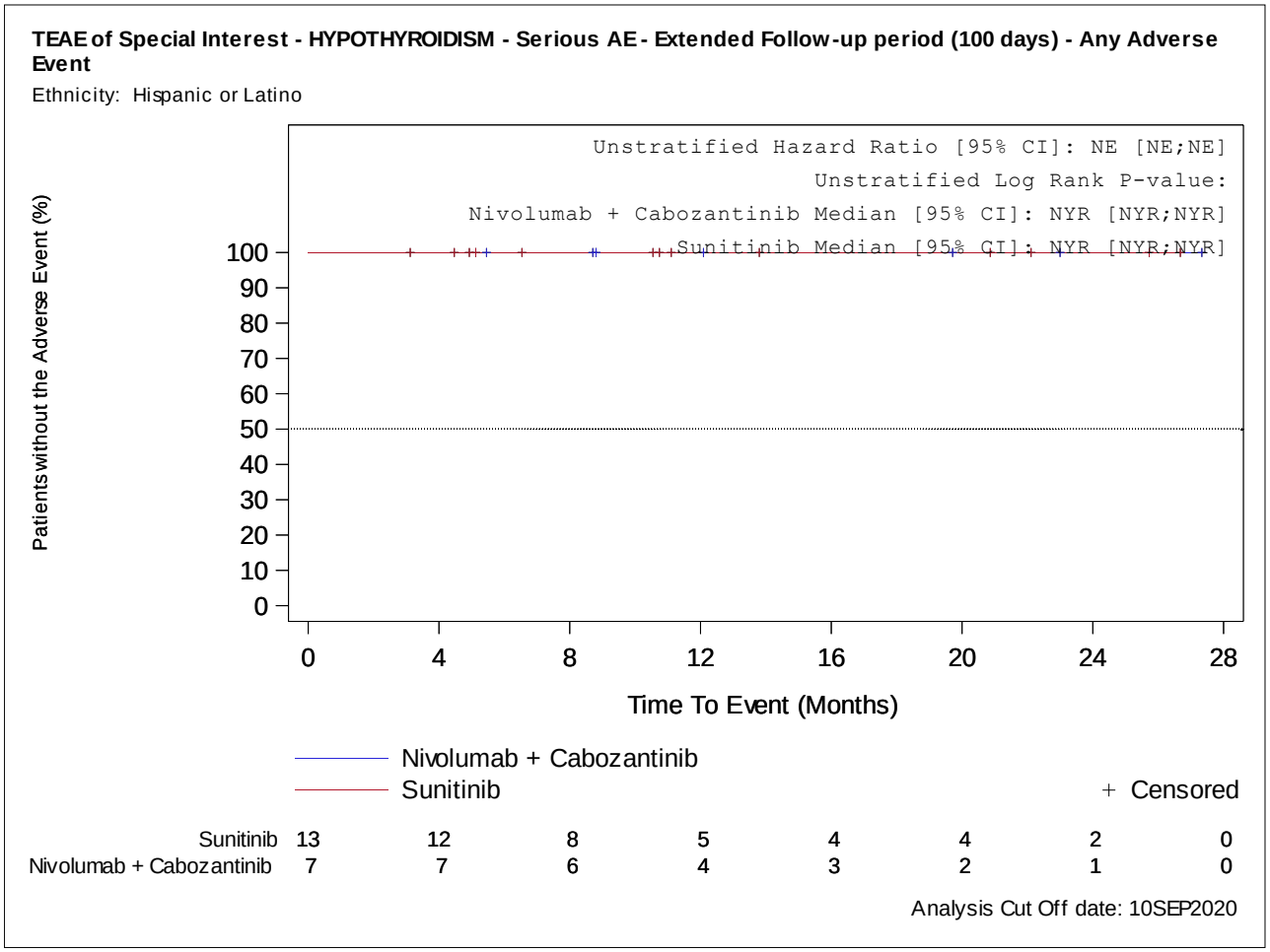

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:06:06

FIGURE 3.106.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



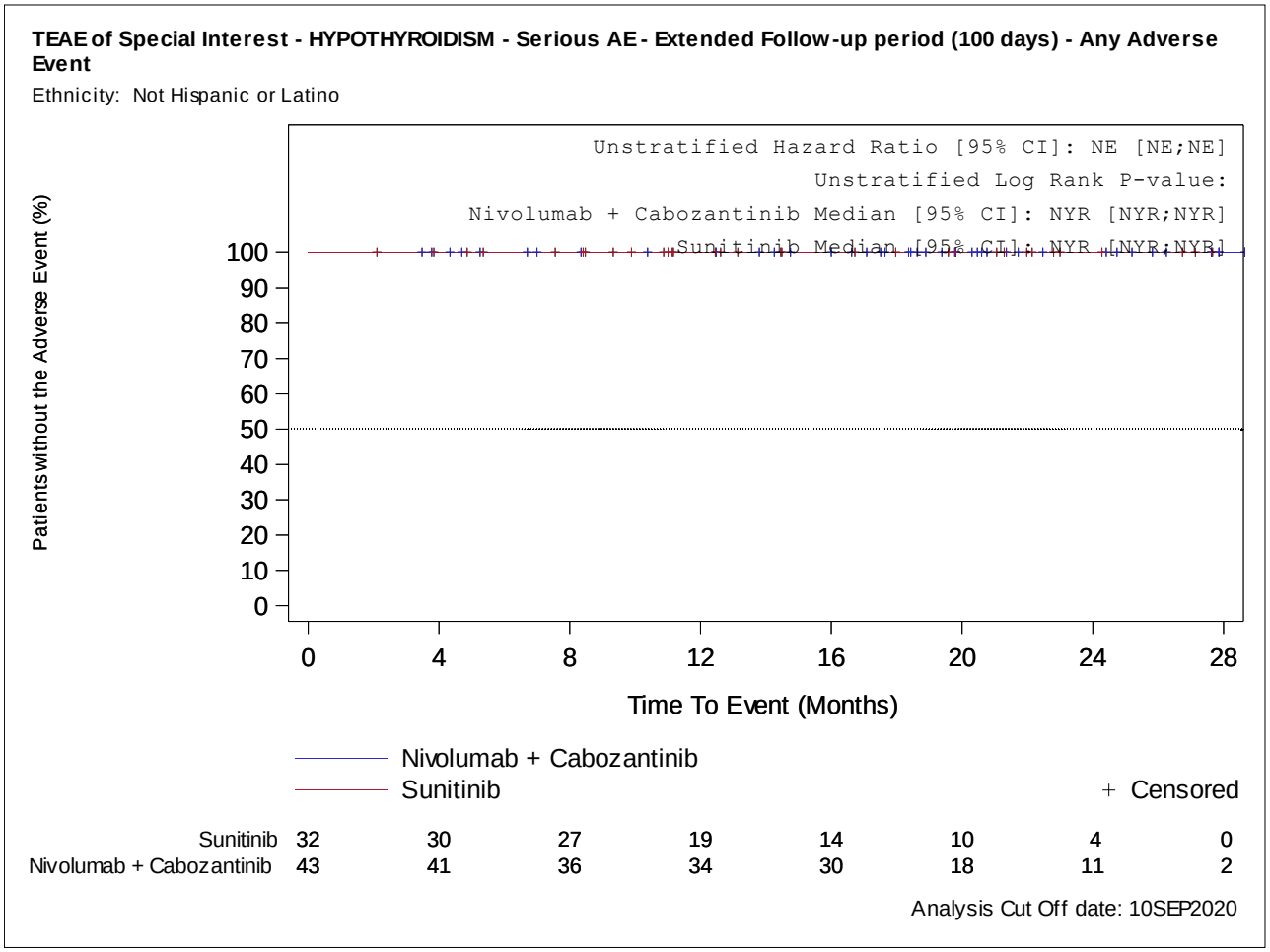

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:06:11

FIGURE 3.106.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



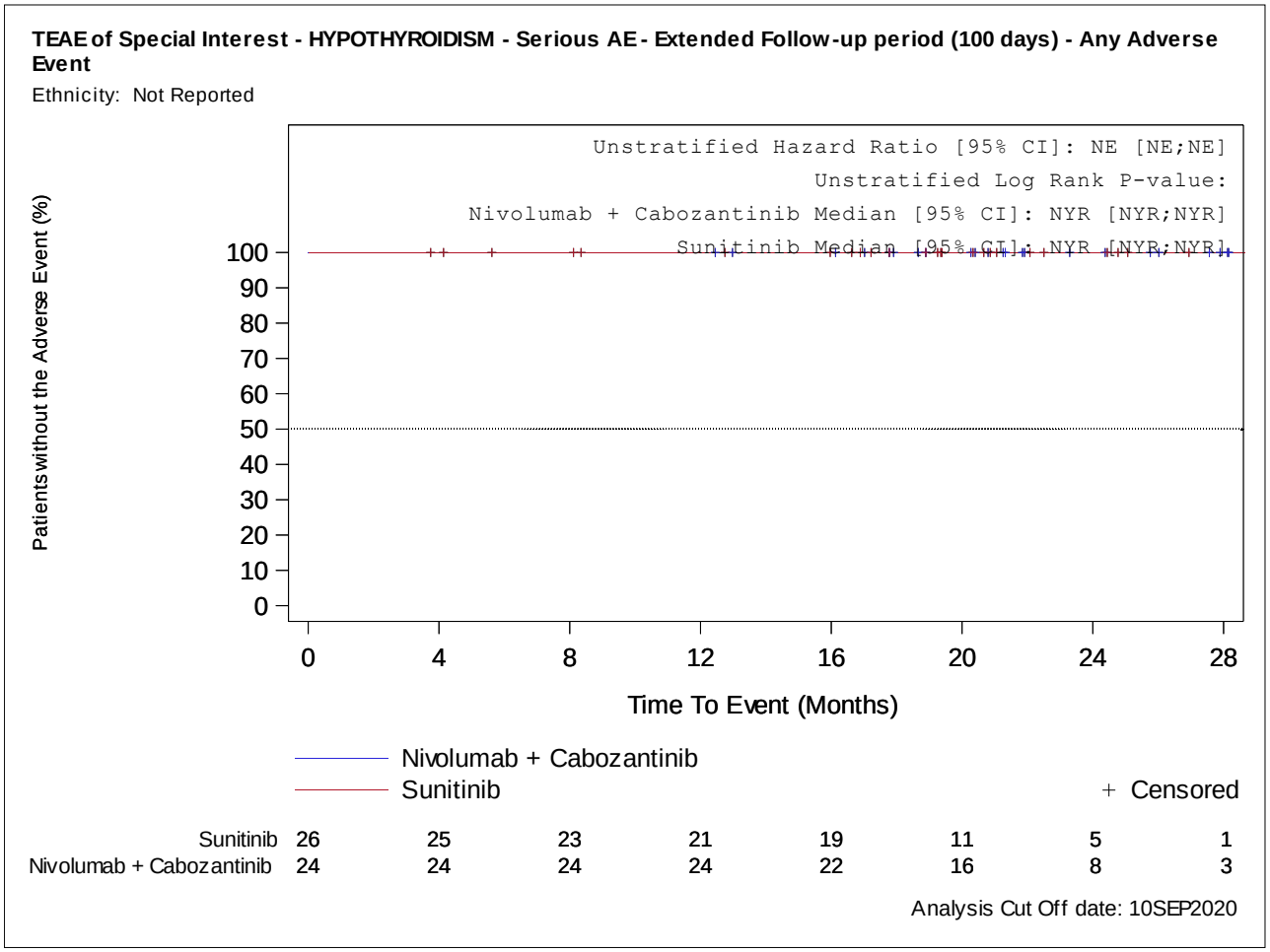

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:06:16

FIGURE 3.106.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



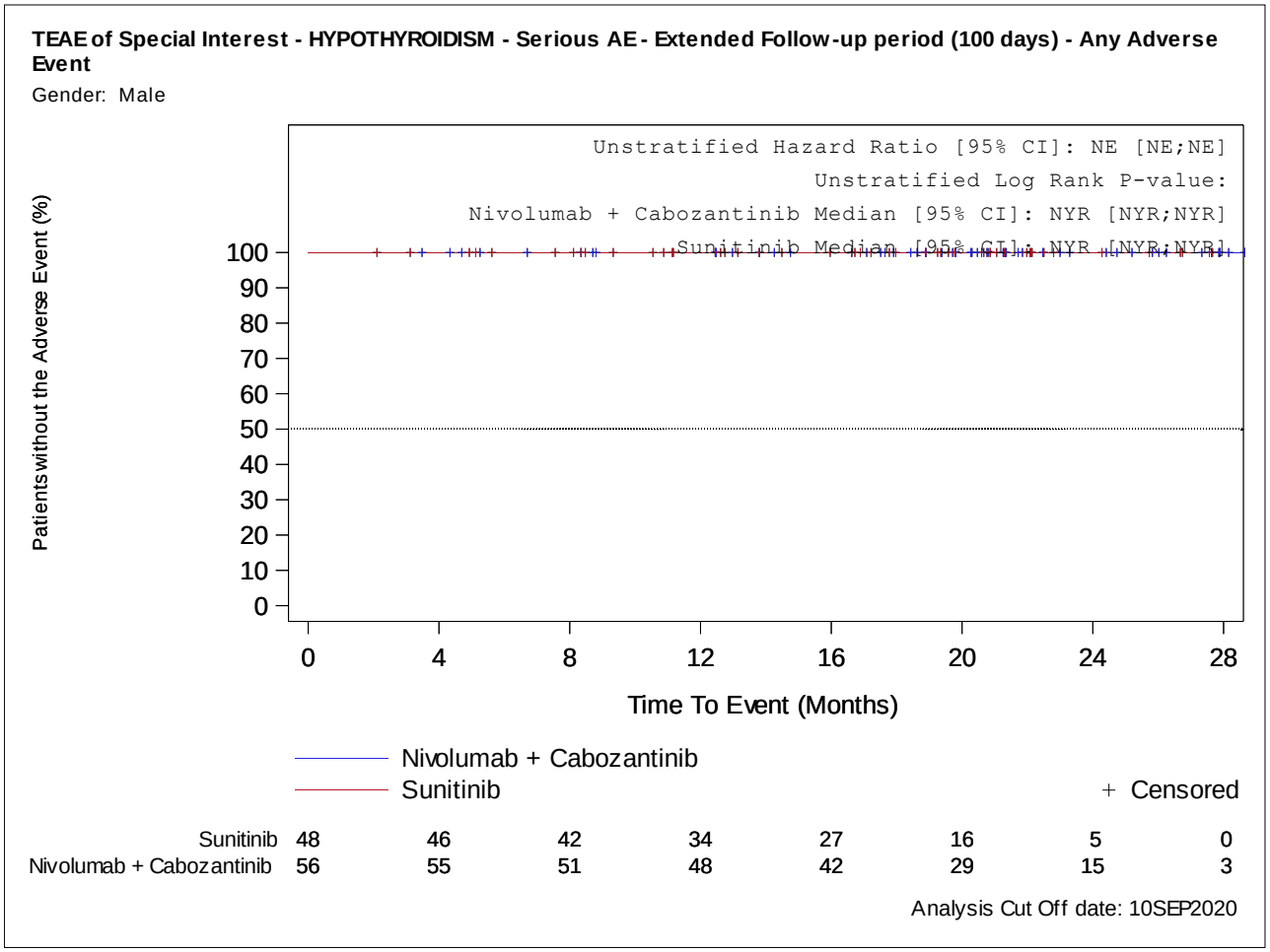

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:06:22

FIGURE 3.106.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



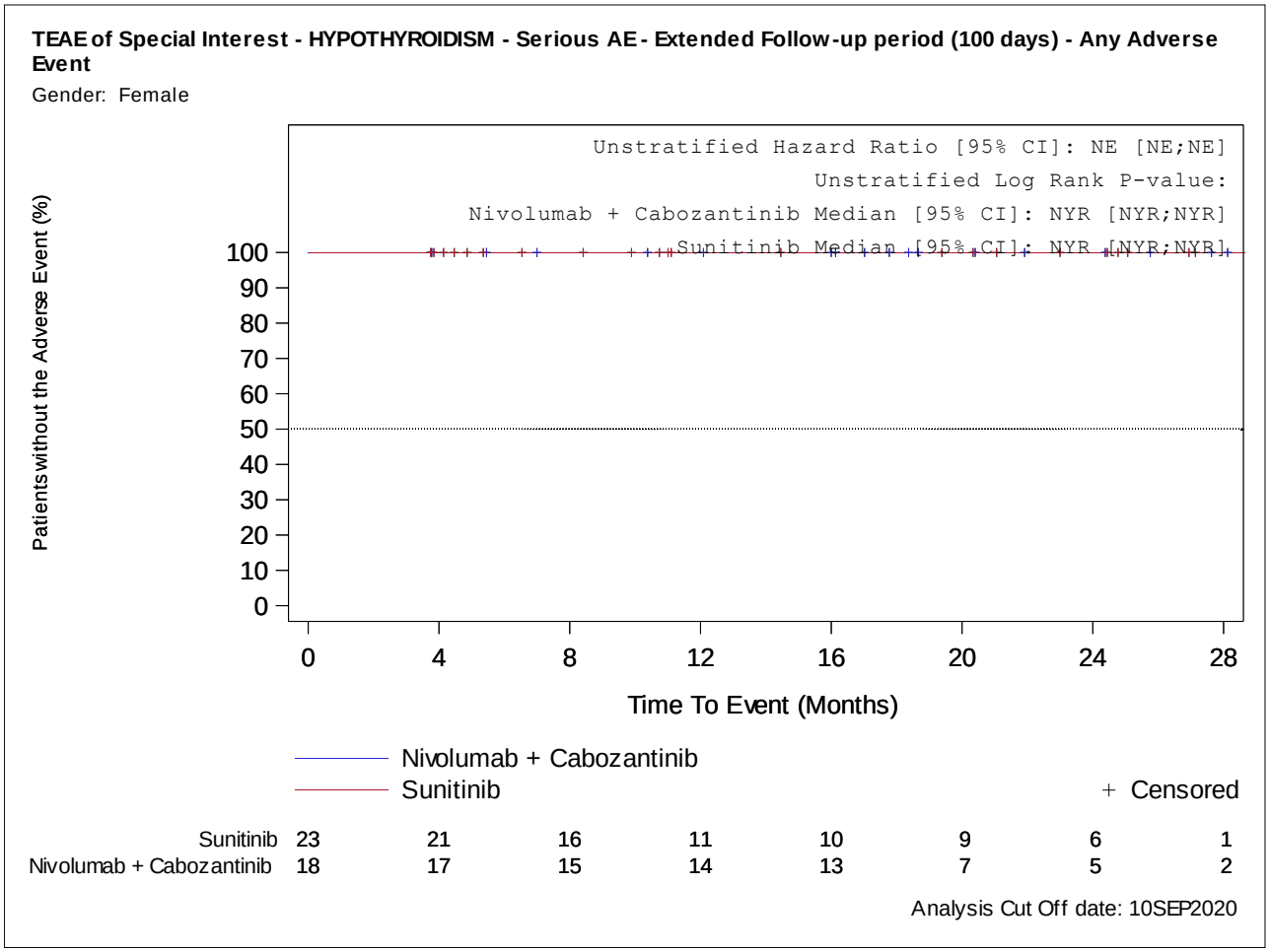

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:06:27

FIGURE 3.106.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



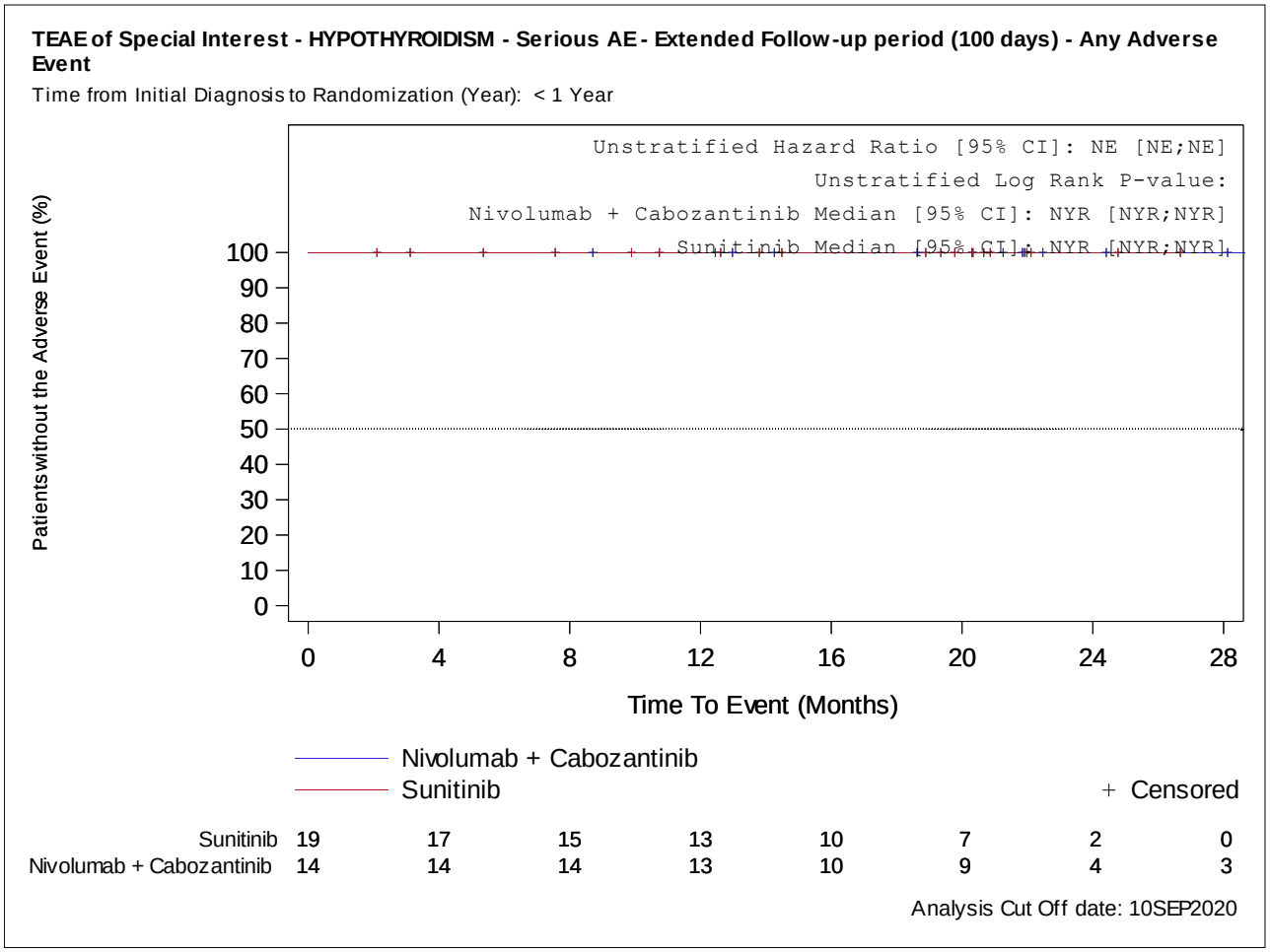

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:06:32

FIGURE 3.106.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:06:38

FIGURE 3.106.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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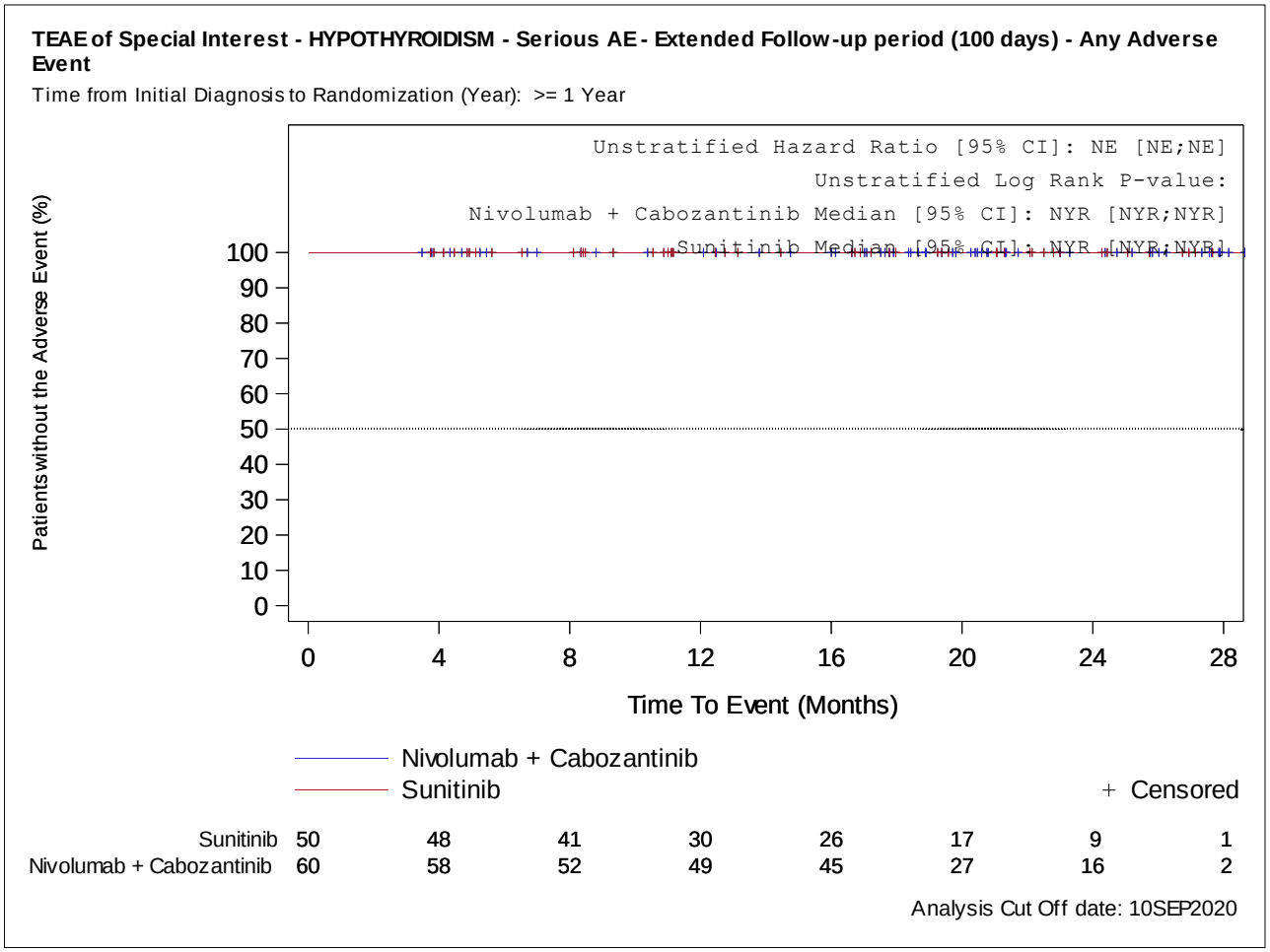
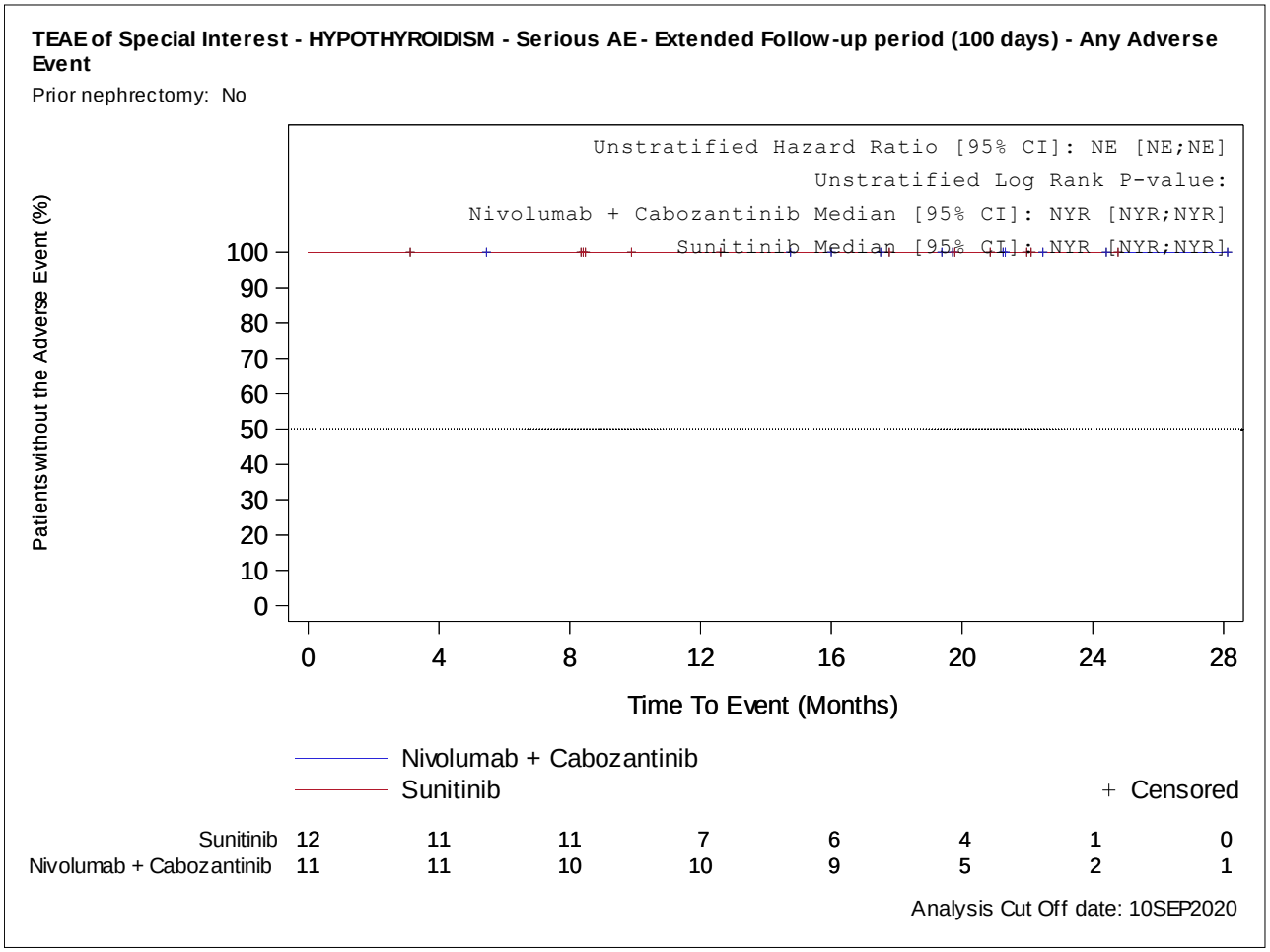
FIGURE 3.106.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



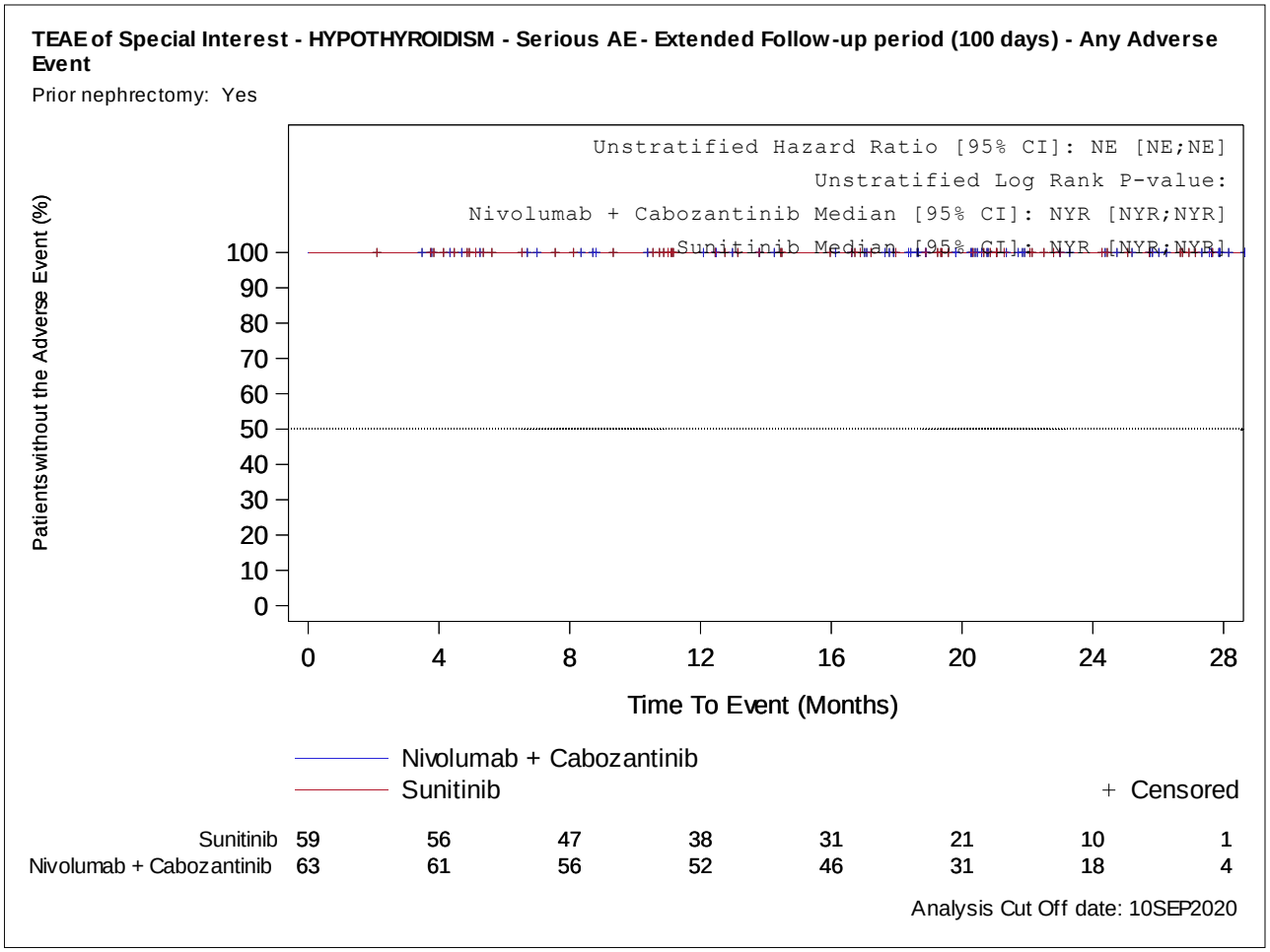

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:07:00

FIGURE 3.106.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



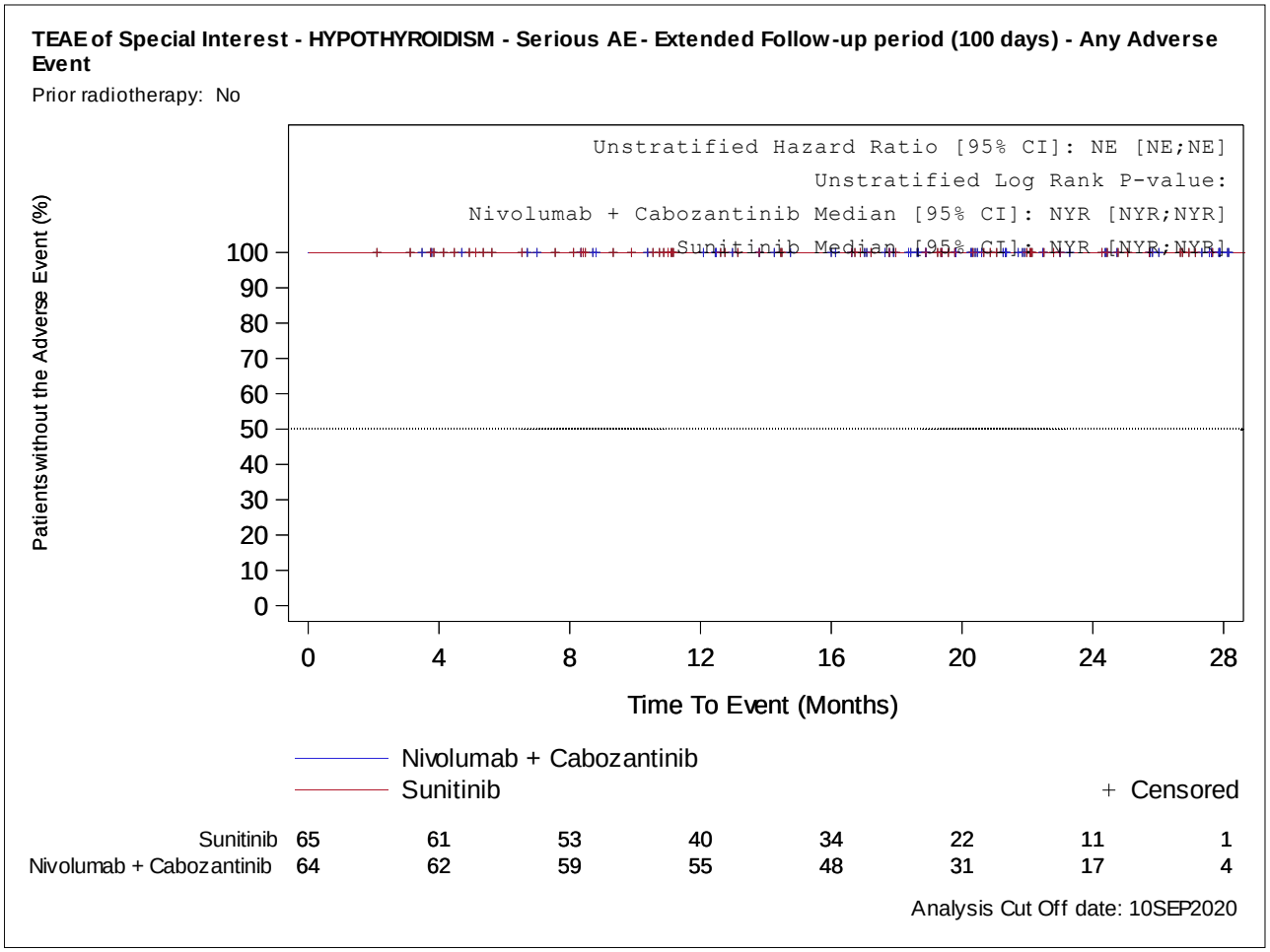

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:07:46

FIGURE 3.106.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



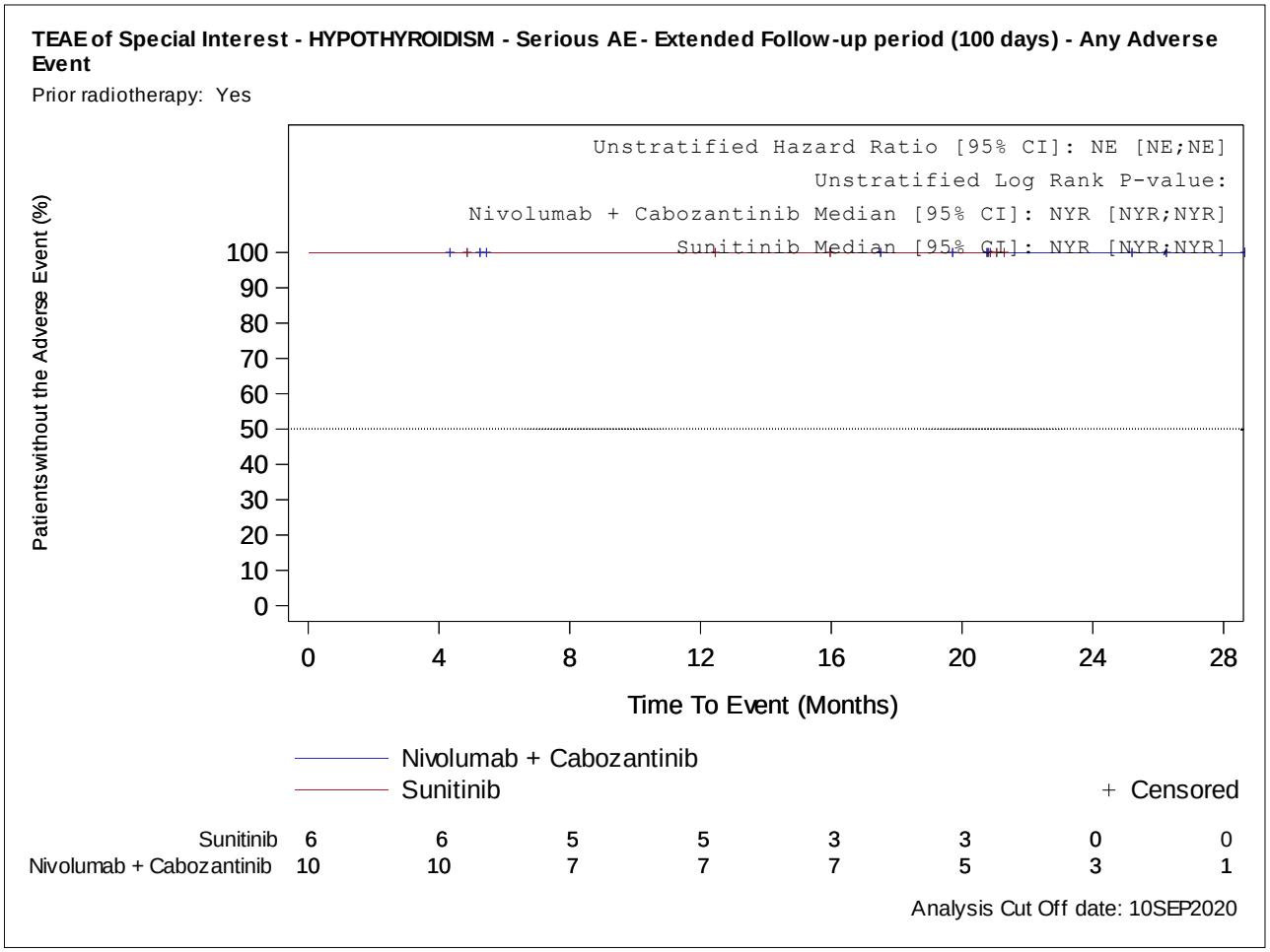

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:07:51

FIGURE 3.106.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:07:57

FIGURE 3.106.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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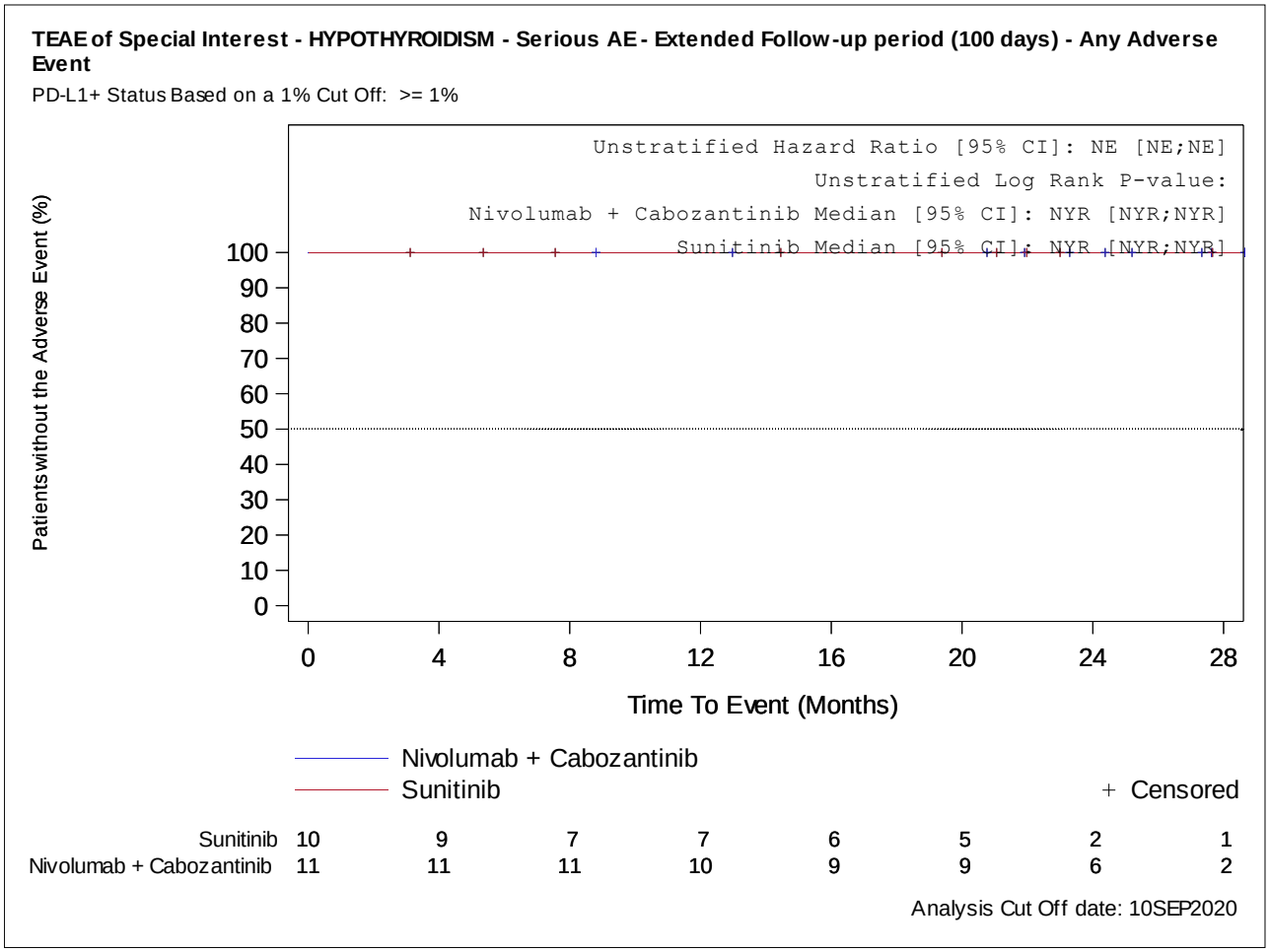
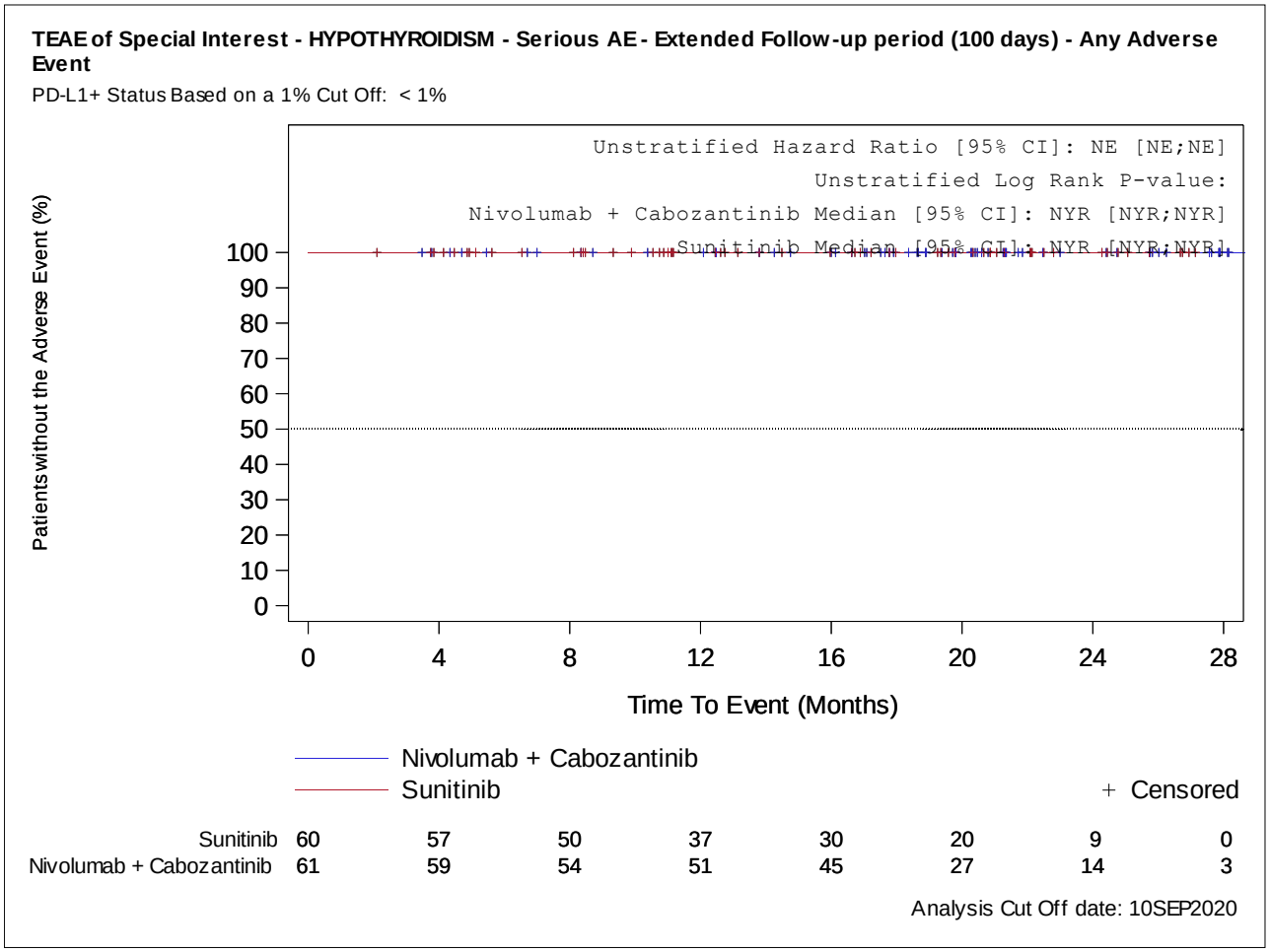
FIGURE 3.106.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



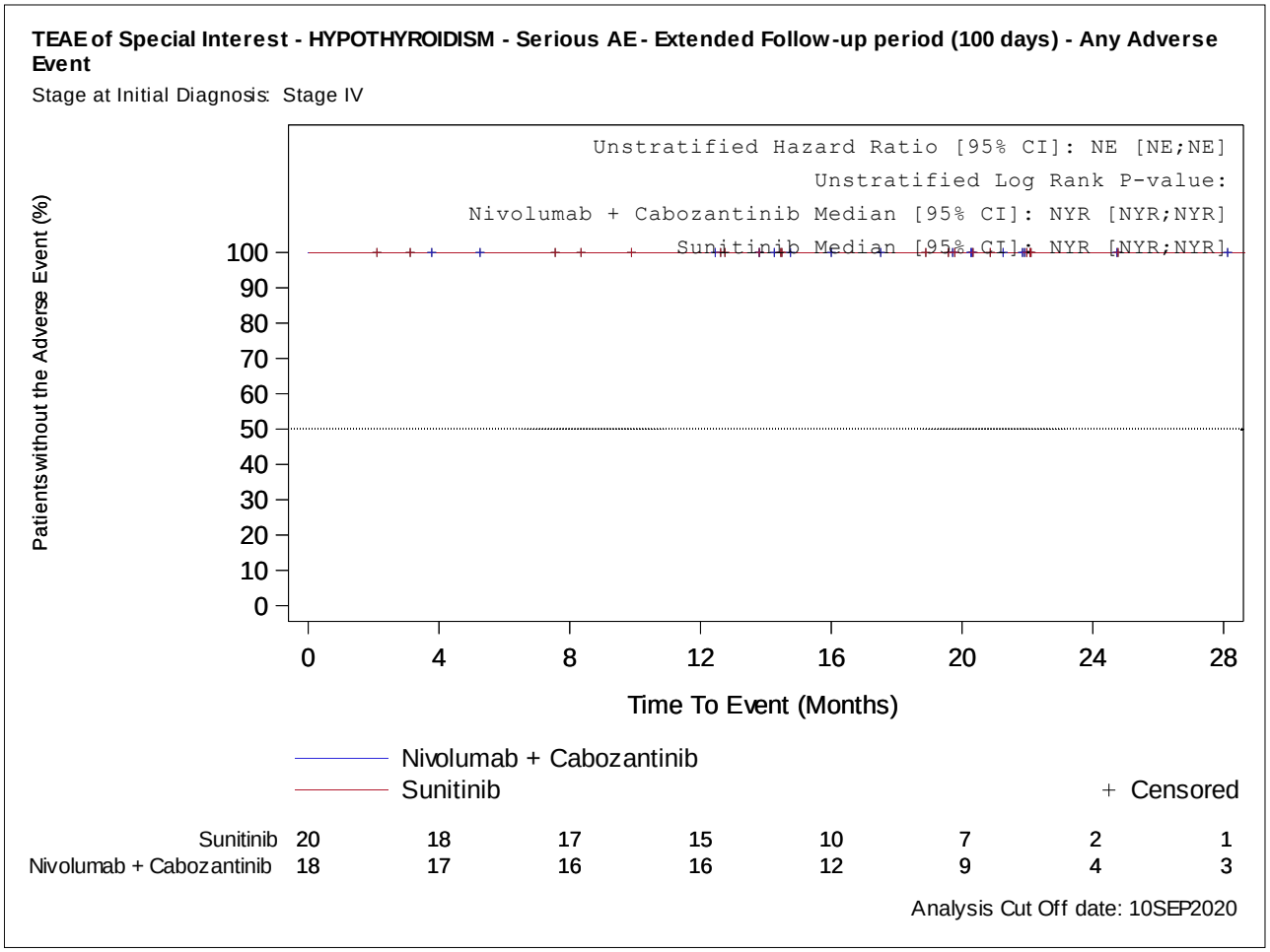

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:08:07

FIGURE 3.106.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



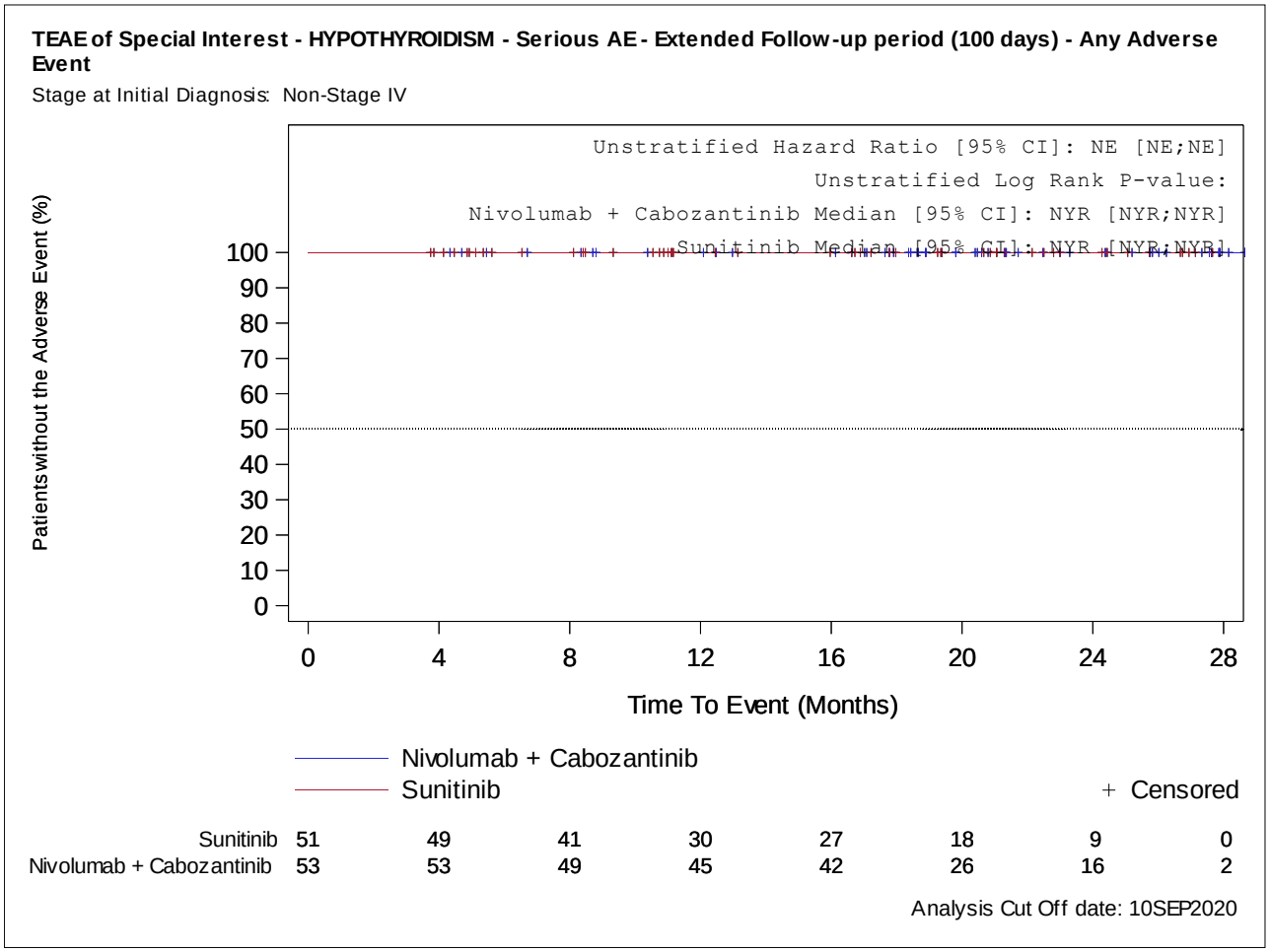

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:08:12

FIGURE 3.106.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:08:38

FIGURE 3.106.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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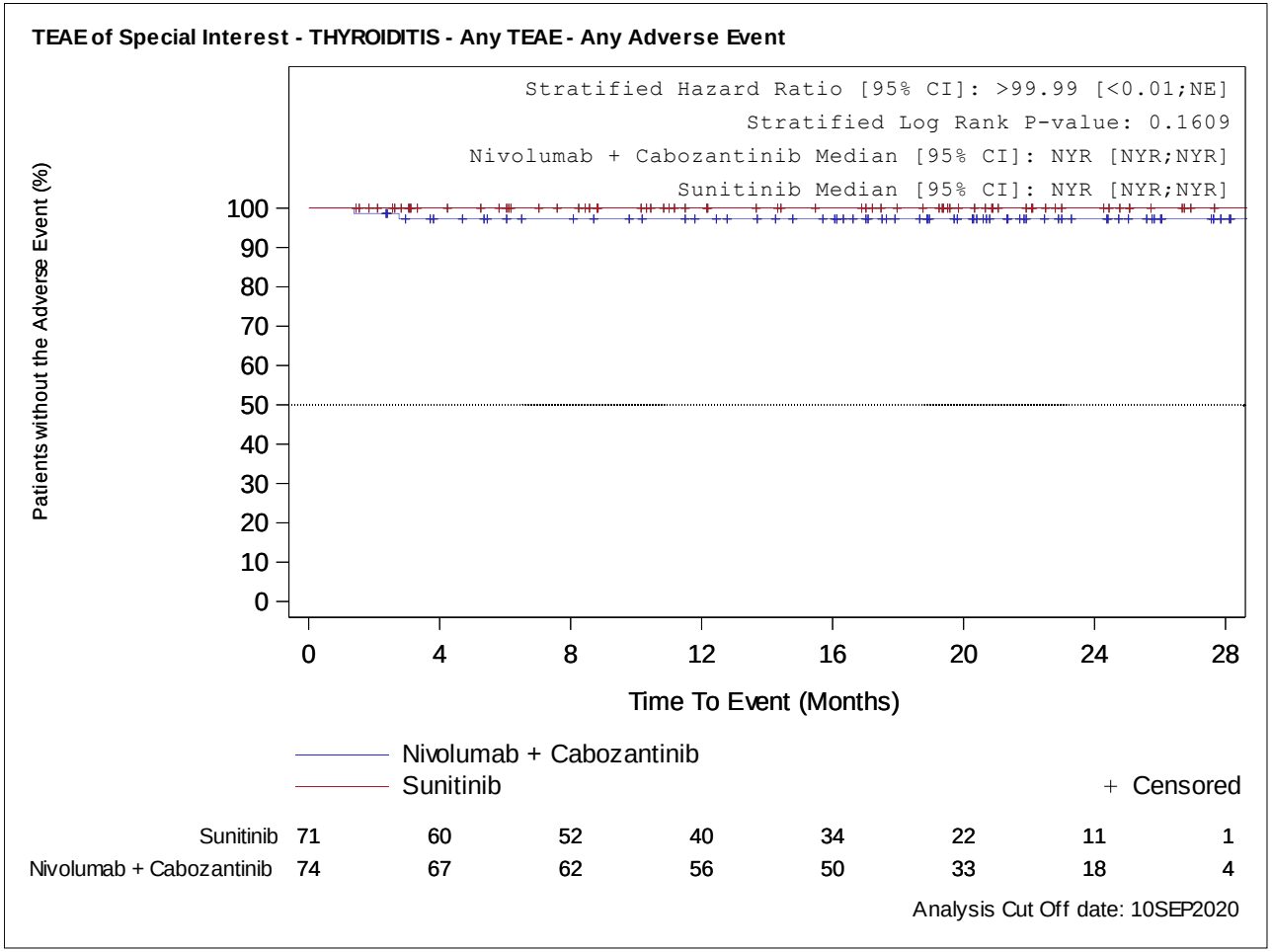
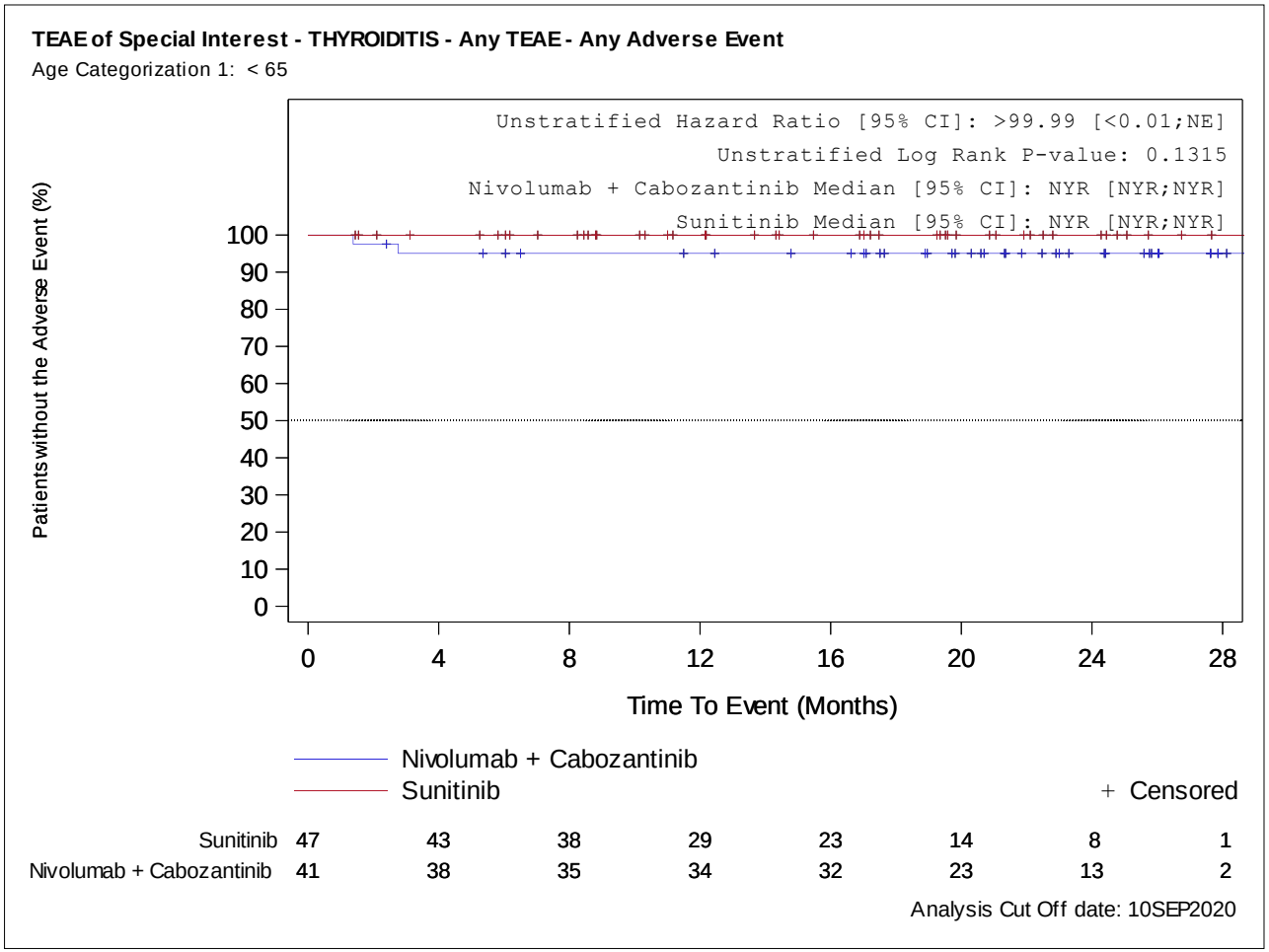
FIGURE 3.107.1: TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:11:42

FIGURE 3.107.2.1: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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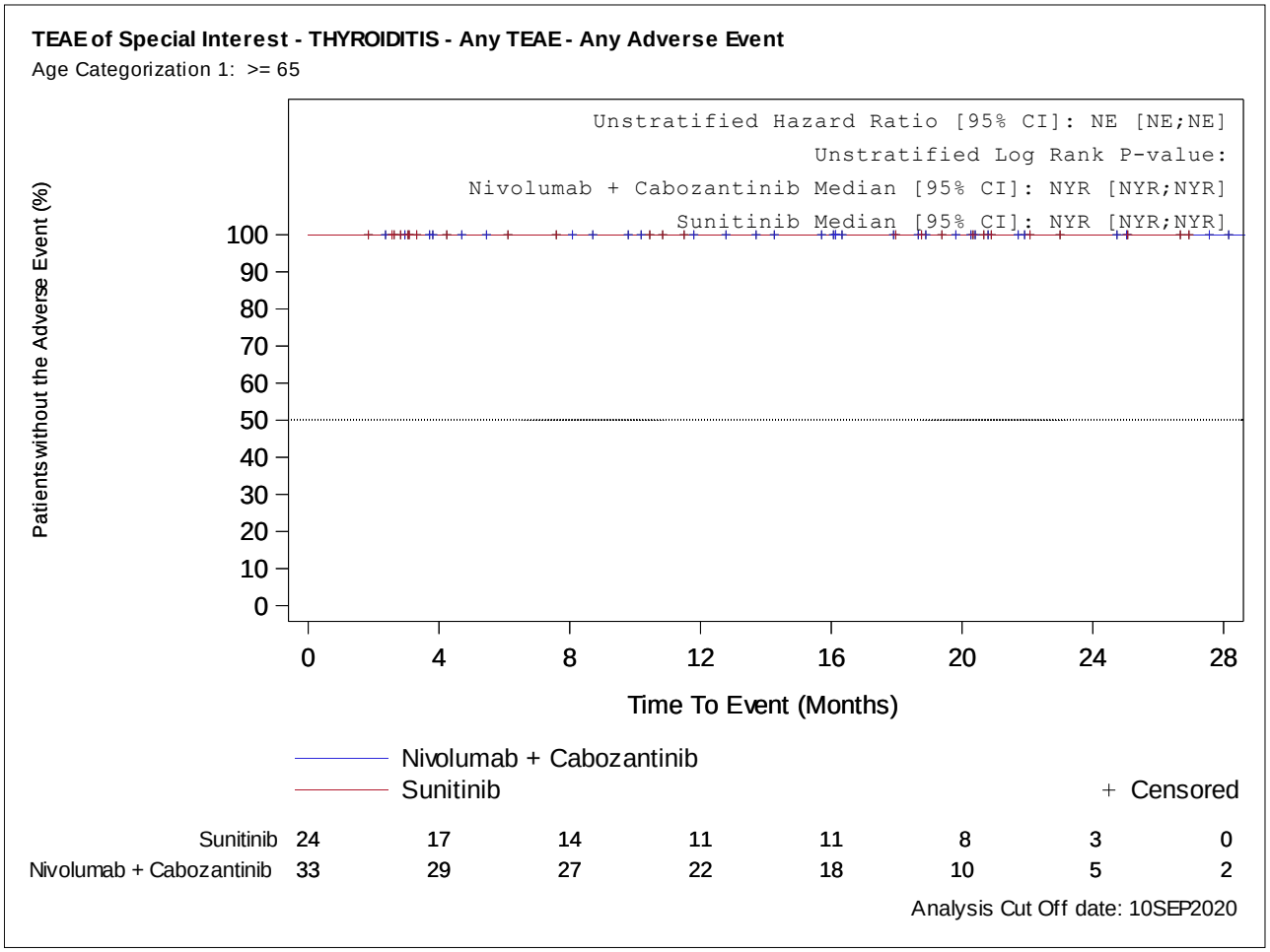
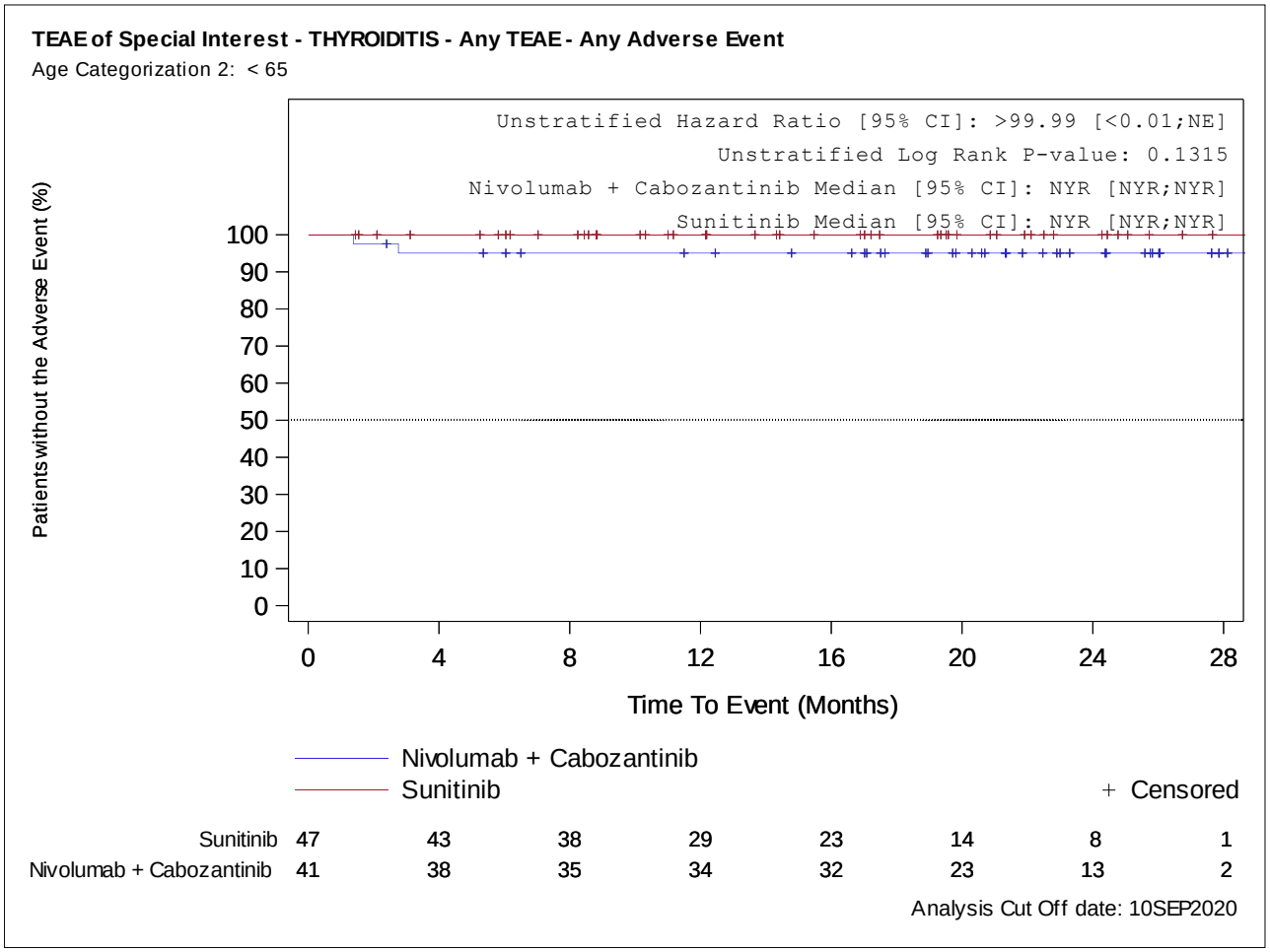
FIGURE 3.107.2.2: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



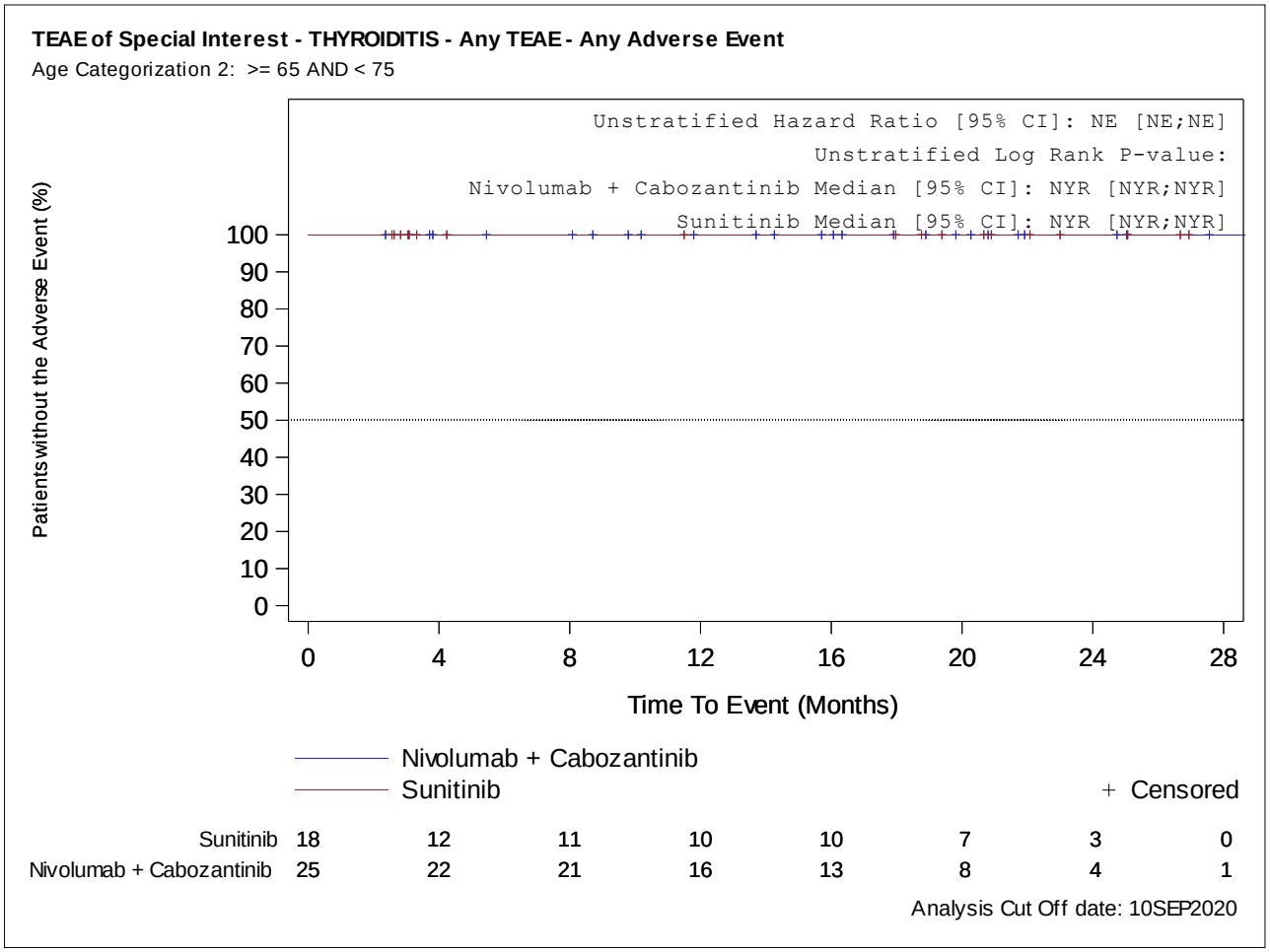

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:11:51

FIGURE 3.107.2.3: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



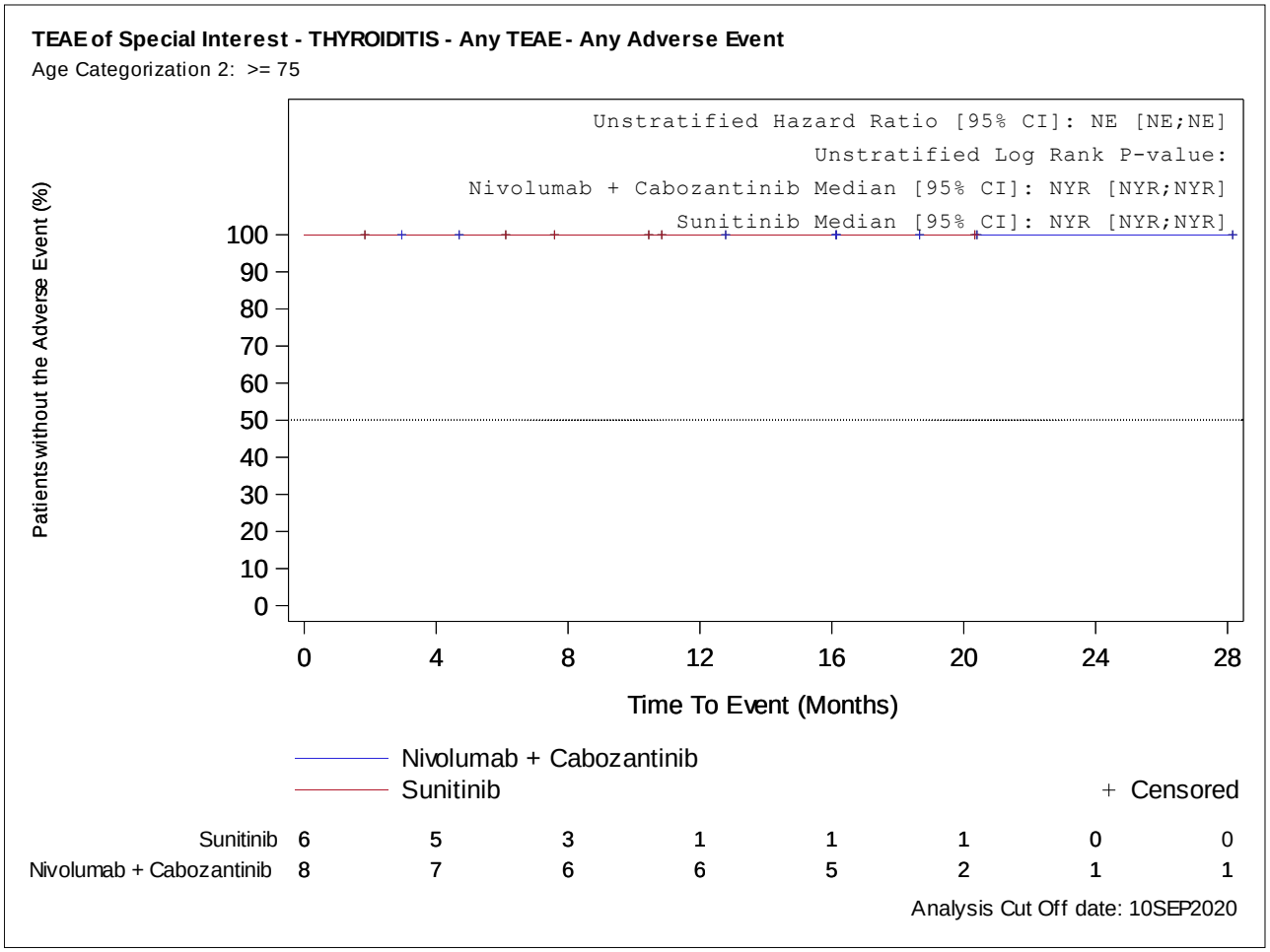

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:11:56

FIGURE 3.107.2.4: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



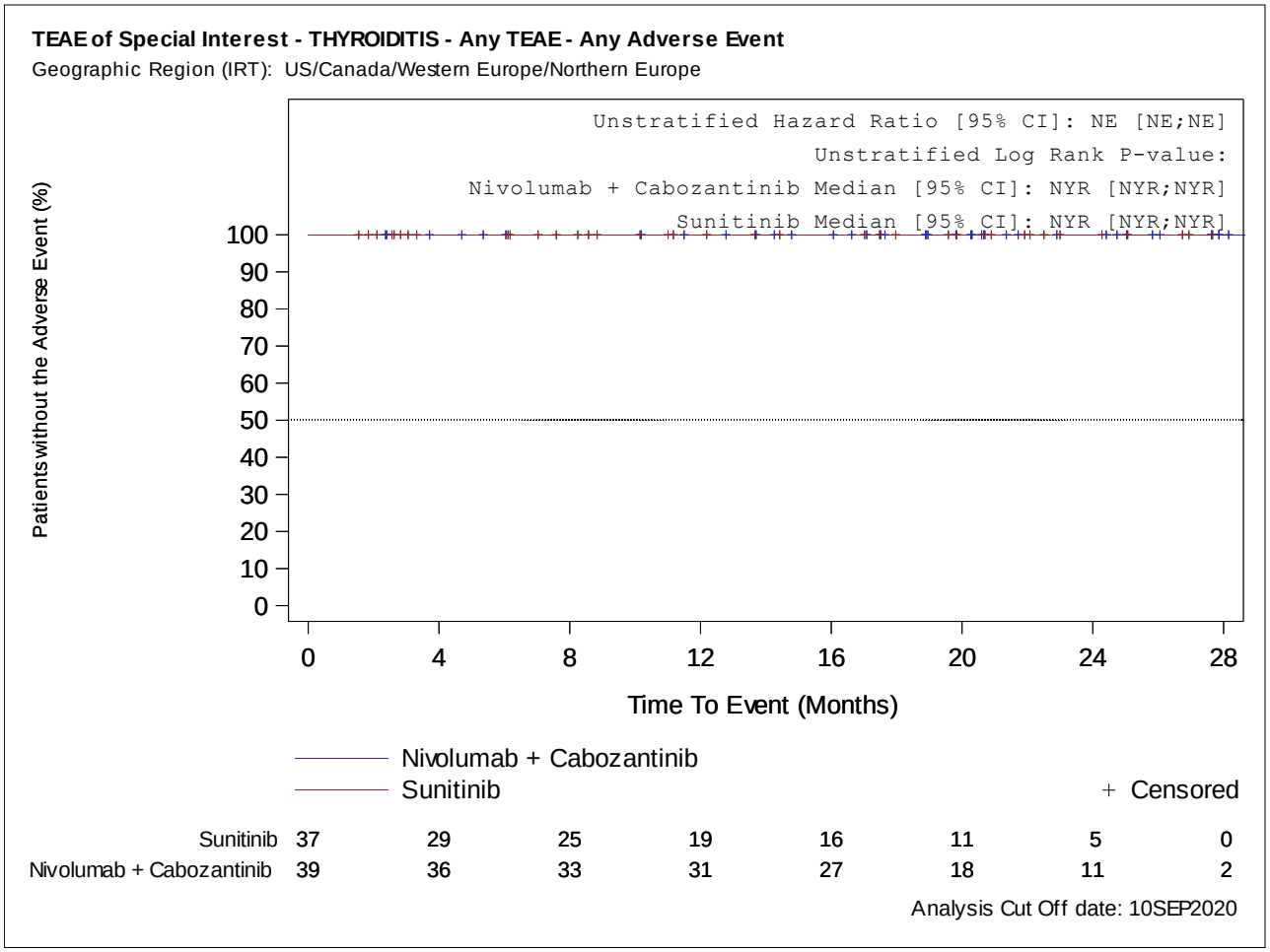

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:12:01

FIGURE 3.107.2.5: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



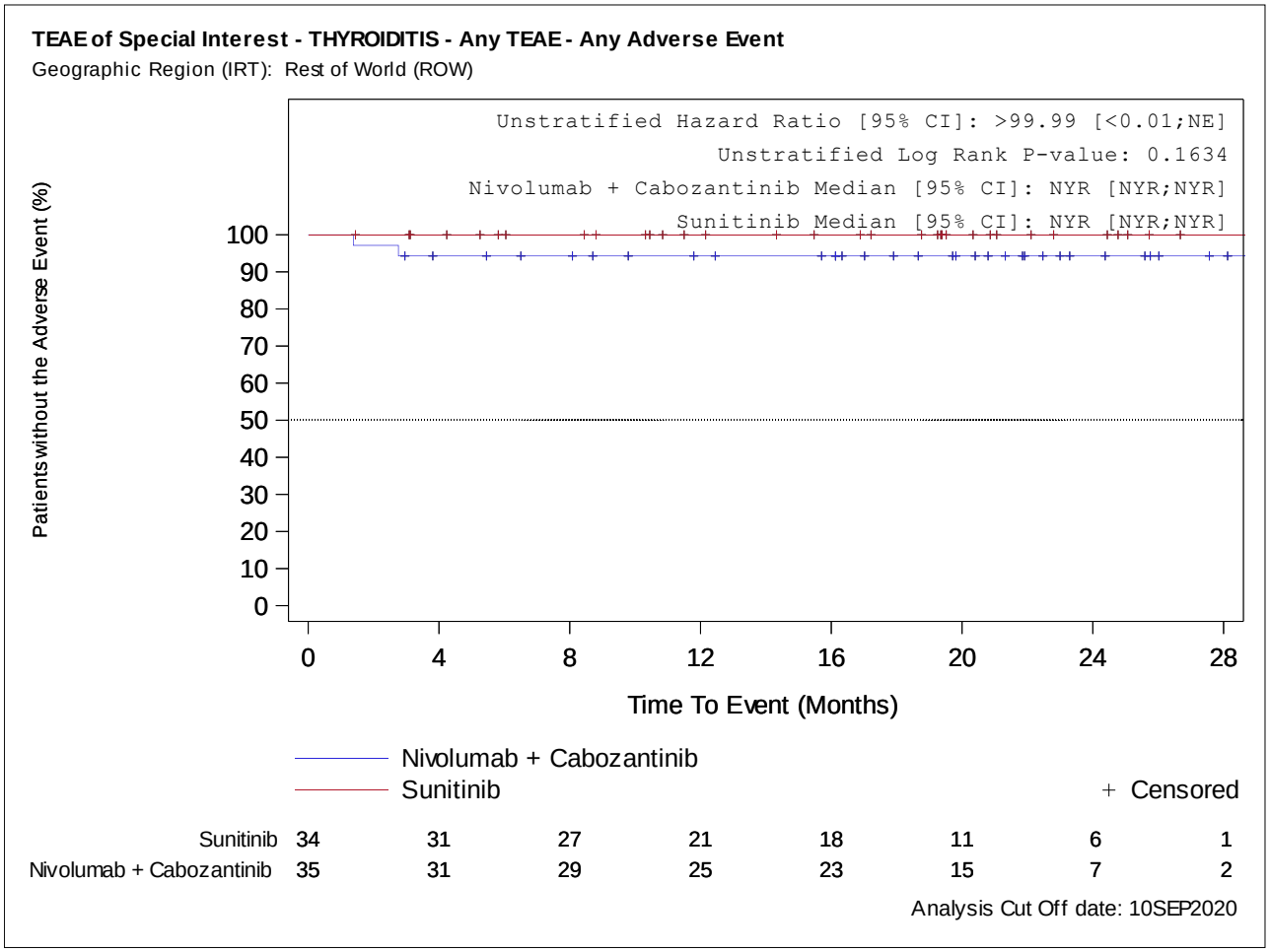

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:12:07

FIGURE 3.107.2.6: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



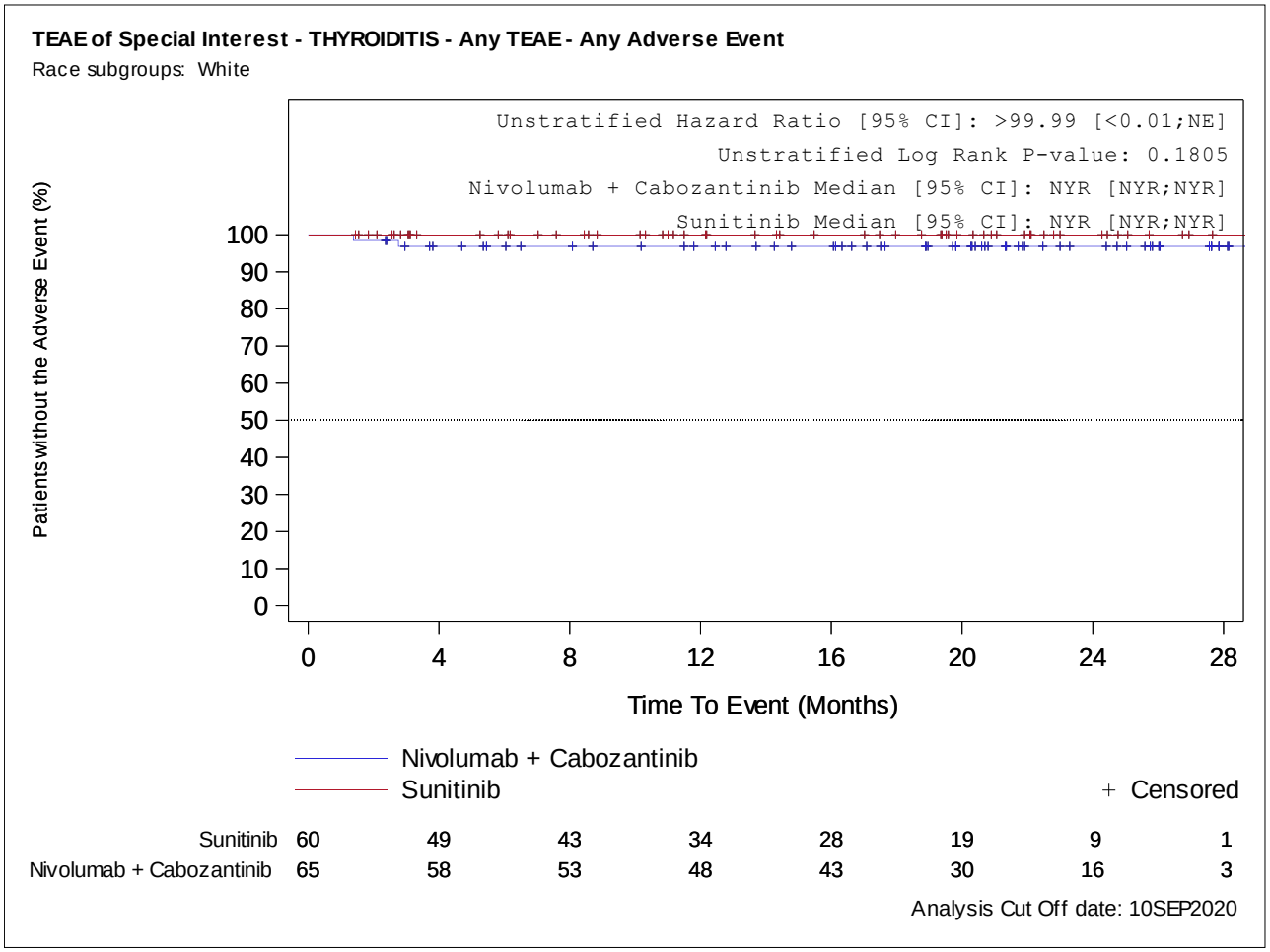

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:12:12

FIGURE 3.107.2.7: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



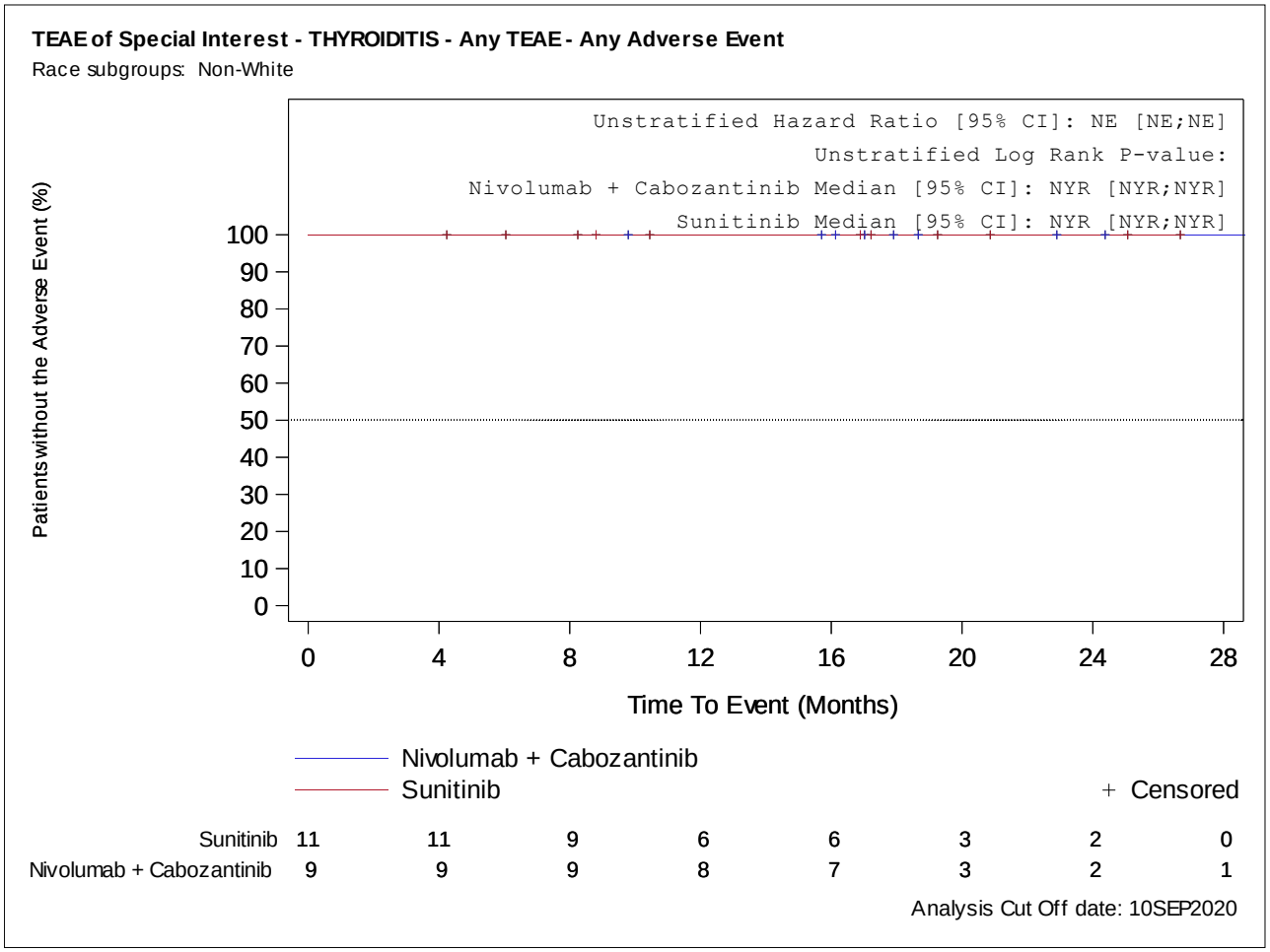

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:12:17

FIGURE 3.107.2.8: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



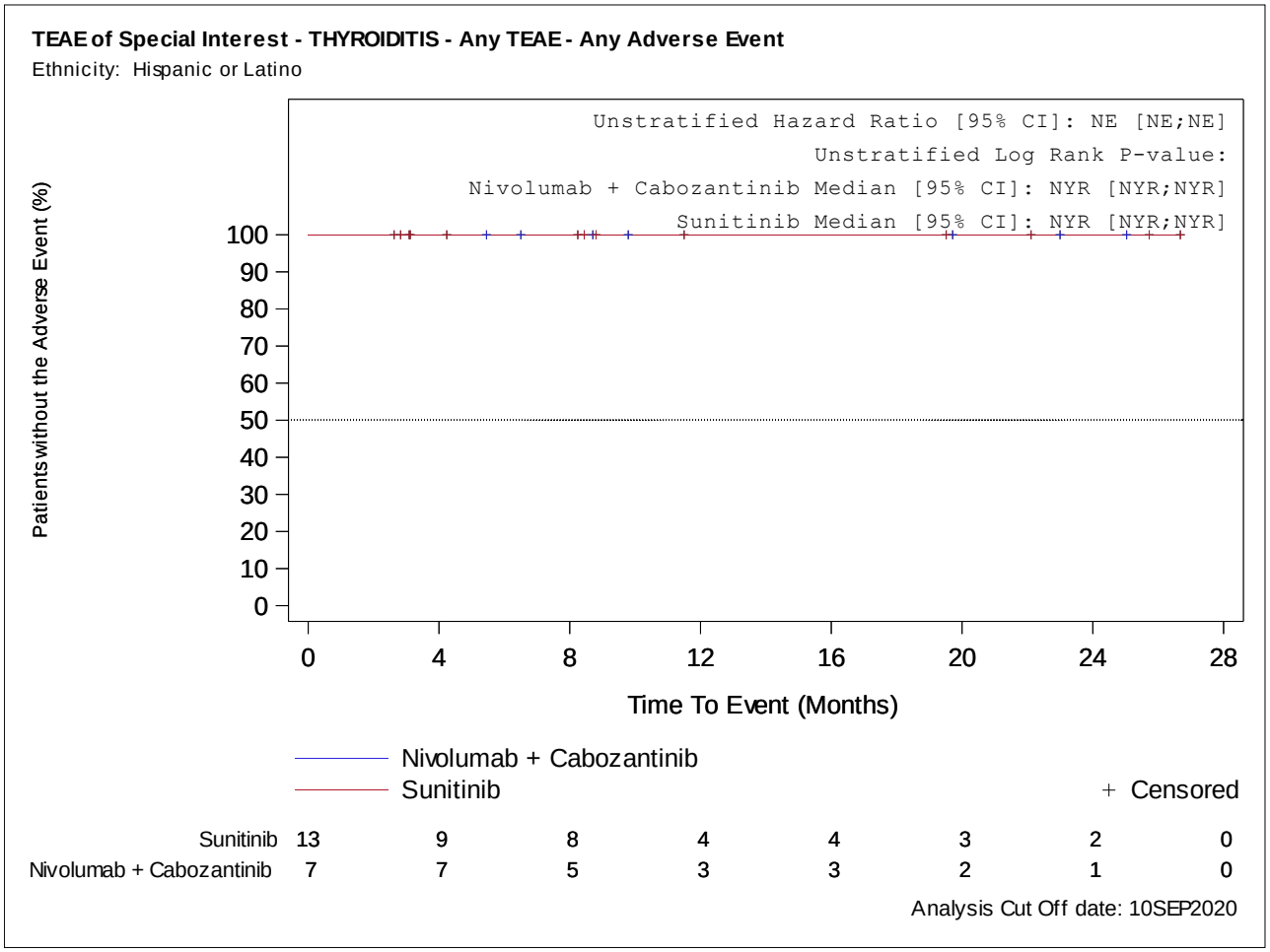

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:12:23

FIGURE 3.107.2.9: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



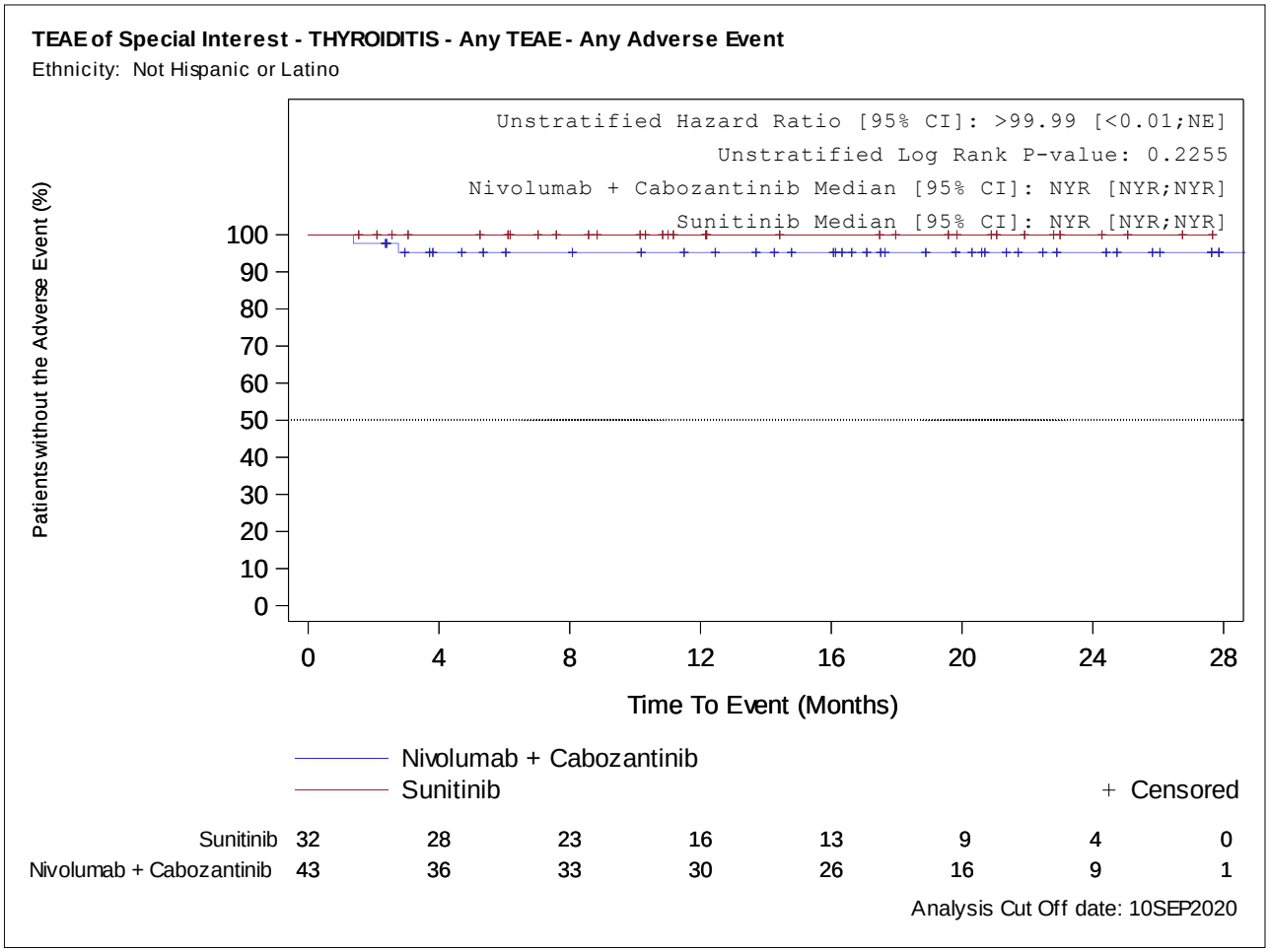

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:12:28

FIGURE 3.107.2.10: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



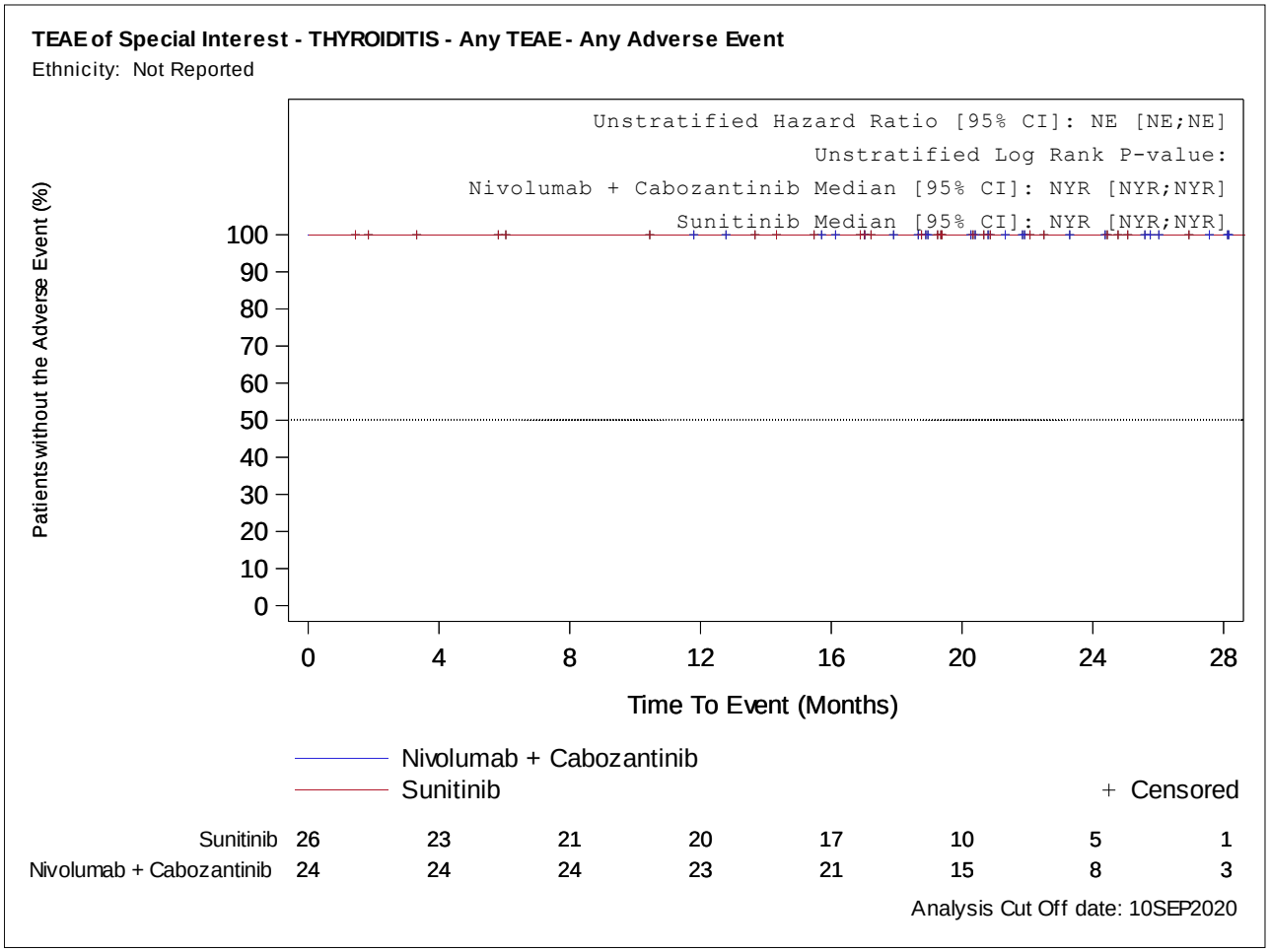

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:12:33

FIGURE 3.107.2.11: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:12:38

FIGURE 3.107.2.12: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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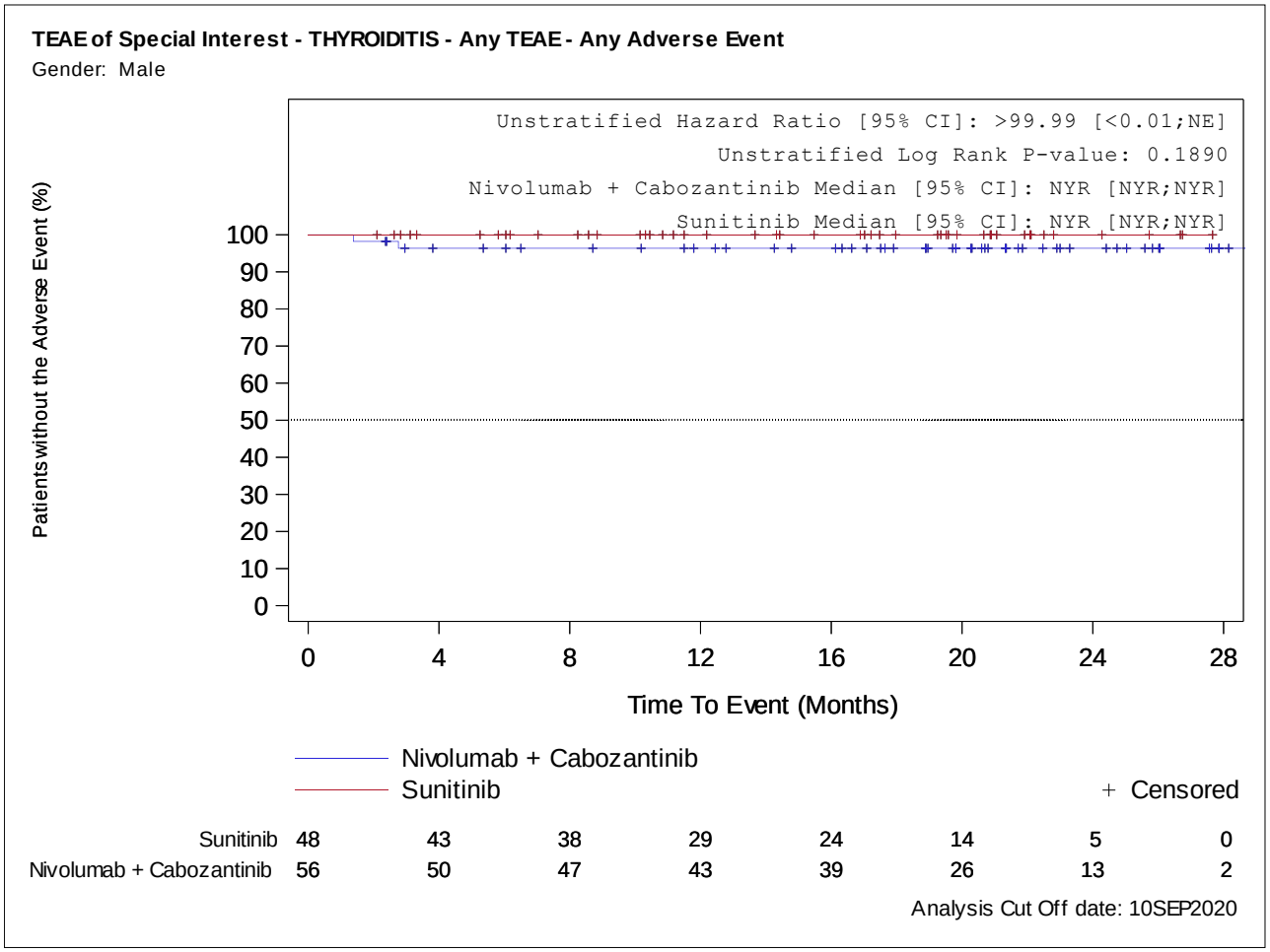
FIGURE 3.107.2.13: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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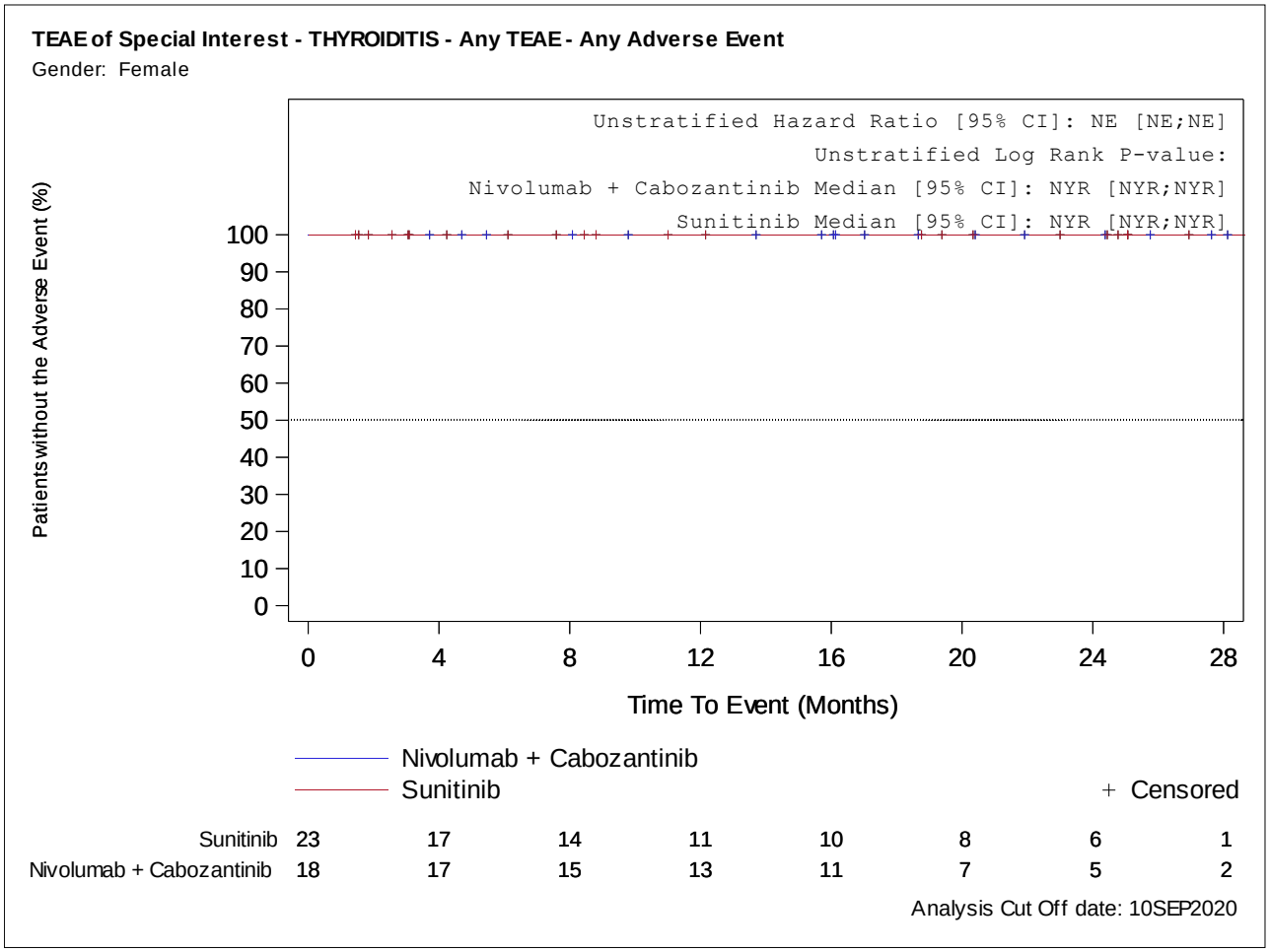
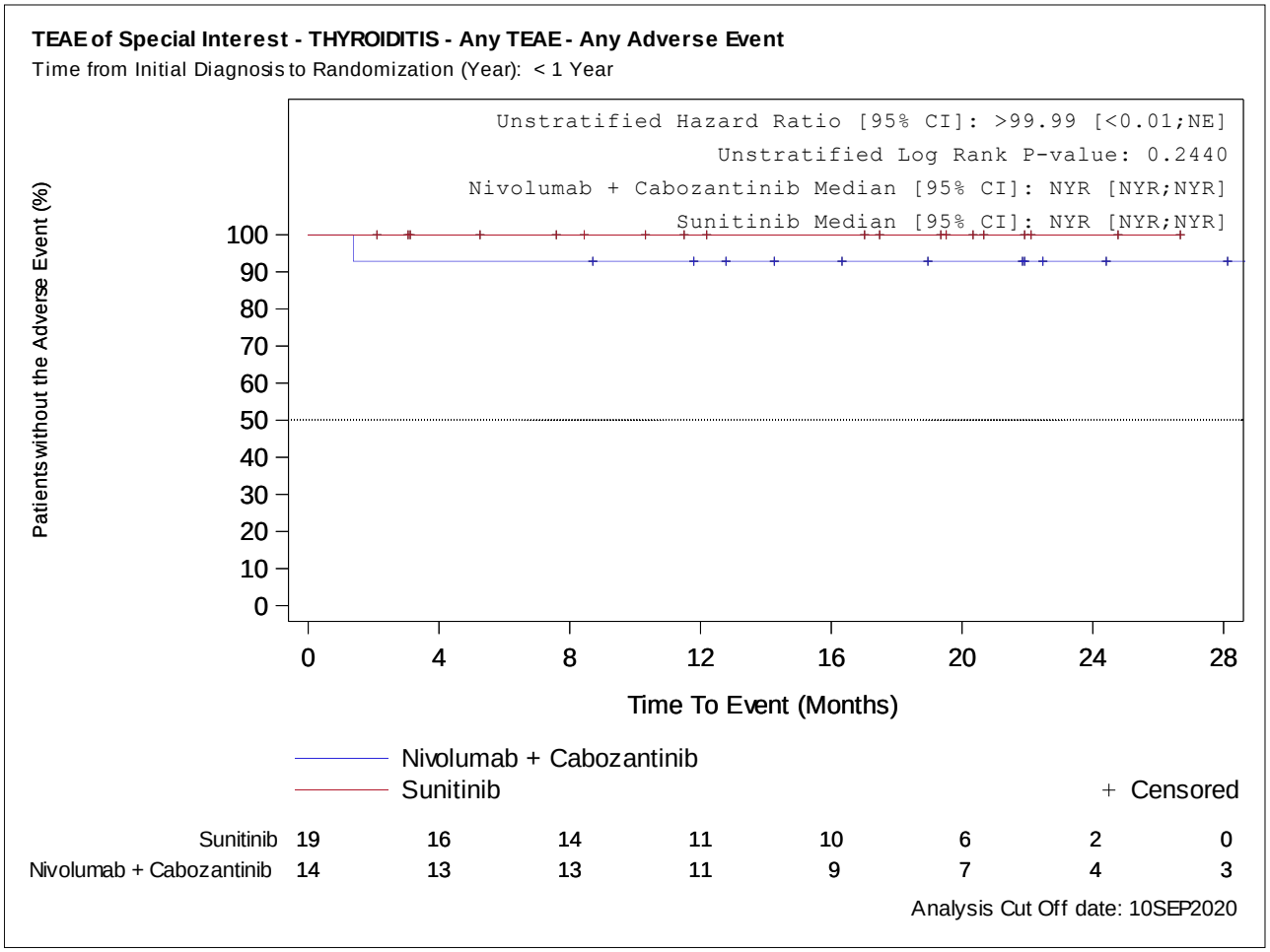
FIGURE 3.107.2.14: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



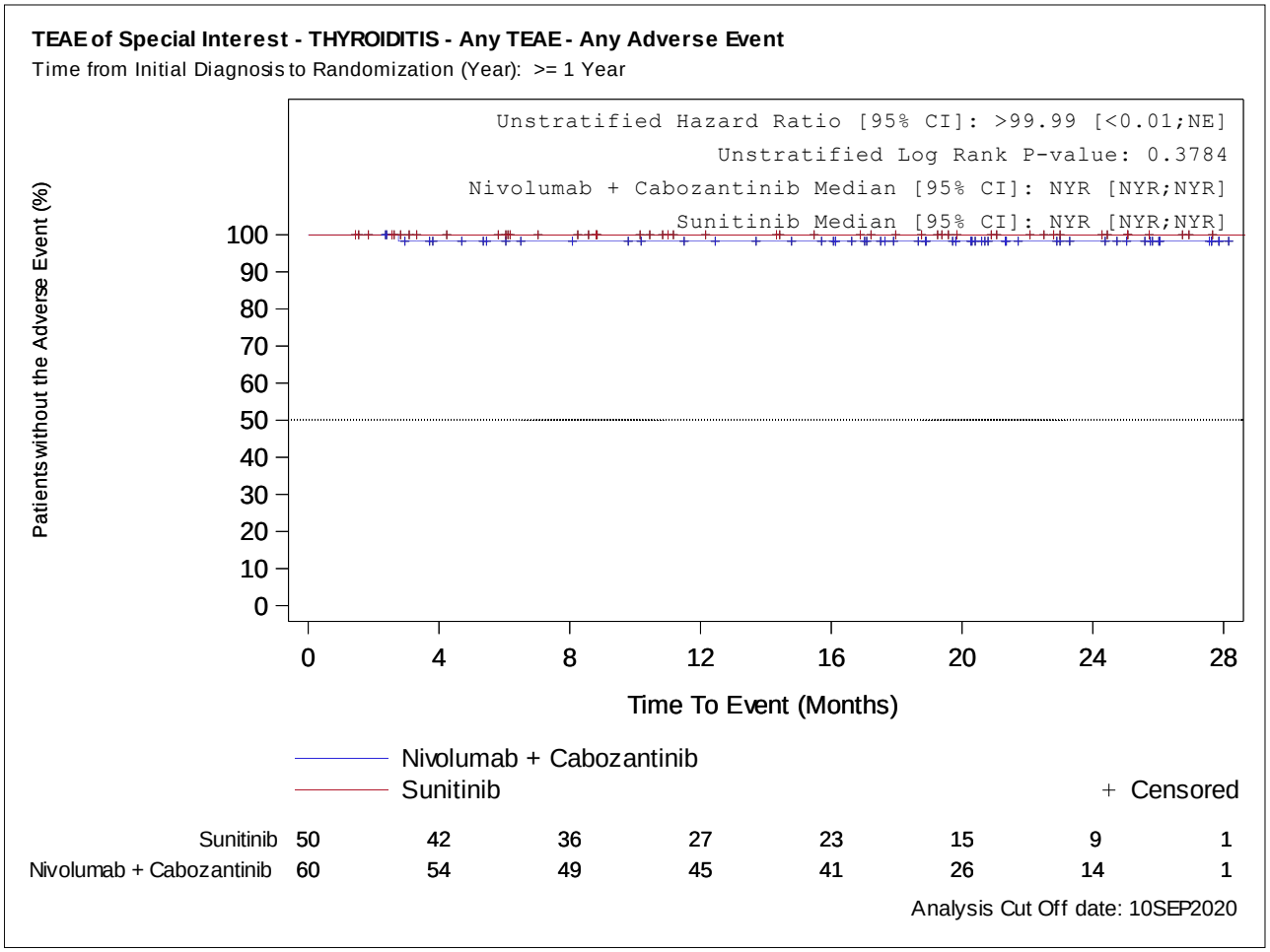

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:12:54

FIGURE 3.107.2.15: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



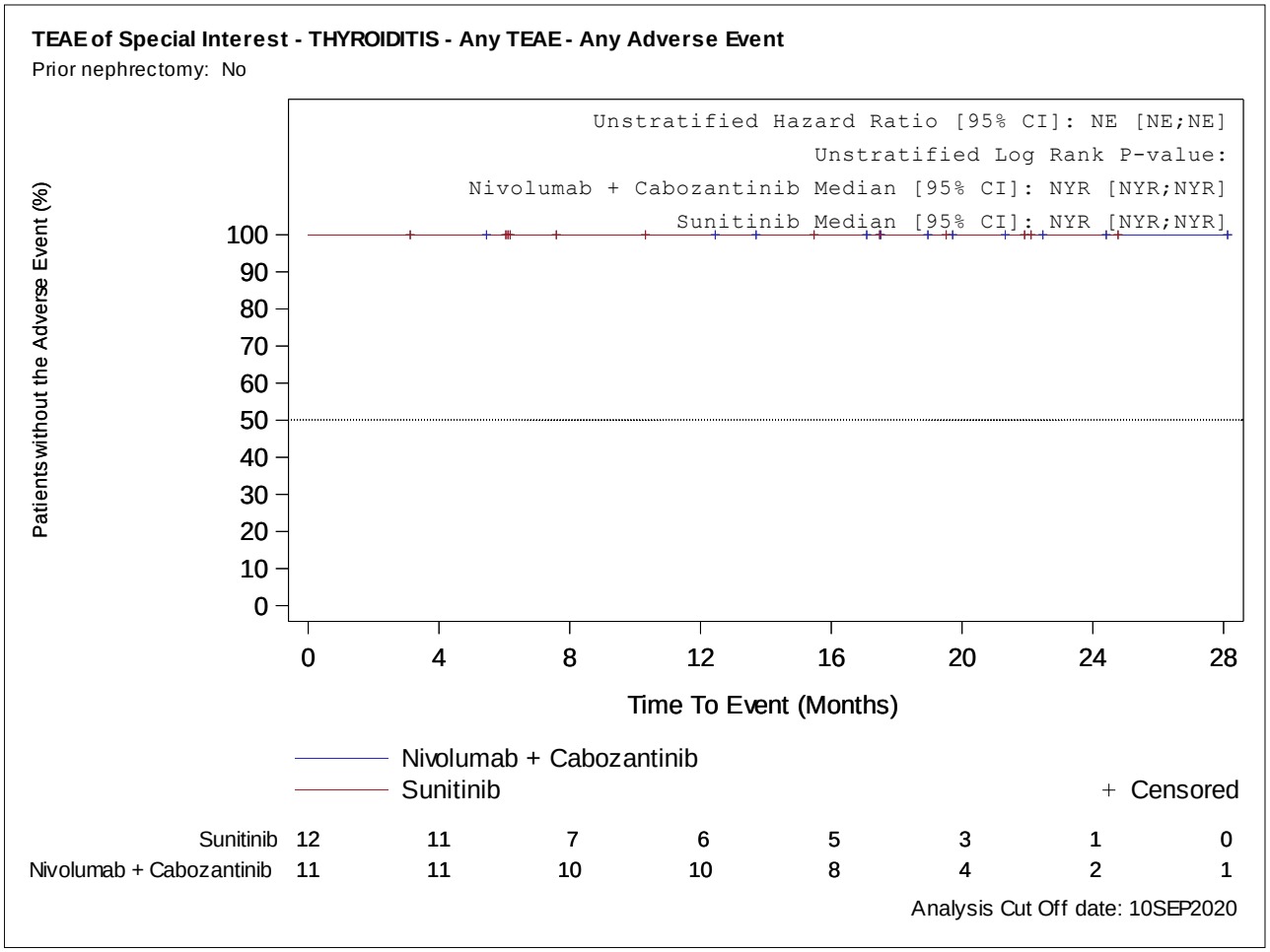

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:13:09

FIGURE 3.107.2.16: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:13:15

FIGURE 3.107.2.17: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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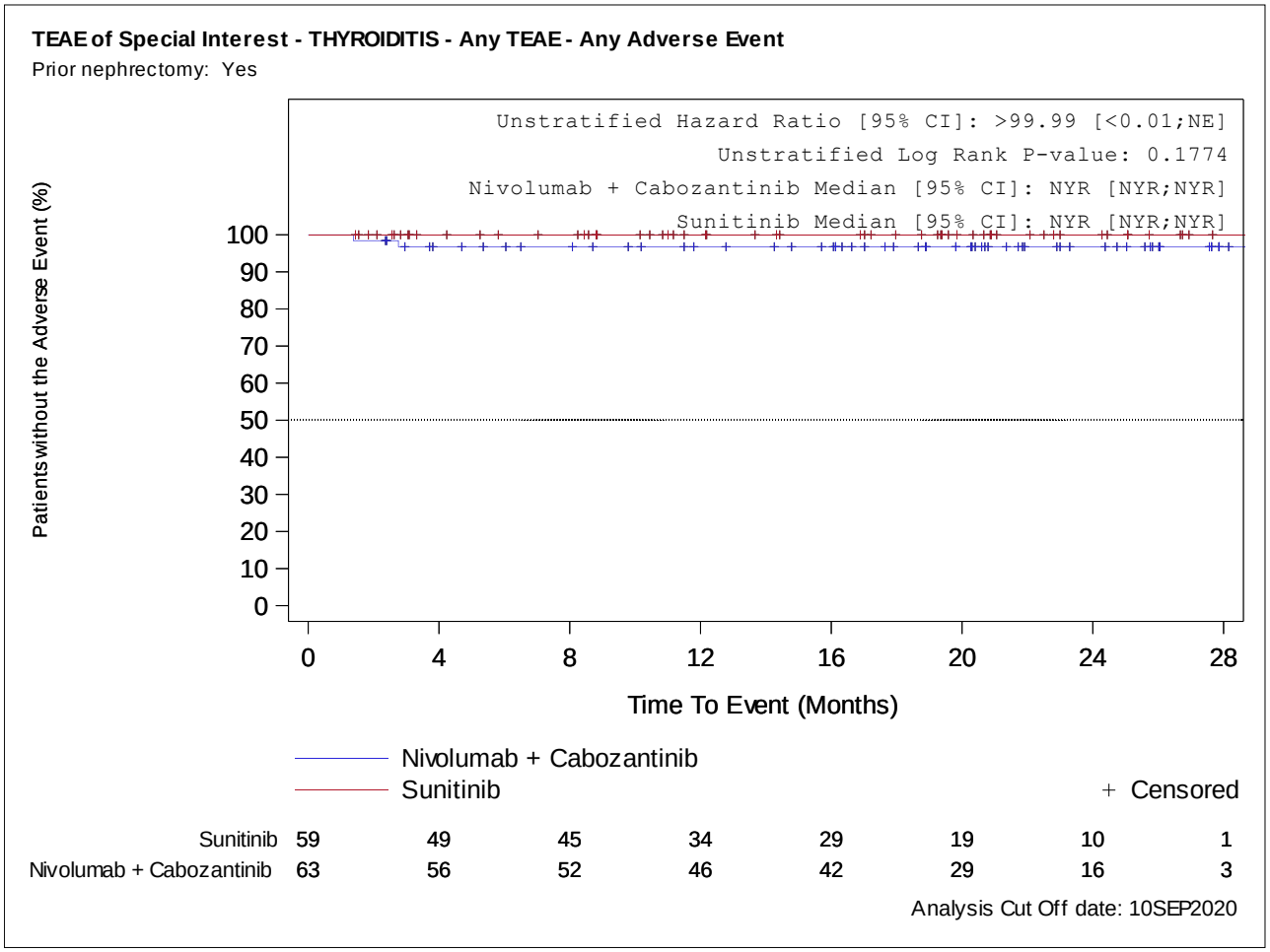
FIGURE 3.107.2.18: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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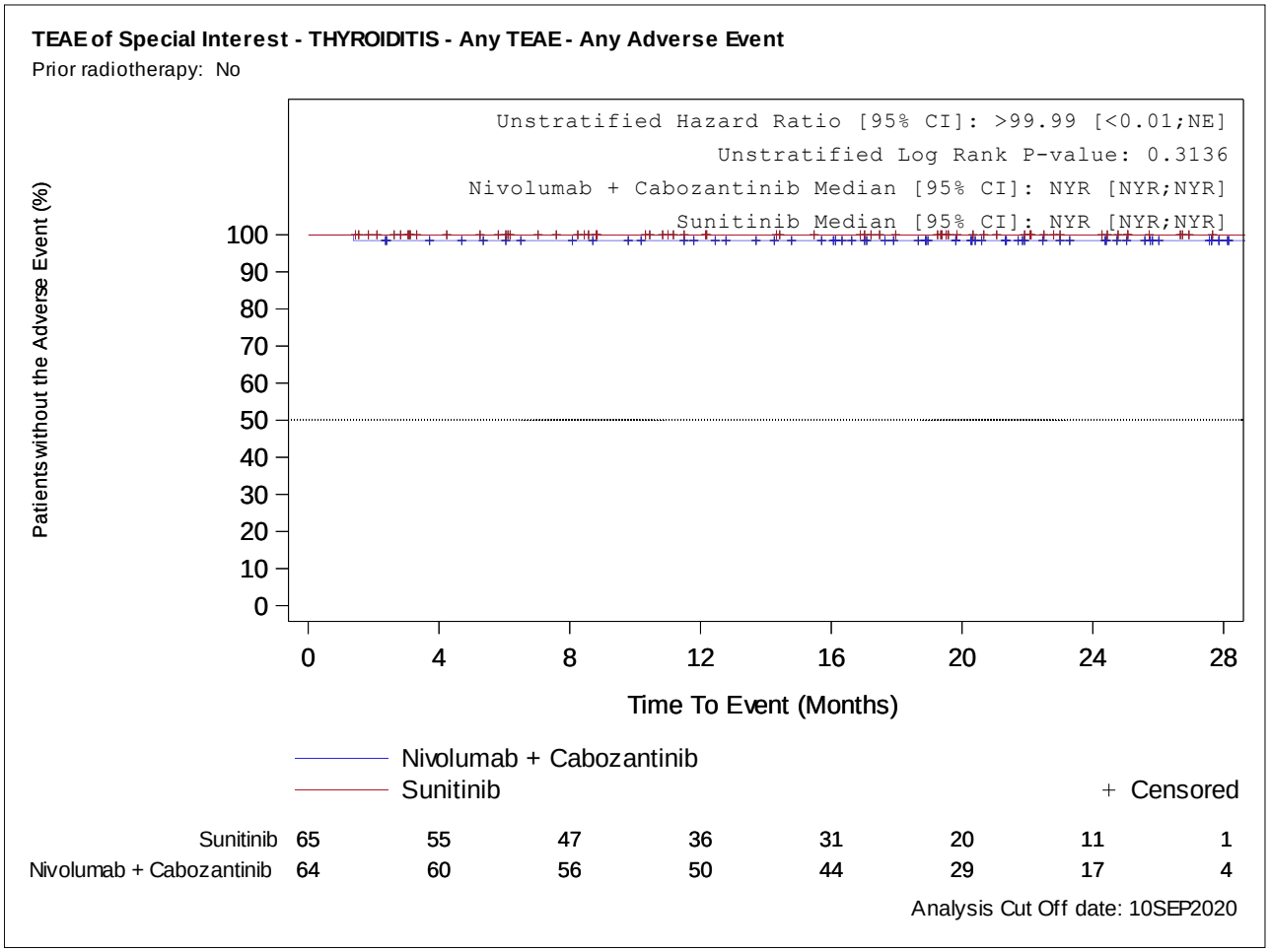
FIGURE 3.107.2.19: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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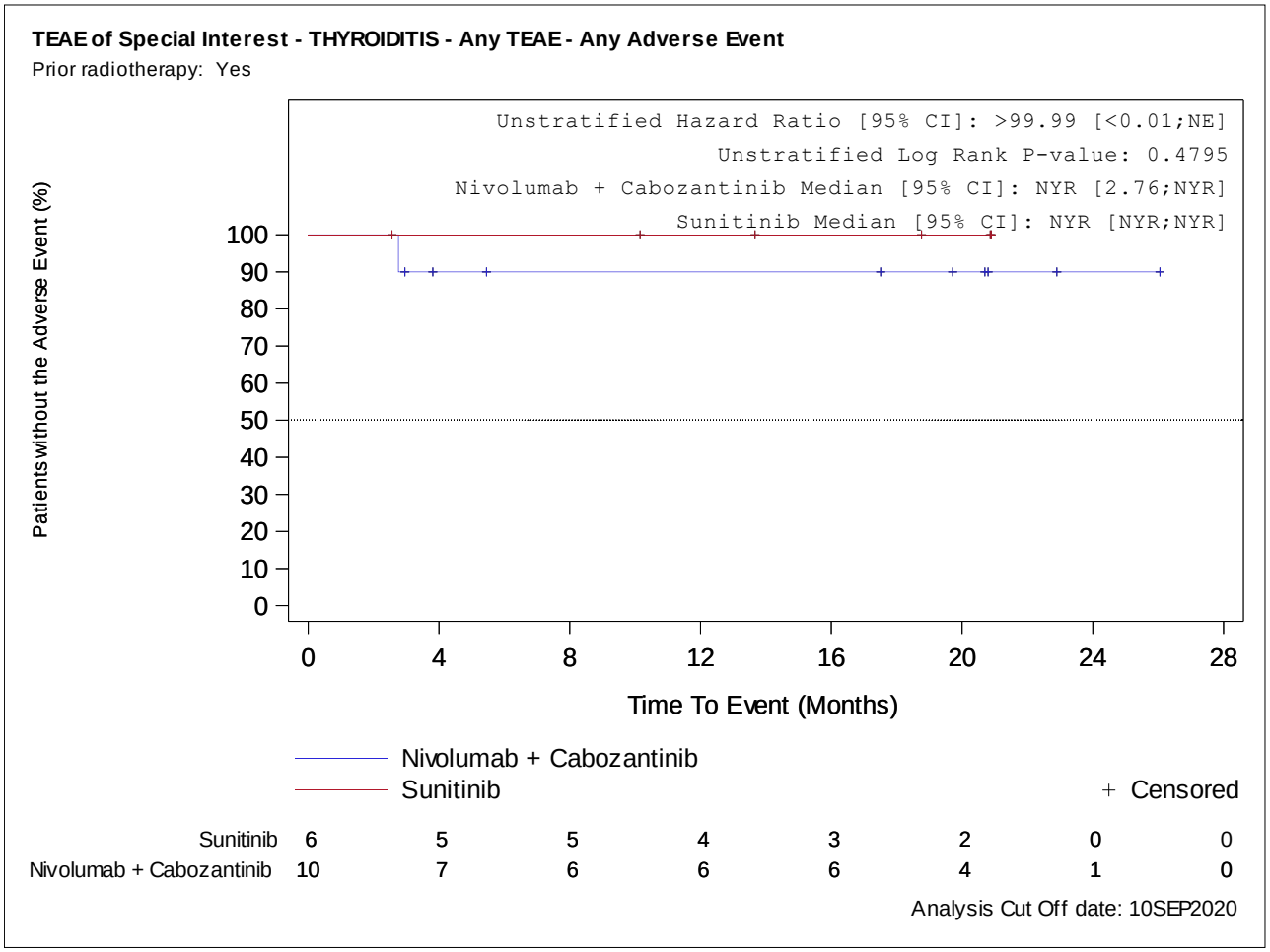
FIGURE 3.107.2.20: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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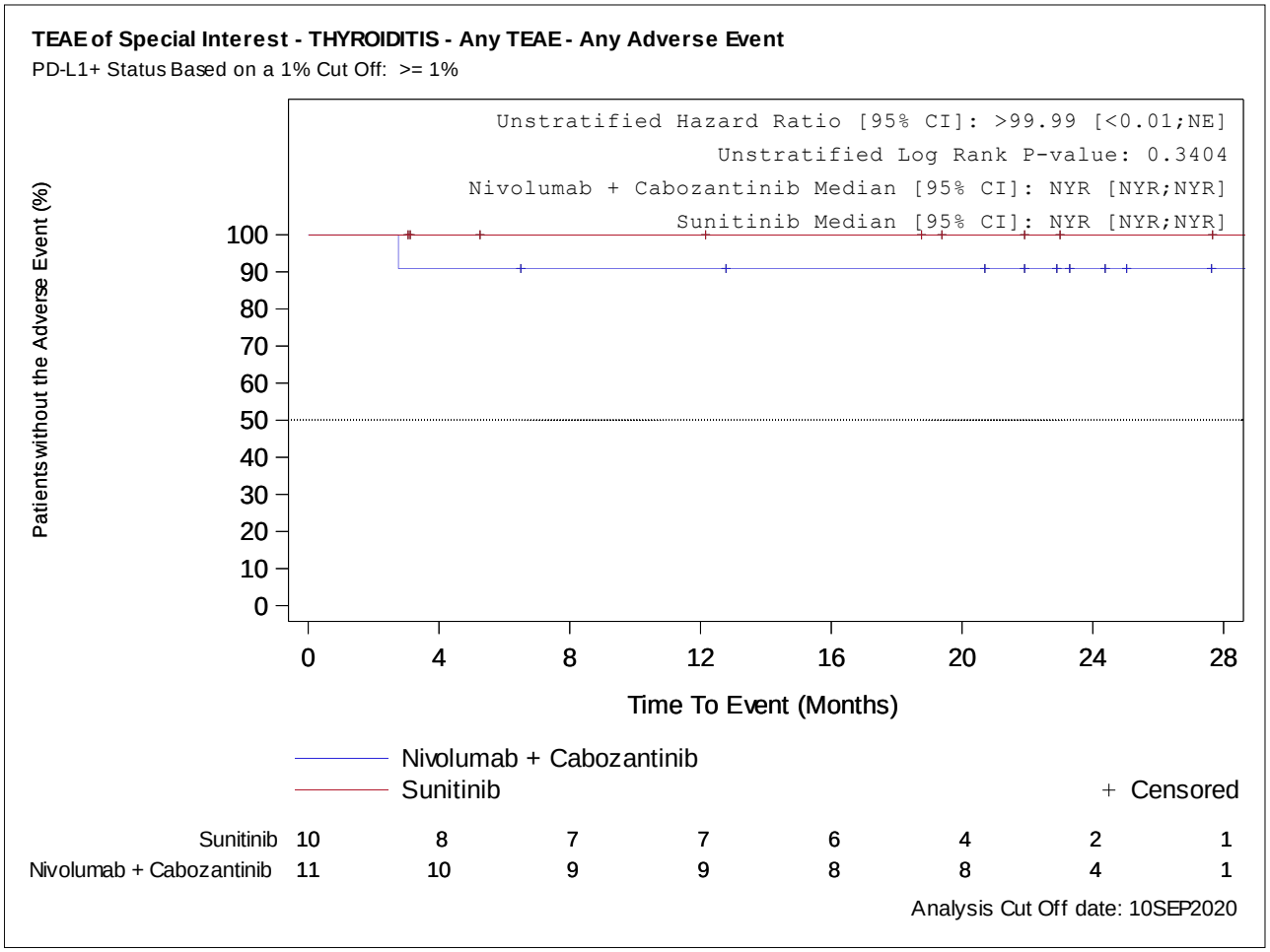
FIGURE 3.107.2.21: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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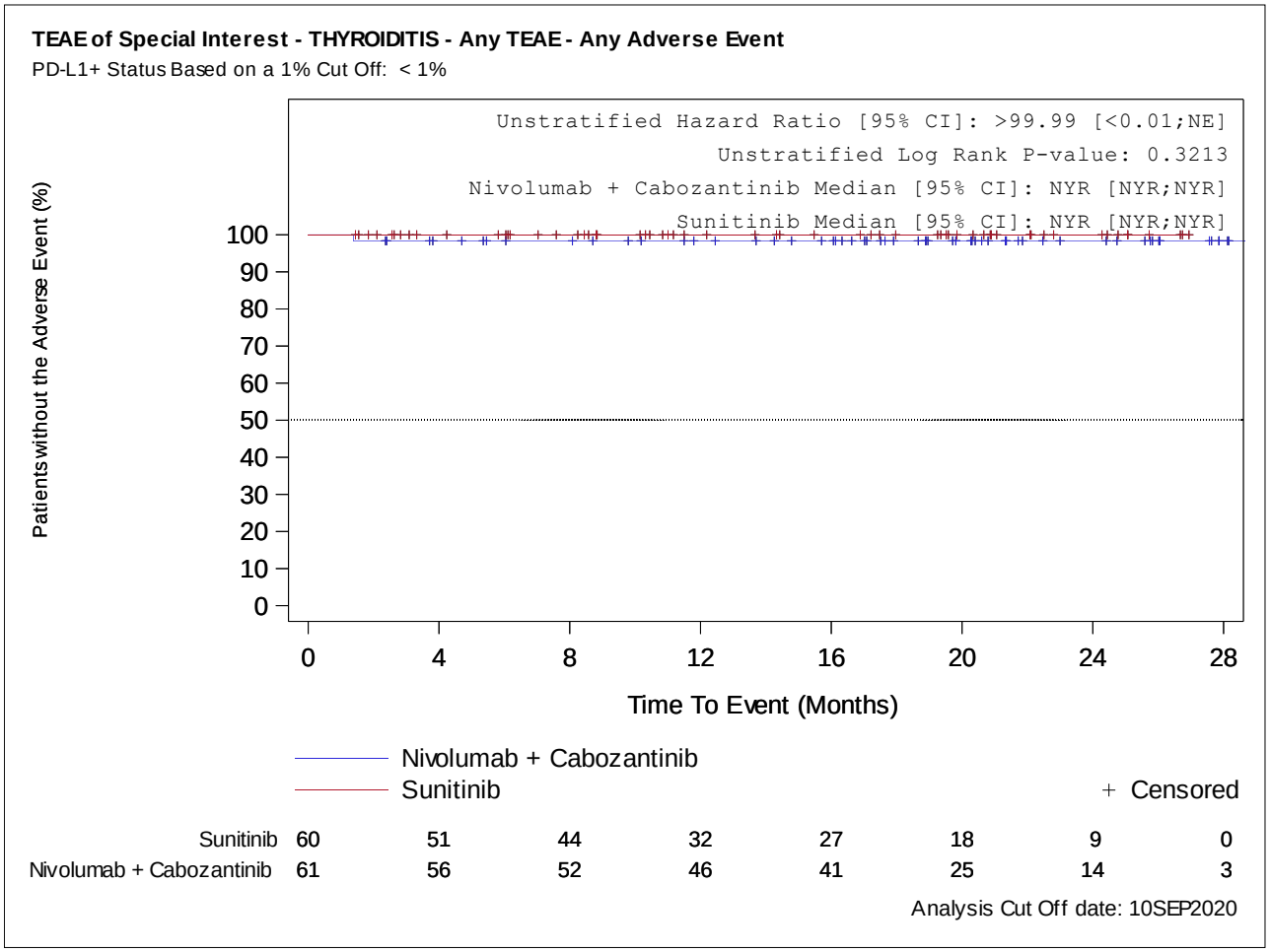
FIGURE 3.107.2.22: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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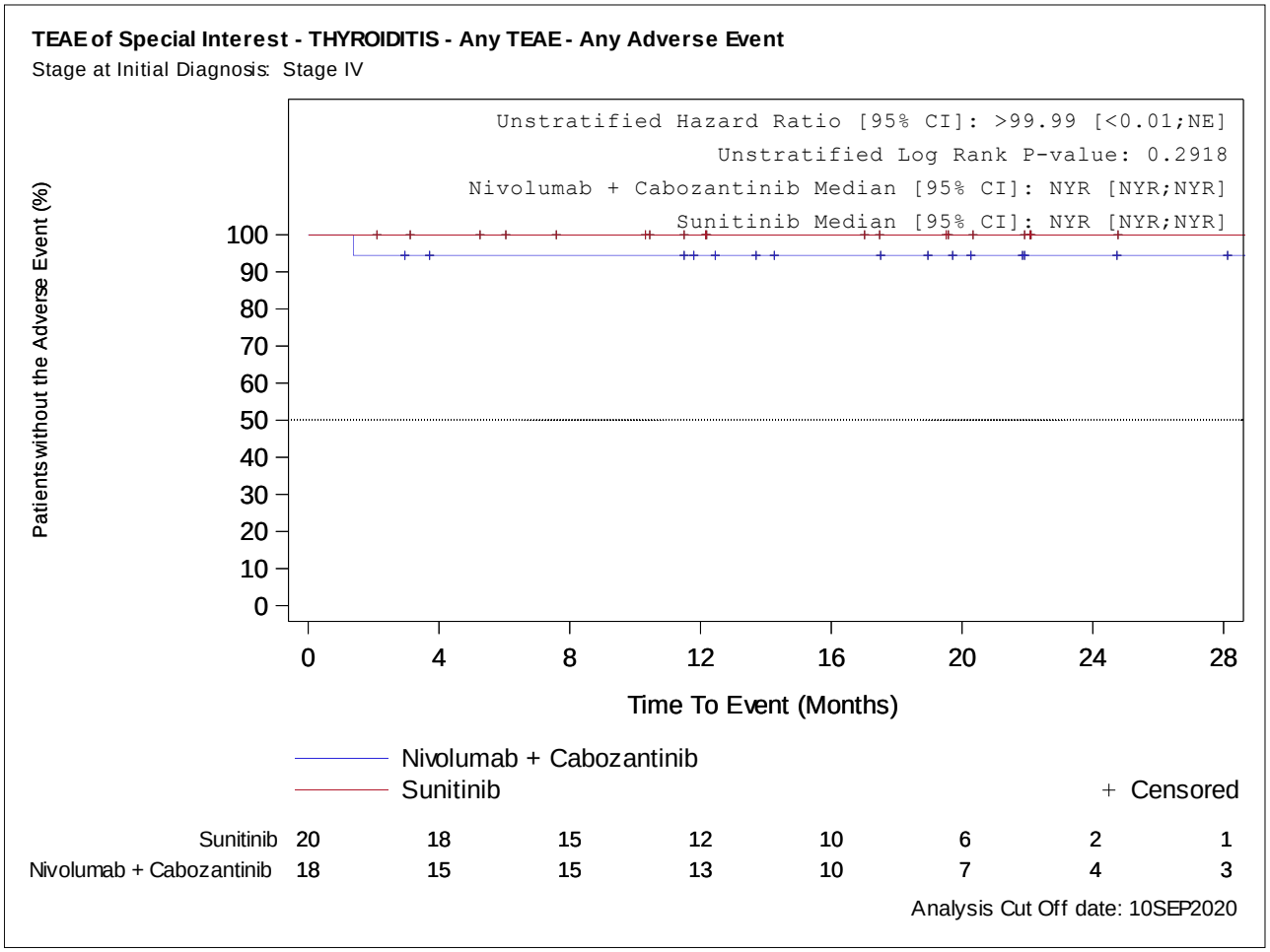
FIGURE 3.107.2.23: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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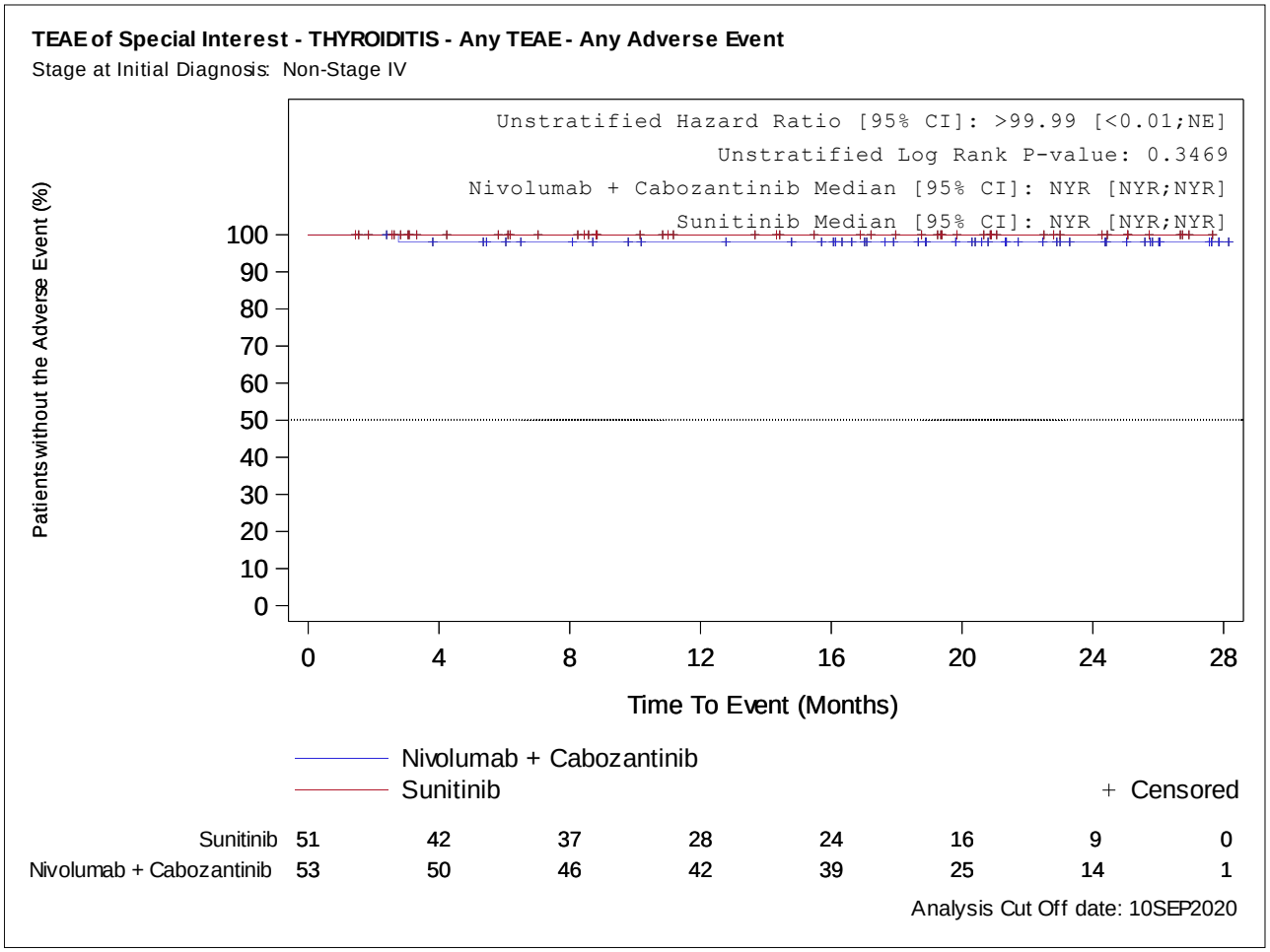
FIGURE 3.107.2.24: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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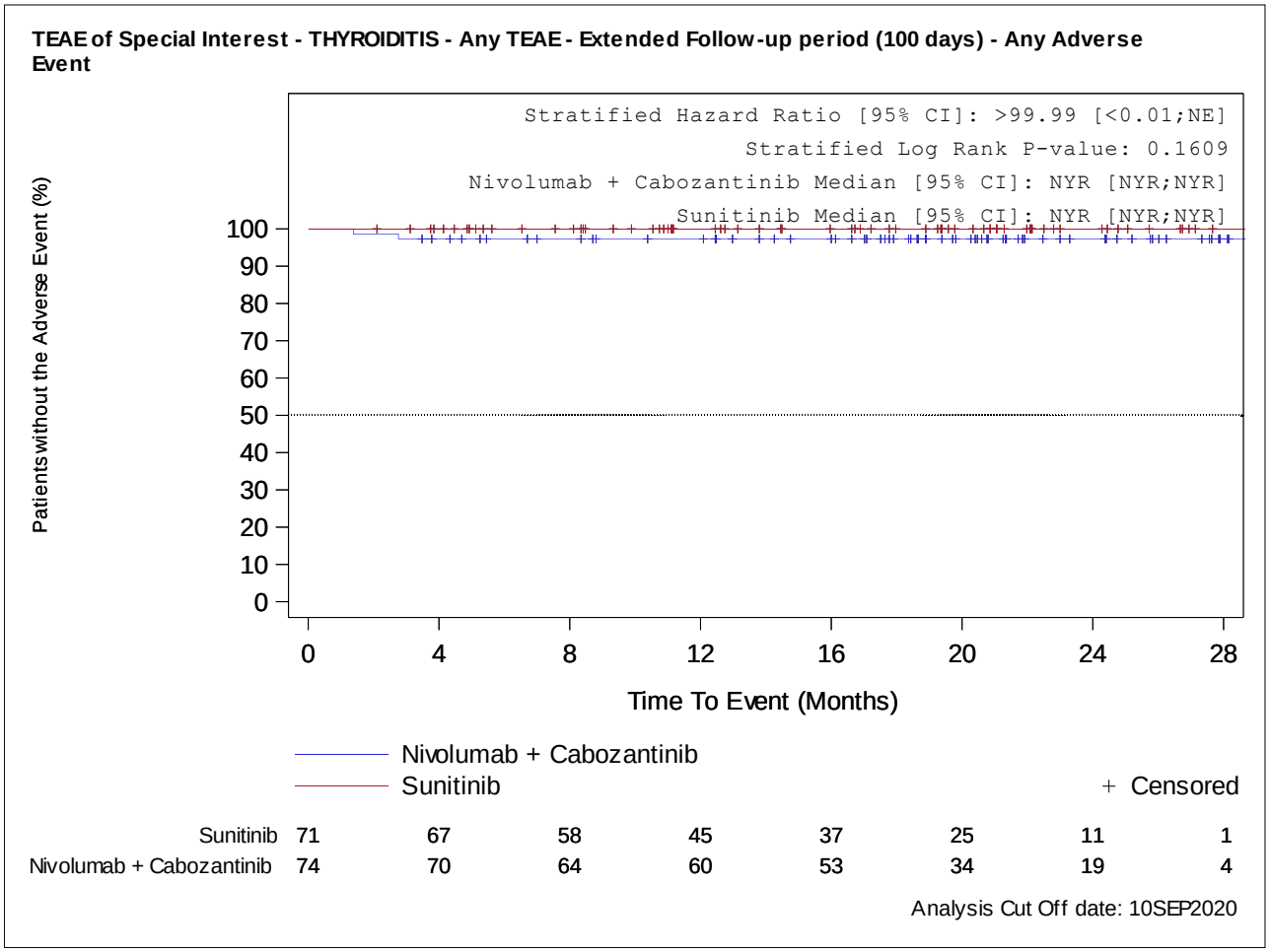
FIGURE 3.108.1: TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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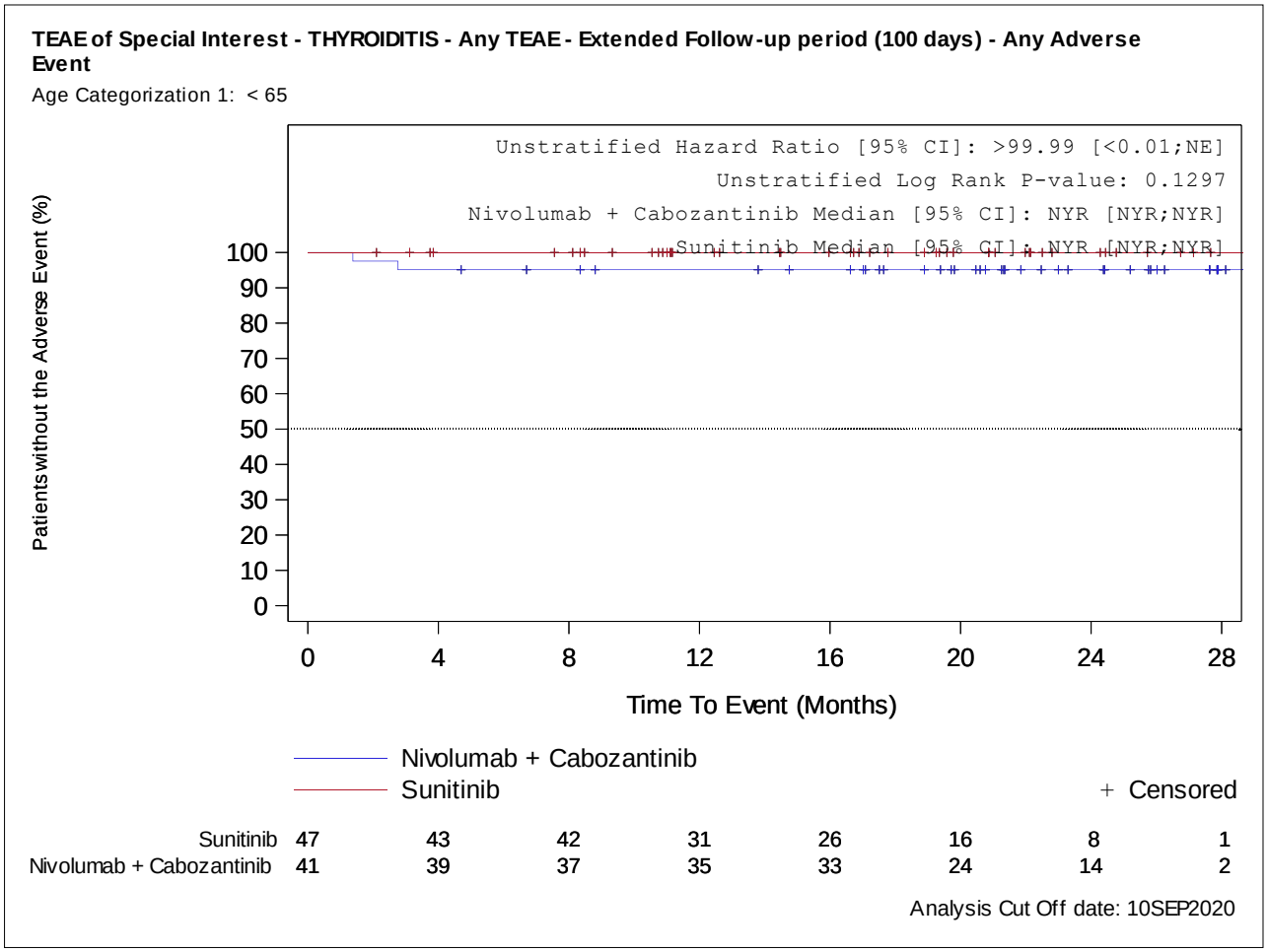
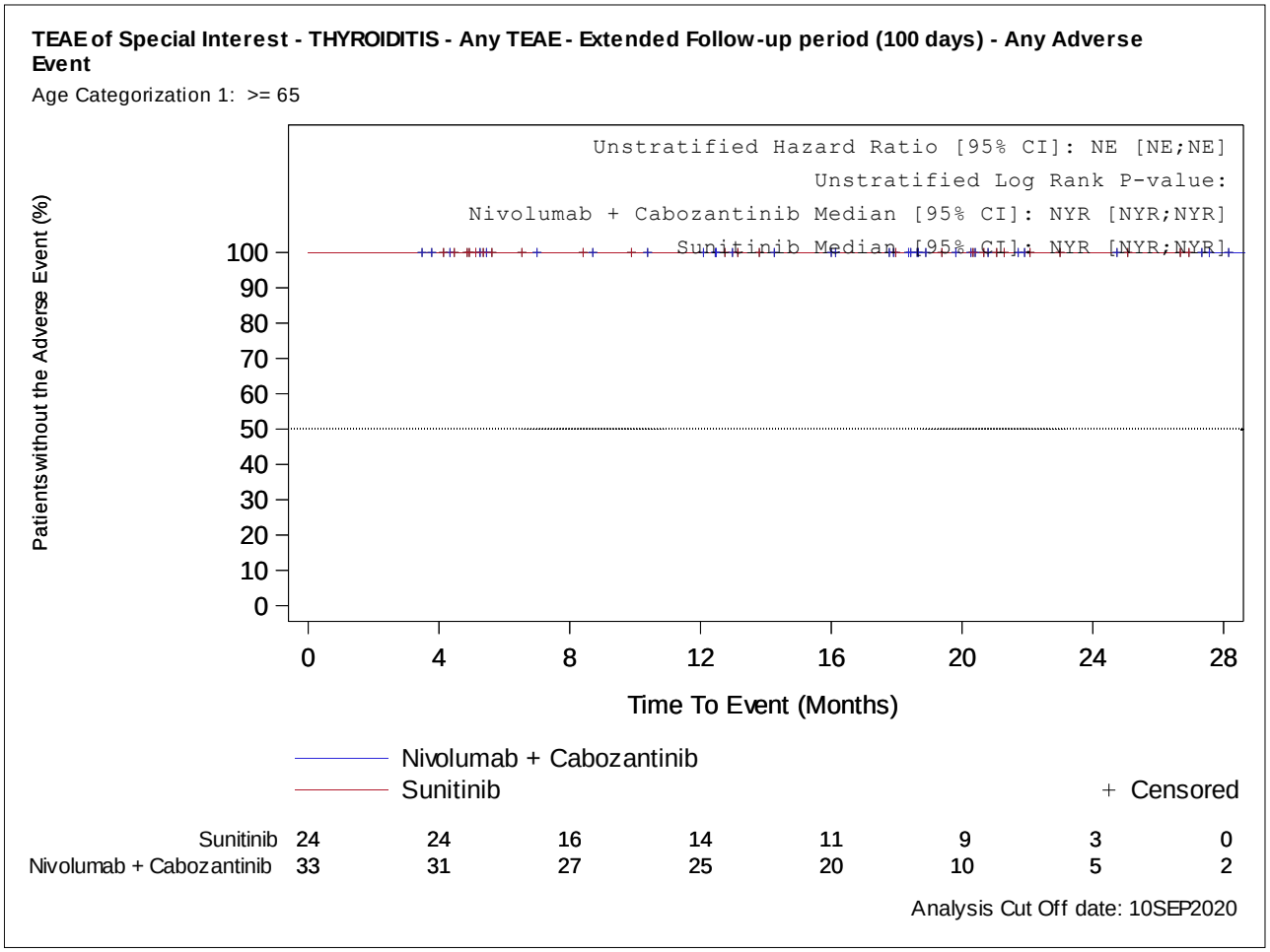
FIGURE 3.108.2.1: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:17:56

FIGURE 3.108.2.2: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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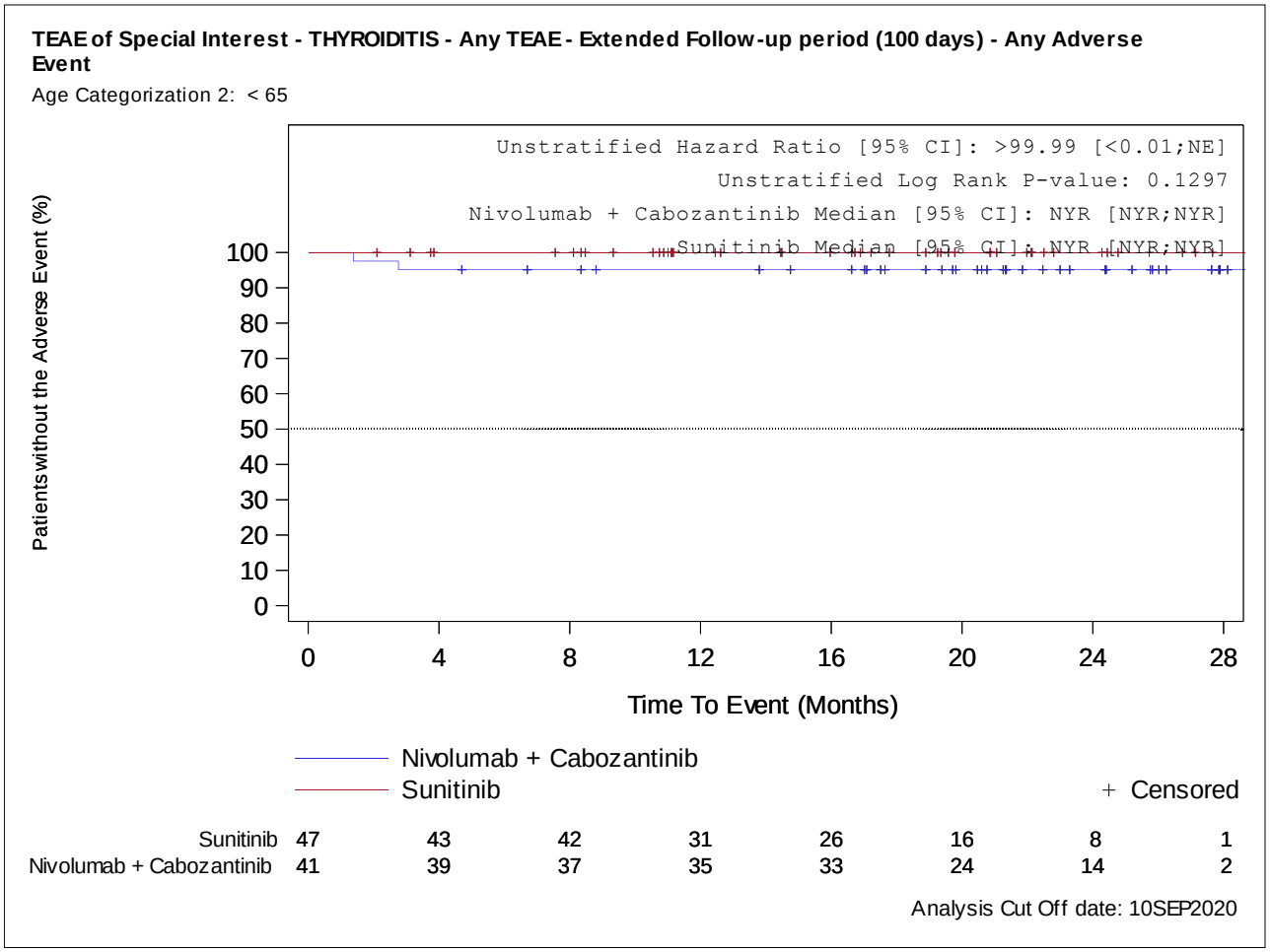
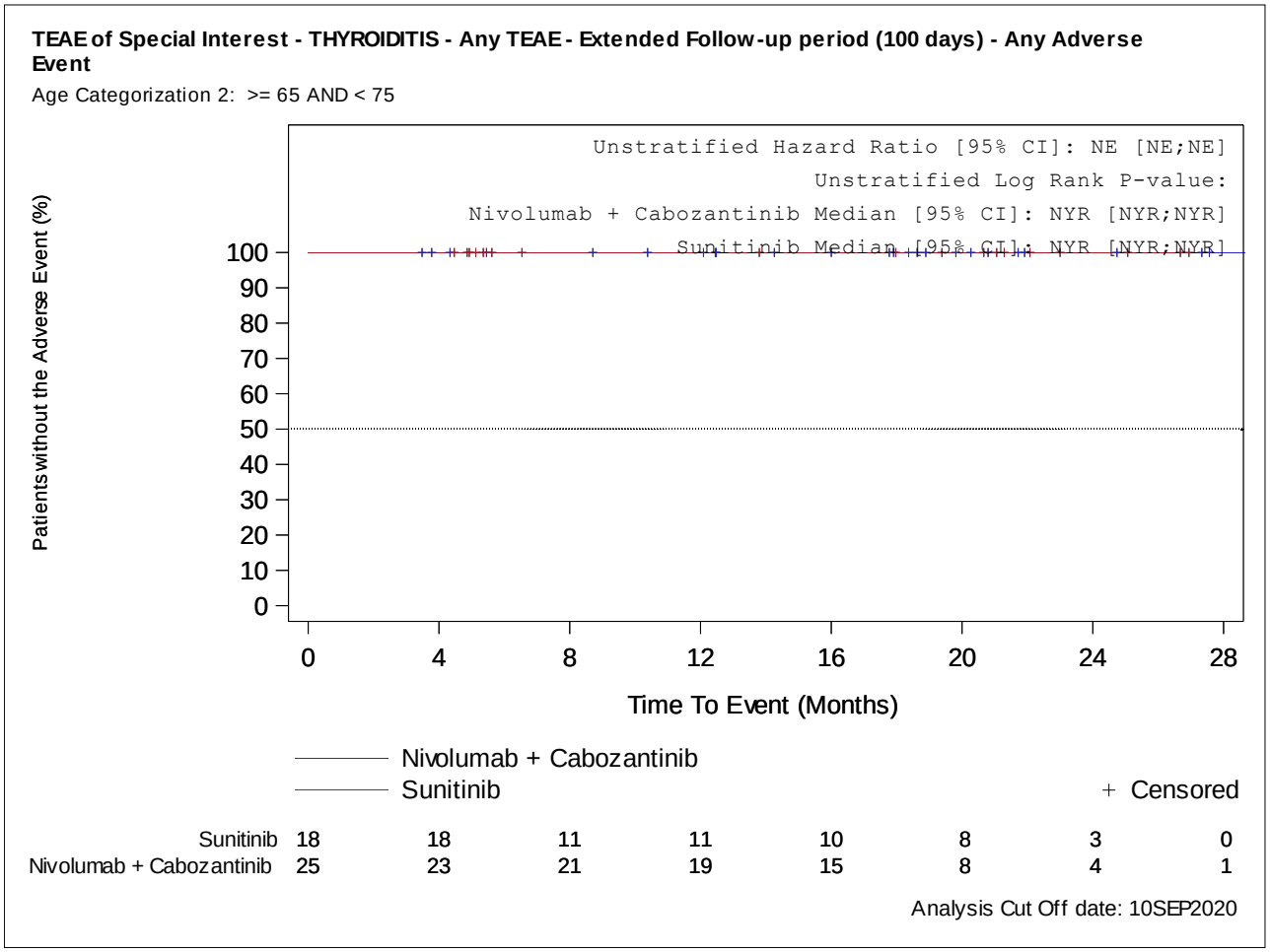
FIGURE 3.108.2.3: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



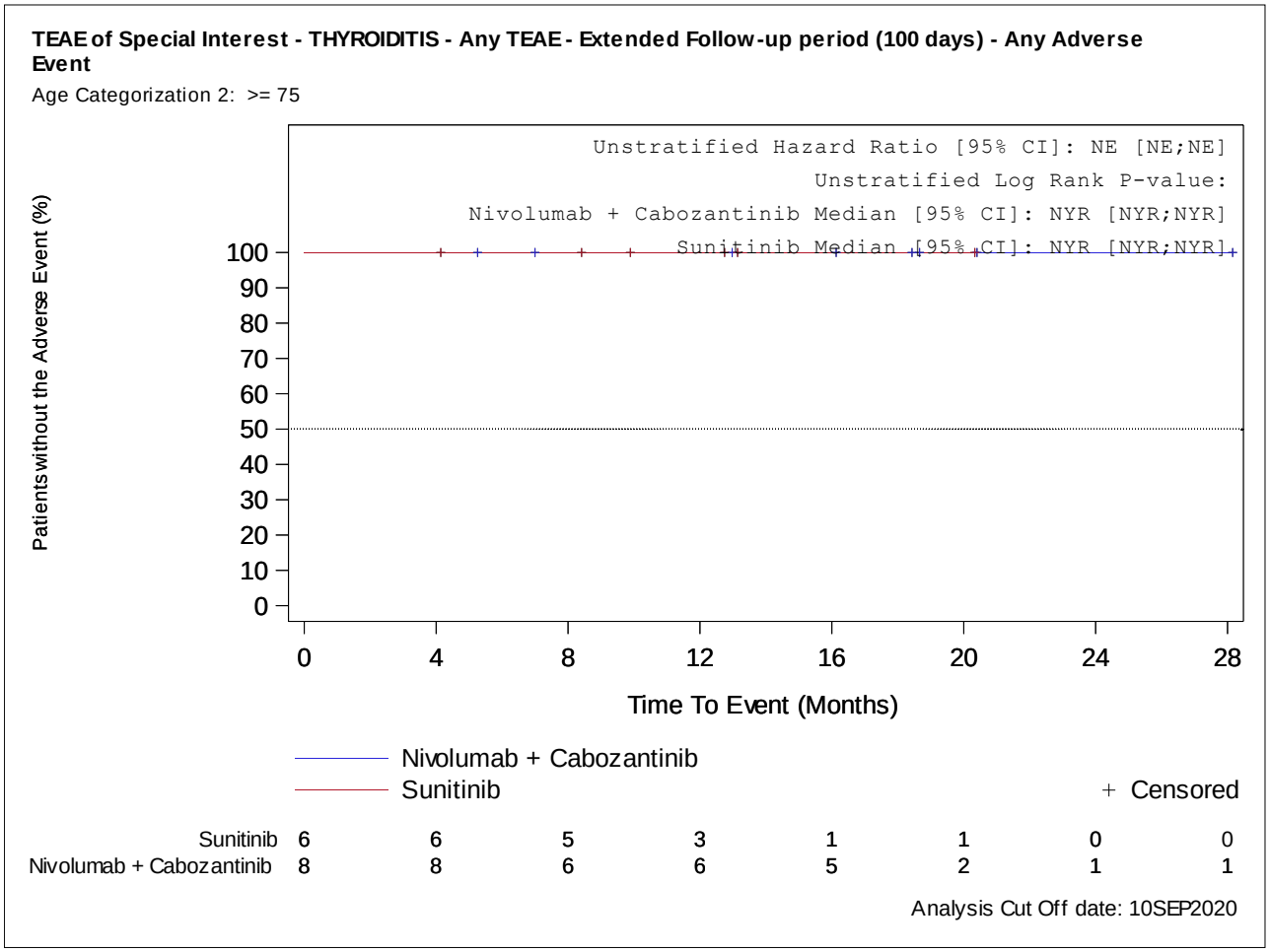

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:18:07

FIGURE 3.108.2.4: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



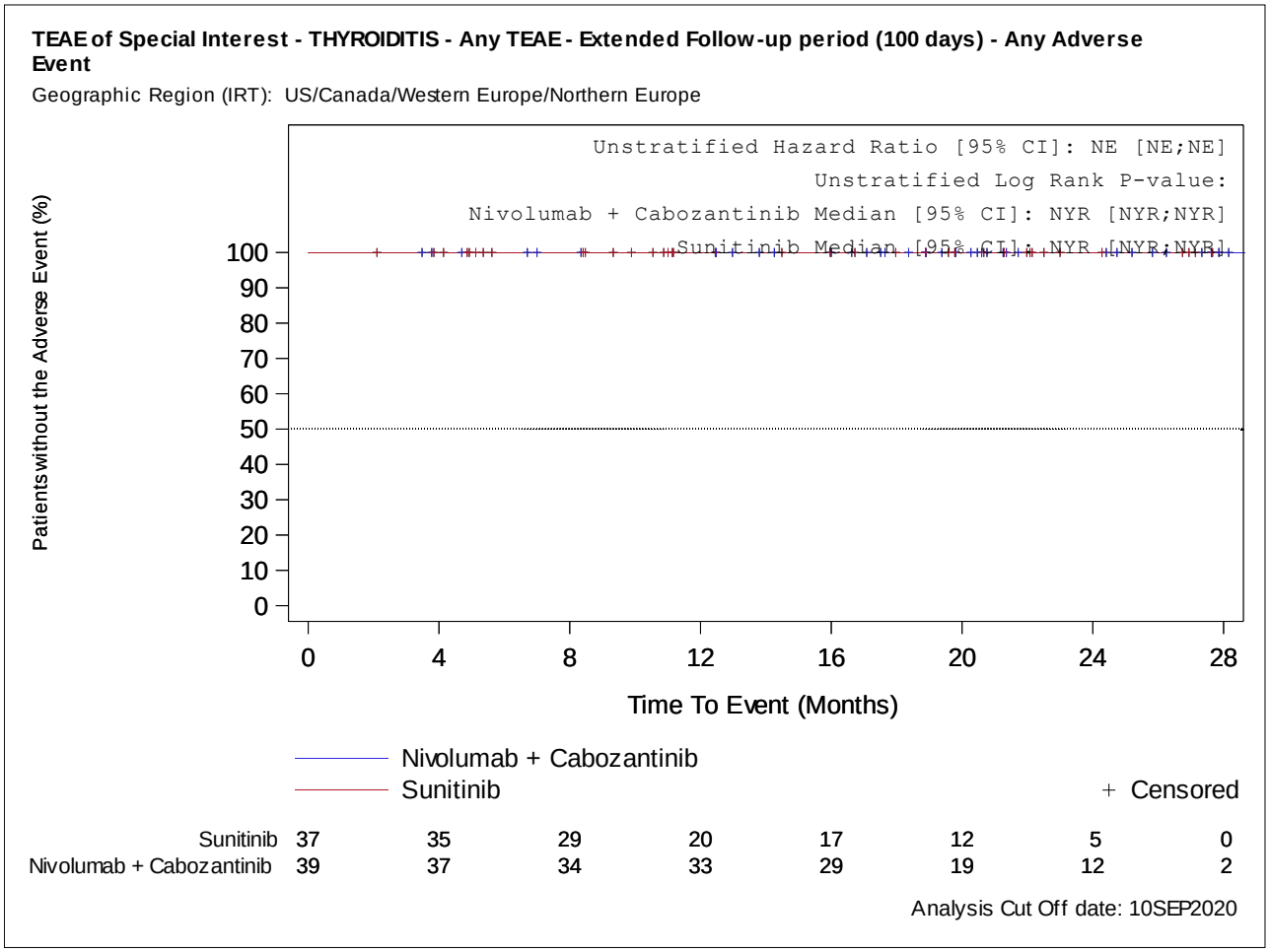

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:18:12

FIGURE 3.108.2.5: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



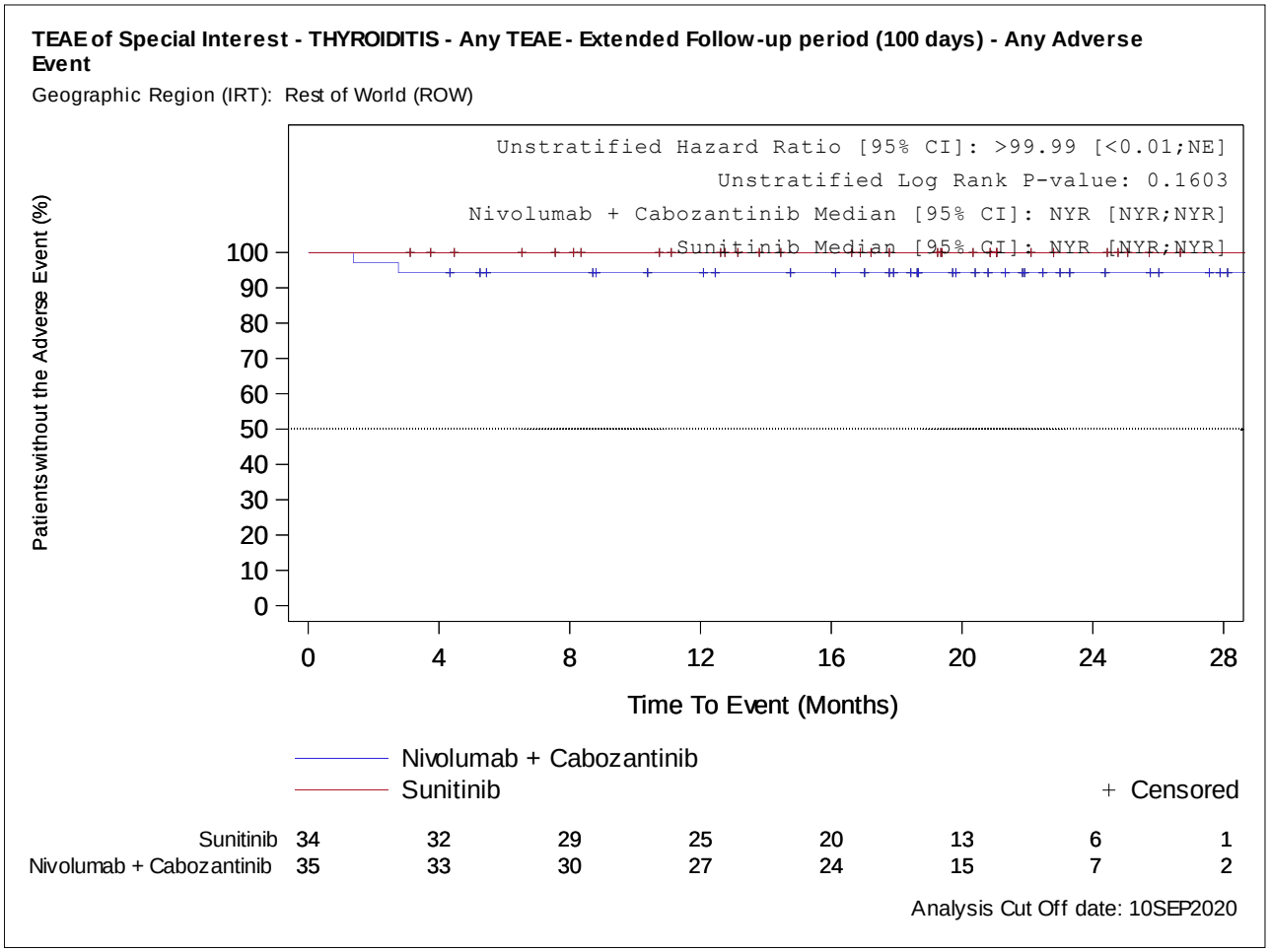

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:18:18

FIGURE 3.108.2.6: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



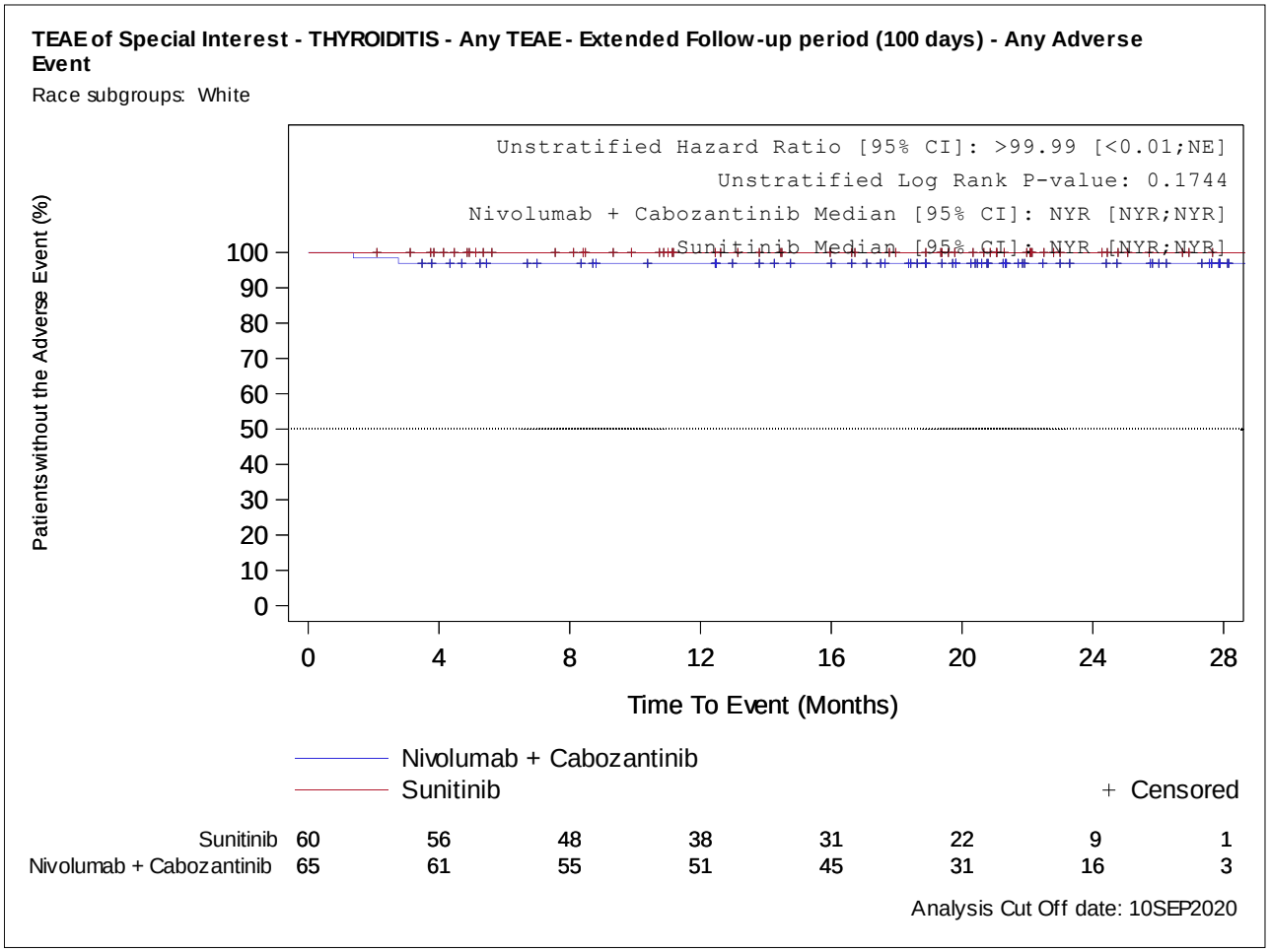

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:18:23

FIGURE 3.108.2.7: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:18:28

FIGURE 3.108.2.8: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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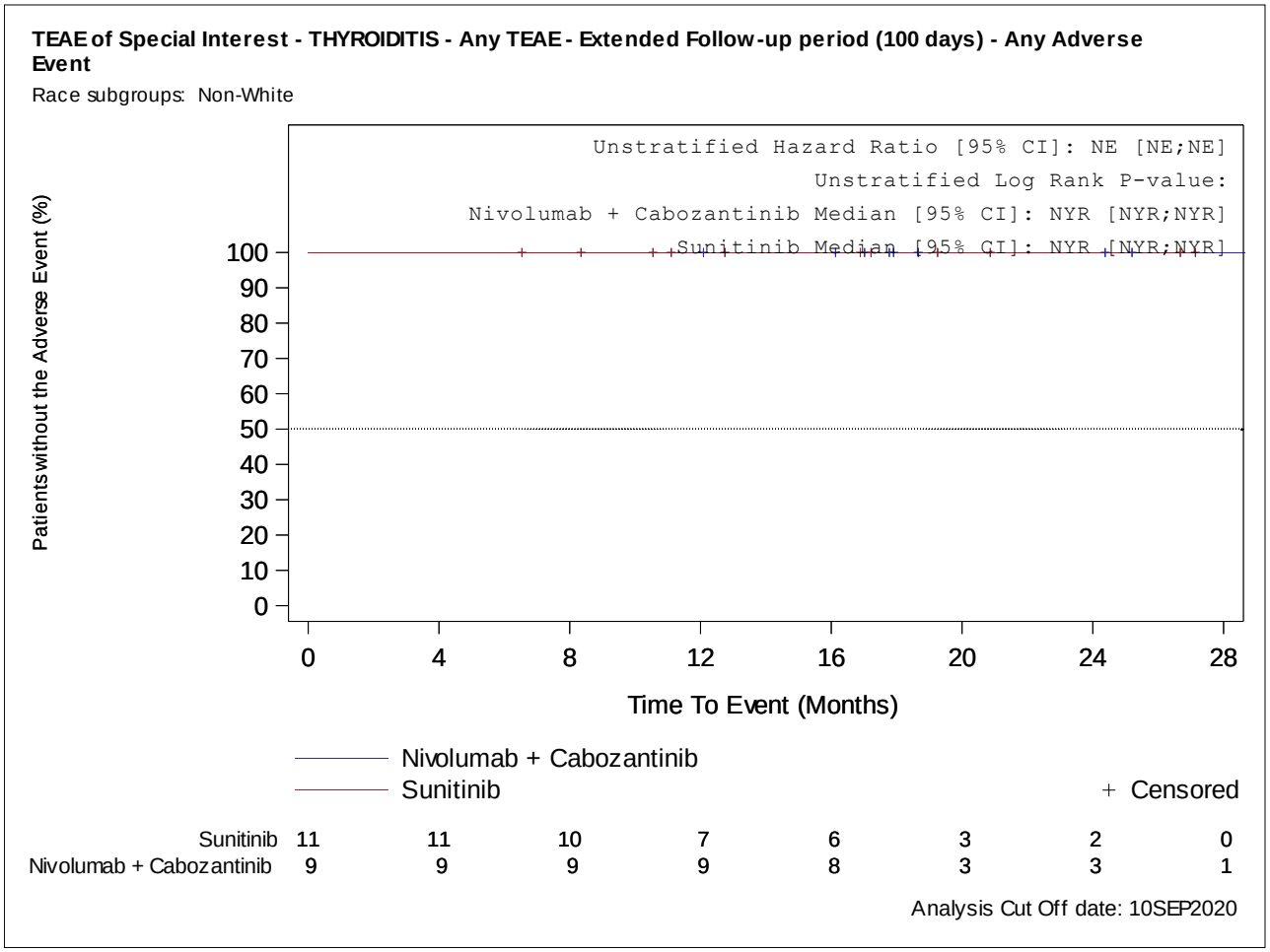
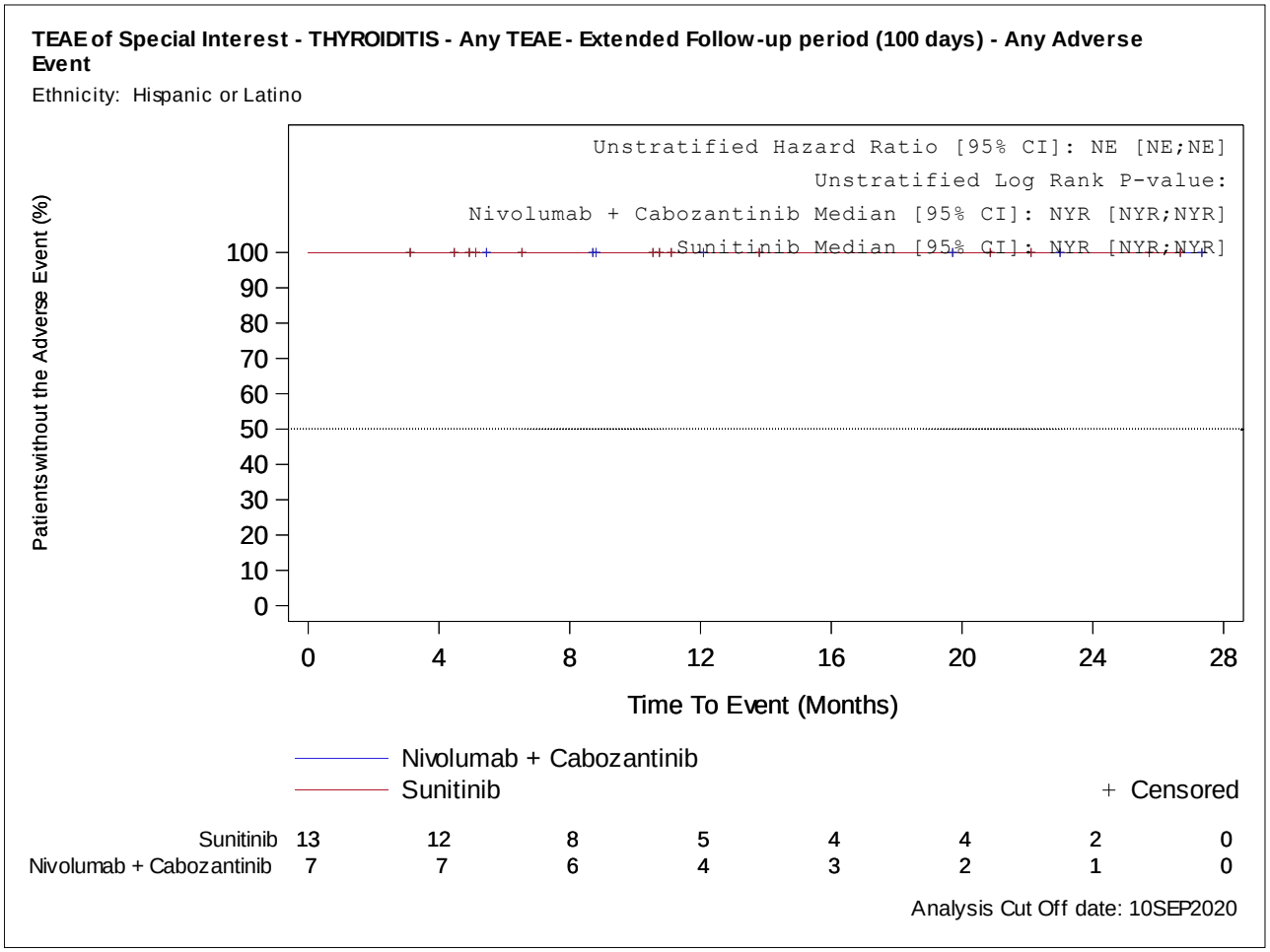
FIGURE 3.108.2.9: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



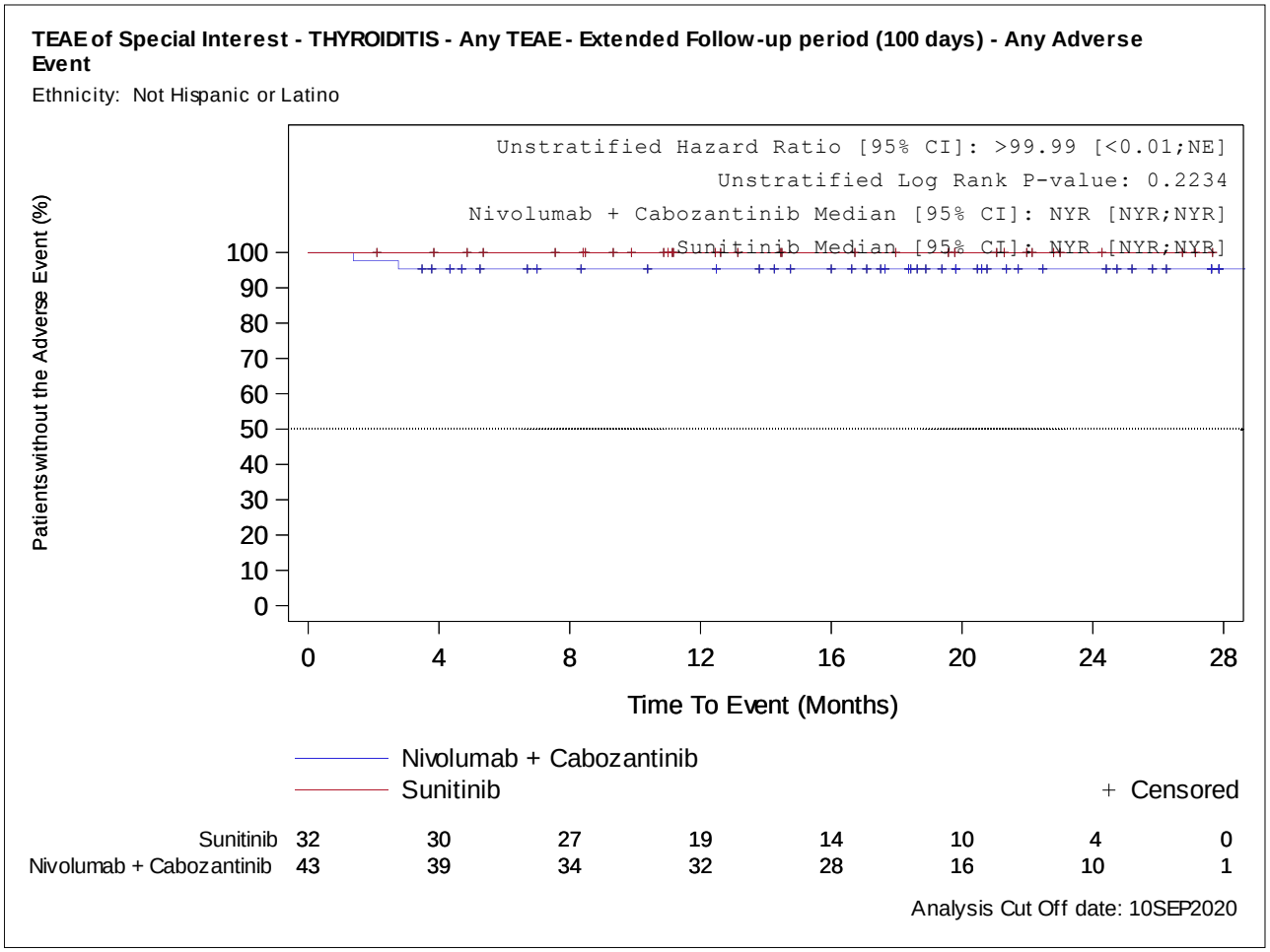

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:18:39

FIGURE 3.108.2.10: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



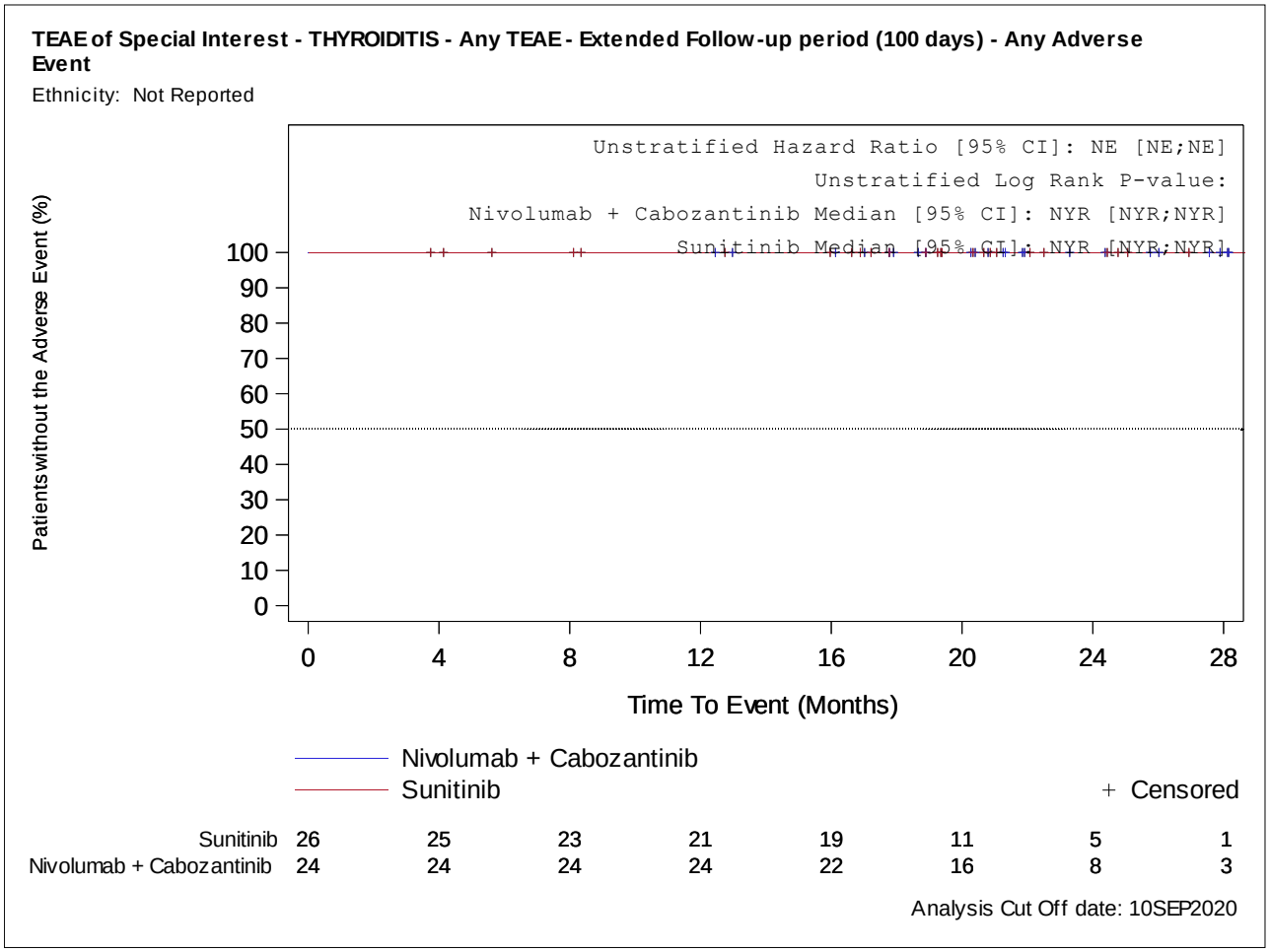

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:18:44

FIGURE 3.108.2.11: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



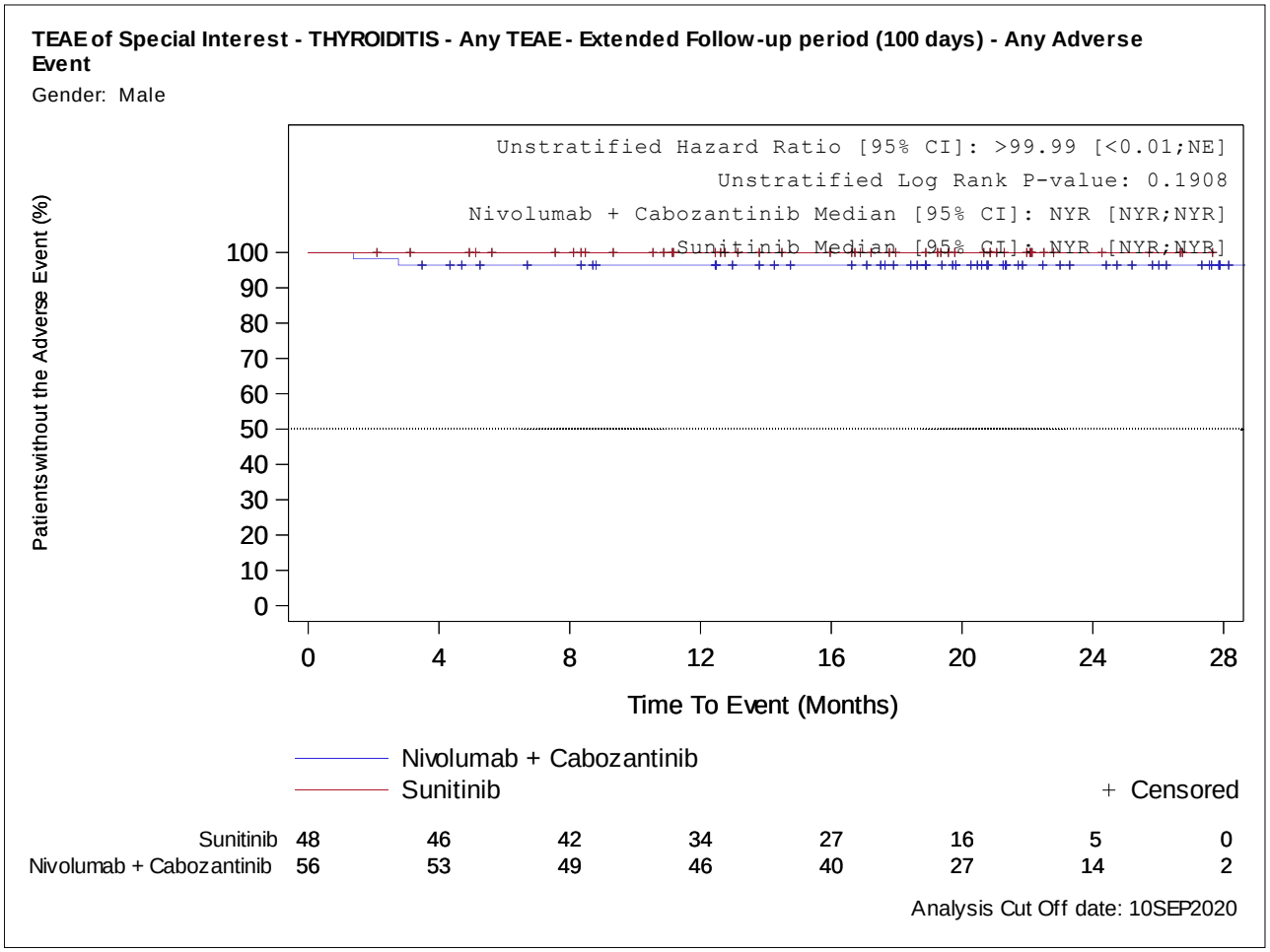

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:18:50

FIGURE 3.108.2.12: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



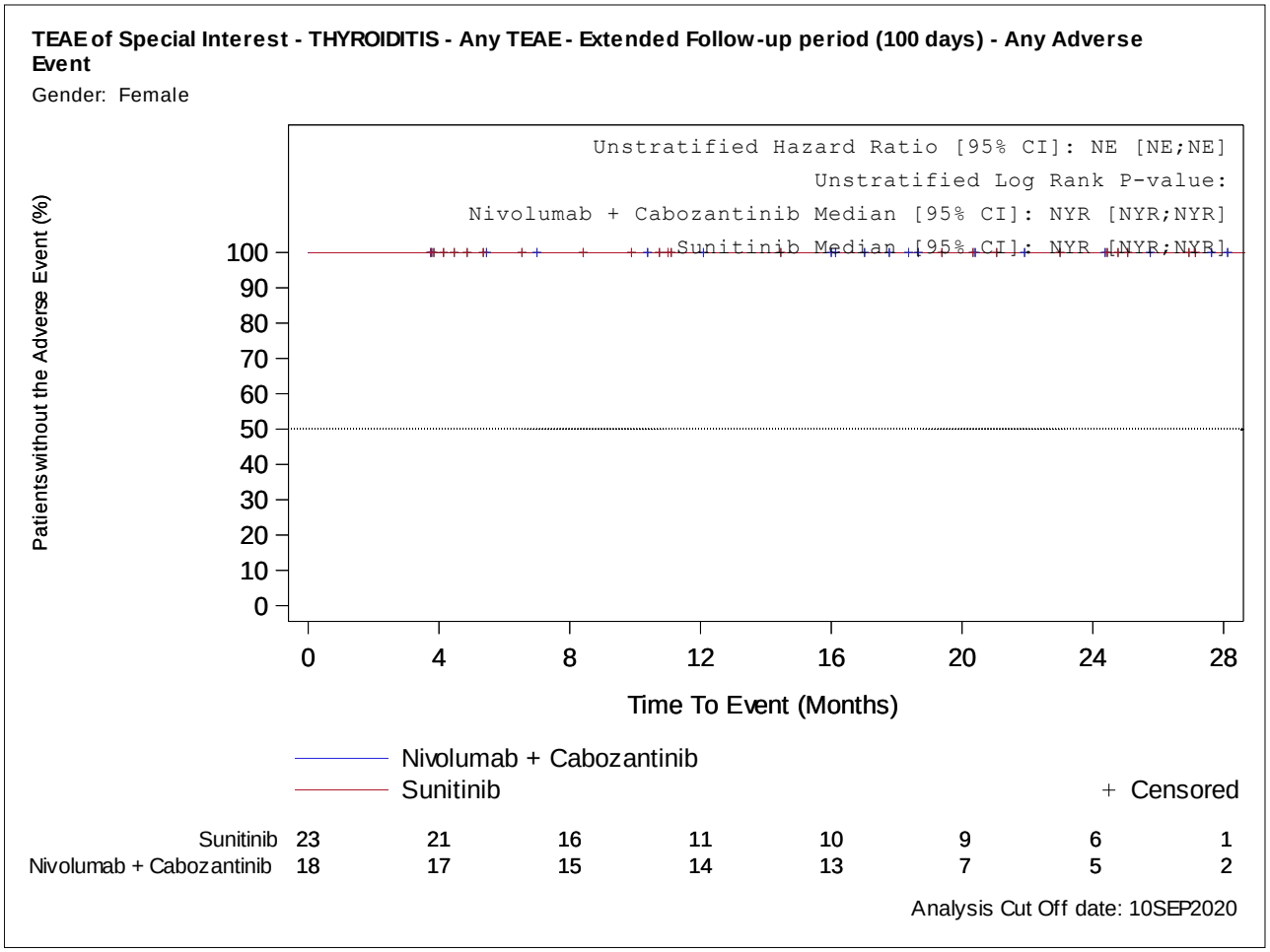

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:18:55

FIGURE 3.108.2.13: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



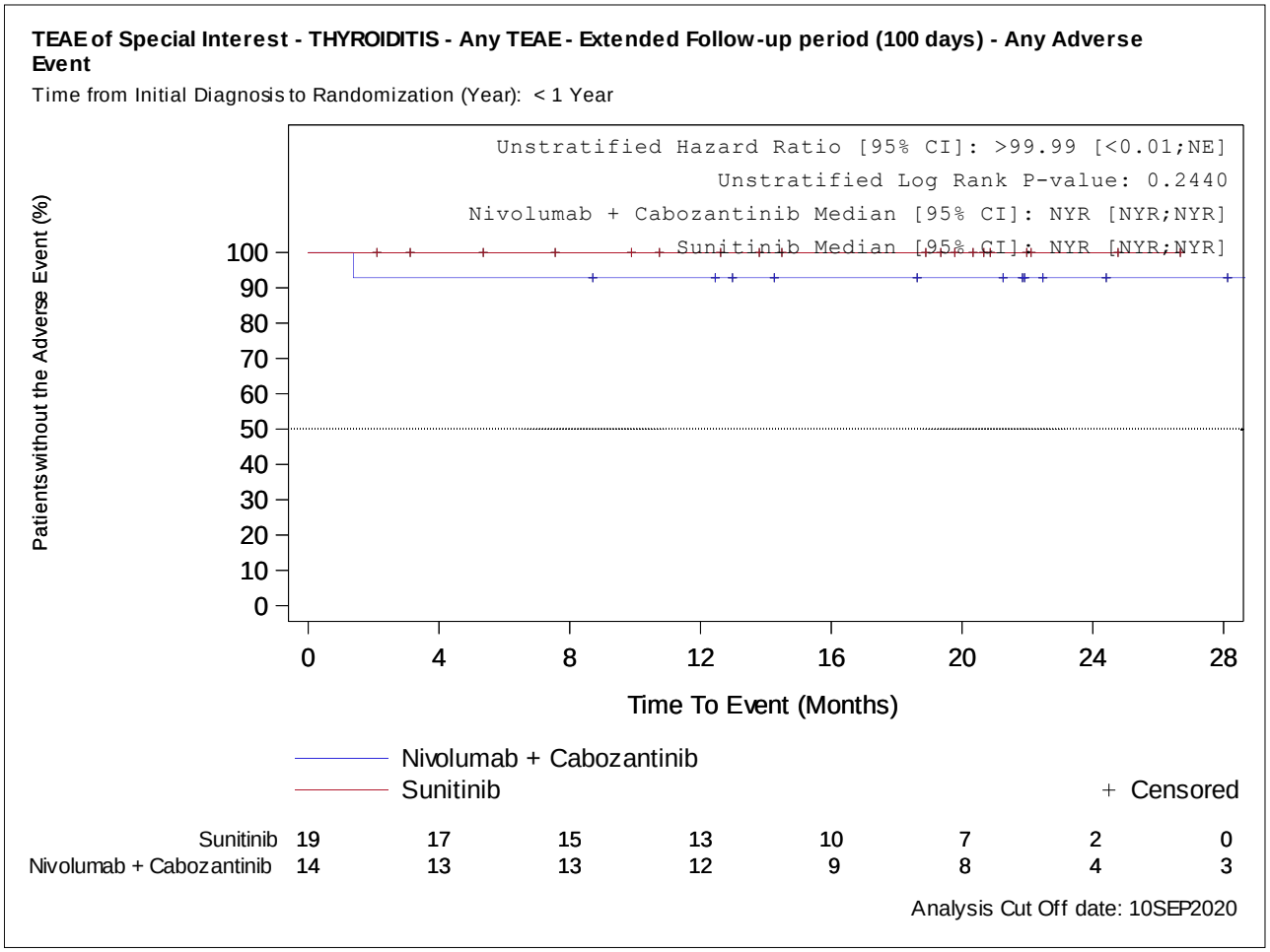

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:19:00

FIGURE 3.108.2.14: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:19:05

FIGURE 3.108.2.15: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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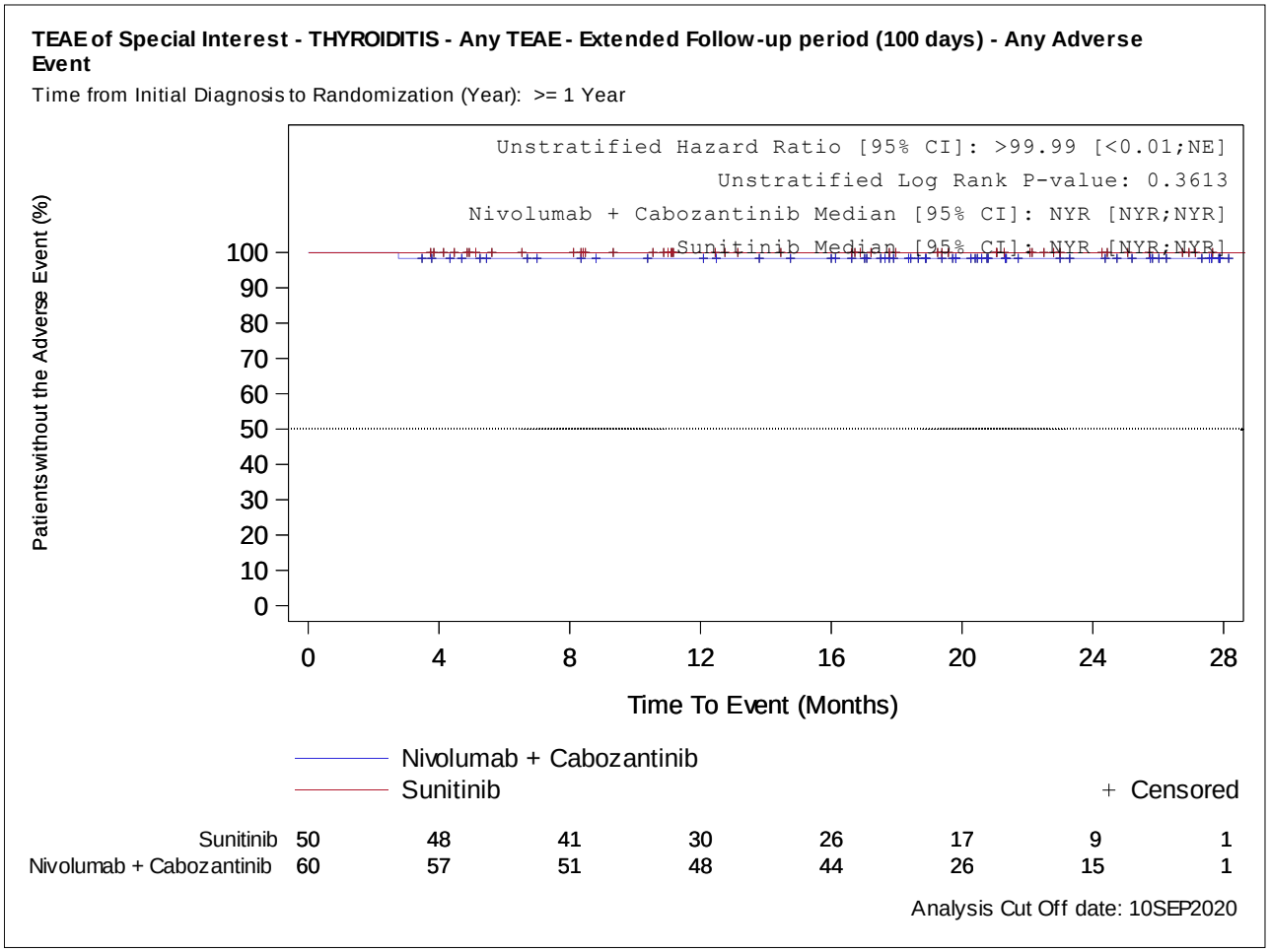
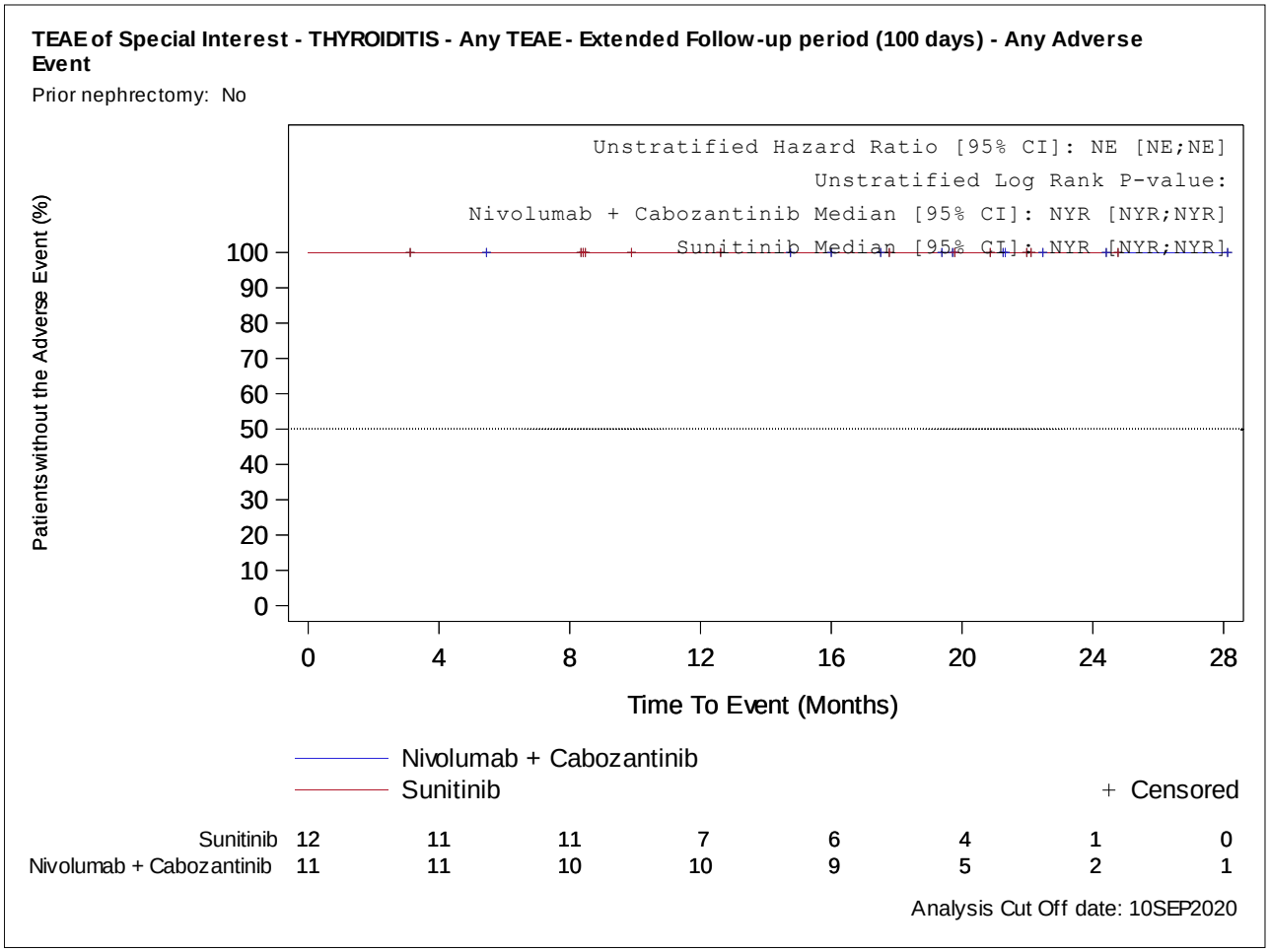
FIGURE 3.108.2.16: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



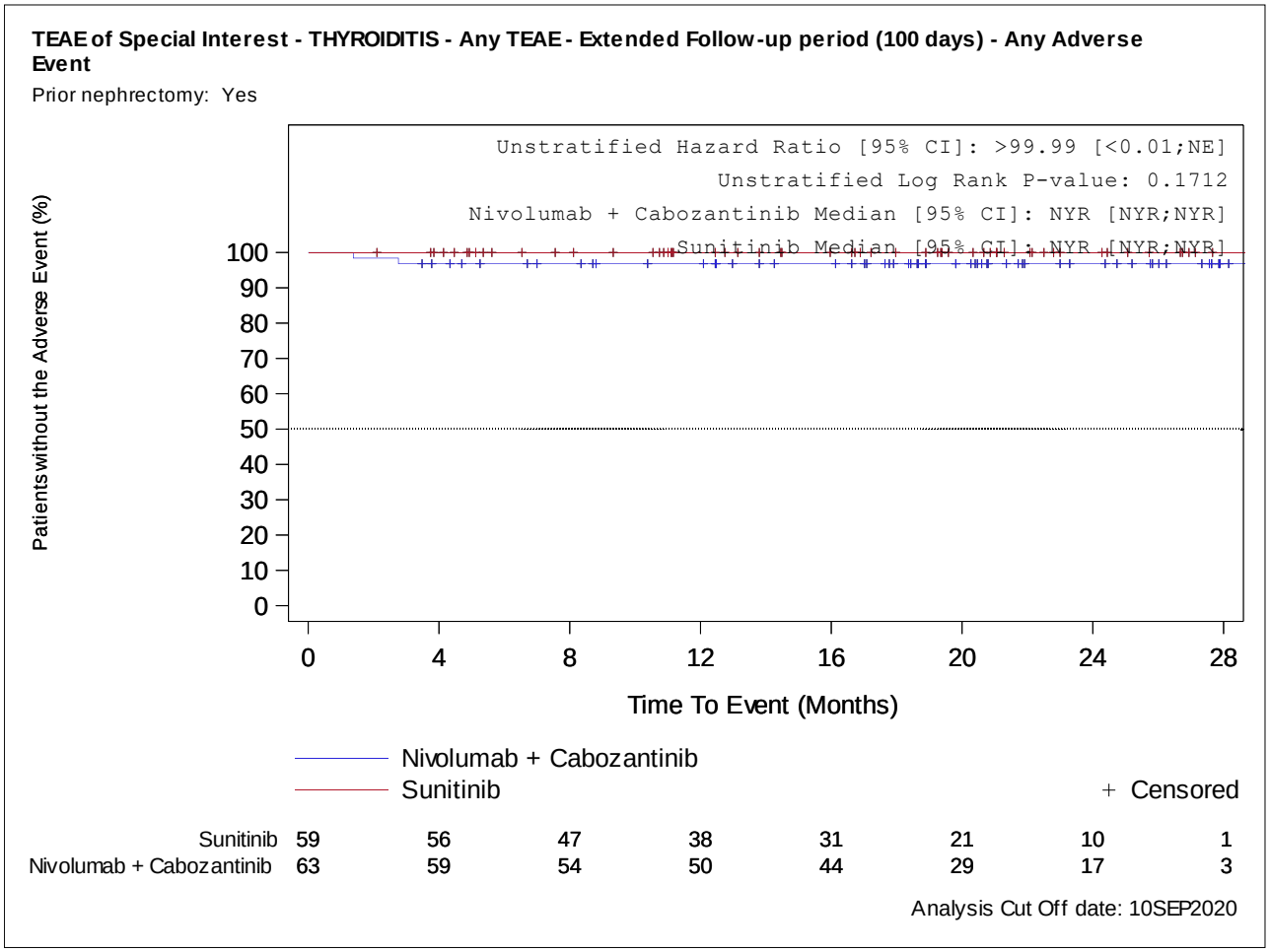

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:19:27

FIGURE 3.108.2.17: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



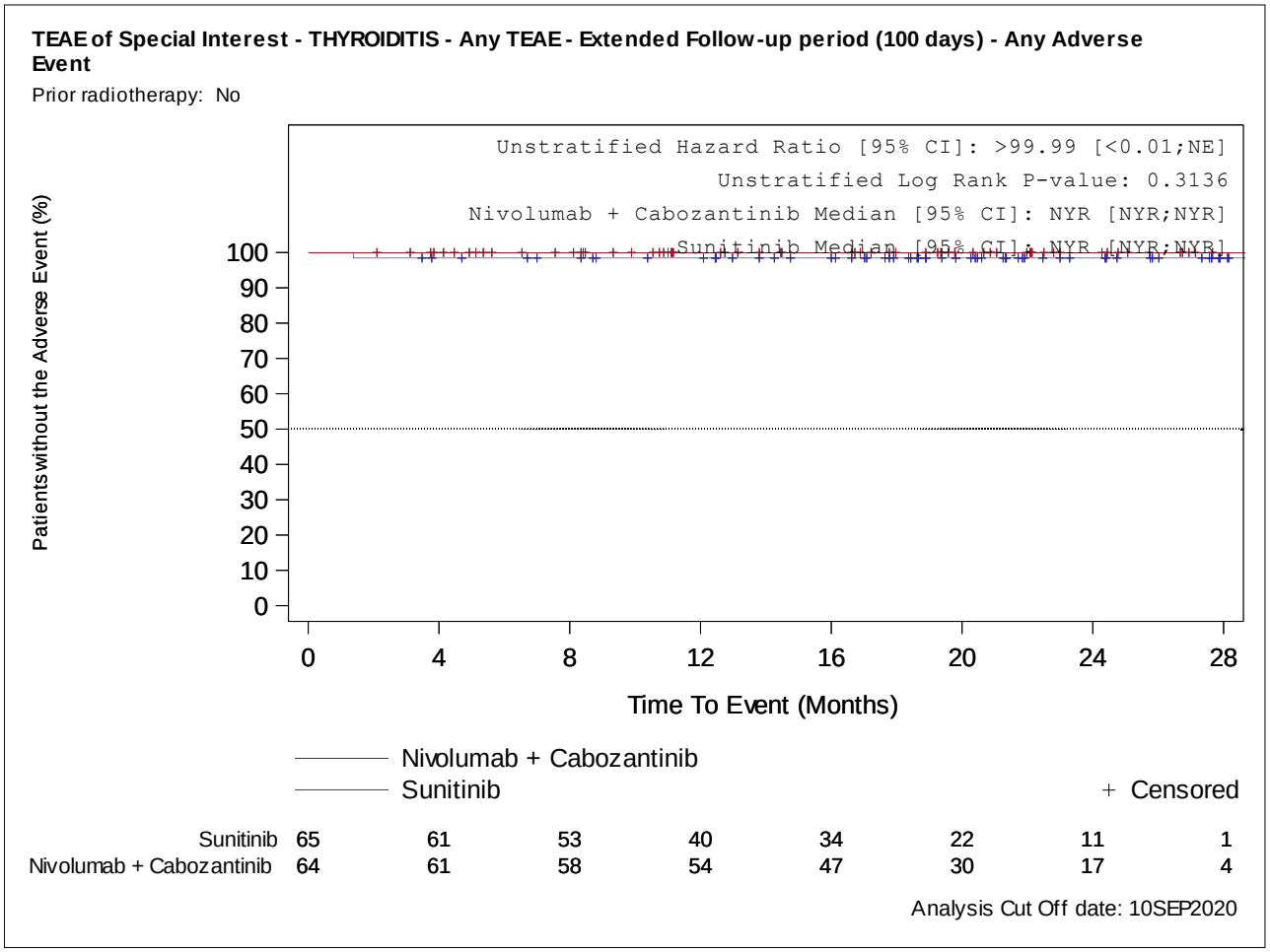

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:20:14

FIGURE 3.108.2.18: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



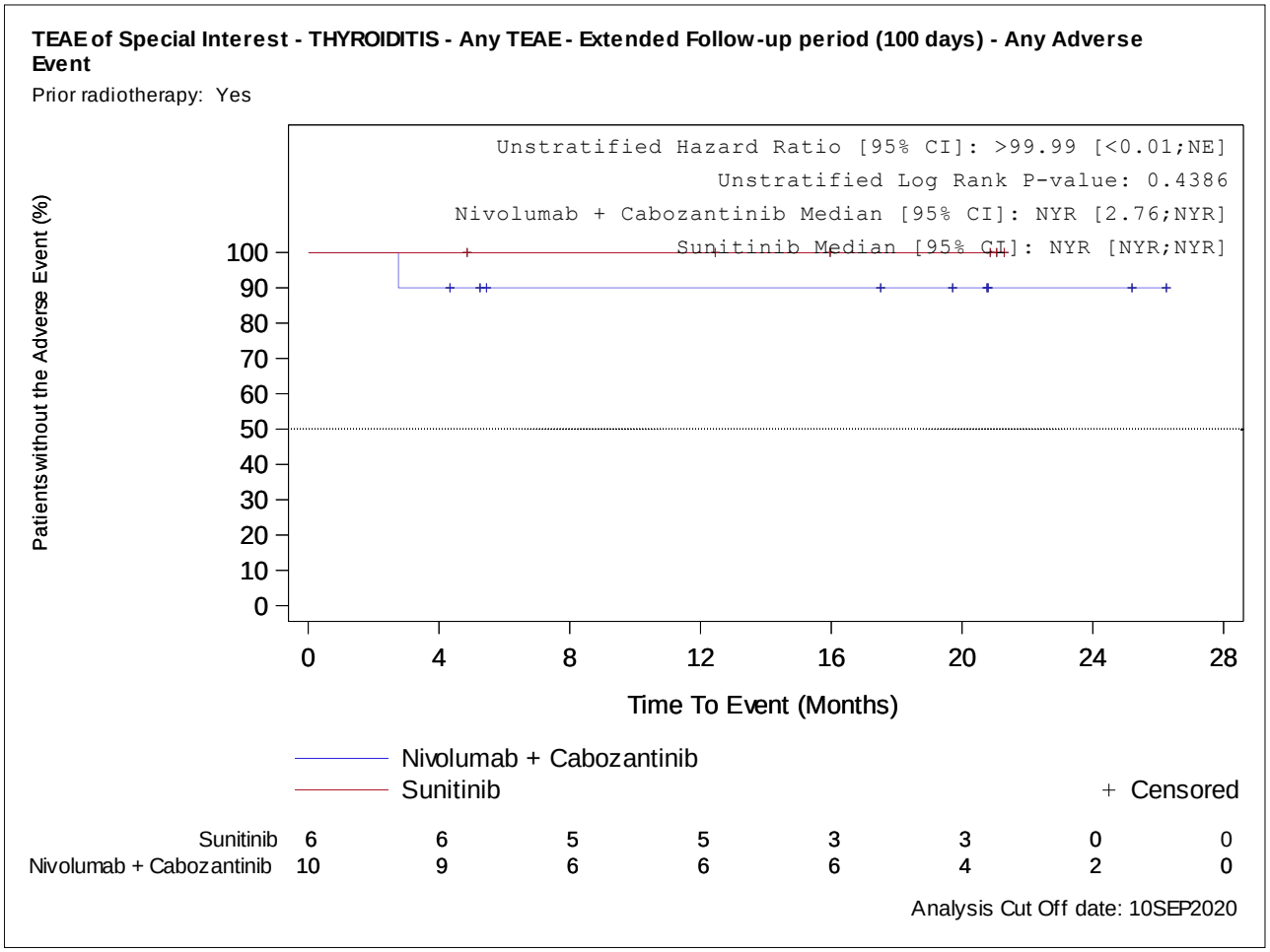

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:20:19

FIGURE 3.108.2.19: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



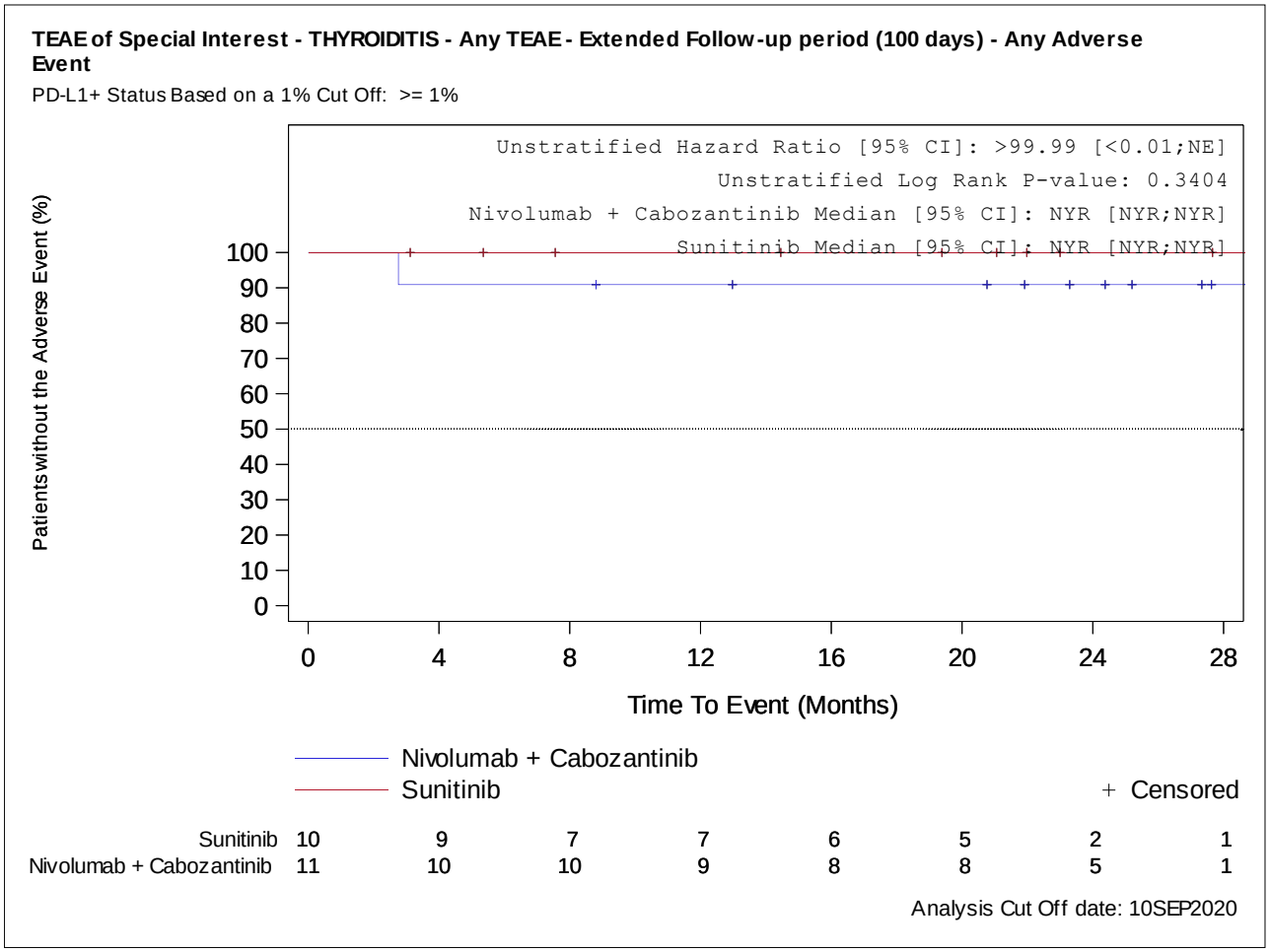

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:20:24

FIGURE 3.108.2.20: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:20:30

FIGURE 3.108.2.21: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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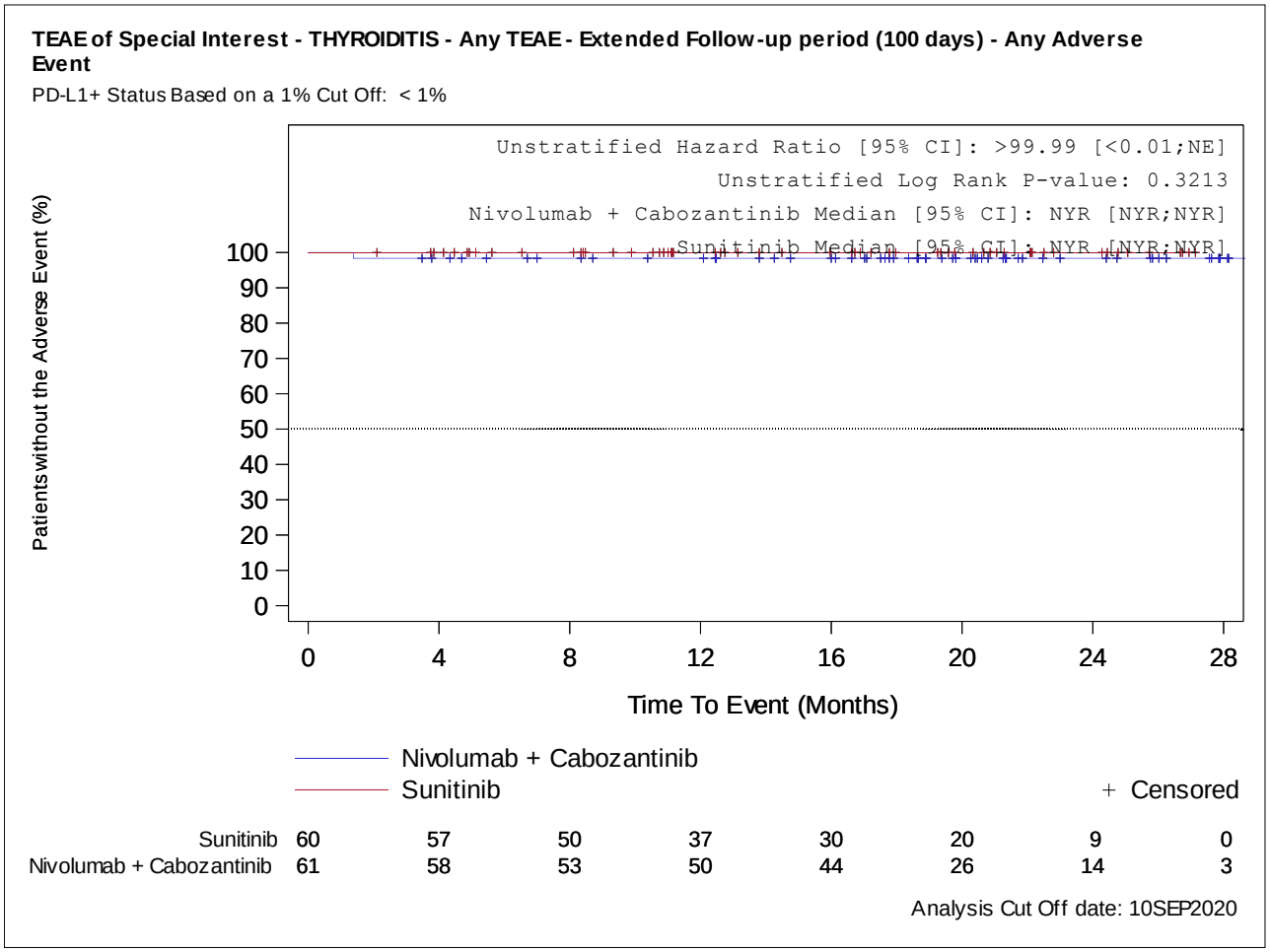
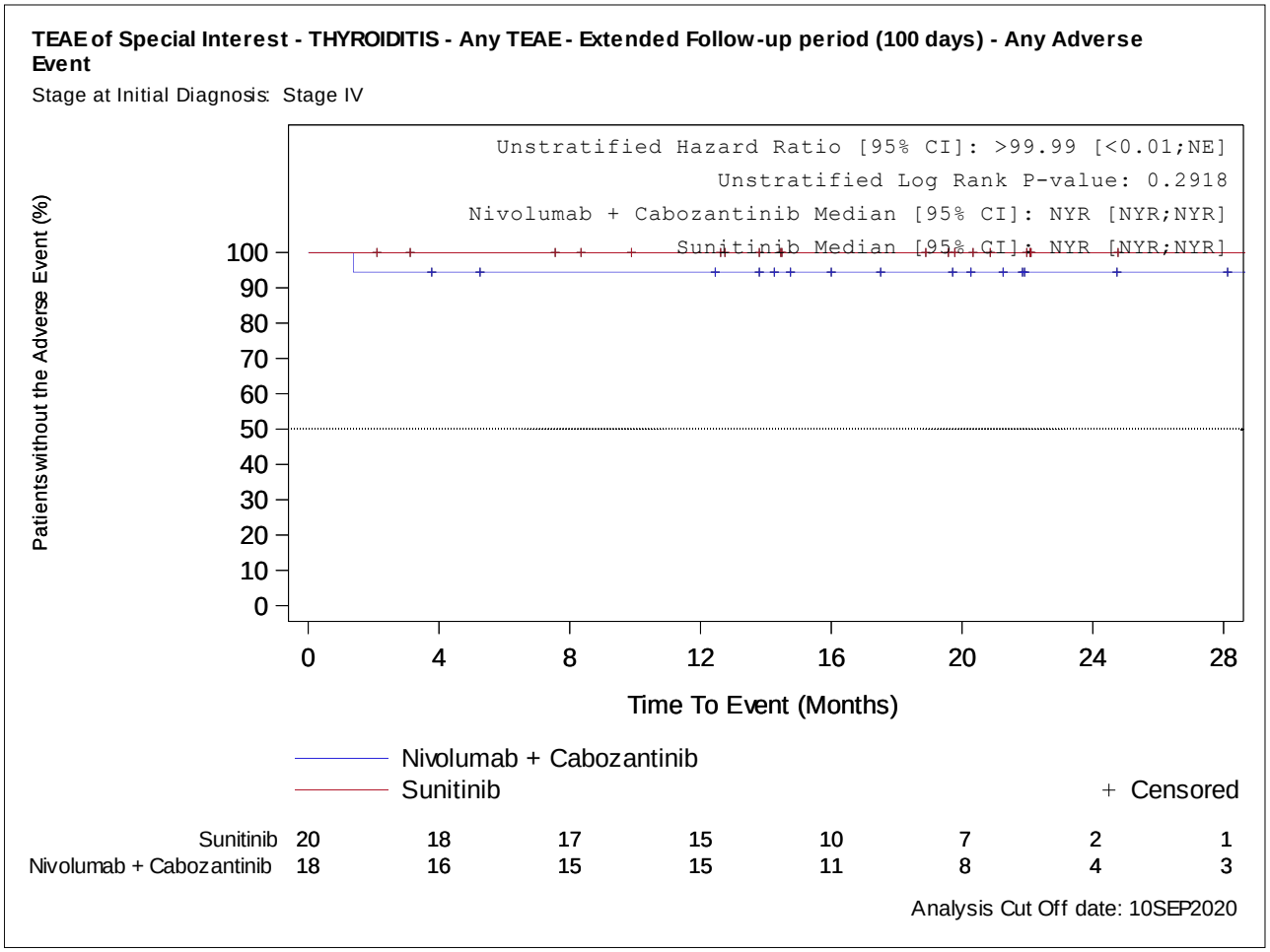
FIGURE 3.108.2.22: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



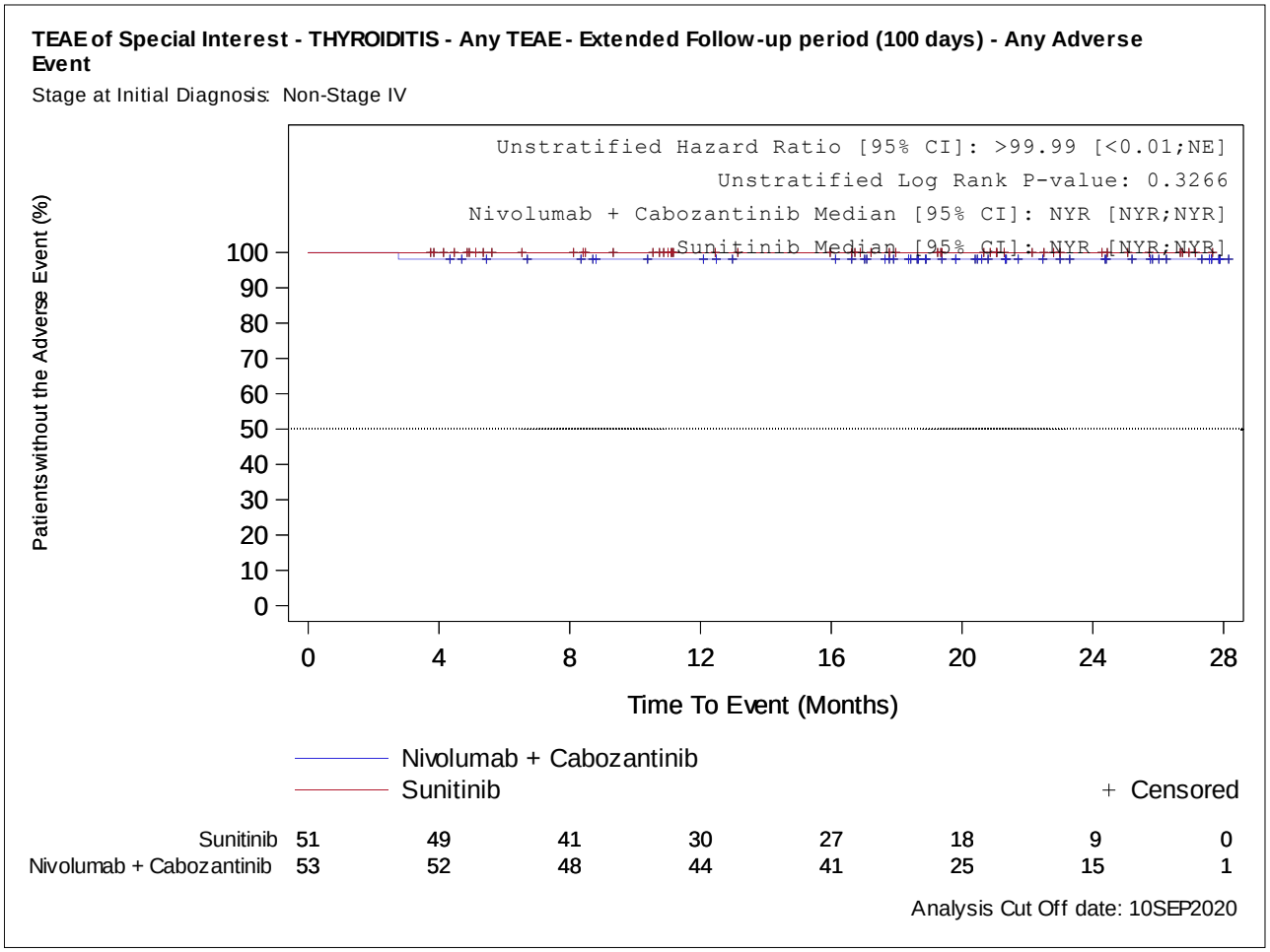

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:20:40

FIGURE 3.108.2.23: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



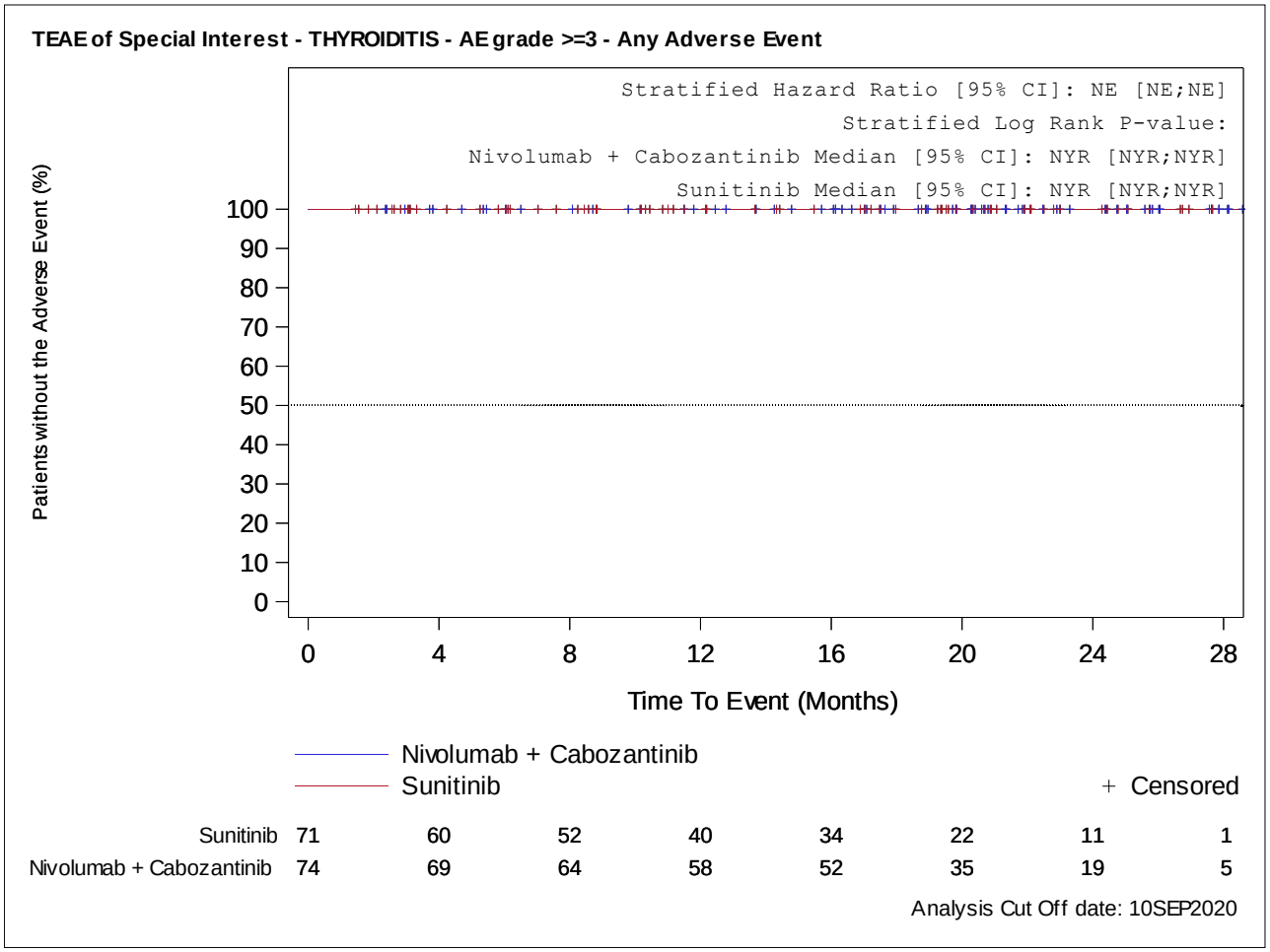

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:21:06

FIGURE 3.108.2.24: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



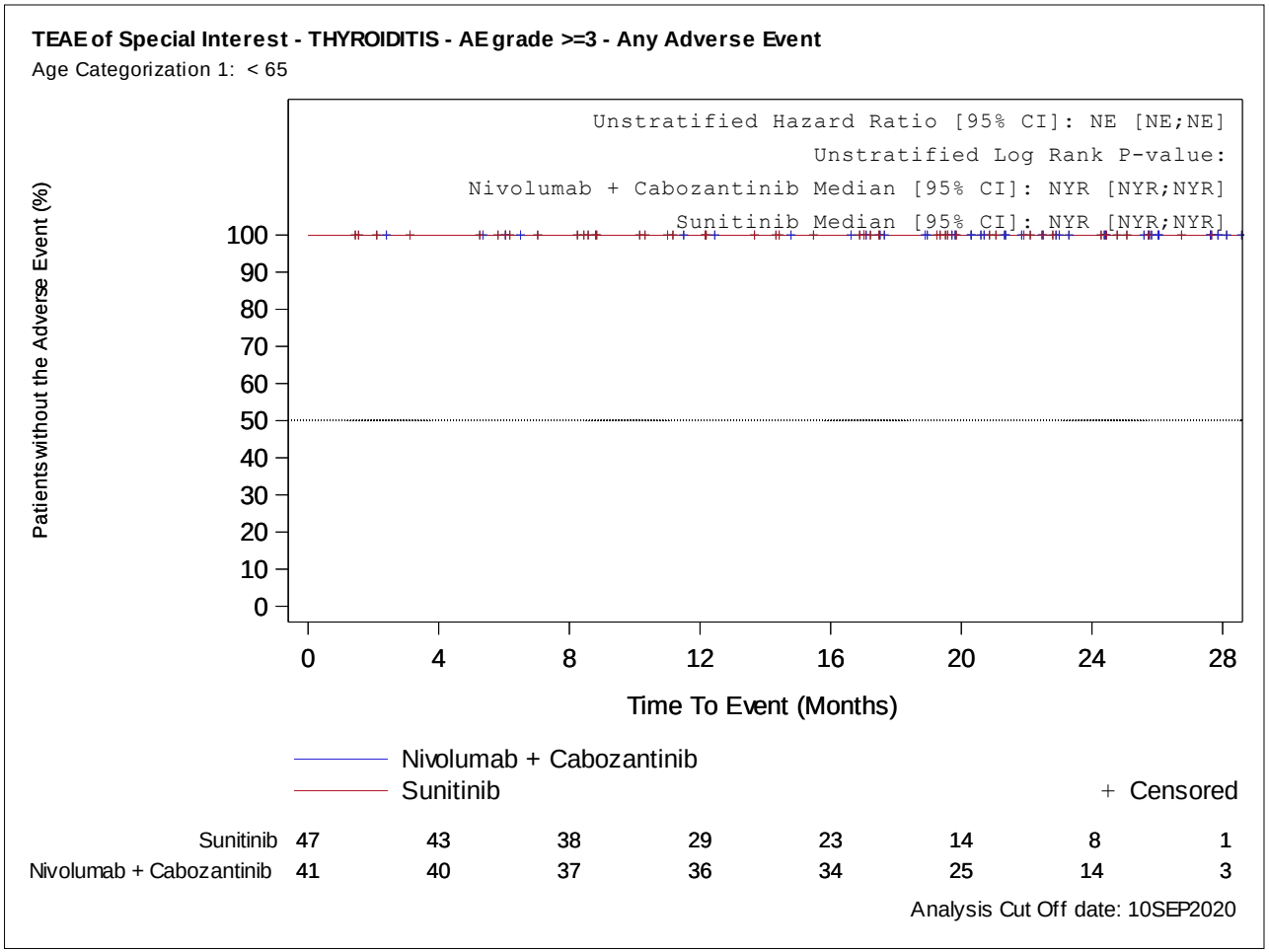

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:21:11

FIGURE 3.109.1: TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



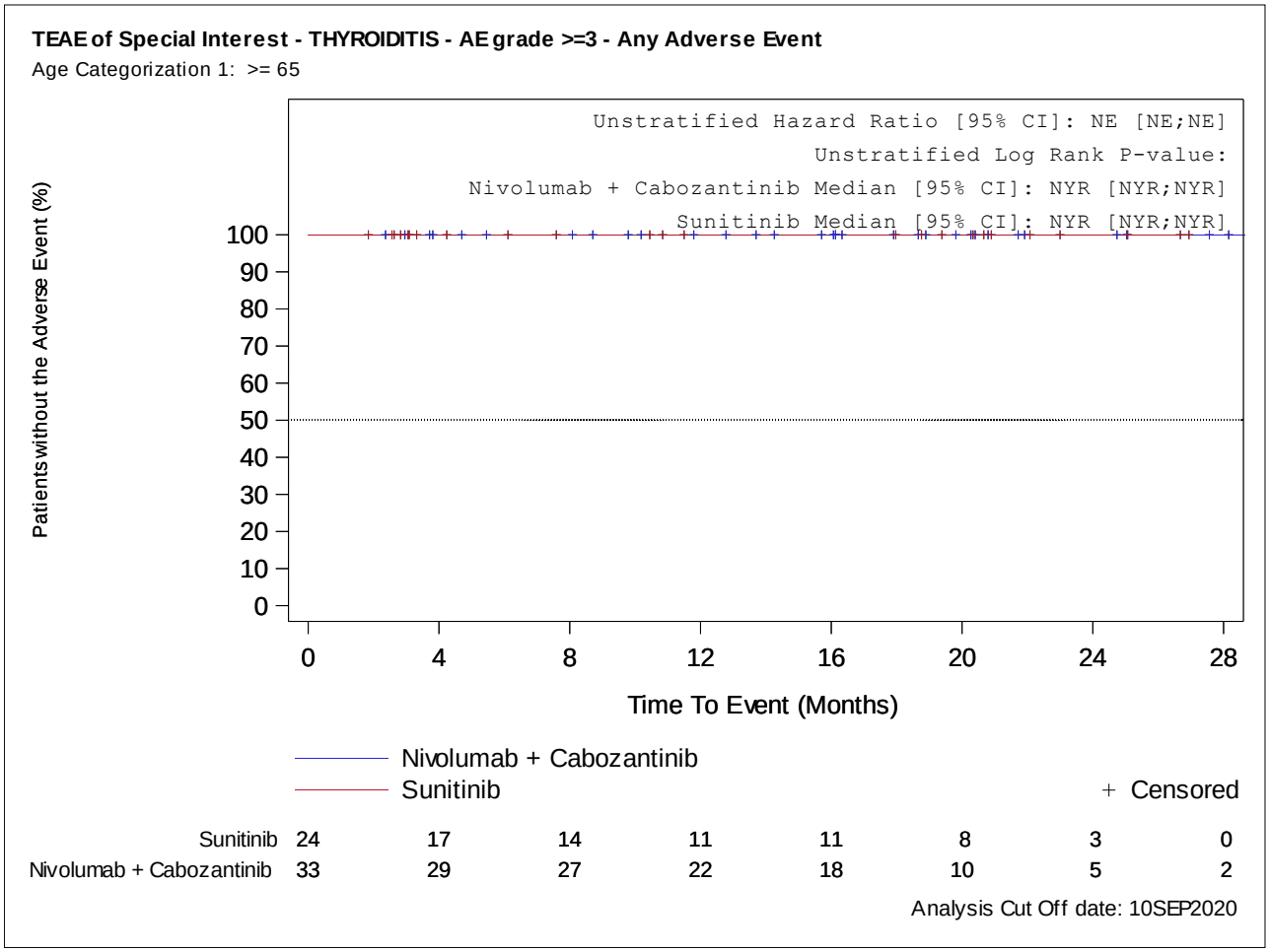

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:07

FIGURE 3.109.2.1: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



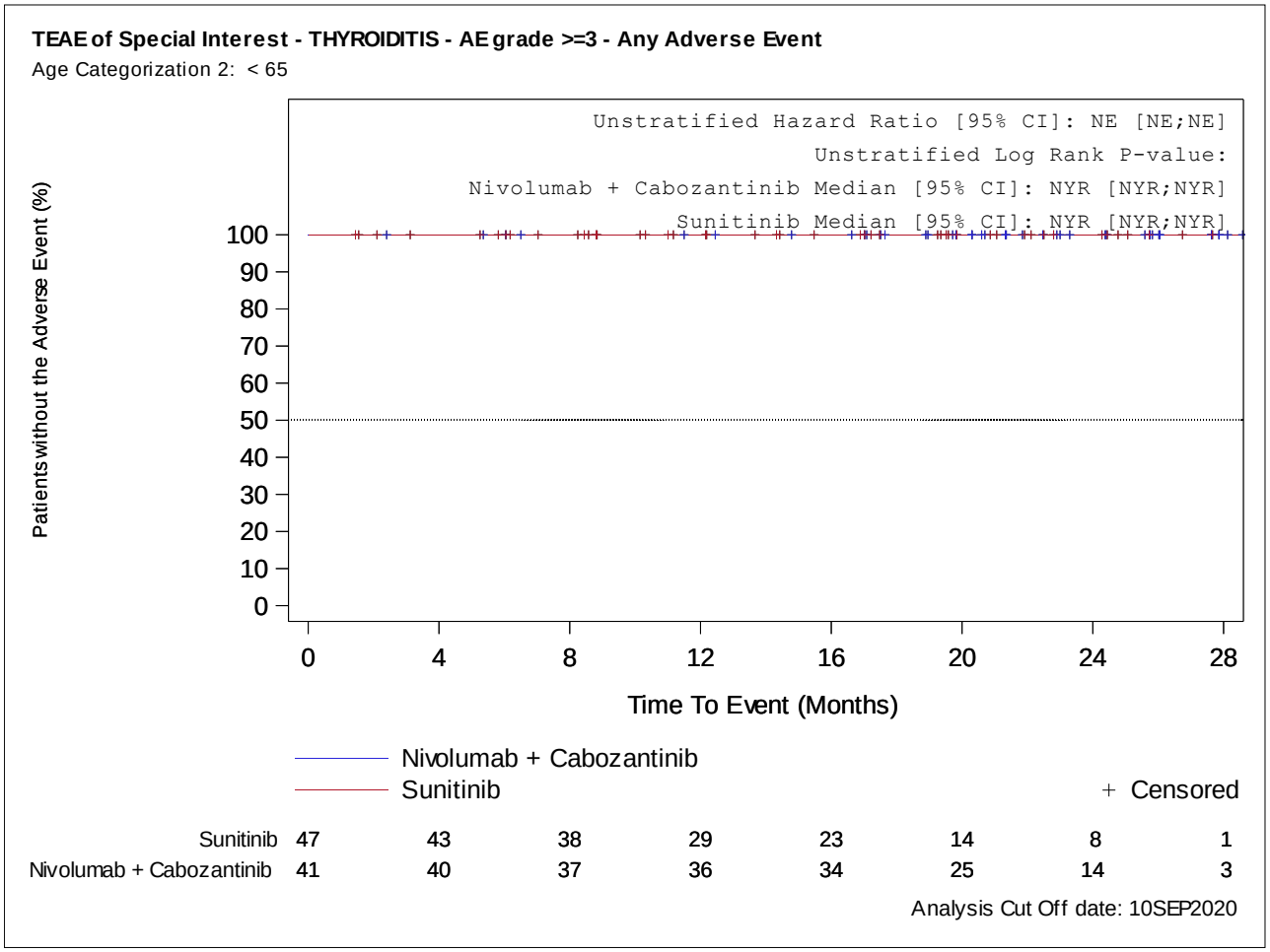

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:10

FIGURE 3.109.2.2: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



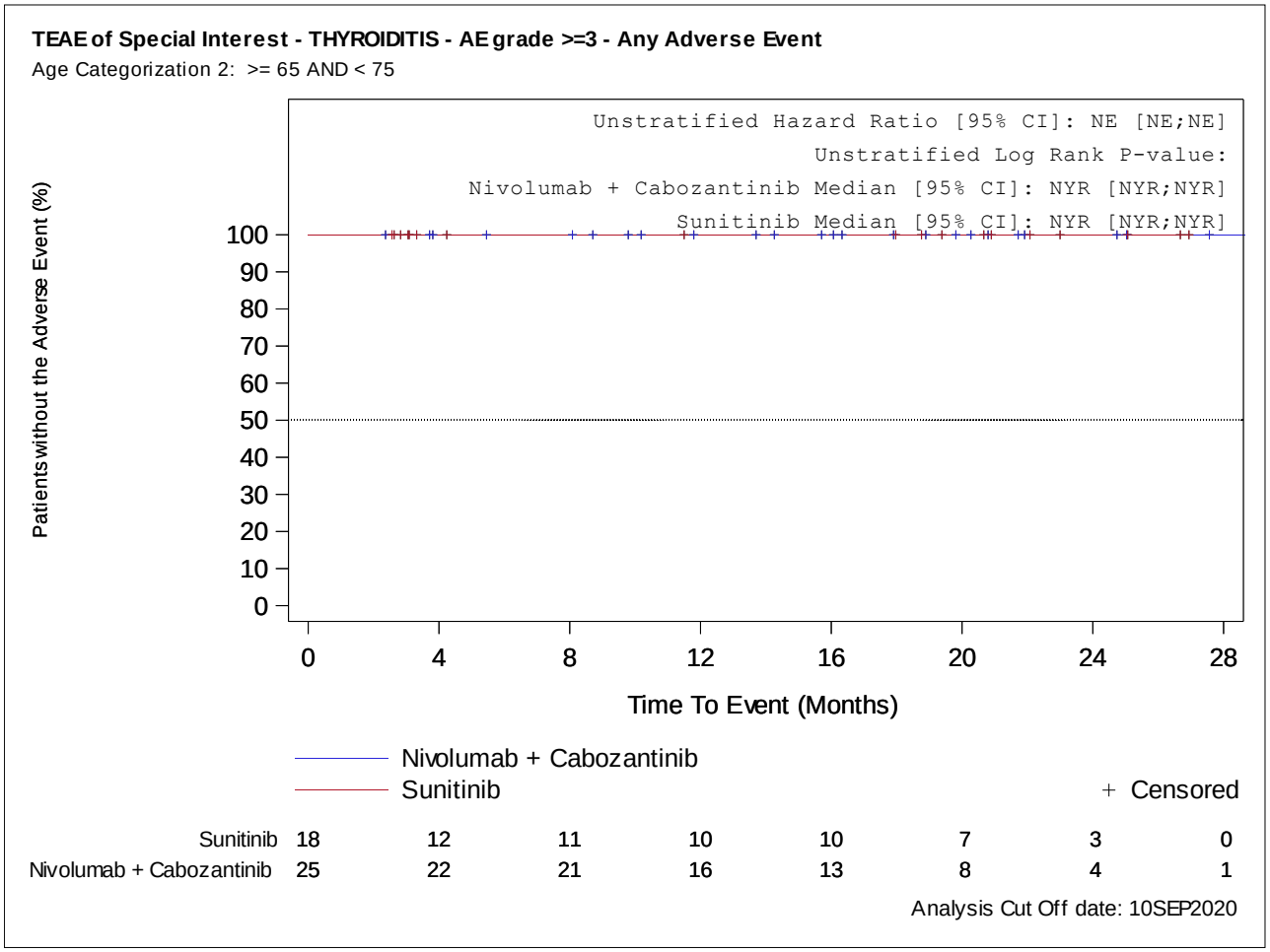

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:15

FIGURE 3.109.2.3: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



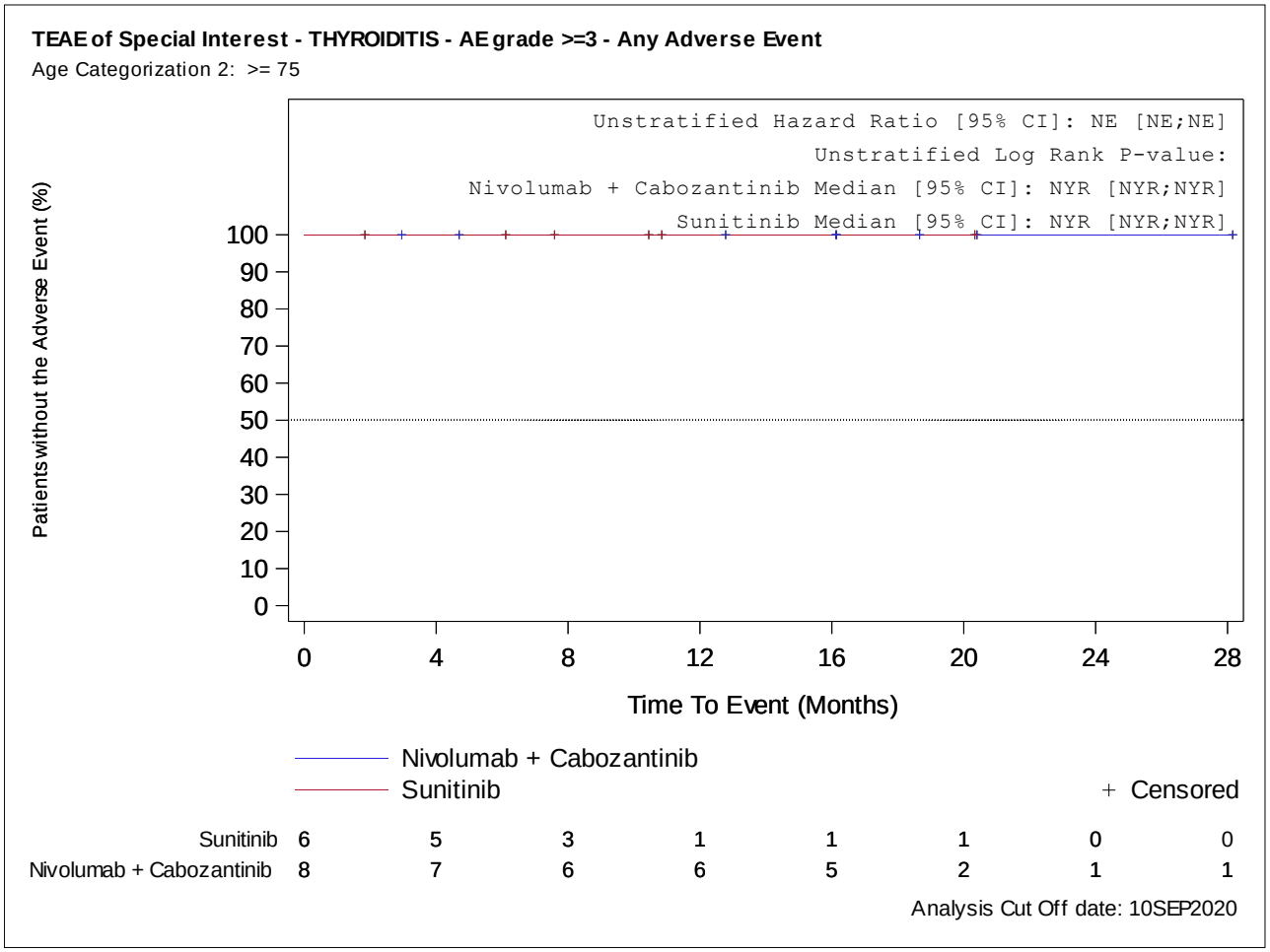

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:21

FIGURE 3.109.2.4: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



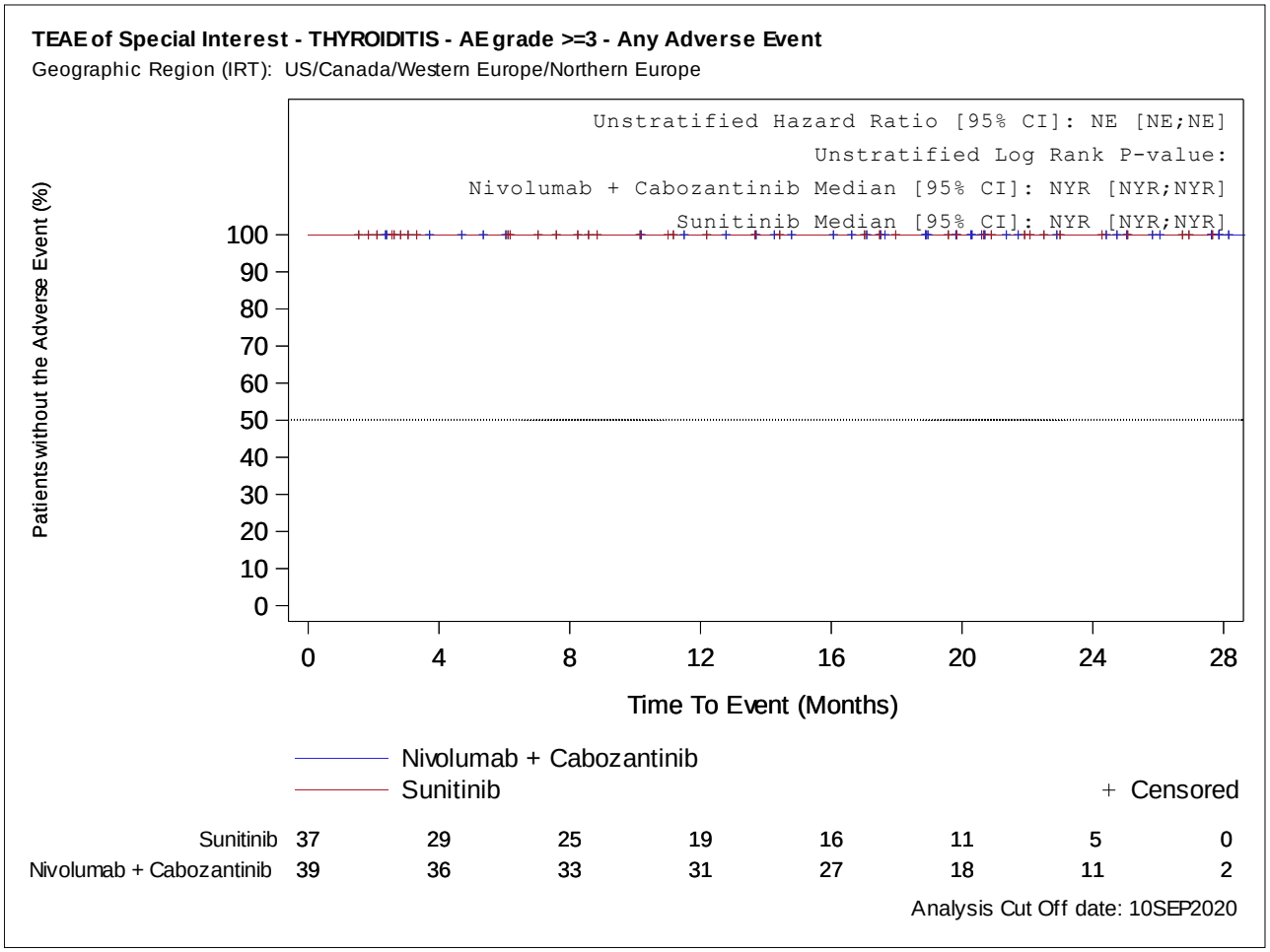

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:26

FIGURE 3.109.2.5: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



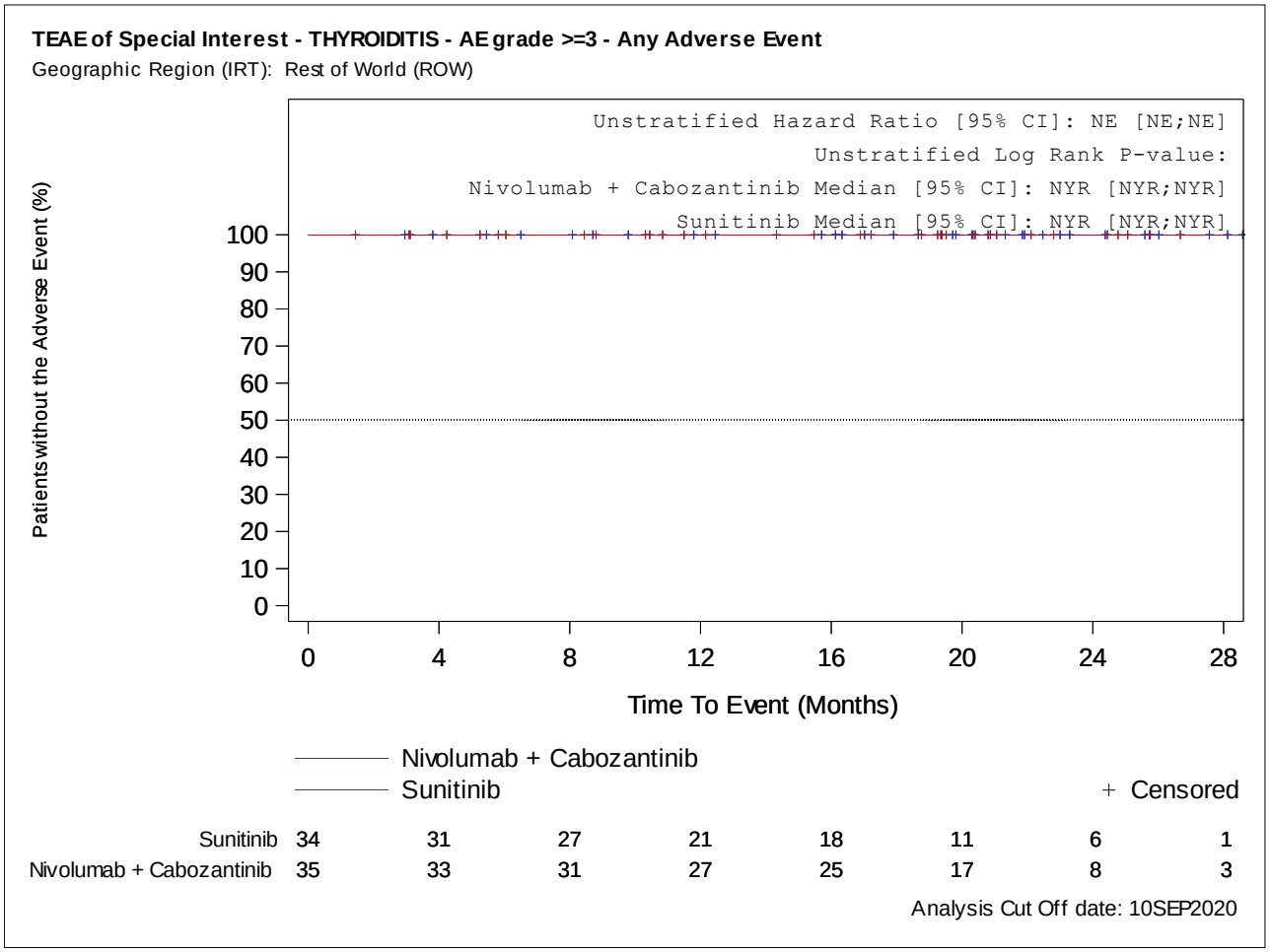

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:24:31

FIGURE 3.109.2.6: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



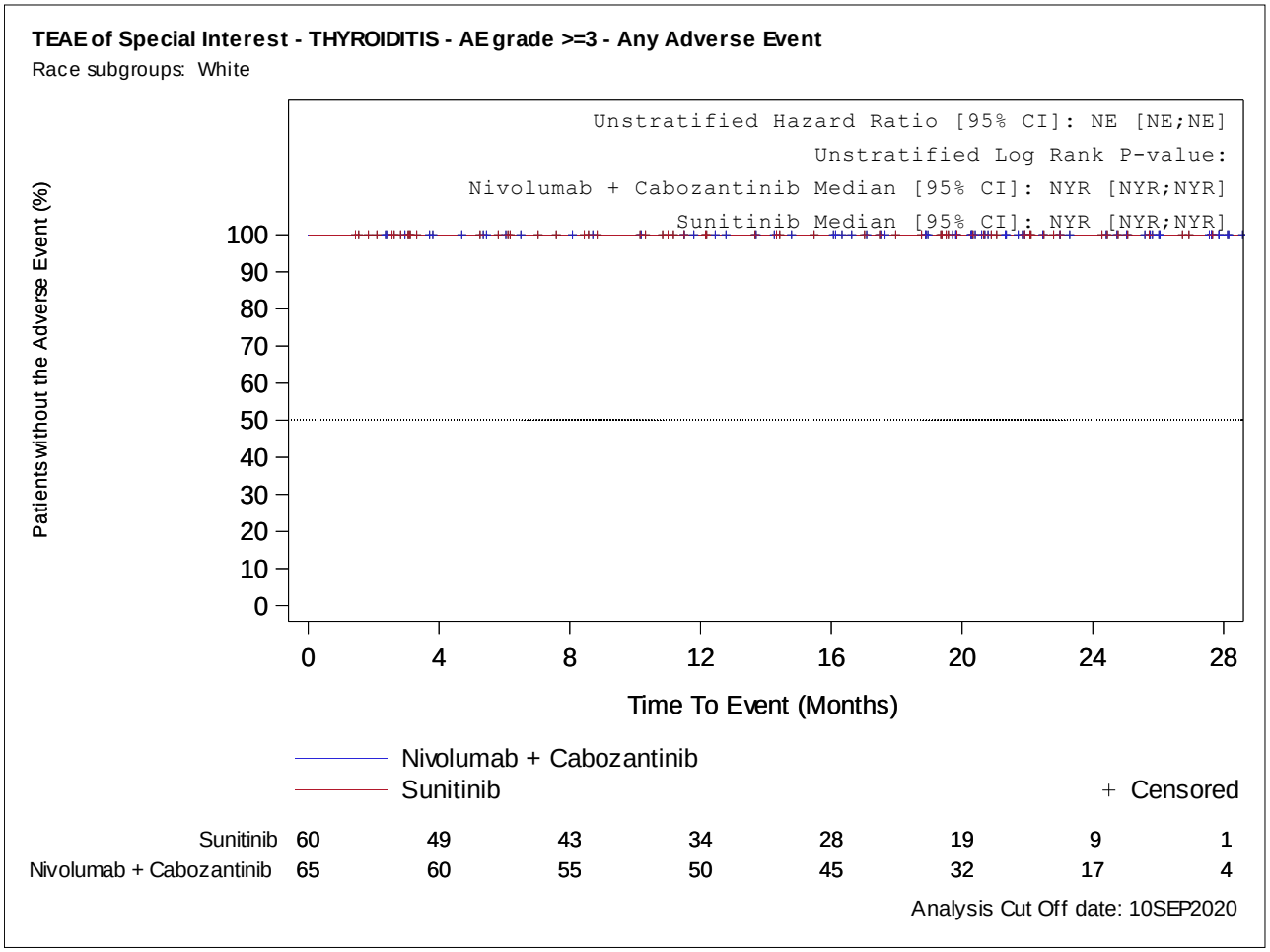

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:36

FIGURE 3.109.2.7: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



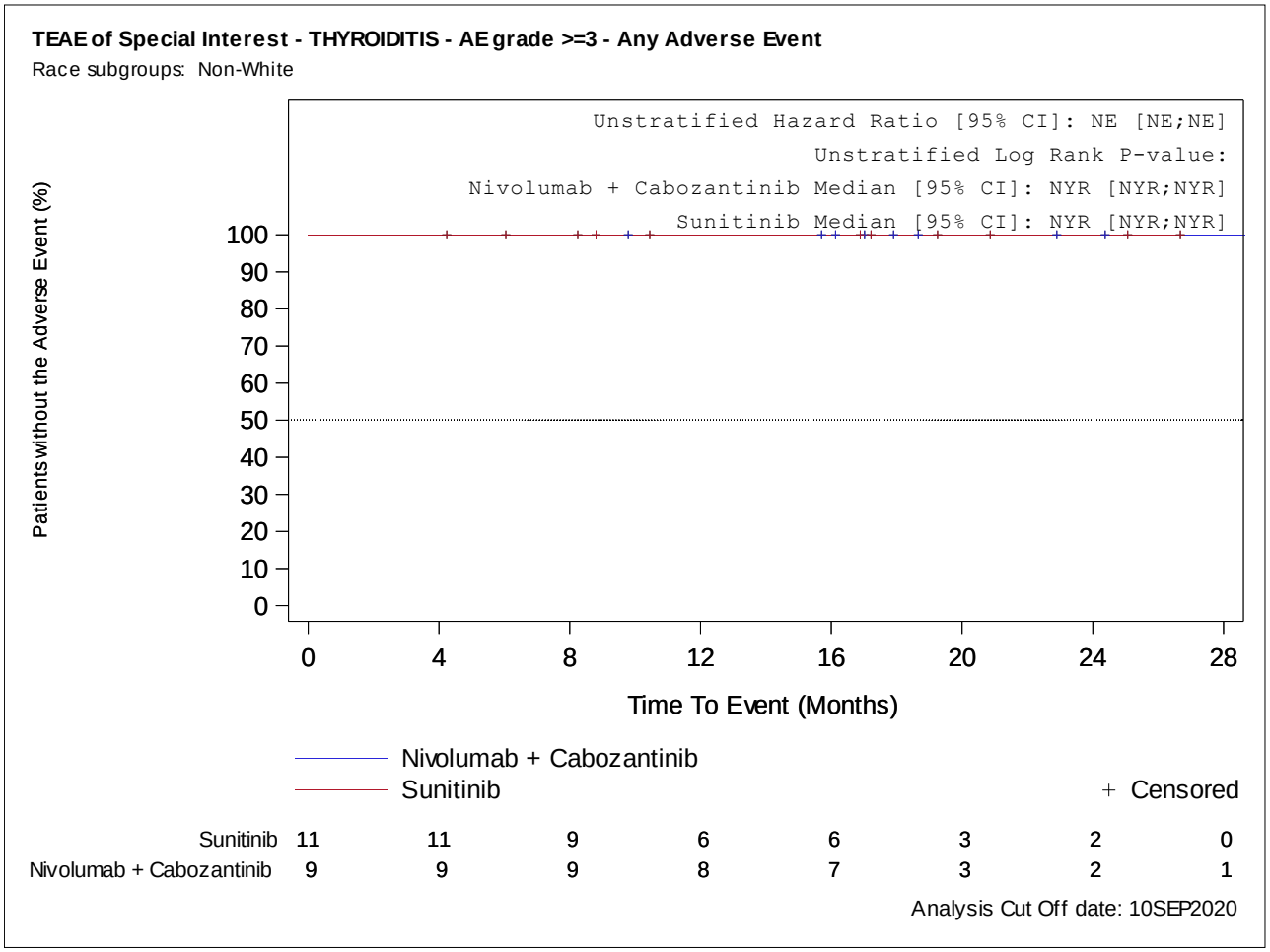

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:41

FIGURE 3.109.2.8: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



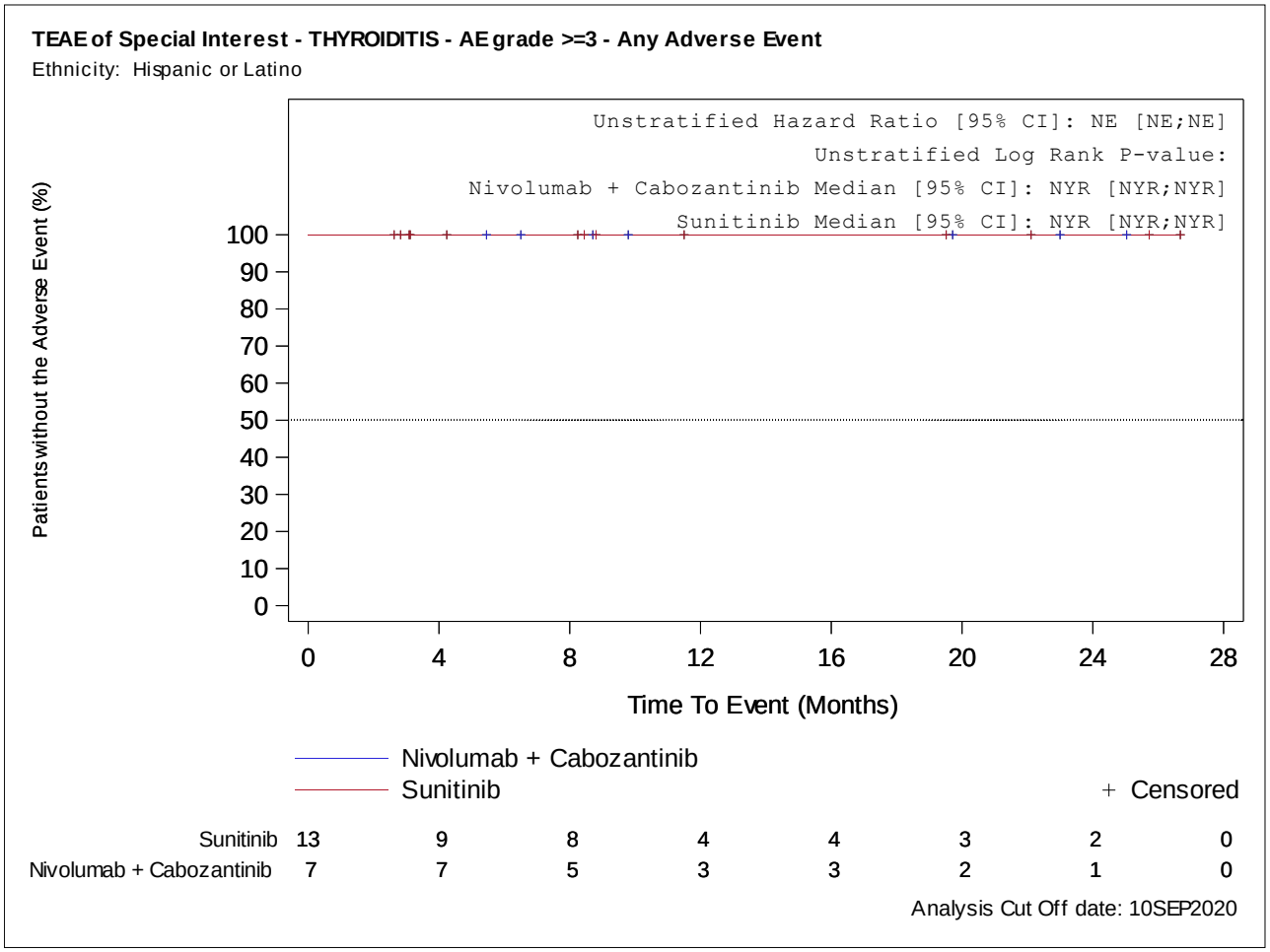

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:47

FIGURE 3.109.2.9: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



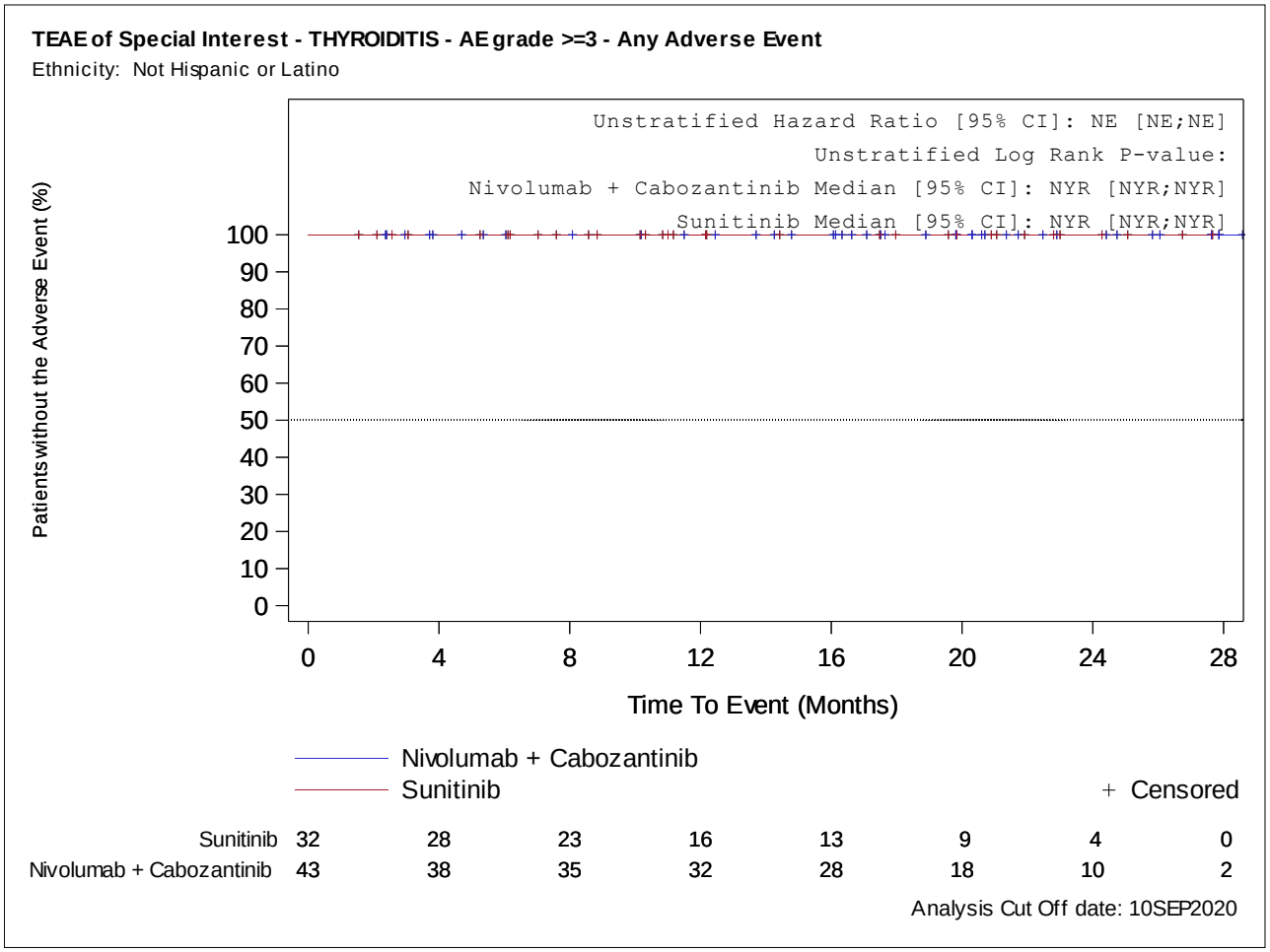

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:52

FIGURE 3.109.2.10: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



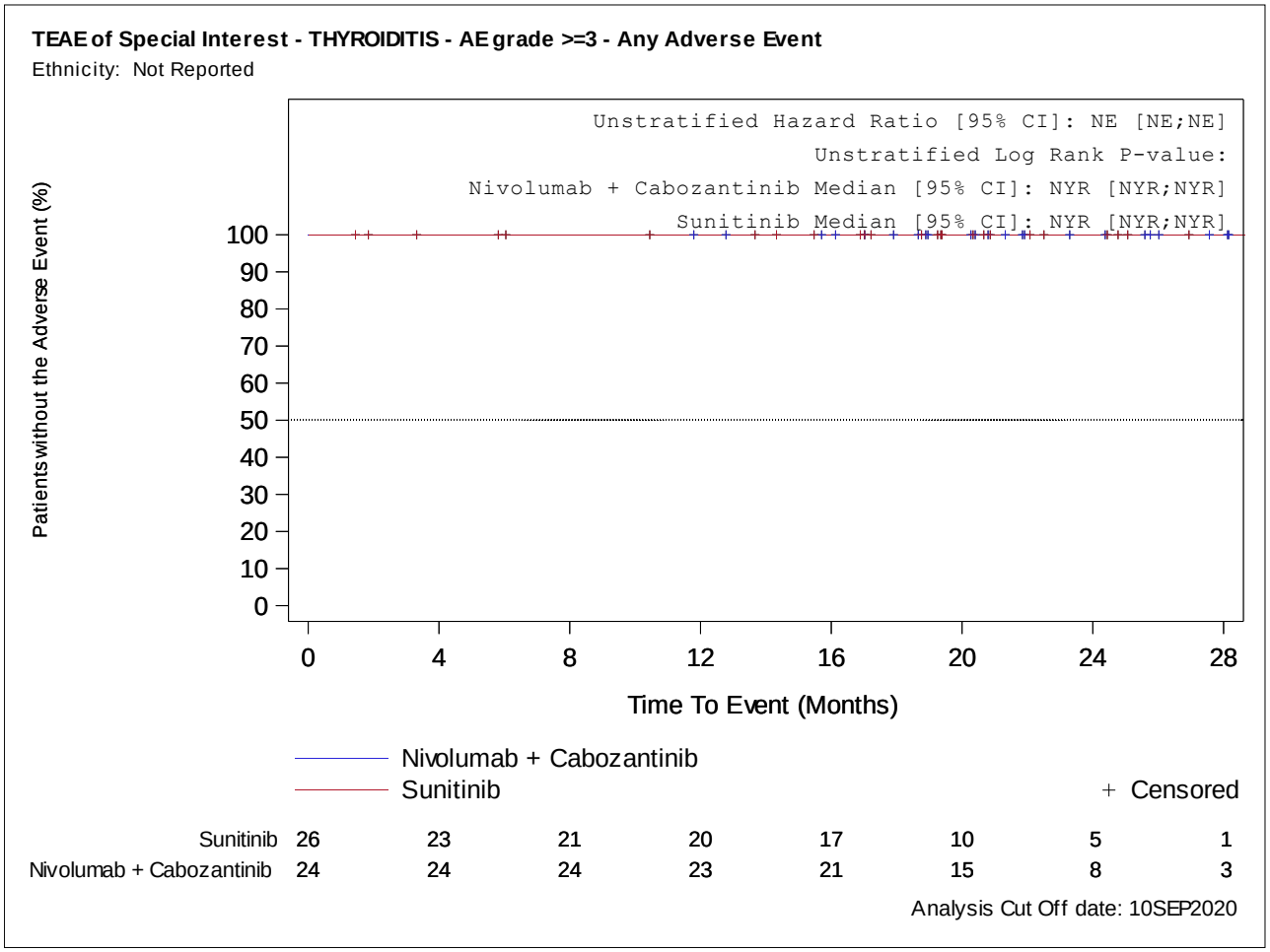

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:24:57

FIGURE 3.109.2.11: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



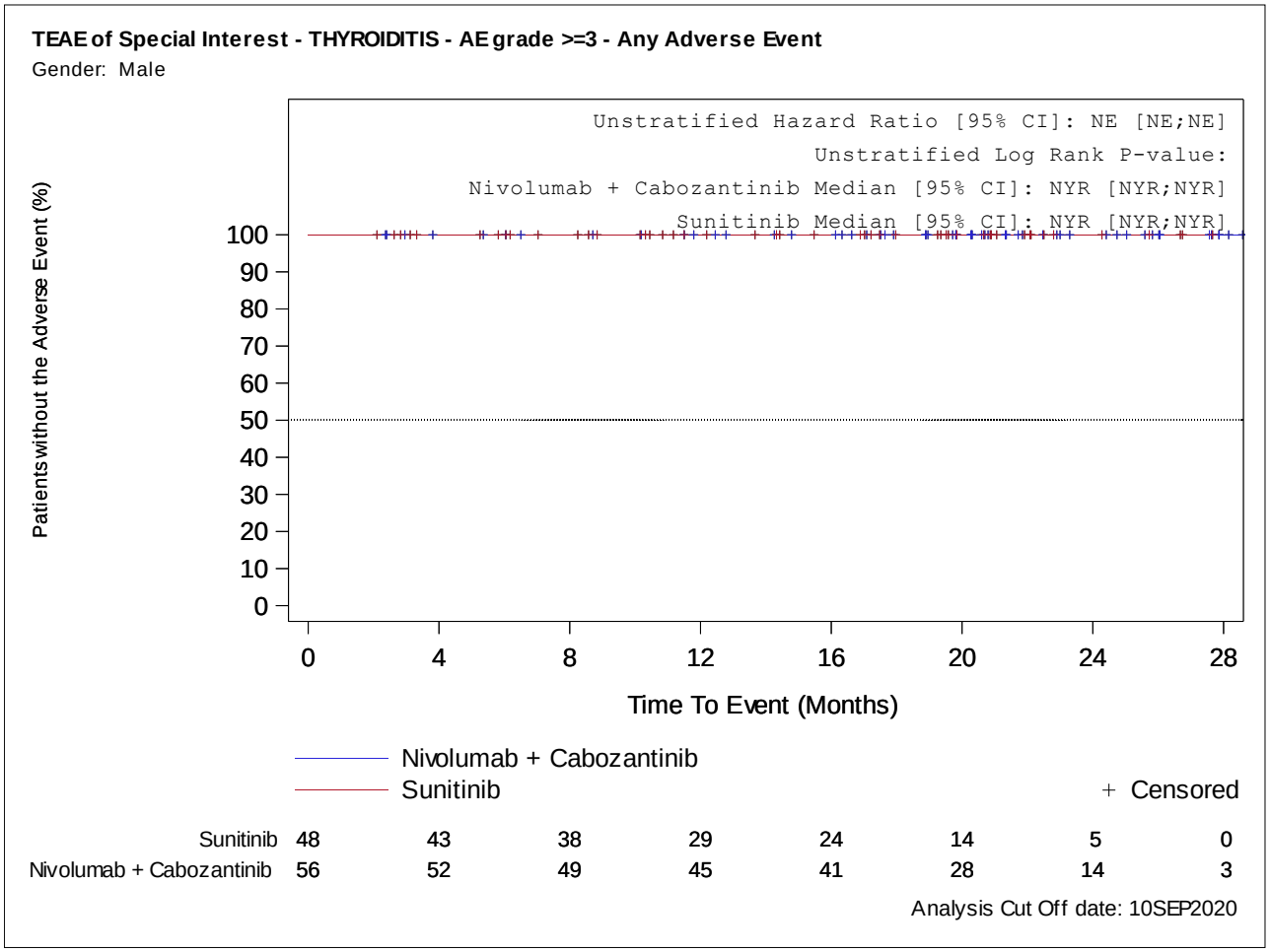

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:25:03

FIGURE 3.109.2.12: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



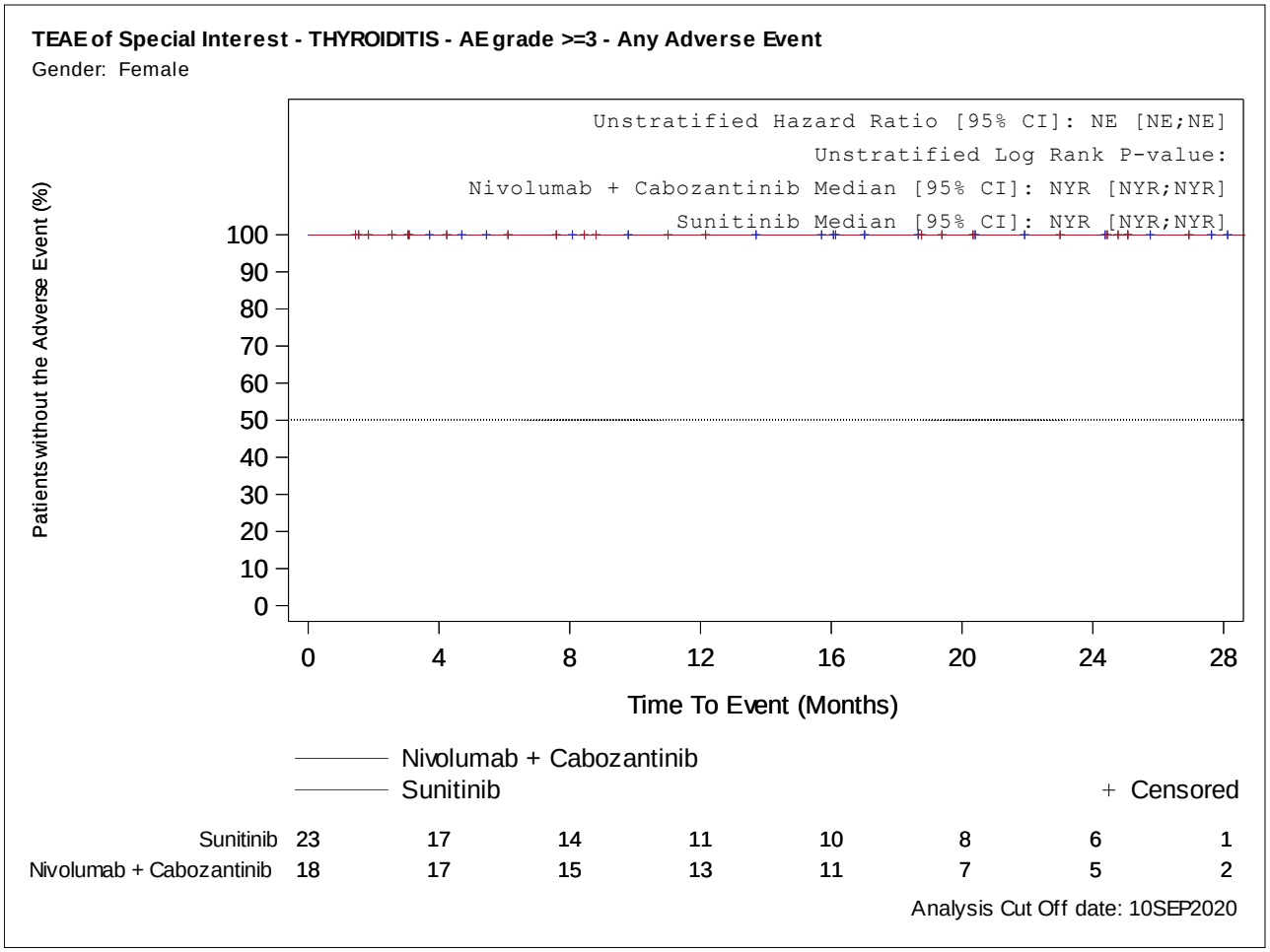

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:25:08

FIGURE 3.109.2.13: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



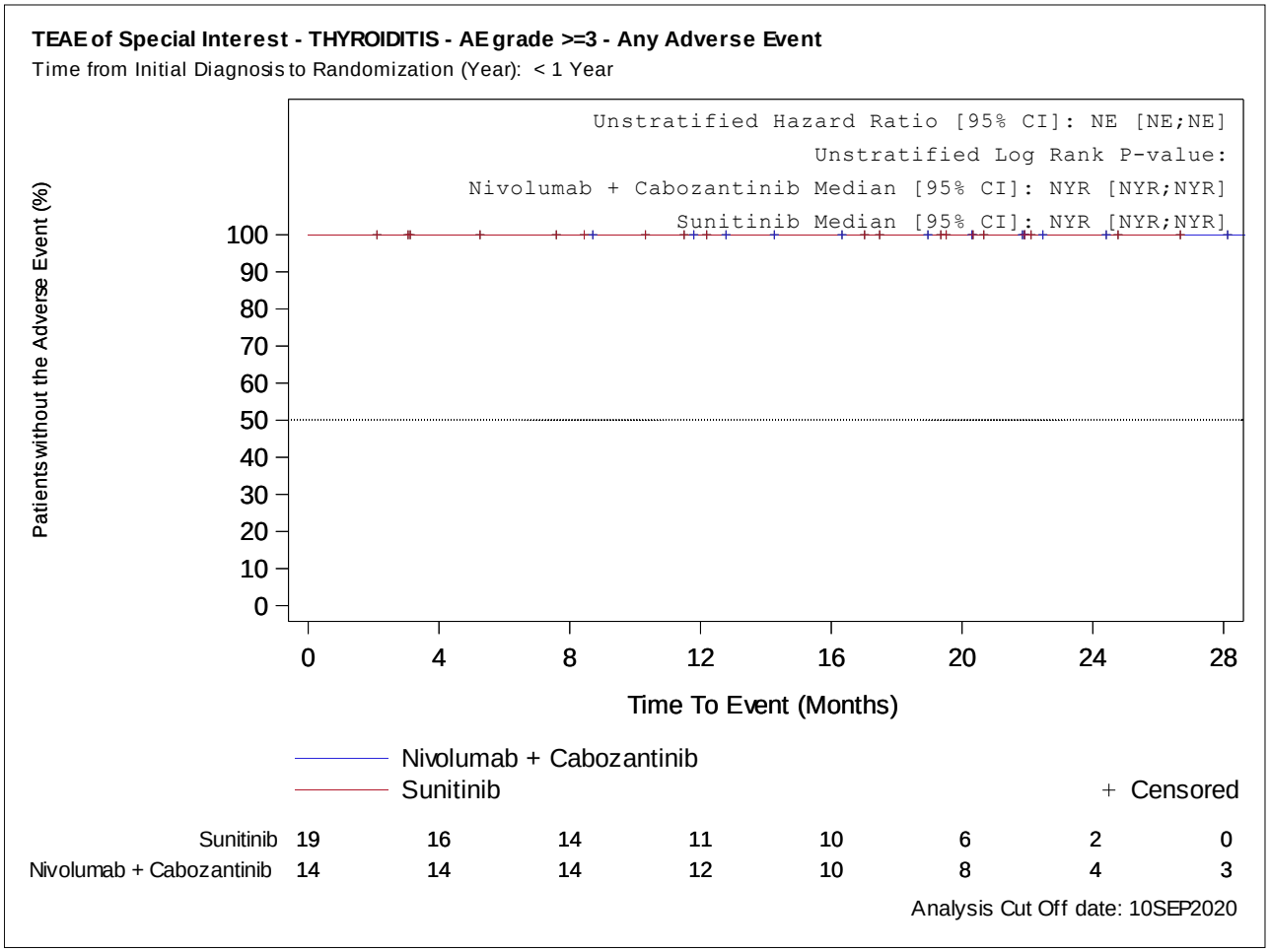

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:25:13

FIGURE 3.109.2.14: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



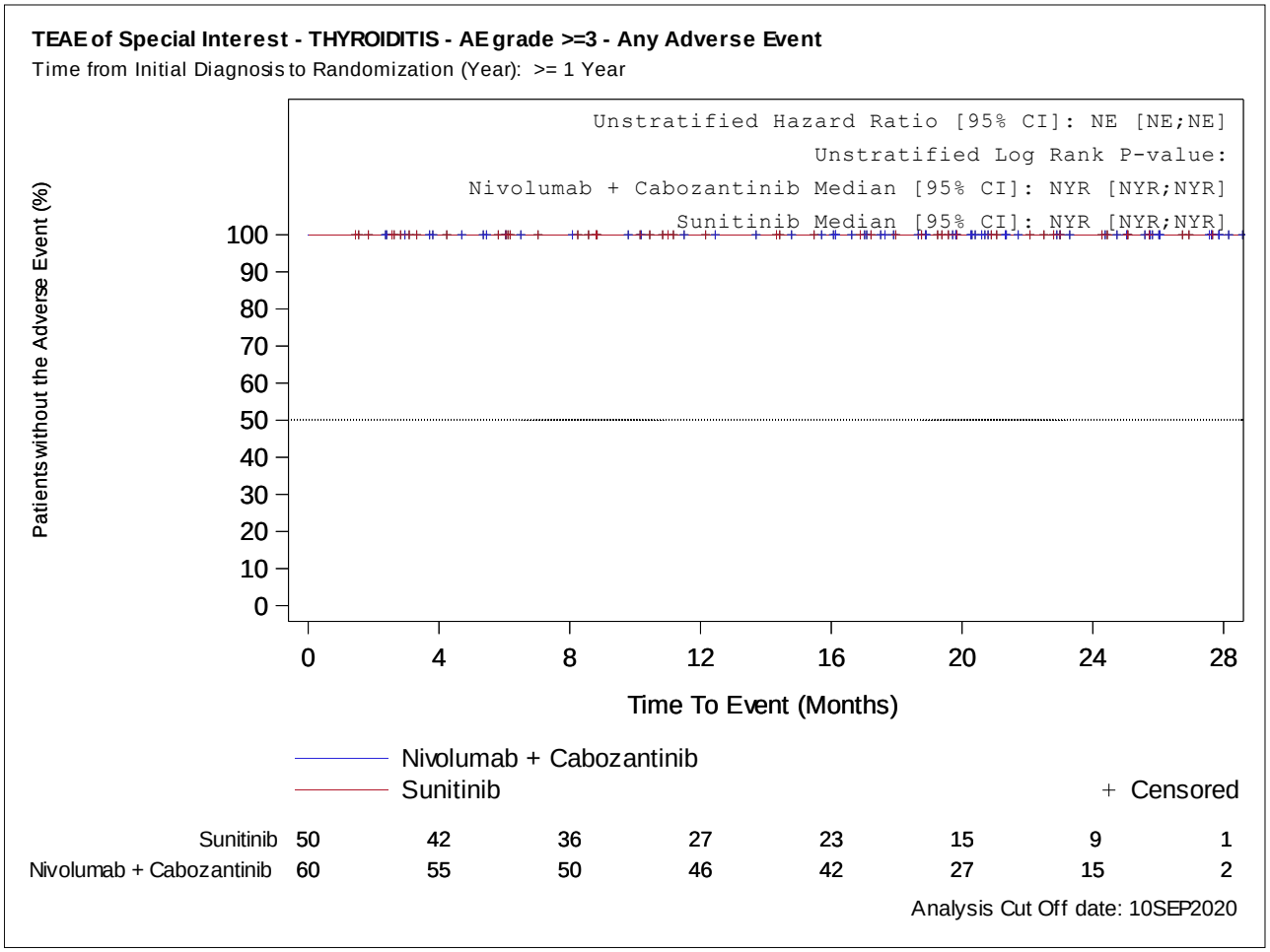

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:25:18

FIGURE 3.109.2.15: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



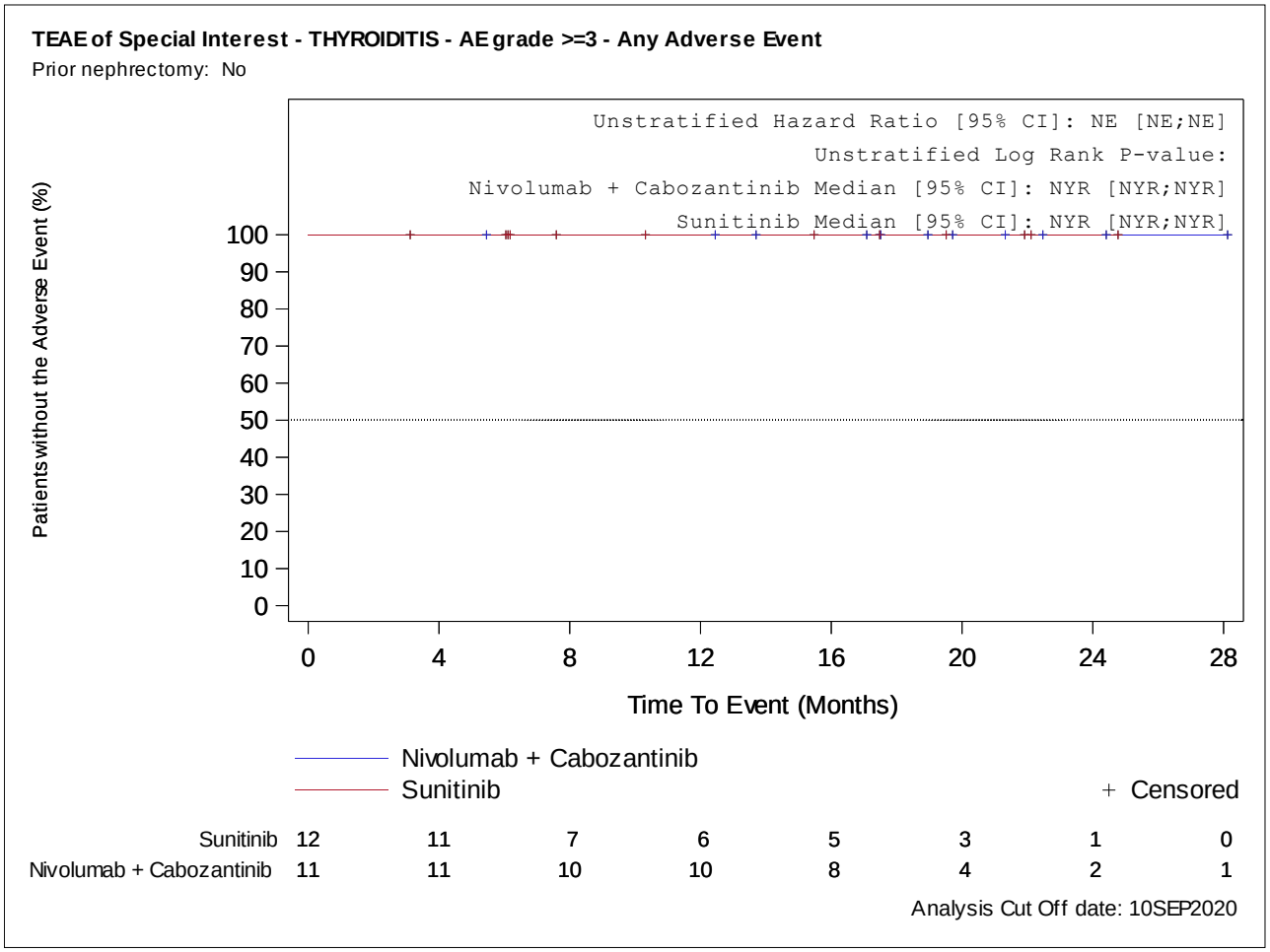

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:25:34

FIGURE 3.109.2.16: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



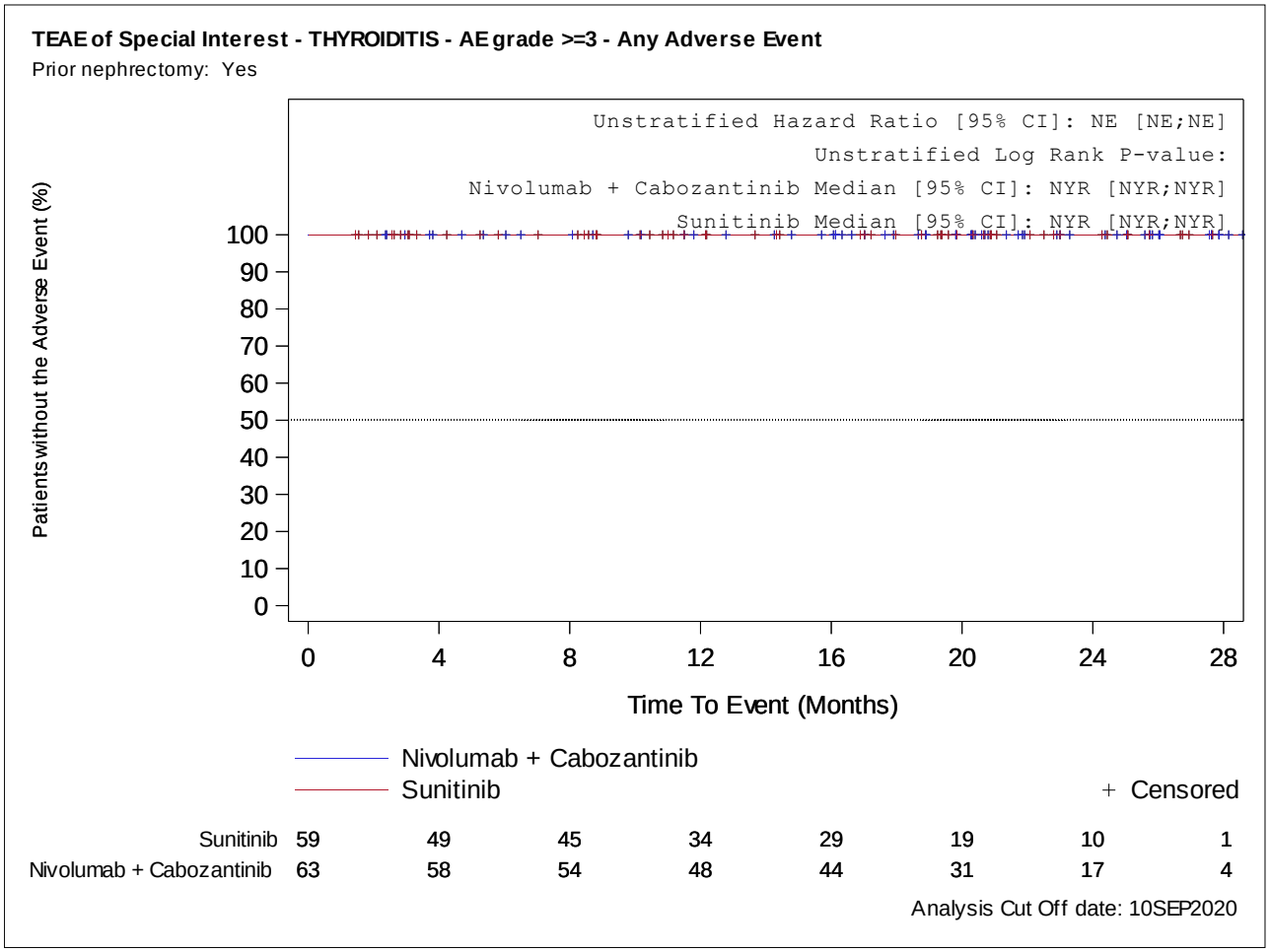

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:25:39

FIGURE 3.109.2.17: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



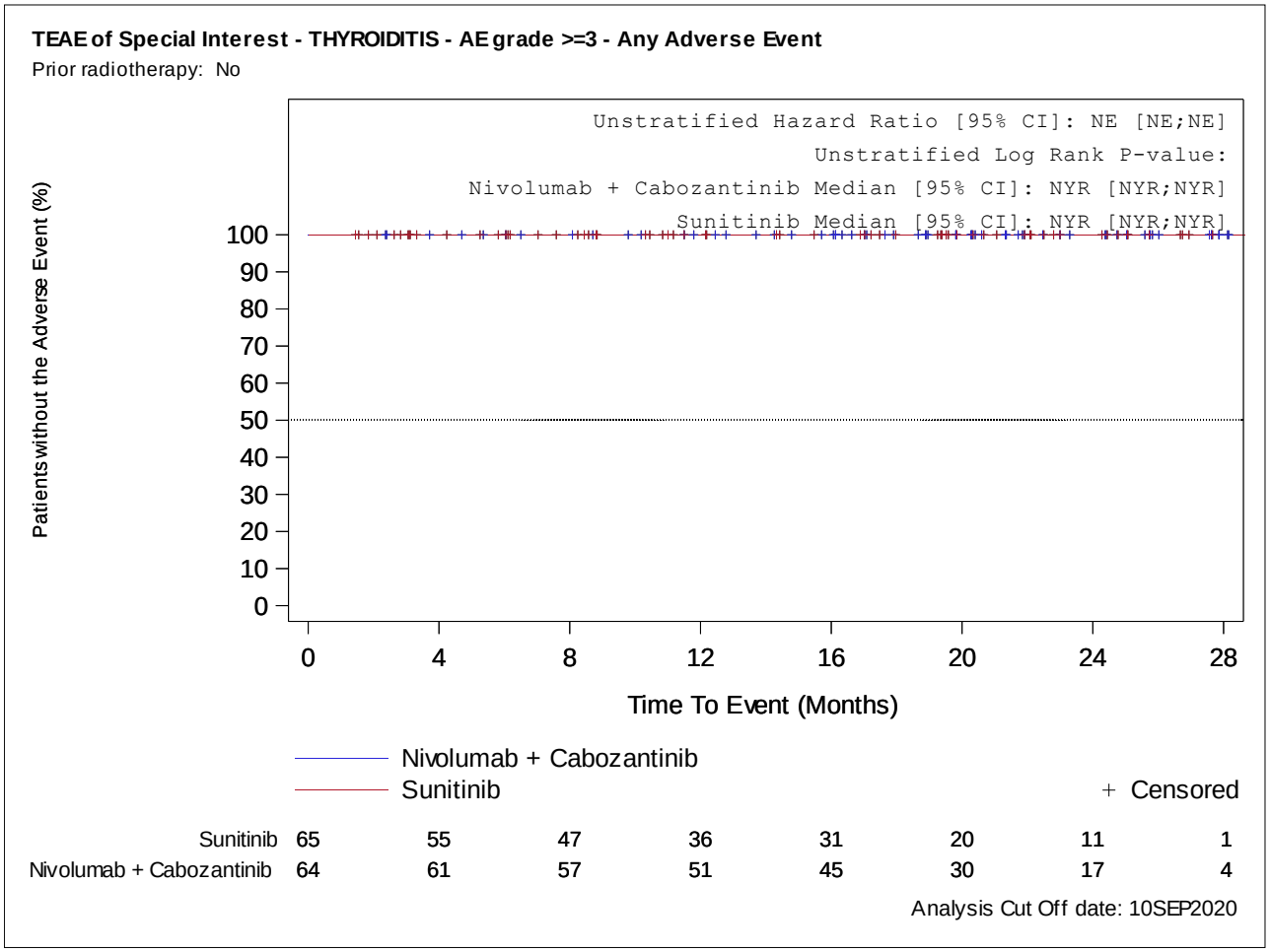

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:26:24

FIGURE 3.109.2.18: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



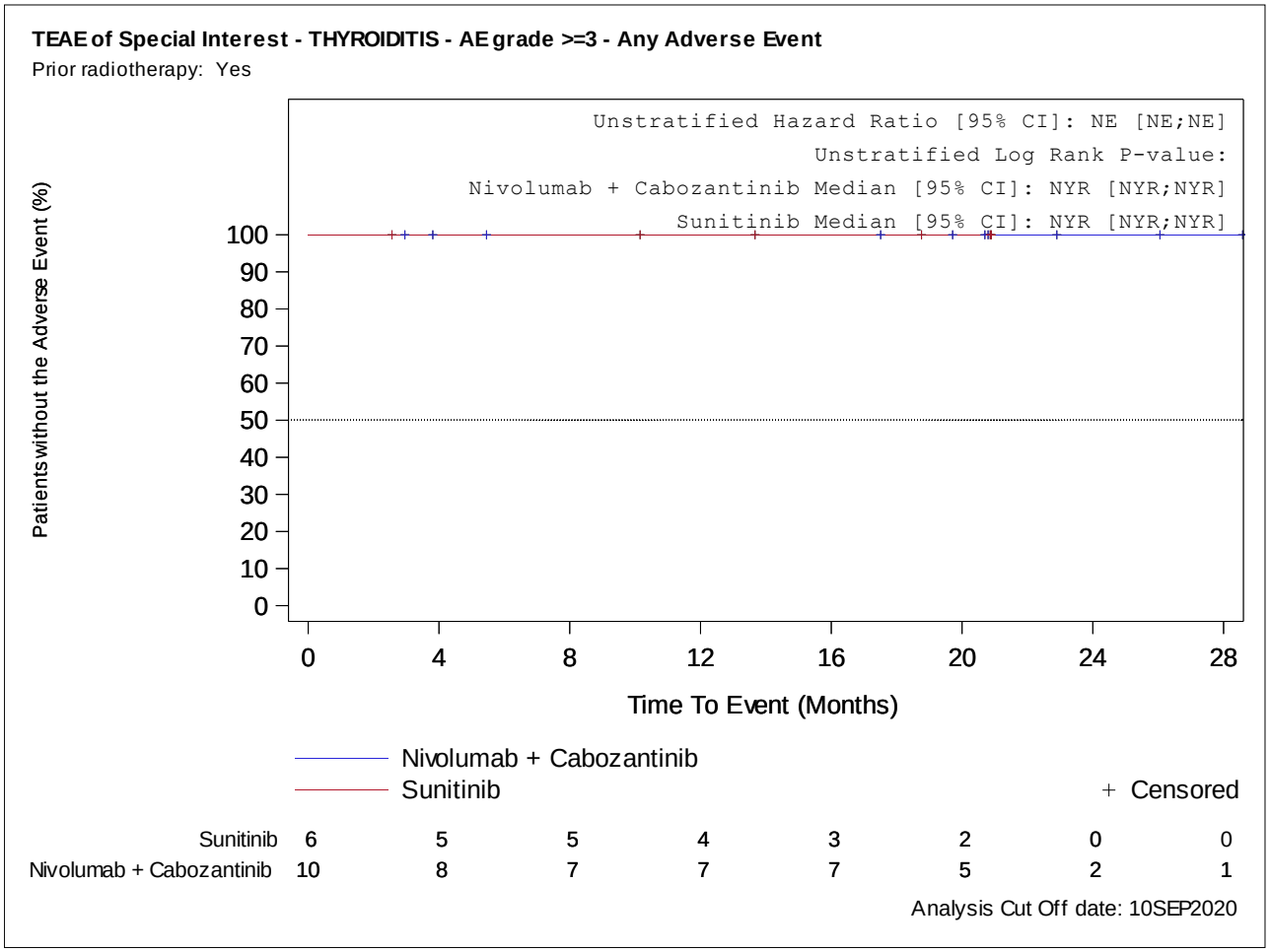

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:26:30

FIGURE 3.109.2.19: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



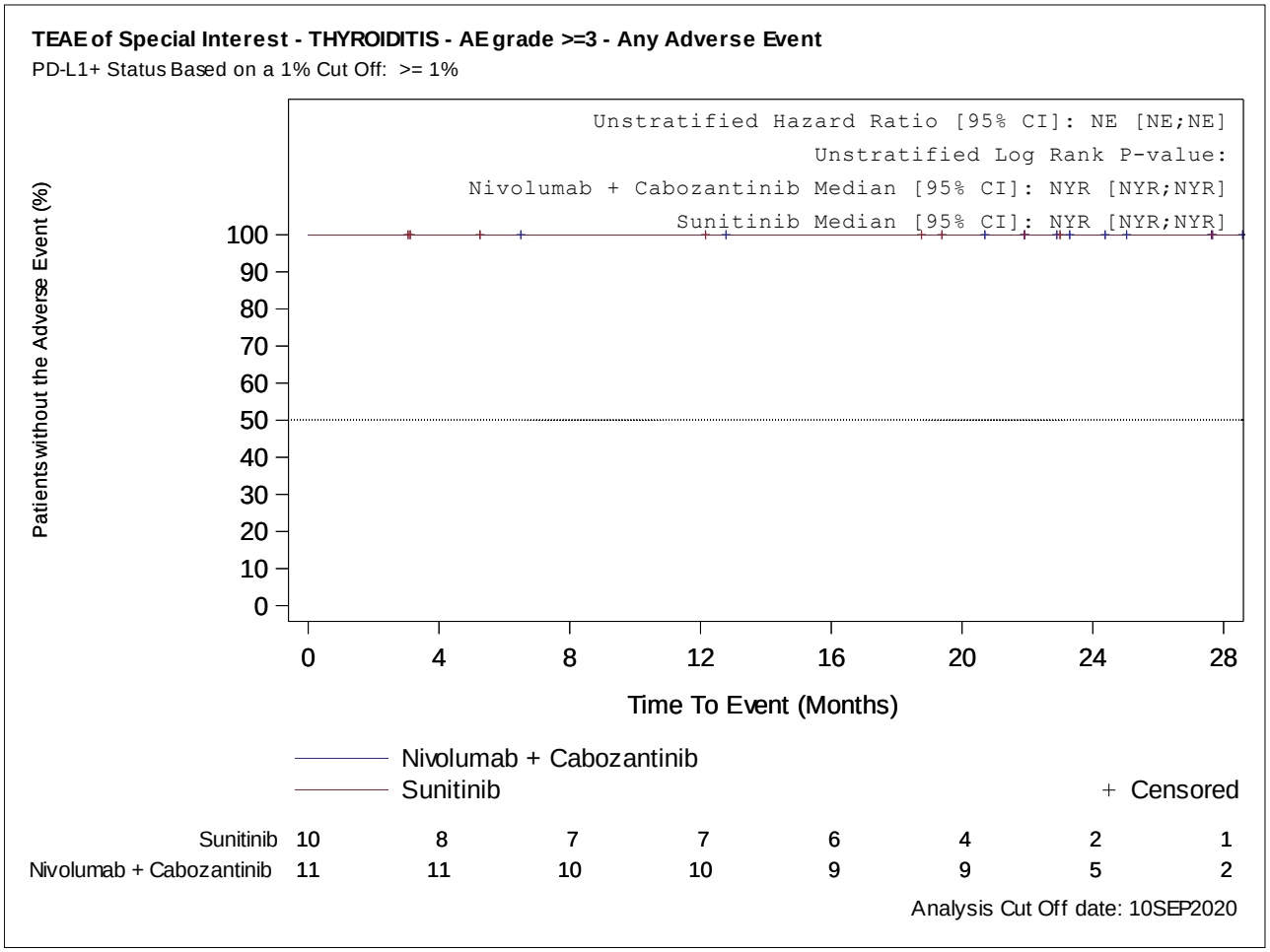

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:26:35

FIGURE 3.109.2.20: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



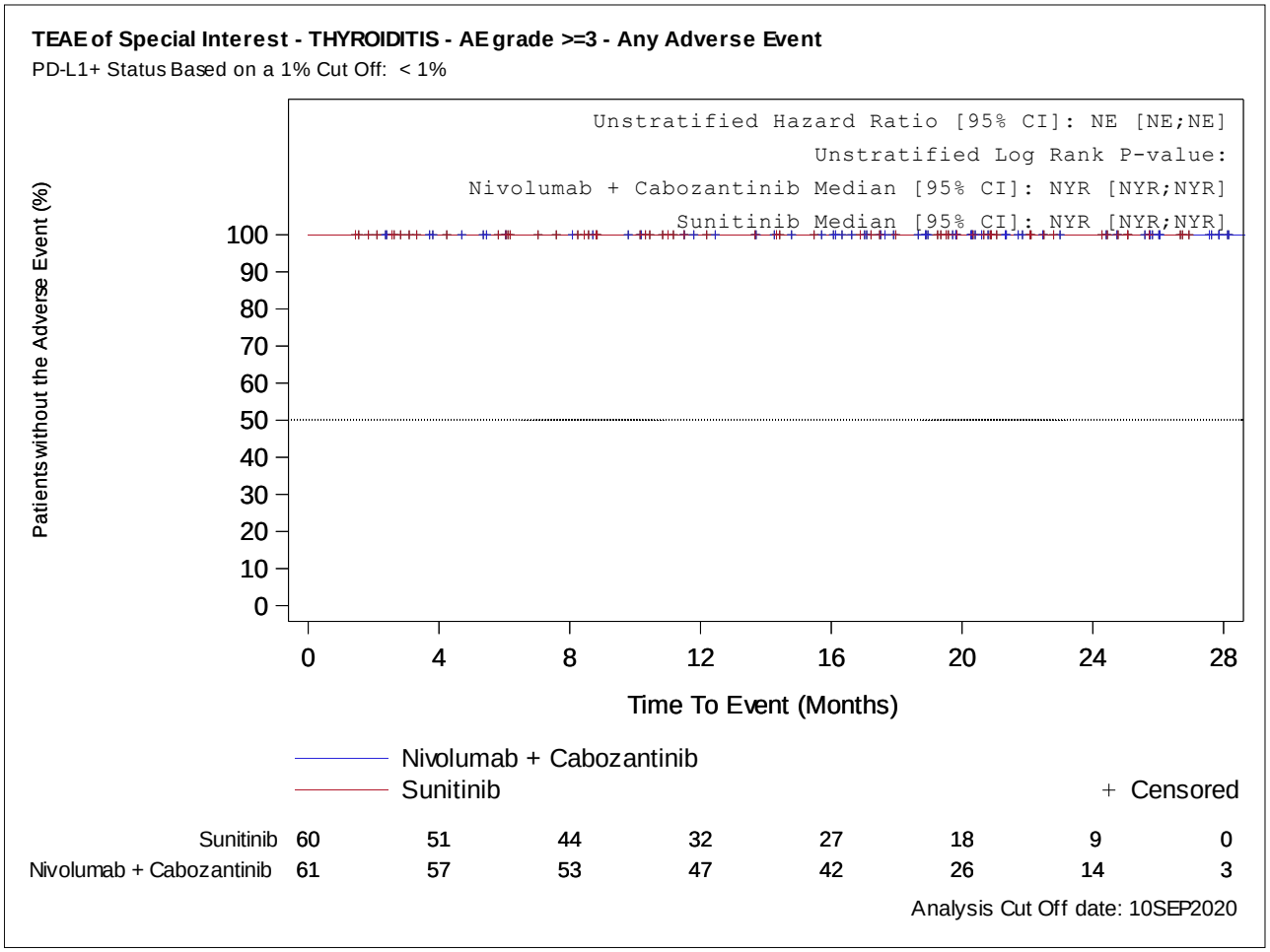

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:26:40

FIGURE 3.109.2.21: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off:  >= 1%



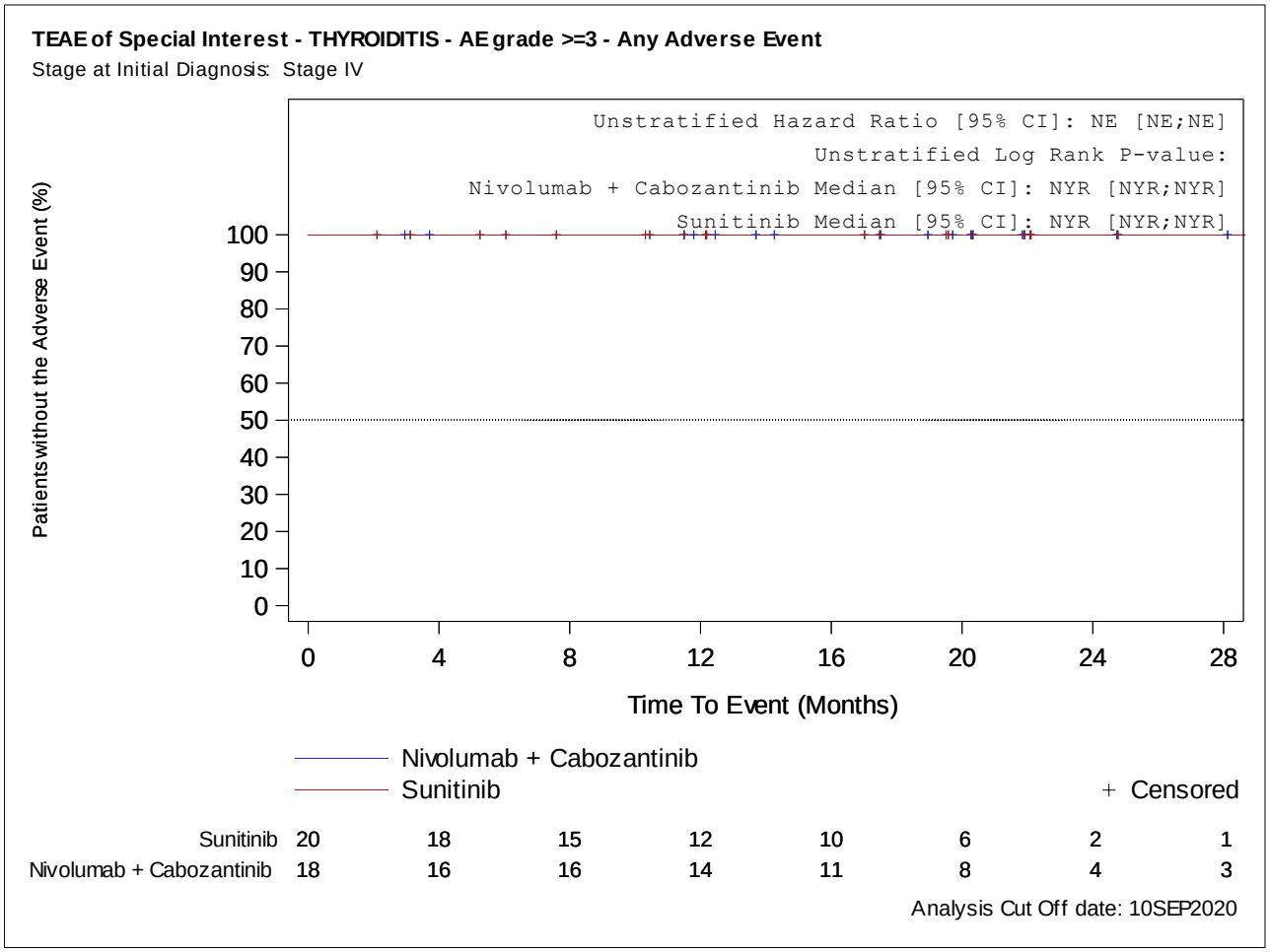

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:26:46

FIGURE 3.109.2.22: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



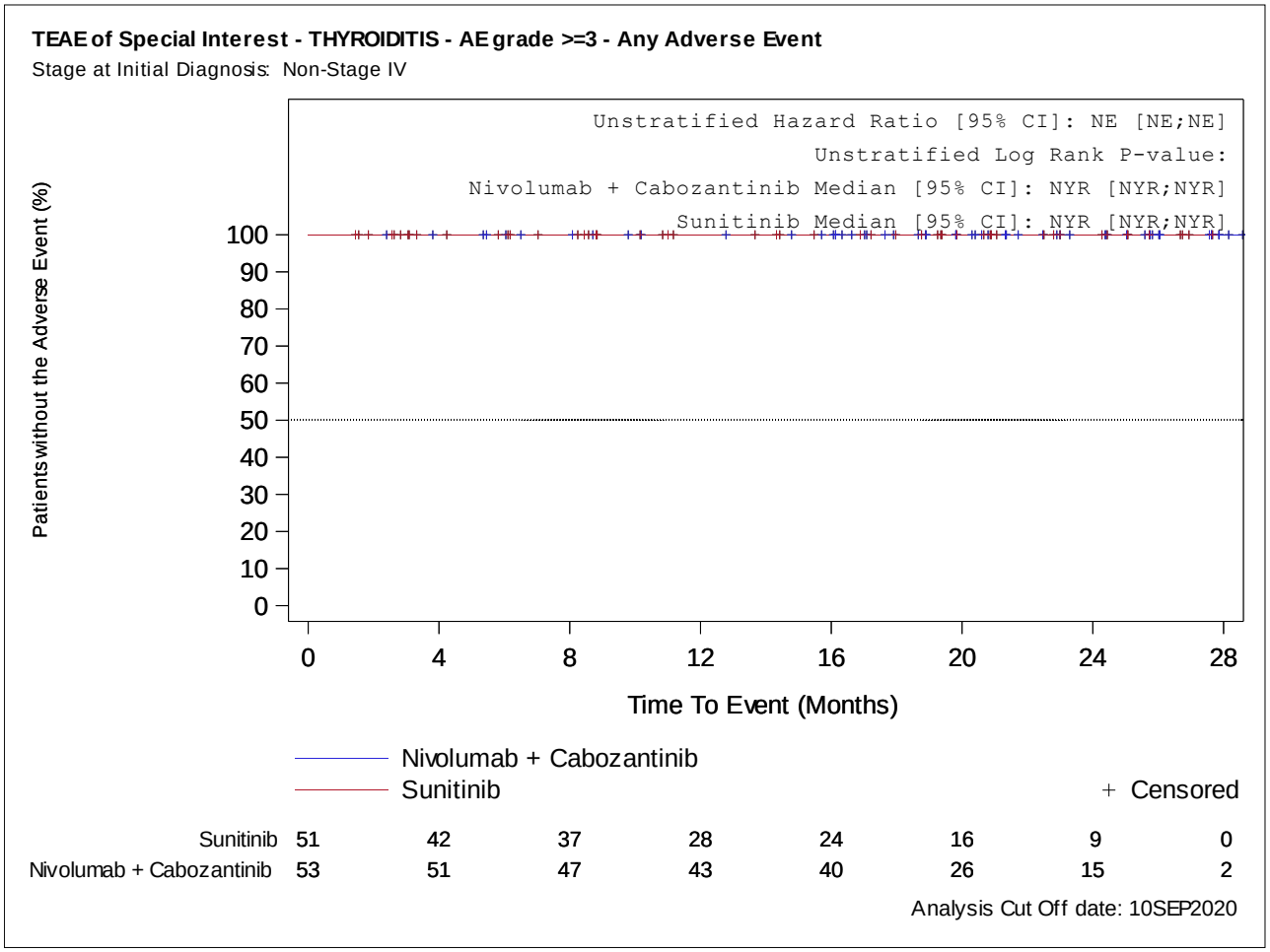

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:26:51

FIGURE 3.109.2.23: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



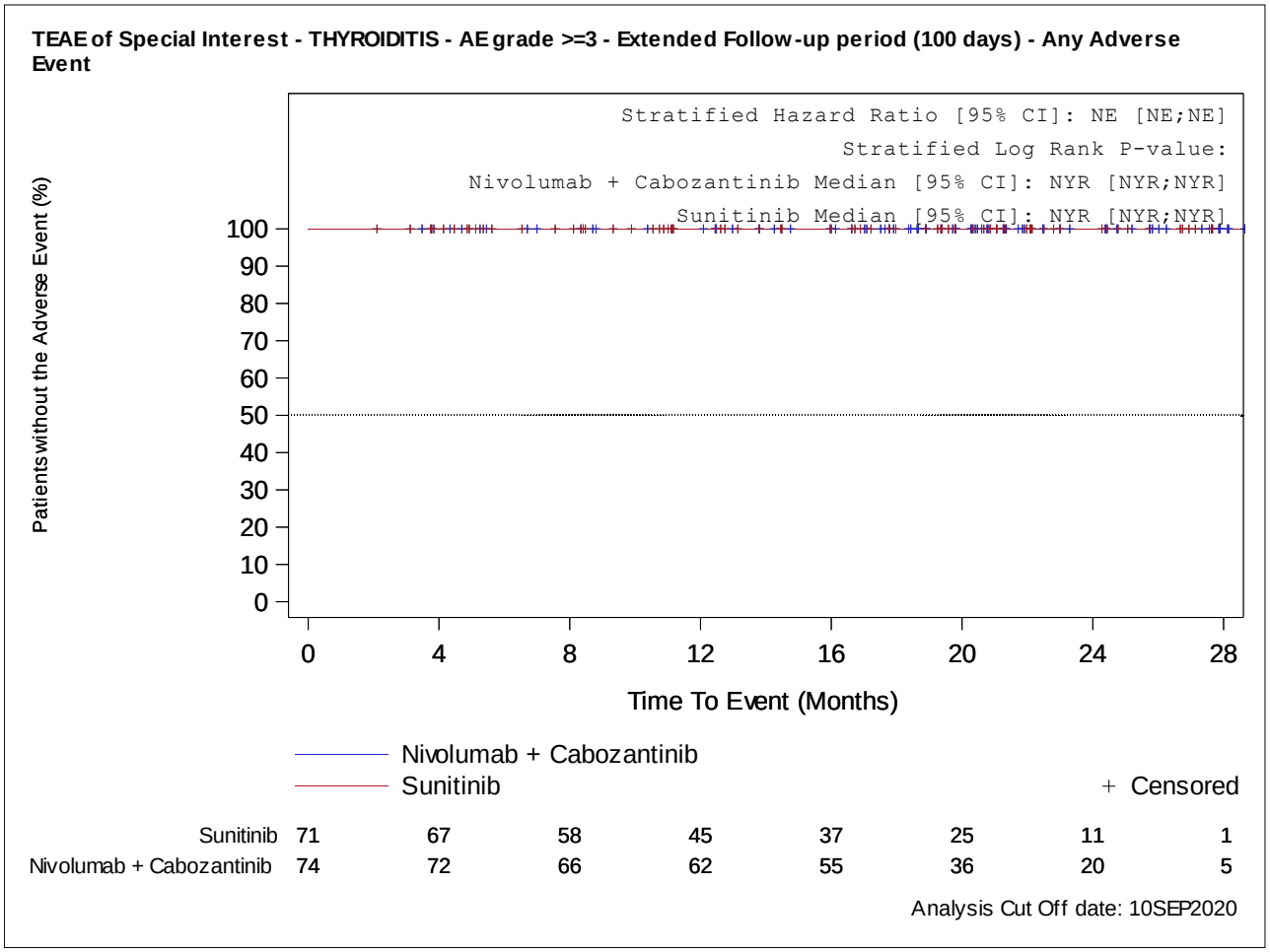

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:27:17

FIGURE 3.109.2.24: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



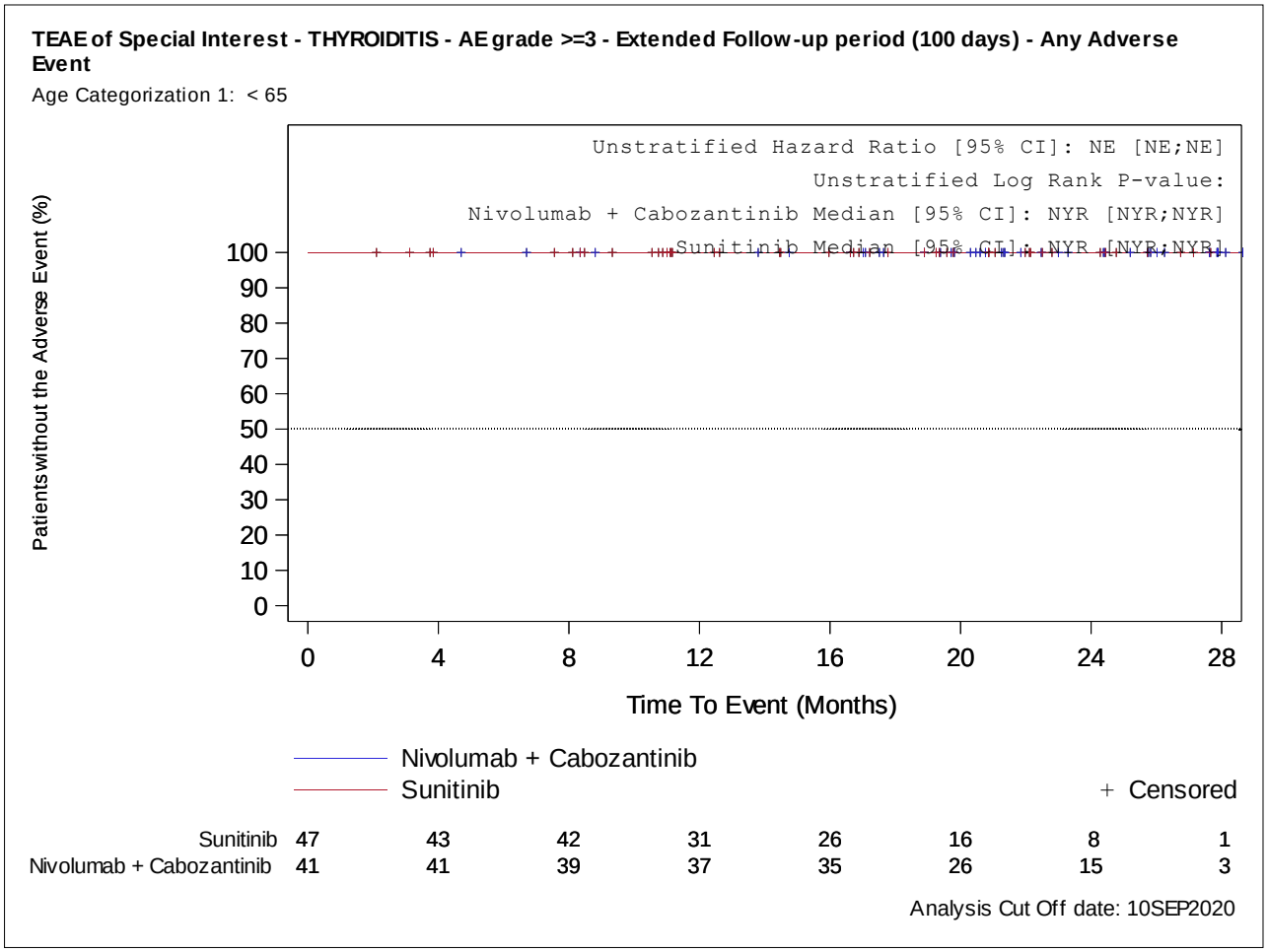

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:27:22

FIGURE 3.110.1: TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



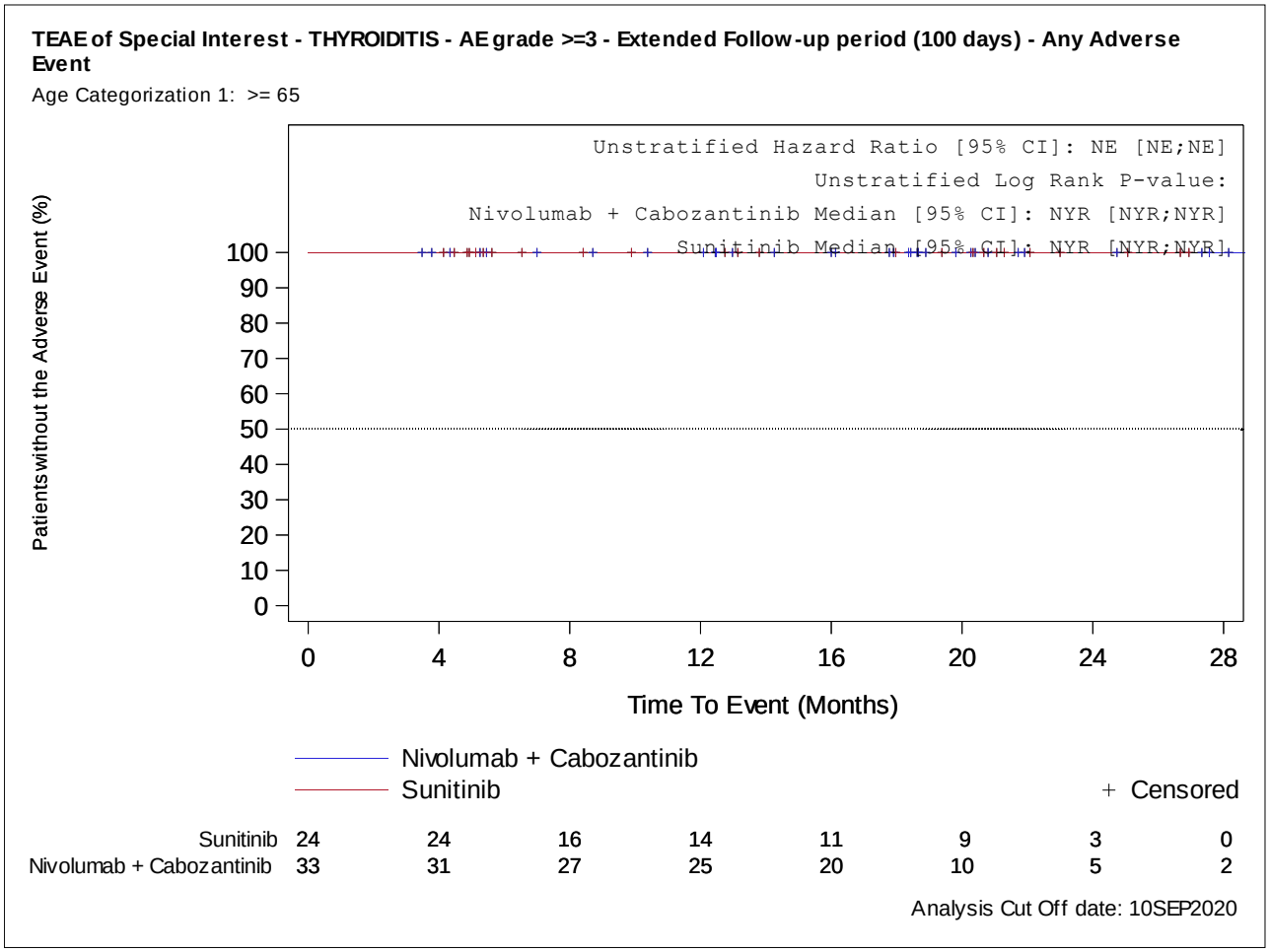

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:30:18

FIGURE 3.110.2.1: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



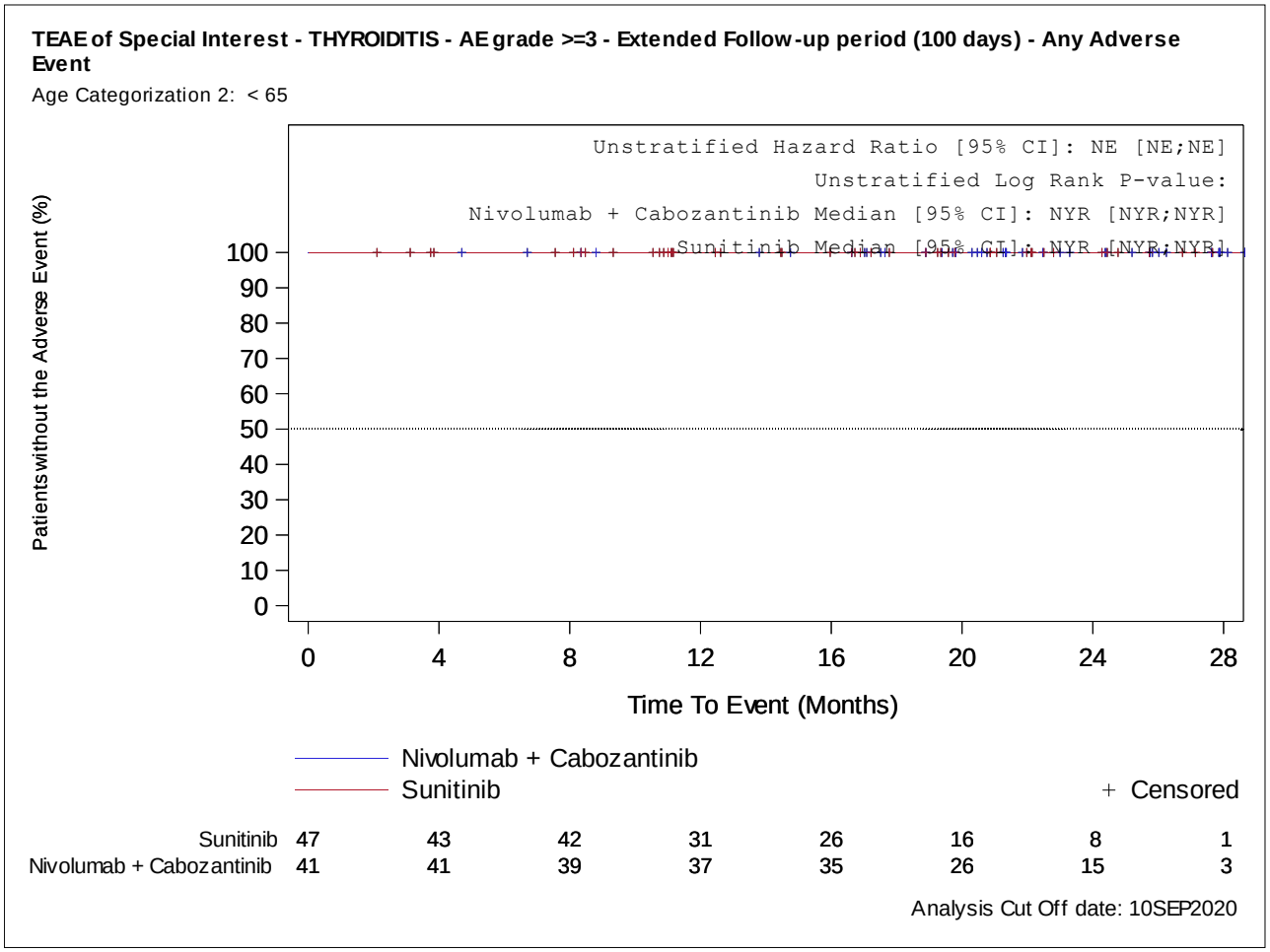

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:30:20

FIGURE 3.110.2.2: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



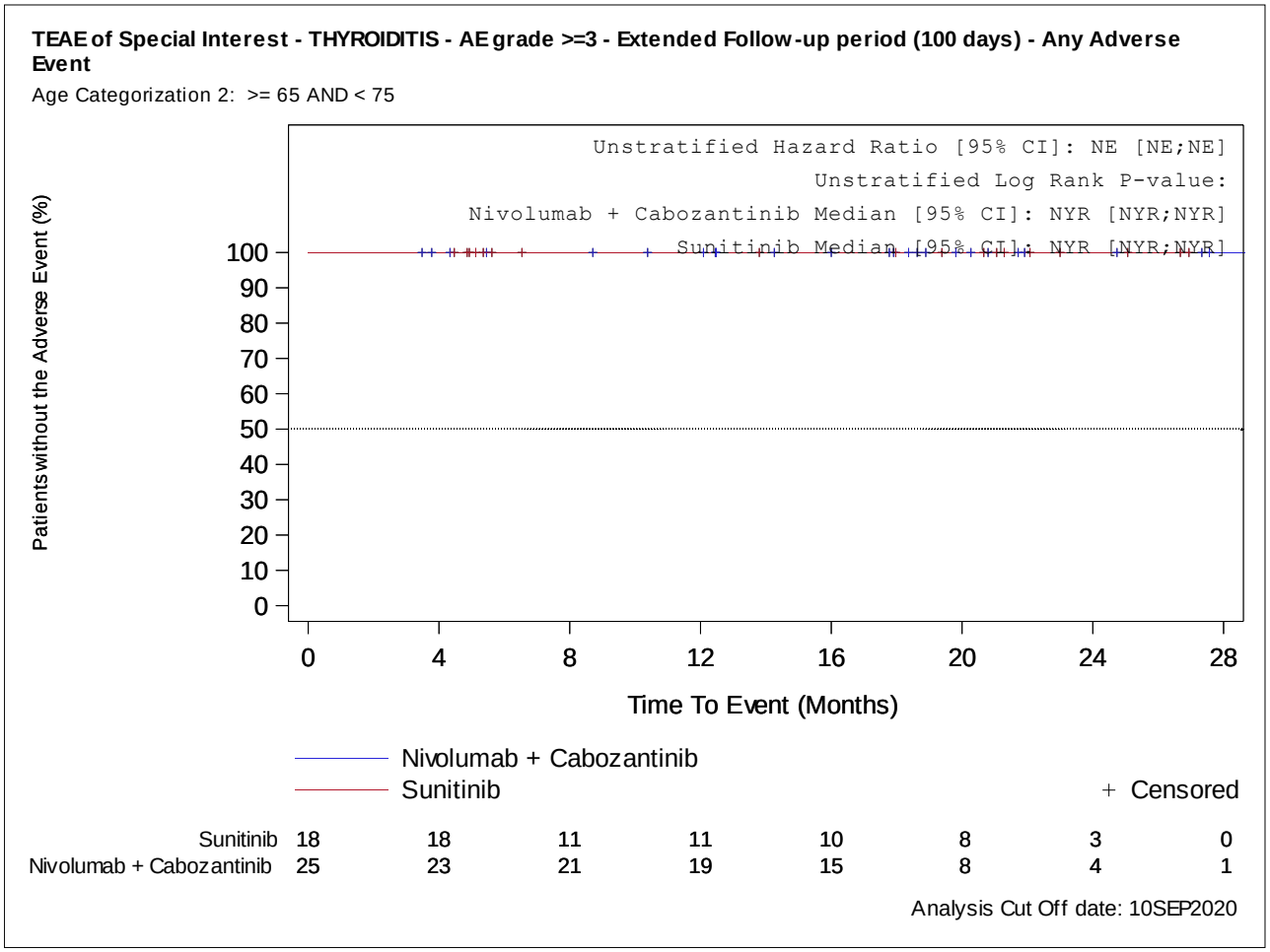

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:30:26

FIGURE 3.110.2.3: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  < 65



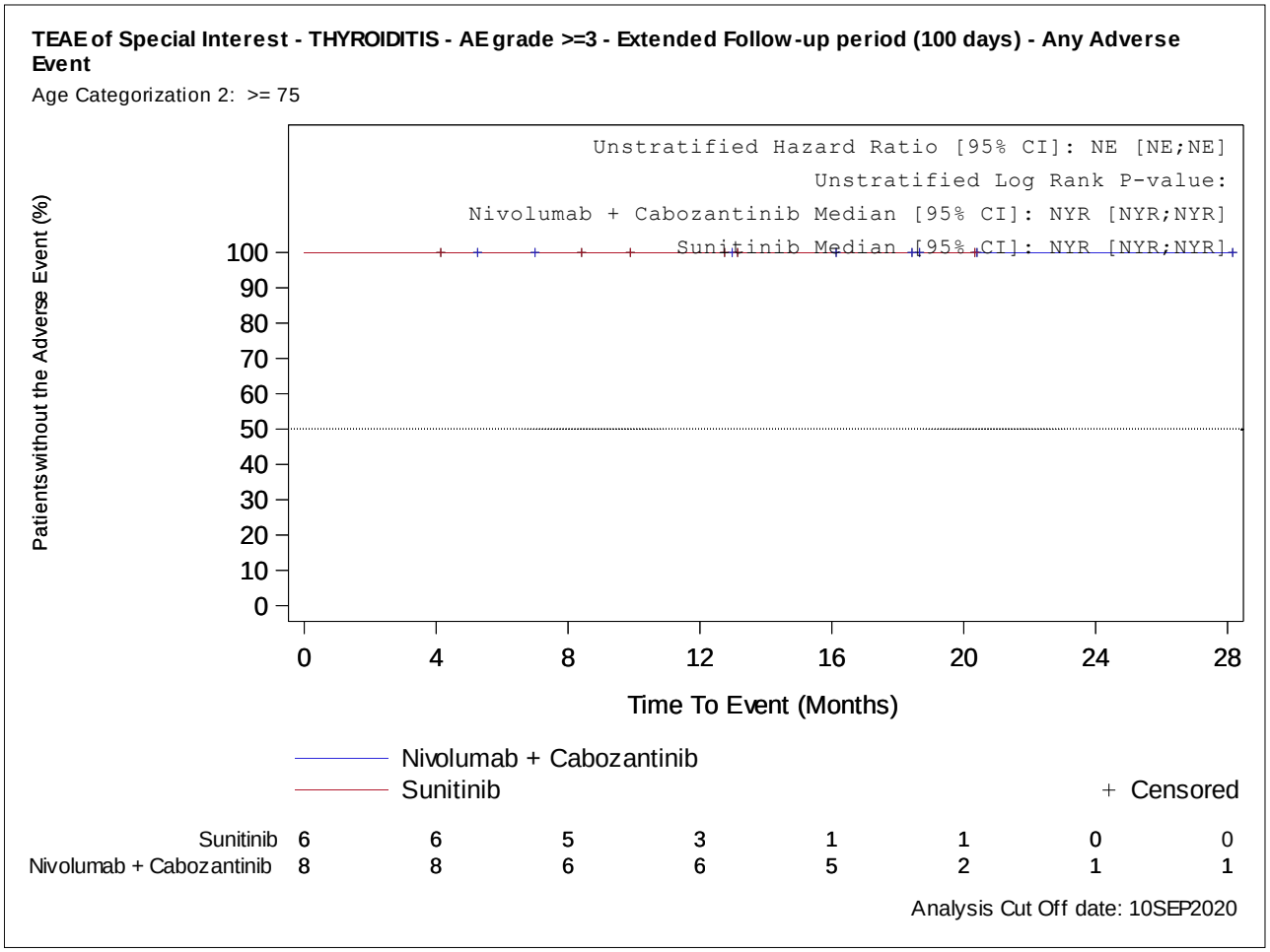

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:30:31

FIGURE 3.110.2.4: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



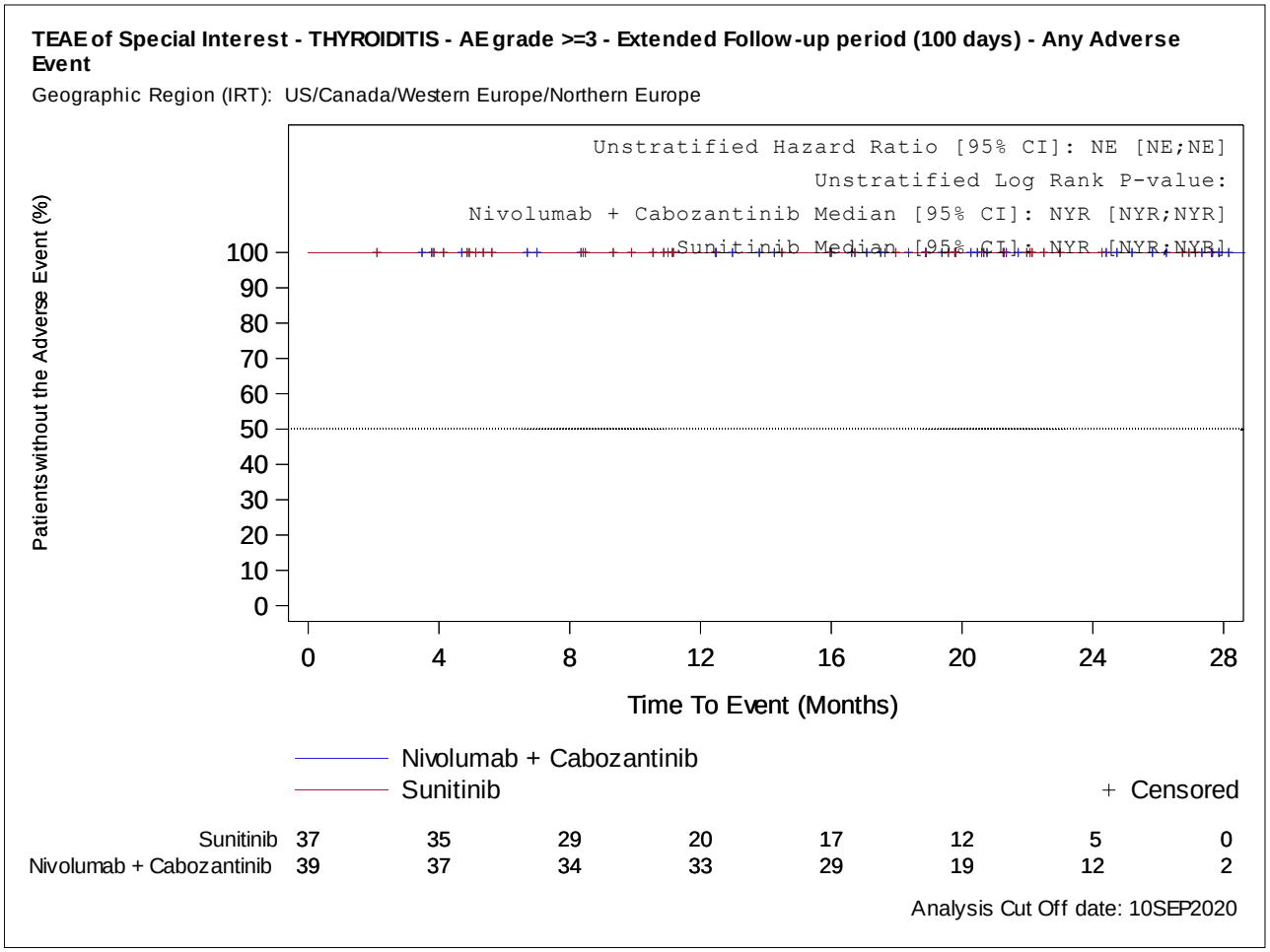

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:30:36

FIGURE 3.110.2.5: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



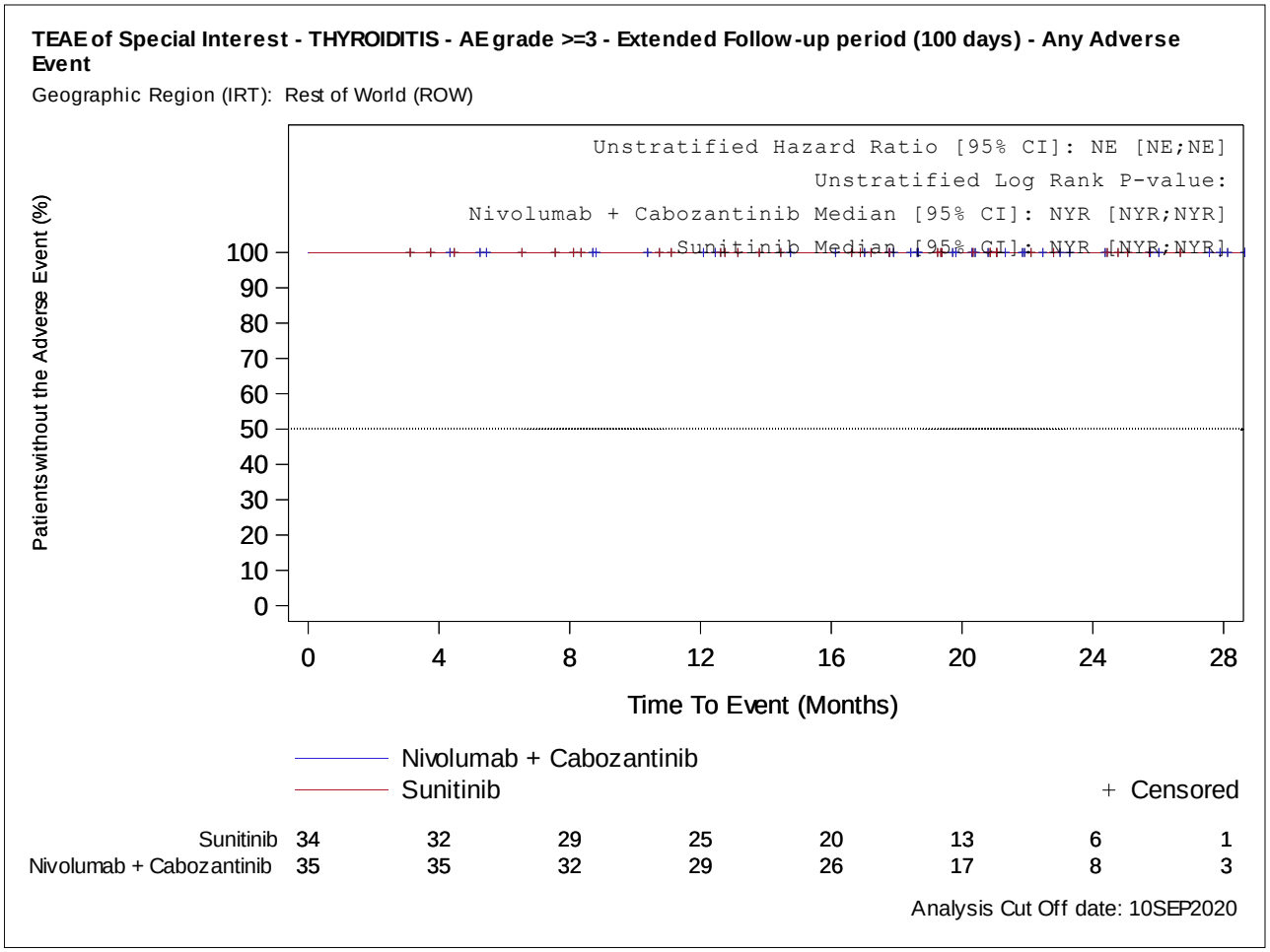

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:30:41

FIGURE 3.110.2.6: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



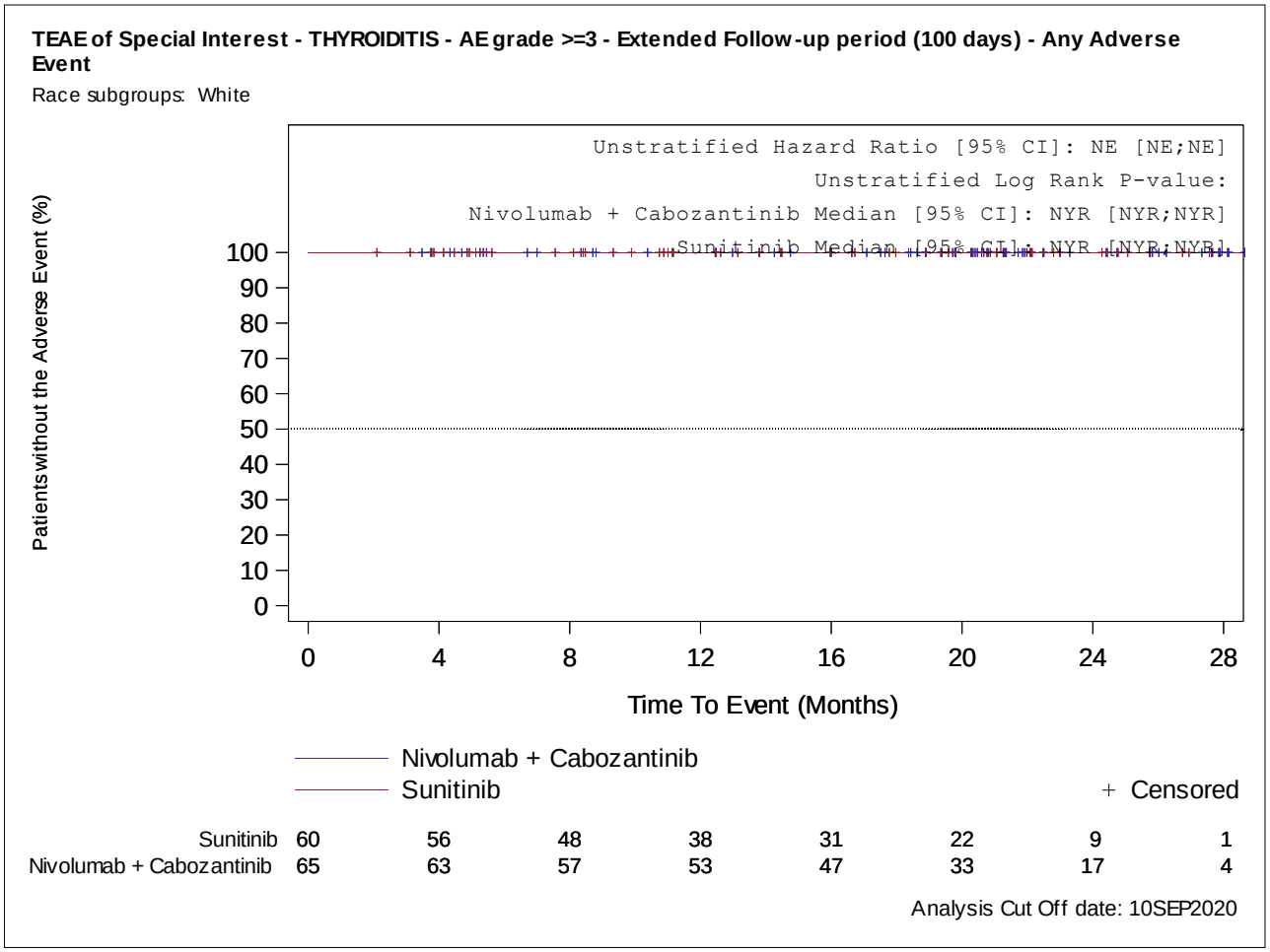

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:30:46

FIGURE 3.110.2.7: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



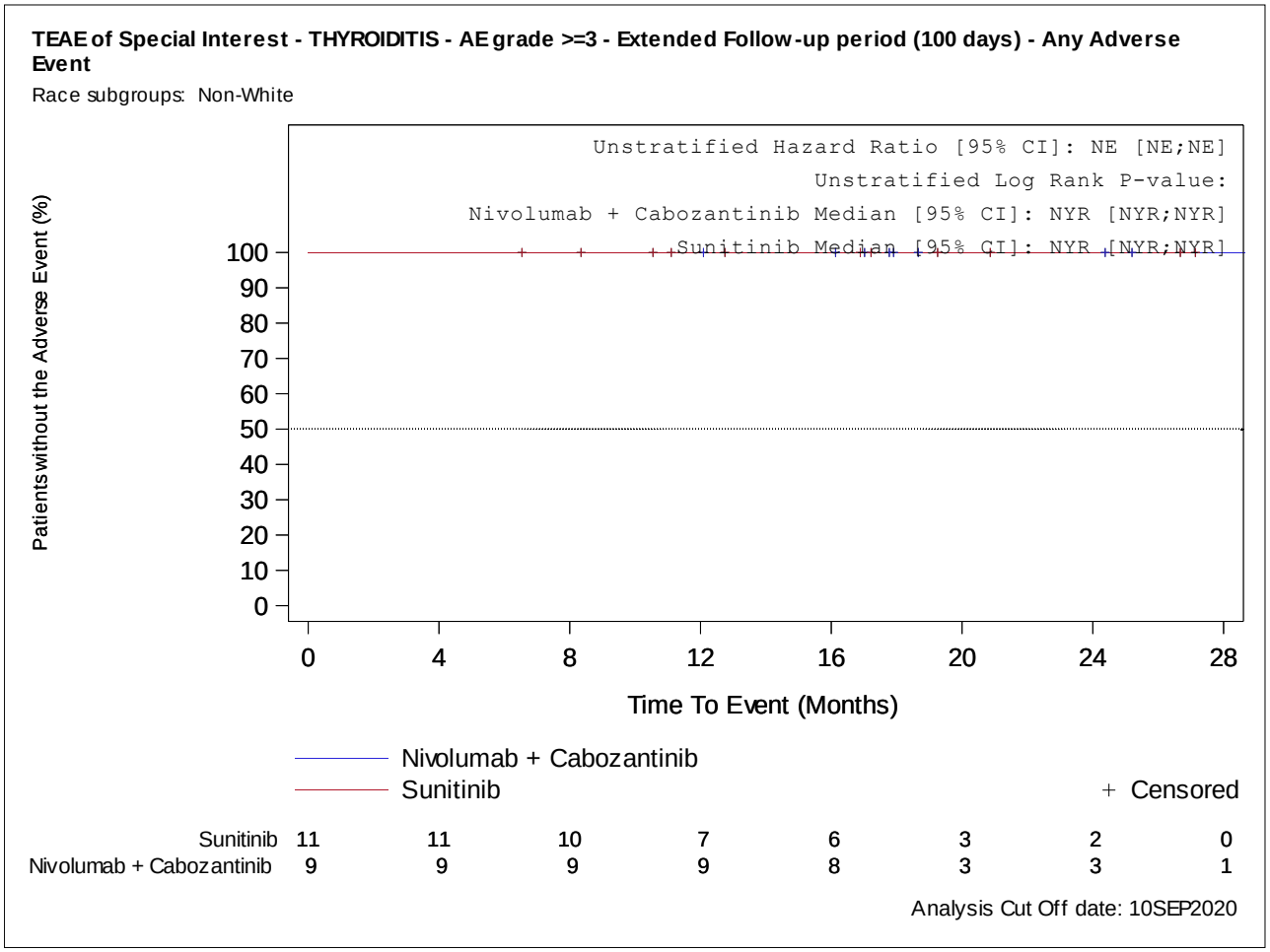

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:30:52

FIGURE 3.110.2.8: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



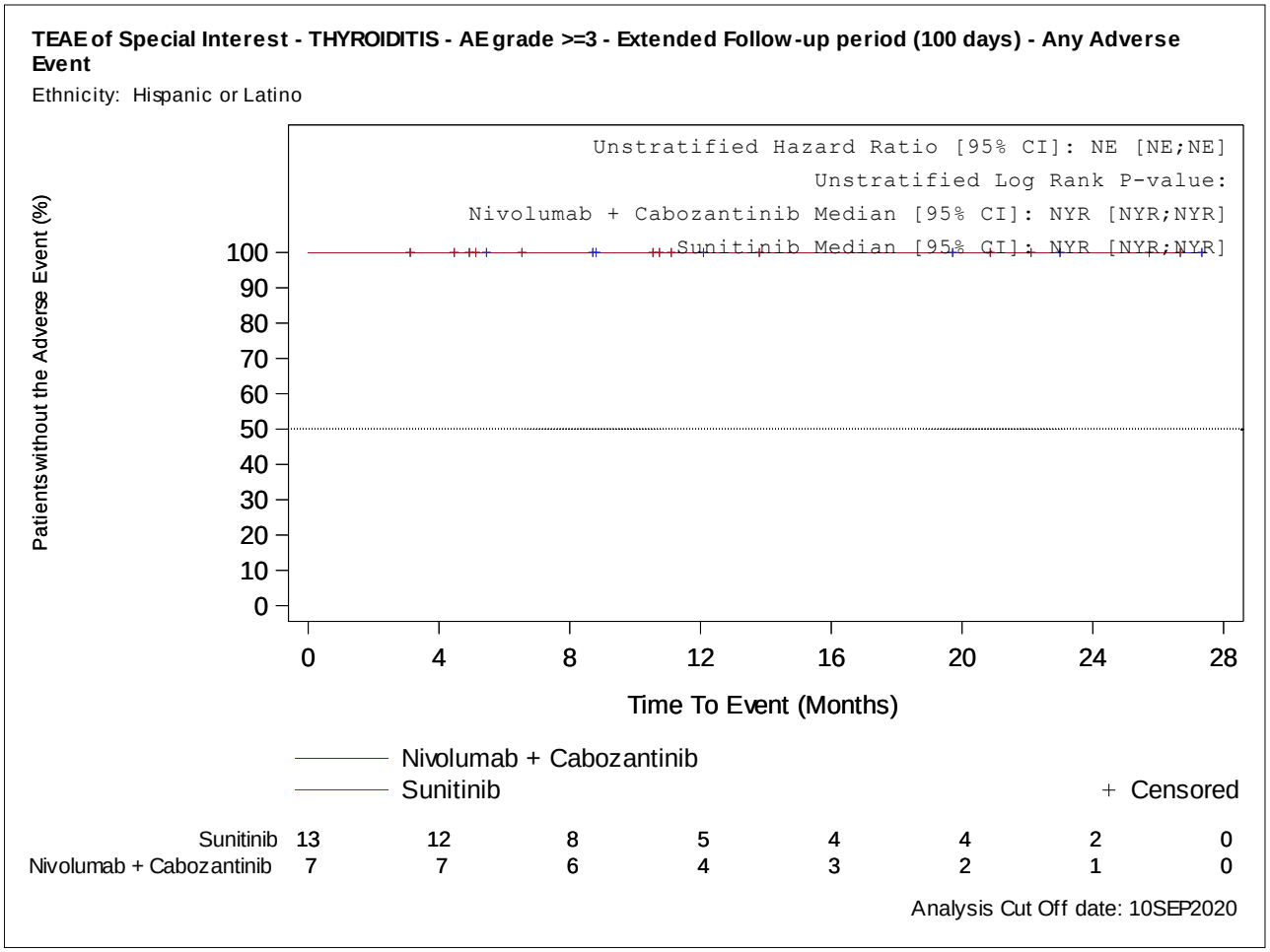

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:30:57

FIGURE 3.110.2.9: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



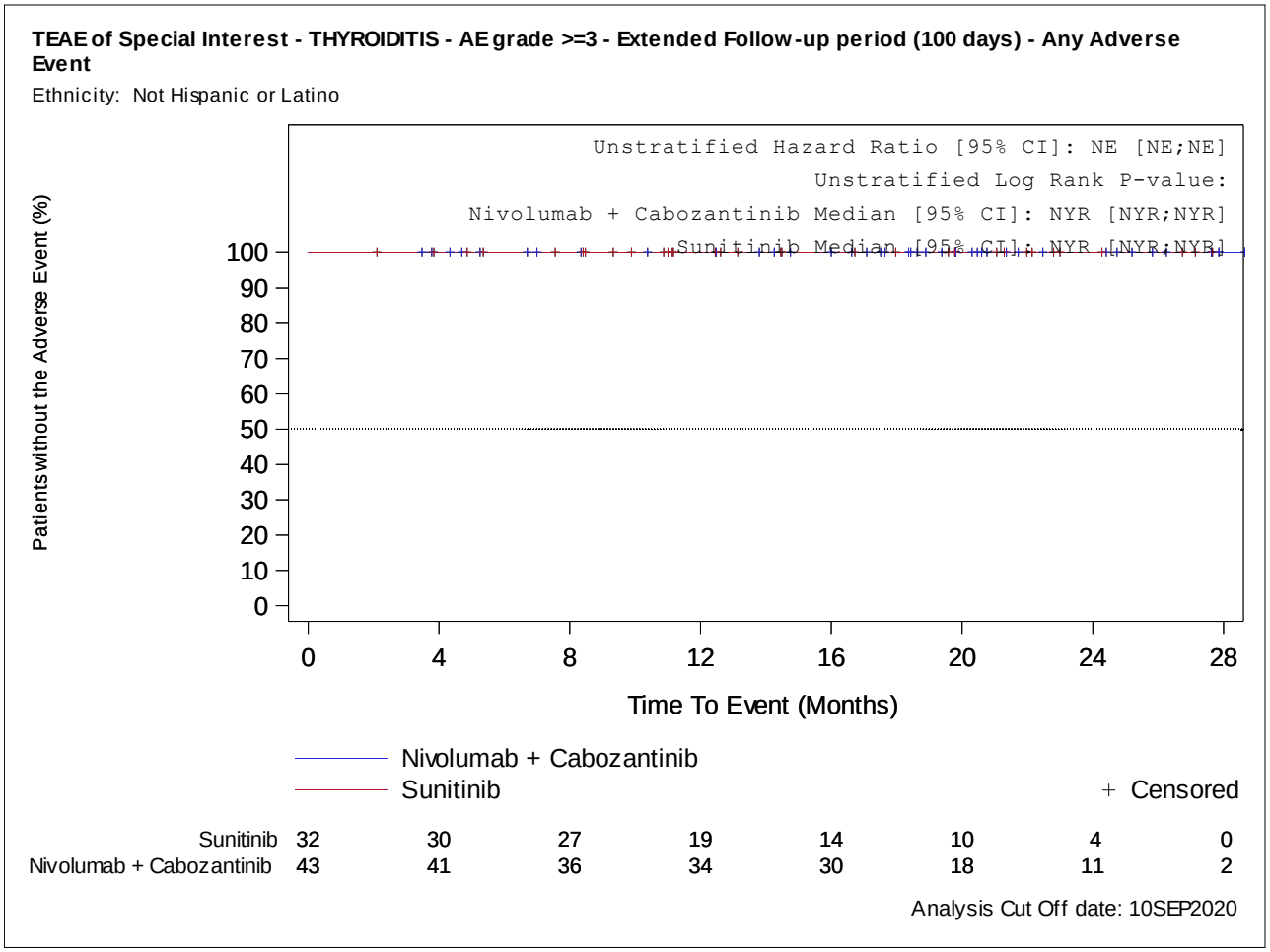

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:31:02

FIGURE 3.110.2.10: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



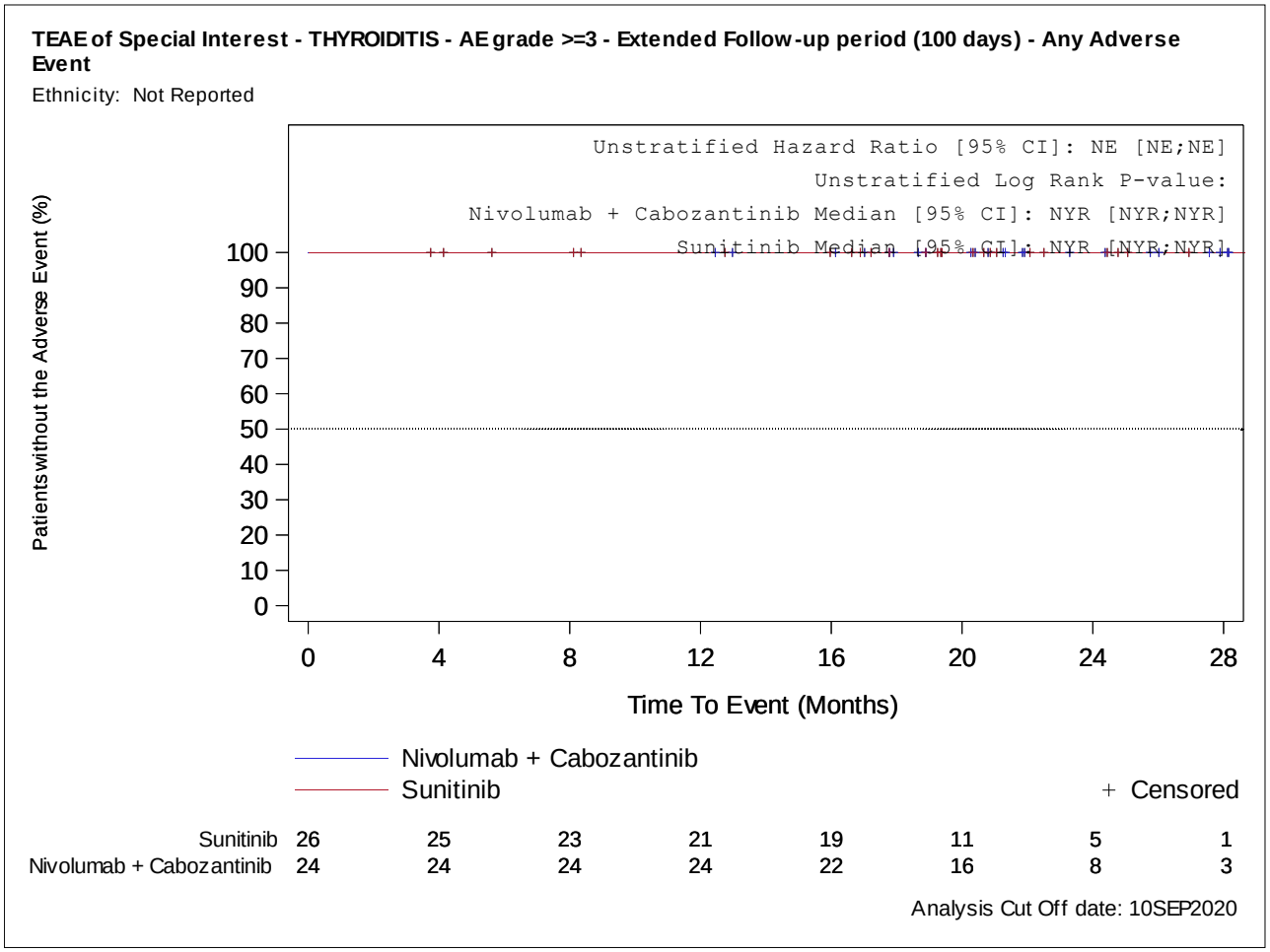

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:31:07

FIGURE 3.110.2.11: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



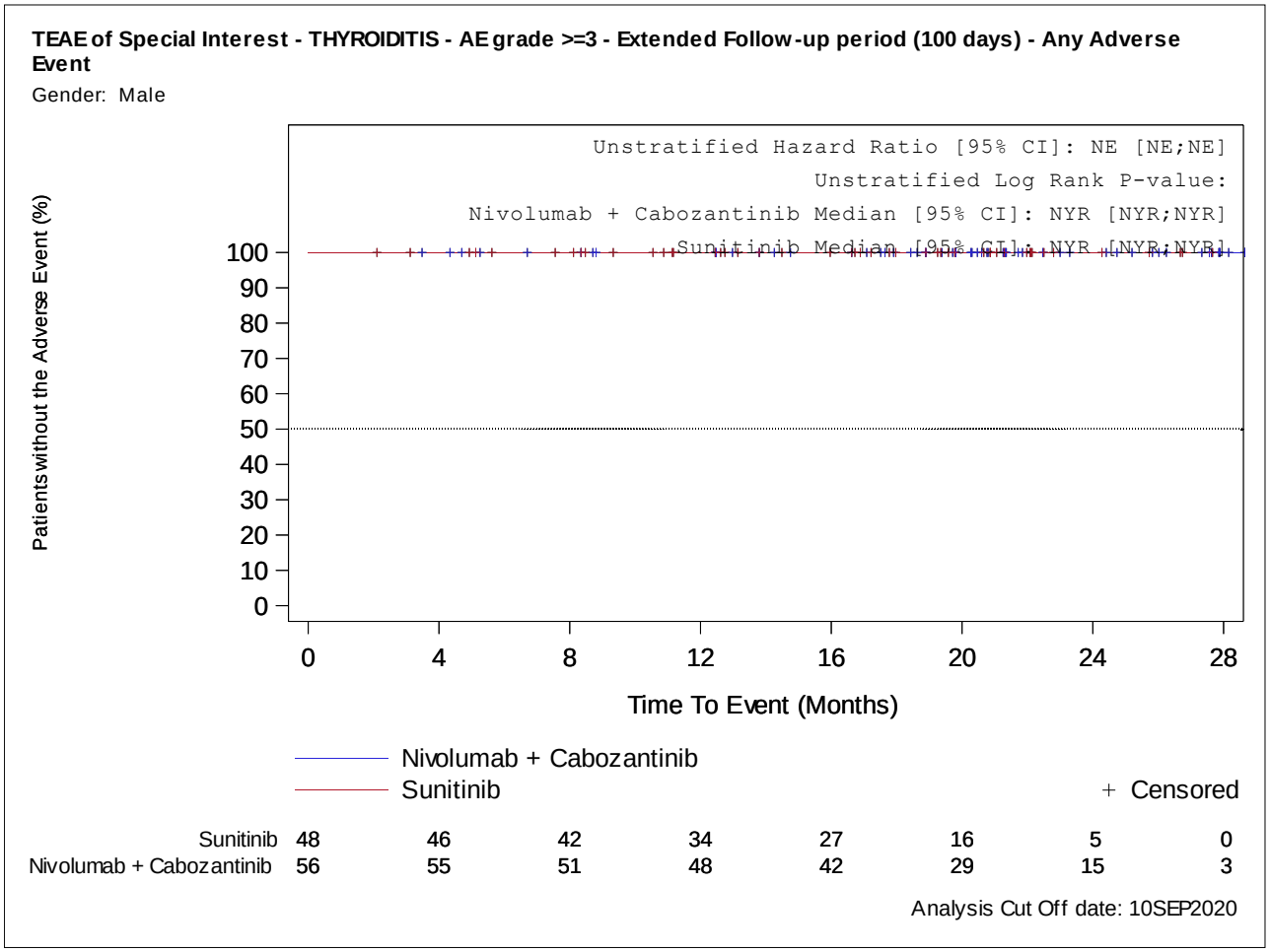

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:31:12

FIGURE 3.110.2.12: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



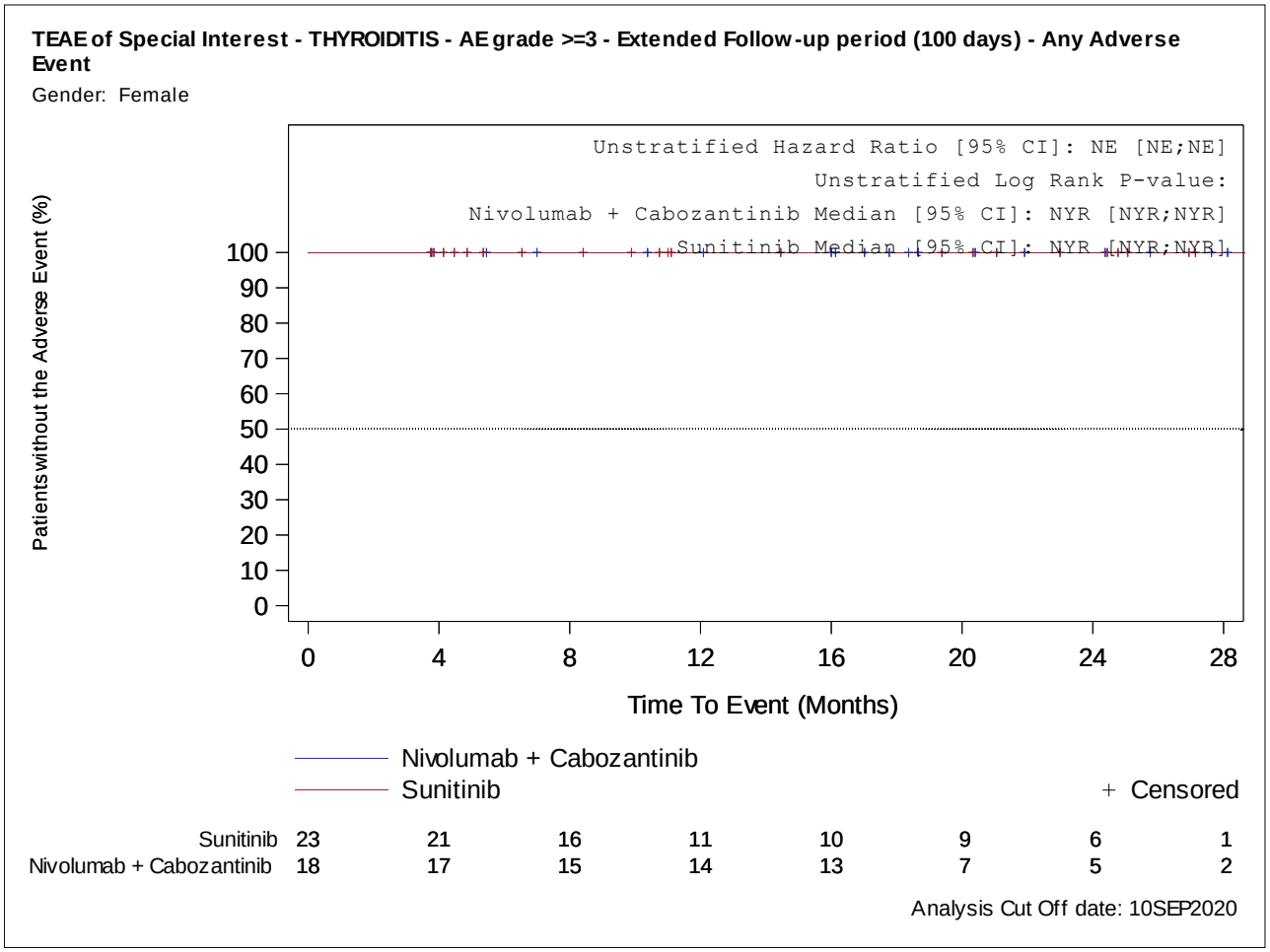

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:31:17

FIGURE 3.110.2.13: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



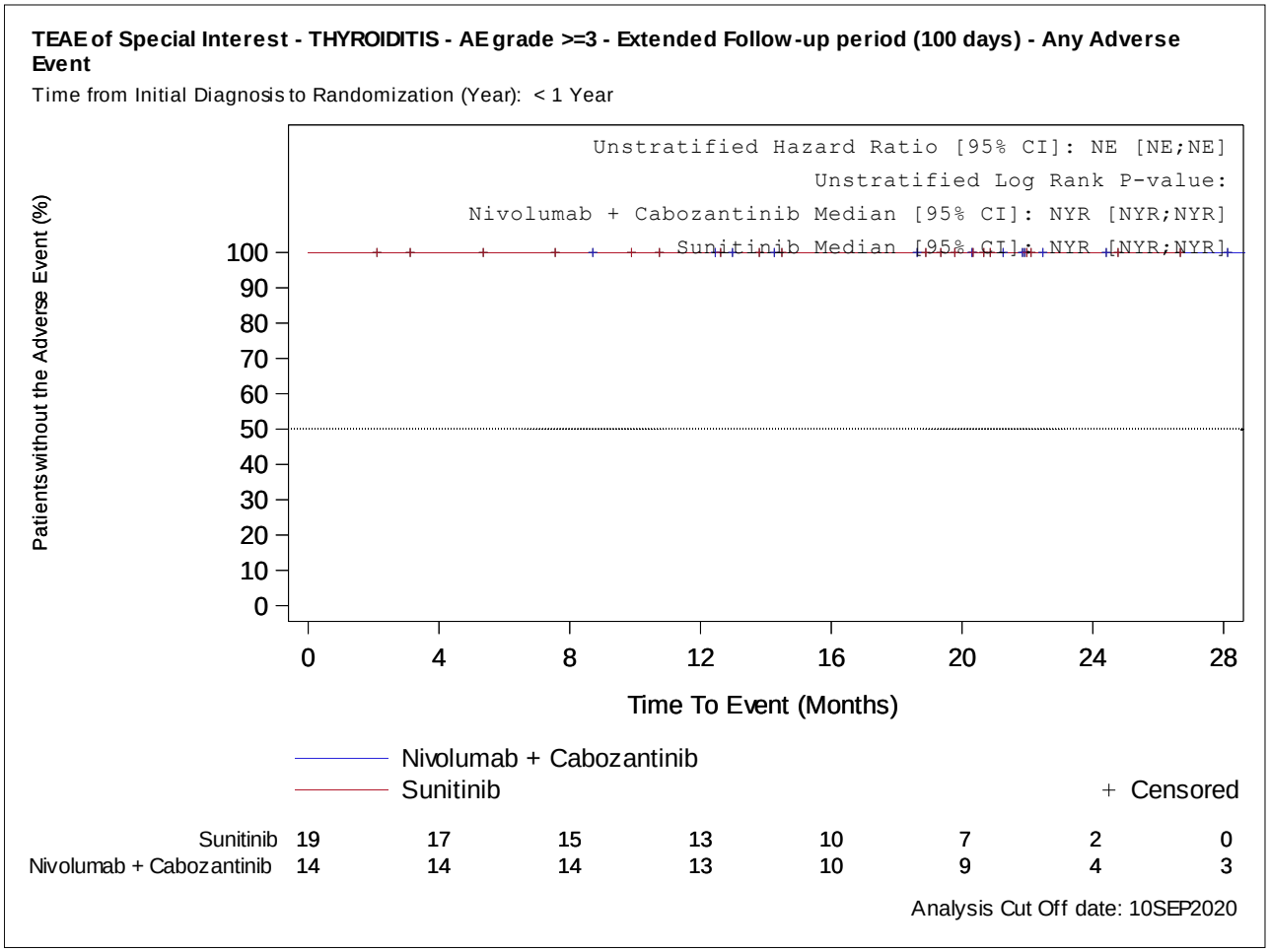

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:31:23

FIGURE 3.110.2.14: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



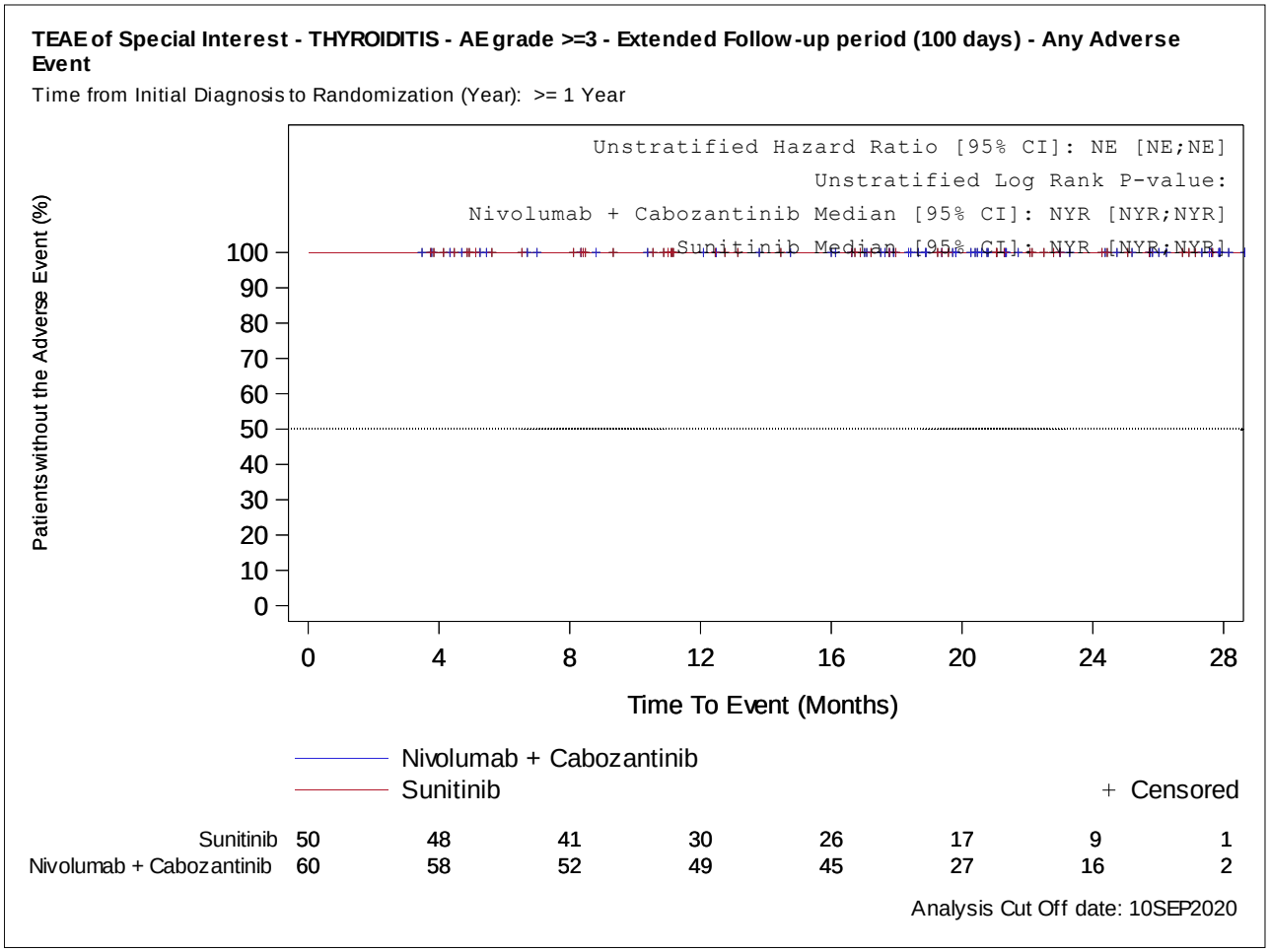

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:31:28

FIGURE 3.110.2.15: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:31:44

FIGURE 3.110.2.16: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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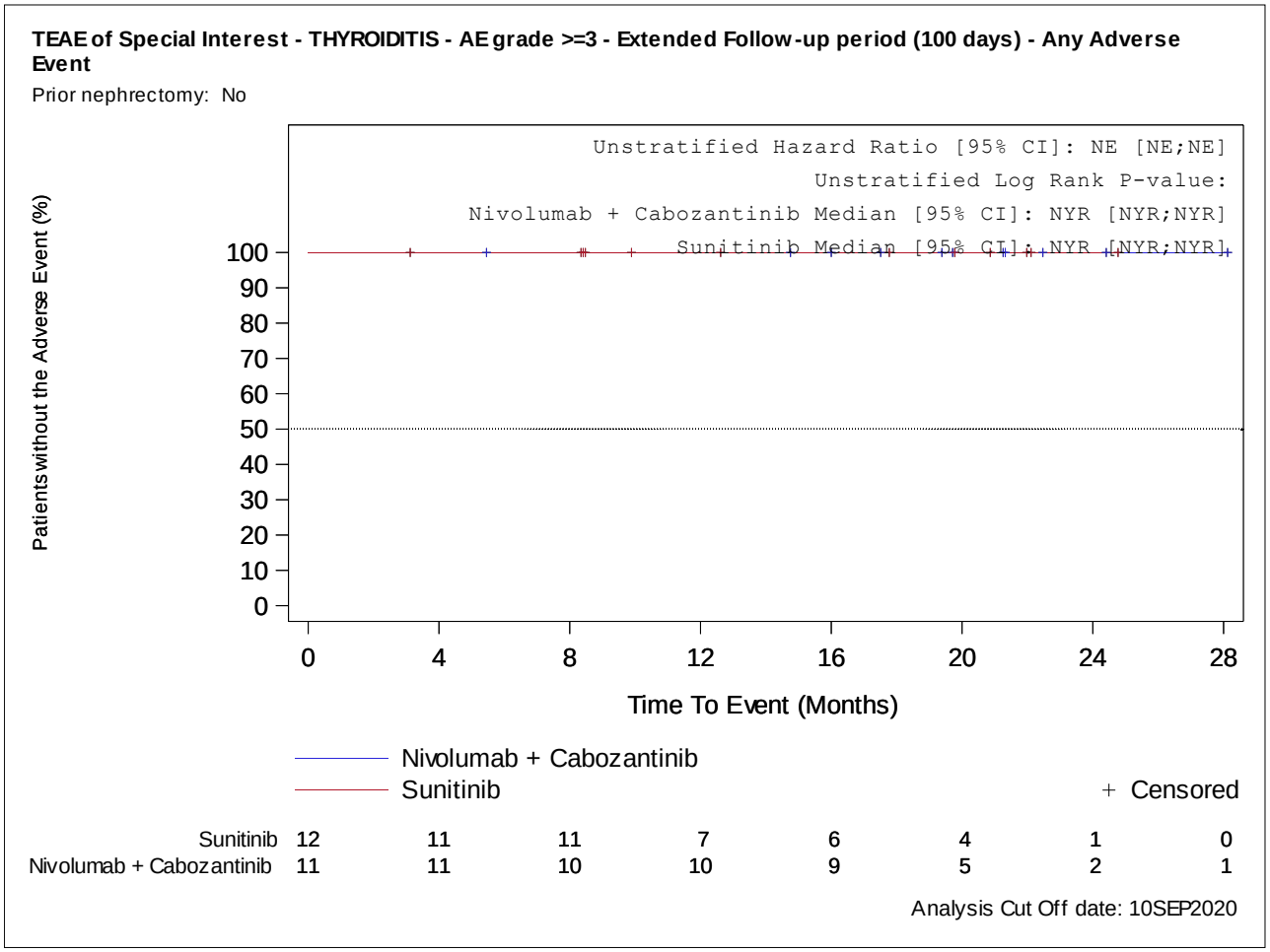
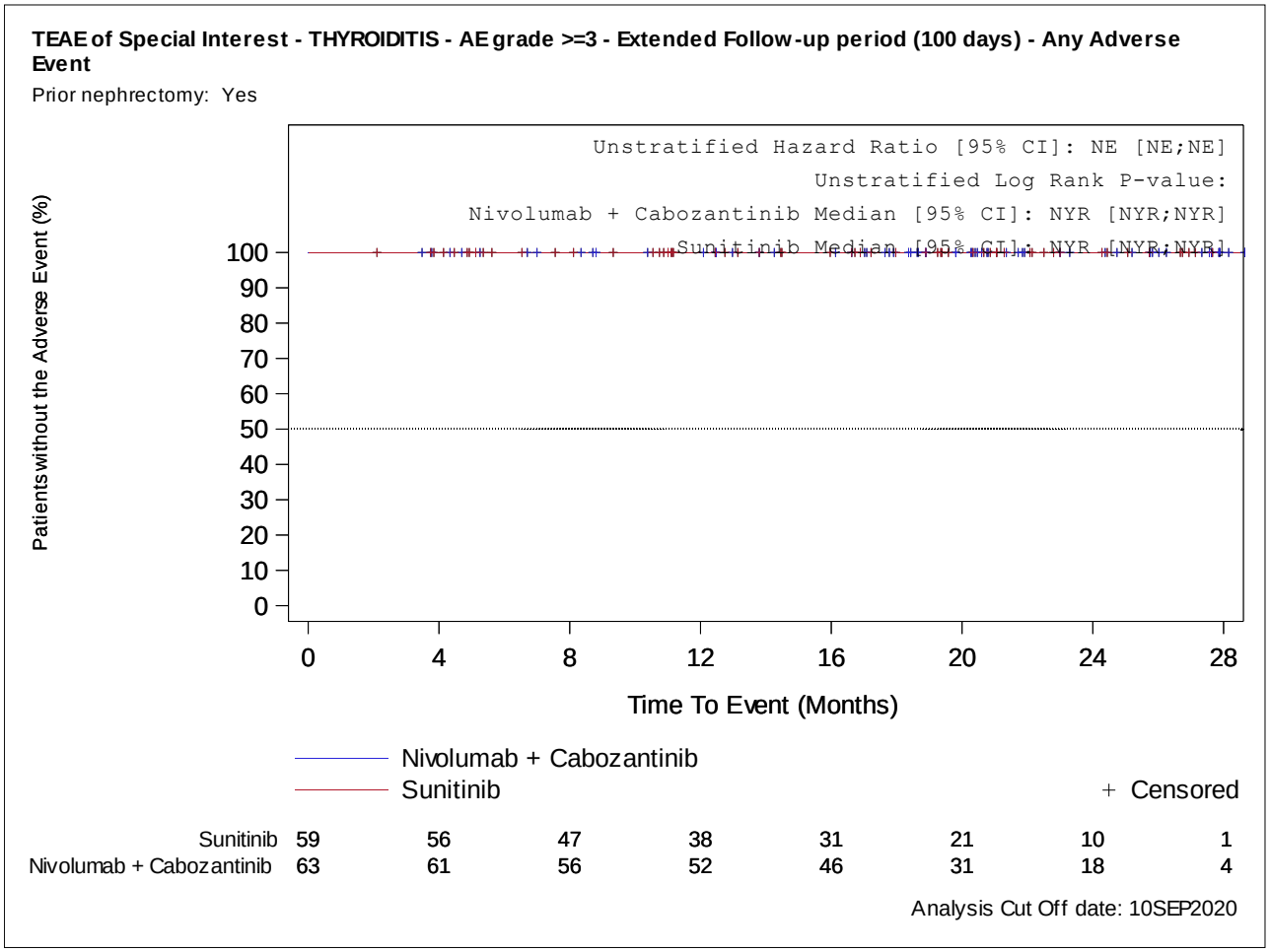
FIGURE 3.110.2.17: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



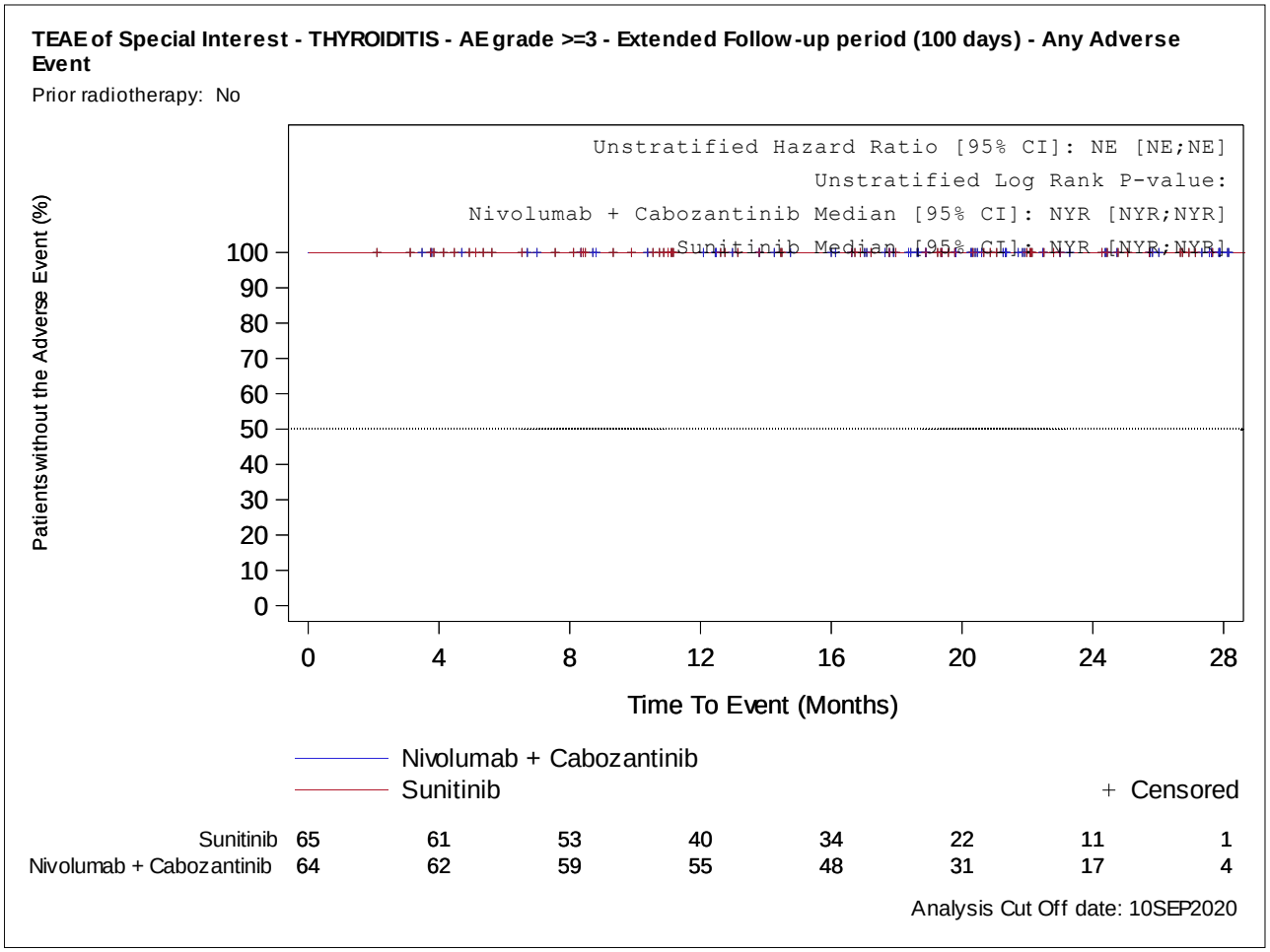

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:32:37

FIGURE 3.110.2.18: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



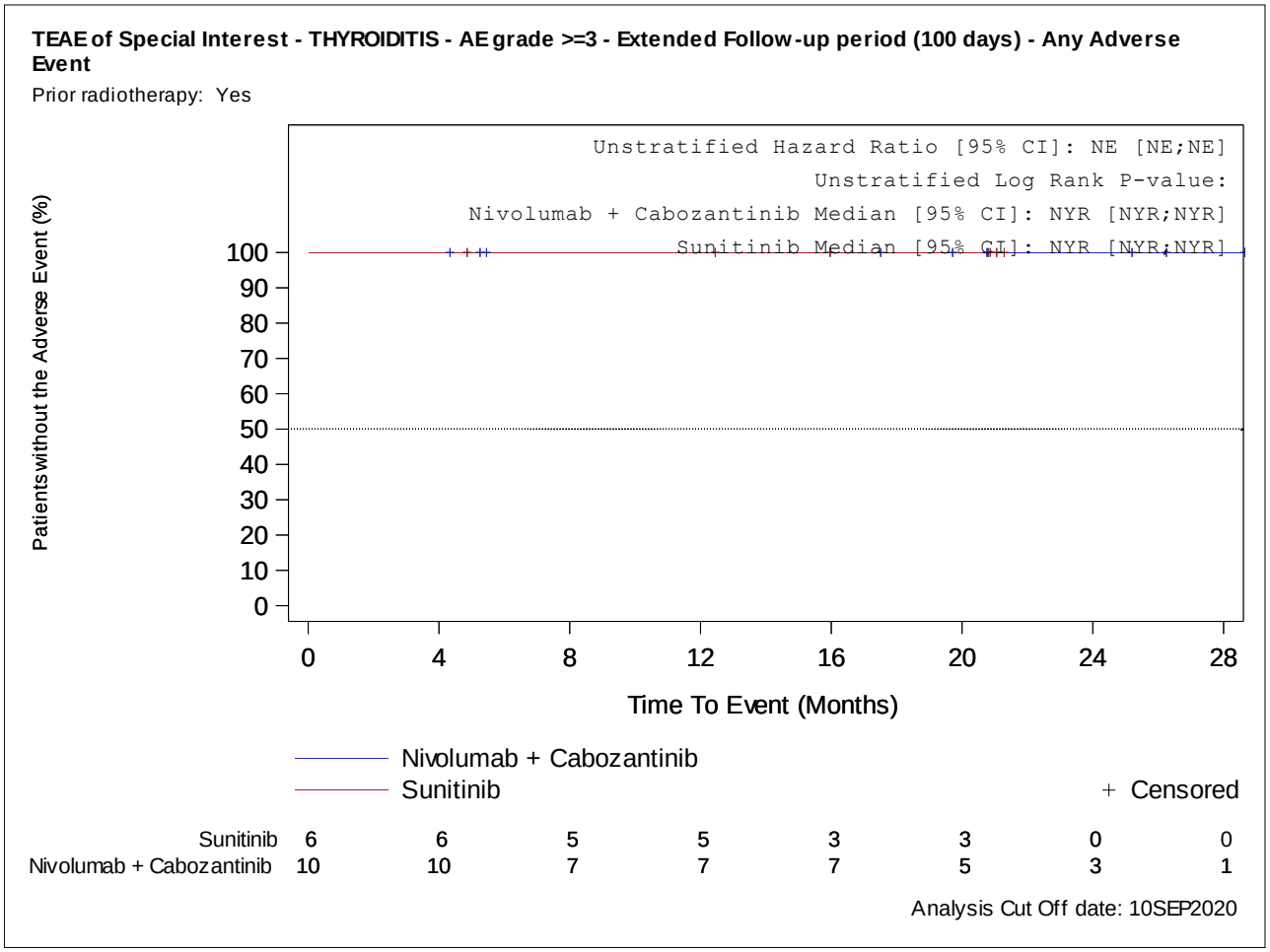

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:32:42

FIGURE 3.110.2.19: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



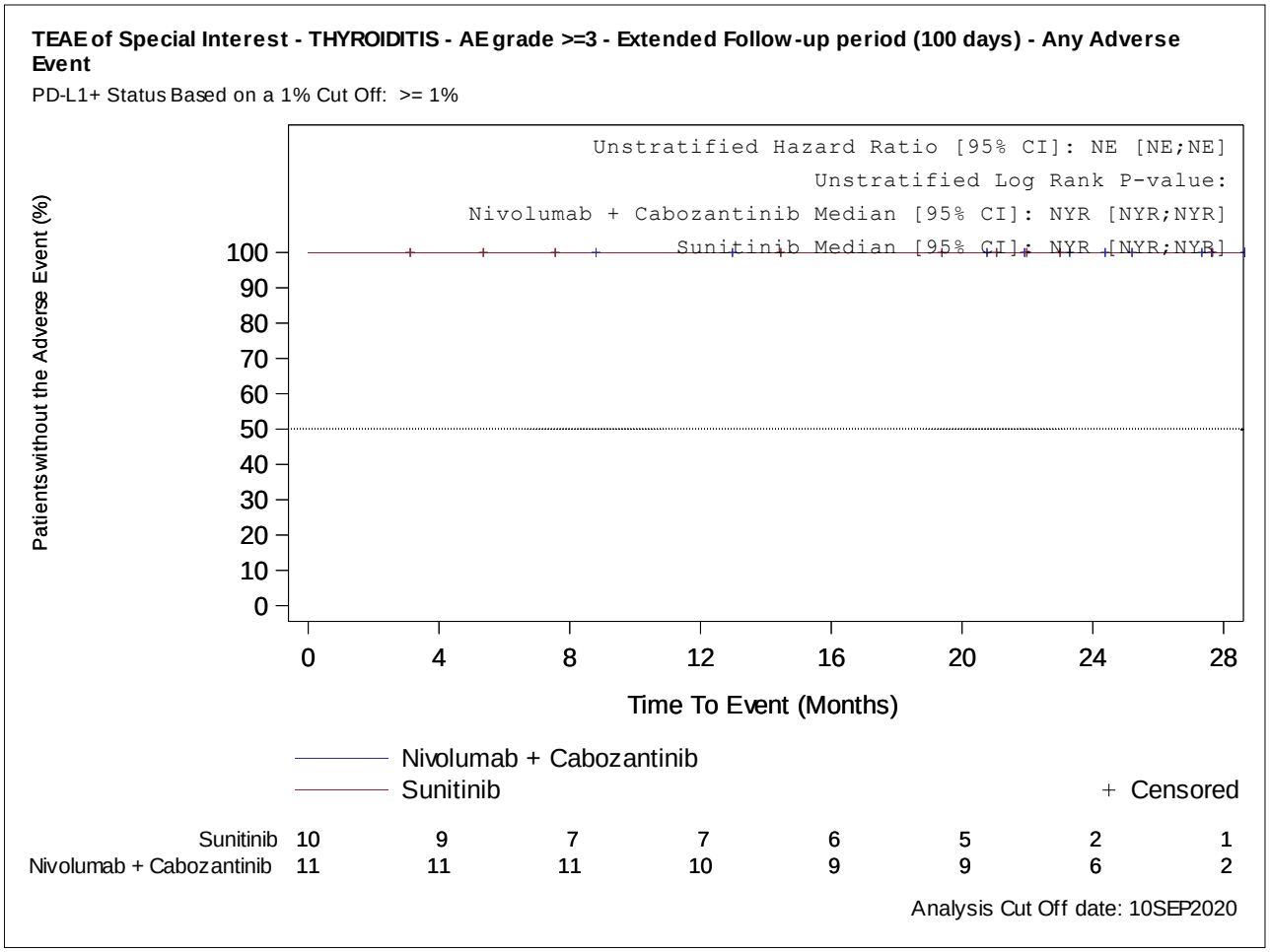

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:32:48

FIGURE 3.110.2.20: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



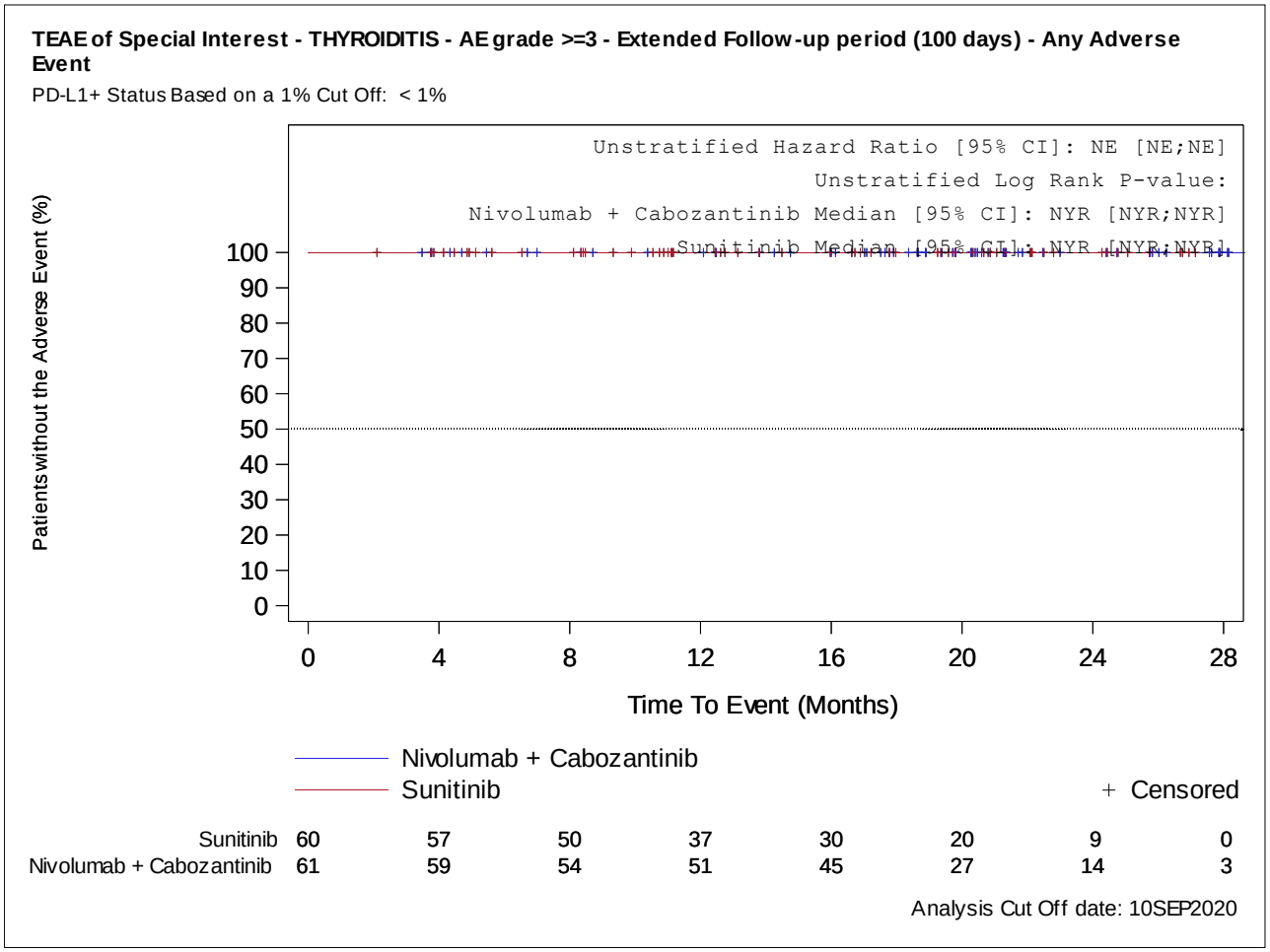

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:32:53

FIGURE 3.110.2.21: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off:  >= 1%



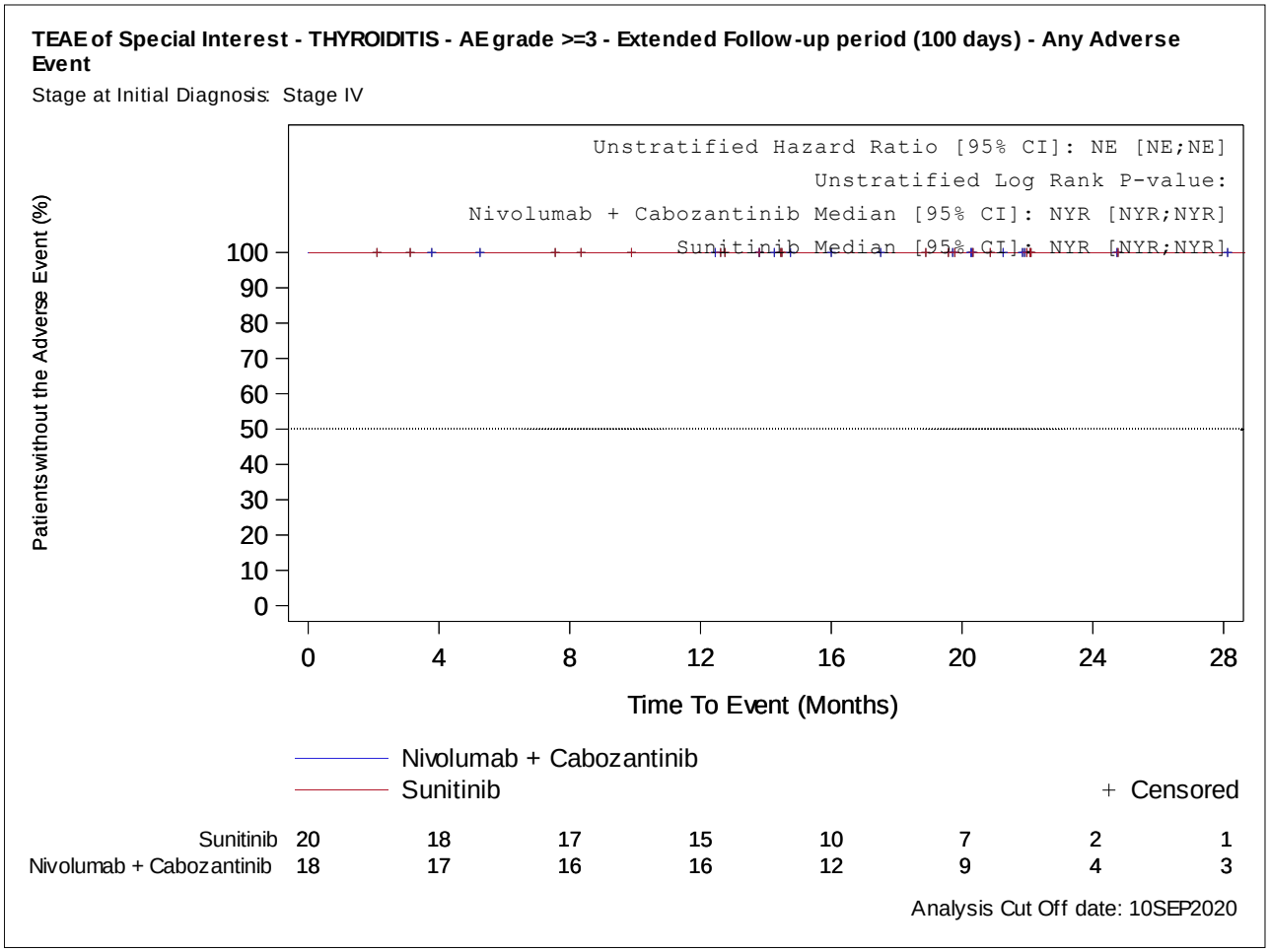

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:32:58

FIGURE 3.110.2.22: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:33:03

FIGURE 3.110.2.23: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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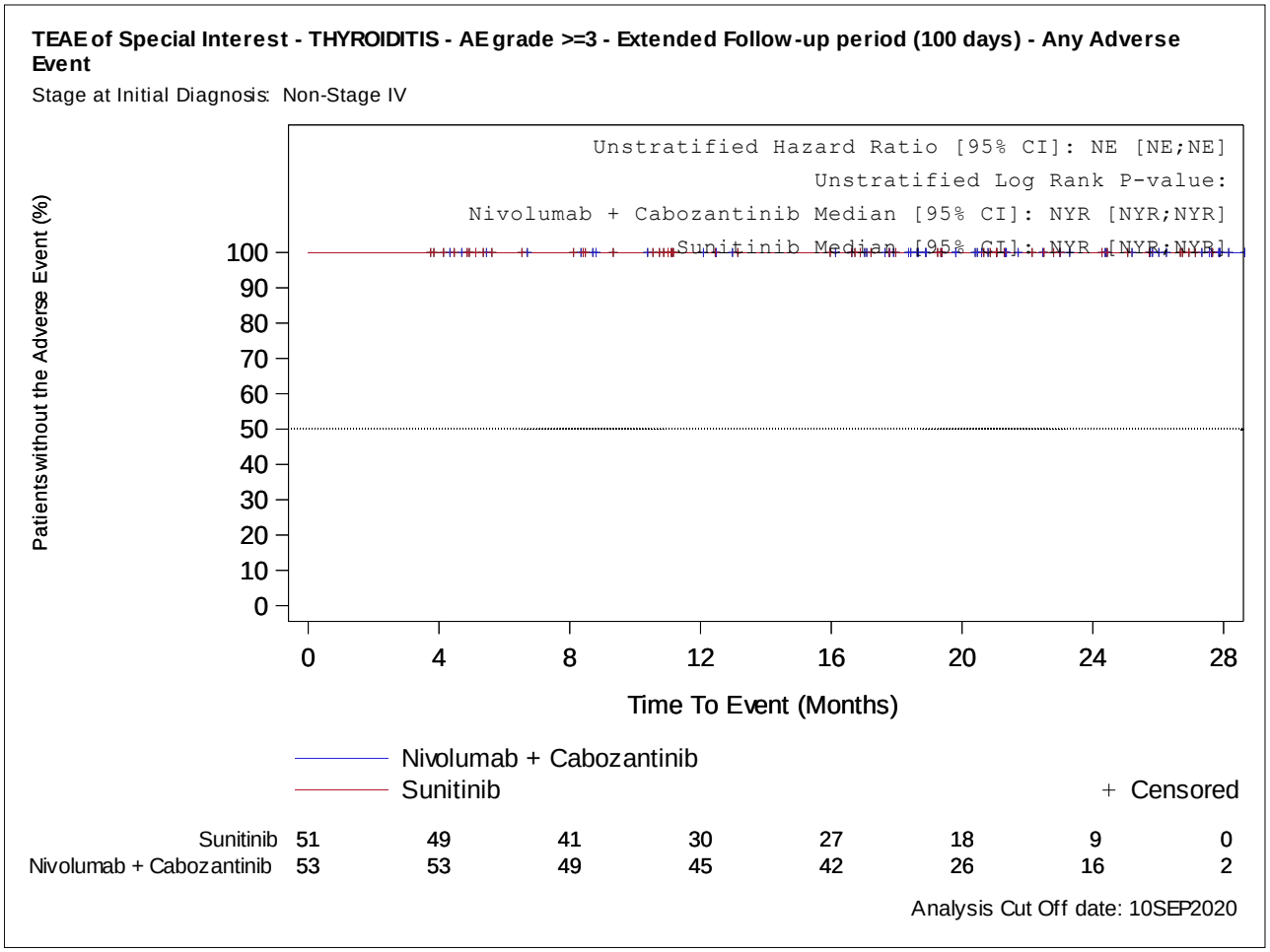
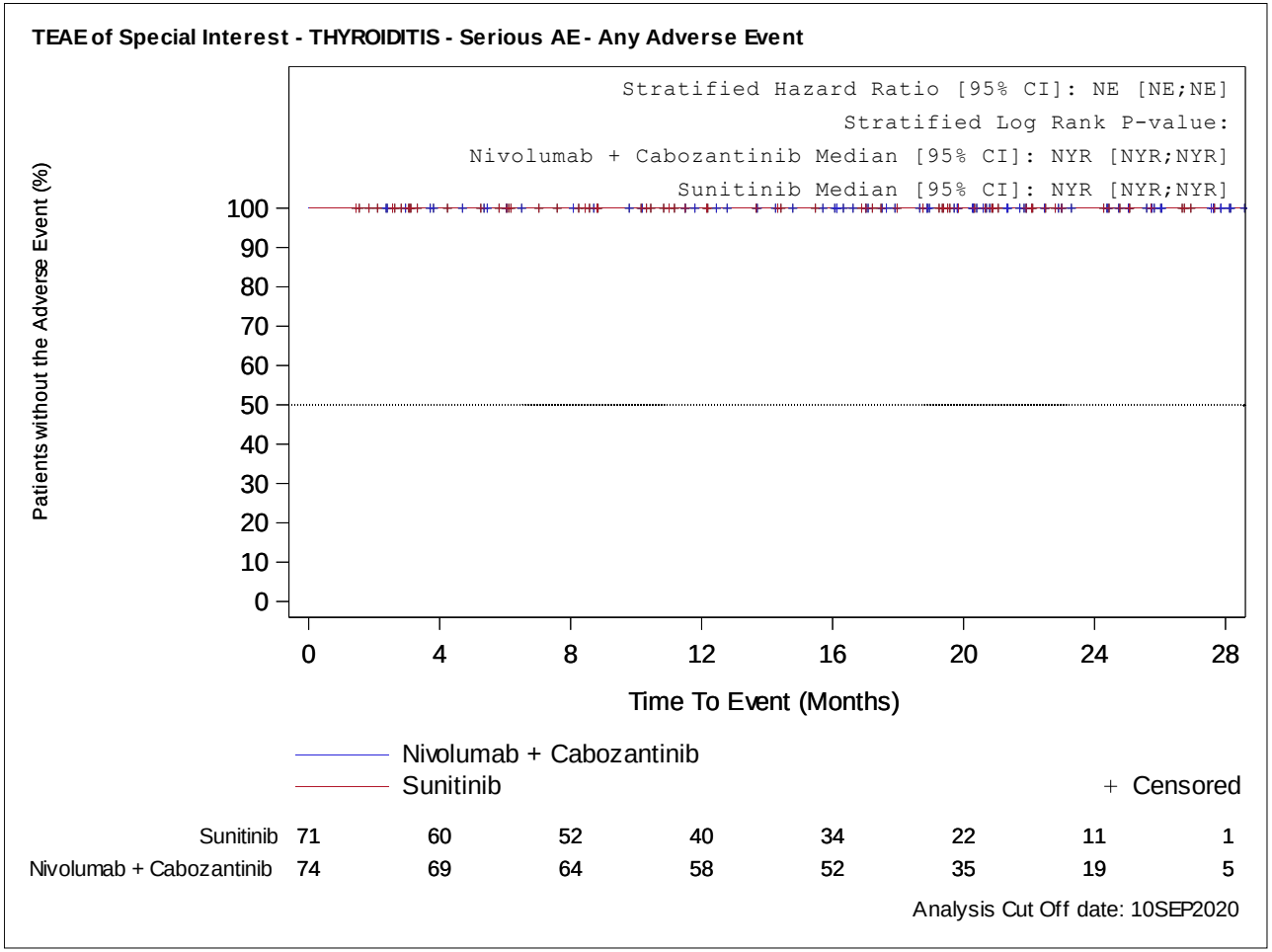
FIGURE 3.110.2.24: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



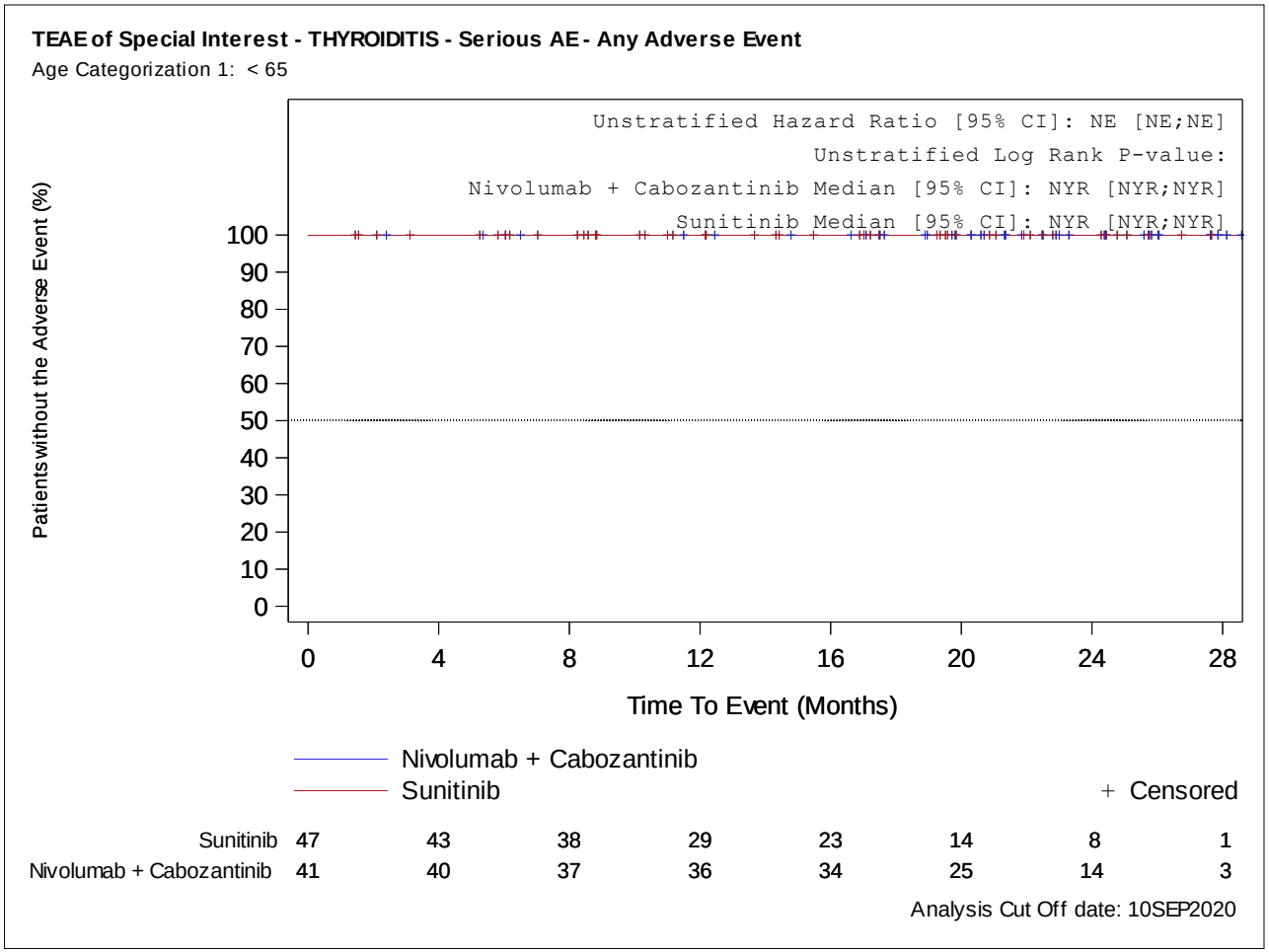

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:33:35

FIGURE 3.111.1: TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



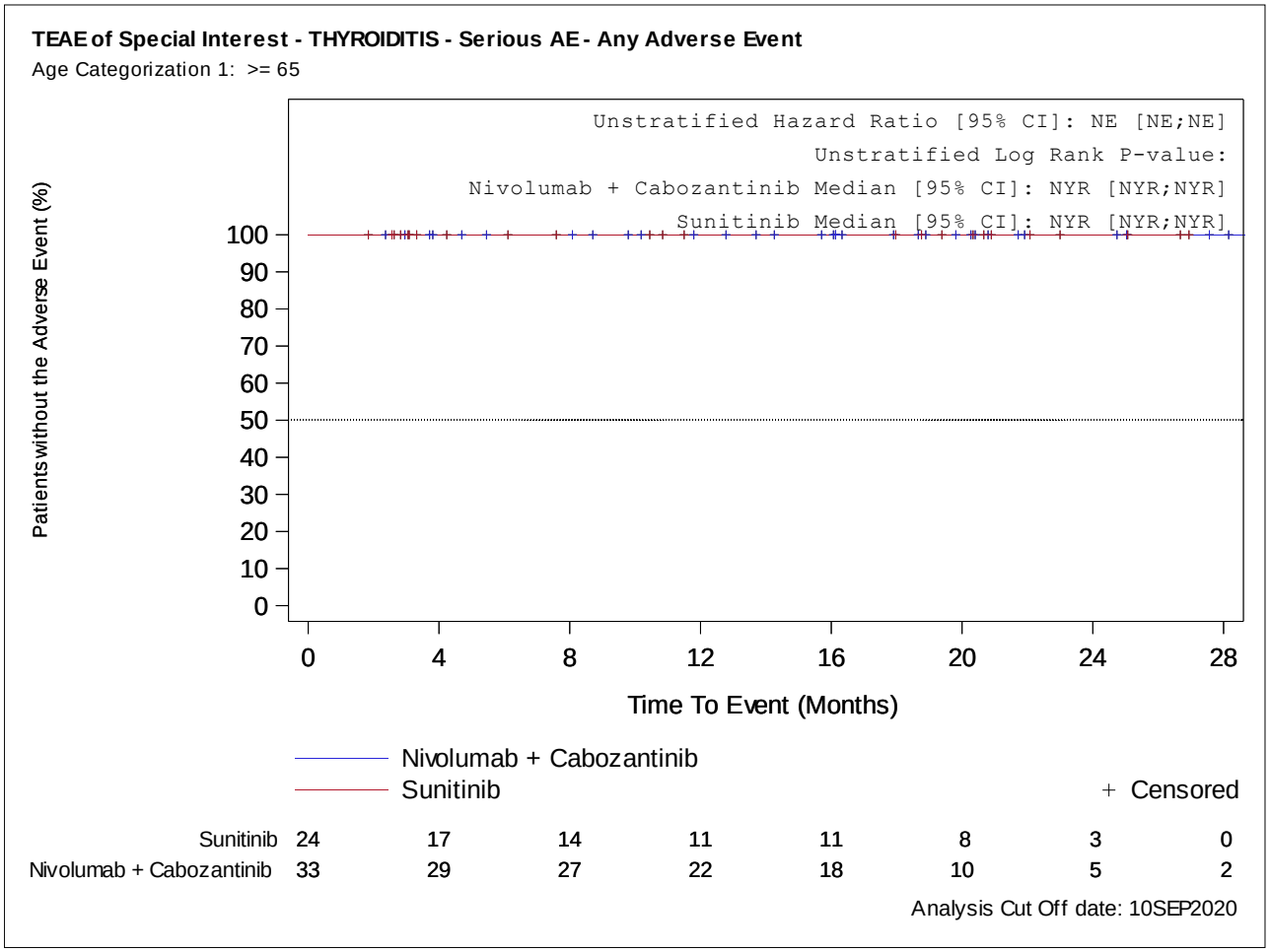

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:36:34

FIGURE 3.111.2.1: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



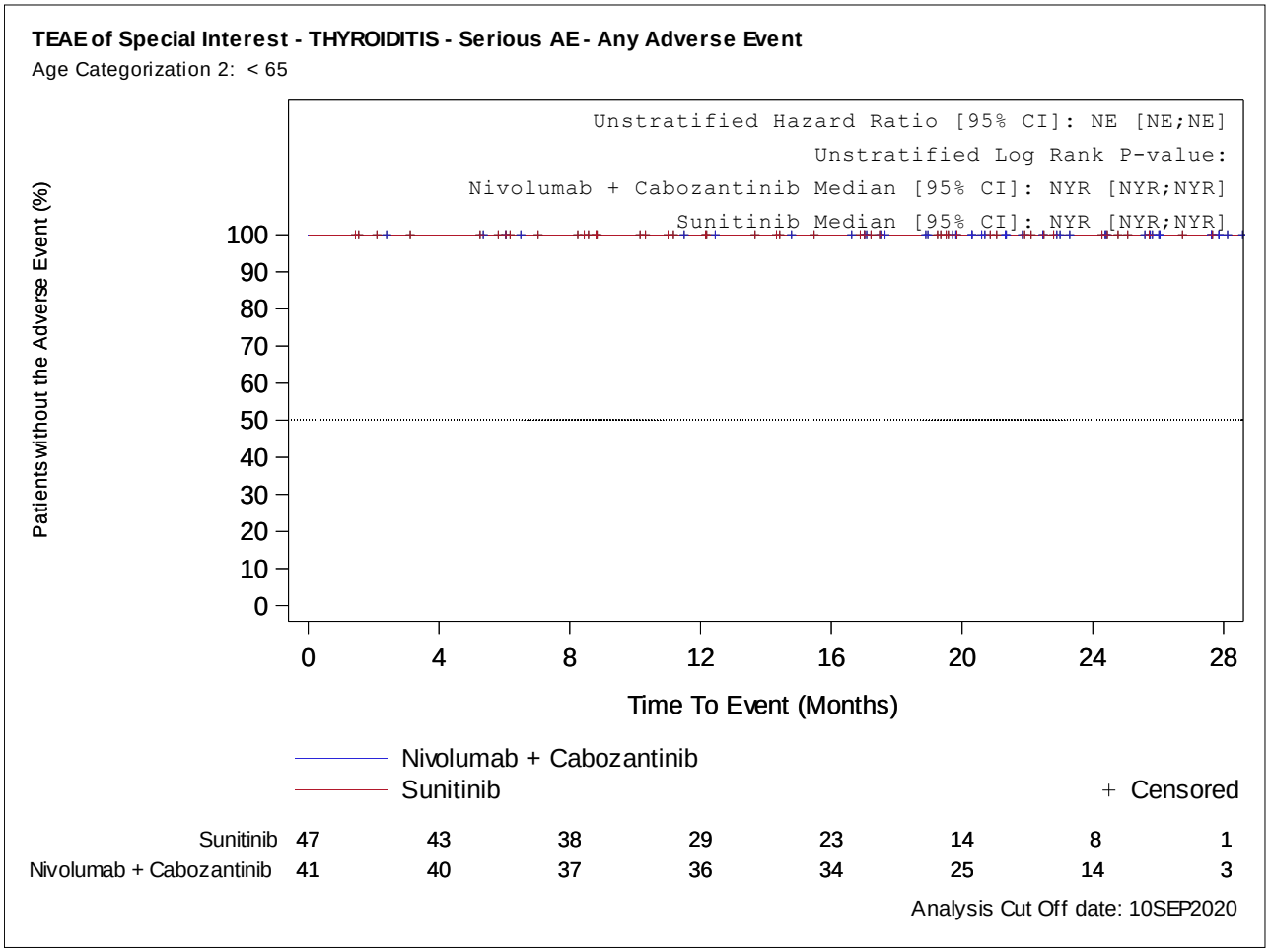

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:36:37

FIGURE 3.111.2.2: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



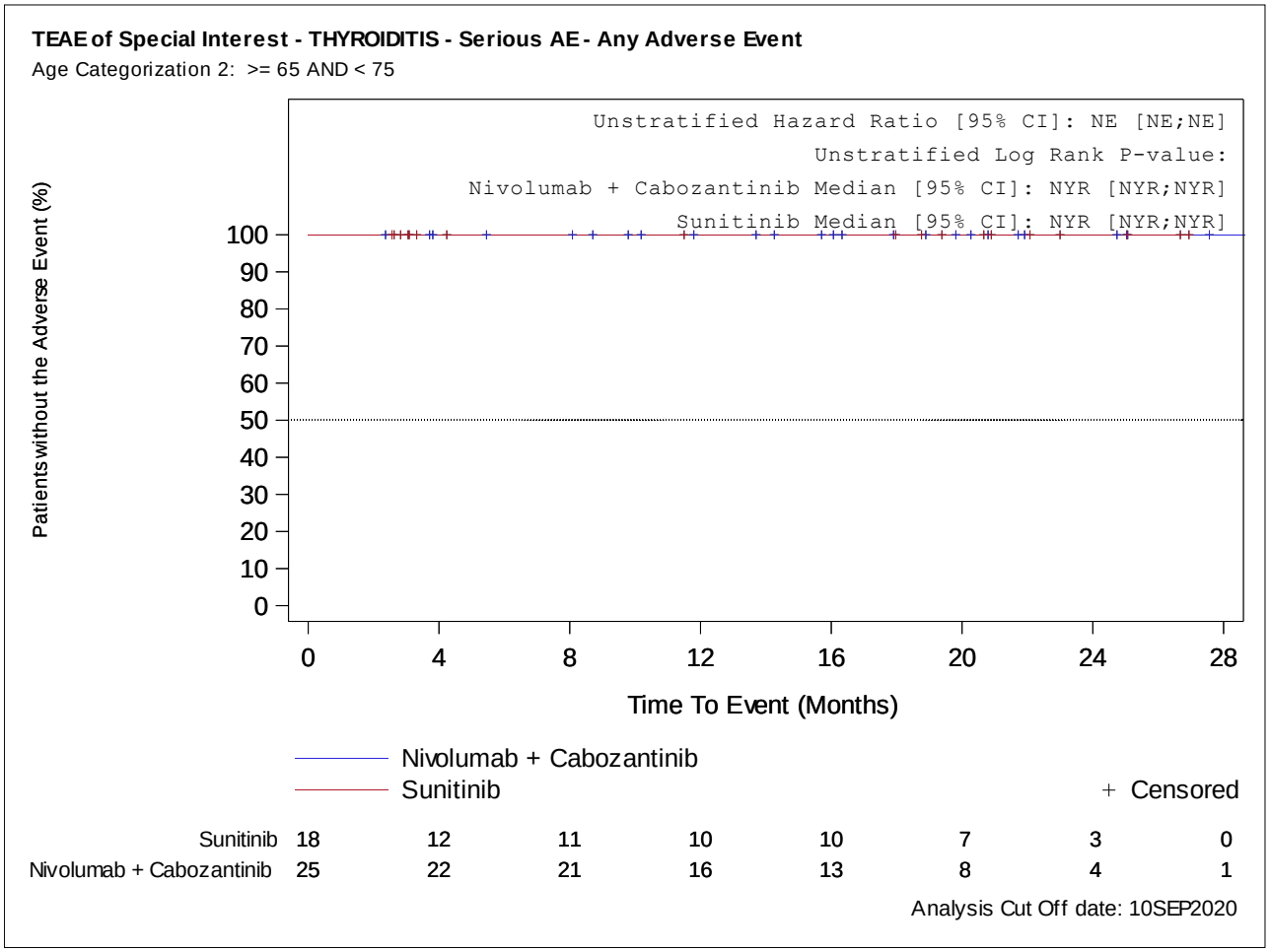

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:36:42

FIGURE 3.111.2.3: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



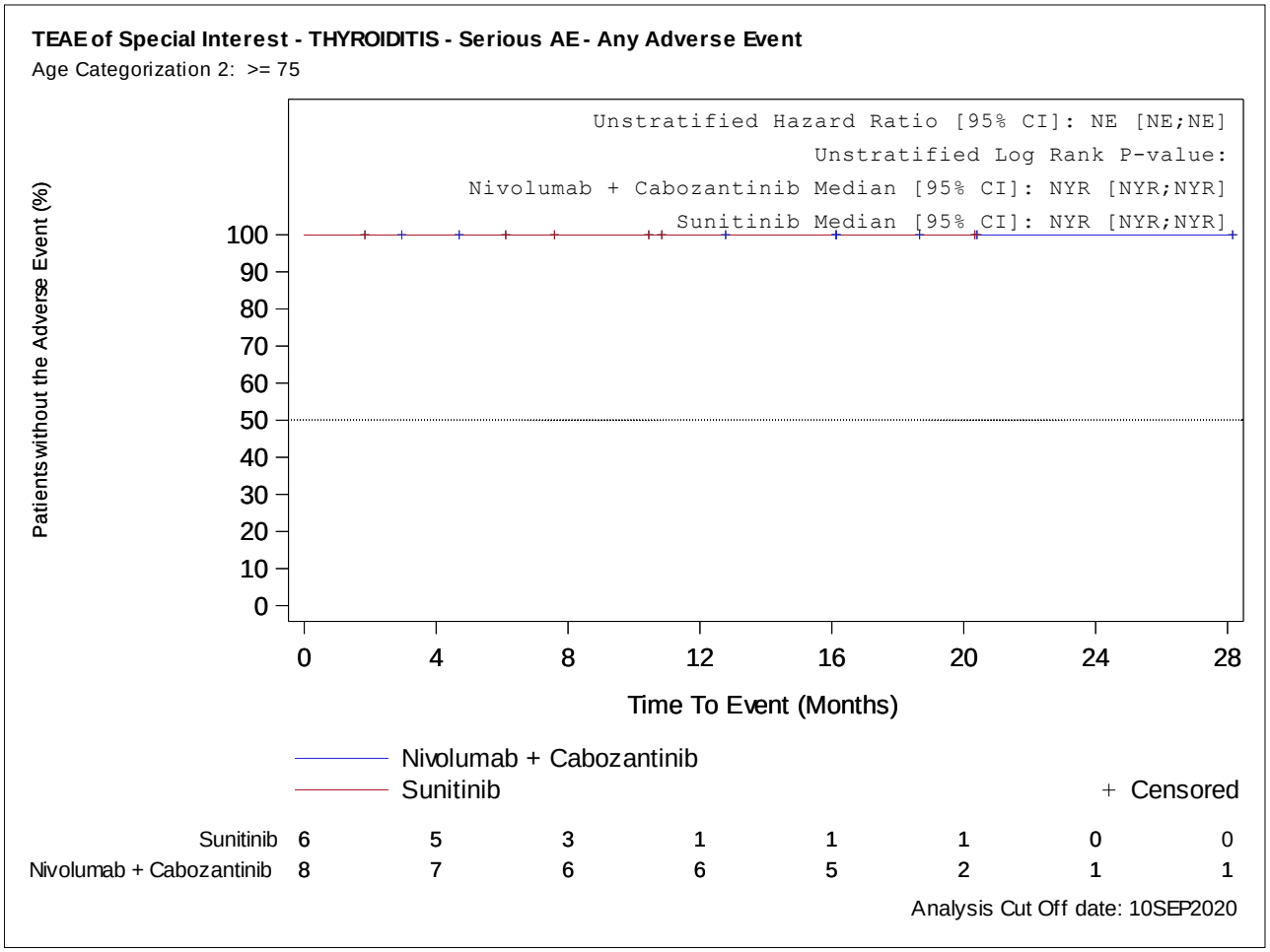

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:36:48

FIGURE 3.111.2.4: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



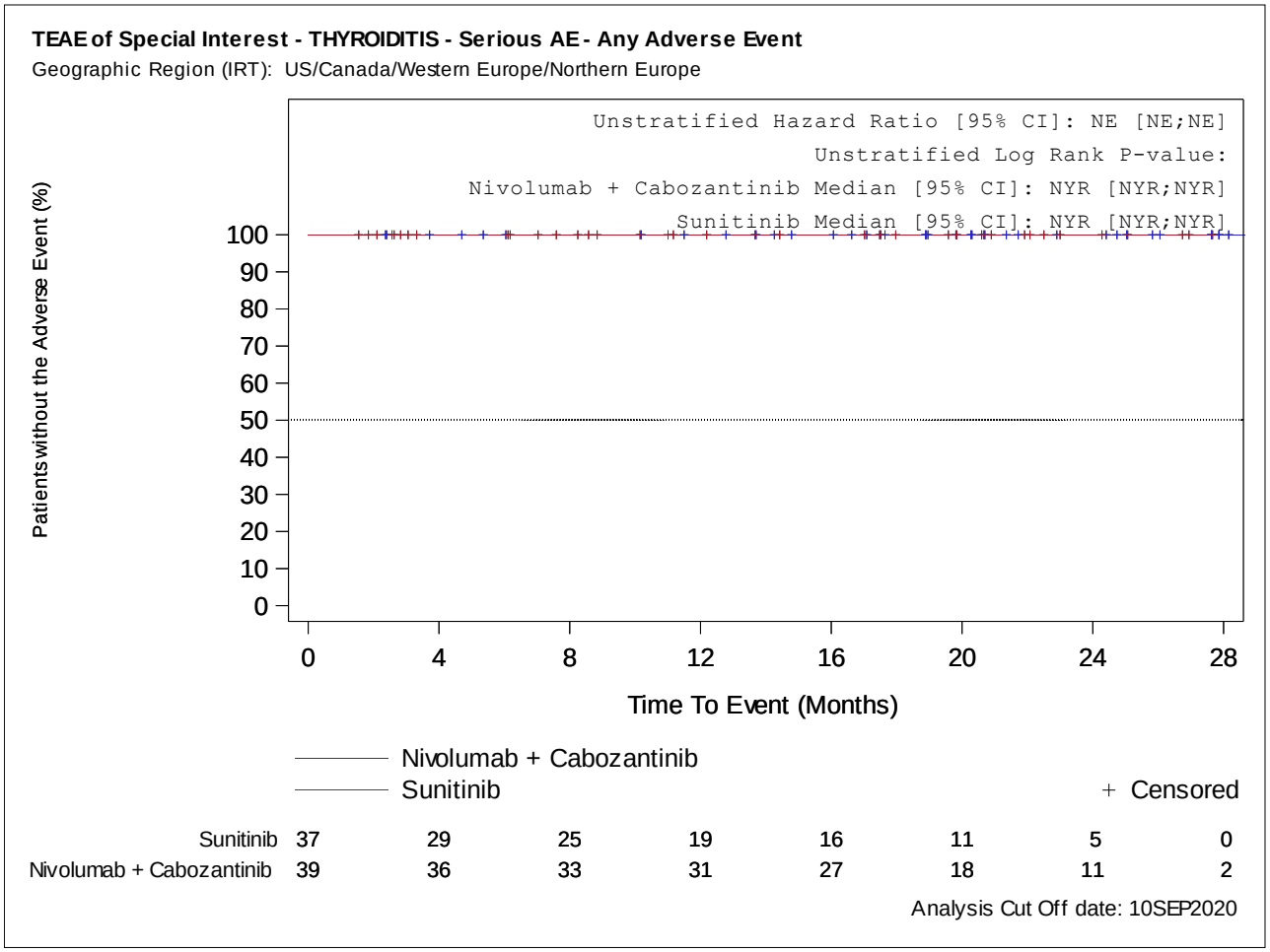

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:36:53

FIGURE 3.111.2.5: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



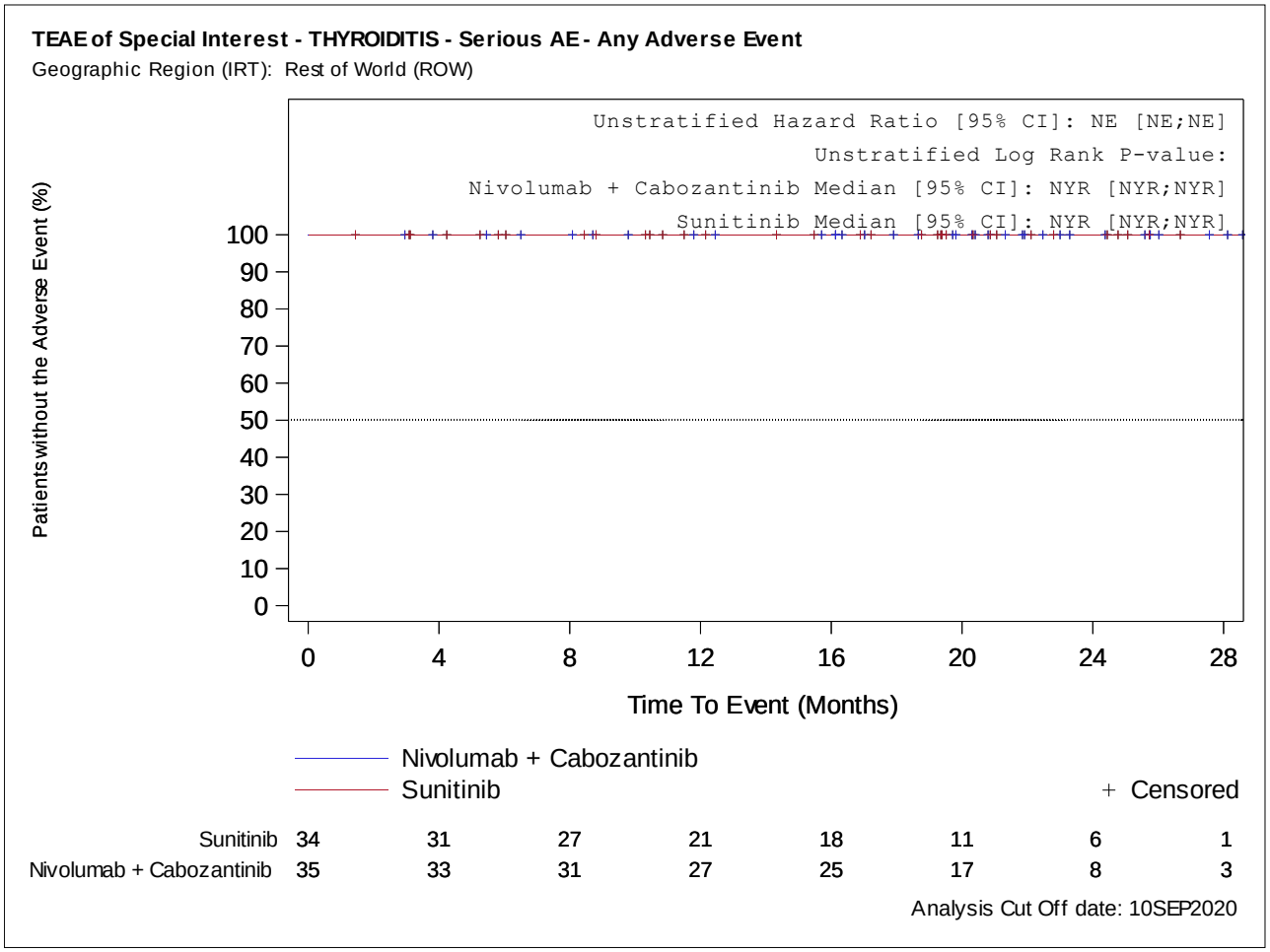

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:36:58

FIGURE 3.111.2.6: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



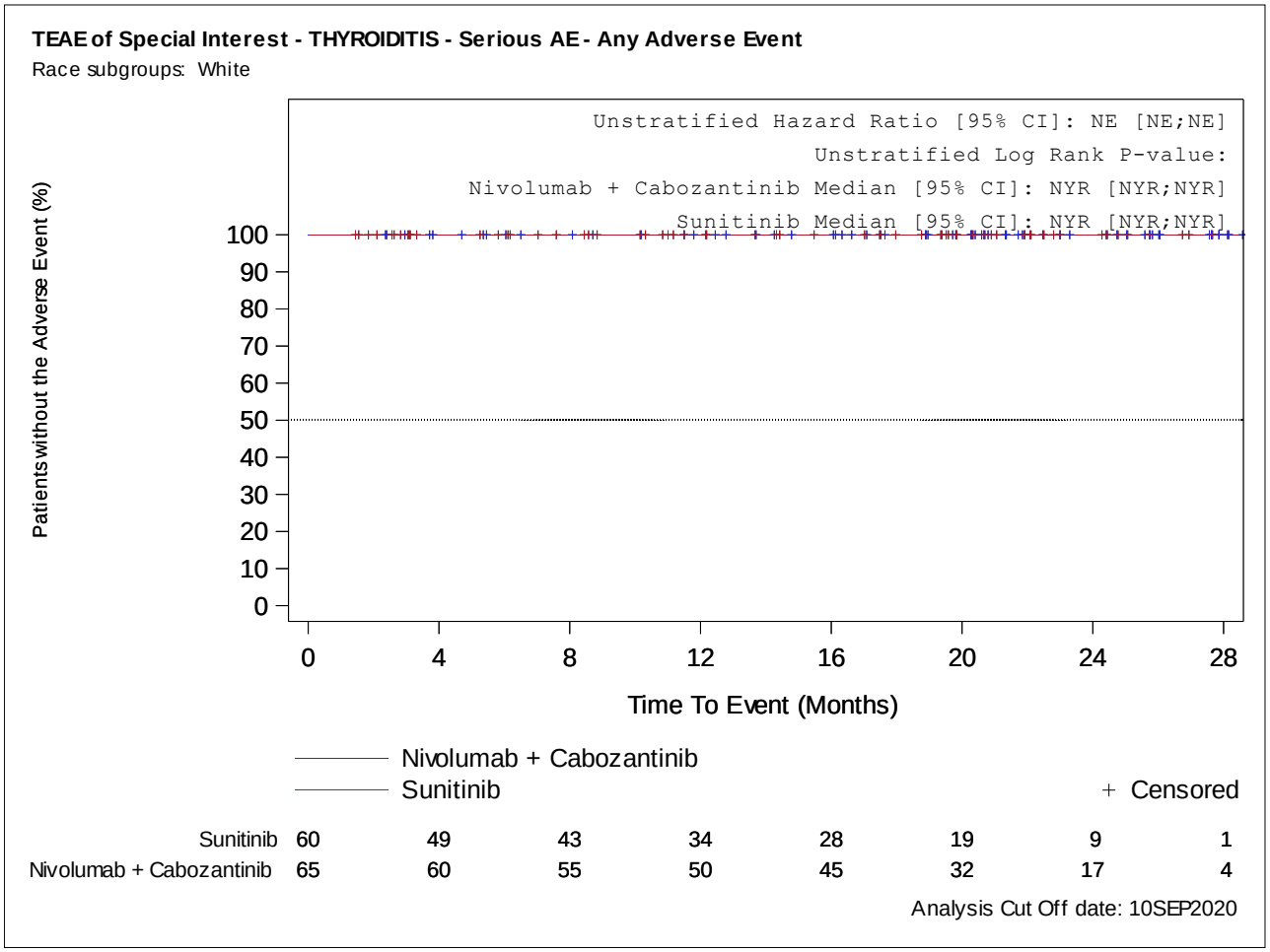

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:03

FIGURE 3.111.2.7: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



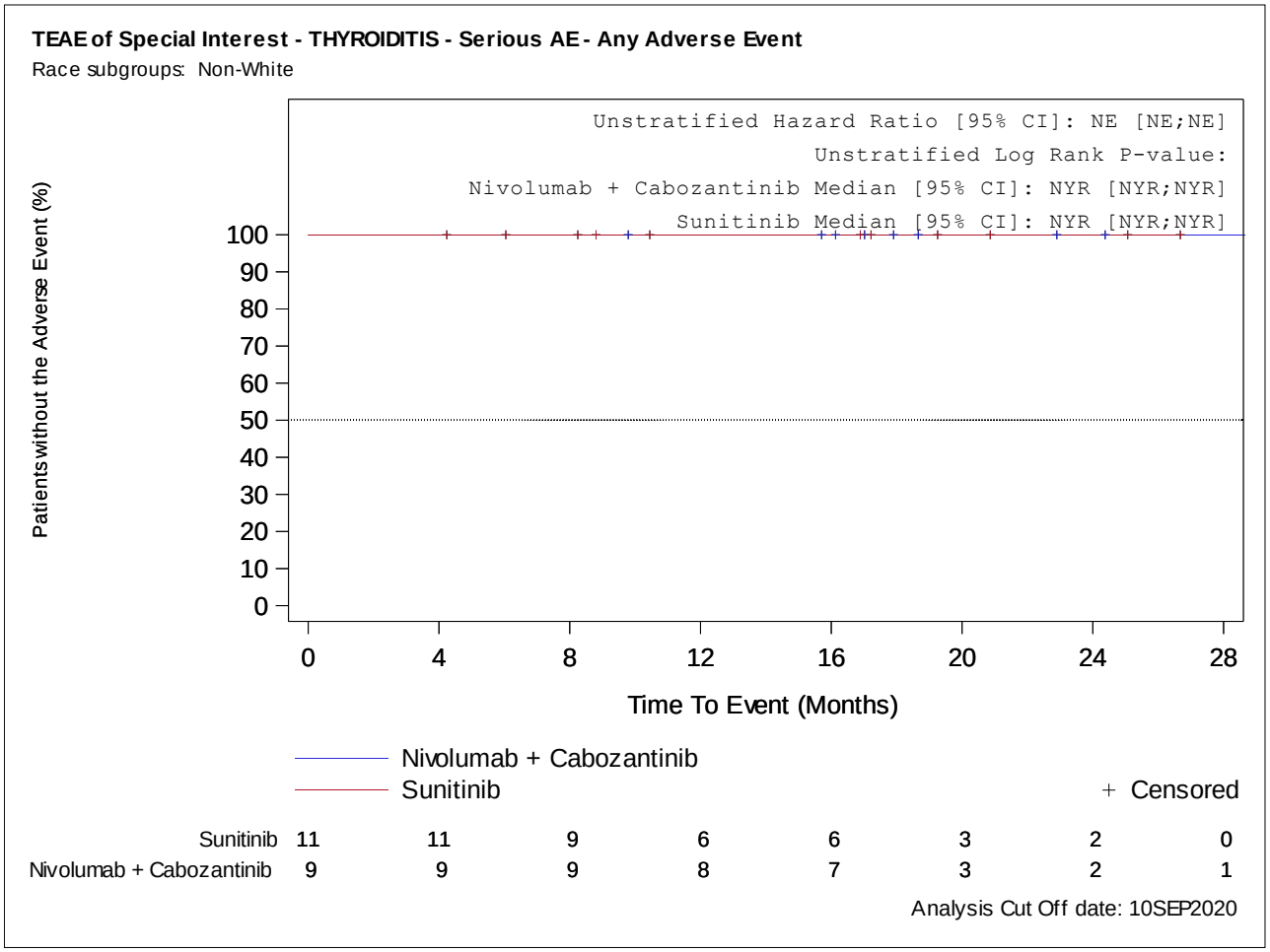

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:09

FIGURE 3.111.2.8: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



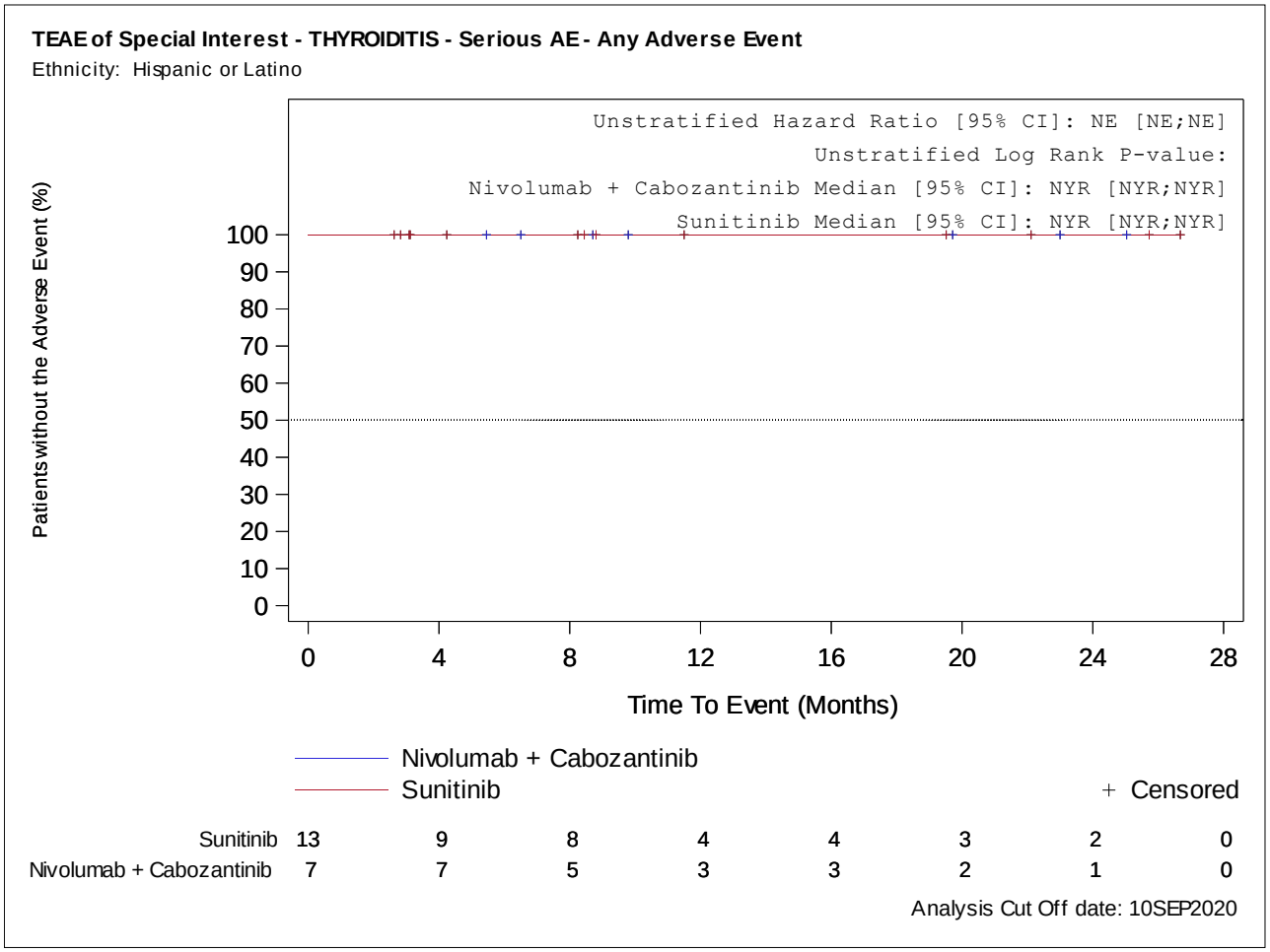

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:14

FIGURE 3.111.2.9: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



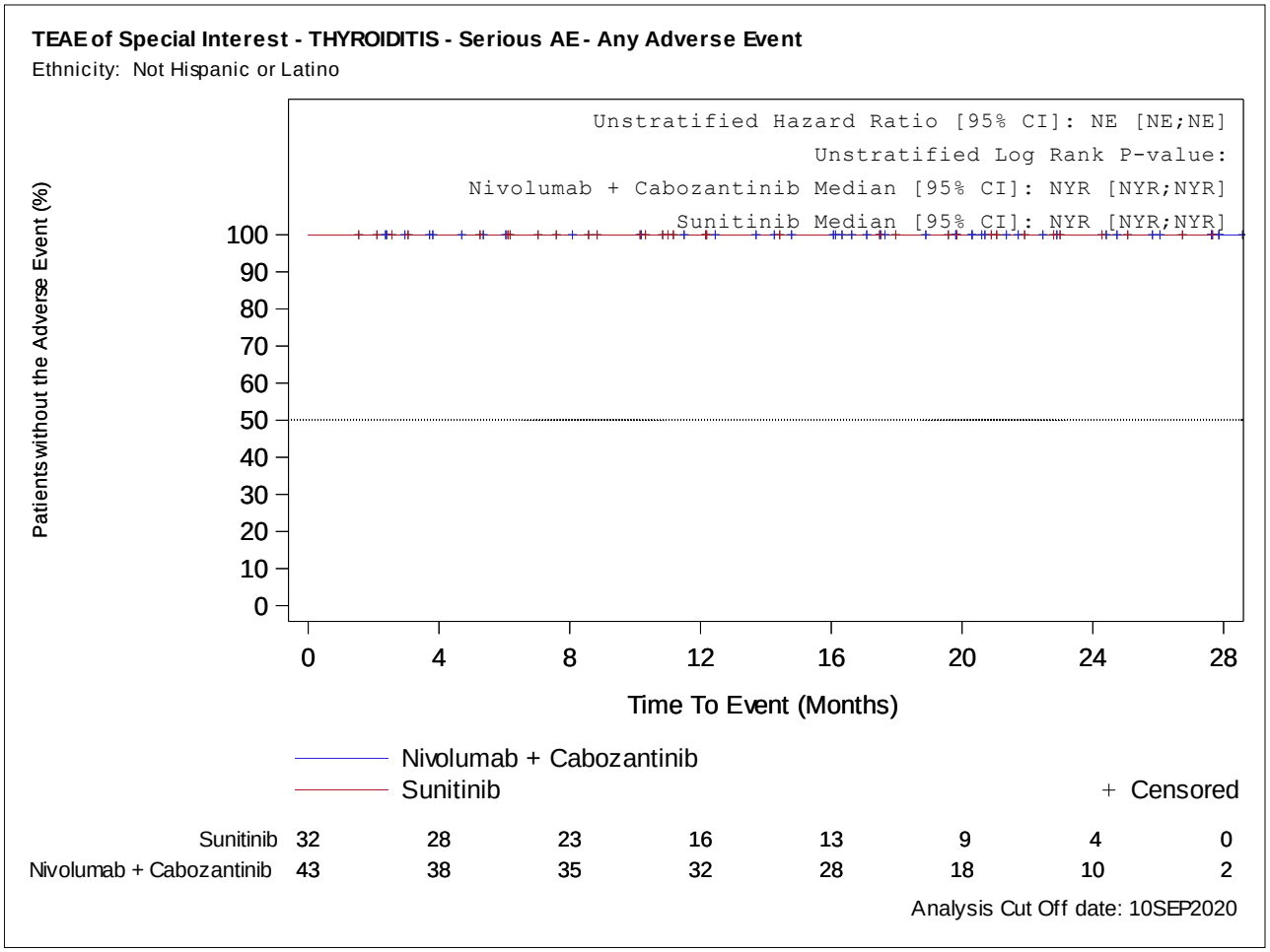

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:19

FIGURE 3.111.2.10: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



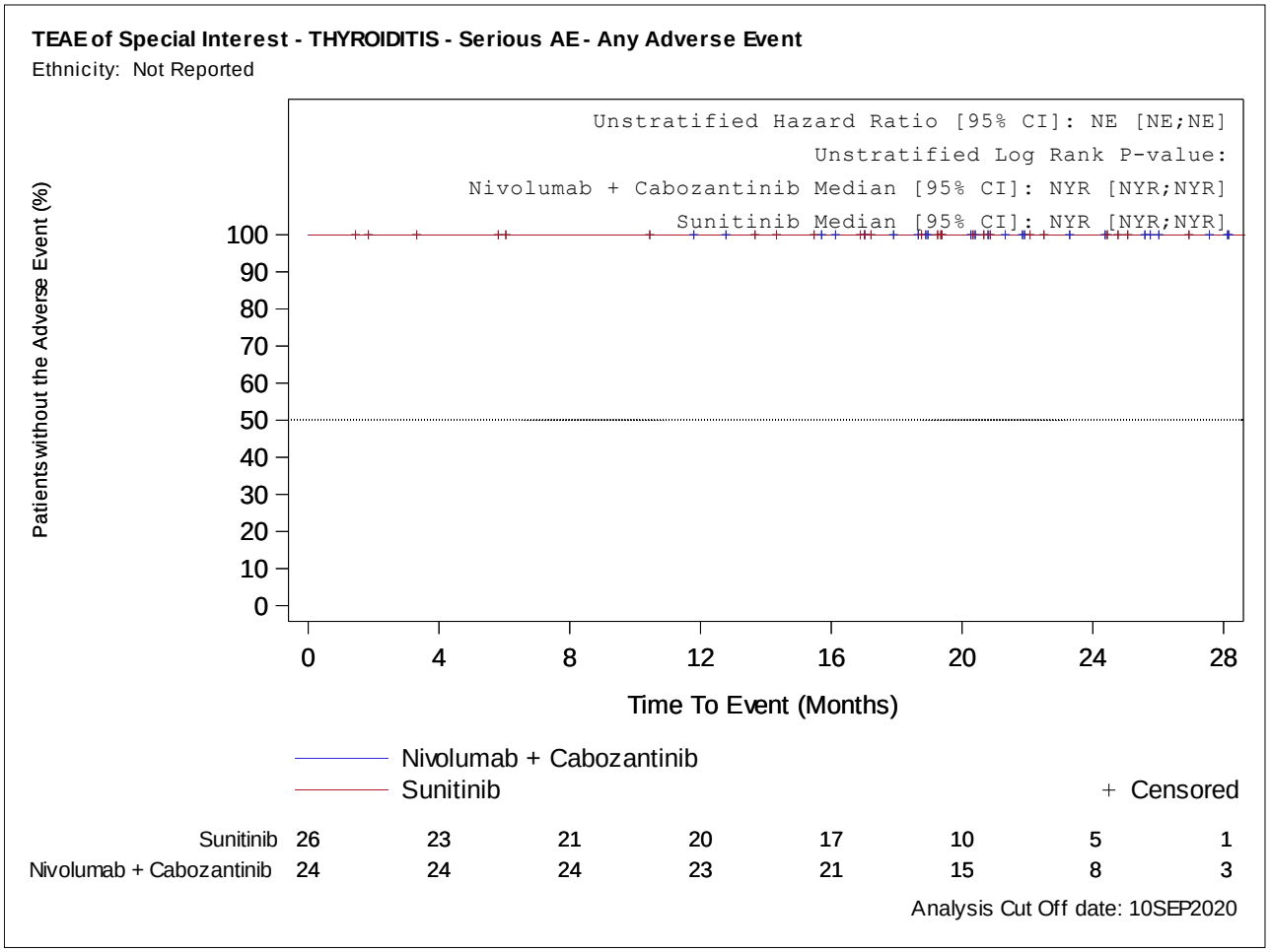

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:24

FIGURE 3.111.2.11: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



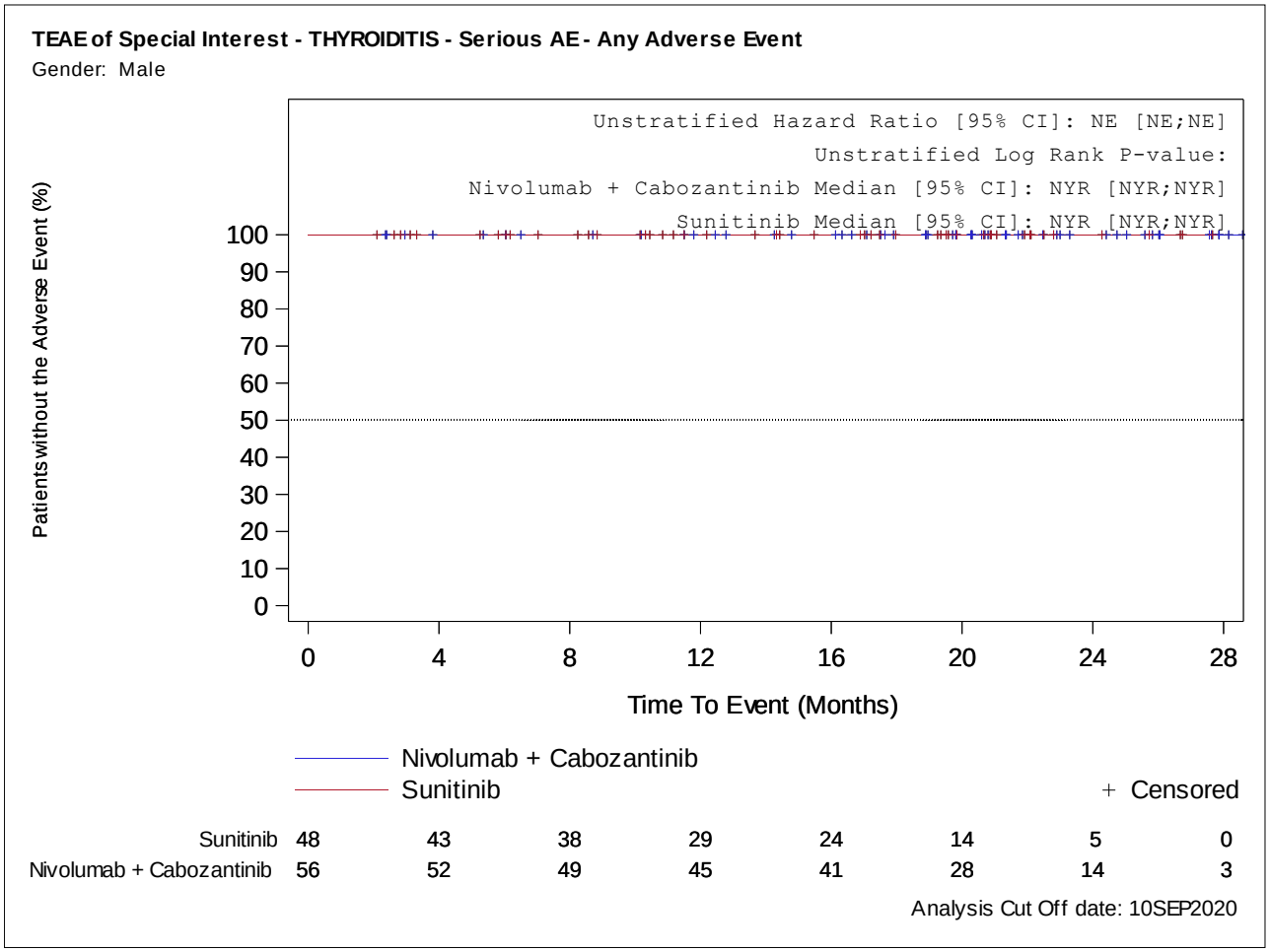

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:29

FIGURE 3.111.2.12: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



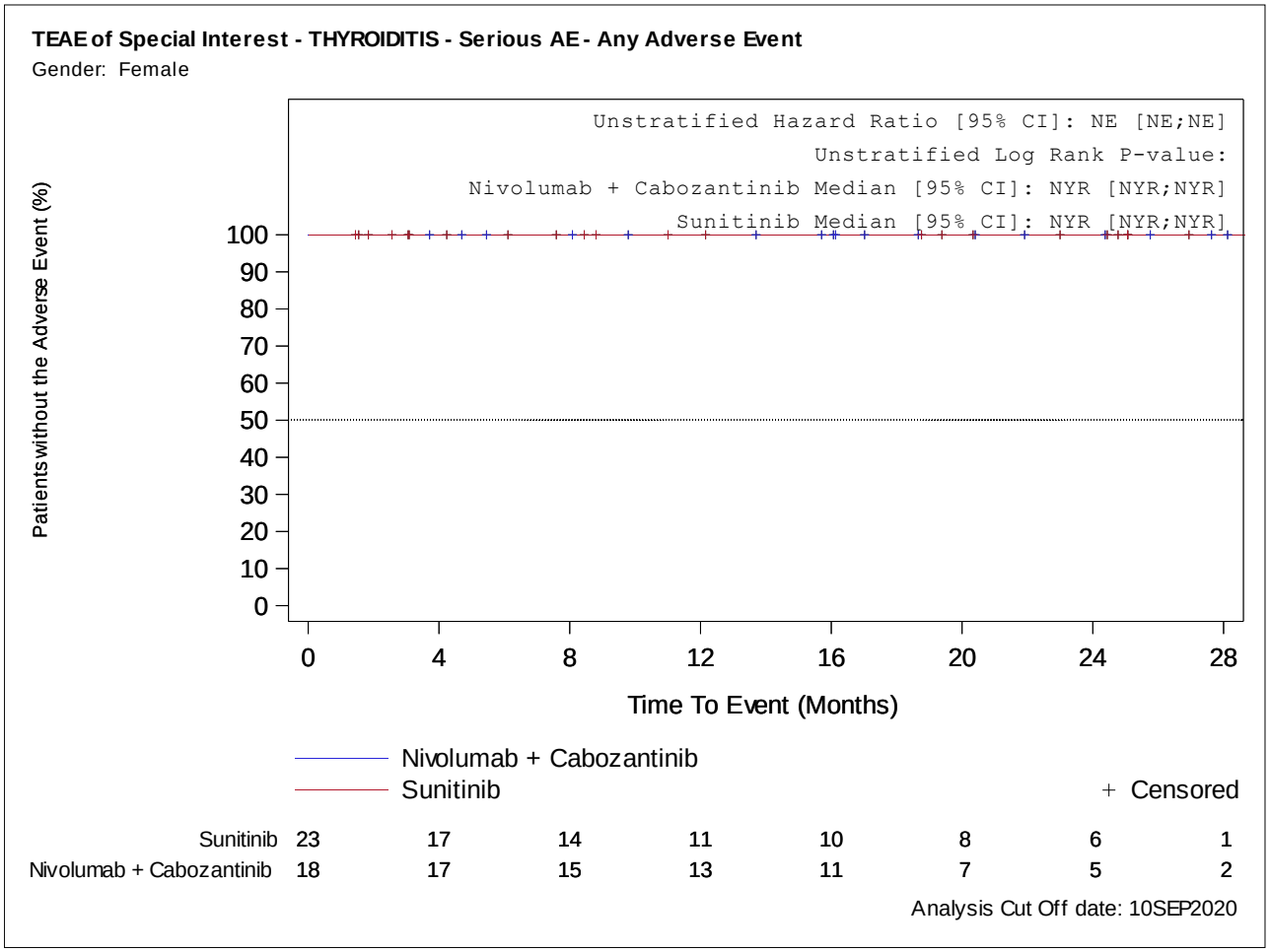

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:35

FIGURE 3.111.2.13: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



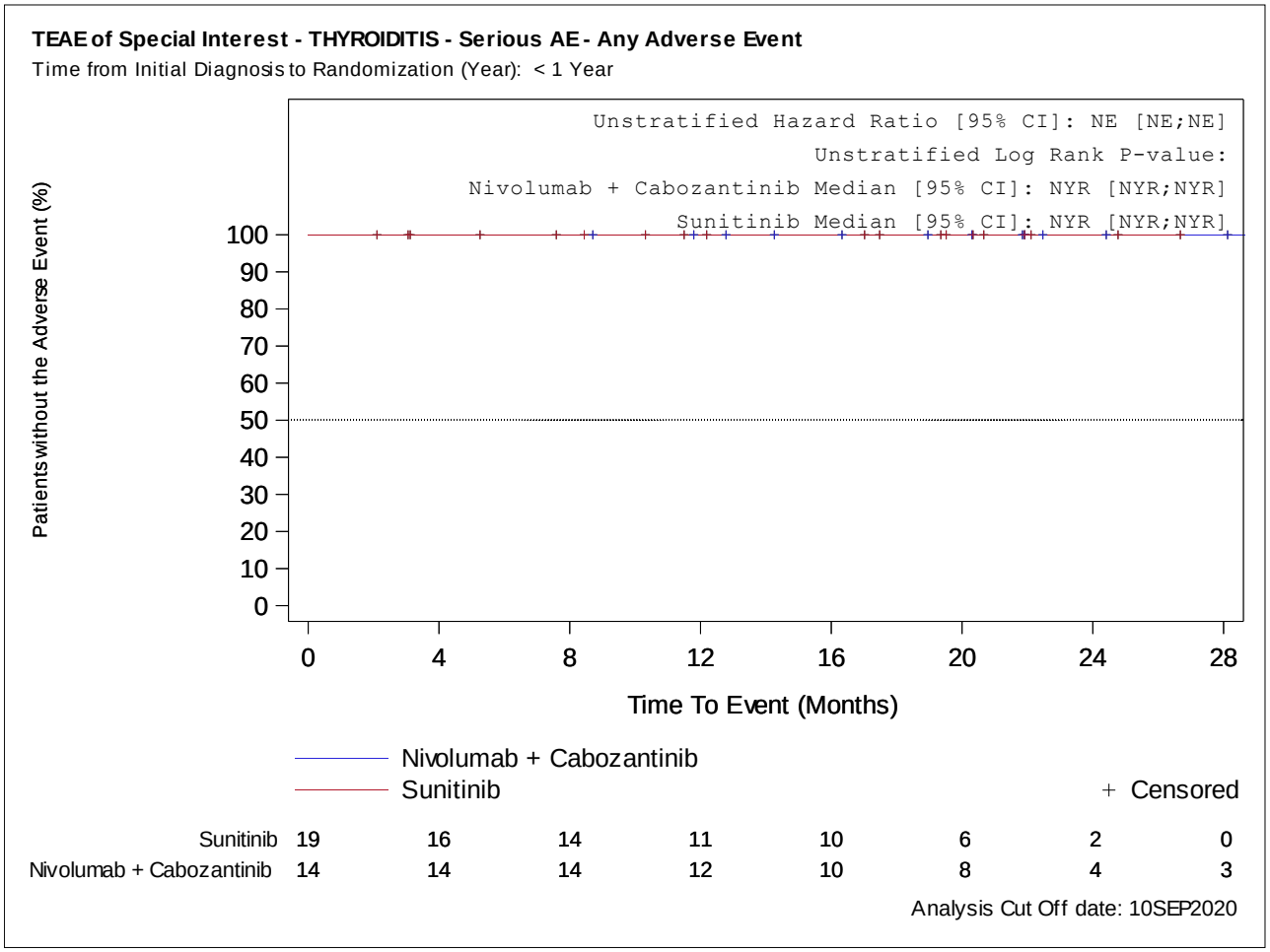

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:40

FIGURE 3.111.2.14: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



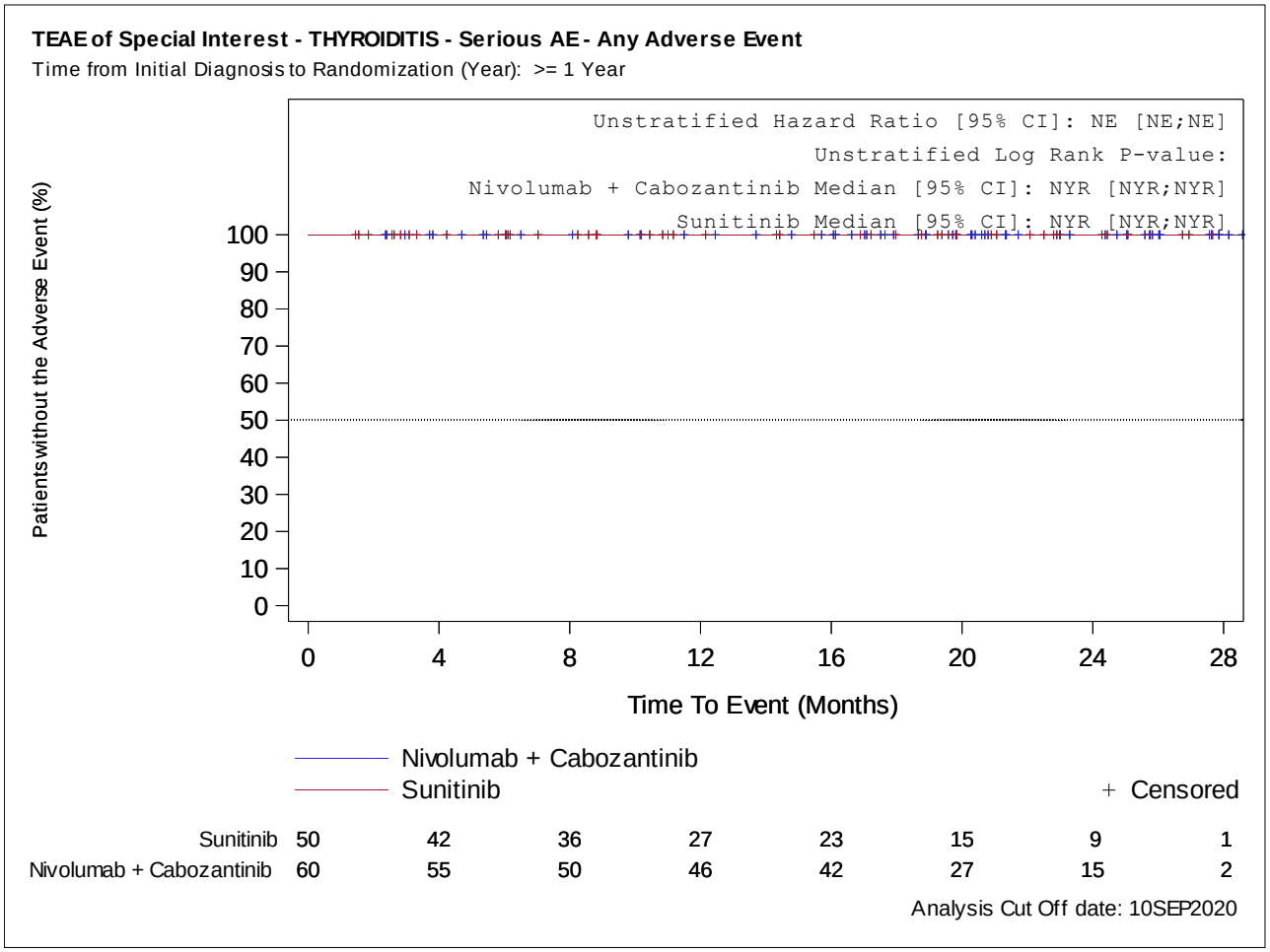

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:37:45

FIGURE 3.111.2.15: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:38:01

FIGURE 3.111.2.16: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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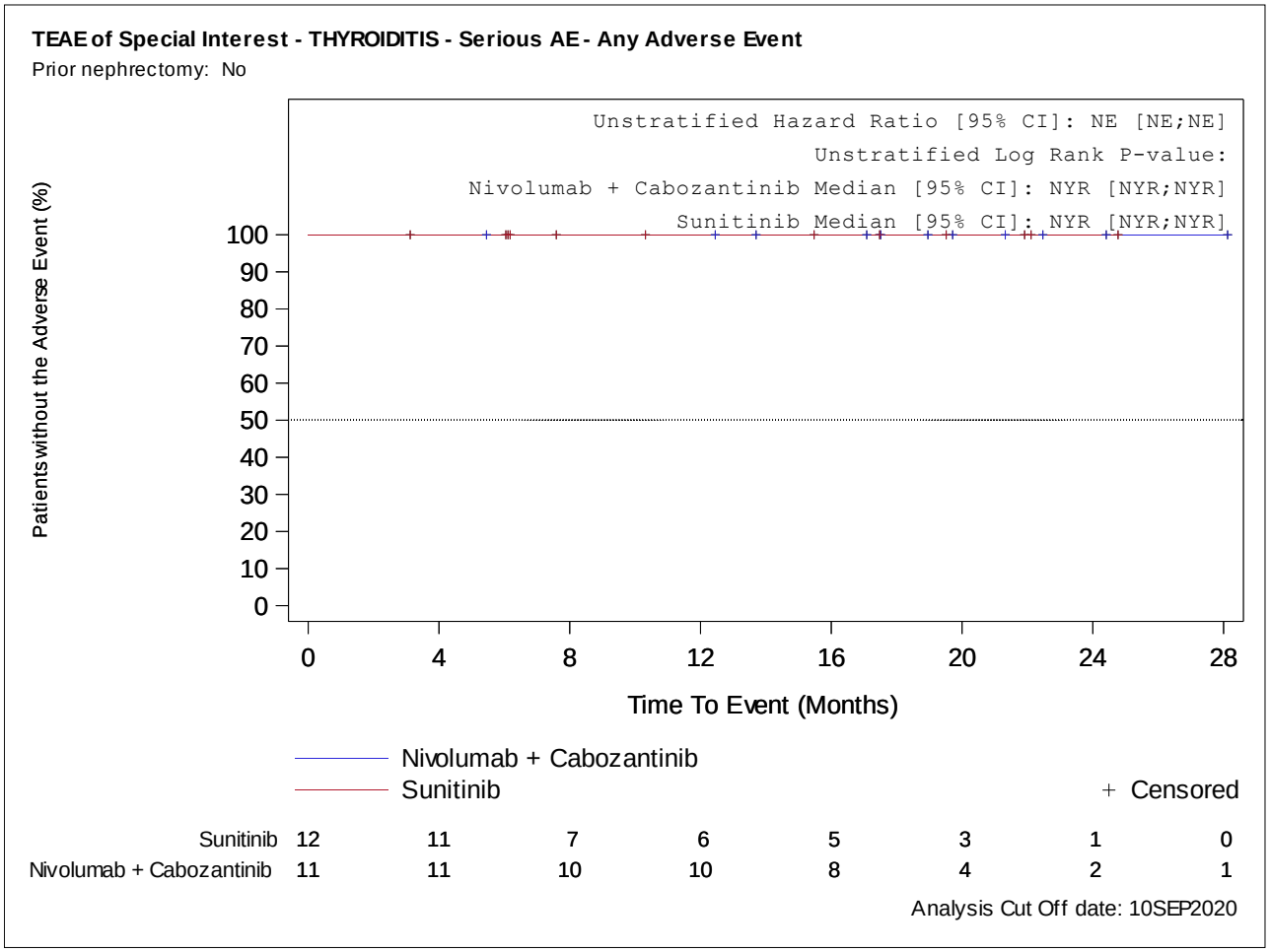
FIGURE 3.111.2.17: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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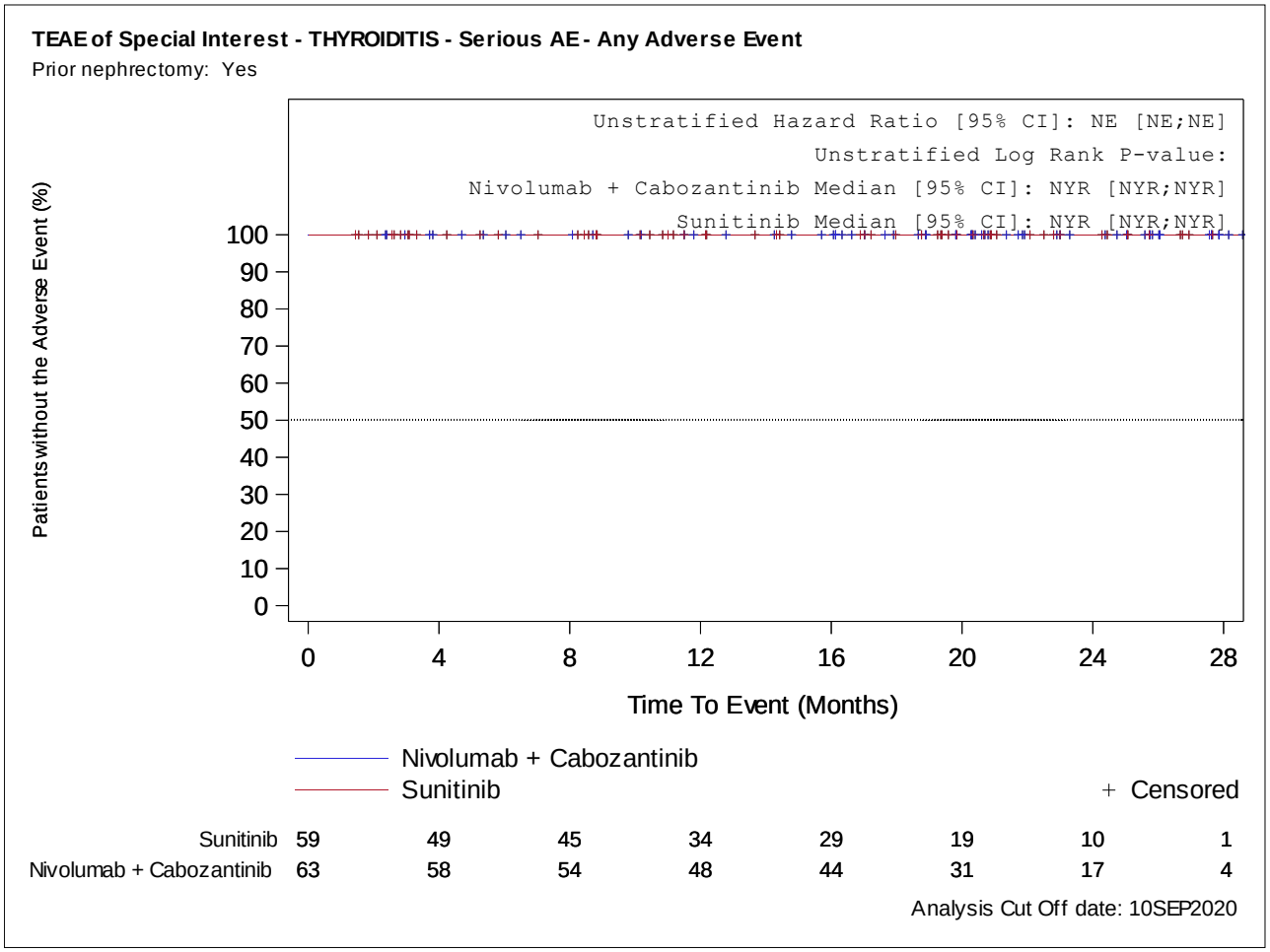
FIGURE 3.111.2.18: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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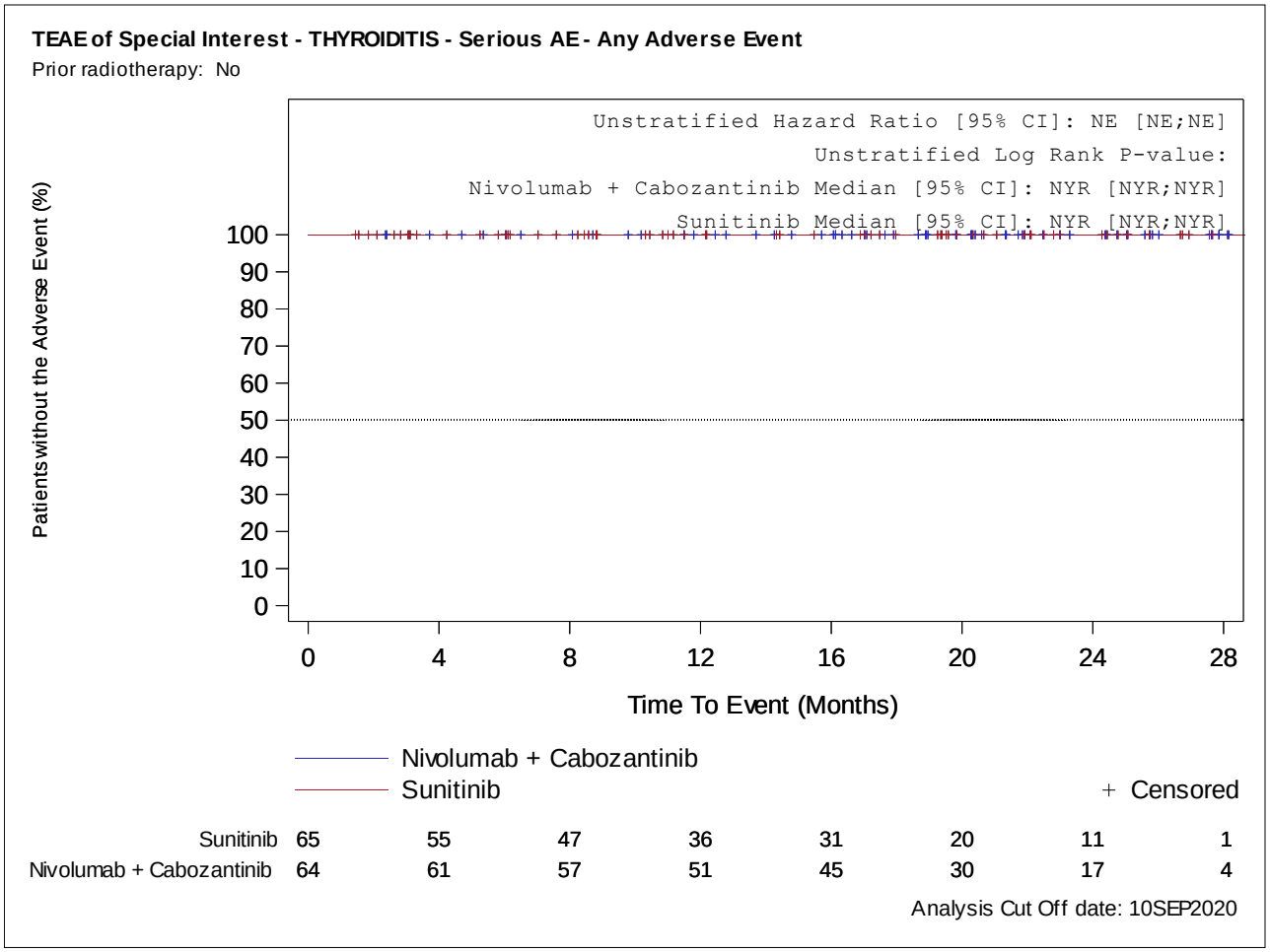
FIGURE 3.111.2.19: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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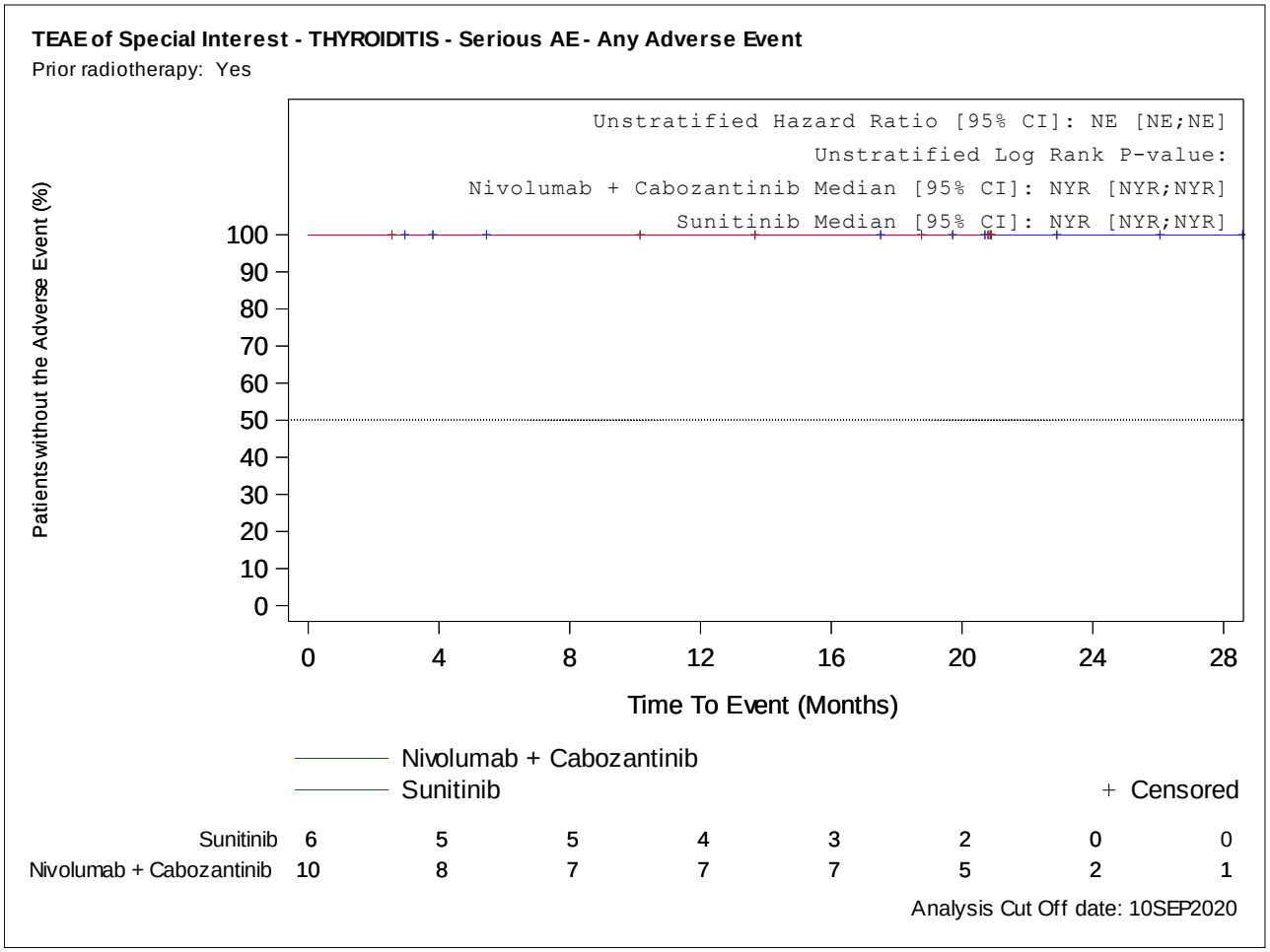
FIGURE 3.111.2.20: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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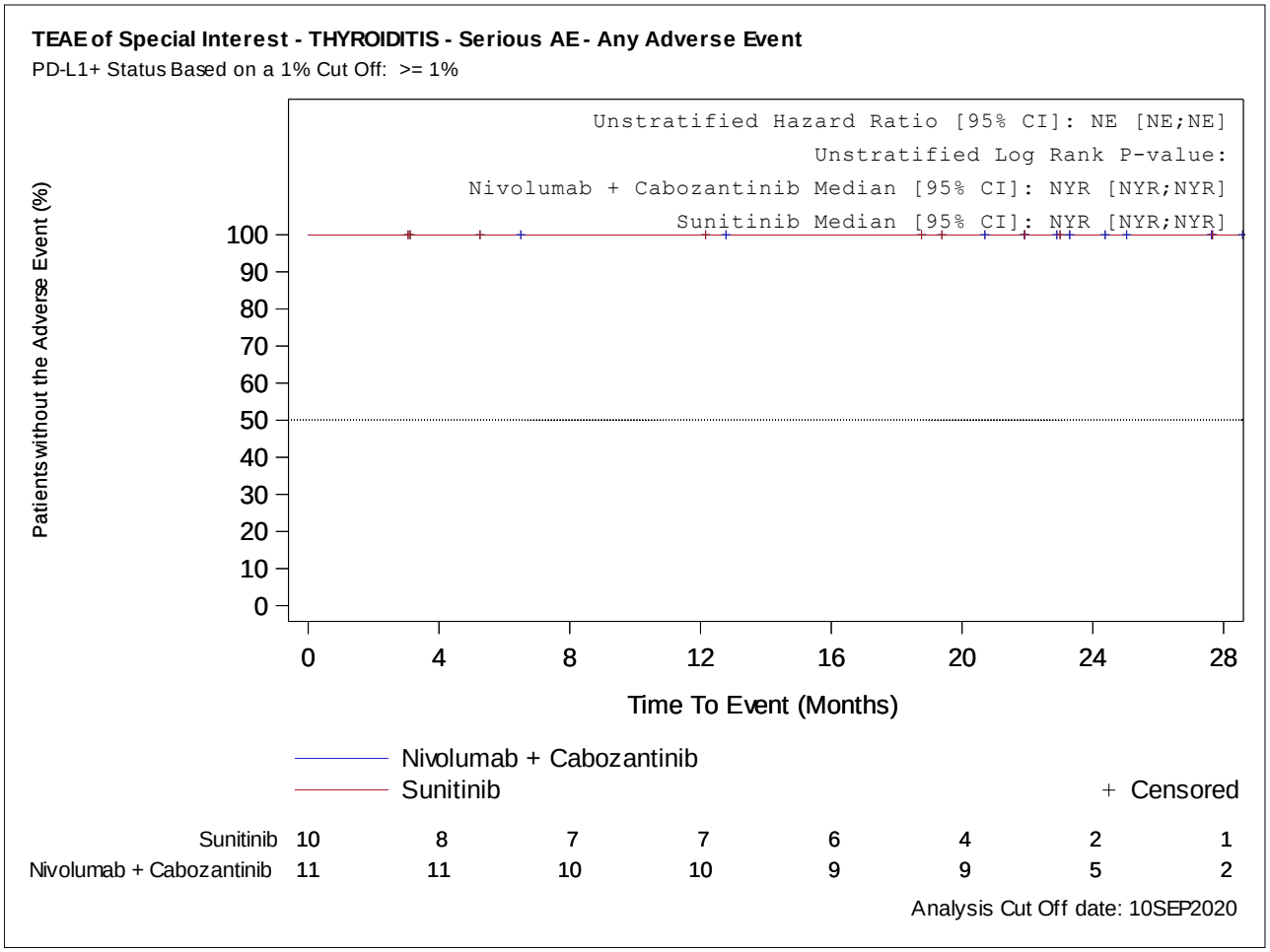
FIGURE 3.111.2.21: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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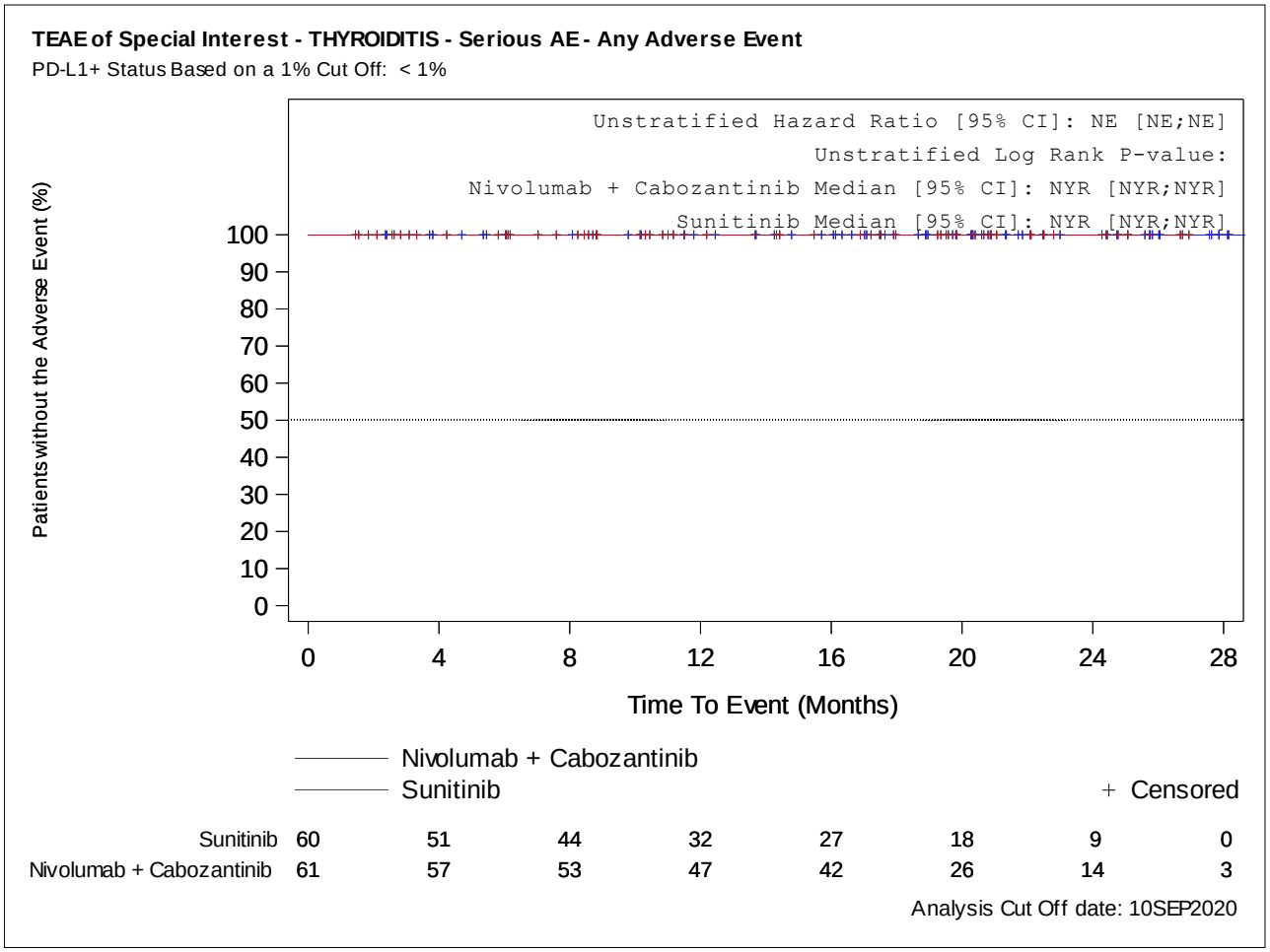
FIGURE 3.111.2.22: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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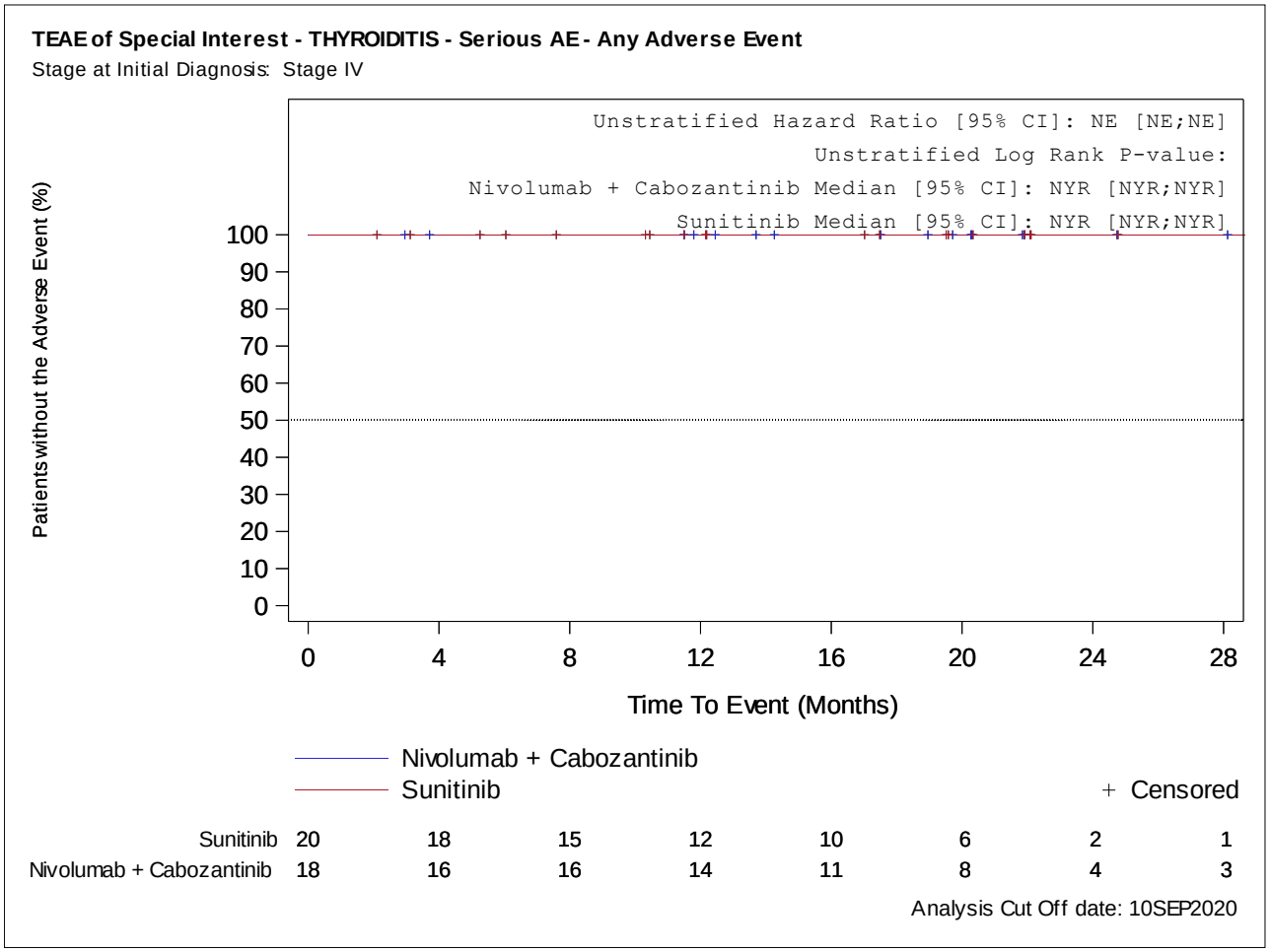
FIGURE 3.111.2.23: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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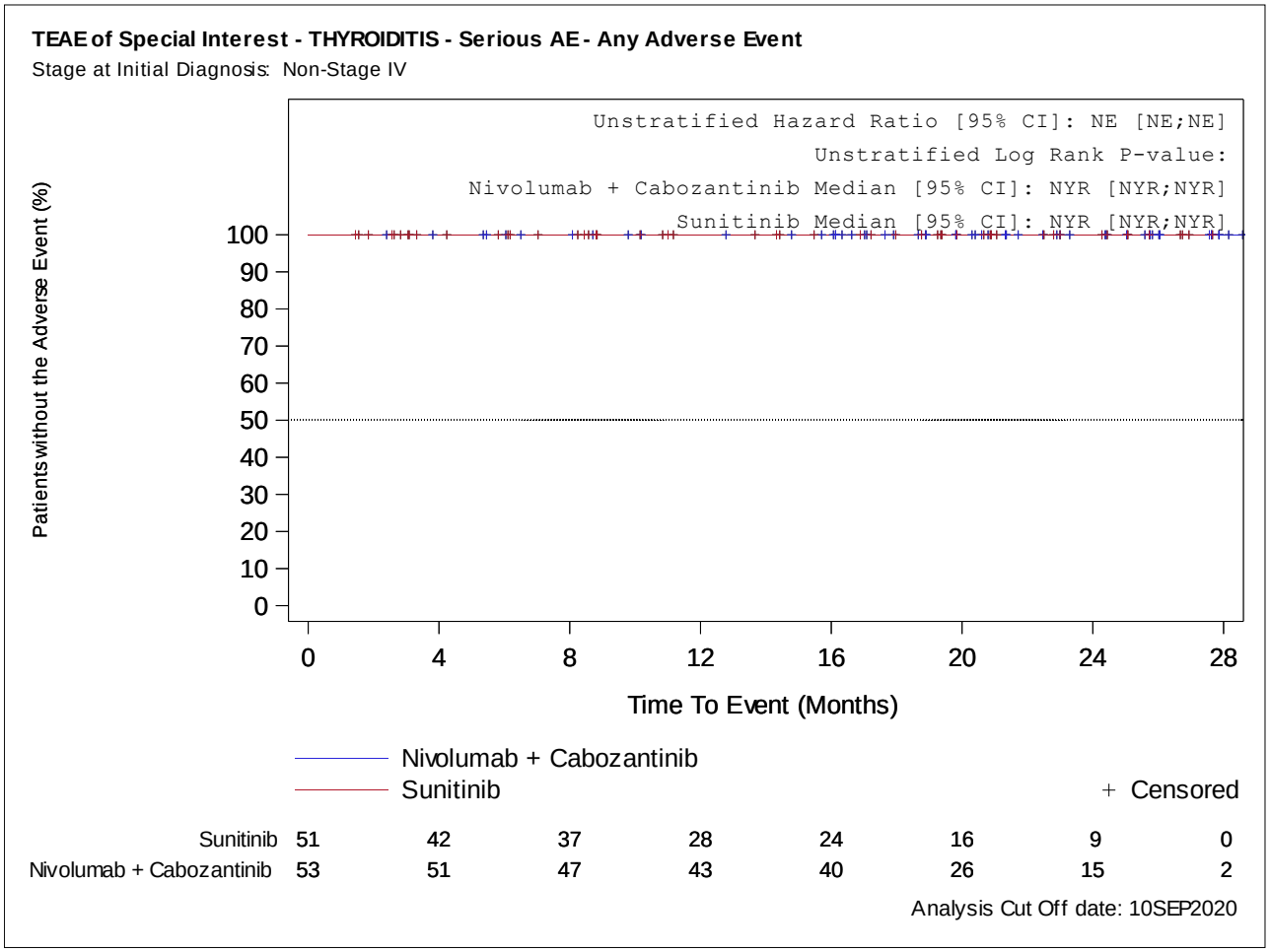
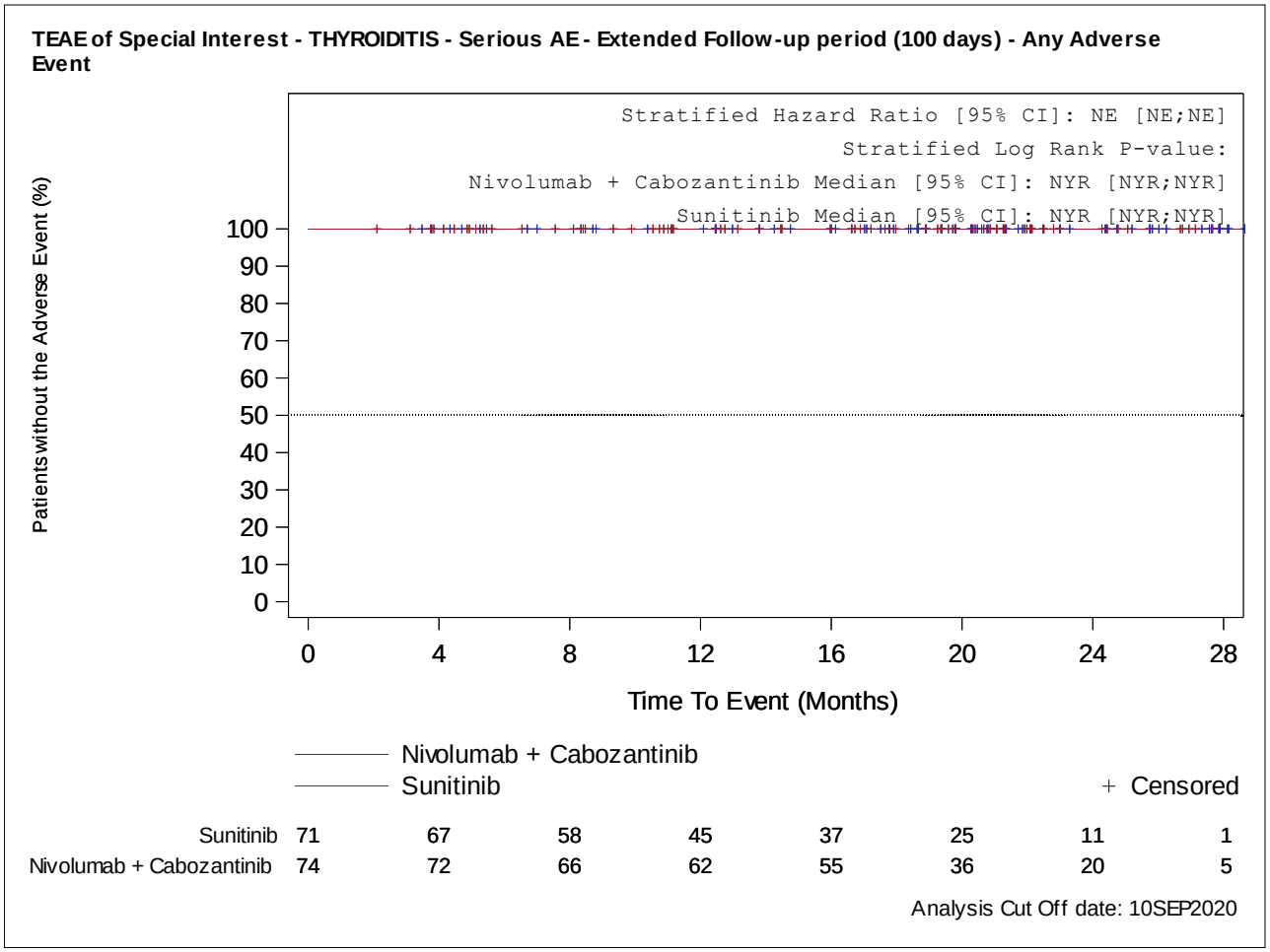
FIGURE 3.111.2.24: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



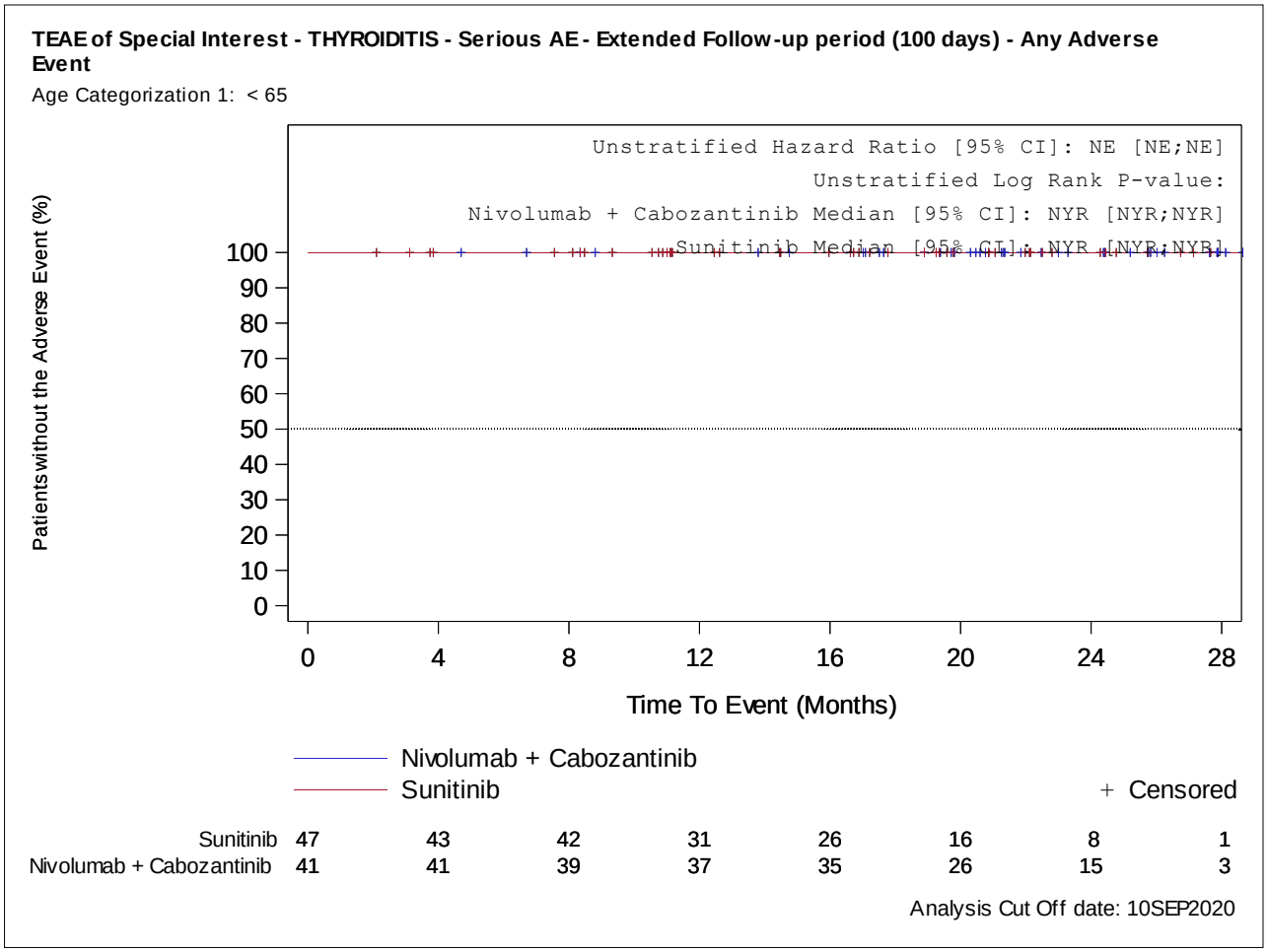

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:39:51

FIGURE 3.112.1: TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:42:48

FIGURE 3.112.2.1: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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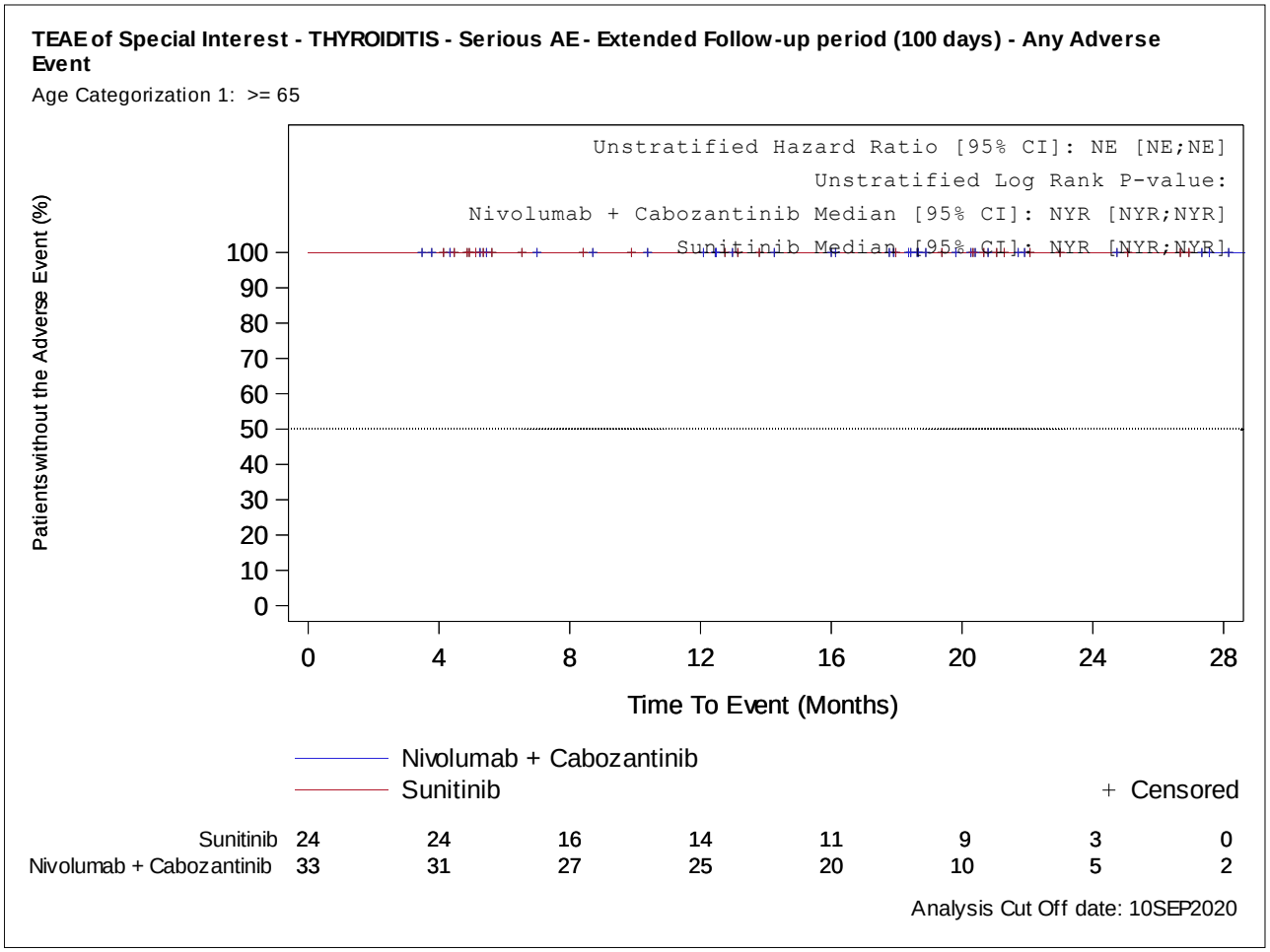
FIGURE 3.112.2.2: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
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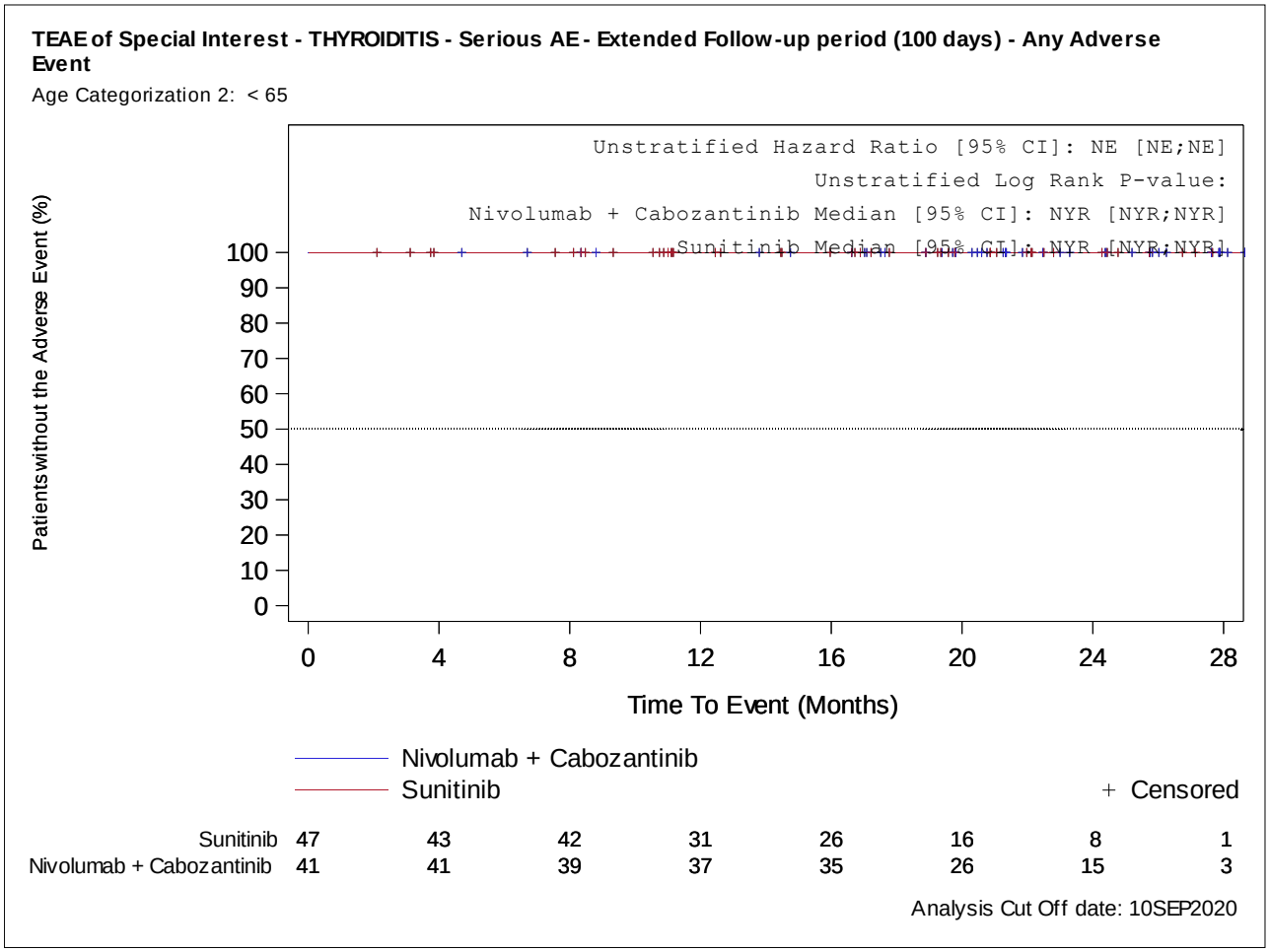
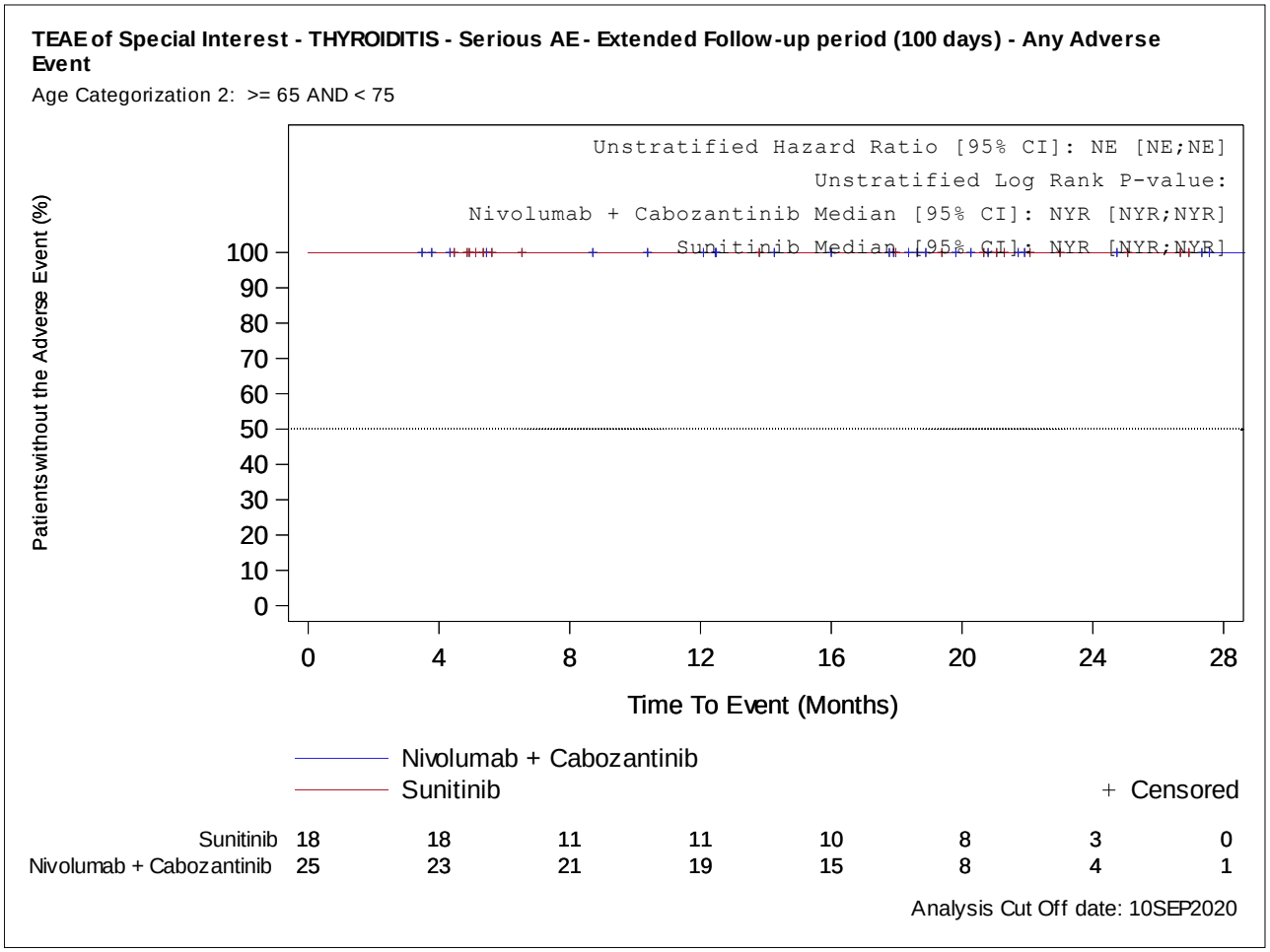
FIGURE 3.112.2.3: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:43:01

FIGURE 3.112.2.4: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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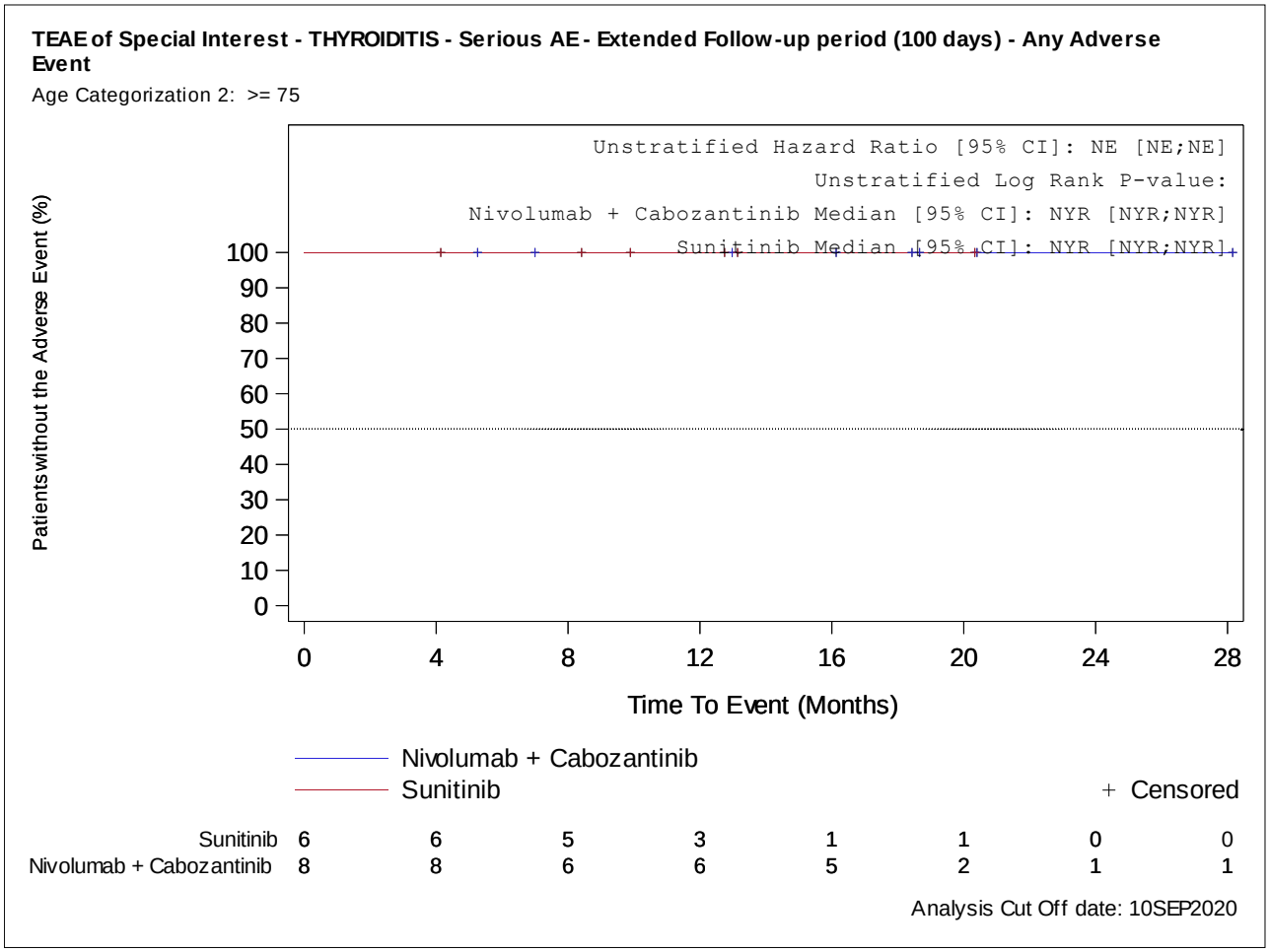
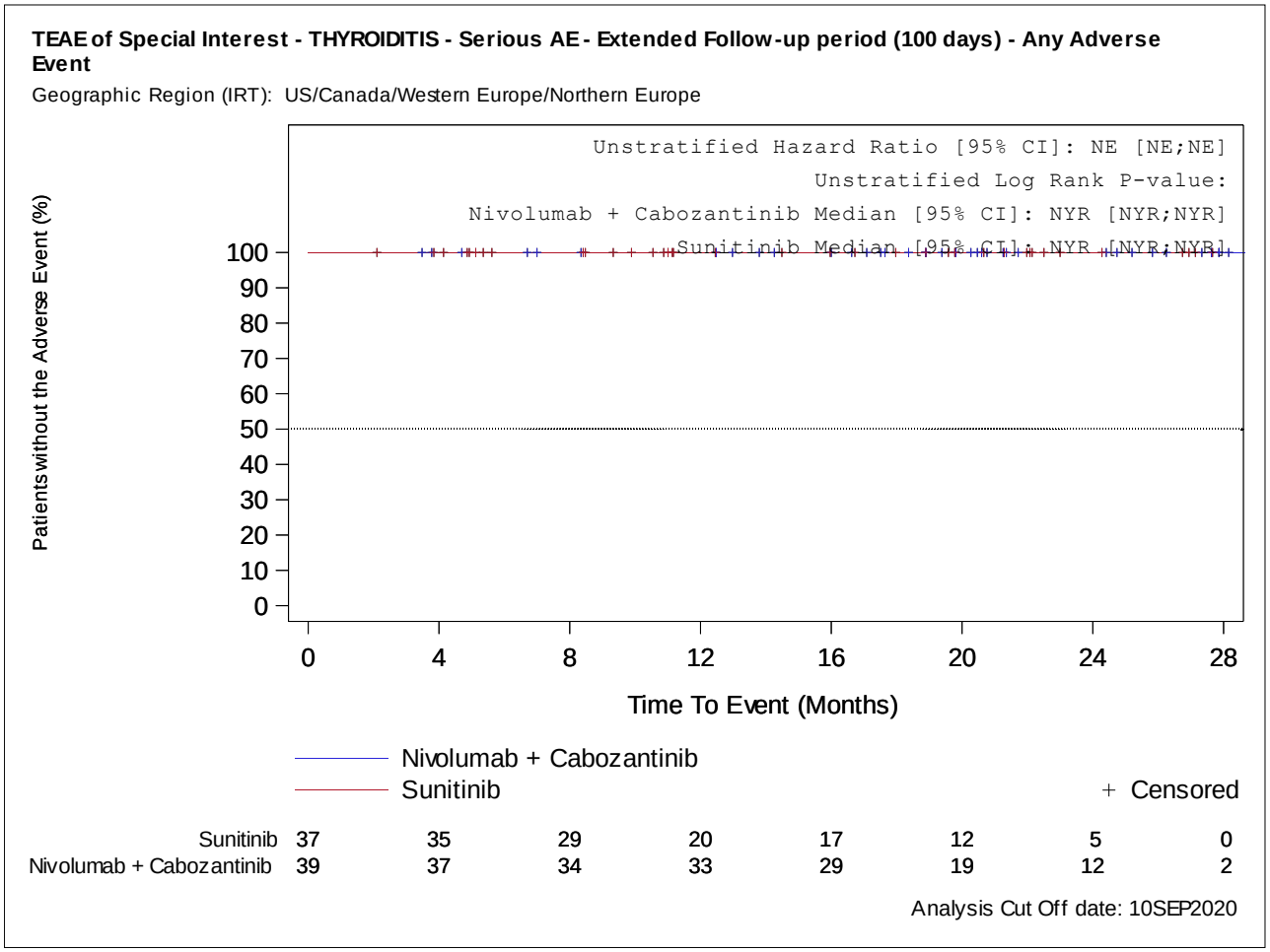
FIGURE 3.112.2.5: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



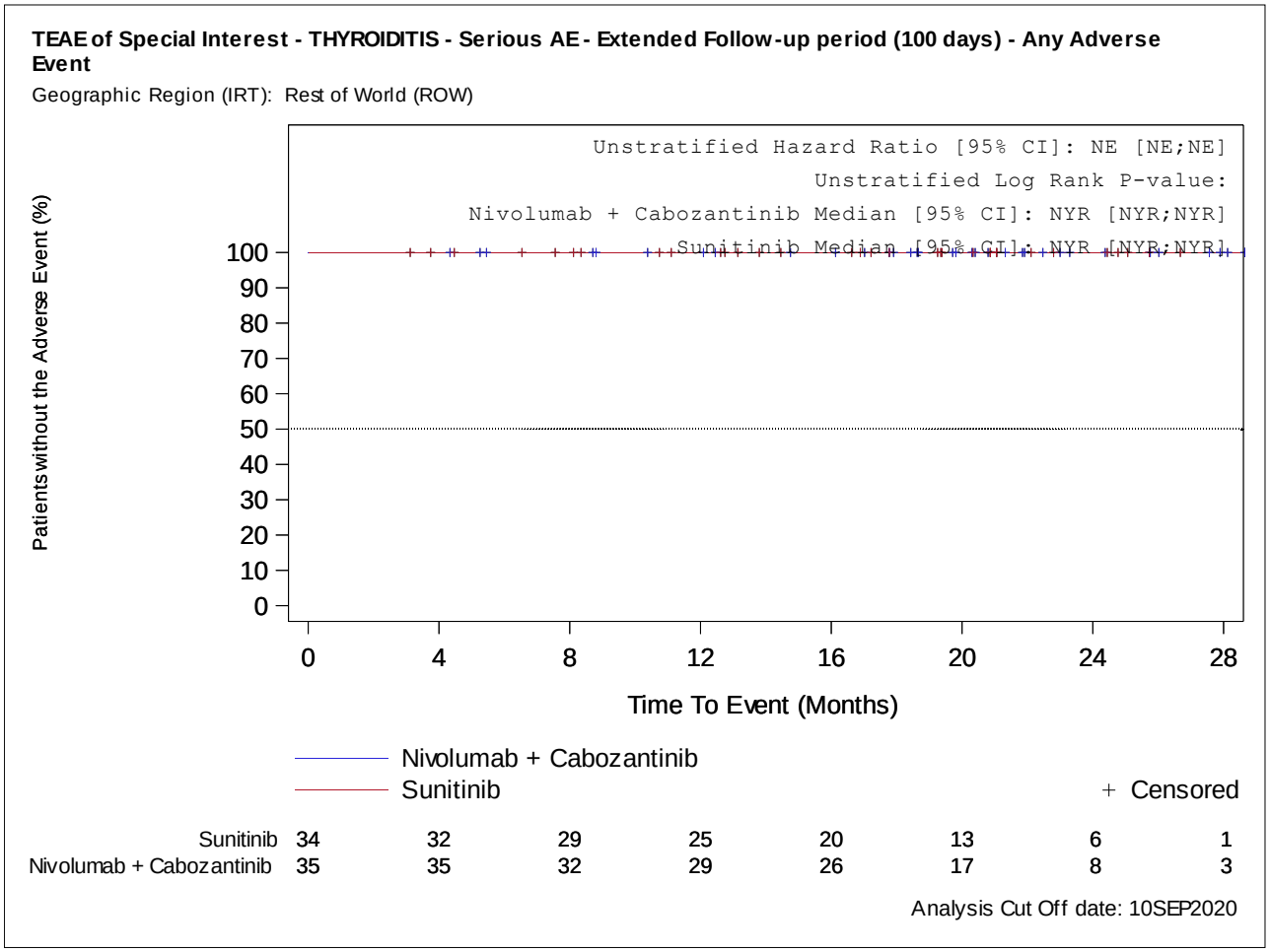

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at  0:43:11

FIGURE 3.112.2.6: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



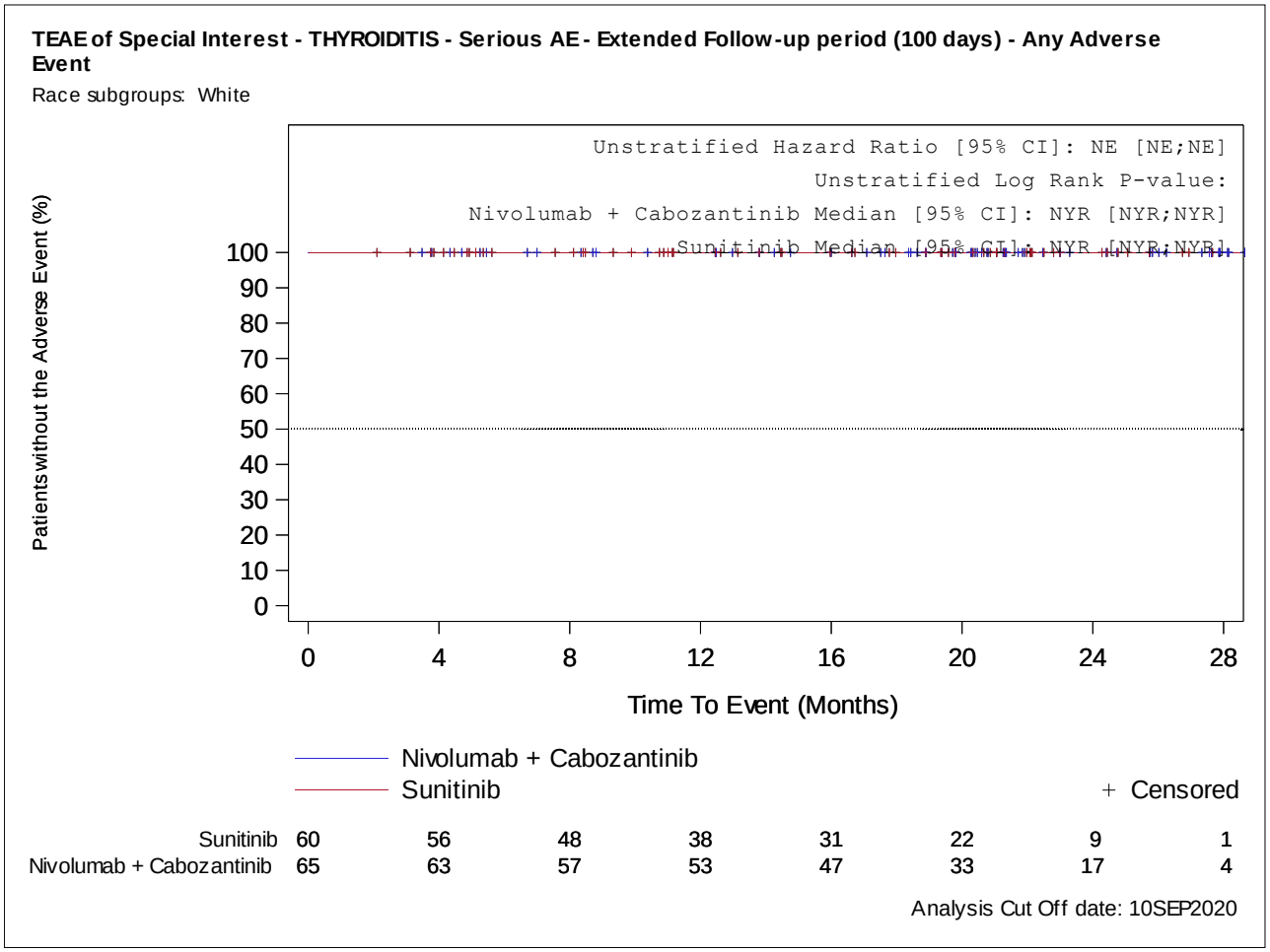

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:43:17

FIGURE 3.112.2.7: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



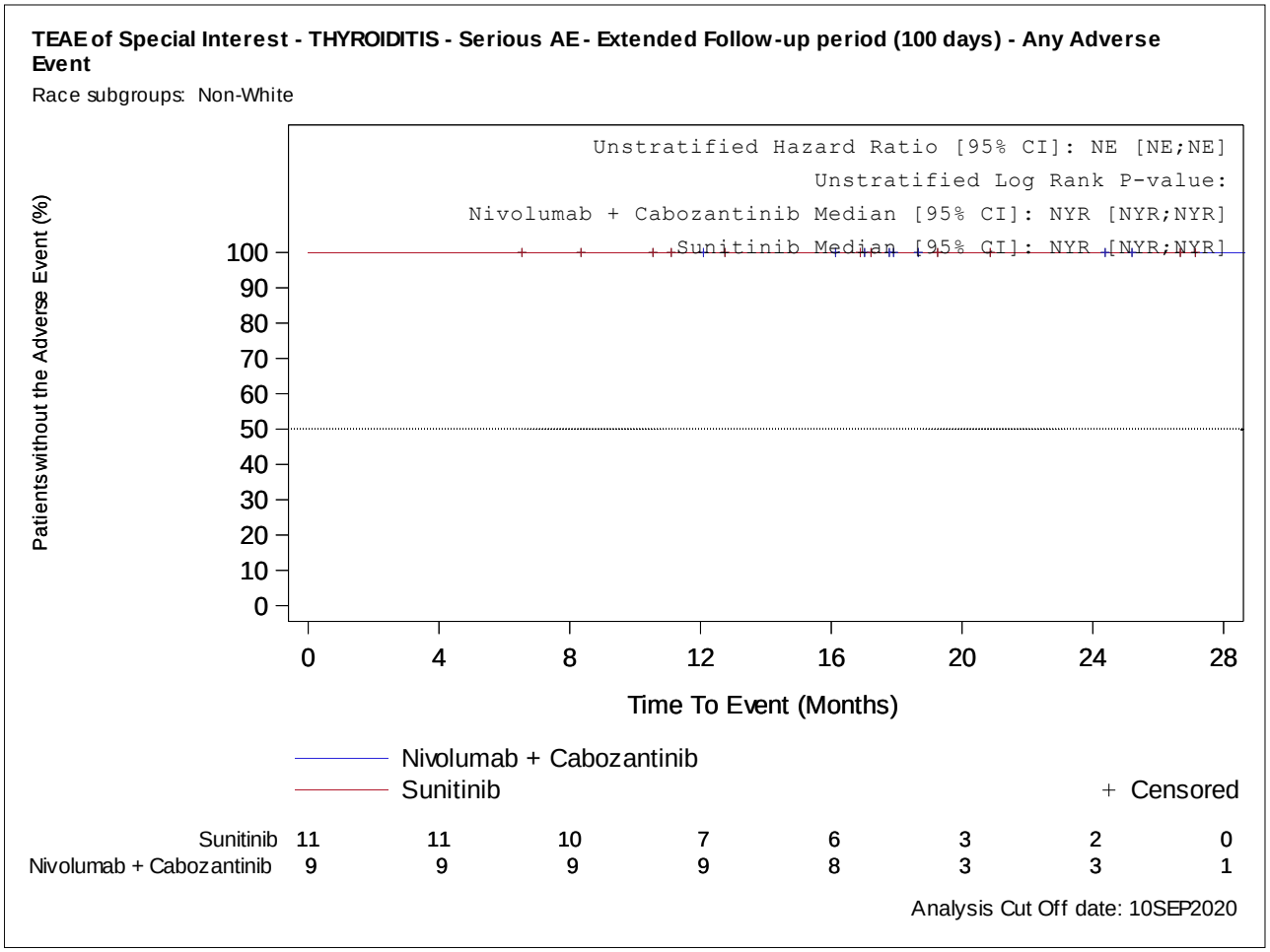

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:43:22

FIGURE 3.112.2.8: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



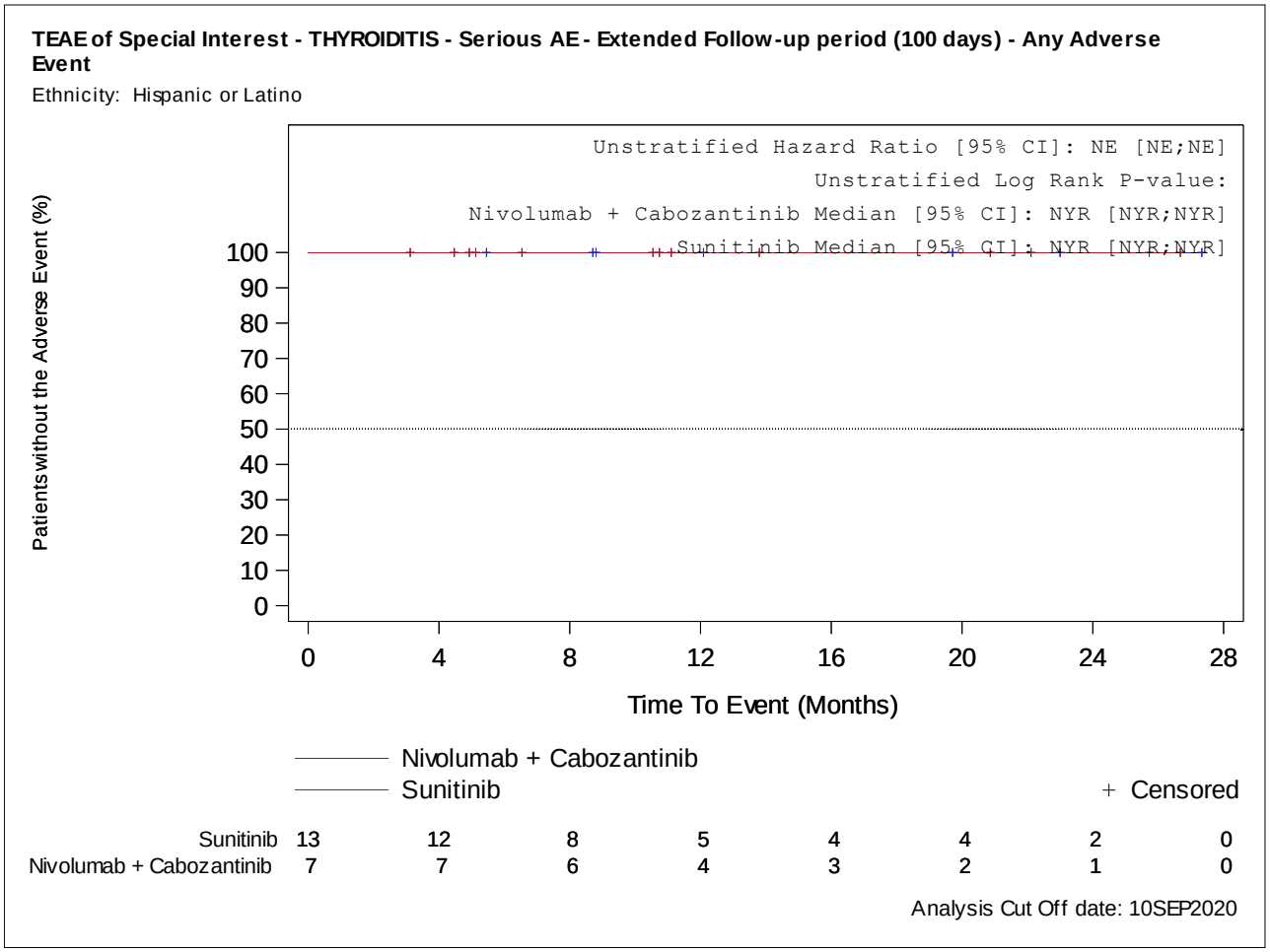

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:43:27

FIGURE 3.112.2.9: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



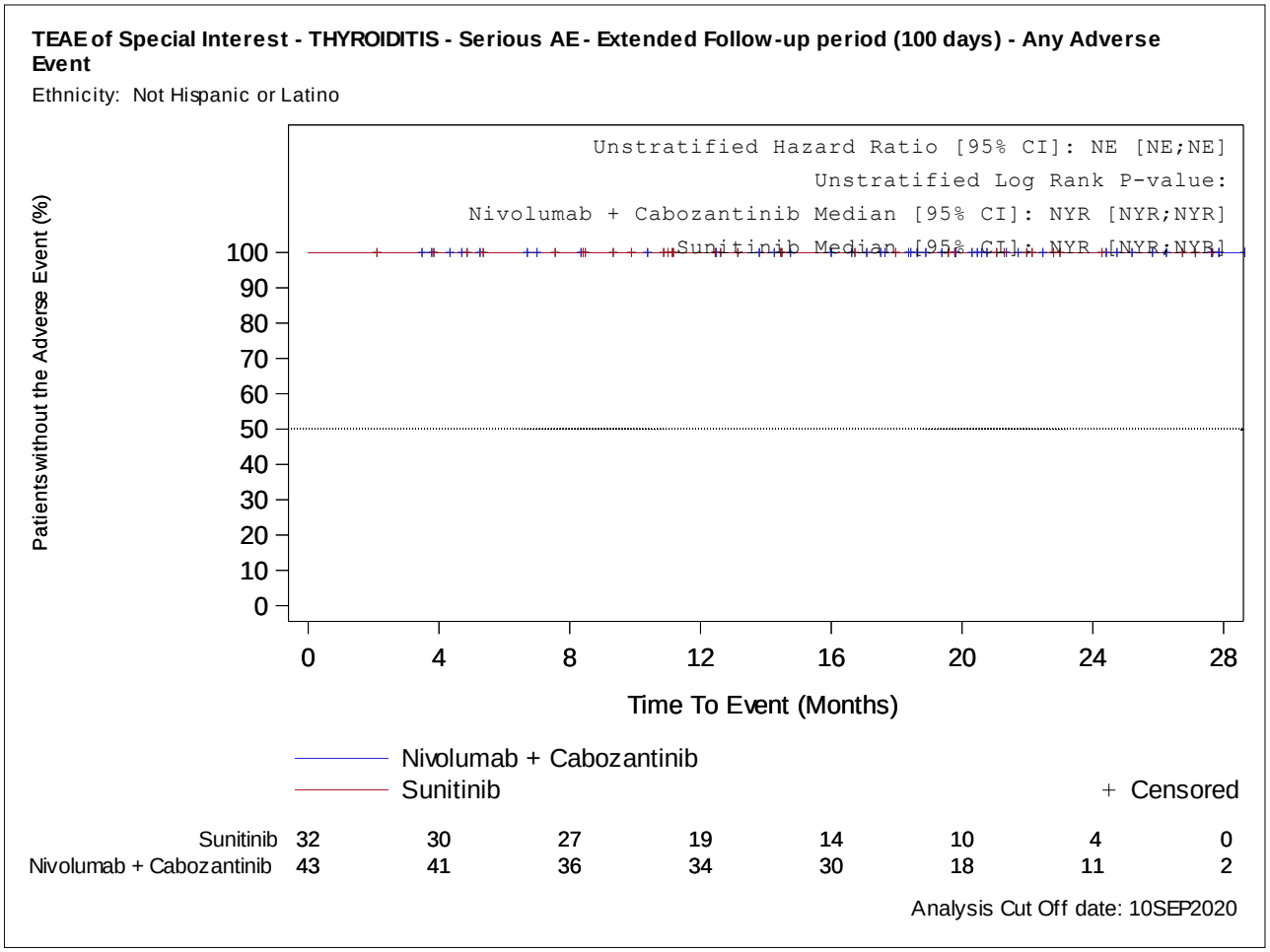

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:43:32

FIGURE 3.112.2.10: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:43:37

FIGURE 3.112.2.11: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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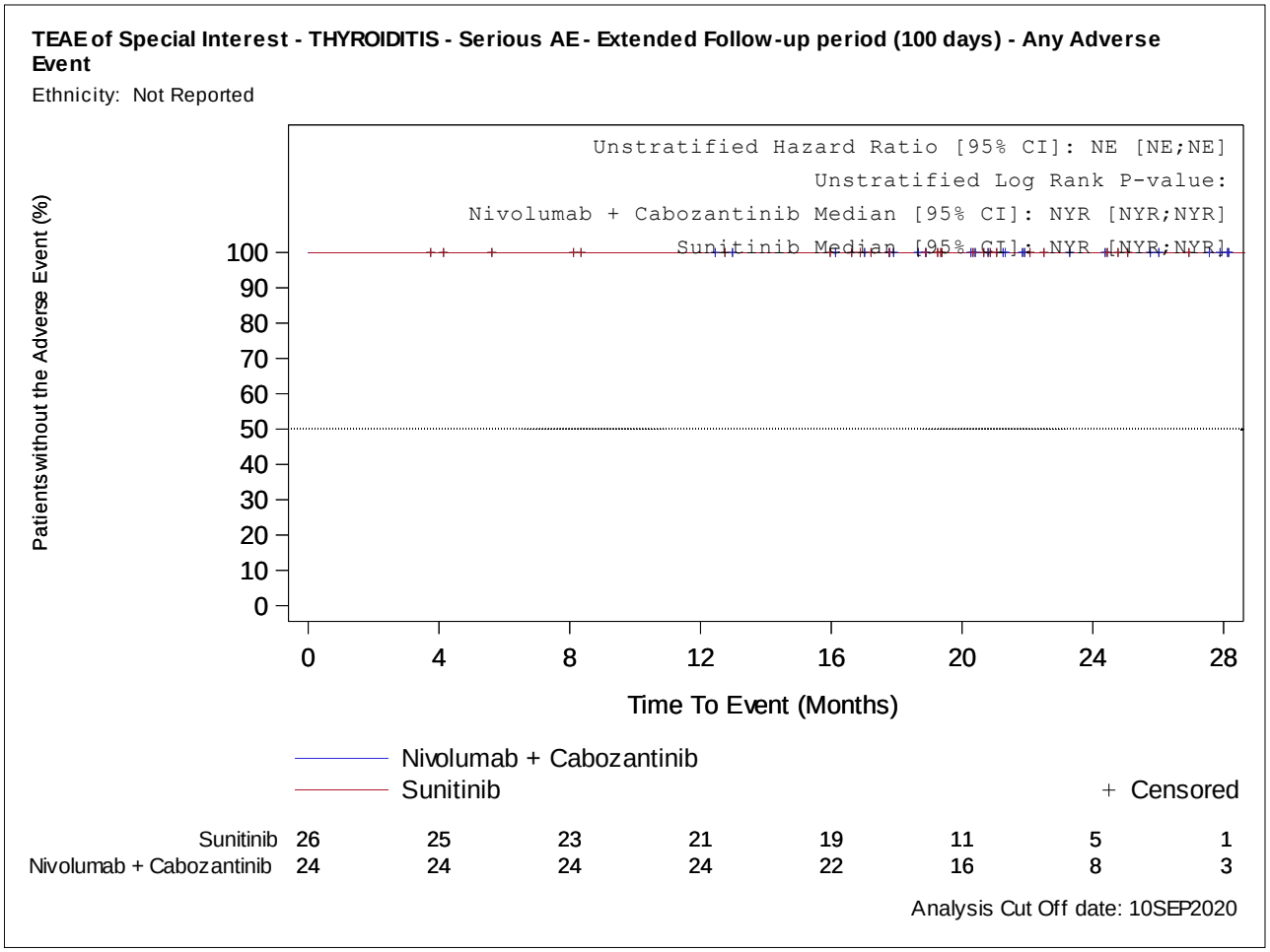
FIGURE 3.112.2.12: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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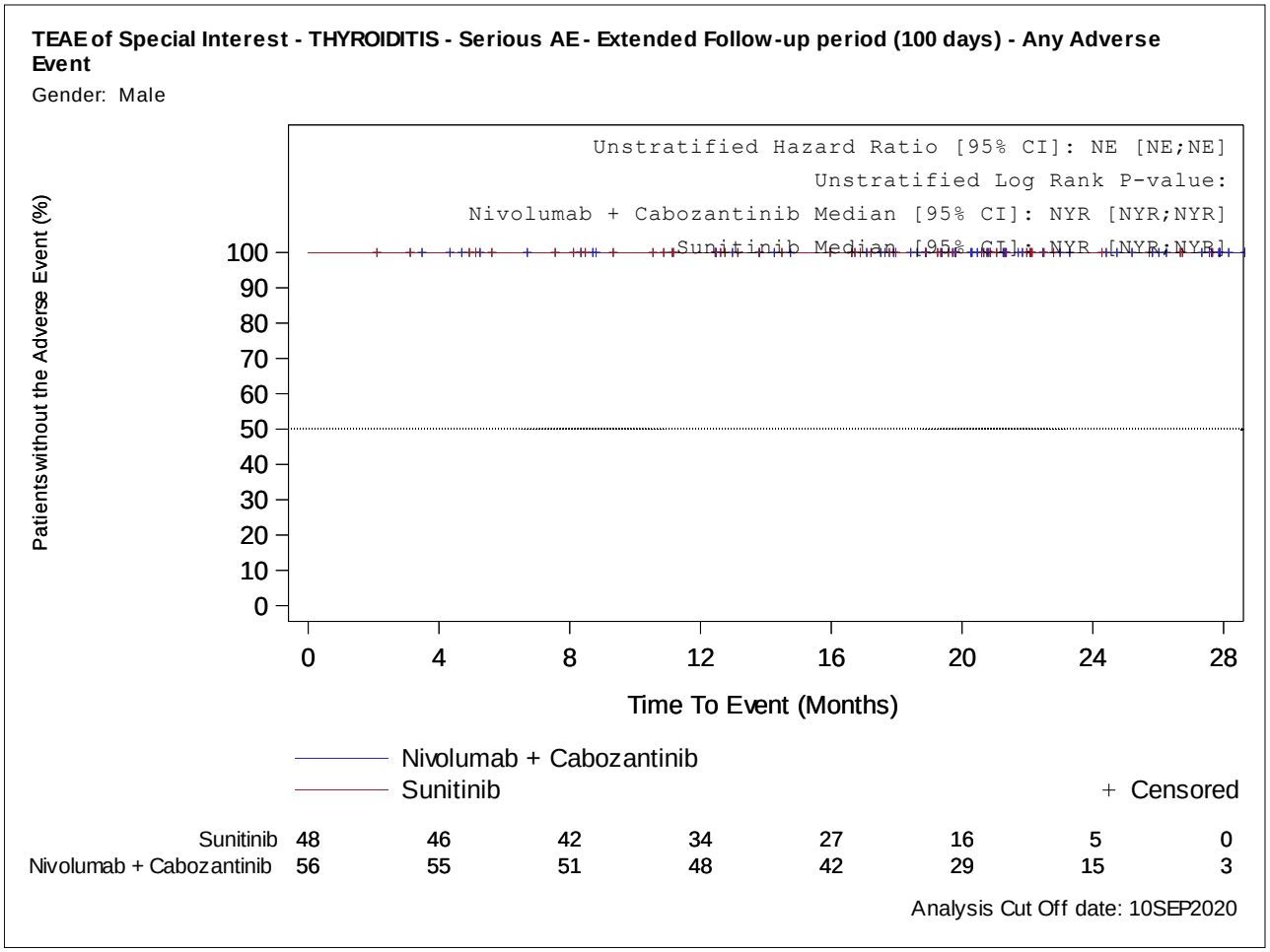
FIGURE 3.112.2.13: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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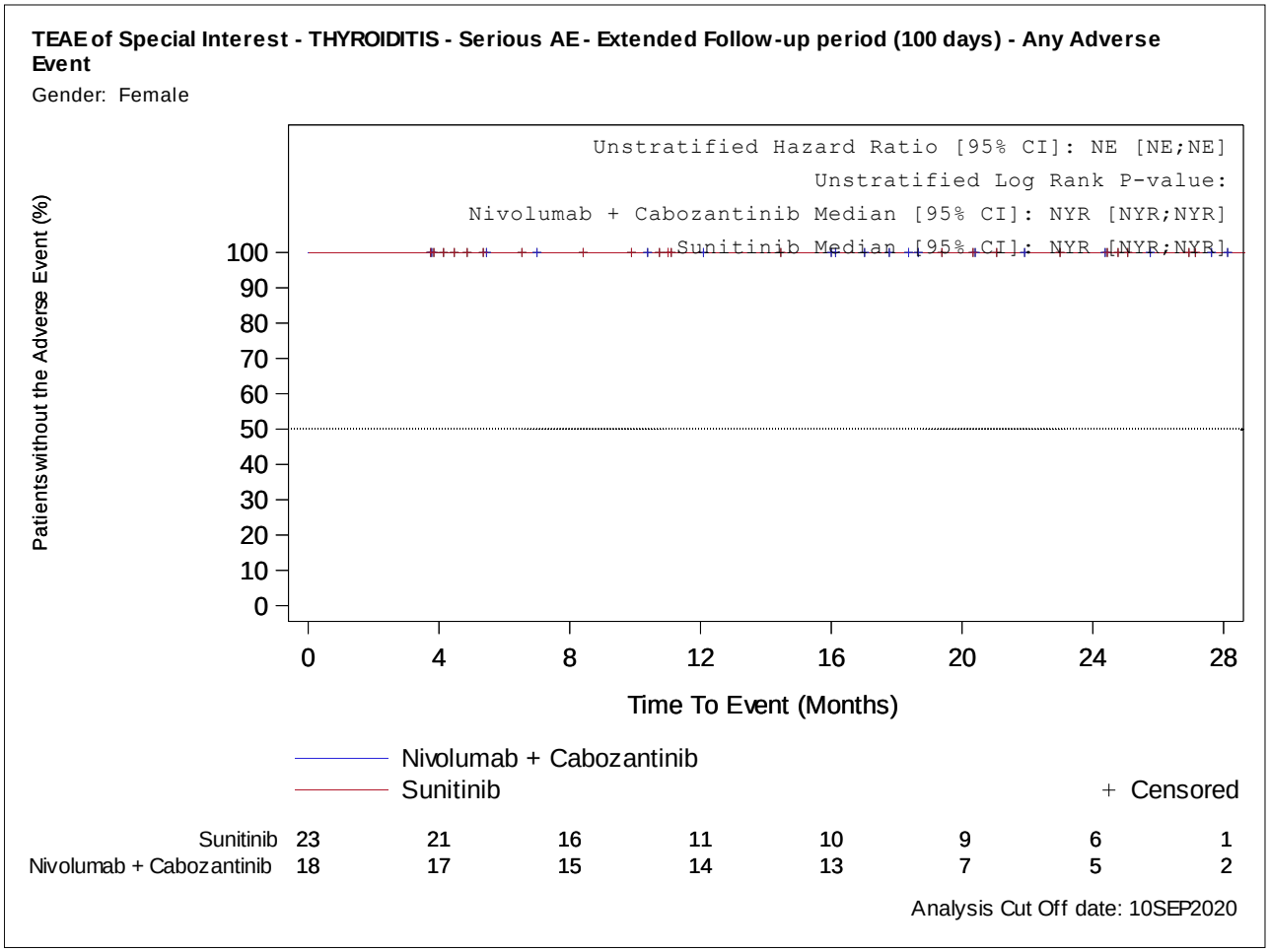
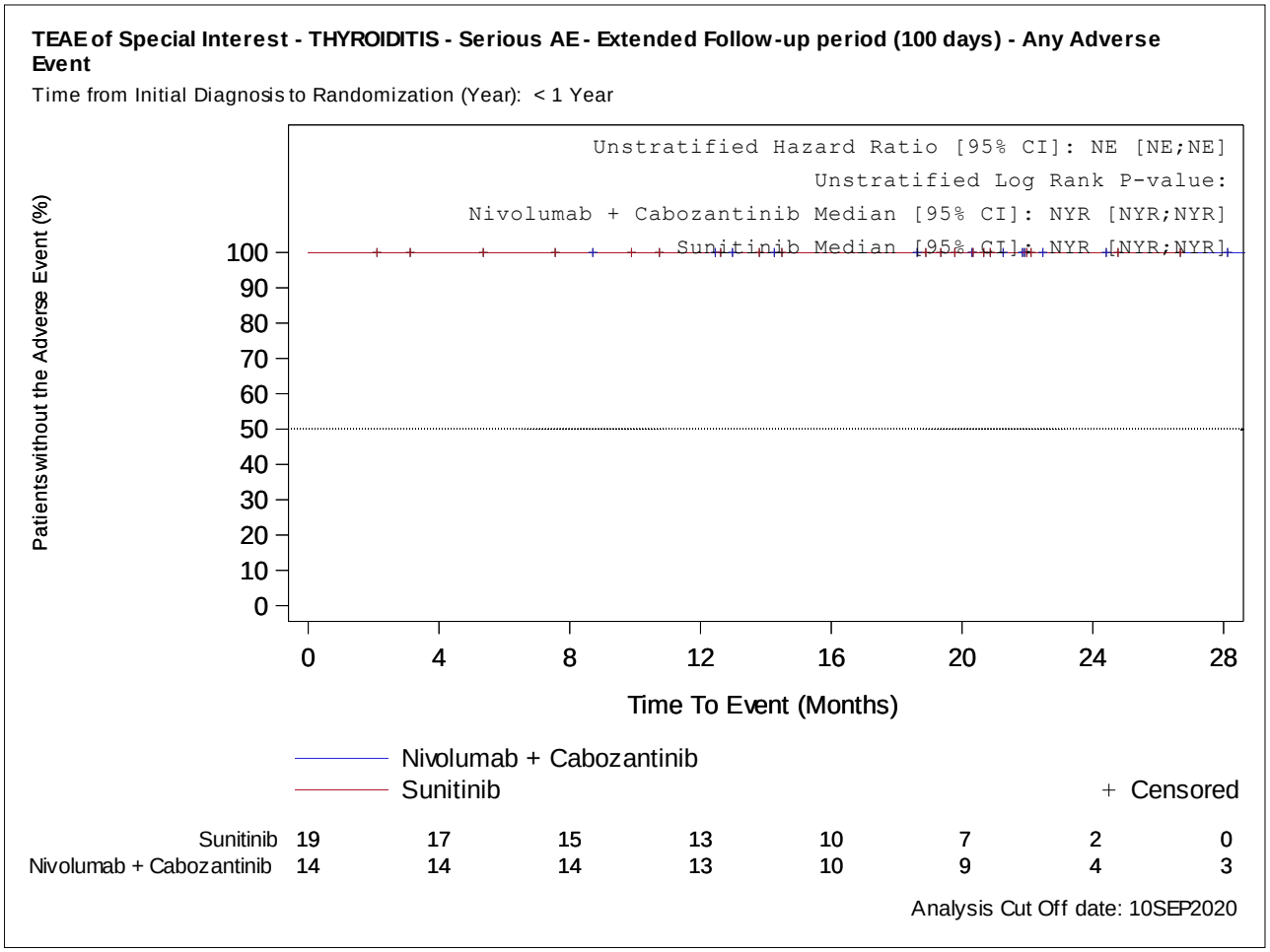
FIGURE 3.112.2.14: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



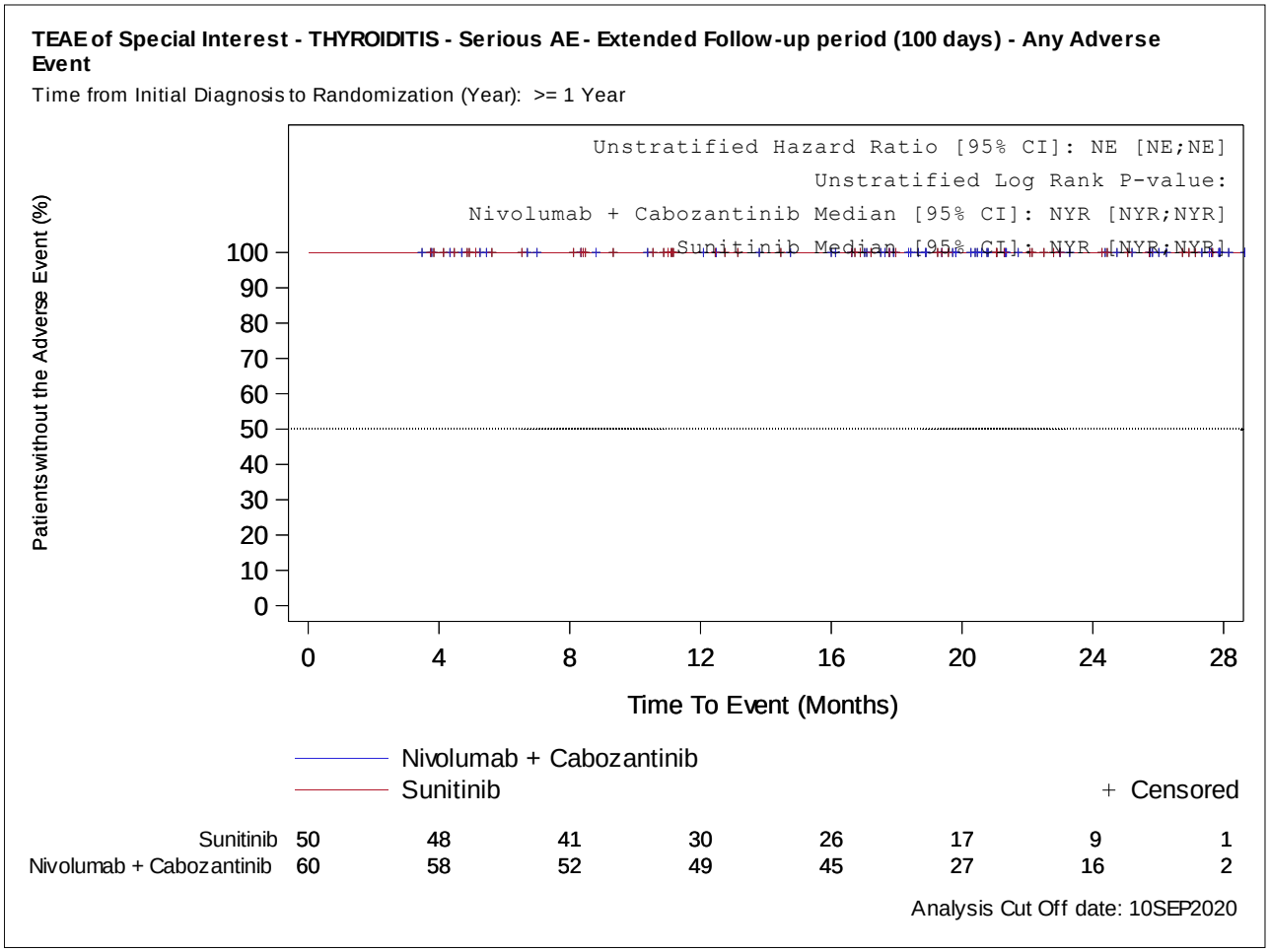

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:43:59

FIGURE 3.112.2.15: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



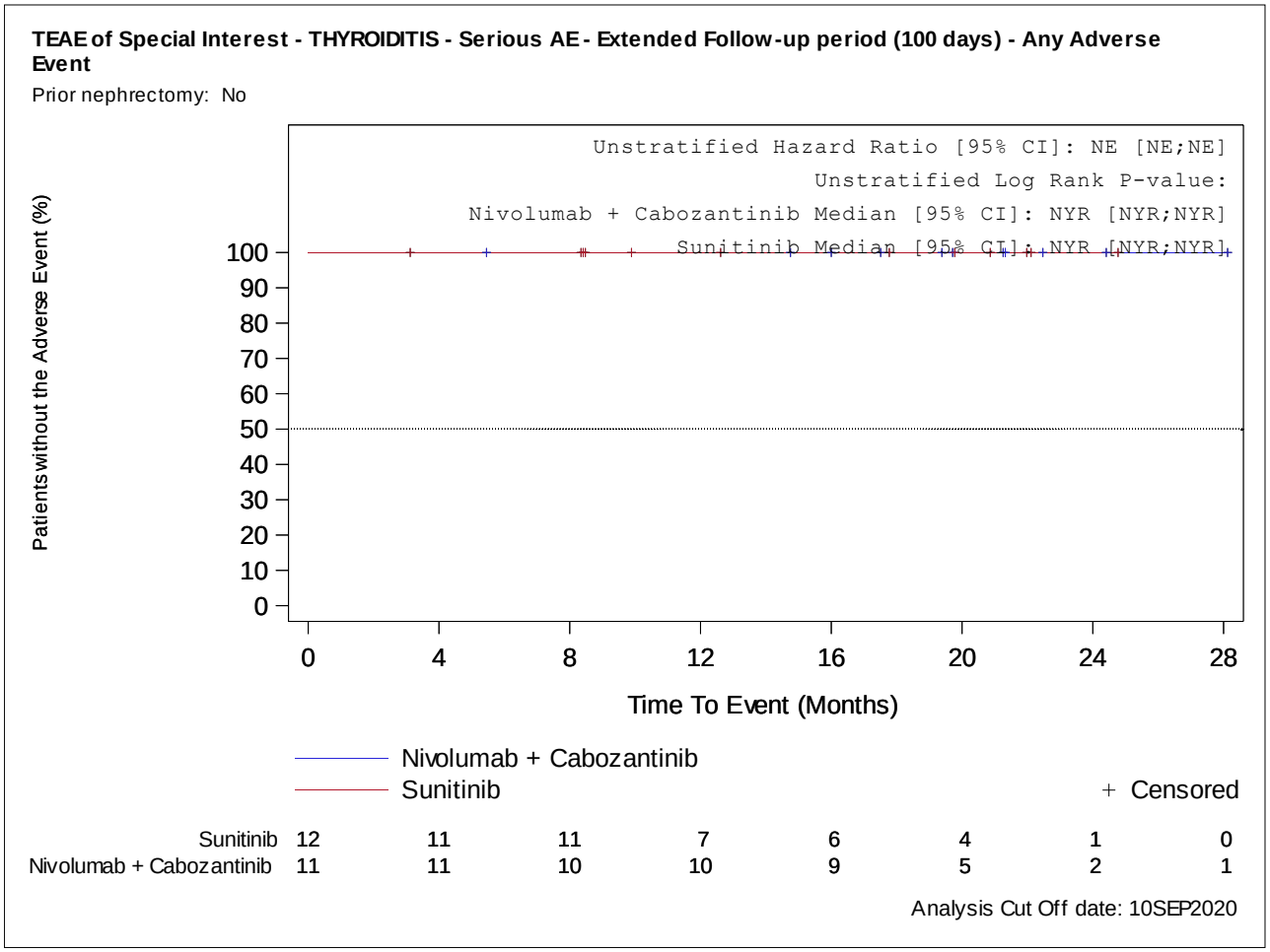

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:44:14

FIGURE 3.112.2.16: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



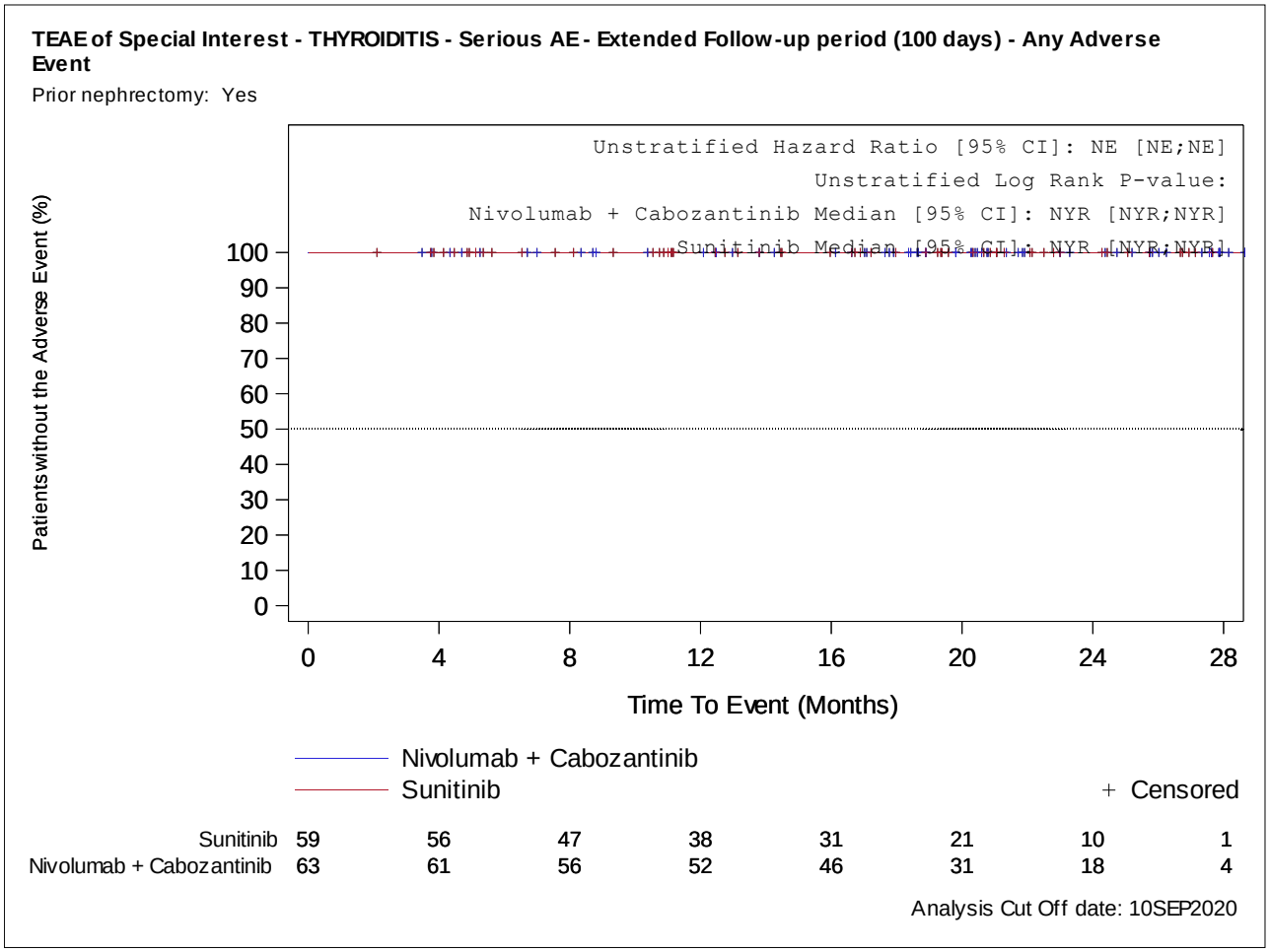

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:44:20

FIGURE 3.112.2.17: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



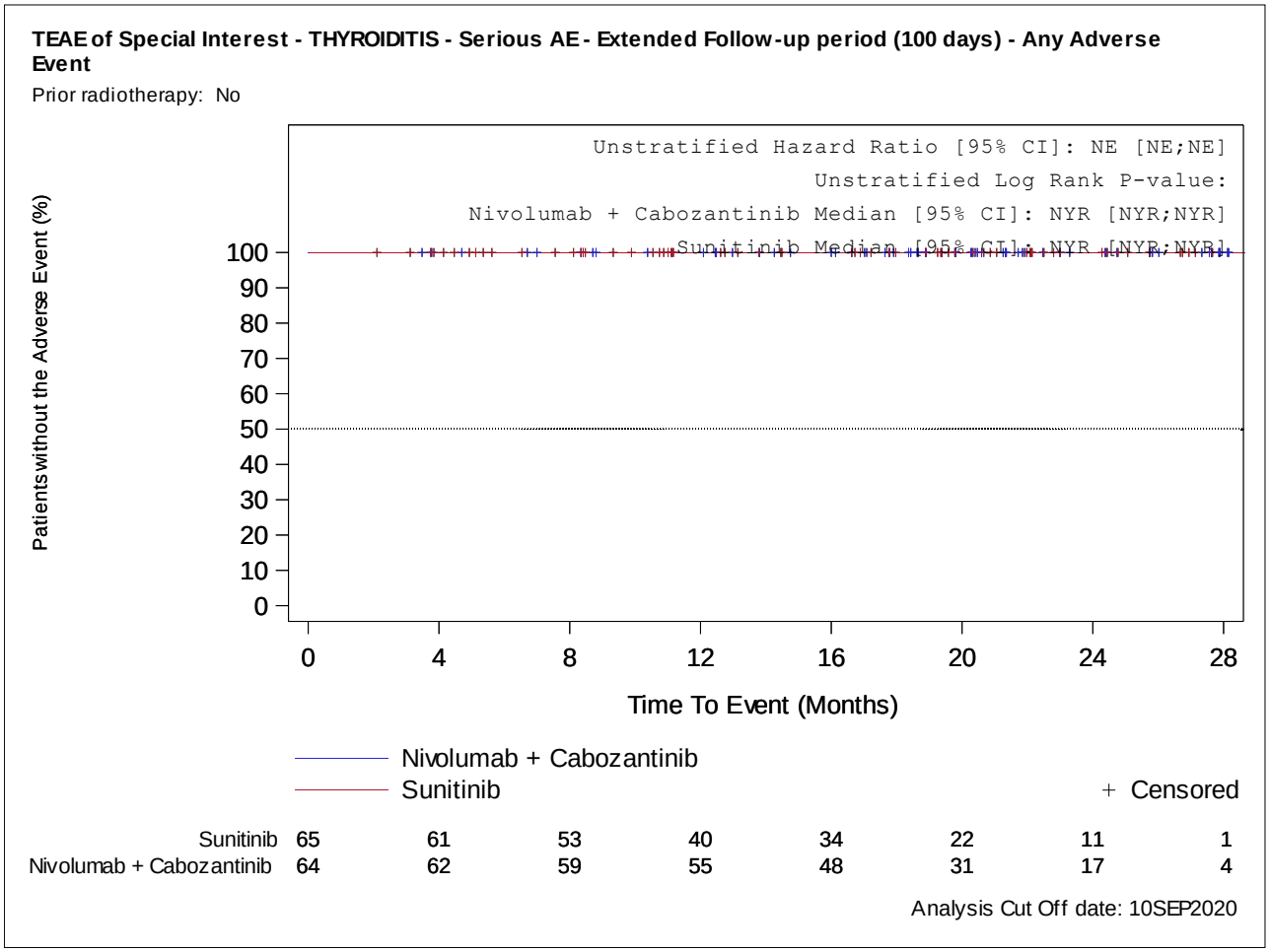

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:45:07

FIGURE 3.112.2.18: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:45:12

FIGURE 3.112.2.19: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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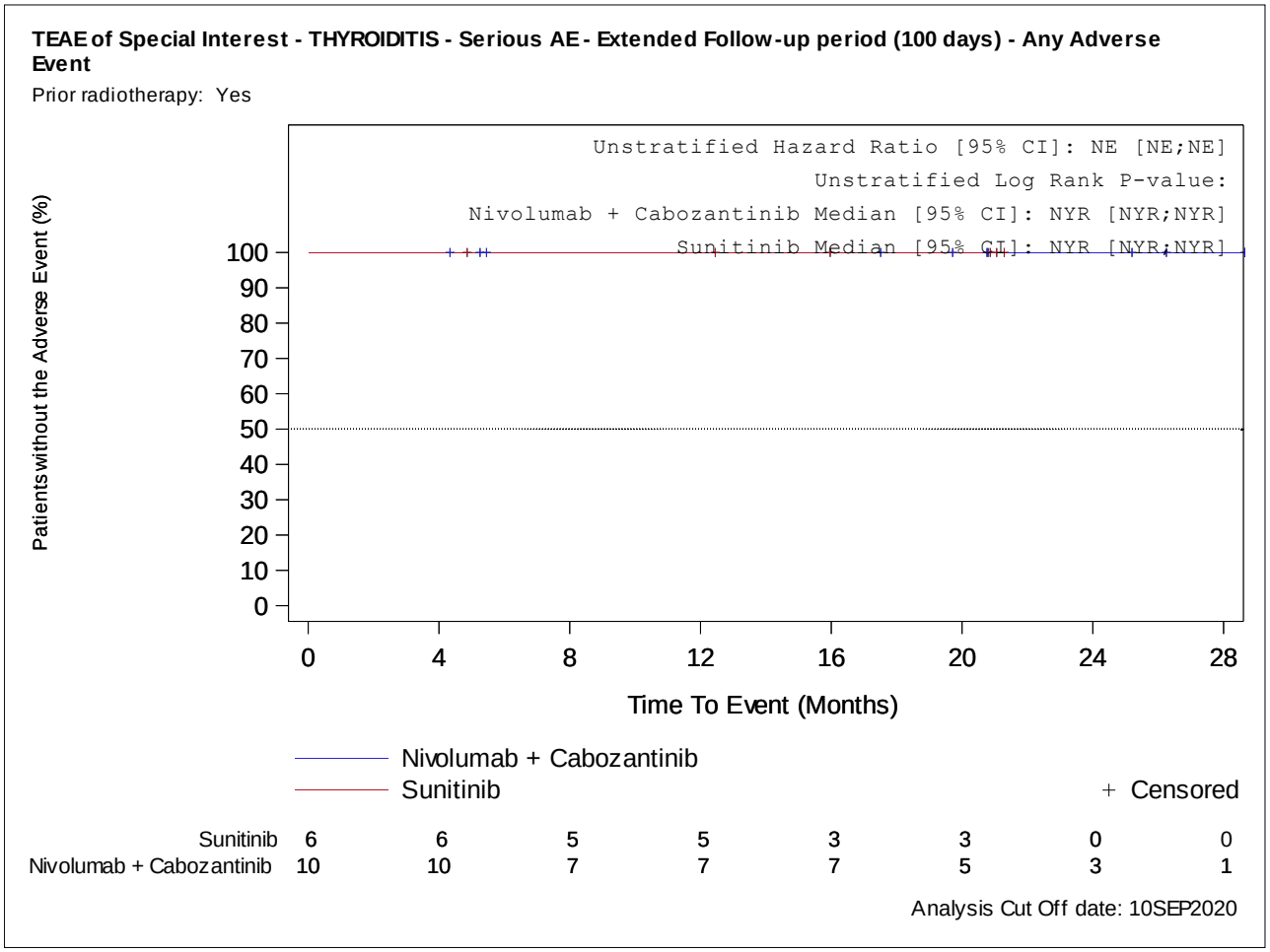
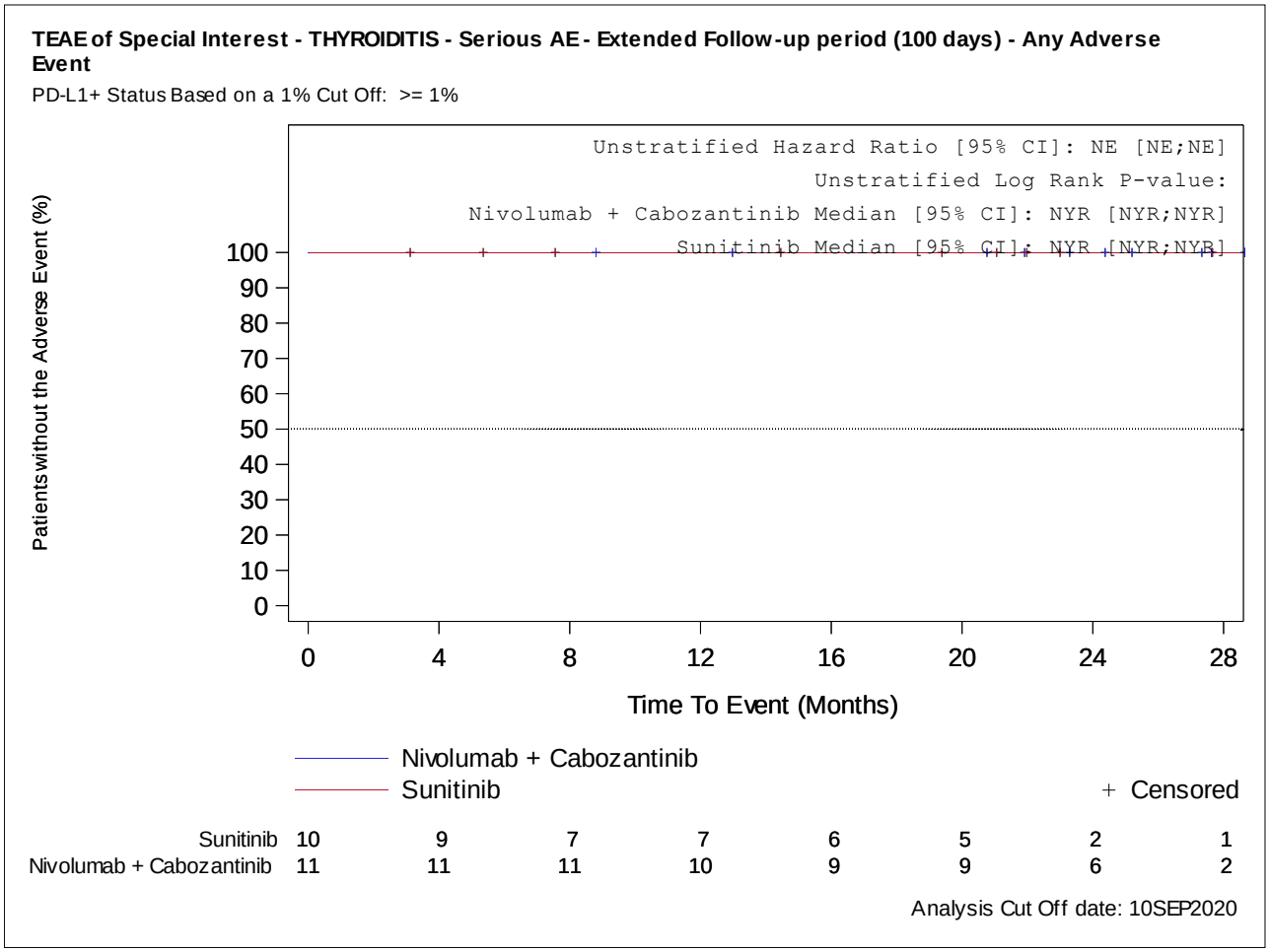
FIGURE 3.112.2.20: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:45:24

FIGURE 3.112.2.21: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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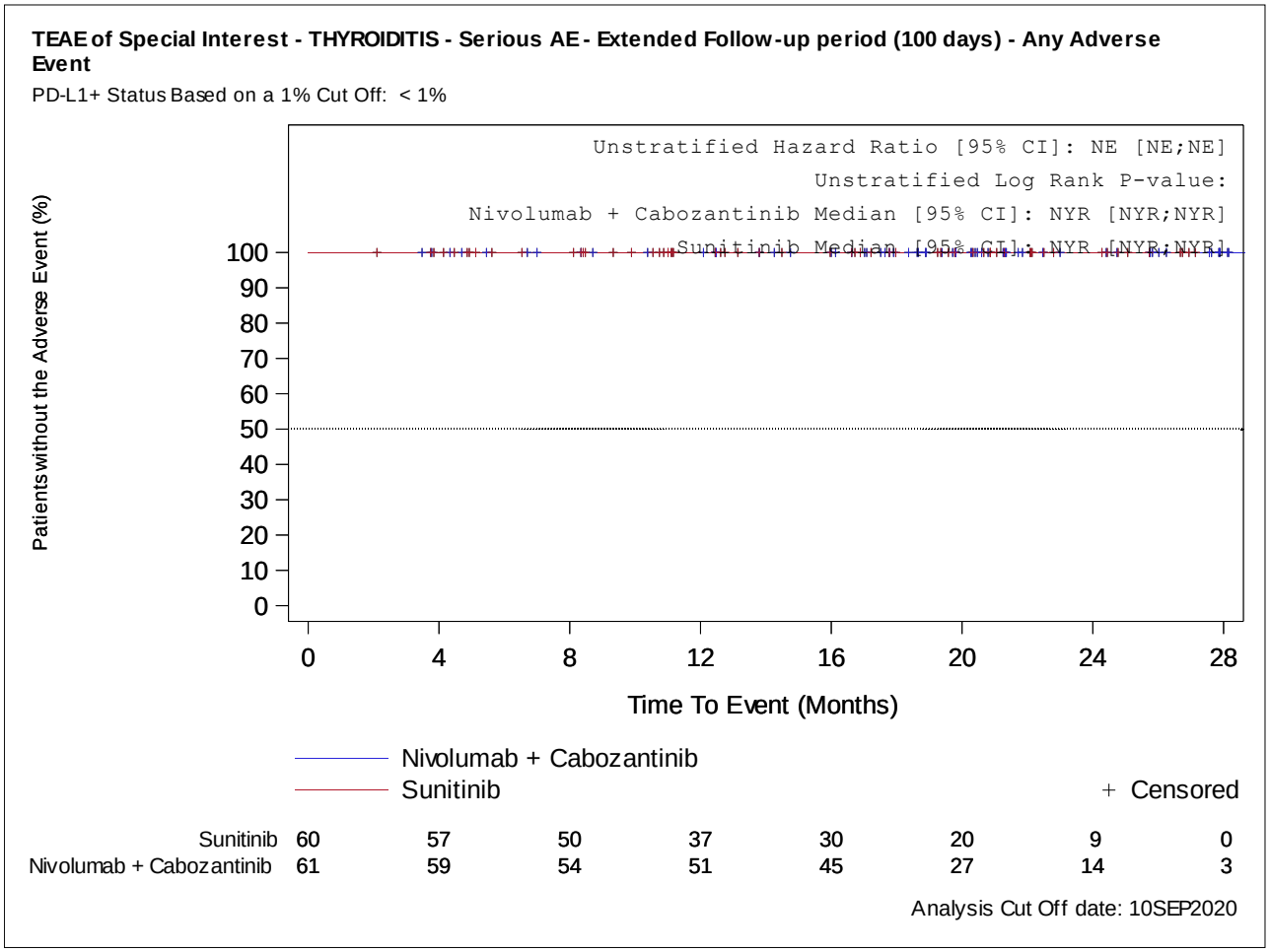
FIGURE 3.112.2.22: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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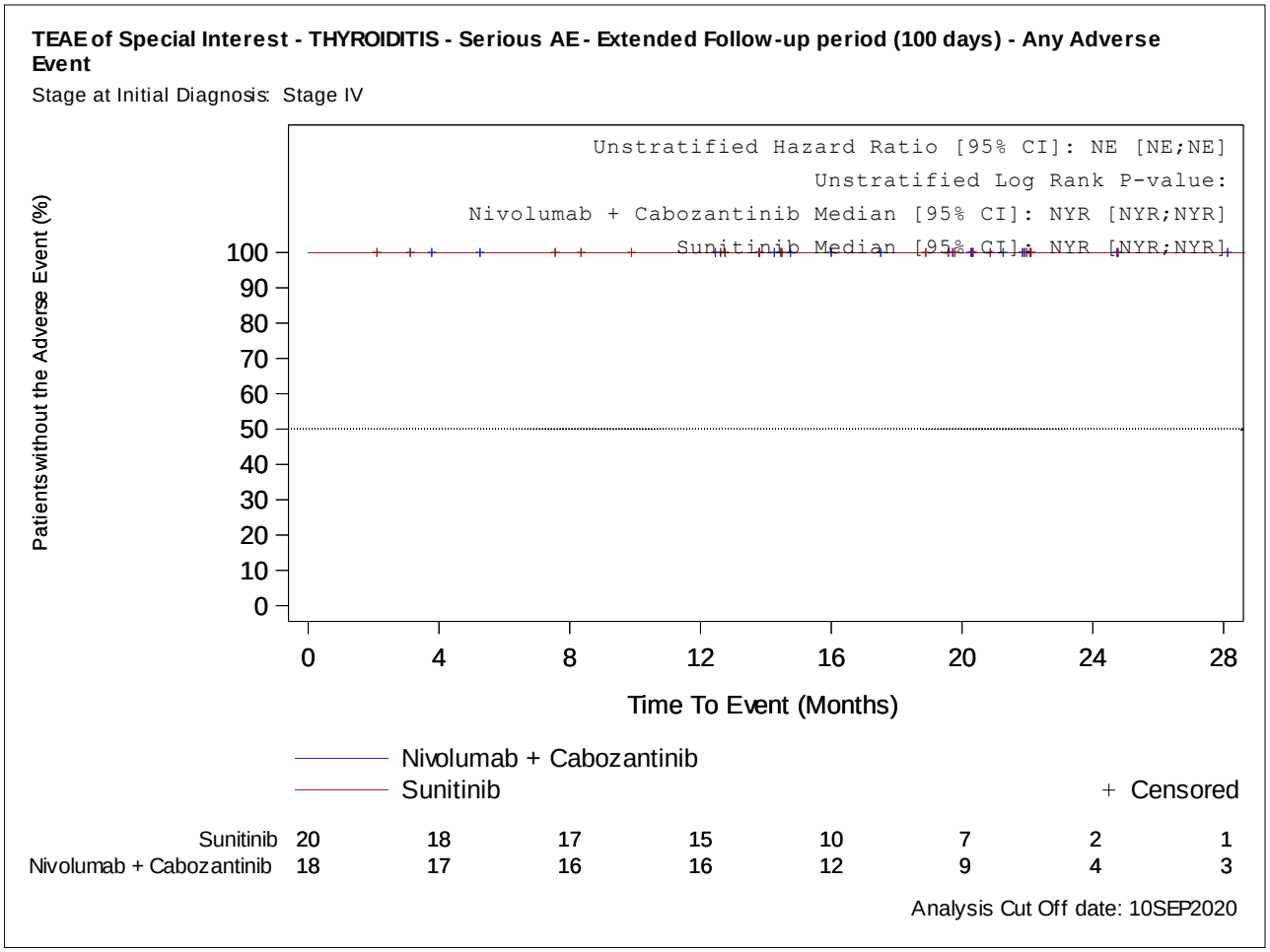
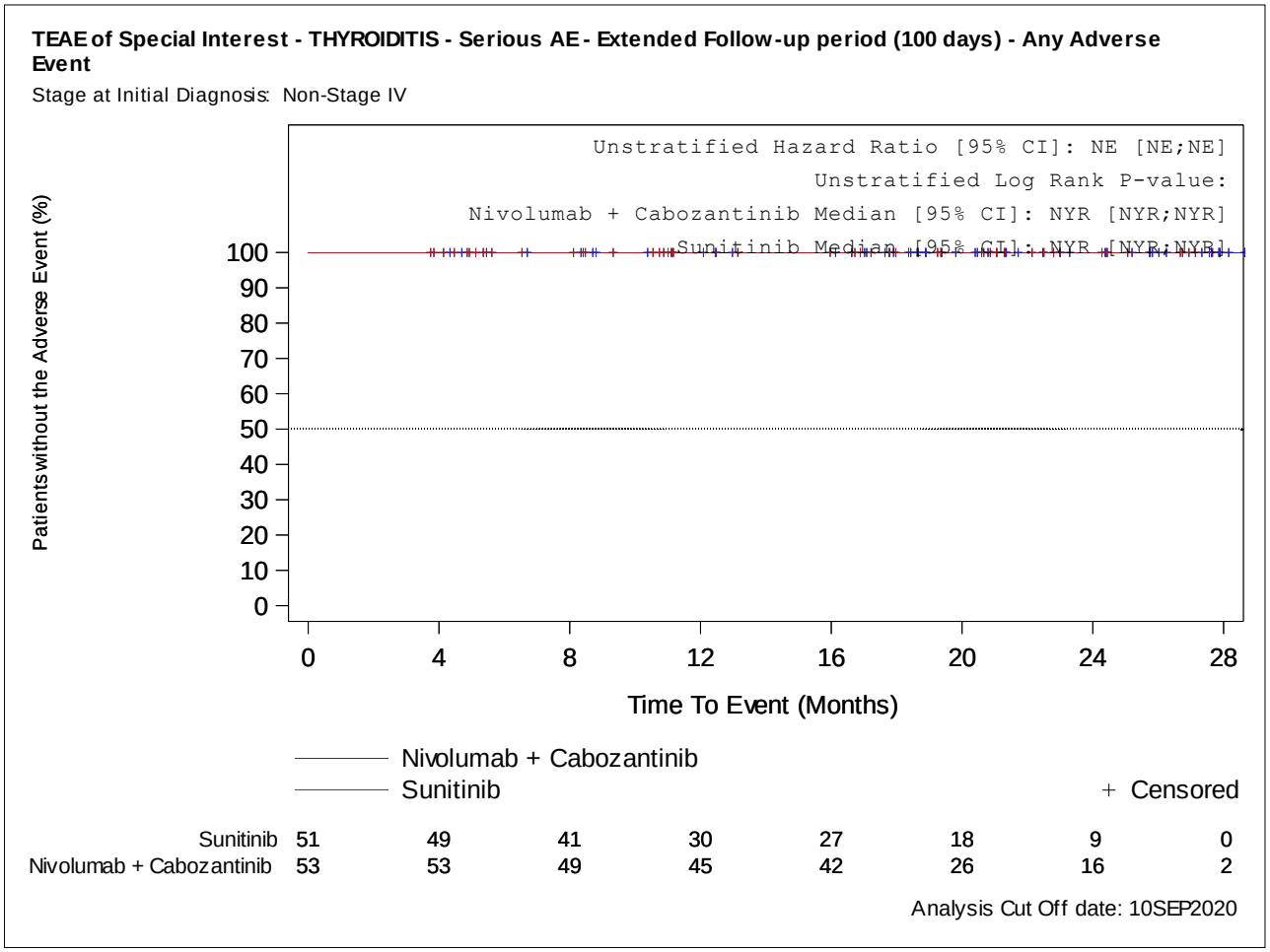
FIGURE 3.112.2.23: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



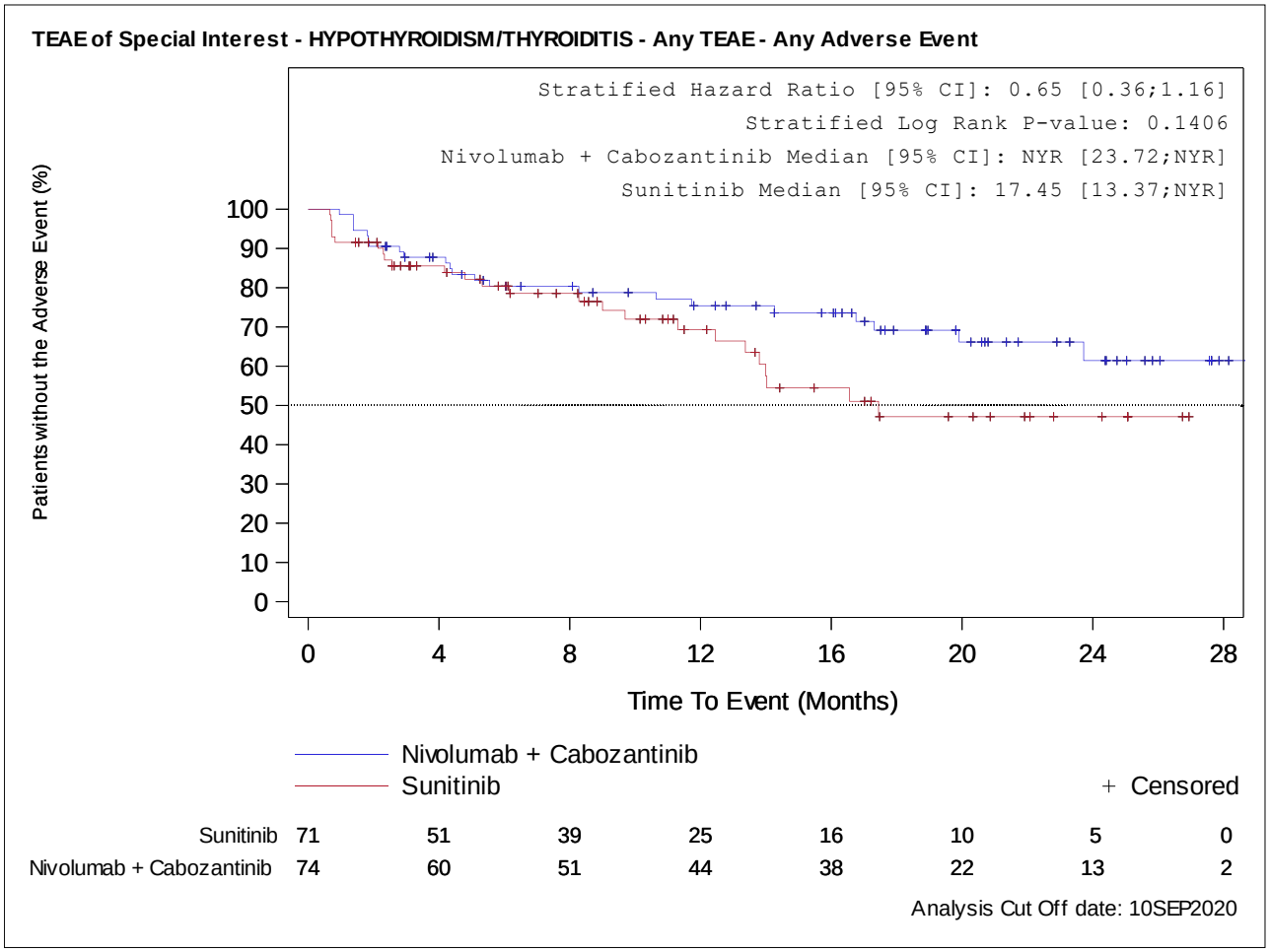

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:46:00

FIGURE 3.112.2.24: Kaplan-Meier curve - TEAE of Special Interest - THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



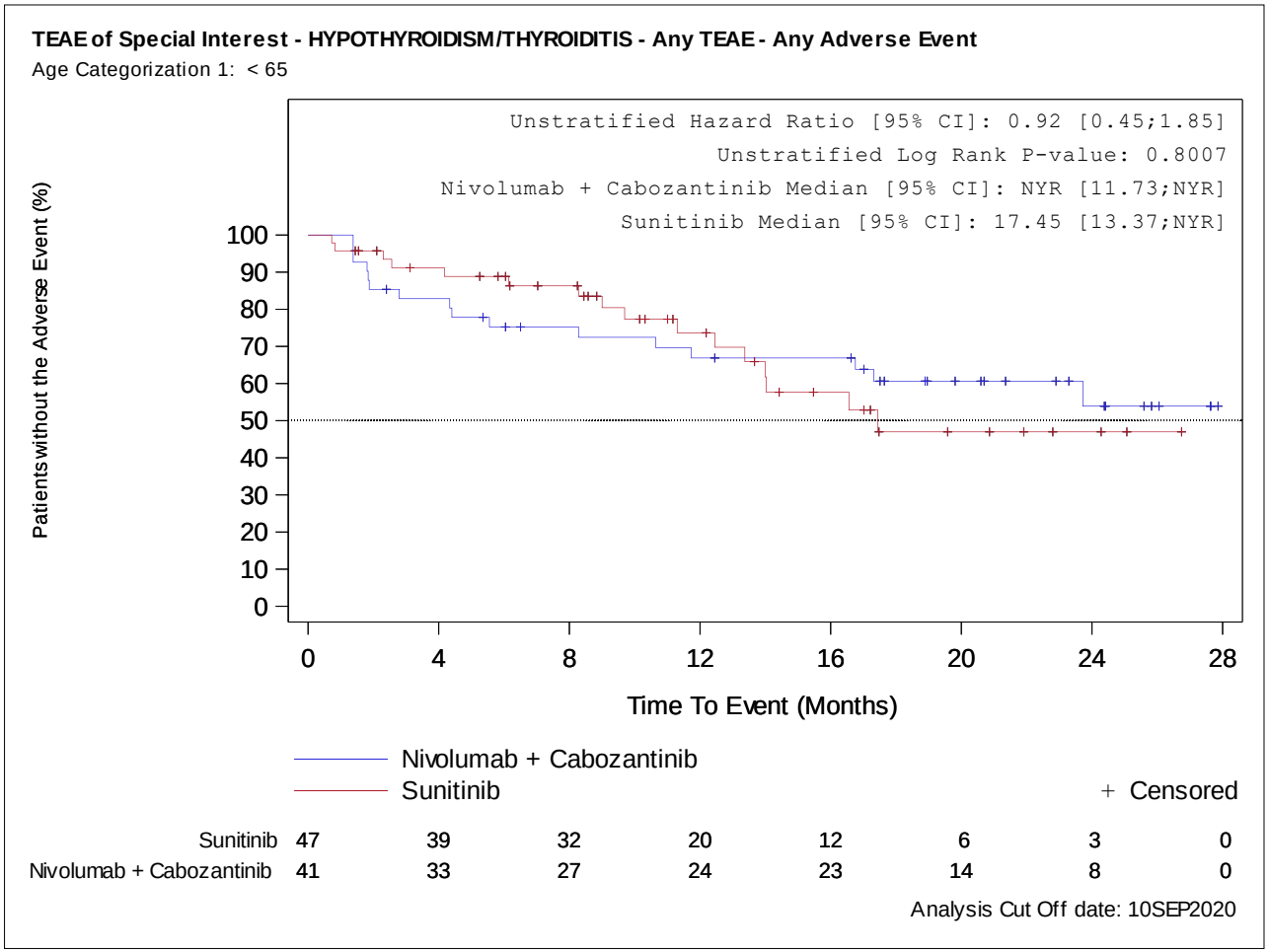

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Tuesday, March 23, 2021 at 0:46:06

FIGURE 3.113.1: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



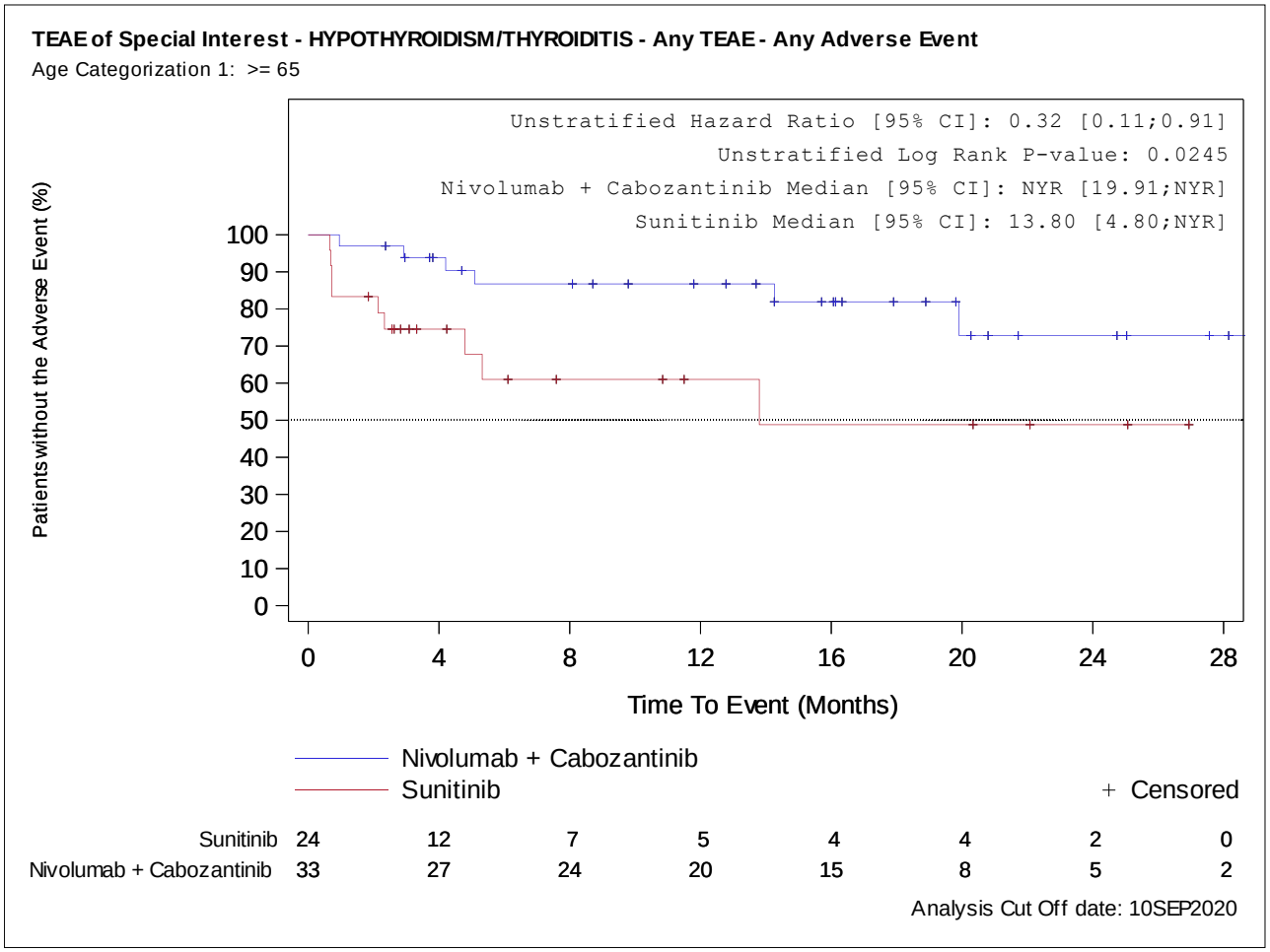

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:46:22

FIGURE 3.113.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



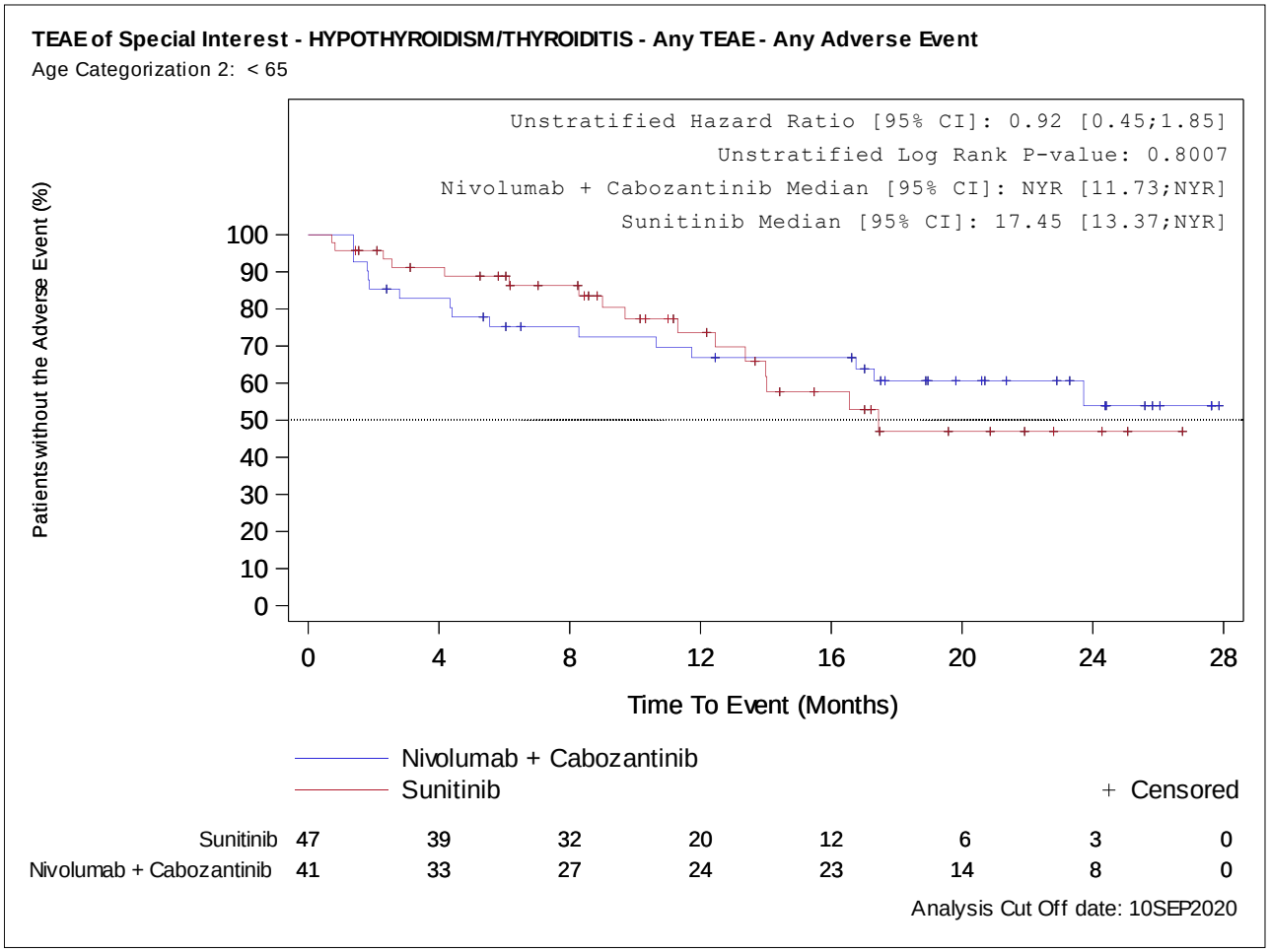

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:46:25

FIGURE 3.113.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



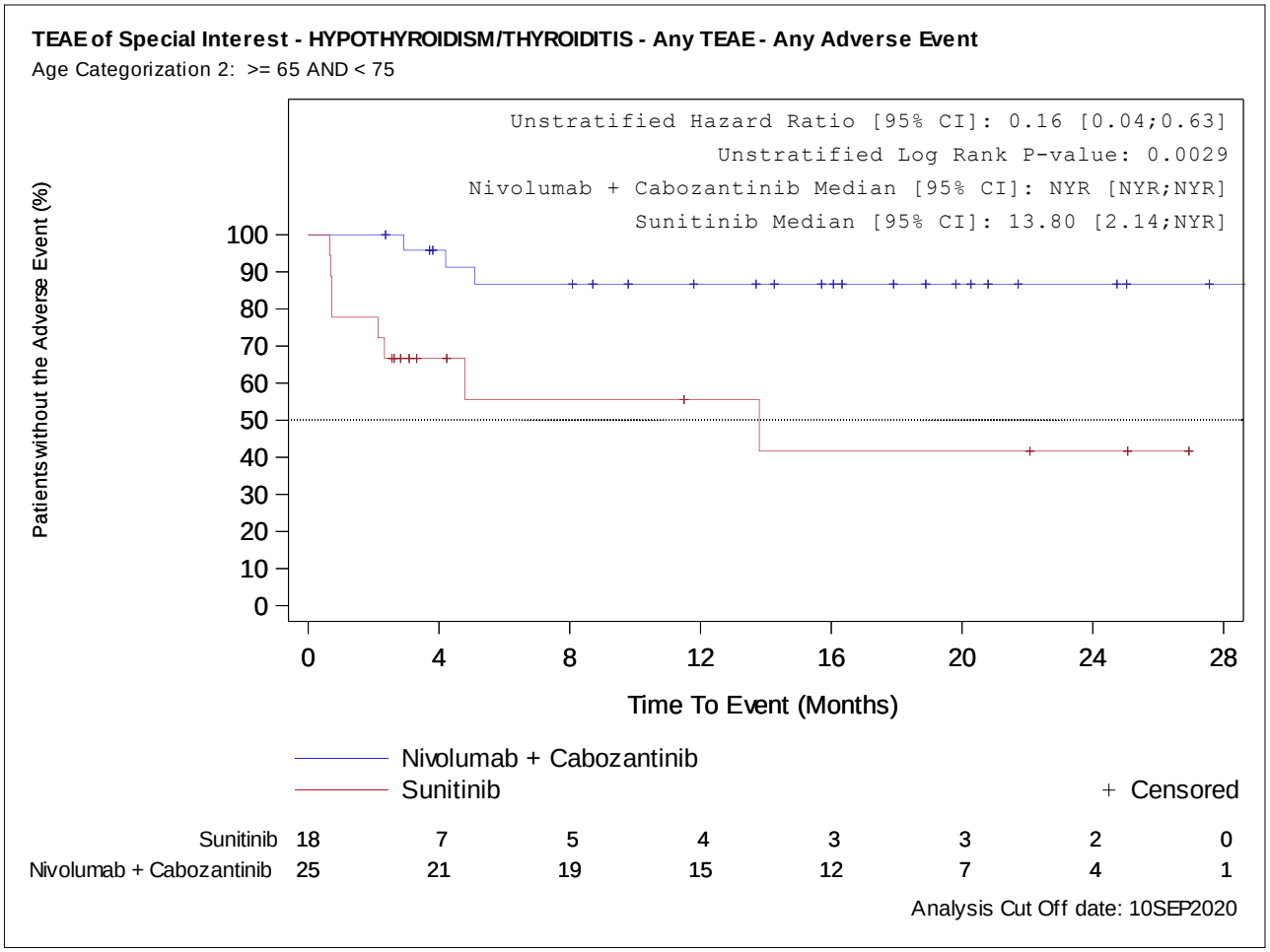

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:46:32

FIGURE 3.113.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



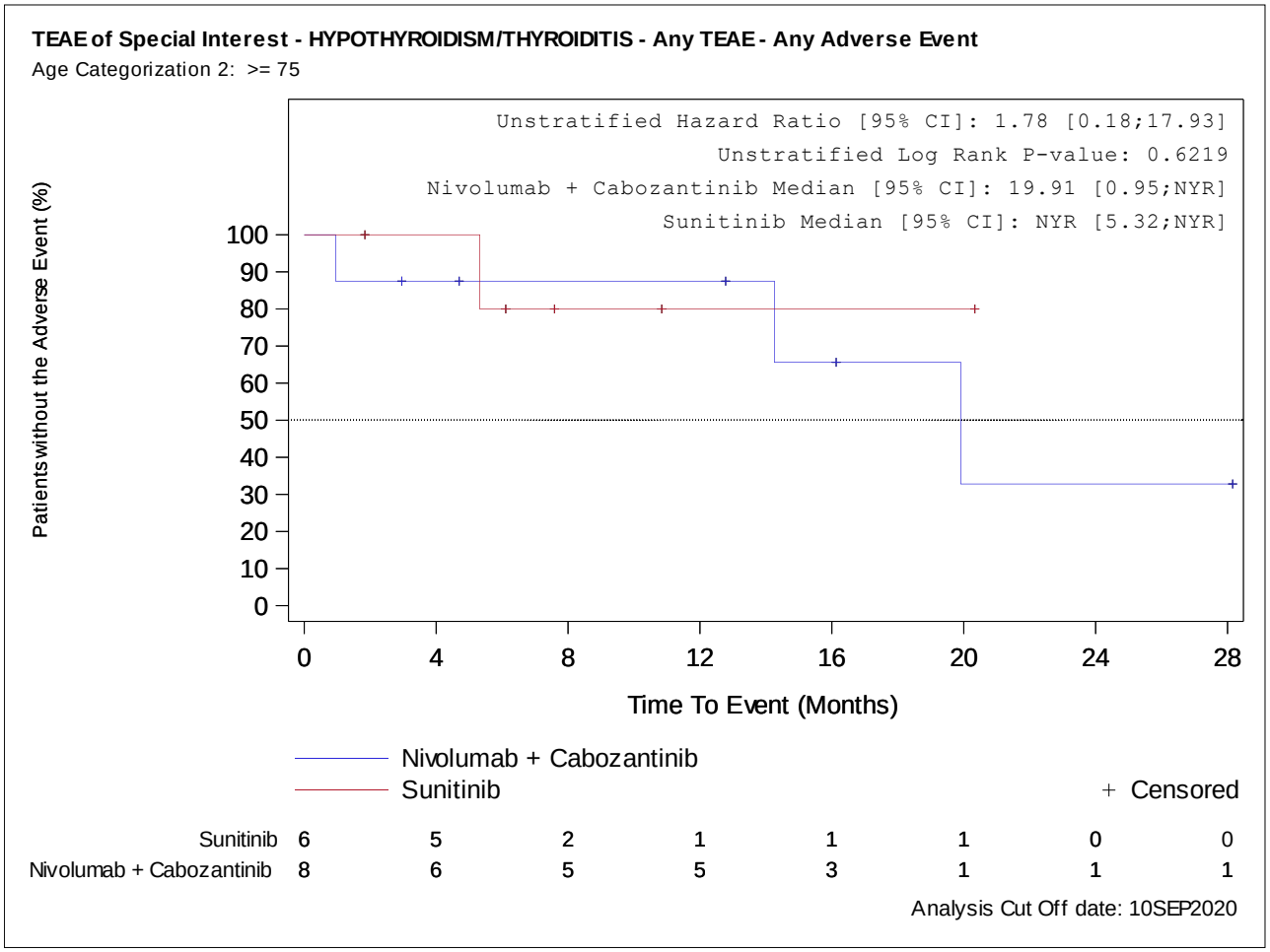

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:46:38

FIGURE 3.113.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



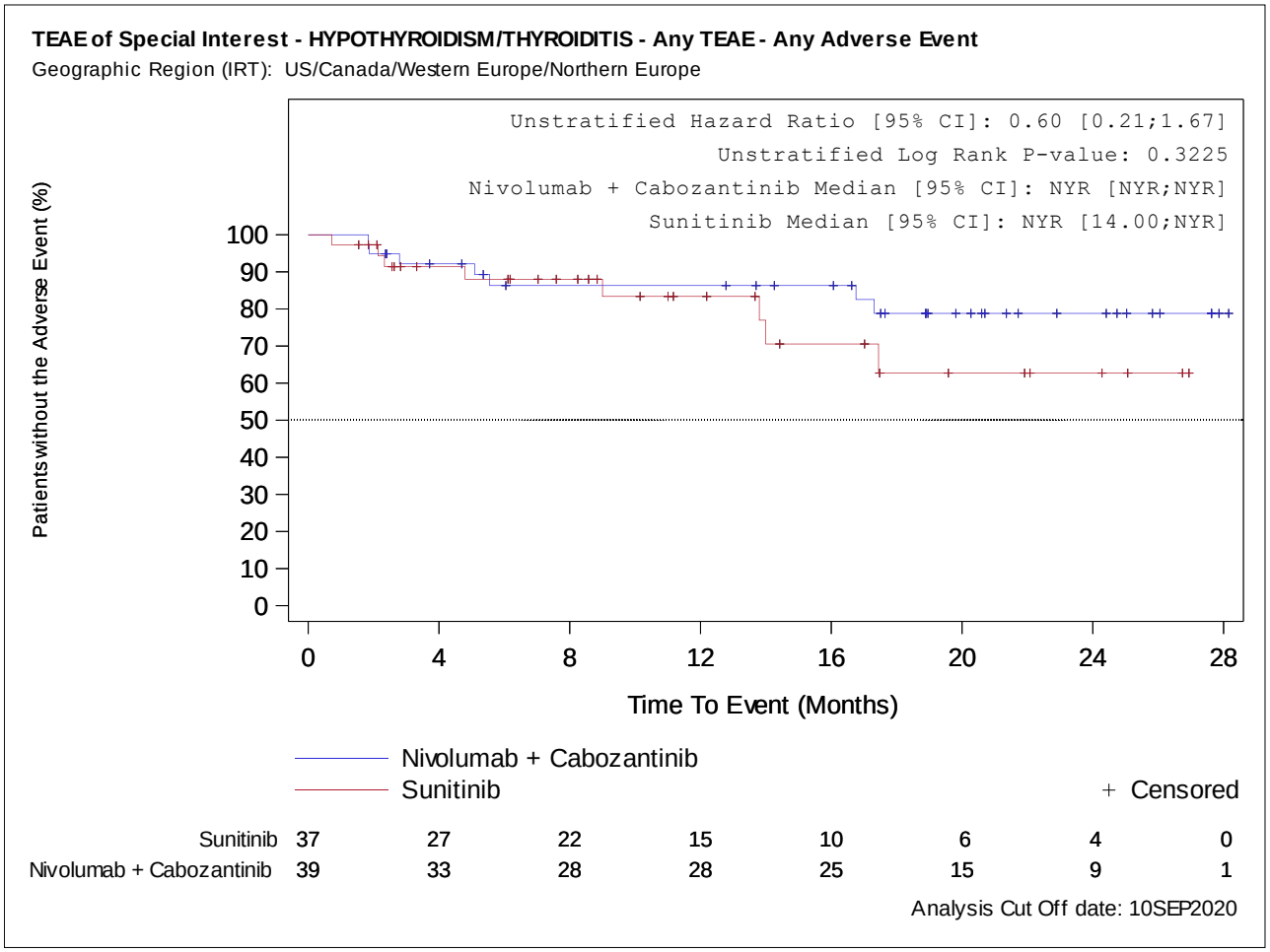

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:46:43

FIGURE 3.113.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



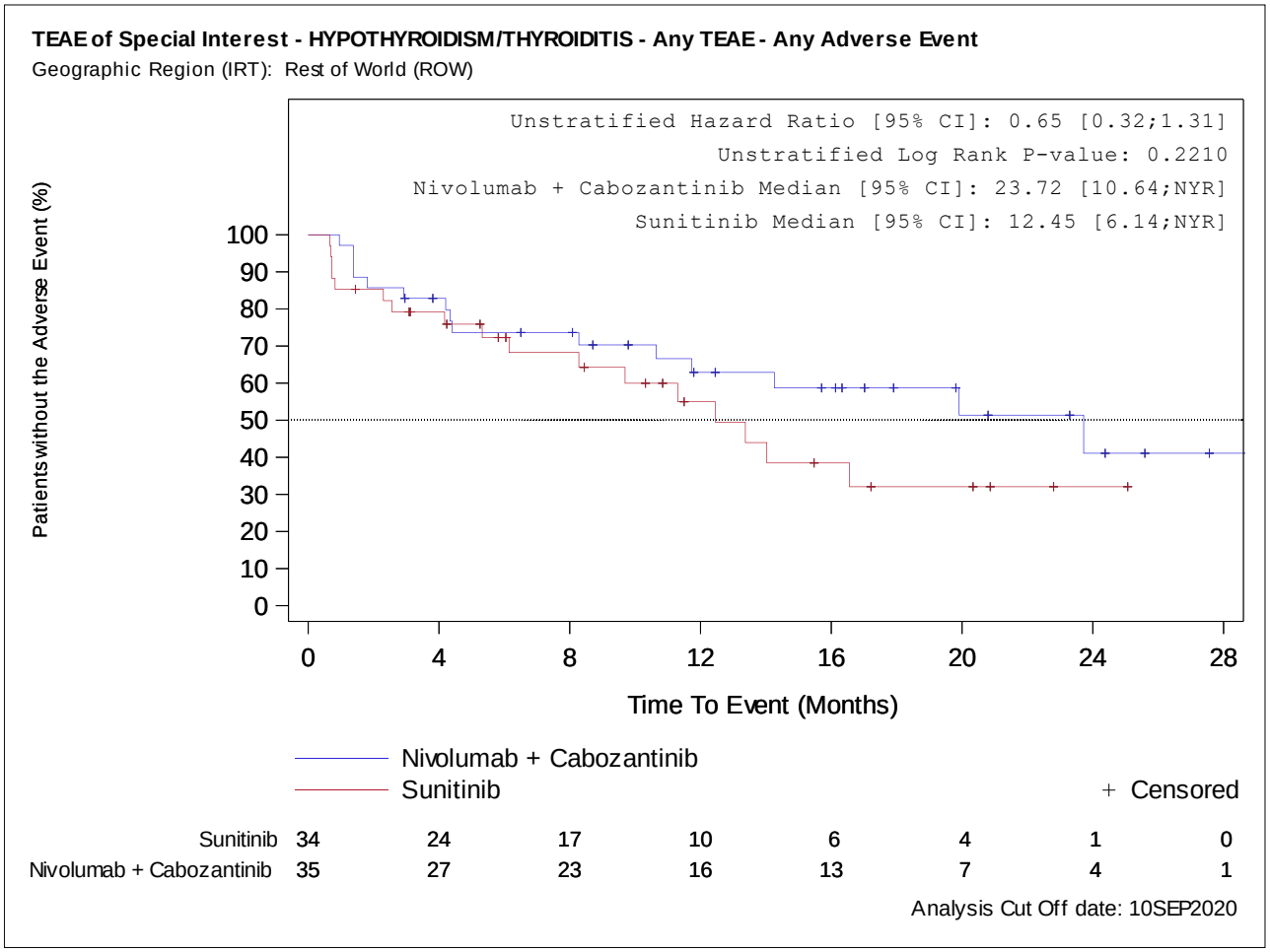

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:46:49

FIGURE 3.113.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



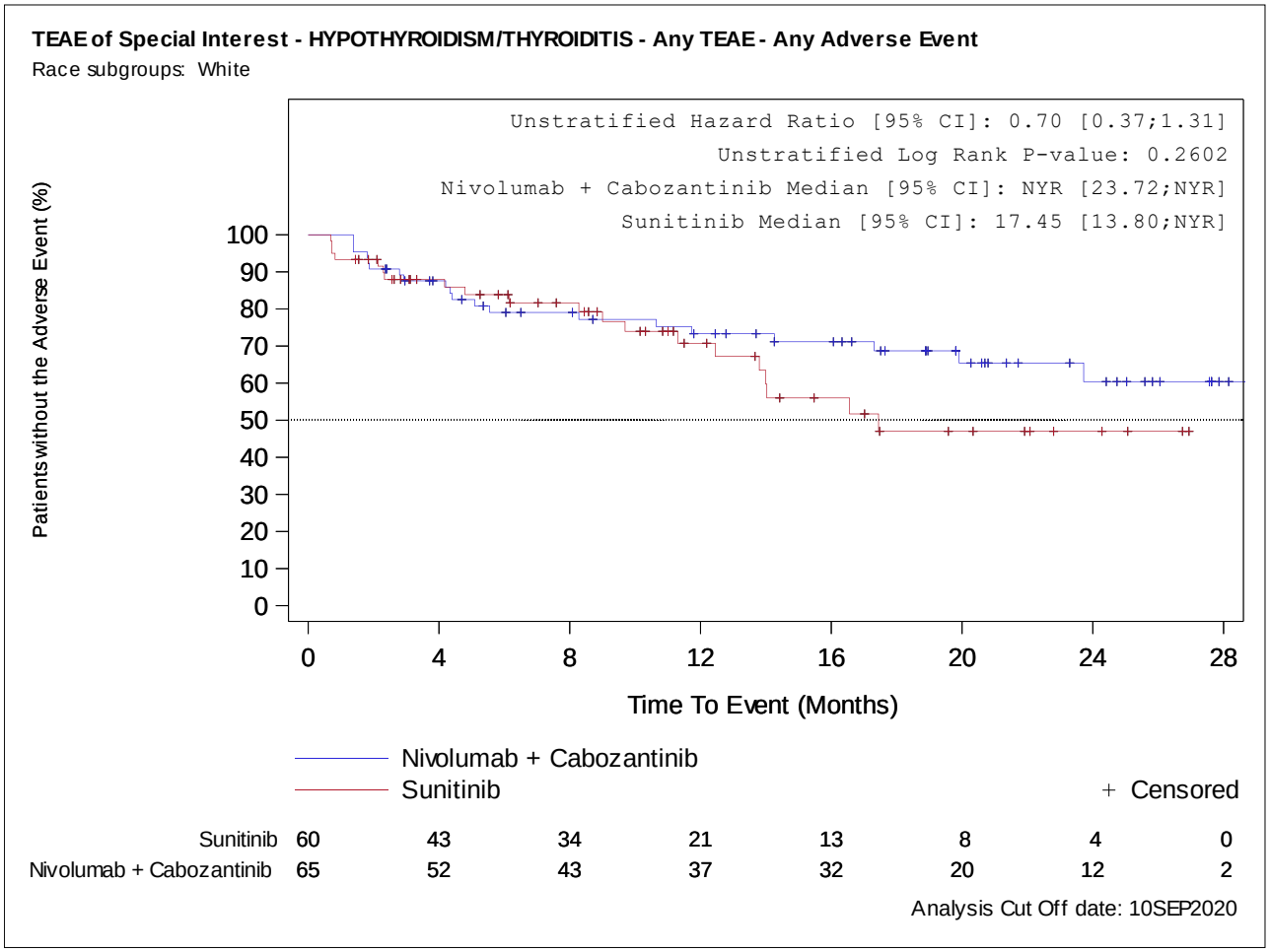

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:46:55

FIGURE 3.113.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



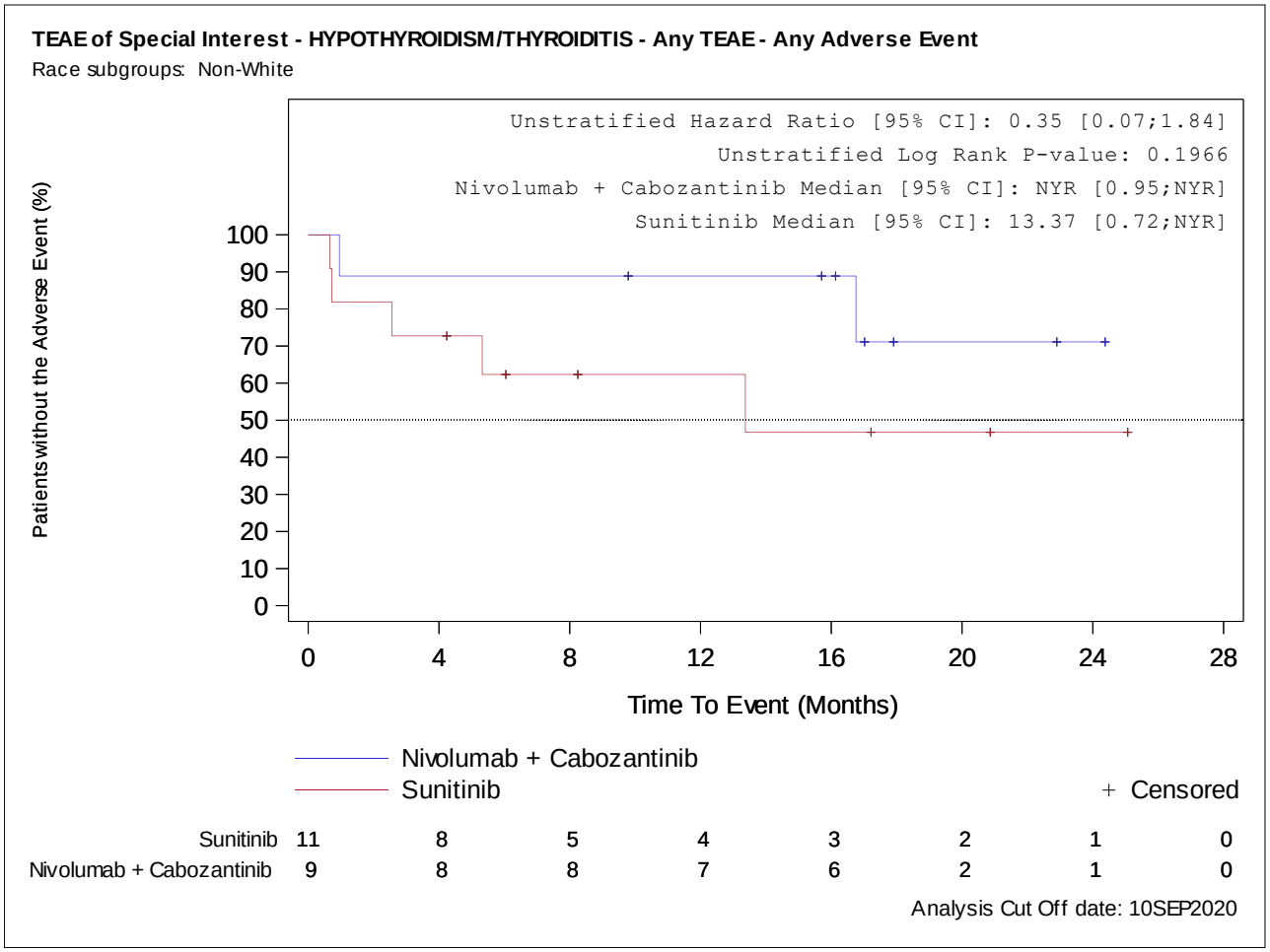

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:47:02

FIGURE 3.113.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



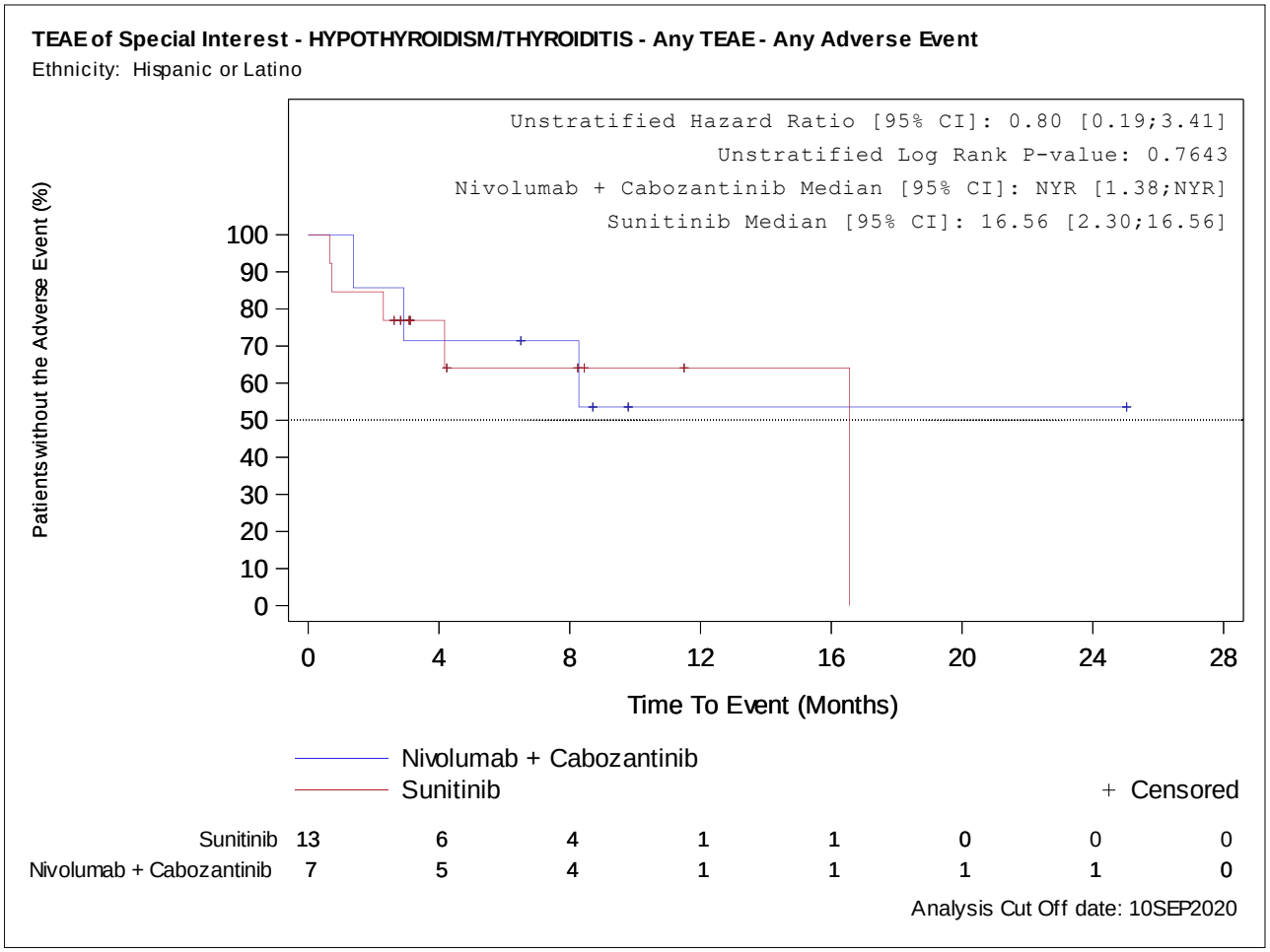

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:47:08

FIGURE 3.113.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



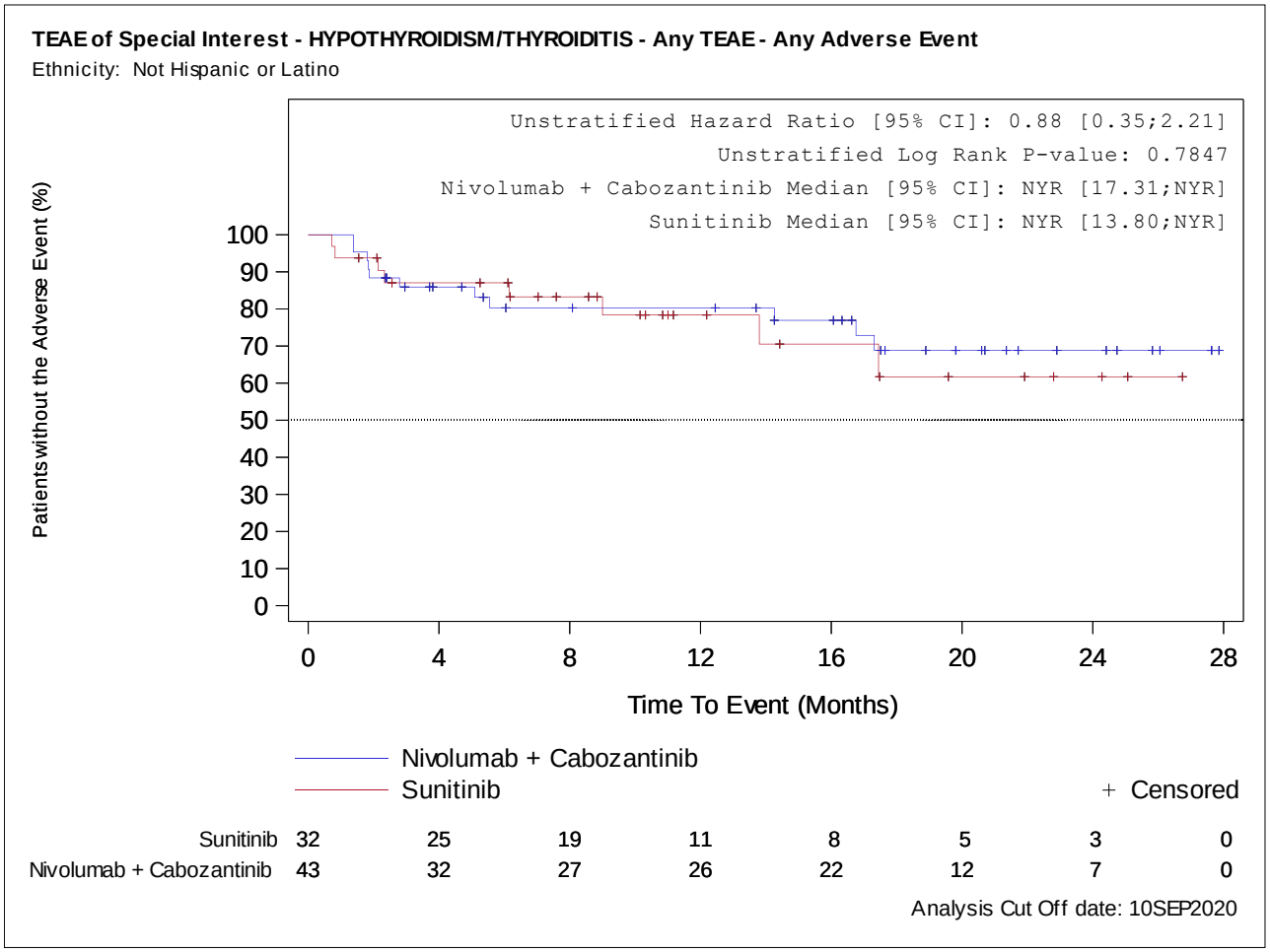

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:47:13

FIGURE 3.113.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



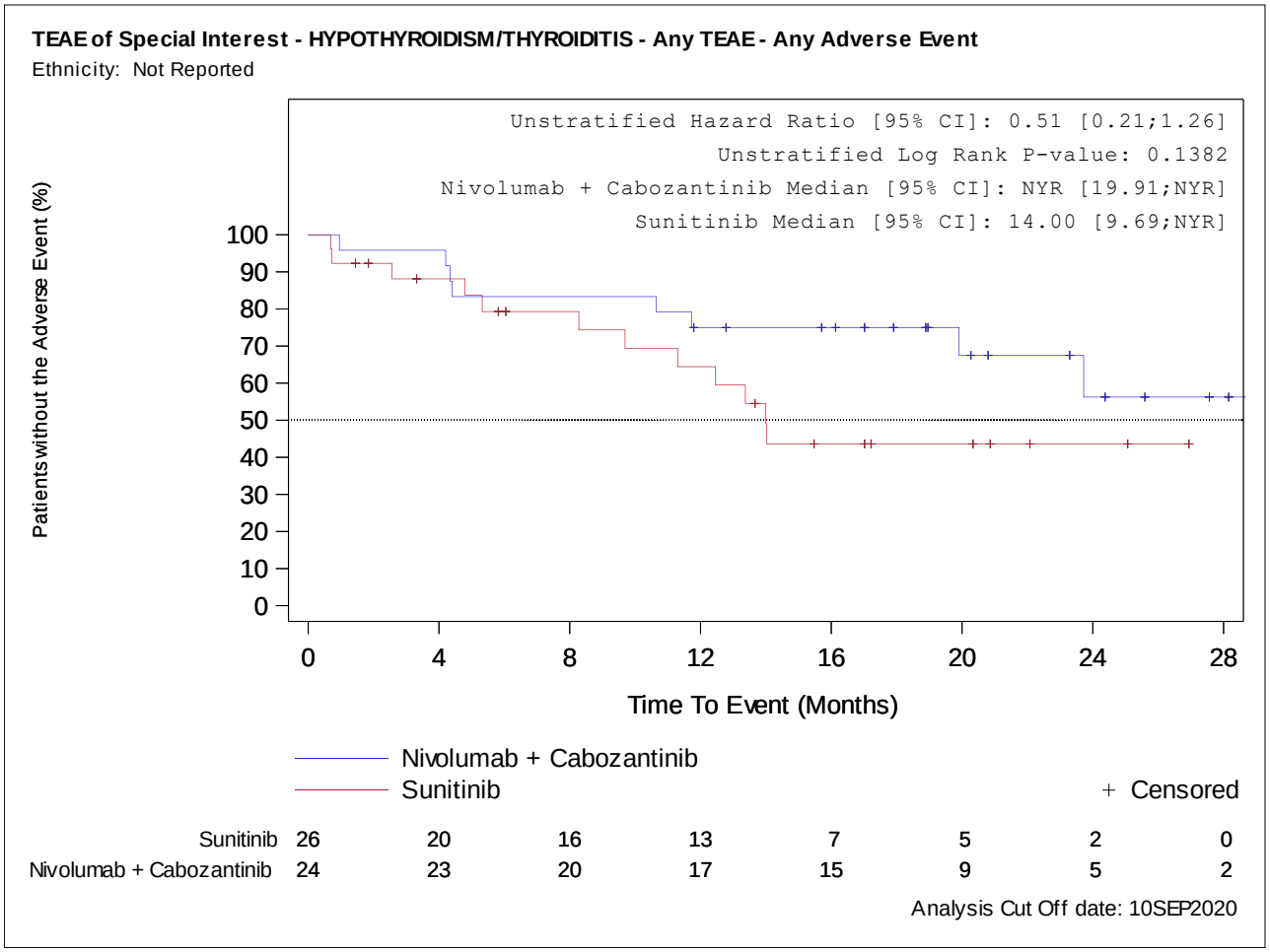

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:47:19

FIGURE 3.113.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



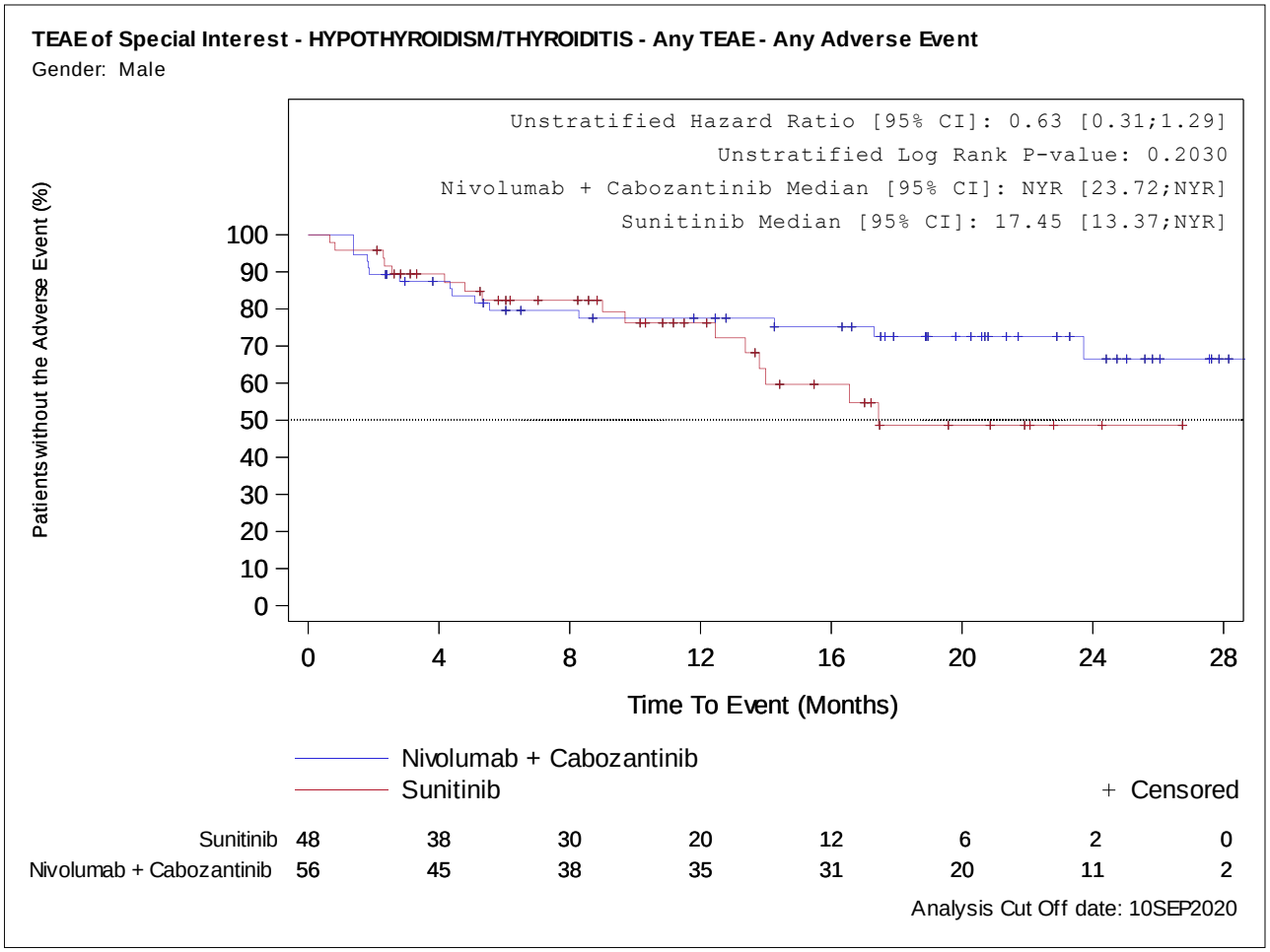

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:47:26

FIGURE 3.113.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



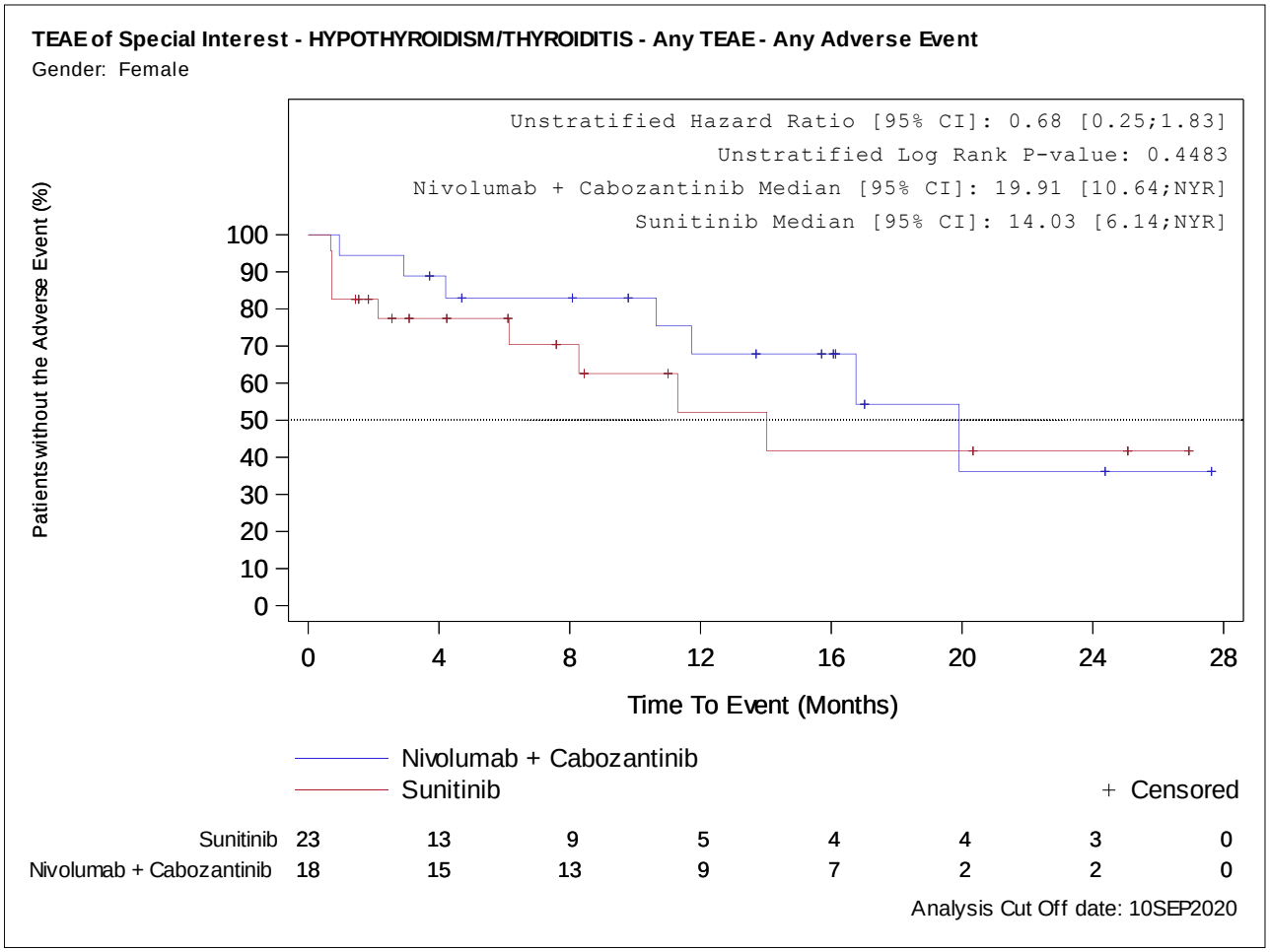

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:47:33

FIGURE 3.113.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



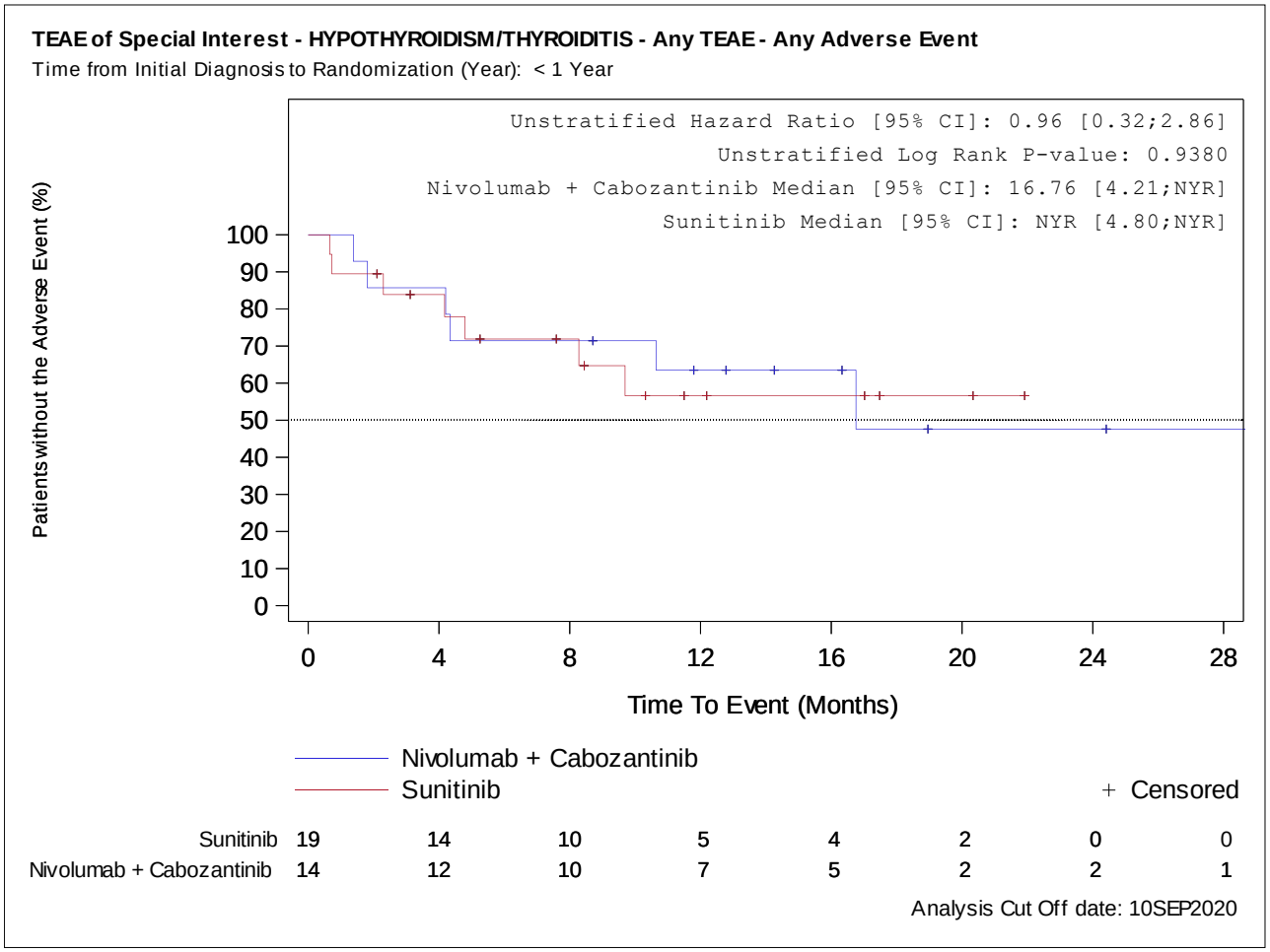

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:47:39

FIGURE 3.113.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



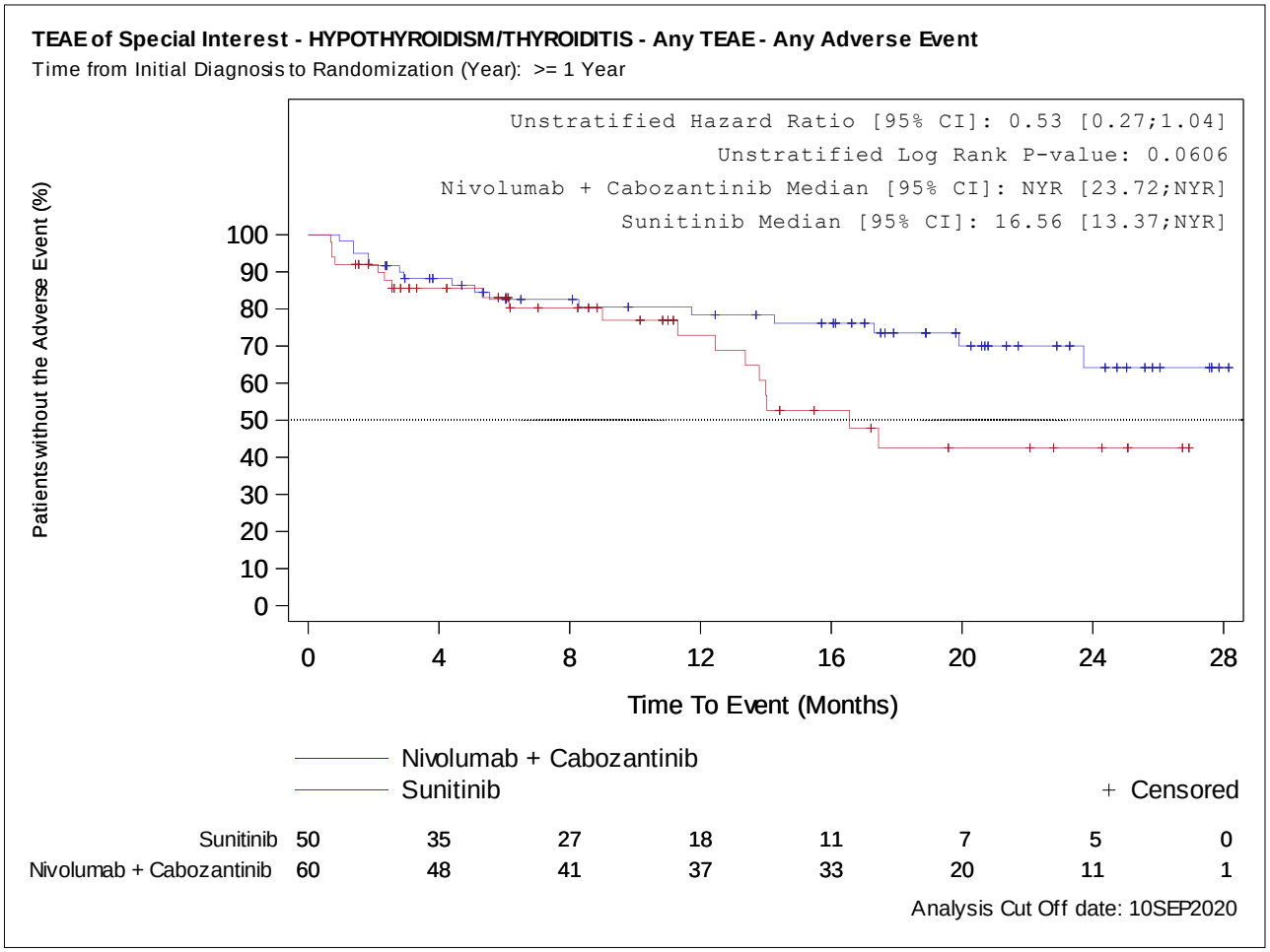

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:47:46

FIGURE 3.113.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:48:05

FIGURE 3.113.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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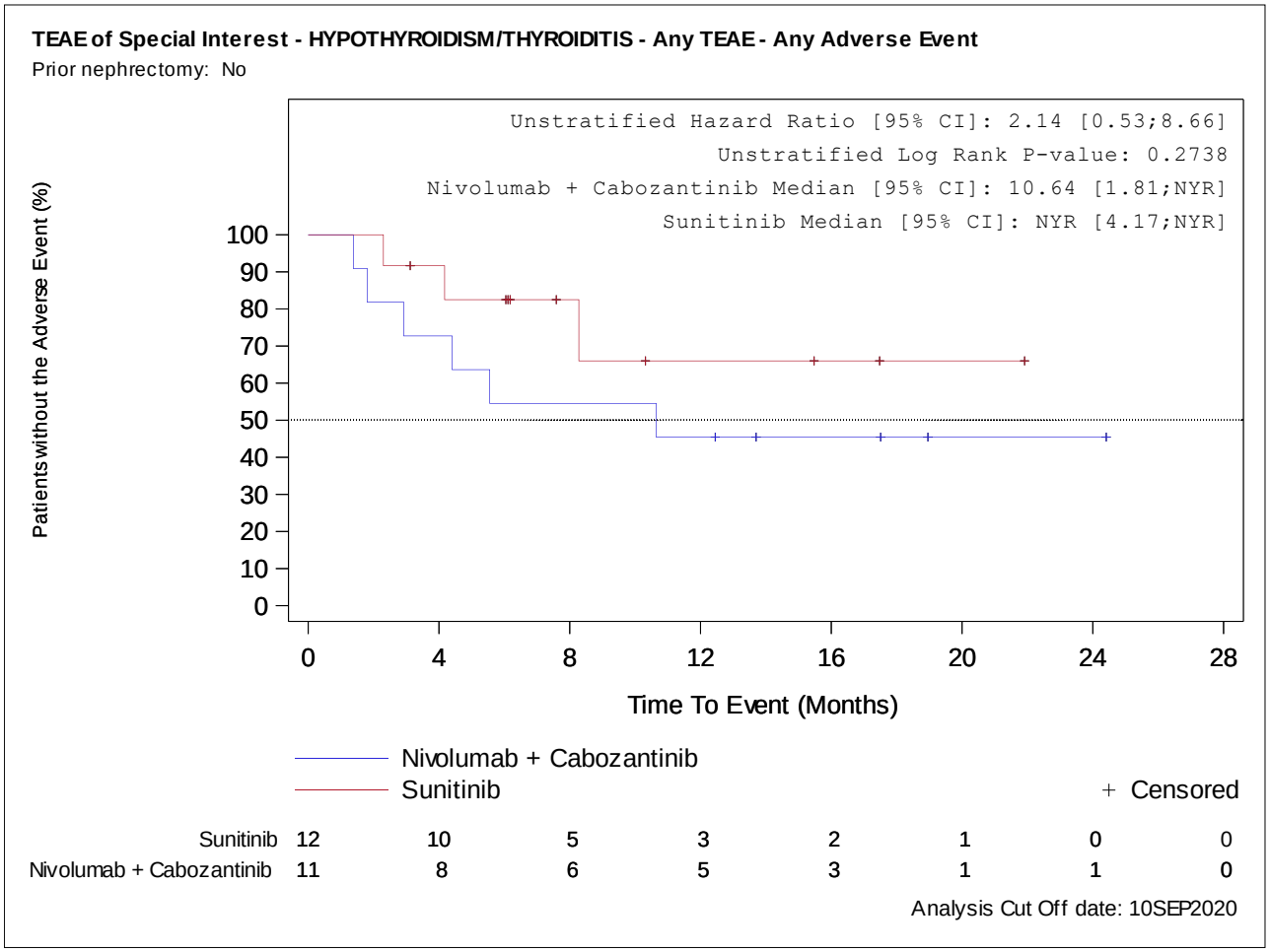
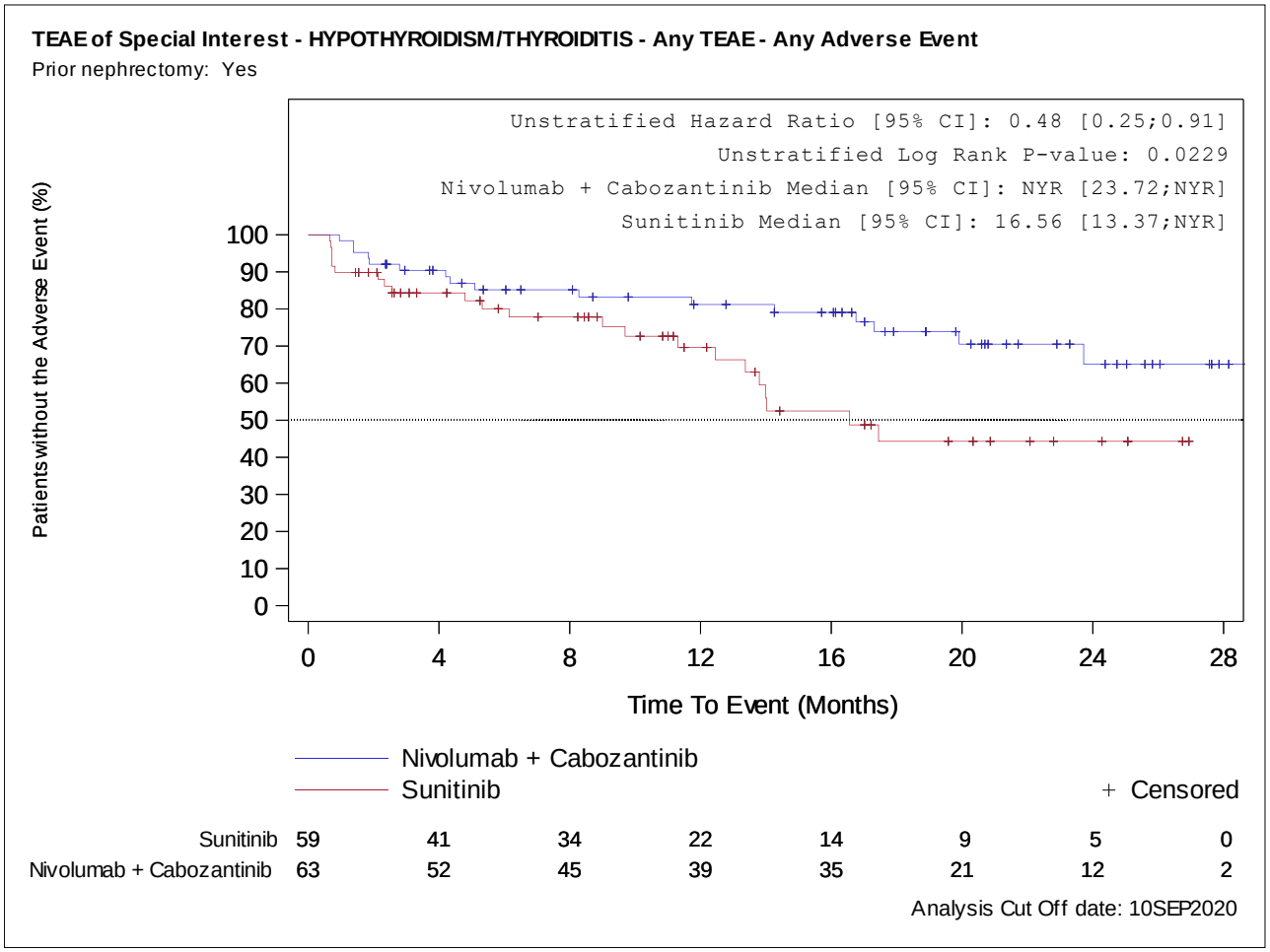
FIGURE 3.113.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



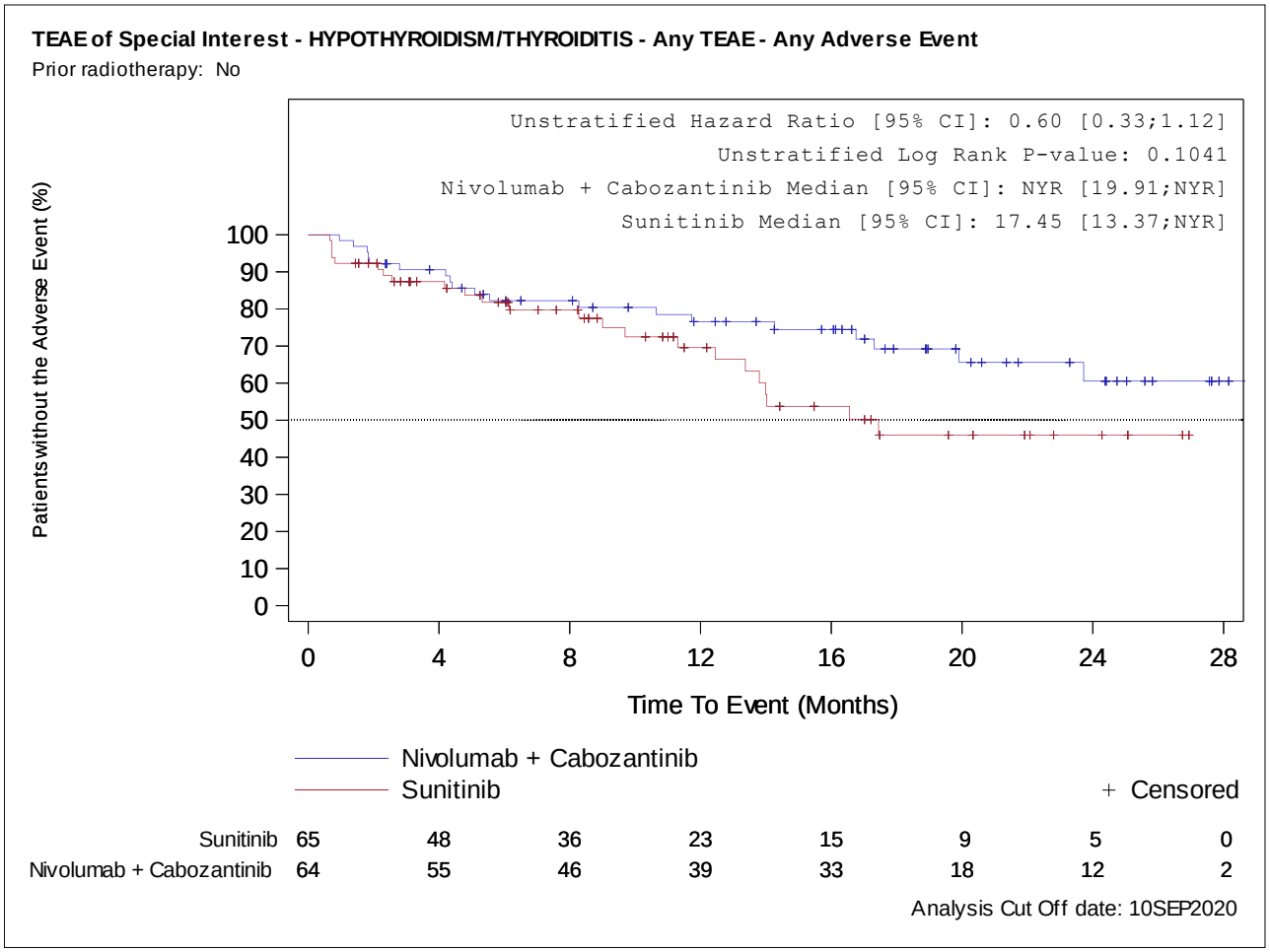

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:49:06

FIGURE 3.113.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:49:12

FIGURE 3.113.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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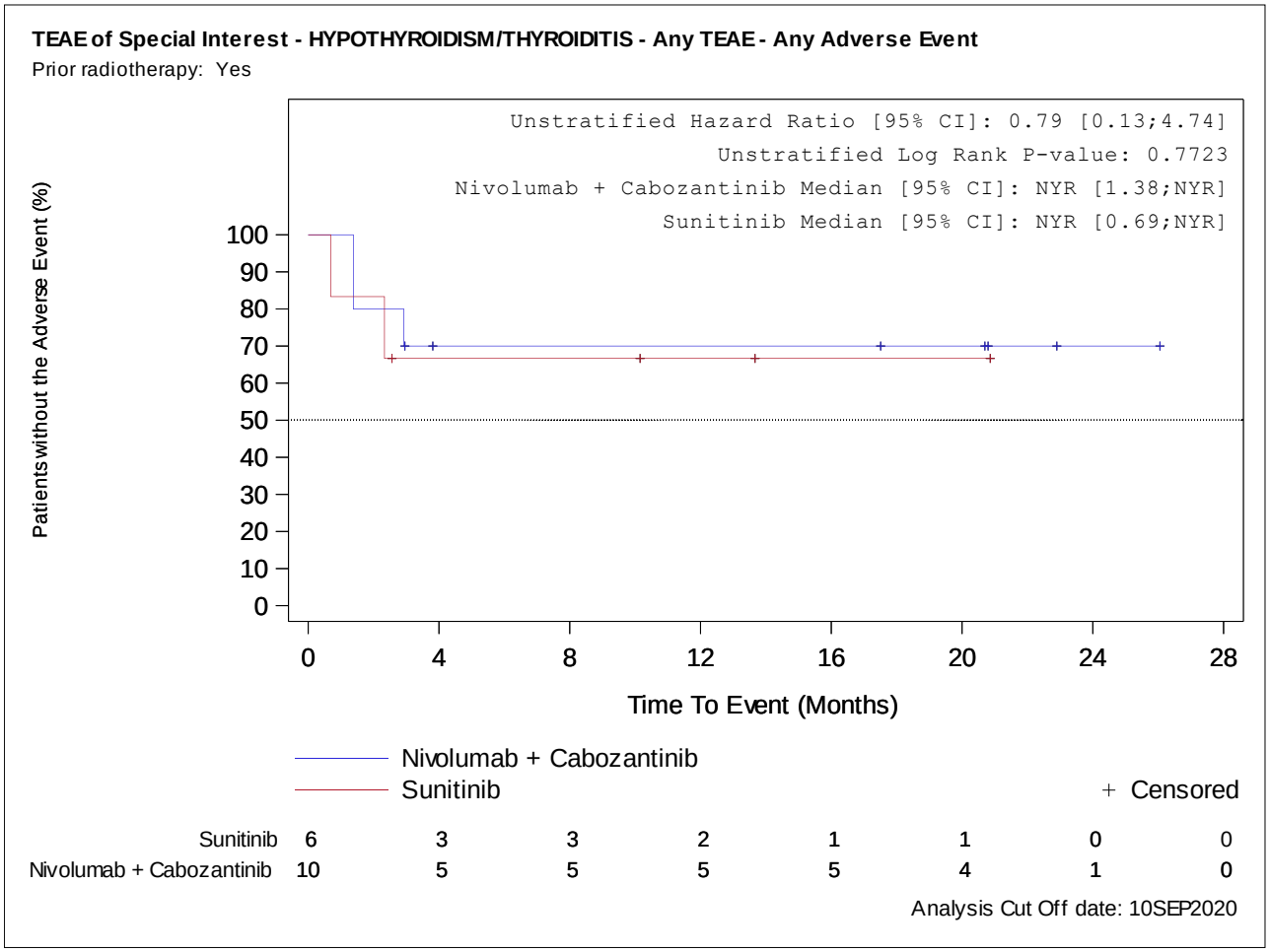
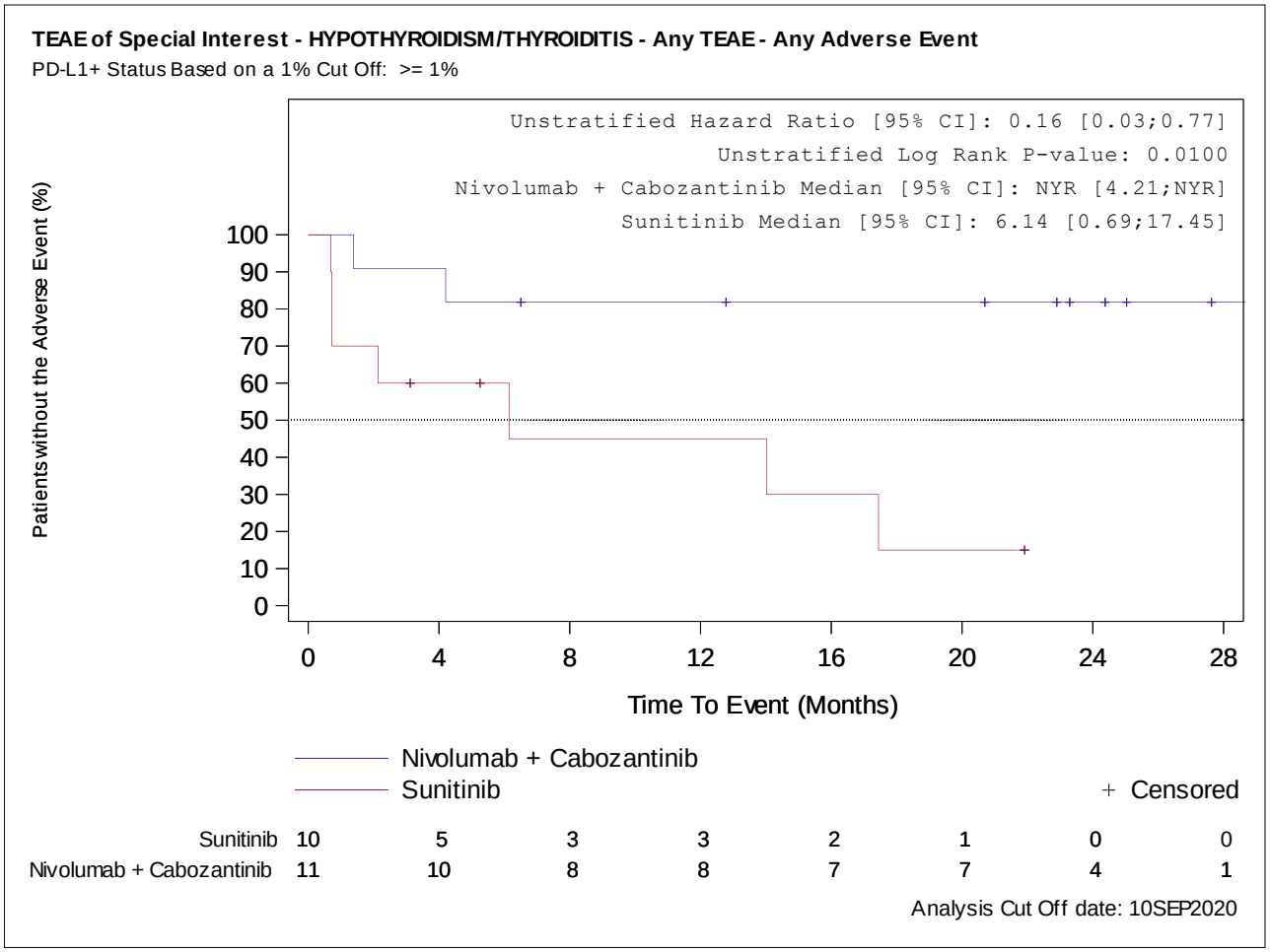
FIGURE 3.113.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:49:24

FIGURE 3.113.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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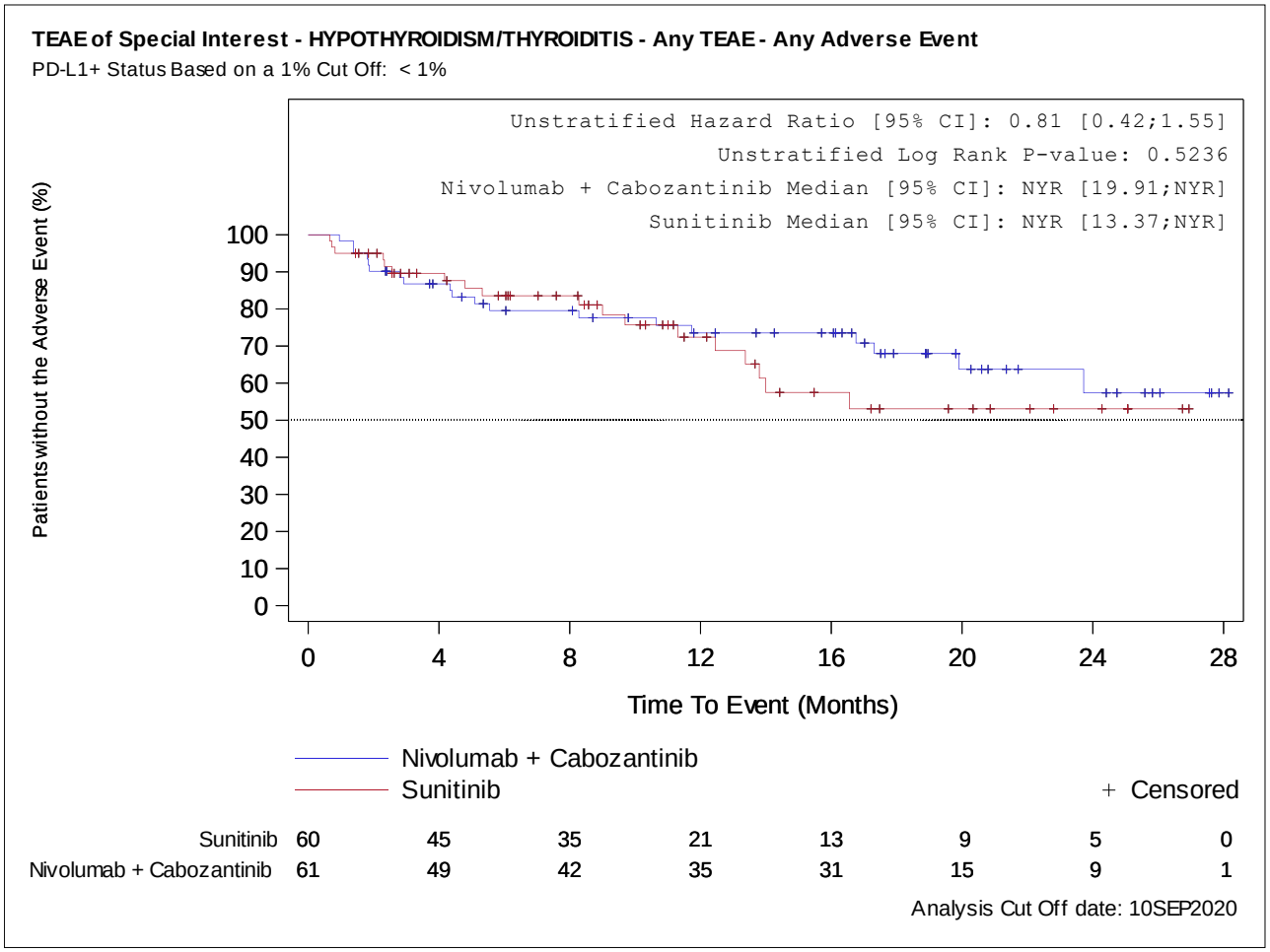
FIGURE 3.113.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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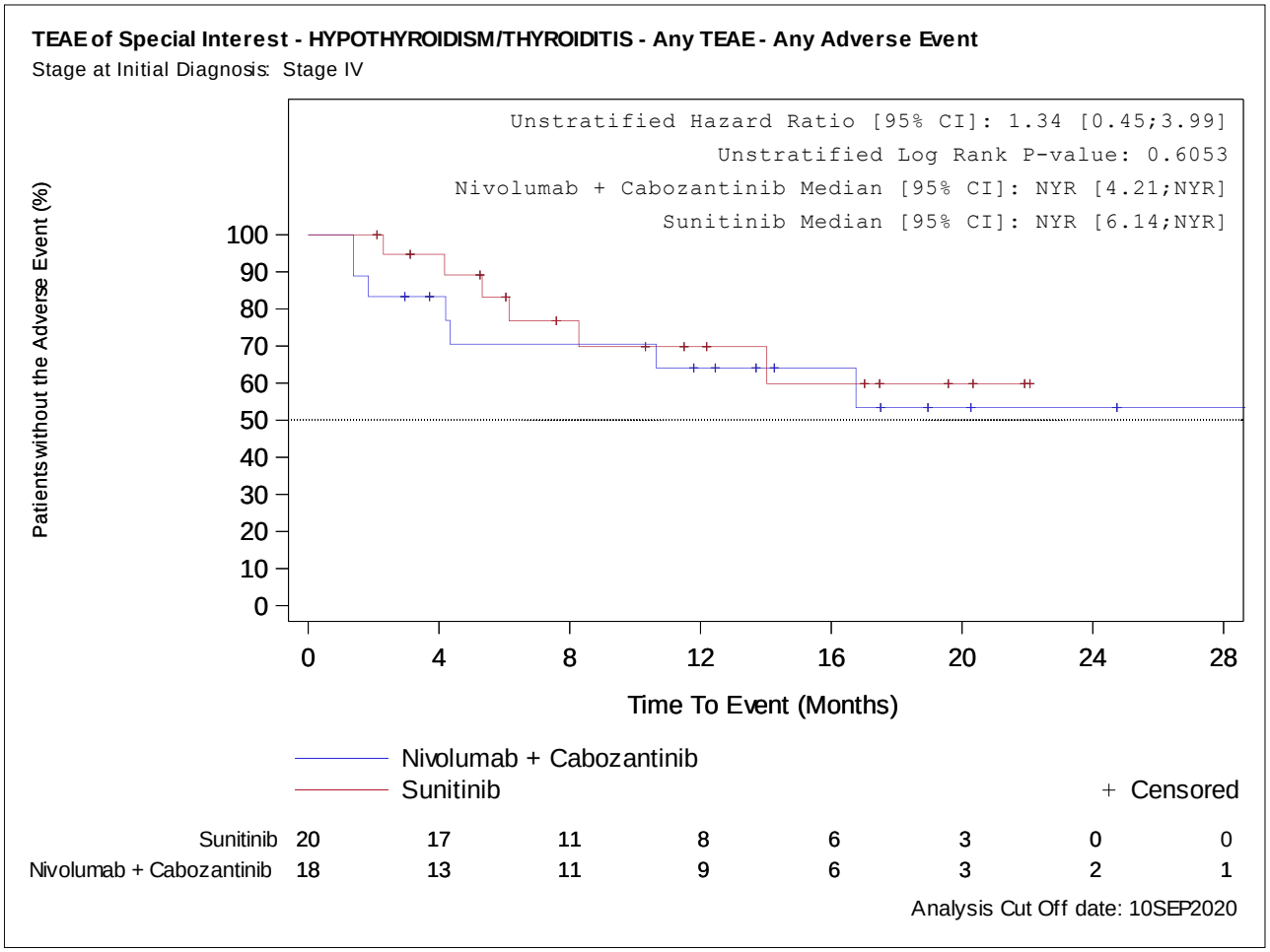
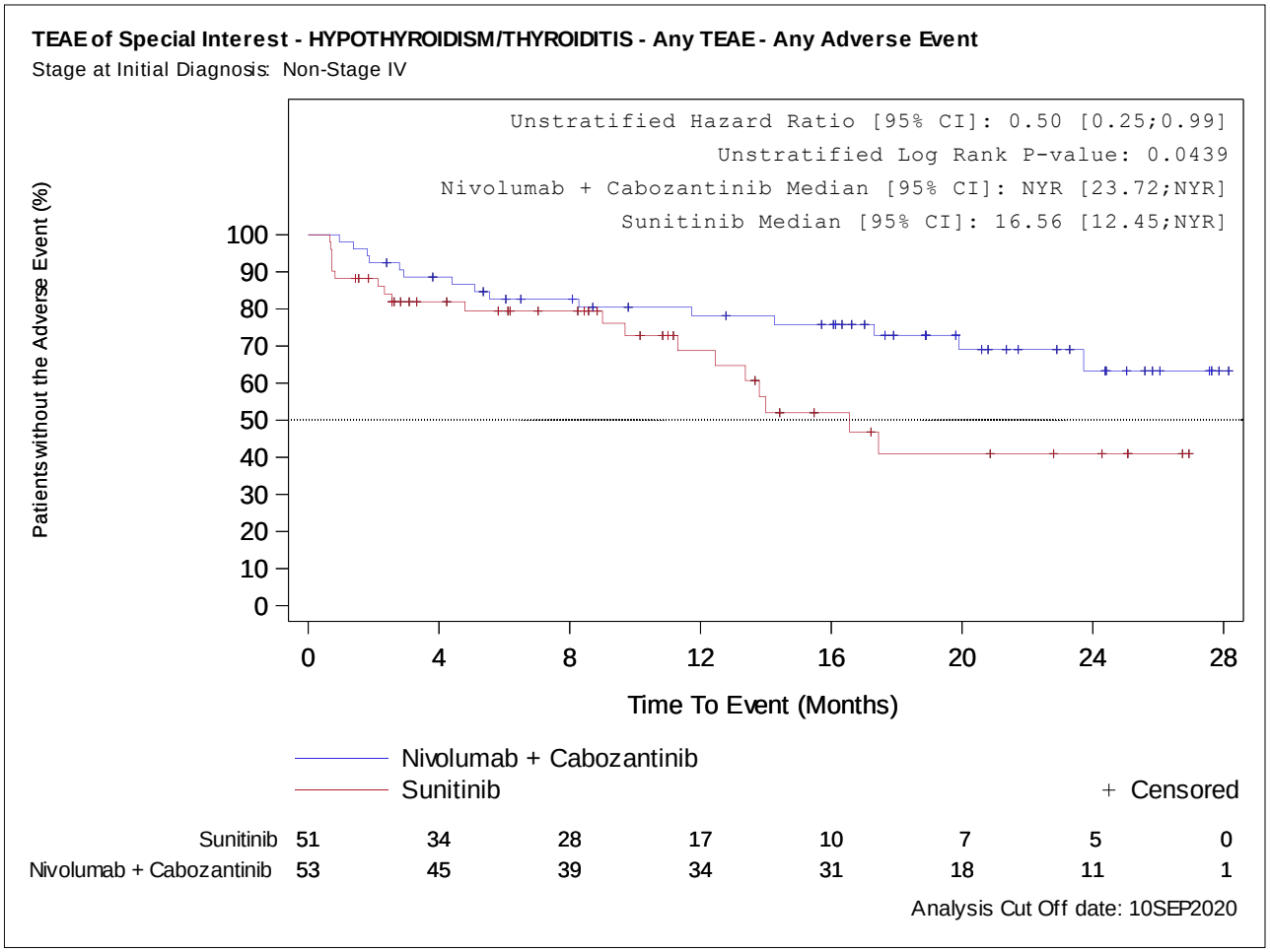
FIGURE 3.113.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



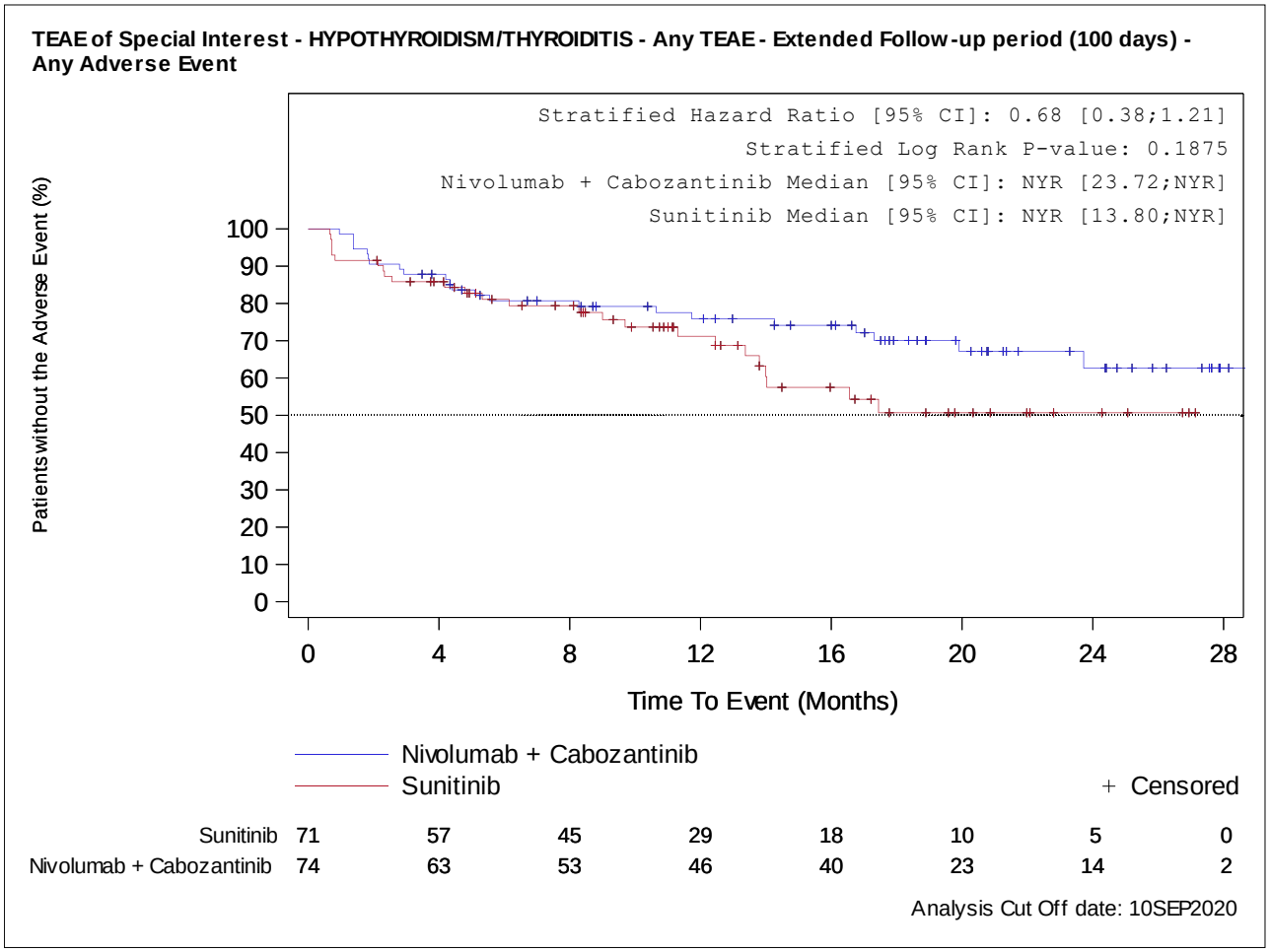

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:50:07

FIGURE 3.113.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



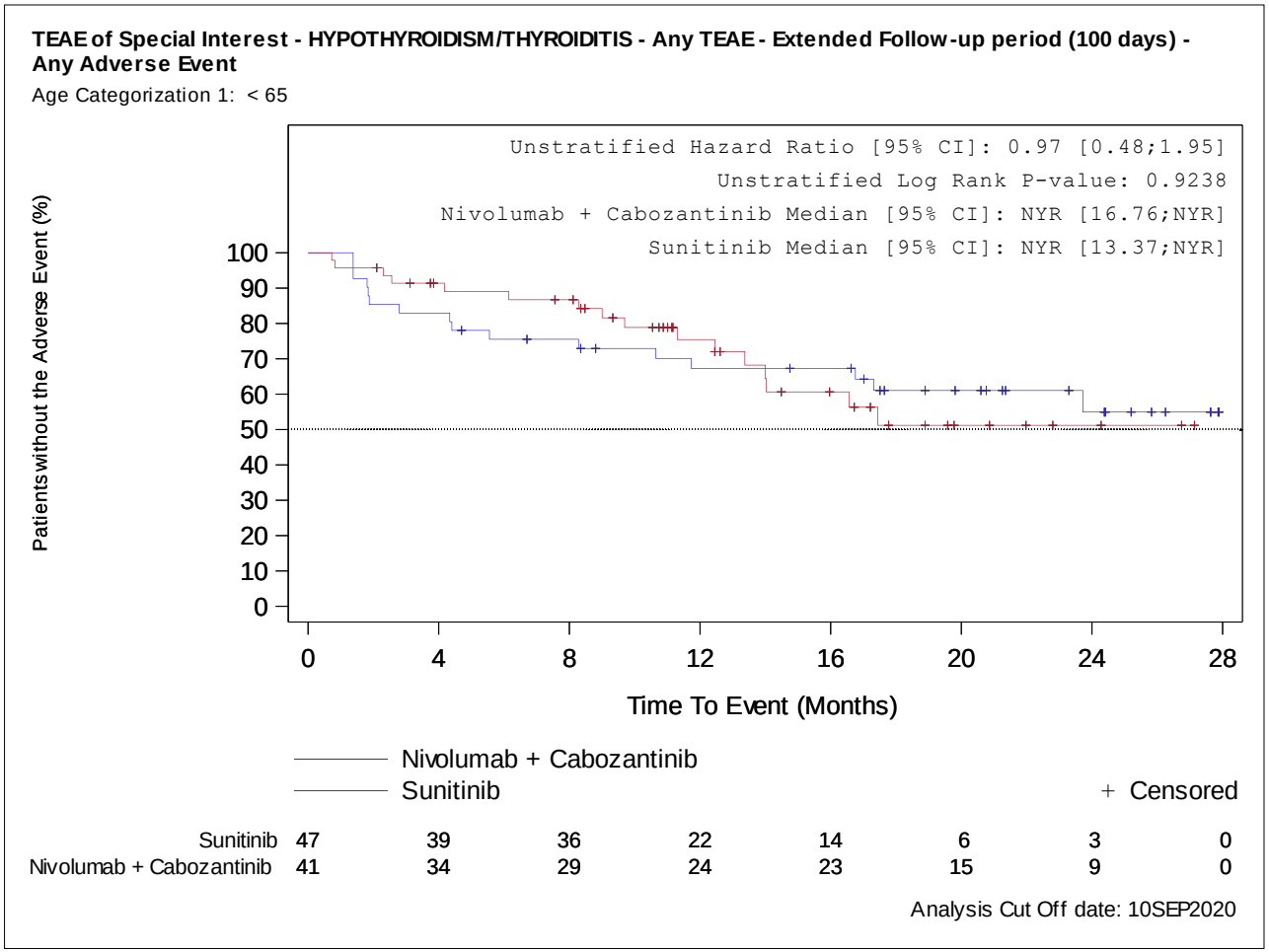

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:50:13

FIGURE 3.114.1: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:53:39

FIGURE 3.114.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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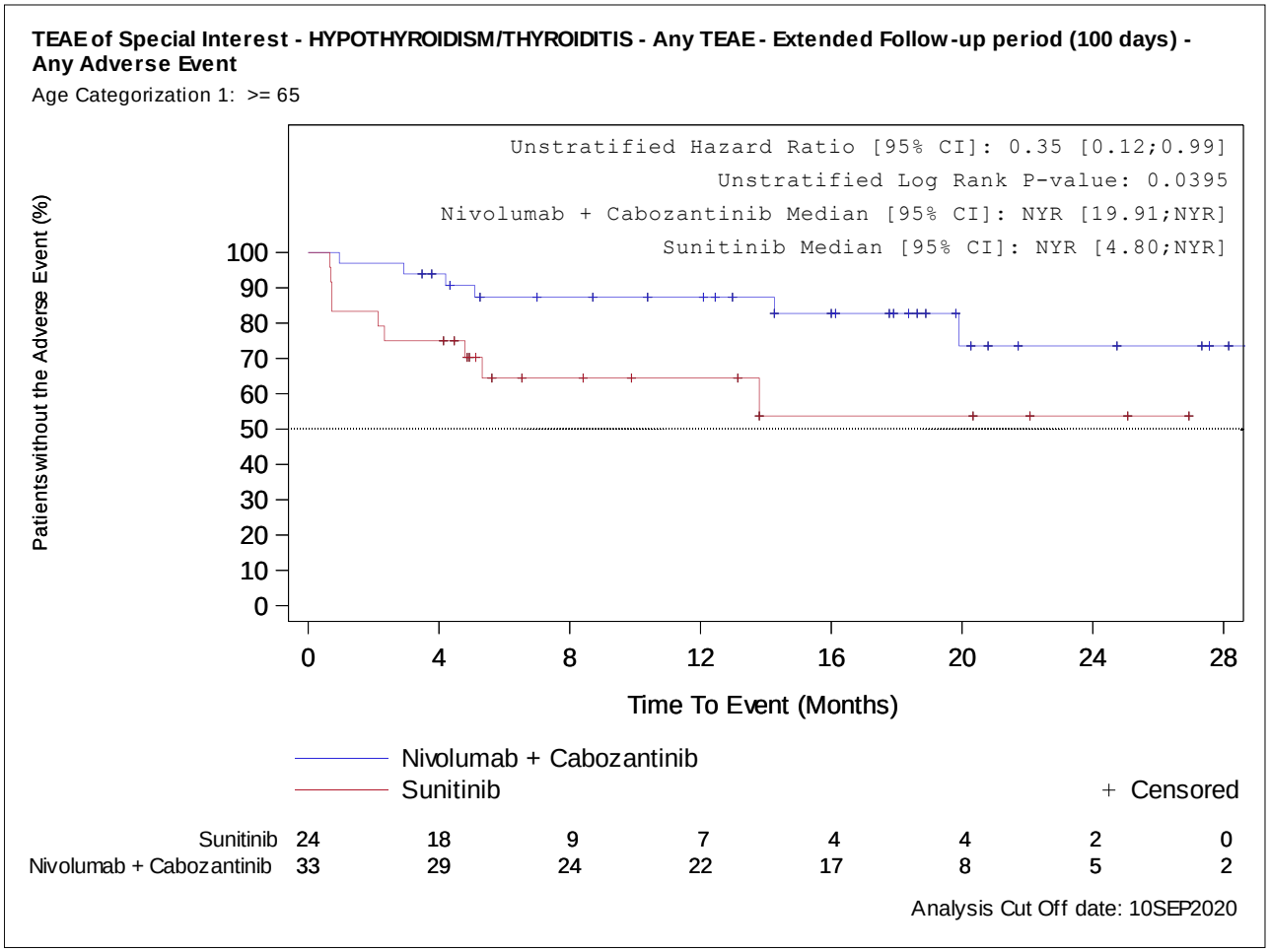
FIGURE 3.114.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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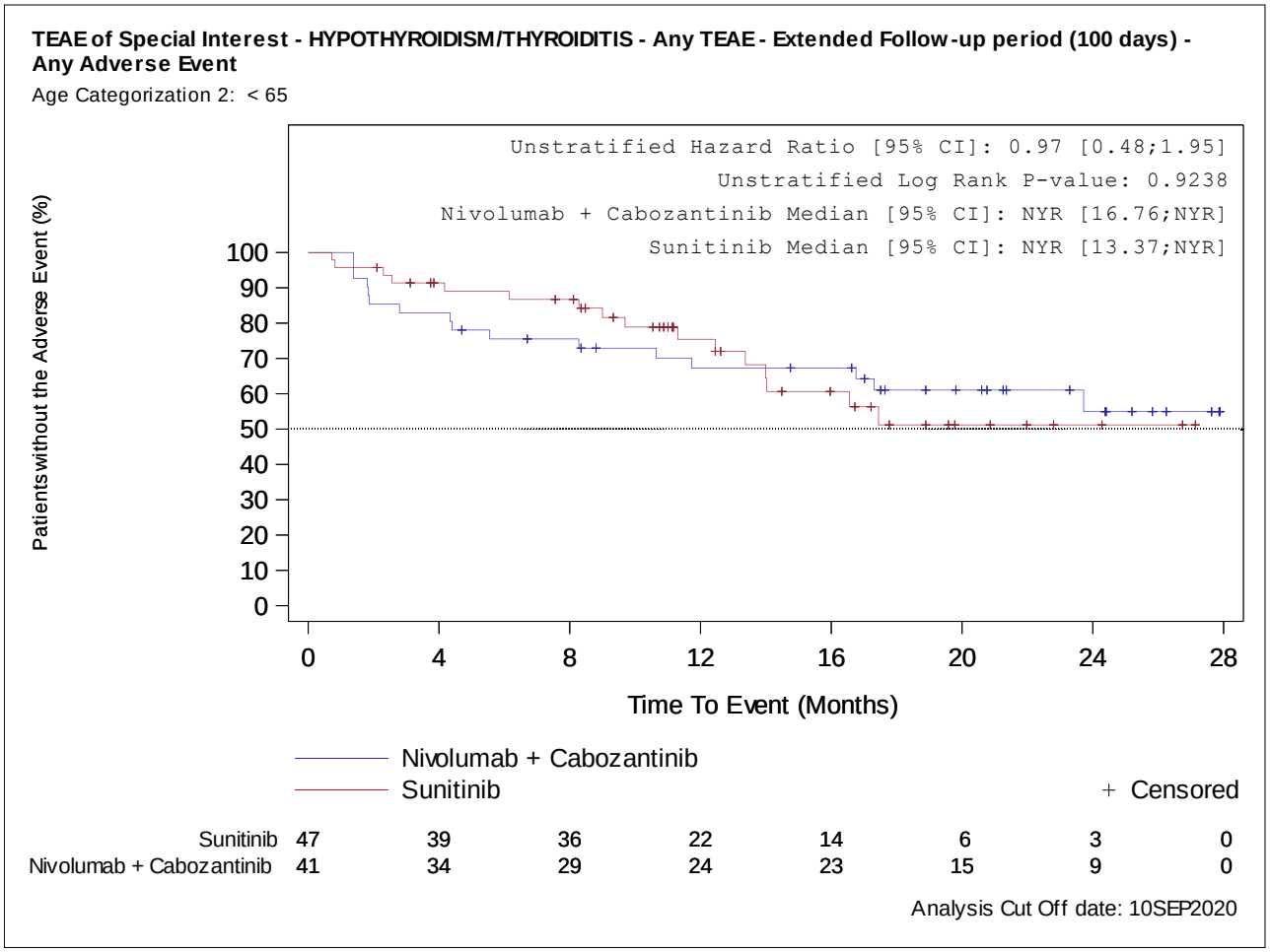
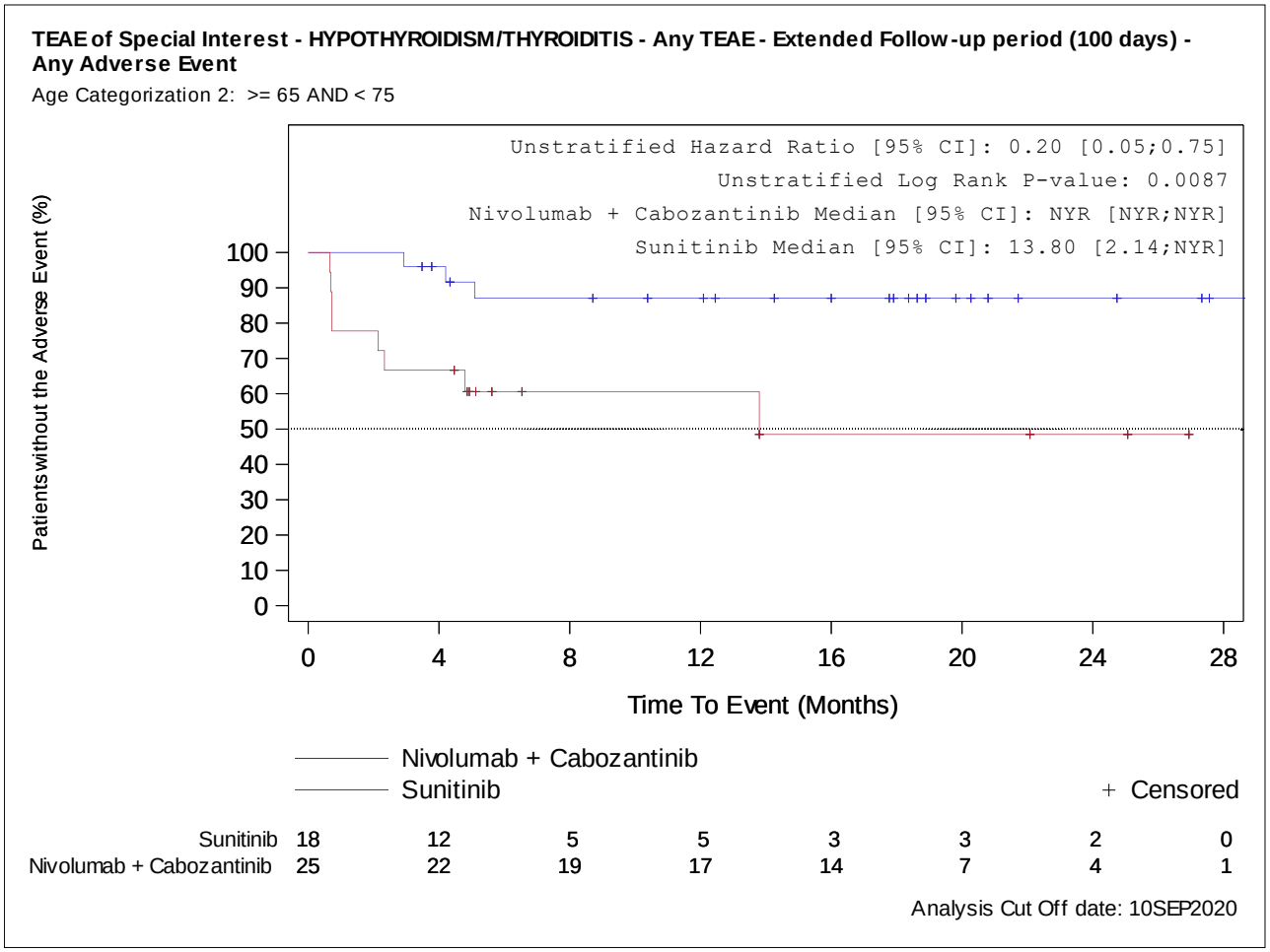
FIGURE 3.114.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



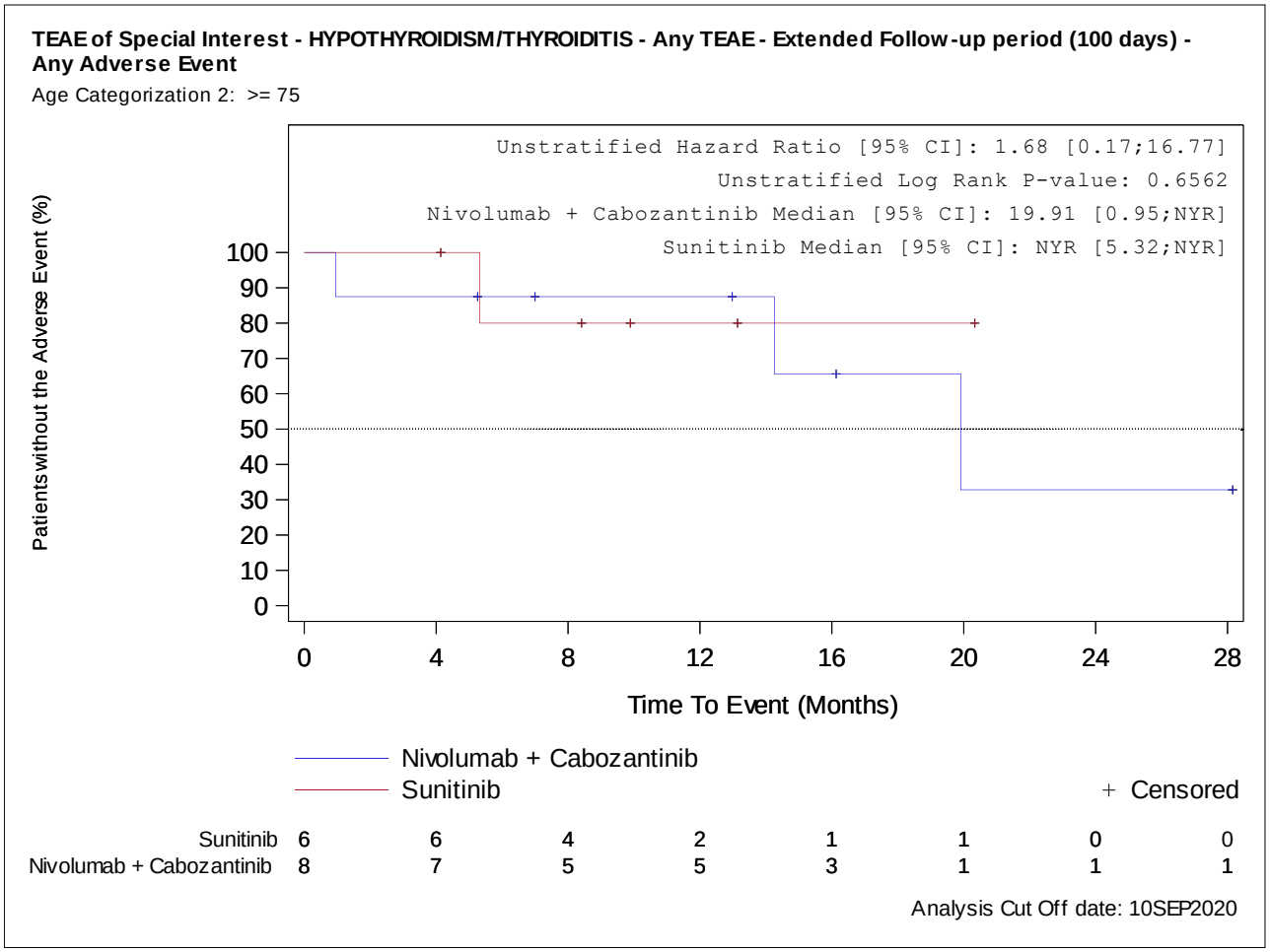

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:53:56

FIGURE 3.114.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



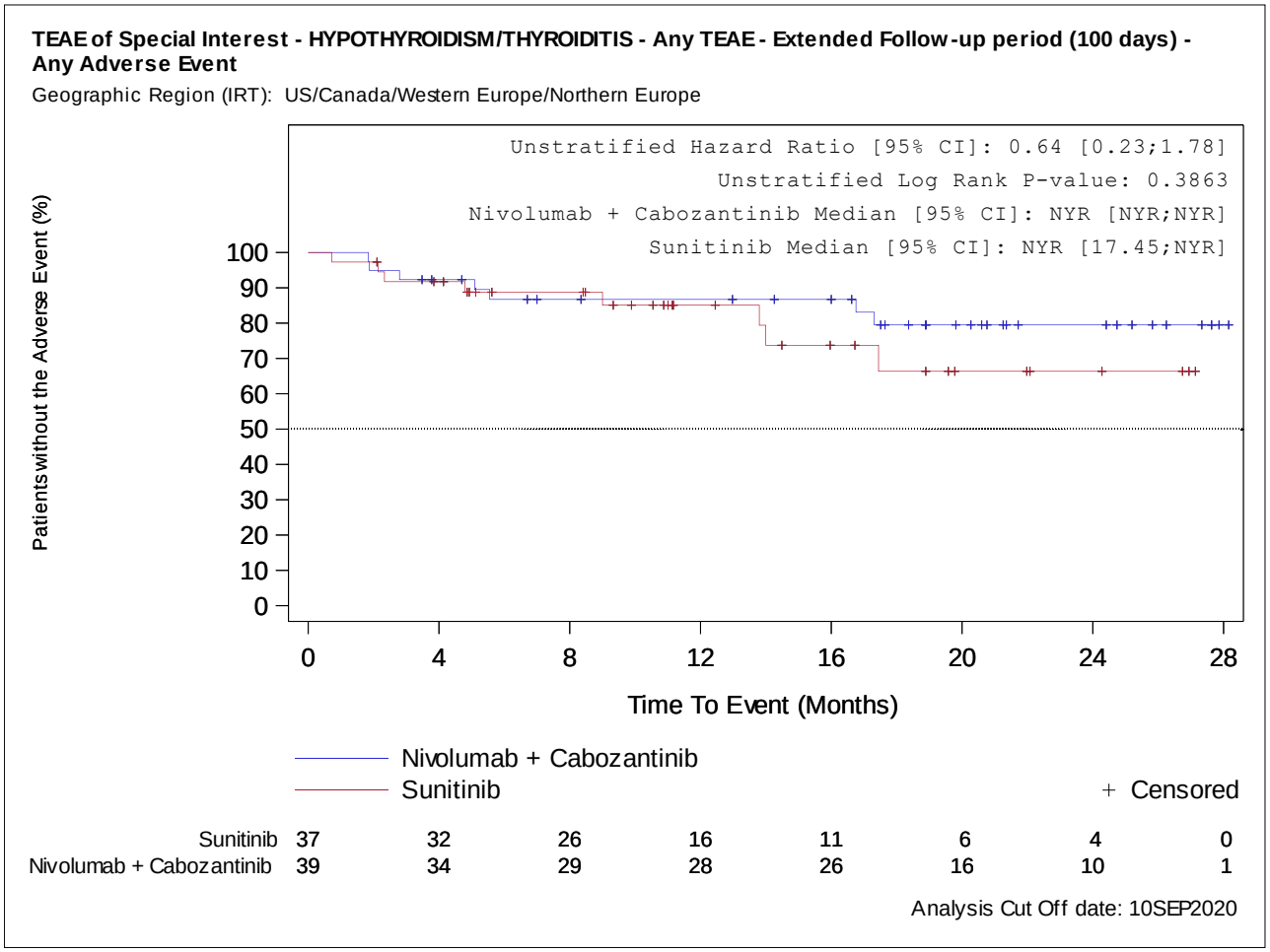

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:54:02

FIGURE 3.114.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



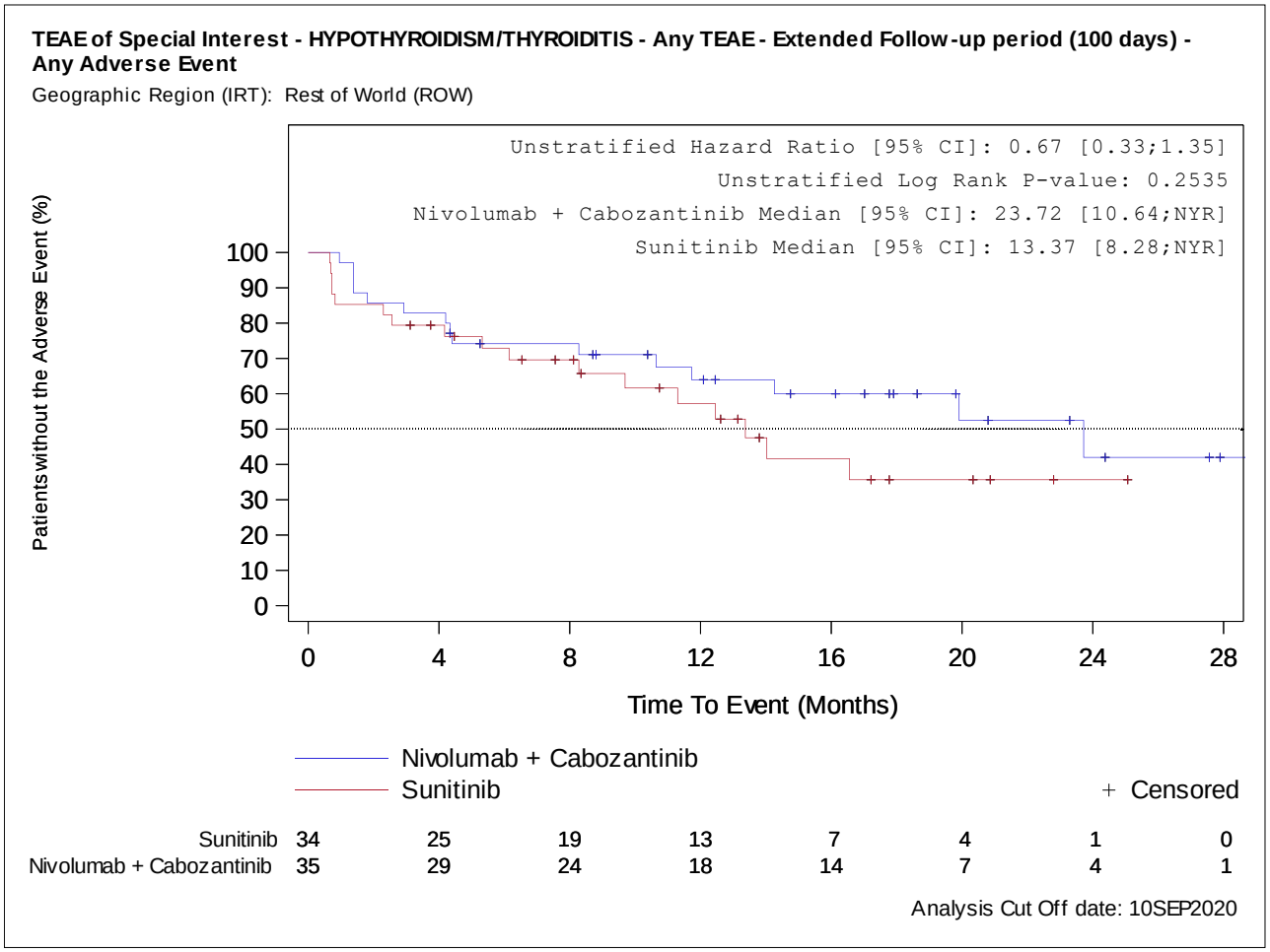

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:54:08

FIGURE 3.114.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:54:14

FIGURE 3.114.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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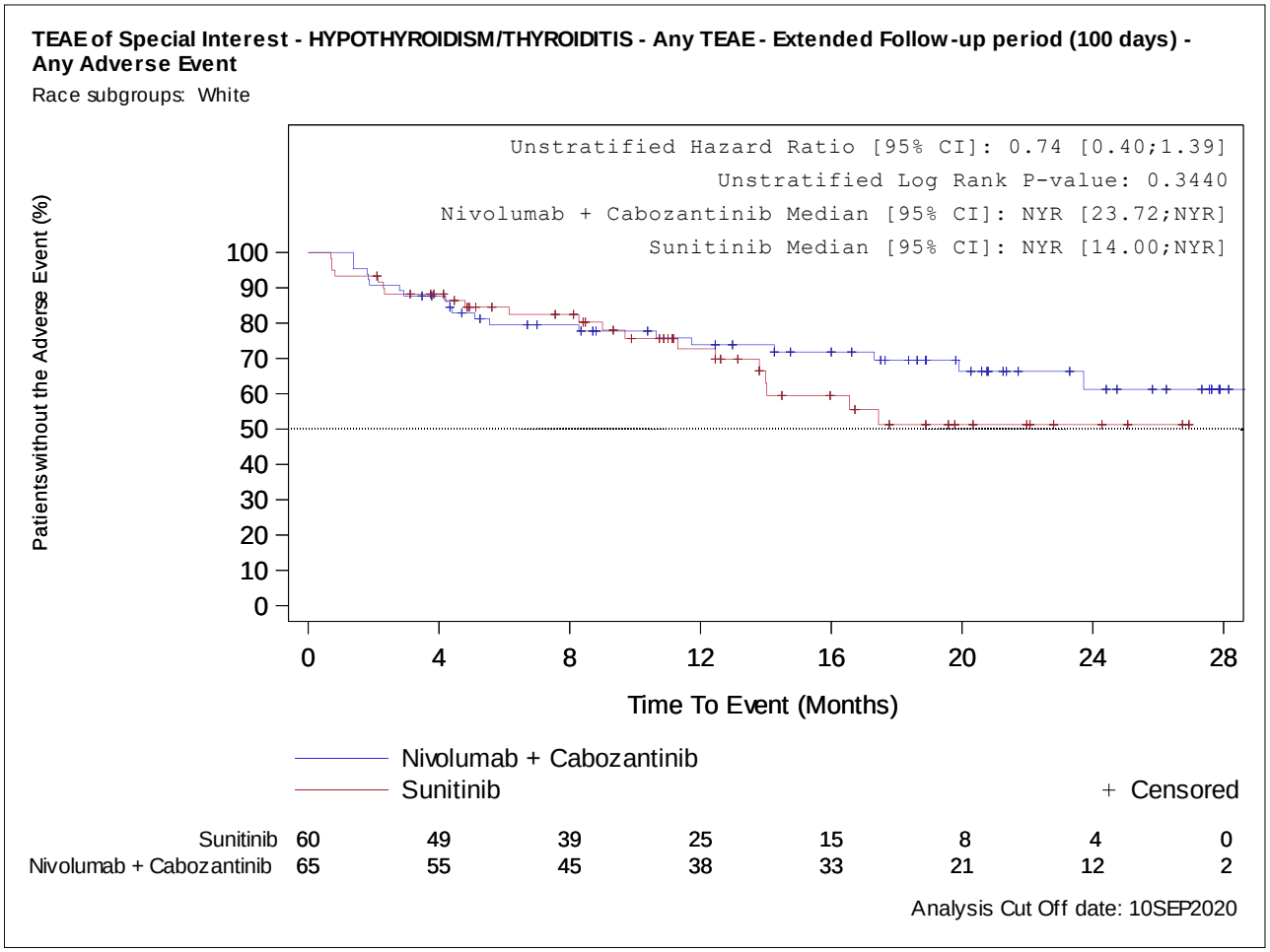
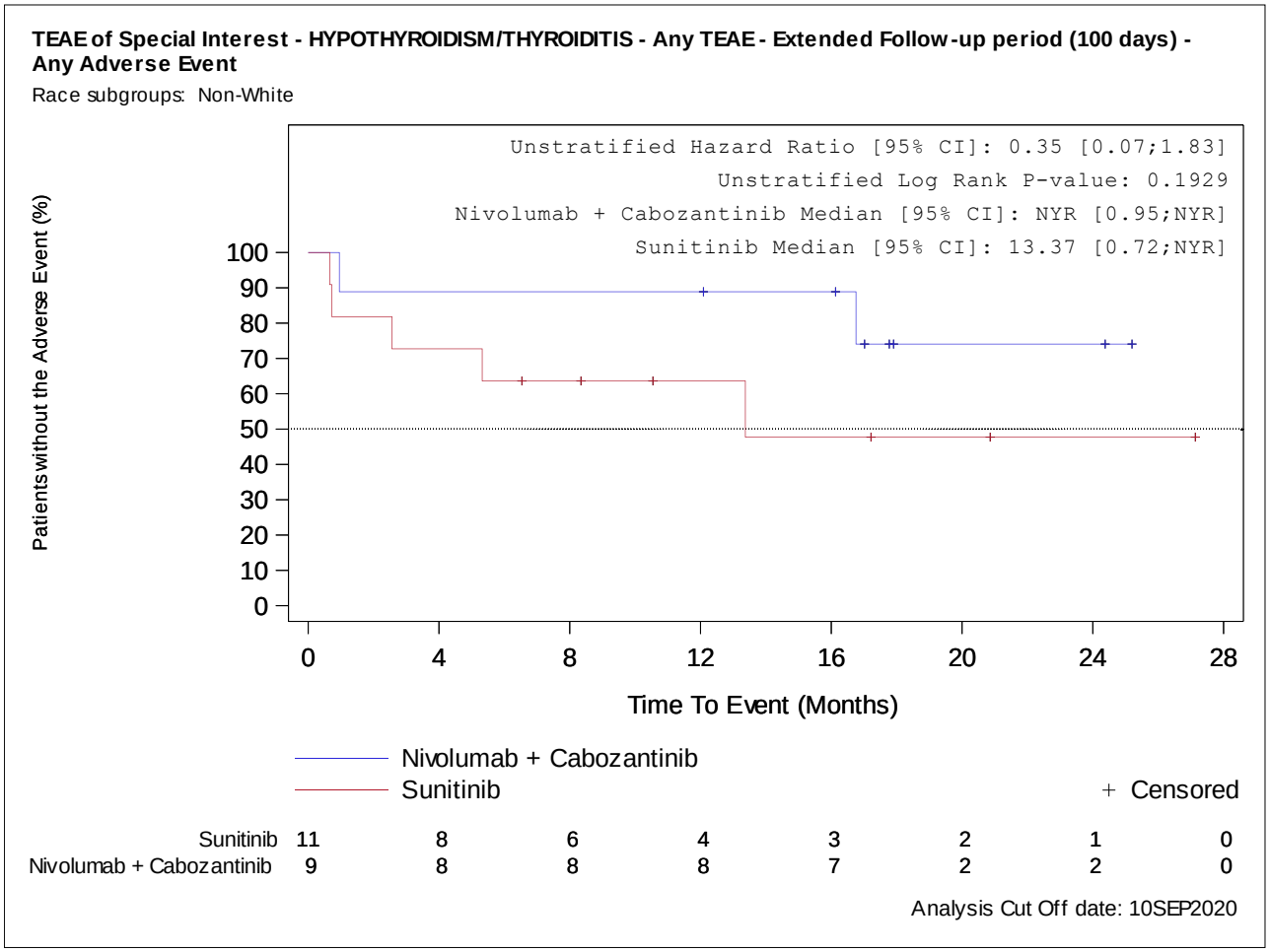
FIGURE 3.114.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:54:26

FIGURE 3.114.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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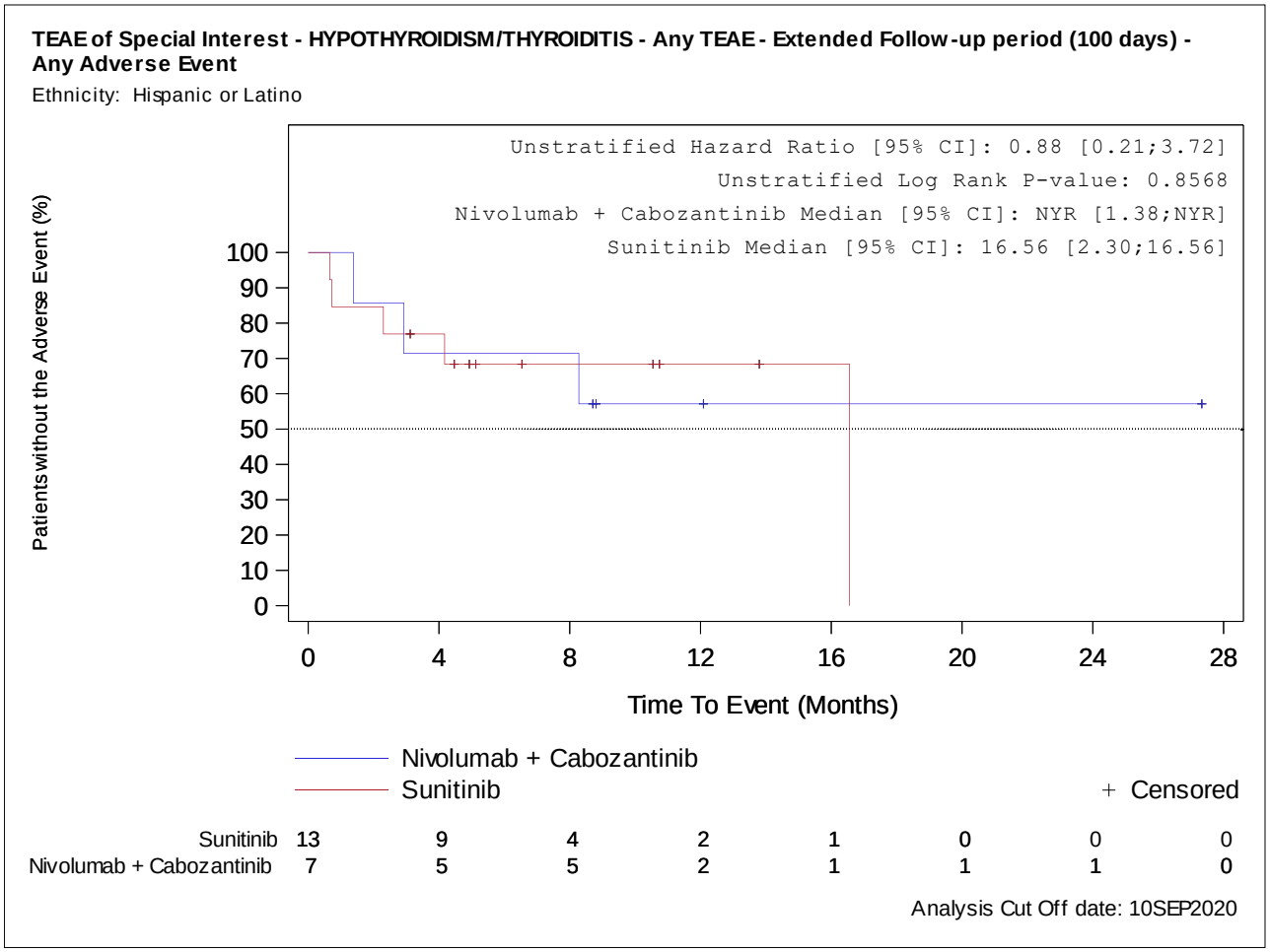
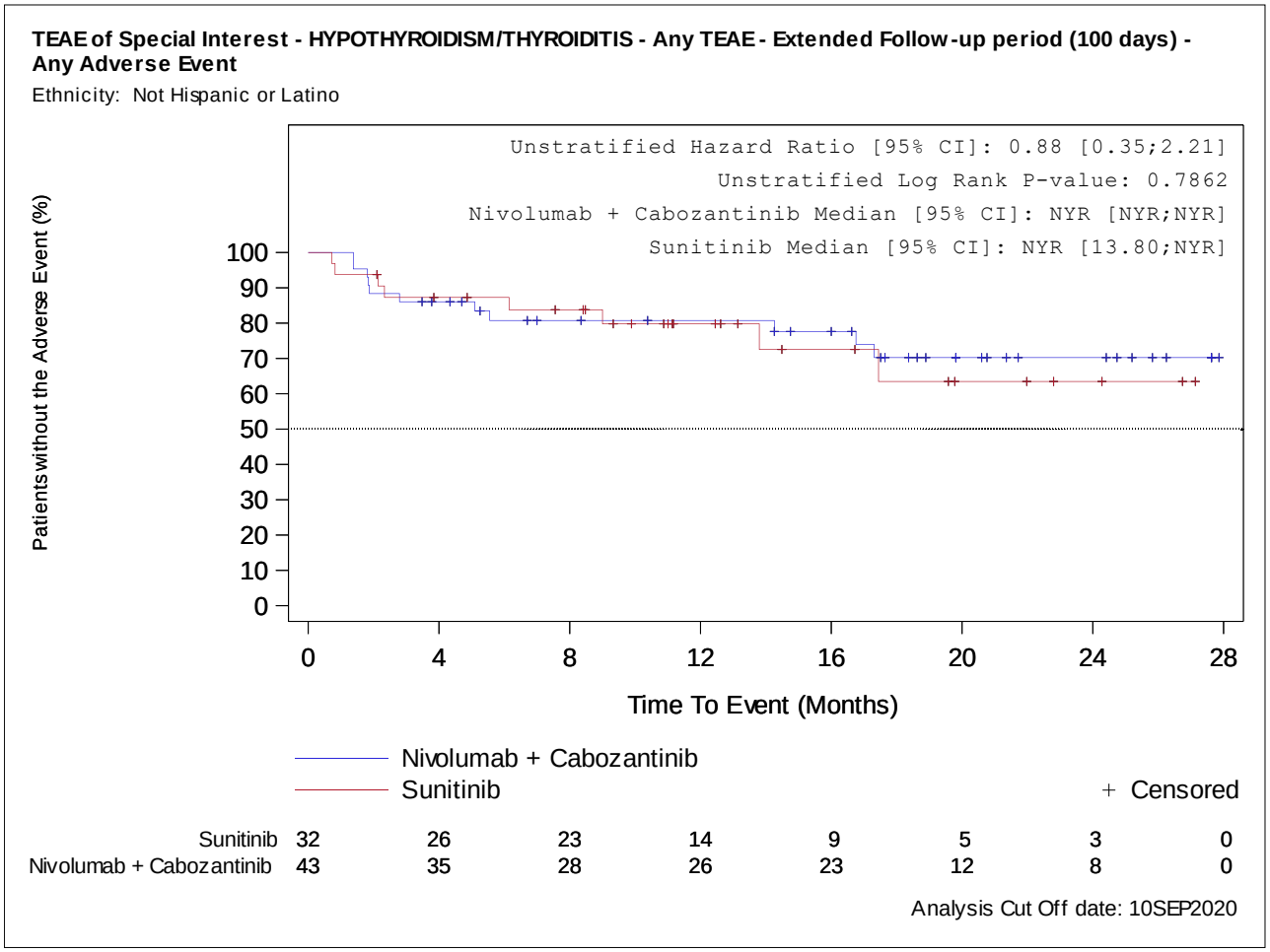
FIGURE 3.114.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



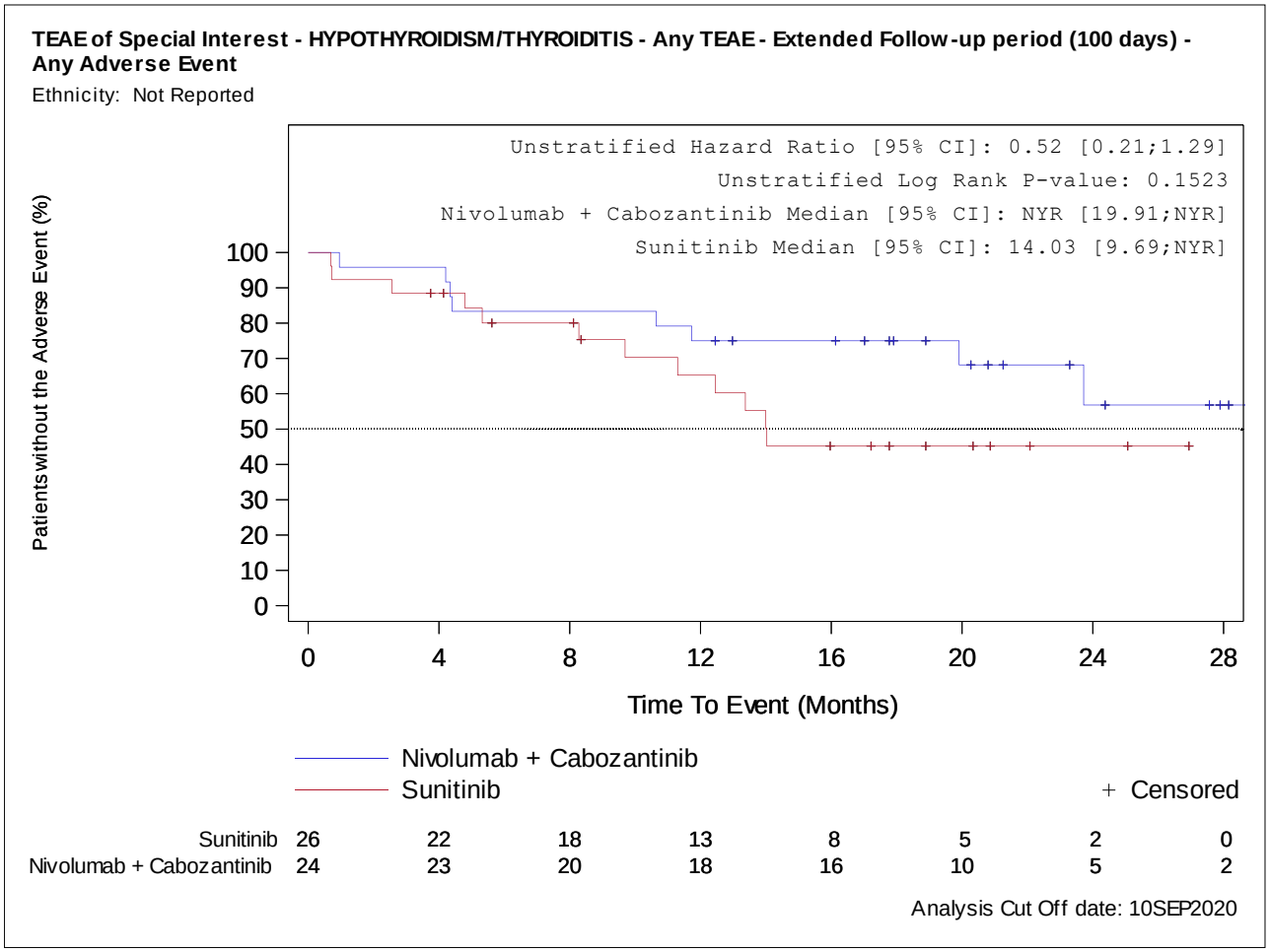

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:54:38

FIGURE 3.114.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



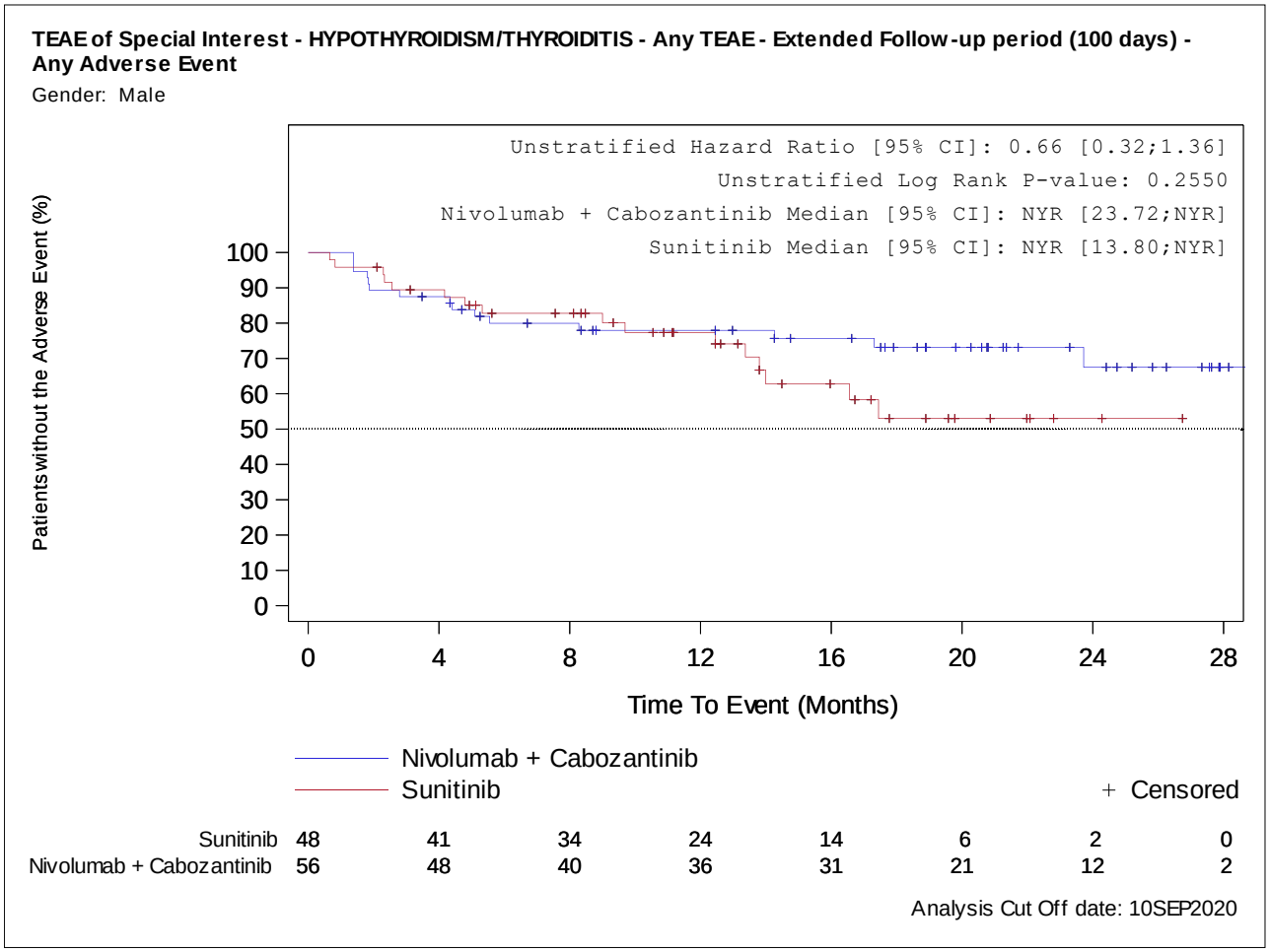

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:54:44

FIGURE 3.114.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



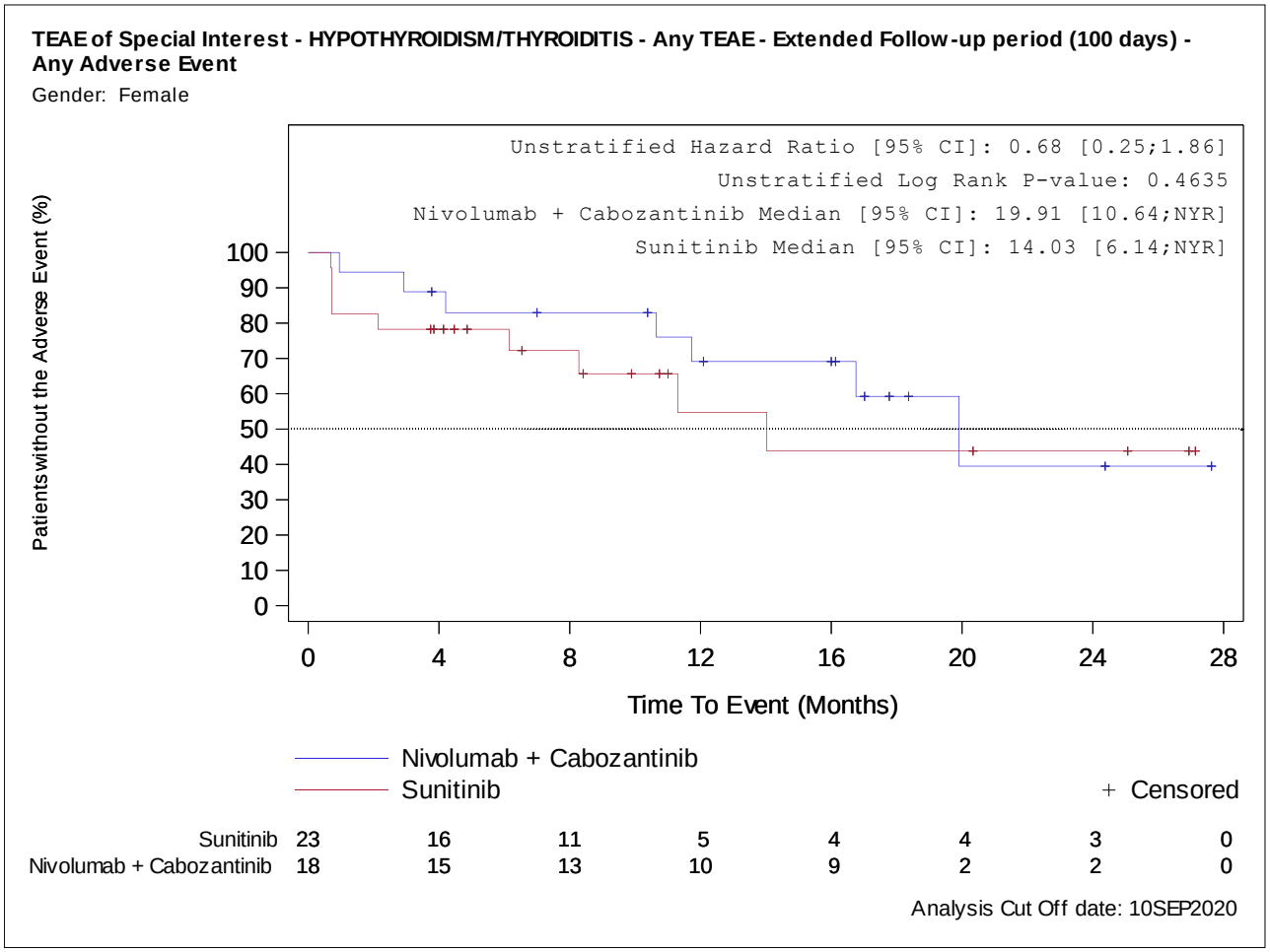

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:54:50

FIGURE 3.114.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:54:56

FIGURE 3.114.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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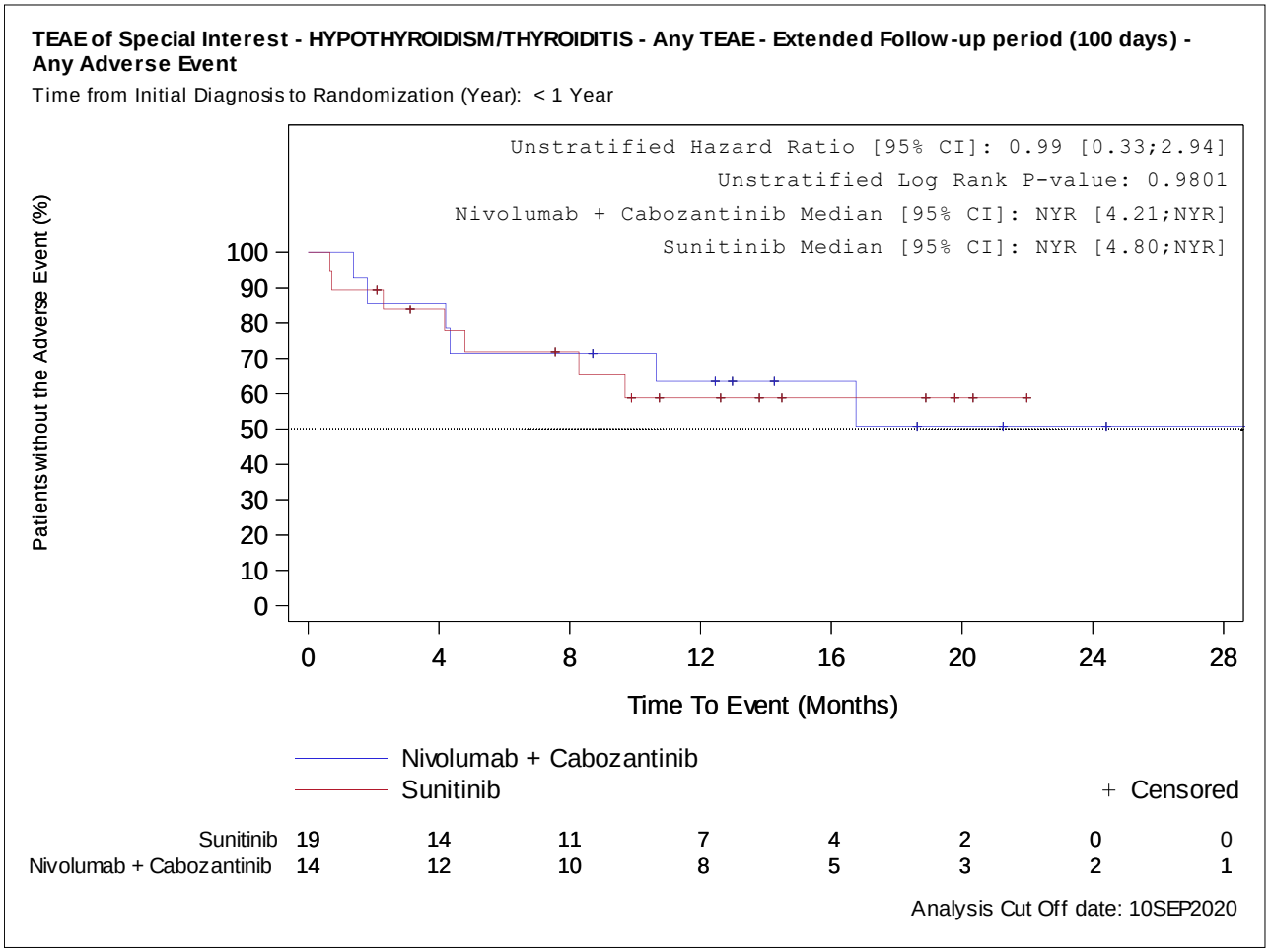
FIGURE 3.114.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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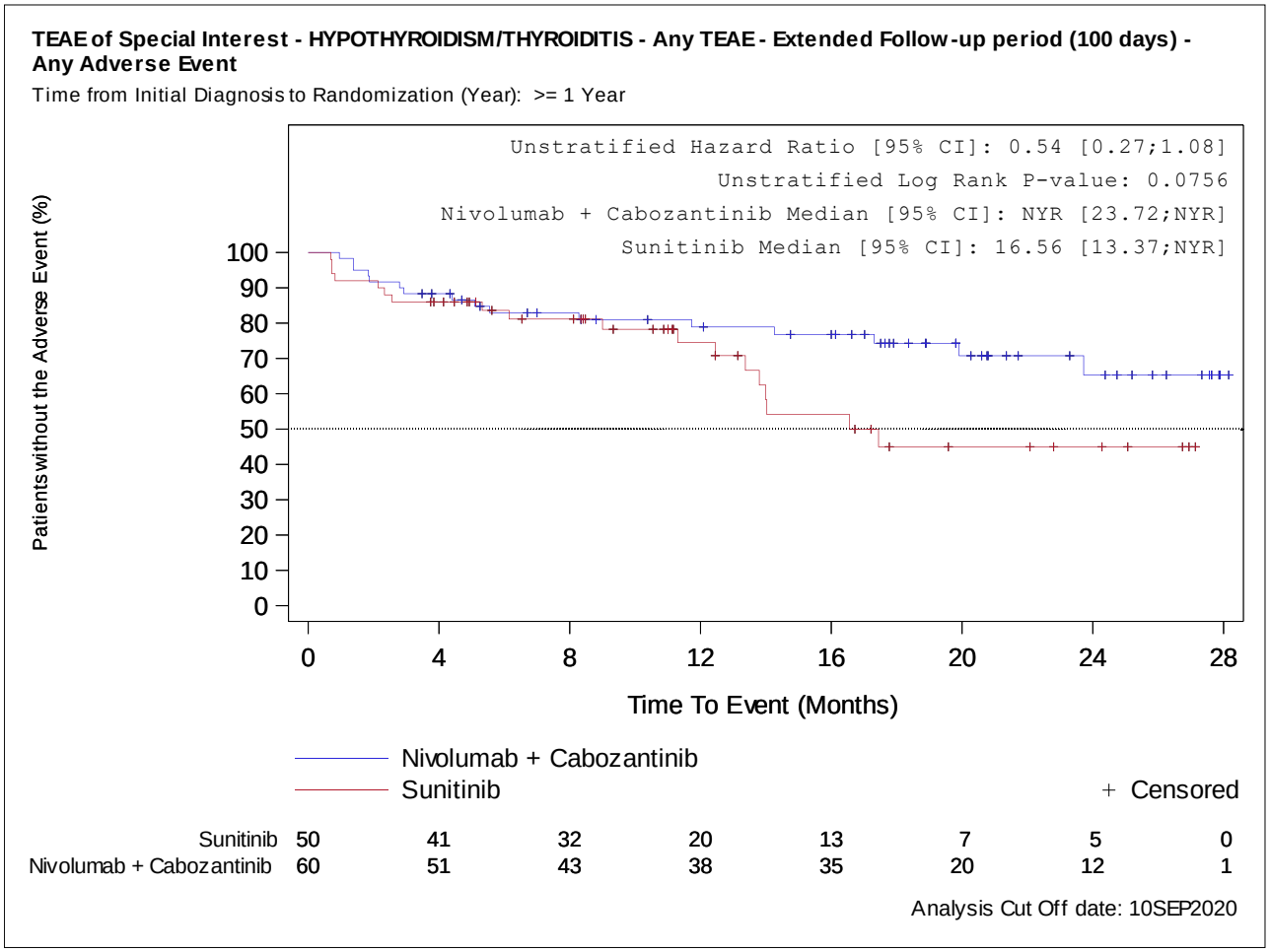
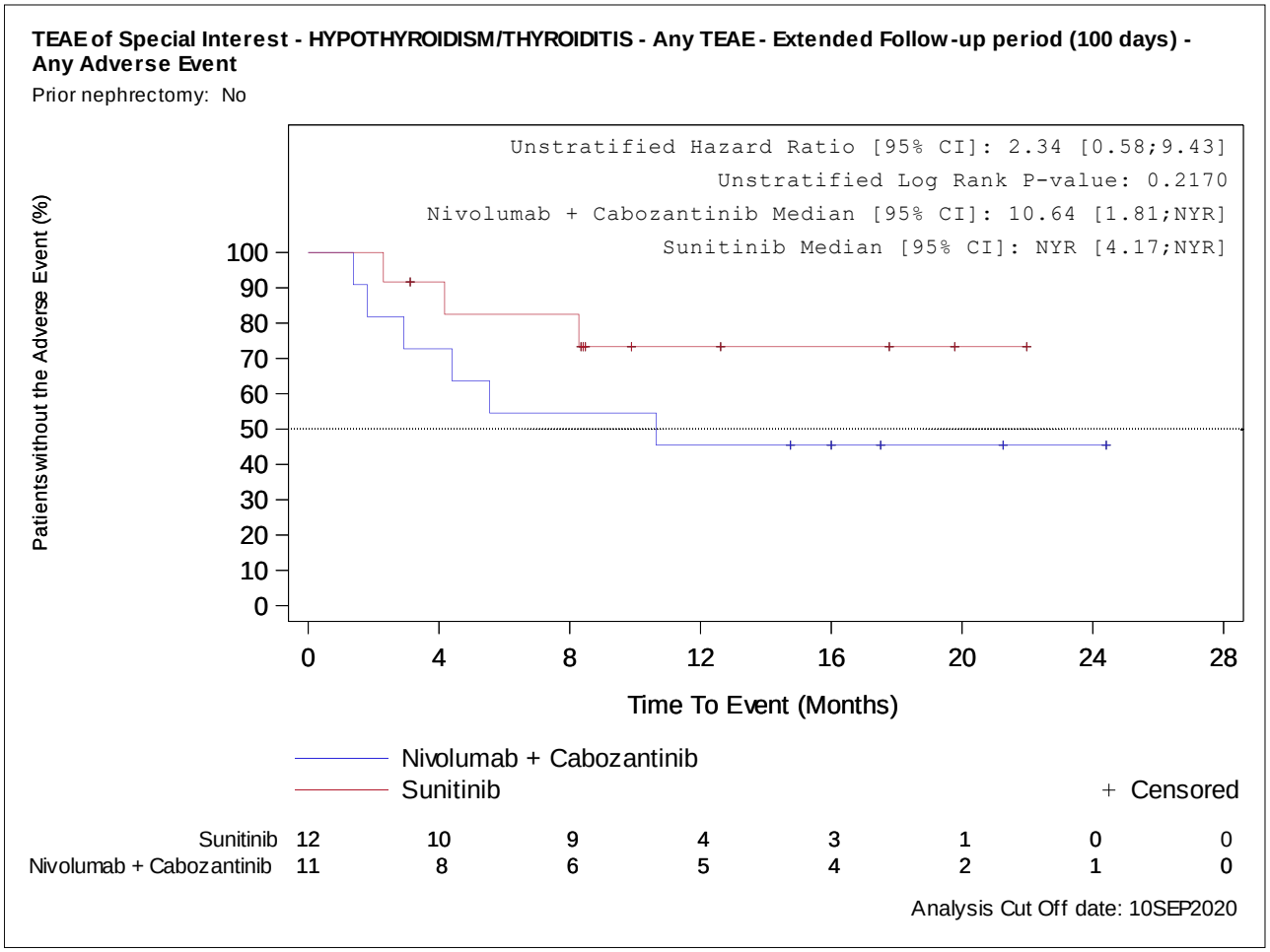
FIGURE 3.114.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:55:27

FIGURE 3.114.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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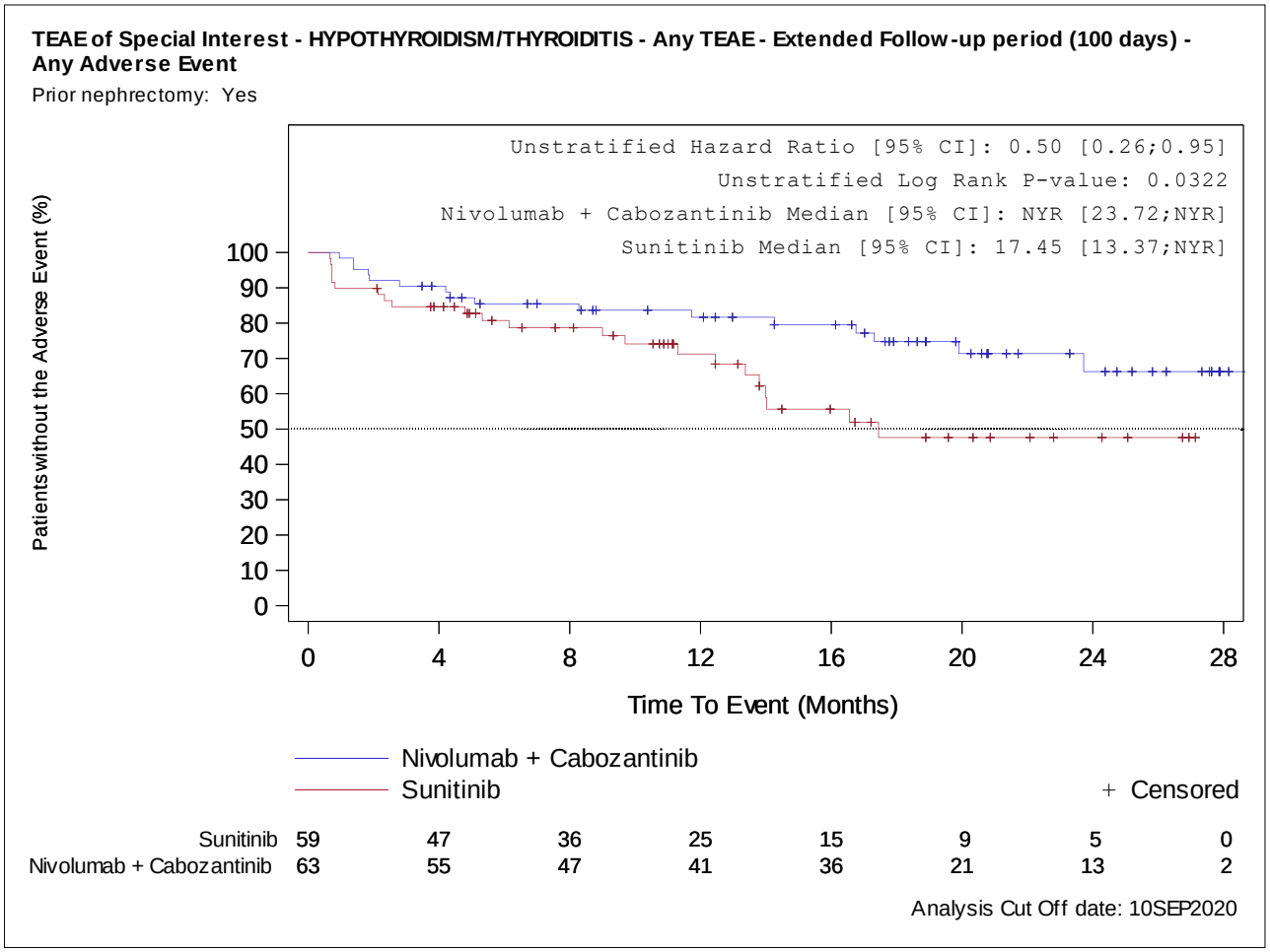
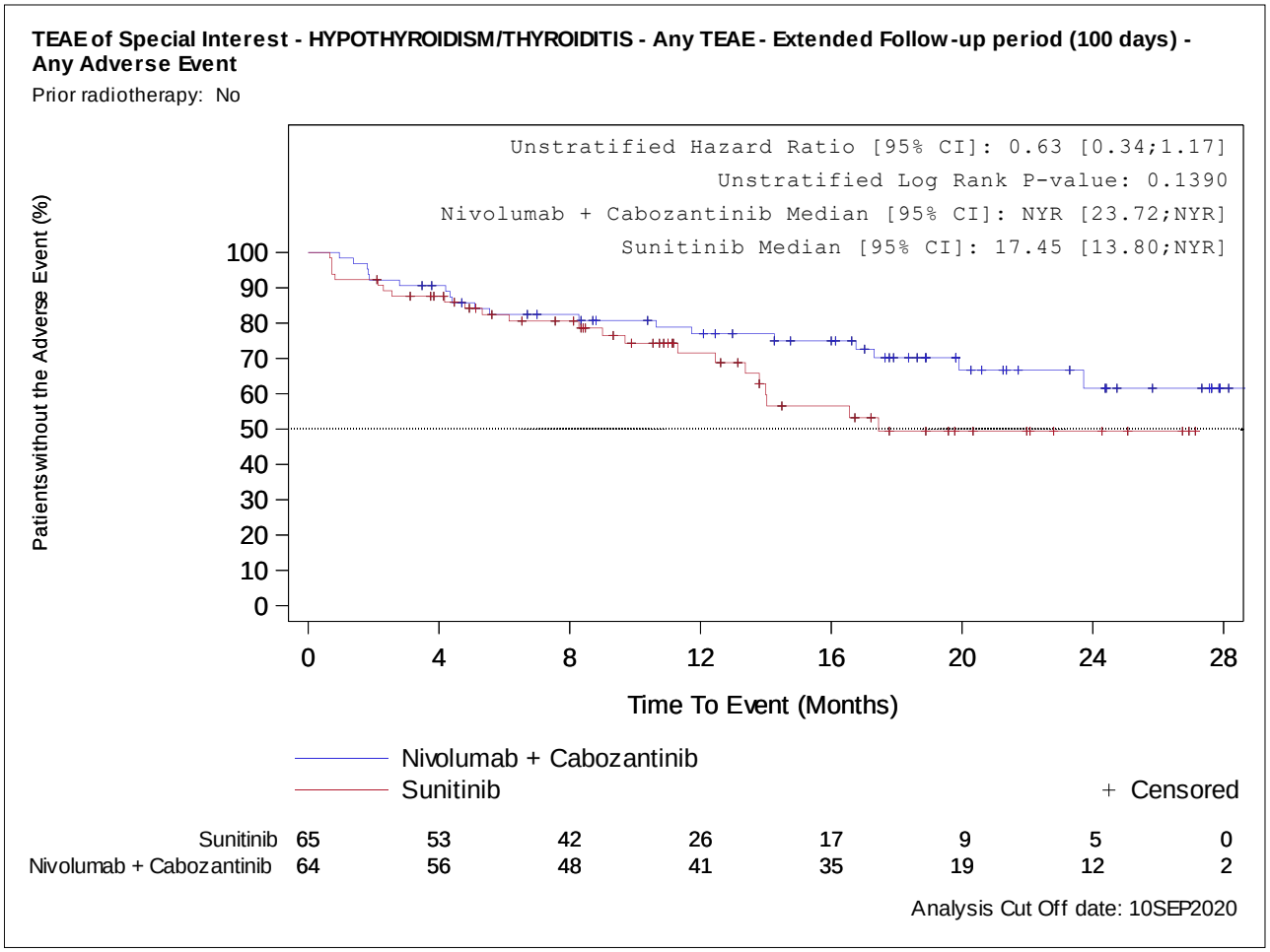
FIGURE 3.114.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



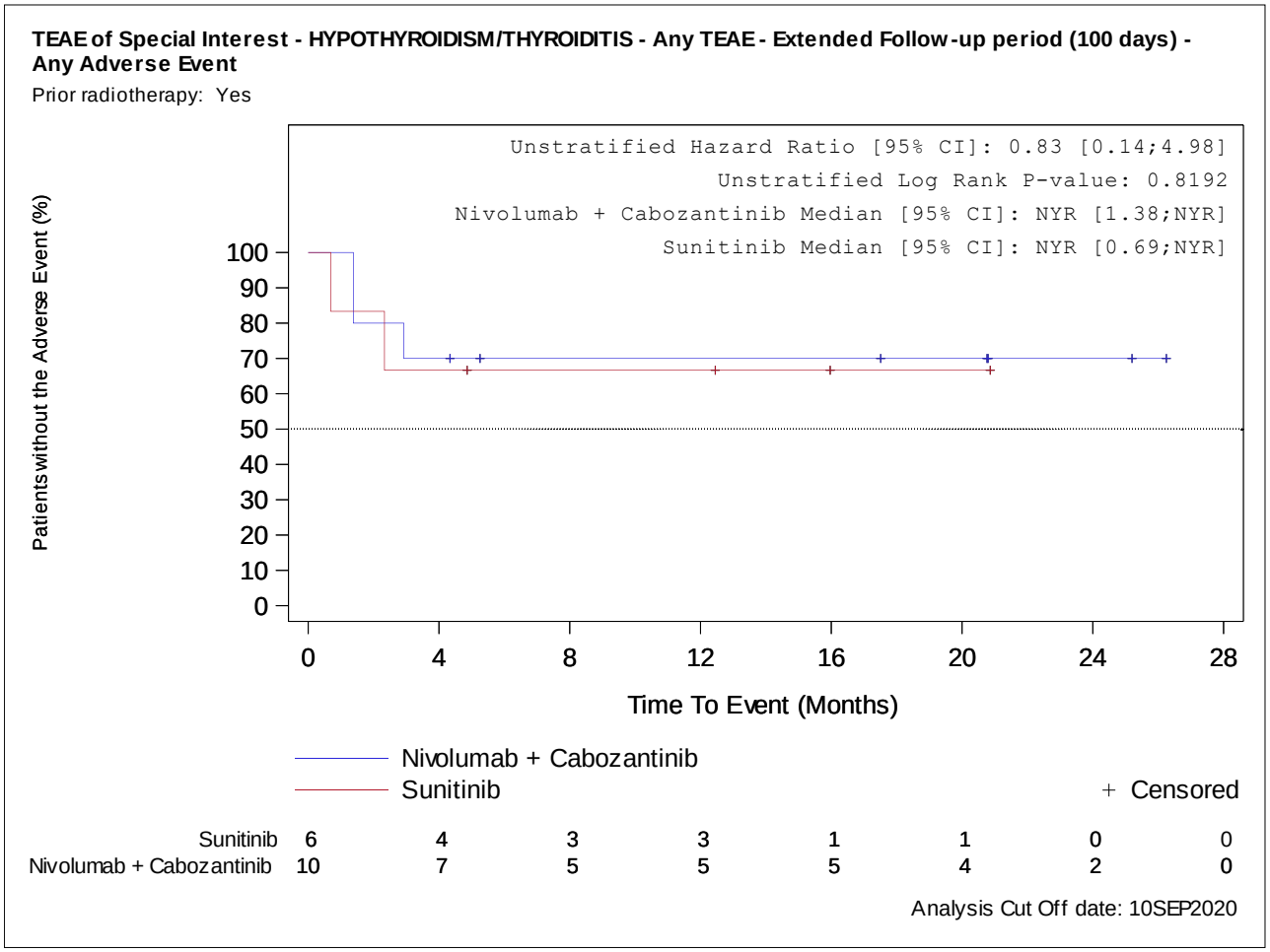

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:56:27

FIGURE 3.114.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:56:34

FIGURE 3.114.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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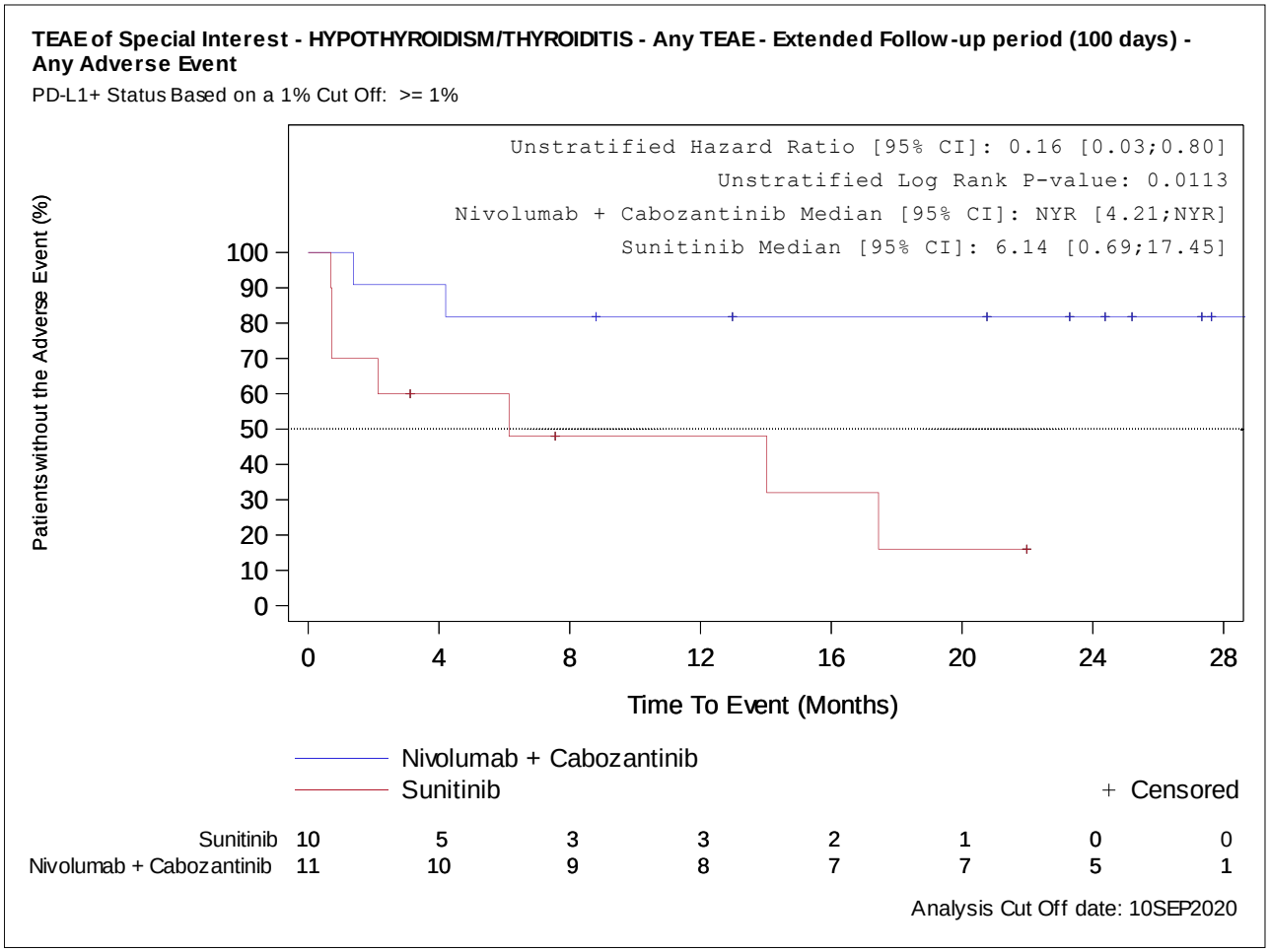
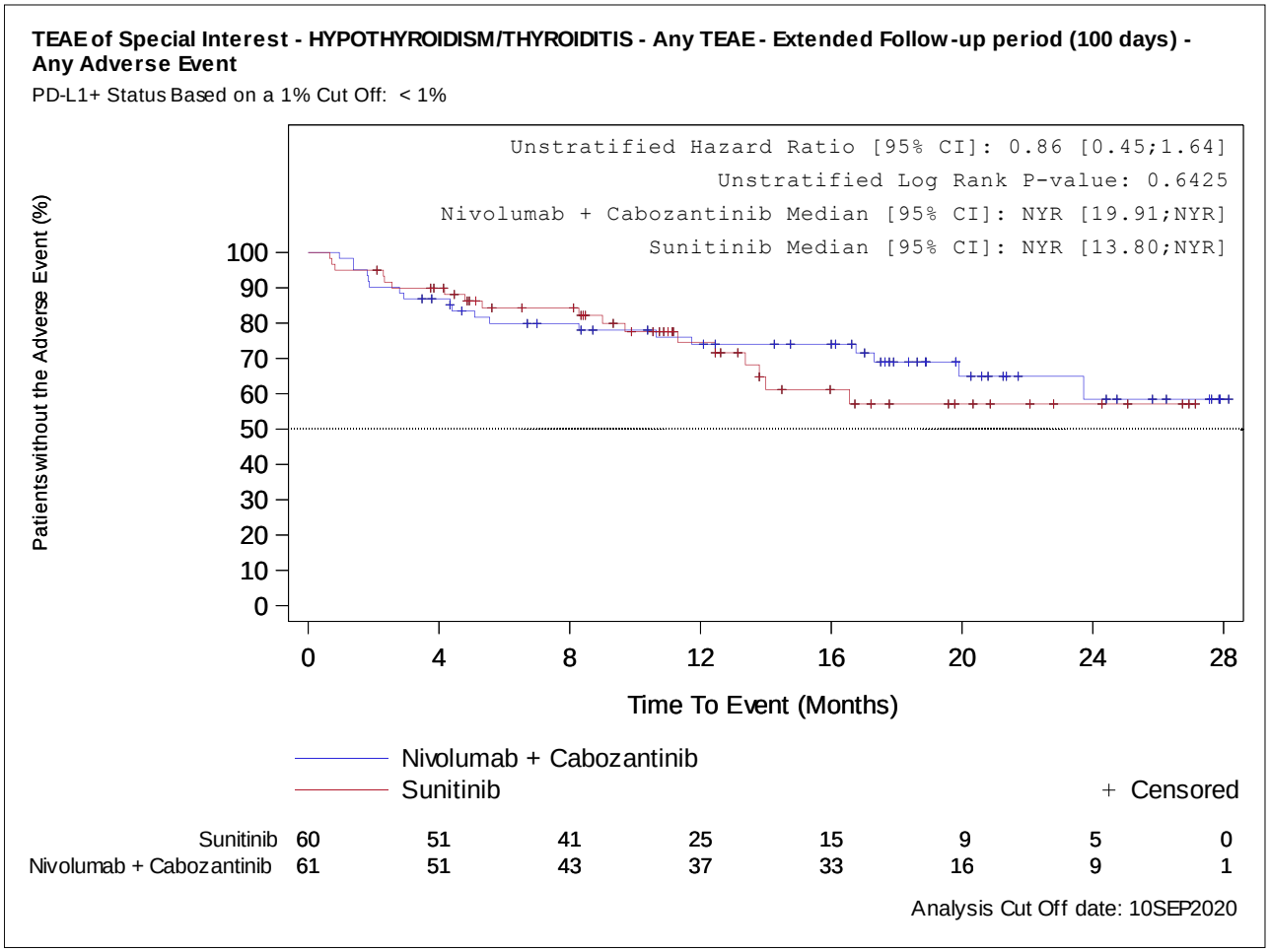
FIGURE 3.114.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:56:47

FIGURE 3.114.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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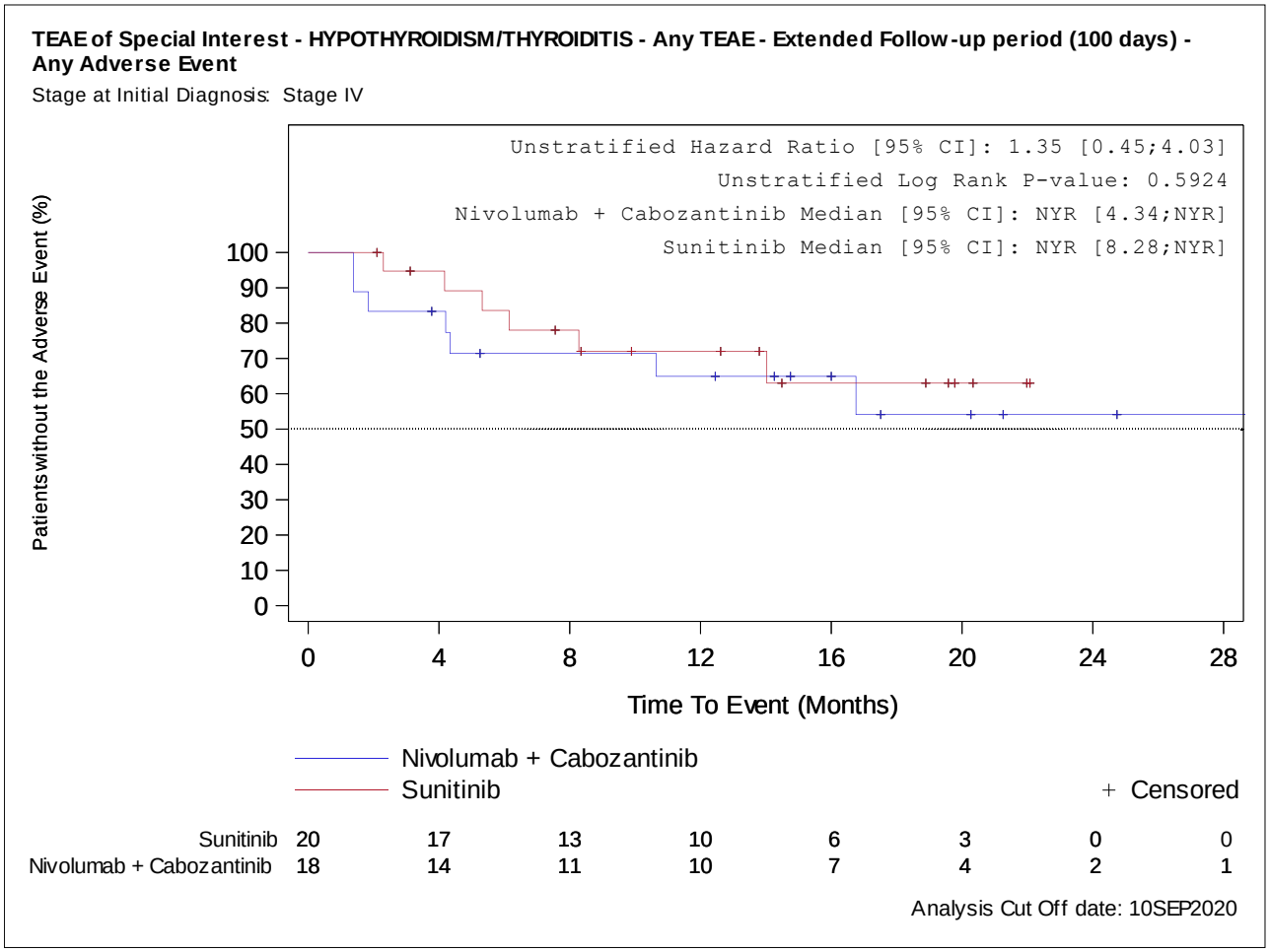
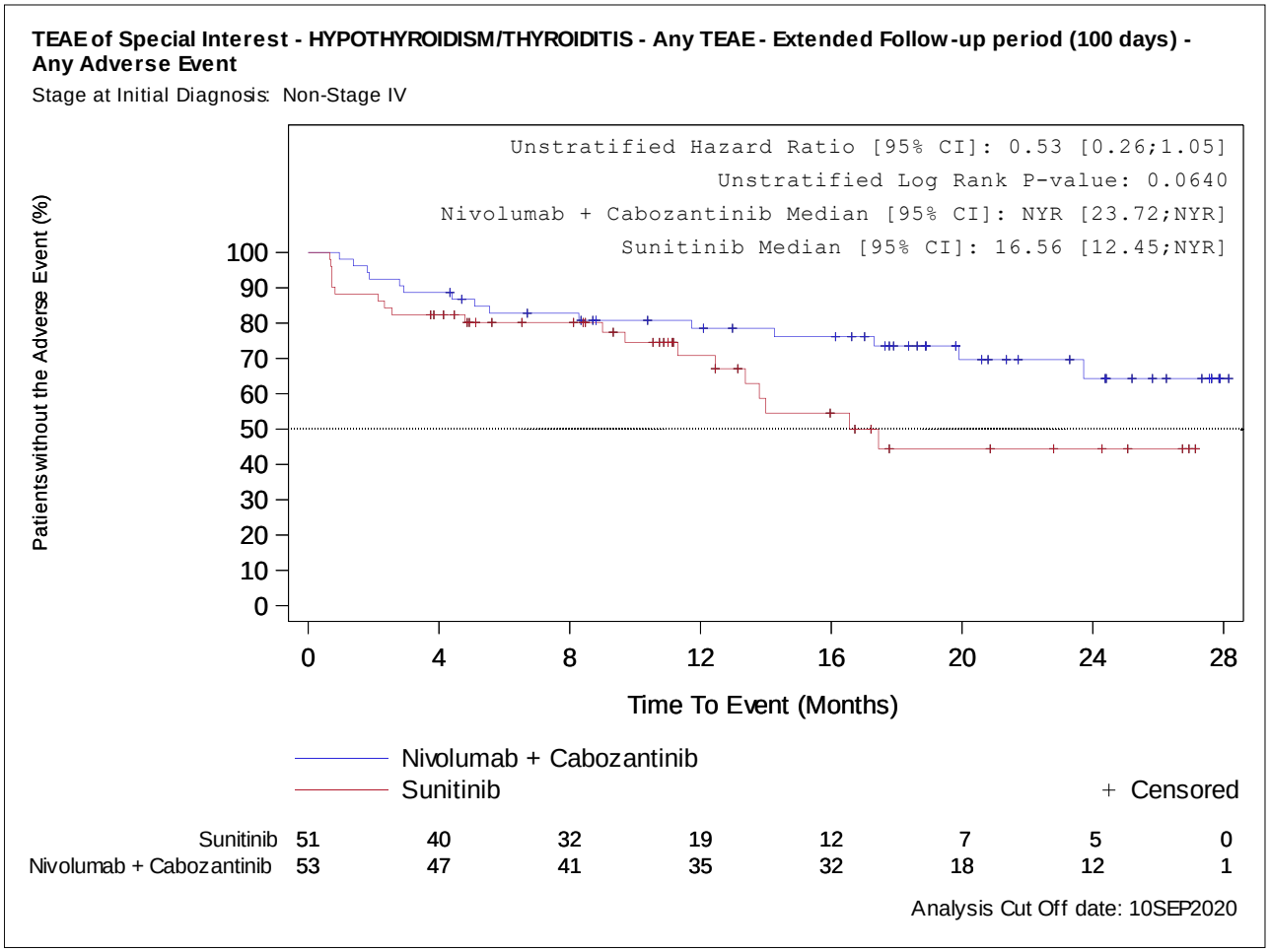
FIGURE 3.114.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



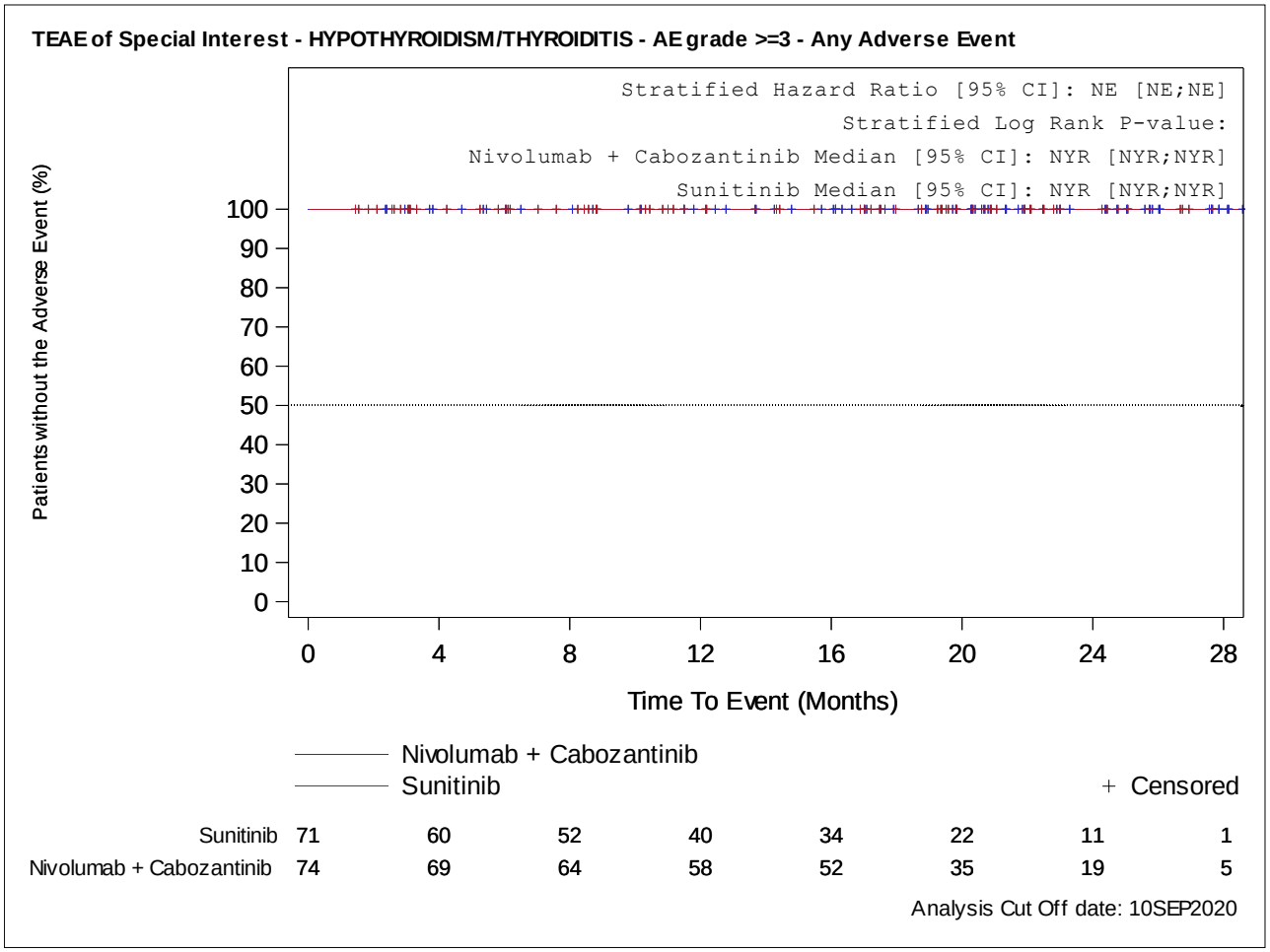

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:57:25

FIGURE 3.114.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



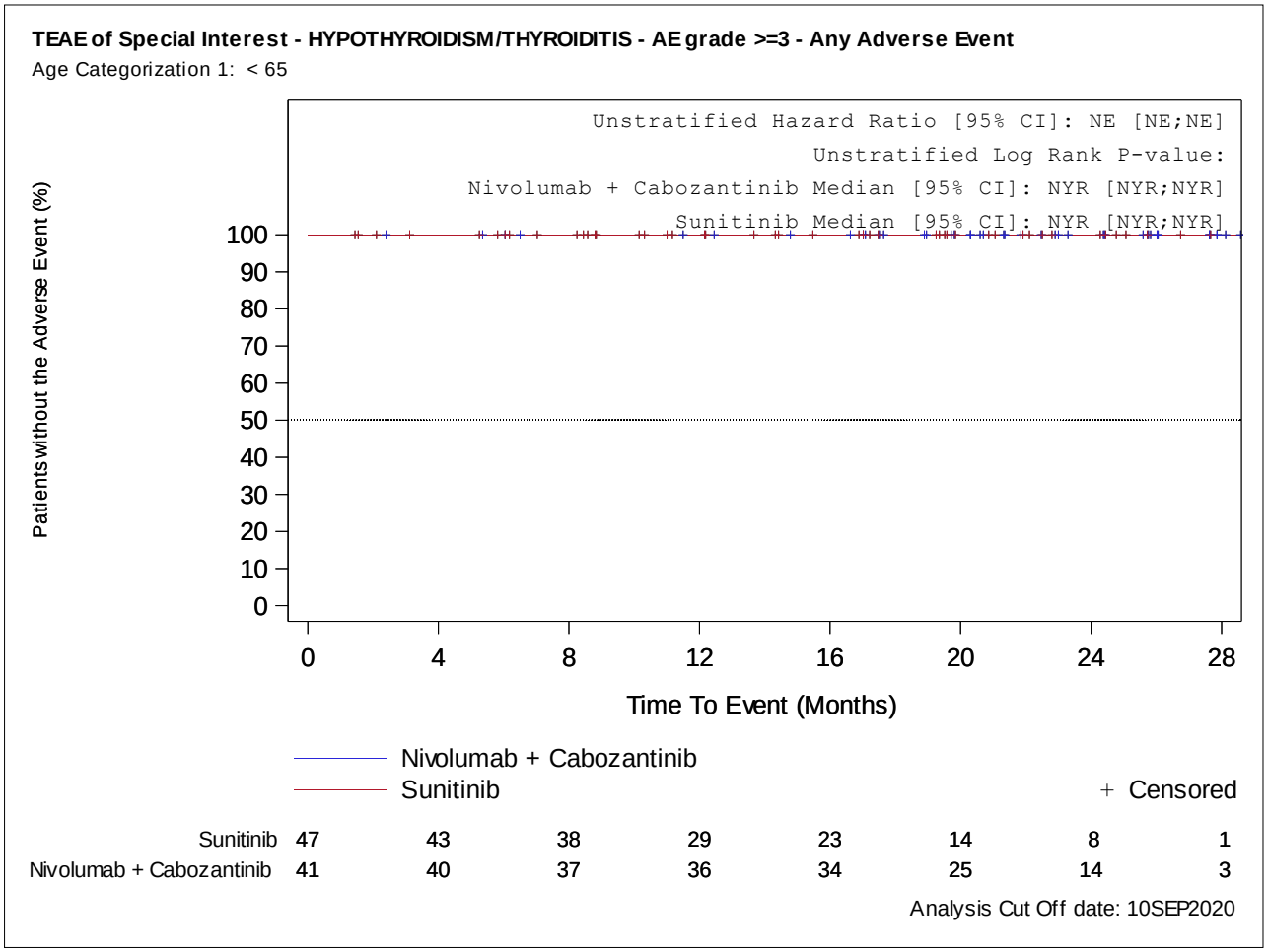

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 15:57:32

FIGURE 3.115.1: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:01:01

FIGURE 3.115.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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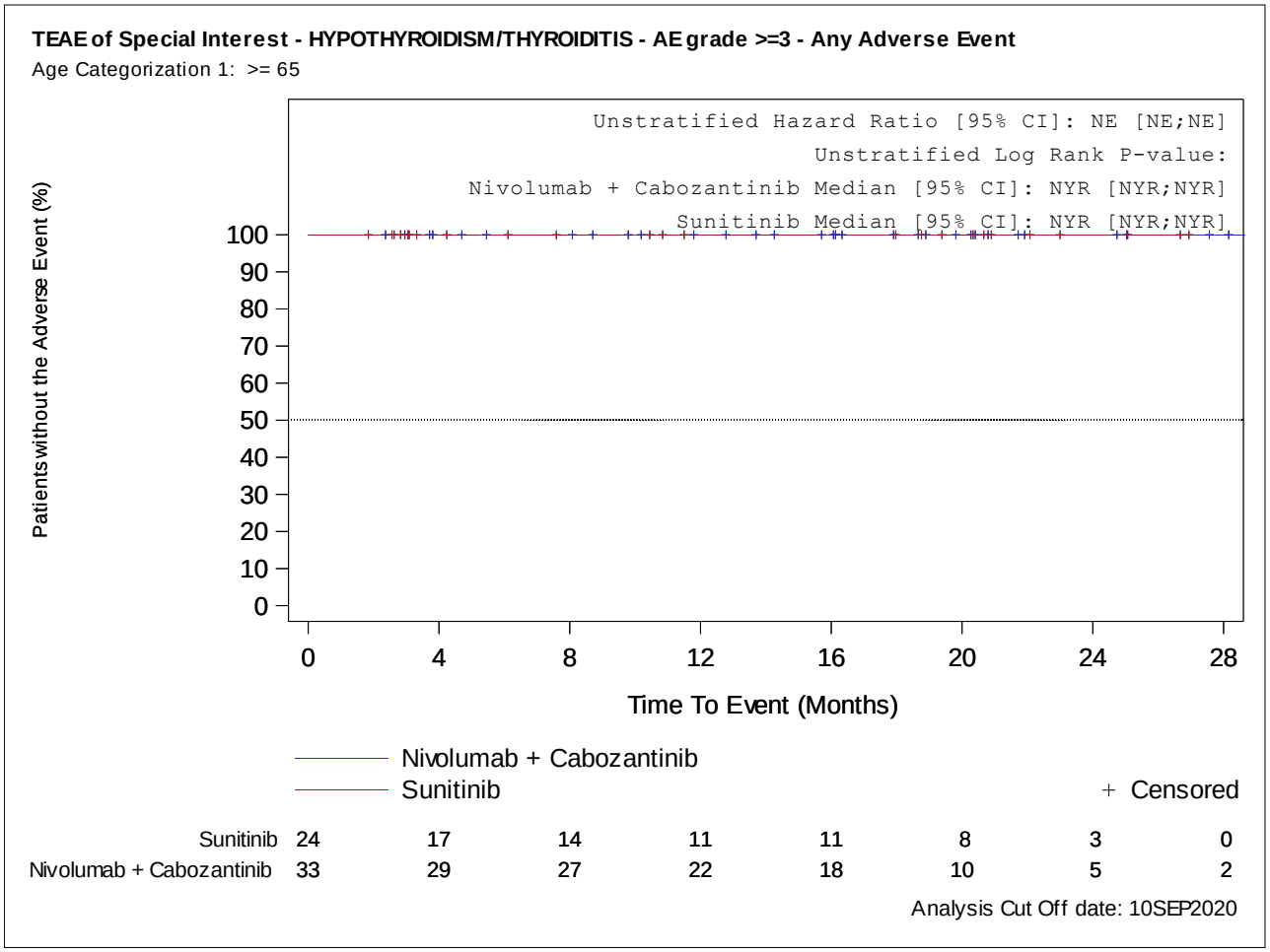
FIGURE 3.115.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65




Analysis Cut Off date: 10SEP2020
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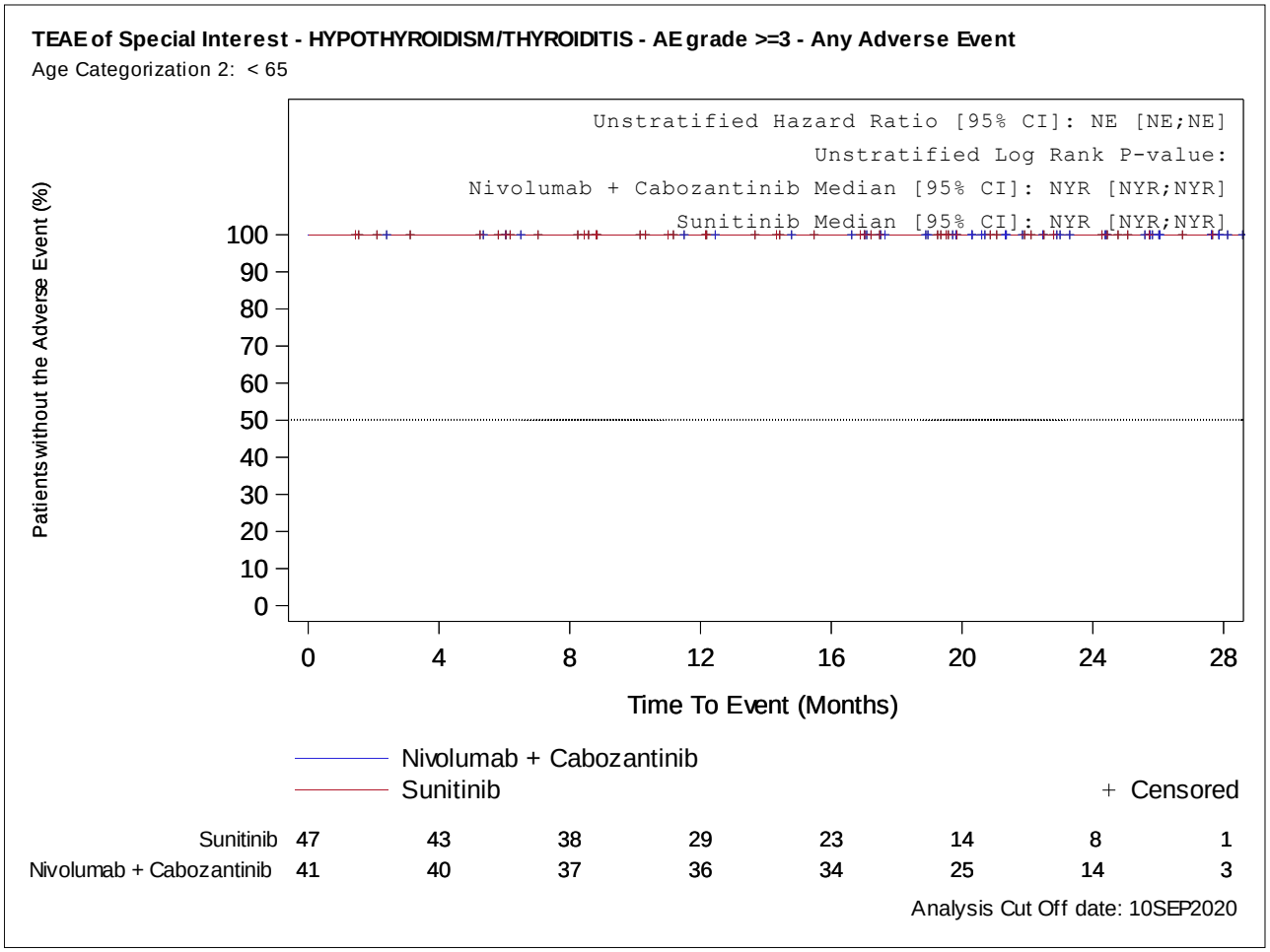
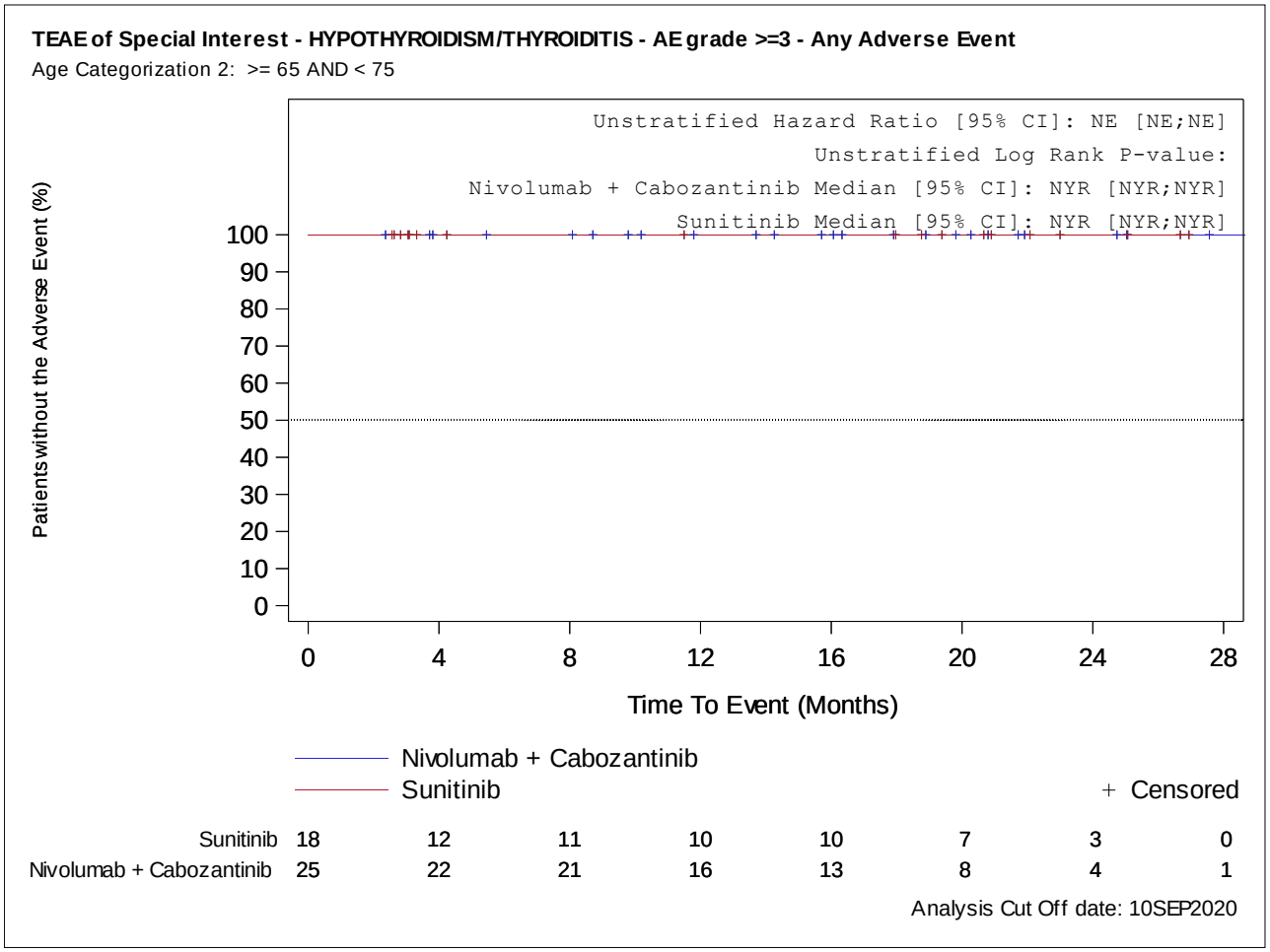
FIGURE 3.115.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:01:17

FIGURE 3.115.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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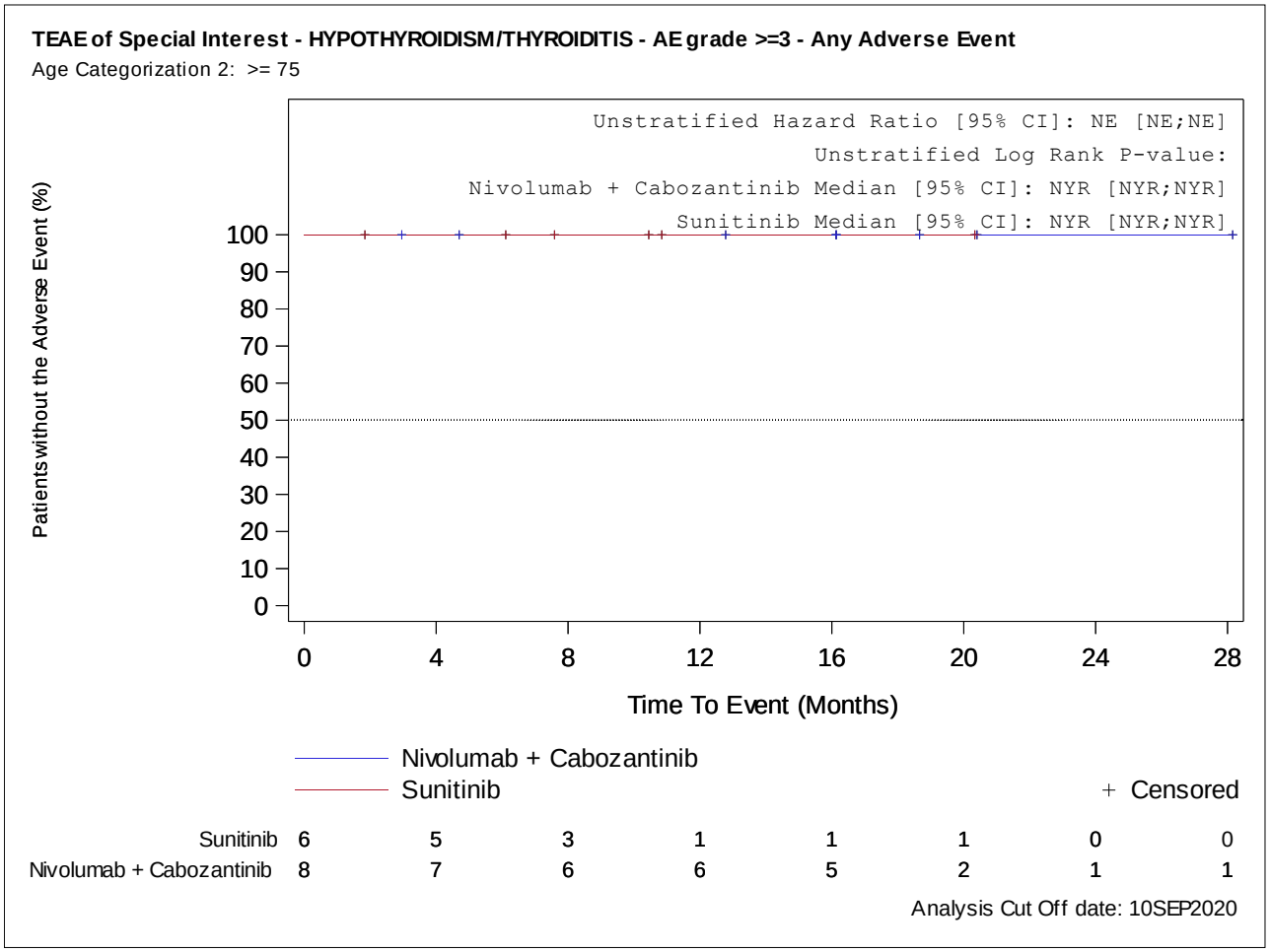
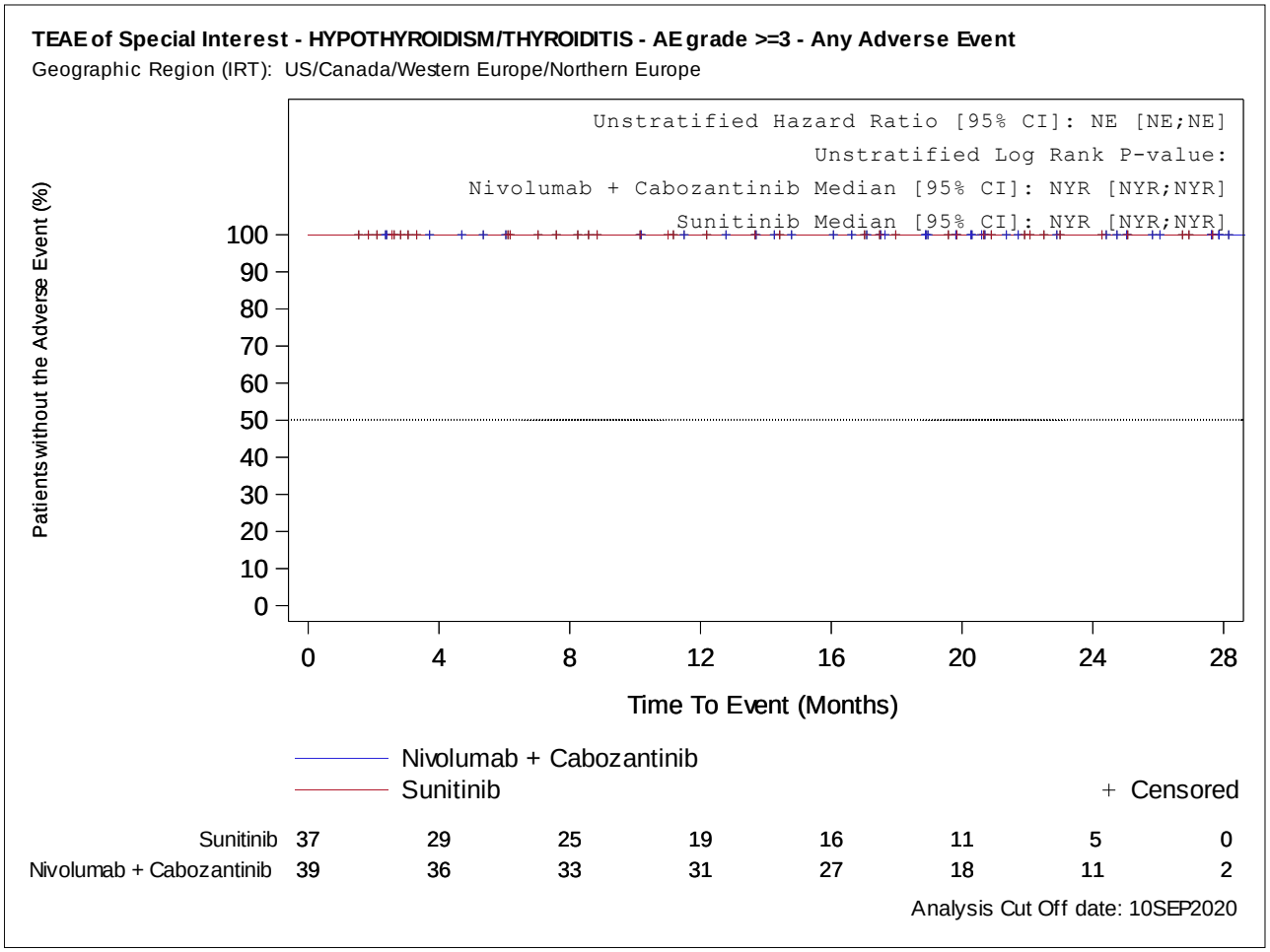
FIGURE 3.115.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



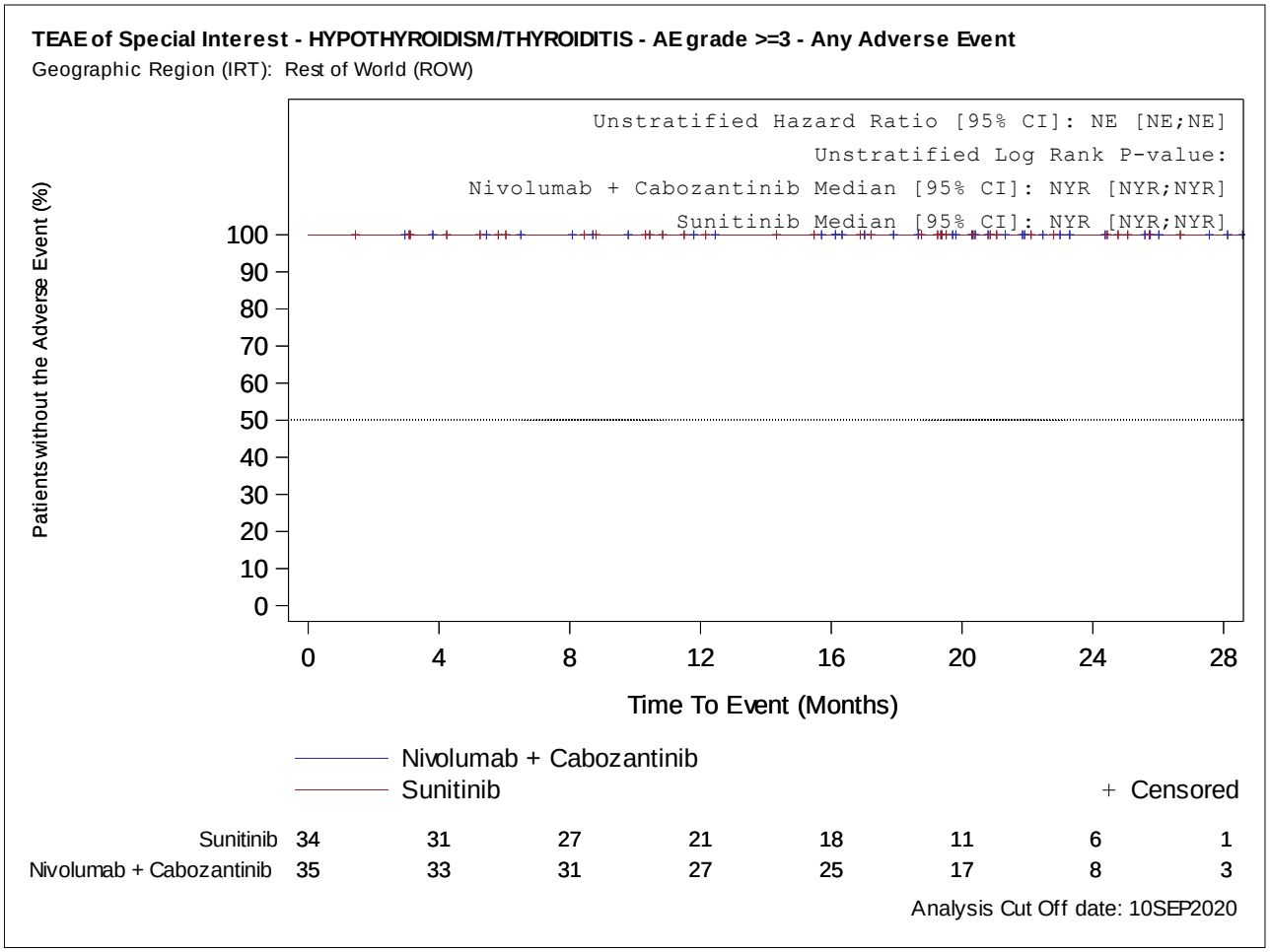

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:01:29

FIGURE 3.115.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



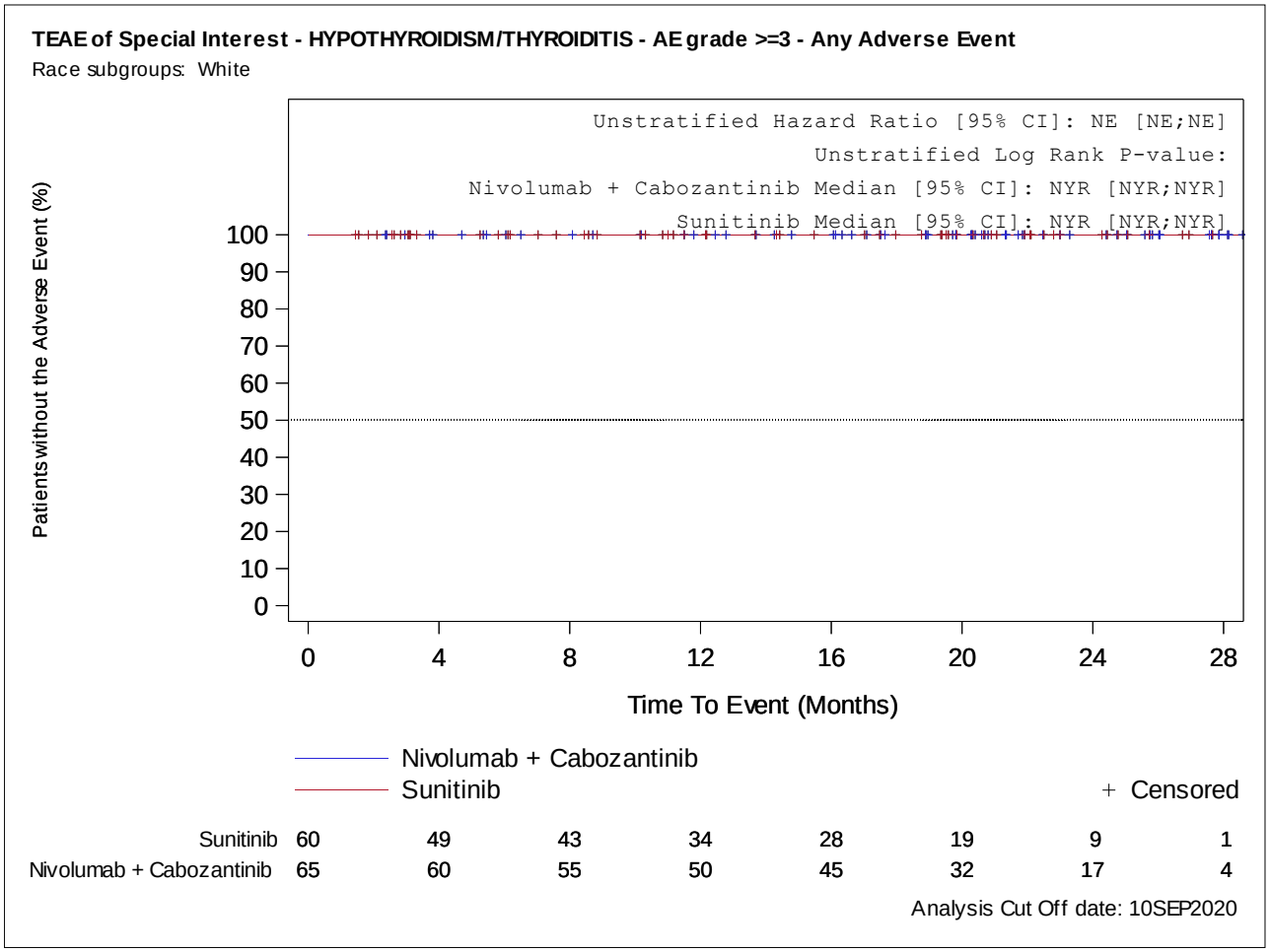

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:01:36

FIGURE 3.115.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:01:41

FIGURE 3.115.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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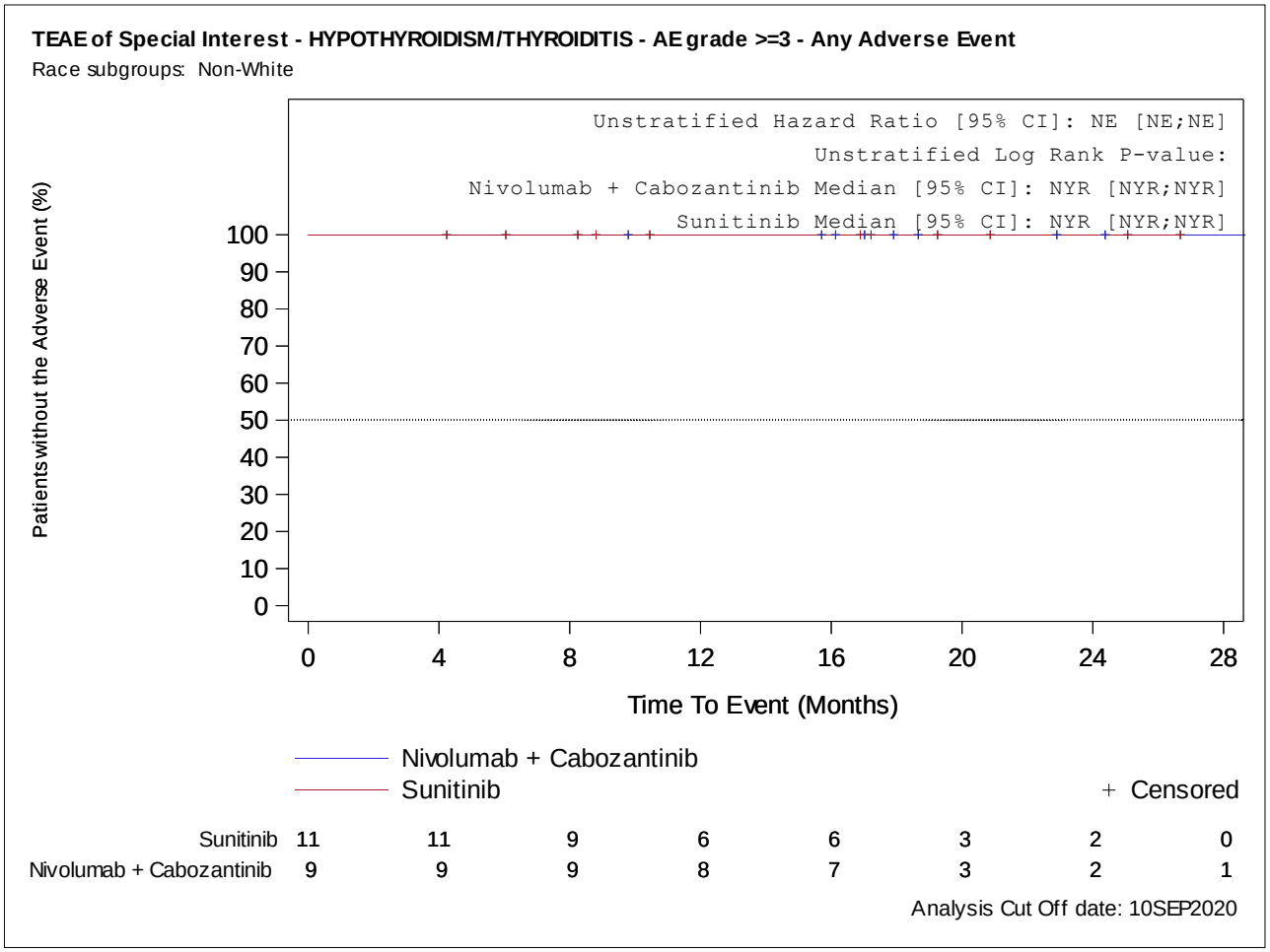
FIGURE 3.115.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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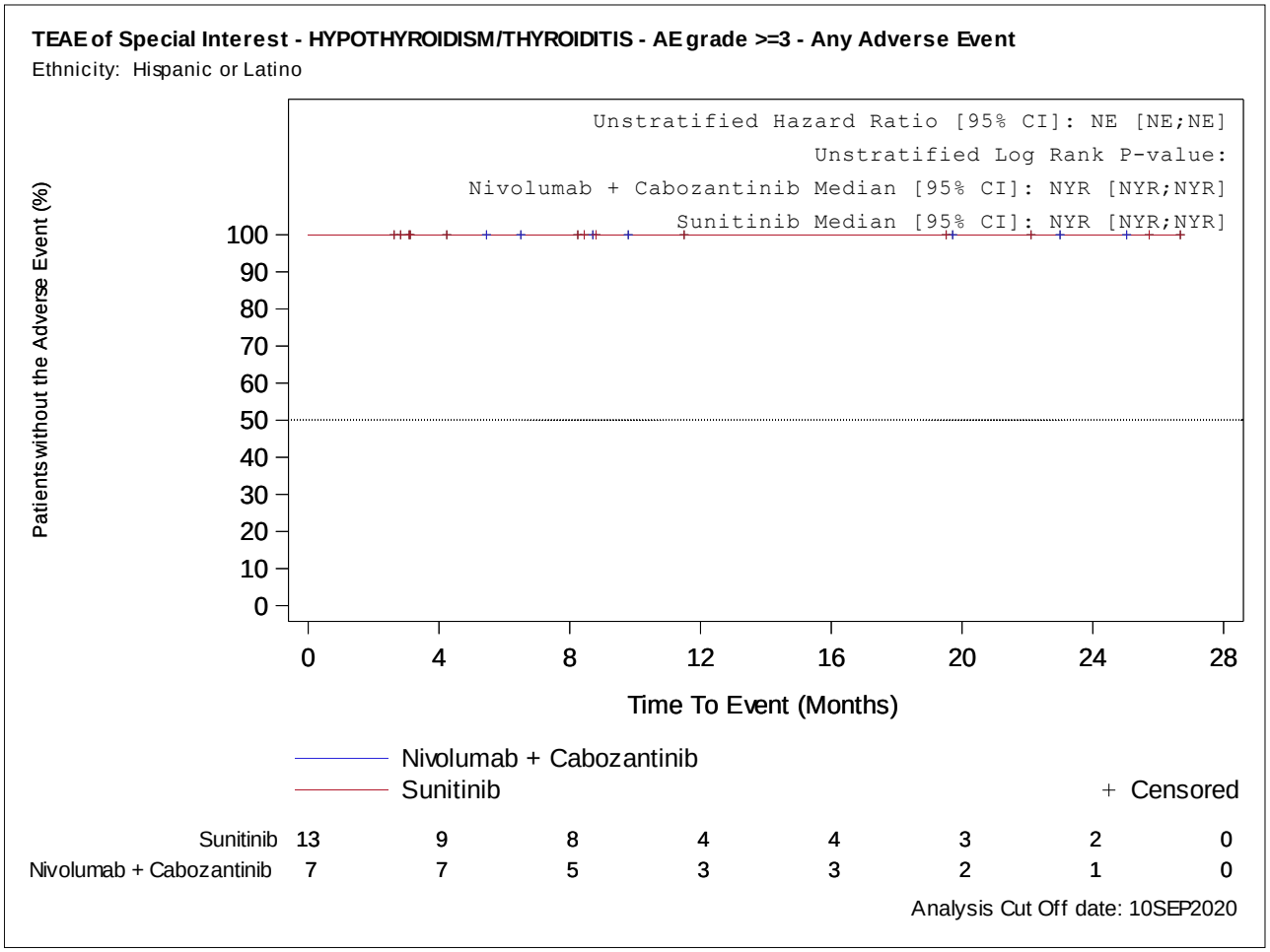
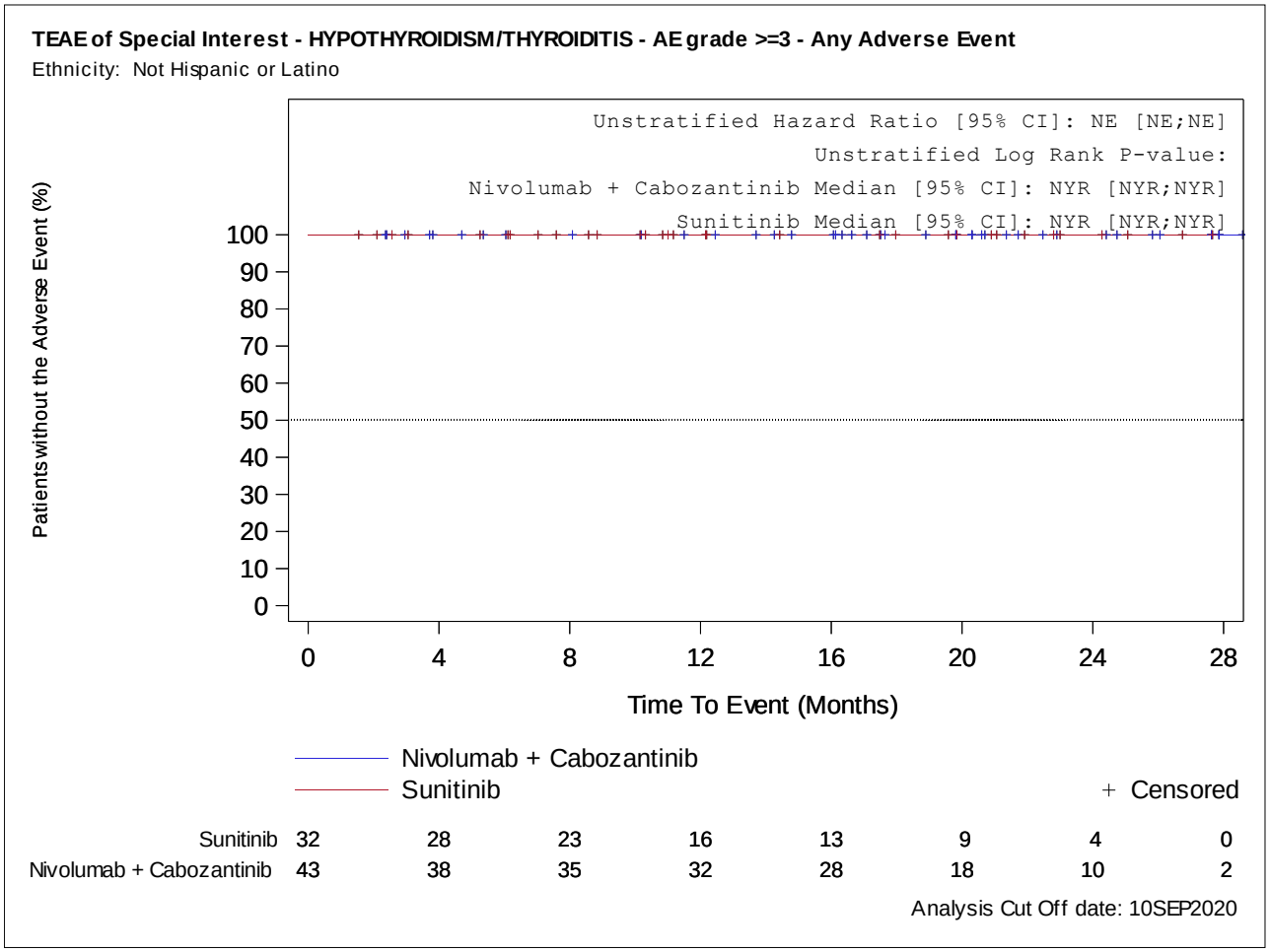
FIGURE 3.115.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:01:59

FIGURE 3.115.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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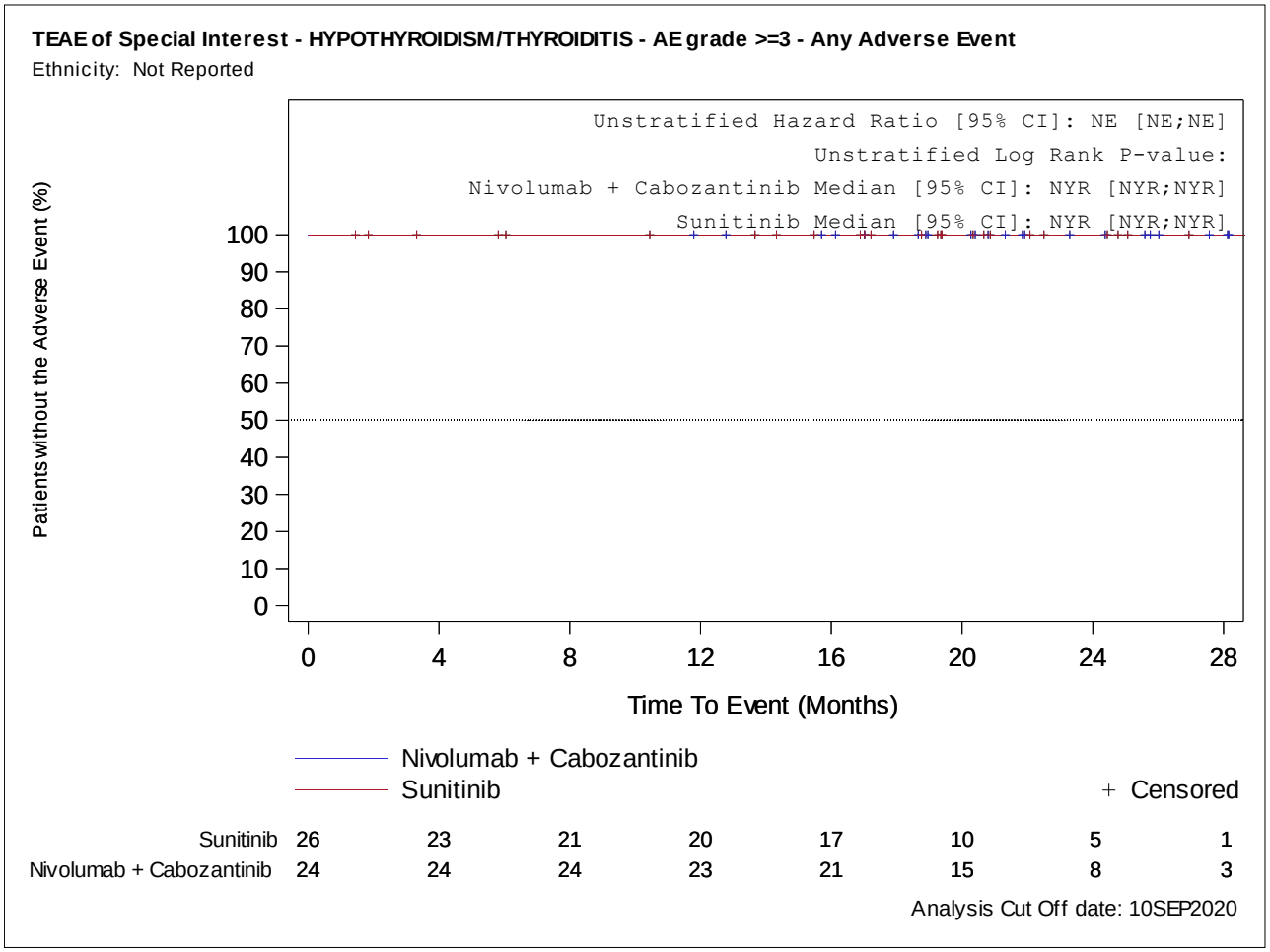
FIGURE 3.115.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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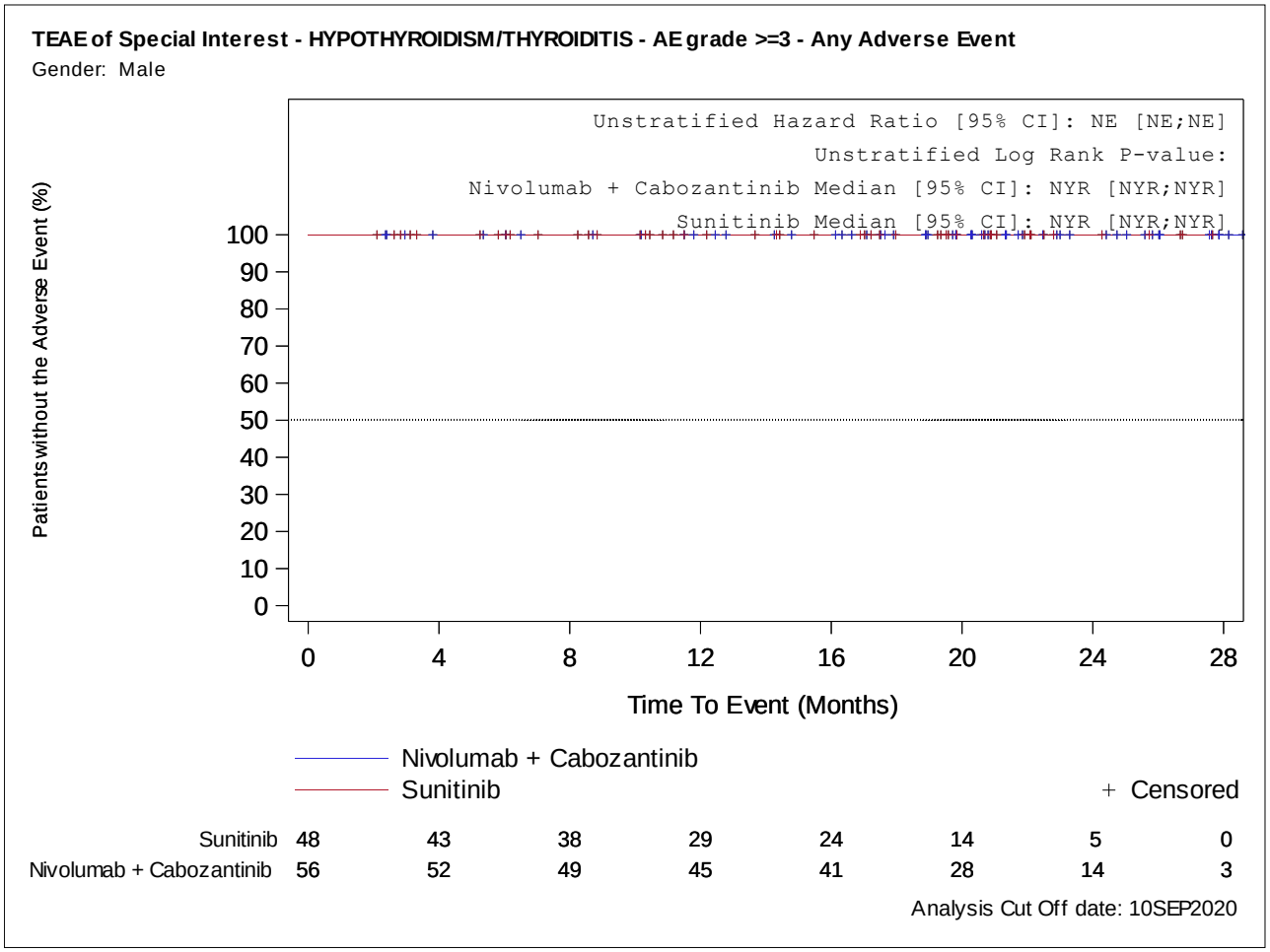
FIGURE 3.115.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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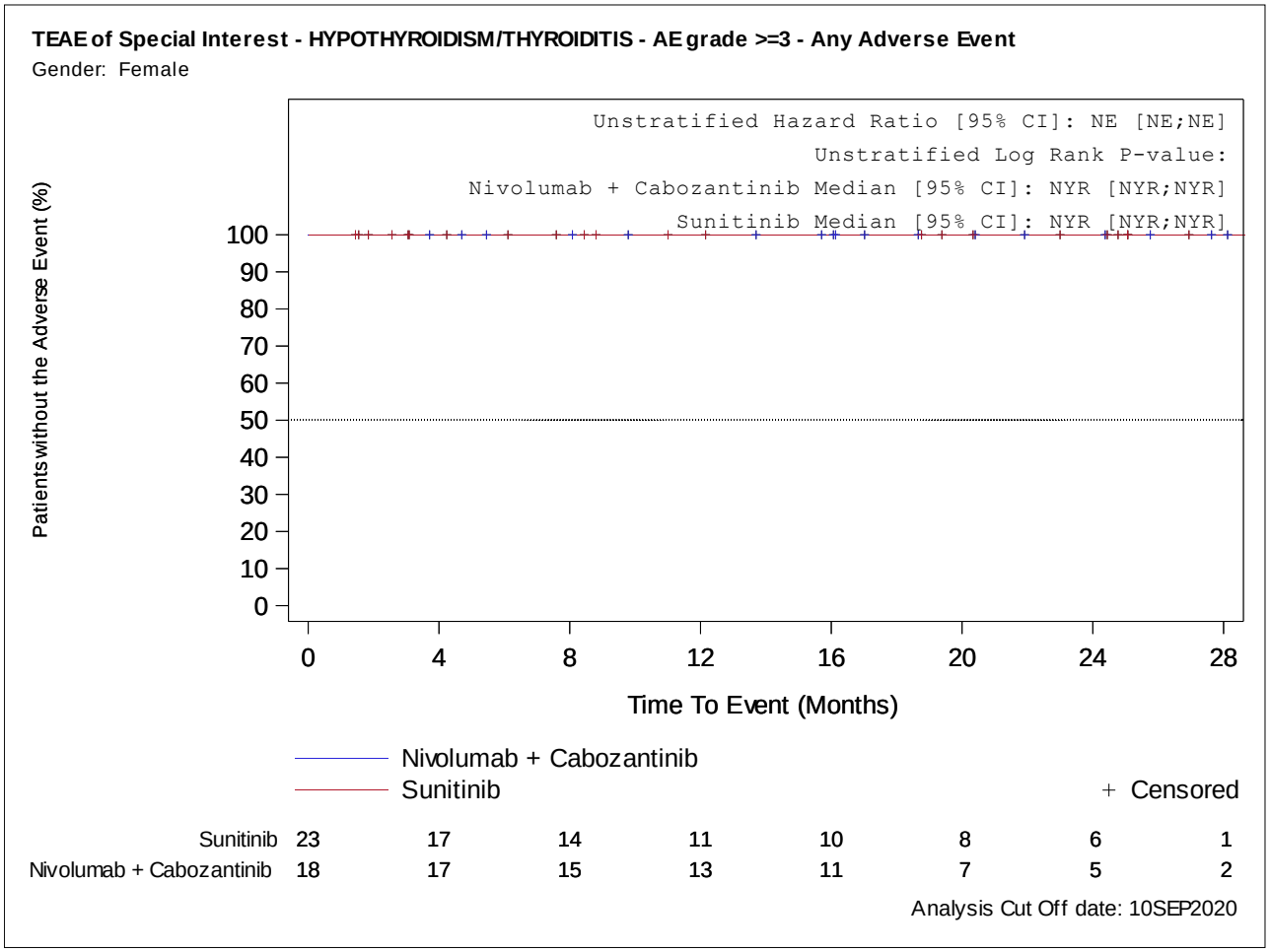
FIGURE 3.115.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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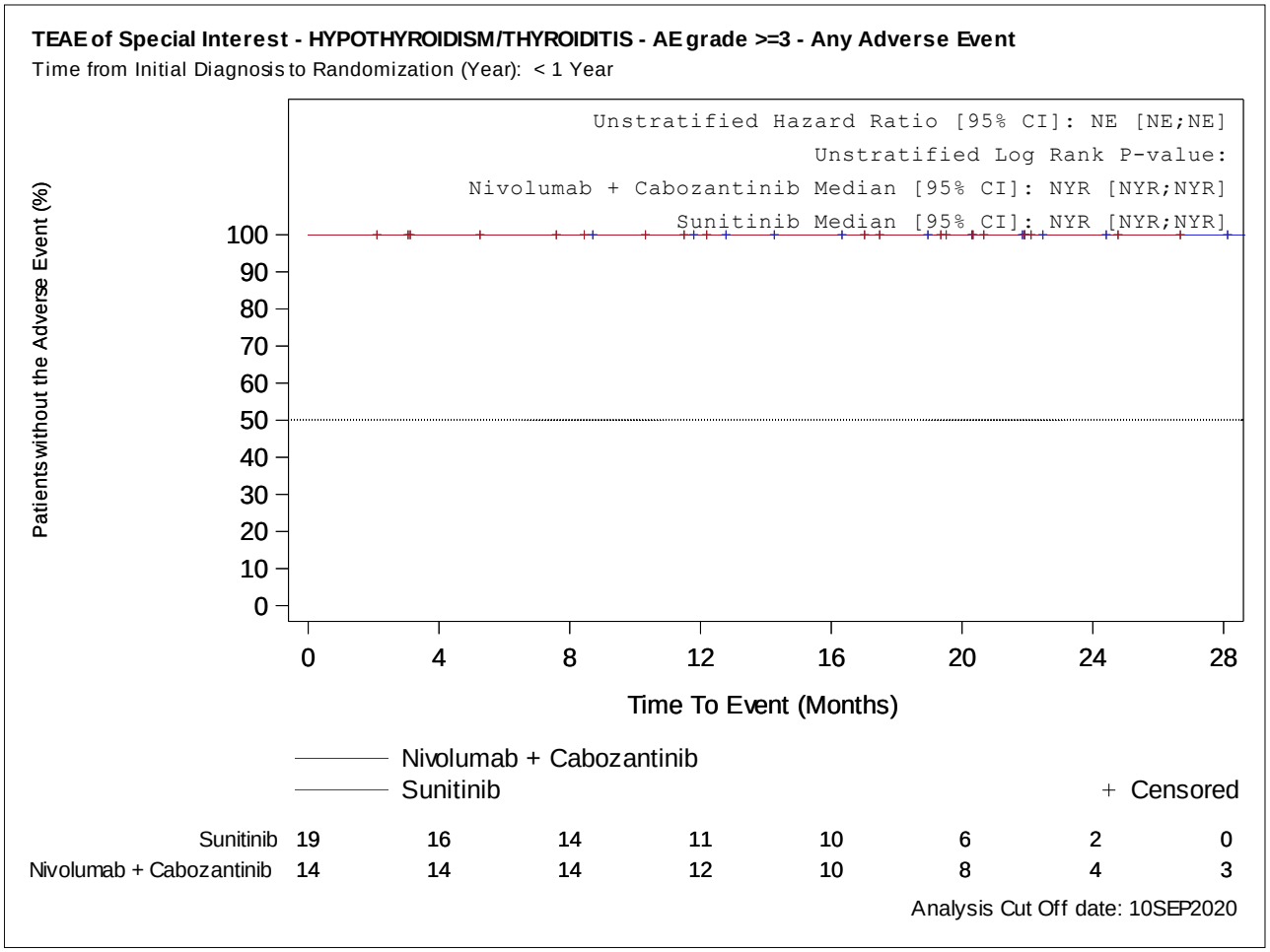
FIGURE 3.115.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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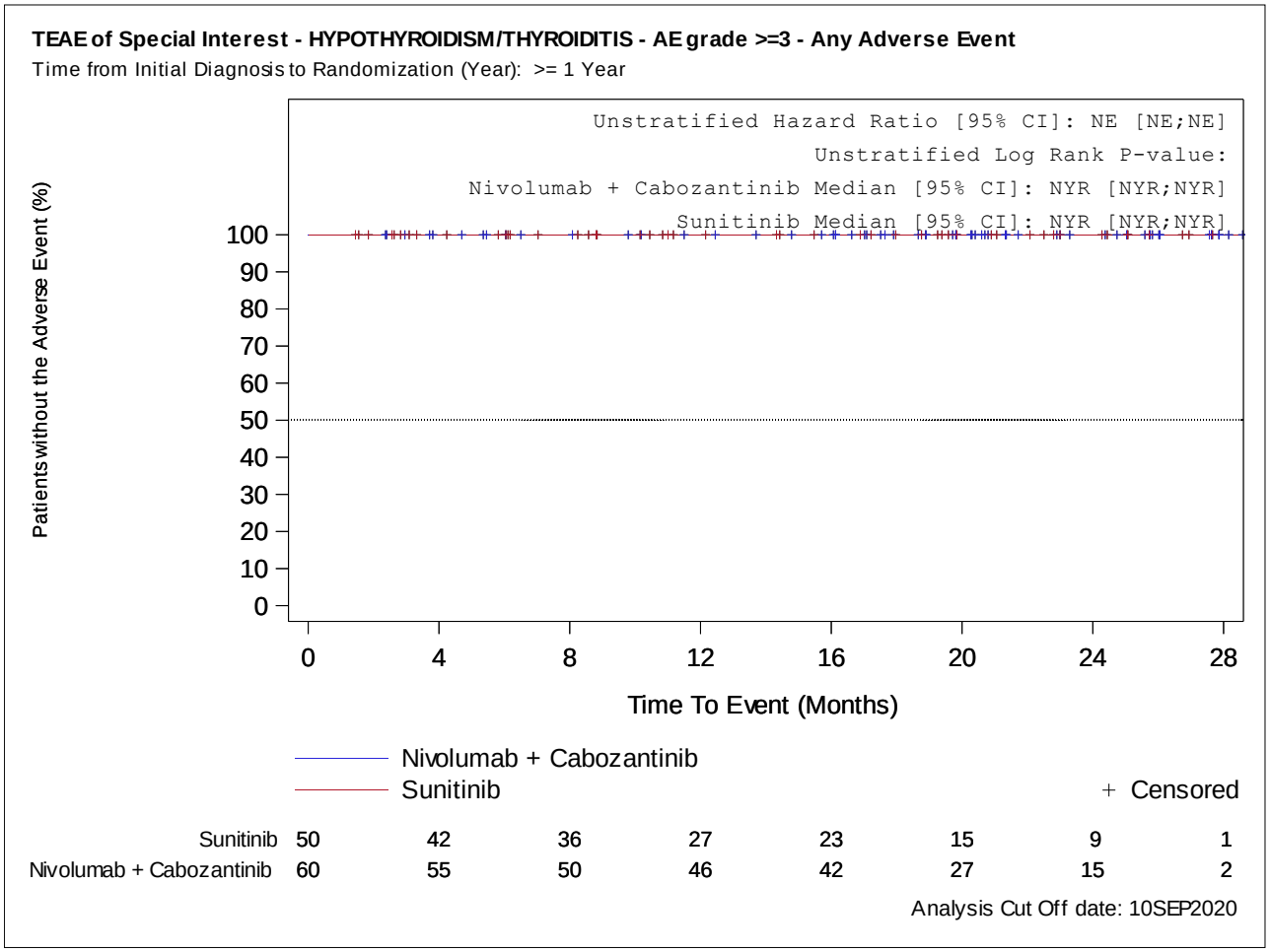
FIGURE 3.115.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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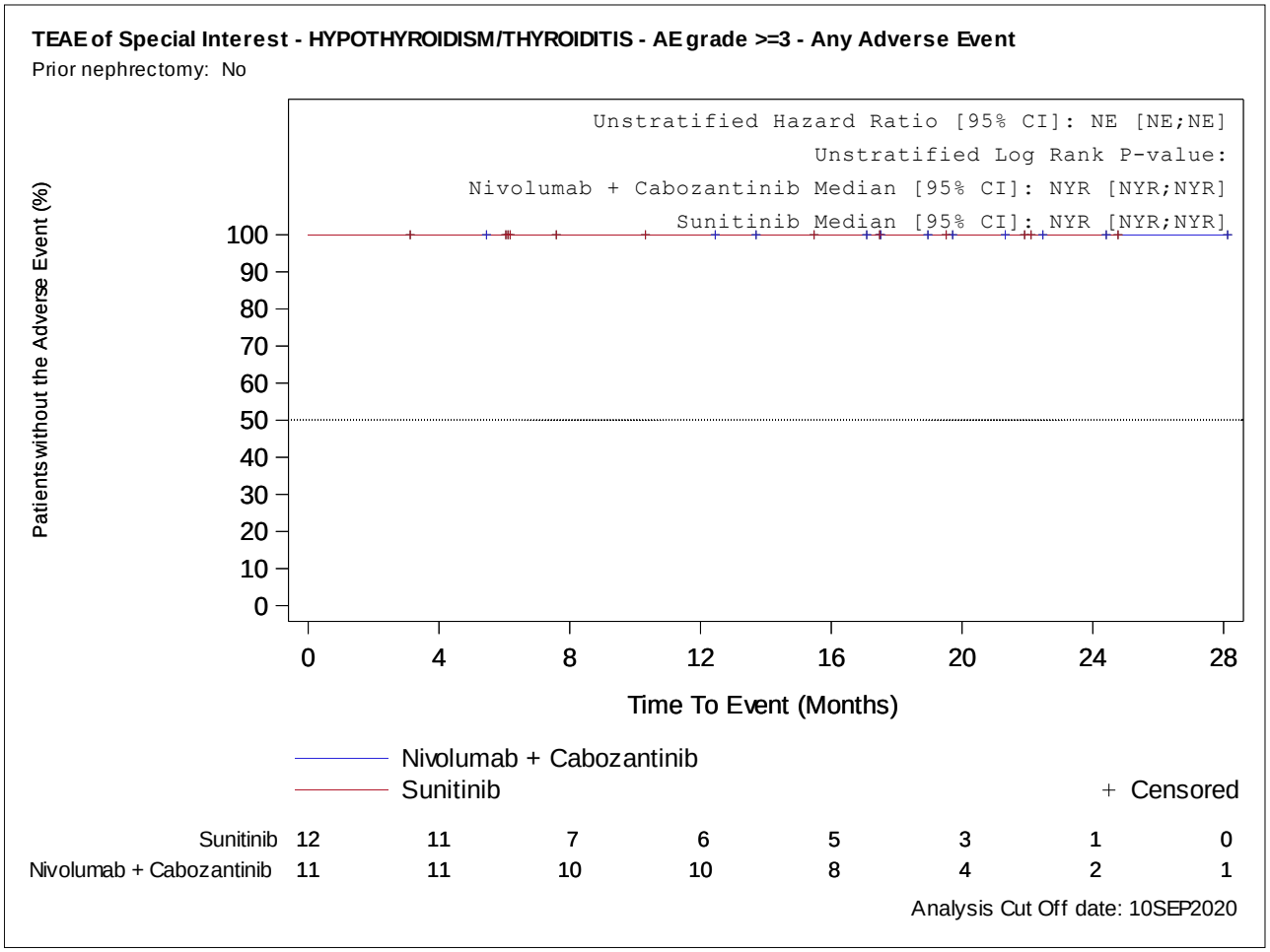
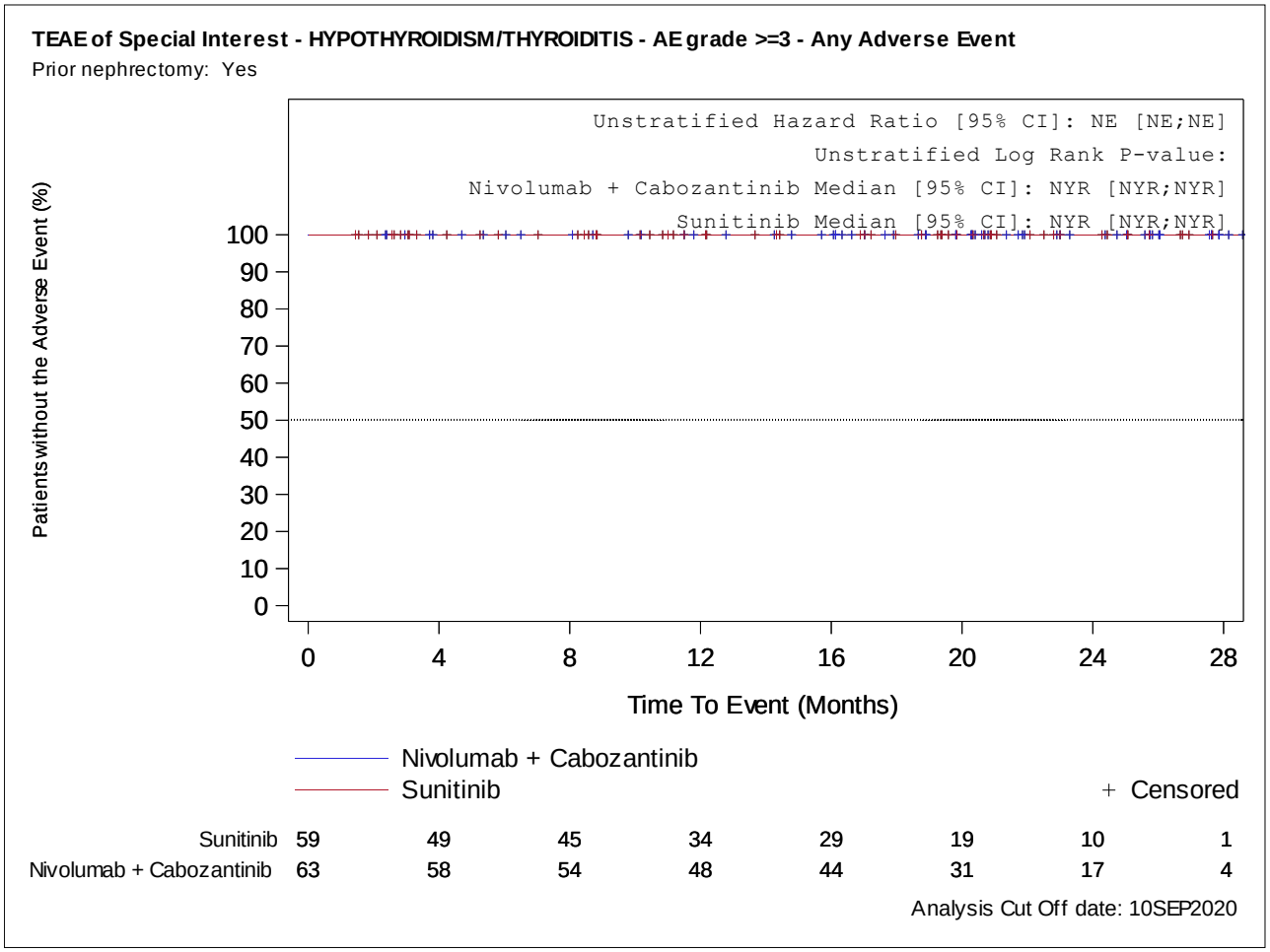
FIGURE 3.115.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



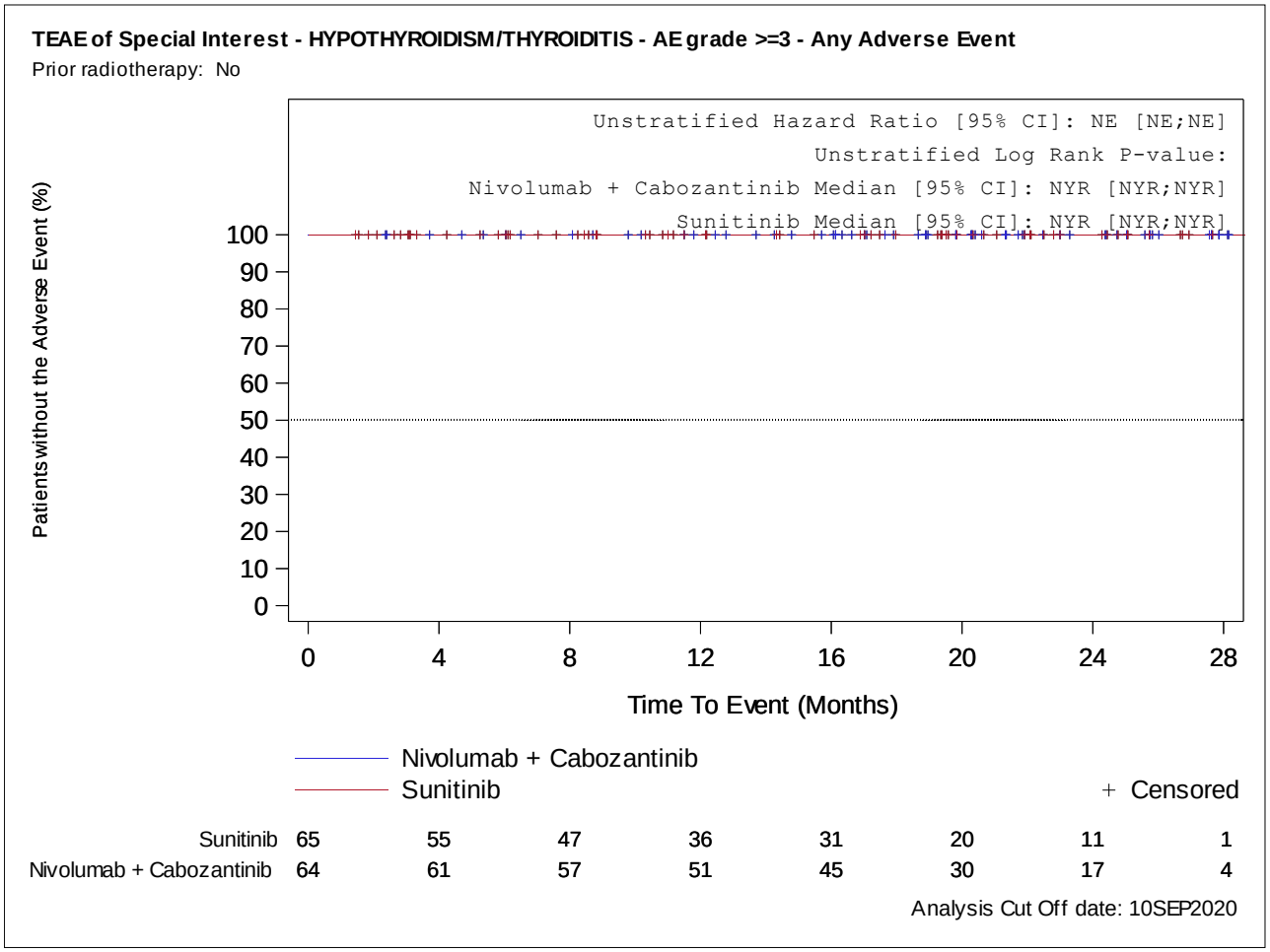

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:03:45

FIGURE 3.115.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



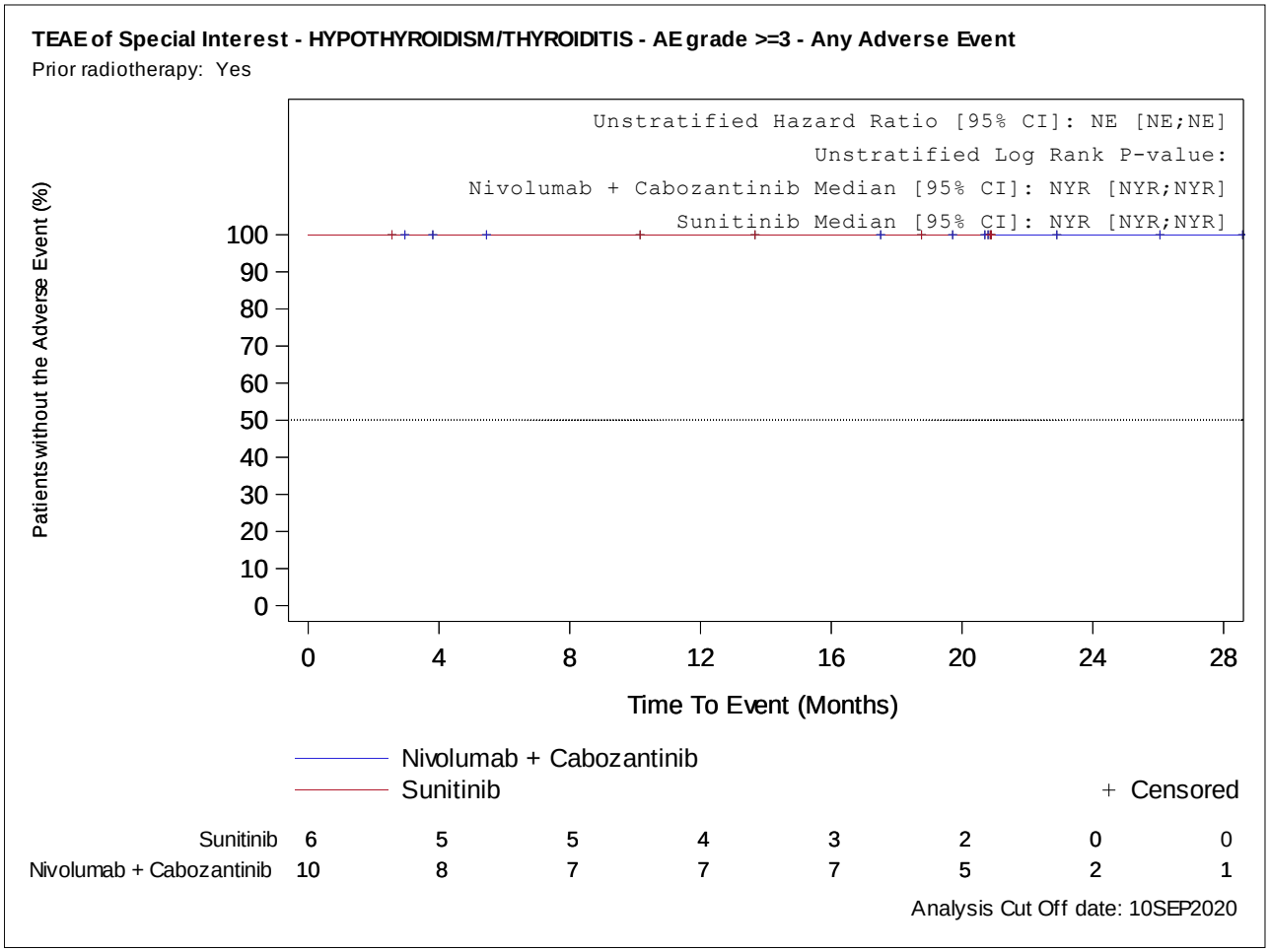

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:03:51

FIGURE 3.115.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



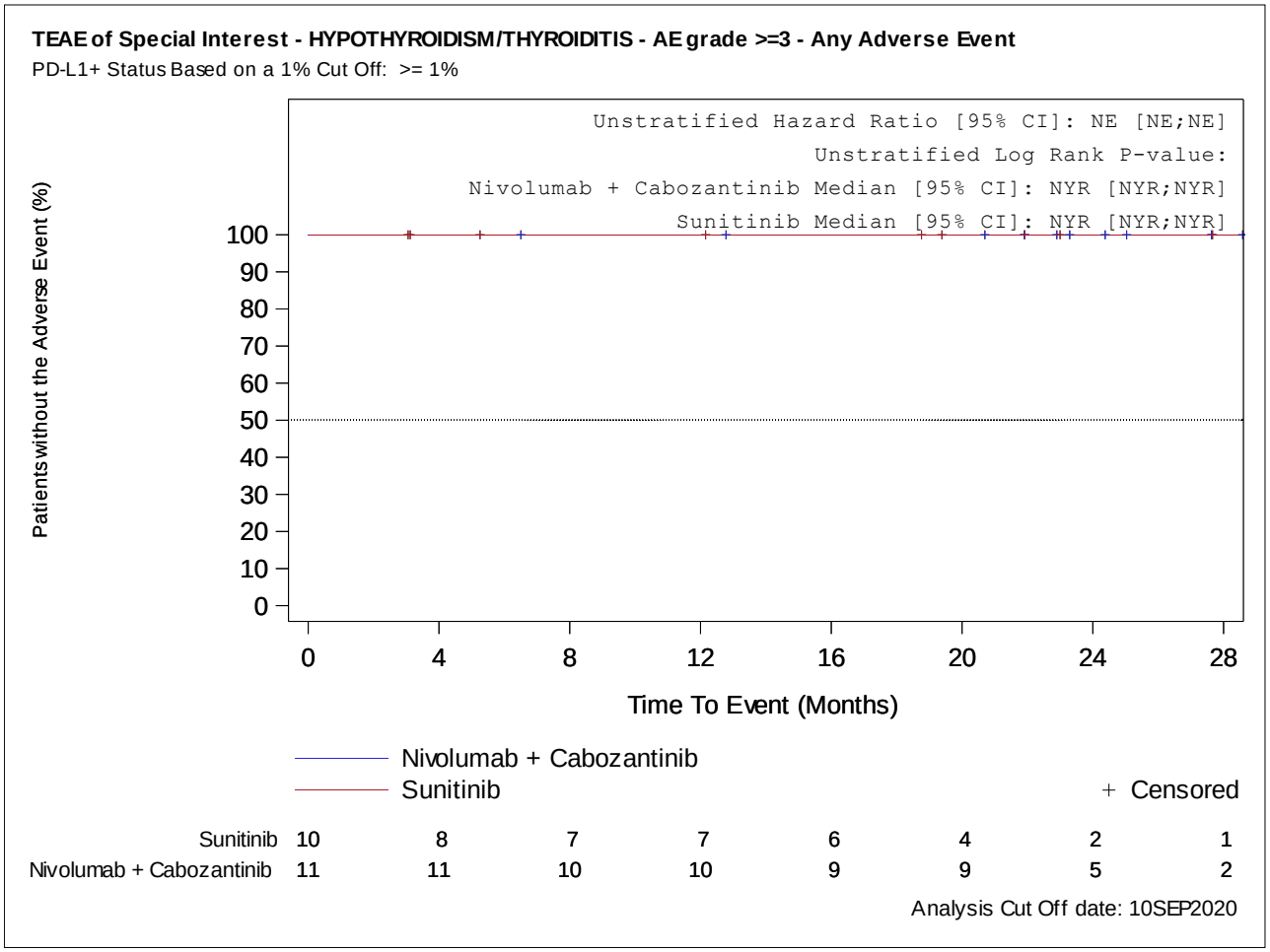

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:03:57

FIGURE 3.115.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



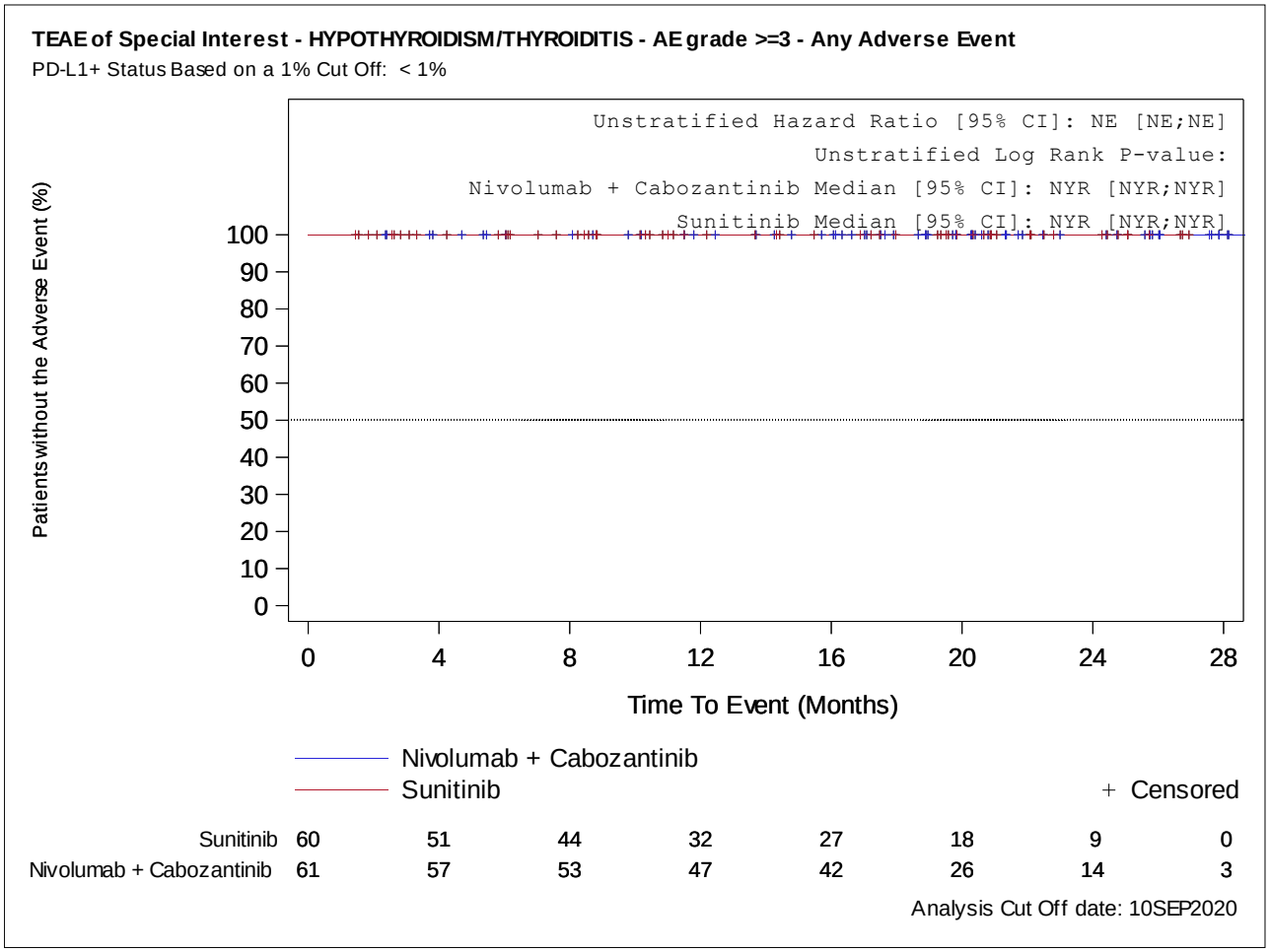

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:04:03

FIGURE 3.115.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



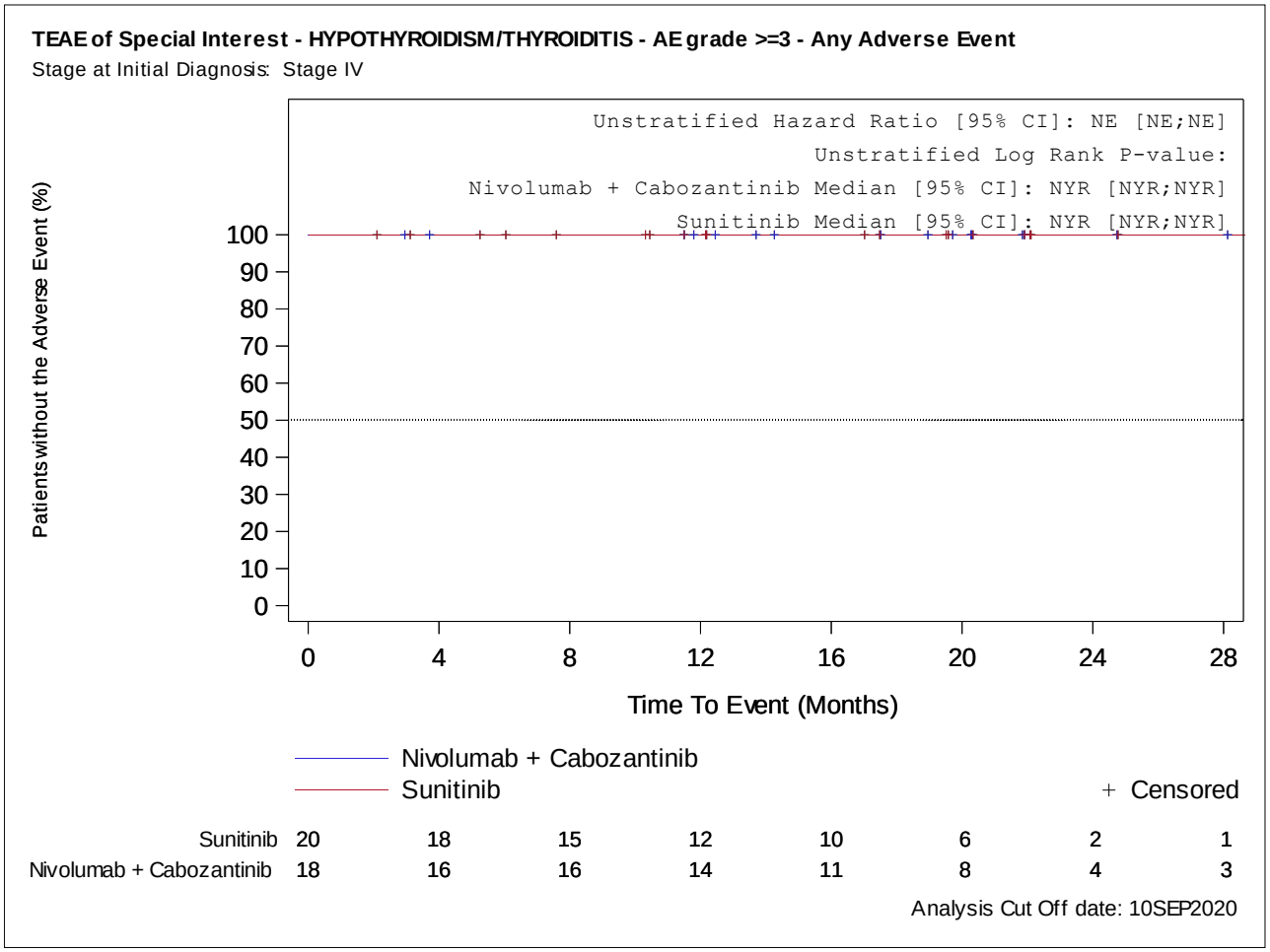

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:04:09

FIGURE 3.115.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



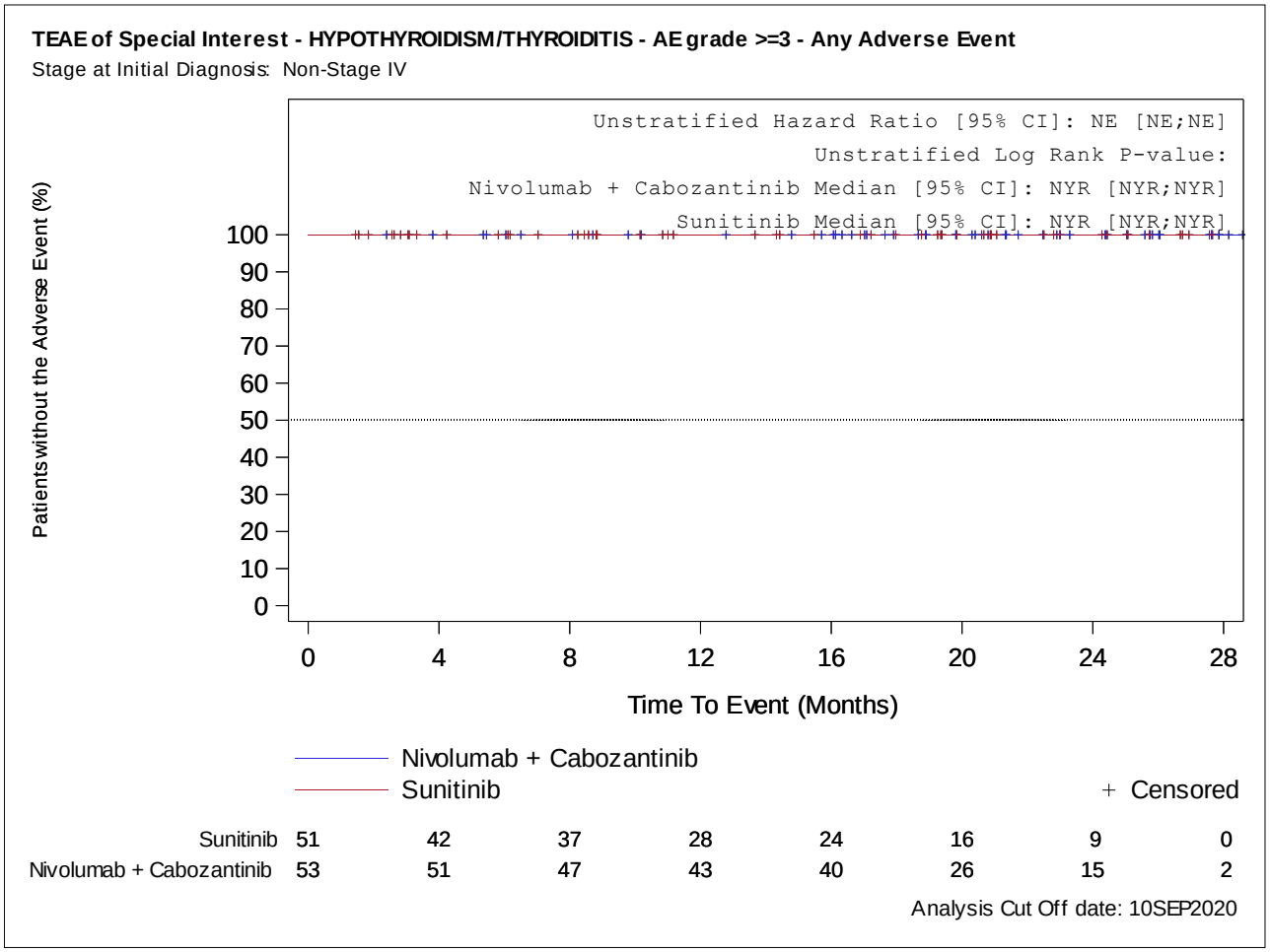

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:04:16

FIGURE 3.115.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



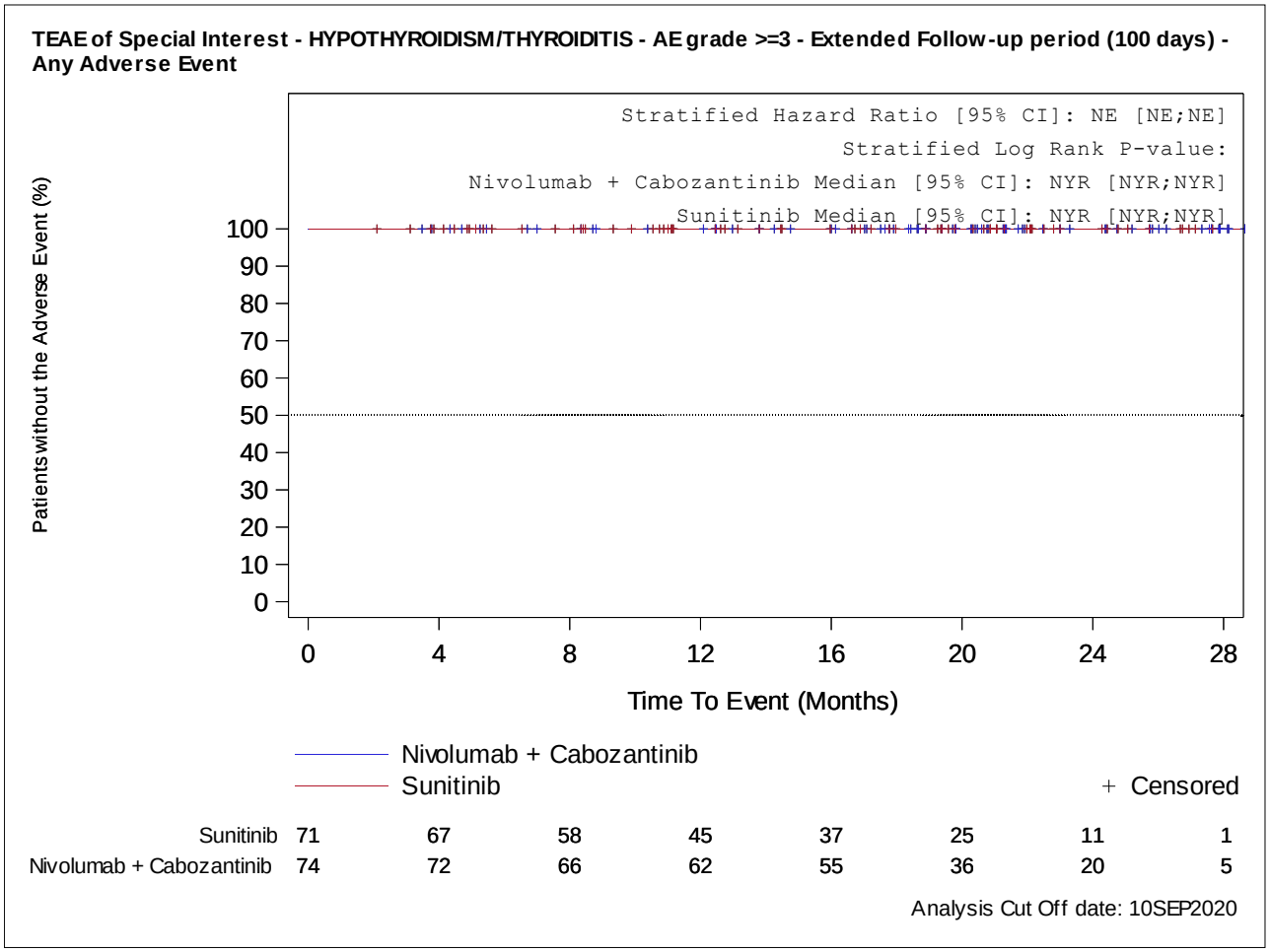

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:04:47

FIGURE 3.115.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



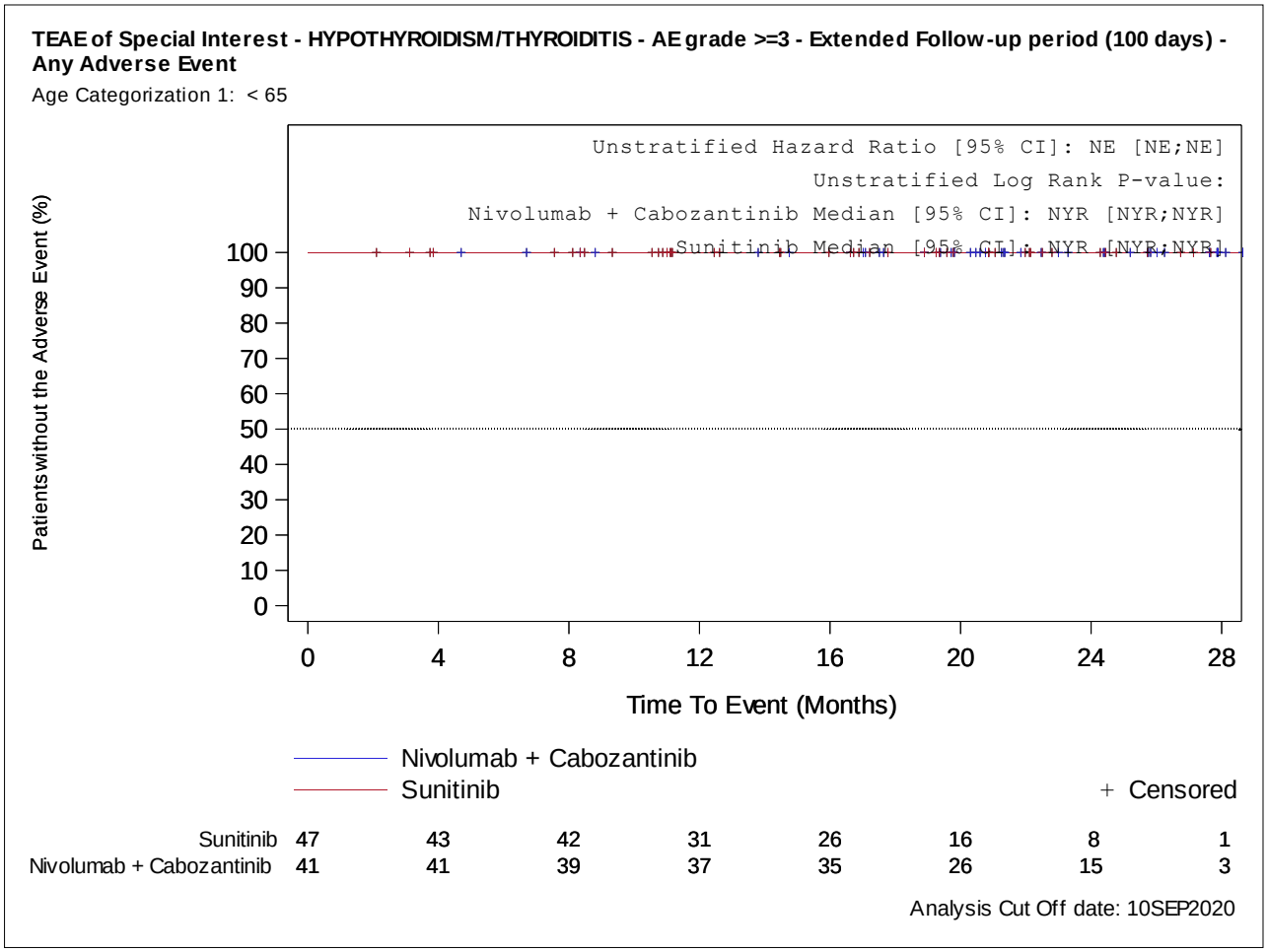

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:04:52

FIGURE 3.116.1: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



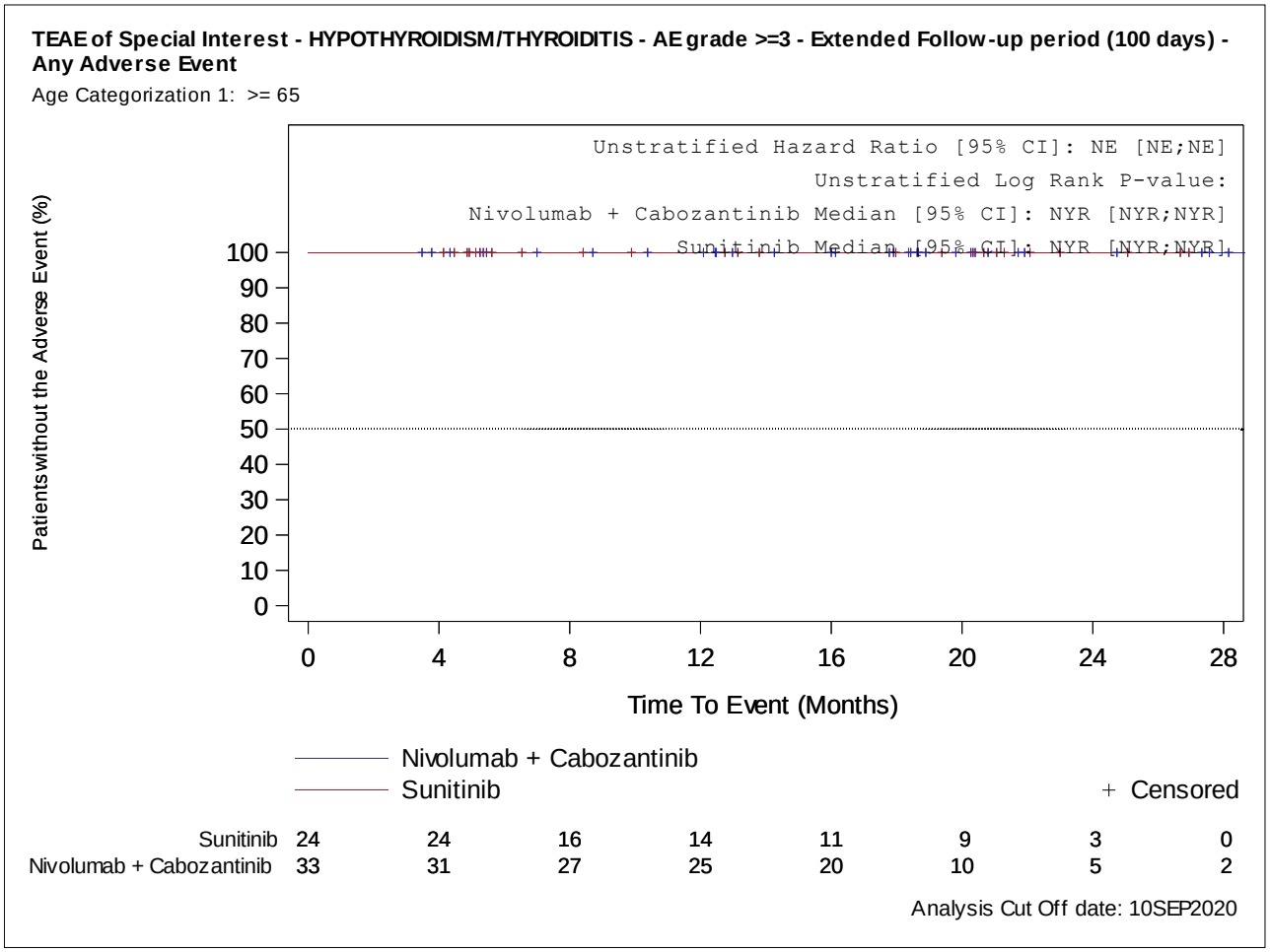

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:08:21

FIGURE 3.116.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



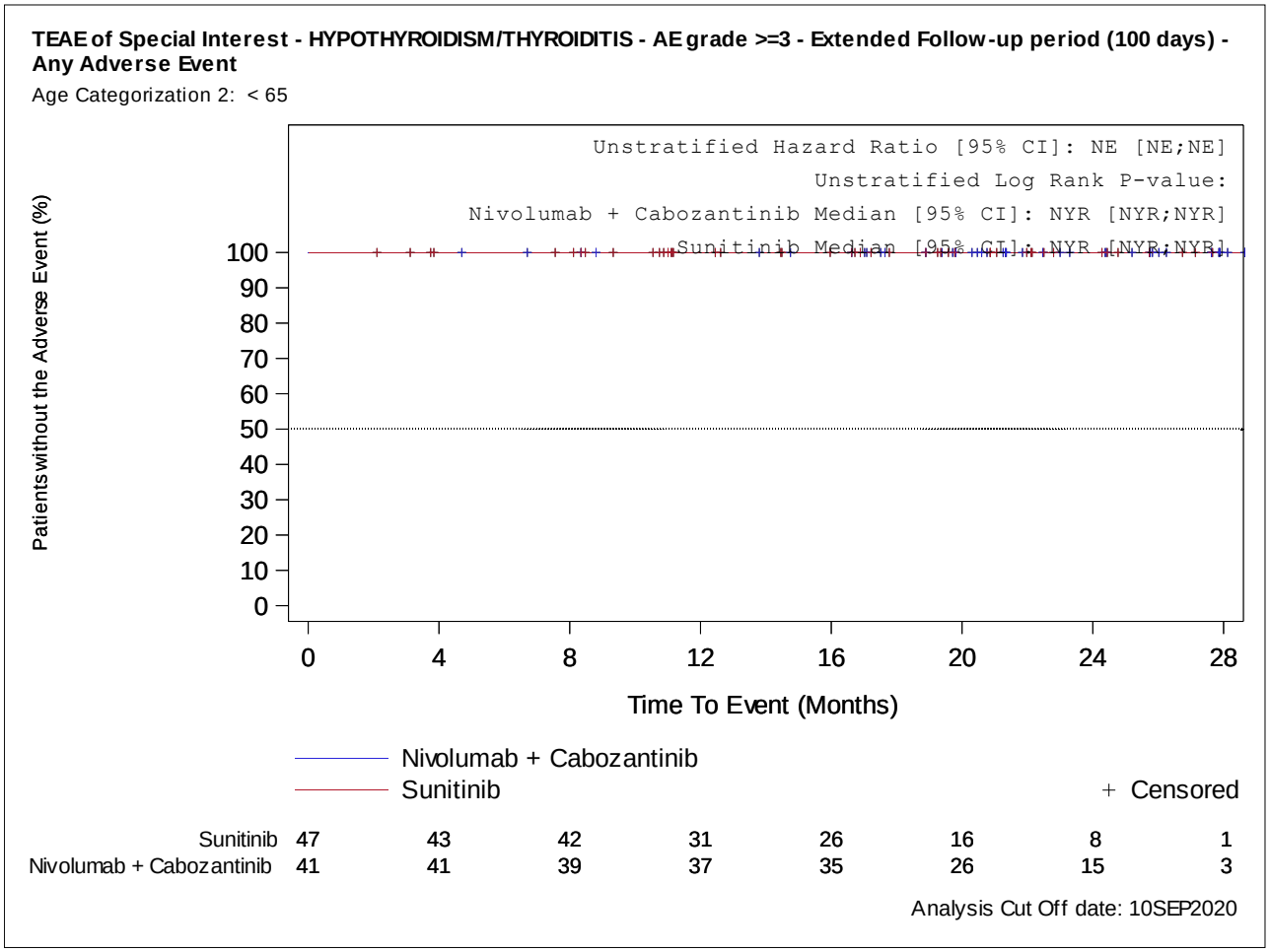

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:08:24

FIGURE 3.116.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



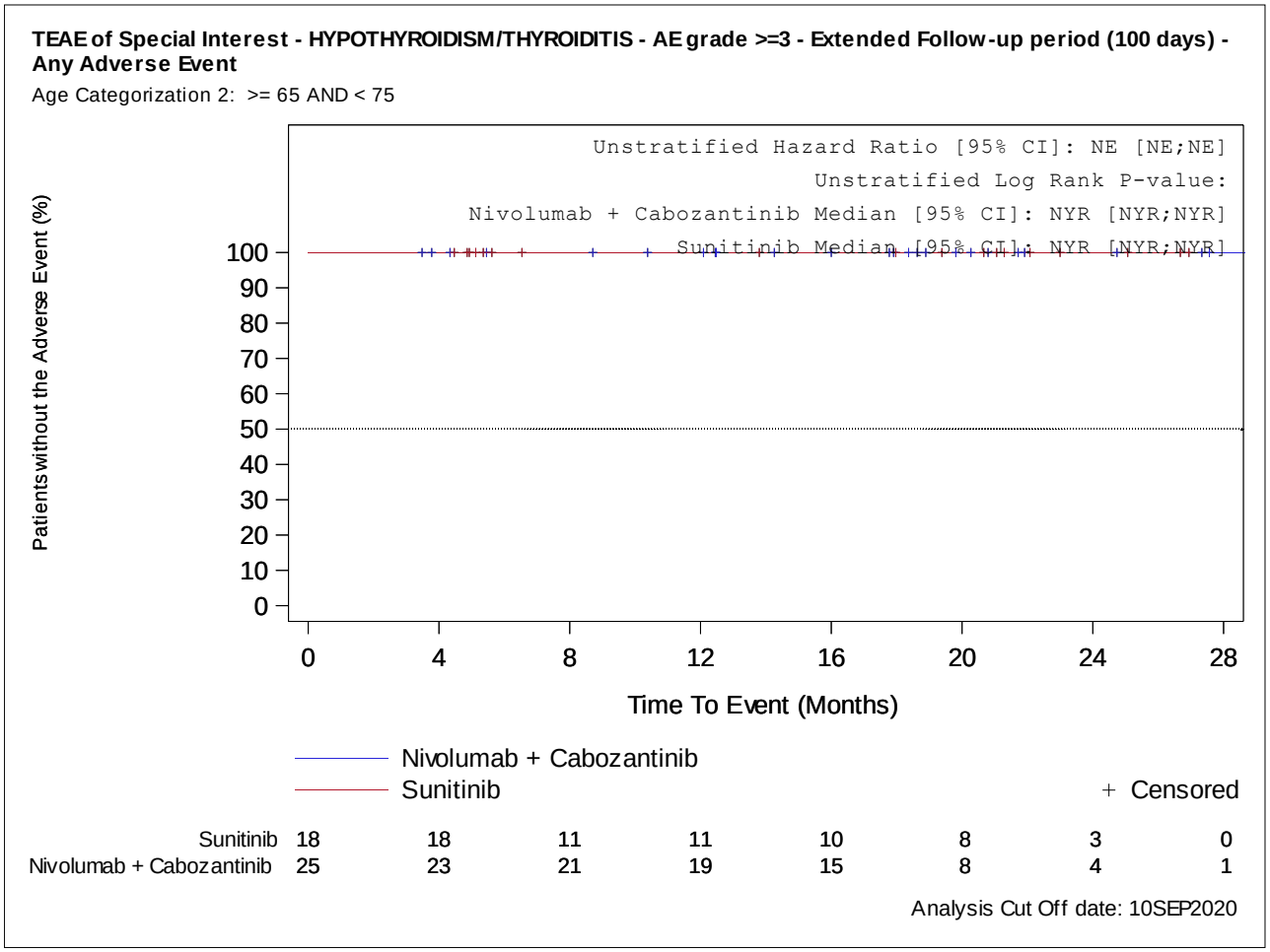

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:08:30

FIGURE 3.116.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



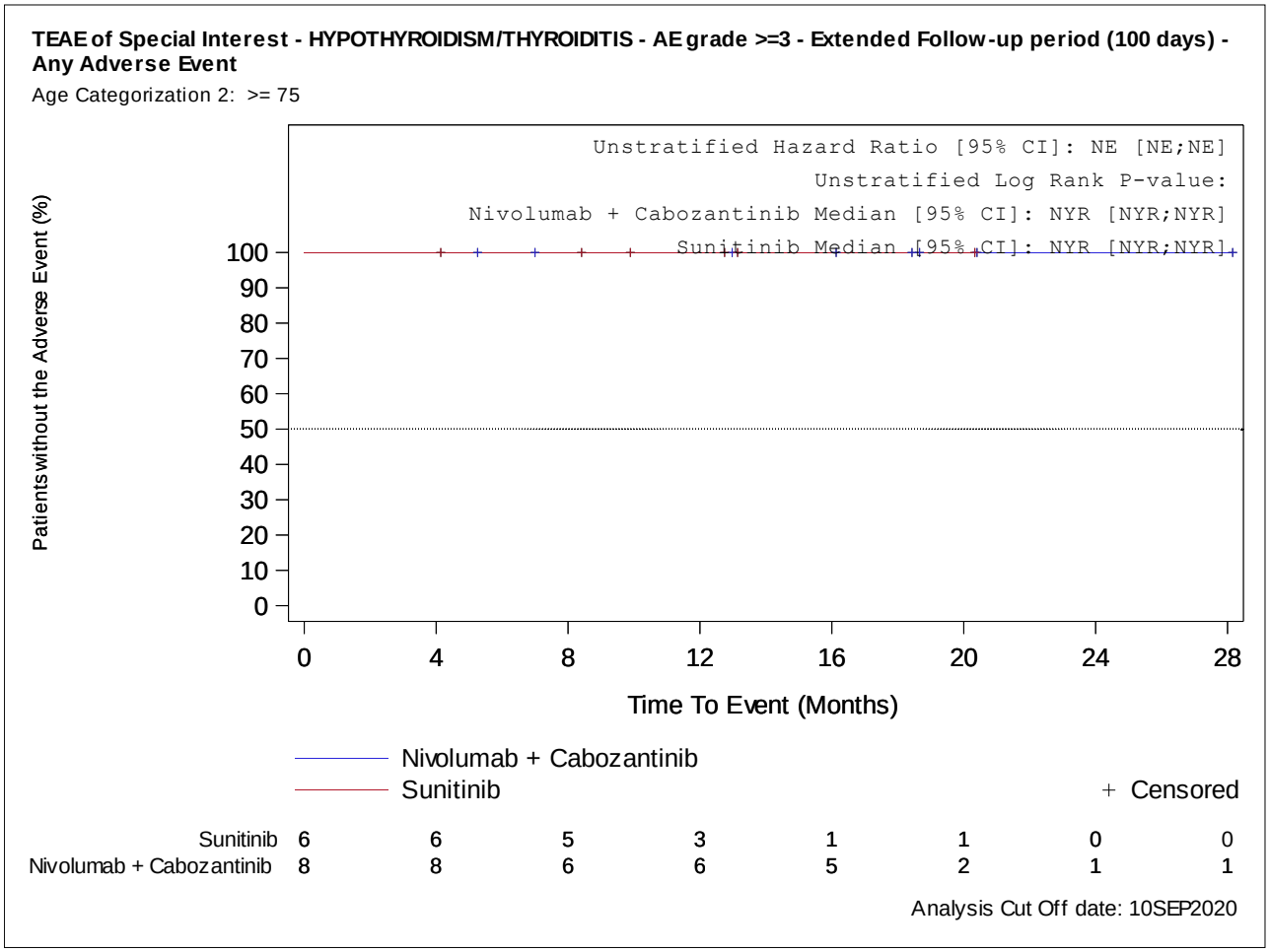

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:08:37

FIGURE 3.116.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



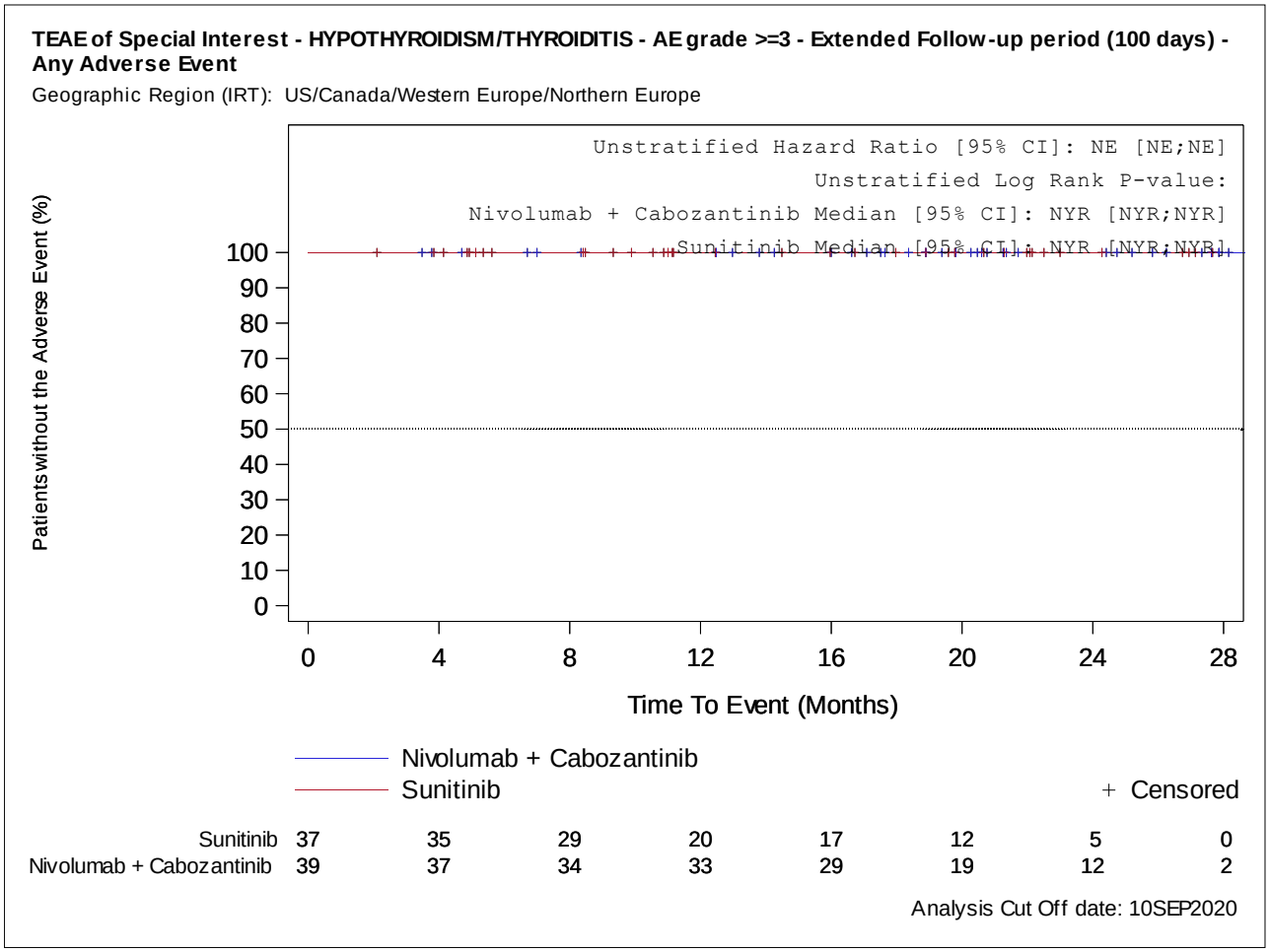

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:08:43

FIGURE 3.116.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



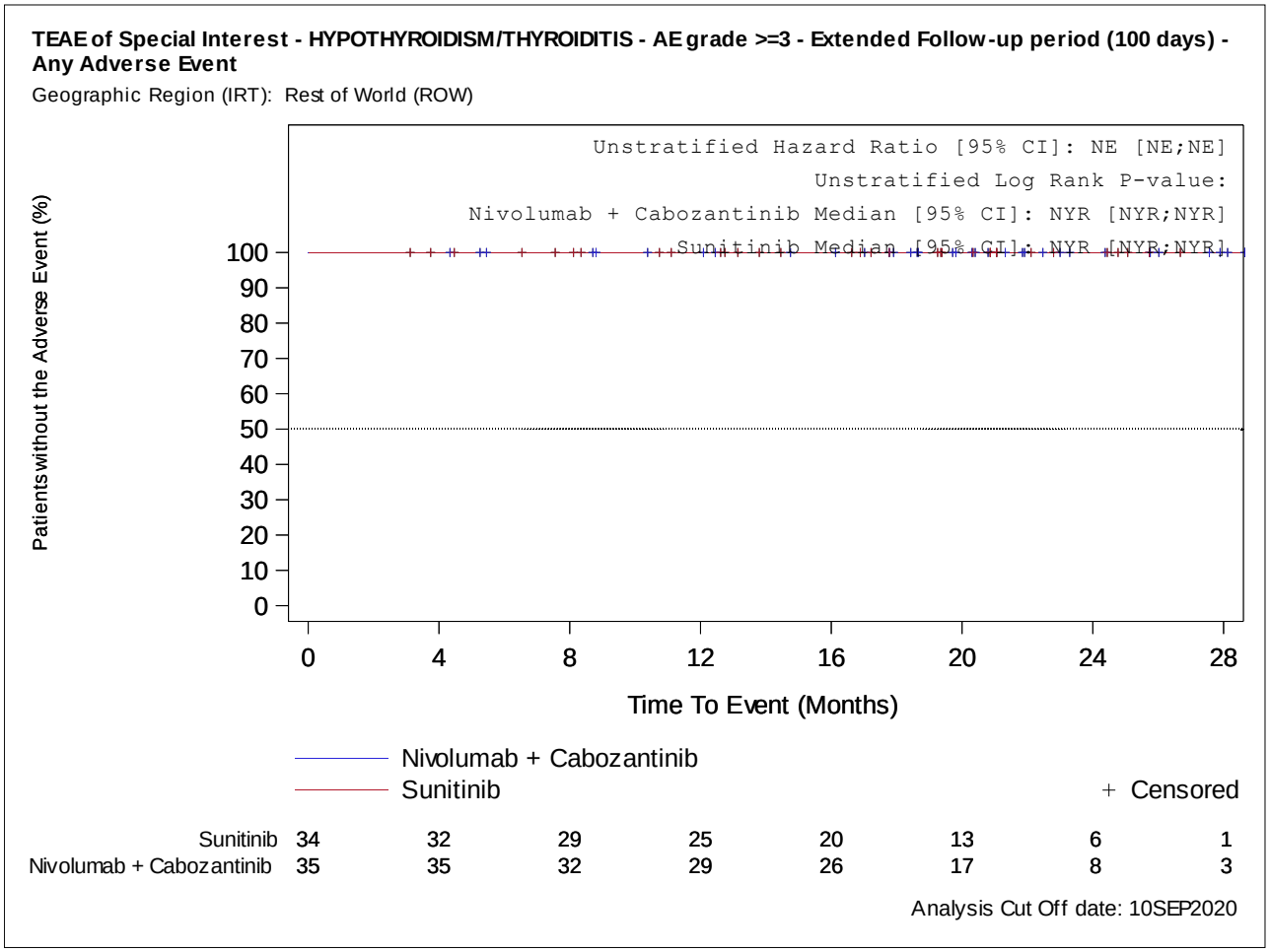

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:08:50

FIGURE 3.116.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



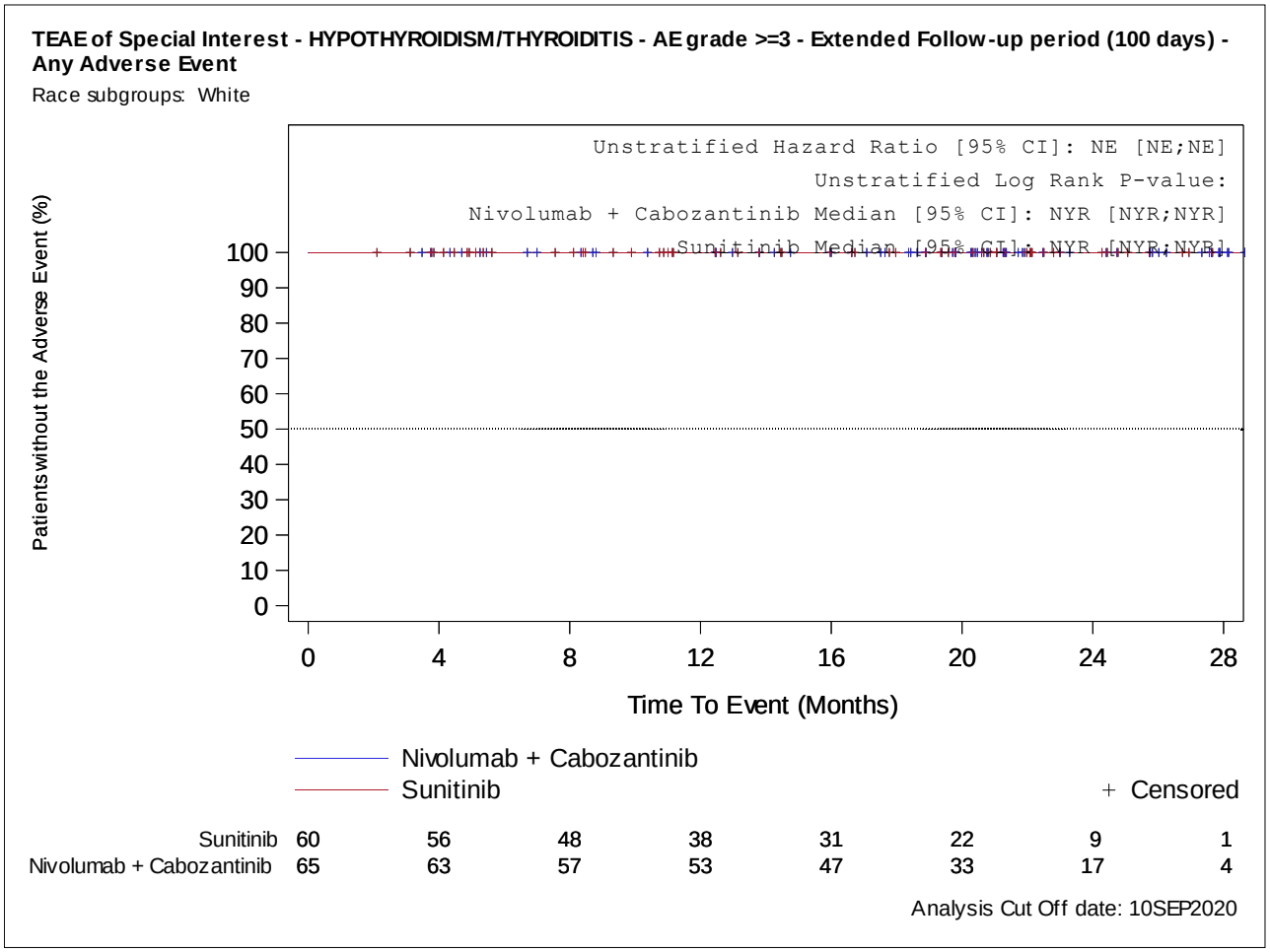

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:08:57

FIGURE 3.116.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



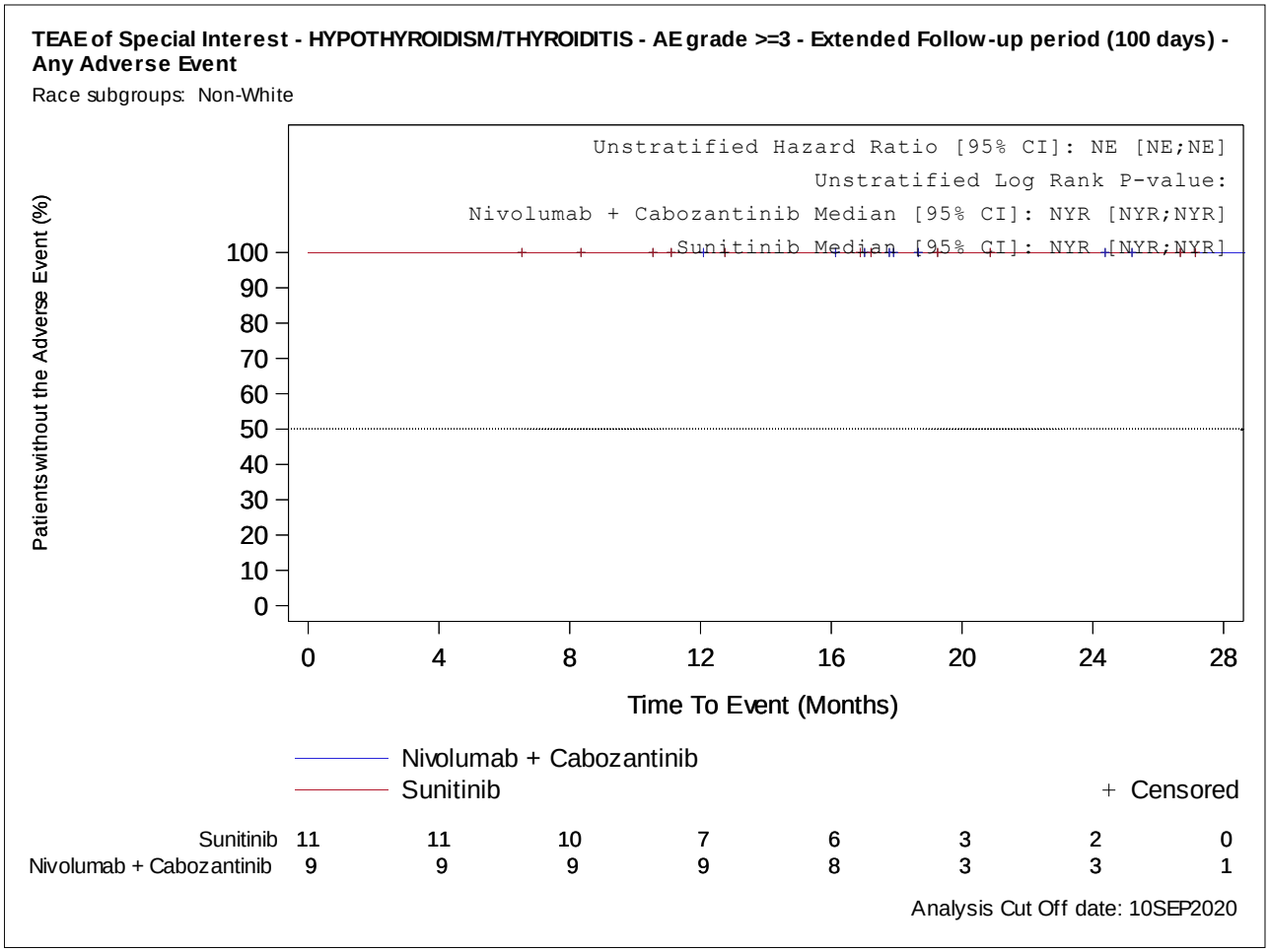

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:09:03

FIGURE 3.116.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



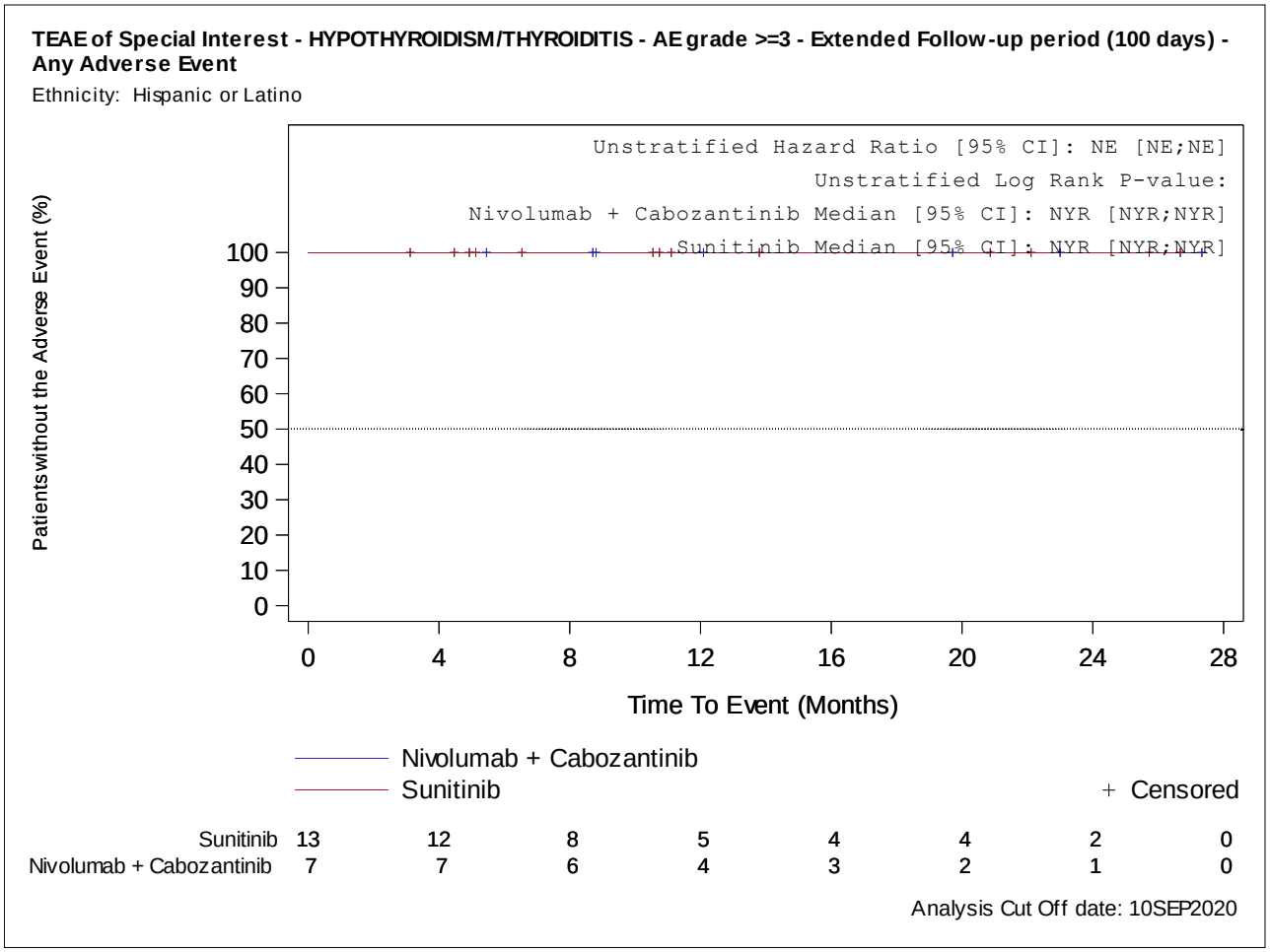

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:09:10

FIGURE 3.116.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



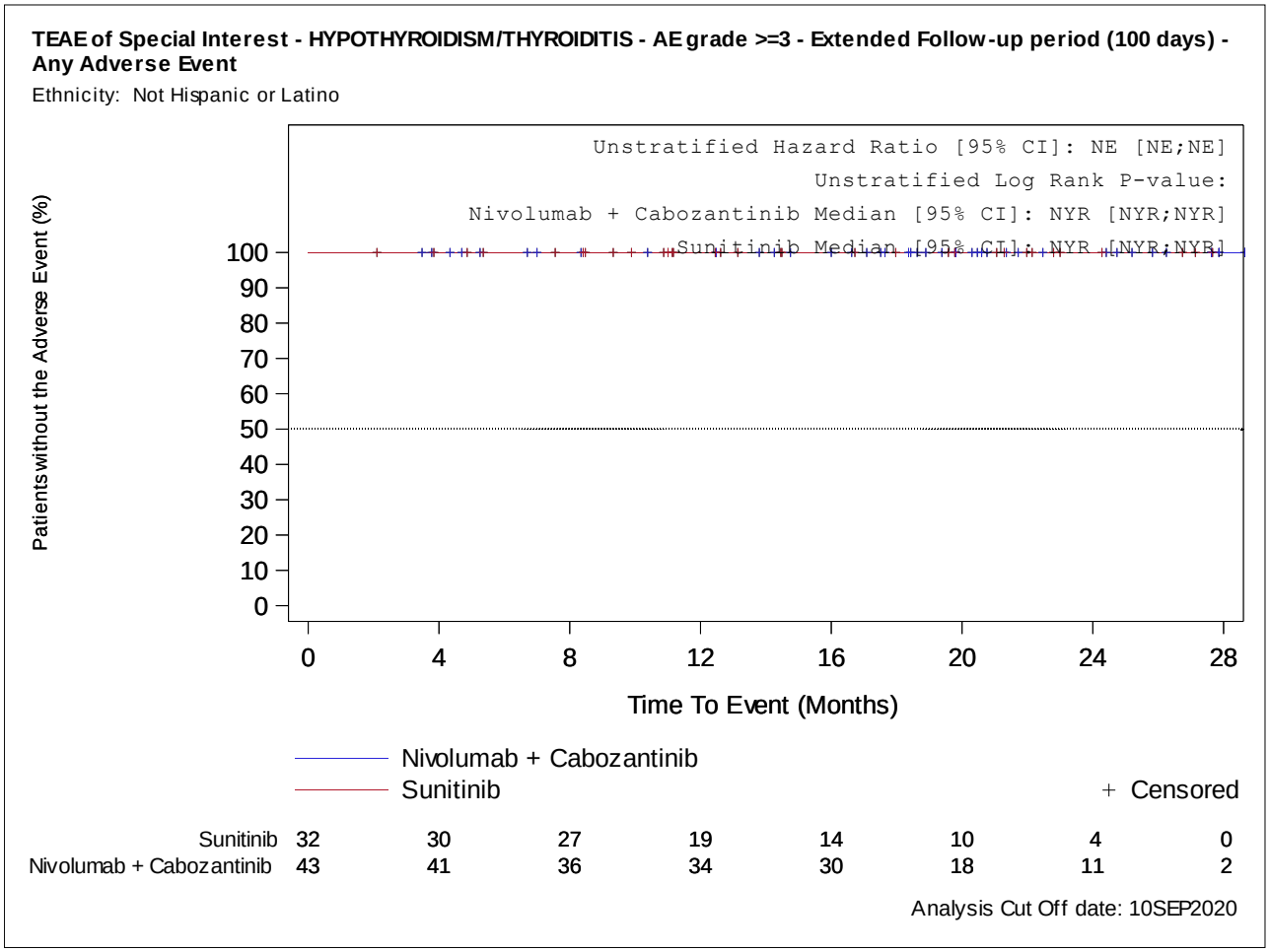

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:09:17

FIGURE 3.116.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



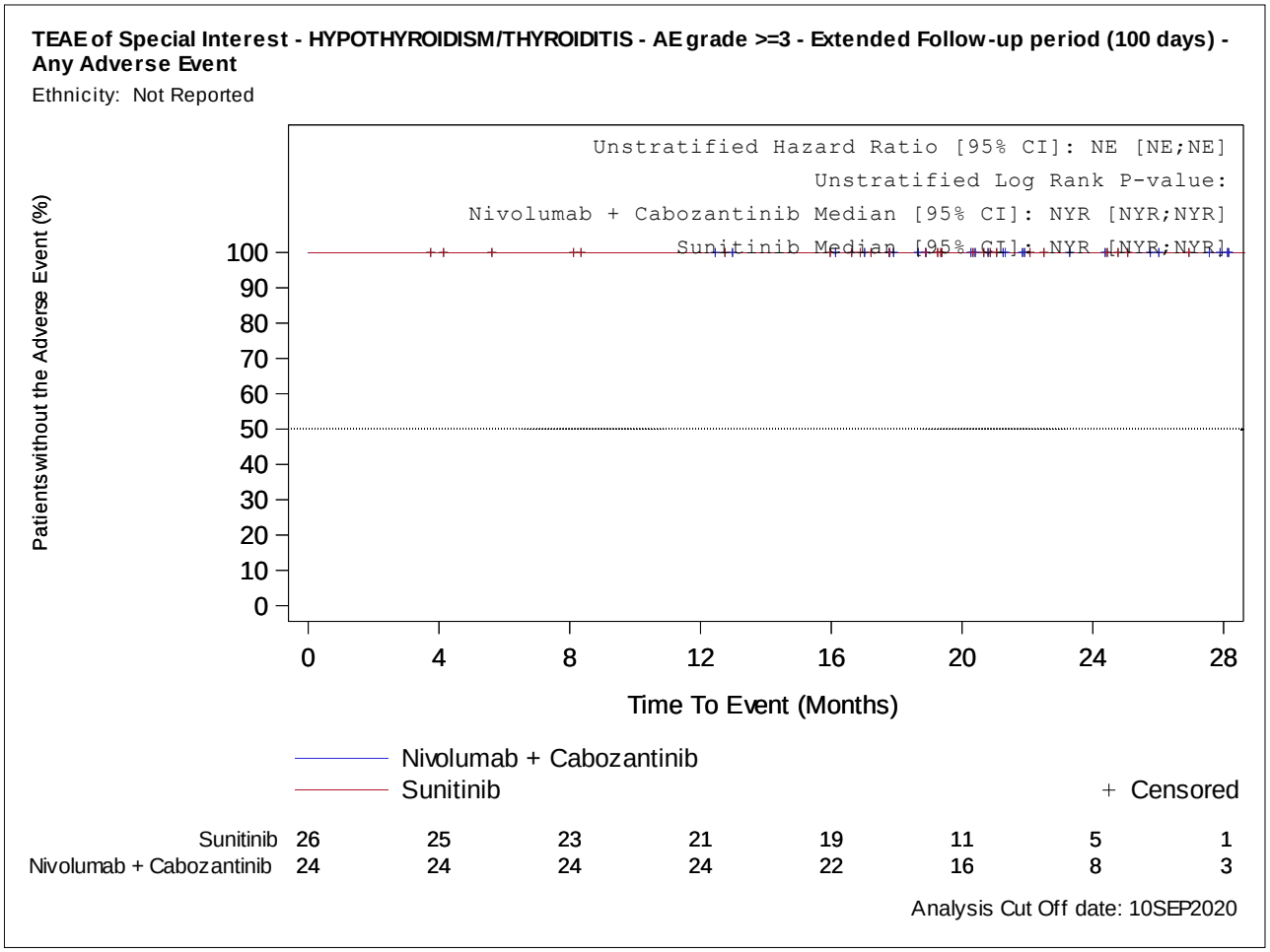

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:09:24

FIGURE 3.116.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



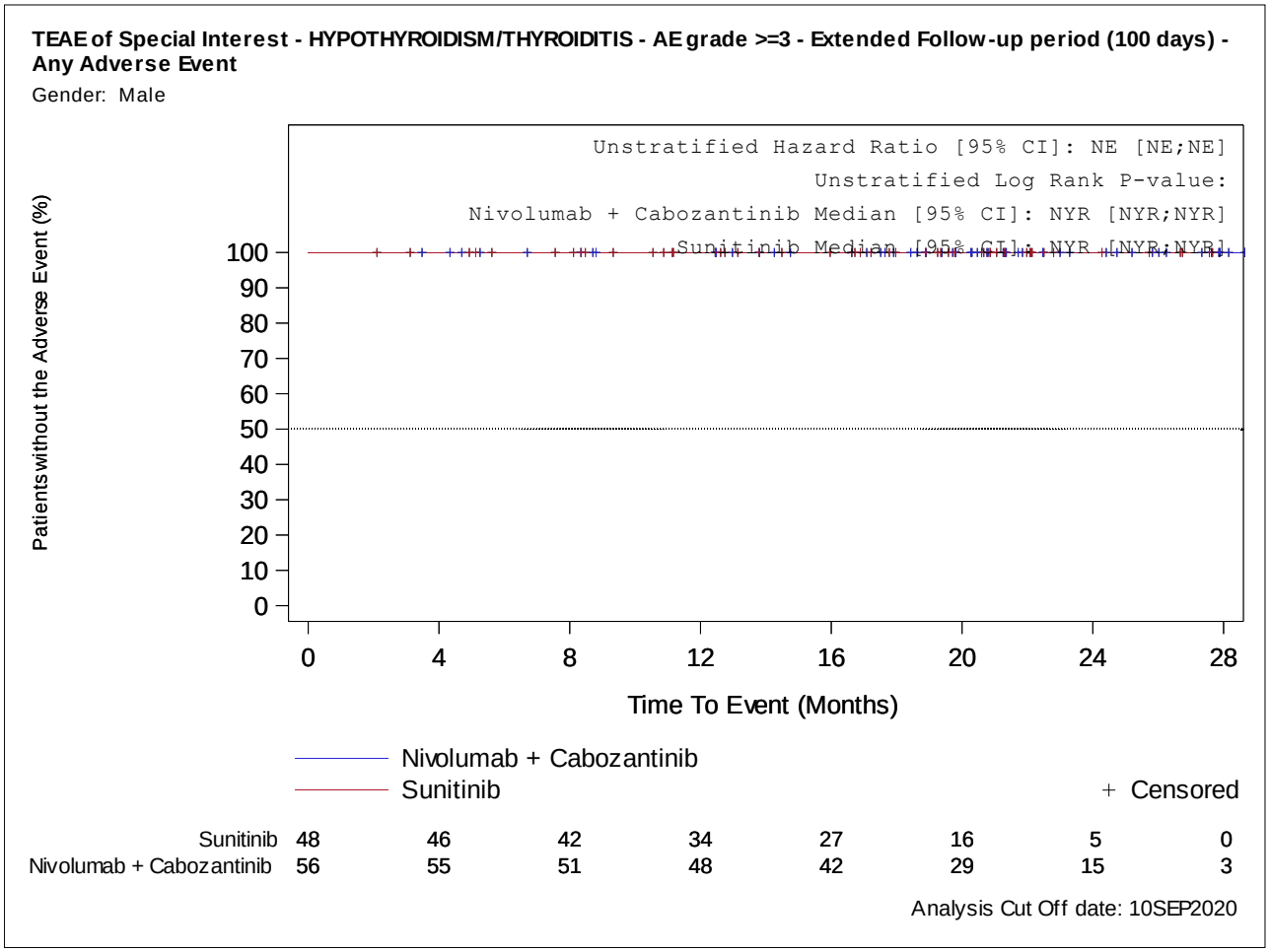

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:09:30

FIGURE 3.116.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



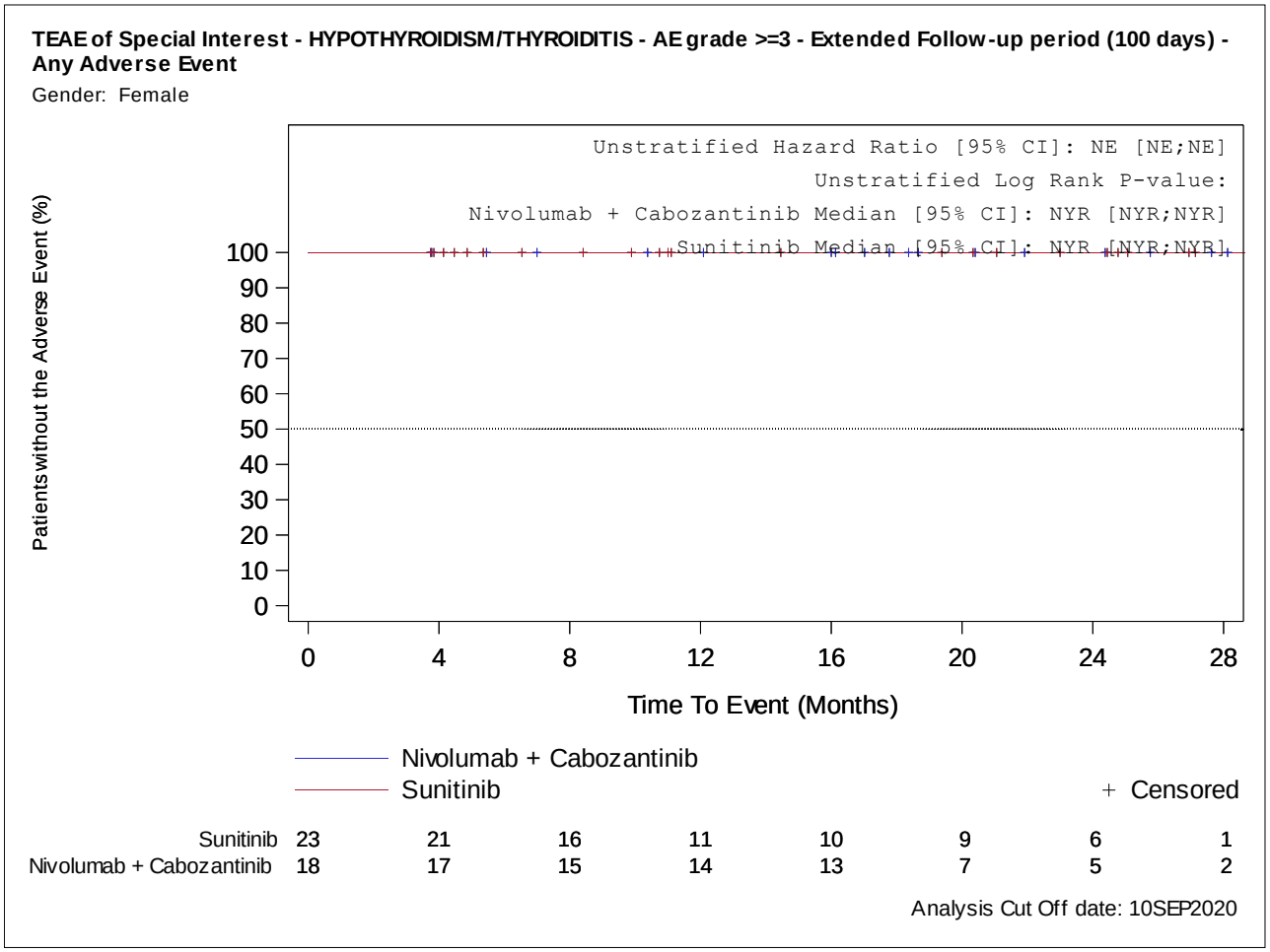

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:09:37

FIGURE 3.116.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



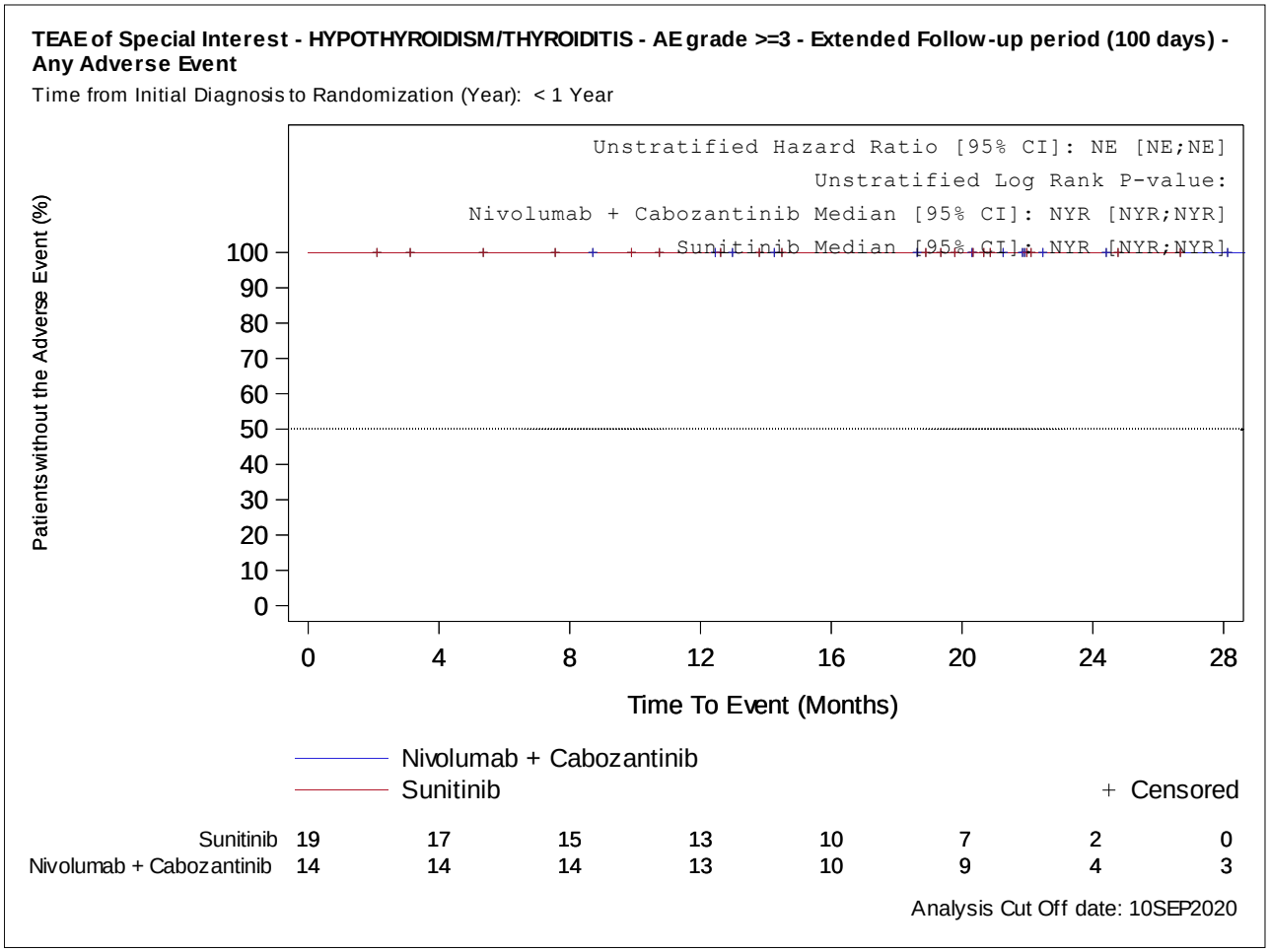

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:09:44

FIGURE 3.116.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



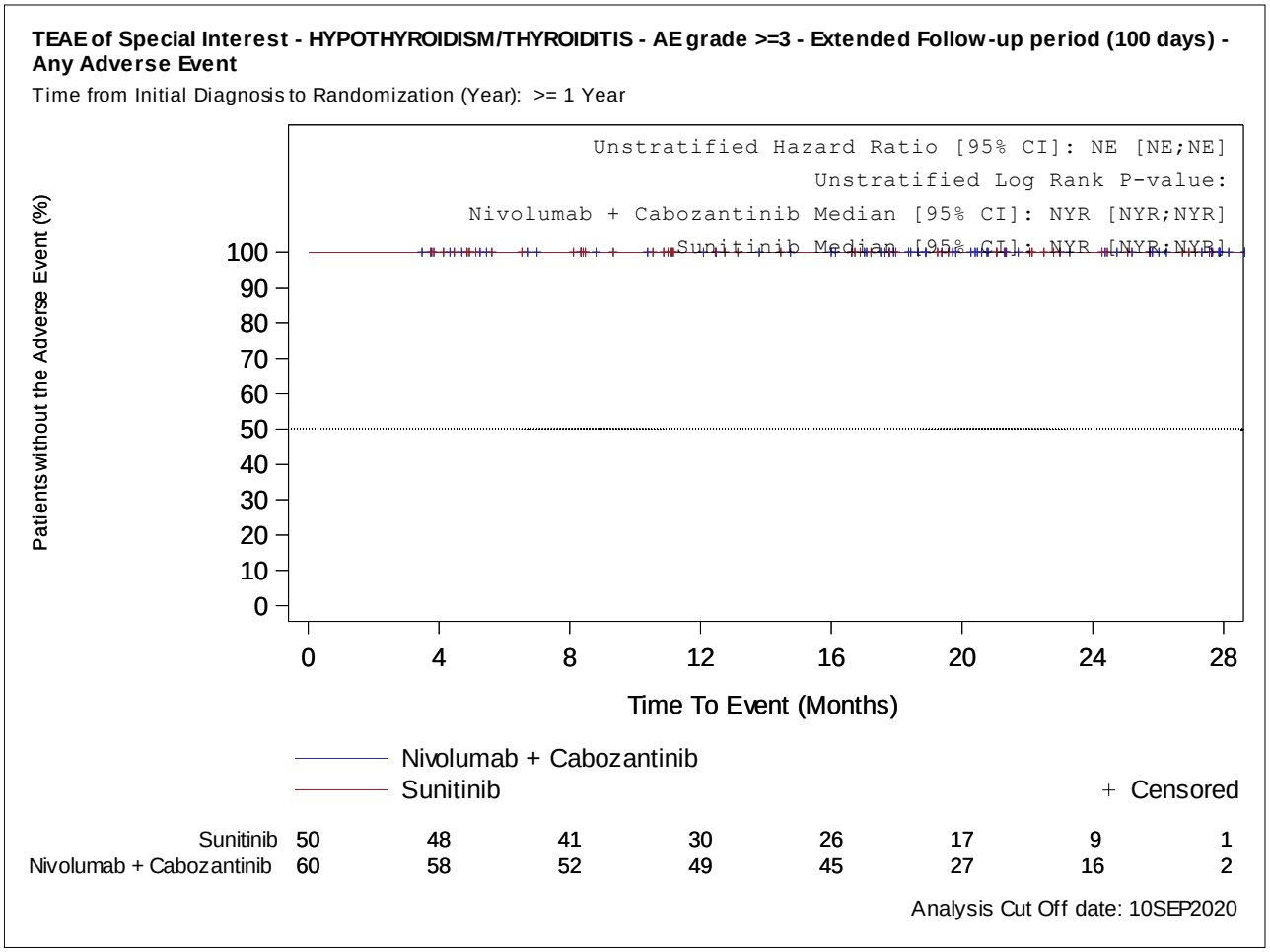

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:09:50

FIGURE 3.116.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



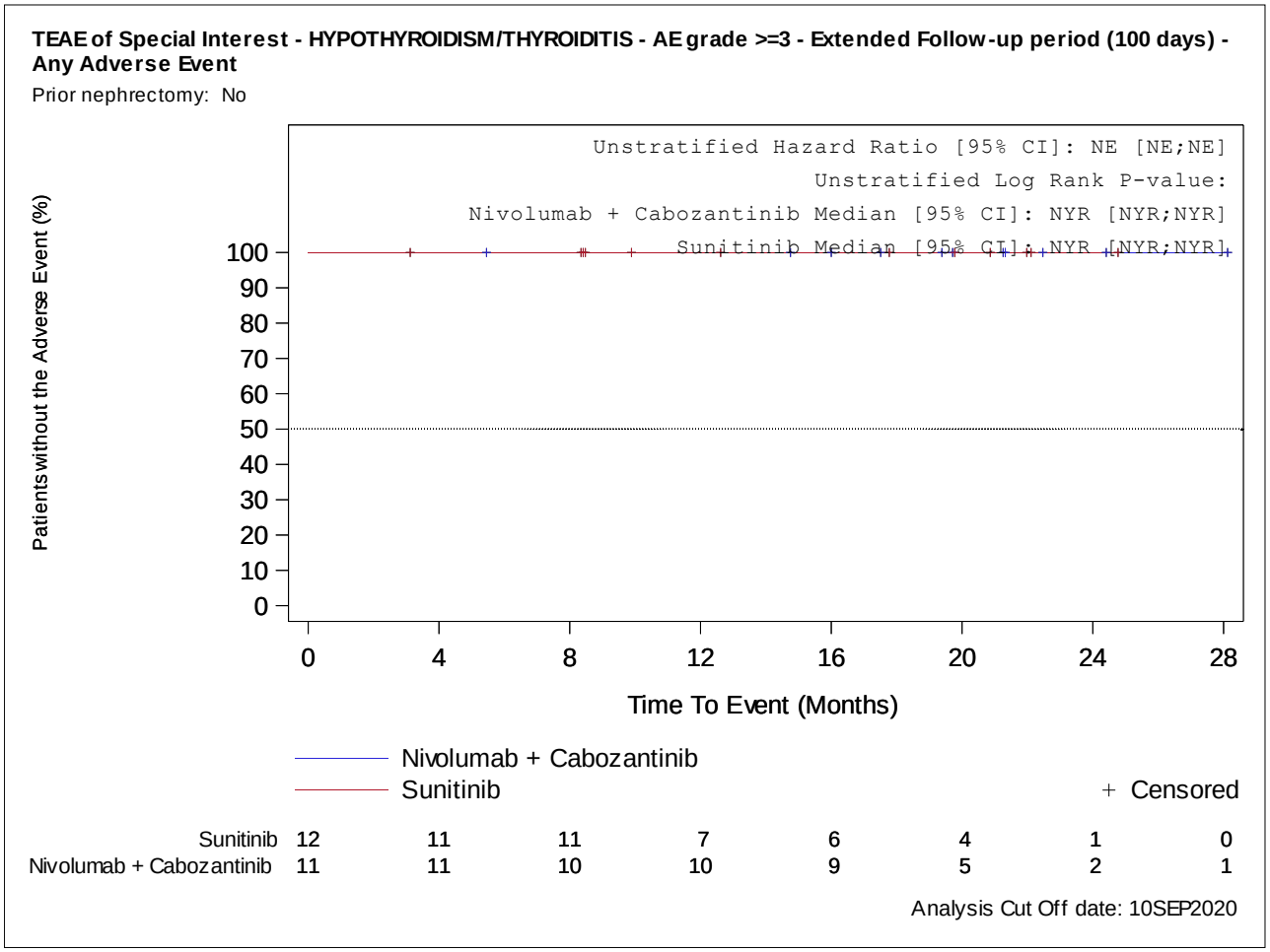

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:10:08

FIGURE 3.116.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:10:15

FIGURE 3.116.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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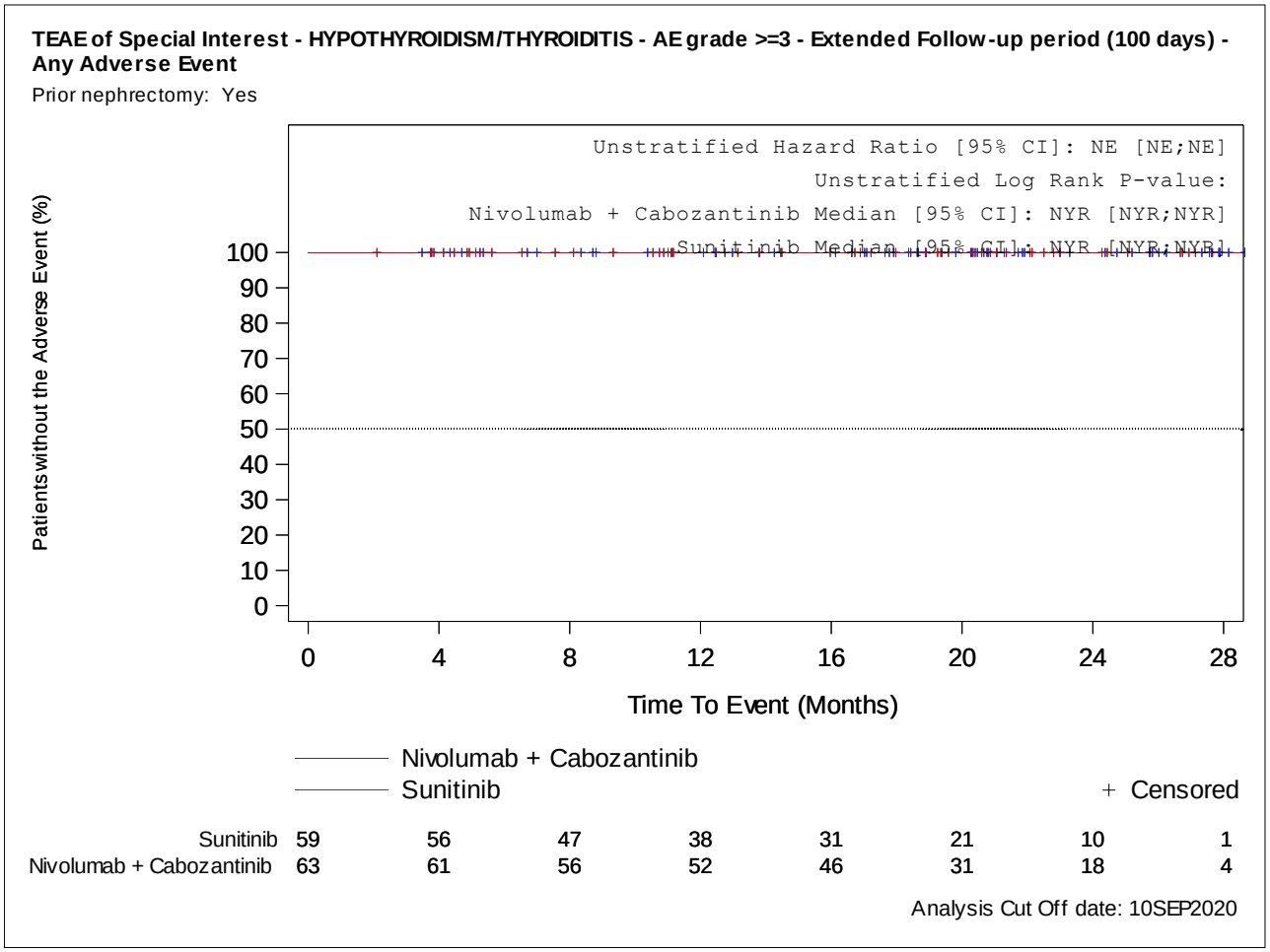
FIGURE 3.116.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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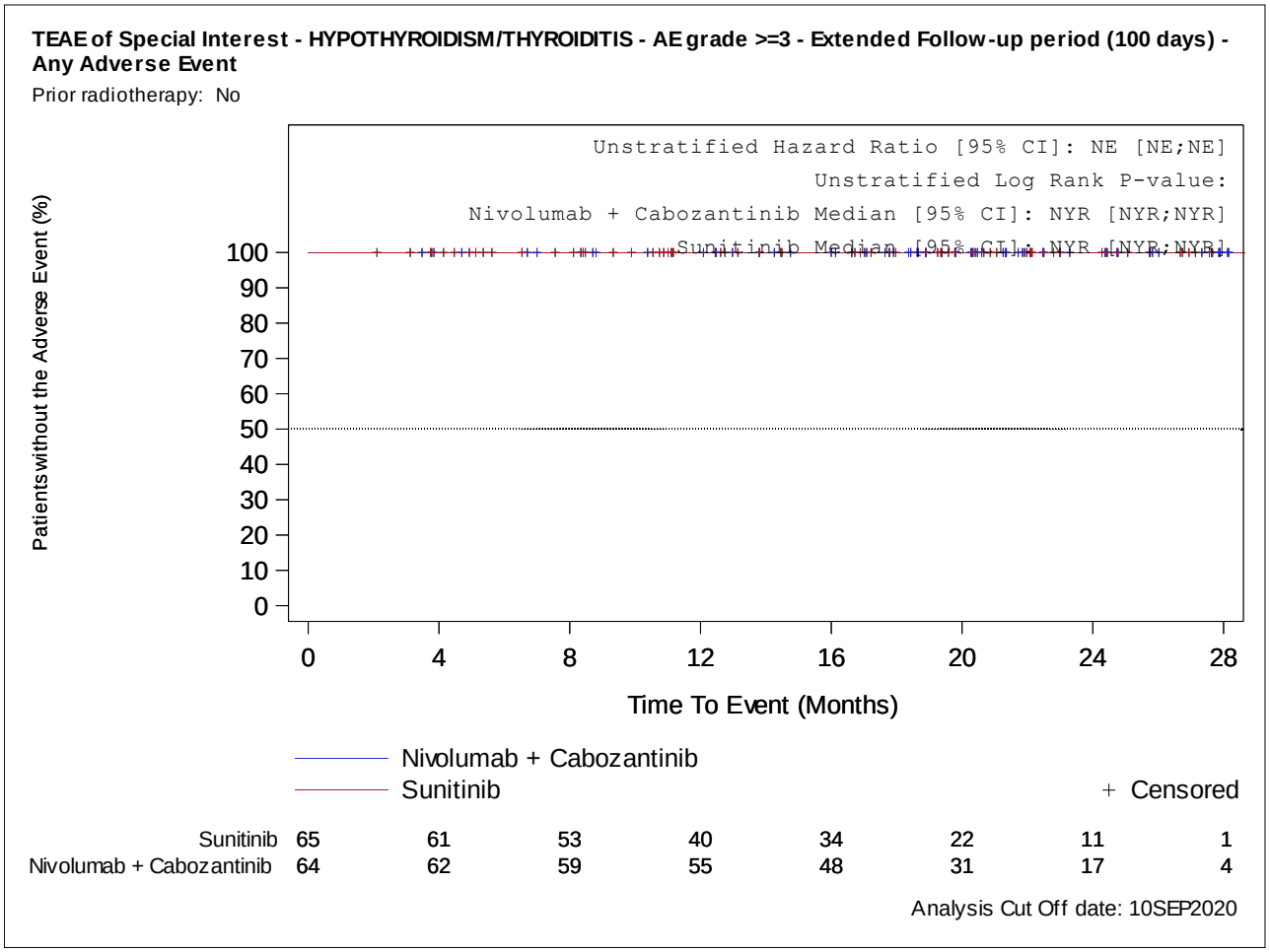
FIGURE 3.116.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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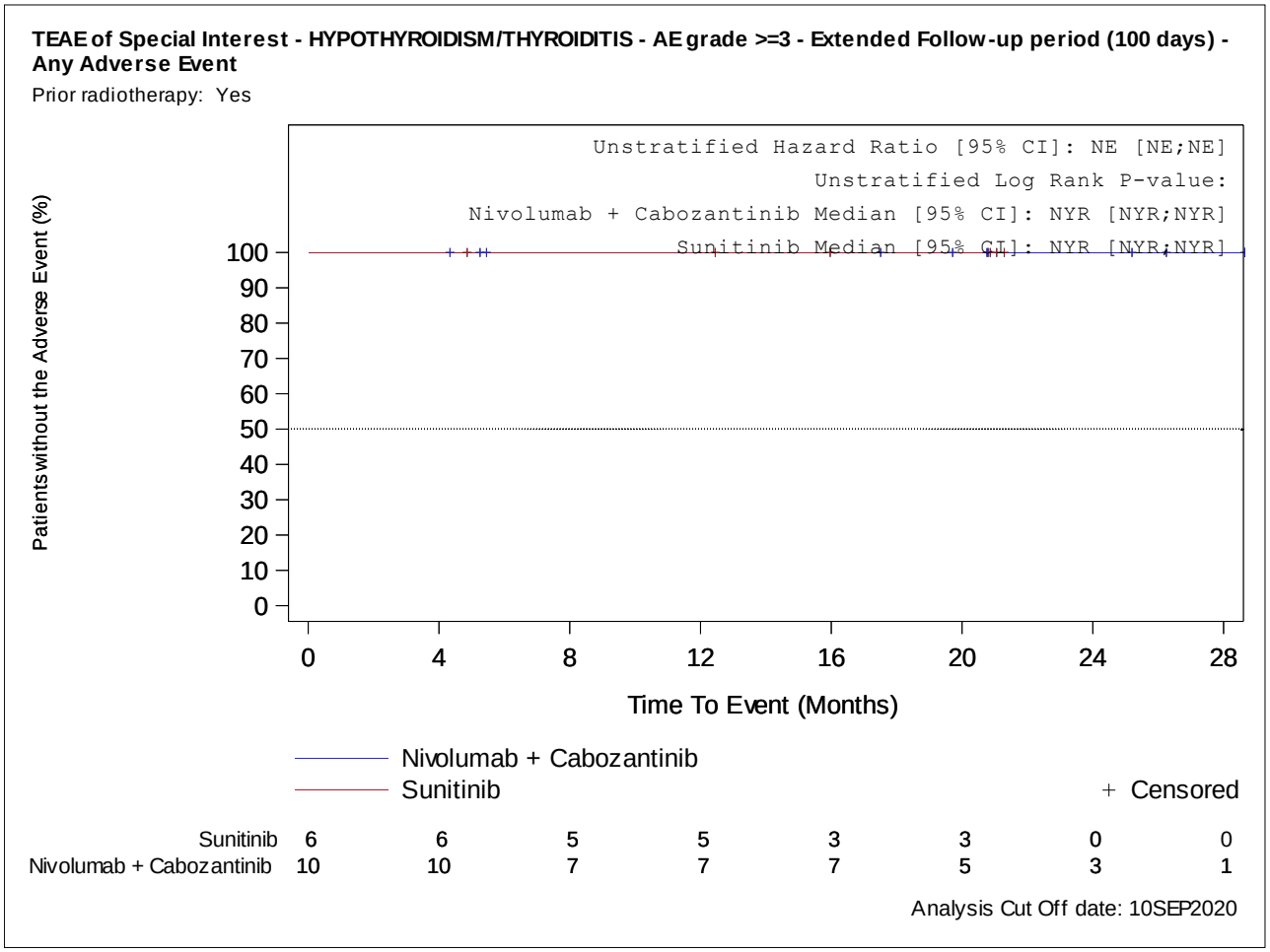
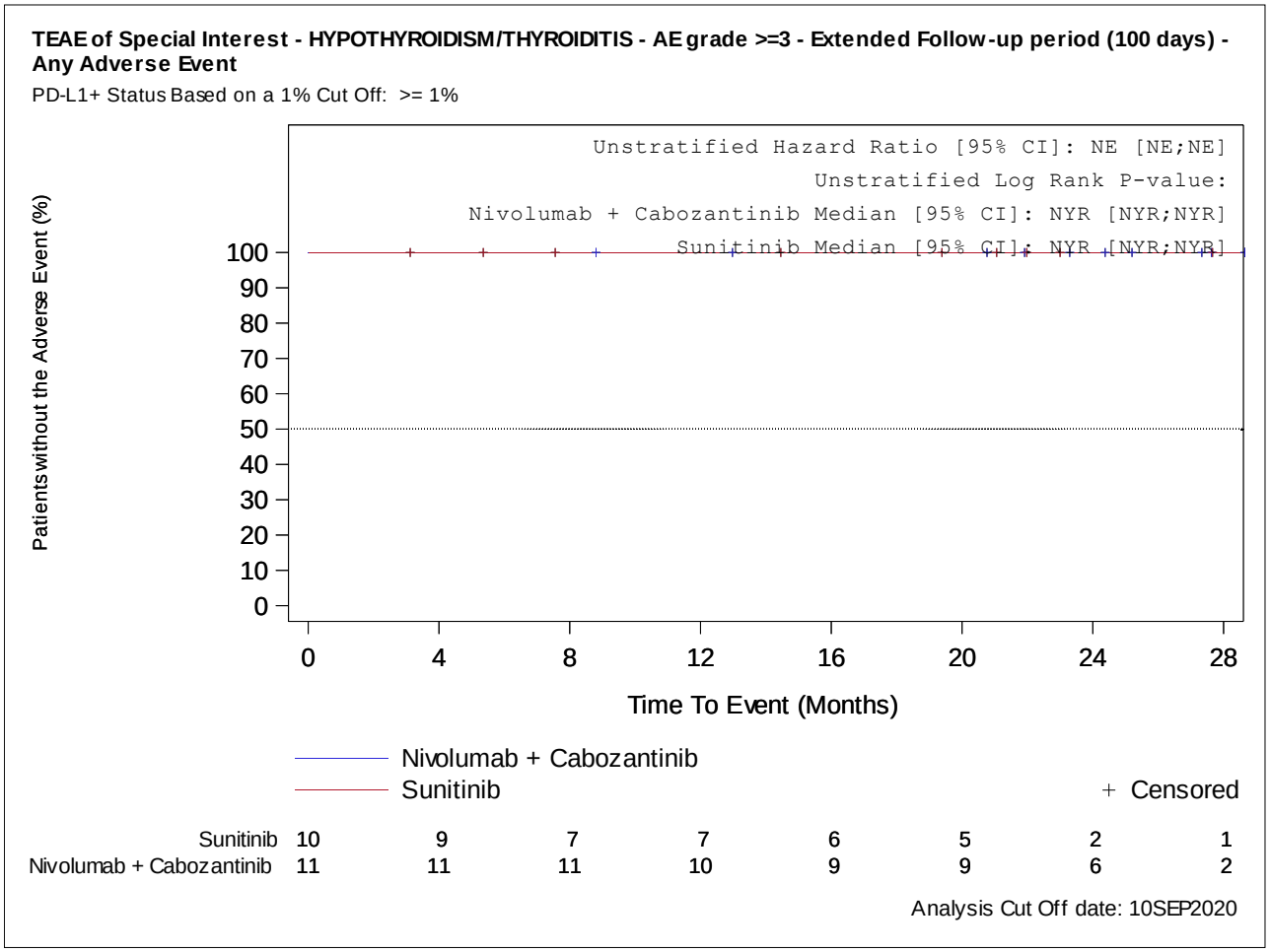
FIGURE 3.116.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:11:29

FIGURE 3.116.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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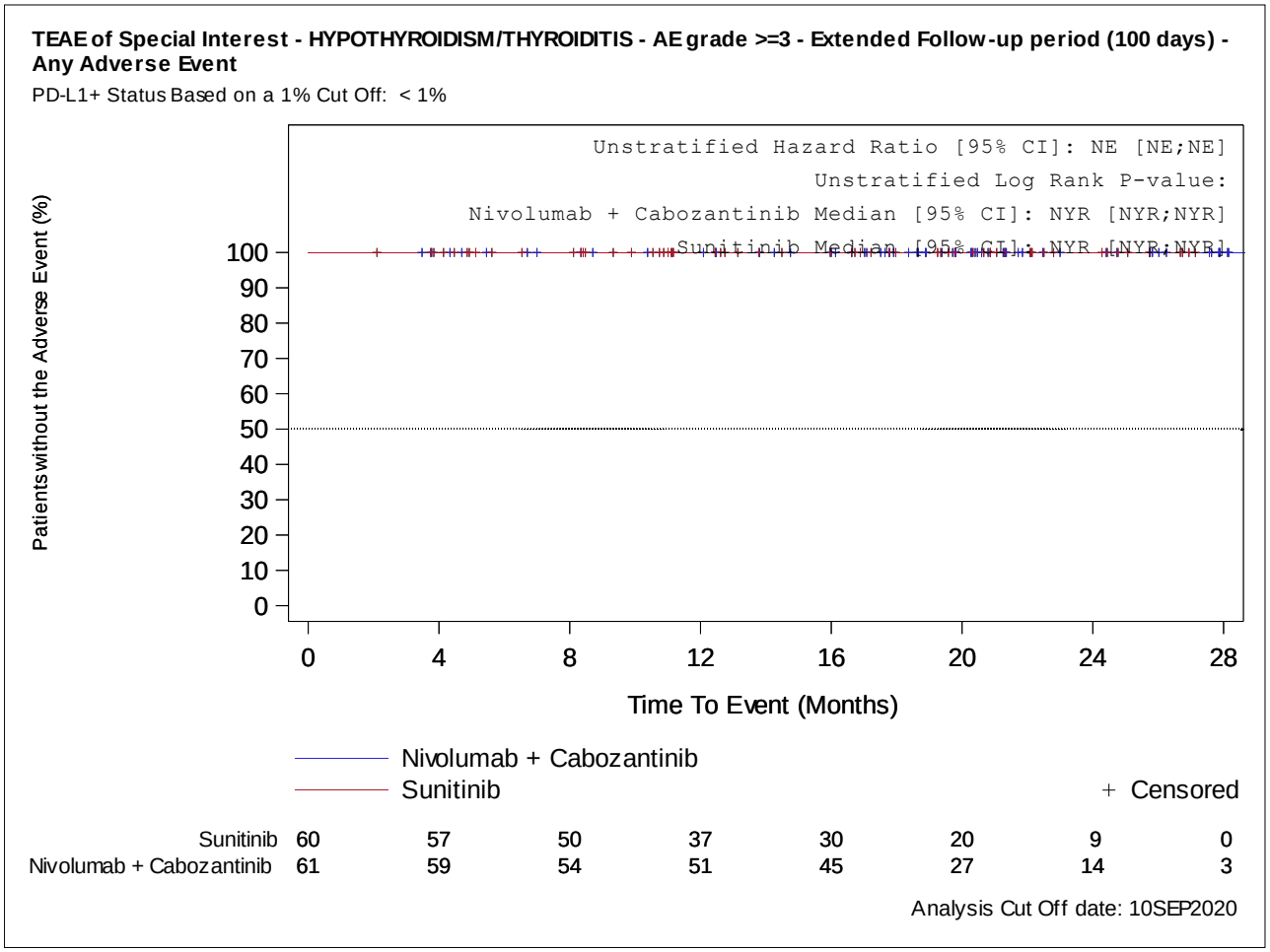
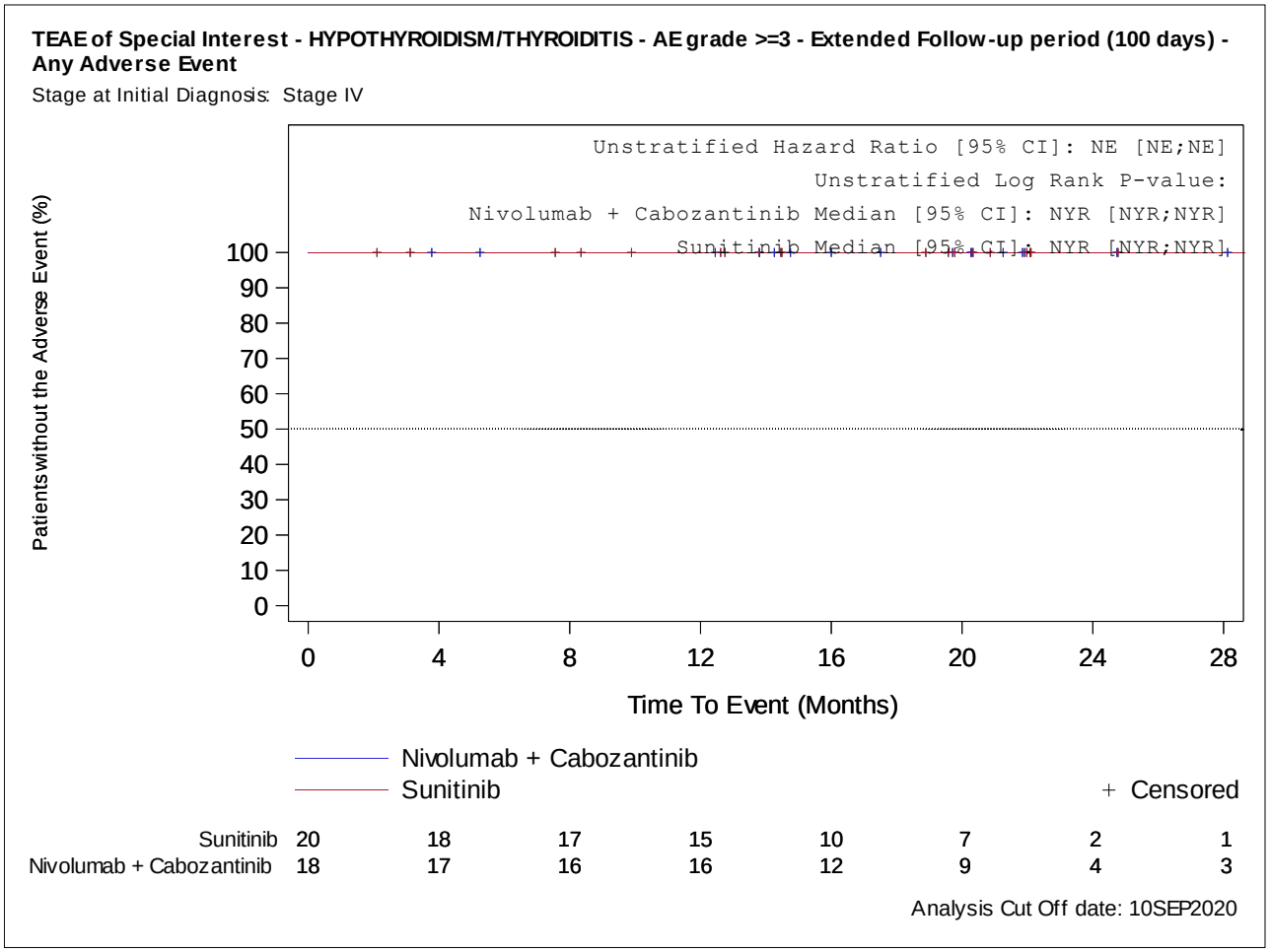
FIGURE 3.116.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



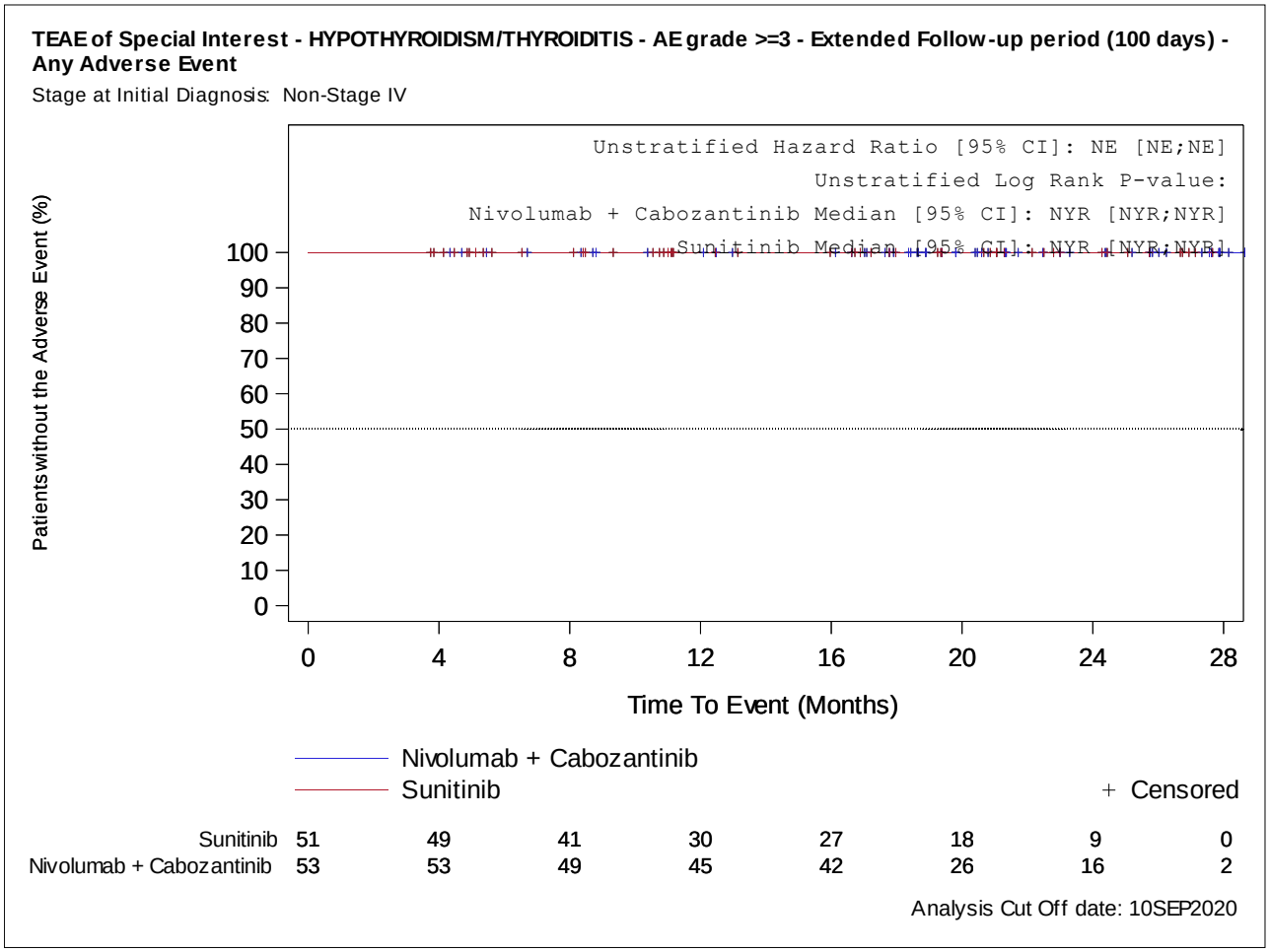

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:11:42

FIGURE 3.116.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



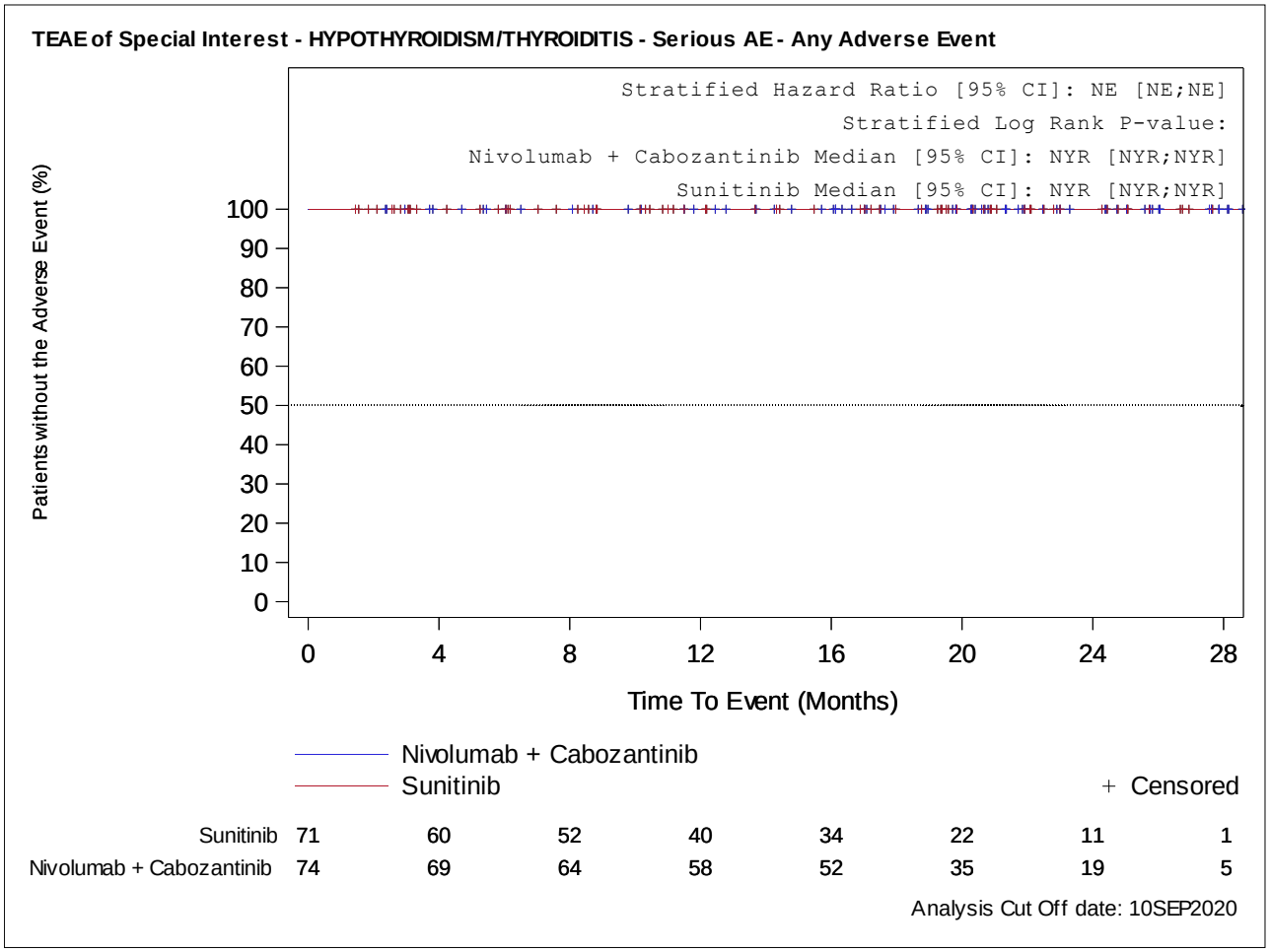

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:12:14

FIGURE 3.116.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



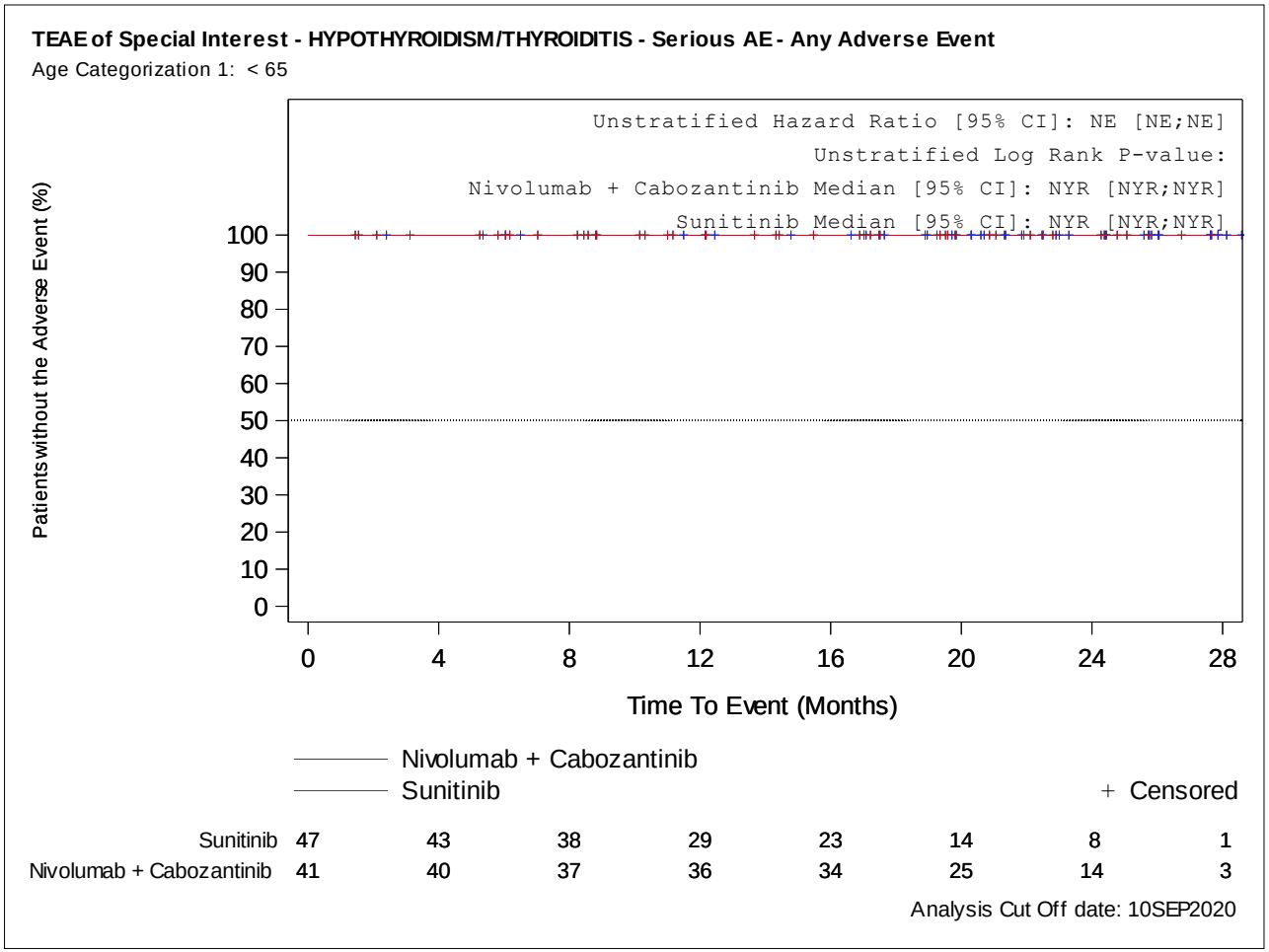

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:12:20

FIGURE 3.117.1: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



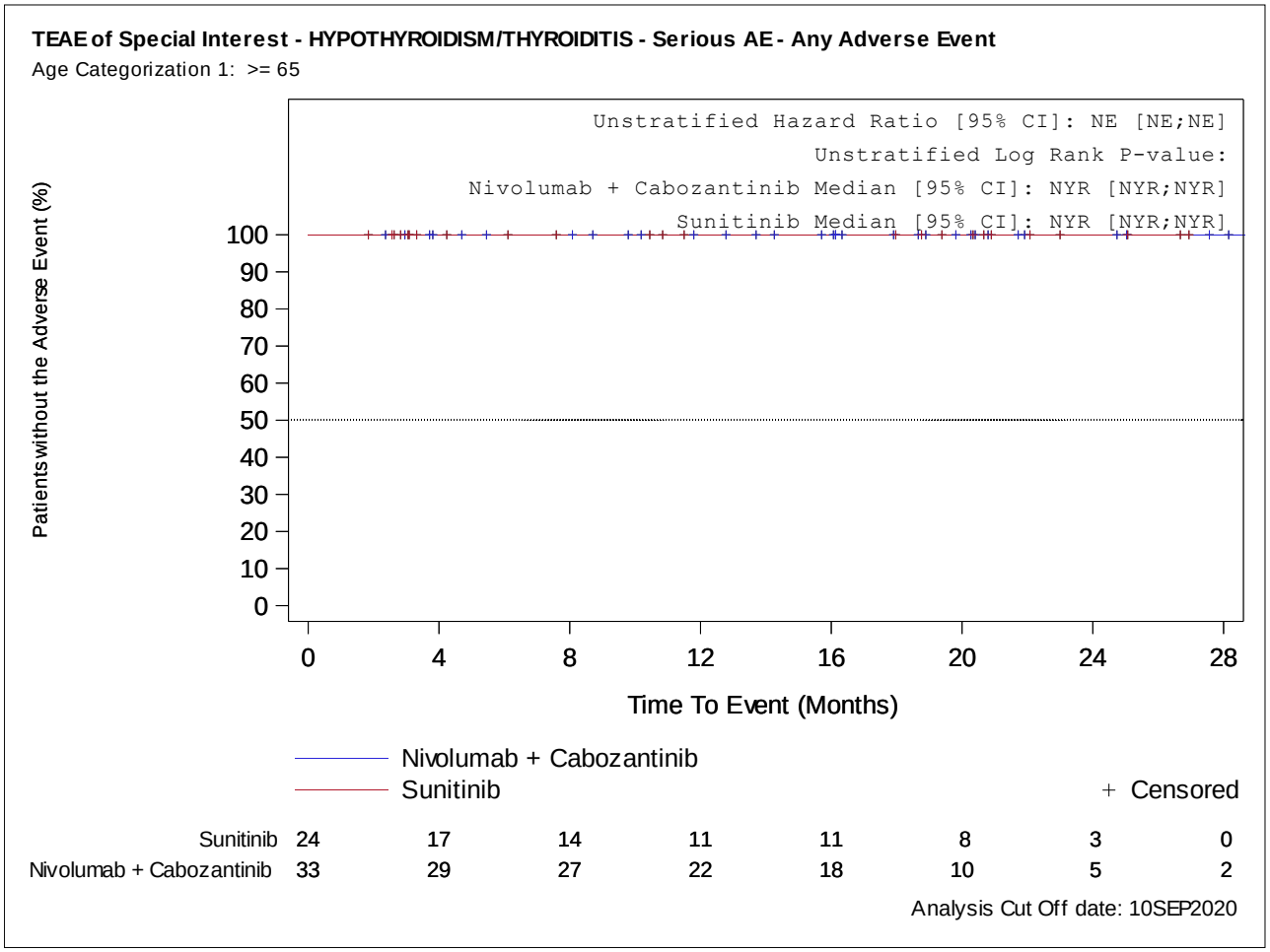

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:15:48

FIGURE 3.117.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:15:52

FIGURE 3.117.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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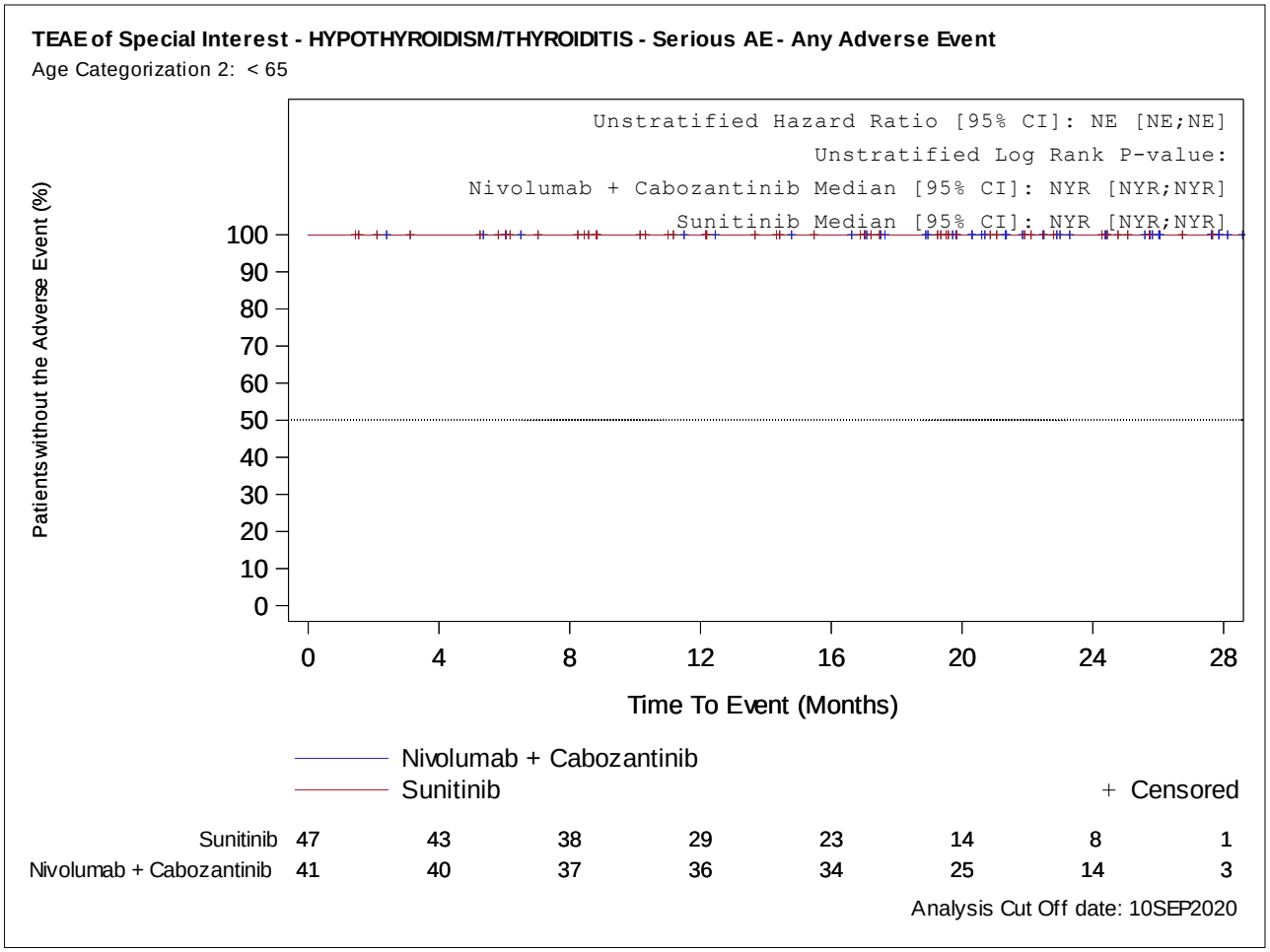
FIGURE 3.117.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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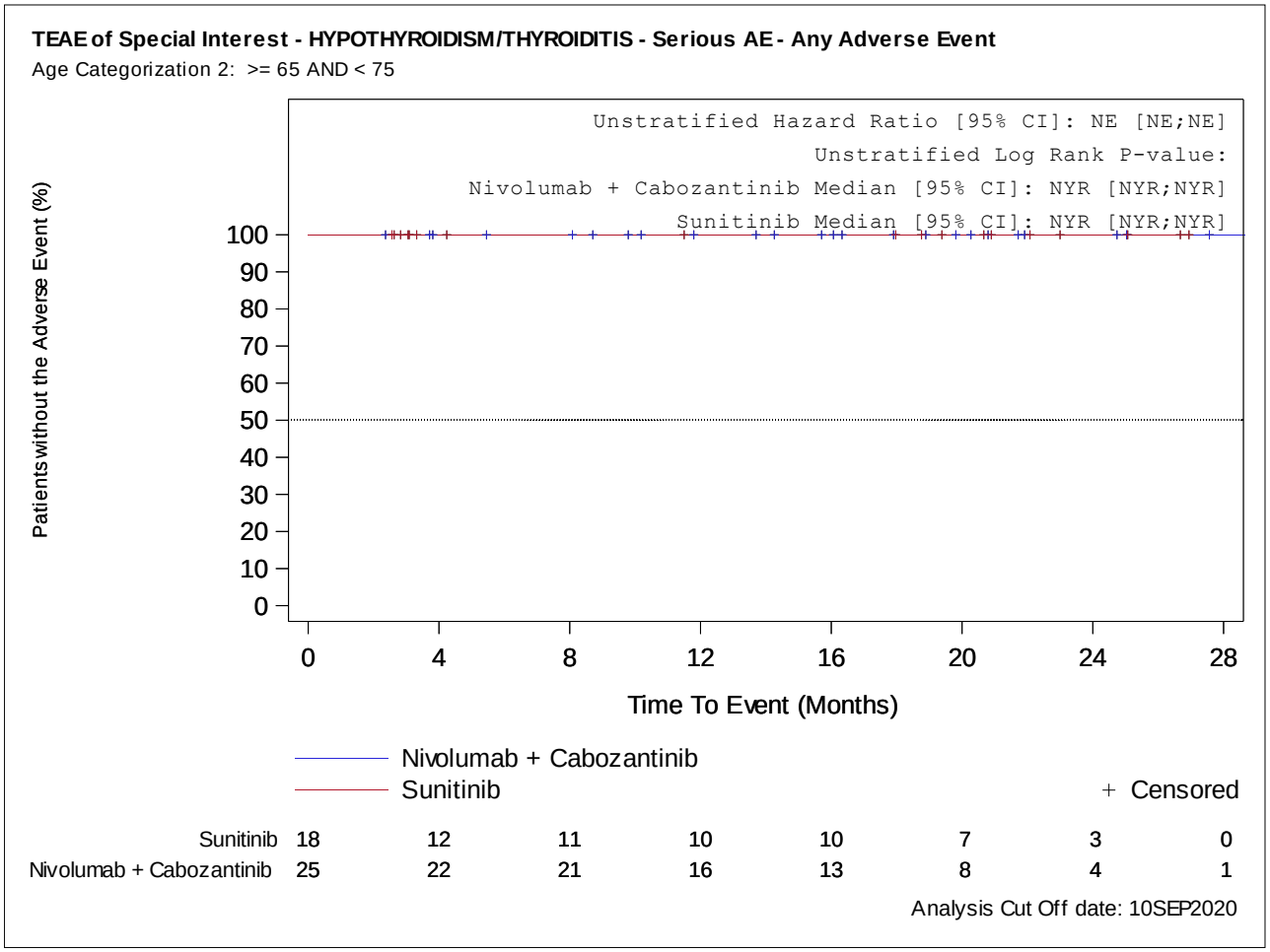
FIGURE 3.117.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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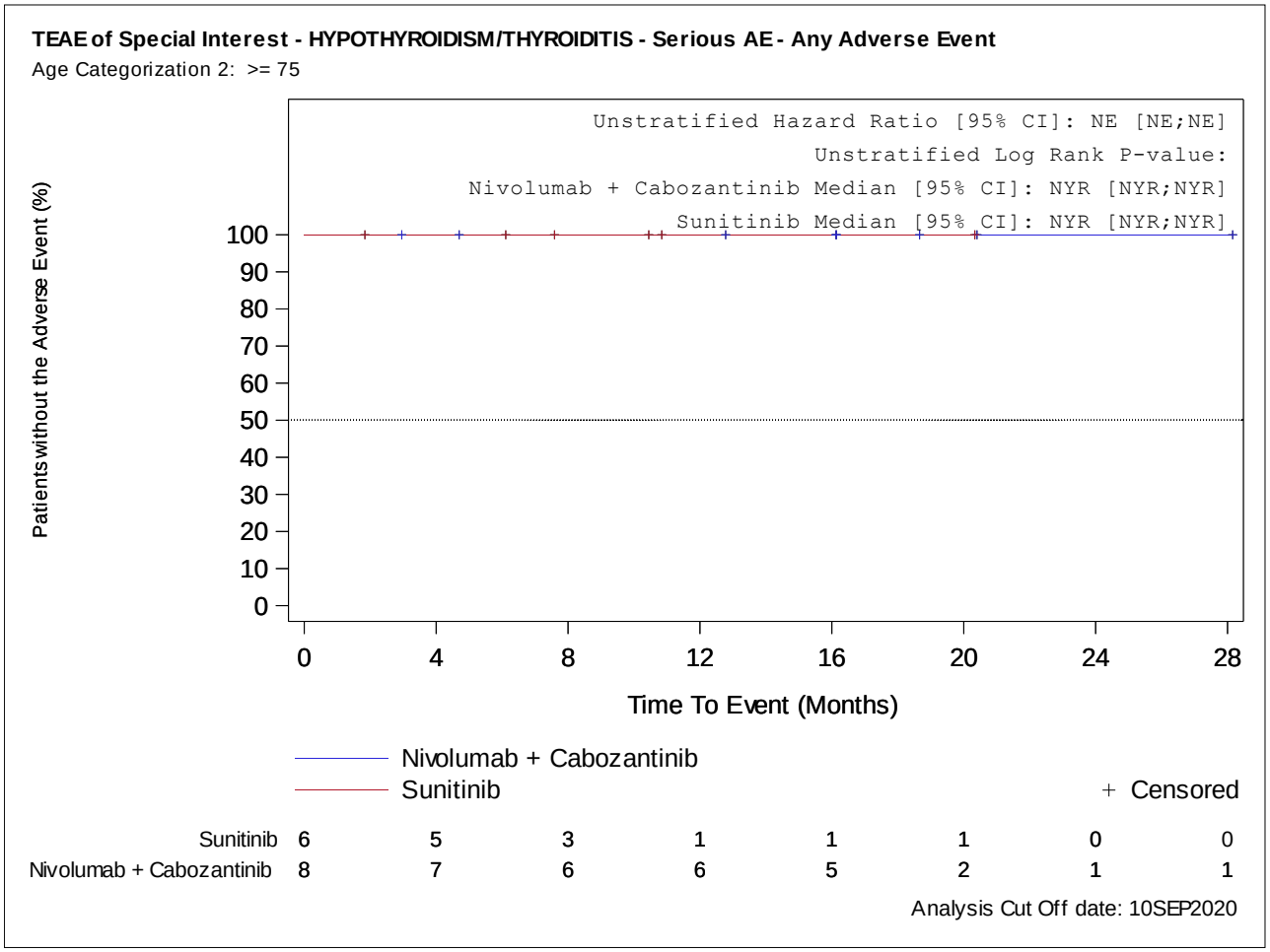
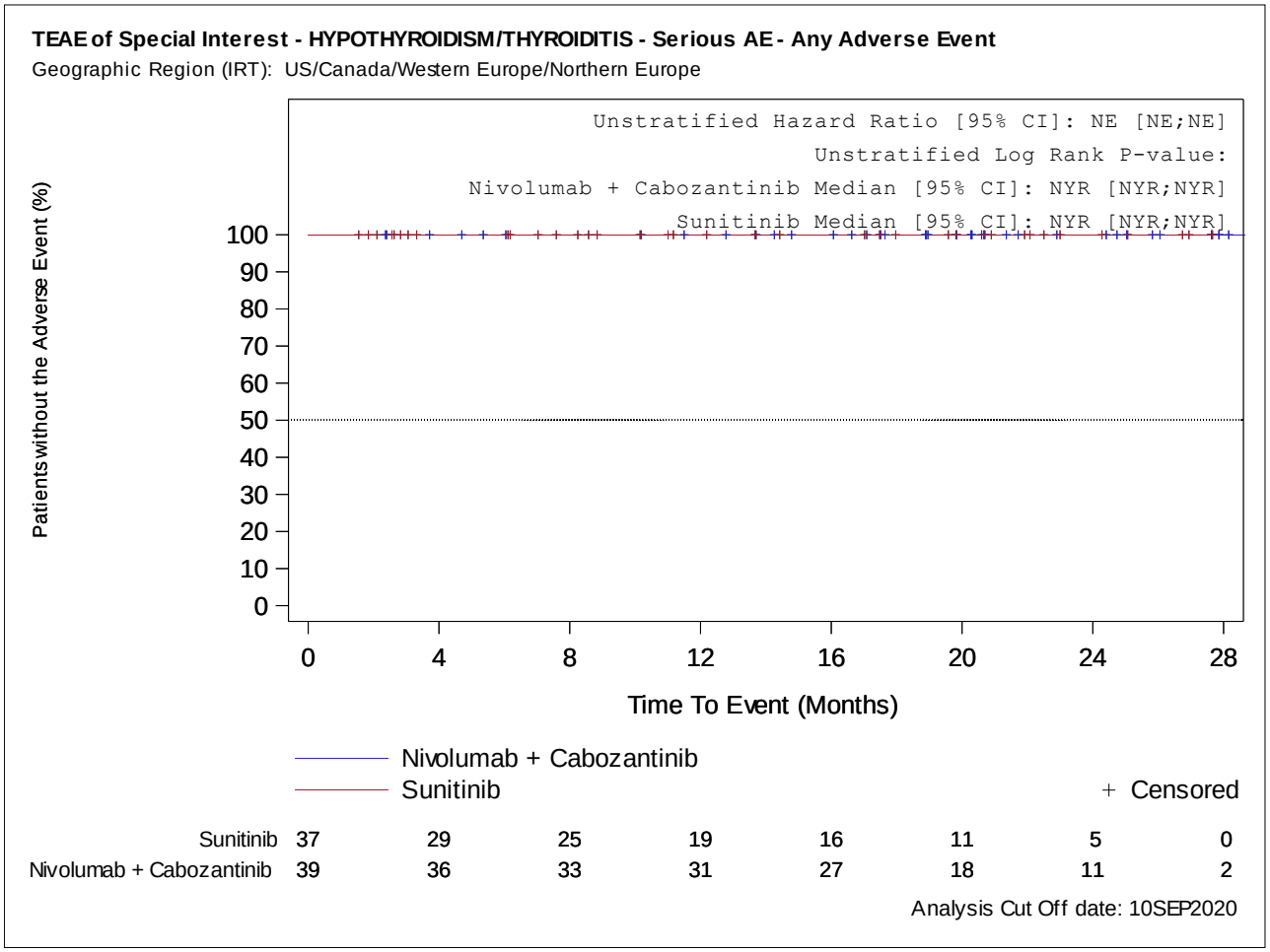
FIGURE 3.117.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



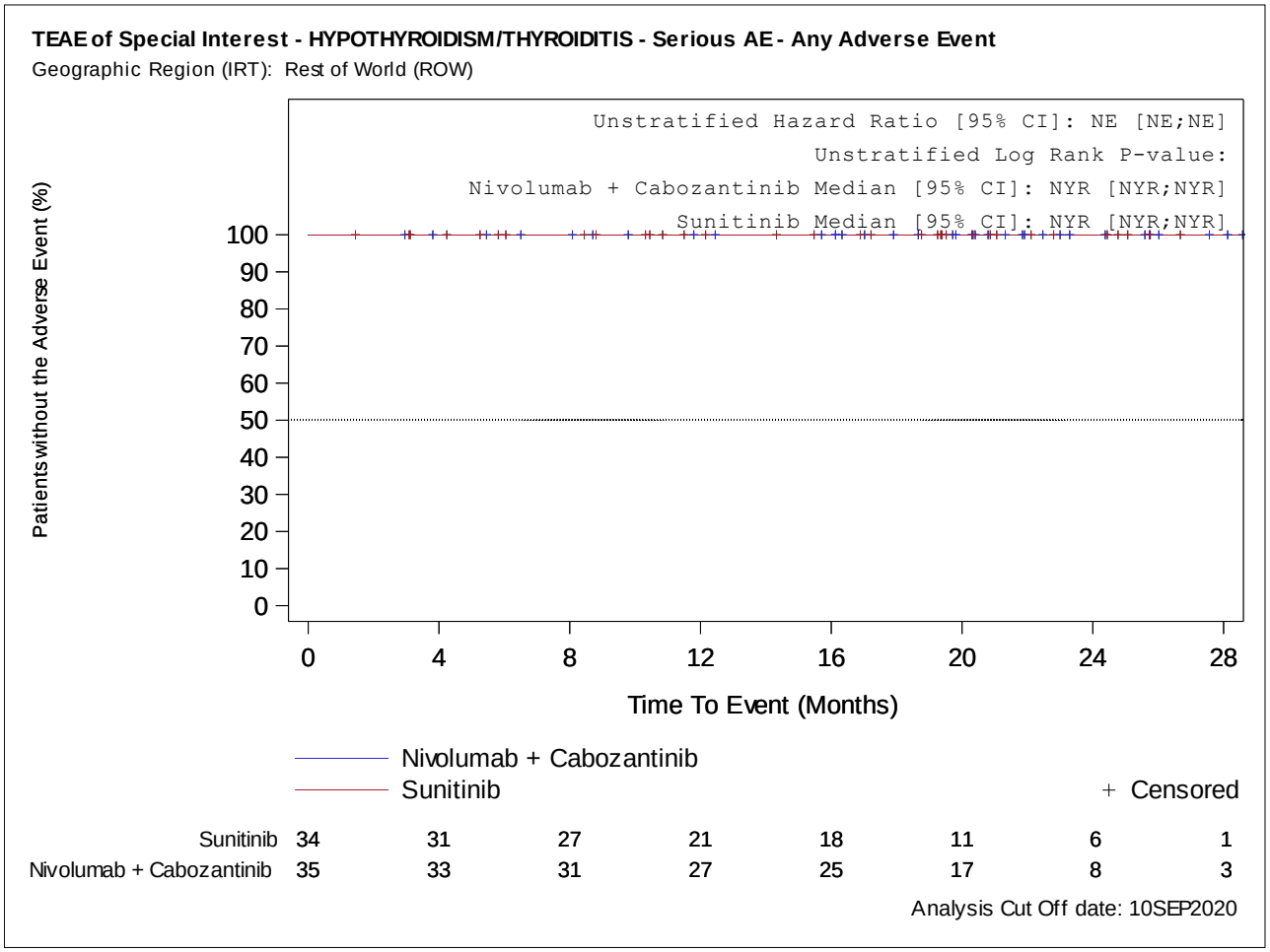

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:16:17

FIGURE 3.117.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



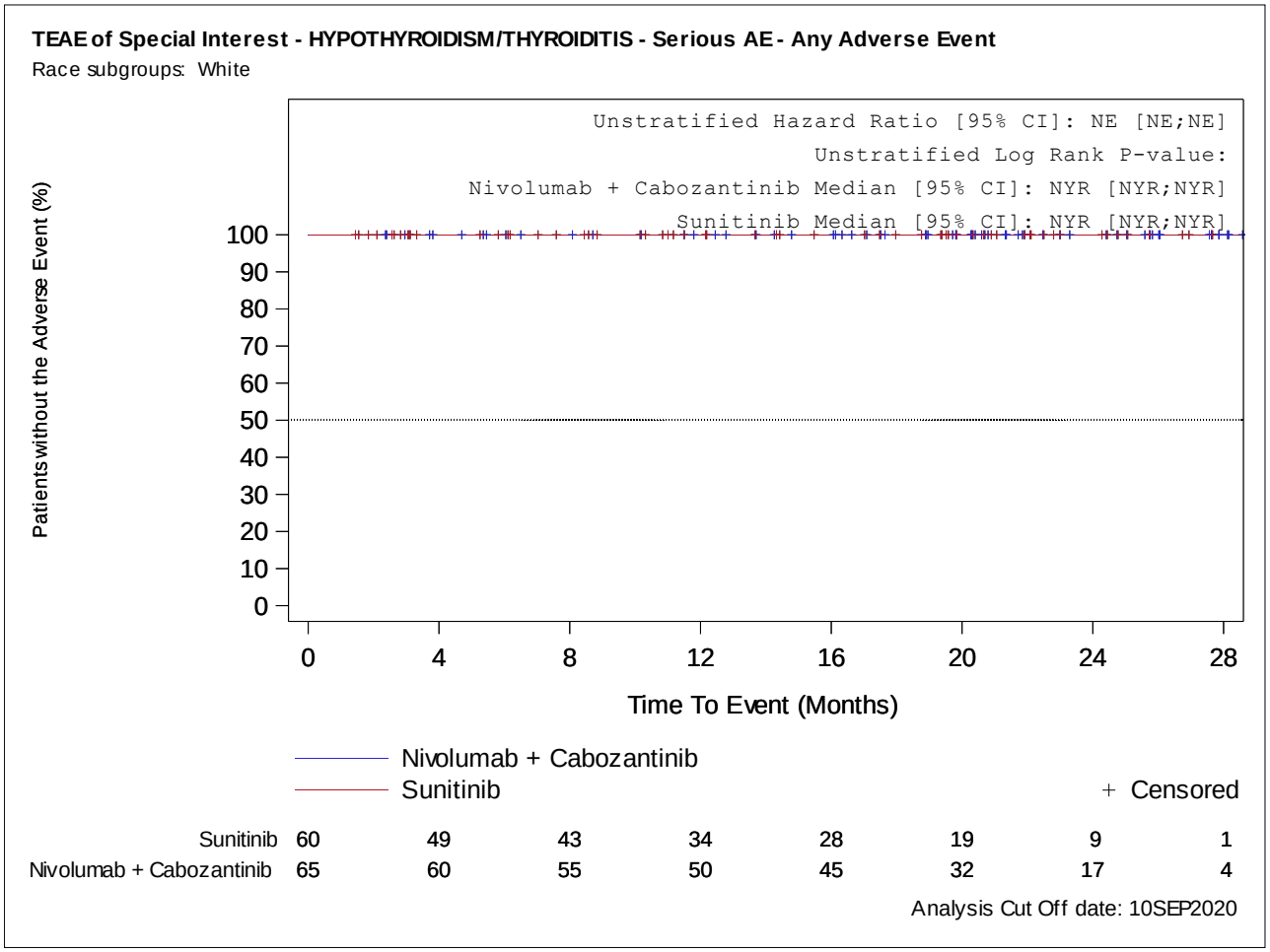

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:16:23

FIGURE 3.117.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



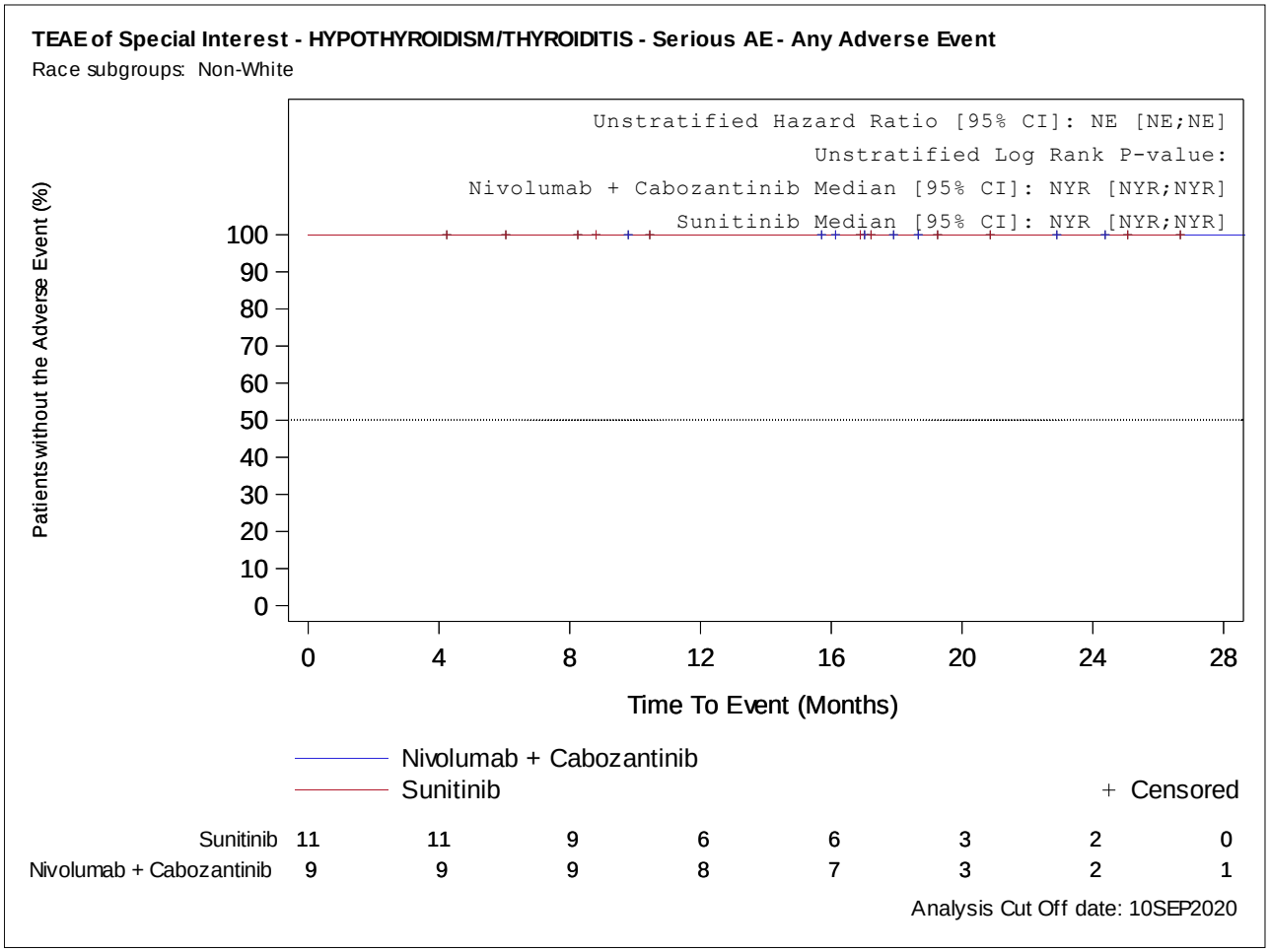

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:16:29

FIGURE 3.117.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:16:35

FIGURE 3.117.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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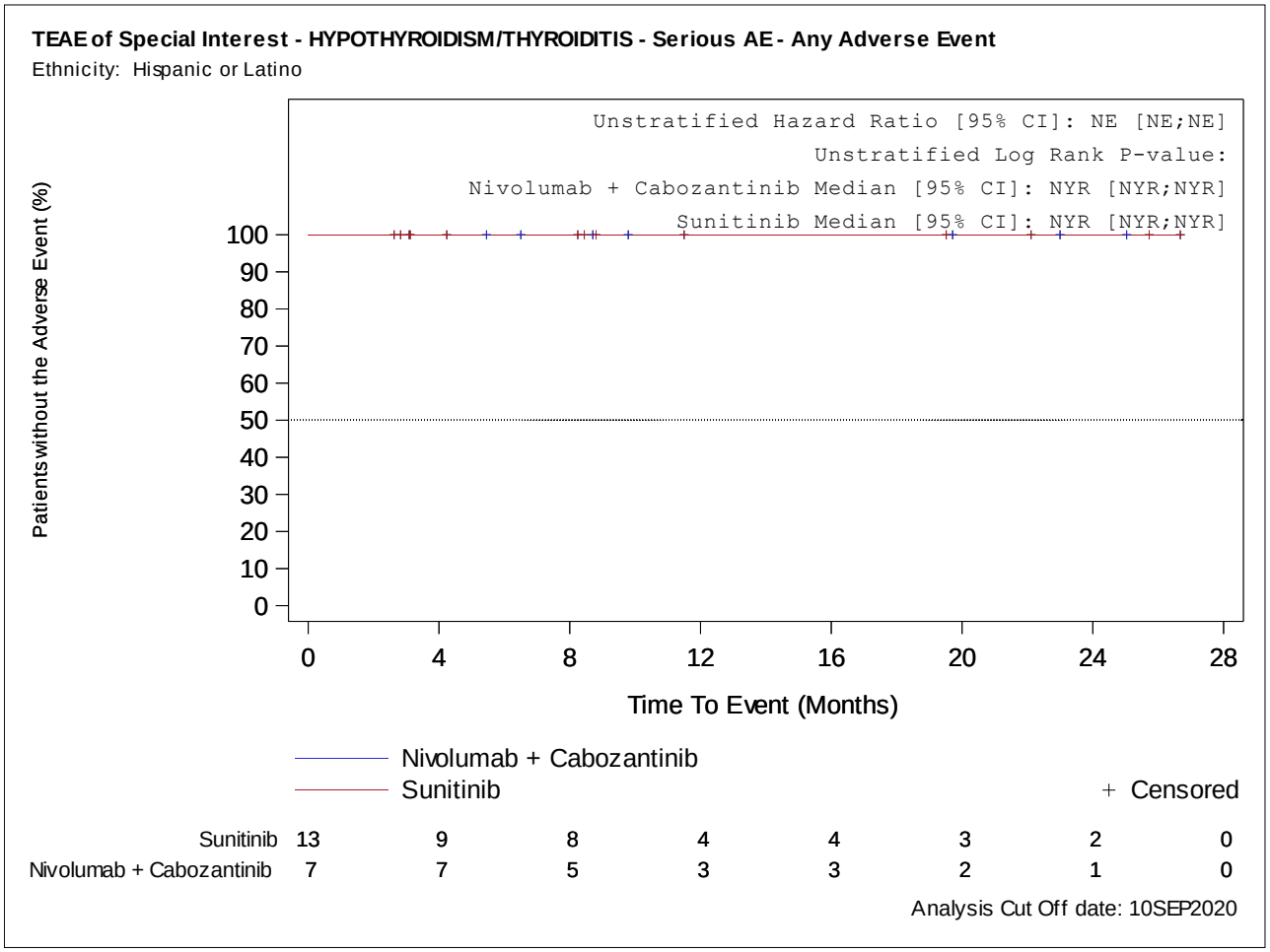
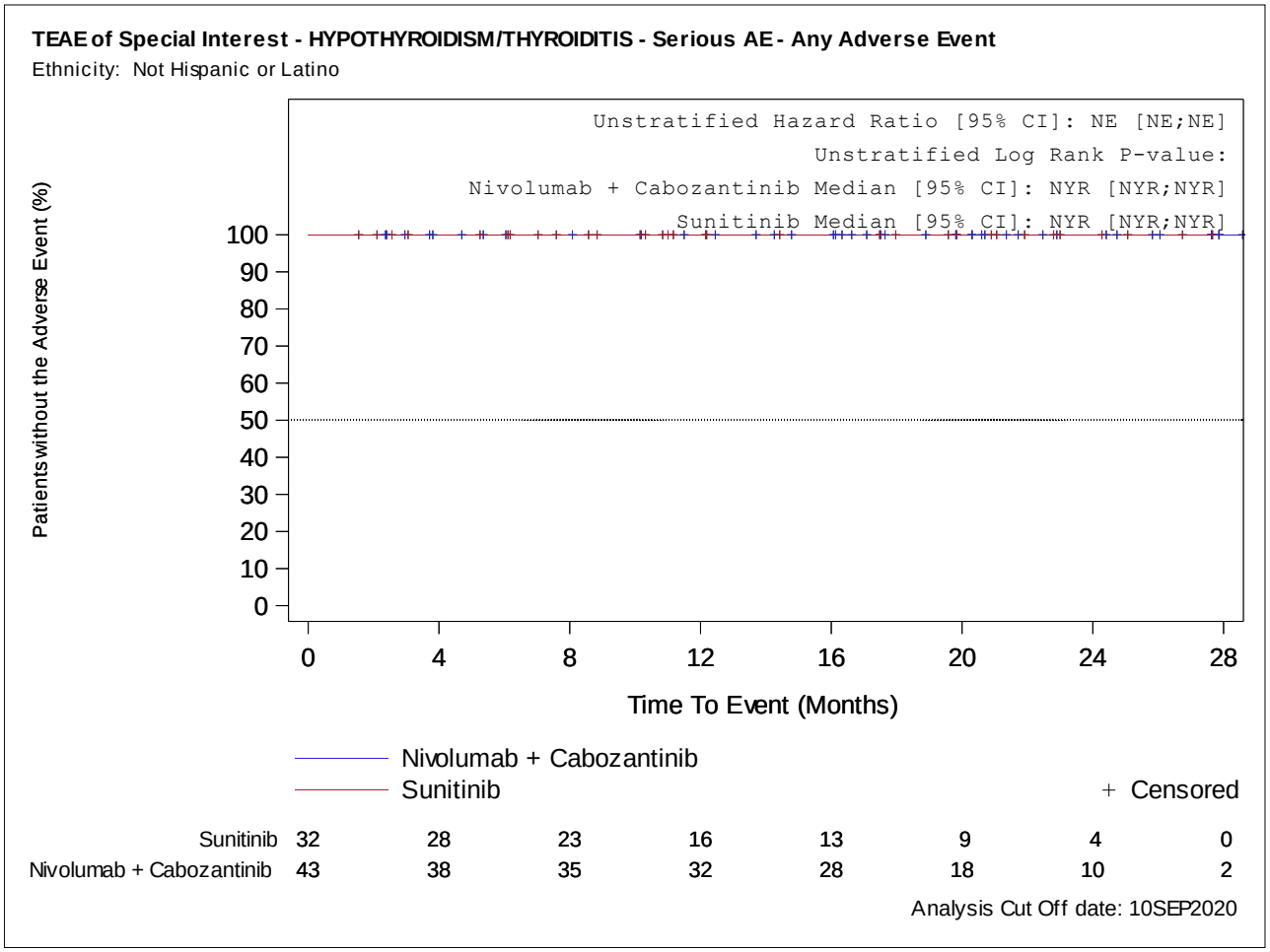
FIGURE 3.117.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



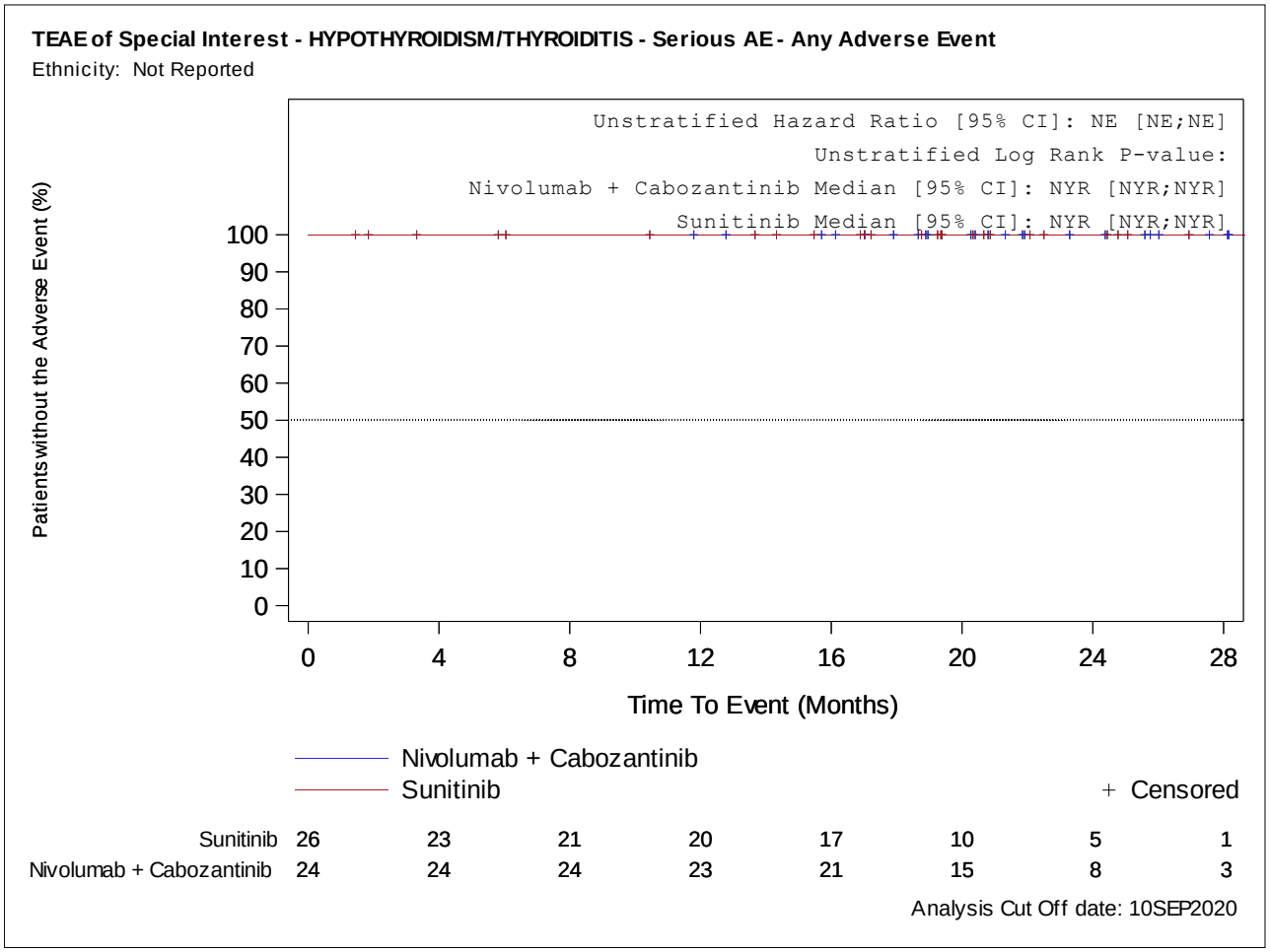

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:16:47

FIGURE 3.117.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



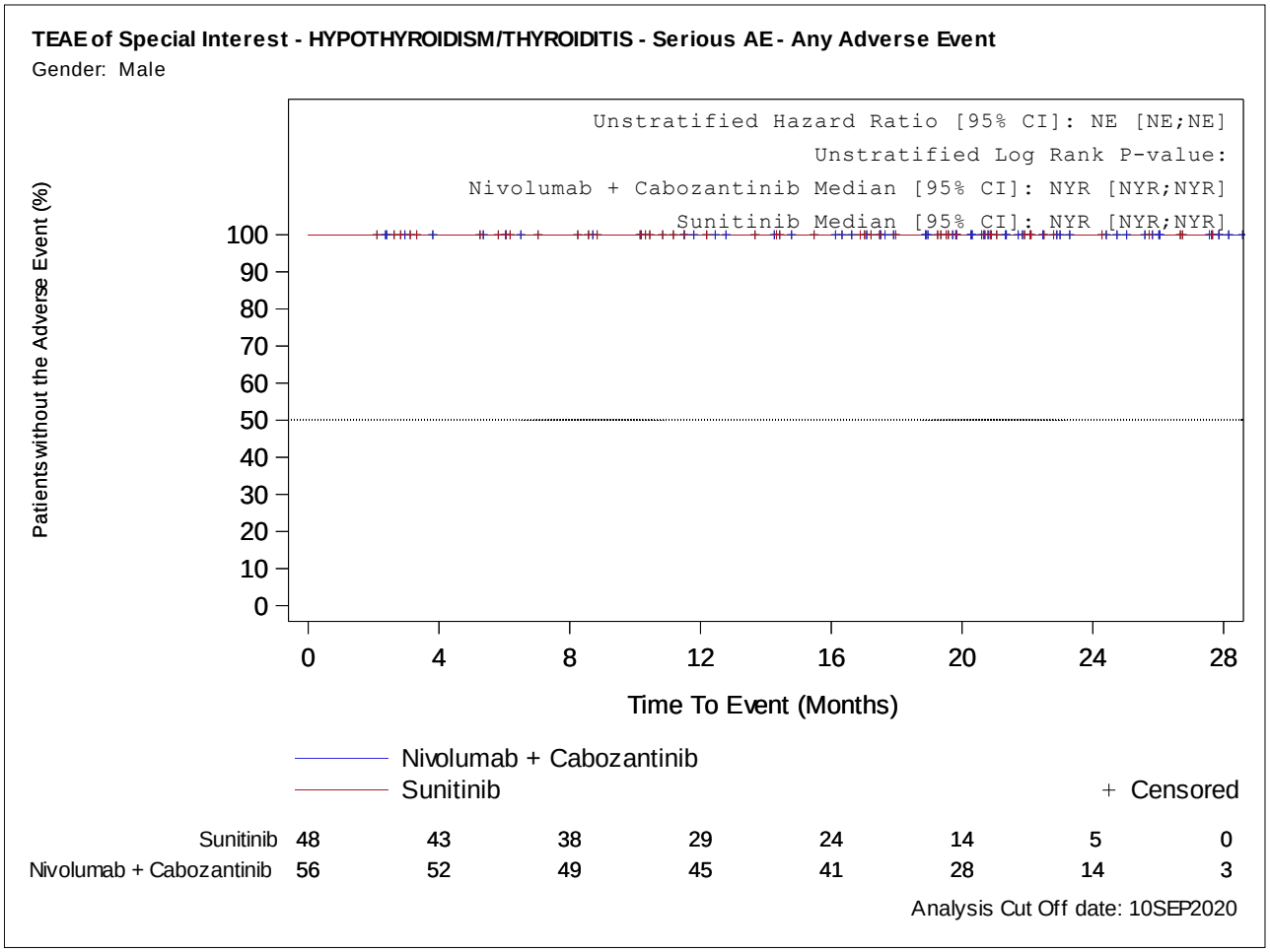

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:16:52

FIGURE 3.117.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



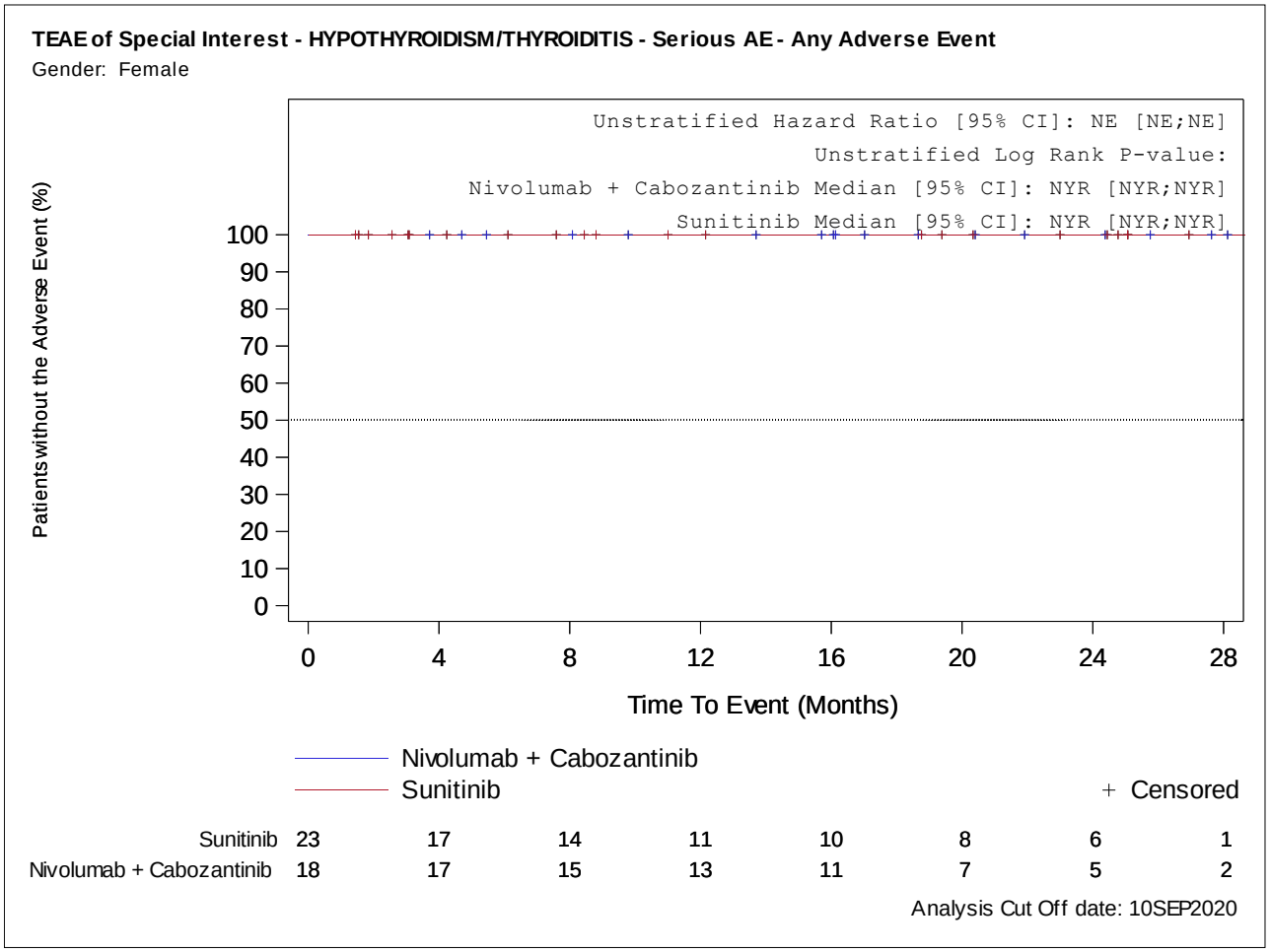

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:16:58

FIGURE 3.117.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



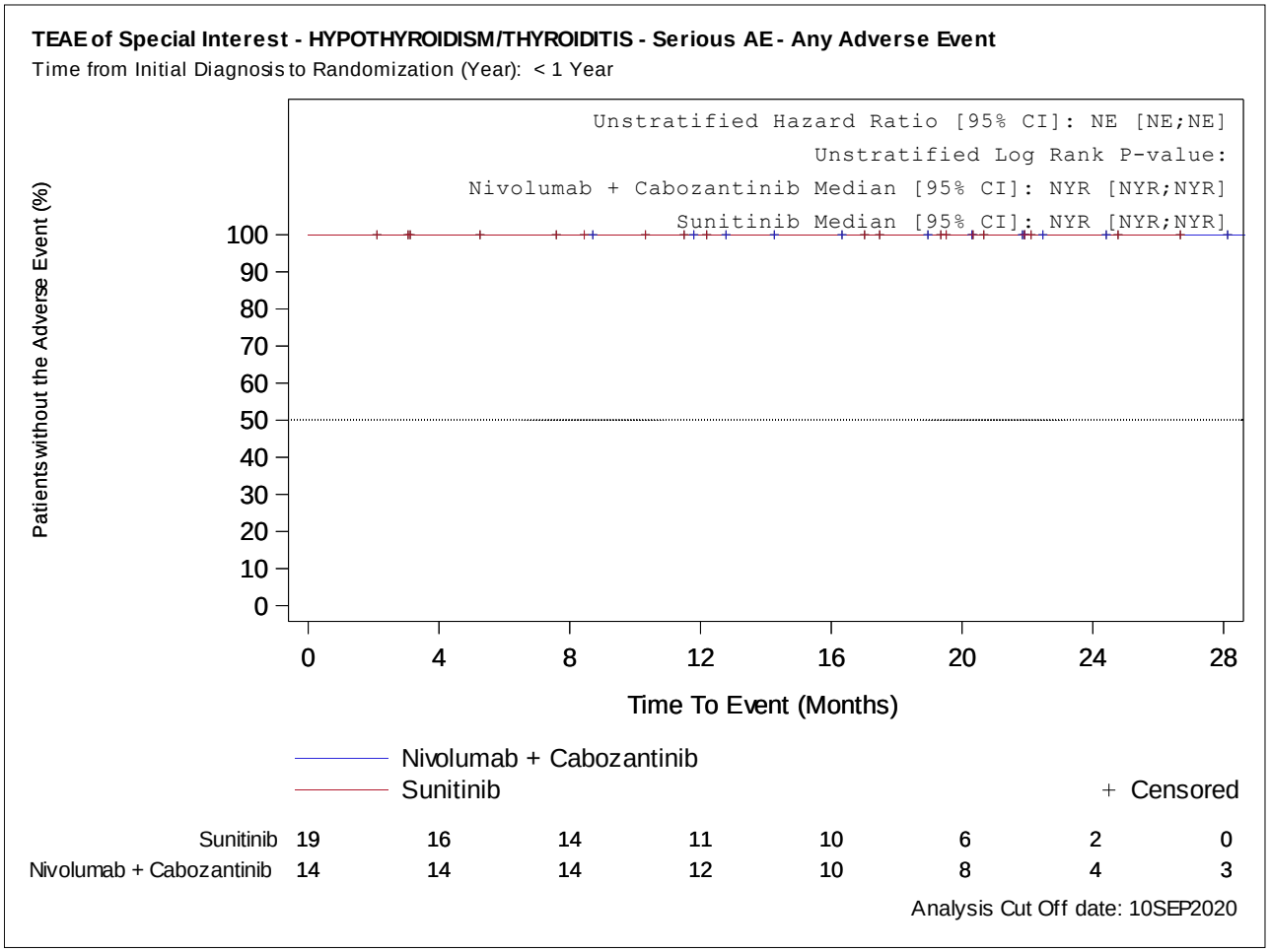

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:17:04

FIGURE 3.117.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



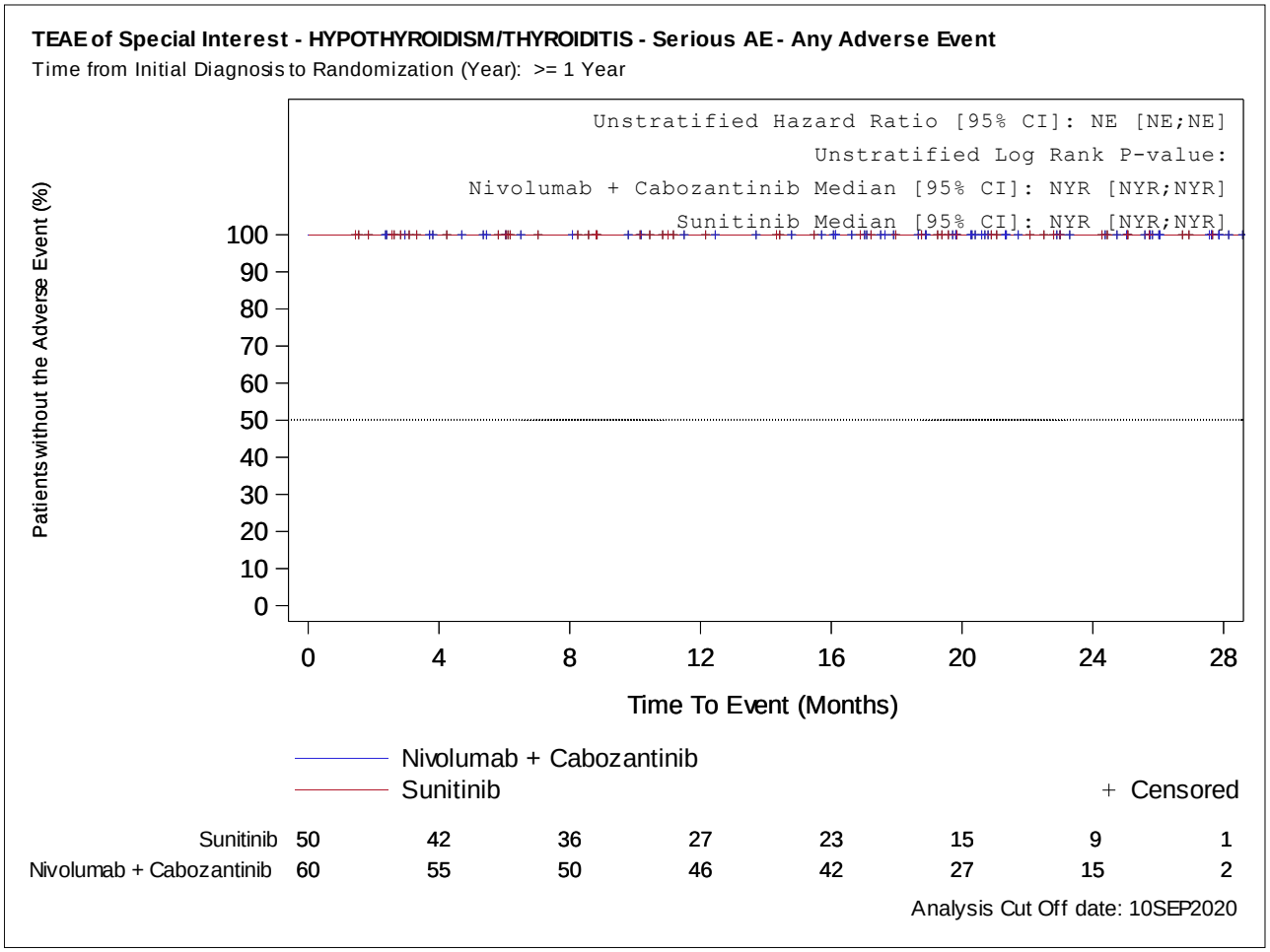

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:17:11

FIGURE 3.117.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



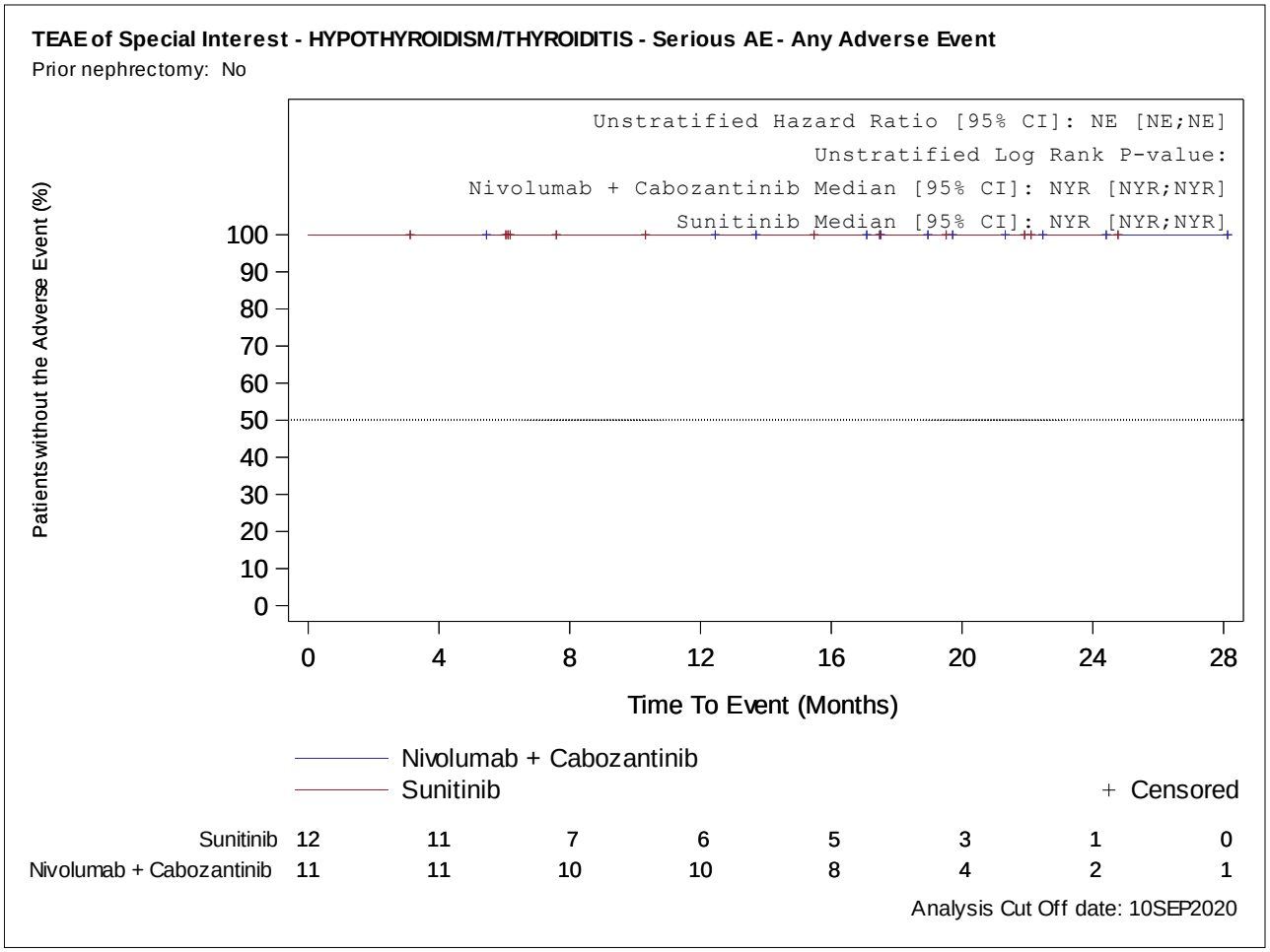

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:17:29

FIGURE 3.117.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



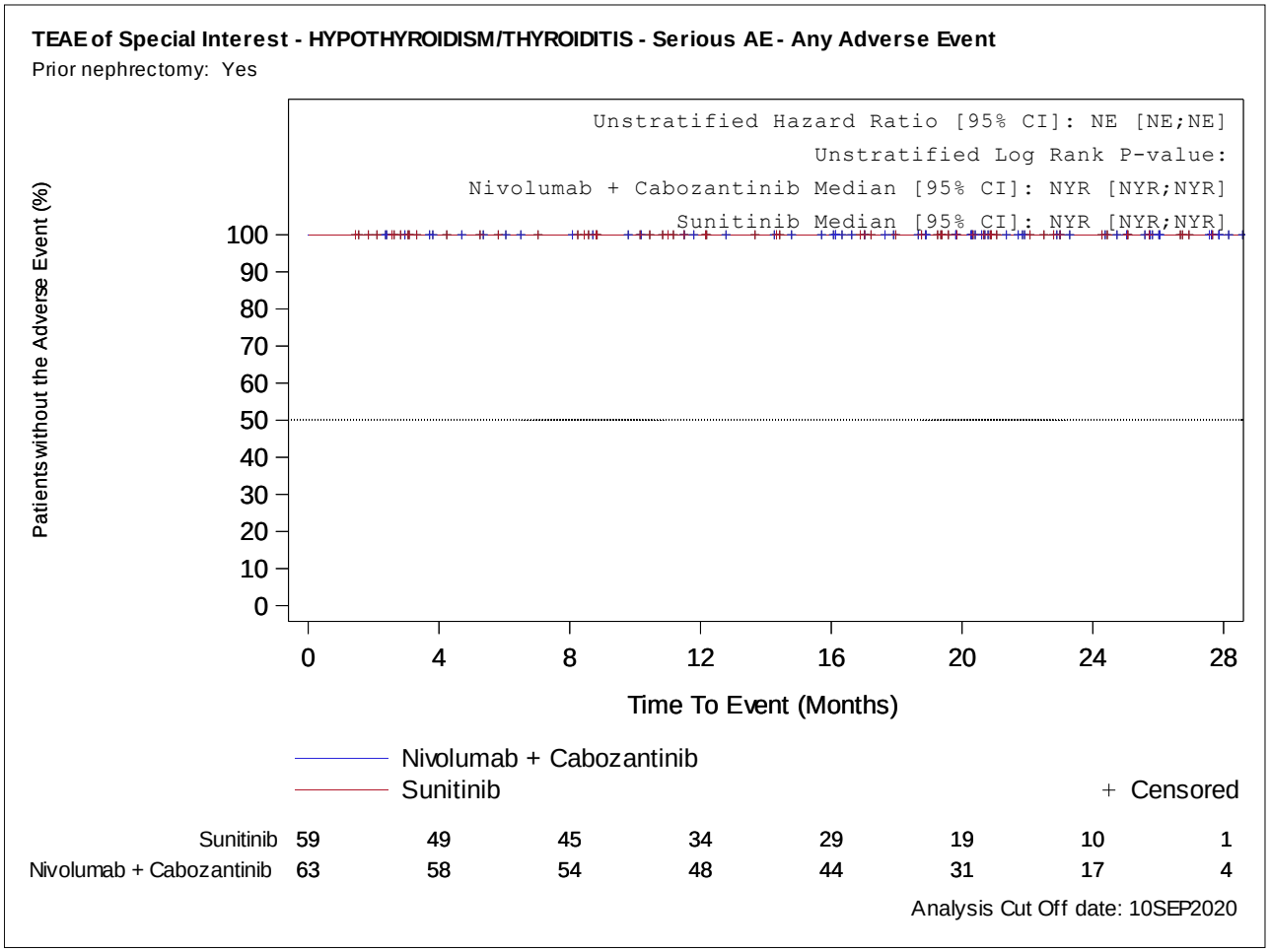

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:17:36

FIGURE 3.117.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:18:34

FIGURE 3.117.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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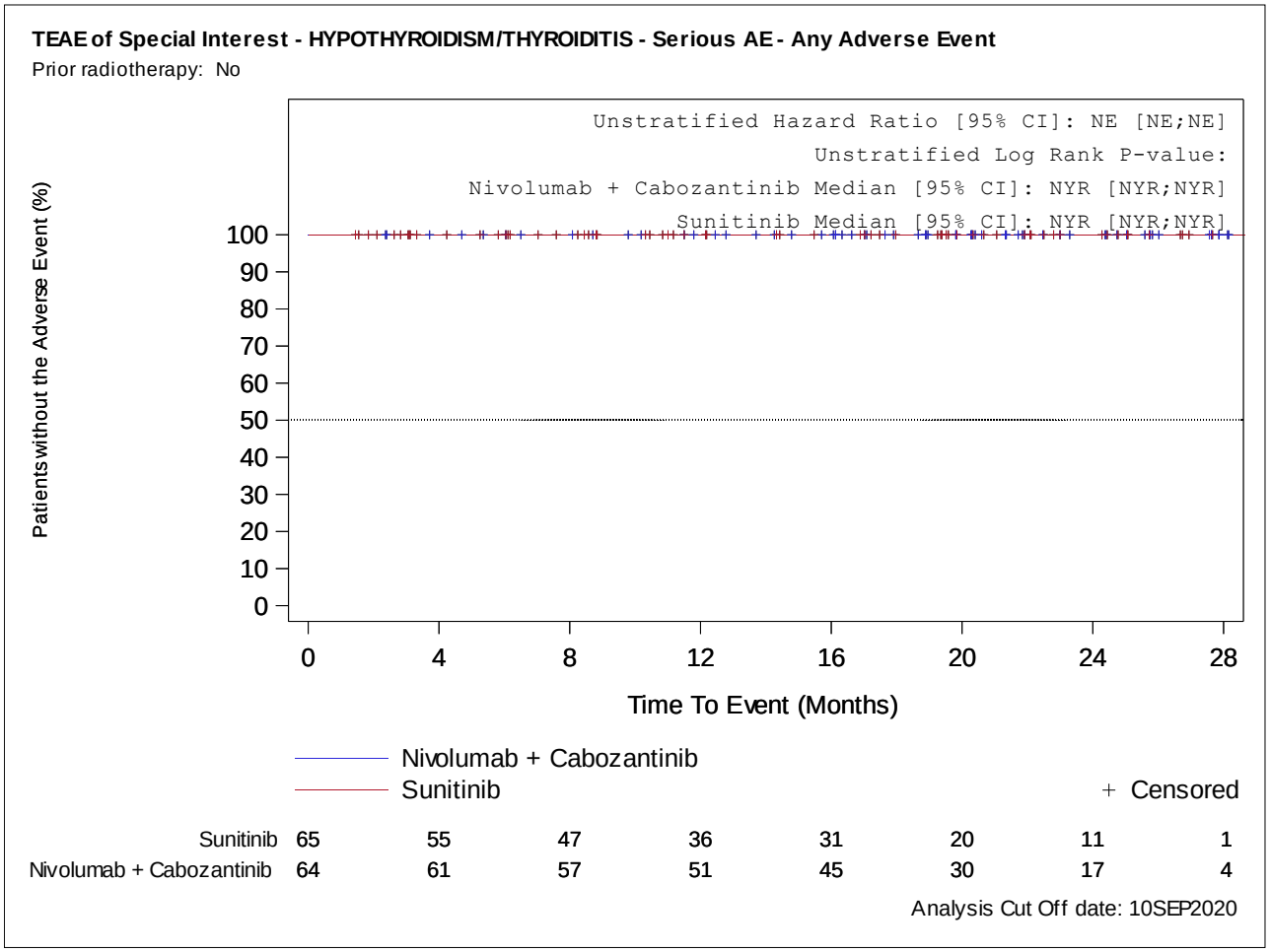
FIGURE 3.117.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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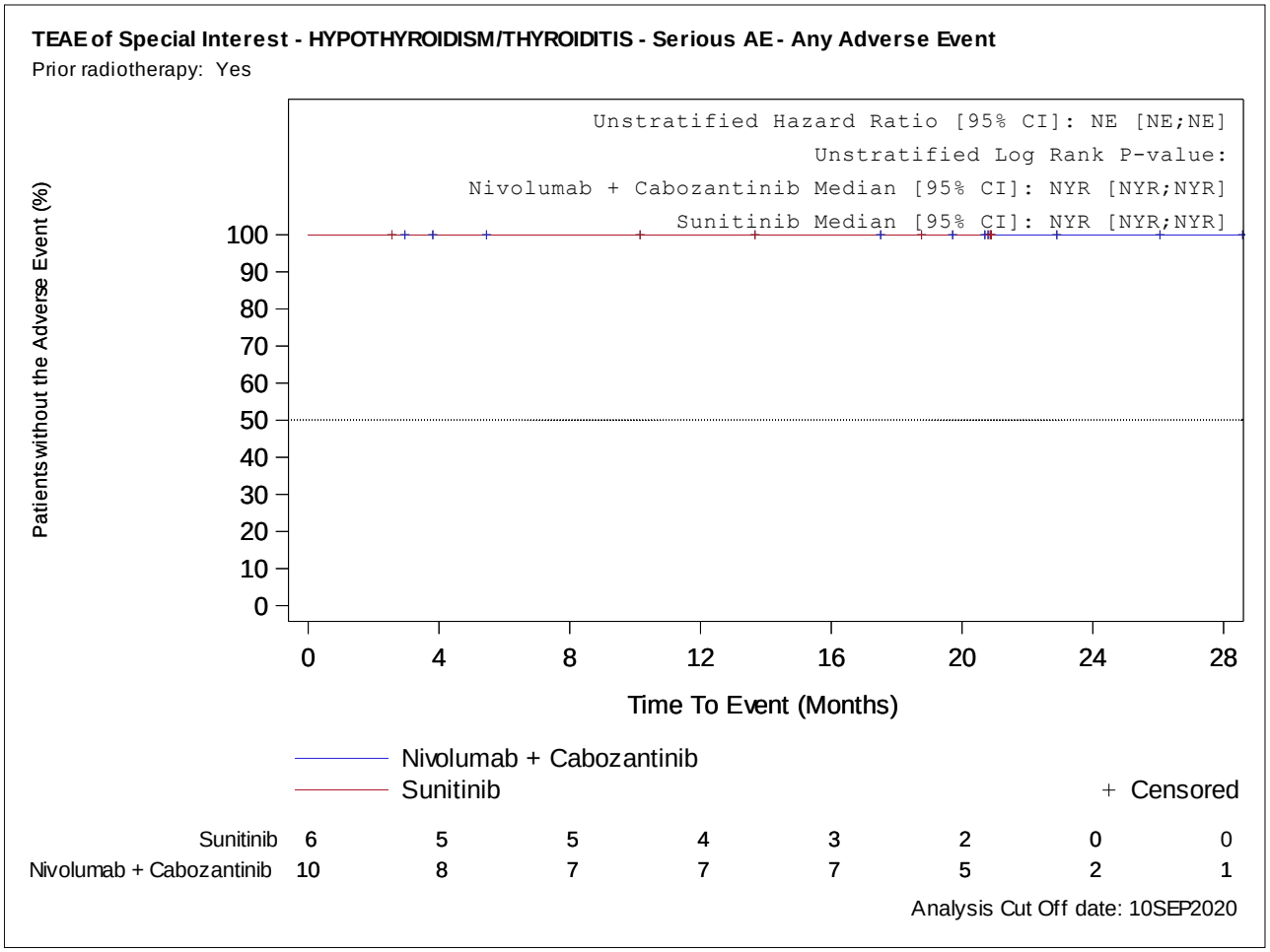
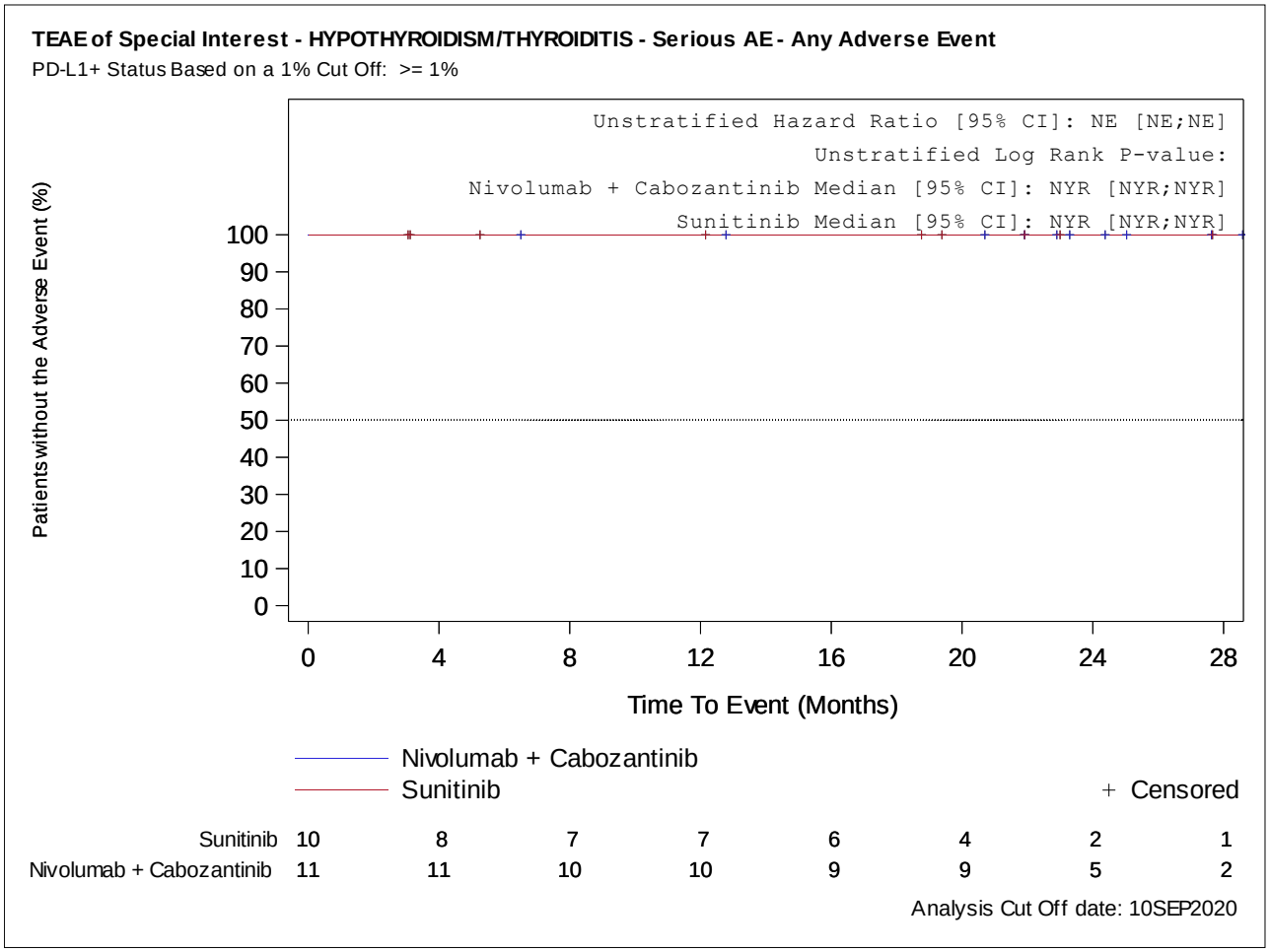
FIGURE 3.117.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



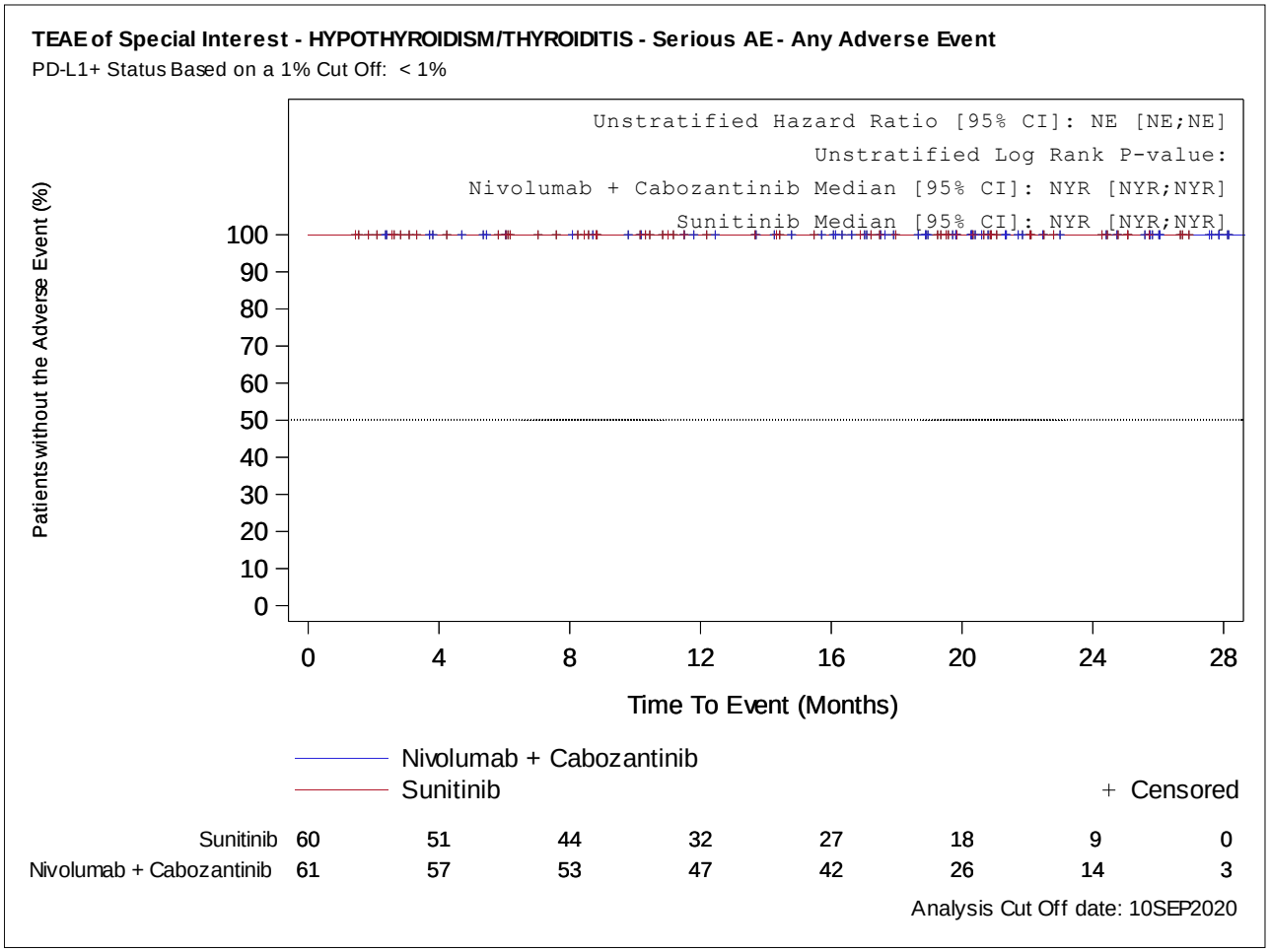

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:18:52

FIGURE 3.117.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



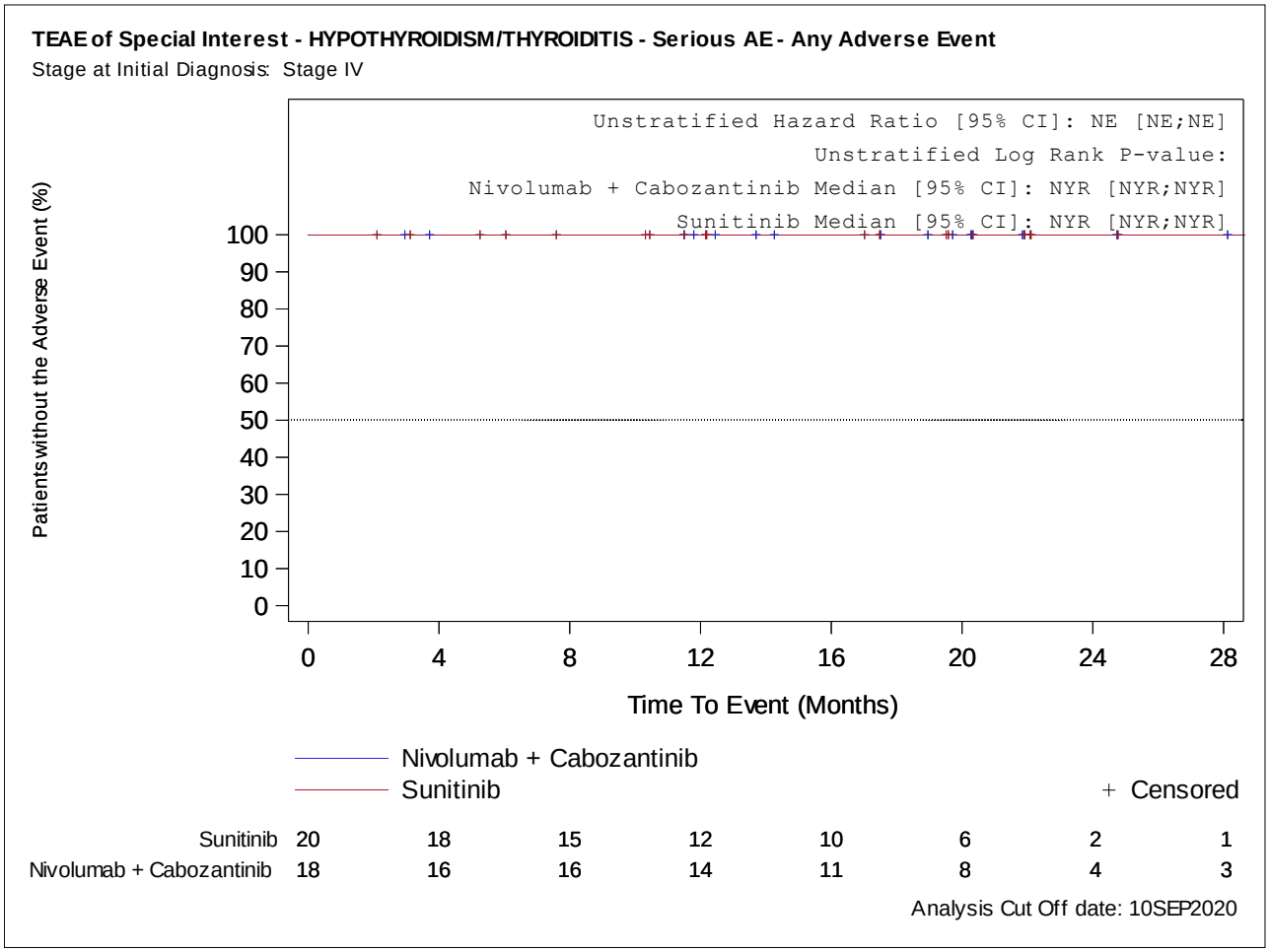

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:18:58

FIGURE 3.117.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



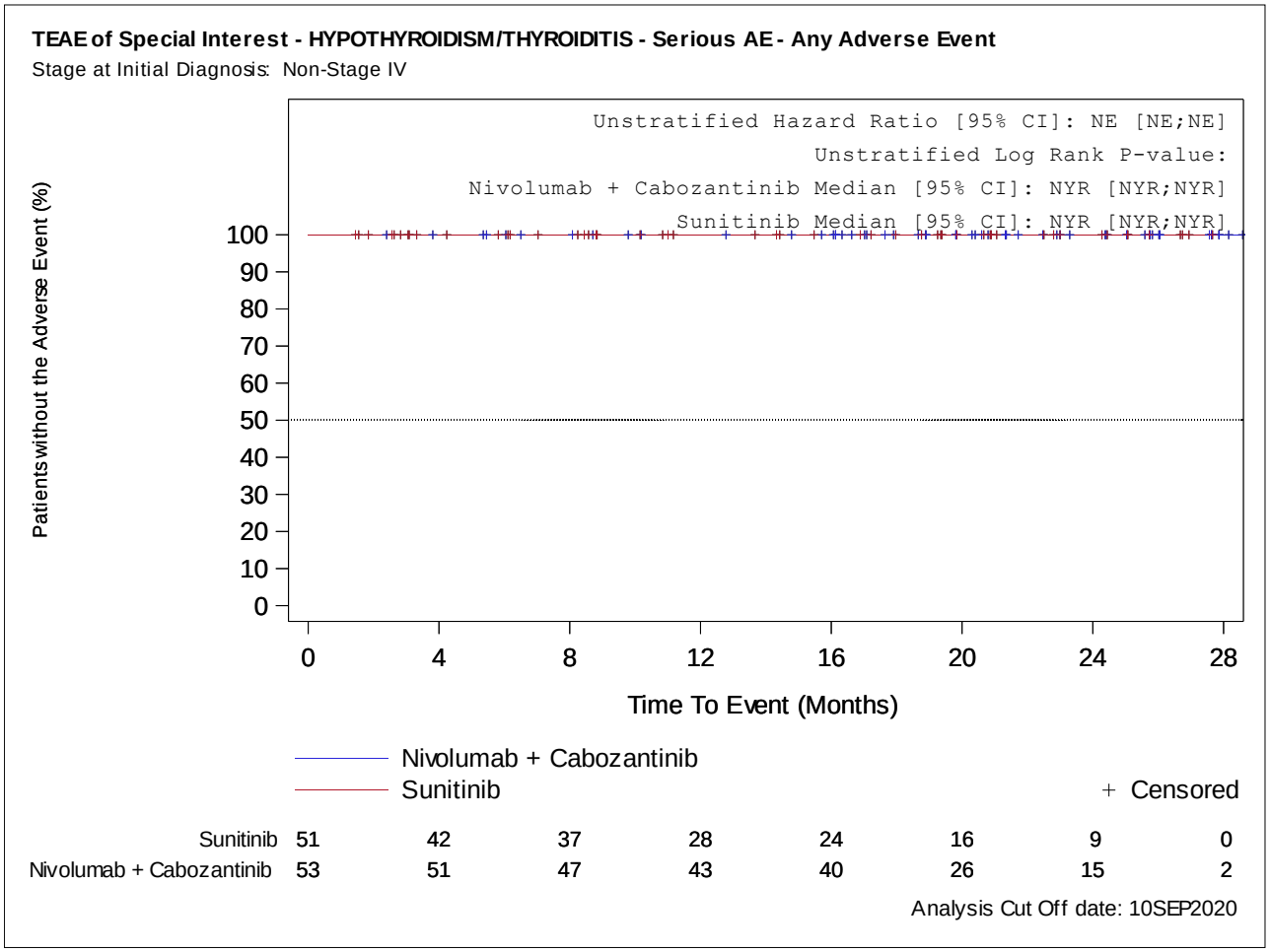

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:19:04

FIGURE 3.117.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



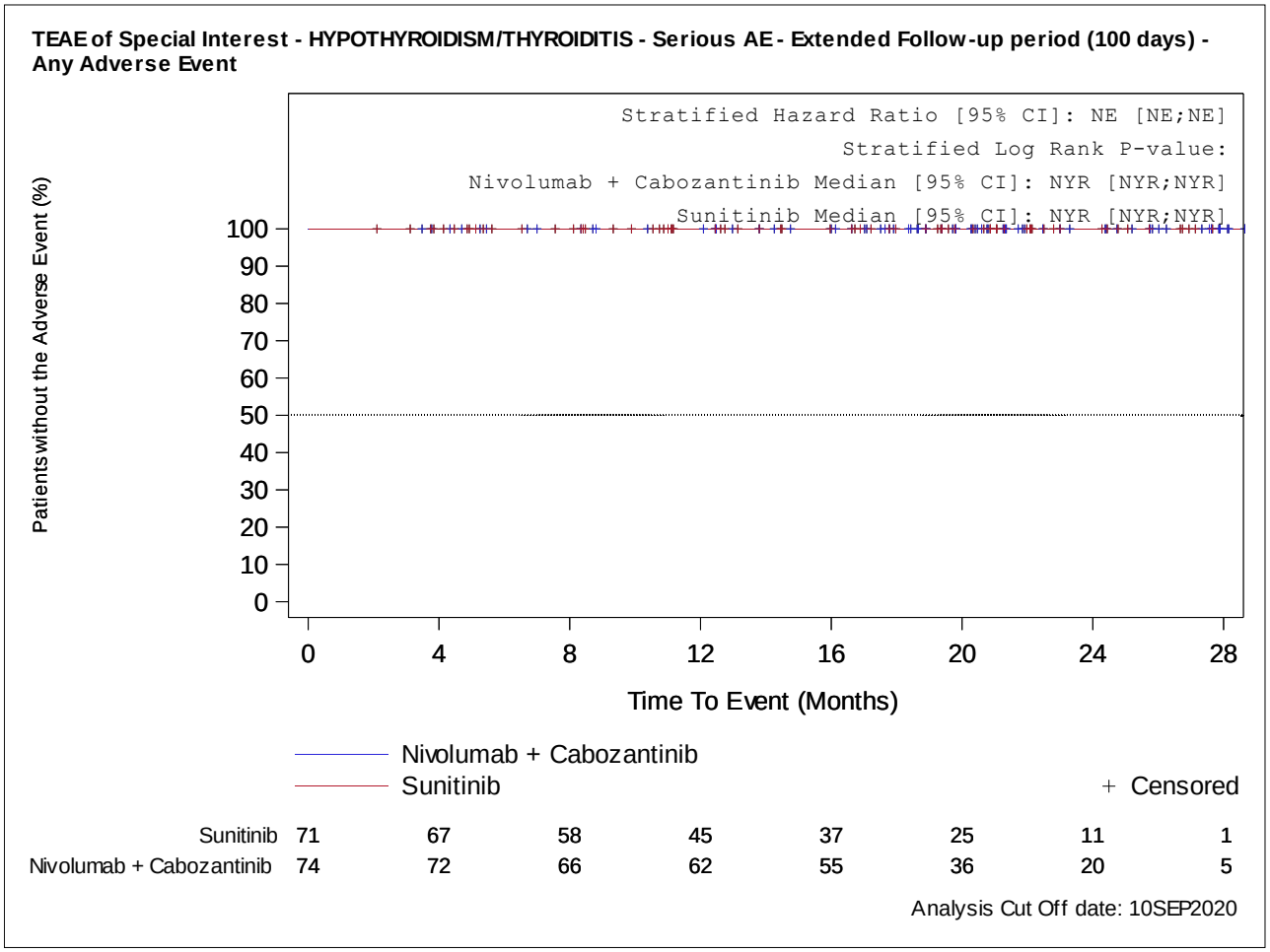

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:19:35

FIGURE 3.117.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



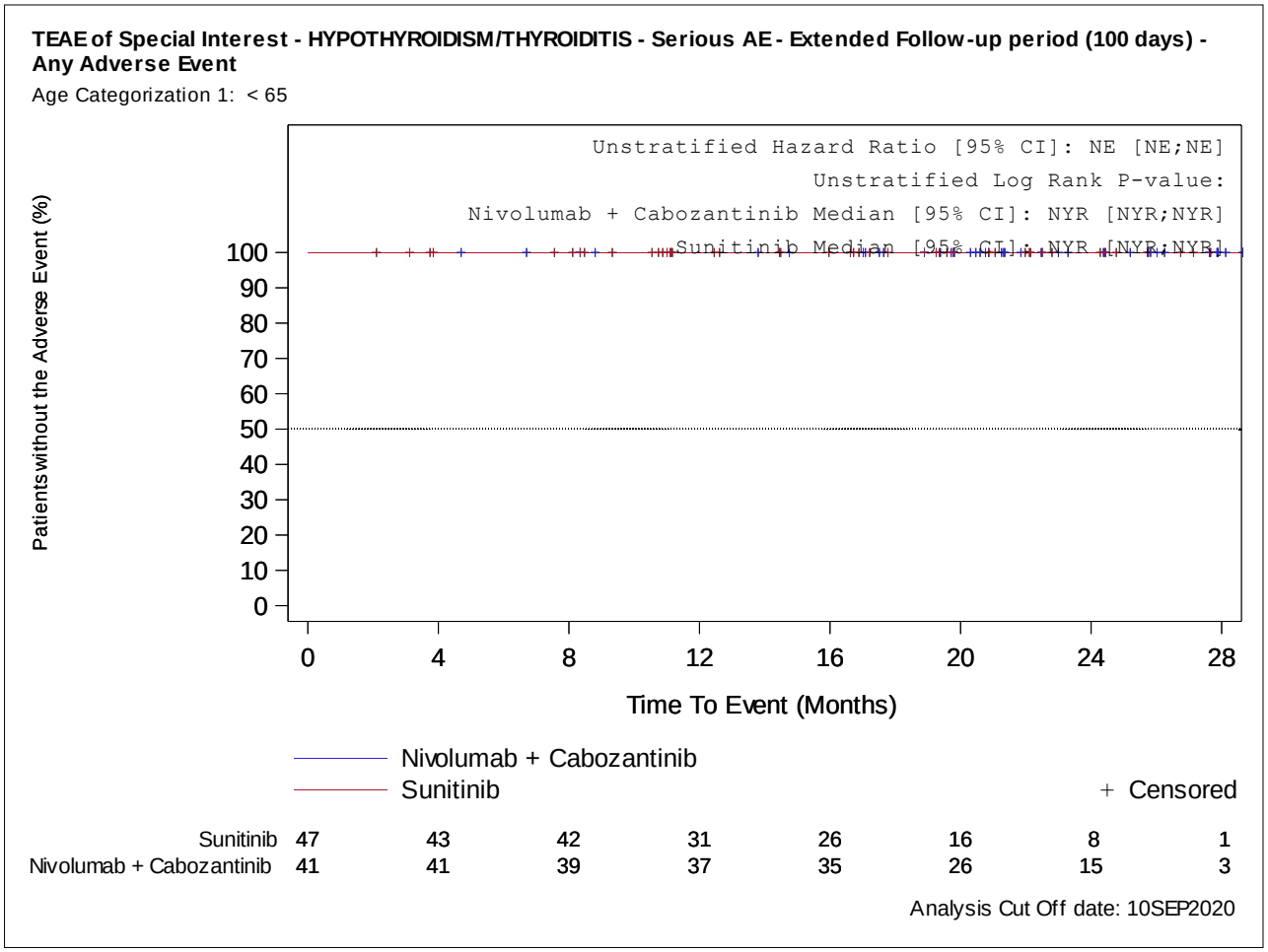

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:19:41

FIGURE 3.118.1: TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



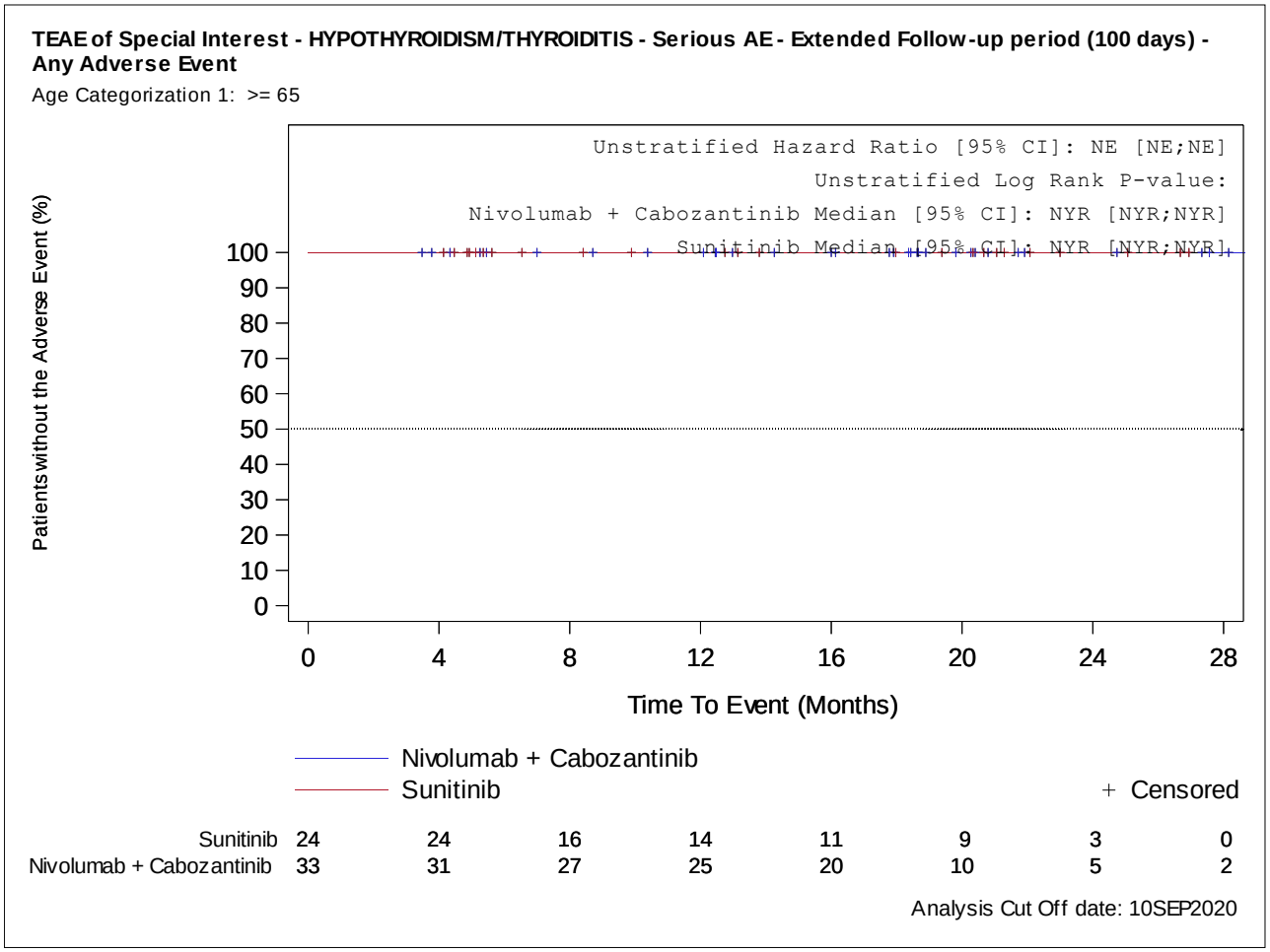

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:23:11

FIGURE 3.118.2.1: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



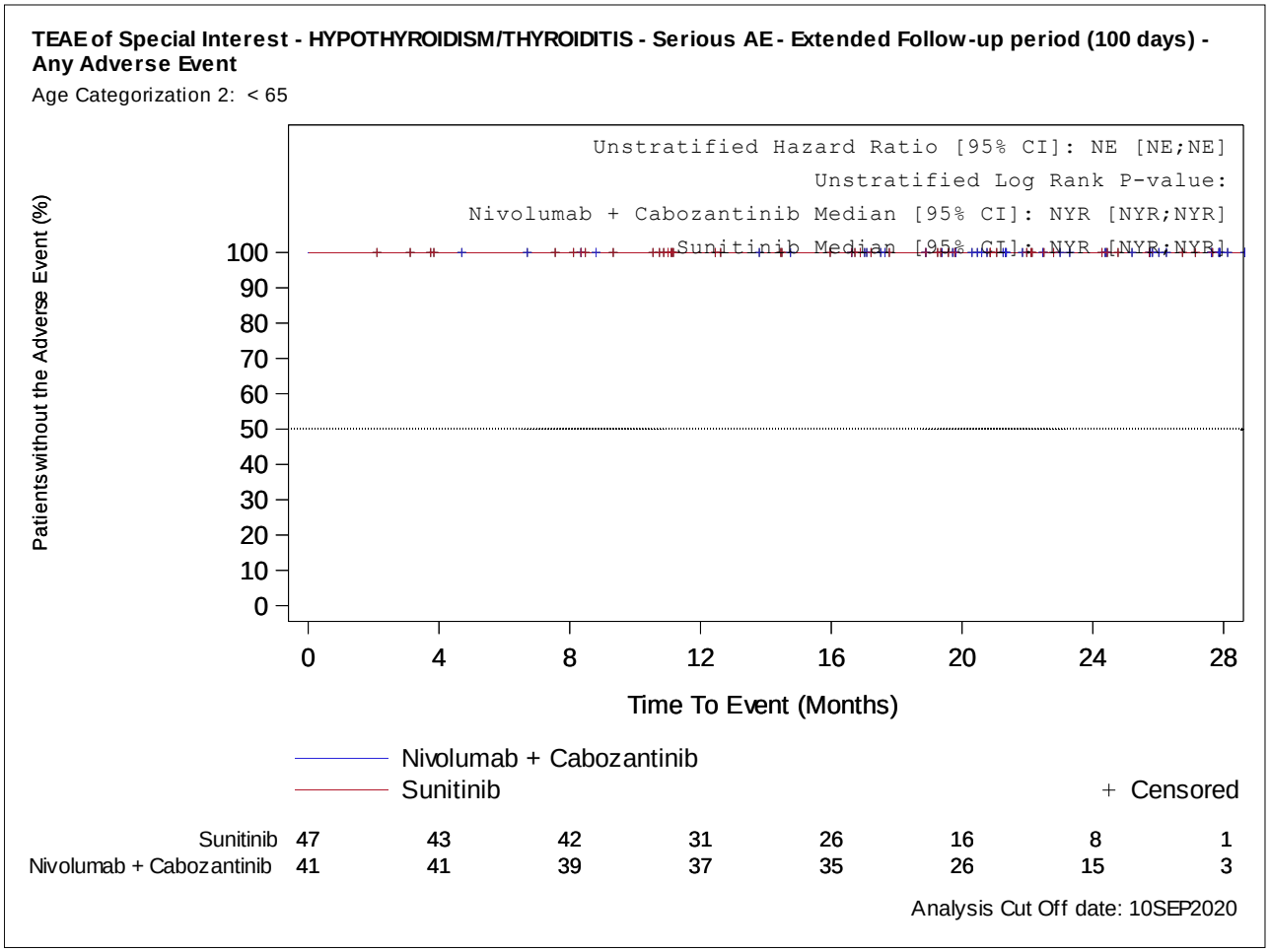

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:23:15

FIGURE 3.118.2.2: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



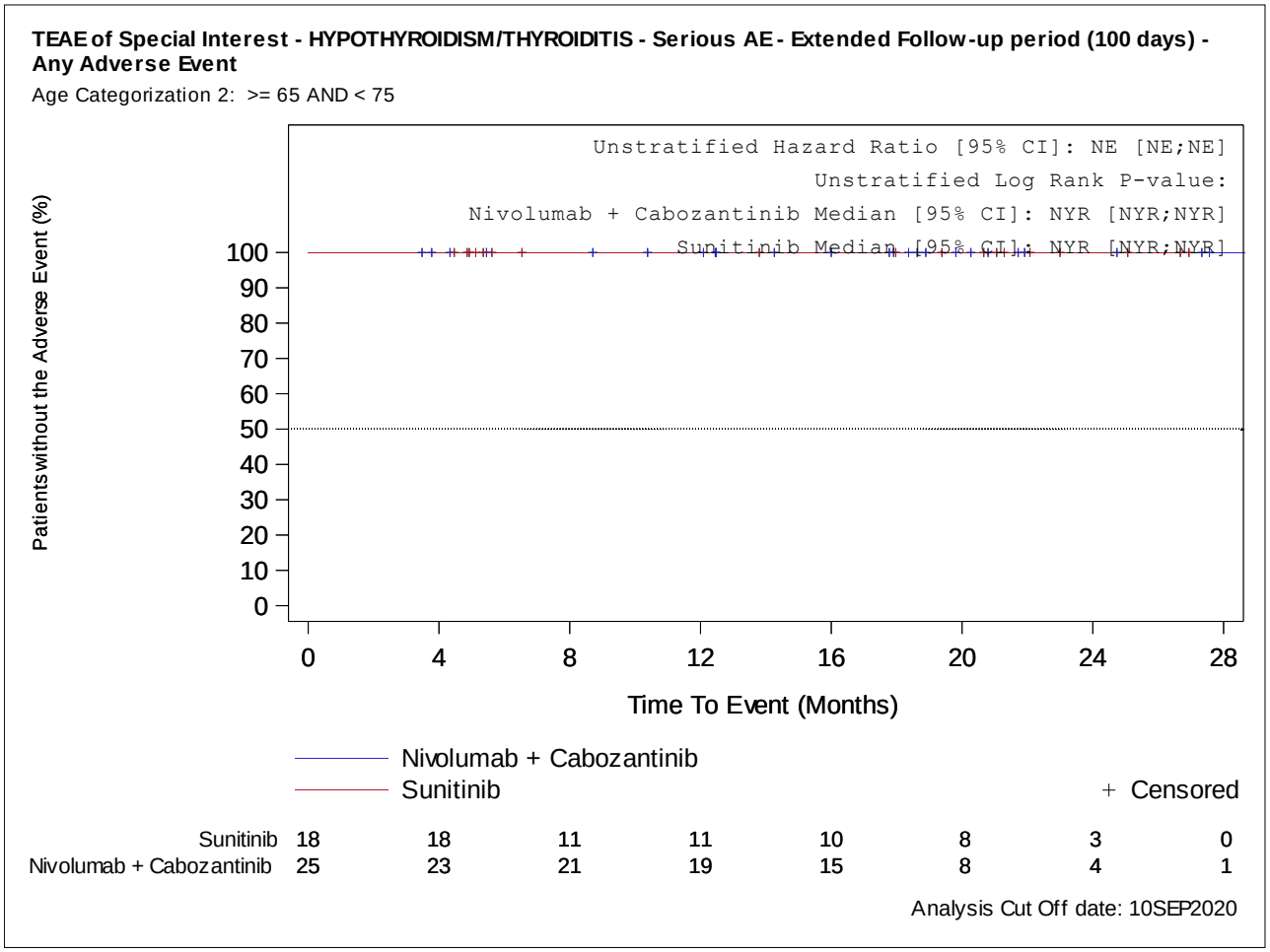

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:23:22

FIGURE 3.118.2.3: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



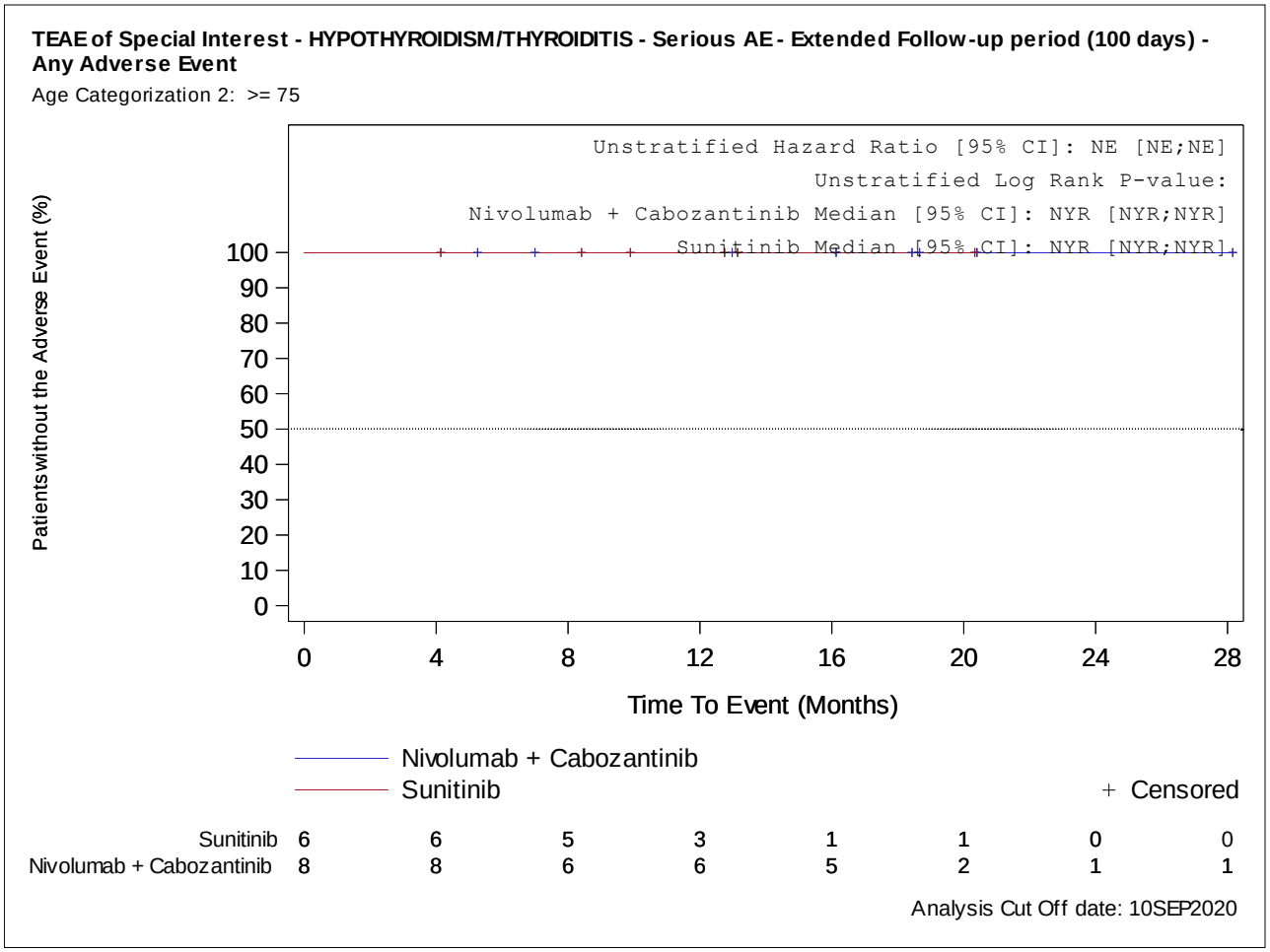

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:23:28

FIGURE 3.118.2.4: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



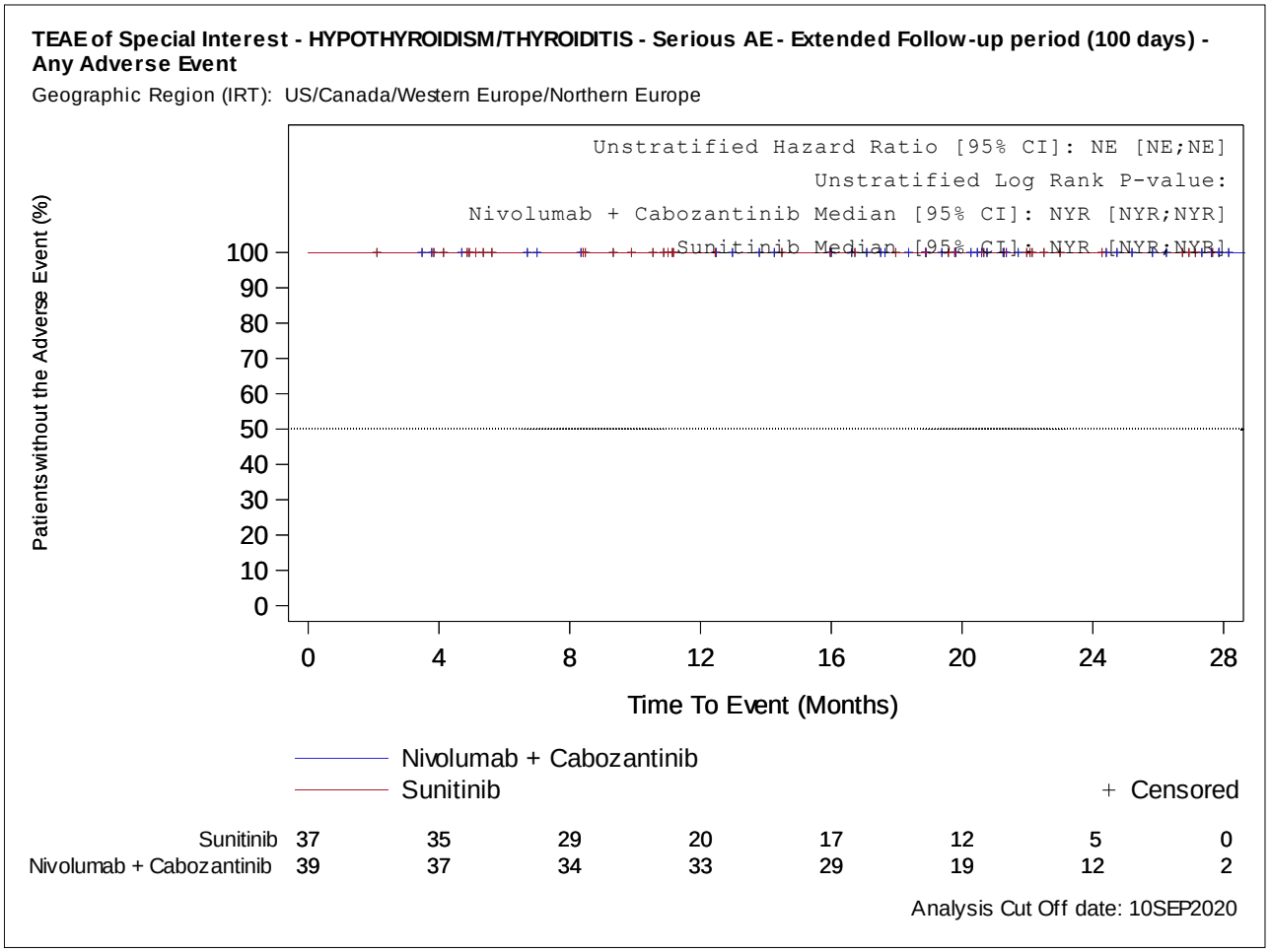

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:23:34

FIGURE 3.118.2.5: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



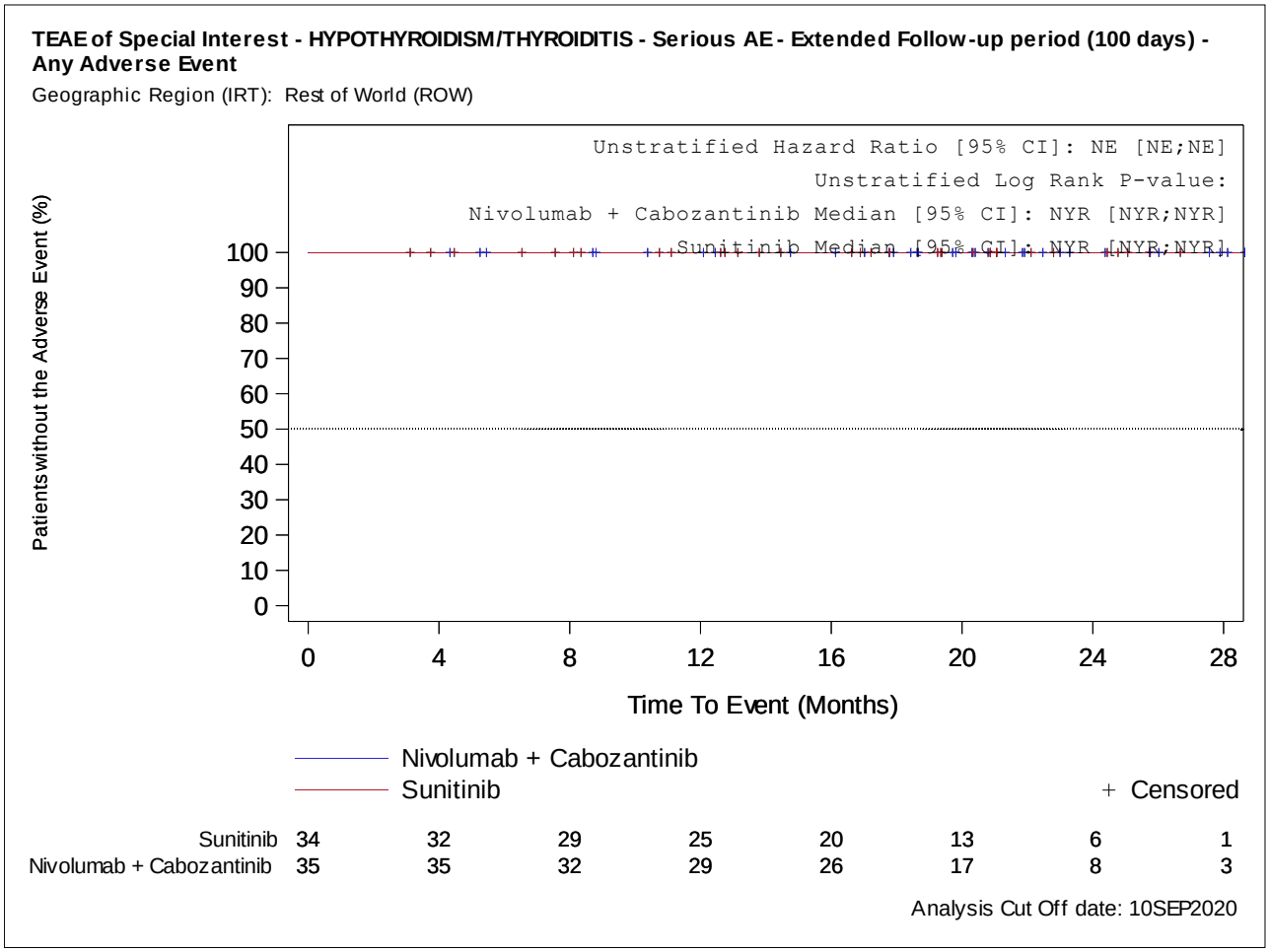

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:23:41

FIGURE 3.118.2.6: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



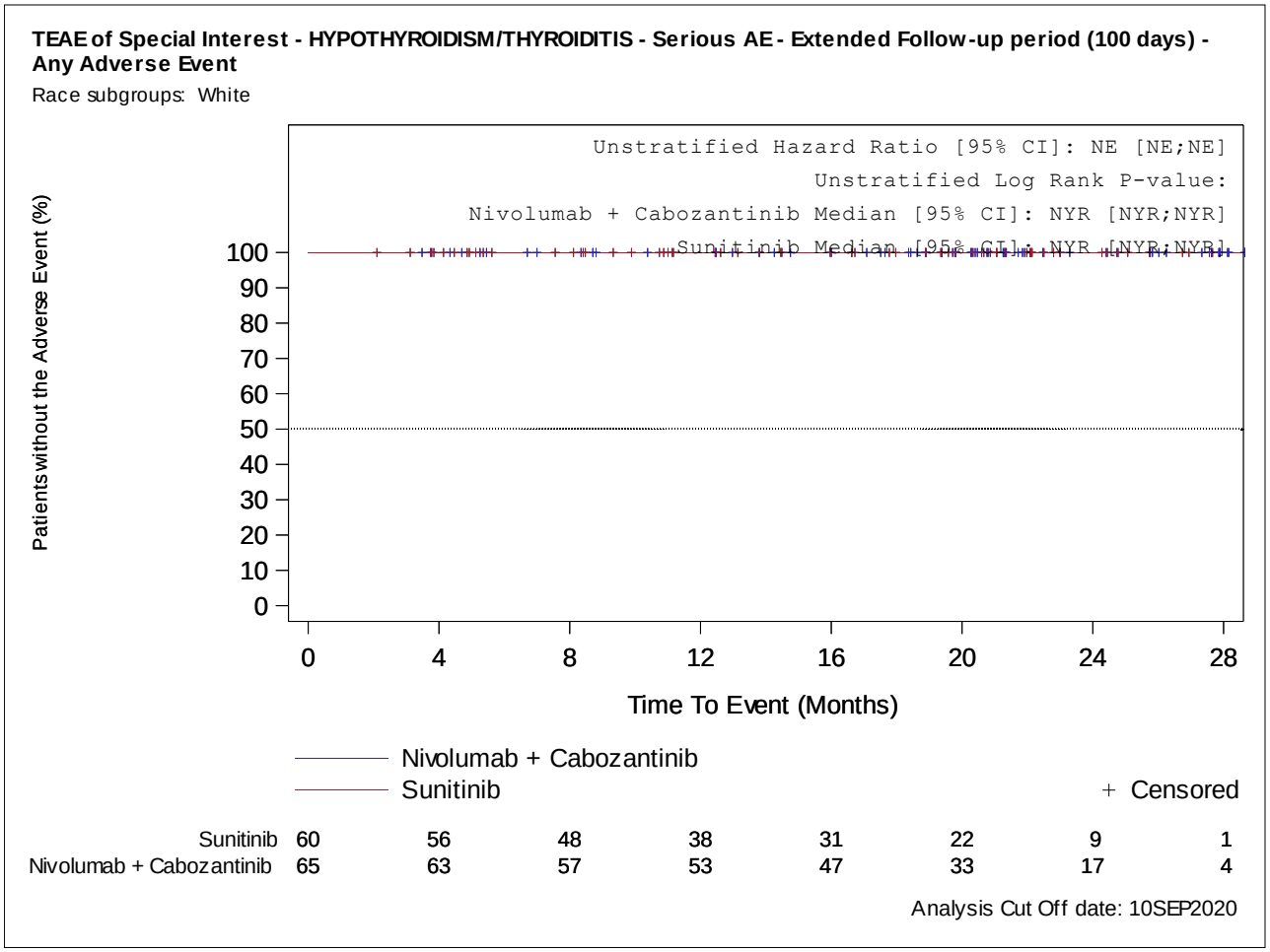

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:23:47

FIGURE 3.118.2.7: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



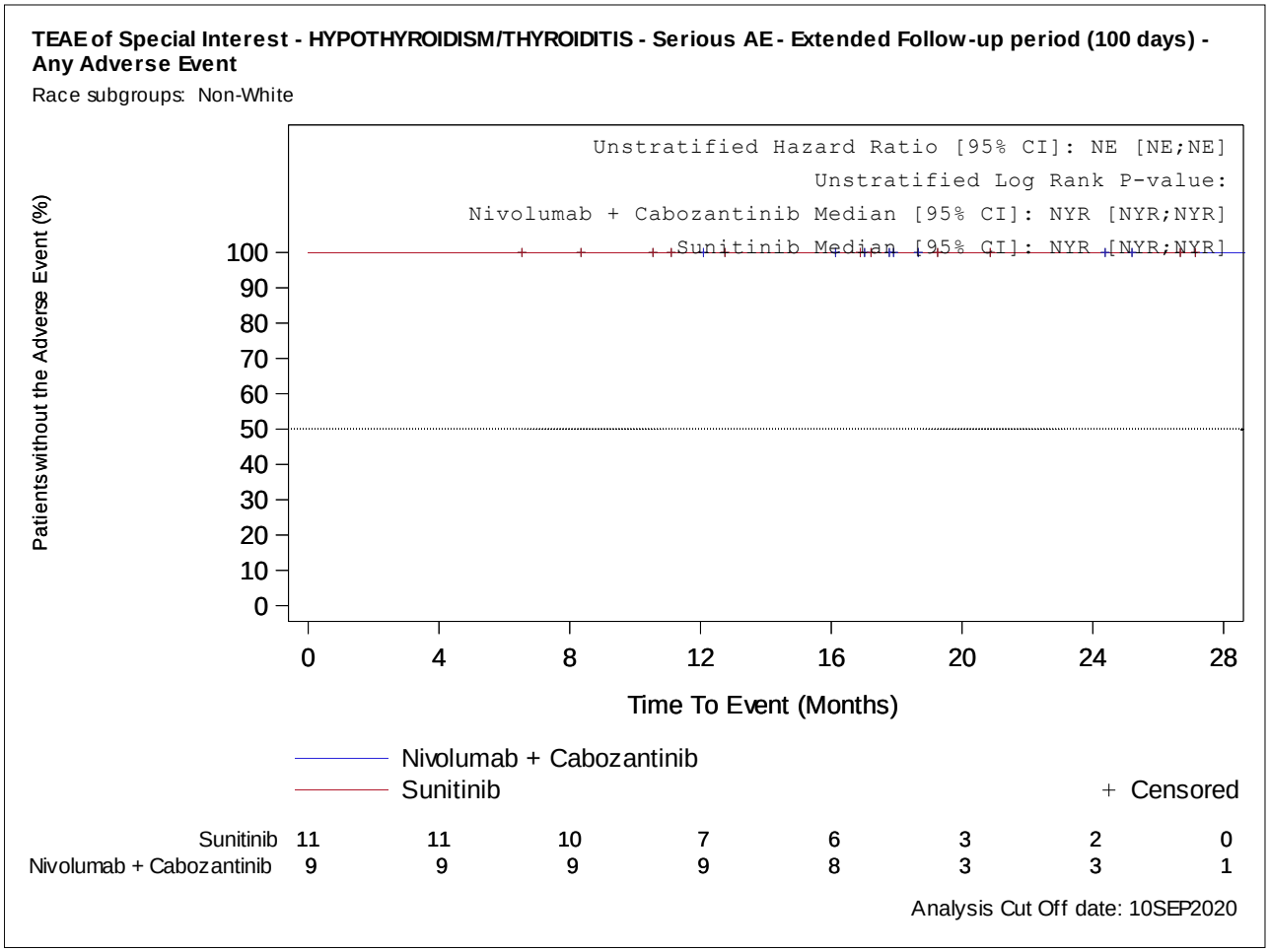

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:23:53

FIGURE 3.118.2.8: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



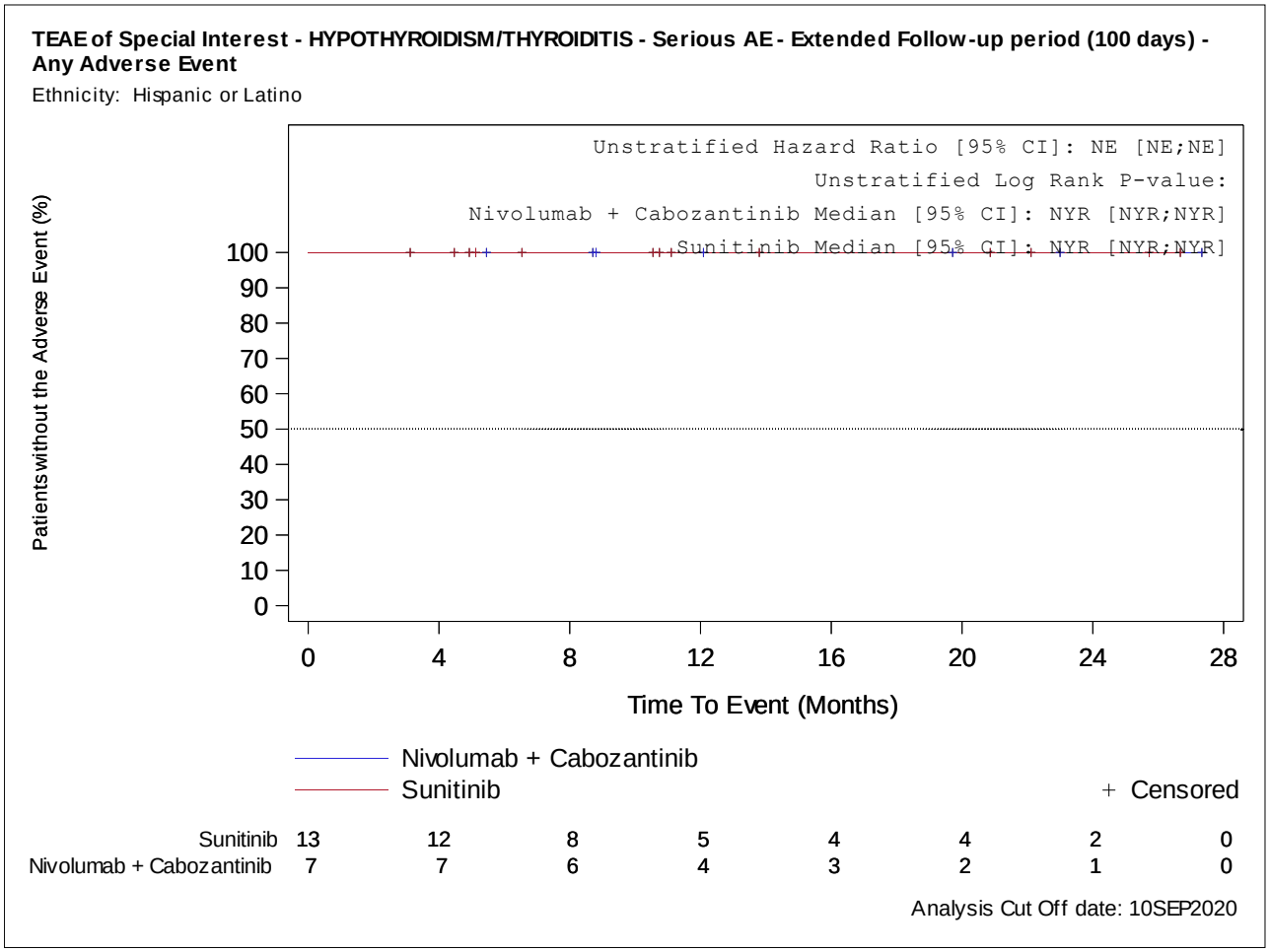

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:23:59

FIGURE 3.118.2.9: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



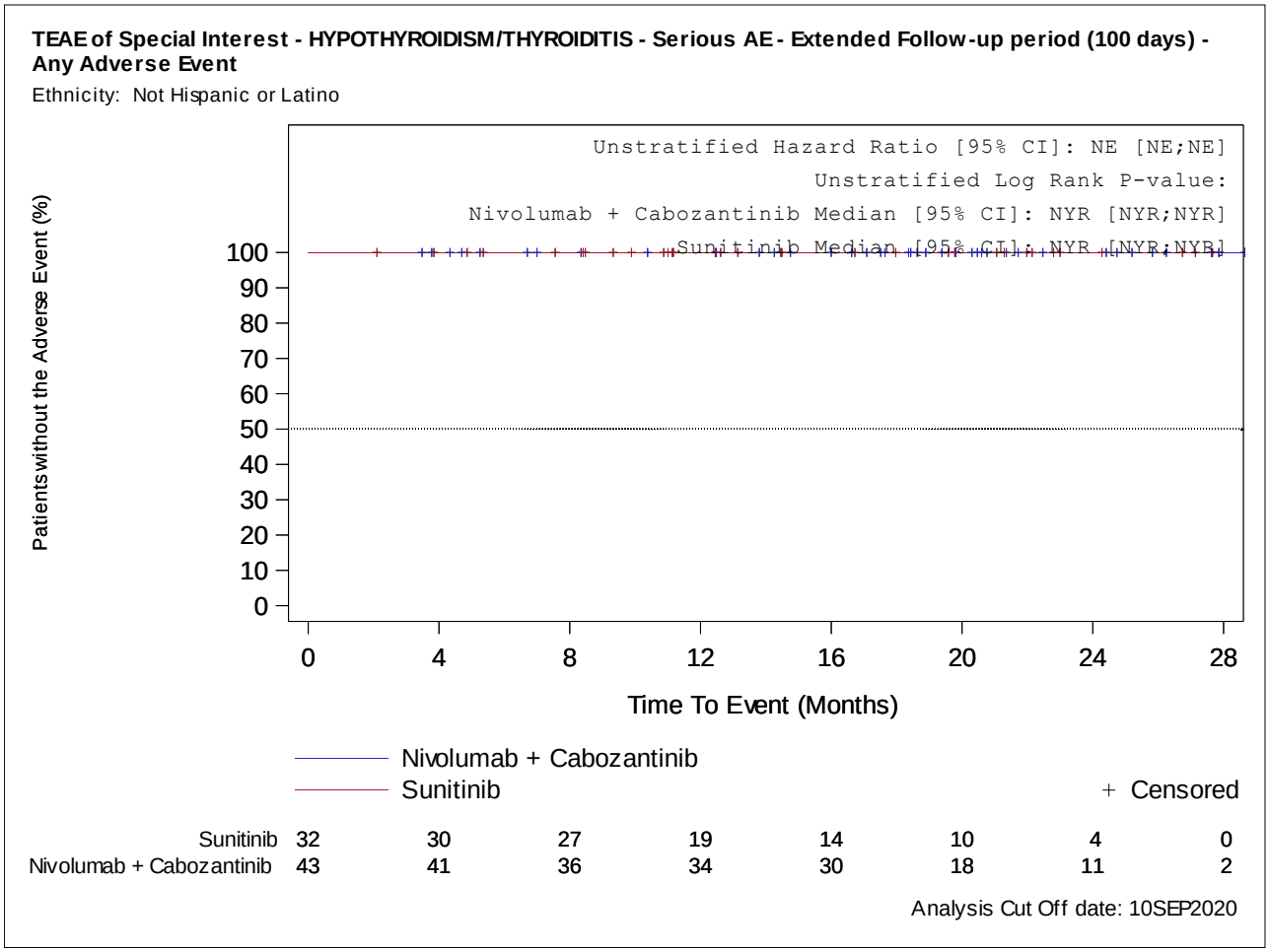

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:24:05

FIGURE 3.118.2.10: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



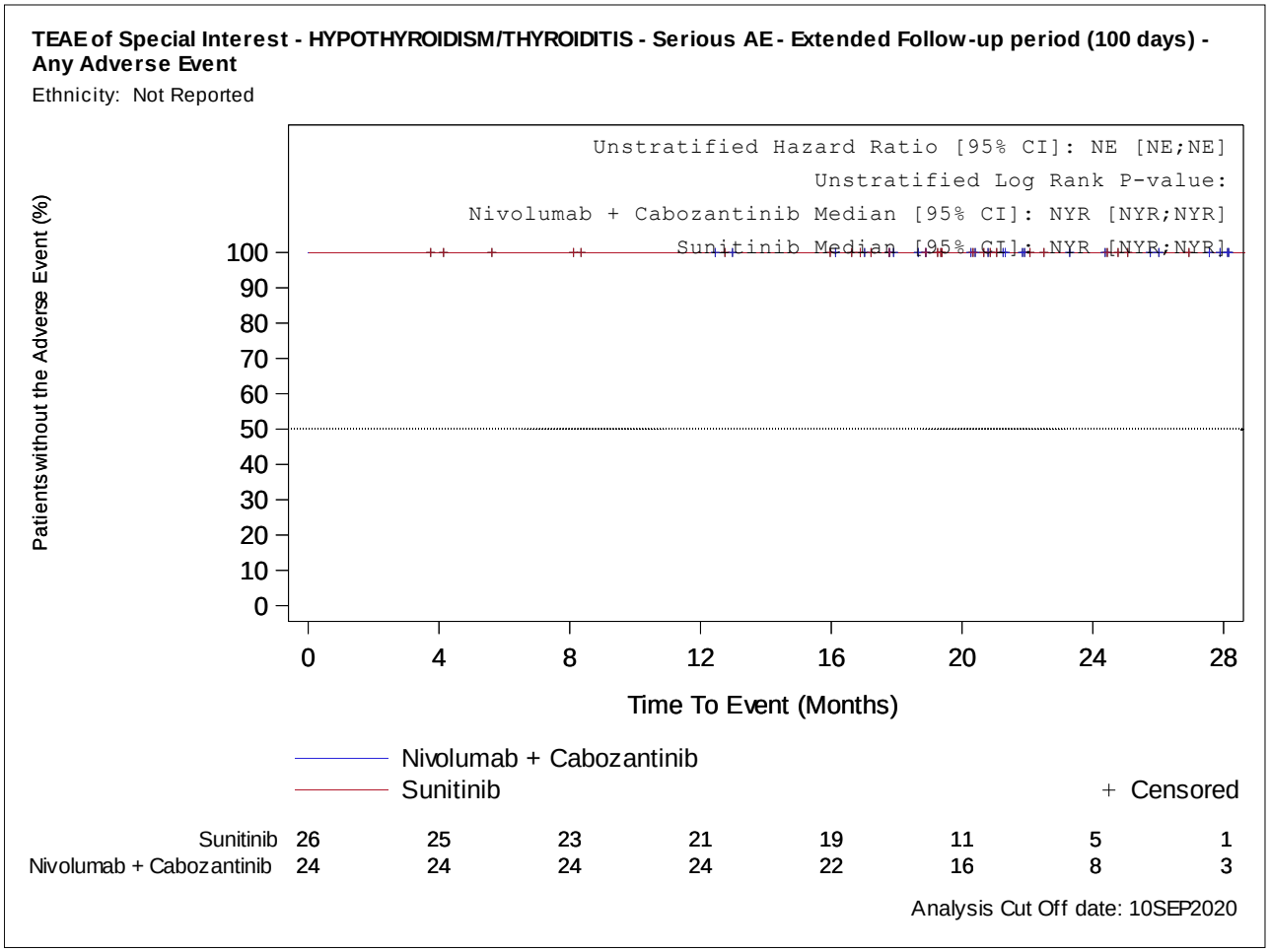

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:24:11

FIGURE 3.118.2.11: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



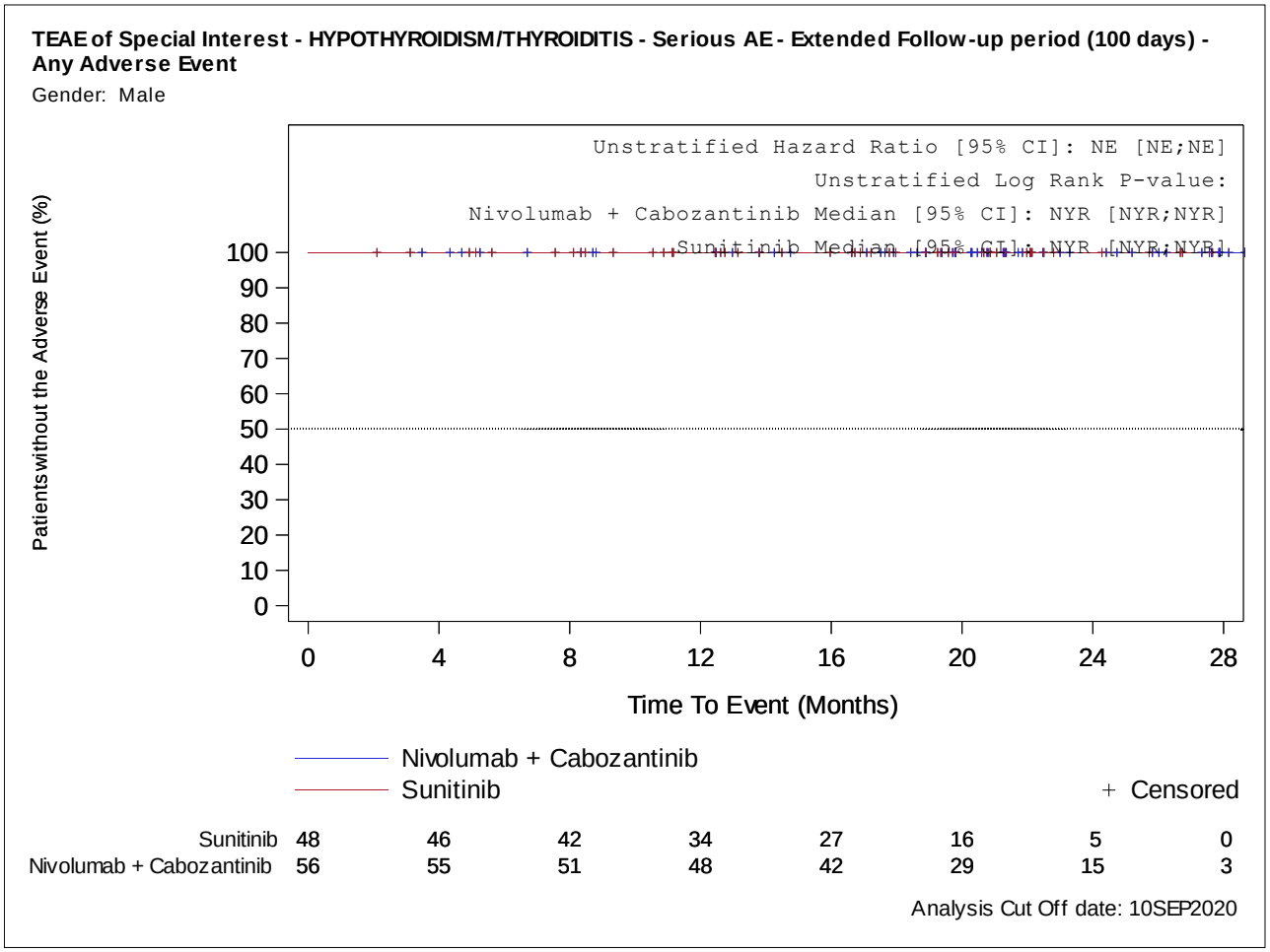

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:24:17

FIGURE 3.118.2.12: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



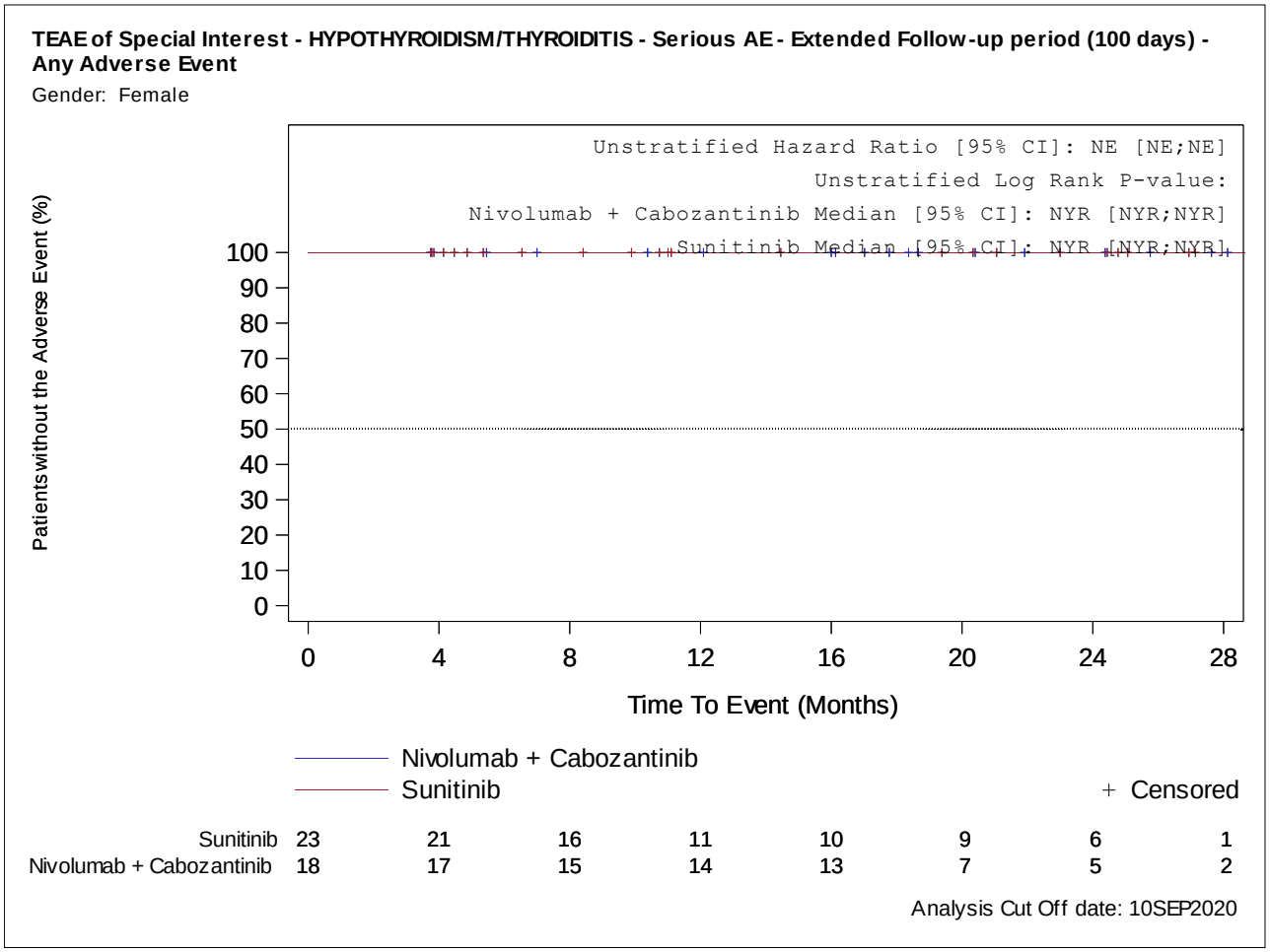

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:24:23

FIGURE 3.118.2.13: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



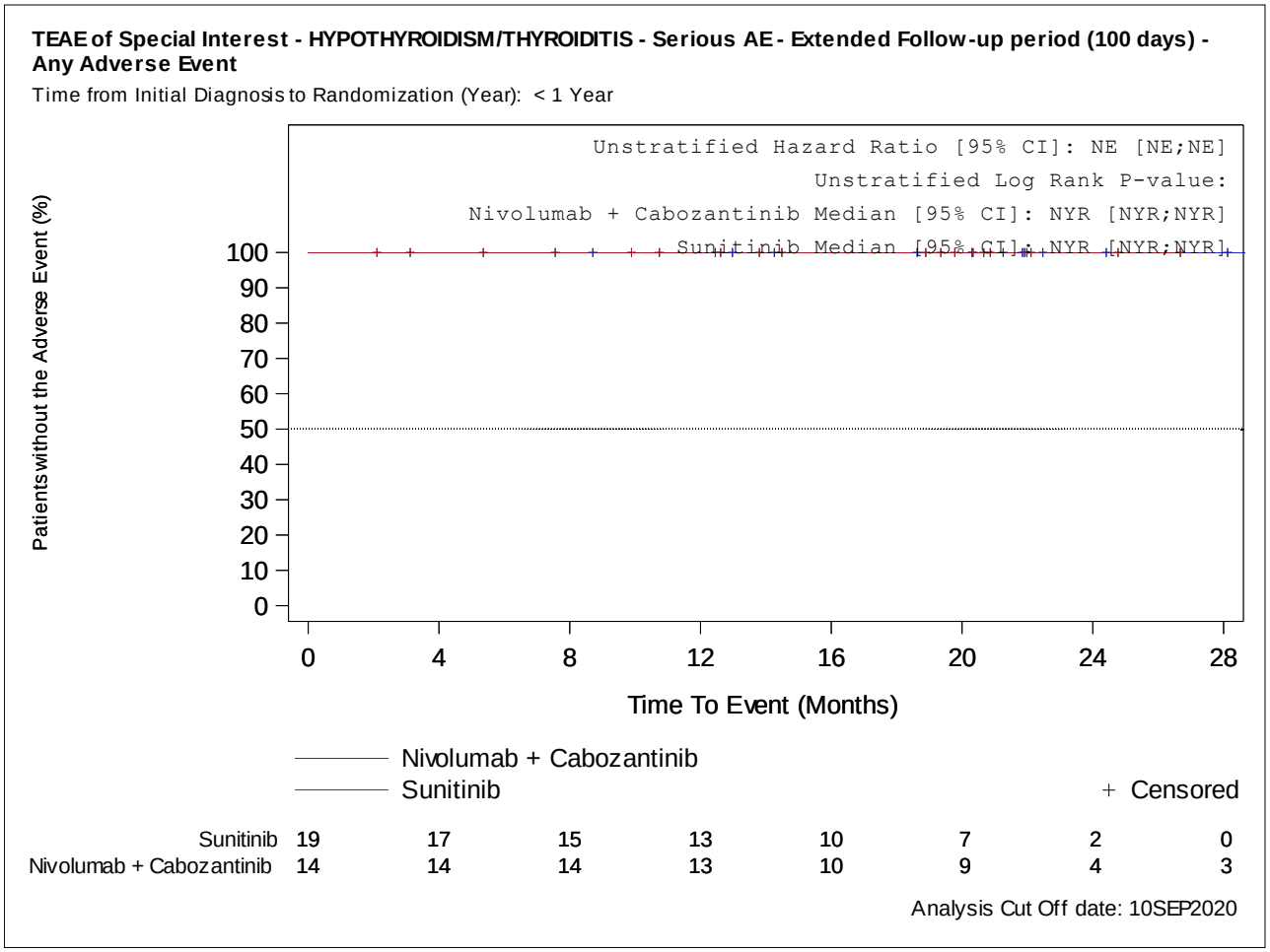

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:24:29

FIGURE 3.118.2.14: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:24:36

FIGURE 3.118.2.15: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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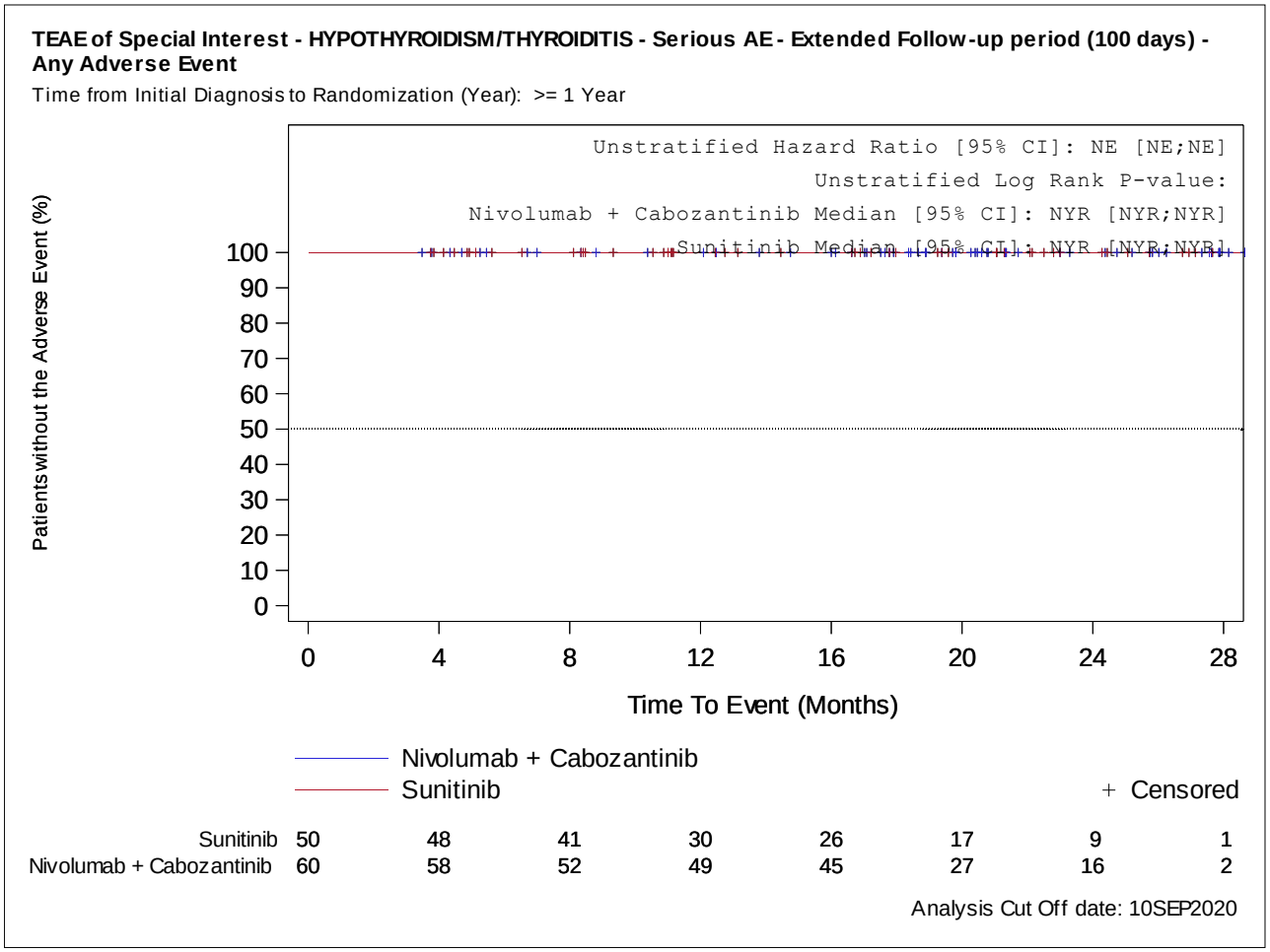
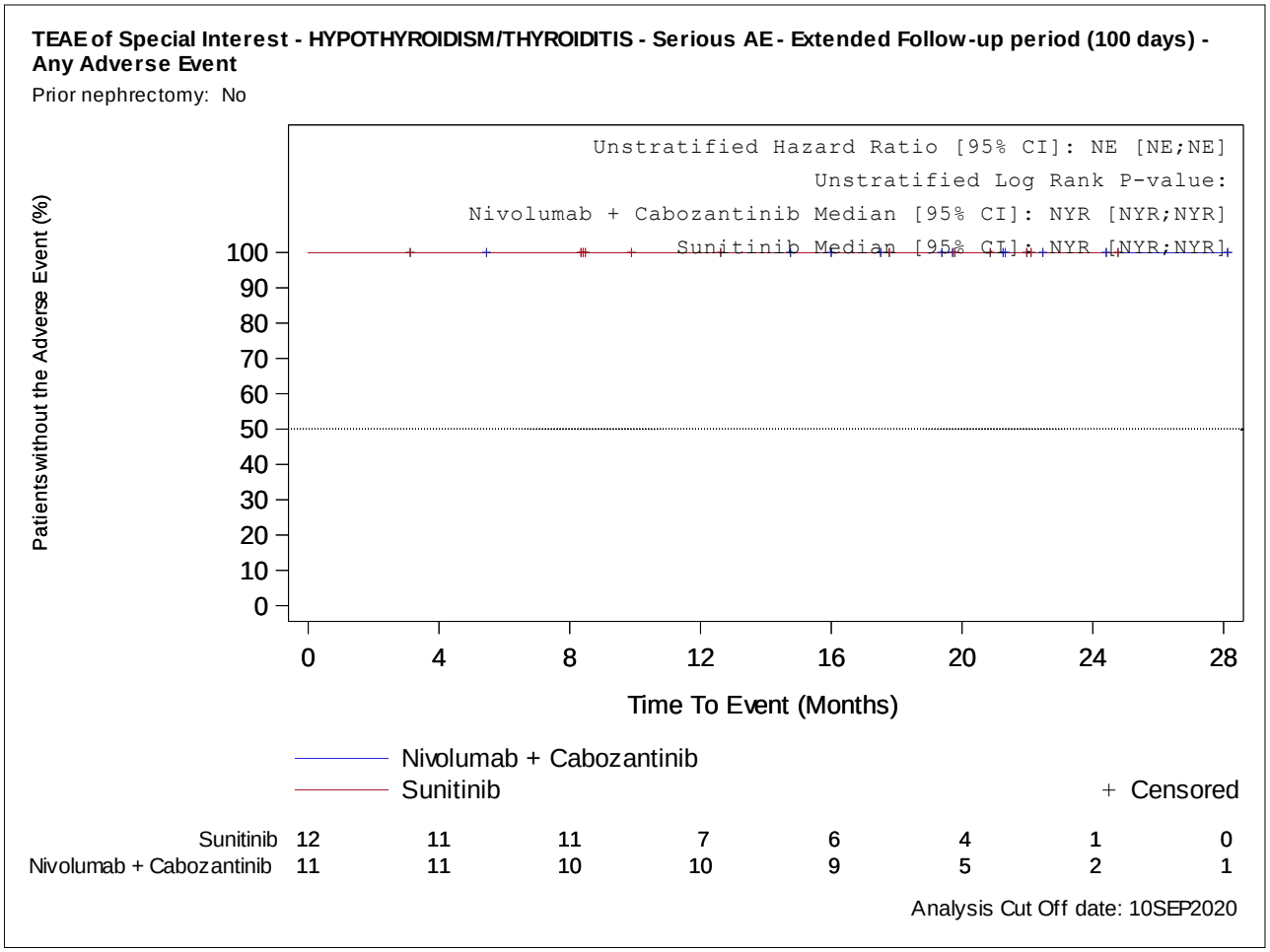
FIGURE 3.118.2.16: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:25:01

FIGURE 3.118.2.17: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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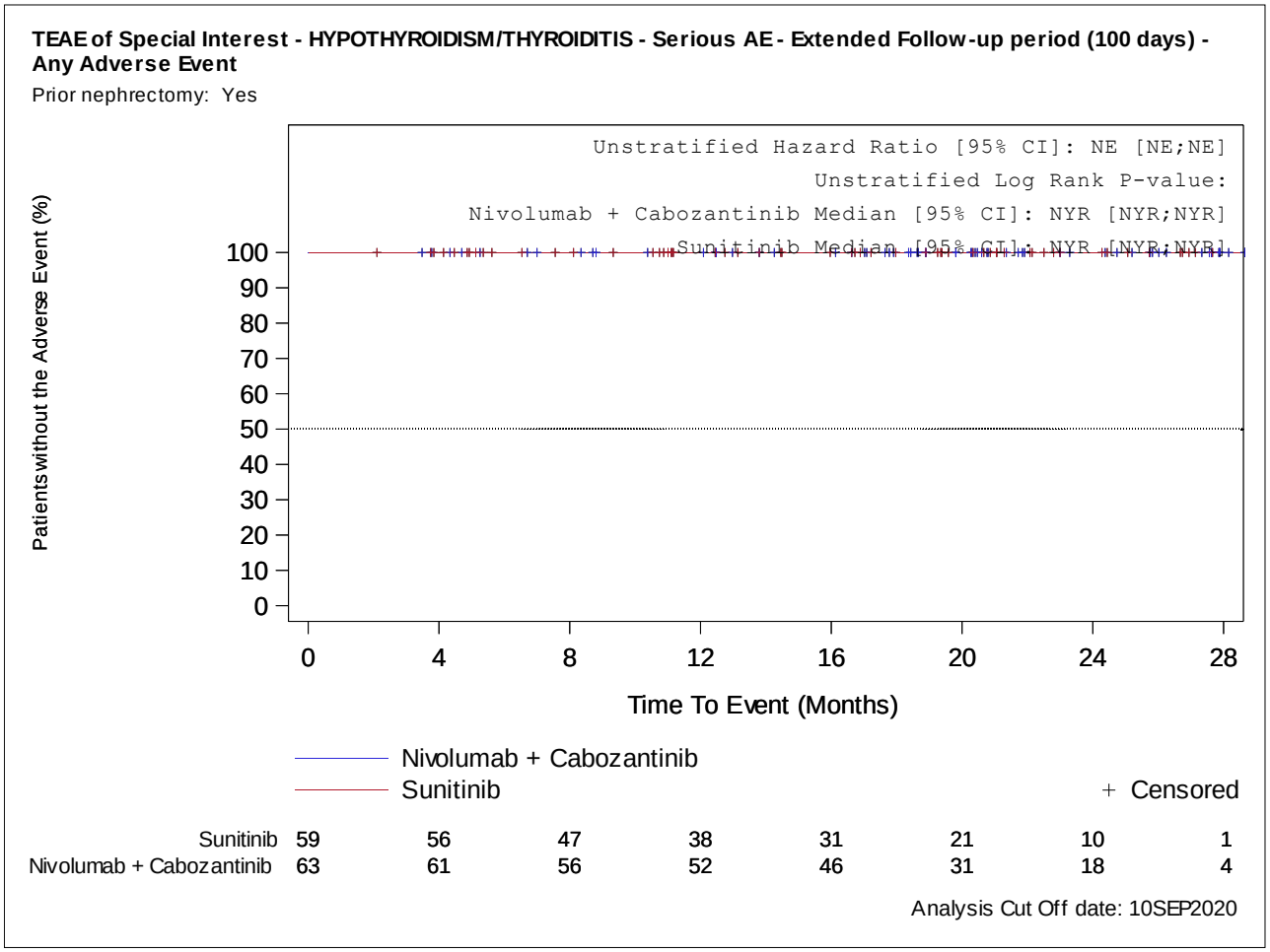
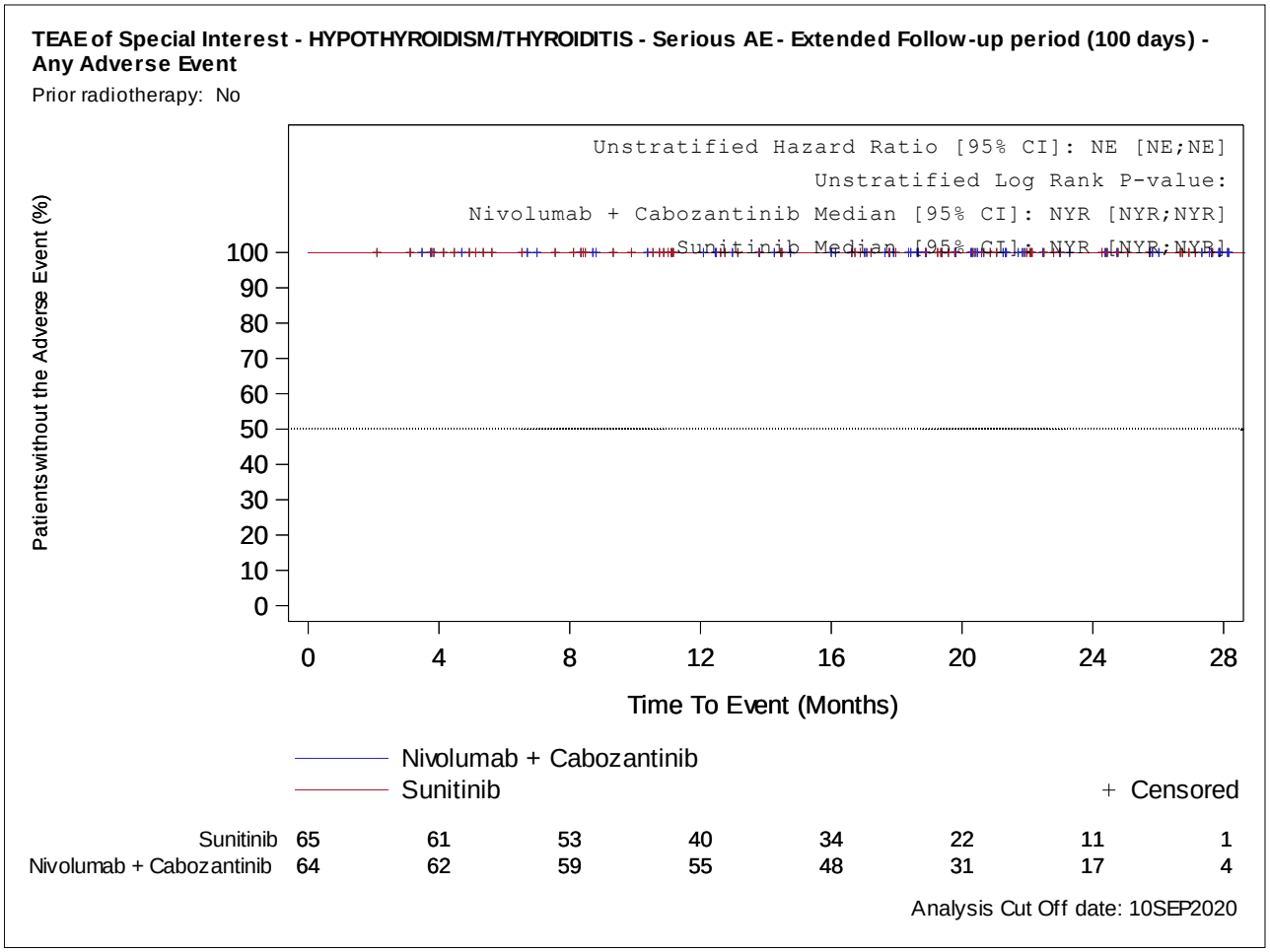
FIGURE 3.118.2.18: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



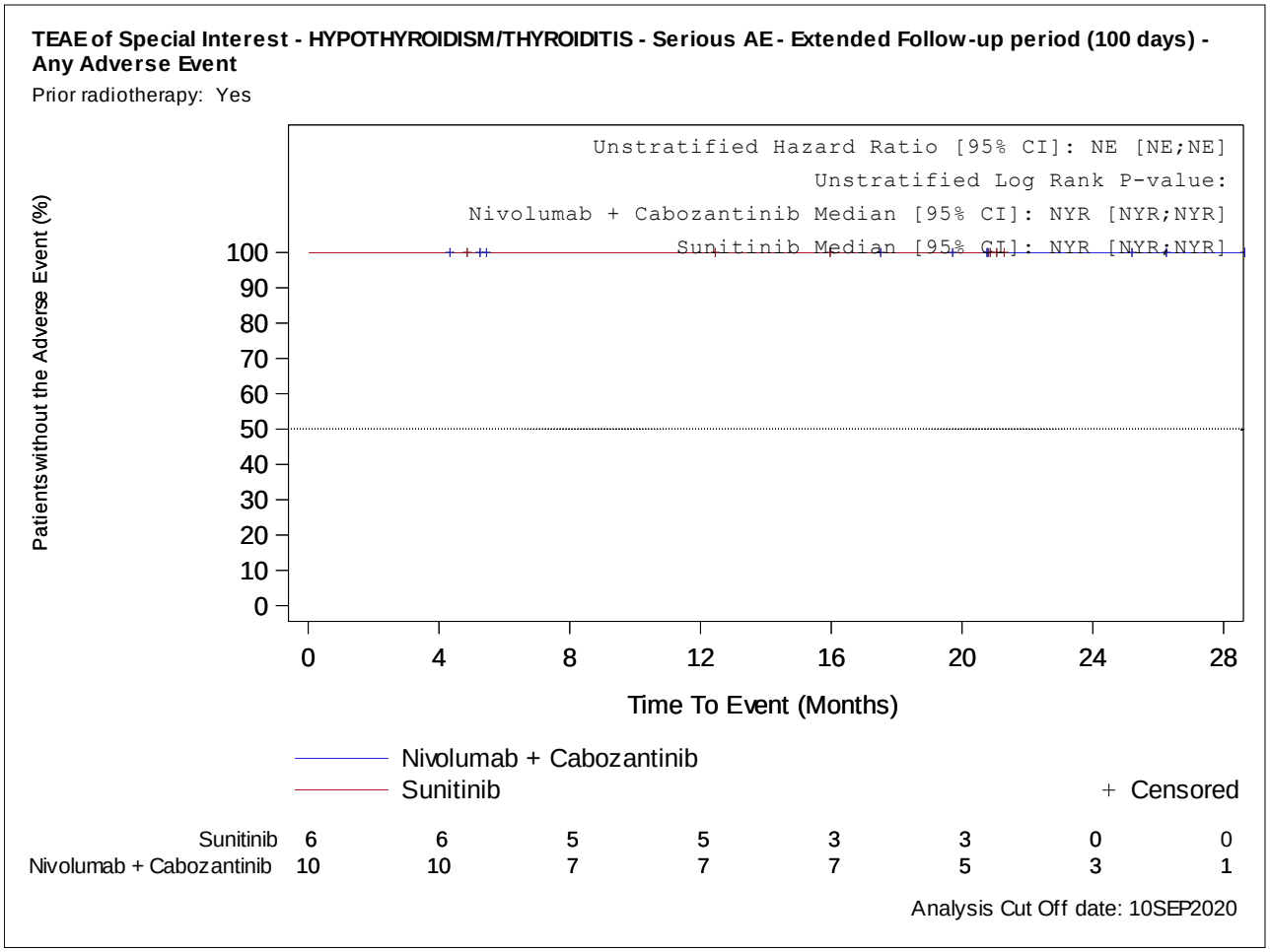

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:26:05

FIGURE 3.118.2.19: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



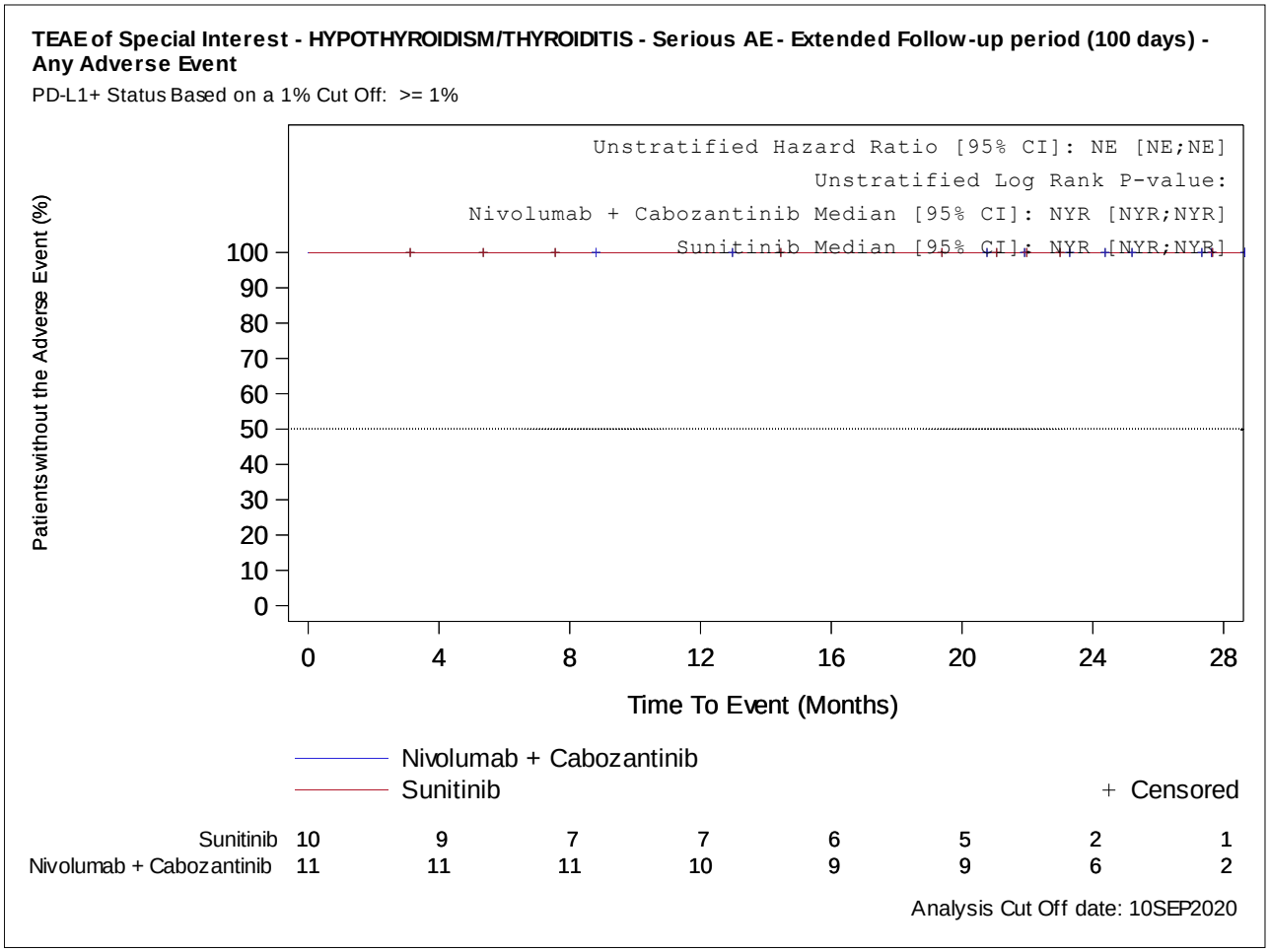

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:26:12

FIGURE 3.118.2.20: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:26:17

FIGURE 3.118.2.21: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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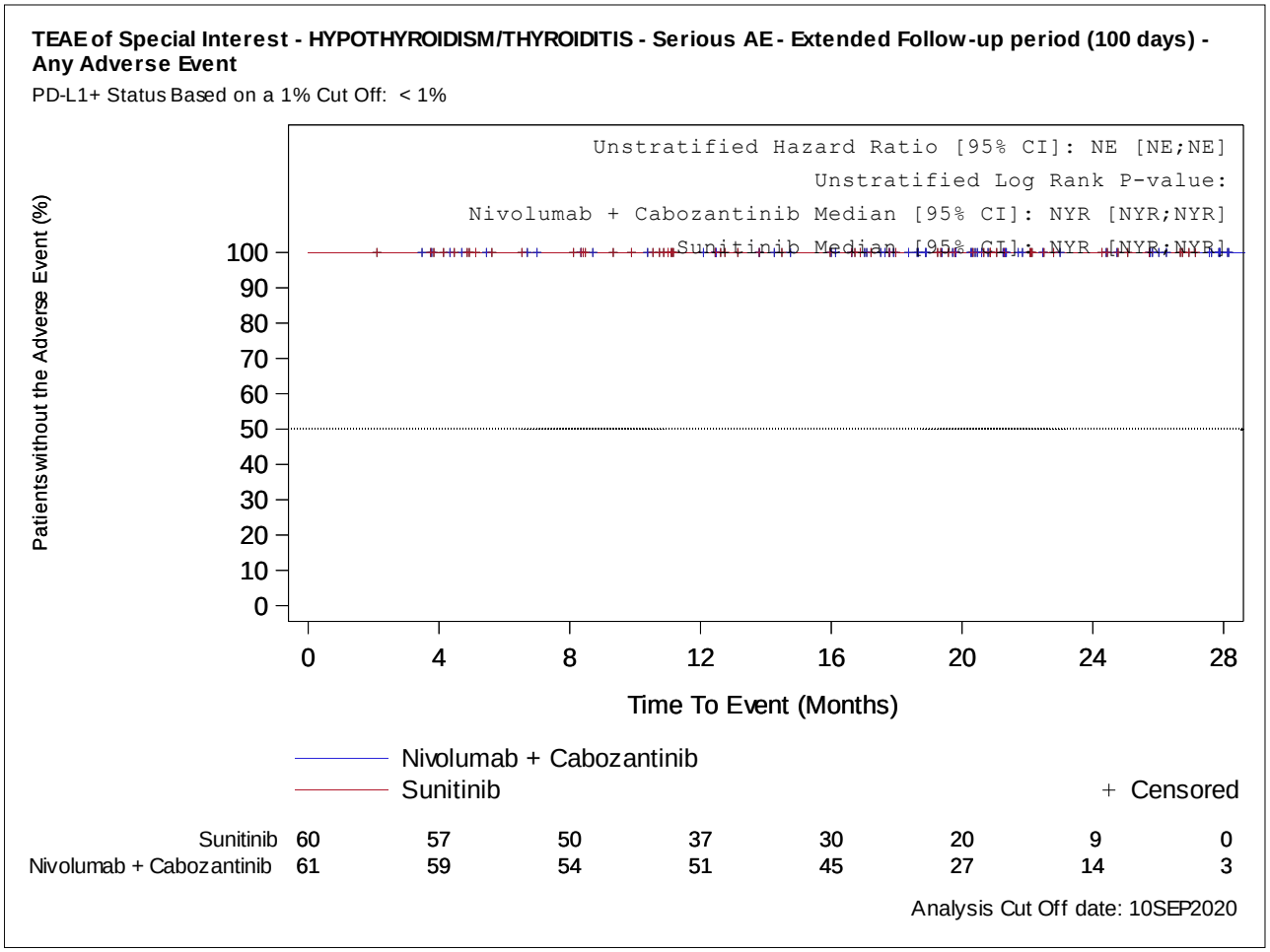
FIGURE 3.118.2.22: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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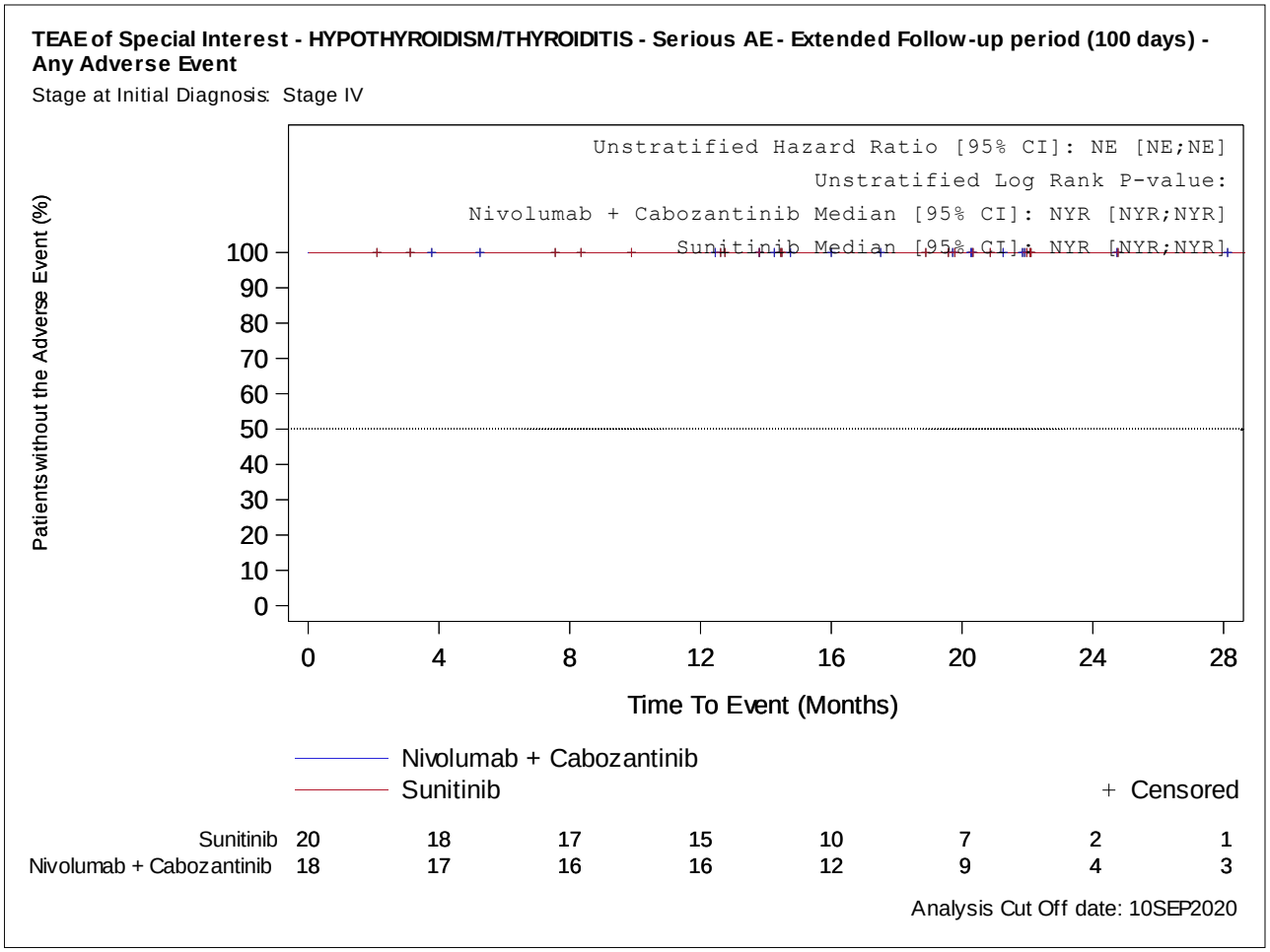
FIGURE 3.118.2.23: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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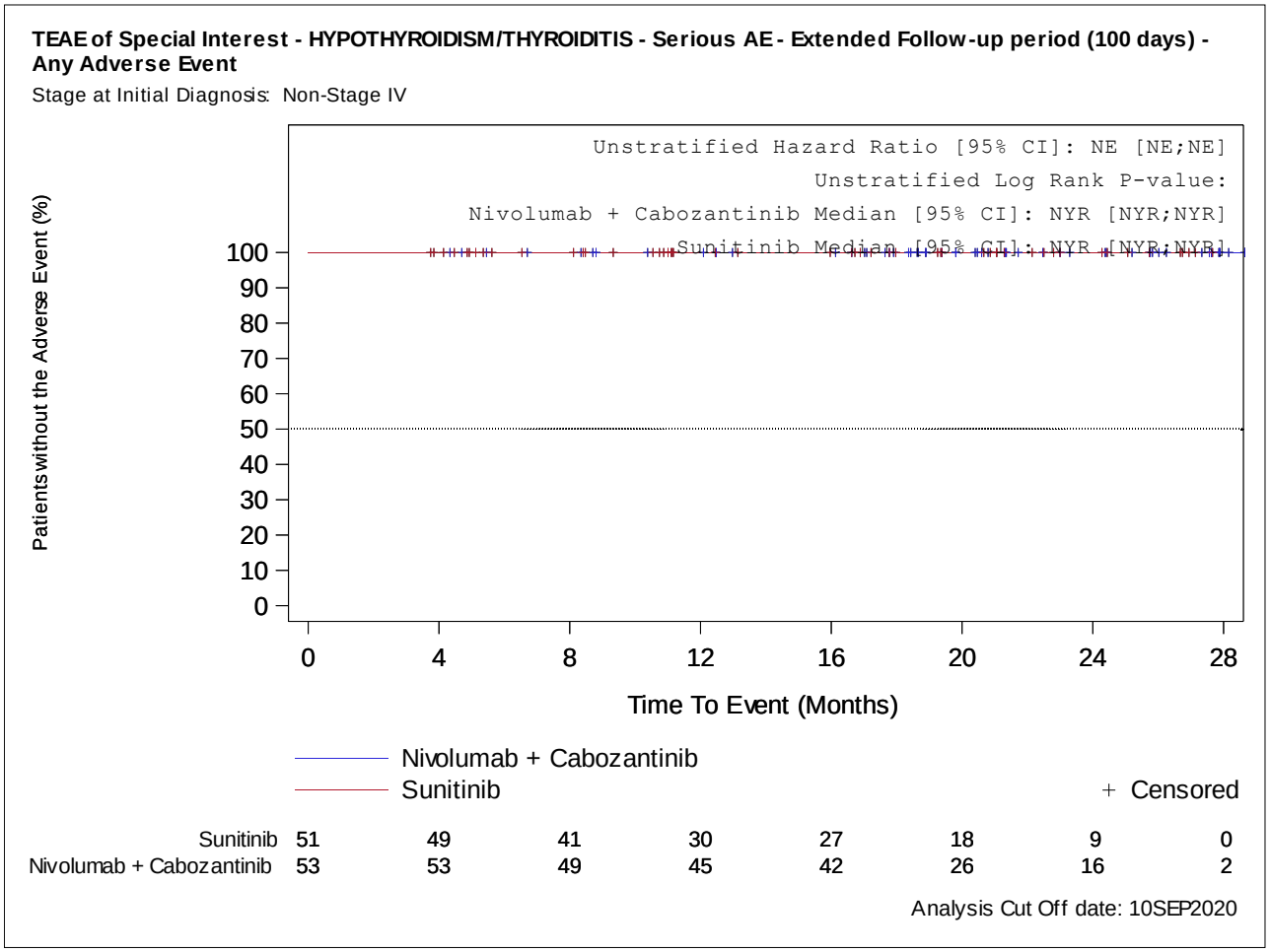
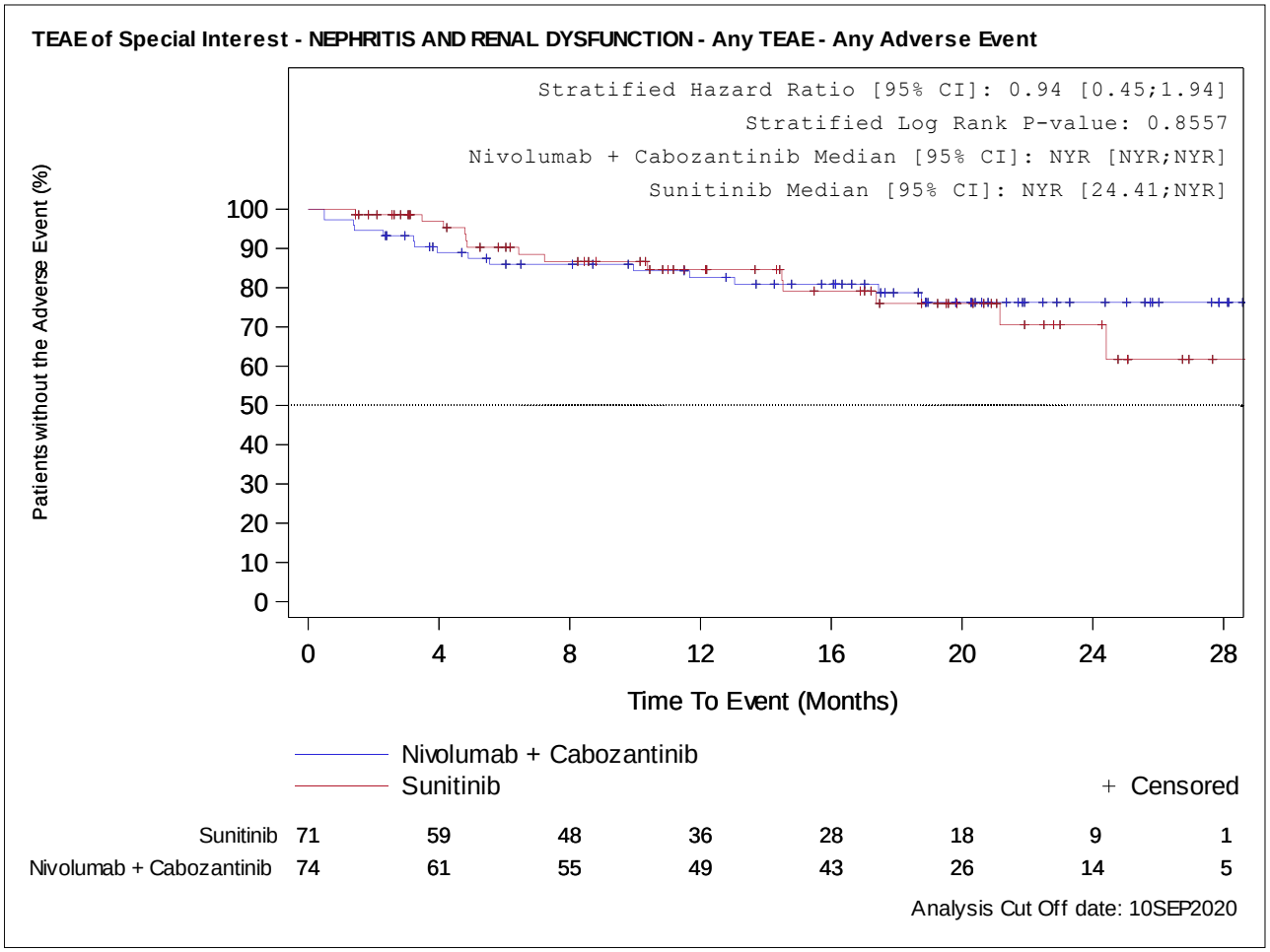
FIGURE 3.118.2.24: Kaplan-Meier curve - TEAE of Special Interest - HYPOTHYROIDISM/THYROIDITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



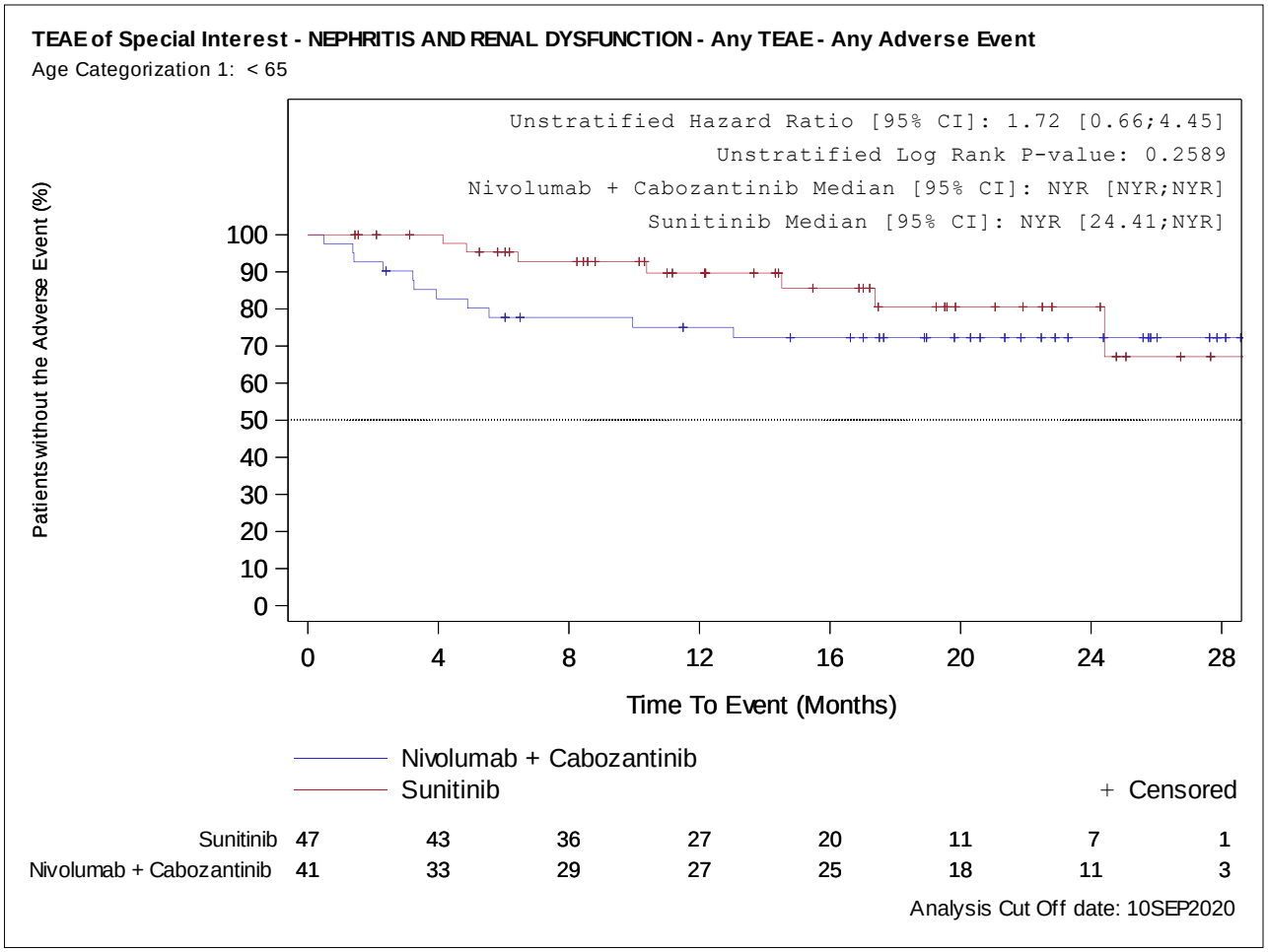

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:27:09

FIGURE 3.119.1: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:30:35

FIGURE 3.119.2.1: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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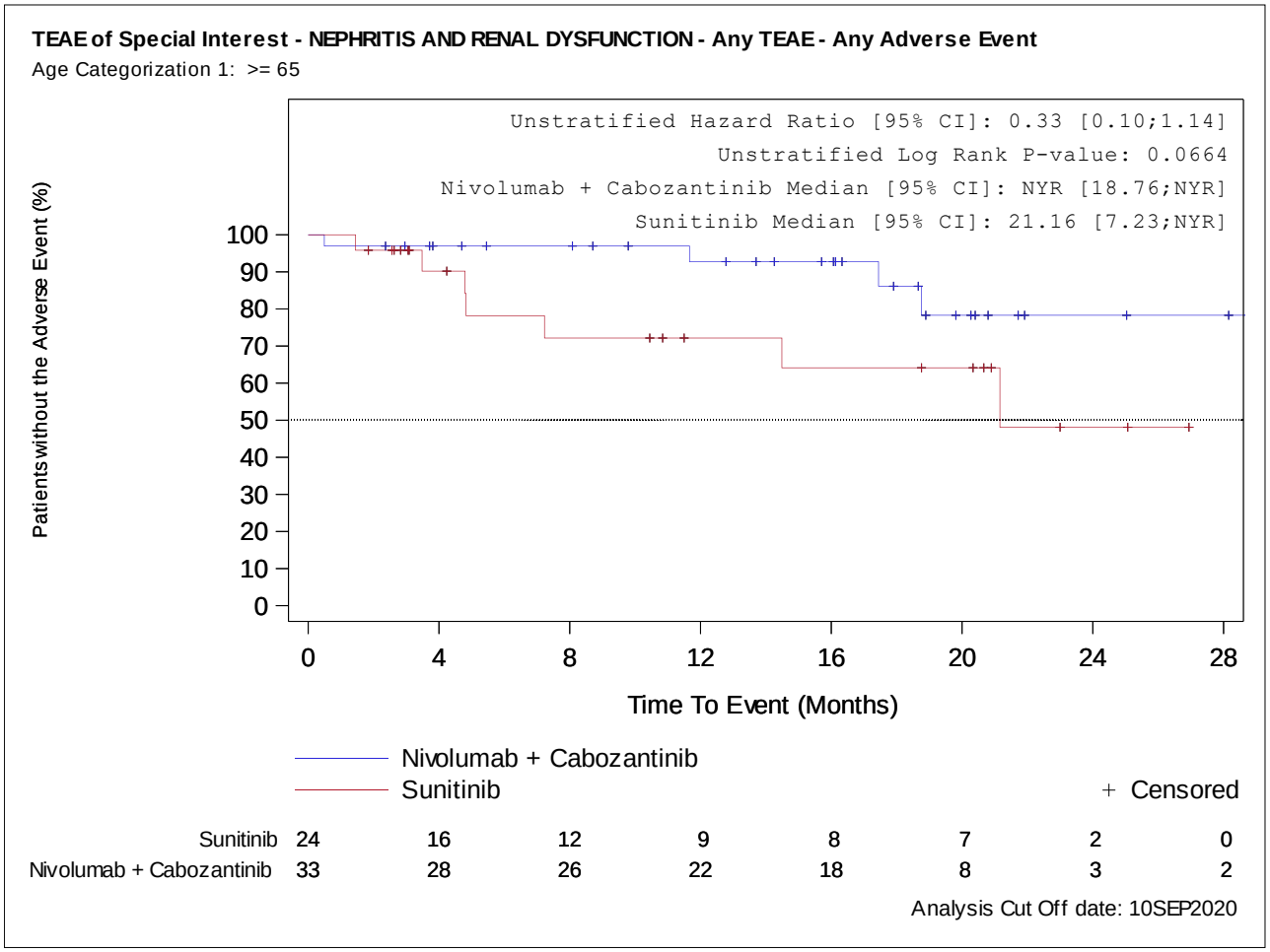
FIGURE 3.119.2.2: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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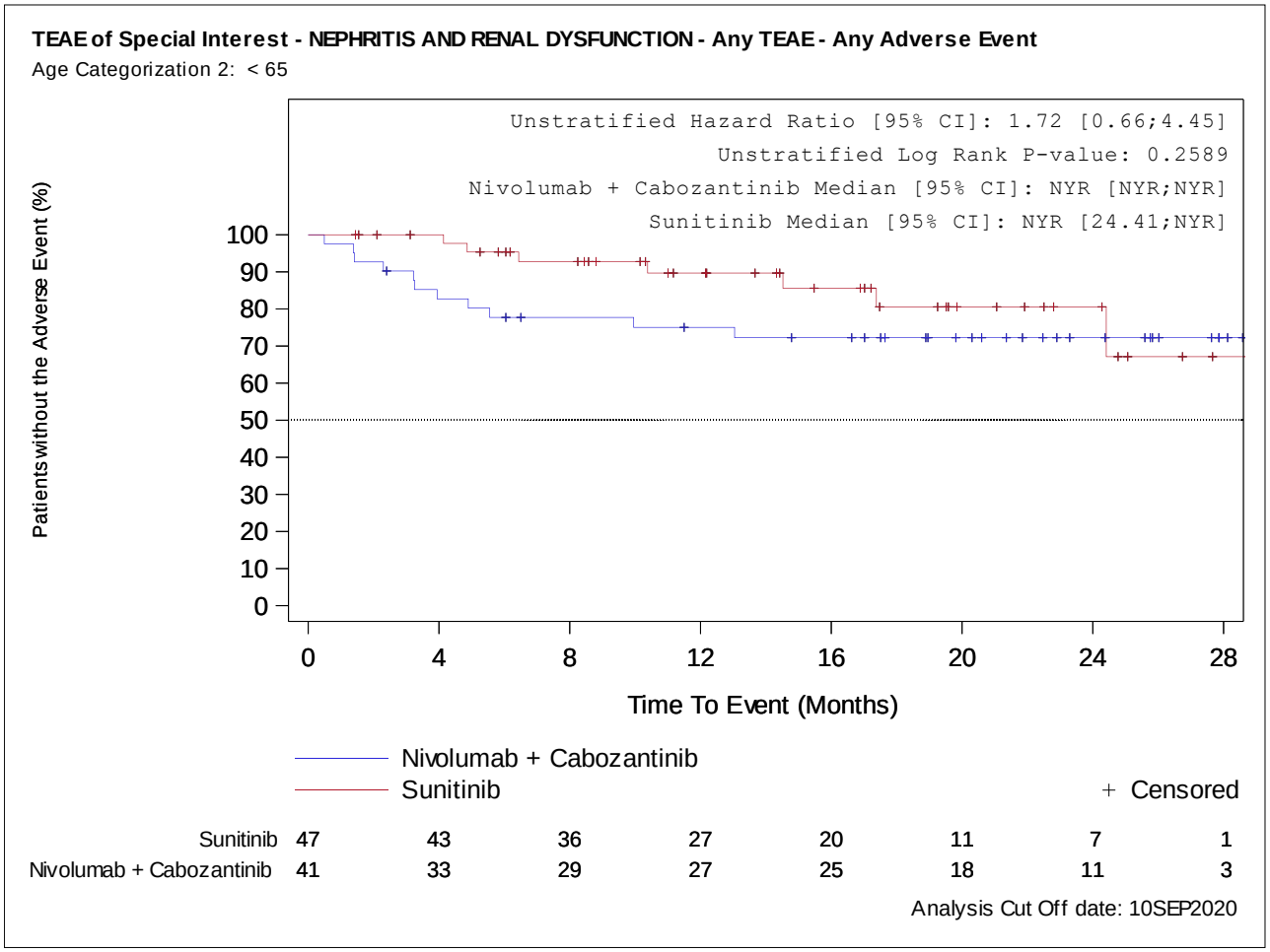
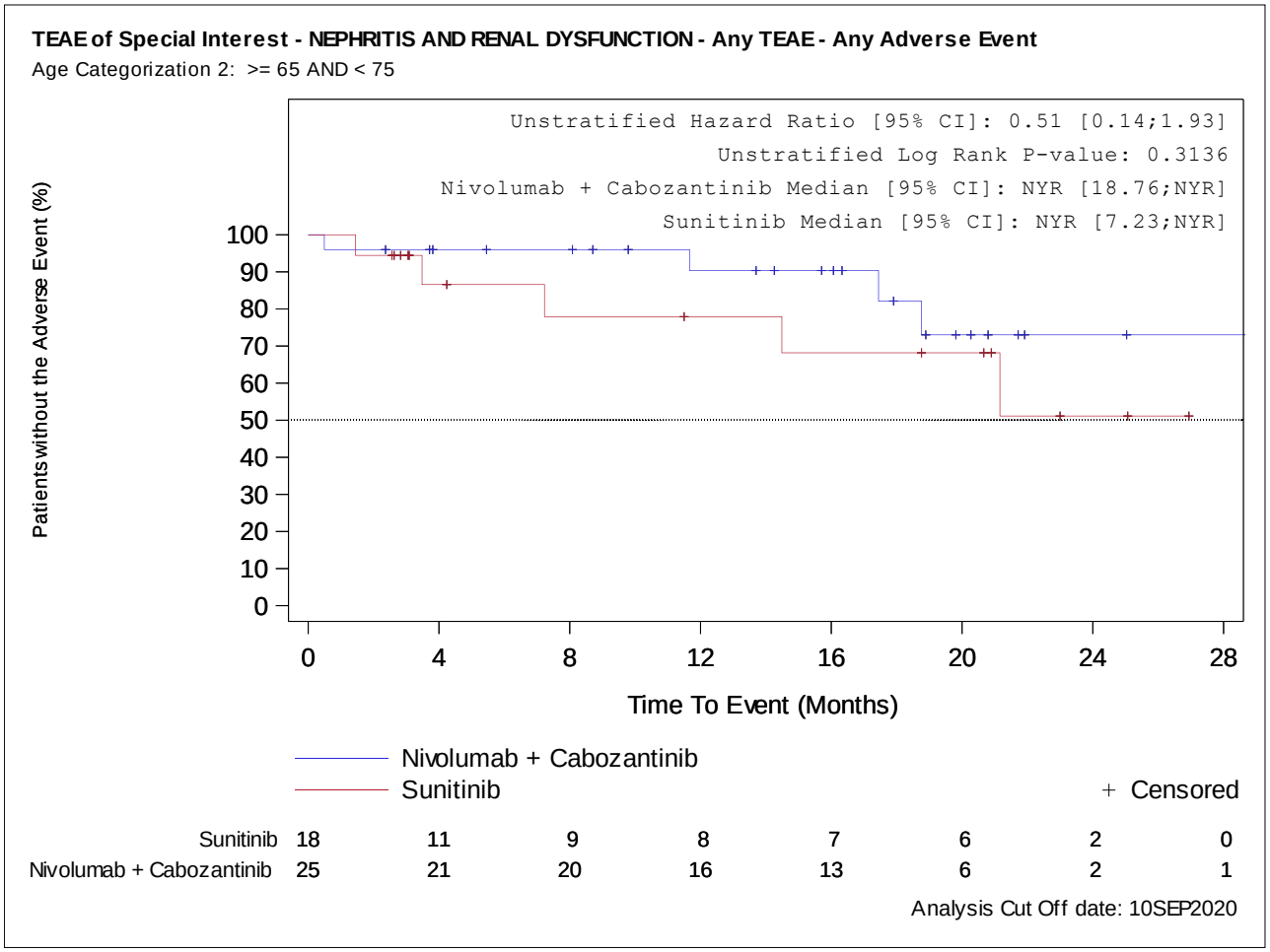
FIGURE 3.119.2.3: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:30:51

FIGURE 3.119.2.4: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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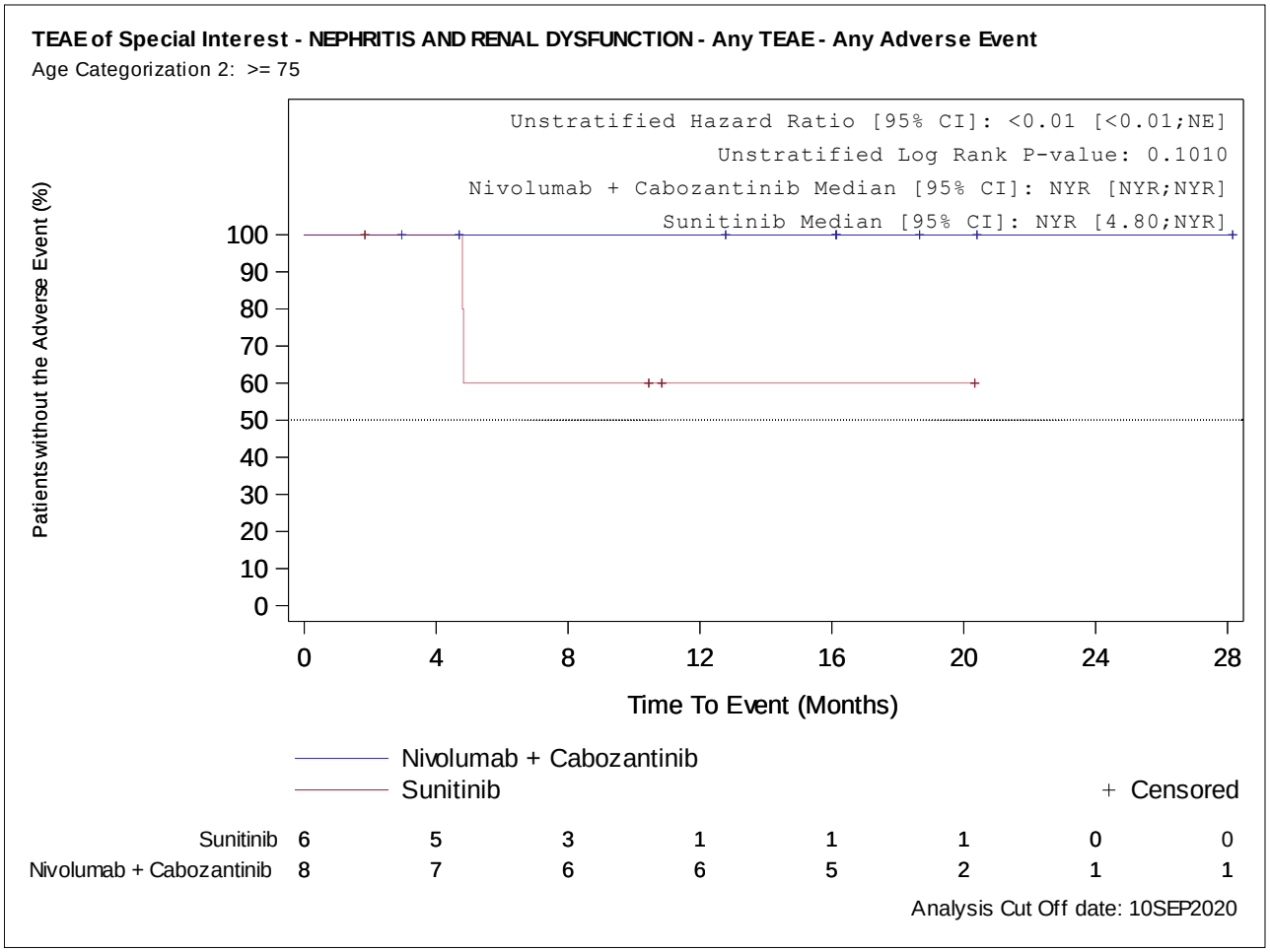
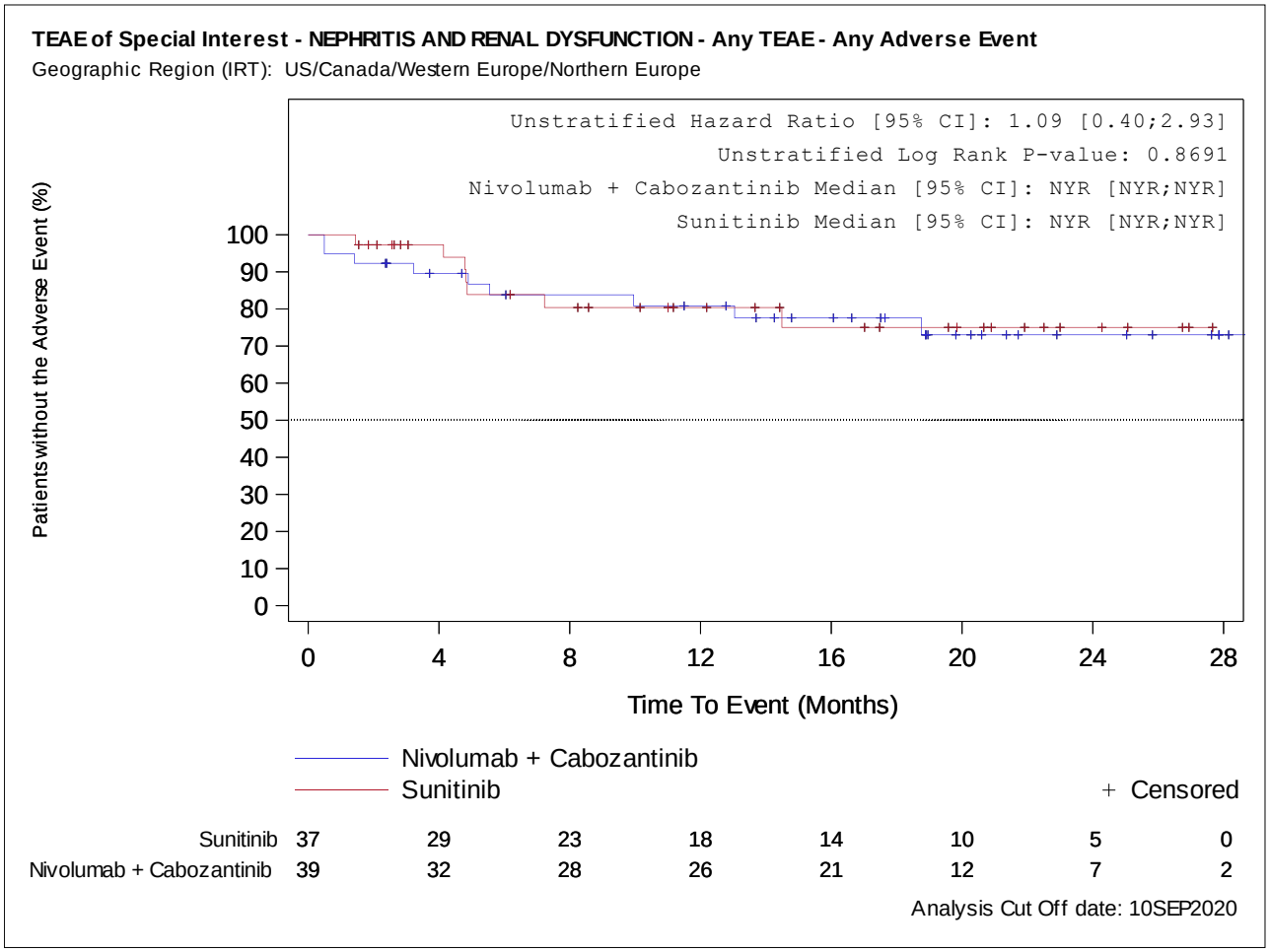
FIGURE 3.119.2.5: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:31:02

FIGURE 3.119.2.6: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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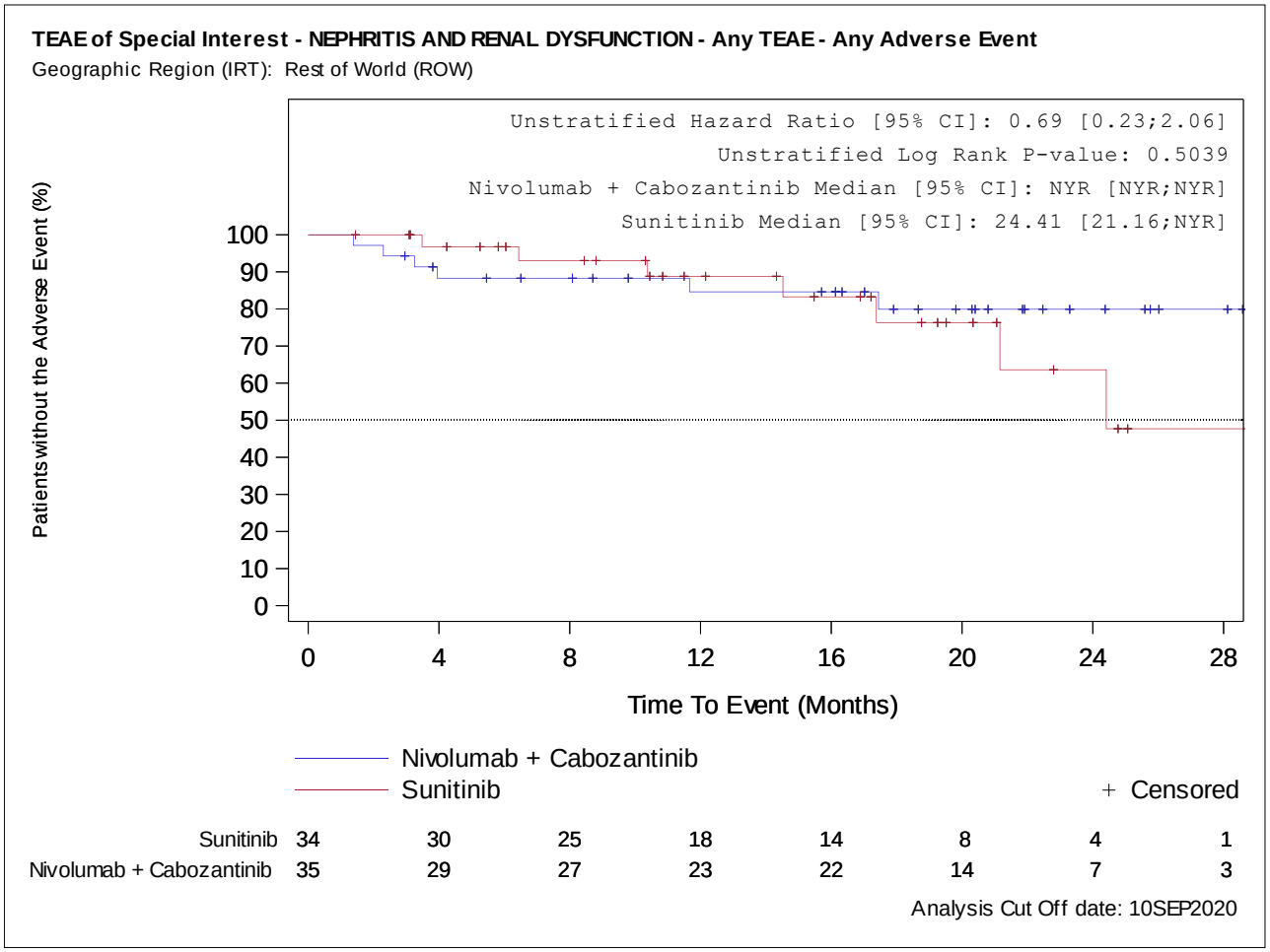
FIGURE 3.119.2.7: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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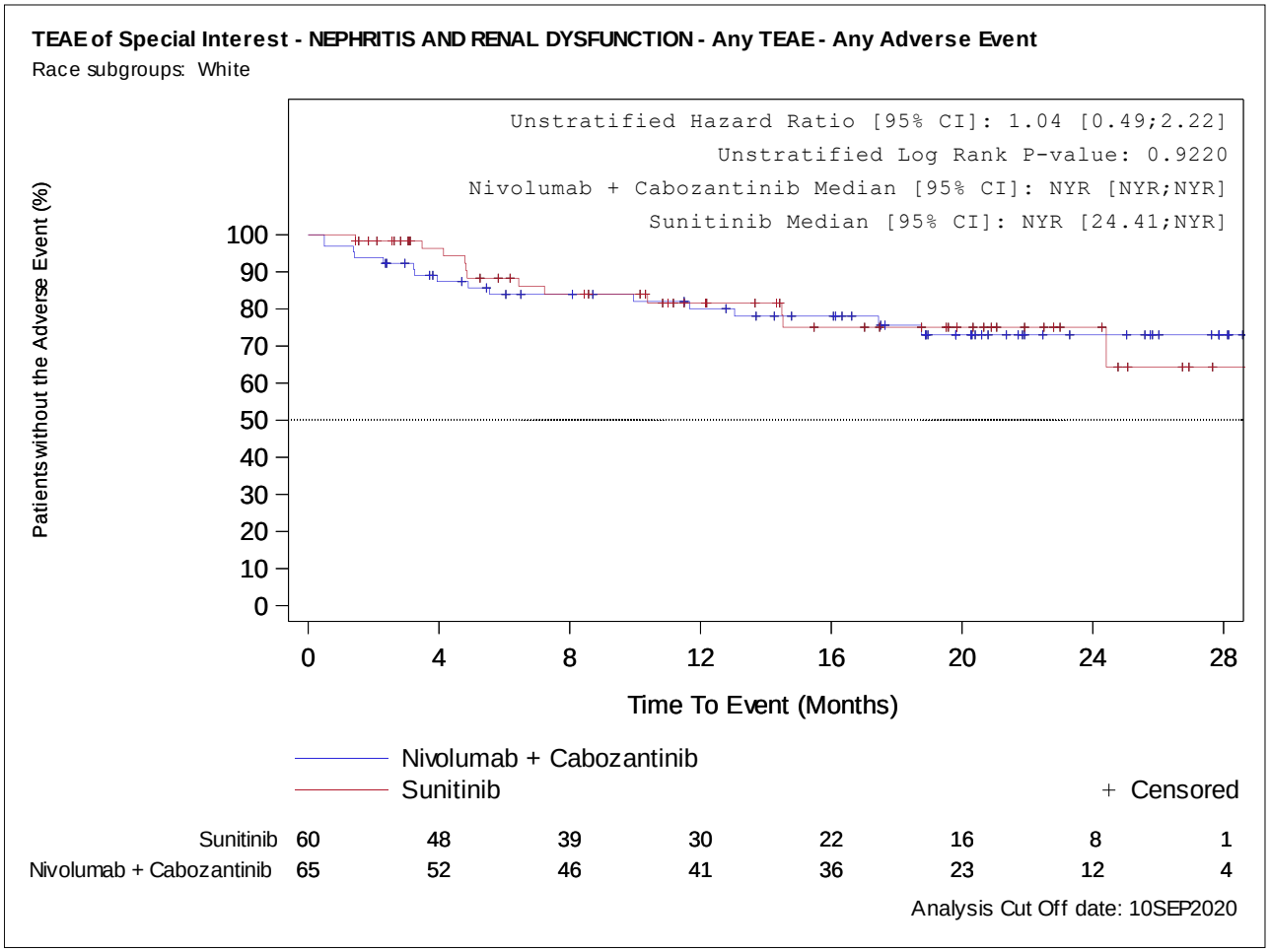
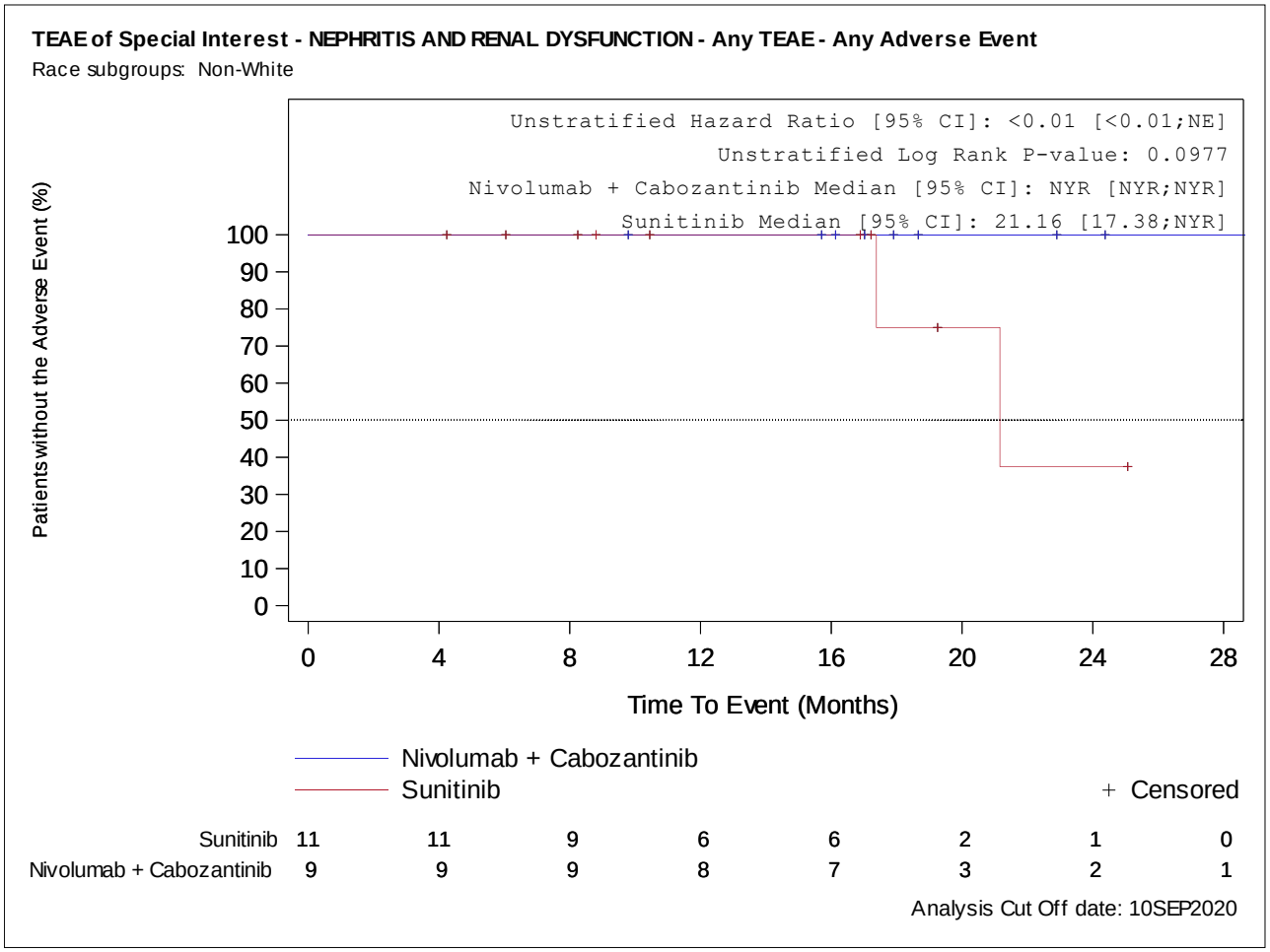
FIGURE 3.119.2.8: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:31:20

FIGURE 3.119.2.9: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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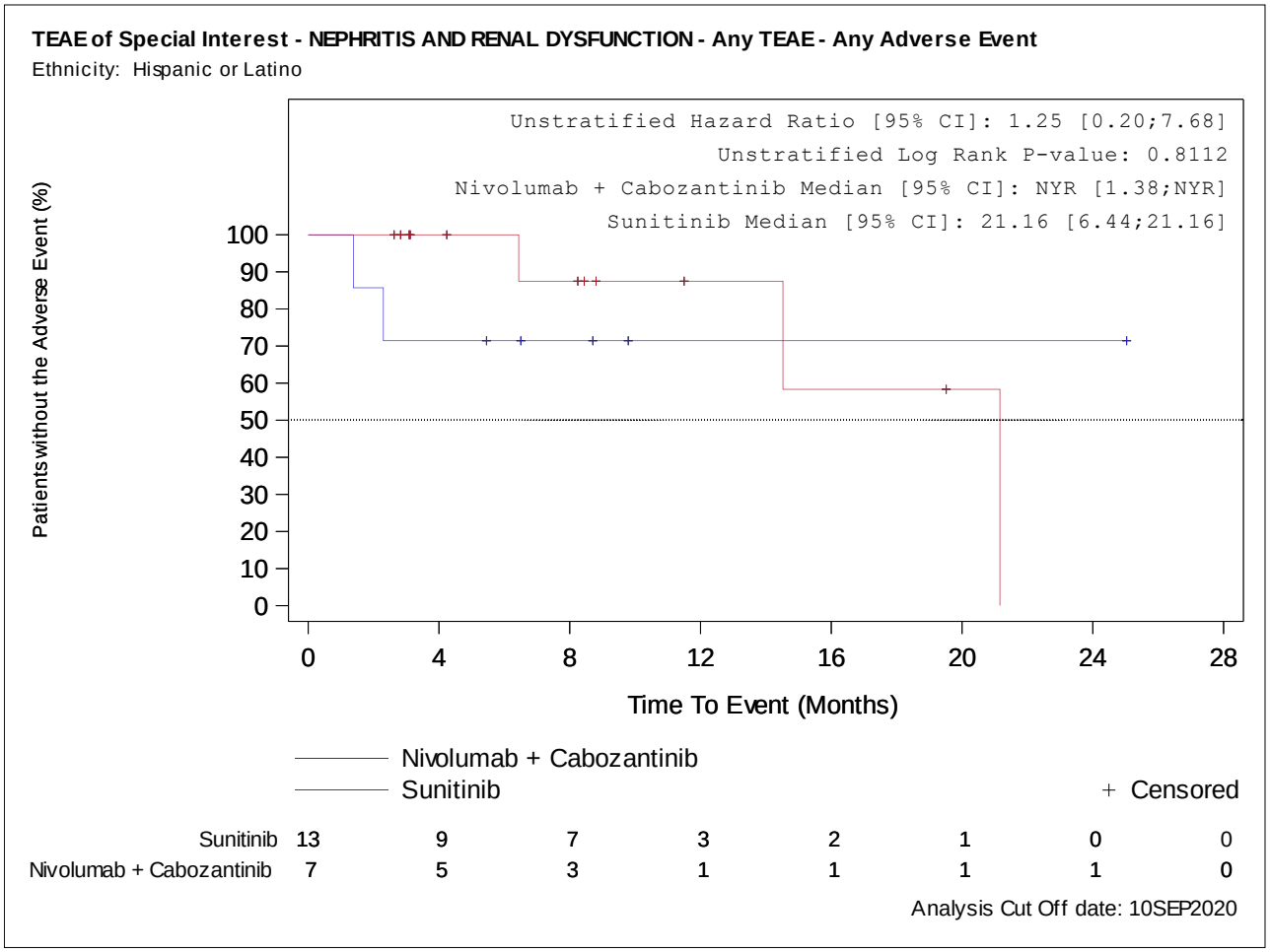
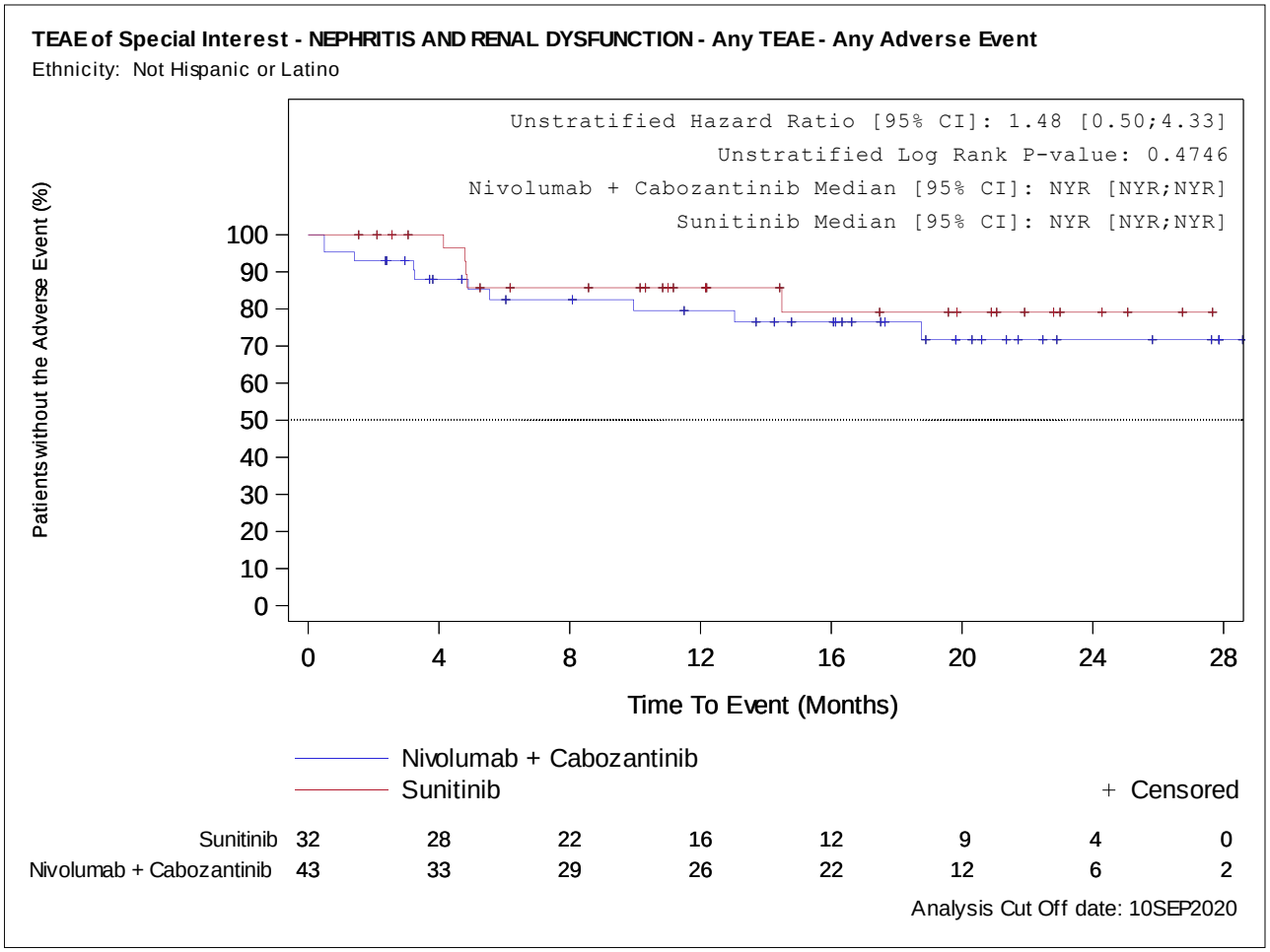
FIGURE 3.119.2.10: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



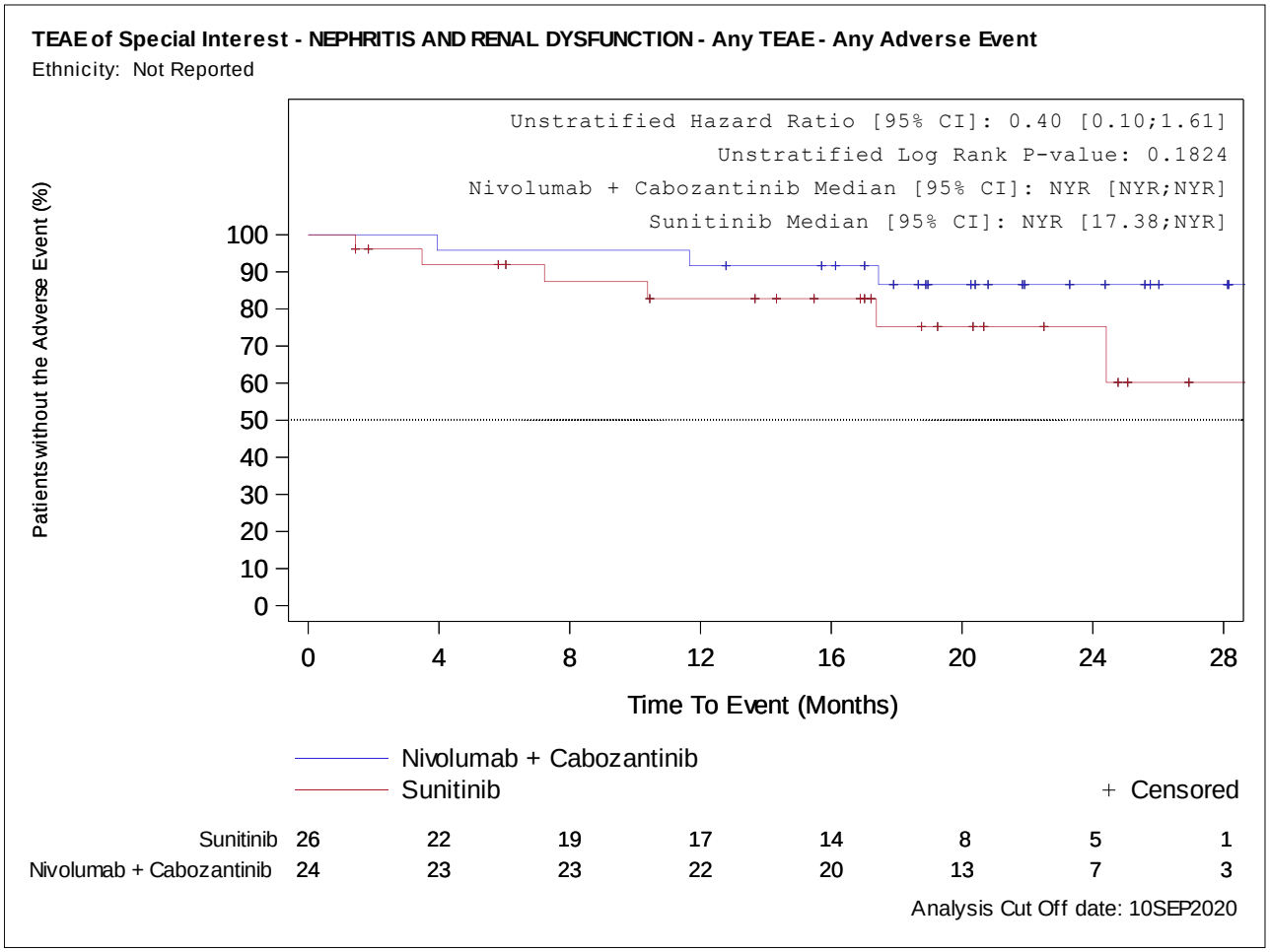

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:31:33

FIGURE 3.119.2.11: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



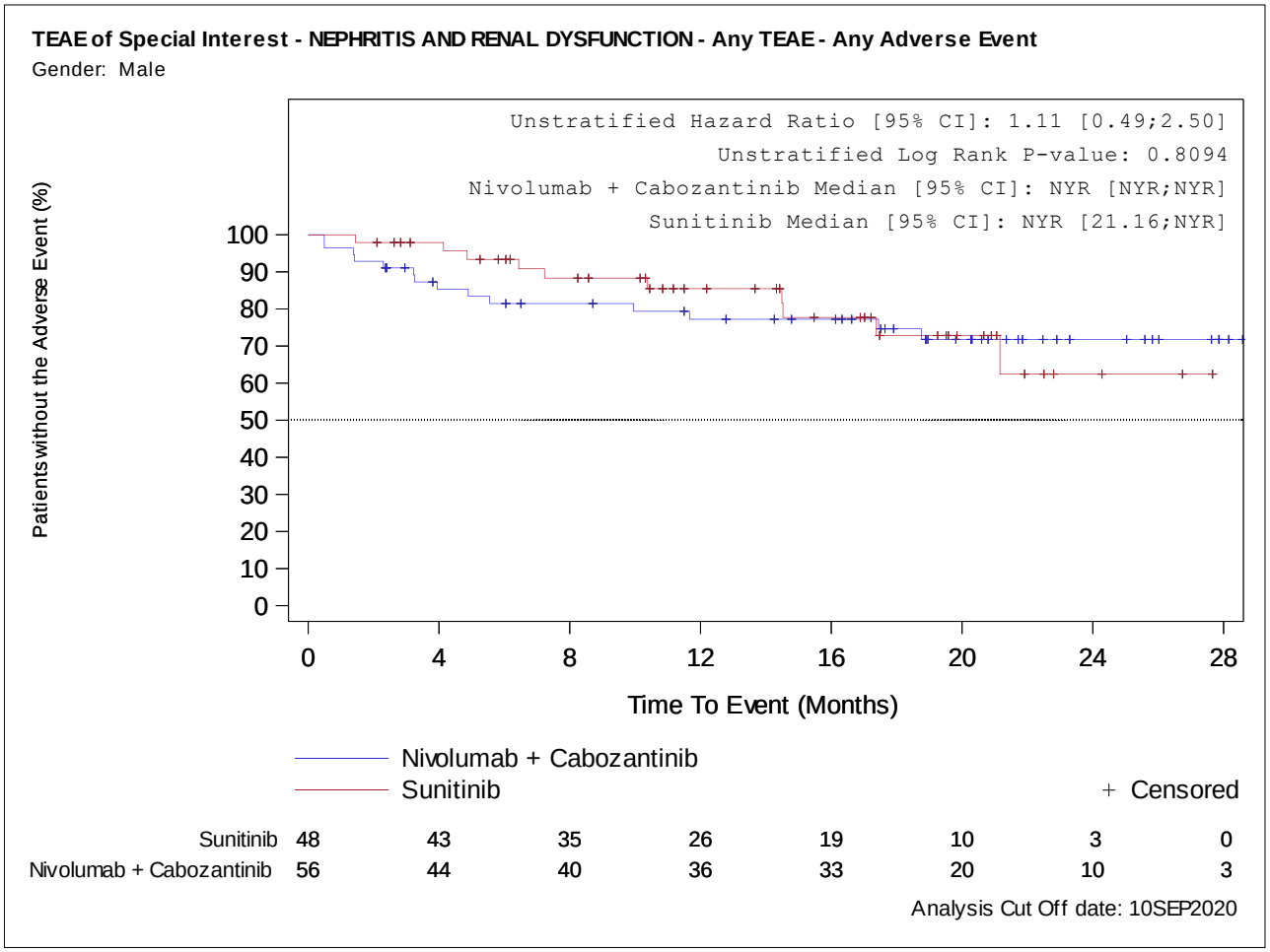

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:31:39

FIGURE 3.119.2.12: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



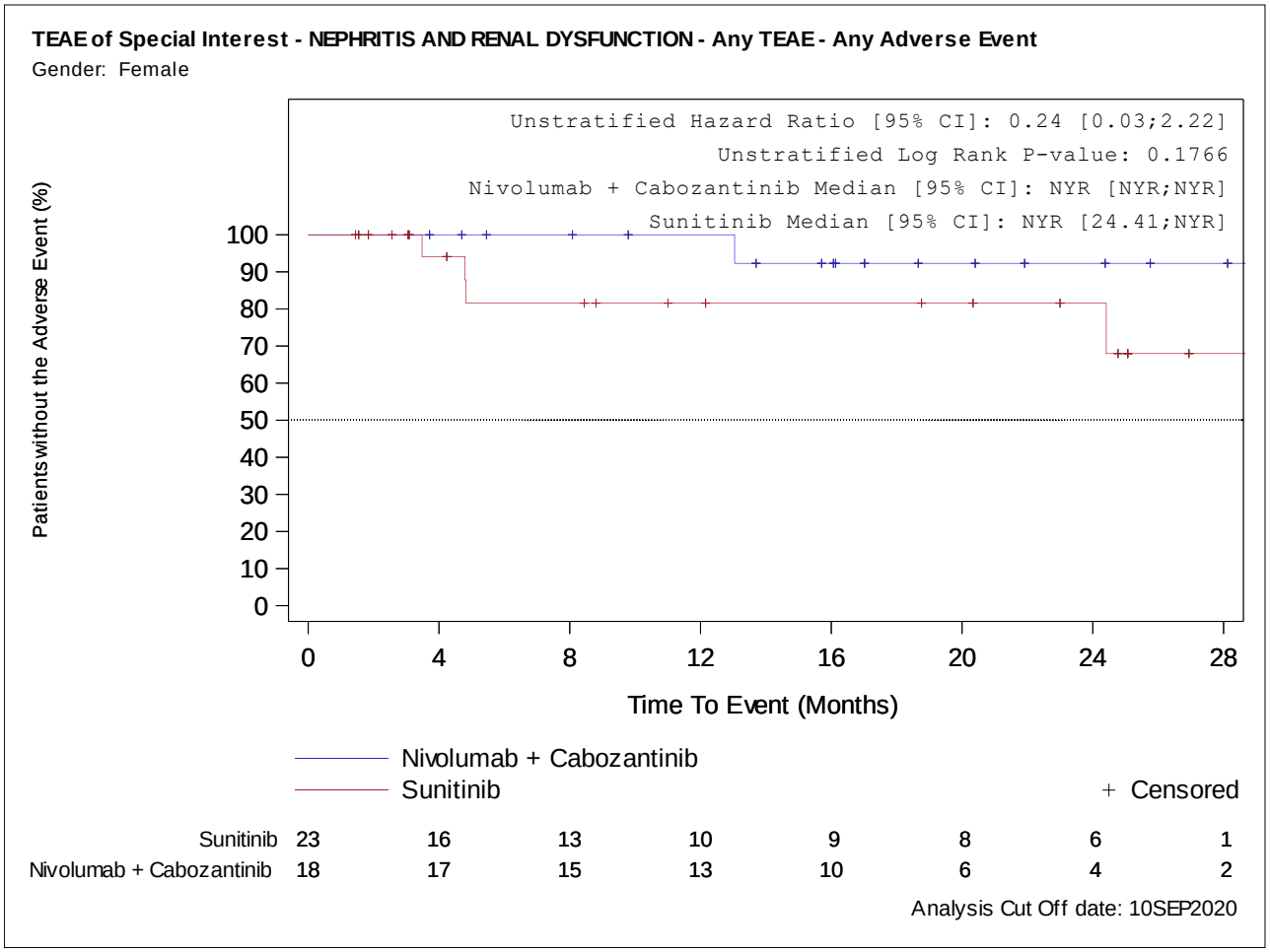

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:31:46

FIGURE 3.119.2.13: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



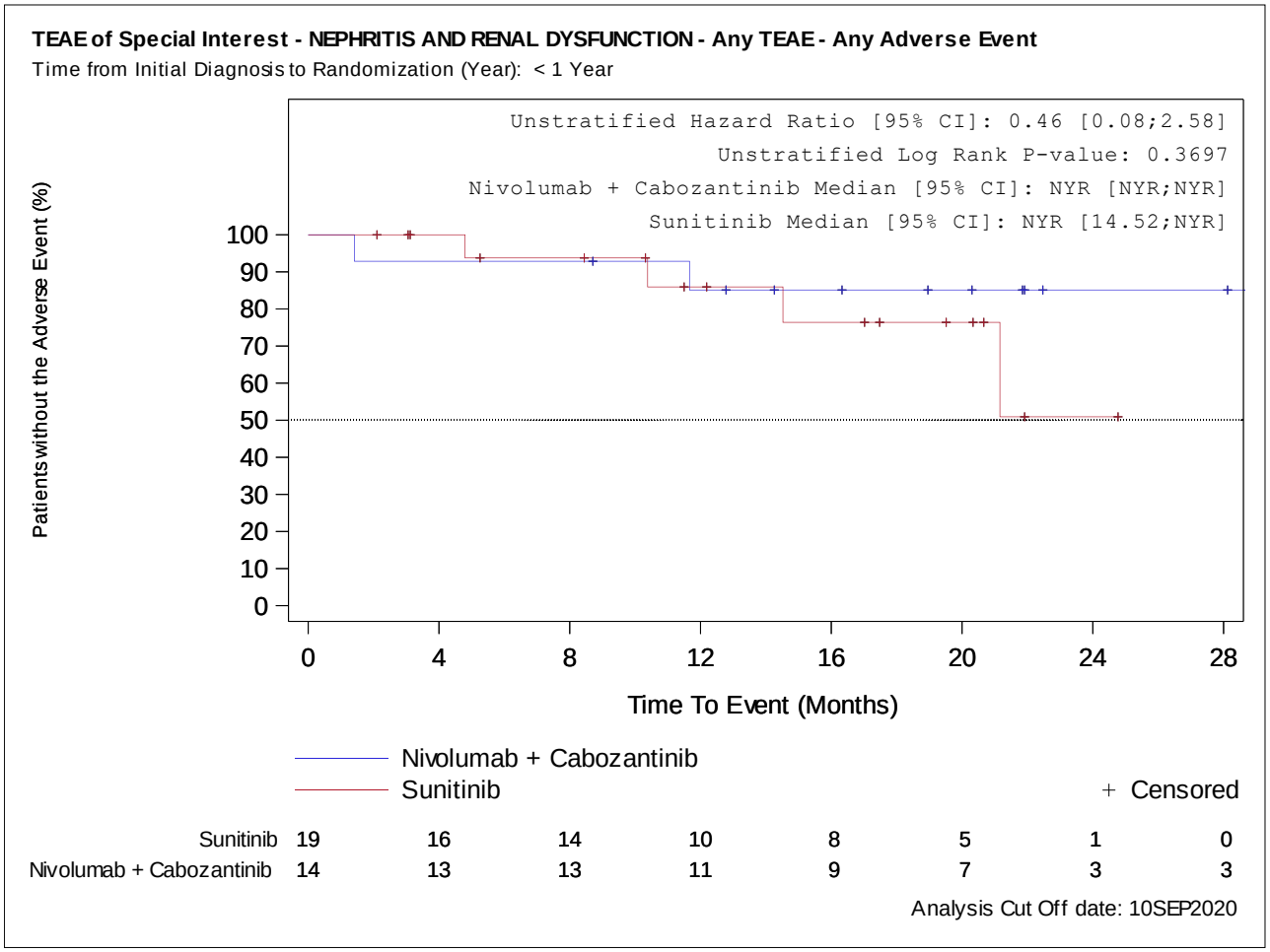

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:31:52

FIGURE 3.119.2.14: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



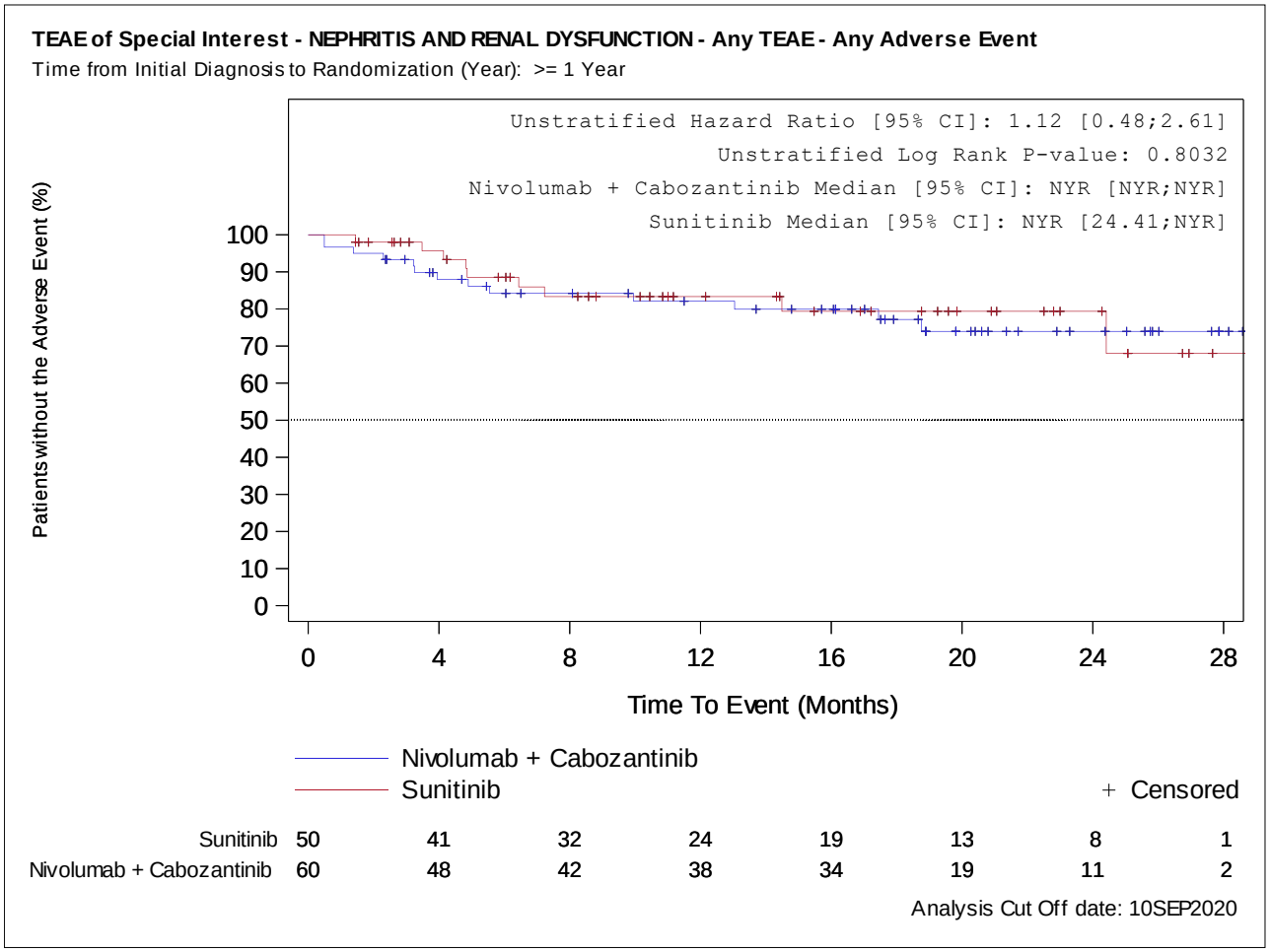

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:31:59

FIGURE 3.119.2.15: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



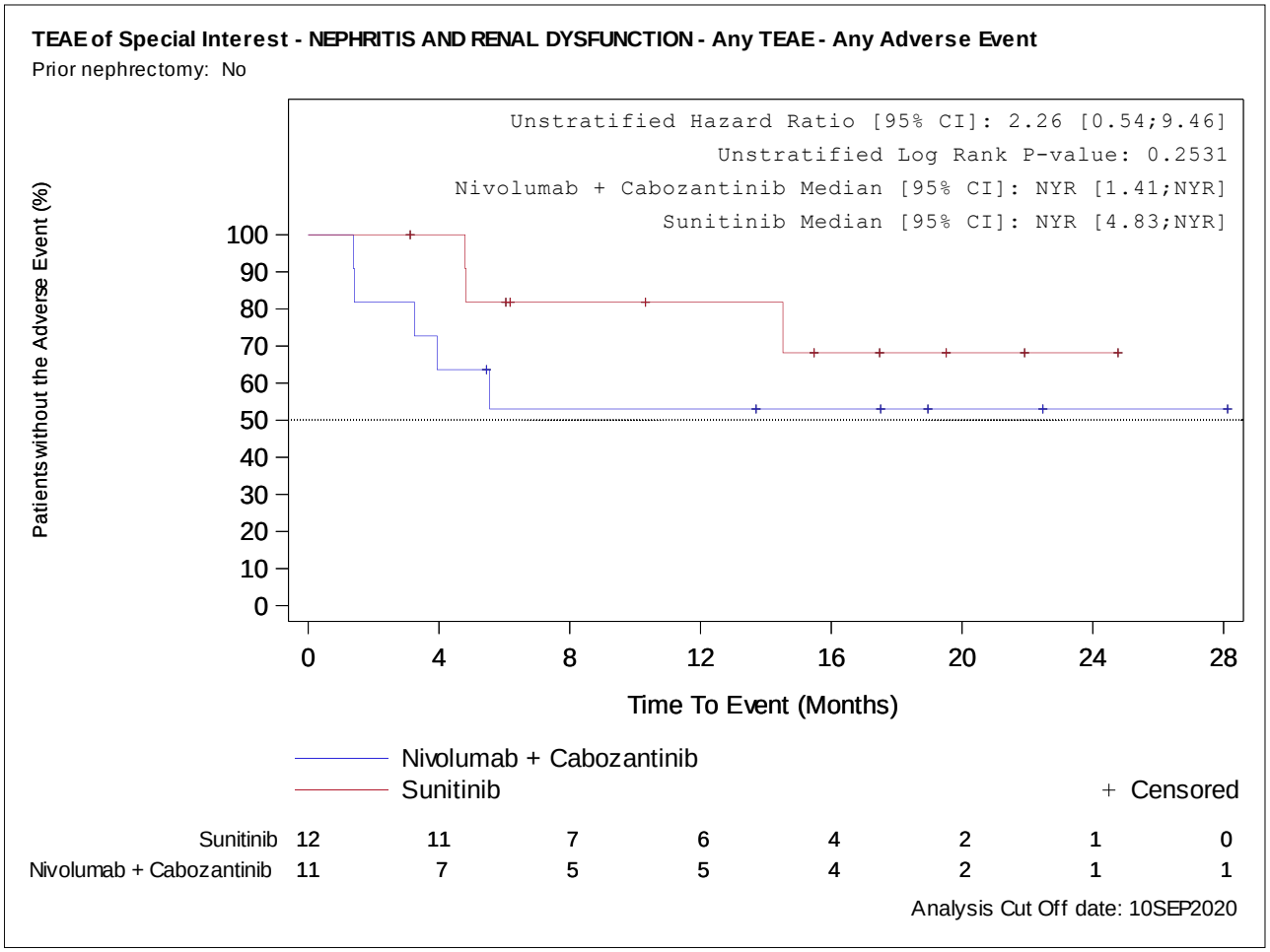

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:32:20

FIGURE 3.119.2.16: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



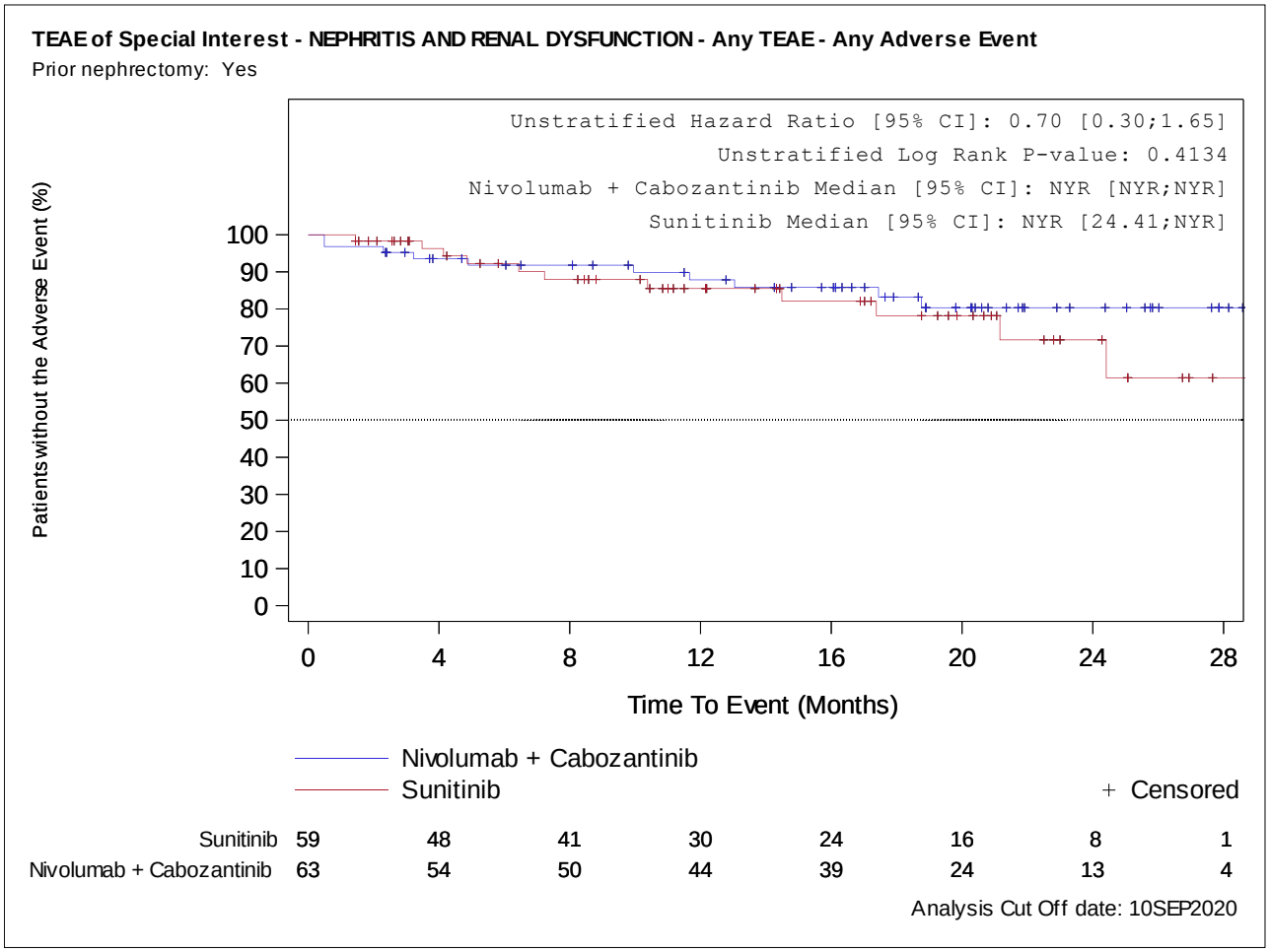

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:32:27

FIGURE 3.119.2.17: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



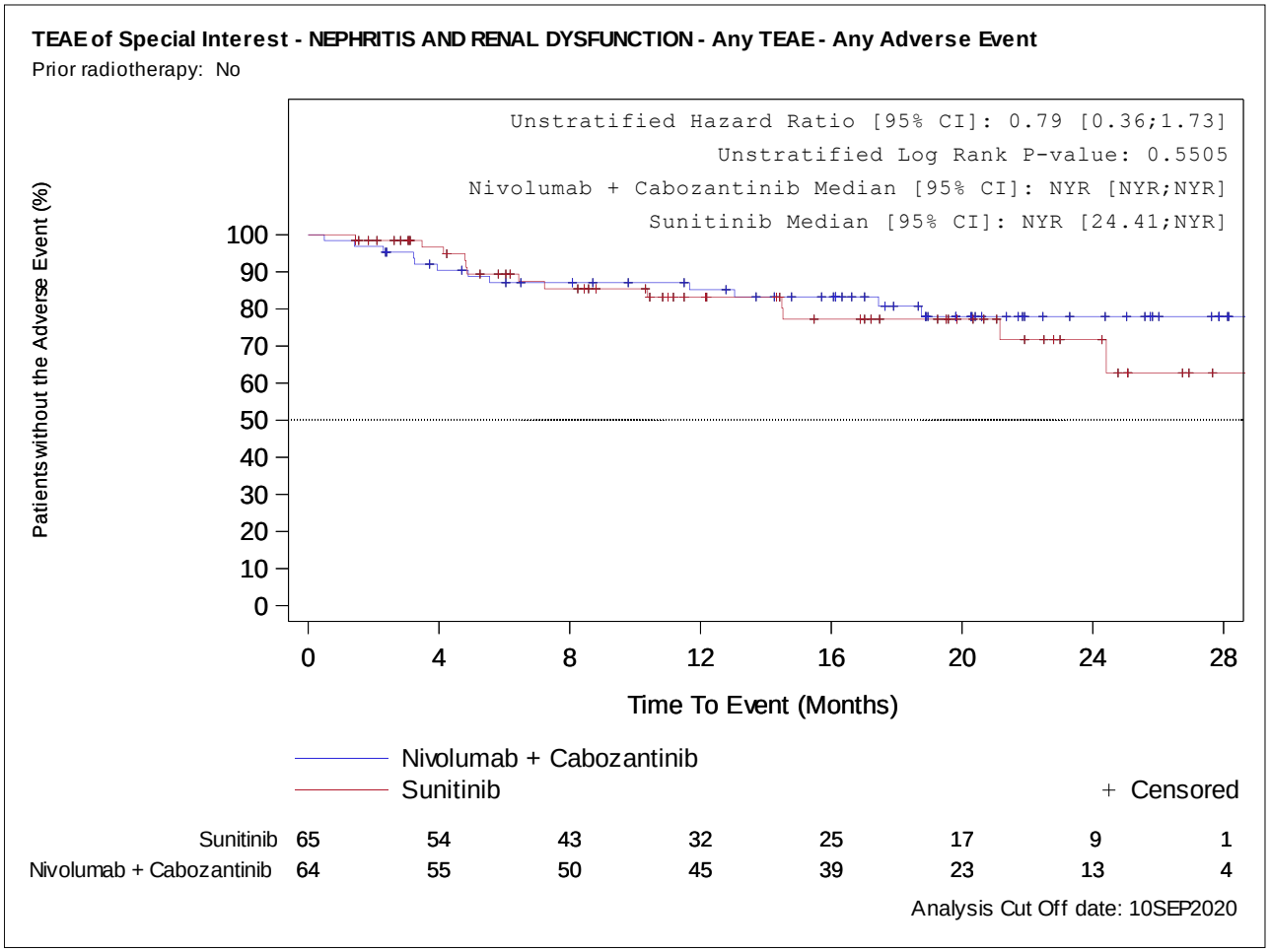

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:33:23

FIGURE 3.119.2.18: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



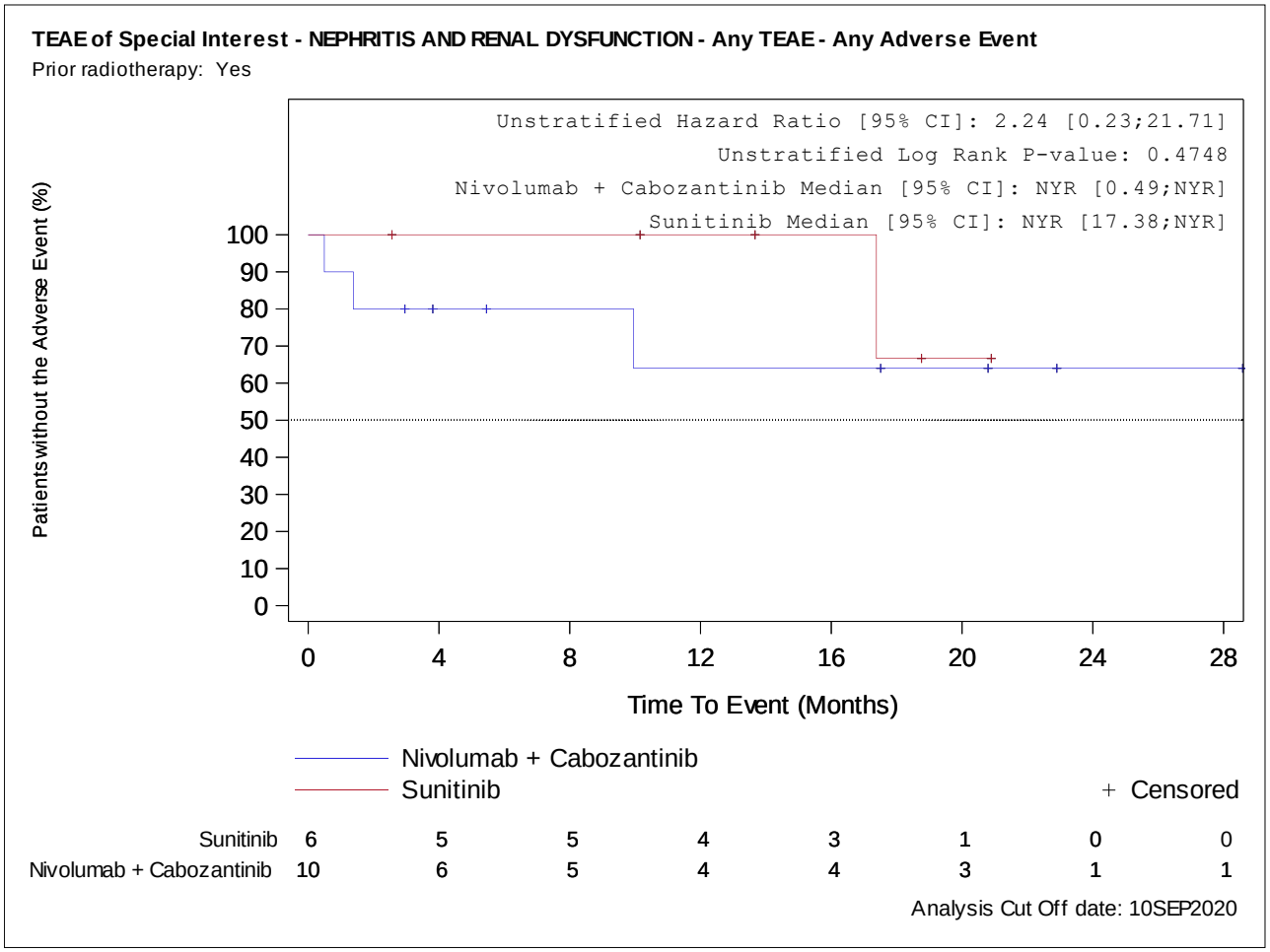

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:33:29

FIGURE 3.119.2.19: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



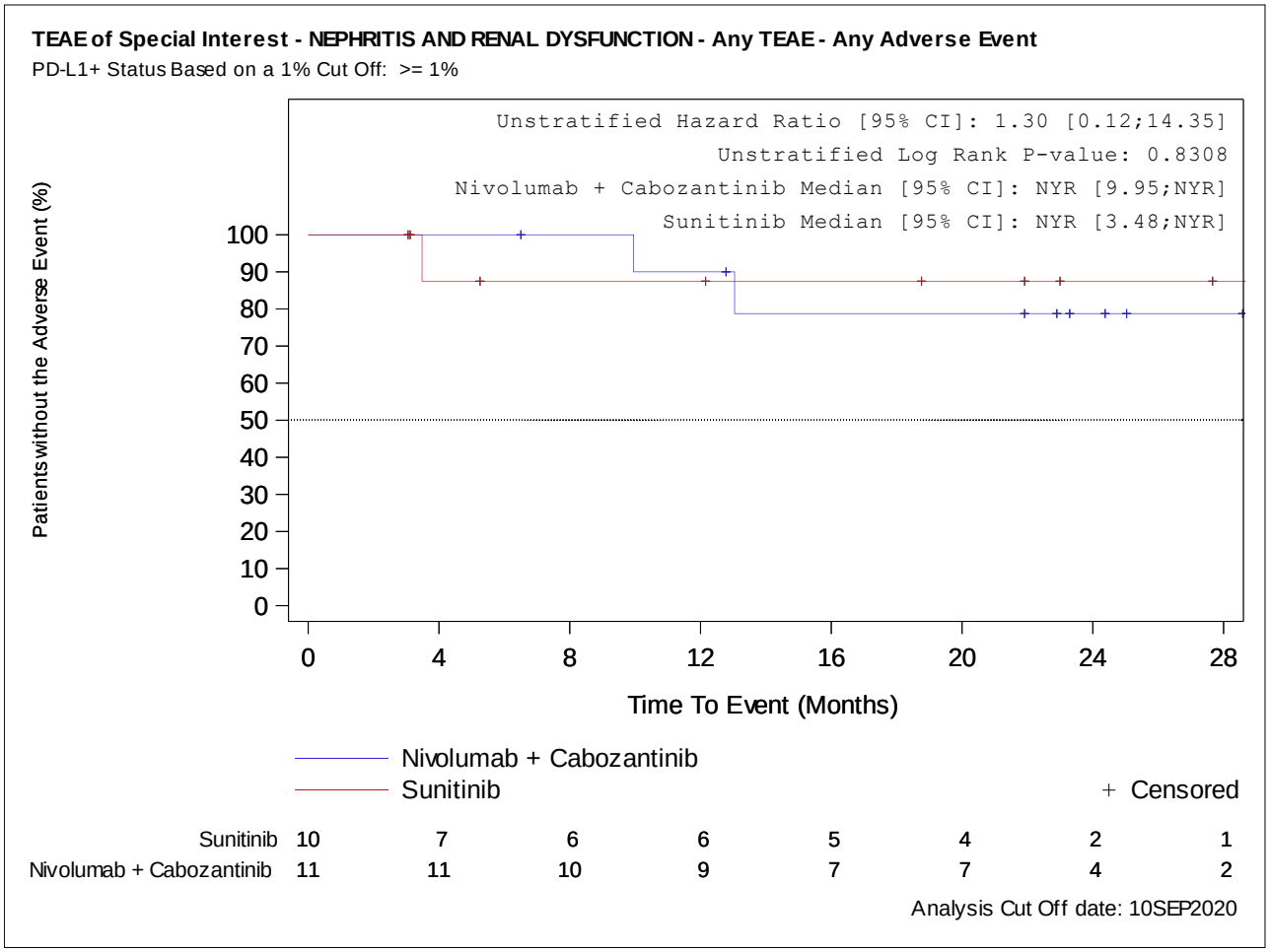

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:33:37

FIGURE 3.119.2.20: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



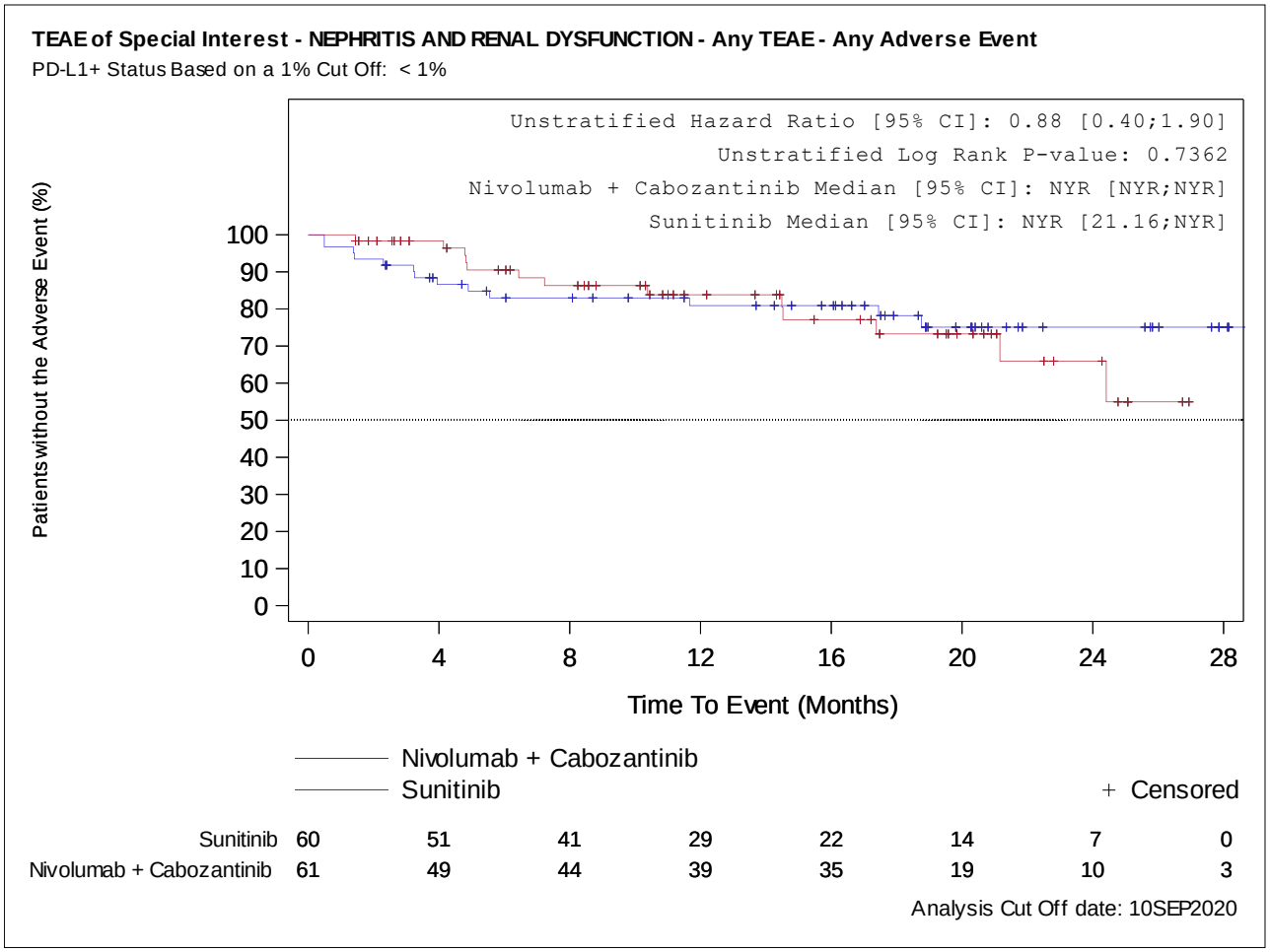

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:33:43

FIGURE 3.119.2.21: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



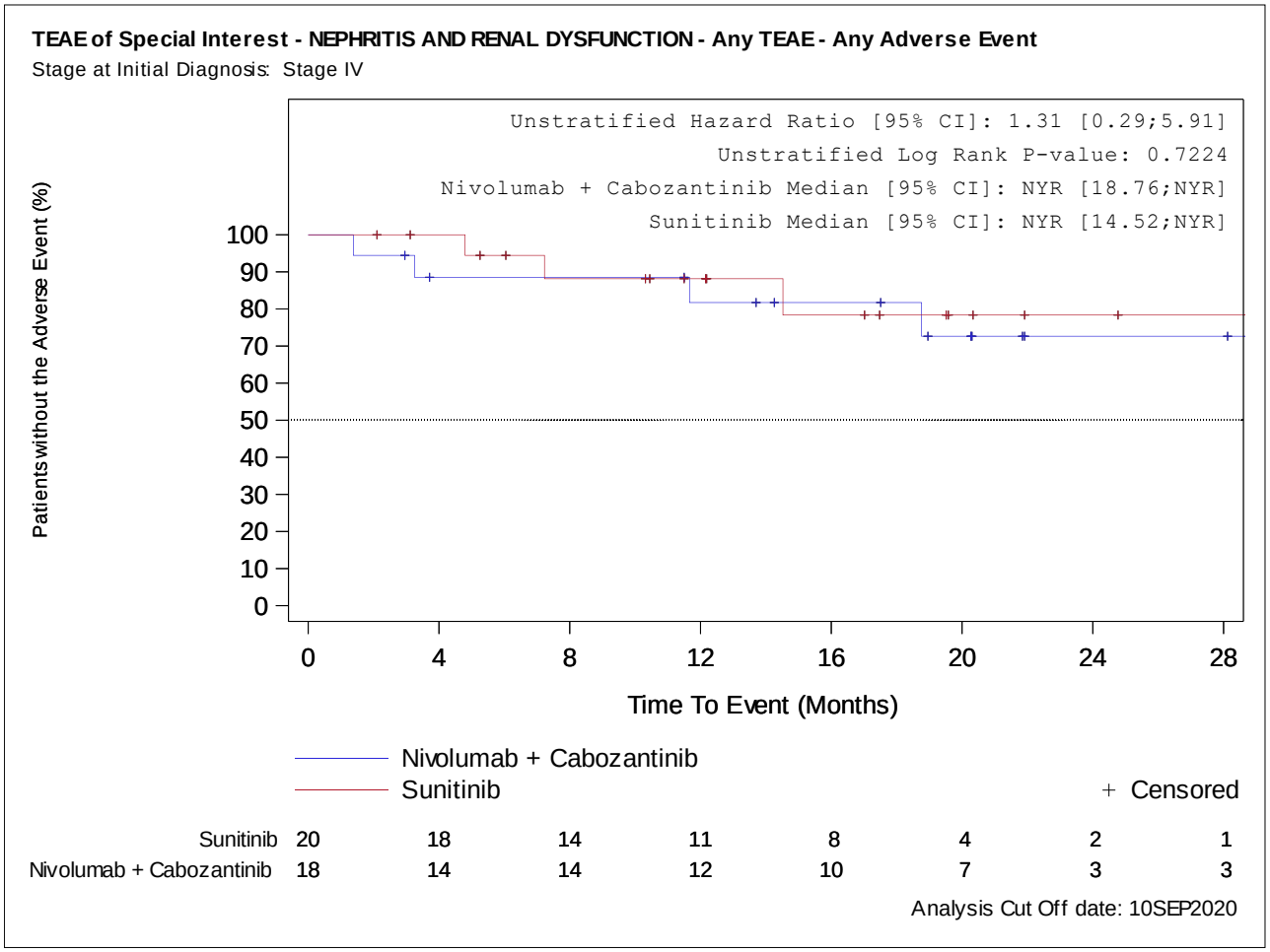

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:33:51

FIGURE 3.119.2.22: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



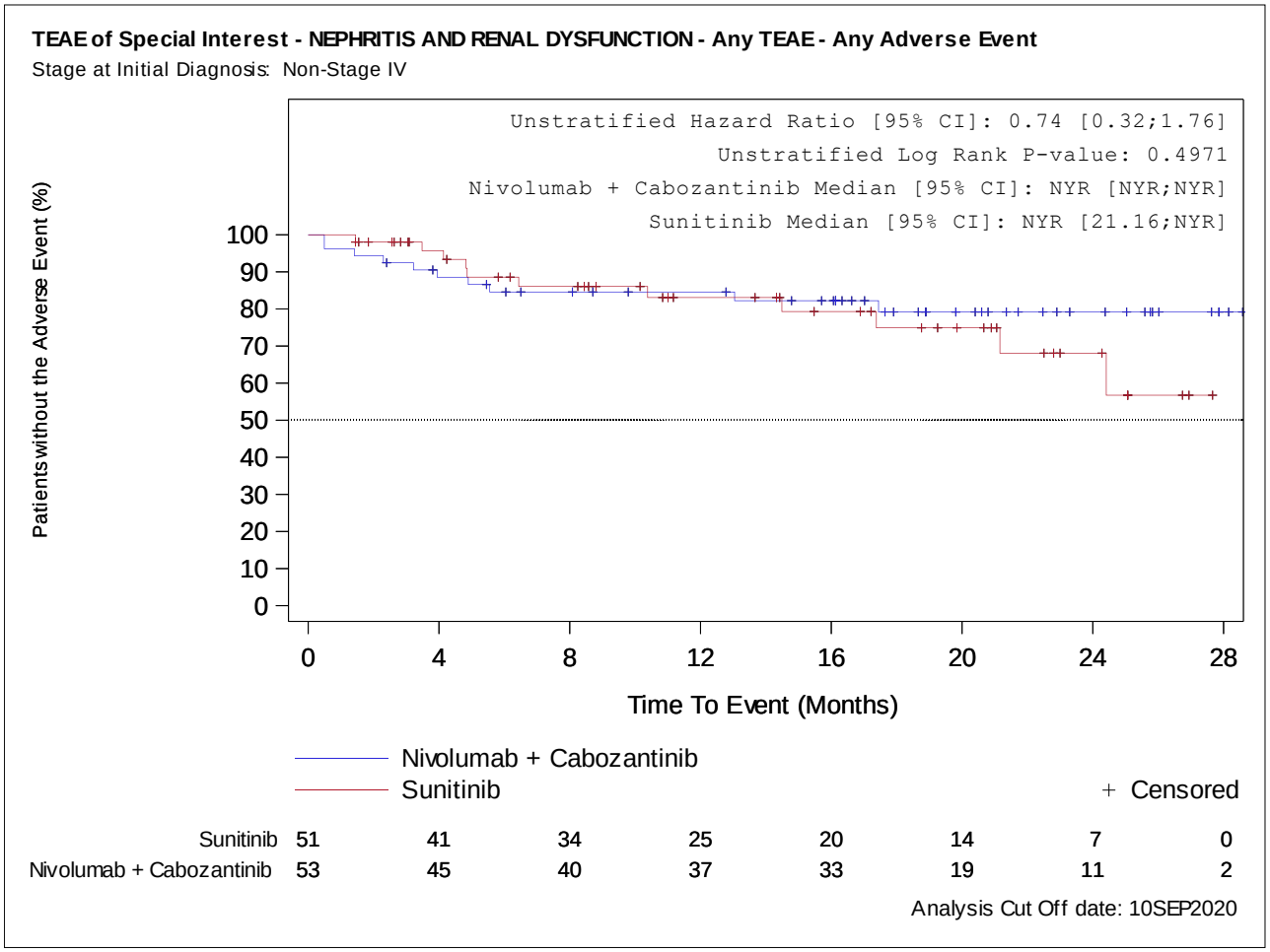

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:33:57

FIGURE 3.119.2.23: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



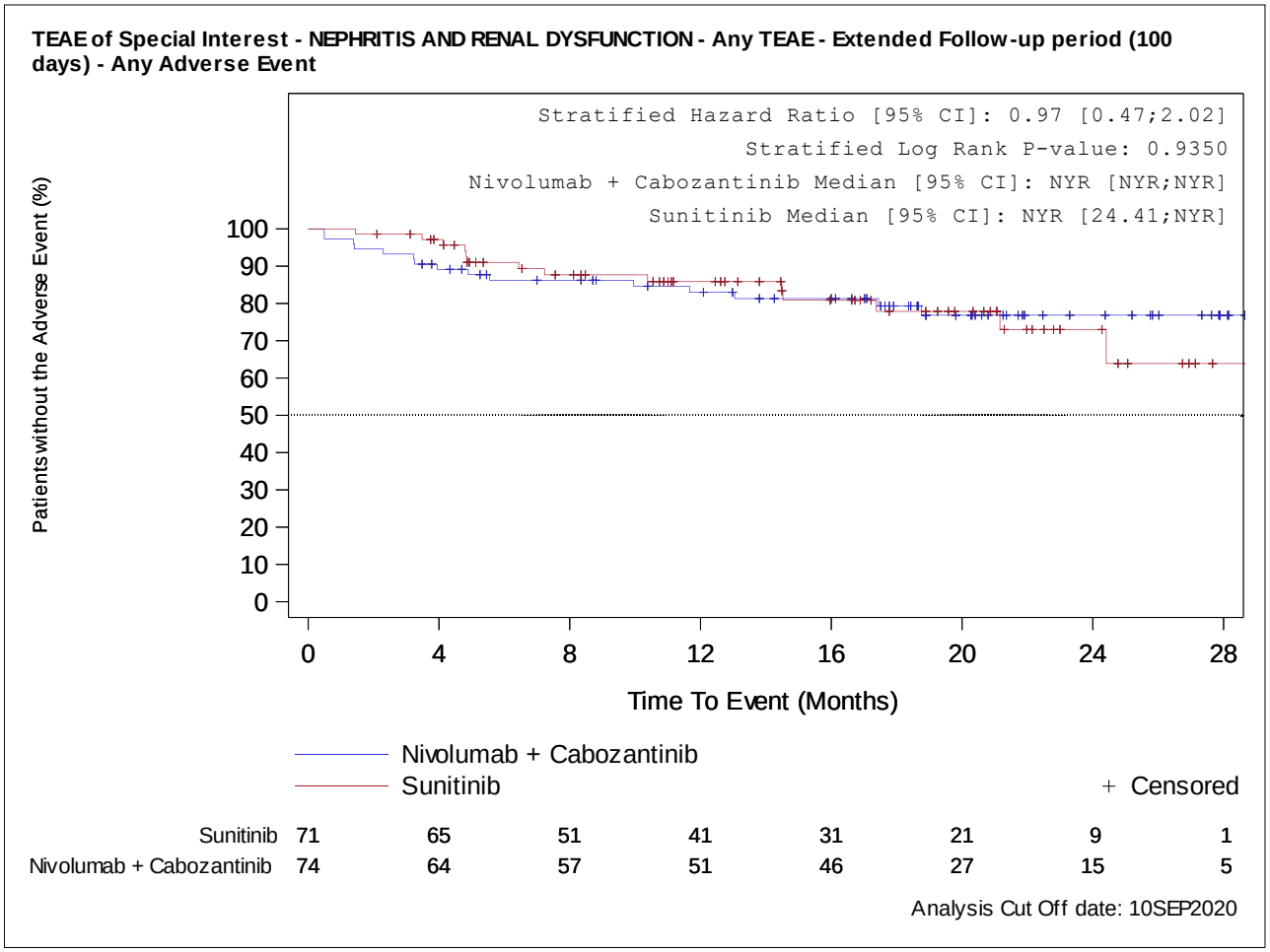

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:34:30

FIGURE 3.119.2.24: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



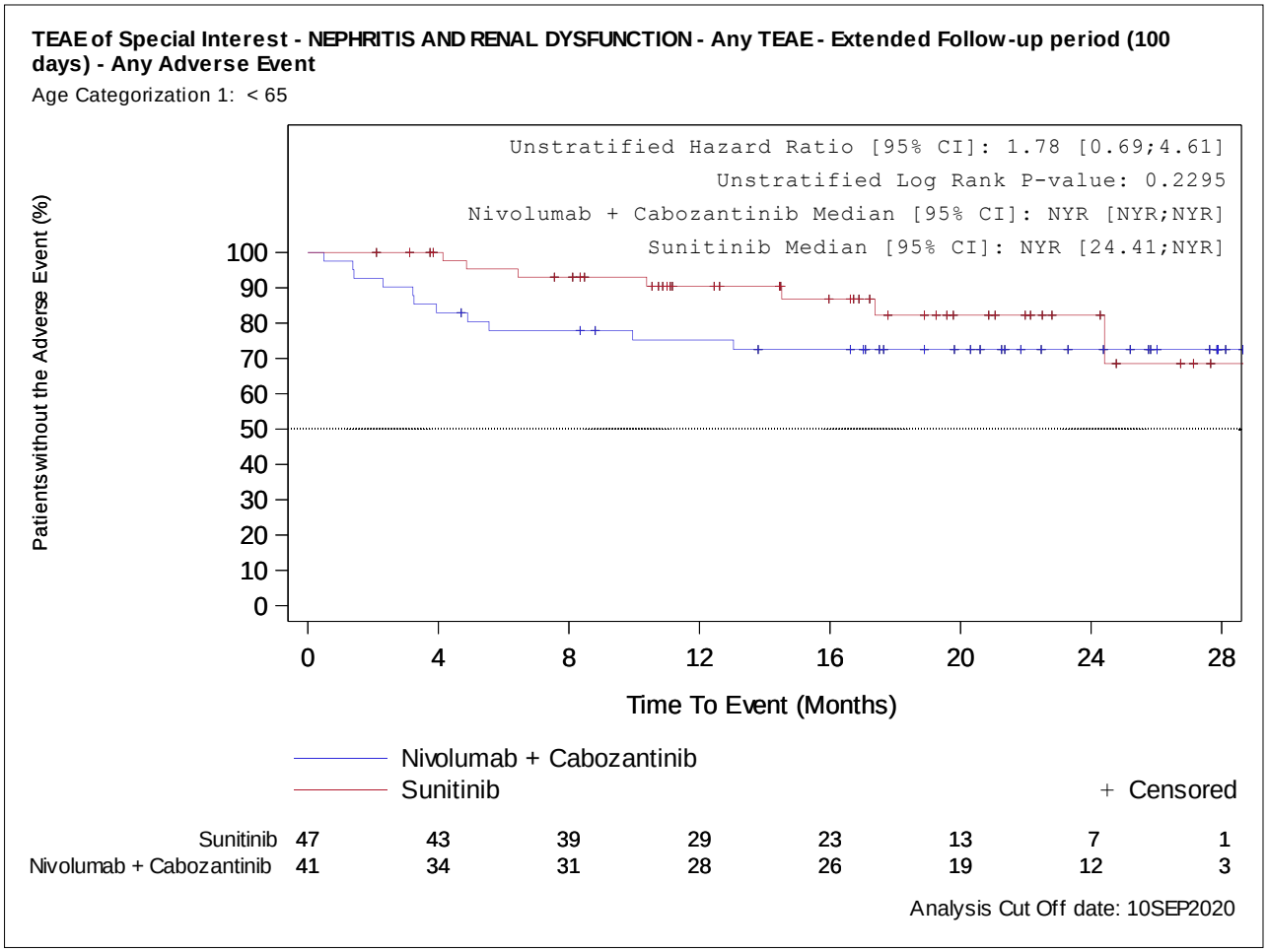

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:34:37

FIGURE 3.120.1: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



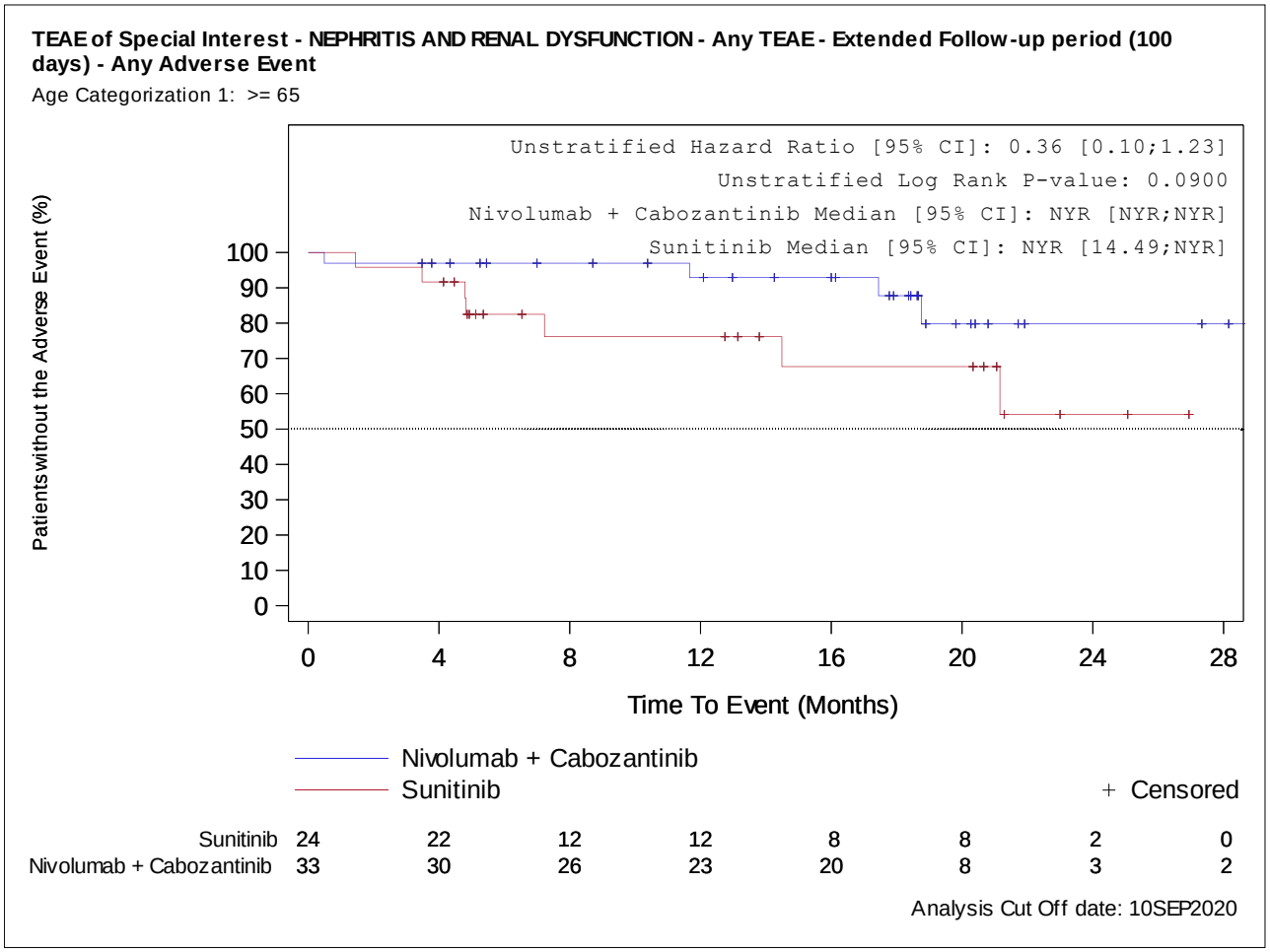

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:38:06

FIGURE 3.120.2.1: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



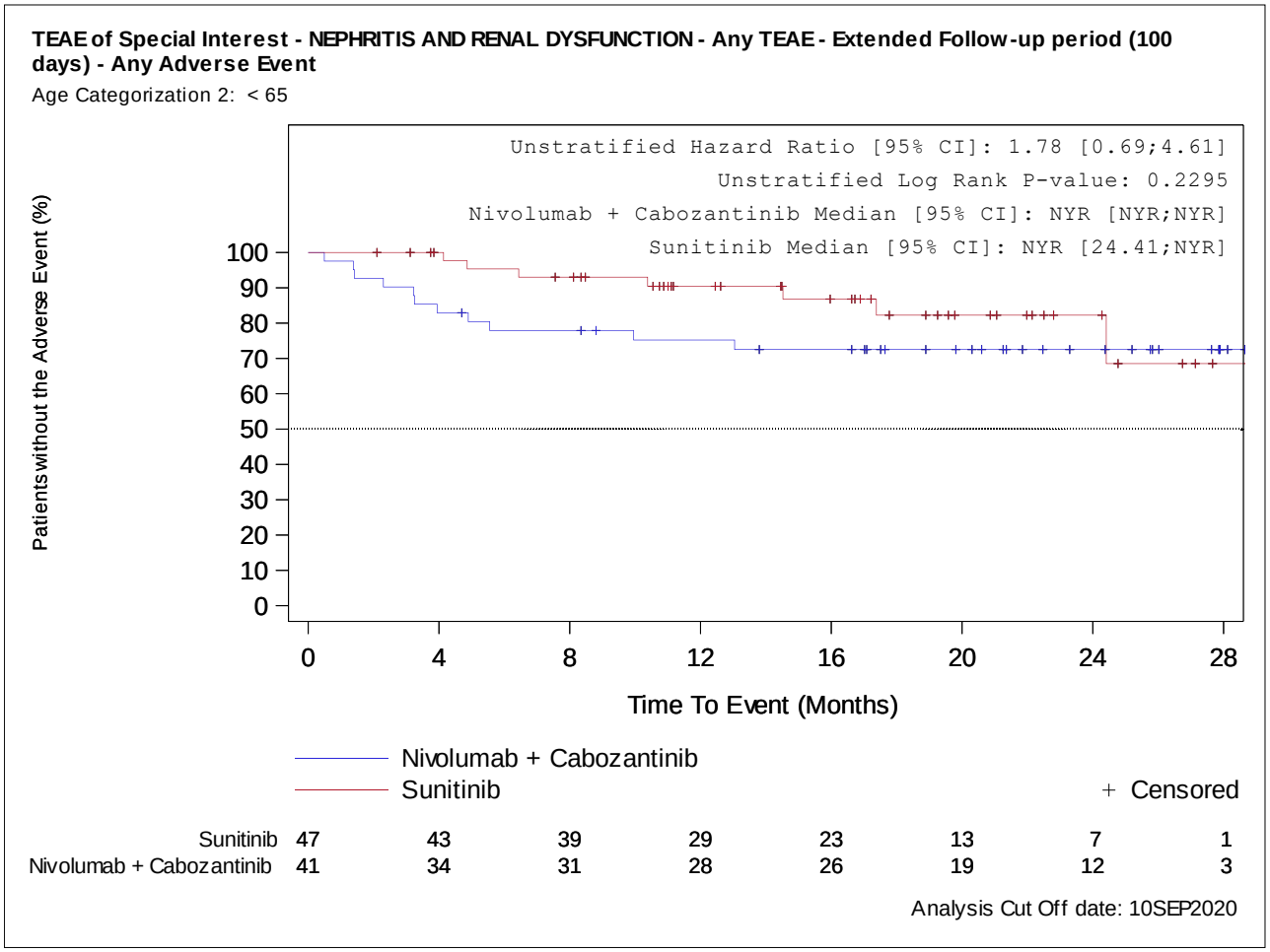

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:38:09

FIGURE 3.120.2.2: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



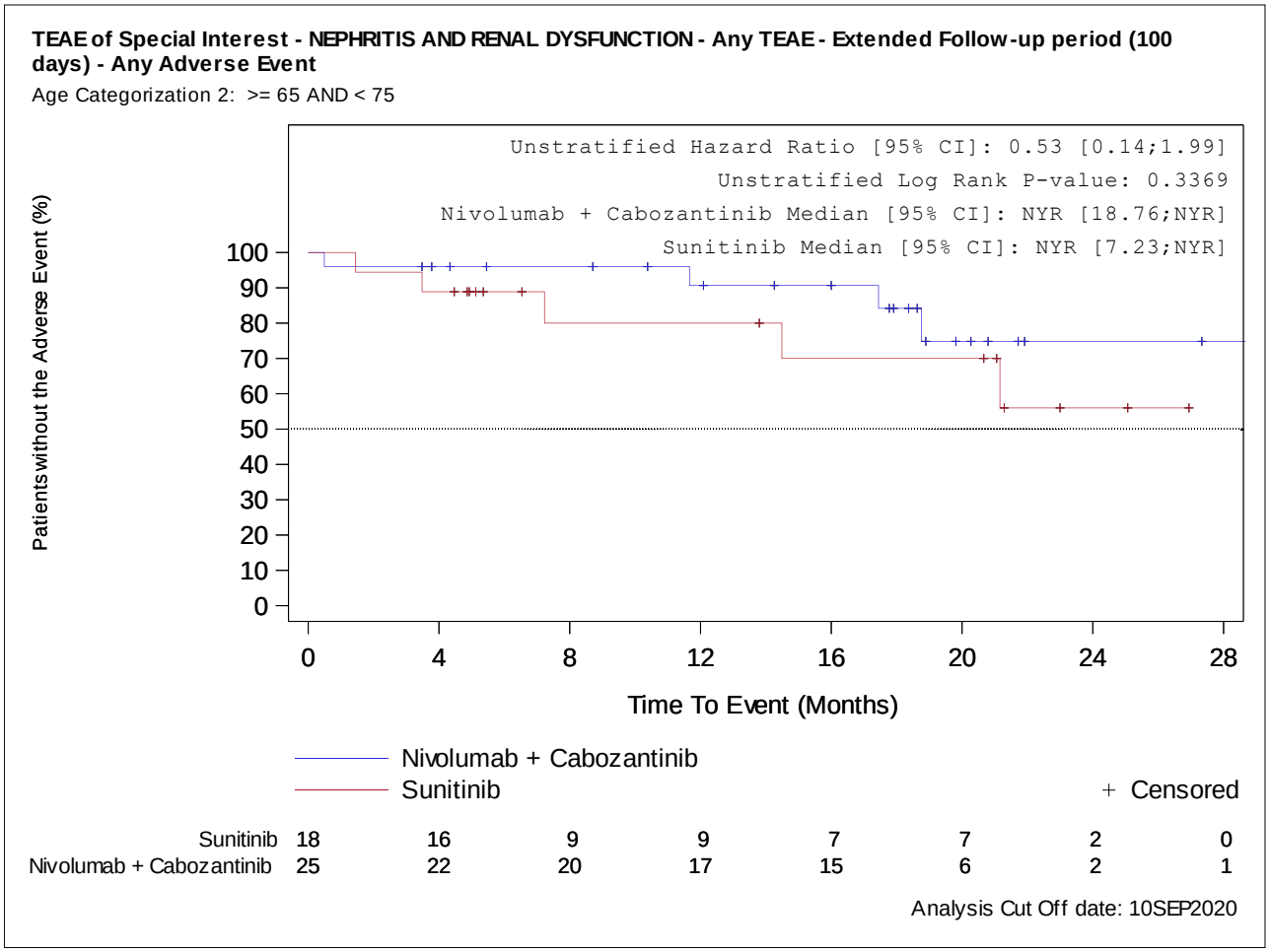

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:38:16

FIGURE 3.120.2.3: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



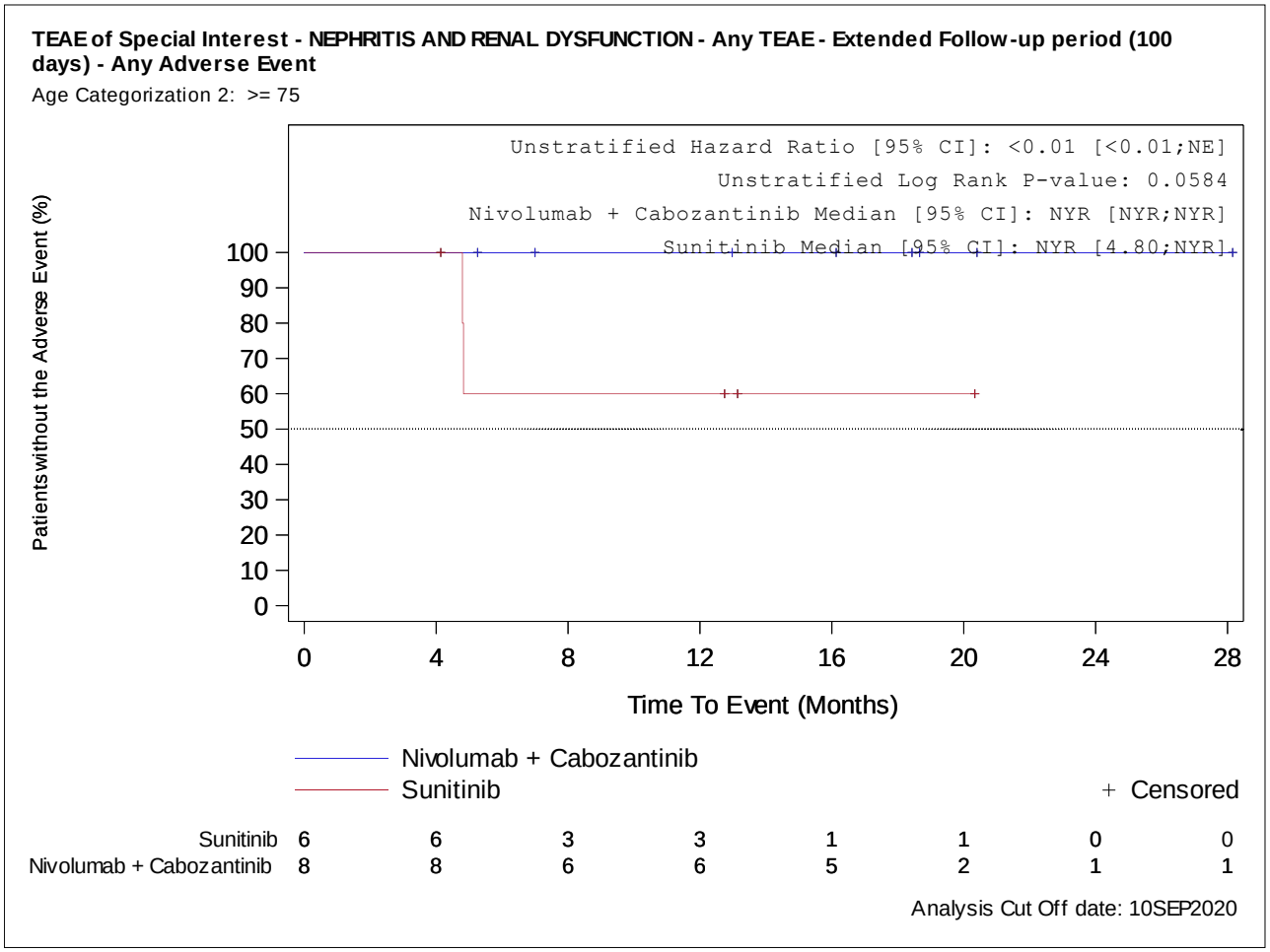

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:38:21

FIGURE 3.120.2.4: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



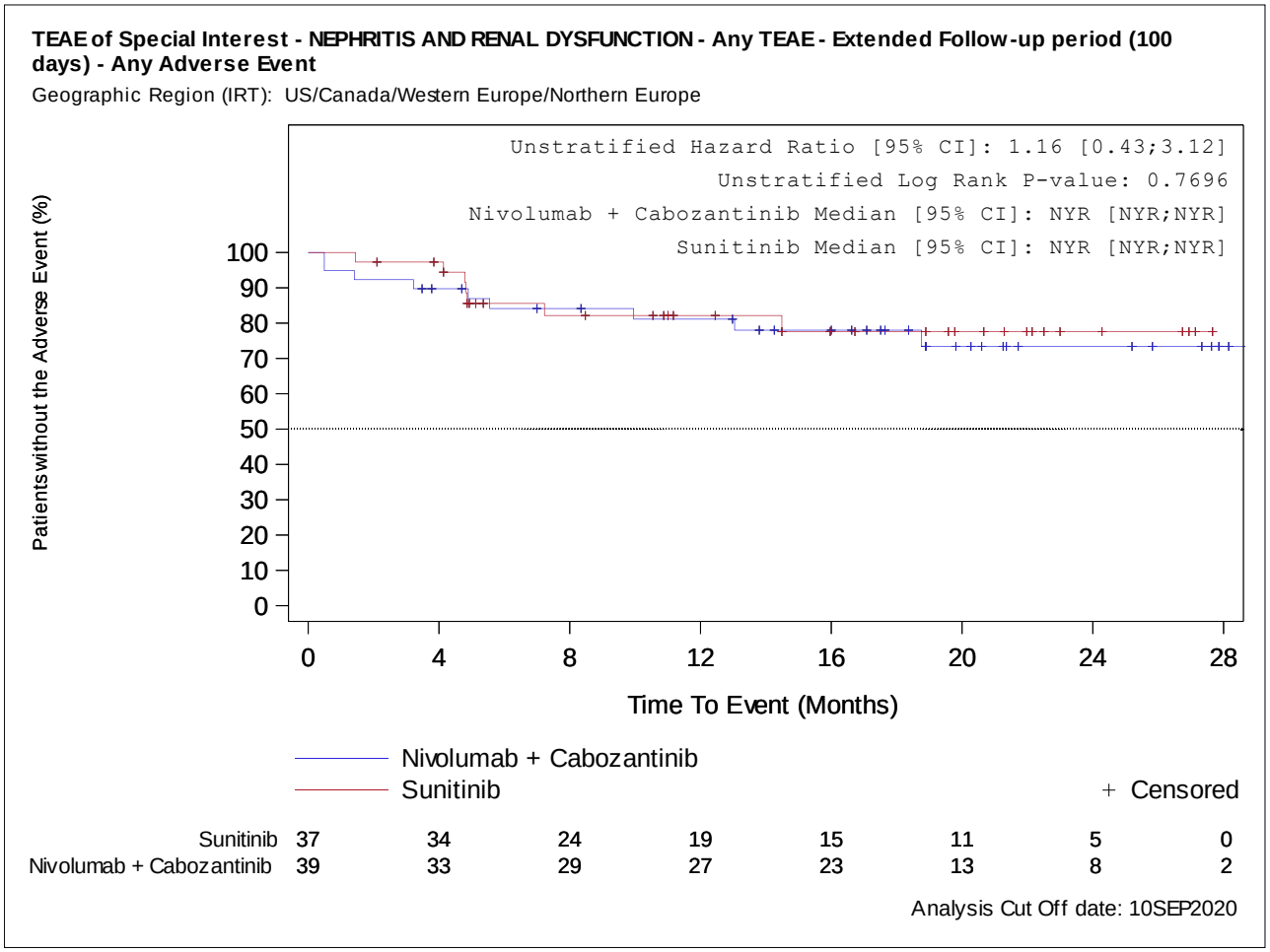

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:38:27

FIGURE 3.120.2.5: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



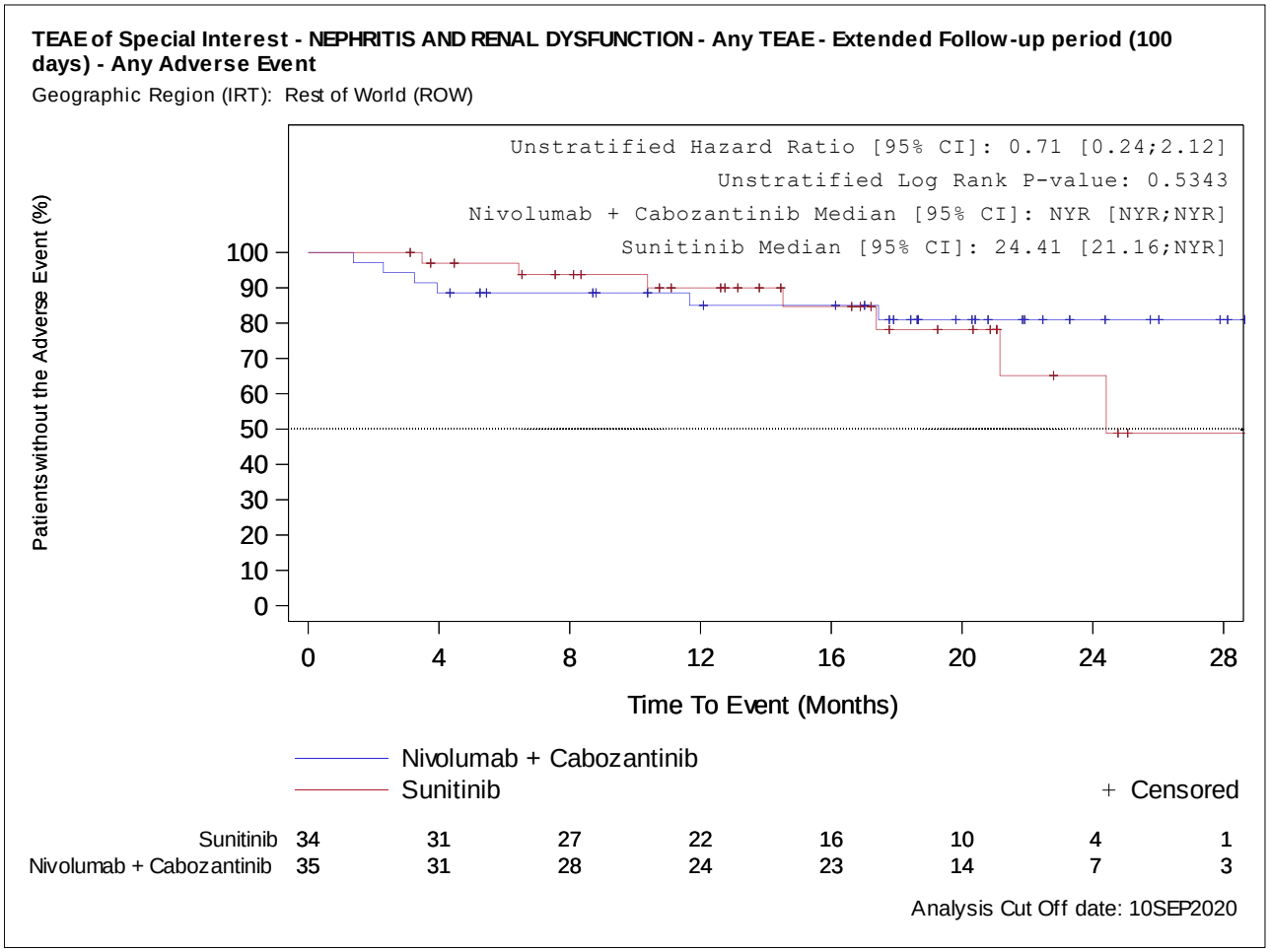

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:38:33

FIGURE 3.120.2.6: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



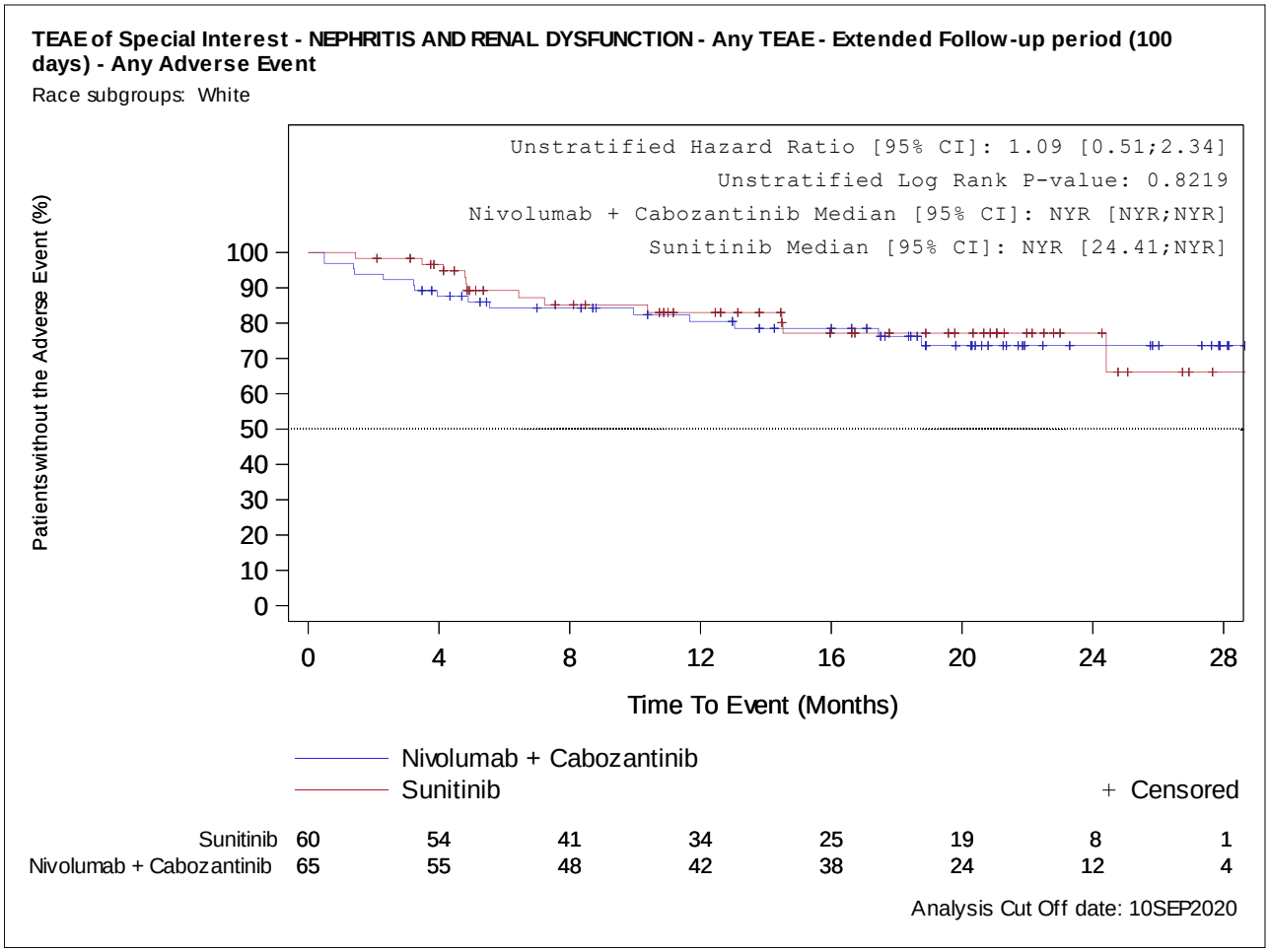

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:38:39

FIGURE 3.120.2.7: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



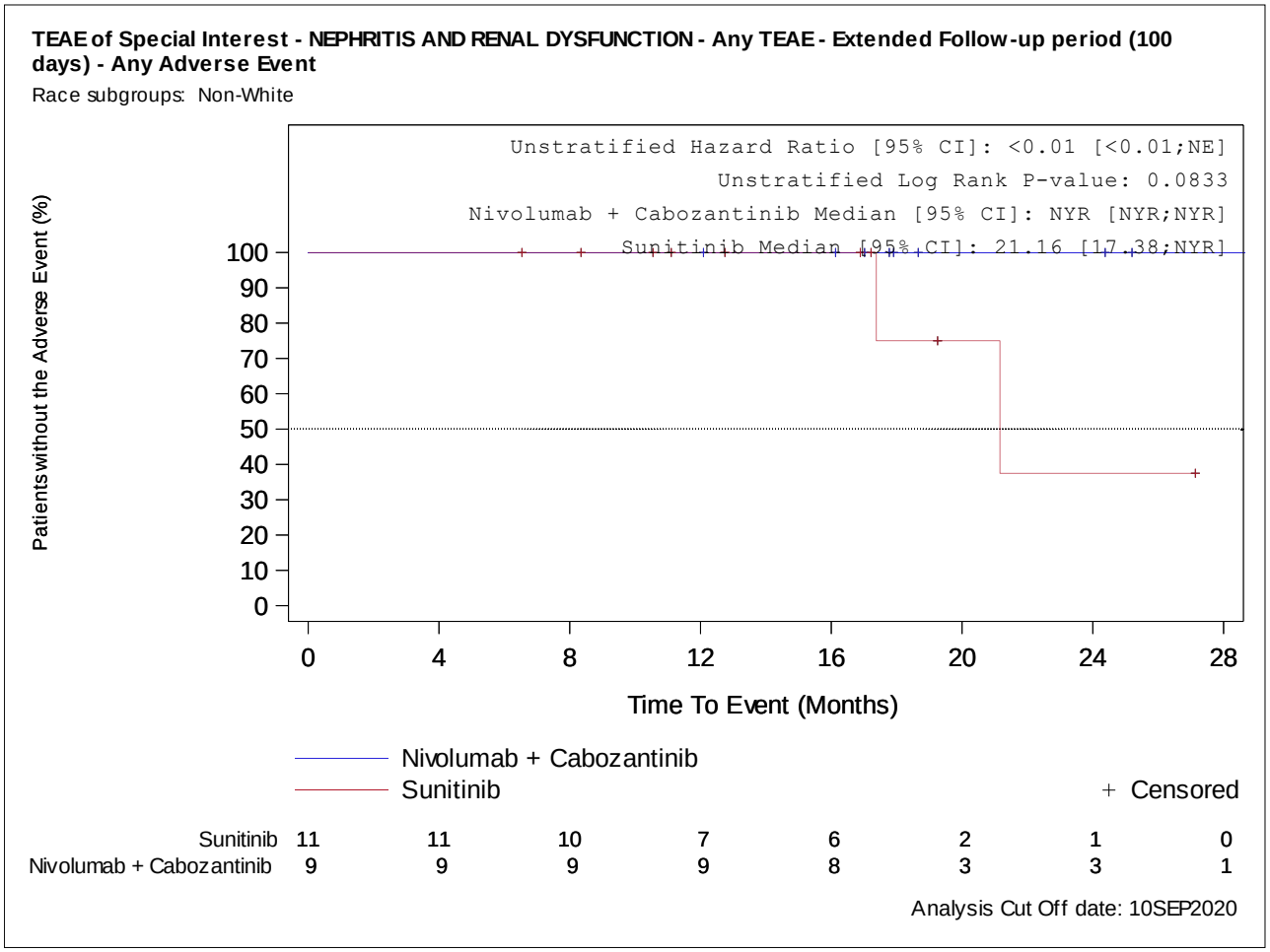

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:38:45

FIGURE 3.120.2.8: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



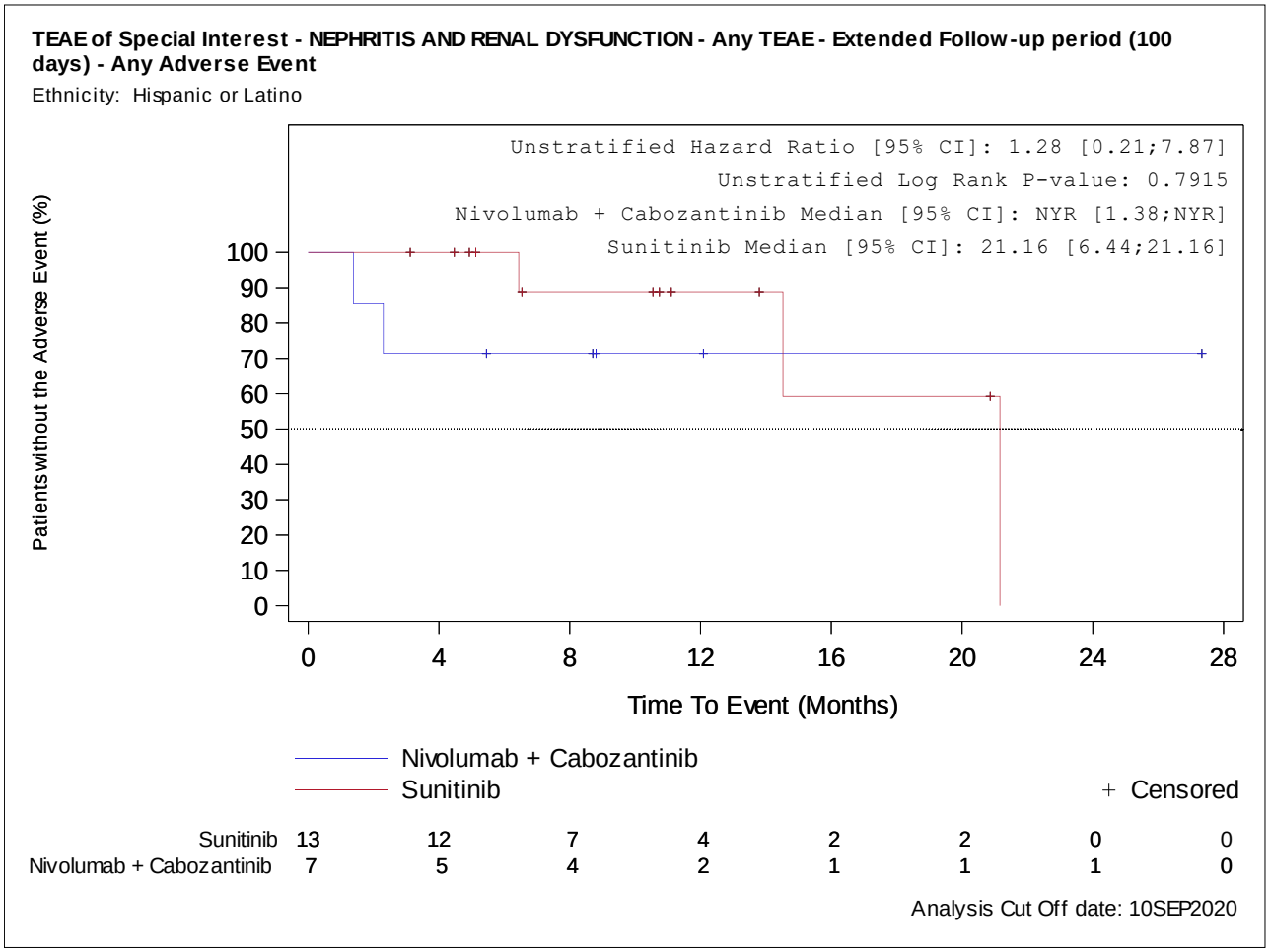

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:38:51

FIGURE 3.120.2.9: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



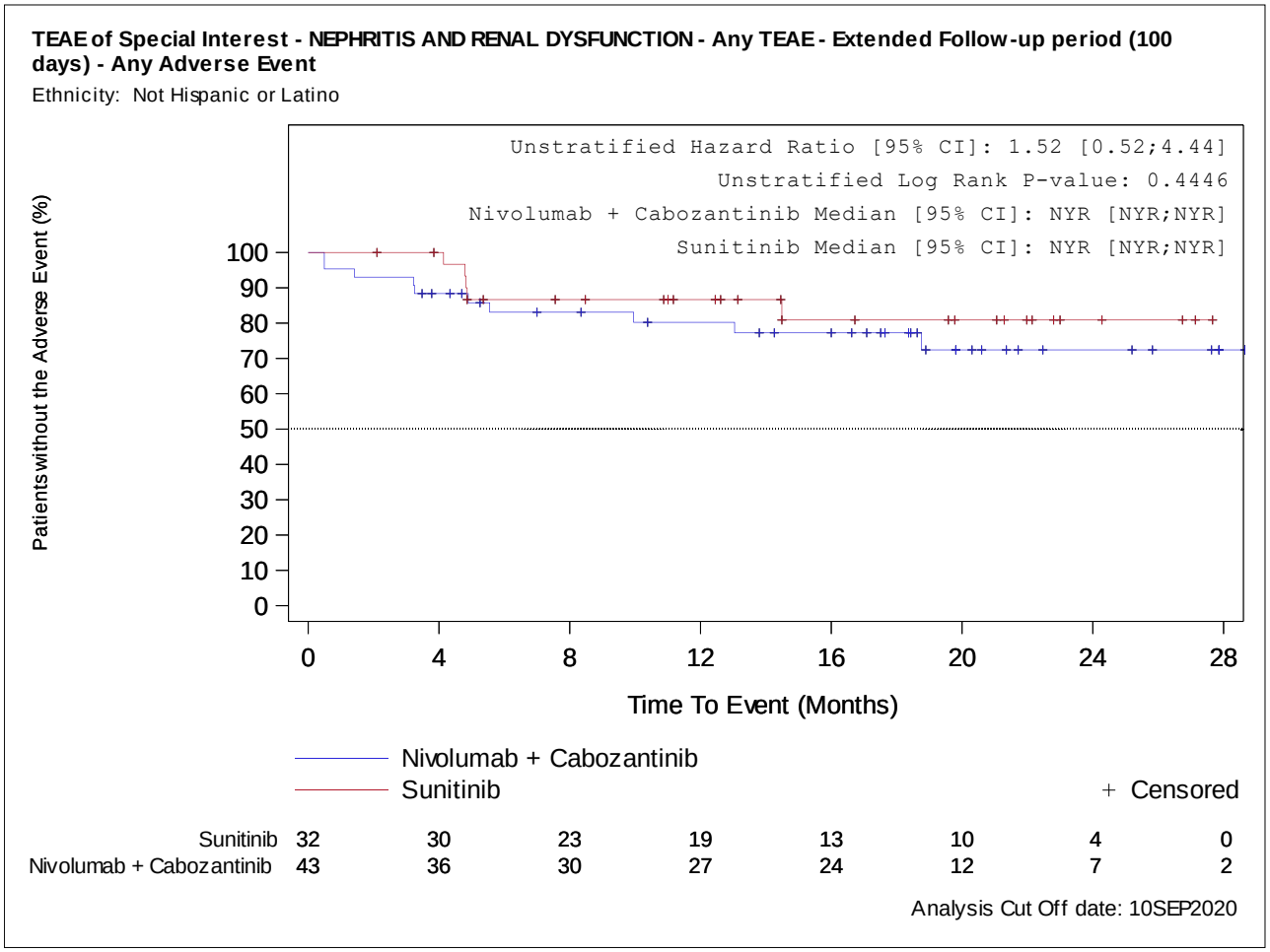

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:38:57

FIGURE 3.120.2.10: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



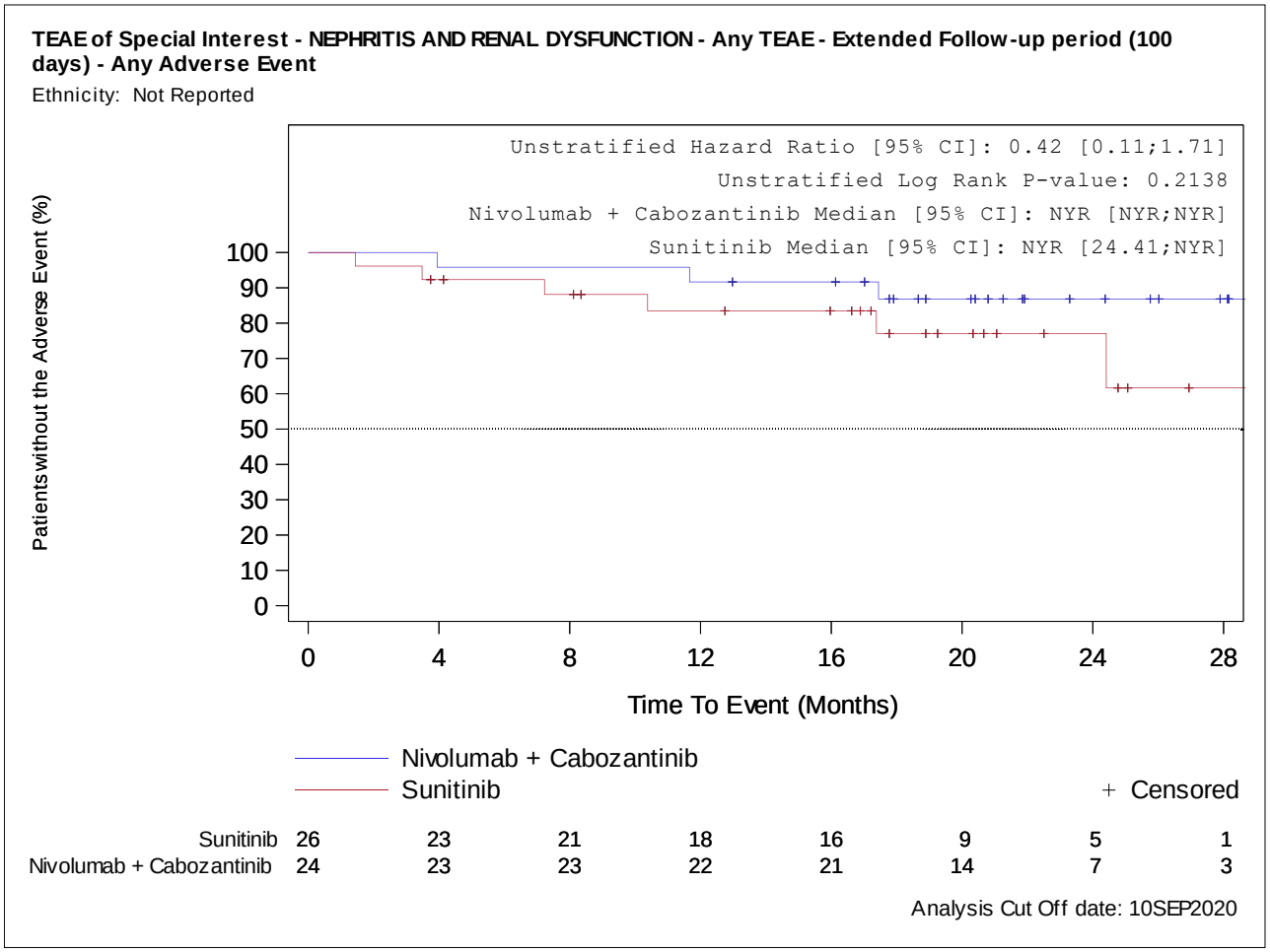

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:39:04

FIGURE 3.120.2.11: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



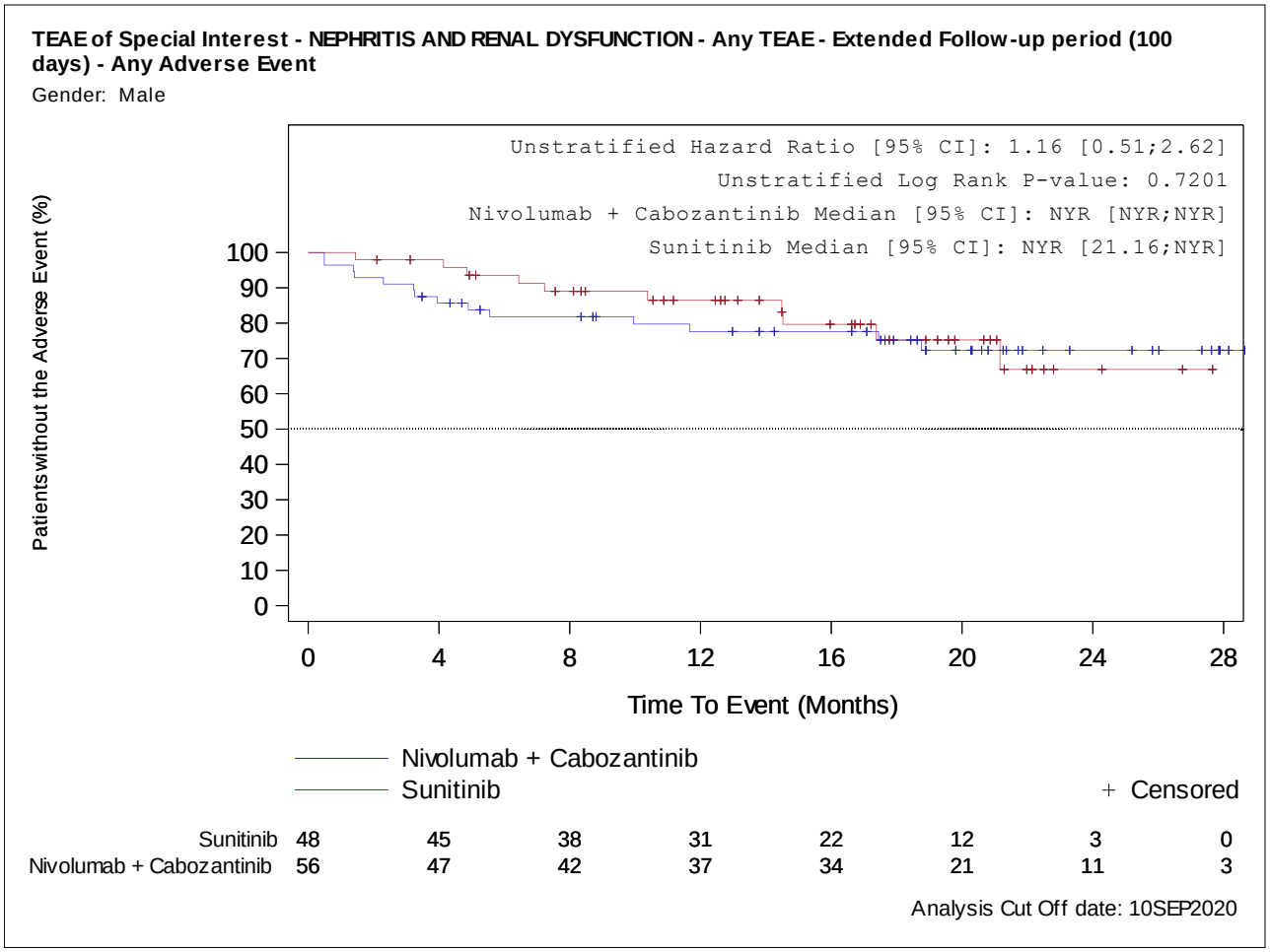

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:39:10

FIGURE 3.120.2.12: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



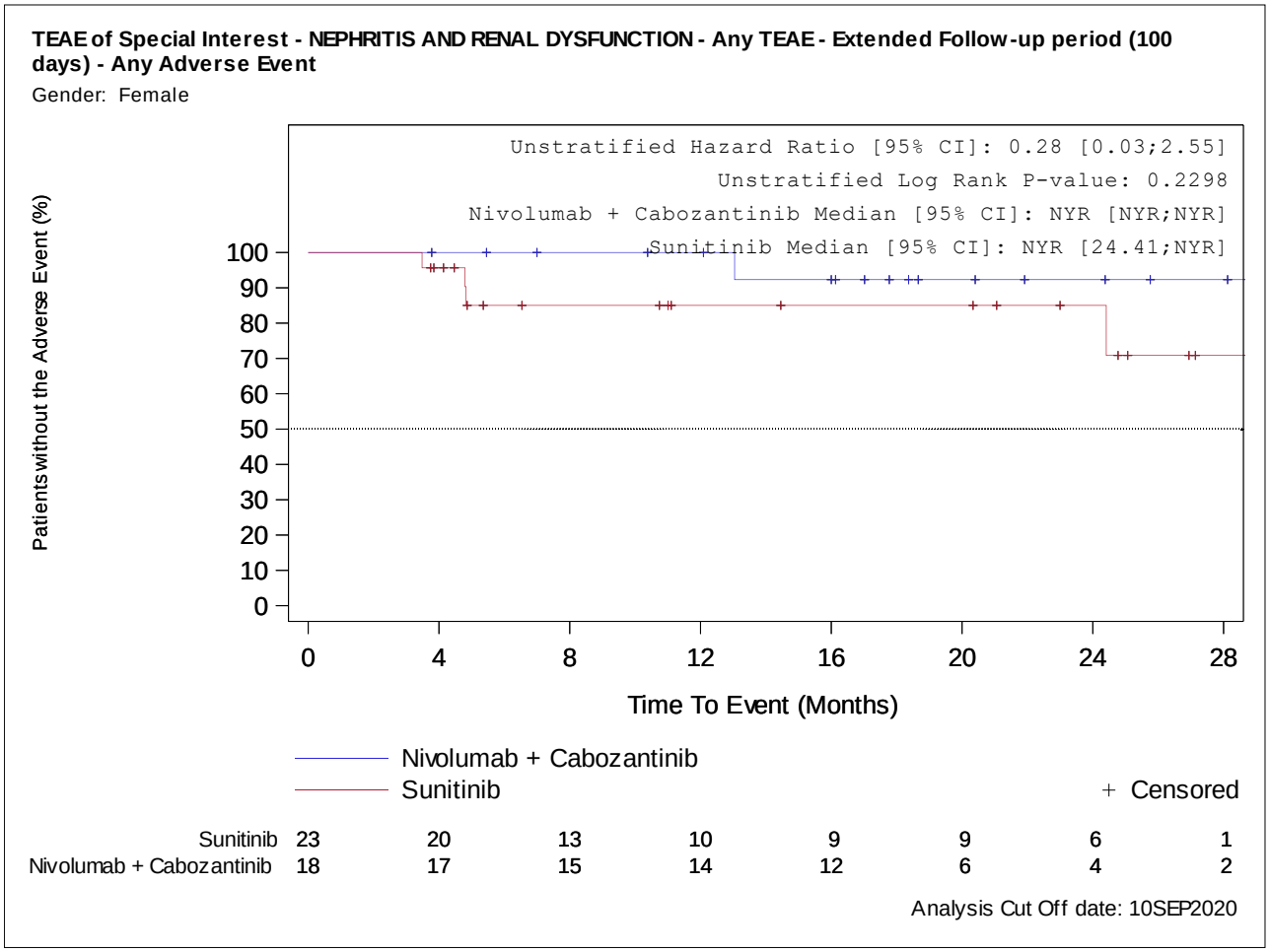

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:39:17

FIGURE 3.120.2.13: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:39:24

FIGURE 3.120.2.14: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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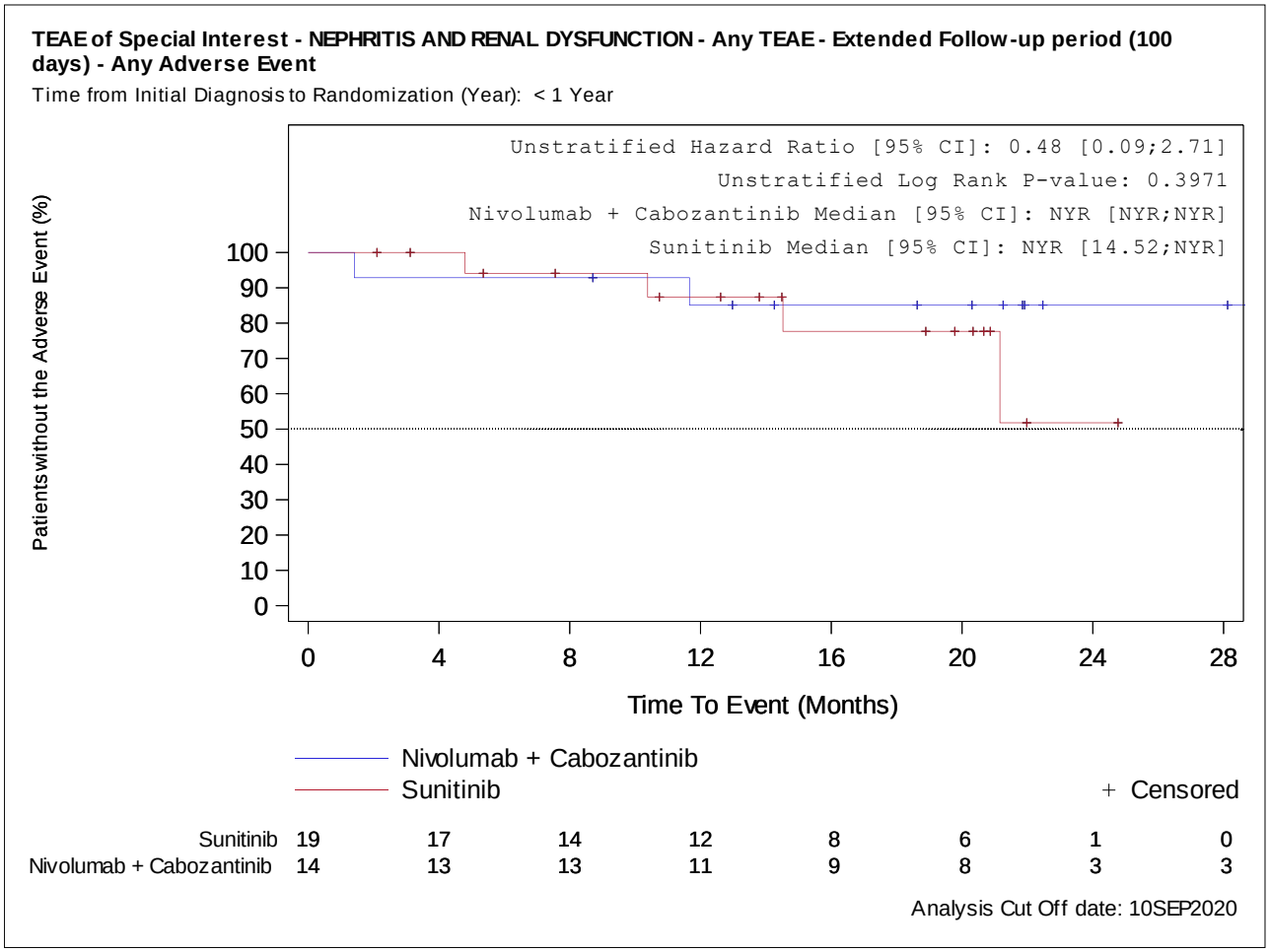
FIGURE 3.120.2.15: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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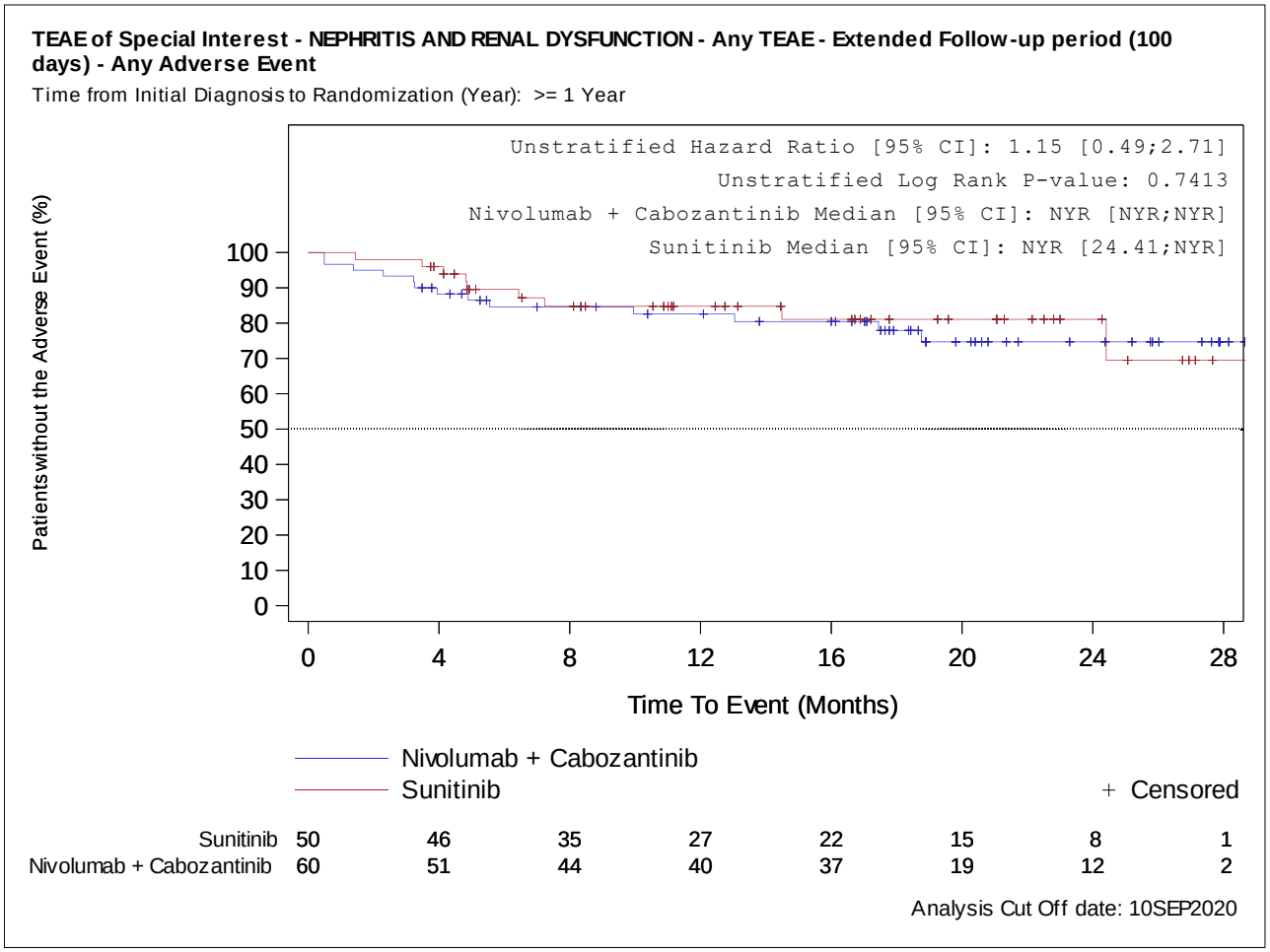
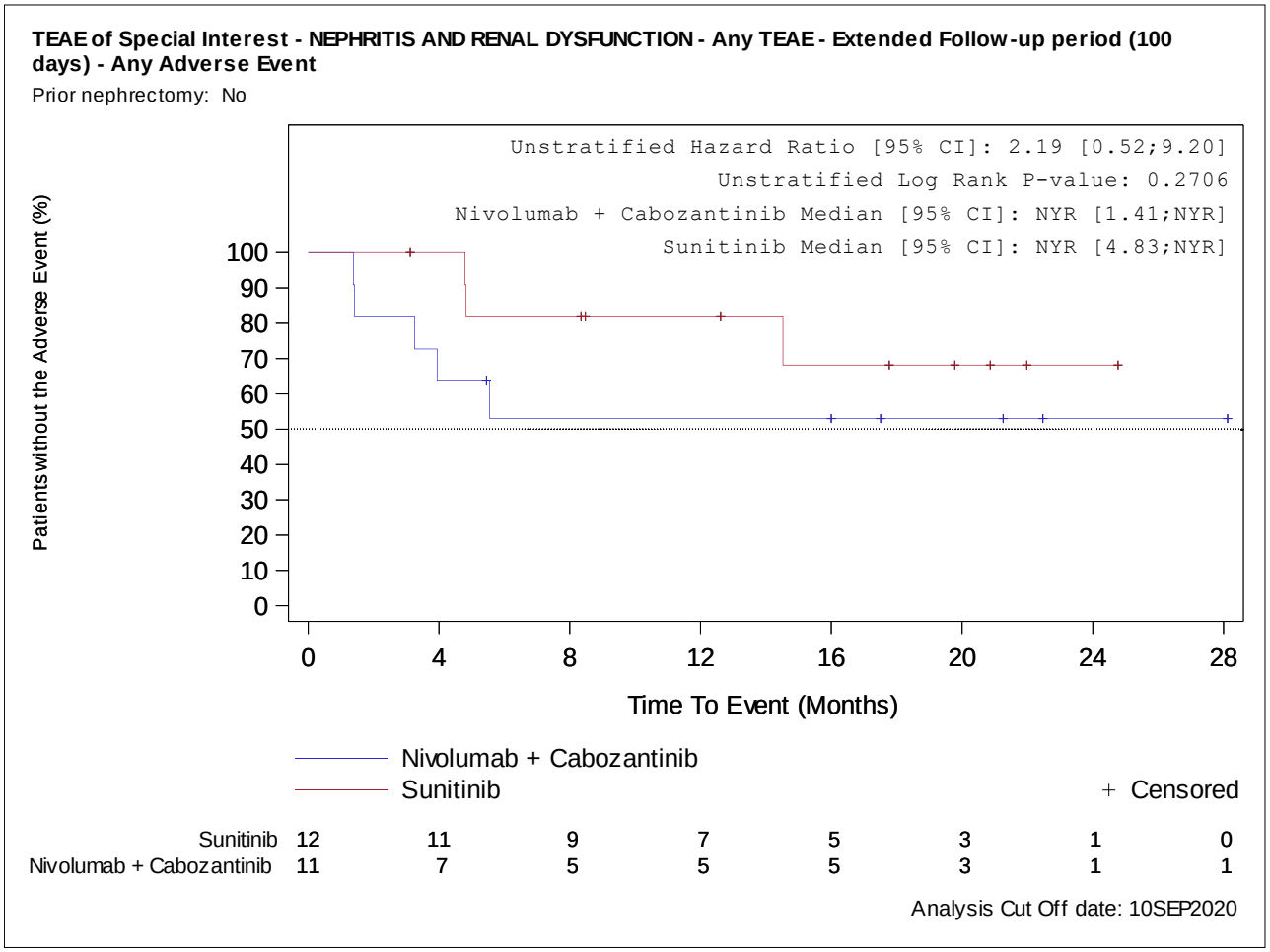
FIGURE 3.120.2.16: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



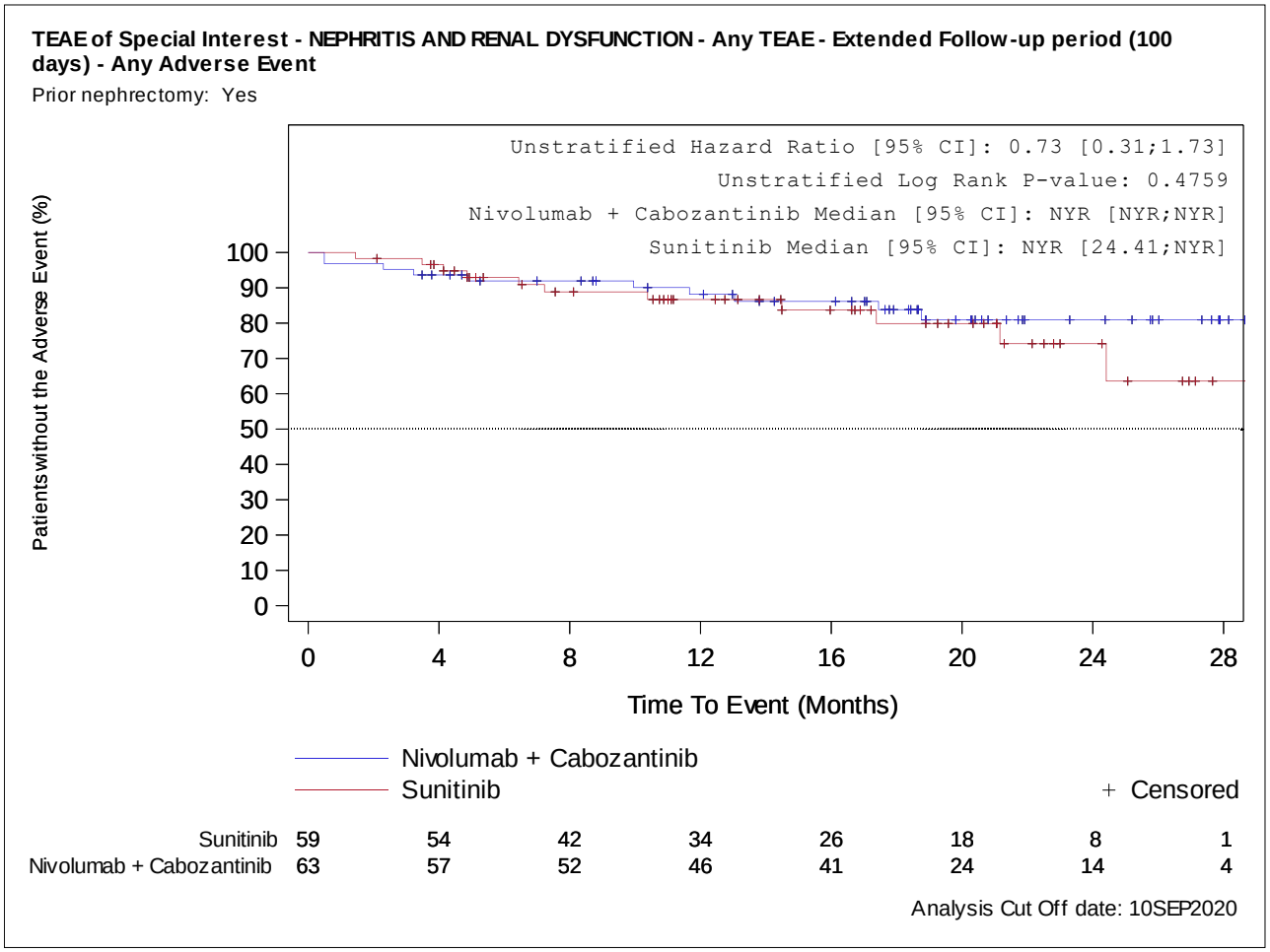

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:39:56

FIGURE 3.120.2.17: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



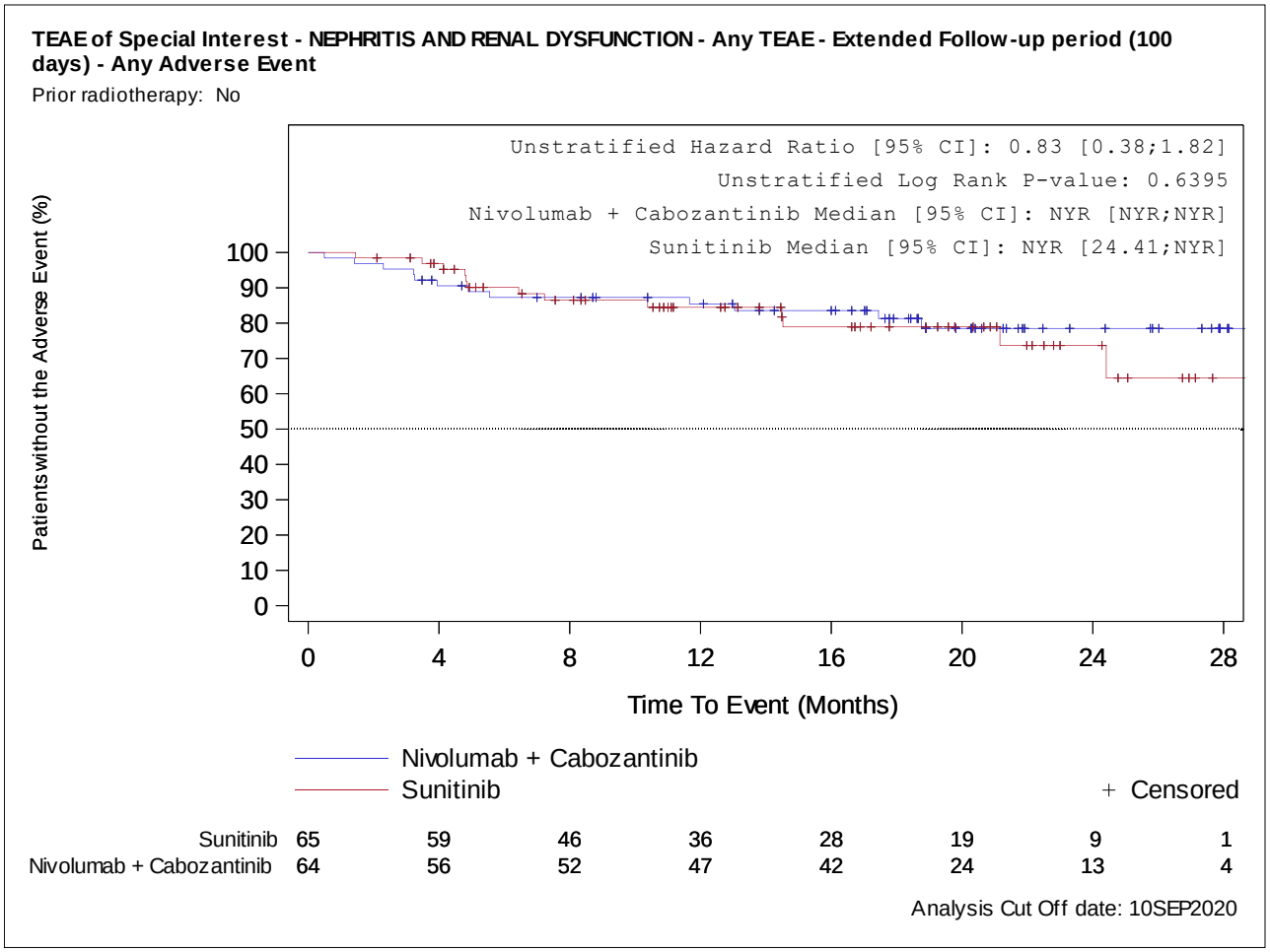

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:40:54

FIGURE 3.120.2.18: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



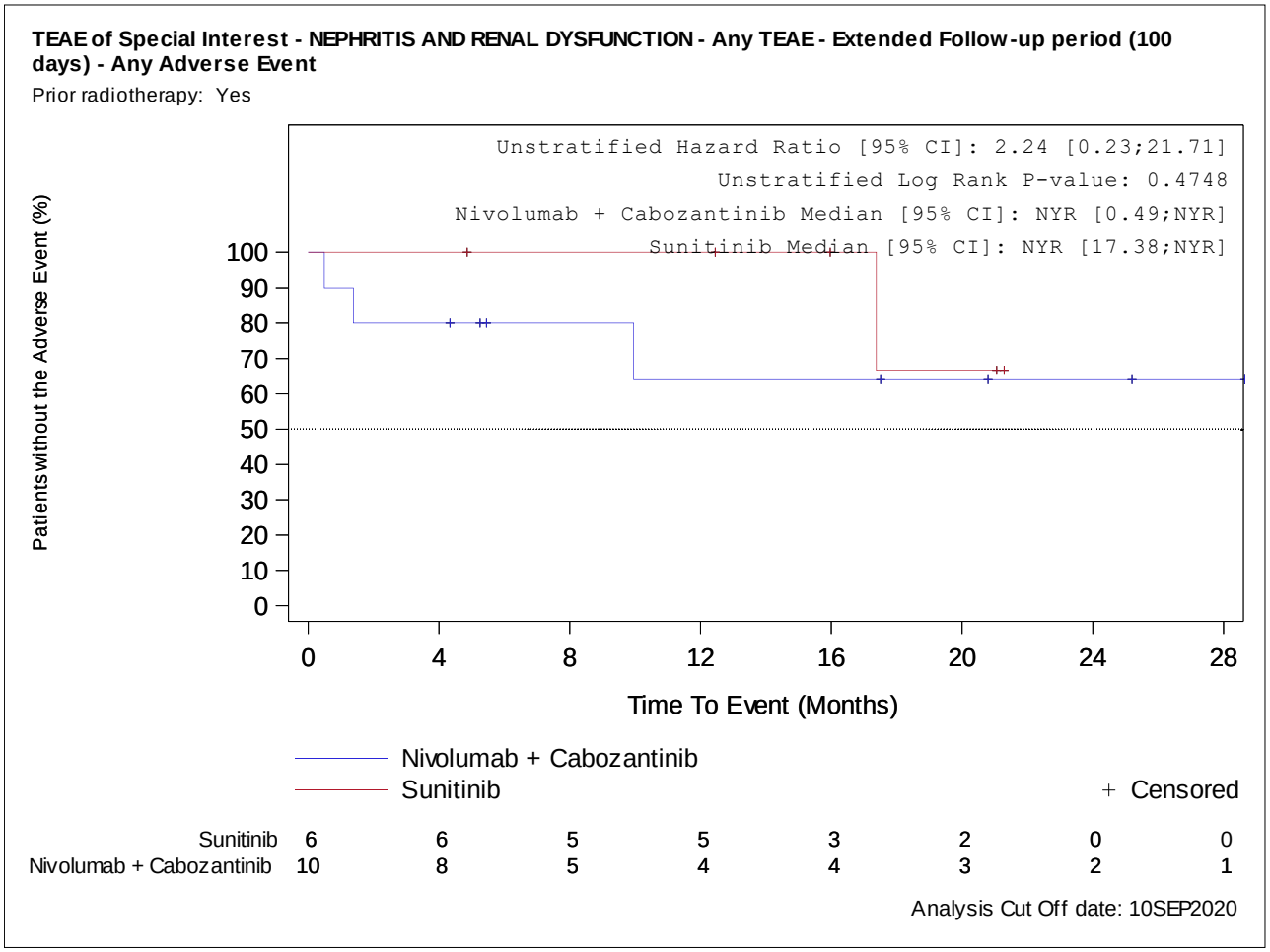

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:41:01

FIGURE 3.120.2.19: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



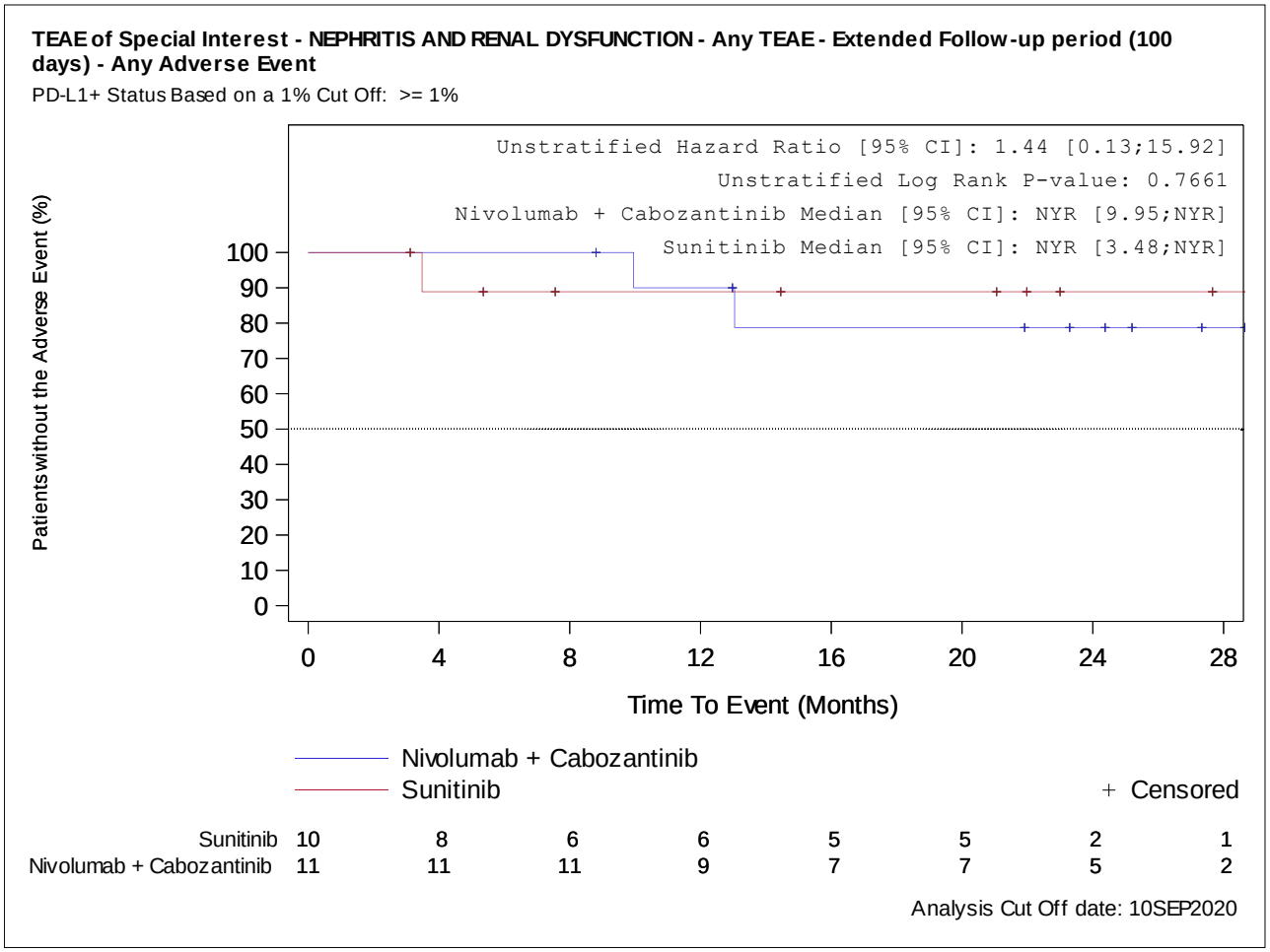

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:41:07

FIGURE 3.120.2.20: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



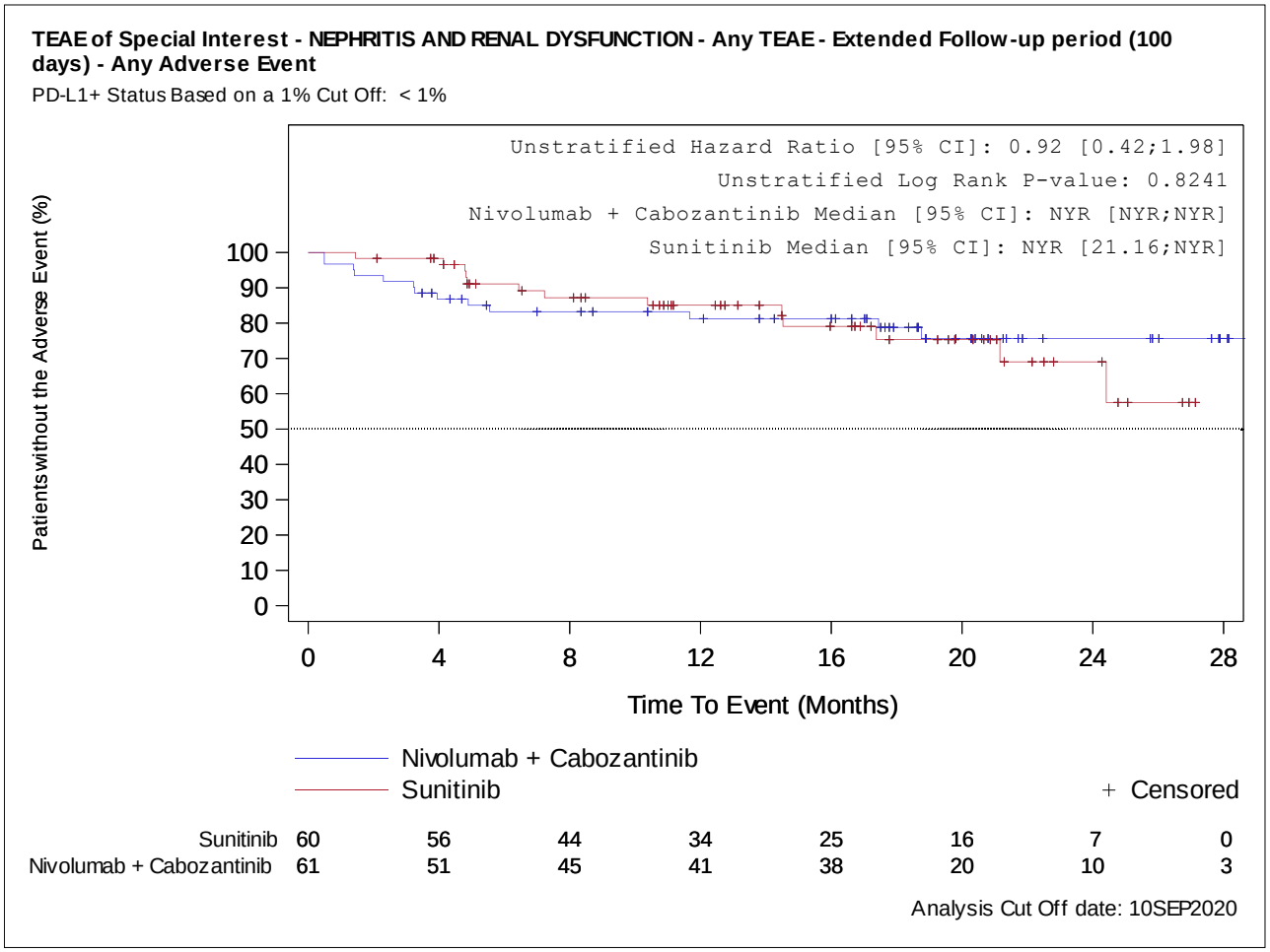

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:41:13

FIGURE 3.120.2.21: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



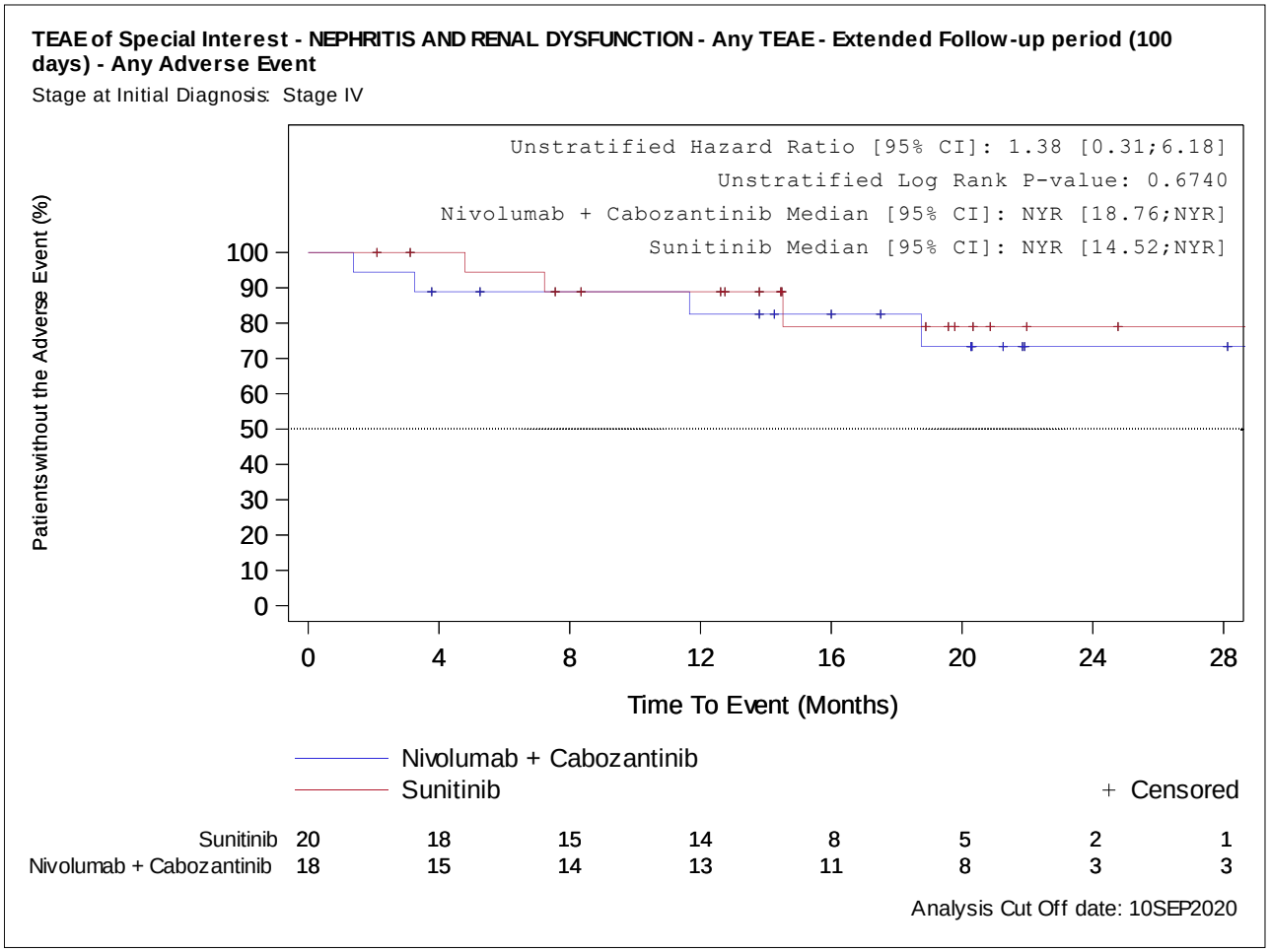

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:41:20

FIGURE 3.120.2.22: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



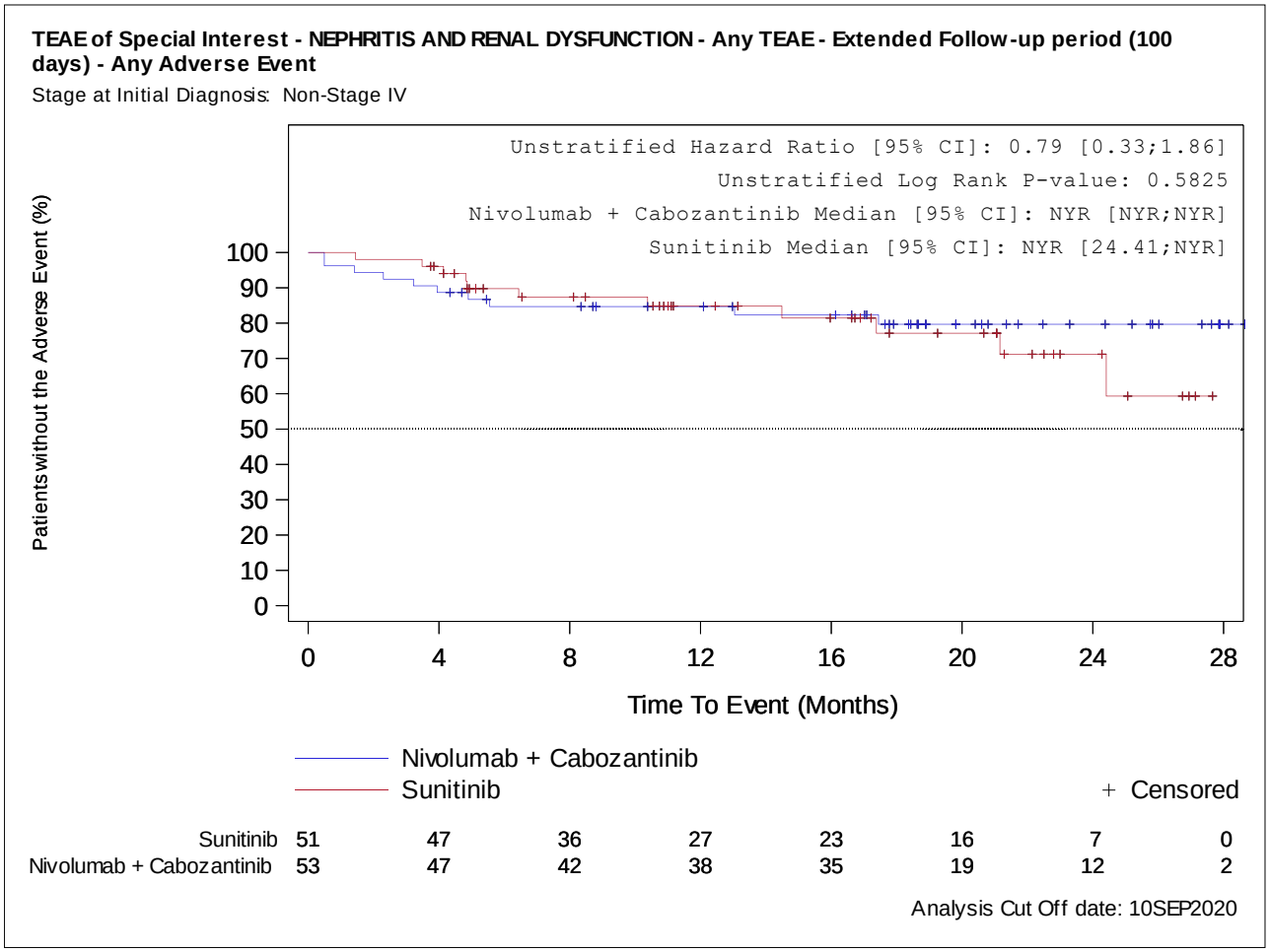

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:41:26

FIGURE 3.120.2.23: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



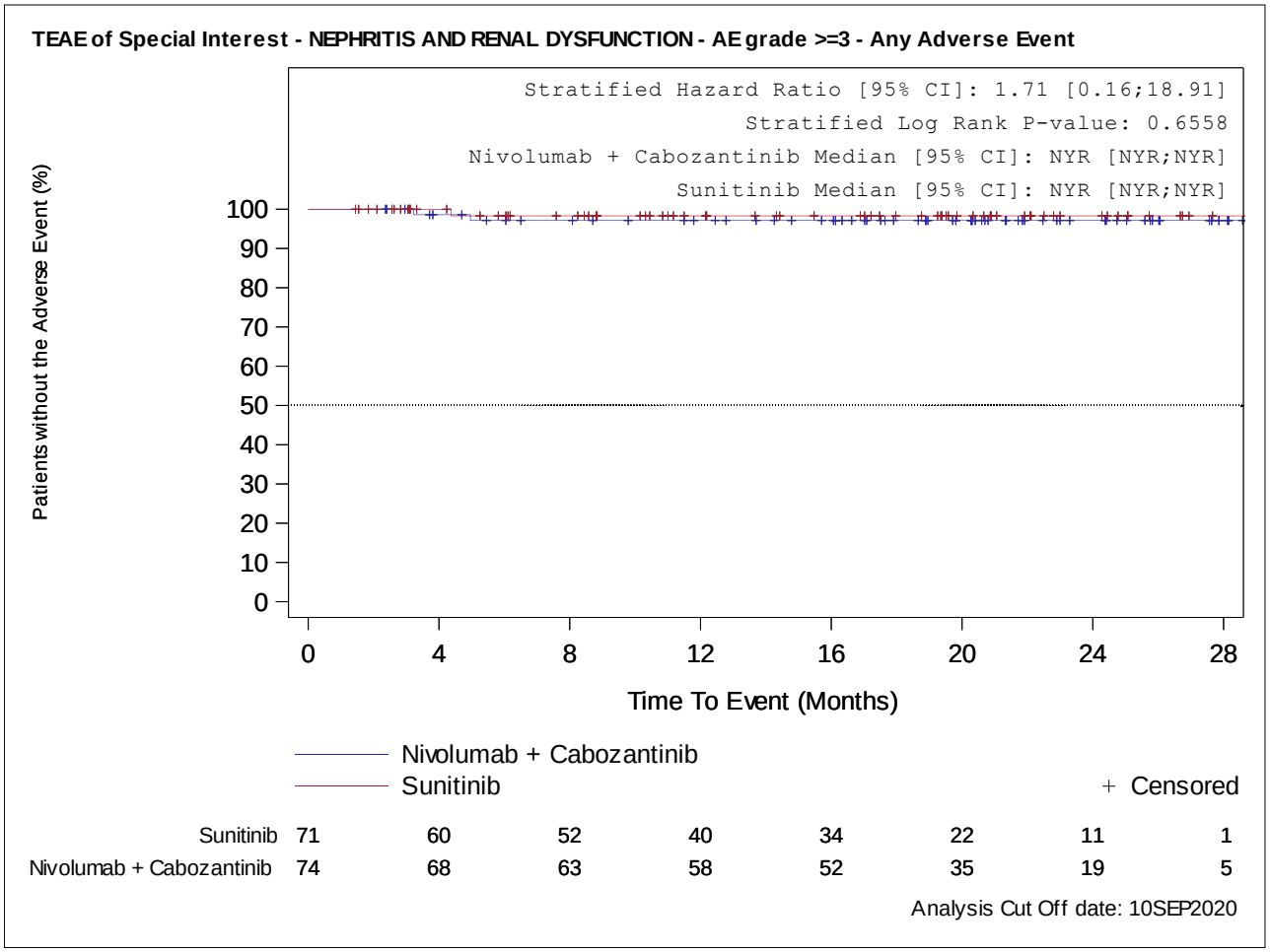

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:41:58

FIGURE 3.120.2.24: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



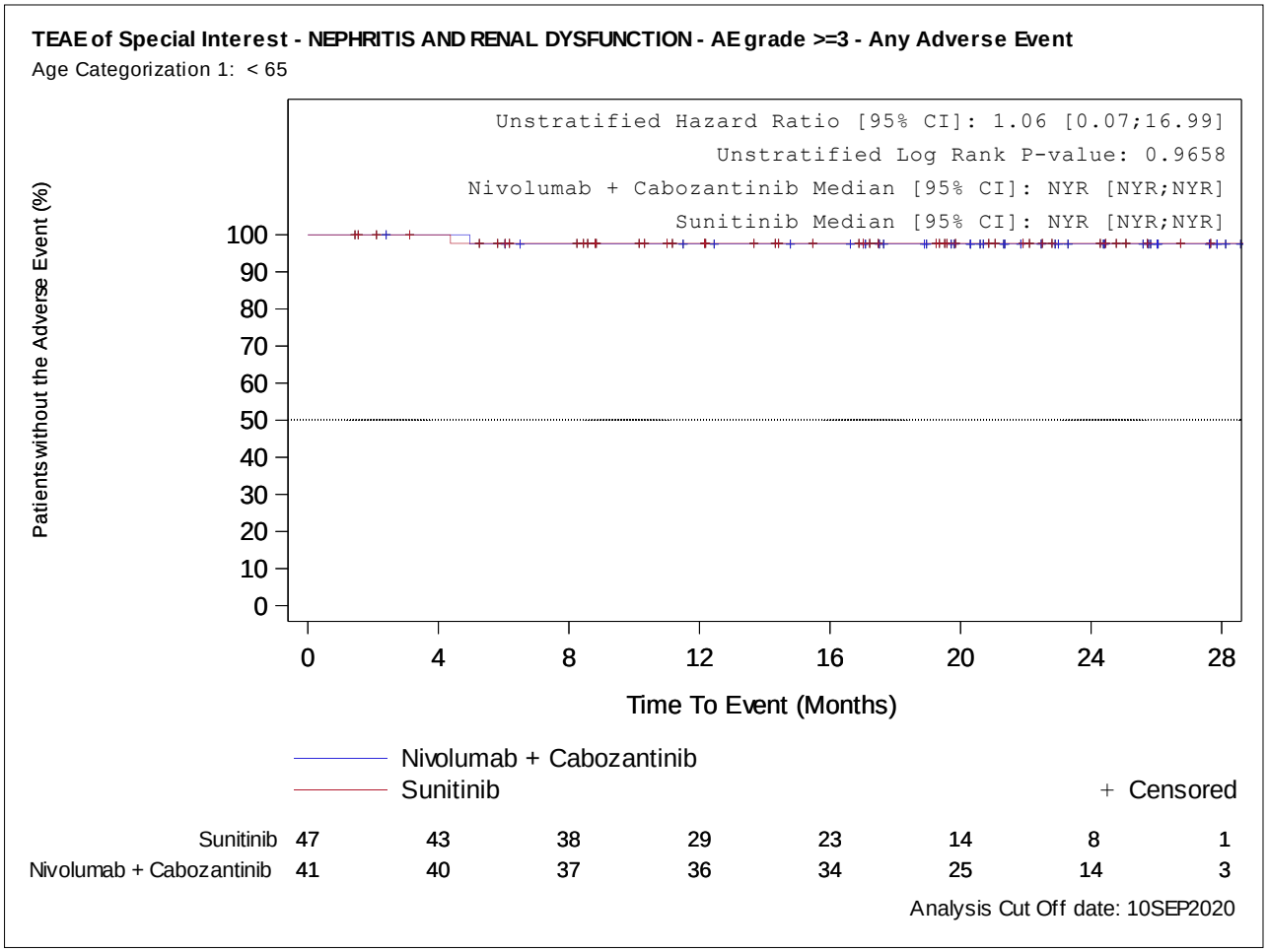

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:42:05

FIGURE 3.121.1: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



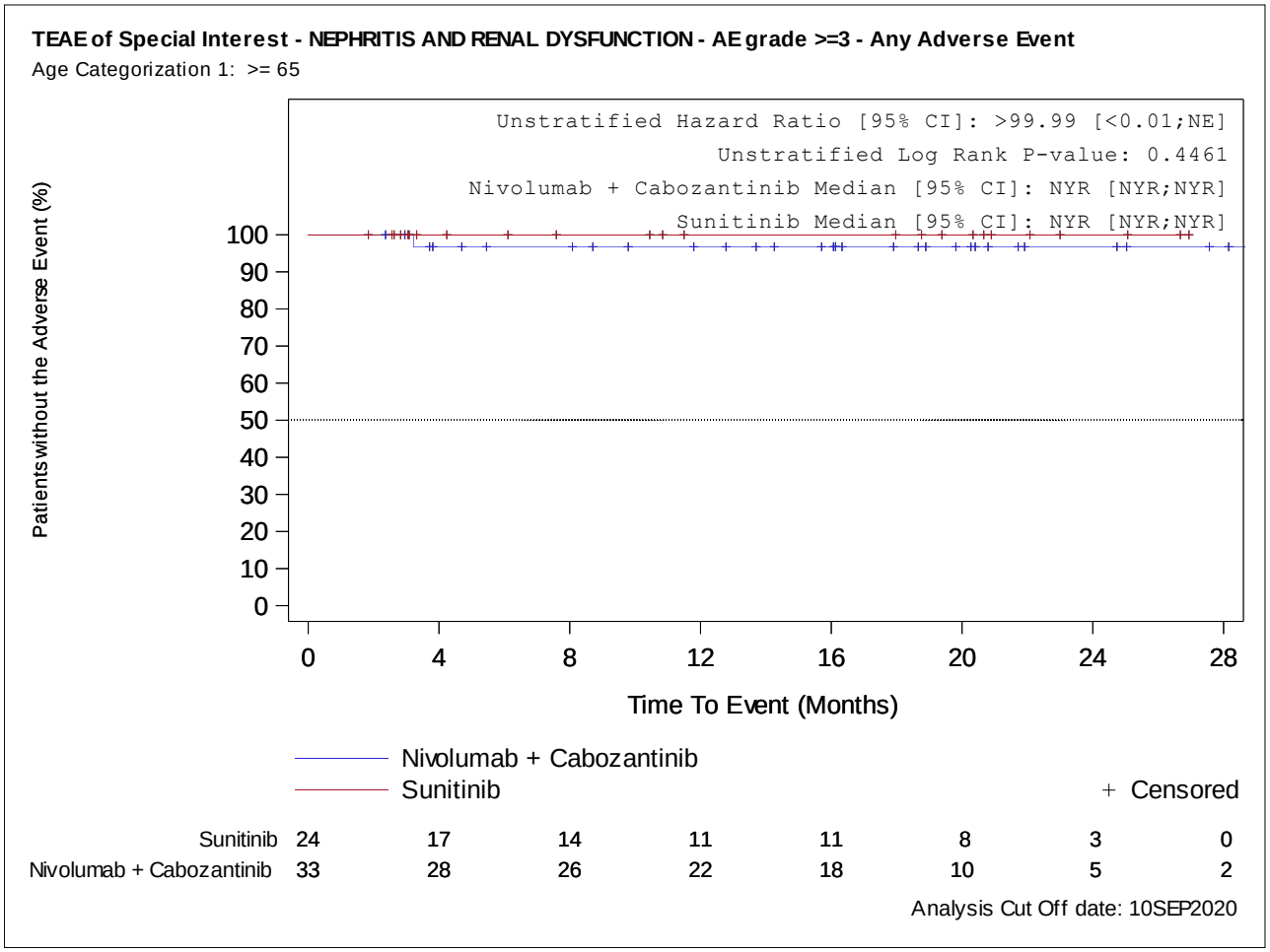

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:45:42

FIGURE 3.121.2.1: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



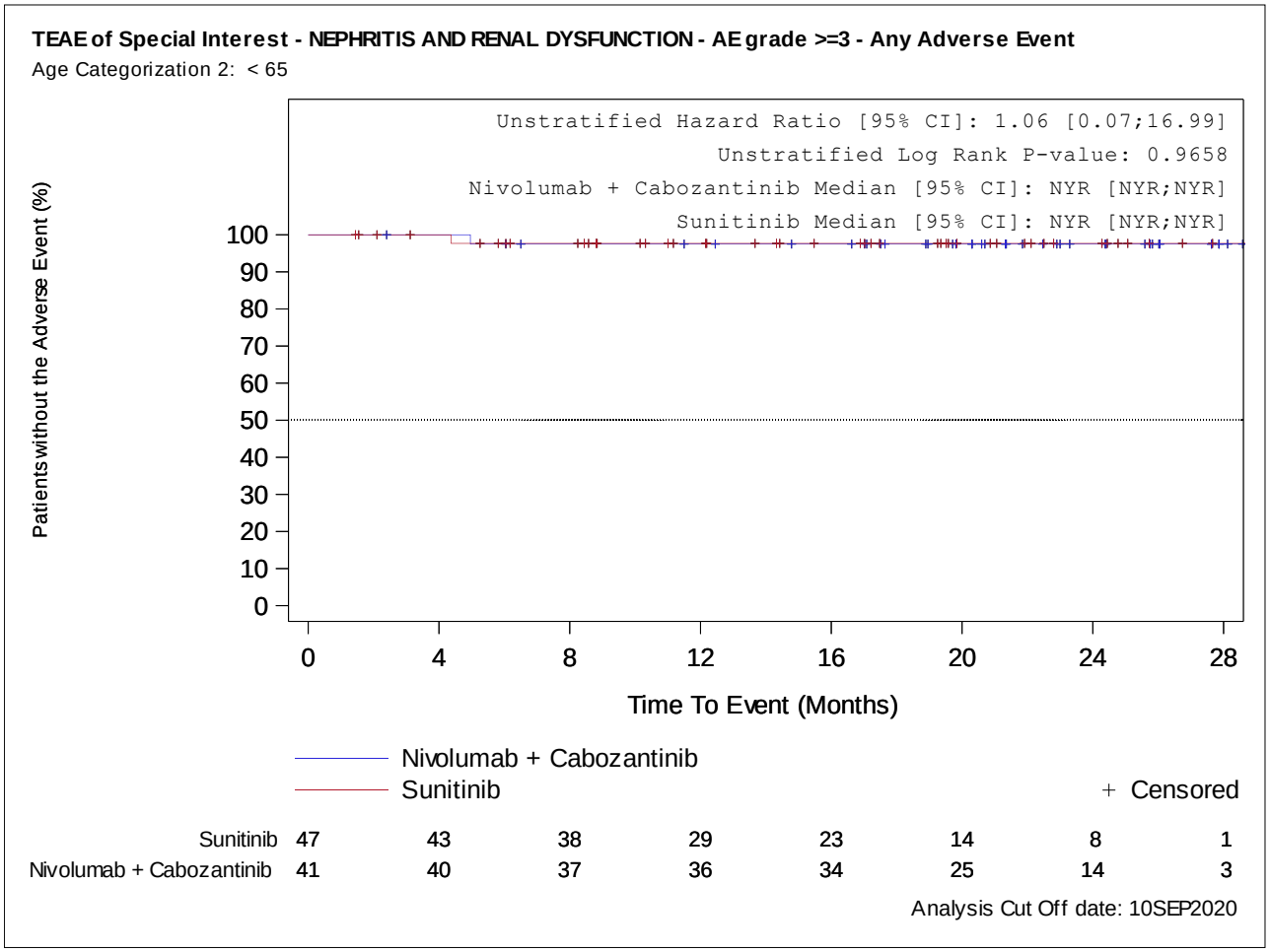

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:45:45

FIGURE 3.121.2.2: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



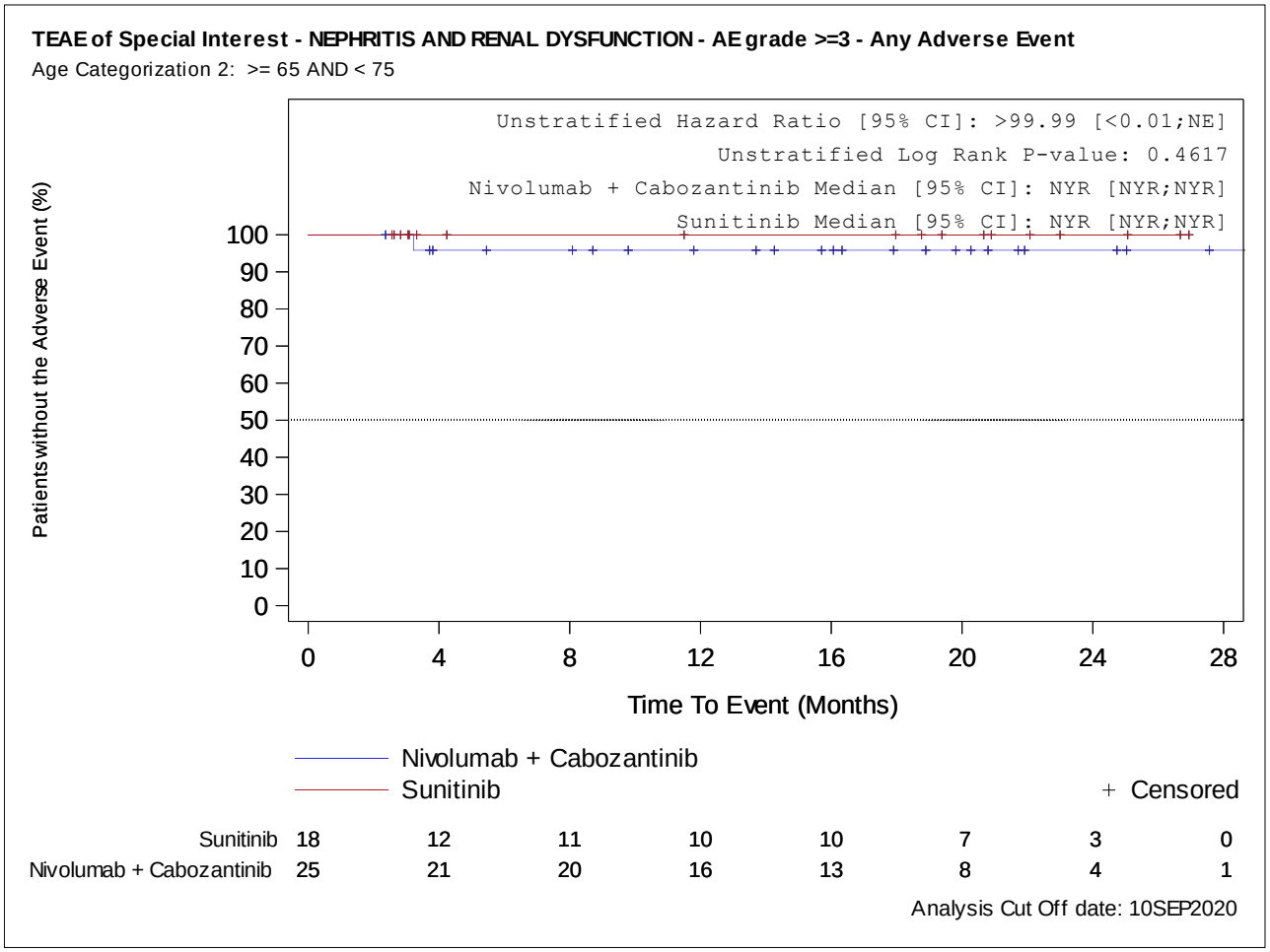

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:45:51

FIGURE 3.121.2.3: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



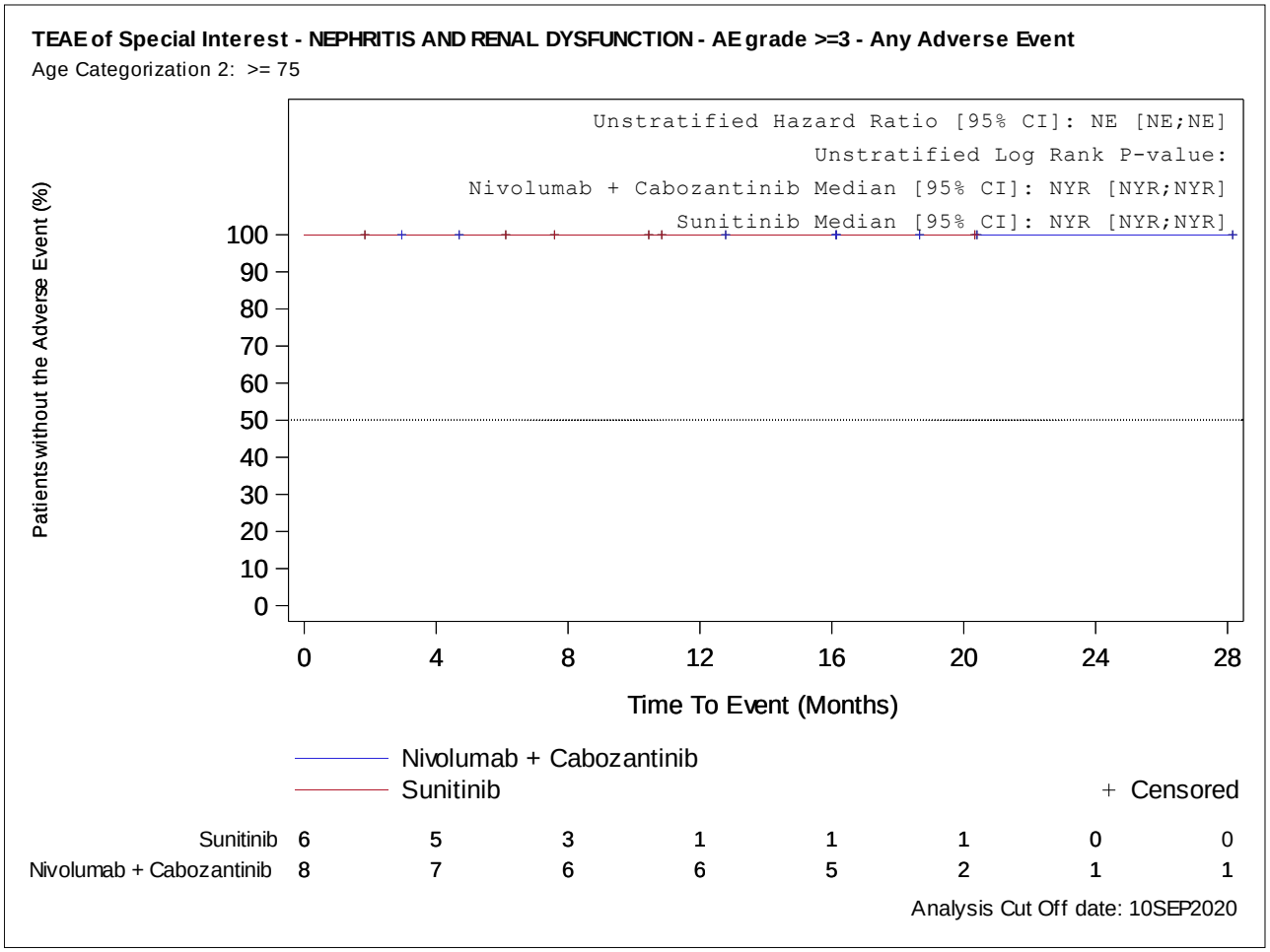

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:45:57

FIGURE 3.121.2.4: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



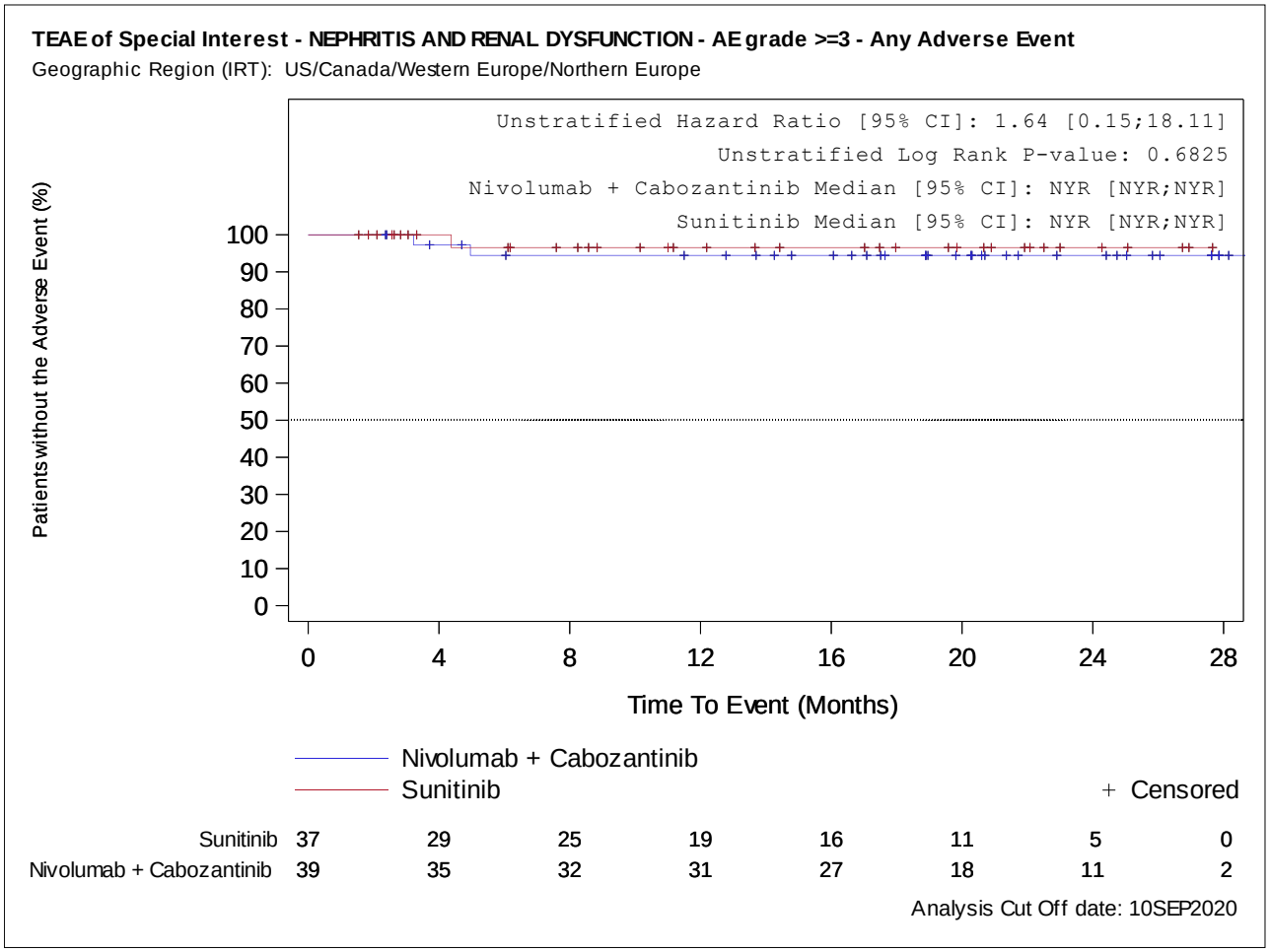

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:46:03

FIGURE 3.121.2.5: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



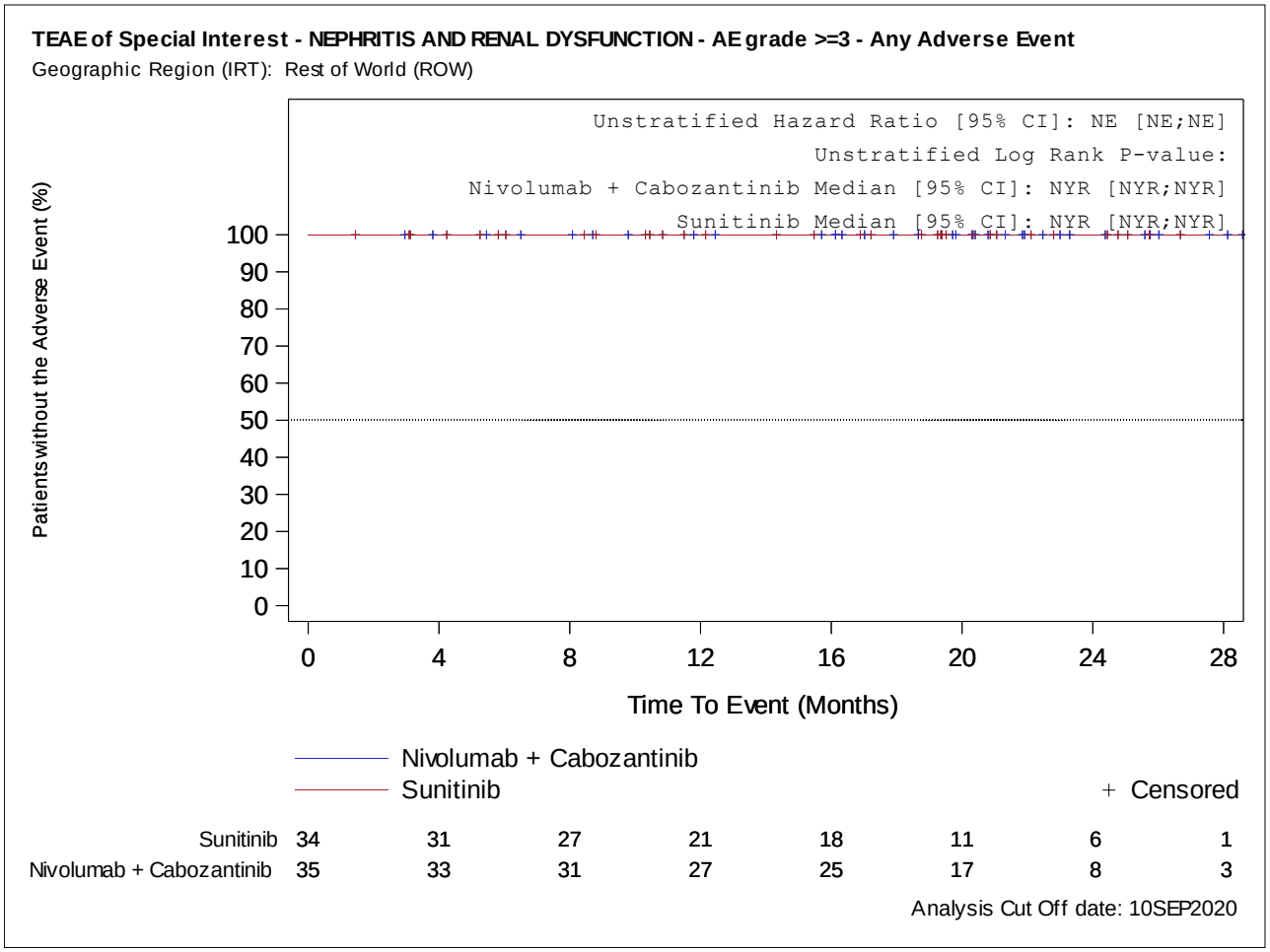

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:46:09

FIGURE 3.121.2.6: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



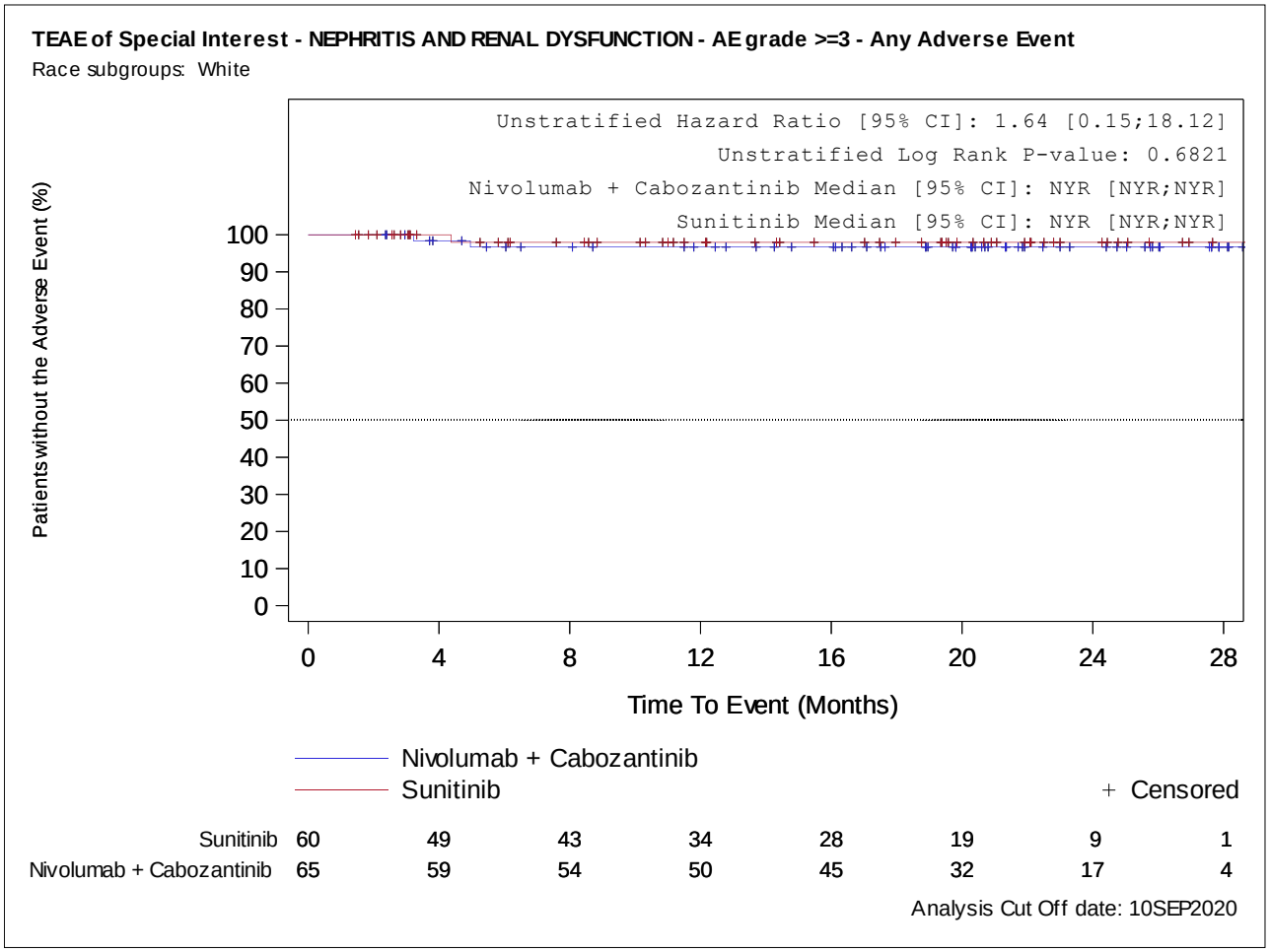

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:46:15

FIGURE 3.121.2.7: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



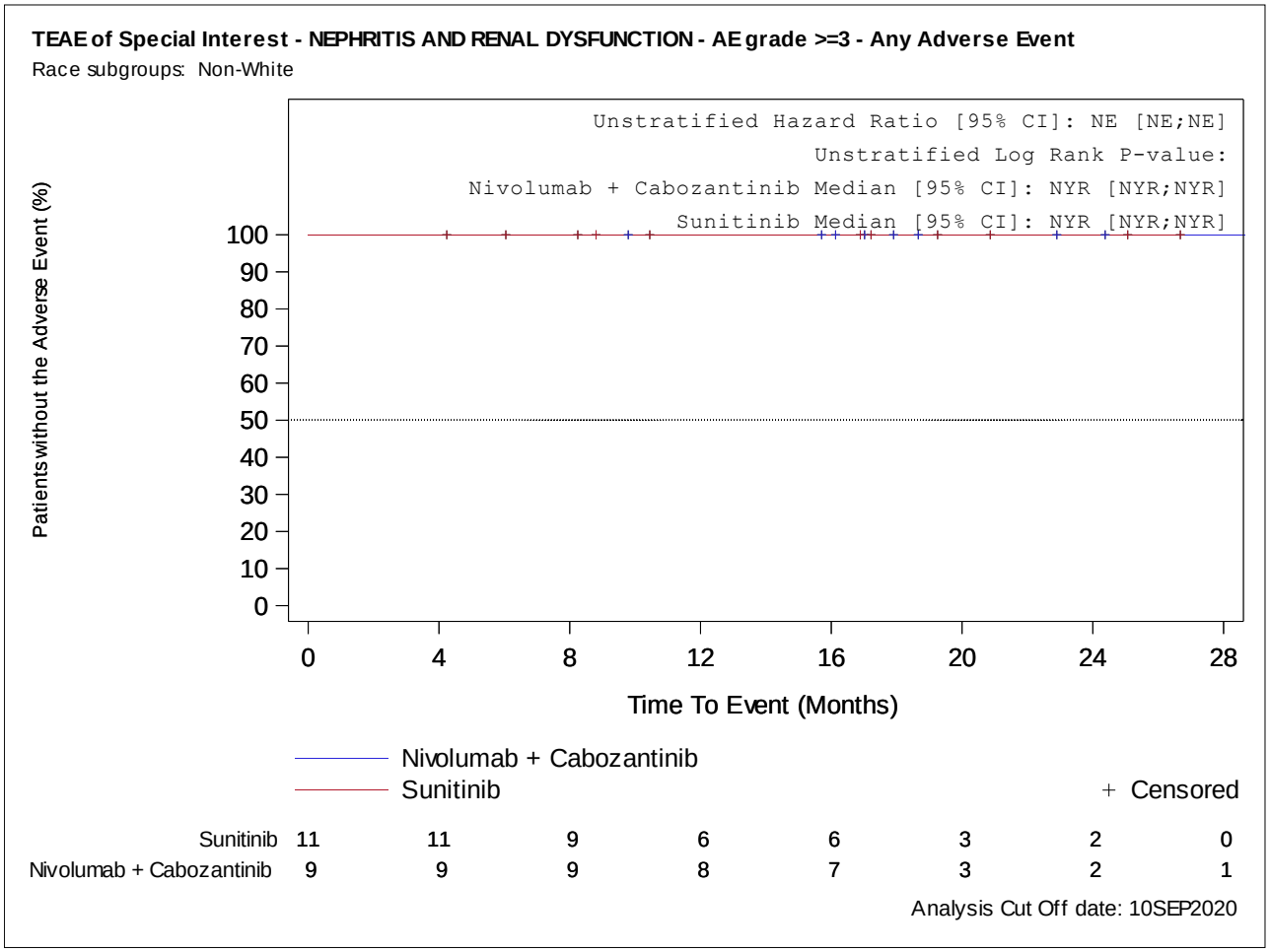

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:46:21

FIGURE 3.121.2.8: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



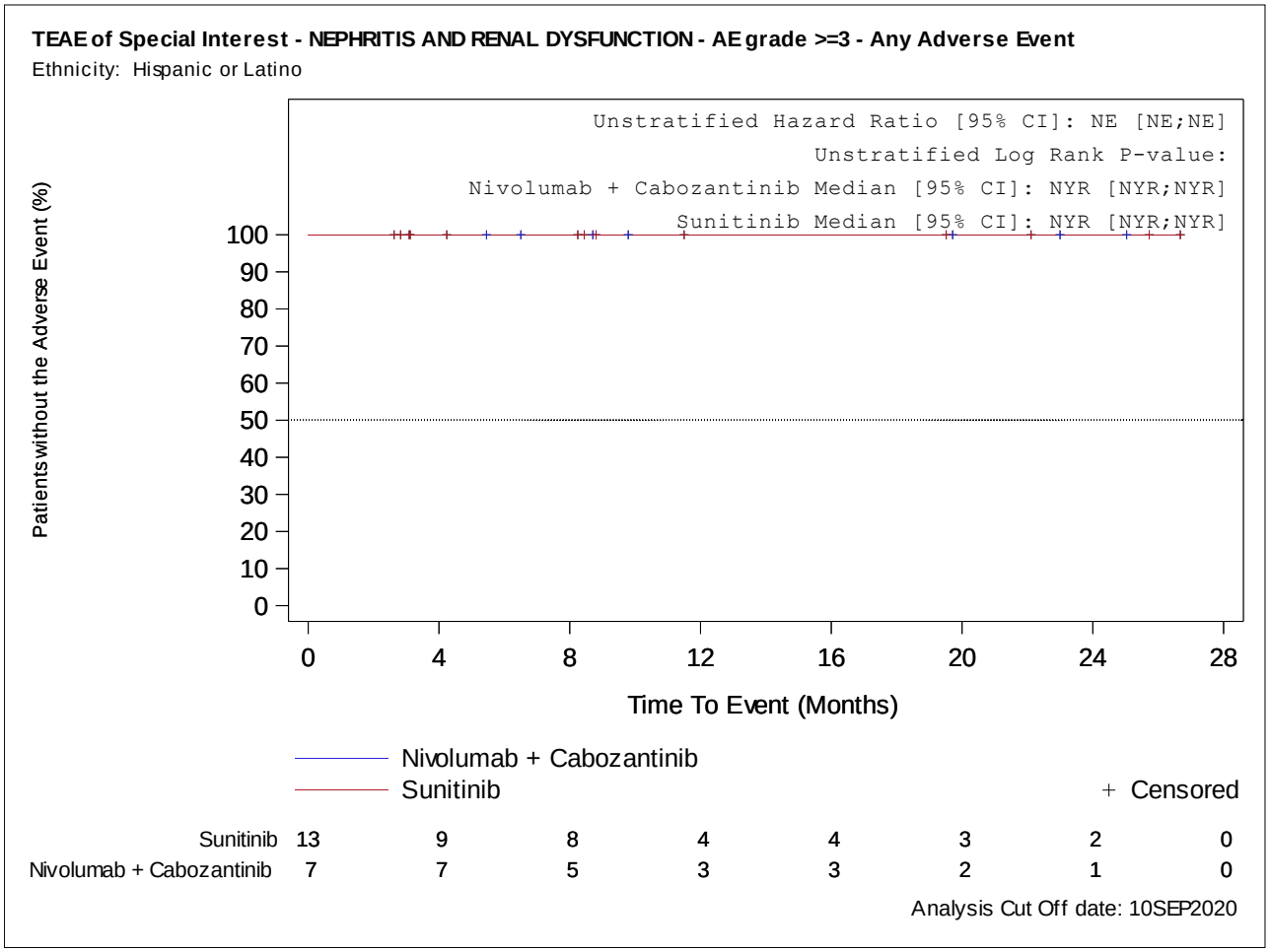

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:46:27

FIGURE 3.121.2.9: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



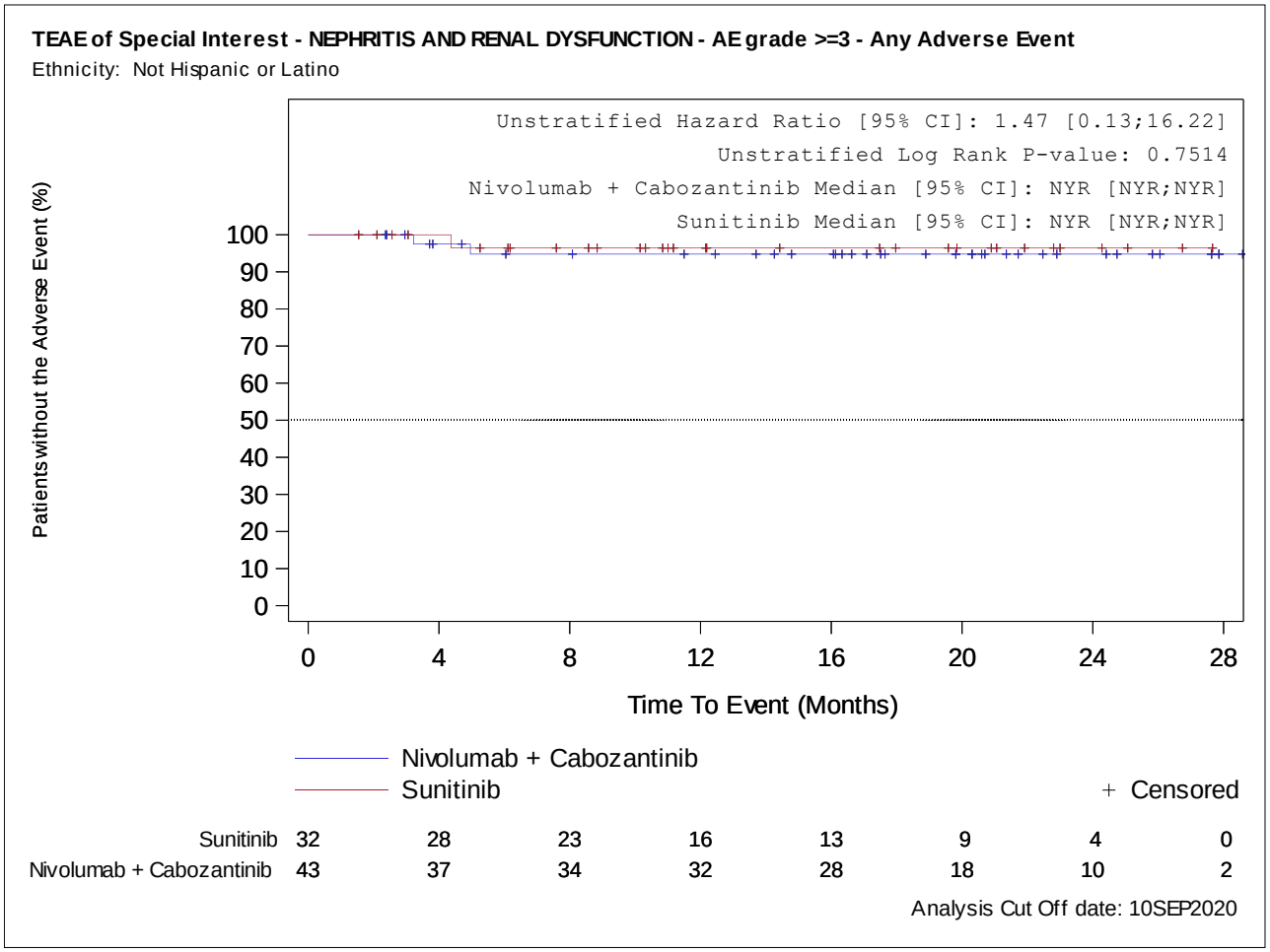

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:46:34

FIGURE 3.121.2.10: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



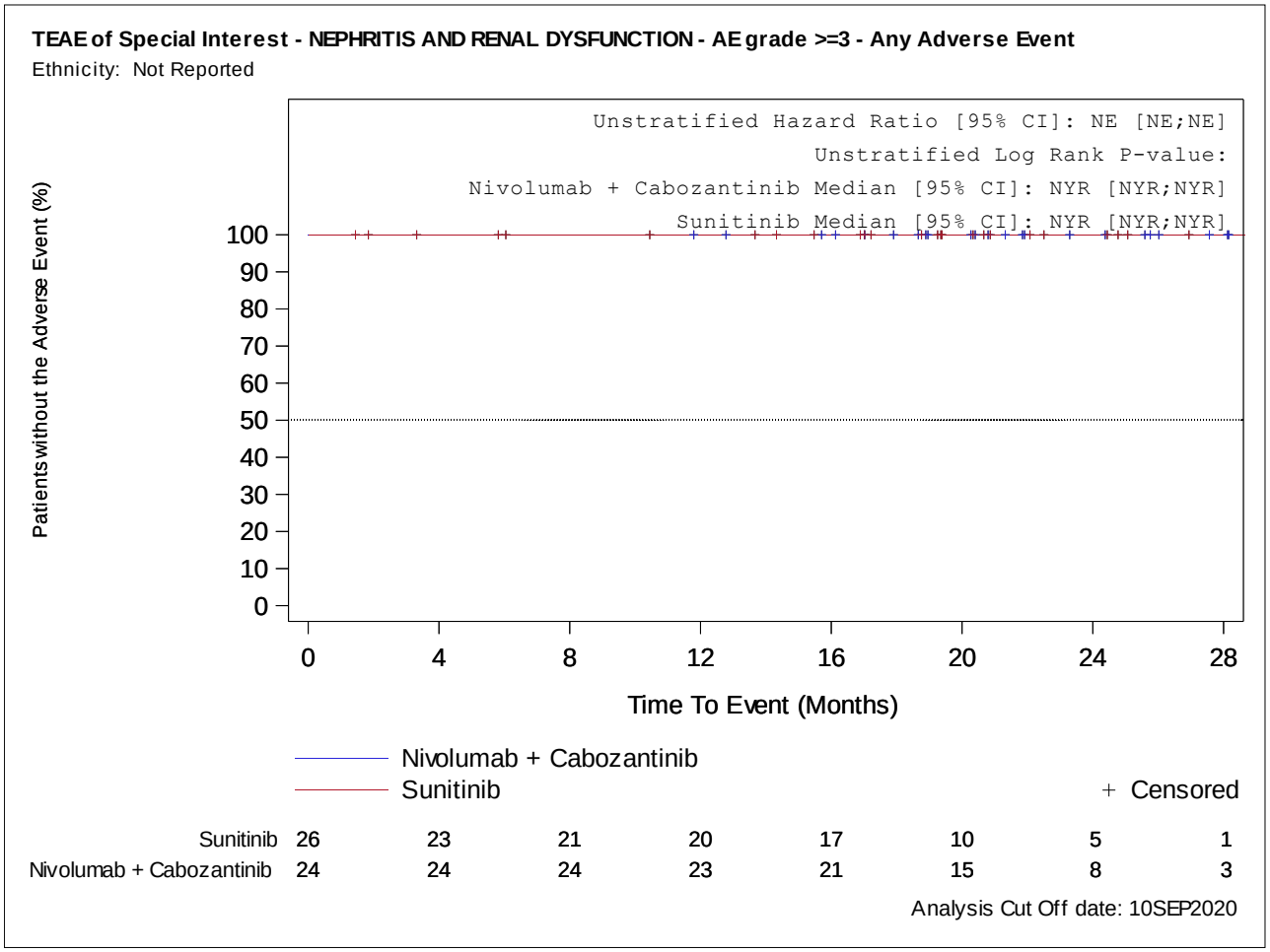

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:46:41

FIGURE 3.121.2.11: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



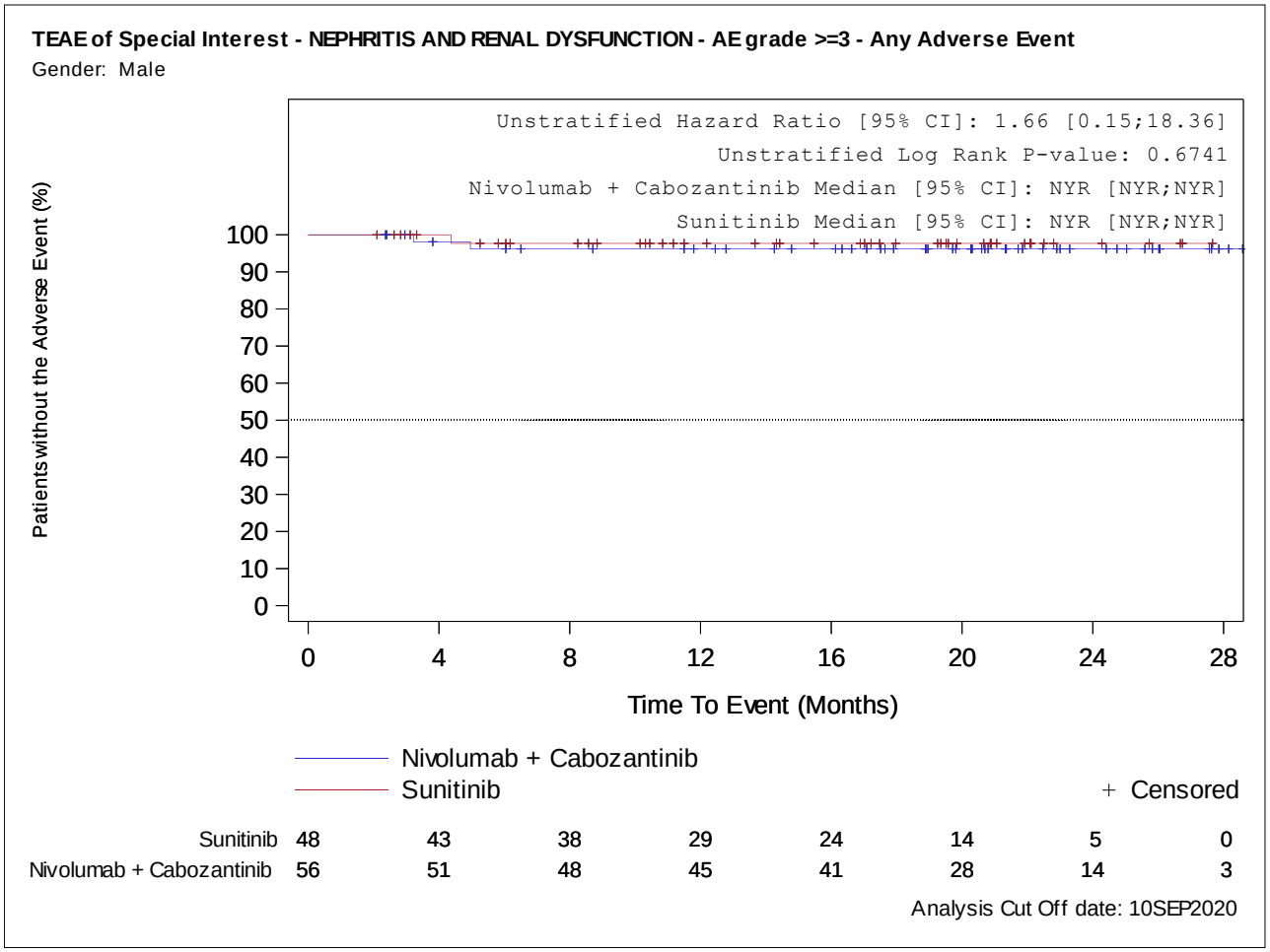

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:46:47

FIGURE 3.121.2.12: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



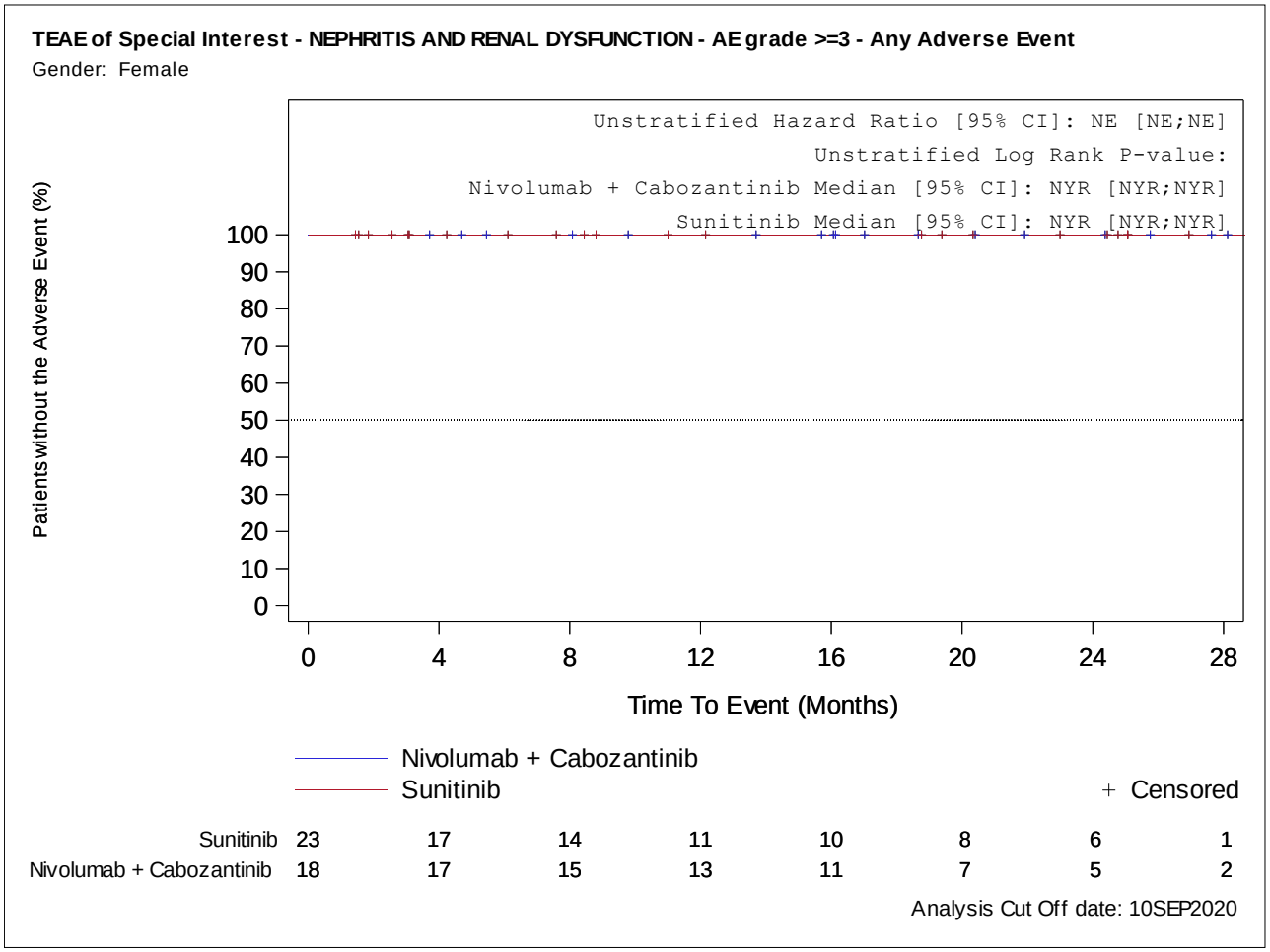

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:46:54

FIGURE 3.121.2.13: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



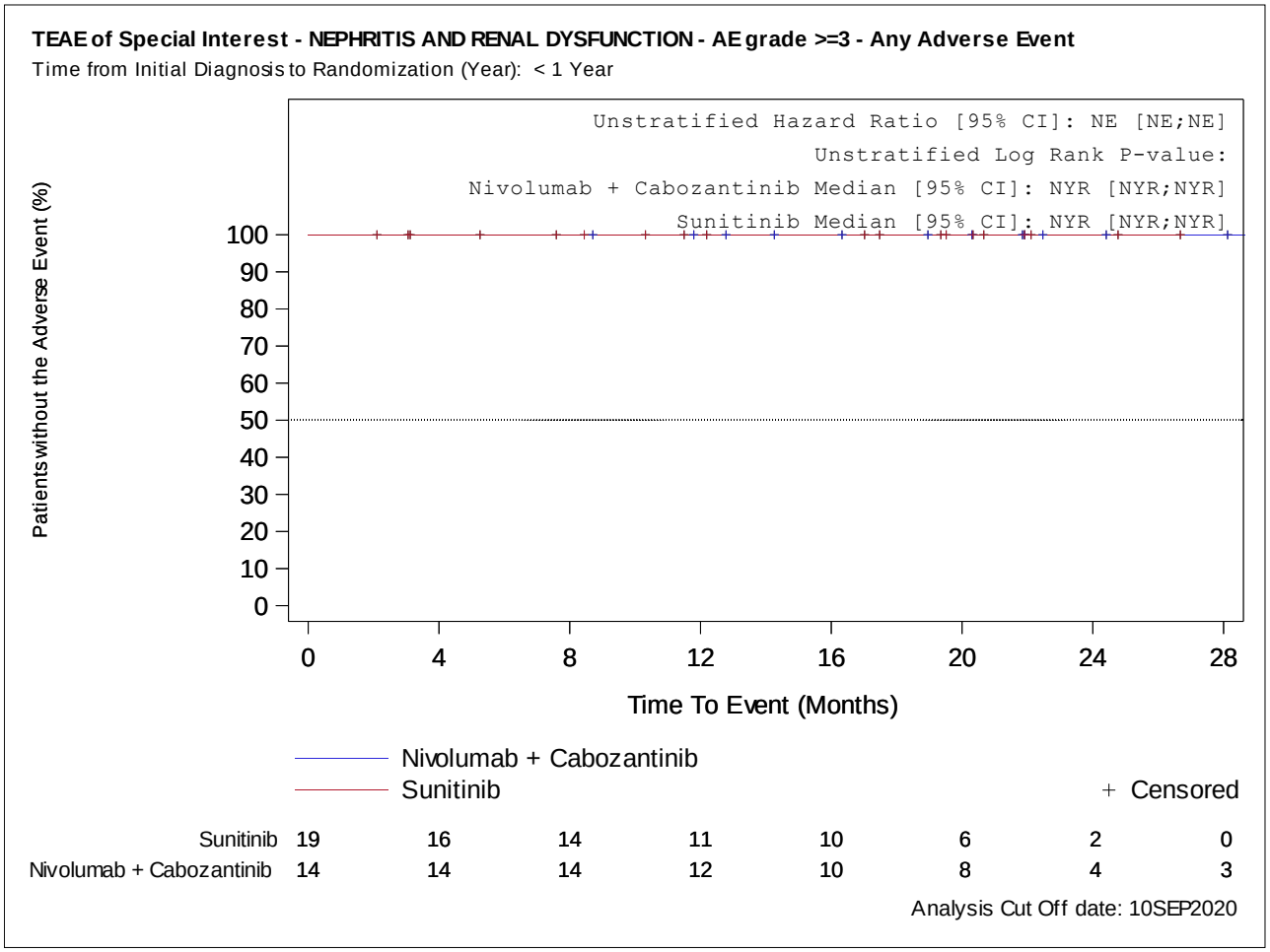

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:46:59

FIGURE 3.121.2.14: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



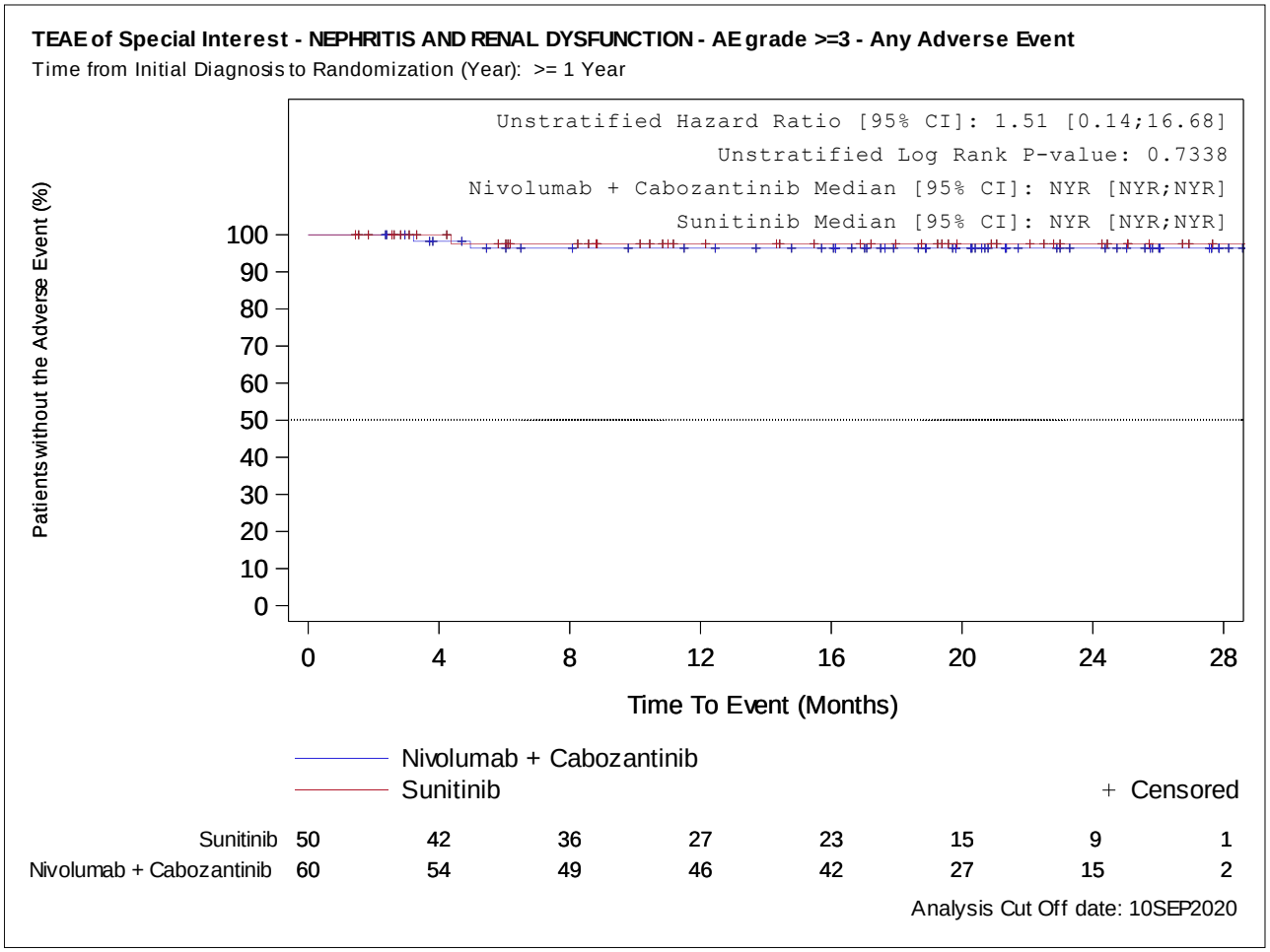

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:47:06

FIGURE 3.121.2.15: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



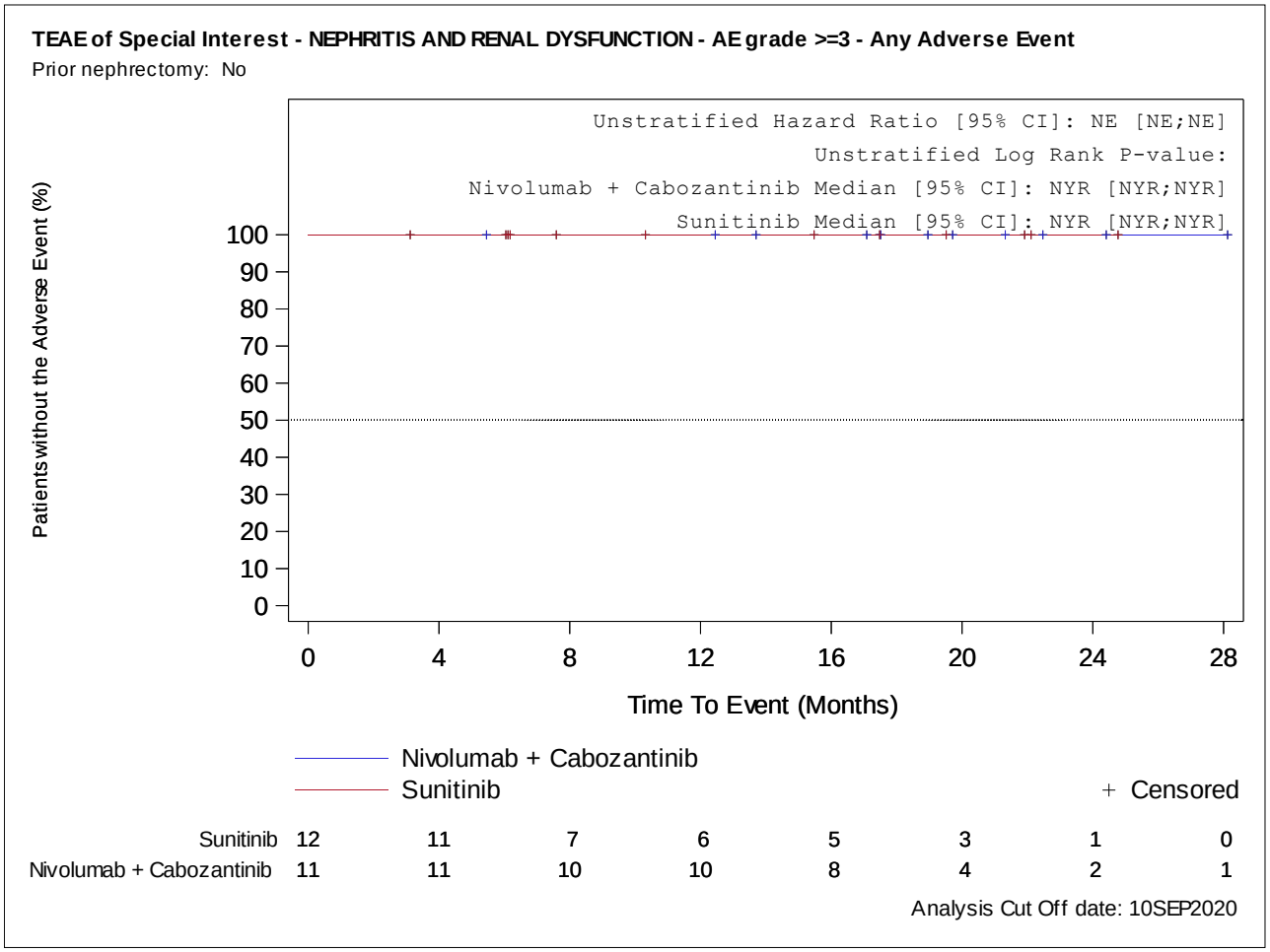

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:47:23

FIGURE 3.121.2.16: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



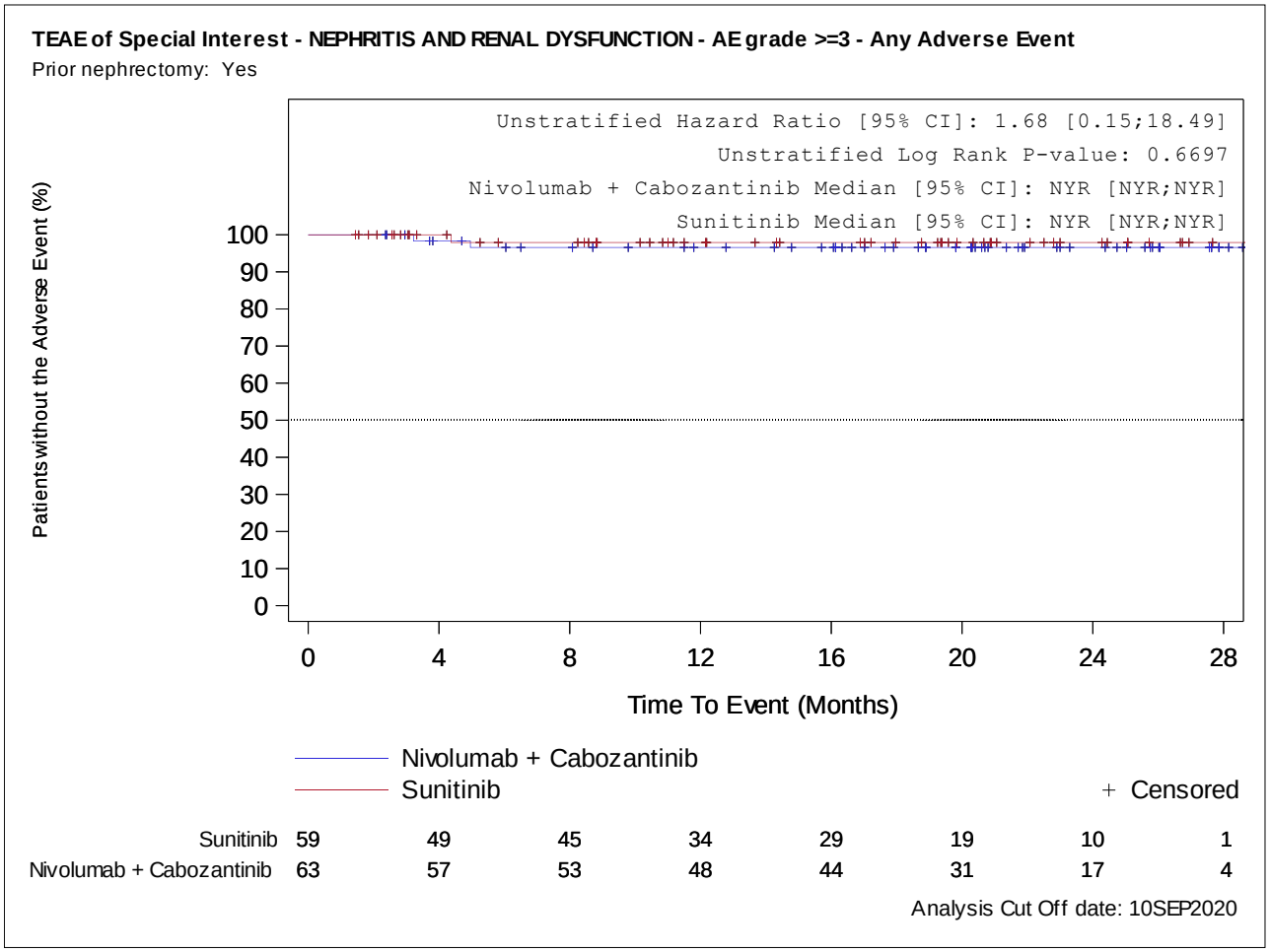

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:47:29

FIGURE 3.121.2.17: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:48:24

FIGURE 3.121.2.18: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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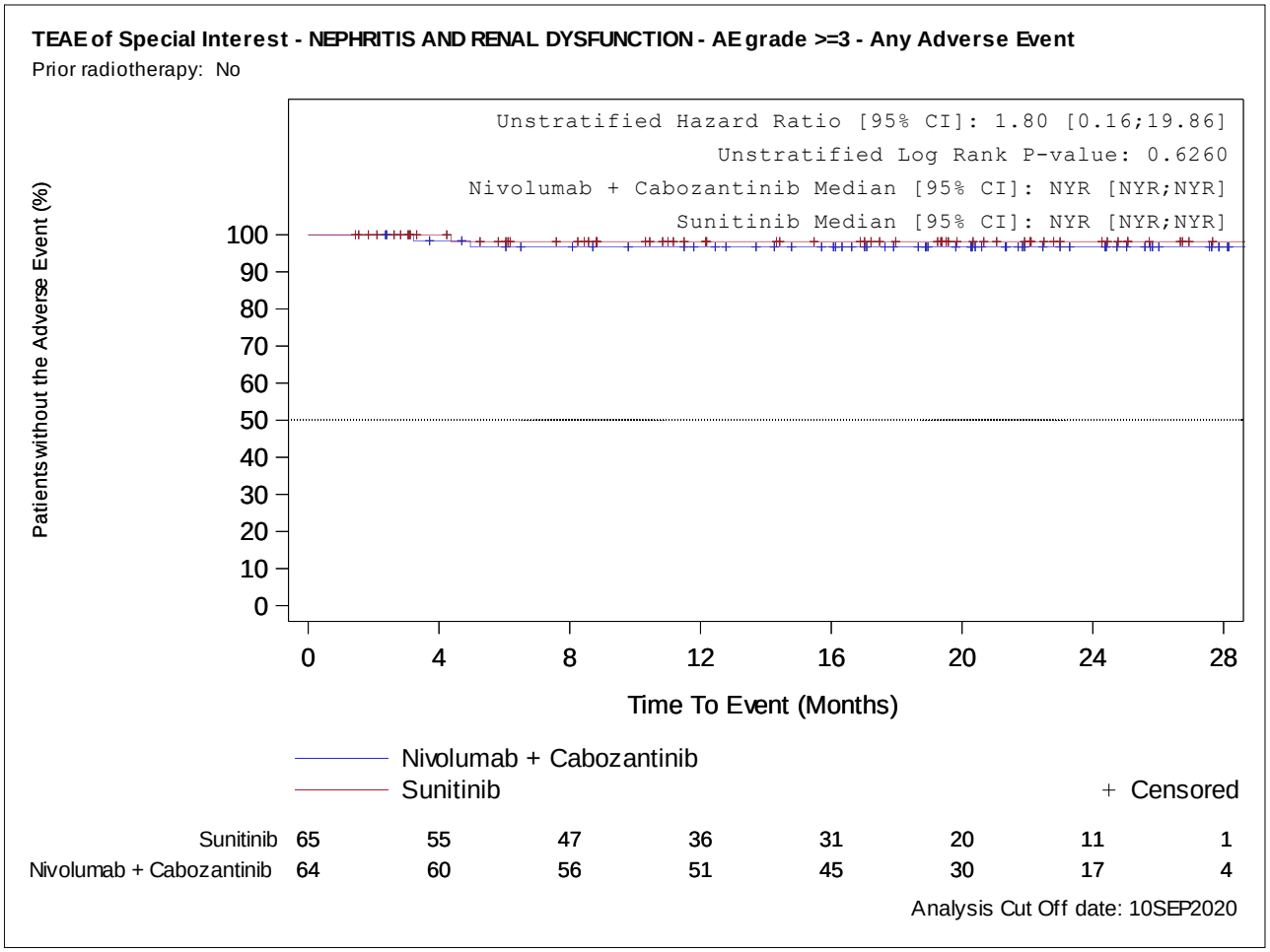
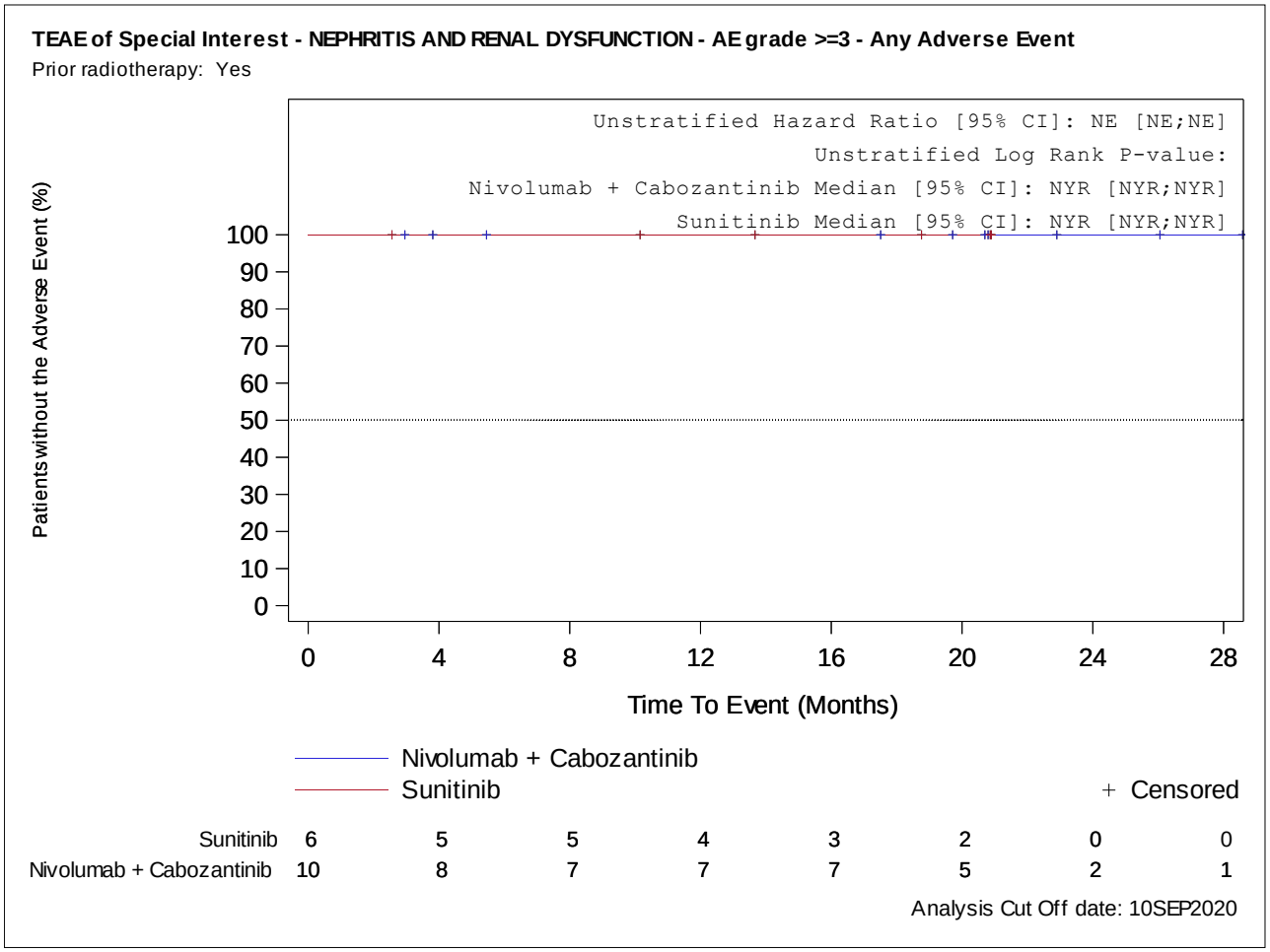
FIGURE 3.121.2.19: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



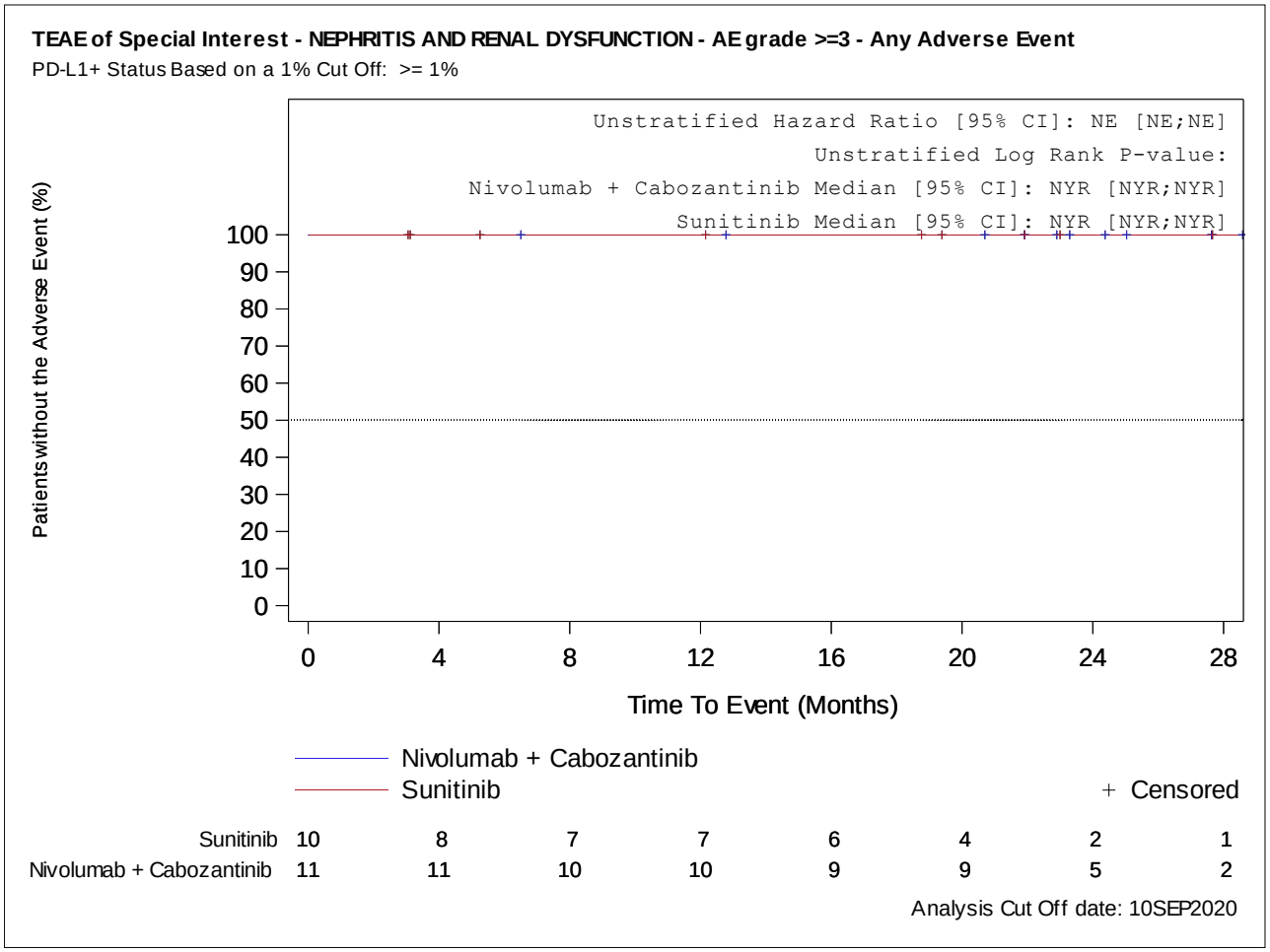

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:48:36

FIGURE 3.121.2.20: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



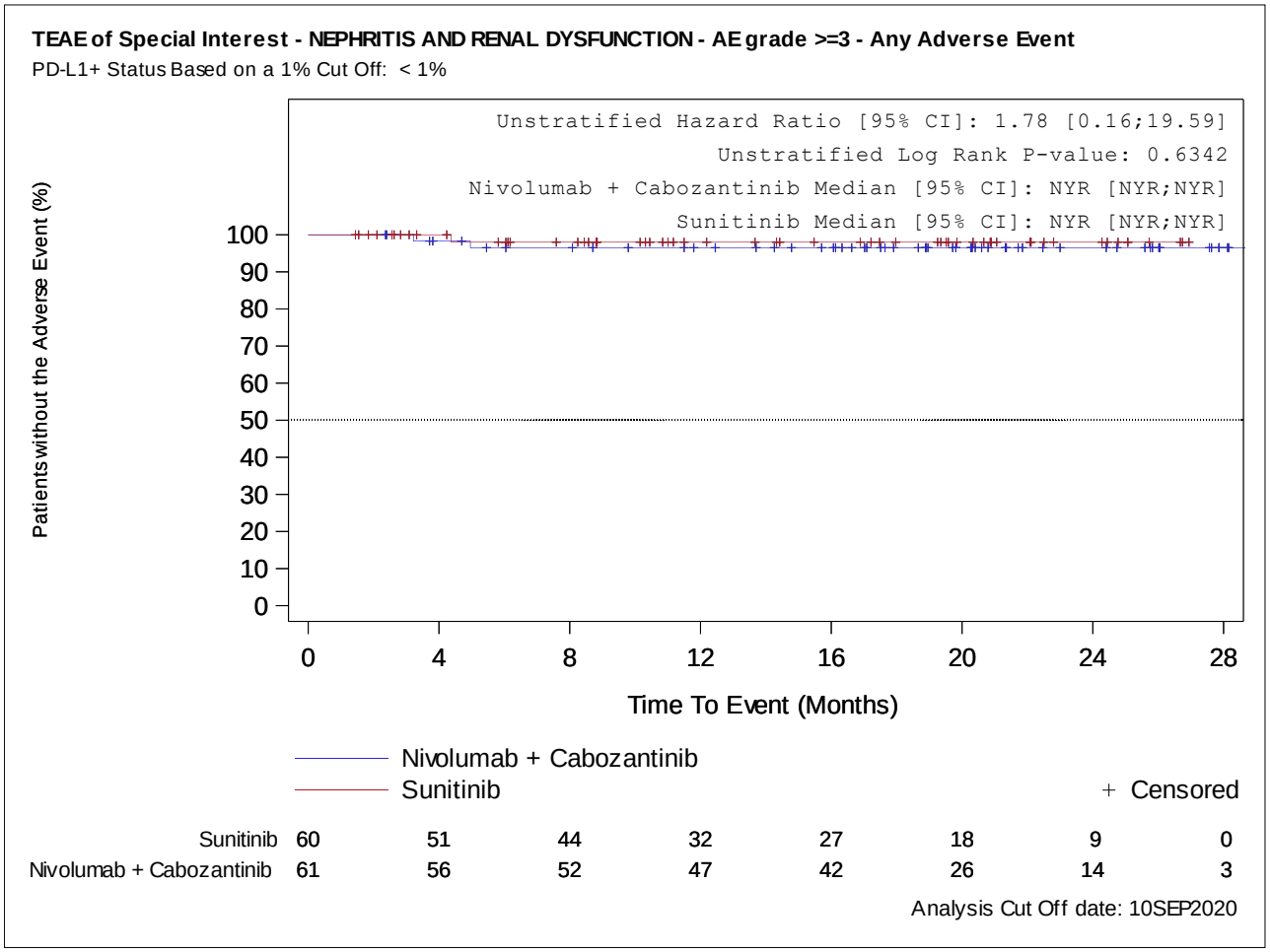

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:48:41

FIGURE 3.121.2.21: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



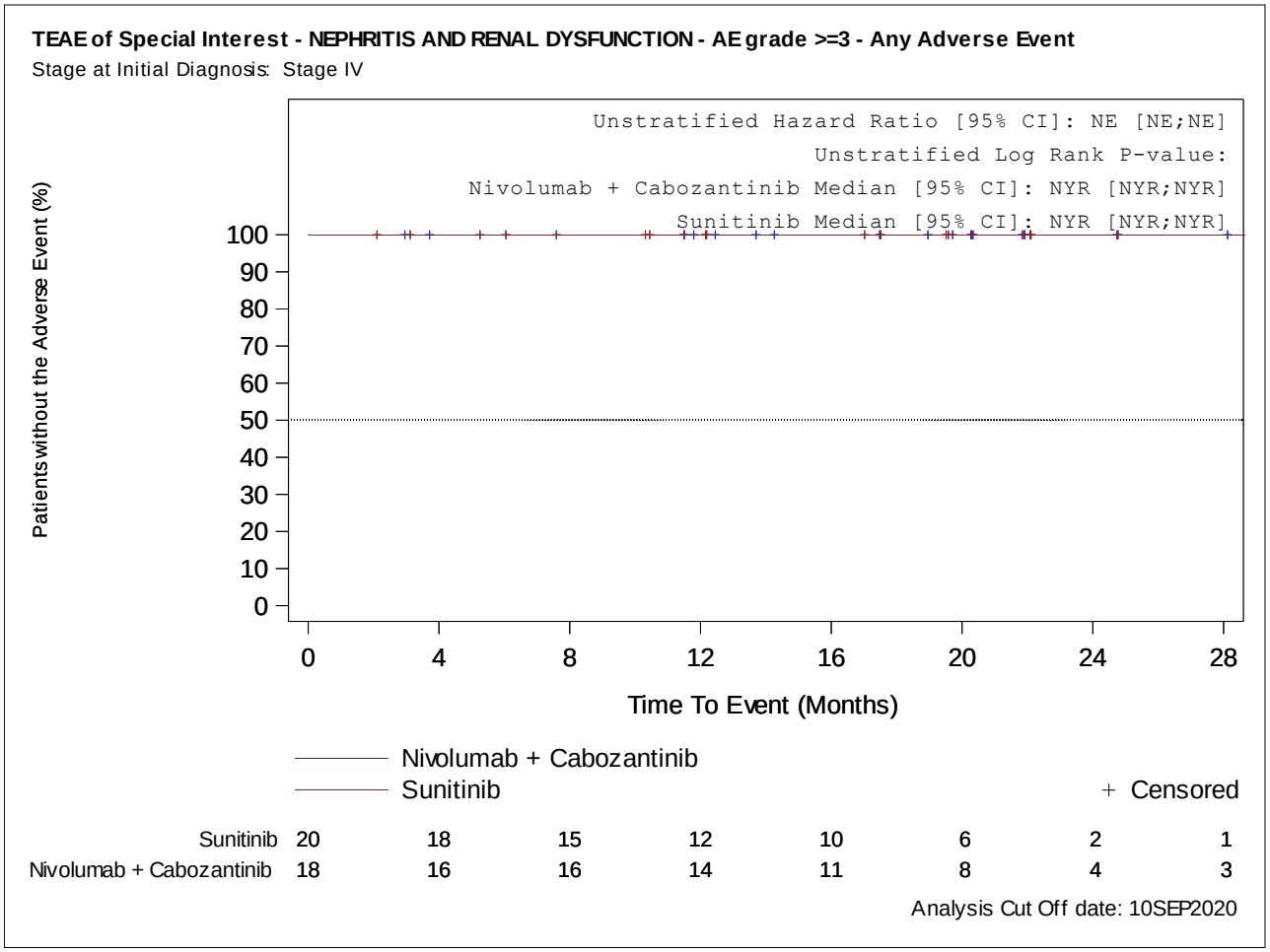

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:48:47

FIGURE 3.121.2.22: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



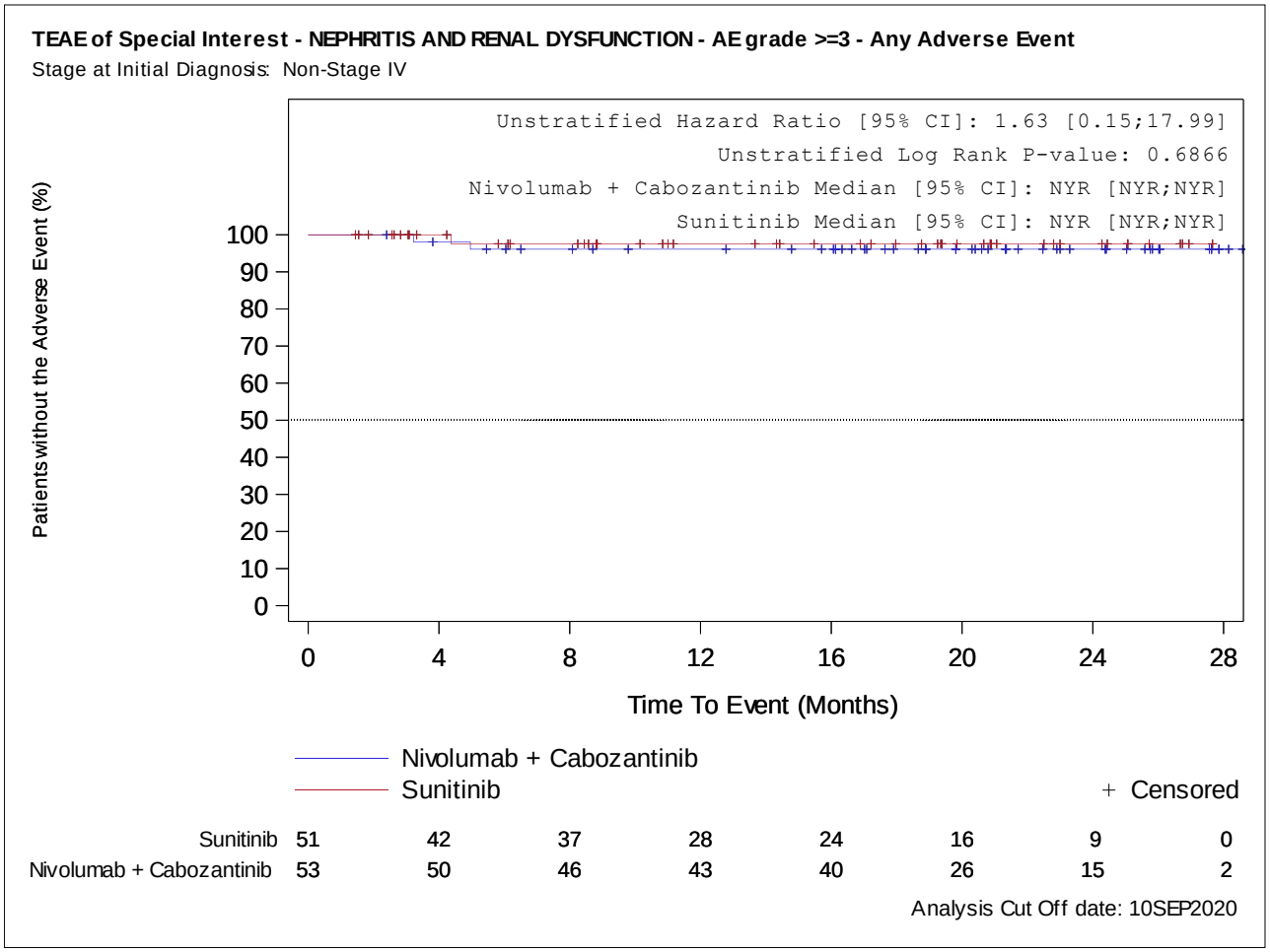

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:48:53

FIGURE 3.121.2.23: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



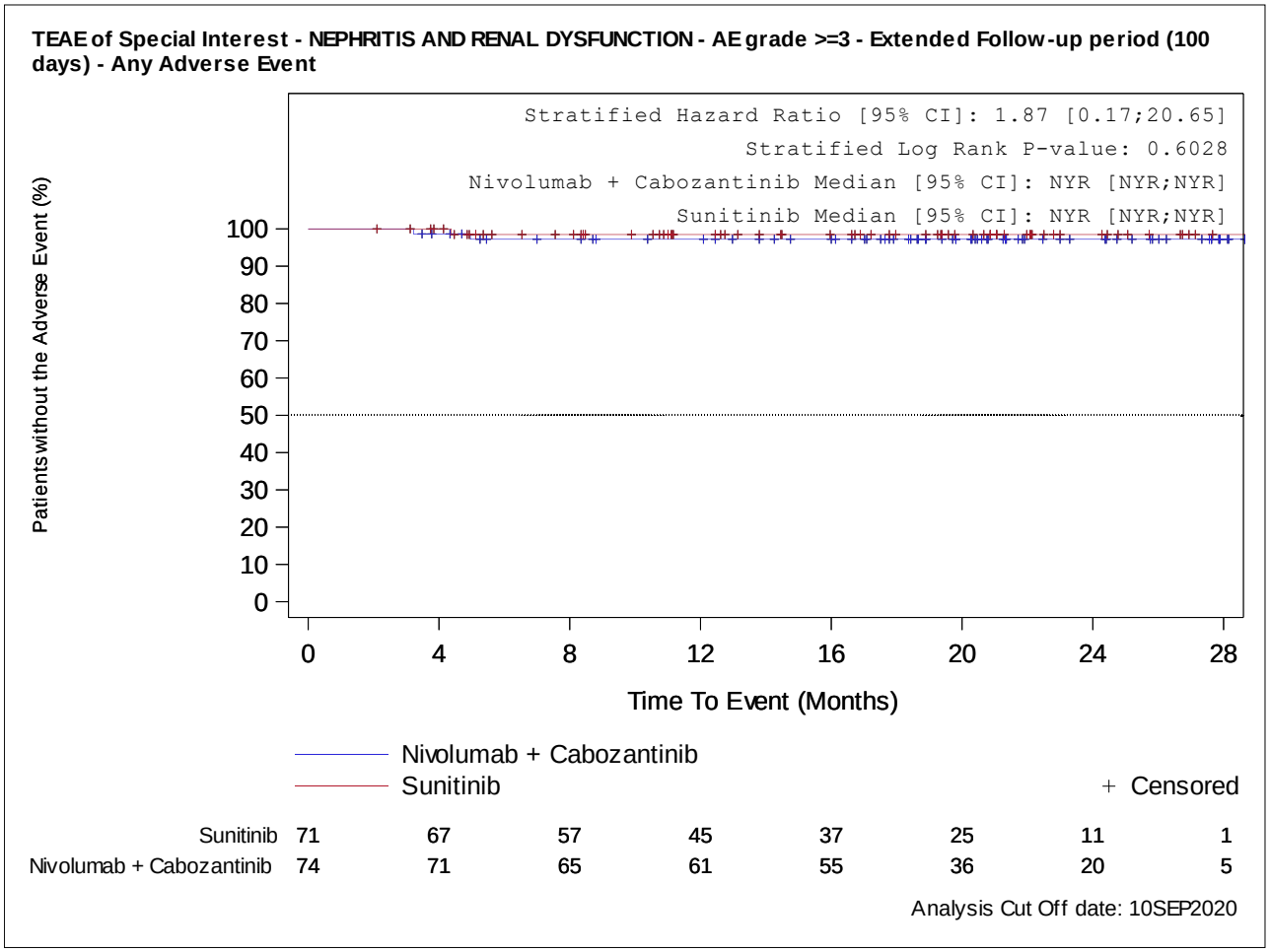

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:49:22

FIGURE 3.121.2.24: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:49:33

FIGURE 3.122.1: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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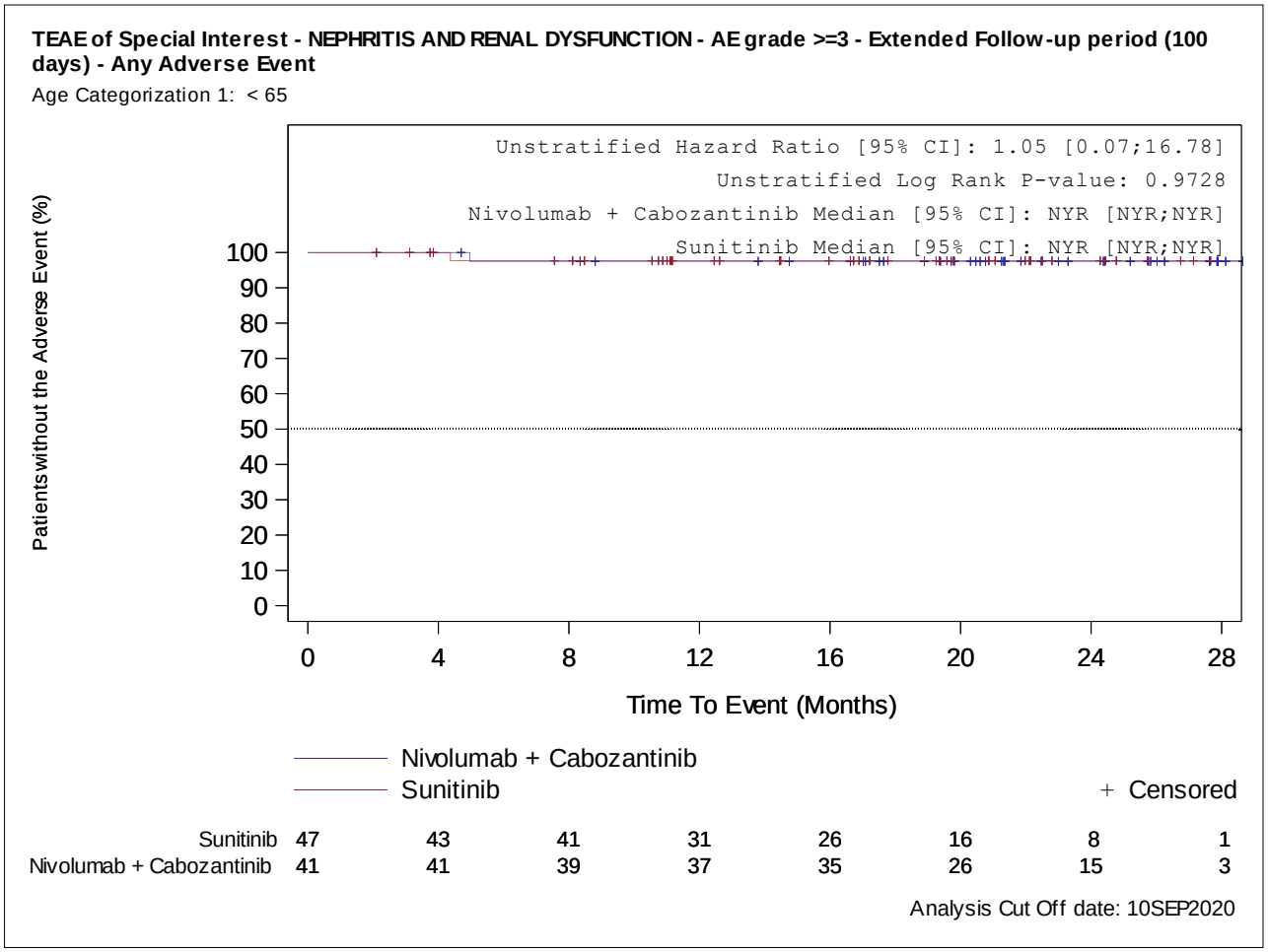
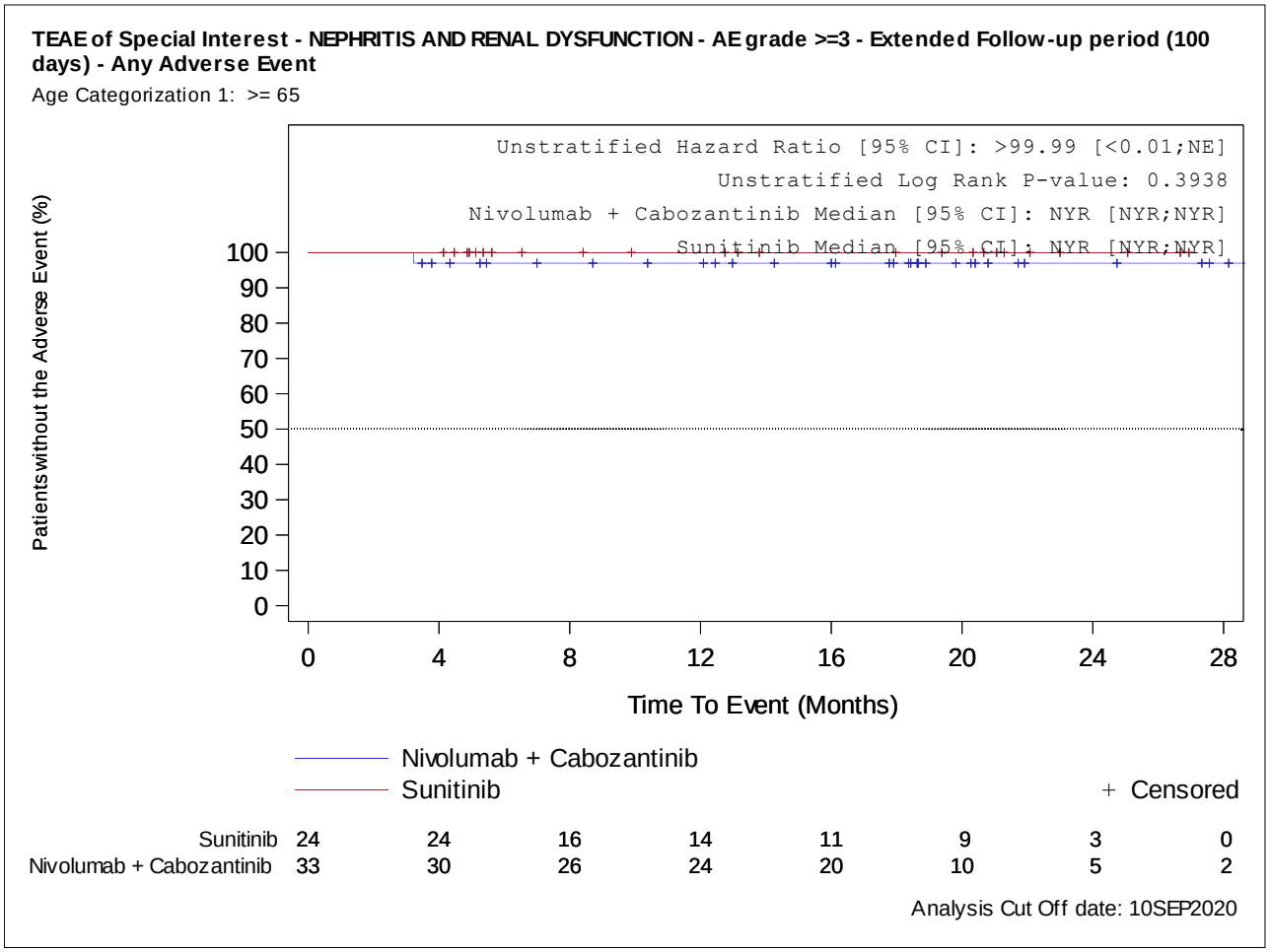
FIGURE 3.122.2.1: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



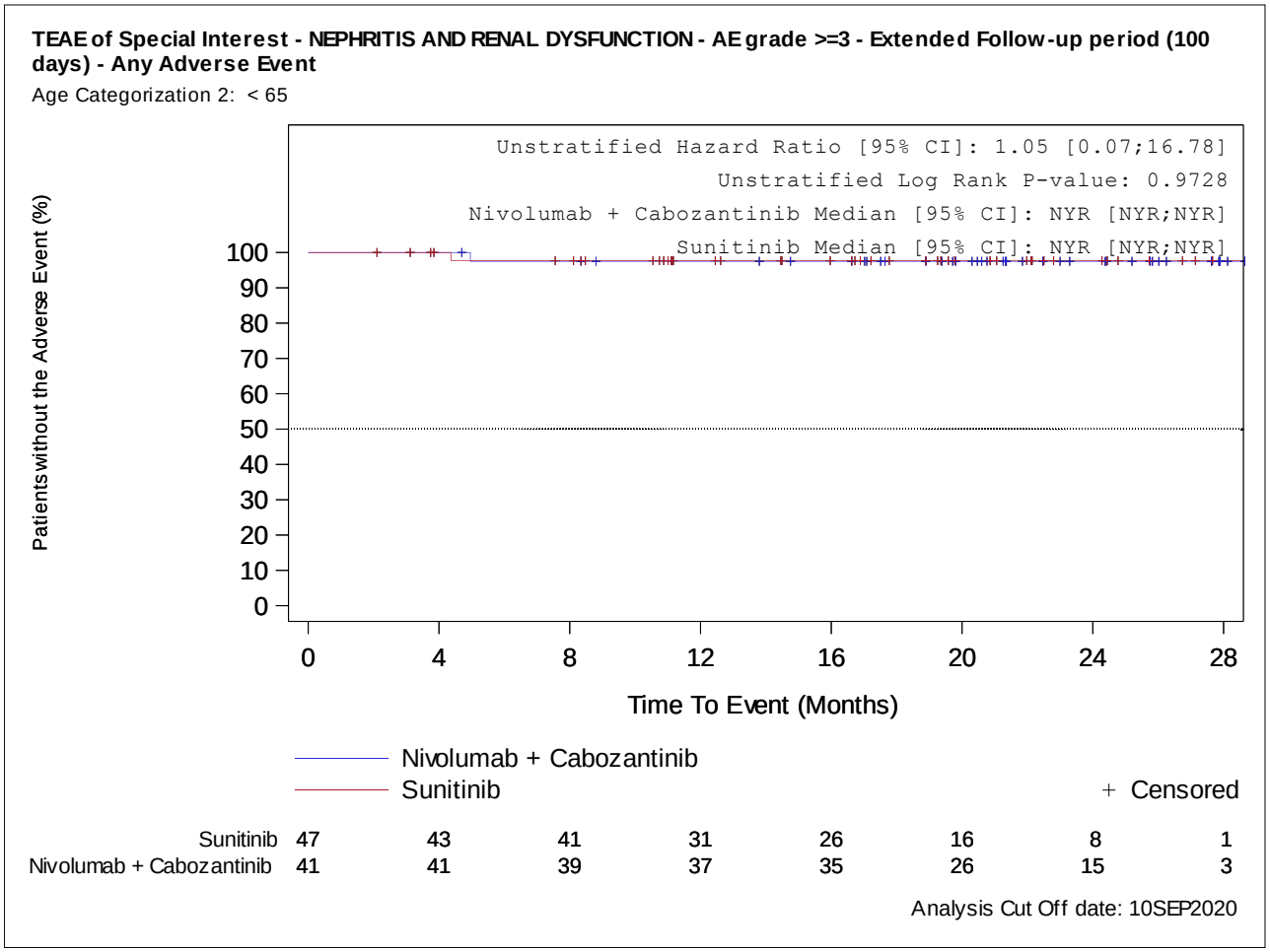

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:53:11

FIGURE 3.122.2.2: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



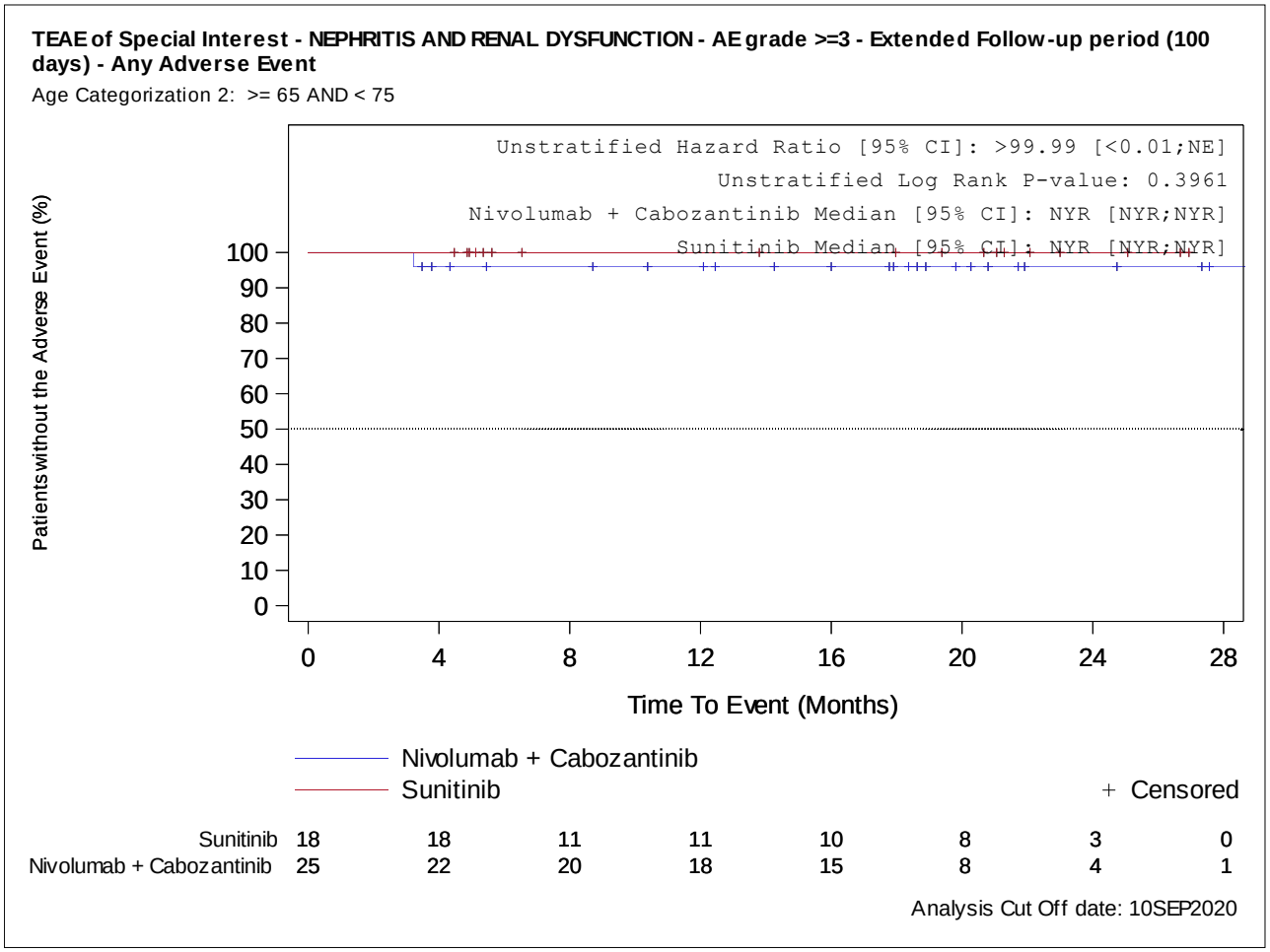

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:53:19

FIGURE 3.122.2.3: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  < 65



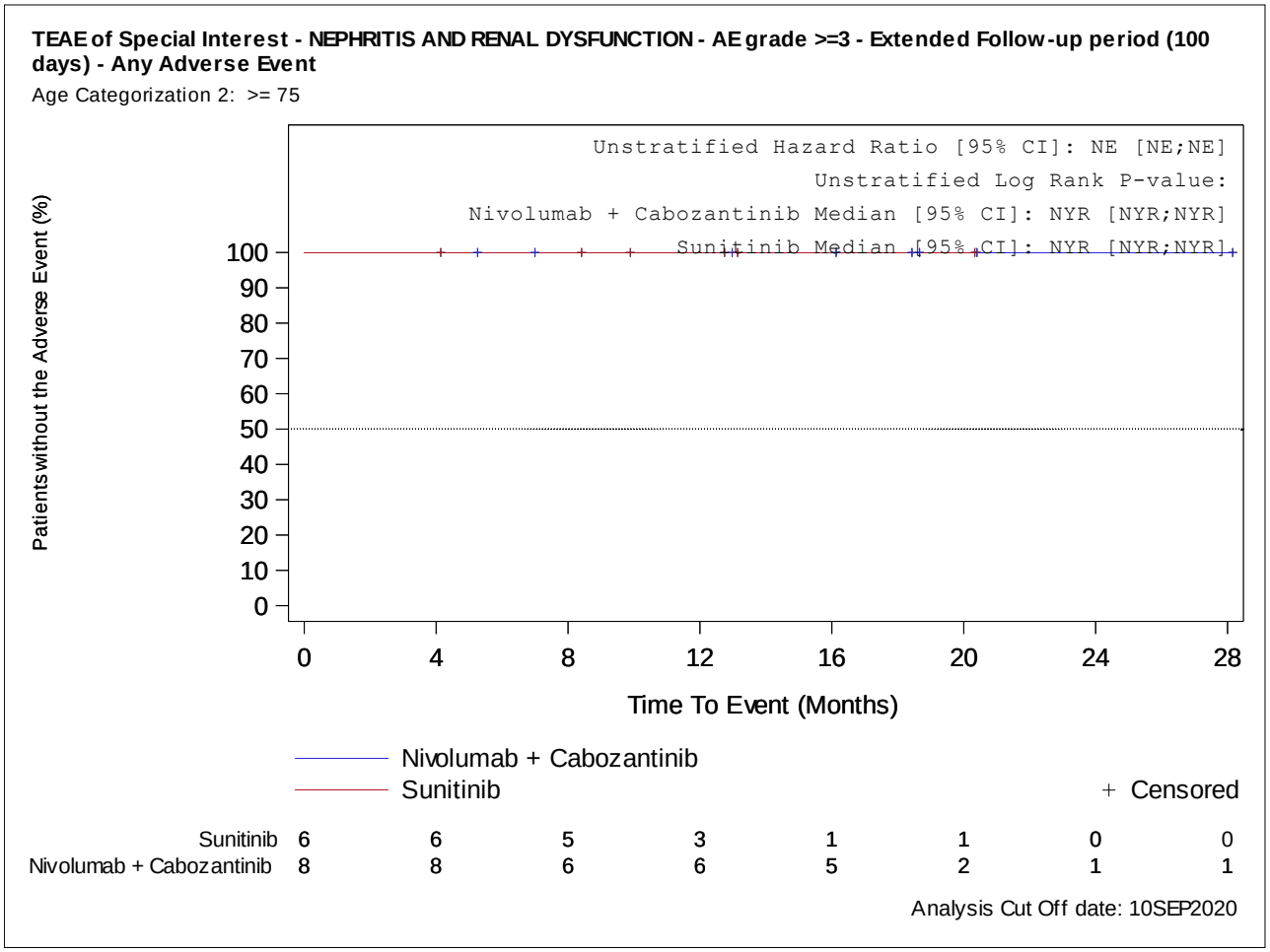

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:53:25

FIGURE 3.122.2.4: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



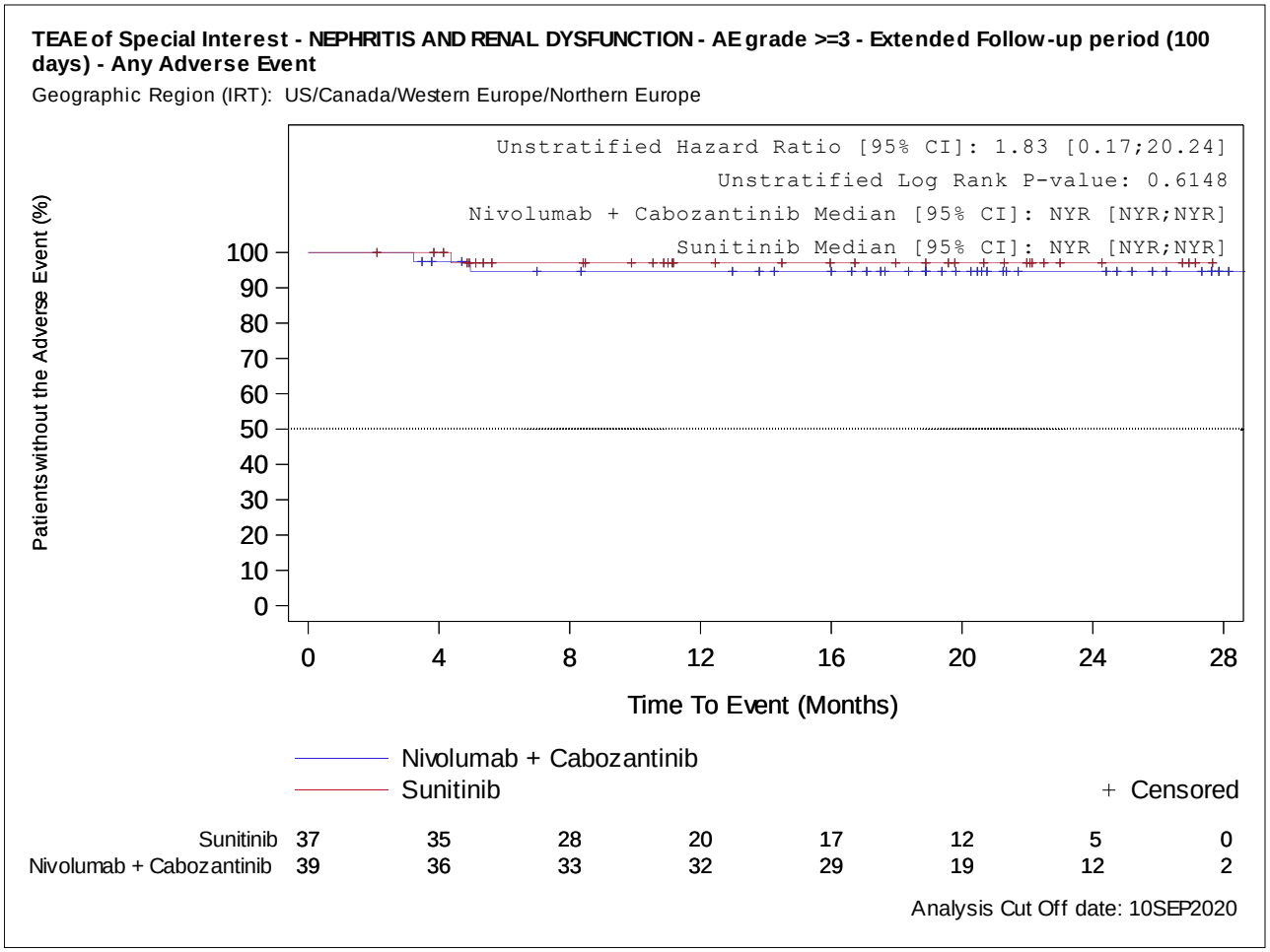

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:53:32

FIGURE 3.122.2.5: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



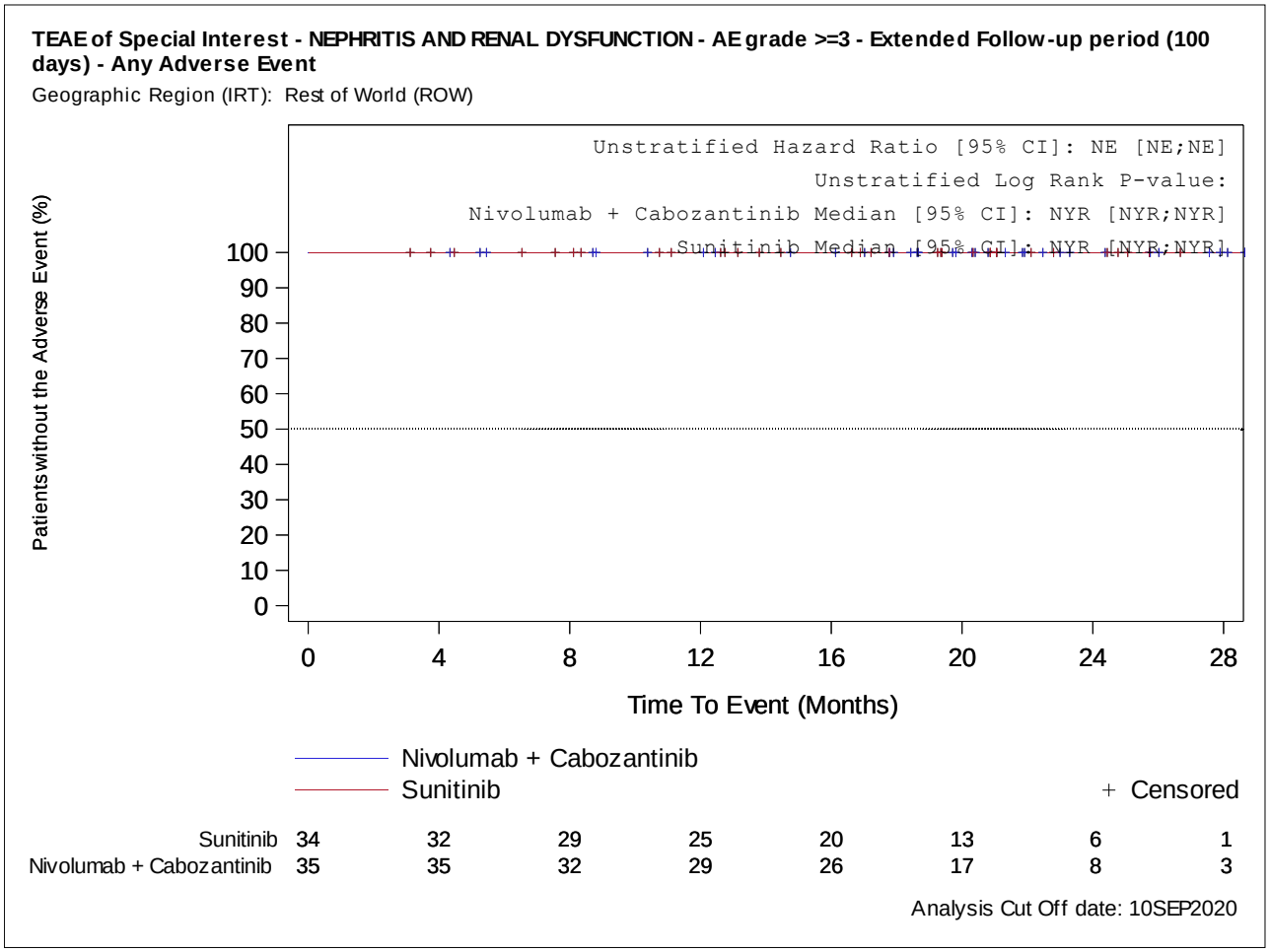

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:53:37

FIGURE 3.122.2.6: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



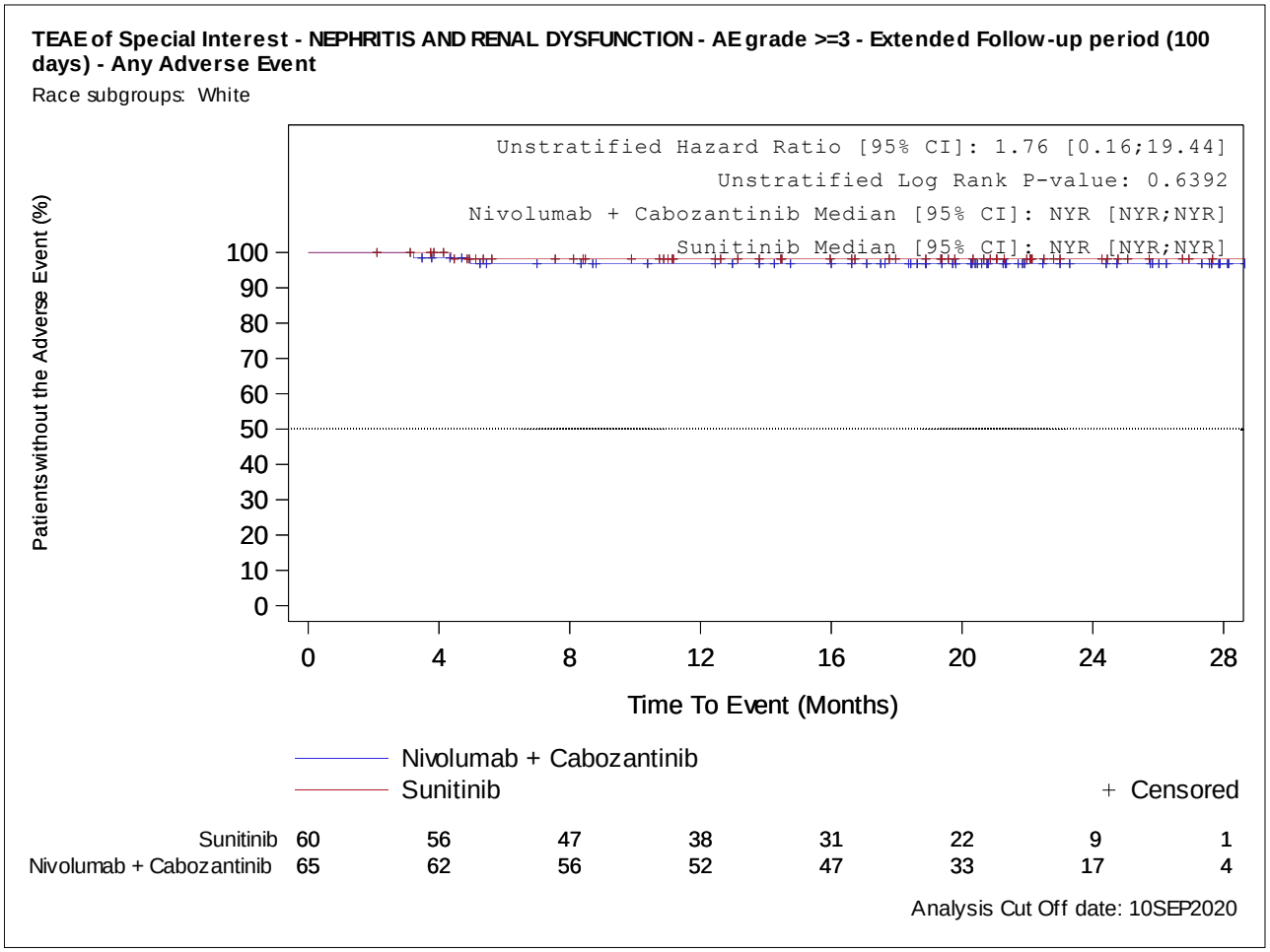

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:53:43

FIGURE 3.122.2.7: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



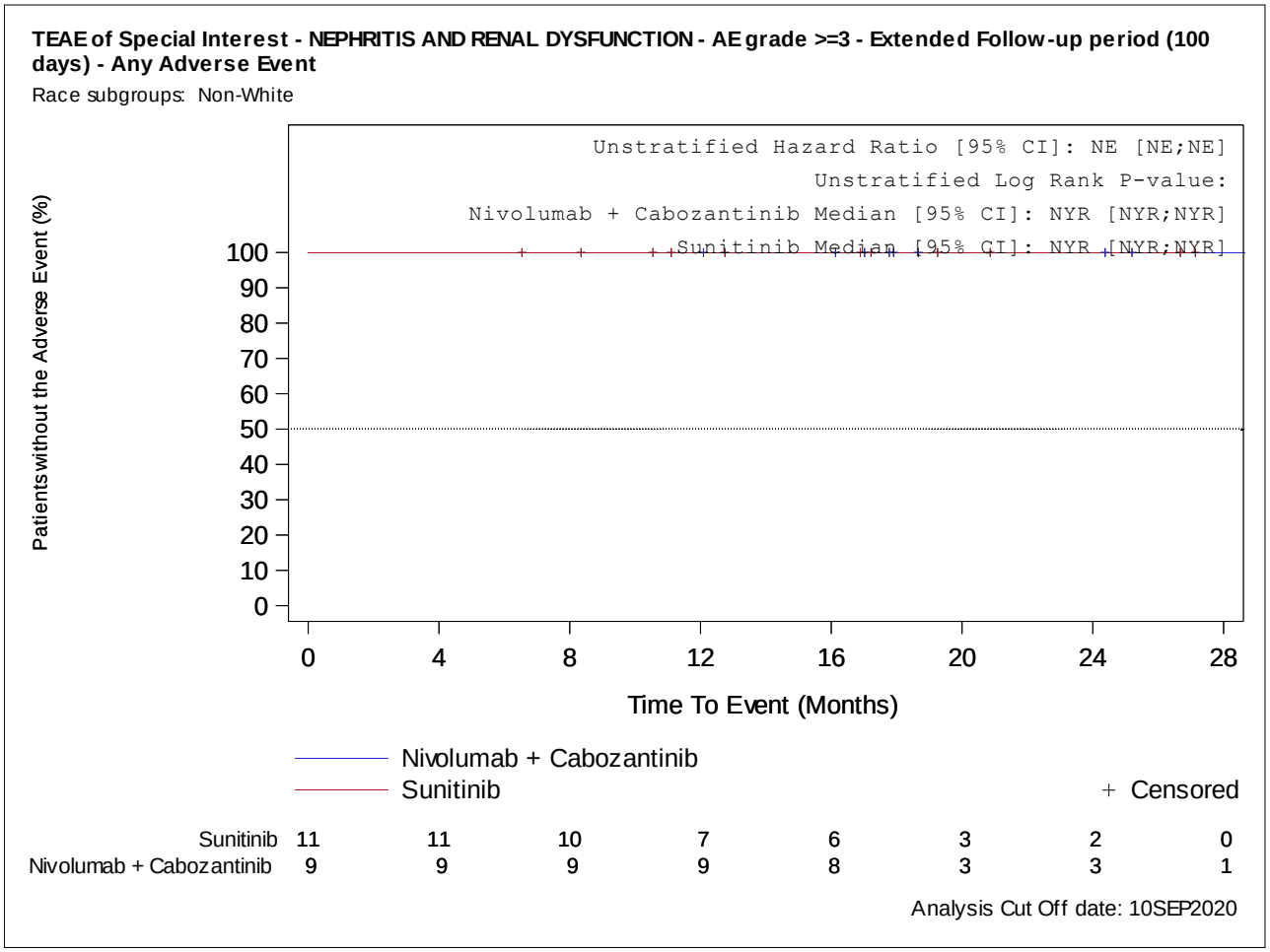

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:53:49

FIGURE 3.122.2.8: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



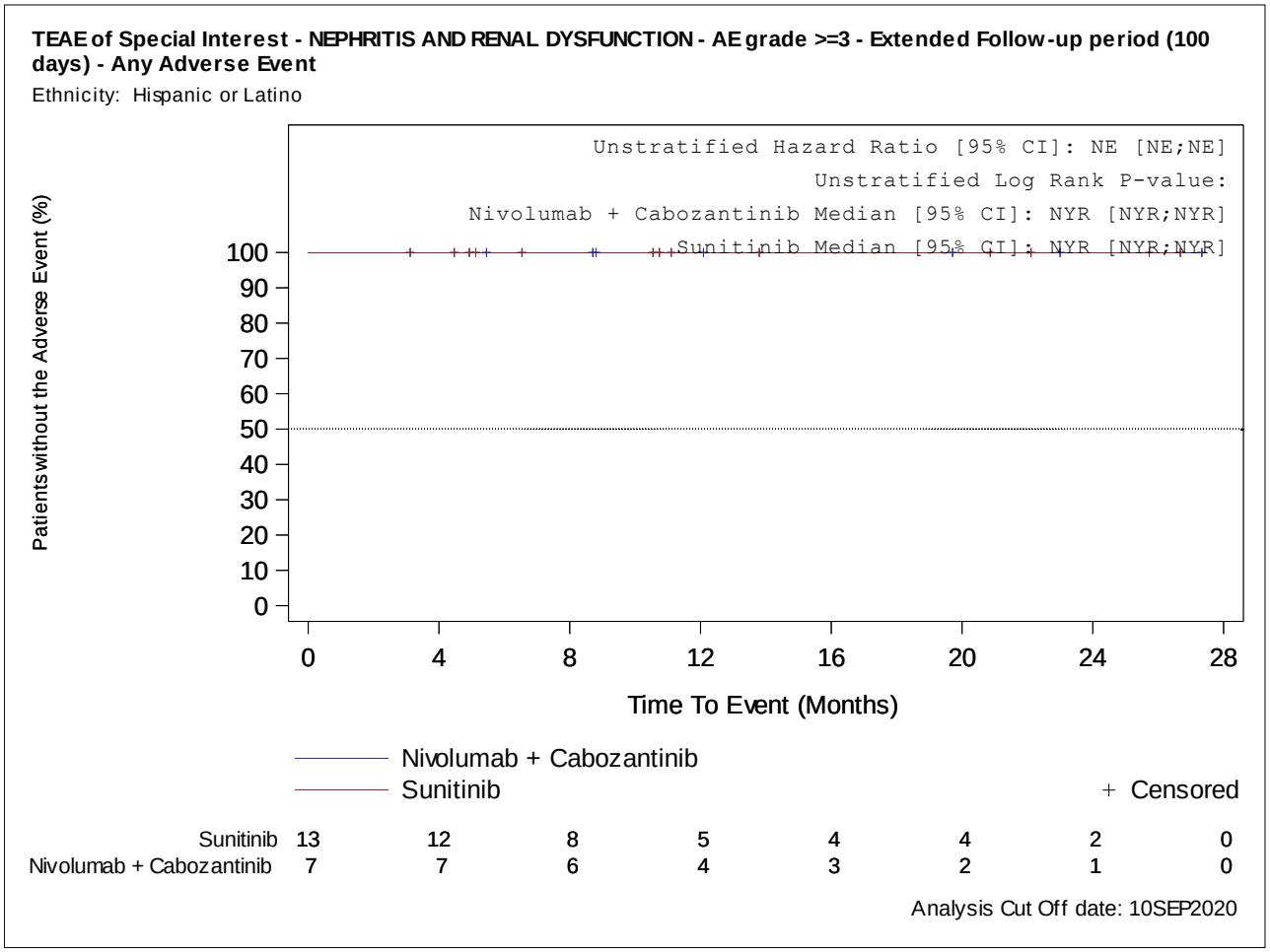

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:53:55

FIGURE 3.122.2.9: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



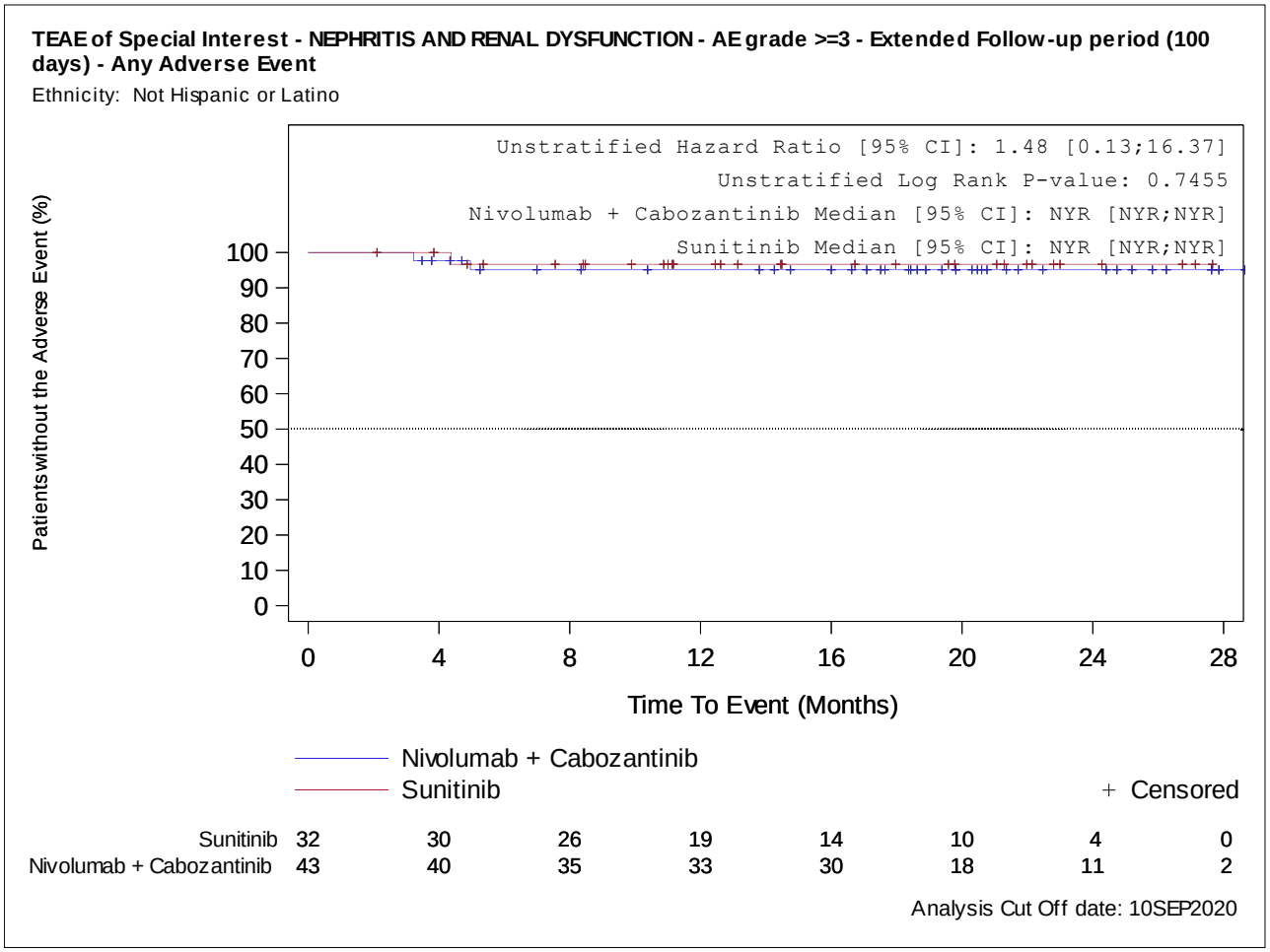

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:54:01

FIGURE 3.122.2.10: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



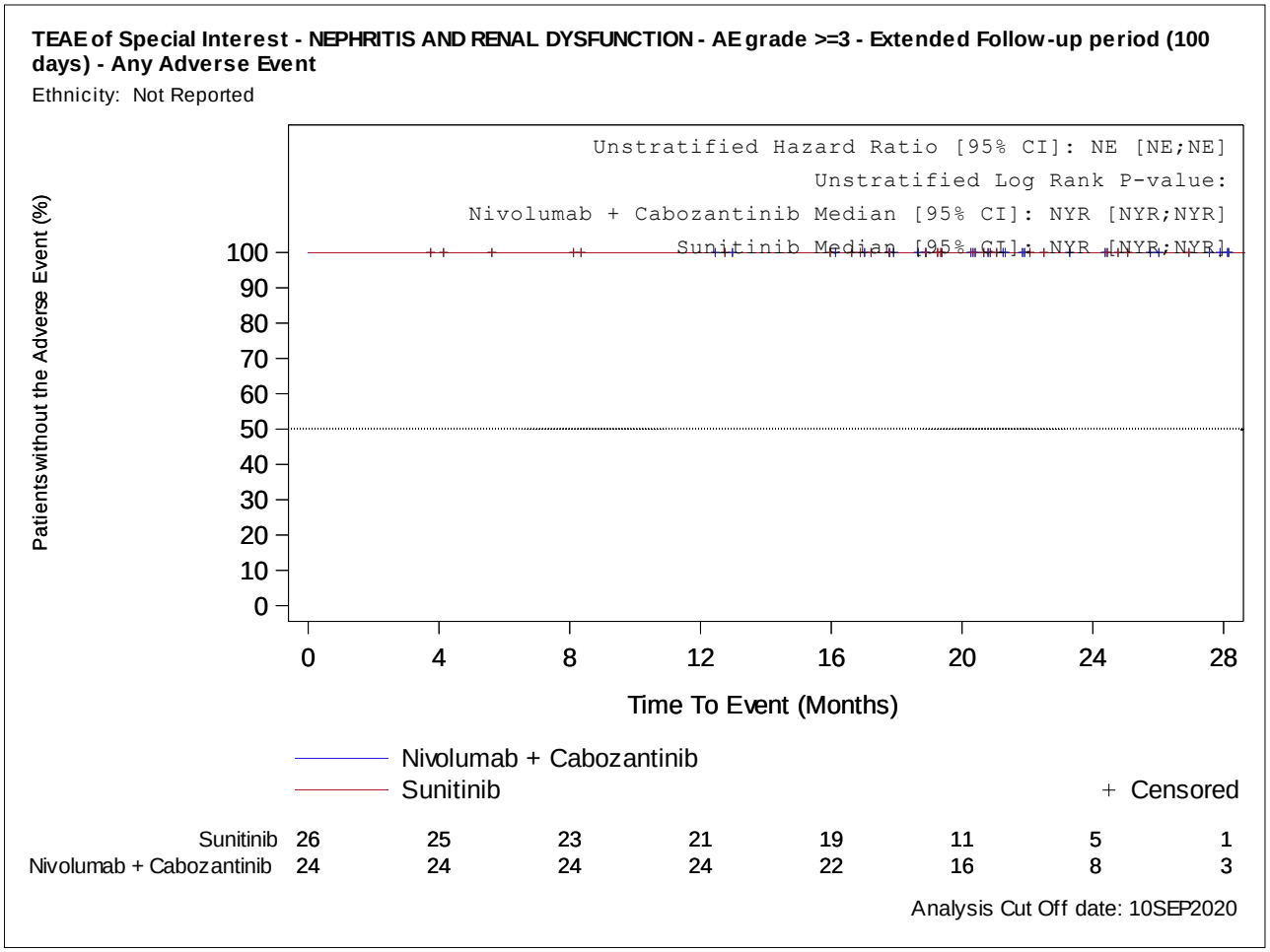

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:54:06

FIGURE 3.122.2.11: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity:  Not Hispanic or Latino



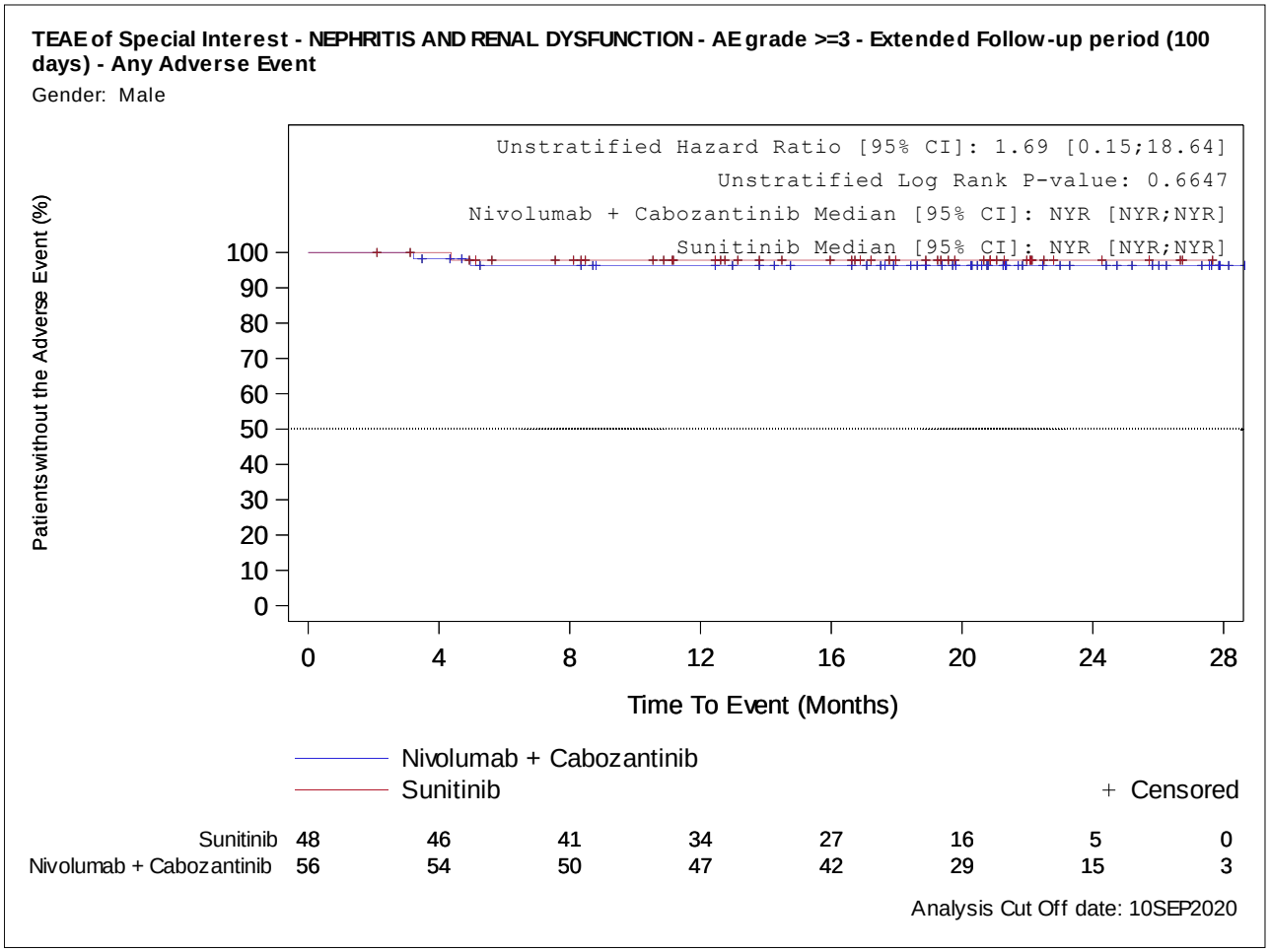

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:54:12

FIGURE 3.122.2.12: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



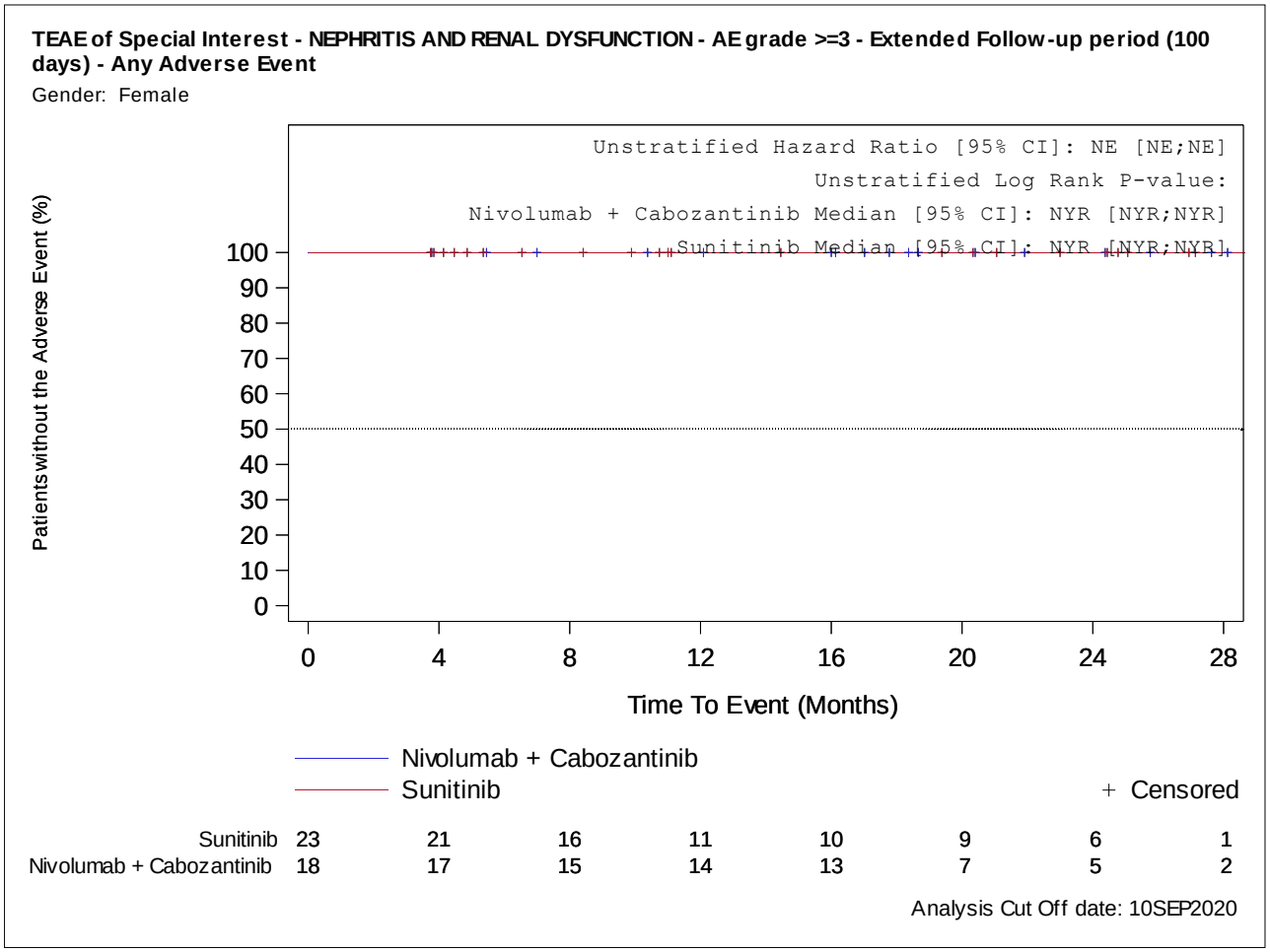

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:54:18

FIGURE 3.122.2.13: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



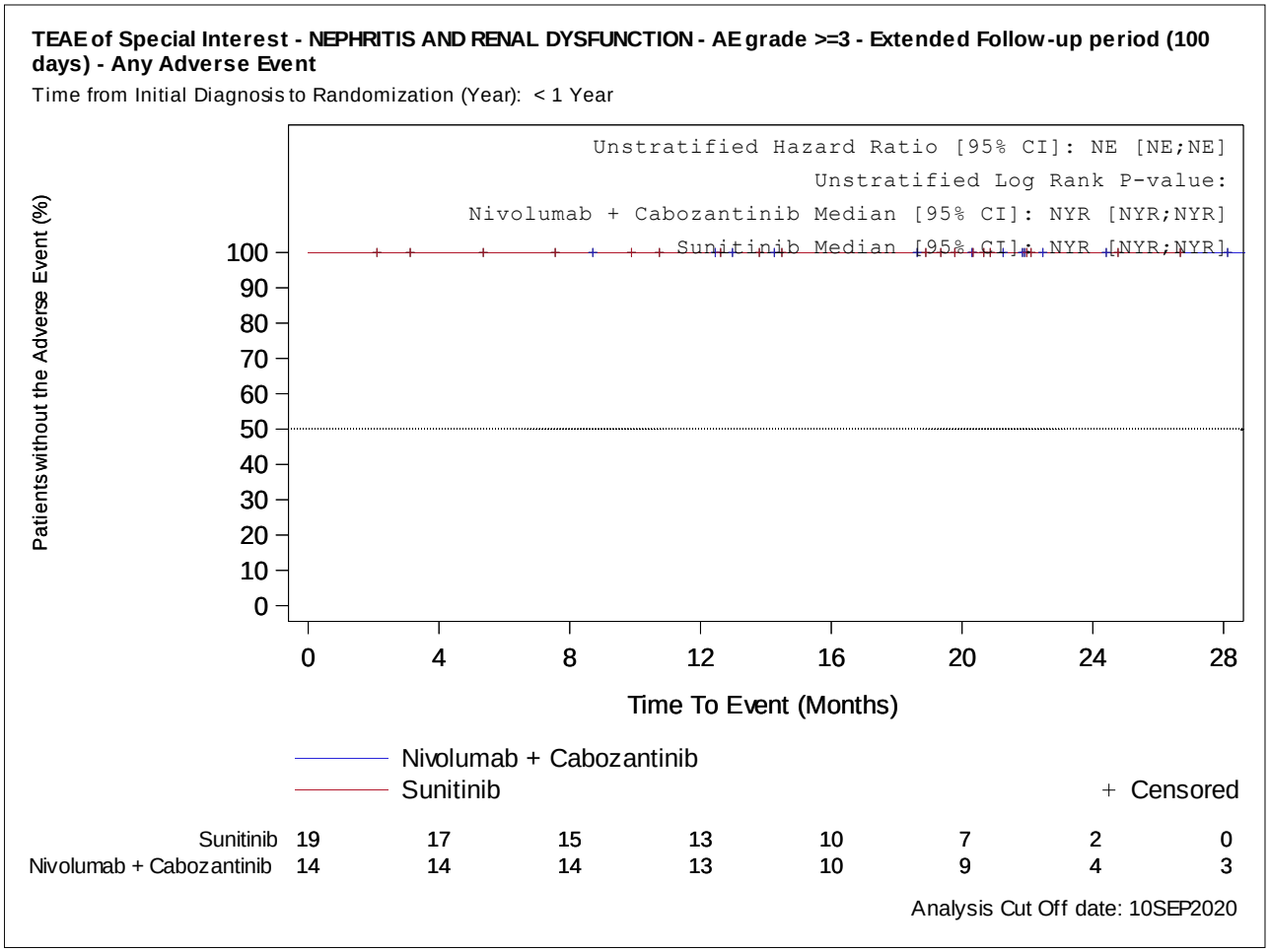

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:54:24

FIGURE 3.122.2.14: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



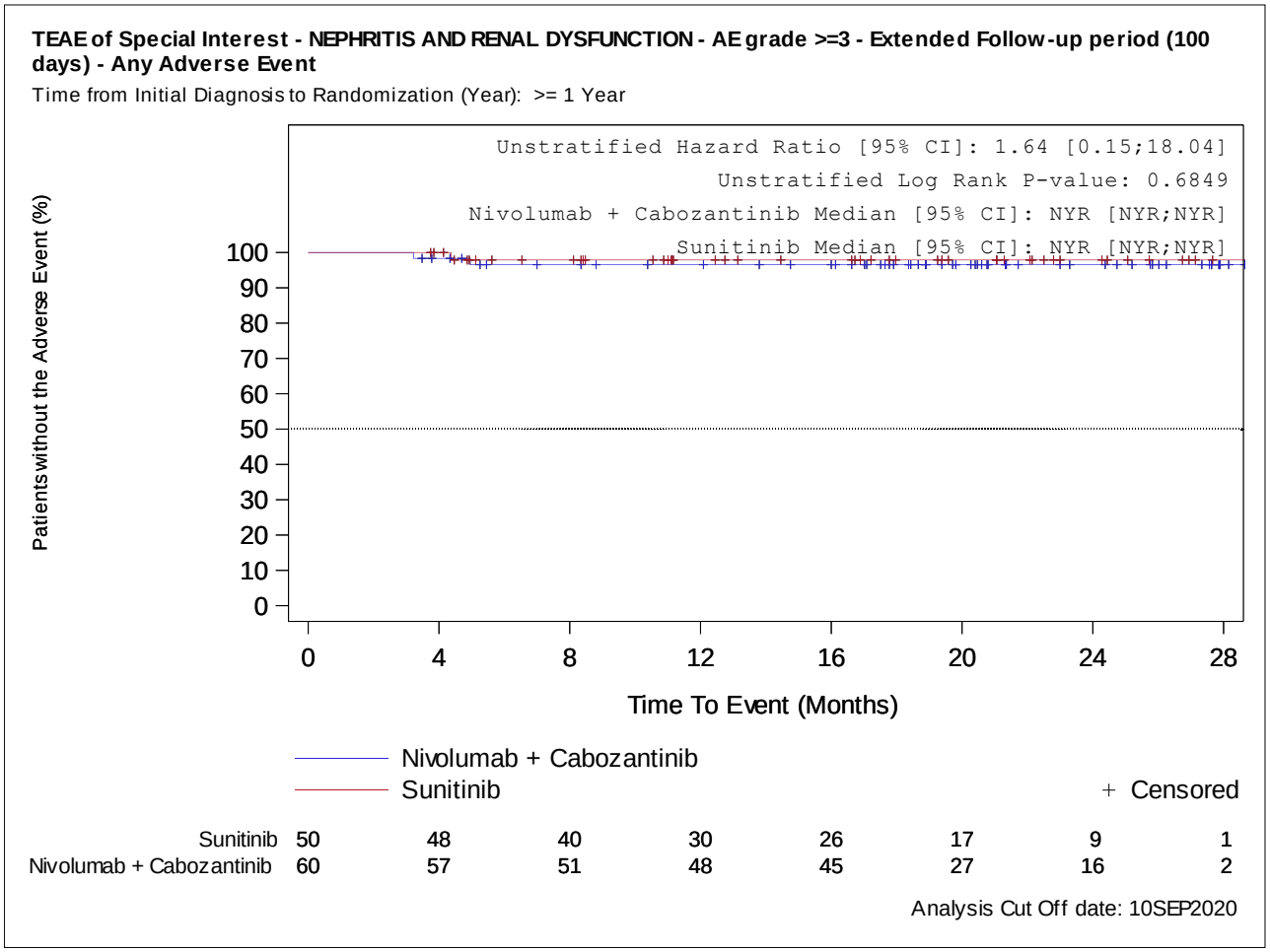

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:54:30

FIGURE 3.122.2.15: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



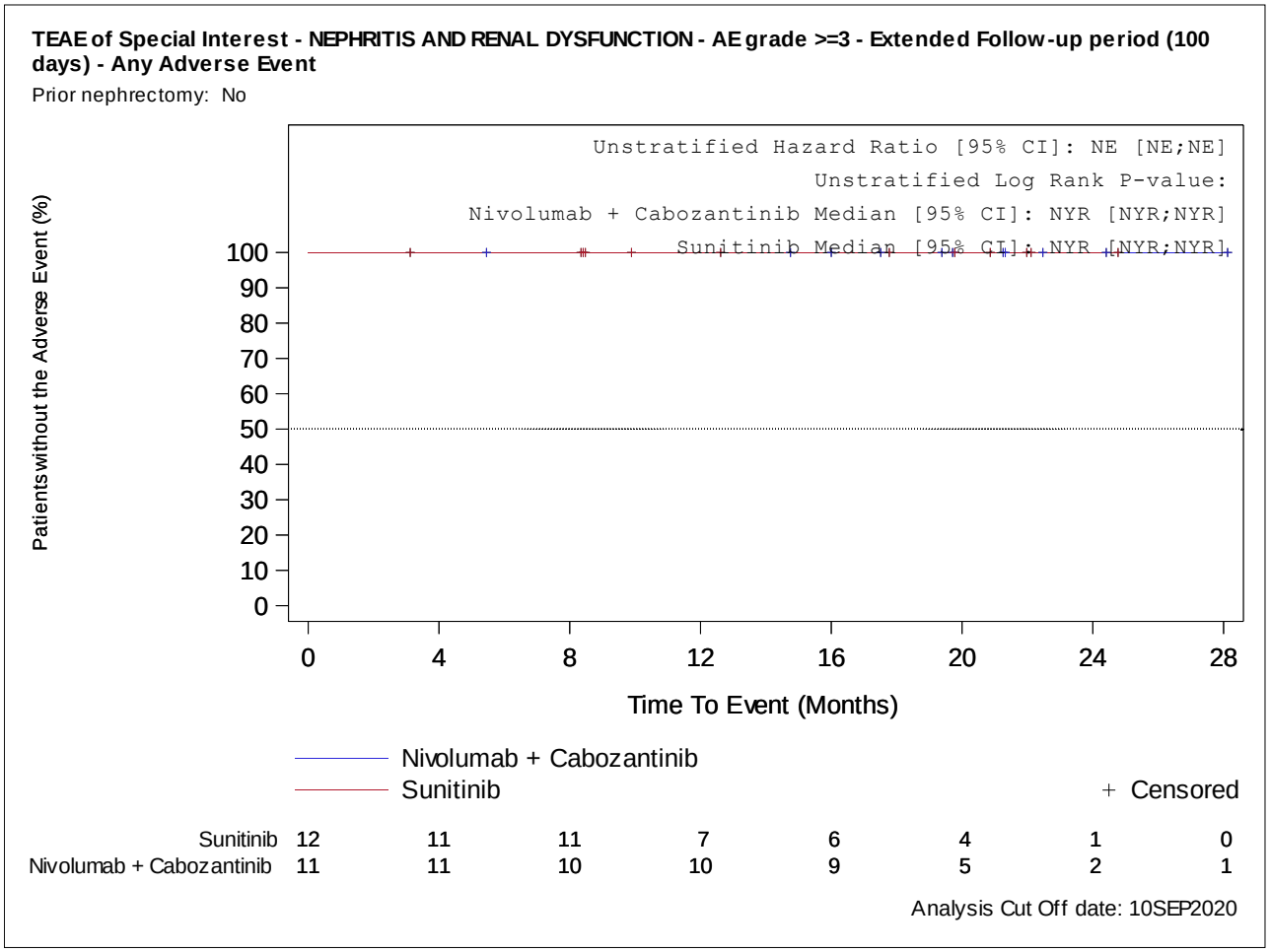

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:54:49

FIGURE 3.122.2.16: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:54:55

FIGURE 3.122.2.17: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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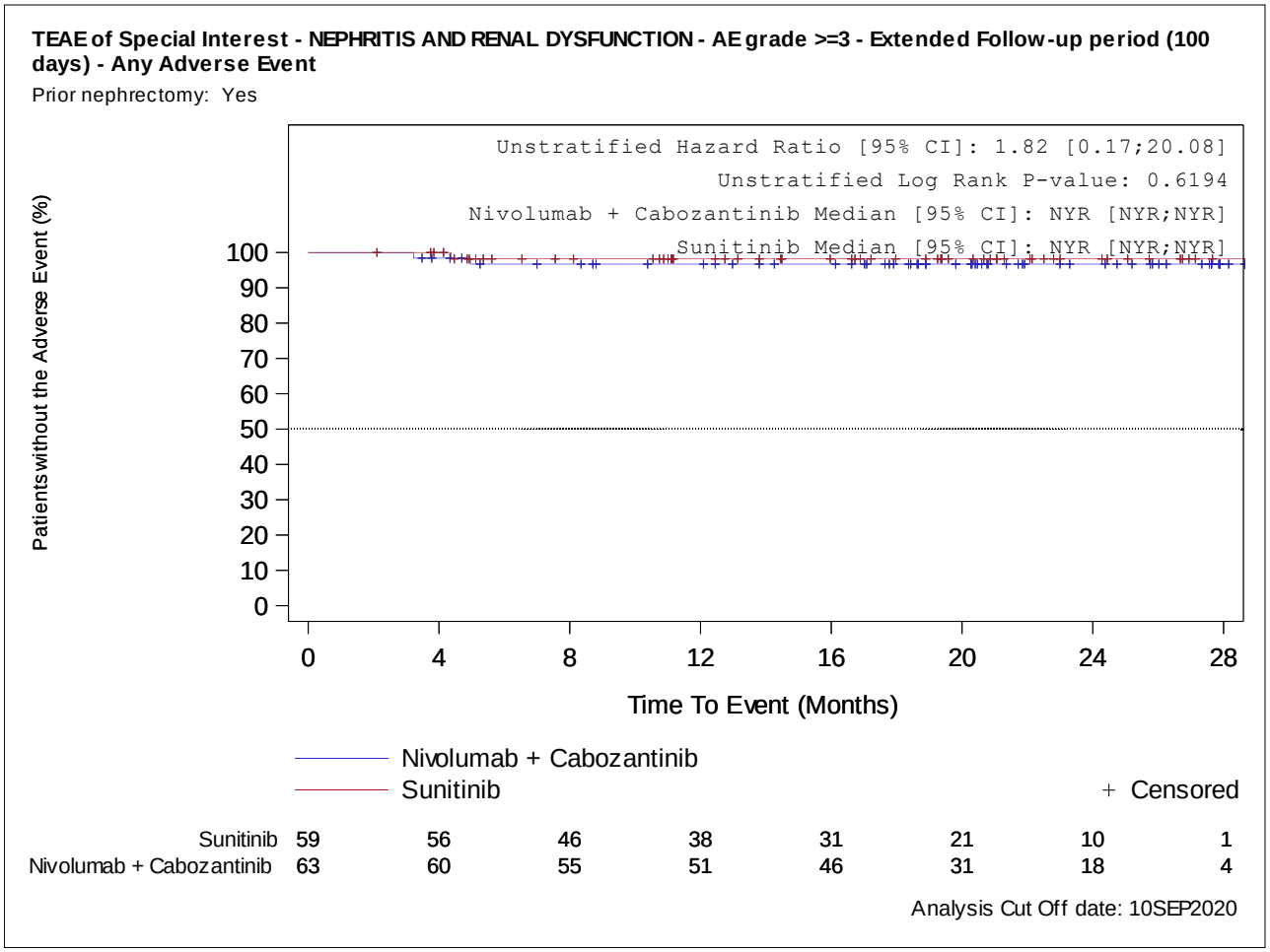
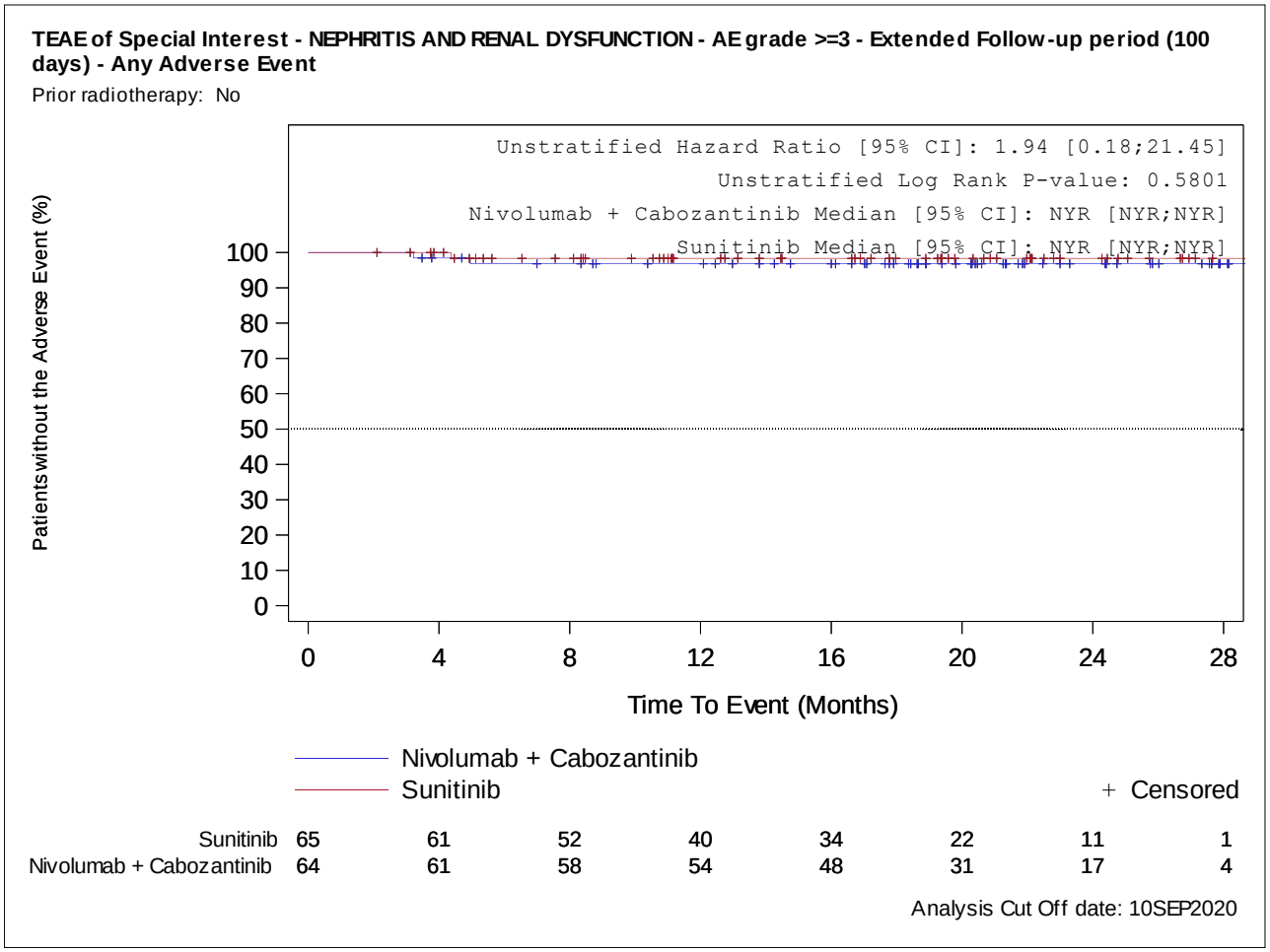
FIGURE 3.122.2.18: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:55:51

FIGURE 3.122.2.19: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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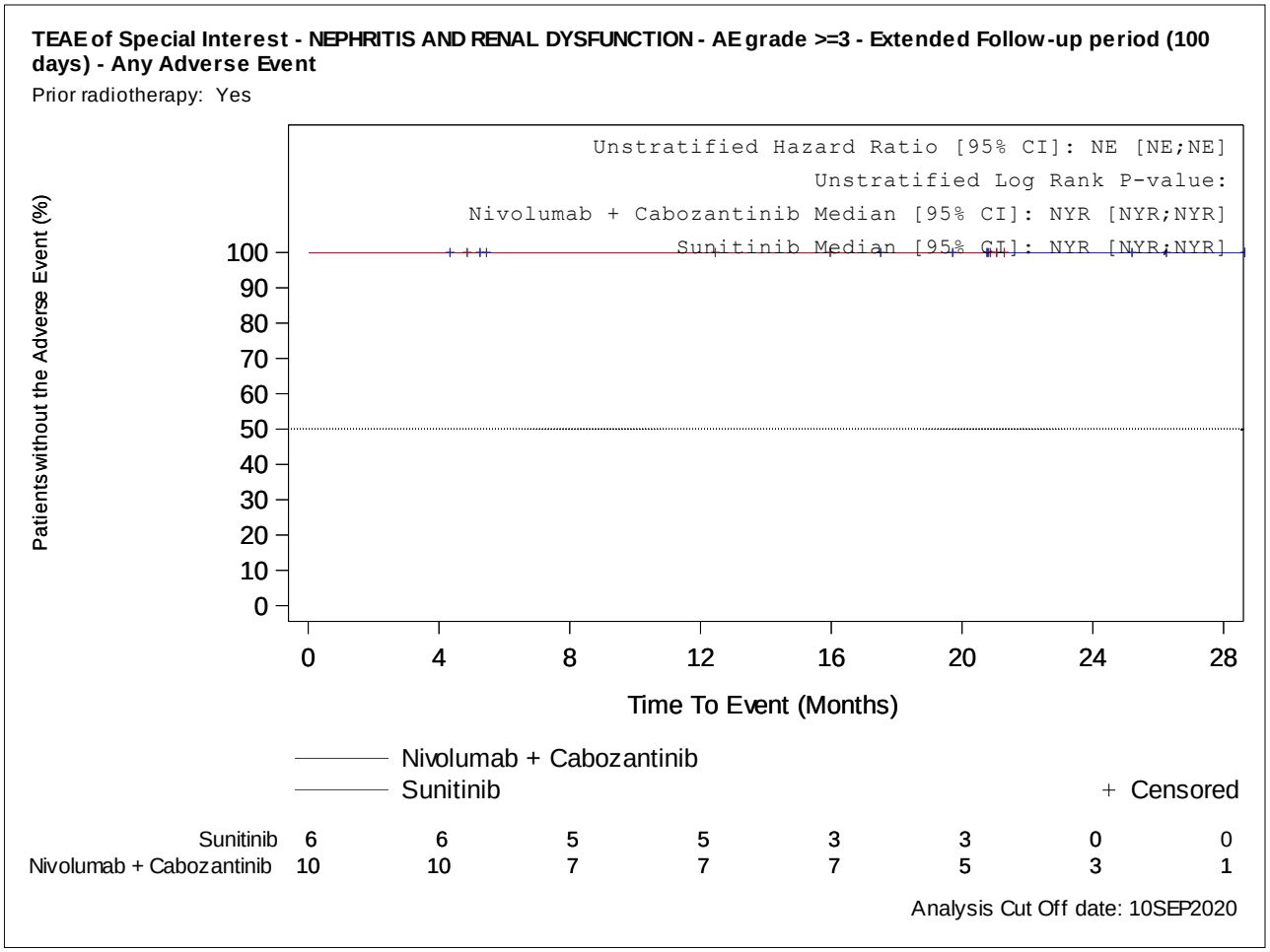
FIGURE 3.122.2.20: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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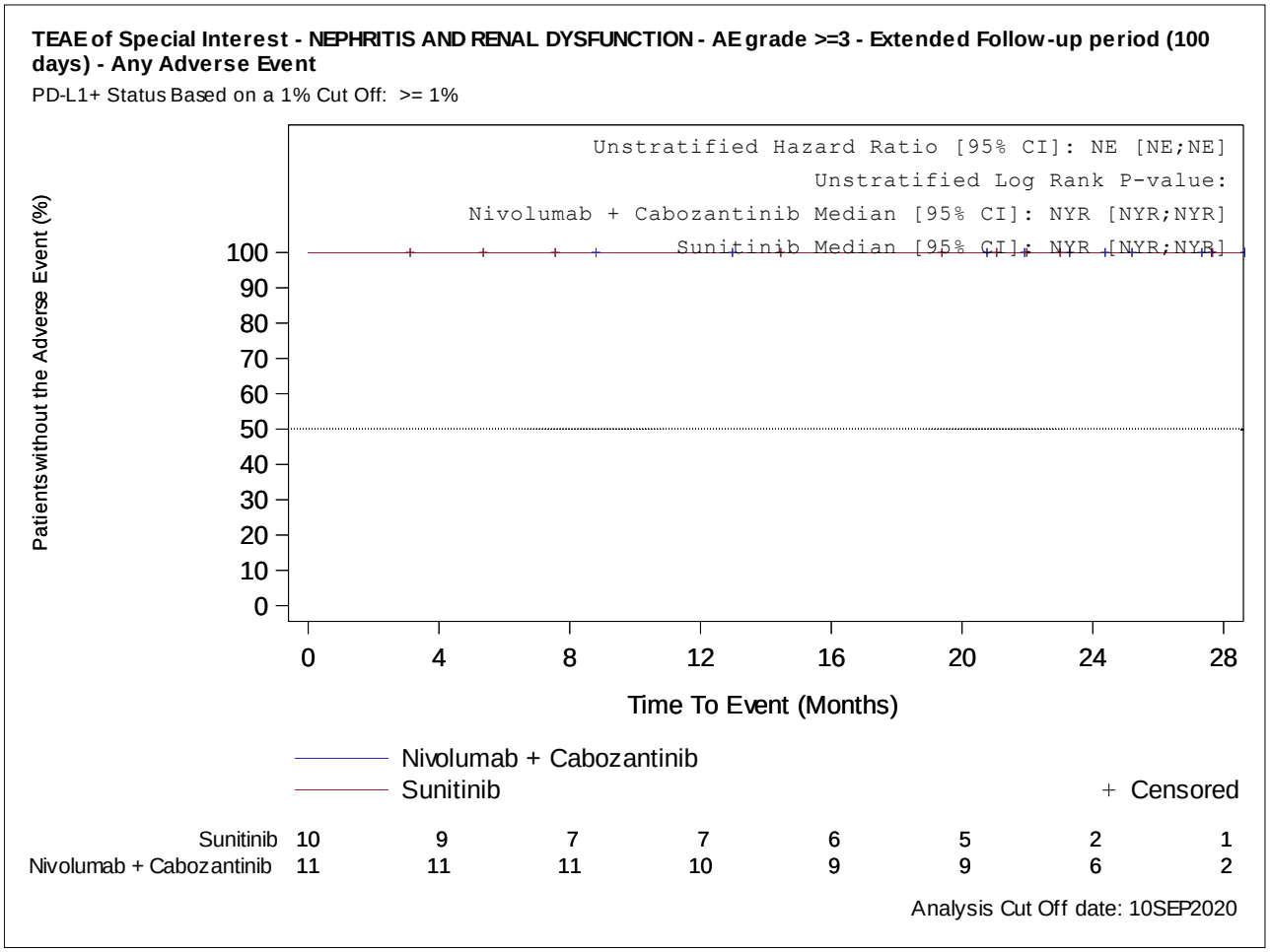
FIGURE 3.122.2.21: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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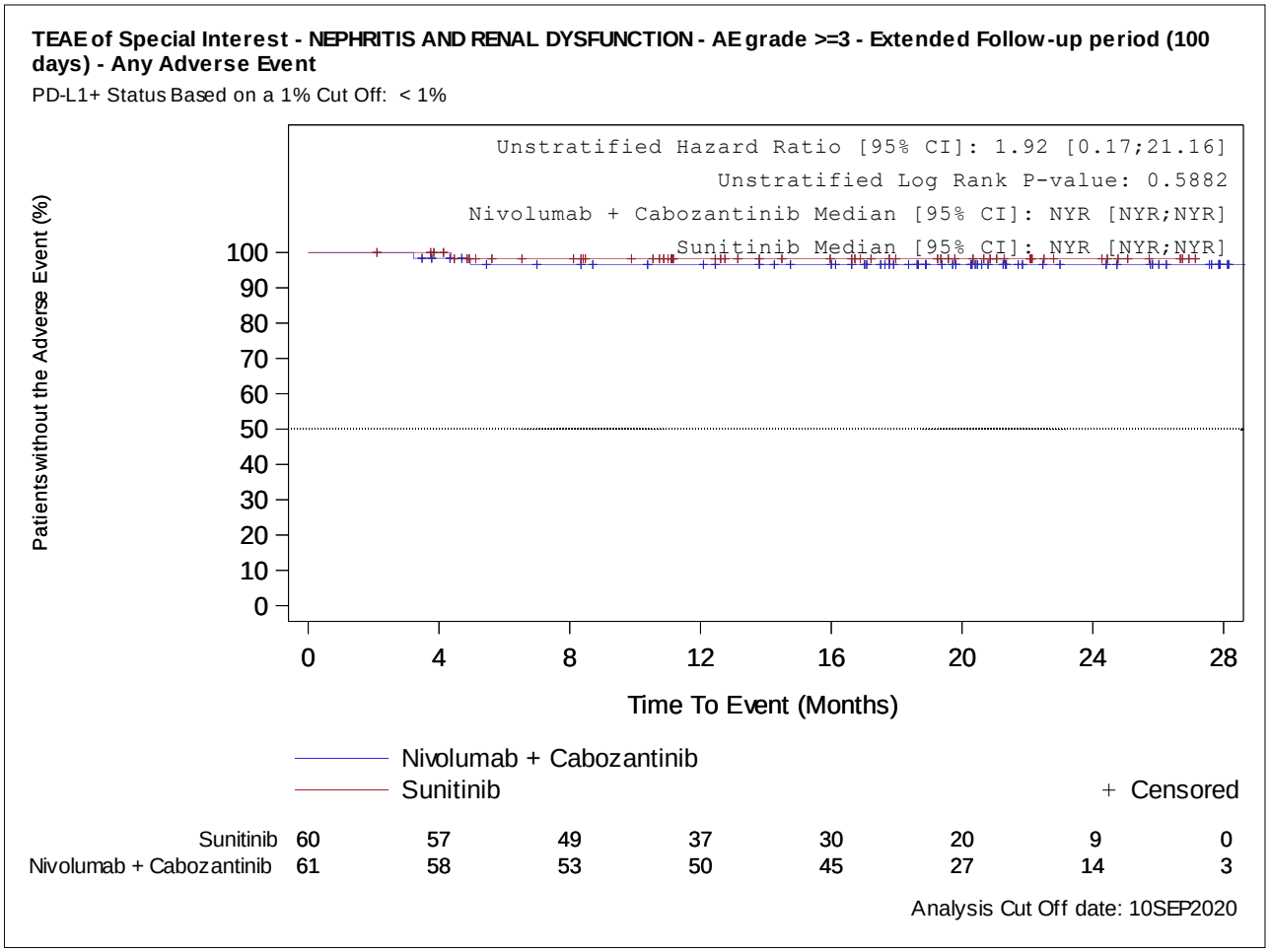
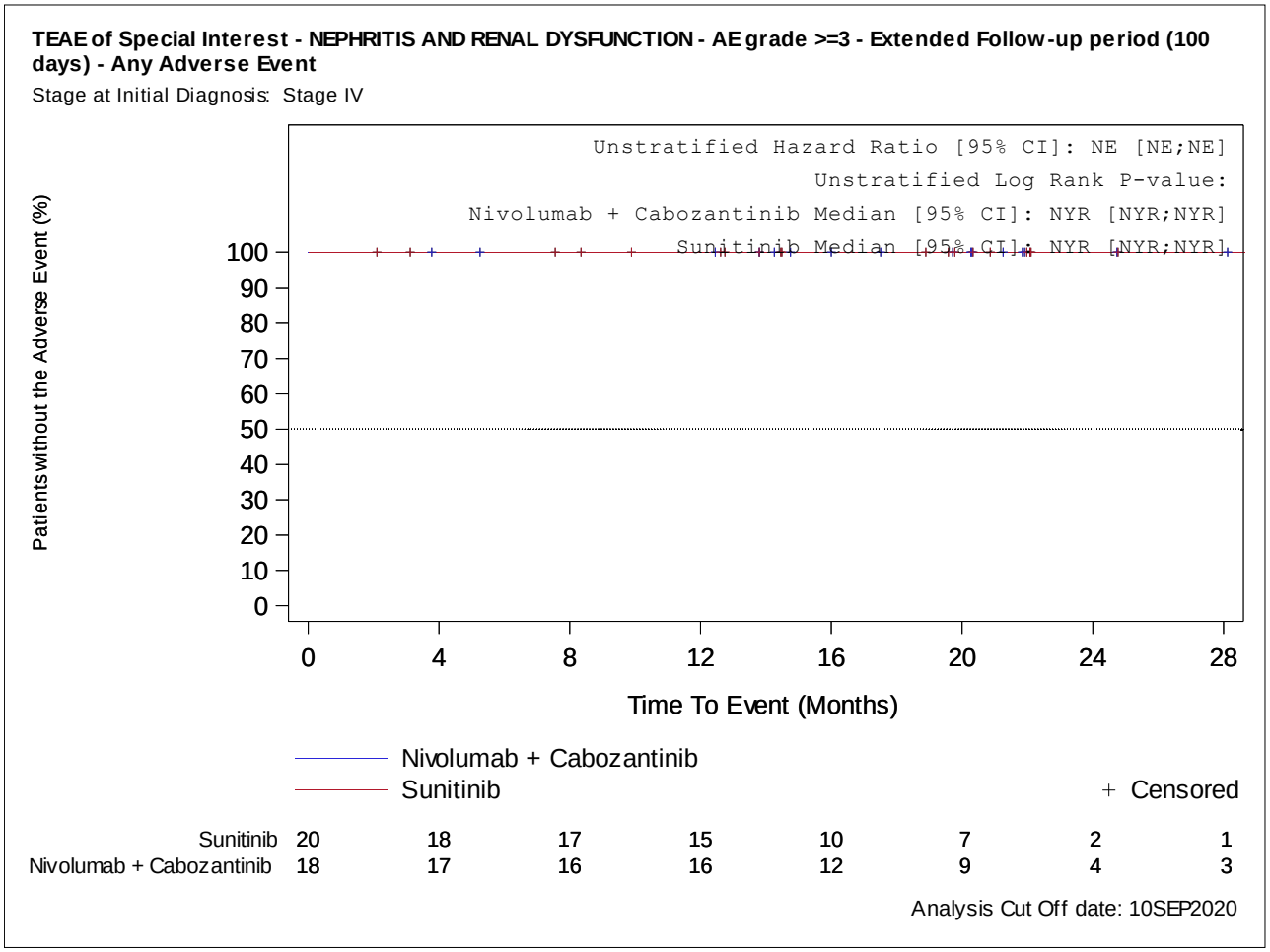
FIGURE 3.122.2.22: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:56:12

FIGURE 3.122.2.23: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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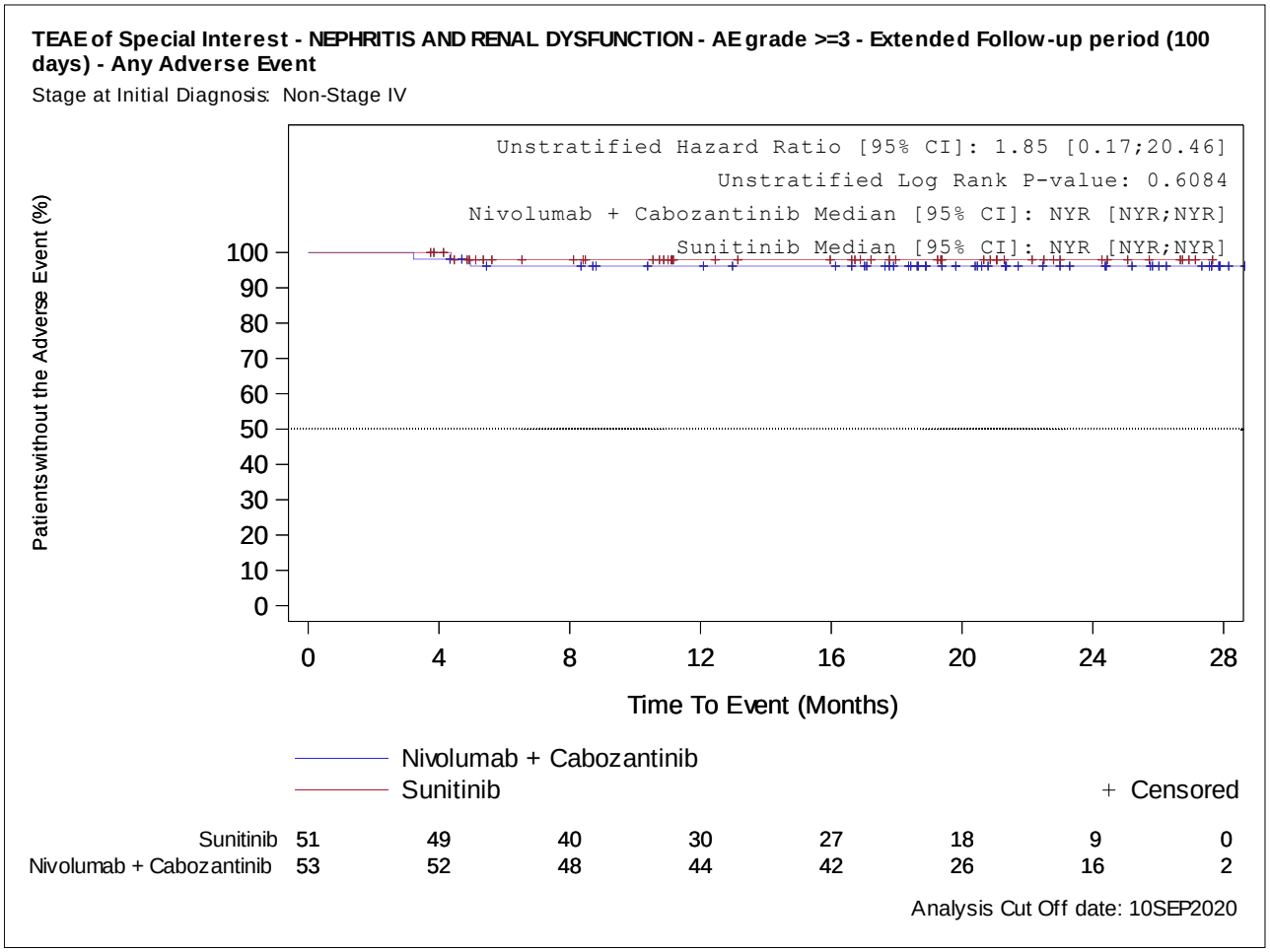
FIGURE 3.122.2.24: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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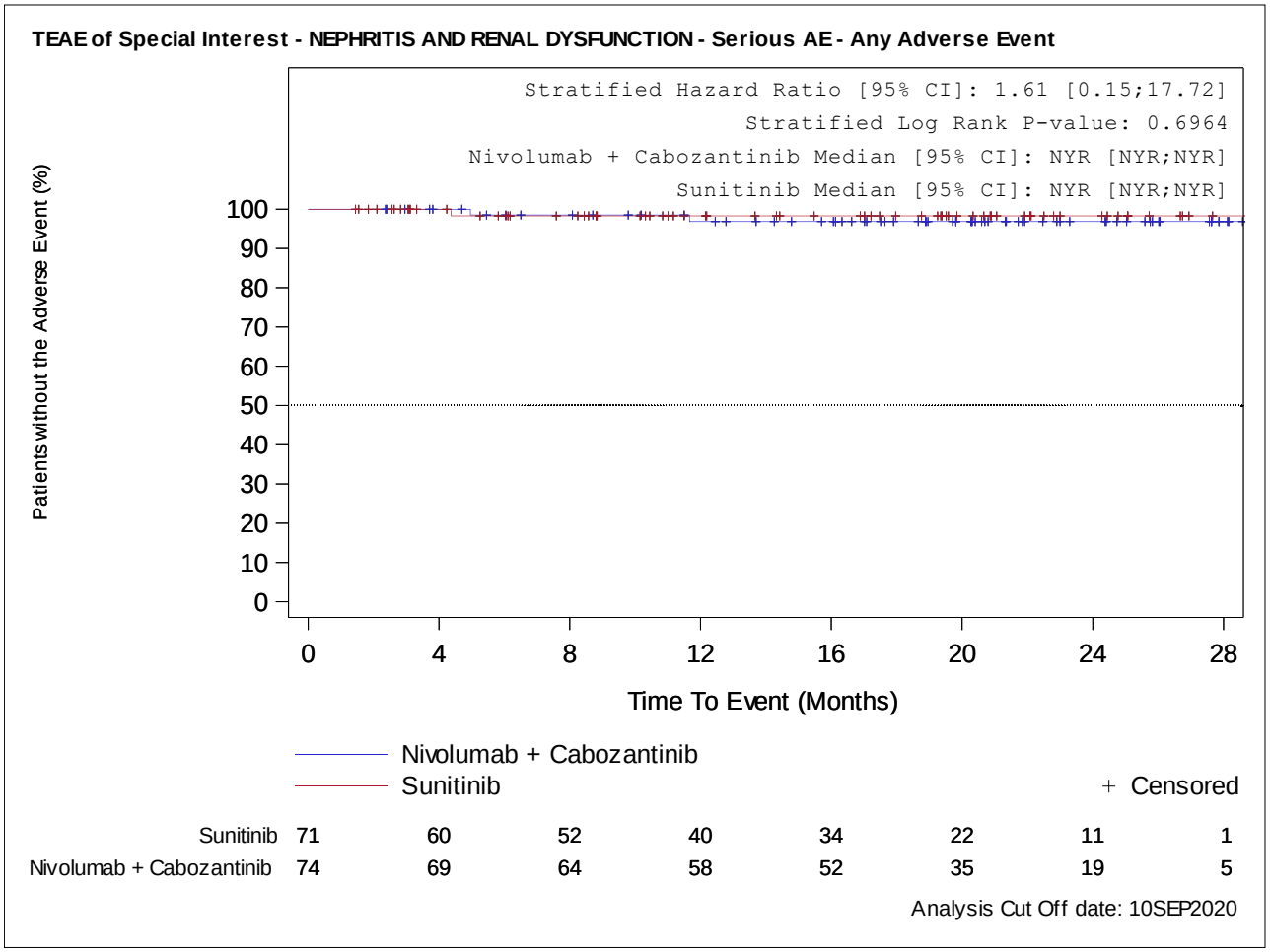
FIGURE 3.123.1: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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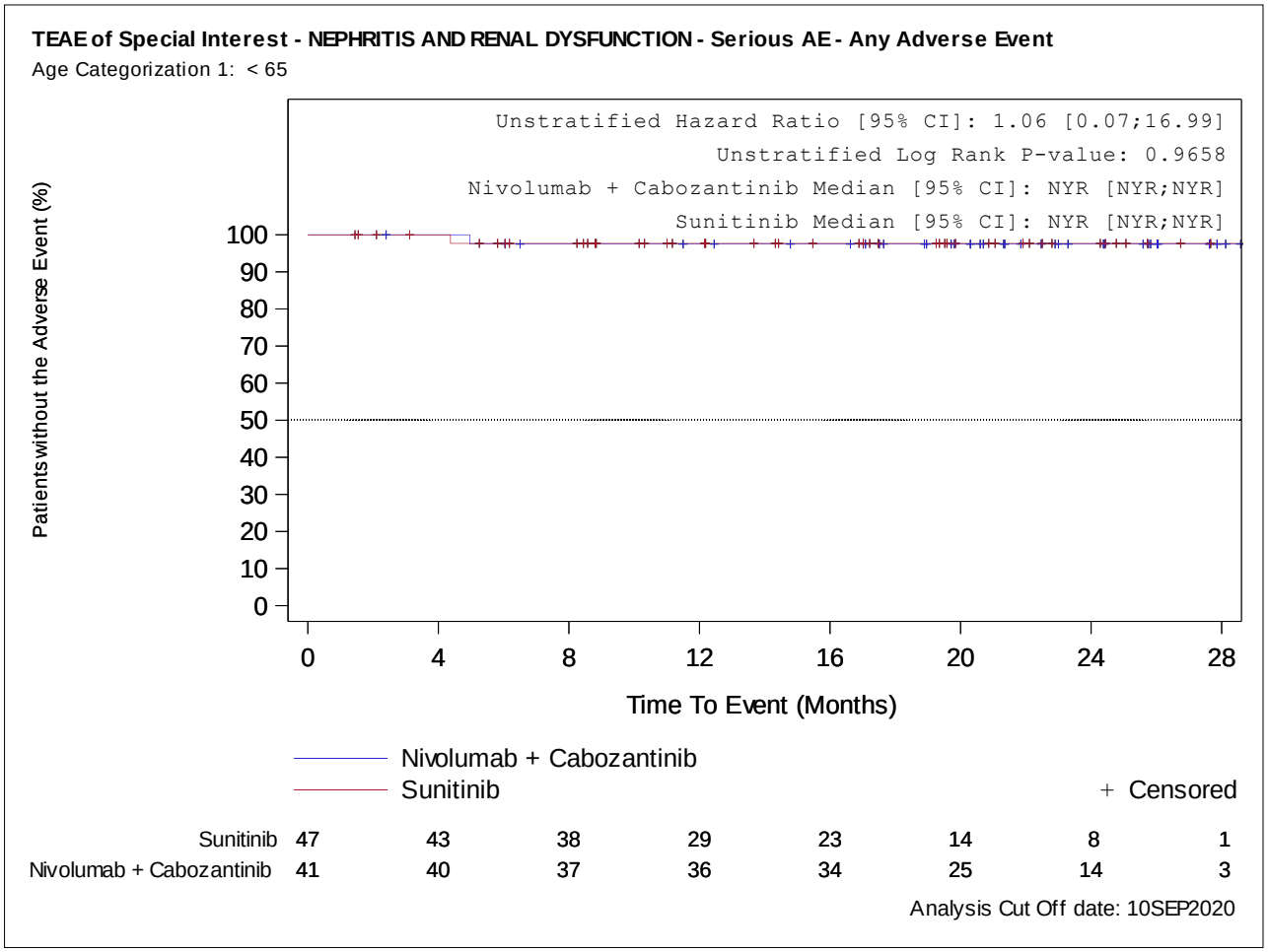
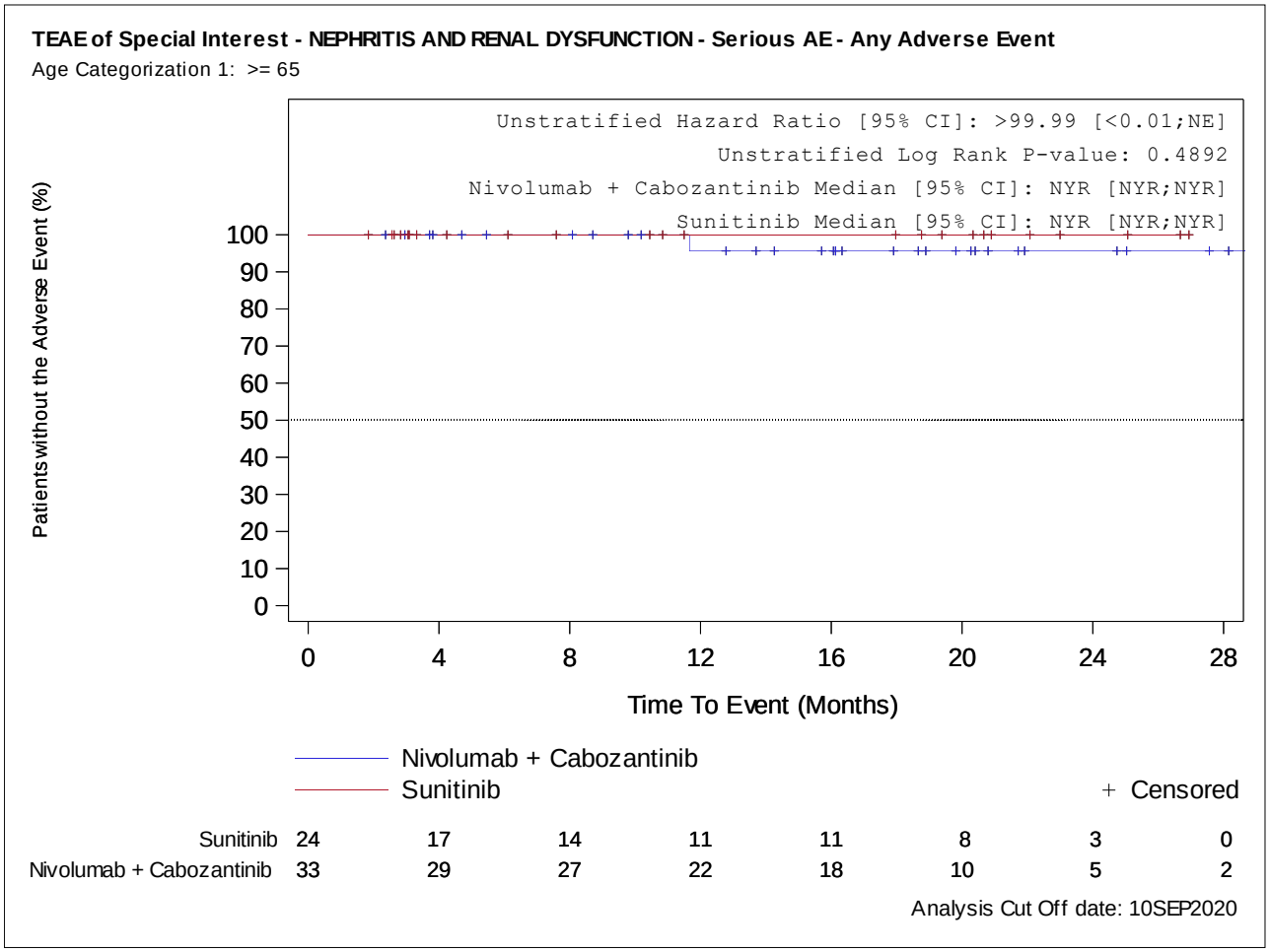
FIGURE 3.123.2.1: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 16:59:58

FIGURE 3.123.2.2: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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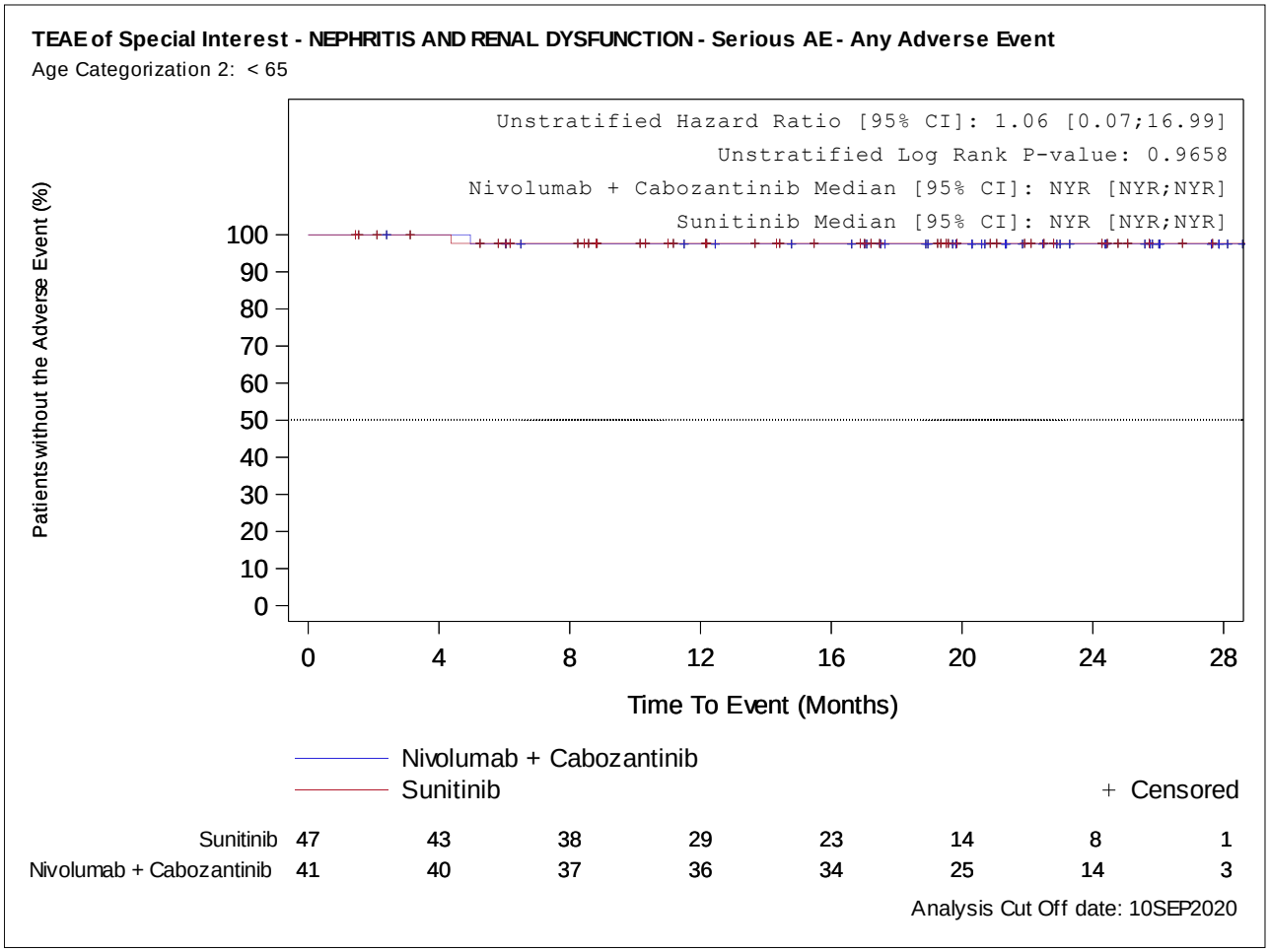
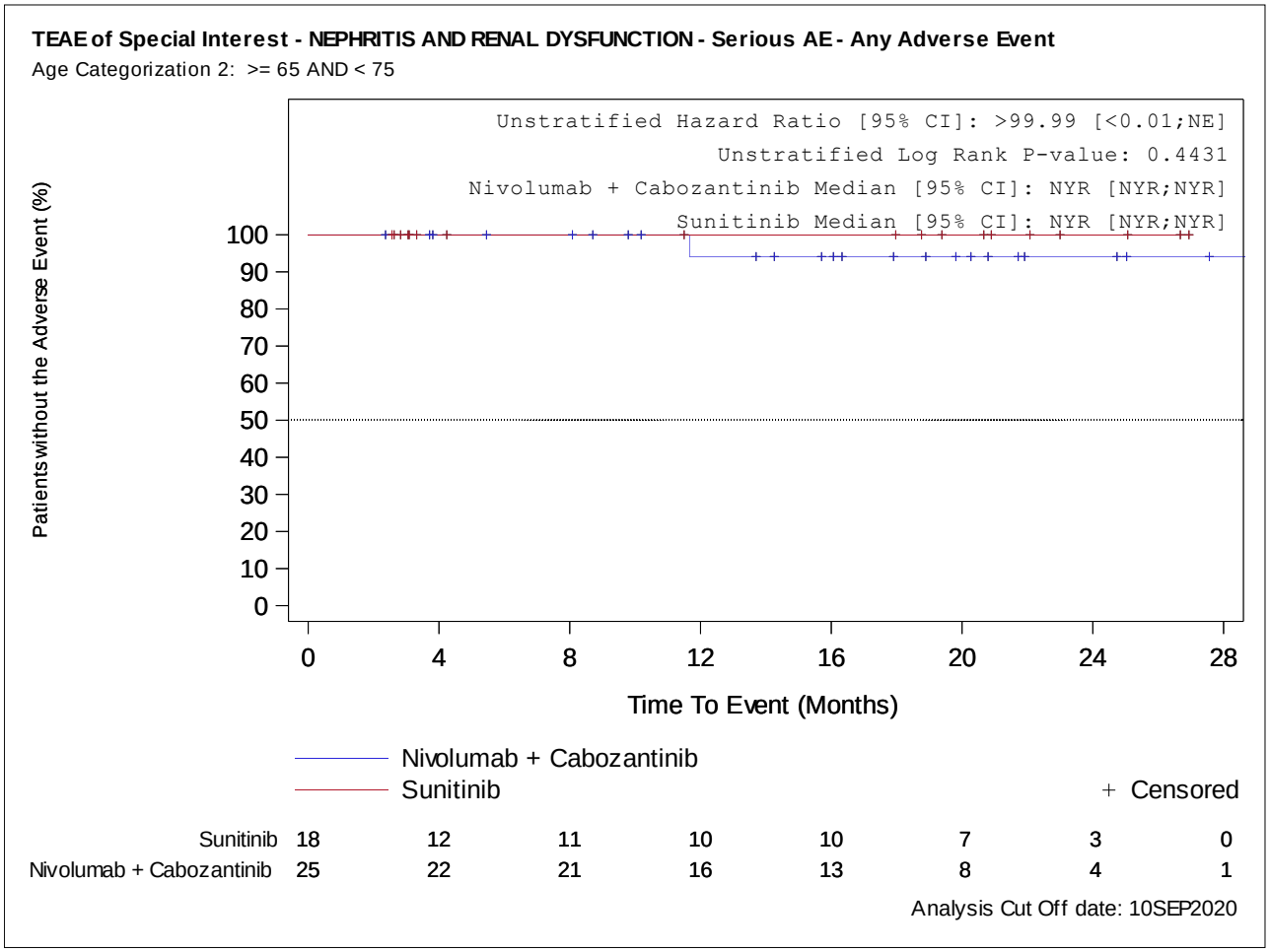
FIGURE 3.123.2.3: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



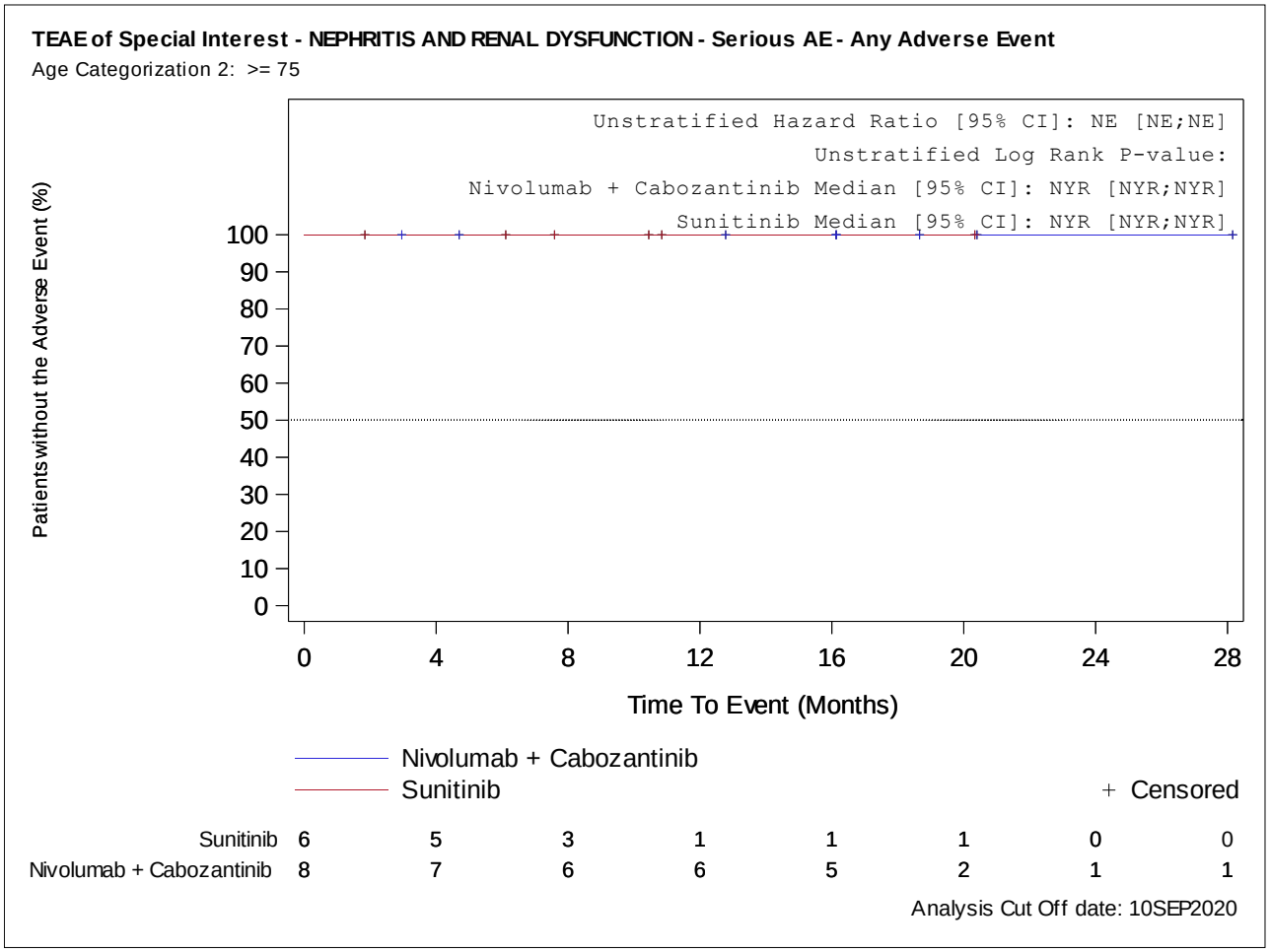

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:00:08

FIGURE 3.123.2.4: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



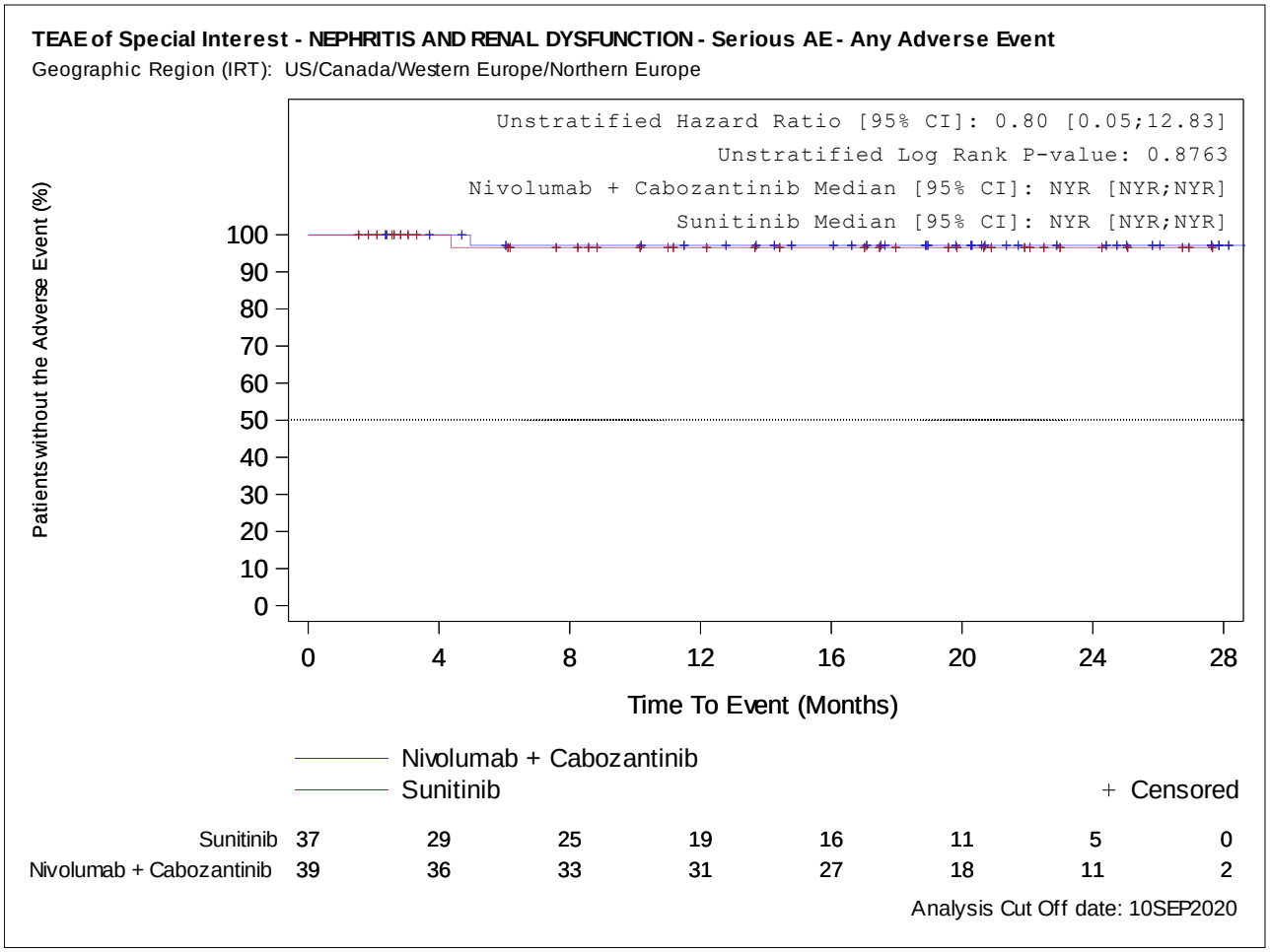

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:00:14

FIGURE 3.123.2.5: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



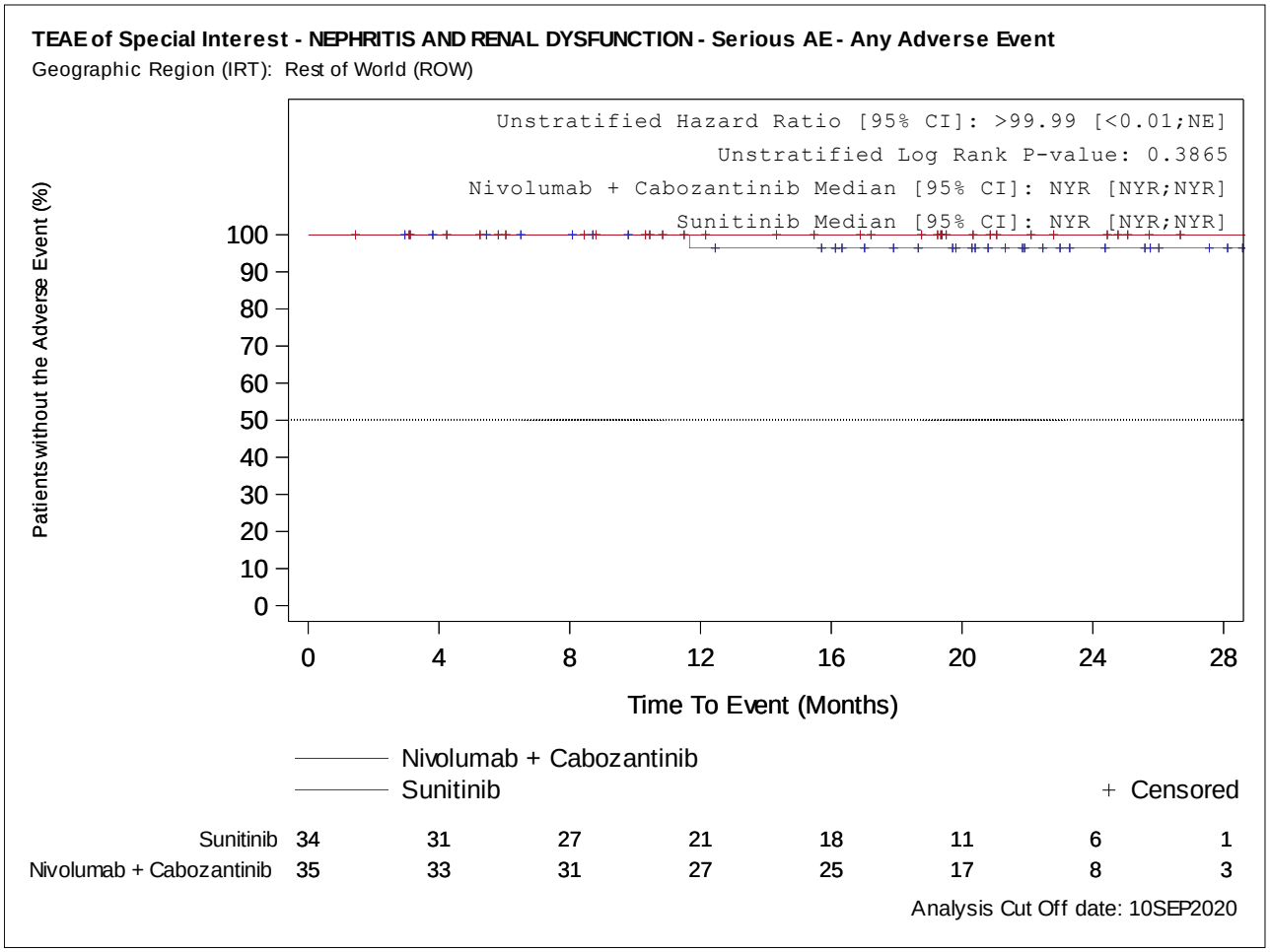

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:00:19

FIGURE 3.123.2.6: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



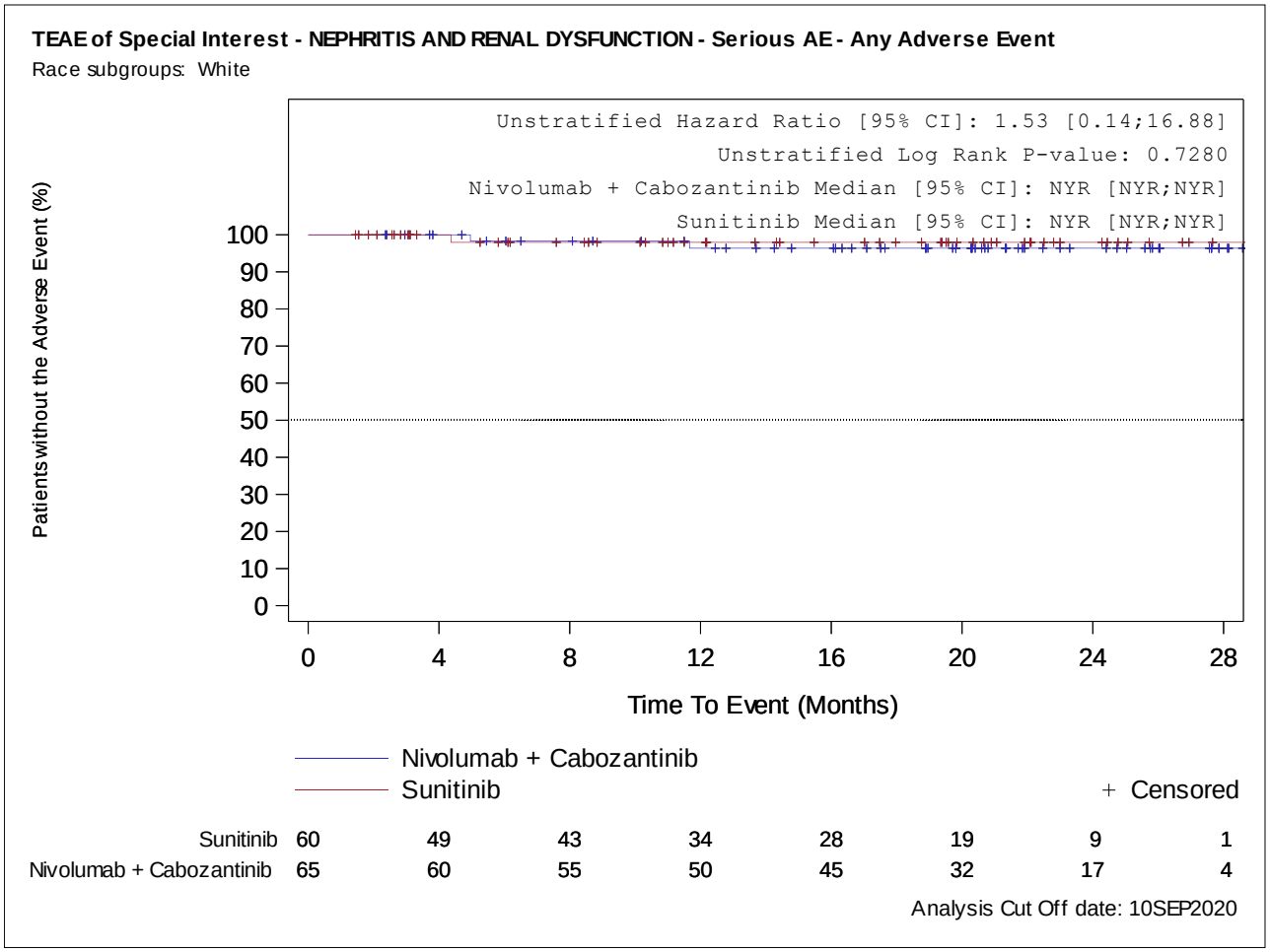

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:00:25

FIGURE 3.123.2.7: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



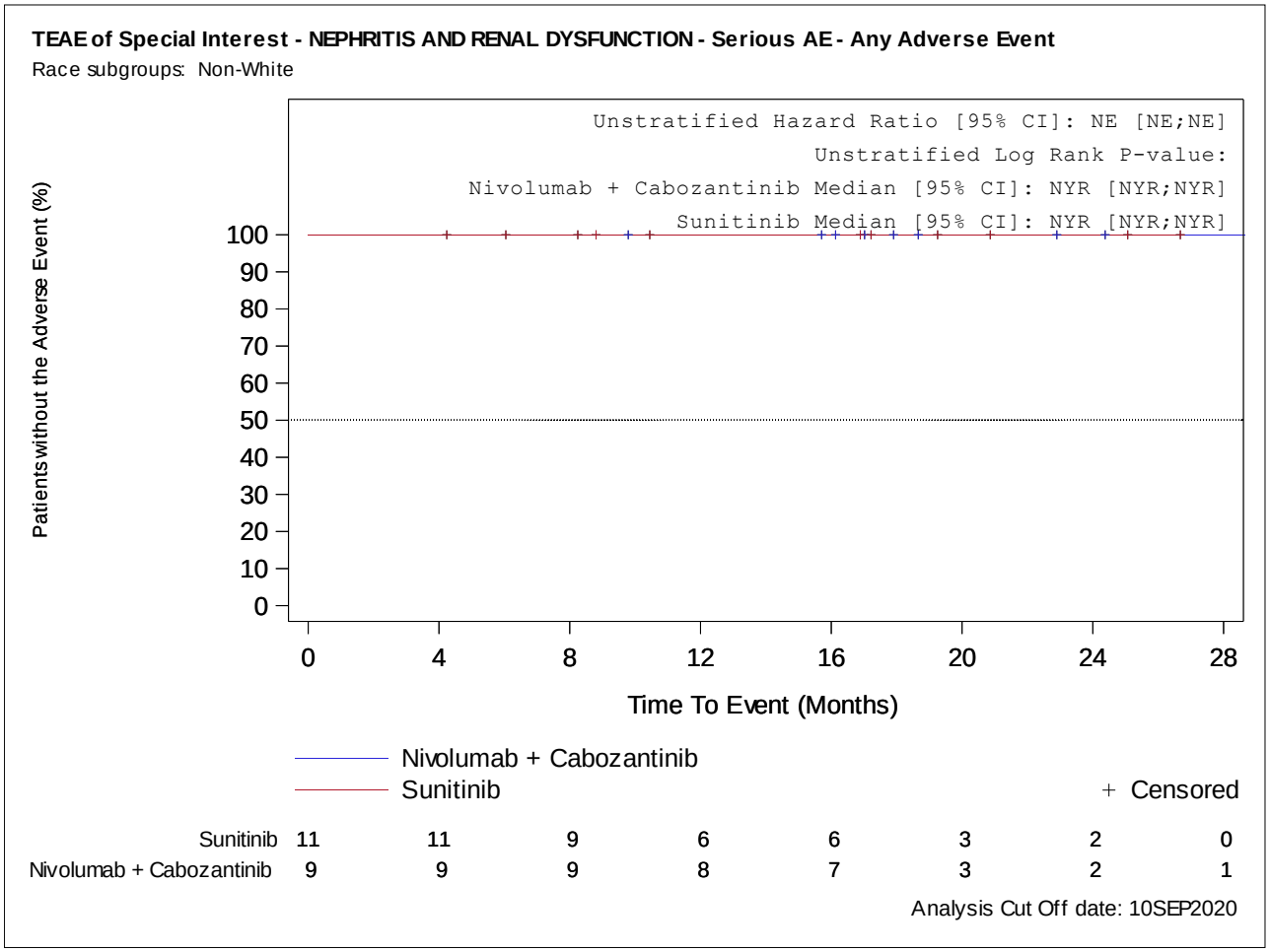

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:00:31

FIGURE 3.123.2.8: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



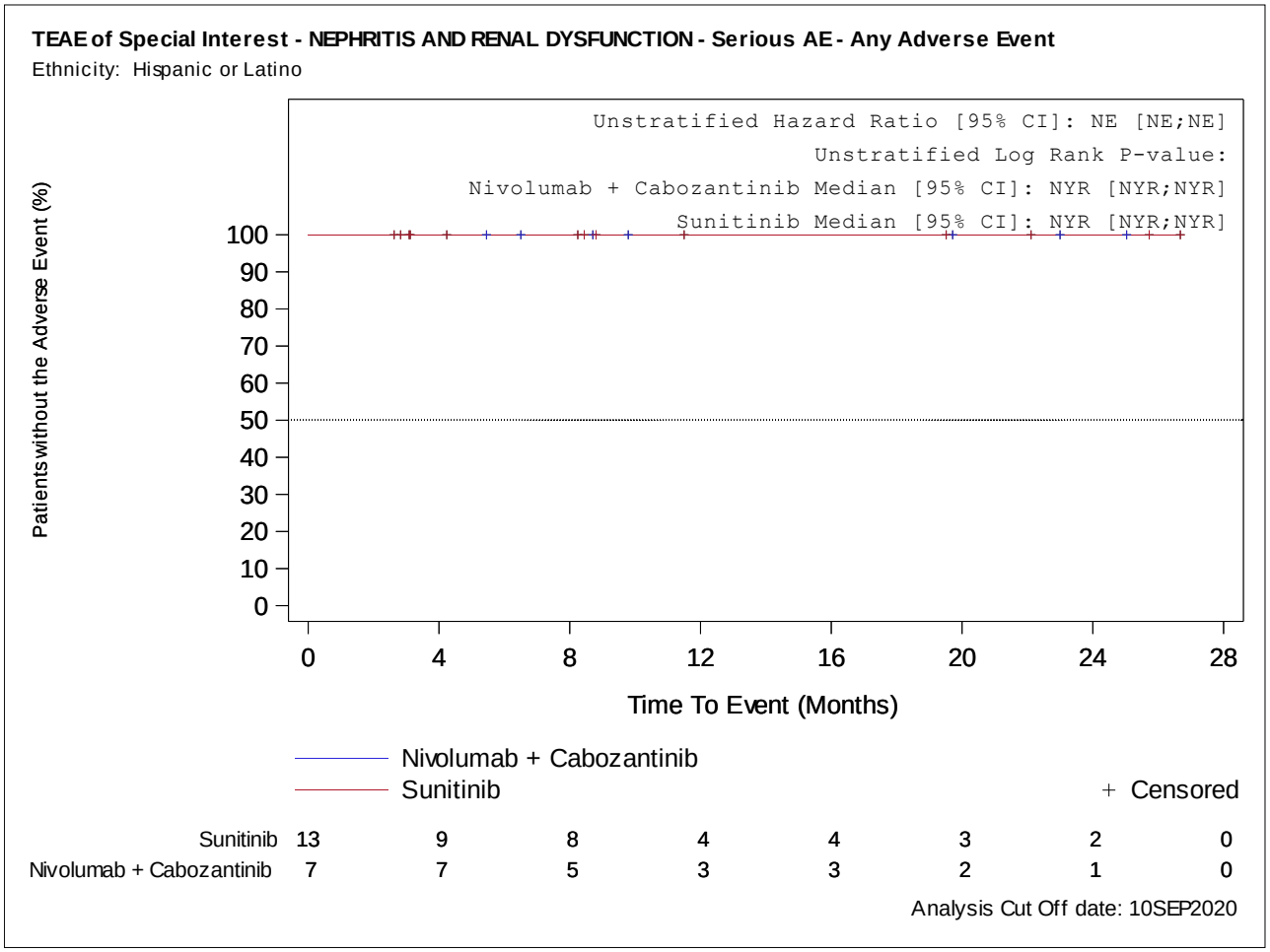

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:00:36

FIGURE 3.123.2.9: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



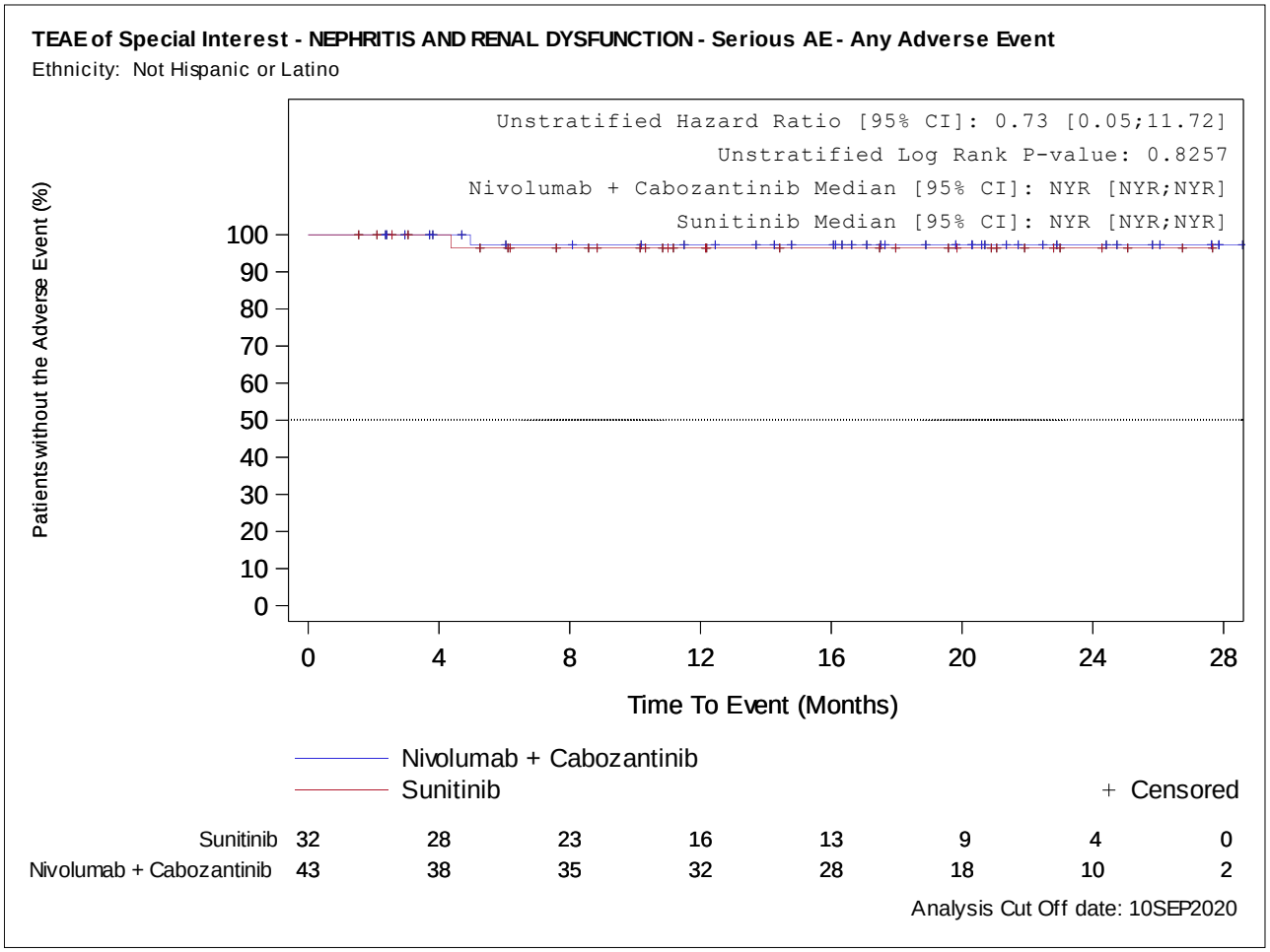

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:00:42

FIGURE 3.123.2.10: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



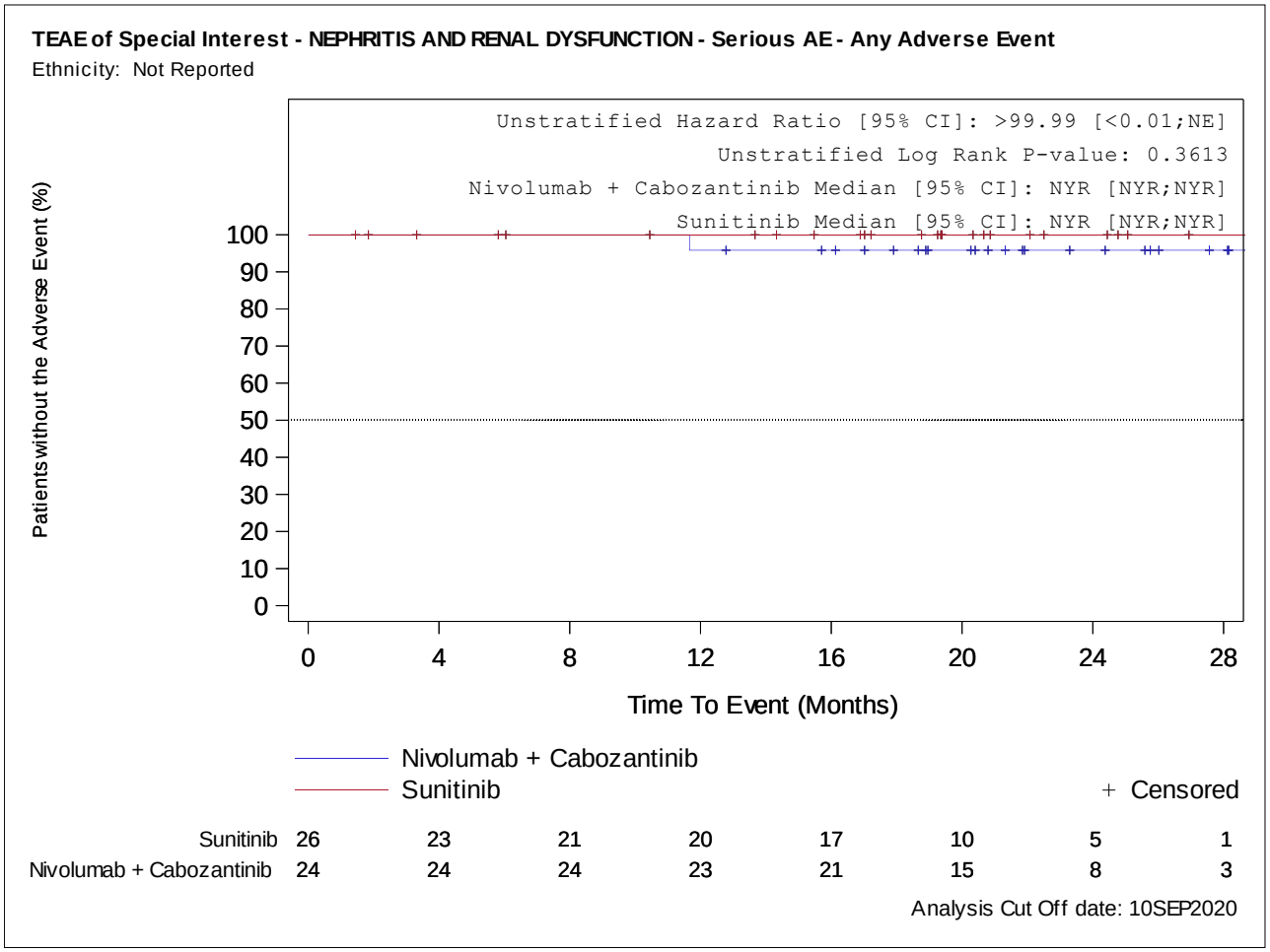

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:00:47

FIGURE 3.123.2.11: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



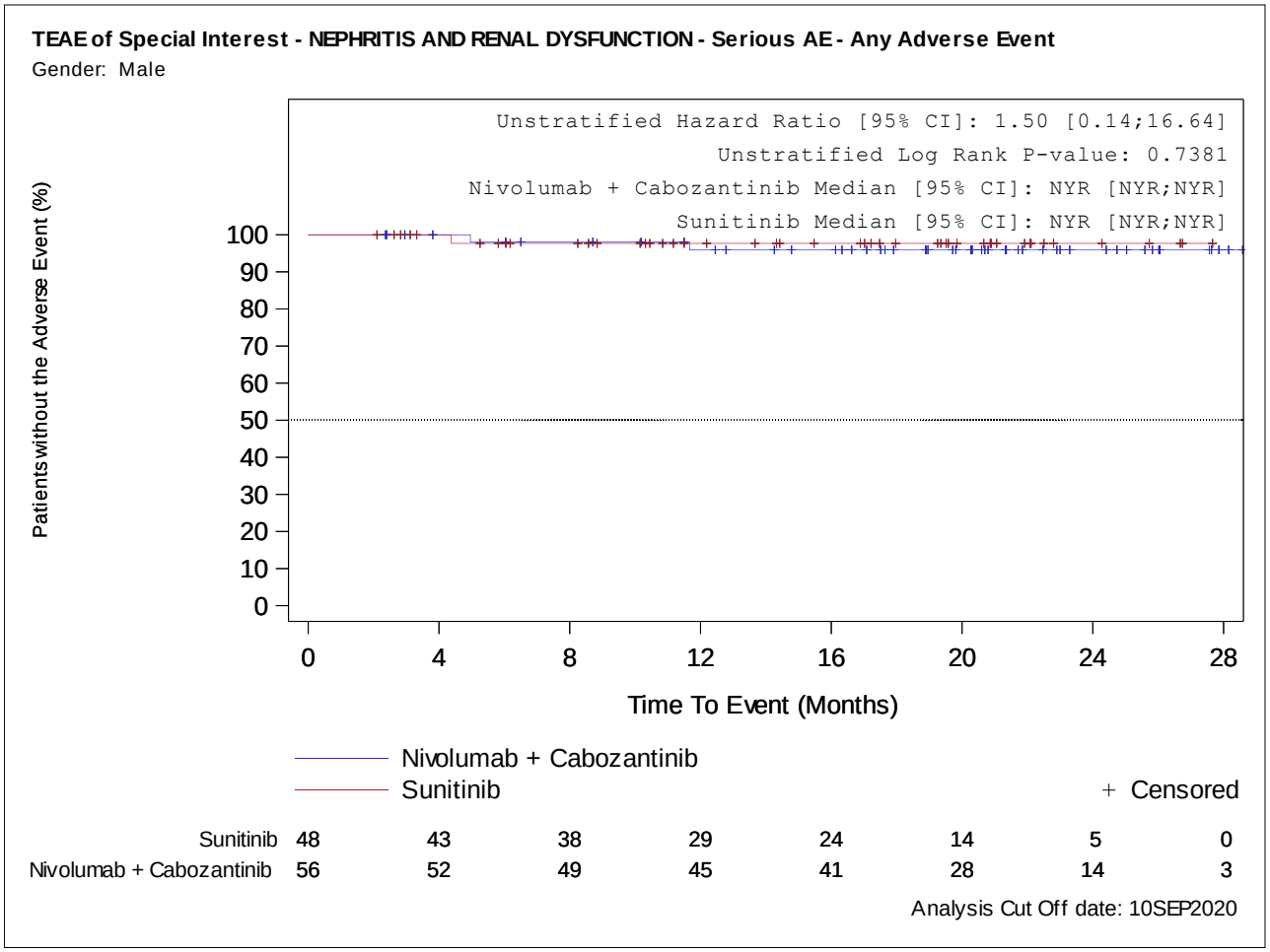

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:00:53

FIGURE 3.123.2.12: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:00:59

FIGURE 3.123.2.13: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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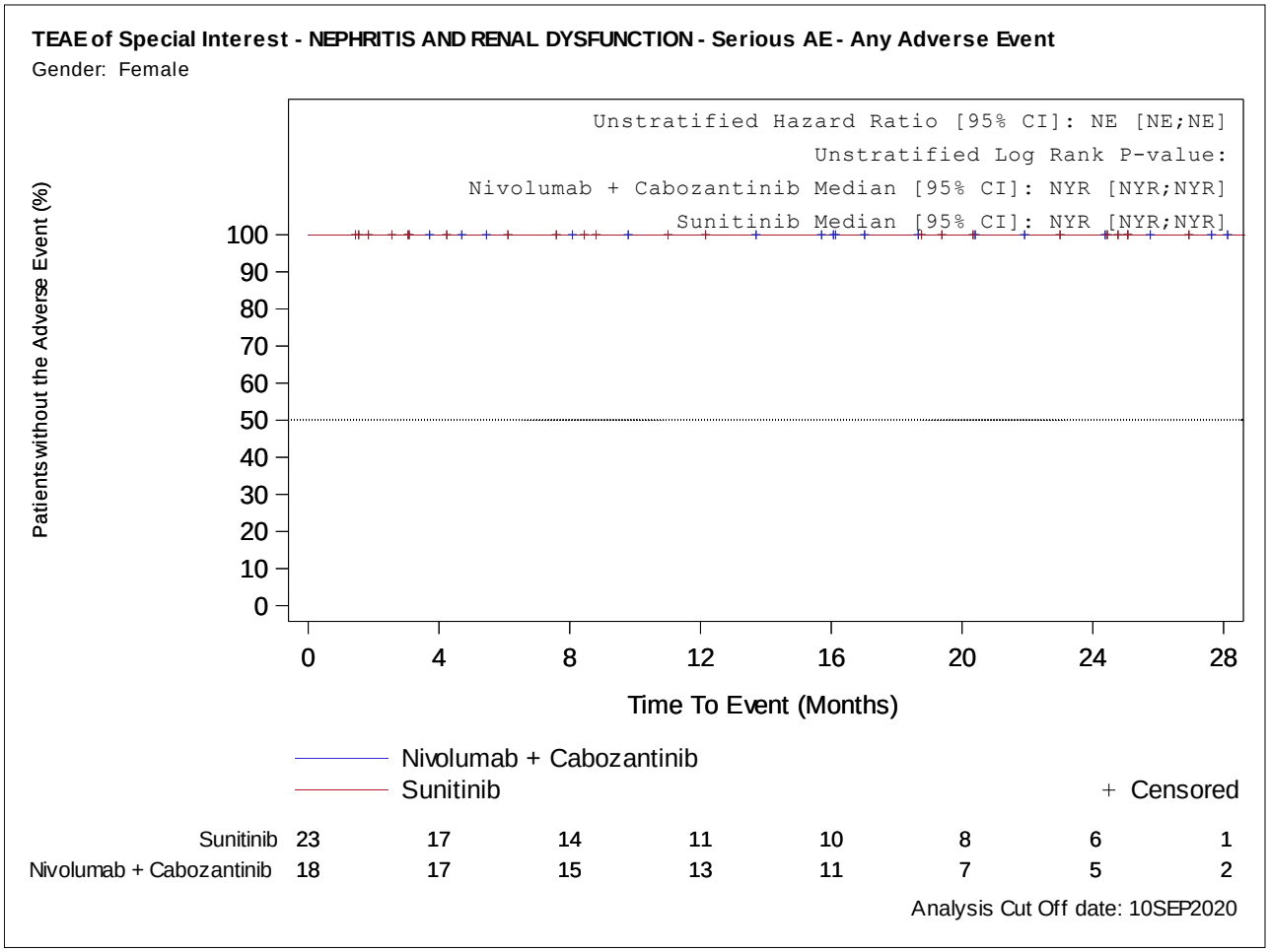
FIGURE 3.123.2.14: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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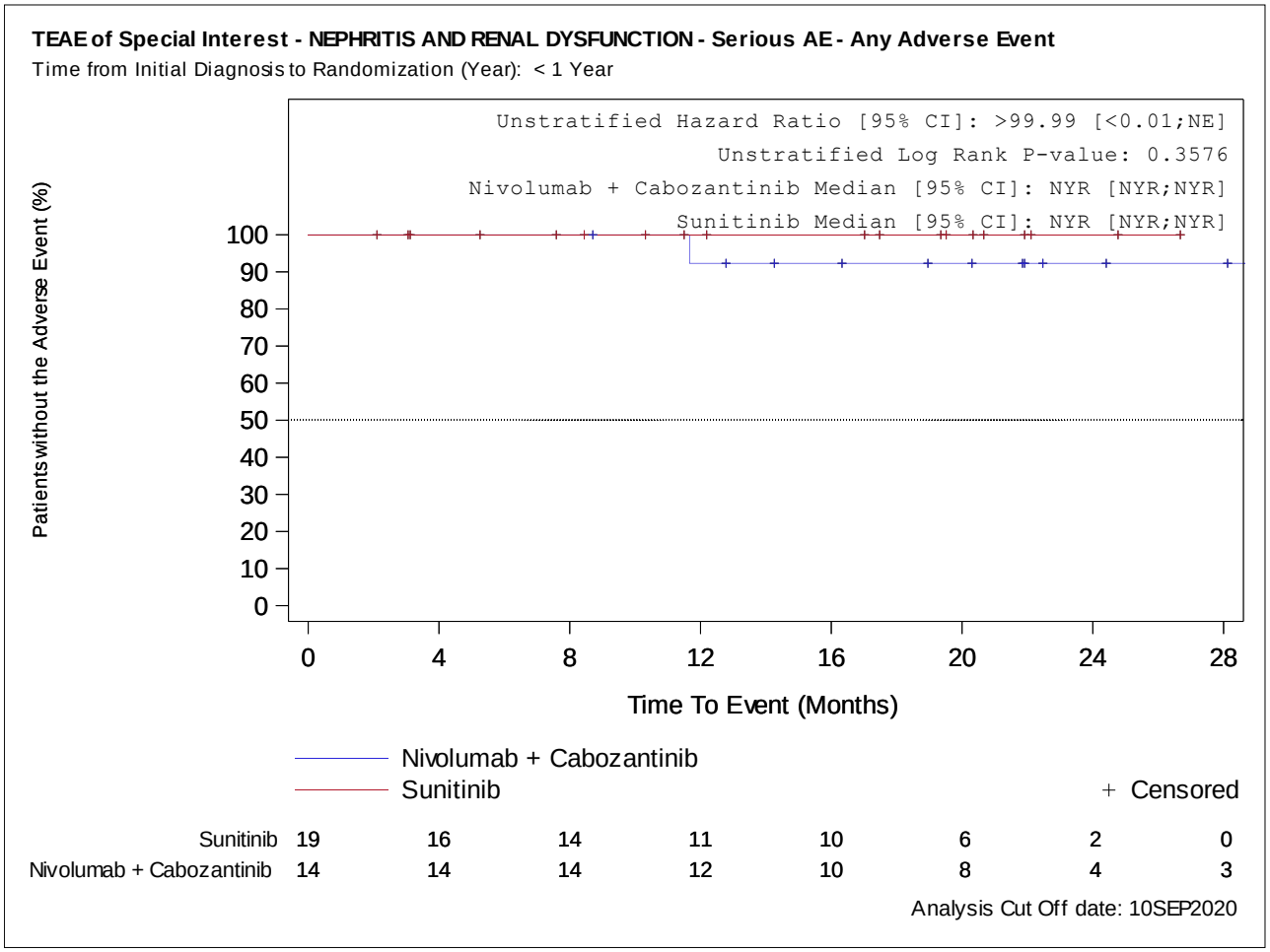
FIGURE 3.123.2.15: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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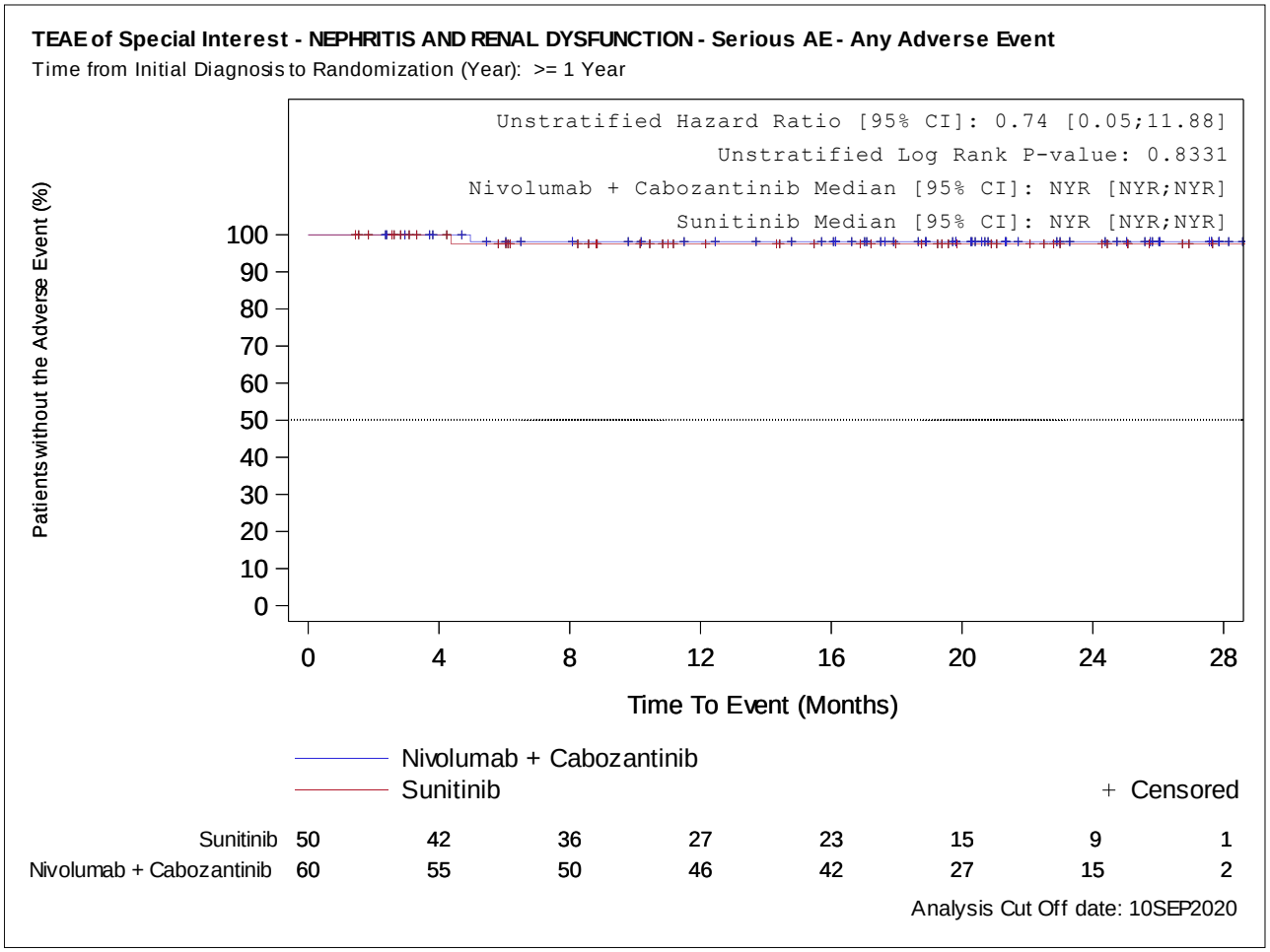
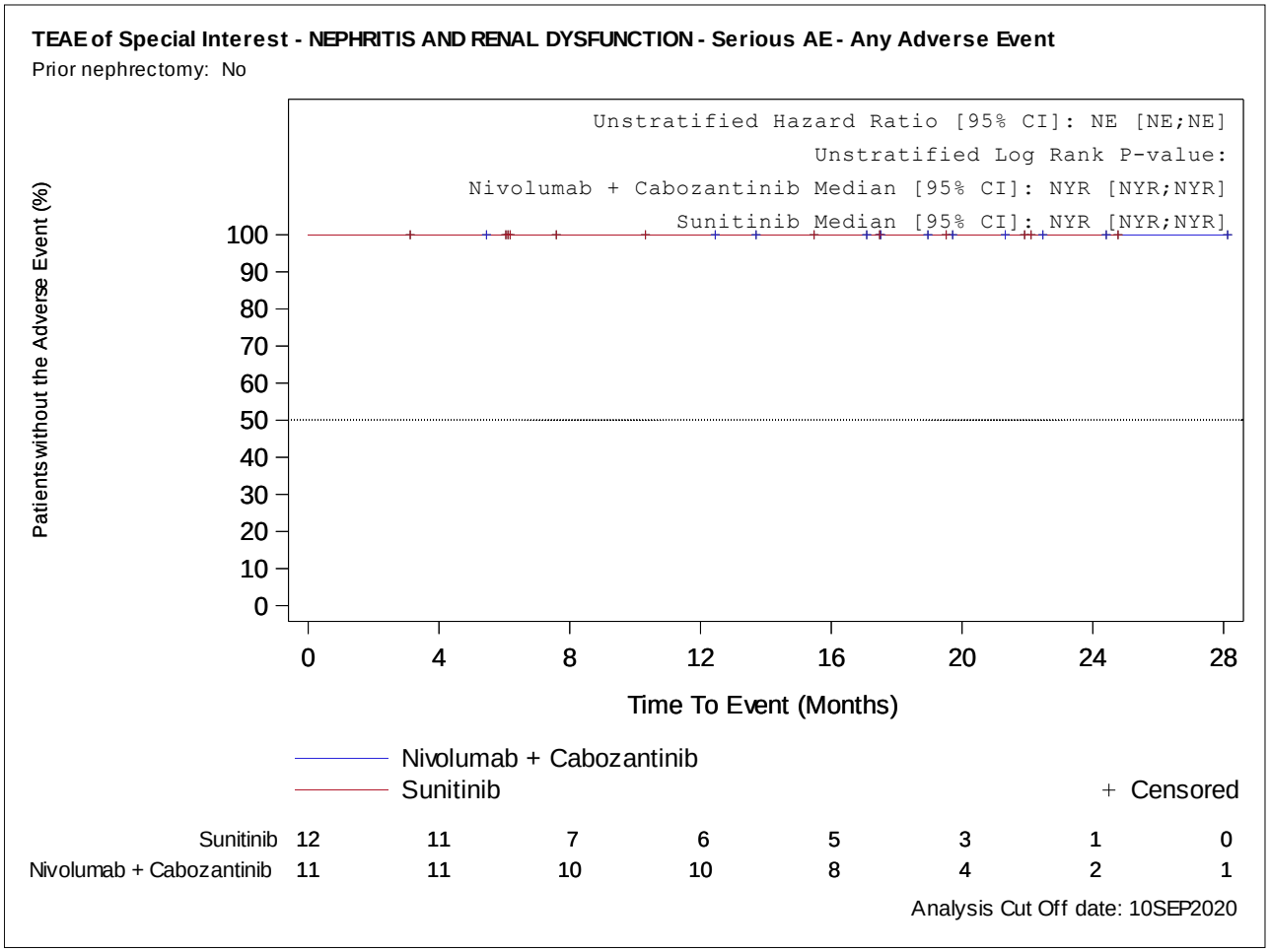
FIGURE 3.123.2.16: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



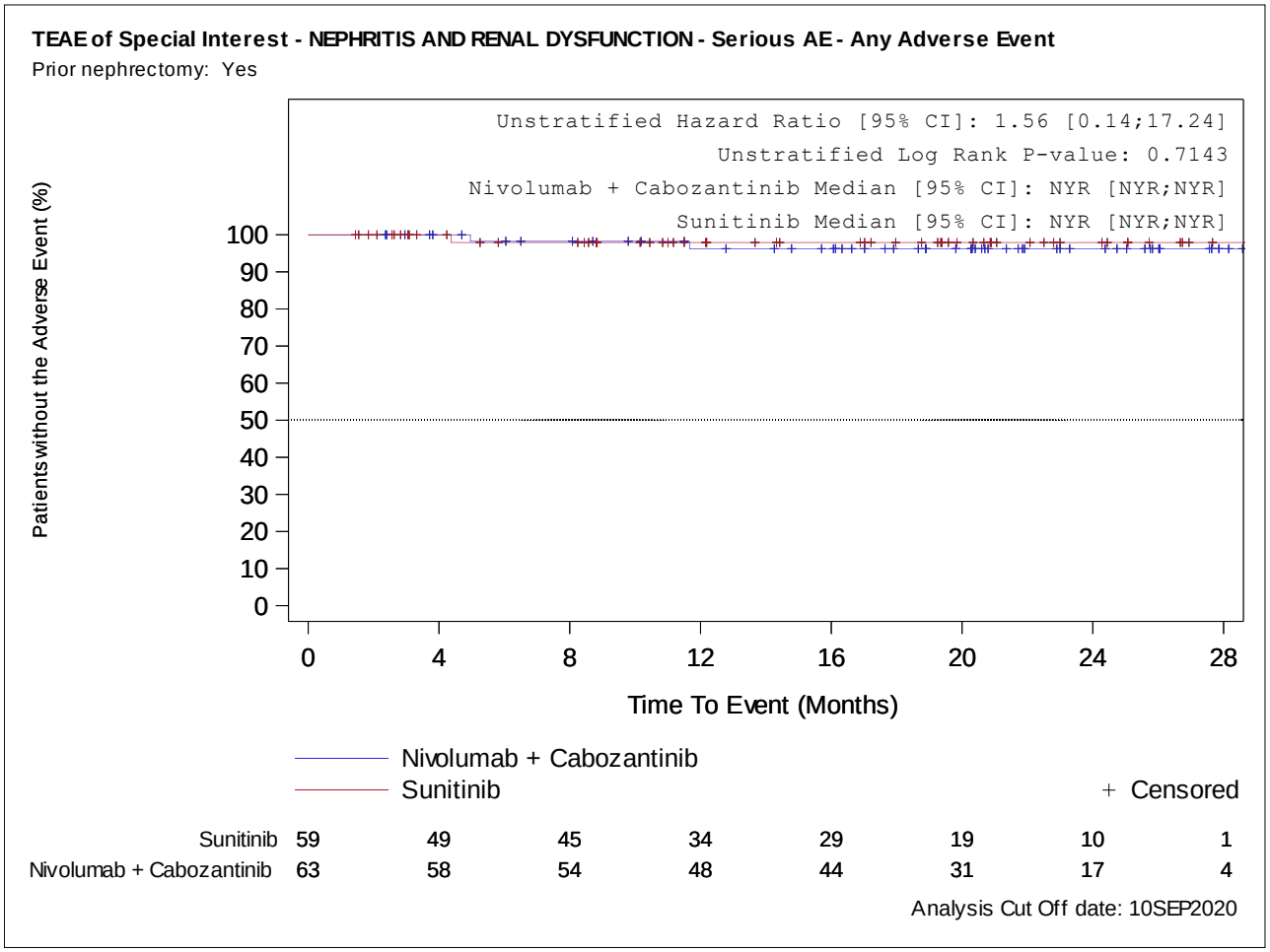

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:01:33

FIGURE 3.123.2.17: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:02:23

FIGURE 3.123.2.18: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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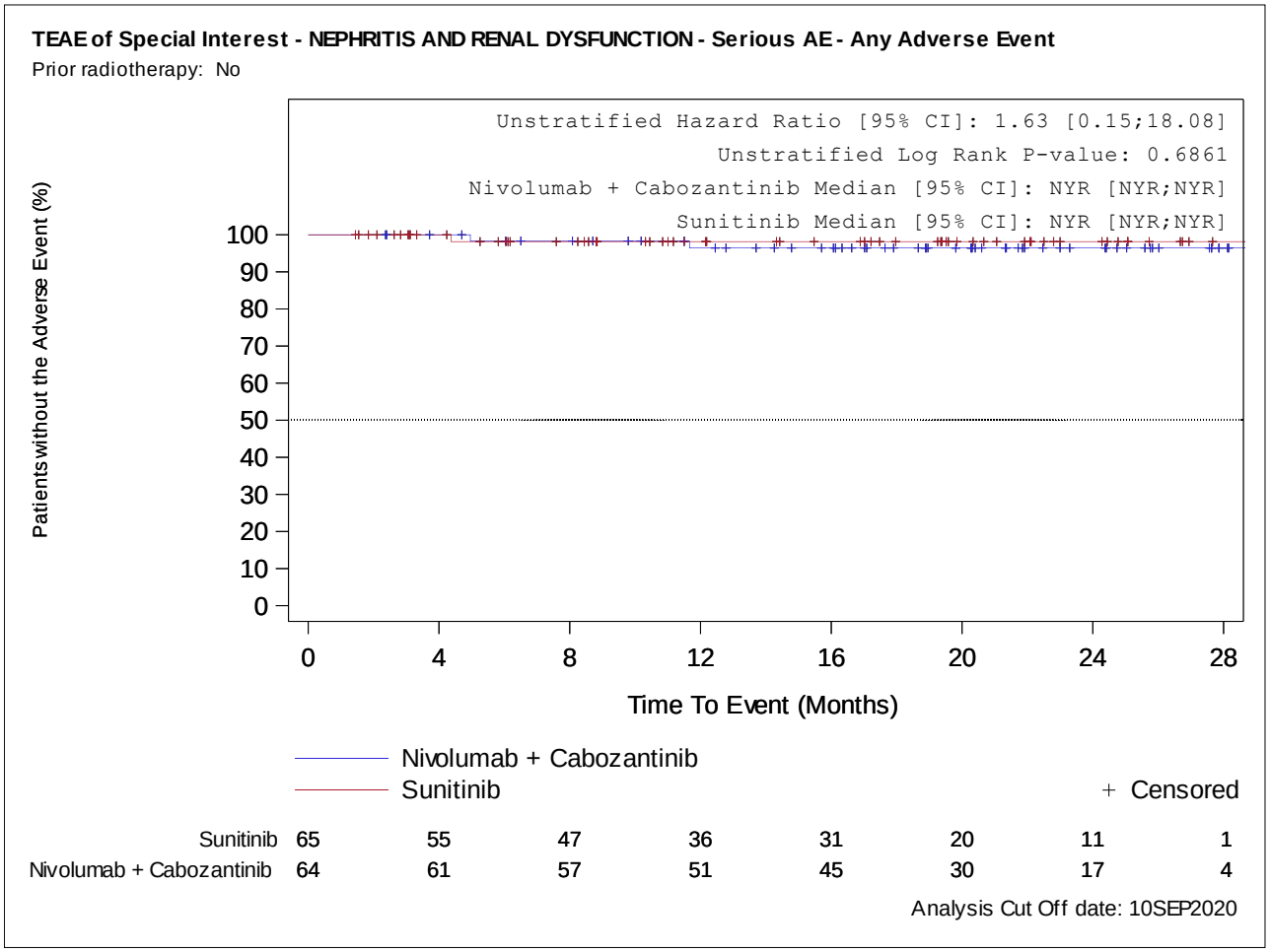
FIGURE 3.123.2.19: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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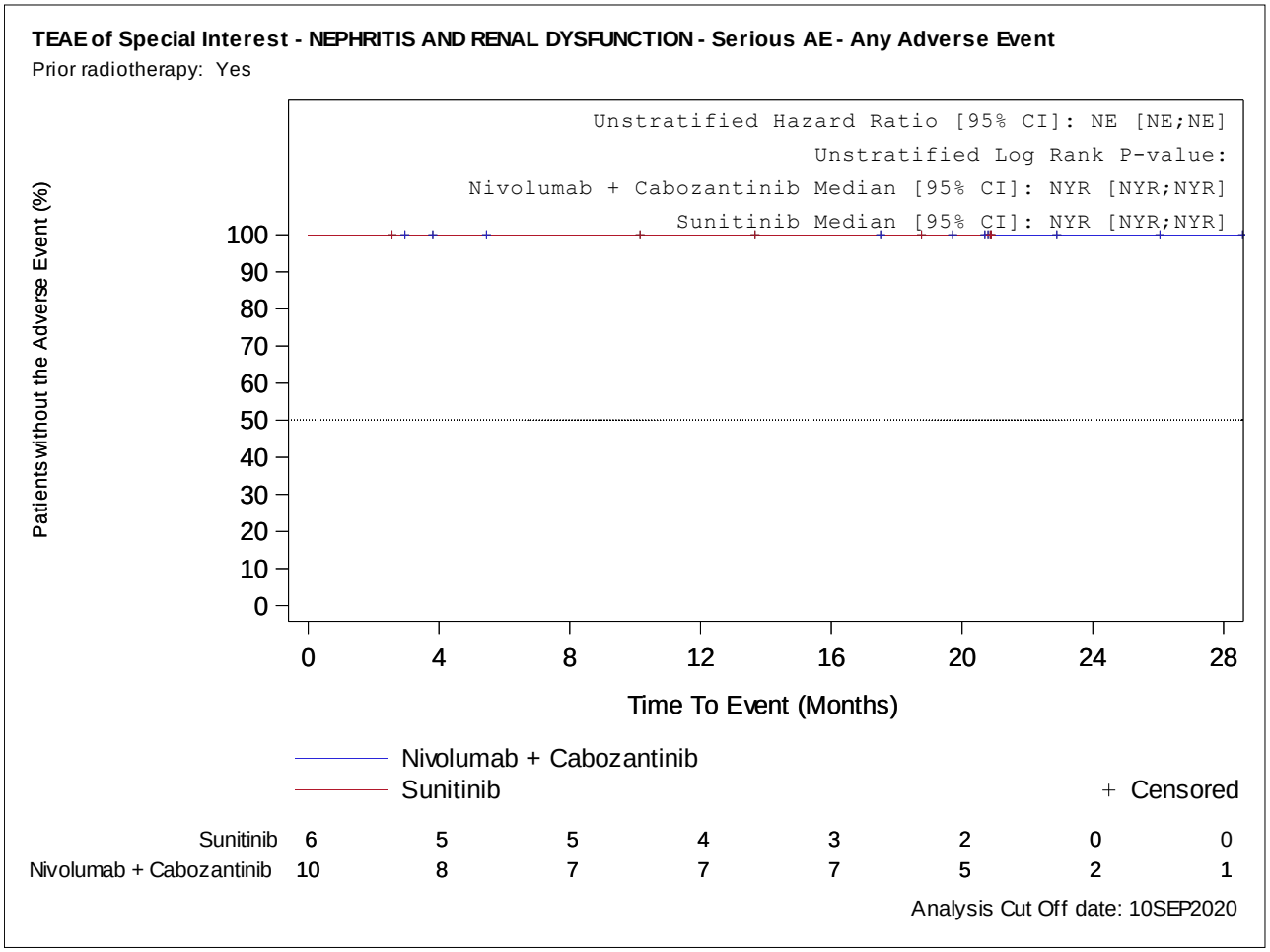
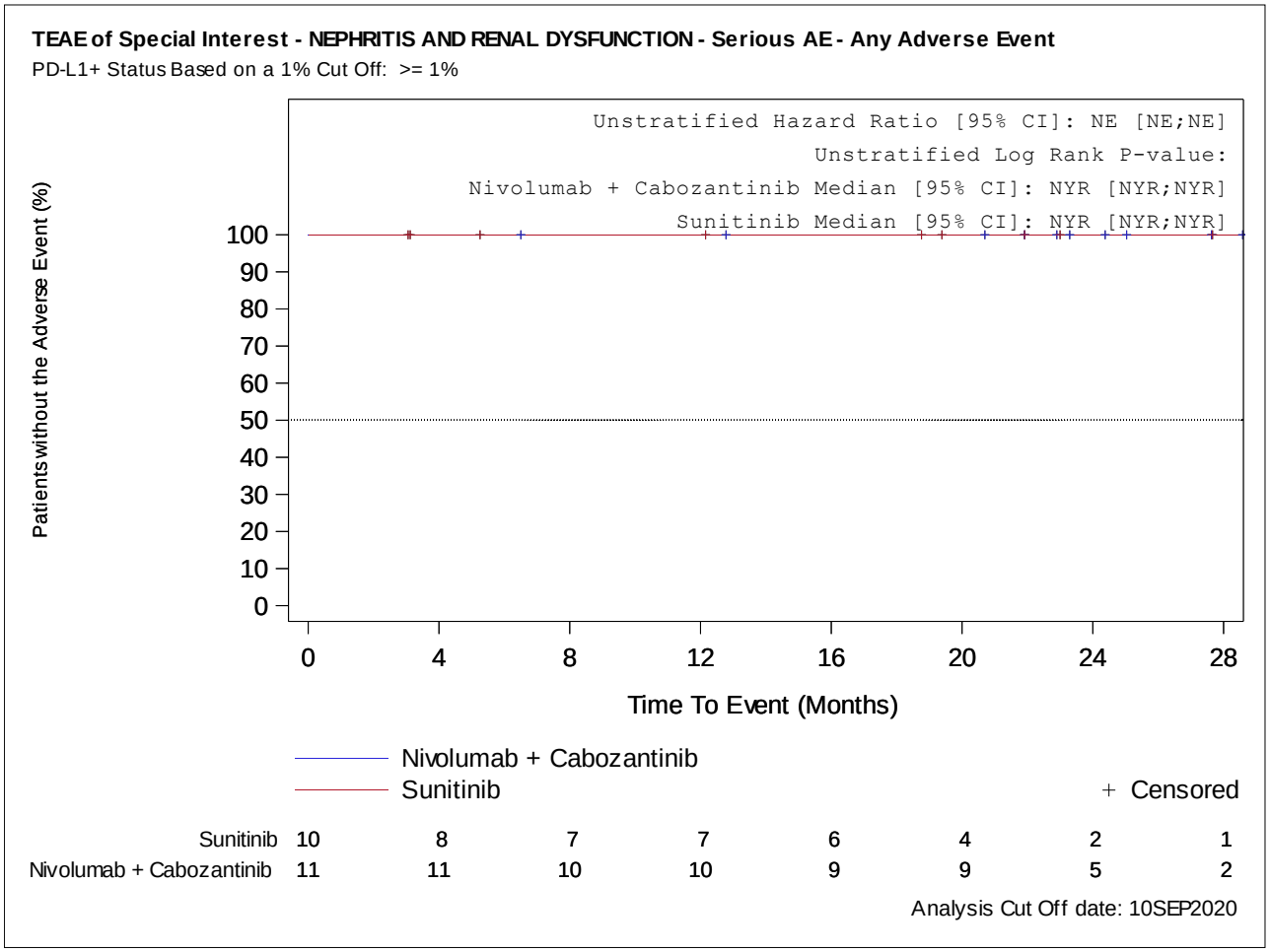
FIGURE 3.123.2.20: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:02:41

FIGURE 3.123.2.21: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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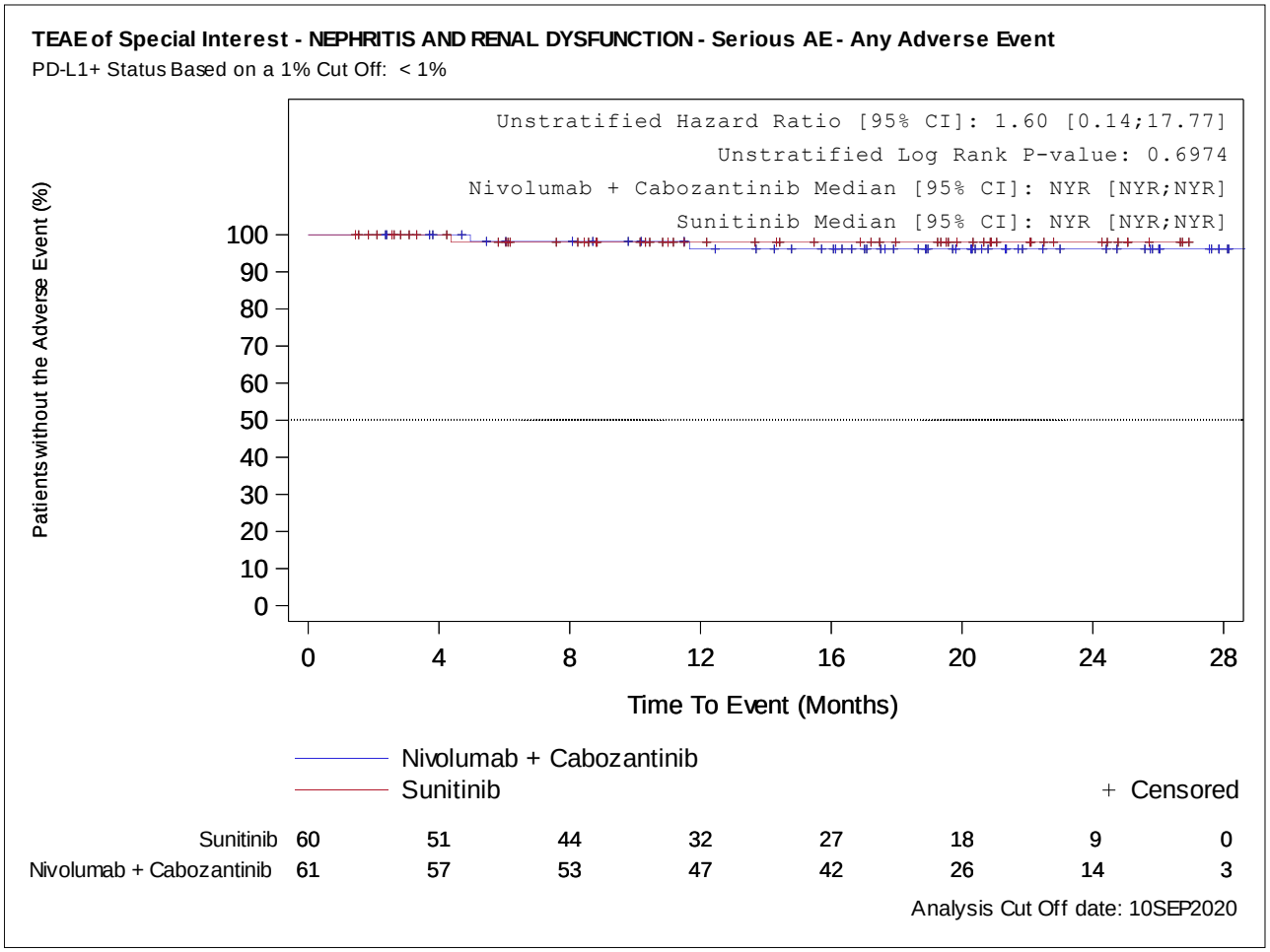
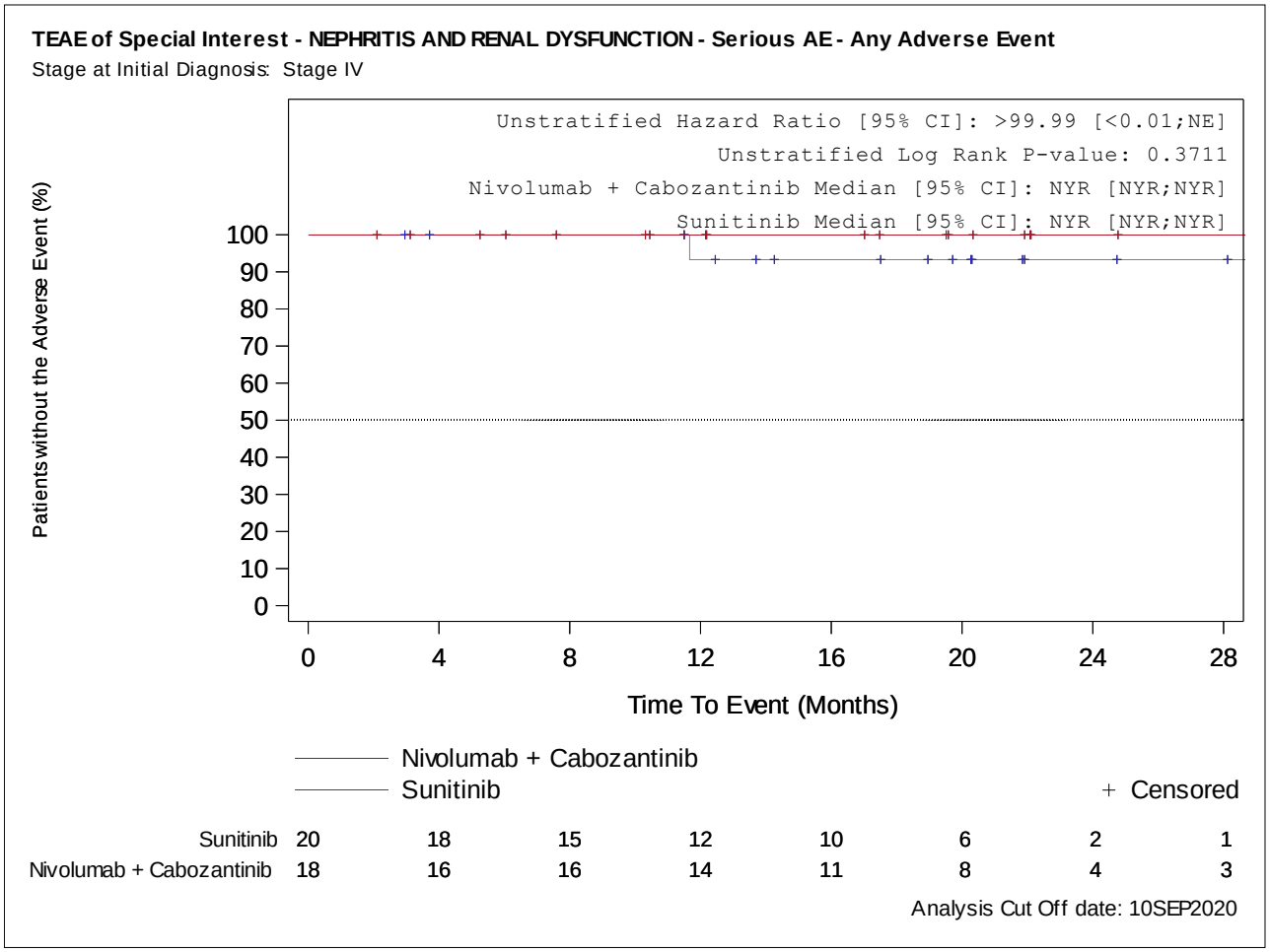
FIGURE 3.123.2.22: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



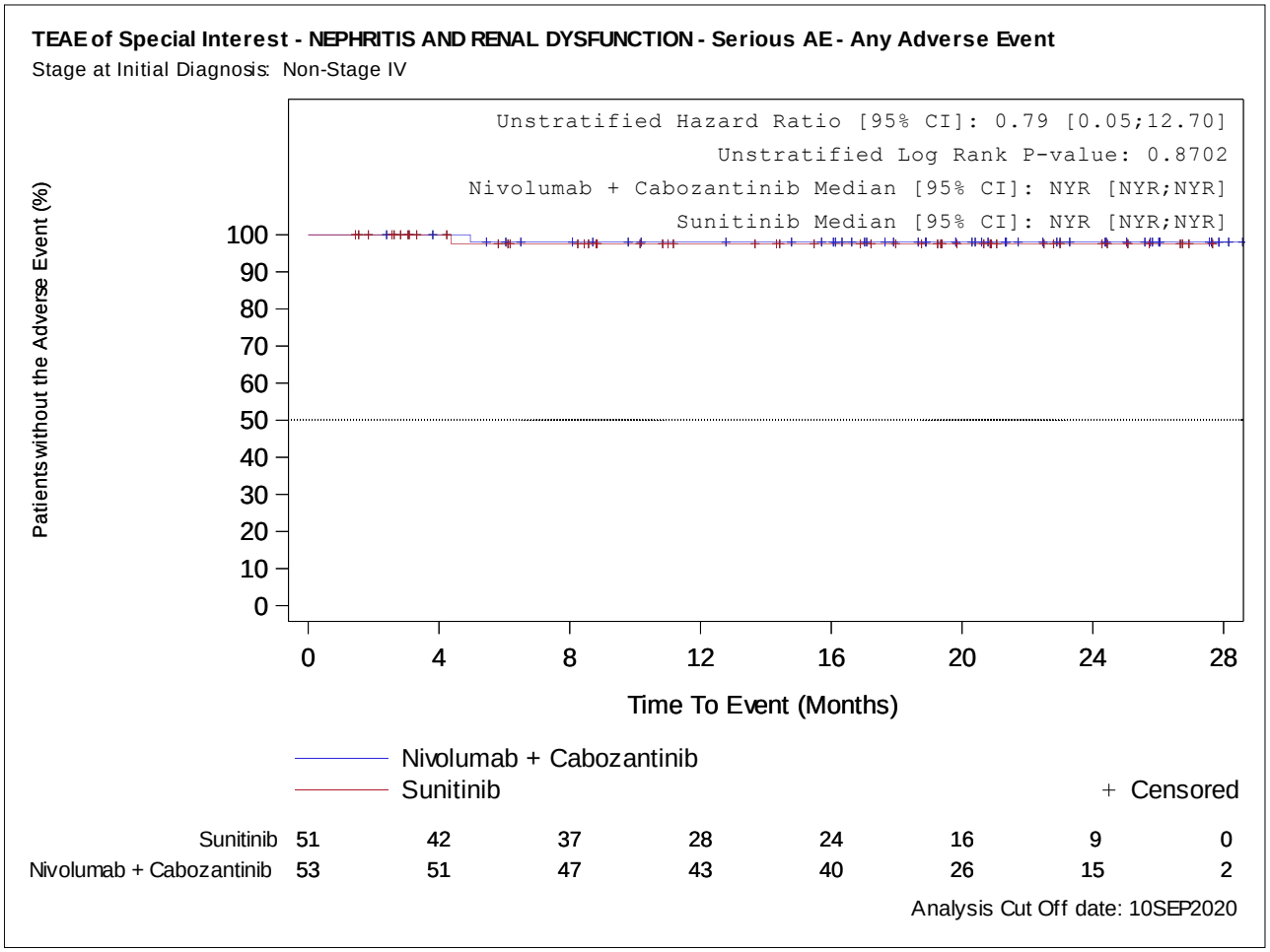

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:02:51

FIGURE 3.123.2.23: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



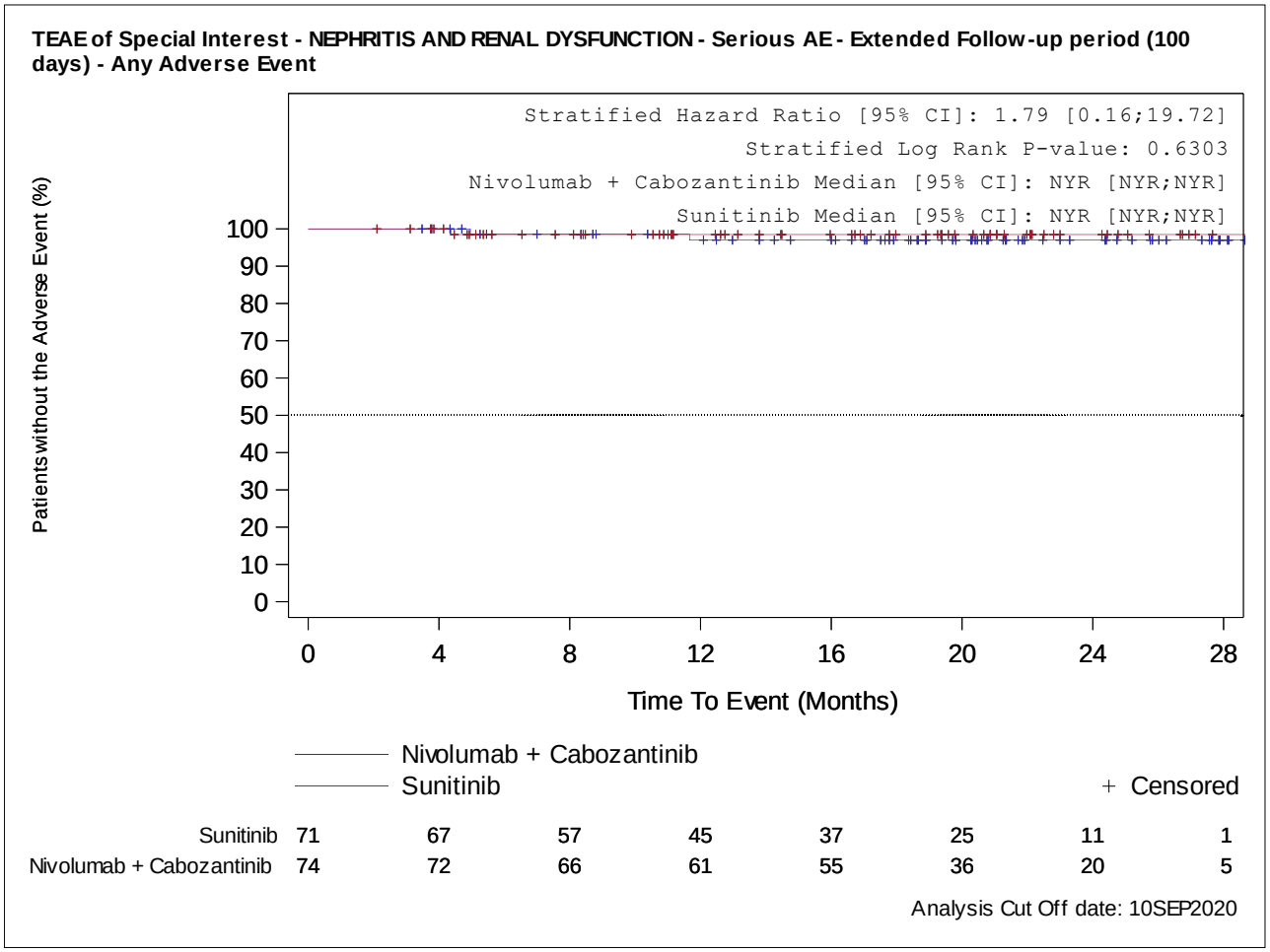

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:03:18

FIGURE 3.123.2.24: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



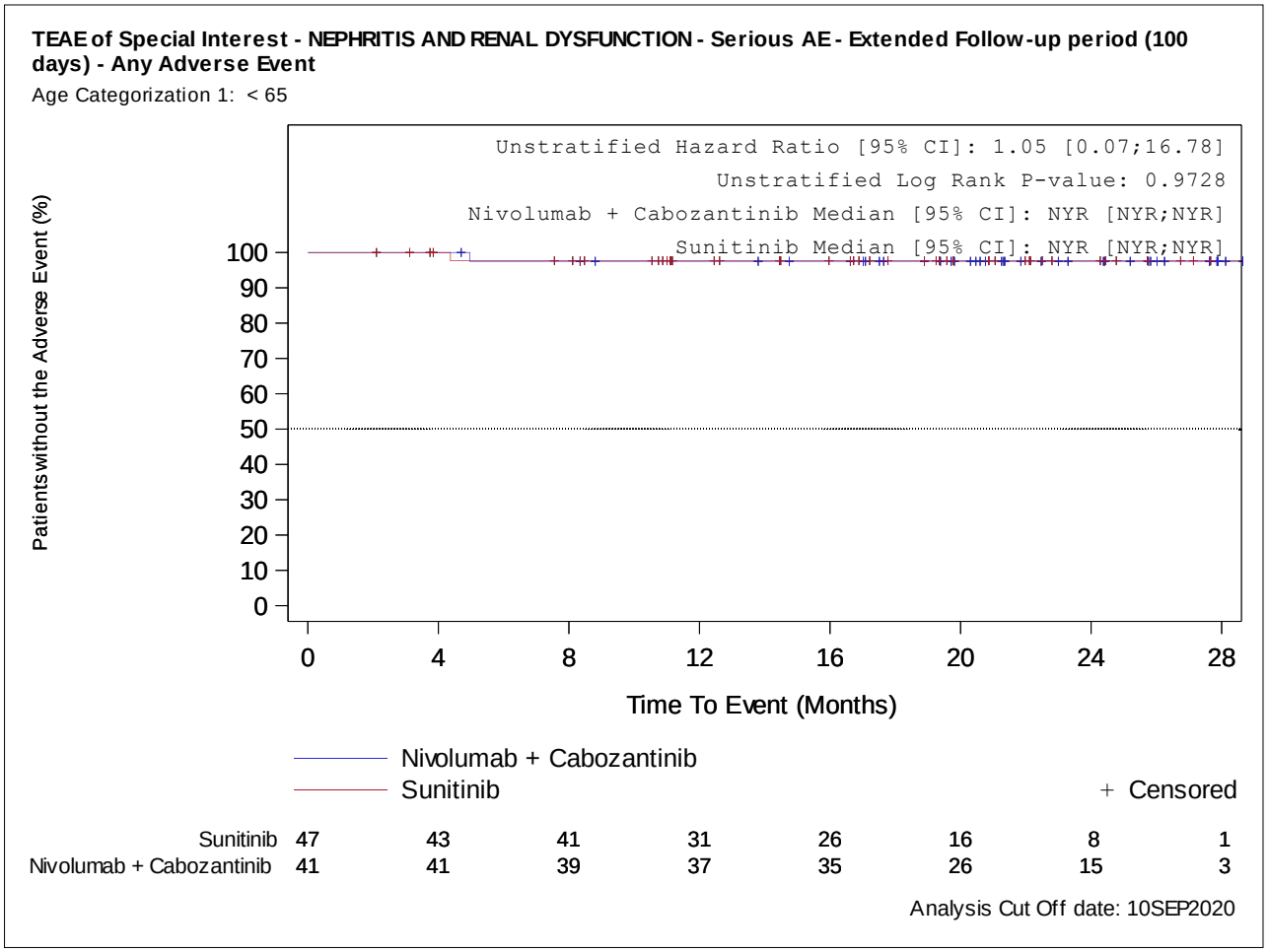

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:03:23

FIGURE 3.124.1: TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



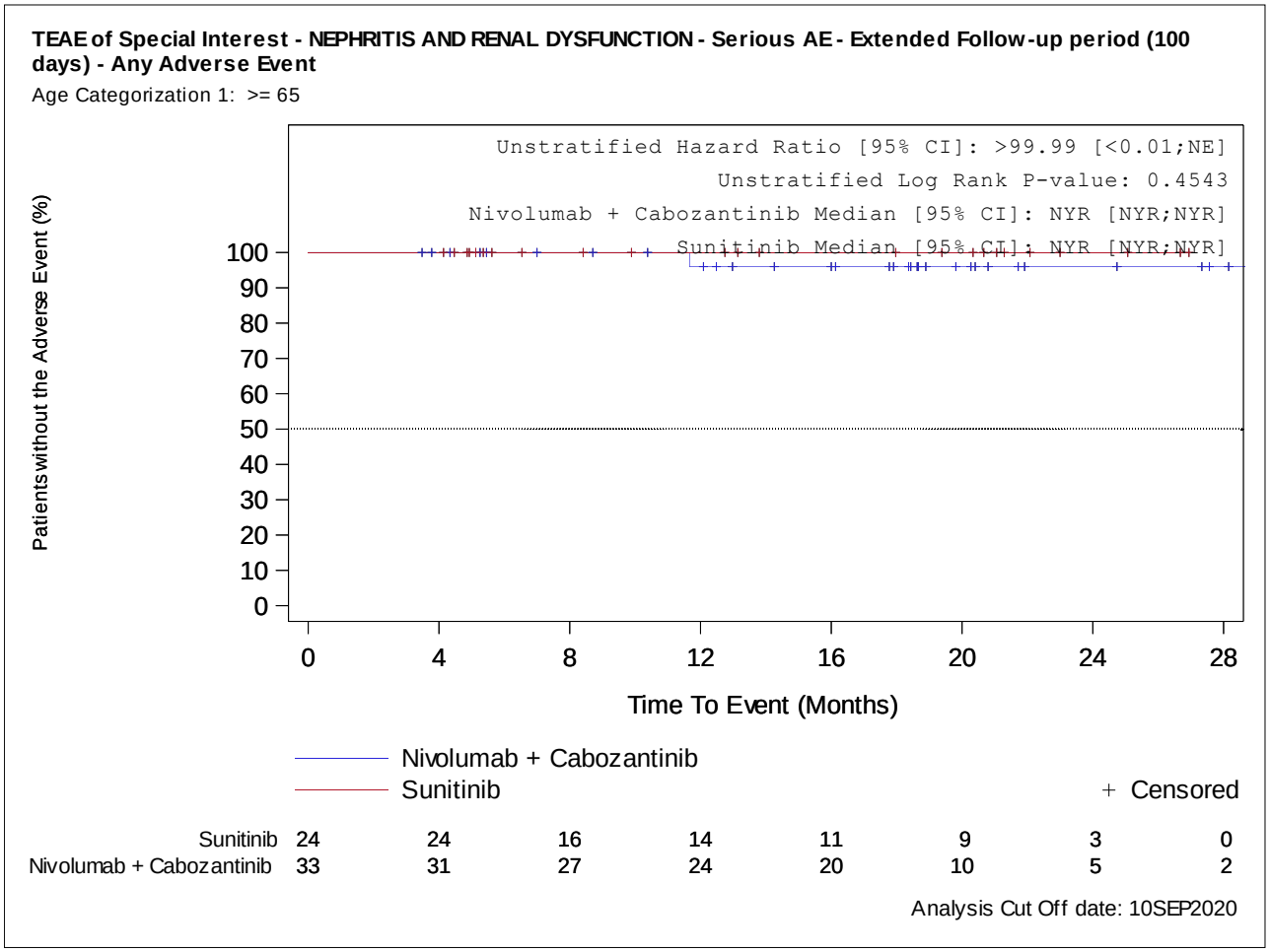

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:06:31

FIGURE 3.124.2.1: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



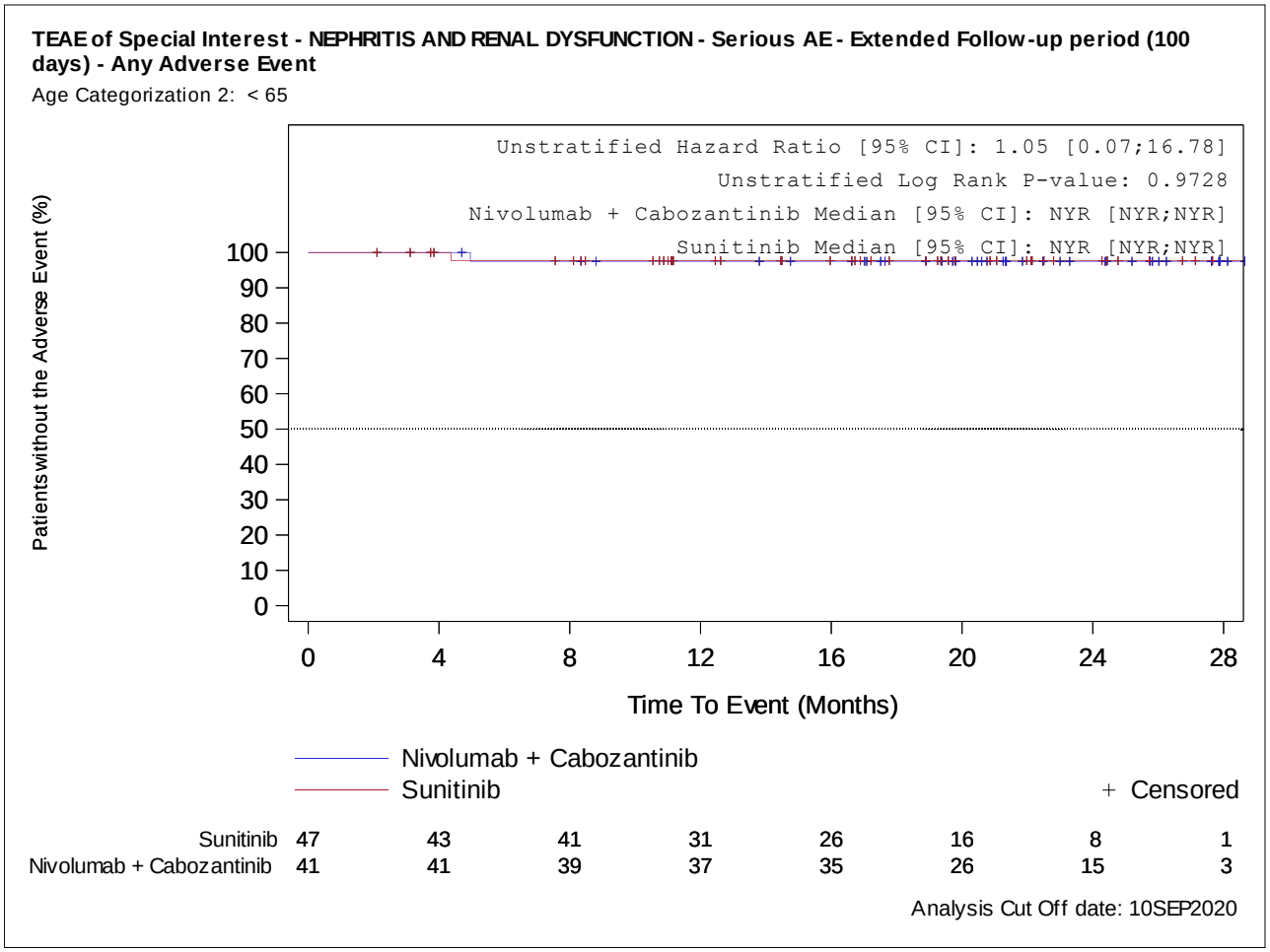

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:06:33

FIGURE 3.124.2.2: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



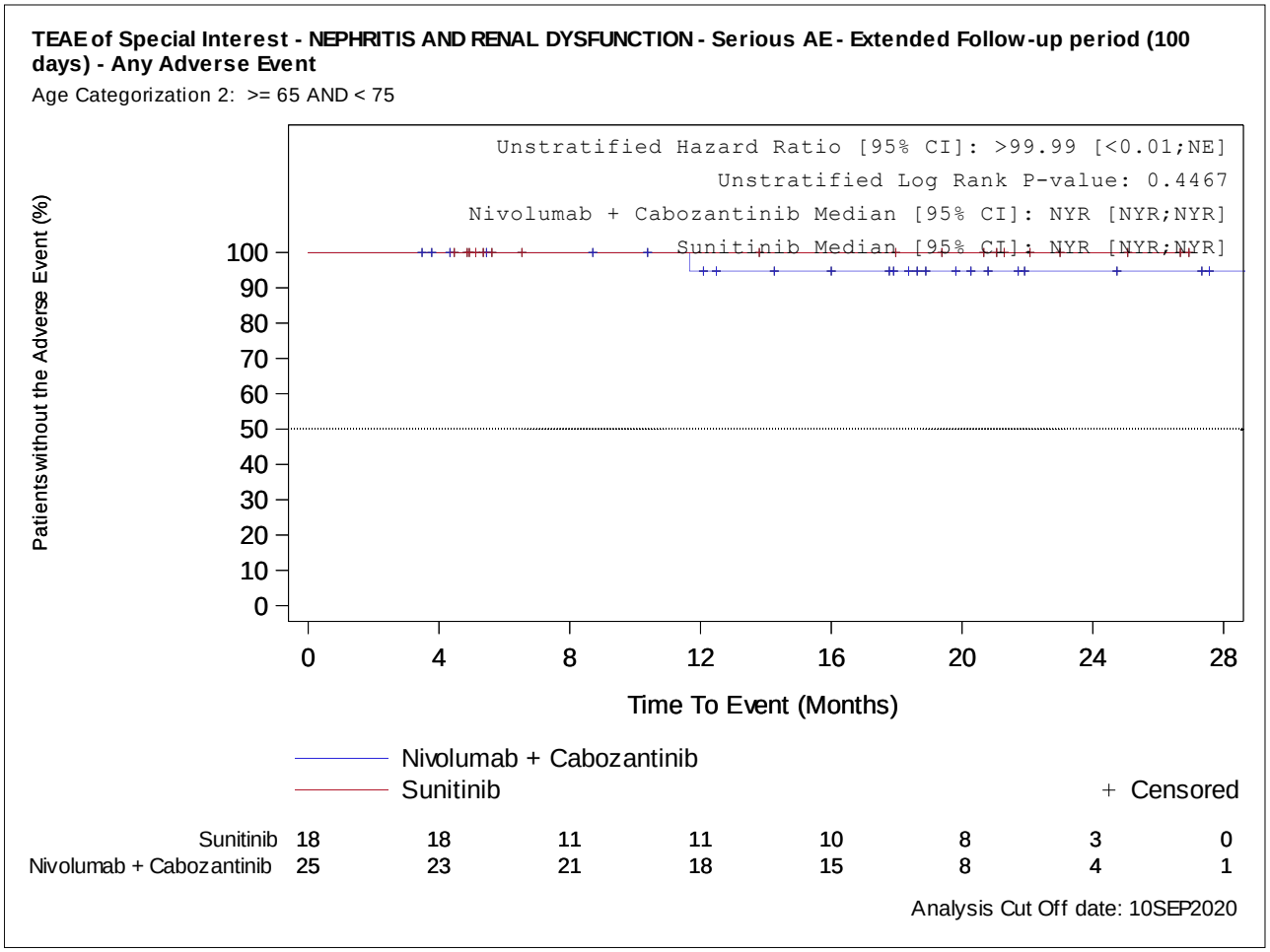

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:06:39

FIGURE 3.124.2.3: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:06:45

FIGURE 3.124.2.4: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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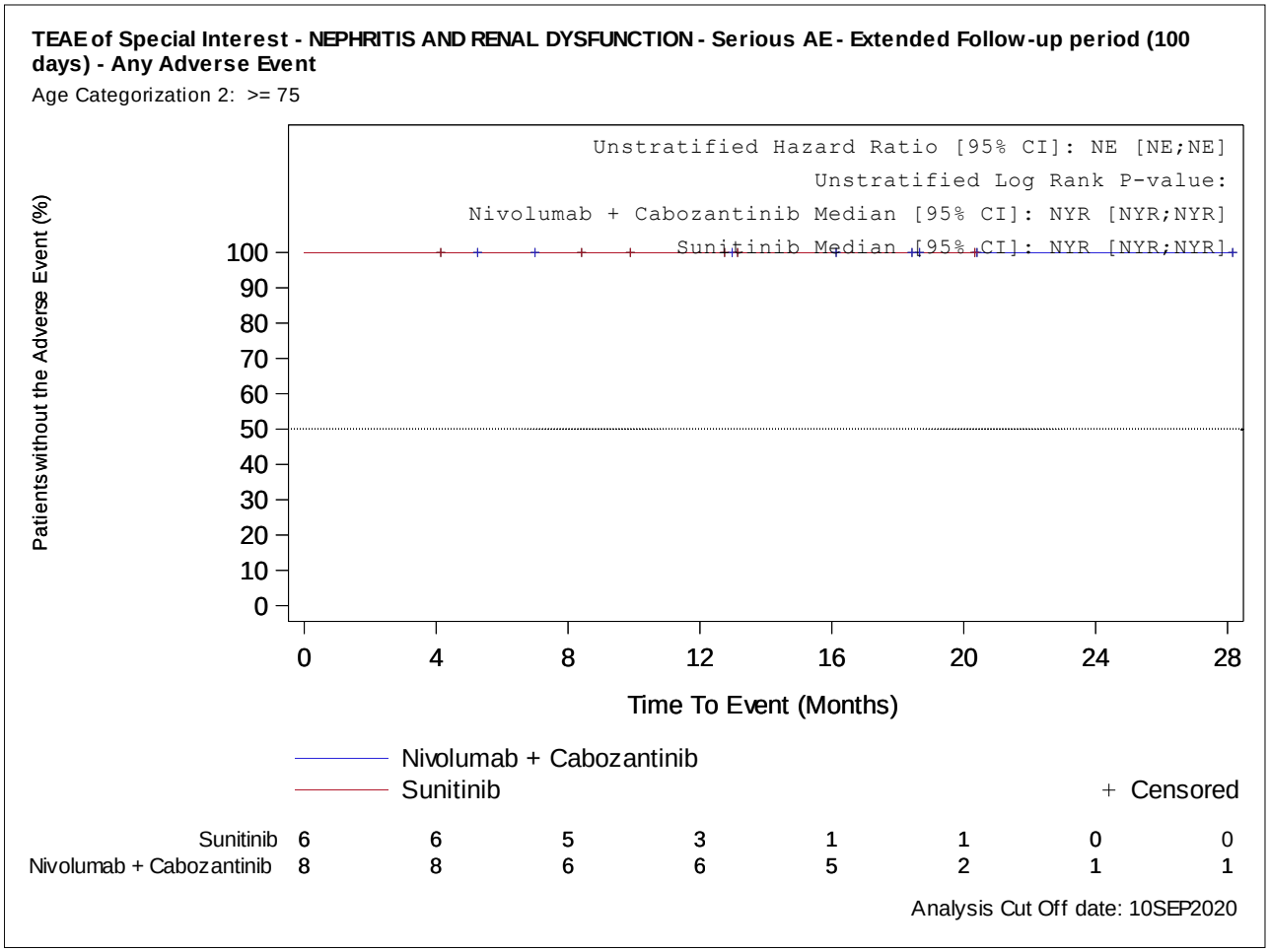
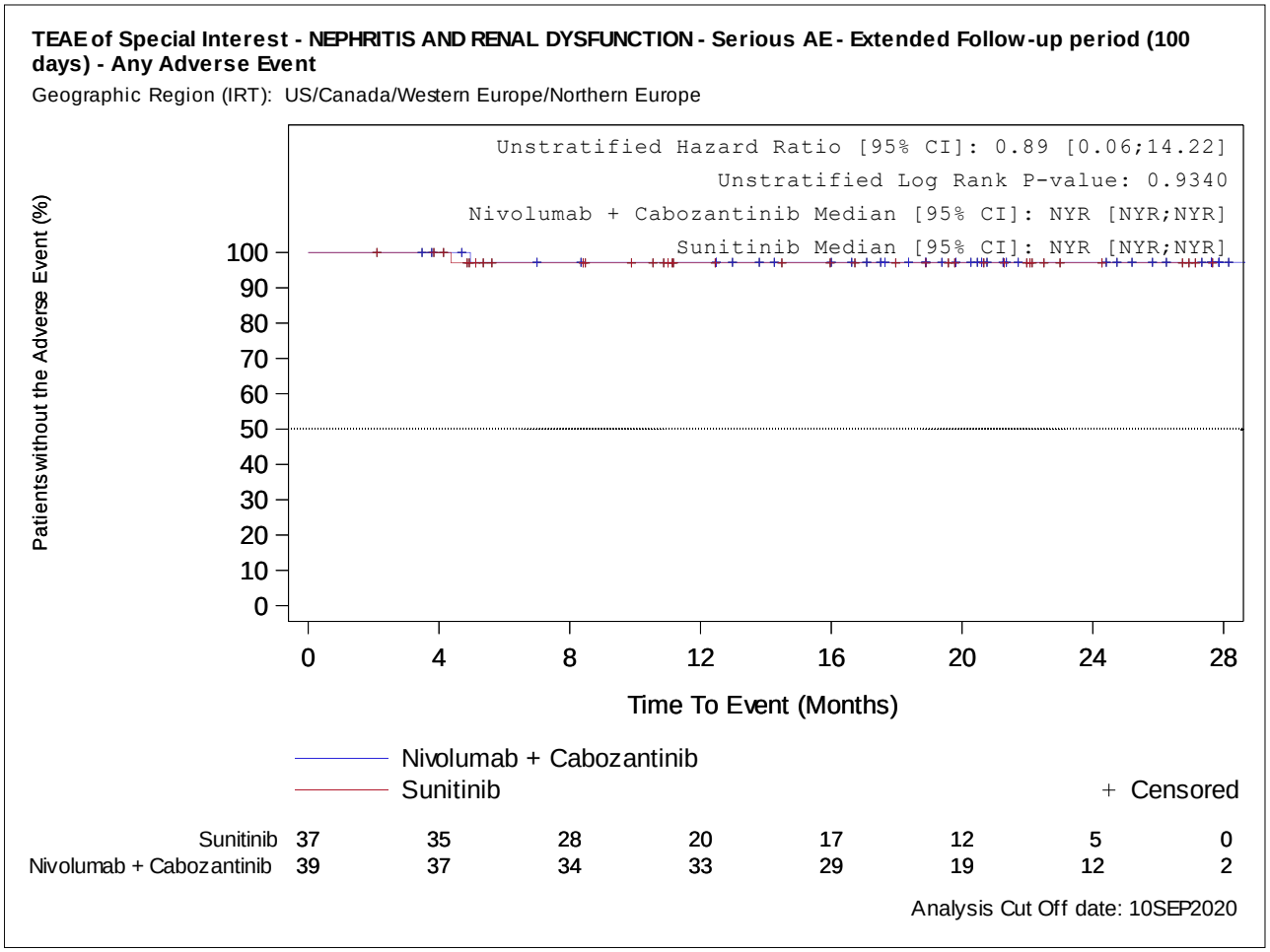
FIGURE 3.124.2.5: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



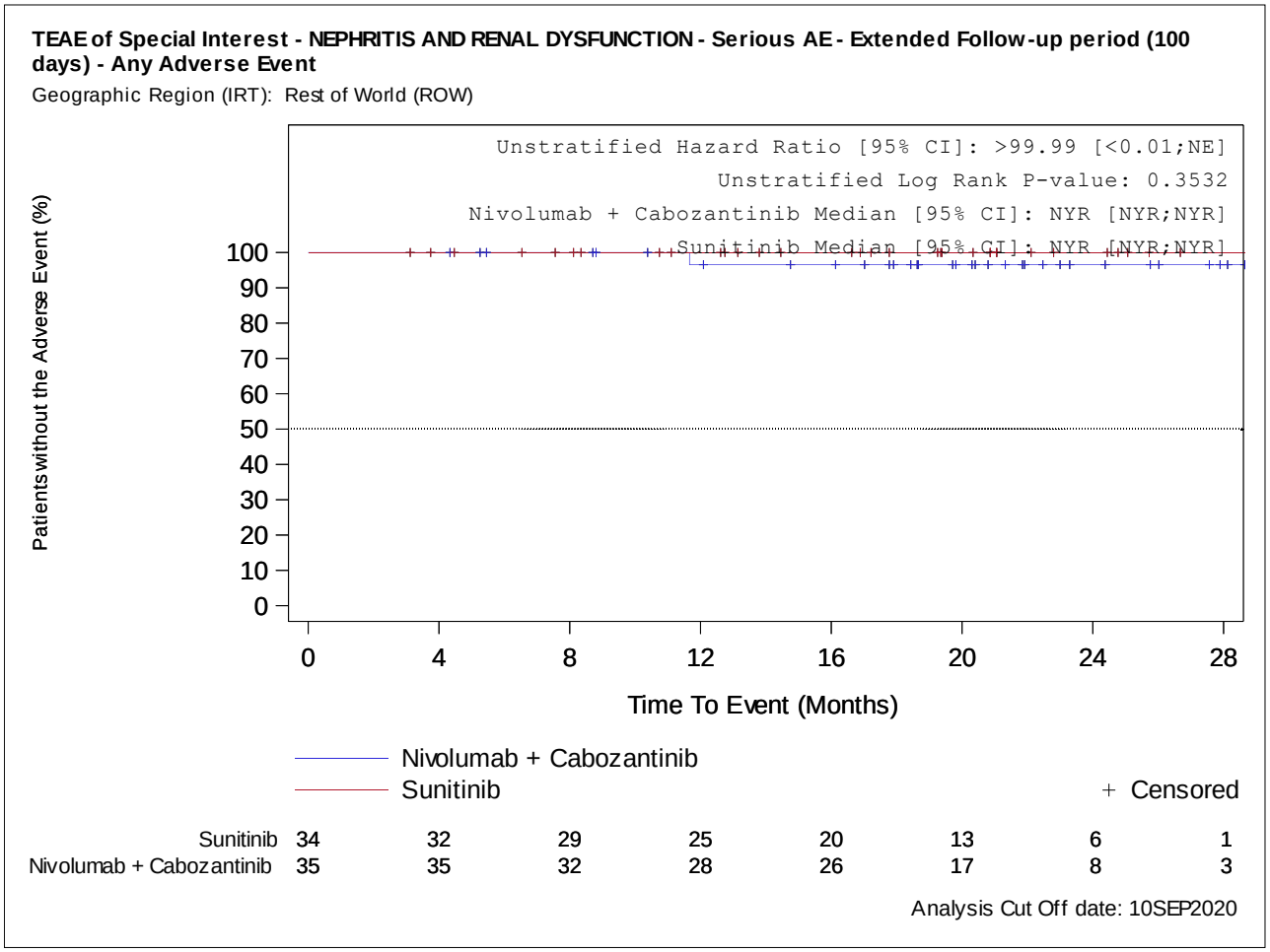

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:06:57

FIGURE 3.124.2.6: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



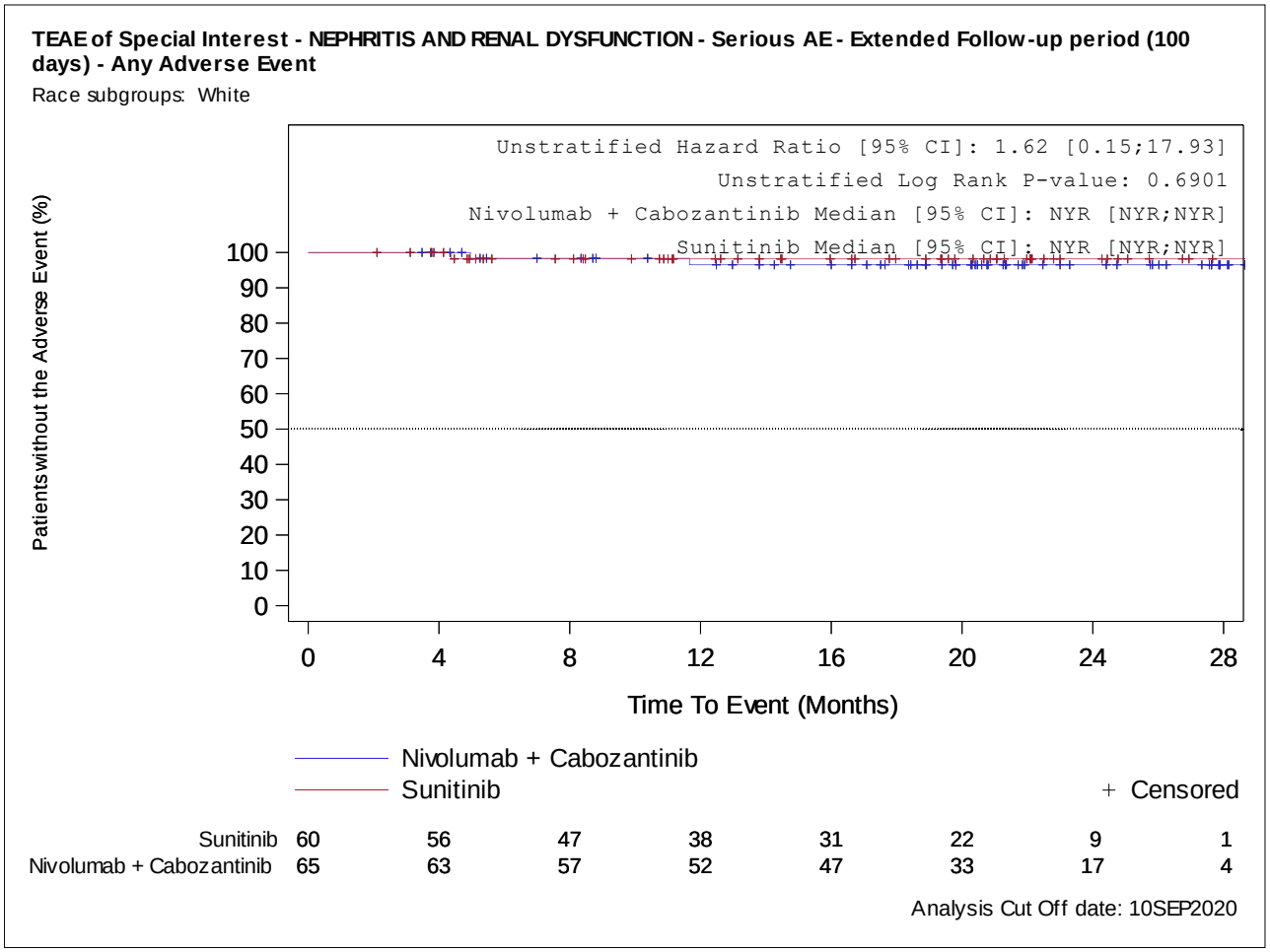

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:07:03

FIGURE 3.124.2.7: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



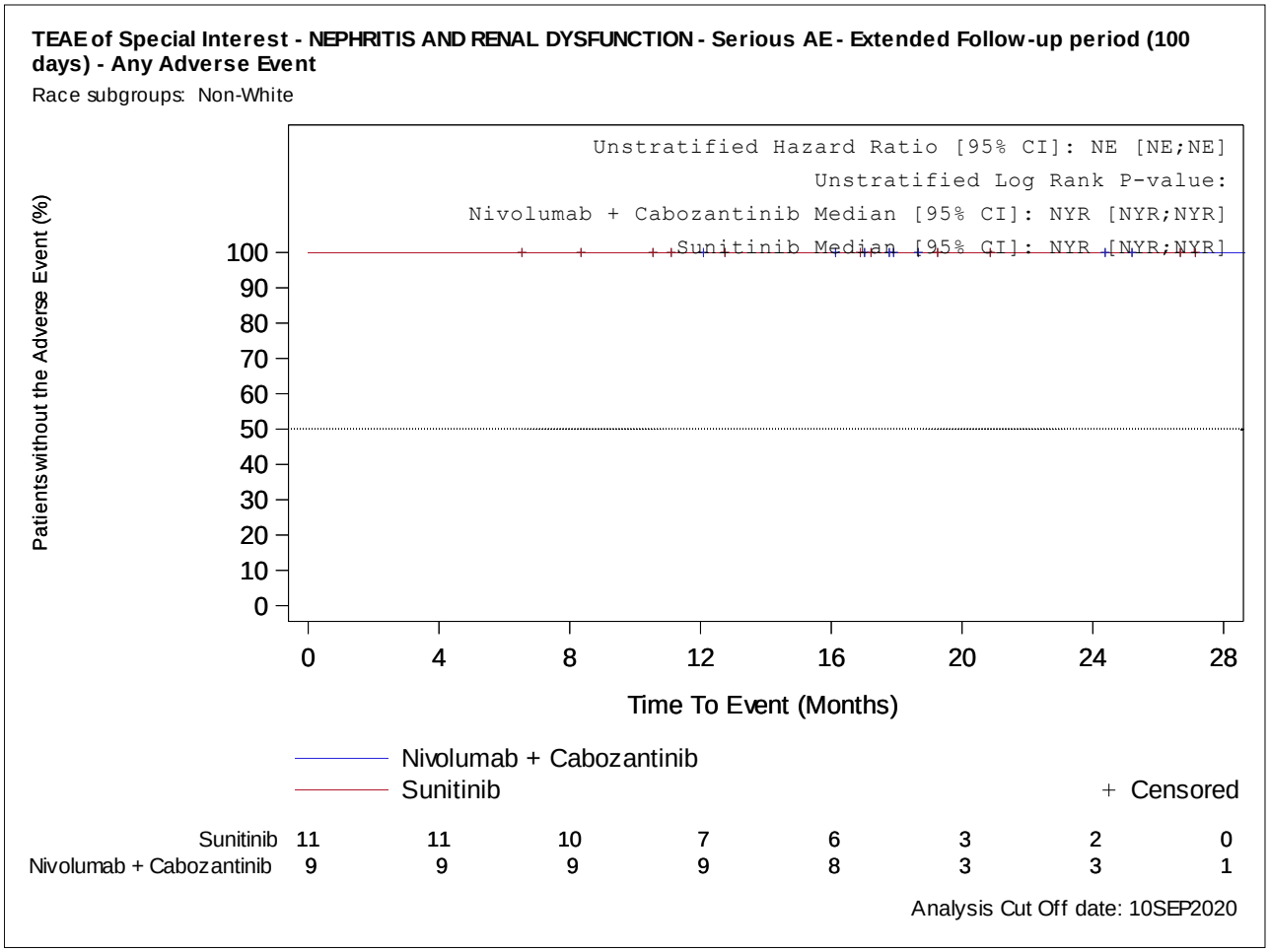

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:07:09

FIGURE 3.124.2.8: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



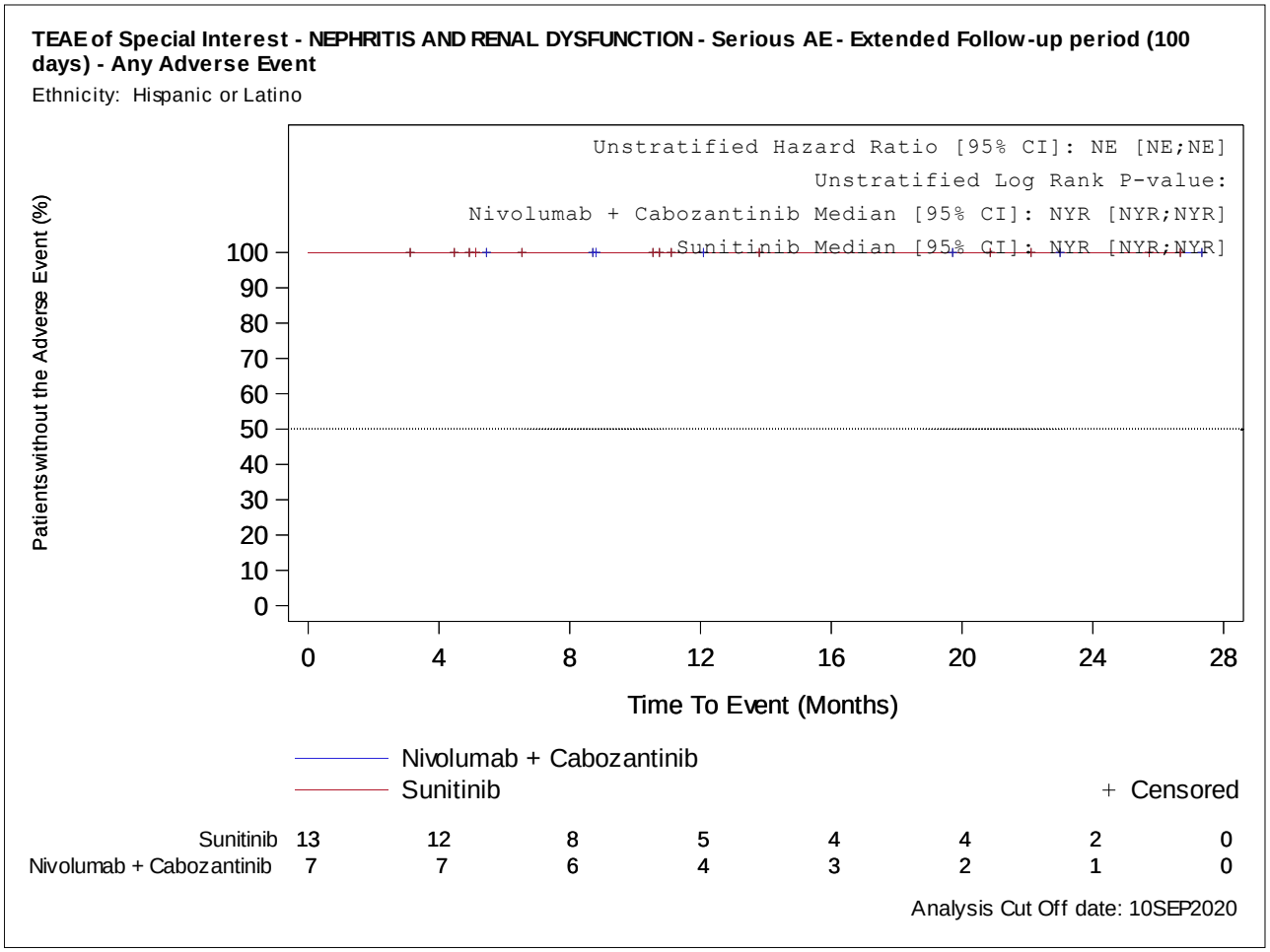

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:07:14

FIGURE 3.124.2.9: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



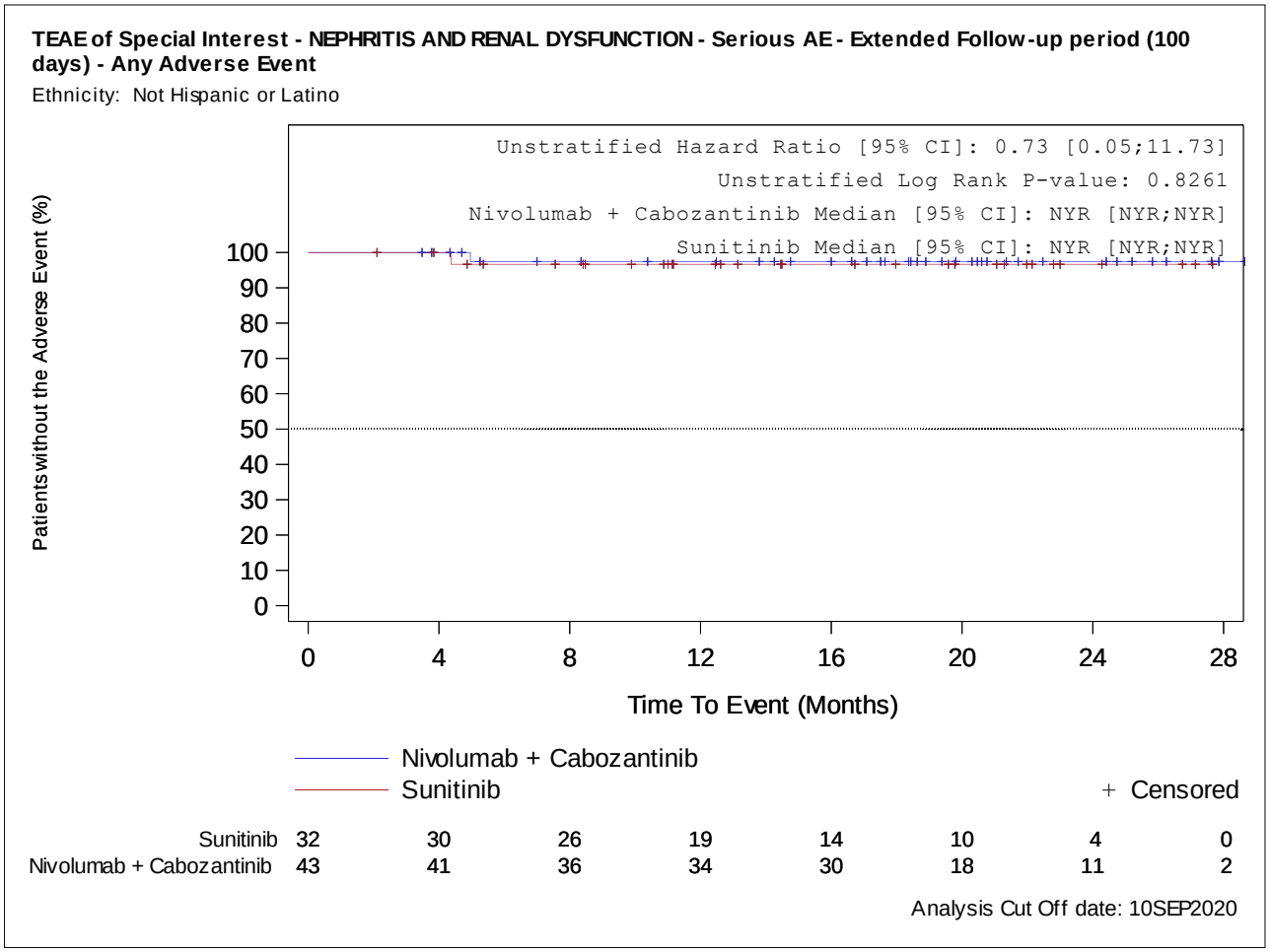

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:07:20

FIGURE 3.124.2.10: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



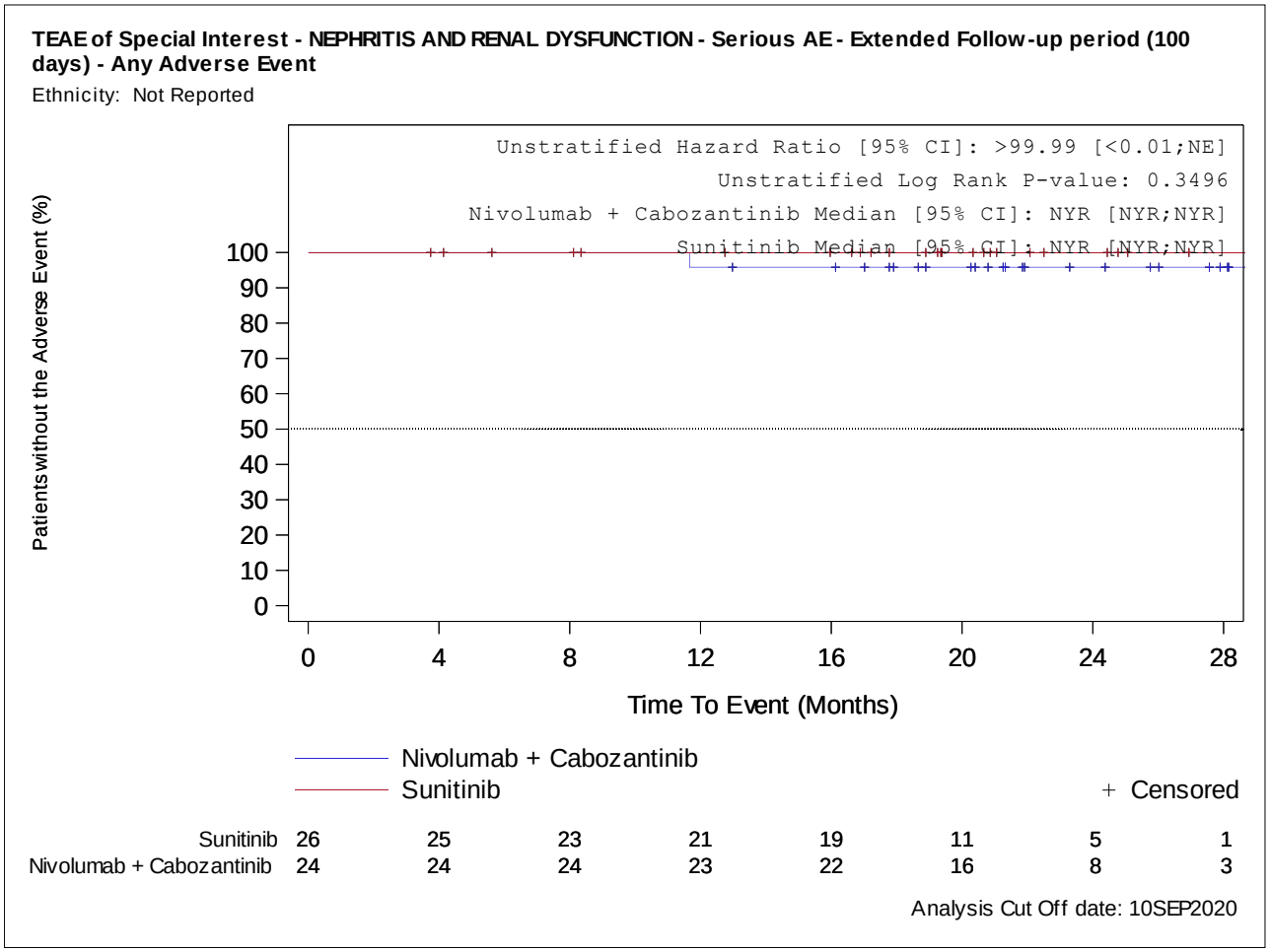

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:07:26

FIGURE 3.124.2.11: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



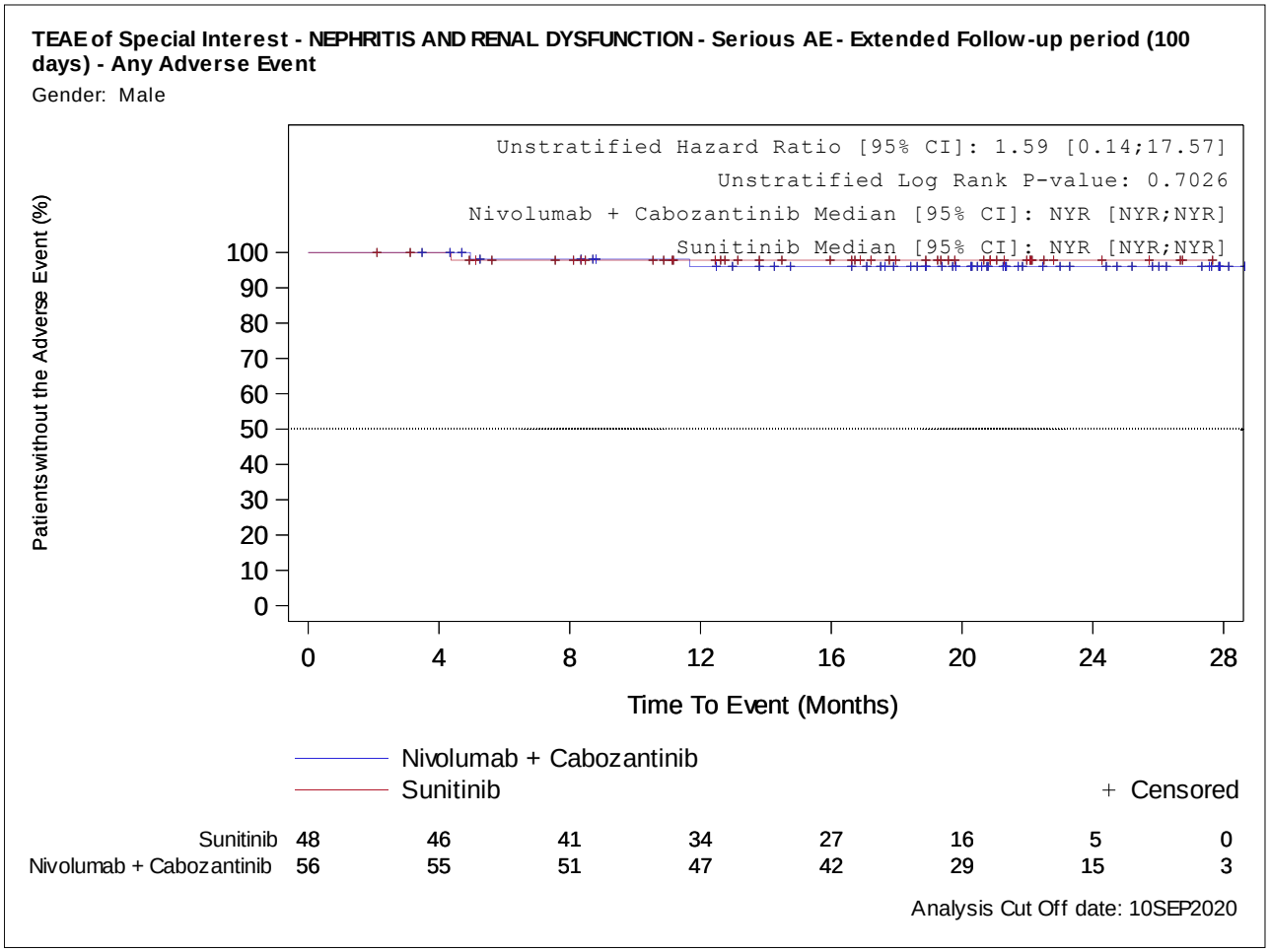

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:07:31

FIGURE 3.124.2.12: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



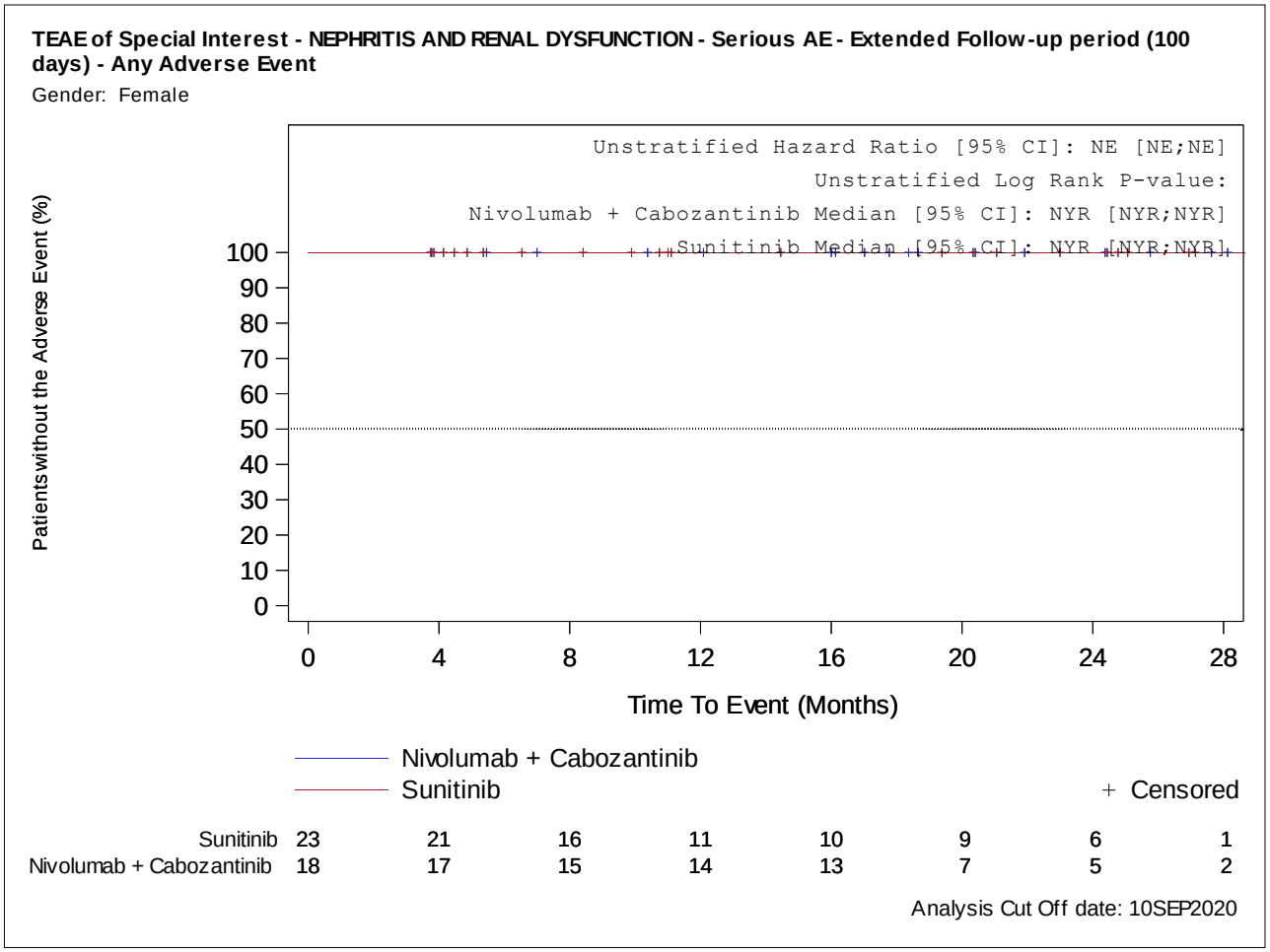

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:07:37

FIGURE 3.124.2.13: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



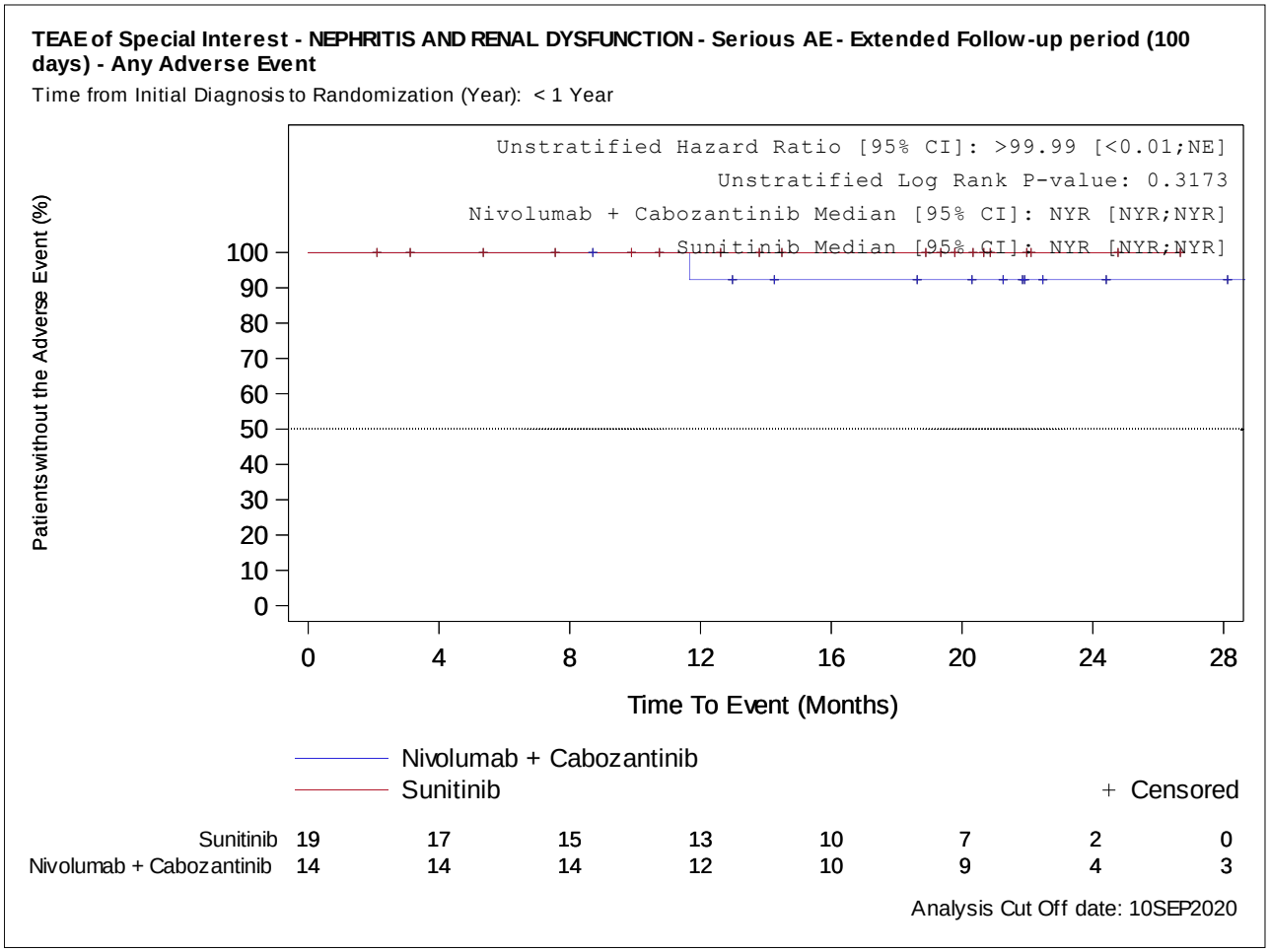

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:07:43

FIGURE 3.124.2.14: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



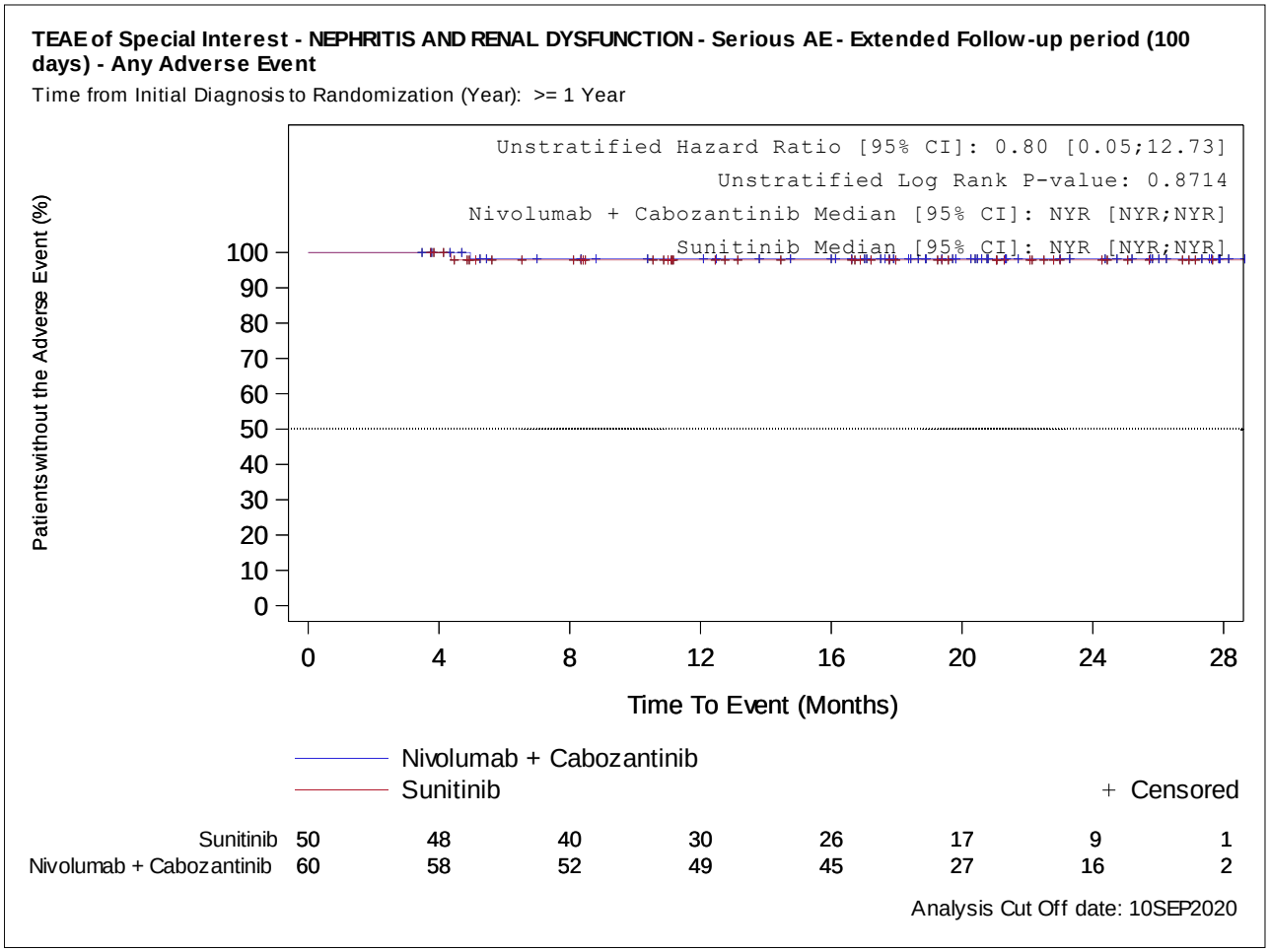

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:07:49

FIGURE 3.124.2.15: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



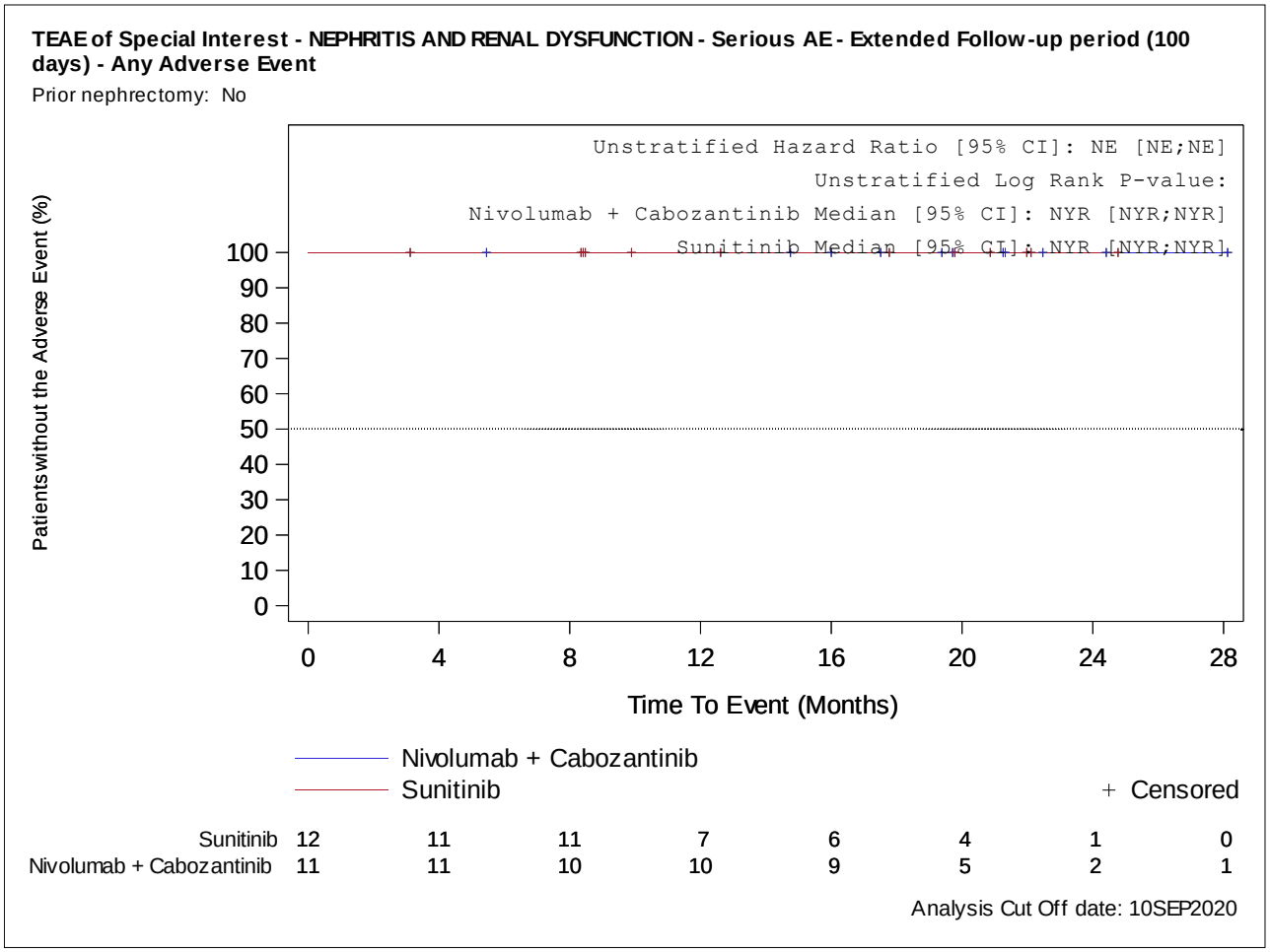

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:08:05

FIGURE 3.124.2.16: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



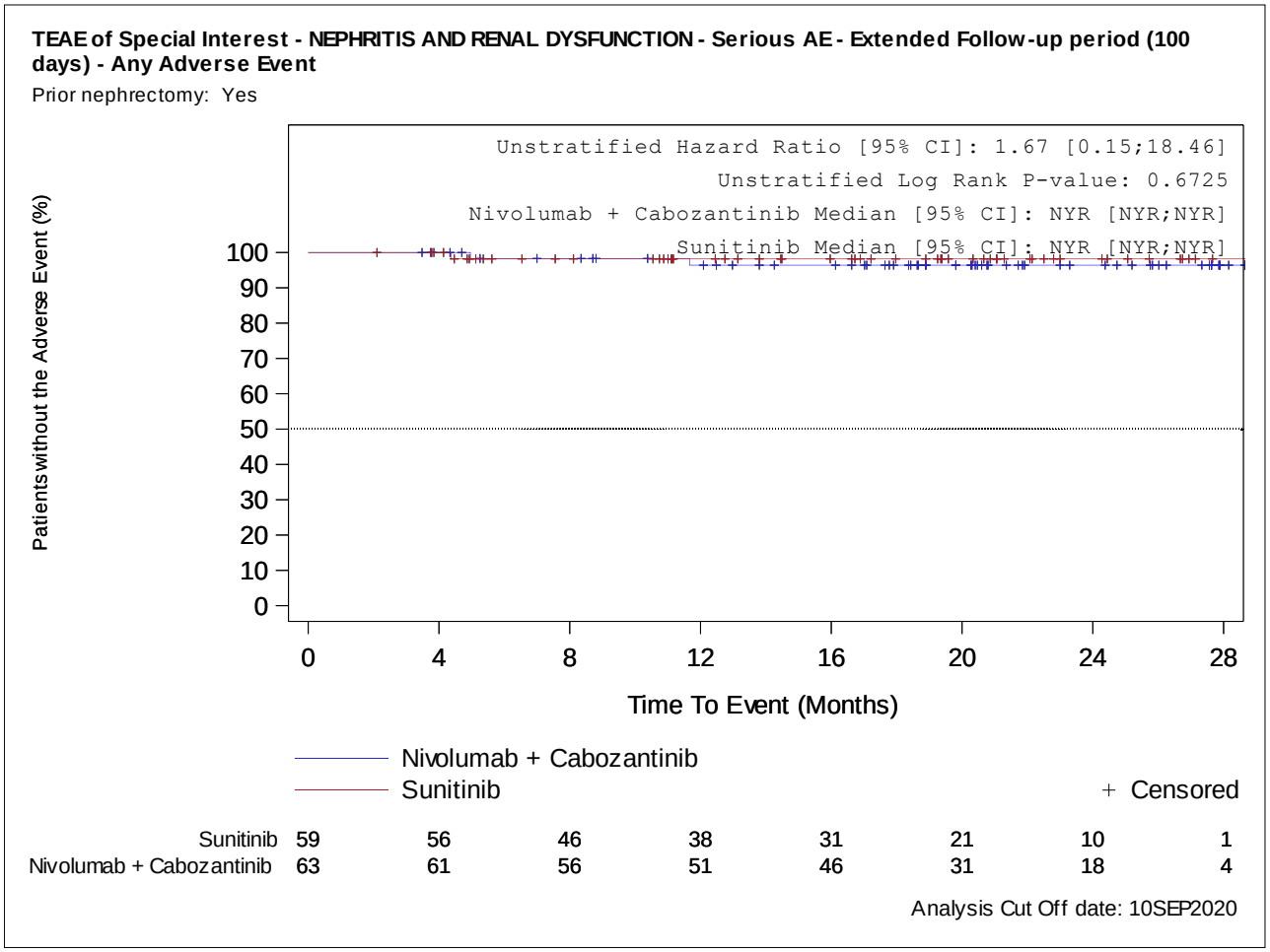

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:08:11

FIGURE 3.124.2.17: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



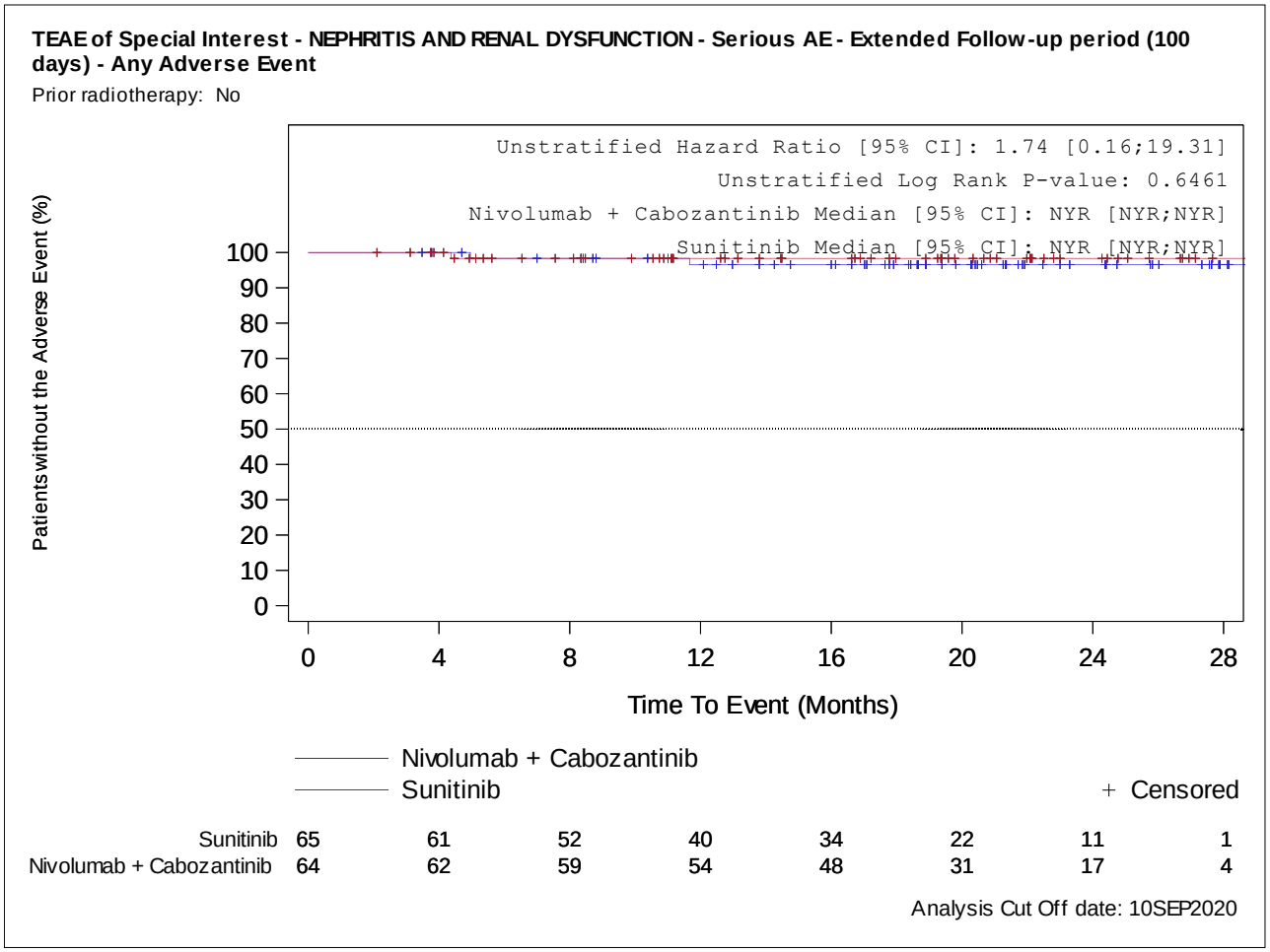

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:09:02

FIGURE 3.124.2.18: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



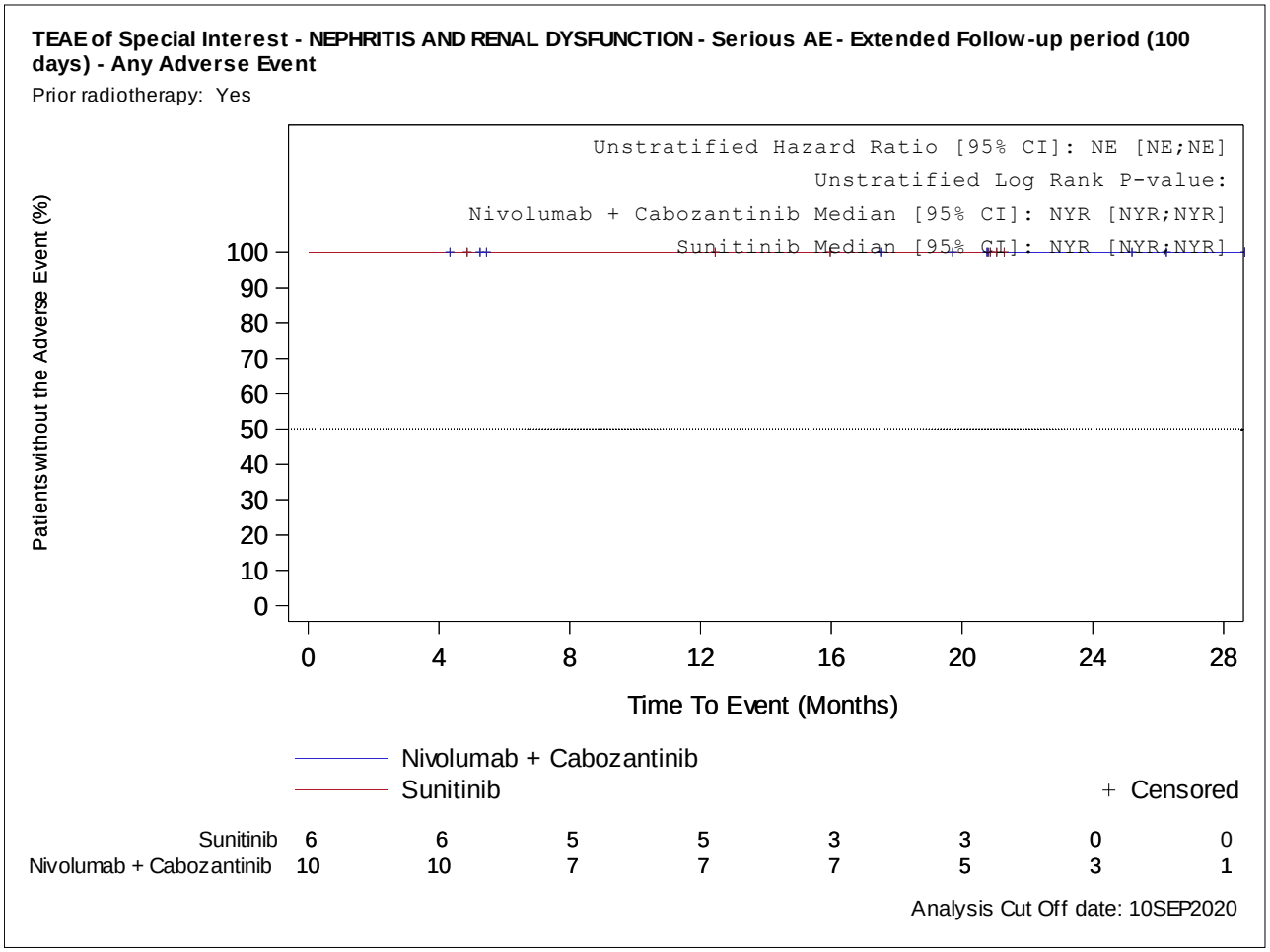

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:09:07

FIGURE 3.124.2.19: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



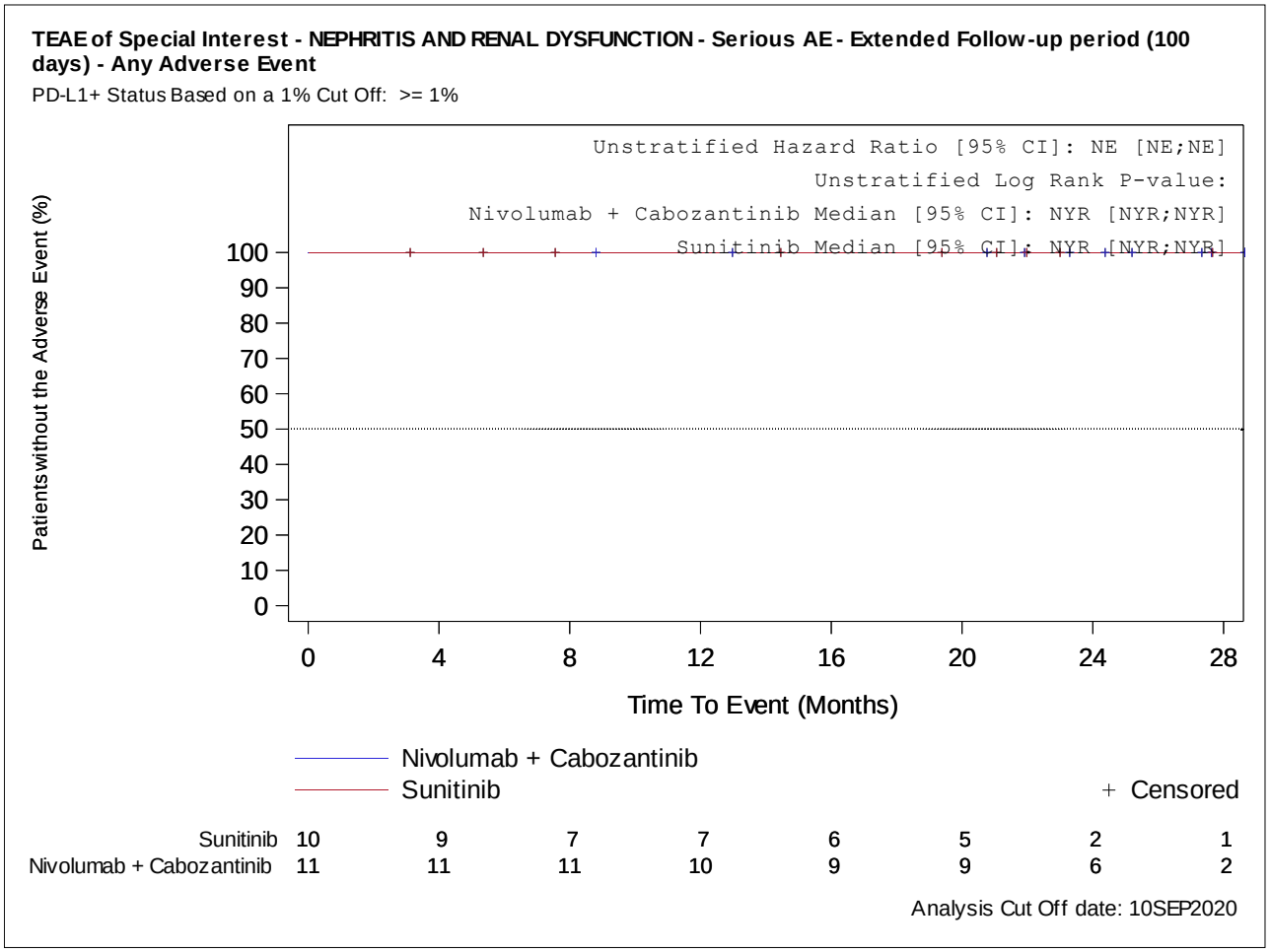

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:09:13

FIGURE 3.124.2.20: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



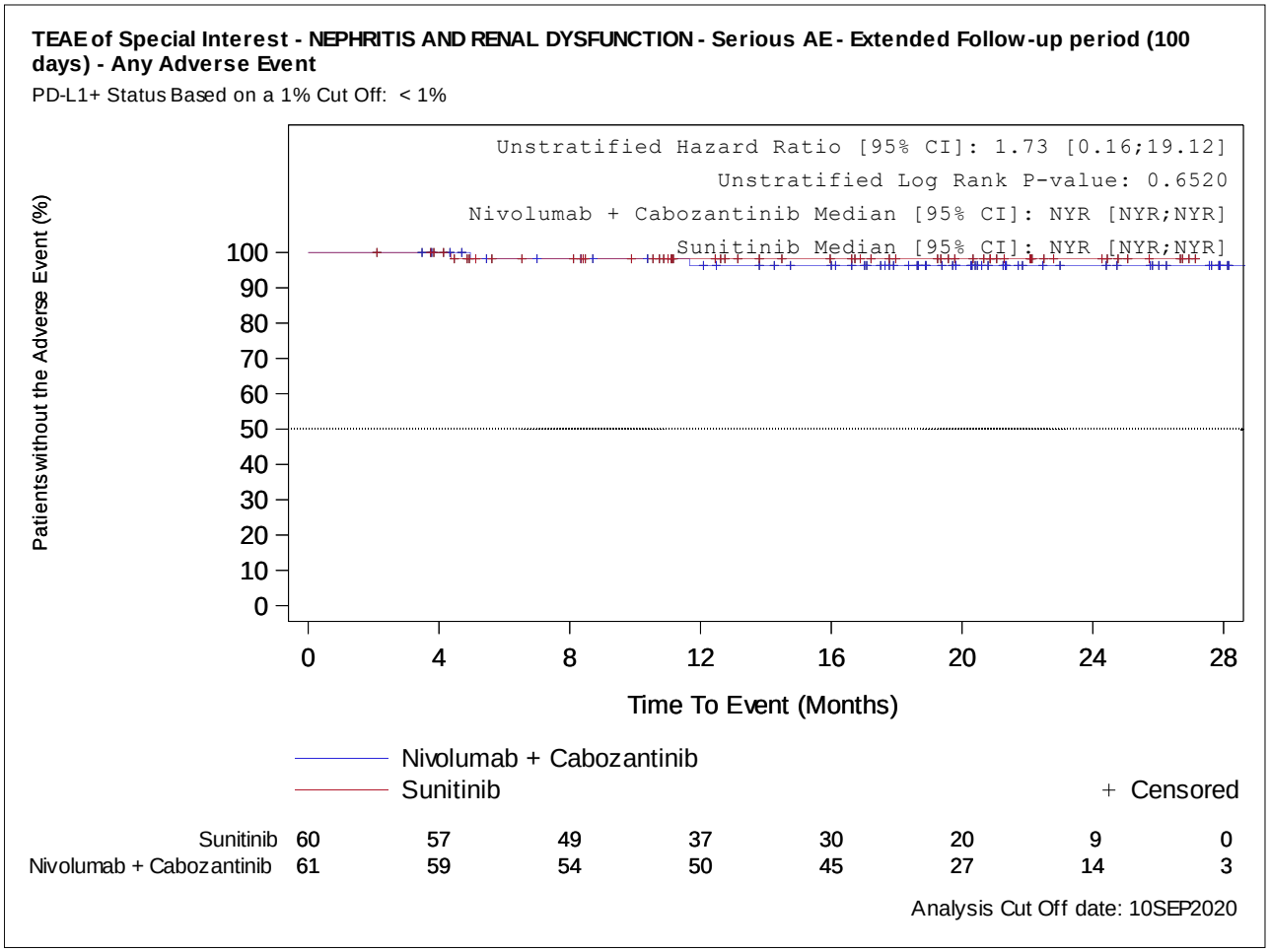

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:09:19

FIGURE 3.124.2.21: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



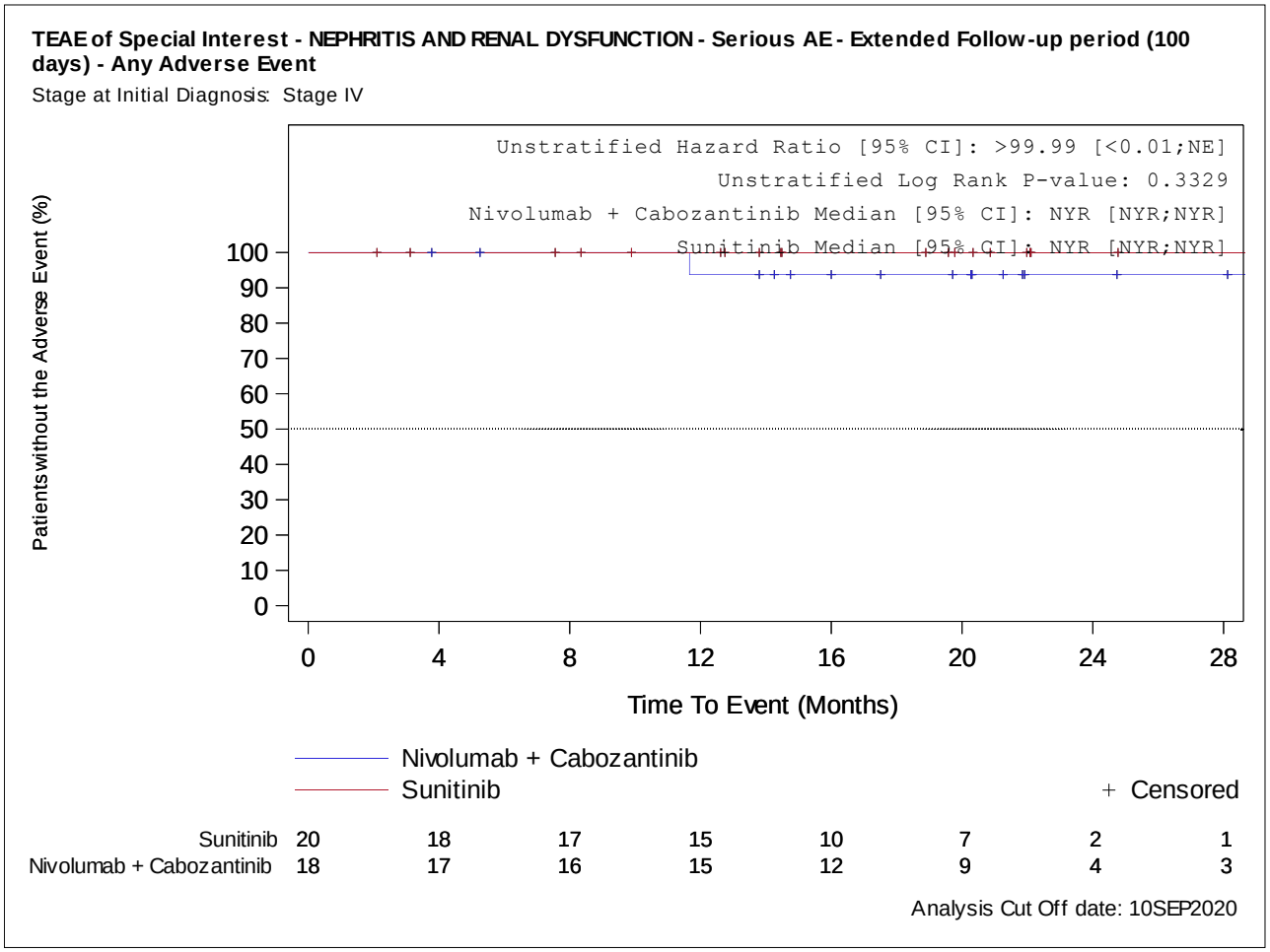

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:09:25

FIGURE 3.124.2.22: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



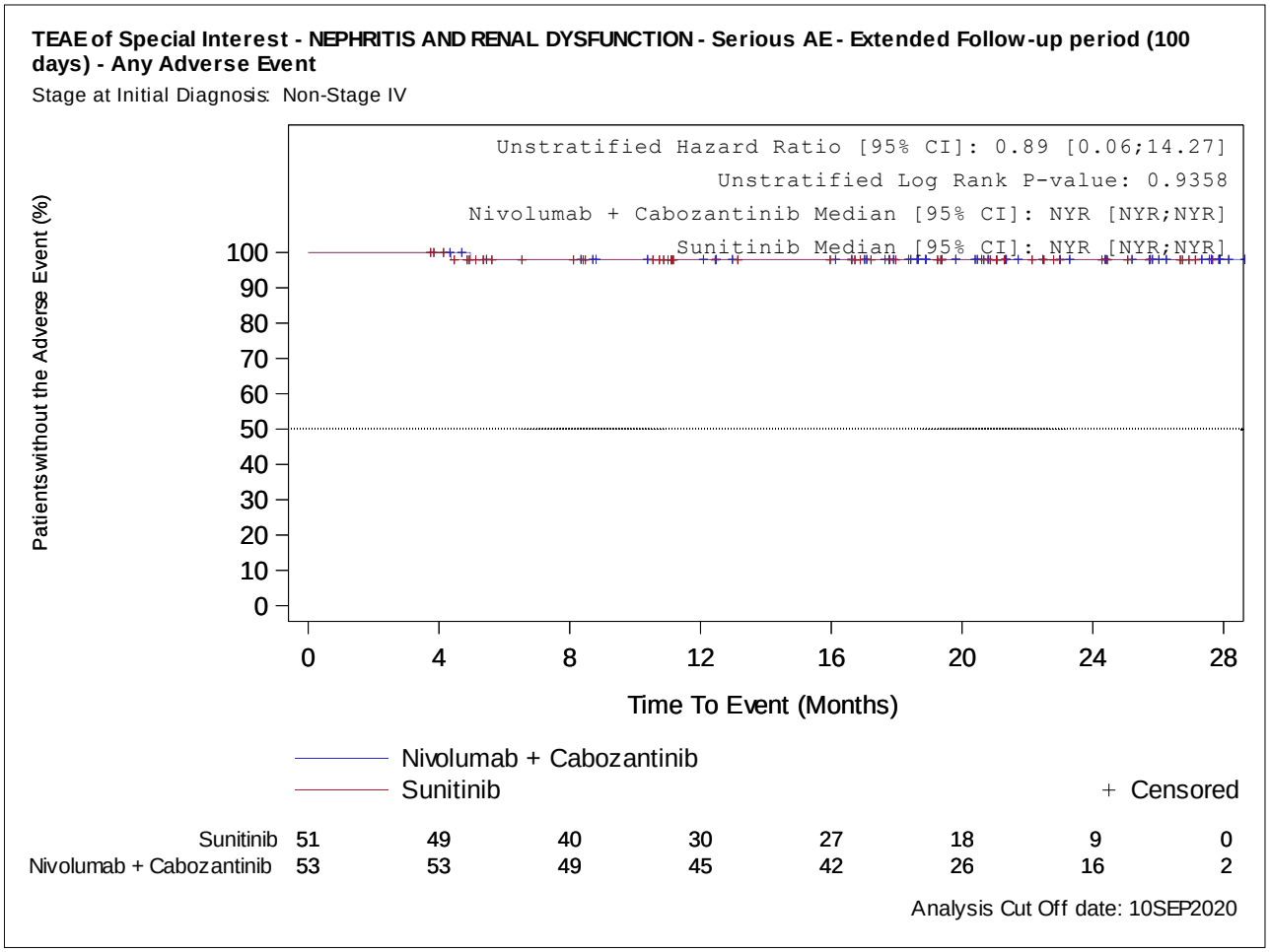

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:09:31

FIGURE 3.124.2.23: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



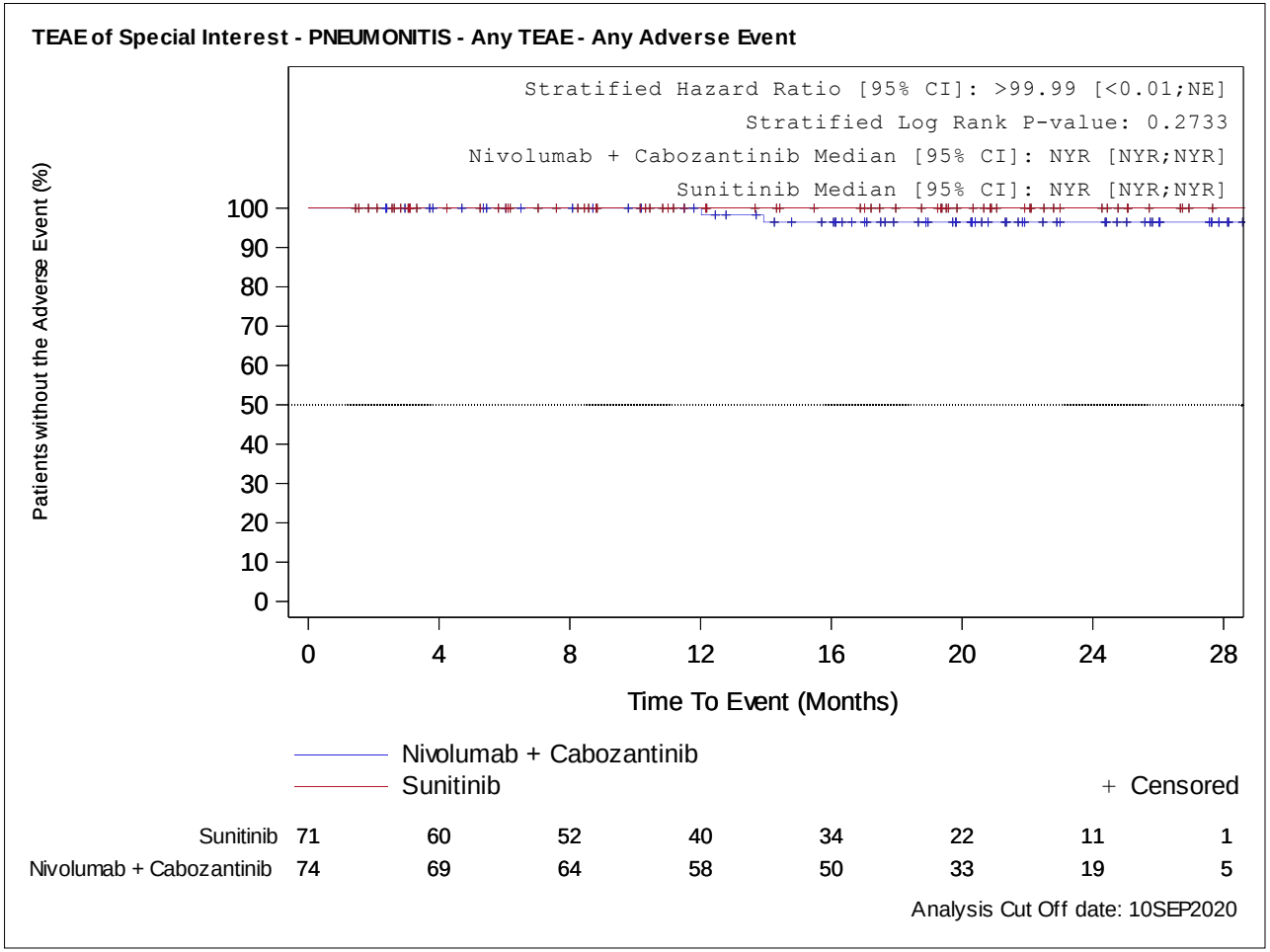

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:09:59

FIGURE 3.124.2.24: Kaplan-Meier curve - TEAE of Special Interest - NEPHRITIS AND RENAL DYSFUNCTION - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



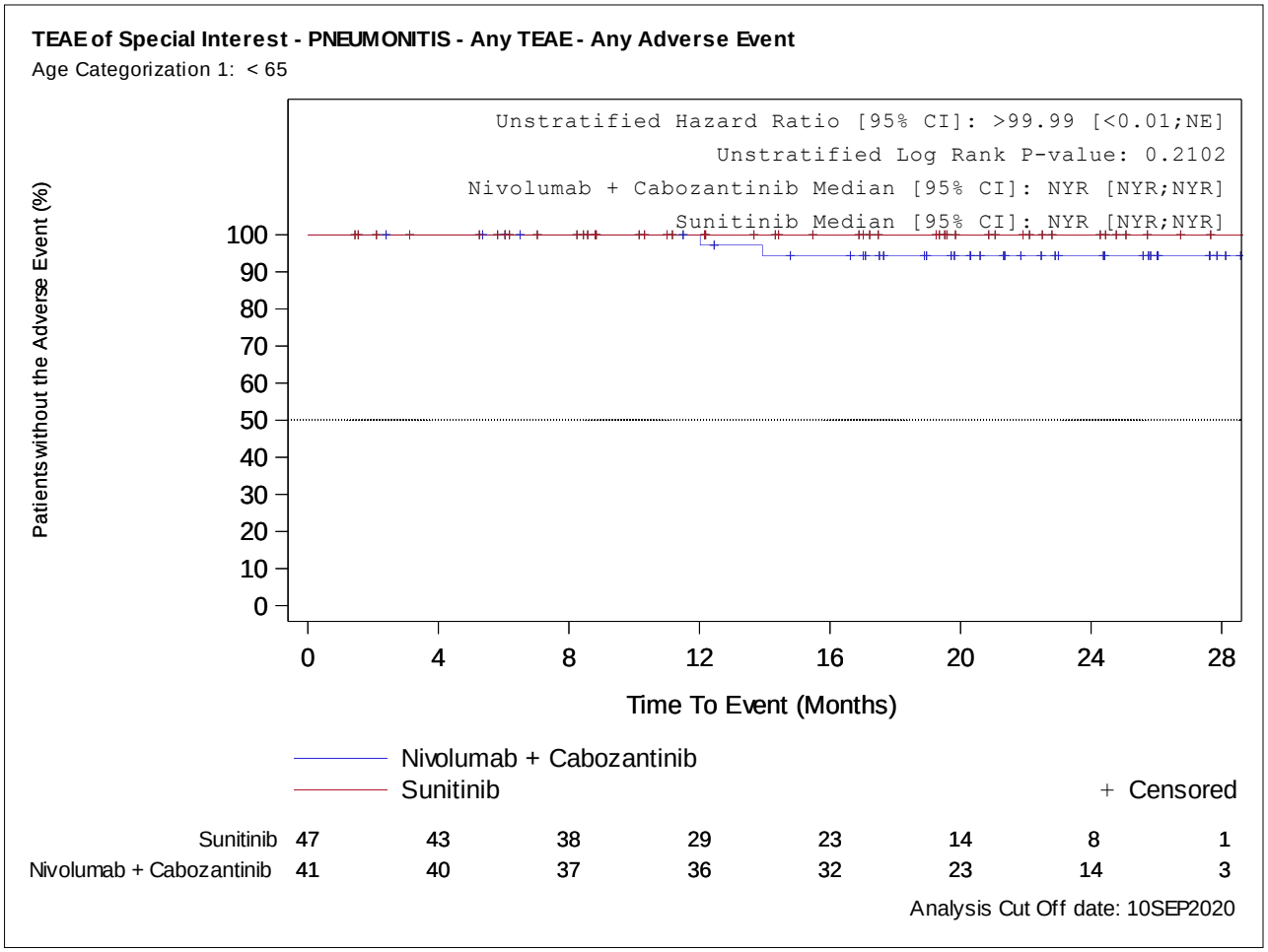

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:10:04

FIGURE 3.125.1: TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



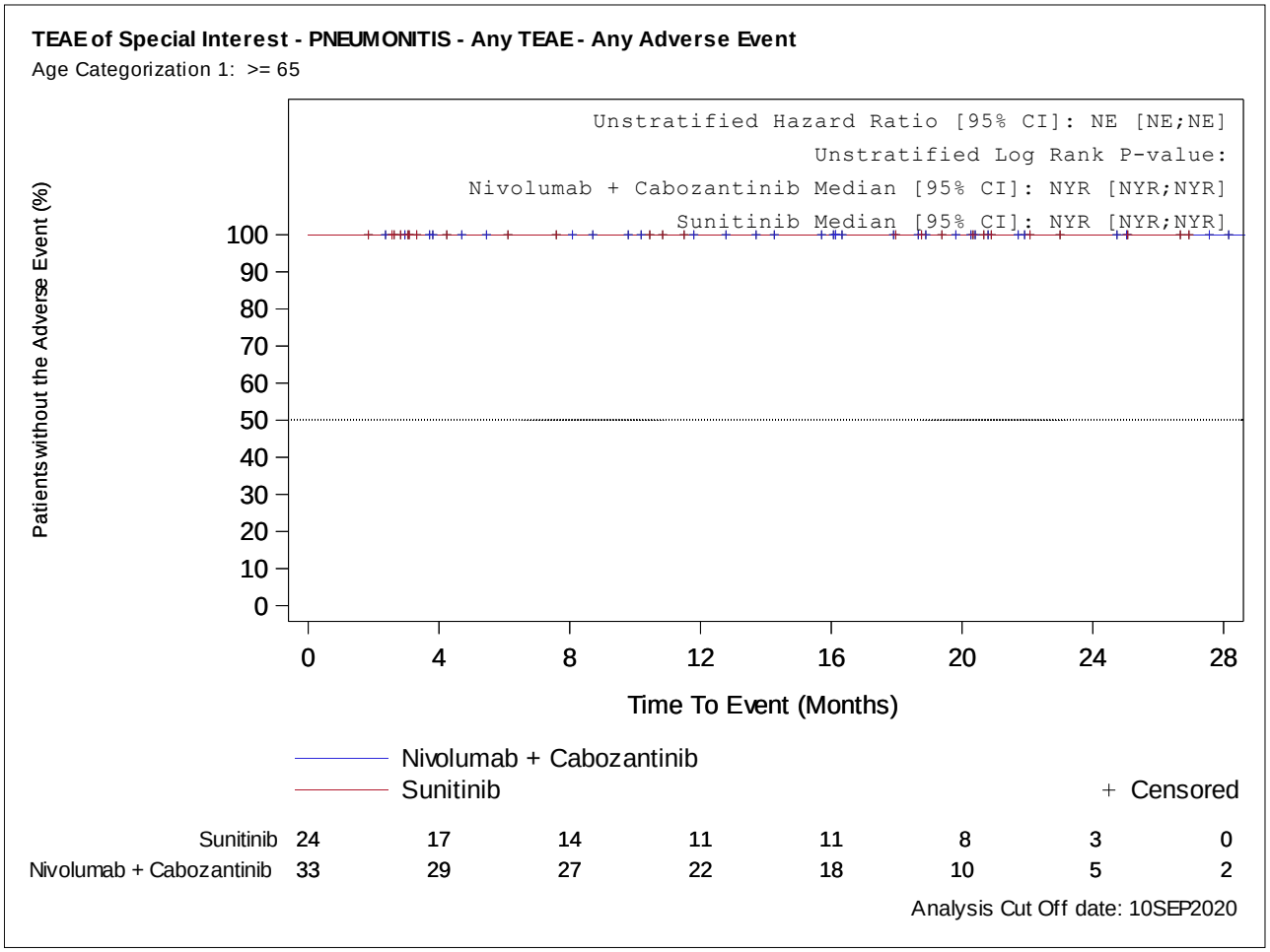

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:13:12

FIGURE 3.125.2.1: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



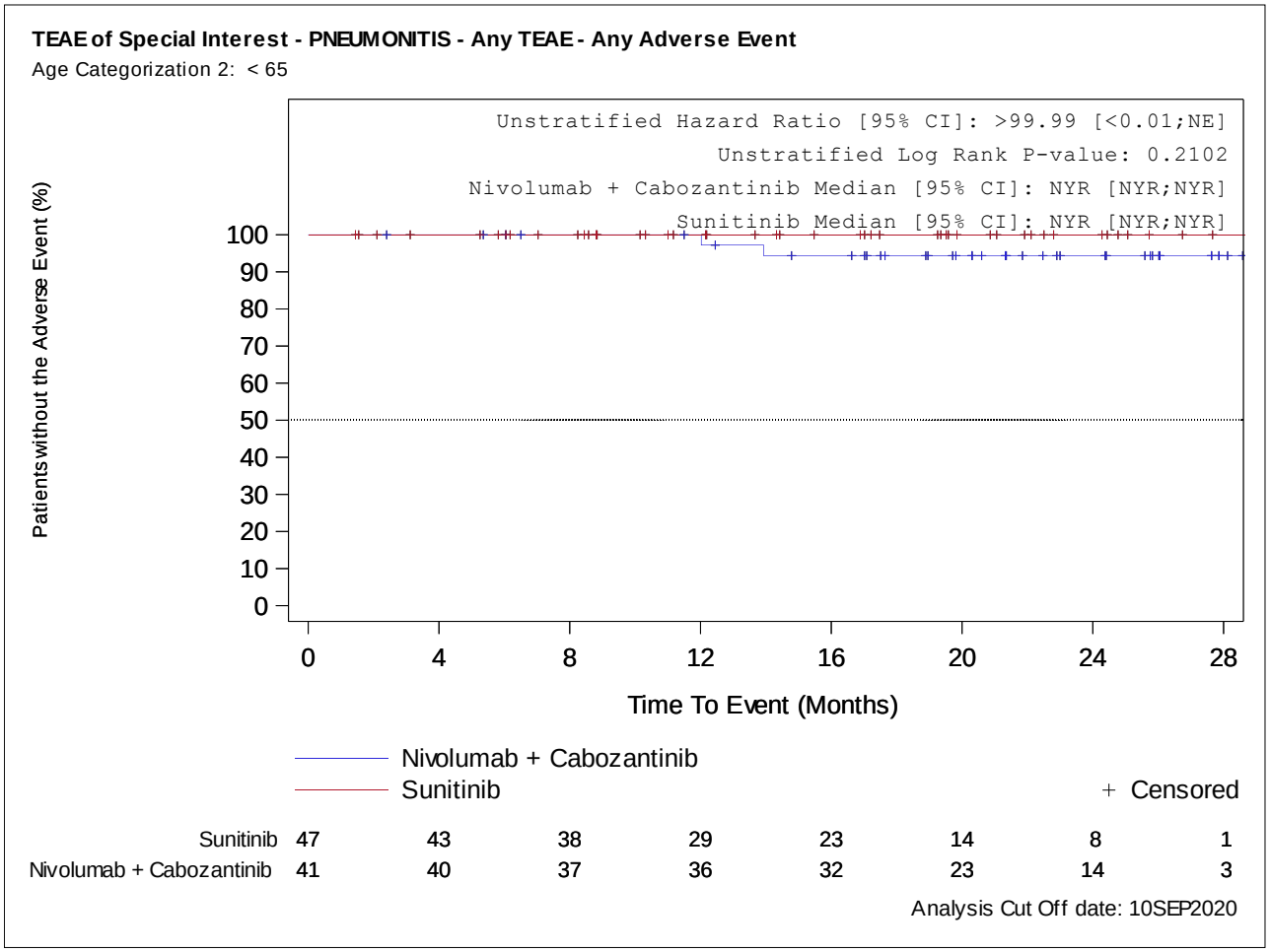

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:13:15

FIGURE 3.125.2.2: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



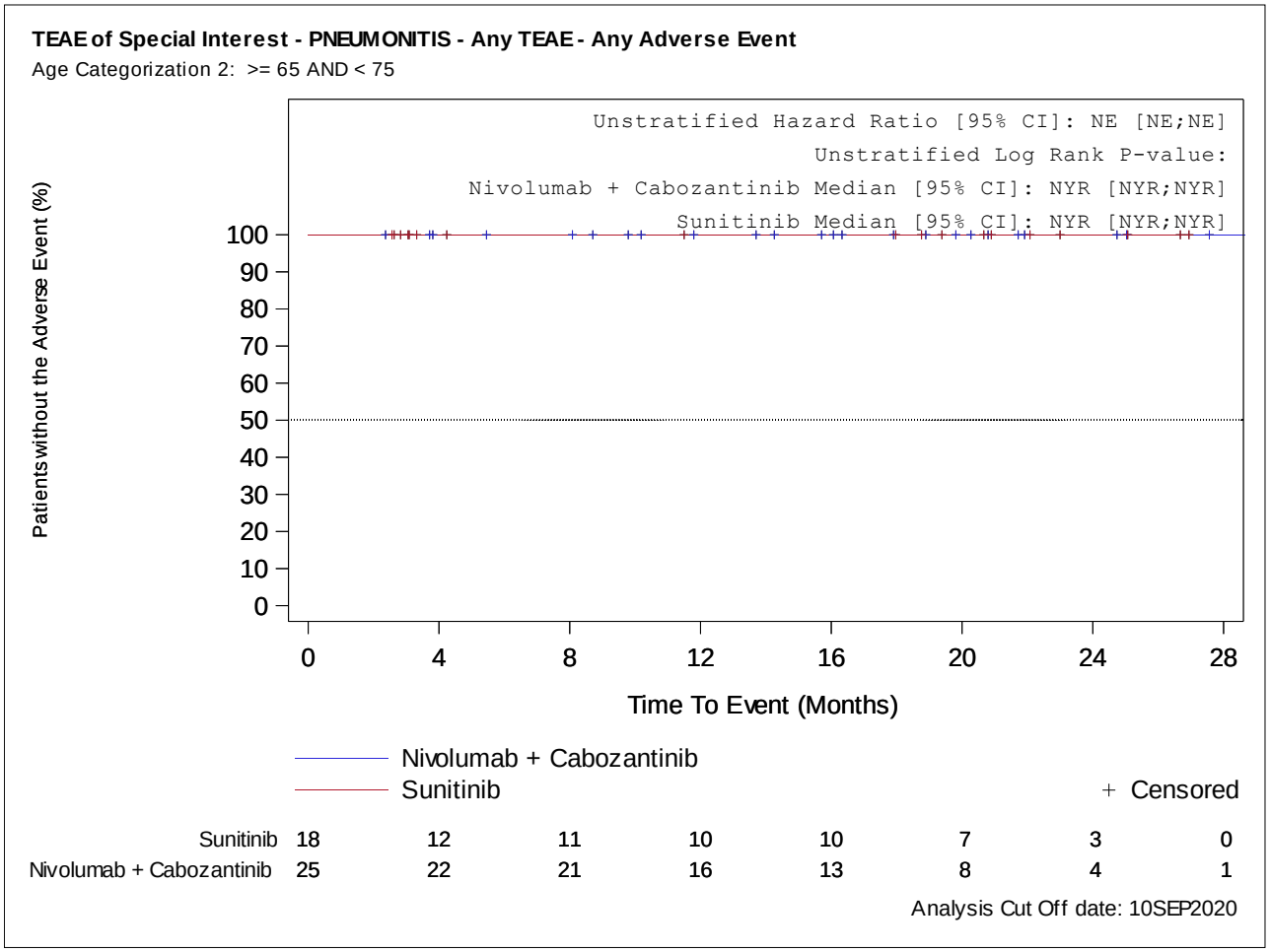

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:13:21

FIGURE 3.125.2.3: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



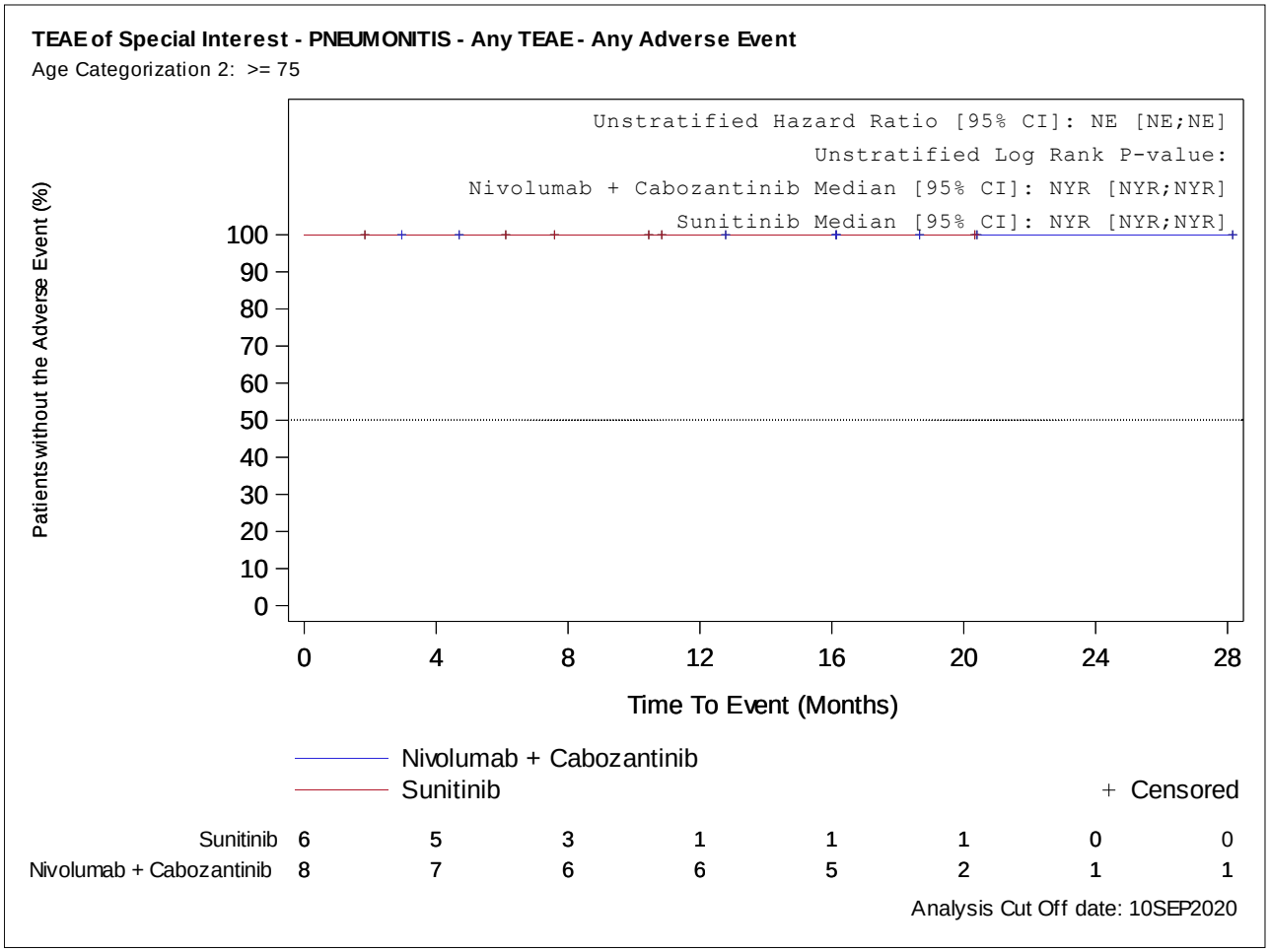

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:13:27

FIGURE 3.125.2.4: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



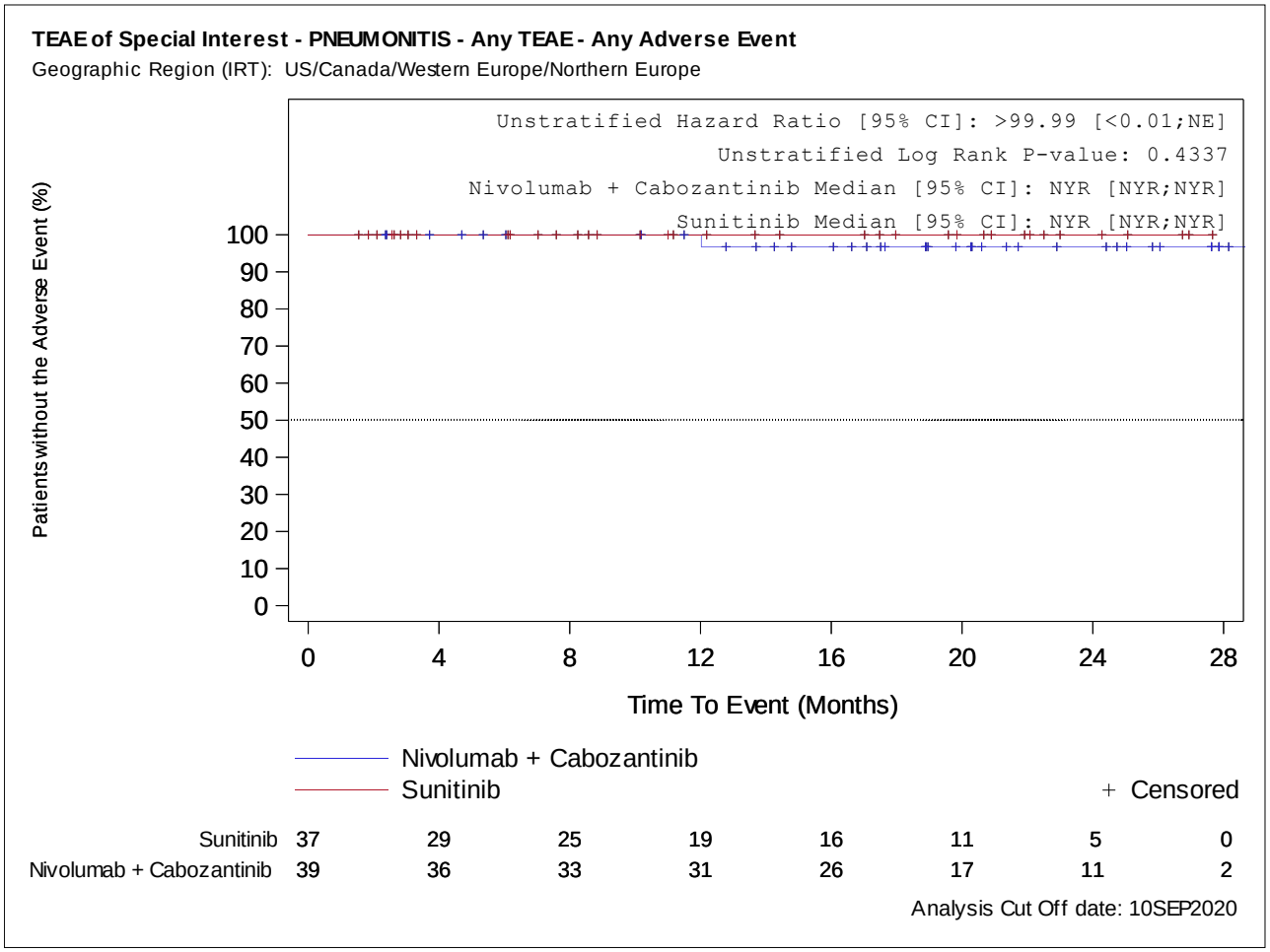

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:13:32

FIGURE 3.125.2.5: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



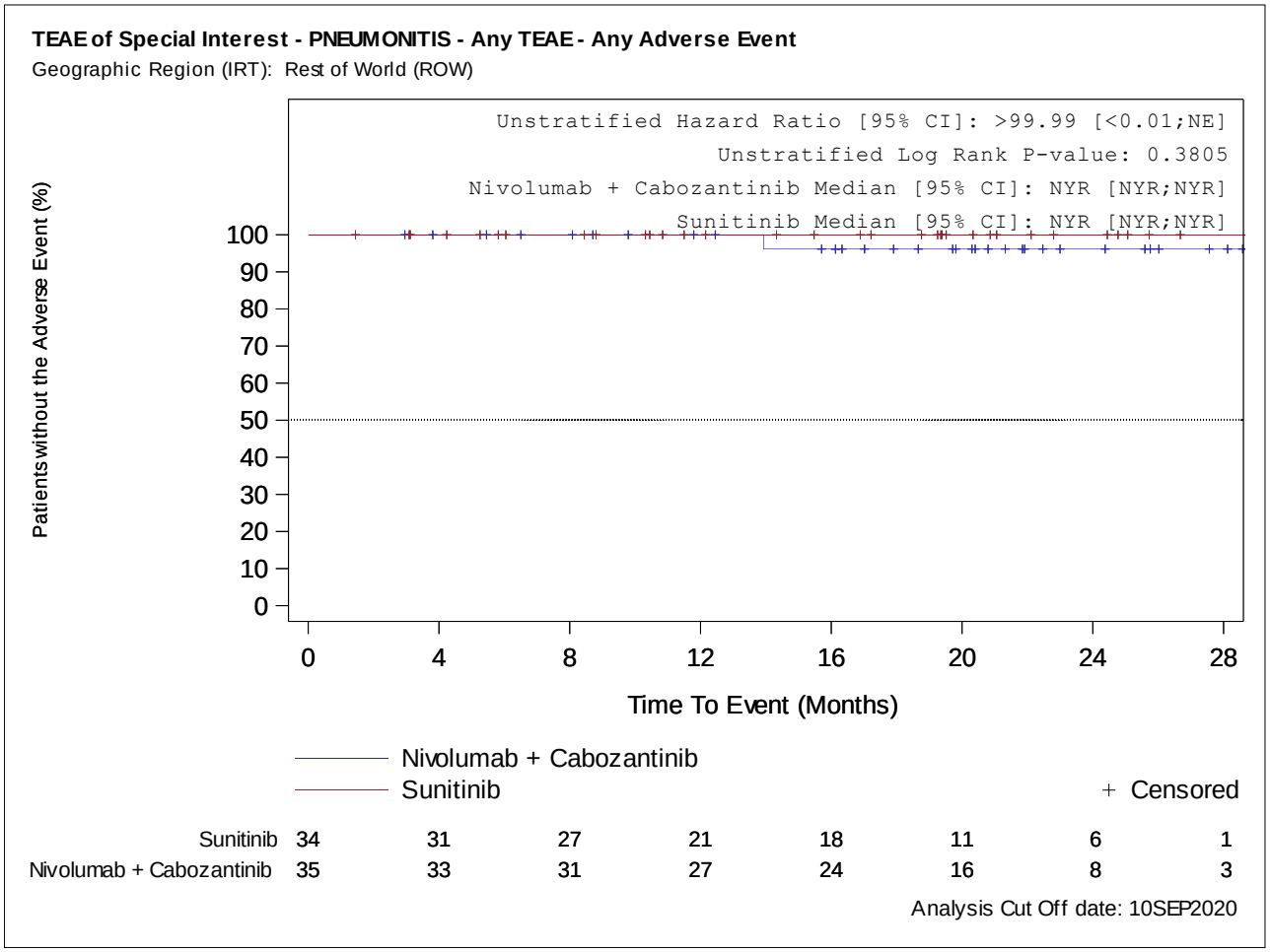

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:13:38

FIGURE 3.125.2.6: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



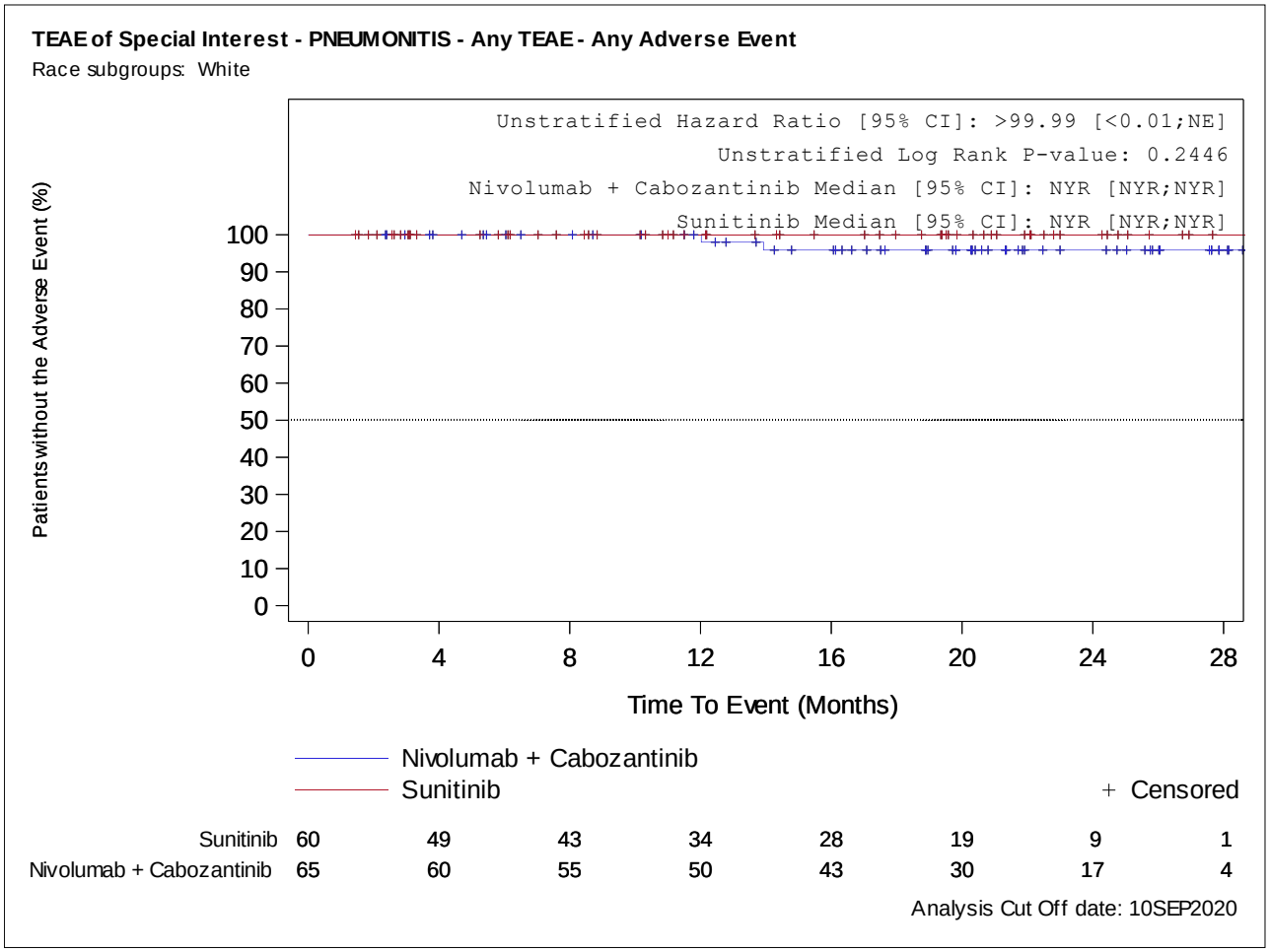

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:13:44

FIGURE 3.125.2.7: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



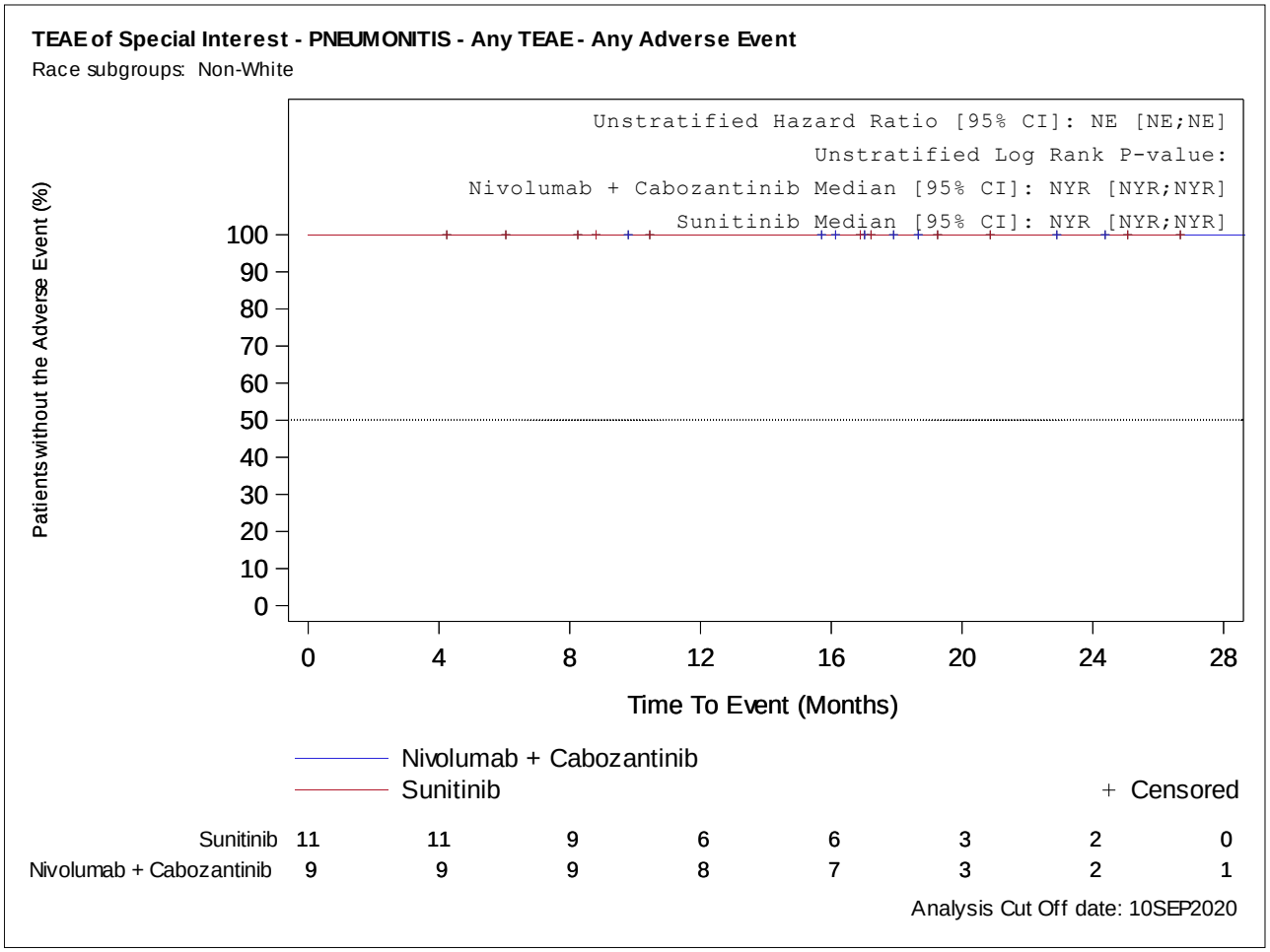

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:13:50

FIGURE 3.125.2.8: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



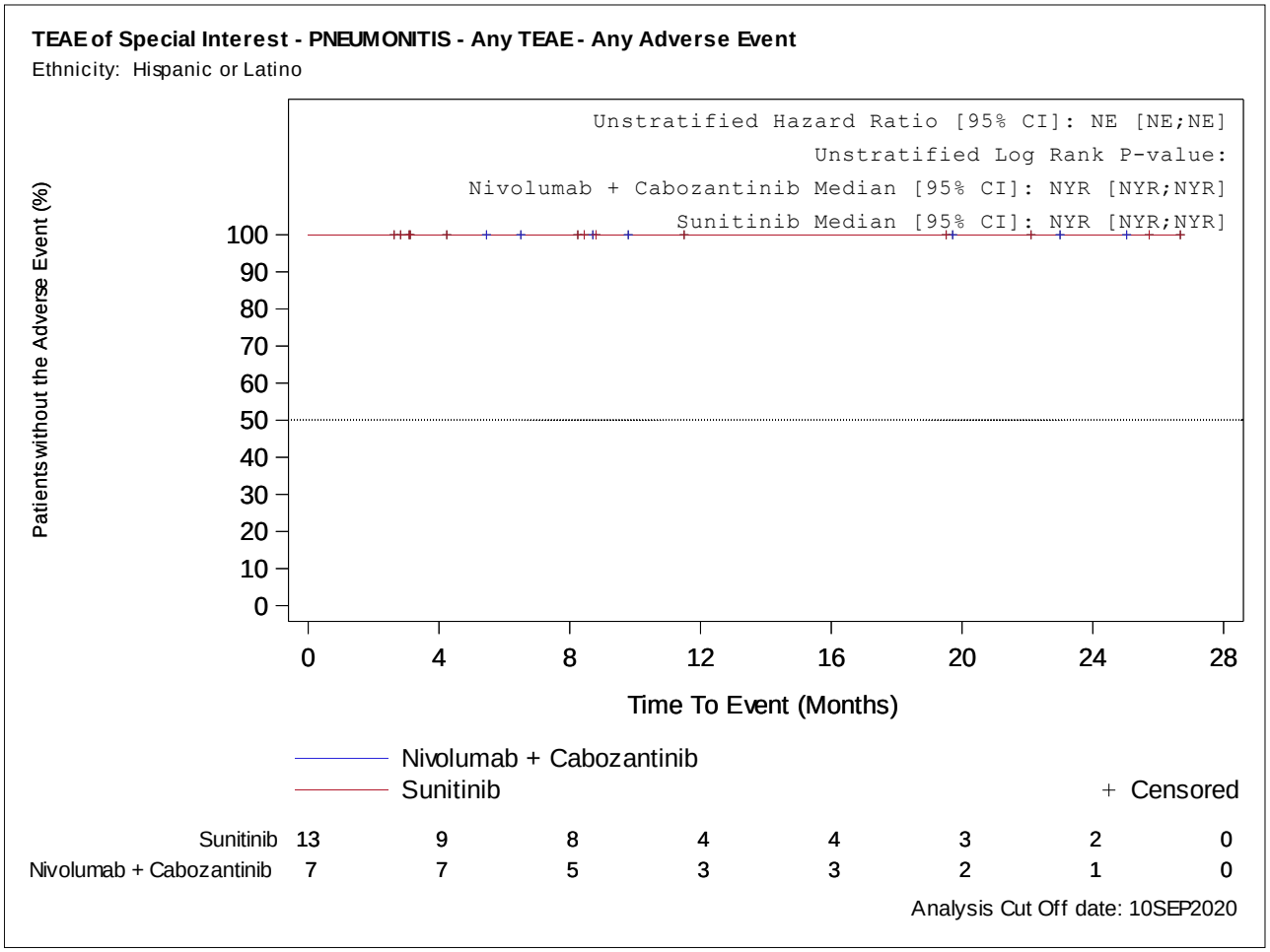

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:13:55

FIGURE 3.125.2.9: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



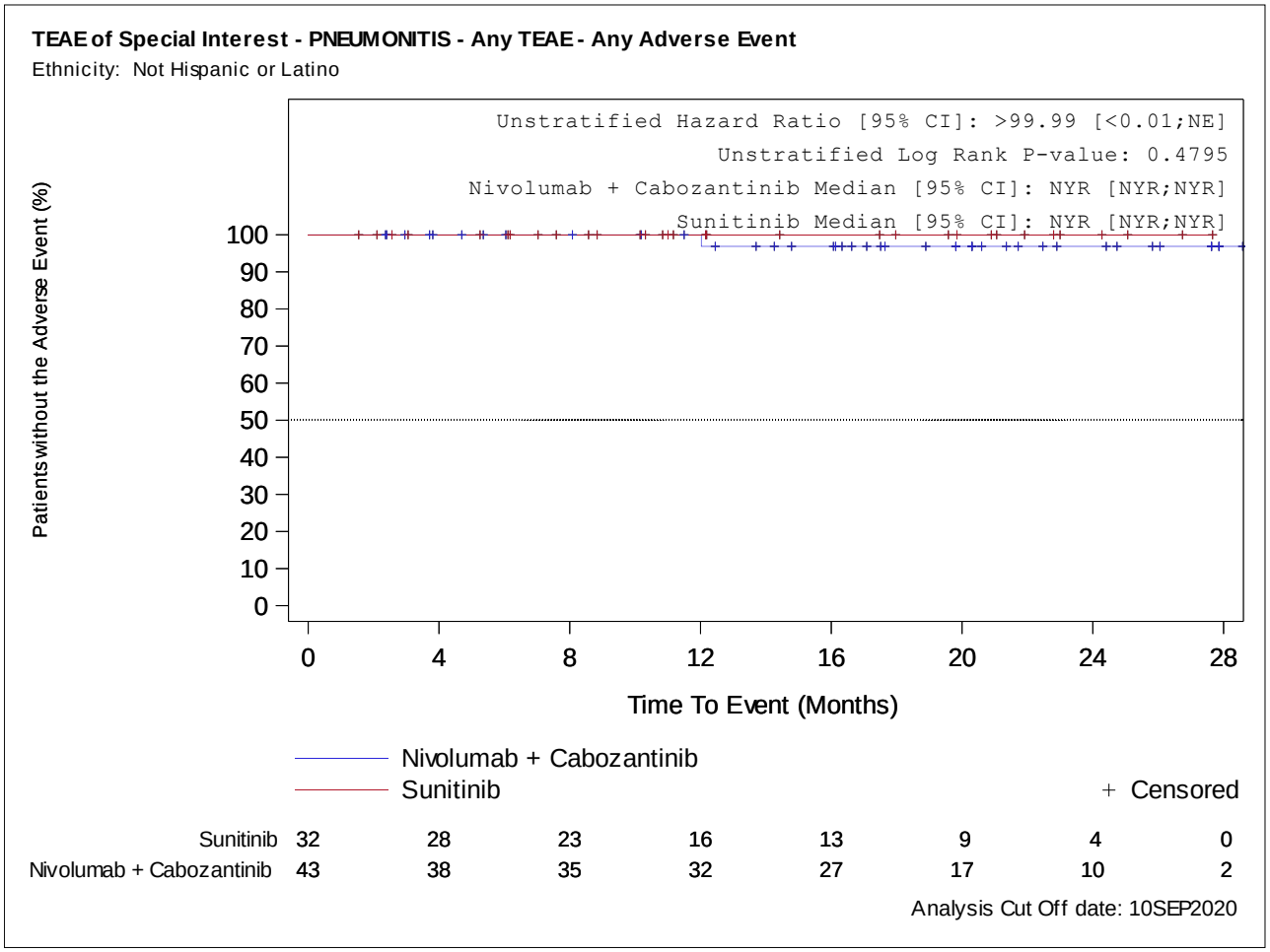

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:14:00

FIGURE 3.125.2.10: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



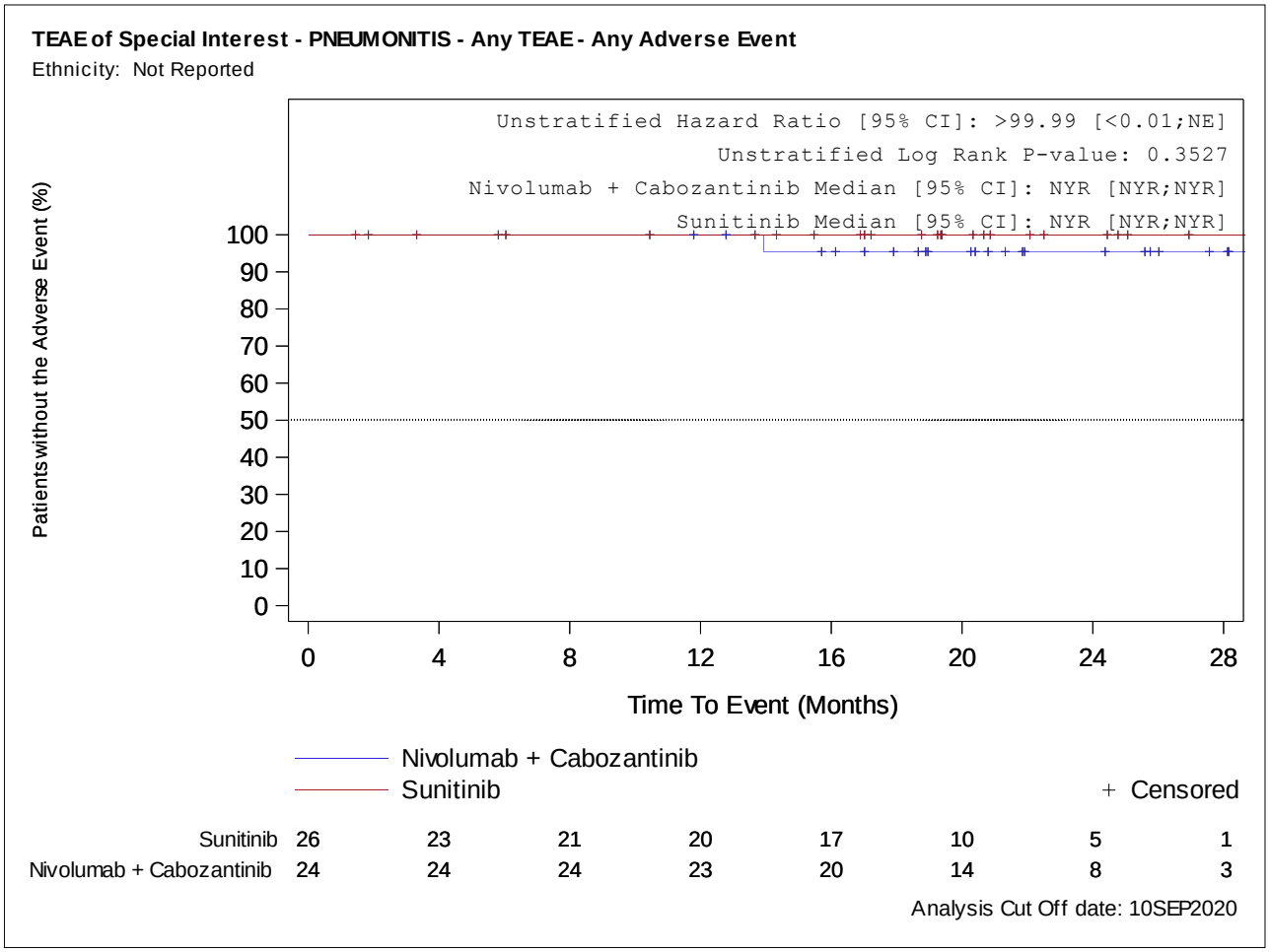

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:14:06

FIGURE 3.125.2.11: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



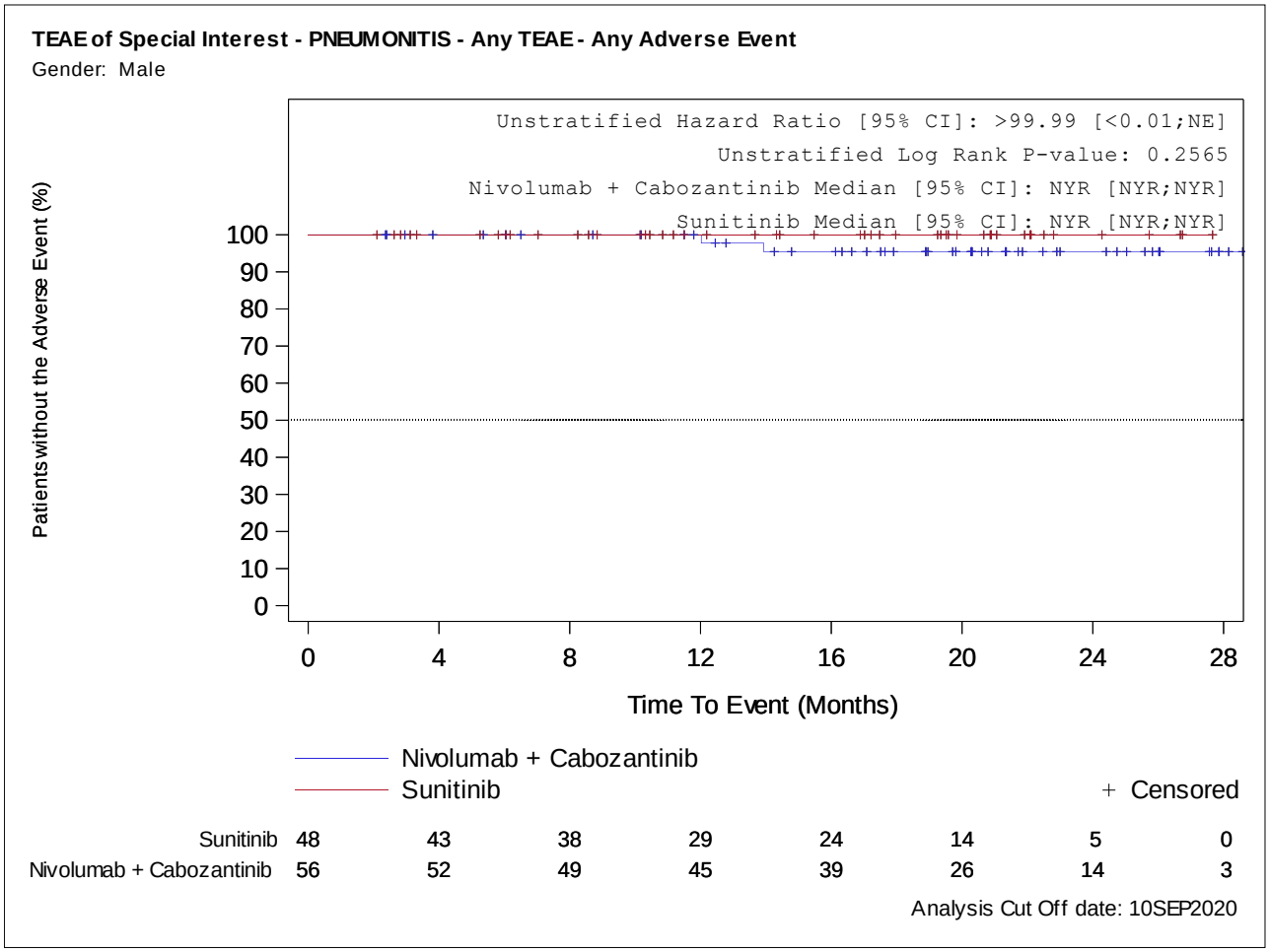

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:14:11

FIGURE 3.125.2.12: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



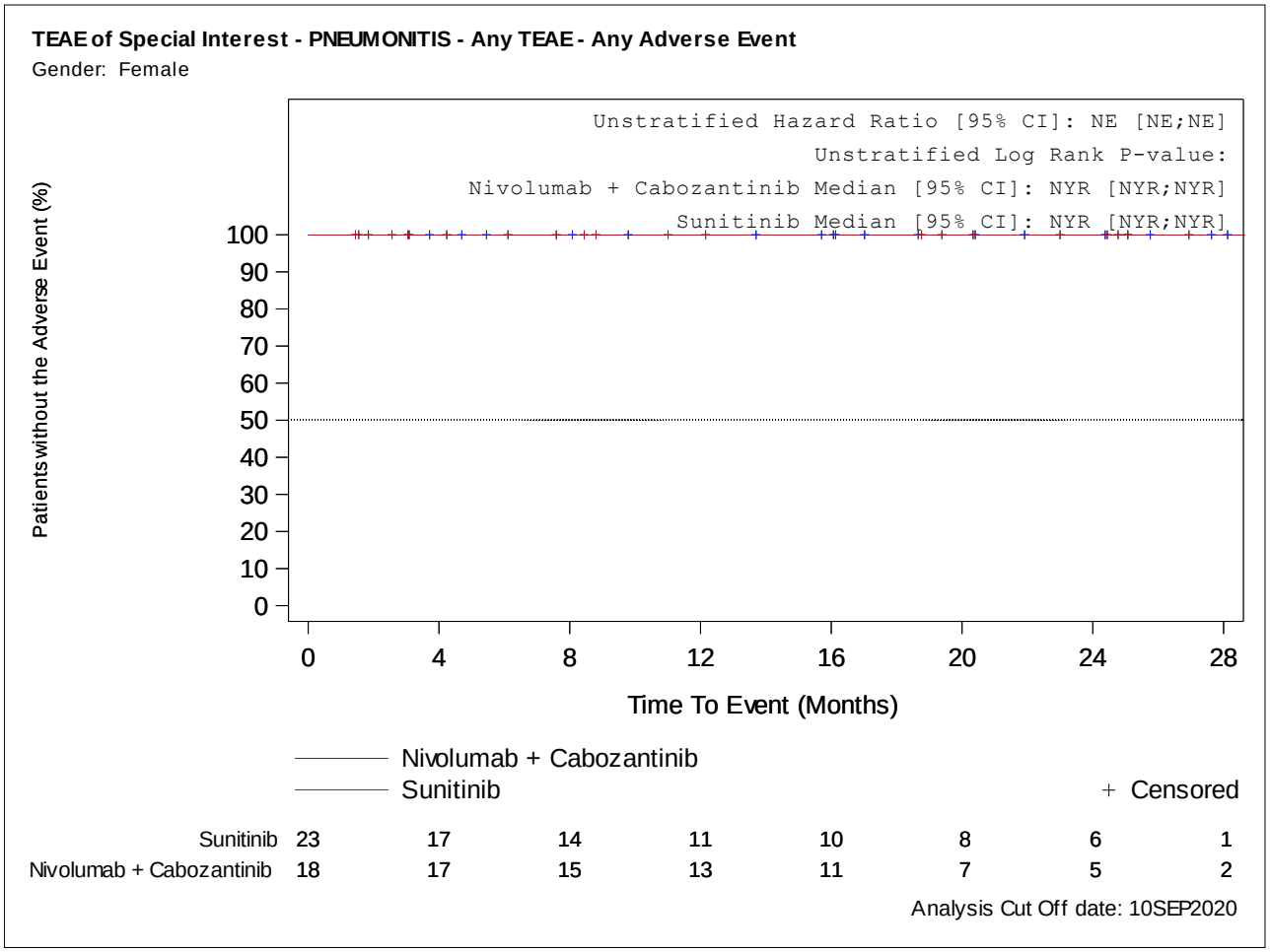

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:14:17

FIGURE 3.125.2.13: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



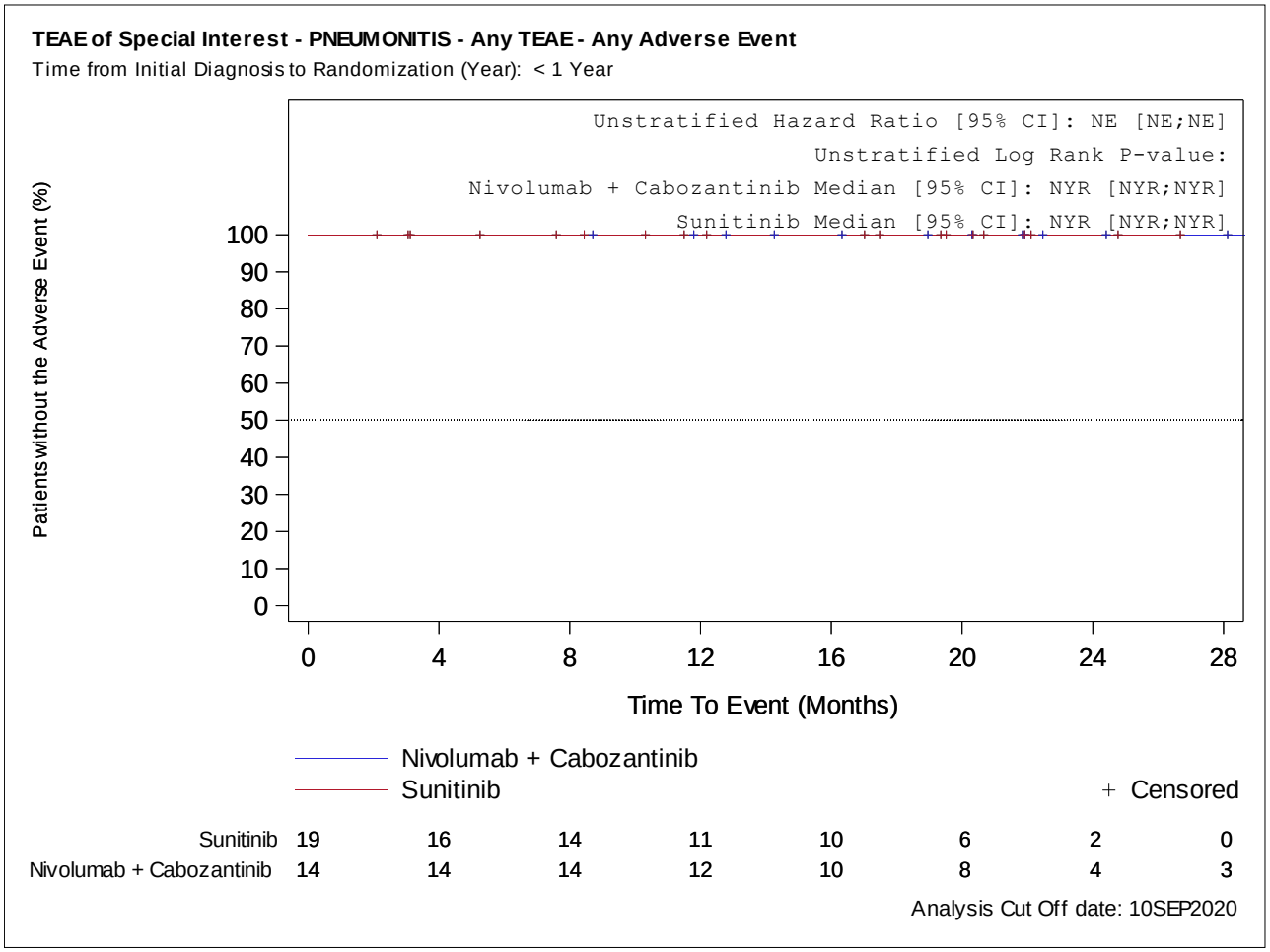

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:14:22

FIGURE 3.125.2.14: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



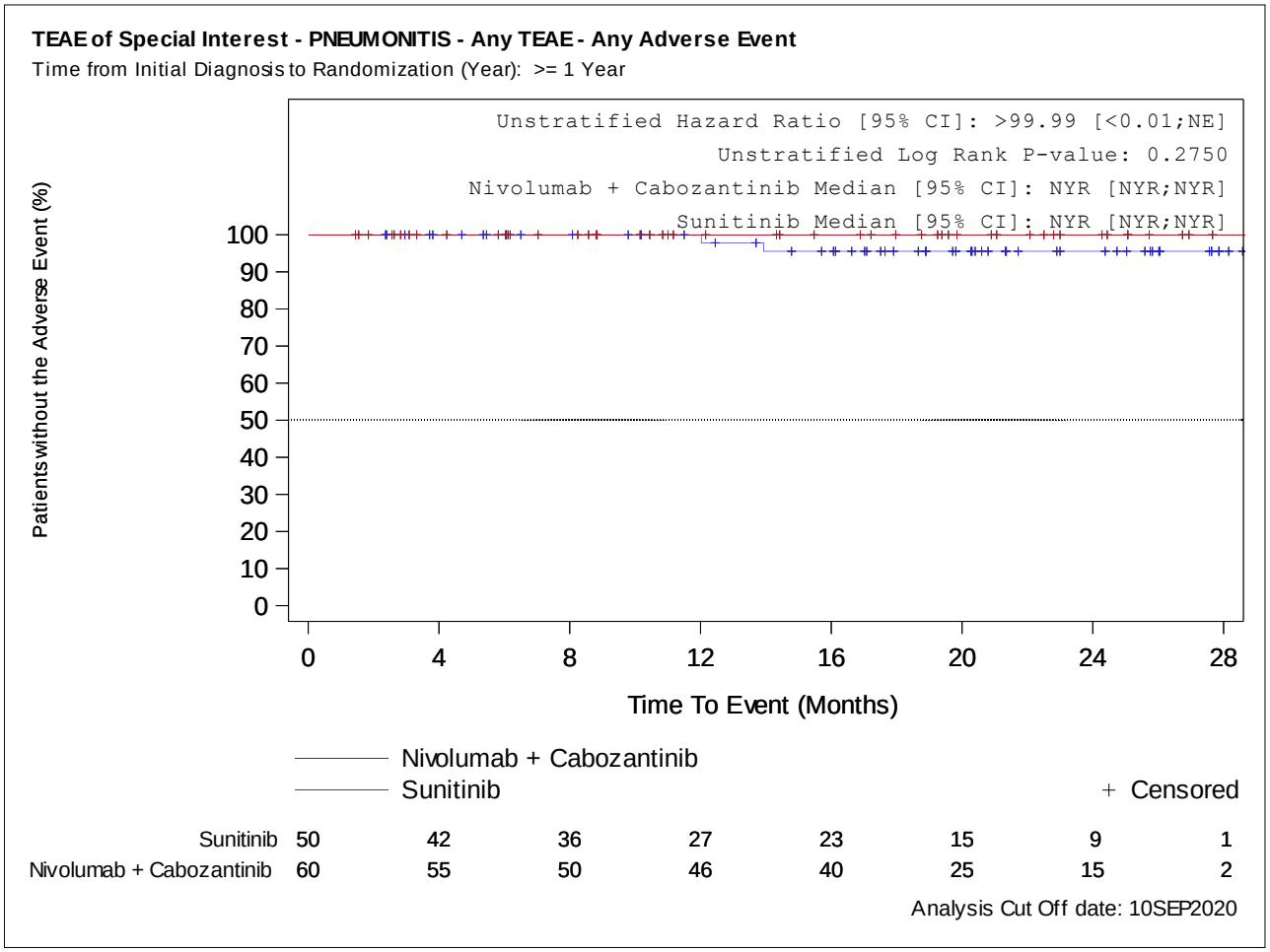

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:14:28

FIGURE 3.125.2.15: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



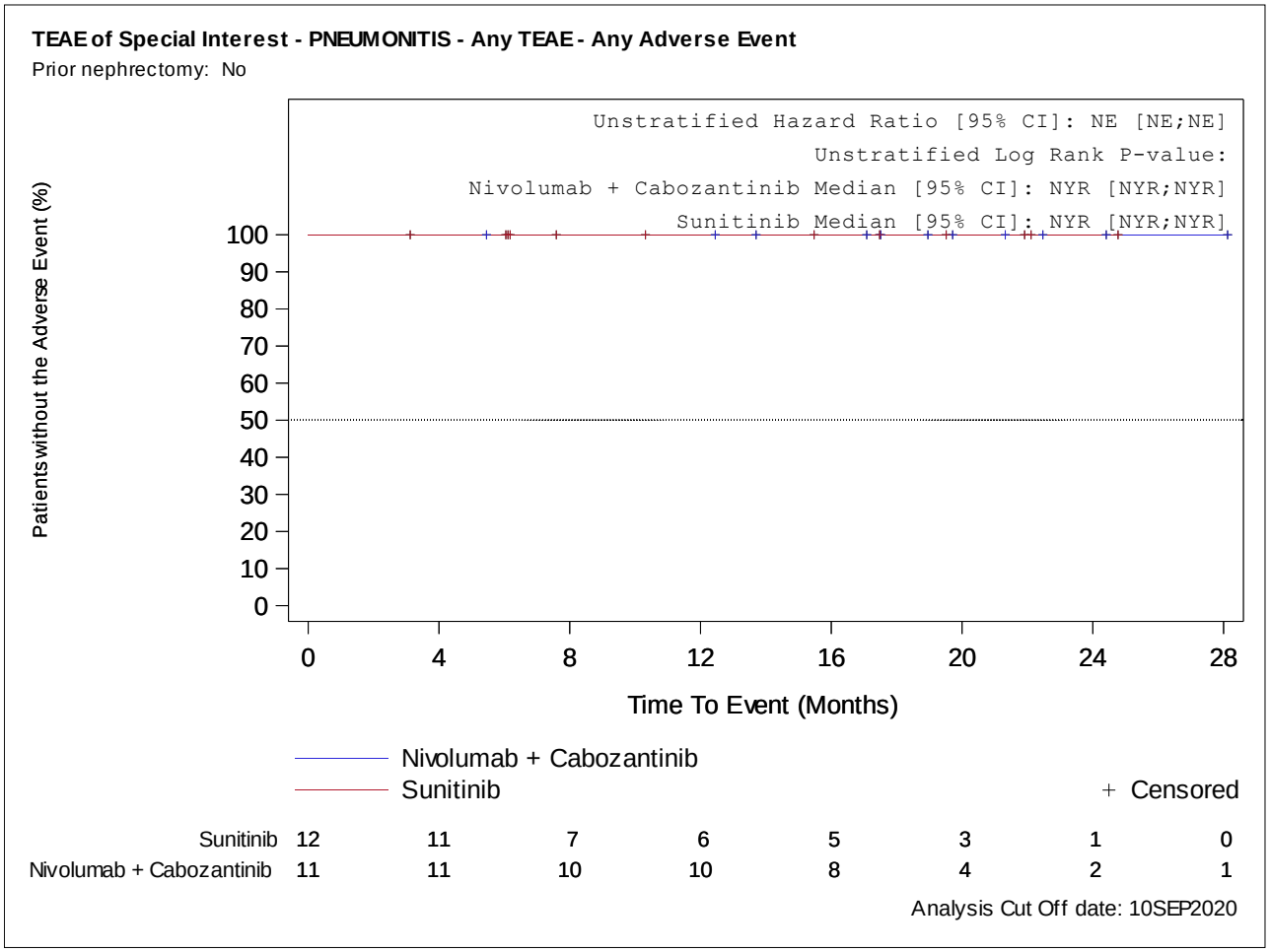

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:14:45

FIGURE 3.125.2.16: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



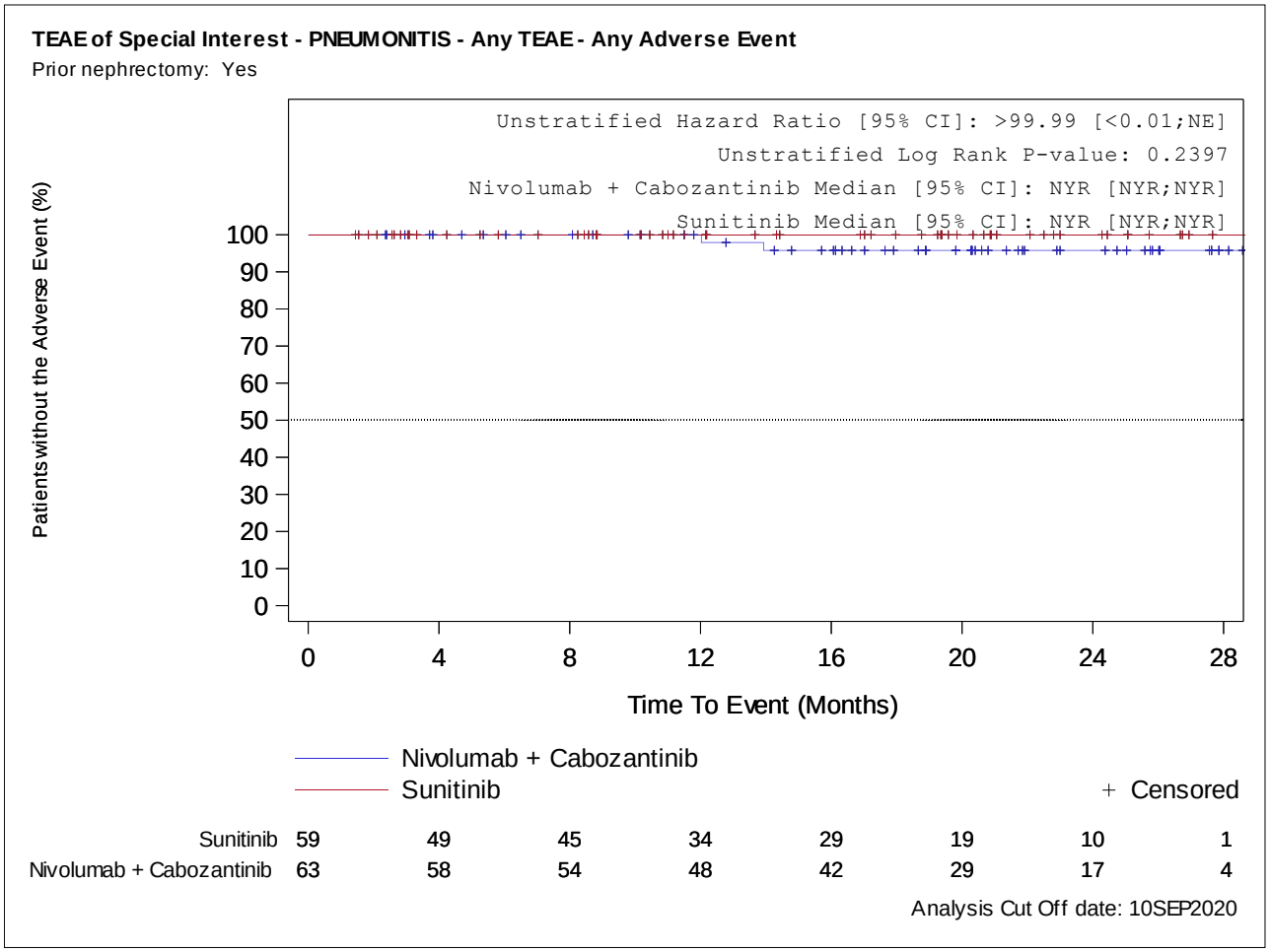

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:14:50

FIGURE 3.125.2.17: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



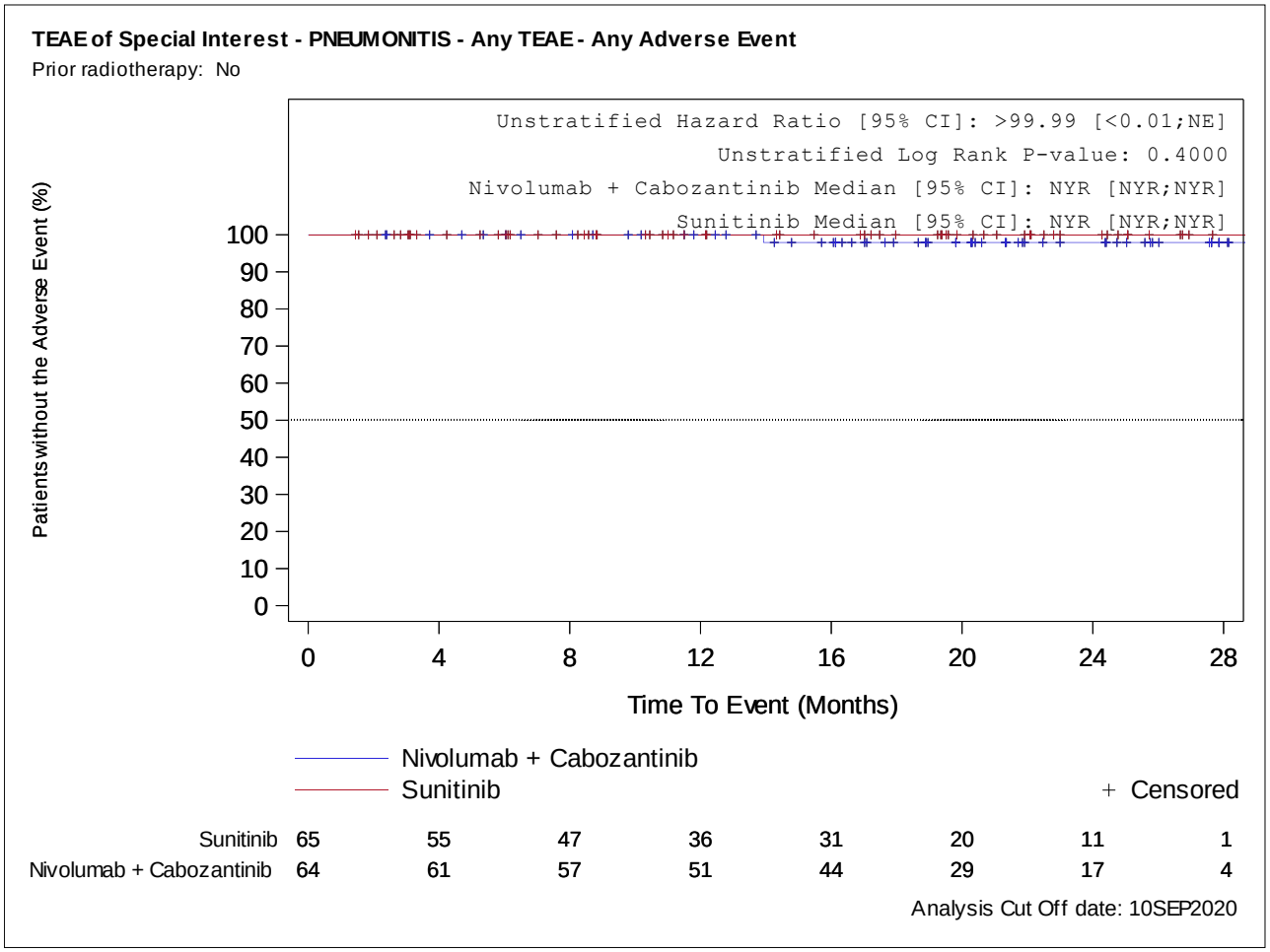

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:15:42

FIGURE 3.125.2.18: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



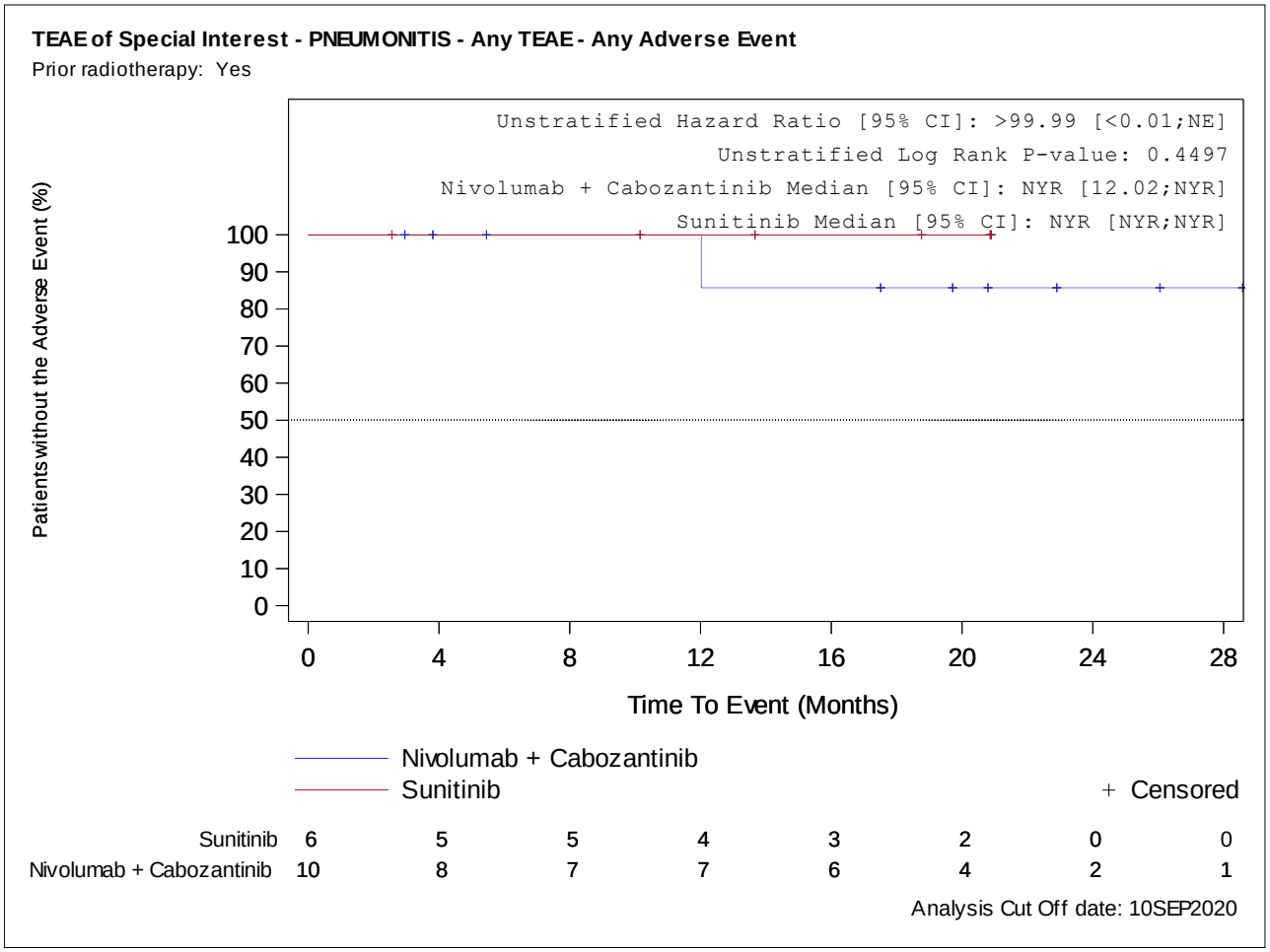

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:15:48

FIGURE 3.125.2.19: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



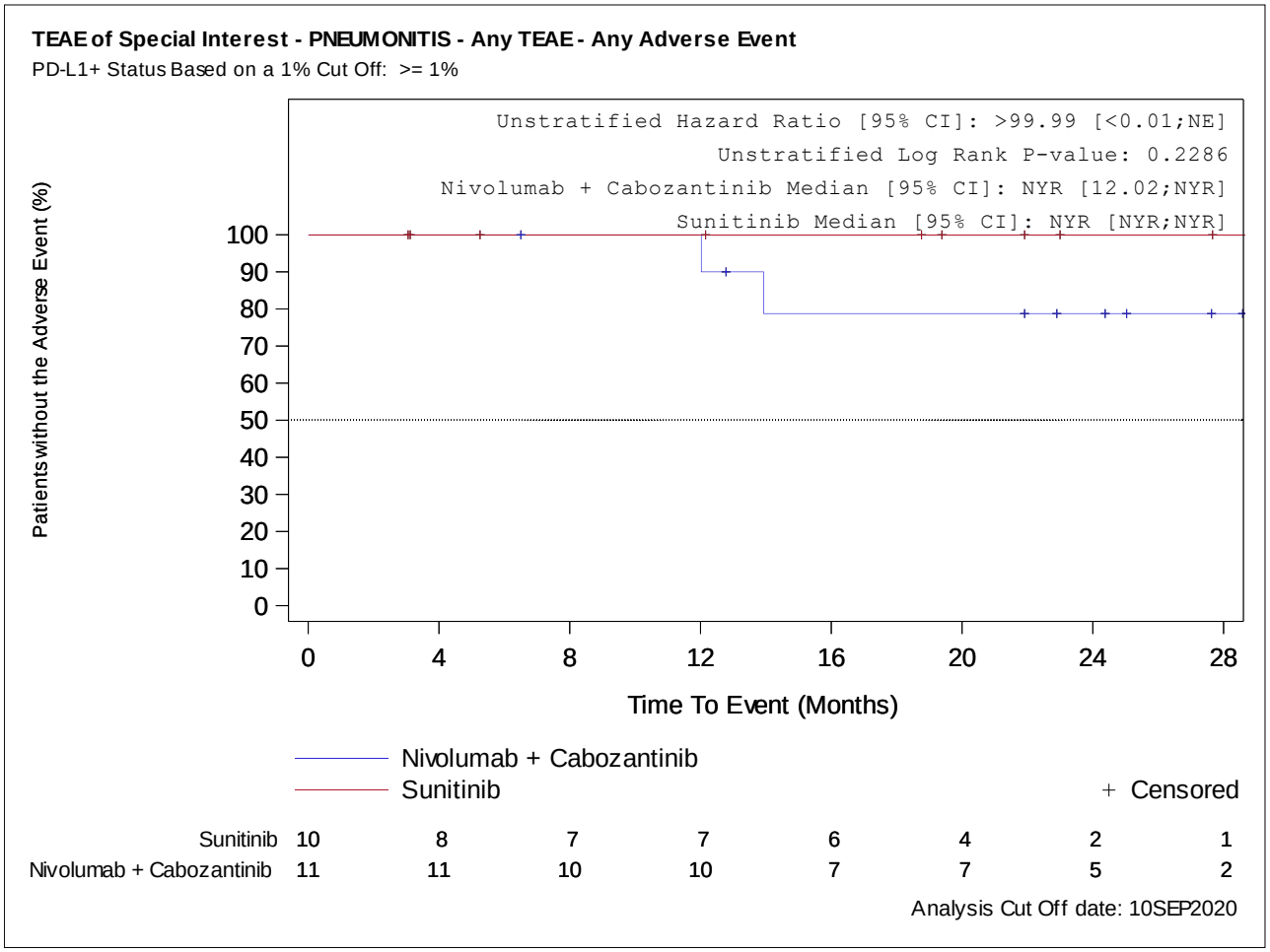

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:15:54

FIGURE 3.125.2.20: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



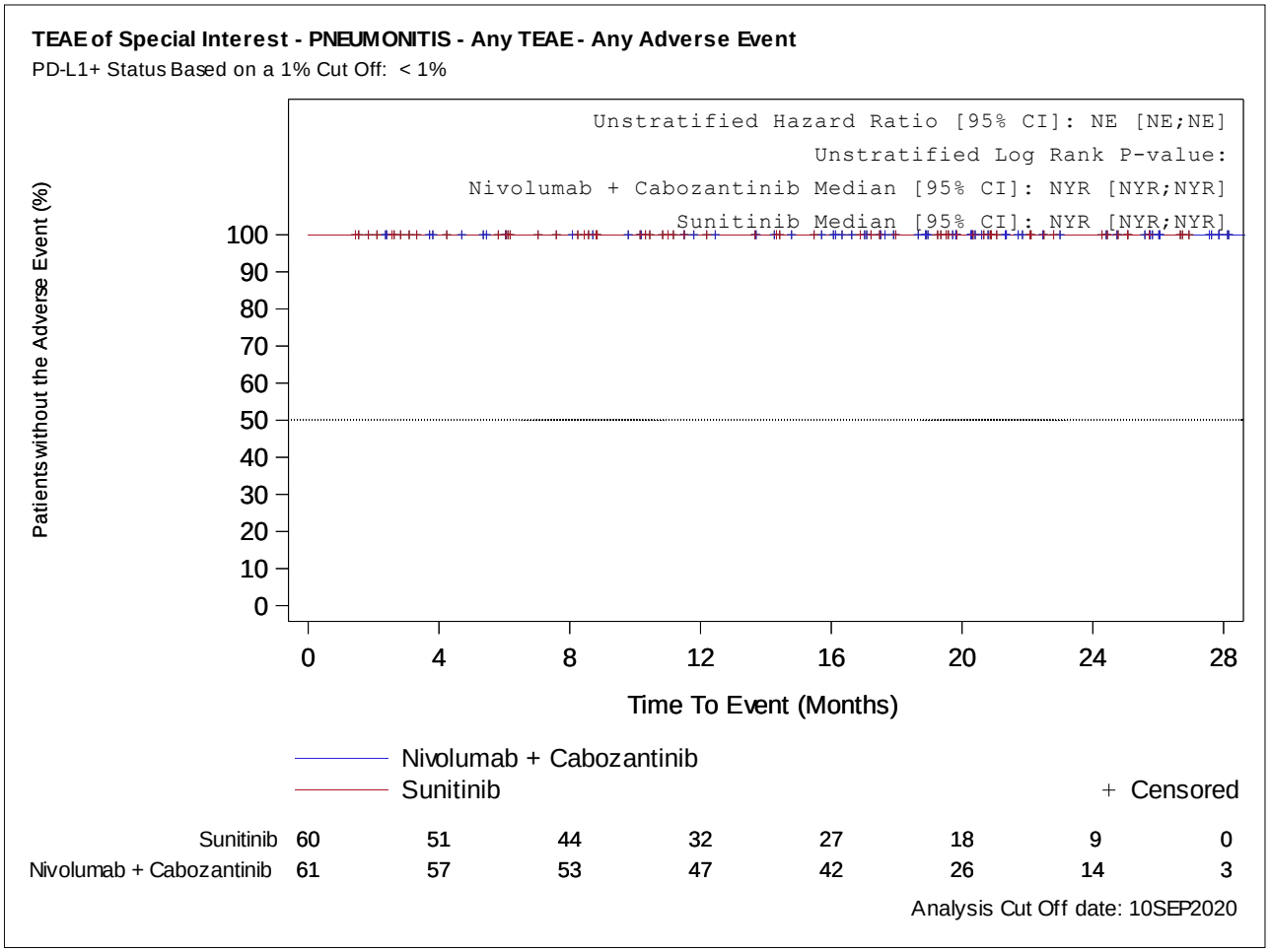

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:15:59

FIGURE 3.125.2.21: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



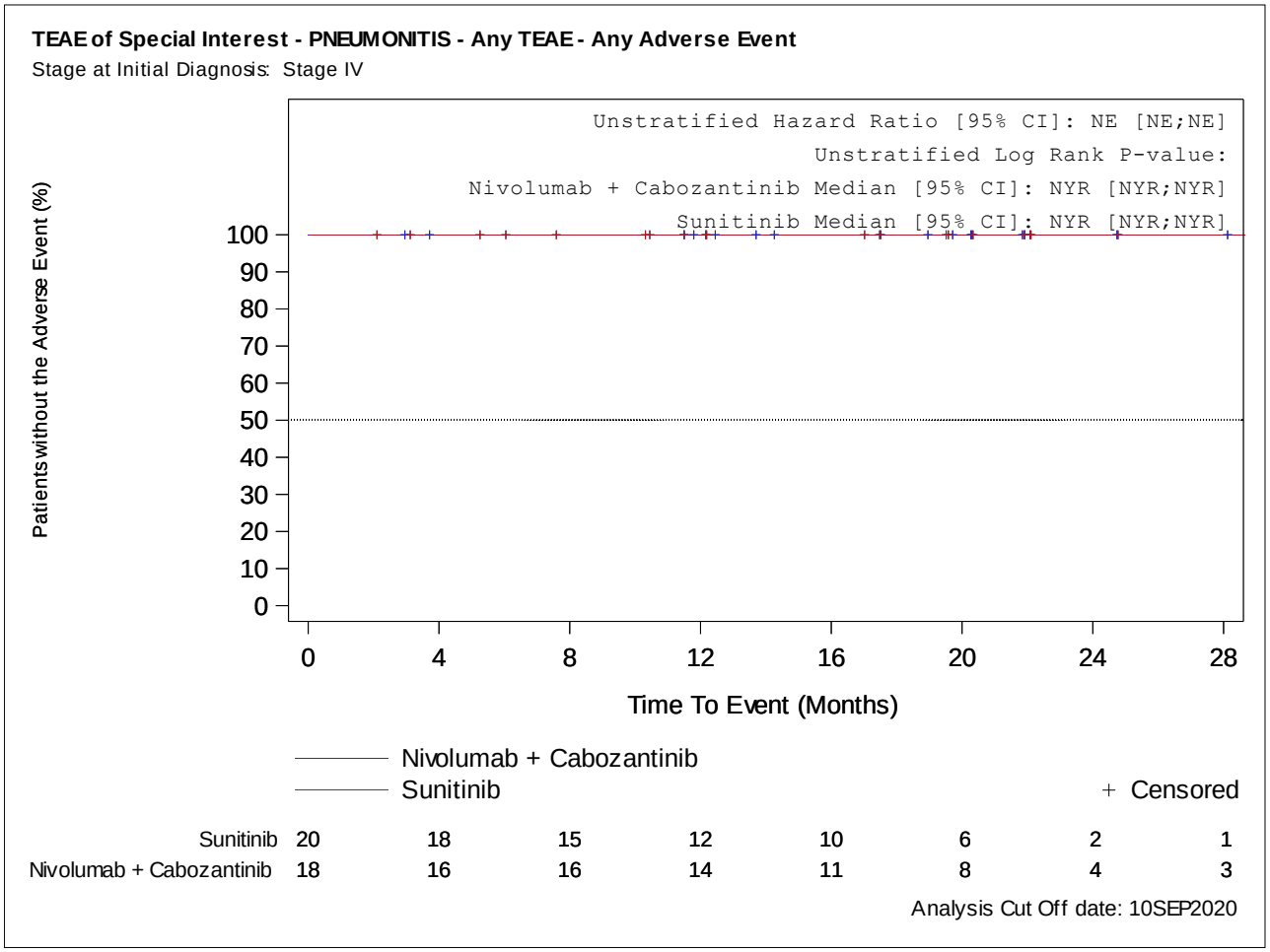

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:16:04

FIGURE 3.125.2.22: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



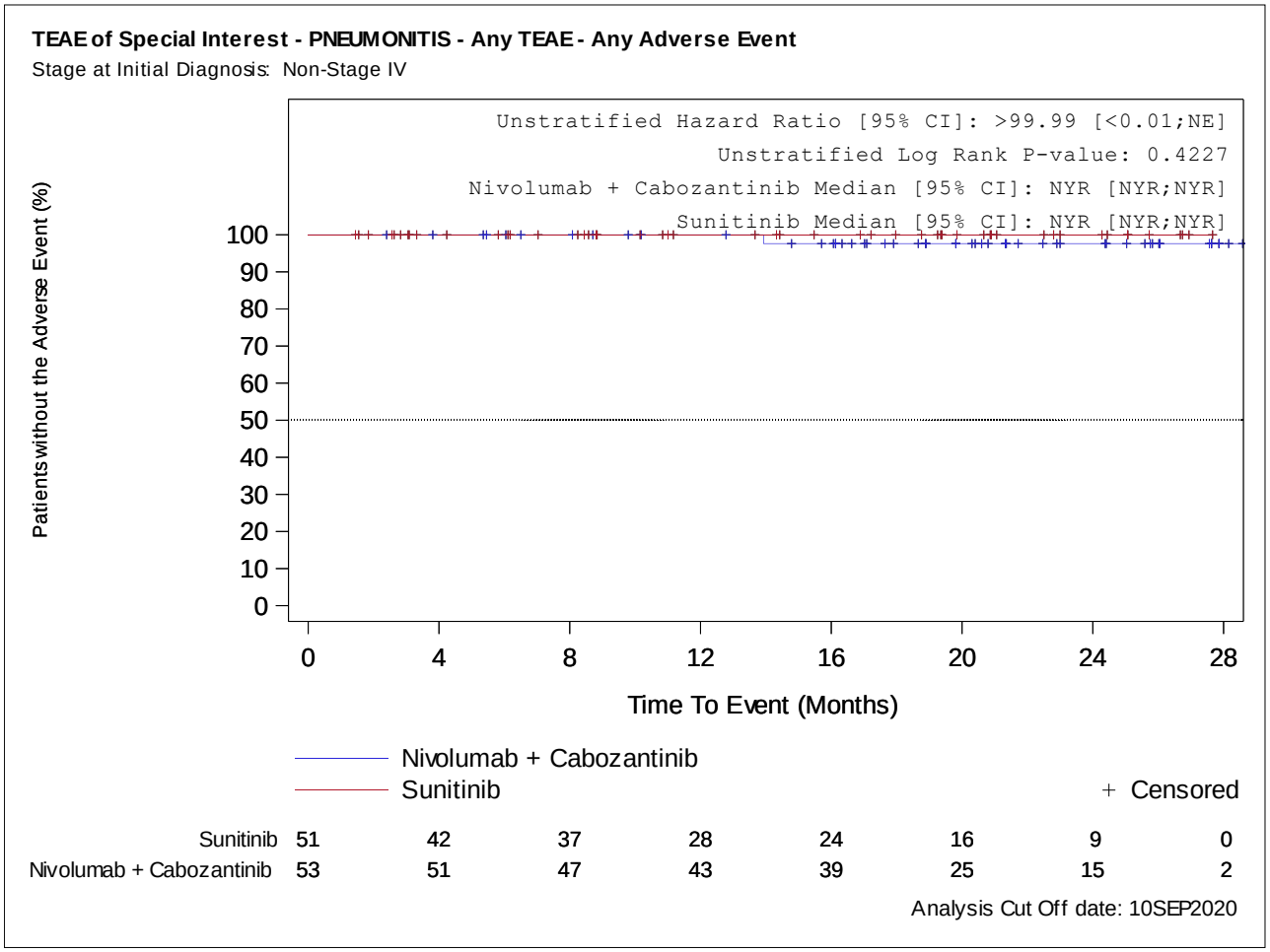

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:16:10

FIGURE 3.125.2.23: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



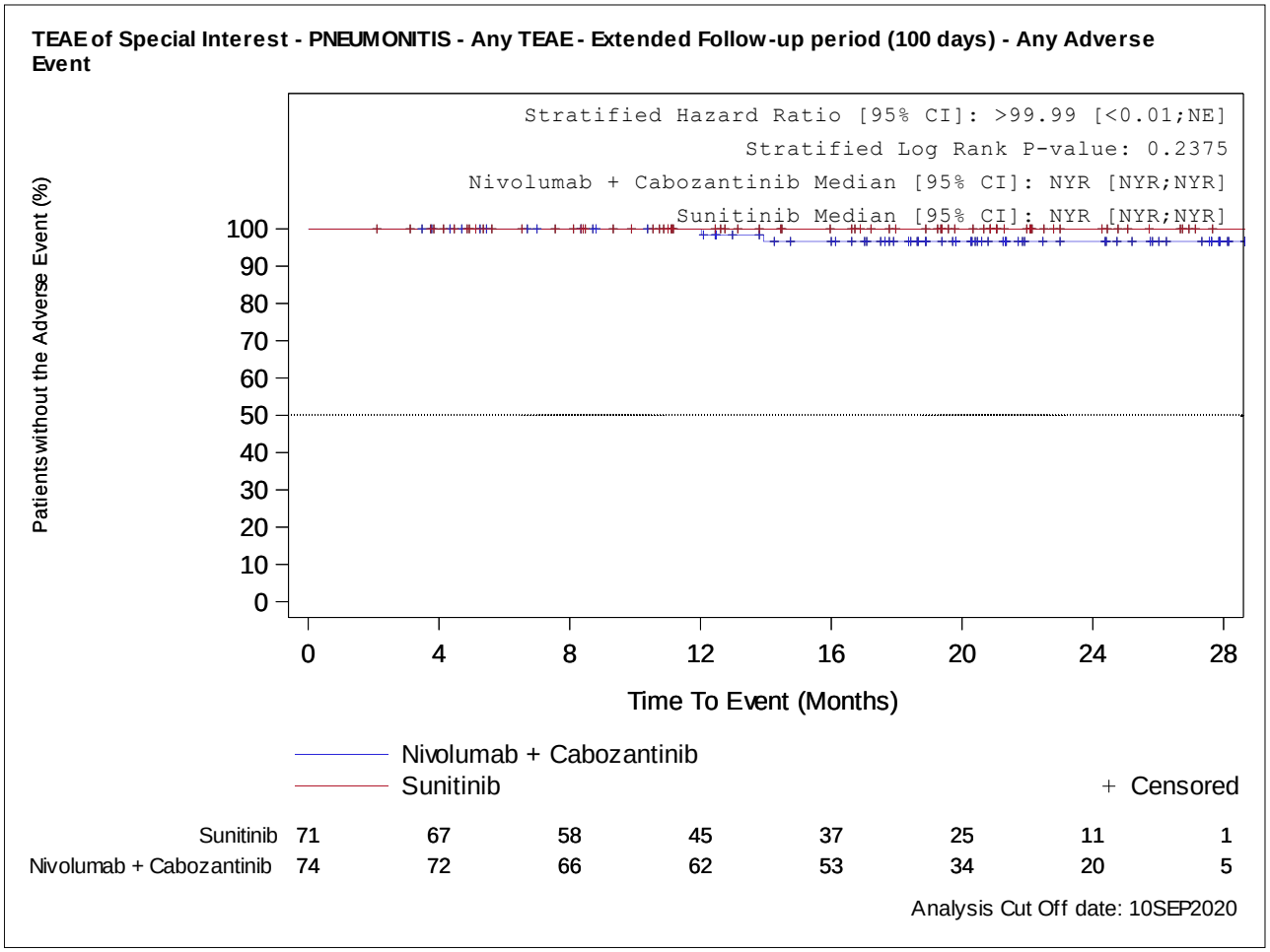

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:16:38

FIGURE 3.125.2.24: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



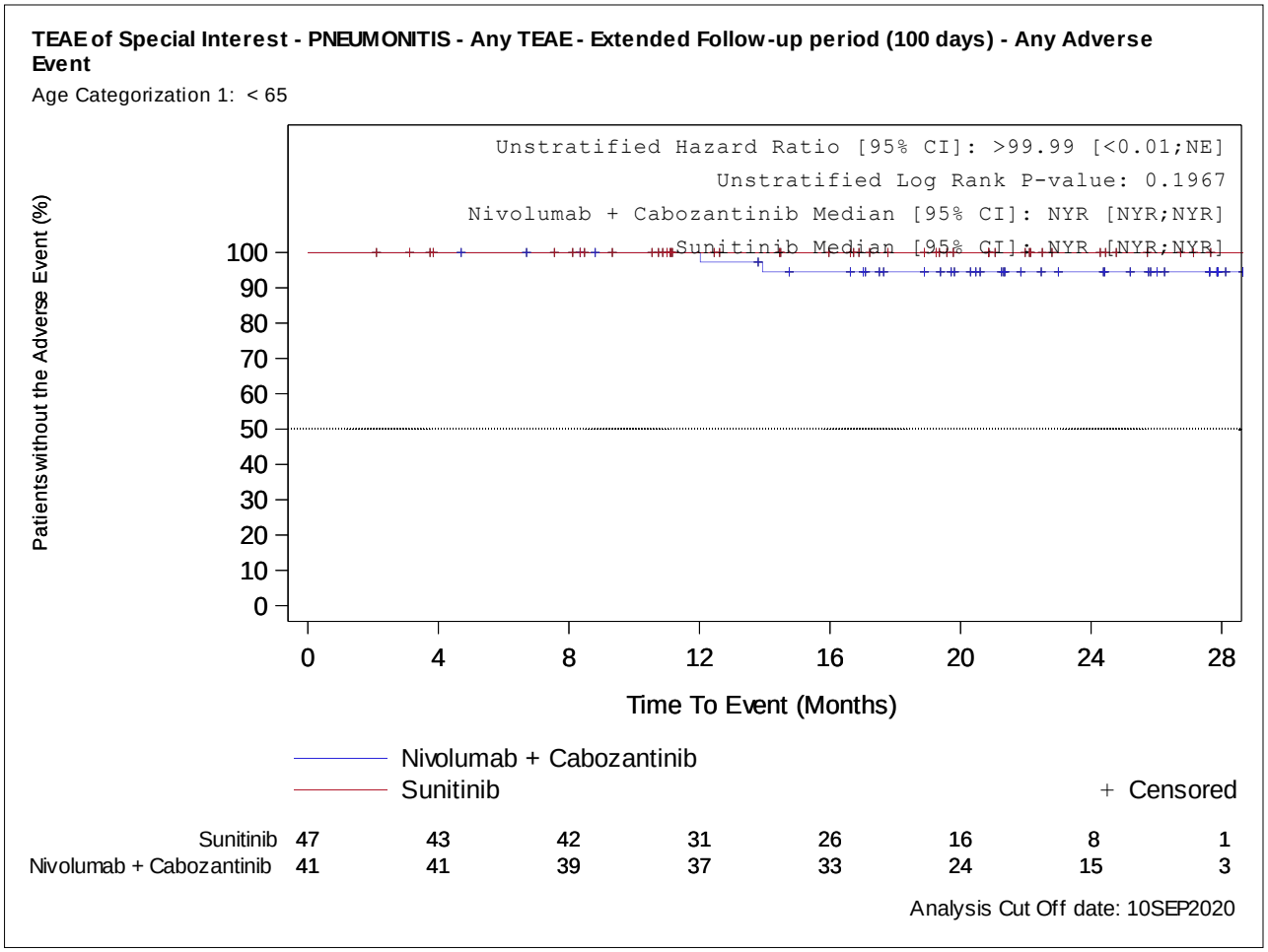

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:16:43

FIGURE 3.126.1: TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



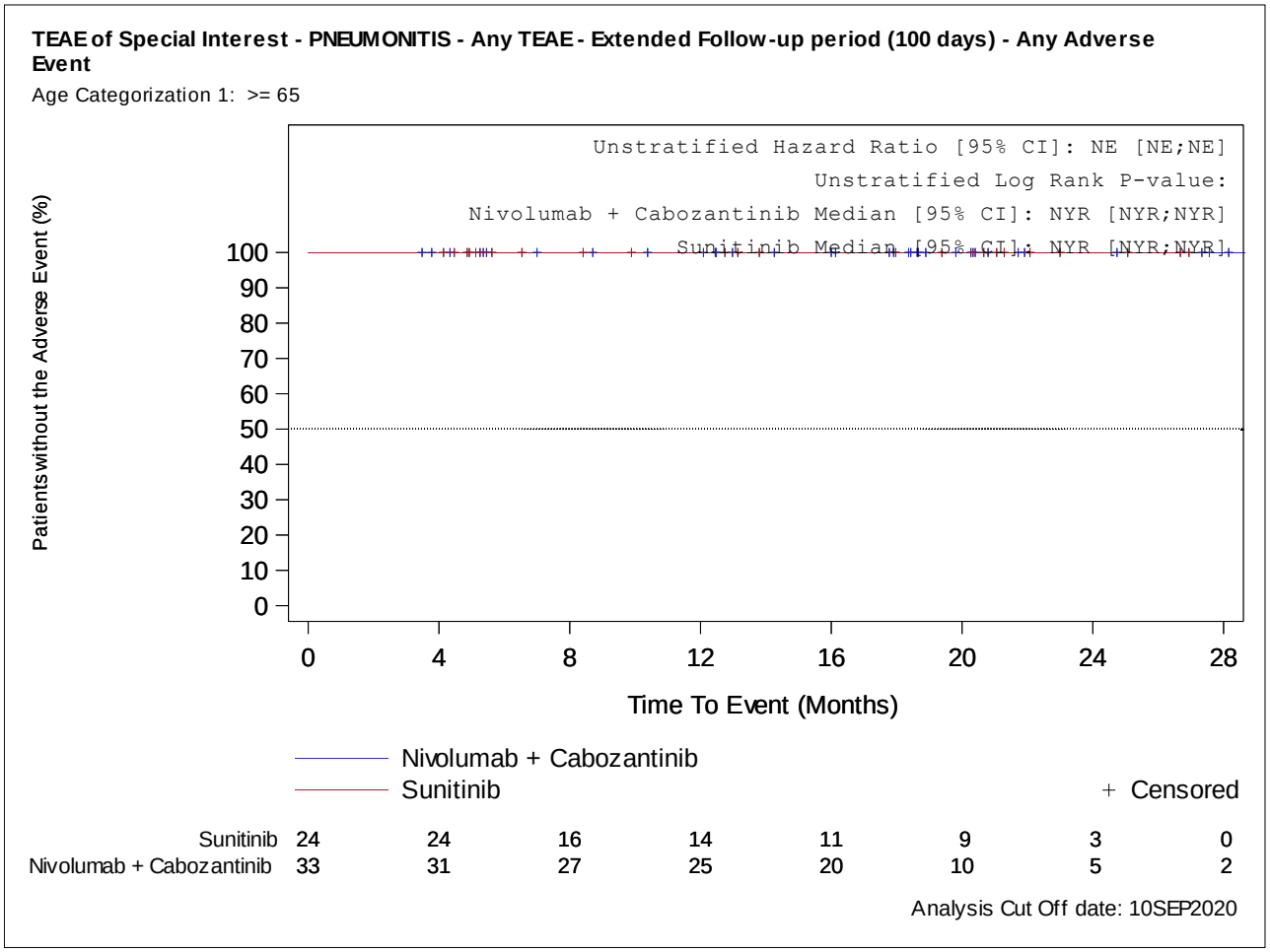

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:19:53

FIGURE 3.126.2.1: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



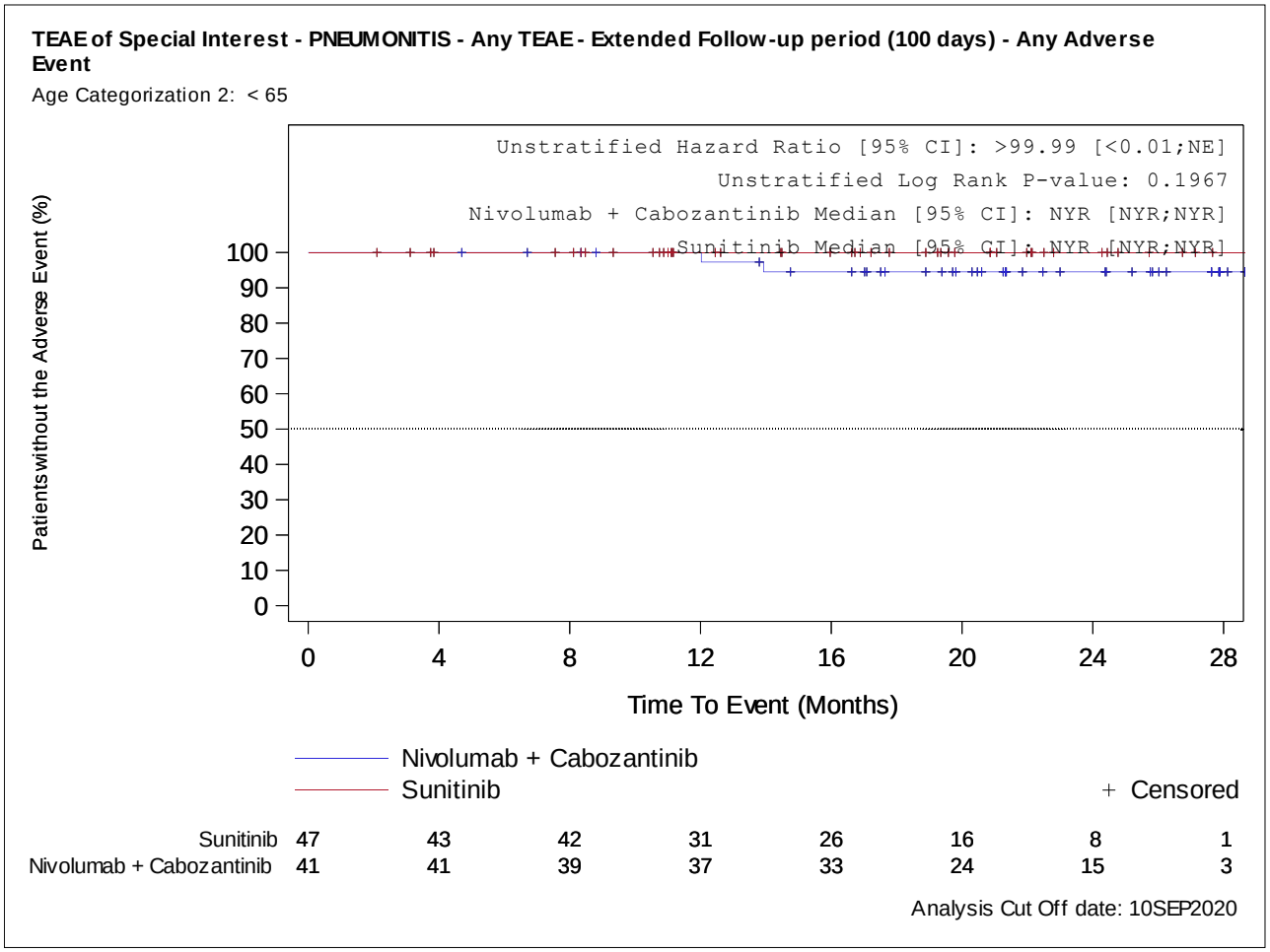

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:19:55

FIGURE 3.126.2.2: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



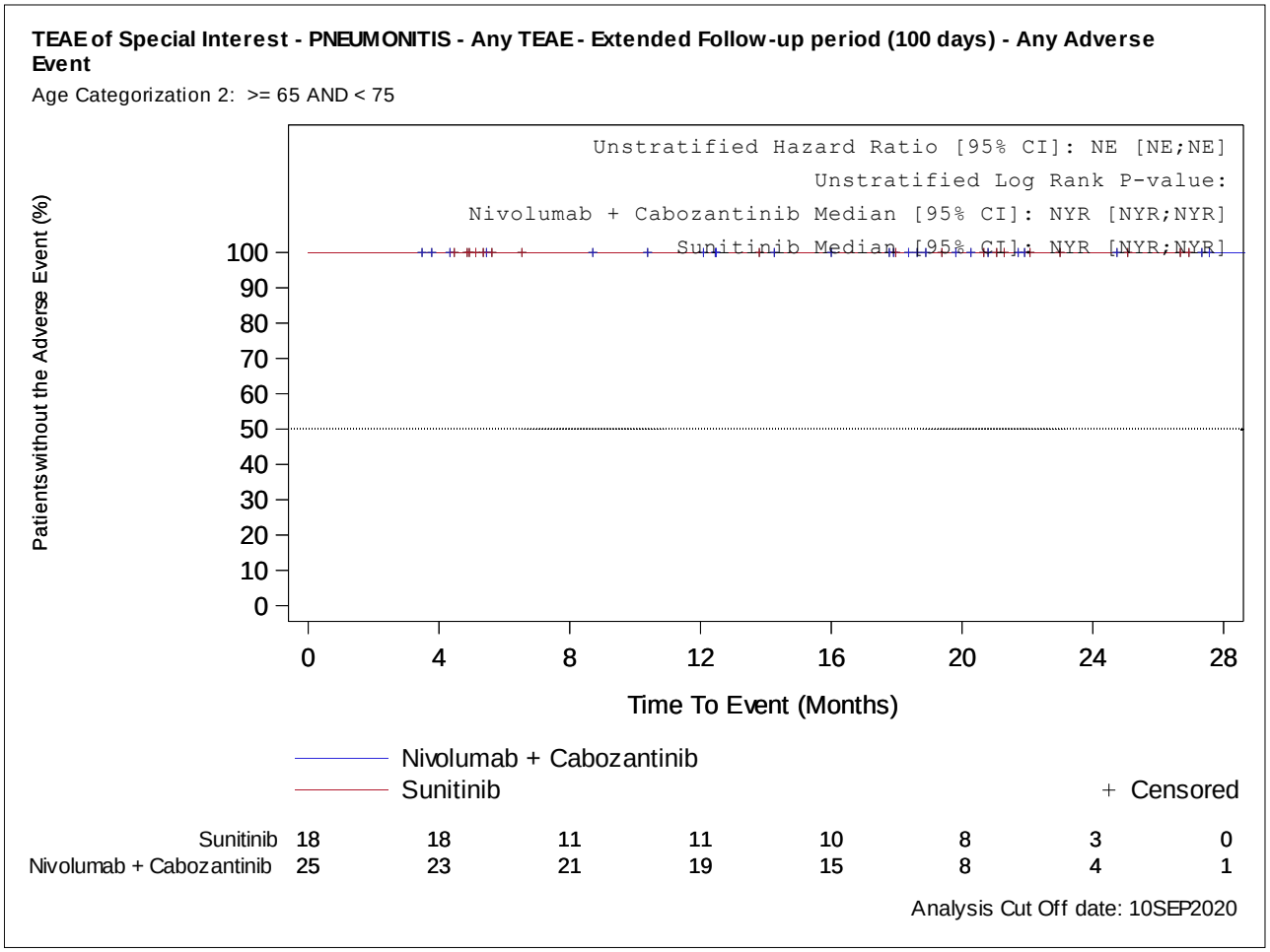

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:20:01

FIGURE 3.126.2.3: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



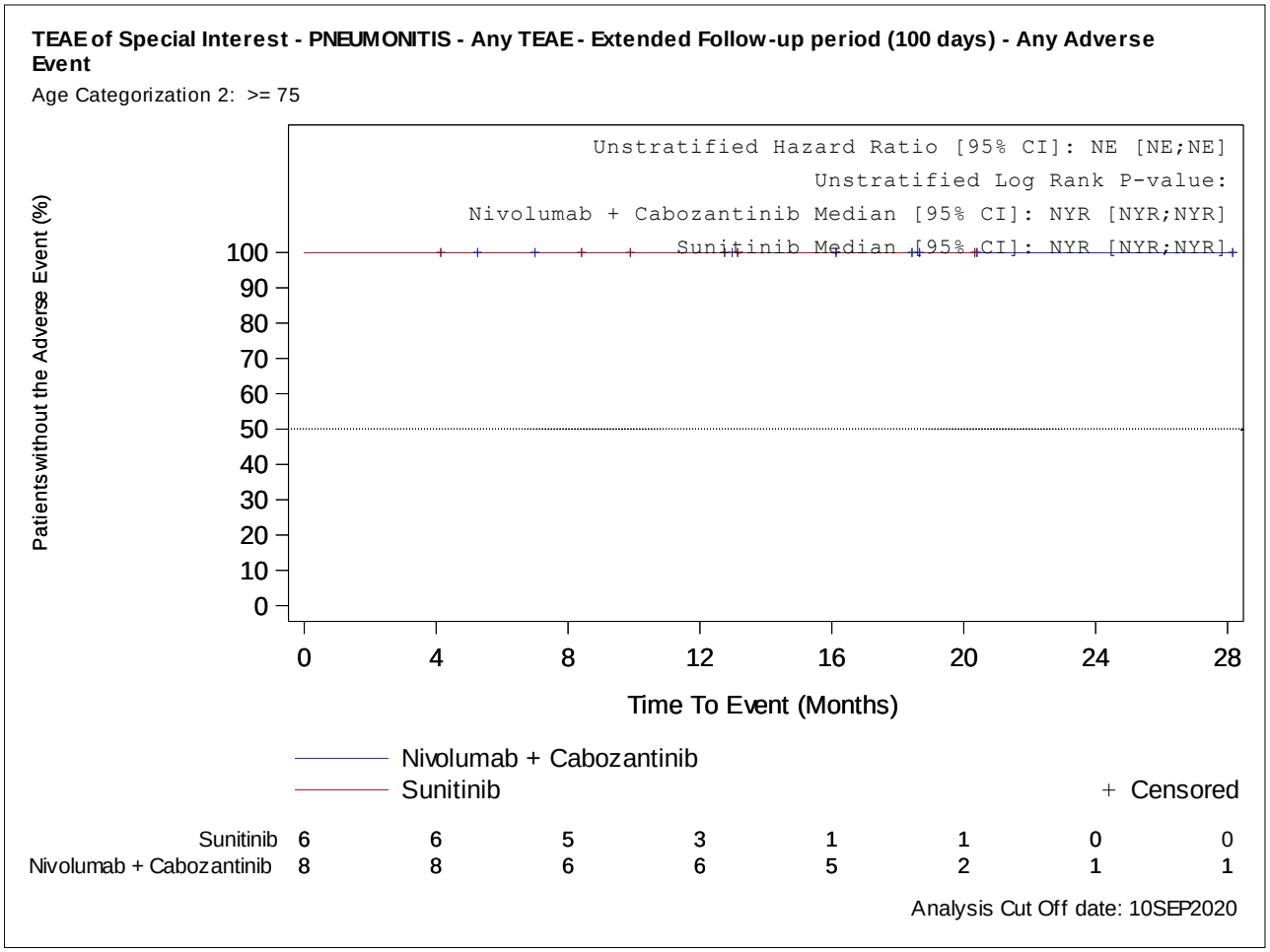

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:20:06

FIGURE 3.126.2.4: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



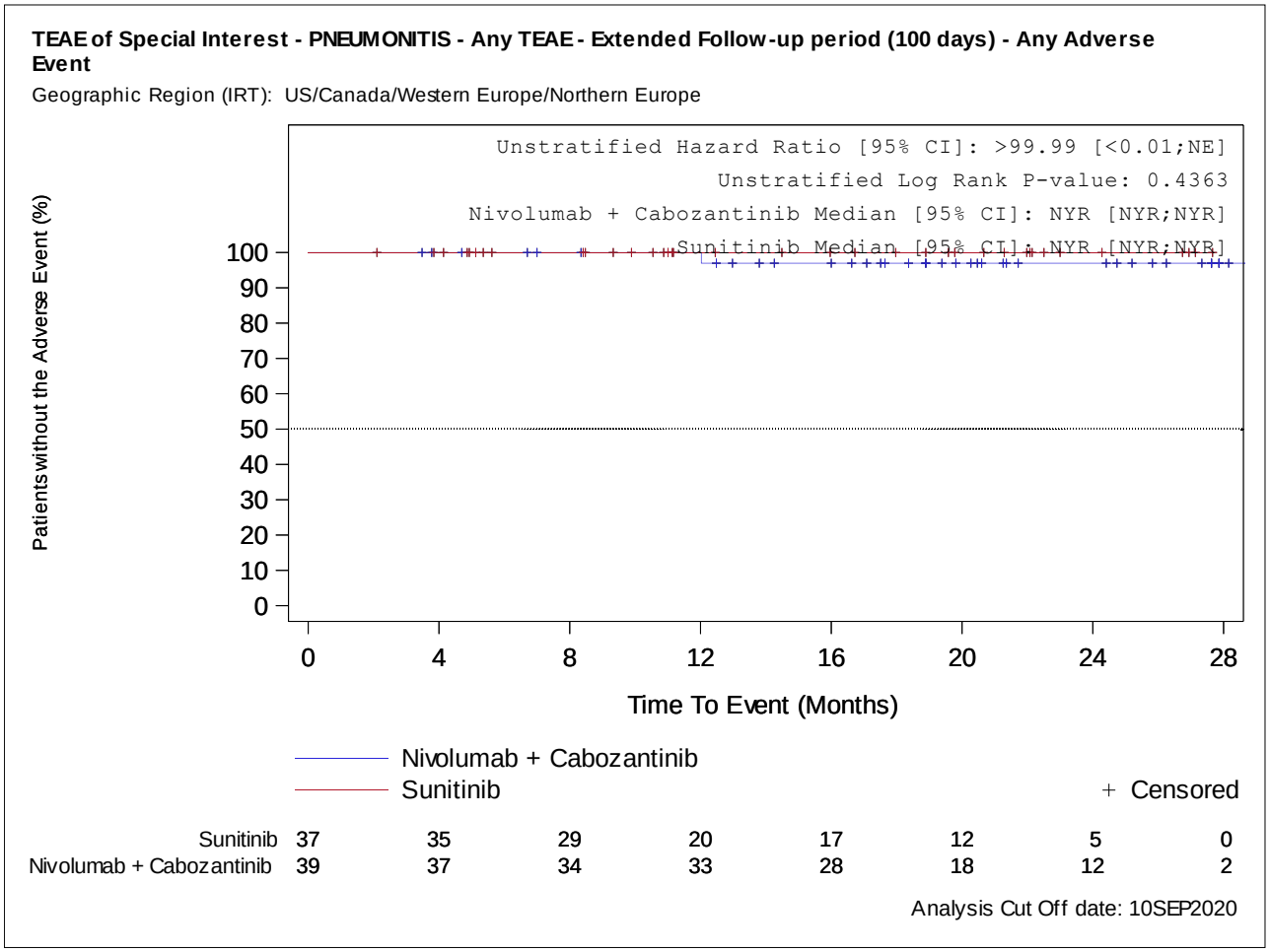

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:20:12

FIGURE 3.126.2.5: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



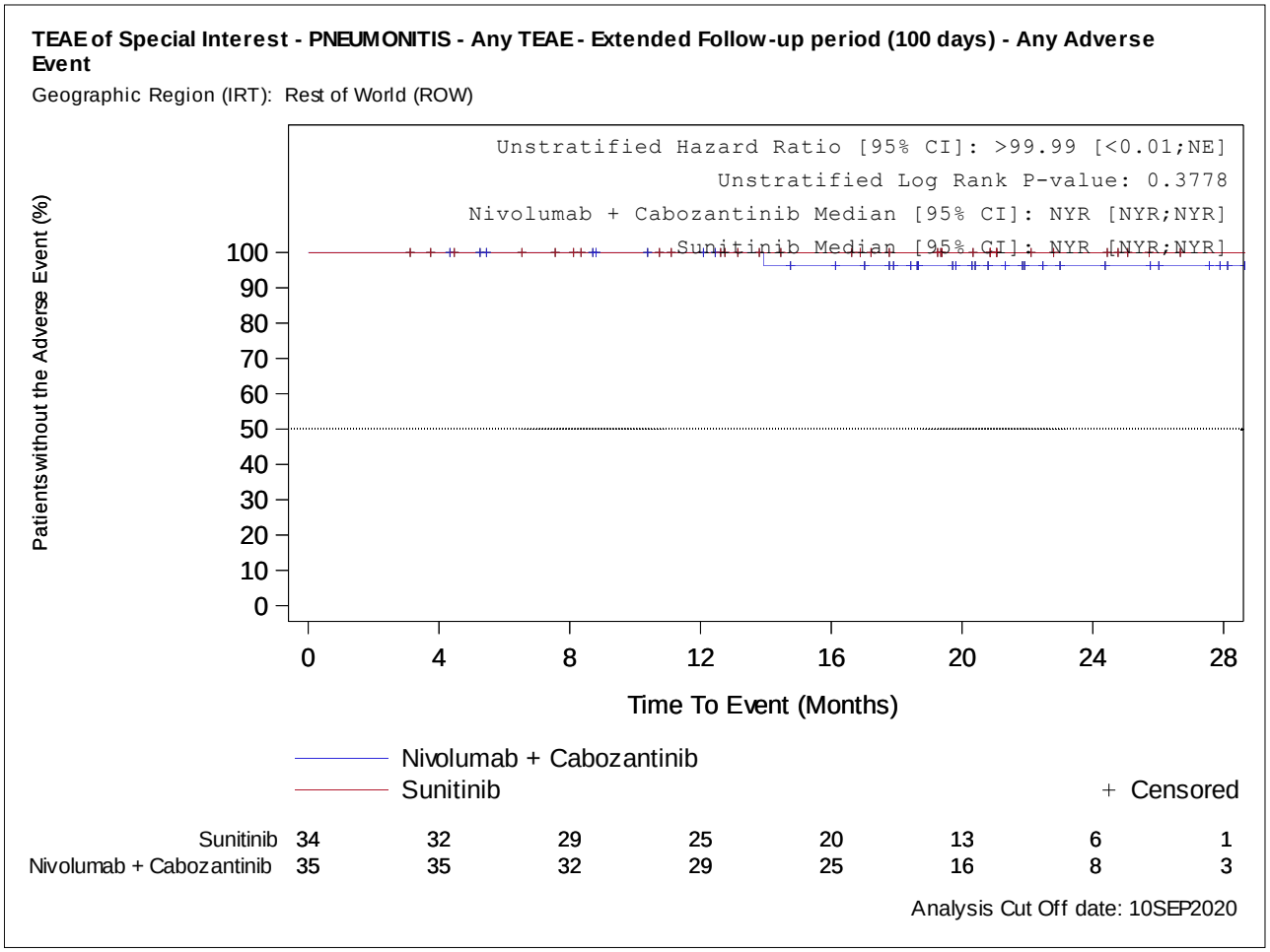

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:20:17

FIGURE 3.126.2.6: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



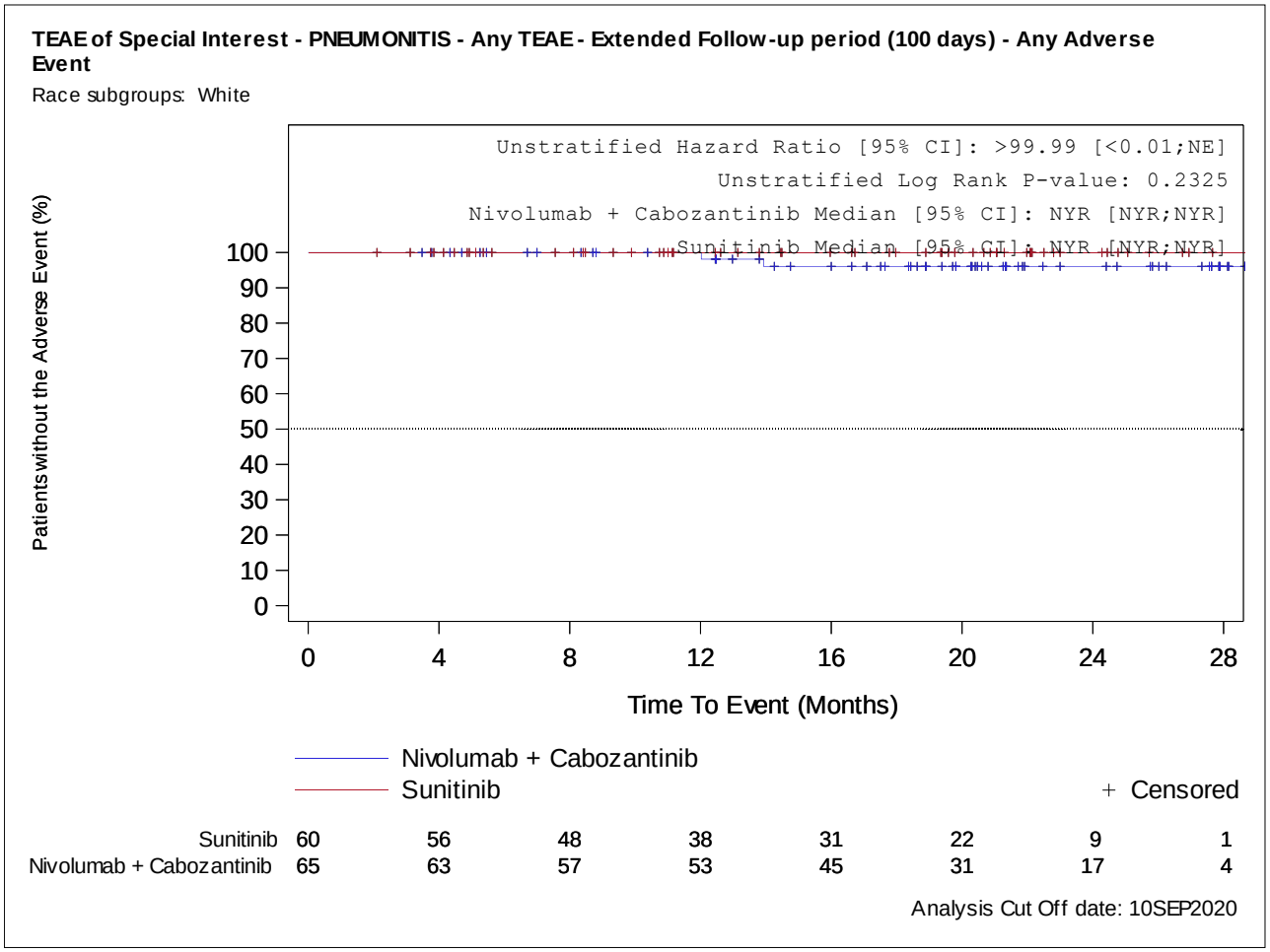

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:20:23

FIGURE 3.126.2.7: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



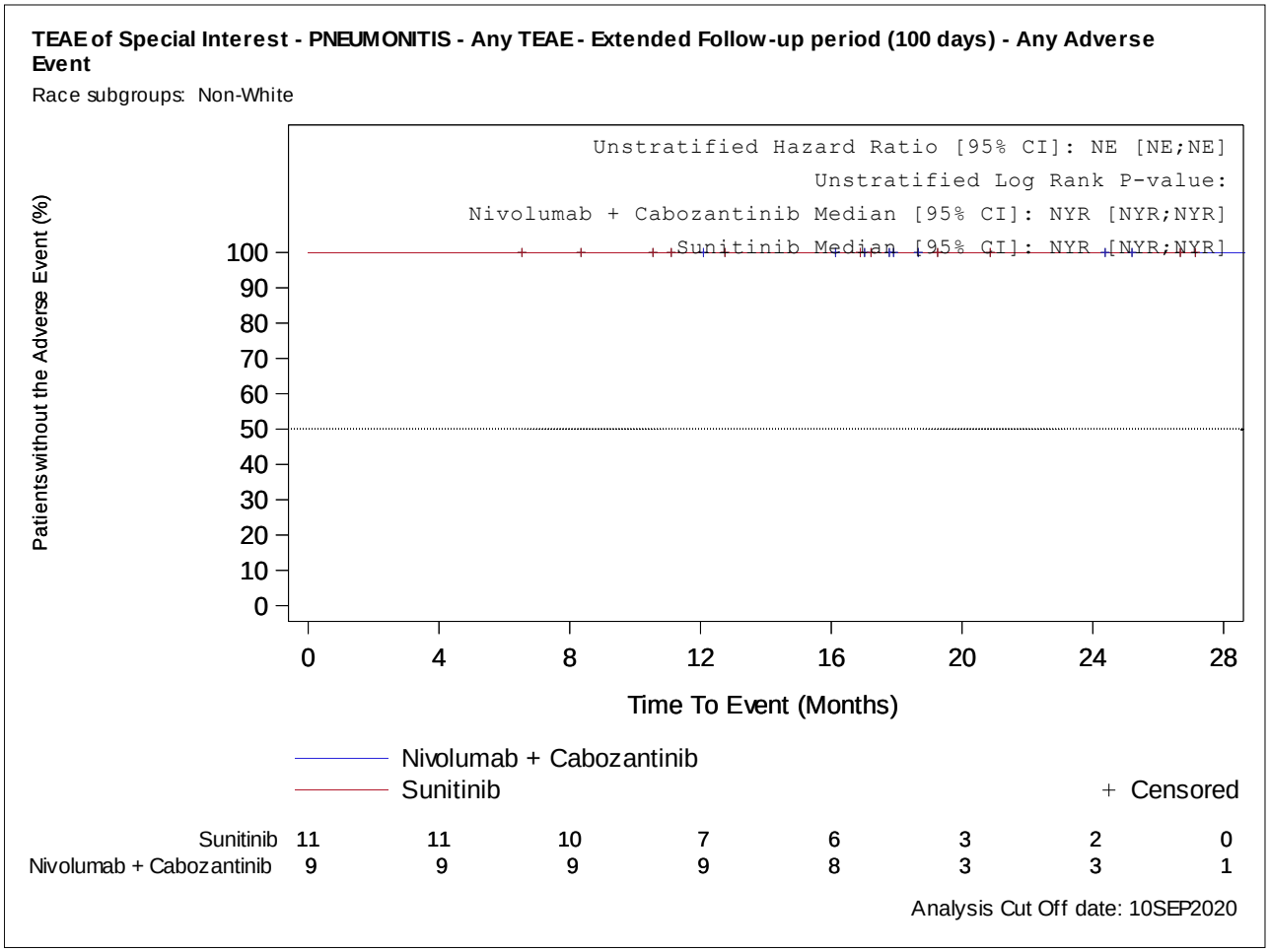

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:20:28

FIGURE 3.126.2.8: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



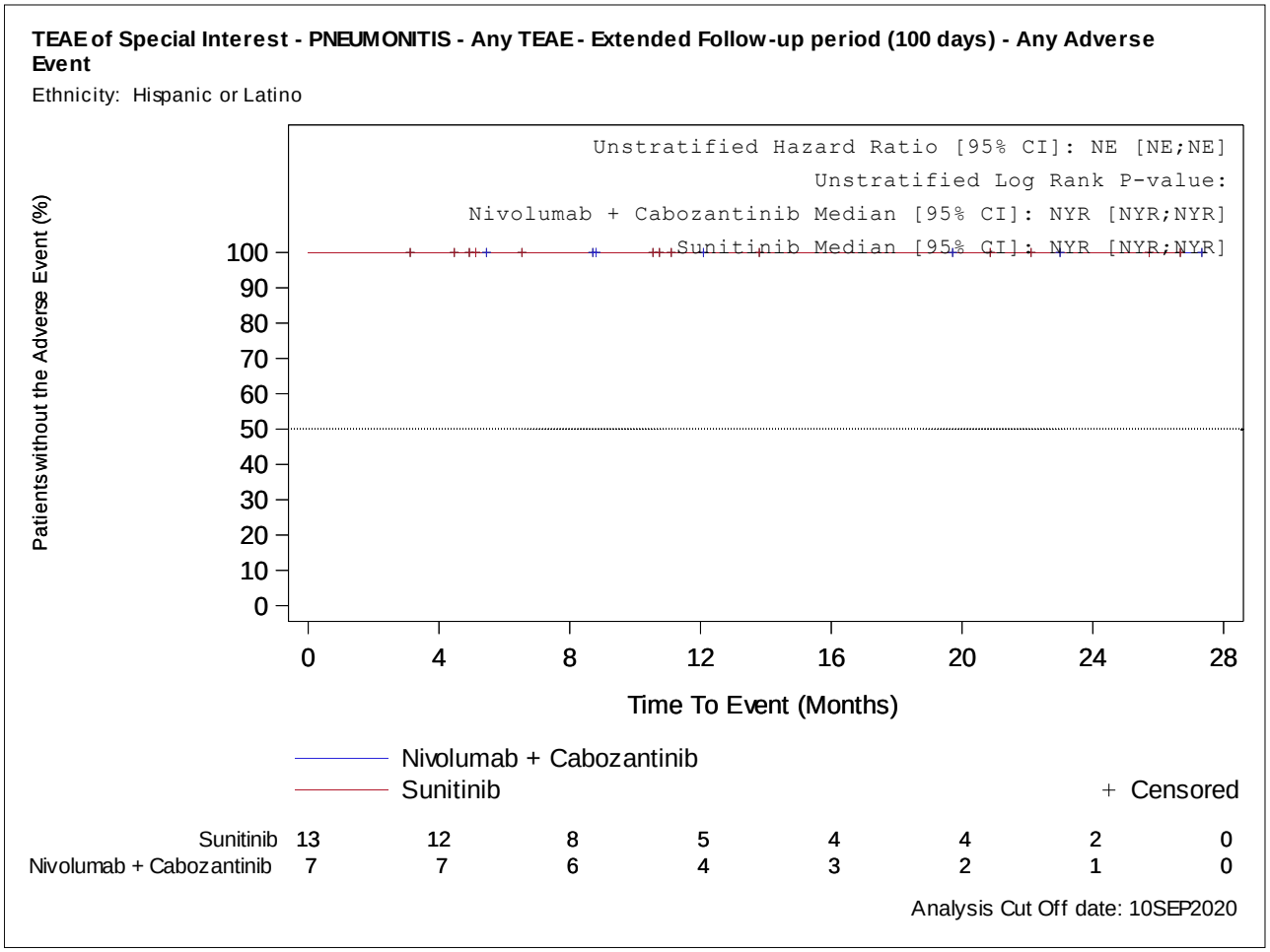

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:20:34

FIGURE 3.126.2.9: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



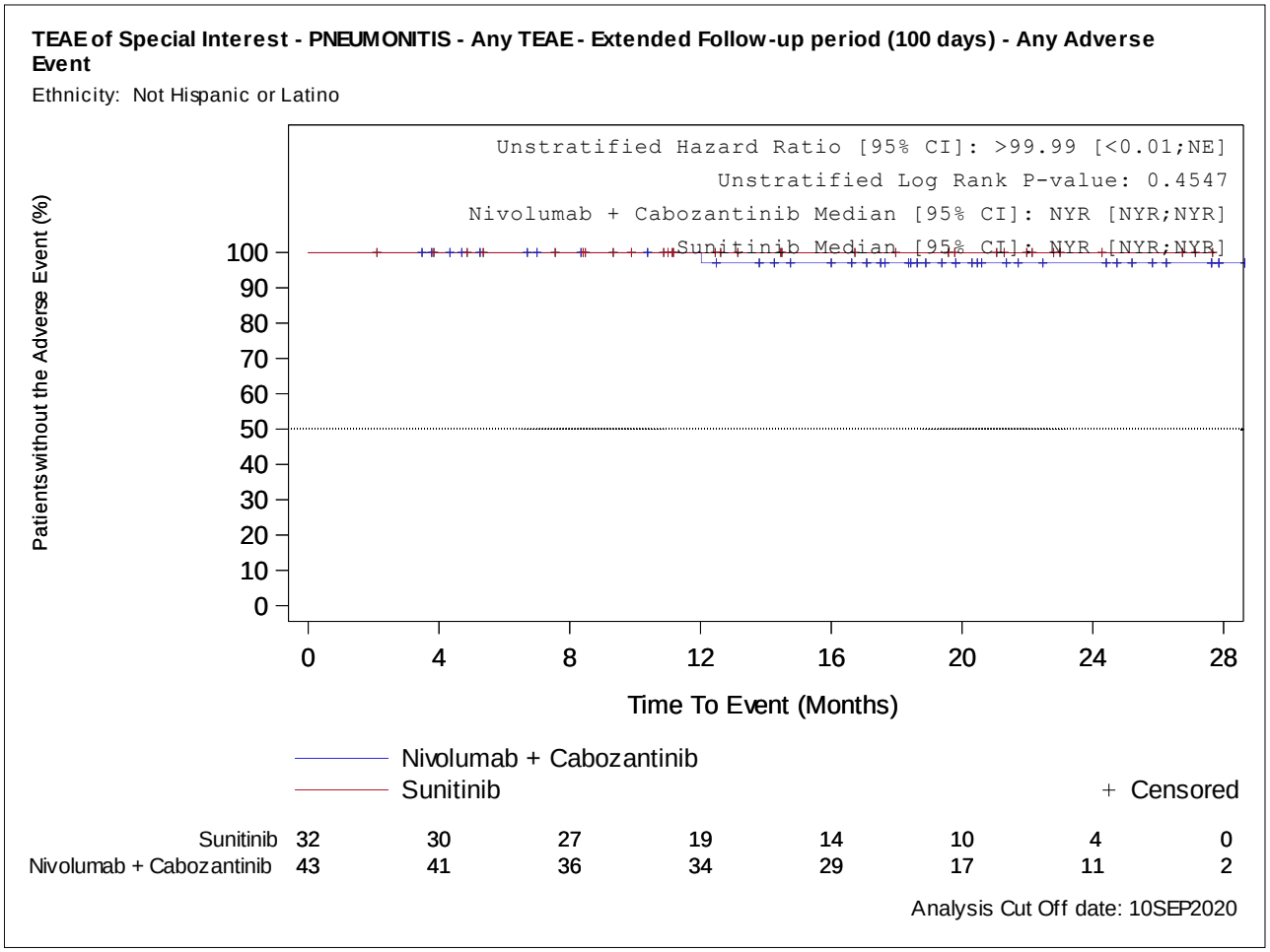

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:20:39

FIGURE 3.126.2.10: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



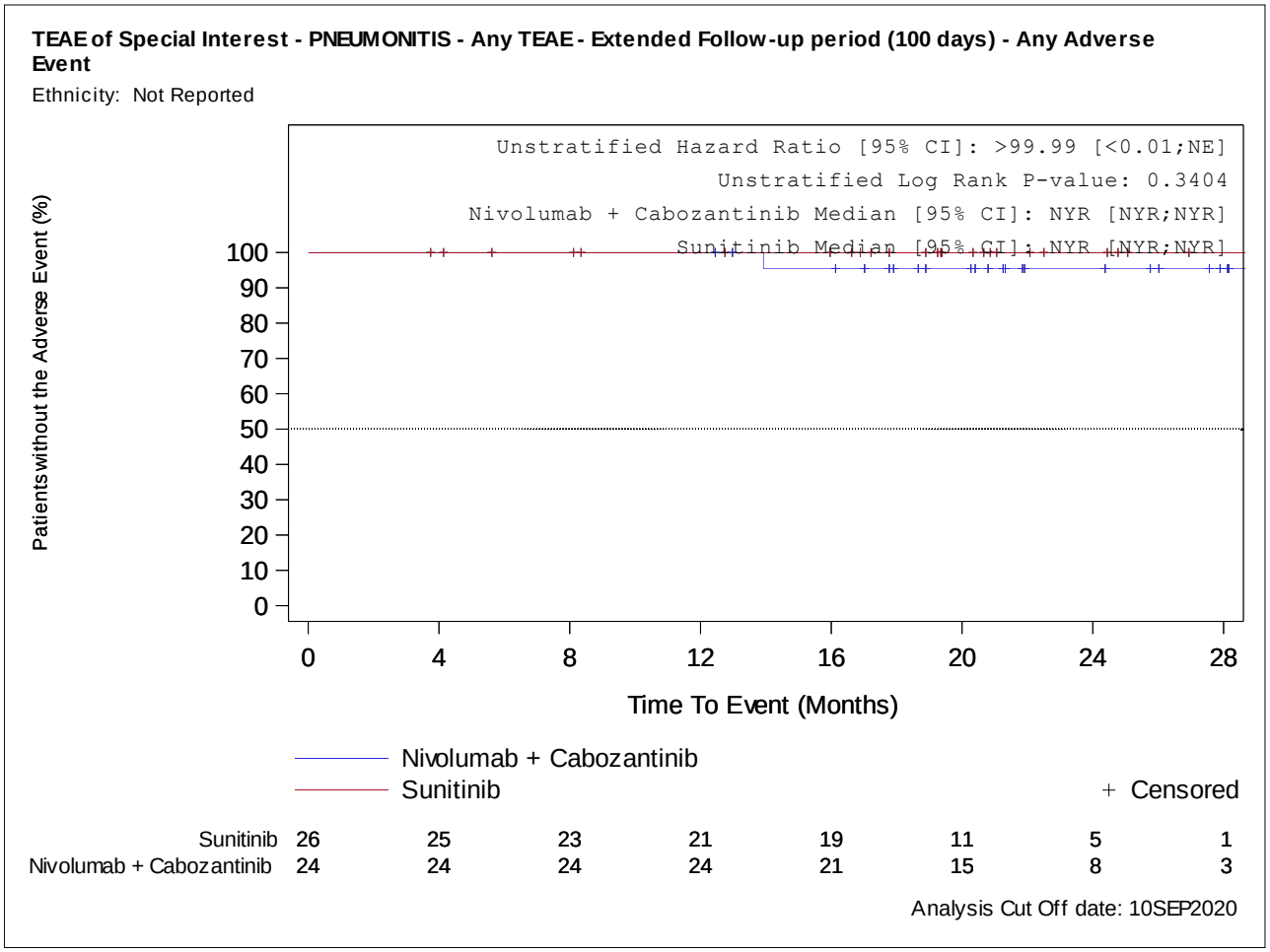

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:20:45

FIGURE 3.126.2.11: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



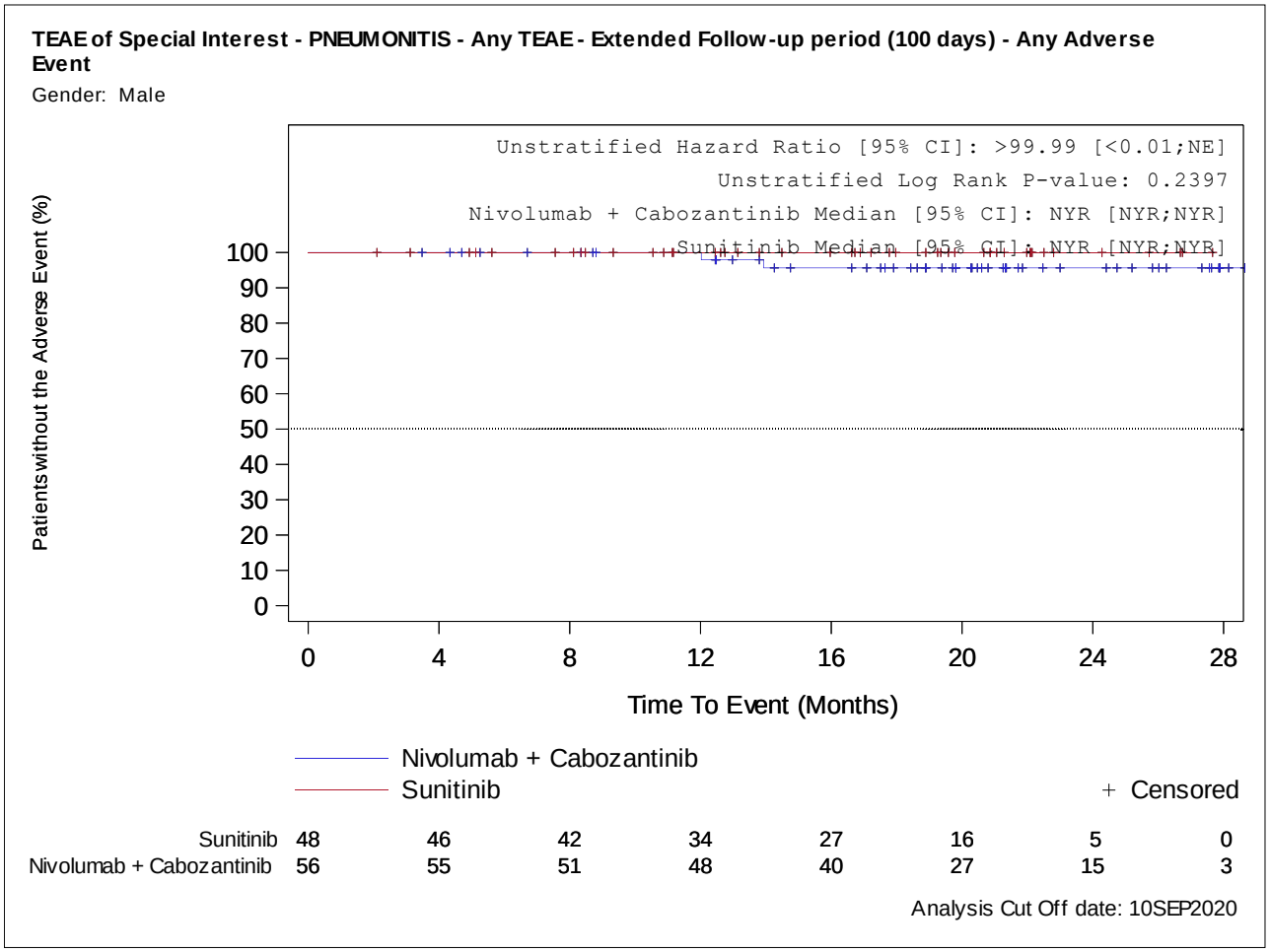

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:20:51

FIGURE 3.126.2.12: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



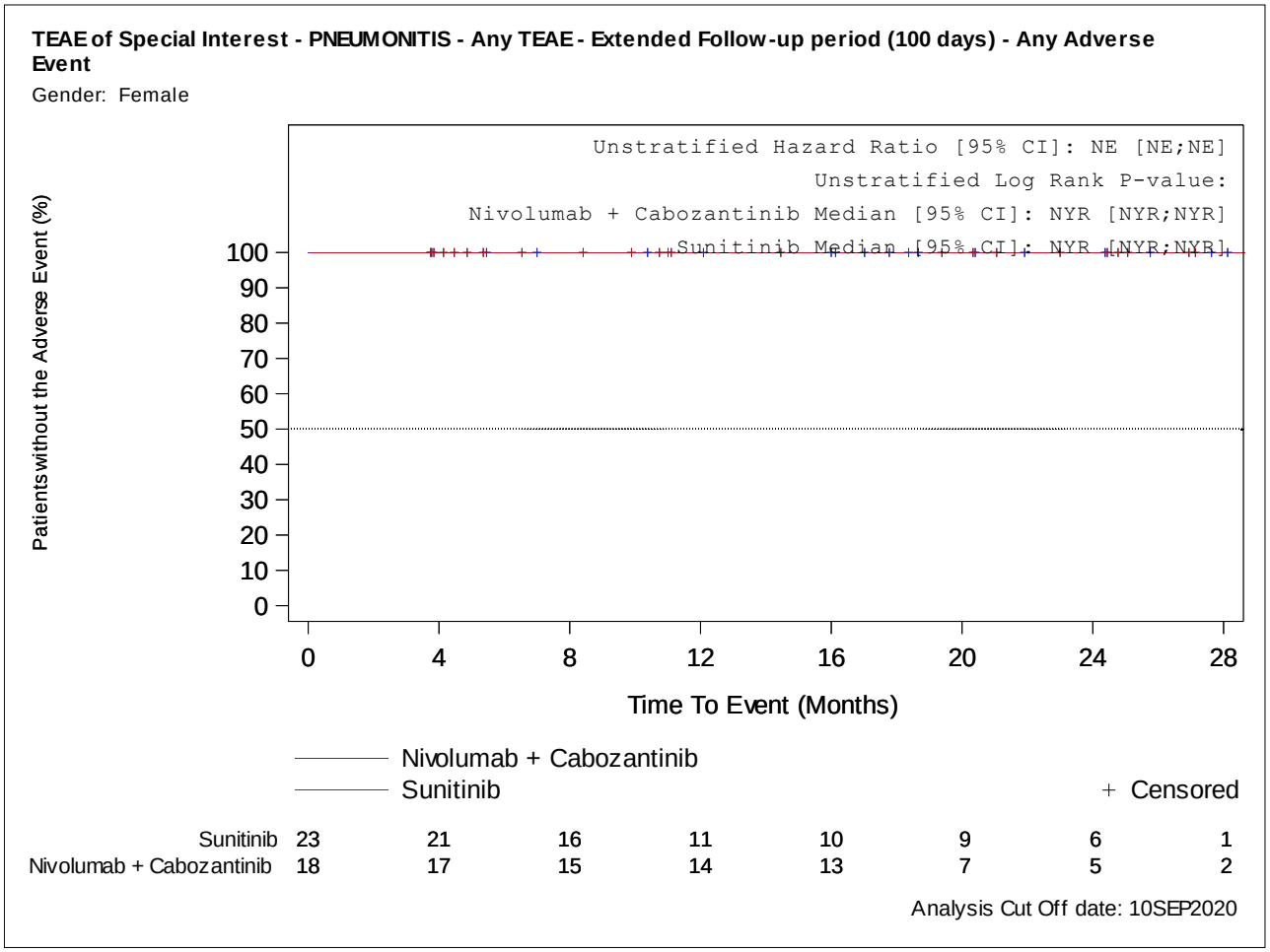

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:20:56

FIGURE 3.126.2.13: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



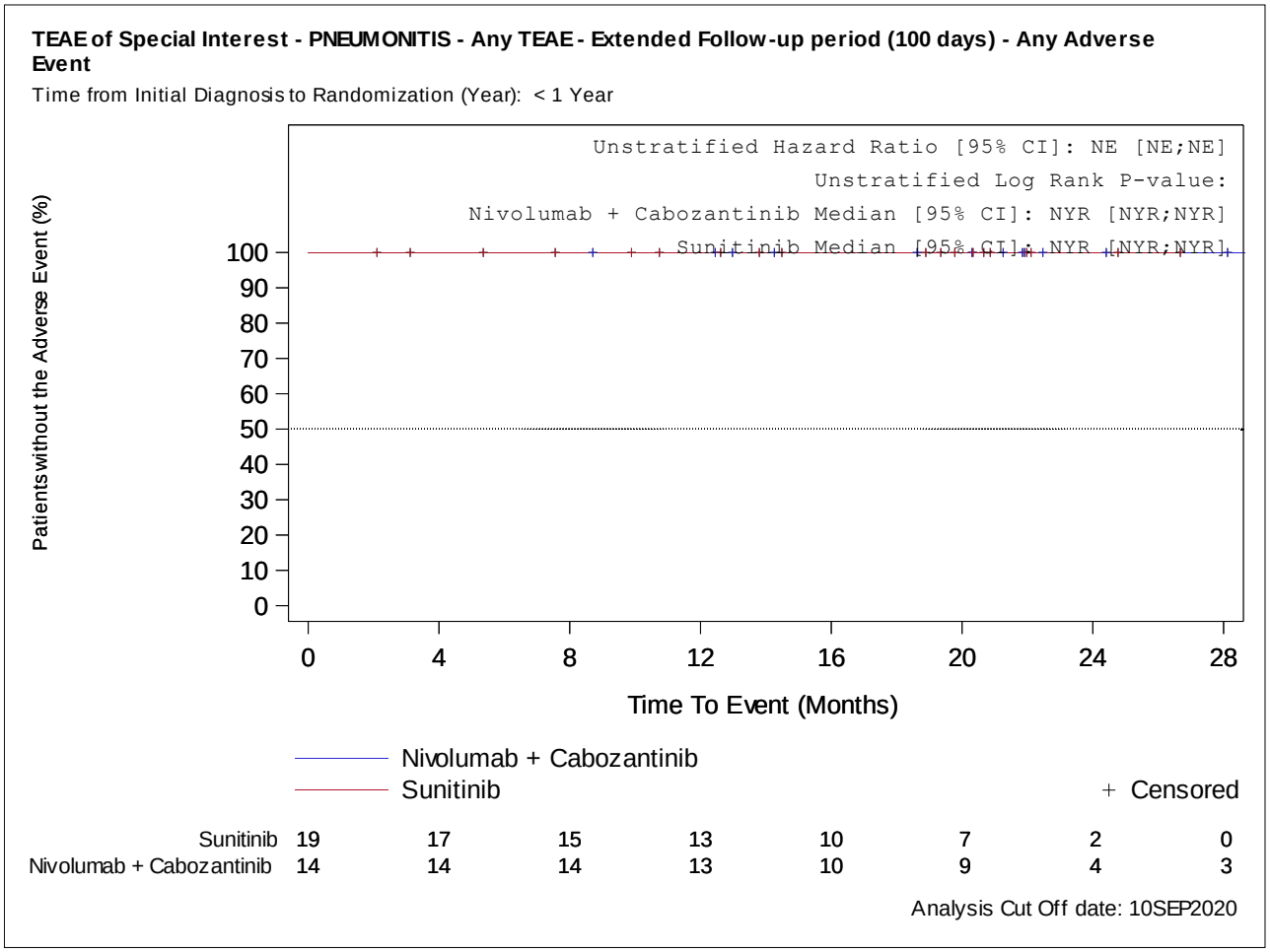

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:21:02

FIGURE 3.126.2.14: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



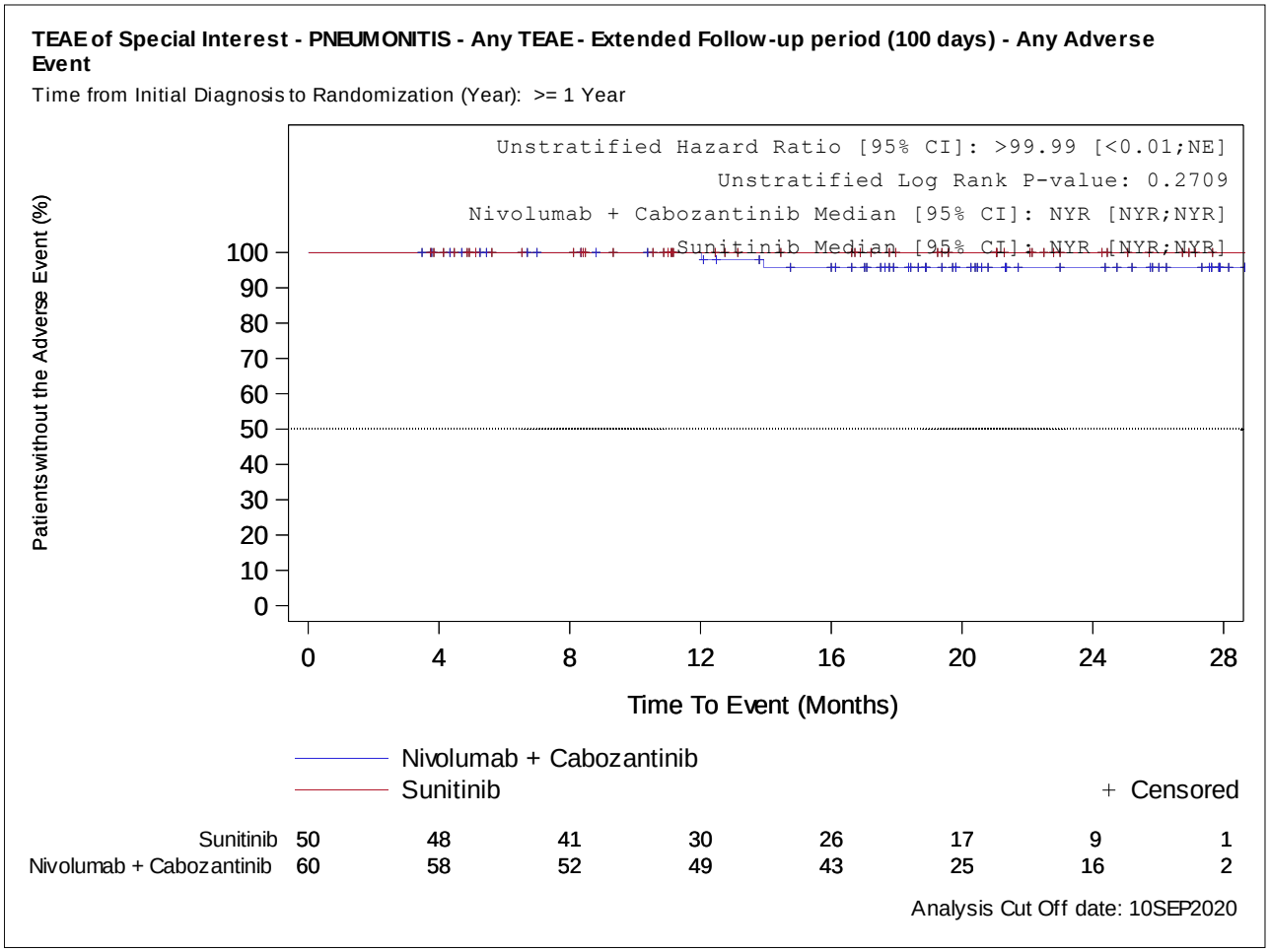

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:21:08

FIGURE 3.126.2.15: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



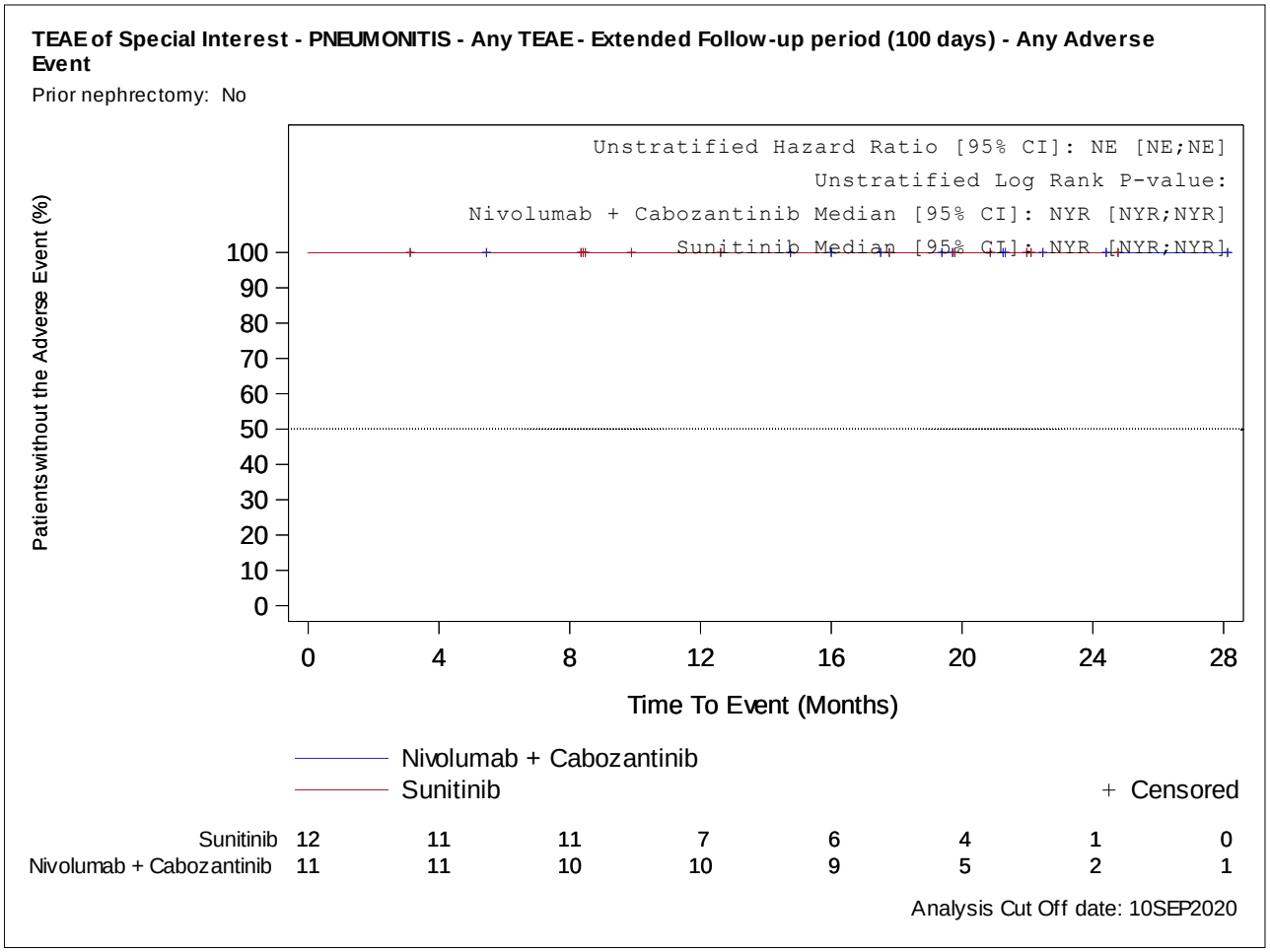

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:21:24

FIGURE 3.126.2.16: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



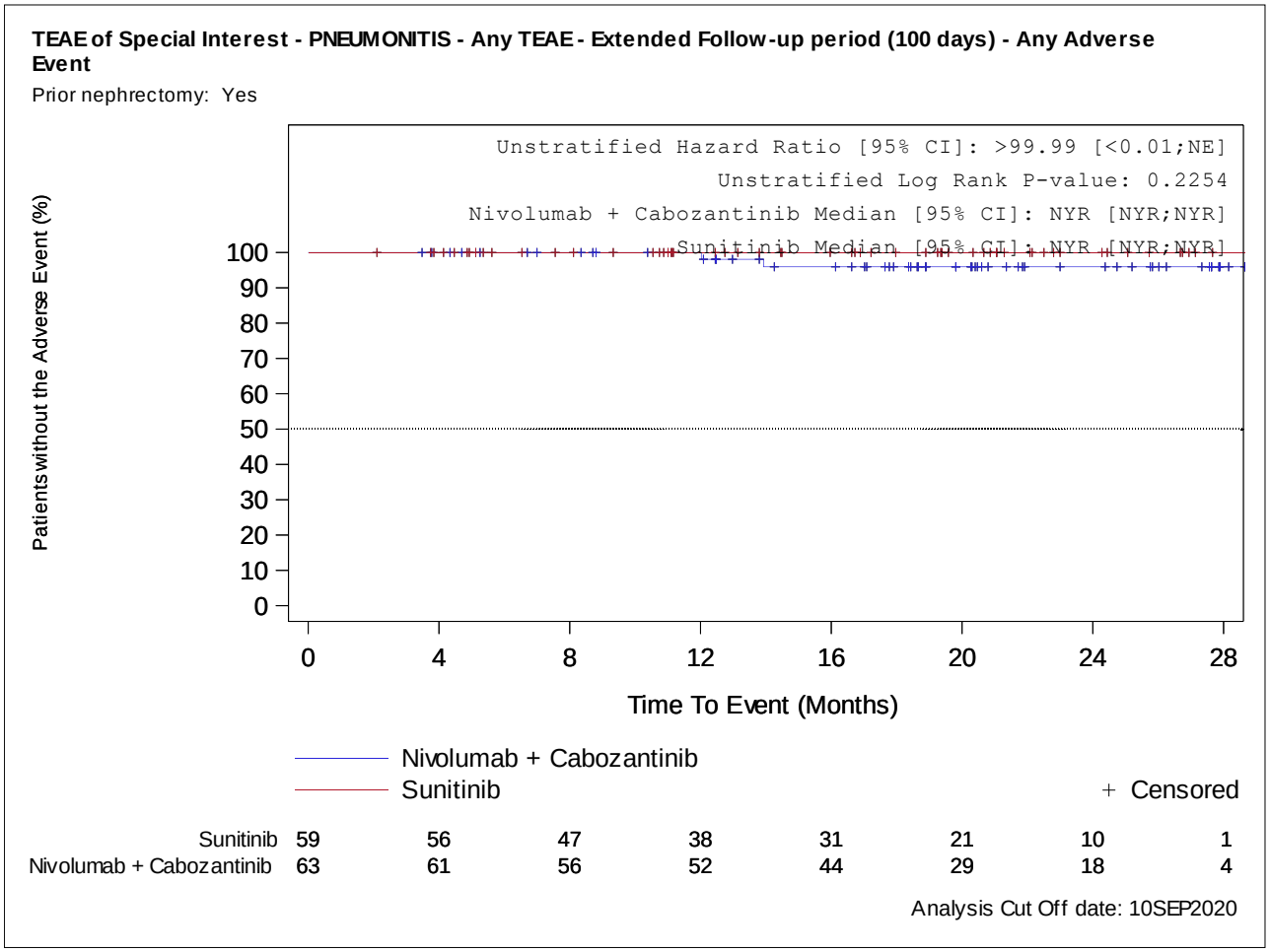

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:21:29

FIGURE 3.126.2.17: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



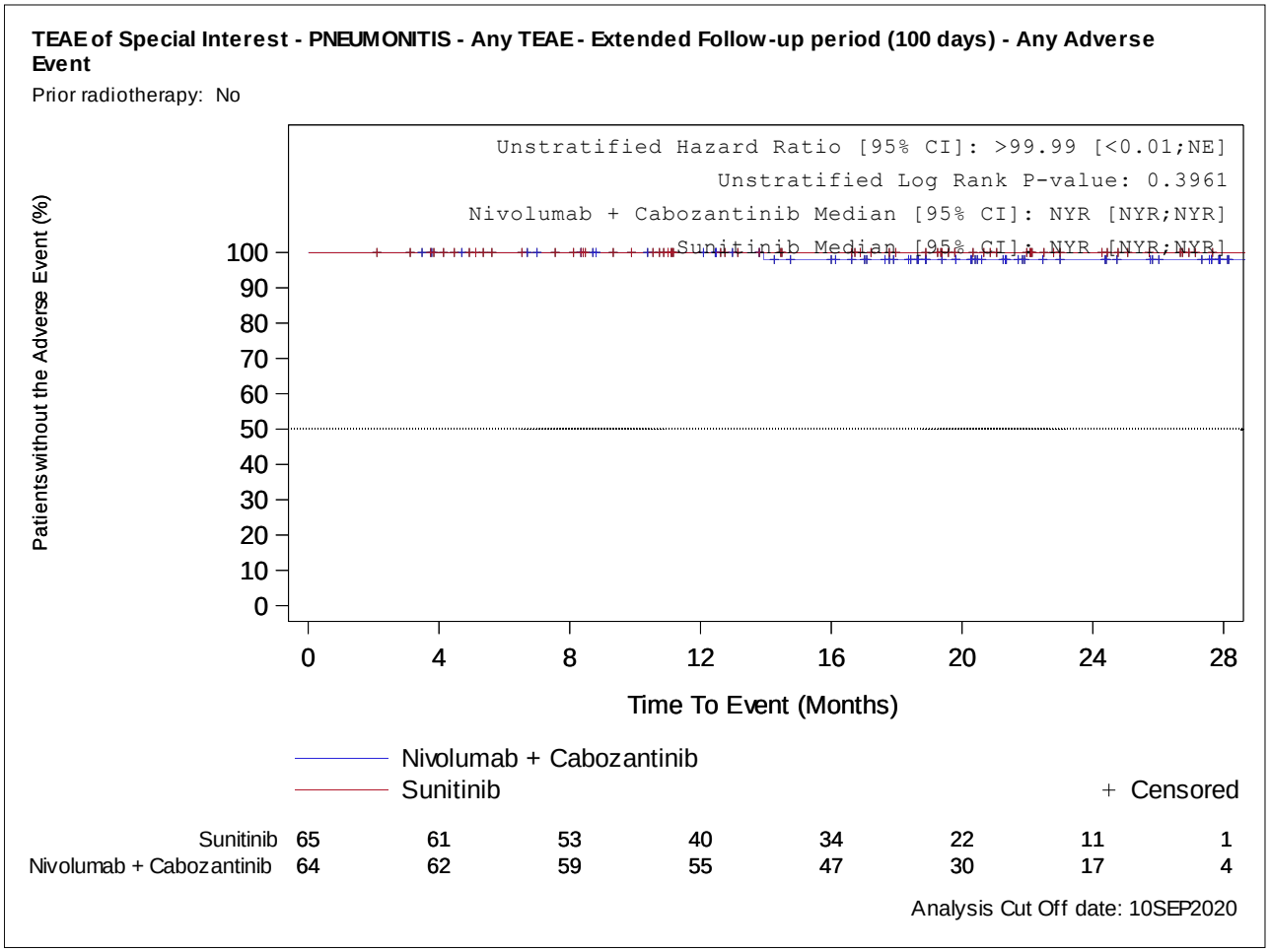

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:22:21

FIGURE 3.126.2.18: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



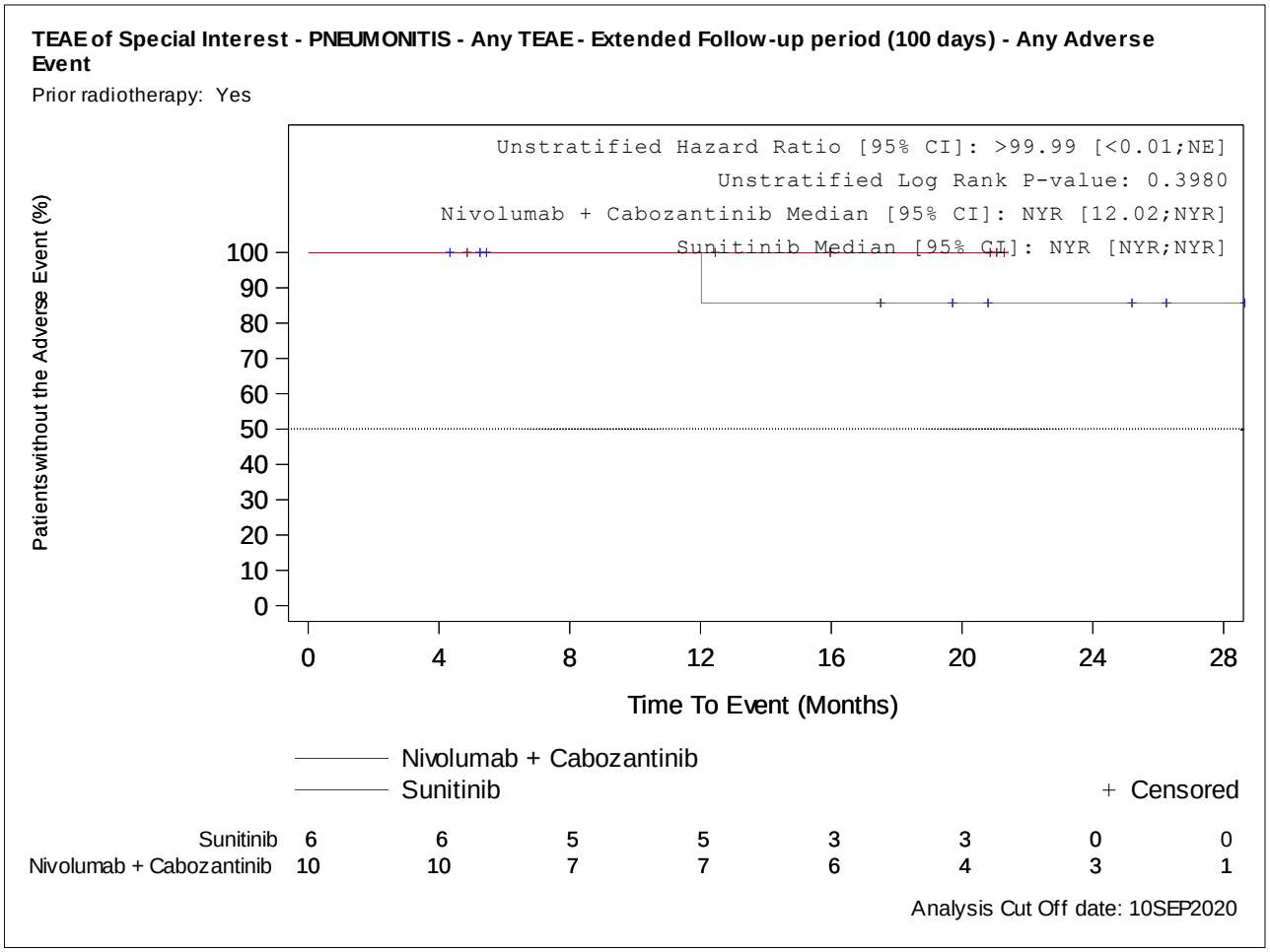

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:22:27

FIGURE 3.126.2.19: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



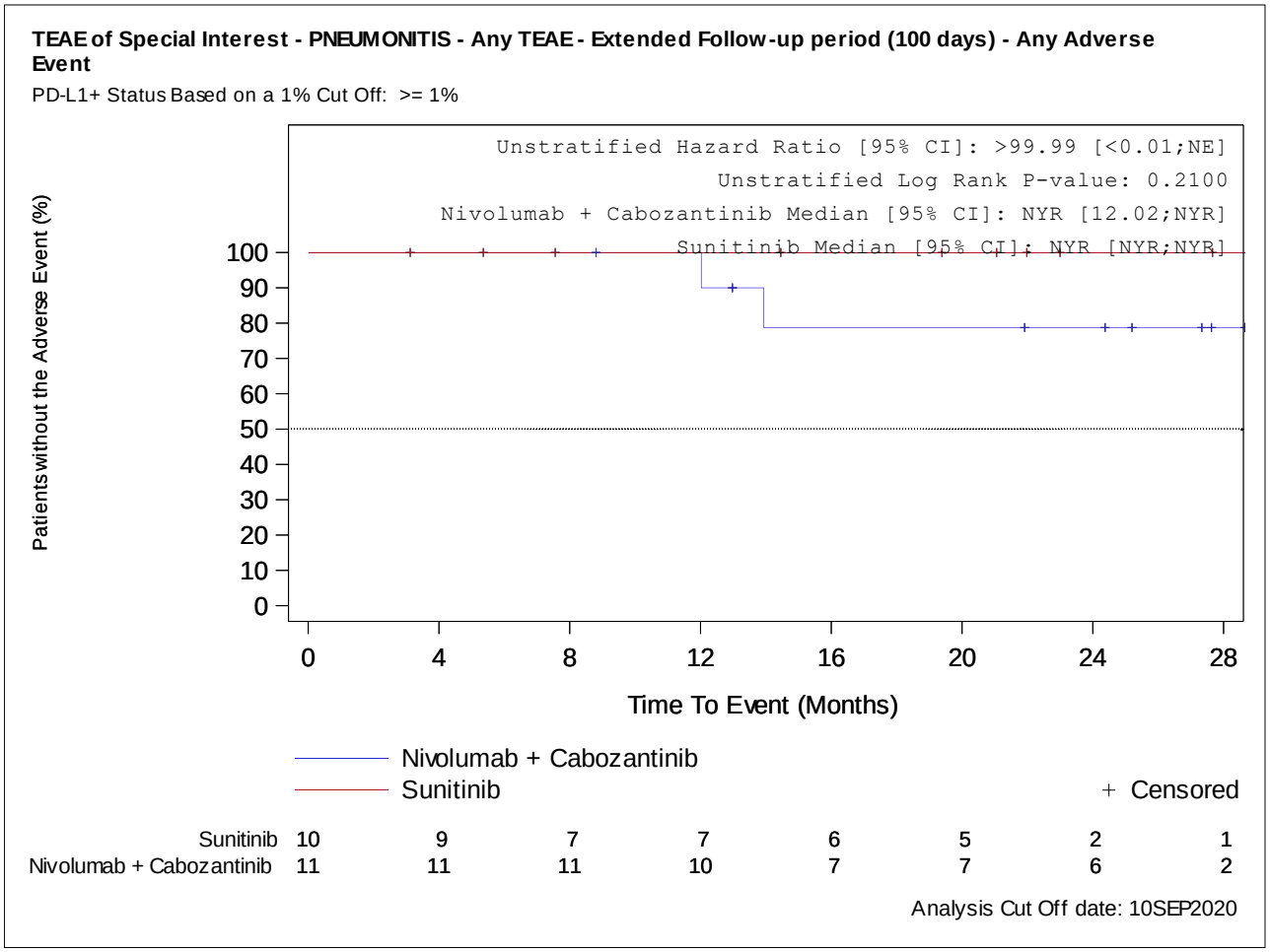

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:22:33

FIGURE 3.126.2.20: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



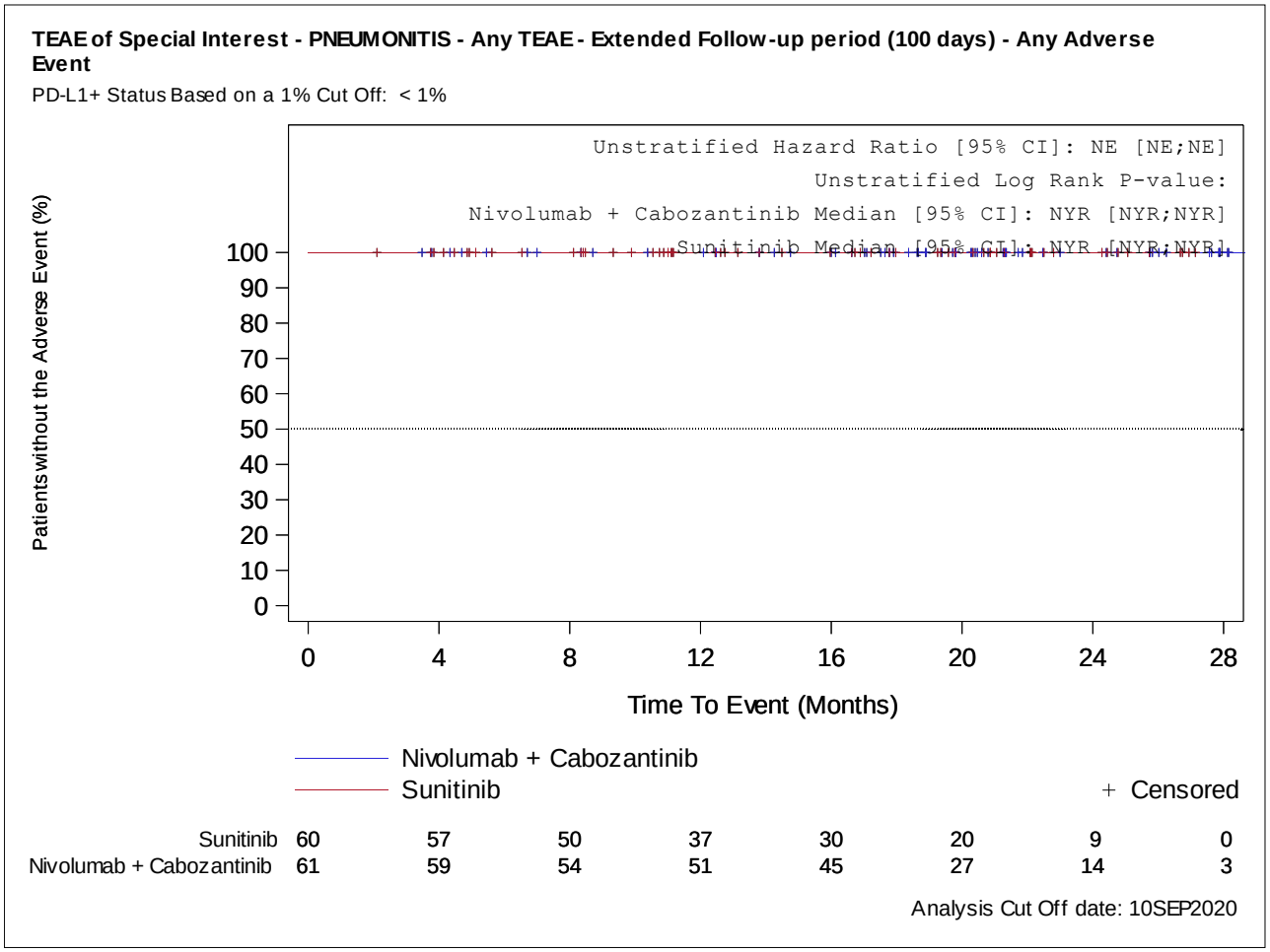

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:22:39

FIGURE 3.126.2.21: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



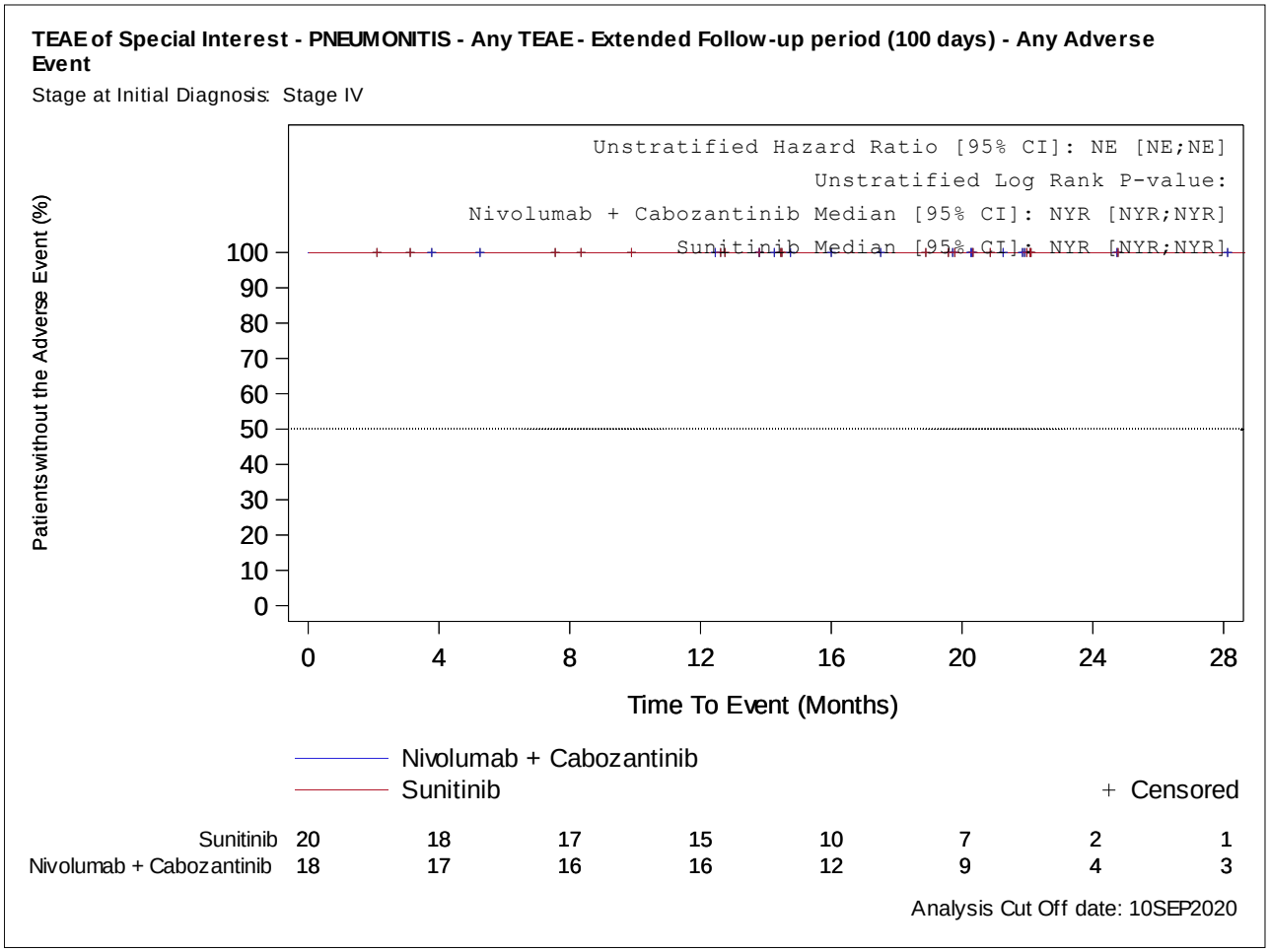

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:22:44

FIGURE 3.126.2.22: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



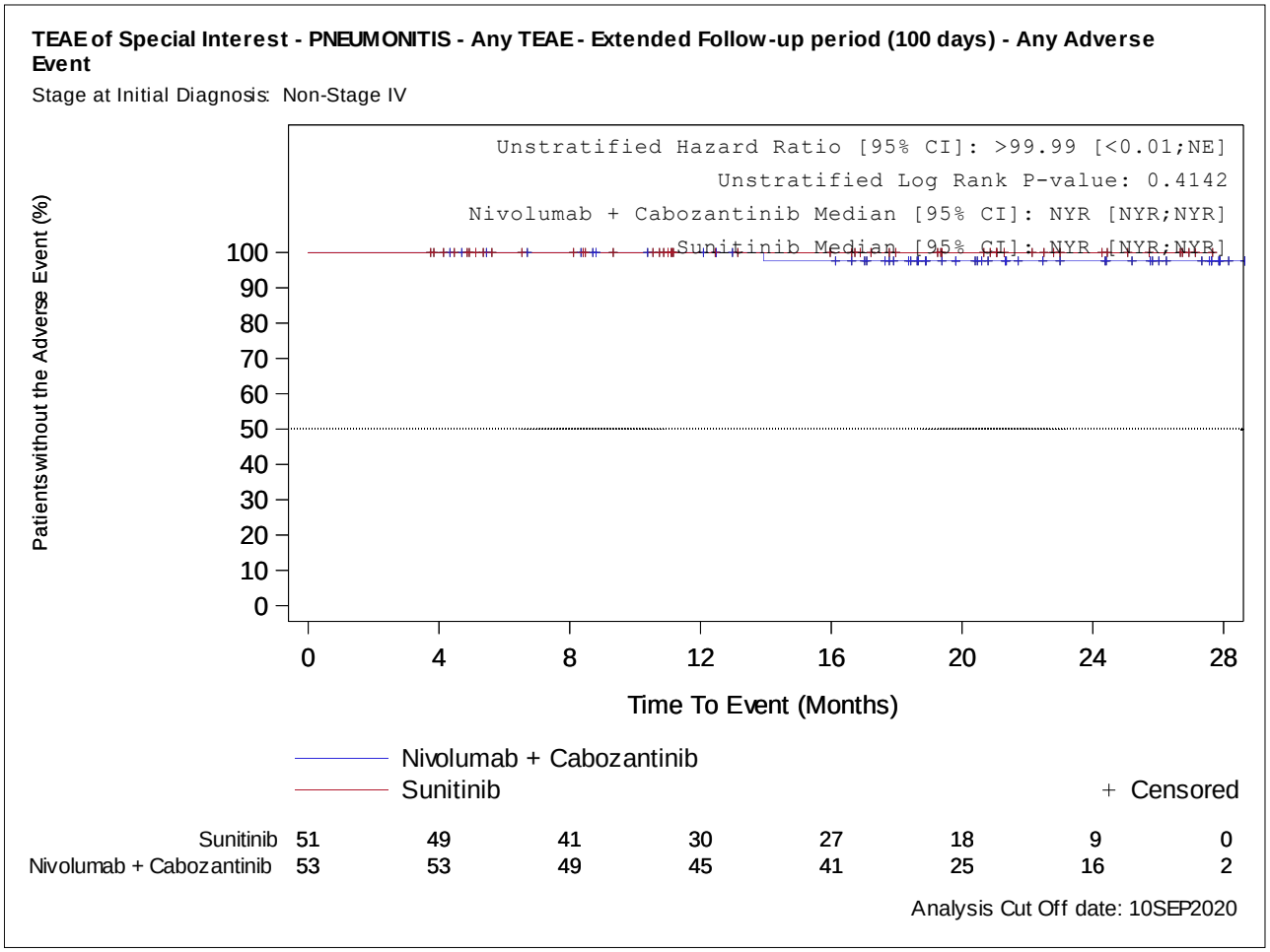

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:22:50

FIGURE 3.126.2.23: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



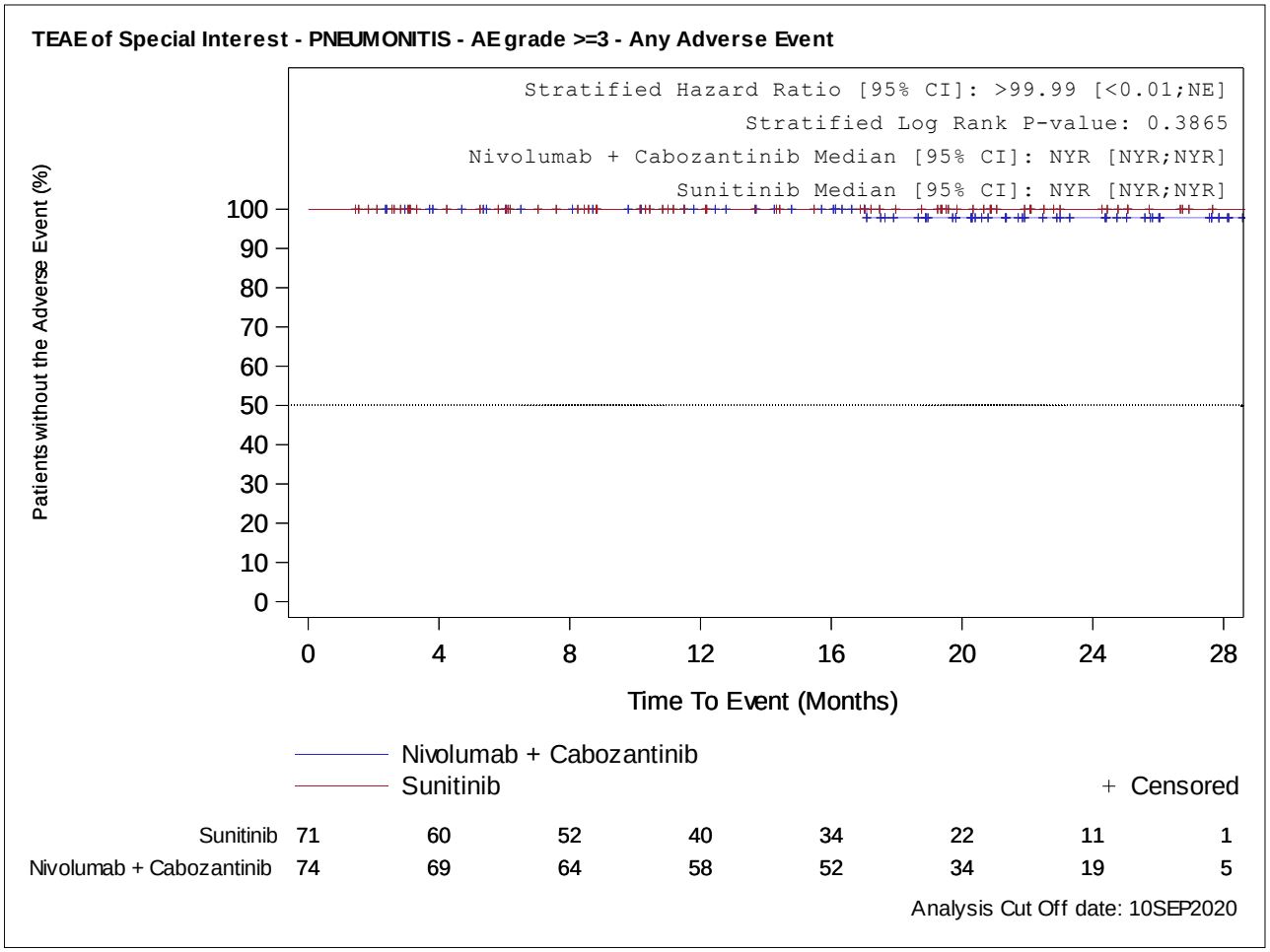

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:23:17

FIGURE 3.126.2.24: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



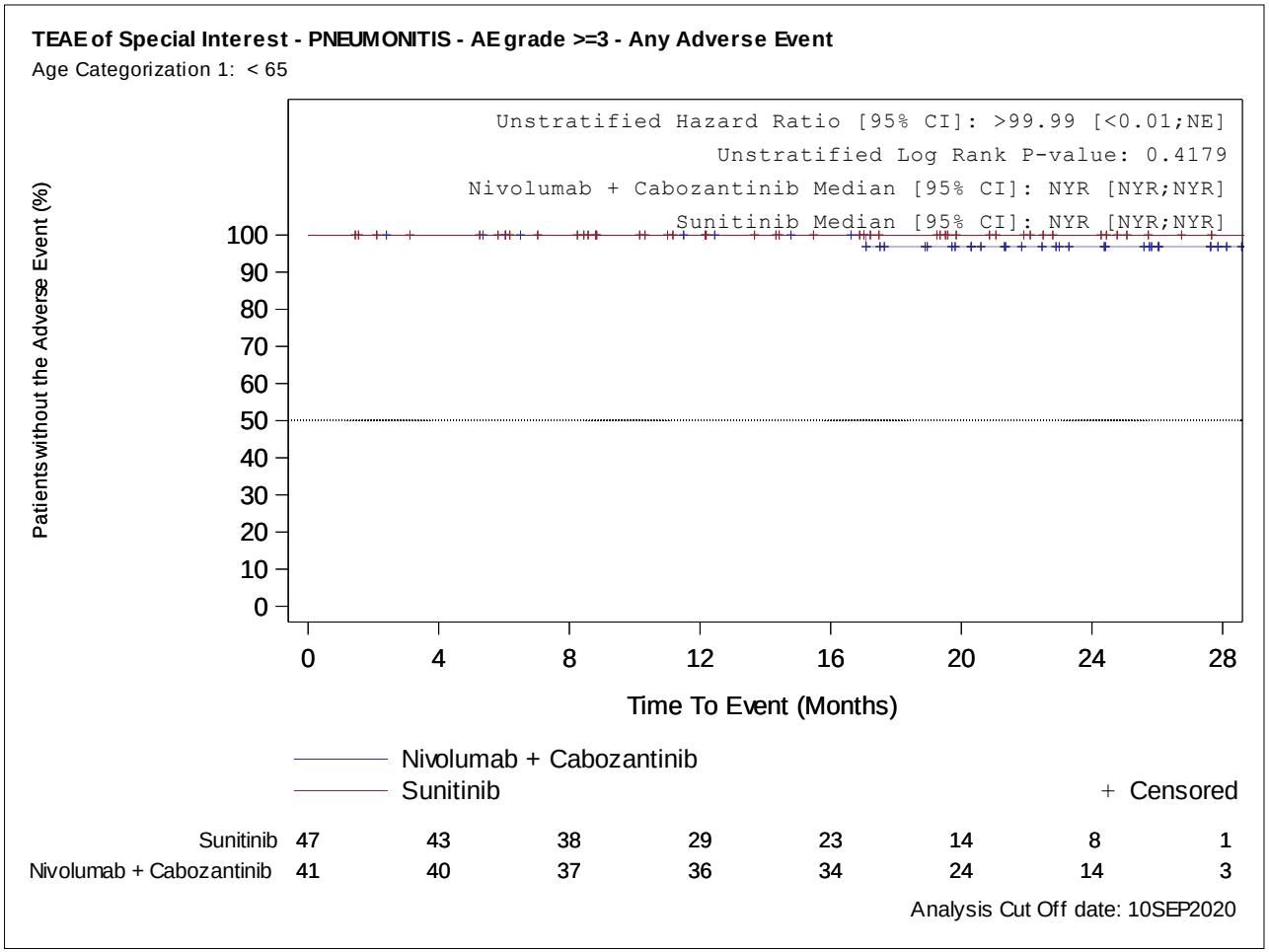

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:23:23

FIGURE 3.127.1: TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



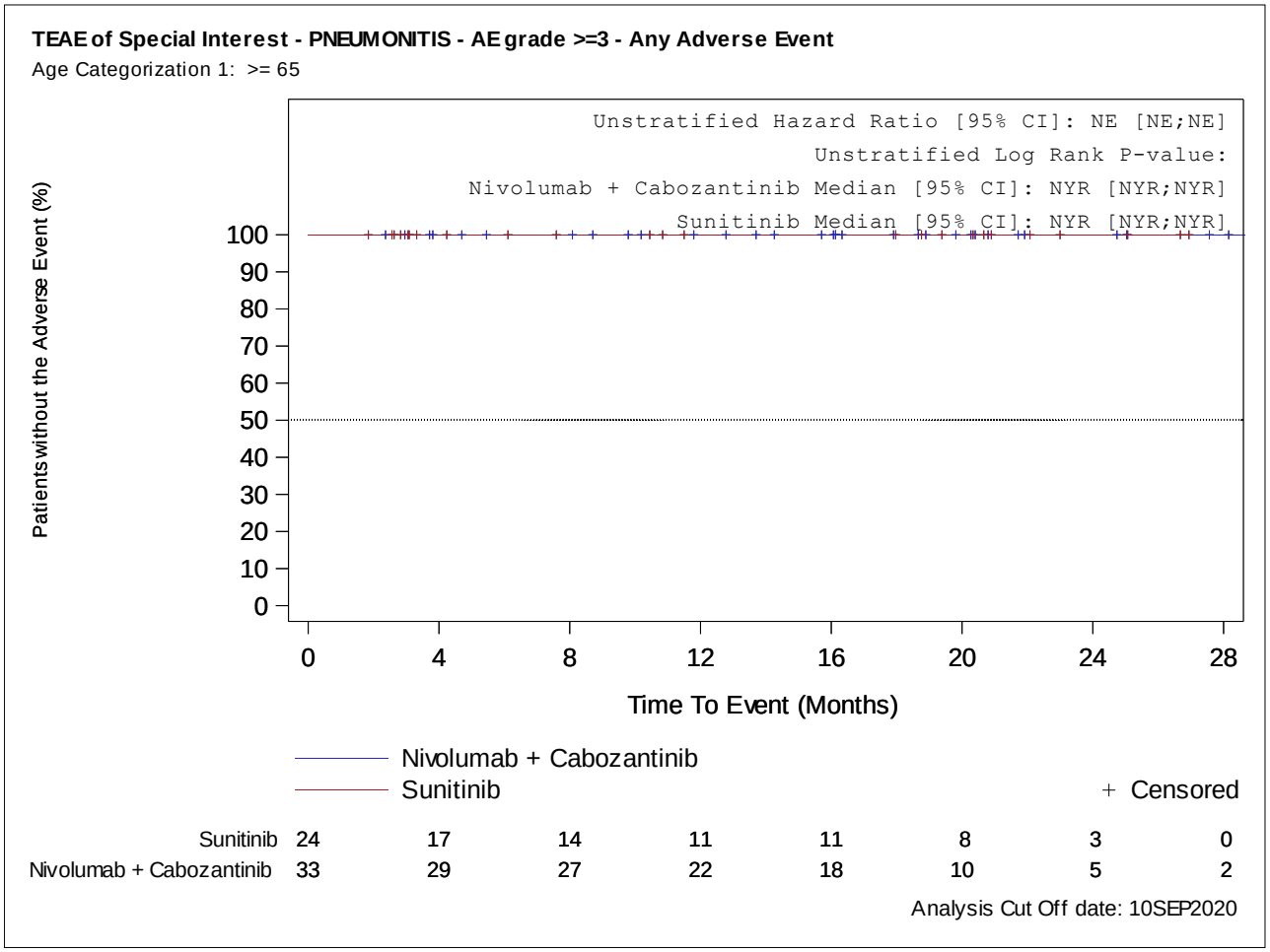

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:26:26

FIGURE 3.127.2.1: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



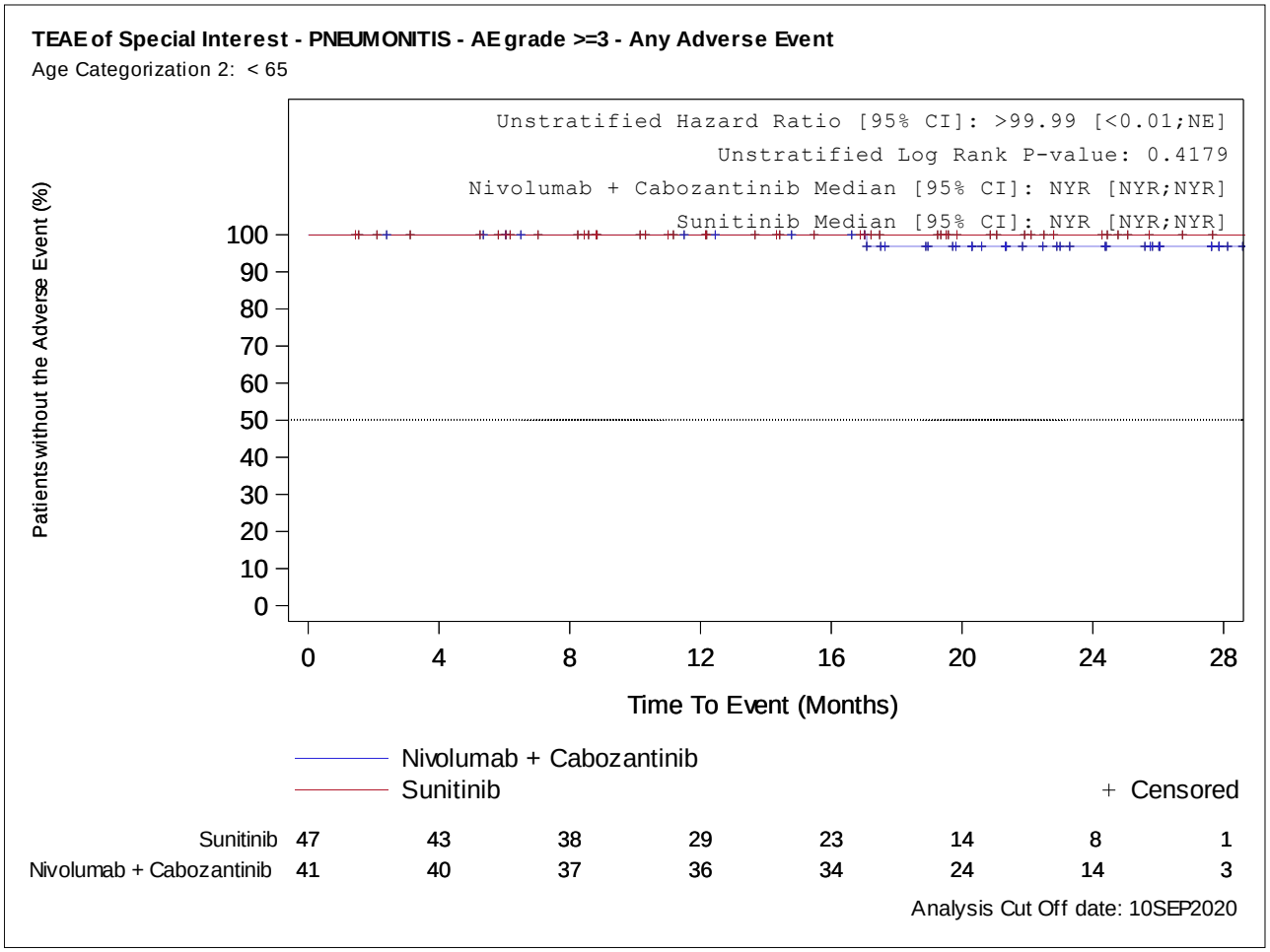

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:26:28

FIGURE 3.127.2.2: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



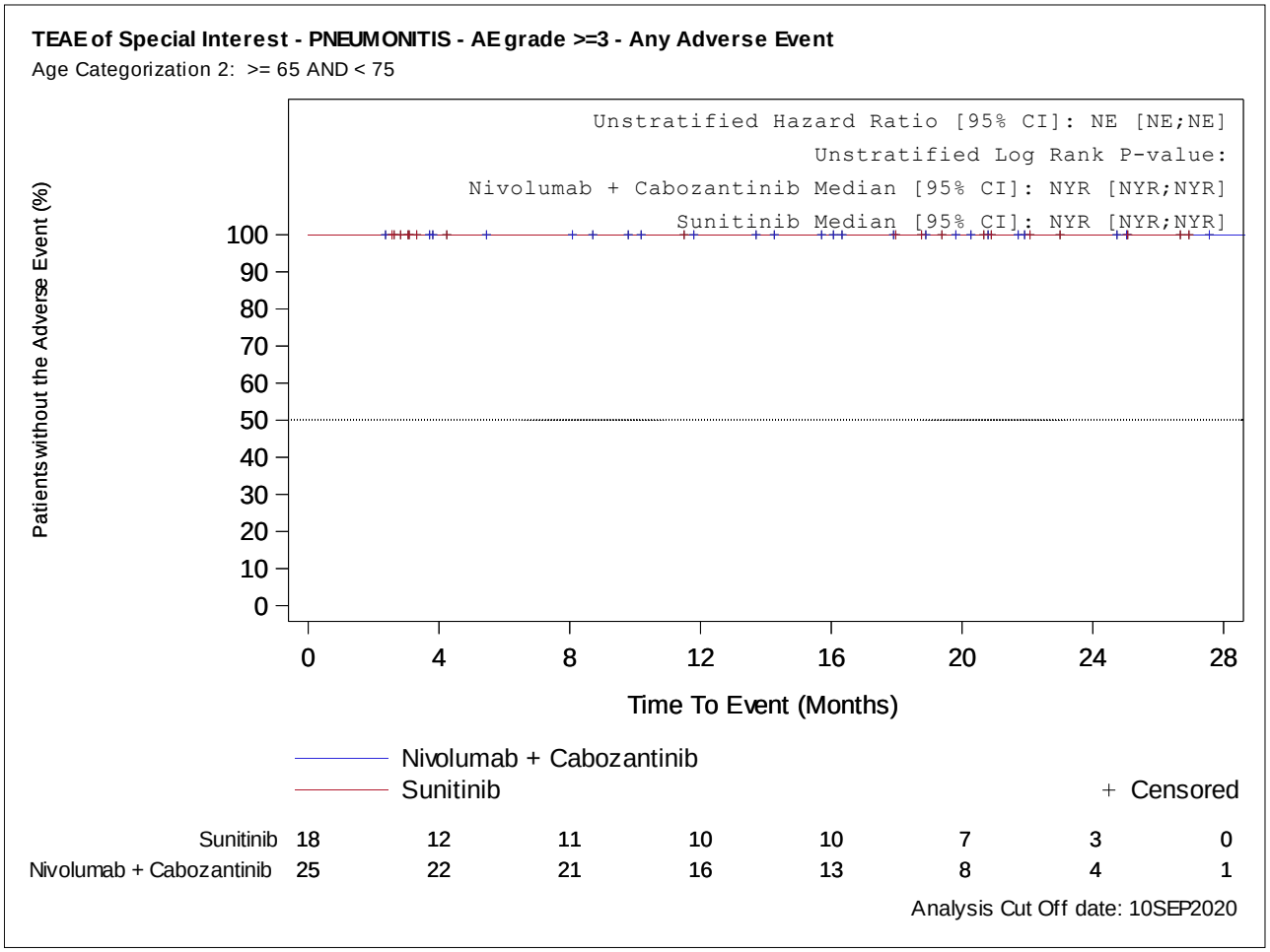

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:26:34

FIGURE 3.127.2.3: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:26:40

FIGURE 3.127.2.4: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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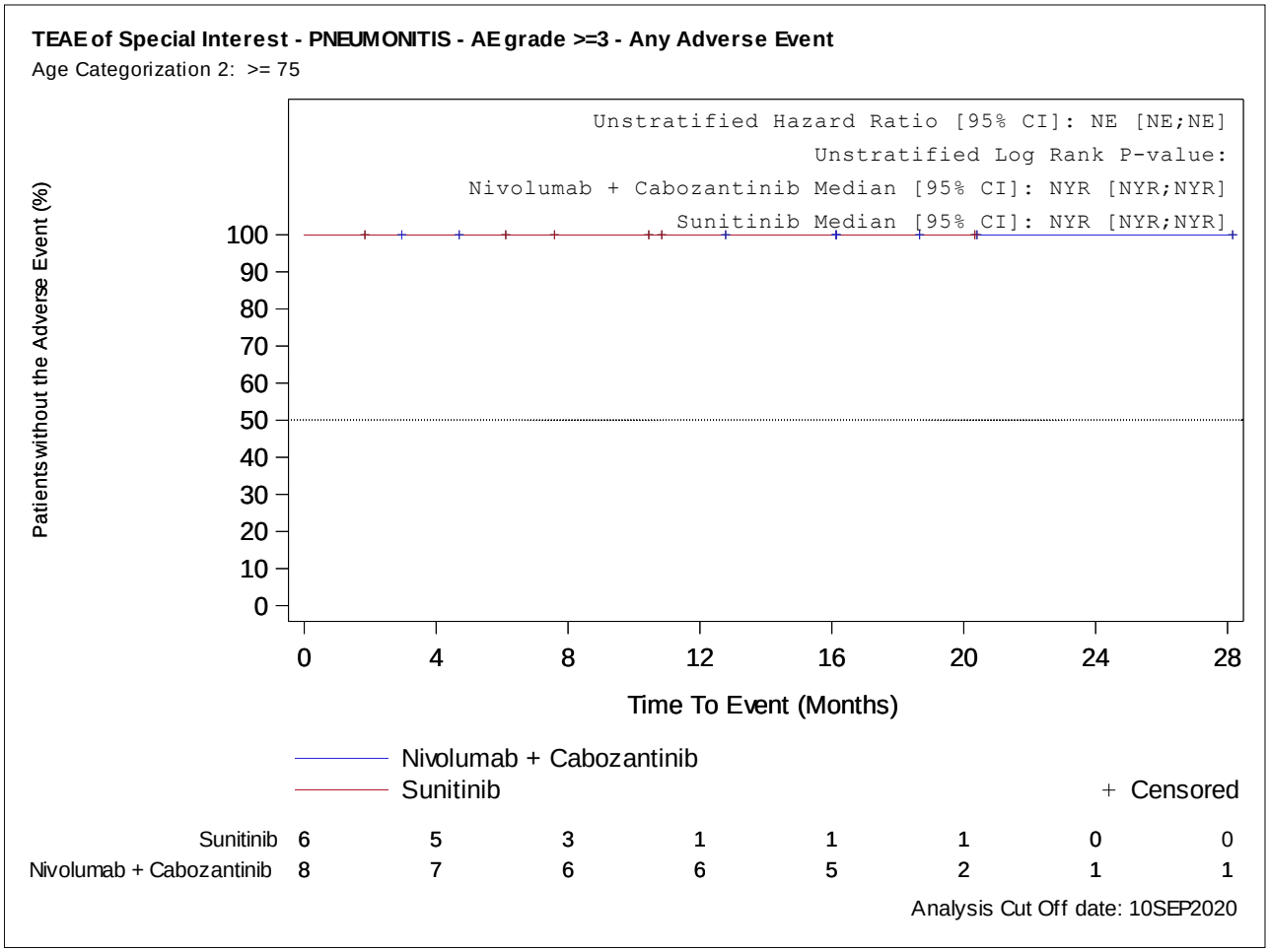
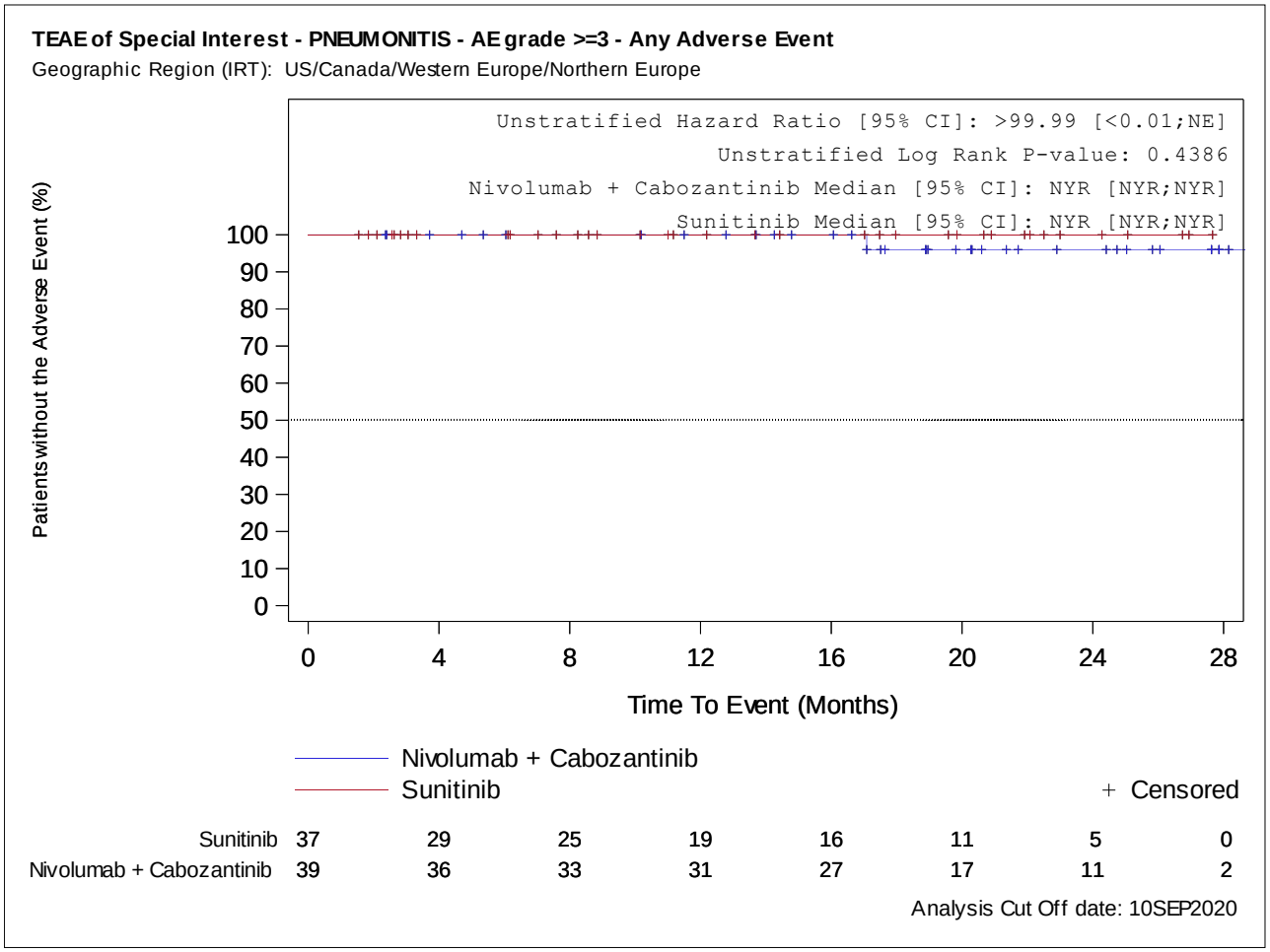
FIGURE 3.127.2.5: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



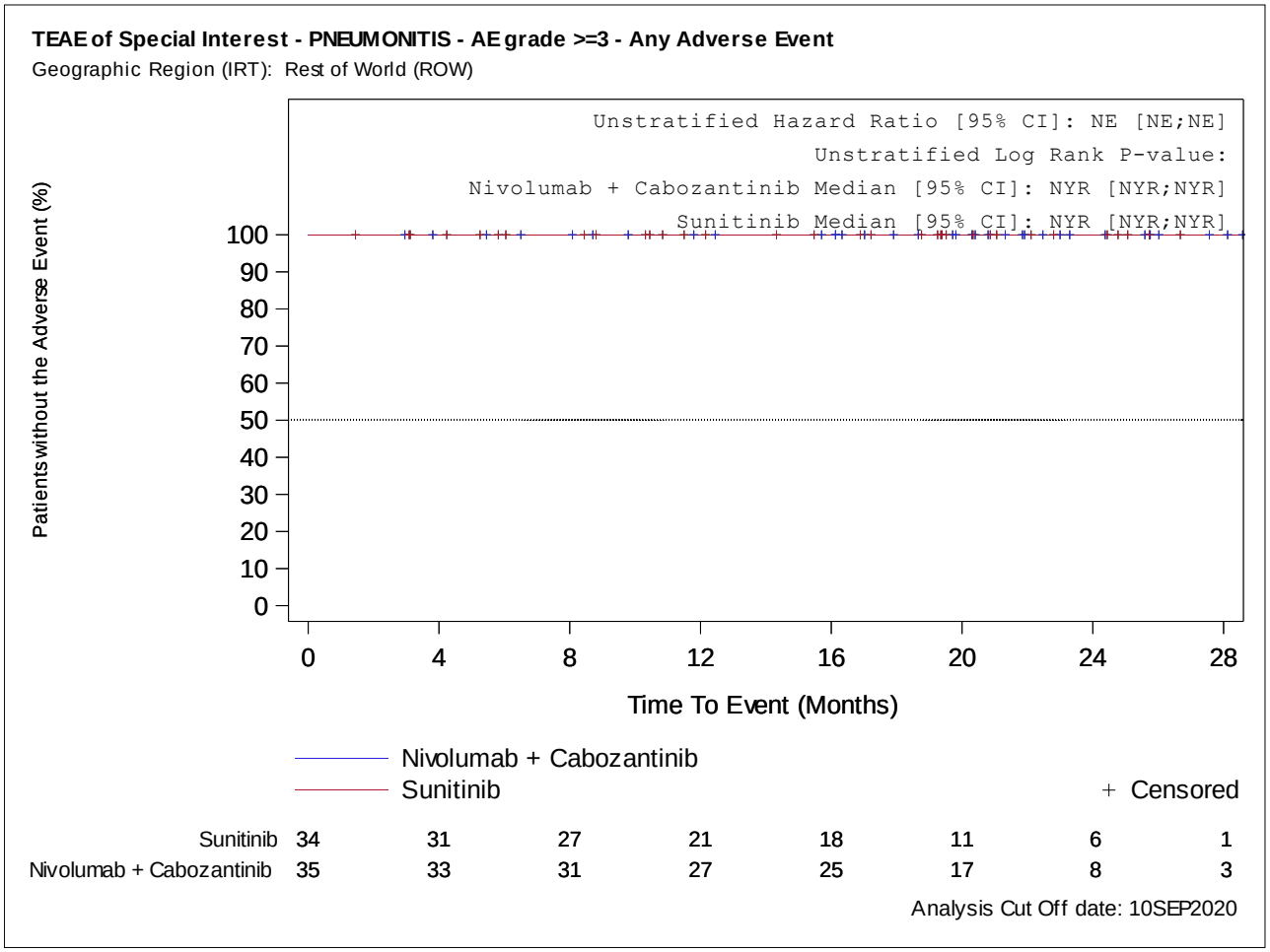

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:26:51

FIGURE 3.127.2.6: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



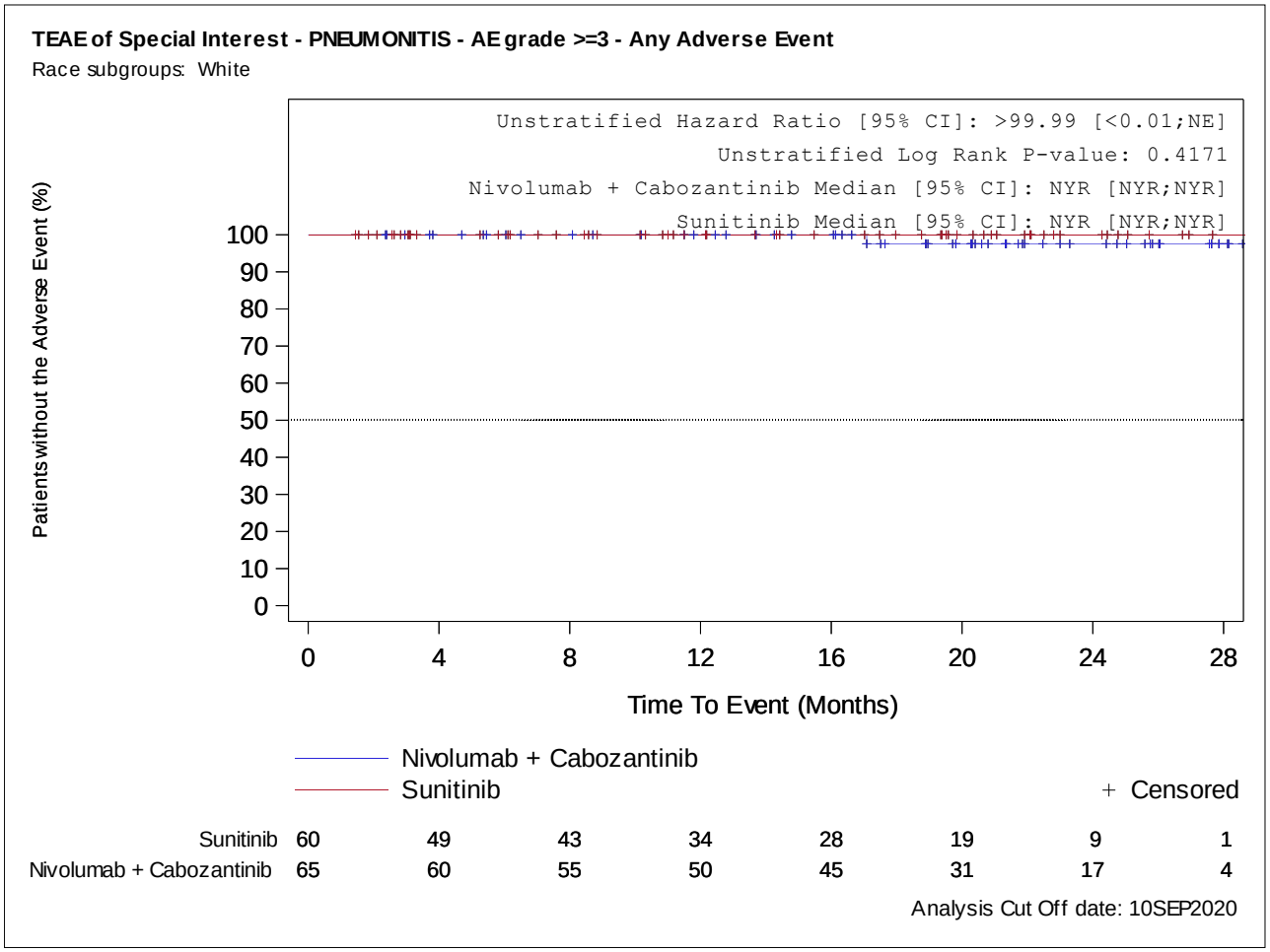

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:26:57

FIGURE 3.127.2.7: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



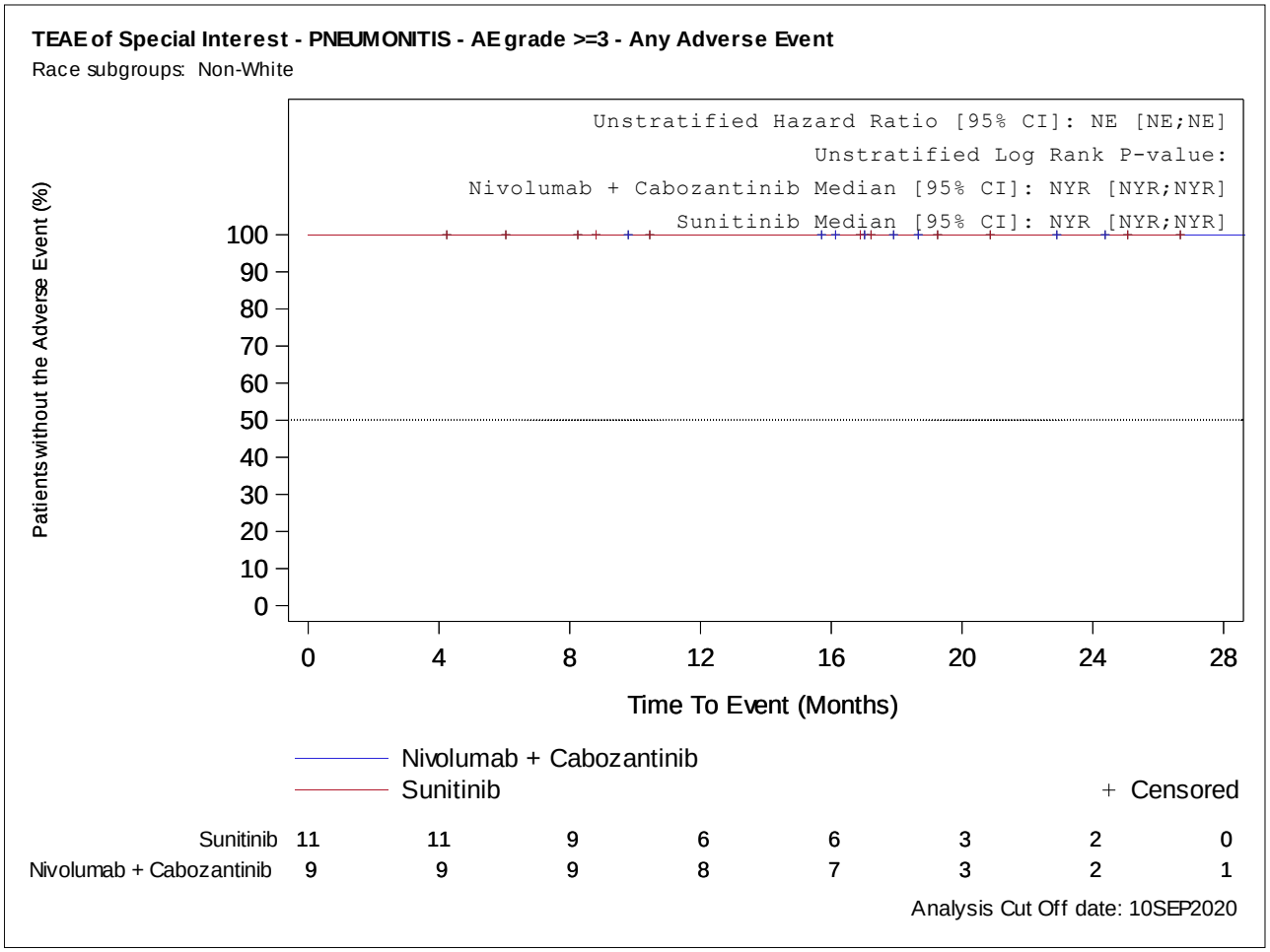

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:27:03

FIGURE 3.127.2.8: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



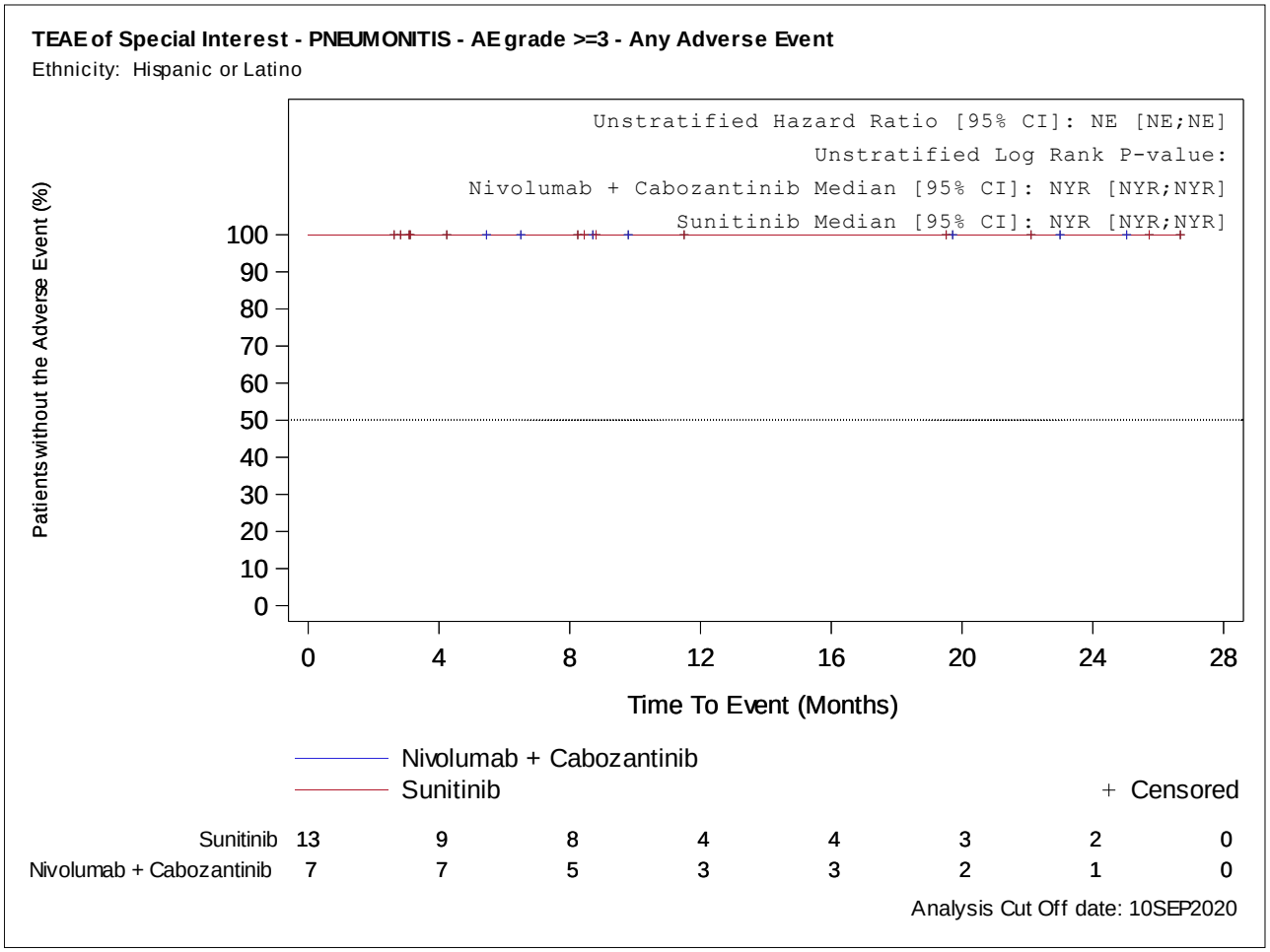

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:27:09

FIGURE 3.127.2.9: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



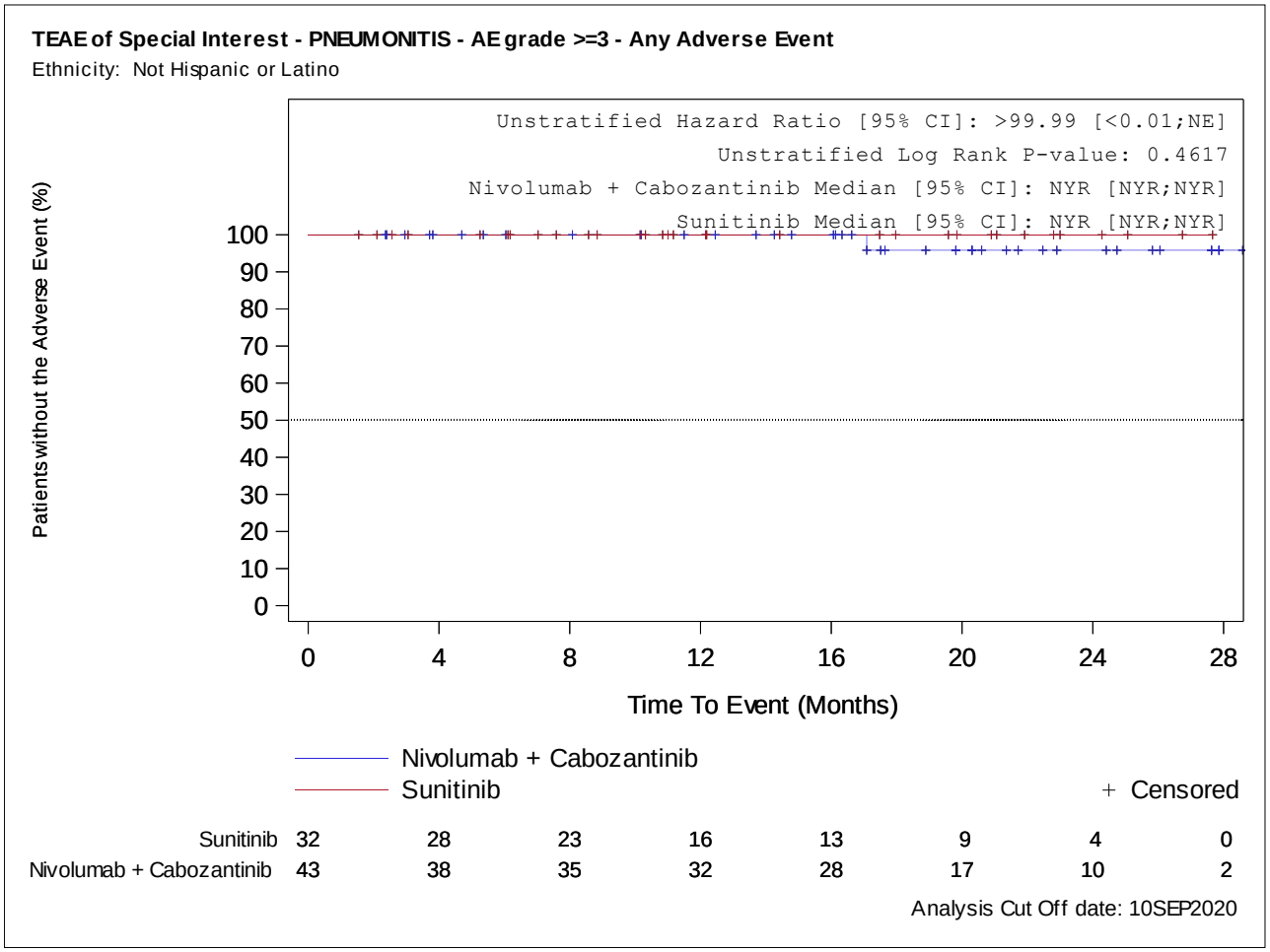

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:27:16

FIGURE 3.127.2.10: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



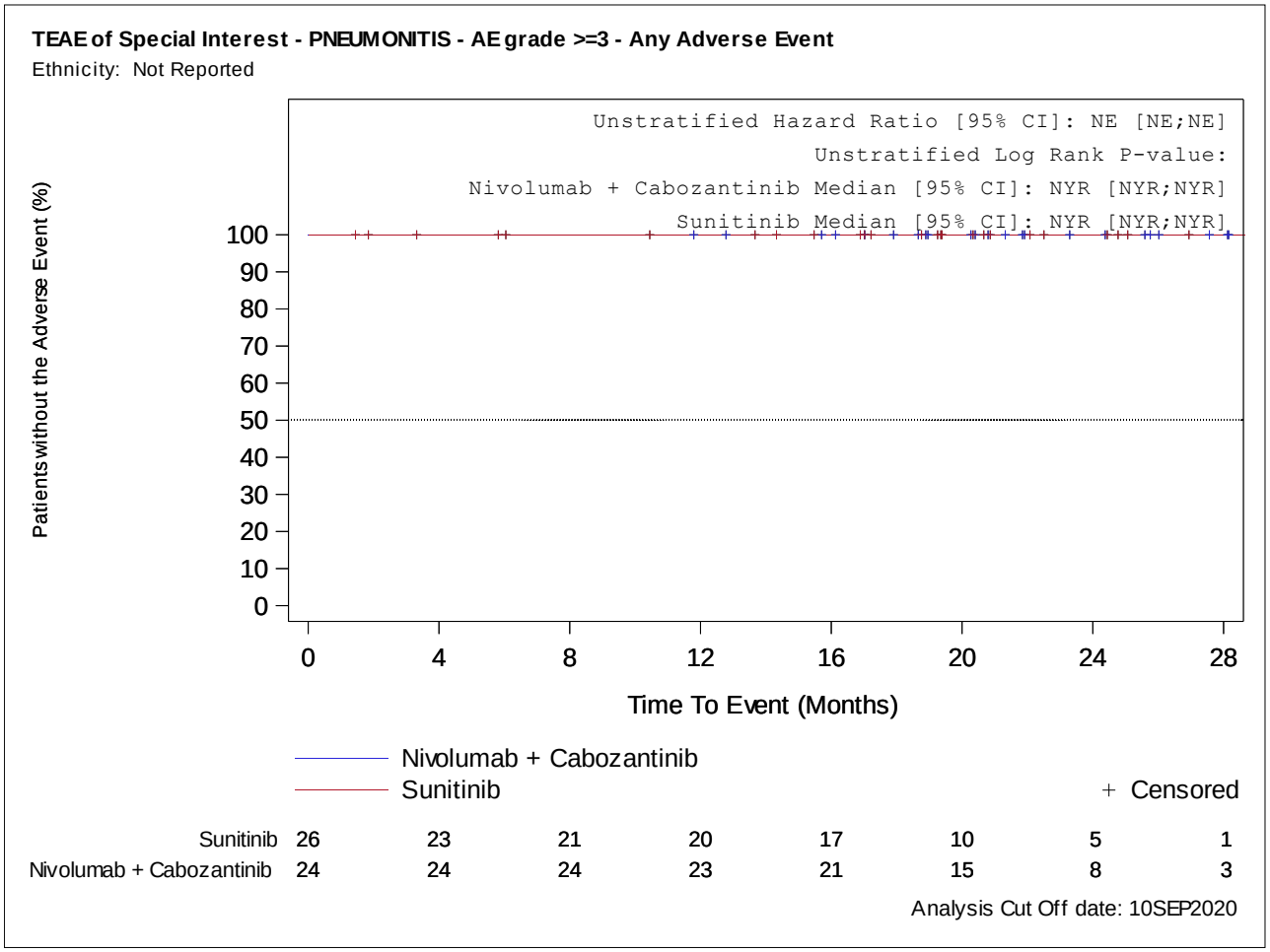

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:27:21

FIGURE 3.127.2.11: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



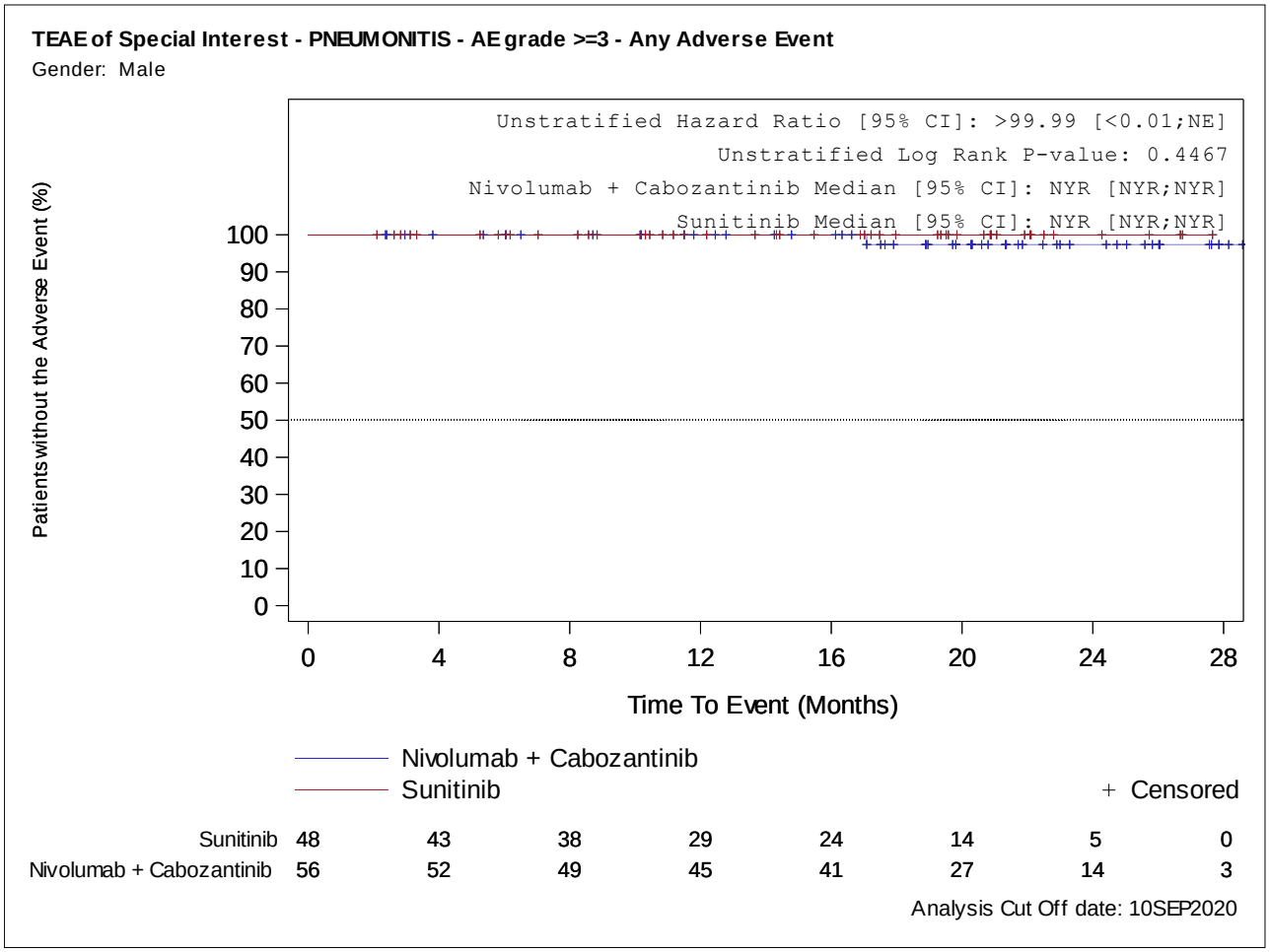

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:27:28

FIGURE 3.127.2.12: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



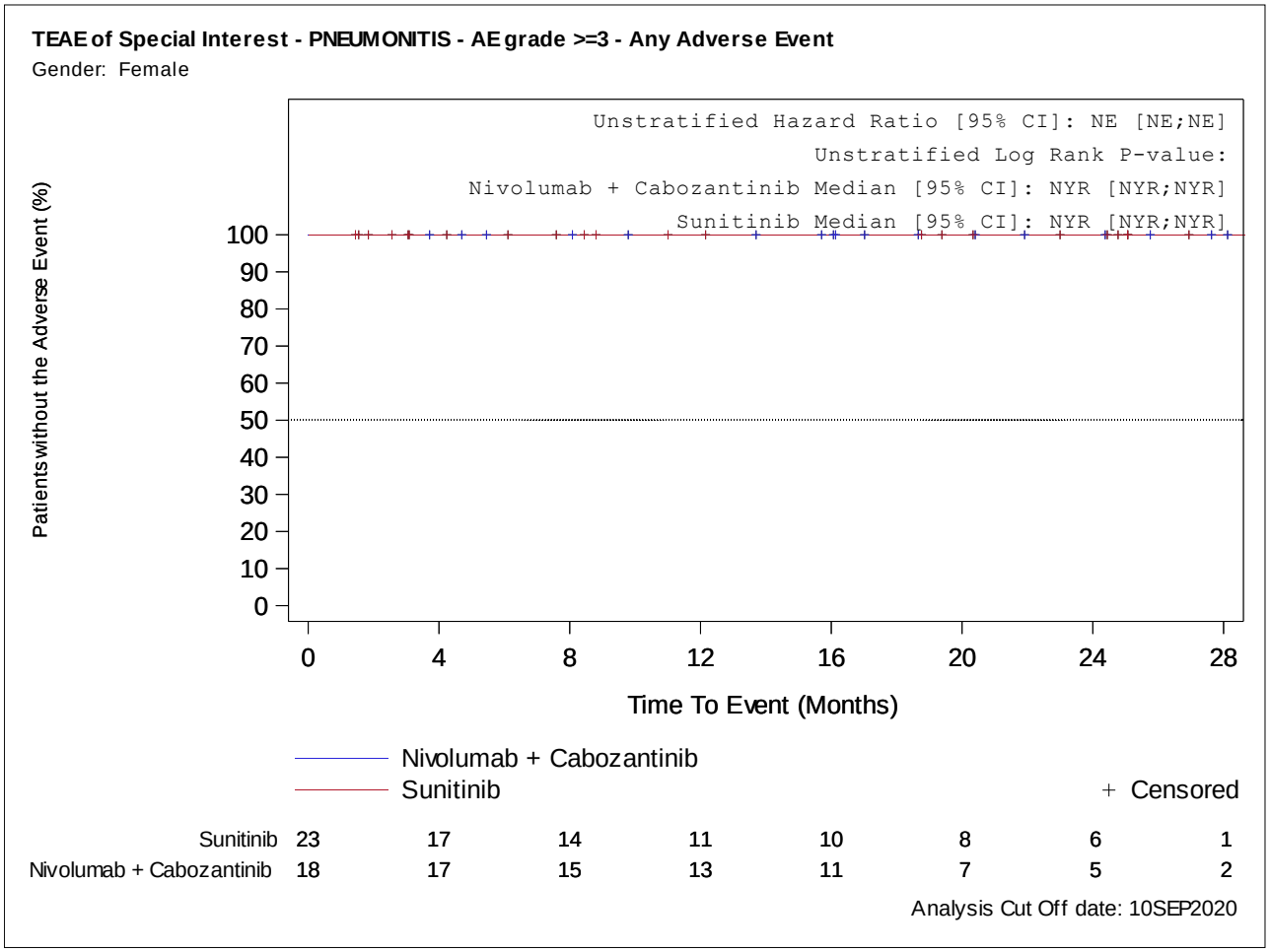

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:27:34

FIGURE 3.127.2.13: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



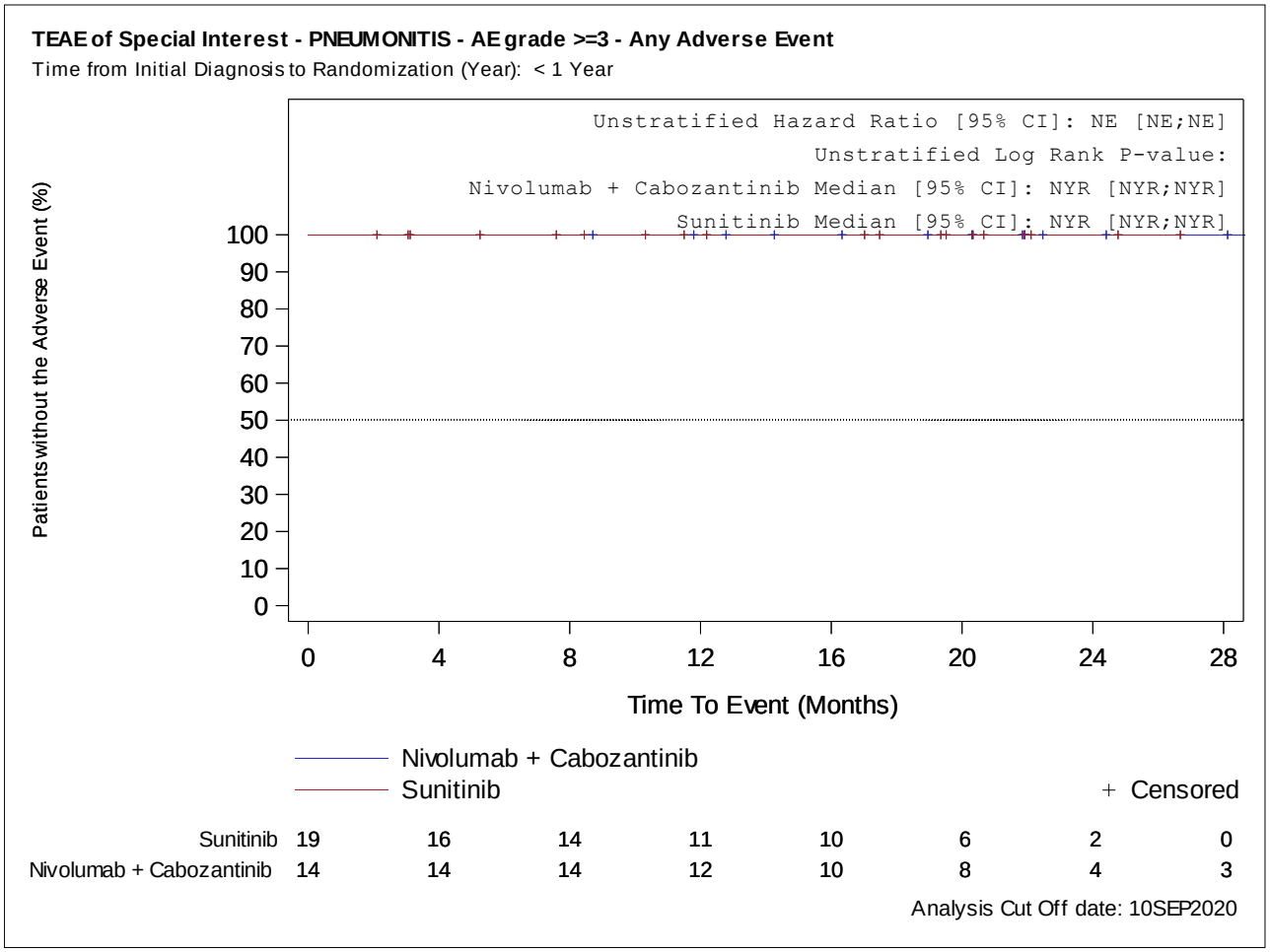

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:27:41

FIGURE 3.127.2.14: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



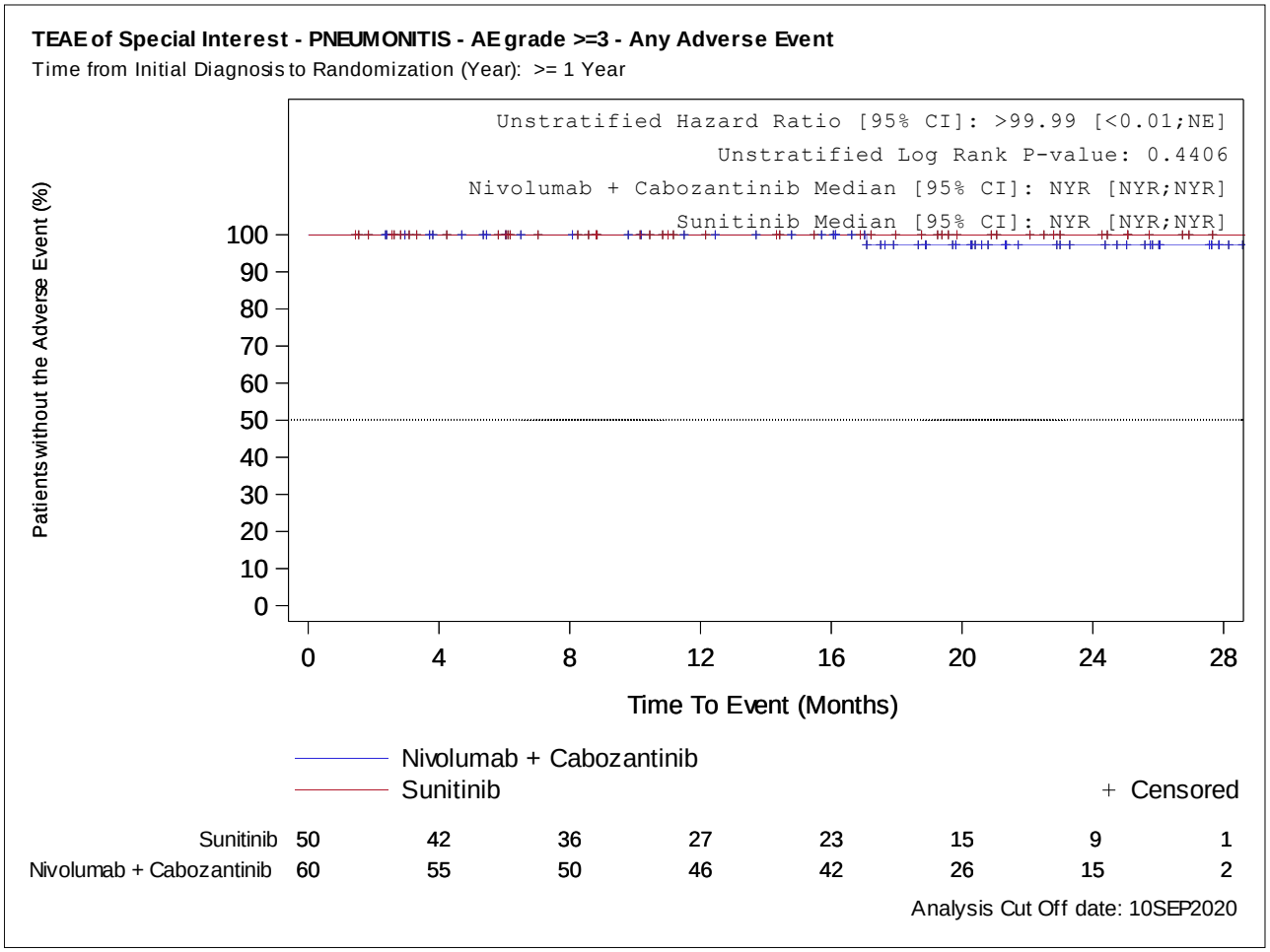

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:27:46

FIGURE 3.127.2.15: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



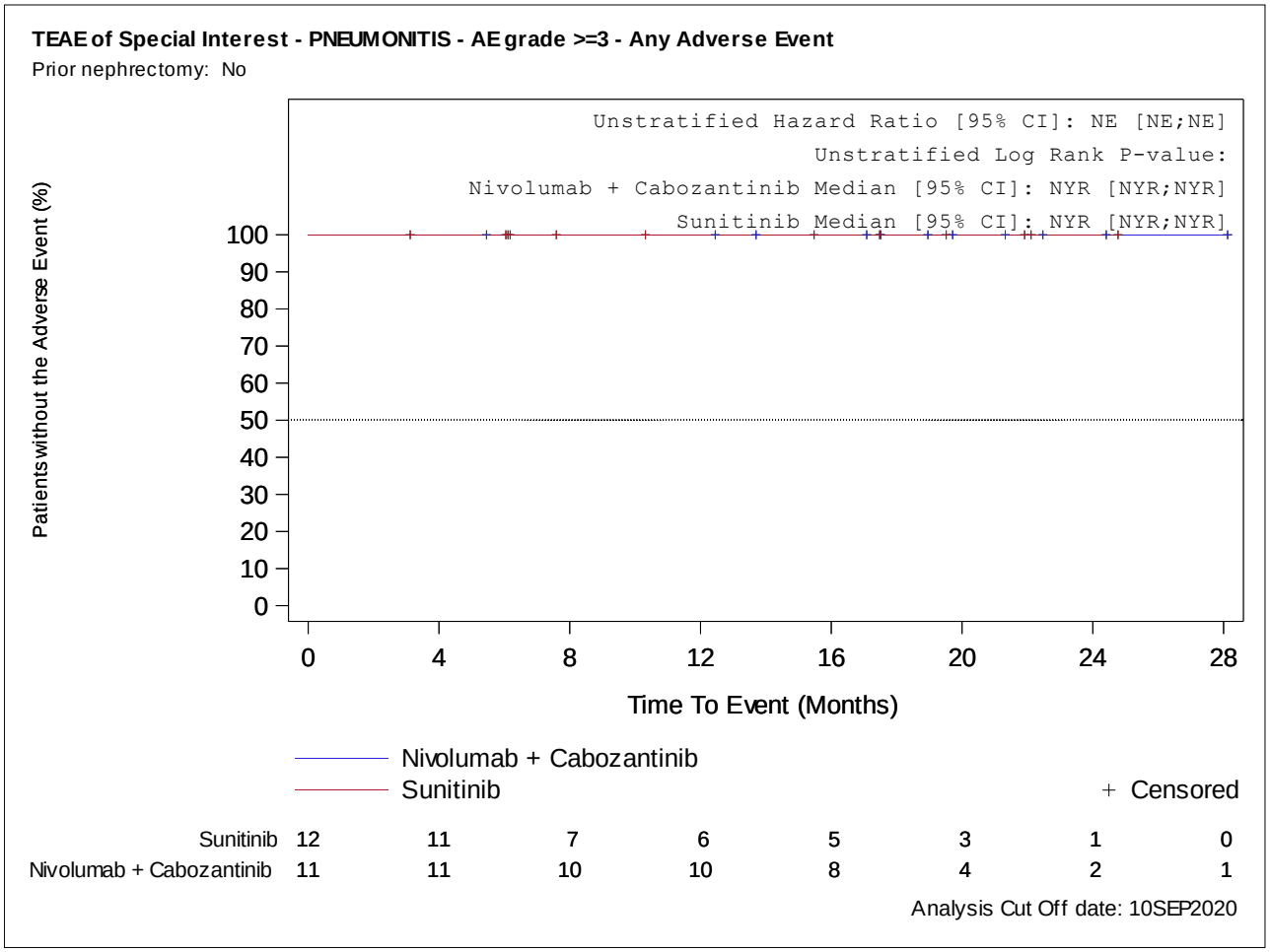

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:28:04

FIGURE 3.127.2.16: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



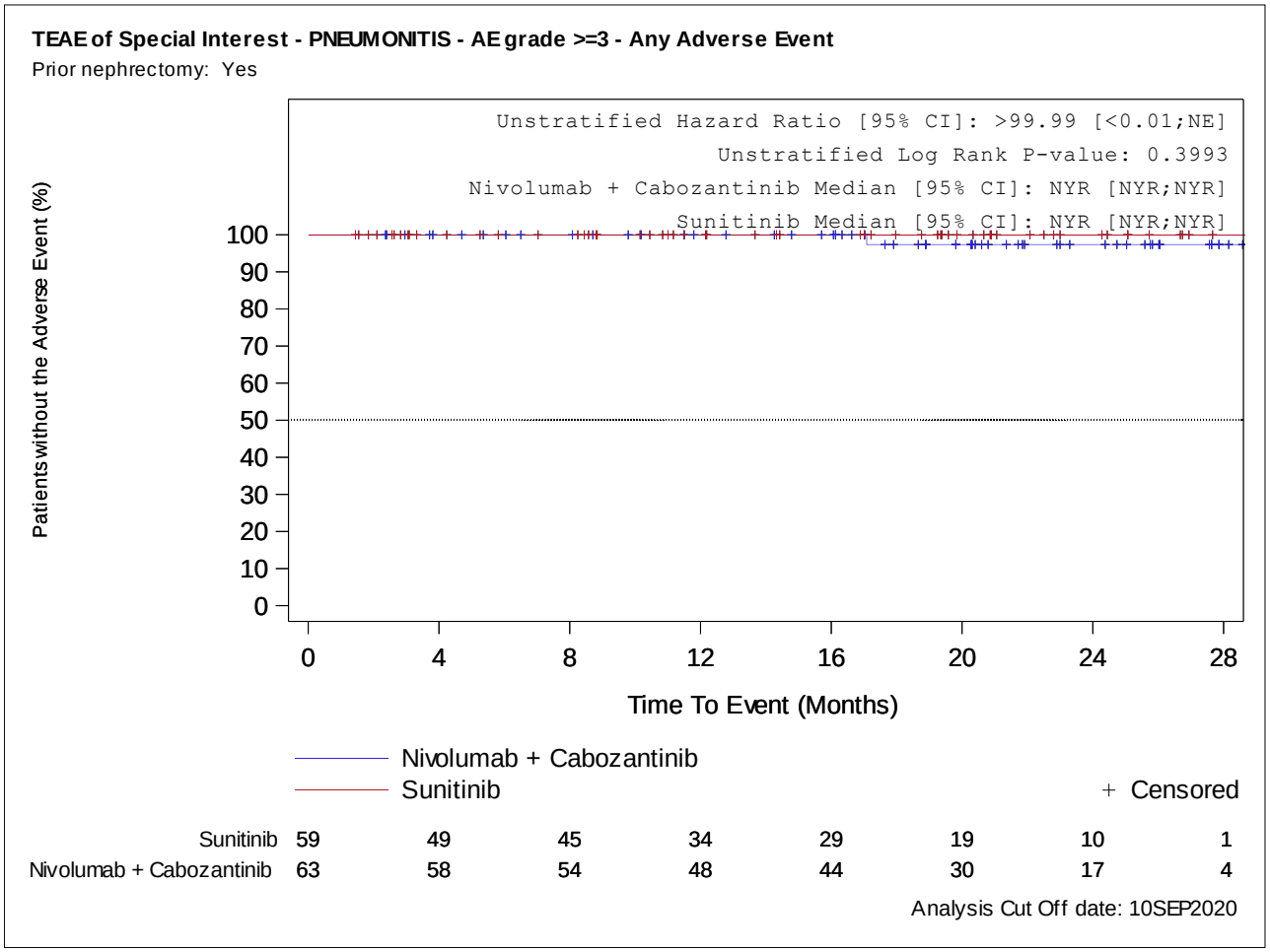

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:28:09

FIGURE 3.127.2.17: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



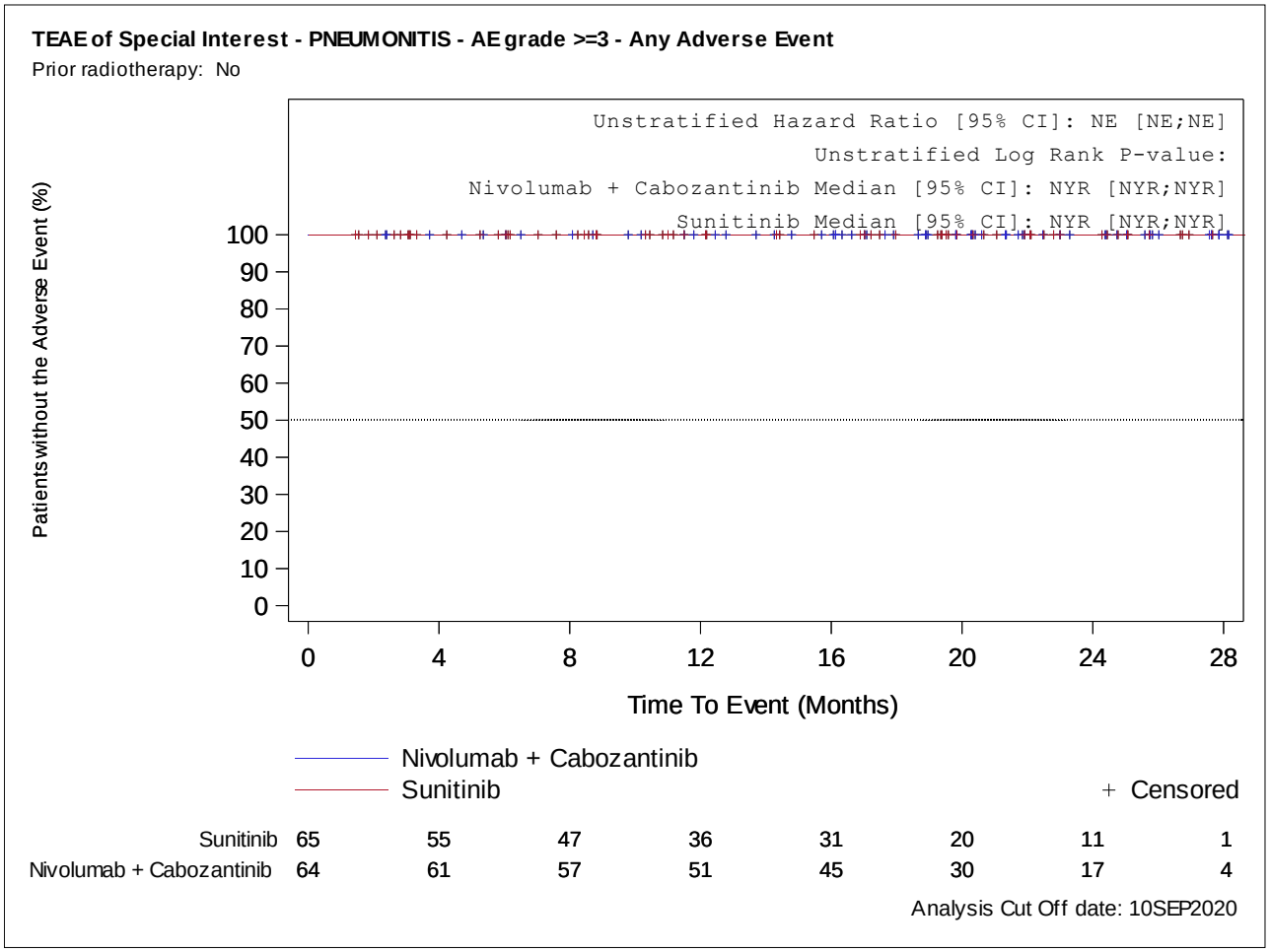

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:29:00

FIGURE 3.127.2.18: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



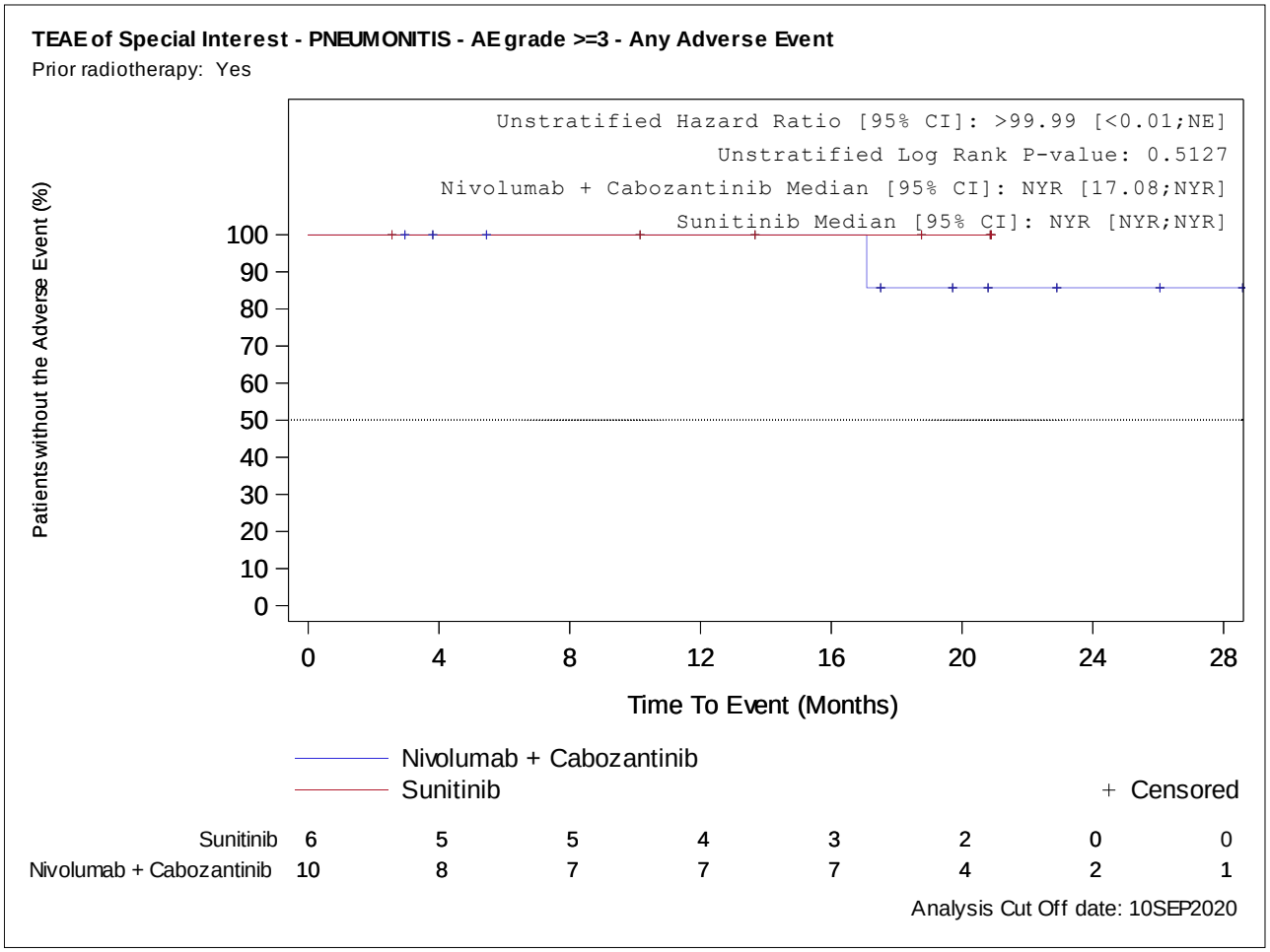

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:29:05

FIGURE 3.127.2.19: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



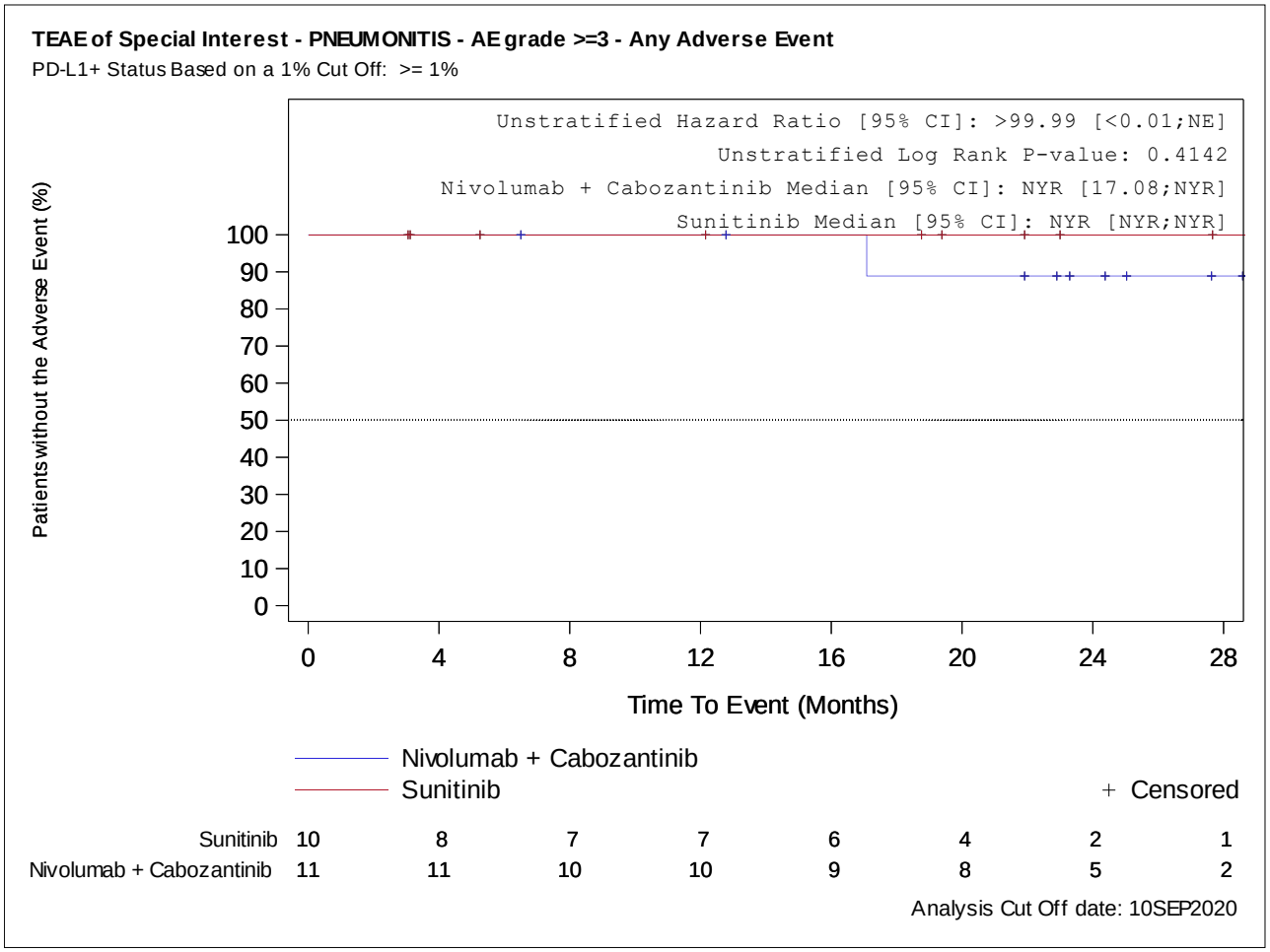

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:29:11

FIGURE 3.127.2.20: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



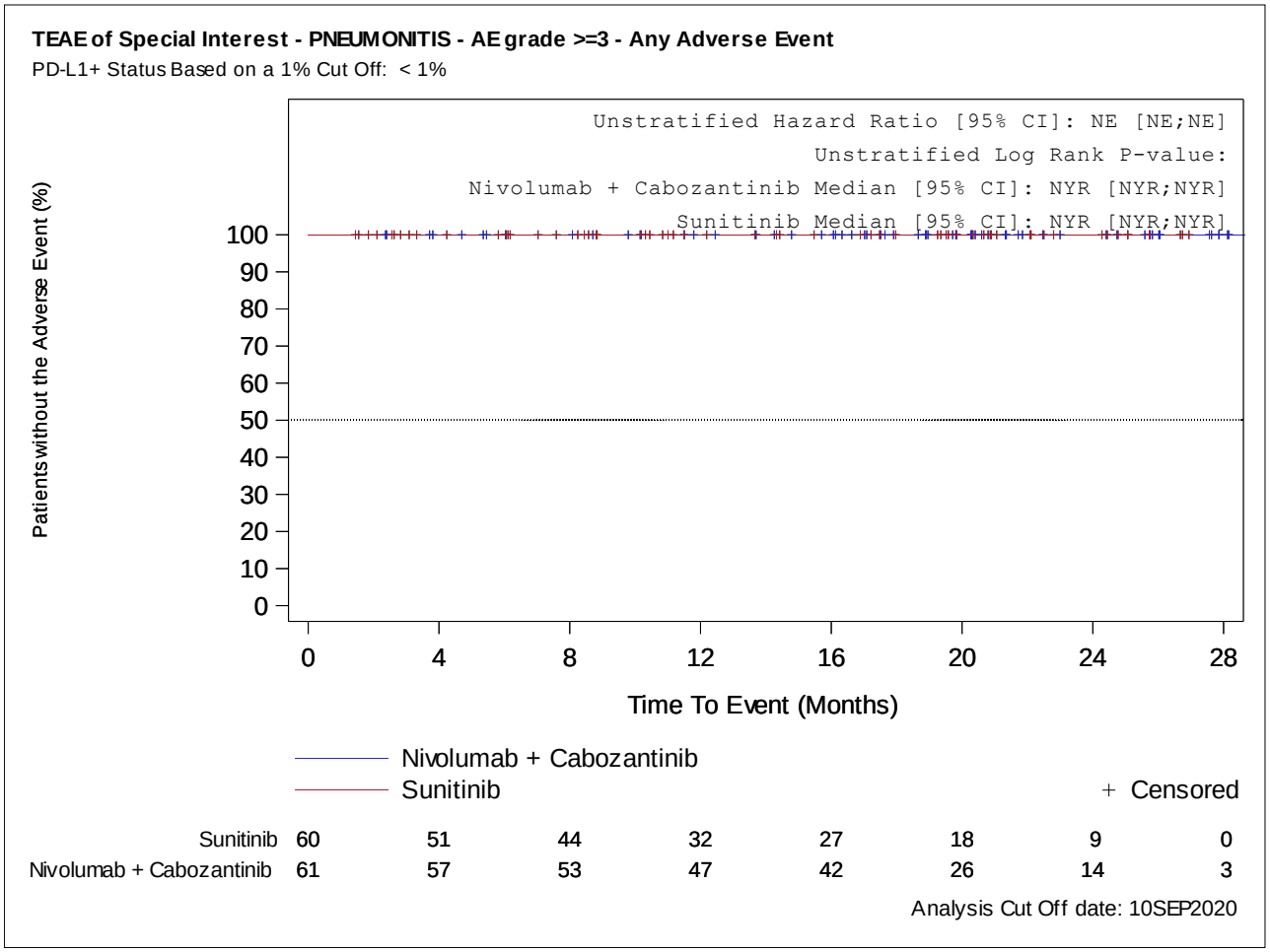

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:29:16

FIGURE 3.127.2.21: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off:  >= 1%



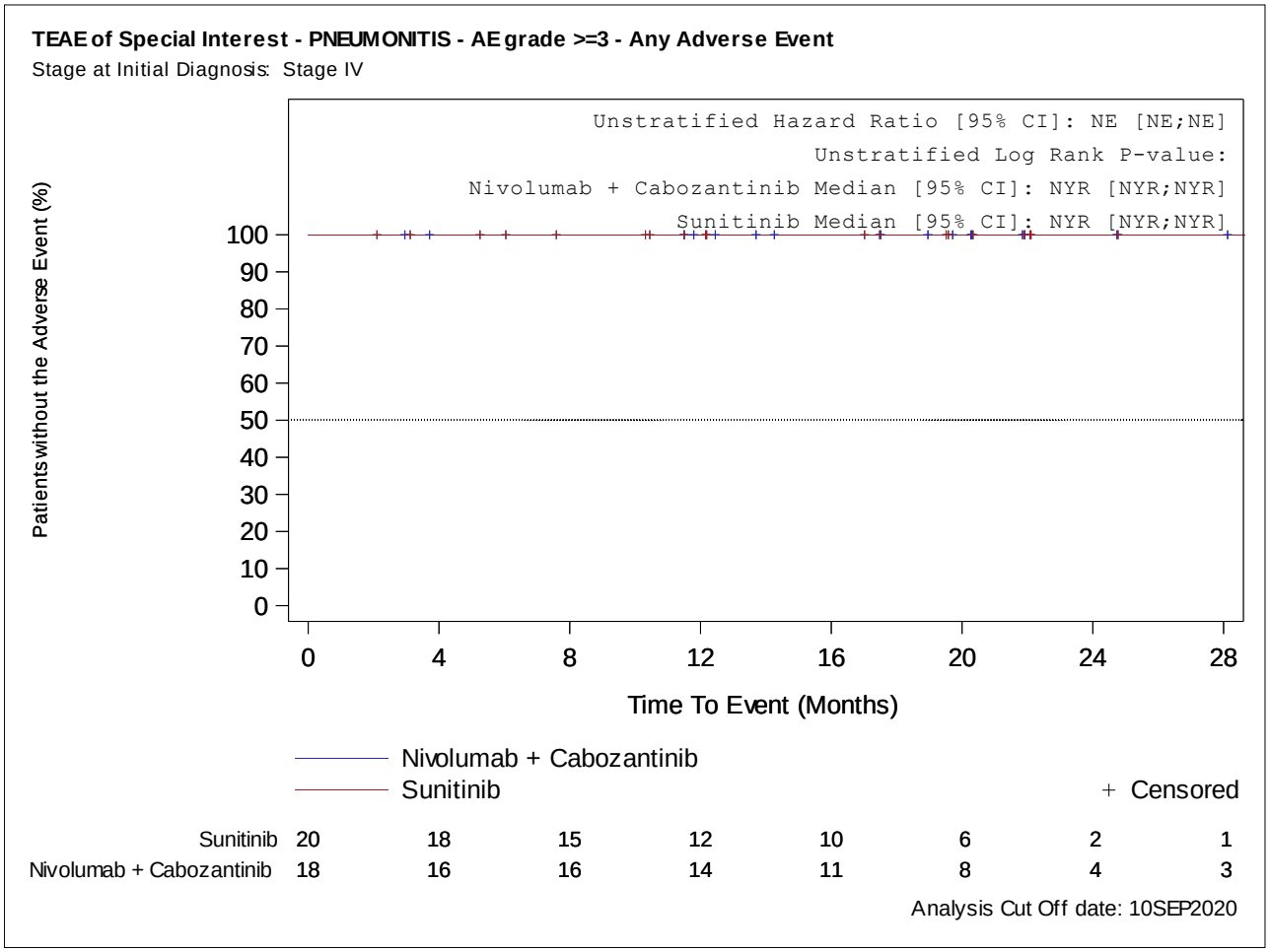

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:29:22

FIGURE 3.127.2.22: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:29:27

FIGURE 3.127.2.23: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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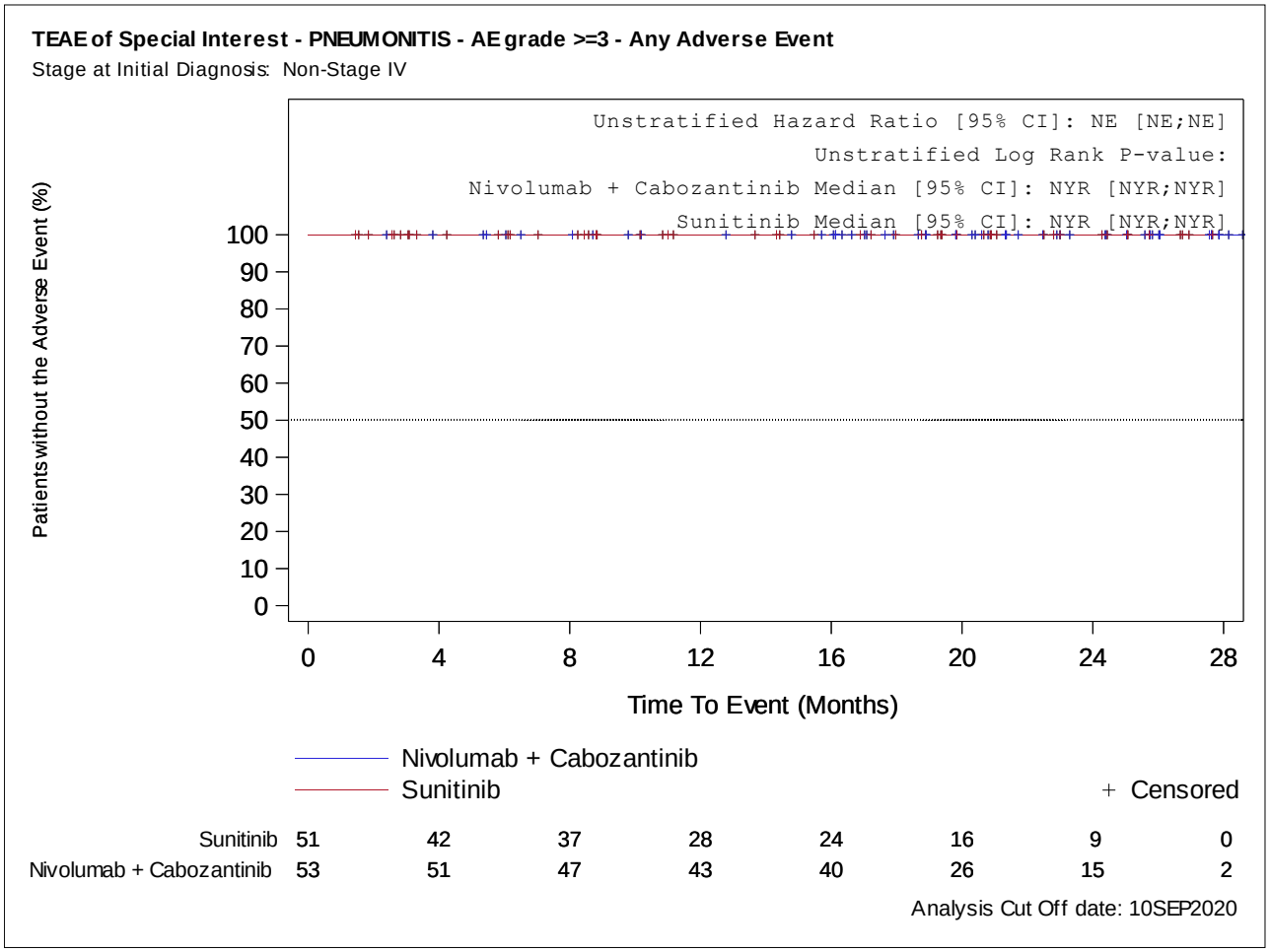
FIGURE 3.127.2.24: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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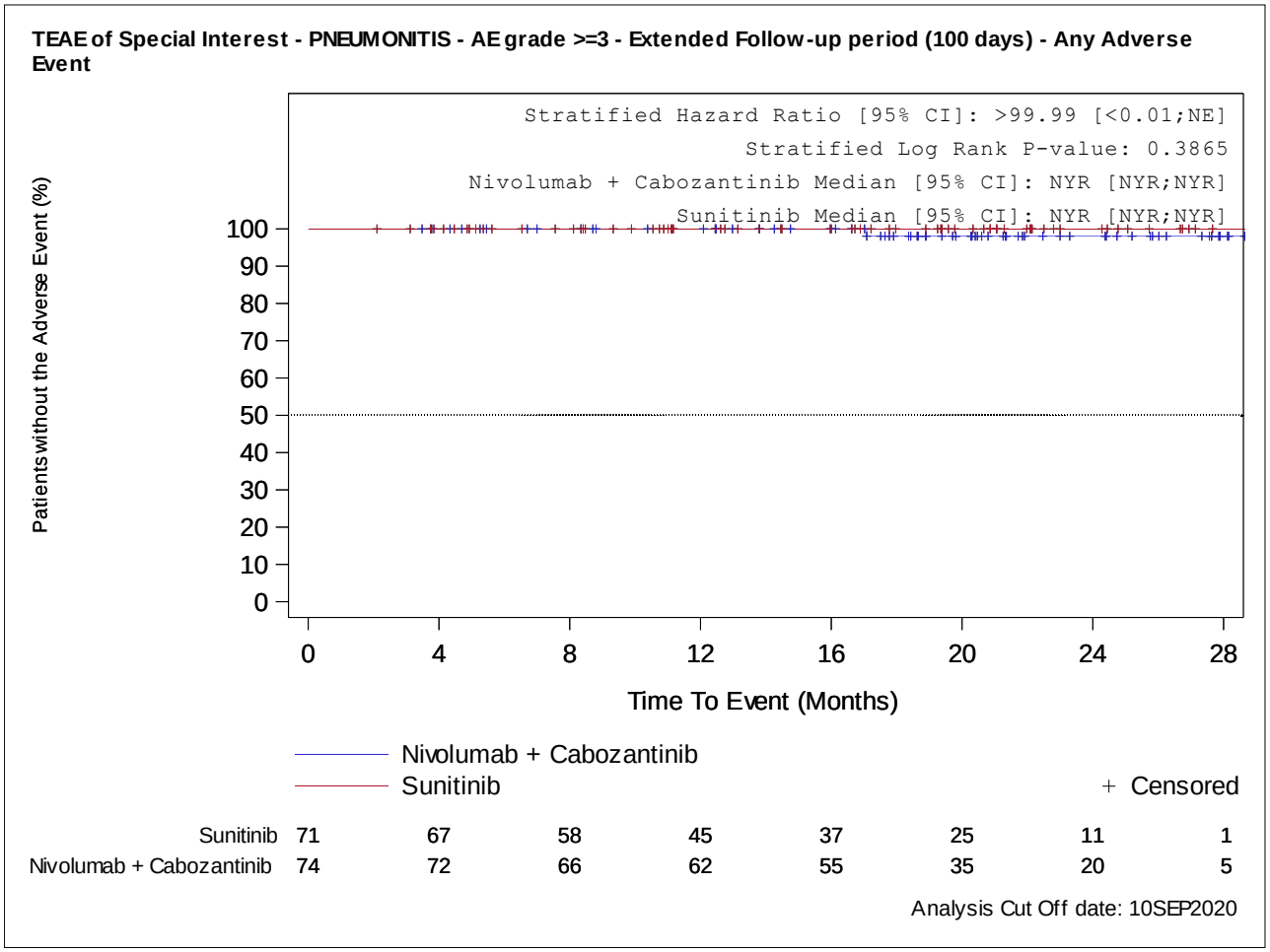
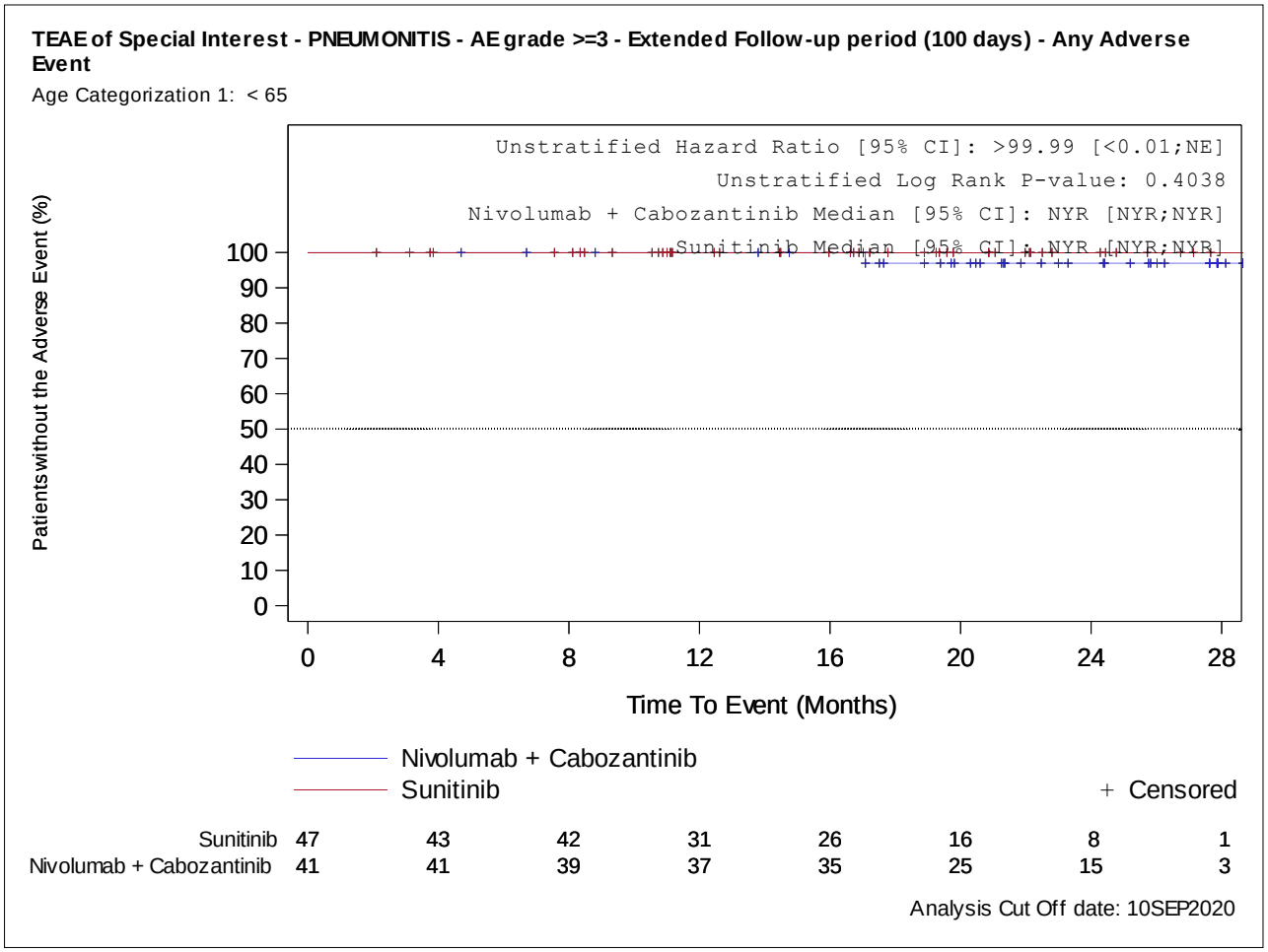
FIGURE 3.128.1: TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



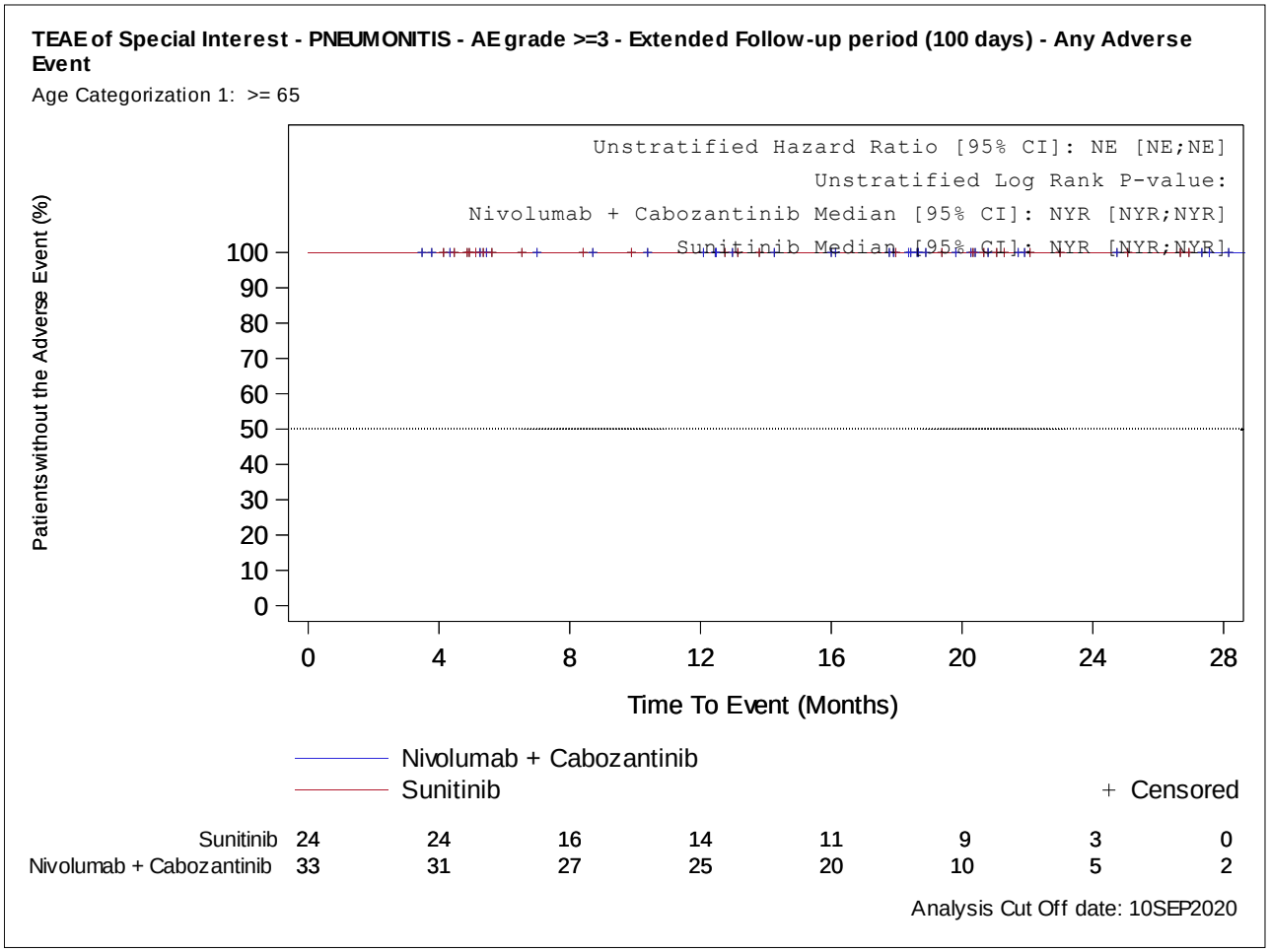

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:33:06

FIGURE 3.128.2.1: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



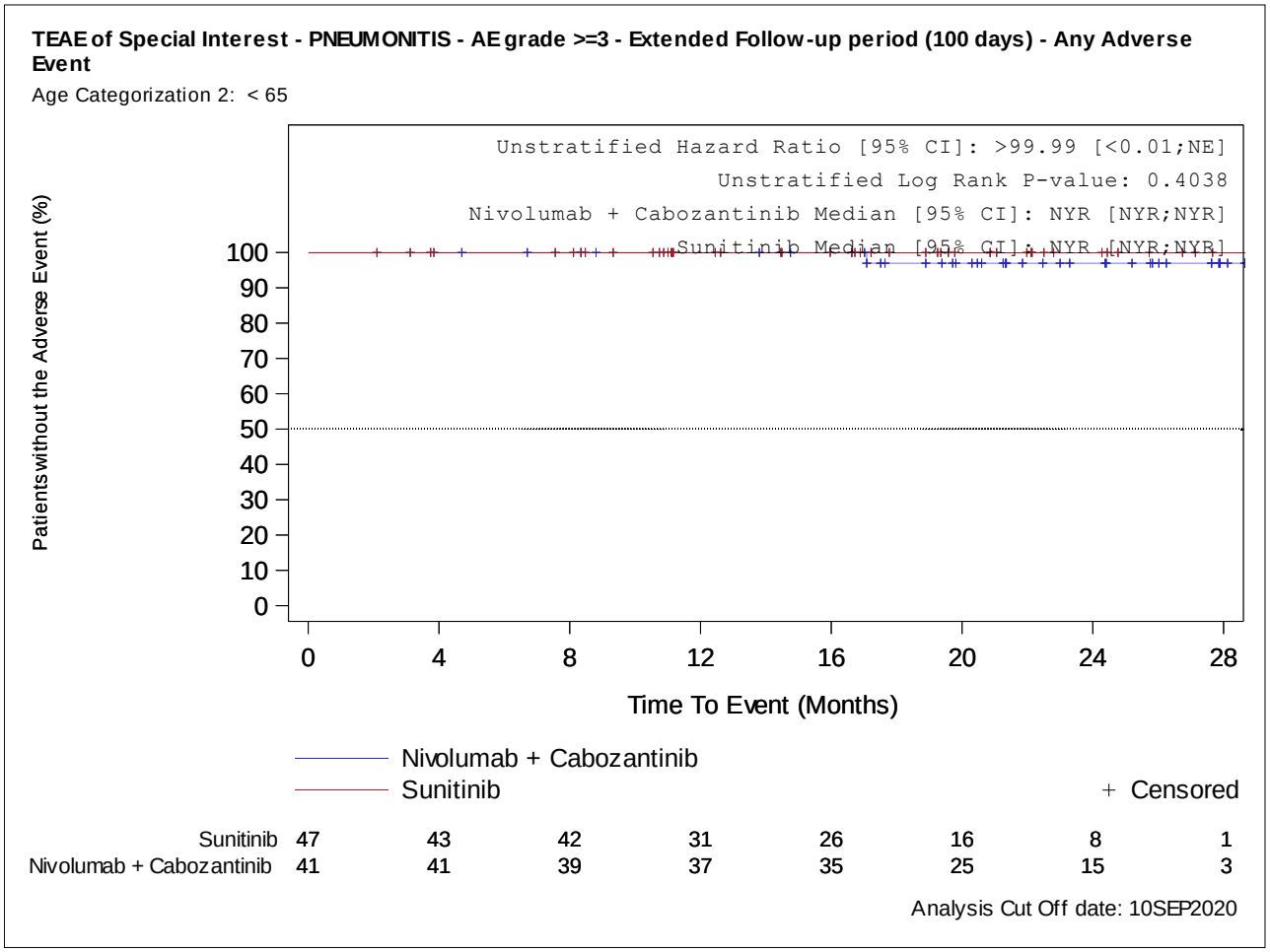

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:33:09

FIGURE 3.128.2.2: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



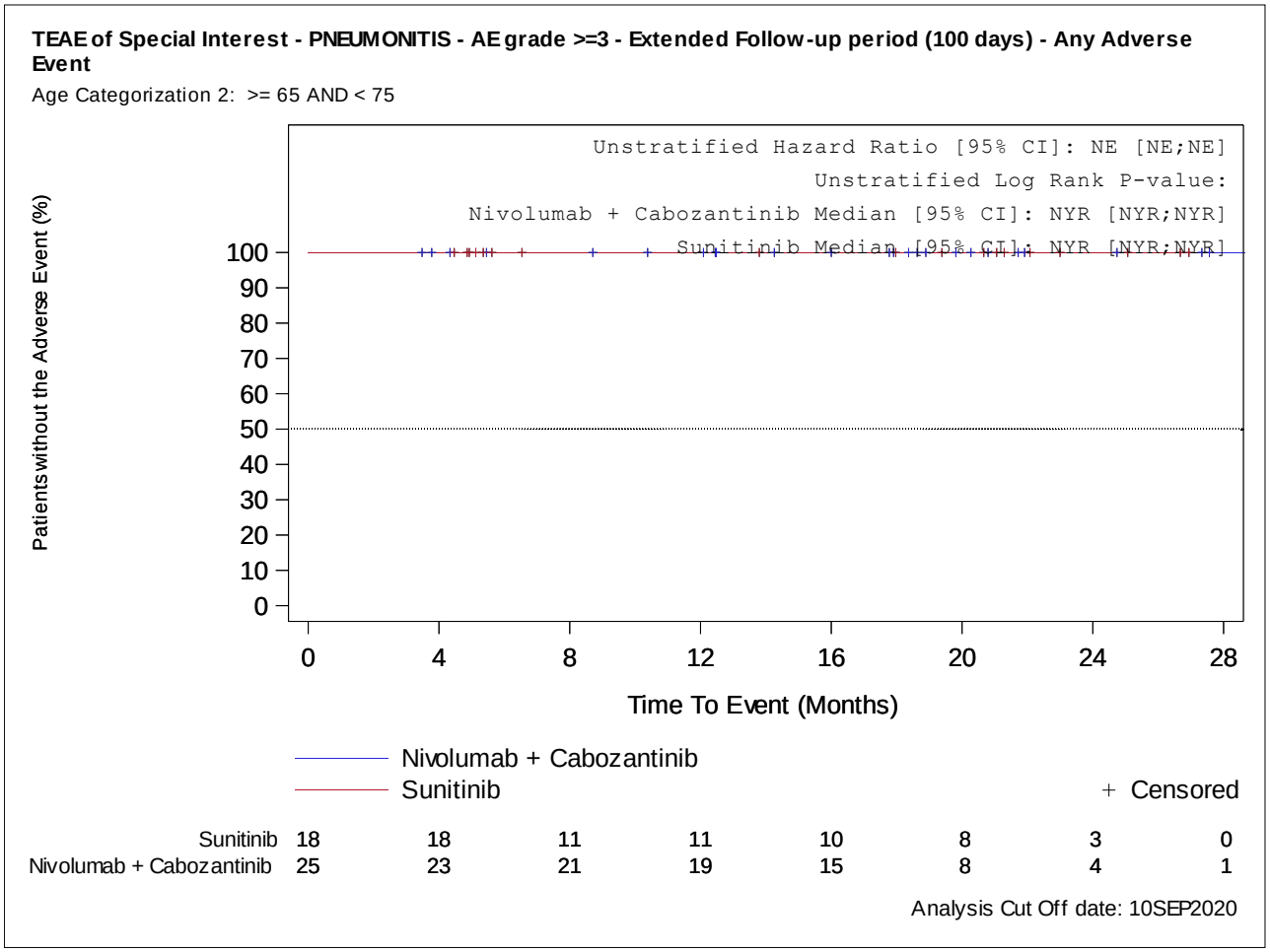

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:33:14

FIGURE 3.128.2.3: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



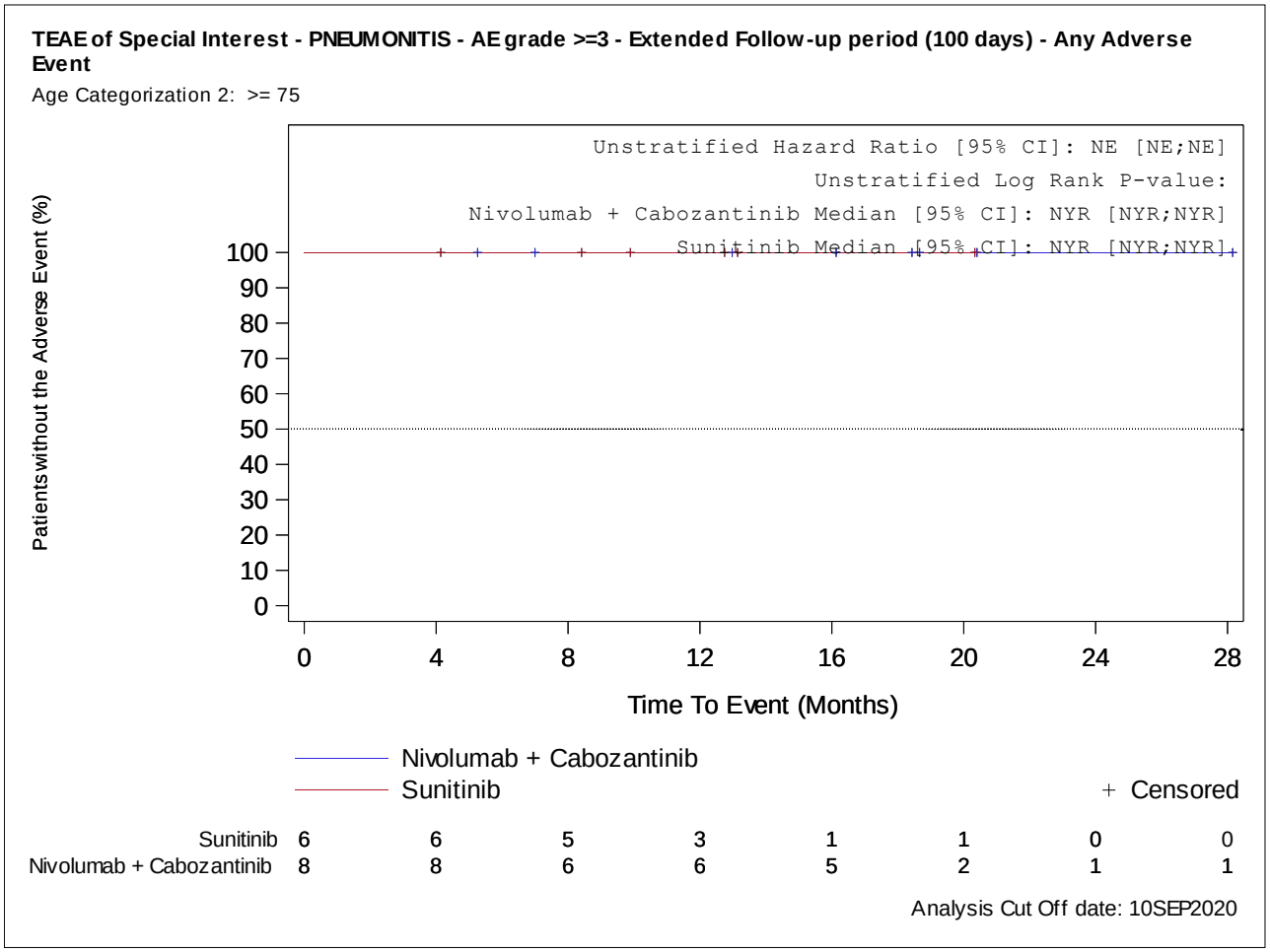

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:33:20

FIGURE 3.128.2.4: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



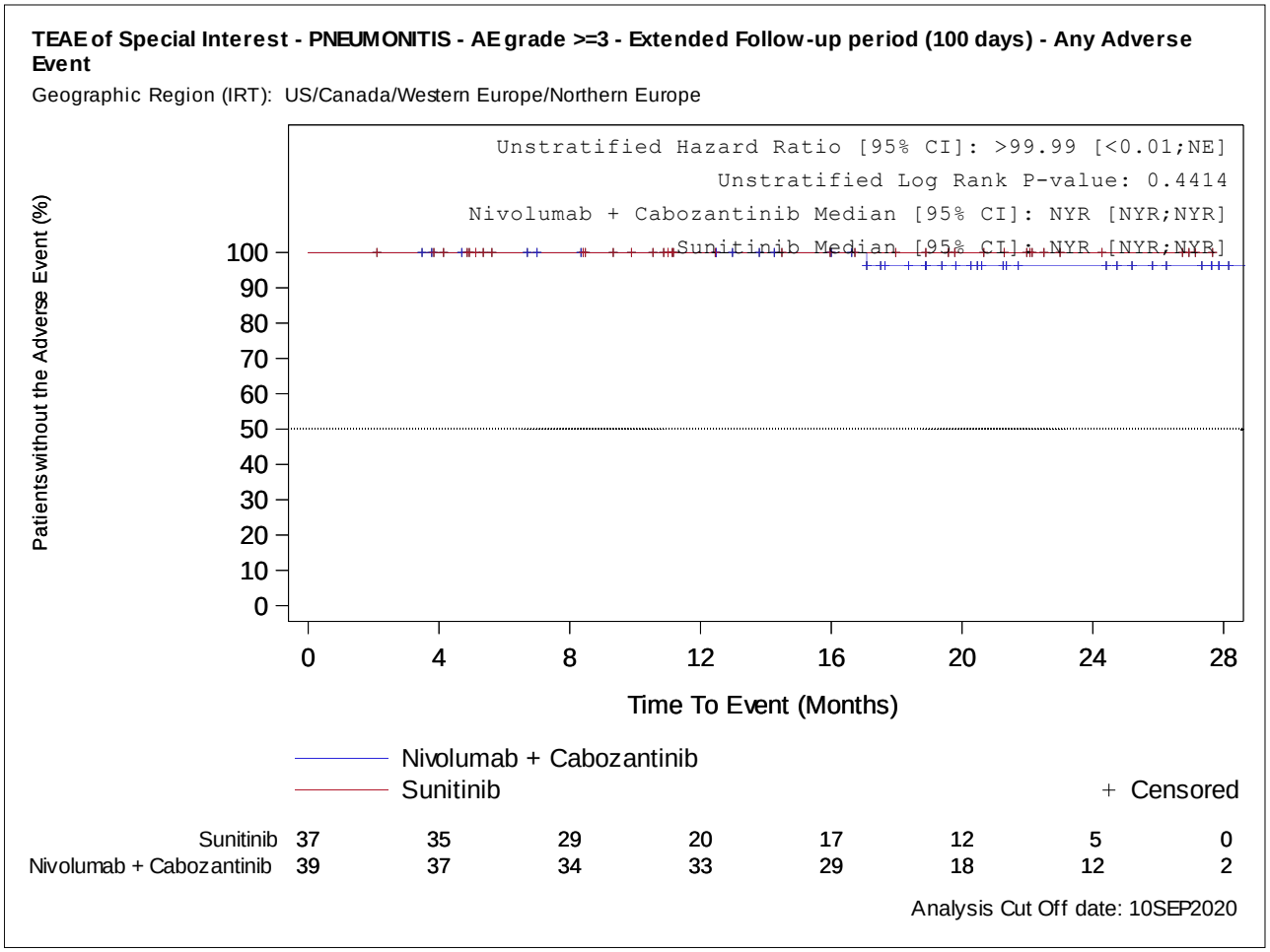

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:33:26

FIGURE 3.128.2.5: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



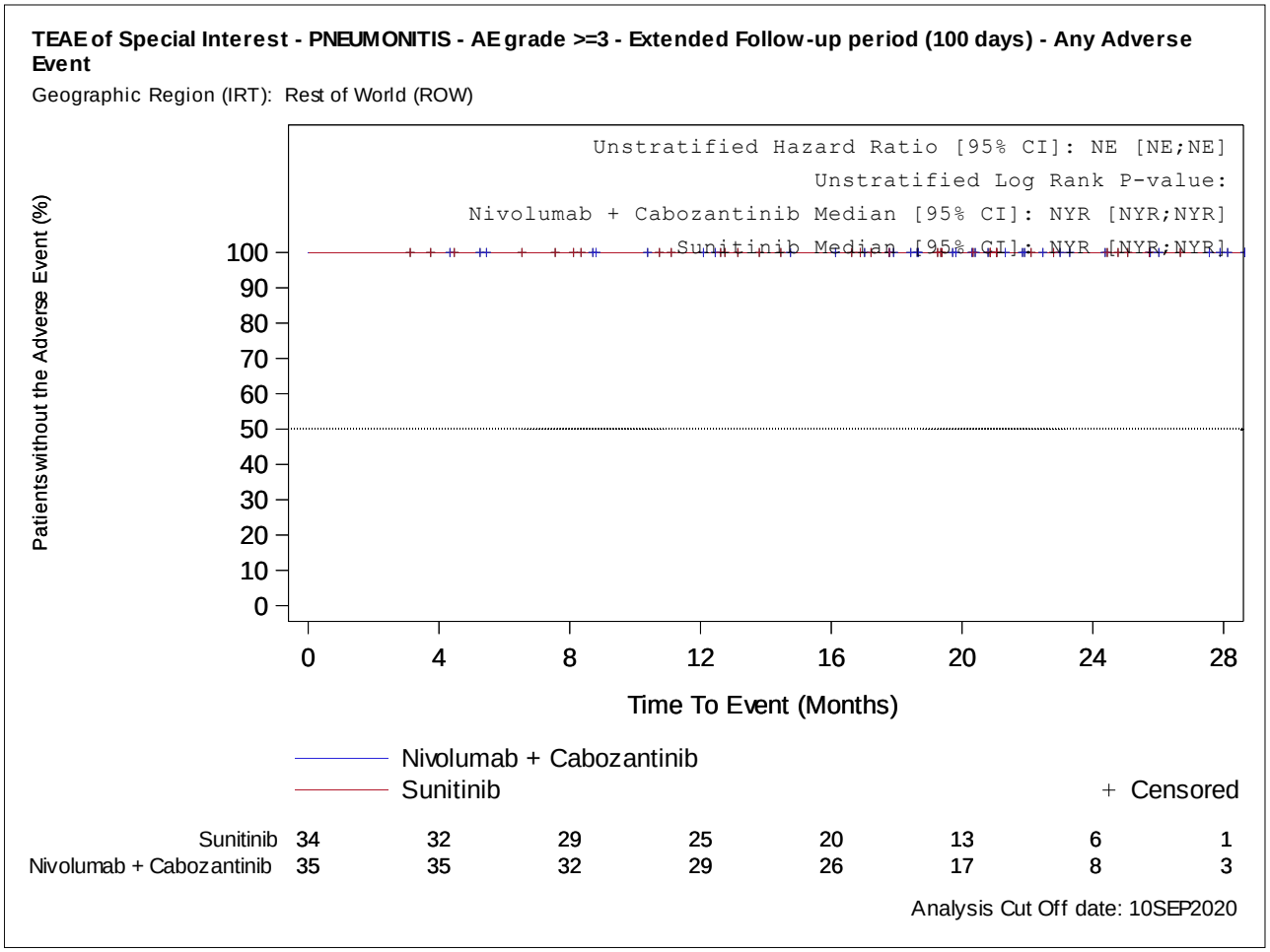

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:33:31

FIGURE 3.128.2.6: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



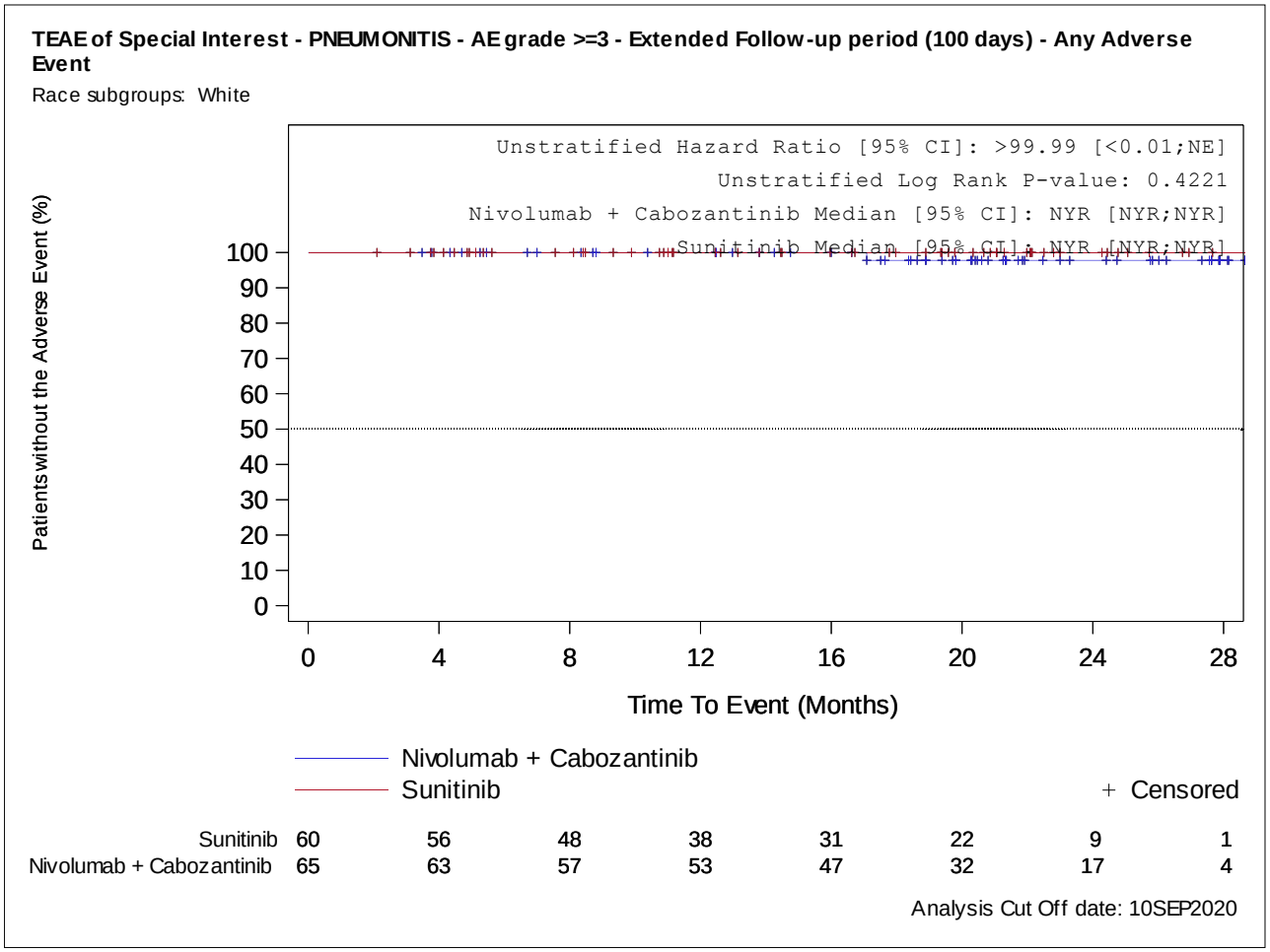

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:33:37

FIGURE 3.128.2.7: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



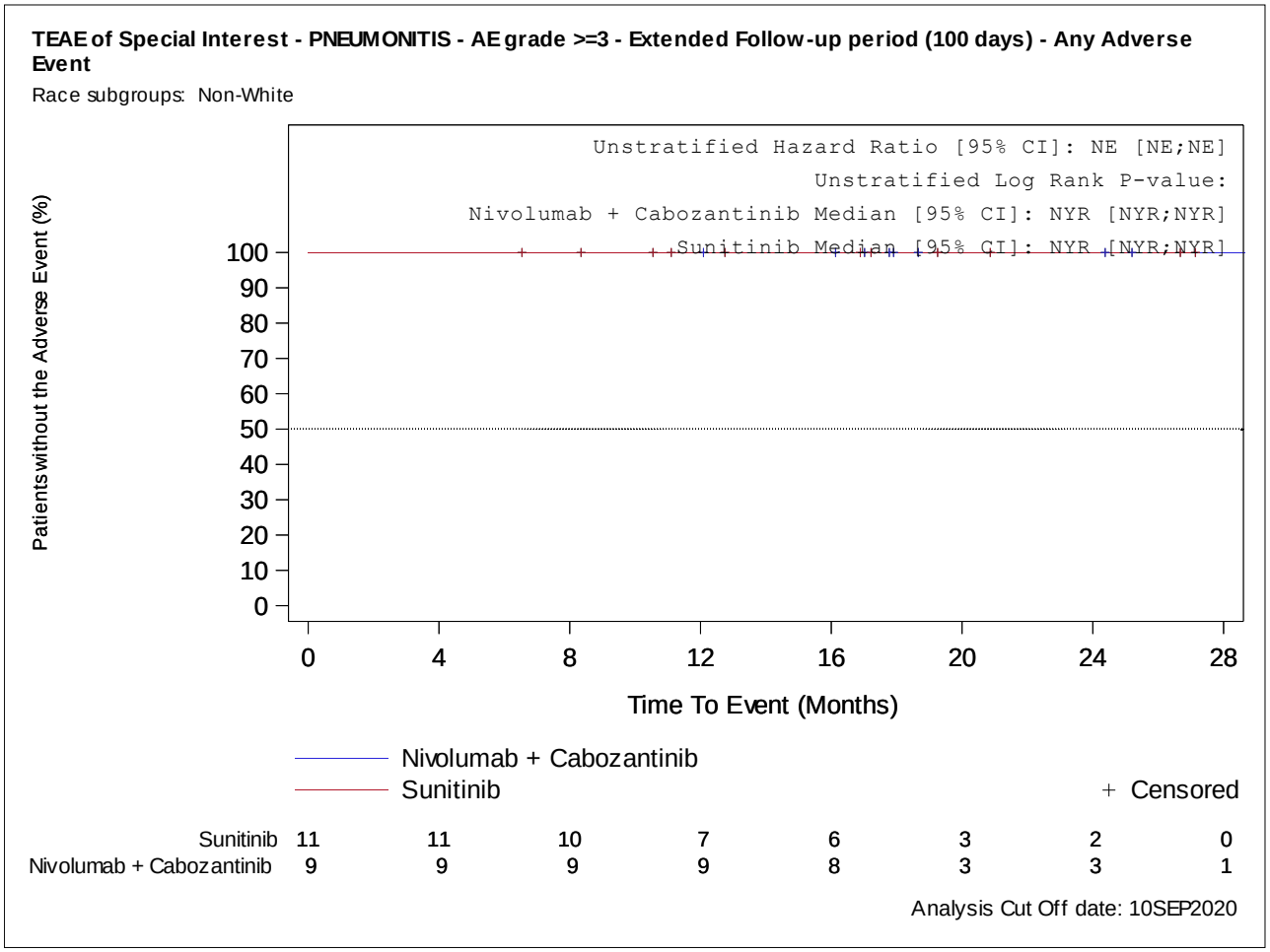

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:33:43

FIGURE 3.128.2.8: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



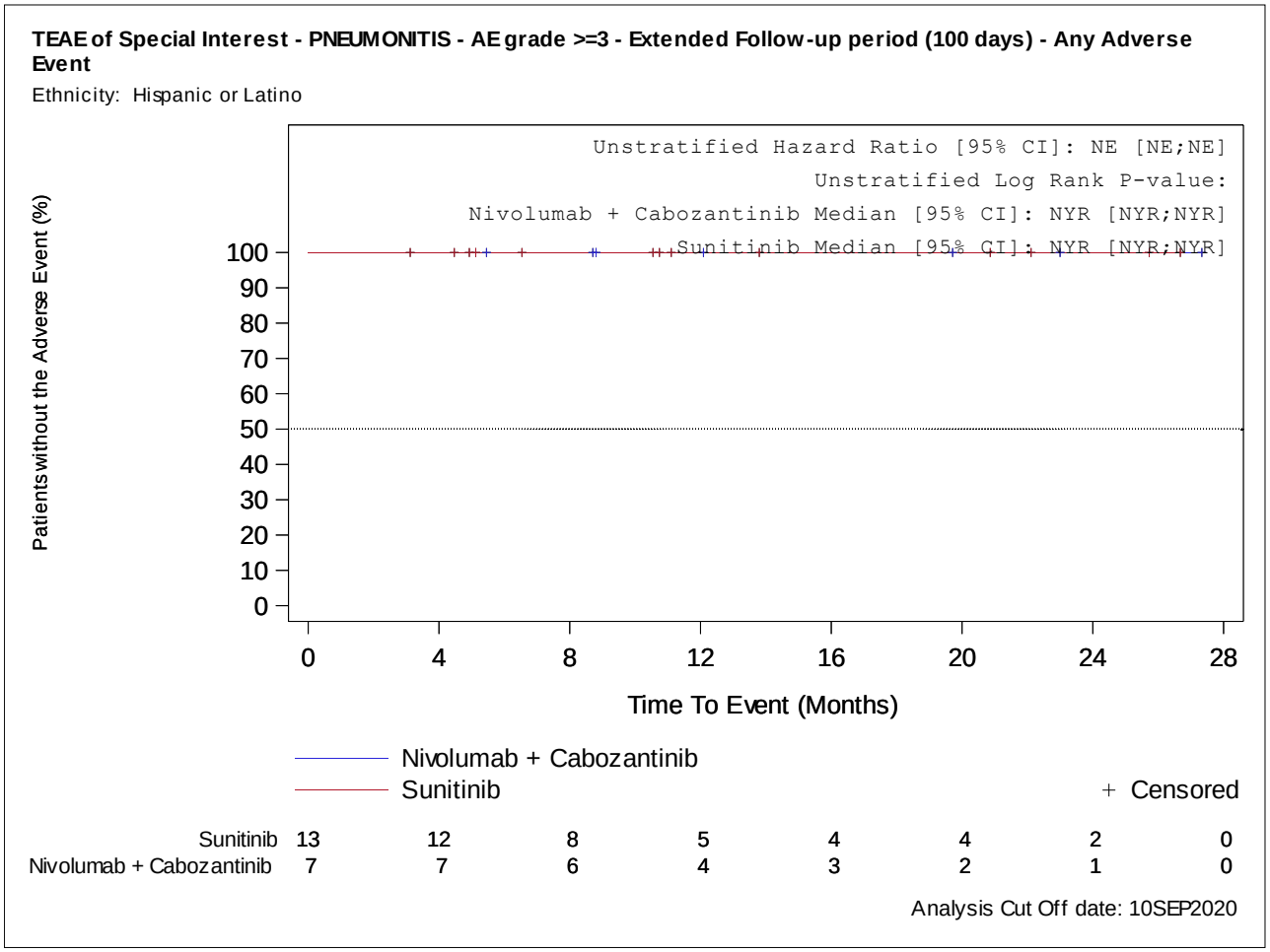

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:33:48

FIGURE 3.128.2.9: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



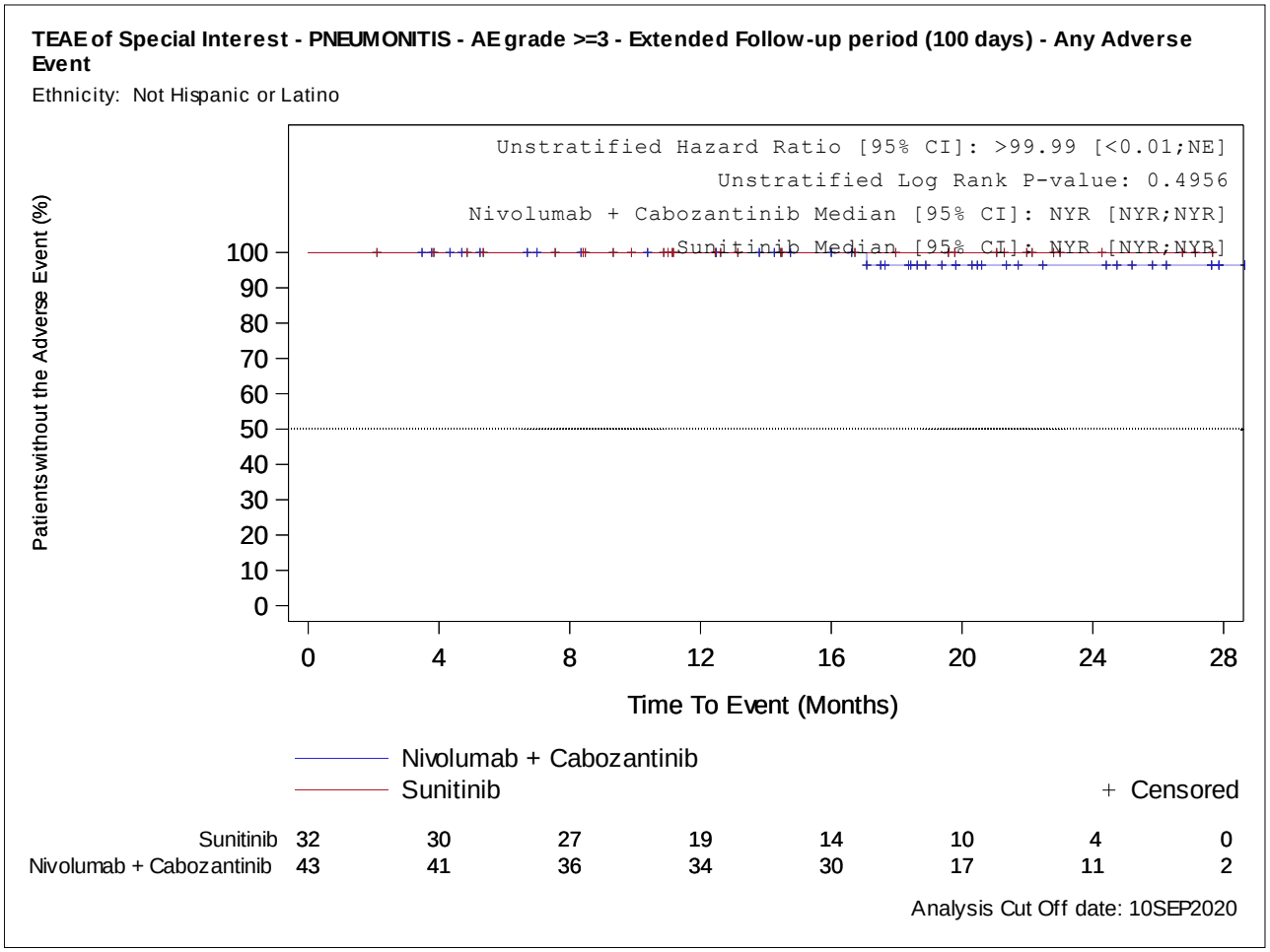

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:33:54

FIGURE 3.128.2.10: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



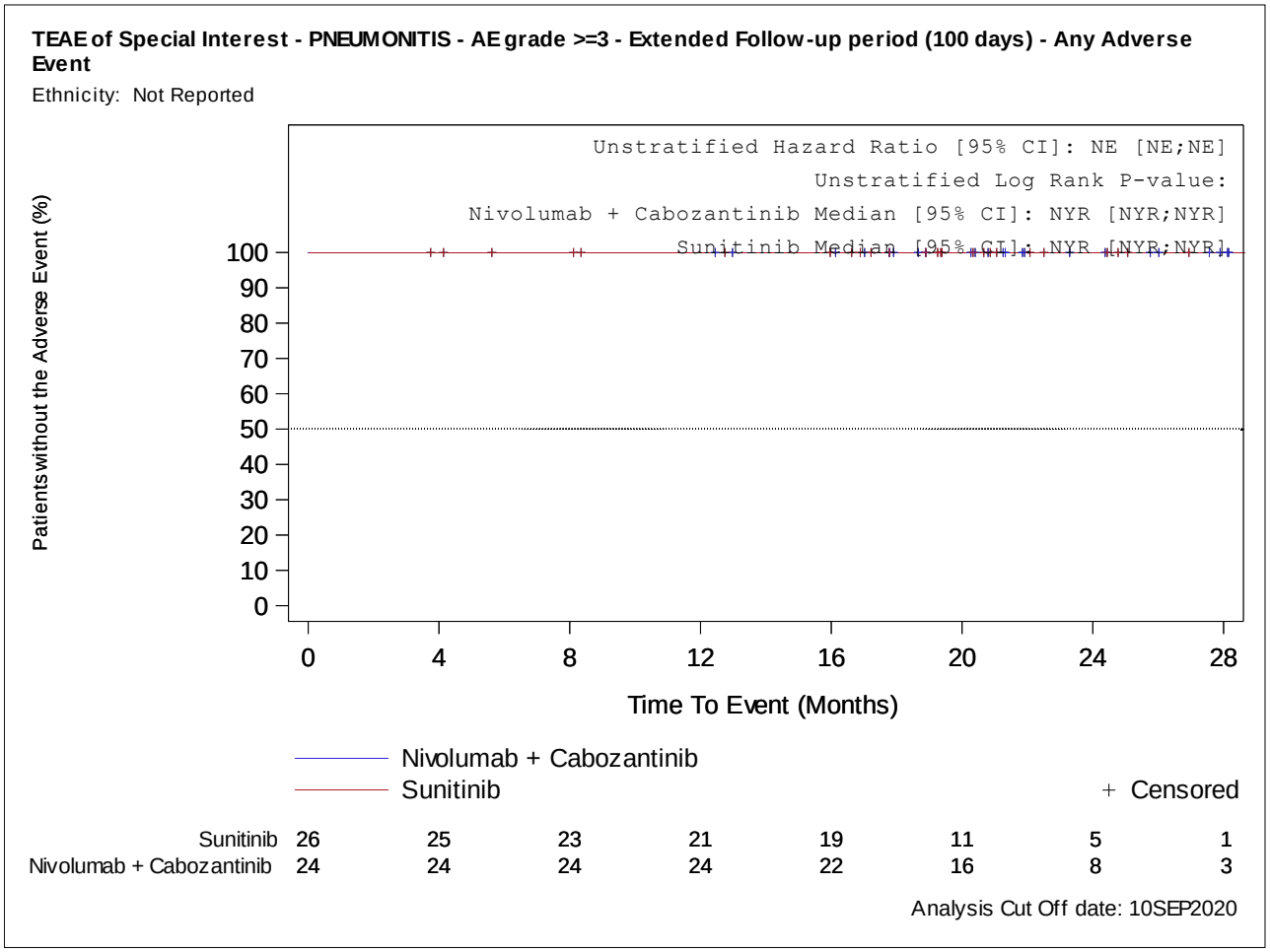

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:34:00

FIGURE 3.128.2.11: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



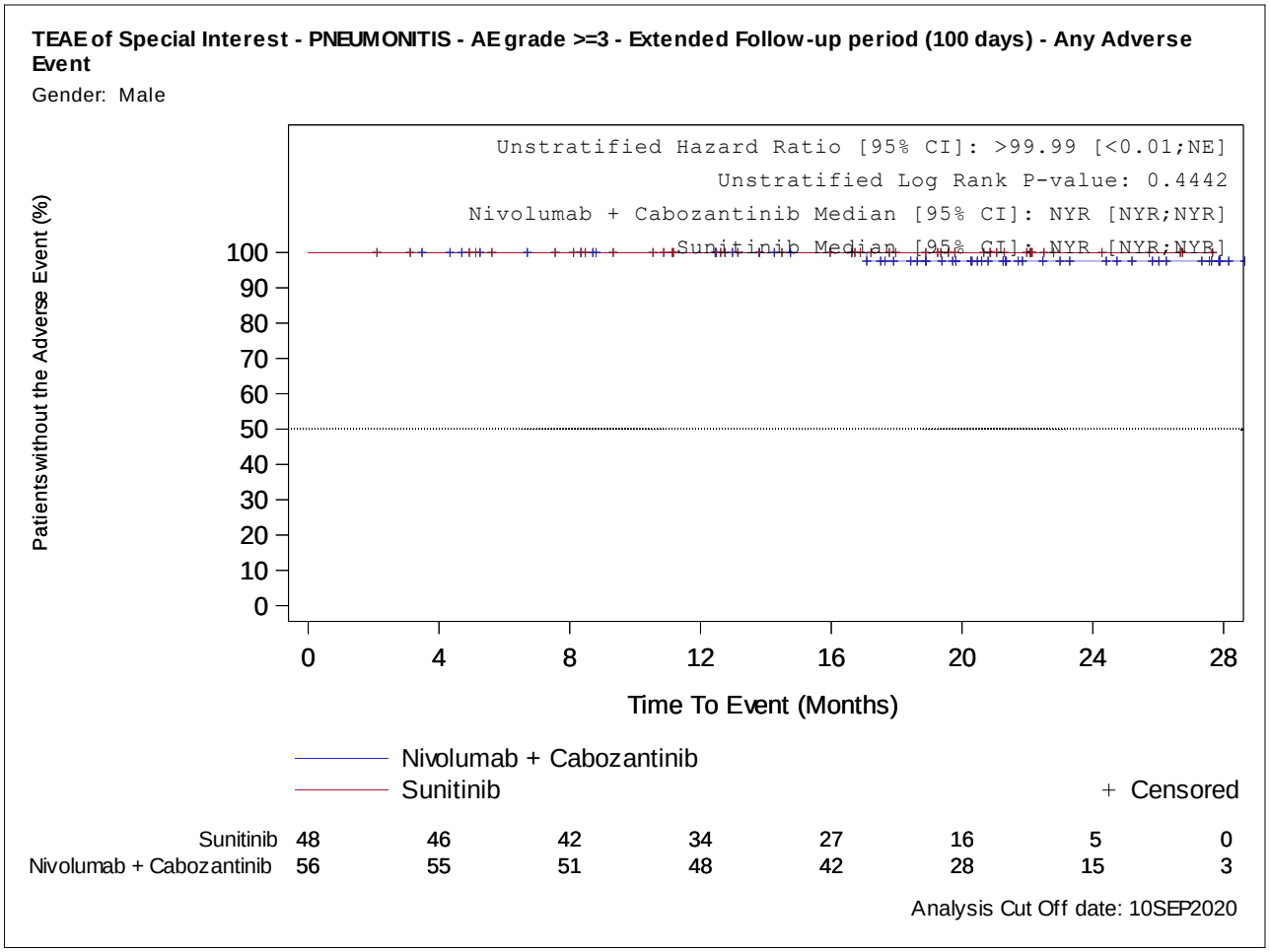

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:34:05

FIGURE 3.128.2.12: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



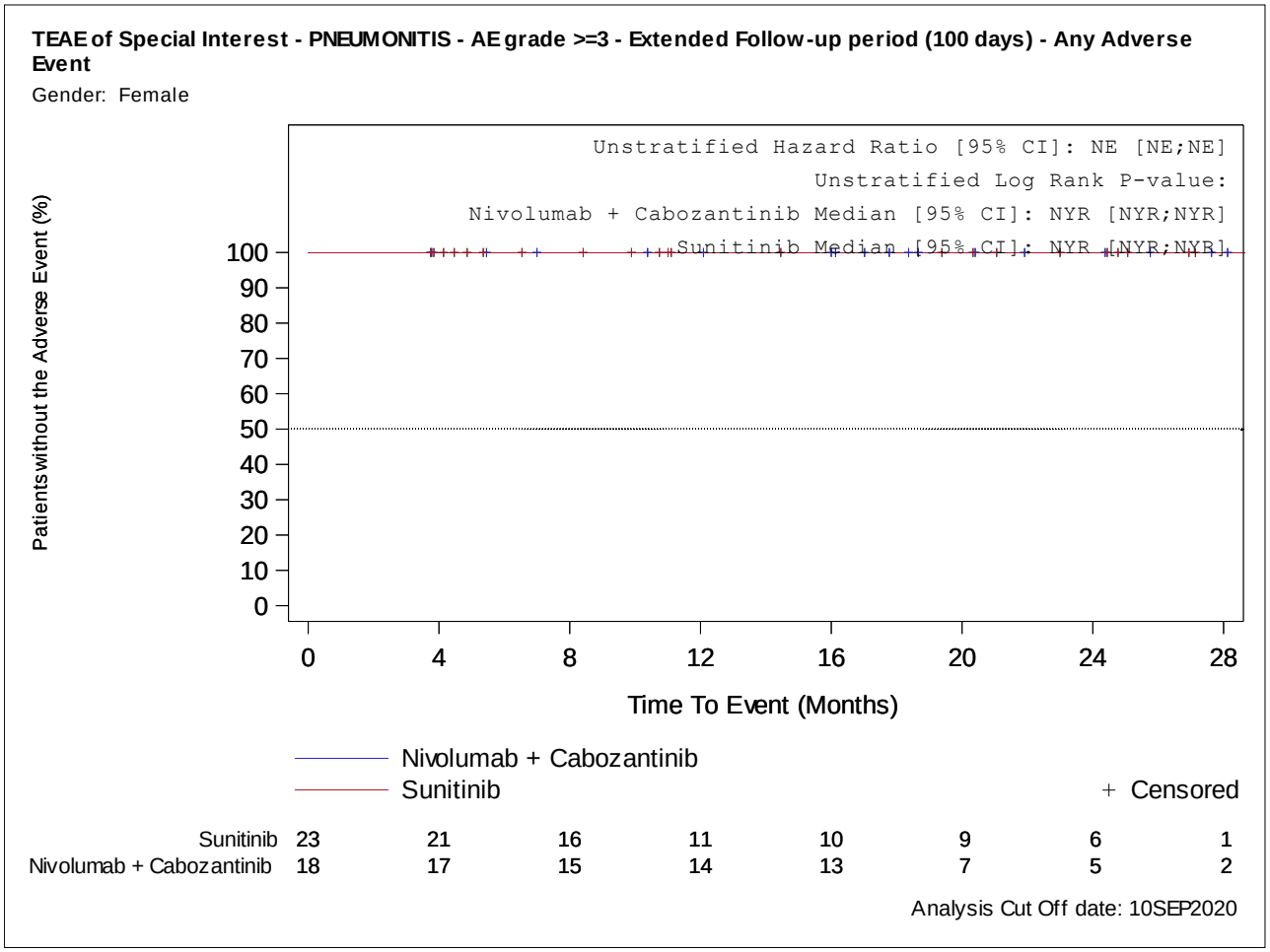

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:34:12

FIGURE 3.128.2.13: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



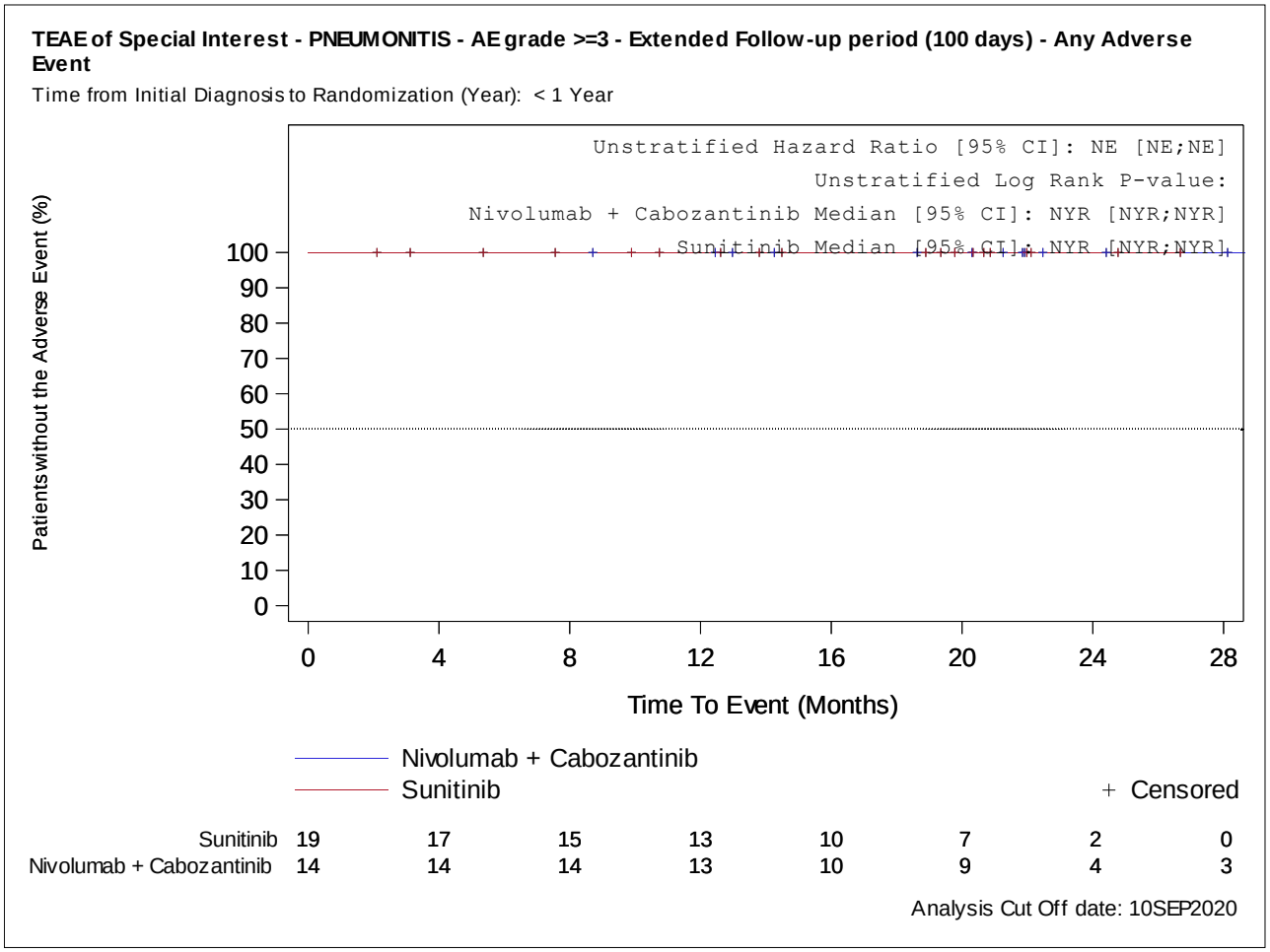

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:34:18

FIGURE 3.128.2.14: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



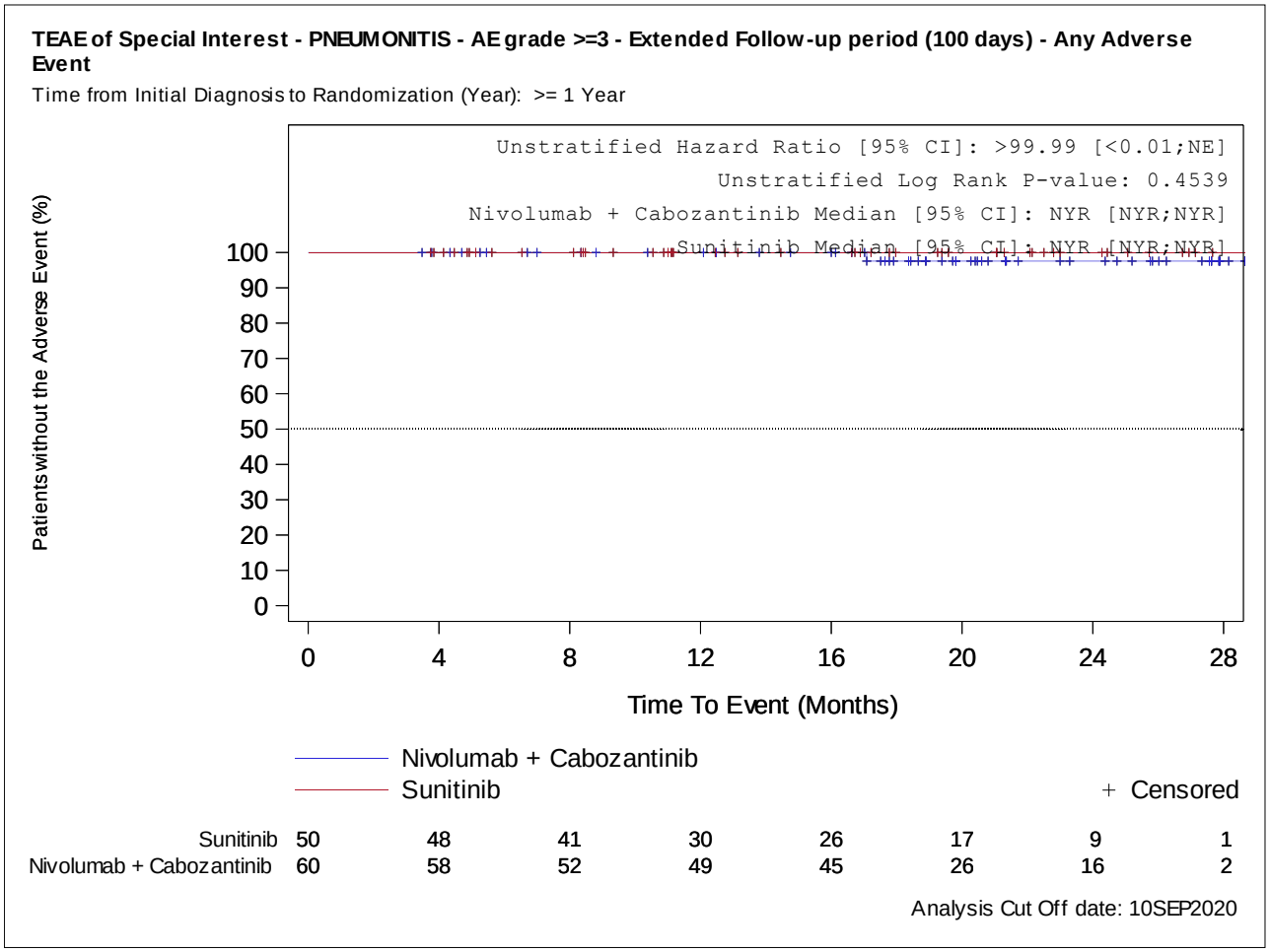

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:34:23

FIGURE 3.128.2.15: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



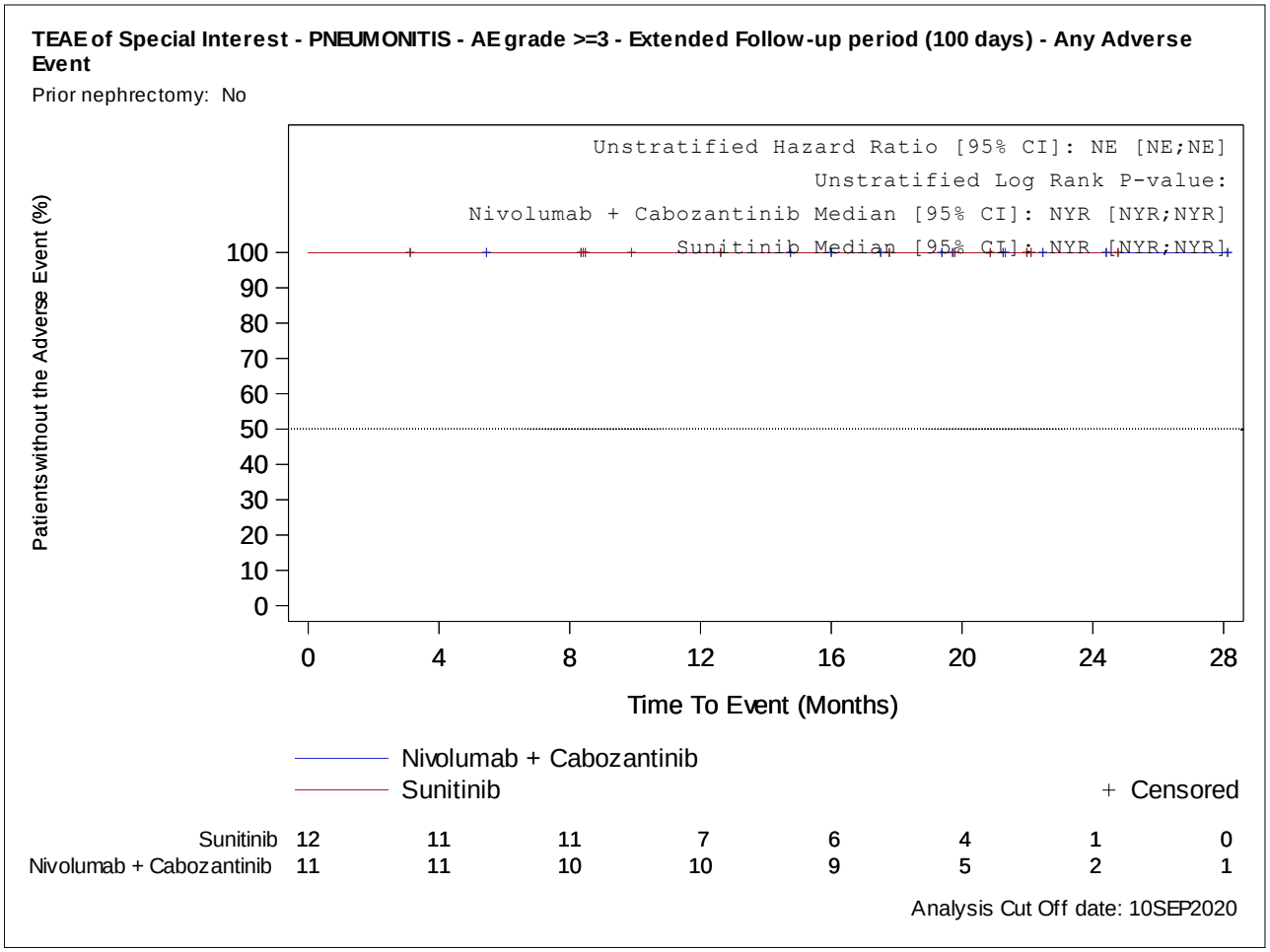

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:34:39

FIGURE 3.128.2.16: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



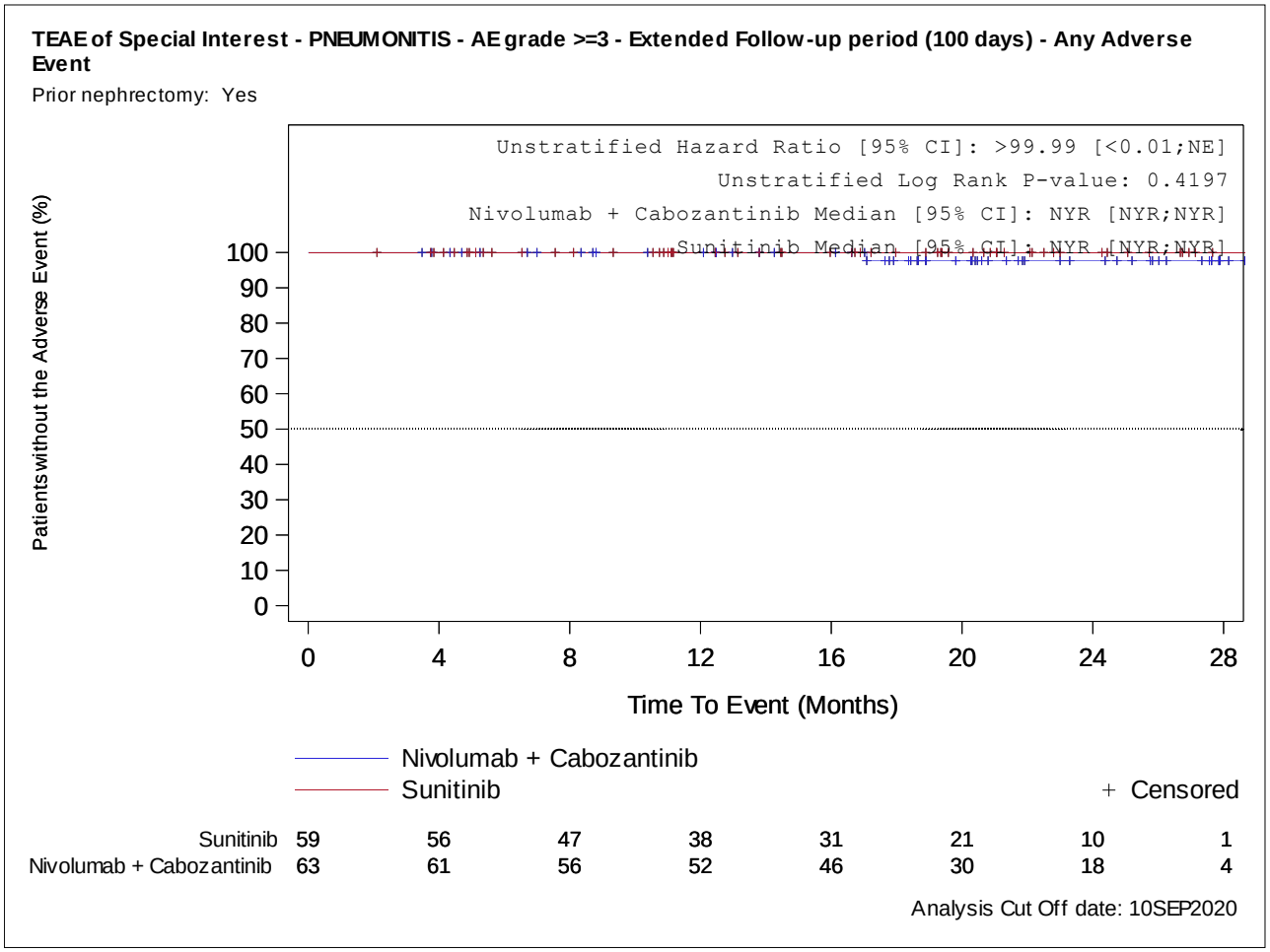

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:34:45

FIGURE 3.128.2.17: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



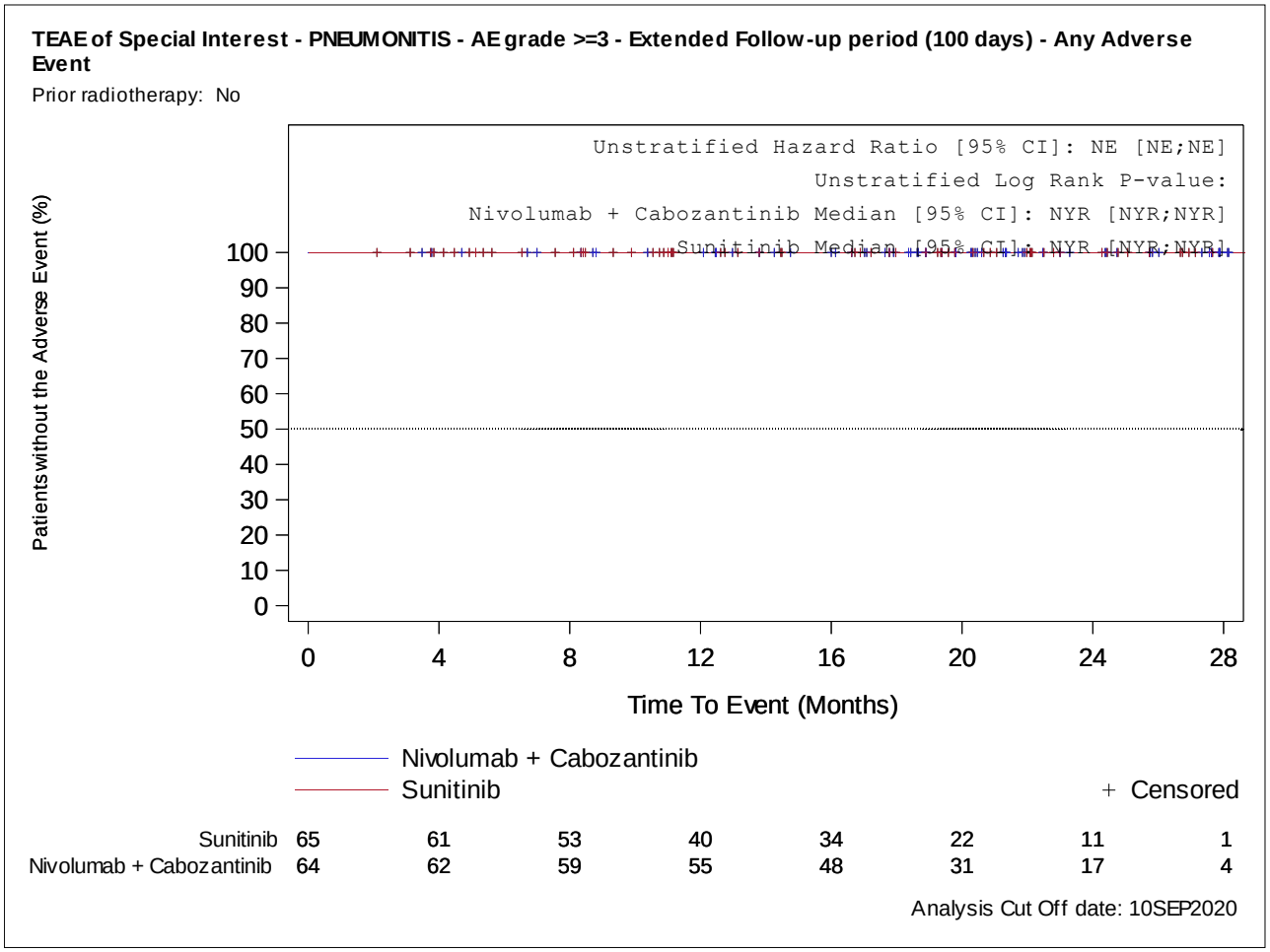

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:35:34

FIGURE 3.128.2.18: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



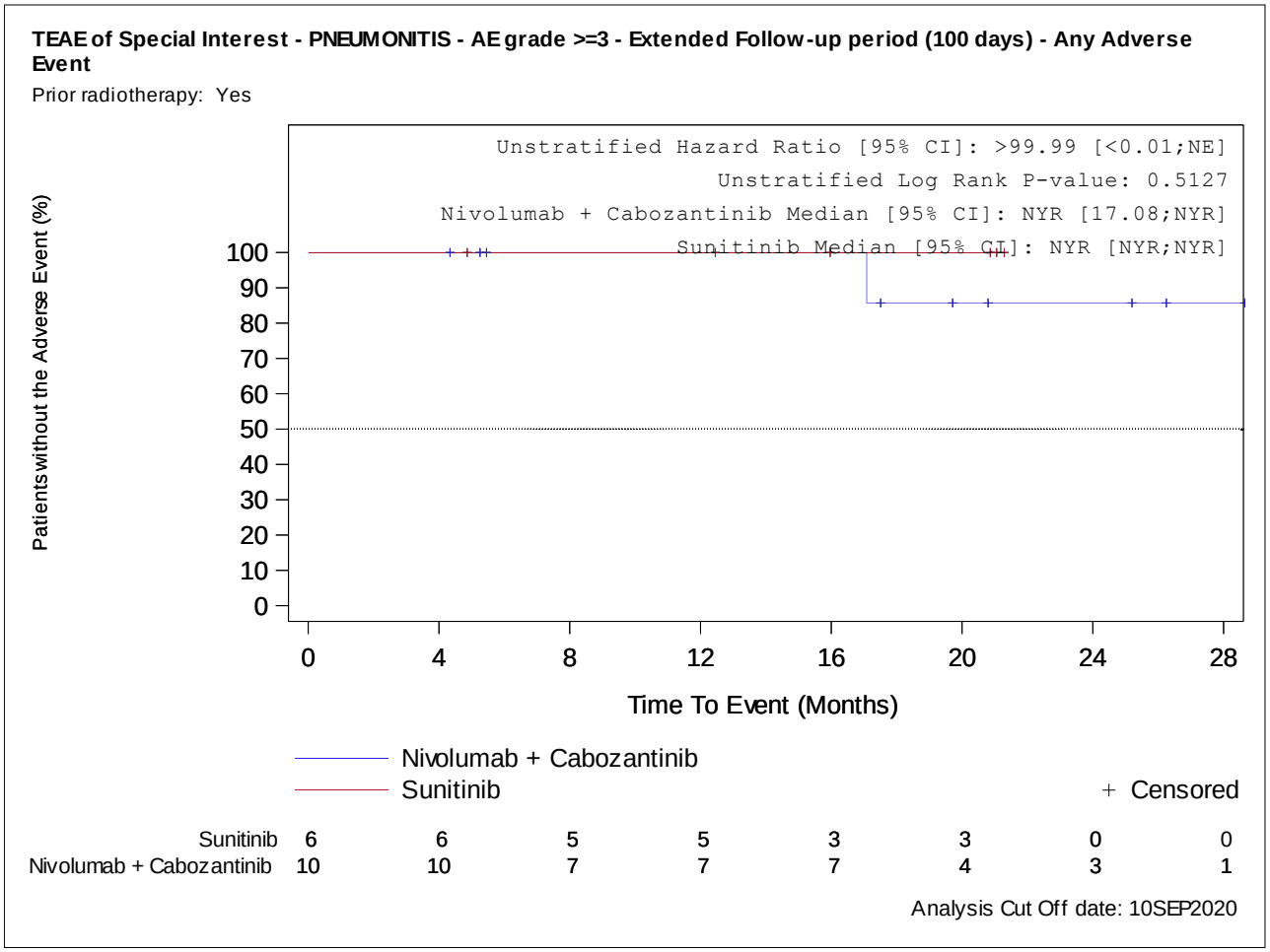

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:35:39

FIGURE 3.128.2.19: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



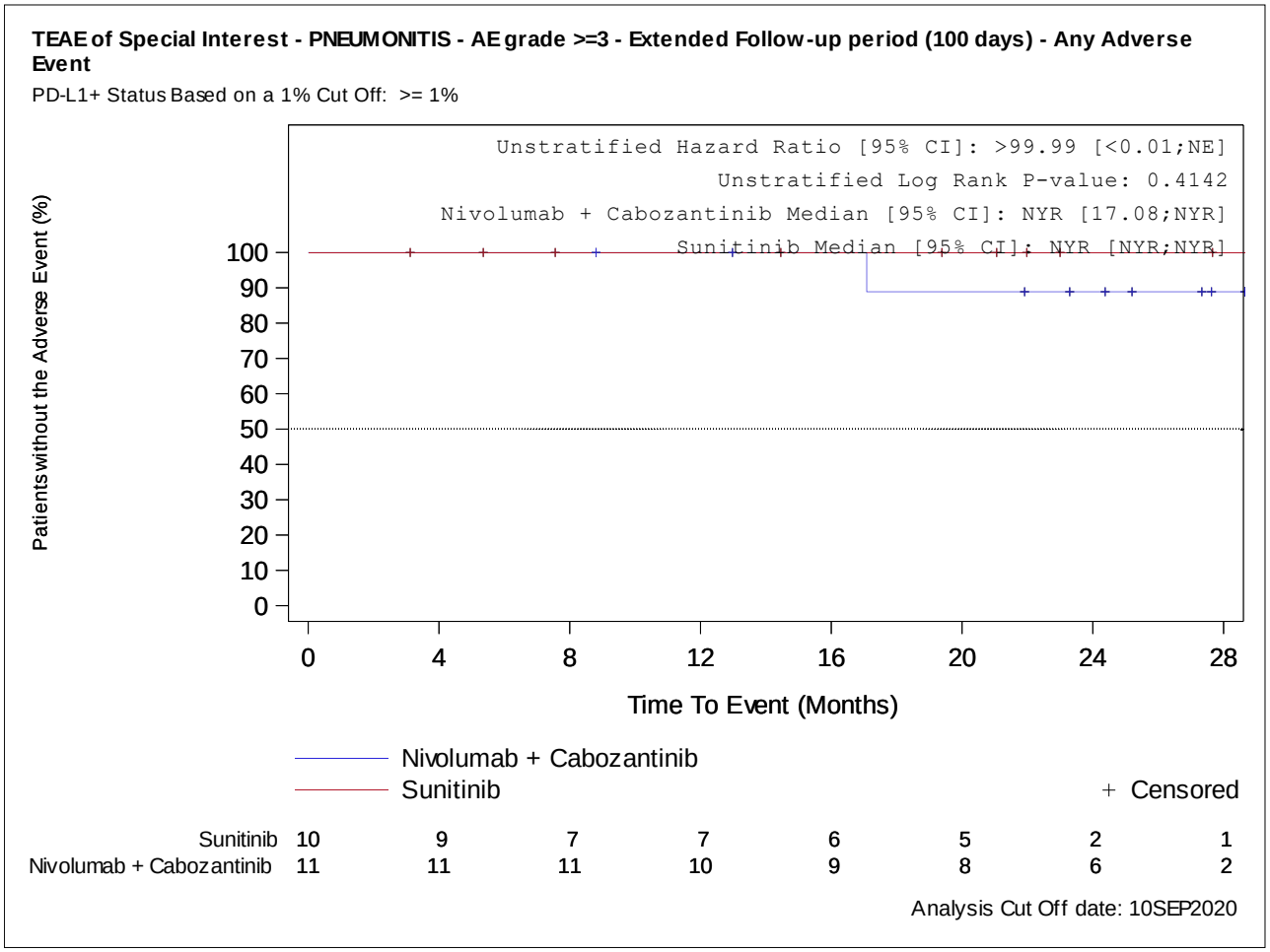

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:35:44

FIGURE 3.128.2.20: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



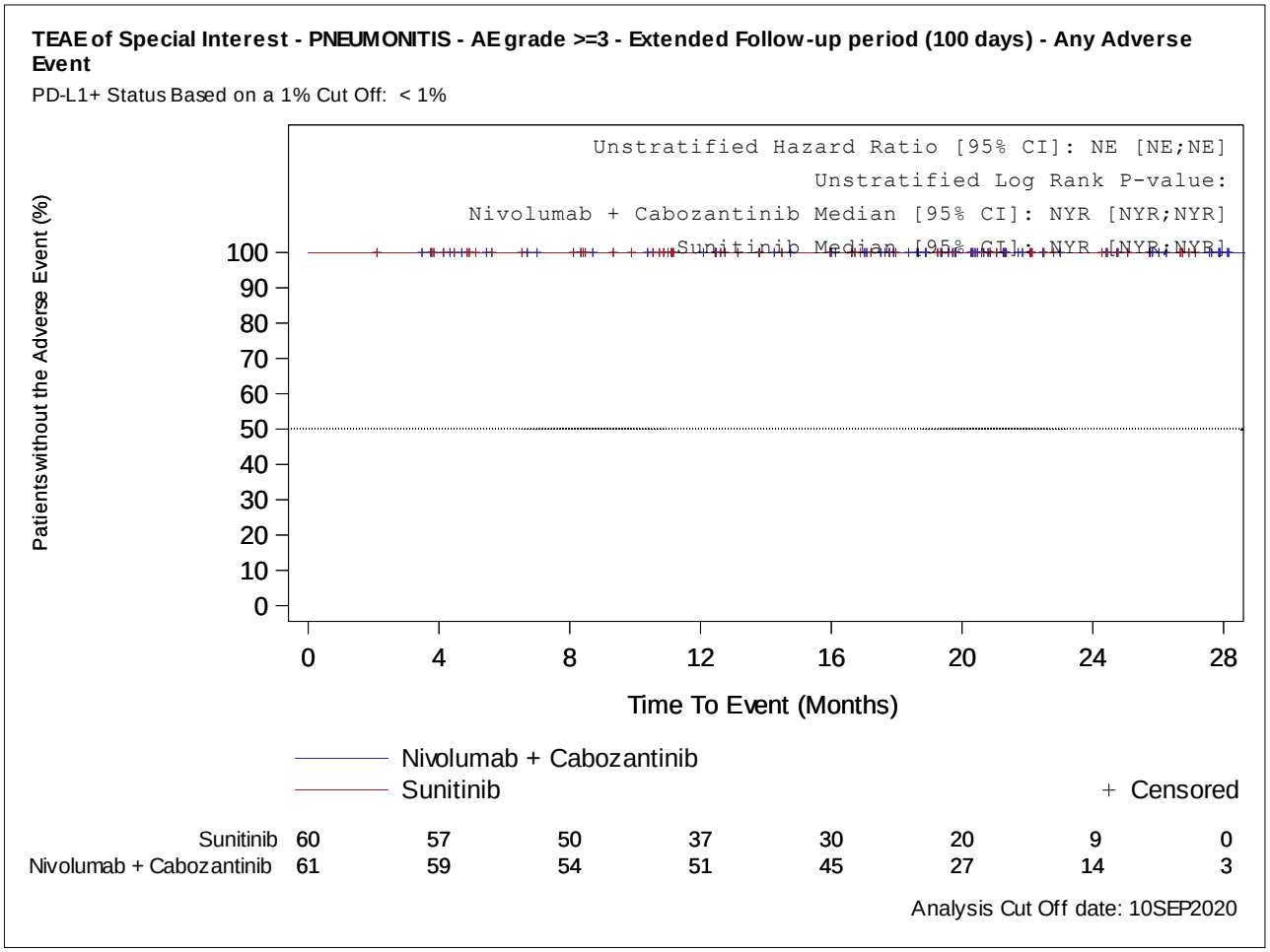

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:35:49

FIGURE 3.128.2.21: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



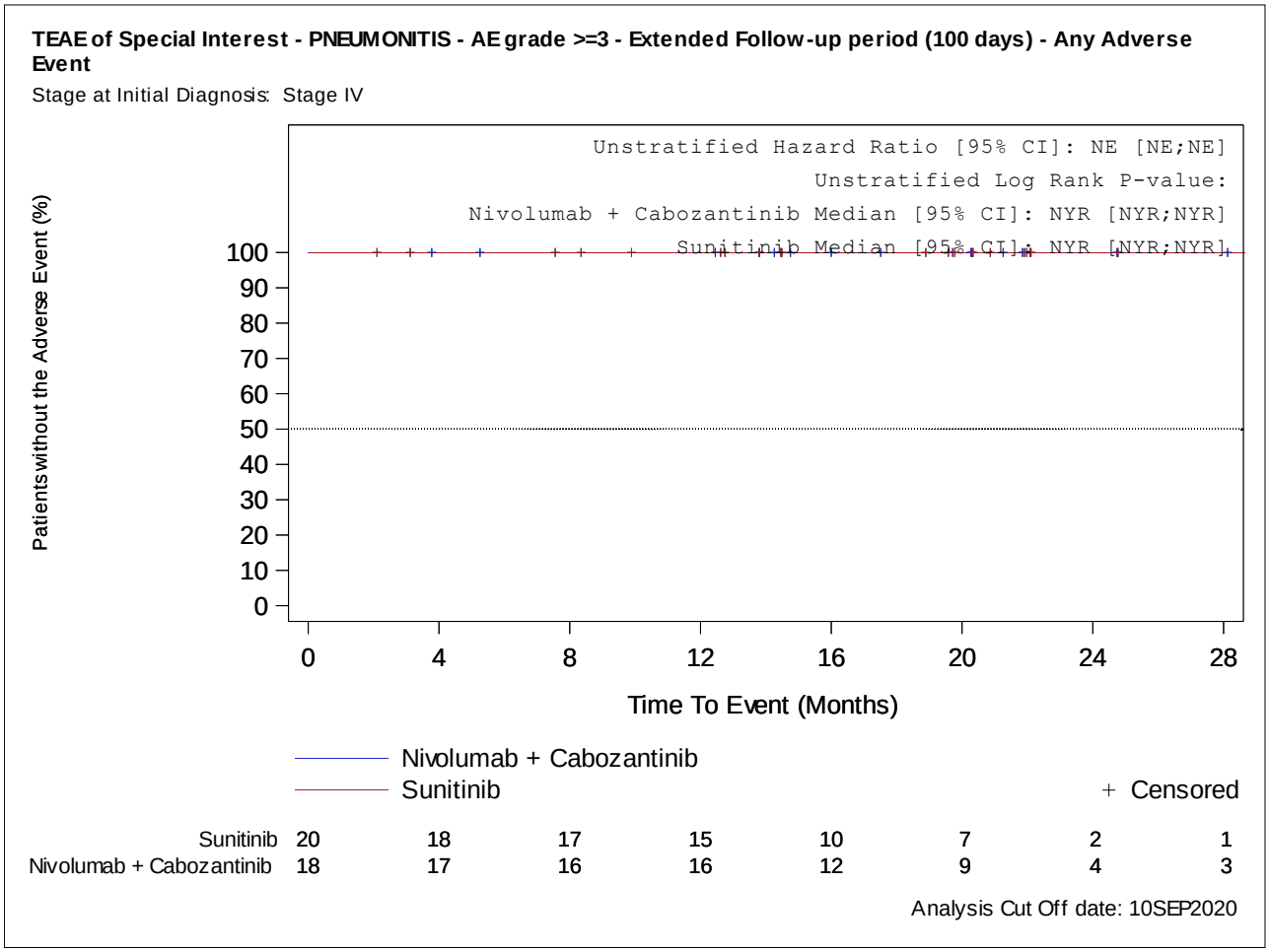

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:35:54

FIGURE 3.128.2.22: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



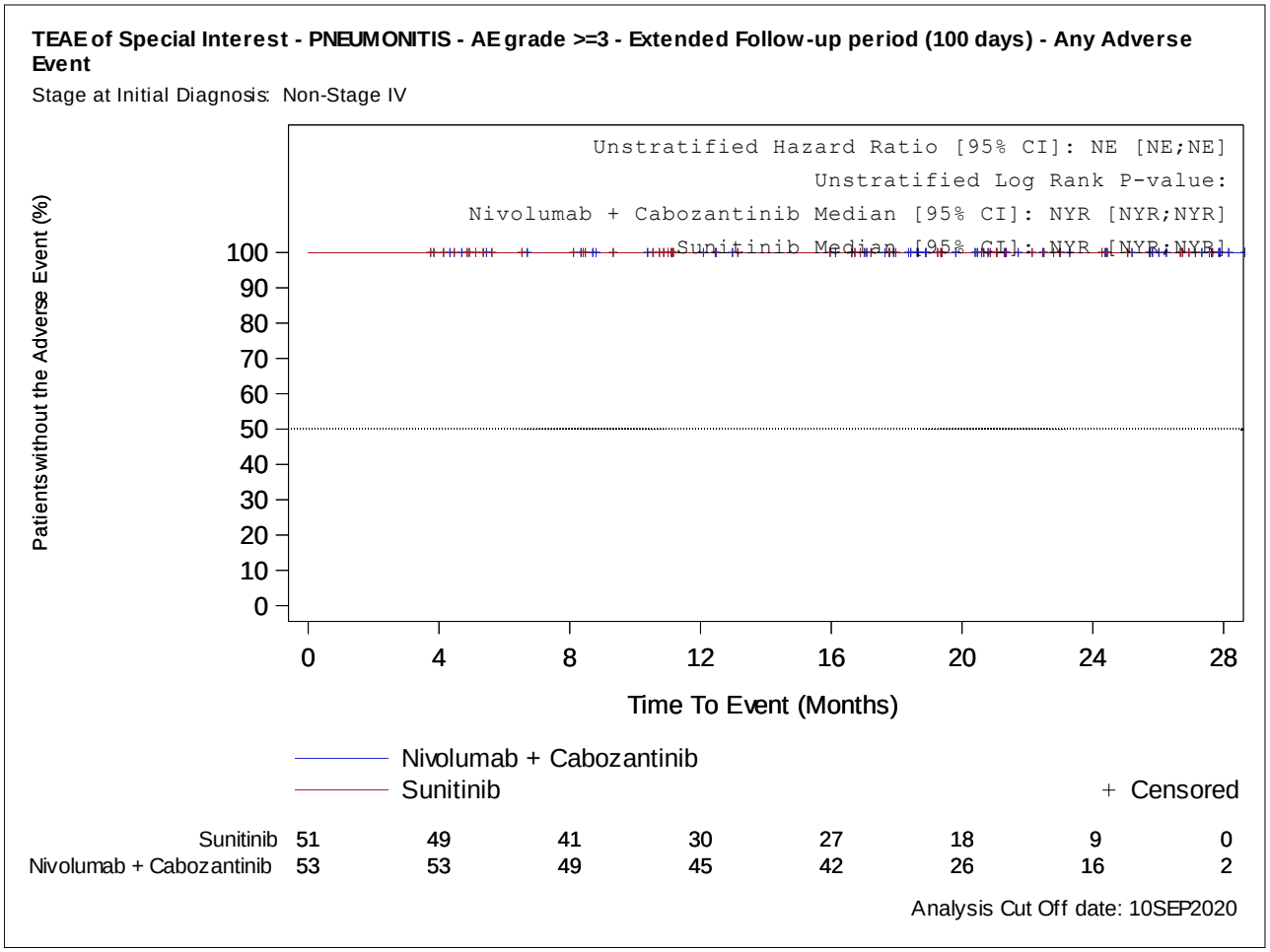

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:36:00

FIGURE 3.128.2.23: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



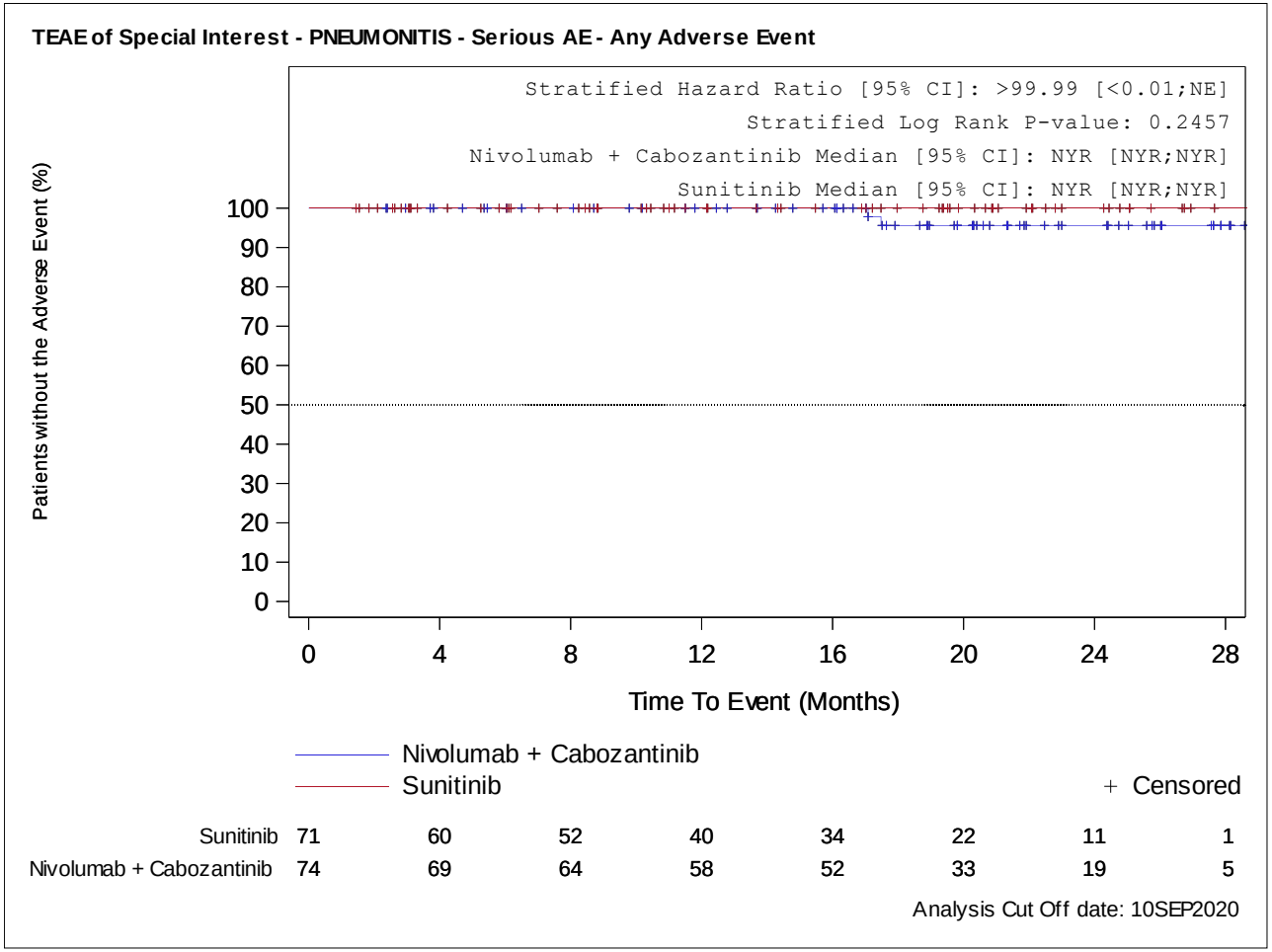

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:36:29

FIGURE 3.128.2.24: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



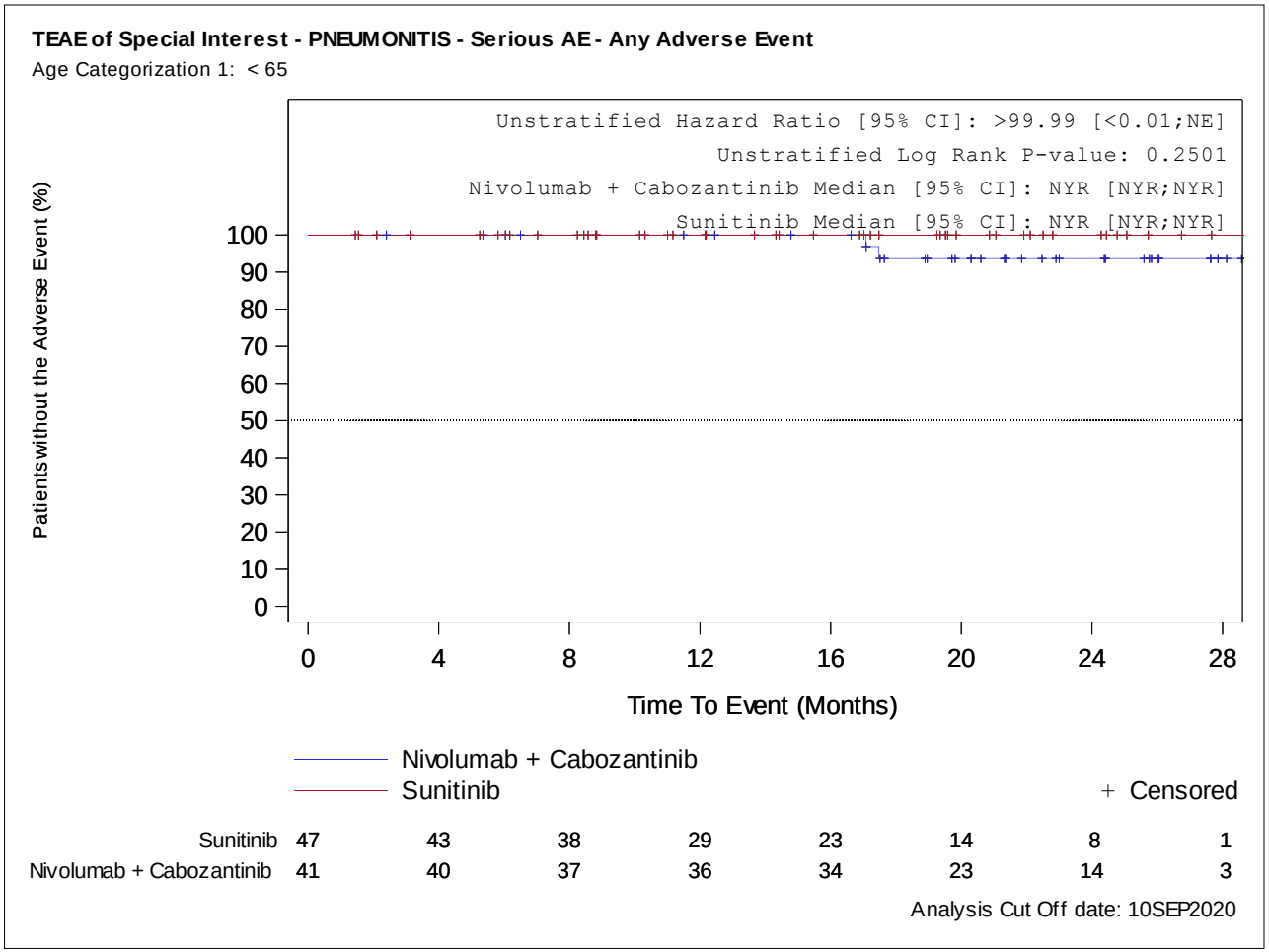

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:36:34

FIGURE 3.129.1: TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



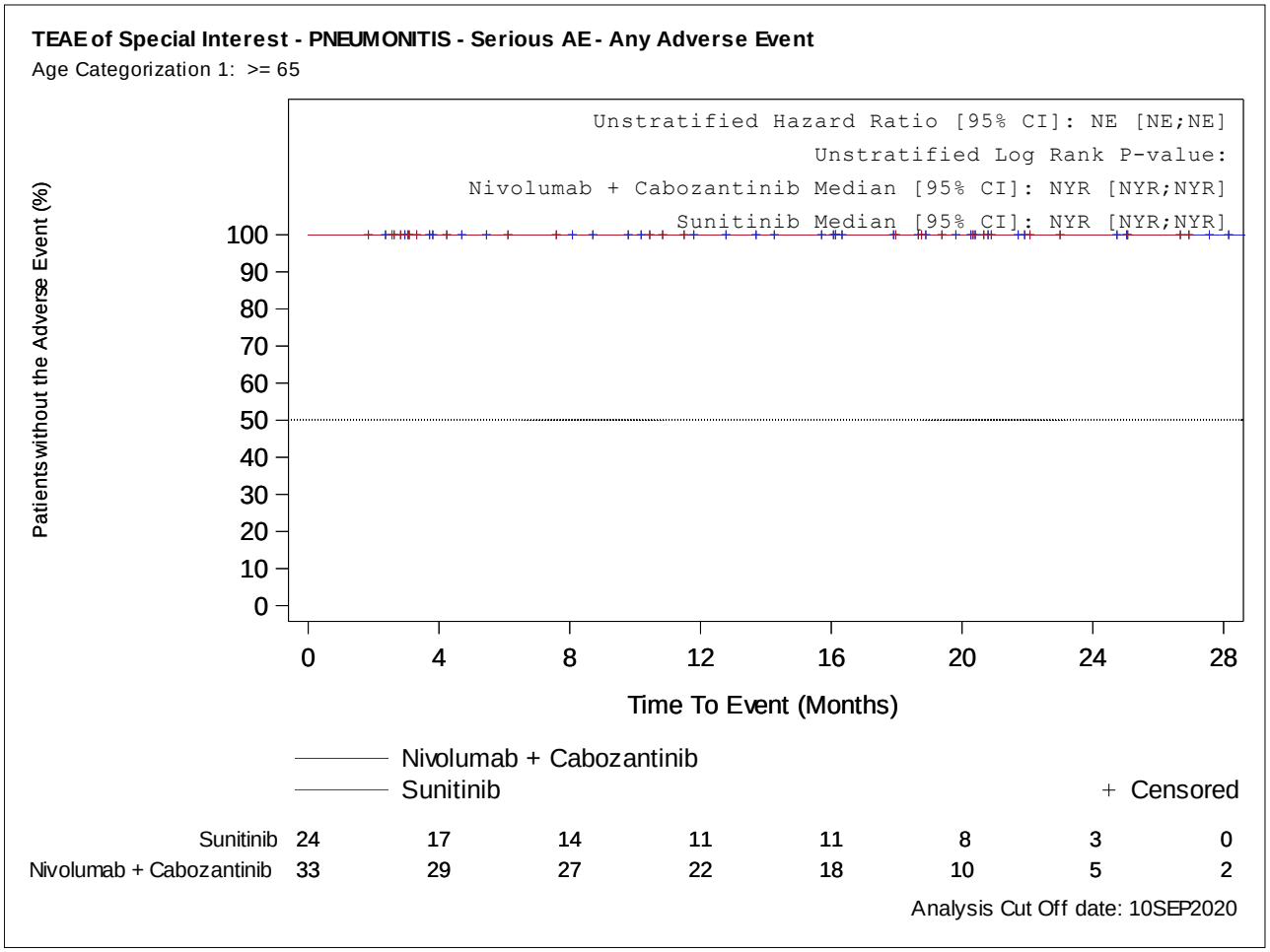

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:39:33

FIGURE 3.129.2.1: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



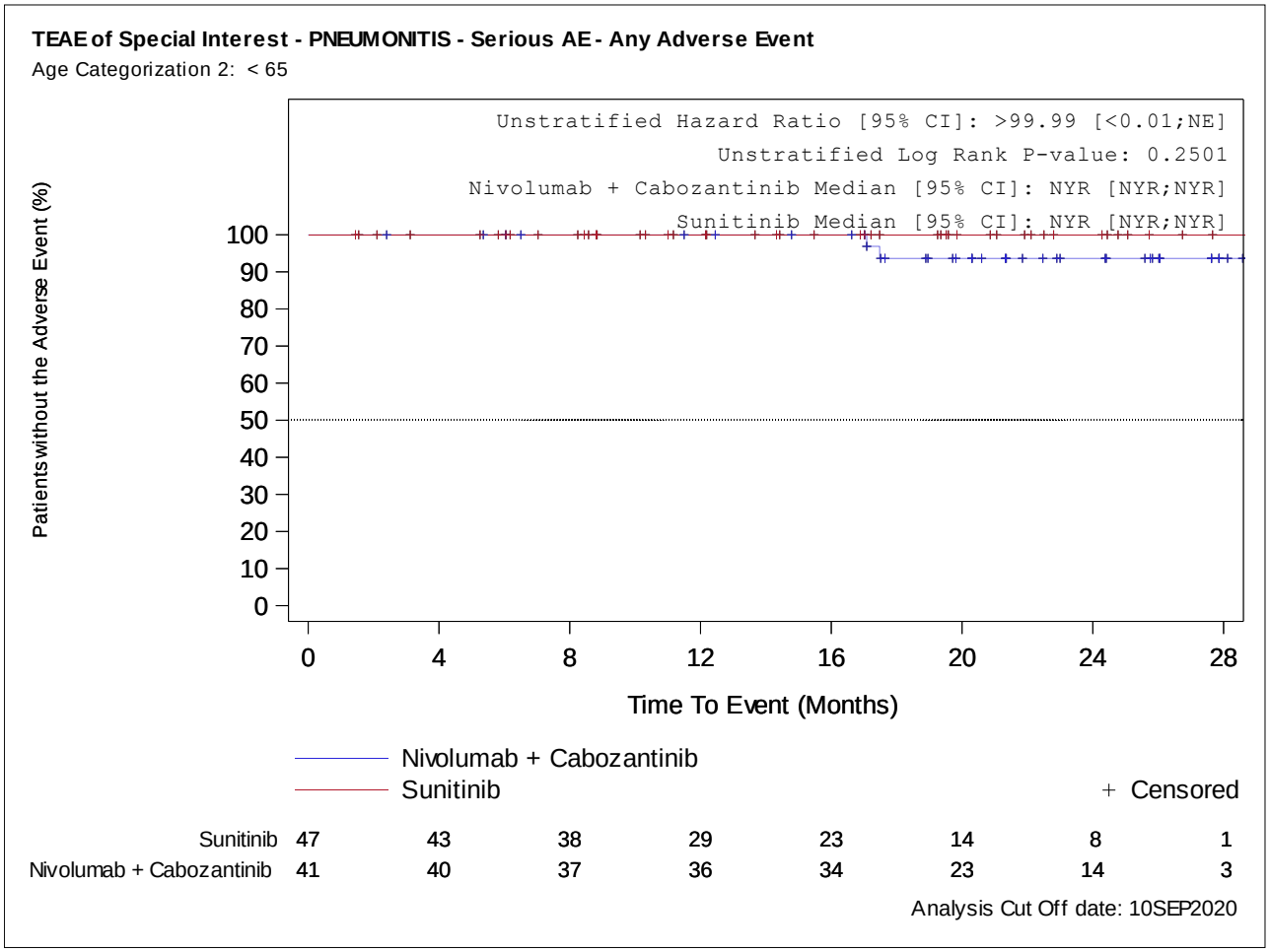

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:39:35

FIGURE 3.129.2.2: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:39:41

FIGURE 3.129.2.3: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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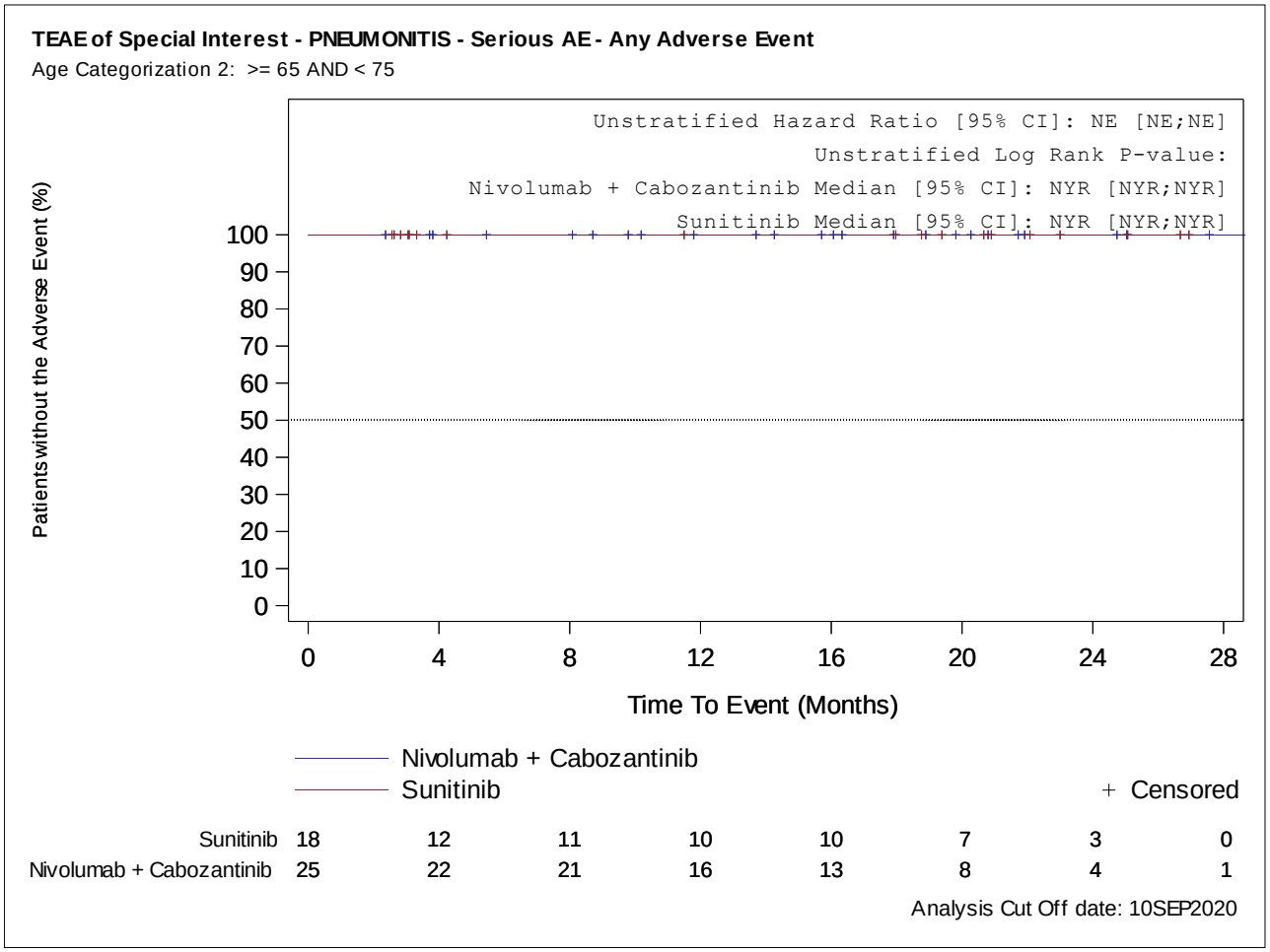
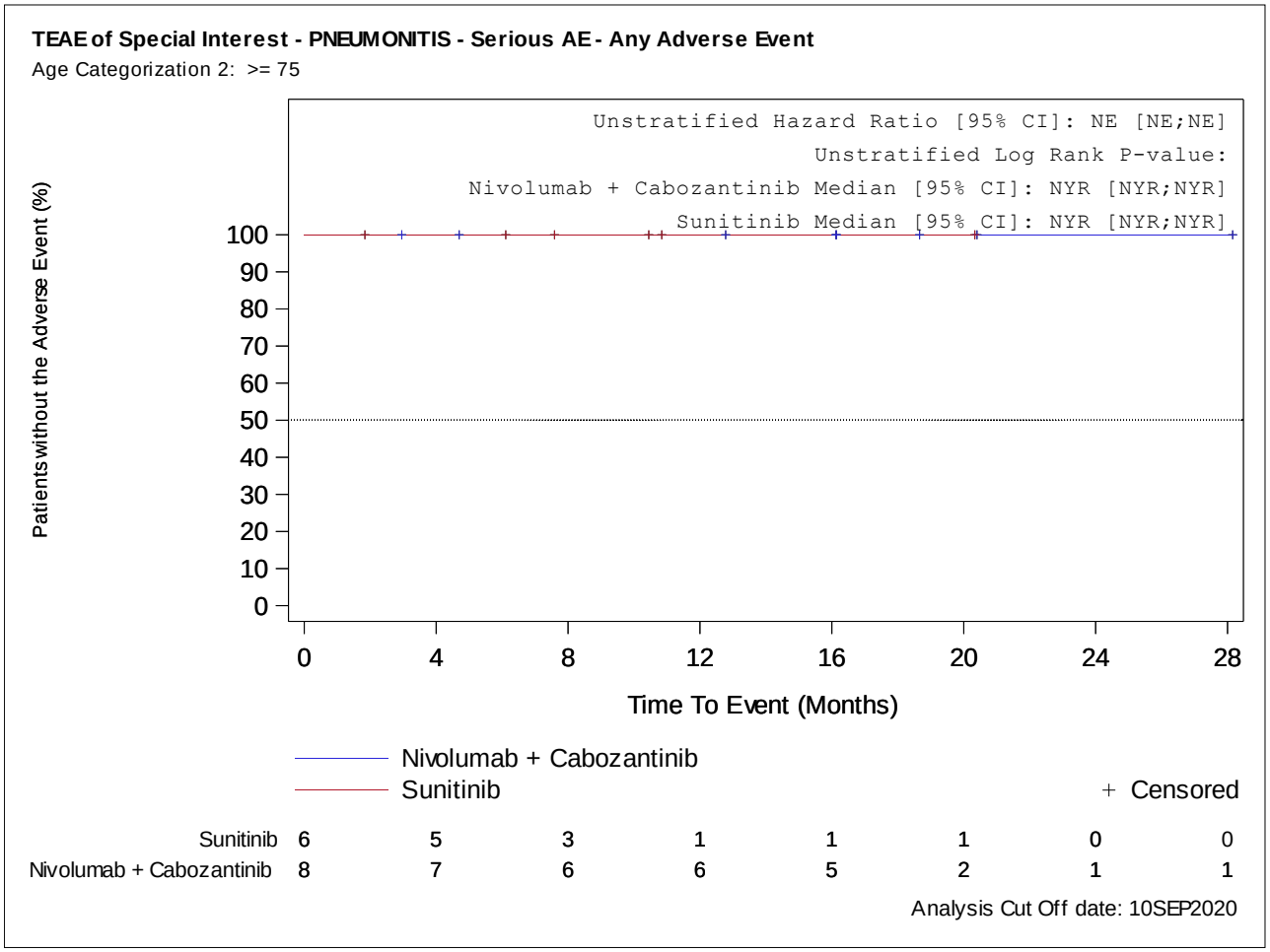
FIGURE 3.129.2.4: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



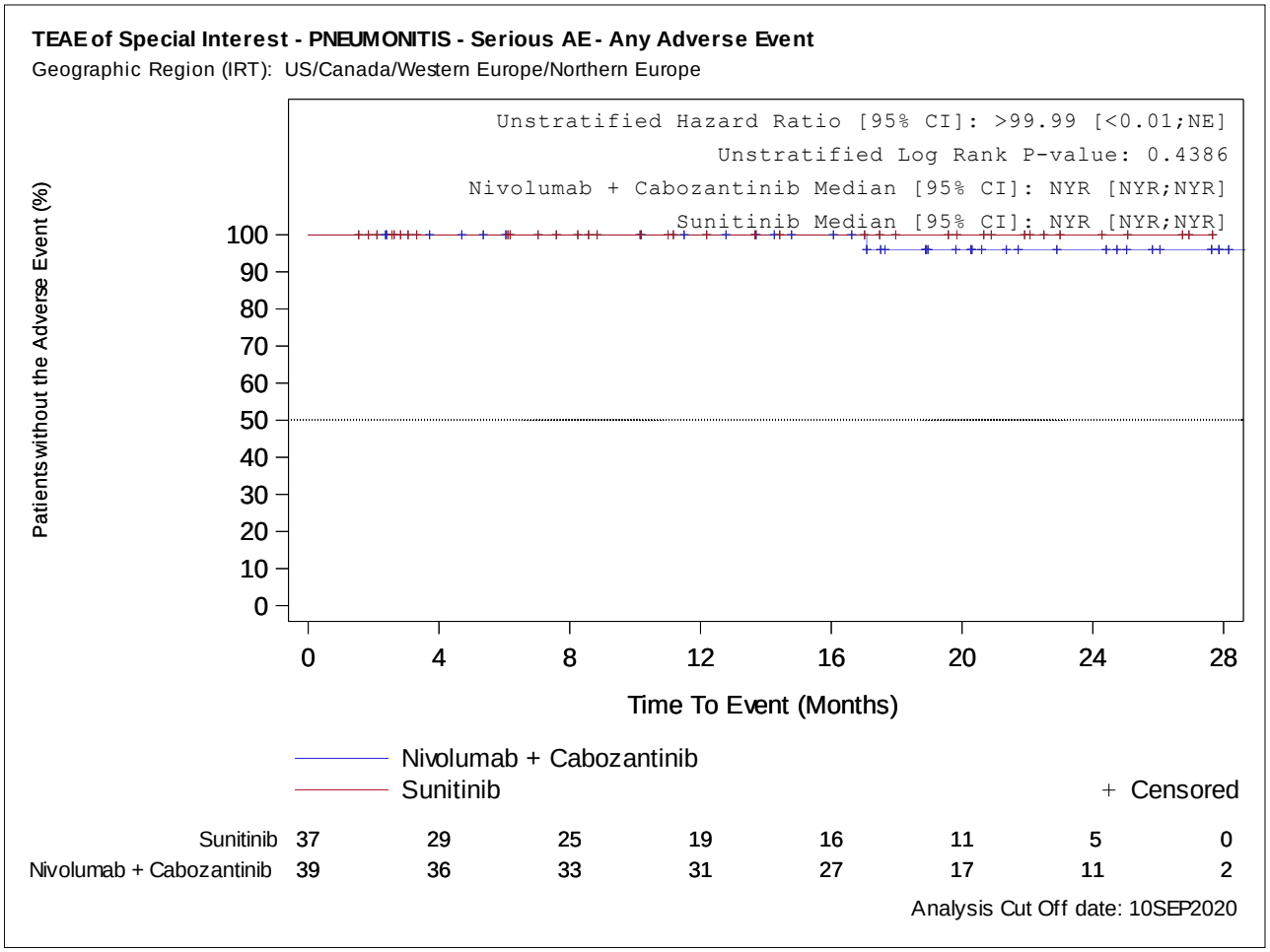

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:39:51

FIGURE 3.129.2.5: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



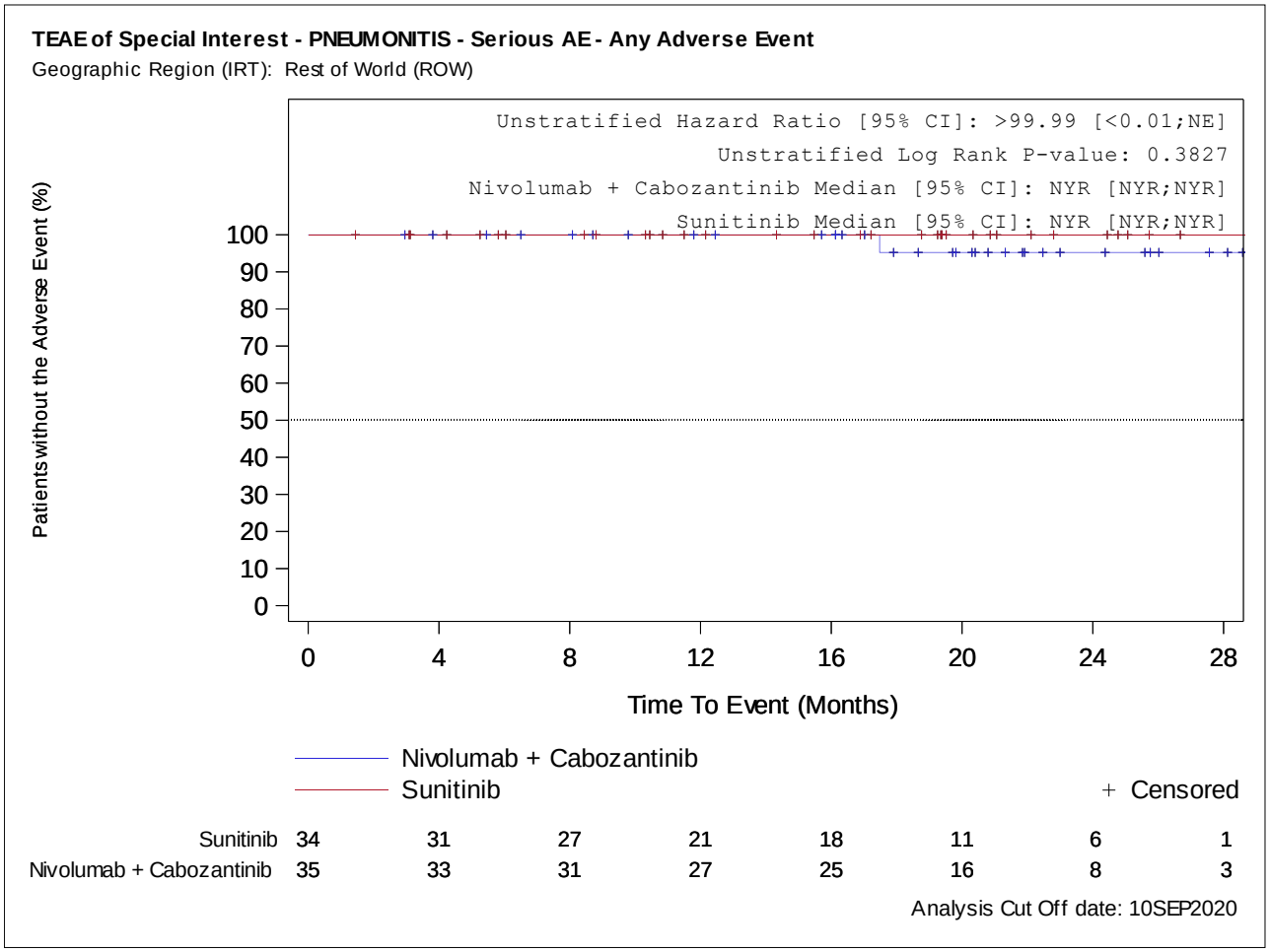

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:39:57

FIGURE 3.129.2.6: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



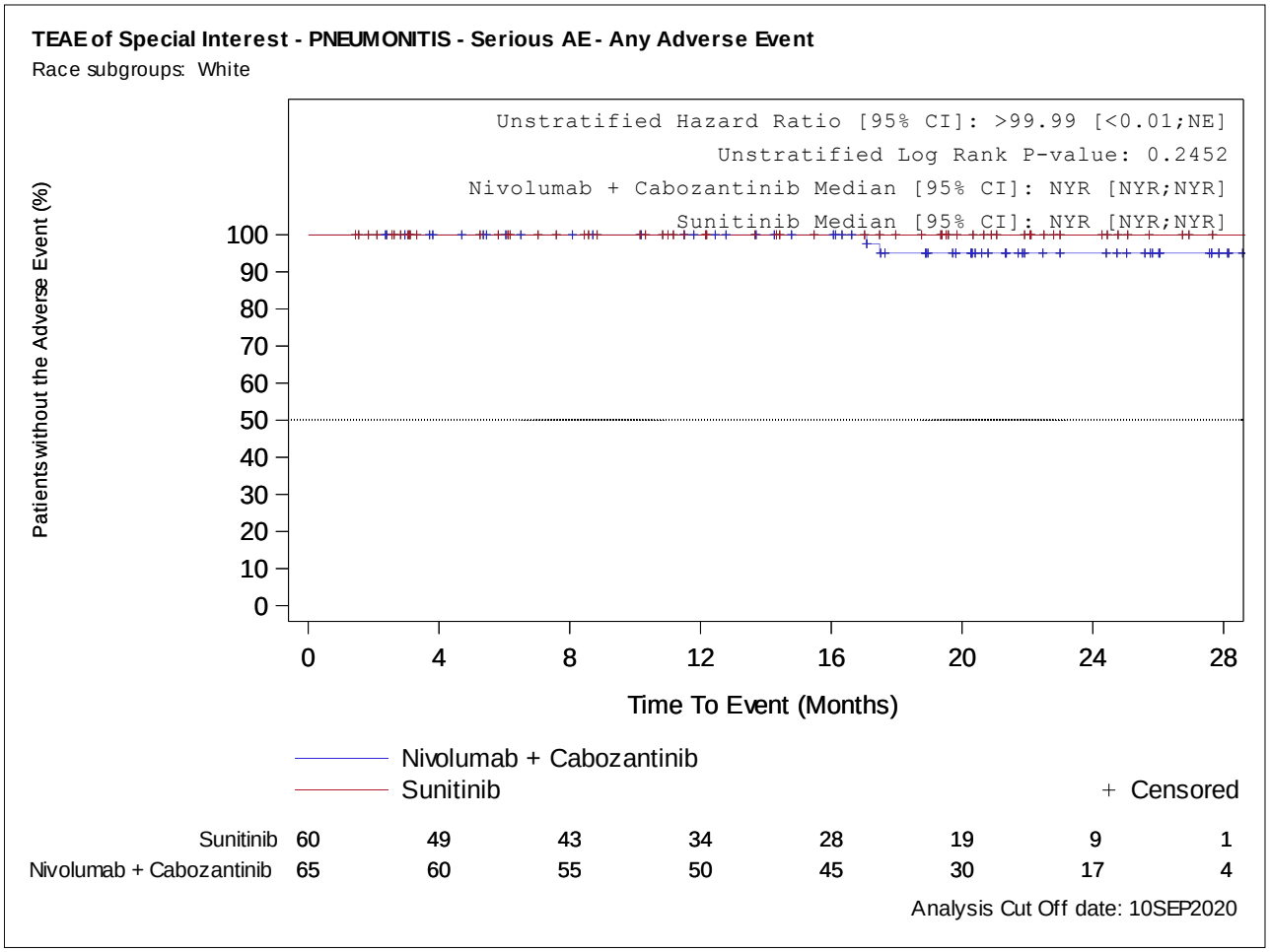

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:40:02

FIGURE 3.129.2.7: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



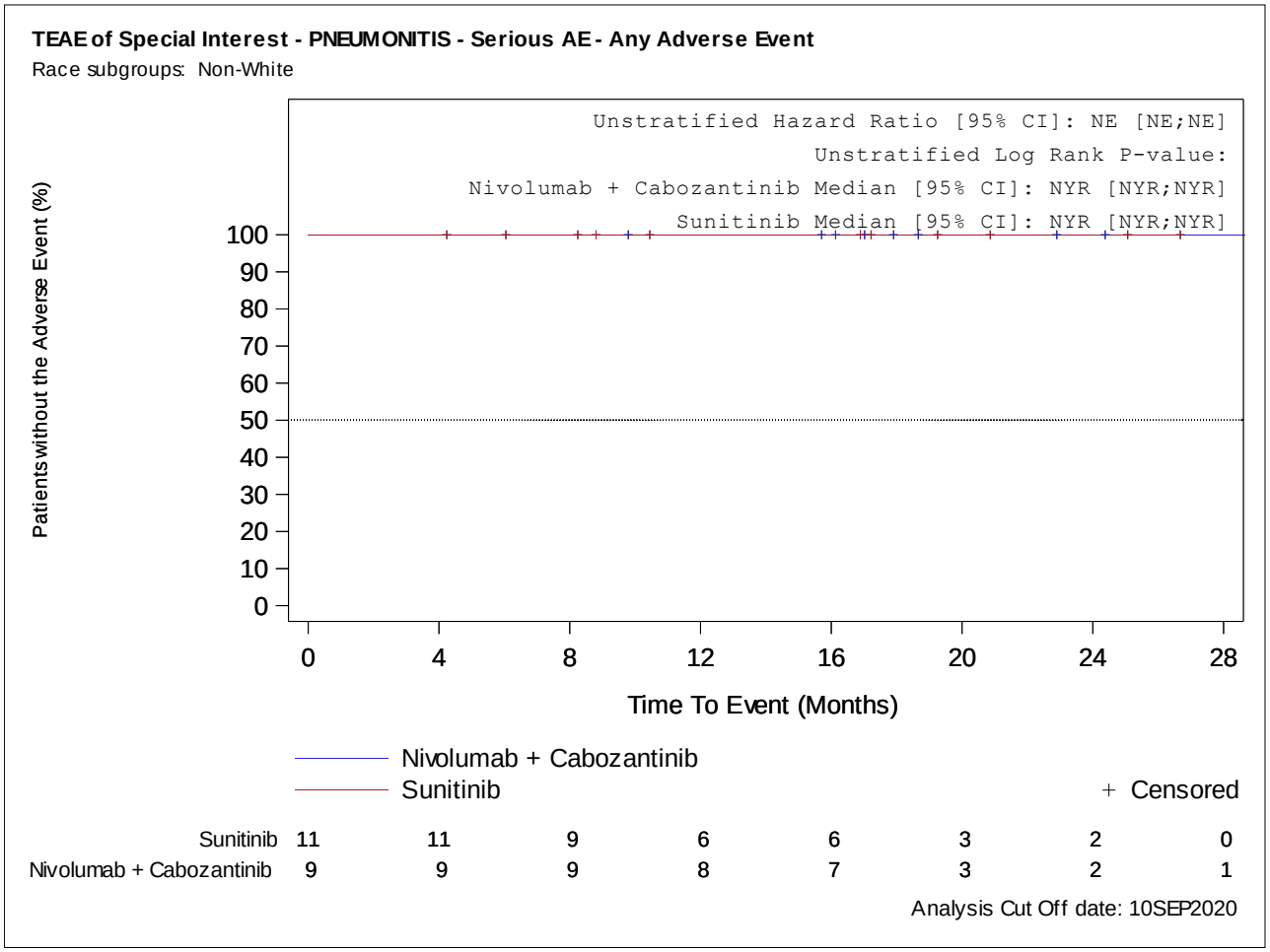

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:40:08

FIGURE 3.129.2.8: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



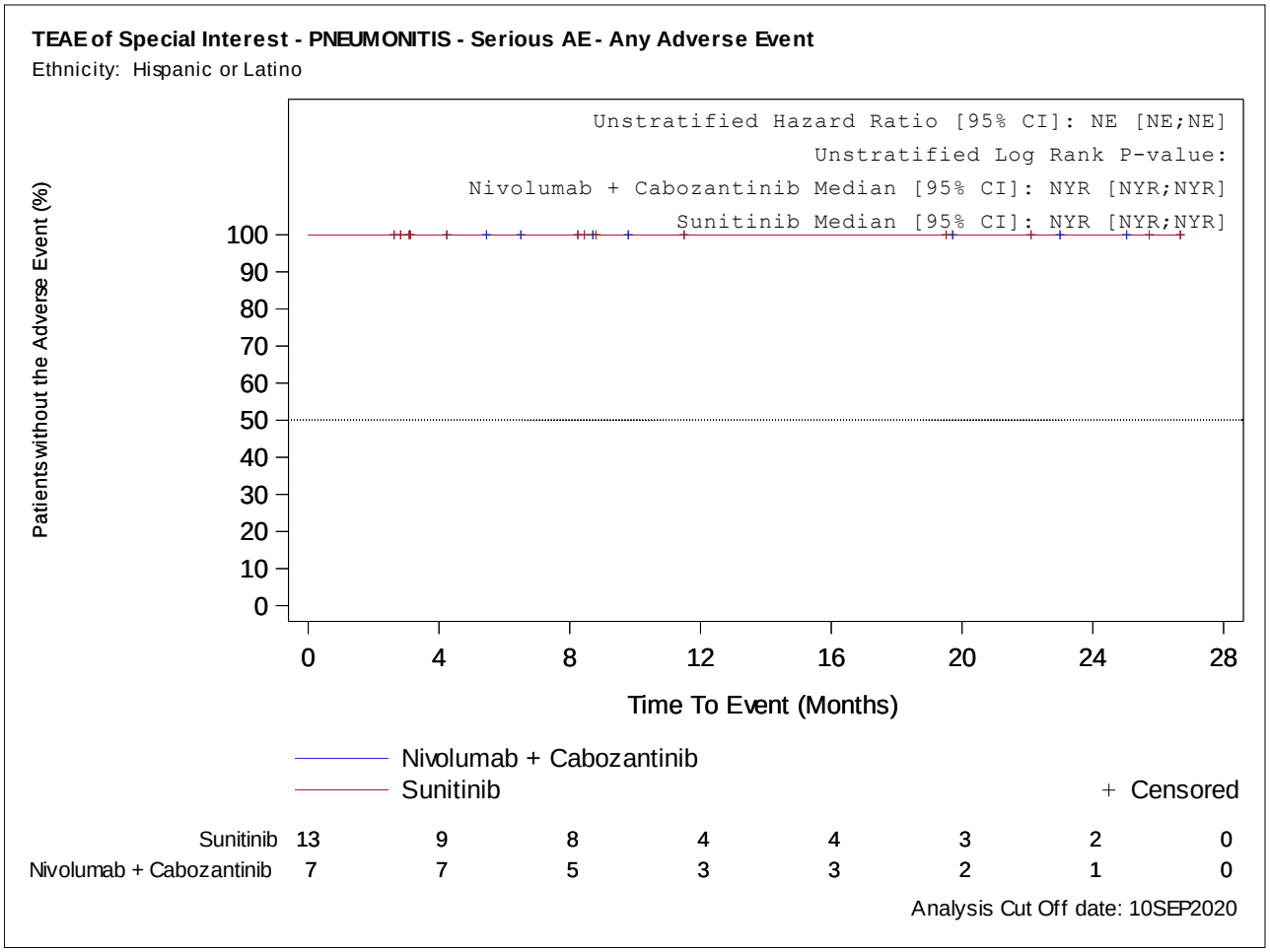

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:40:13

FIGURE 3.129.2.9: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



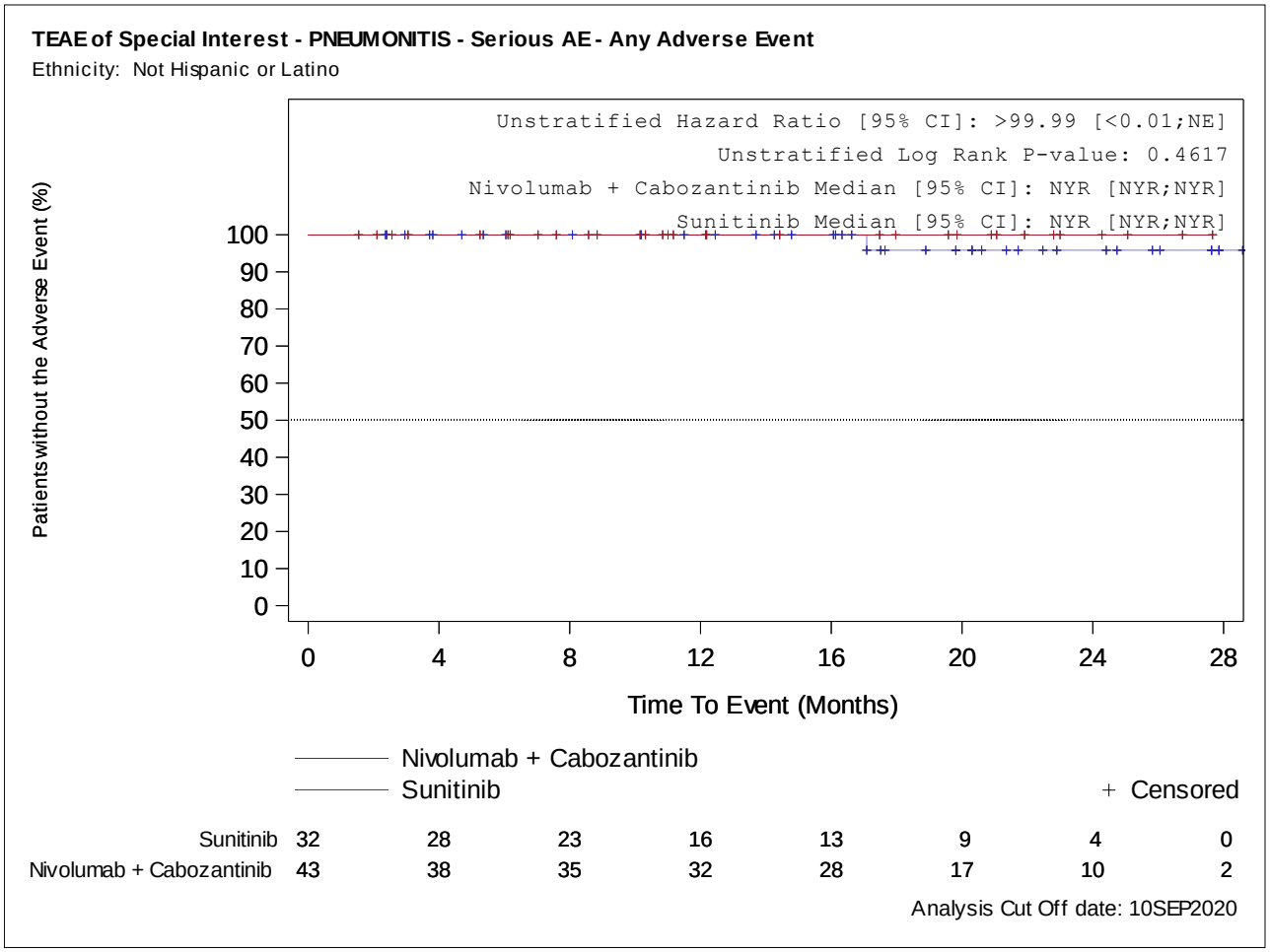

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:40:19

FIGURE 3.129.2.10: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



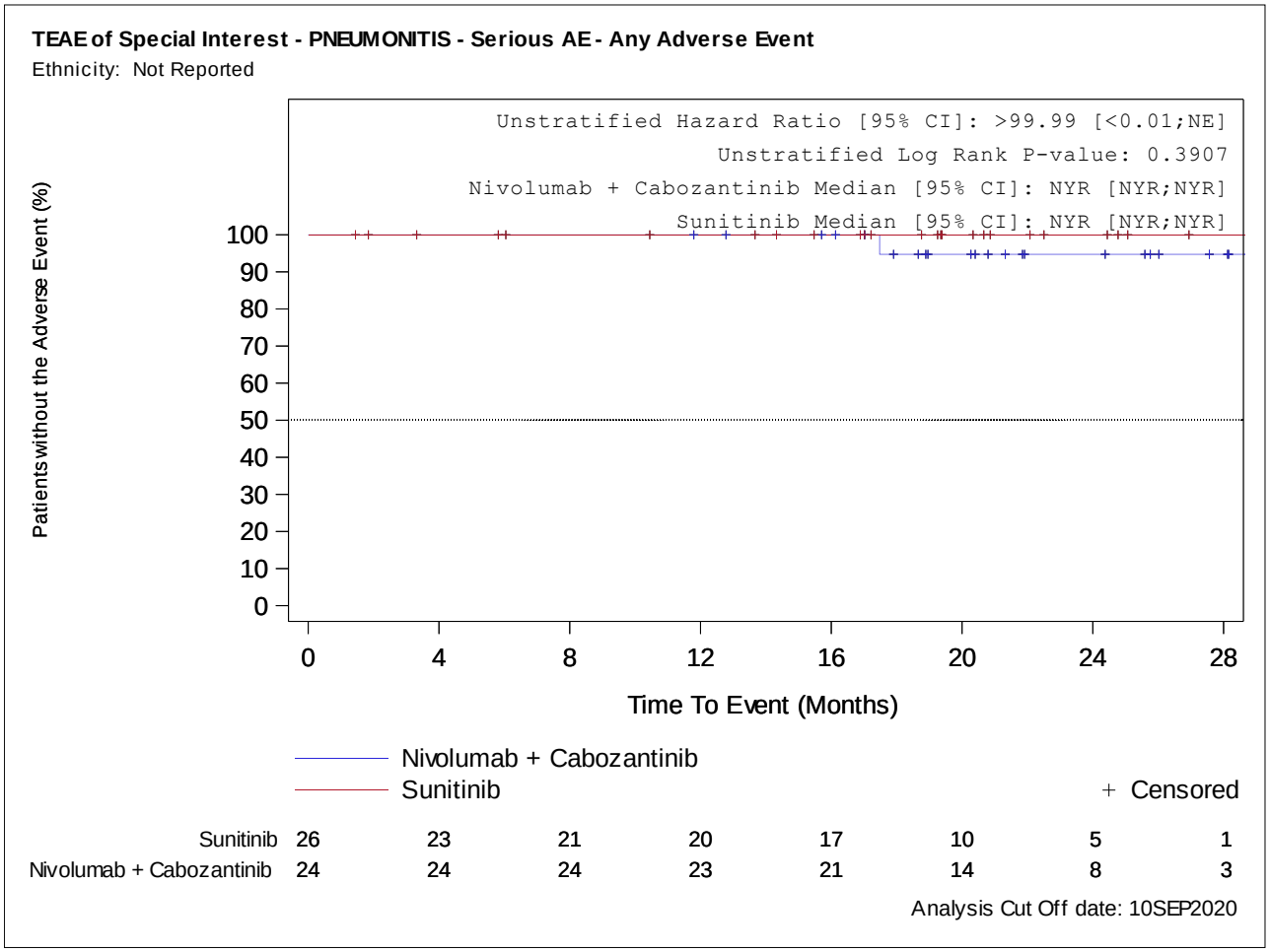

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:40:24

FIGURE 3.129.2.11: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



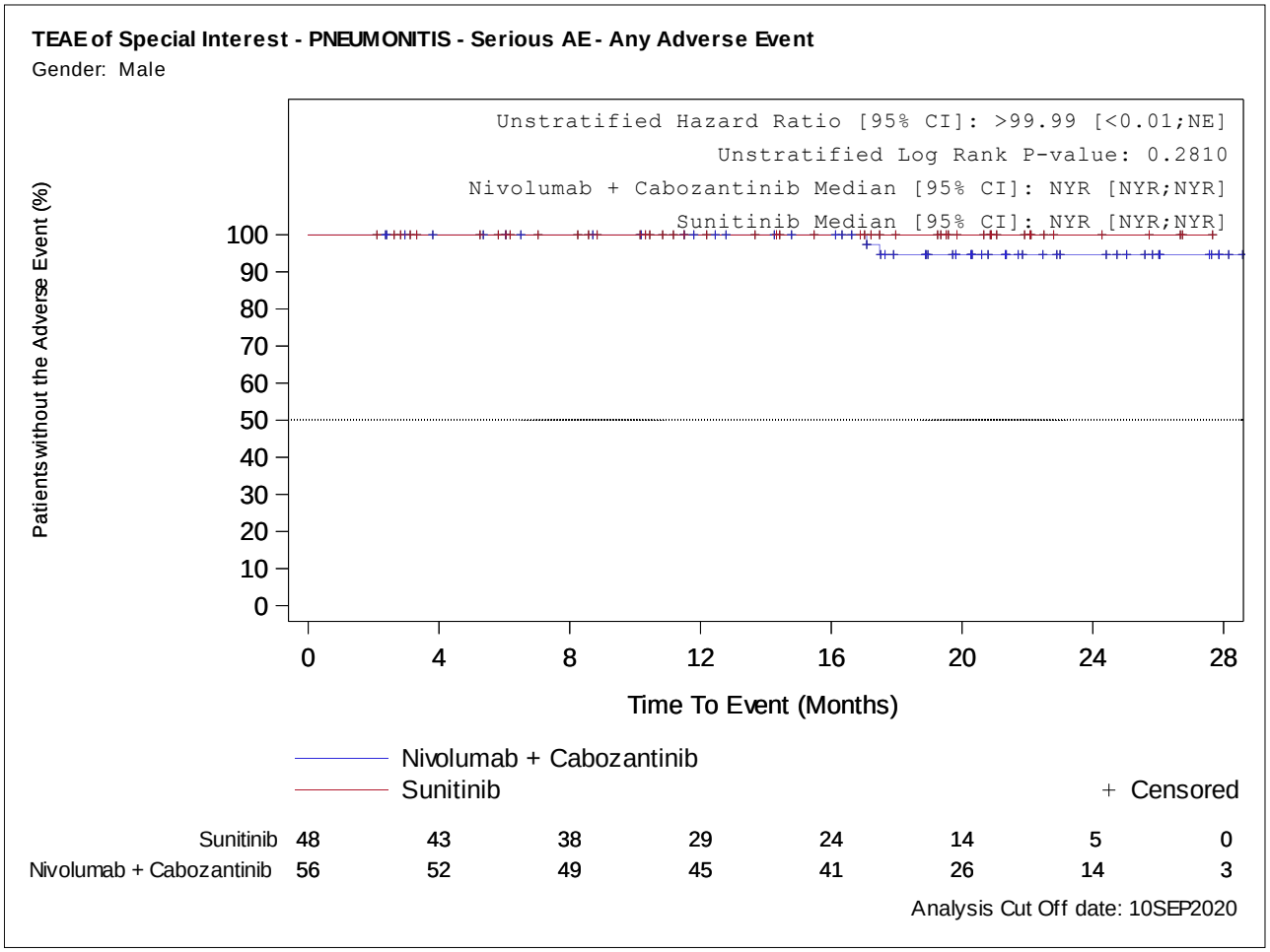

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:40:30

FIGURE 3.129.2.12: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



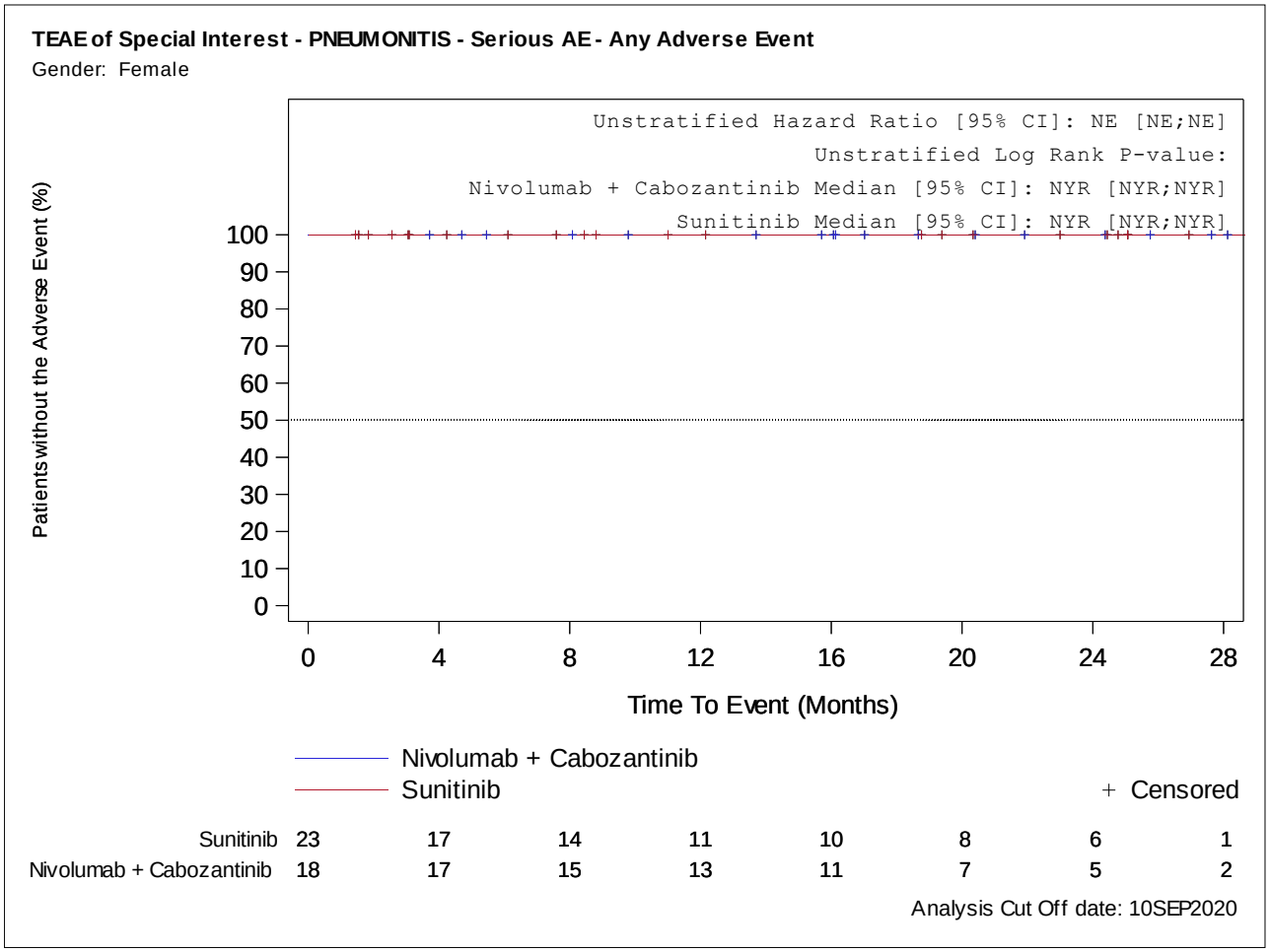

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:40:35

FIGURE 3.129.2.13: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



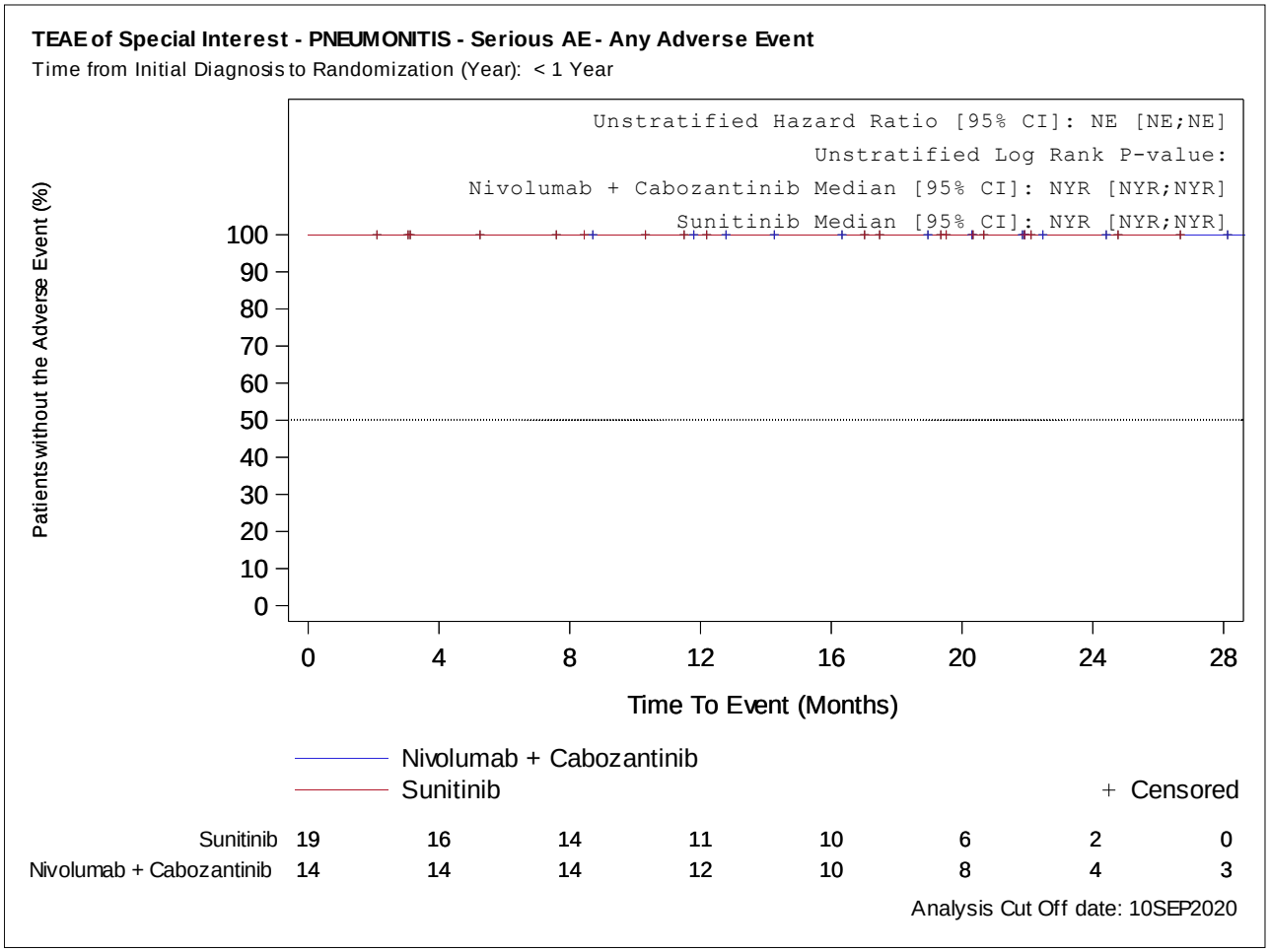

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:40:41

FIGURE 3.129.2.14: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



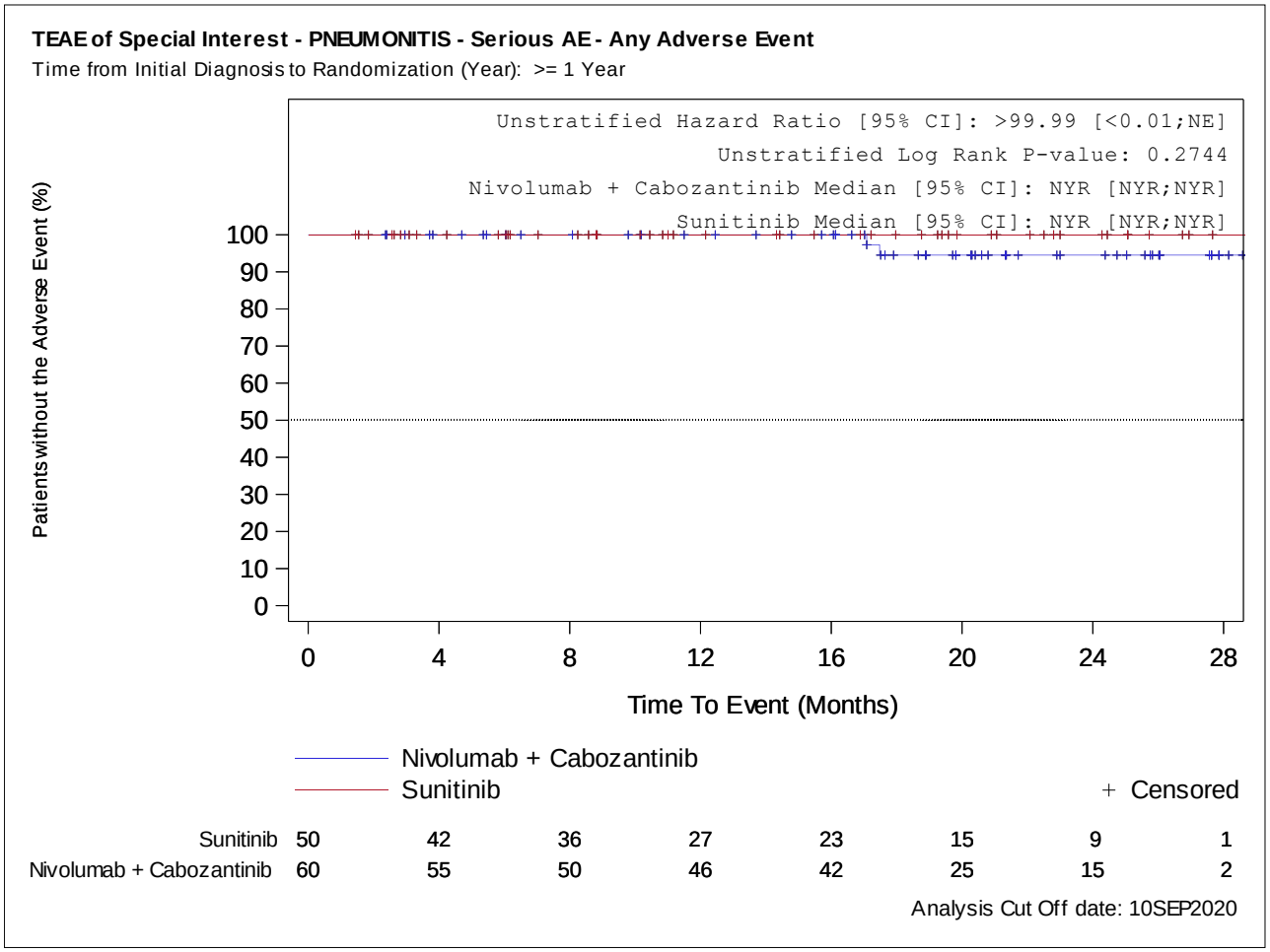

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:40:47

FIGURE 3.129.2.15: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



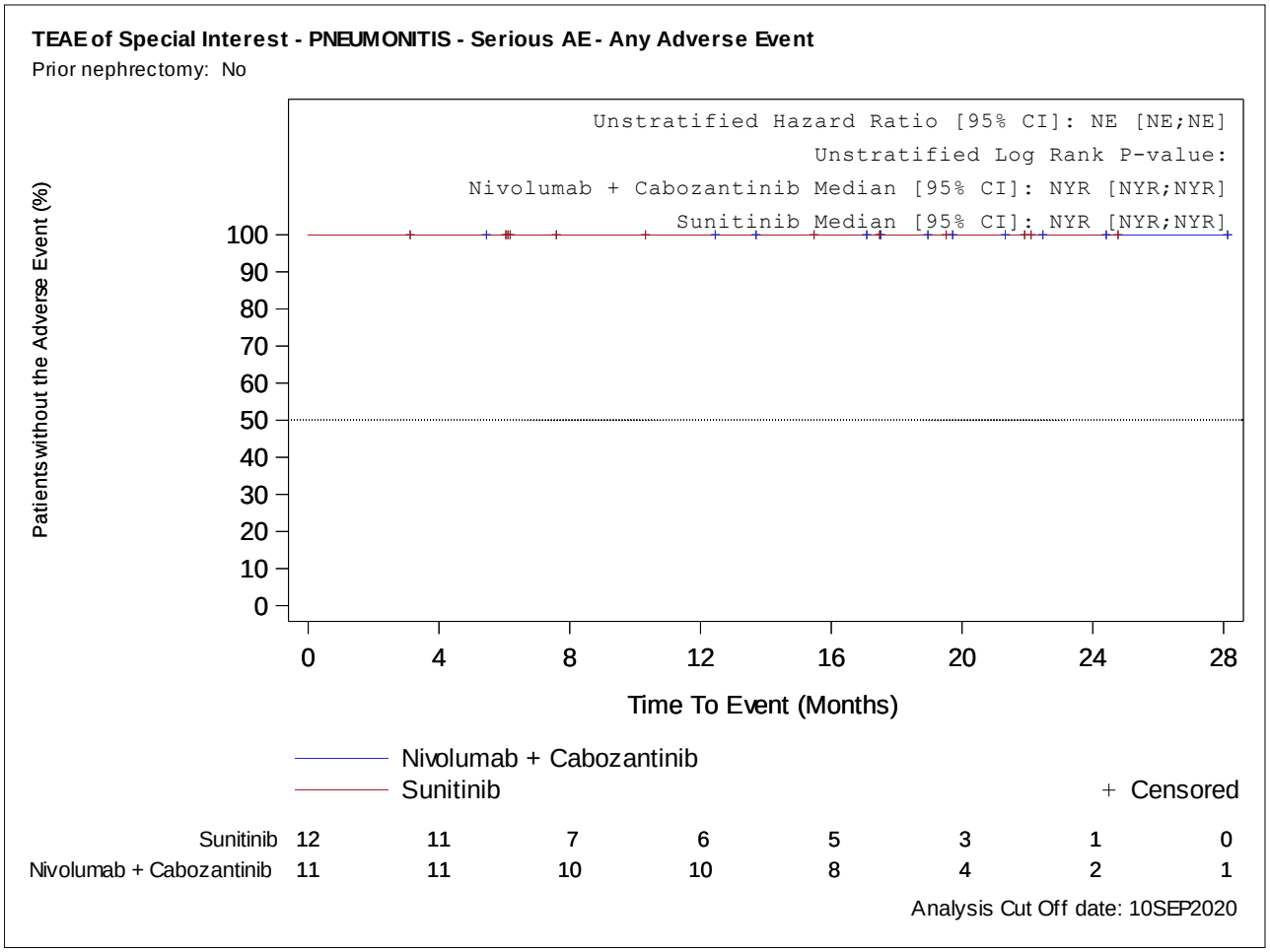

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:41:03

FIGURE 3.129.2.16: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



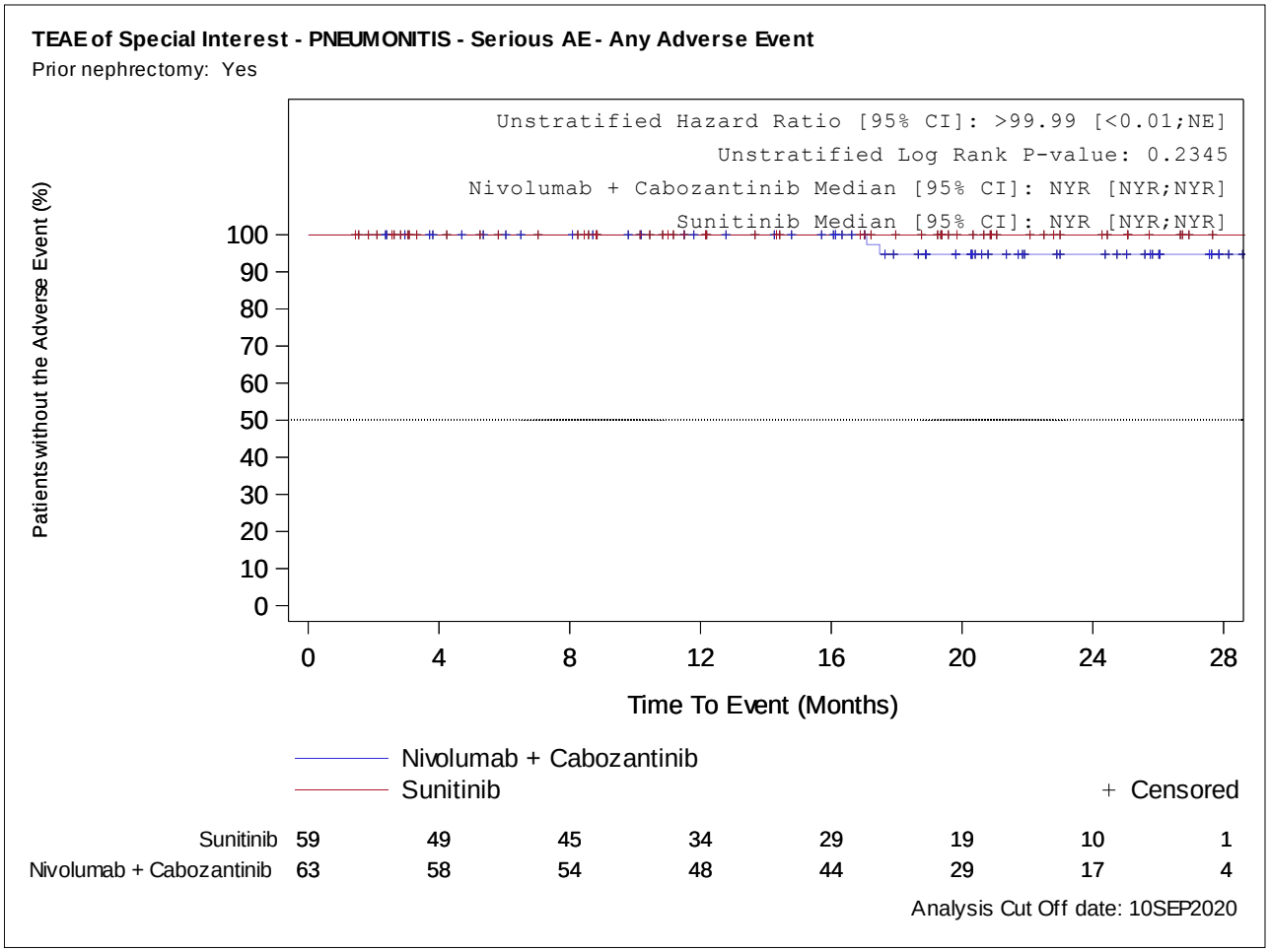

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:41:08

FIGURE 3.129.2.17: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



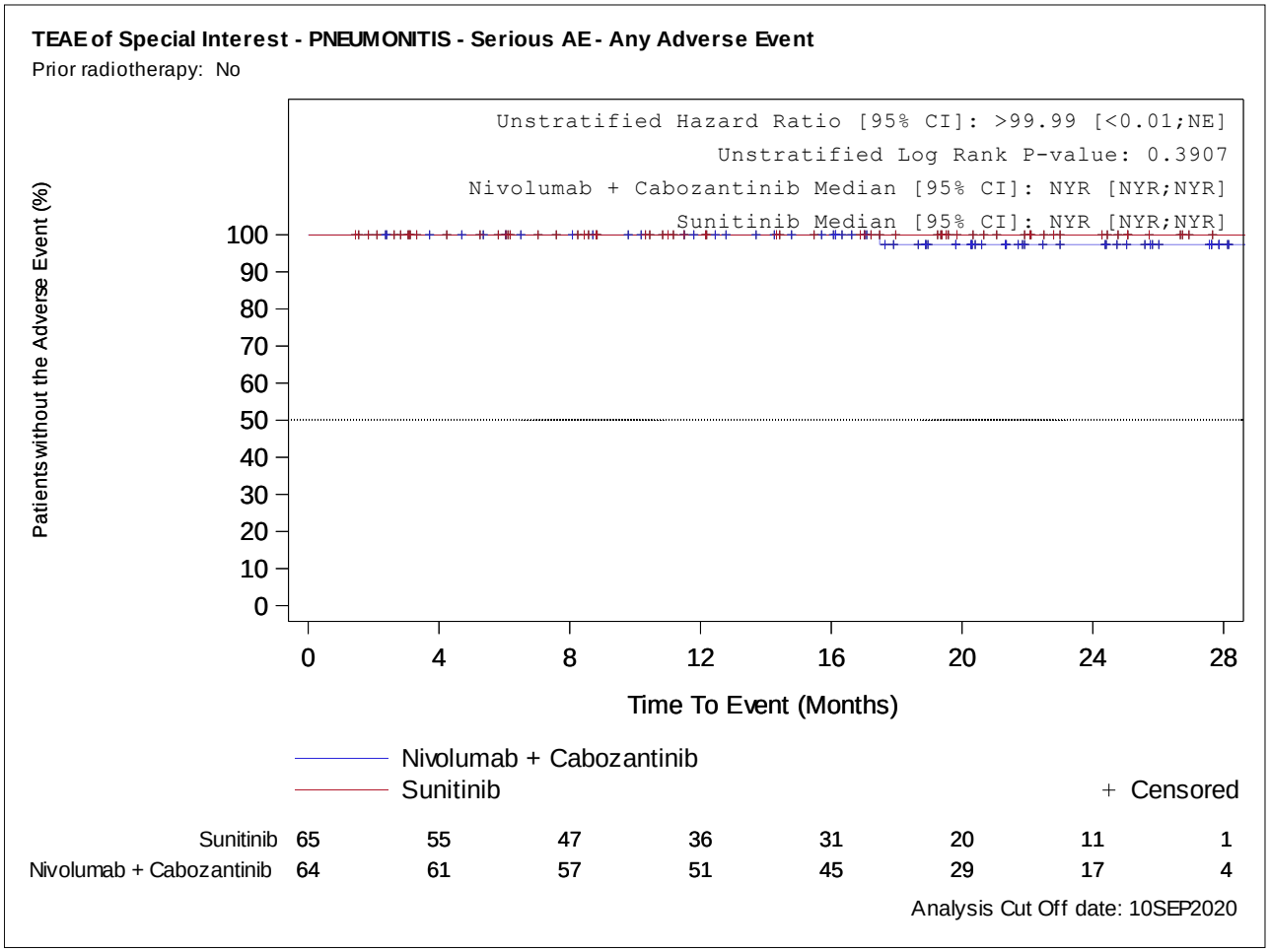

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:41:57

FIGURE 3.129.2.18: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



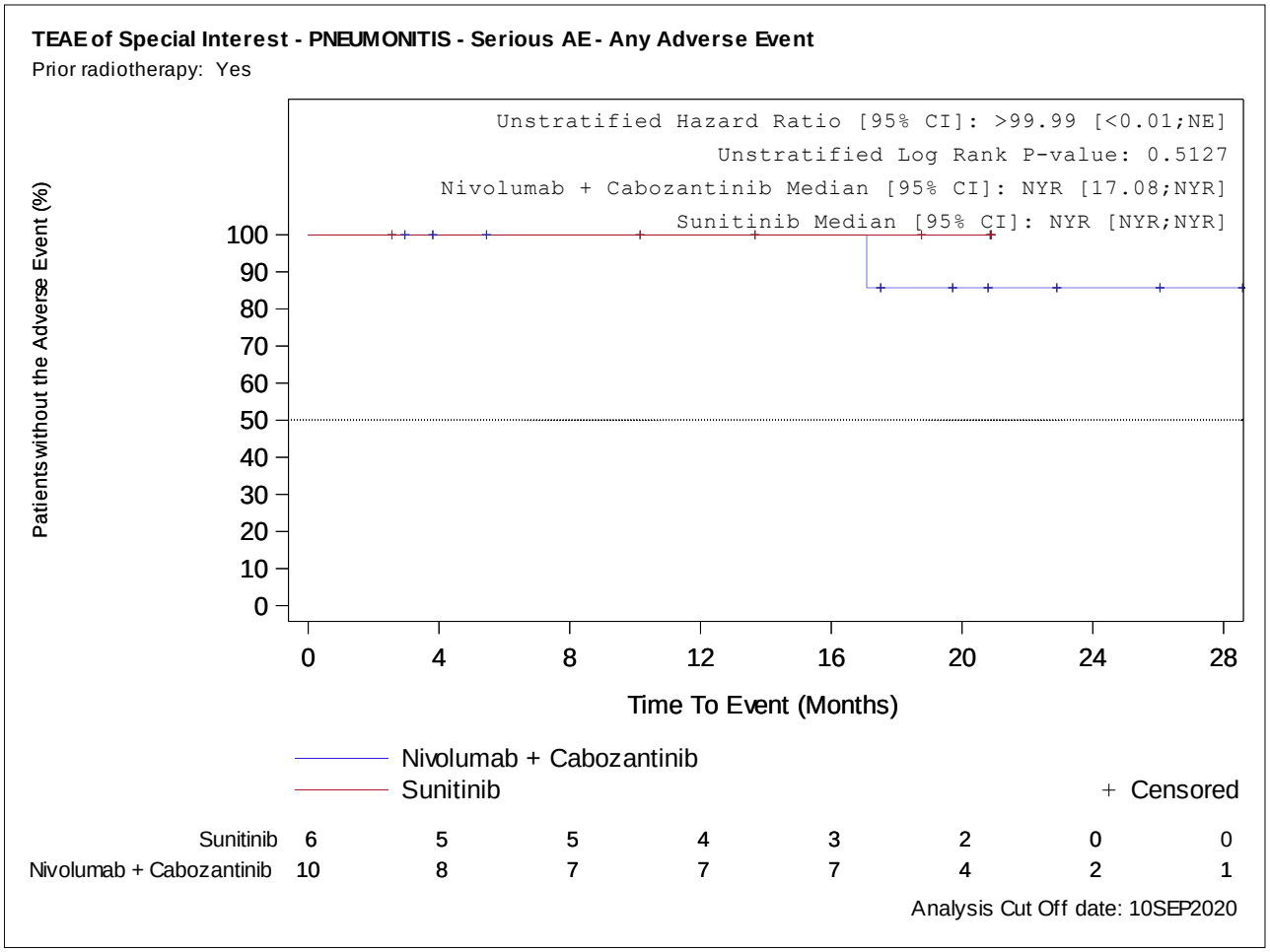

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:42:02

FIGURE 3.129.2.19: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



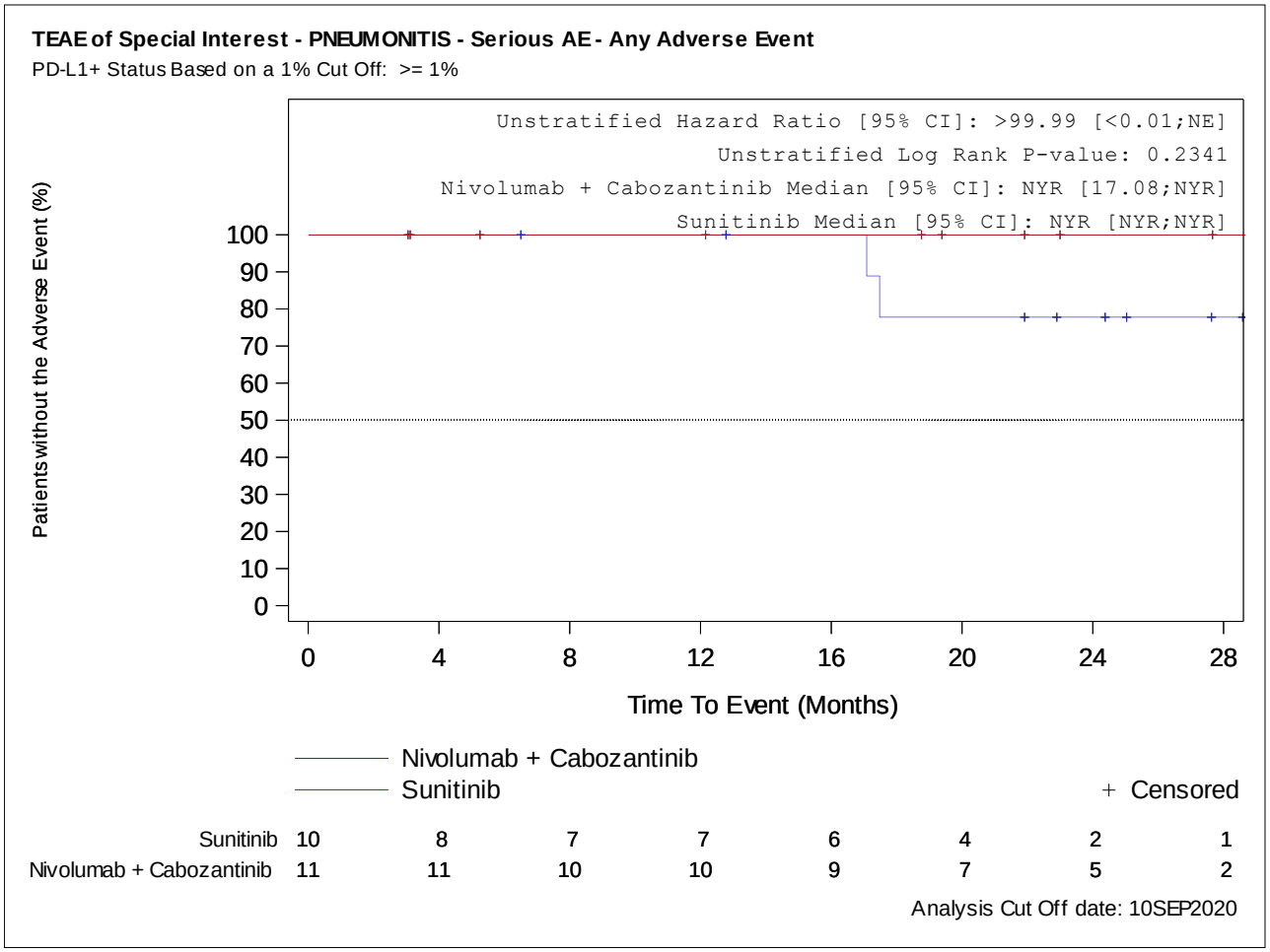

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:42:07

FIGURE 3.129.2.20: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



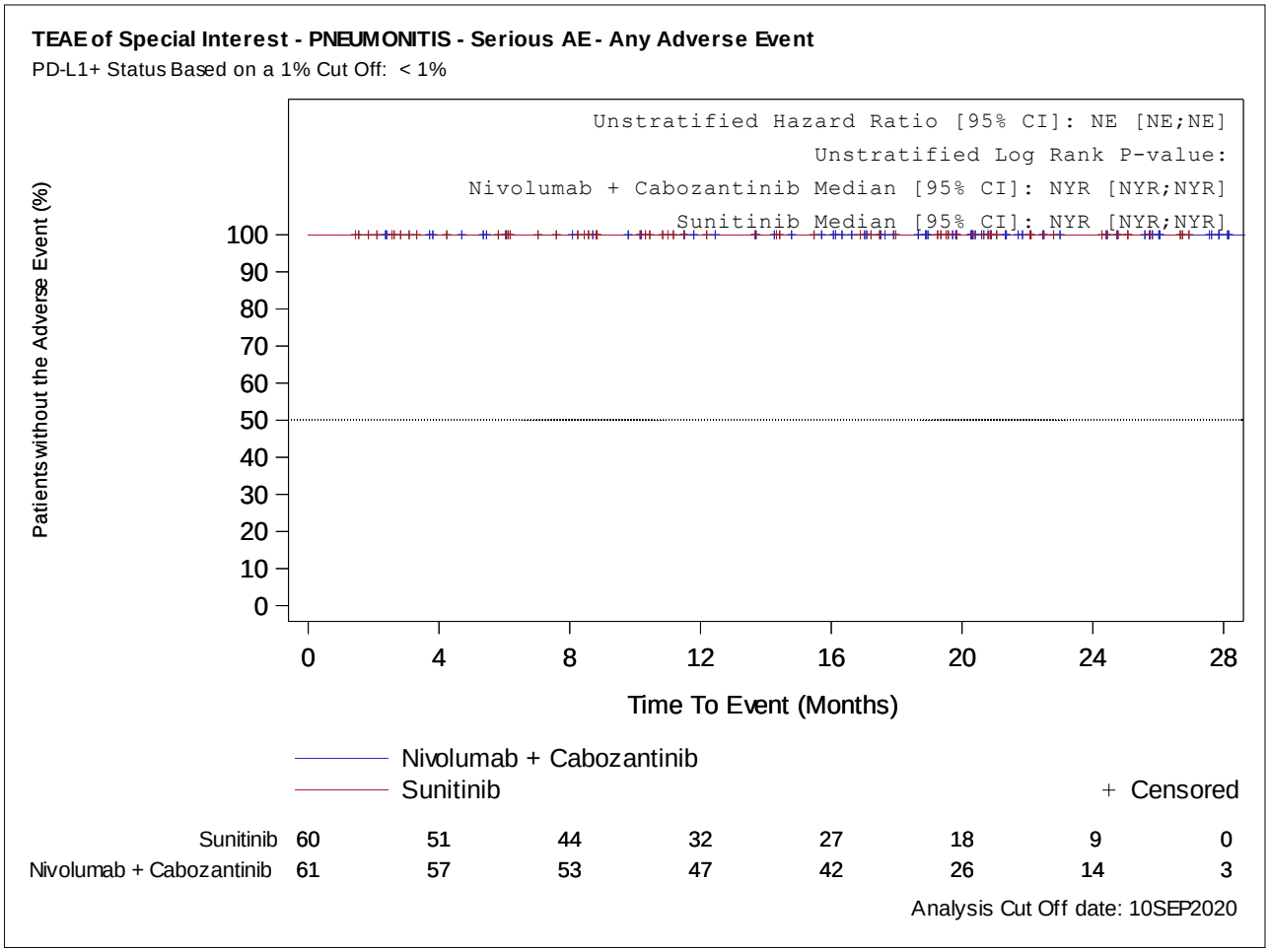

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:42:13

FIGURE 3.129.2.21: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



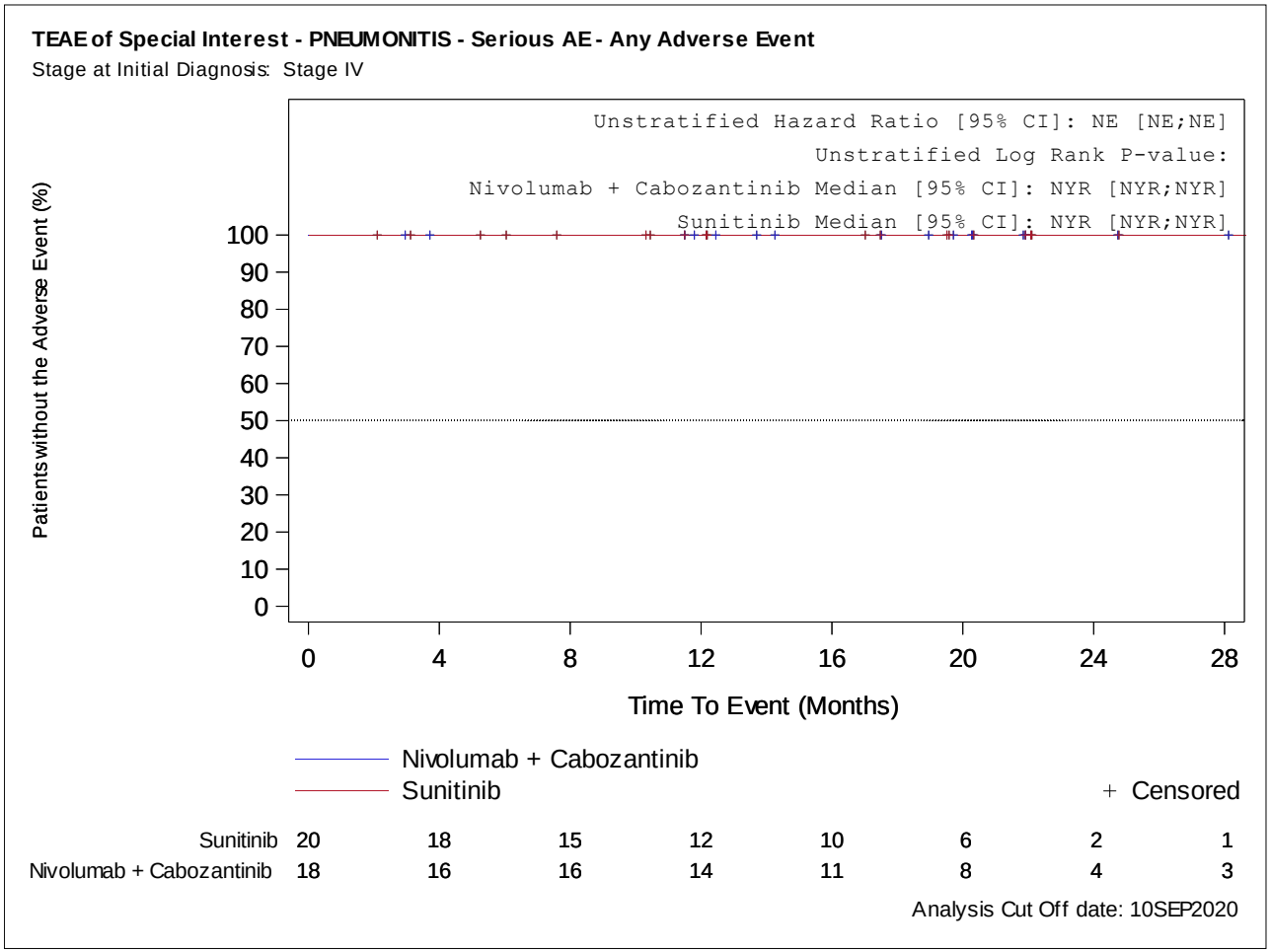

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:42:18

FIGURE 3.129.2.22: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



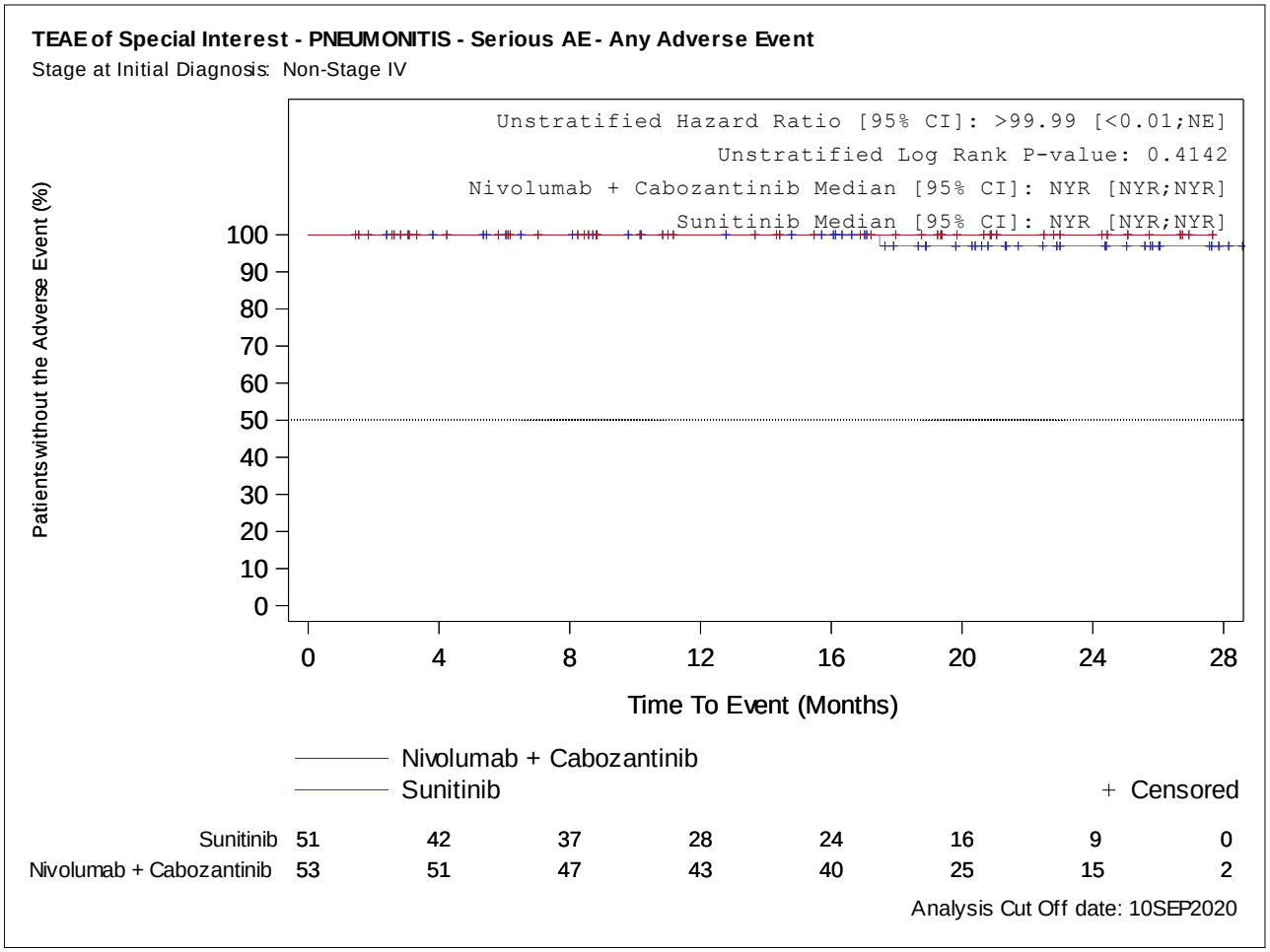

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:42:24

FIGURE 3.129.2.23: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



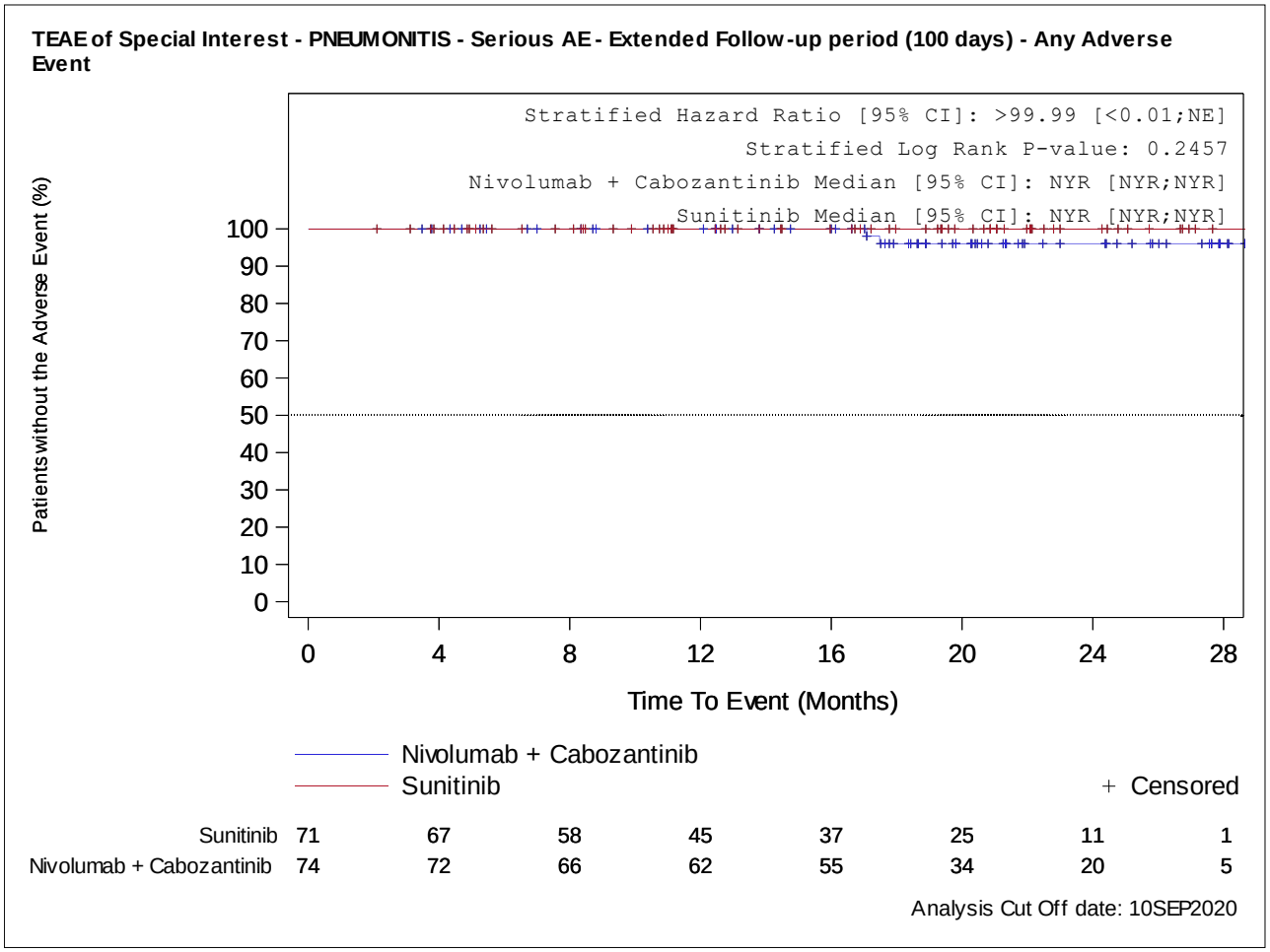

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:42:51

FIGURE 3.129.2.24: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



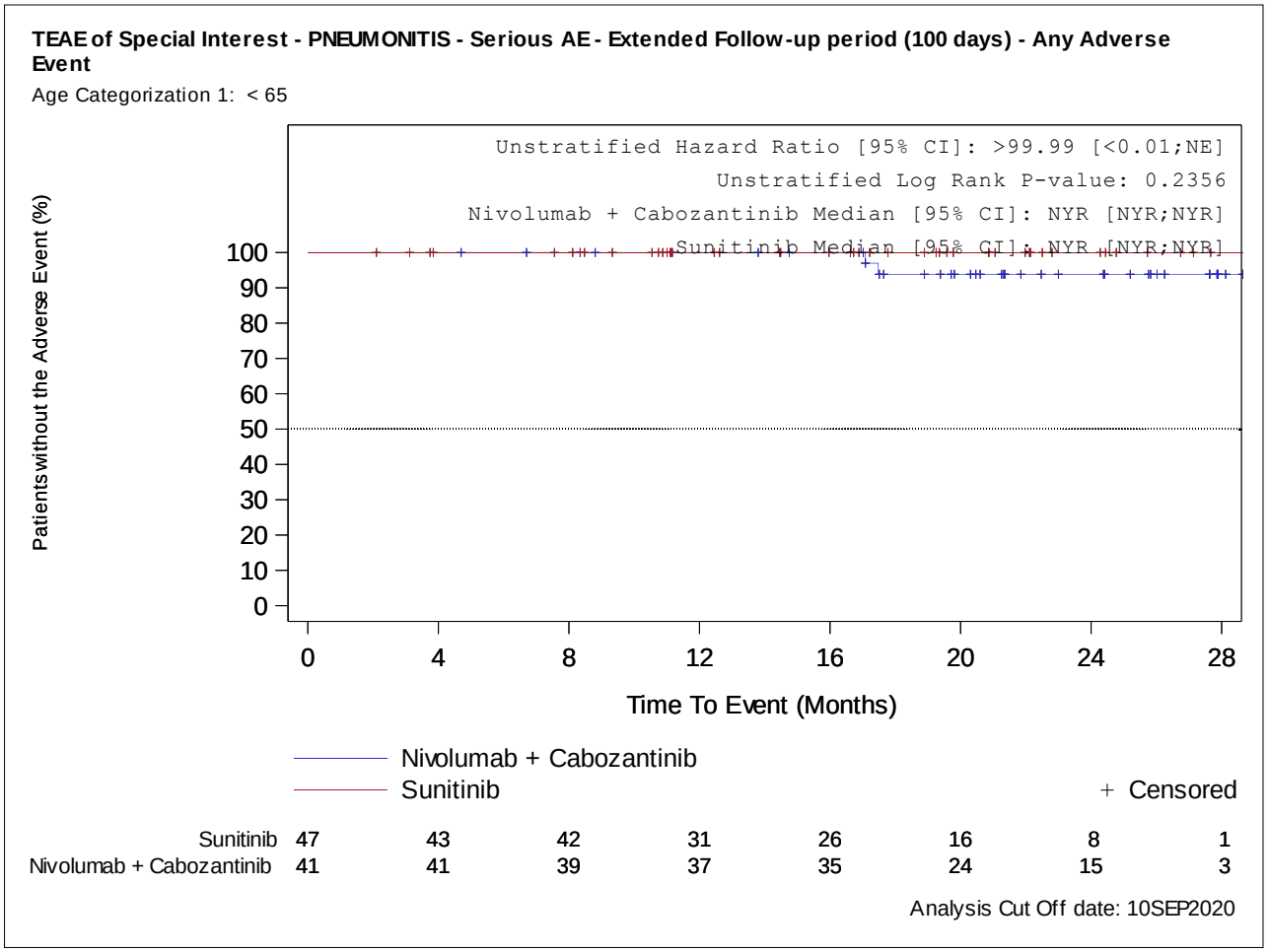

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:42:56

FIGURE 3.130.1: TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



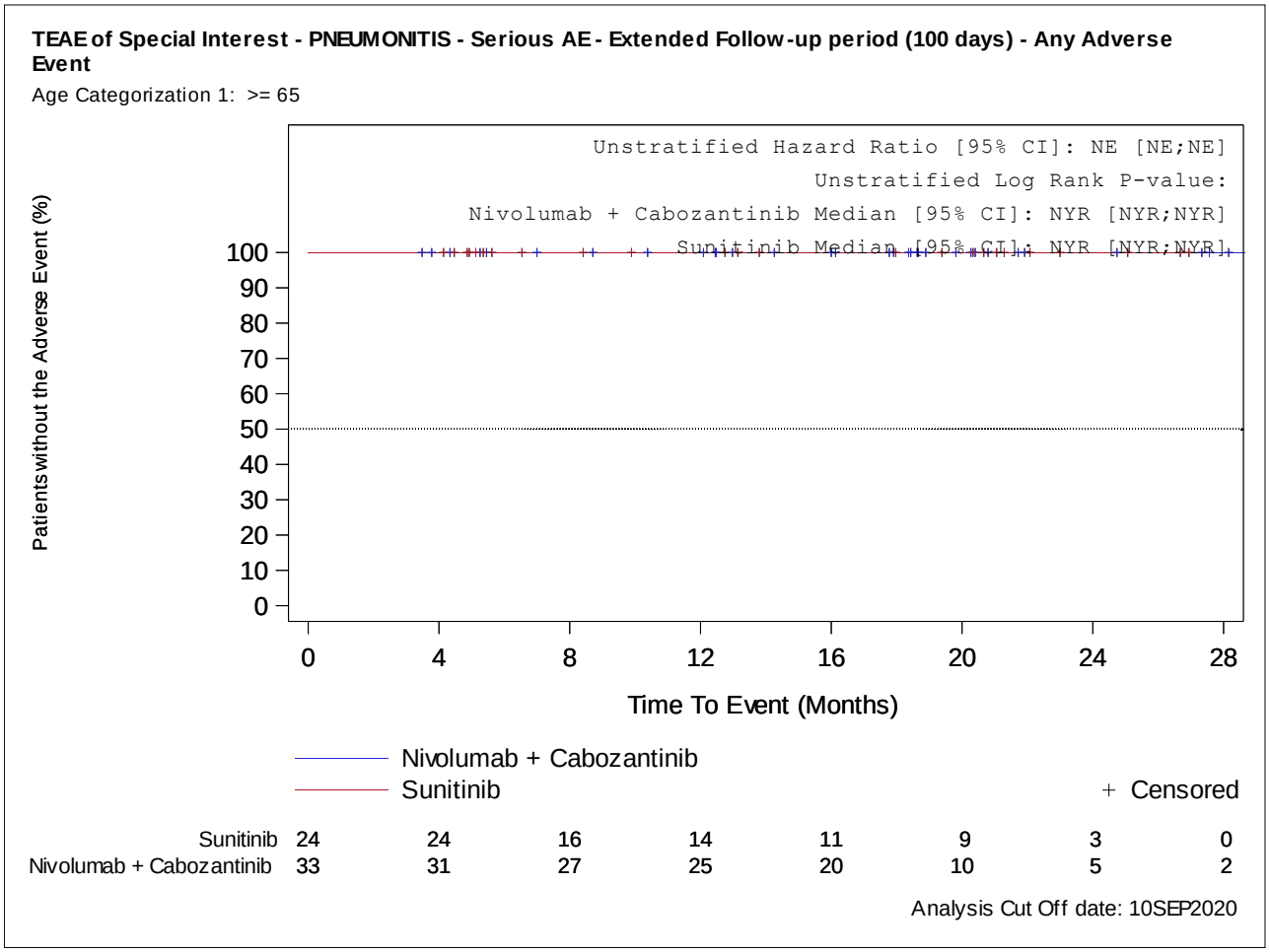

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:45:56

FIGURE 3.130.2.1: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



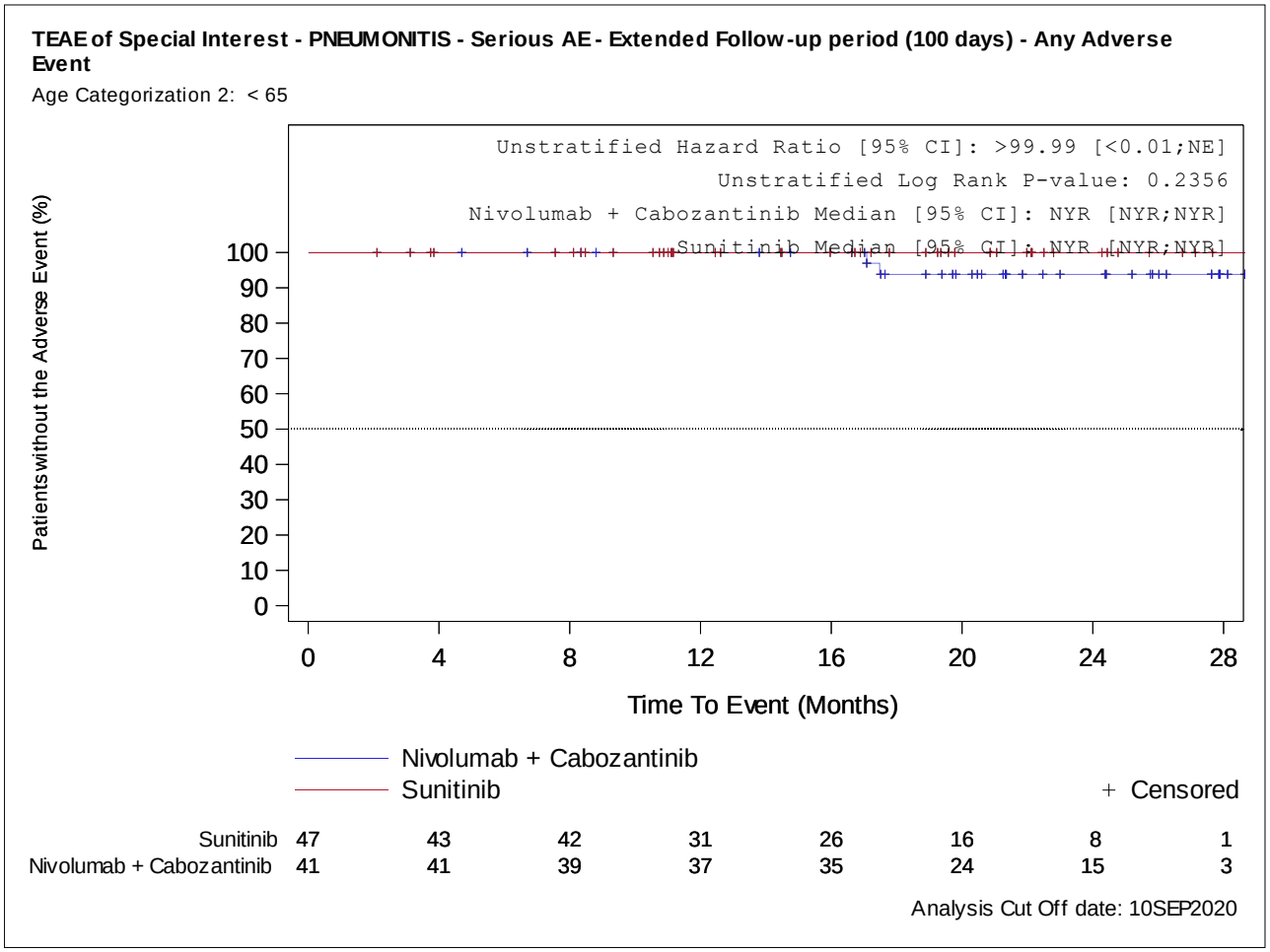

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:45:58

FIGURE 3.130.2.2: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



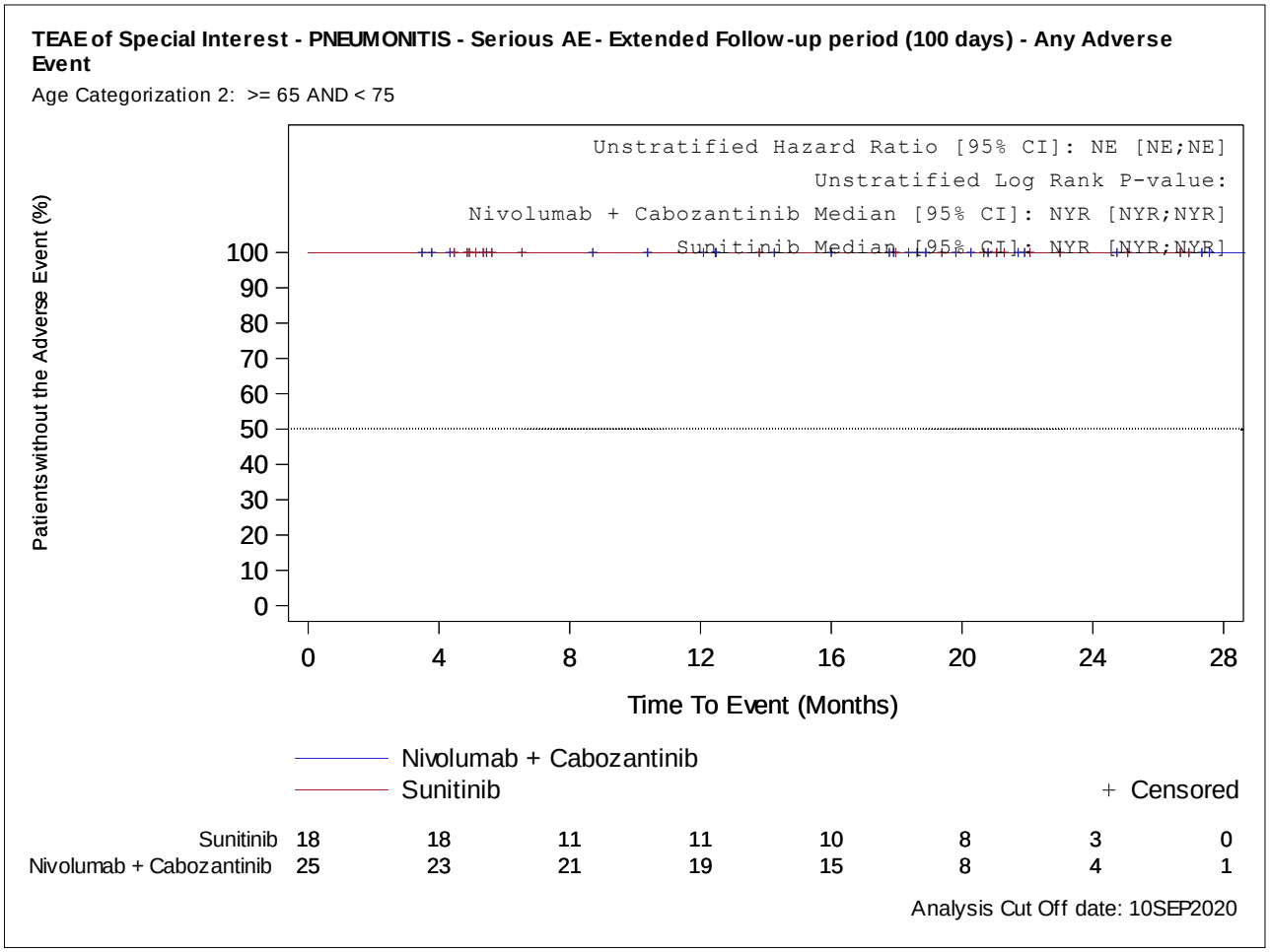

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:46:03

FIGURE 3.130.2.3: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



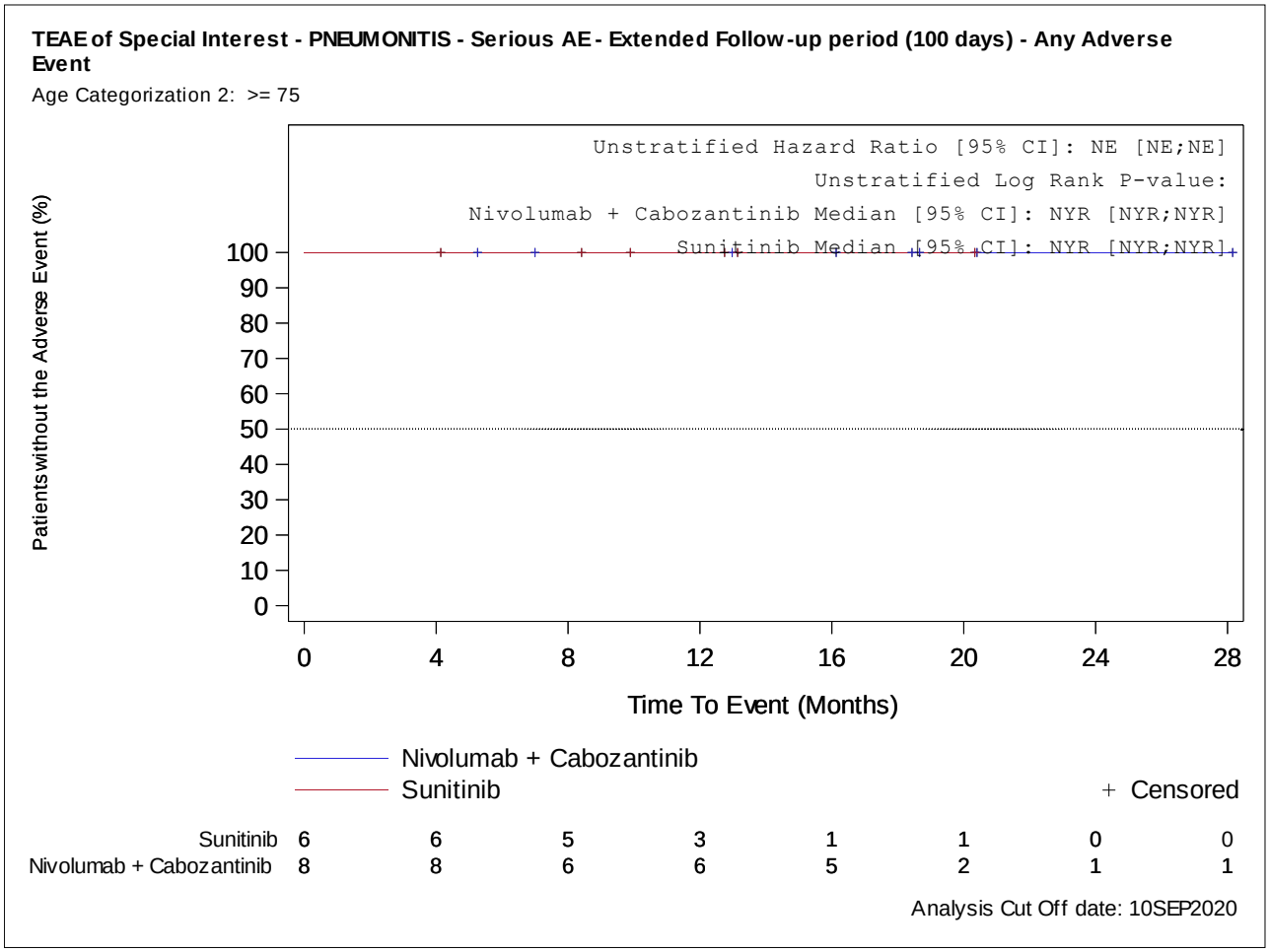

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:46:09

FIGURE 3.130.2.4: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



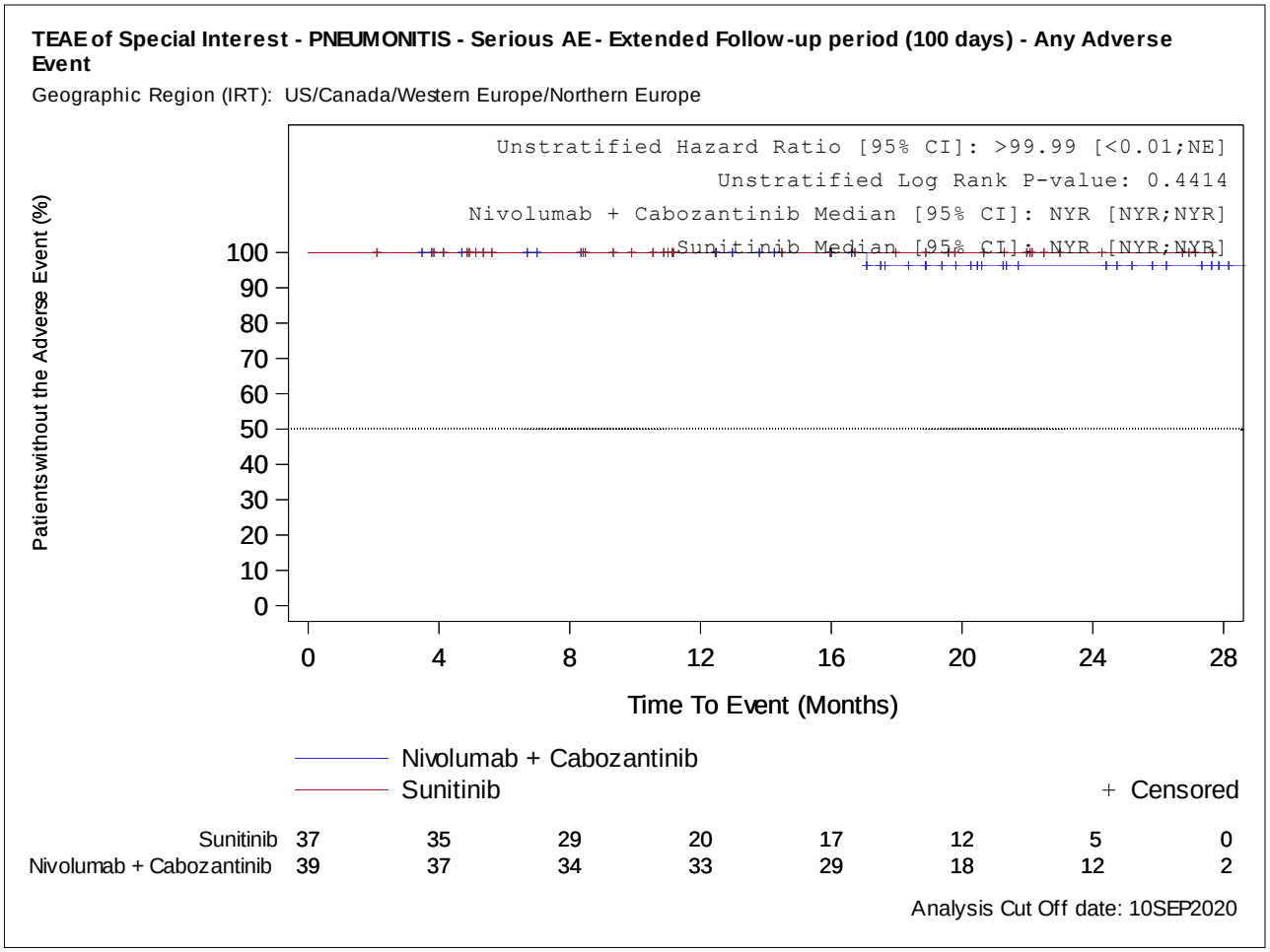

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:46:15

FIGURE 3.130.2.5: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



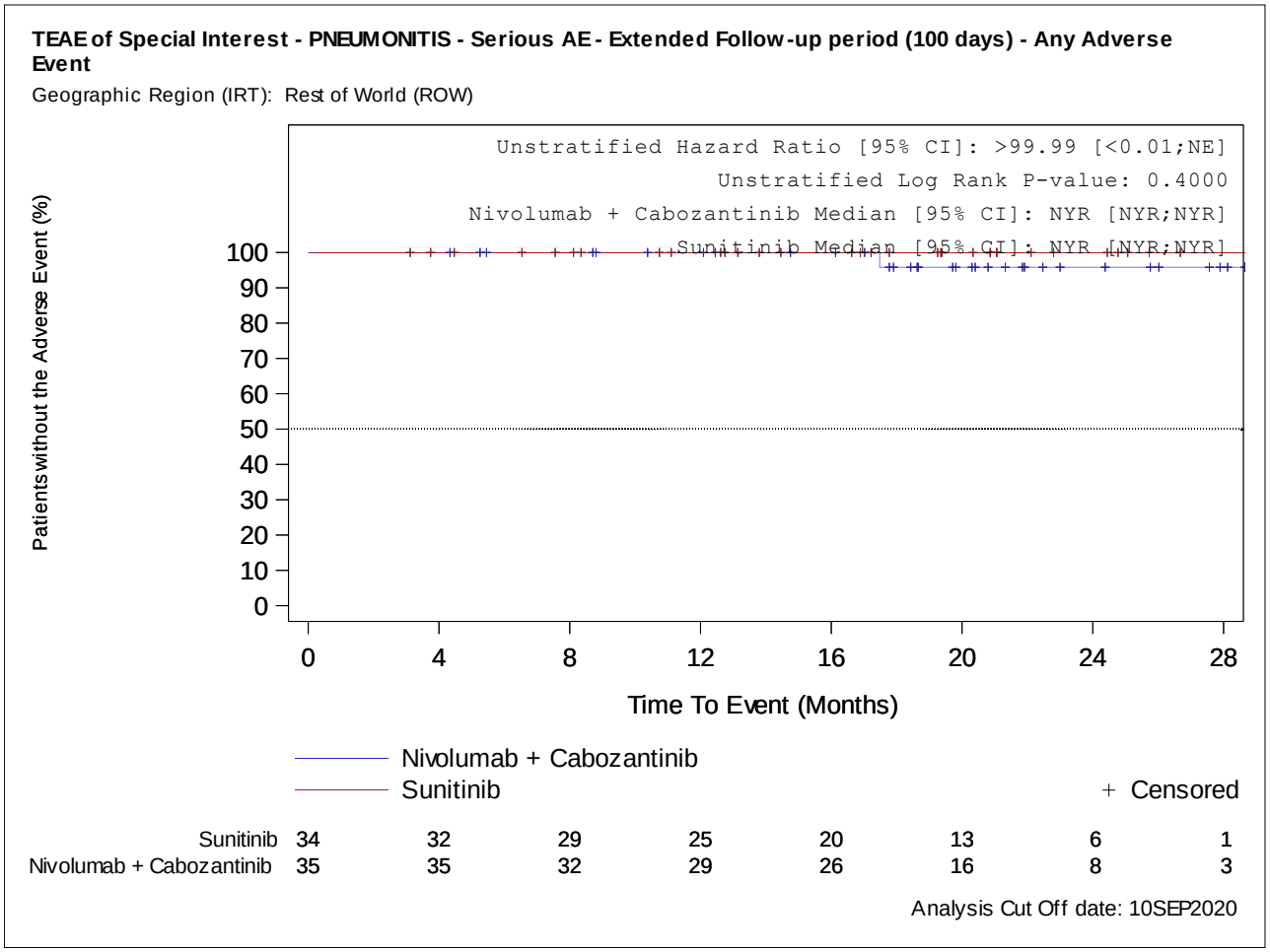

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:46:20

FIGURE 3.130.2.6: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



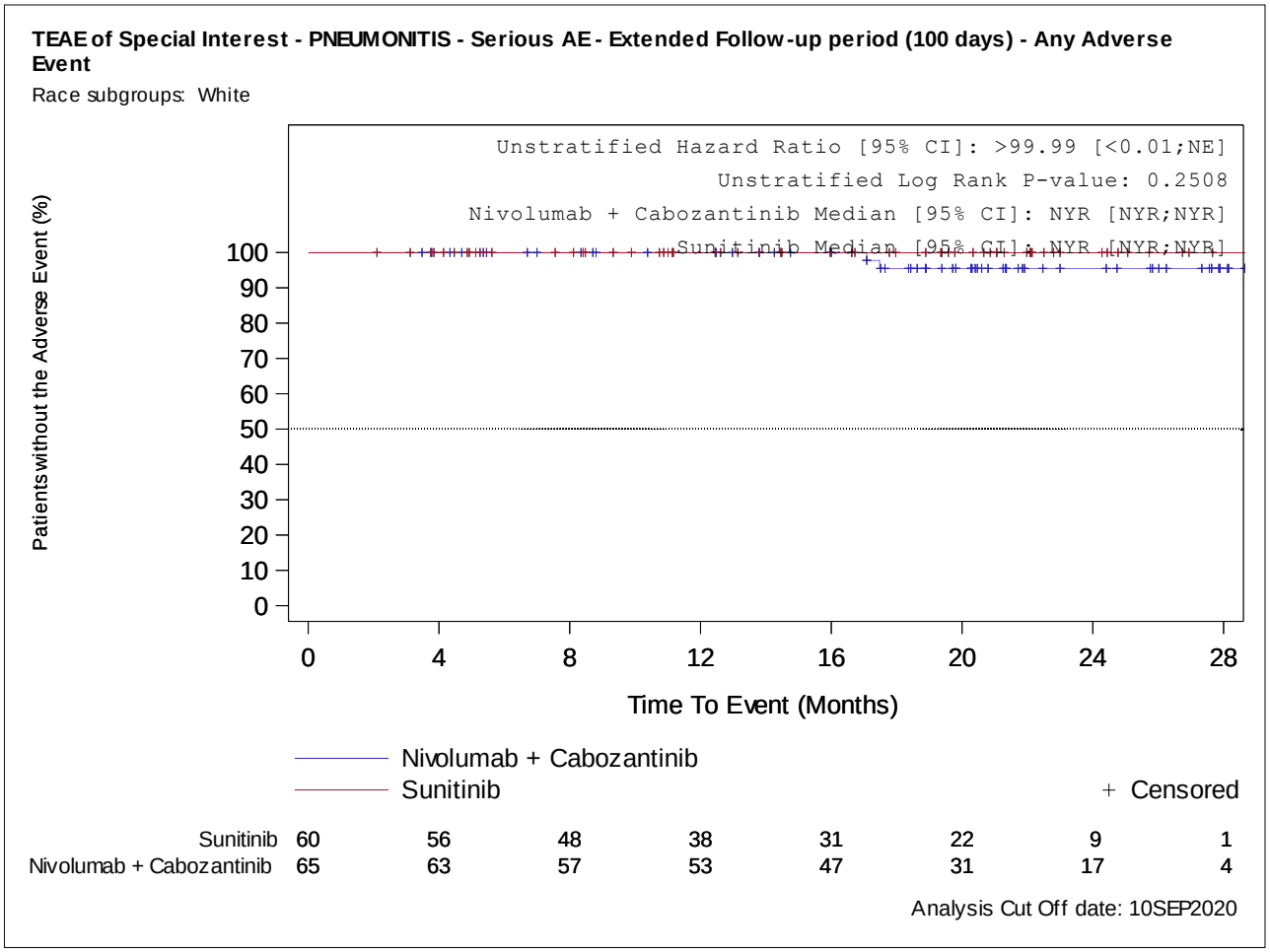

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:46:26

FIGURE 3.130.2.7: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



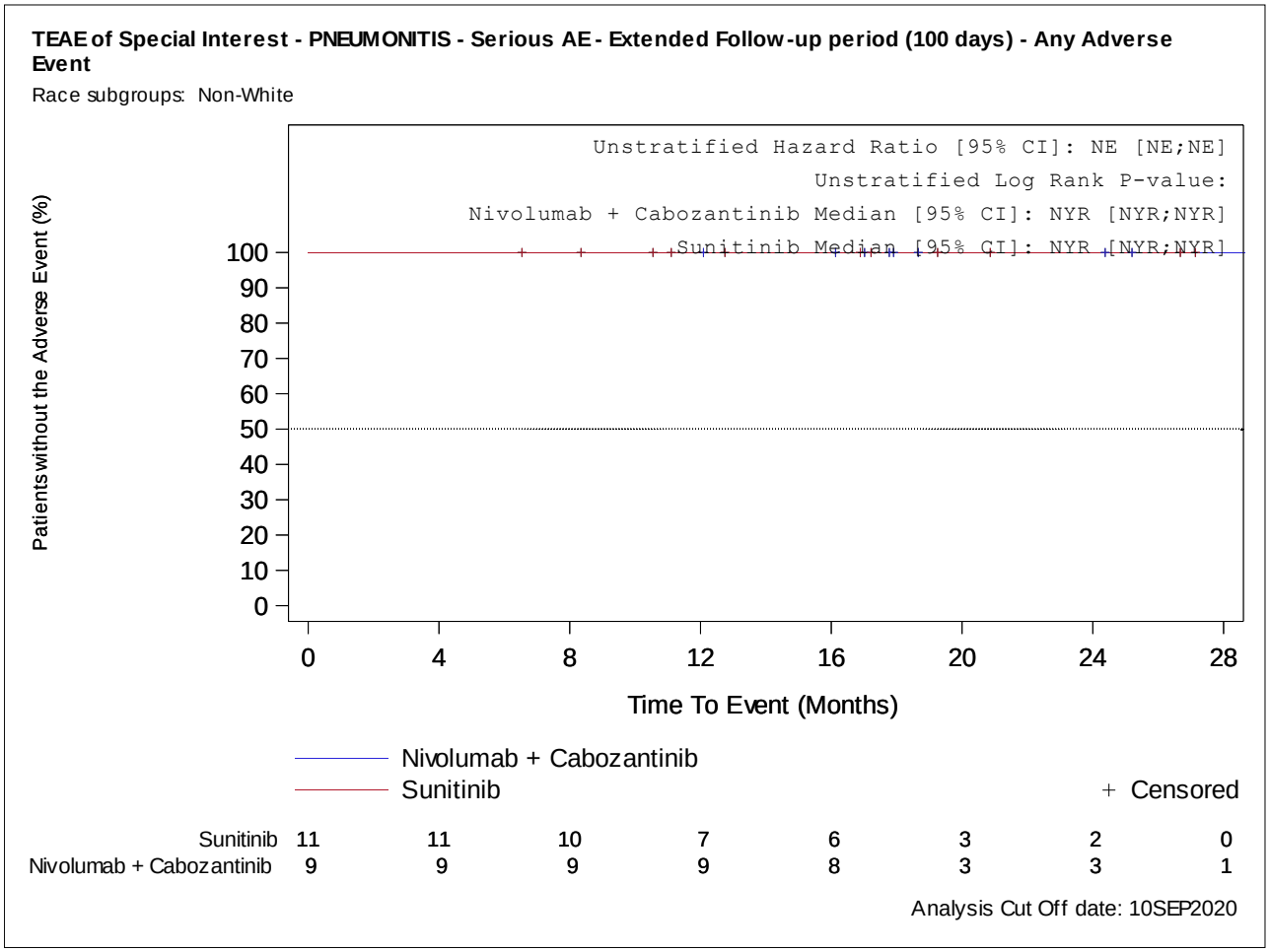

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:46:31

FIGURE 3.130.2.8: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



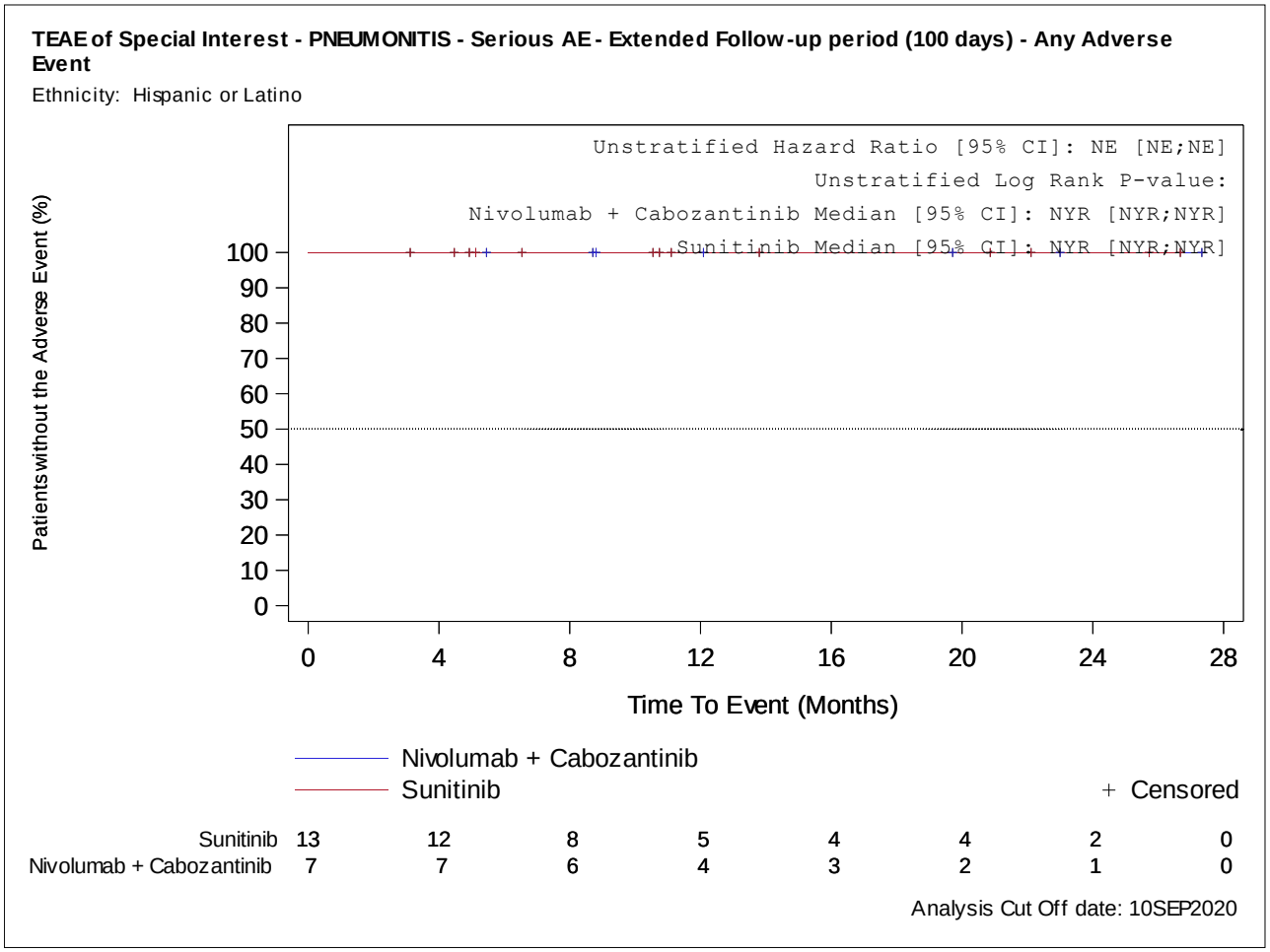

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:46:37

FIGURE 3.130.2.9: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



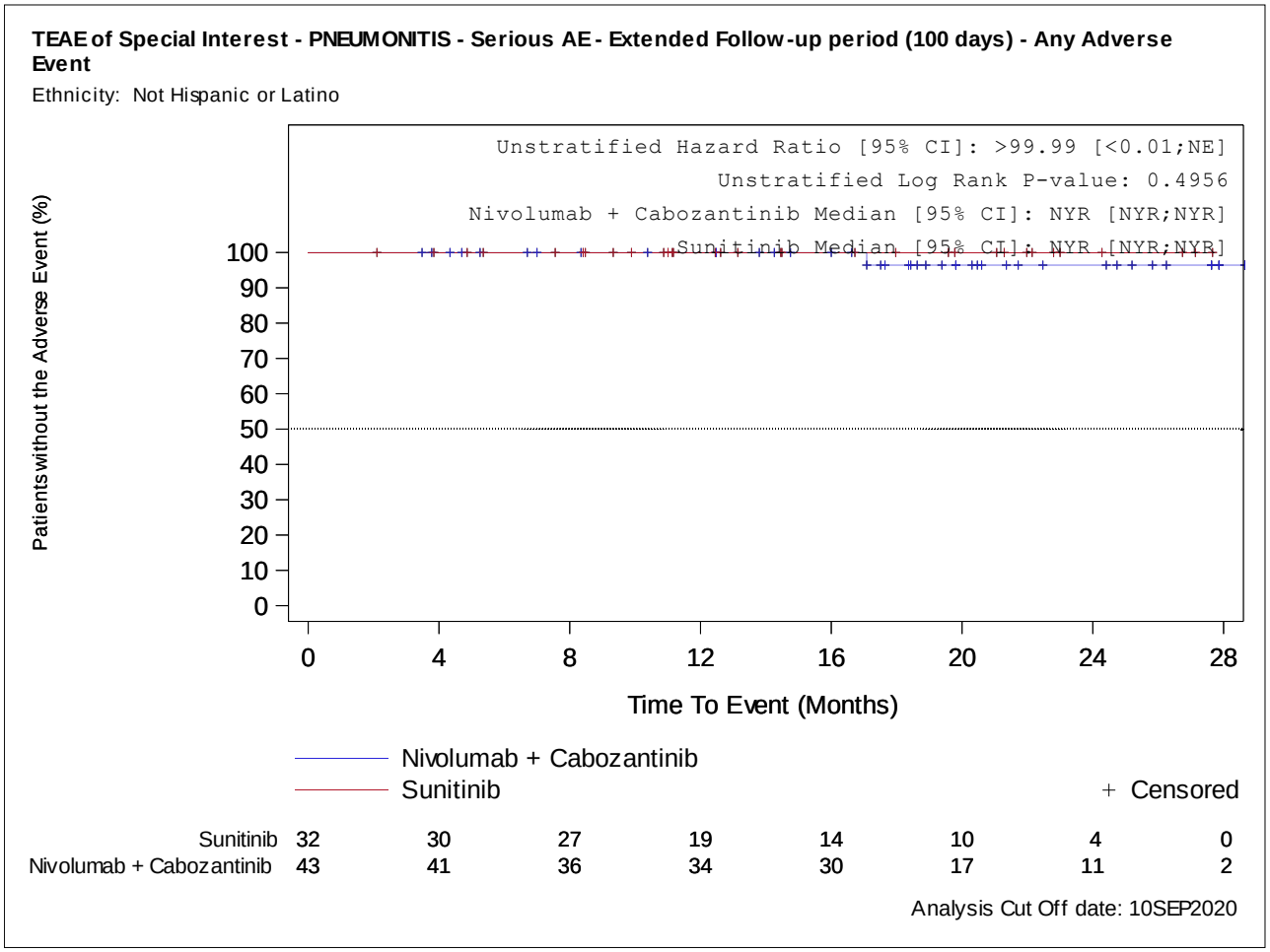

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:46:42

FIGURE 3.130.2.10: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



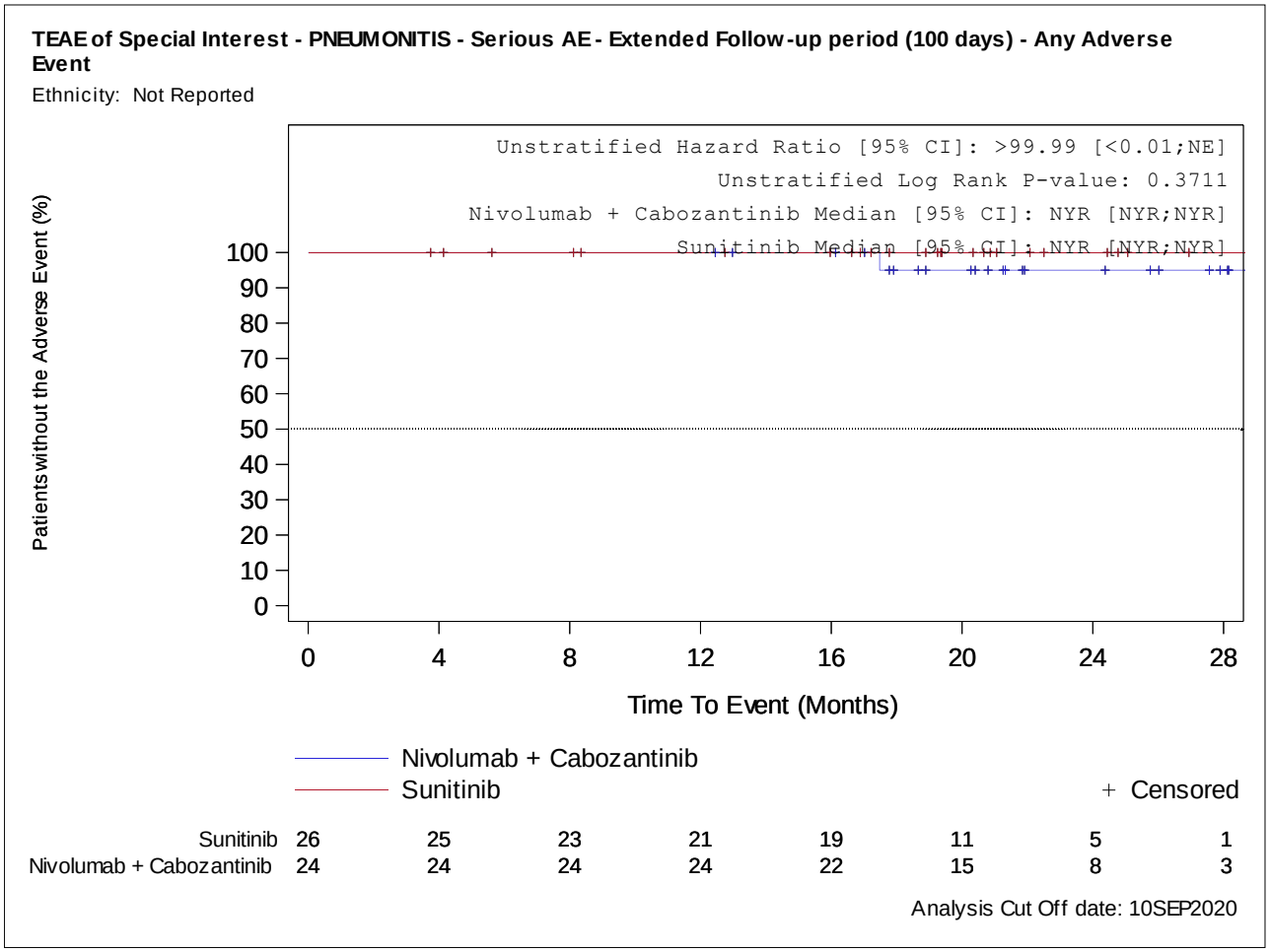

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:46:47

FIGURE 3.130.2.11: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



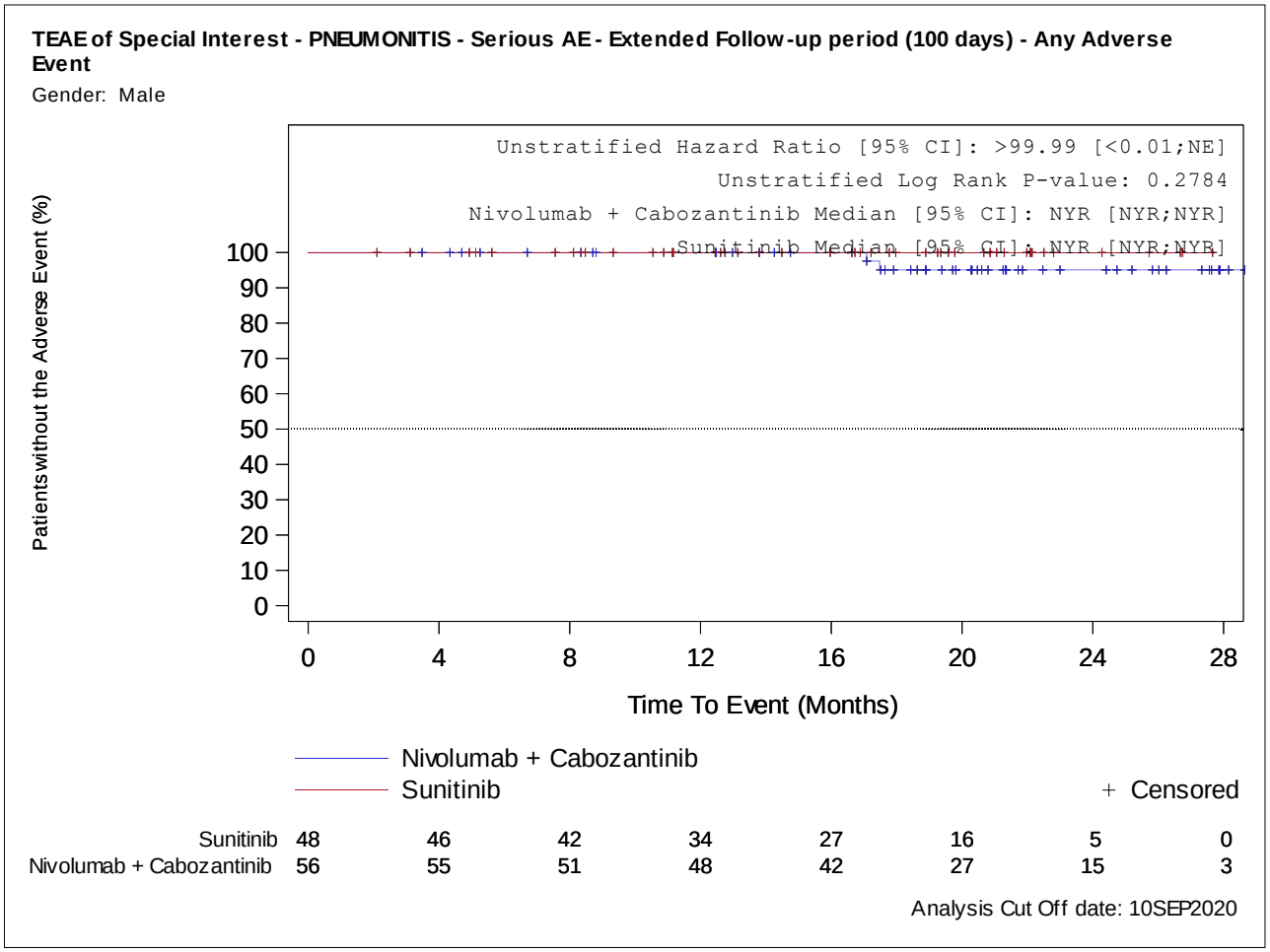

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:46:52

FIGURE 3.130.2.12: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



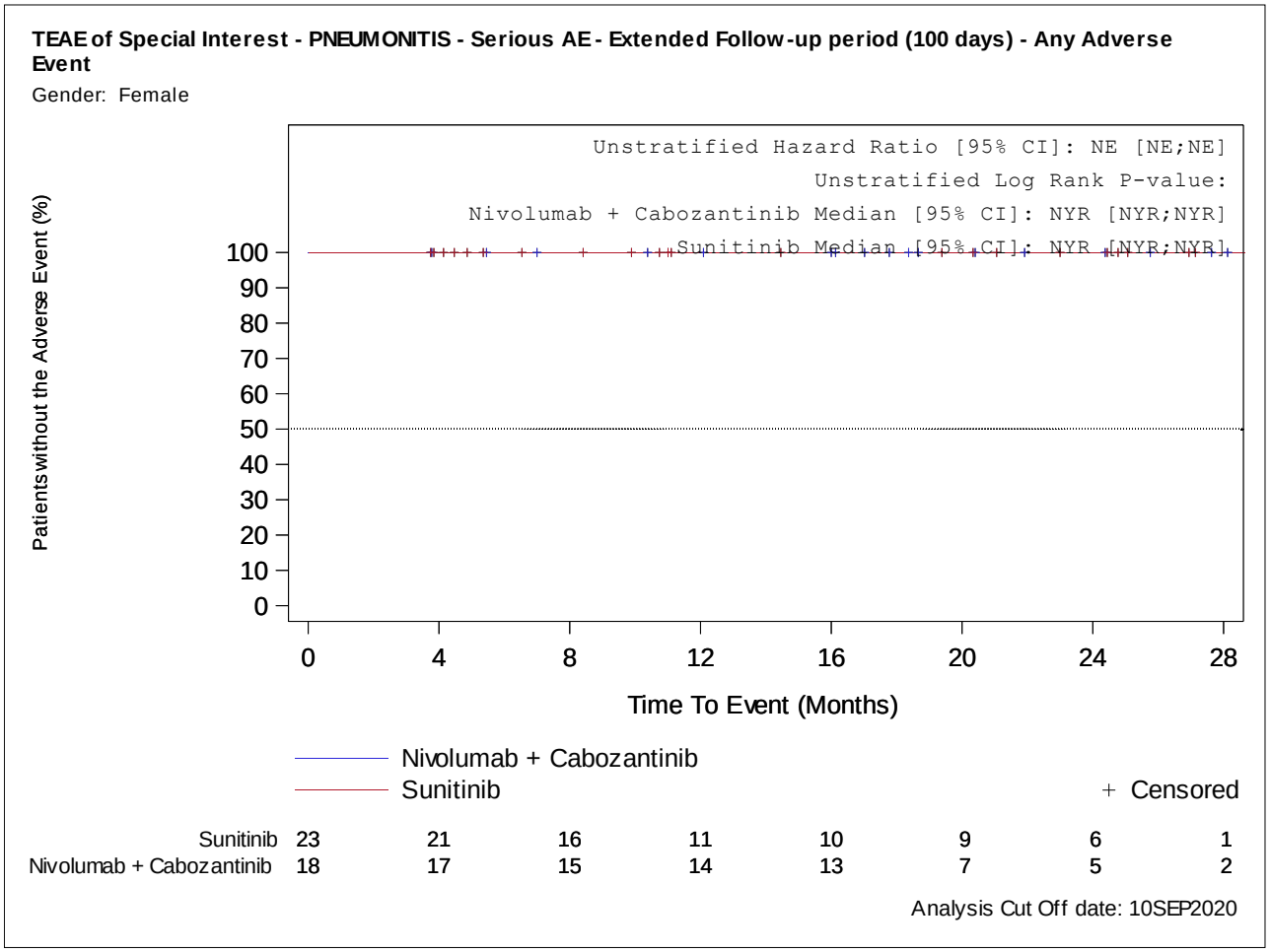

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:46:58

FIGURE 3.130.2.13: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



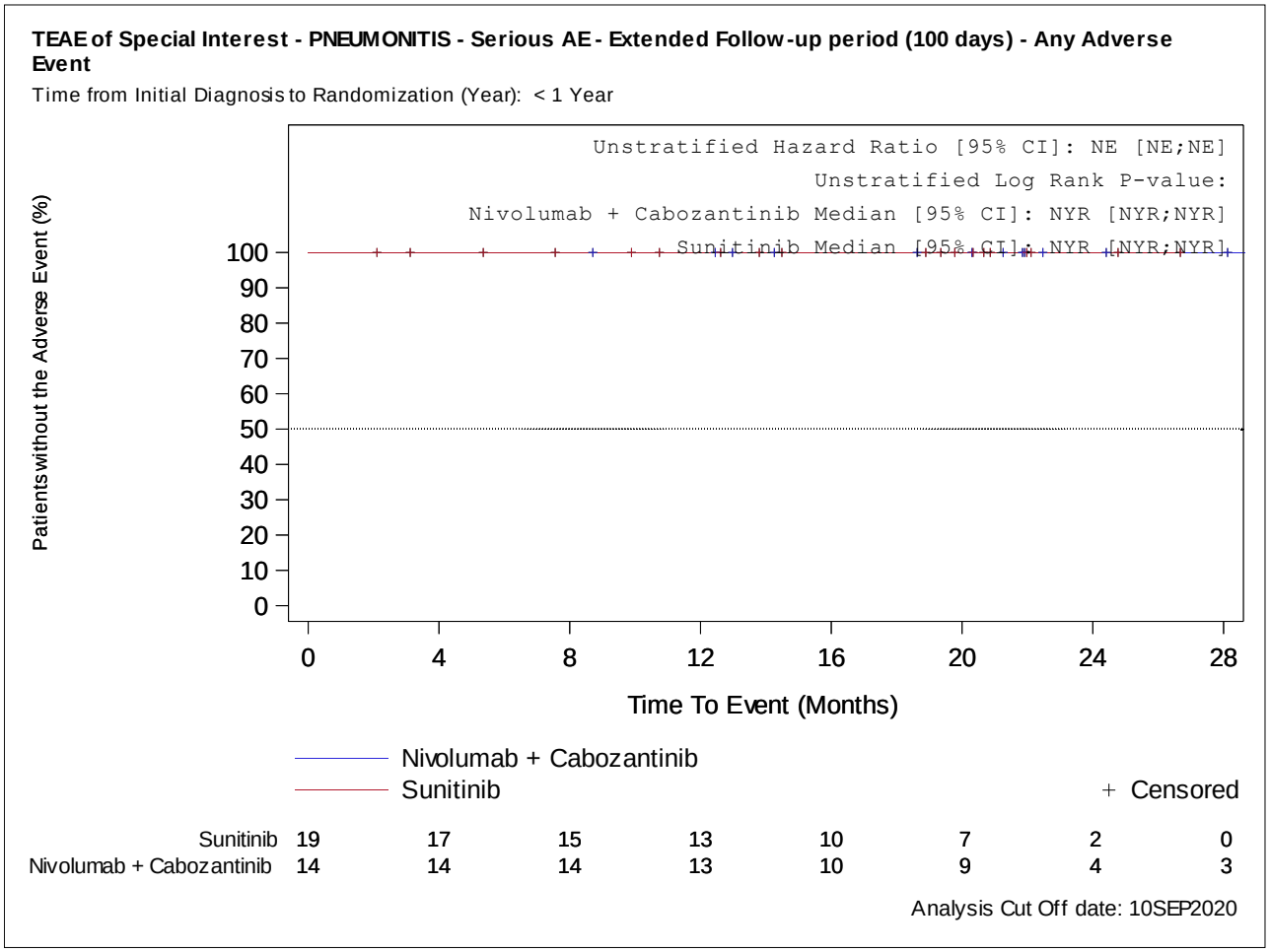

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:47:03

FIGURE 3.130.2.14: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



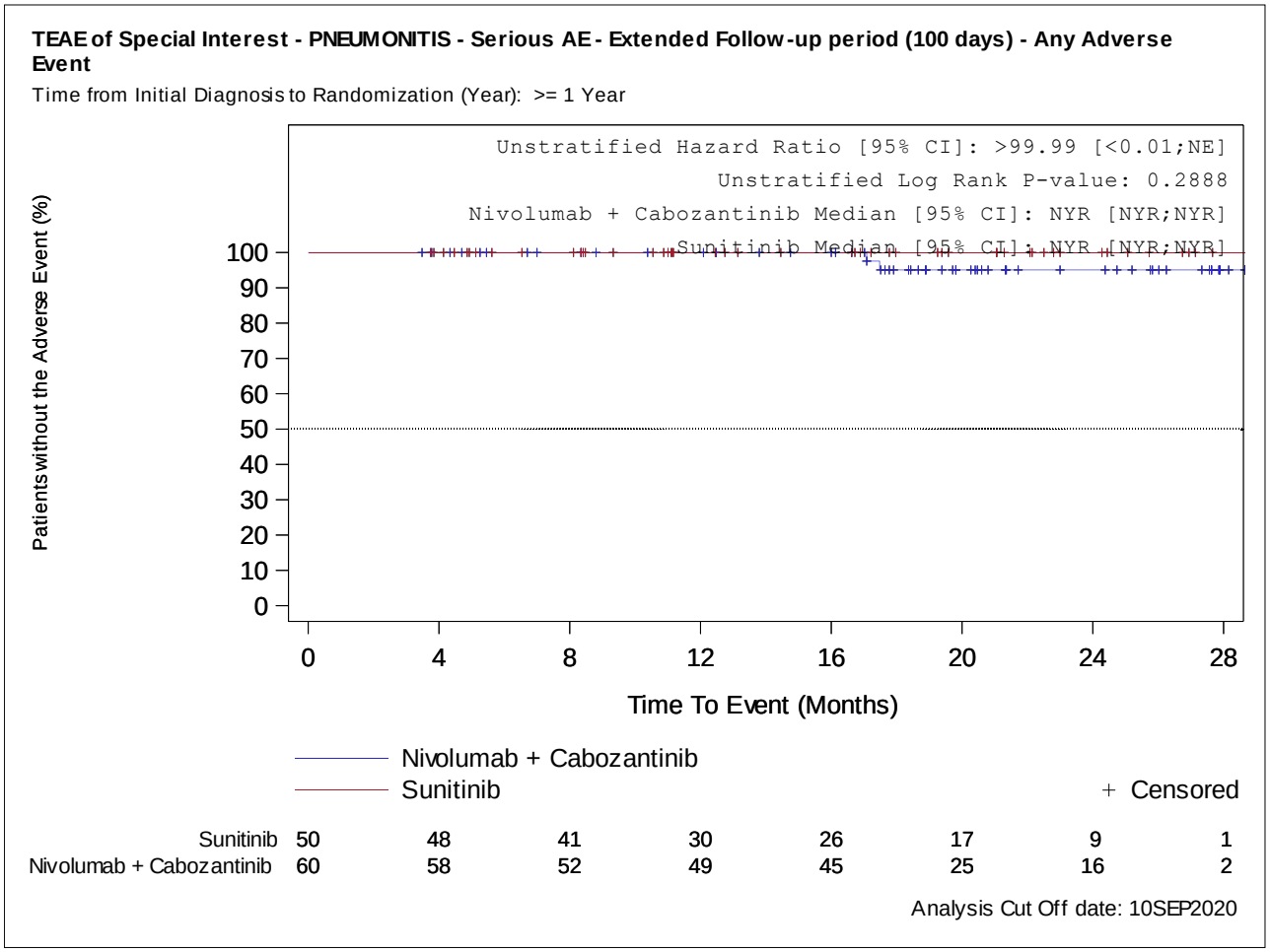

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:47:09

FIGURE 3.130.2.15: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



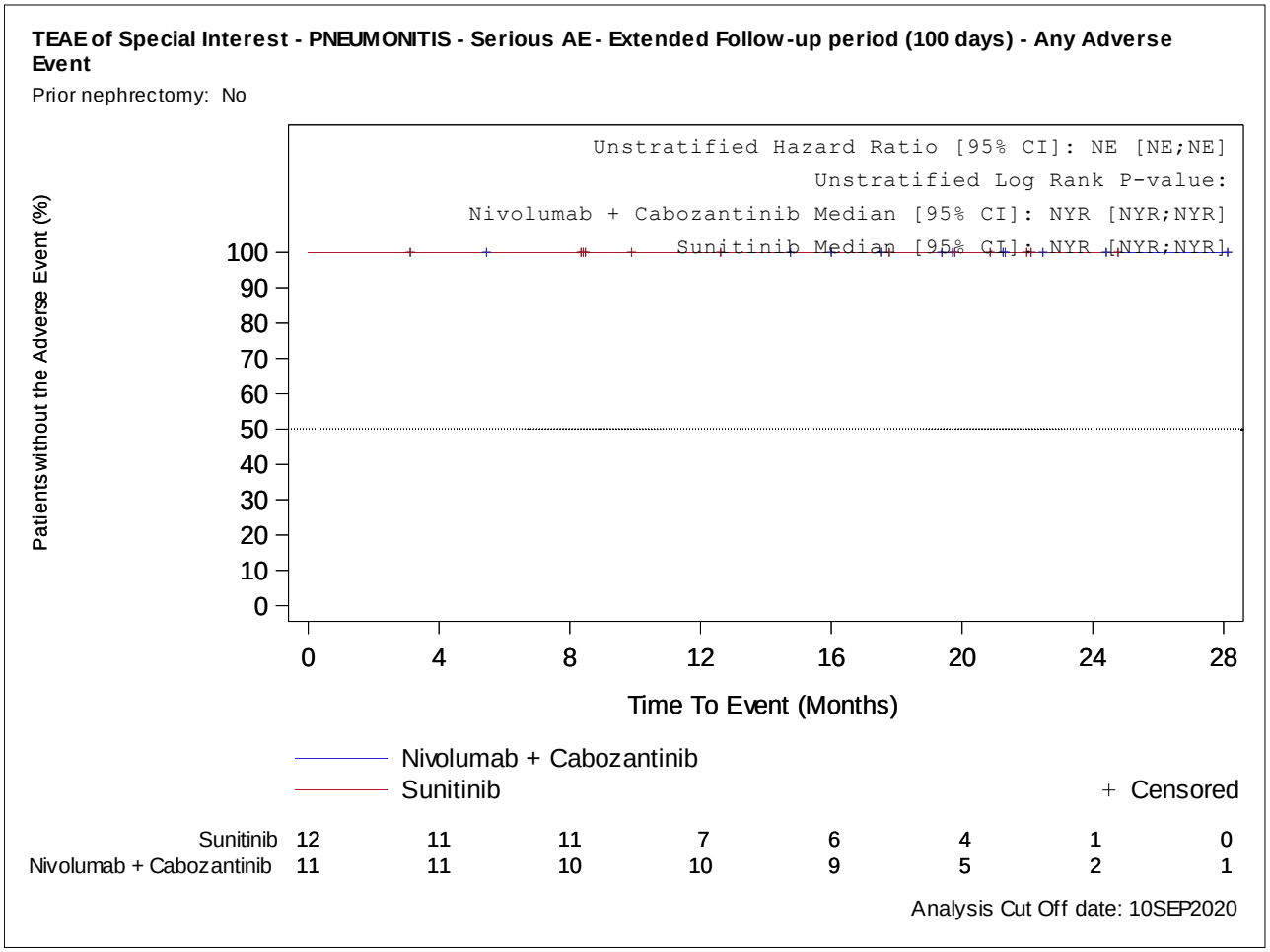

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:47:24

FIGURE 3.130.2.16: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



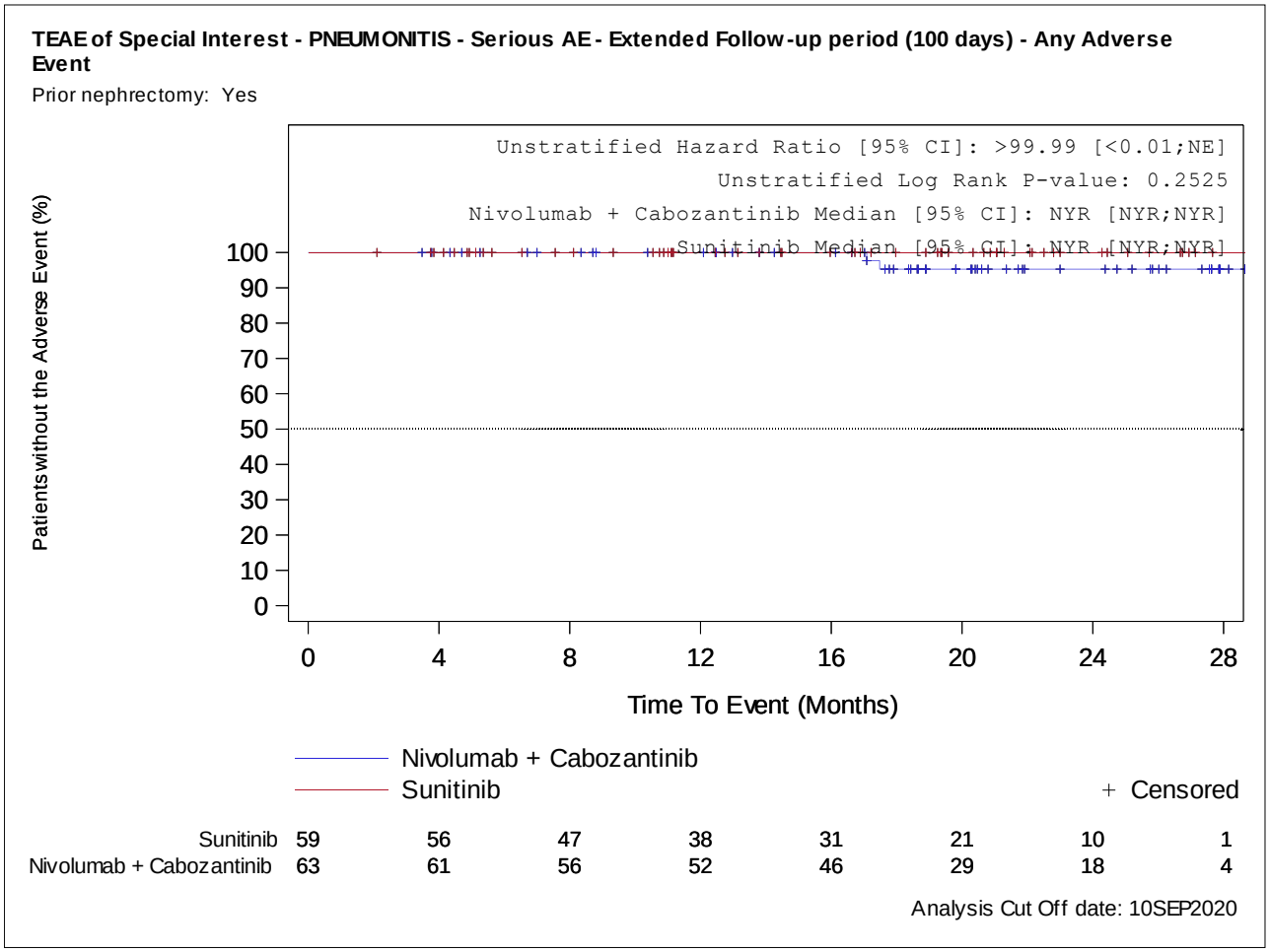

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:47:30

FIGURE 3.130.2.17: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



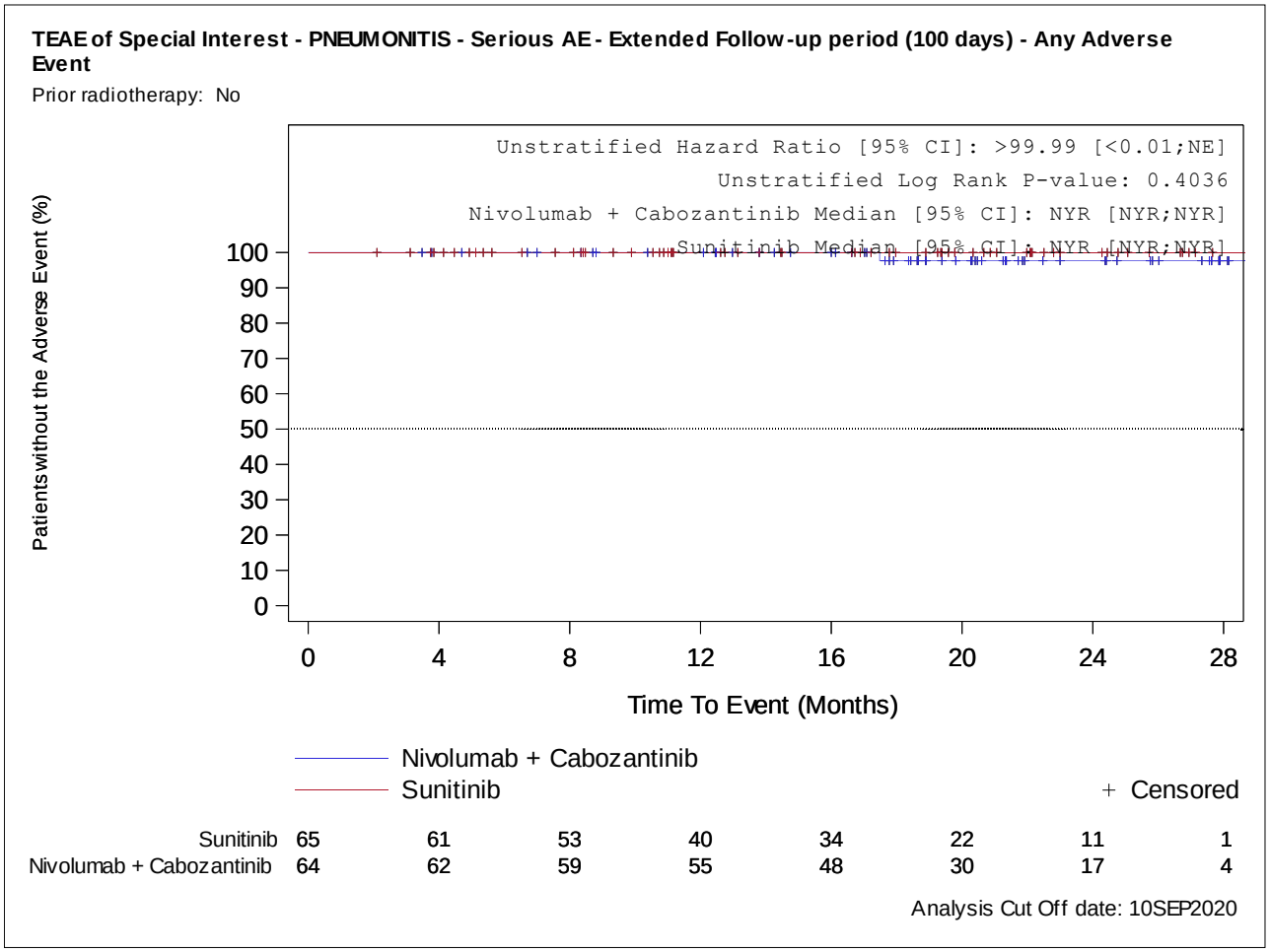

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:48:16

FIGURE 3.130.2.18: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



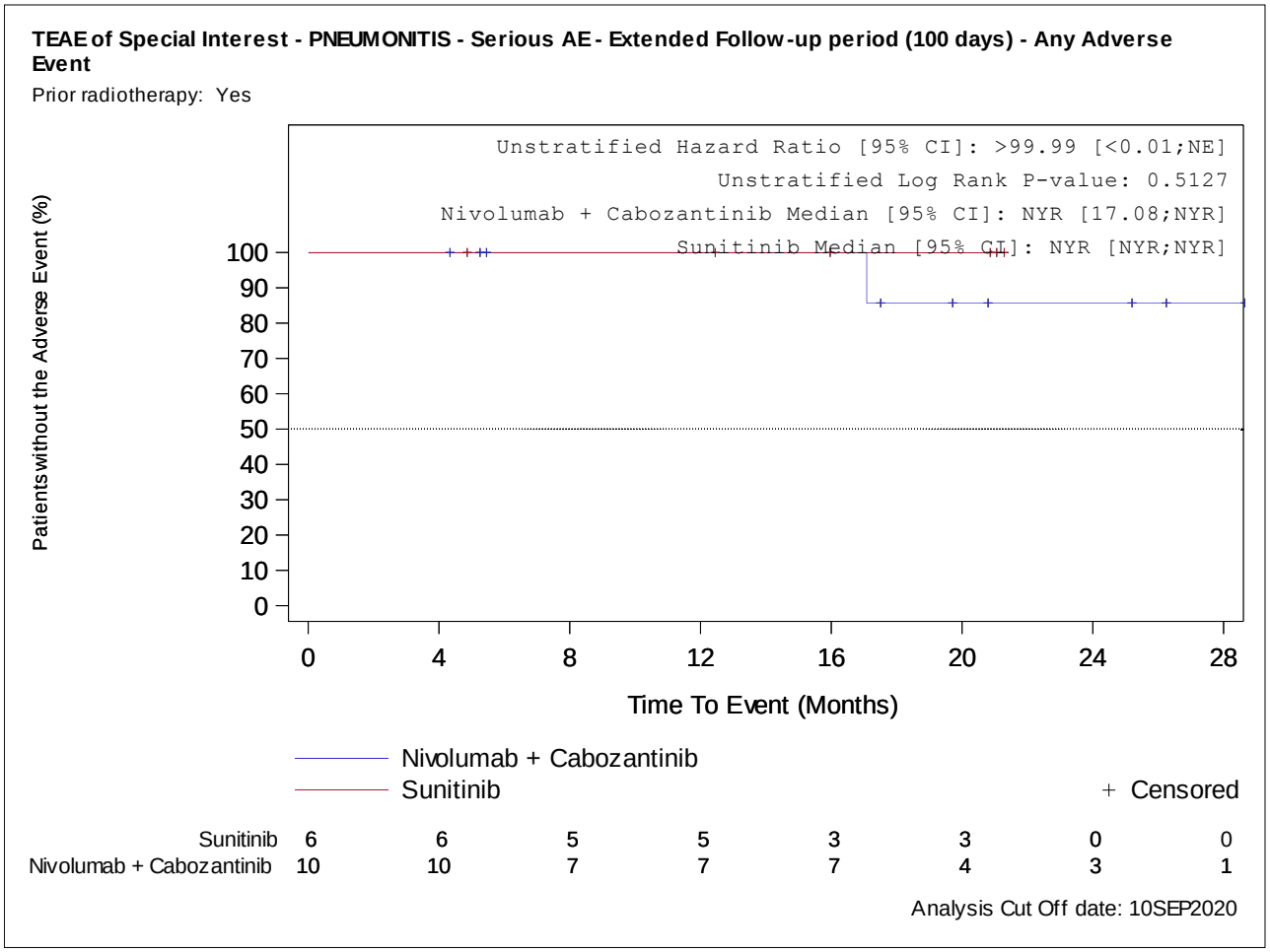

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:48:21

FIGURE 3.130.2.19: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



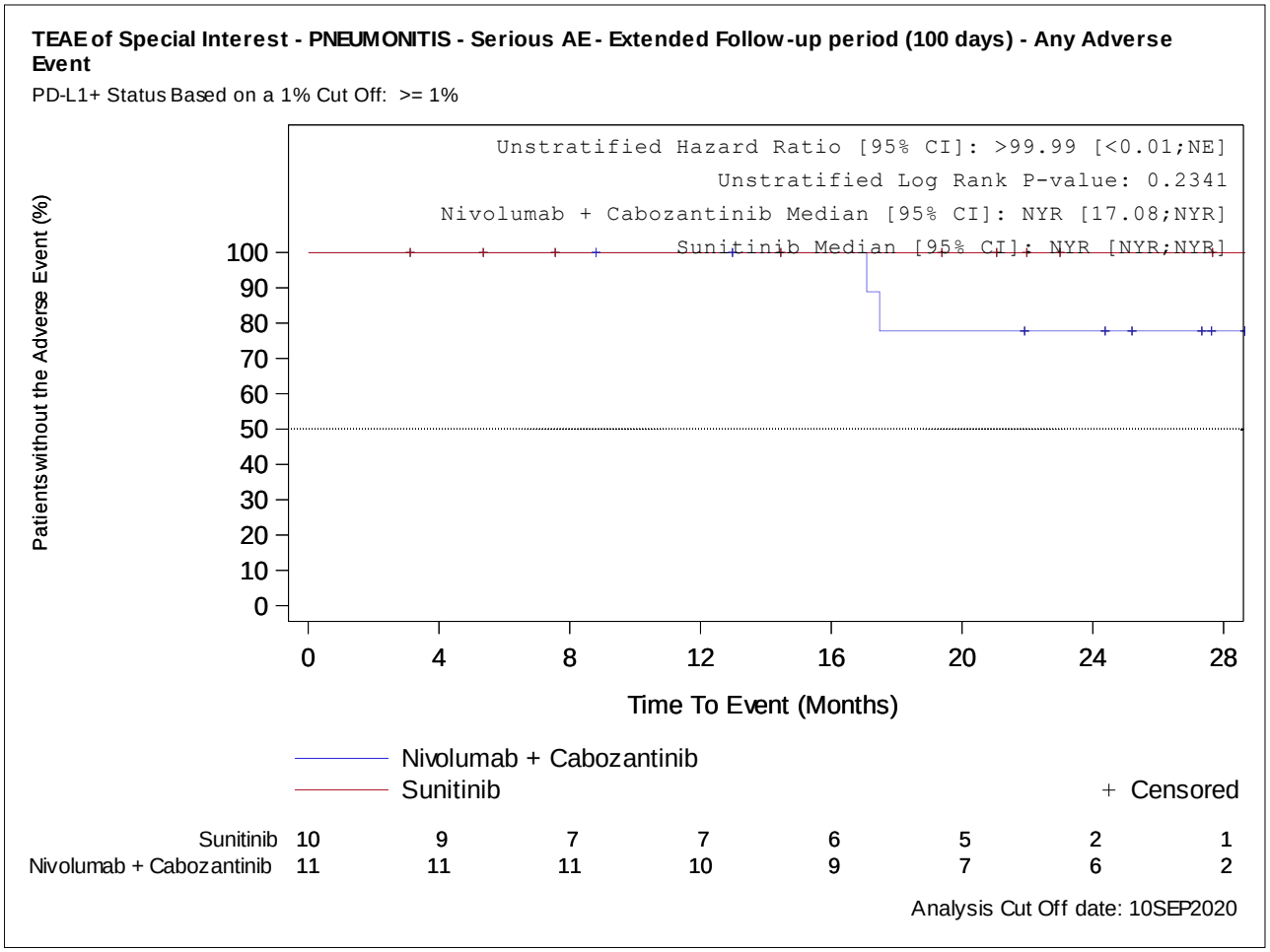

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:48:27

FIGURE 3.130.2.20: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



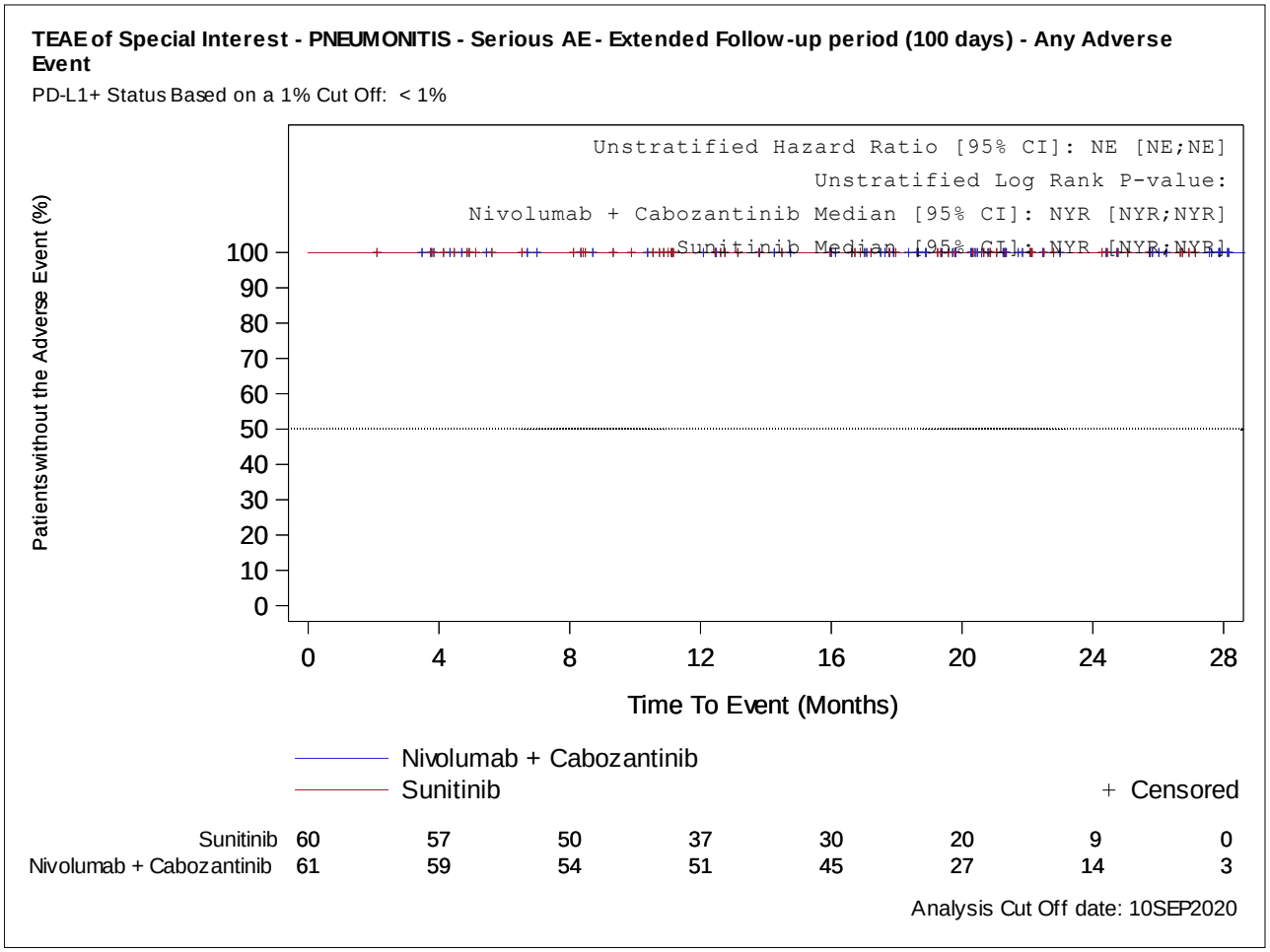

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:48:32

FIGURE 3.130.2.21: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



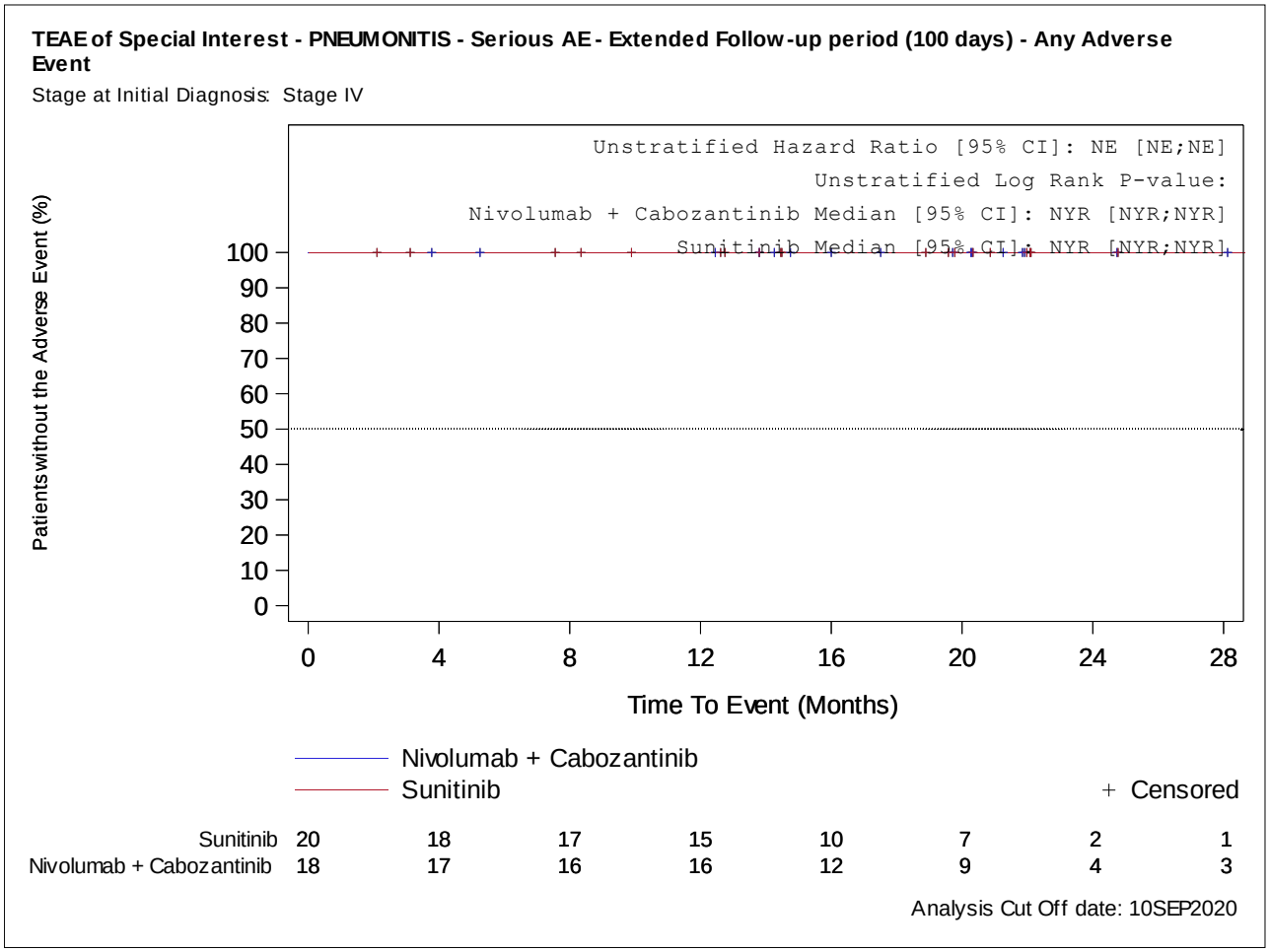

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:48:38

FIGURE 3.130.2.22: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



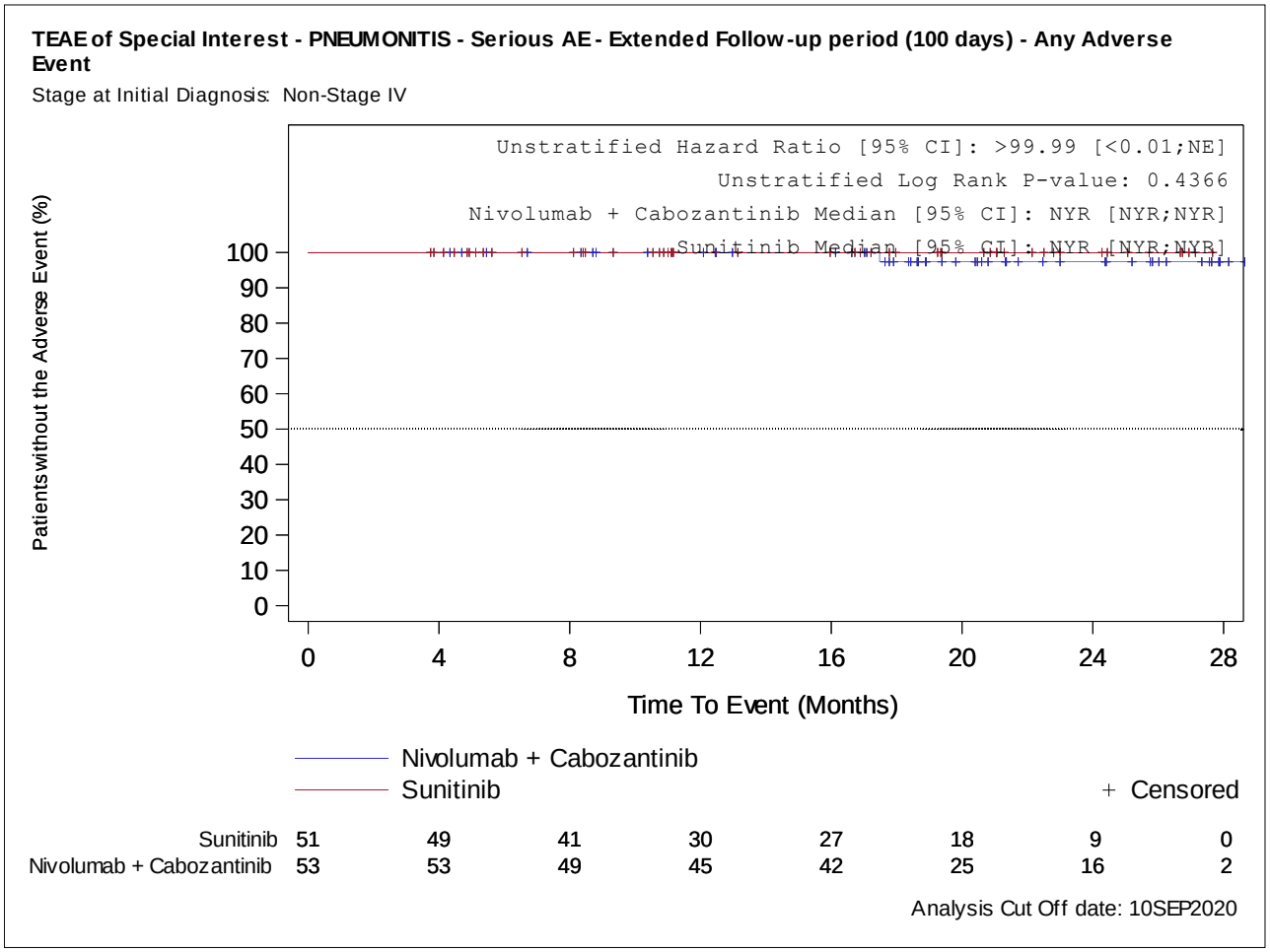

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:48:44

FIGURE 3.130.2.23: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



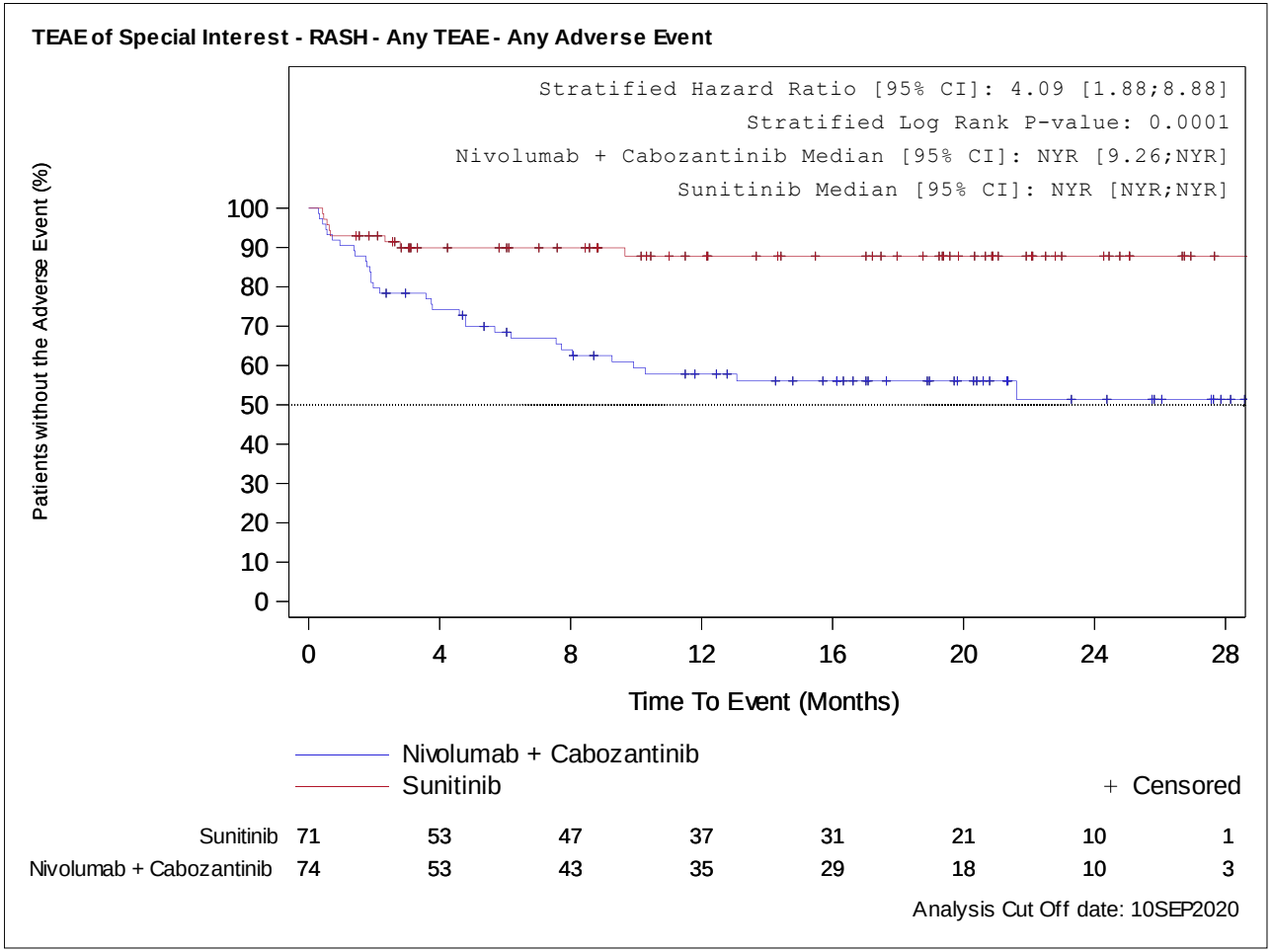

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:49:11

FIGURE 3.130.2.24: Kaplan-Meier curve - TEAE of Special Interest - PNEUMONITIS - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



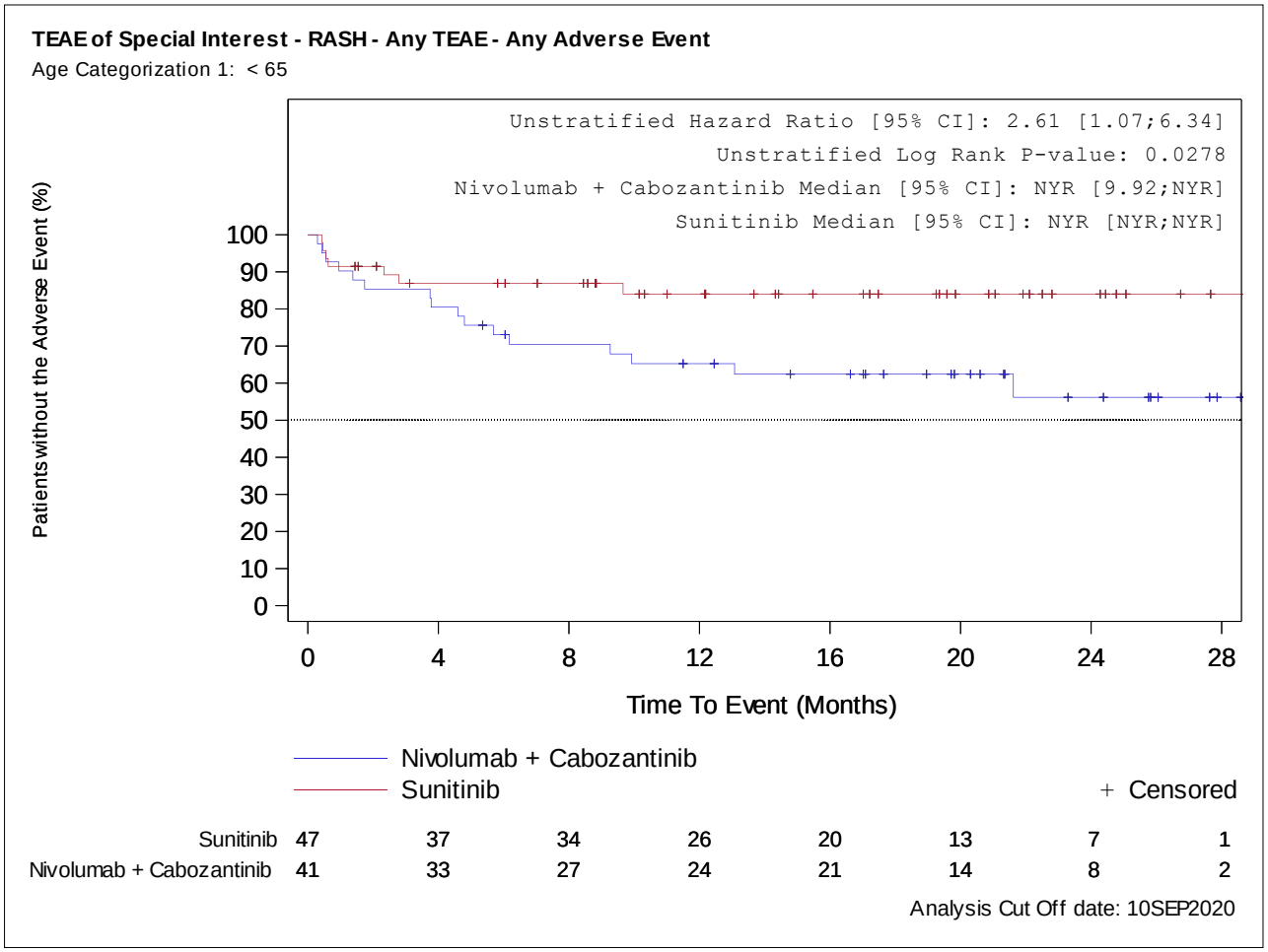

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:49:17

FIGURE 3.131.1: TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



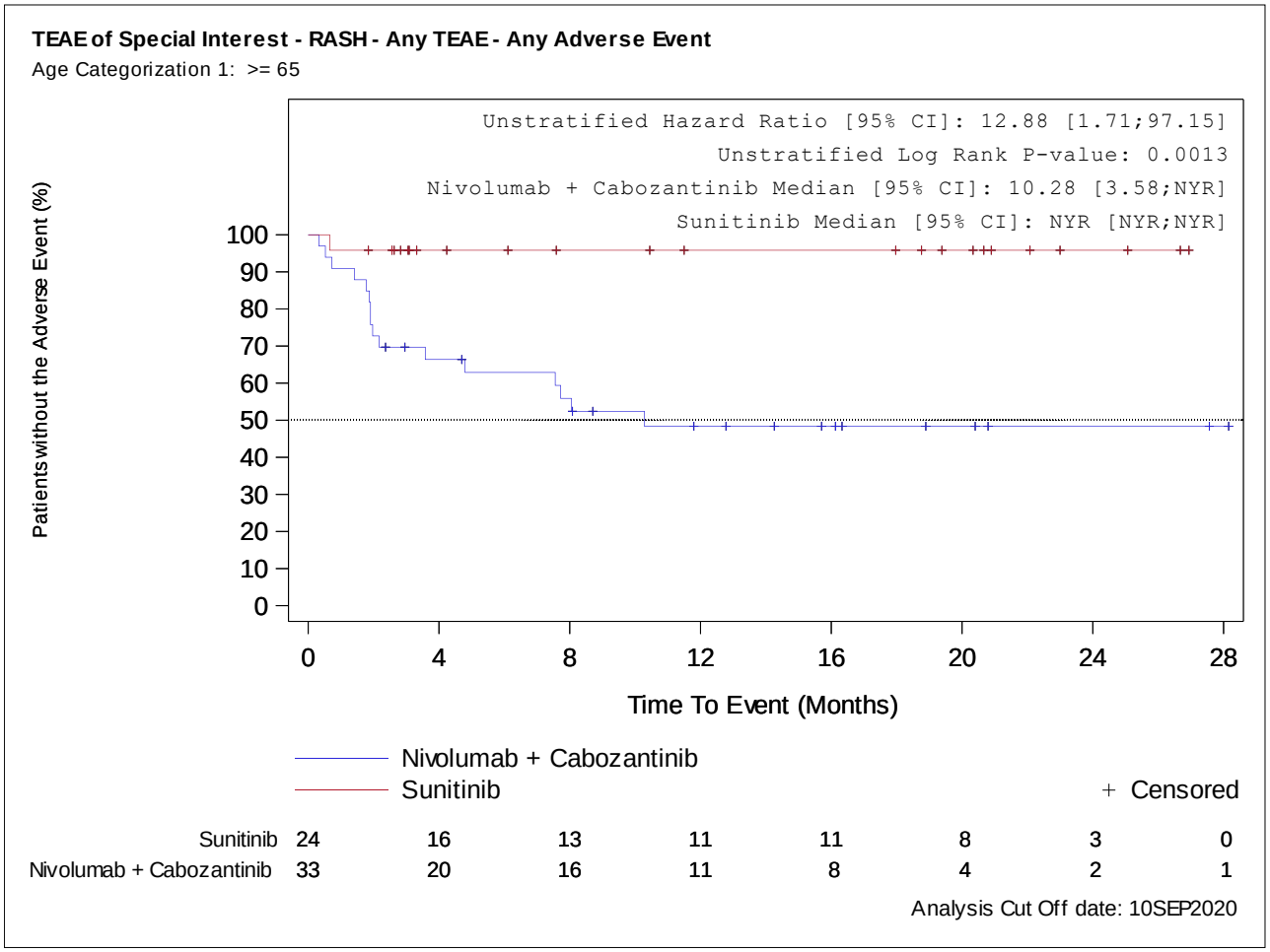

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:52:13

FIGURE 3.131.2.1: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



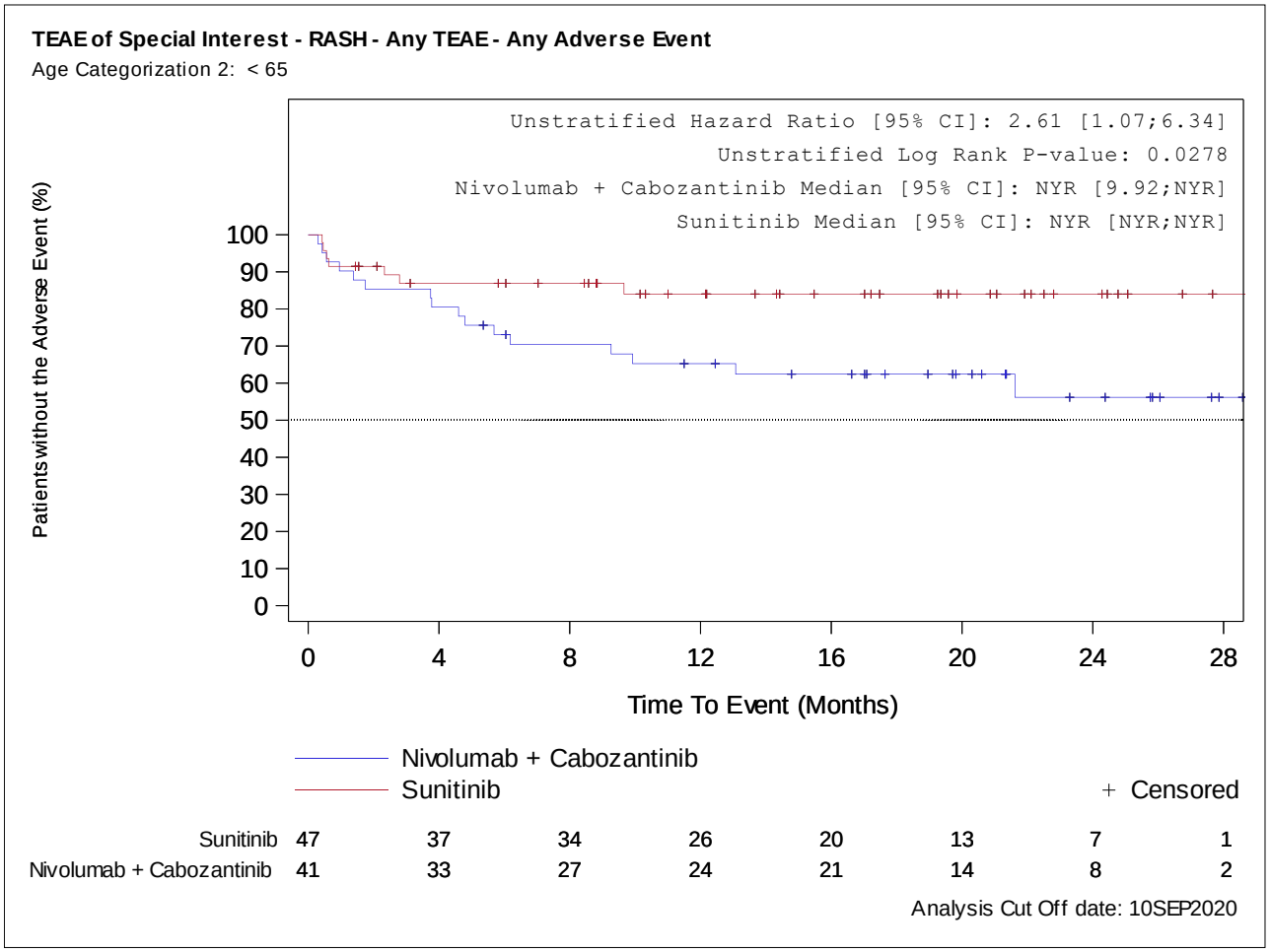

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:52:16

FIGURE 3.131.2.2: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



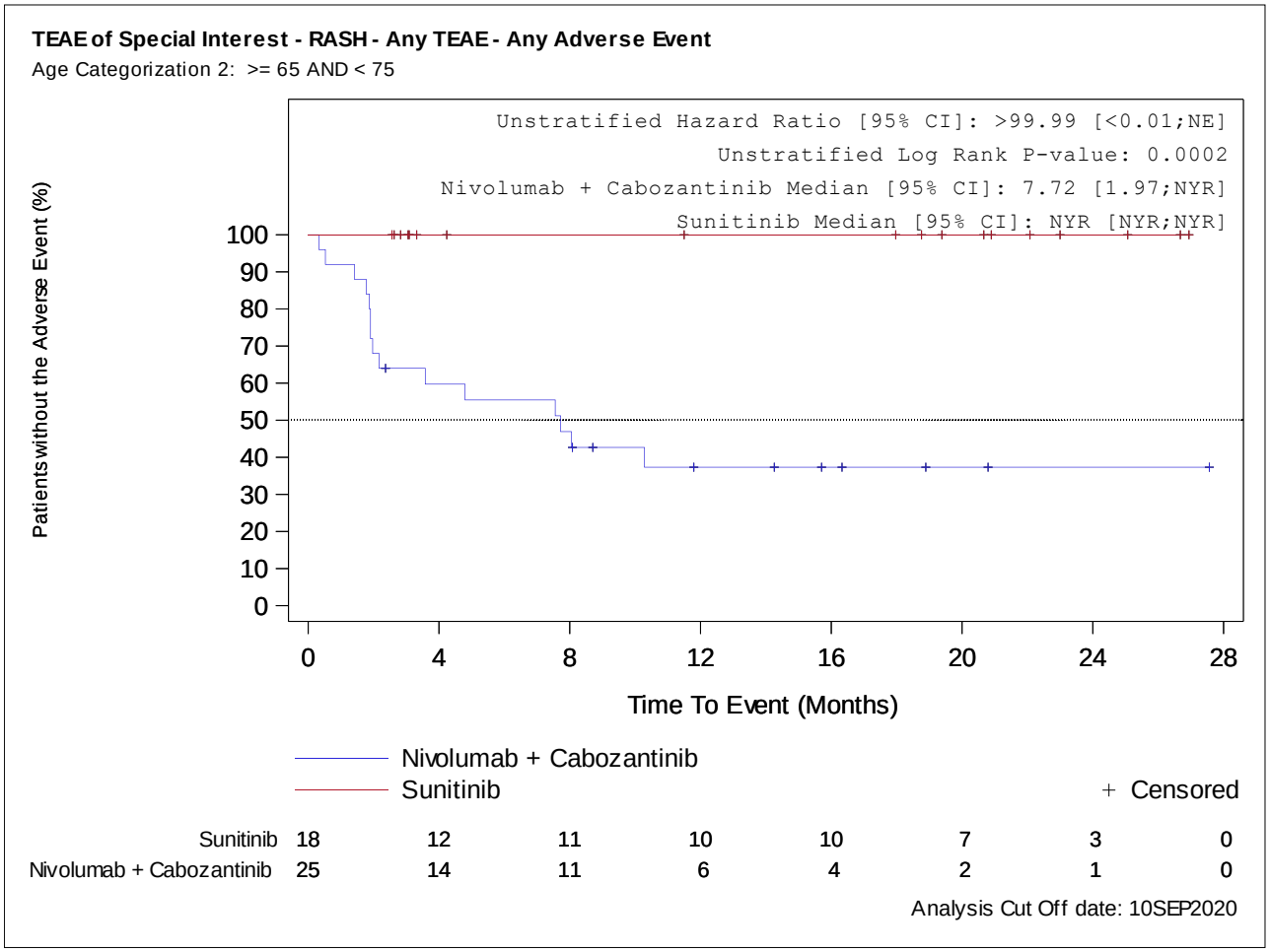

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:52:21

FIGURE 3.131.2.3: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



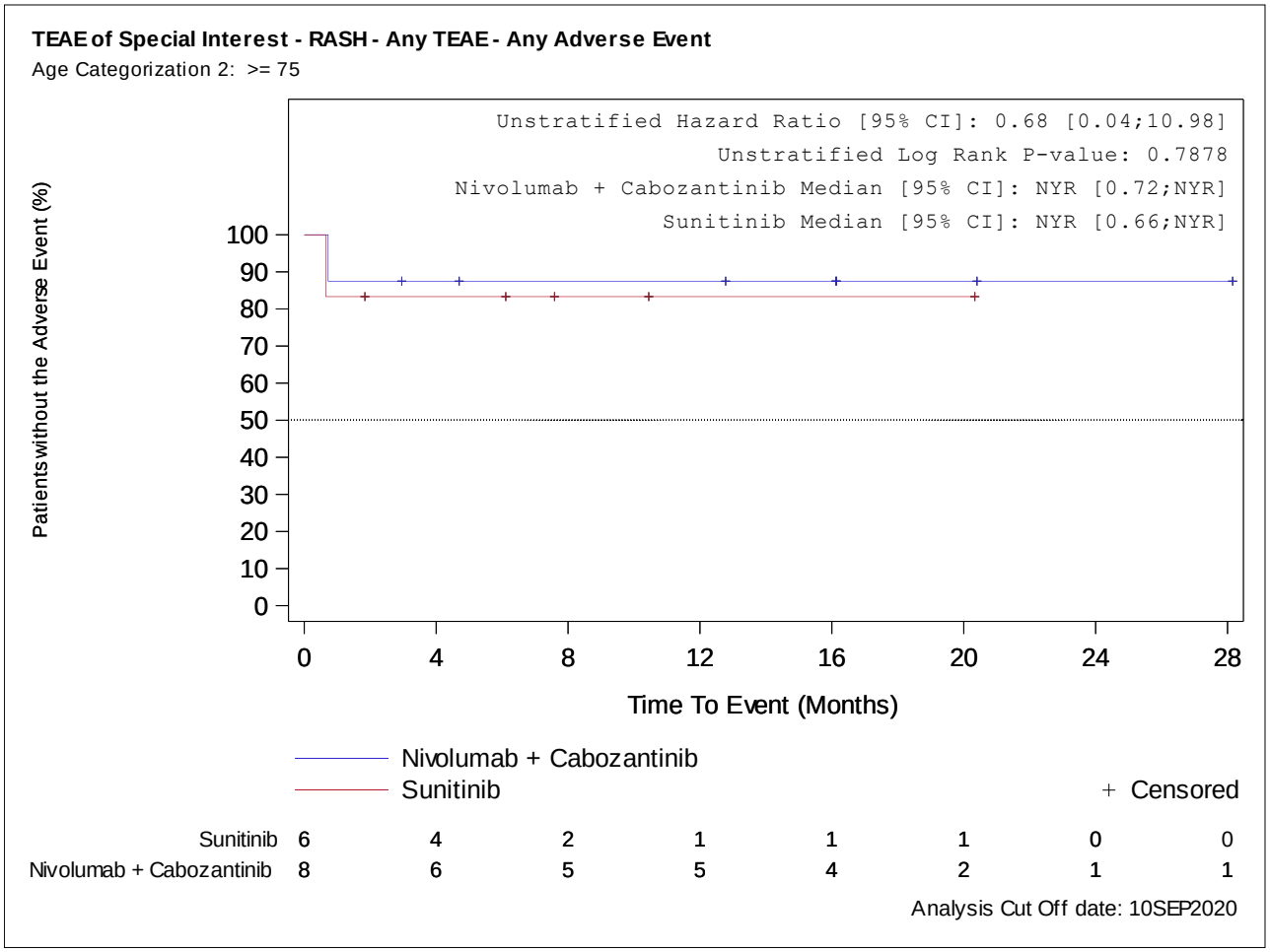

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:52:26

FIGURE 3.131.2.4: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



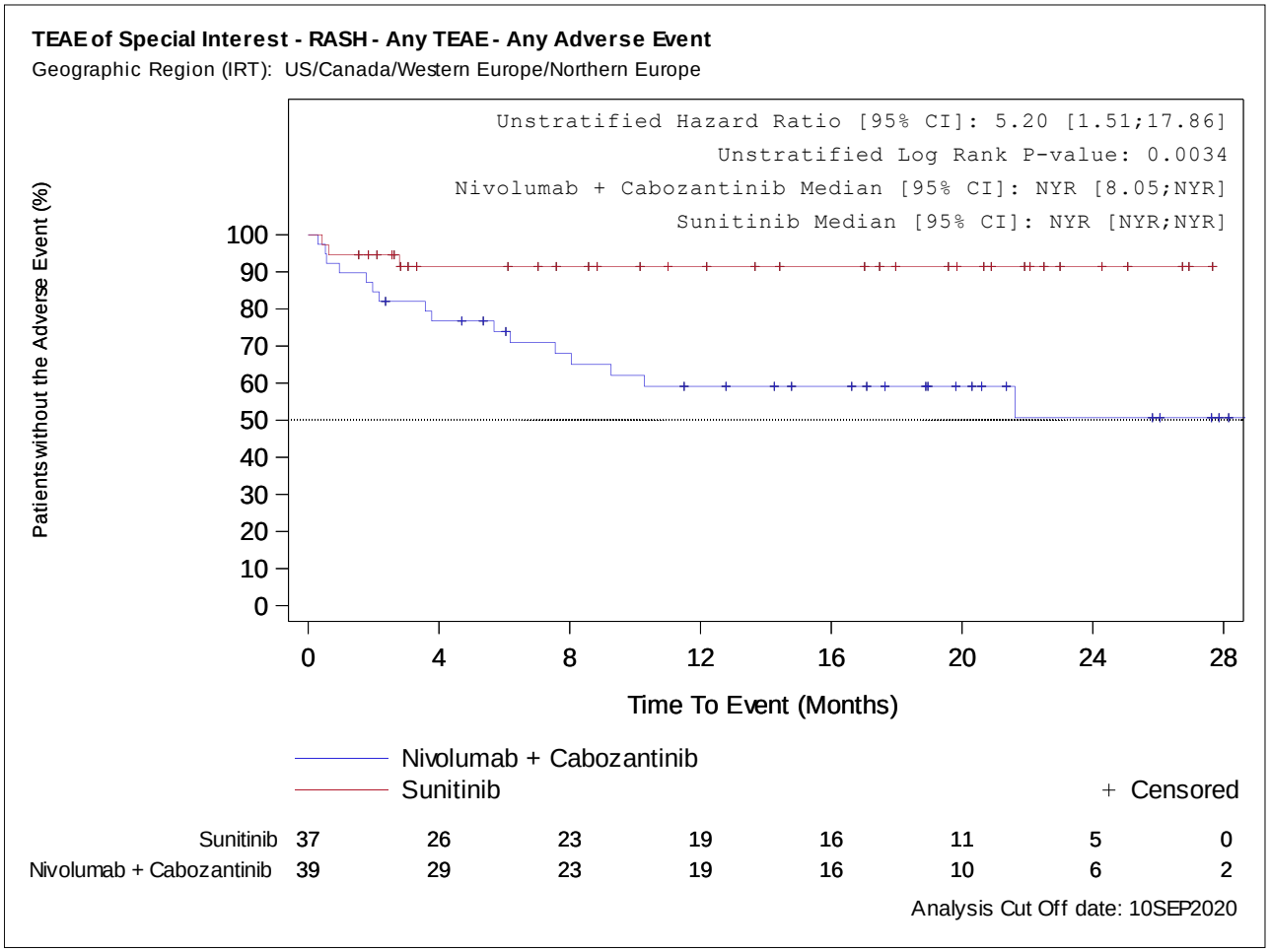

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:52:32

FIGURE 3.131.2.5: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



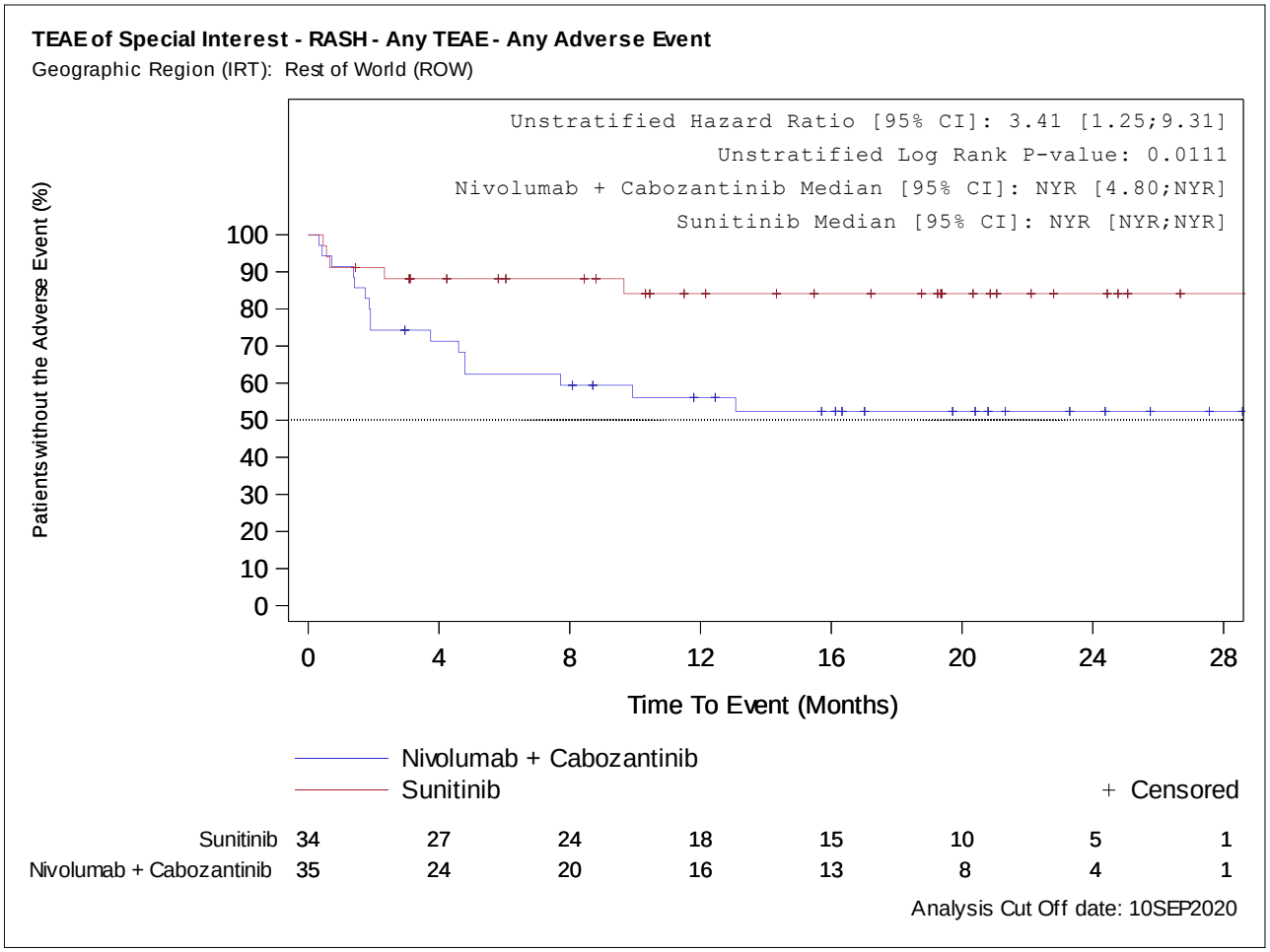

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:52:37

FIGURE 3.131.2.6: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



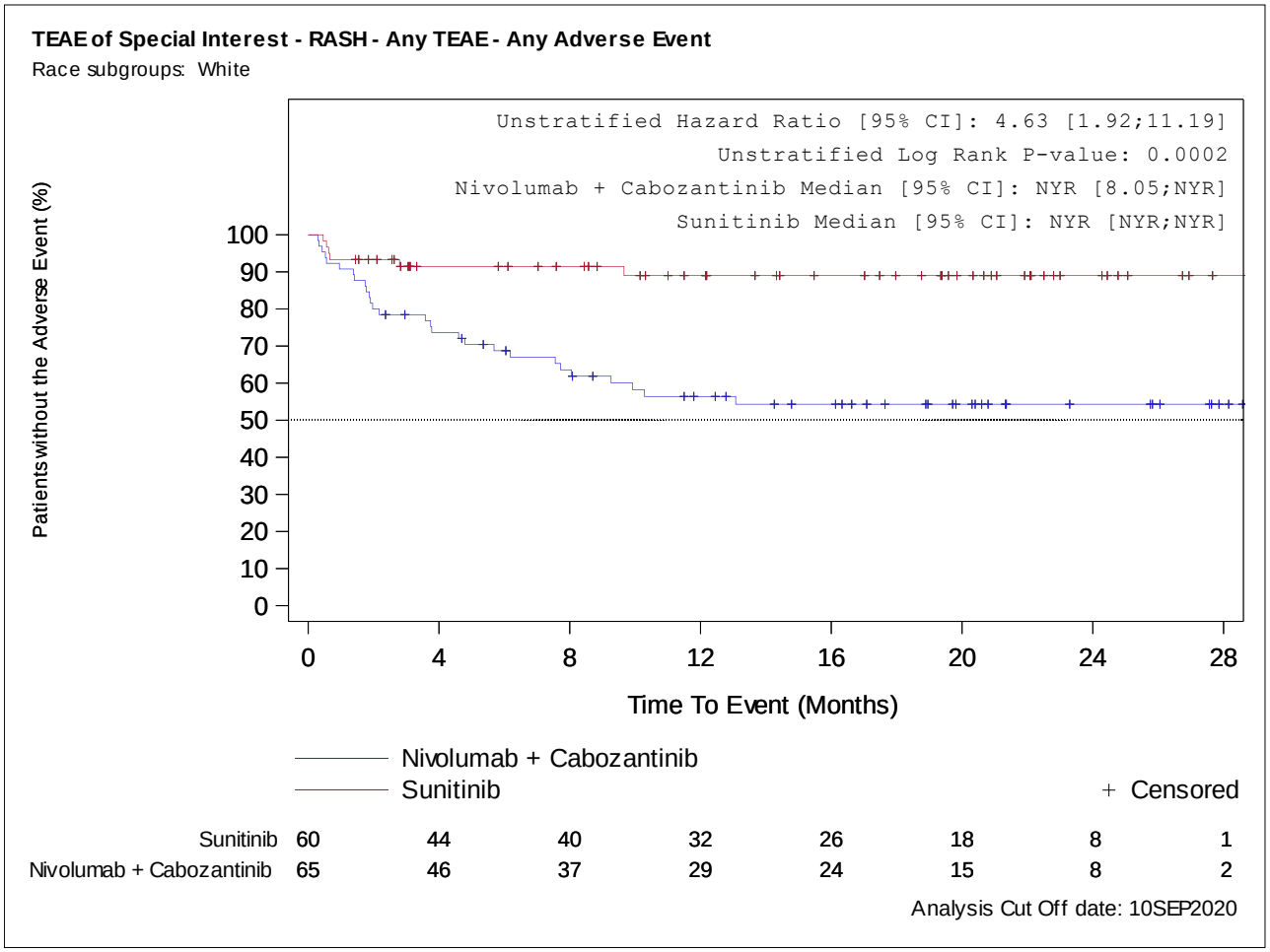

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:52:43

FIGURE 3.131.2.7: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



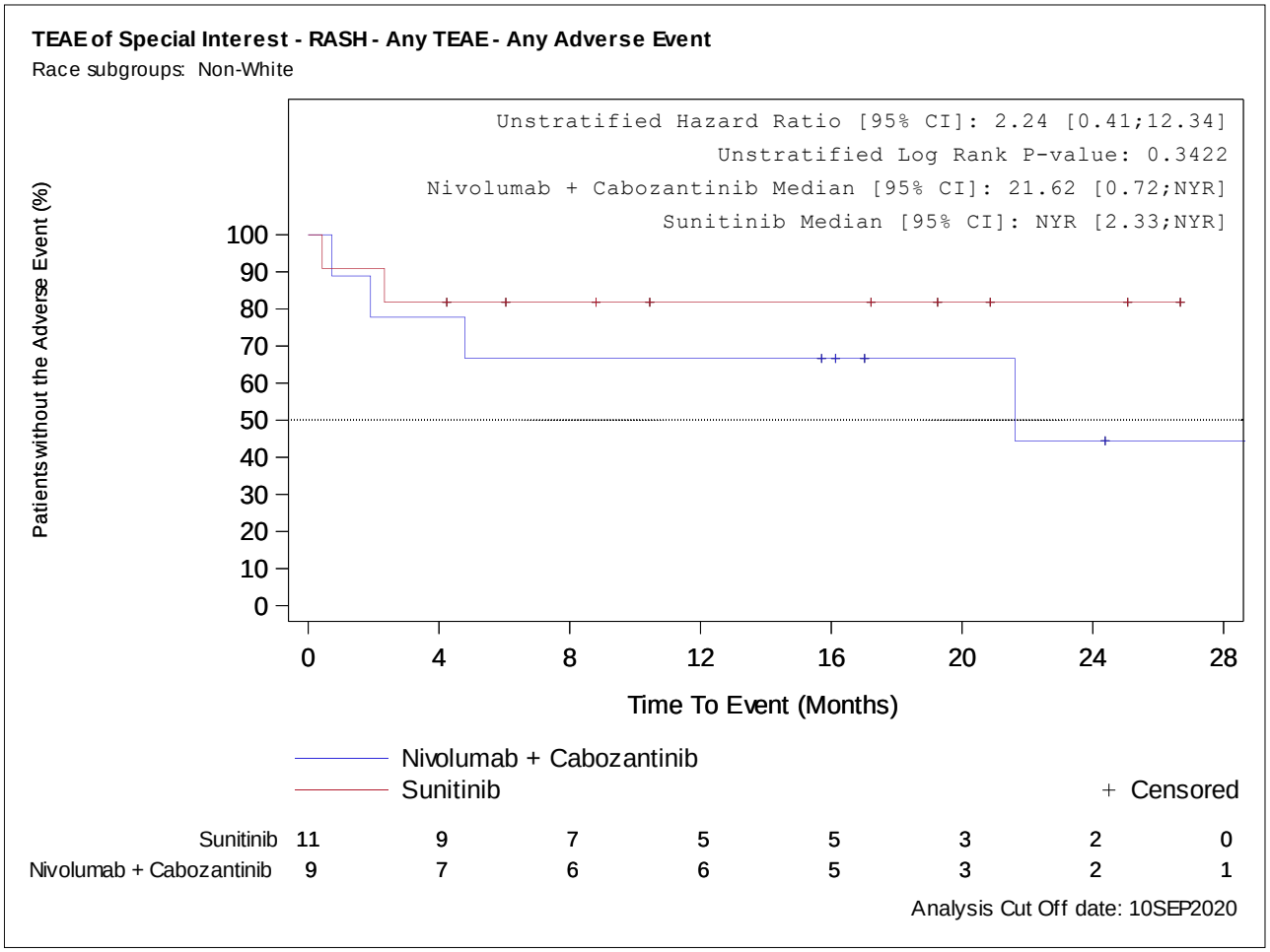

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:52:49

FIGURE 3.131.2.8: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



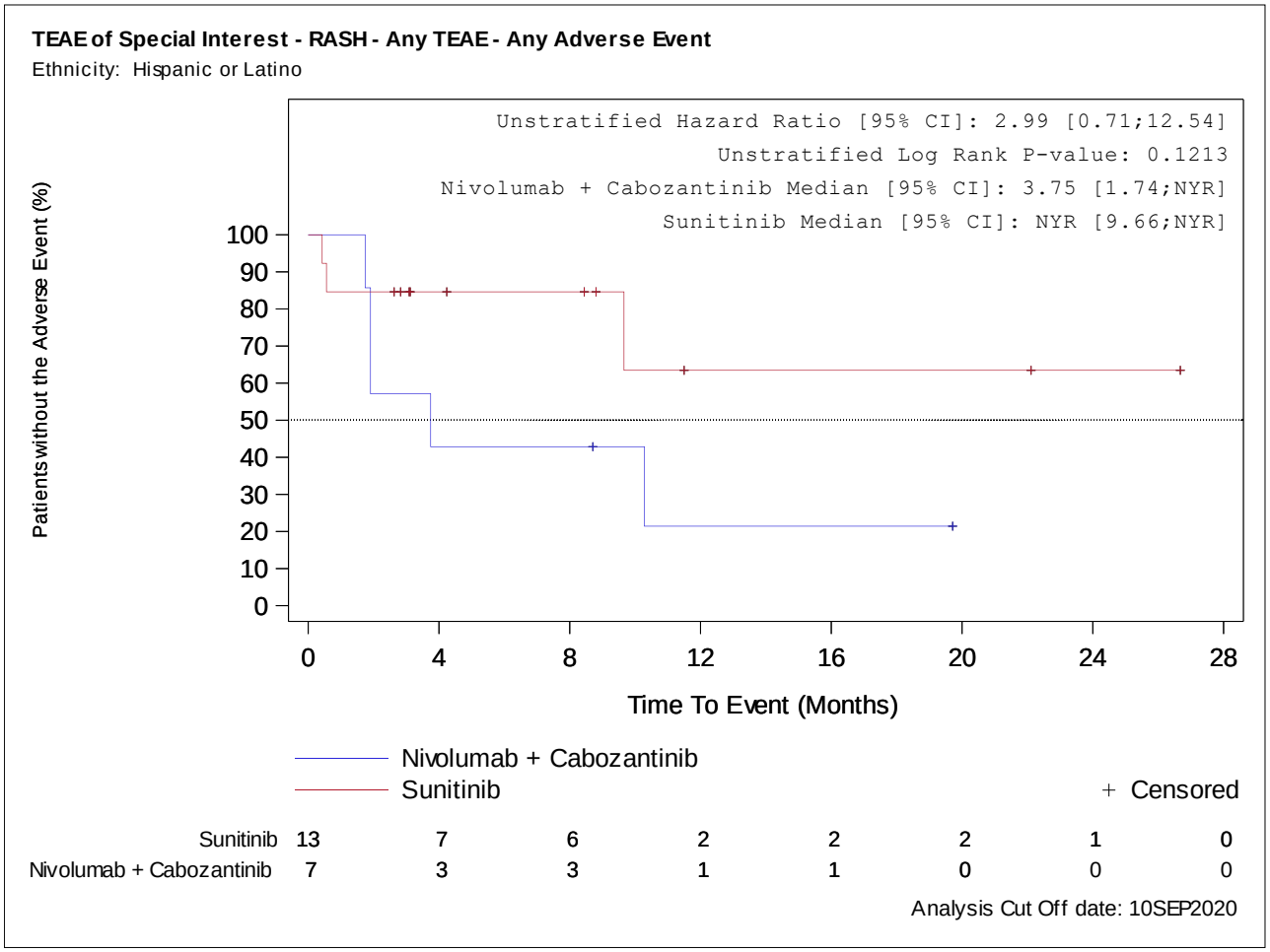

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:52:54

FIGURE 3.131.2.9: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



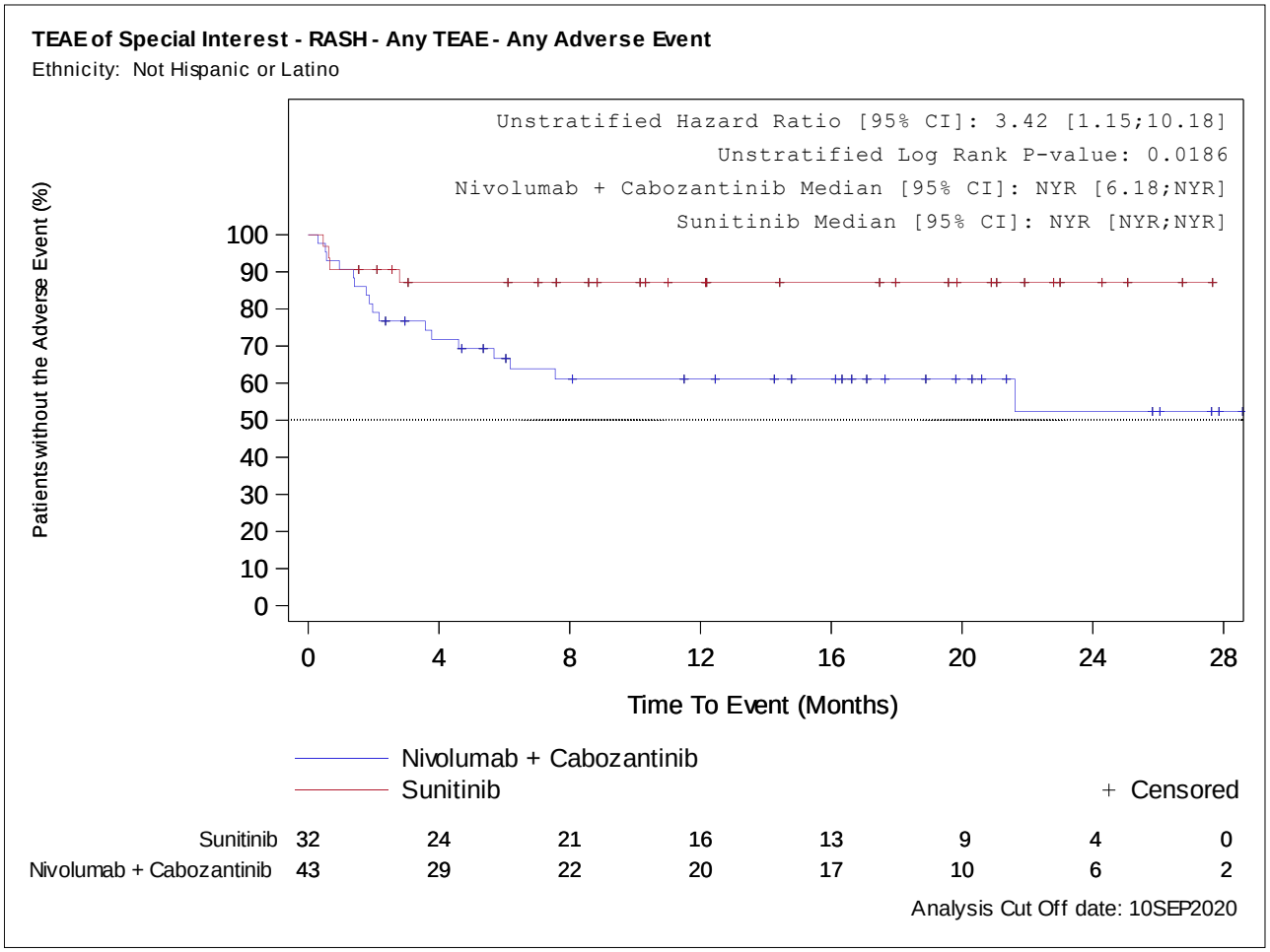

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:53:00

FIGURE 3.131.2.10: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



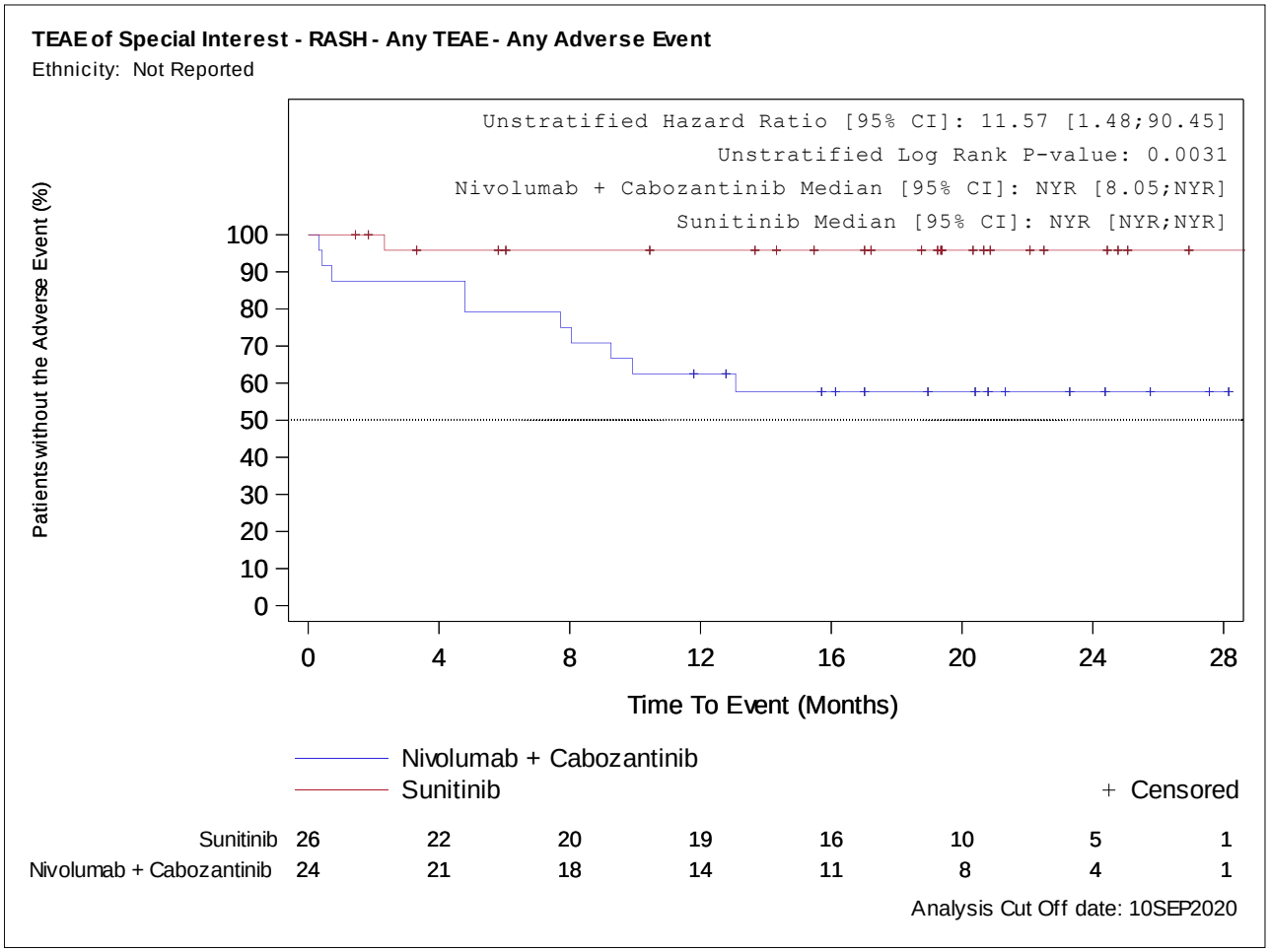

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:53:05

FIGURE 3.131.2.11: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



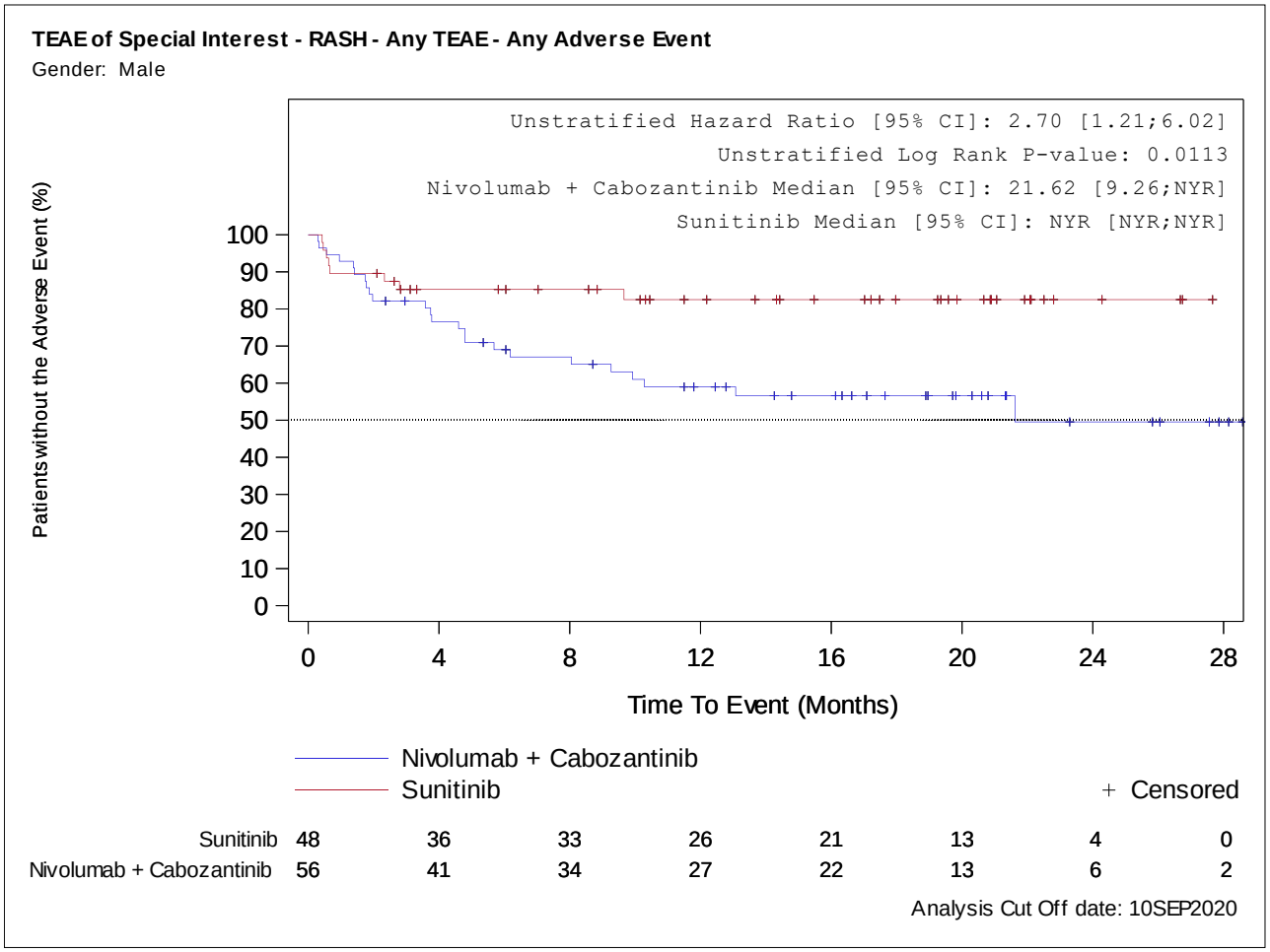

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:53:11

FIGURE 3.131.2.12: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



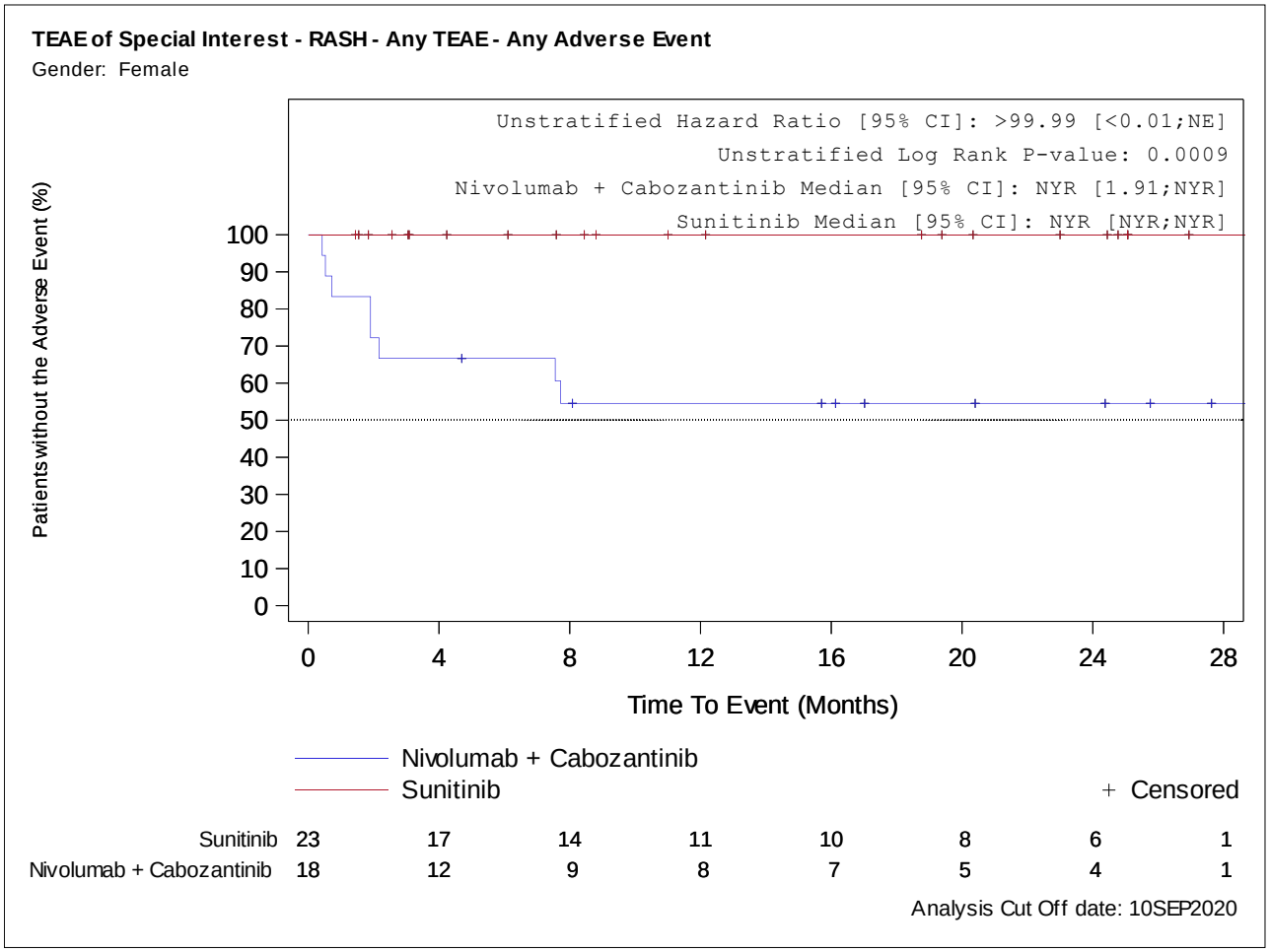

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:53:16

FIGURE 3.131.2.13: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



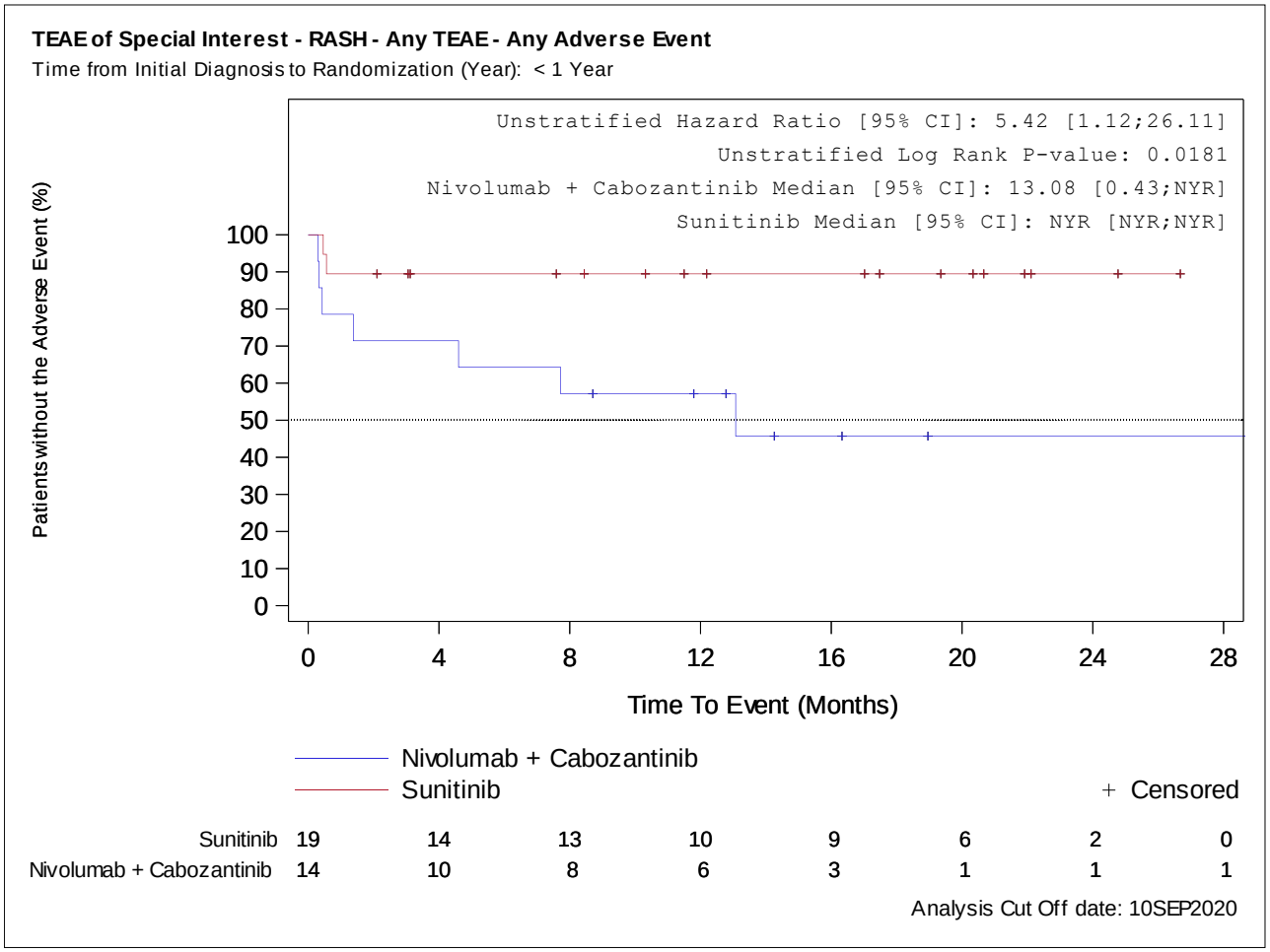

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:53:21

FIGURE 3.131.2.14: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



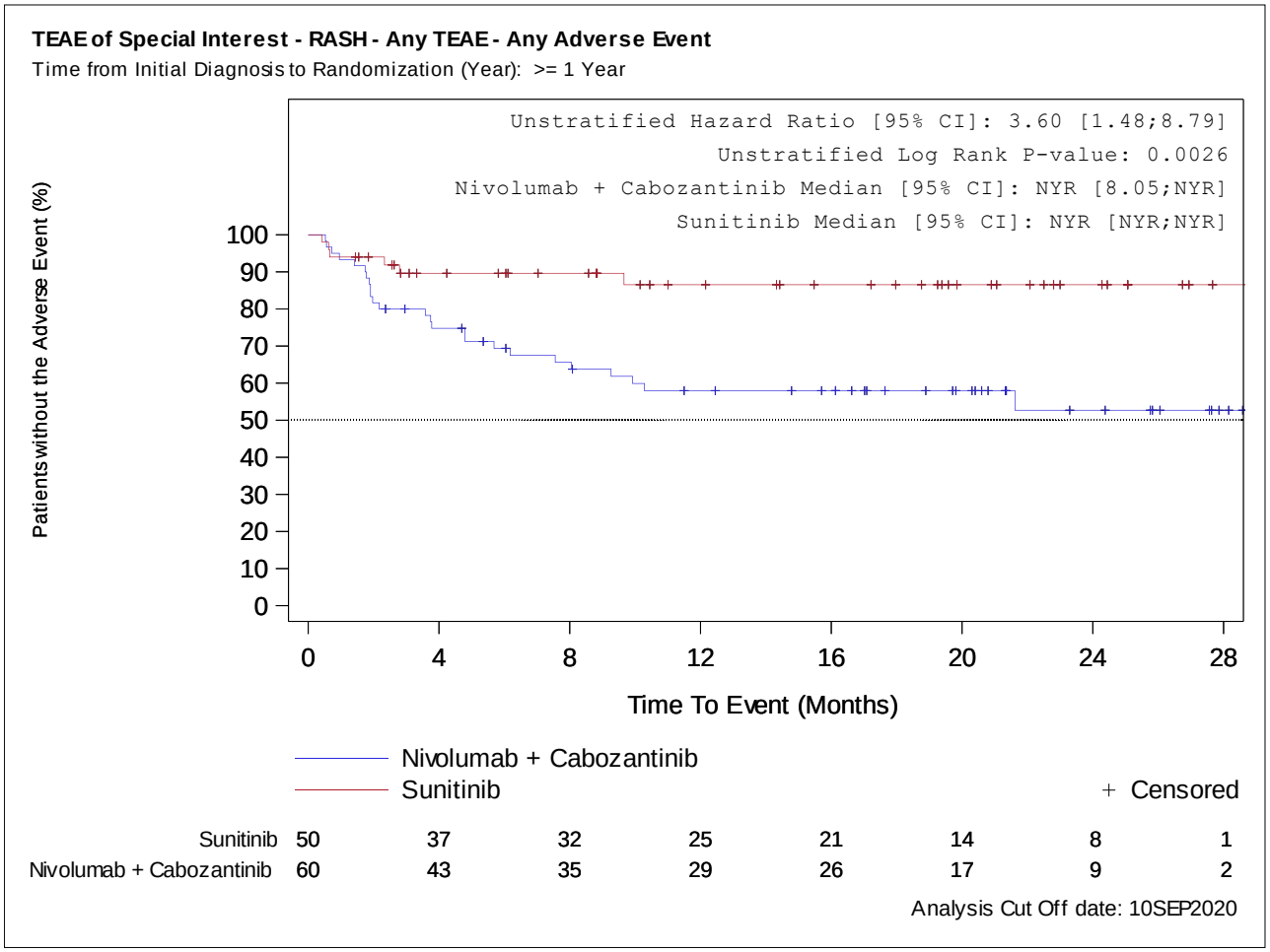

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:53:26

FIGURE 3.131.2.15: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



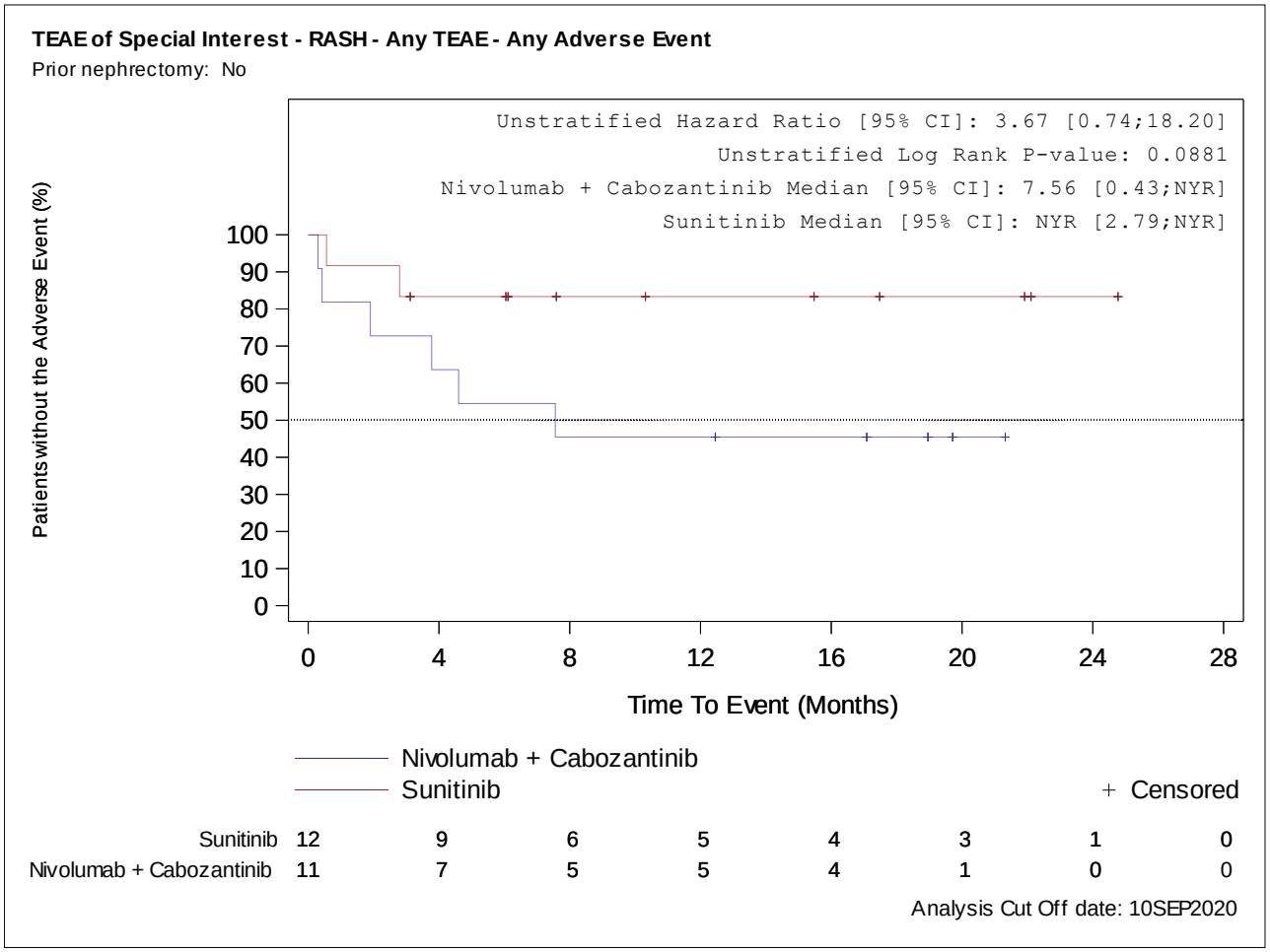

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:53:43

FIGURE 3.131.2.16: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



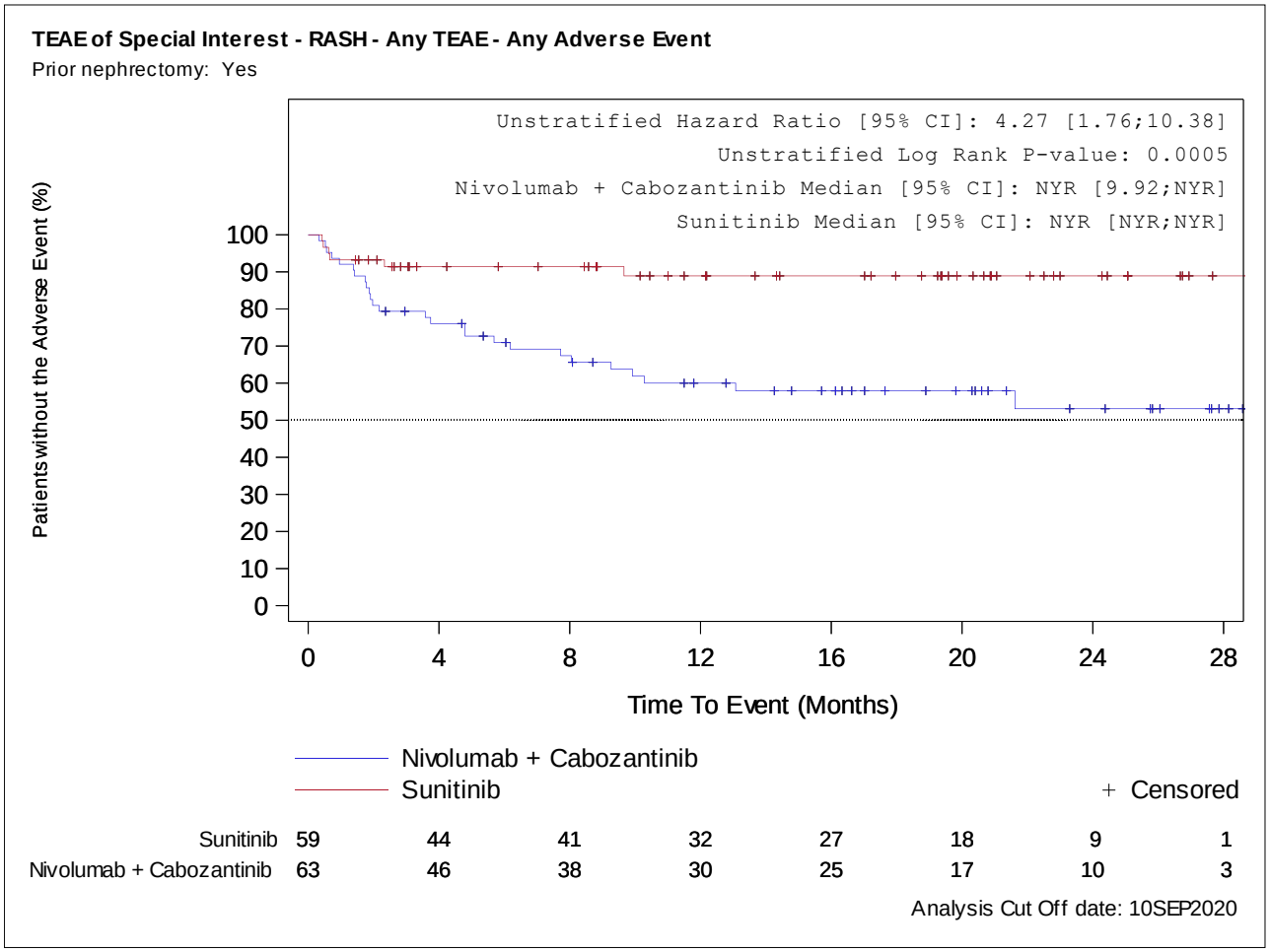

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:53:48

FIGURE 3.131.2.17: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



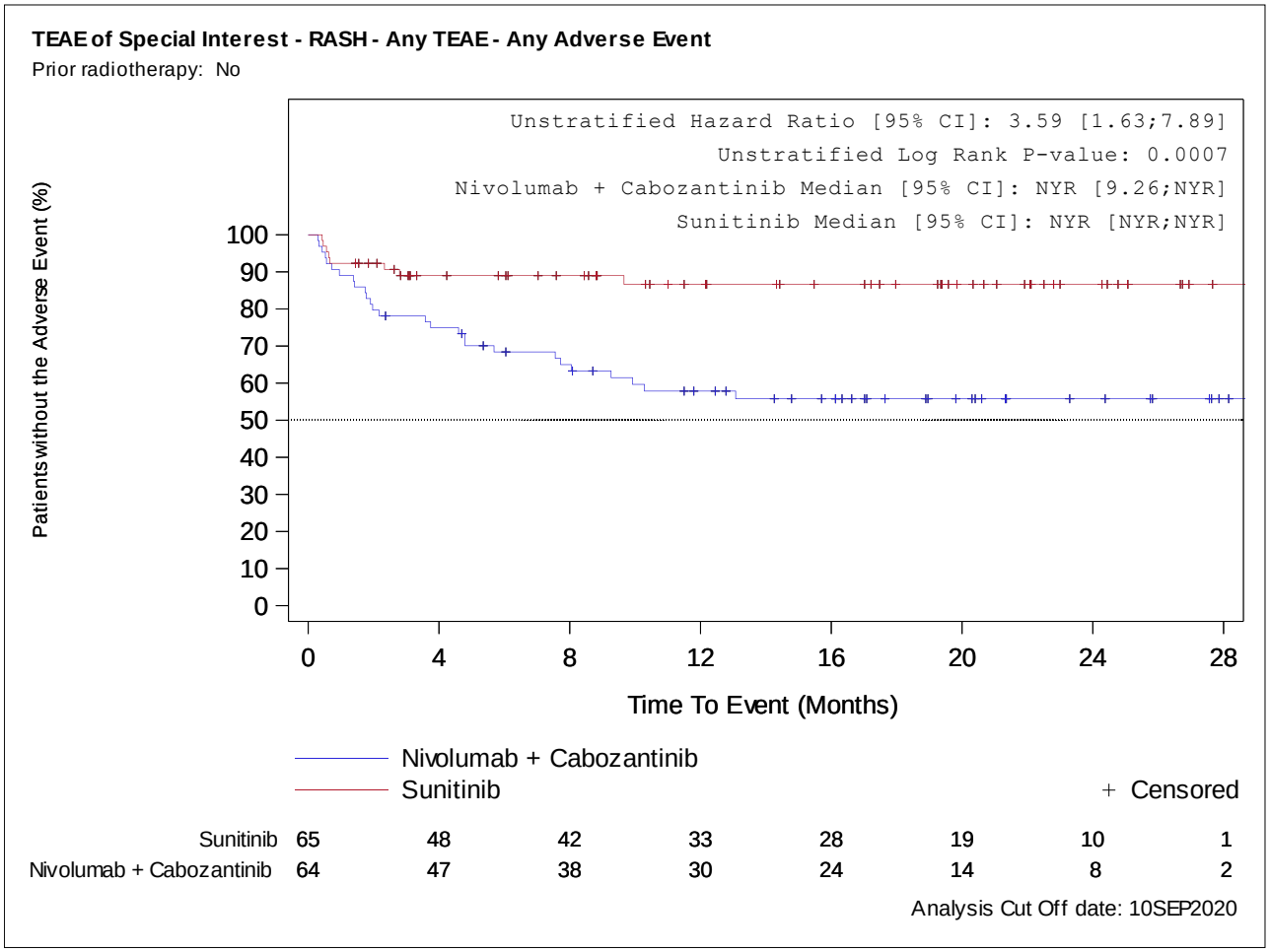

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:54:36

FIGURE 3.131.2.18: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



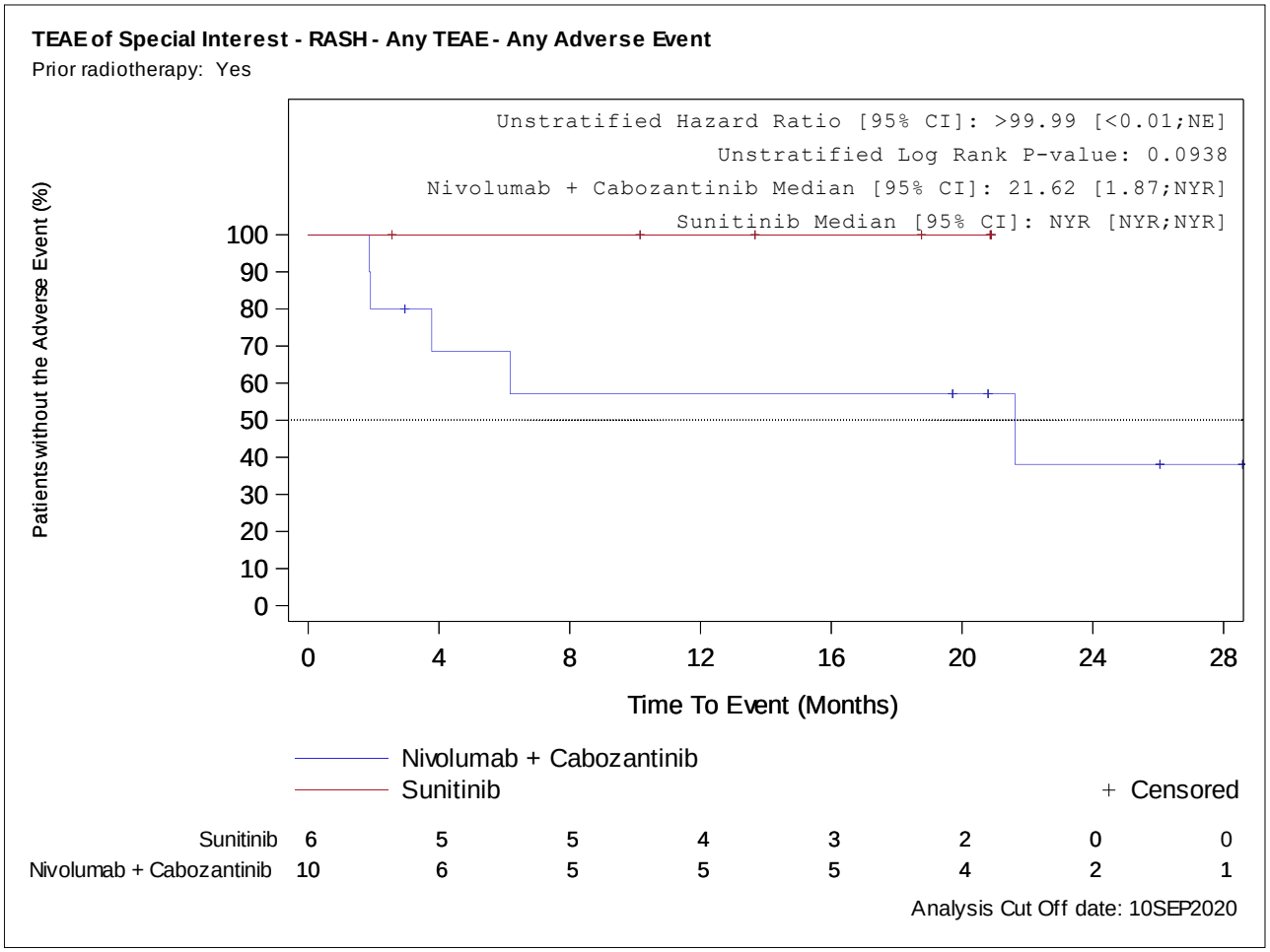

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:54:41

FIGURE 3.131.2.19: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:54:47

FIGURE 3.131.2.20: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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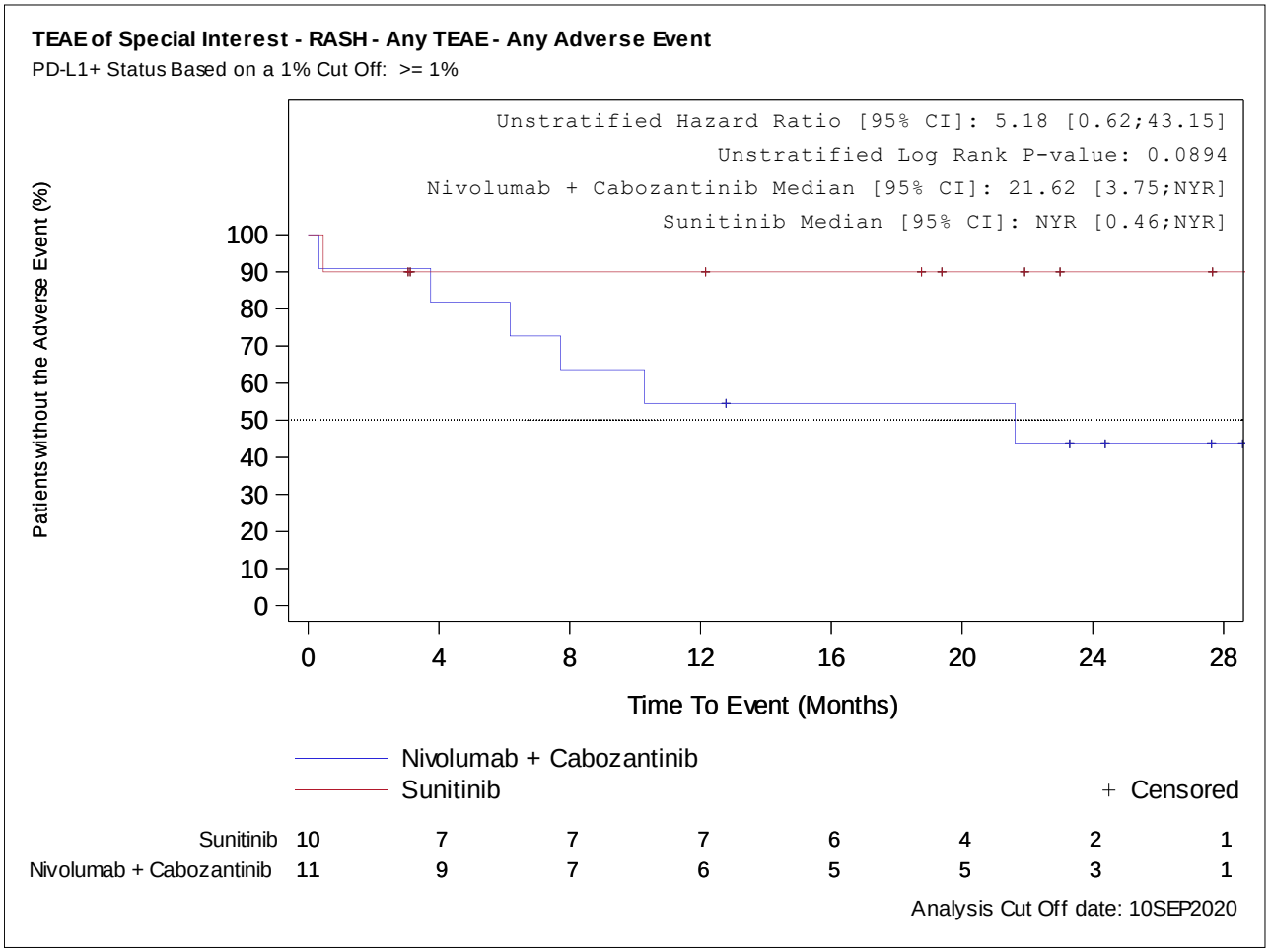
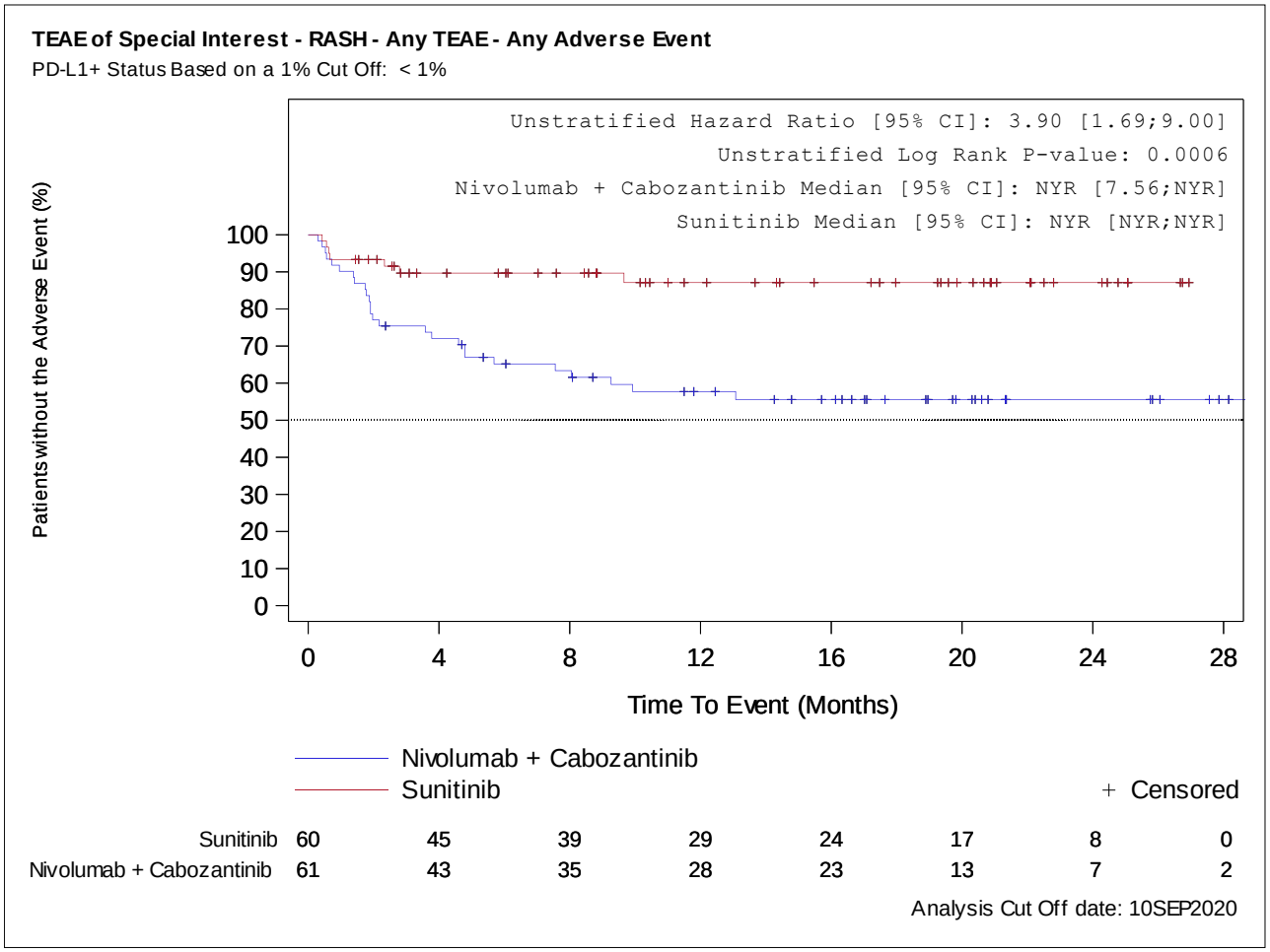
FIGURE 3.131.2.21: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:54:58

FIGURE 3.131.2.22: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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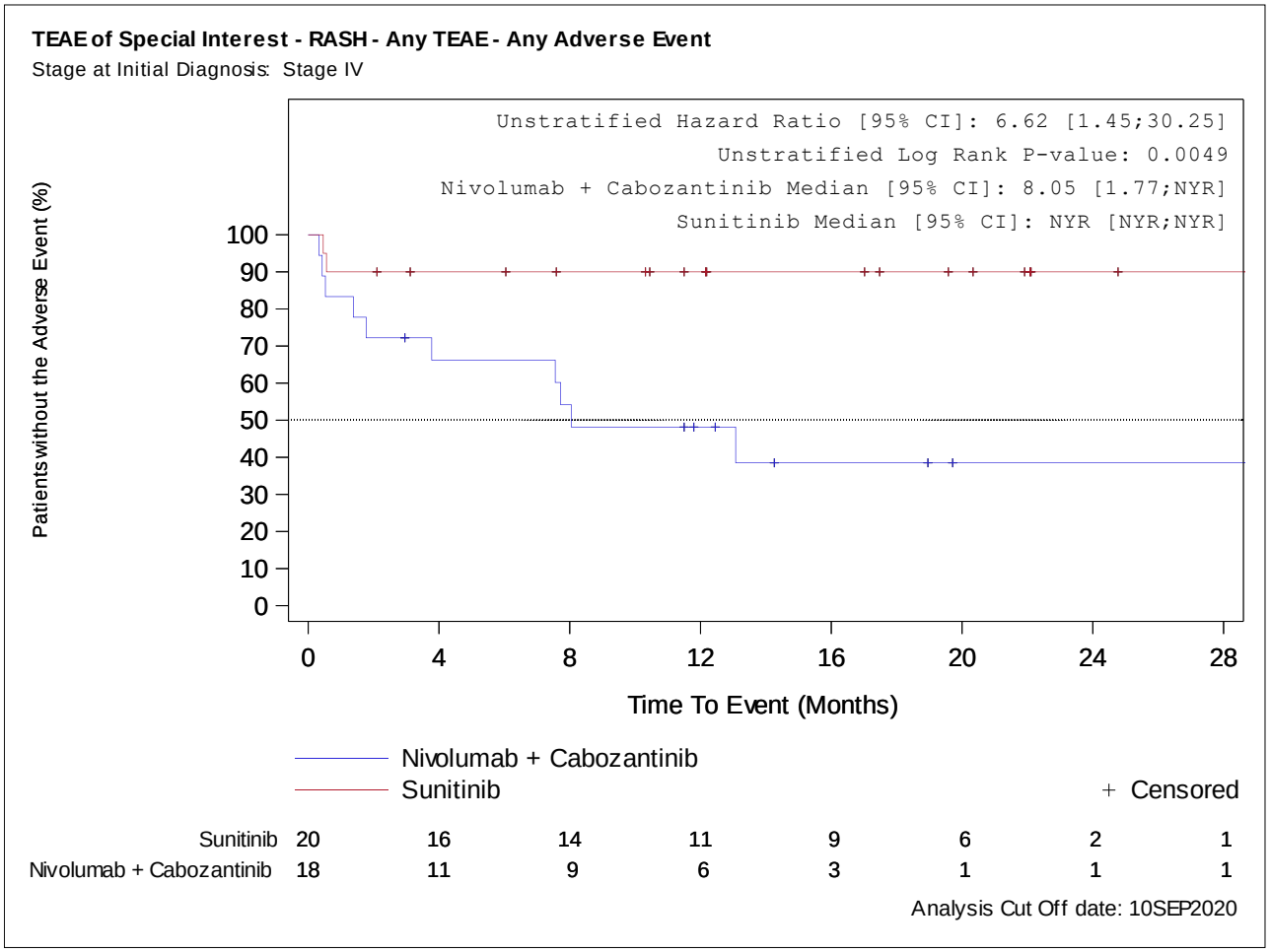
FIGURE 3.131.2.23: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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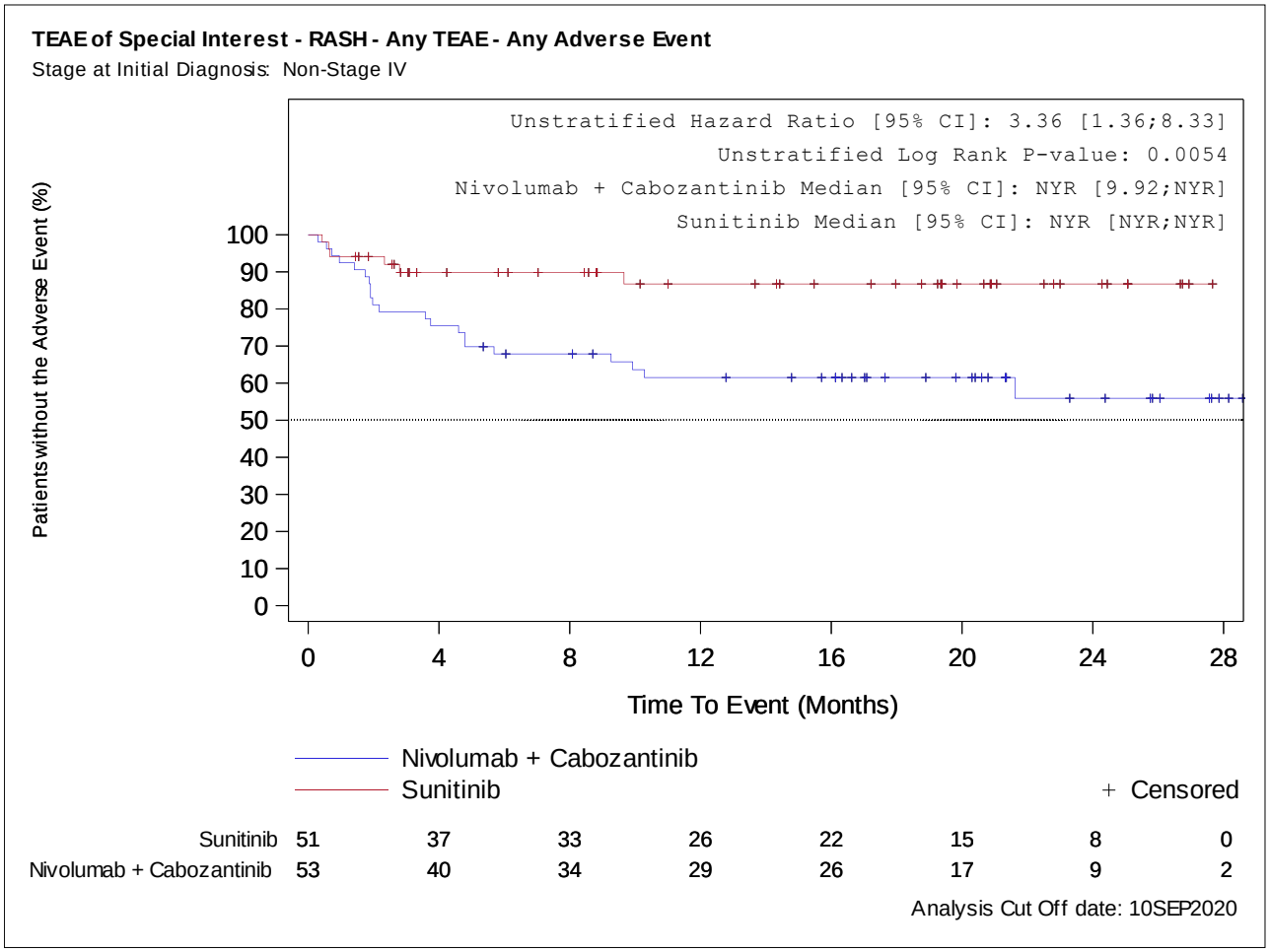
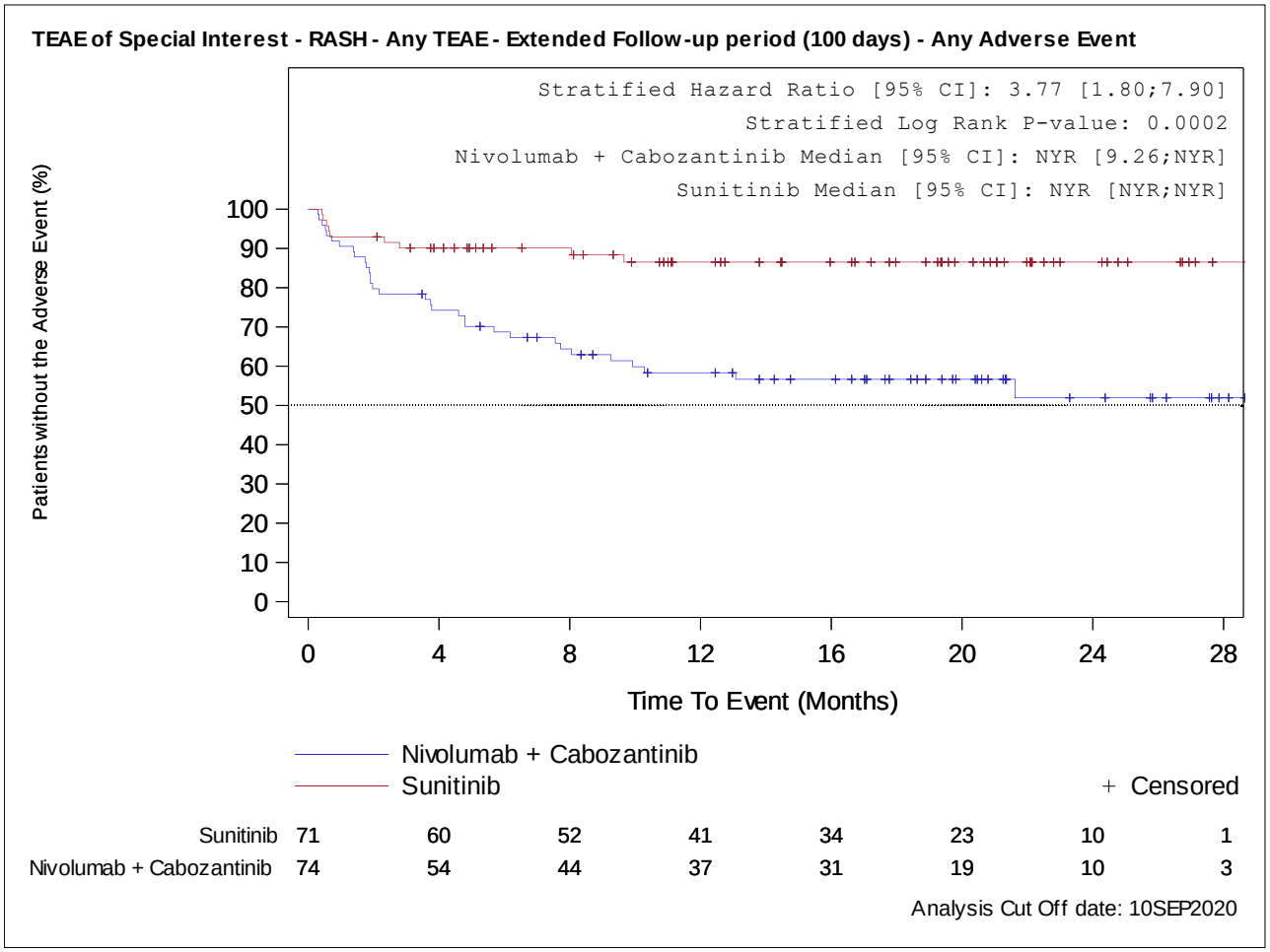
FIGURE 3.131.2.24: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



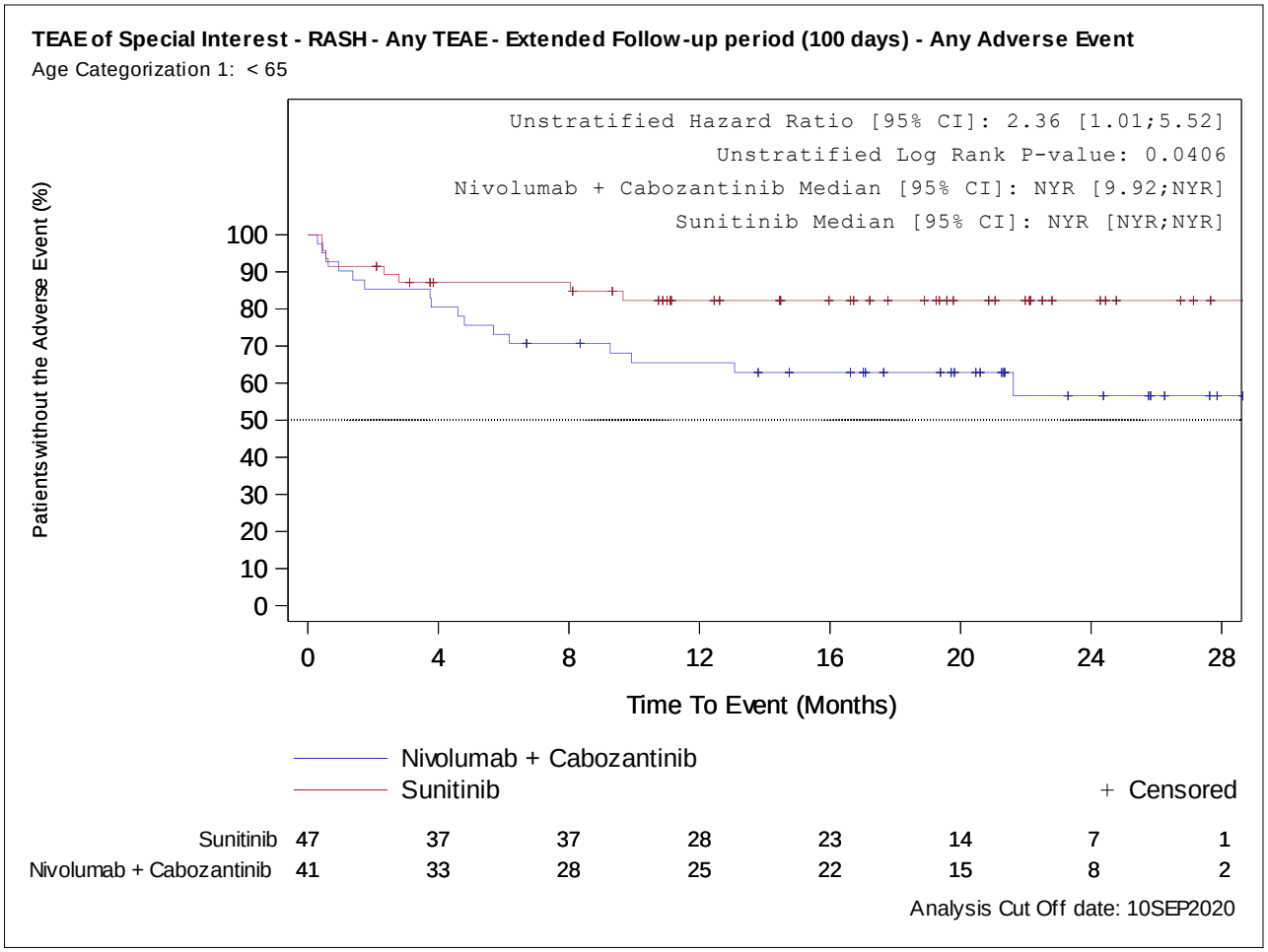

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:55:36

FIGURE 3.132.1: TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



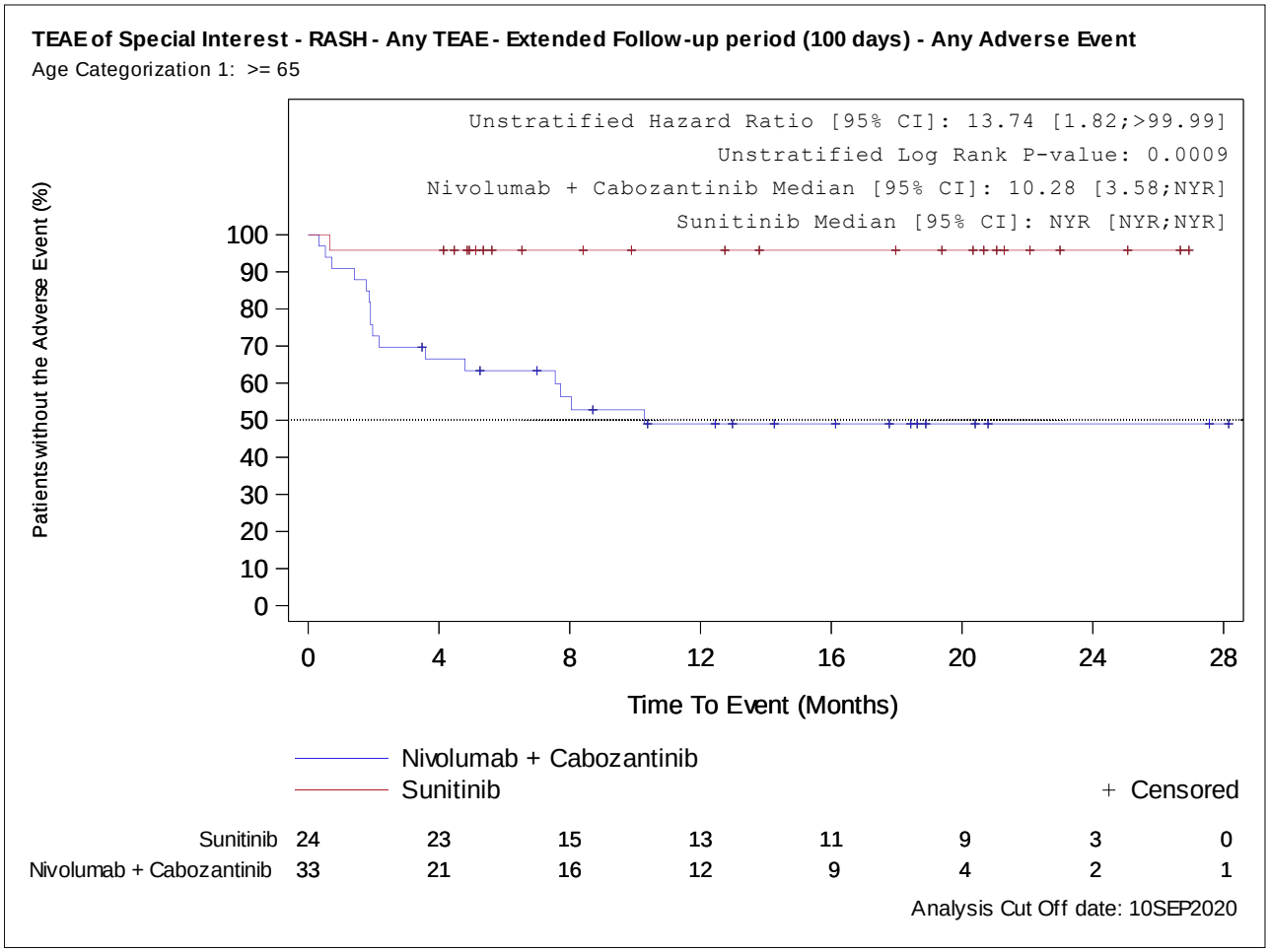

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:58:34

FIGURE 3.132.2.1: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



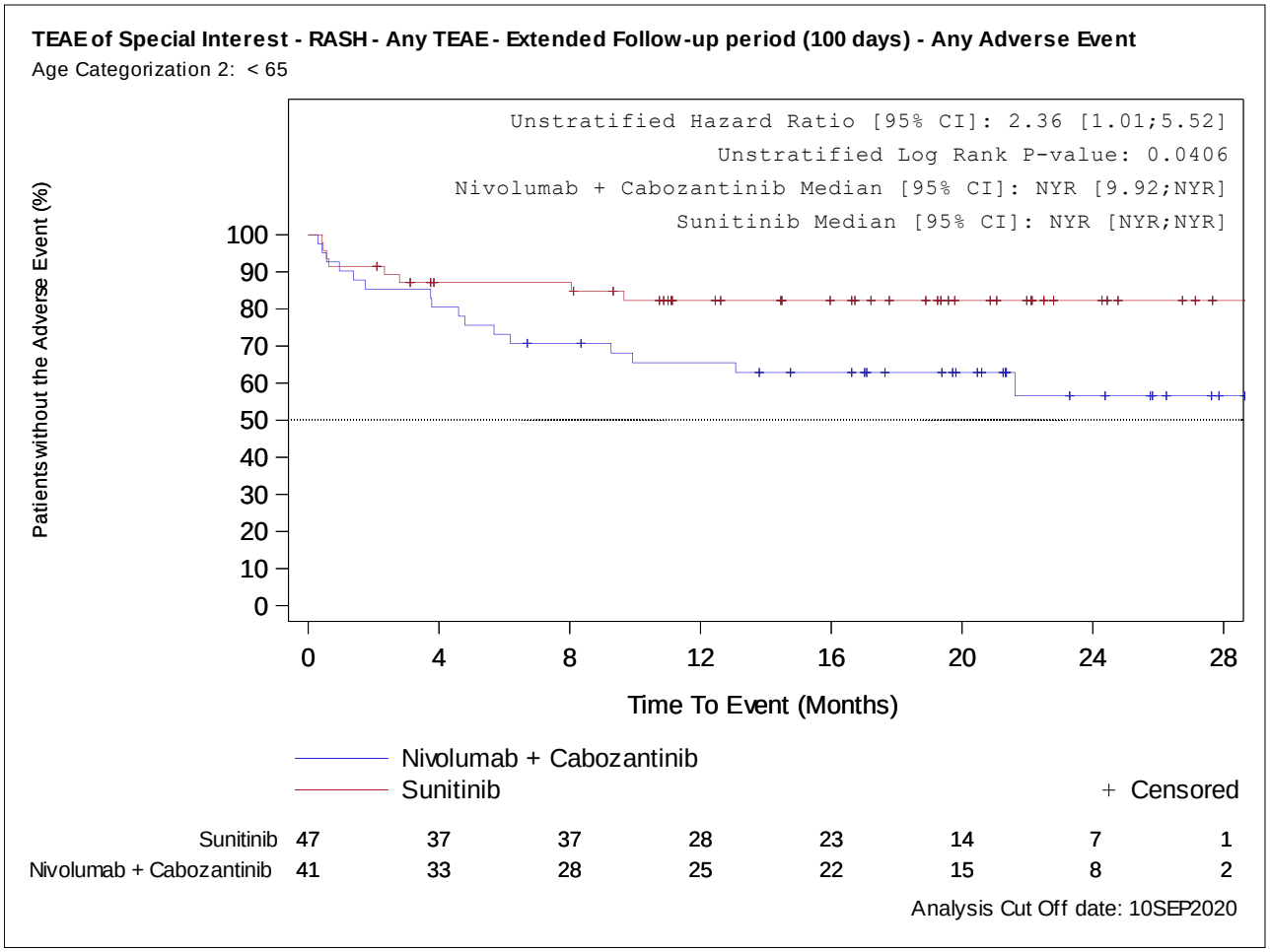

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:58:36

FIGURE 3.132.2.2: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



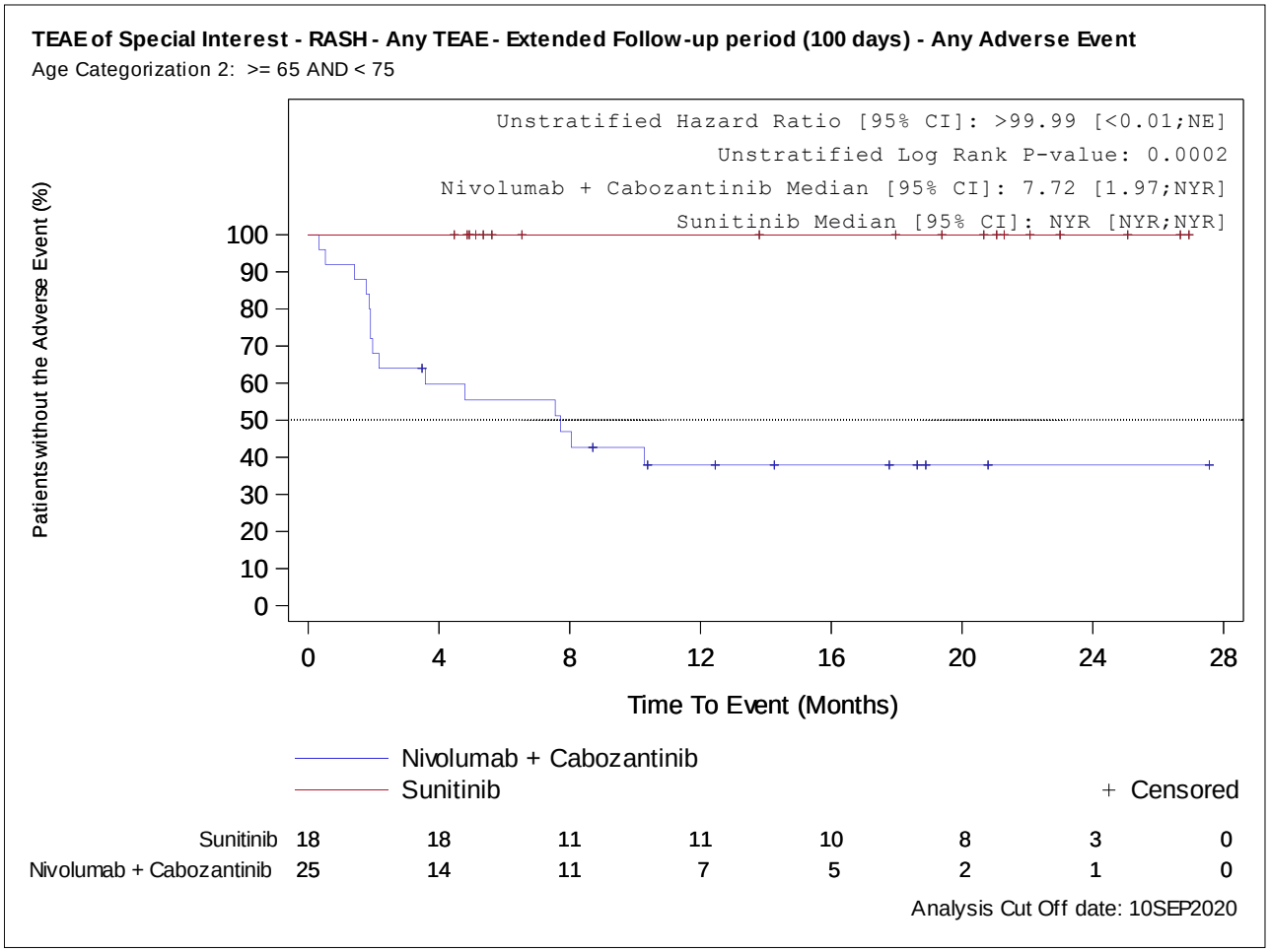

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:58:41

FIGURE 3.132.2.3: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



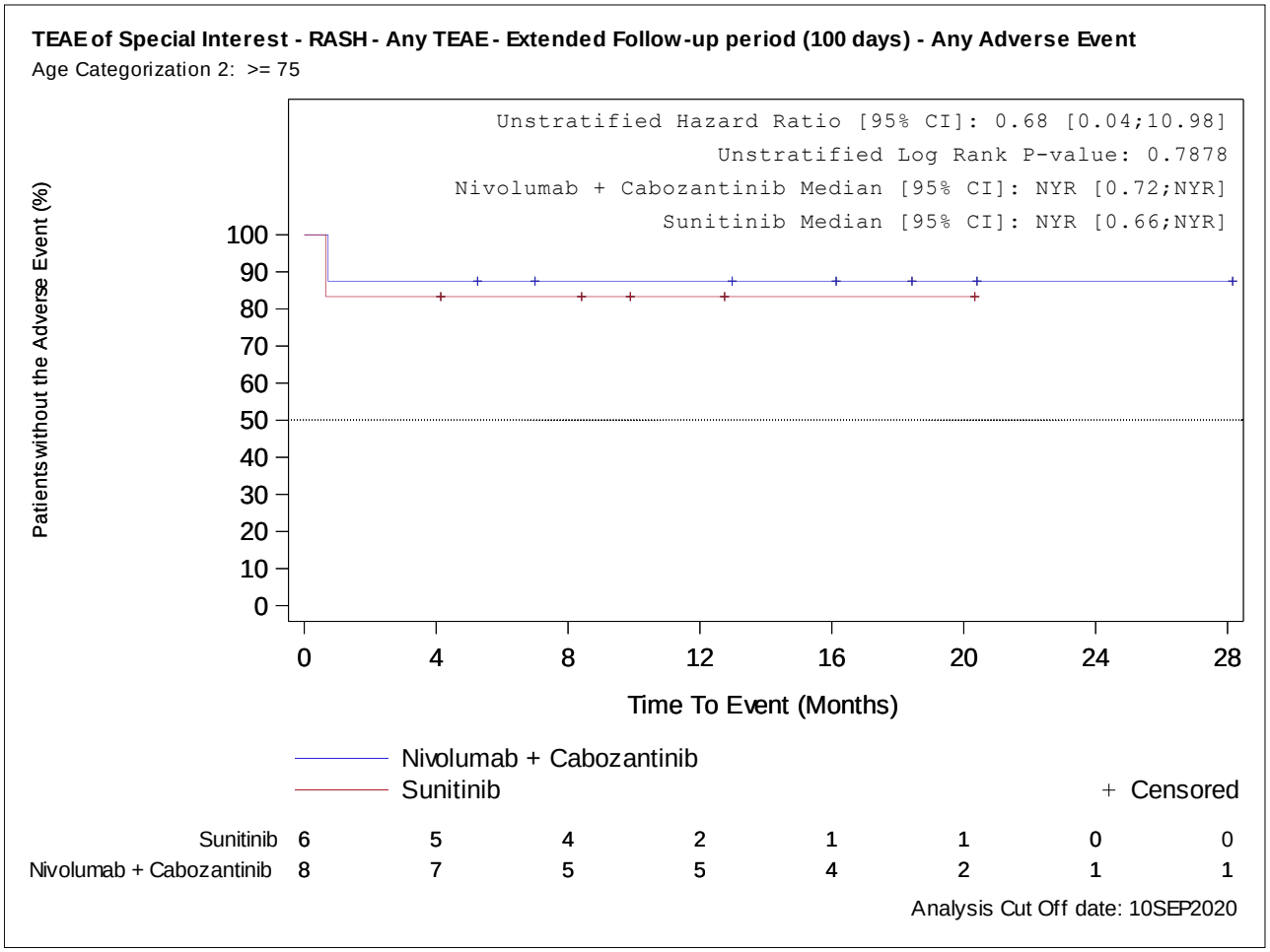

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:58:46

FIGURE 3.132.2.4: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



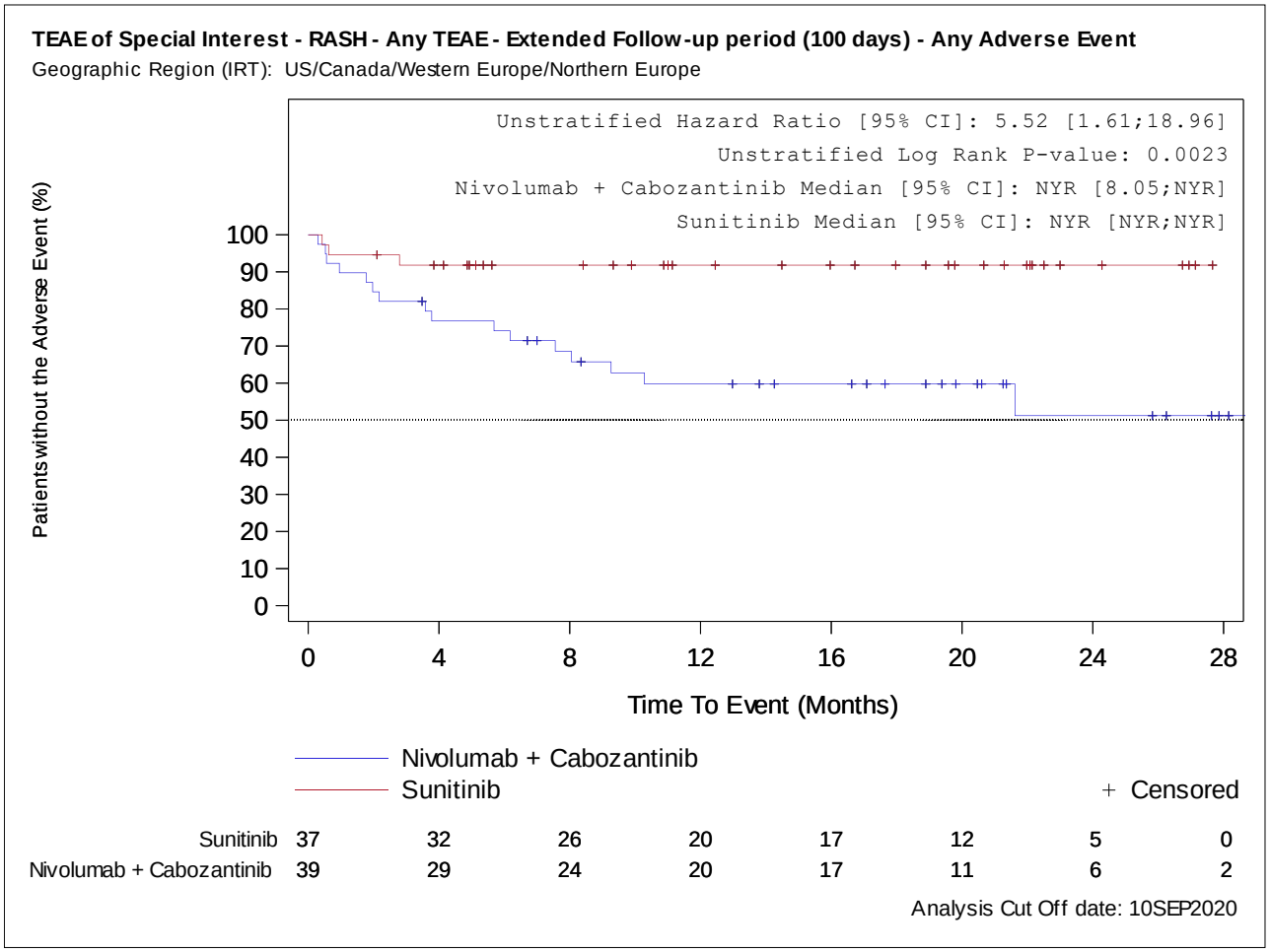

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:58:52

FIGURE 3.132.2.5: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



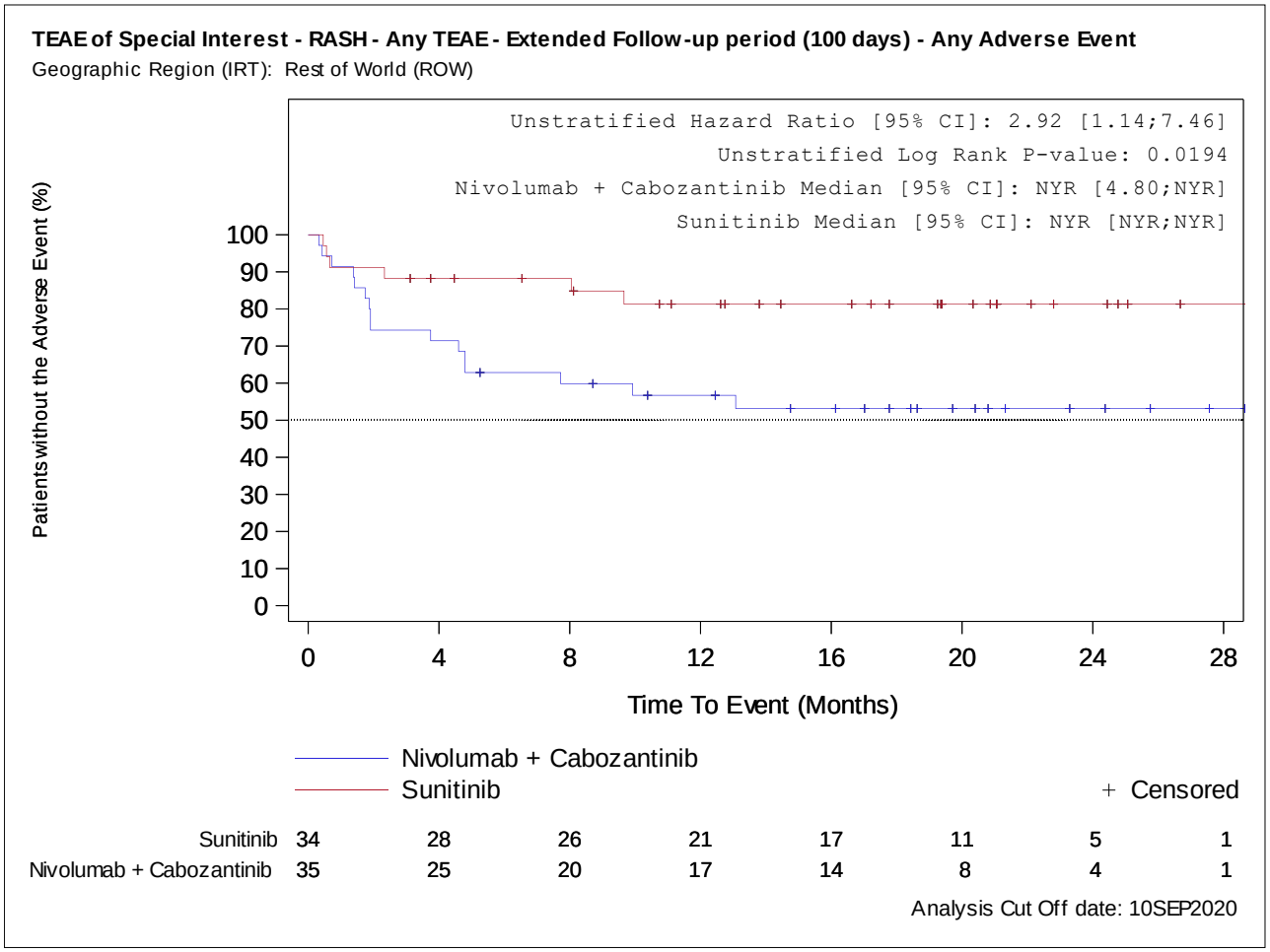

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:58:57

FIGURE 3.132.2.6: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



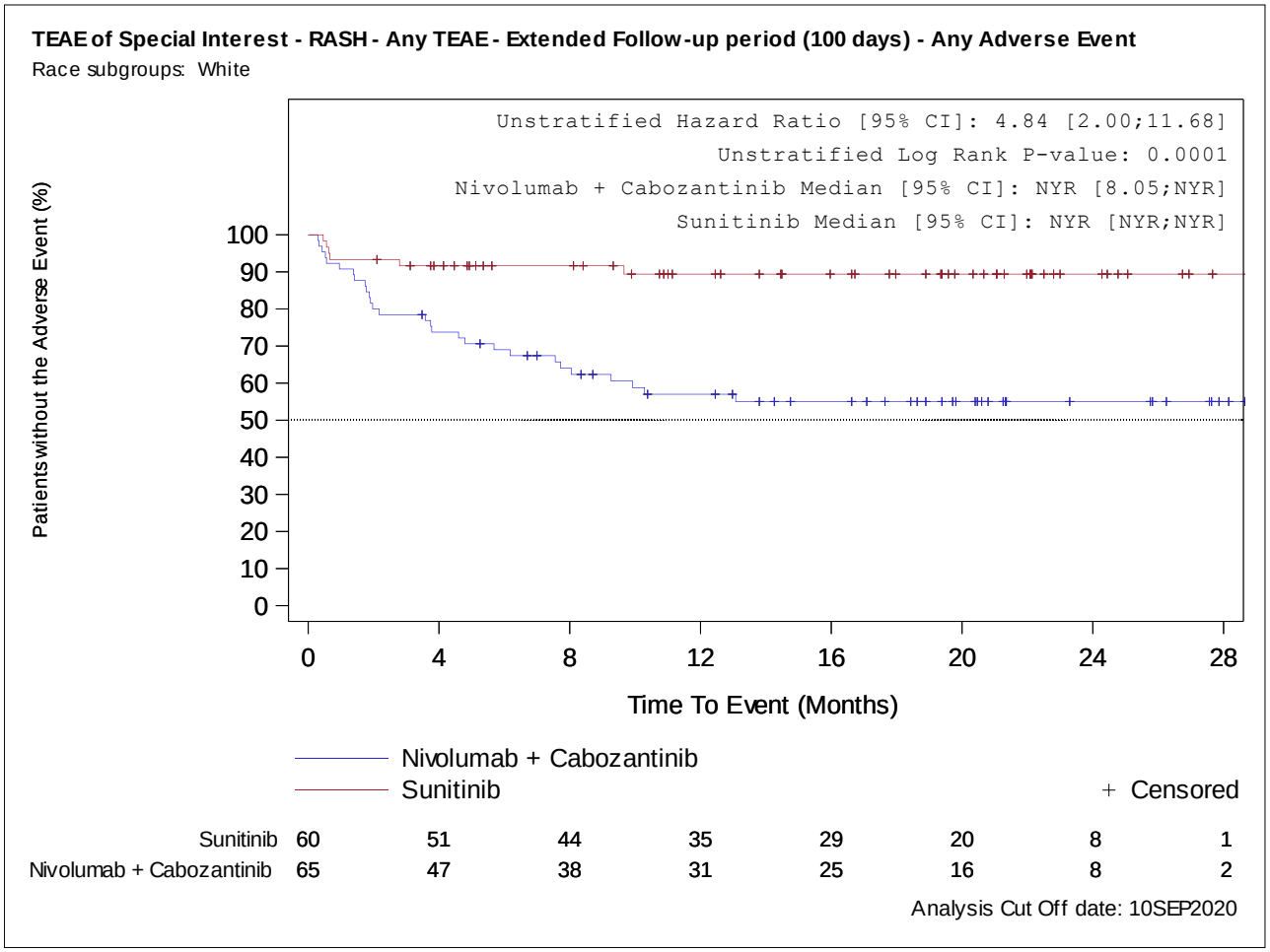

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:59:03

FIGURE 3.132.2.7: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



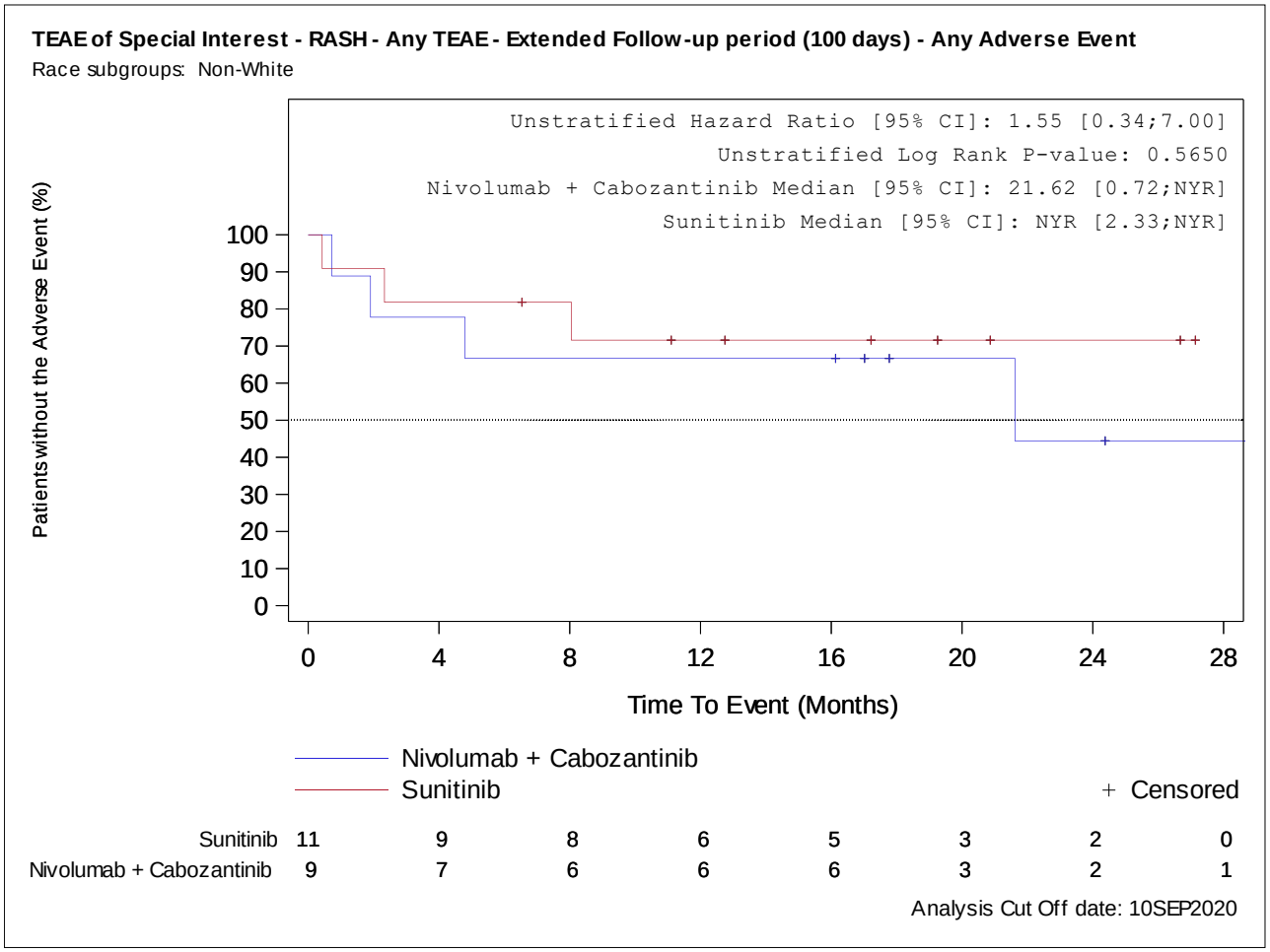

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:59:08

FIGURE 3.132.2.8: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



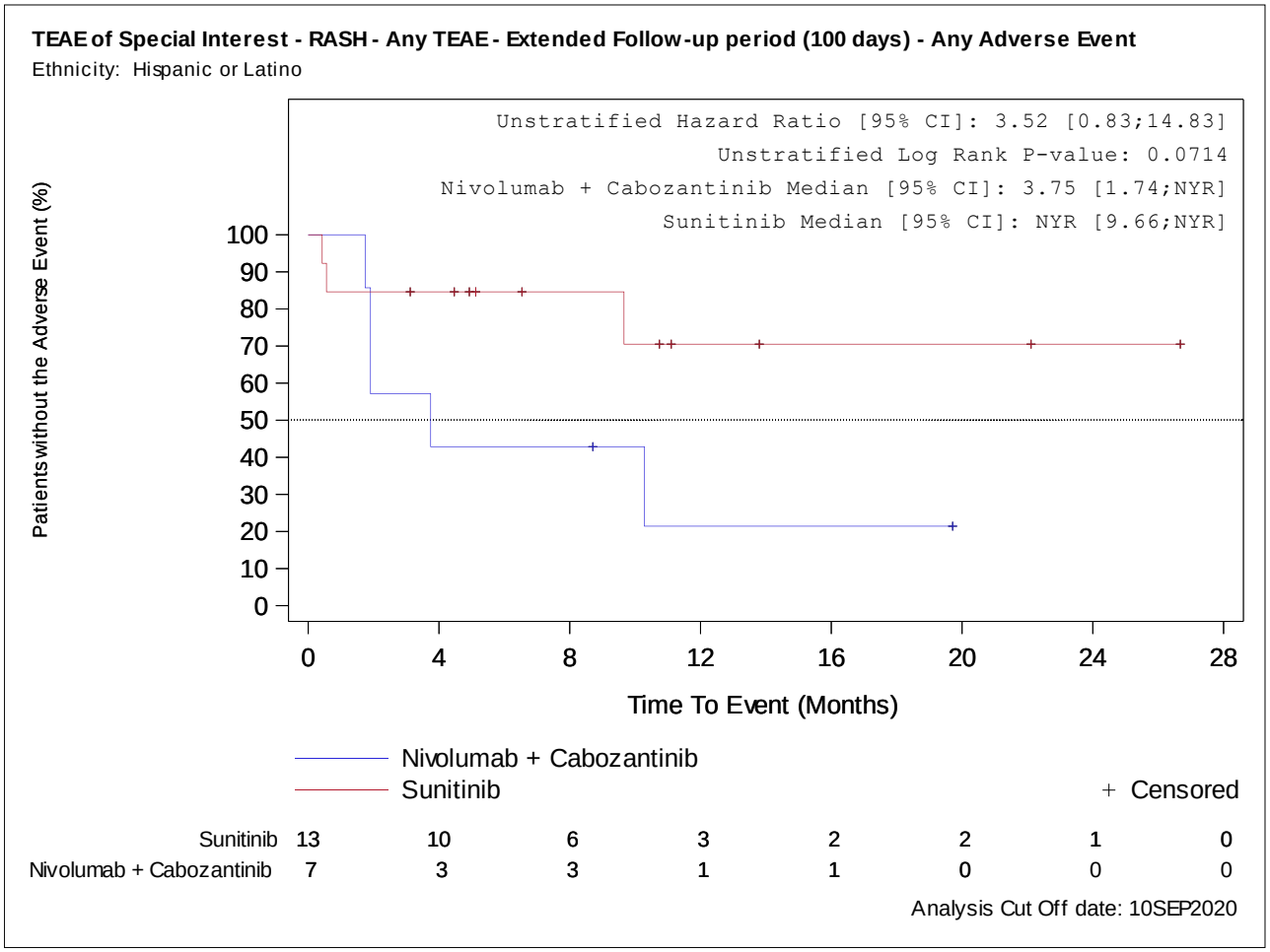

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:59:13

FIGURE 3.132.2.9: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



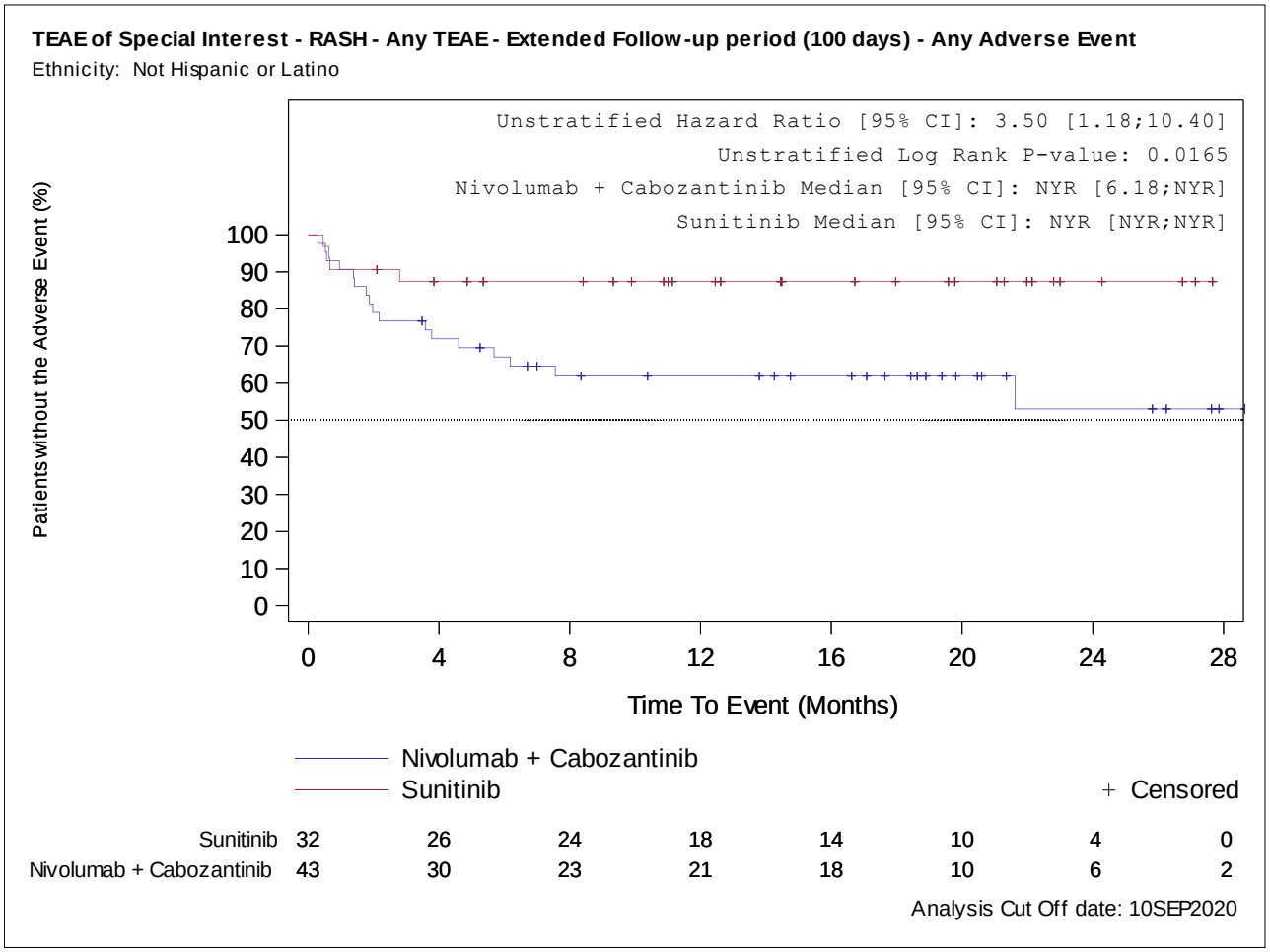

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:59:18

FIGURE 3.132.2.10: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



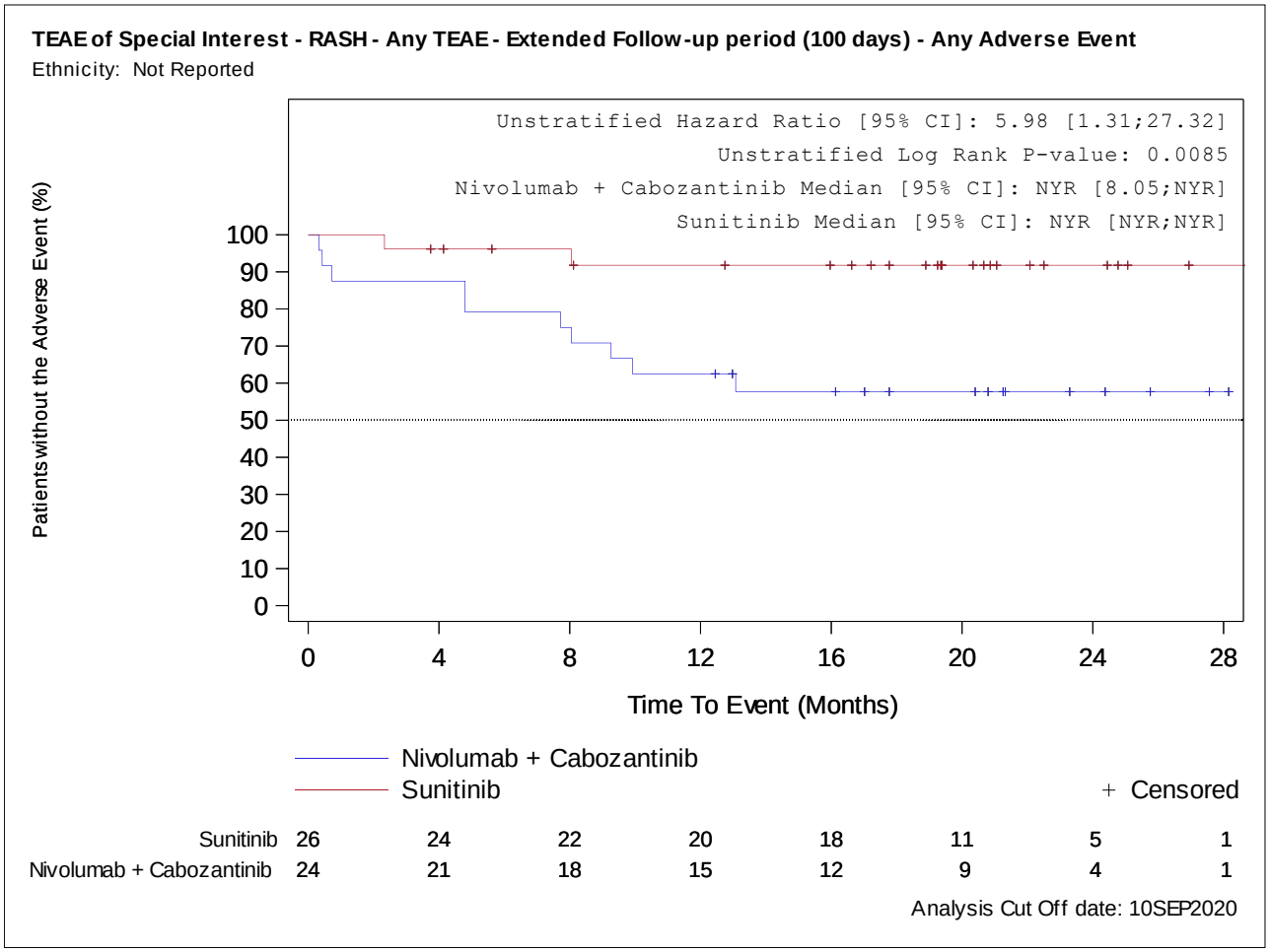

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:59:24

FIGURE 3.132.2.11: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



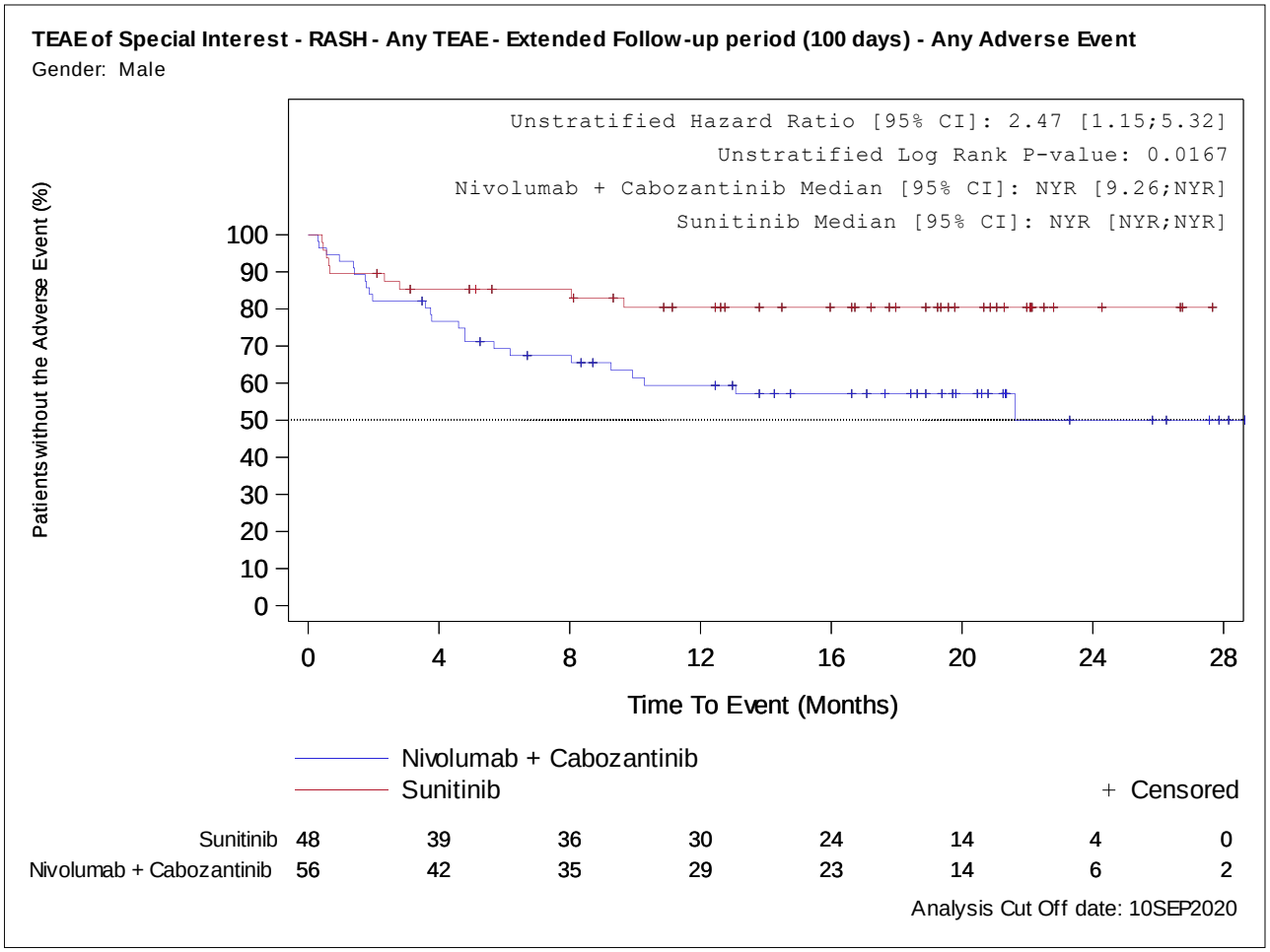

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:59:29

FIGURE 3.132.2.12: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



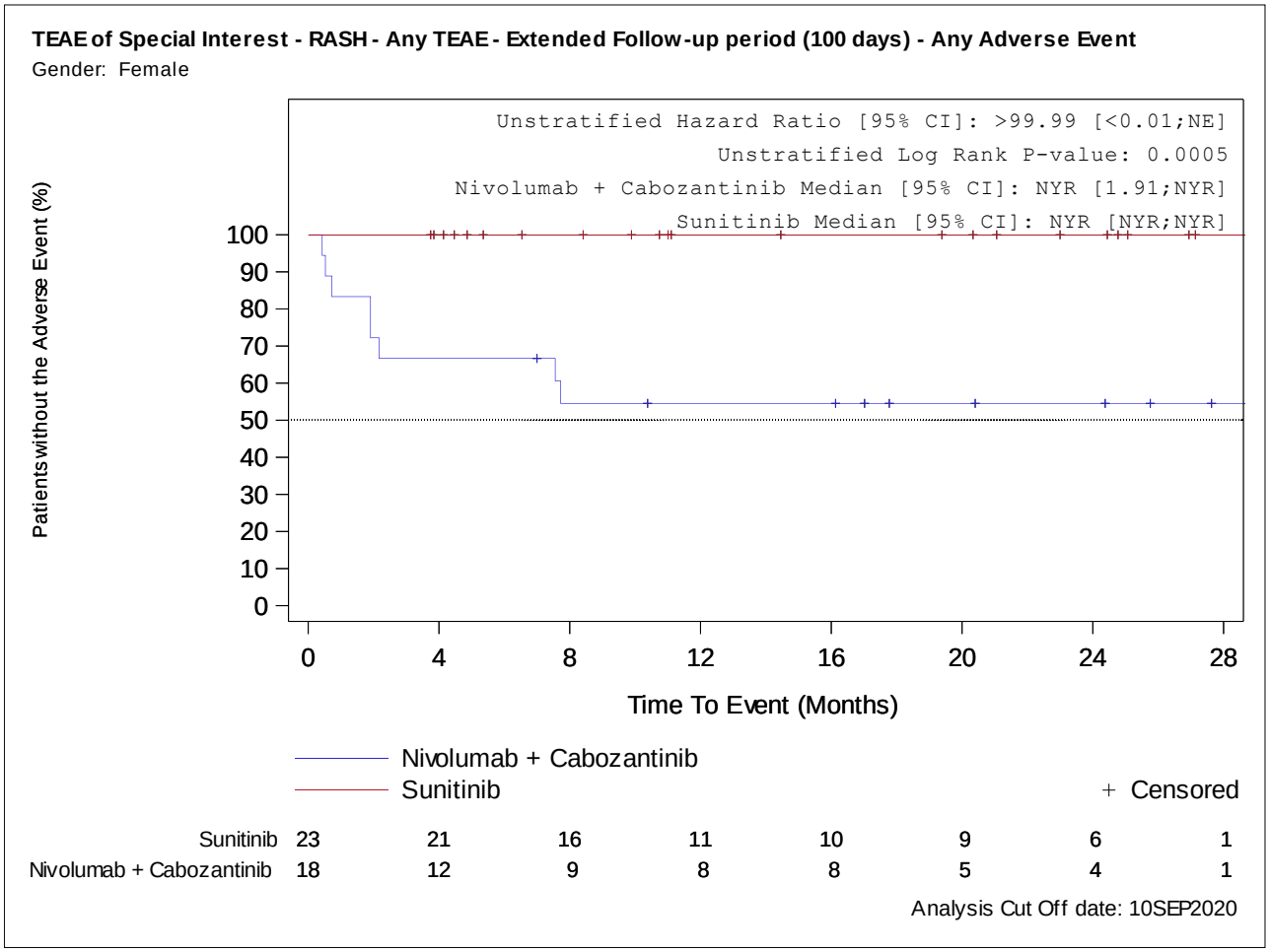

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:59:34

FIGURE 3.132.2.13: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



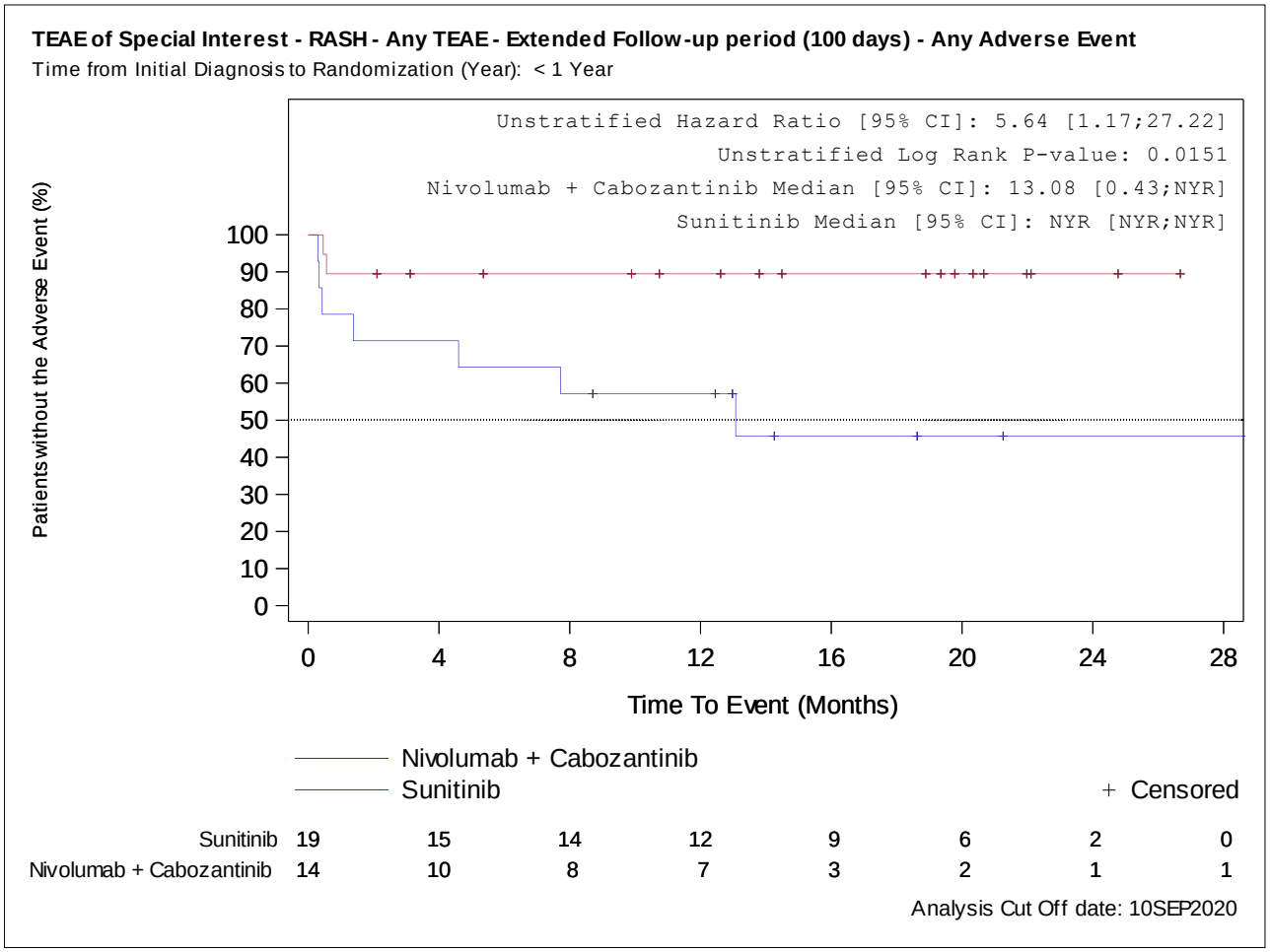

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:59:39

FIGURE 3.132.2.14: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



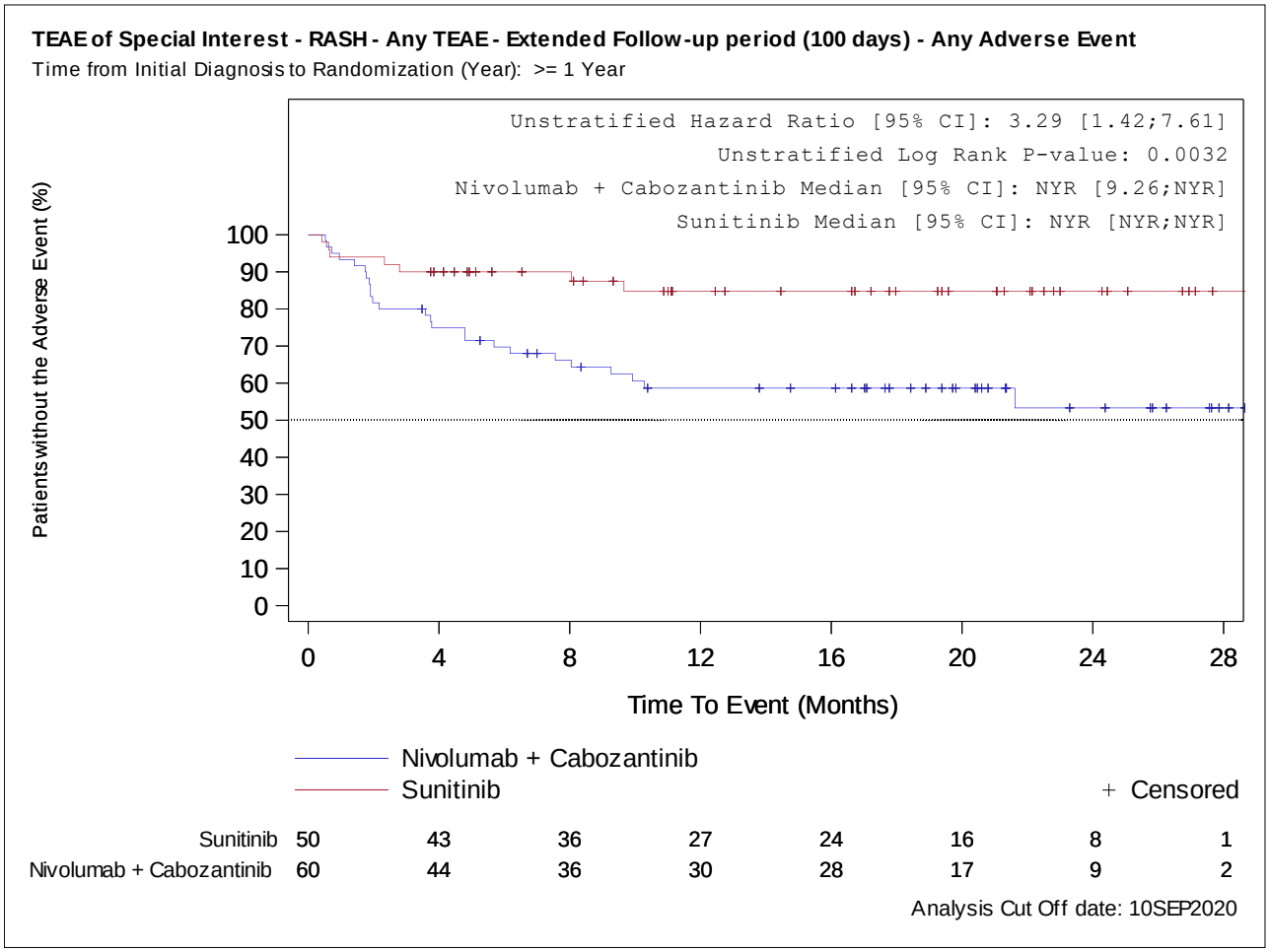

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 17:59:44

FIGURE 3.132.2.15: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



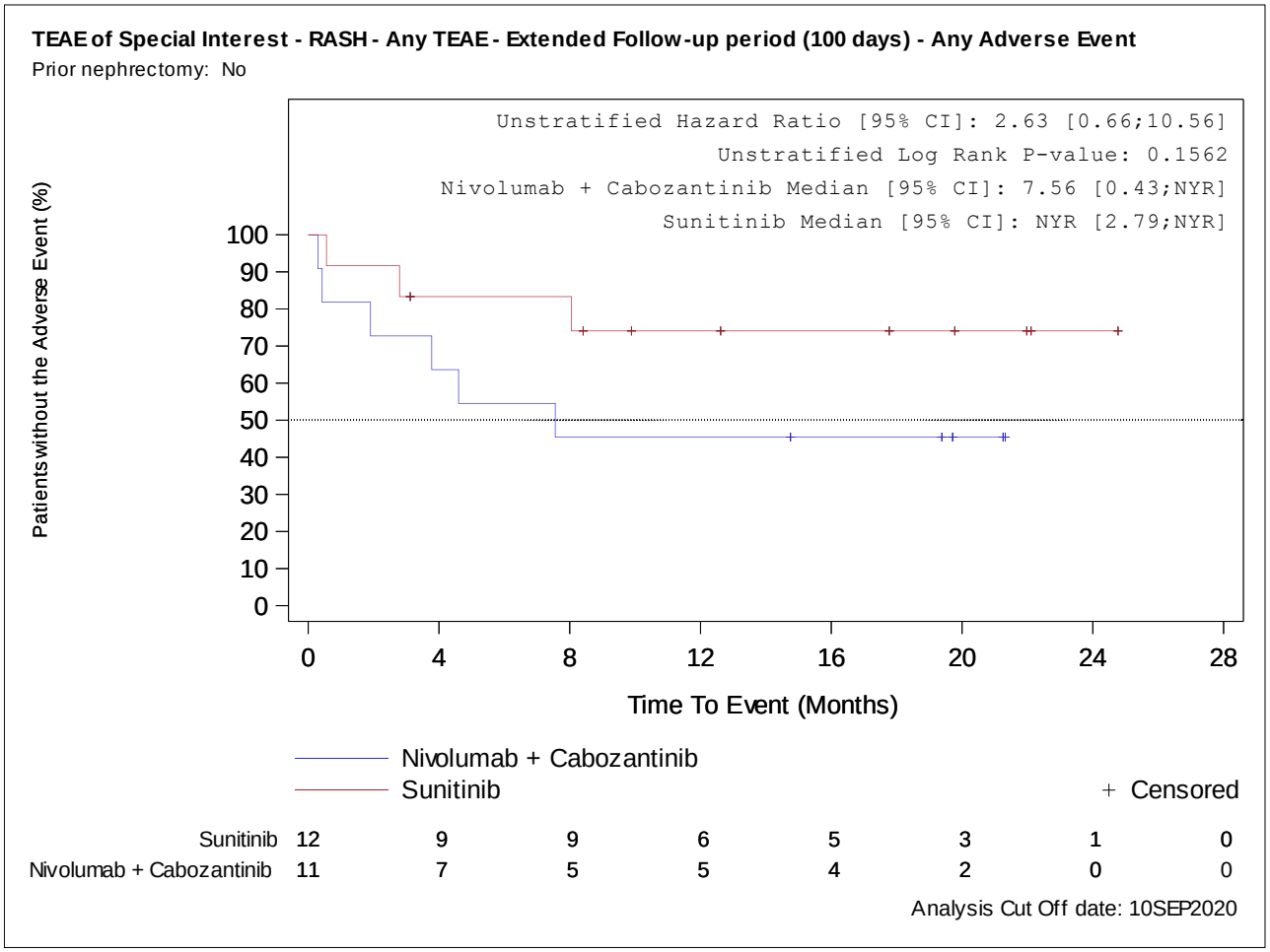

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:00:00

FIGURE 3.132.2.16: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



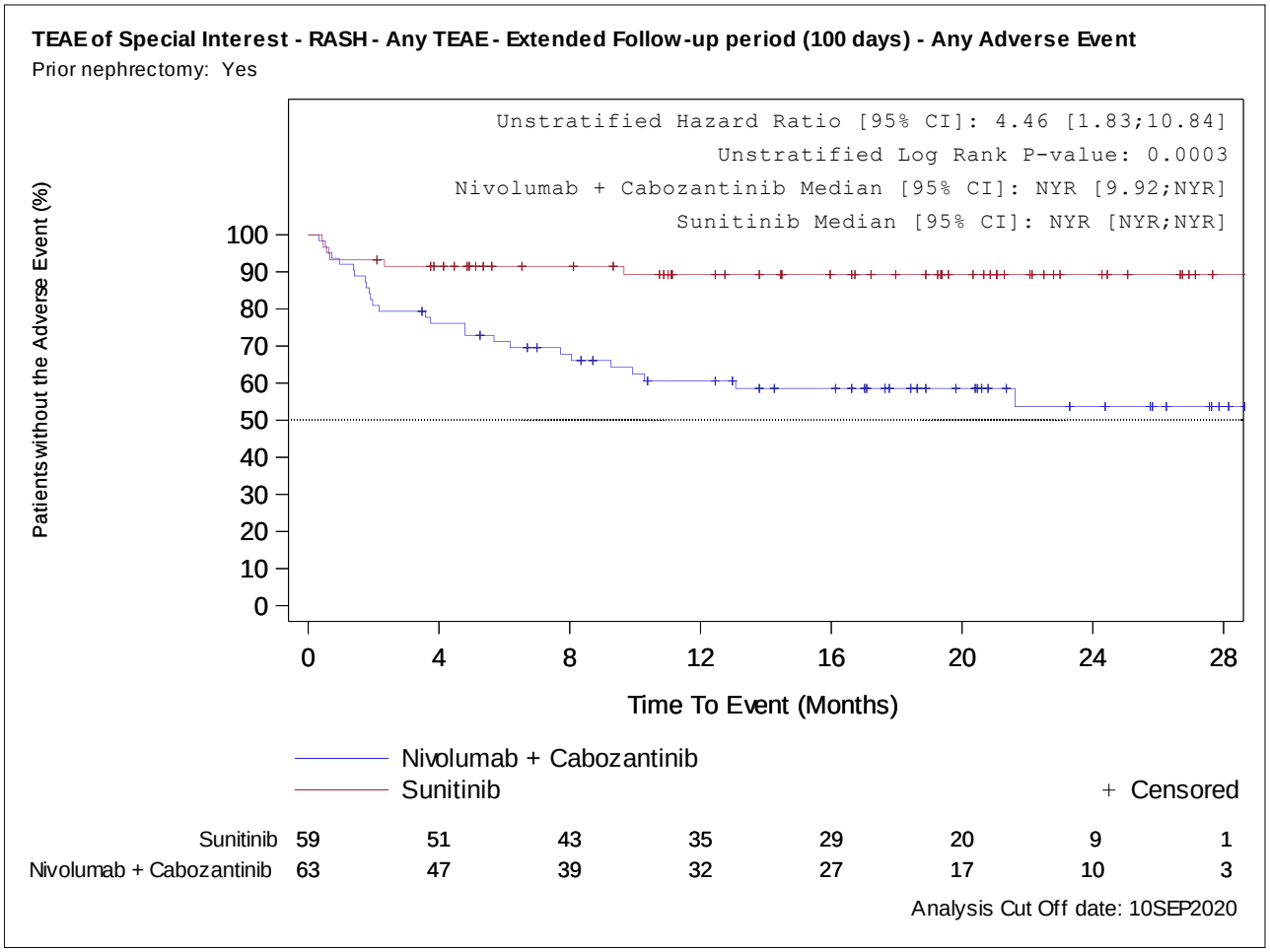

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:00:05

FIGURE 3.132.2.17: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



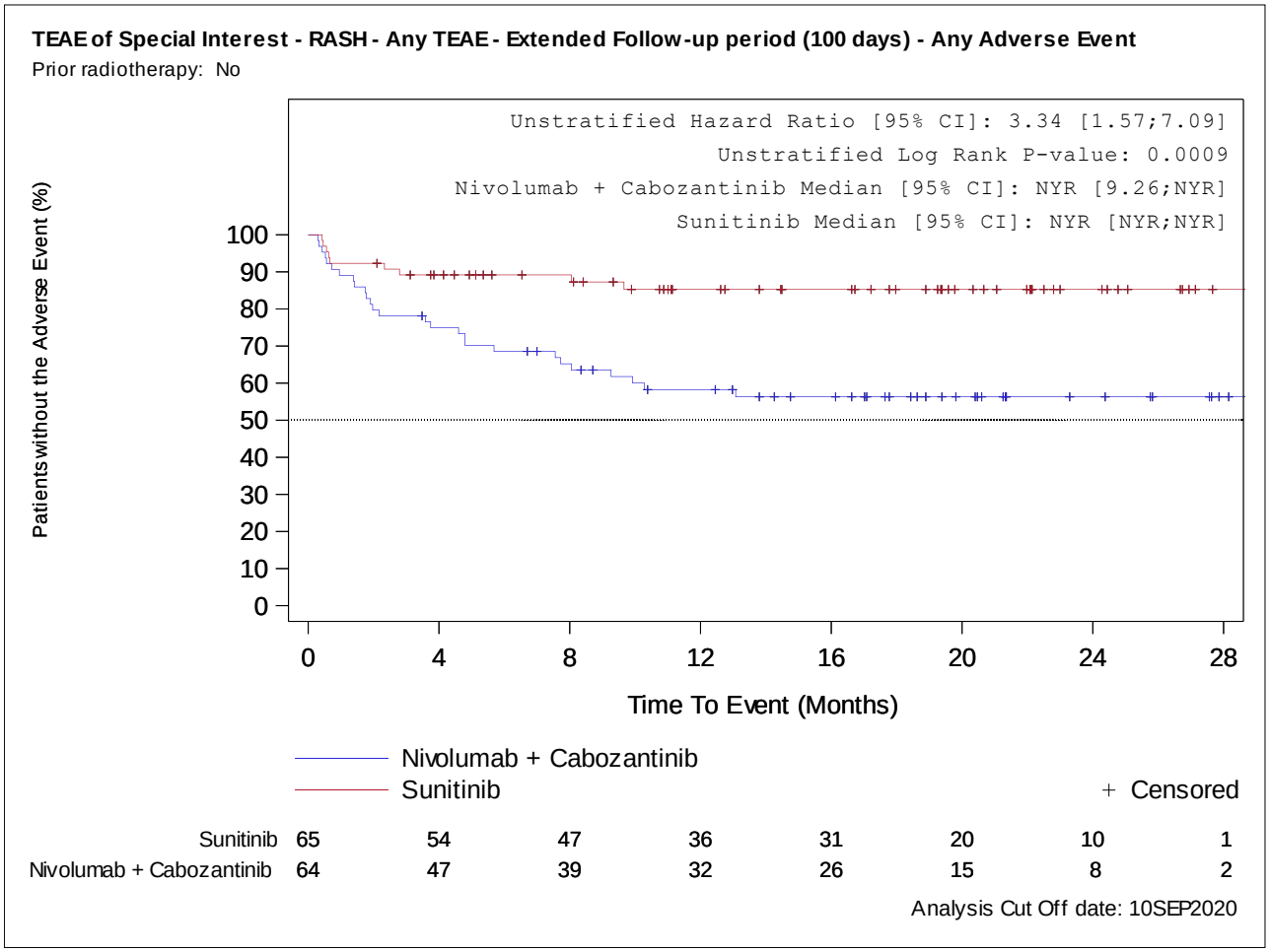

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:00:53

FIGURE 3.132.2.18: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



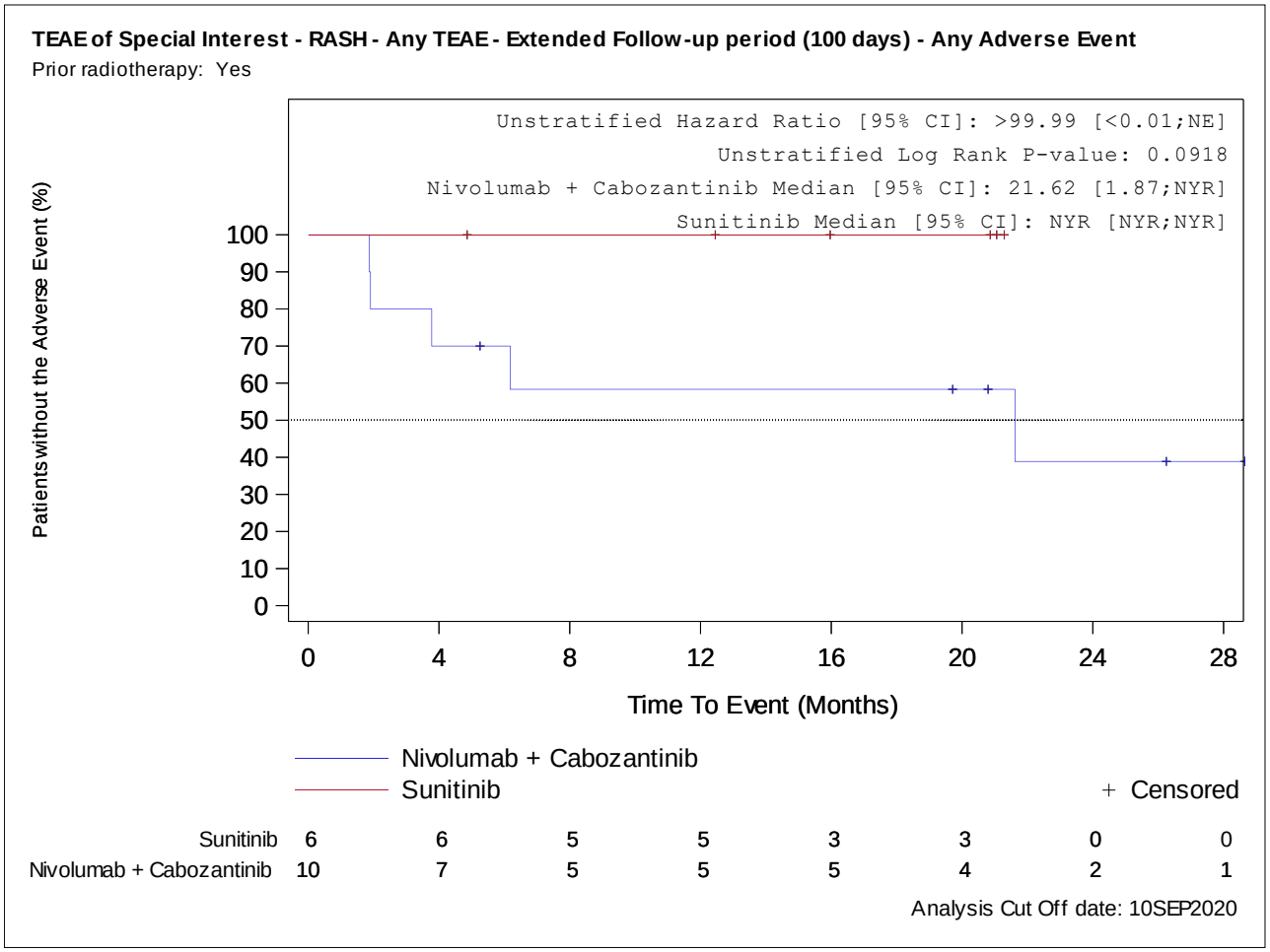

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:00:58

FIGURE 3.132.2.19: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



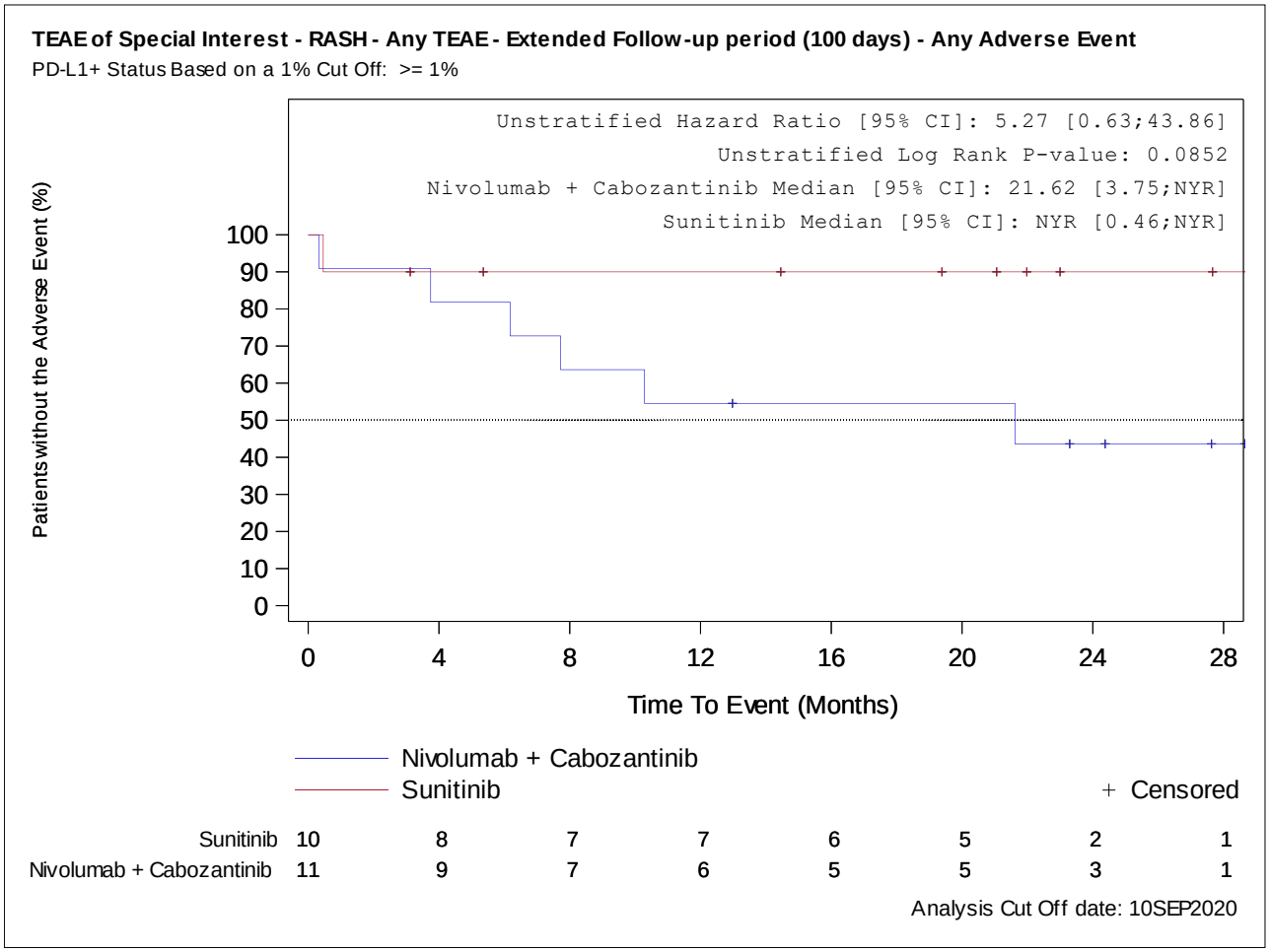

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:01:03

FIGURE 3.132.2.20: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



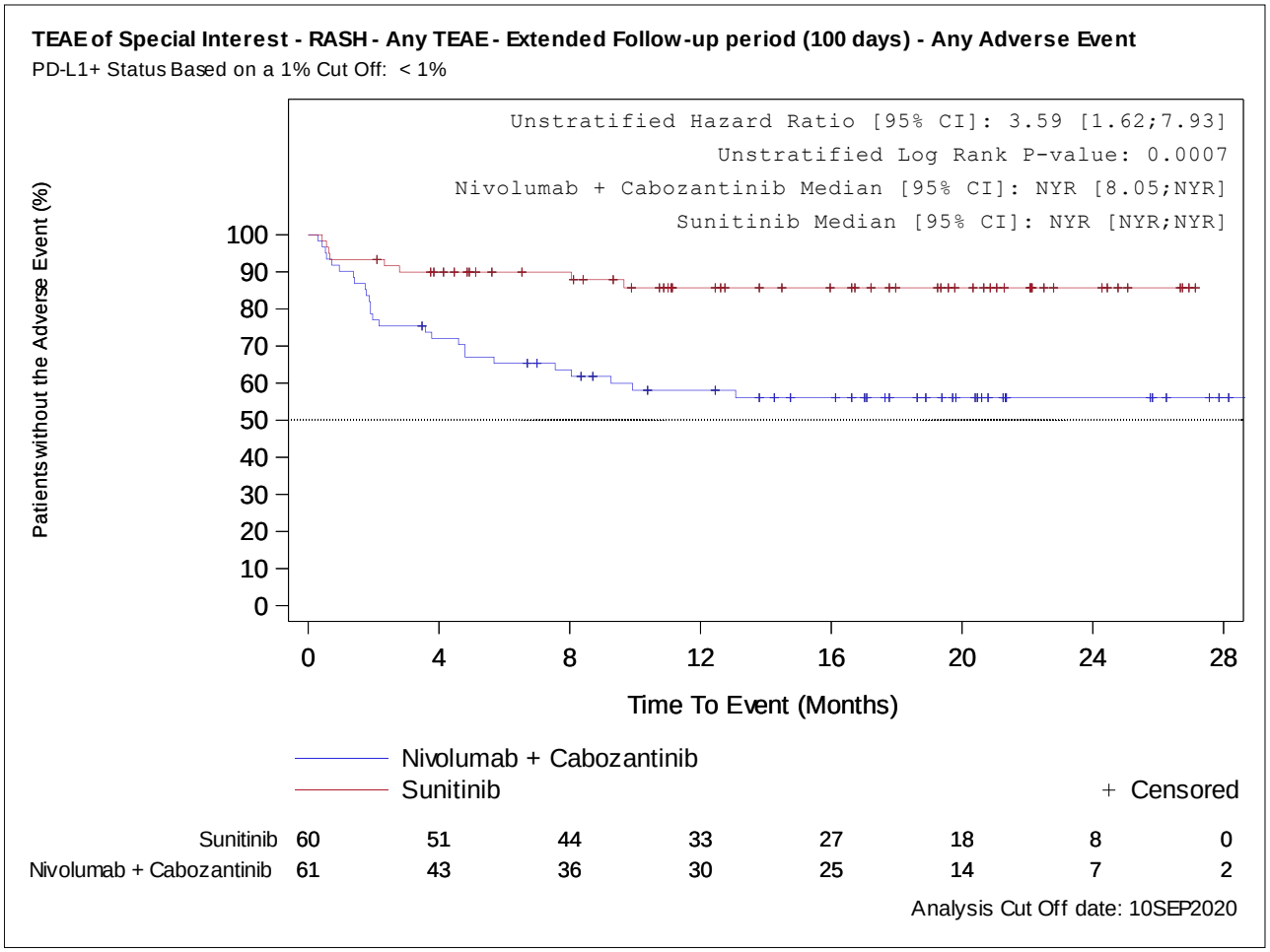

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:01:09

FIGURE 3.132.2.21: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



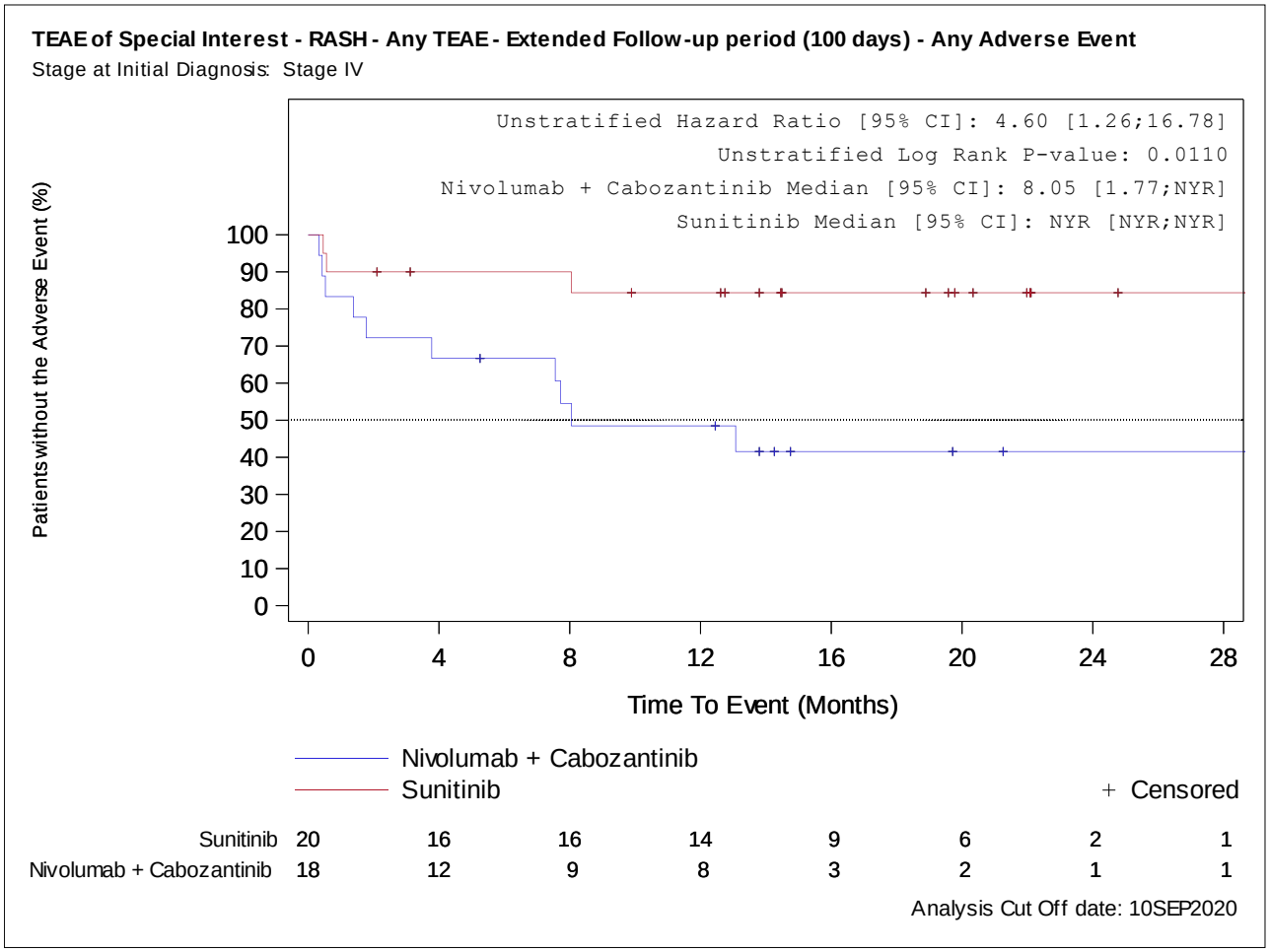

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:01:14

FIGURE 3.132.2.22: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



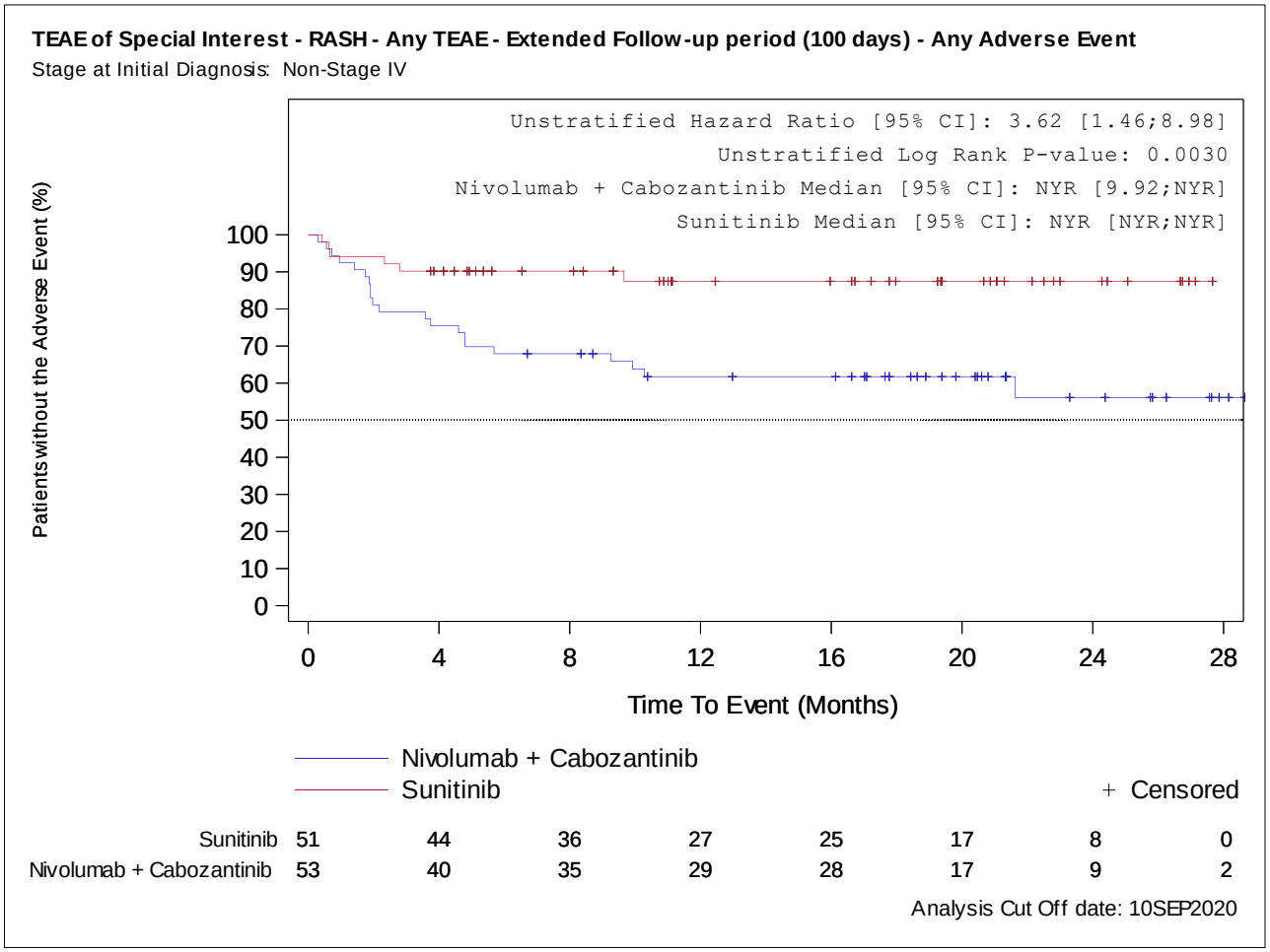

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:01:19

FIGURE 3.132.2.23: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



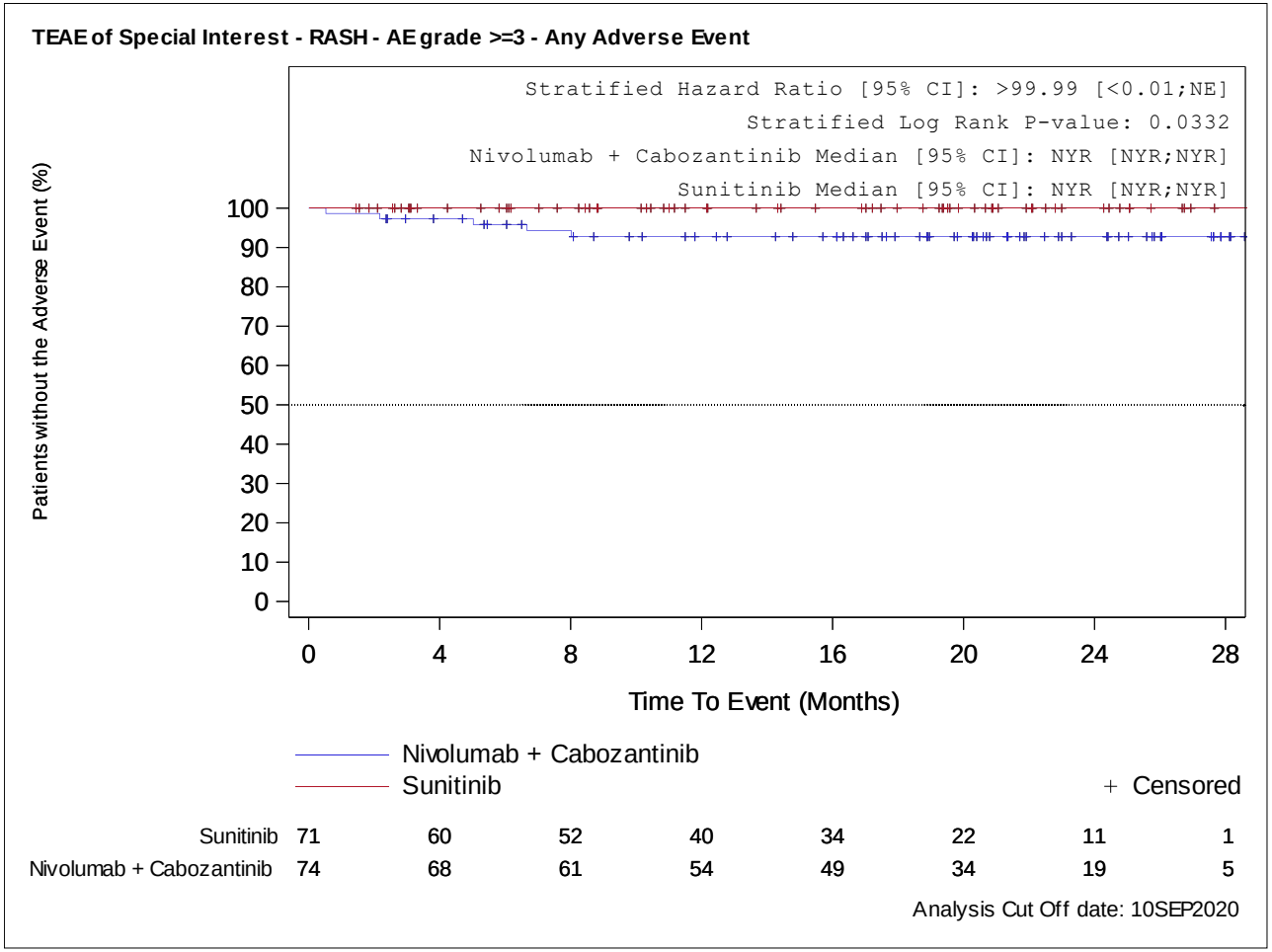

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:01:48

FIGURE 3.132.2.24: Kaplan-Meier curve - TEAE of Special Interest - RASH - Any TEAE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



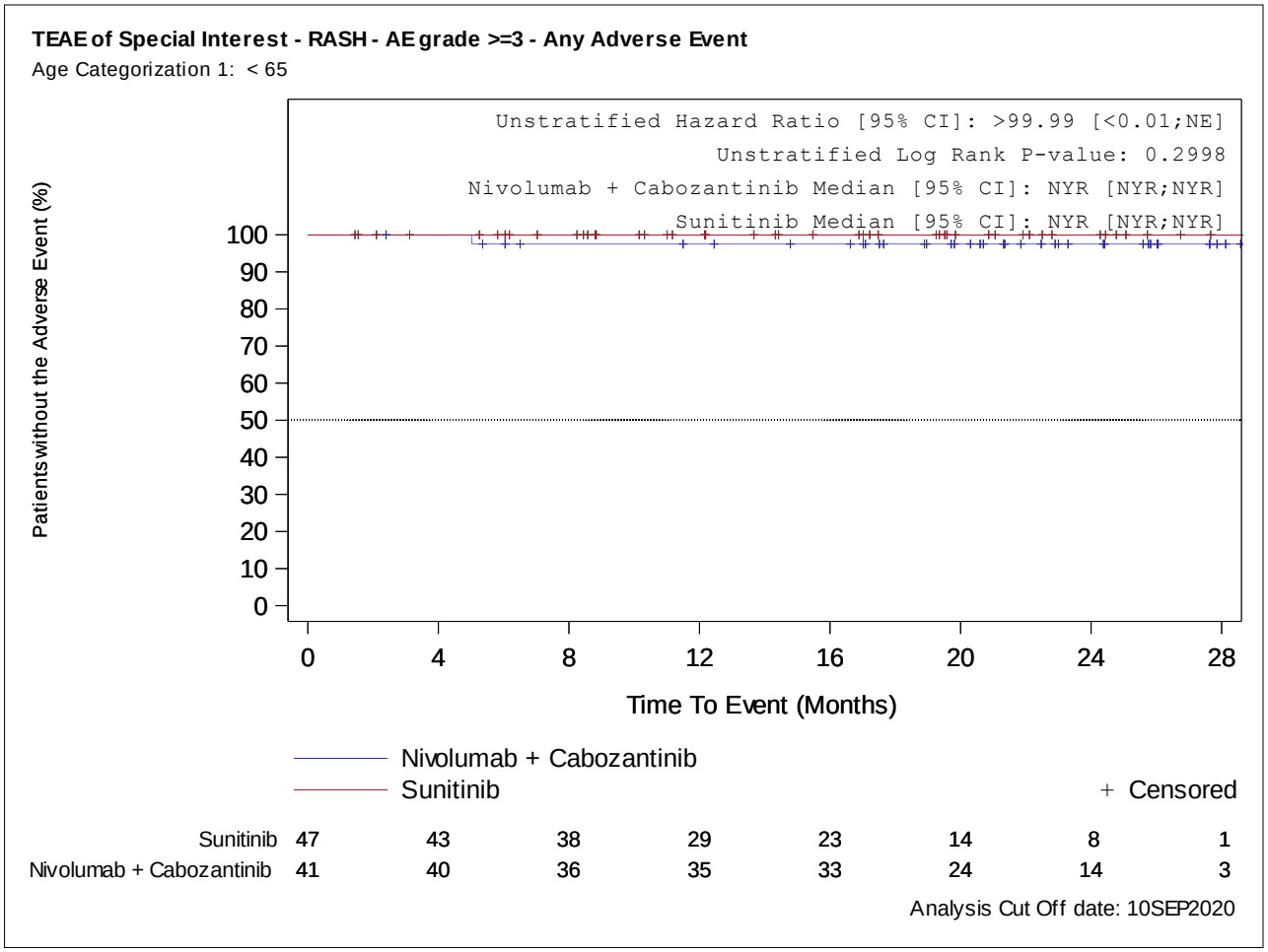

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:01:53

FIGURE 3.133.1: TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



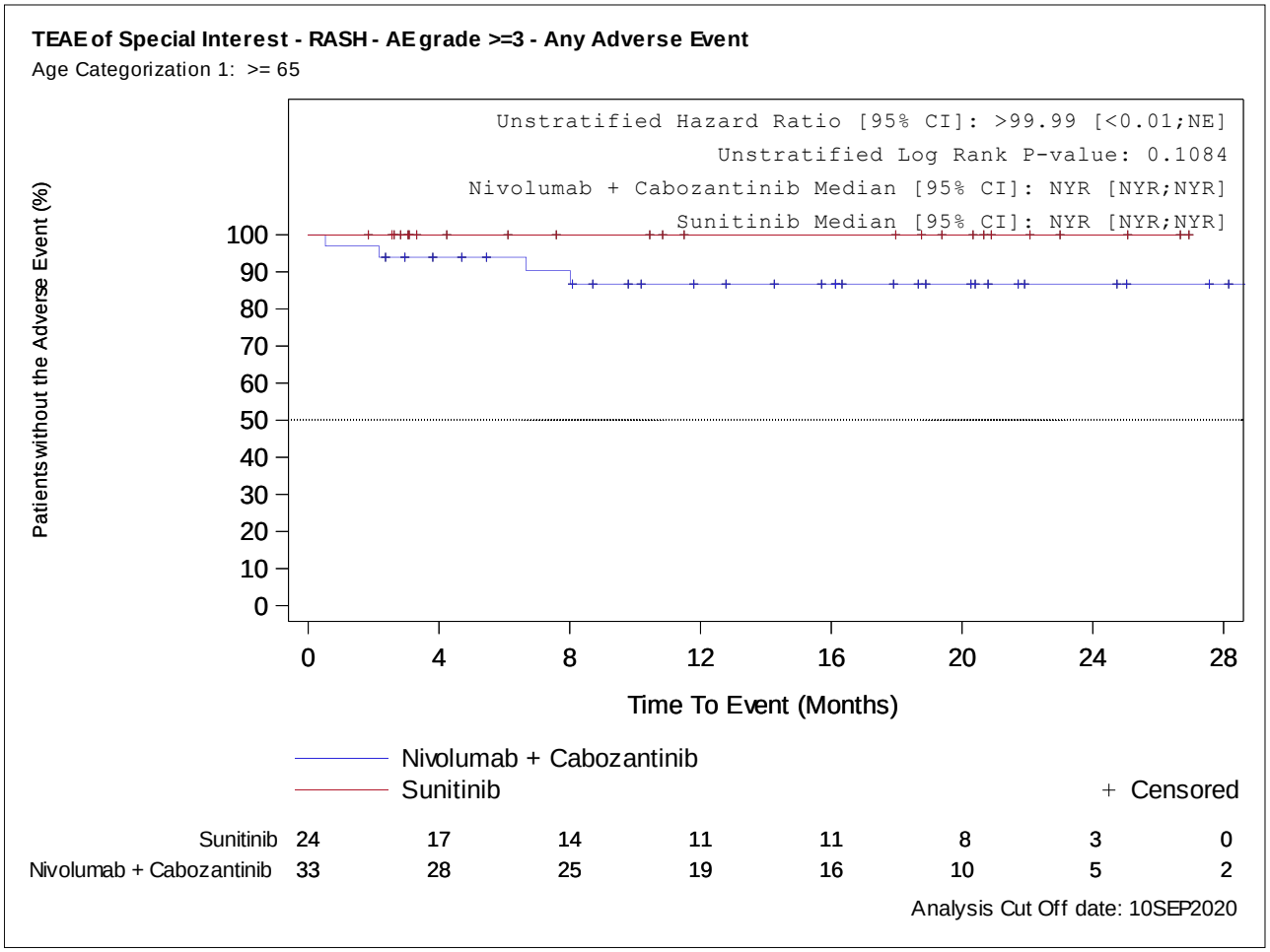

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:04:51

FIGURE 3.133.2.1: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



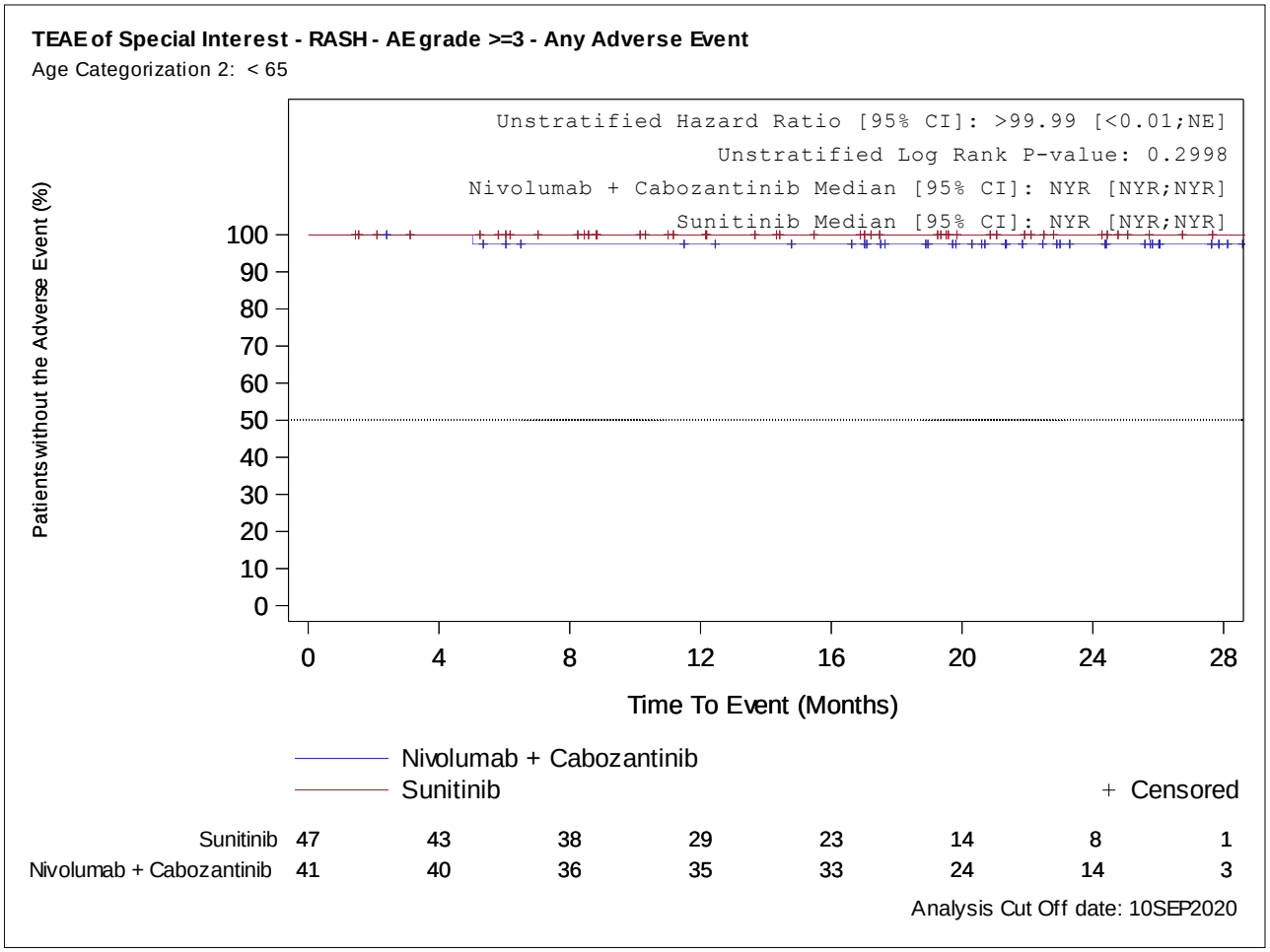

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:04:54

FIGURE 3.133.2.2: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1:  >= 65



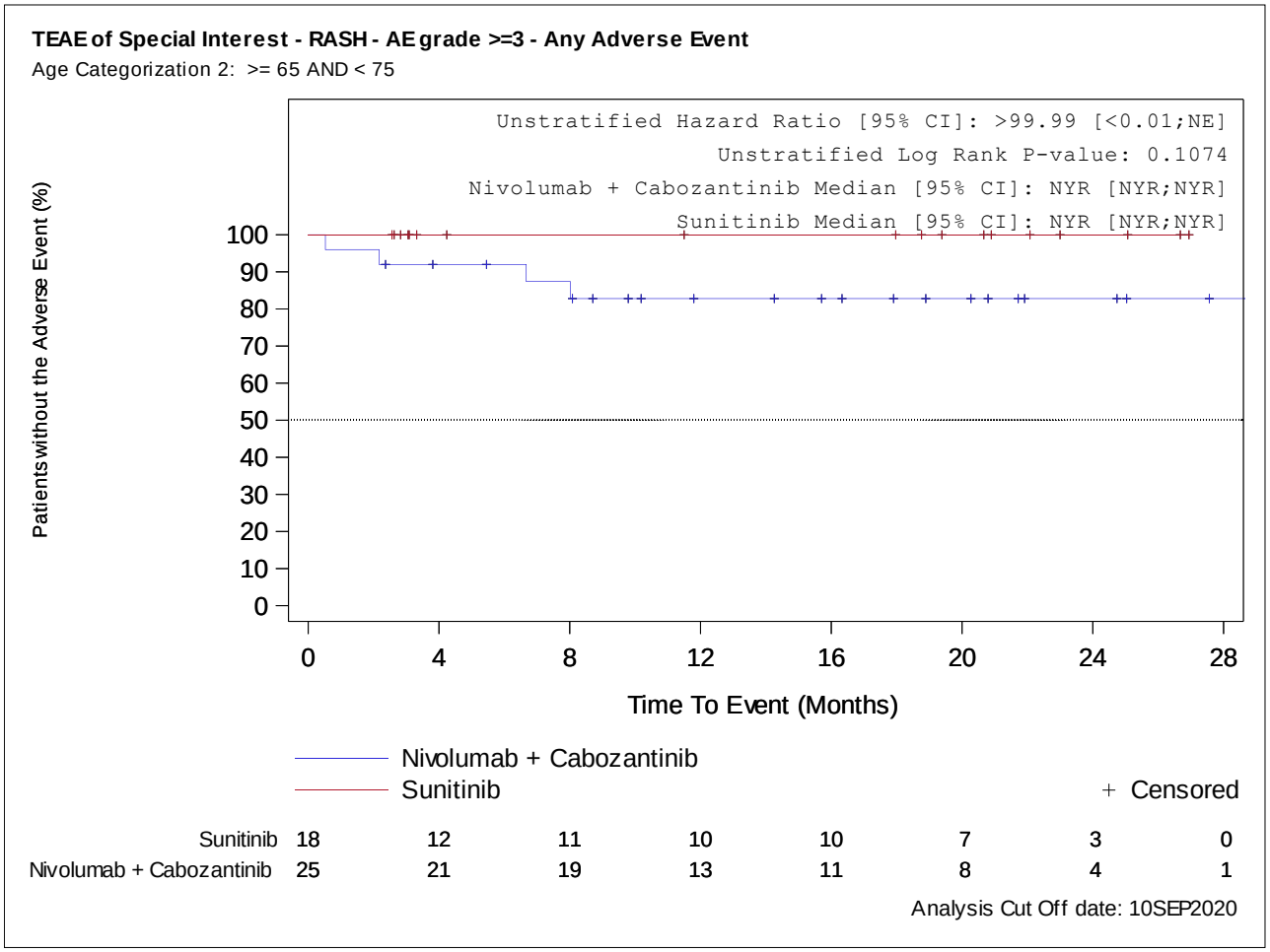

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:04:59

FIGURE 3.133.2.3: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



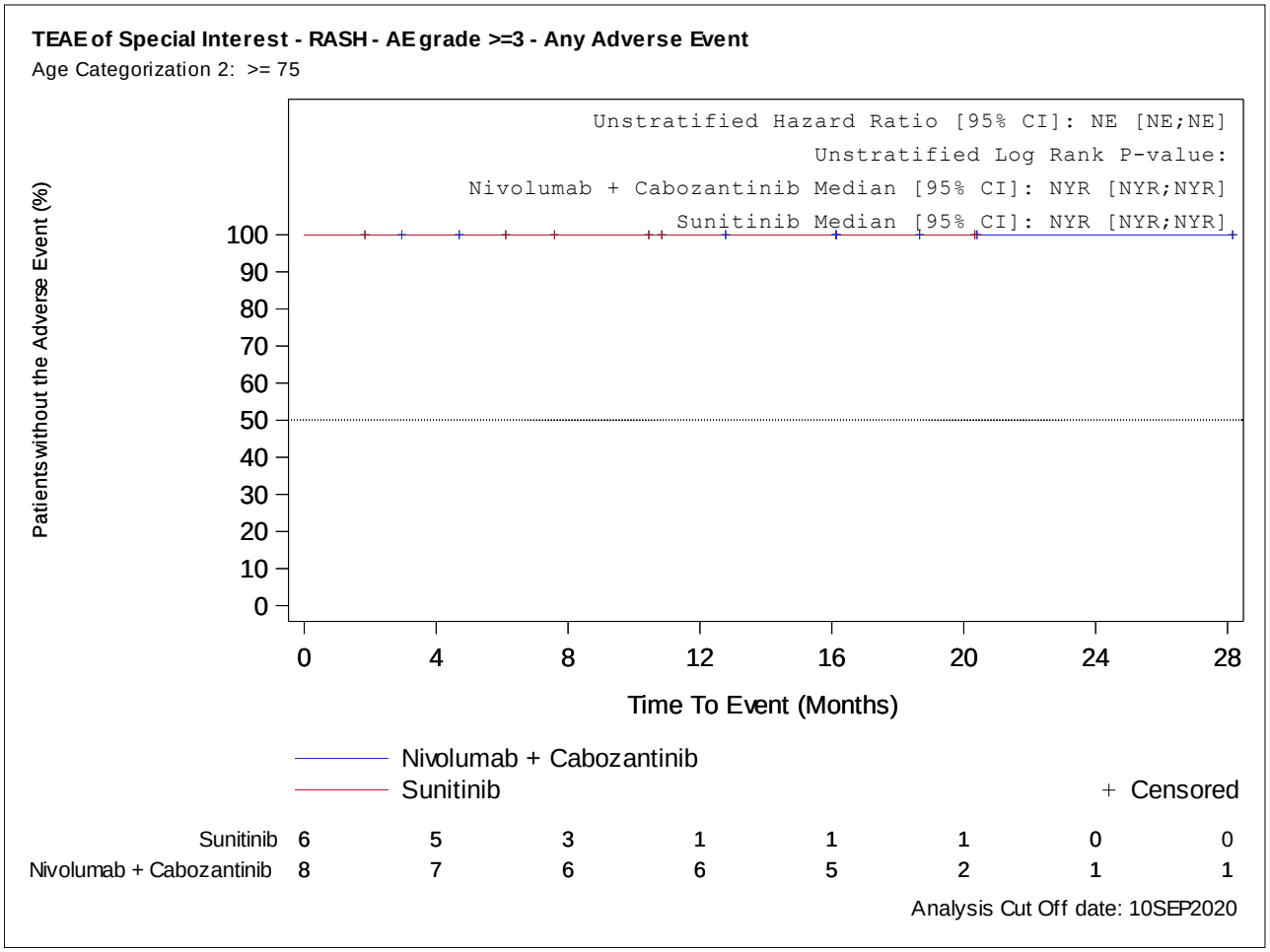

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:05:04

FIGURE 3.133.2.4: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



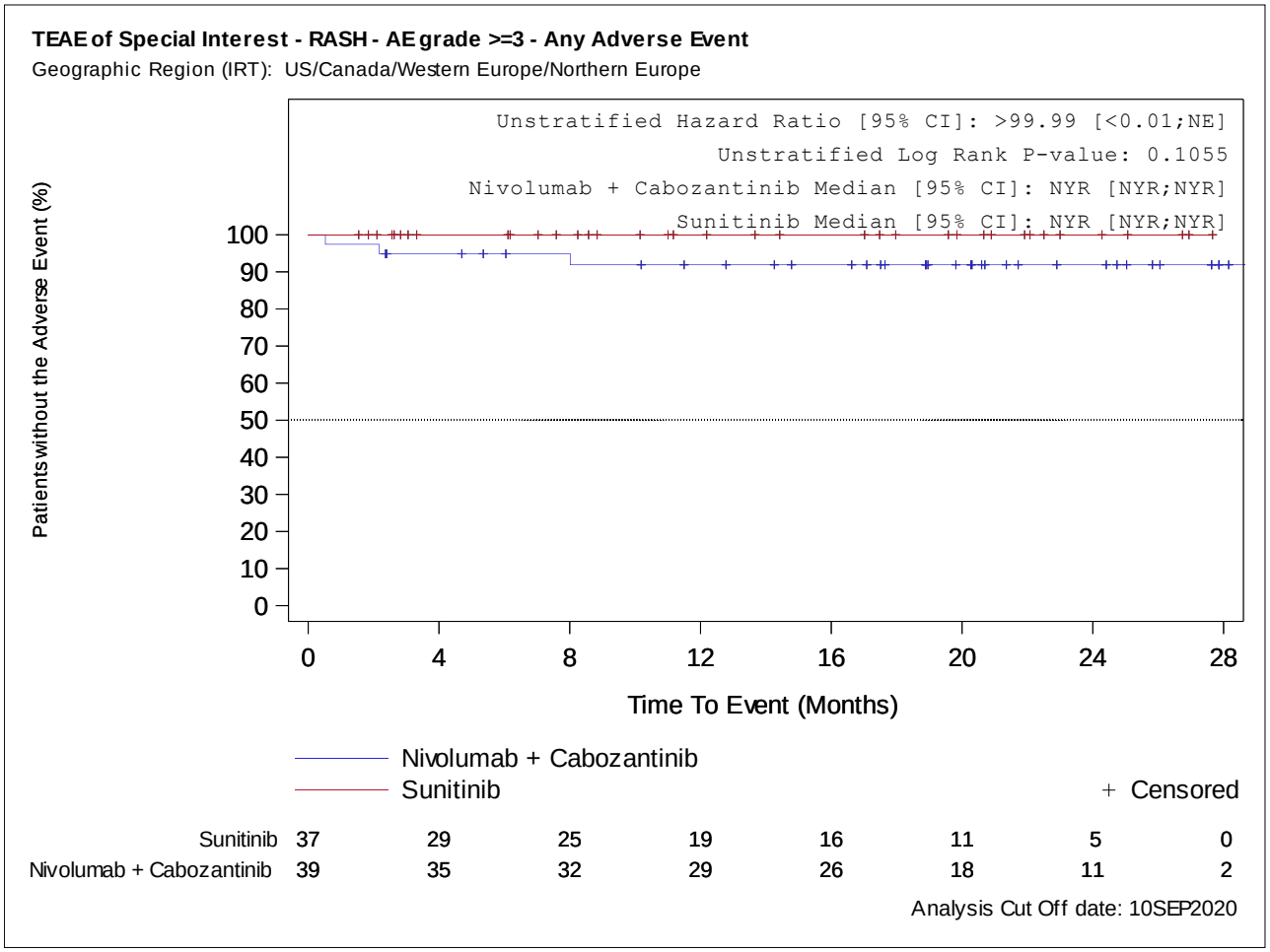

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:05:10

FIGURE 3.133.2.5: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



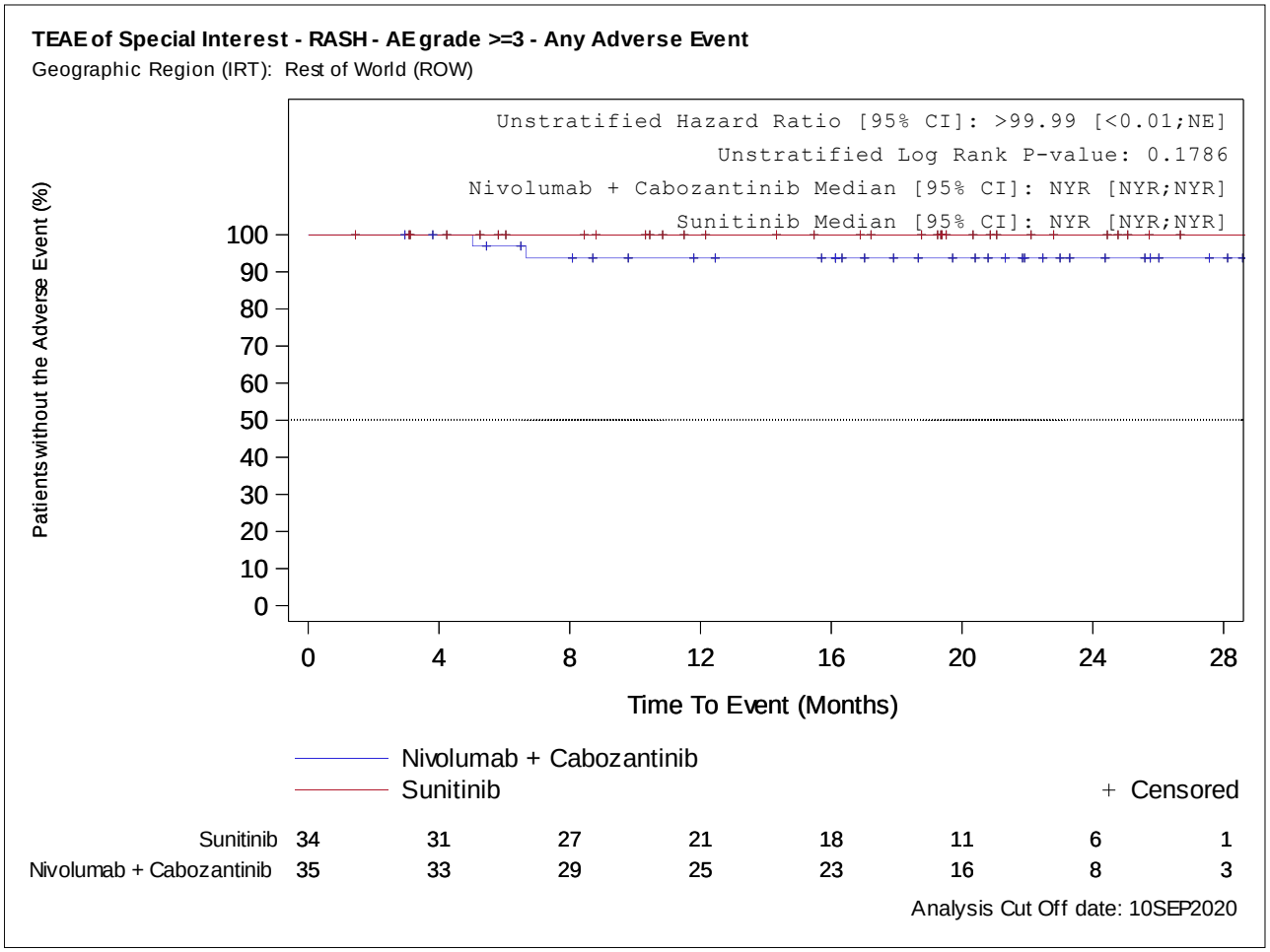

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:05:15

FIGURE 3.133.2.6: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



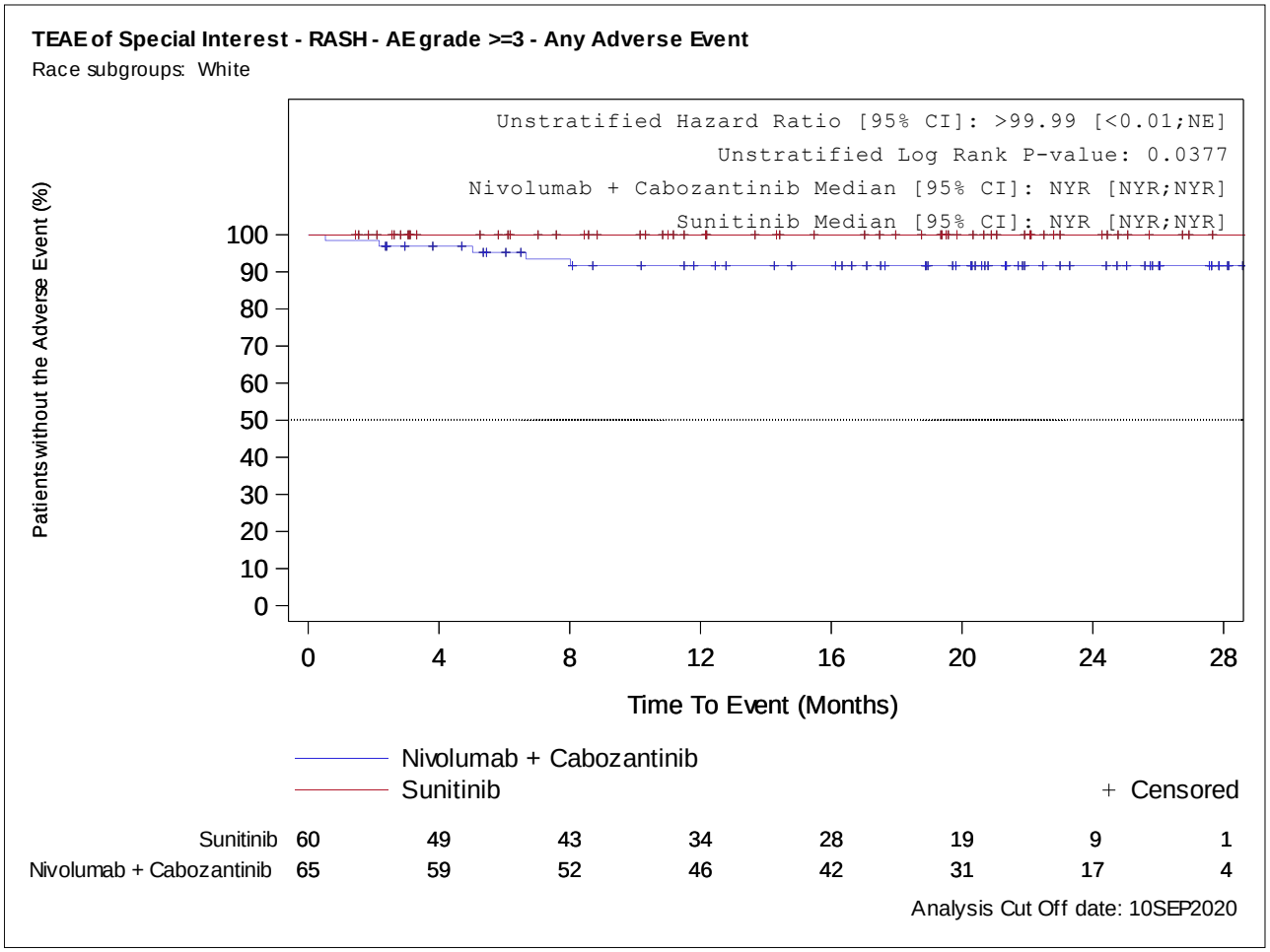

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:05:20

FIGURE 3.133.2.7: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



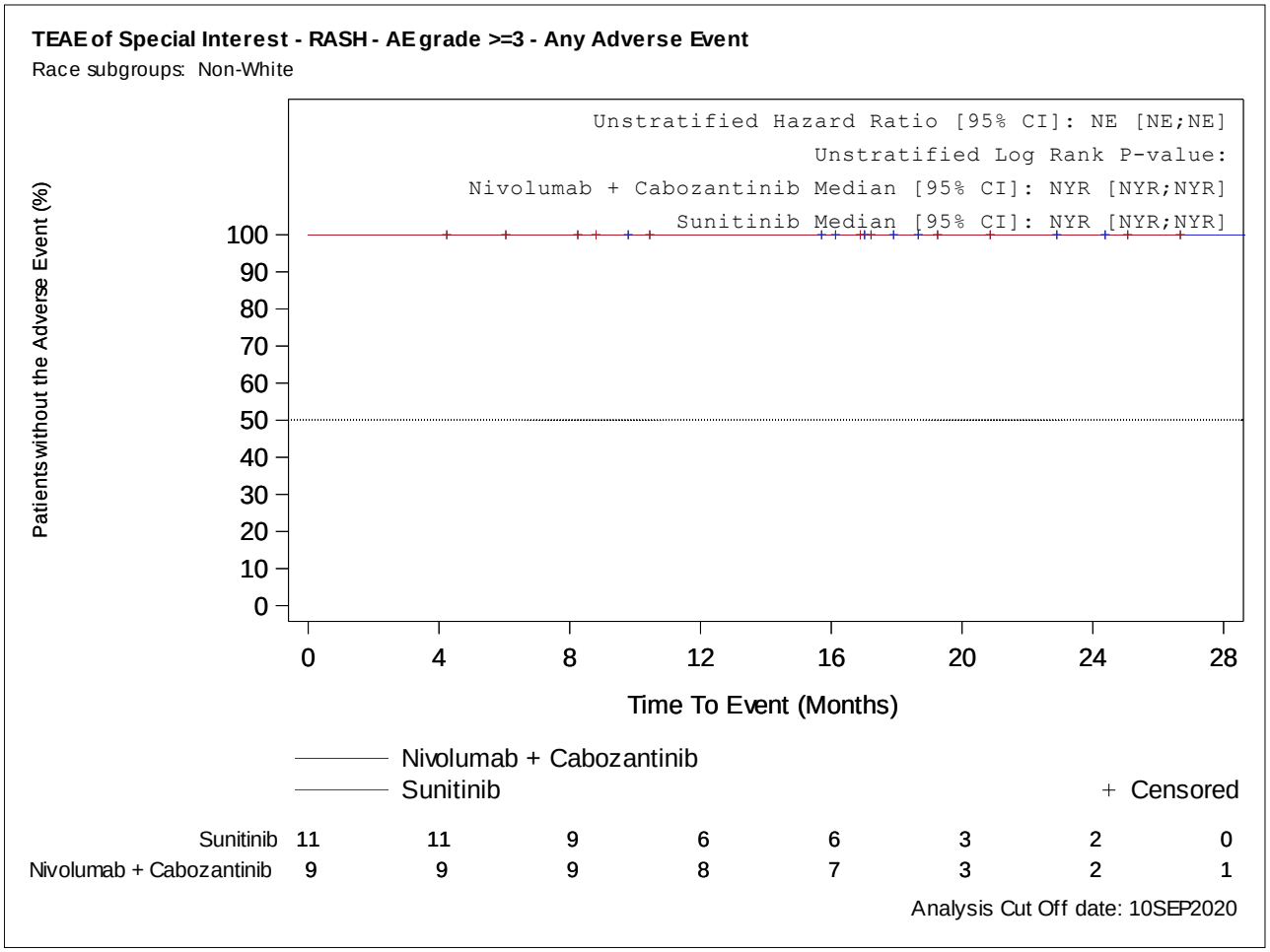

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:05:25

FIGURE 3.133.2.8: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



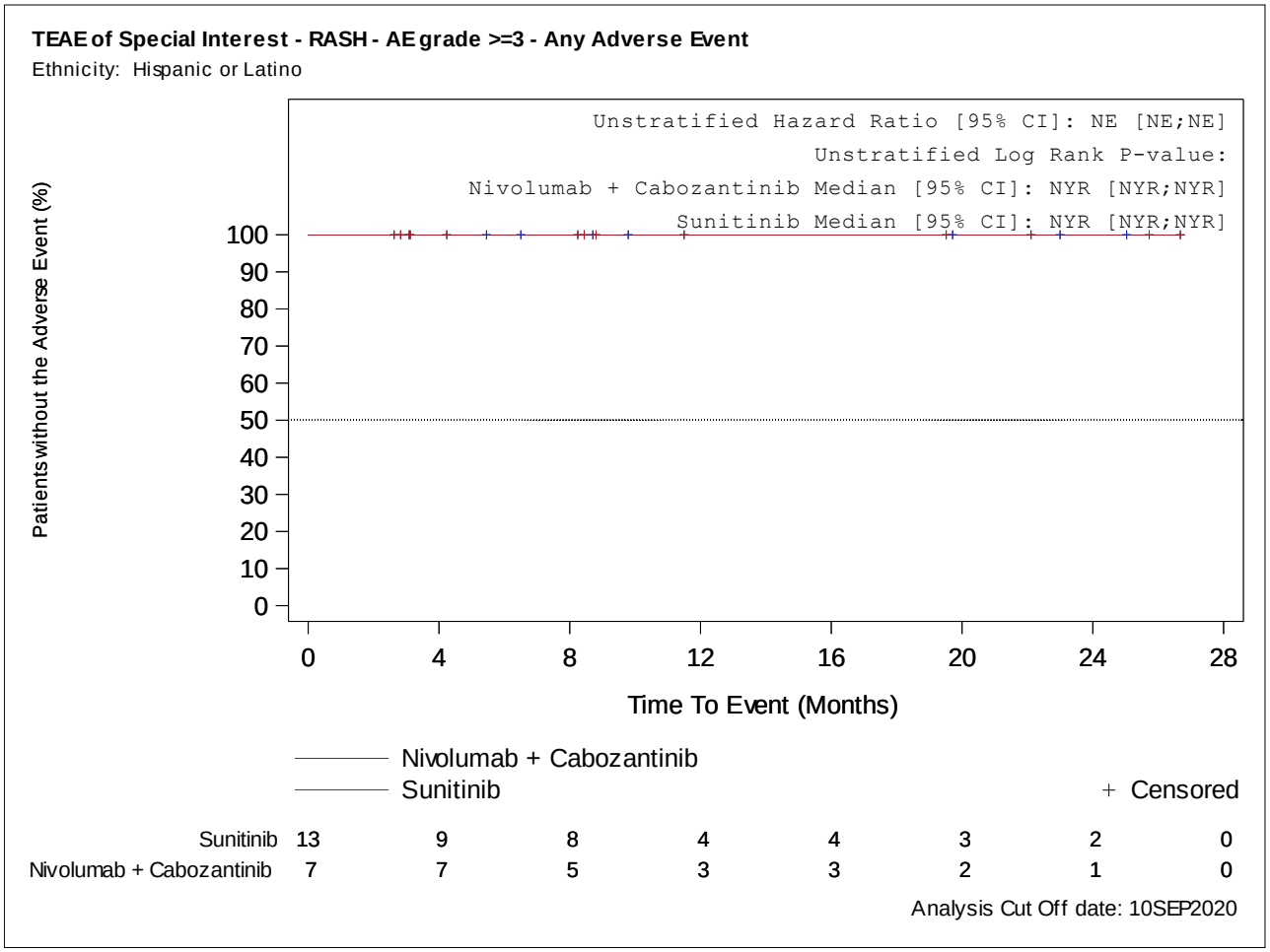

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:05:31

FIGURE 3.133.2.9: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



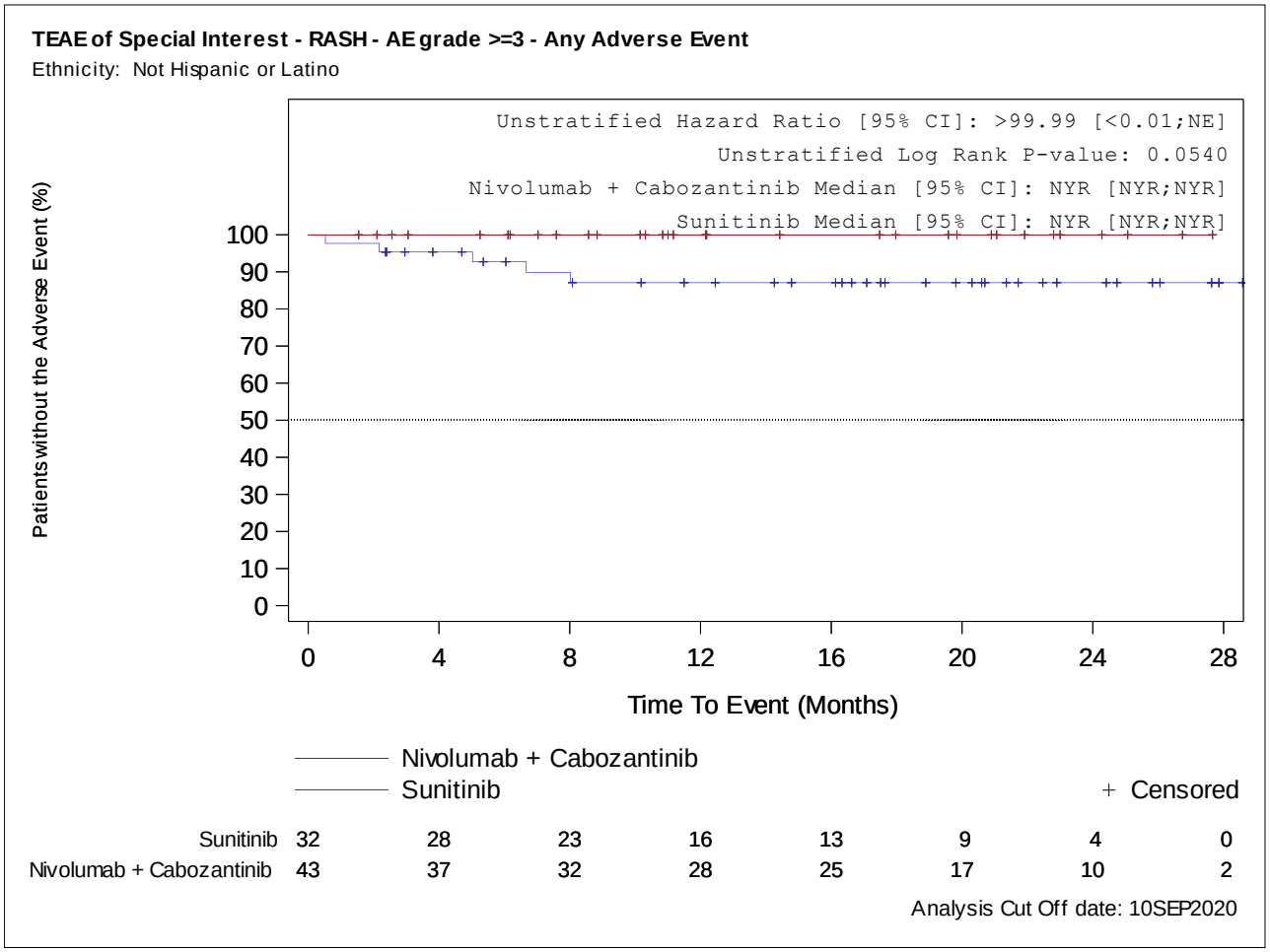

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:05:36

FIGURE 3.133.2.10: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



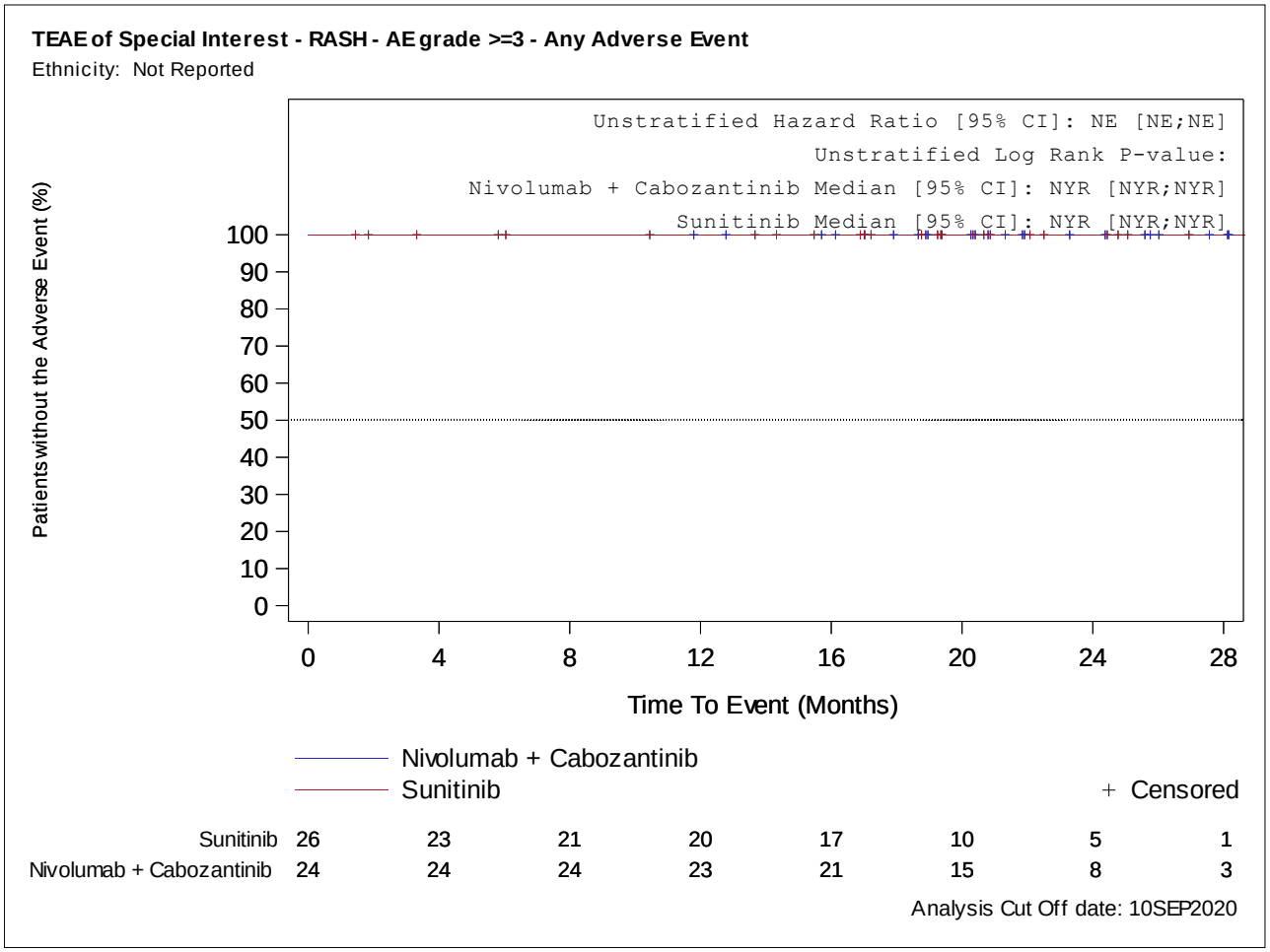

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:05:41

FIGURE 3.133.2.11: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



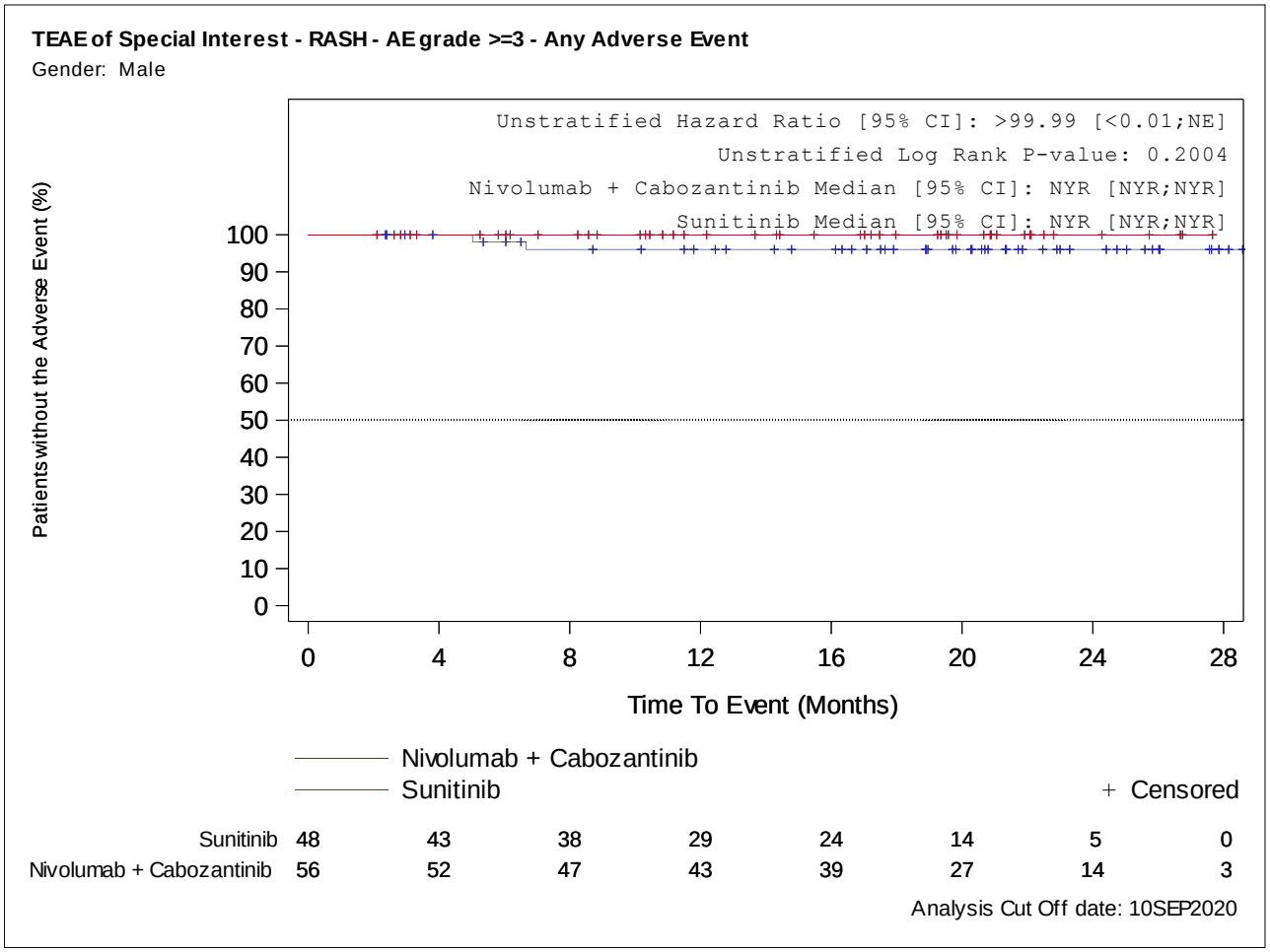

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:05:46

FIGURE 3.133.2.12: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



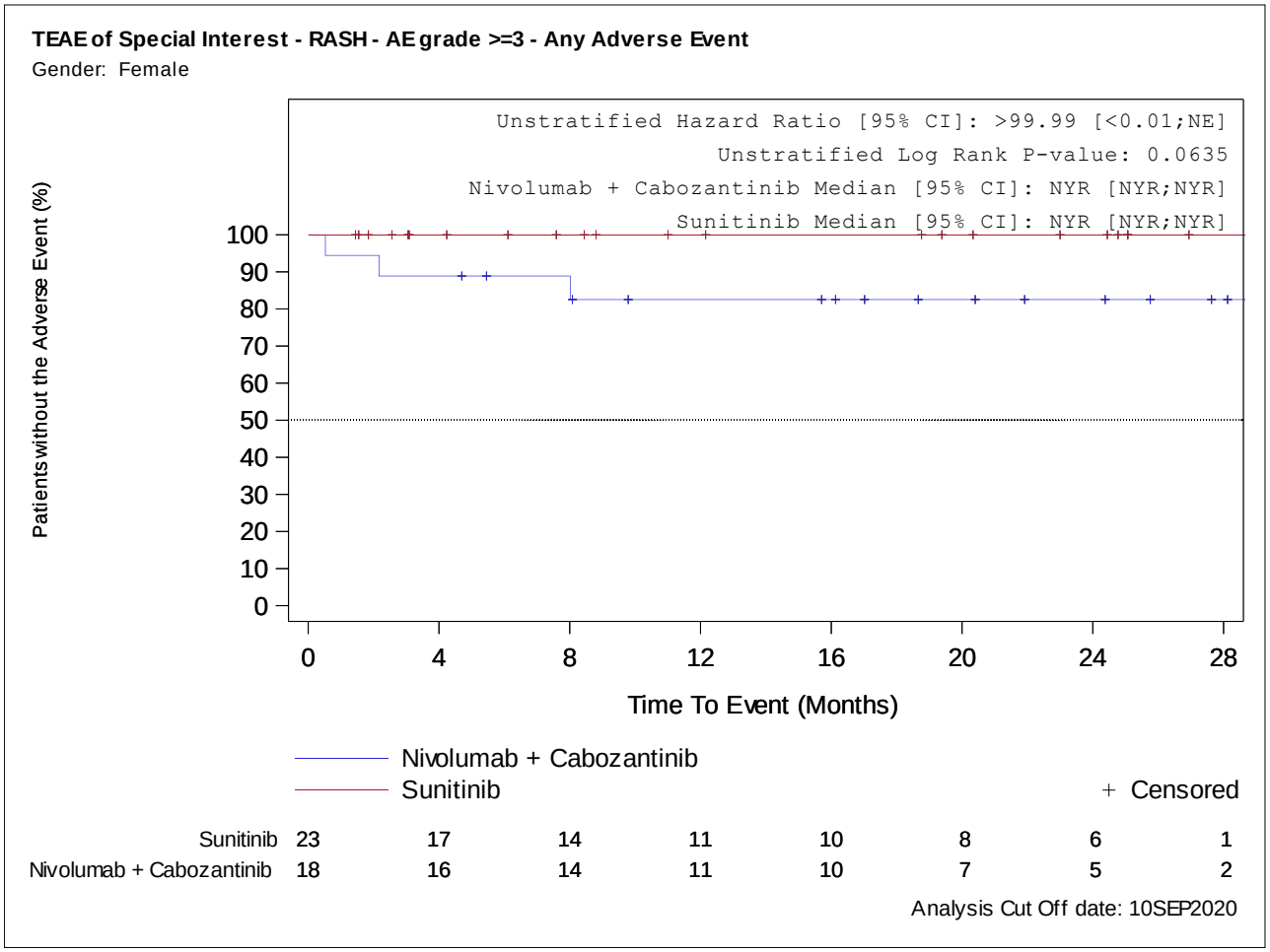

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:05:52

FIGURE 3.133.2.13: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



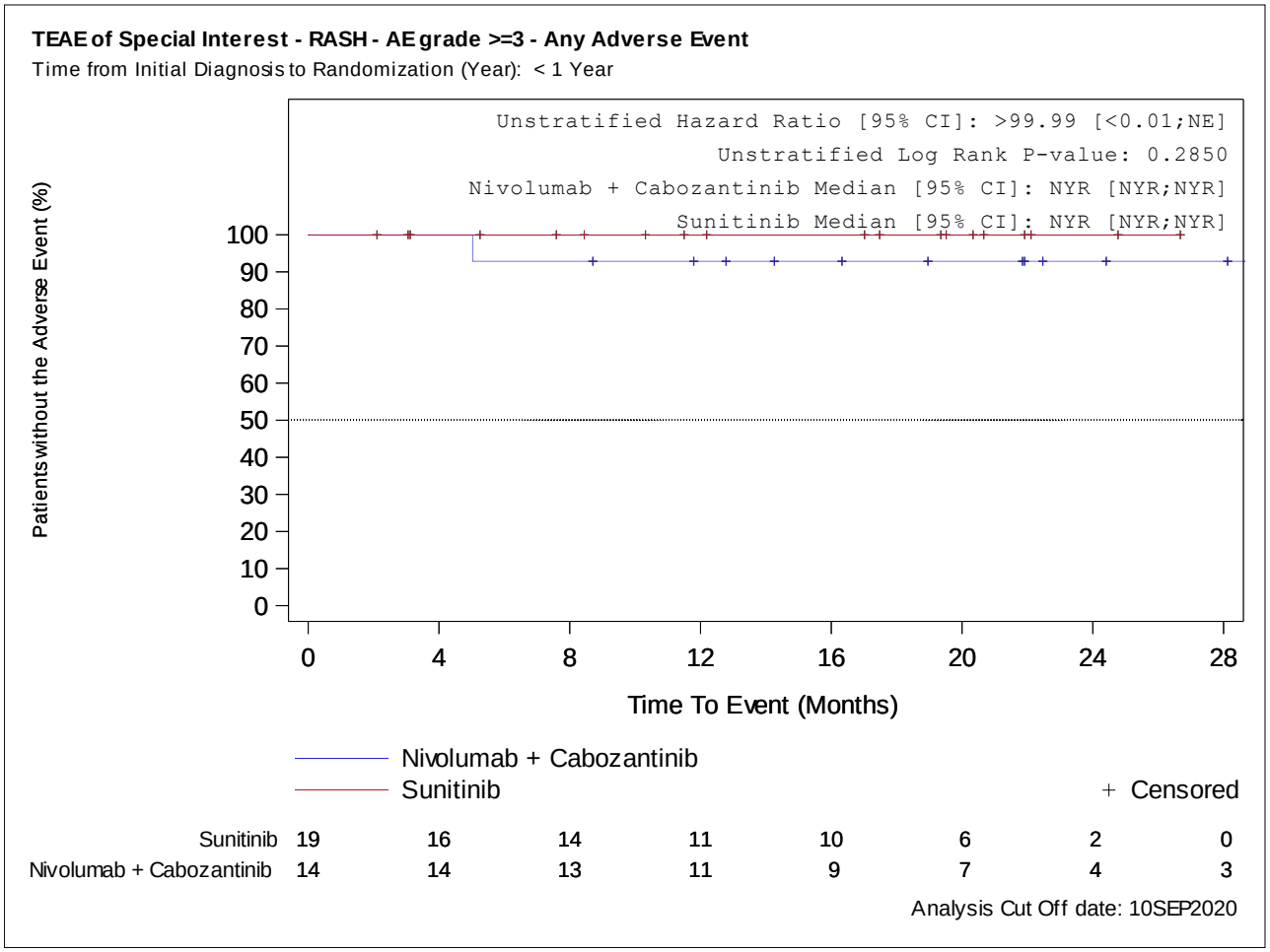

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:05:58

FIGURE 3.133.2.14: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



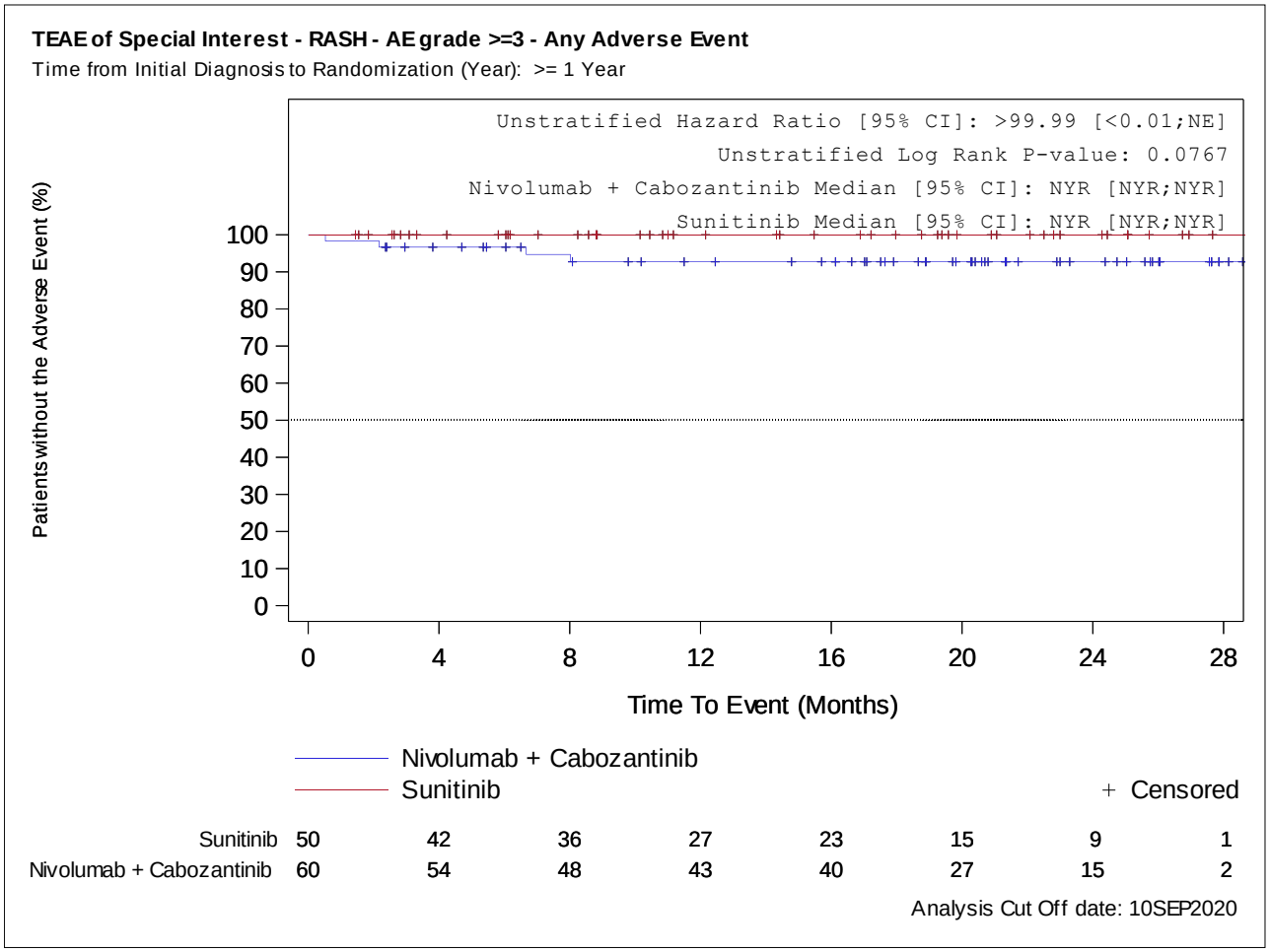

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:06:03

FIGURE 3.133.2.15: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



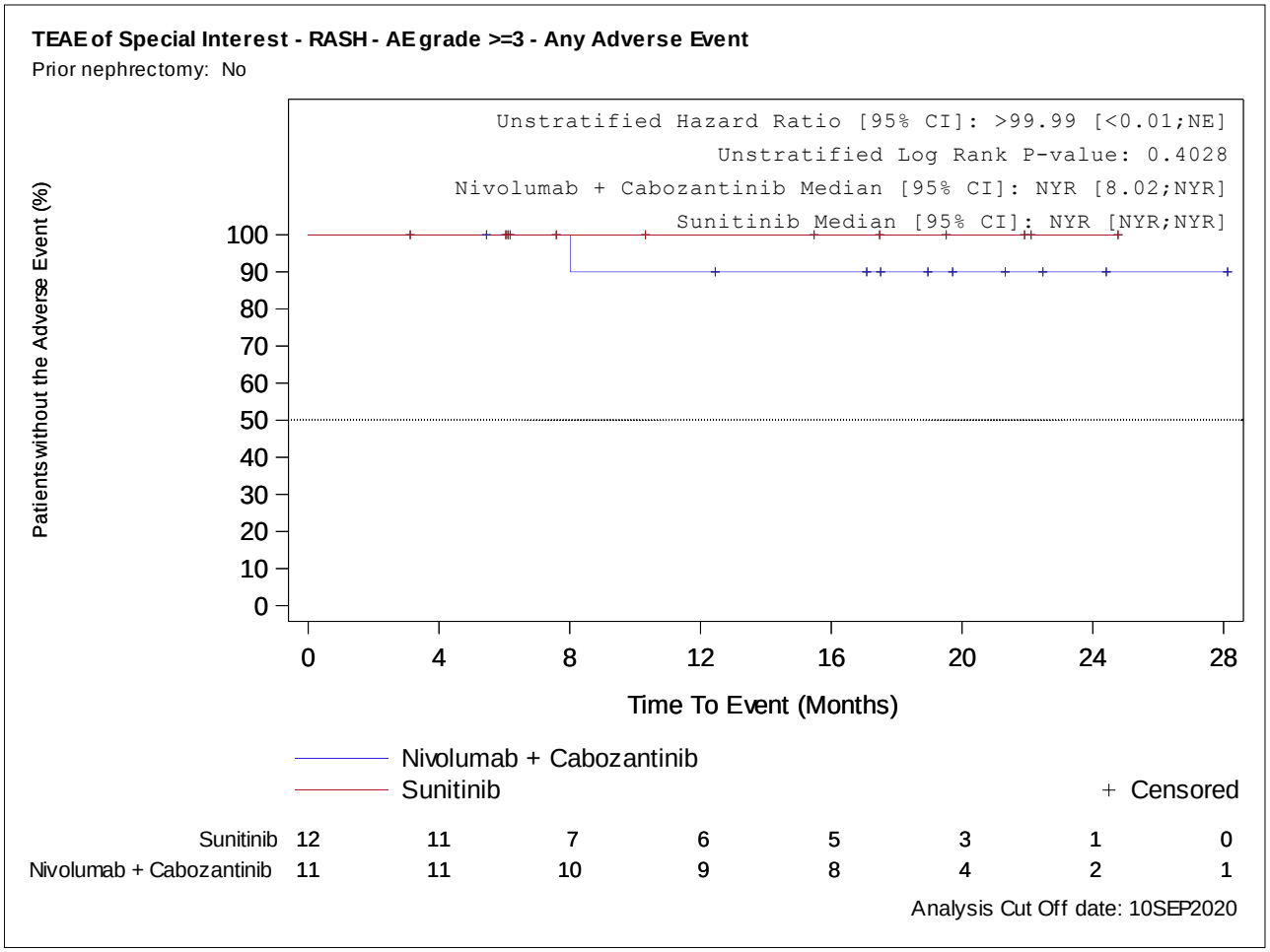

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:06:20

FIGURE 3.133.2.16: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



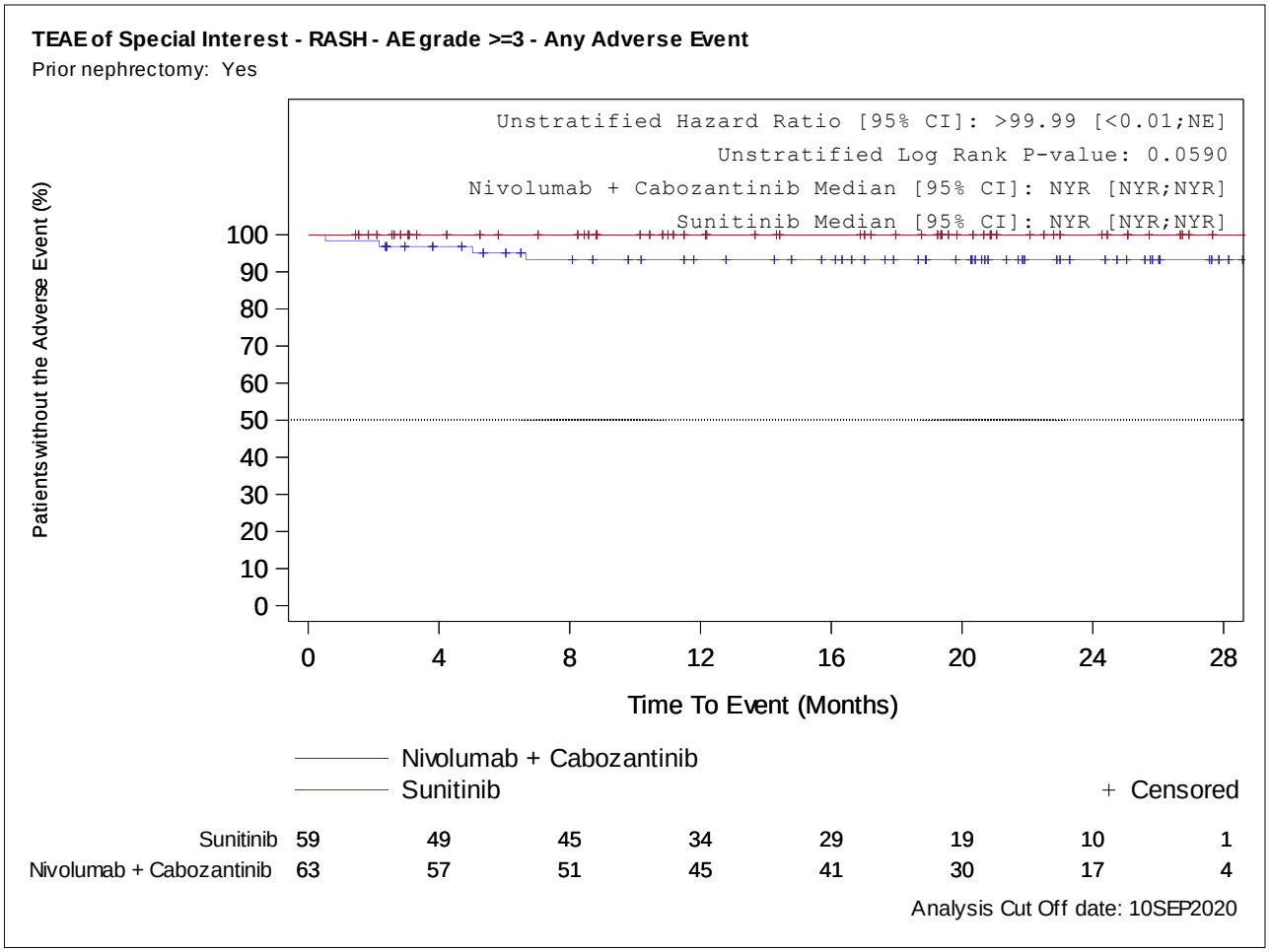

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:06:25

FIGURE 3.133.2.17: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



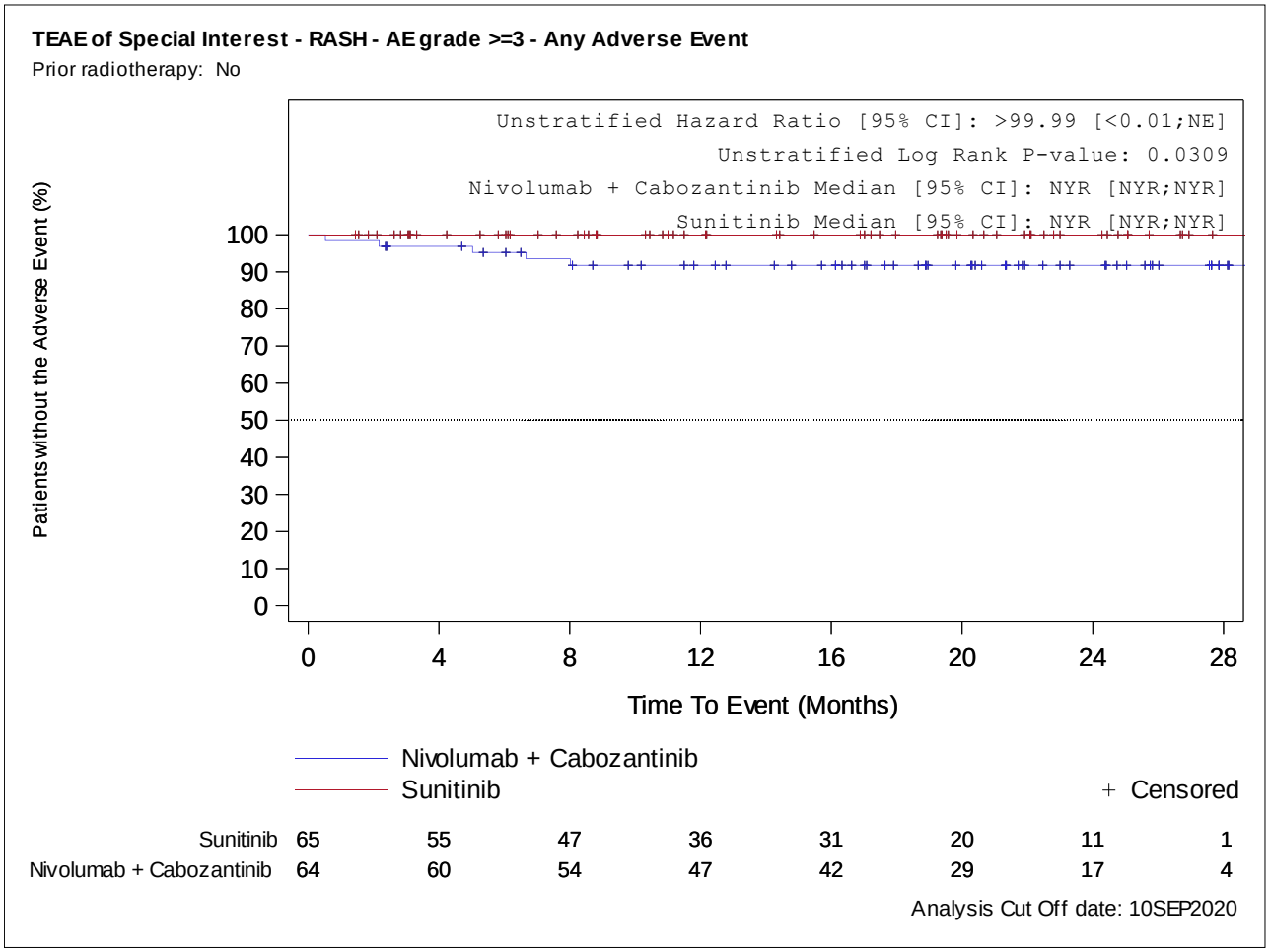

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:07:13

FIGURE 3.133.2.18: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



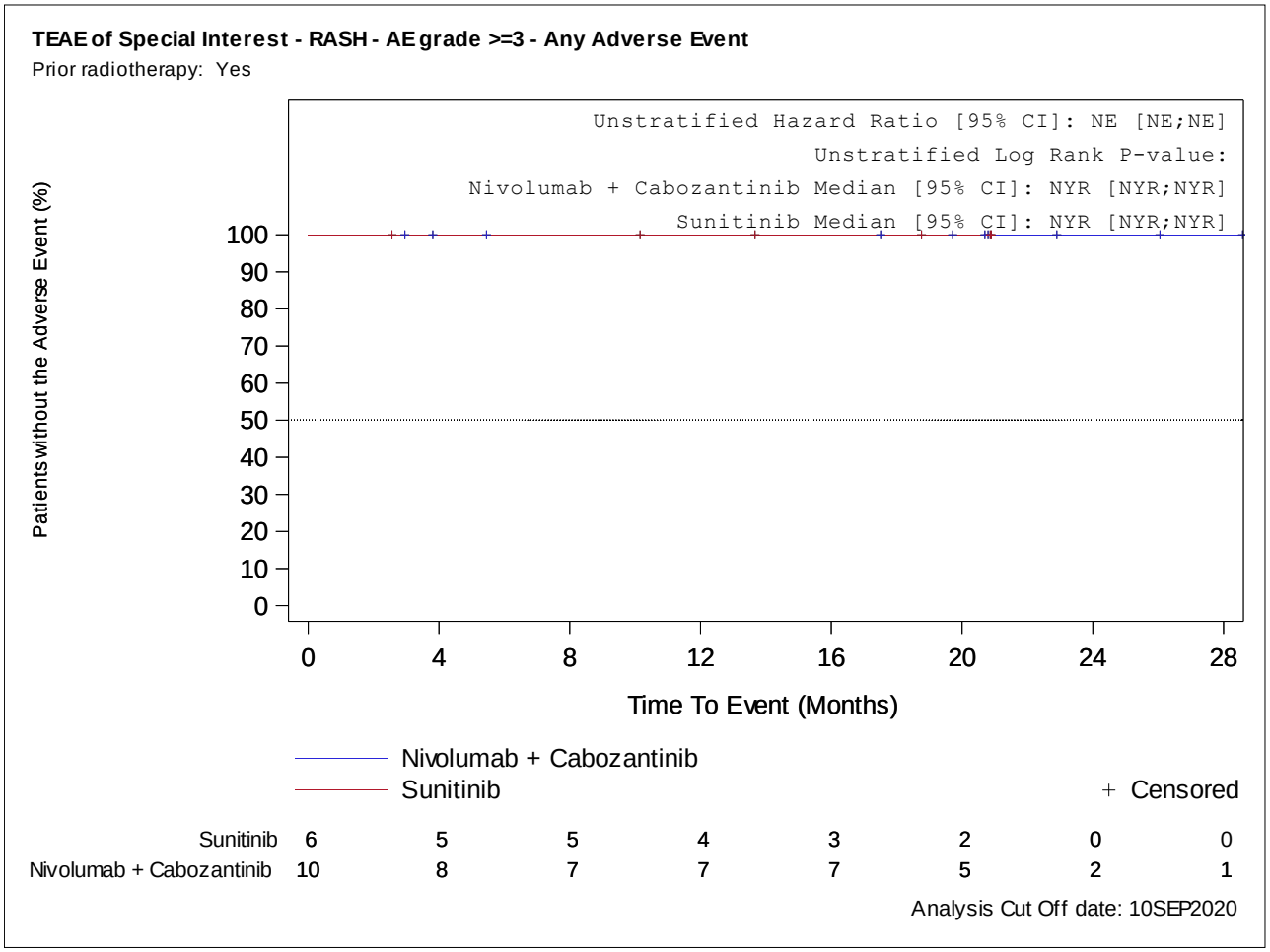

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:07:18

FIGURE 3.133.2.19: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



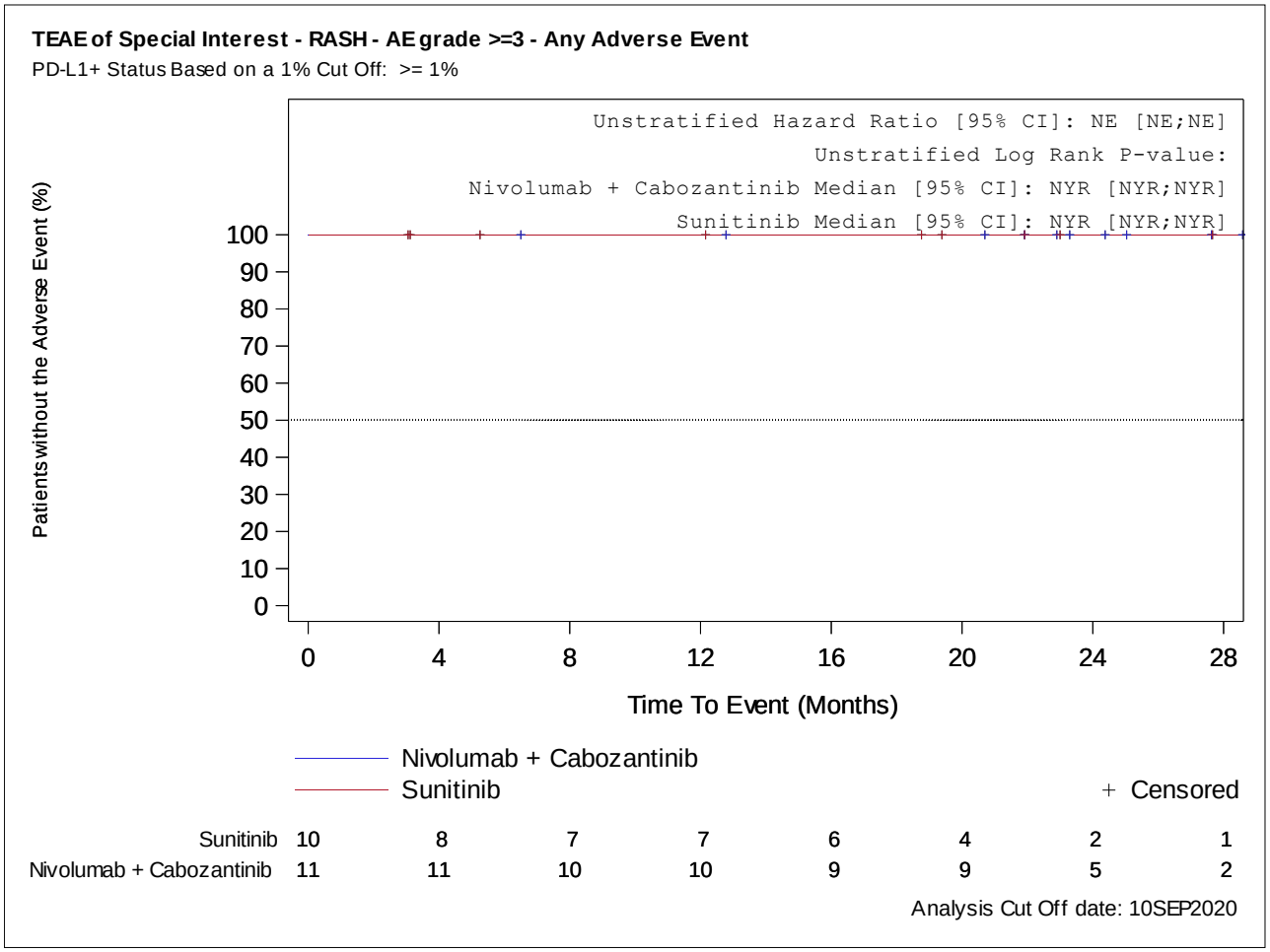

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:07:23

FIGURE 3.133.2.20: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



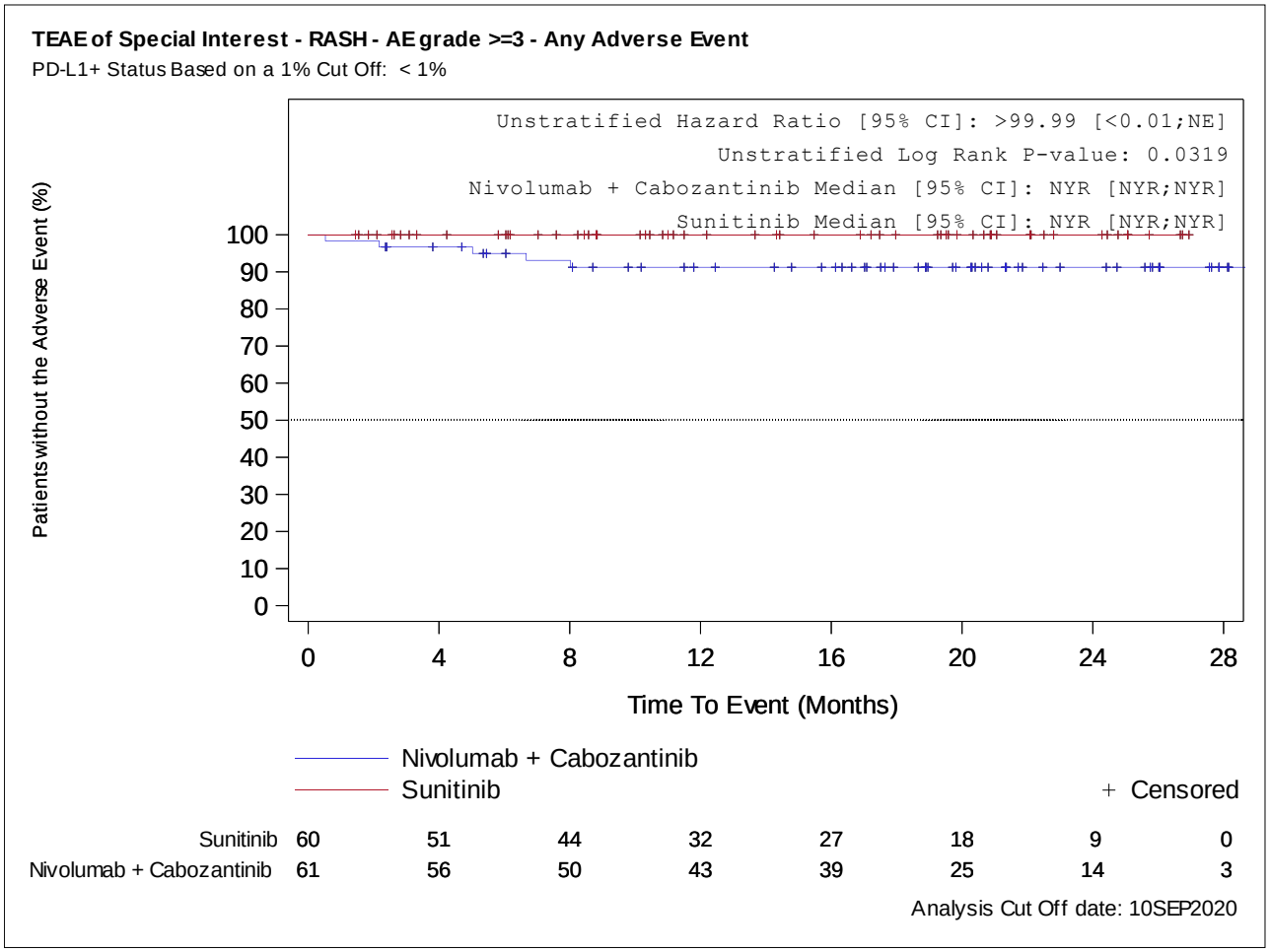

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:07:29

FIGURE 3.133.2.21: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



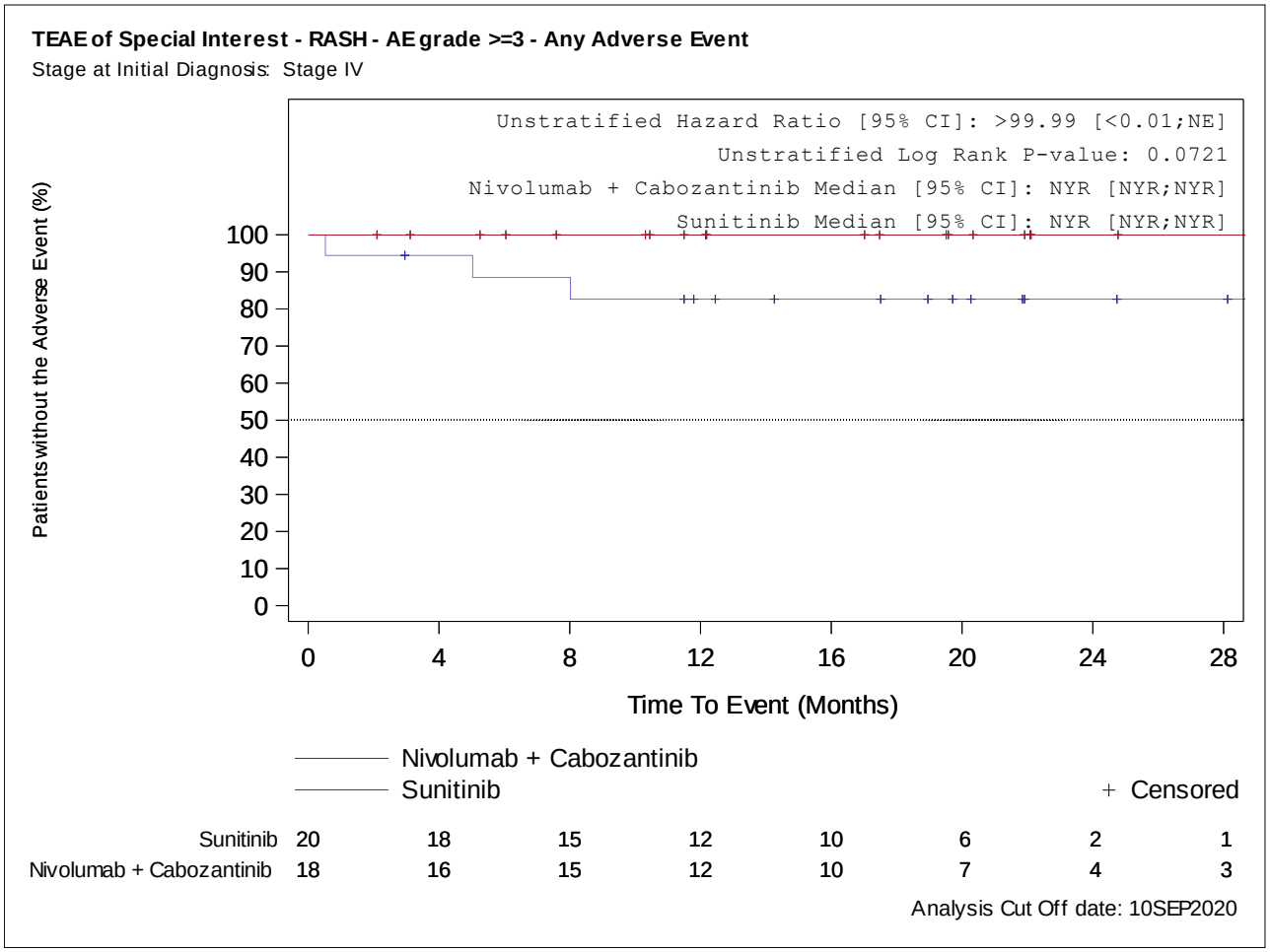

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:07:34

FIGURE 3.133.2.22: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



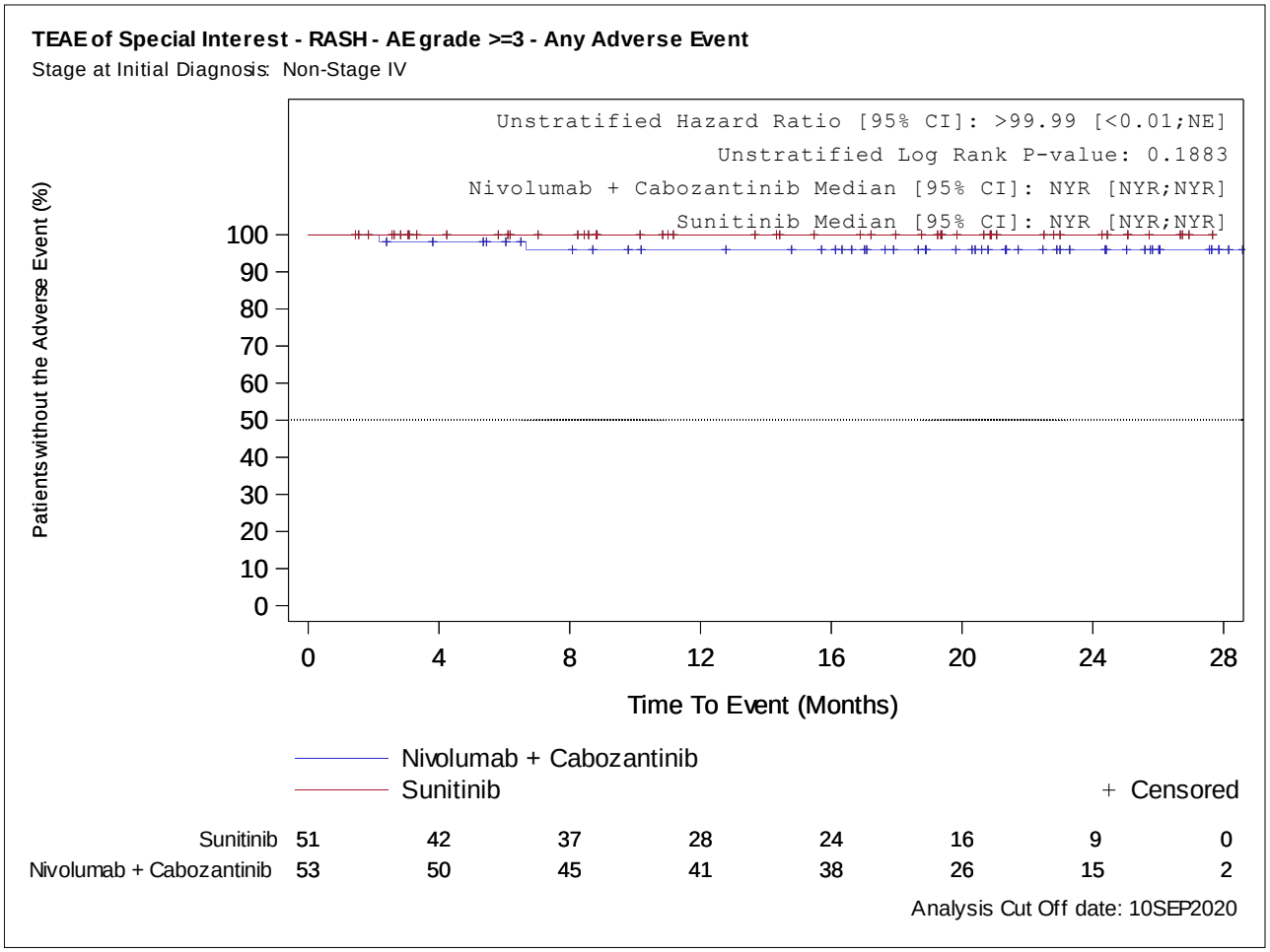

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:07:39

FIGURE 3.133.2.23: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



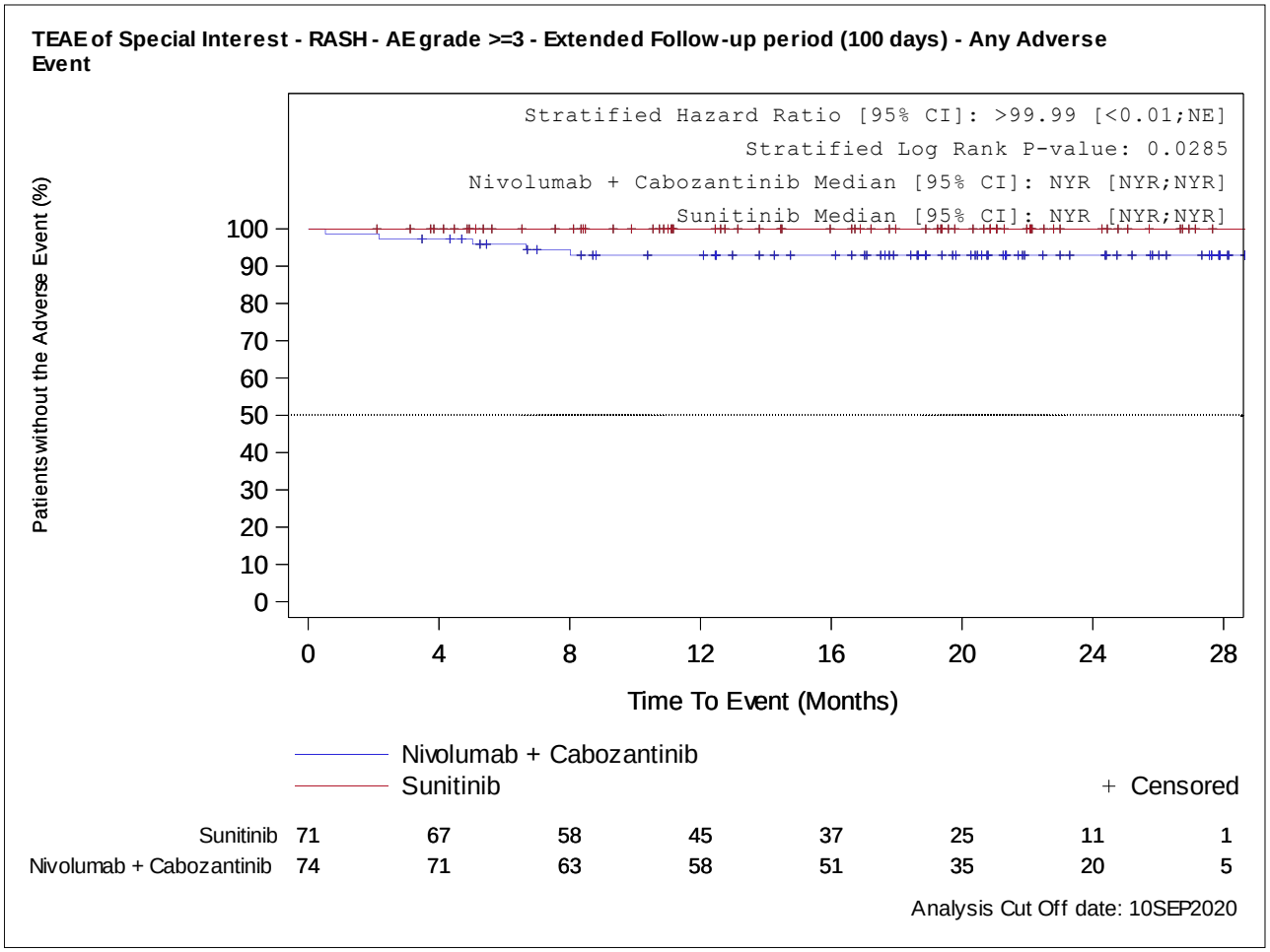

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:08:06

FIGURE 3.133.2.24: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



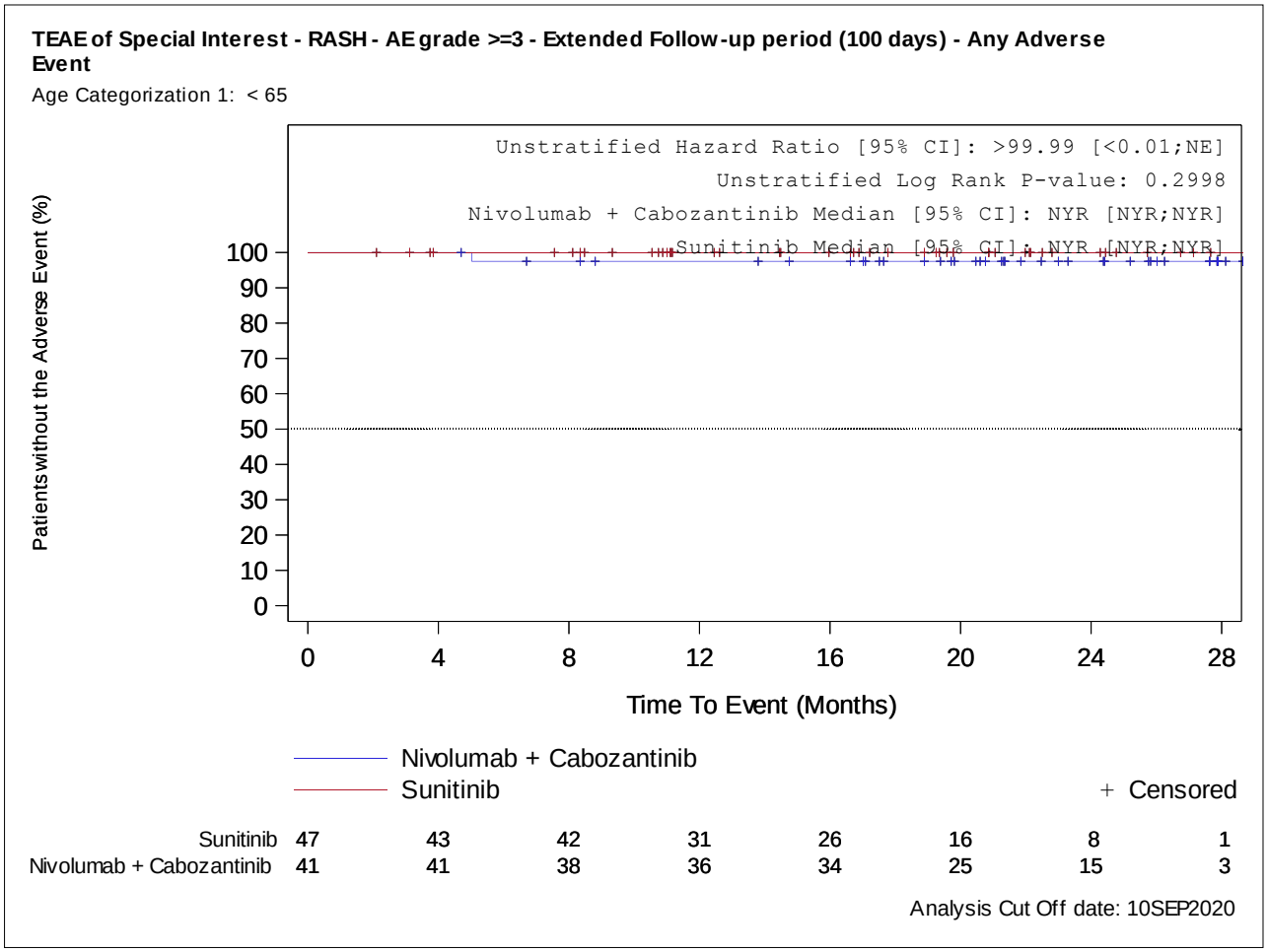

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:08:12

FIGURE 3.134.1: TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



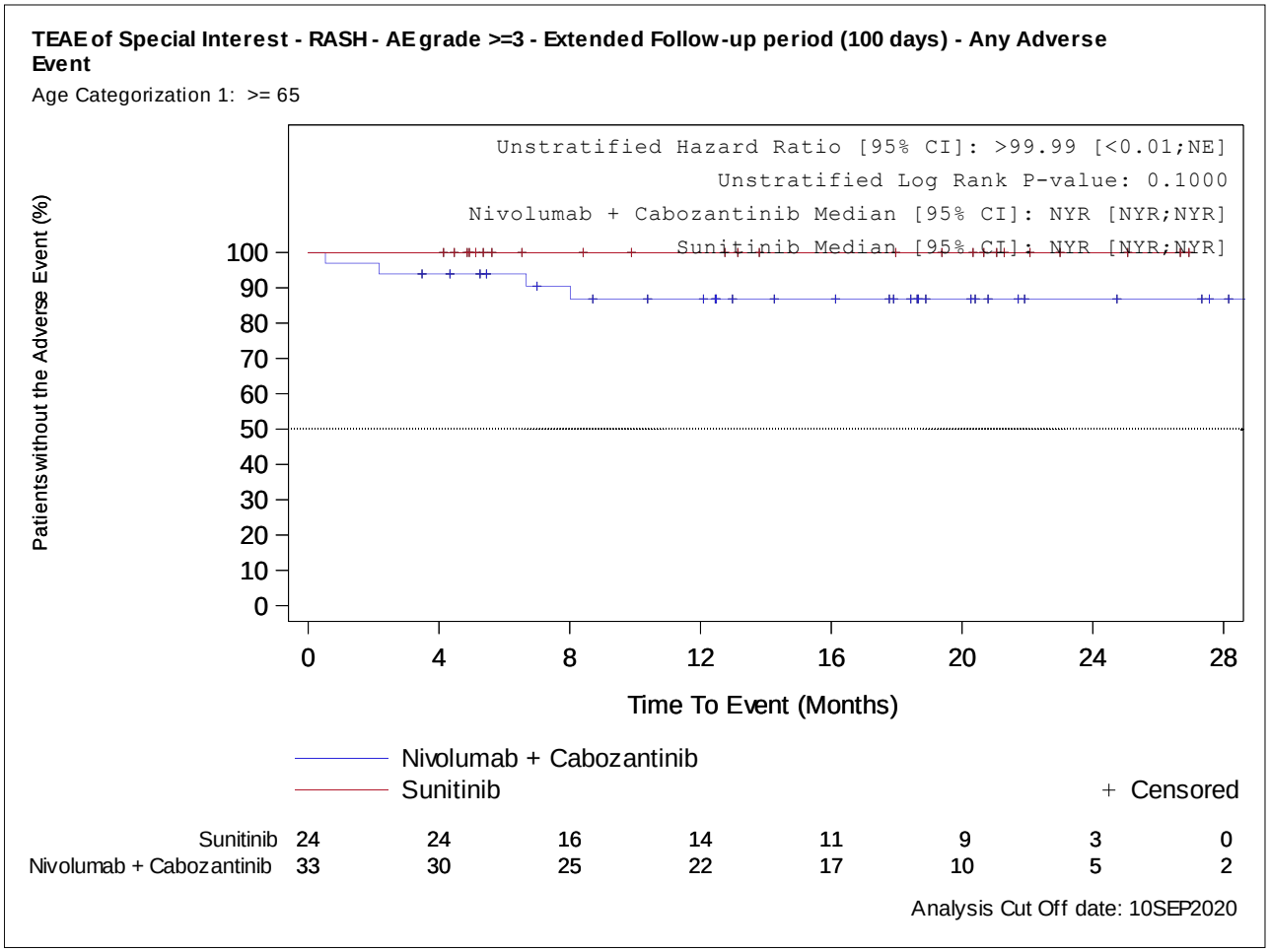

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:11:10

FIGURE 3.134.2.1: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



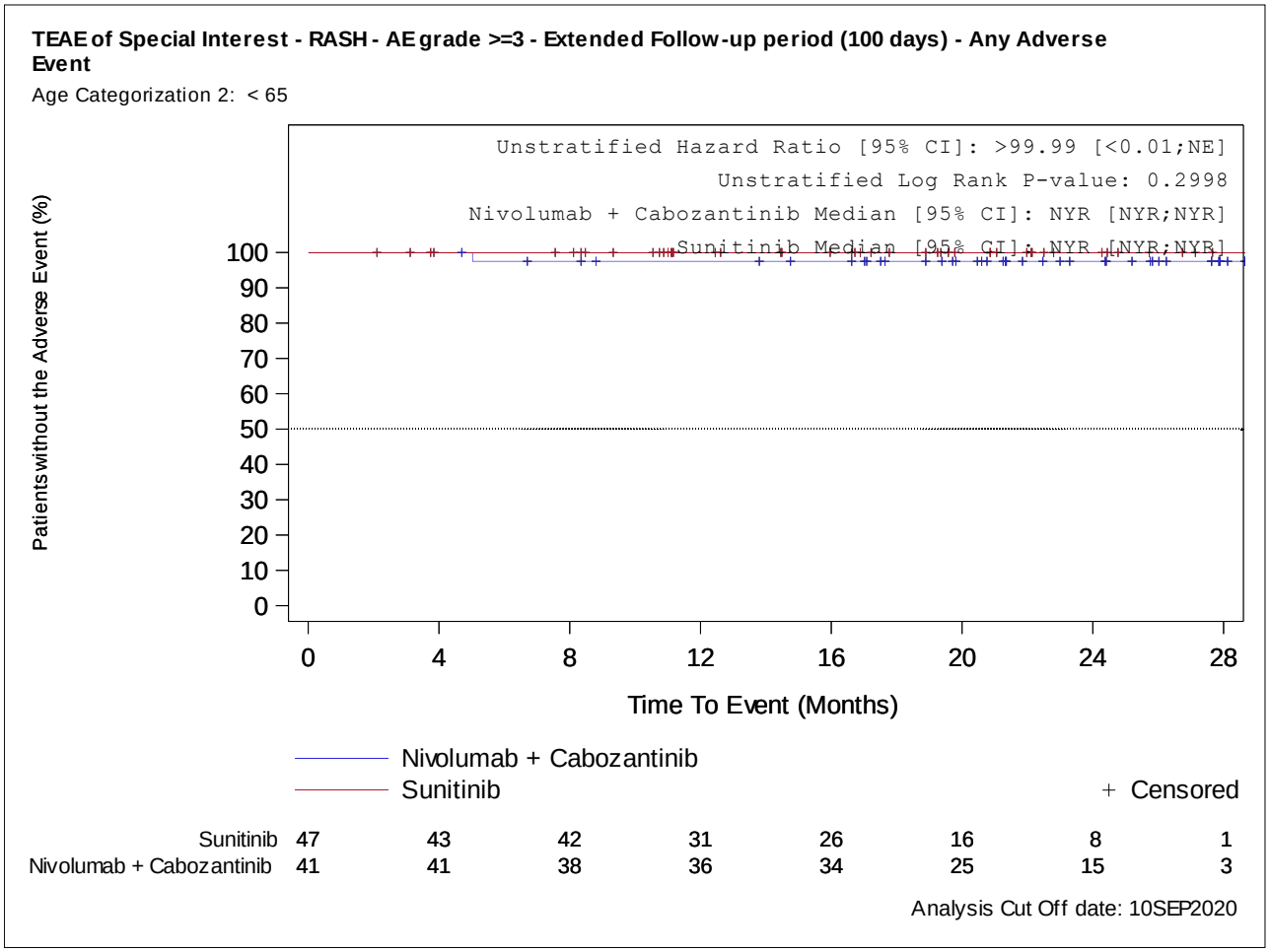

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:11:13

FIGURE 3.134.2.2: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



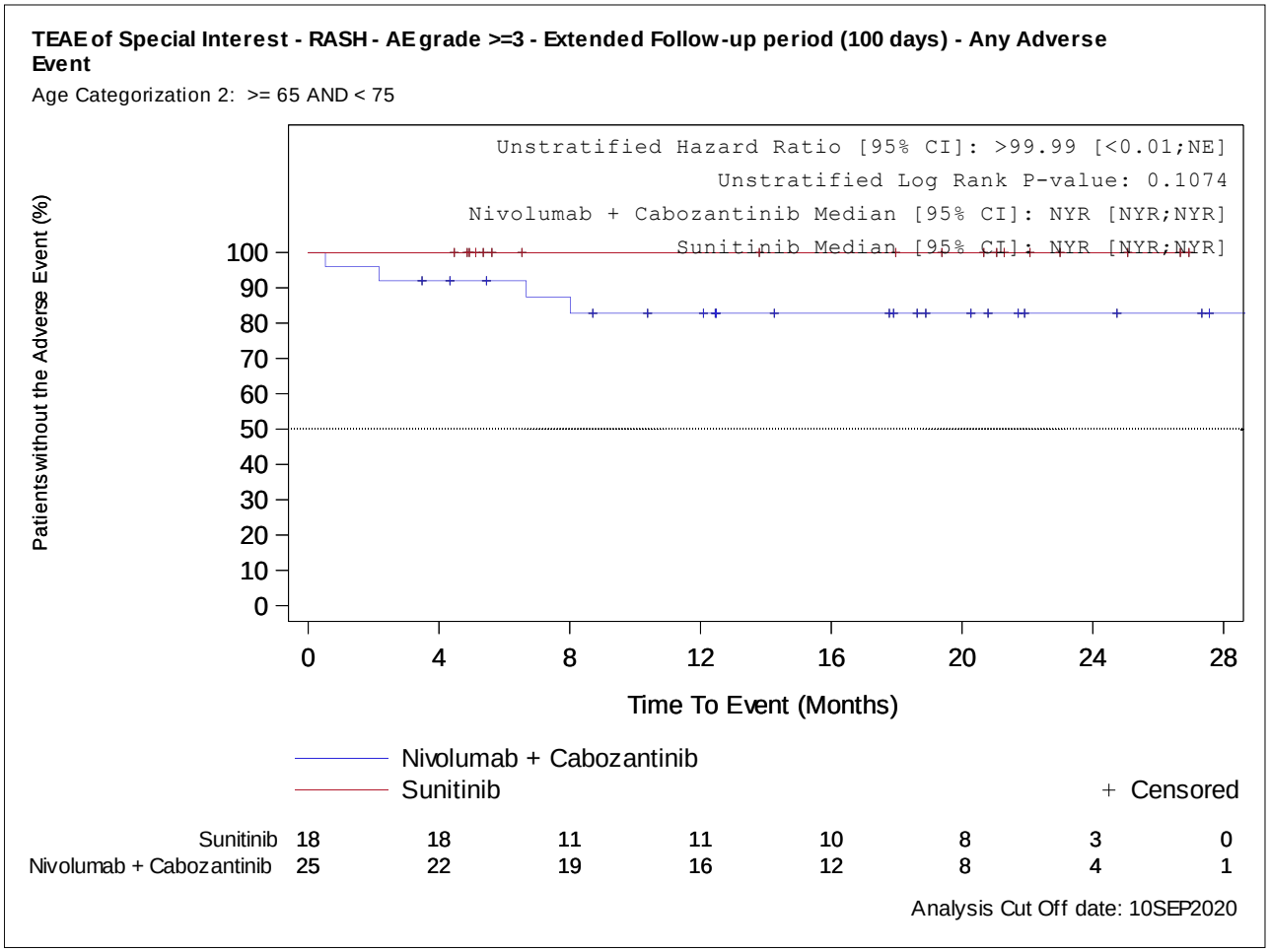

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:11:18

FIGURE 3.134.2.3: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



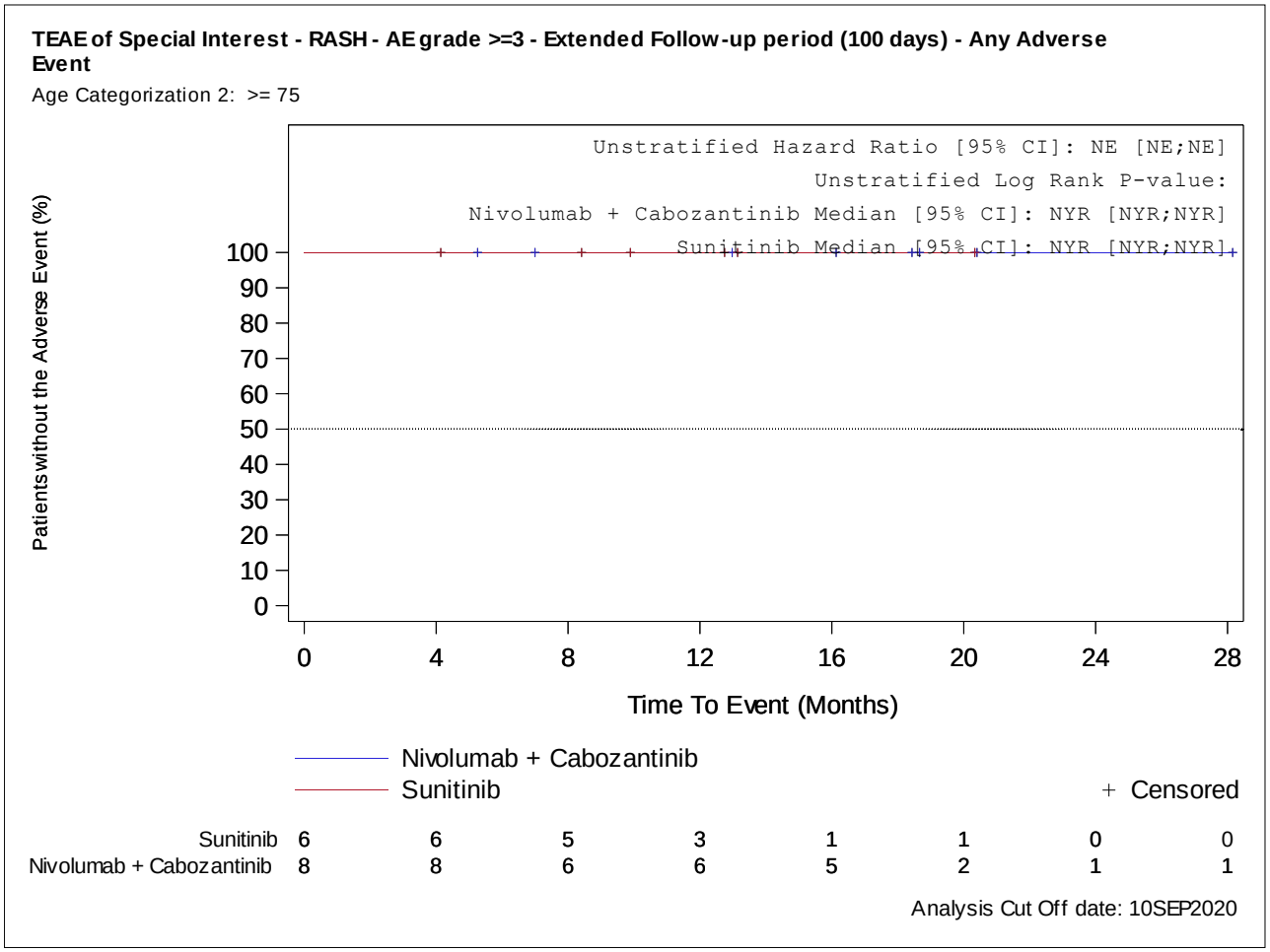

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:11:24

FIGURE 3.134.2.4: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



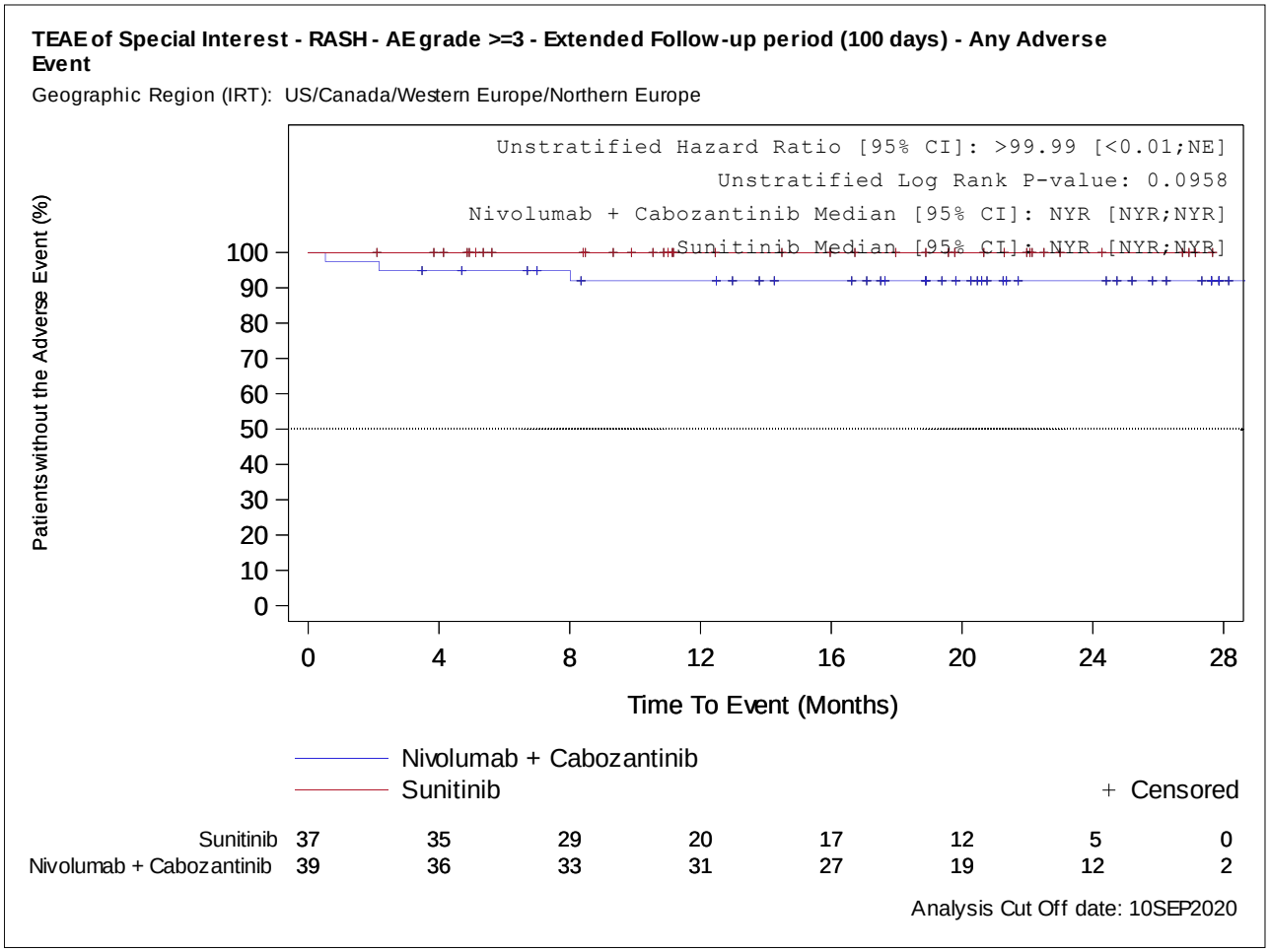

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:11:29

FIGURE 3.134.2.5: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



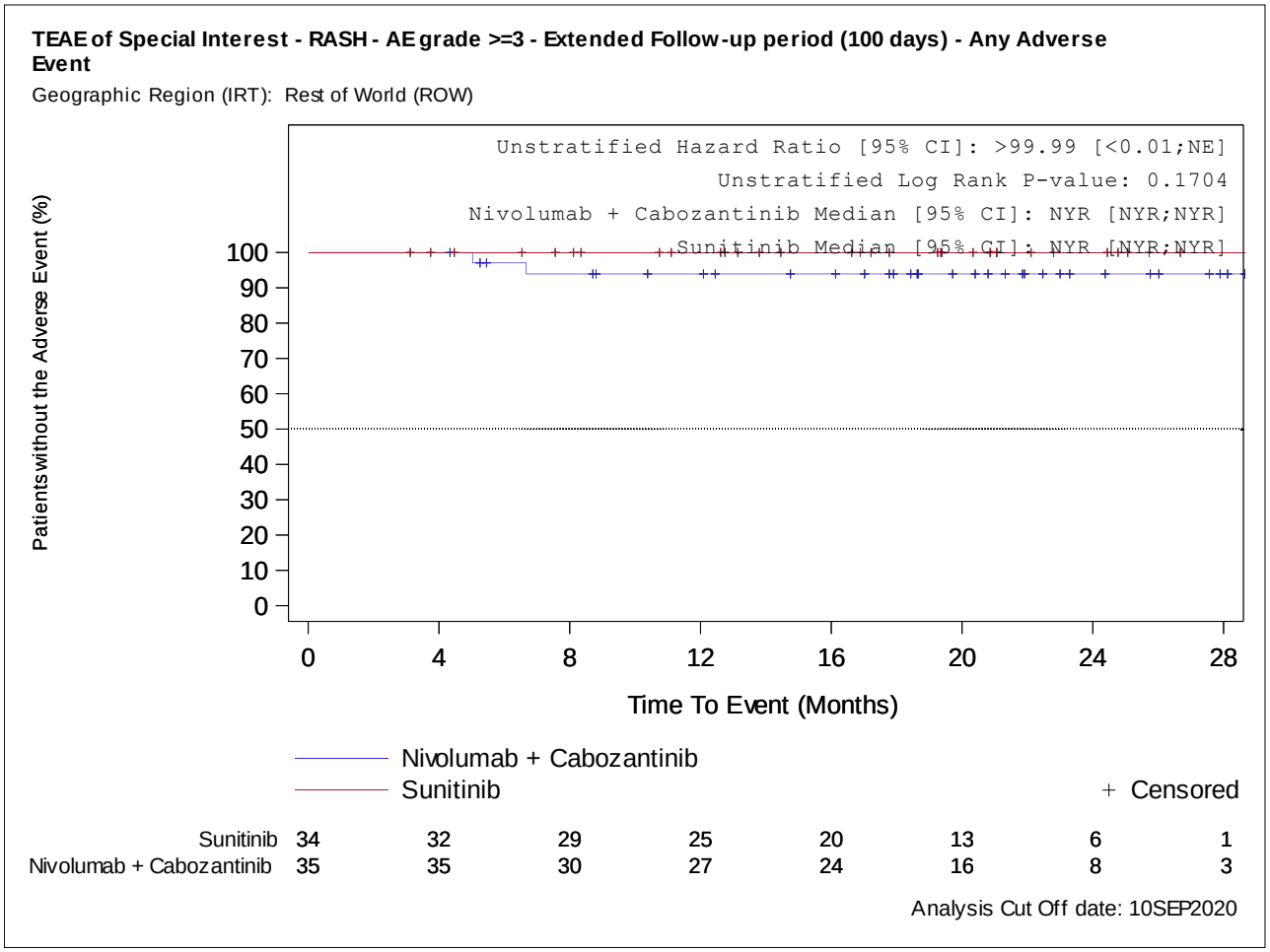

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:11:34

FIGURE 3.134.2.6: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



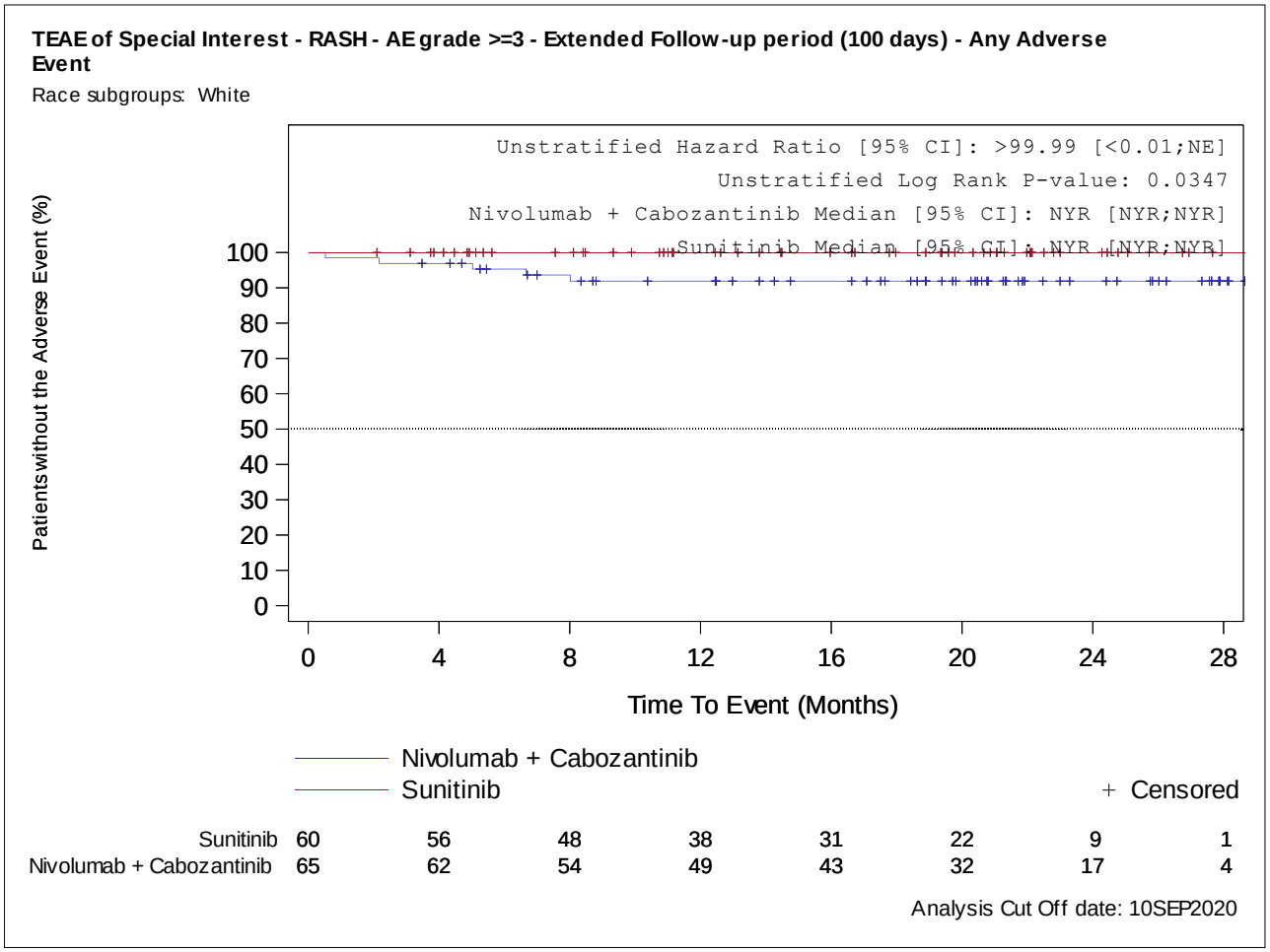

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:11:40

FIGURE 3.134.2.7: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



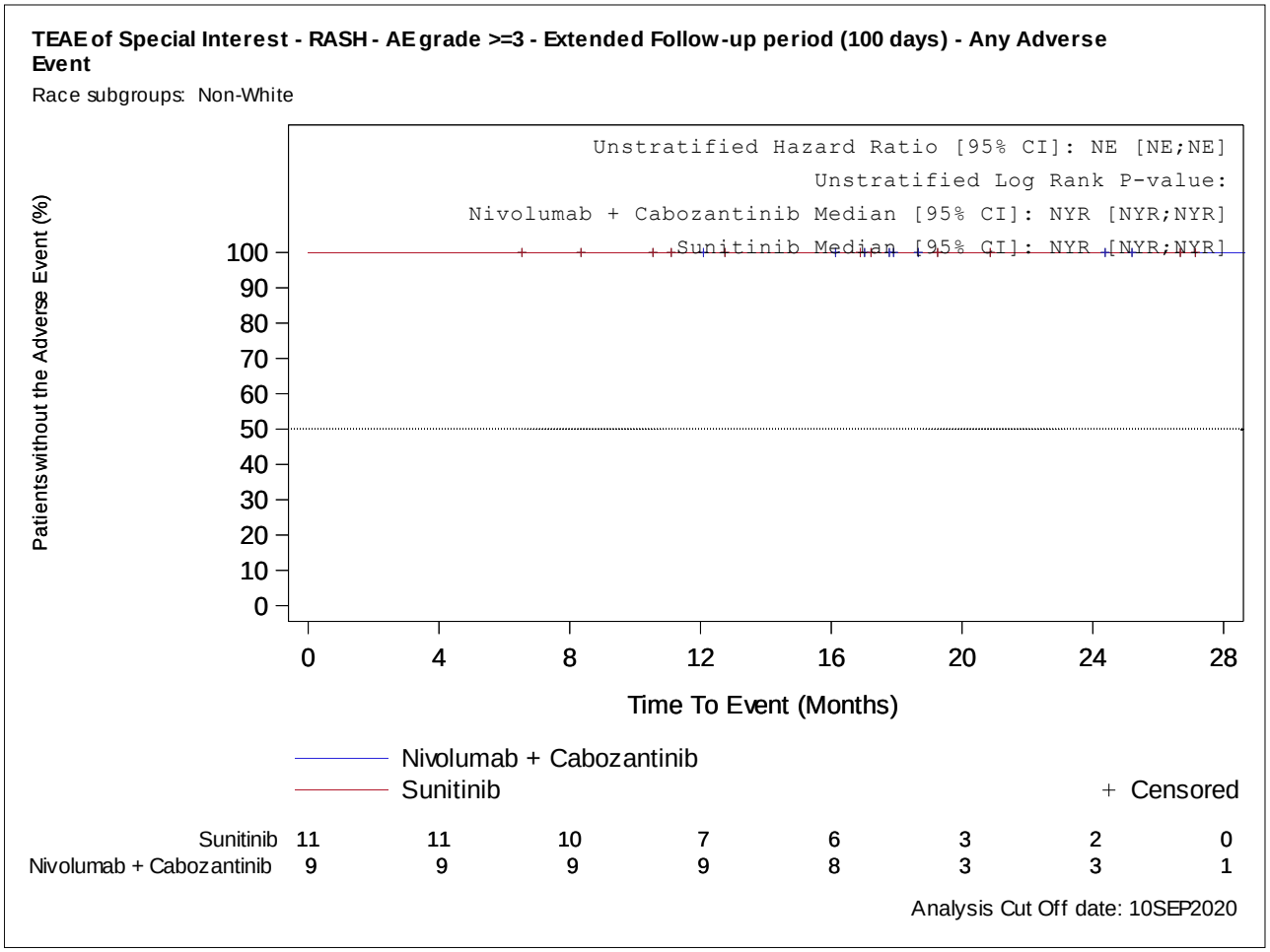

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:11:45

FIGURE 3.134.2.8: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



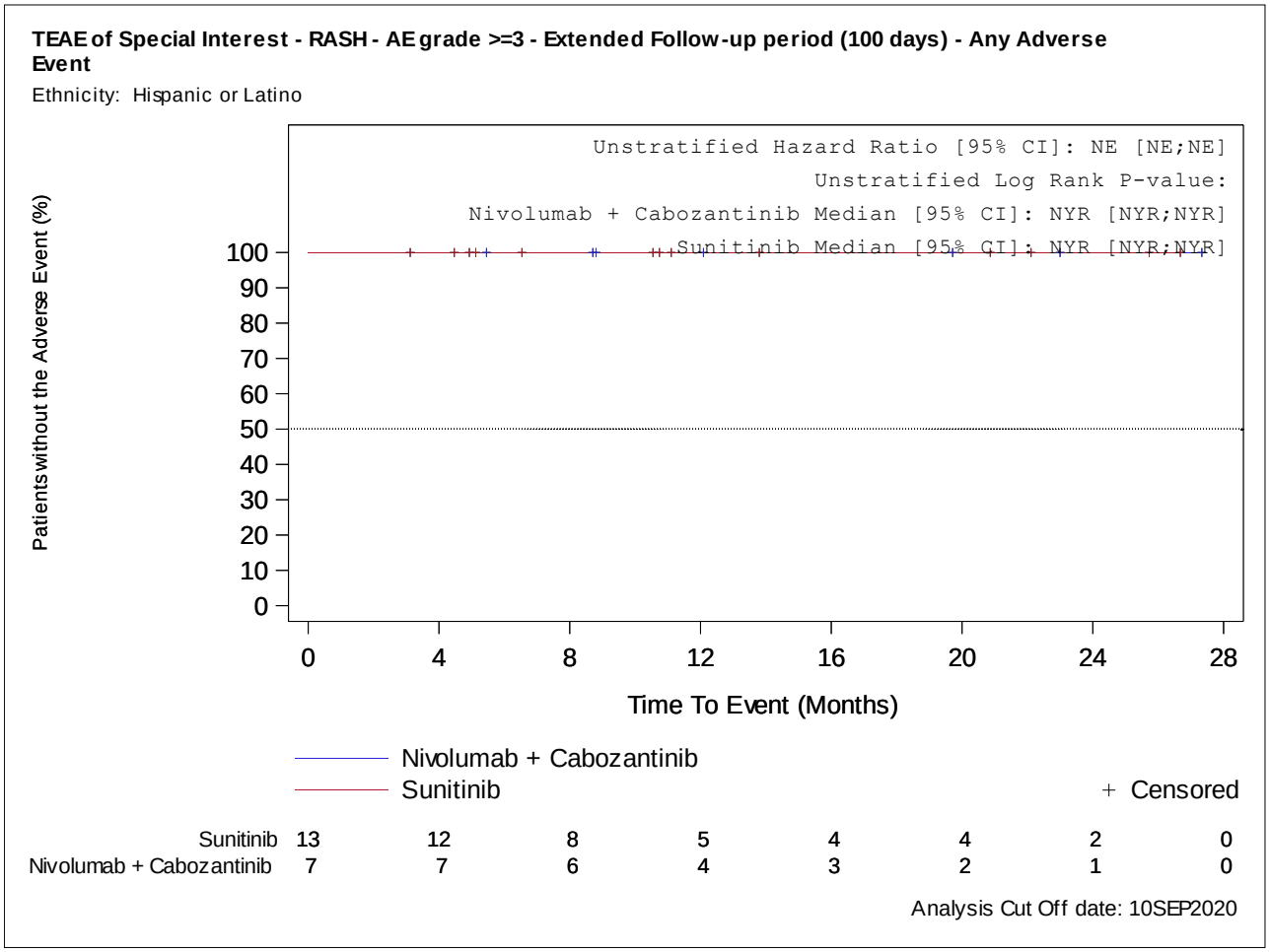

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:11:50

FIGURE 3.134.2.9: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



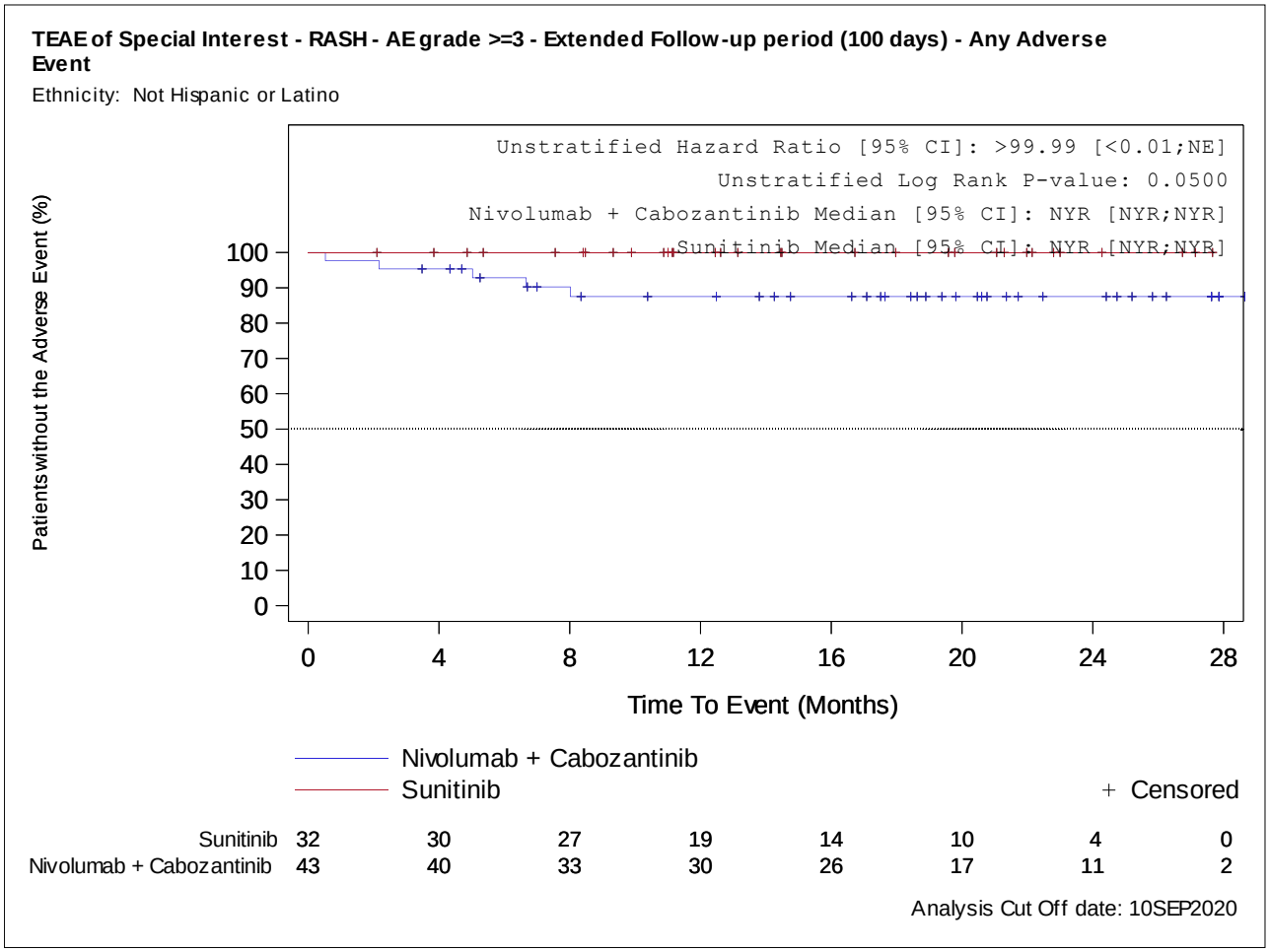

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:11:55

FIGURE 3.134.2.10: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



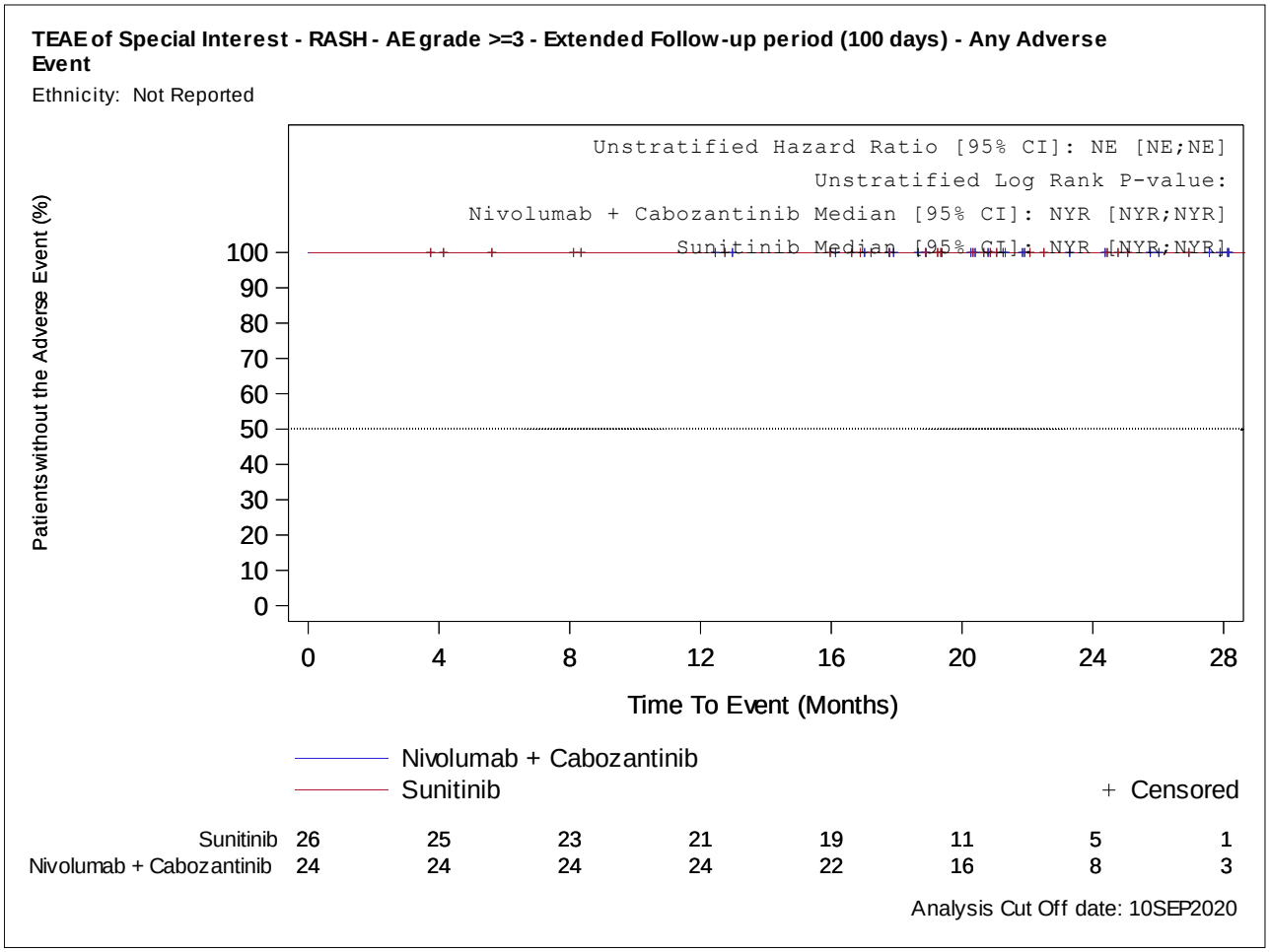

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:12:01

FIGURE 3.134.2.11: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



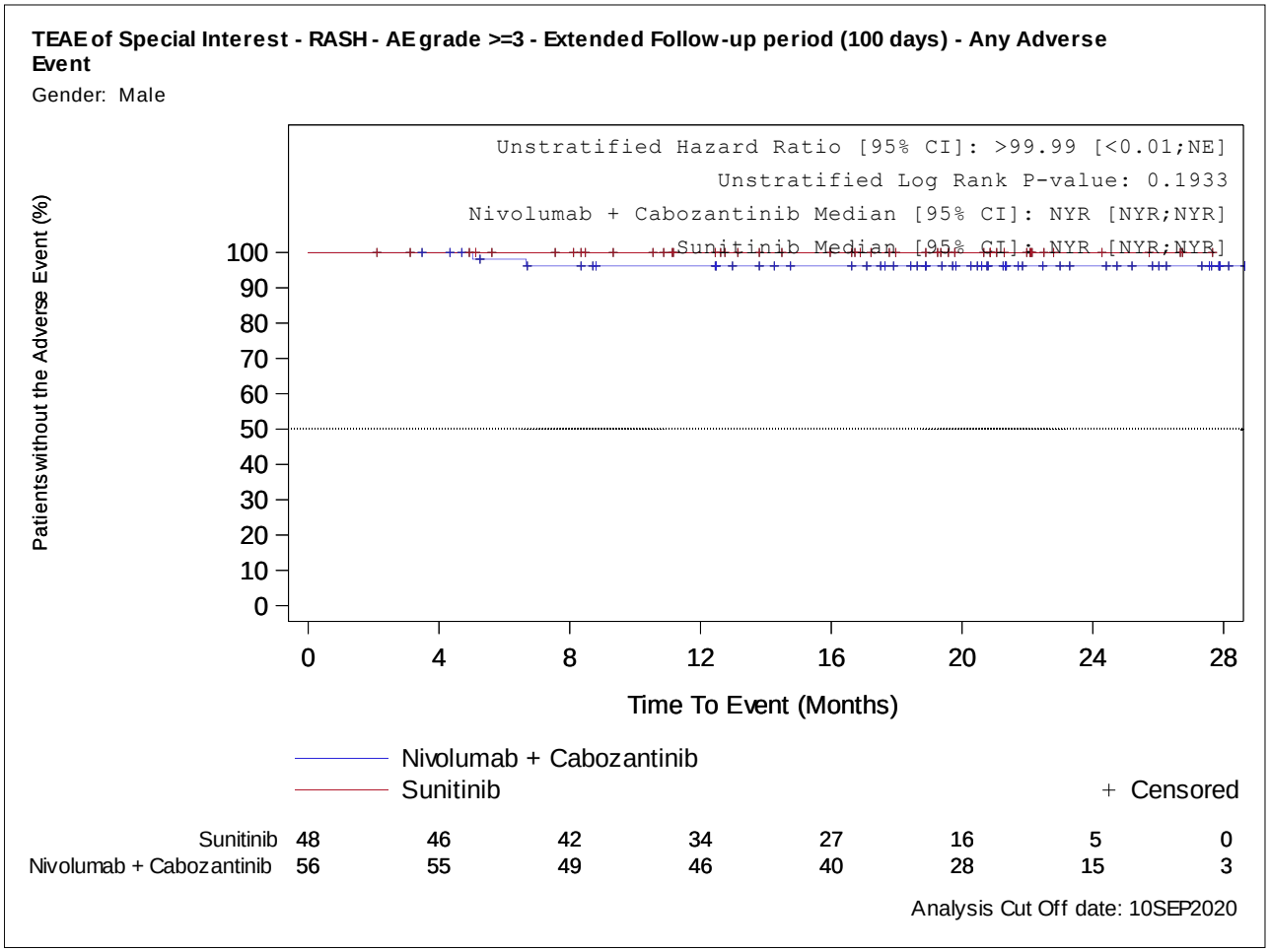

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:12:06

FIGURE 3.134.2.12: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



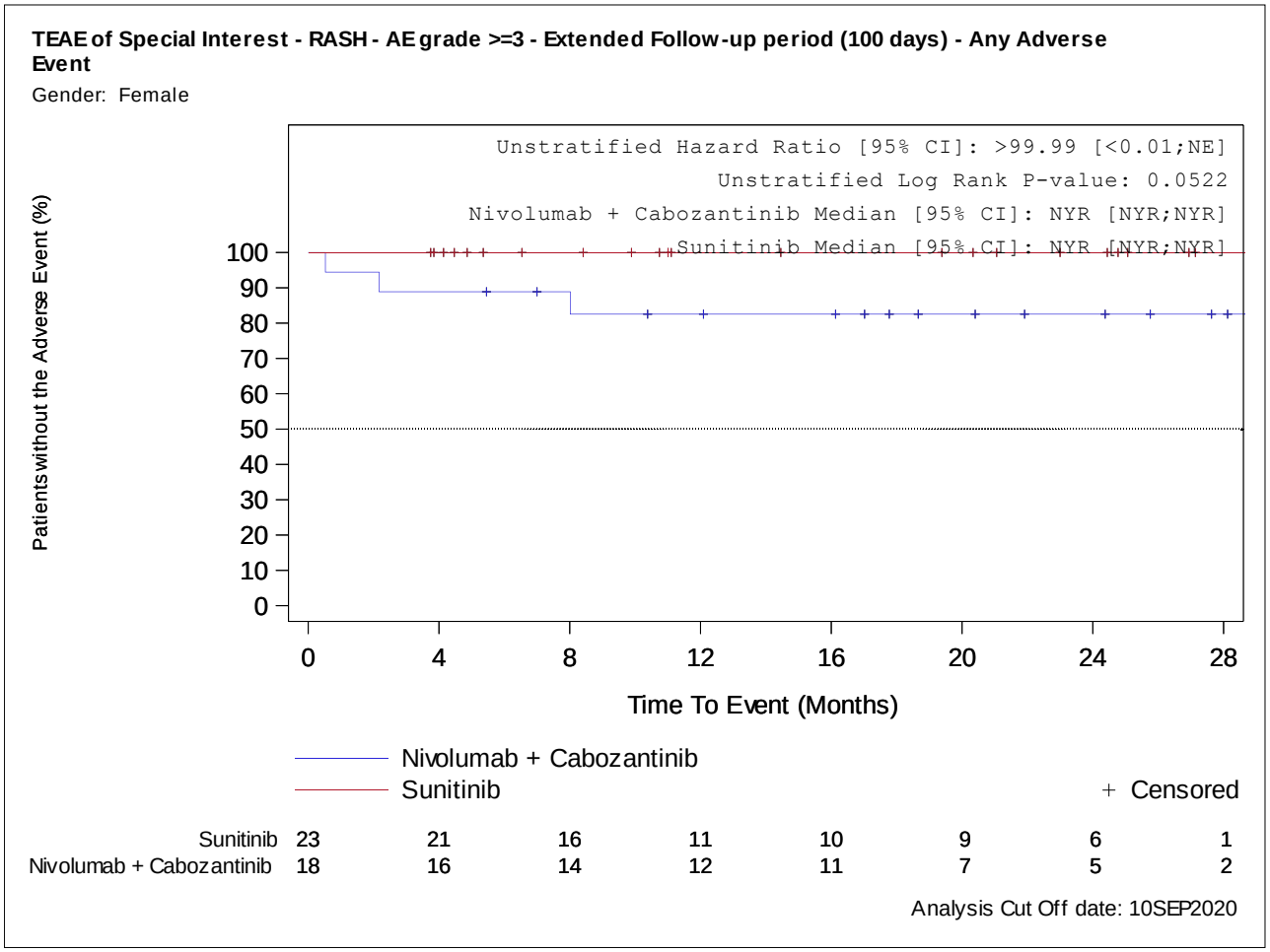

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:12:12

FIGURE 3.134.2.13: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



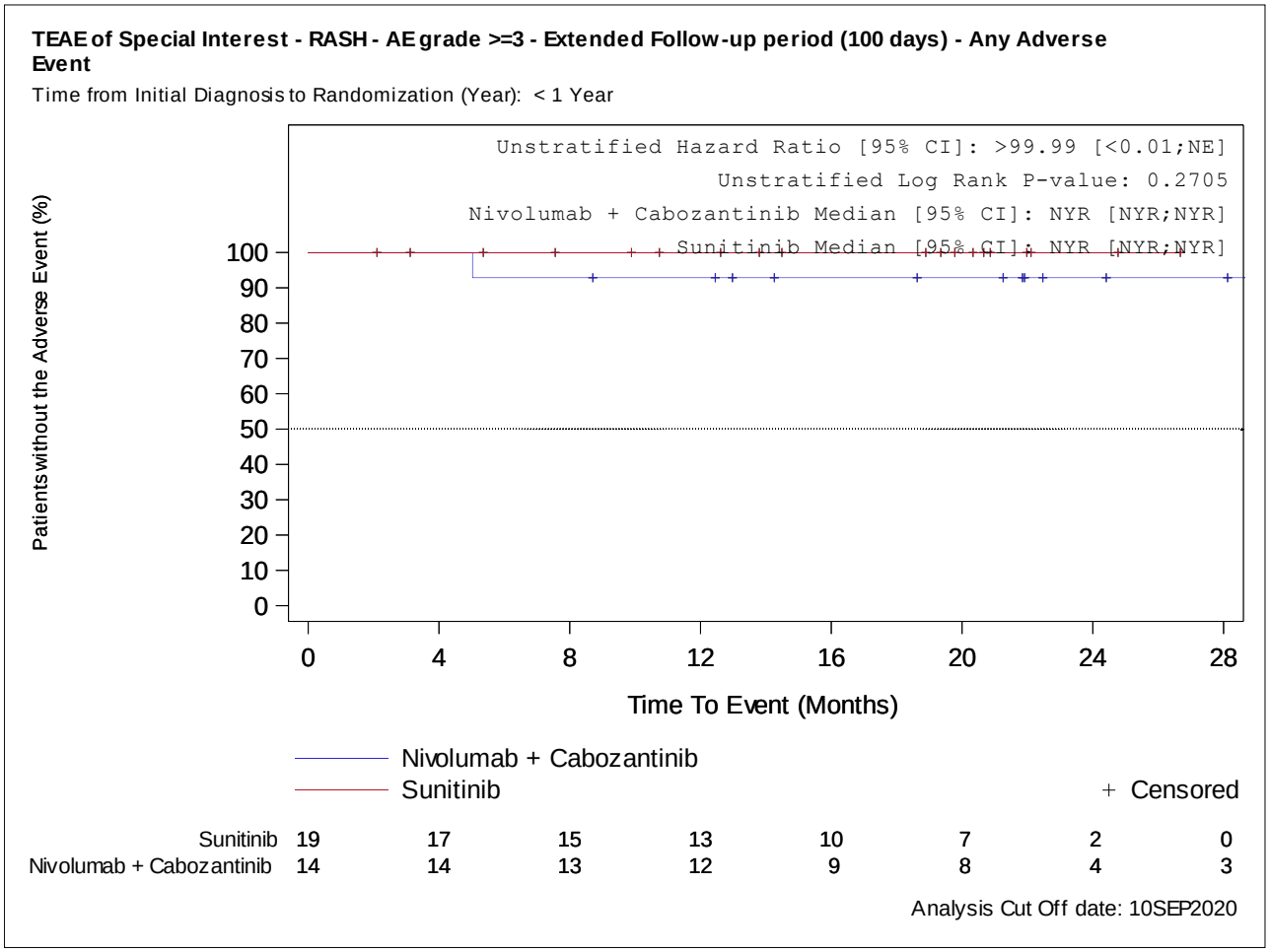

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:12:17

FIGURE 3.134.2.14: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



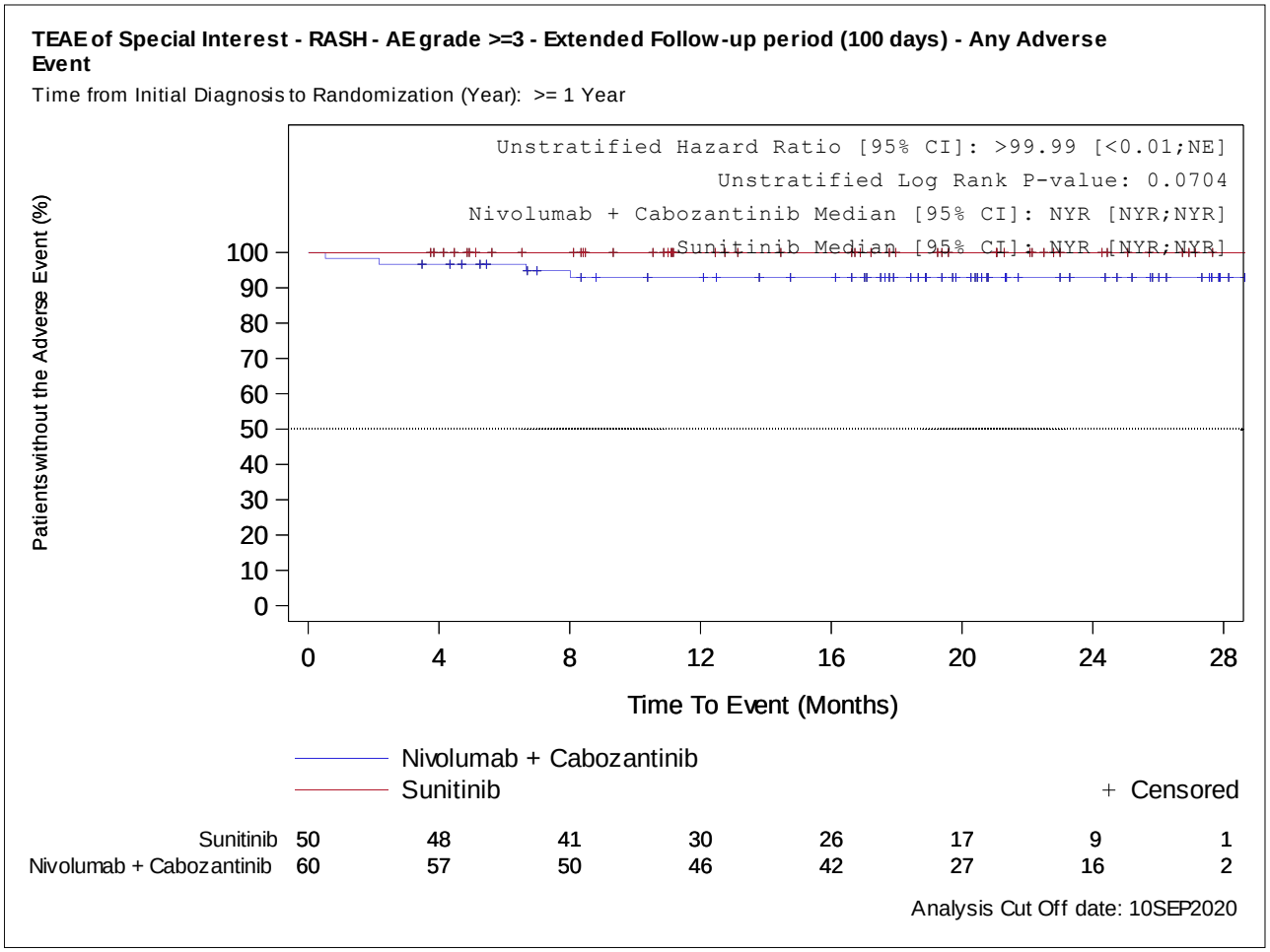

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:12:22

FIGURE 3.134.2.15: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



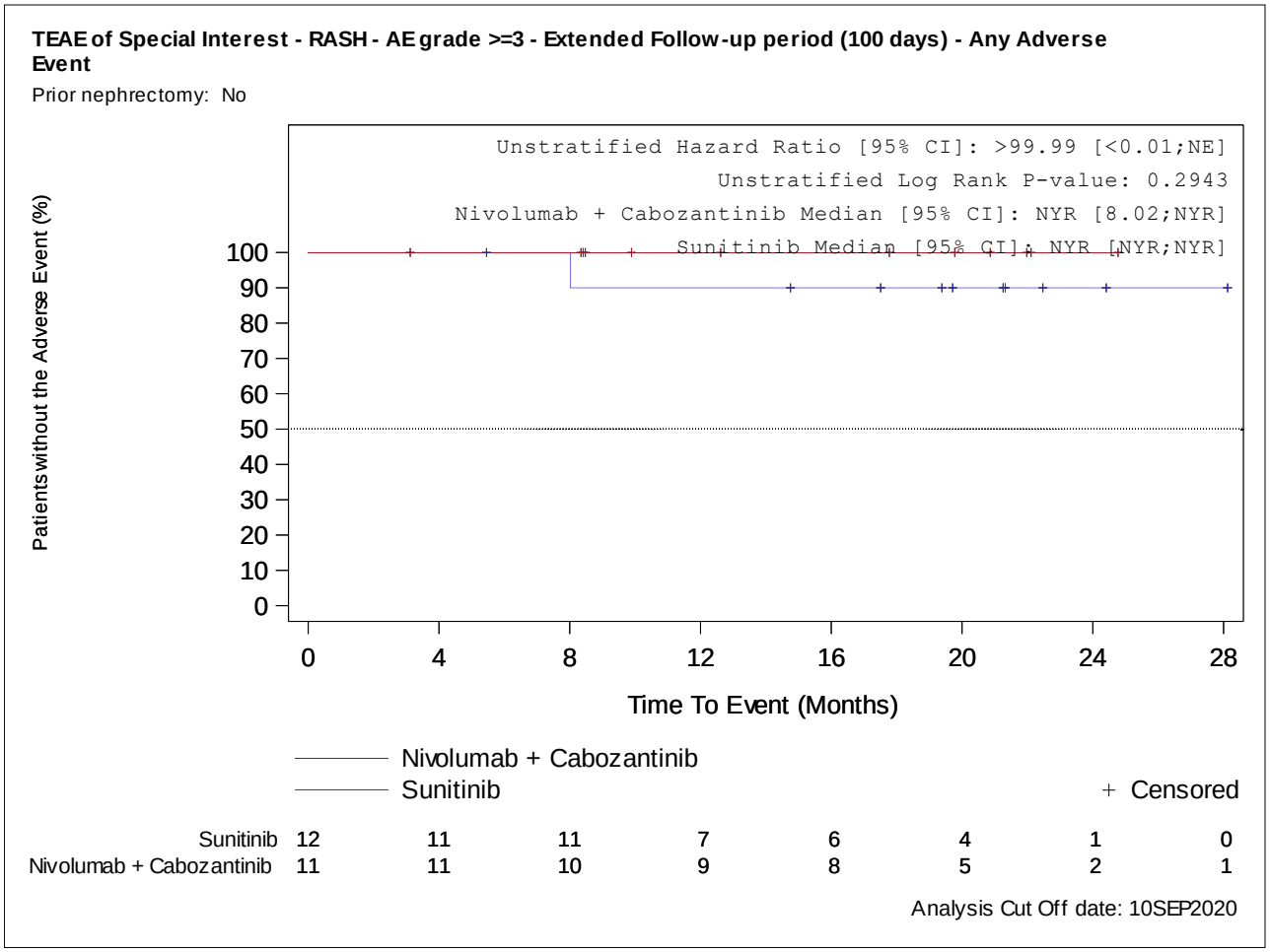

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:12:39

FIGURE 3.134.2.16: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



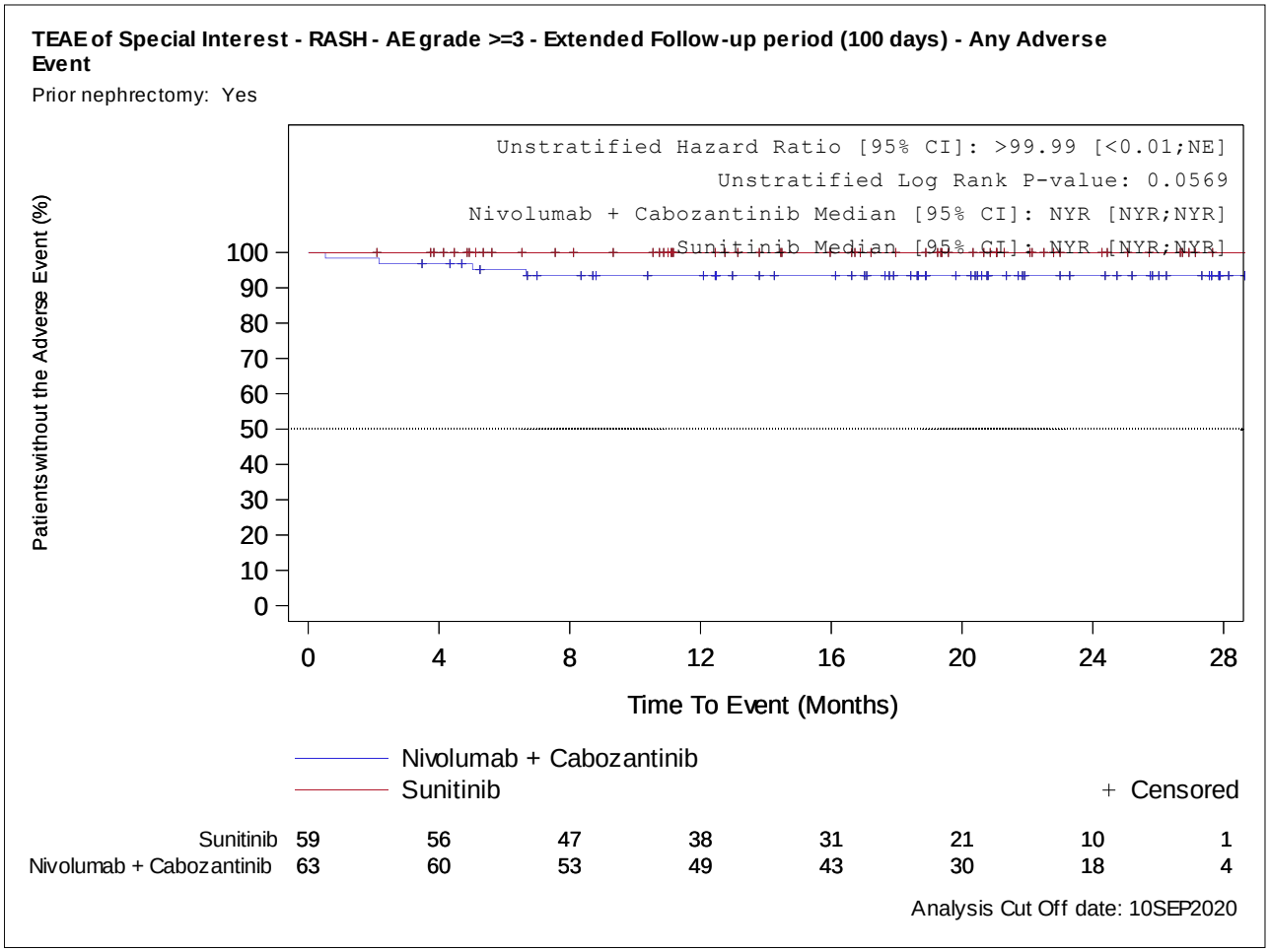

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:12:45

FIGURE 3.134.2.17: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



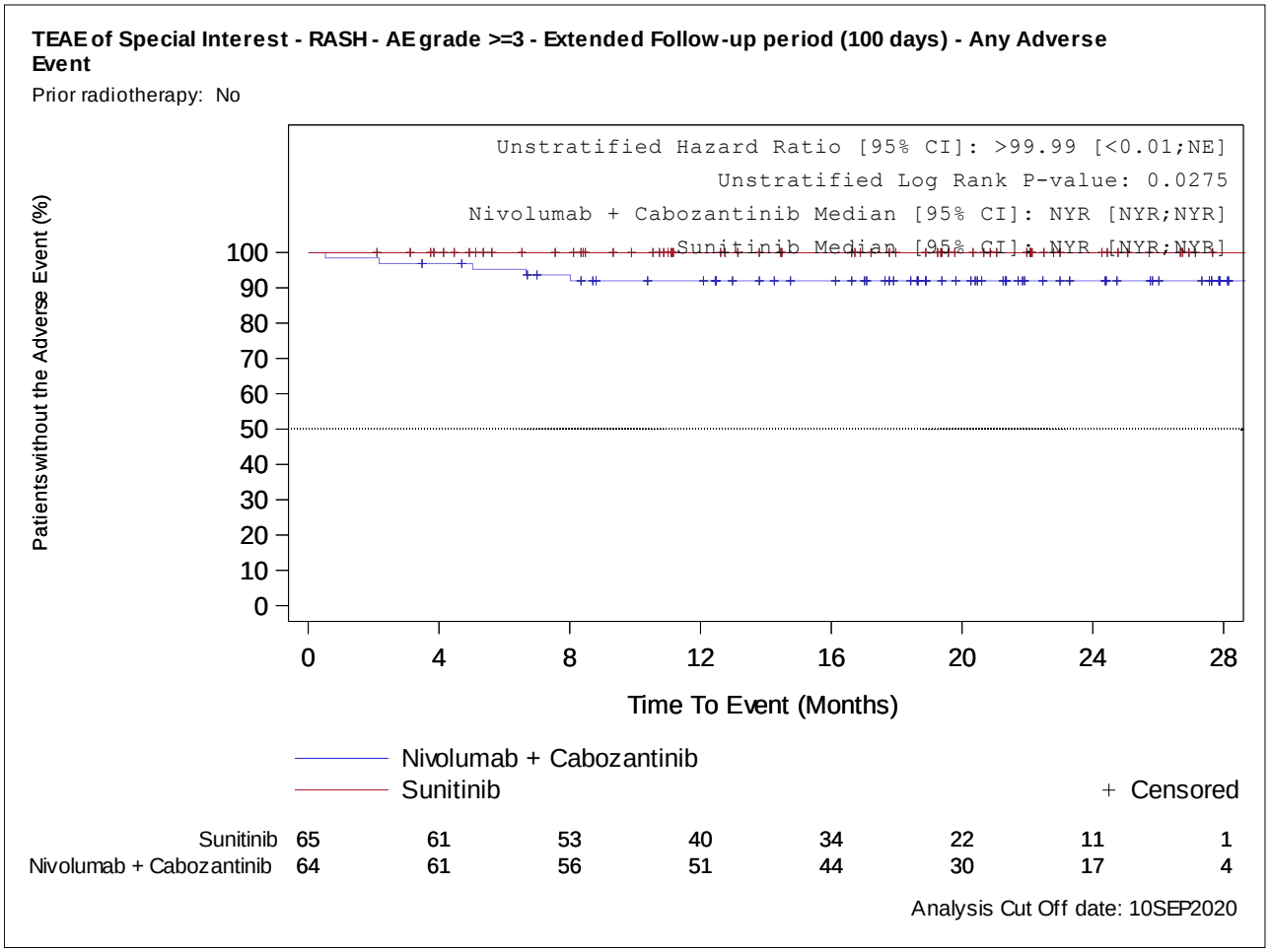

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:13:34

FIGURE 3.134.2.18: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



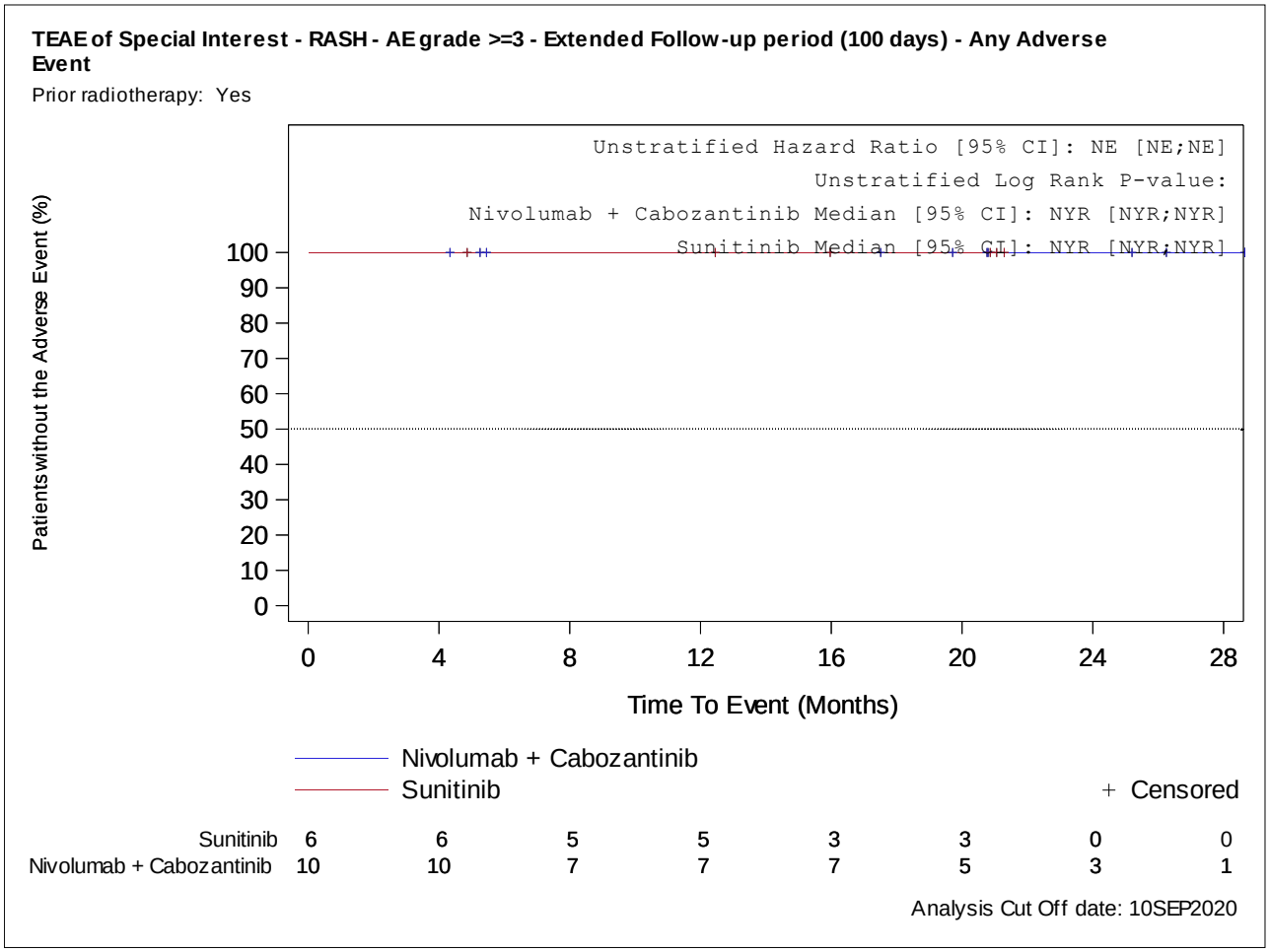

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:13:40

FIGURE 3.134.2.19: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



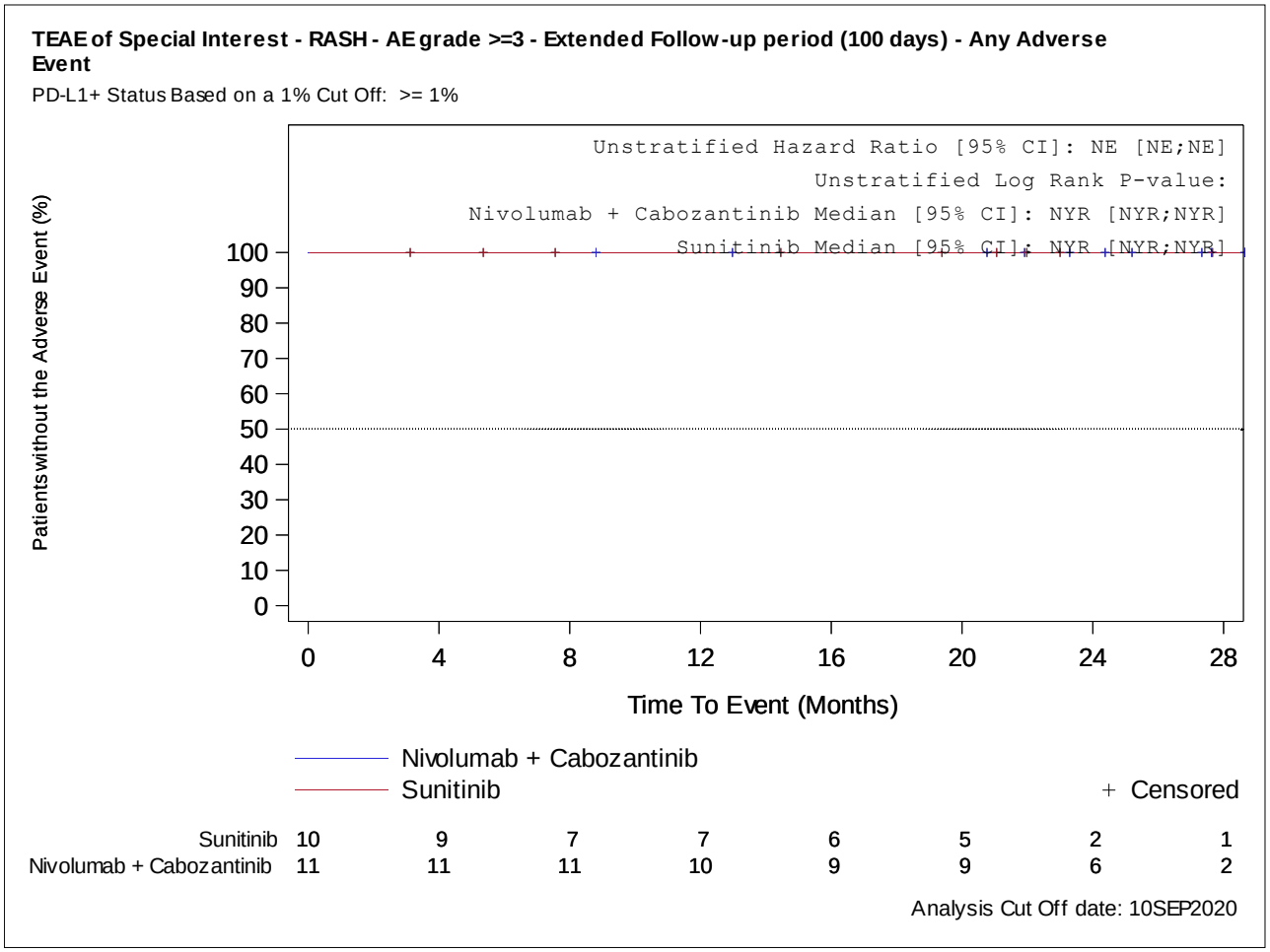

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:13:45

FIGURE 3.134.2.20: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



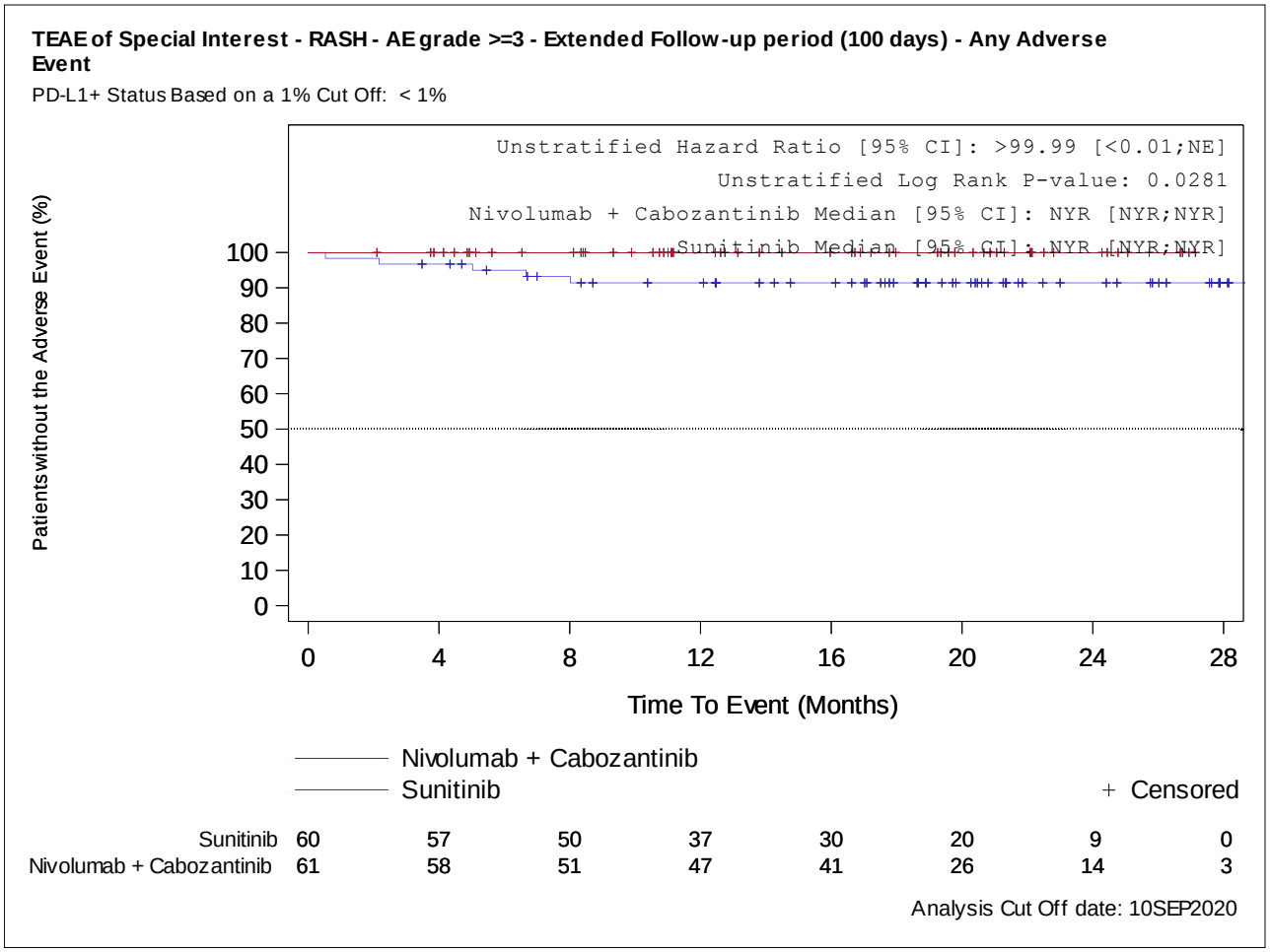

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:13:50

FIGURE 3.134.2.21: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



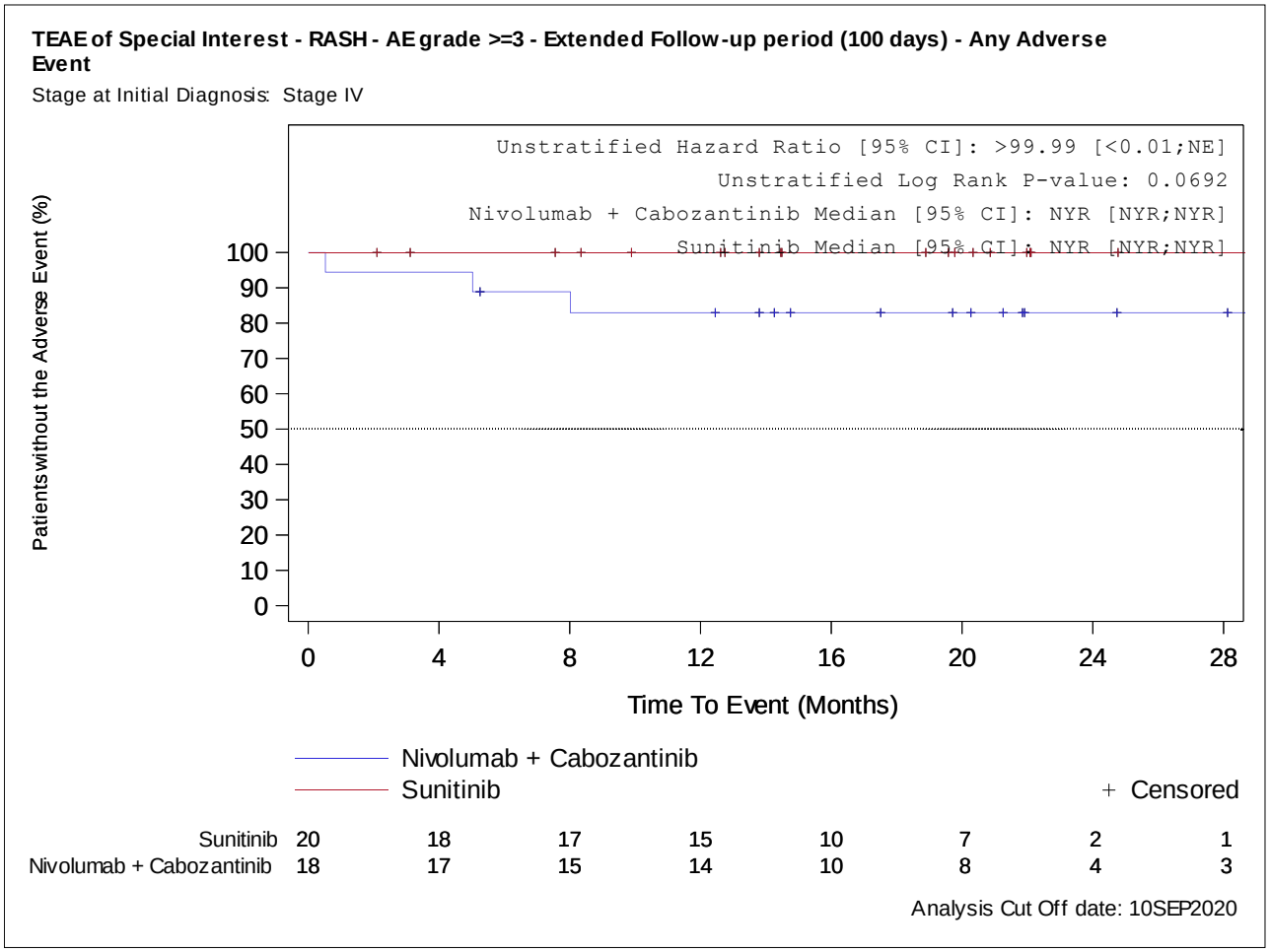

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:13:55

FIGURE 3.134.2.22: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



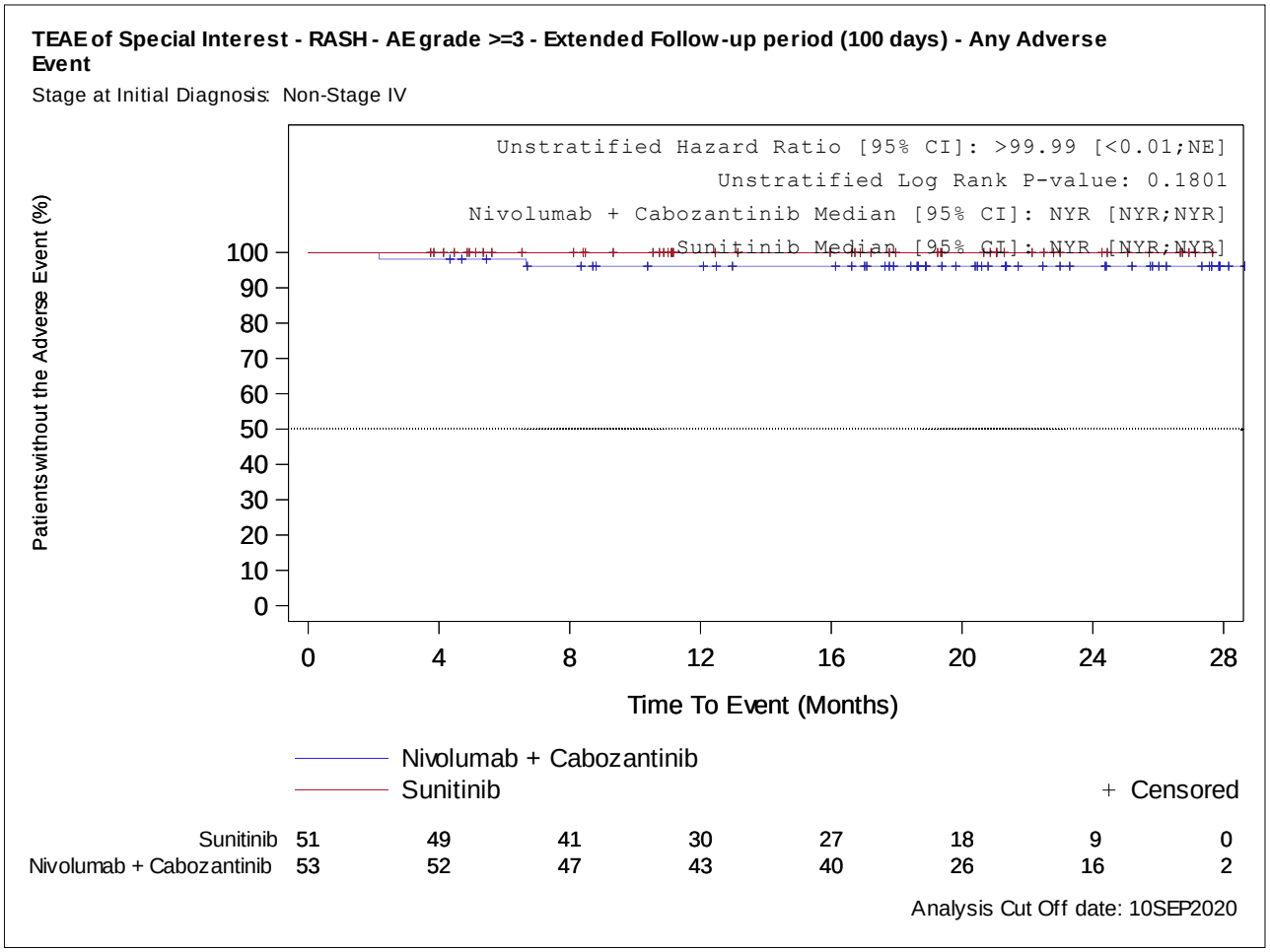

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:14:01

FIGURE 3.134.2.23: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



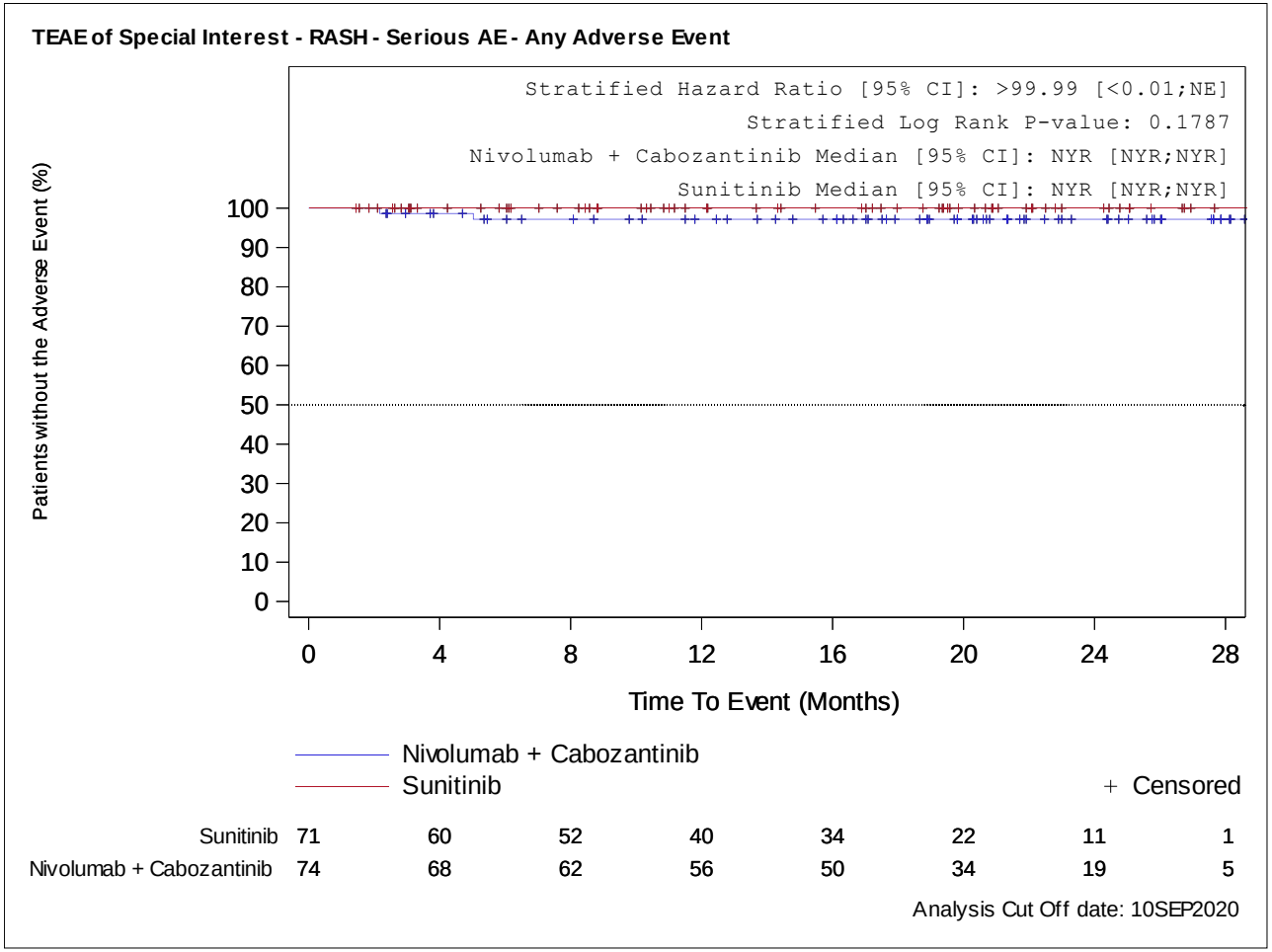

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:14:27

FIGURE 3.134.2.24: Kaplan-Meier curve - TEAE of Special Interest - RASH - AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



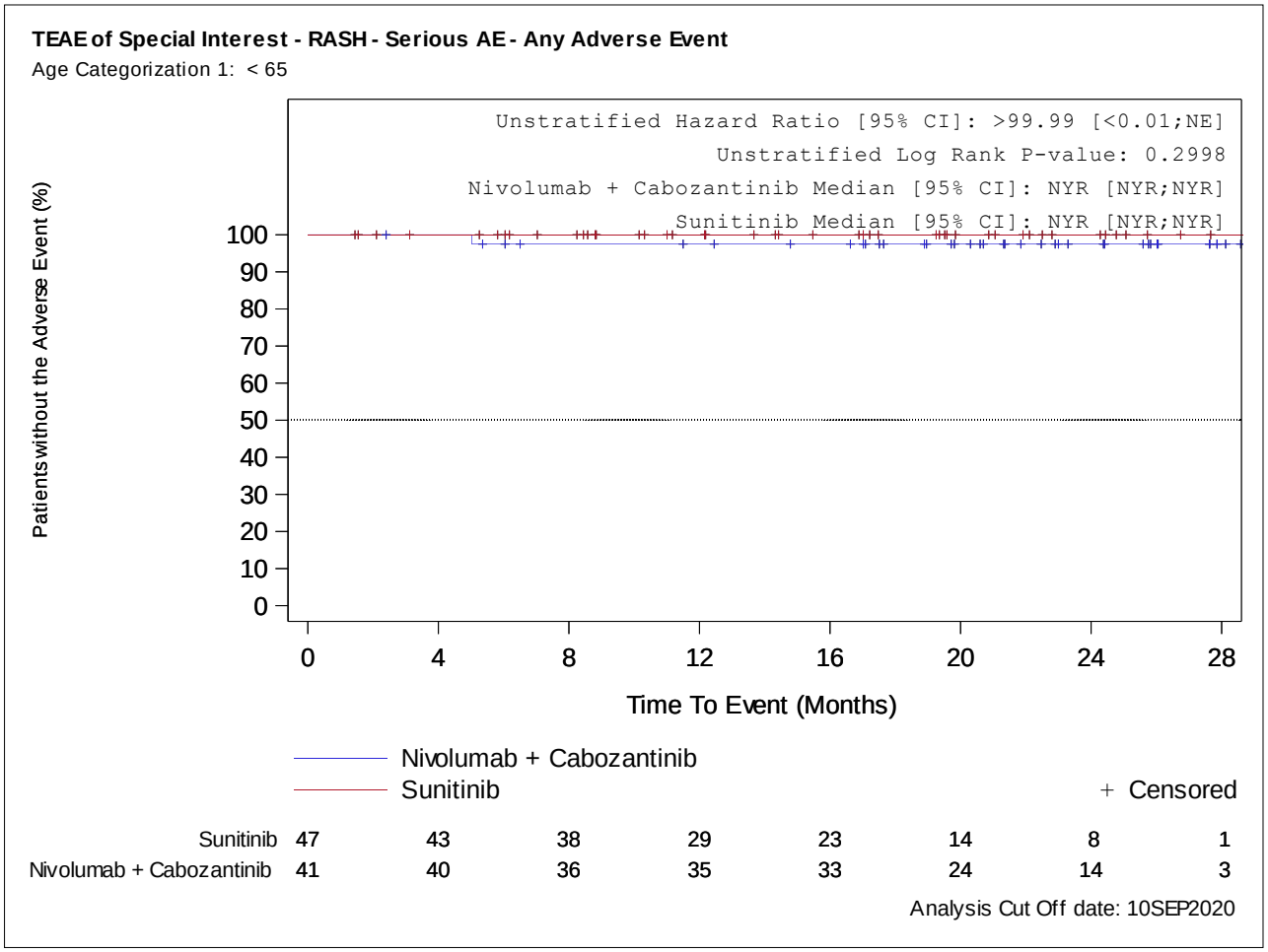

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:14:32

FIGURE 3.135.1: TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



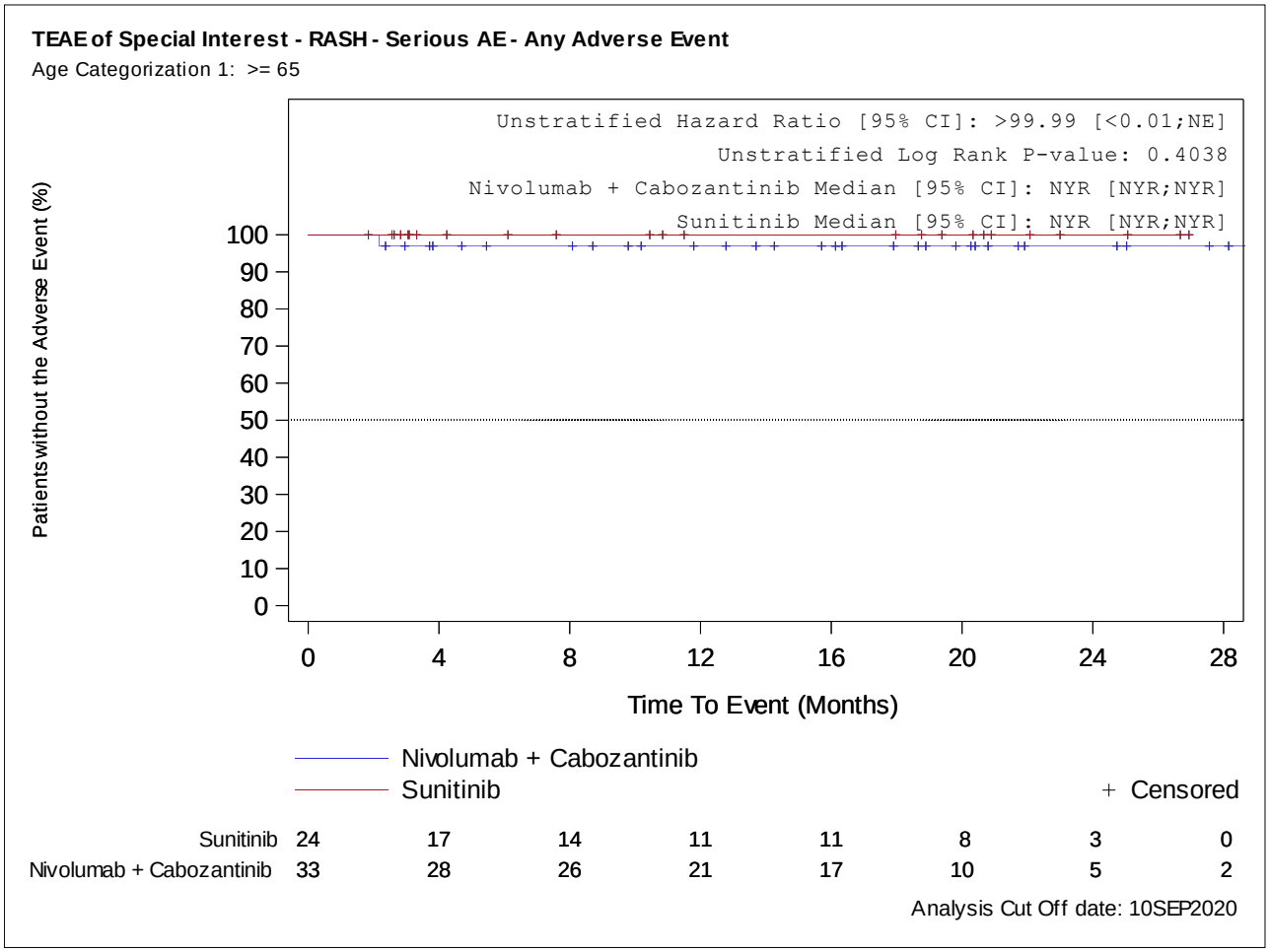

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:17:28

FIGURE 3.135.2.1: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



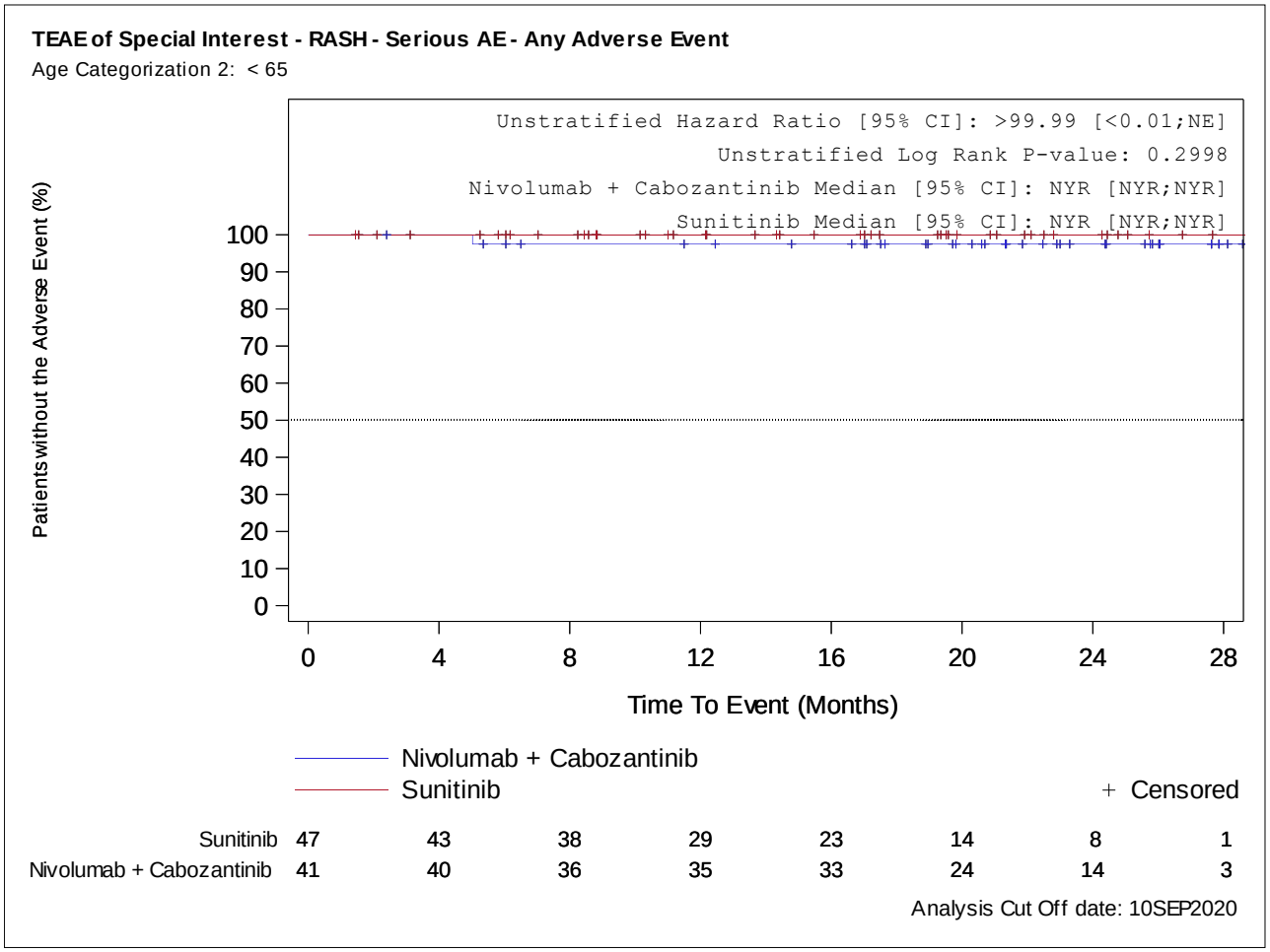

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:17:30

FIGURE 3.135.2.2: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



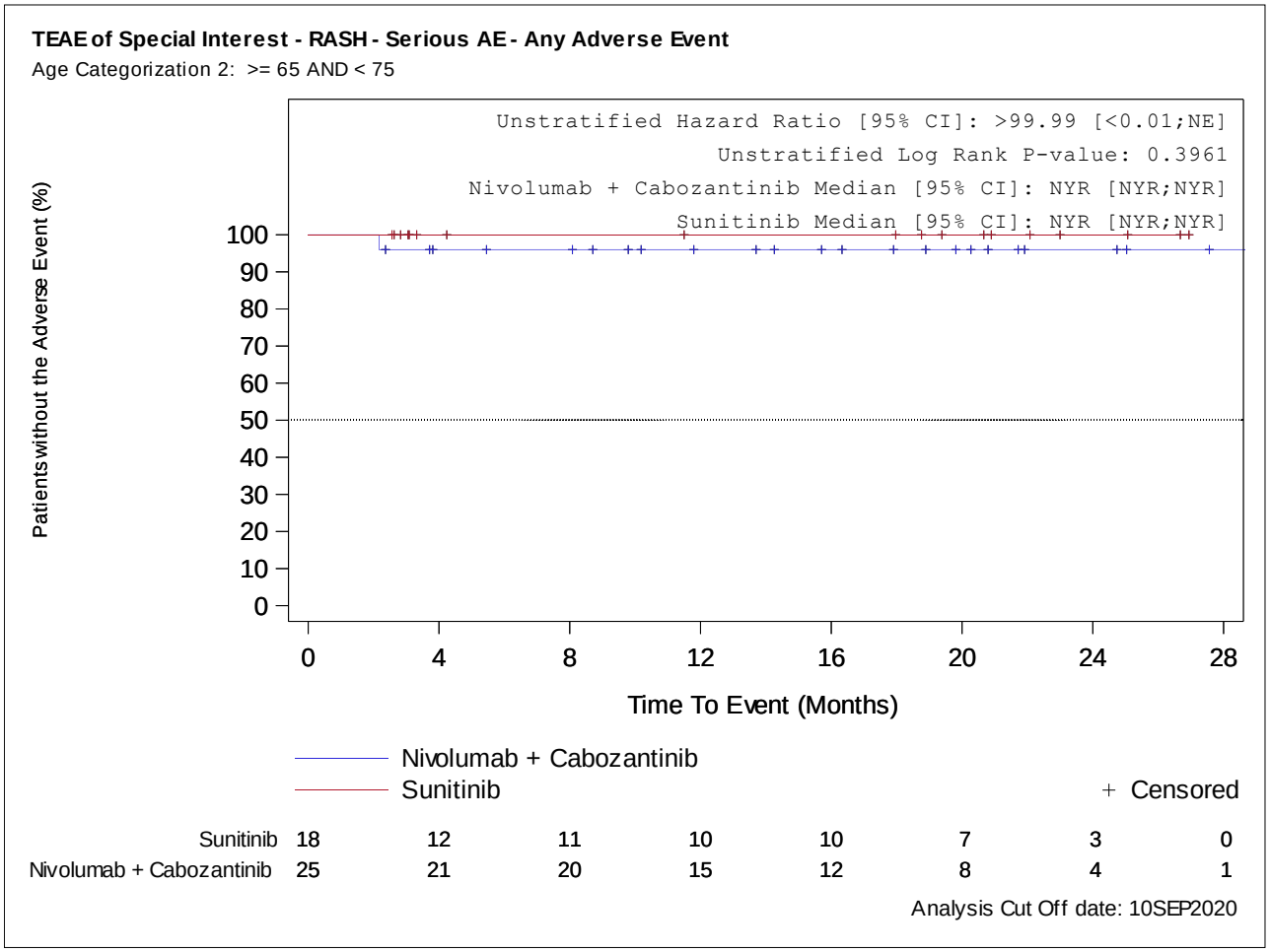

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:17:36

FIGURE 3.135.2.3: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



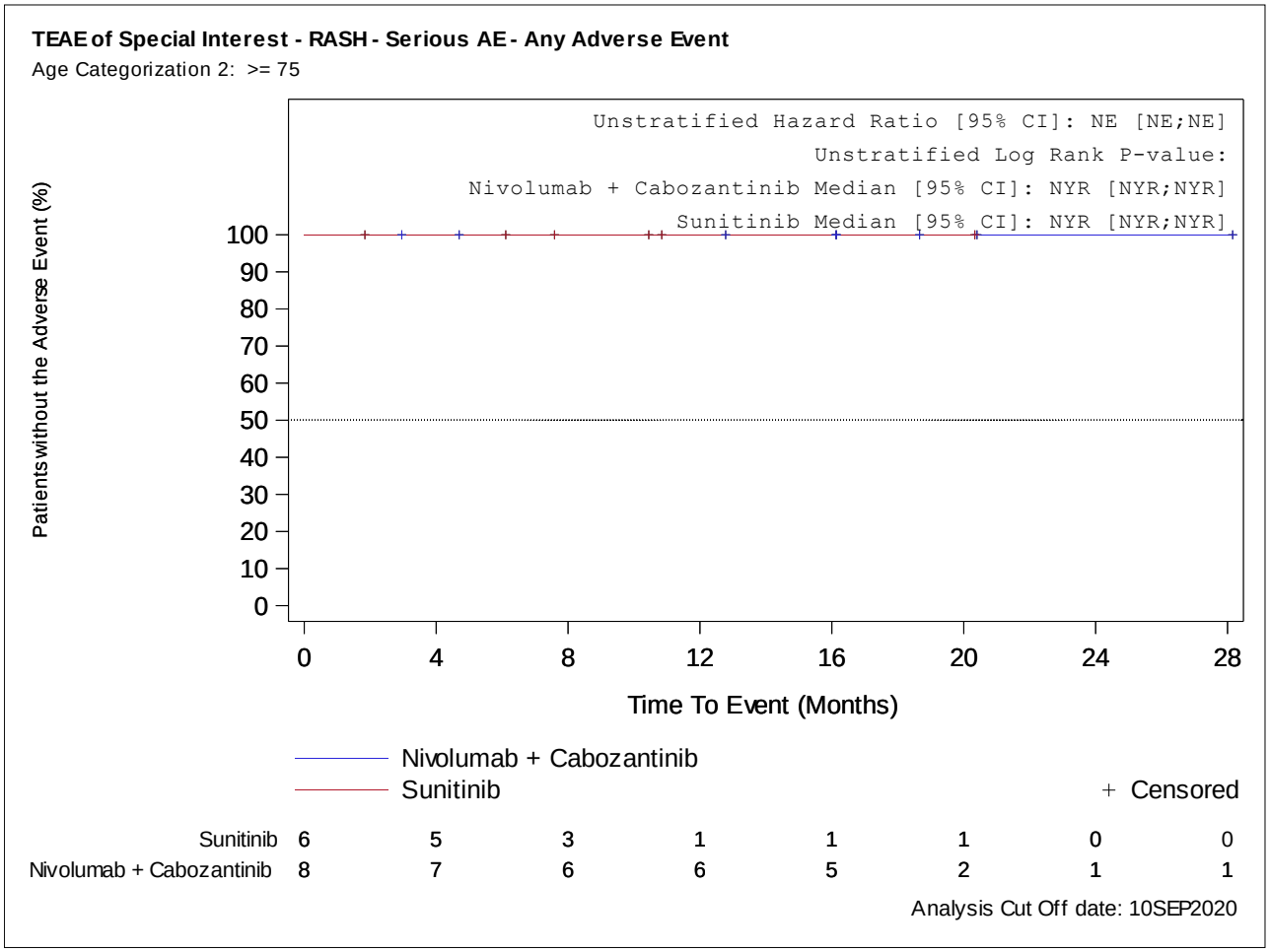

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:17:41

FIGURE 3.135.2.4: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 65 AND < 75



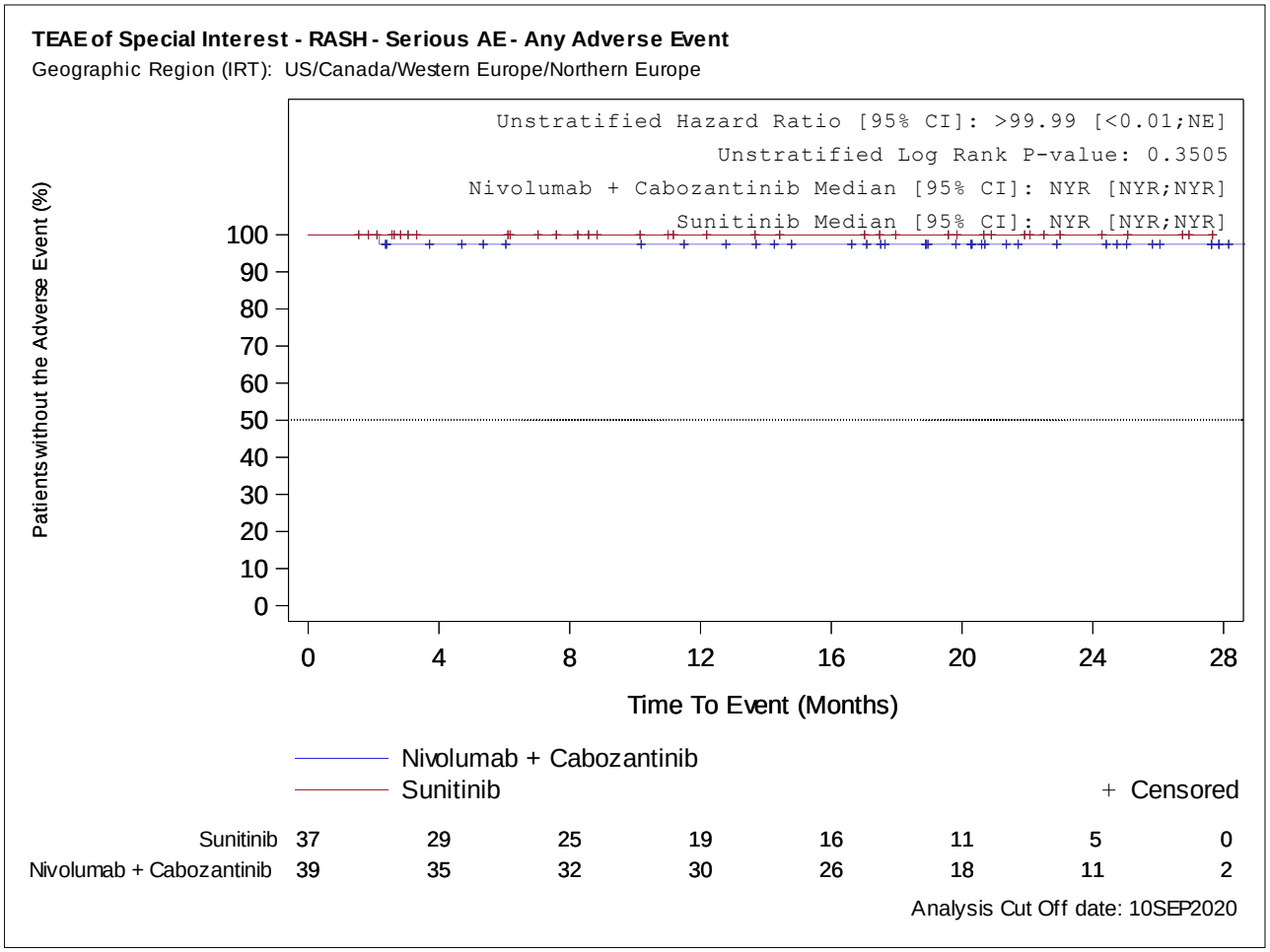

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:17:47

FIGURE 3.135.2.5: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2:  >= 75



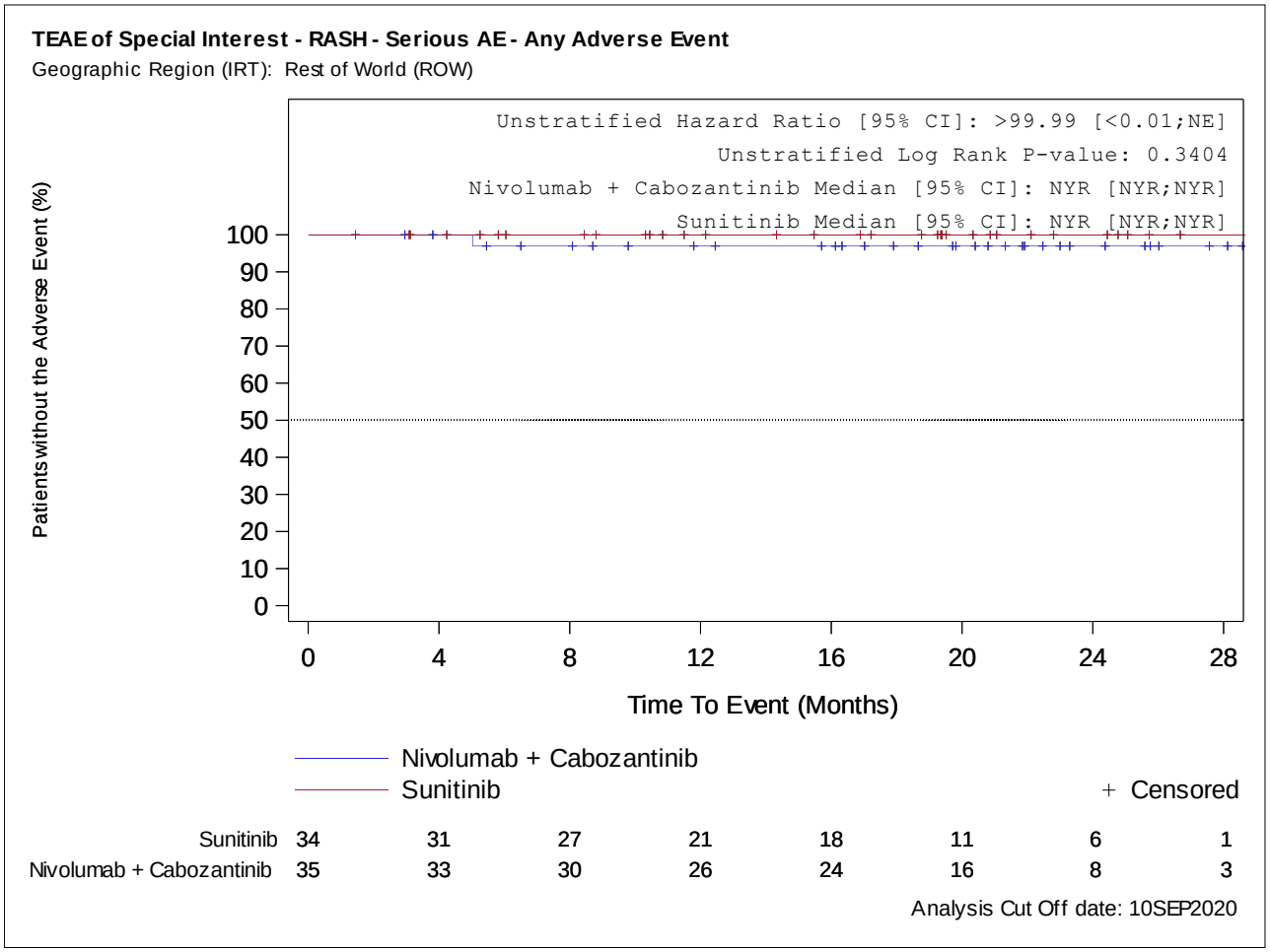

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:17:52

FIGURE 3.135.2.6: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



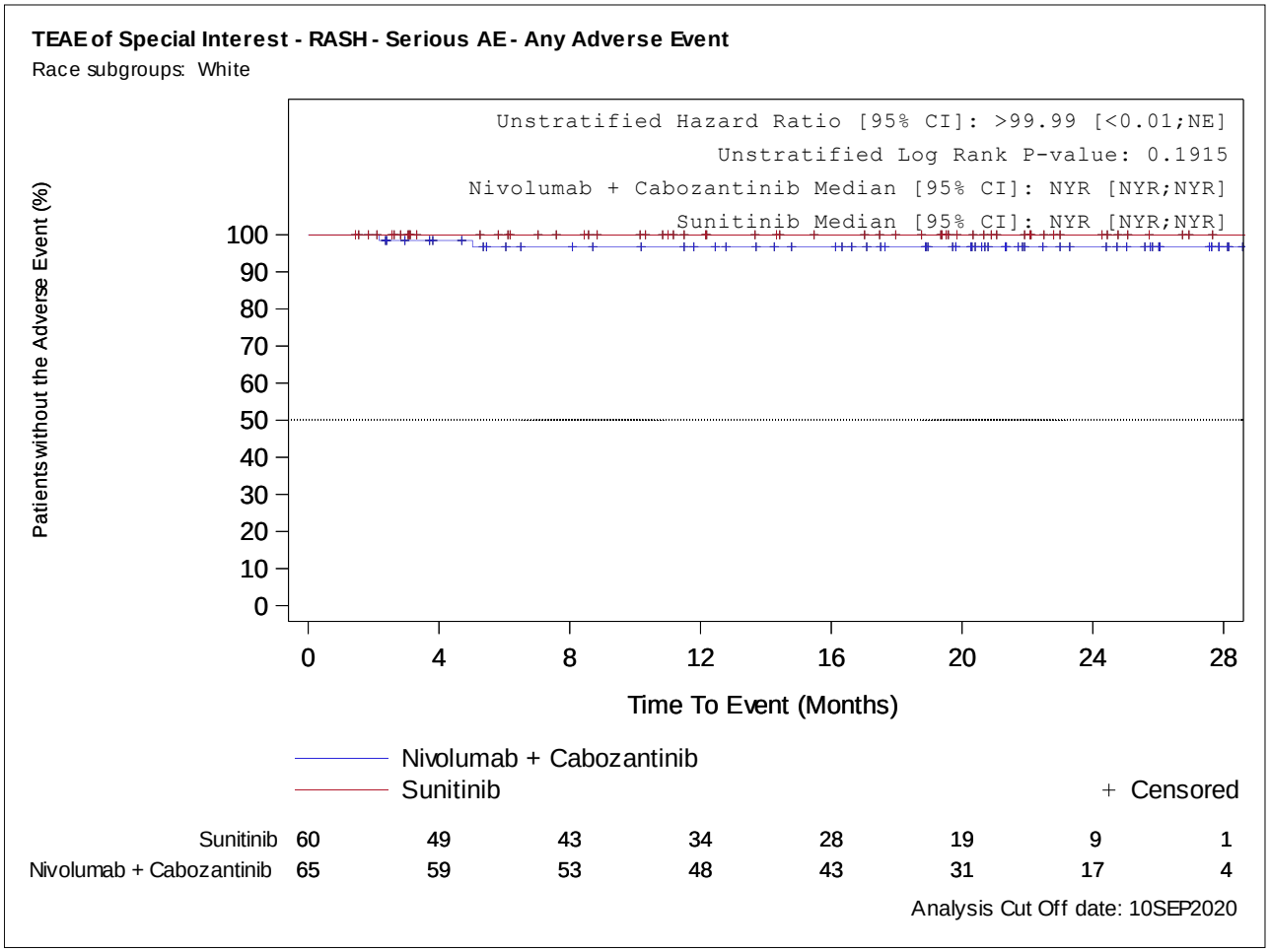

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:17:57

FIGURE 3.135.2.7: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



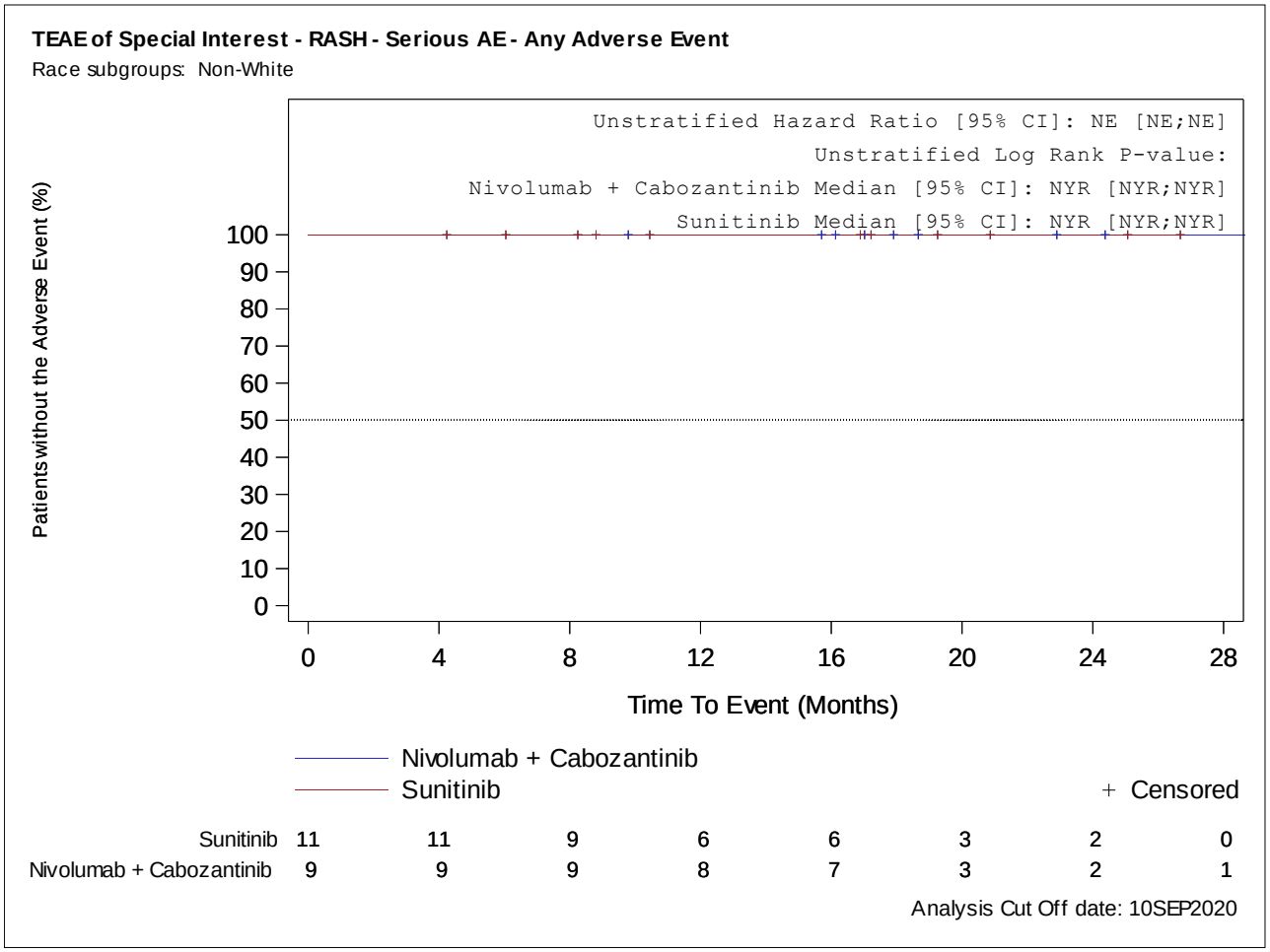

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:18:03

FIGURE 3.135.2.8: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



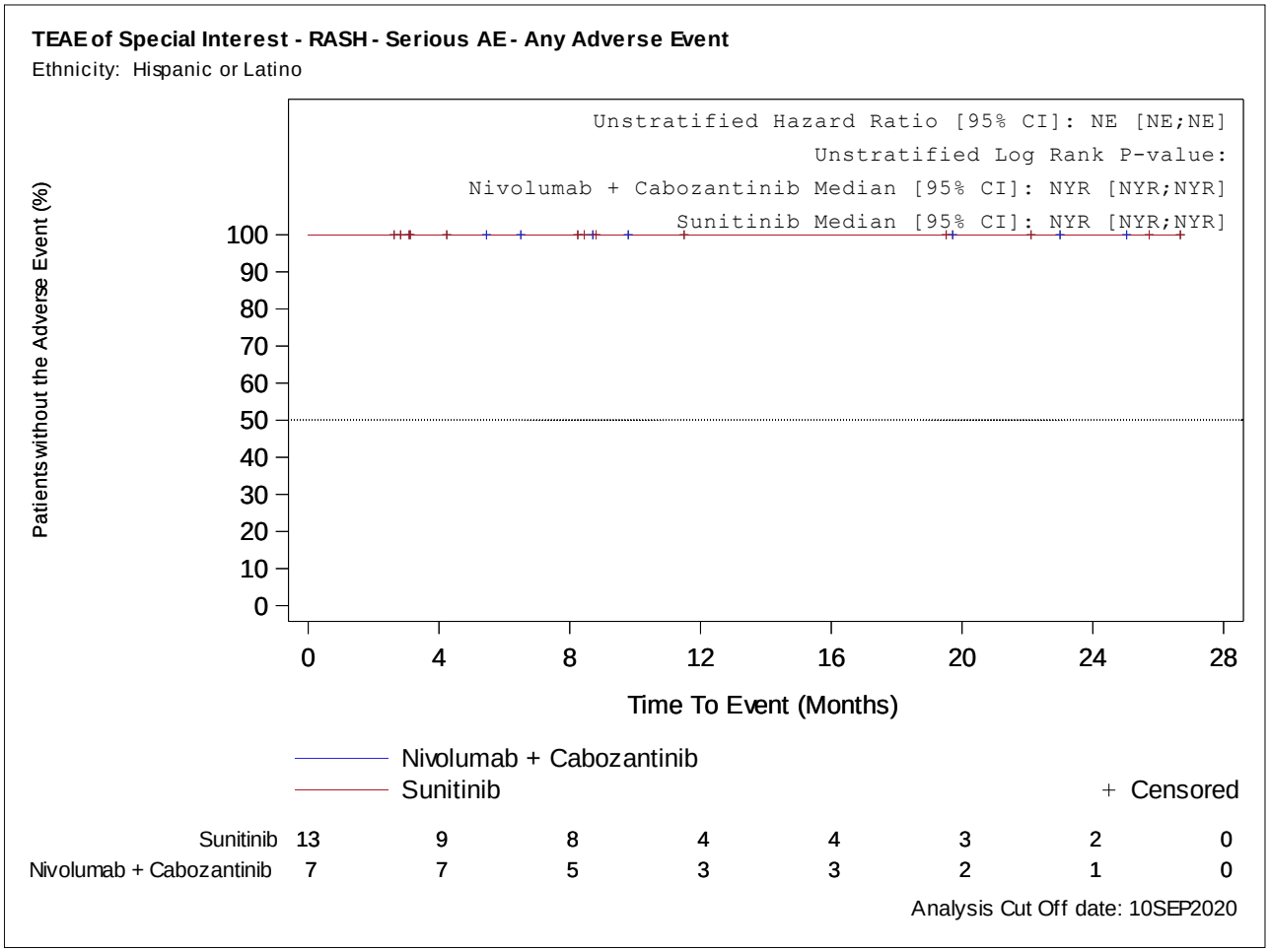

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:18:08

FIGURE 3.135.2.9: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



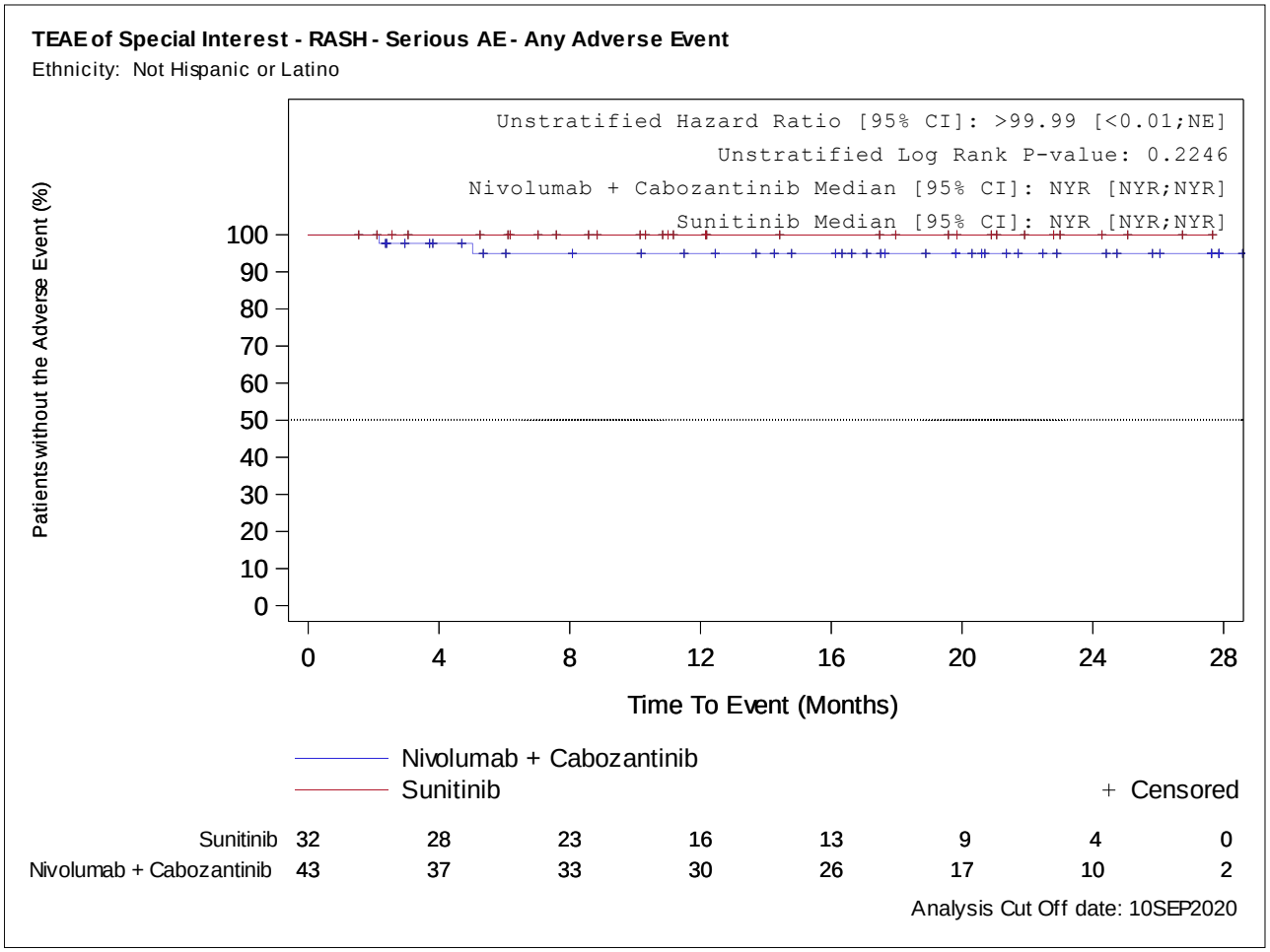

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:18:13

FIGURE 3.135.2.10: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



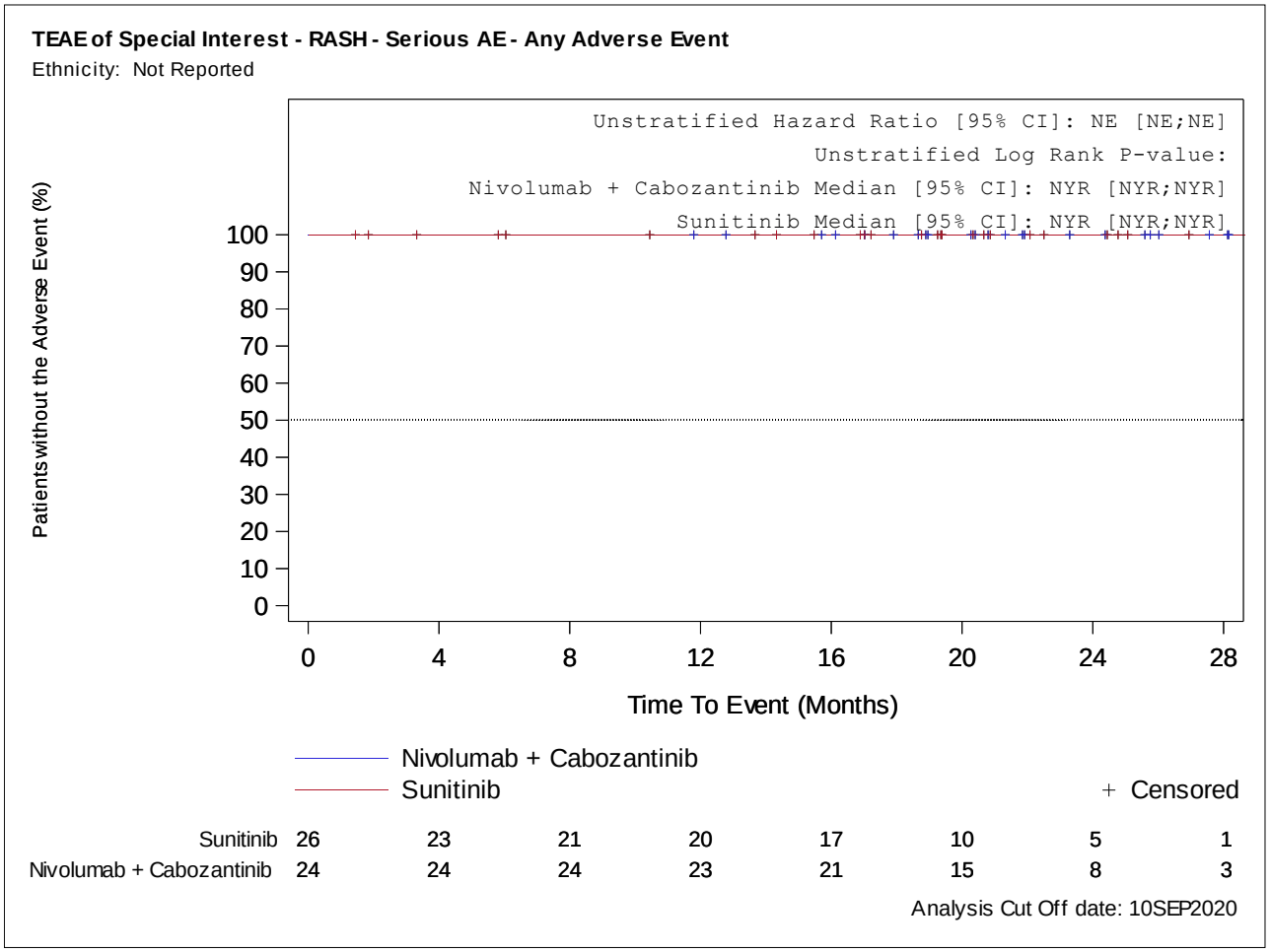

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:18:18

FIGURE 3.135.2.11: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



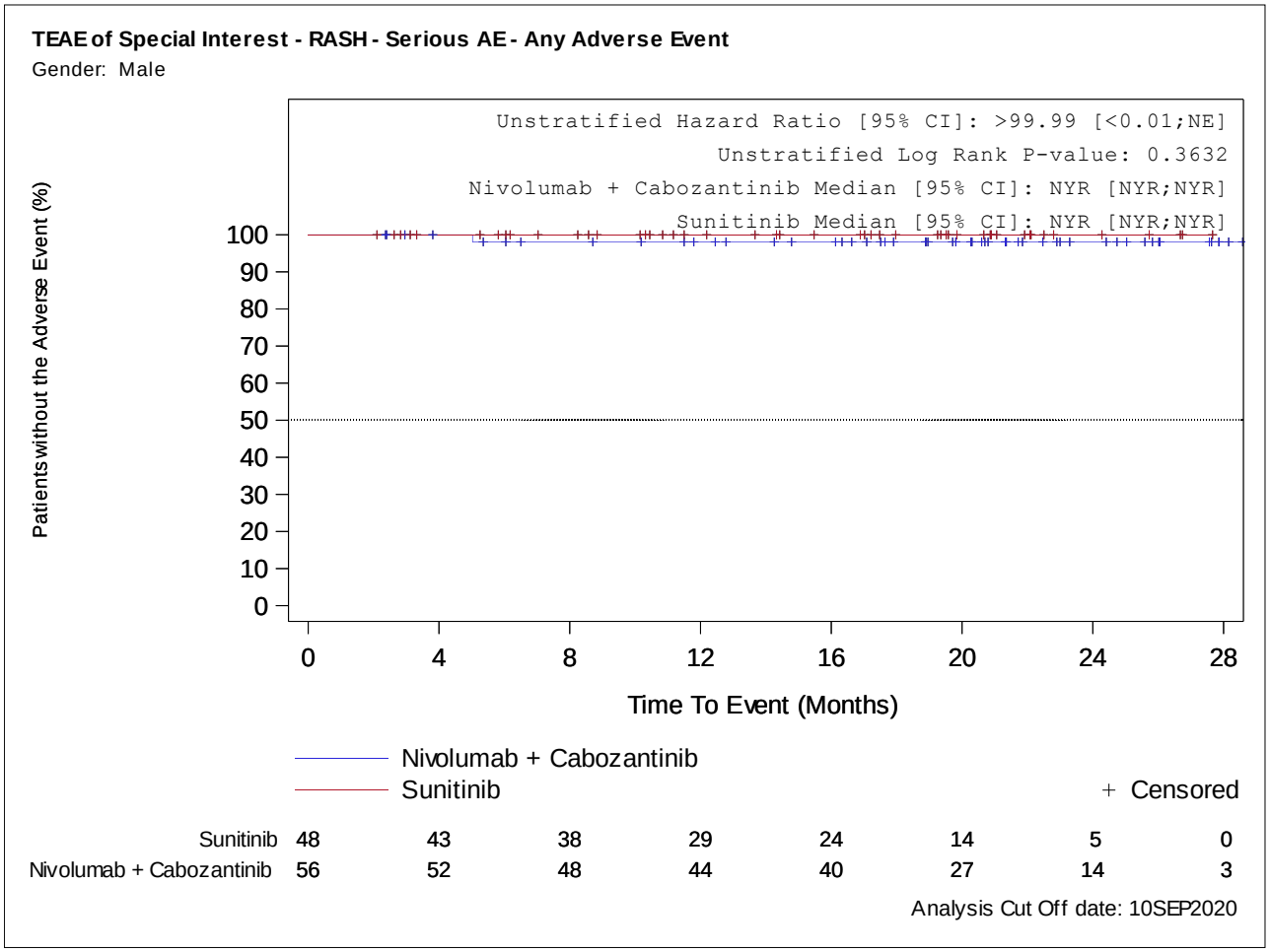

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:18:24

FIGURE 3.135.2.12: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



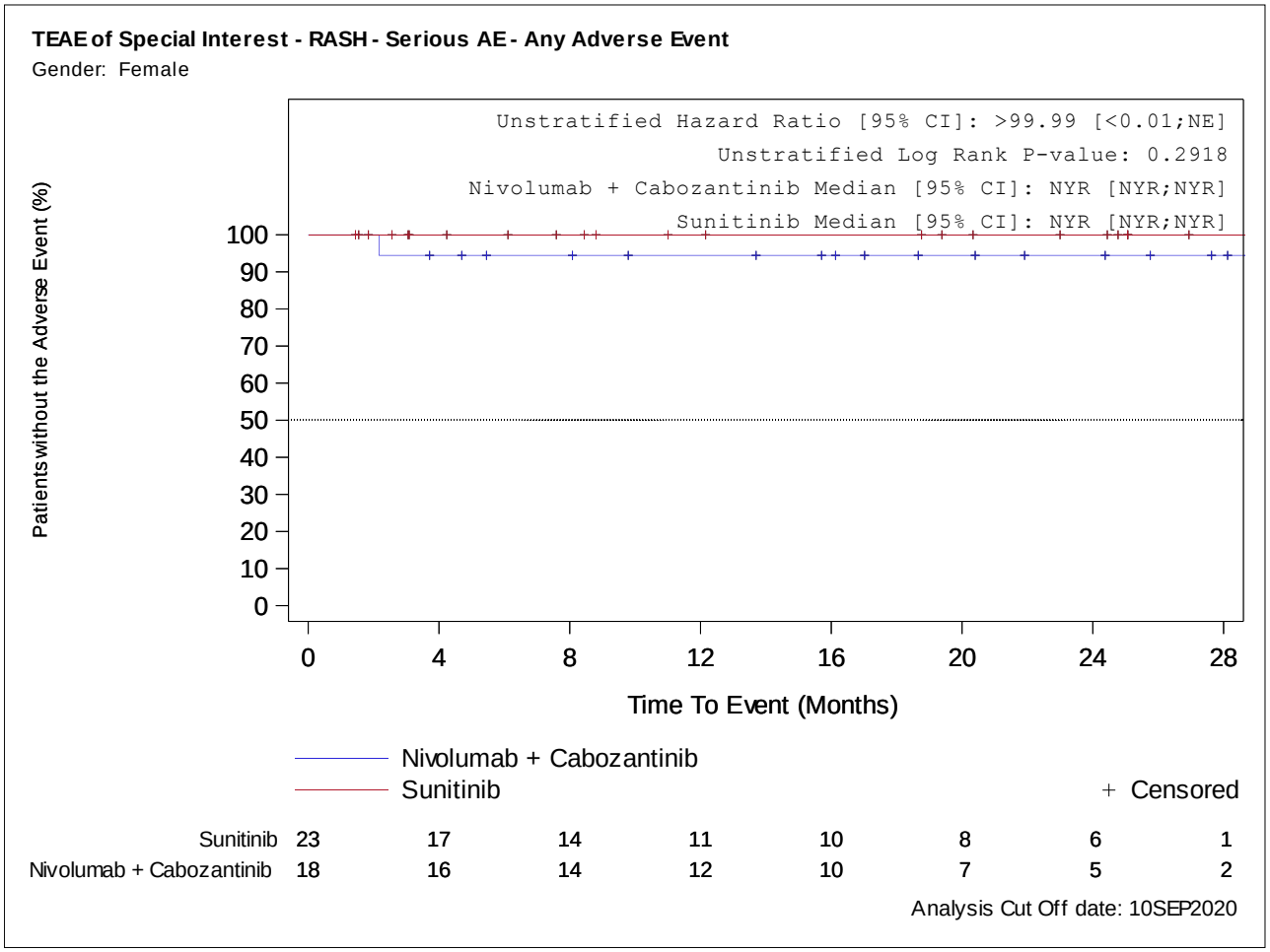

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:18:29

FIGURE 3.135.2.13: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



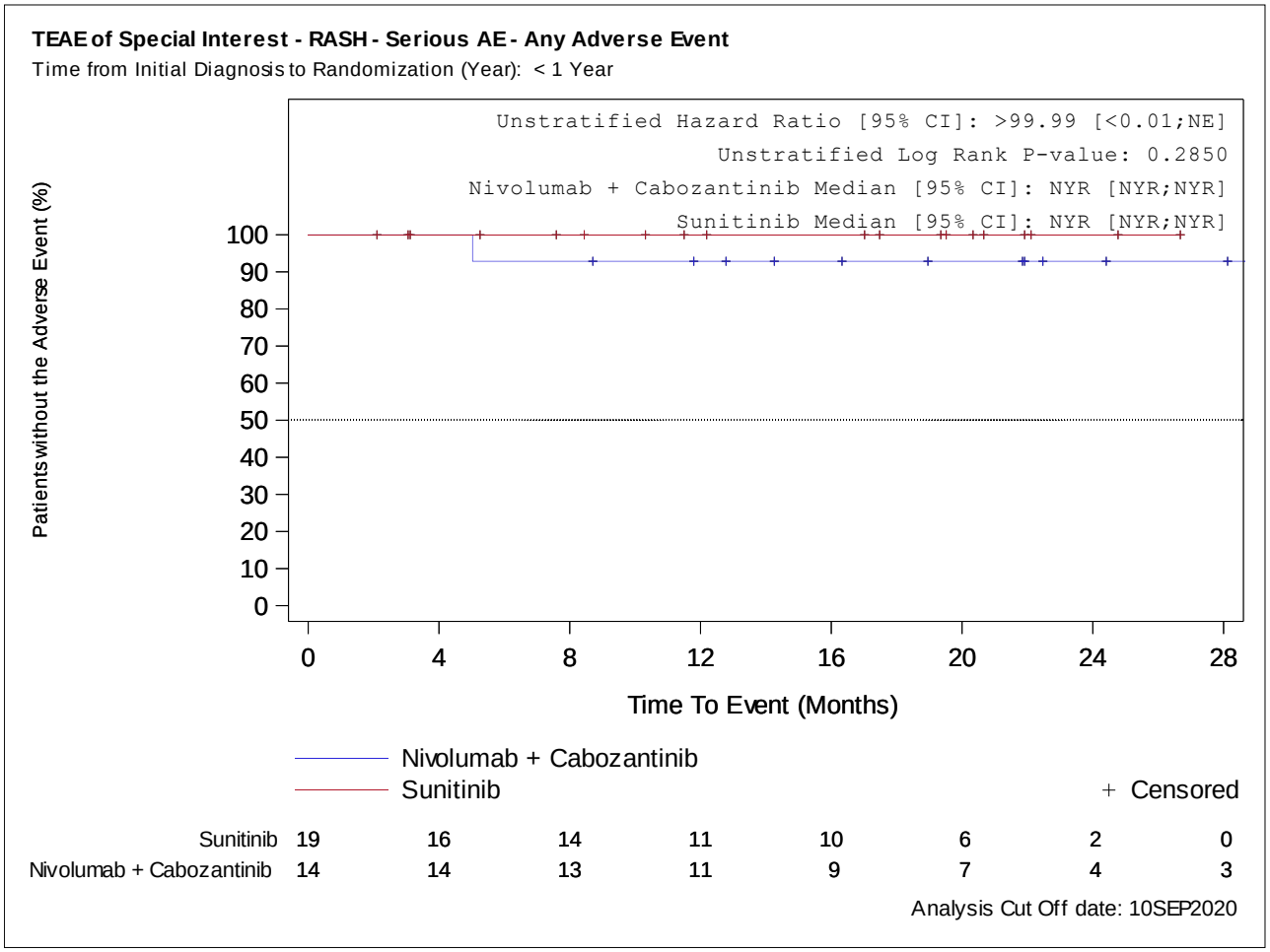

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:18:35

FIGURE 3.135.2.14: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



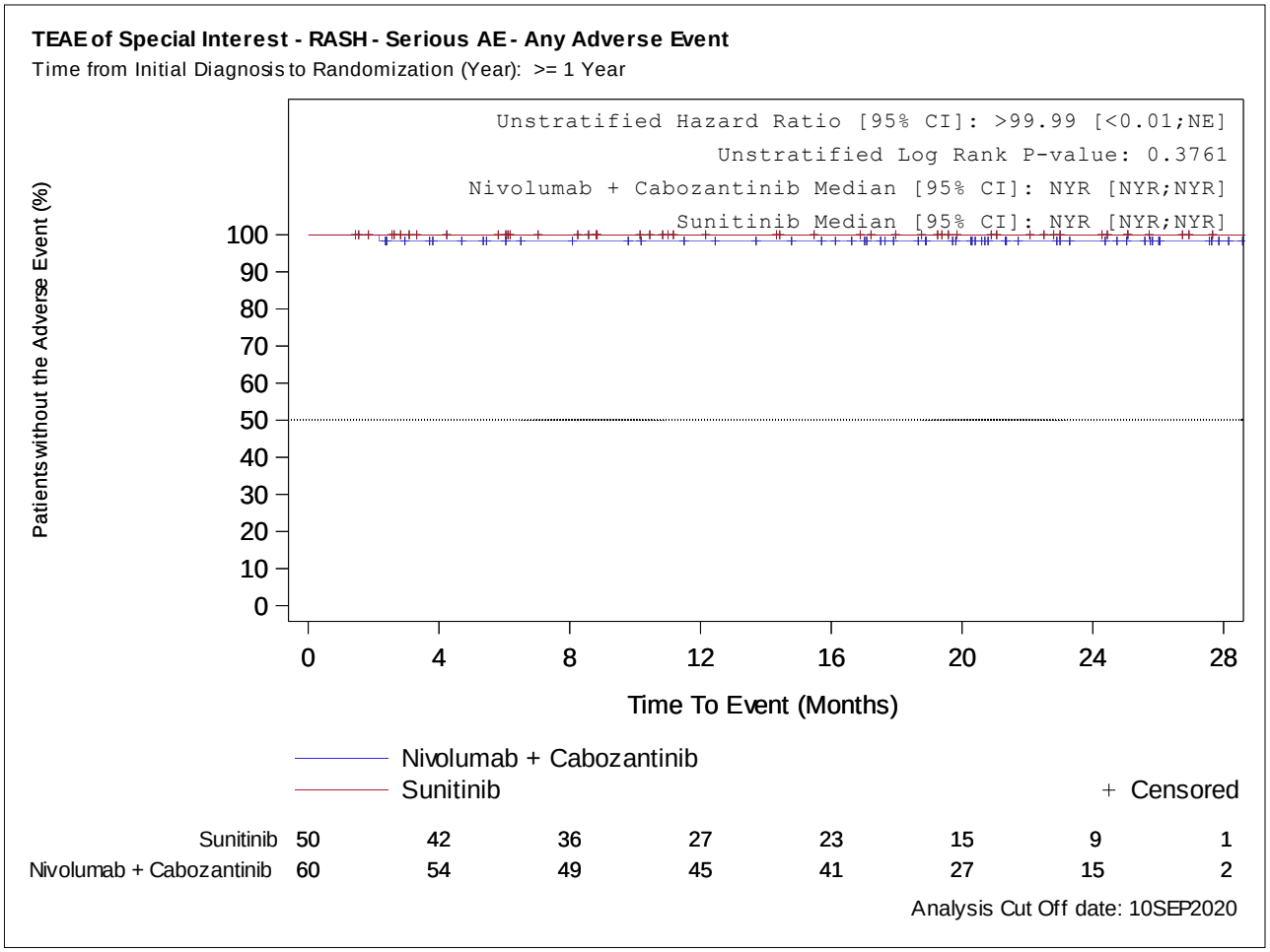

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:18:41

FIGURE 3.135.2.15: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



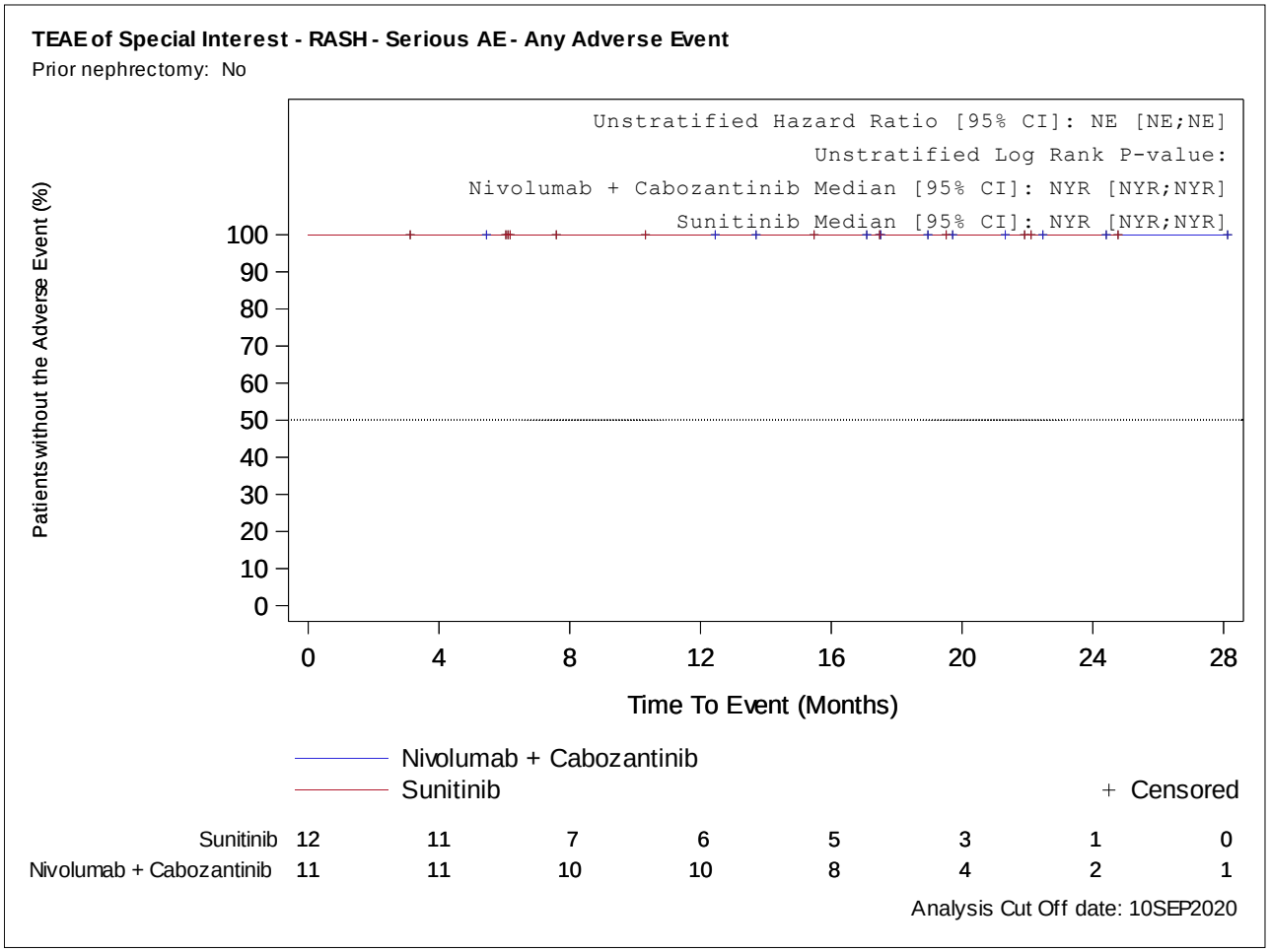

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:18:57

FIGURE 3.135.2.16: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



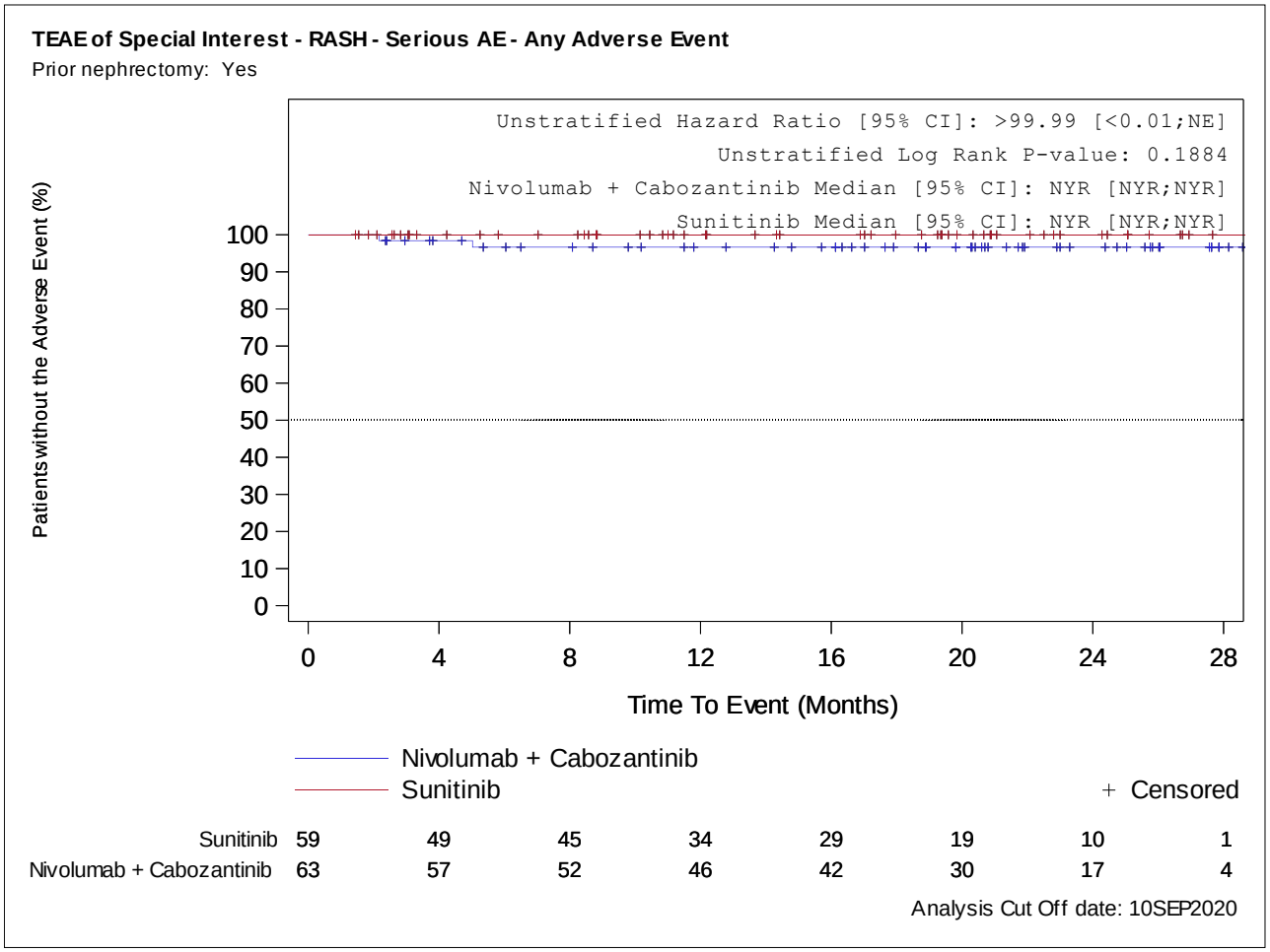

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:19:02

FIGURE 3.135.2.17: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



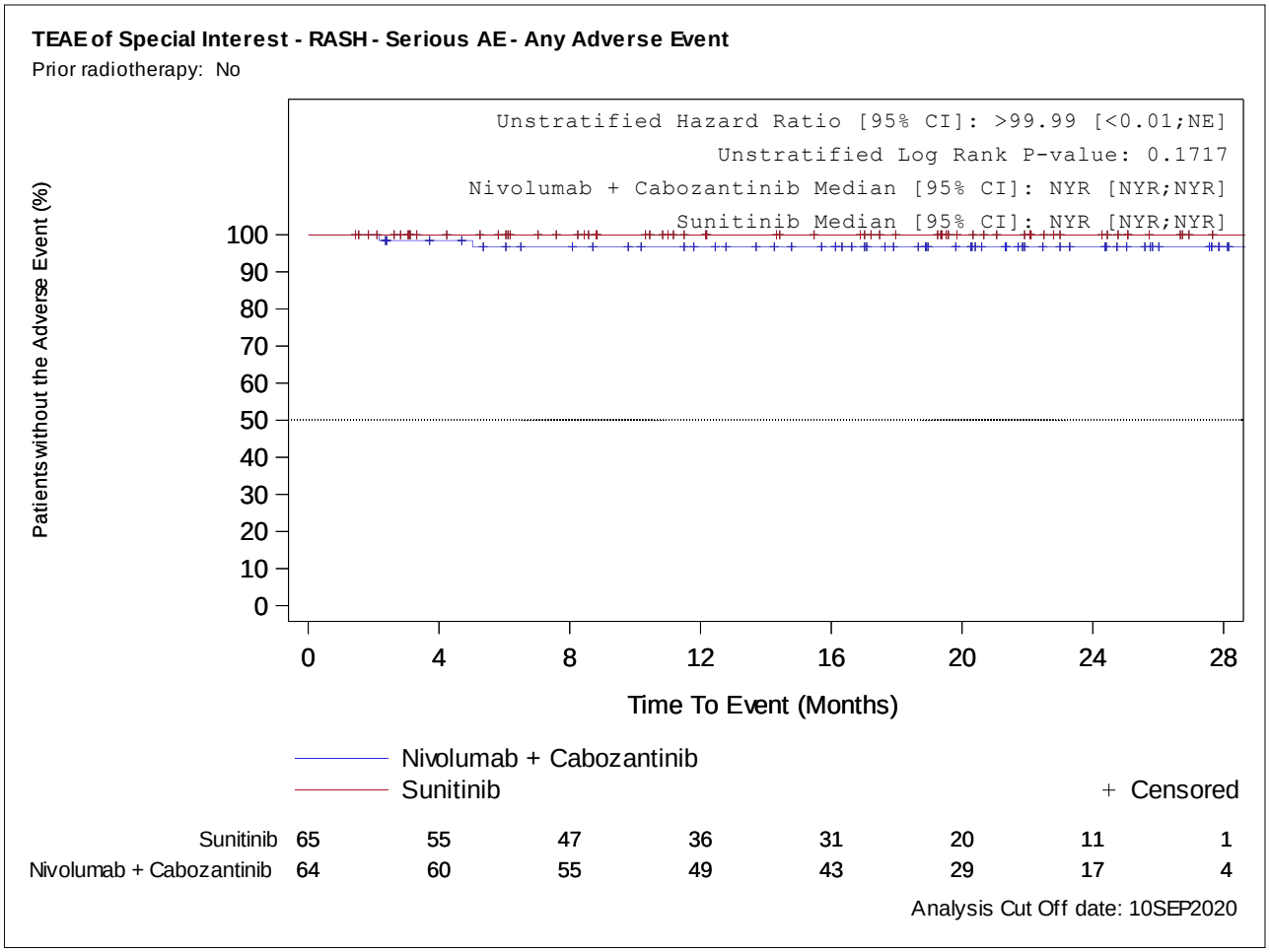

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:19:50

FIGURE 3.135.2.18: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



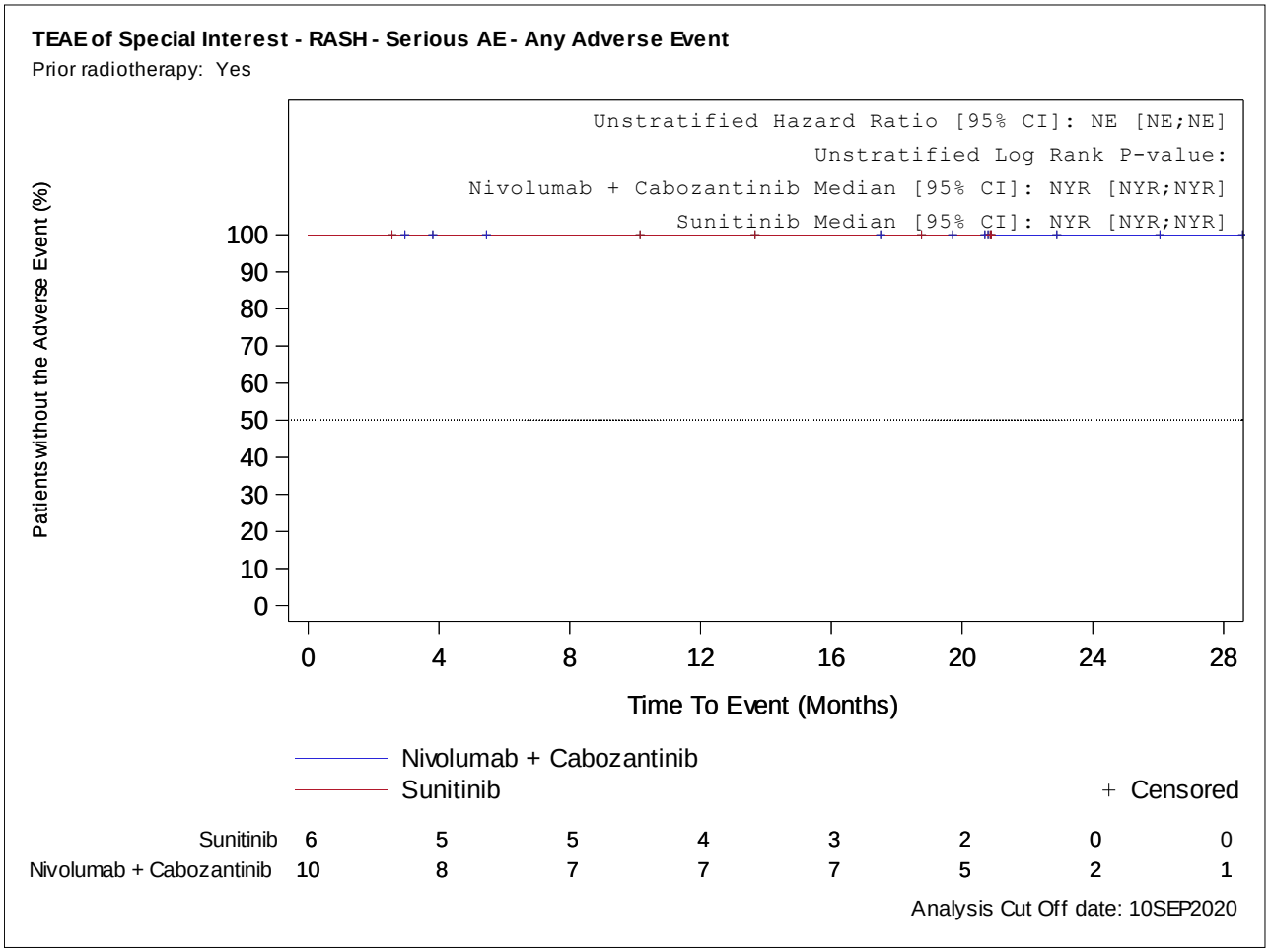

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:19:56

FIGURE 3.135.2.19: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:20:01

FIGURE 3.135.2.20: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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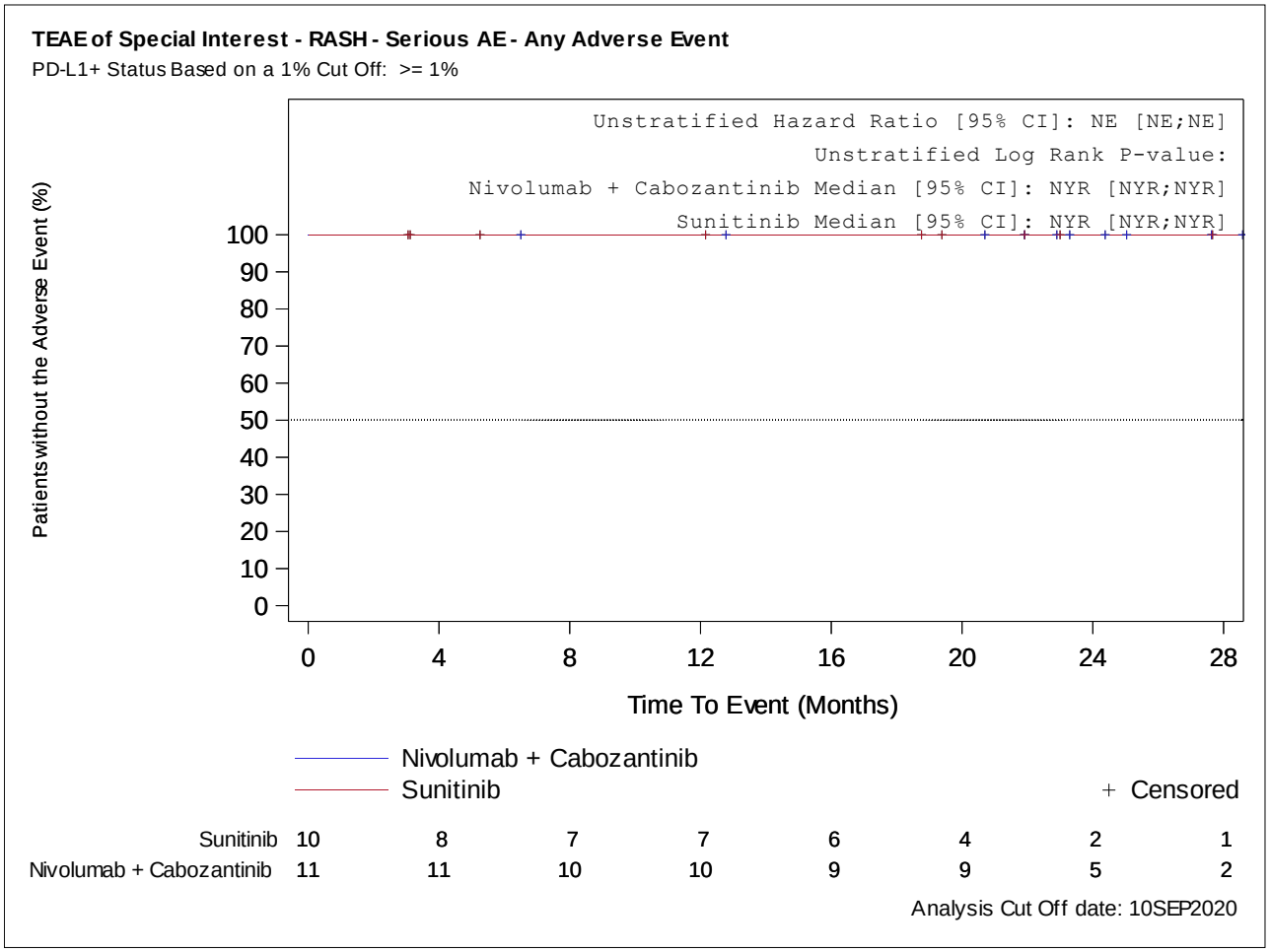
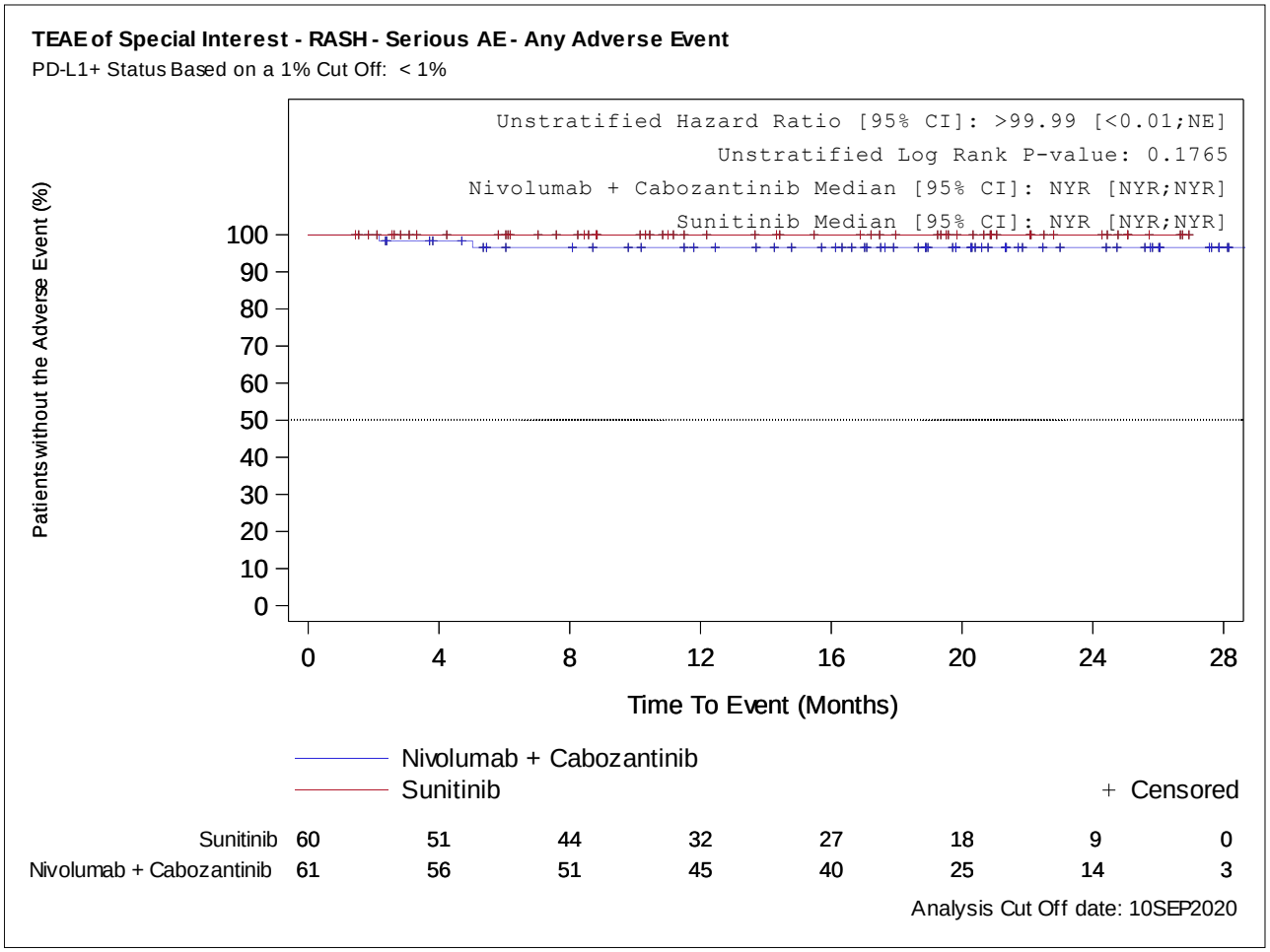
FIGURE 3.135.2.21: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:20:12

FIGURE 3.135.2.22: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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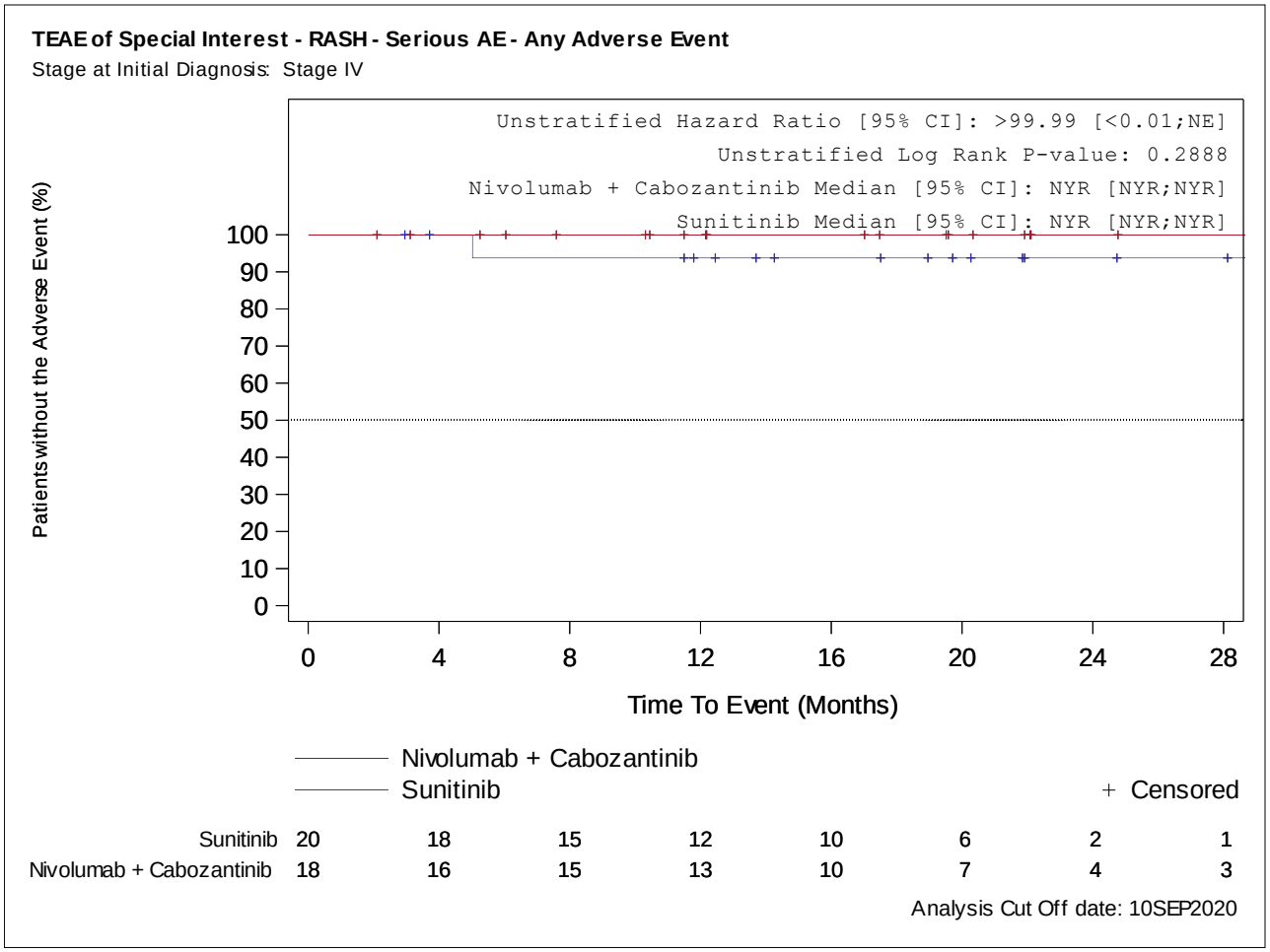
FIGURE 3.135.2.23: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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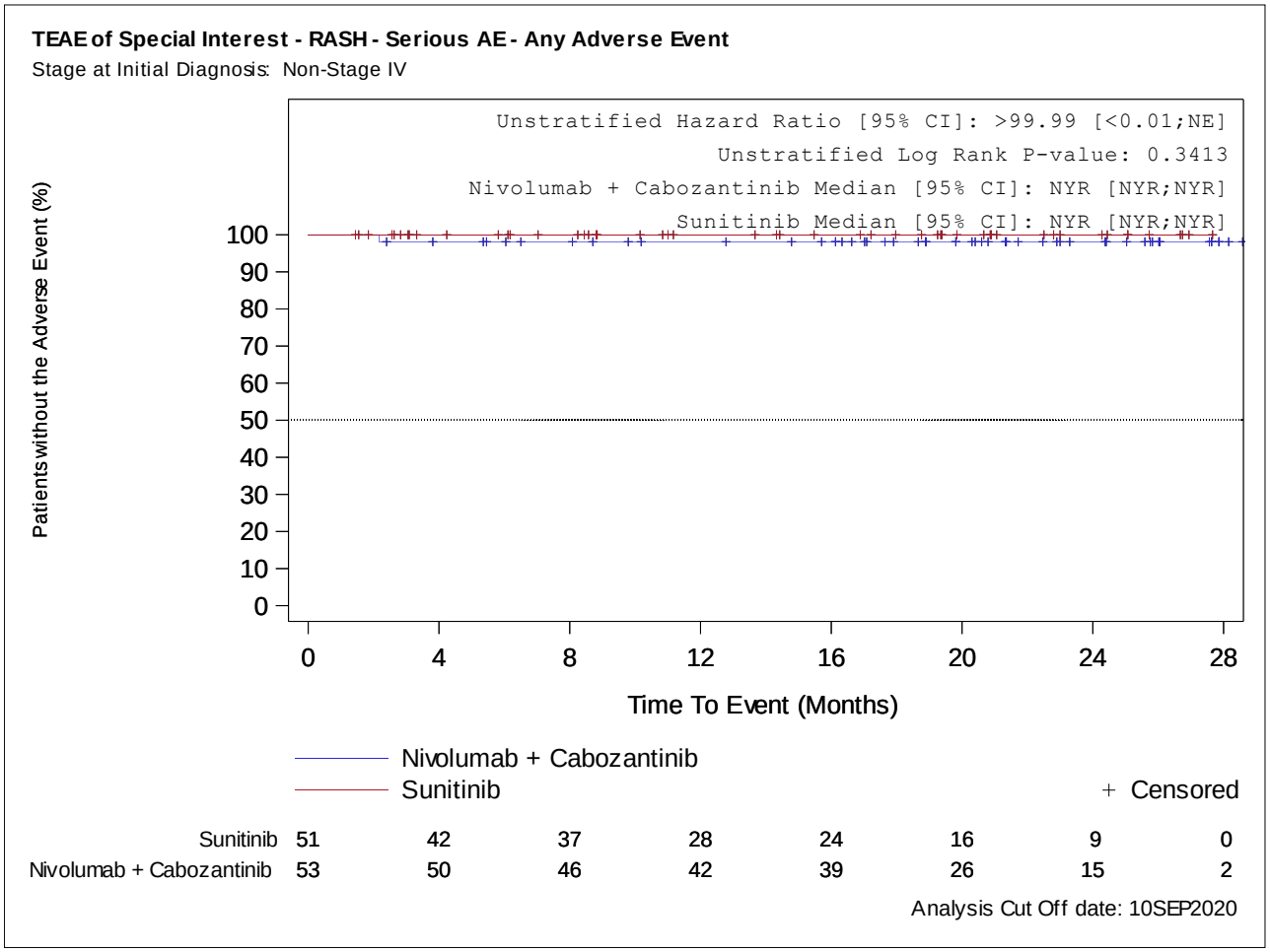
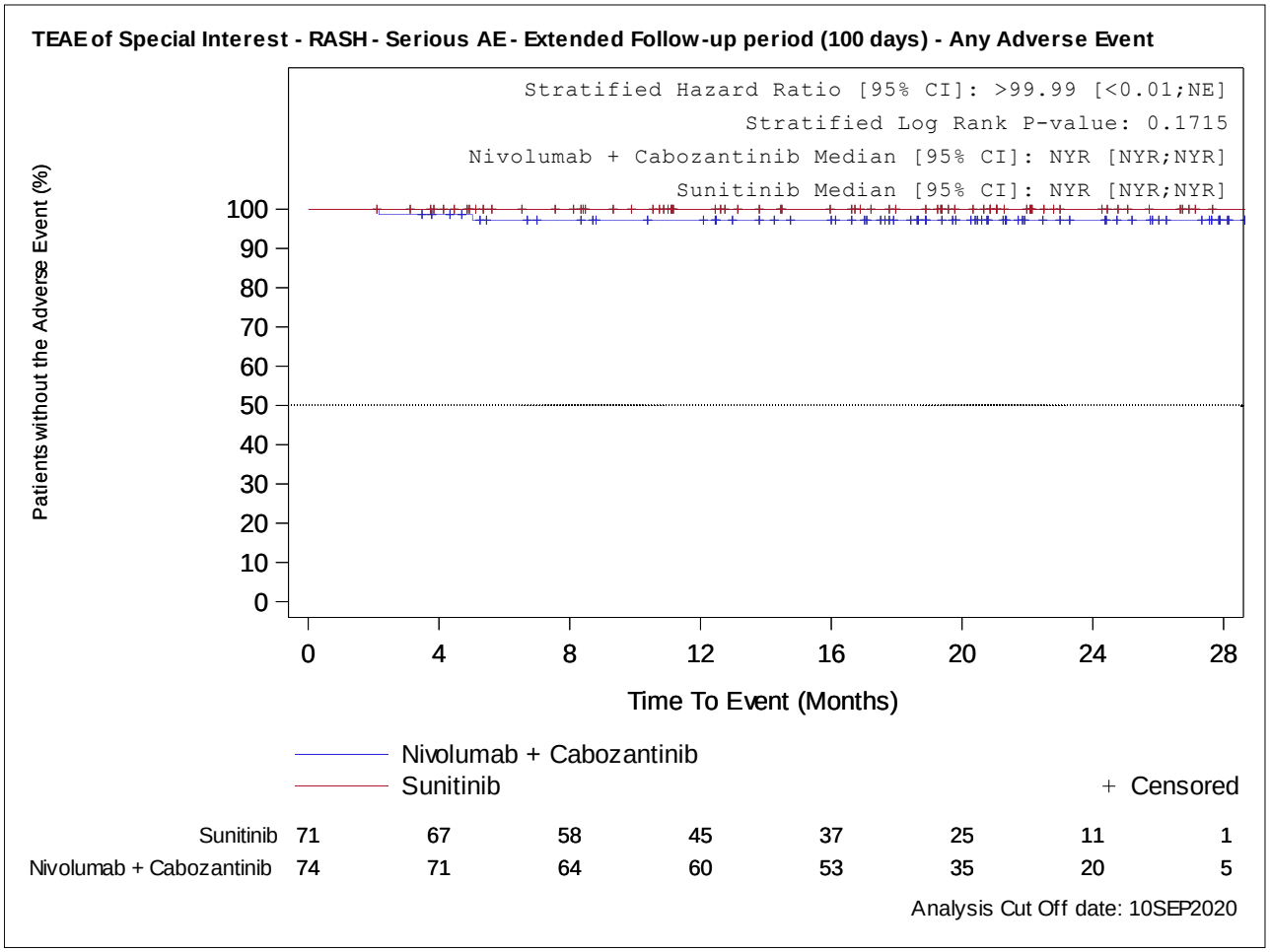
FIGURE 3.135.2.24: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



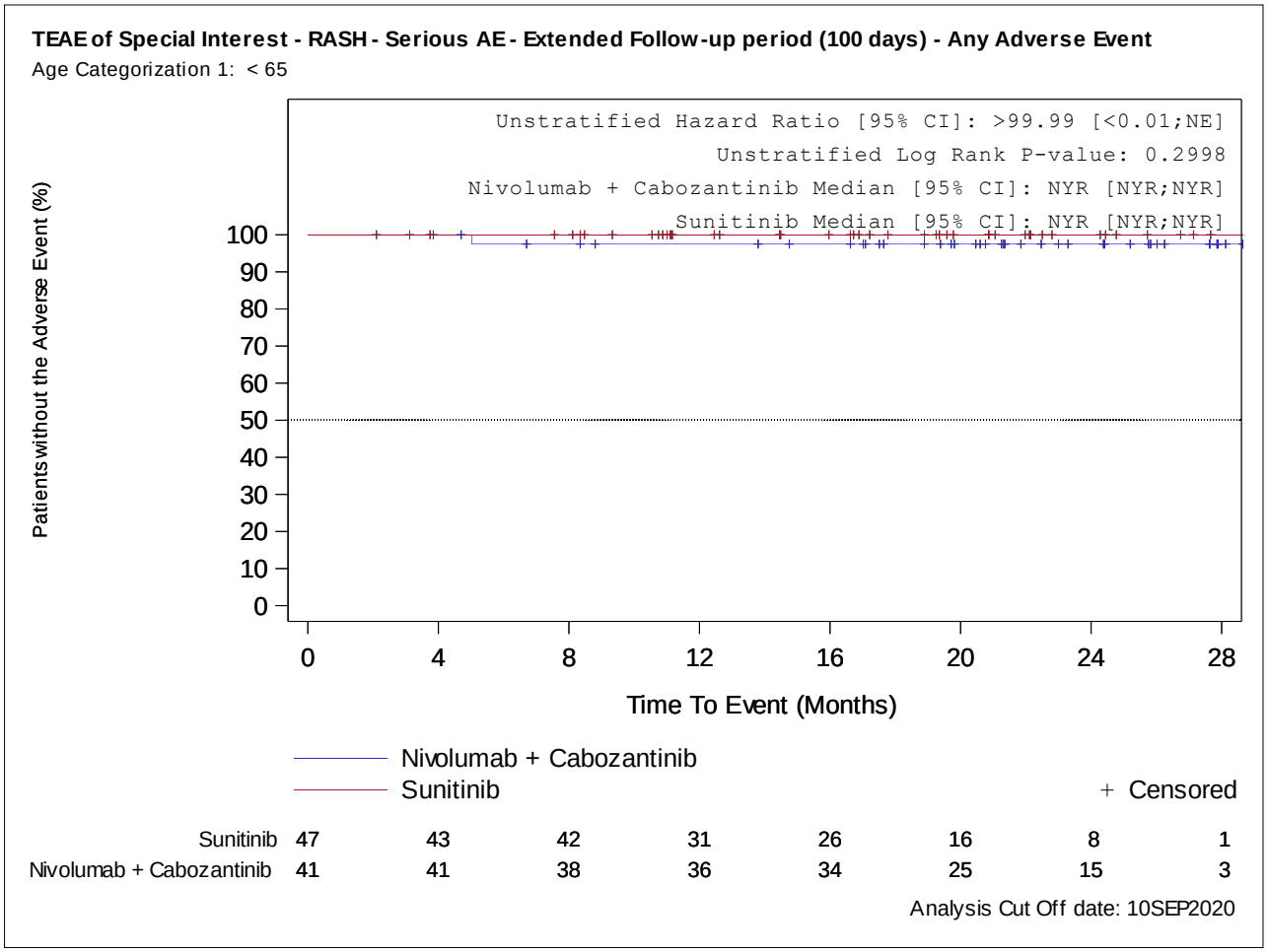

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:20:50

FIGURE 3.136.1: TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



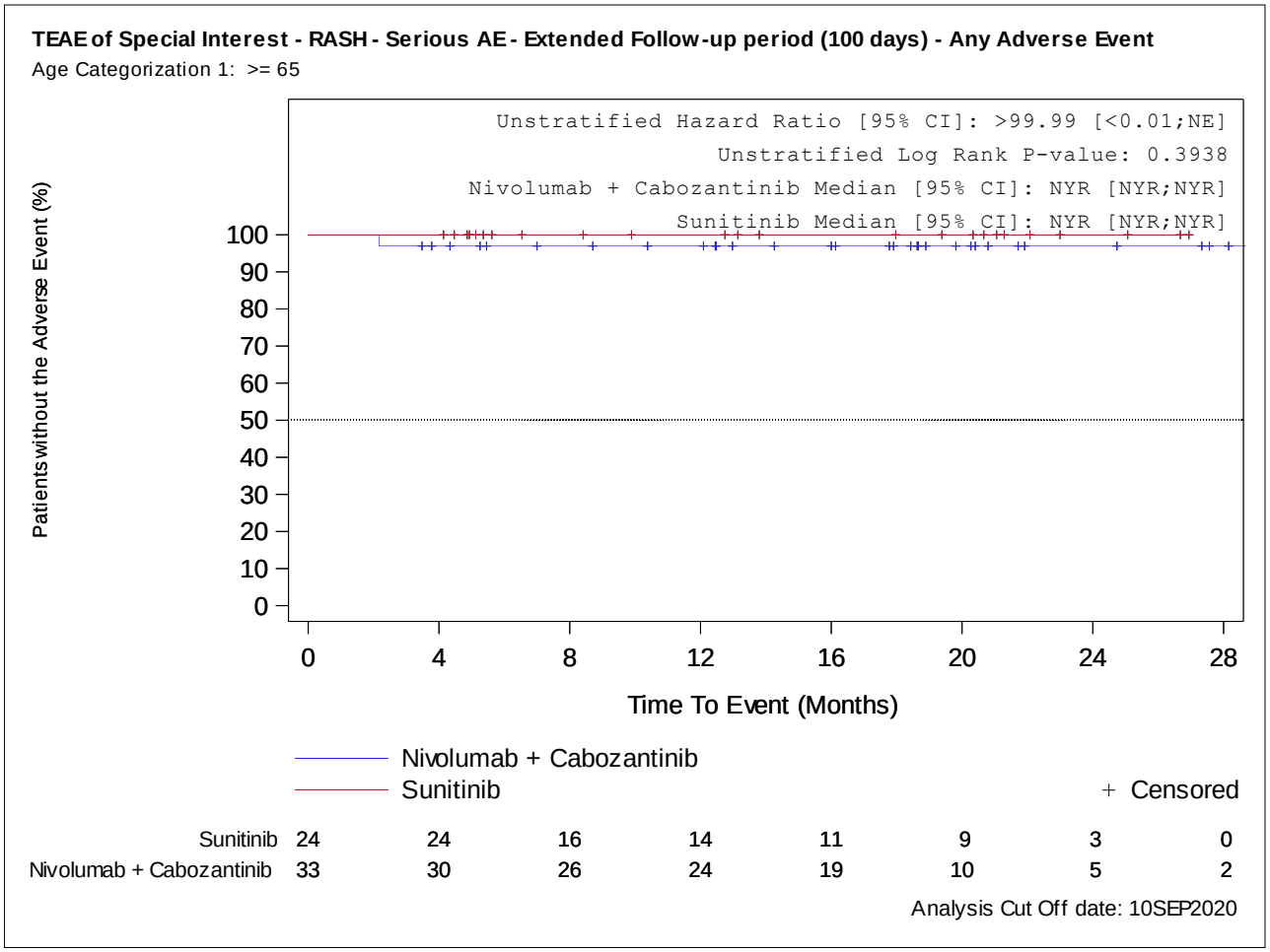

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:23:51

FIGURE 3.136.2.1: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



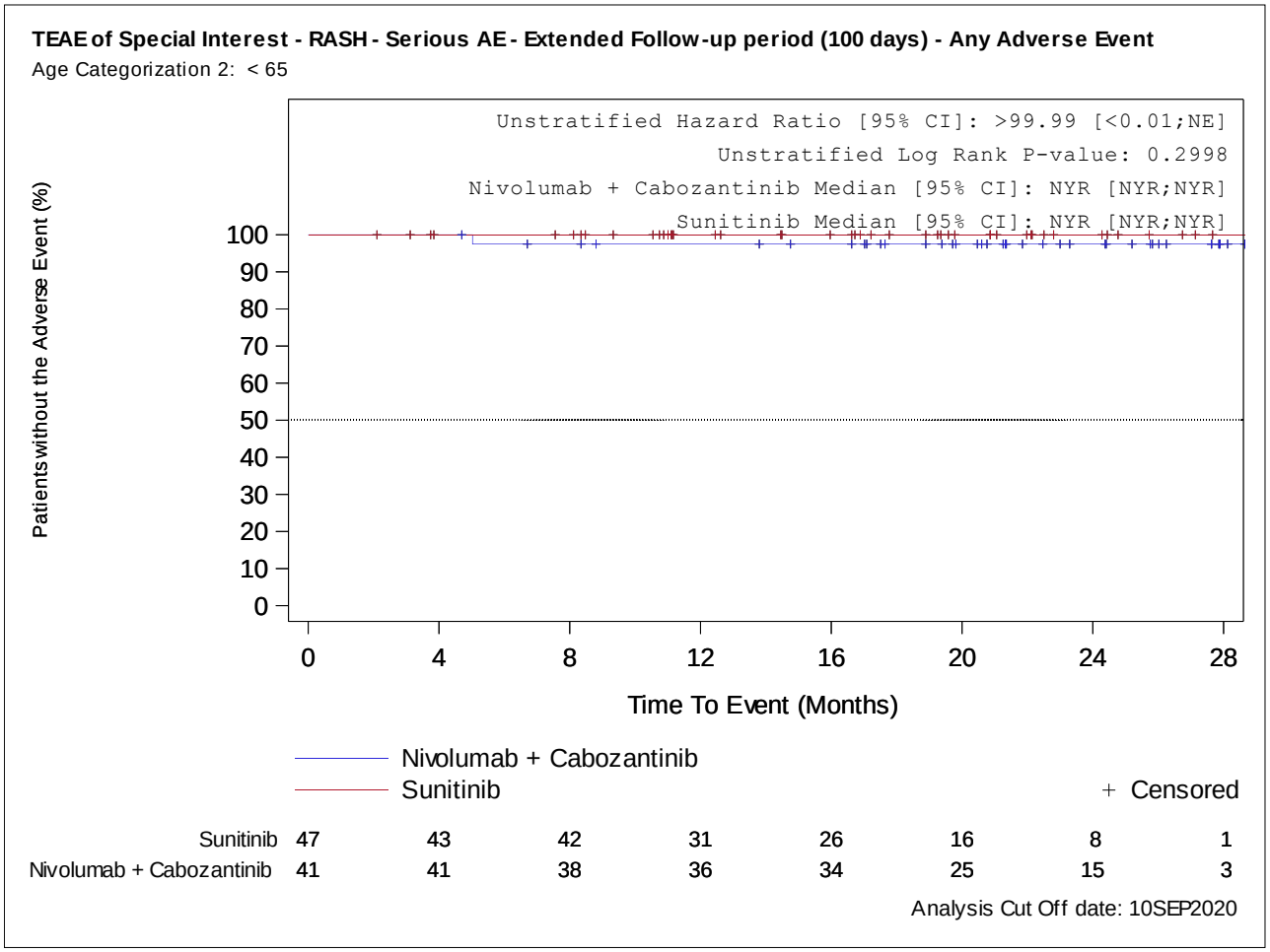

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:23:53

FIGURE 3.136.2.2: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



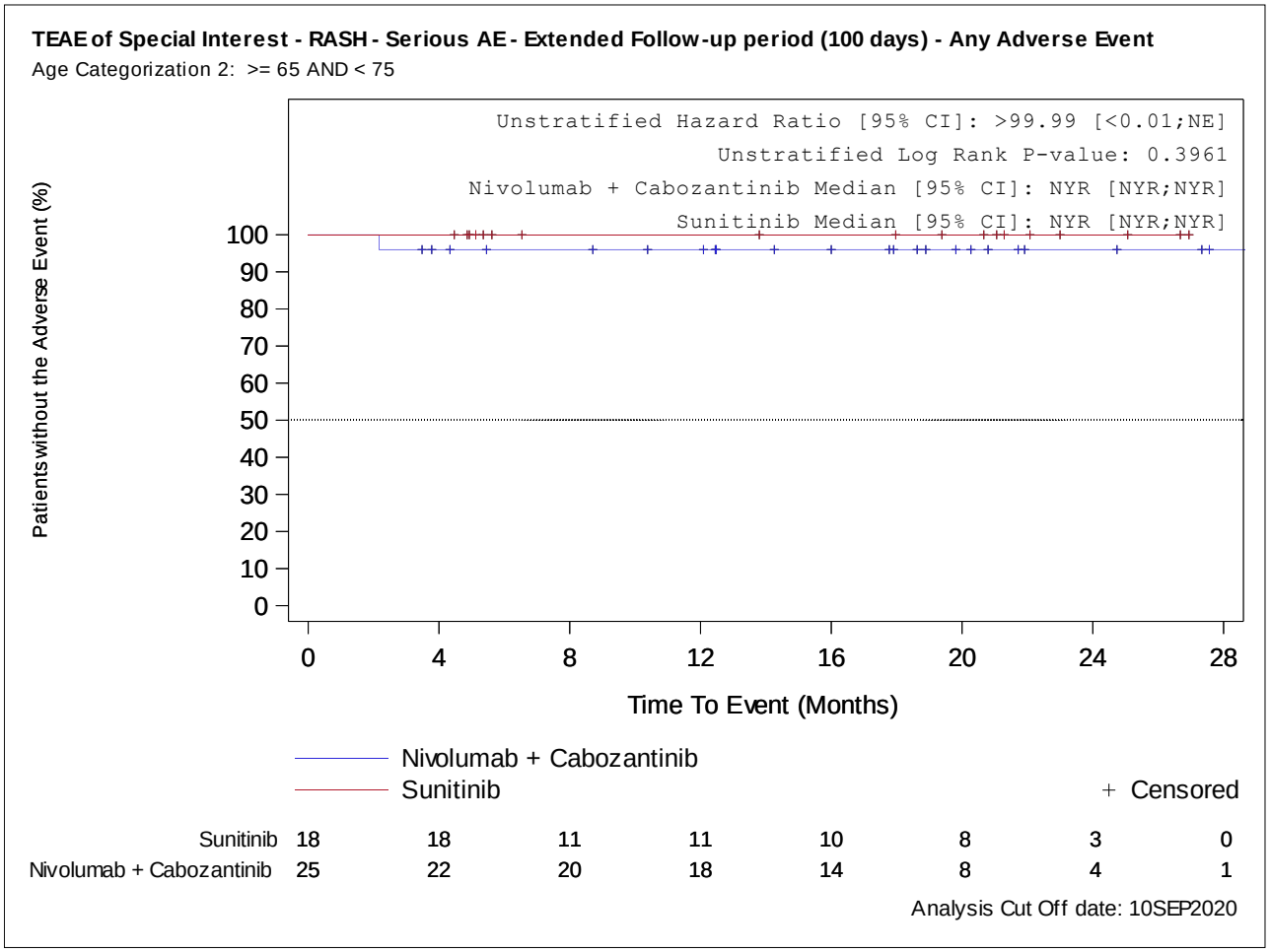

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:23:59

FIGURE 3.136.2.3: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



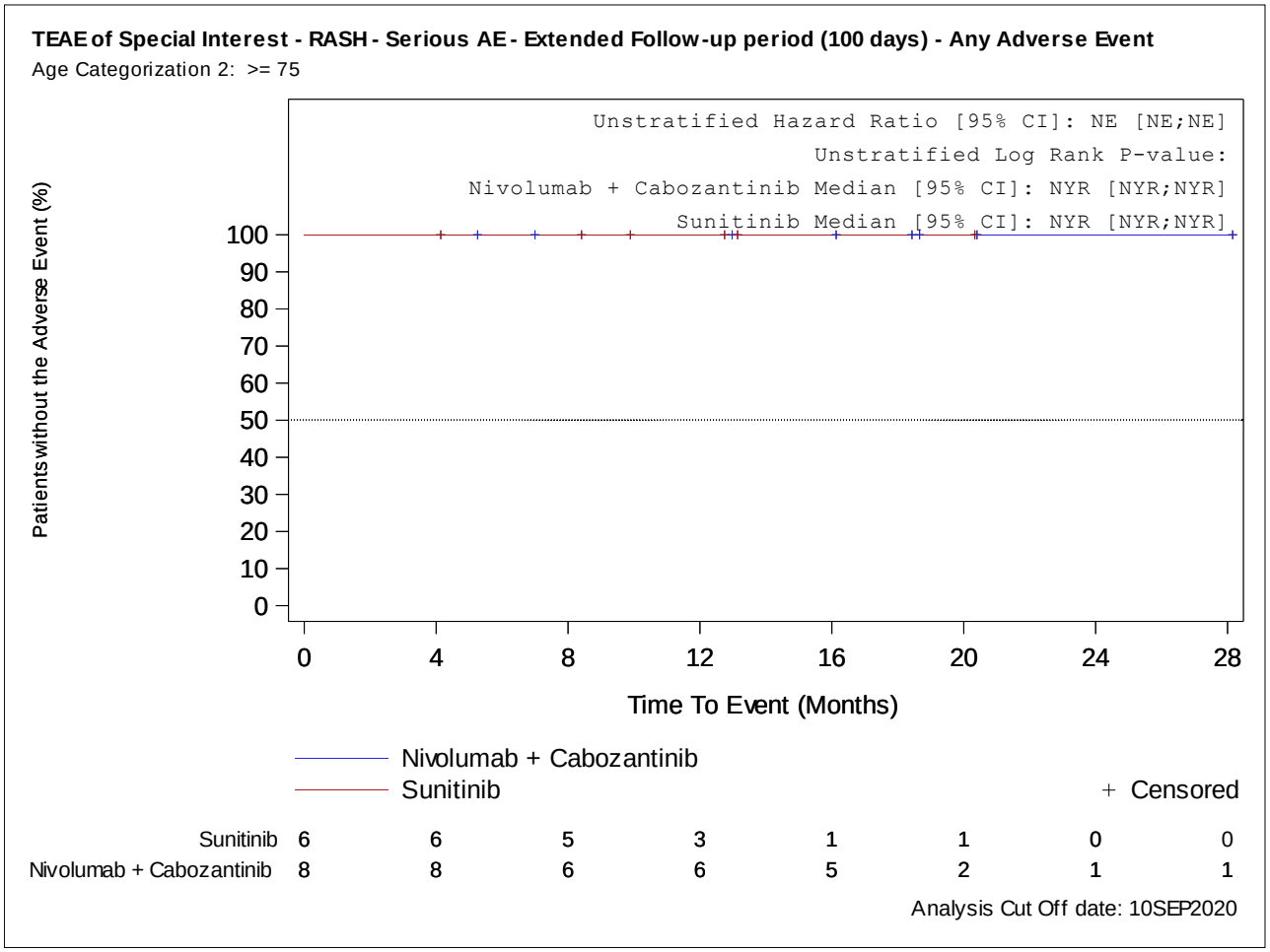

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:24:04

FIGURE 3.136.2.4: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



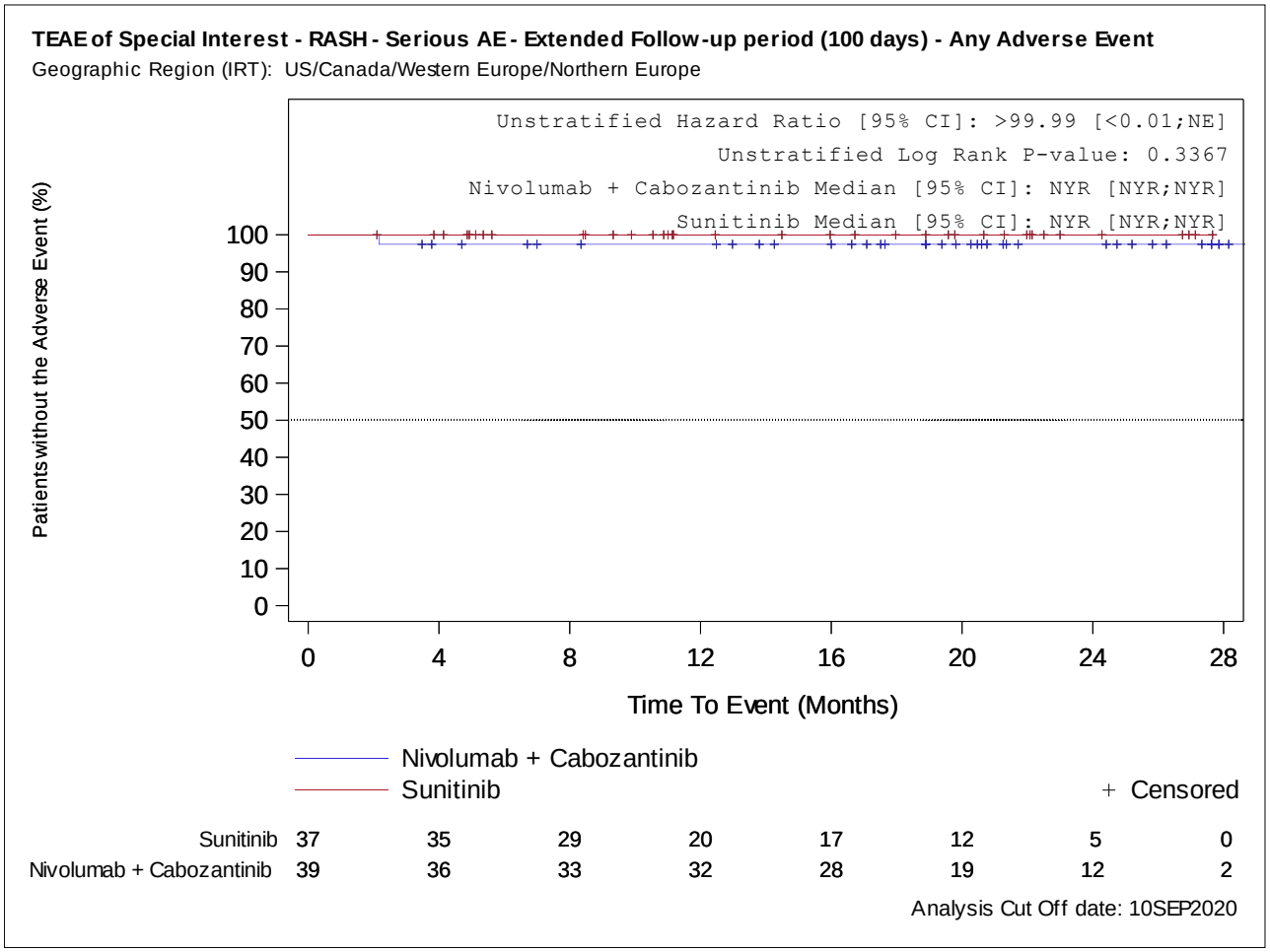

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:24:09

FIGURE 3.136.2.5: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



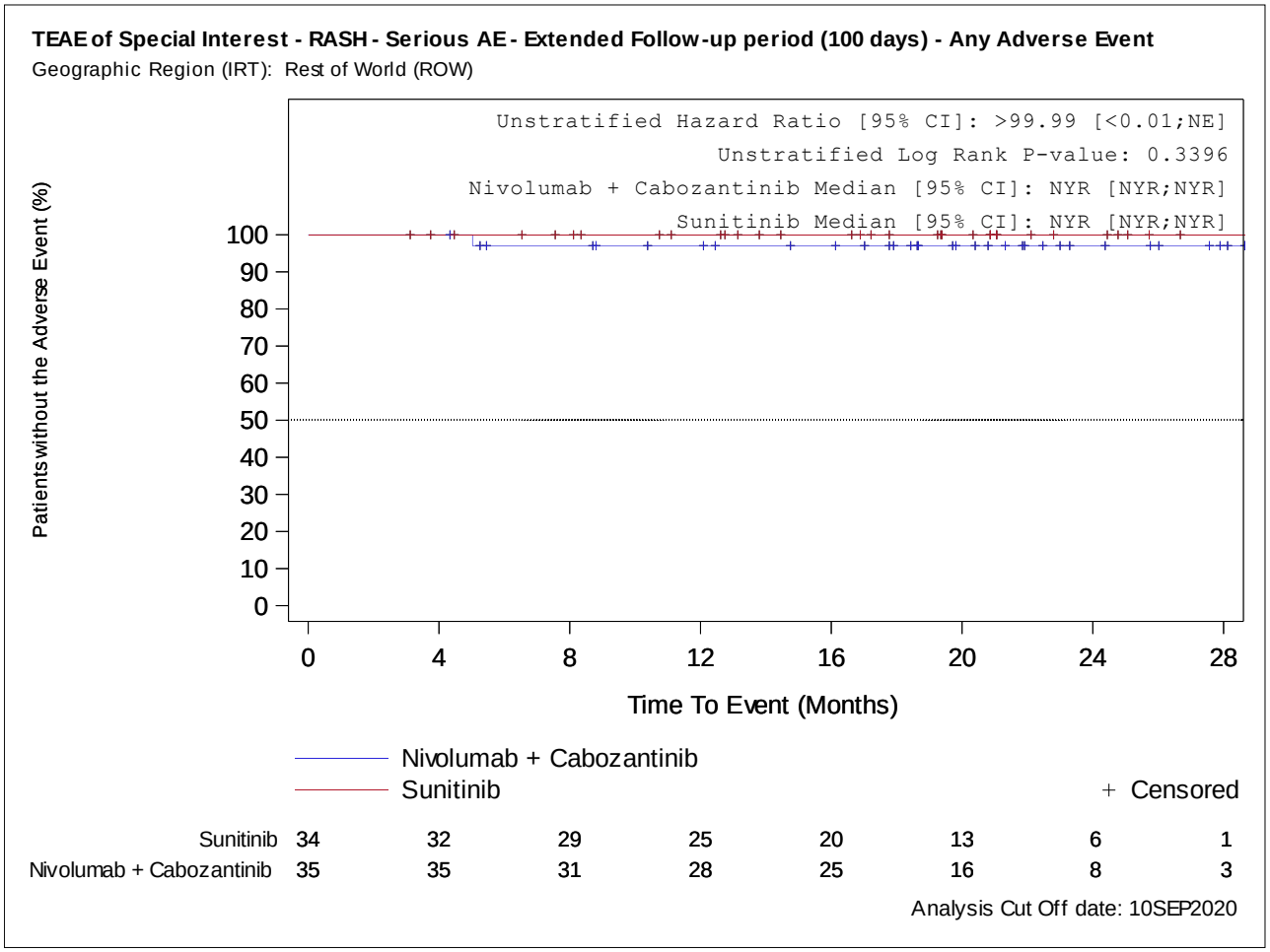

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:24:14

FIGURE 3.136.2.6: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



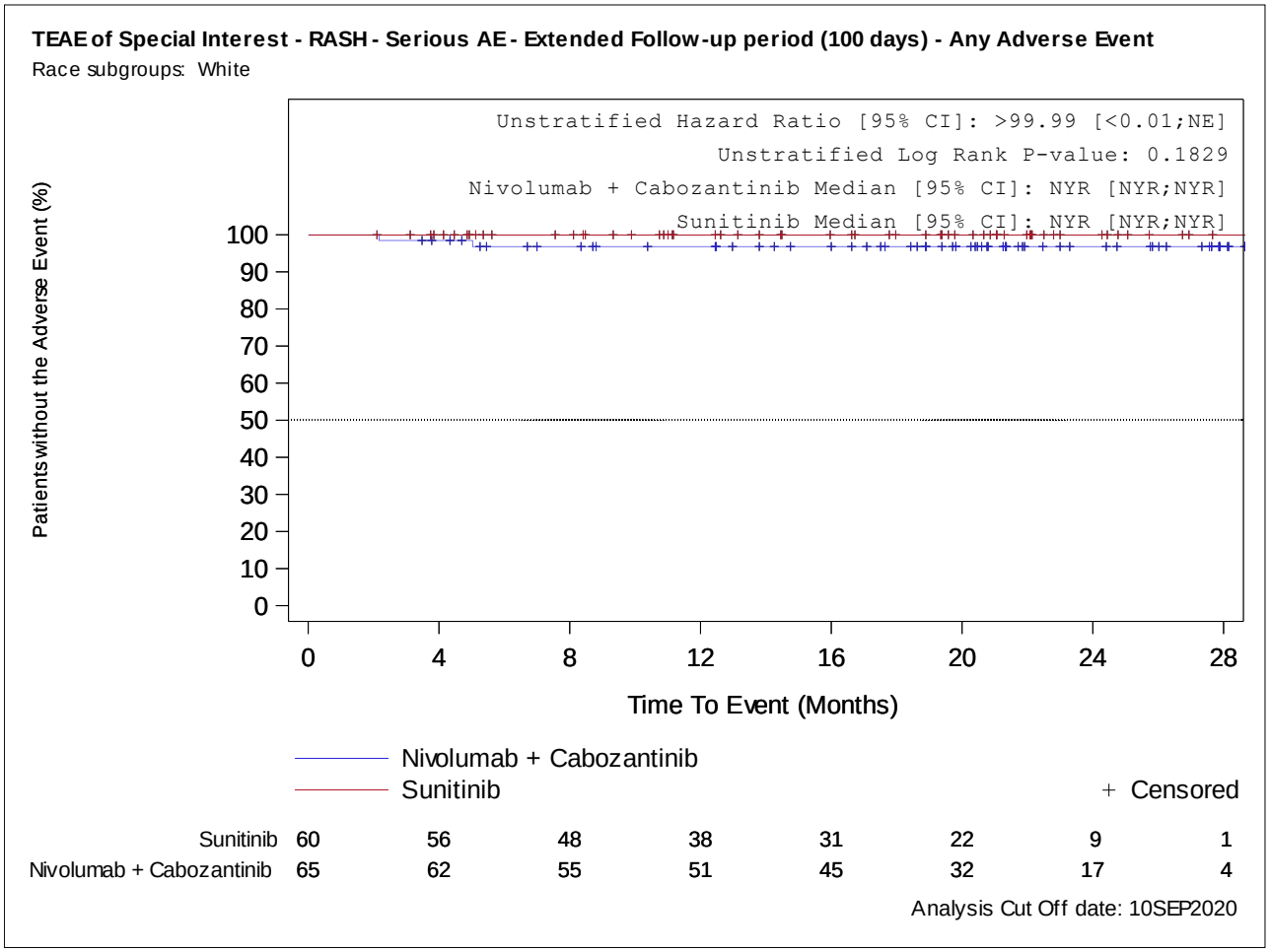

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:24:19

FIGURE 3.136.2.7: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



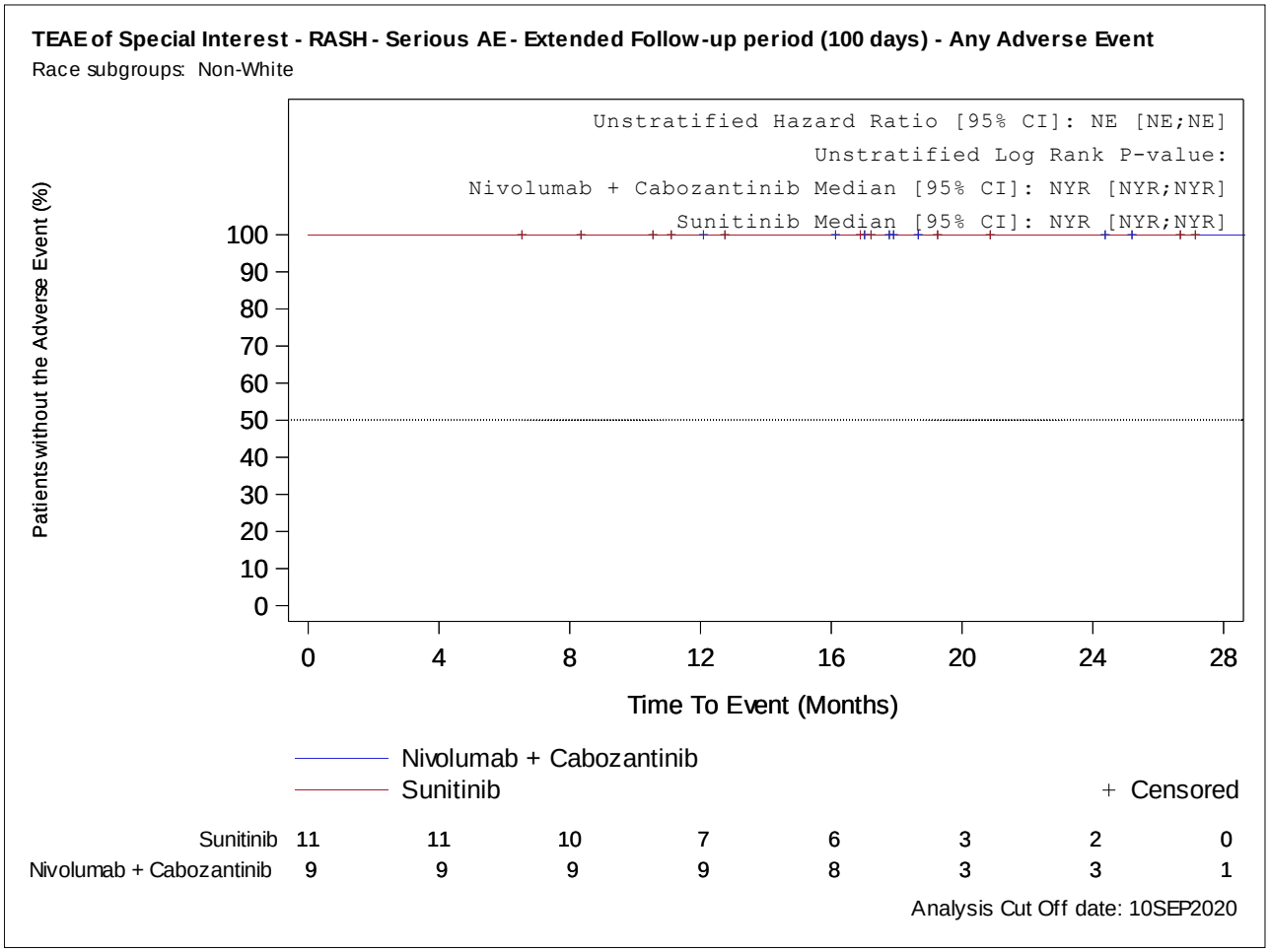

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:24:24

FIGURE 3.136.2.8: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



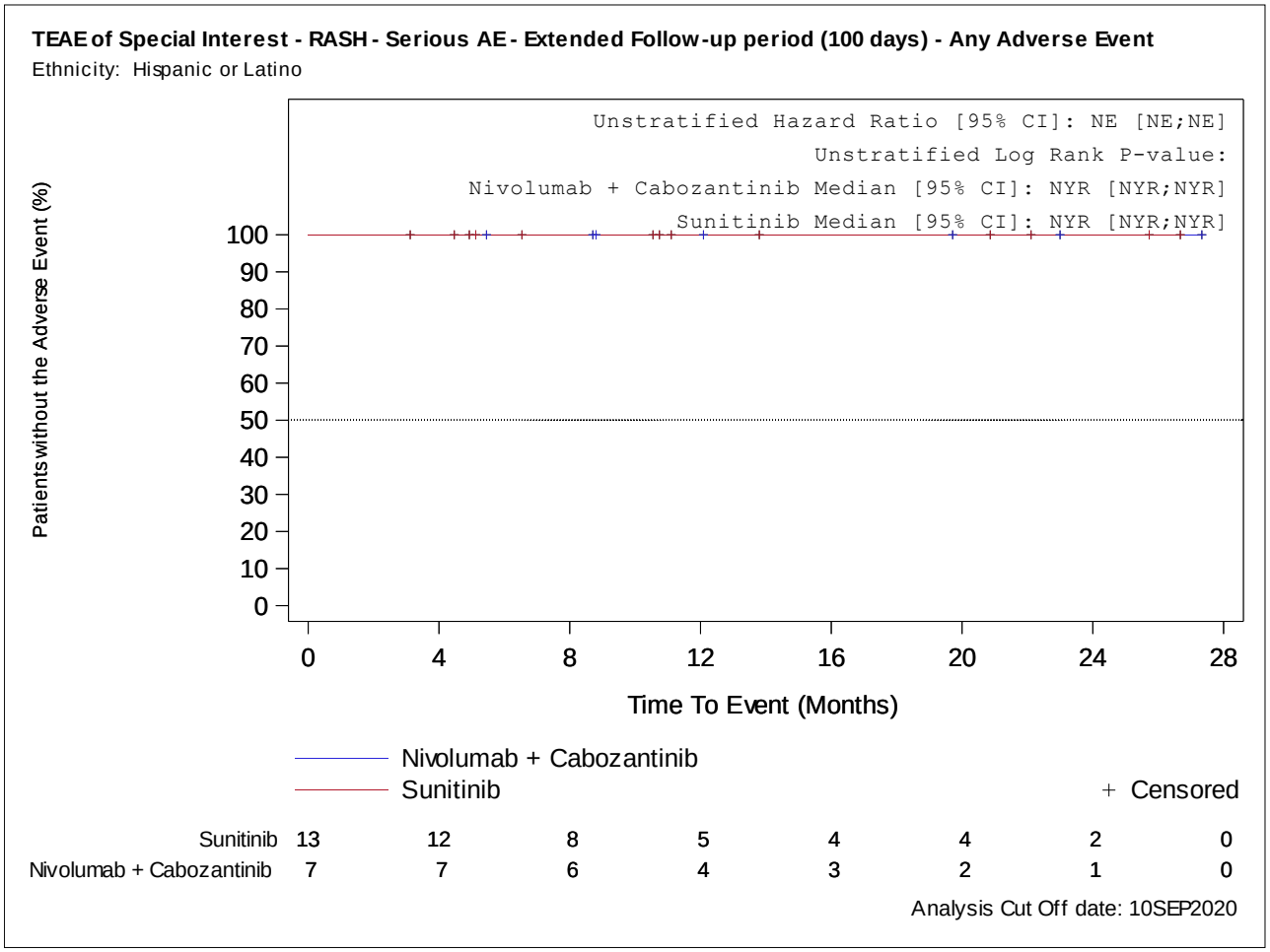

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:24:30

FIGURE 3.136.2.9: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



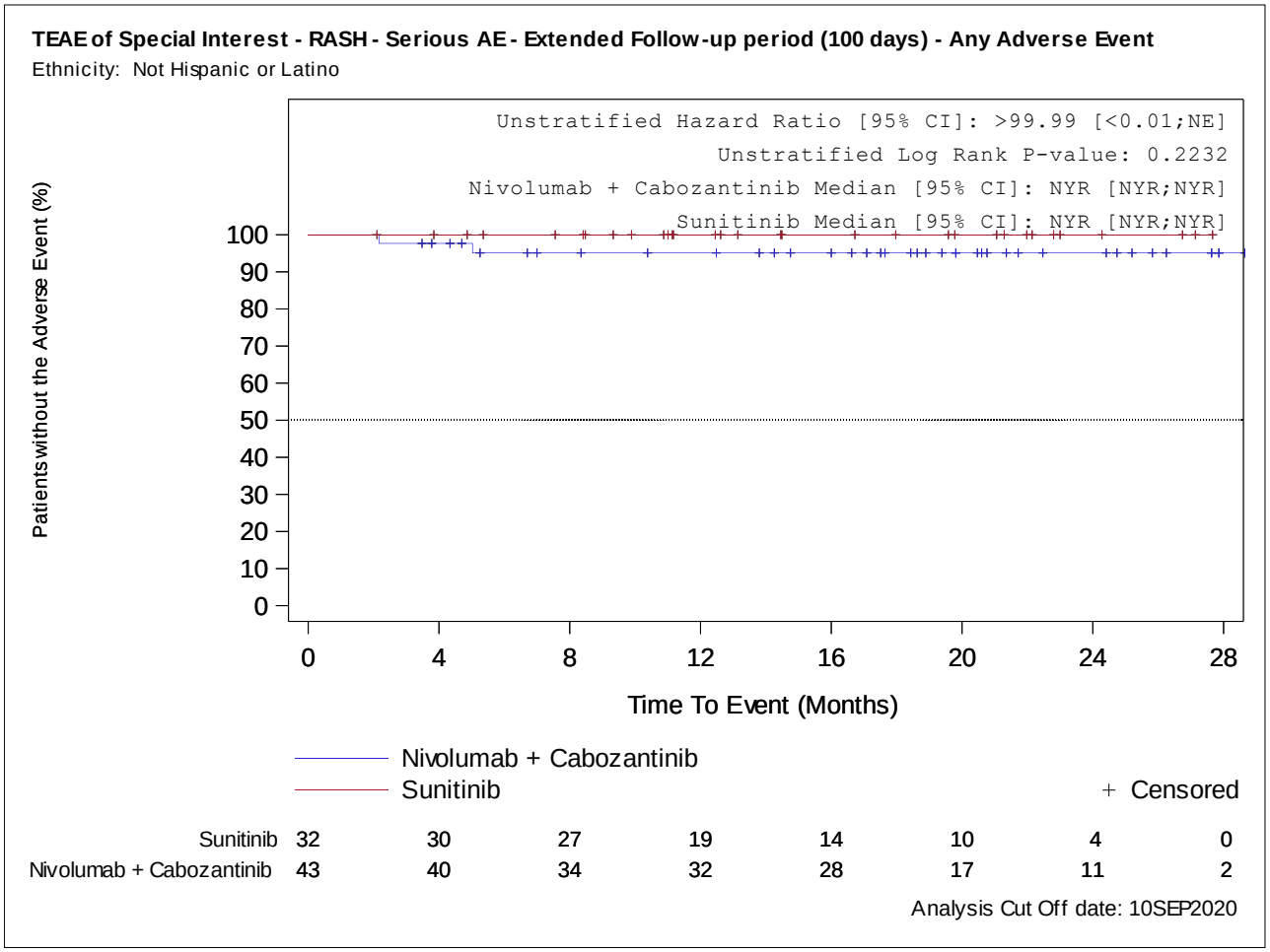

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:24:35

FIGURE 3.136.2.10: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



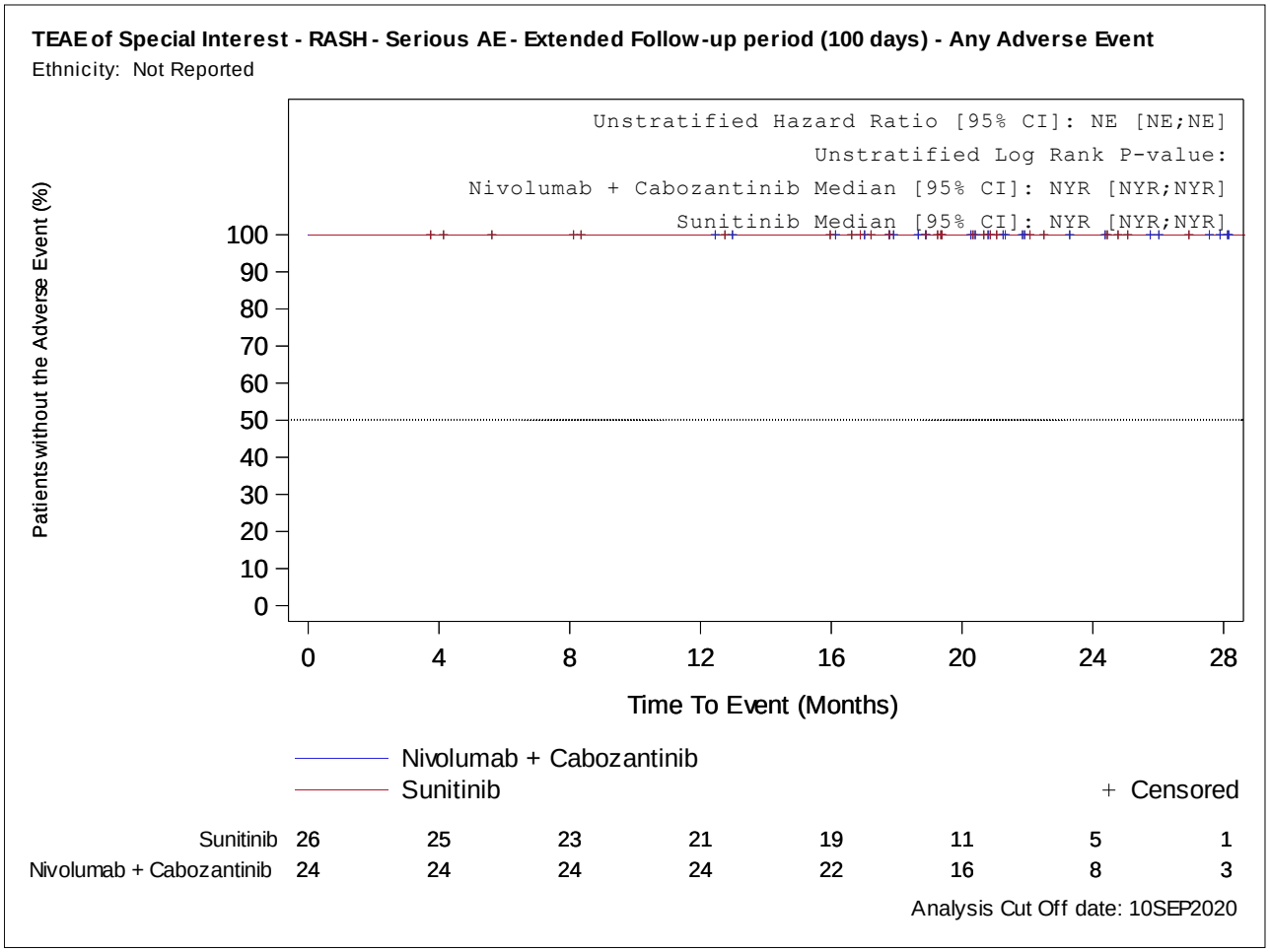

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:24:40

FIGURE 3.136.2.11: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



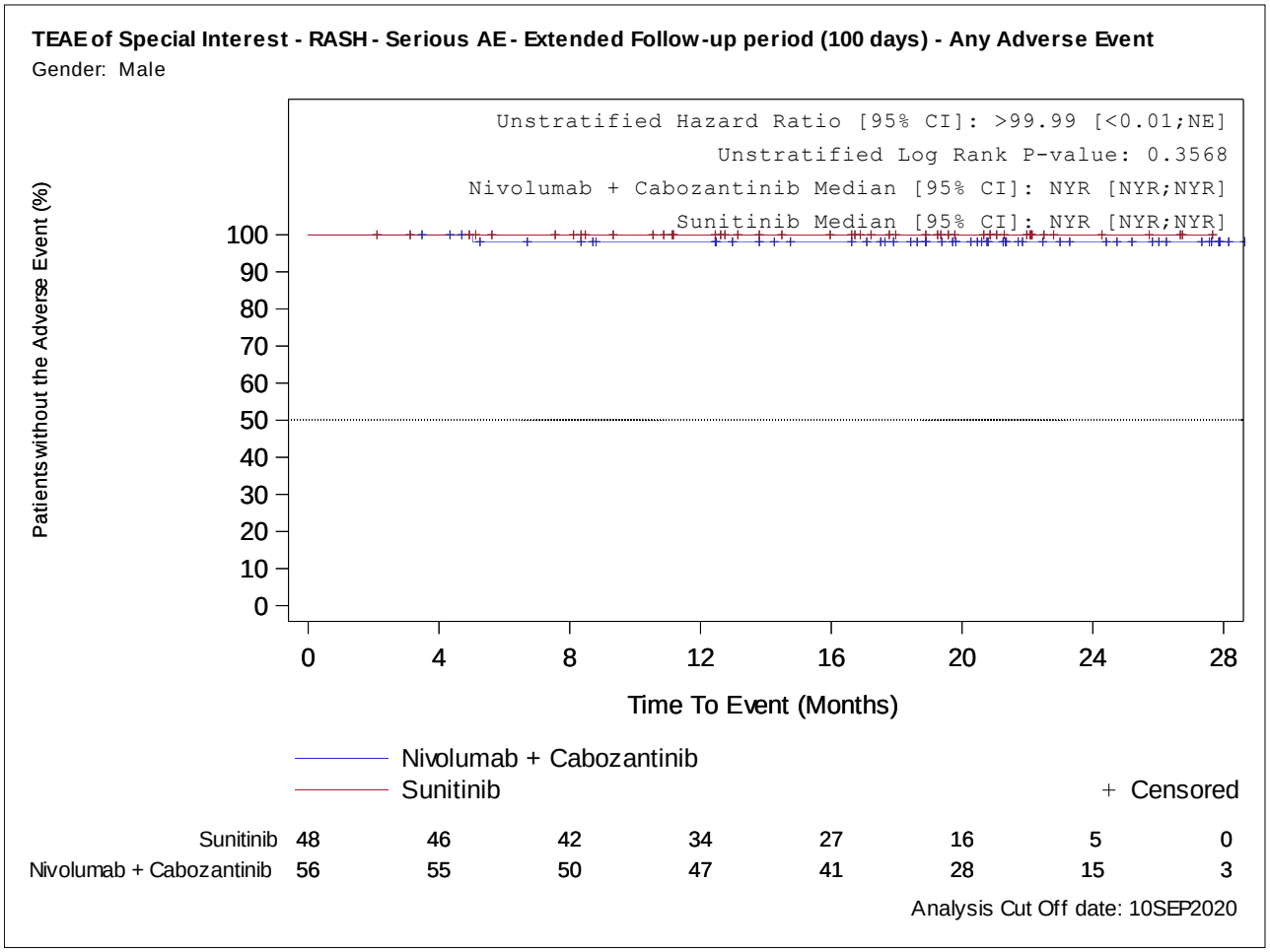

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:24:45

FIGURE 3.136.2.12: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



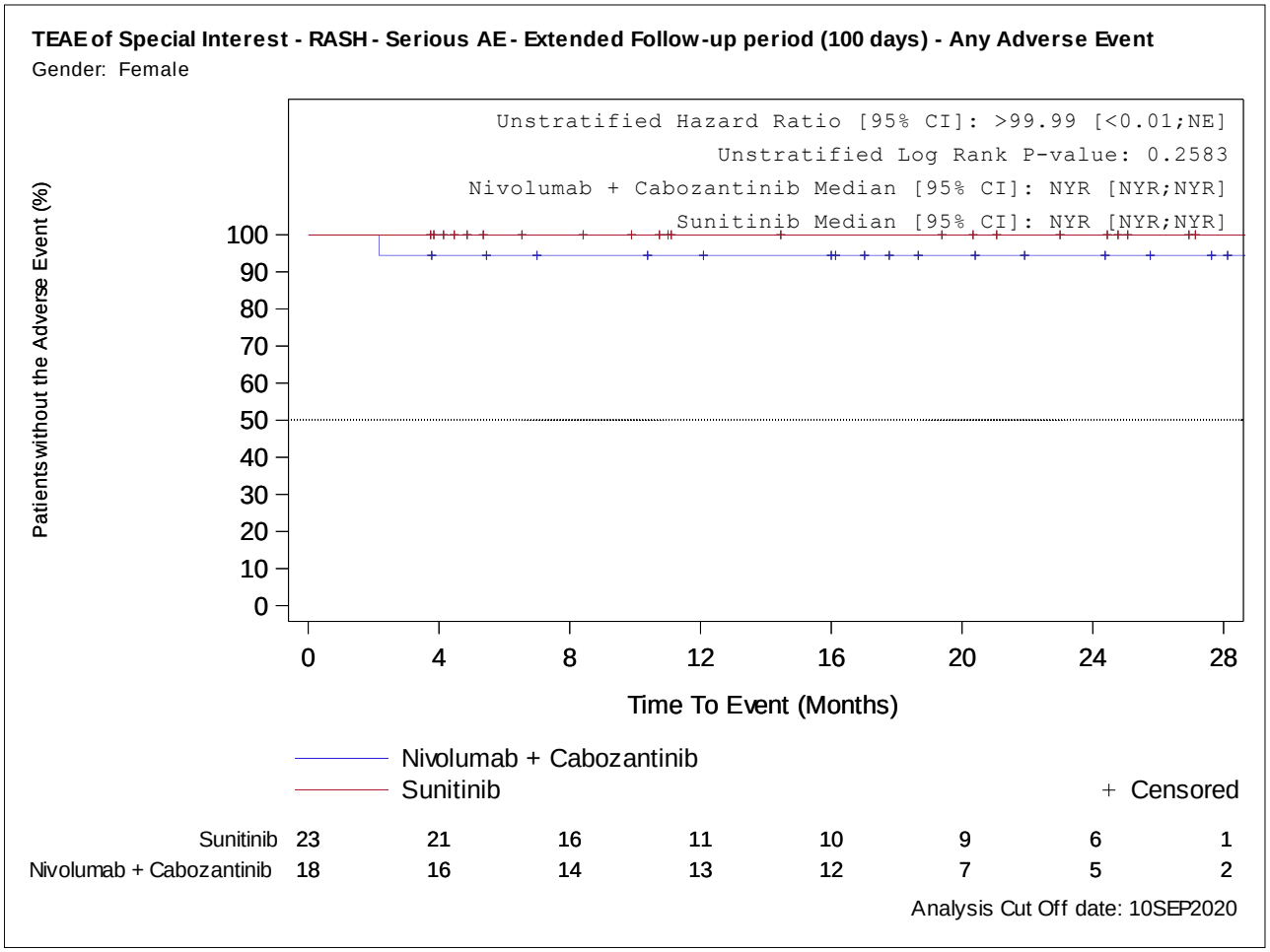

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:24:51

FIGURE 3.136.2.13: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



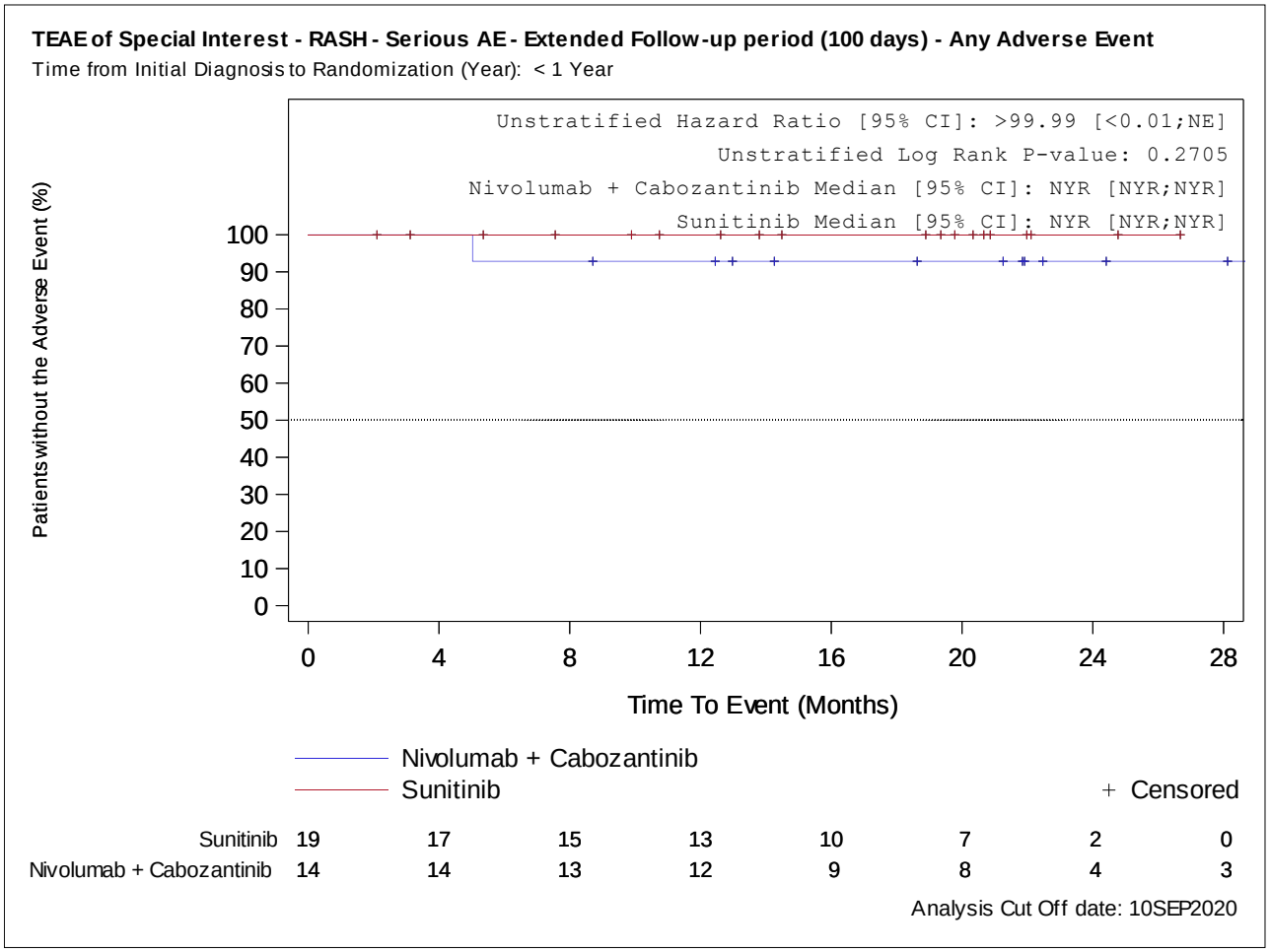

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:24:56

FIGURE 3.136.2.14: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



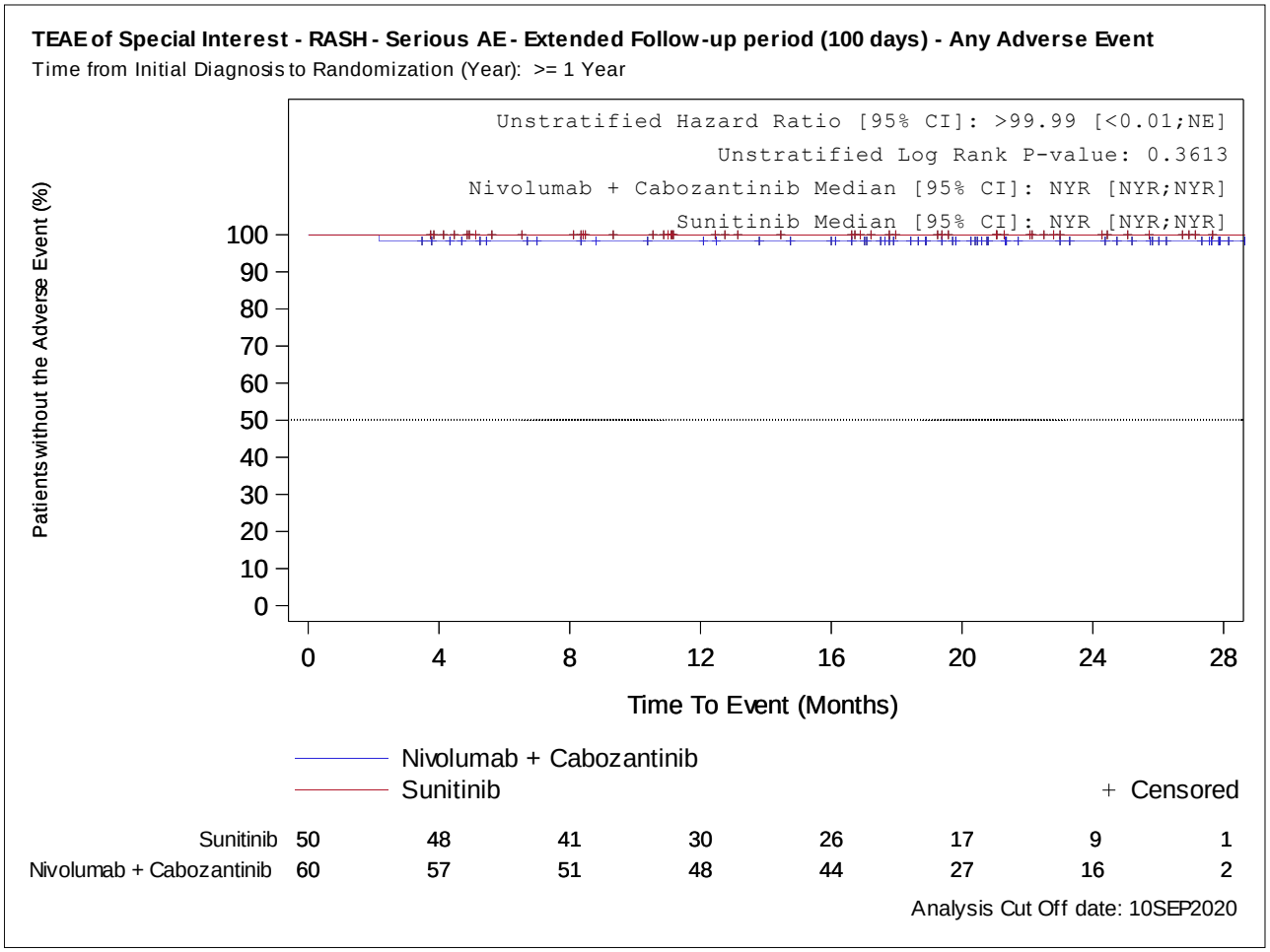

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:25:01

FIGURE 3.136.2.15: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



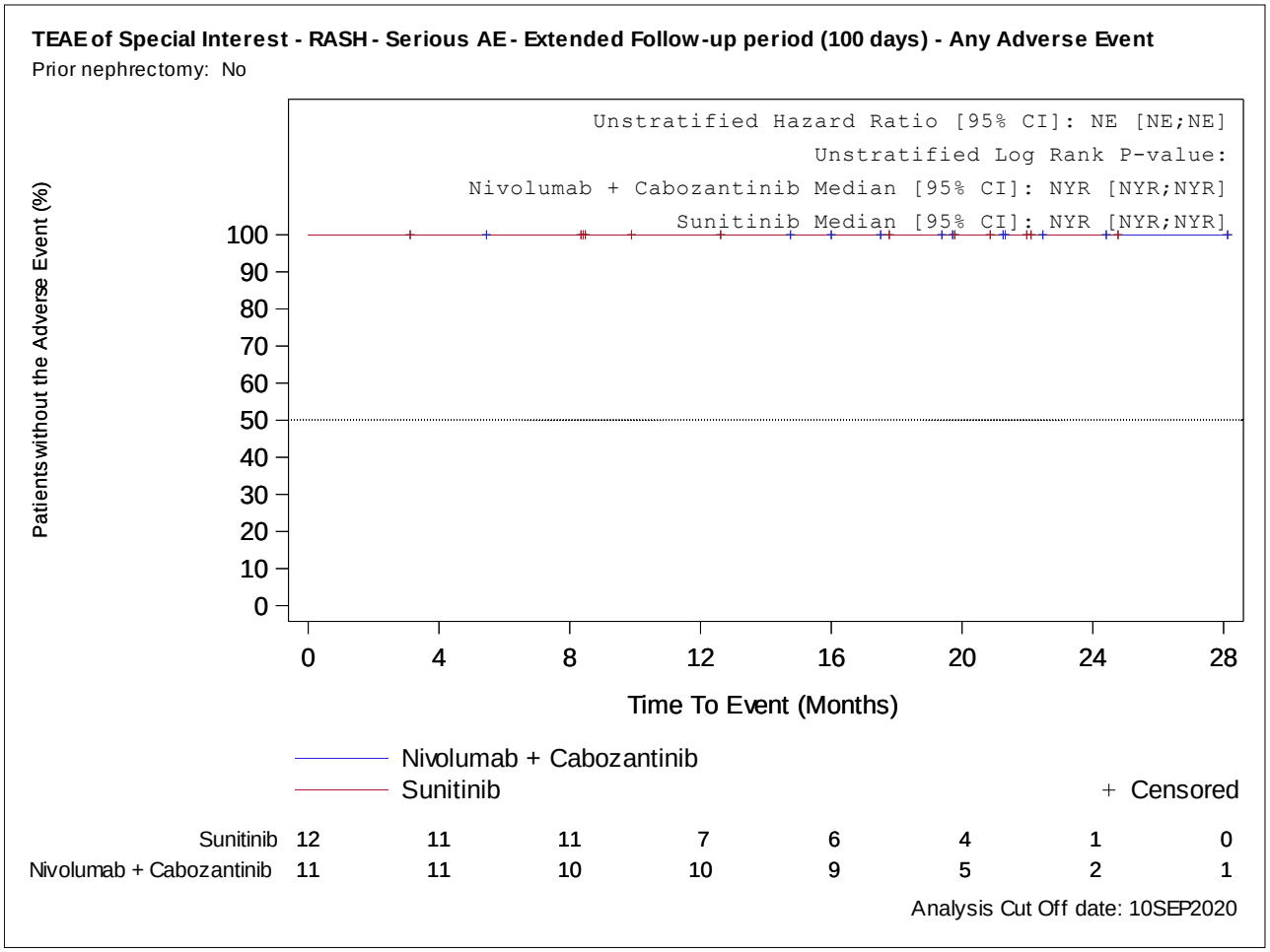

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:25:17

FIGURE 3.136.2.16: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



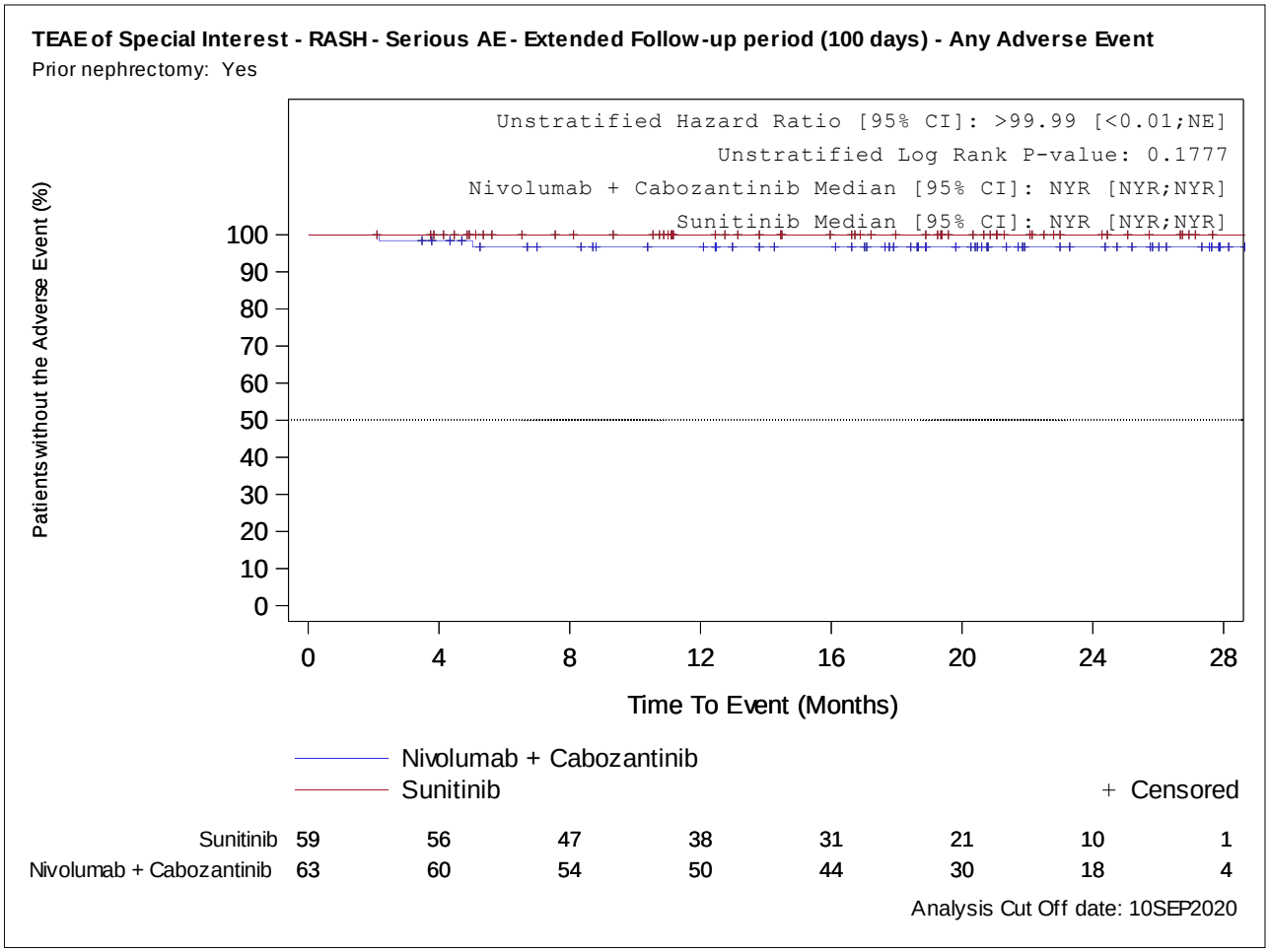

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:25:22

FIGURE 3.136.2.17: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



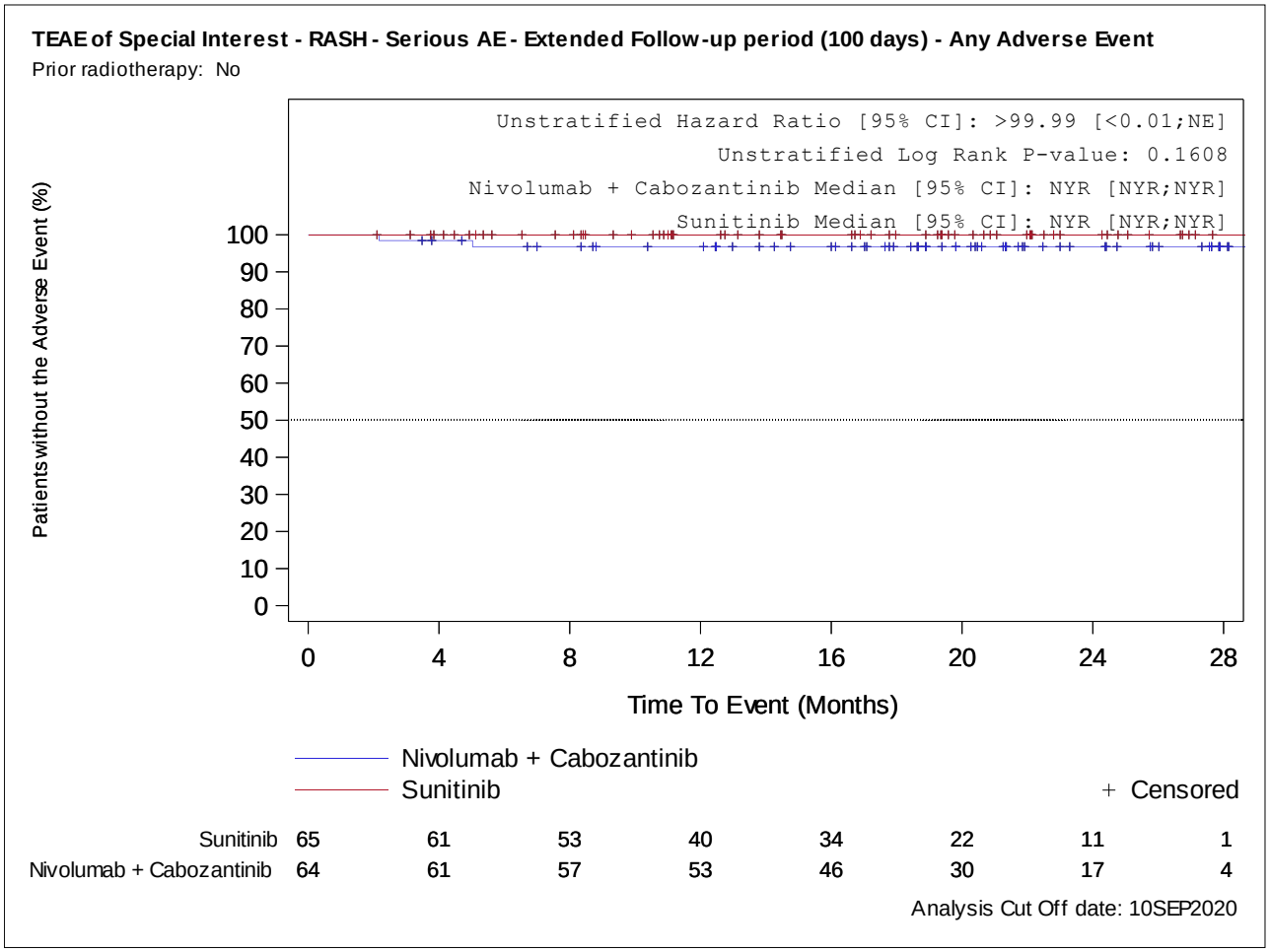

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:26:12

FIGURE 3.136.2.18: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



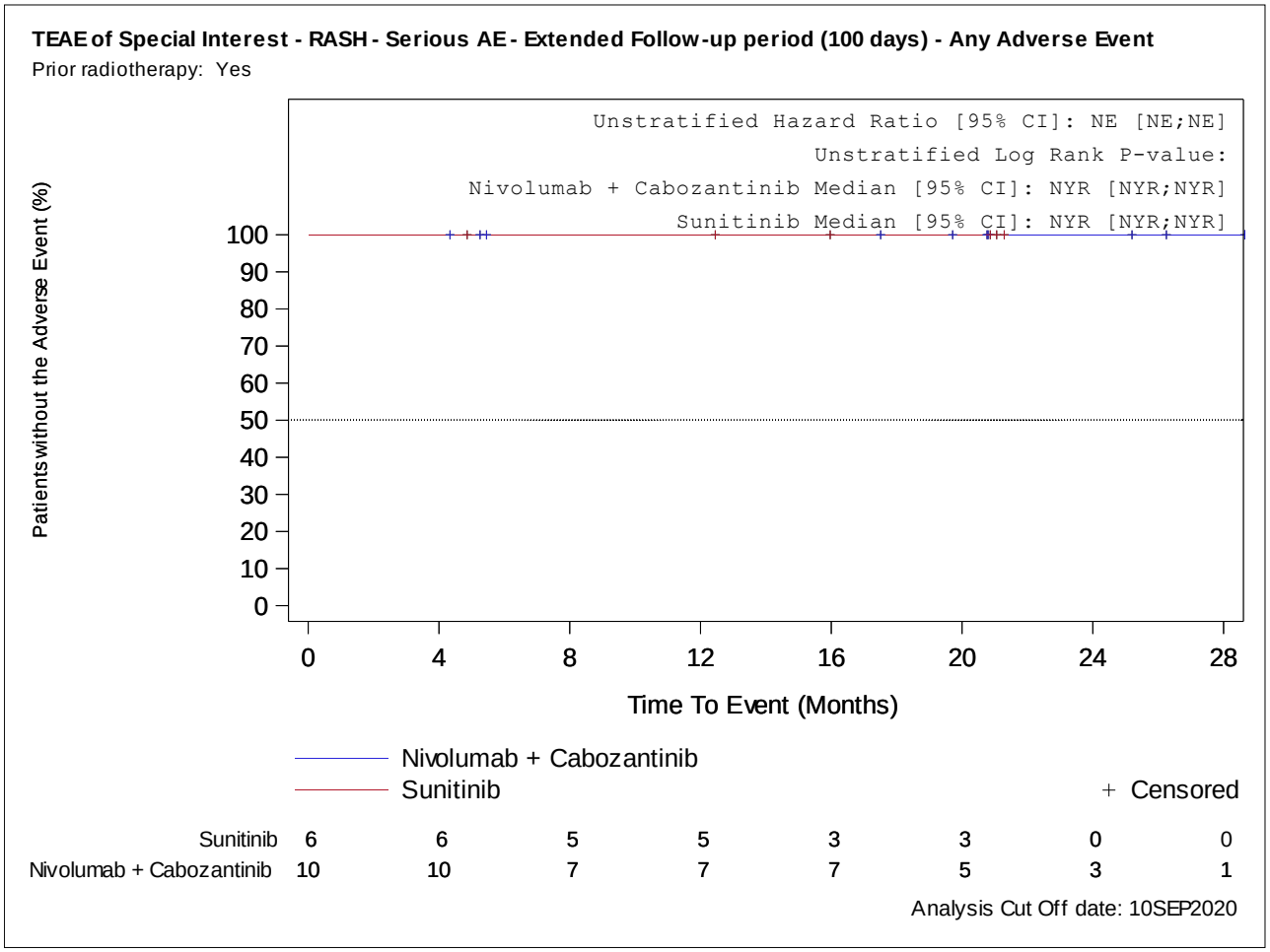

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:26:17

FIGURE 3.136.2.19: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



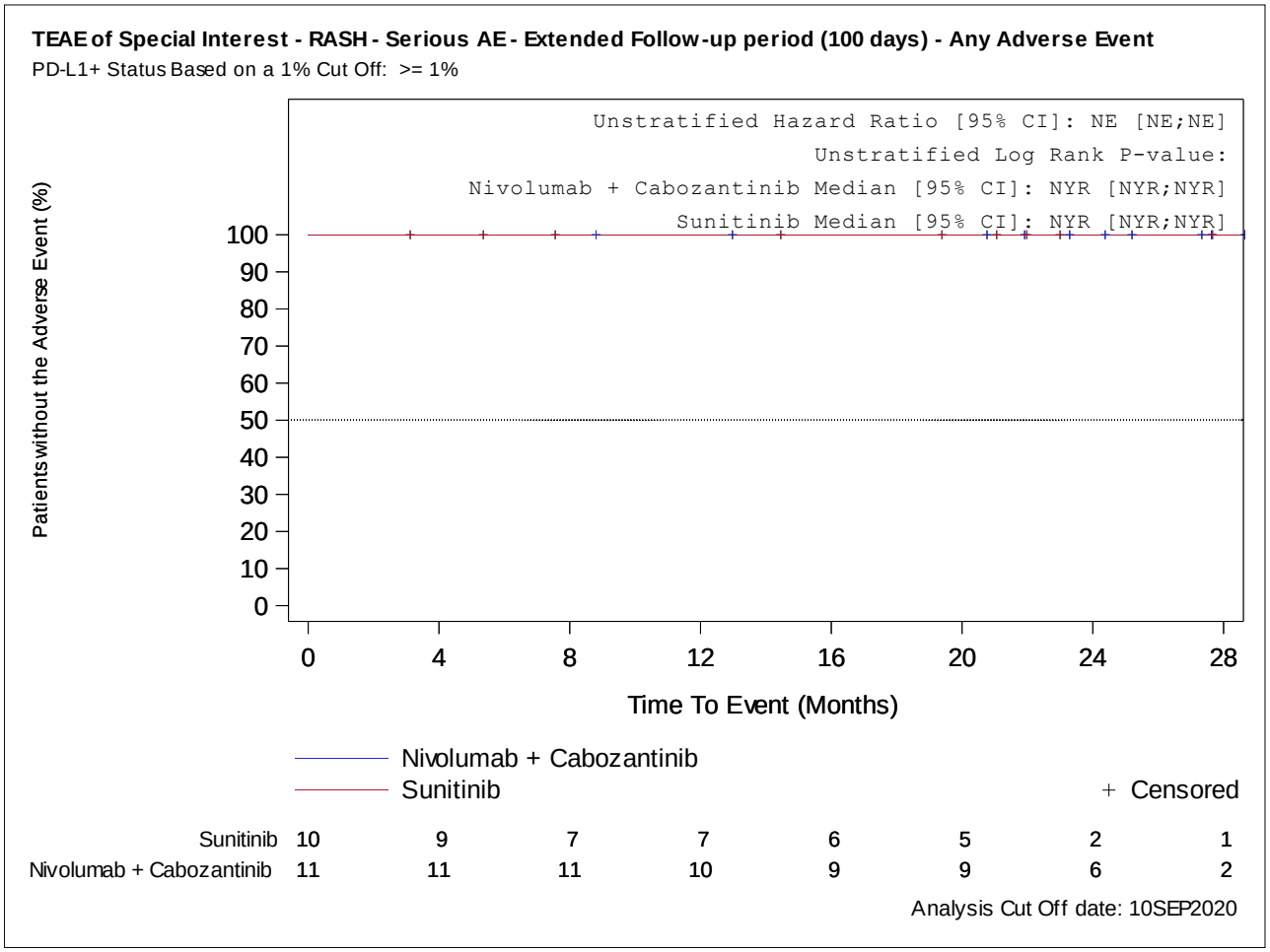

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:26:22

FIGURE 3.136.2.20: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



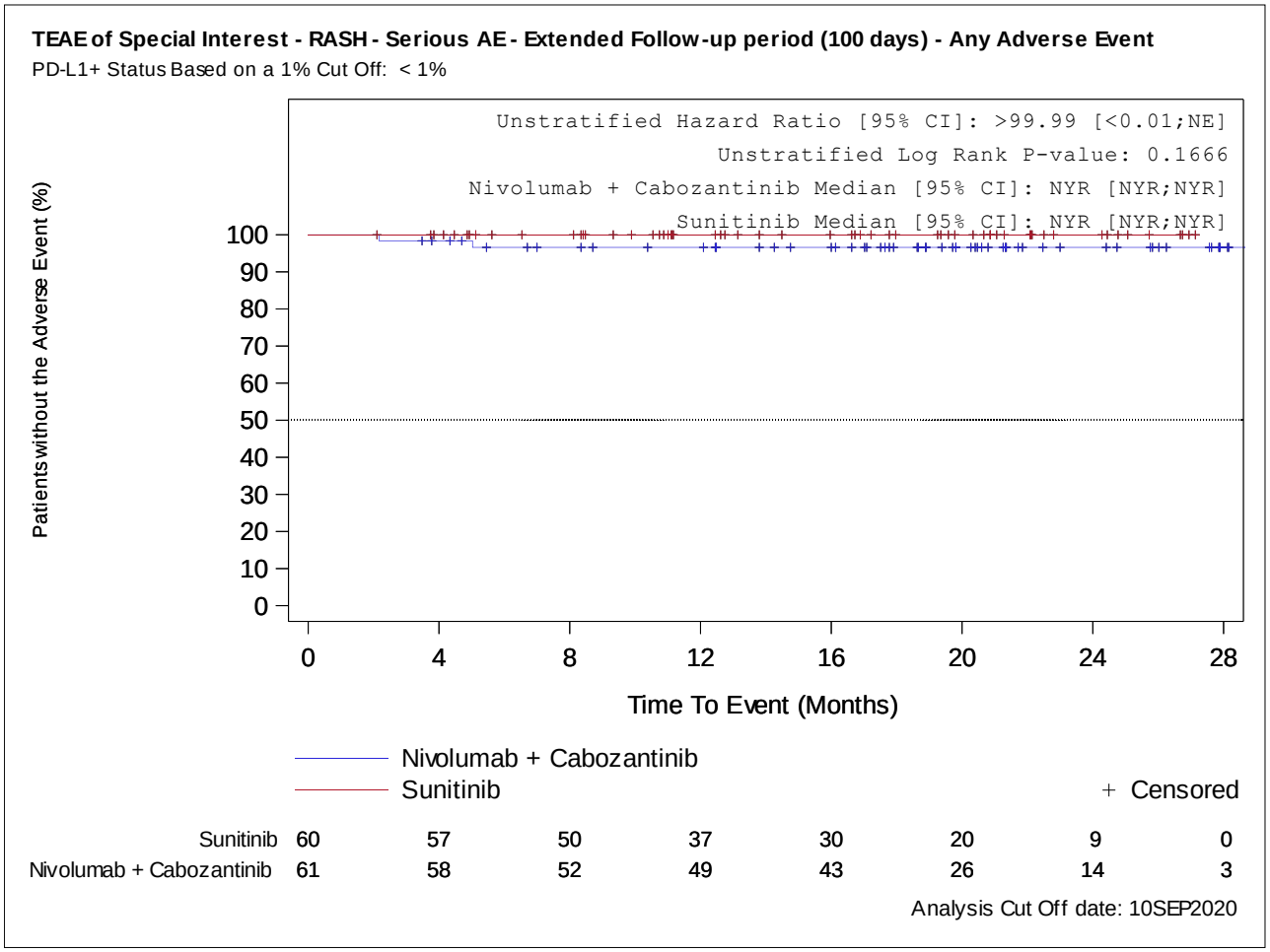

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:26:27

FIGURE 3.136.2.21: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



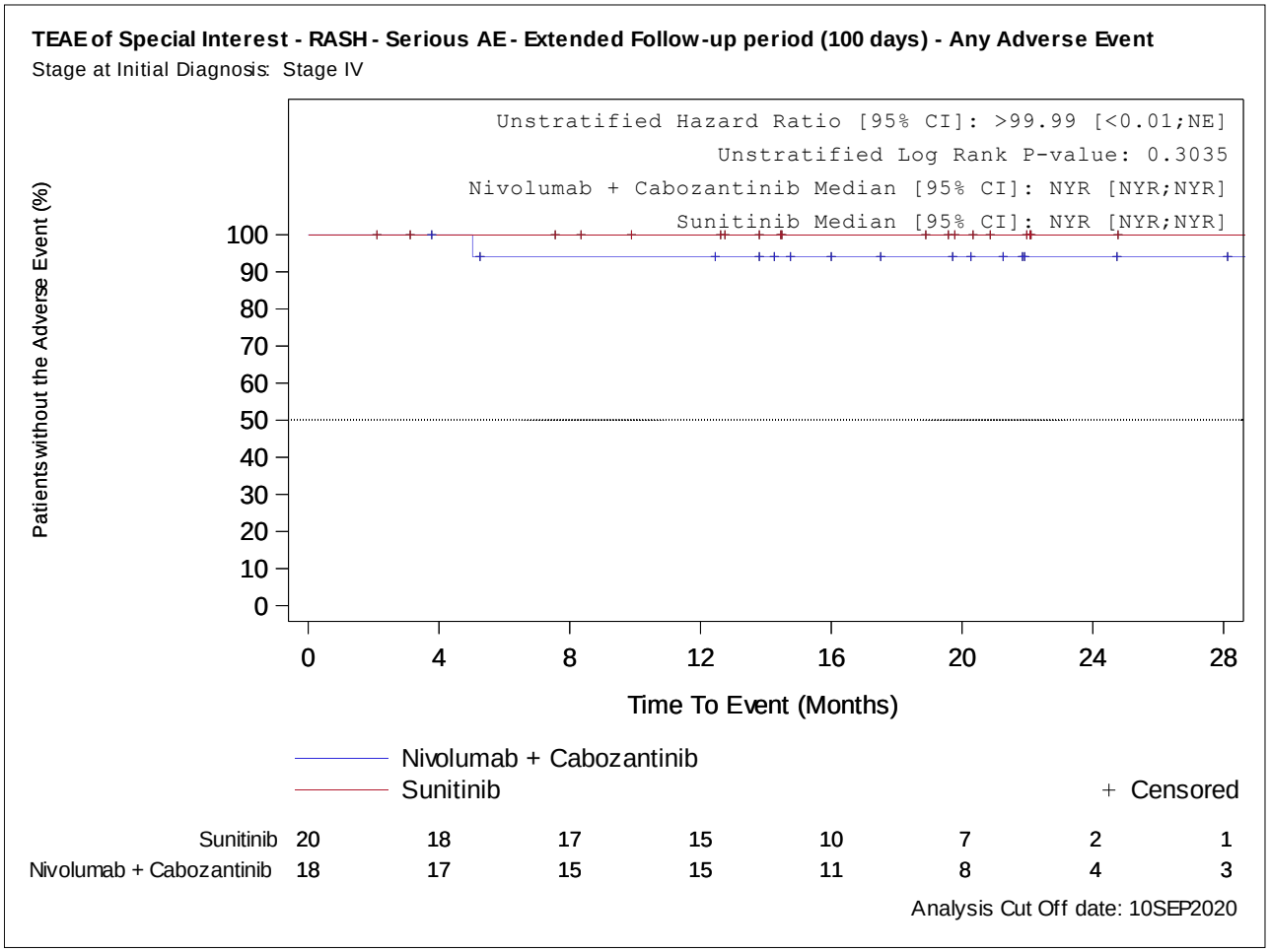

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:26:32

FIGURE 3.136.2.22: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



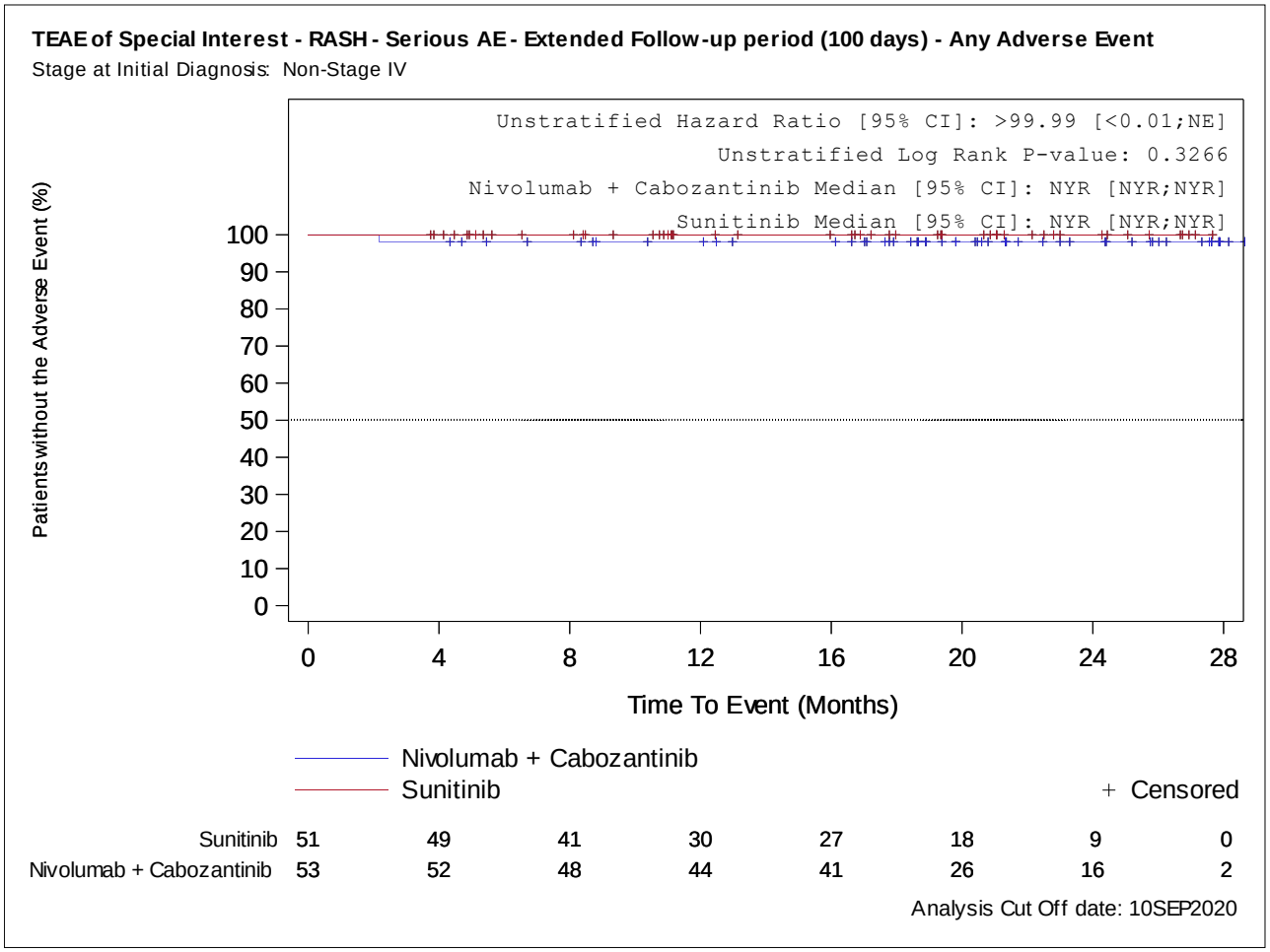

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:26:38

FIGURE 3.136.2.23: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:27:04

FIGURE 3.136.2.24: Kaplan-Meier curve - TEAE of Special Interest - RASH - Serious AE - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.03 KM safety by subgroups.sas] run Monday, March 22, 2021 at 18:27:09

TABLE 4.1.1: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 74 (100.0%) | 71 (100.0%) |
| Number of censored cases | N | 0 (0.0%) | 0 (0.0%) |
| Time to first event (Months) | Mean (SE) | 0.58 (0.08) | 0.71 (0.18) |
| | Q1 [95% CI] | 0.1 [0.07;0.26] | 0.2 [0.10;0.30] |
| | Median [95% CI] | 0.46 [0.26;0.49] | 0.39 [0.33;0.49] |
| | Q3 [95% CI] | 0.7 [0.49;0.95] | 0.7 [0.49;0.72] |
| | p-value (a) | 0.8761 | |
| Stratified Cox PH model | HR (b) | 0.98 [0.70;1.37] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 15:51:11

TABLE 4.1.2: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - by SOC/PT - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| Overall | 74 | 74 (100.0%) | 0.46 [0.26;0.49] | 71 | 71 (100.0%) | 0.39 [0.33;0.49] | 0.98 [0.70;1.37] | 0.8761 |
| SOC Blood and lymphatic system disorders | 74 | 23 (31.1%) | NYR [NYR;NYR] | 71 | 36 (50.7%) | 11.04 [5.52;NYR] | 0.47 [0.28;0.80] | 0.0046 |
| PT Anaemia | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 18 (25.4%) | NYR [NYR;NYR] | 0.36 [0.16;0.82] | 0.0110 |
| PT Leukopenia | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 0.22 [0.06;0.82] | 0.0140 |
| PT Lymphopenia | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.47 [0.04;5.22] | 0.5321 |
| PT Neutropenia | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 15 (21.1%) | NYR [22.54;NYR] | 0.31 [0.12;0.81] | 0.0121 |
| PT Thrombocytopenia | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 23 (32.4%) | NYR [NYR;NYR] | 0.36 [0.17;0.75] | 0.0045 |
| SOC Cardiac disorders | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 2.07 [0.53;8.07] | 0.2847 |
| SOC Ear and labyrinth disorders | 74 | 6 (8.1%) | NYR [26.22;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.24 [0.35;4.42] | 0.7400 |
| PT Vertigo | 74 | 4 (5.4%) | NYR [26.22;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 3.36 [0.37;30.37] | 0.2517 |
| SOC Endocrine disorders | 74 | 30 (40.5%) | NYR [14.69;NYR] | 71 | 28 (39.4%) | 16.56 [12.45;NYR] | 0.88 [0.53;1.49] | 0.6425 |
| PT Adrenal insufficiency | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1273 |
| PT Hyperthyroidism | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 1.29 [0.49;3.39] | 0.6026 |
| PT Hypothyroidism | 74 | 22 (29.7%) | NYR [23.72;NYR] | 71 | 25 (35.2%) | 17.45 [13.37;NYR] | 0.65 [0.36;1.16] | 0.1381 |
| SOC Eye disorders | 74 | 14 (18.9%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 1.62 [0.65;4.04] | 0.2984 |
| PT Vision blurred | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0623 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 15:51:11

TABLE 4.1.2: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| SOC Gastrointestinal disorders | 74 | 65 (87.8%) | 1.79 [1.41;2.33] | 71 | 64 (90.1%) | 0.62 [0.46;0.95] | 0.61 [0.43;0.87] | 0.0067 |
| PT Abdominal distension | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.33 [0.03;3.66] | 0.3414 |
| PT Abdominal pain | 74 | 11 (14.9%) | NYR [NYR;NYR] | 71 | 12 (16.9%) | NYR [NYR;NYR] | 0.70 [0.31;1.61] | 0.3982 |
| PT Abdominal pain upper | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 1.38 [0.45;4.24] | 0.5685 |
| PT Constipation | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 11 (15.5%) | NYR [NYR;NYR] | 0.63 [0.25;1.56] | 0.3082 |
| PT Diarrhoea | 74 | 56 (75.7%) | 4.37 [2.27;10.61] | 71 | 37 (52.1%) | 8.71 [3.48;NYR] | 1.54 [1.01;2.34] | 0.0434 |
| PT Dry mouth | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.41 [0.33;5.99] | 0.6367 |
| PT Dyspepsia | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 12 (16.9%) | NYR [NYR;NYR] | 0.70 [0.30;1.62] | 0.3986 |
| PT Dysphagia | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 0.64 [0.04;10.21] | 0.7488 |
| PT Flatulence | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 6 (8.5%) | NYR [NYR;NYR] | 0.74 [0.24;2.32] | 0.6084 |
| PT Gastritis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.88 [0.17;20.73] | 0.6004 |
| PT Gastrooesophageal reflux disease | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 10 (14.1%) | 28.75 [NYR;NYR] | 0.74 [0.30;1.84] | 0.5203 |
| PT Gingival bleeding | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0242 |
| PT Haemorrhoids | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 2.49 [0.26;24.11] | 0.4153 |
| PT Mouth ulceration | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.97 [0.14;6.92] | 0.9795 |
| PT Nausea | 74 | 25 (33.8%) | NYR [23.85;NYR] | 71 | 28 (39.4%) | NYR [9.99;NYR] | 0.72 [0.42;1.25] | 0.2483 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.1.2: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| PT Odynophagia | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.45 [0.04;4.96] | 0.5022 |
| PT Oral pain | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.90 [0.13;6.37] | 0.9132 |
| PT Stomatitis | 74 | 12 (16.2%) | NYR [NYR;NYR] | 71 | 25 (35.2%) | NYR [18.17;NYR] | 0.33 [0.16;0.66] | 0.0010 |
| PT Toothache | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 2.32 [0.24;22.43] | 0.4544 |
| PT Vomiting | 74 | 15 (20.3%) | NYR [NYR;NYR] | 71 | 17 (23.9%) | NYR [NYR;NYR] | 0.68 [0.34;1.37] | 0.2782 |
| SOC General disorders and administration site conditions | 74 | 59 (79.7%) | 2.33 [1.41;3.38] | 71 | 56 (78.9%) | 1.61 [0.72;2.07] | 0.89 [0.61;1.29] | 0.5356 |
| PT Asthenia | 74 | 16 (21.6%) | NYR [NYR;NYR] | 71 | 13 (18.3%) | NYR [NYR;NYR] | 1.08 [0.52;2.26] | 0.8286 |
| PT Chest pain | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.36 [0.03;4.13] | 0.3942 |
| PT Chills | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.13 [0.41;11.00] | 0.3570 |
| PT Face oedema | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [23.20;NYR] | 0.41 [0.06;2.63] | 0.3330 |
| PT Fatigue | 74 | 30 (40.5%) | NYR [8.54;NYR] | 71 | 37 (52.1%) | 8.64 [2.83;NYR] | 0.69 [0.43;1.12] | 0.1349 |
| PT Influenza like illness | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 3.50 [0.39;31.35] | 0.2322 |
| PT Malaise | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.86 [0.47;7.45] | 0.3717 |
| PT Mucosal inflammation | 74 | 21 (28.4%) | NYR [NYR;NYR] | 71 | 26 (36.6%) | NYR [17.48;NYR] | 0.65 [0.36;1.16] | 0.1394 |
| PT Non-cardiac chest pain | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1263 |
| PT Oedema peripheral | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 1.55 [0.52;4.62] | 0.4275 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.1.2: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| PT Pain | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.56 [0.09;3.35] | 0.5175 |
| PT Pyrexia | 74 | 13 (17.6%) | NYR [NYR;NYR] | 71 | 6 (8.5%) | NYR [NYR;NYR] | 1.69 [0.64;4.47] | 0.2822 |
| SOC Hepatobiliary disorders | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 10 (14.1%) | NYR [NYR;NYR] | 0.84 [0.34;2.06] | 0.6950 |
| PT Hepatic function abnormal | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.95 [0.18;21.54] | 0.5777 |
| PT Hepatotoxicity | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 0.77 [0.21;2.85] | 0.6898 |
| PT Hyperbilirubinaemia | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.61 [0.10;3.66] | 0.5863 |
| PT Jaundice | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.1534 |
| SOC Immune system disorders | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.09 [0.41;10.69] | 0.3670 |
| SOC Infections and infestations | 74 | 41 (55.4%) | 11.17 [7.20;25.46] | 71 | 24 (33.8%) | NYR [9.79;NYR] | 1.39 [0.83;2.33] | 0.2133 |
| PT Bronchitis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.85 [0.17;20.43] | 0.6092 |
| PT Conjunctivitis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.42 [0.13;15.85] | 0.7744 |
| PT Influenza | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.73 [0.32;9.45] | 0.5243 |
| PT Lower respiratory tract infection | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1453 |
| PT Nasopharyngitis | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 0.90 [0.22;3.58] | 0.8768 |
| PT Pneumonia | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.46 [0.27;8.04] | 0.6617 |
| PT Respiratory tract infection | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.1.2: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| PT Rhinitis | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.37 [0.03;4.08] | 0.3963 |
| PT Sinusitis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1647 |
| PT Tooth abscess | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2275 |
| PT Tooth infection | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.15 [0.19;6.92] | 0.8764 |
| PT Upper respiratory tract infection | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.30 [0.37;4.50] | 0.6816 |
| PT Urinary tract infection | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [24.35;NYR] | 0.50 [0.16;1.61] | 0.2357 |
| SOC Injury, poisoning and procedural complications | 74 | 12 (16.2%) | NYR [NYR;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 1.07 [0.45;2.56] | 0.8752 |
| PT Contusion | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 2.05 [0.21;20.11] | 0.5283 |
| PT Fall | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 |
| SOC Investigations | 74 | 56 (75.7%) | 2.37 [1.84;3.65] | 71 | 49 (69.0%) | 4.80 [2.10;10.38] | 1.27 [0.86;1.87] | 0.2287 |
| PT Alanine aminotransferase increased | 74 | 22 (29.7%) | NYR [24.80;NYR] | 71 | 11 (15.5%) | NYR [NYR;NYR] | 1.82 [0.88;3.76] | 0.1009 |
| PT Amylase increased | 74 | 15 (20.3%) | 31.74 [NYR;NYR] | 71 | 10 (14.1%) | NYR [NYR;NYR] | 1.27 [0.56;2.87] | 0.5632 |
| PT Aspartate aminotransferase increased | 74 | 22 (29.7%) | NYR [26.64;NYR] | 71 | 13 (18.3%) | NYR [23.72;NYR] | 1.56 [0.78;3.11] | 0.2038 |
| PT Blood alkaline phosphatase increased | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 1.02 [0.37;2.81] | 0.9608 |
| PT Blood bilirubin increased | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.33 [0.37;4.72] | 0.6580 |
| PT Blood cholesterol increased | 74 | 5 (6.8%) | NYR [28.06;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 0.56 [0.15;2.16] | 0.3969 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.1.2: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| PT Blood creatinine increased | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 13 (18.3%) | NYR [24.41;NYR] | 0.59 [0.25;1.40] | 0.2263 |
| PT Blood lactate dehydrogenase increased | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 5.72 [0.69;47.55] | 0.0683 |
| PT Blood magnesium decreased | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.37 [0.46;12.25] | 0.2870 |
| PT Blood pressure increased | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1046 |
| PT Blood sodium decreased | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | 28.06 [NYR;NYR] | 1.43 [0.26;7.91] | 0.6788 |
| PT Blood thyroid stimulating hormone increased | 74 | 11 (14.9%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 3.51 [0.98;12.59] | 0.0401 |
| PT Gamma-glutamyltransferase increased | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.1342 |
| PT Lipase increased | 74 | 14 (18.9%) | NYR [NYR;NYR] | 71 | 15 (21.1%) | NYR [NYR;NYR] | 0.79 [0.38;1.65] | 0.5447 |
| PT Lymphocyte count decreased | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.0338 |
| PT Neutrophil count decreased | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 0.49 [0.16;1.47] | 0.1960 |
| PT Platelet count decreased | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 17 (23.9%) | NYR [24.15;NYR] | 0.39 [0.17;0.90] | 0.0234 |
| PT Transaminases increased | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.46 [0.42;5.09] | 0.5487 |
| PT Weight decreased | 74 | 13 (17.6%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | 28.75 [NYR;NYR] | 6.18 [1.39;27.46] | 0.0063 |
| PT White blood cell count decreased | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.28 [0.03;2.69] | 0.2375 |
| SOC Metabolism and nutrition disorders | 74 | 59 (79.7%) | 4.73 [2.33;8.90] | 71 | 35 (49.3%) | 16.56 [4.27;NYR] | 1.76 [1.15;2.69] | 0.0078 |
| PT Decreased appetite | 74 | 33 (44.6%) | NYR [11.93;NYR] | 71 | 15 (21.1%) | NYR [NYR;NYR] | 2.01 [1.09;3.71] | 0.0225 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 4.1.2: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| PT Dehydration | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.58 [0.10;3.47] | 0.5418 |
| PT Hypercalcaemia | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3674 |
| PT Hyperglycaemia | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 0.99 [0.36;2.74] | 0.9850 |
| PT Hyperkalaemia | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 4.83 [0.58;40.30] | 0.1077 |
| PT Hypertriglyceridaemia | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 0.49 [0.12;2.06] | 0.3201 |
| PT Hyperuricaemia | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0339 |
| PT Hypoalbuminaemia | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.23 [0.43;11.54] | 0.3258 |
| PT Hypocalcaemia | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 3.27 [0.69;15.42] | 0.1138 |
| PT Hypoglycaemia | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3865 |
| PT Hypokalaemia | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.42 [0.34;5.95] | 0.6311 |
| PT Hypomagnesaemia | 74 | 16 (21.6%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 4.77 [1.39;16.39] | 0.0062 |
| PT Hyponatraemia | 74 | 13 (17.6%) | NYR [NYR;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 1.22 [0.52;2.87] | 0.6470 |
| PT Hypophosphataemia | 74 | 11 (14.9%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 2.61 [0.83;8.22] | 0.0879 |
| SOC Musculoskeletal and connective tissue disorders | 74 | 44 (59.5%) | 7.95 [4.99;20.40] | 71 | 35 (49.3%) | 10.25 [5.91;NYR] | 1.06 [0.68;1.66] | 0.8043 |
| PT Arthralgia | 74 | 17 (23.0%) | NYR [NYR;NYR] | 71 | 8 (11.3%) | NYR [NYR;NYR] | 1.72 [0.74;4.01] | 0.2022 |
| PT Arthritis | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3545 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.1.2: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | p-value[d] |
|---|---|---|---|---|---|---|---|---|
| PT Back pain | 74 | 14 (18.9%) | 30.36 [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 1.62 [0.65;4.07] | 0.2968 |
| PT Bone pain | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.40 [0.04;4.43] | 0.4390 |
| PT Flank pain | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.45 [0.13;16.10] | 0.7631 |
| PT Muscle spasms | 74 | 12 (16.2%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 5.50 [1.23;24.61] | 0.0120 |
| PT Muscular weakness | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.64 [0.30;9.01] | 0.5643 |
| PT Musculoskeletal chest pain | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.40 [0.06;2.51] | 0.3105 |
| PT Musculoskeletal pain | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.17 [0.42;11.25] | 0.3431 |
| PT Myalgia | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 0.49 [0.14;1.66] | 0.2388 |
| PT Neck pain | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 3.96 [0.46;33.98] | 0.1761 |
| PT Pain in extremity | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 10 (14.1%) | NYR [NYR;NYR] | 0.54 [0.20;1.45] | 0.2150 |
| SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.17 [0.31;4.36] | 0.8159 |
| PT Malignant neoplasm progression | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.46 [0.04;5.06] | 0.5137 |
| SOC Nervous system disorders | 74 | 46 (62.2%) | 7.52 [2.56;19.48] | 71 | 41 (57.7%) | 5.32 [2.79;14.42] | 0.94 [0.61;1.43] | 0.7694 |
| PT Dizziness | 74 | 13 (17.6%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 2.07 [0.73;5.89] | 0.1632 |
| PT Dysgeusia | 74 | 22 (29.7%) | NYR [NYR;NYR] | 71 | 23 (32.4%) | NYR [NYR;NYR] | 0.80 [0.45;1.44] | 0.4620 |
| PT Headache | 74 | 14 (18.9%) | NYR [26.22;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 1.36 [0.59;3.16] | 0.4695 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.1.2: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| PT Paraesthesia | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.41 [0.41;4.85] | 0.5834 |
| PT Peripheral sensory neuropathy | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0983 |
| PT Sciatica | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.68 [0.09;4.92] | 0.7001 |
| PT Syncope | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1858 |
| PT Taste disorder | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.81 [0.16;20.05] | 0.6218 |
| PT Tremor | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1132 |
| SOC Psychiatric disorders | 74 | 15 (20.3%) | NYR [26.68;NYR] | 71 | 10 (14.1%) | NYR [NYR;NYR] | 1.10 [0.49;2.48] | 0.8103 |
| PT Anxiety | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.79 [0.16;3.93] | 0.7724 |
| PT Depression | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.42 [0.25;8.00] | 0.6895 |
| PT Insomnia | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.48 [0.44;4.97] | 0.5211 |
| SOC Renal and urinary disorders | 74 | 24 (32.4%) | NYR [19.91;NYR] | 71 | 19 (26.8%) | NYR [20.04;NYR] | 1.09 [0.60;2.00] | 0.7674 |
| PT Acute kidney injury | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.54 [0.28;8.42] | 0.6180 |
| PT Dysuria | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.49 [0.27;8.28] | 0.6465 |
| PT Haematuria | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.79 [0.16;3.97] | 0.7786 |
| PT Proteinuria | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 0.89 [0.35;2.25] | 0.8070 |
| PT Renal failure | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.65 [0.30;9.09] | 0.5583 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.1.2: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| PT Urinary retention | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.72 [0.16;19.05] | 0.6528 |
| SOC Reproductive system and breast disorders | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 0.79 [0.31;2.00] | 0.6134 |
| SOC Respiratory, thoracic and mediastinal disorders | 74 | 42 (56.8%) | 11.73 [4.07;NYR] | 71 | 26 (36.6%) | NYR [12.88;NYR] | 1.57 [0.96;2.57] | 0.0674 |
| PT Cough | 74 | 16 (21.6%) | NYR [NYR;NYR] | 71 | 13 (18.3%) | NYR [NYR;NYR] | 1.04 [0.50;2.18] | 0.9050 |
| PT Dysphonia | 74 | 16 (21.6%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 15.70 [2.08;>99.99] | 0.0003 |
| PT Dyspnoea | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 8 (11.3%) | NYR [NYR;NYR] | 0.85 [0.32;2.24] | 0.7408 |
| PT Epistaxis | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 0.50 [0.14;1.70] | 0.2558 |
| PT Haemoptysis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.50 [0.13;16.67] | 0.7405 |
| PT Nasal congestion | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2438 |
| PT Oropharyngeal pain | 74 | 14 (18.9%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 3.18 [1.04;9.67] | 0.0315 |
| PT Pleural effusion | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 |
| PT Pneumonitis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2733 |
| PT Productive cough | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.10 [0.18;6.64] | 0.9155 |
| PT Pulmonary embolism | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 7.23 [0.90;57.92] | 0.0291 |
| PT Rhinorrhoea | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 3.01 [0.34;27.00] | 0.3004 |
| PT Upper-airway cough syndrome | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3711 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.1.2: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| SOC Skin and subcutaneous tissue disorders | 74 | 61 (82.4%) | 2.17 [1.74;2.60] | 71 | 50 (70.4%) | 3.25 [1.71;4.73] | 1.25 [0.85;1.83] | 0.2508 |
| PT Alopecia | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 8.18 [1.04;64.68] | 0.0174 |
| PT Dermatitis | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 2.73 [0.28;26.29] | 0.3648 |
| PT Dermatitis acneiform | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.98 [0.18;21.84] | 0.5695 |
| PT Dry skin | 74 | 11 (14.9%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 3.04 [0.84;10.91] | 0.0736 |
| PT Erythema | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.72 [0.31;9.41] | 0.5259 |
| PT Hair colour changes | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.57 [0.14;17.40] | 0.7126 |
| PT Palmar-plantar erythrodysaesthesia syndrome | 74 | 33 (44.6%) | NYR [5.13;NYR] | 71 | 41 (57.7%) | 6.21 [3.35;11.10] | 0.69 [0.43;1.09] | 0.1033 |
| PT Pruritus | 74 | 20 (27.0%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 6.51 [1.93;21.96] | 0.0005 |
| PT Rash | 74 | 18 (24.3%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 3.32 [1.23;8.96] | 0.0120 |
| PT Rash maculo-papular | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 7.65 [0.96;61.14] | 0.0235 |
| PT Skin discolouration | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.1463 |
| PT Skin ulcer | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.86 [0.17;20.50] | 0.6070 |
| PT Yellow skin | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 8 (11.3%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.0033 |
| SOC Vascular disorders | 74 | 35 (47.3%) | NYR [3.61;NYR] | 71 | 38 (53.5%) | 6.24 [2.20;NYR] | 0.80 [0.50;1.27] | 0.3484 |
| PT Deep vein thrombosis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1689 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 4.1.2: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| PT Hypertension | 74 | 33 (44.6%) | NYR [5.19;NYR] | 71 | 37 (52.1%) | 6.24 [2.73;NYR] | 0.79 [0.49;1.27] | 0.3259 |
| PT Hypotension | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.2248 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 4.2.1: Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent AE grade >=3 - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 58 (78.4%) | 51 (71.8%) |
| Number of censored cases | N | 16 (21.6%) | 20 (28.2%) |
| Time to first event (Months) | Mean (SE) | 8.38 (1.00) | 9.24 (1.24) |
| | Q1 [95% CI] | 1.4 [0.92;1.77] | 1.0 [0.69;2.04] |
| | Median [95% CI] | 3.24 [2.40;8.08] | 3.68 [2.07;5.68] |
| | Q3 [95% CI] | 17.4 [9.17;NYR] | 24.4 [7.23;NYR] |
| | p-value (a) | 0.9044 | |
| Stratified Cox PH model | HR (b) | 0.98 [0.67;1.43] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 4.2.2: Treatment Emergent AE grade >=3 - Any Adverse Event - by SOC/PT - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| Overall | 74 | 58 (78.4%) | 3.24 [2.40;8.08] | 71 | 51 (71.8%) | 3.68 [2.07;5.68] | 0.98 [0.67;1.43] | 0.9044 |
| SOC Blood and lymphatic system disorders | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 8 (11.3%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.0030 |
| PT Anaemia | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3101 |
| PT Neutropenia | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.0338 |
| PT Thrombocytopenia | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.0409 |
| SOC Cardiac disorders | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.07 [0.40;10.71] | 0.3751 |
| SOC Endocrine disorders | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1924 |
| SOC Gastrointestinal disorders | 74 | 16 (21.6%) | NYR [NYR;NYR] | 71 | 12 (16.9%) | NYR [24.61;NYR] | 1.03 [0.49;2.20] | 0.9304 |
| PT Diarrhoea | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.64 [0.49;5.47] | 0.4146 |
| PT Stomatitis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.54 [0.09;3.27] | 0.4986 |
| SOC General disorders and administration site conditions | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 1.28 [0.48;3.36] | 0.6205 |
| PT Asthenia | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 5.09 [0.61;42.41] | 0.0937 |
| PT Fatigue | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.64 [0.11;3.85] | 0.6253 |
| PT Mucosal inflammation | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.0709 |
| SOC Hepatobiliary disorders | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.90 [0.35;10.37] | 0.4514 |
| SOC Infections and infestations | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.53 [0.52;12.21] | 0.2314 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.2.2: Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| PT Pneumonia | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2260 |
| PT Urinary tract infection | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | . [.;NE] | . |
| SOC Injury, poisoning and procedural complications | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 0.82 [0.05;13.08] | 0.8859 |
| SOC Investigations | 74 | 13 (17.6%) | NYR [NYR;NYR] | 71 | 20 (28.2%) | NYR [24.41;NYR] | 0.55 [0.27;1.10] | 0.0875 |
| PT Alanine aminotransferase increased | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.37 [0.33;5.78] | 0.6624 |
| PT Amylase increased | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.84 [0.17;4.18] | 0.8303 |
| PT Aspartate aminotransferase increased | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2121 |
| PT Lipase increased | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 0.87 [0.25;3.00] | 0.8218 |
| PT Neutrophil count decreased | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 6 (8.5%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.0058 |
| PT Platelet count decreased | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.1425 |
| SOC Metabolism and nutrition disorders | 74 | 21 (28.4%) | NYR [22.18;NYR] | 71 | 15 (21.1%) | NYR [NYR;NYR] | 1.24 [0.64;2.43] | 0.5206 |
| PT Decreased appetite | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 0.79 [0.05;12.78] | 0.8696 |
| PT Hyponatraemia | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 0.85 [0.30;2.44] | 0.7618 |
| PT Hypophosphataemia | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 4.26 [0.49;36.68] | 0.1512 |
| SOC Musculoskeletal and connective tissue disorders | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 0.78 [0.19;3.16] | 0.7311 |
| PT Back pain | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3683 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.2.2: Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.58 [0.10;3.48] | 0.5459 |
| PT Malignant neoplasm progression | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.46 [0.04;5.06] | 0.5137 |
| SOC Nervous system disorders | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.85 [0.34;10.09] | 0.4722 |
| SOC Renal and urinary disorders | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.37 [0.33;5.77] | 0.6637 |
| PT Proteinuria | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.25 [0.21;7.56] | 0.8046 |
| SOC Respiratory, thoracic and mediastinal disorders | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 4.56 [1.00;20.82] | 0.0317 |
| PT Pulmonary embolism | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 6.31 [0.77;51.35] | 0.0484 |
| SOC Skin and subcutaneous tissue disorders | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 10 (14.1%) | NYR [NYR;NYR] | 0.84 [0.35;2.03] | 0.7042 |
| PT Palmar-plantar erythrodysaesthesia syndrome | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 10 (14.1%) | NYR [NYR;NYR] | 0.39 [0.13;1.16] | 0.0790 |
| SOC Vascular disorders | 74 | 12 (16.2%) | NYR [NYR;NYR] | 71 | 15 (21.1%) | NYR [NYR;NYR] | 0.74 [0.34;1.59] | 0.4333 |
| PT Hypertension | 74 | 12 (16.2%) | NYR [NYR;NYR] | 71 | 15 (21.1%) | NYR [NYR;NYR] | 0.74 [0.34;1.59] | 0.4333 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.3.1: Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Serious Treatment Emergent Adverse Events - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 35 (47.3%) | 21 (29.6%) |
| Number of censored cases | N | 39 (52.7%) | 50 (70.4%) |
| Time to first event (Months) | Mean (SE) | 13.63 (0.88) | 18.46 (1.20) |
| | Q1 [95% CI] | 5.4 [2.73;9.95] | 5.7 [2.30;NYR] |
| | Median [95% CI] | 19.58 [14.16;NYR] | NYR [24.61;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.1000 | |
| Stratified Cox PH model | HR (b) | 1.58 [0.91;2.74] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 4.3.2: Serious Treatment Emergent Adverse Events - Any Adverse Event - by SOC/PT - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| Overall | 74 | 35 (47.3%) | 19.58 [14.16;NYR] | 71 | 21 (29.6%) | NYR [24.61;NYR] | 1.58 [0.91;2.74] | 0.1000 |
| SOC Blood and lymphatic system disorders | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3000 |
| PT Anaemia | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | . [.;NE] | . |
| SOC Cardiac disorders | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.07 [0.40;10.71] | 0.3751 |
| SOC Endocrine disorders | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1937 |
| SOC Gastrointestinal disorders | 74 | 12 (16.2%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [24.61;NYR] | 3.23 [0.91;11.53] | 0.0558 |
| PT Diarrhoea | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0274 |
| SOC General disorders and administration site conditions | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.21 [0.27;5.40] | 0.8066 |
| PT Pyrexia | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.70 [0.15;18.85] | 0.6631 |
| SOC Hepatobiliary disorders | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.92 [0.13;6.56] | 0.9363 |
| SOC Infections and infestations | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 4.50 [0.54;37.46] | 0.1272 |
| PT Pneumonia | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2260 |
| PT Urinary tract infection | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | . [.;NE] | . |
| SOC Injury, poisoning and procedural complications | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3683 |
| SOC Metabolism and nutrition disorders | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.01 [0.27;3.77] | 0.9937 |
| PT Hyponatraemia | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.81 [0.11;5.79] | 0.8297 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.3.2: Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| SOC Musculoskeletal and connective tissue disorders | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.50 [0.08;3.05] | 0.4461 |
| SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.88 [0.18;4.36] | 0.8737 |
| PT Malignant neoplasm progression | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.46 [0.04;5.06] | 0.5137 |
| SOC Nervous system disorders | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 3.80 [0.42;34.01] | 0.1991 |
| SOC Renal and urinary disorders | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.17 [0.20;7.05] | 0.8617 |
| SOC Respiratory, thoracic and mediastinal disorders | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 4.94 [0.59;41.22] | 0.1017 |
| PT Pleural effusion | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | . [.;NE] | . |
| PT Pulmonary embolism | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0956 |
| SOC Vascular disorders | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 2.67 [0.28;25.77] | 0.3776 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.4.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 74 (100.0%) | 71 (100.0%) |
| Number of censored cases | N | 0 (0.0%) | 0 (0.0%) |
| Time to first event (Months) | Mean (SE) | 0.58 (0.08) | 0.71 (0.18) |
| | Q1 [95% CI] | 0.1 [0.07;0.26] | 0.2 [0.10;0.30] |
| | Median [95% CI] | 0.46 [0.26;0.49] | 0.39 [0.33;0.49] |
| | Q3 [95% CI] | 0.7 [0.49;0.95] | 0.7 [0.49;0.72] |
| | p-value (a) | 0.8761 | |
| Stratified Cox PH model | HR (b) | 0.98 [0.70;1.37] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:19:29

TABLE 4.4.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - by SOC/PT - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | |
|---|---|---|---|---|---|---|---|---|
| Overall<br>System Organ Class (SOC)<br>Preferred Term (PT) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | Hazard Ratio<br>[95% CI][c] | p-value[d] |
| Overall | 74 | 74 (100.0%) | 0.46 [0.26;0.49] | 71 | 71 (100.0%) | 0.39 [0.33;0.49] | 0.98<br>[0.70;1.37] | 0.8761 |
| SOC Blood and lymphatic system disorders | 74 | 23 (31.1%) | NYR [NYR;NYR] | 71 | 37 (52.1%) | 11.04 [3.75;NYR] | 0.47<br>[0.28;0.80] | 0.0041 |
| PT Anaemia | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 19 (26.8%) | NYR [NYR;NYR] | 0.36<br>[0.16;0.80] | 0.0089 |
| PT Leukopenia | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 0.24<br>[0.06;0.88] | 0.0197 |
| PT Lymphopenia | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.47<br>[0.04;5.16] | 0.5245 |
| PT Neutropenia | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 15 (21.1%) | NYR [22.54;NYR] | 0.33<br>[0.13;0.85] | 0.0156 |
| PT Thrombocytopenia | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 23 (32.4%) | NYR [NYR;NYR] | 0.37<br>[0.17;0.77] | 0.0058 |
| SOC Cardiac disorders | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 2.27<br>[0.58;8.82] | 0.2248 |
| PT Tachycardia | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.4421 |
| SOC Ear and labyrinth disorders | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.33<br>[0.37;4.74] | 0.6577 |
| PT Vertigo | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 3.57<br>[0.40;32.13] | 0.2254 |
| SOC Endocrine disorders | 74 | 30 (40.5%) | NYR [16.76;NYR] | 71 | 28 (39.4%) | 17.45 [13.37;NYR] | 0.93<br>[0.55;1.56] | 0.7700 |
| PT Adrenal insufficiency | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.1270 |
| PT Hyperthyroidism | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 1.32<br>[0.50;3.47] | 0.5694 |
| PT Hypothyroidism | 74 | 22 (29.7%) | NYR [23.72;NYR] | 71 | 25 (35.2%) | NYR [13.80;NYR] | 0.68<br>[0.38;1.21] | 0.1835 |
| SOC Eye disorders | 74 | 14 (18.9%) | NYR [NYR;NYR] | 71 | 8 (11.3%) | NYR [NYR;NYR] | 1.48<br>[0.62;3.55] | 0.3746 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:19:29

TABLE 4.4.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| PT Vision blurred | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0534 |
| SOC Gastrointestinal disorders | 74 | 65 (87.8%) | 1.79 [1.41;2.33] | 71 | 64 (90.1%) | 0.62 [0.46;0.95] | 0.63 [0.44;0.90] | 0.0115 |
| PT Abdominal distension | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.33 [0.03;3.65] | 0.3406 |
| PT Abdominal pain | 74 | 11 (14.9%) | NYR [NYR;NYR] | 71 | 12 (16.9%) | NYR [NYR;NYR] | 0.74 [0.32;1.68] | 0.4660 |
| PT Abdominal pain upper | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 1.39 [0.45;4.28] | 0.5599 |
| PT Constipation | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 11 (15.5%) | NYR [NYR;NYR] | 0.64 [0.26;1.59] | 0.3314 |
| PT Diarrhoea | 74 | 56 (75.7%) | 4.37 [2.27;10.61] | 71 | 37 (52.1%) | 9.36 [3.88;NYR] | 1.61 [1.06;2.45] | 0.0260 |
| PT Dry mouth | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.45 [0.34;6.15] | 0.6112 |
| PT Dyspepsia | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 12 (16.9%) | NYR [NYR;NYR] | 0.72 [0.31;1.67] | 0.4439 |
| PT Dysphagia | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 0.70 [0.04;11.29] | 0.8028 |
| PT Flatulence | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 6 (8.5%) | NYR [NYR;NYR] | 0.76 [0.24;2.39] | 0.6422 |
| PT Gastritis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.88 [0.17;20.75] | 0.5998 |
| PT Gastrooesophageal reflux disease | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 10 (14.1%) | 28.75 [NYR;NYR] | 0.78 [0.32;1.94] | 0.5979 |
| PT Gingival bleeding | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0219 |
| PT Haemorrhoids | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 2.65 [0.27;25.69] | 0.3811 |
| PT Mouth ulceration | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.98 [0.14;6.99] | 0.9870 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 4.4.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | |
|---|---|---|---|---|---|---|---|---|
| Overall<br>System Organ Class (SOC)<br>Preferred Term (PT) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | Hazard Ratio<br>[95% CI][c] | p-value[d] |
| PT Nausea | 74 | 25 (33.8%) | NYR [23.85;NYR] | 71 | 28 (39.4%) | NYR [12.35;NYR] | 0.73<br>[0.42;1.26] | 0.2633 |
| PT Odynophagia | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.47<br>[0.04;5.21] | 0.5310 |
| PT Oral pain | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.88<br>[0.12;6.25] | 0.8941 |
| PT Stomatitis | 74 | 12 (16.2%) | NYR [NYR;NYR] | 71 | 26 (36.6%) | NYR [18.17;NYR] | 0.32<br>[0.16;0.65] | 0.0008 |
| PT Toothache | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 2.51<br>[0.26;24.28] | 0.4103 |
| PT Vomiting | 74 | 15 (20.3%) | NYR [NYR;NYR] | 71 | 17 (23.9%) | NYR [NYR;NYR] | 0.70<br>[0.35;1.40] | 0.3057 |
| SOC General disorders and administration site conditions | 74 | 59 (79.7%) | 2.33 [1.41;3.71] | 71 | 56 (78.9%) | 1.61 [0.72;2.07] | 0.89<br>[0.61;1.30] | 0.5636 |
| PT Asthenia | 74 | 16 (21.6%) | NYR [NYR;NYR] | 71 | 13 (18.3%) | NYR [NYR;NYR] | 1.13<br>[0.54;2.36] | 0.7419 |
| PT Chest pain | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.37<br>[0.03;4.24] | 0.4064 |
| PT Chills | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.18<br>[0.42;11.26] | 0.3419 |
| PT Face oedema | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [23.20;NYR] | 0.41<br>[0.06;2.65] | 0.3362 |
| PT Fatigue | 74 | 30 (40.5%) | NYR [8.54;NYR] | 71 | 37 (52.1%) | 8.97 [2.83;NYR] | 0.70<br>[0.43;1.13] | 0.1438 |
| PT Influenza like illness | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 3.68<br>[0.41;32.94] | 0.2119 |
| PT Malaise | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.91<br>[0.48;7.64] | 0.3517 |
| PT Mucosal inflammation | 74 | 21 (28.4%) | NYR [NYR;NYR] | 71 | 26 (36.6%) | NYR [17.48;NYR] | 0.65<br>[0.36;1.17] | 0.1486 |
| PT Non-cardiac chest pain | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.1125 |

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TABLE 4.4.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| PT Oedema peripheral | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 1.63 [0.55;4.86] | 0.3721 |
| PT Pain | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.56 [0.09;3.38] | 0.5232 |
| PT Pyrexia | 74 | 13 (17.6%) | NYR [NYR;NYR] | 71 | 6 (8.5%) | NYR [NYR;NYR] | 1.74 [0.66;4.60] | 0.2559 |
| SOC Hepatobiliary disorders | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 10 (14.1%) | NYR [NYR;NYR] | 0.86 [0.35;2.12] | 0.7372 |
| PT Hepatic function abnormal | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.95 [0.18;21.54] | 0.5777 |
| PT Hepatotoxicity | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 0.78 [0.21;2.91] | 0.7125 |
| PT Hyperbilirubinaemia | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.64 [0.11;3.83] | 0.6217 |
| PT Jaundice | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.1499 |
| SOC Immune system disorders | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.31 [0.46;11.63] | 0.2952 |
| SOC Infections and infestations | 74 | 42 (56.8%) | 11.79 [8.61;25.46] | 71 | 25 (35.2%) | NYR [12.91;NYR] | 1.46 [0.88;2.44] | 0.1390 |
| PT Bronchitis | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 2.94 [0.31;28.23] | 0.3278 |
| PT Conjunctivitis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.52 [0.14;16.98] | 0.7299 |
| PT Influenza | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.71 [0.31;9.34] | 0.5333 |
| PT Lower respiratory tract infection | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1409 |
| PT Nasopharyngitis | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 0.94 [0.24;3.77] | 0.9334 |
| PT Pneumonia | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.55 [0.28;8.51] | 0.6134 |

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| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | |
|---|---|---|---|---|---|---|---|---|
| Overall<br>System Organ Class (SOC)<br>Preferred Term (PT) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | Hazard Ratio<br>[95% CI][c] | p-value[d] |
| PT Respiratory tract infection | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.3711 |
| PT Rhinitis | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.40<br>[0.04;4.43] | 0.4392 |
| PT Sinusitis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.1609 |
| PT Tooth abscess | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.2223 |
| PT Tooth infection | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.25<br>[0.21;7.52] | 0.8077 |
| PT Upper respiratory tract infection | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.40<br>[0.40;4.84] | 0.5981 |
| PT Urinary tract infection | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [24.35;NYR] | 0.54<br>[0.17;1.72] | 0.2882 |
| SOC Injury, poisoning and procedural complications | 74 | 12 (16.2%) | NYR [NYR;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 1.13<br>[0.48;2.70] | 0.7785 |
| PT Contusion | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 2.26<br>[0.23;21.83] | 0.4708 |
| PT Fall | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.3711 |
| SOC Investigations | 74 | 56 (75.7%) | 2.37 [1.84;3.65] | 71 | 49 (69.0%) | 4.83 [2.10;10.38] | 1.29<br>[0.87;1.91] | 0.1915 |
| PT Alanine aminotransferase increased | 74 | 22 (29.7%) | NYR [24.80;NYR] | 71 | 11 (15.5%) | NYR [NYR;NYR] | 1.89<br>[0.92;3.91] | 0.0794 |
| PT Amylase increased | 74 | 15 (20.3%) | 31.74 [NYR;NYR] | 71 | 10 (14.1%) | NYR [NYR;NYR] | 1.28<br>[0.57;2.88] | 0.5537 |
| PT Aspartate aminotransferase increased | 74 | 22 (29.7%) | NYR [26.64;NYR] | 71 | 13 (18.3%) | NYR [23.72;NYR] | 1.56<br>[0.78;3.11] | 0.2044 |
| PT Blood alkaline phosphatase increased | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 1.05<br>[0.38;2.89] | 0.9142 |
| PT Blood bilirubin increased | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.41<br>[0.40;4.99] | 0.5952 |

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| Overall<br>System Organ Class (SOC)<br>Preferred Term (PT) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | Hazard Ratio<br>[95% CI][c] | p-value[d] |
| PT Blood cholesterol increased | 74 | 5 (6.8%) | NYR [28.06;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 0.64<br>[0.17;2.42] | 0.5112 |
| PT Blood creatinine increased | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 13 (18.3%) | NYR [24.41;NYR] | 0.60<br>[0.25;1.42] | 0.2378 |
| PT Blood lactate dehydrogenase increased | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 5.75<br>[0.69;47.85] | 0.0671 |
| PT Blood magnesium decreased | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.45<br>[0.47;12.65] | 0.2688 |
| PT Blood pressure increased | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.0983 |
| PT Blood sodium decreased | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | 28.06 [NYR;NYR] | 1.31<br>[0.24;7.32] | 0.7541 |
| PT Blood thyroid stimulating hormone increased | 74 | 11 (14.9%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 3.59<br>[1.00;12.89] | 0.0359 |
| PT Gamma-glutamyltransferase increased | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | <0.01<br>[<0.01;NE] | 0.1391 |
| PT Lipase increased | 74 | 14 (18.9%) | NYR [NYR;NYR] | 71 | 15 (21.1%) | NYR [NYR;NYR] | 0.81<br>[0.39;1.68] | 0.5780 |
| PT Lymphocyte count decreased | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | <0.01<br>[<0.01;NE] | 0.0365 |
| PT Neutrophil count decreased | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 0.51<br>[0.17;1.53] | 0.2227 |
| PT Platelet count decreased | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 17 (23.9%) | NYR [24.15;NYR] | 0.40<br>[0.17;0.93] | 0.0278 |
| PT Transaminases increased | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.47<br>[0.42;5.11] | 0.5439 |
| PT Weight decreased | 74 | 13 (17.6%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | 28.75 [NYR;NYR] | 6.36<br>[1.43;28.26] | 0.0053 |
| PT White blood cell count decreased | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.28<br>[0.03;2.74] | 0.2443 |
| SOC Metabolism and nutrition disorders | 74 | 59 (79.7%) | 4.73 [2.33;8.90] | 71 | 35 (49.3%) | 16.56 [4.27;NYR] | 1.81<br>[1.19;2.76] | 0.0052 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:19:29

TABLE 4.4.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | |
|---|---|---|---|---|---|---|---|---|
| Overall<br>System Organ Class (SOC)<br>Preferred Term (PT) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | Hazard Ratio<br>[95% CI][c] | p-value[d] |
| PT Decreased appetite | 74 | 33 (44.6%) | NYR [11.93;NYR] | 71 | 15 (21.1%) | NYR [NYR;NYR] | 2.11<br>[1.15;3.89] | 0.0143 |
| PT Dehydration | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.58<br>[0.10;3.52] | 0.5530 |
| PT Hypercalcaemia | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.3248 |
| PT Hyperglycaemia | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 1.01<br>[0.36;2.79] | 0.9863 |
| PT Hyperkalaemia | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 5.06<br>[0.61;42.14] | 0.0954 |
| PT Hypertriglyceridaemia | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 0.51<br>[0.12;2.14] | 0.3495 |
| PT Hyperuricaemia | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.0271 |
| PT Hypoalbuminaemia | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.26<br>[0.44;11.67] | 0.3191 |
| PT Hypocalcaemia | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 3.37<br>[0.71;15.92] | 0.1029 |
| PT Hypoglycaemia | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.3865 |
| PT Hypokalaemia | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.51<br>[0.36;6.32] | 0.5733 |
| PT Hypomagnesaemia | 74 | 16 (21.6%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 4.93<br>[1.44;16.93] | 0.0050 |
| PT Hyponatraemia | 74 | 13 (17.6%) | NYR [NYR;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 1.25<br>[0.53;2.93] | 0.6130 |
| PT Hypophosphataemia | 74 | 11 (14.9%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 2.76<br>[0.88;8.69] | 0.0694 |
| SOC Musculoskeletal and connective tissue disorders | 74 | 44 (59.5%) | 8.87 [4.99;20.40] | 71 | 35 (49.3%) | 10.25 [5.91;NYR] | 1.11<br>[0.71;1.73] | 0.6593 |
| PT Arthralgia | 74 | 18 (24.3%) | NYR [NYR;NYR] | 71 | 8 (11.3%) | NYR [NYR;NYR] | 1.90<br>[0.82;4.38] | 0.1274 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.4.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | |
|---|---|---|---|---|---|---|---|---|
| Overall<br>System Organ Class (SOC)<br>Preferred Term (PT) | N[a] | Subjects with events<br>n (%) | Median [95% CI][b]<br>(Months) | N[a] | Subjects with events<br>n (%) | Median [95% CI][b]<br>(Months) | Hazard Ratio [95% CI][c] | p-value[d] |
| PT Arthritis | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3598 |
| PT Back pain | 74 | 14 (18.9%) | 30.36 [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 1.71 [0.68;4.28] | 0.2484 |
| PT Bone pain | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.44 [0.04;4.85] | 0.4904 |
| PT Flank pain | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.67 [0.15;18.48] | 0.6723 |
| PT Muscle spasms | 74 | 12 (16.2%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 5.63 [1.26;25.17] | 0.0107 |
| PT Muscular weakness | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.84 [0.34;10.05] | 0.4749 |
| PT Musculoskeletal chest pain | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.40 [0.06;2.57] | 0.3169 |
| PT Musculoskeletal pain | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.20 [0.42;11.38] | 0.3358 |
| PT Myalgia | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 0.49 [0.14;1.67] | 0.2444 |
| PT Neck pain | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 4.04 [0.47;34.72] | 0.1688 |
| PT Pain in extremity | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 10 (14.1%) | NYR [NYR;NYR] | 0.56 [0.21;1.49] | 0.2403 |
| SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 1.70 [0.57;5.08] | 0.3404 |
| PT Malignant neoplasm progression | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.19 [0.27;5.37] | 0.8164 |
| SOC Nervous system disorders | 74 | 46 (62.2%) | 7.52 [2.56;19.48] | 71 | 41 (57.7%) | 7.06 [2.79;14.49] | 0.96 [0.63;1.47] | 0.8569 |
| PT Dizziness | 74 | 13 (17.6%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 2.17 [0.76;6.16] | 0.1376 |
| PT Dysgeusia | 74 | 22 (29.7%) | NYR [NYR;NYR] | 71 | 23 (32.4%) | NYR [NYR;NYR] | 0.82 [0.46;1.48] | 0.5170 |

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b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 4.4.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | |
|---|---|---|---|---|---|---|---|---|
| Overall<br>System Organ Class (SOC)<br>Preferred Term (PT) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | Hazard Ratio<br>[95% CI][c] | p-value[d] |
| PT Headache | 74 | 14 (18.9%) | NYR [26.22;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 1.43<br>[0.62;3.31] | 0.4014 |
| PT Paraesthesia | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.50<br>[0.44;5.15] | 0.5197 |
| PT Peripheral sensory neuropathy | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.0981 |
| PT Sciatica | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.73<br>[0.10;5.31] | 0.7537 |
| PT Syncope | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.1725 |
| PT Taste disorder | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.84<br>[0.17;20.32] | 0.6142 |
| PT Tremor | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.0967 |
| SOC Psychiatric disorders | 74 | 15 (20.3%) | NYR [26.68;NYR] | 71 | 10 (14.1%) | NYR [NYR;NYR] | 1.20<br>[0.54;2.70] | 0.6505 |
| PT Anxiety | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.85<br>[0.17;4.22] | 0.8436 |
| PT Depression | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.46<br>[0.26;8.25] | 0.6640 |
| PT Insomnia | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.60<br>[0.48;5.36] | 0.4391 |
| SOC Renal and urinary disorders | 74 | 24 (32.4%) | NYR [19.91;NYR] | 71 | 20 (28.2%) | NYR [20.04;NYR] | 1.08<br>[0.59;1.95] | 0.8107 |
| PT Acute kidney injury | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.66<br>[0.30;9.13] | 0.5543 |
| PT Dysuria | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.51<br>[0.27;8.39] | 0.6359 |
| PT Haematuria | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 0.63<br>[0.14;2.82] | 0.5377 |
| PT Proteinuria | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 0.91<br>[0.36;2.29] | 0.8368 |

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b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
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d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 4.4.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| PT Renal failure | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.74 [0.32;9.54] | 0.5187 |
| PT Urinary retention | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.80 [0.16;19.85] | 0.6274 |
| SOC Reproductive system and breast disorders | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 9 (12.7%) | NYR [NYR;NYR] | 0.81 [0.32;2.06] | 0.6557 |
| SOC Respiratory, thoracic and mediastinal disorders | 74 | 42 (56.8%) | 11.73 [4.07;NYR] | 71 | 27 (38.0%) | NYR [12.88;NYR] | 1.58 [0.97;2.56] | 0.0633 |
| PT Cough | 74 | 18 (24.3%) | NYR [NYR;NYR] | 71 | 13 (18.3%) | NYR [NYR;NYR] | 1.21 [0.59;2.49] | 0.5974 |
| PT Dysphonia | 74 | 16 (21.6%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 16.22 [2.15;>99.99] | 0.0002 |
| PT Dyspnoea | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 8 (11.3%) | NYR [NYR;NYR] | 0.90 [0.34;2.37] | 0.8379 |
| PT Epistaxis | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 0.51 [0.15;1.74] | 0.2706 |
| PT Haemoptysis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.58 [0.14;17.68] | 0.7064 |
| PT Nasal congestion | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1563 |
| PT Oropharyngeal pain | 74 | 14 (18.9%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 3.27 [1.07;9.95] | 0.0271 |
| PT Pleural effusion | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4386 |
| PT Pneumonitis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2375 |
| PT Productive cough | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.18 [0.20;7.11] | 0.8574 |
| PT Pulmonary embolism | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 7.87 [0.98;62.92] | 0.0211 |
| PT Respiratory failure | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3085 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 4.4.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| PT Rhinorrhoea | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 3.55 [0.40;31.85] | 0.2271 |
| PT Upper-airway cough syndrome | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3711 |
| SOC Skin and subcutaneous tissue disorders | 74 | 61 (82.4%) | 2.17 [1.74;2.63] | 71 | 50 (70.4%) | 3.25 [1.71;5.65] | 1.29 [0.88;1.89] | 0.1834 |
| PT Alopecia | 74 | 9 (12.2%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 8.63 [1.09;68.13] | 0.0138 |
| PT Dermatitis | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 2.88 [0.30;27.72] | 0.3369 |
| PT Dermatitis acneiform | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.98 [0.18;21.84] | 0.5695 |
| PT Dry skin | 74 | 11 (14.9%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 3.13 [0.87;11.24] | 0.0652 |
| PT Erythema | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.78 [0.33;9.73] | 0.5000 |
| PT Hair colour changes | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.67 [0.15;18.65] | 0.6717 |
| PT Palmar-plantar erythrodysaesthesia syndrome | 74 | 33 (44.6%) | NYR [5.13;NYR] | 71 | 41 (57.7%) | 7.10 [3.35;15.54] | 0.71 [0.44;1.12] | 0.1332 |
| PT Pruritus | 74 | 20 (27.0%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 6.70 [1.99;22.62] | 0.0004 |
| PT Rash | 74 | 18 (24.3%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 3.41 [1.26;9.19] | 0.0101 |
| PT Rash maculo-papular | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 3.96 [0.84;18.65] | 0.0599 |
| PT Skin discolouration | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.1466 |
| PT Skin ulcer | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.87 [0.17;20.61] | 0.6050 |
| PT Yellow skin | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 8 (11.3%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.0035 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.4.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| SOC Vascular disorders | 74 | 35 (47.3%) | NYR [3.61;NYR] | 71 | 39 (54.9%) | 5.45 [2.20;NYR] | 0.79 [0.50;1.26] | 0.3264 |
| PT Deep vein thrombosis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1609 |
| PT Hypertension | 74 | 33 (44.6%) | NYR [5.19;NYR] | 71 | 38 (53.5%) | 6.24 [2.50;NYR] | 0.78 [0.49;1.25] | 0.3019 |
| PT Hypotension | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.2699 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.5.1: Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 59 (79.7%) | 51 (71.8%) |
| Number of censored cases | N | 15 (20.3%) | 20 (28.2%) |
| Time to first event (Months) | Mean (SE) | 8.30 (0.99) | 9.39 (1.24) |
| | Q1 [95% CI] | 1.4 [0.92;1.77] | 1.0 [0.69;2.04] |
| | Median [95% CI] | 3.24 [2.40;8.08] | 3.68 [2.07;5.78] |
| | Q3 [95% CI] | 16.4 [9.17;NYR] | 24.4 [7.56;NYR] |
| | p-value (a) | 0.9263 | |
| Stratified Cox PH model | HR (b) | 1.02 [0.70;1.49] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
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TABLE 4.5.2: Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - by SOC/PT - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | |
|---|---|---|---|---|---|---|---|---|
| Overall<br>System Organ Class (SOC)<br>Preferred Term (PT) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | Hazard Ratio<br>[95% CI][c] | p-value[d] |
| Overall | 74 | 59 (79.7%) | 3.24 [2.40;8.08] | 71 | 51 (71.8%) | 3.68 [2.07;5.78] | 1.02<br>[0.70;1.49] | 0.9263 |
| SOC Blood and lymphatic system disorders | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 8 (11.3%) | NYR [NYR;NYR] | <0.01<br>[<0.01;NE] | 0.0032 |
| PT Anaemia | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | <0.01<br>[<0.01;NE] | 0.3101 |
| PT Neutropenia | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | <0.01<br>[<0.01;NE] | 0.0364 |
| PT Thrombocytopenia | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | <0.01<br>[<0.01;NE] | 0.0419 |
| SOC Cardiac disorders | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.23<br>[0.43;11.55] | 0.3256 |
| SOC Endocrine disorders | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.1873 |
| SOC Gastrointestinal disorders | 74 | 16 (21.6%) | NYR [NYR;NYR] | 71 | 13 (18.3%) | NYR [24.61;NYR] | 0.99<br>[0.47;2.07] | 0.9791 |
| PT Diarrhoea | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.73<br>[0.52;5.74] | 0.3684 |
| PT Stomatitis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.59<br>[0.10;3.56] | 0.5632 |
| PT Vomiting | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.34<br>[0.03;3.82] | 0.3620 |
| SOC General disorders and administration site conditions | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 1.30<br>[0.49;3.43] | 0.5911 |
| PT Asthenia | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 5.36<br>[0.64;44.66] | 0.0818 |
| PT Fatigue | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.65<br>[0.11;3.91] | 0.6383 |
| PT Mucosal inflammation | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | <0.01<br>[<0.01;NE] | 0.0782 |
| SOC Hepatobiliary disorders | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.93<br>[0.35;10.56] | 0.4388 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
Analysis Cut Off date: 10SEP2020
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TABLE 4.5.2: Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | |
|---|---|---|---|---|---|---|---|---|
| Overall<br>System Organ Class (SOC)<br>Preferred Term (PT) | N[a] | Subjects with events<br>n (%) | Median [95% CI][b]<br>(Months) | N[a] | Subjects with events<br>n (%) | Median [95% CI][b]<br>(Months) | Hazard Ratio [95% CI][c] | p-value[d] |
| PT Hepatotoxicity | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 2.95 [0.31;28.38] | 0.3252 |
| SOC Infections and infestations | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.86 [0.59;13.82] | 0.1715 |
| PT Pneumonia | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2165 |
| PT Urinary tract infection | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | . [.;NE] | . |
| SOC Injury, poisoning and procedural complications | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 0.84 [0.05;13.52] | 0.9040 |
| SOC Investigations | 74 | 13 (17.6%) | NYR [NYR;NYR] | 71 | 20 (28.2%) | NYR [24.41;NYR] | 0.56 [0.28;1.14] | 0.1044 |
| PT Alanine aminotransferase increased | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.48 [0.35;6.21] | 0.5888 |
| PT Amylase increased | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.87 [0.17;4.31] | 0.8605 |
| PT Aspartate aminotransferase increased | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2032 |
| PT Lipase increased | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 0.90 [0.26;3.10] | 0.8617 |
| PT Neutrophil count decreased | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 6 (8.5%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.0068 |
| PT Platelet count decreased | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.1464 |
| SOC Metabolism and nutrition disorders | 74 | 21 (28.4%) | NYR [22.18;NYR] | 71 | 15 (21.1%) | NYR [NYR;NYR] | 1.27 [0.65;2.47] | 0.4853 |
| PT Decreased appetite | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 0.87 [0.05;13.98] | 0.9237 |
| PT Hyperglycaemia | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.40 [0.04;4.48] | 0.4423 |
| PT Hyponatraemia | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 7 (9.9%) | NYR [NYR;NYR] | 0.88 [0.31;2.53] | 0.8139 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 4.5.2: Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | |
|---|---|---|---|---|---|---|---|---|
| Overall<br>System Organ Class (SOC)<br>Preferred Term (PT) | N[a] | Subjects with events<br>n (%) | Median [95% CI][b]<br>(Months) | N[a] | Subjects with events<br>n (%) | Median [95% CI][b]<br>(Months) | Hazard Ratio [95% CI][c] | p-value[d] |
| PT Hypophosphataemia | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 4.40 [0.51;37.94] | 0.1407 |
| SOC Musculoskeletal and connective tissue disorders | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 0.80 [0.20;3.24] | 0.7564 |
| PT Back pain | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3657 |
| SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.32 [0.37;4.69] | 0.6693 |
| PT Malignant neoplasm progression | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.19 [0.27;5.37] | 0.8164 |
| SOC Nervous system disorders | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.22 [0.27;5.45] | 0.7980 |
| SOC Renal and urinary disorders | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.40 [0.33;5.90] | 0.6409 |
| PT Proteinuria | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.26 [0.21;7.58] | 0.8014 |
| SOC Respiratory, thoracic and mediastinal disorders | 74 | 11 (14.9%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 3.60 [1.00;12.92] | 0.0355 |
| PT Pulmonary embolism | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 6.90 [0.85;56.10] | 0.0358 |
| PT Respiratory failure | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3085 |
| SOC Skin and subcutaneous tissue disorders | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 10 (14.1%) | NYR [NYR;NYR] | 0.88 [0.36;2.11] | 0.7666 |
| PT Palmar-plantar erythrodysaesthesia syndrome | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 10 (14.1%) | NYR [NYR;NYR] | 0.41 [0.14;1.20] | 0.0916 |
| SOC Vascular disorders | 74 | 12 (16.2%) | NYR [NYR;NYR] | 71 | 16 (22.5%) | NYR [NYR;NYR] | 0.71 [0.34;1.51] | 0.3729 |
| PT Hypertension | 74 | 12 (16.2%) | NYR [NYR;NYR] | 71 | 16 (22.5%) | NYR [NYR;NYR] | 0.71 [0.34;1.51] | 0.3729 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 4.6.1: Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 37 (50.0%) | 23 (32.4%) |
| Number of censored cases | N | 37 (50.0%) | 48 (67.6%) |
| Time to first event (Months) | Mean (SE) | 13.47 (0.87) | 18.31 (1.18) |
| | Q1 [95% CI] | 5.4 [2.73;9.89] | 5.7 [2.30;24.61] |
| | Median [95% CI] | 18.89 [12.65;NYR] | NYR [21.29;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0862 | |
| Stratified Cox PH model | HR (b) | 1.58 [0.93;2.69] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 4.6.2: Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - by SOC/PT - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | |
|---|---|---|---|---|---|---|---|---|
| Overall<br>System Organ Class (SOC)<br>Preferred Term (PT) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | N[a] | Subjects with events<br>n (%) | Median<br>[95% CI][b]<br>(Months) | Hazard Ratio<br>[95% CI][c] | p-value[d] |
| Overall | 74 | 37 (50.0%) | 18.89 [12.65;NYR] | 71 | 23 (32.4%) | NYR [21.29;NYR] | 1.58<br>[0.93;2.69] | 0.0862 |
| SOC Blood and lymphatic system disorders | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | <0.01<br>[<0.01;NE] | 0.3088 |
| PT Anaemia | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | .<br>[.;NE] | . |
| SOC Cardiac disorders | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.23<br>[0.43;11.55] | 0.3256 |
| SOC Endocrine disorders | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.1879 |
| SOC Gastrointestinal disorders | 74 | 13 (17.6%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [24.61;NYR] | 2.65<br>[0.86;8.20] | 0.0780 |
| PT Diarrhoea | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.0252 |
| SOC General disorders and administration site conditions | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.50<br>[0.36;6.29] | 0.5768 |
| PT Pyrexia | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 1.74<br>[0.16;19.26] | 0.6496 |
| SOC Hepatobiliary disorders | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.94<br>[0.13;6.68] | 0.9508 |
| SOC Infections and infestations | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 2.53<br>[0.51;12.55] | 0.2407 |
| PT Pneumonia | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.2165 |
| PT Urinary tract infection | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | .<br>[.;NE] | . |
| SOC Injury, poisoning and procedural complications | 74 | 1 (1.4%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99<br>[<0.01;NE] | 0.3657 |
| SOC Metabolism and nutrition disorders | 74 | 5 (6.8%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.02<br>[0.27;3.83] | 0.9762 |
| PT Hyponatraemia | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 0.84<br>[0.12;6.03] | 0.8648 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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TABLE 4.6.2: Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Overall System Organ Class (SOC) Preferred Term (PT) | Nivolumab + Cabozantinib N[a] | Nivolumab + Cabozantinib Subjects with events n (%) | Nivolumab + Cabozantinib Median [95% CI][b] (Months) | Sunitinib N[a] | Sunitinib Subjects with events n (%) | Sunitinib Median [95% CI][b] (Months) | Nivolumab + Cabozantinib vs. Sunitinib Hazard Ratio [95% CI][c] | Nivolumab + Cabozantinib vs. Sunitinib p-value[d] |
|---|---|---|---|---|---|---|---|---|
| SOC Musculoskeletal and connective tissue disorders | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 0.53 [0.09;3.20] | 0.4788 |
| SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 1.56 [0.45;5.35] | 0.4771 |
| PT Malignant neoplasm progression | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 1.19 [0.27;5.37] | 0.8164 |
| SOC Nervous system disorders | 74 | 4 (5.4%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.87 [0.34;10.22] | 0.4647 |
| SOC Renal and urinary disorders | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 1.26 [0.21;7.60] | 0.7992 |
| SOC Respiratory, thoracic and mediastinal disorders | 74 | 7 (9.5%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 3.11 [0.64;15.04] | 0.1362 |
| PT Pleural effusion | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | . [.;NE] | . |
| PT Pneumonitis | 74 | 2 (2.7%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2457 |
| PT Pulmonary embolism | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0883 |
| PT Respiratory failure | 74 | 0 (0.0%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3085 |
| SOC Vascular disorders | 74 | 3 (4.1%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 2.81 [0.29;27.09] | 0.3493 |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
CI: Confidence Interval; NE: Not Estimable; NYR: (Median) Not Yet Reached.
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FIGURE 4.1.1: Treatment Emergent Adverse Event (TEAE) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

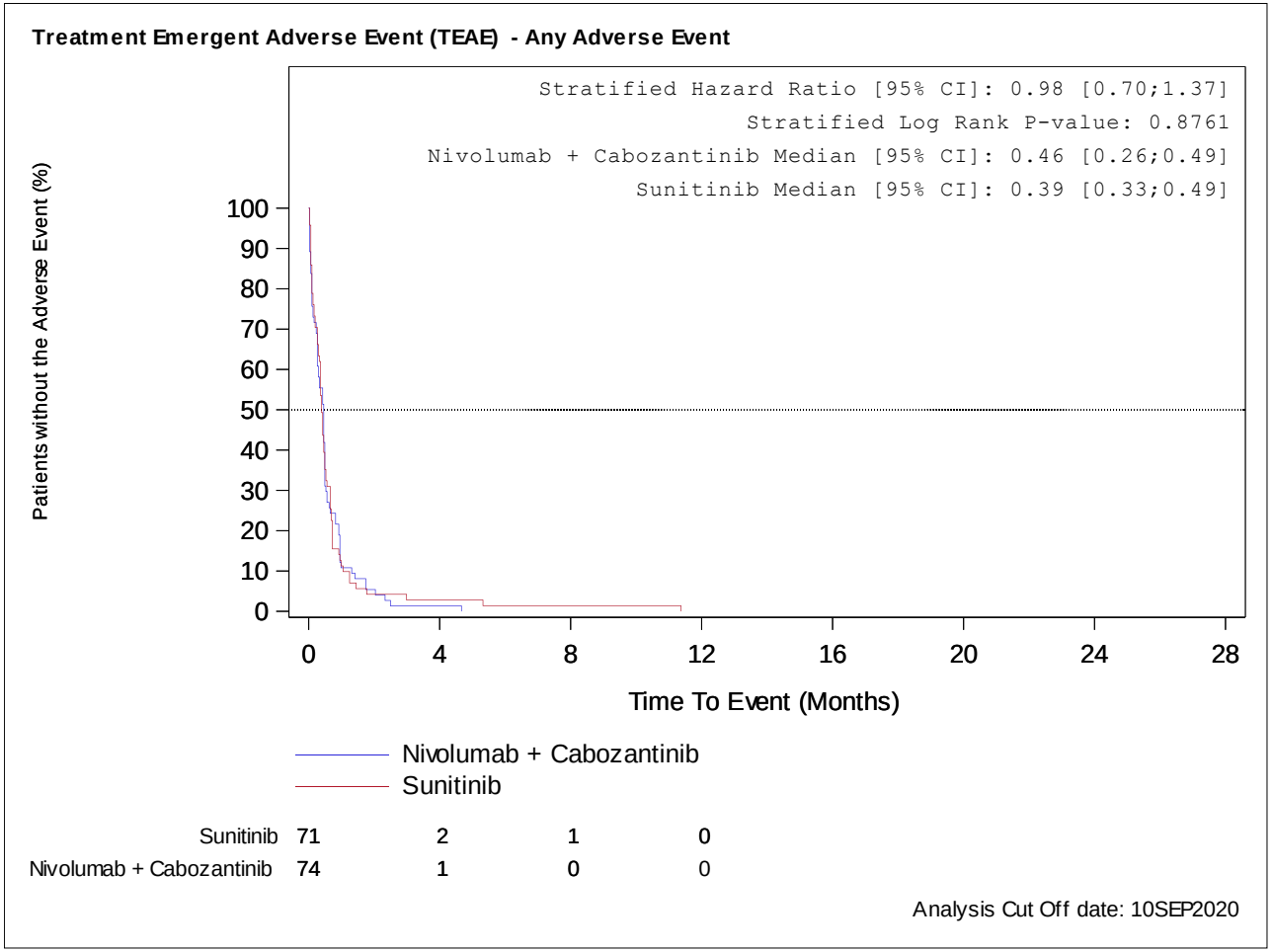


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FIGURE 4.1.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

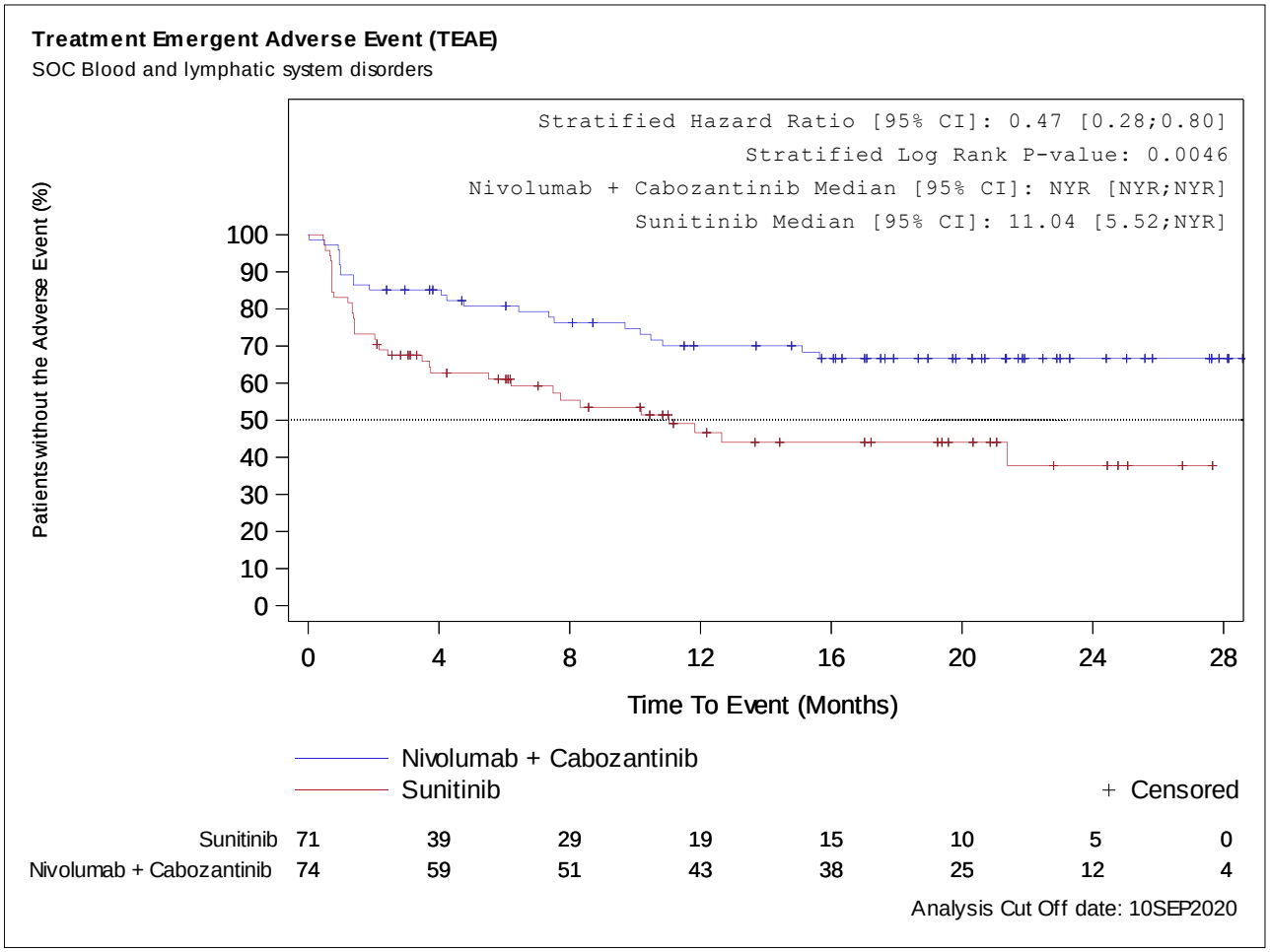


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FIGURE 4.1.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

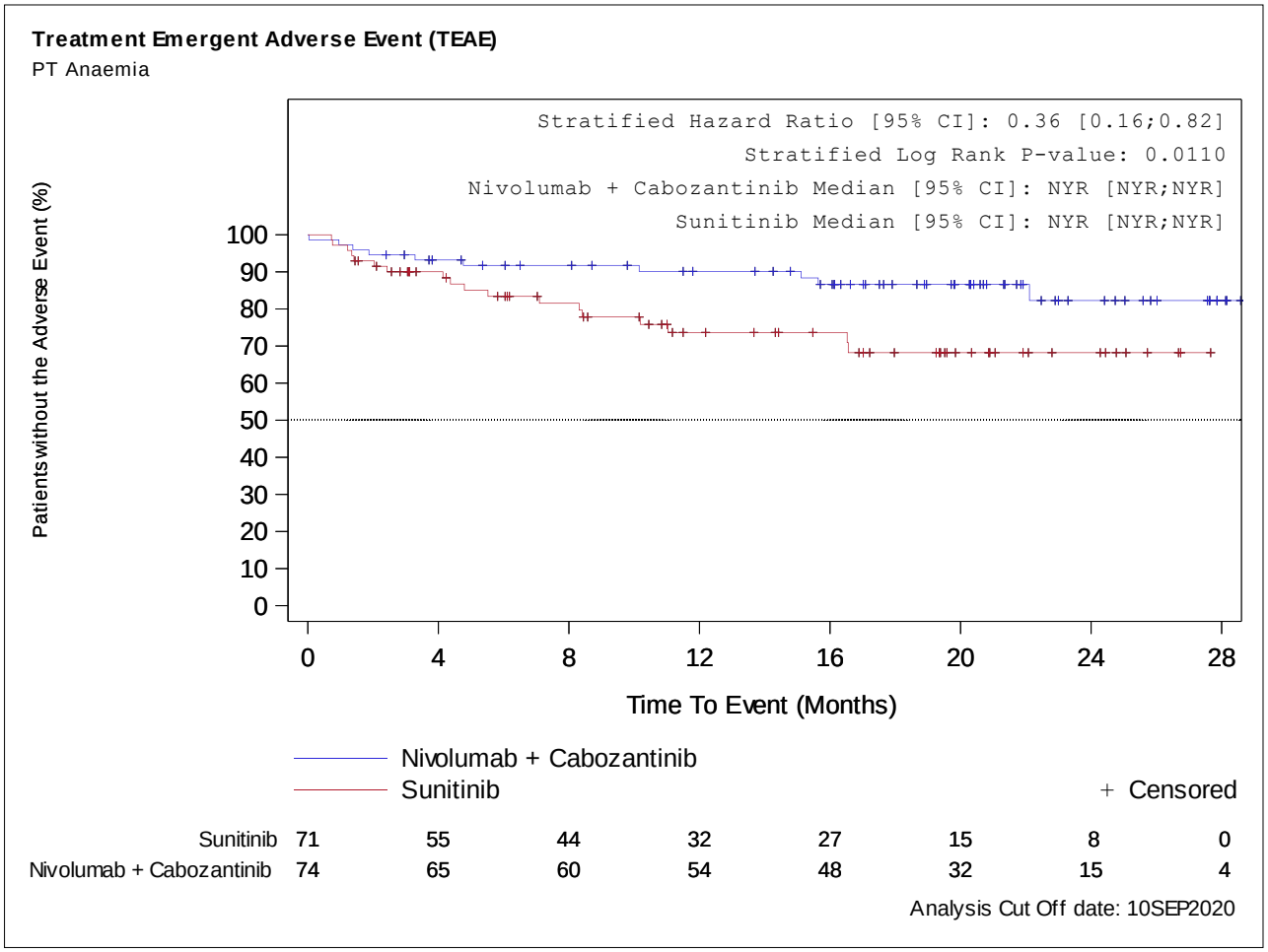


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FIGURE 4.1.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Leukopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

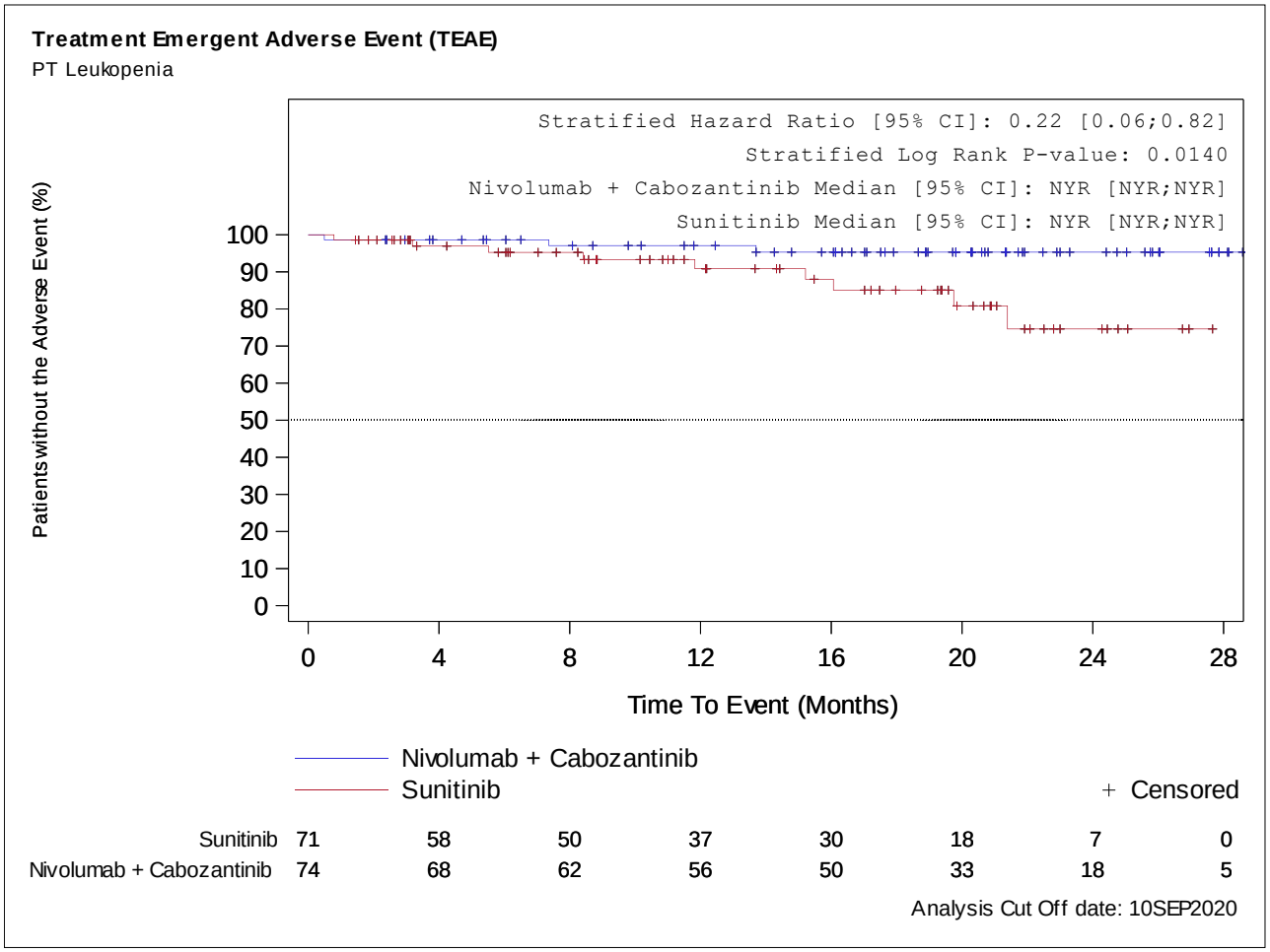


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FIGURE 4.1.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Lymphopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

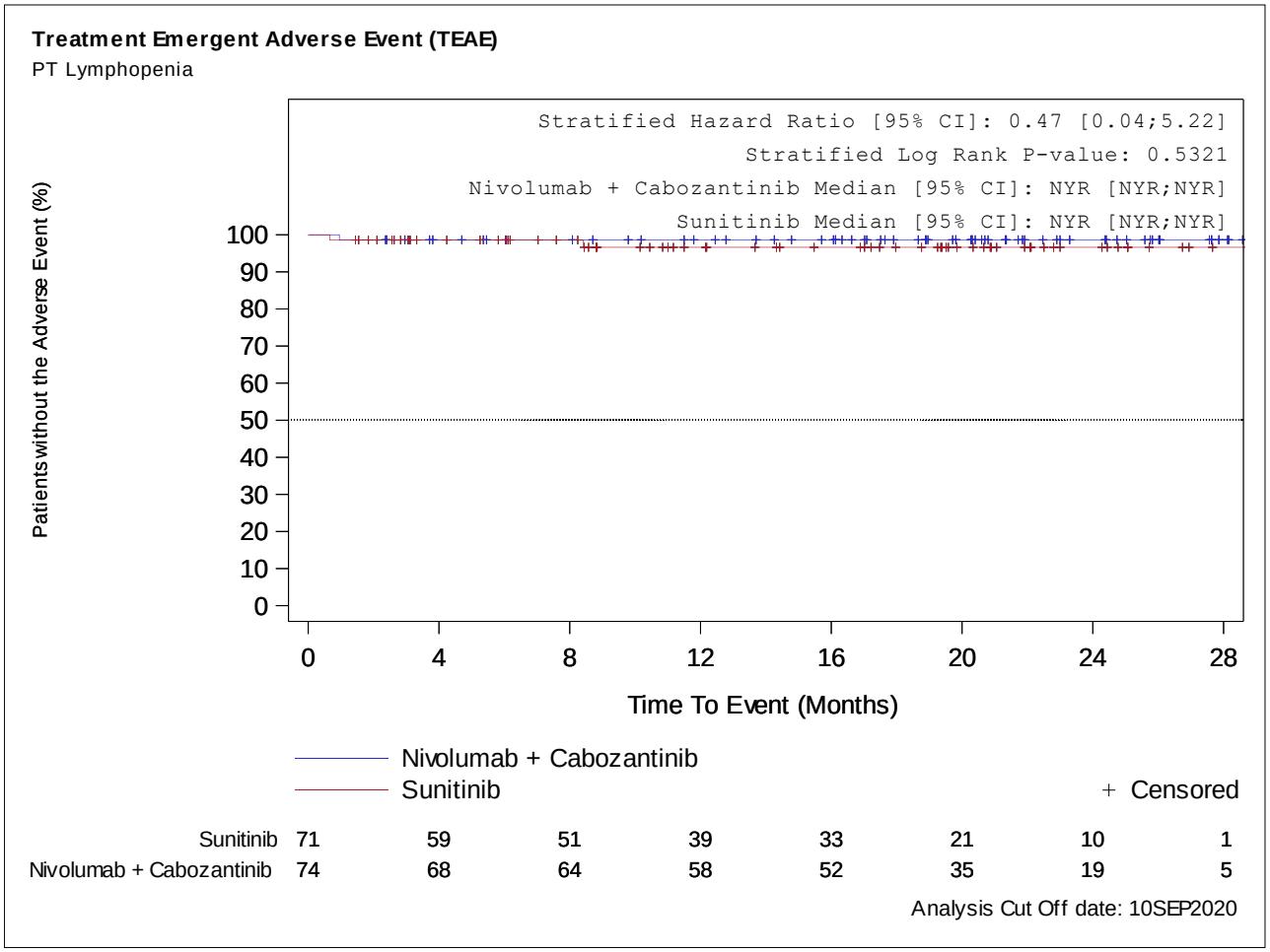


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FIGURE 4.1.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

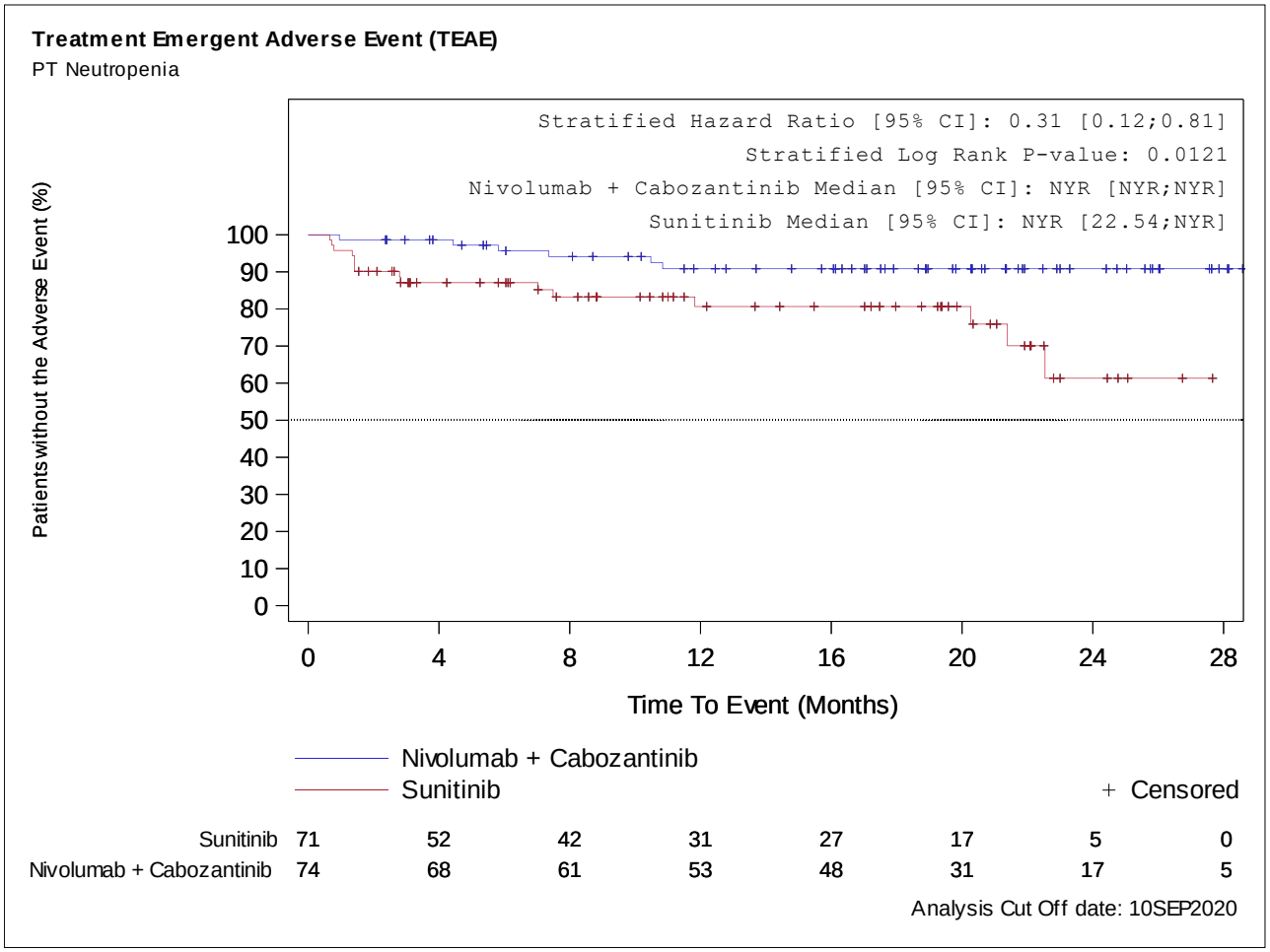


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FIGURE 4.1.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

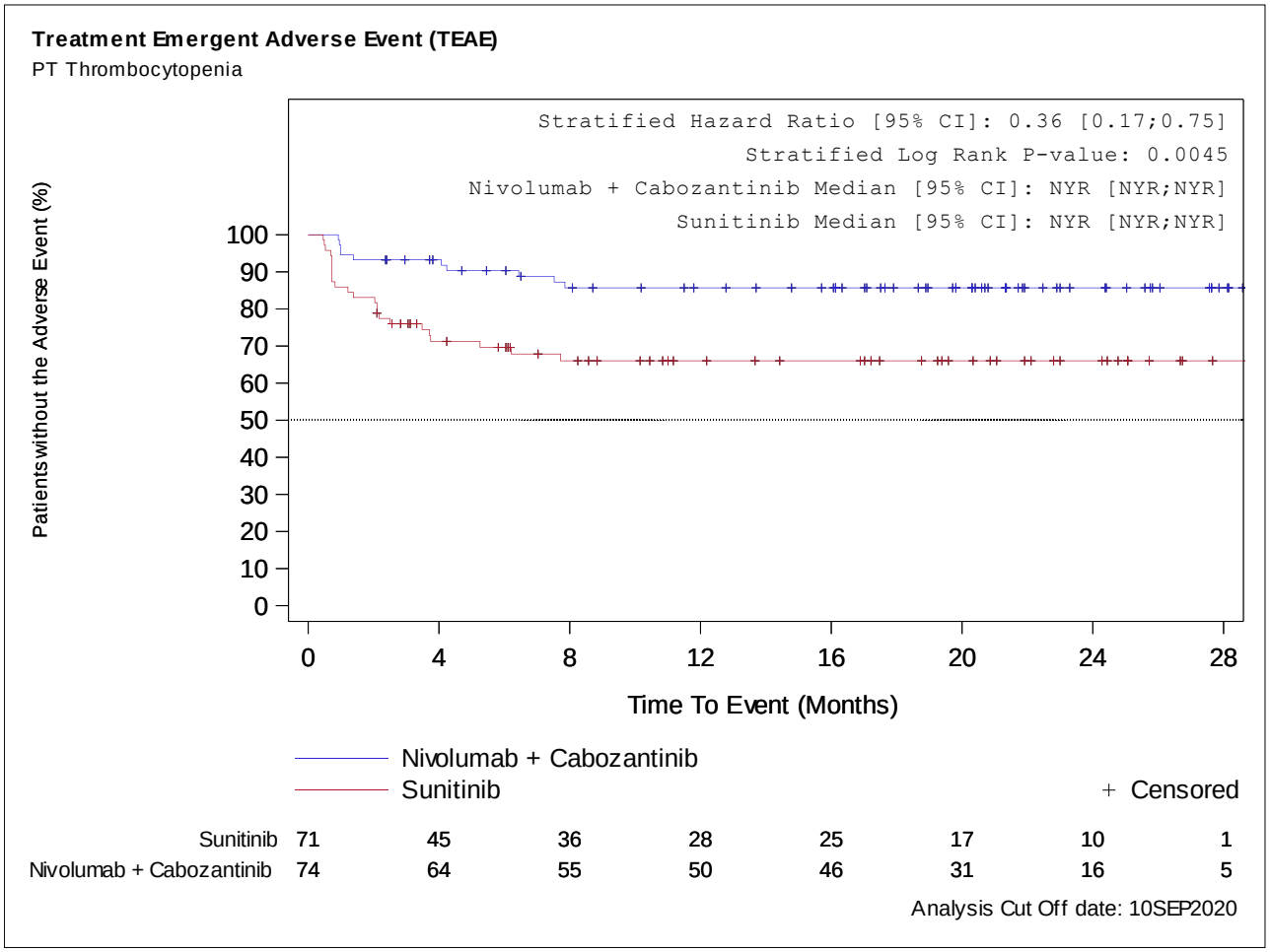


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FIGURE 4.1.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Cardiac disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

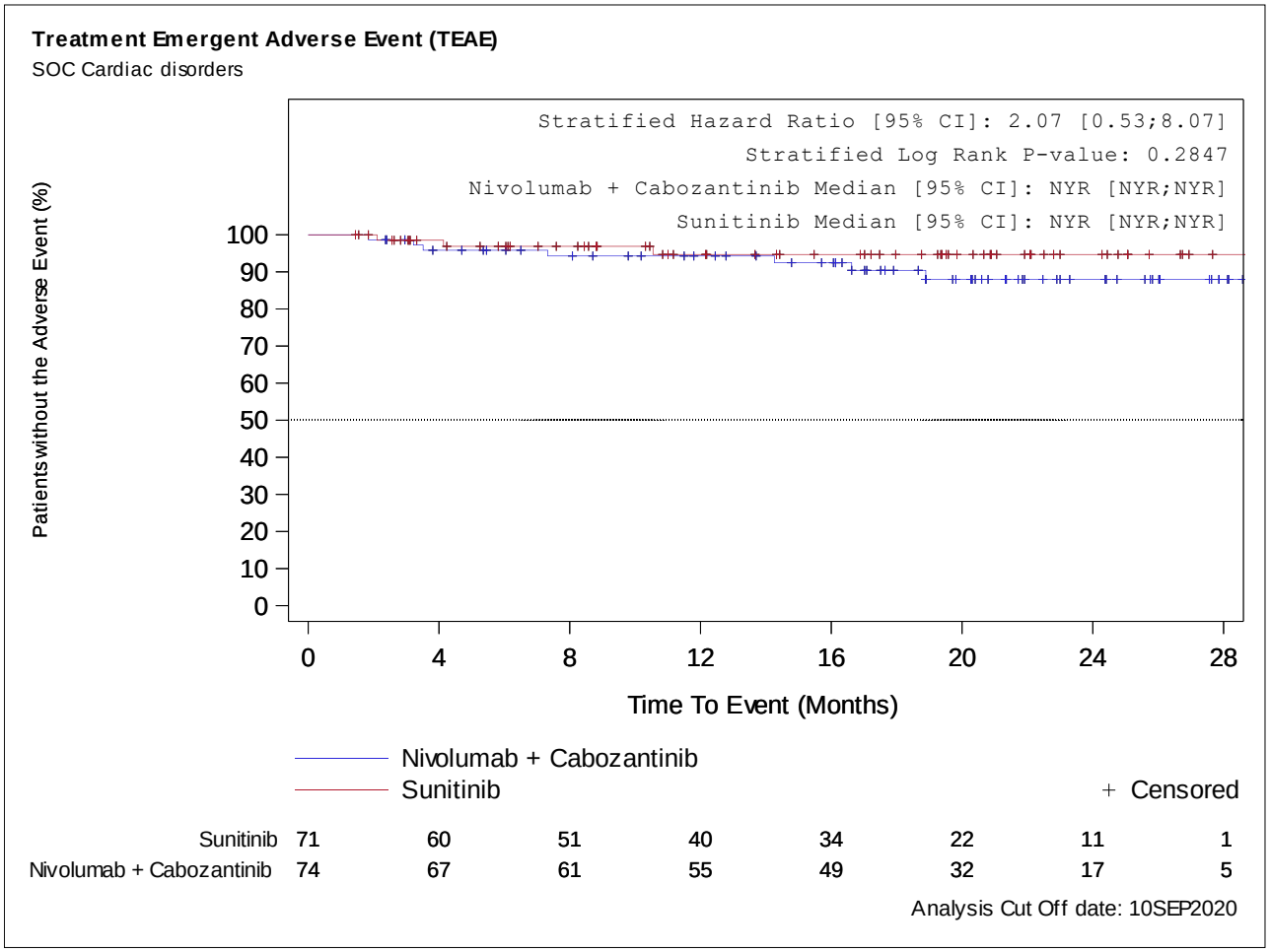


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FIGURE 4.1.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Ear and labyrinth disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

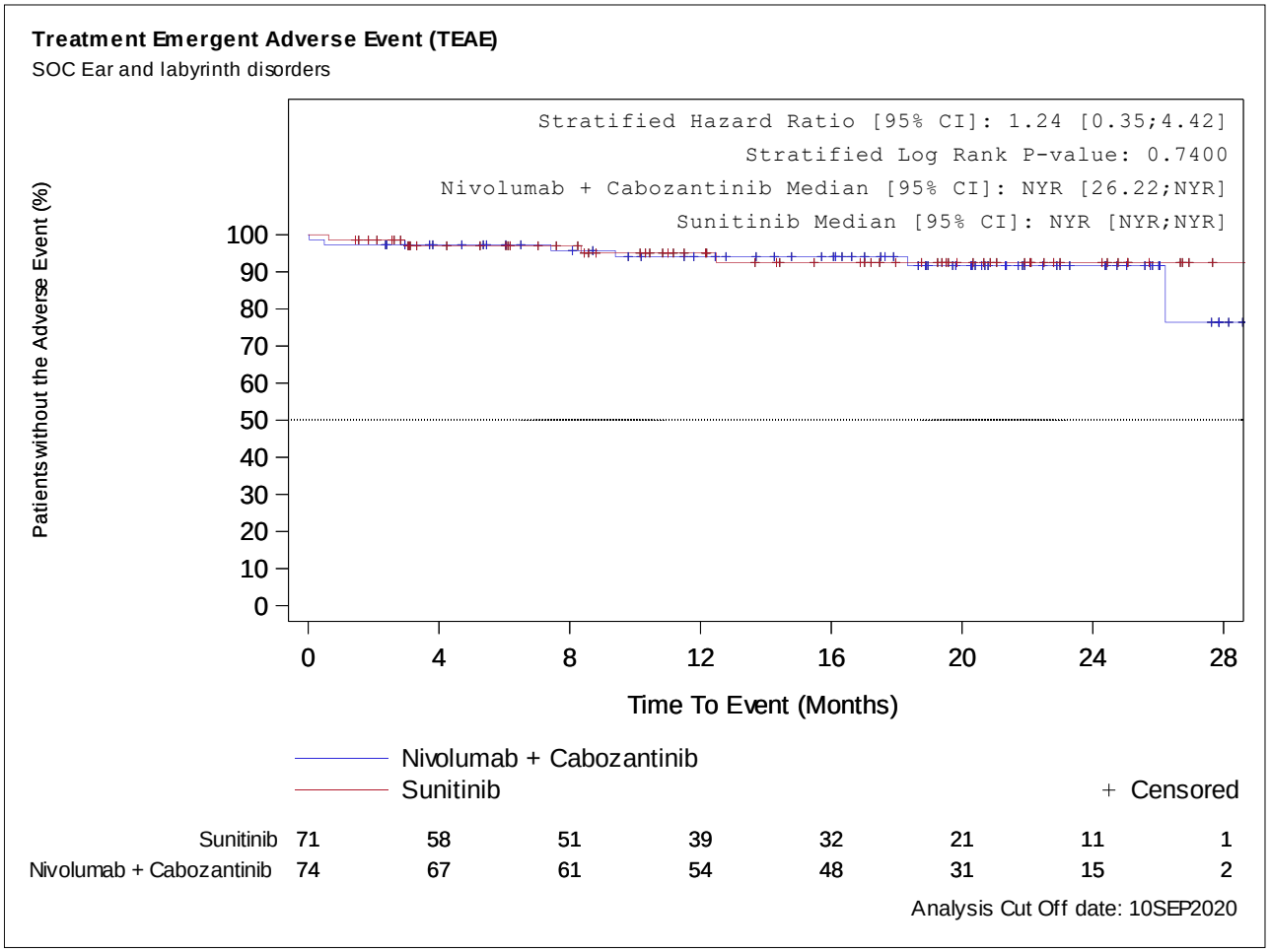


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FIGURE 4.1.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Vertigo - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

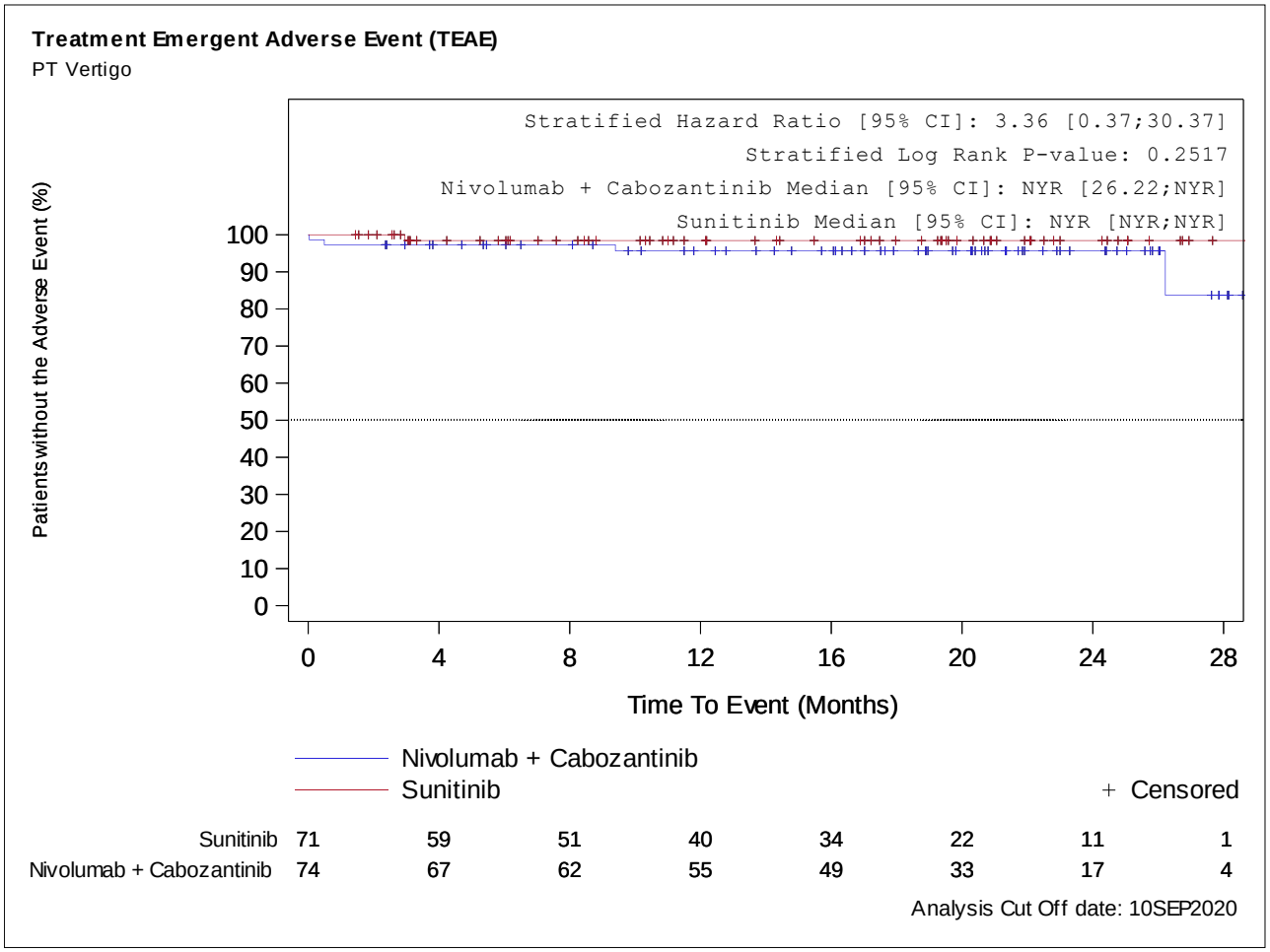


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FIGURE 4.1.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Endocrine disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

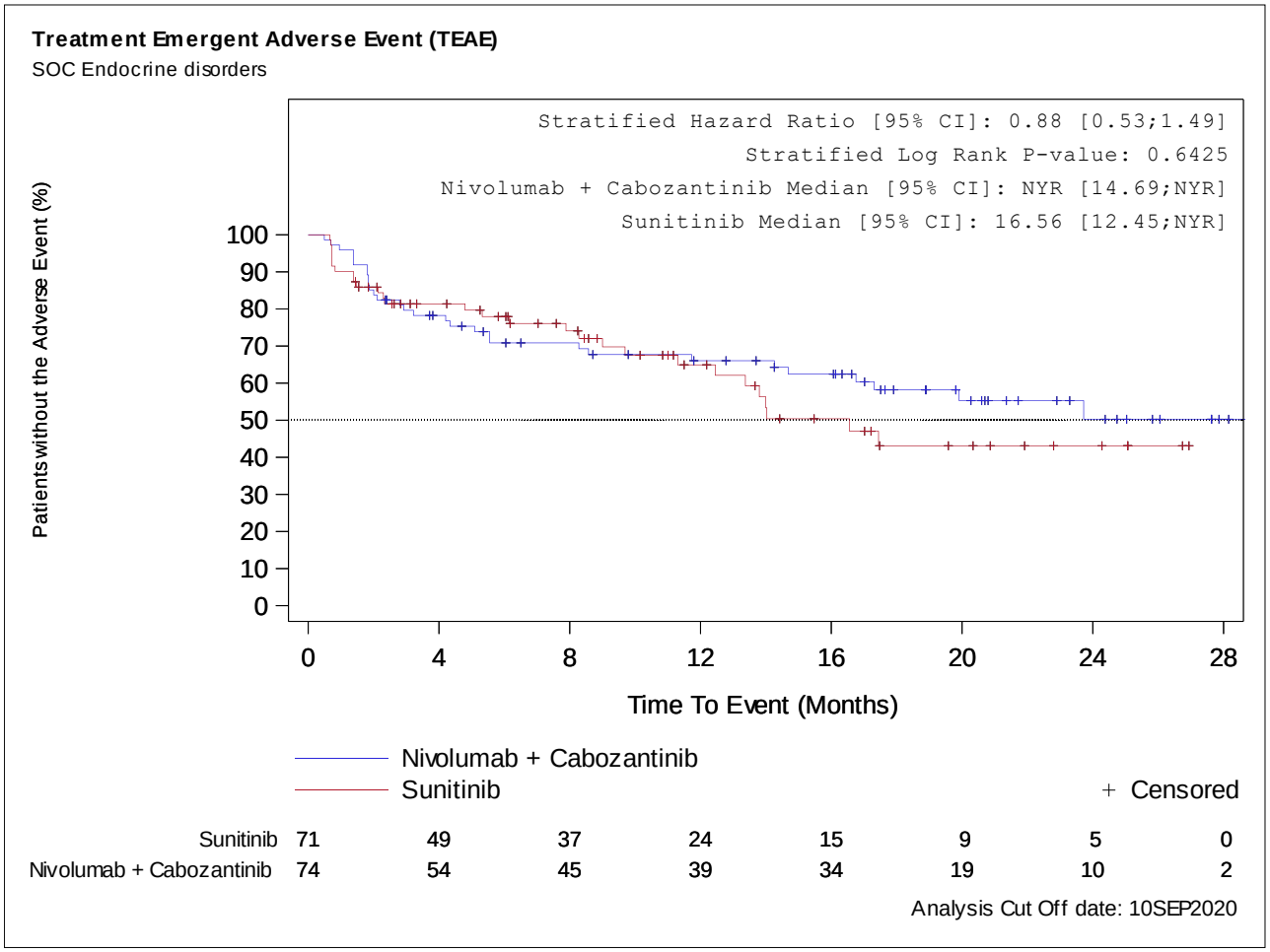


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FIGURE 4.1.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Adrenal insufficiency - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

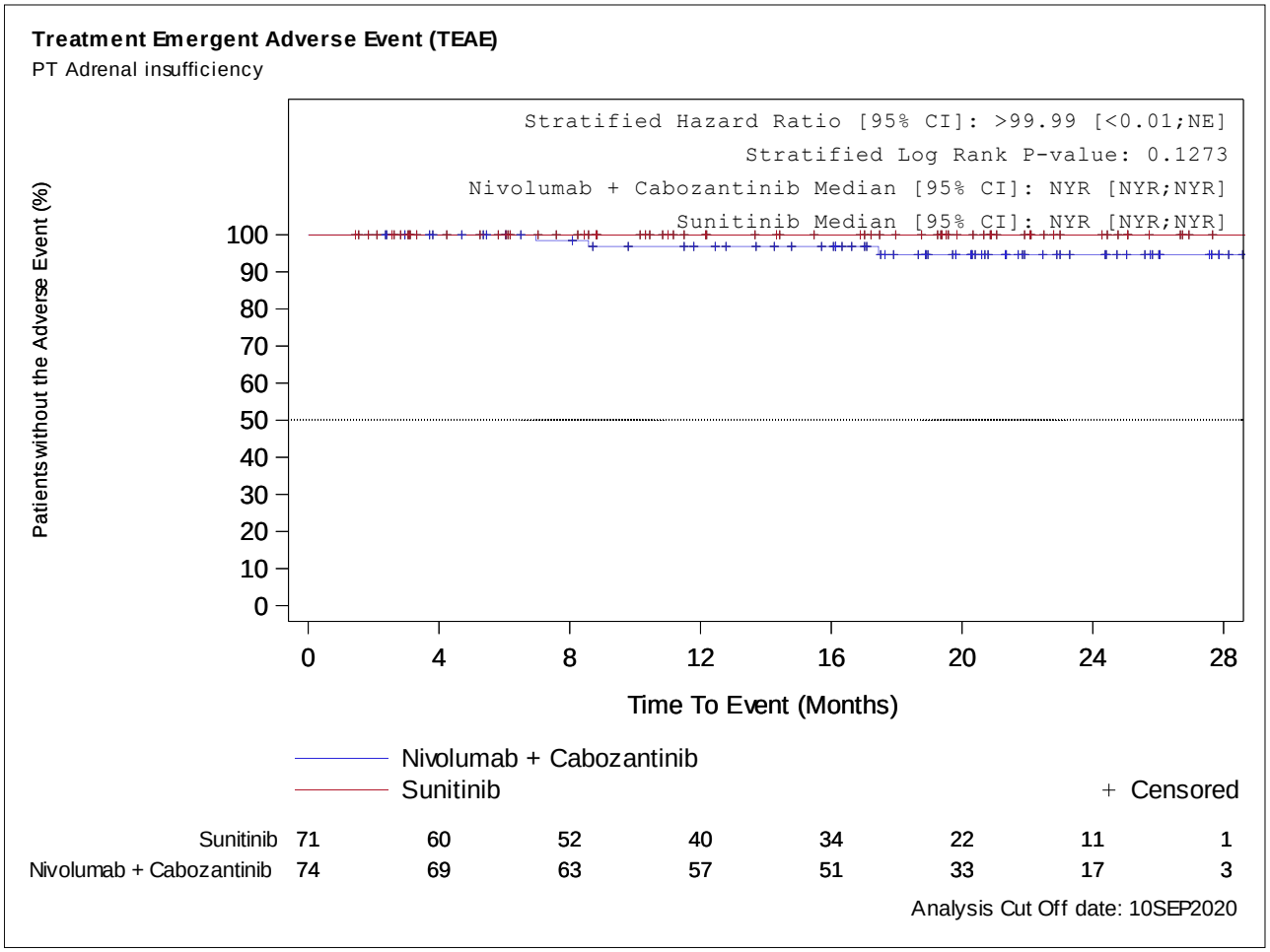


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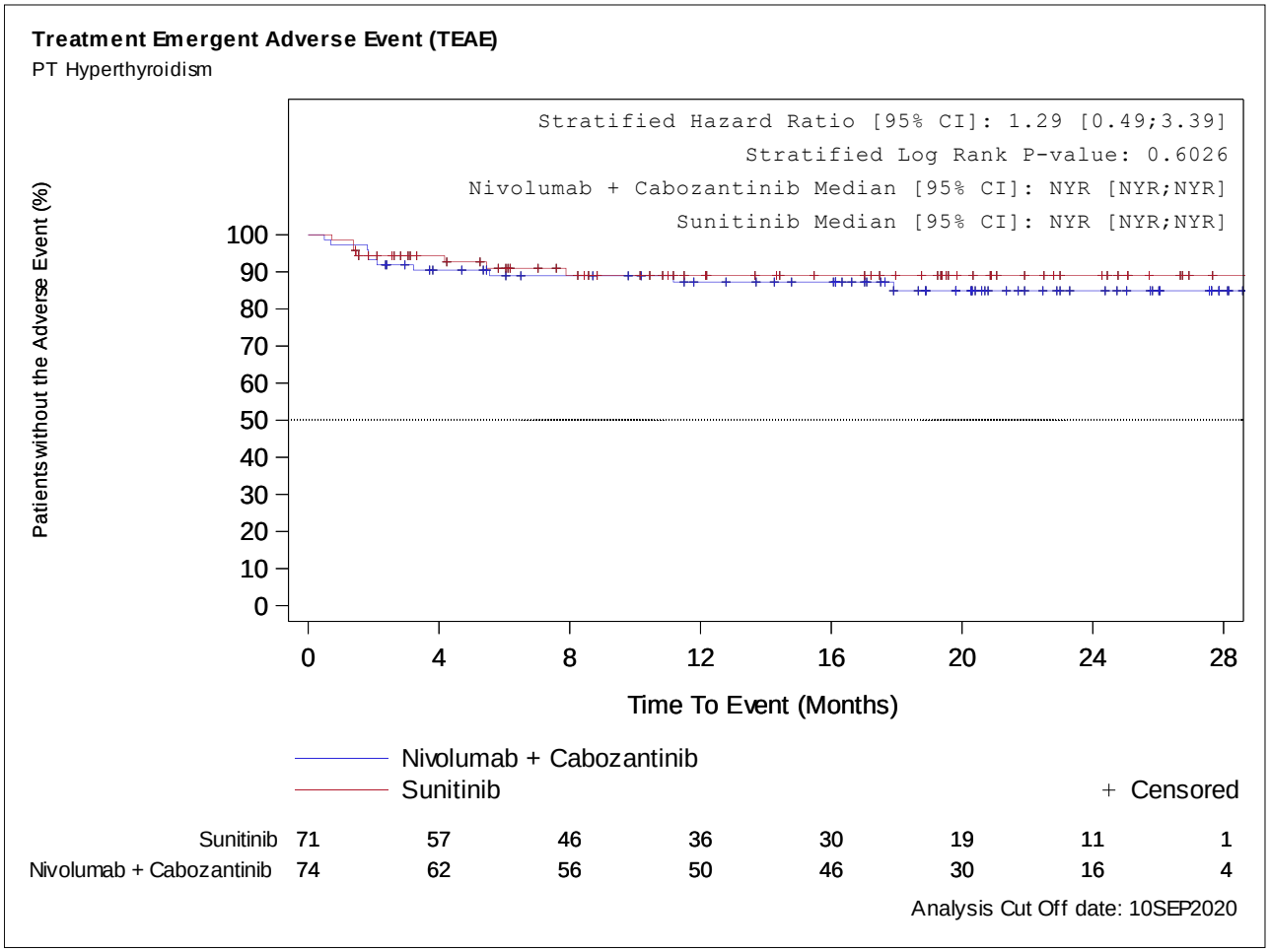
FIGURE 4.1.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hyperthyroidism - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.1.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypothyroidism - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

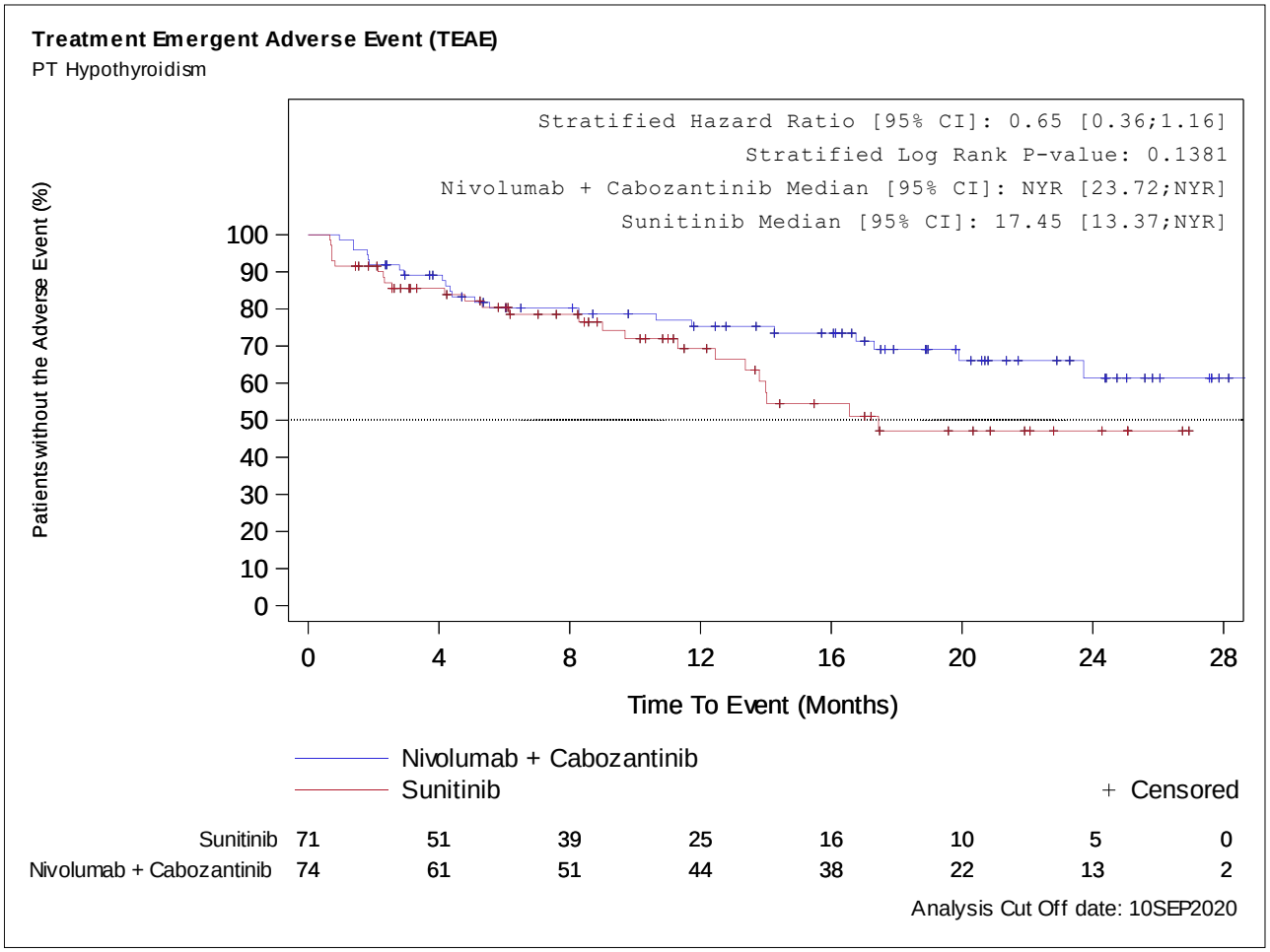


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FIGURE 4.1.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Eye disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

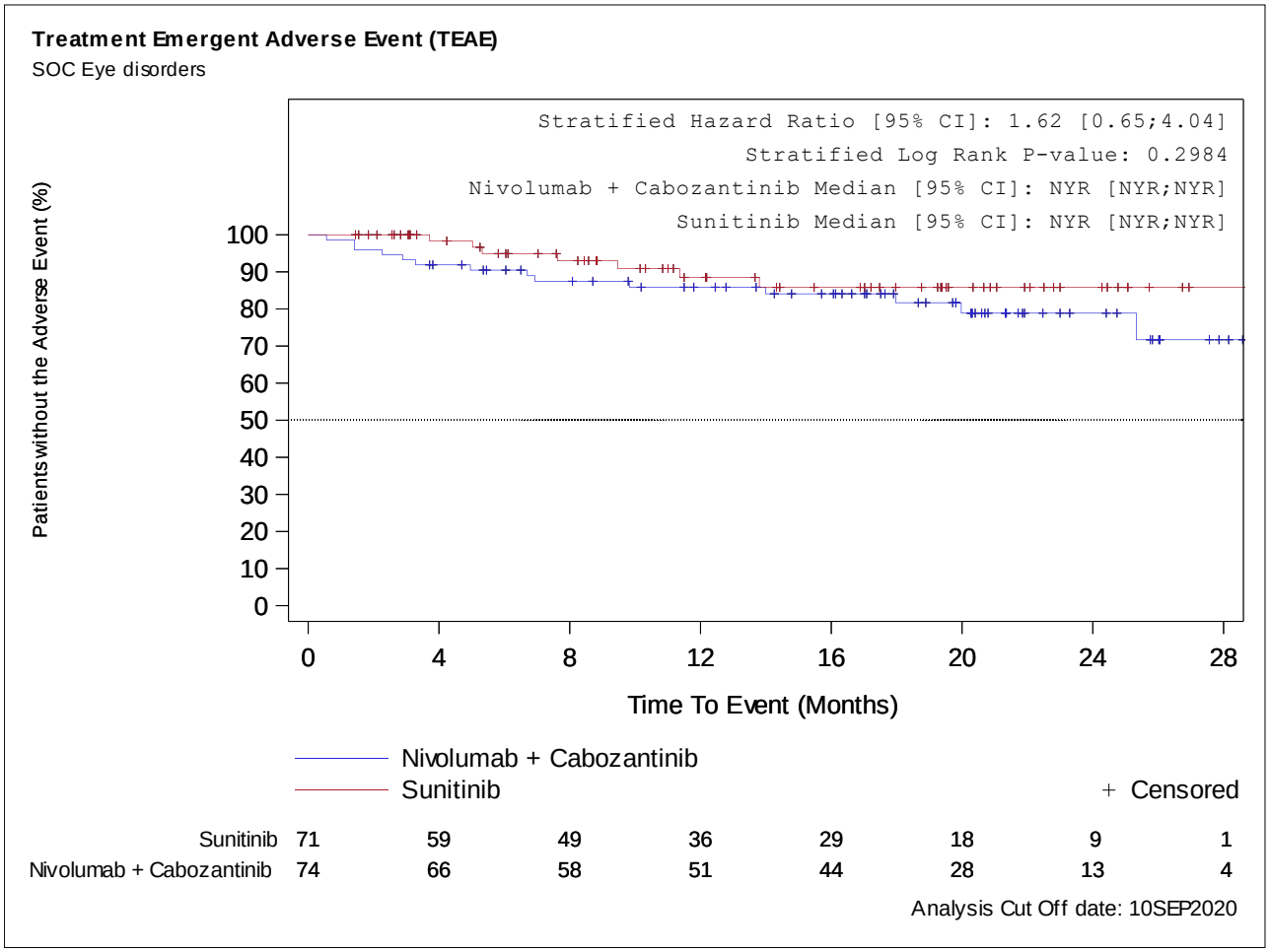


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FIGURE 4.1.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Vision blurred - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

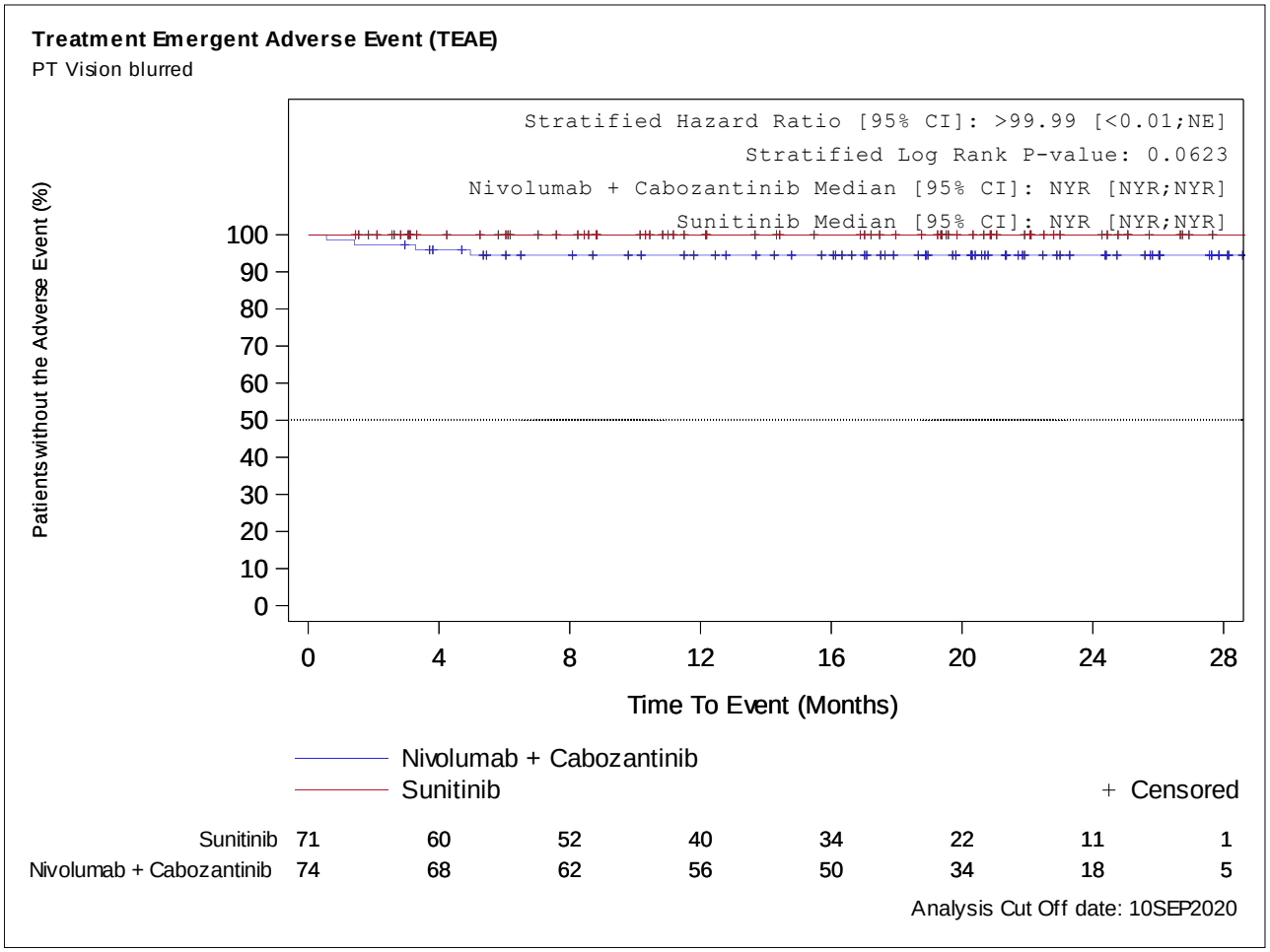


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FIGURE 4.1.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

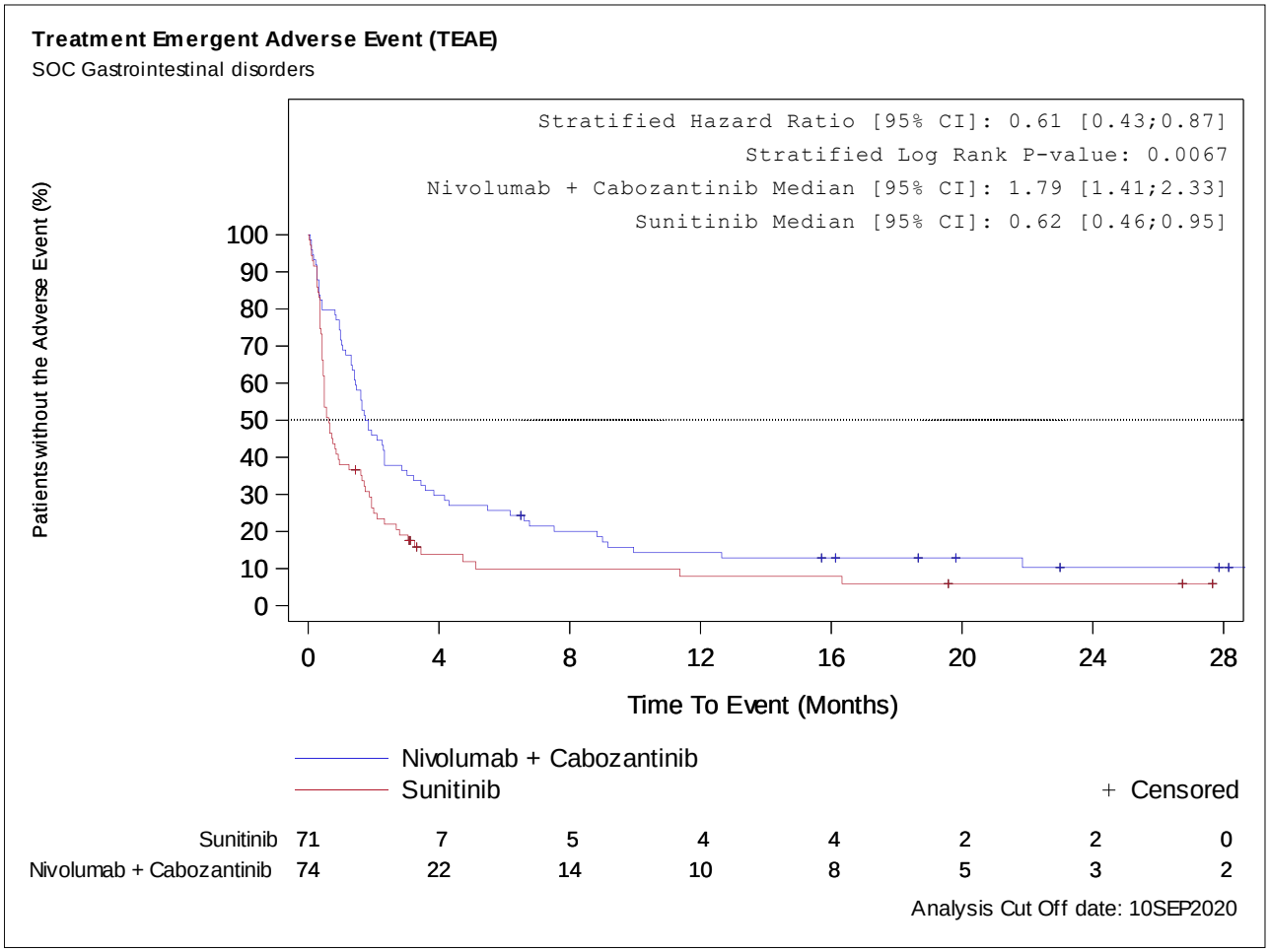


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FIGURE 4.1.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Abdominal distension - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

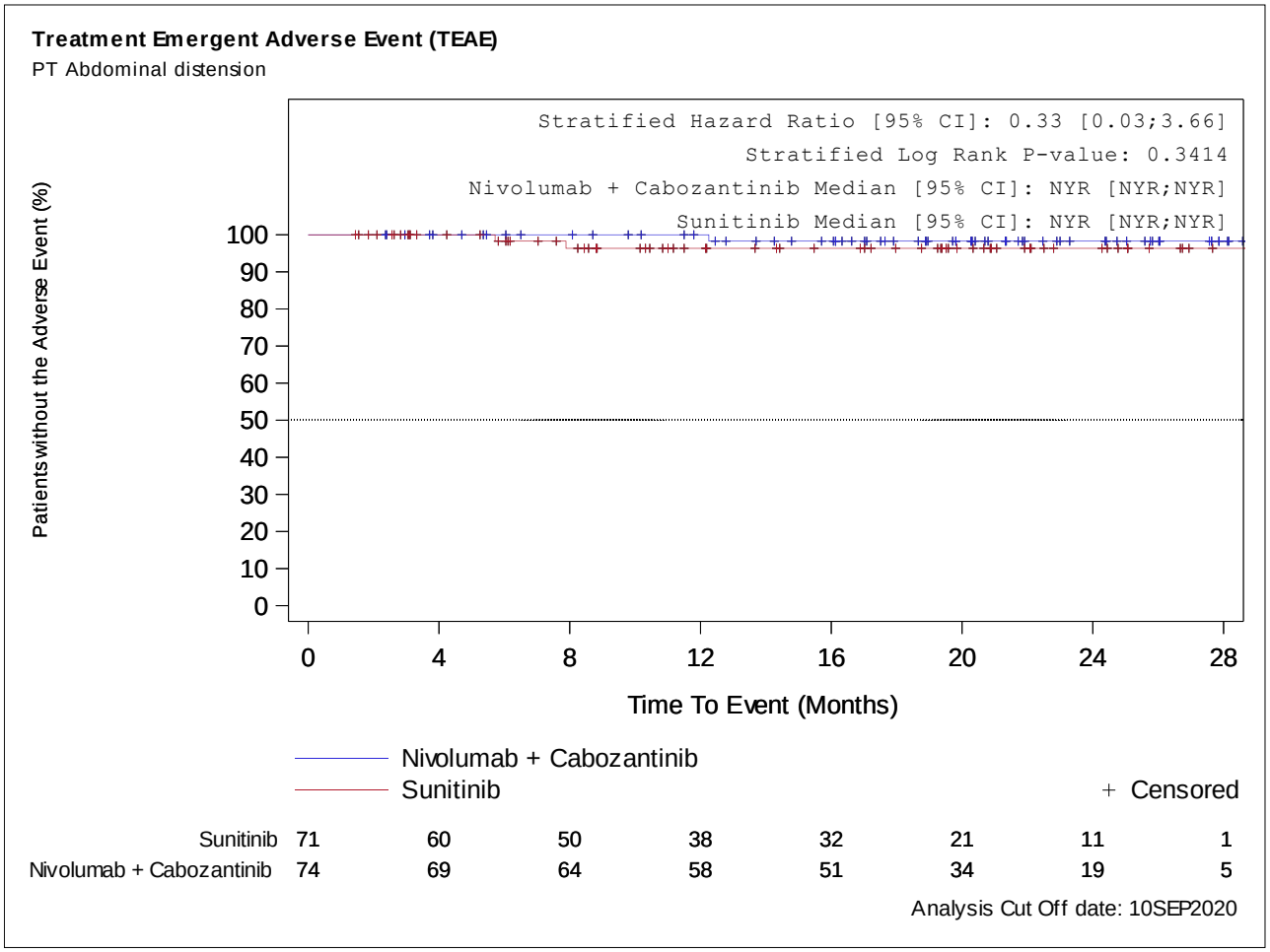


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FIGURE 4.1.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Abdominal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

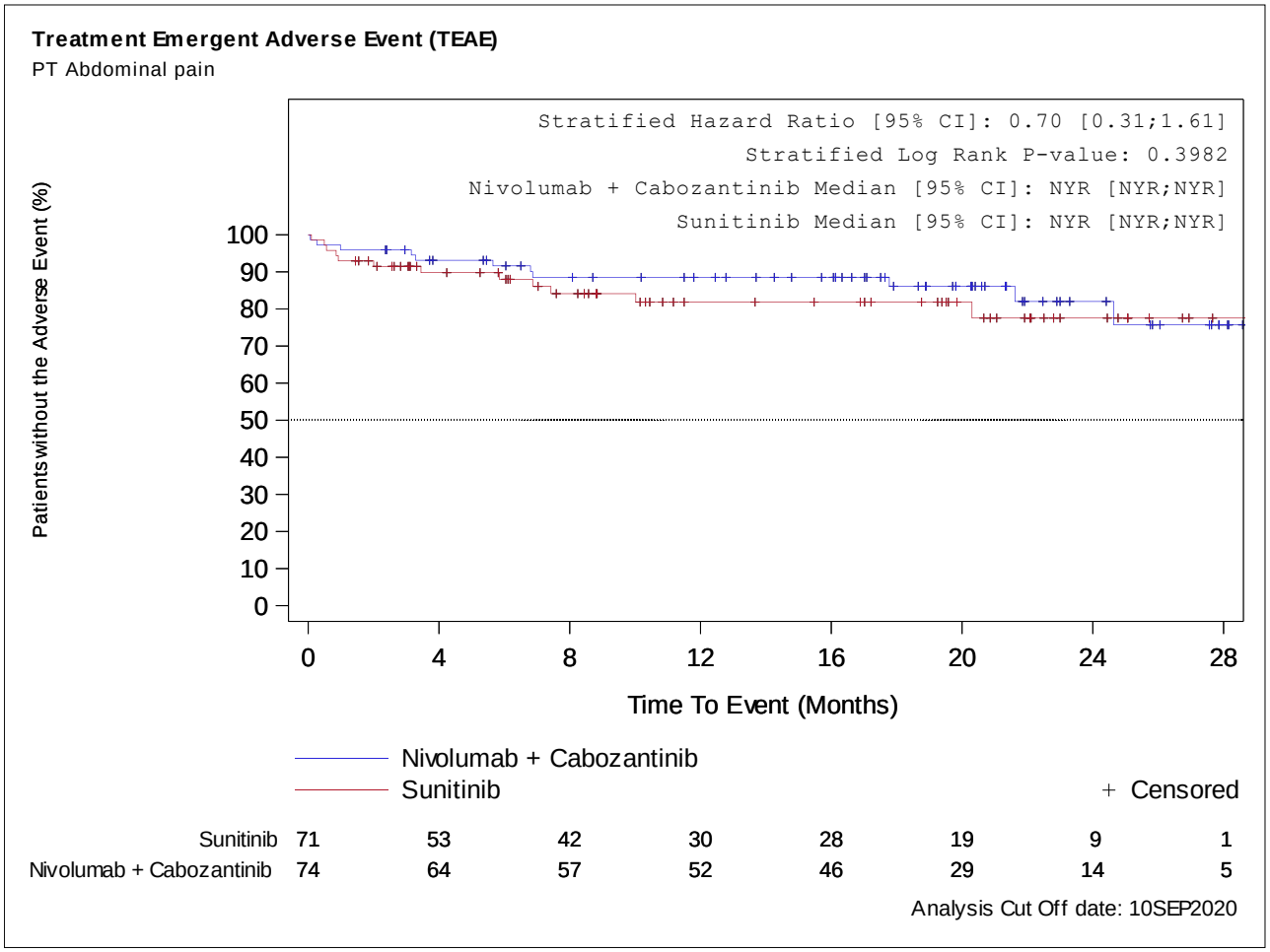


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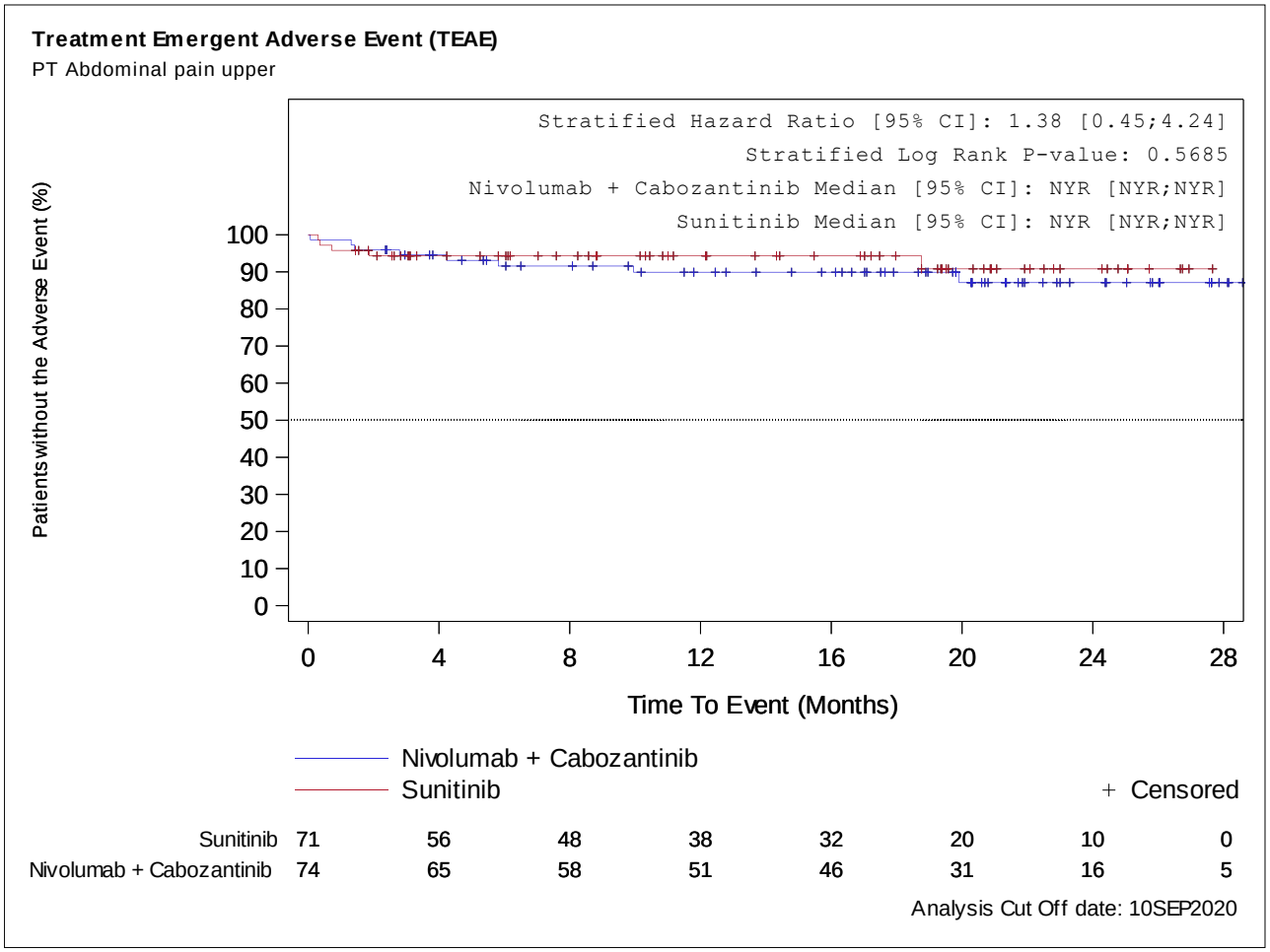
FIGURE 4.1.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Abdominal pain upper - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.1.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Constipation - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

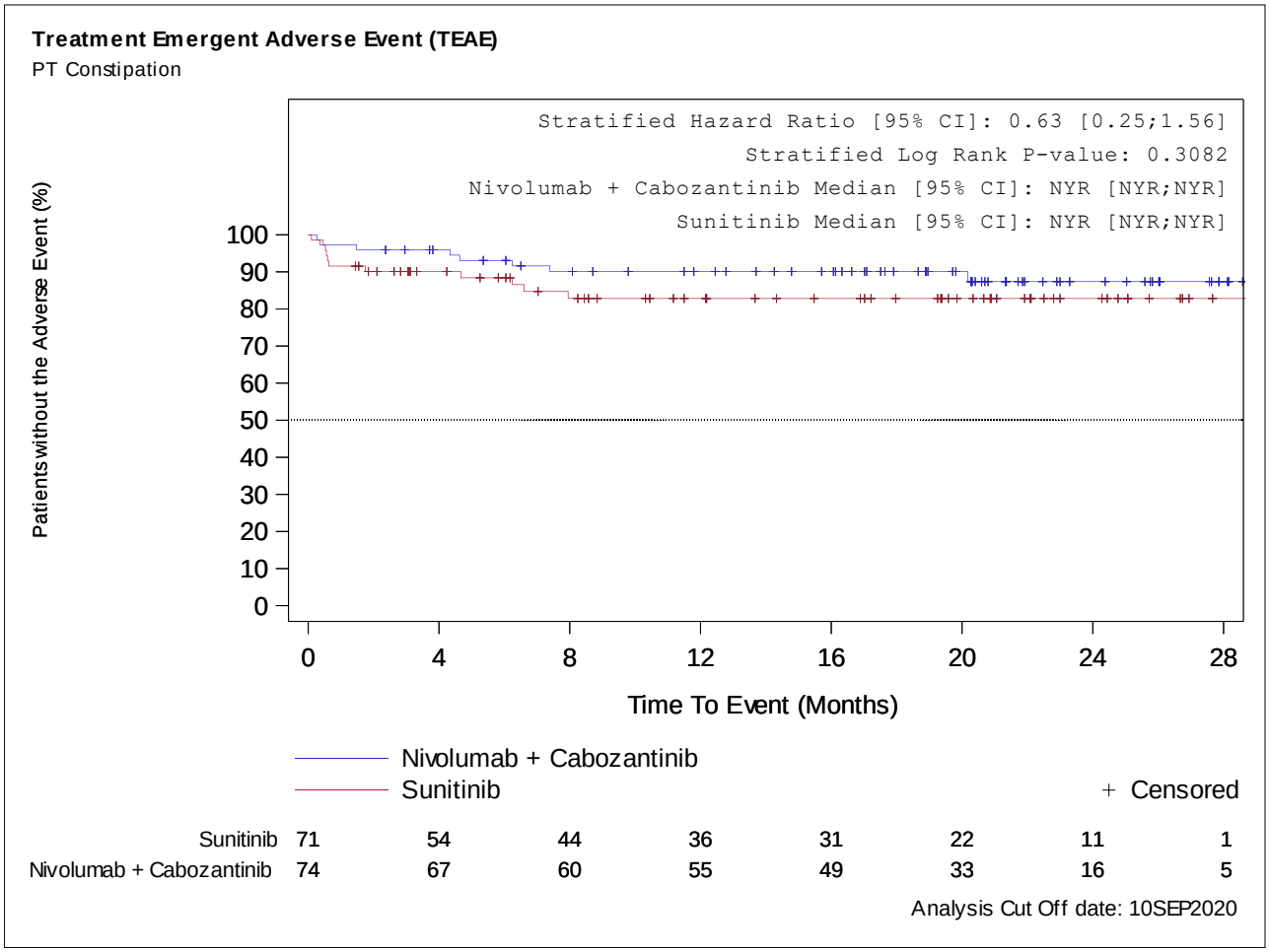


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FIGURE 4.1.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

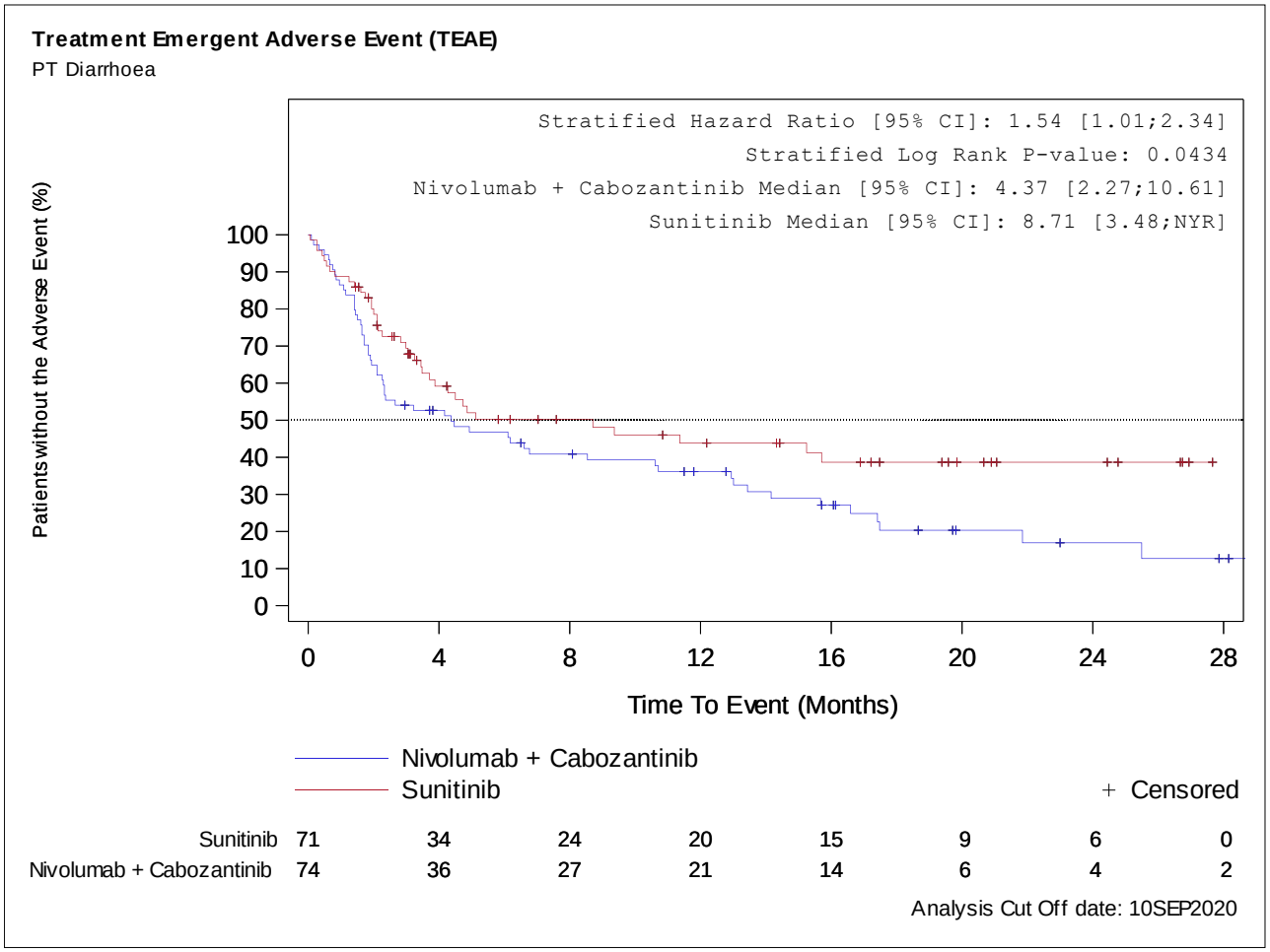


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FIGURE 4.1.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dry mouth - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

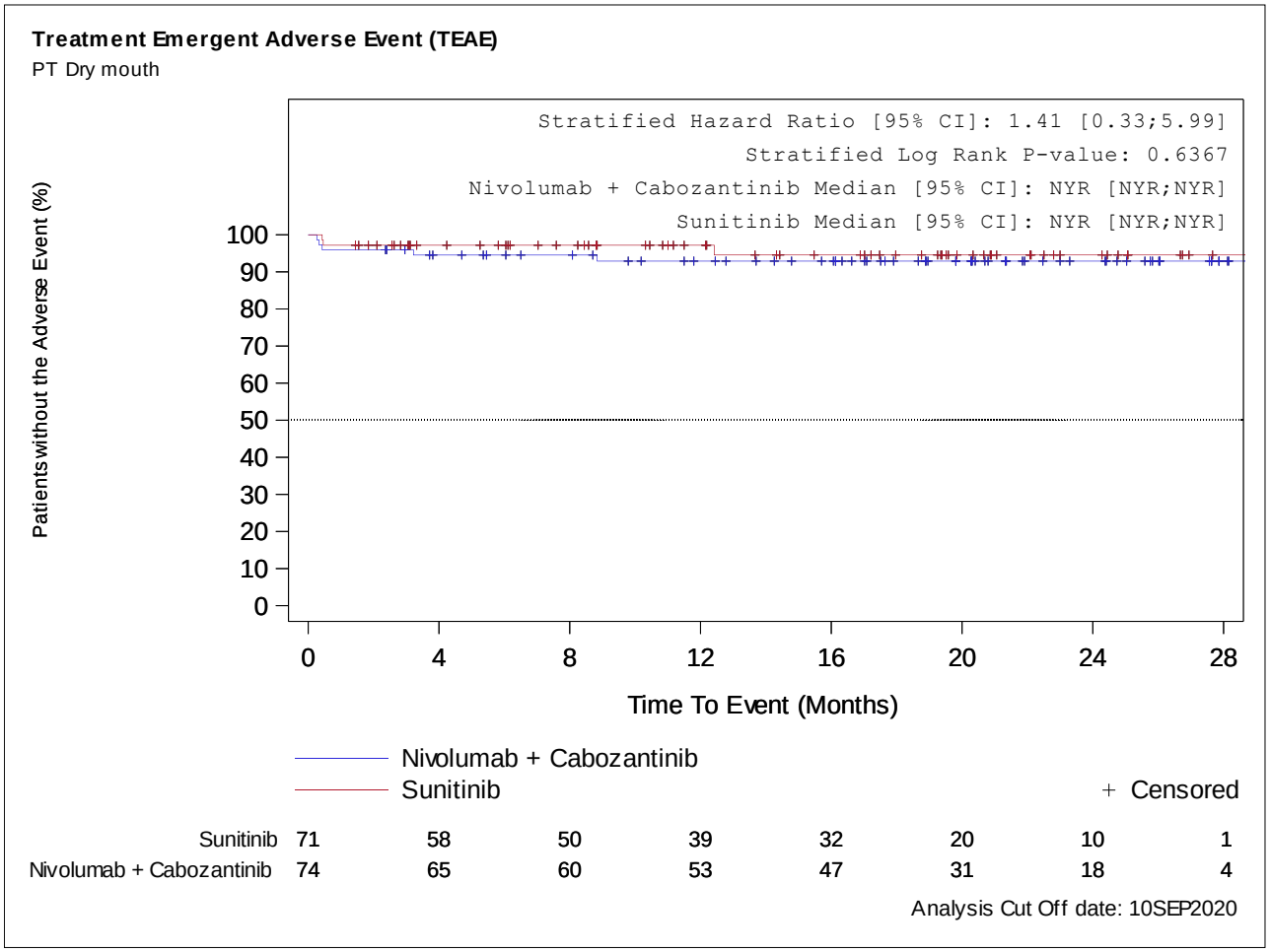


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FIGURE 4.1.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dyspepsia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

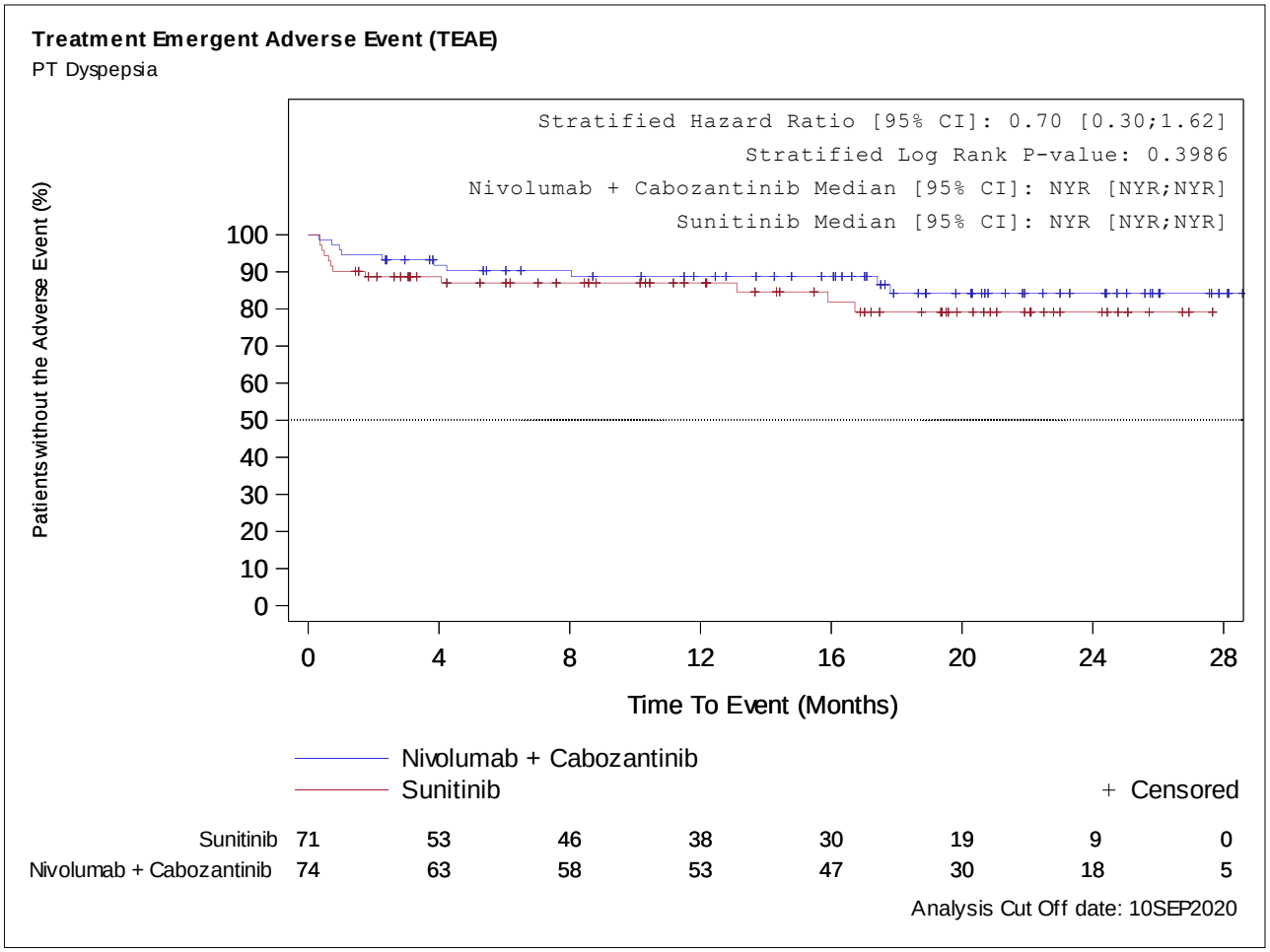


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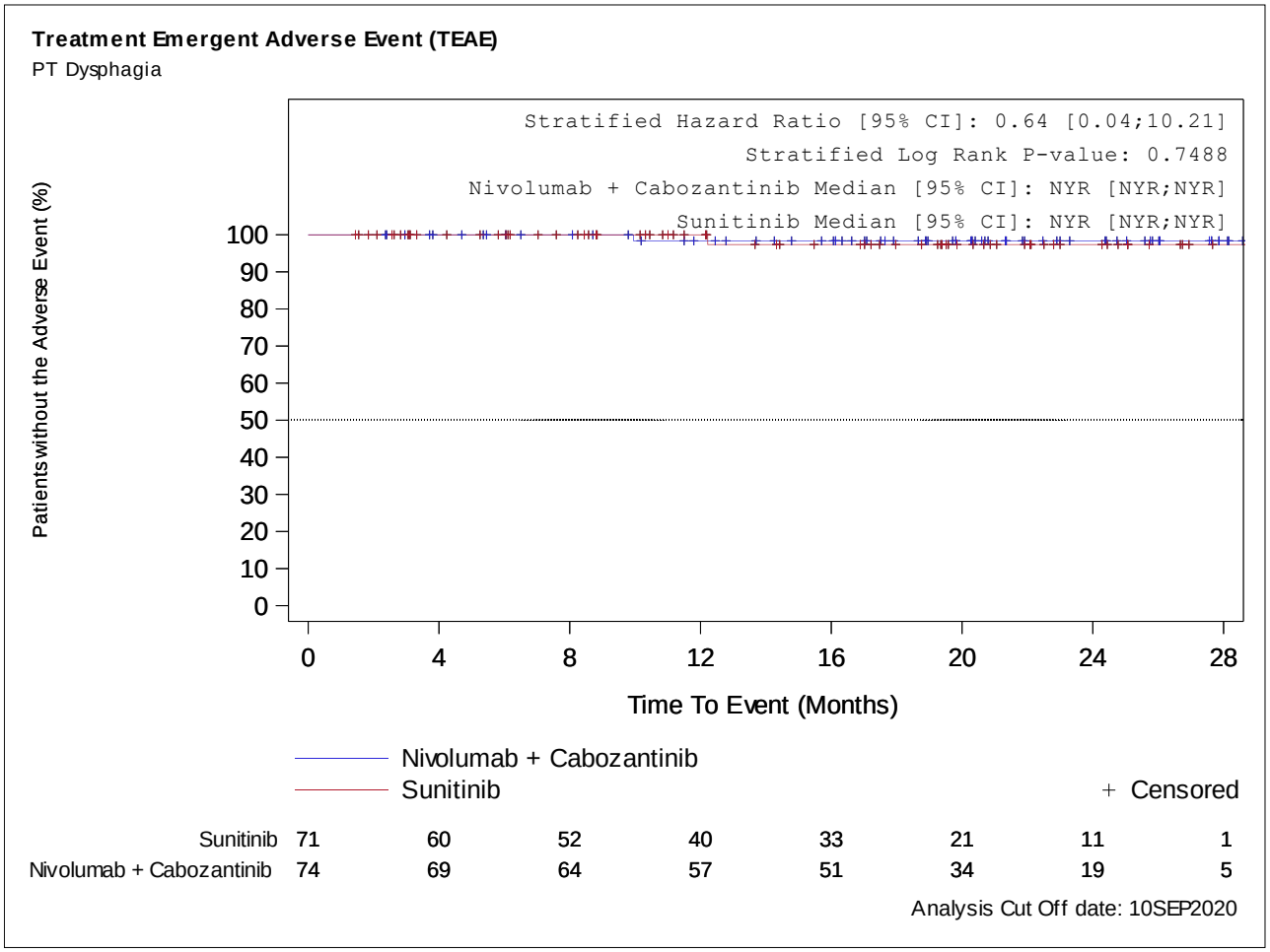
FIGURE 4.1.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphagia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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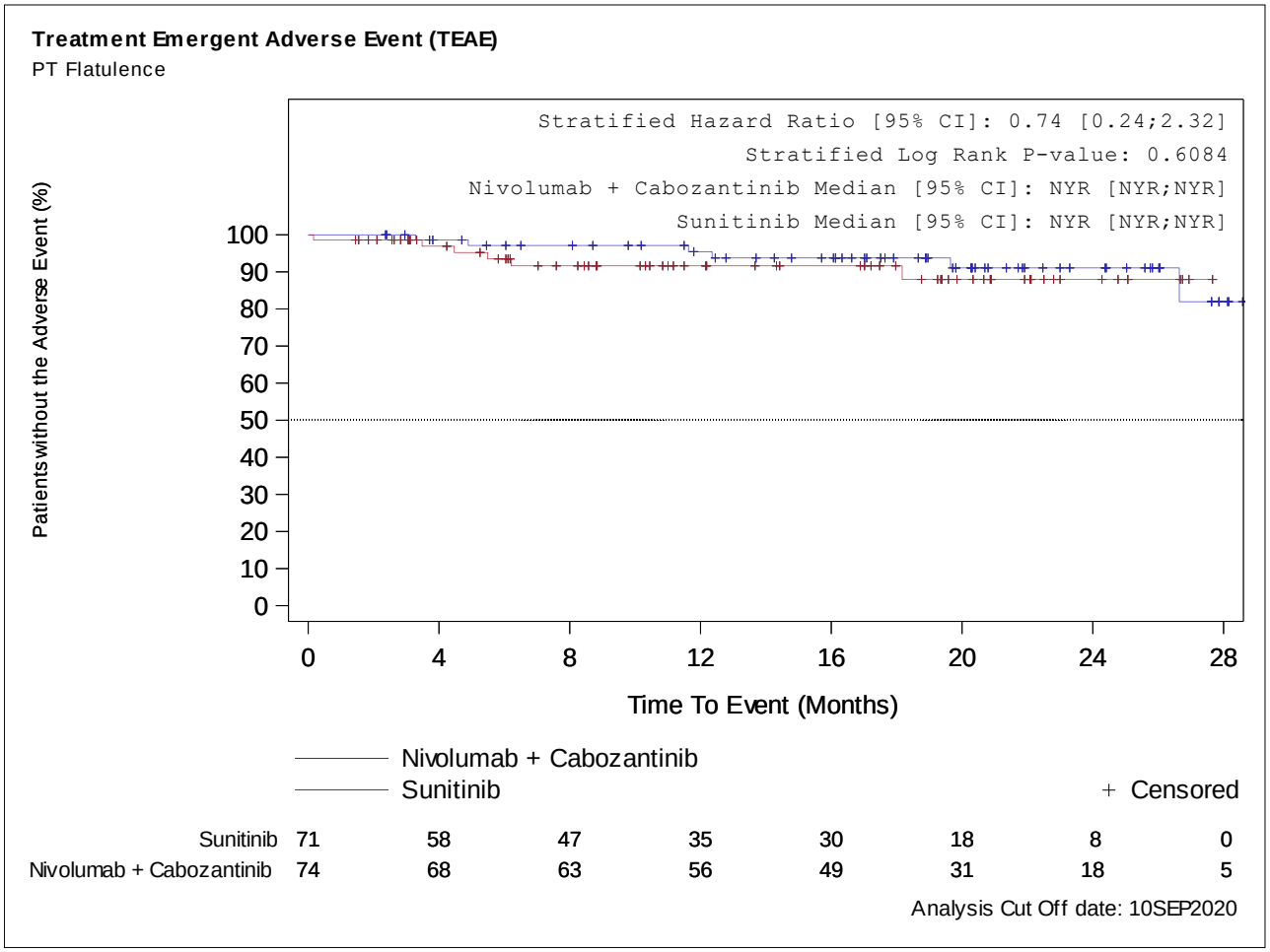
FIGURE 4.1.2.25: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Flatulence - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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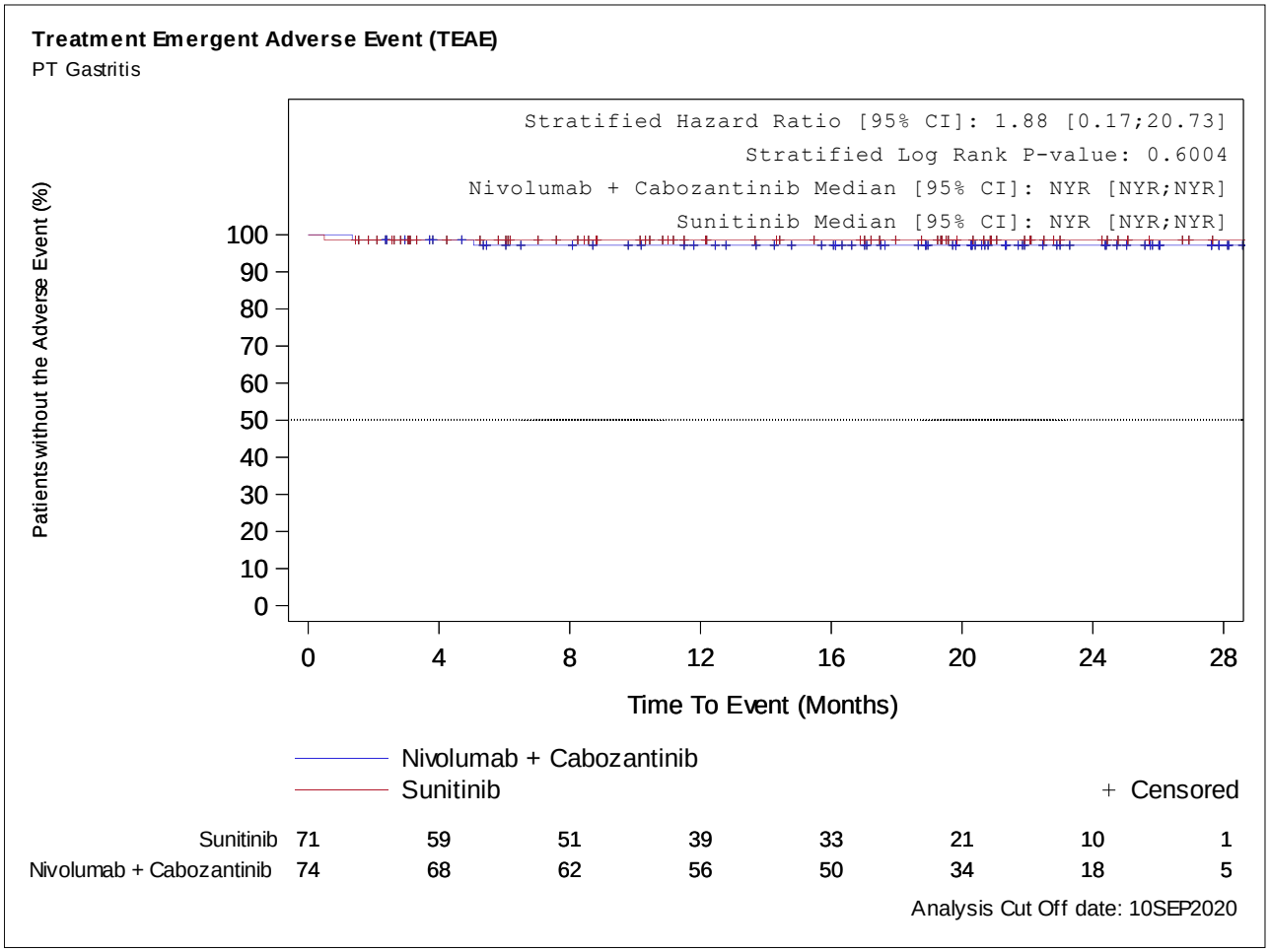
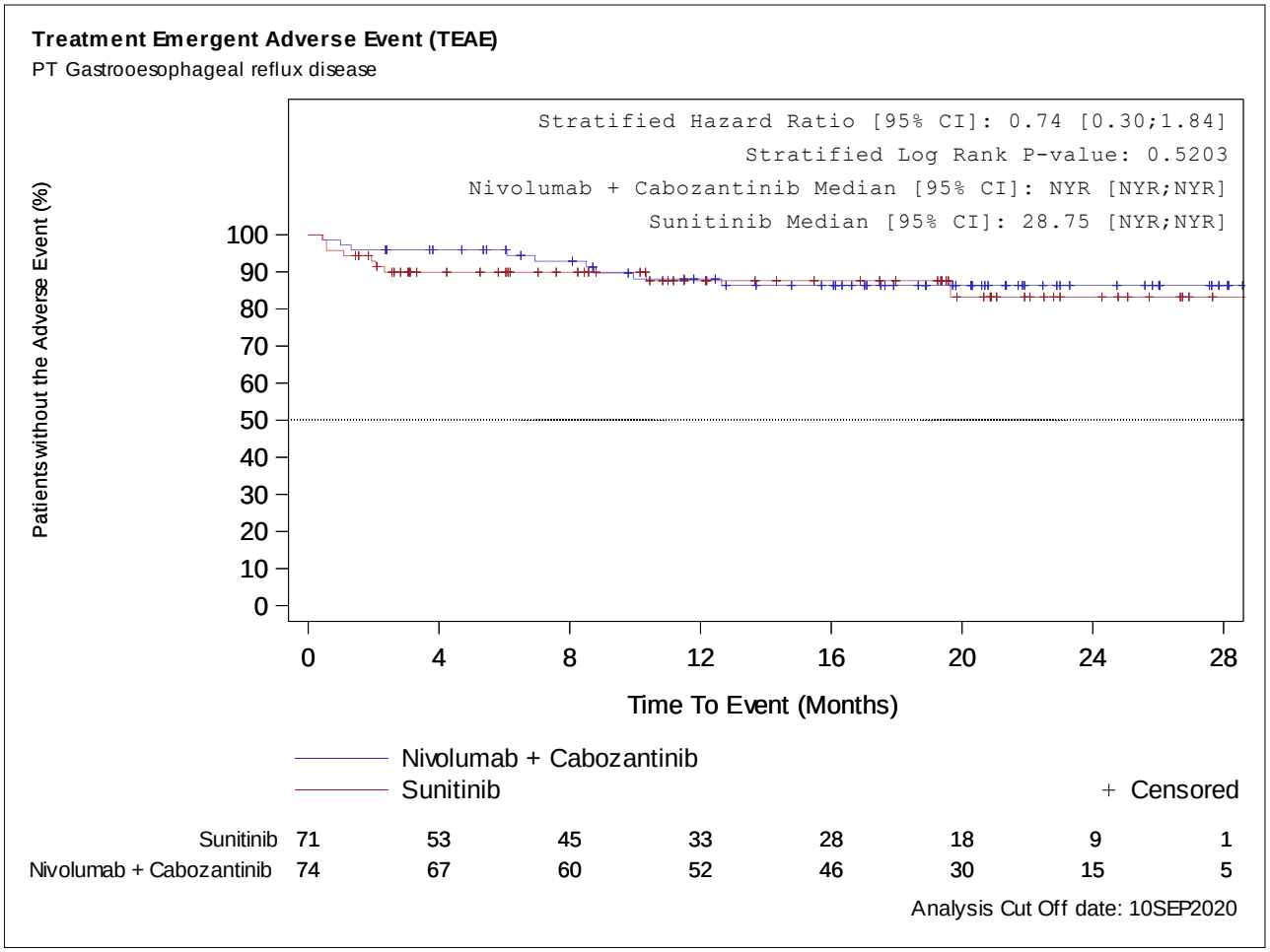
FIGURE 4.1.2.26: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Gastritis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 15:53:11

FIGURE 4.1.2.27: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Gastrooesophageal reflux disease - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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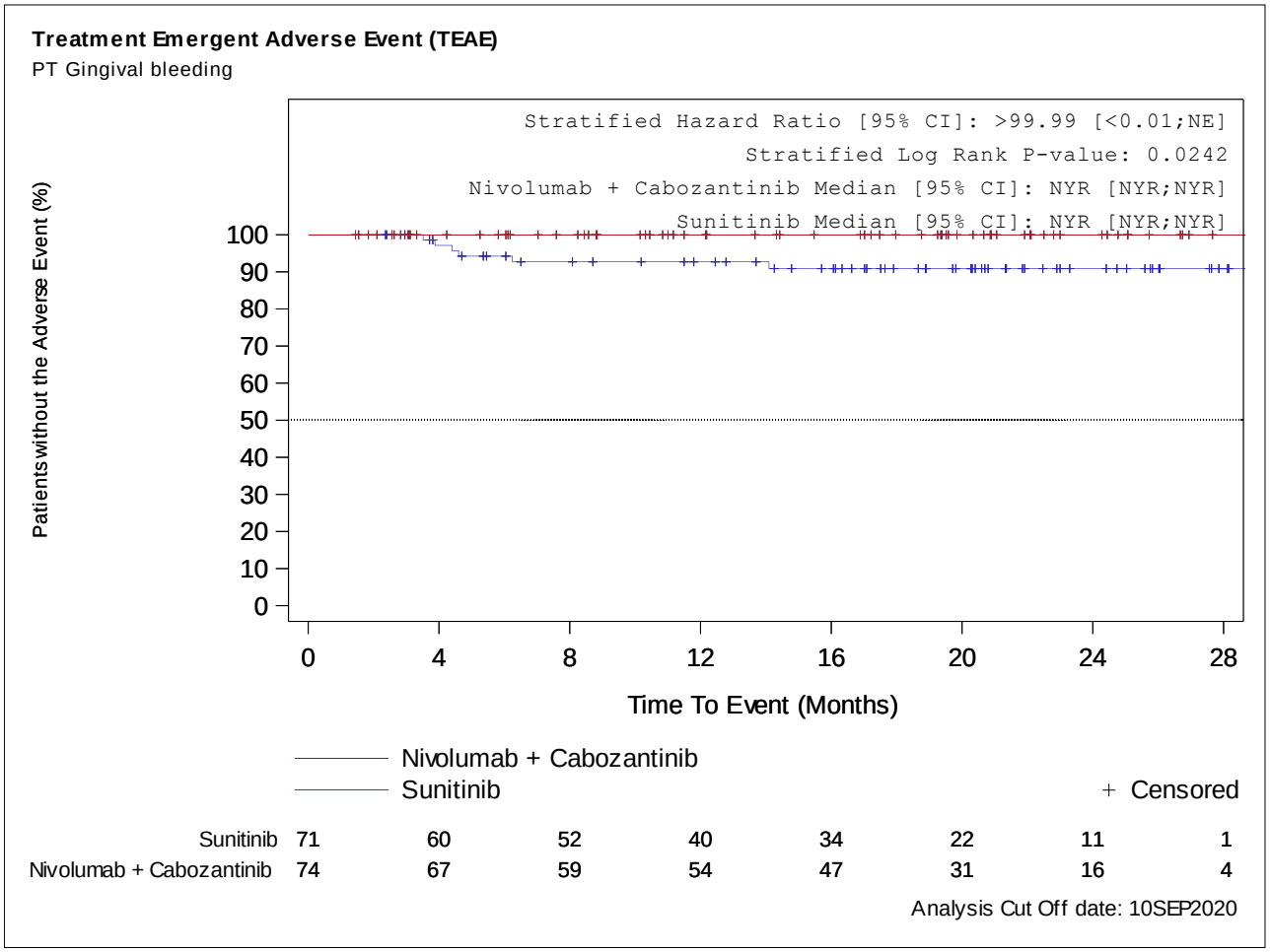
FIGURE 4.1.2.28: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Gingival bleeding - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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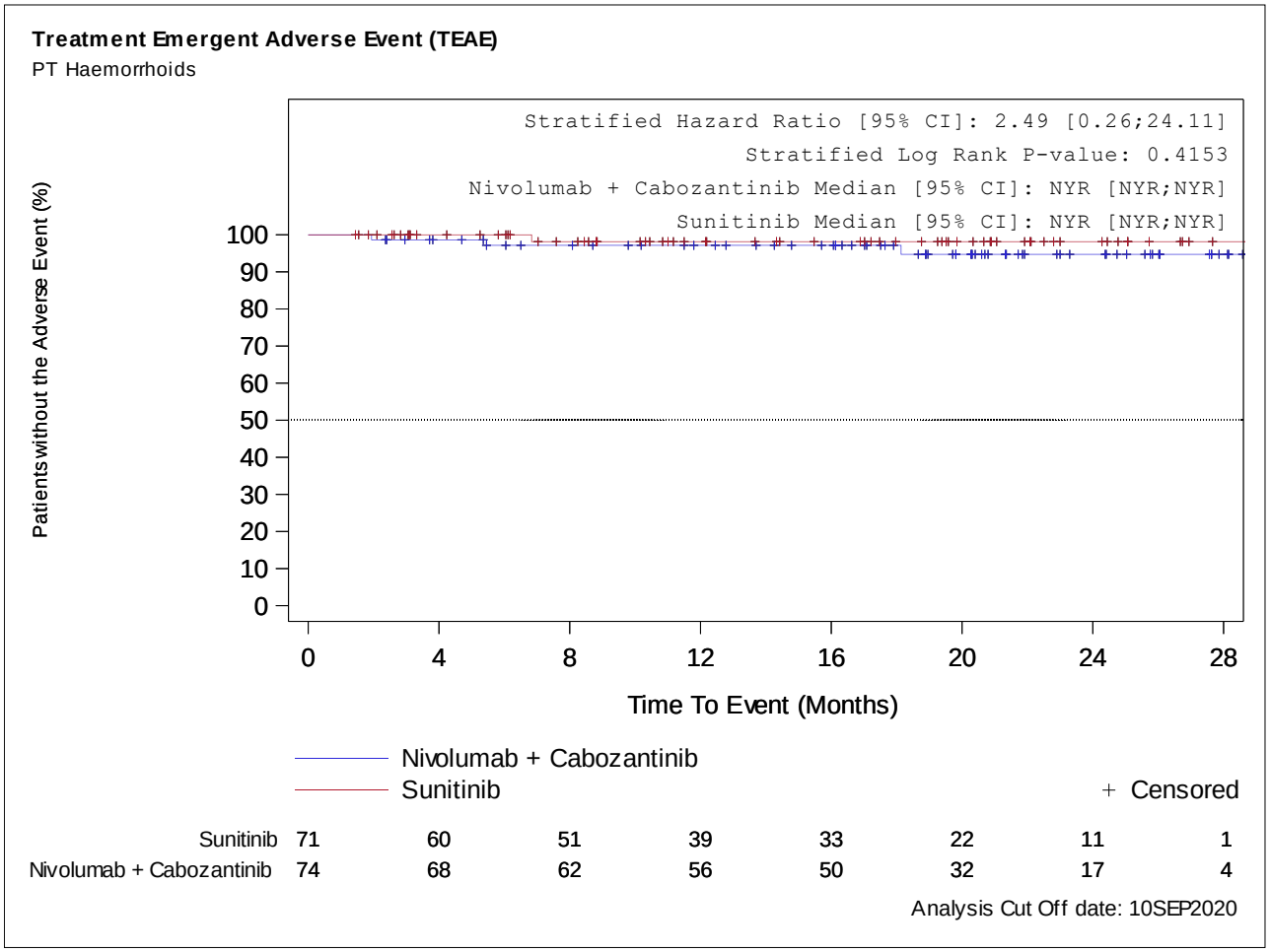
FIGURE 4.1.2.29: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Haemorrhoids - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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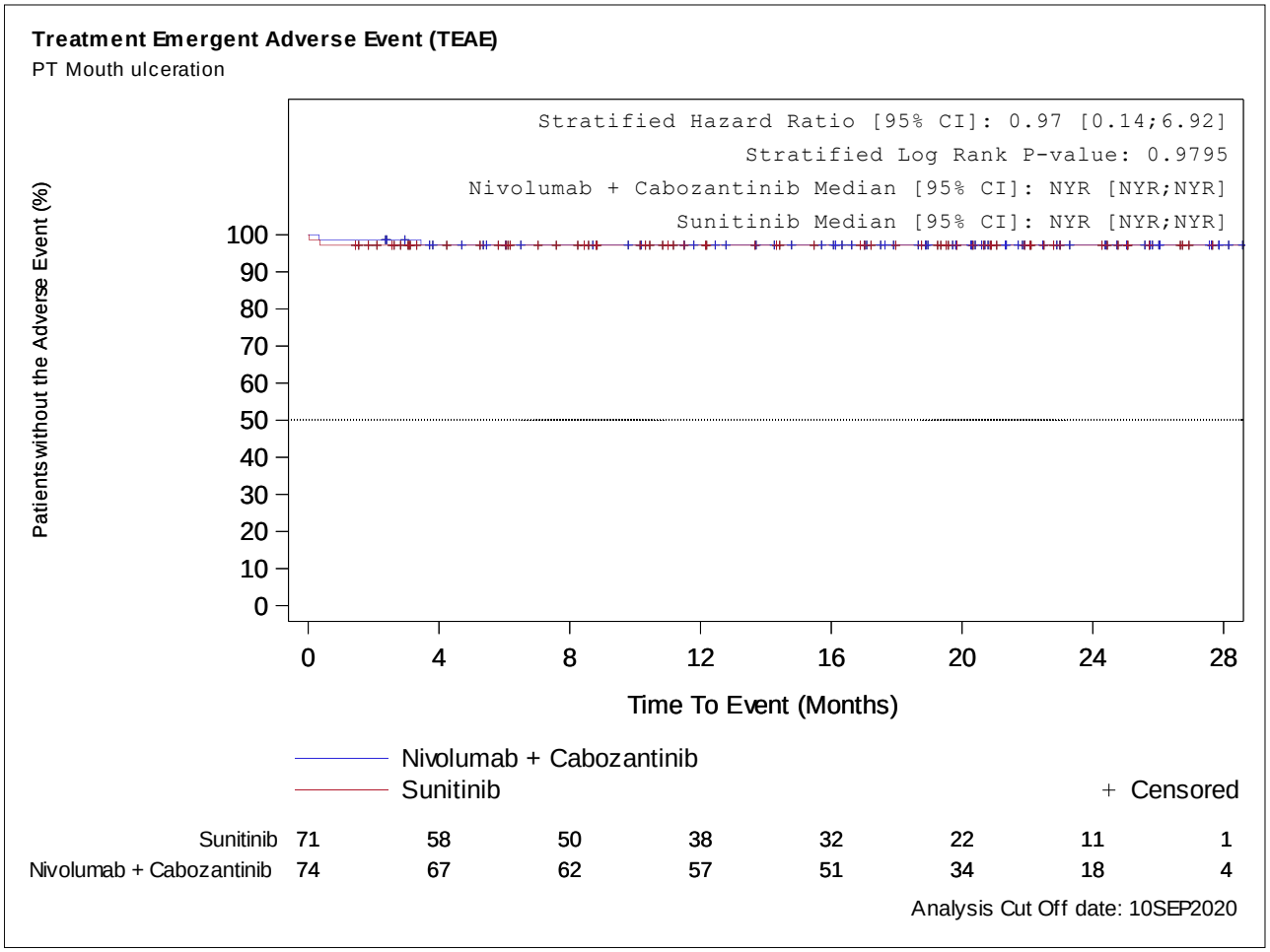
FIGURE 4.1.2.30: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Mouth ulceration - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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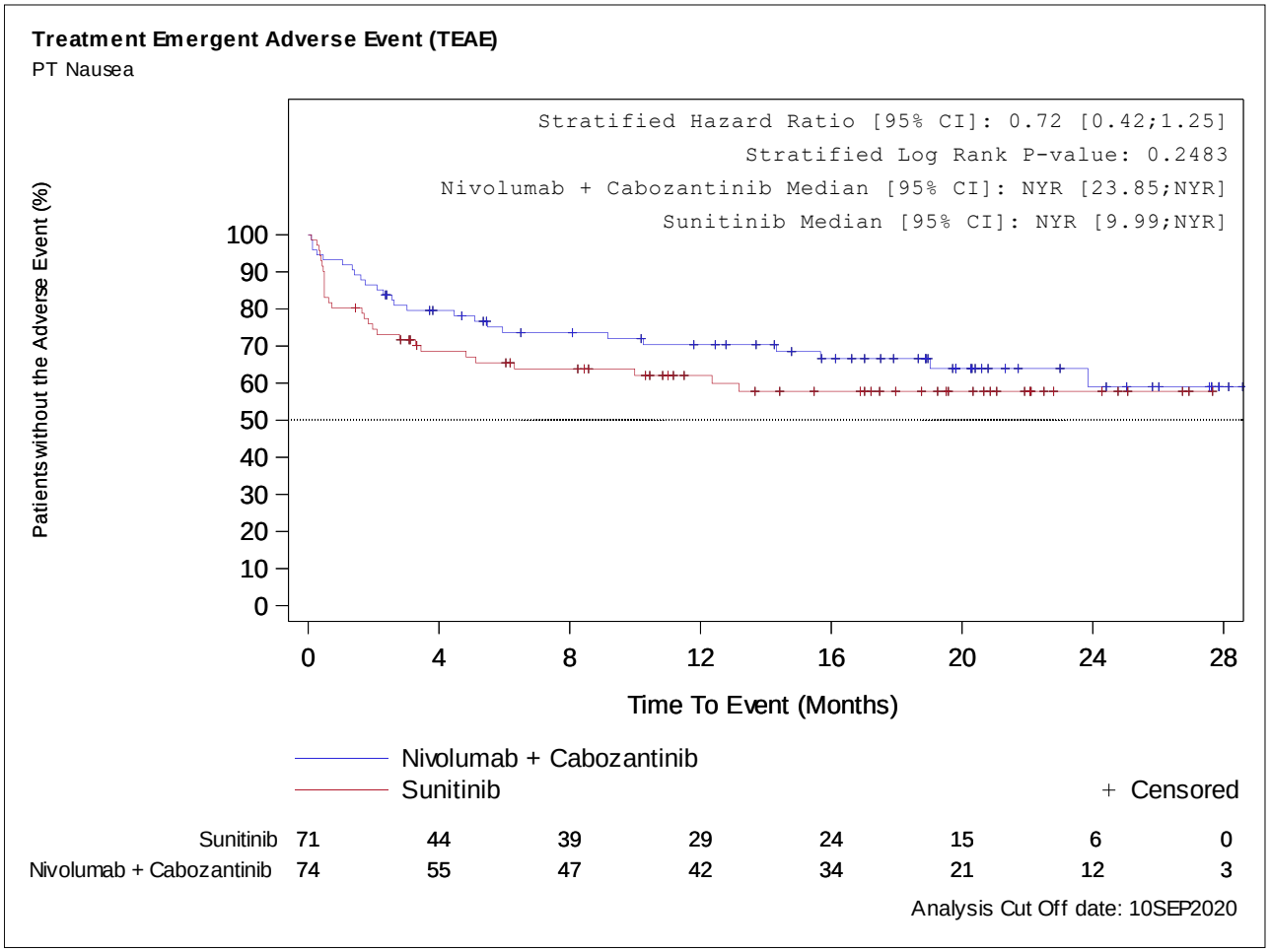
FIGURE 4.1.2.31: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Nausea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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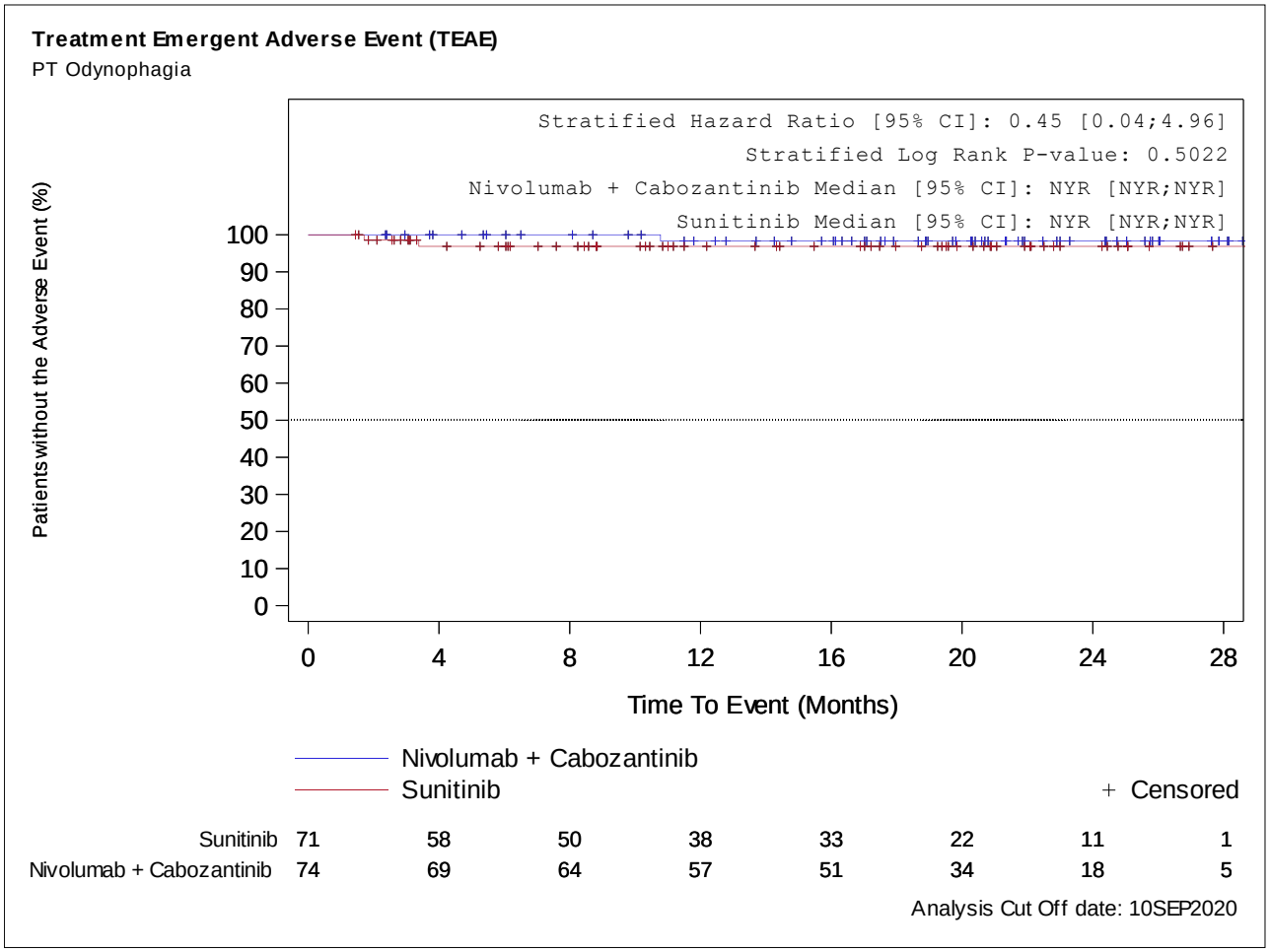
FIGURE 4.1.2.32: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Odynophagia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.1.2.33: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oral pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

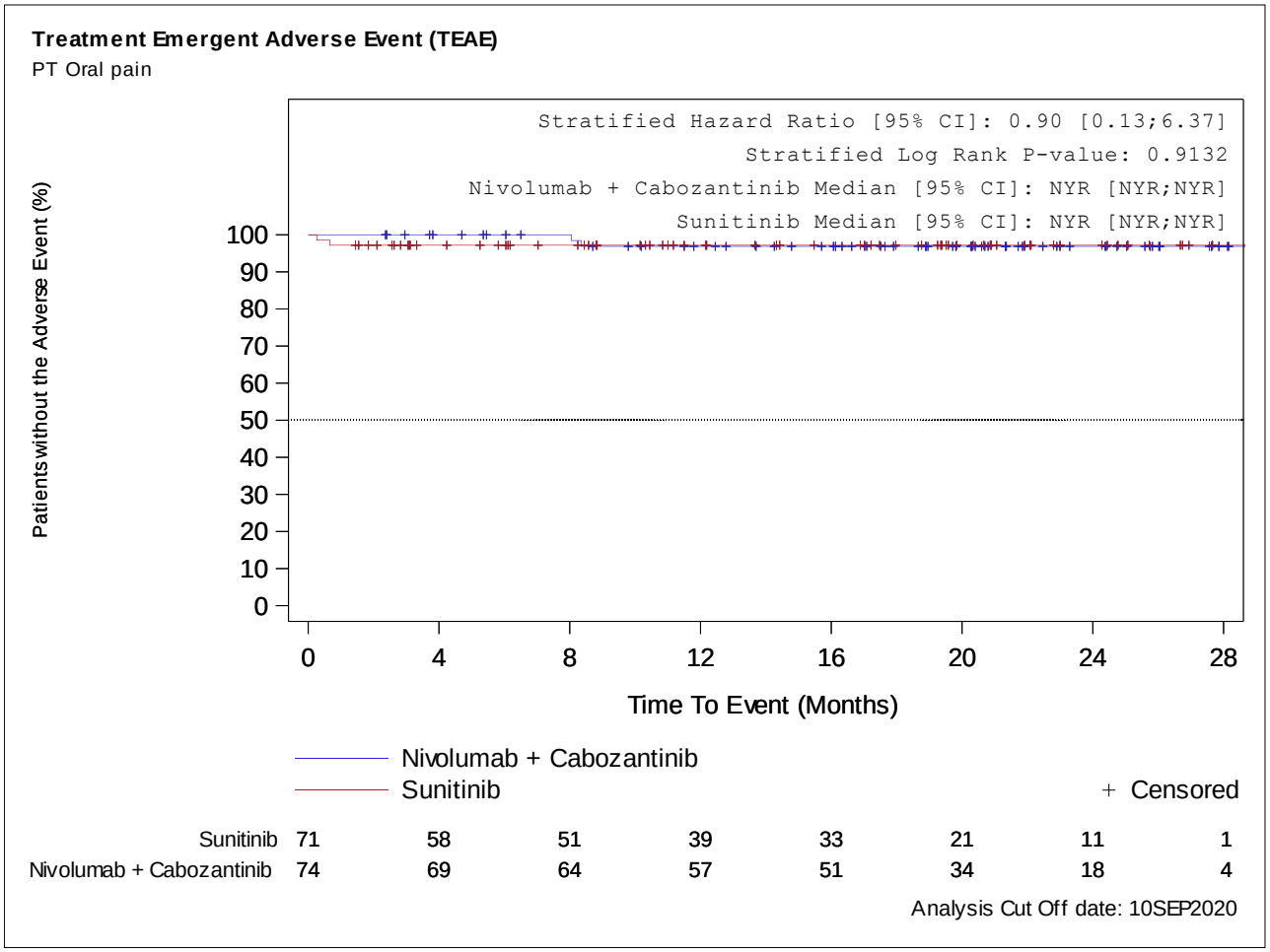


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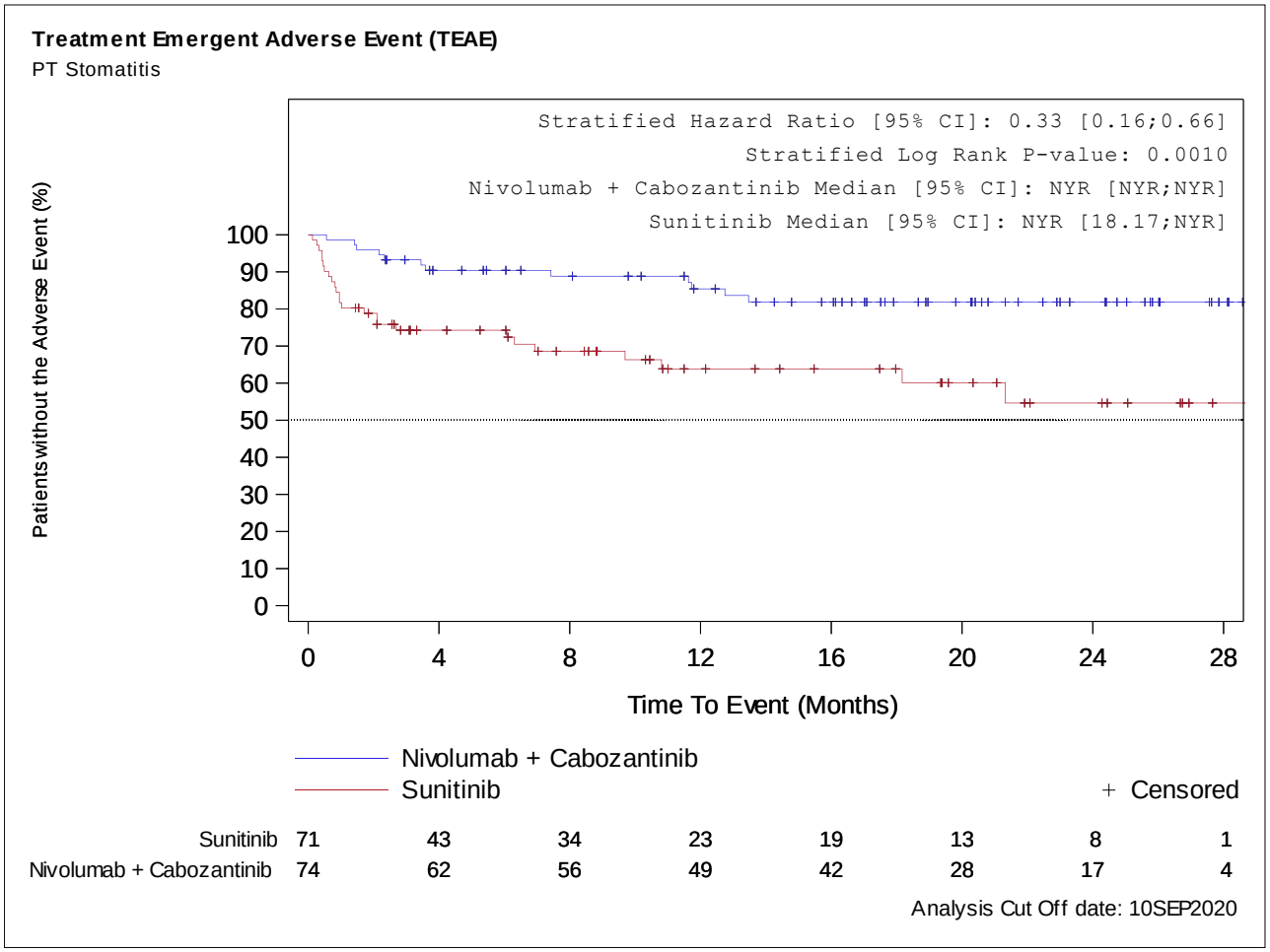
FIGURE 4.1.2.34: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.1.2.35: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Toothache - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

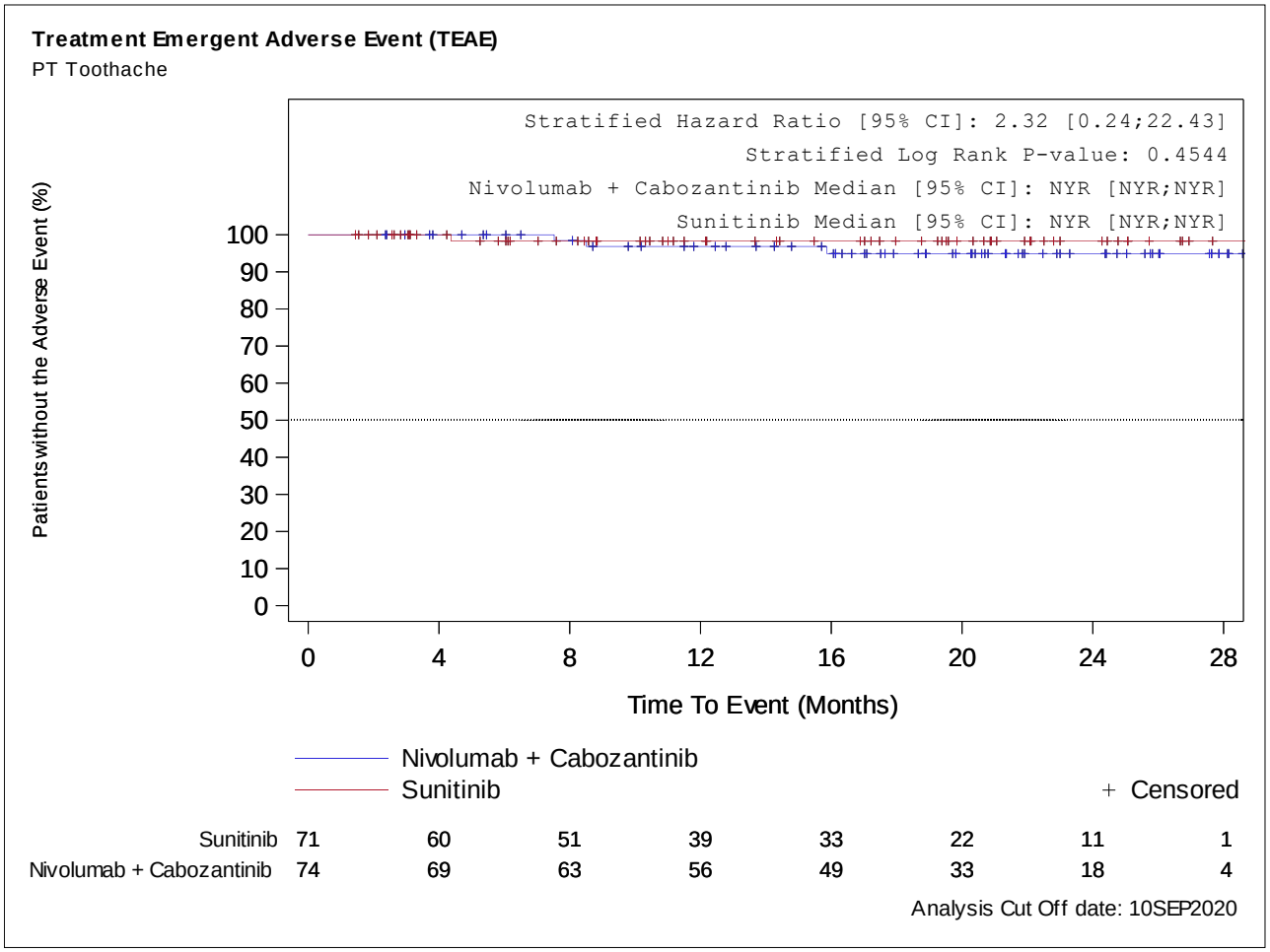


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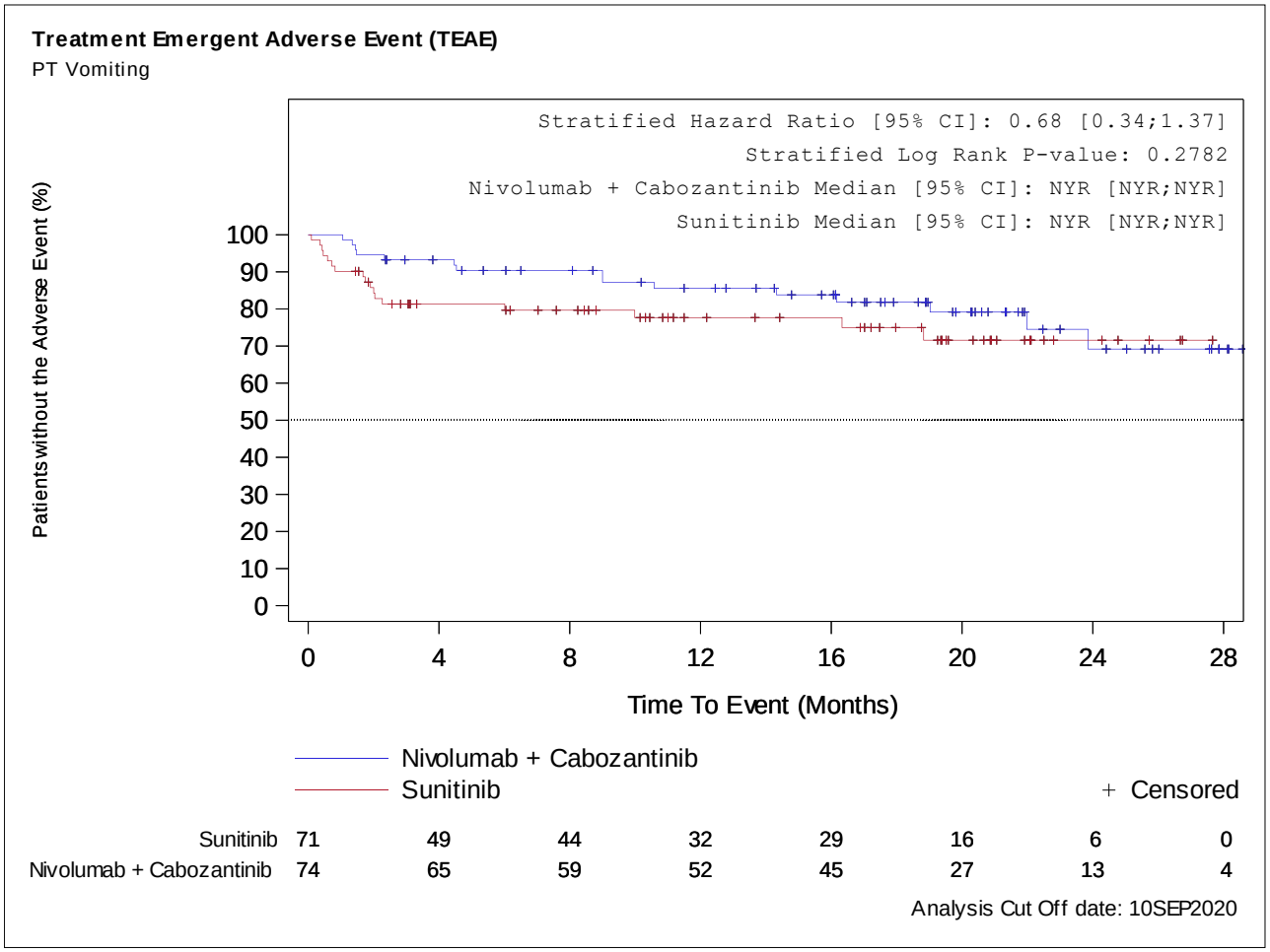
FIGURE 4.1.2.36: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Vomiting - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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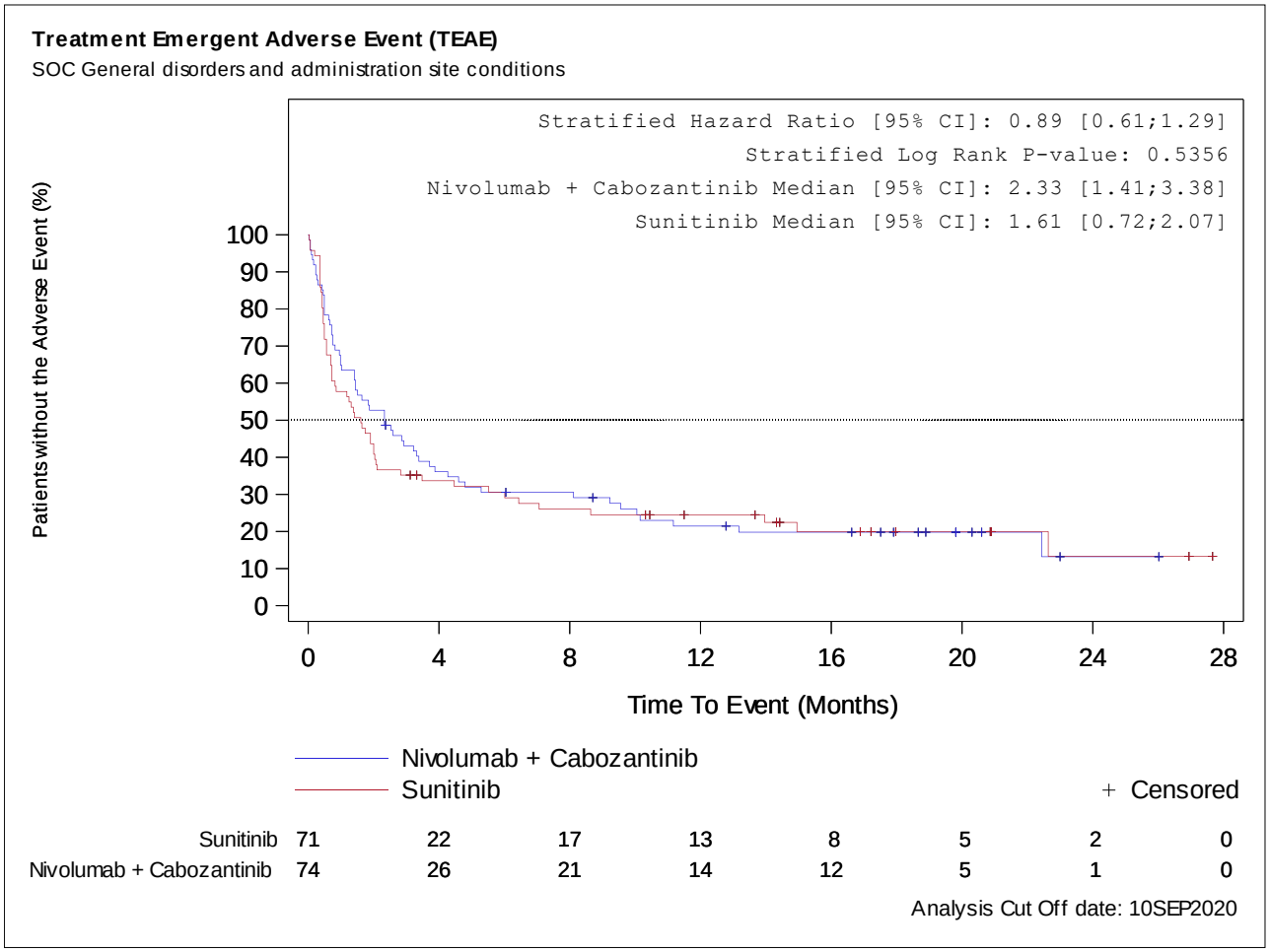
FIGURE 4.1.2.37: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC General disorders and administration site conditions - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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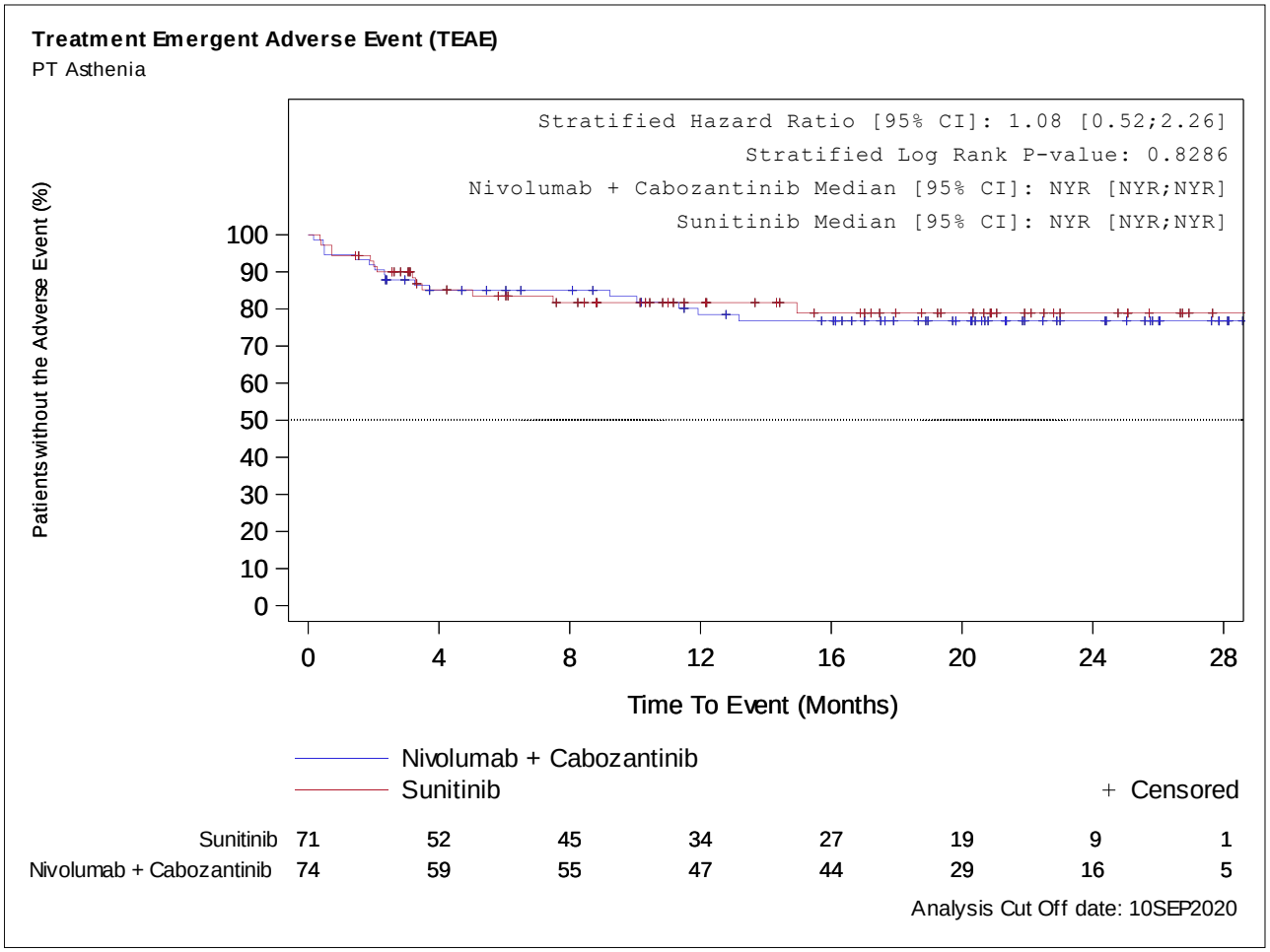
FIGURE 4.1.2.38: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Asthenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.1.2.39: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Chest pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

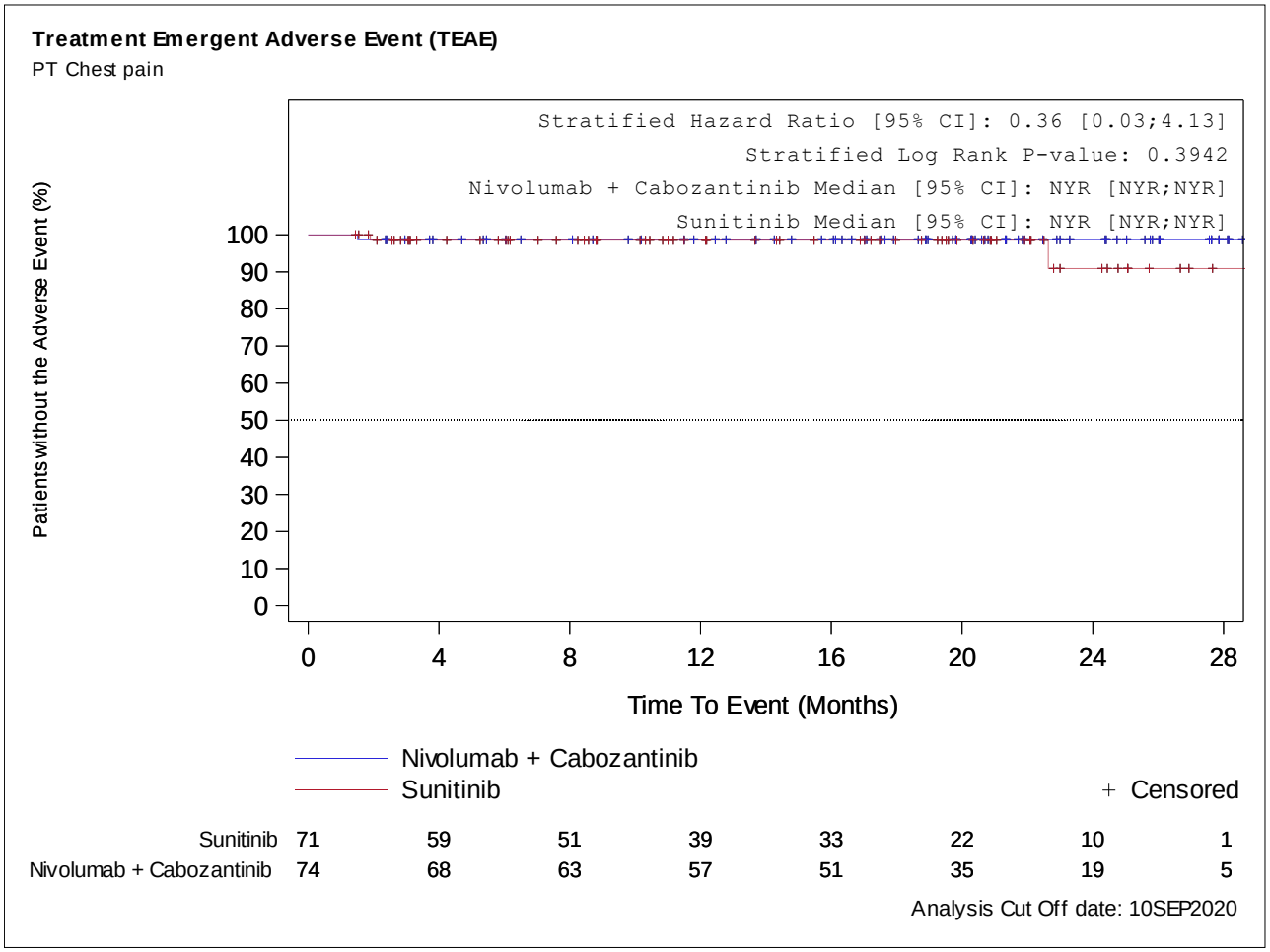


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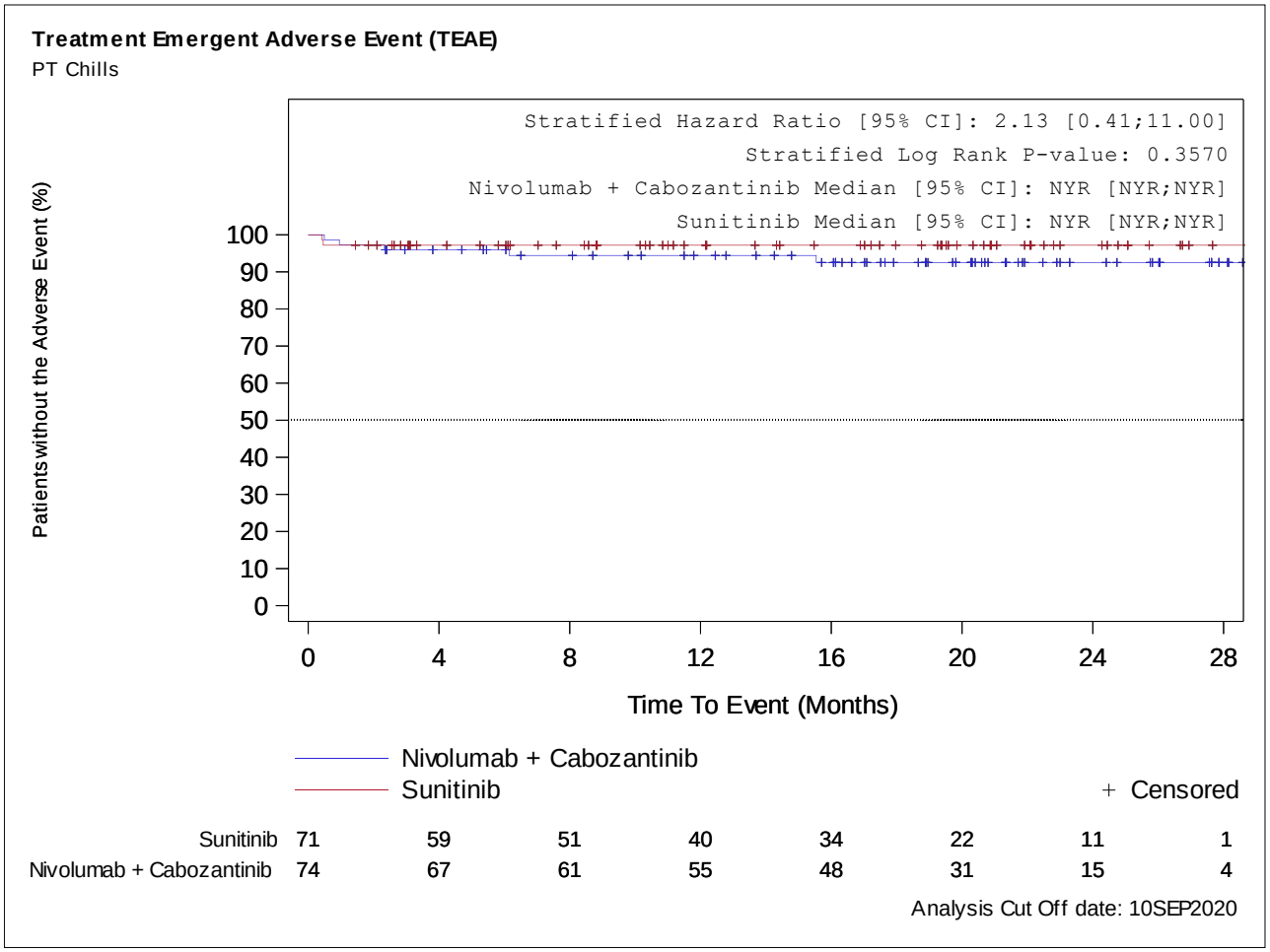
FIGURE 4.1.2.40: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Chills - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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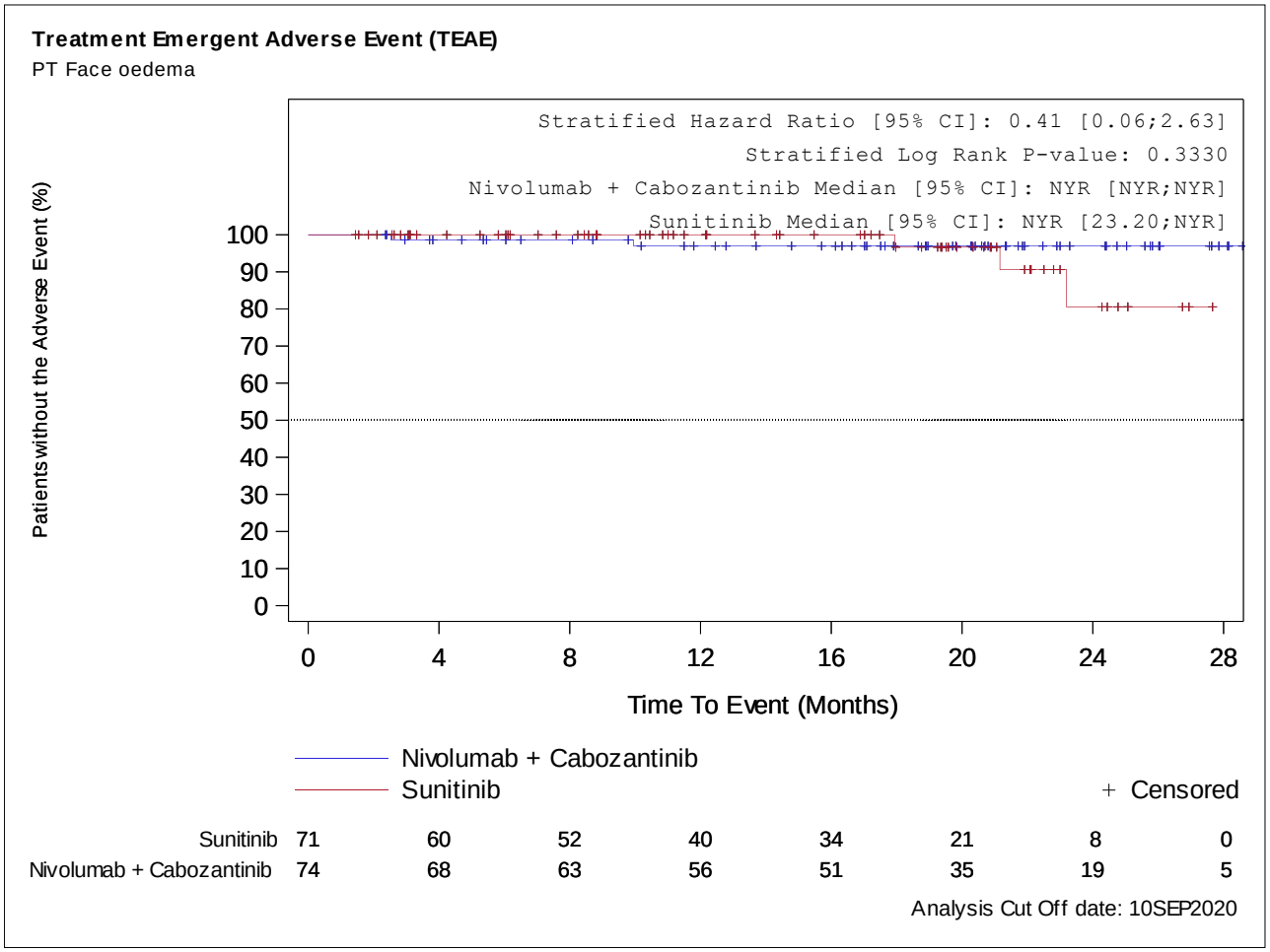
FIGURE 4.1.2.41: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Face oedema - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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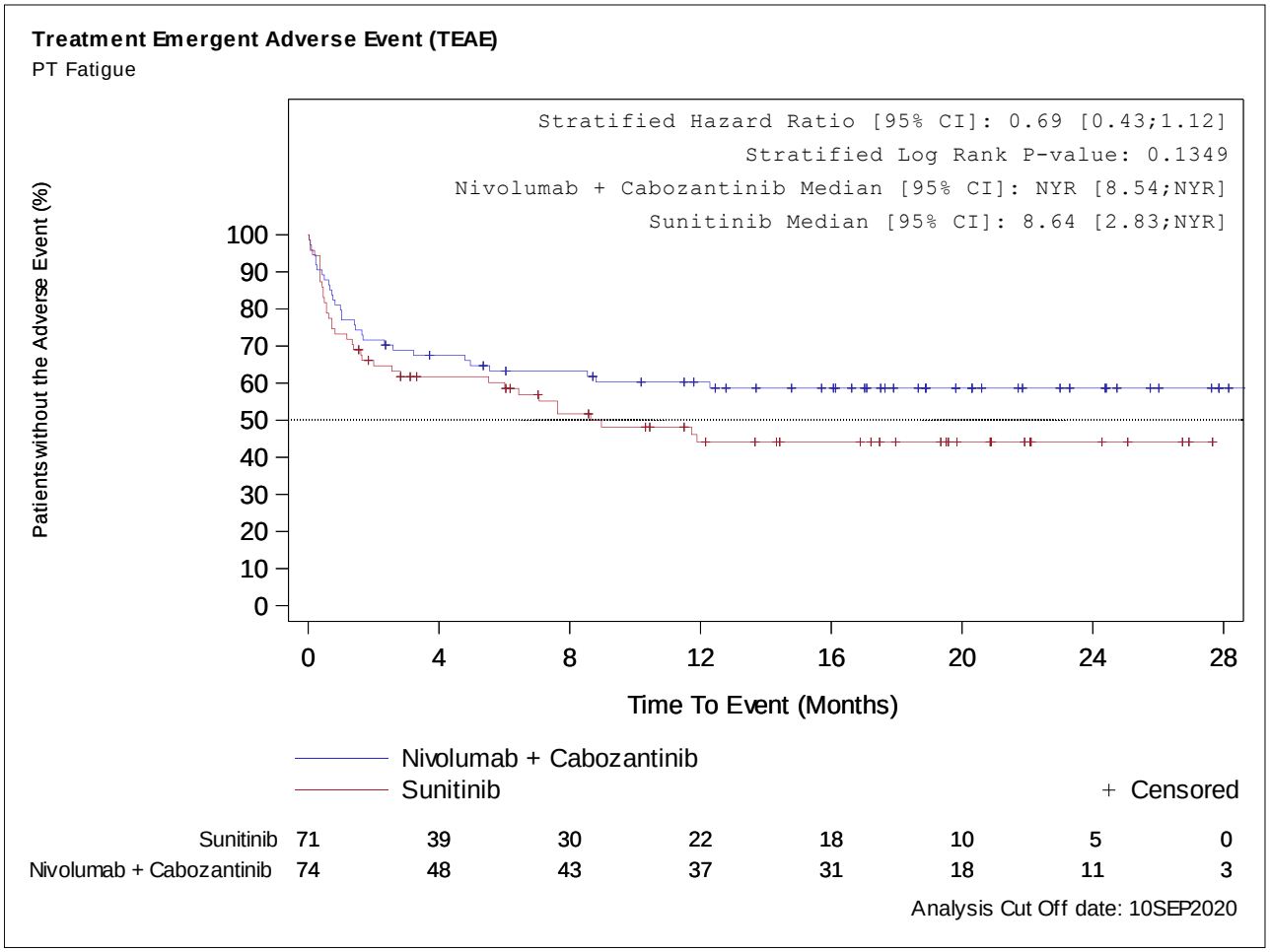
FIGURE 4.1.2.42: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Fatigue - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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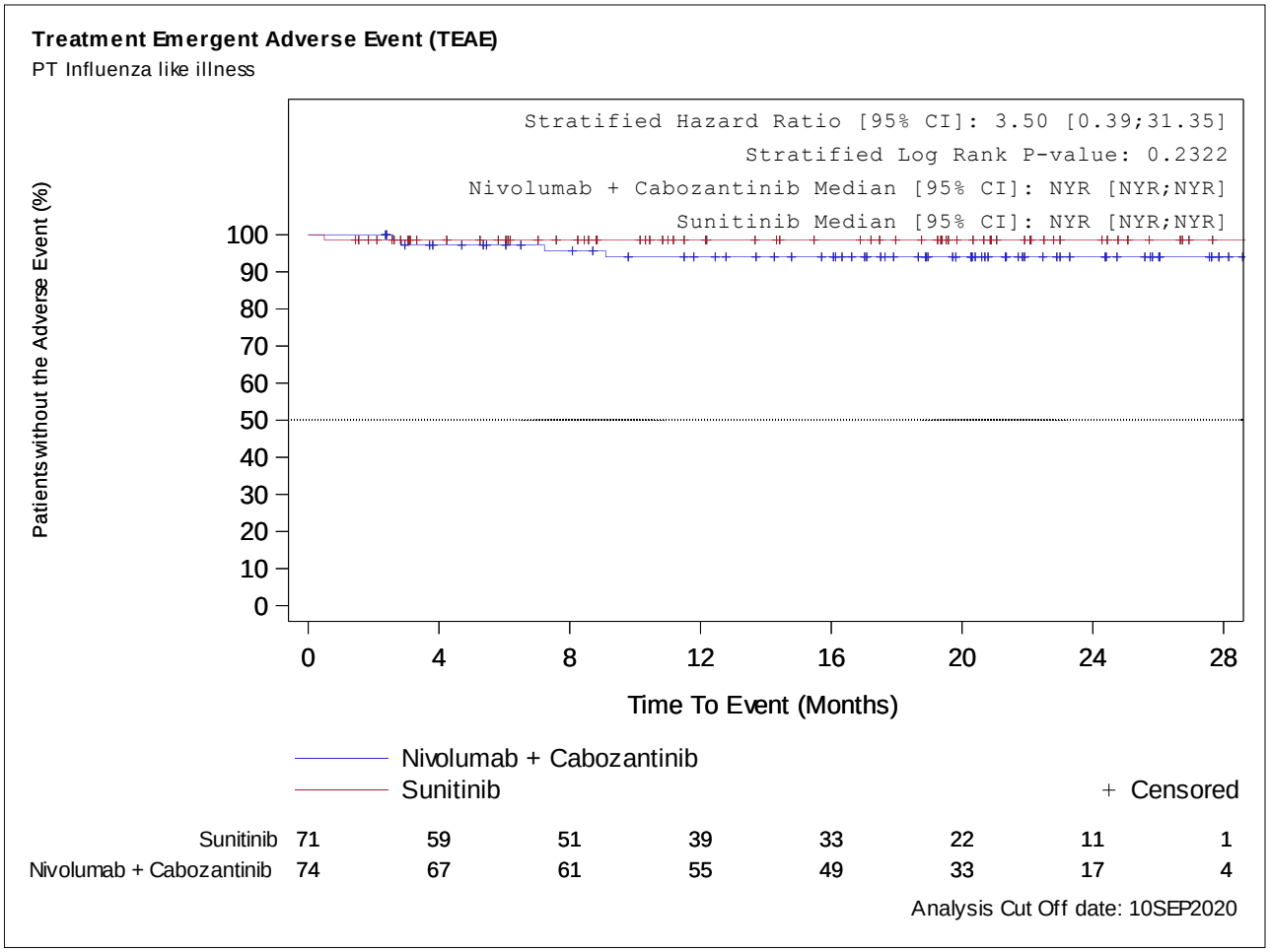
FIGURE 4.1.2.43: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Influenza like illness - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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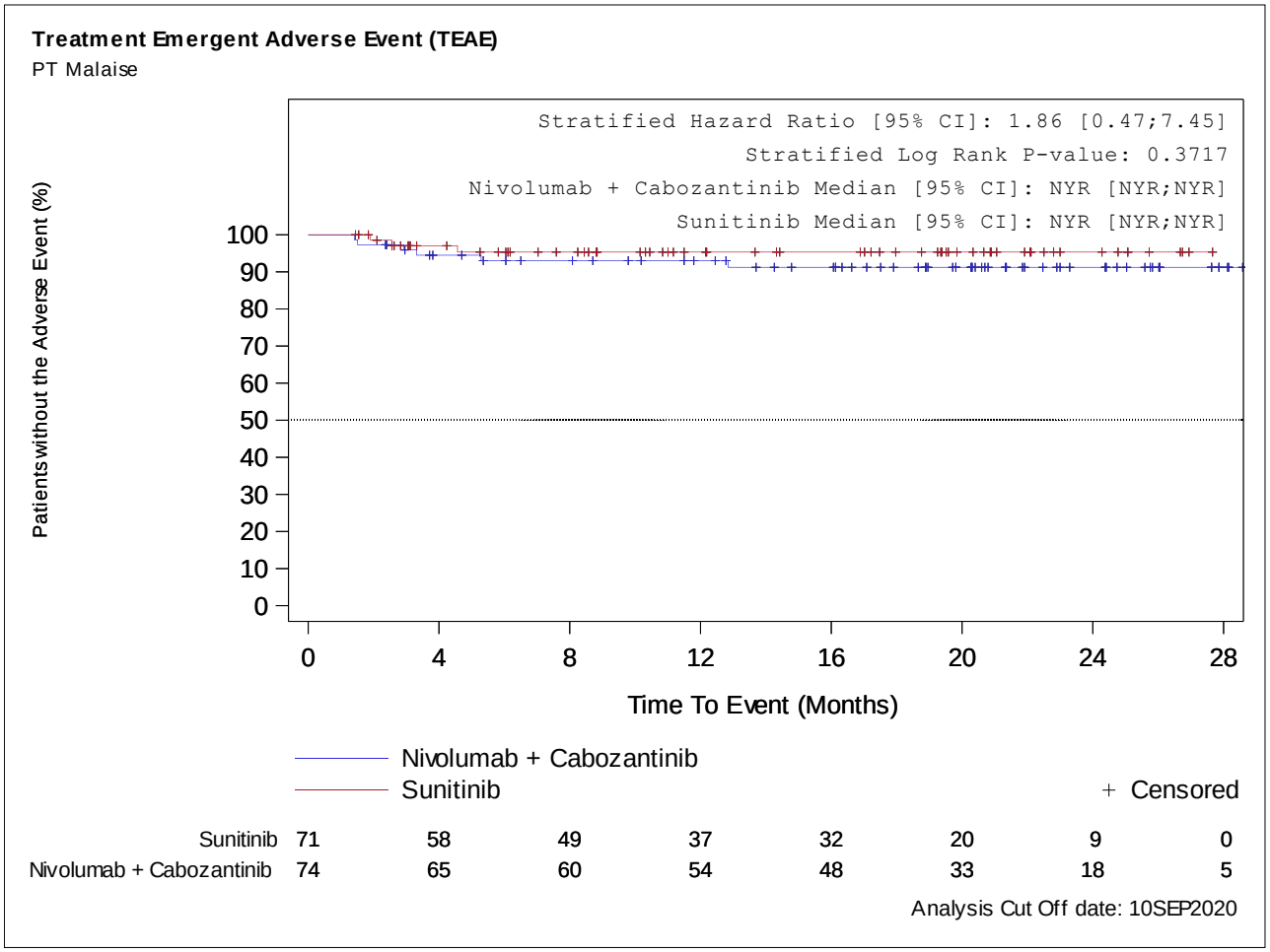
FIGURE 4.1.2.44: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Malaise - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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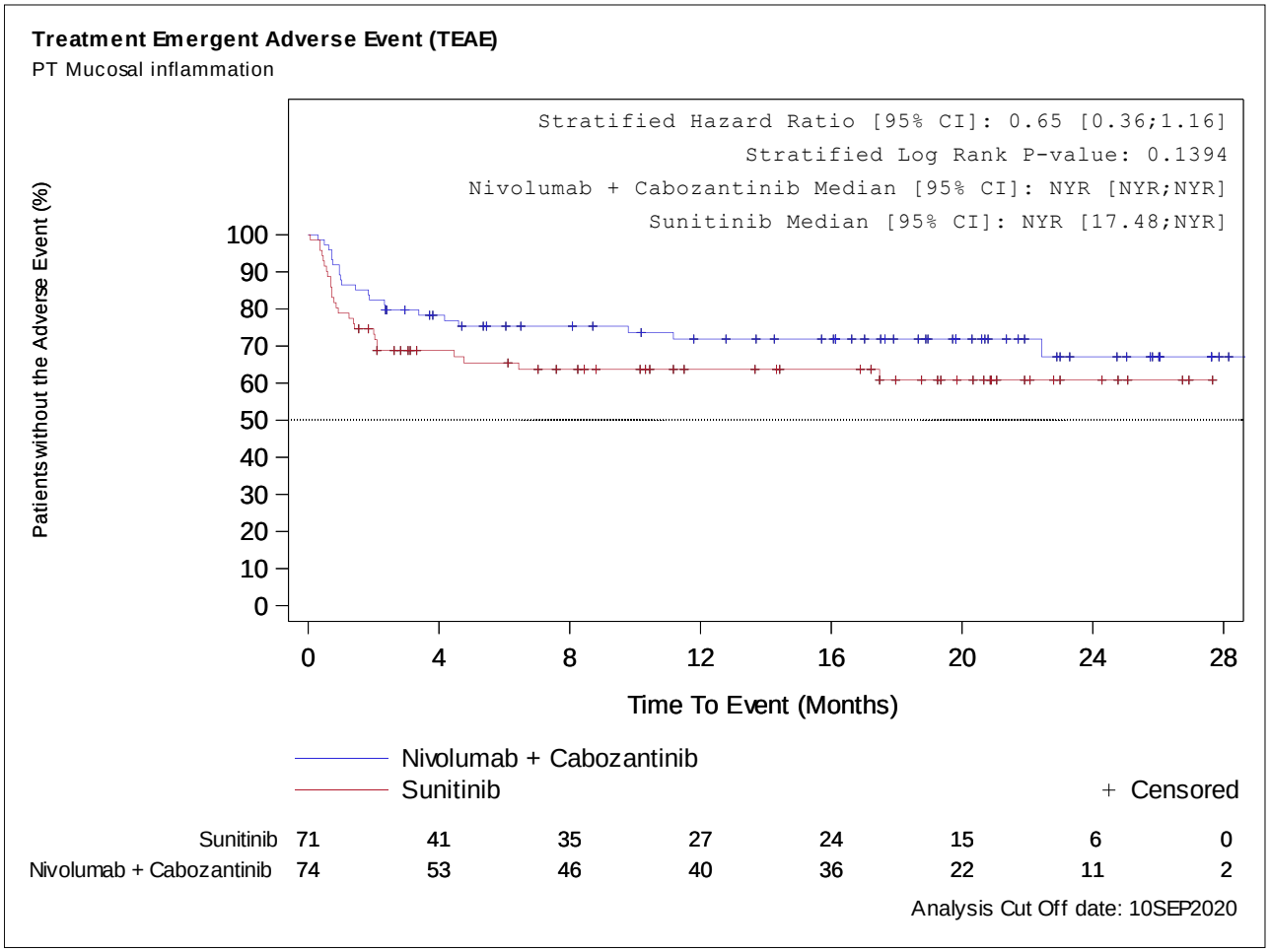
FIGURE 4.1.2.45: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Mucosal inflammation - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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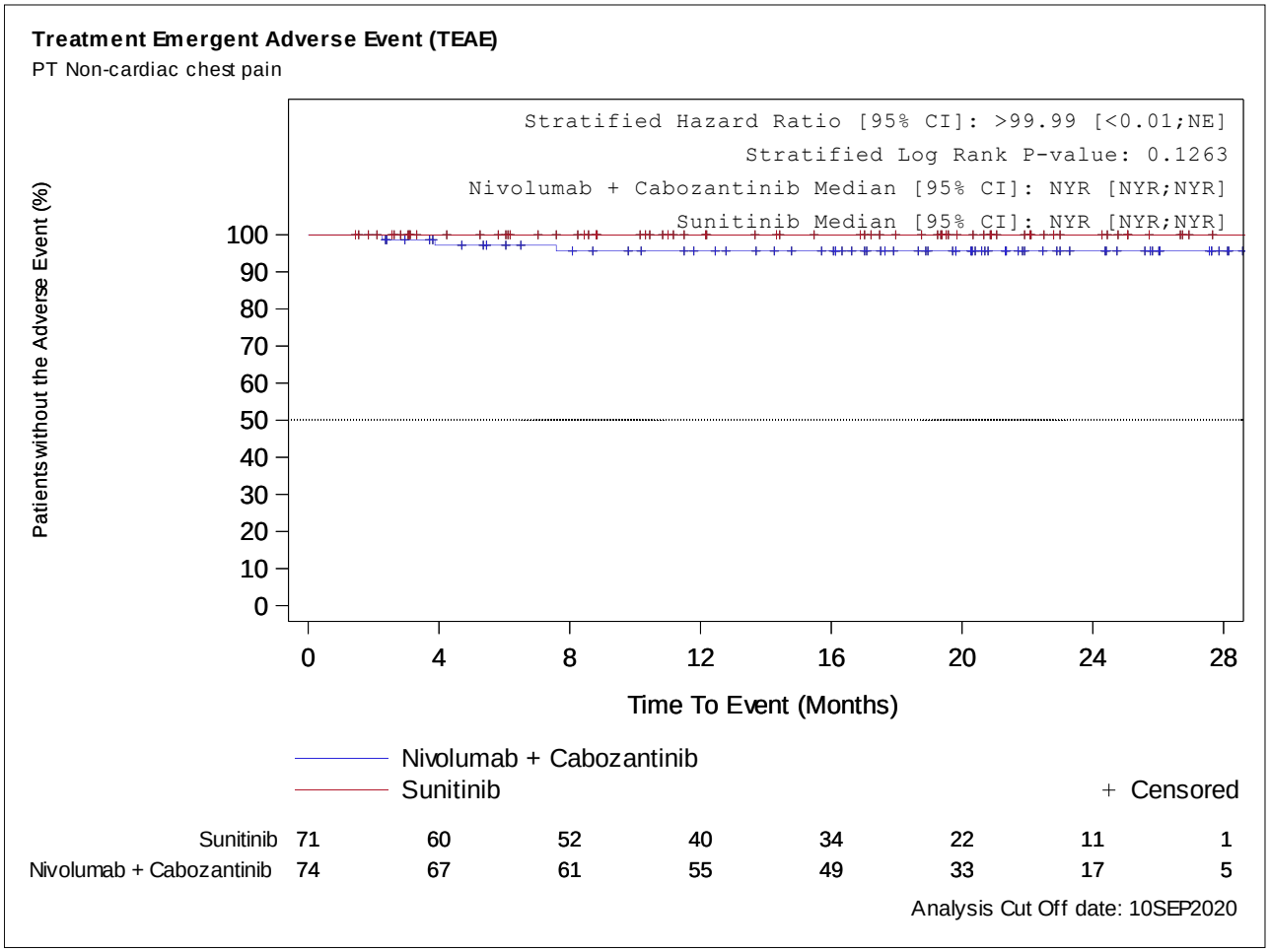
FIGURE 4.1.2.46: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Non-cardiac chest pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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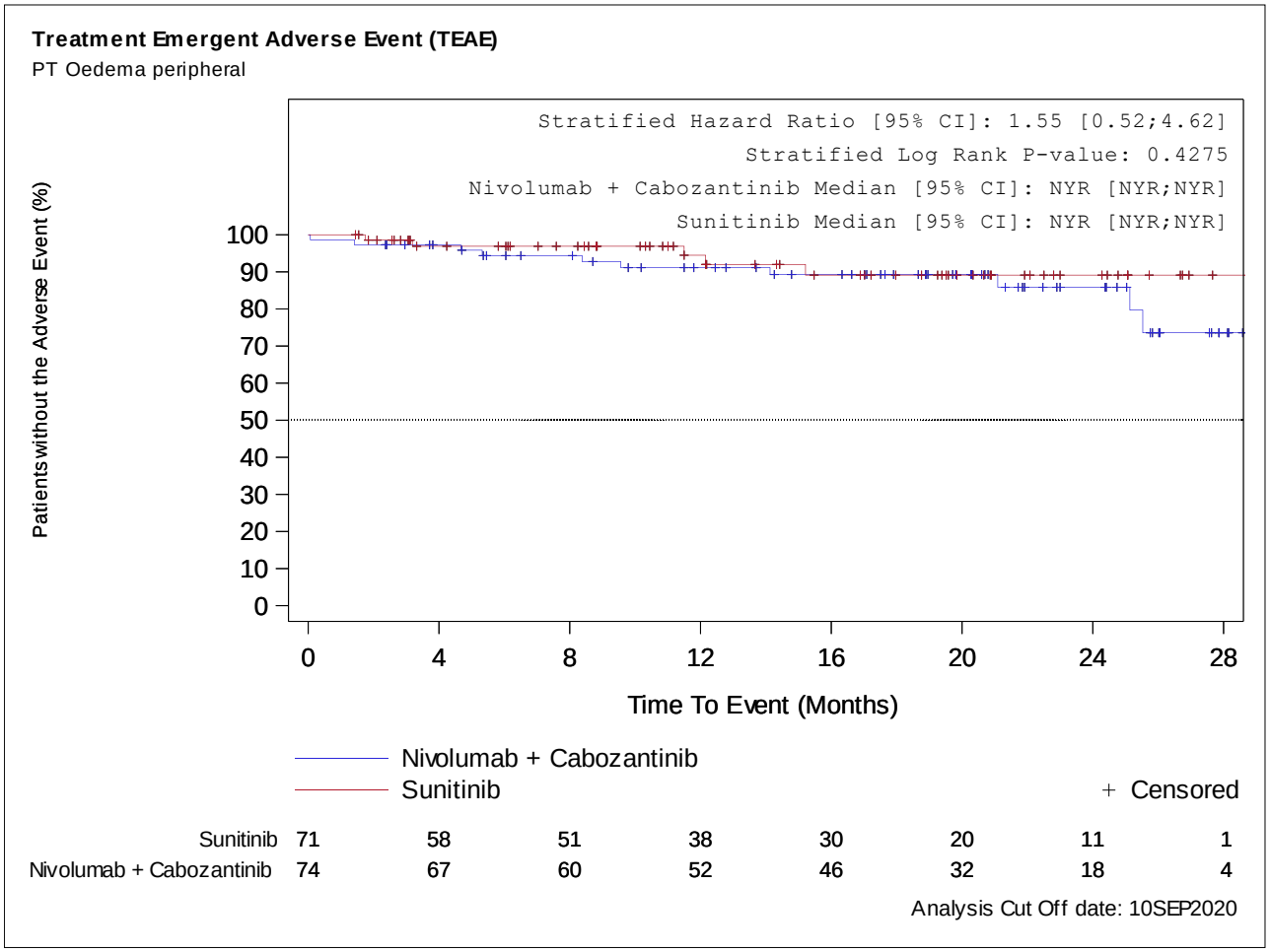
FIGURE 4.1.2.47: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oedema peripheral - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.1.2.48: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

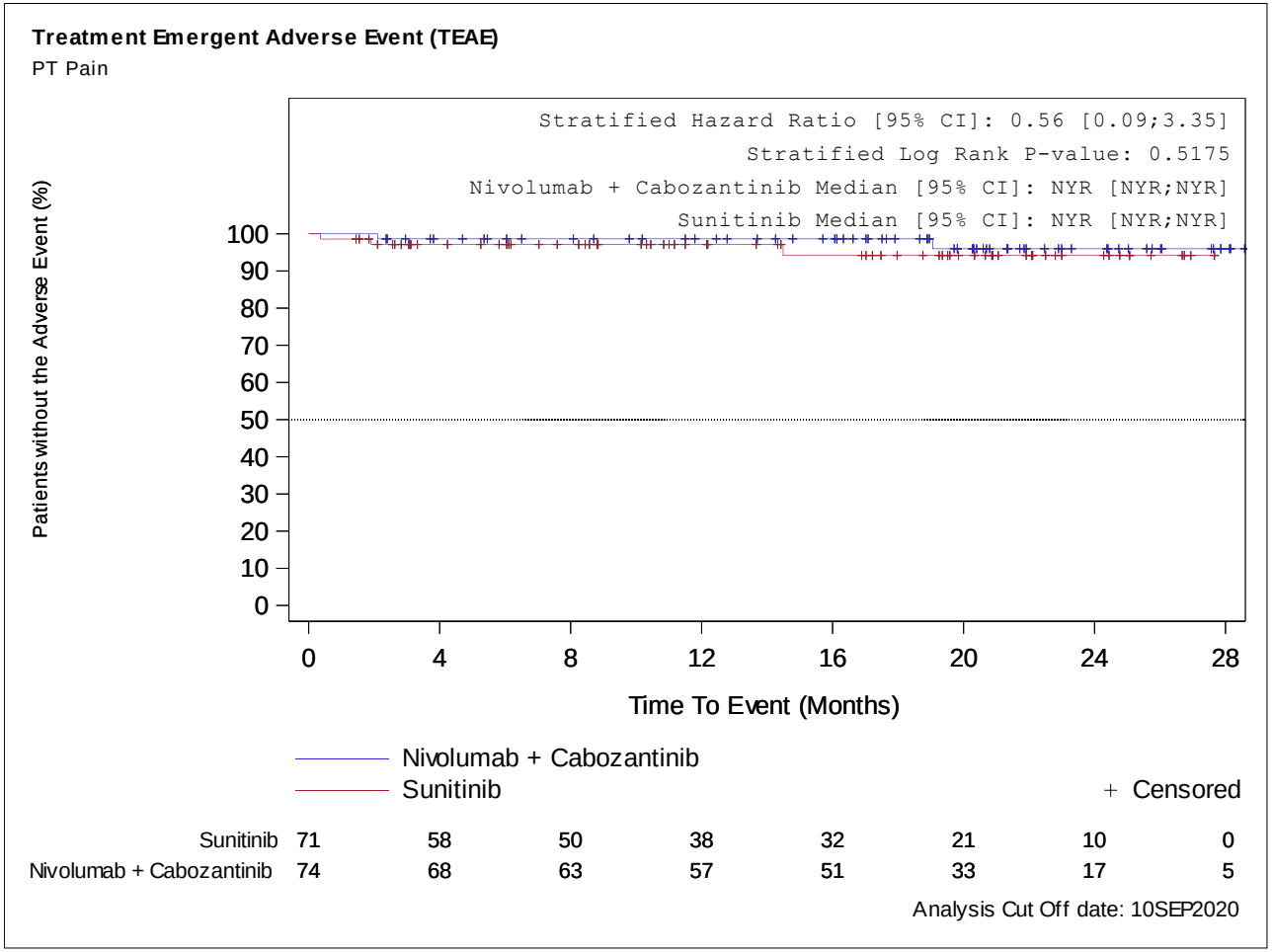


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FIGURE 4.1.2.49: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pyrexia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

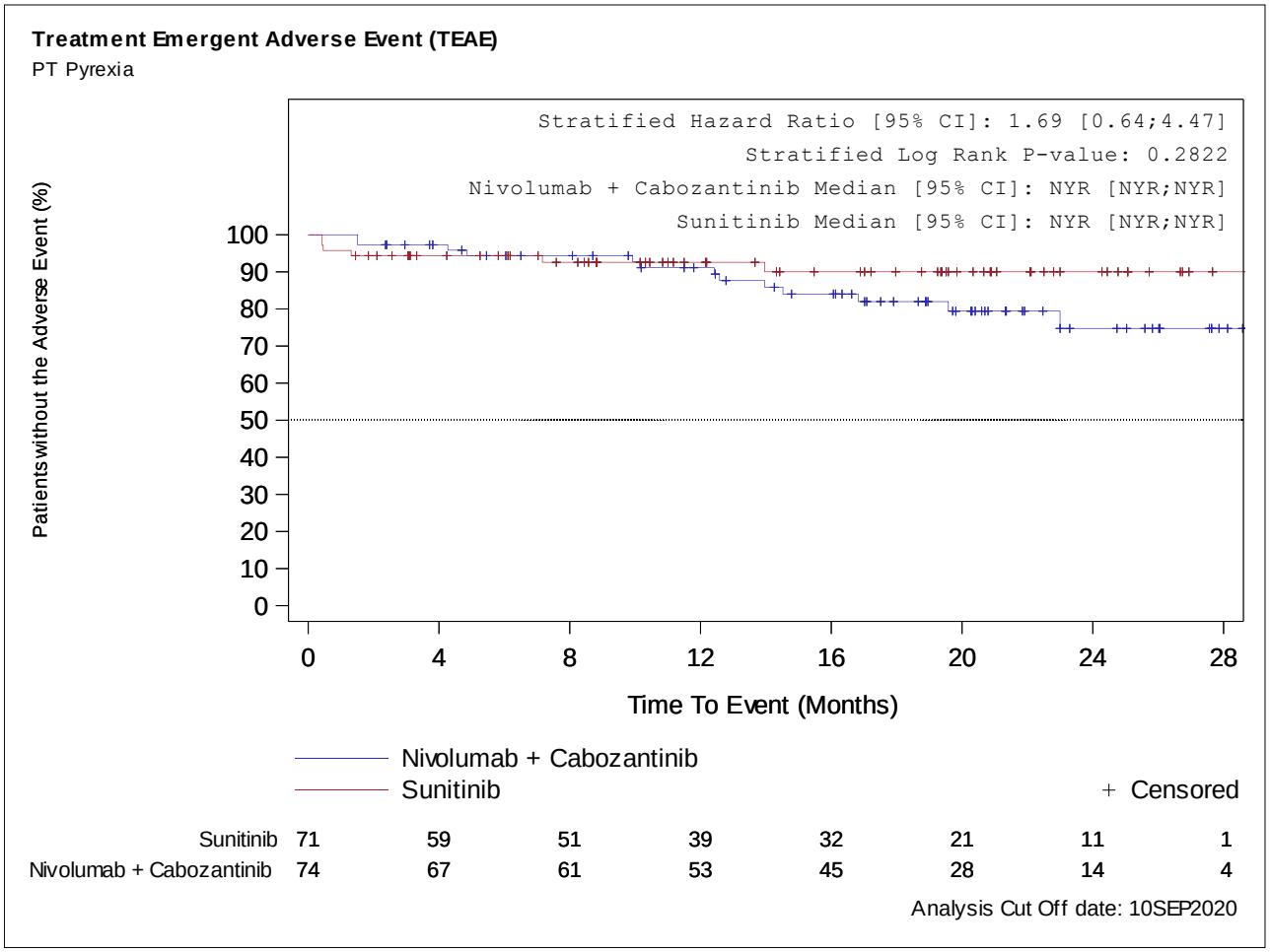


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FIGURE 4.1.2.50: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Hepatobiliary disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

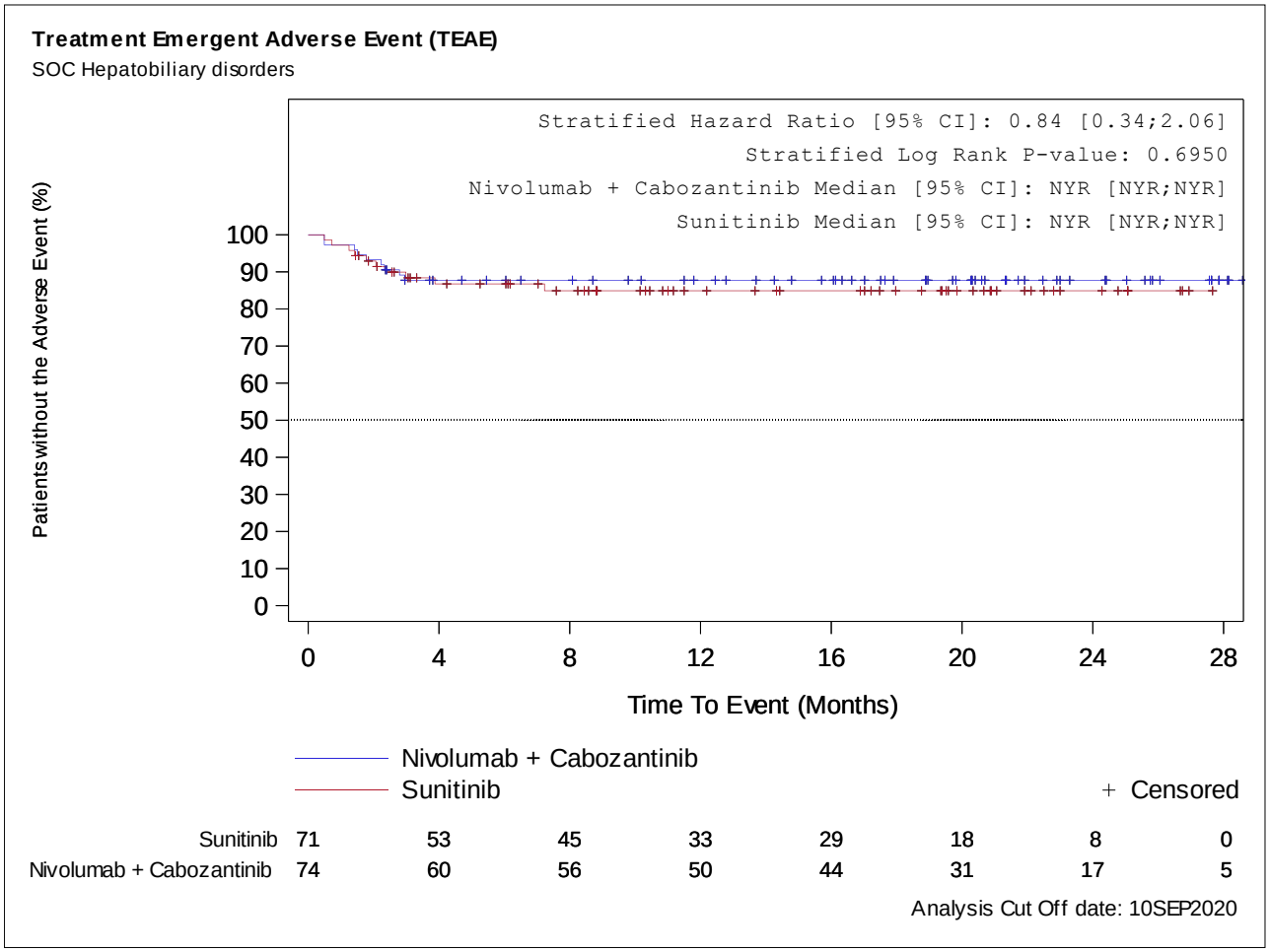


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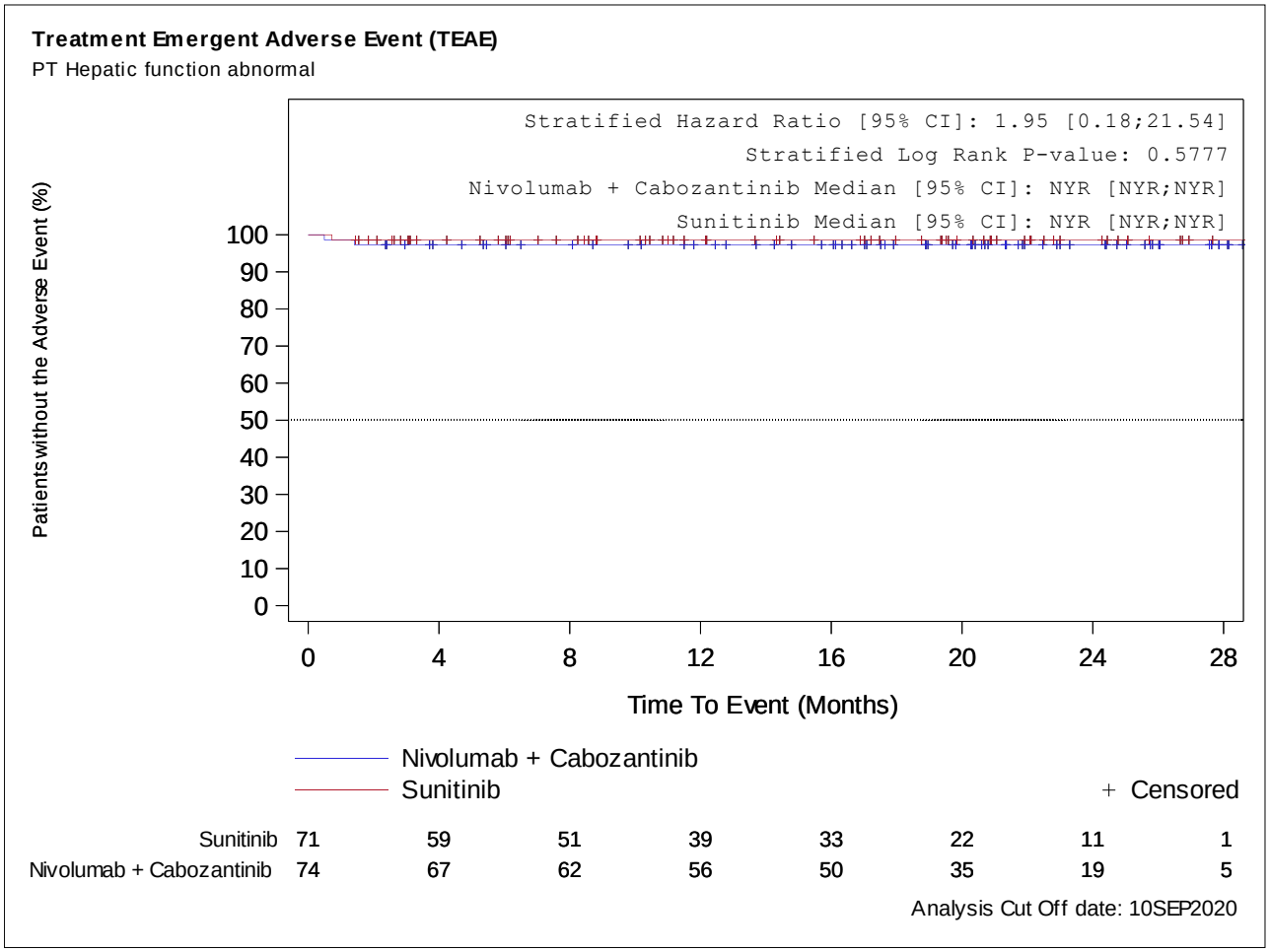
FIGURE 4.1.2.51: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hepatic function abnormal - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.1.2.52: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hepatotoxicity - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

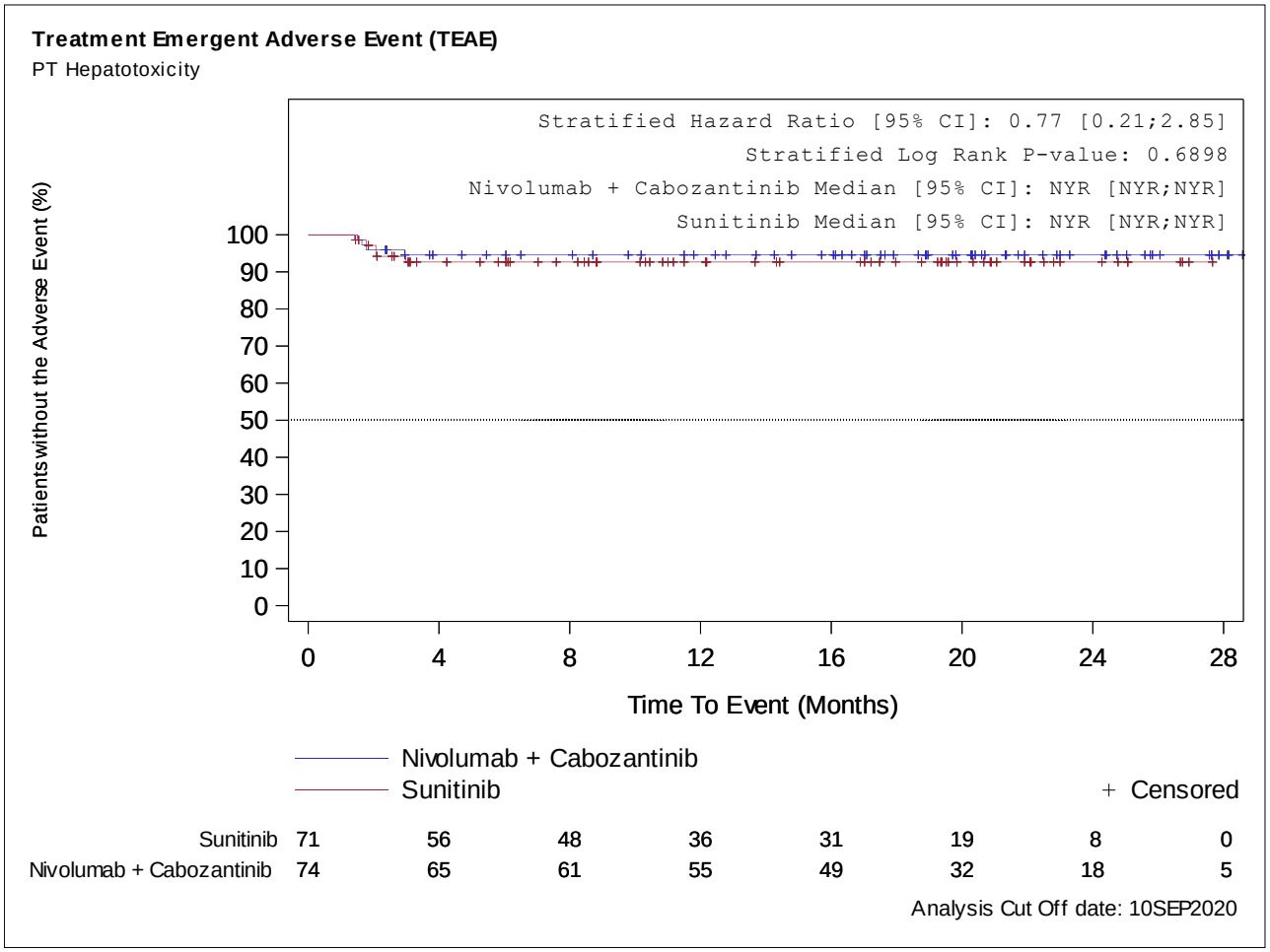


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FIGURE 4.1.2.53: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hyperbilirubinaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

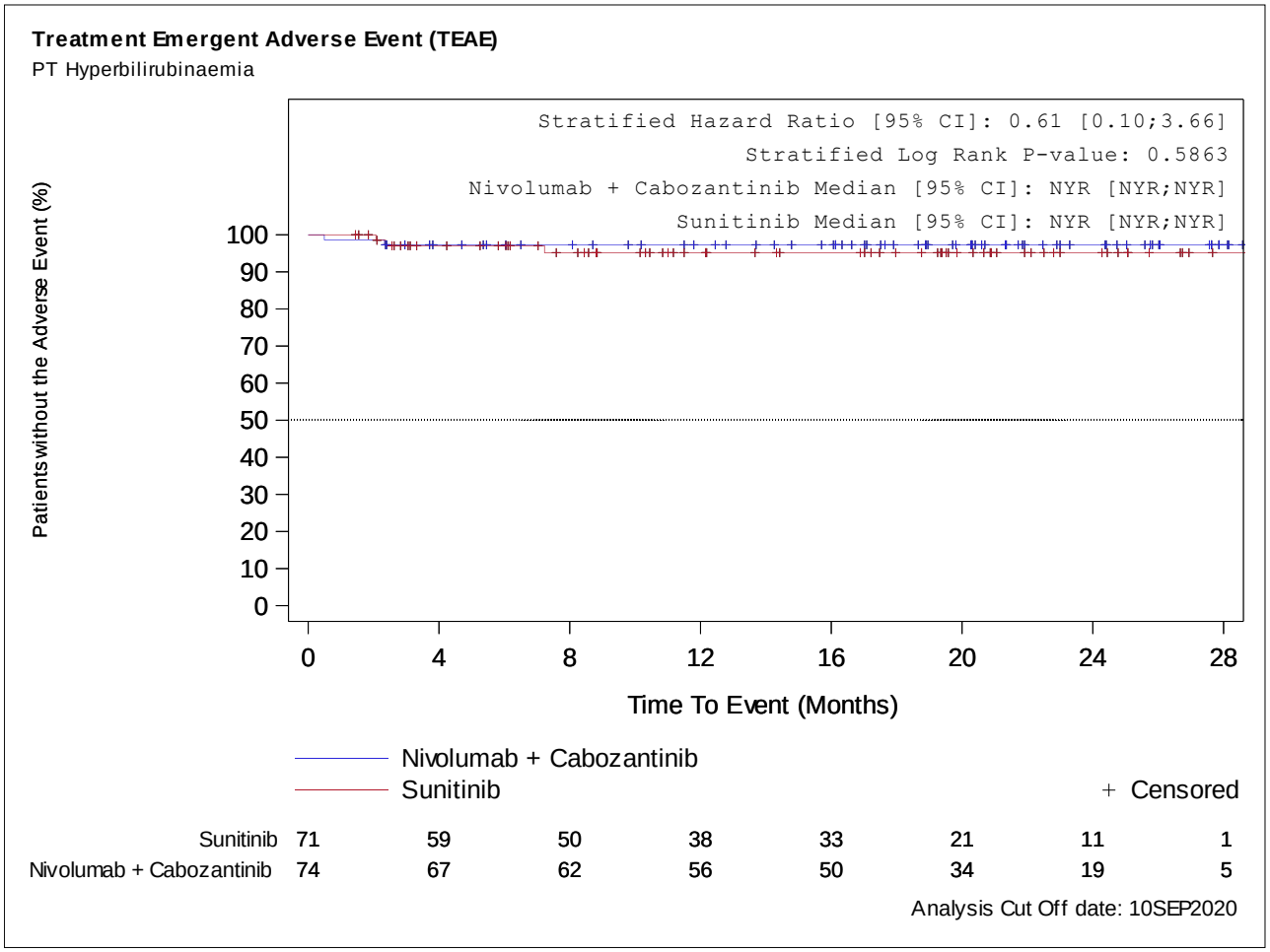


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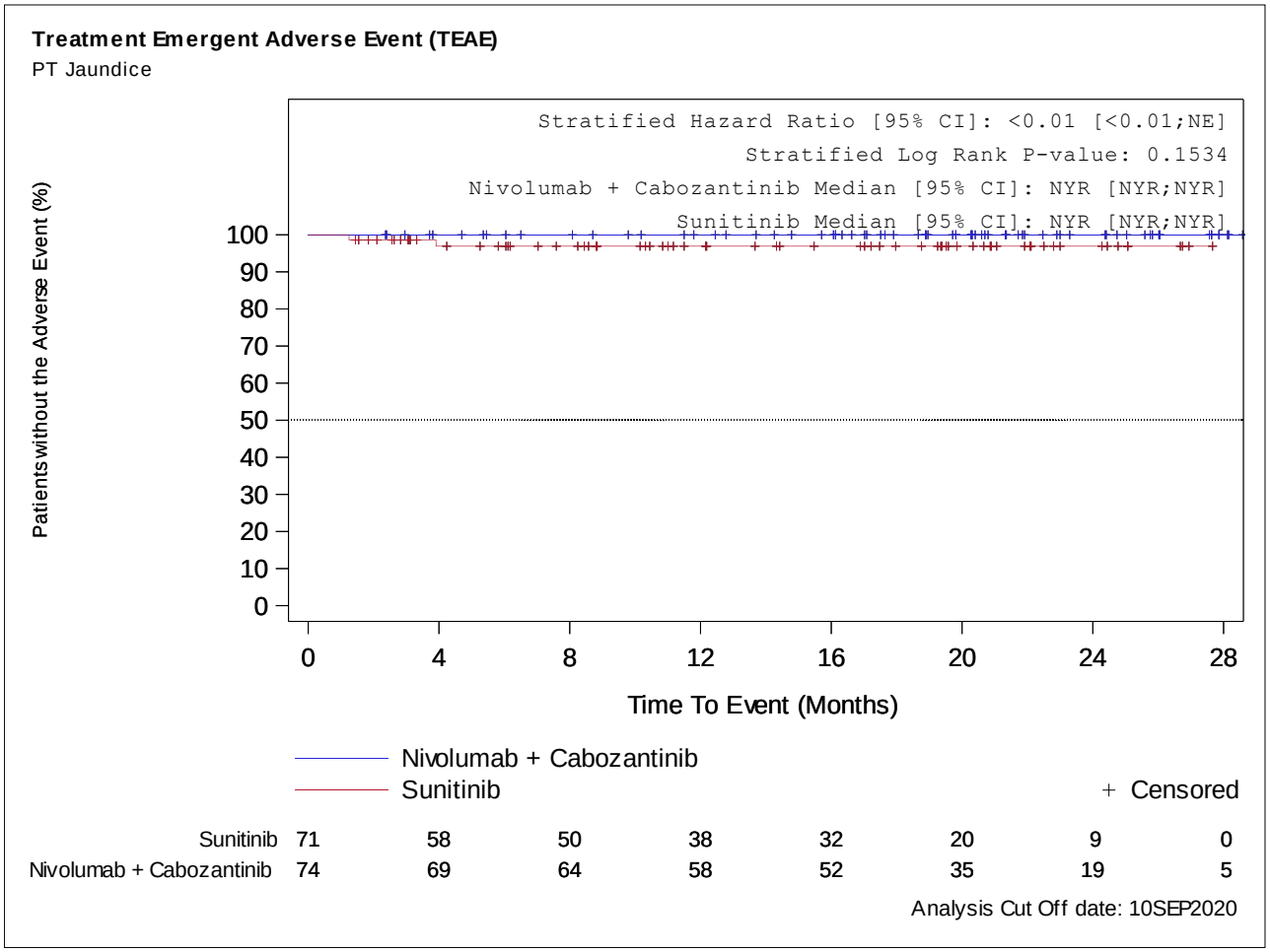
FIGURE 4.1.2.54: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Jaundice - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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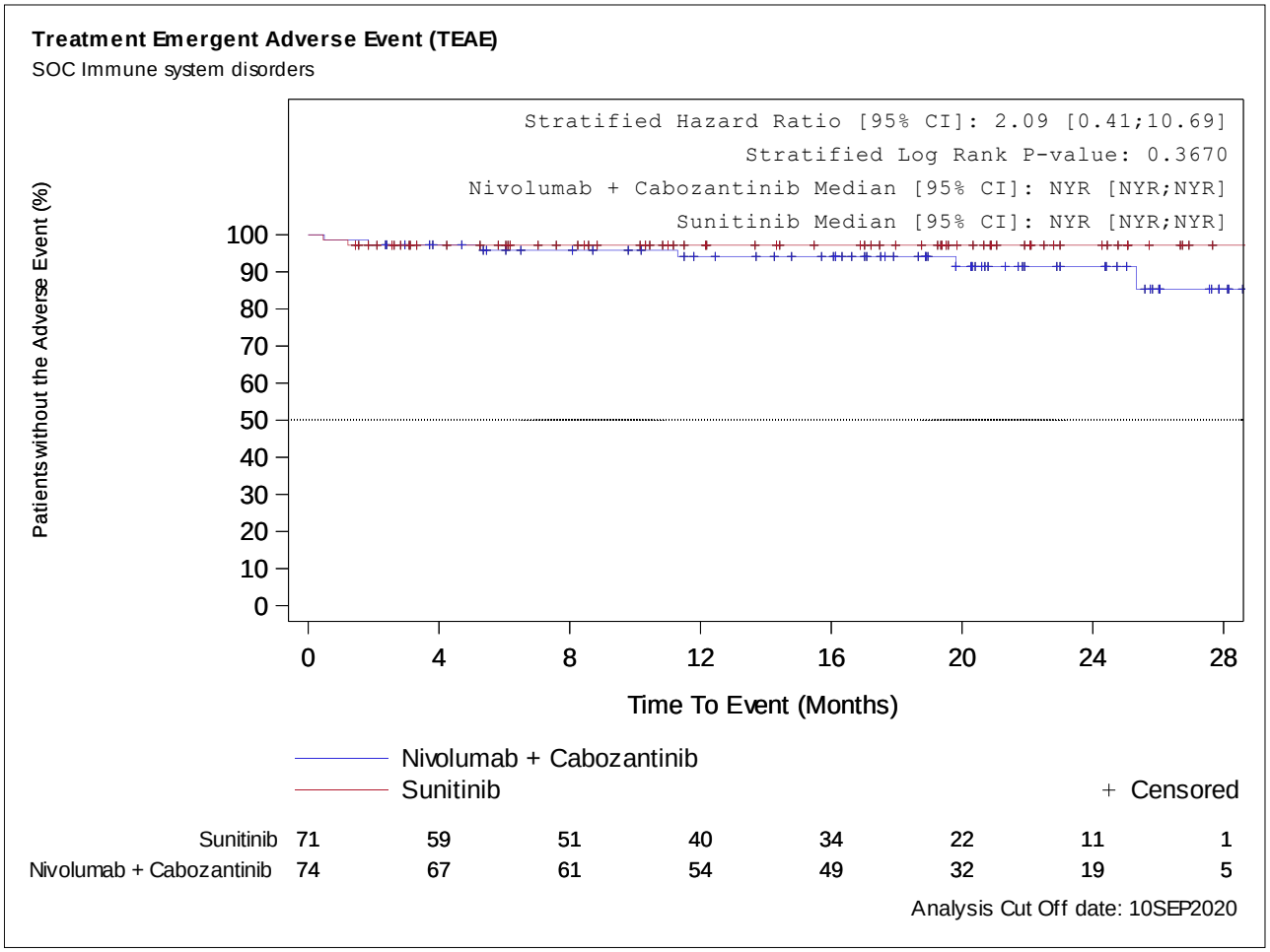
FIGURE 4.1.2.55: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Immune system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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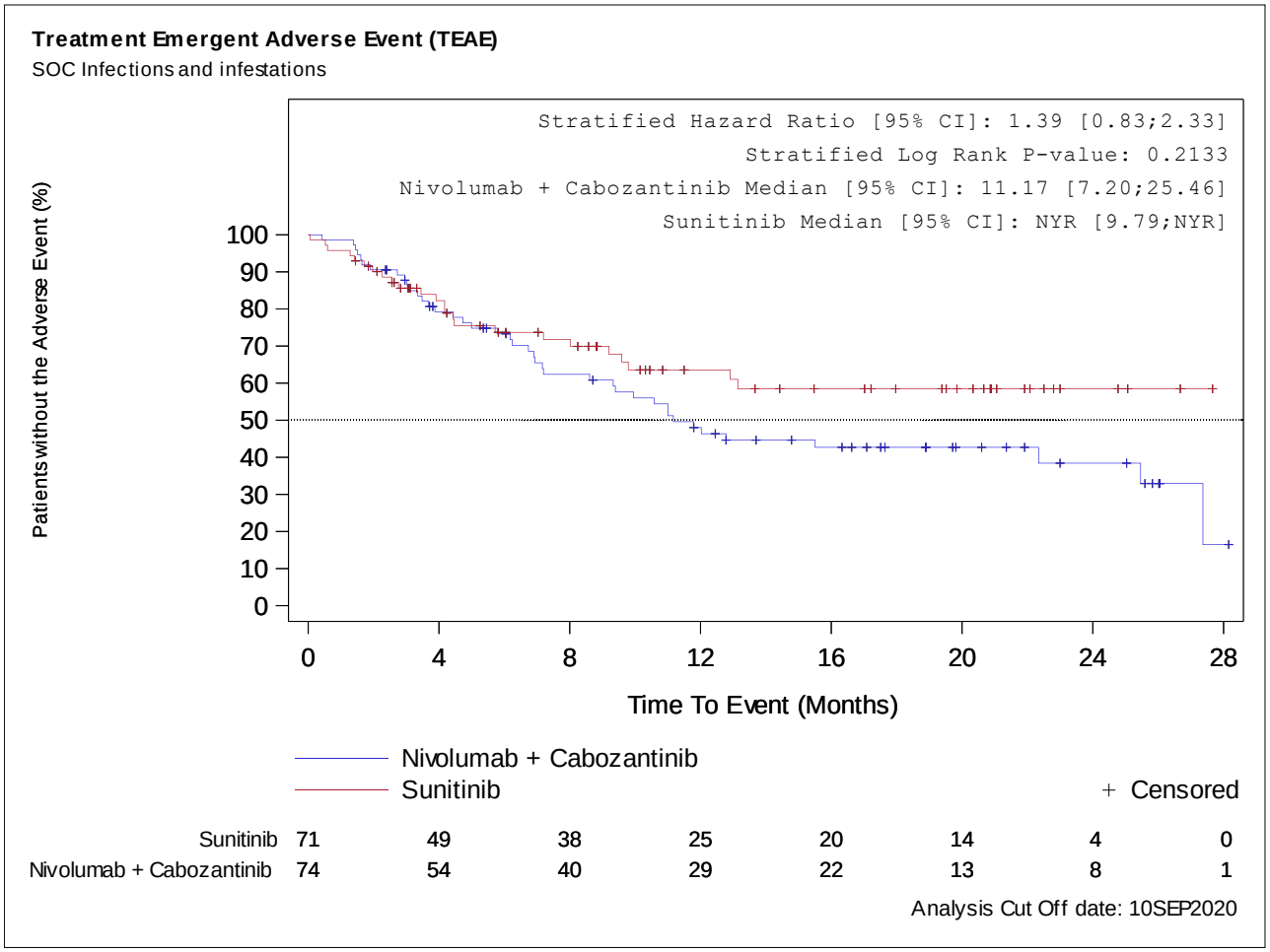
FIGURE 4.1.2.56: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Infections and infestations - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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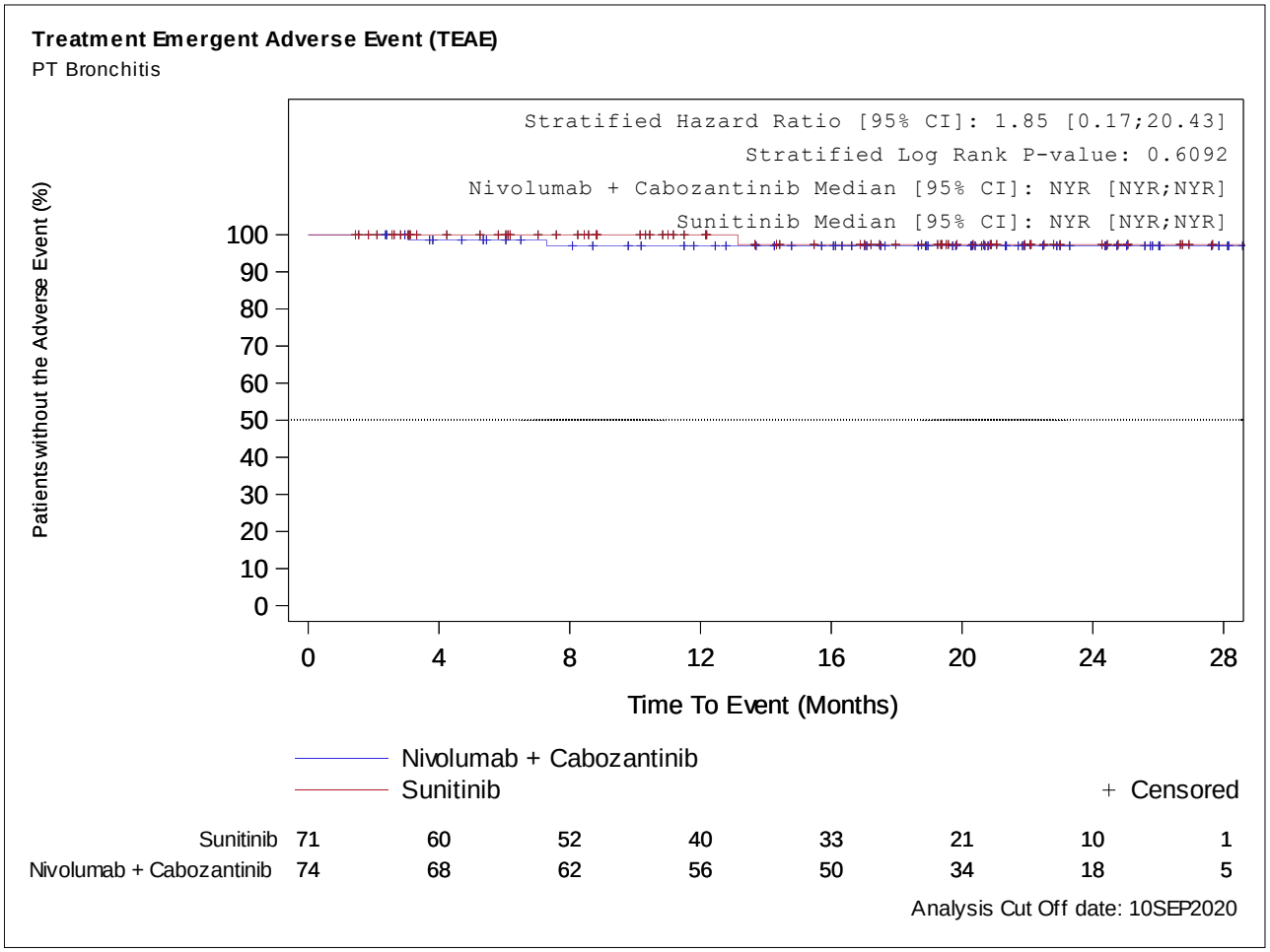
FIGURE 4.1.2.57: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Bronchitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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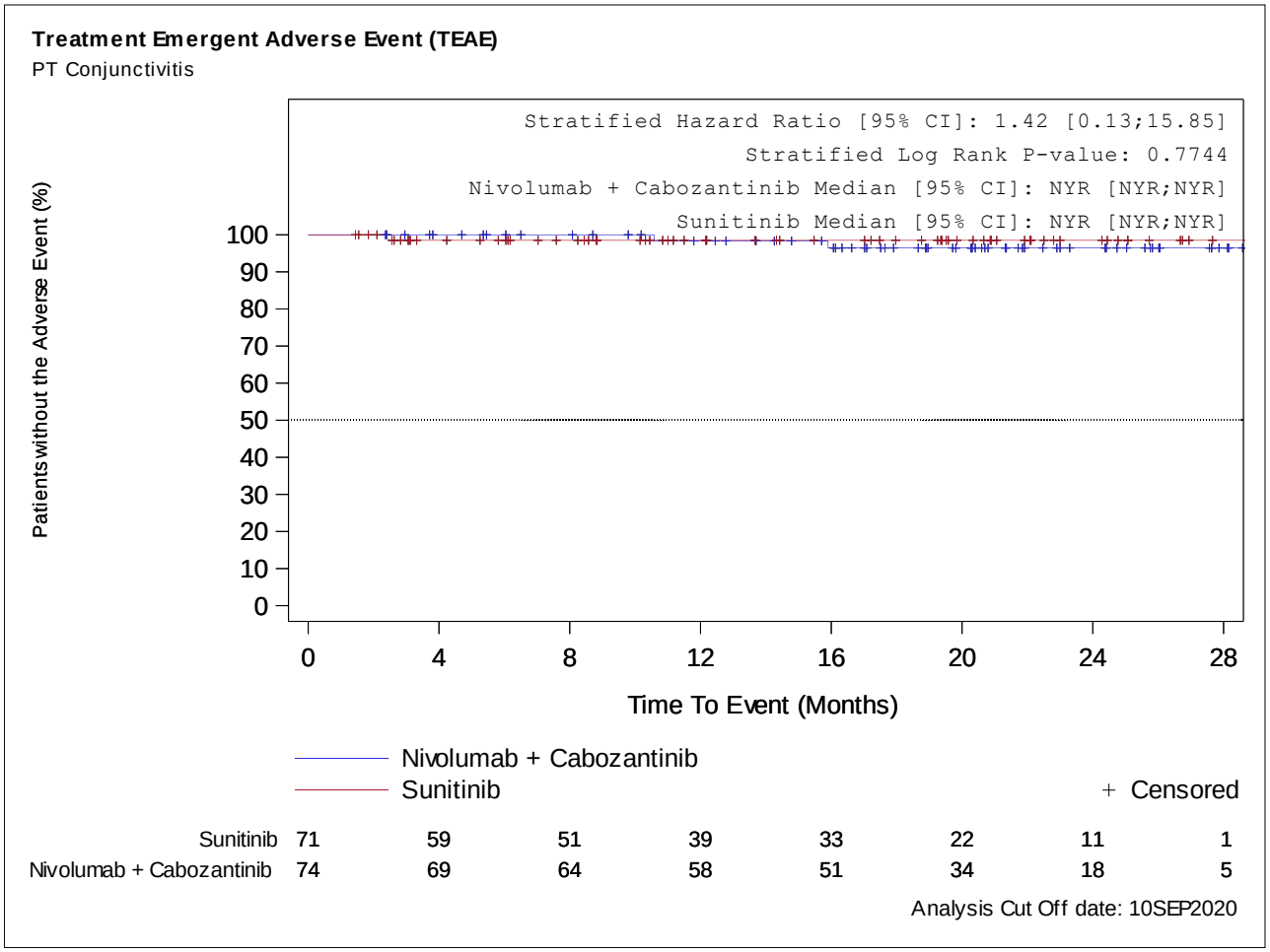
FIGURE 4.1.2.58: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Conjunctivitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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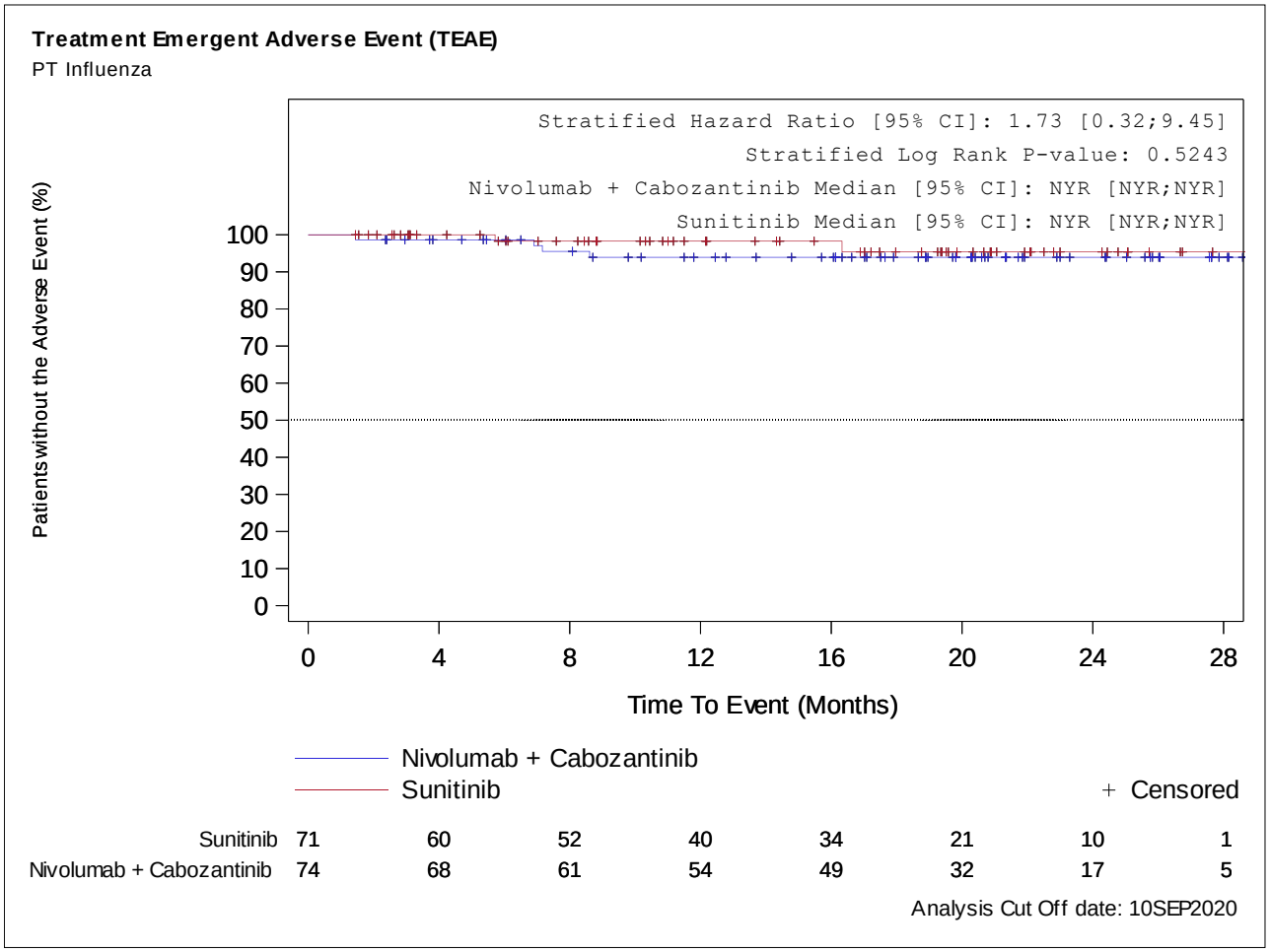
FIGURE 4.1.2.59: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Influenza - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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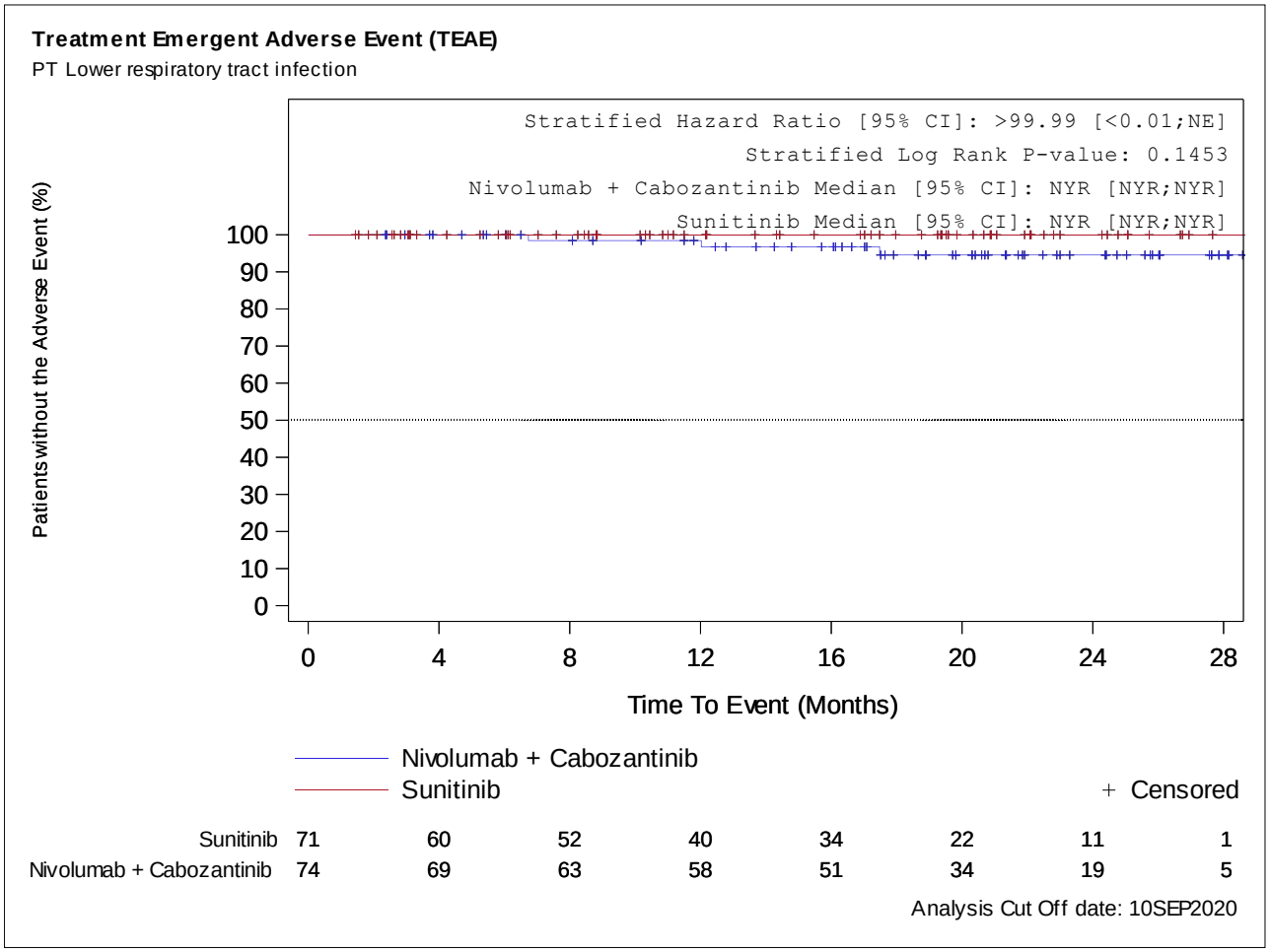
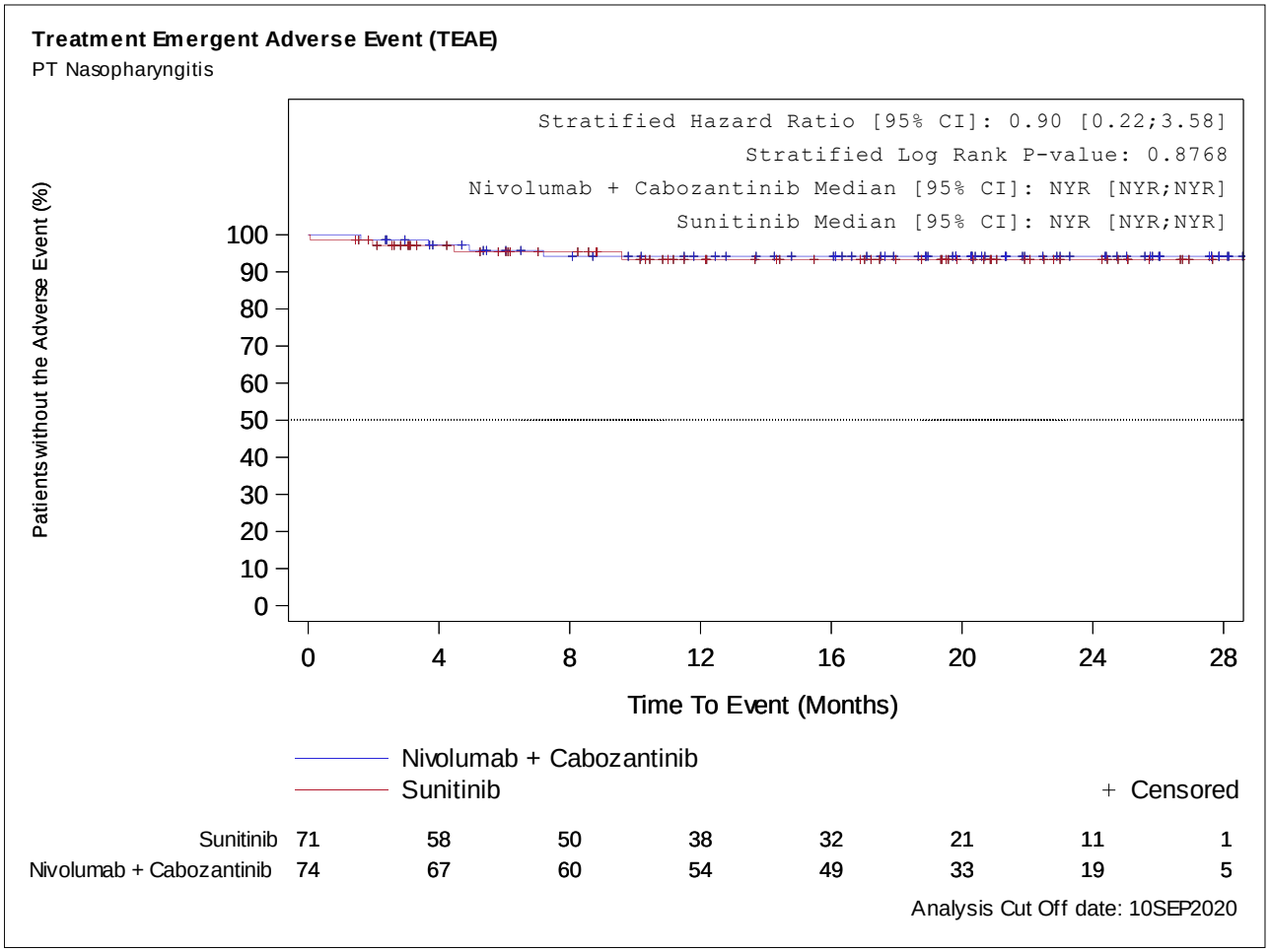
FIGURE 4.1.2.60: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Lower respiratory tract infection - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



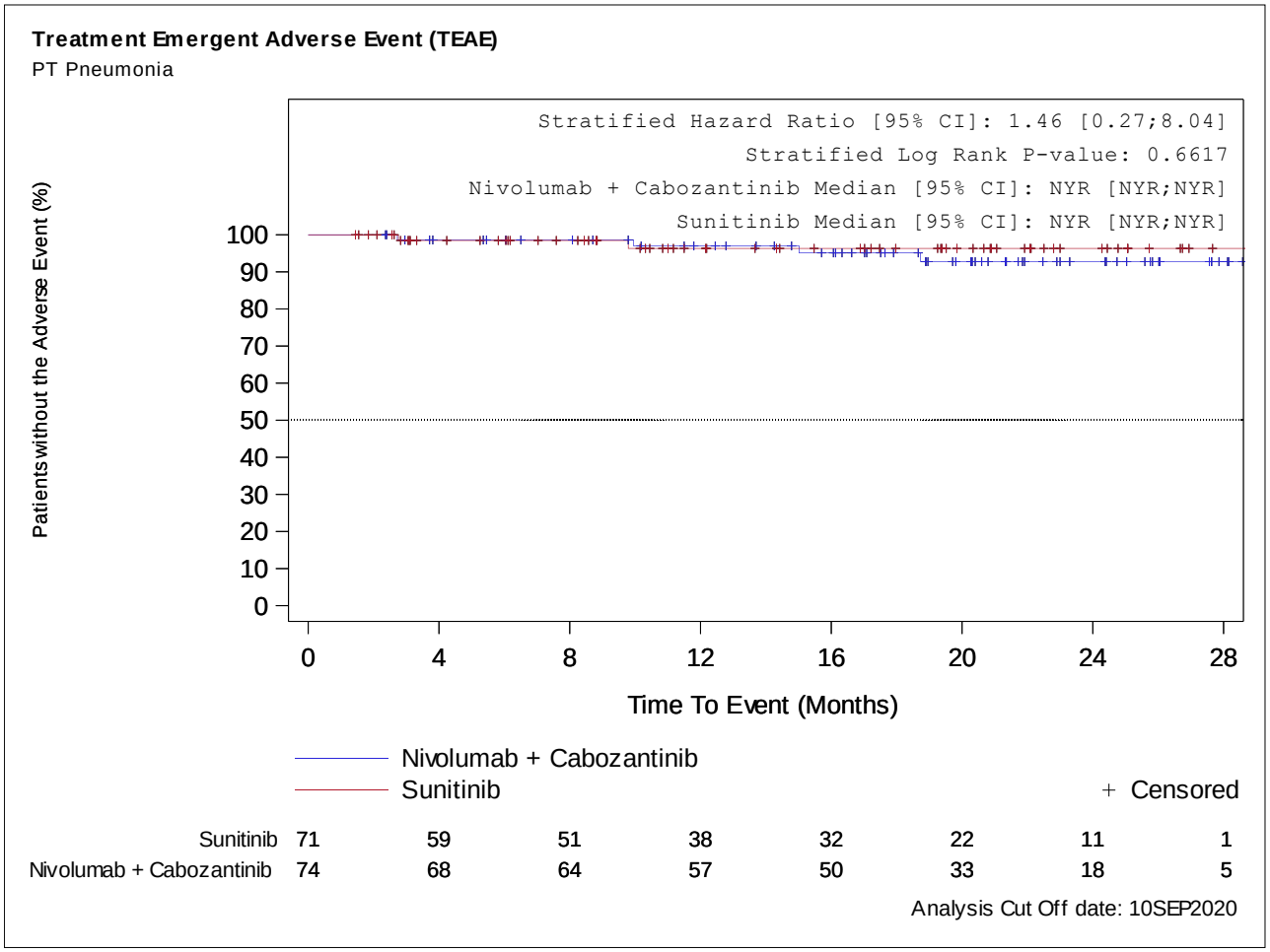

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 15:55:49

FIGURE 4.1.2.61: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Nasopharyngitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 15:55:54

FIGURE 4.1.2.62: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pneumonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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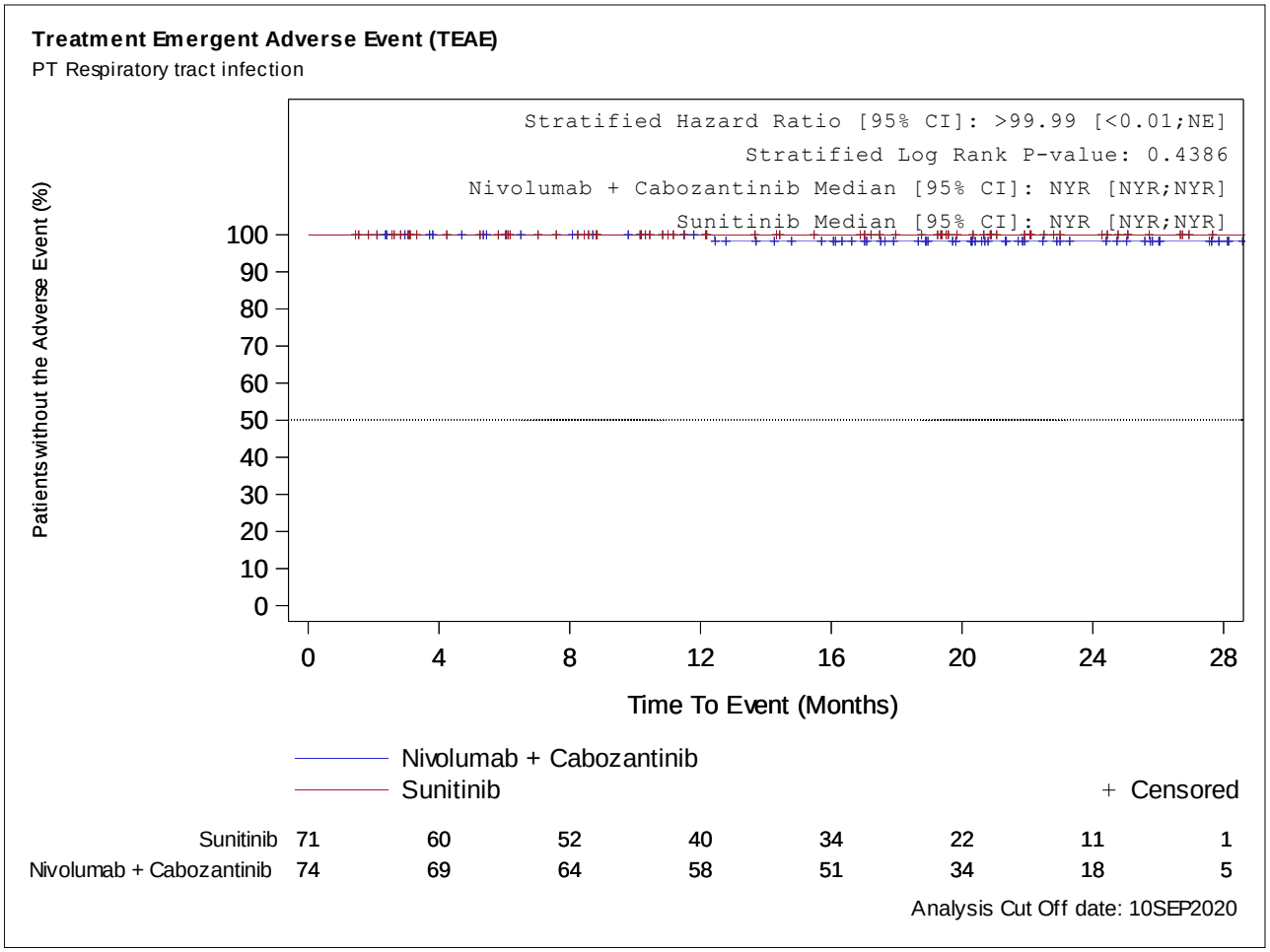
FIGURE 4.1.2.63: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Respiratory tract infection - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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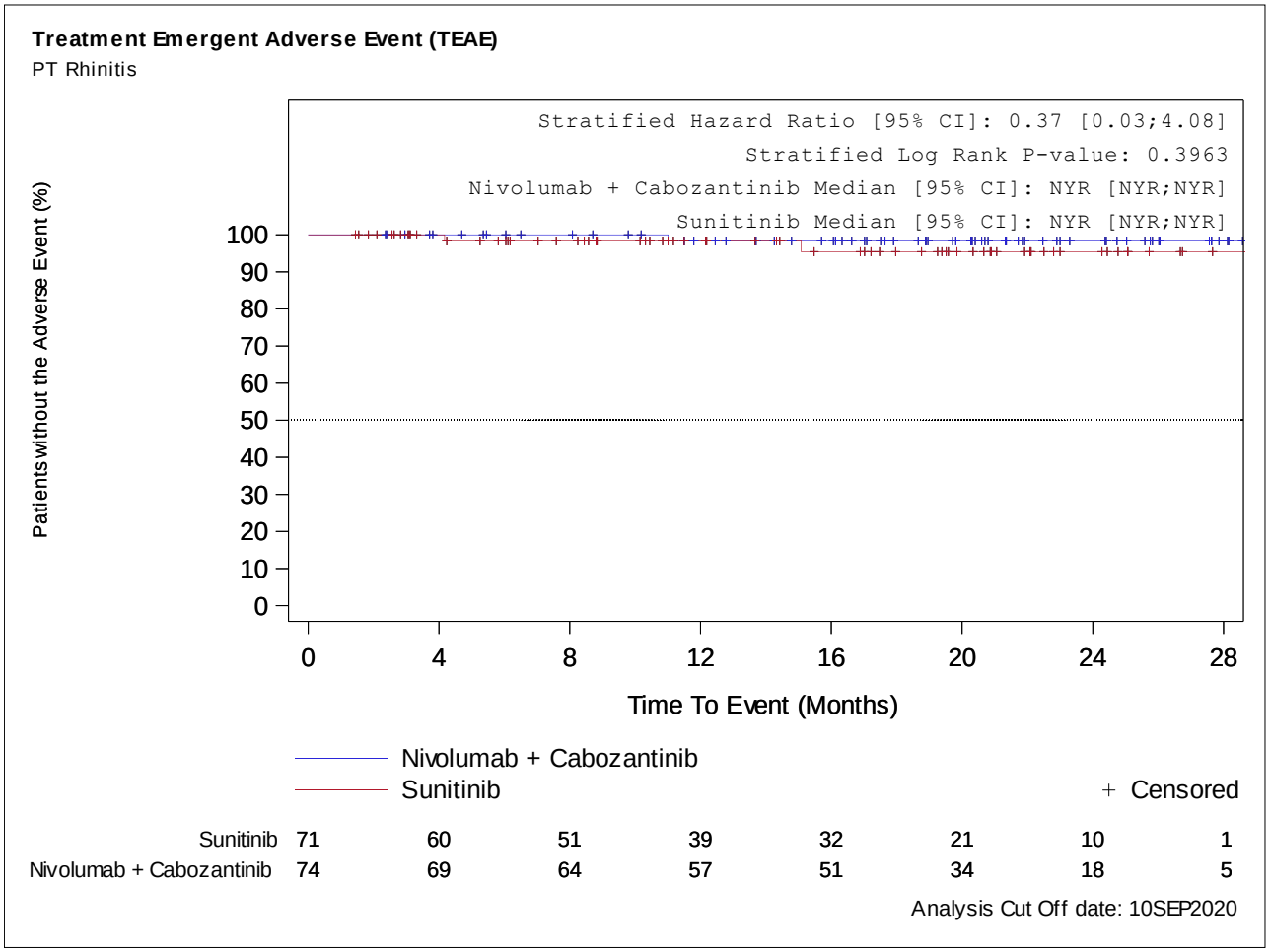
FIGURE 4.1.2.64: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rhinitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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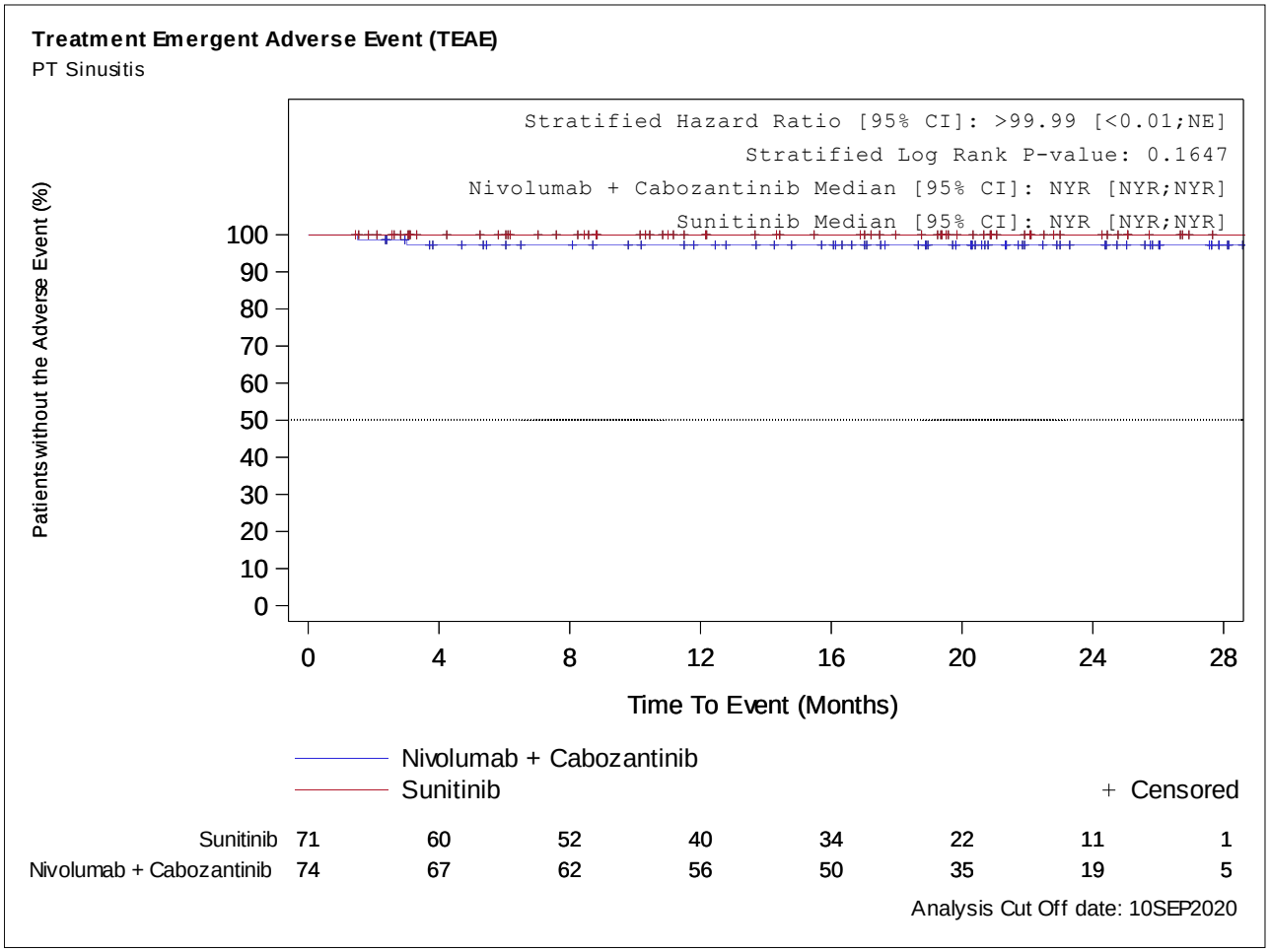
FIGURE 4.1.2.65: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Sinusitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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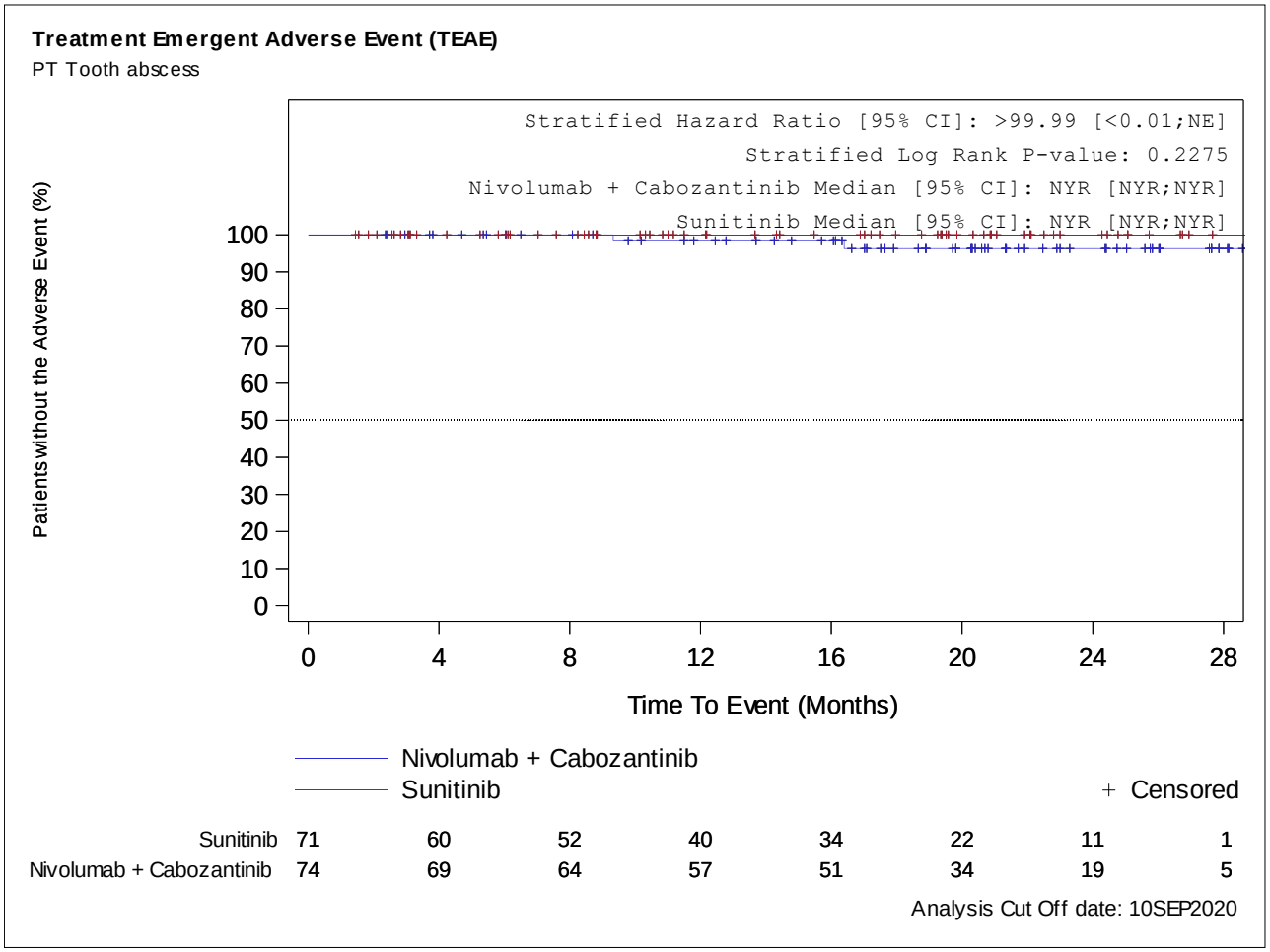
FIGURE 4.1.2.66: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Tooth abscess - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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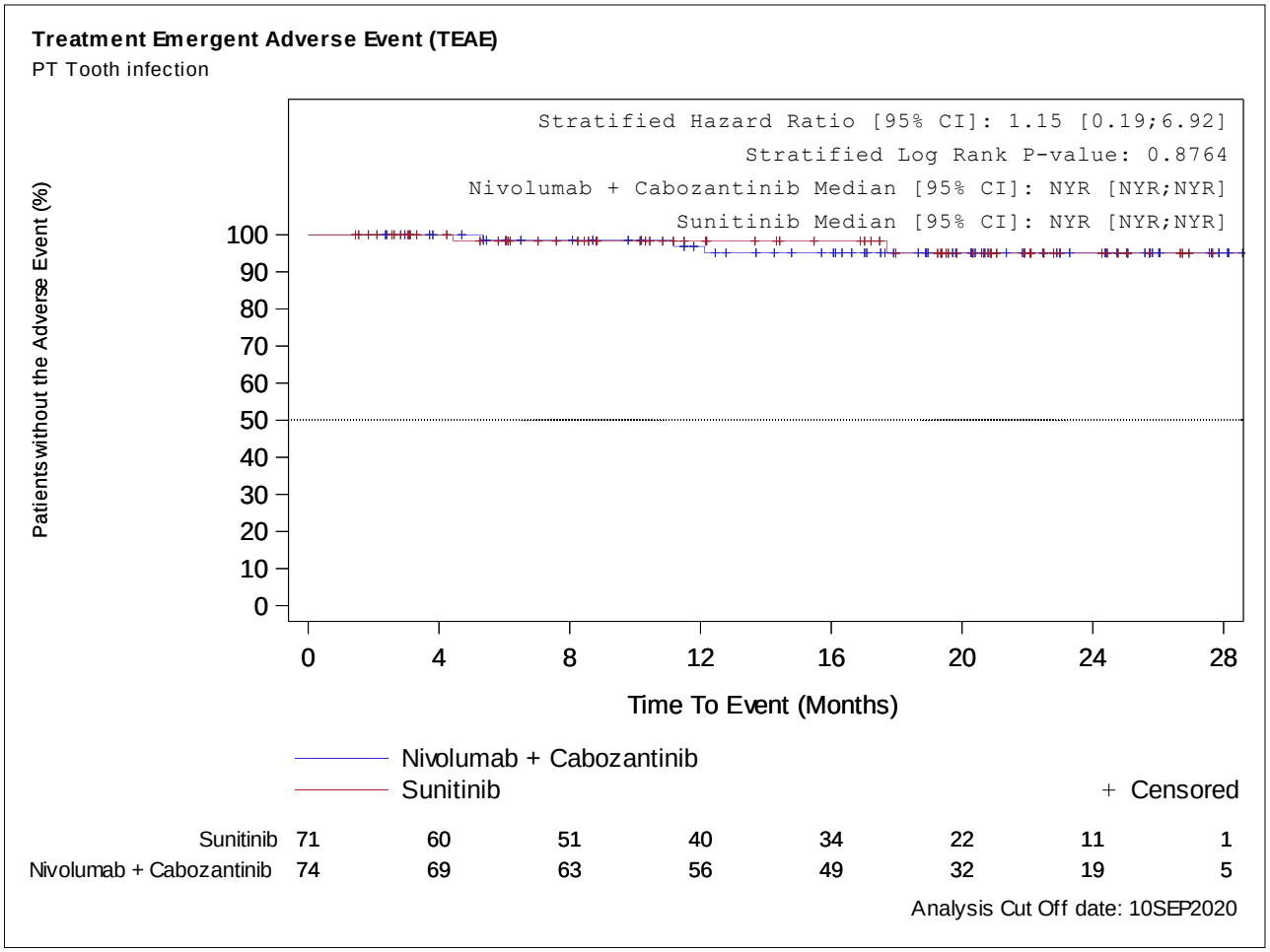
FIGURE 4.1.2.67: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Tooth infection - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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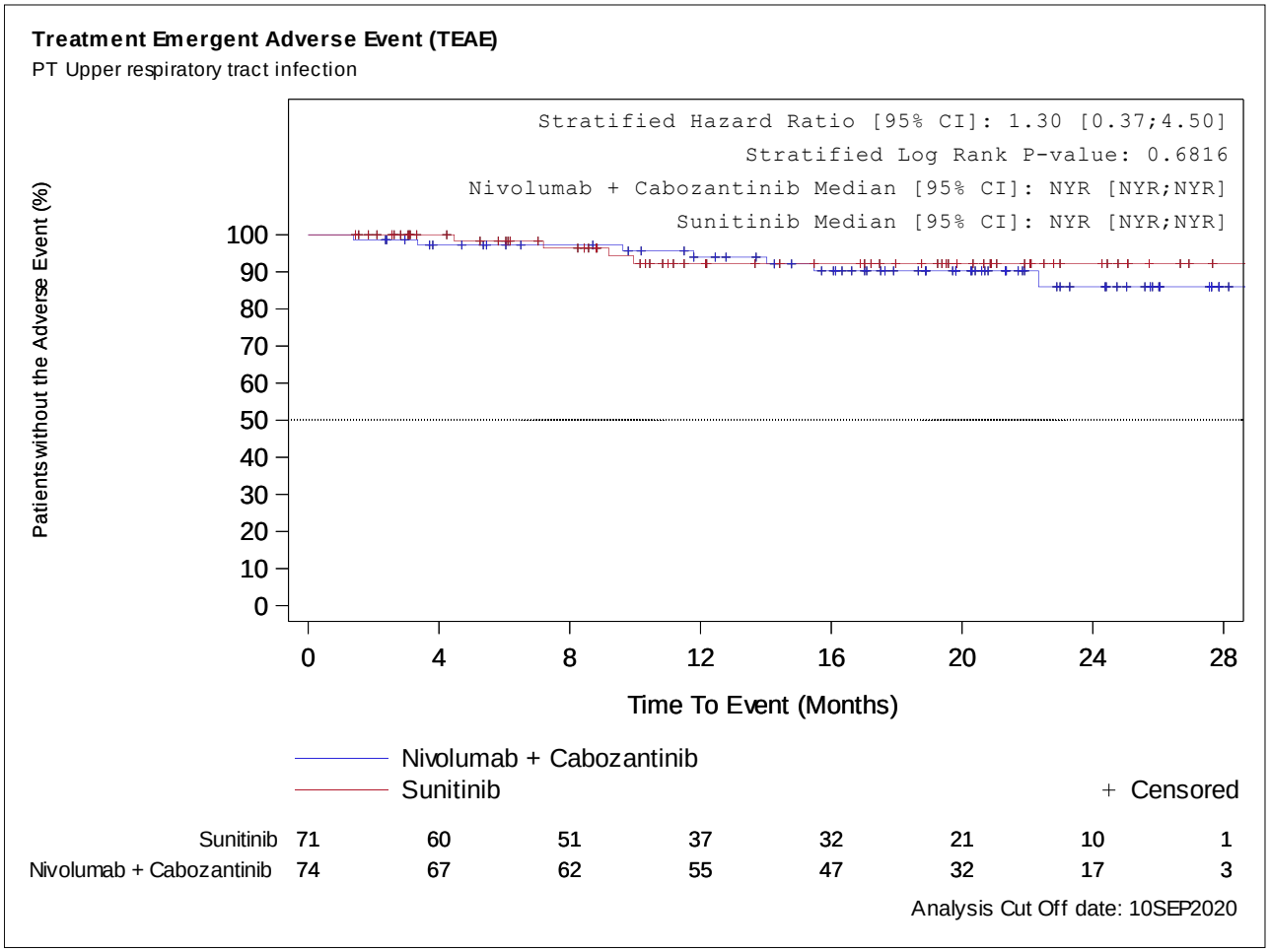
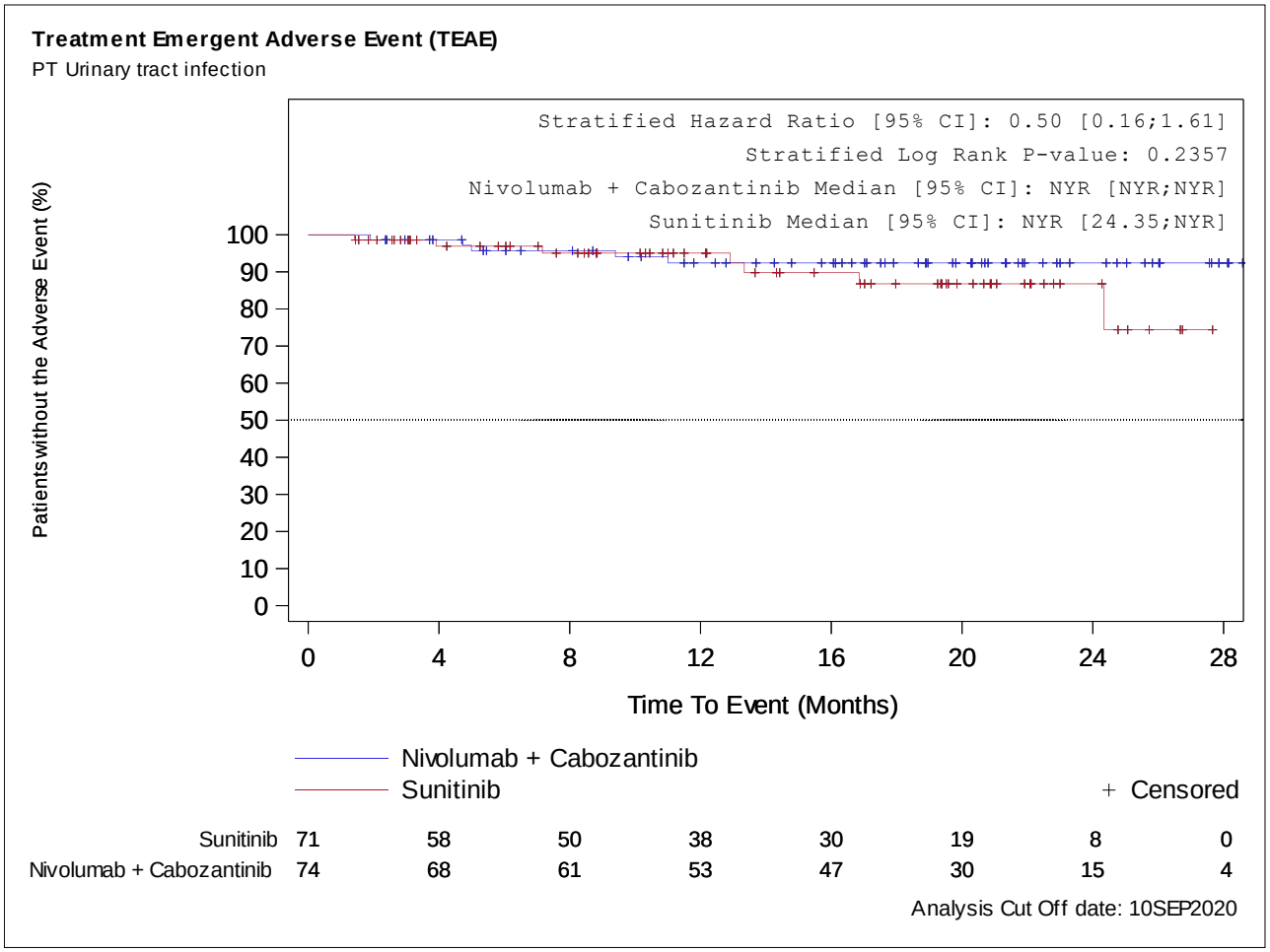
FIGURE 4.1.2.68: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Upper respiratory tract infection - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 15:56:26

FIGURE 4.1.2.69: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Urinary tract infection - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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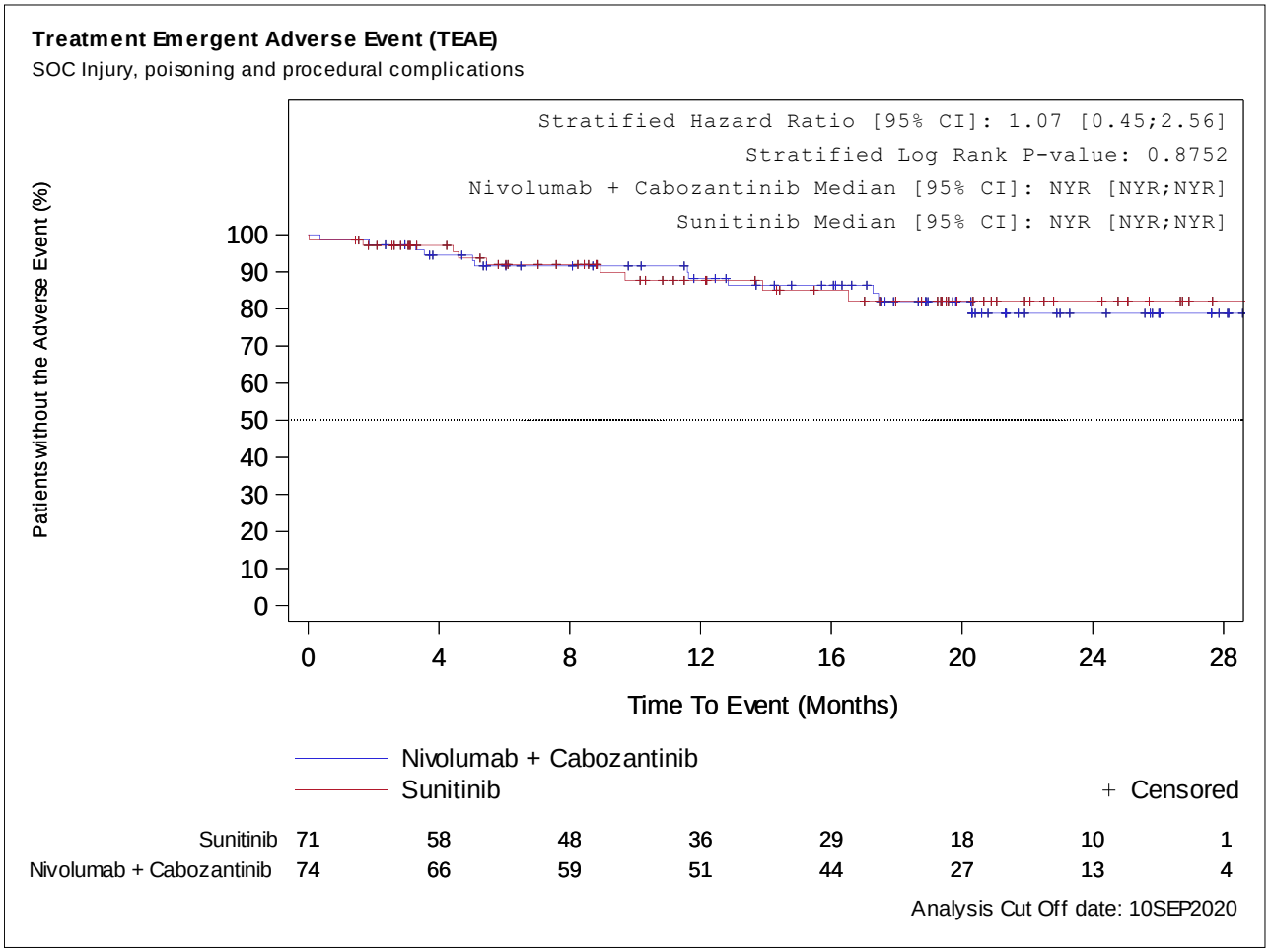
FIGURE 4.1.2.70: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Injury, poisoning and procedural complications - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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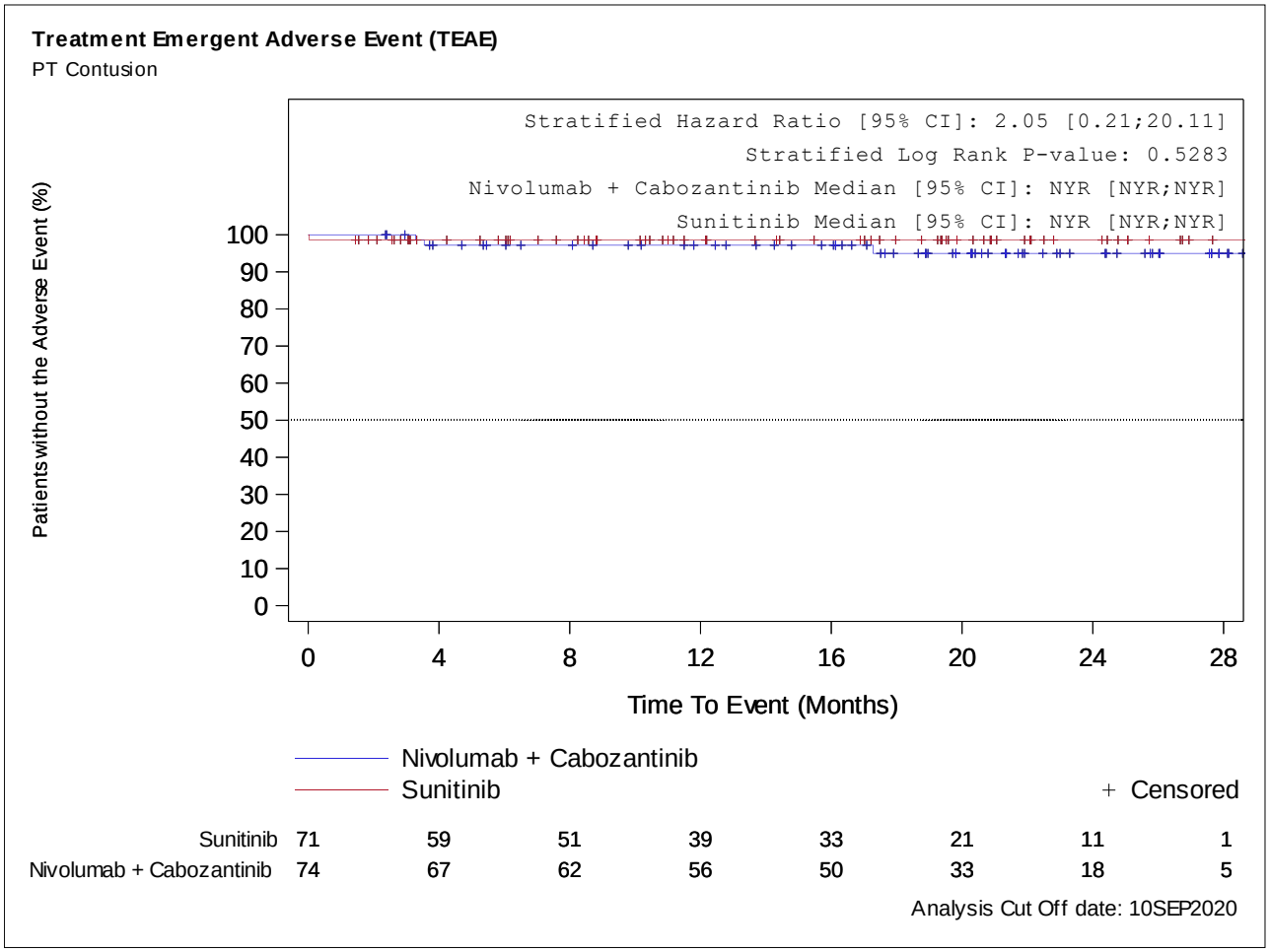
FIGURE 4.1.2.71: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Contusion - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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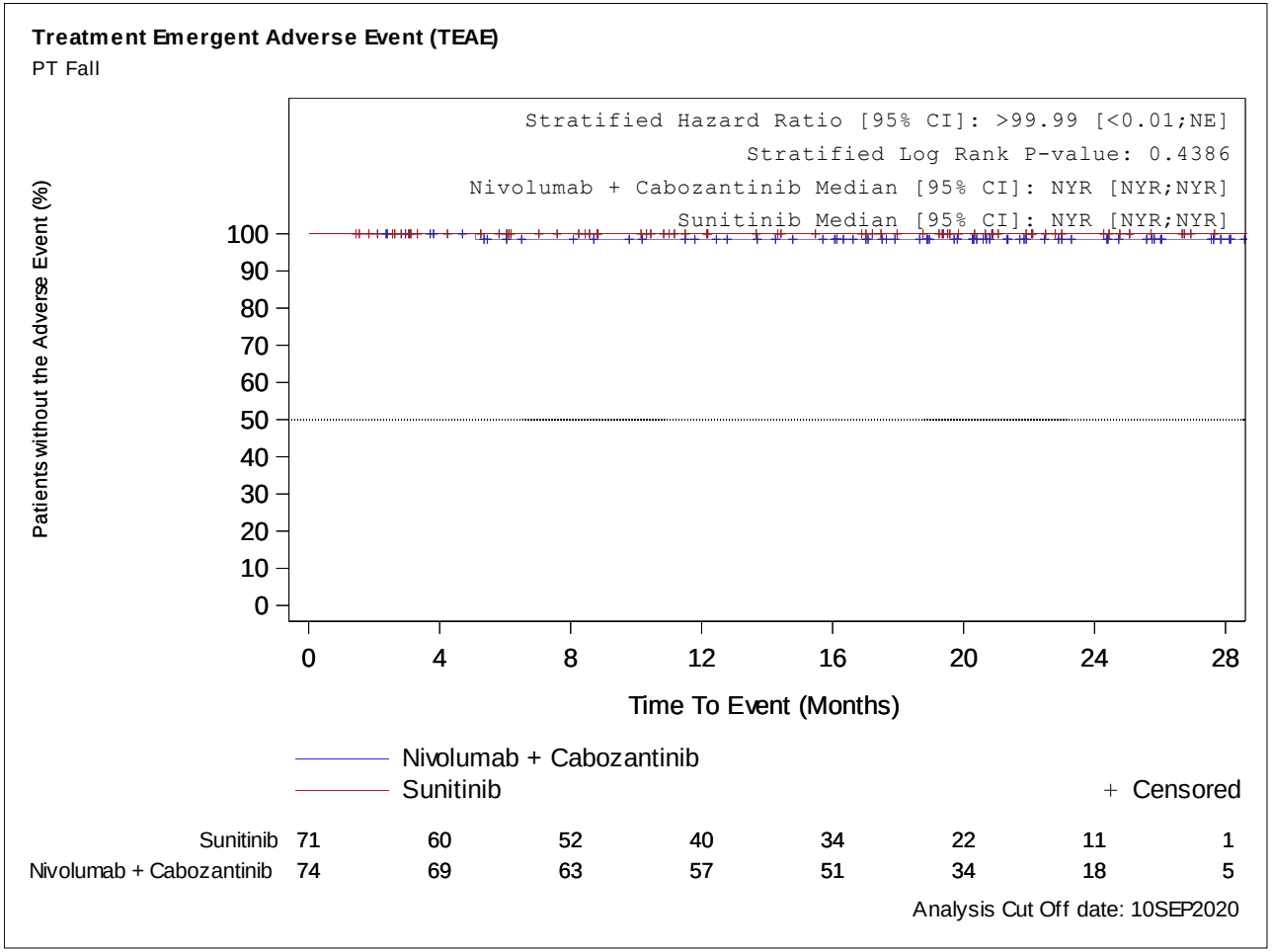
FIGURE 4.1.2.72: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Fall - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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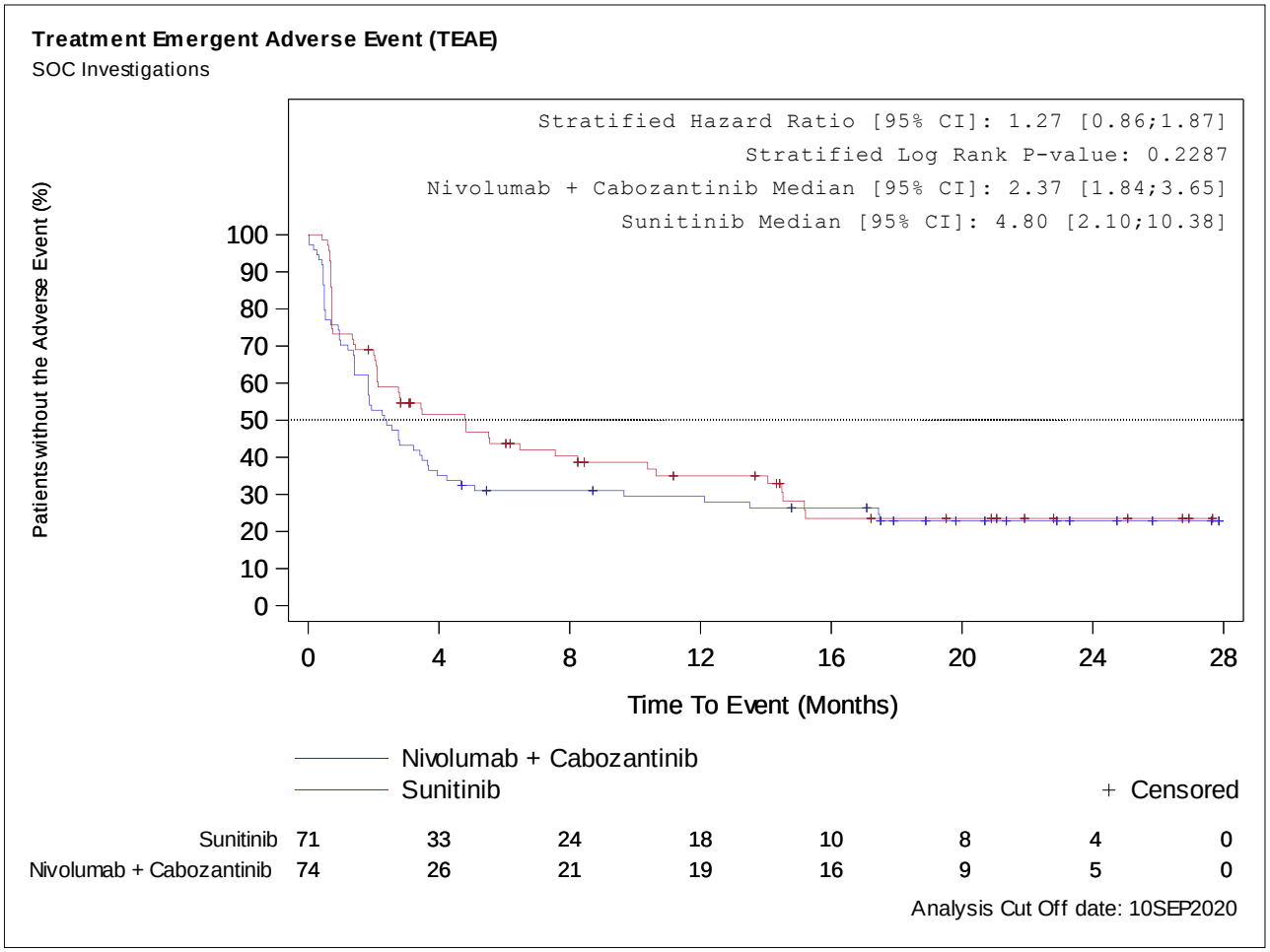
FIGURE 4.1.2.73: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Investigations - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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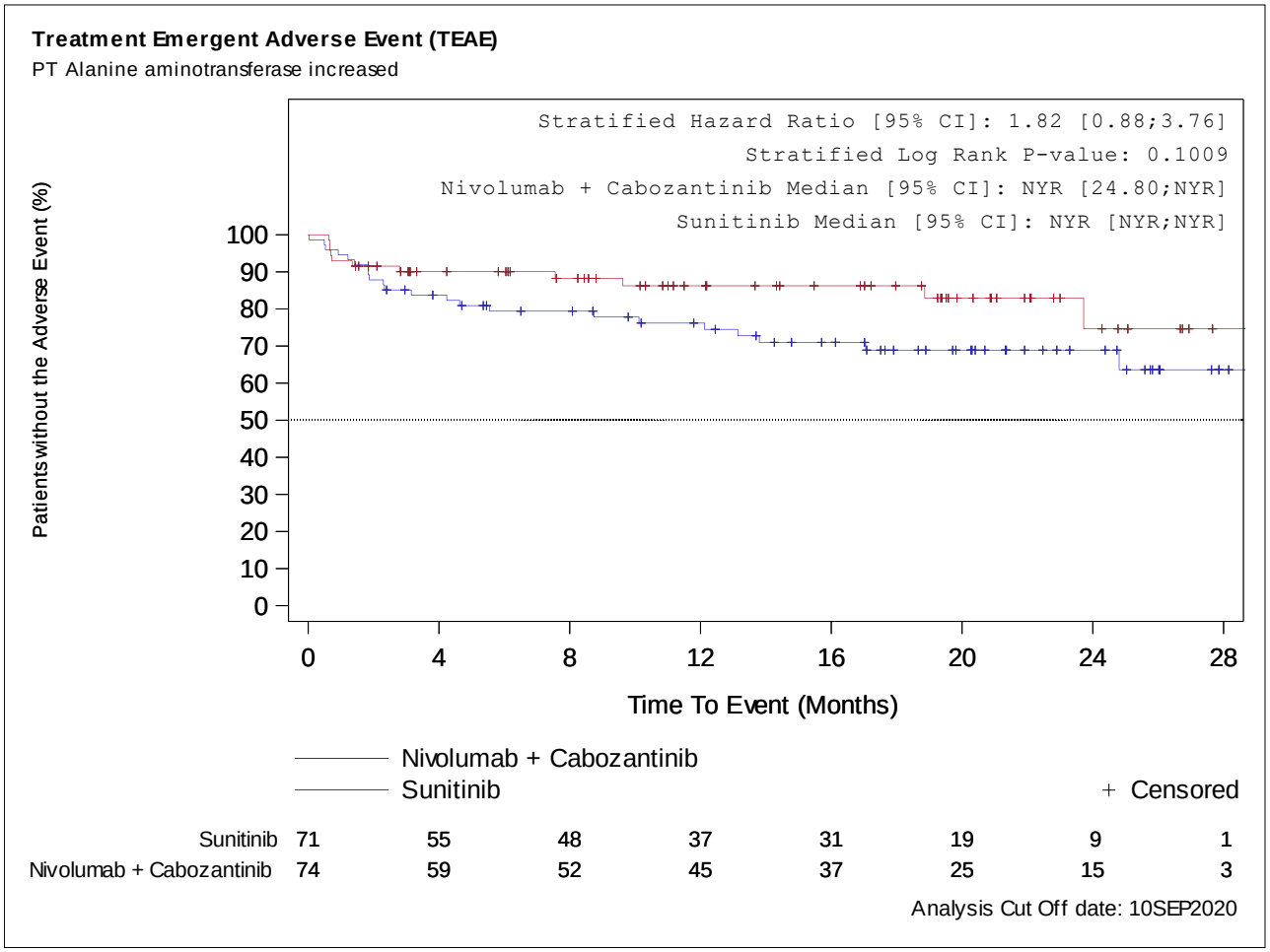
FIGURE 4.1.2.74: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Alanine aminotransferase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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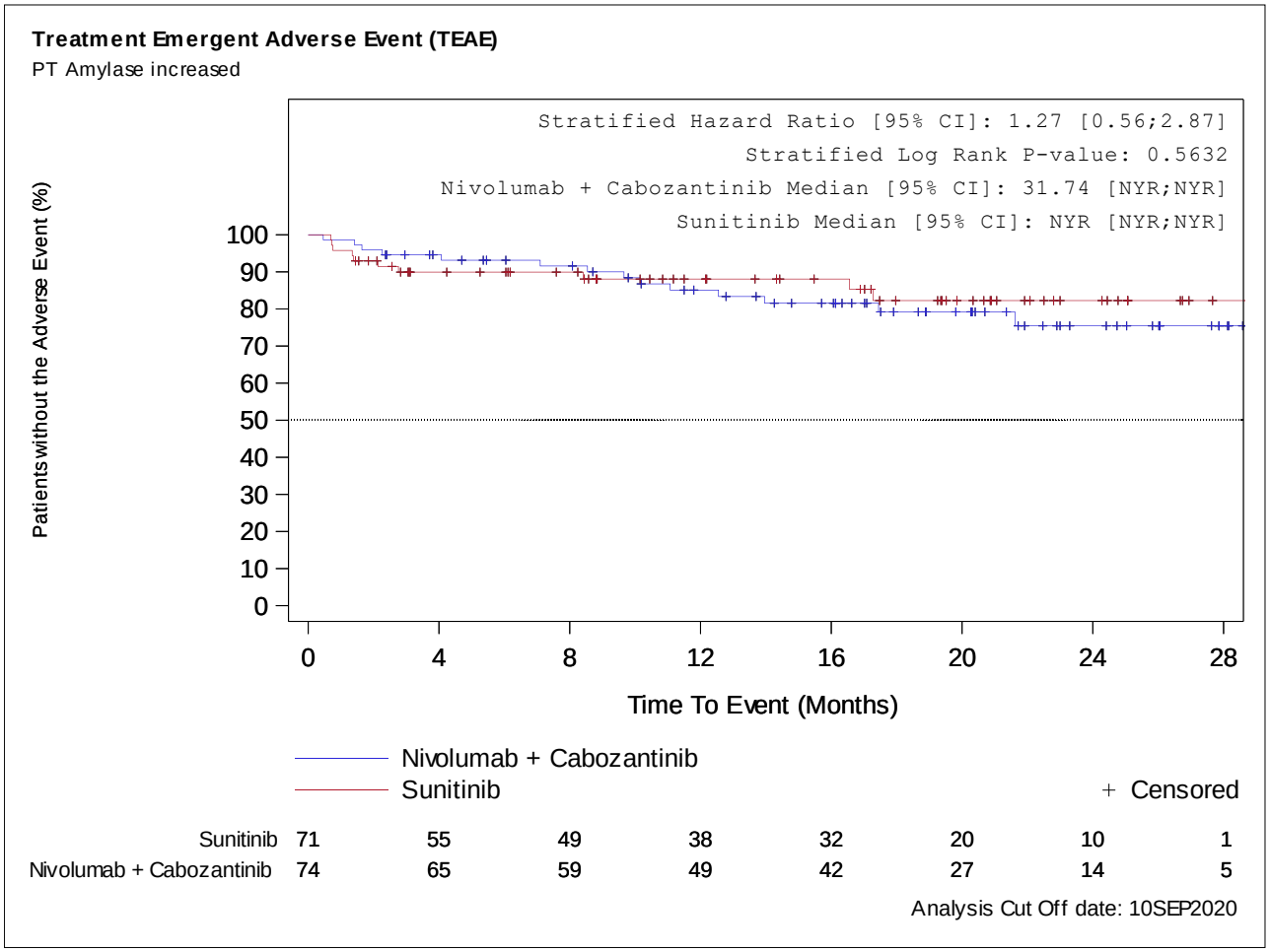
FIGURE 4.1.2.75: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Amylase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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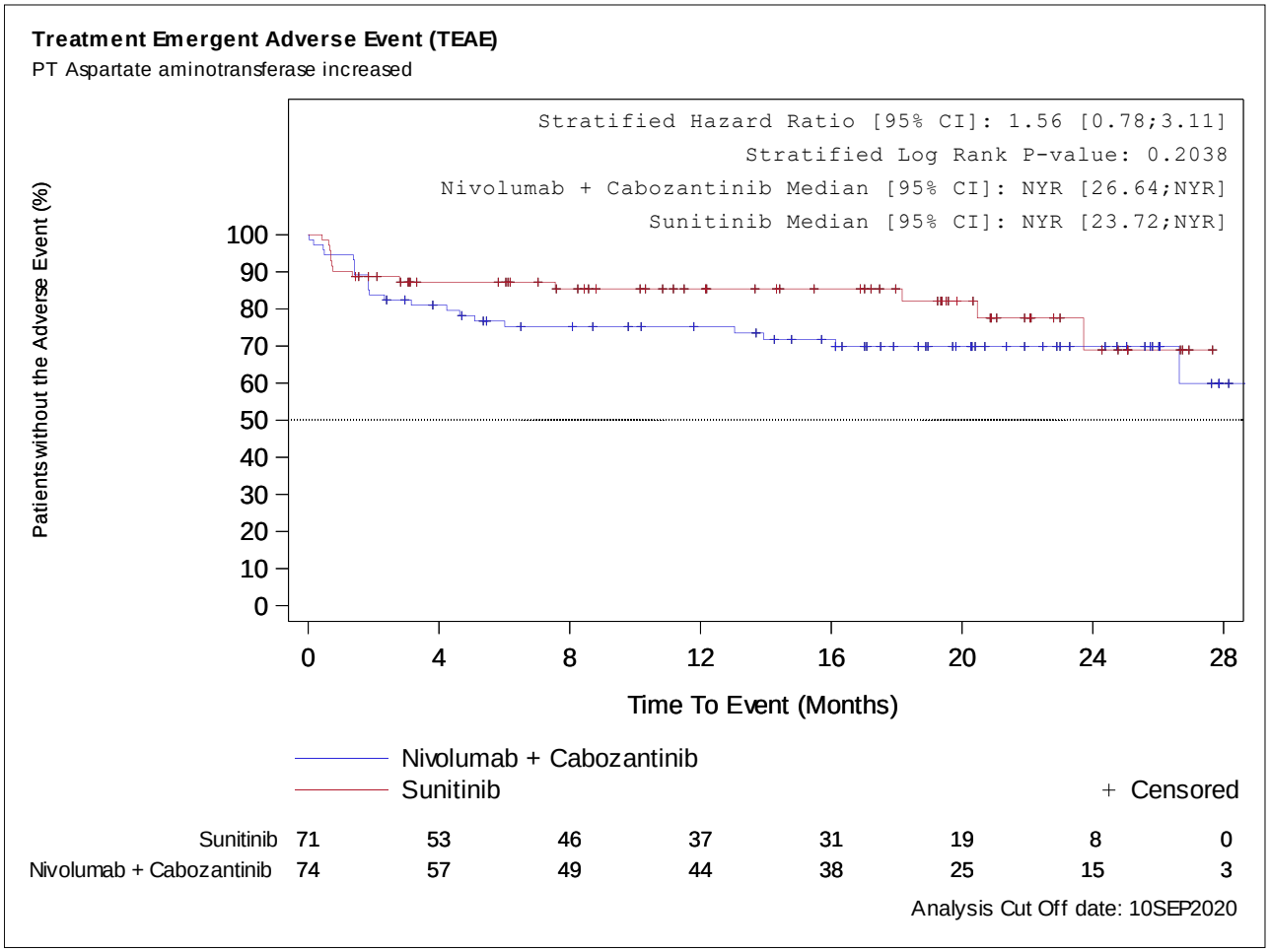
FIGURE 4.1.2.76: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Aspartate aminotransferase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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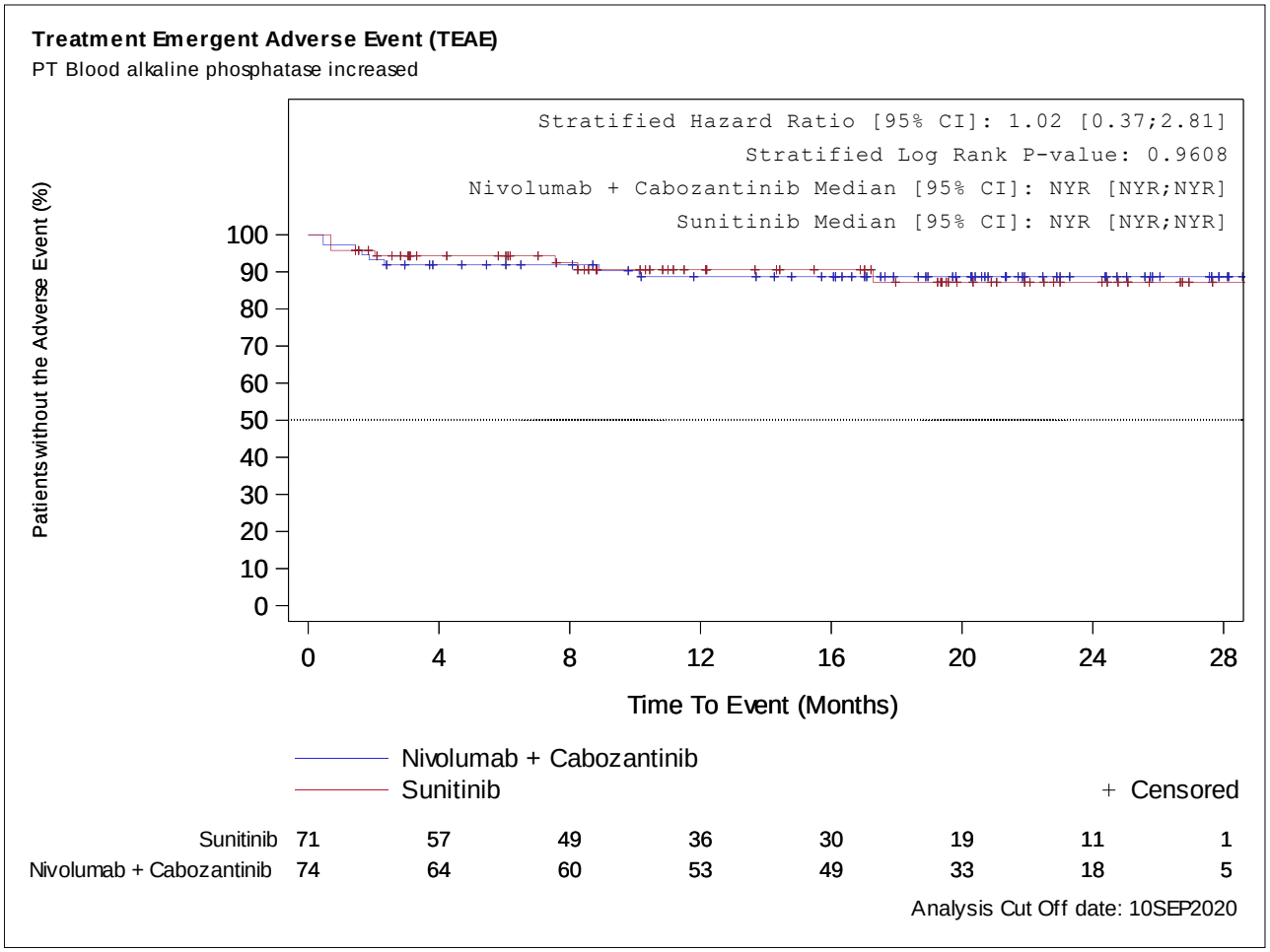
FIGURE 4.1.2.77: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Blood alkaline phosphatase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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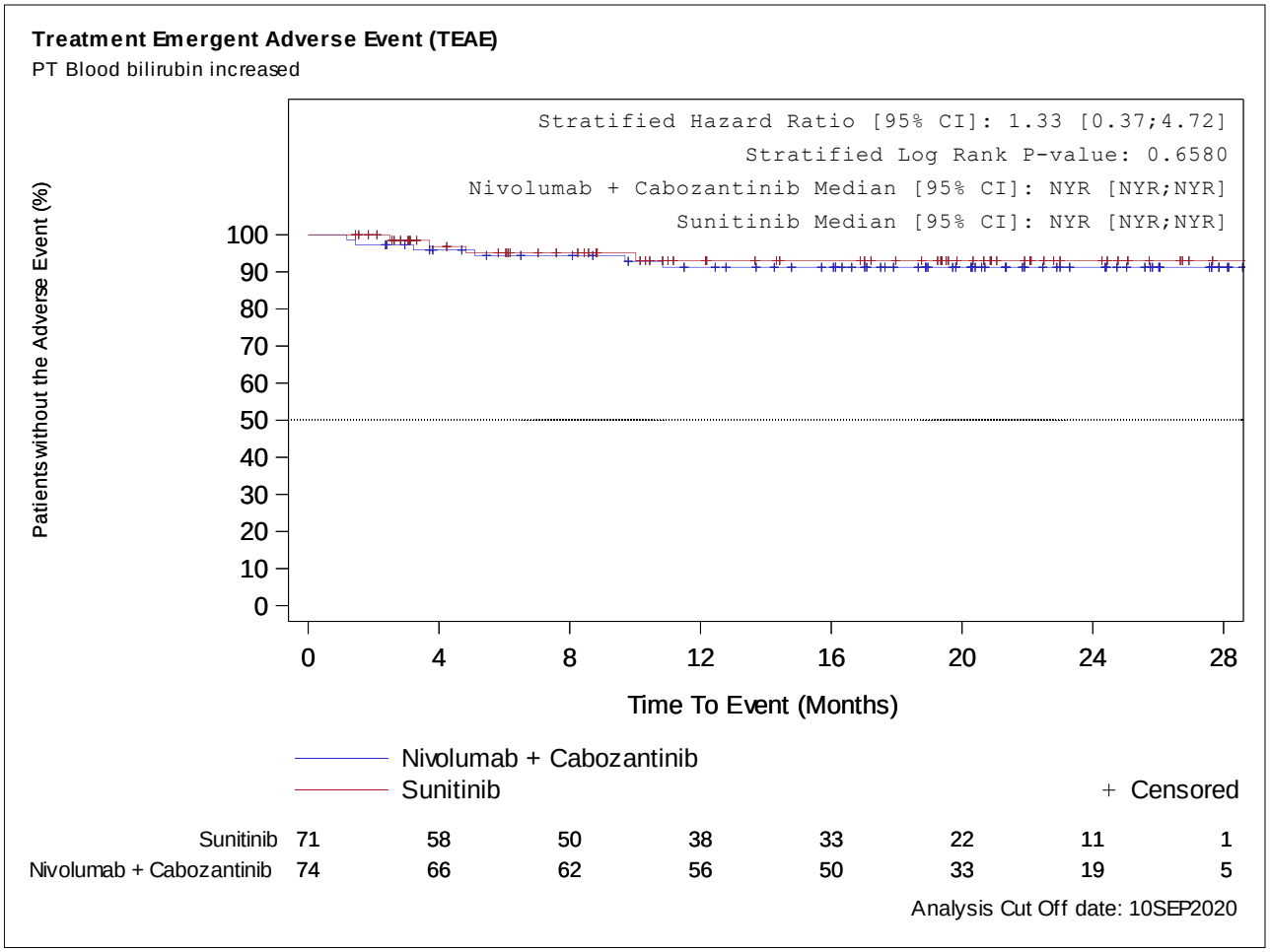
FIGURE 4.1.2.78: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Blood bilirubin increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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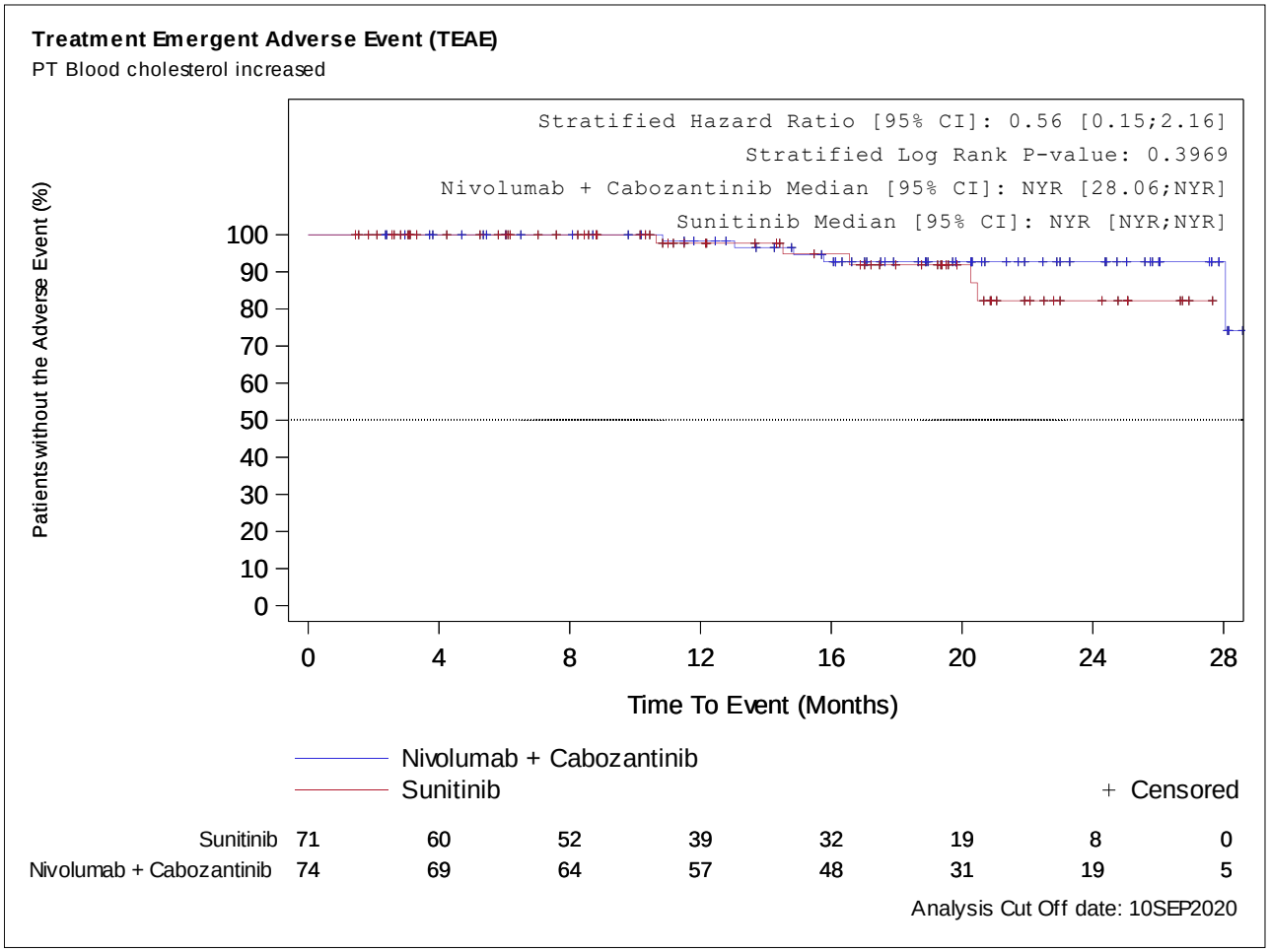
FIGURE 4.1.2.79: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Blood cholesterol increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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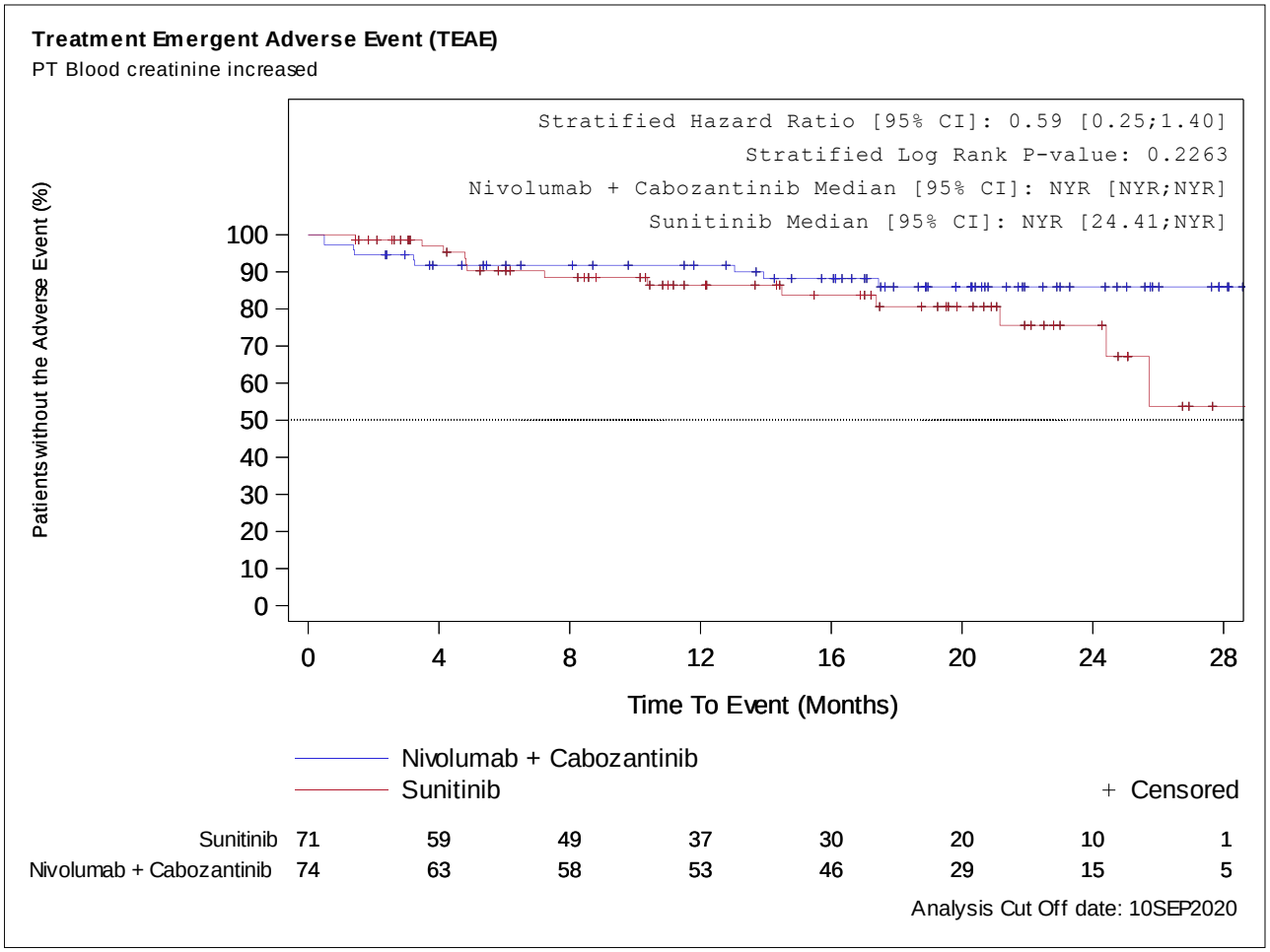
FIGURE 4.1.2.80: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Blood creatinine increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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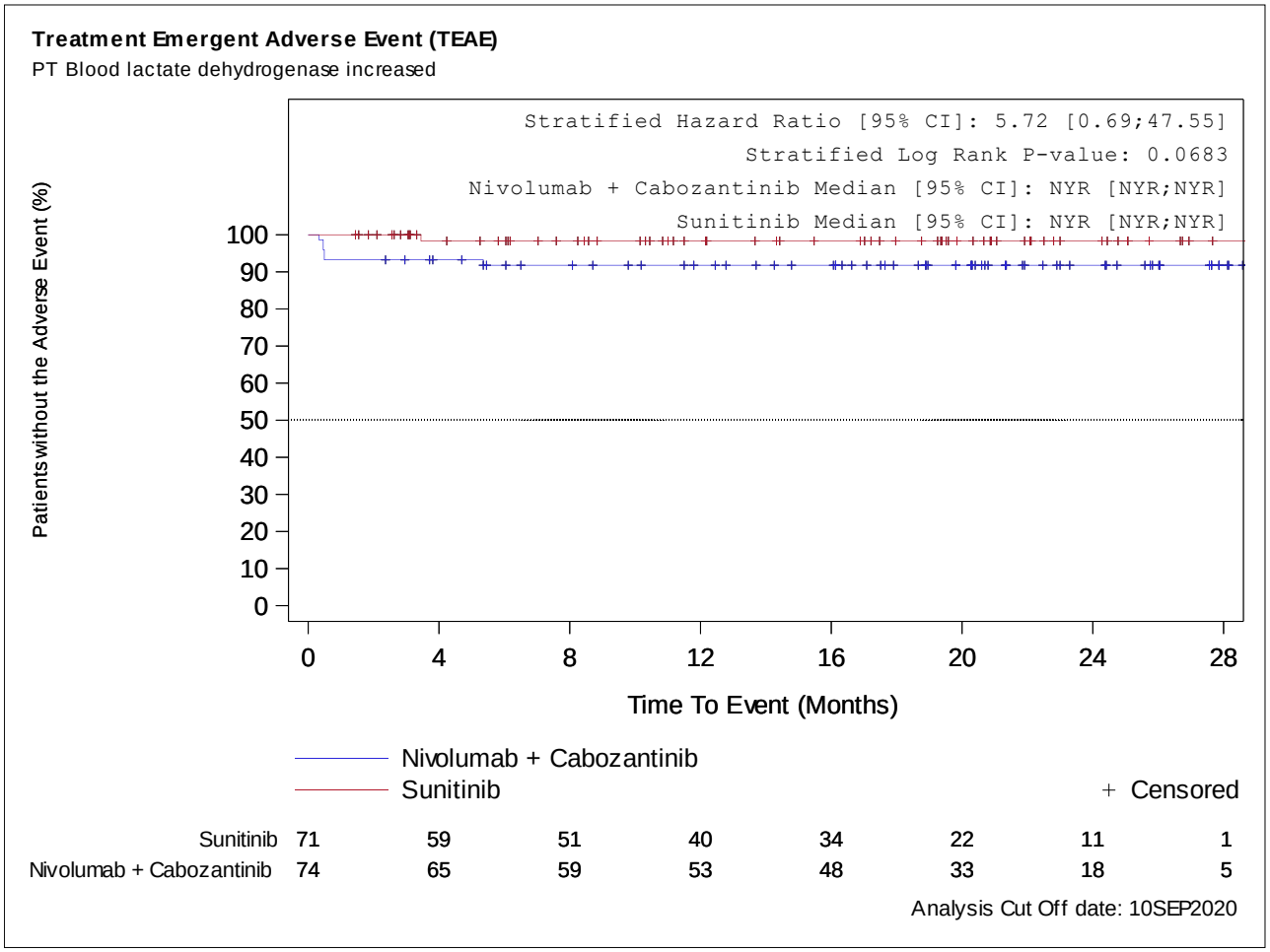
FIGURE 4.1.2.81: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Blood lactate dehydrogenase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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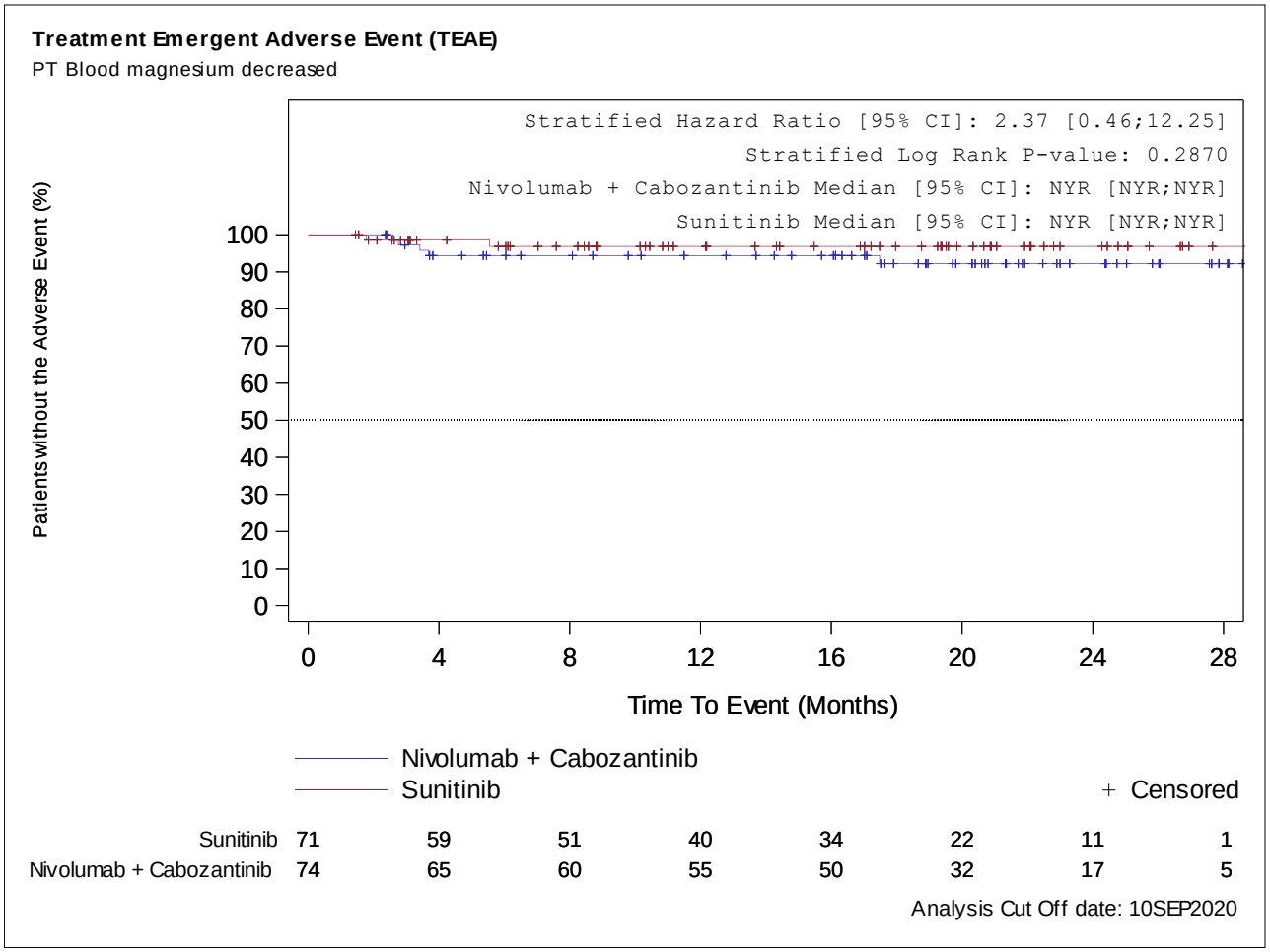
FIGURE 4.1.2.82: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Blood magnesium decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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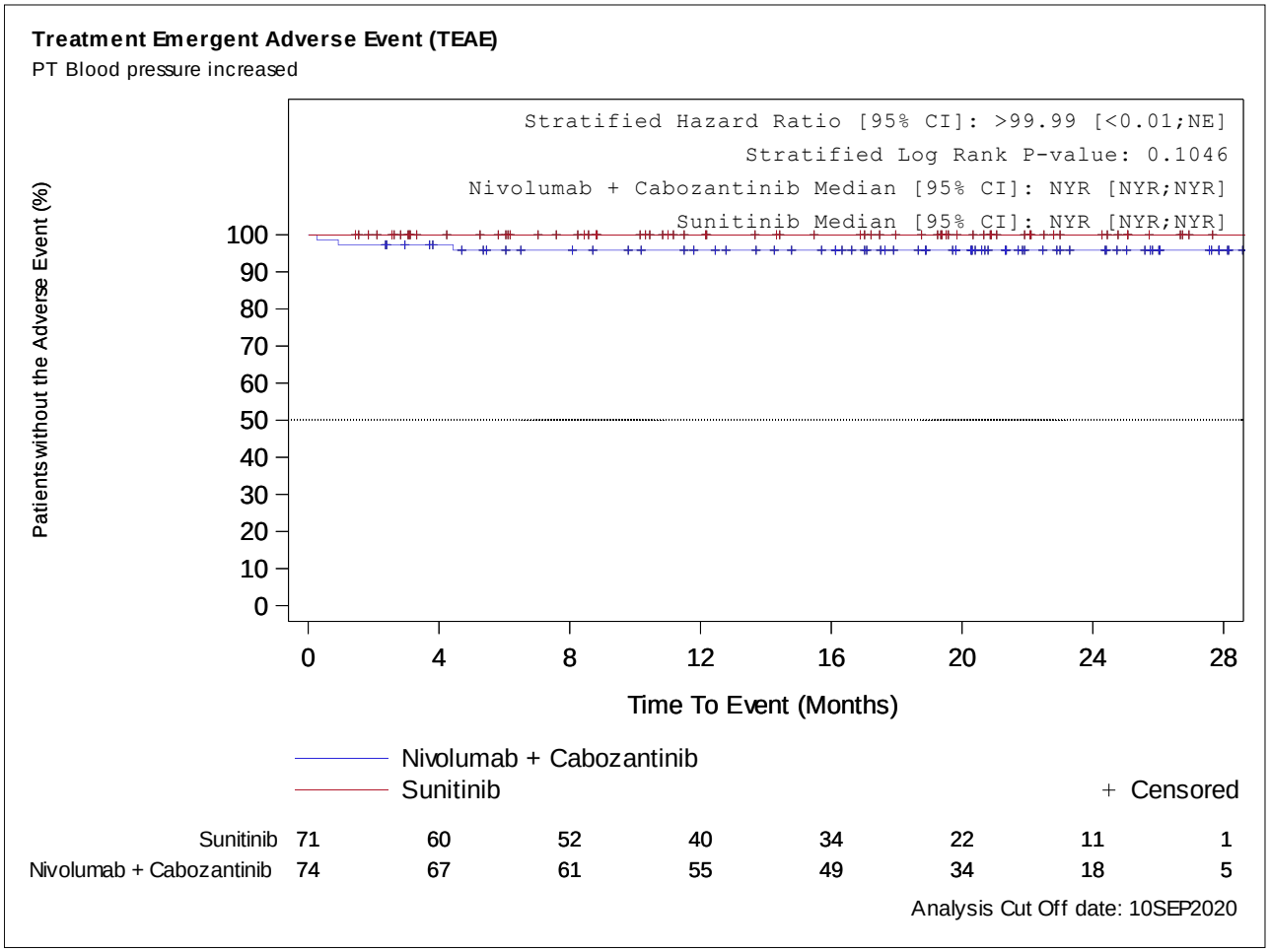
FIGURE 4.1.2.83: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Blood pressure increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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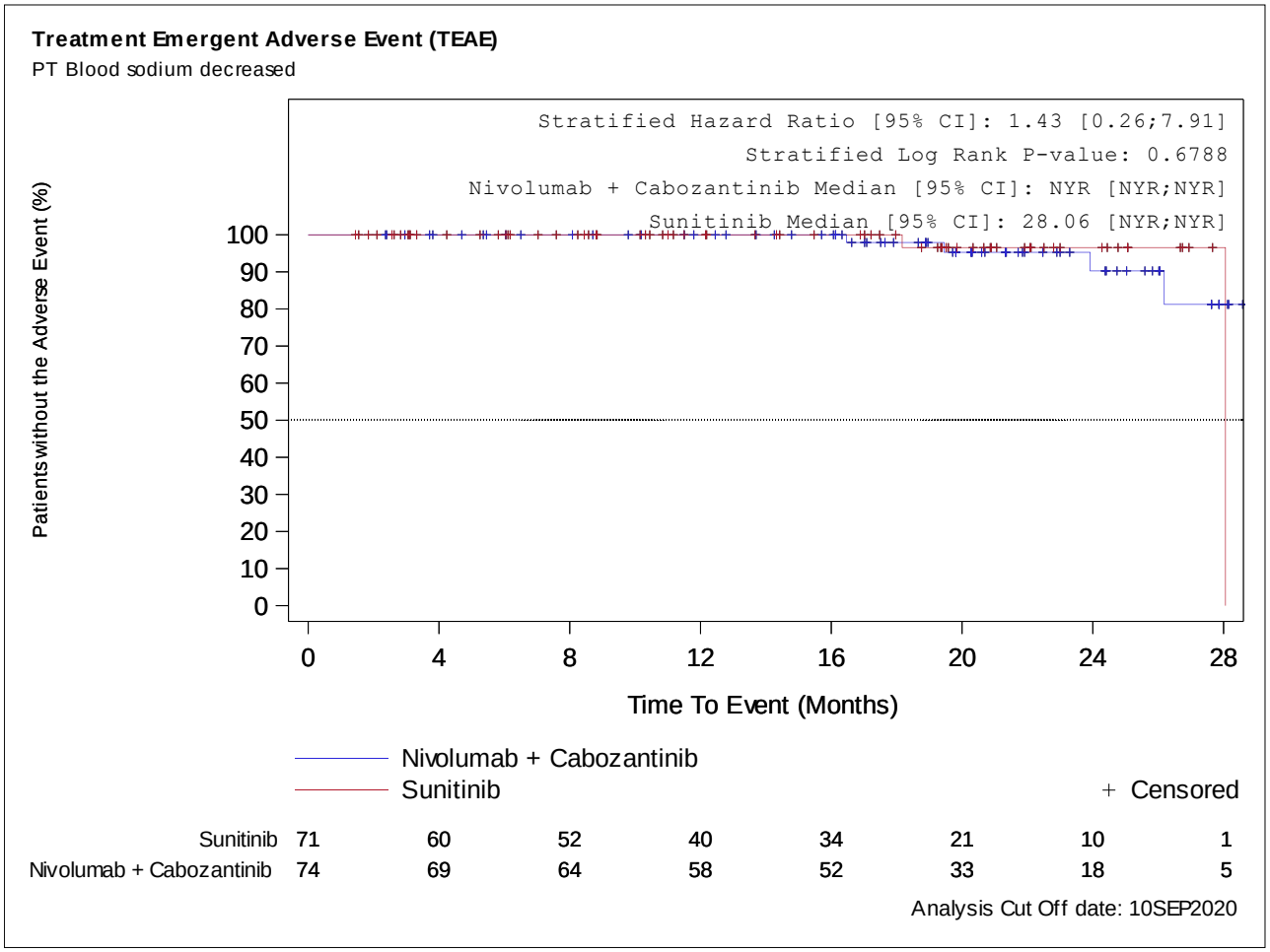
FIGURE 4.1.2.84: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Blood sodium decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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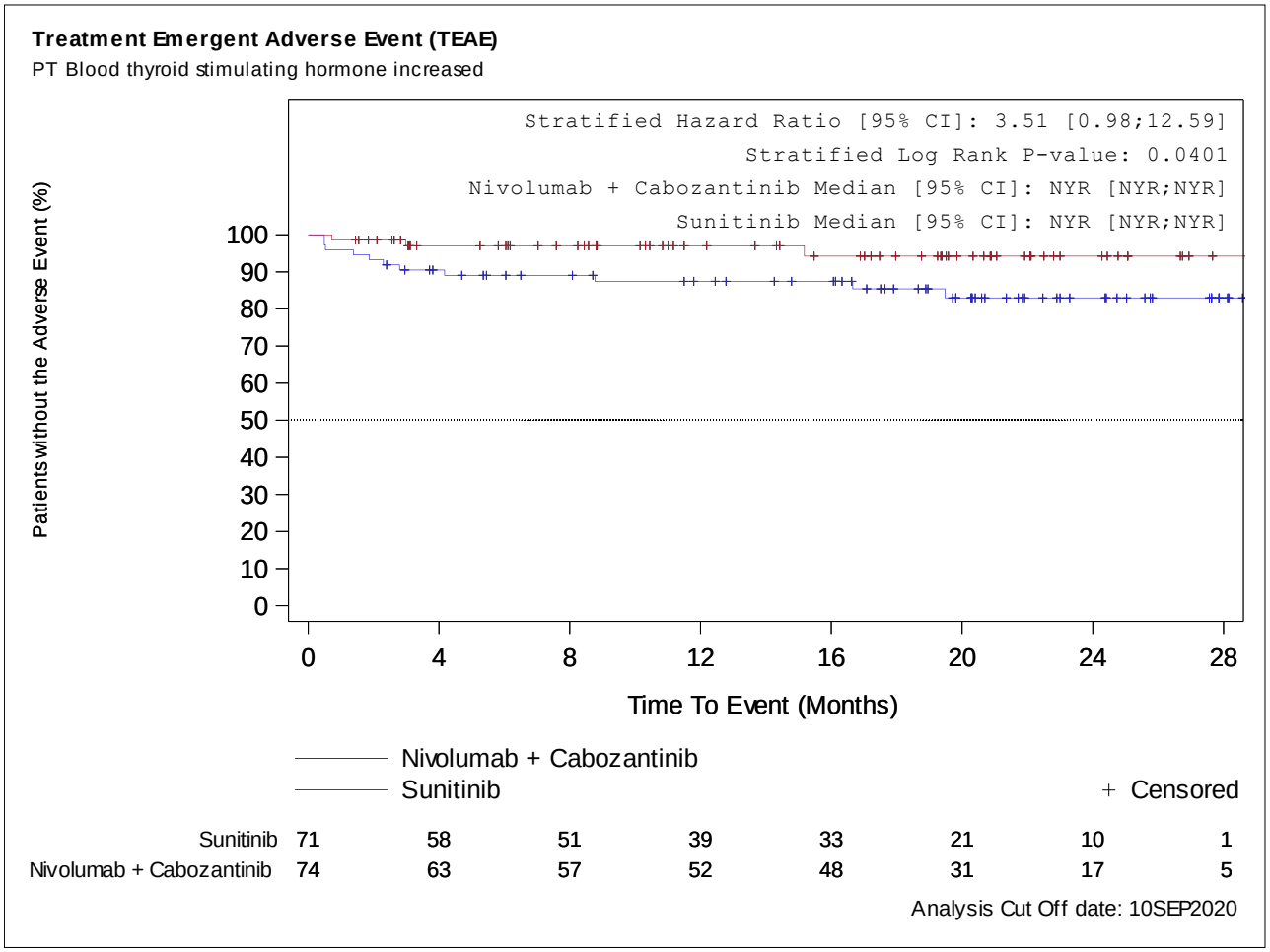
FIGURE 4.1.2.85: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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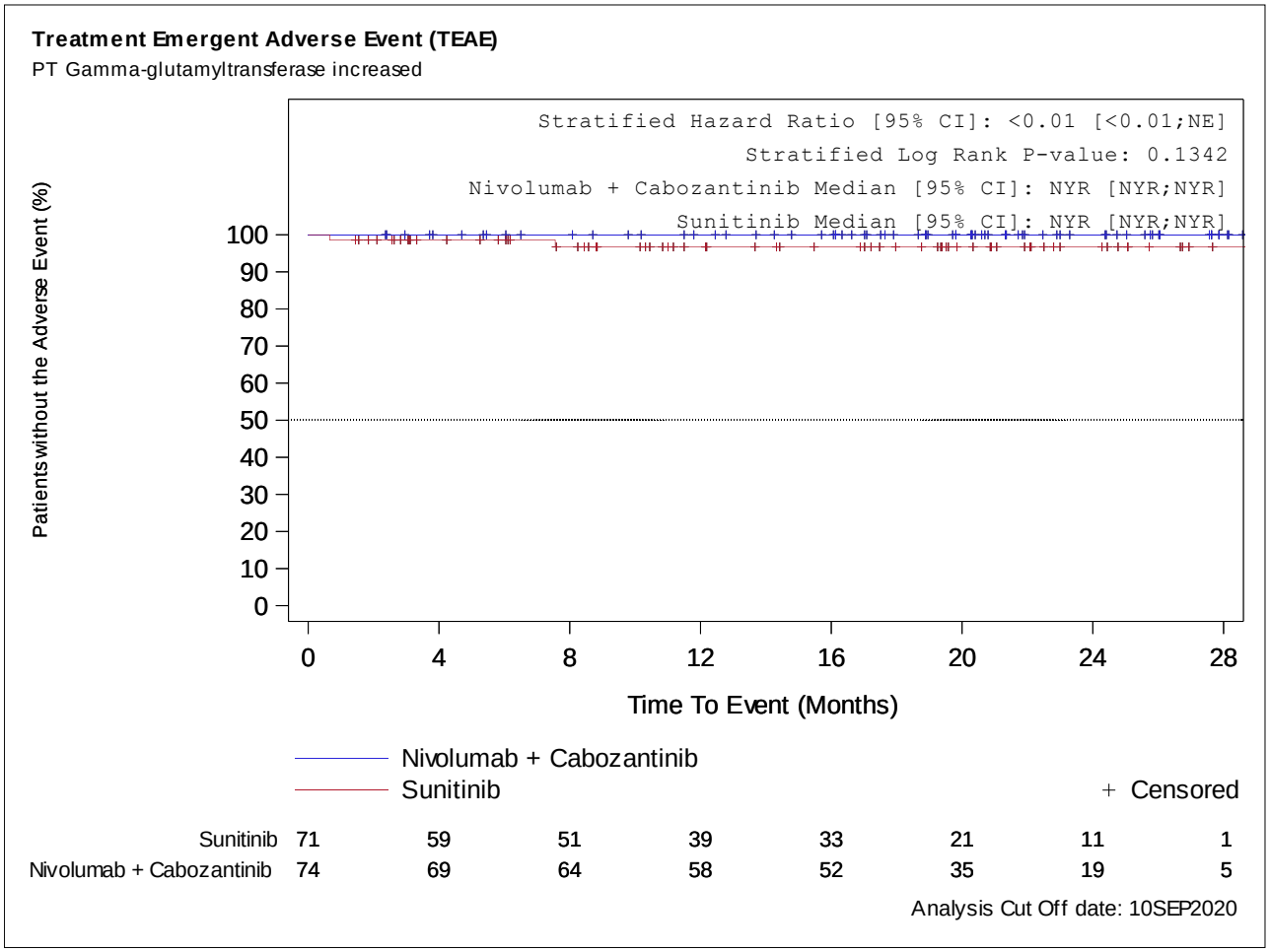
FIGURE 4.1.2.86: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Gamma-glutamyltransferase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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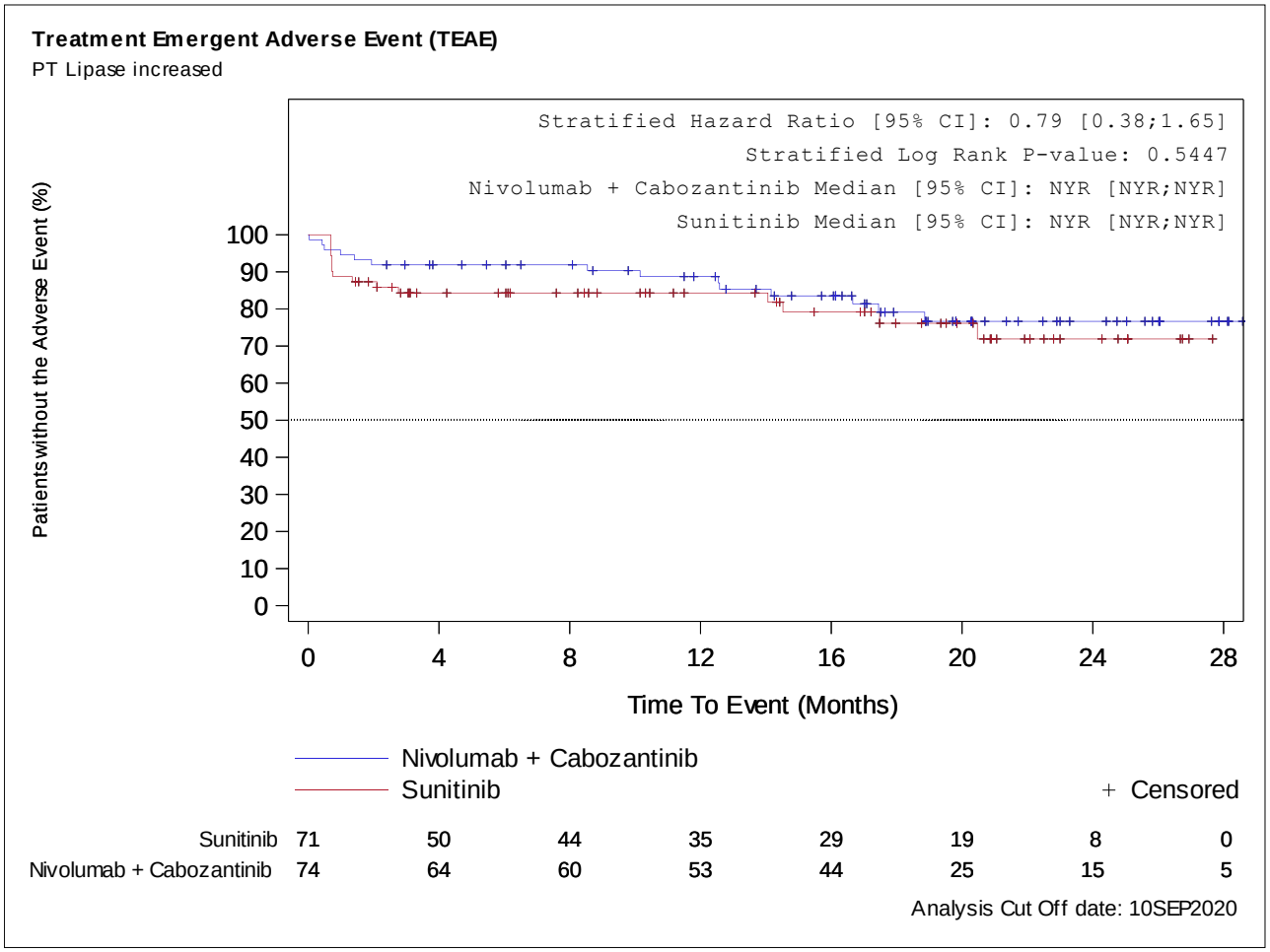
FIGURE 4.1.2.87: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Lipase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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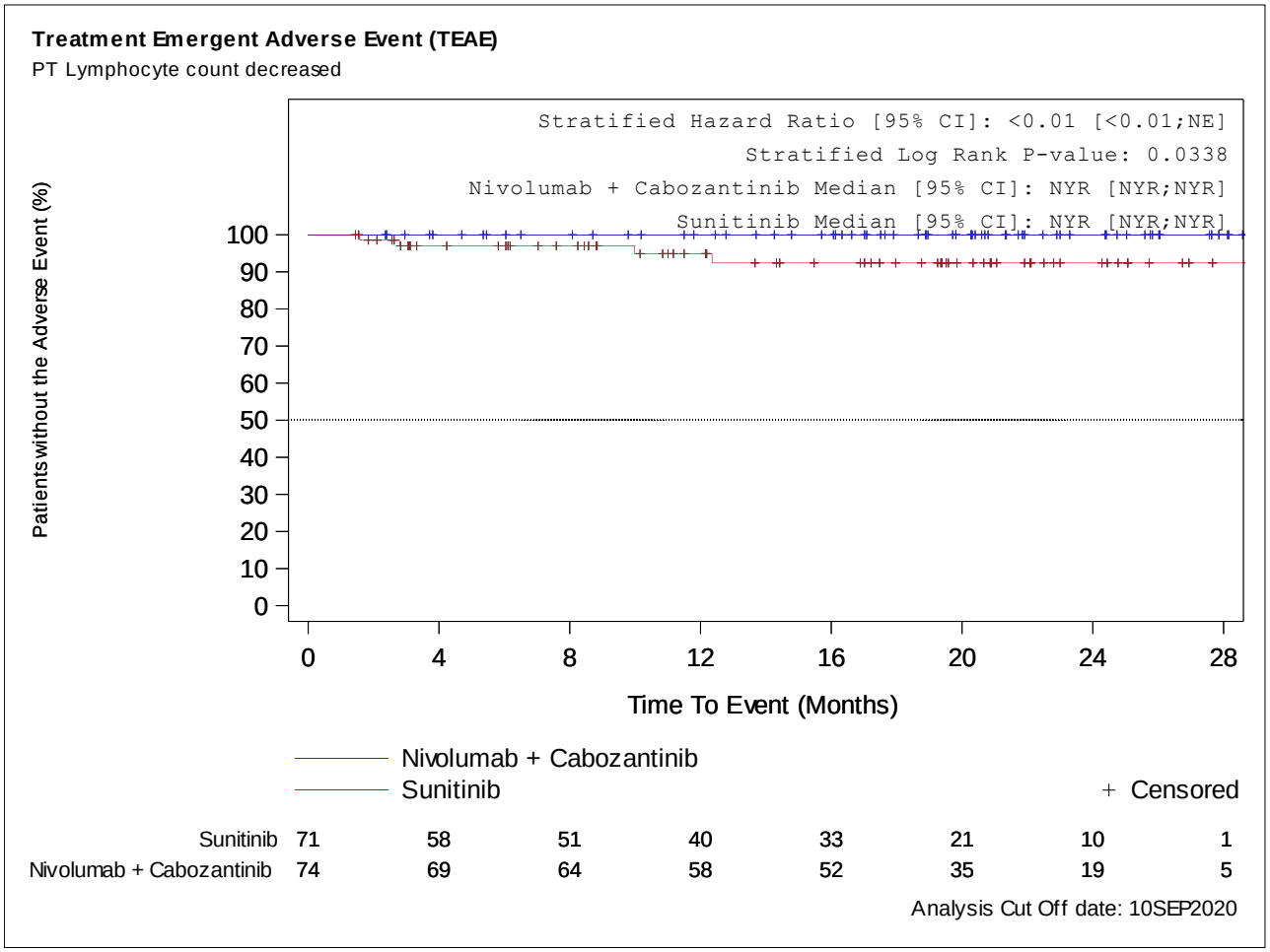
FIGURE 4.1.2.88: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Lymphocyte count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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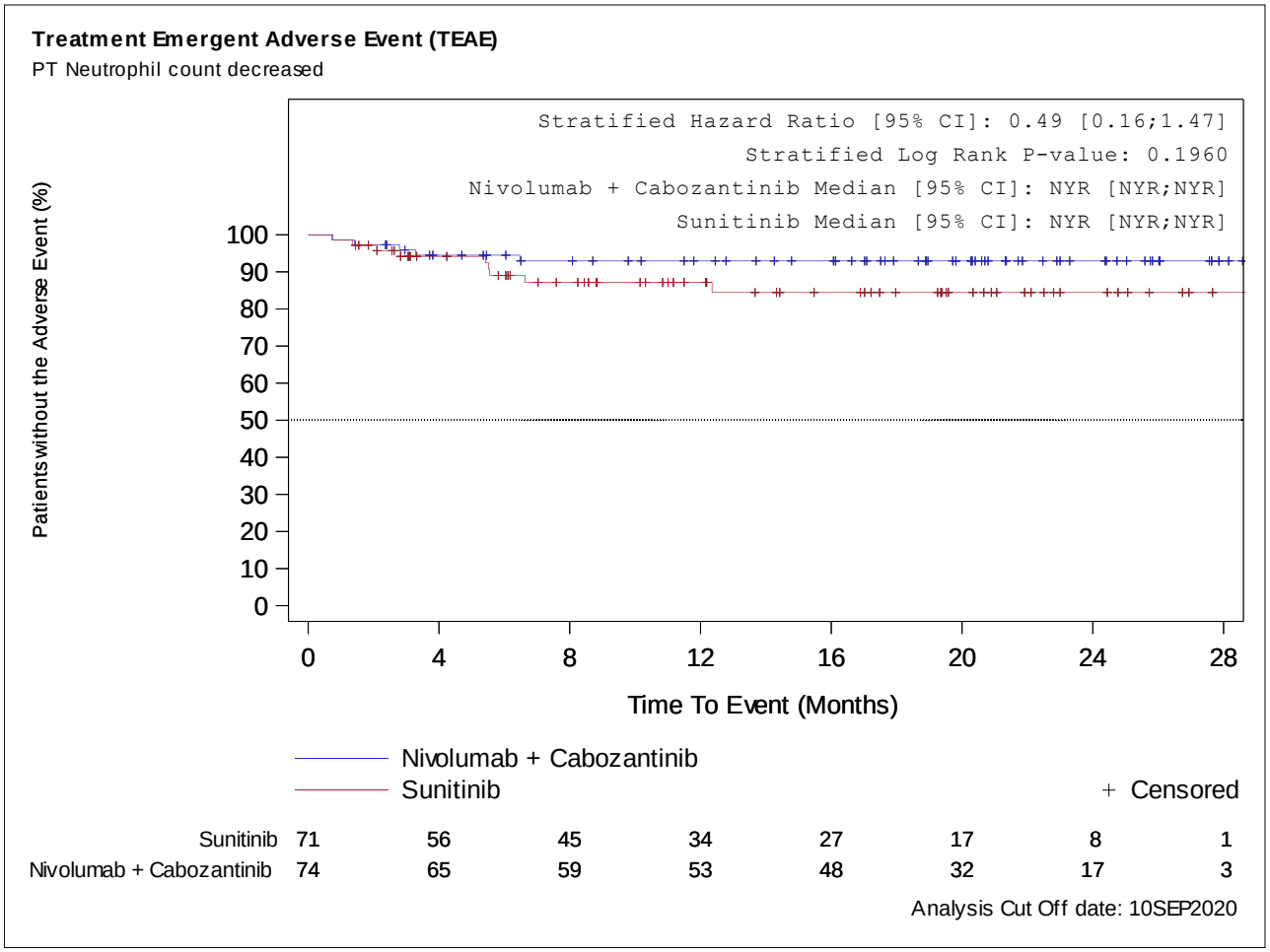
FIGURE 4.1.2.89: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutrophil count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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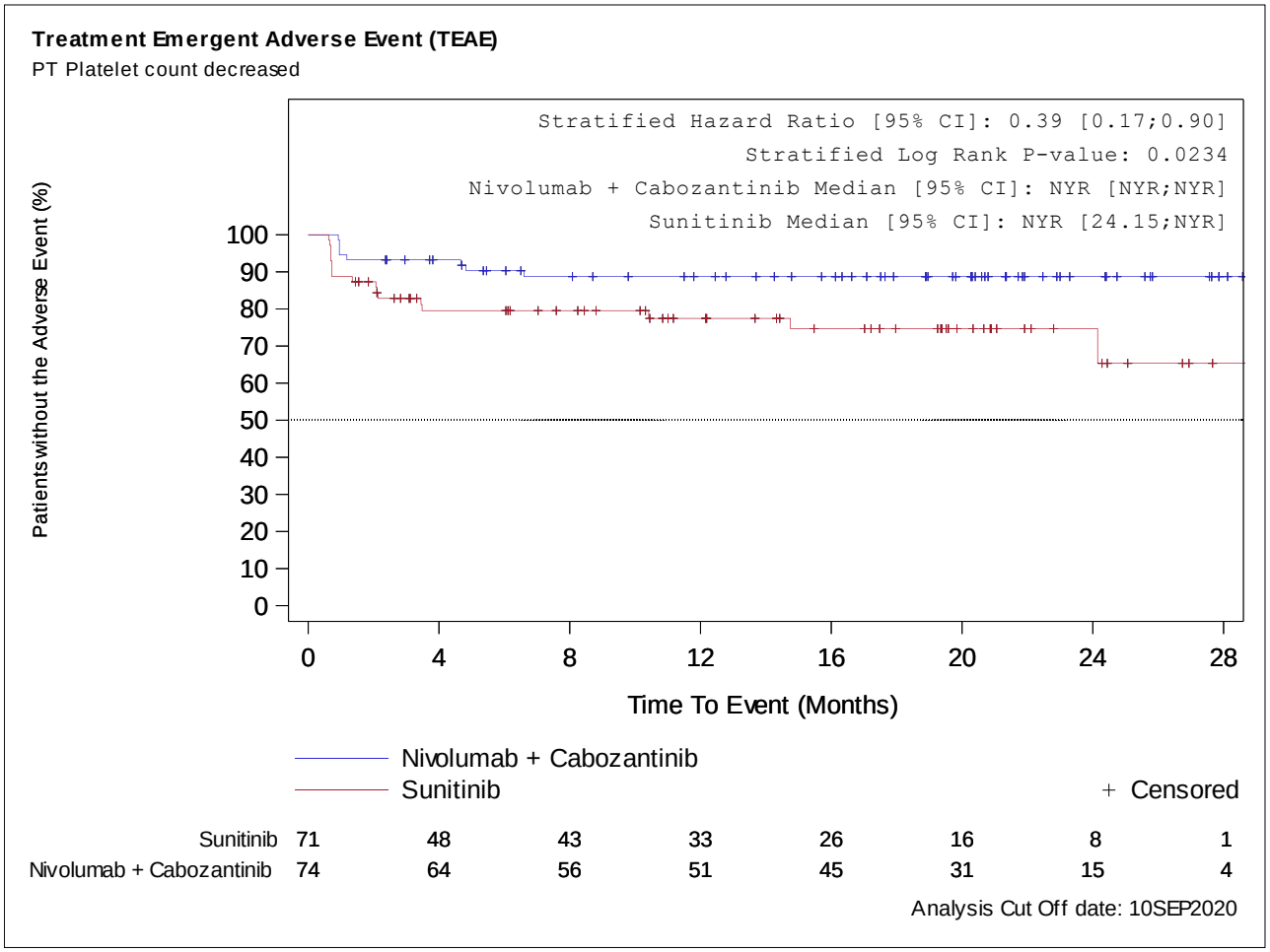
FIGURE 4.1.2.90: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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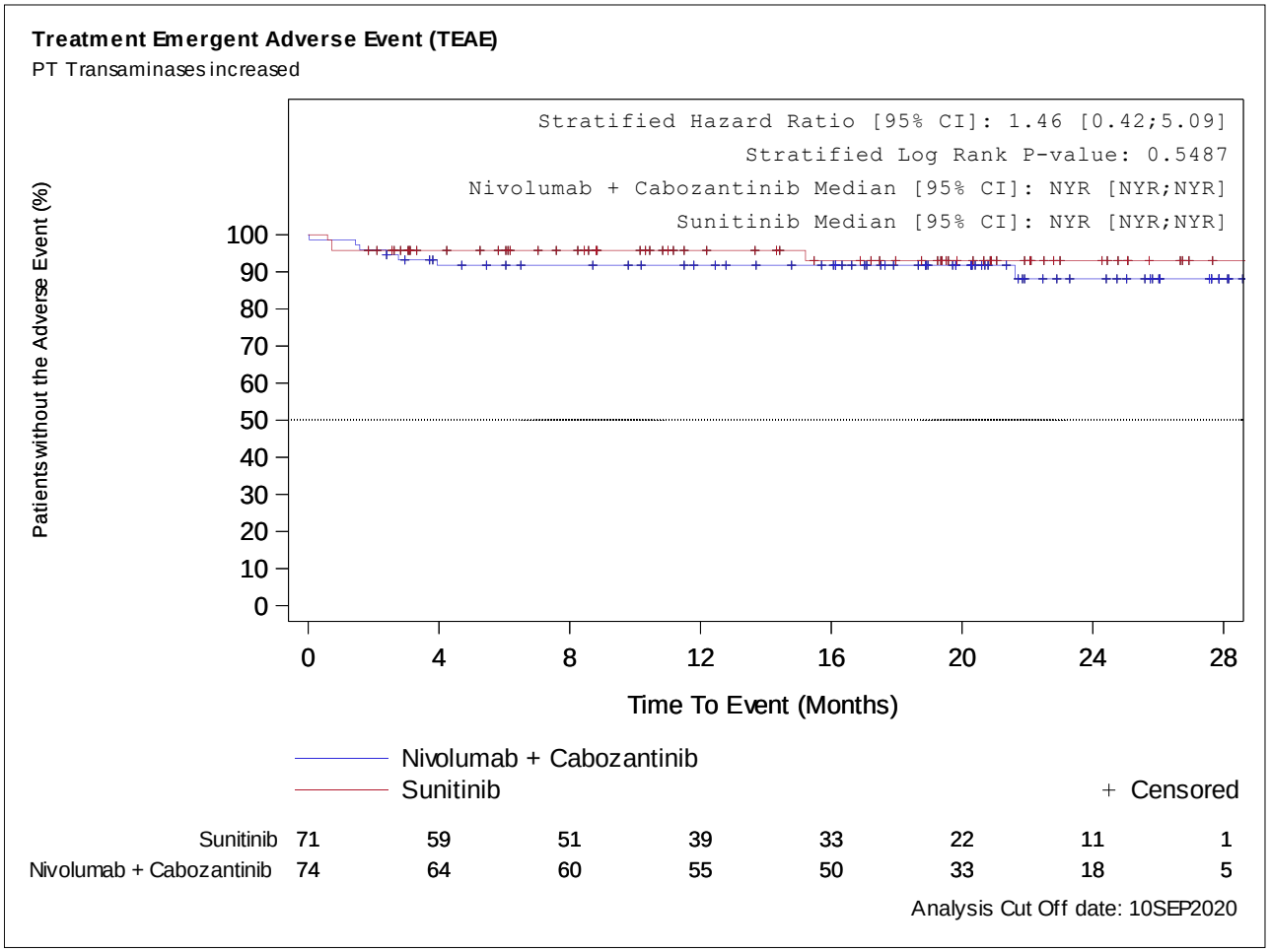
FIGURE 4.1.2.91: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Transaminases increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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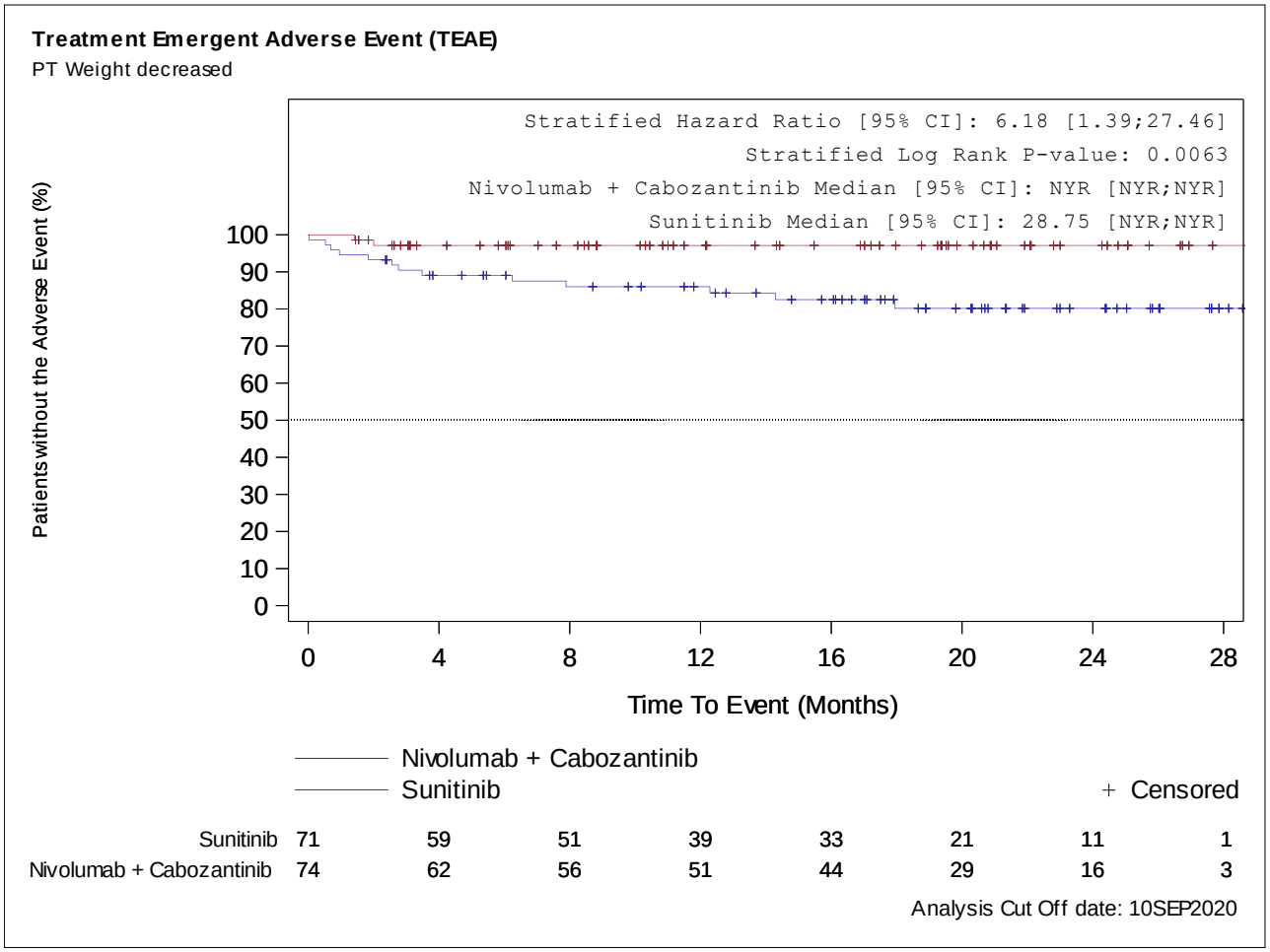
FIGURE 4.1.2.92: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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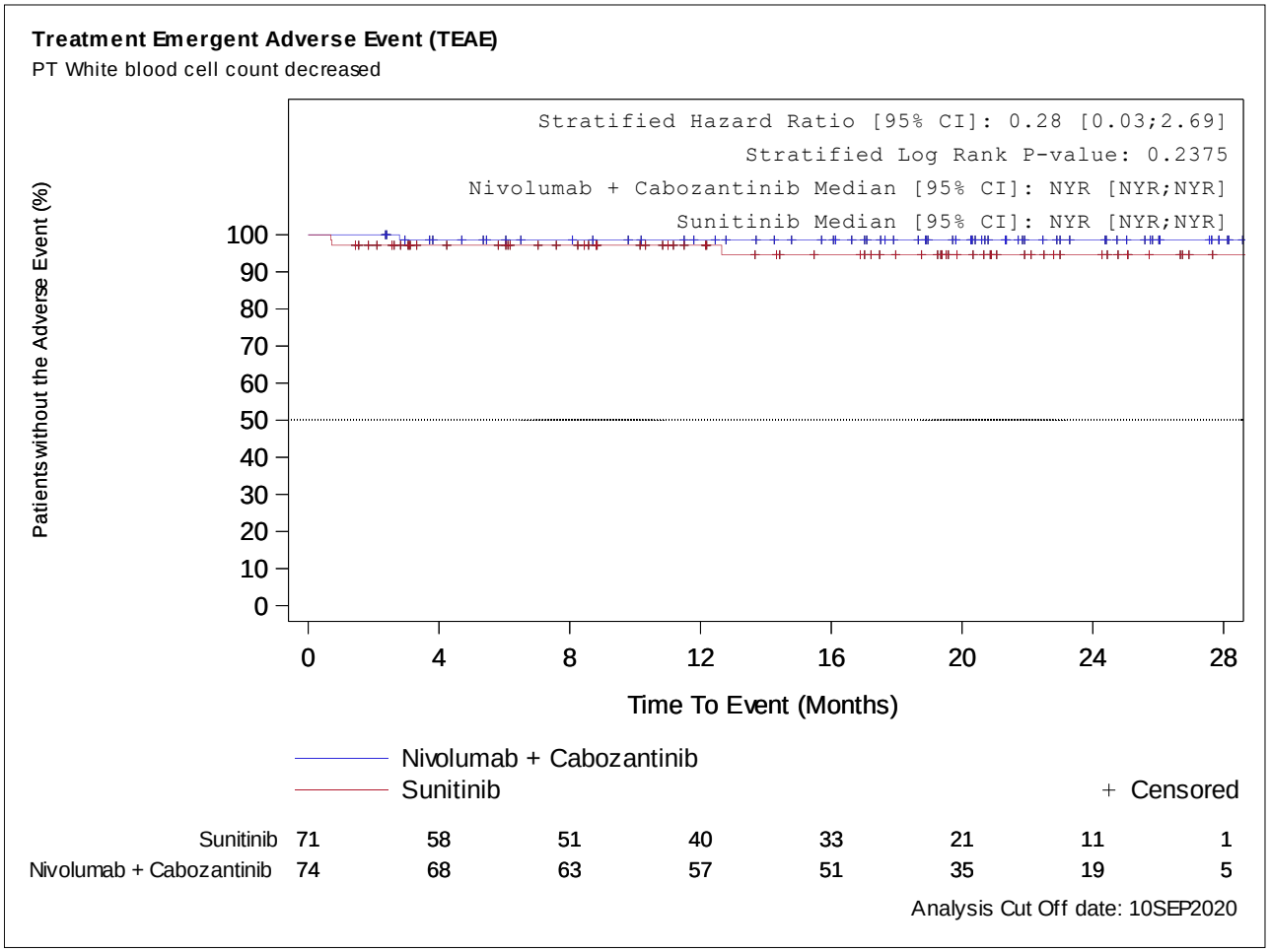
FIGURE 4.1.2.93: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT White blood cell count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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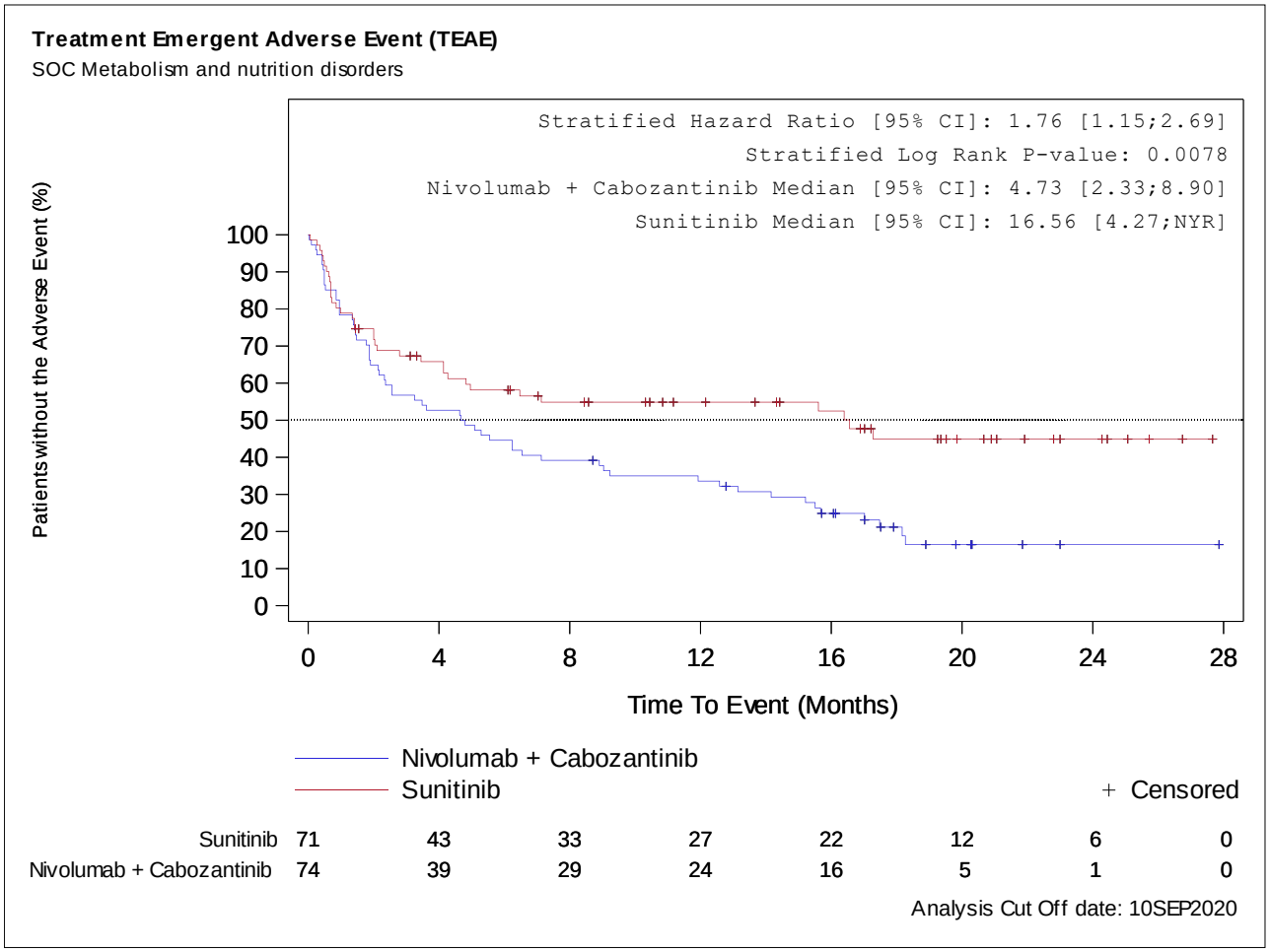
FIGURE 4.1.2.94: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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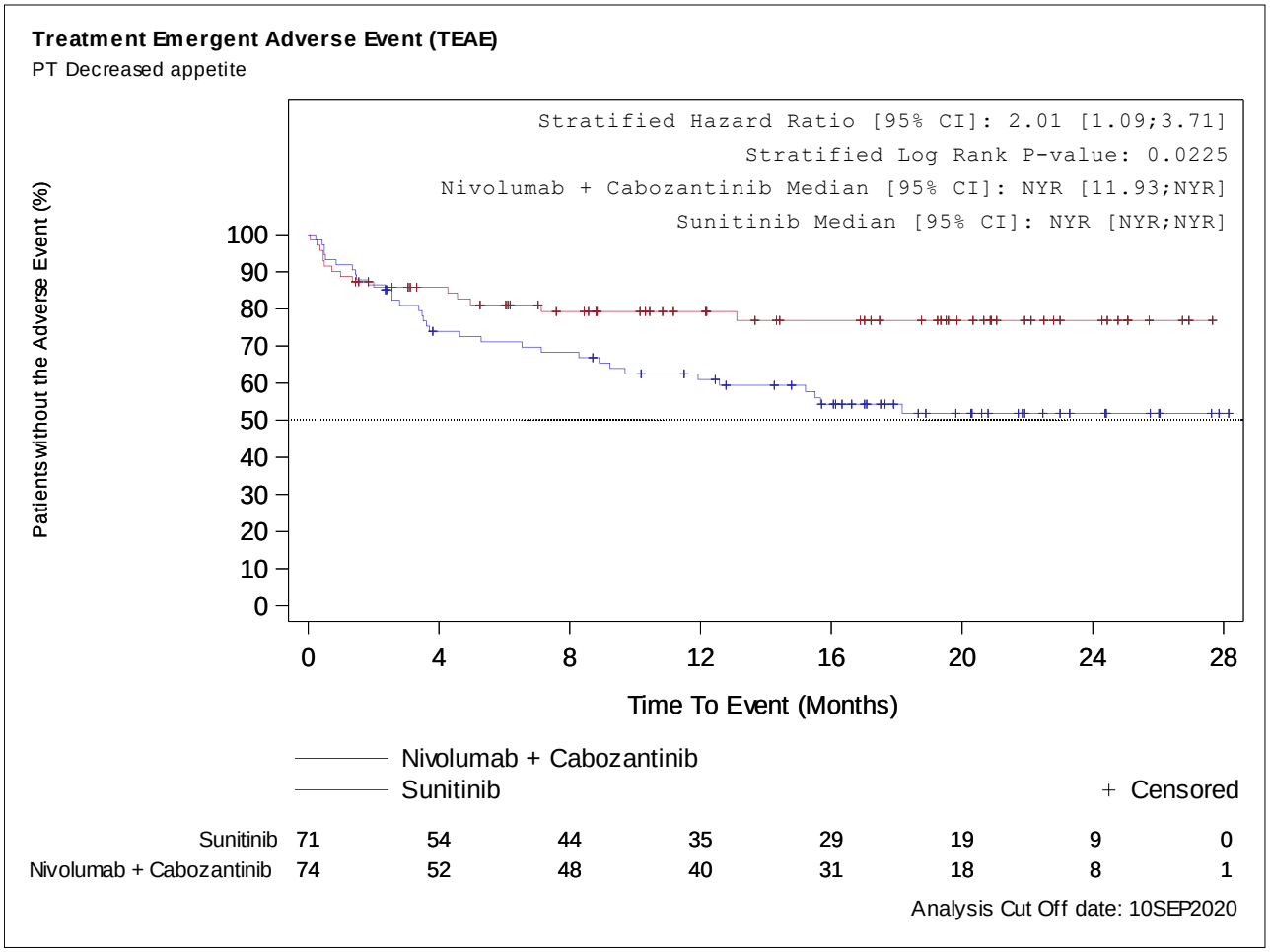
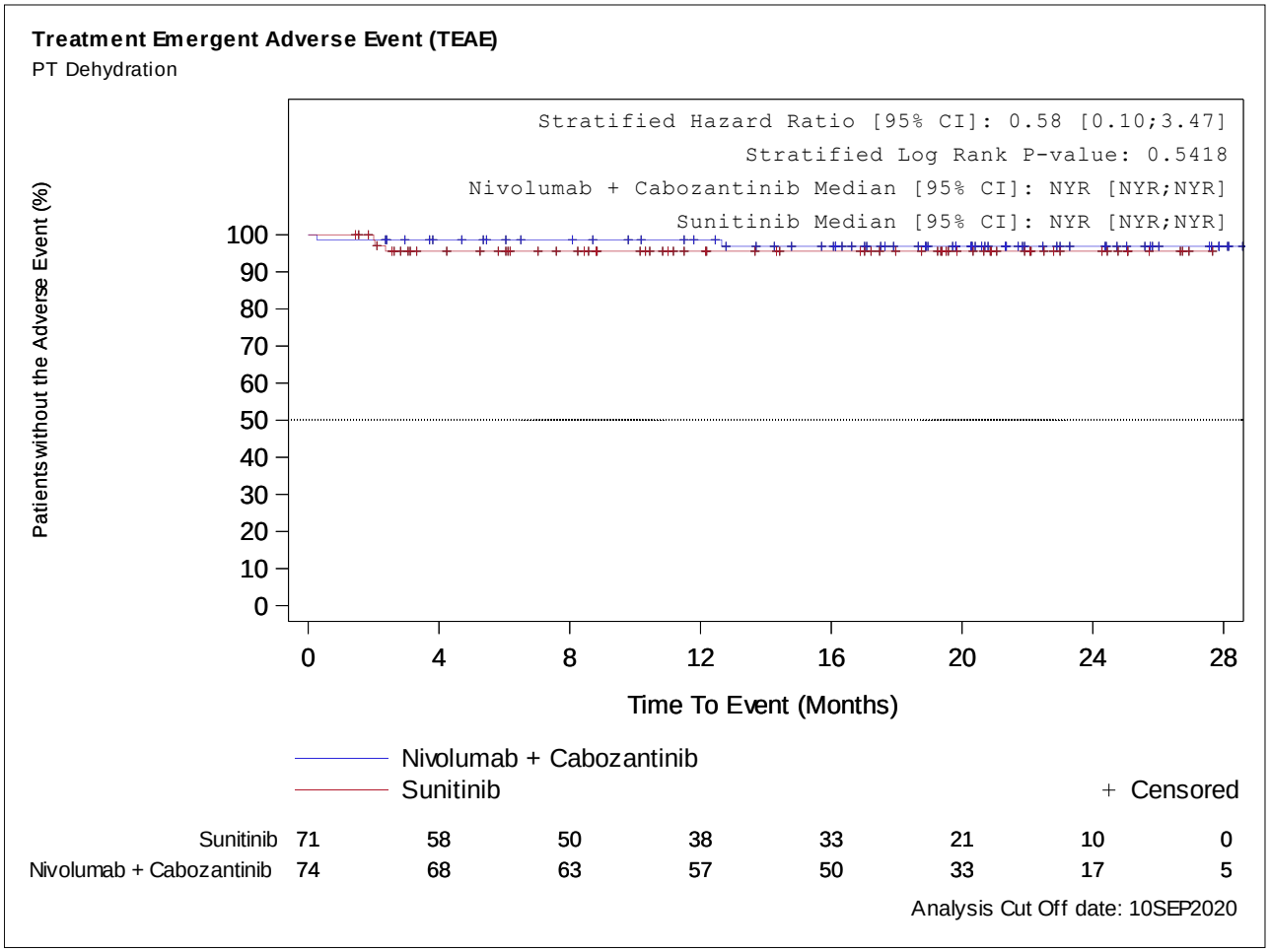
FIGURE 4.1.2.95: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 15:58:33

FIGURE 4.1.2.96: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dehydration - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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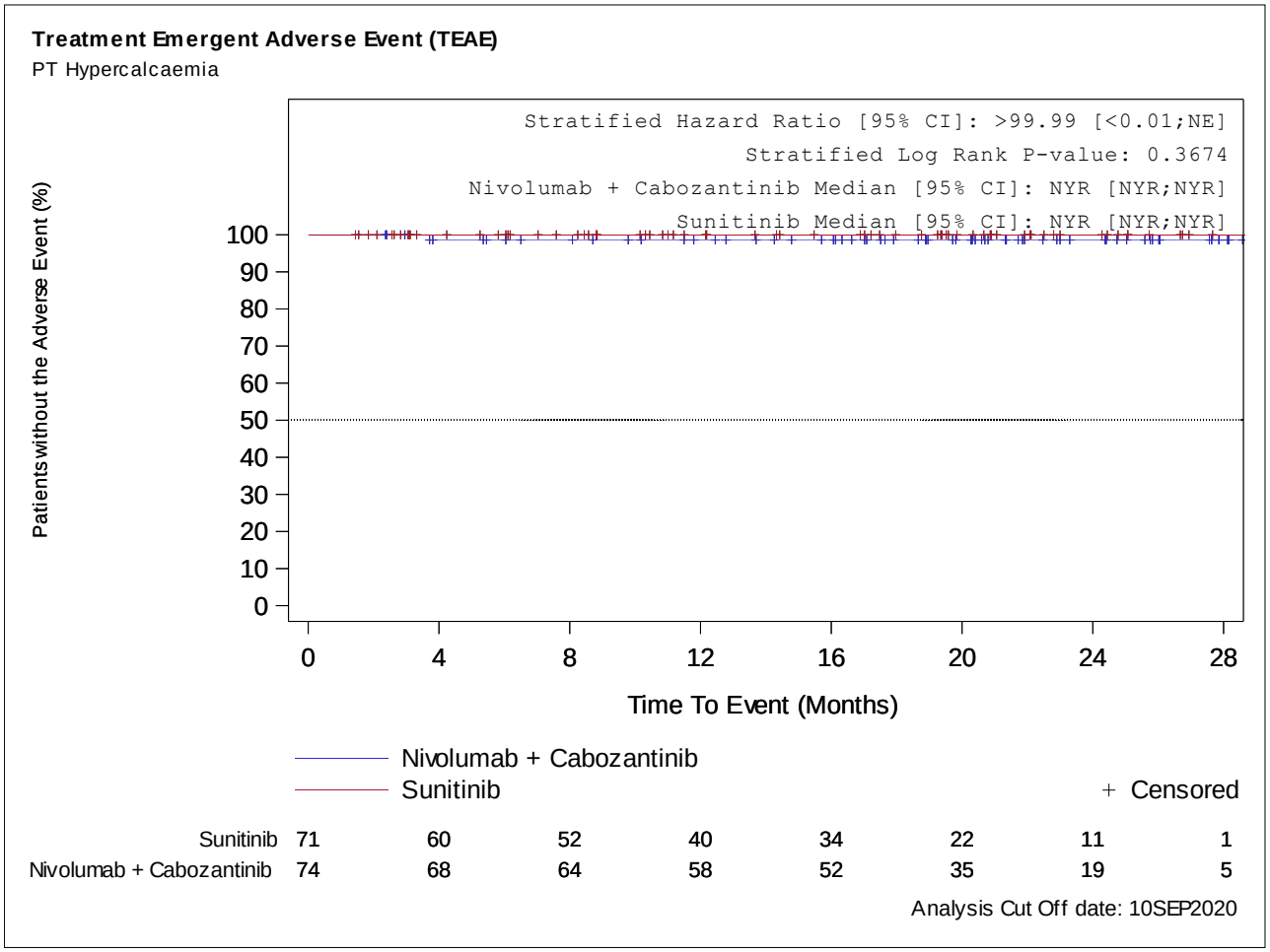
FIGURE 4.1.2.97: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypercalcaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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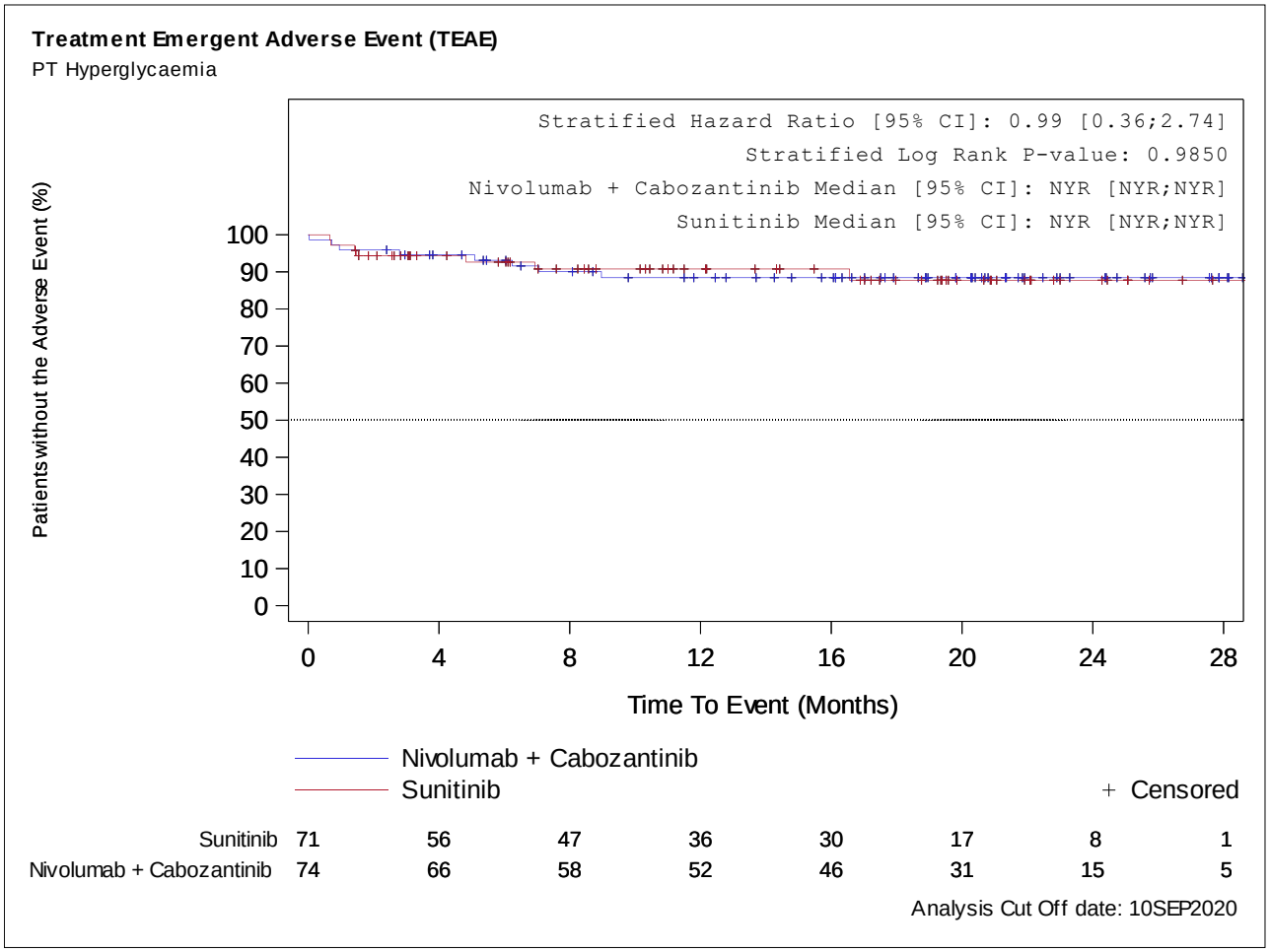
FIGURE 4.1.2.98: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hyperglycaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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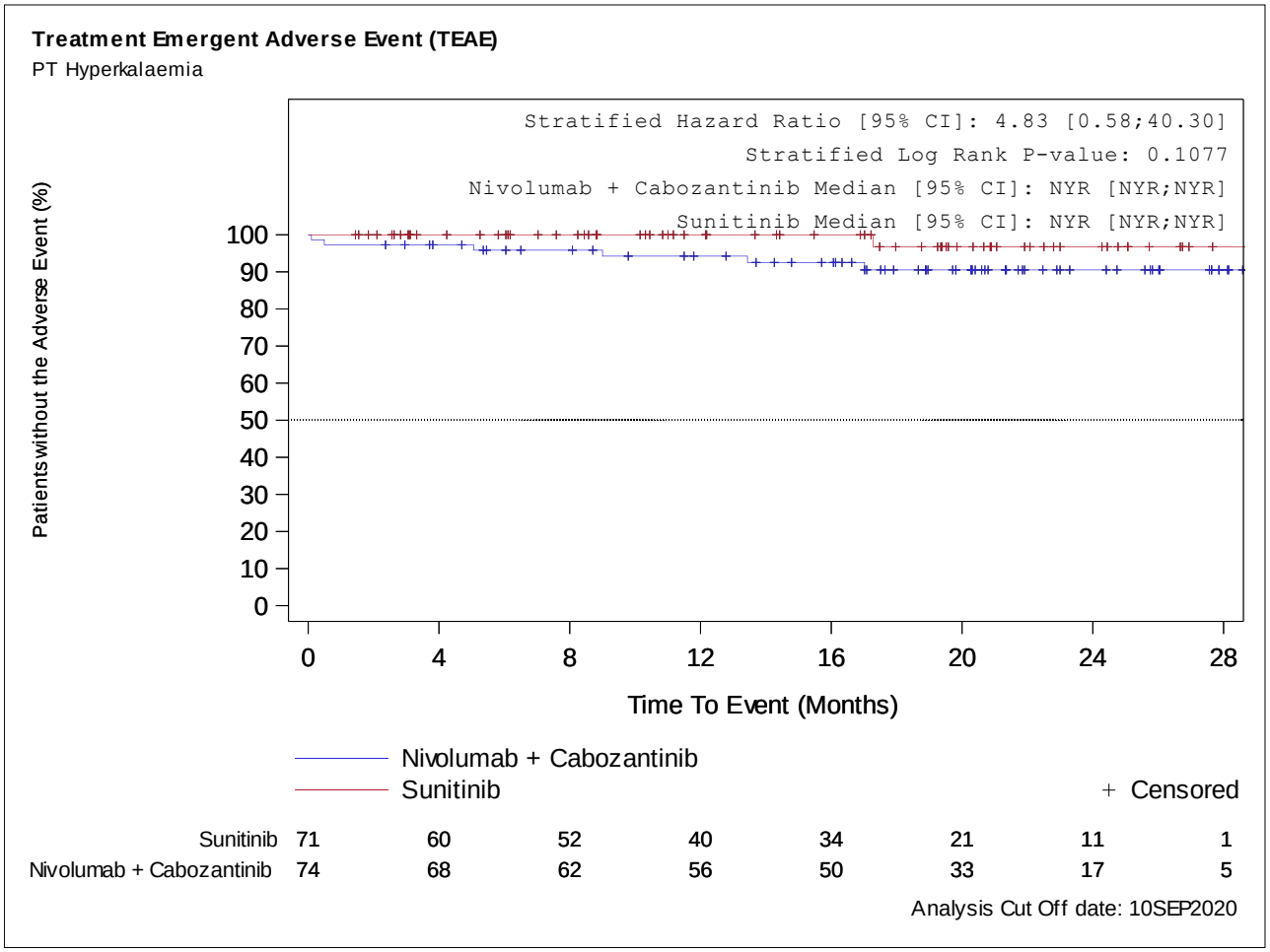
FIGURE 4.1.2.99: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hyperkalaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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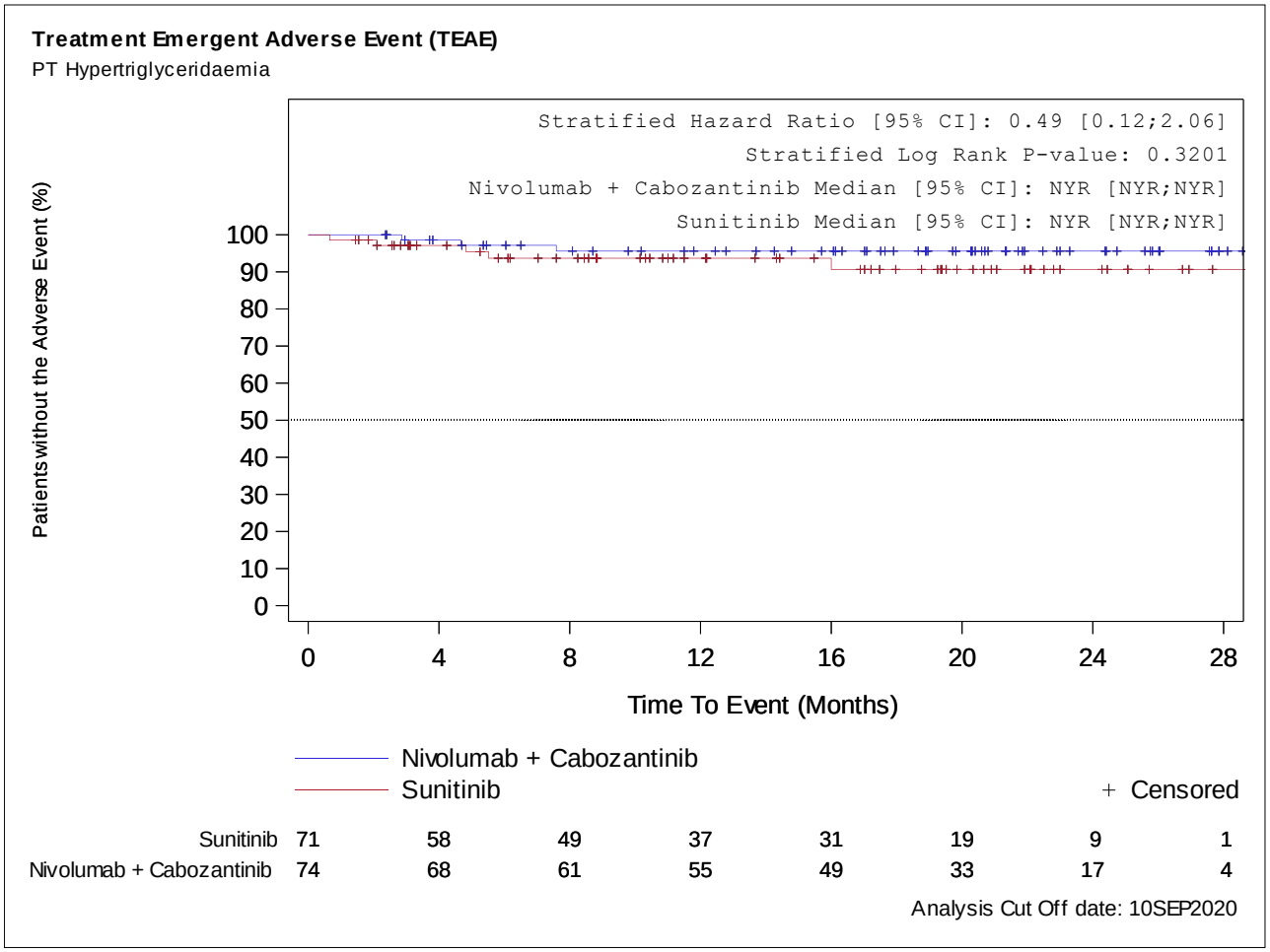
FIGURE 4.1.2.100: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypertriglyceridaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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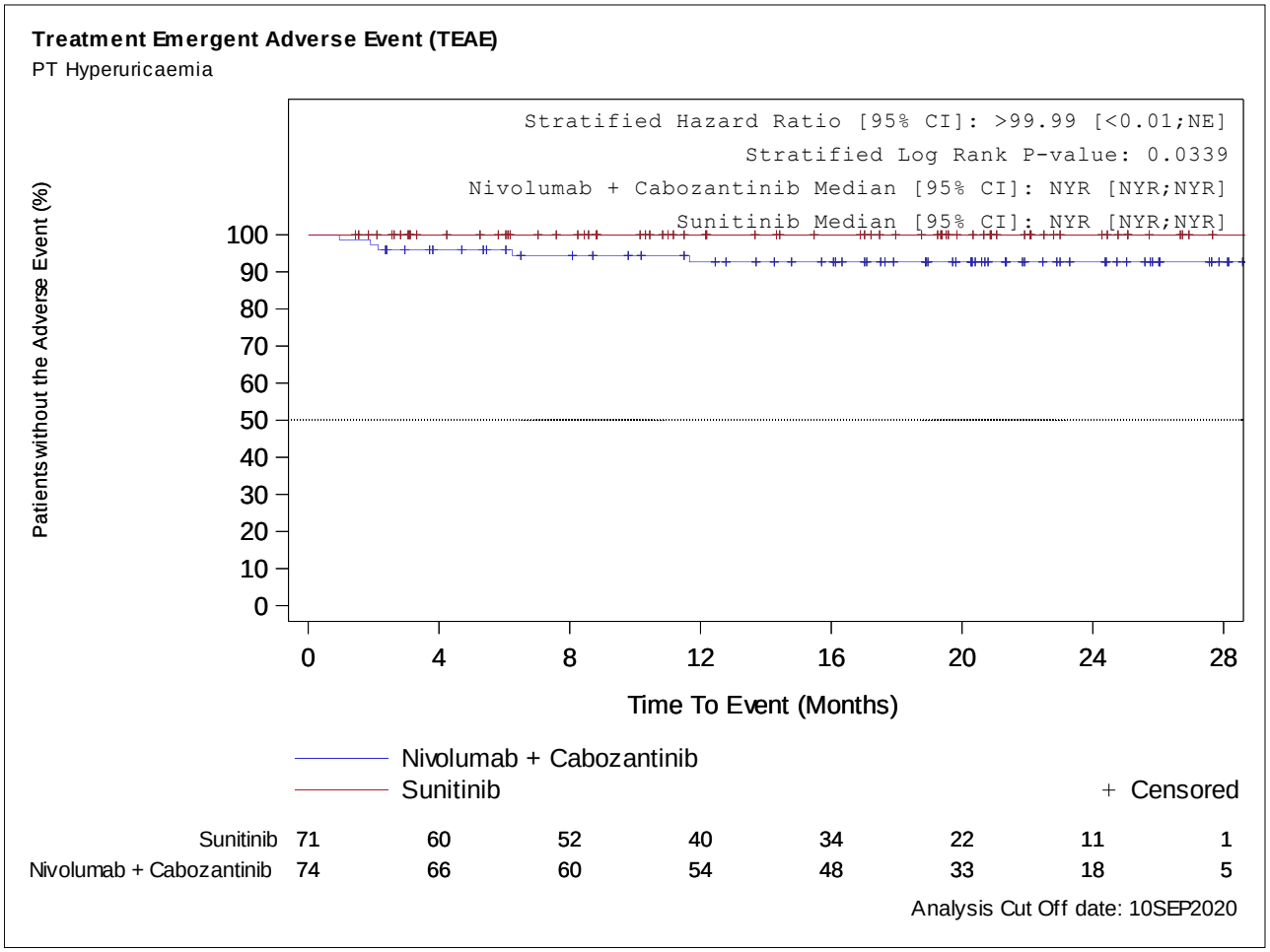
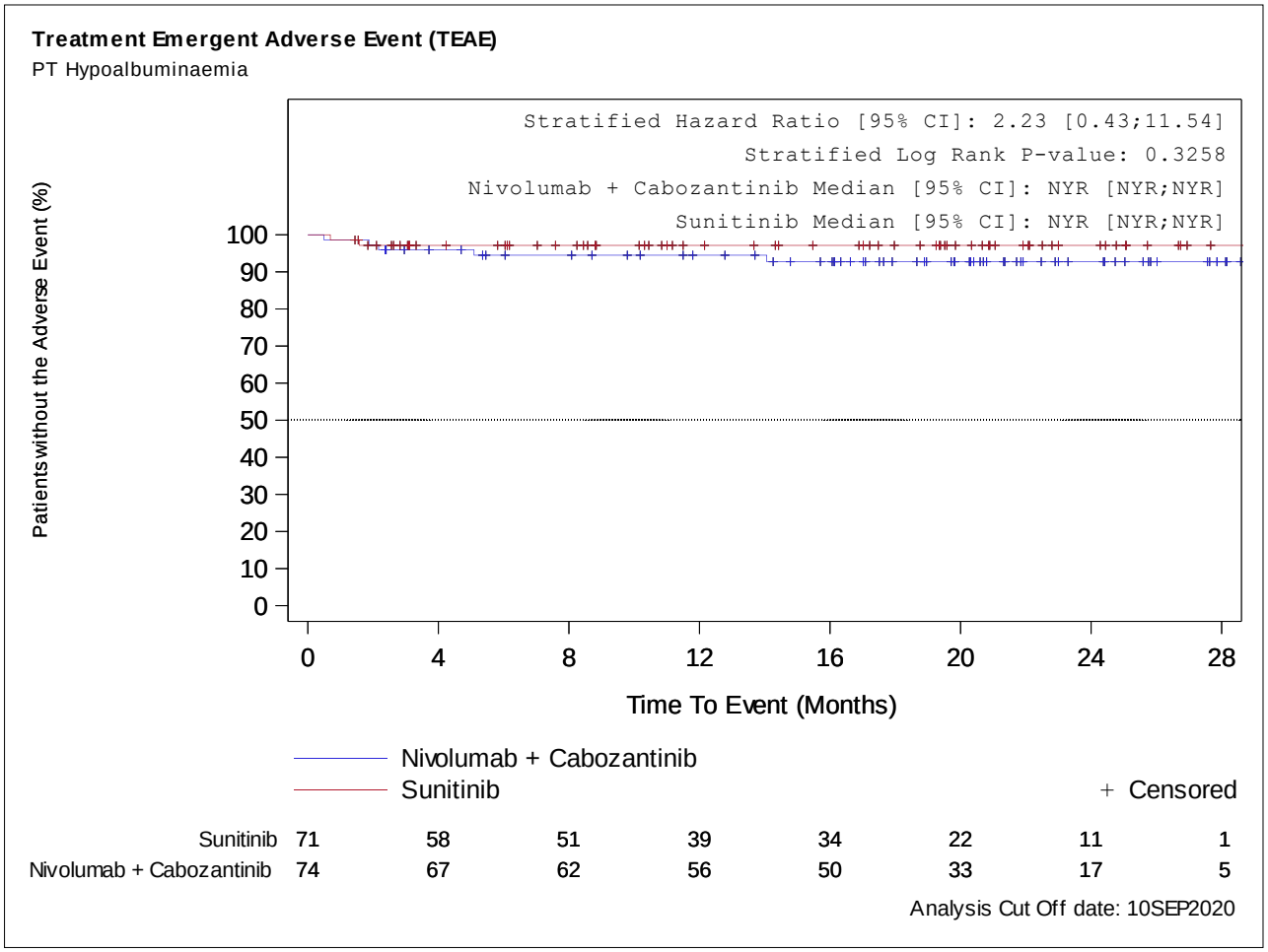
FIGURE 4.1.2.101: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hyperuricaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 15:59:02

FIGURE 4.1.2.102: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypoalbuminaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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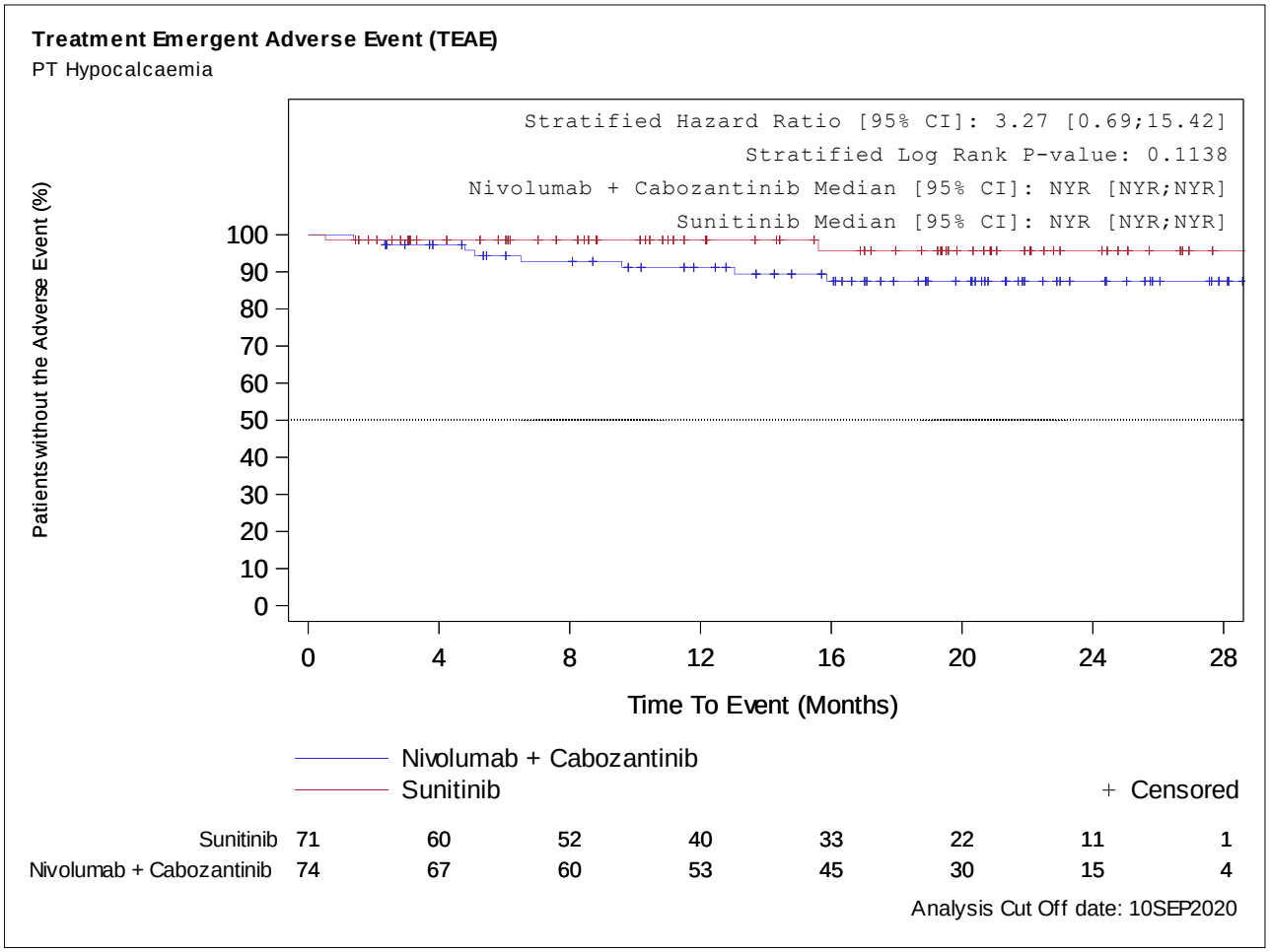
FIGURE 4.1.2.103: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypocalcaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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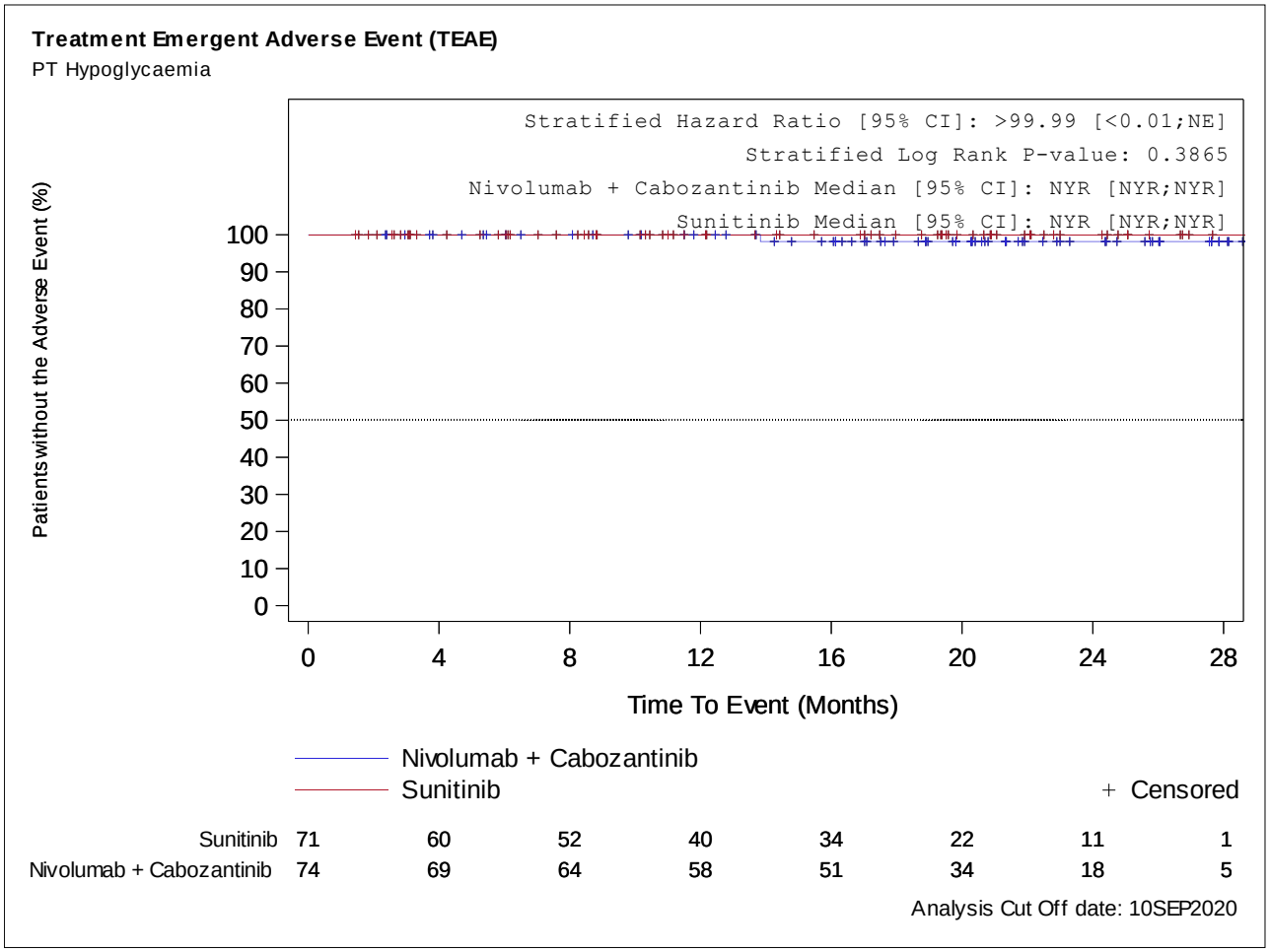
FIGURE 4.1.2.104: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypoglycaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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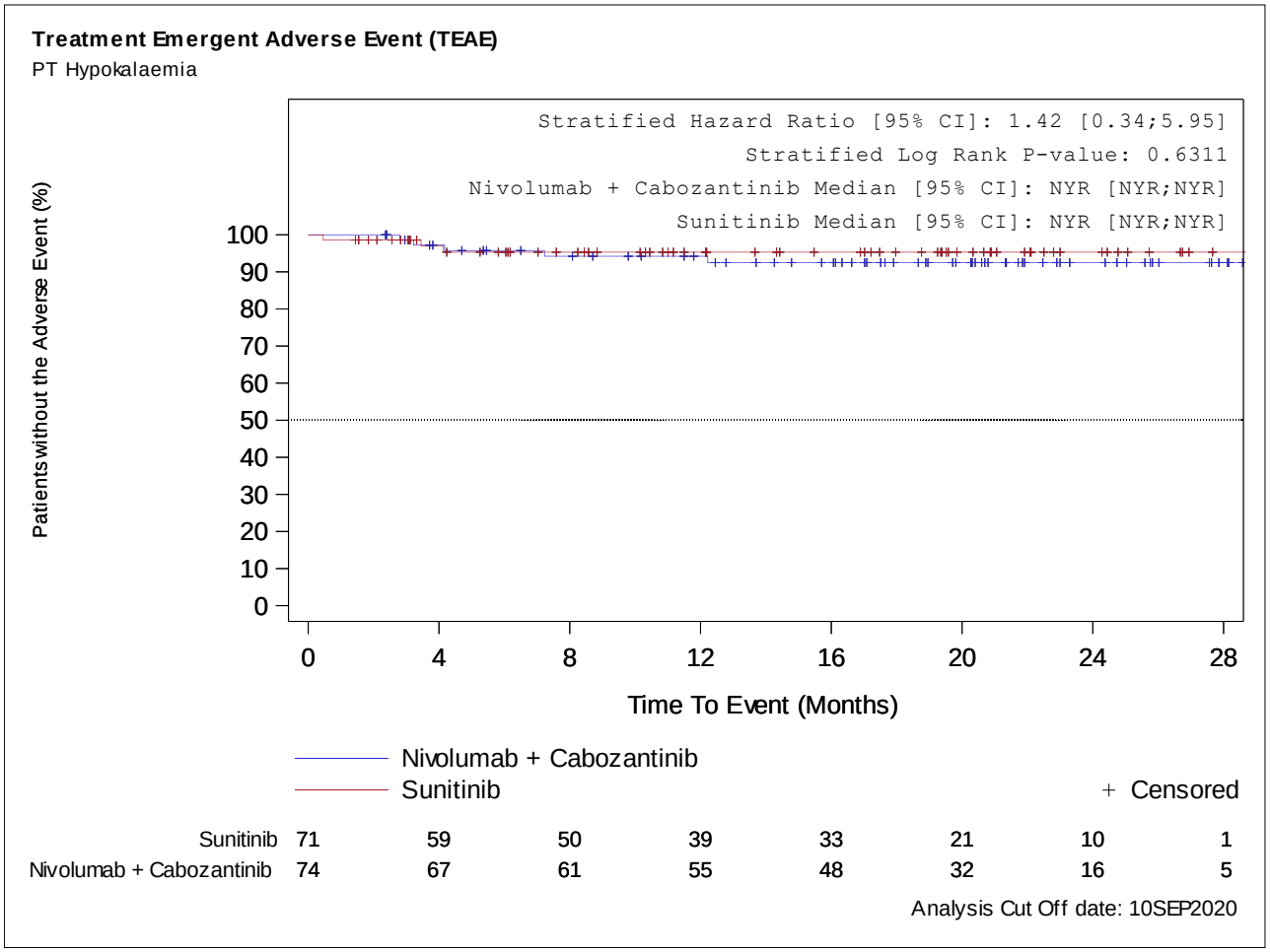
FIGURE 4.1.2.105: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypokalaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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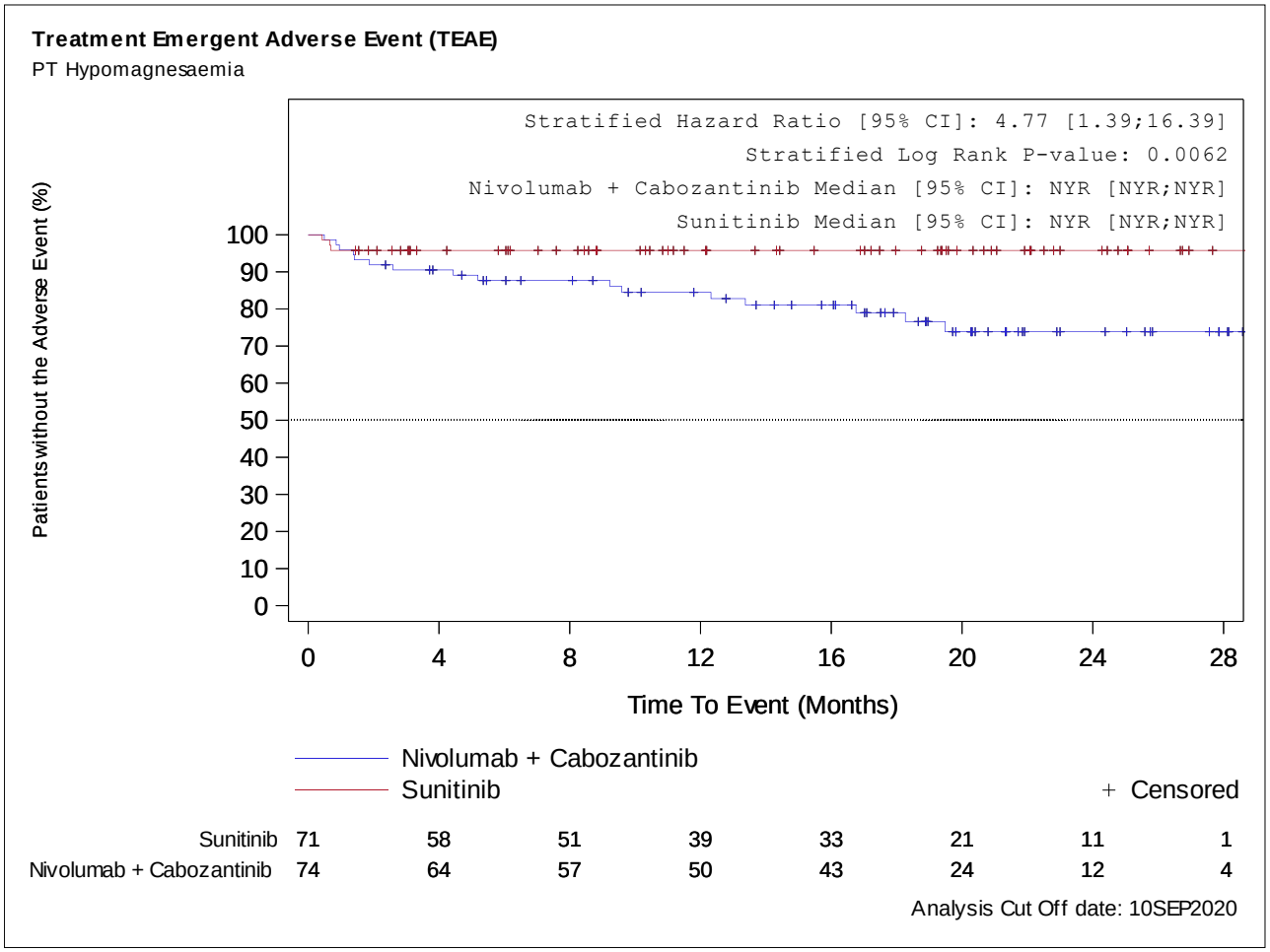
FIGURE 4.1.2.106: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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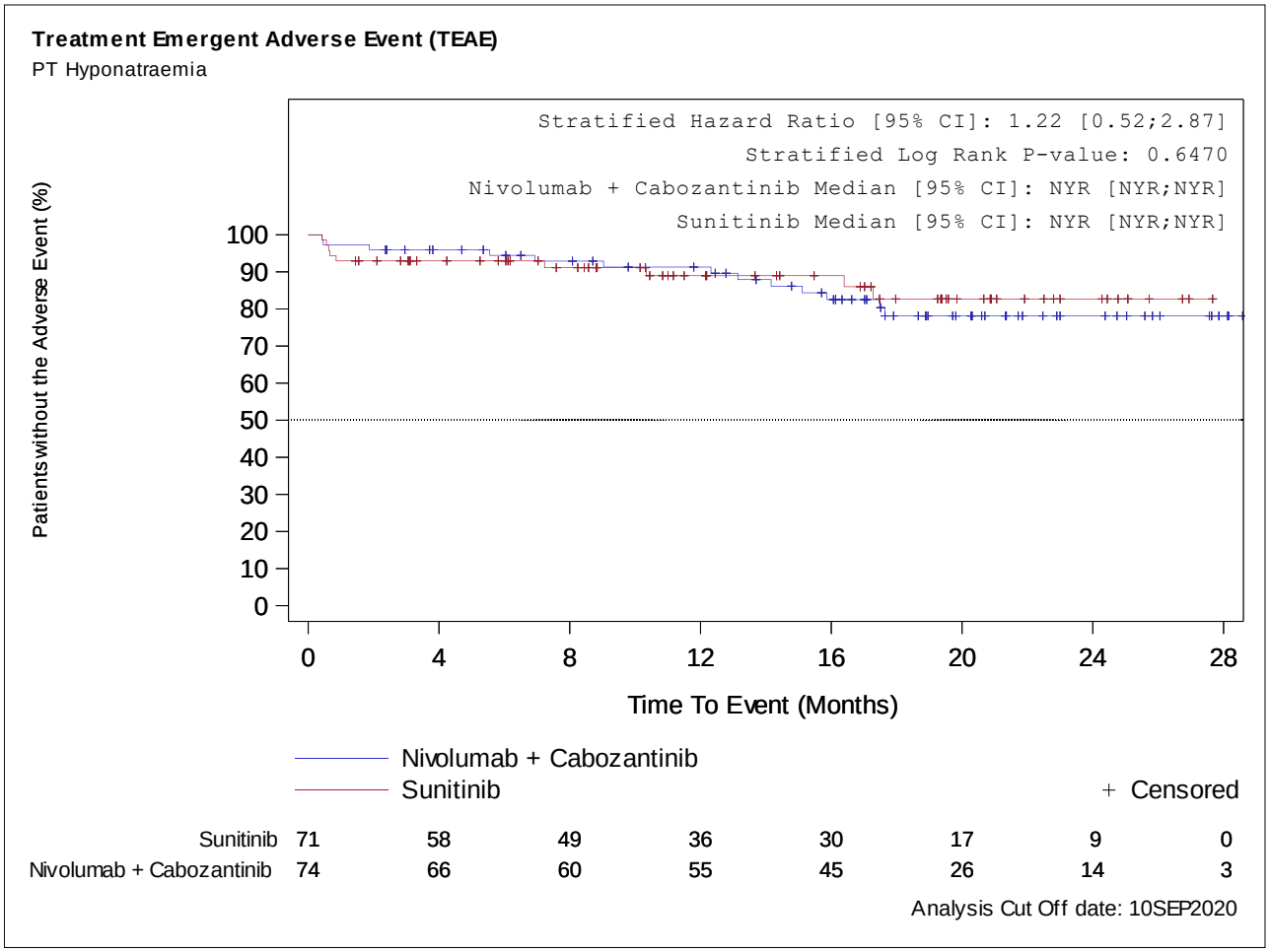
FIGURE 4.1.2.107: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hyponatraemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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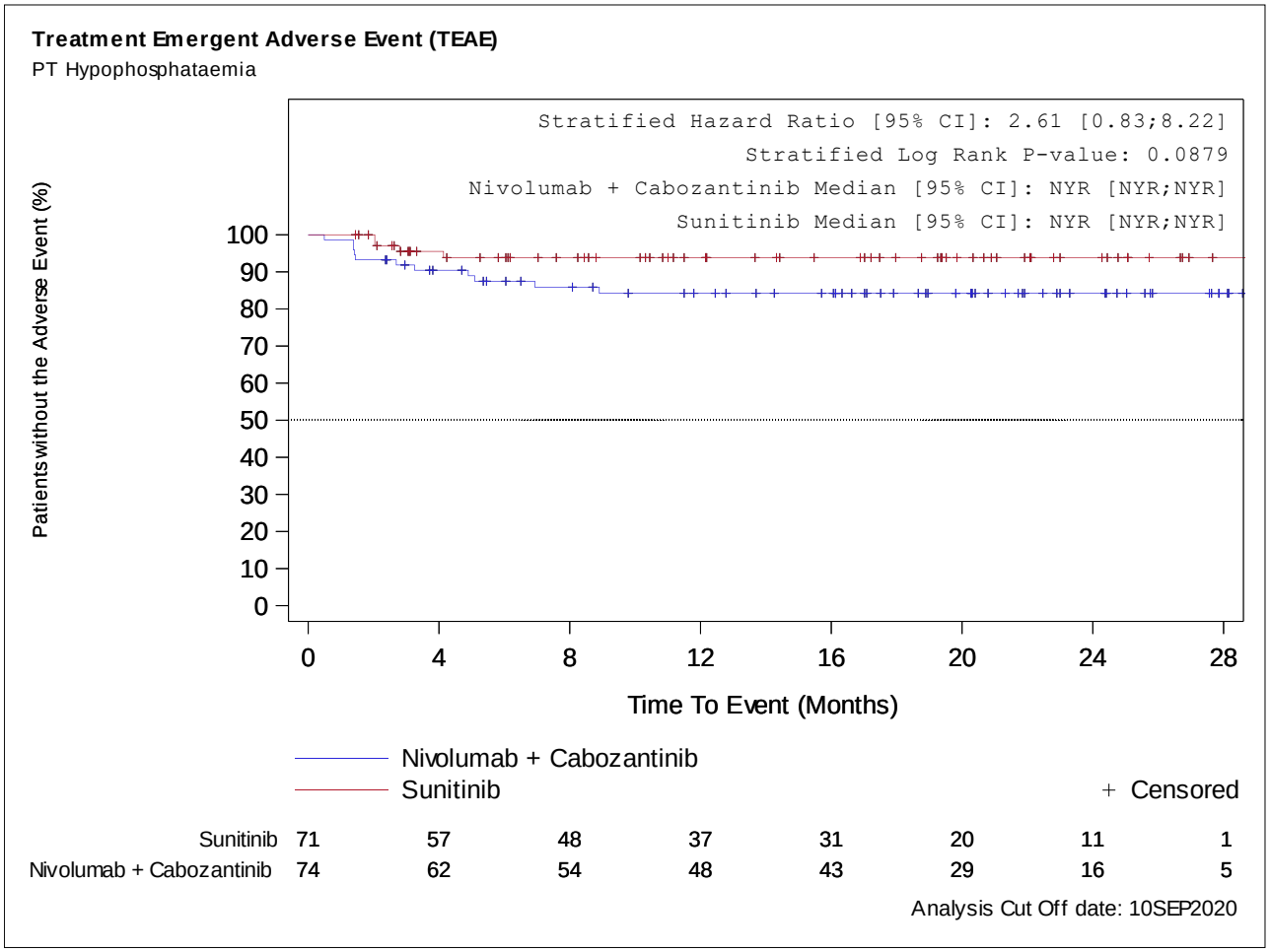
FIGURE 4.1.2.108: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypophosphataemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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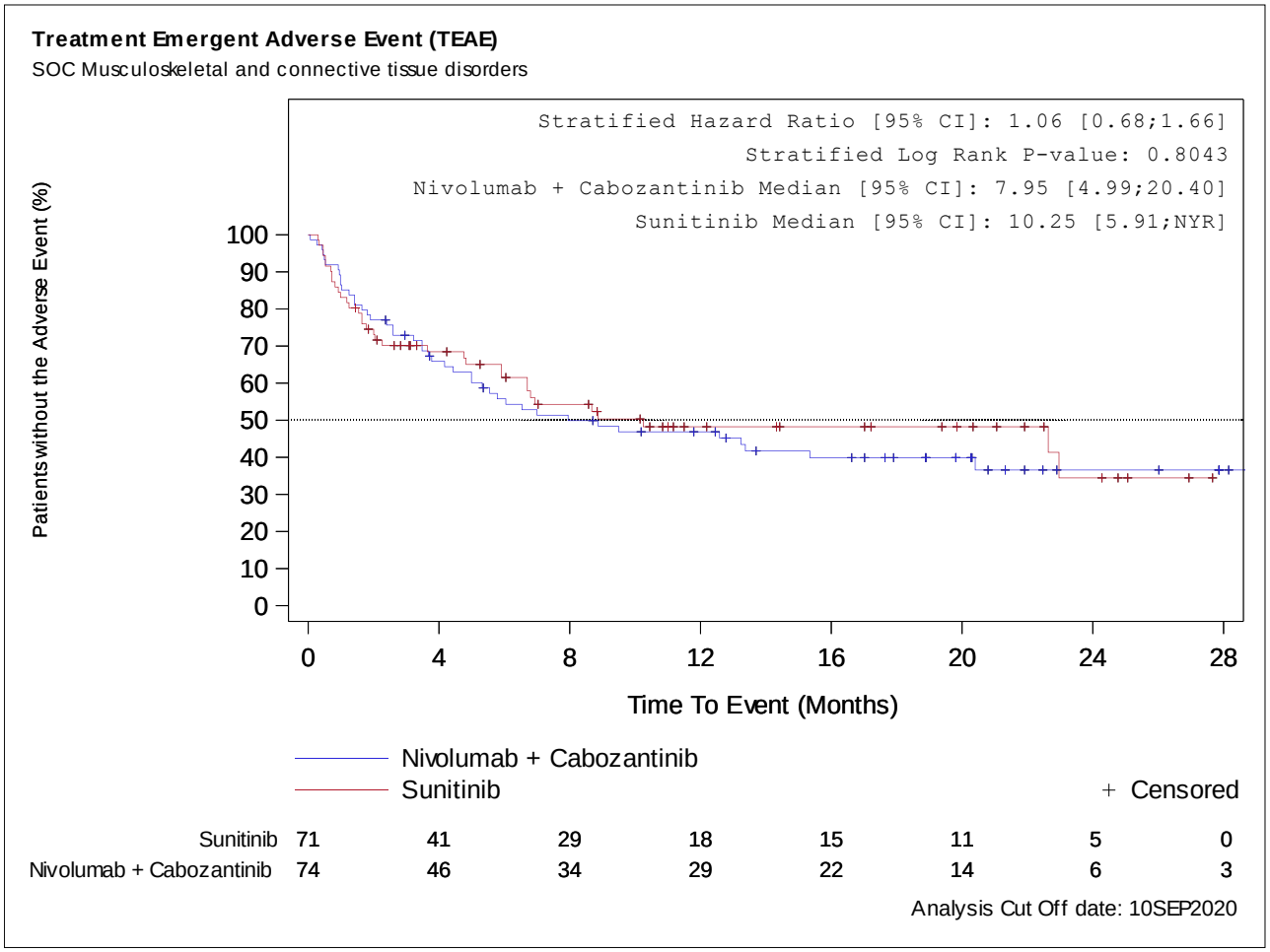
FIGURE 4.1.2.109: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Musculoskeletal and connective tissue disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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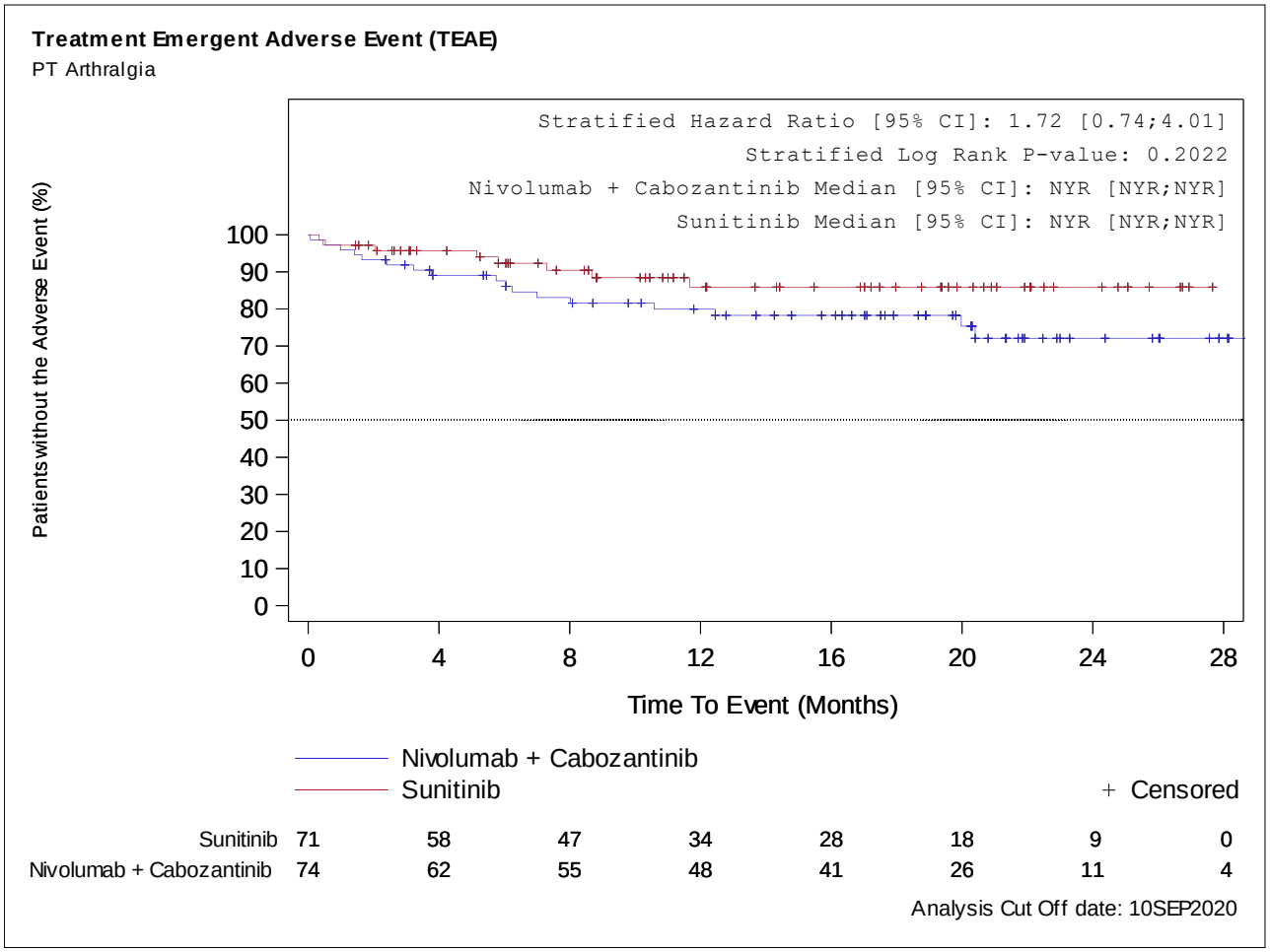
FIGURE 4.1.2.110: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Arthralgia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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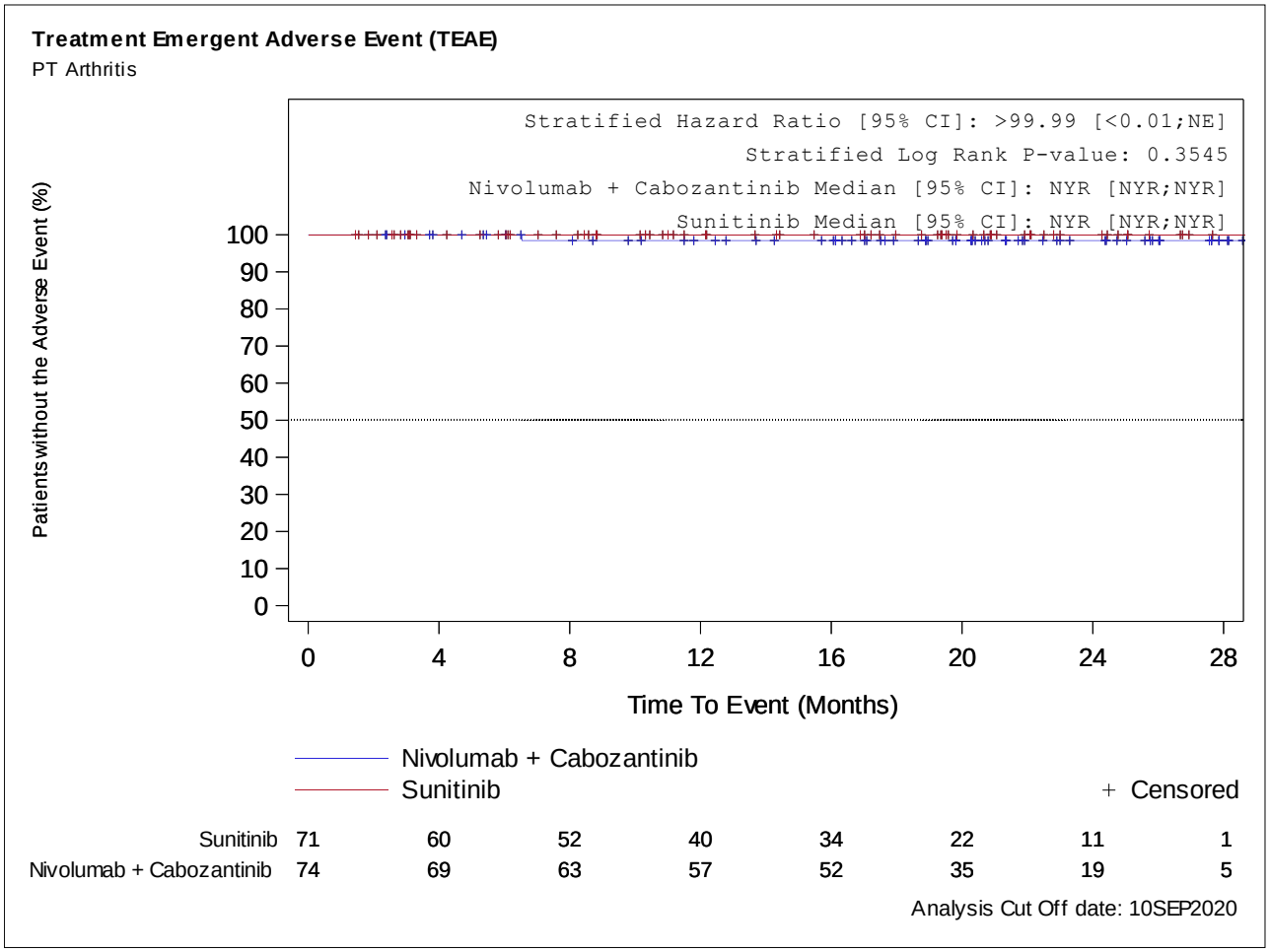
FIGURE 4.1.2.111: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Arthritis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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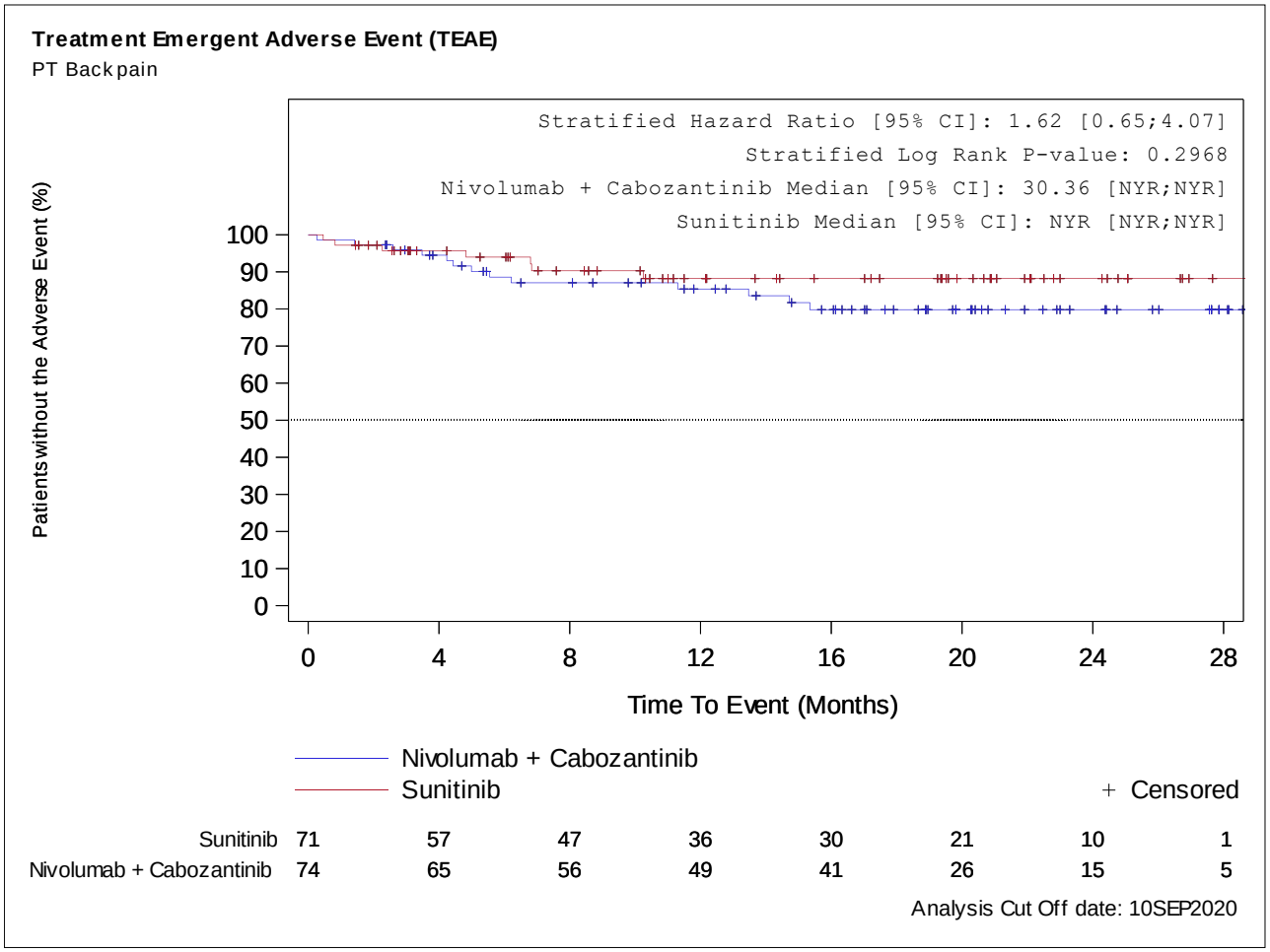
FIGURE 4.1.2.112: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Back pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.1.2.113: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Bone pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

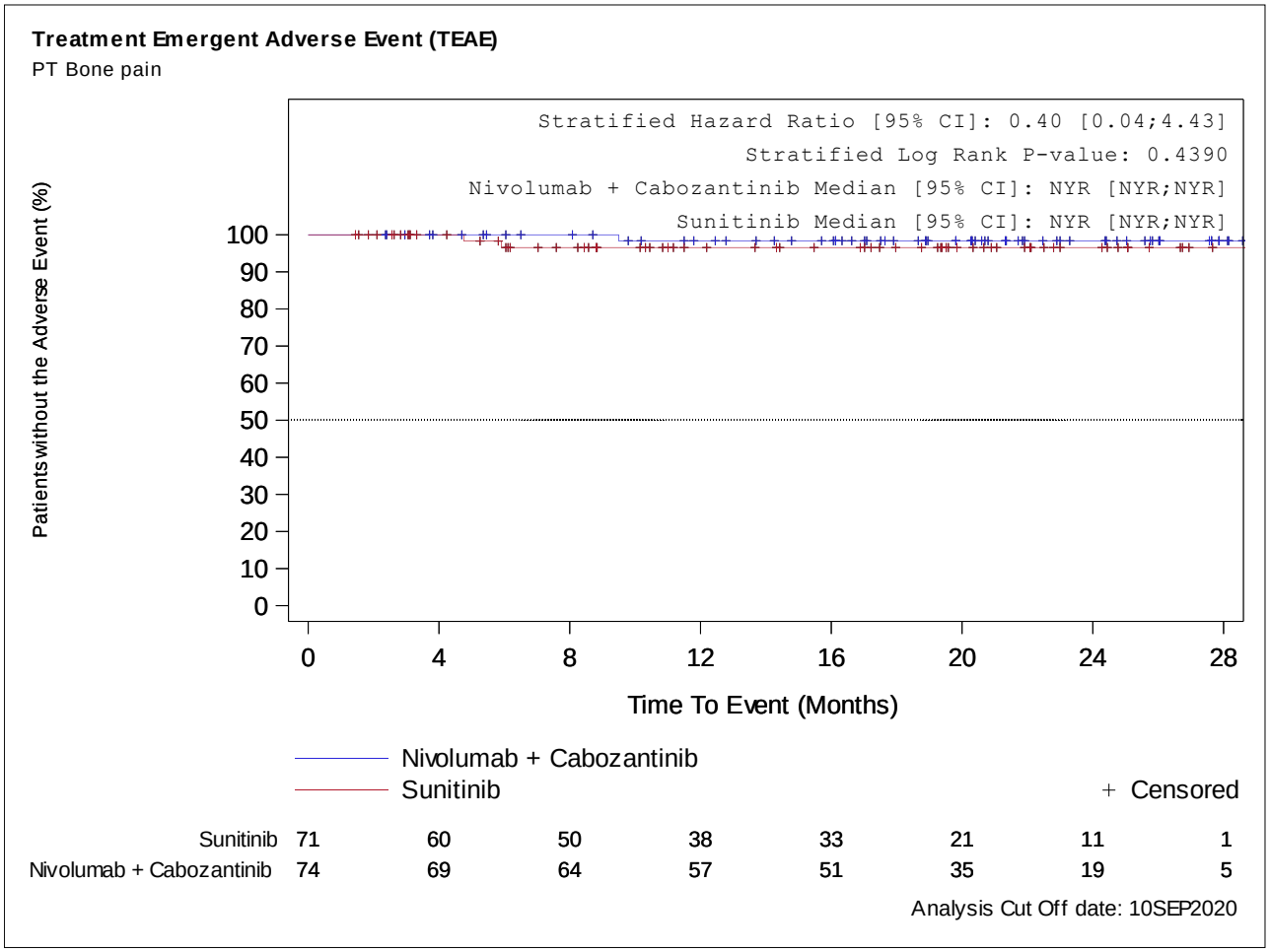


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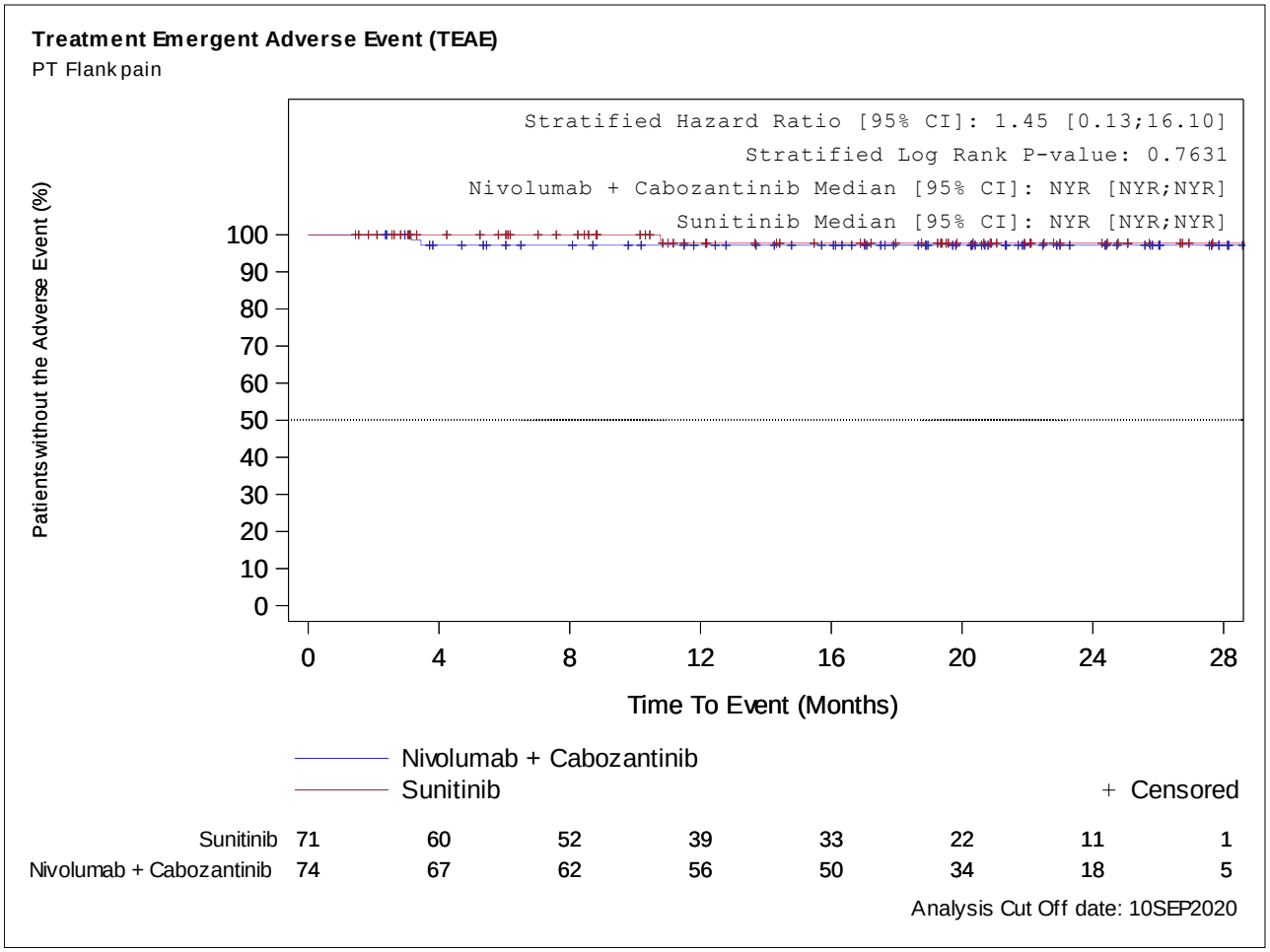
FIGURE 4.1.2.114: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Flank pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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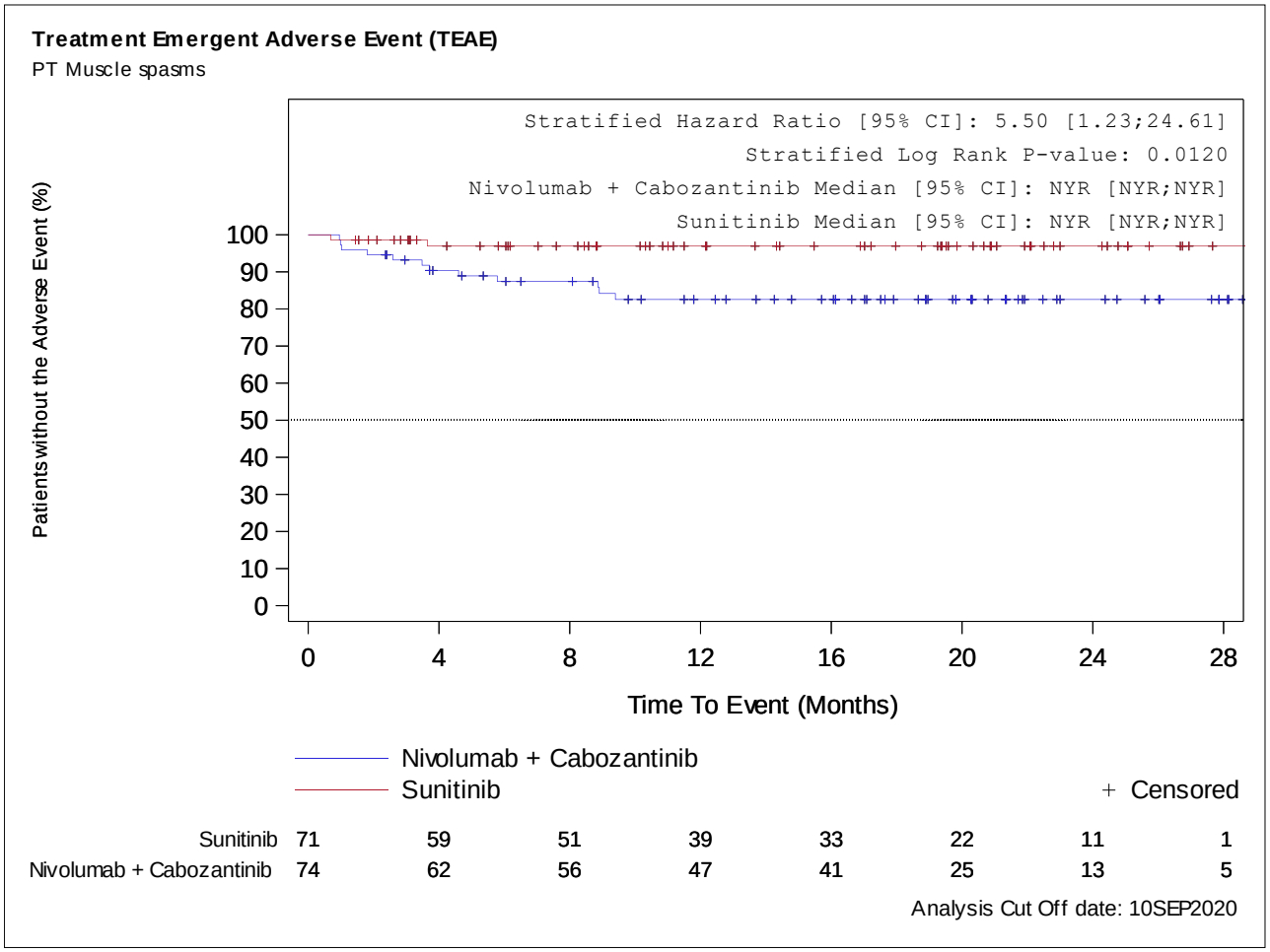
FIGURE 4.1.2.115: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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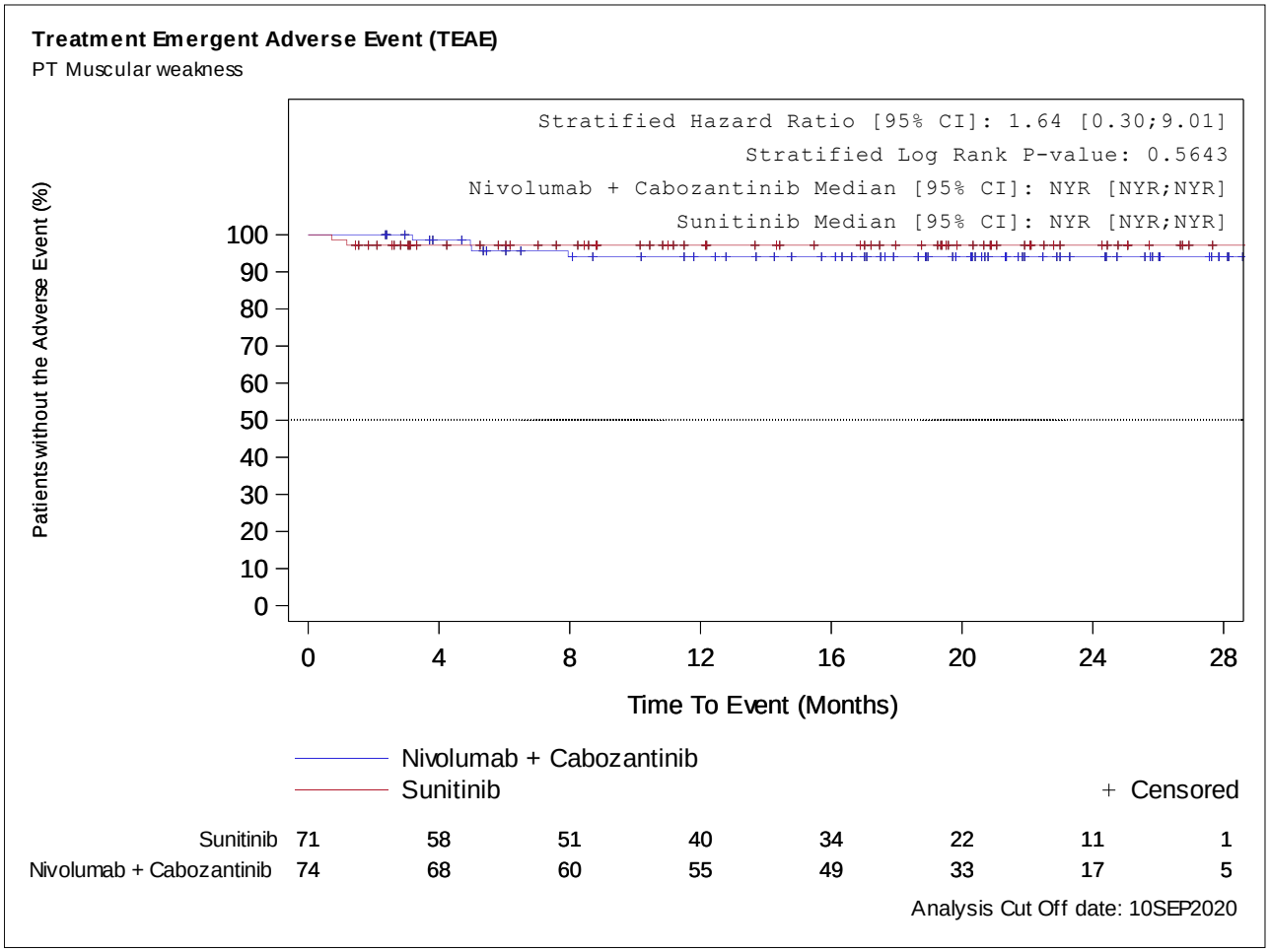
FIGURE 4.1.2.116: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Muscular weakness - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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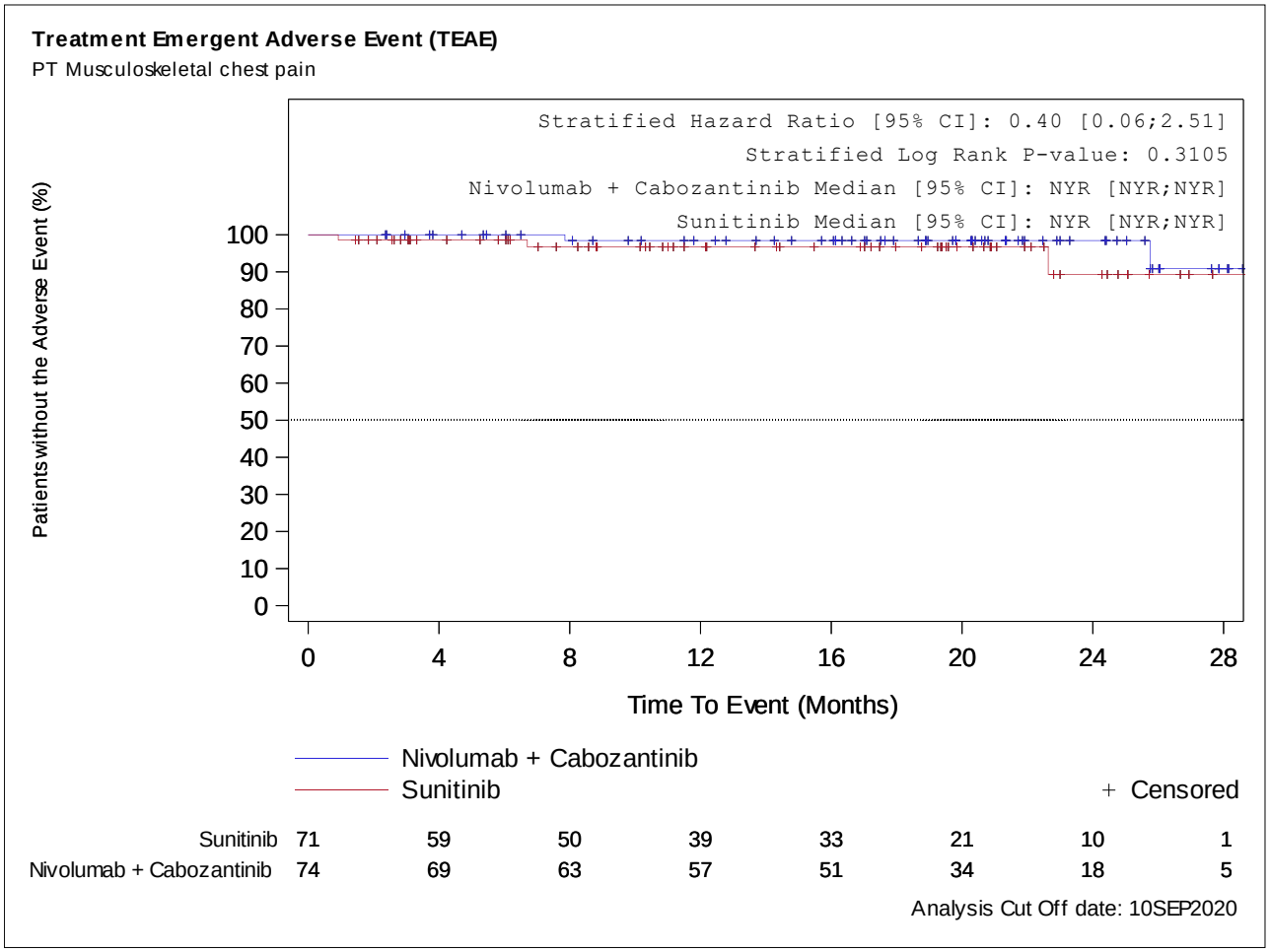
FIGURE 4.1.2.117: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Musculoskeletal chest pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.1.2.118: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Musculoskeletal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

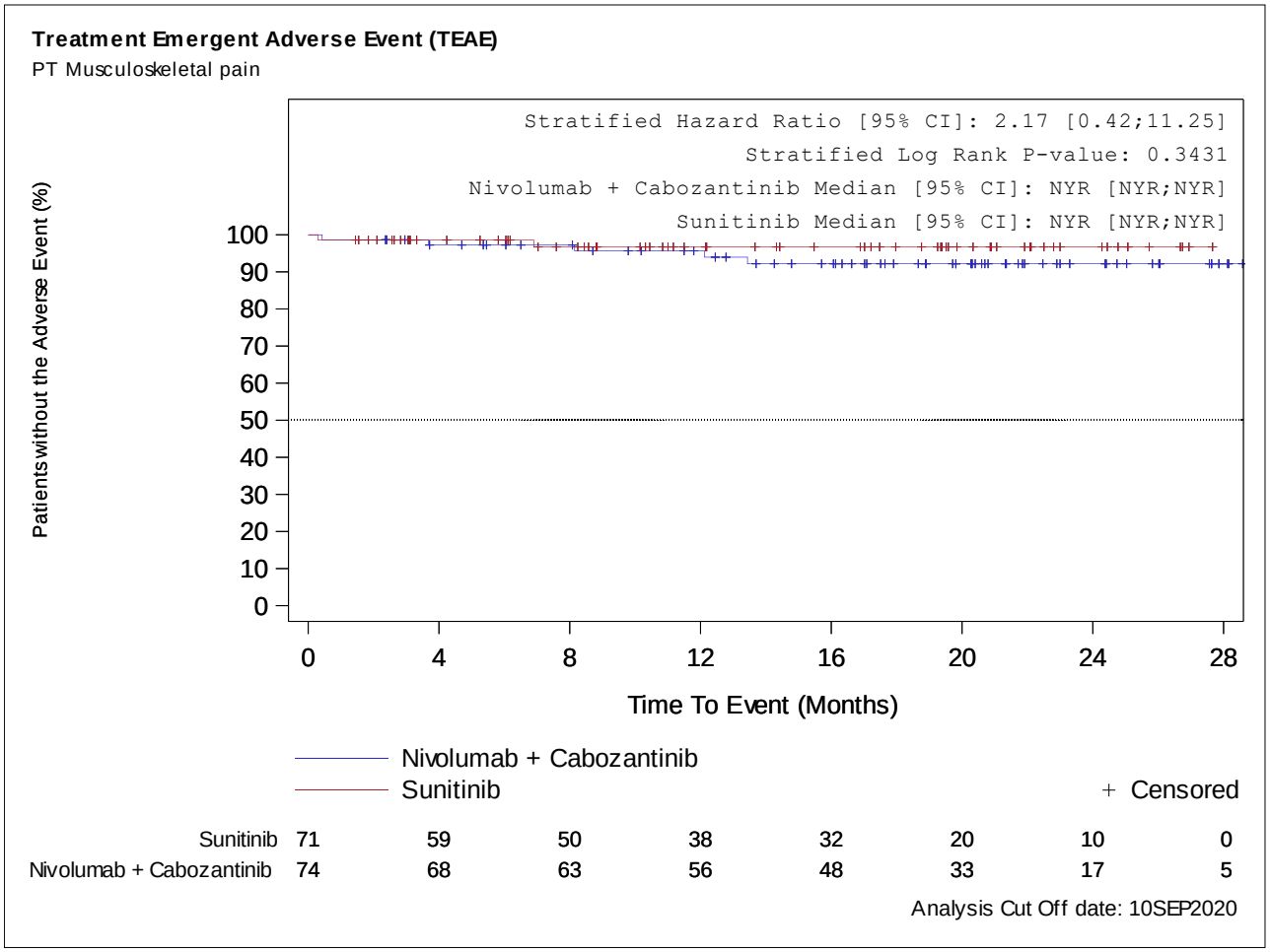


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FIGURE 4.1.2.119: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Myalgia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

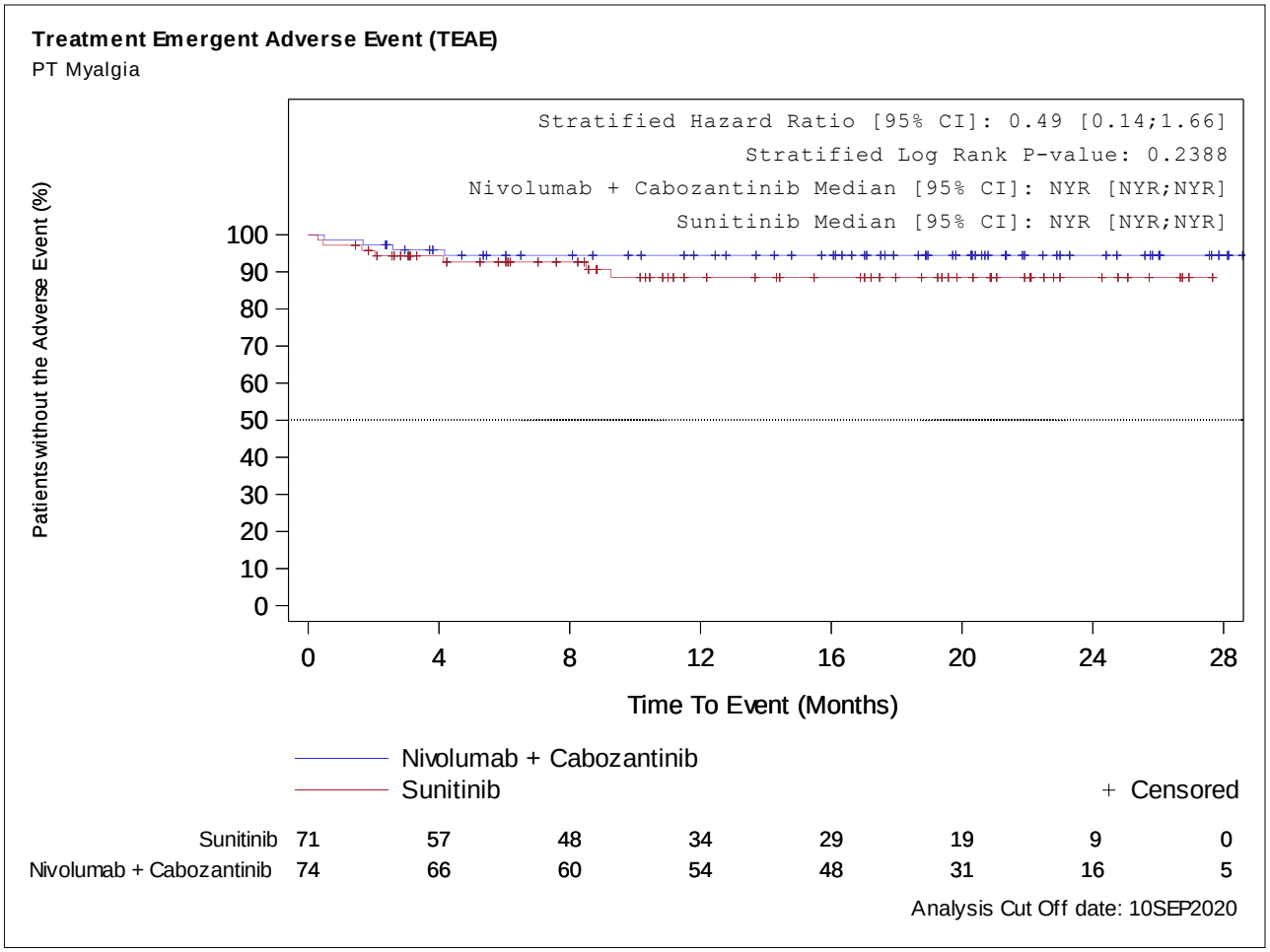


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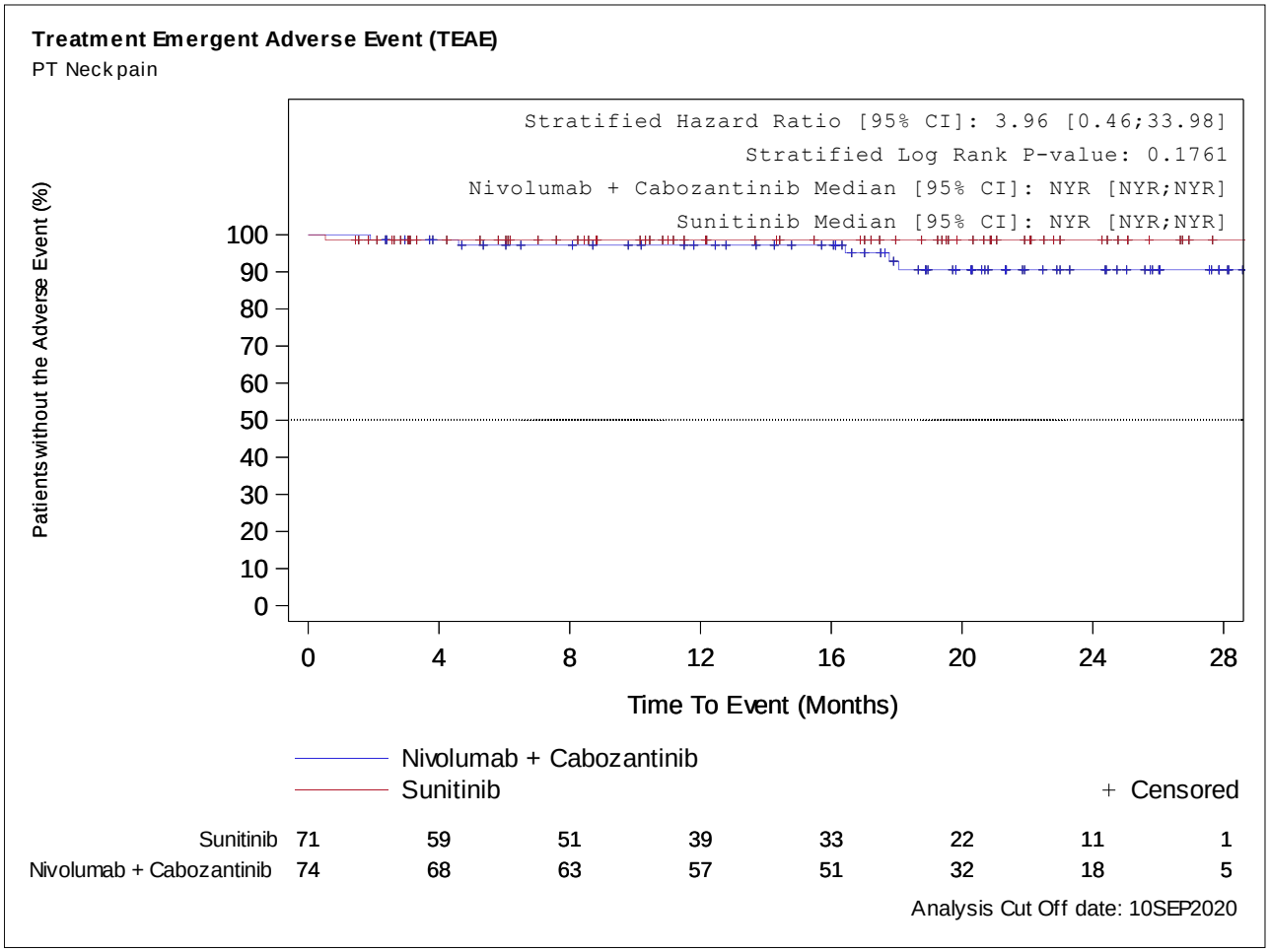
FIGURE 4.1.2.120: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neck pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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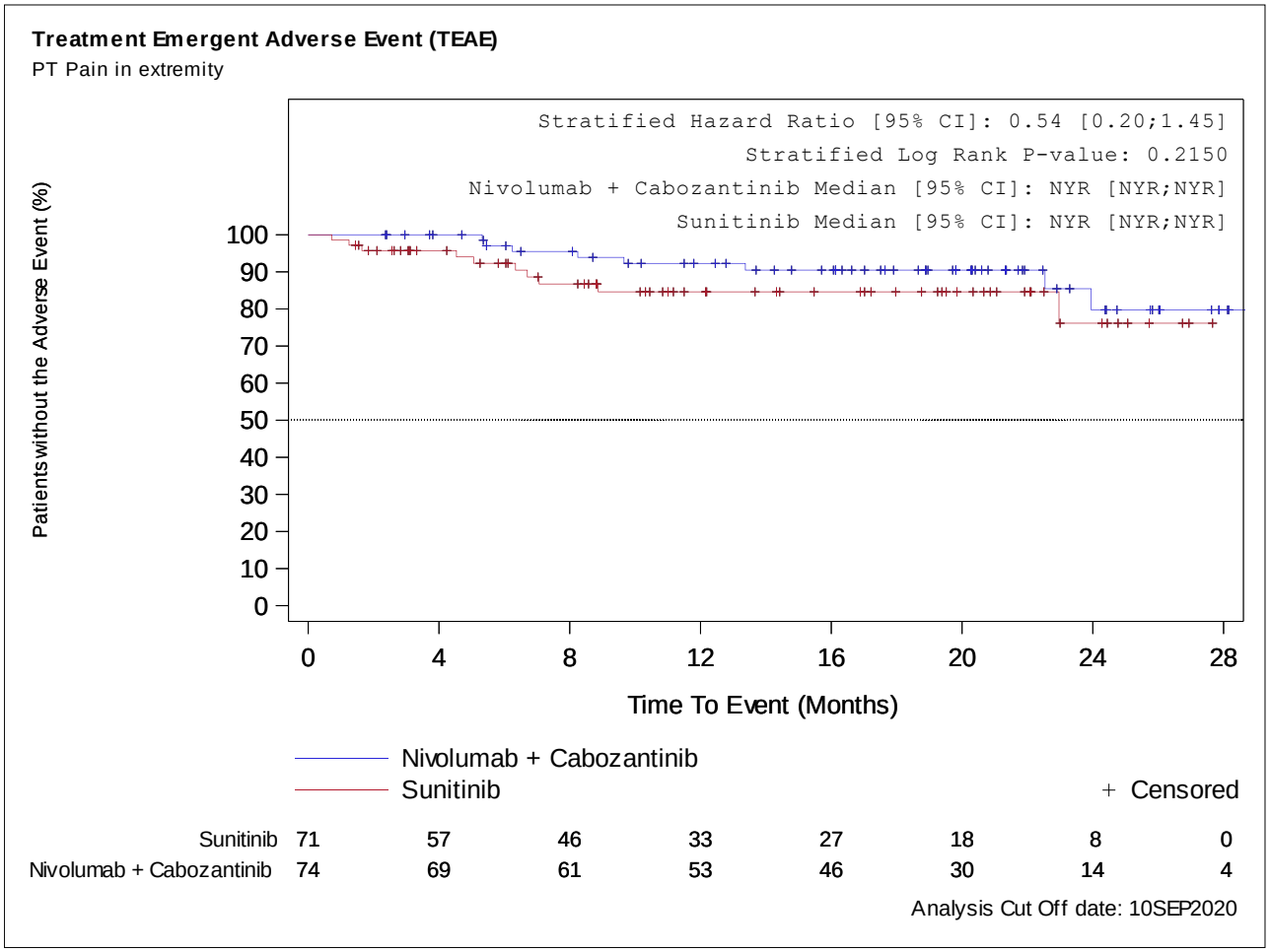
FIGURE 4.1.2.121: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pain in extremity - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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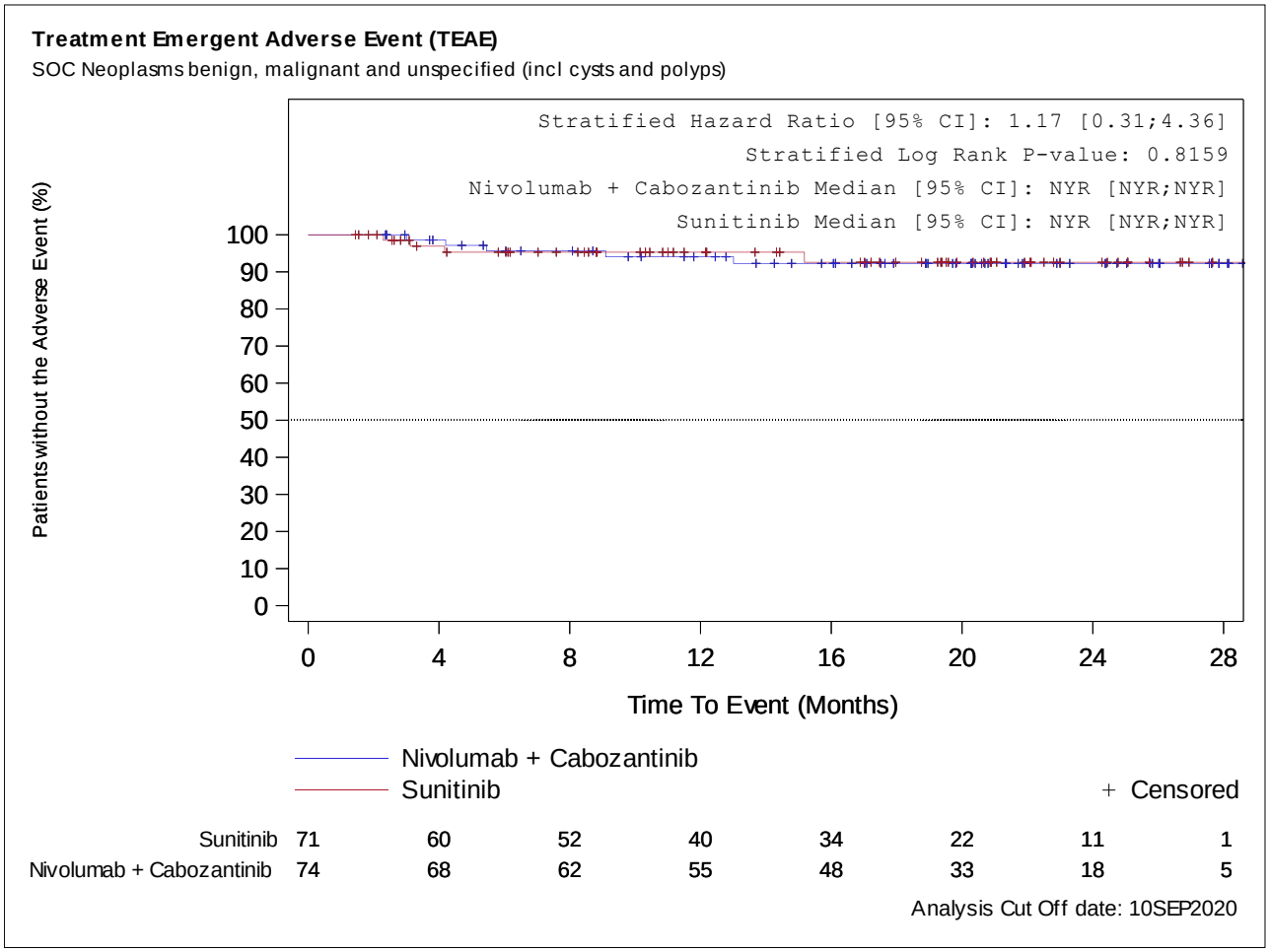
FIGURE 4.1.2.122: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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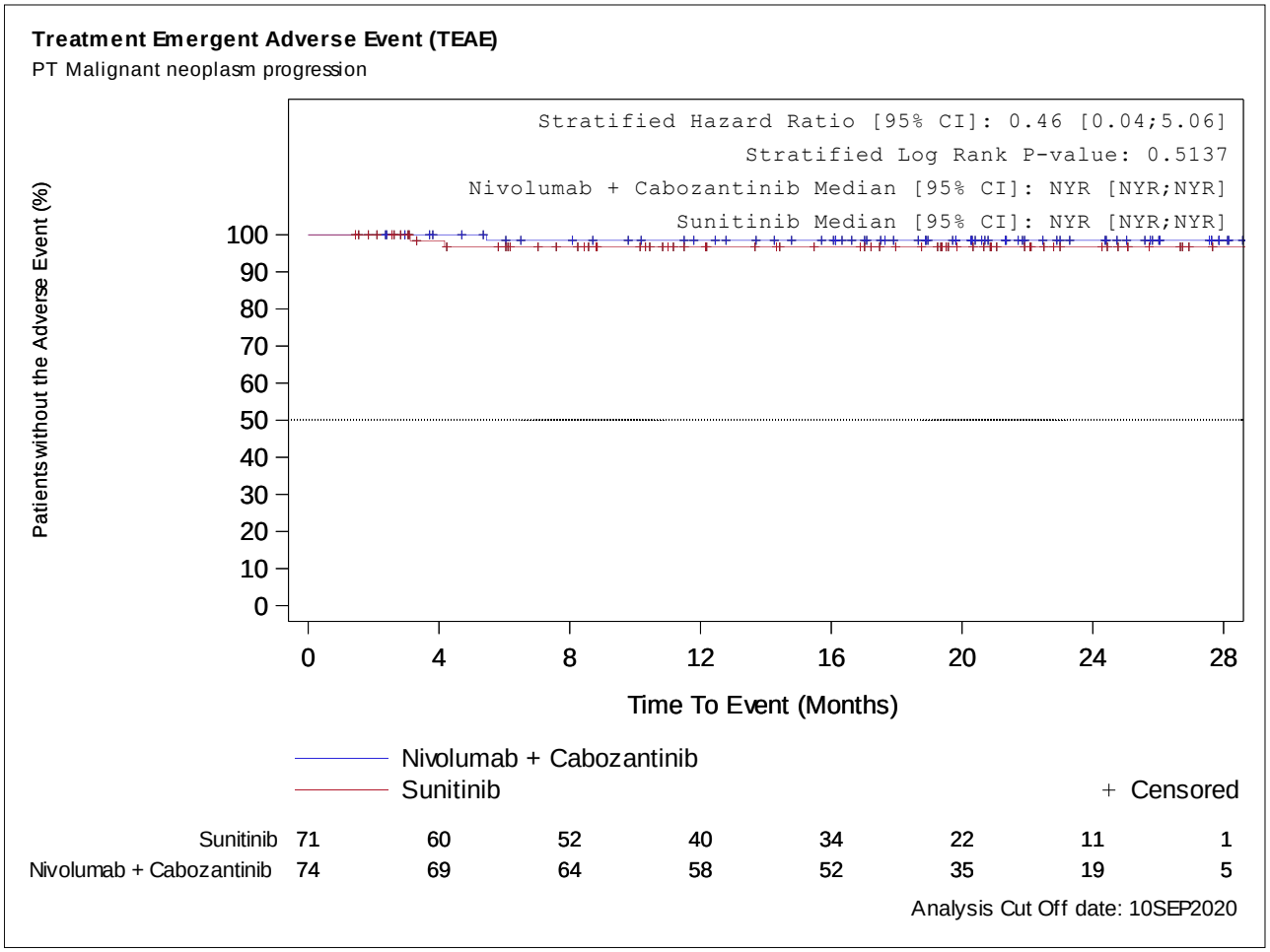
FIGURE 4.1.2.123: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Malignant neoplasm progression - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.1.2.124: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Nervous system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

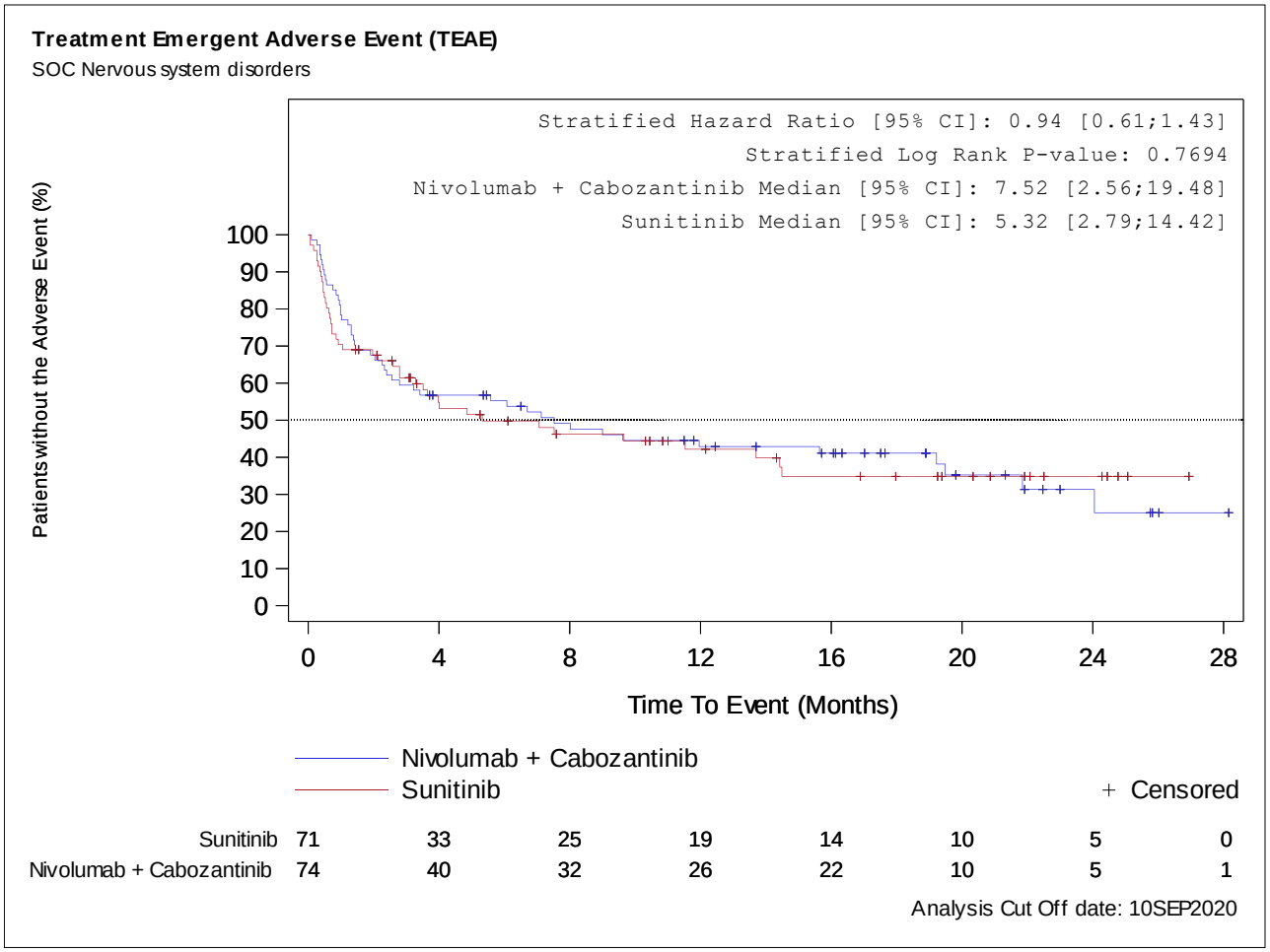


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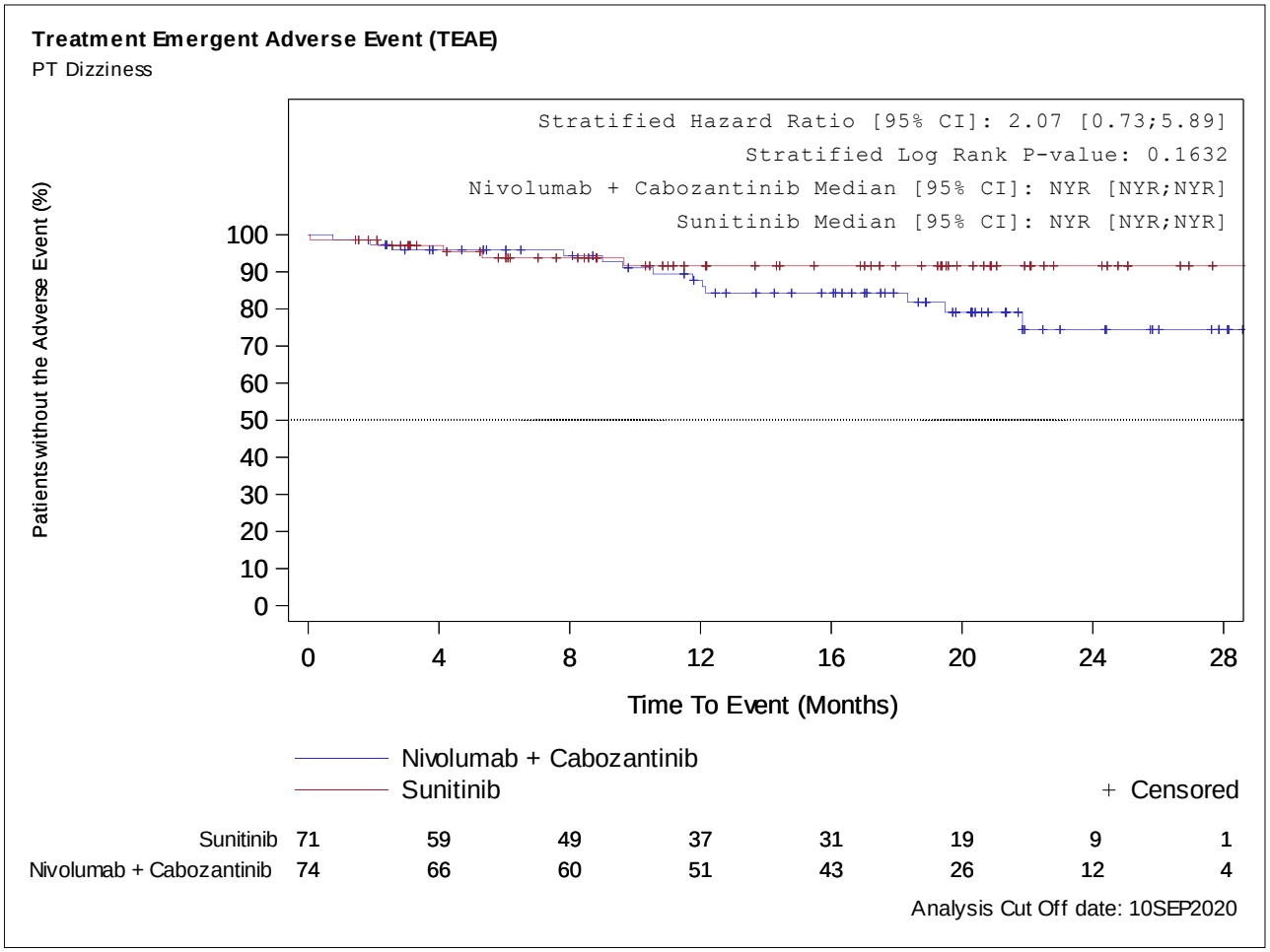
FIGURE 4.1.2.125: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dizziness - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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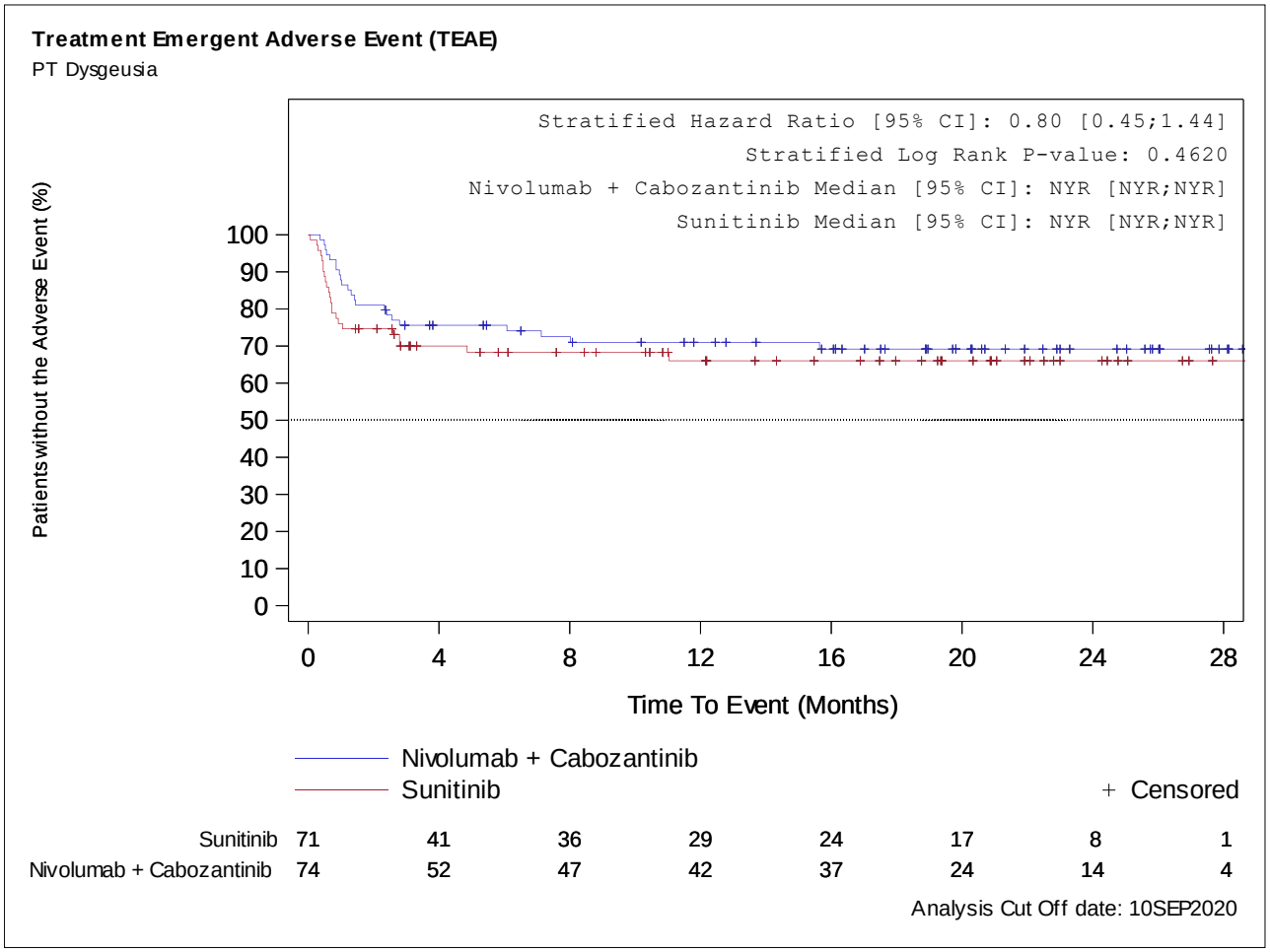
FIGURE 4.1.2.126: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysgeusia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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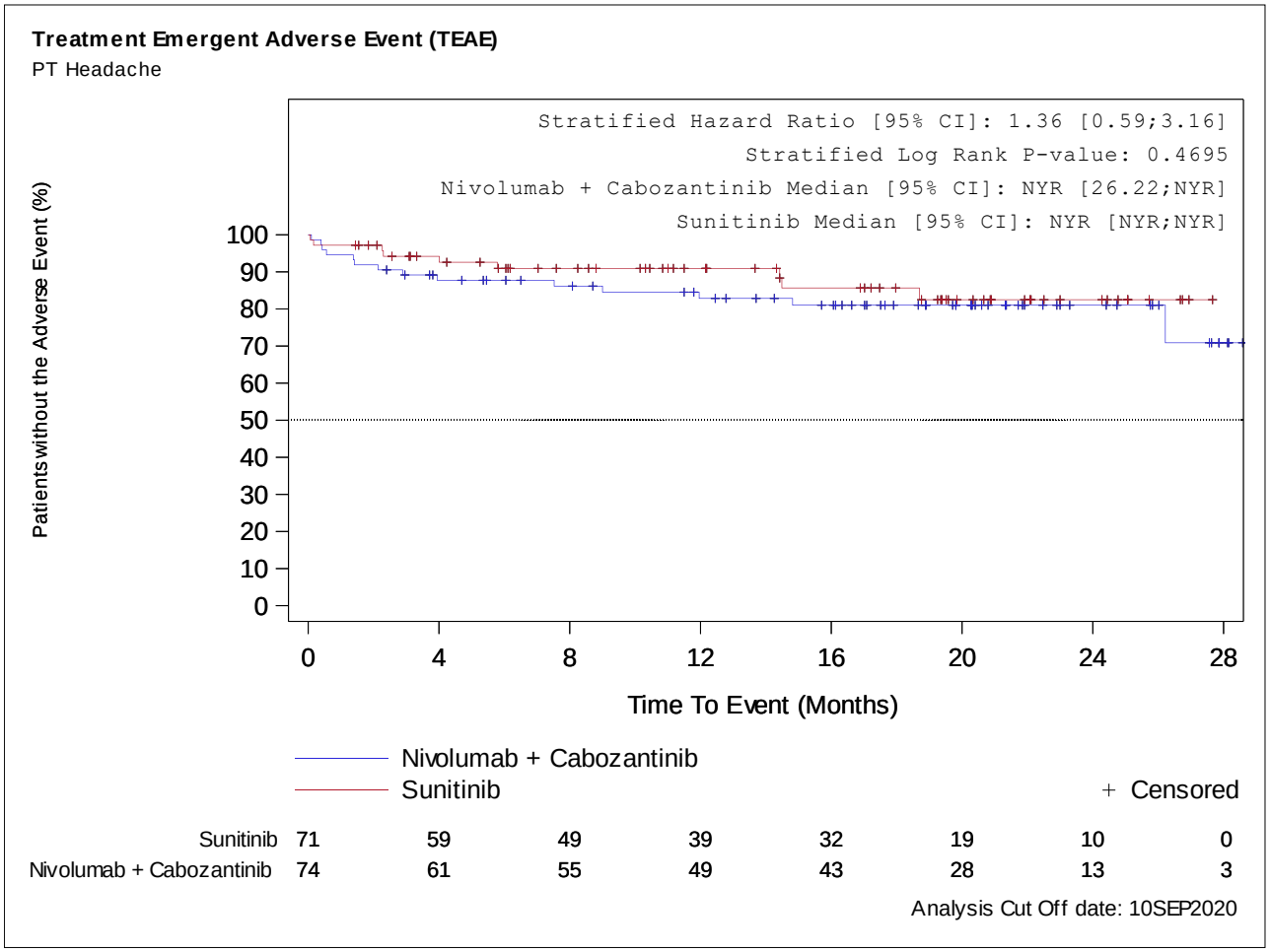
FIGURE 4.1.2.127: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Headache - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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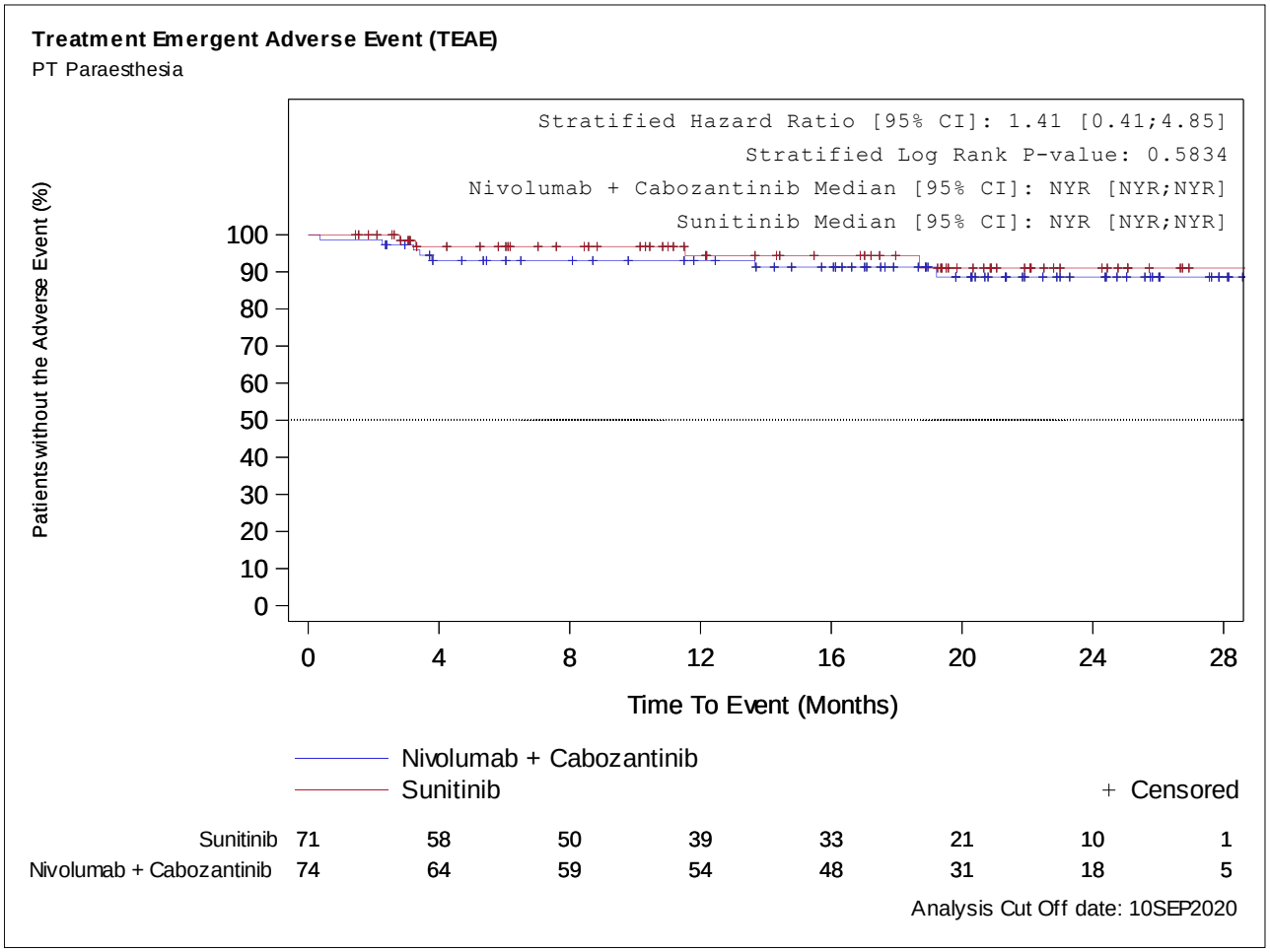
FIGURE 4.1.2.128: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Paraesthesia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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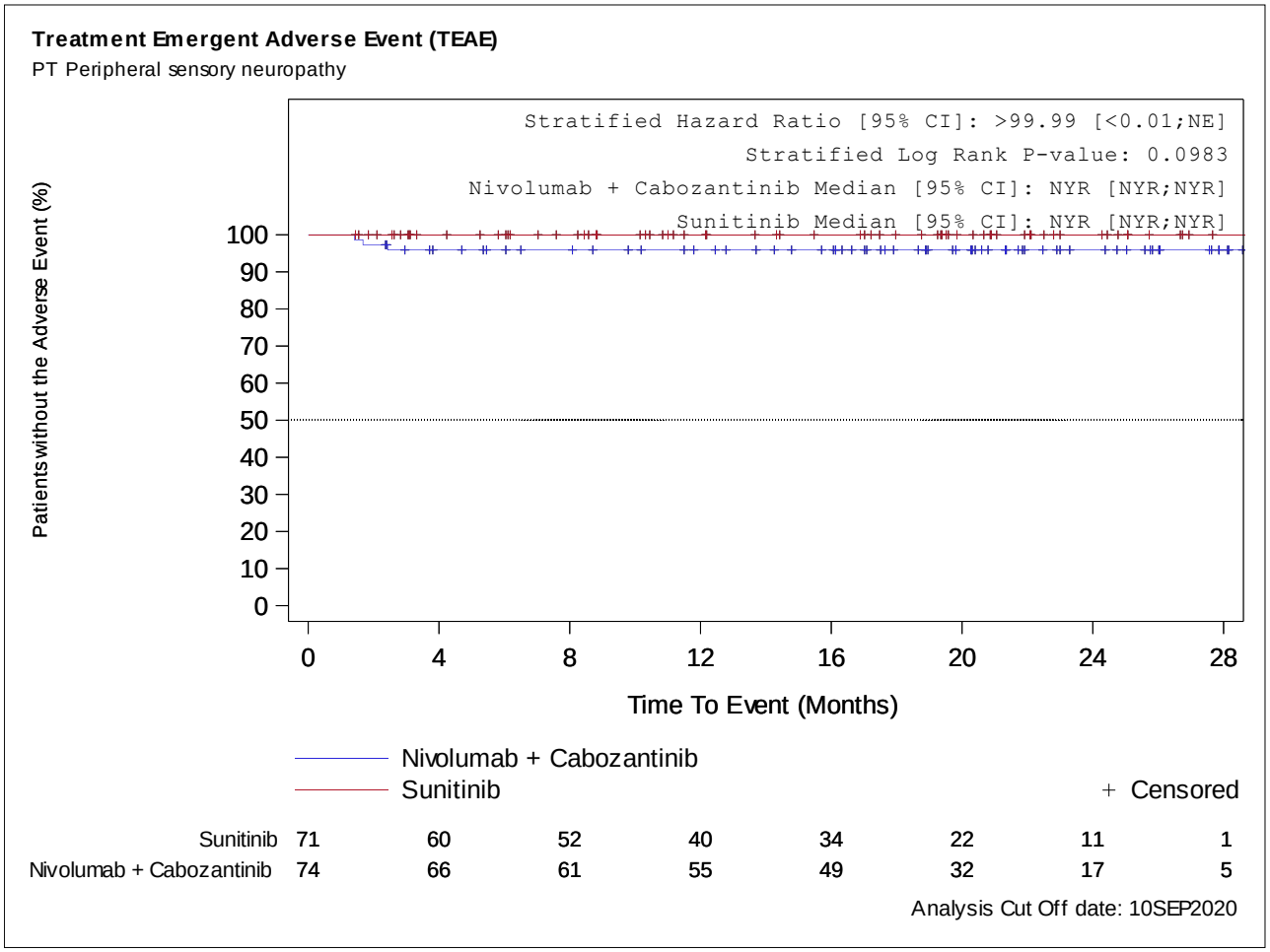
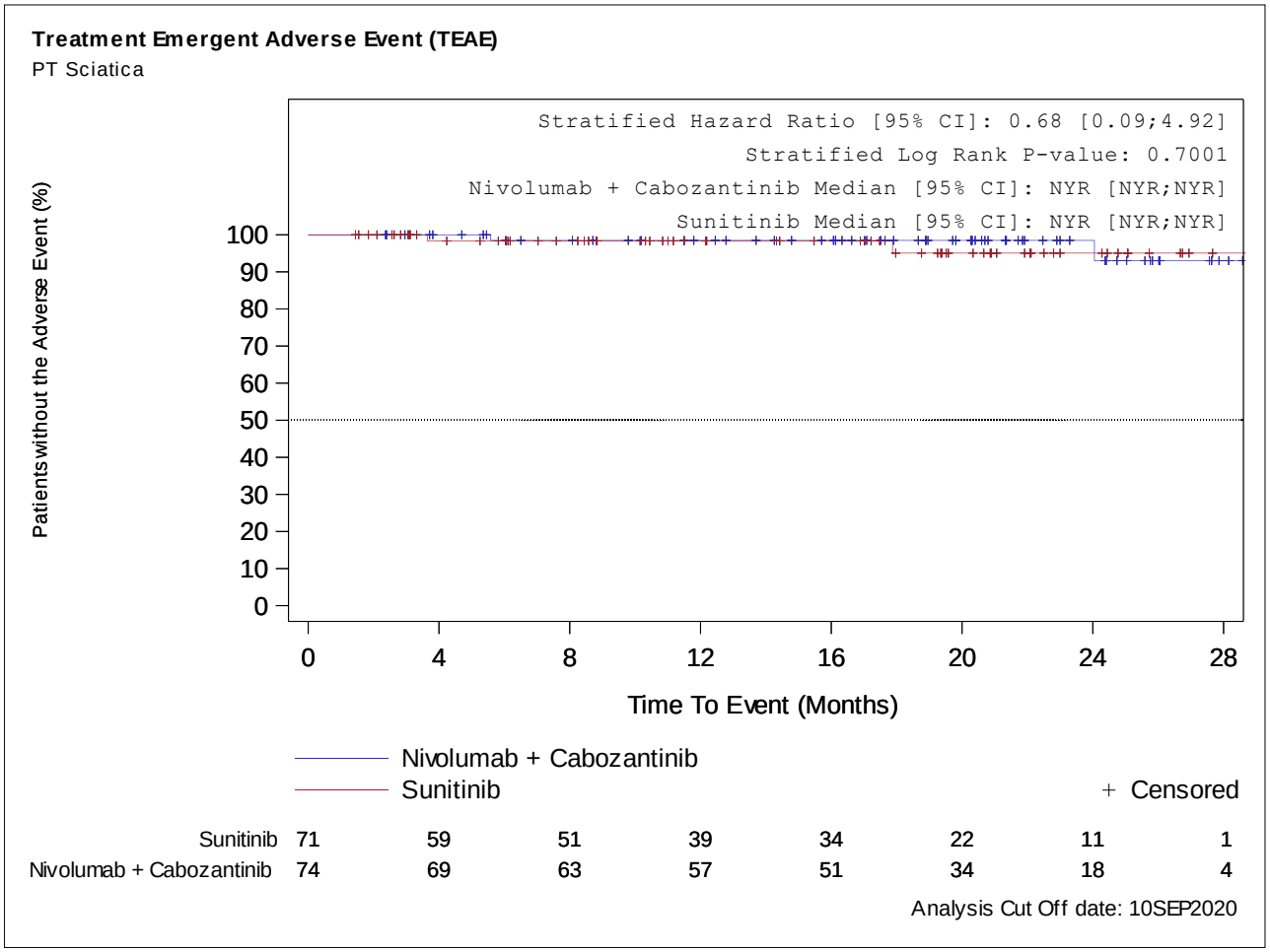
FIGURE 4.1.2.129: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Peripheral sensory neuropathy - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



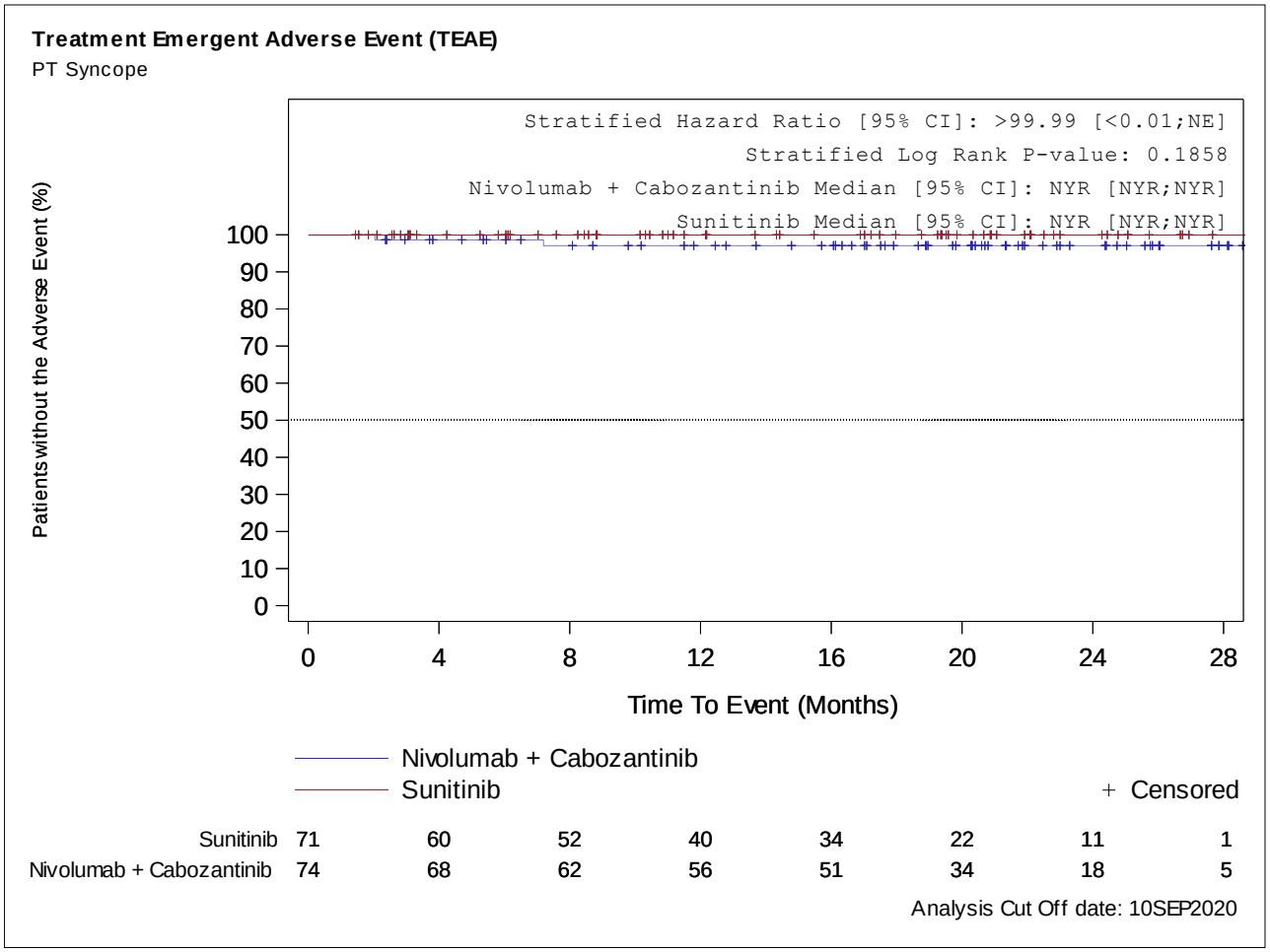

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:01:12

FIGURE 4.1.2.130: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Sciatica - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:01:17

FIGURE 4.1.2.131: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Syncope - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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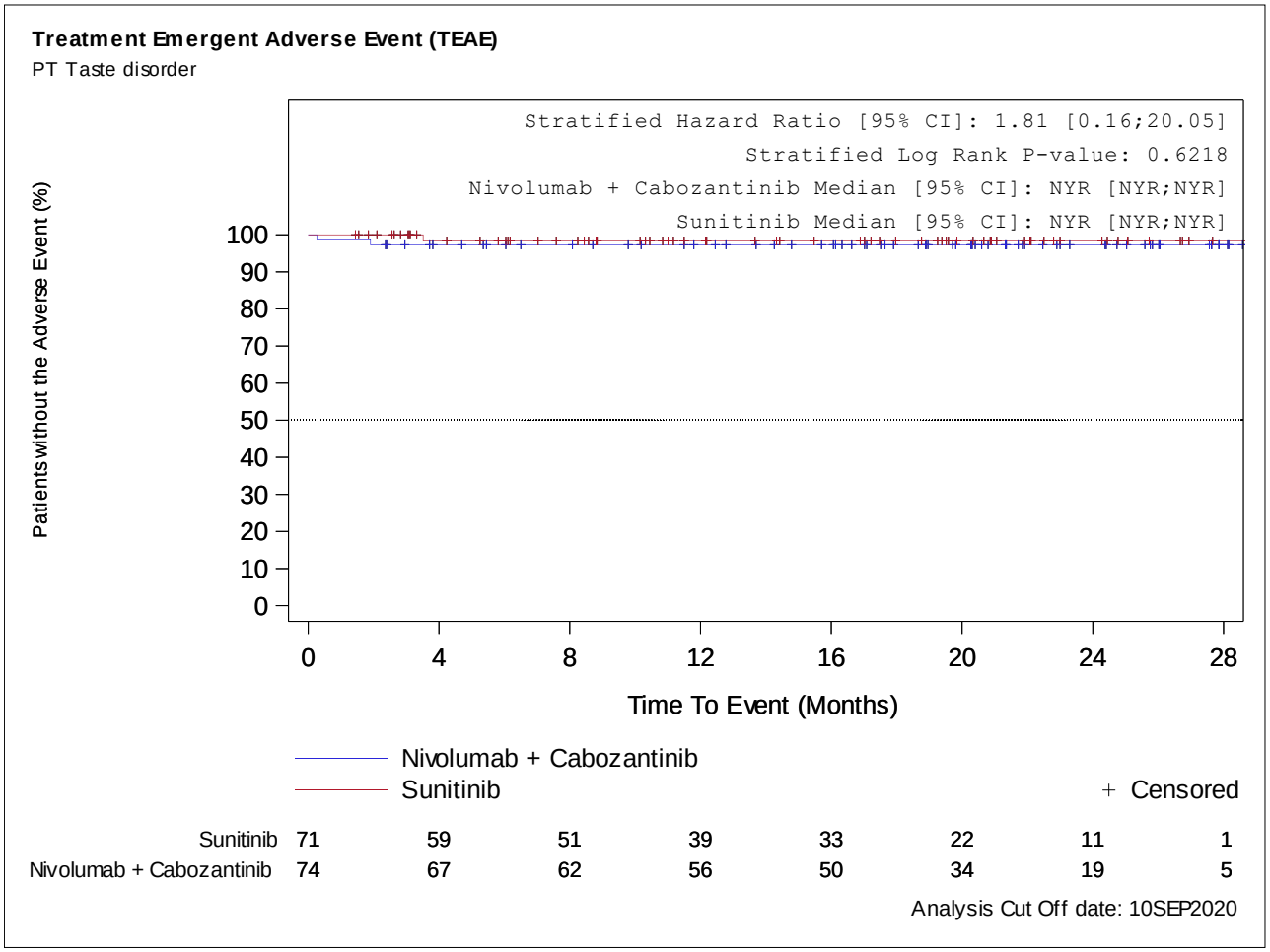
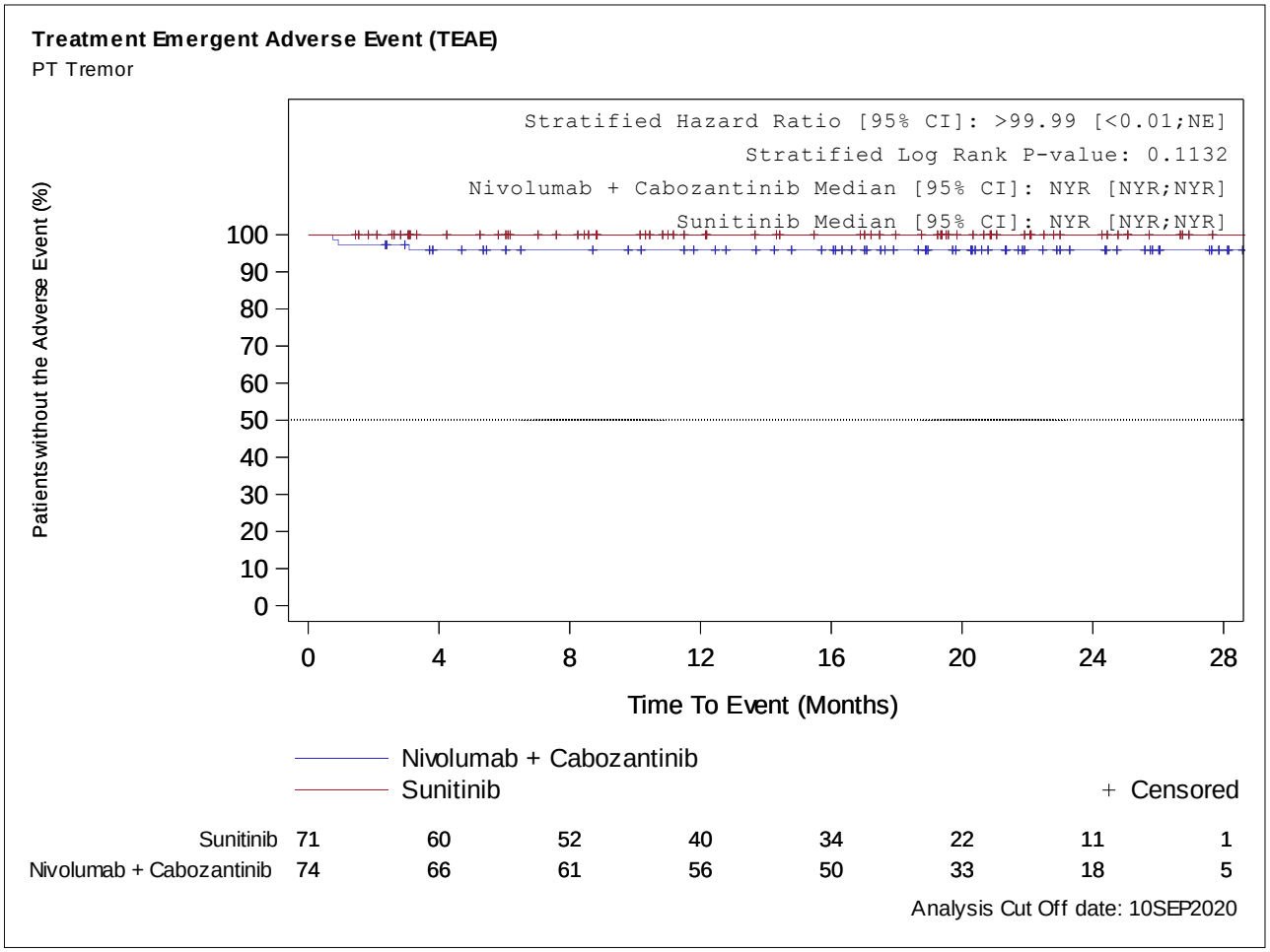
FIGURE 4.1.2.132: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Taste disorder - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



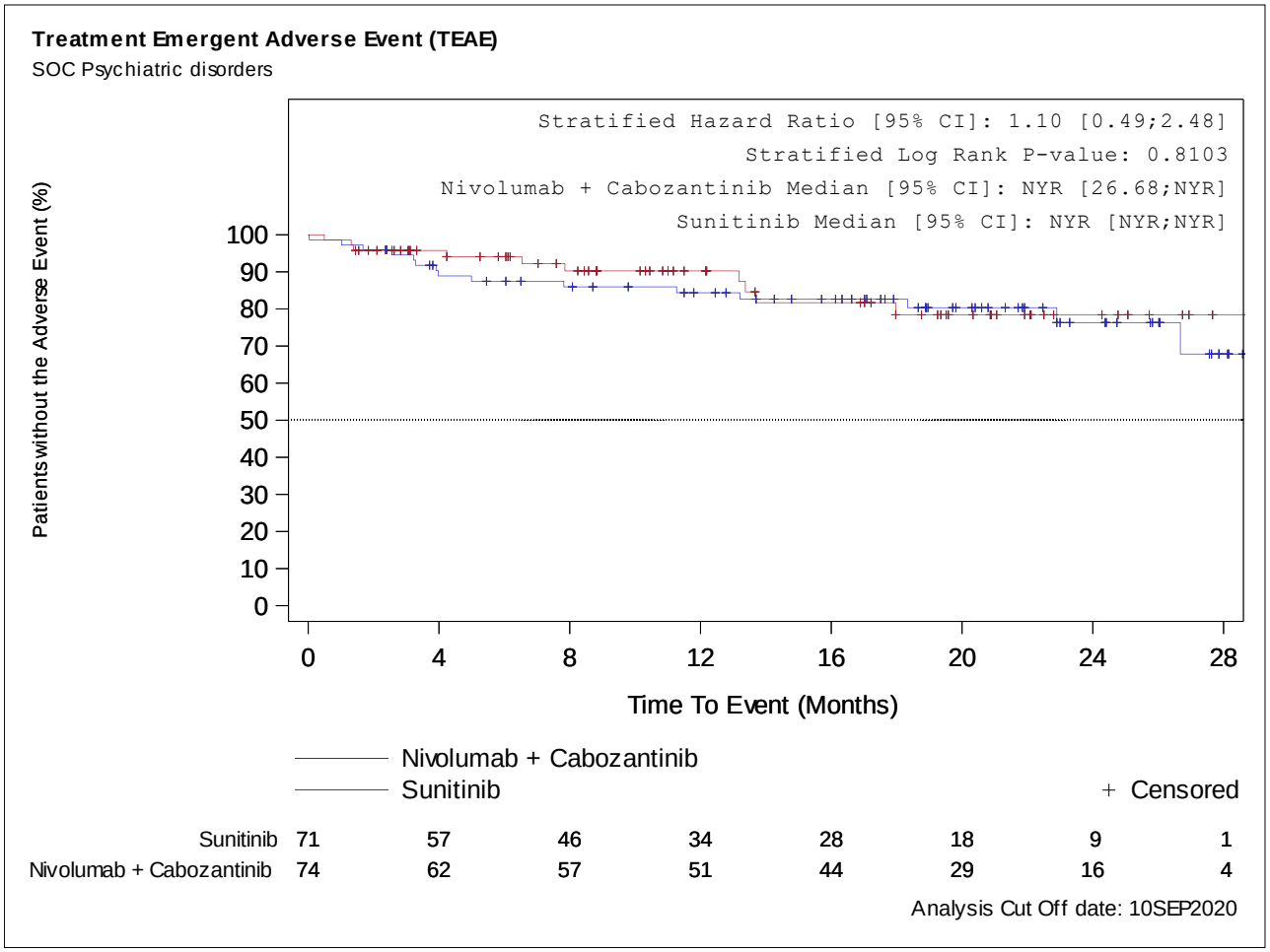

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:01:28

FIGURE 4.1.2.133: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Tremor - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



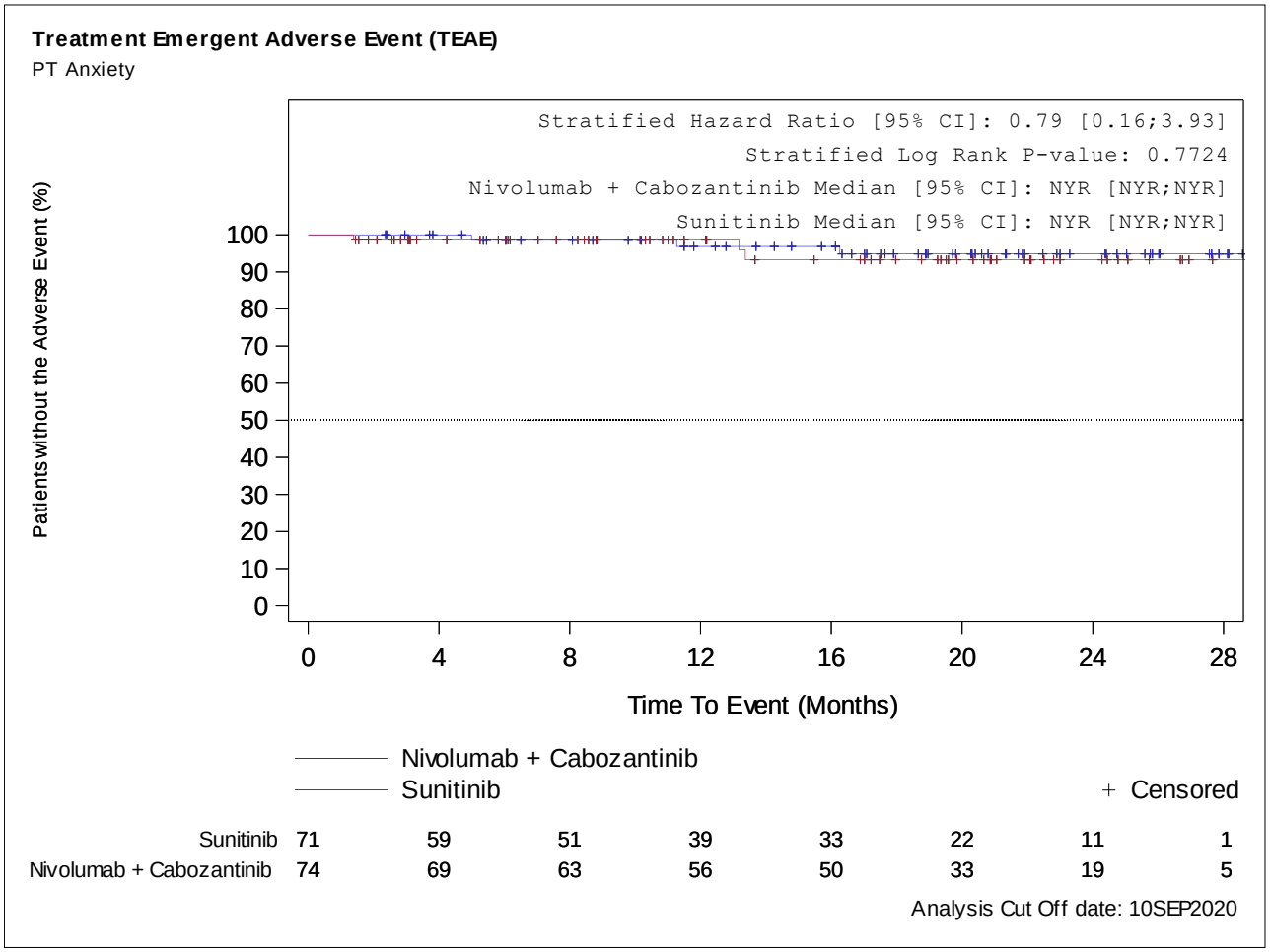

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:01:33

FIGURE 4.1.2.134: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Psychiatric disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:01:39

FIGURE 4.1.2.135: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anxiety - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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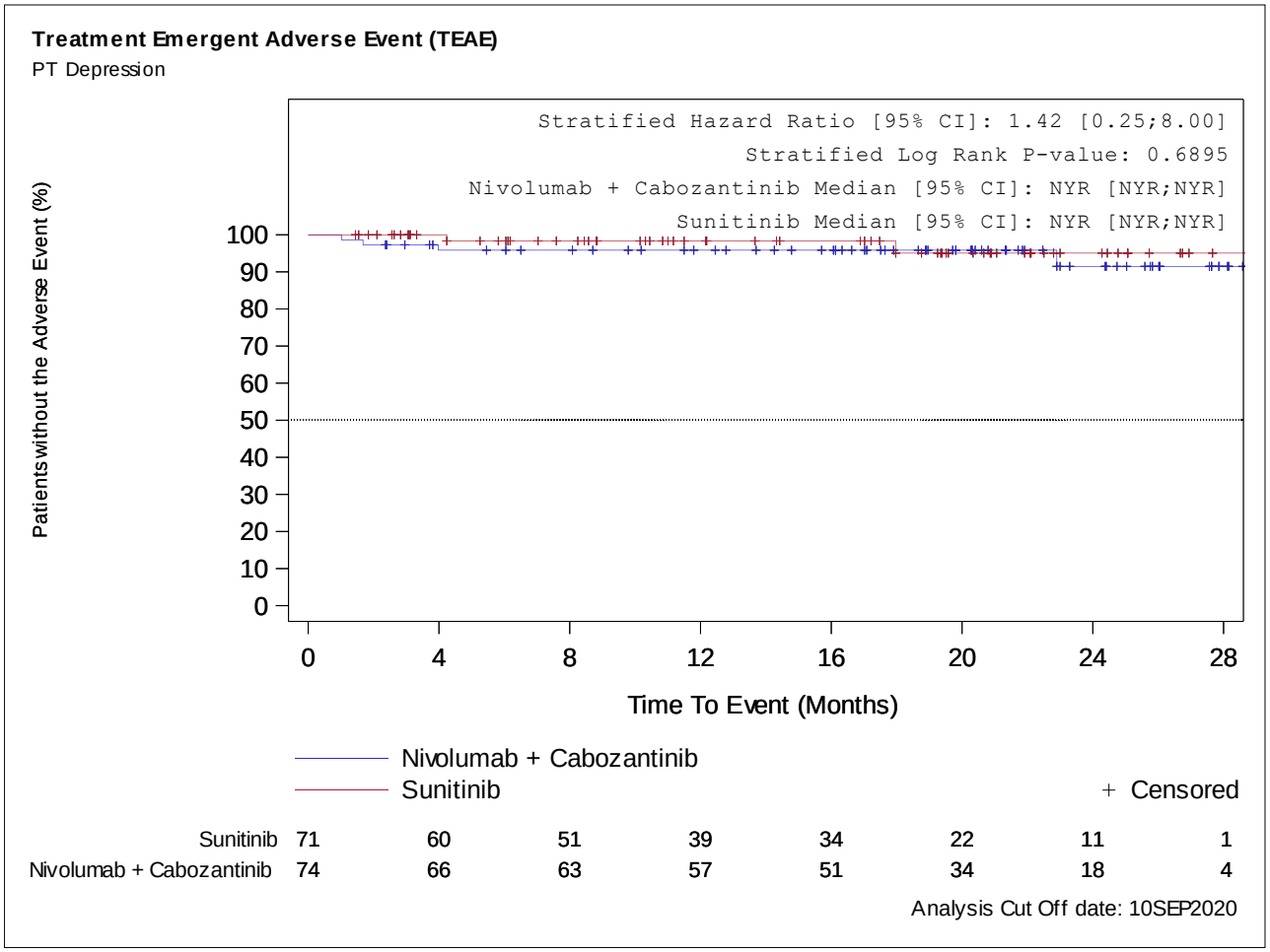
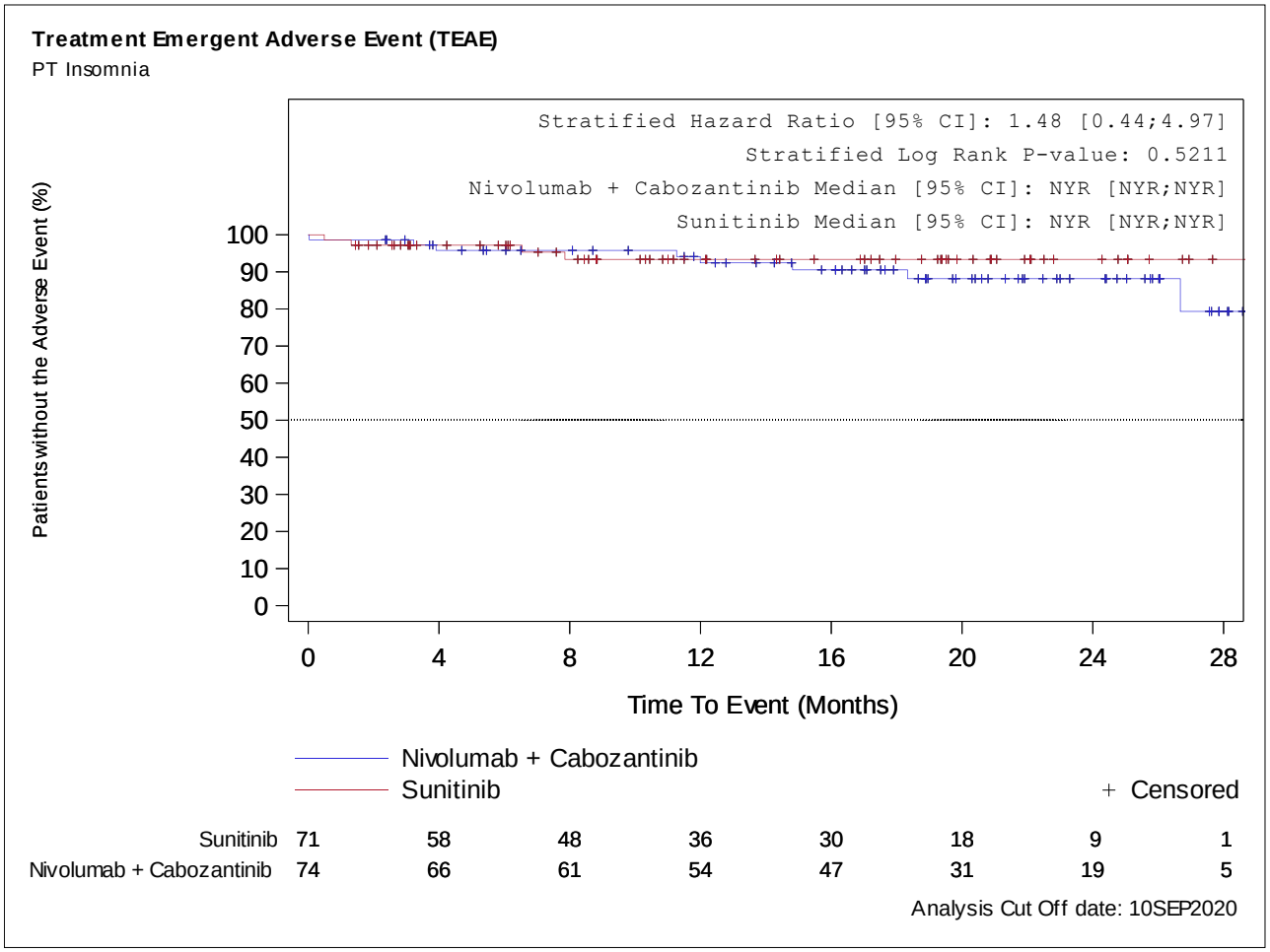
FIGURE 4.1.2.136: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Depression - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



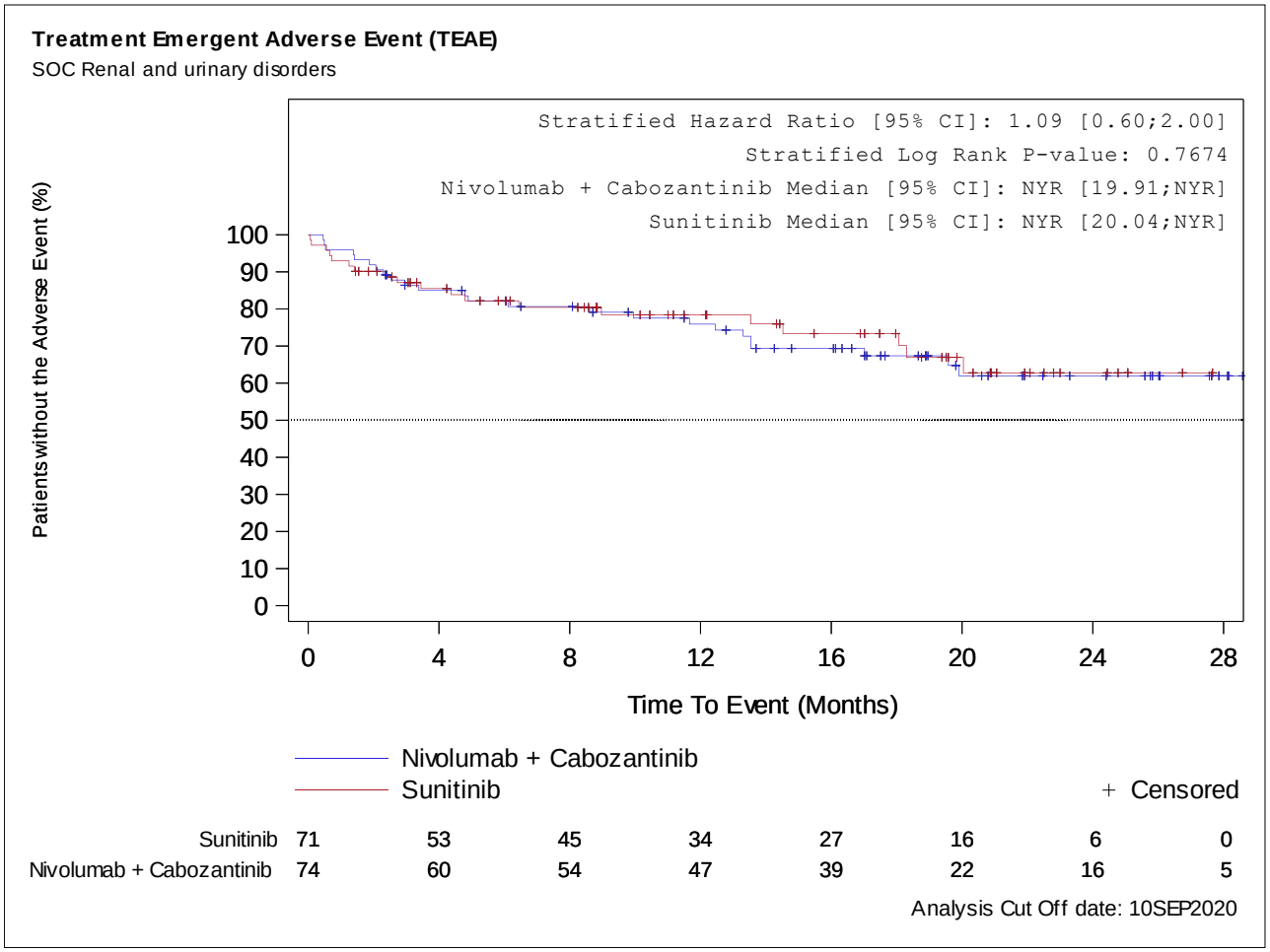

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:01:48

FIGURE 4.1.2.137: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Insomnia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:01:52

FIGURE 4.1.2.138: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Renal and urinary disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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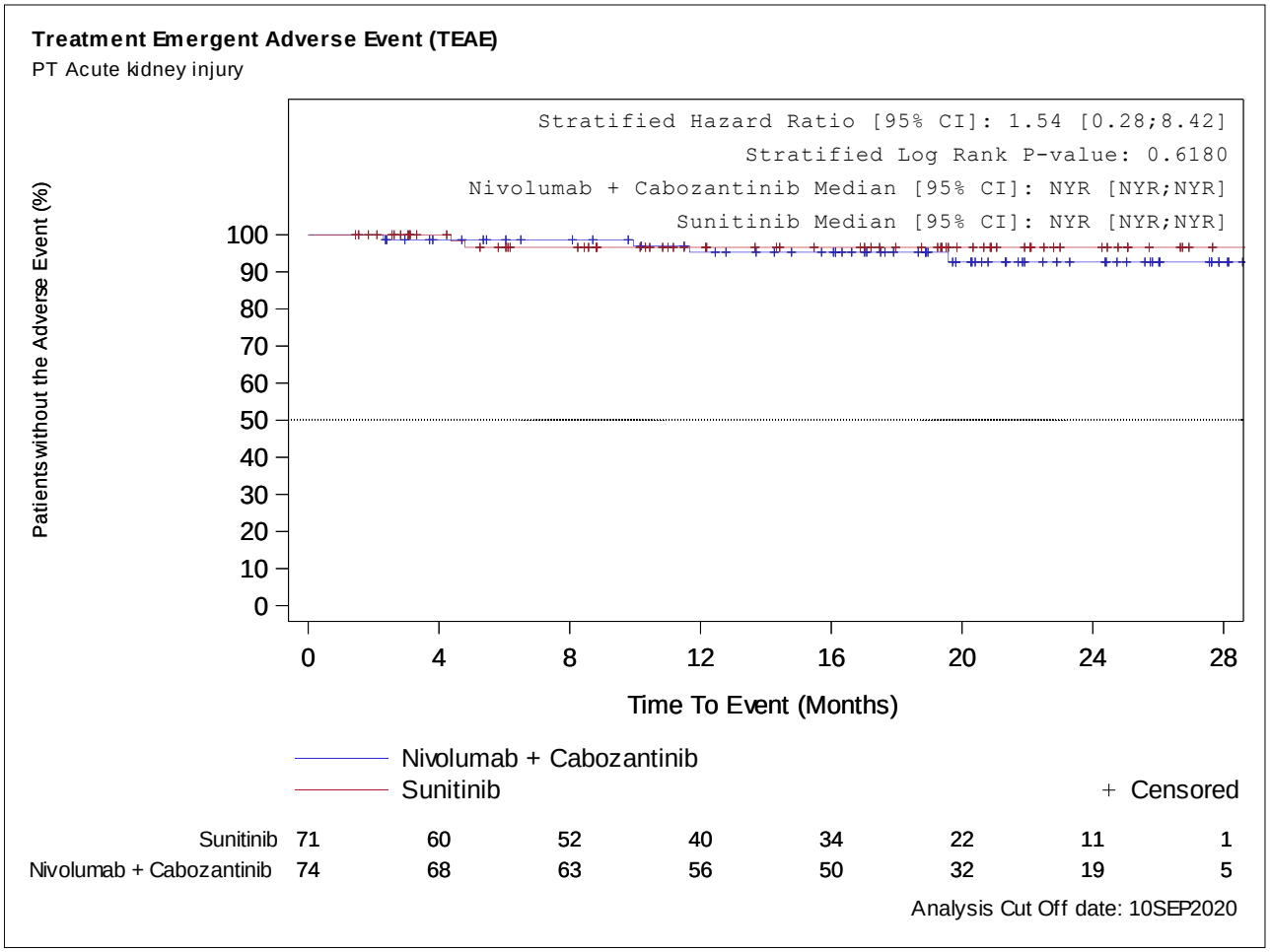
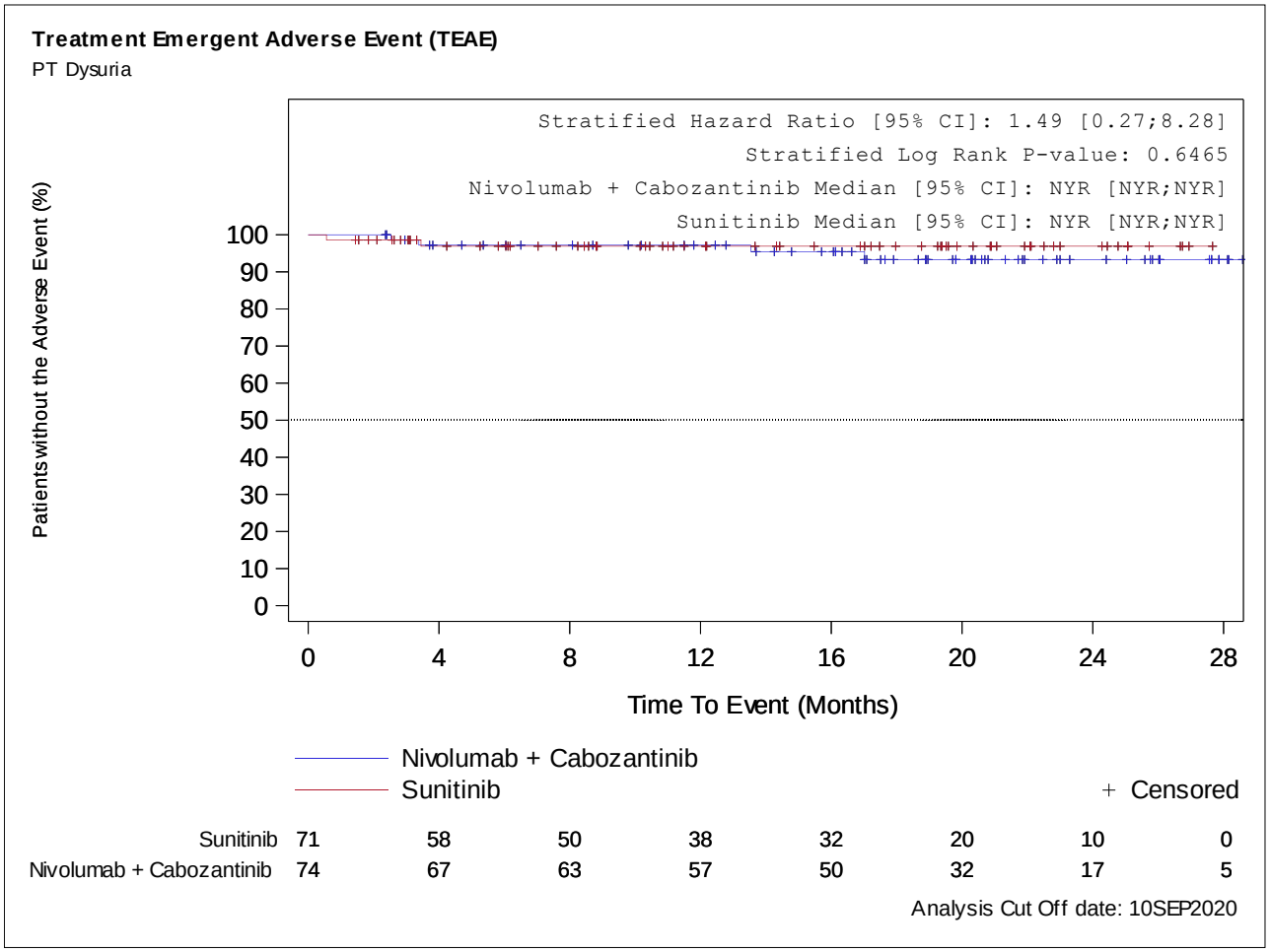
FIGURE 4.1.2.139: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Acute kidney injury - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:02:00

FIGURE 4.1.2.140: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysuria - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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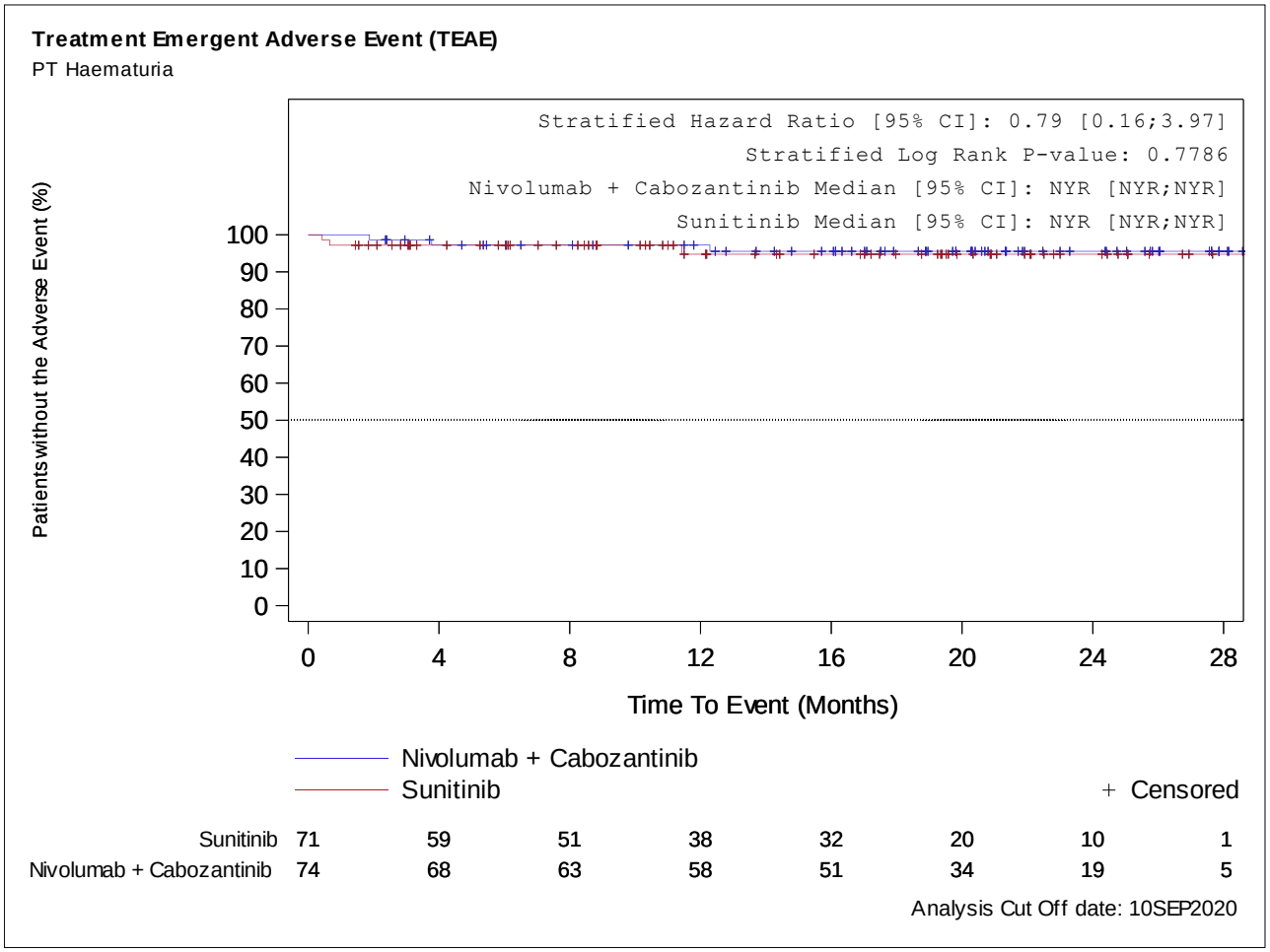
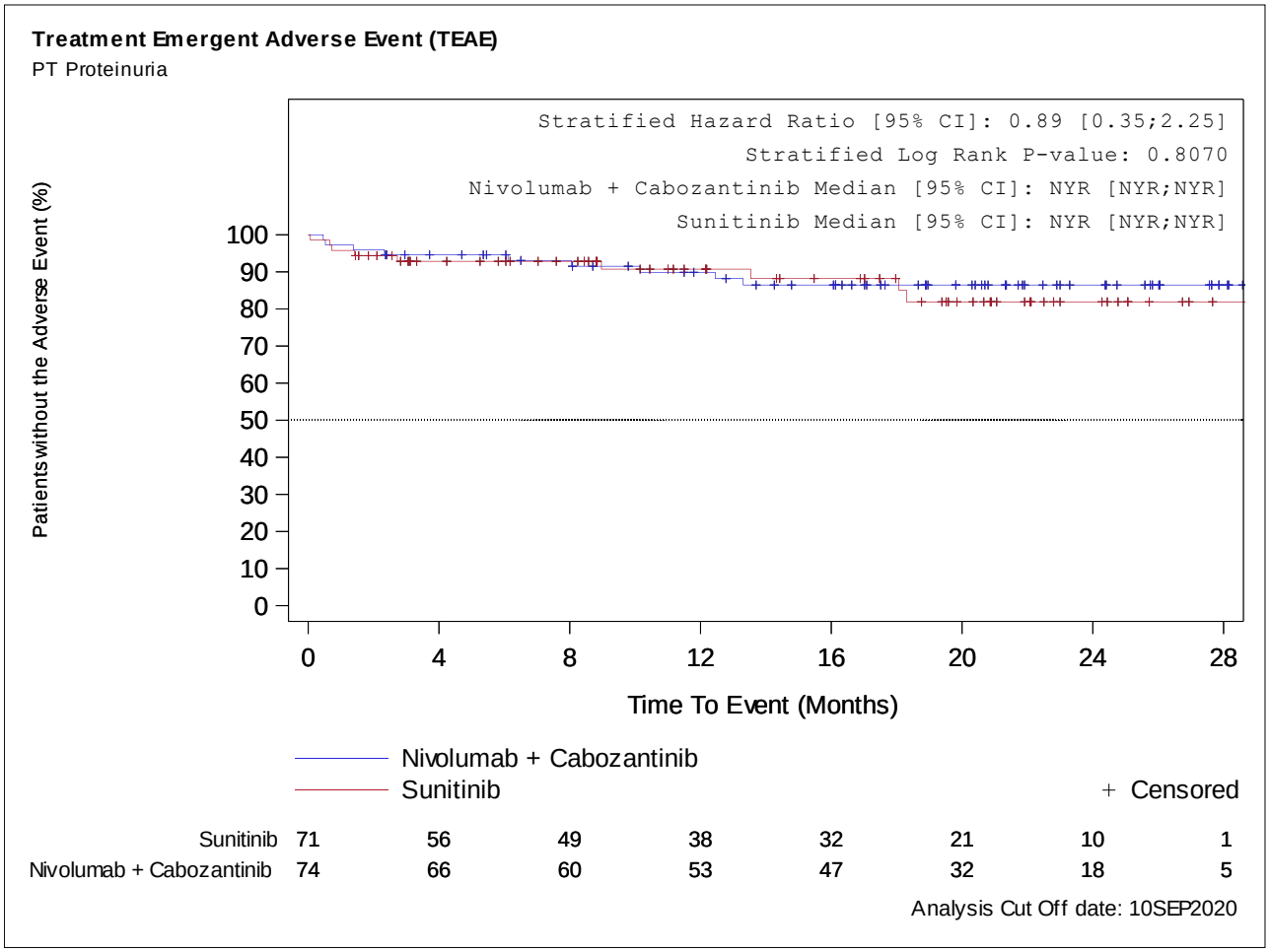
FIGURE 4.1.2.141: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Haematuria - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



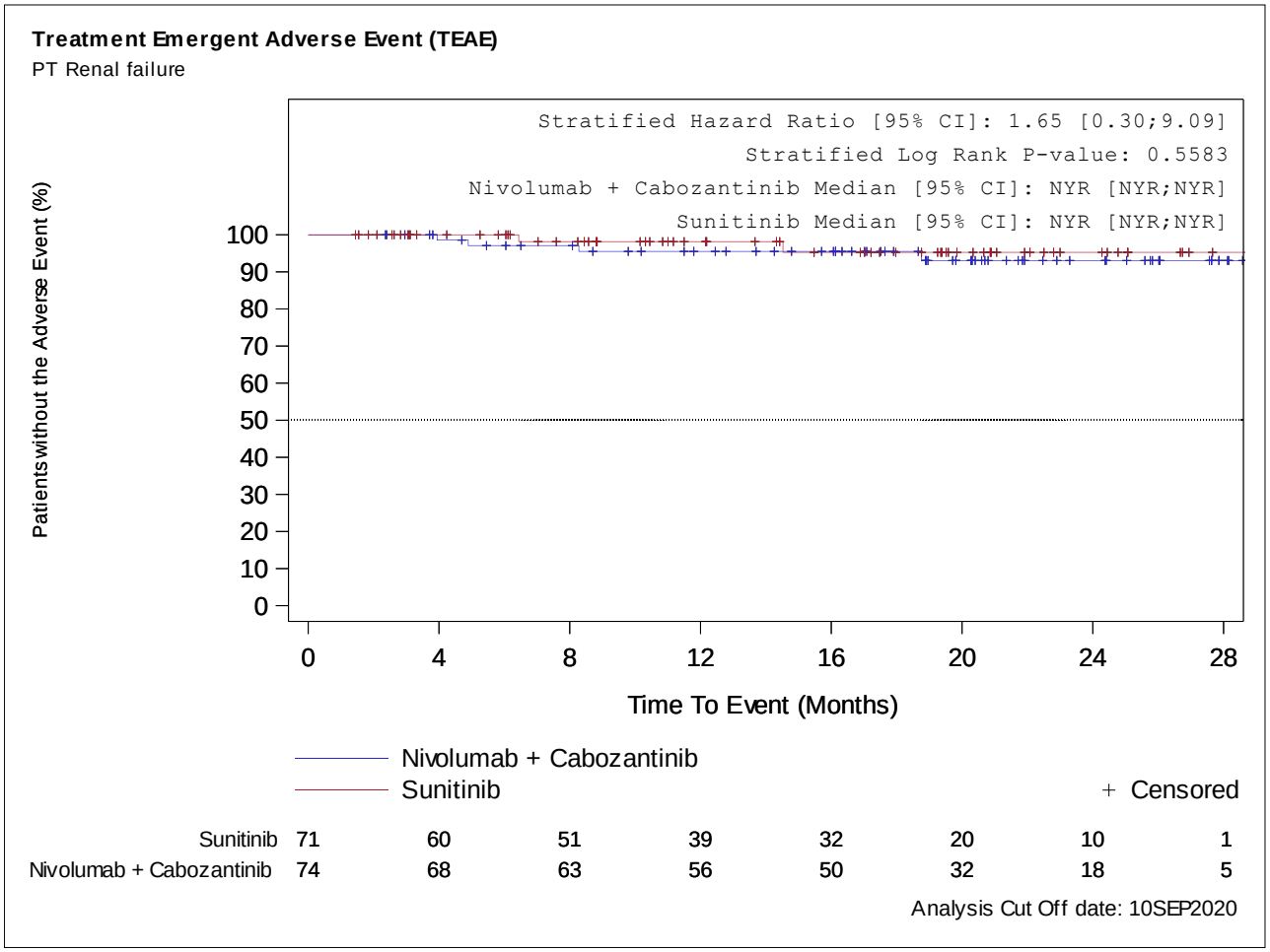

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:02:09

FIGURE 4.1.2.142: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Proteinuria - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:02:13

FIGURE 4.1.2.143: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Renal failure - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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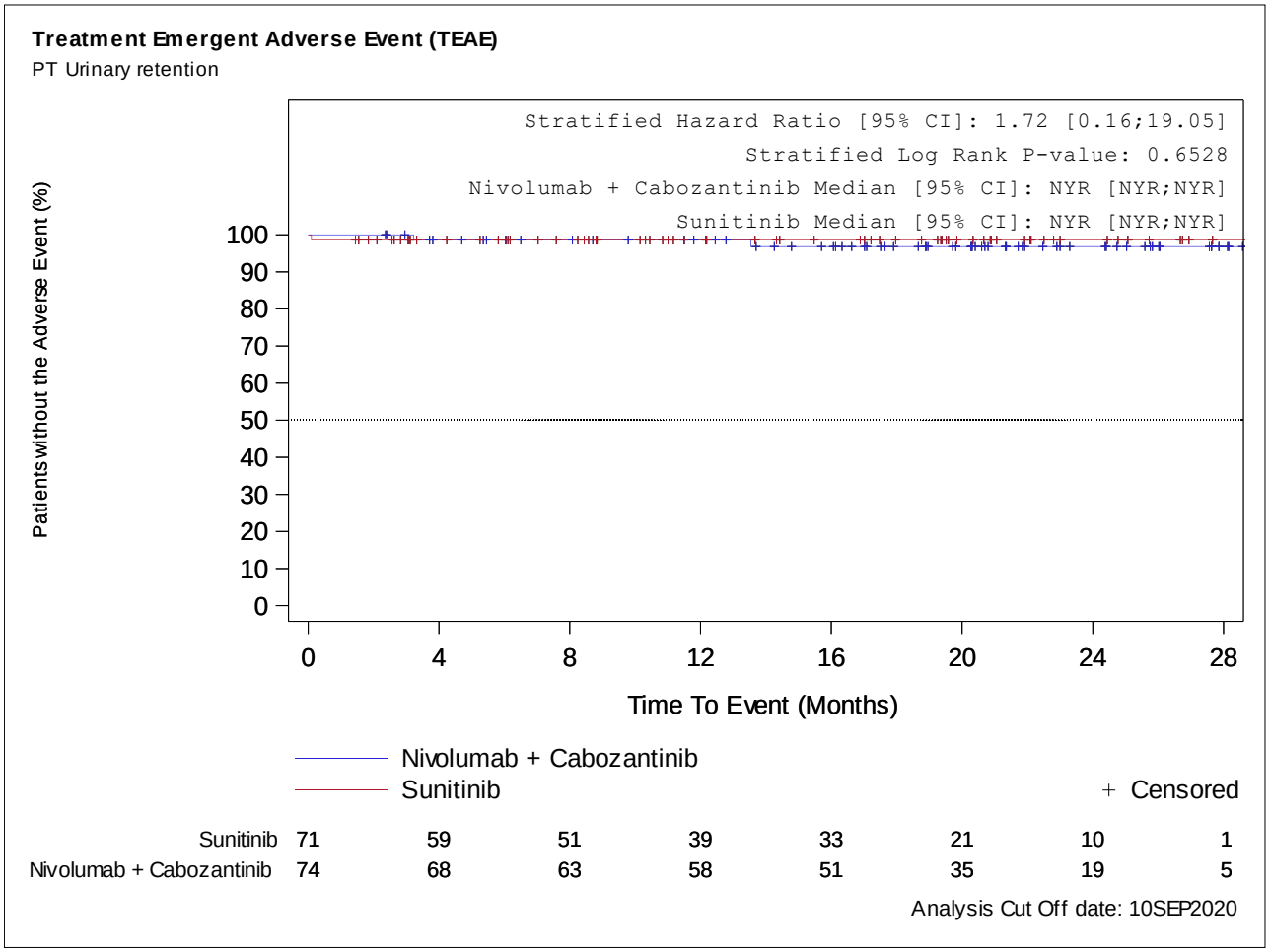
FIGURE 4.1.2.144: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Urinary retention - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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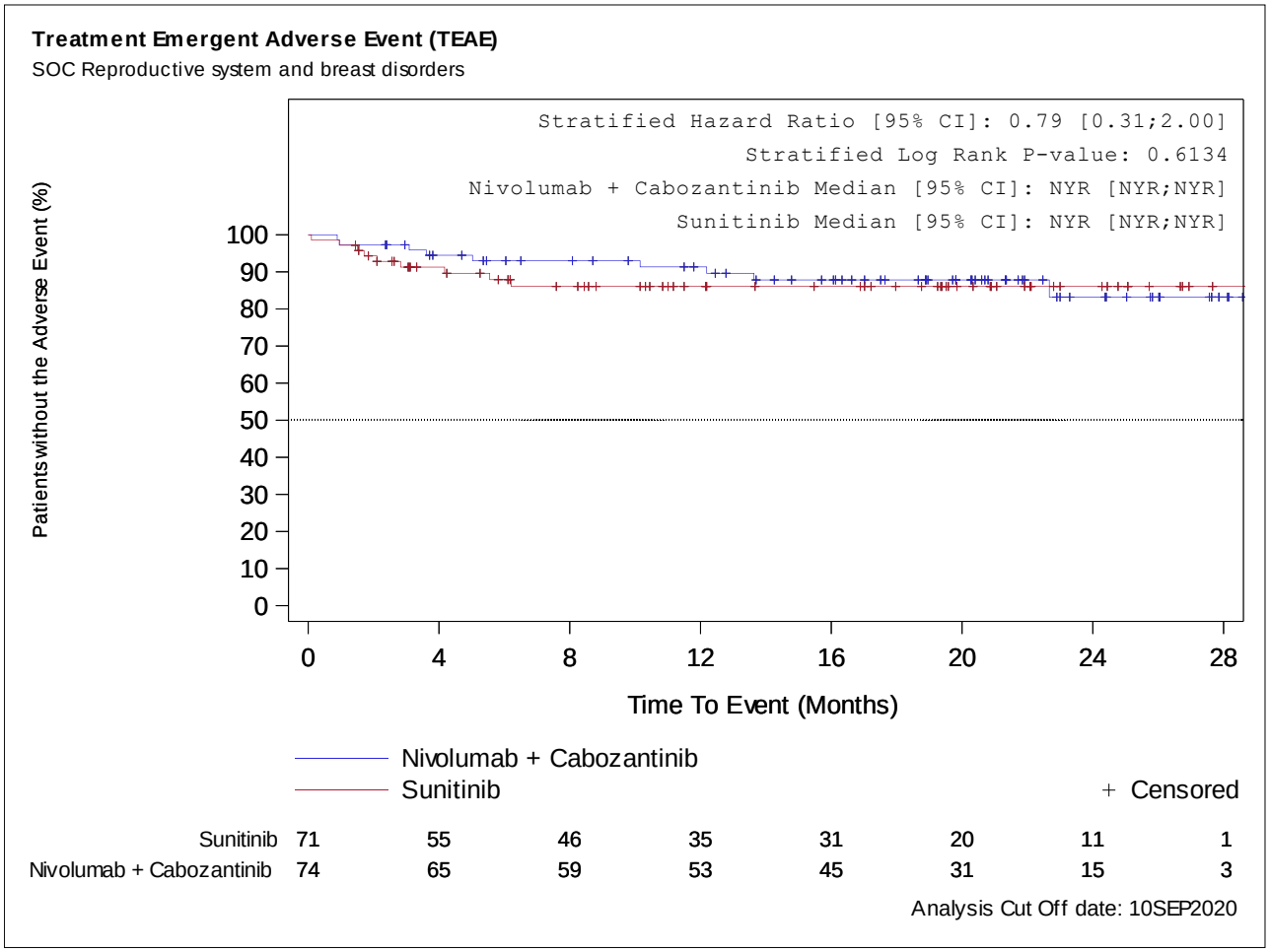
FIGURE 4.1.2.145: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Reproductive system and breast disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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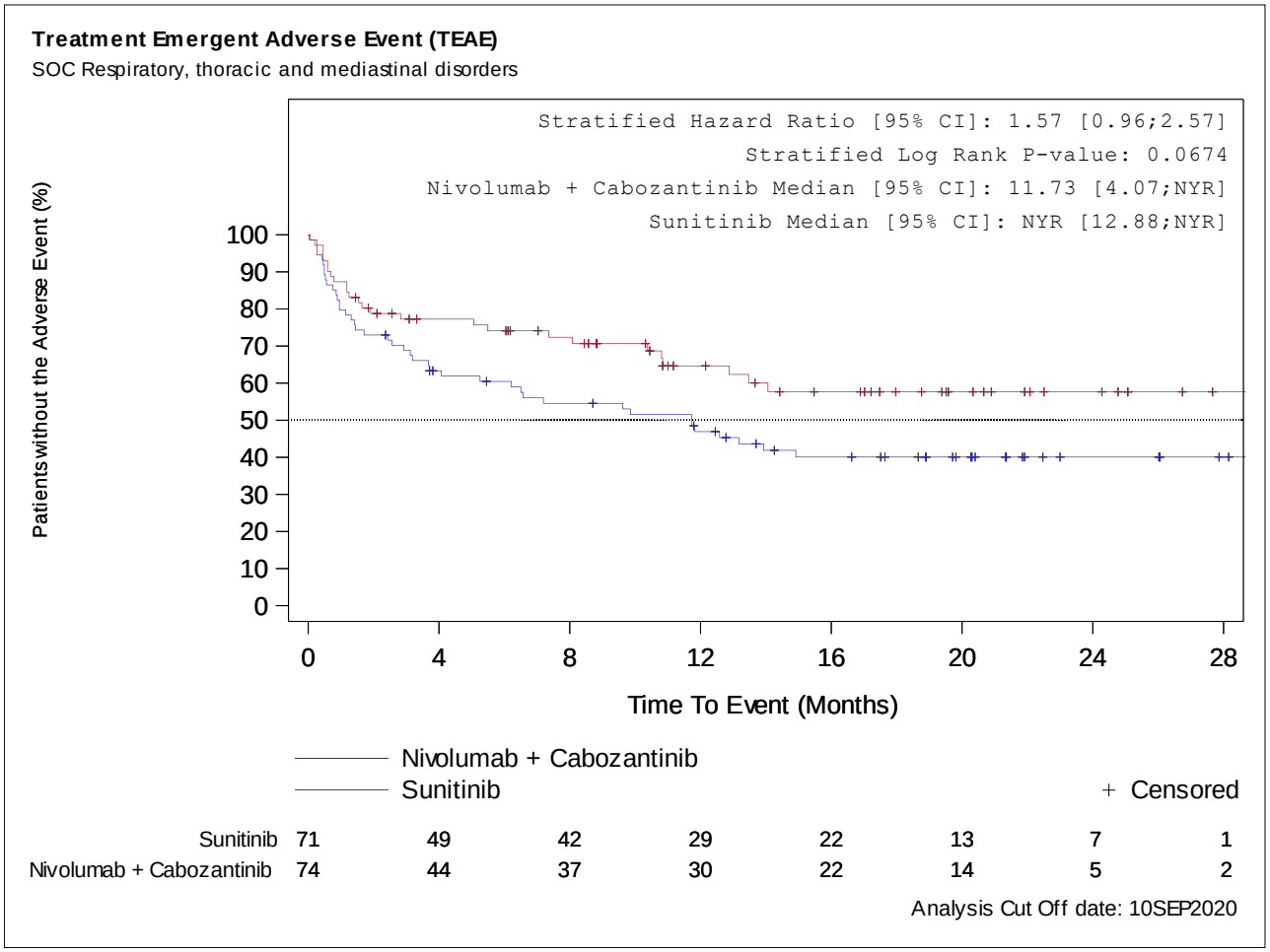
FIGURE 4.1.2.146: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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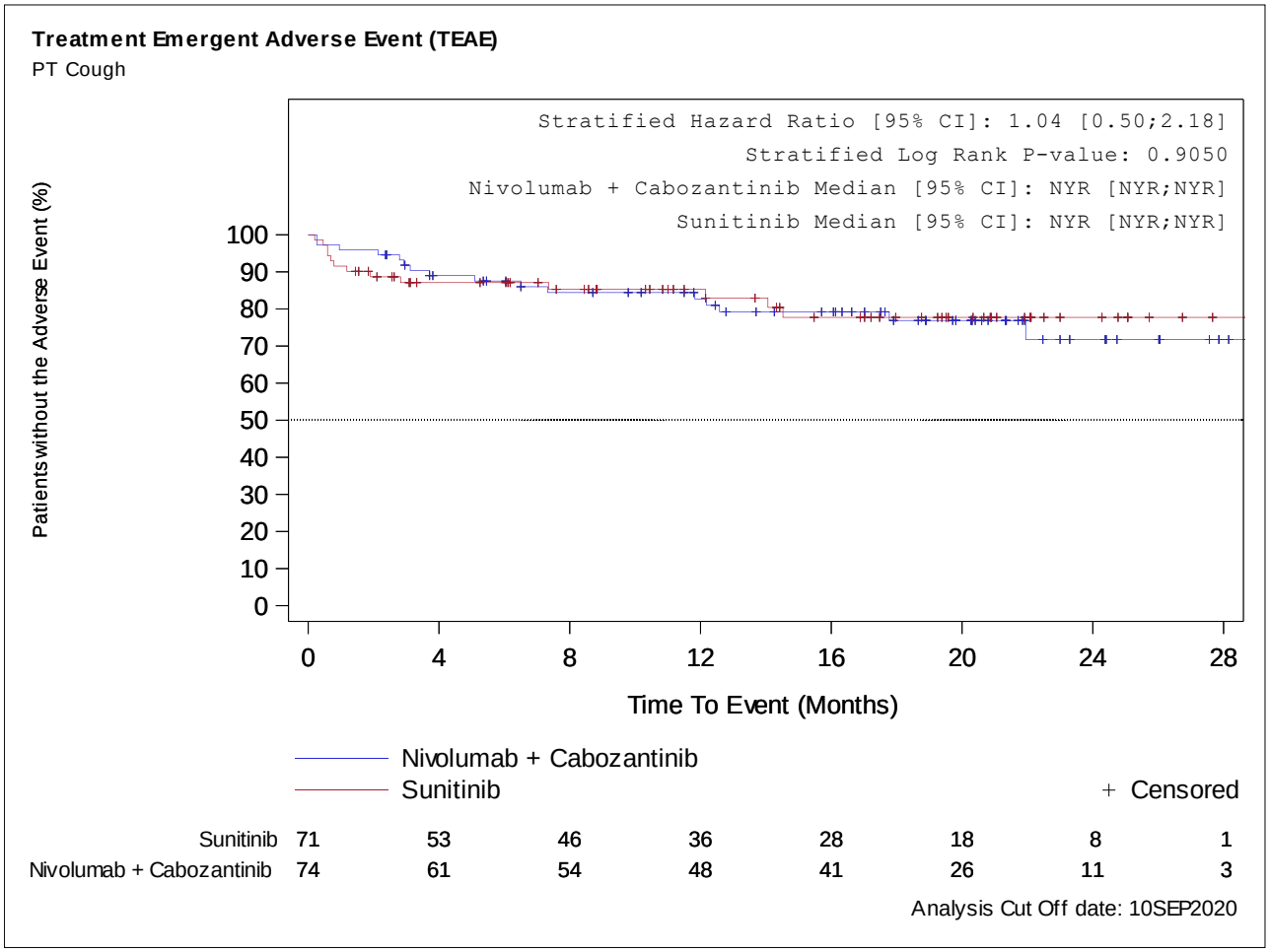
FIGURE 4.1.2.147: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Cough - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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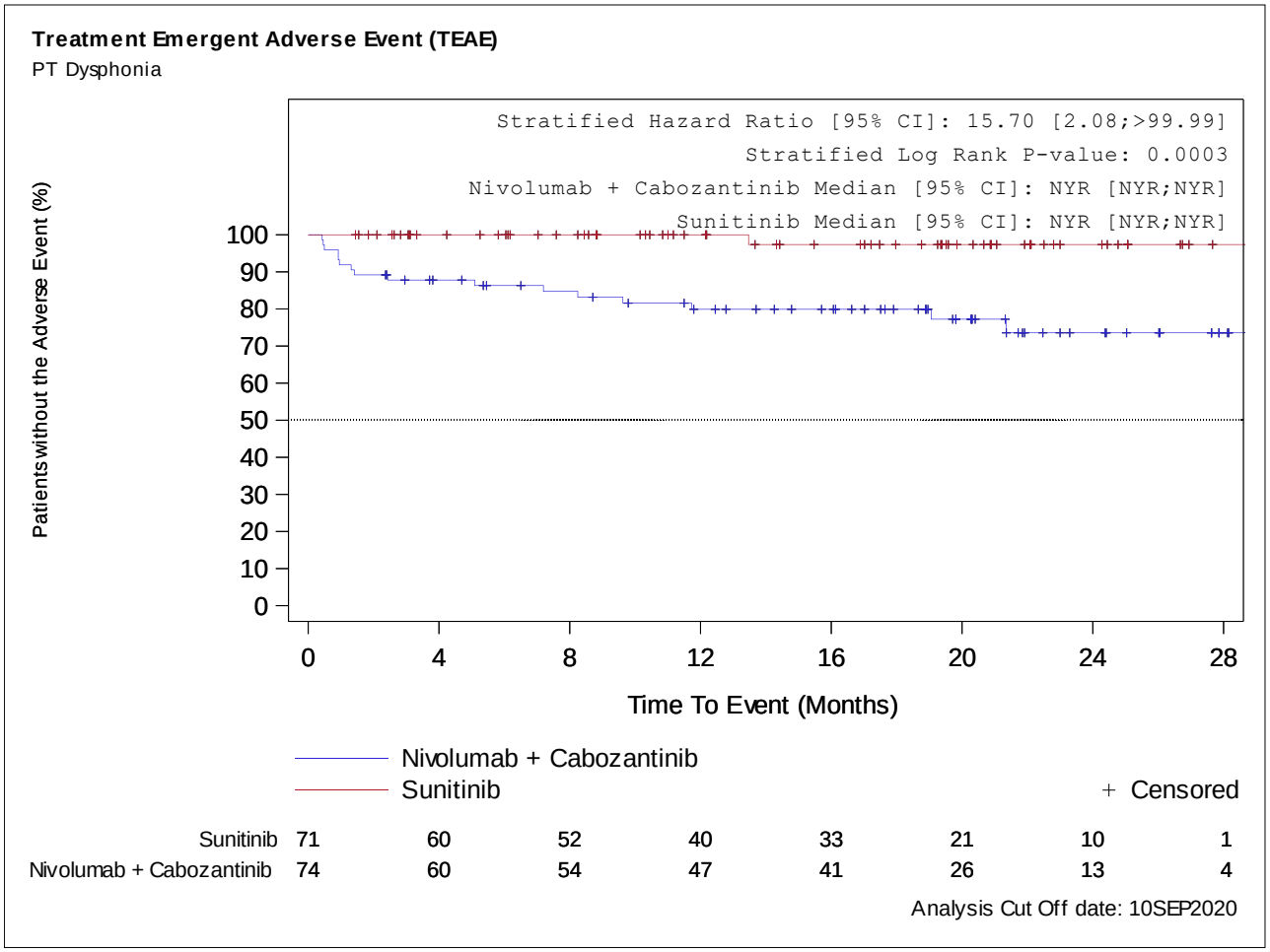
FIGURE 4.1.2.148: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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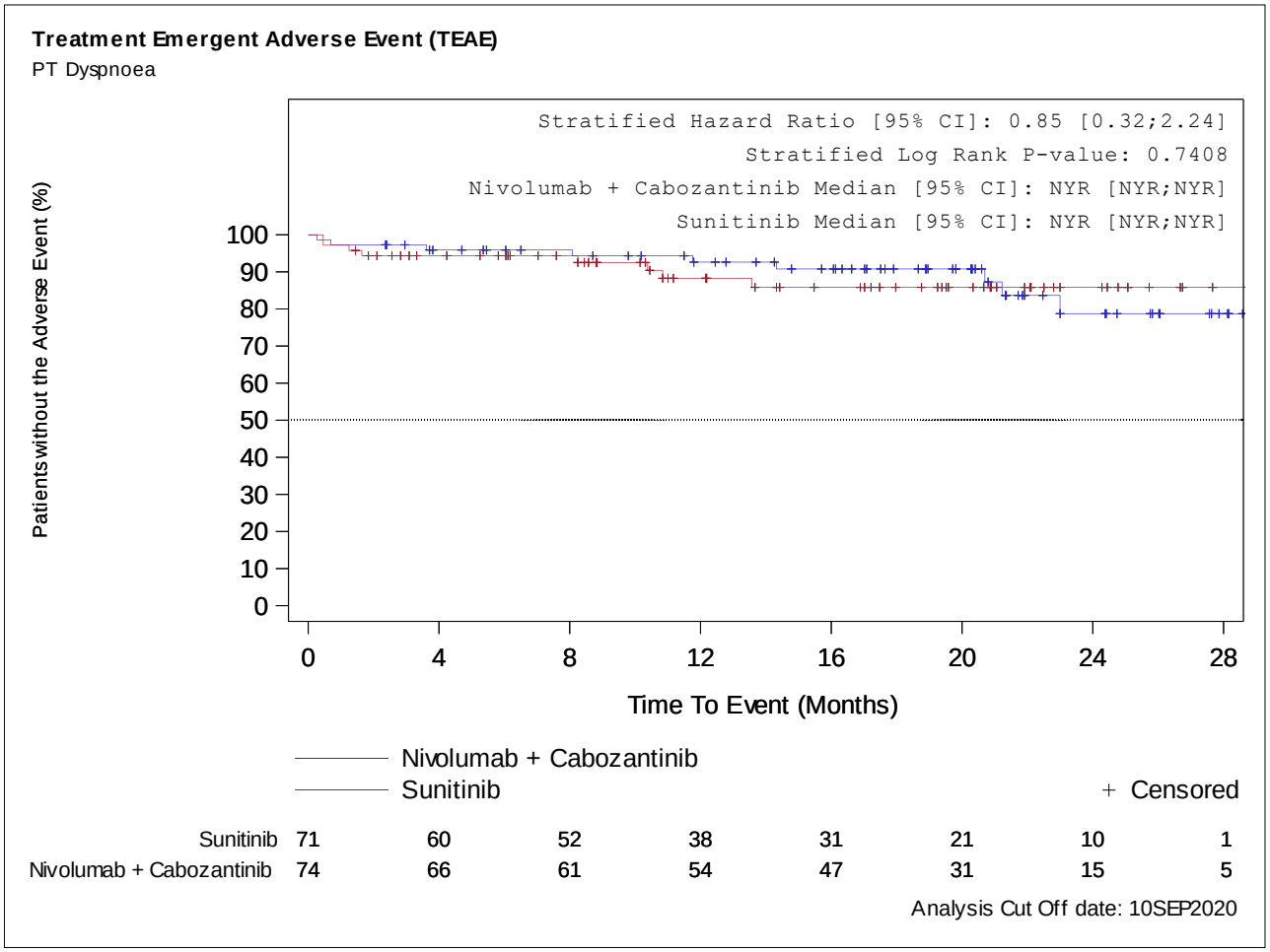
FIGURE 4.1.2.149: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dyspnoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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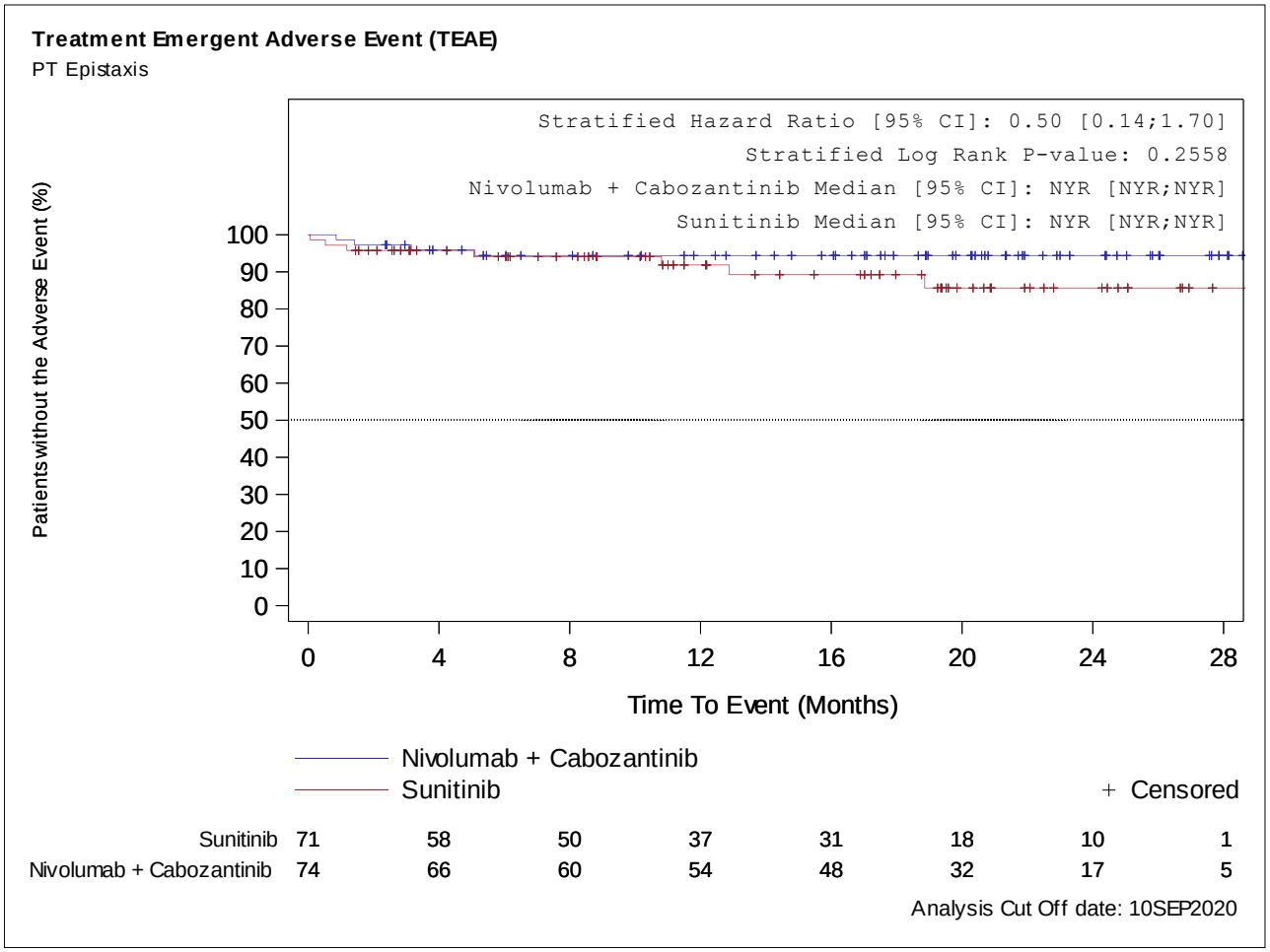
FIGURE 4.1.2.150: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Epistaxis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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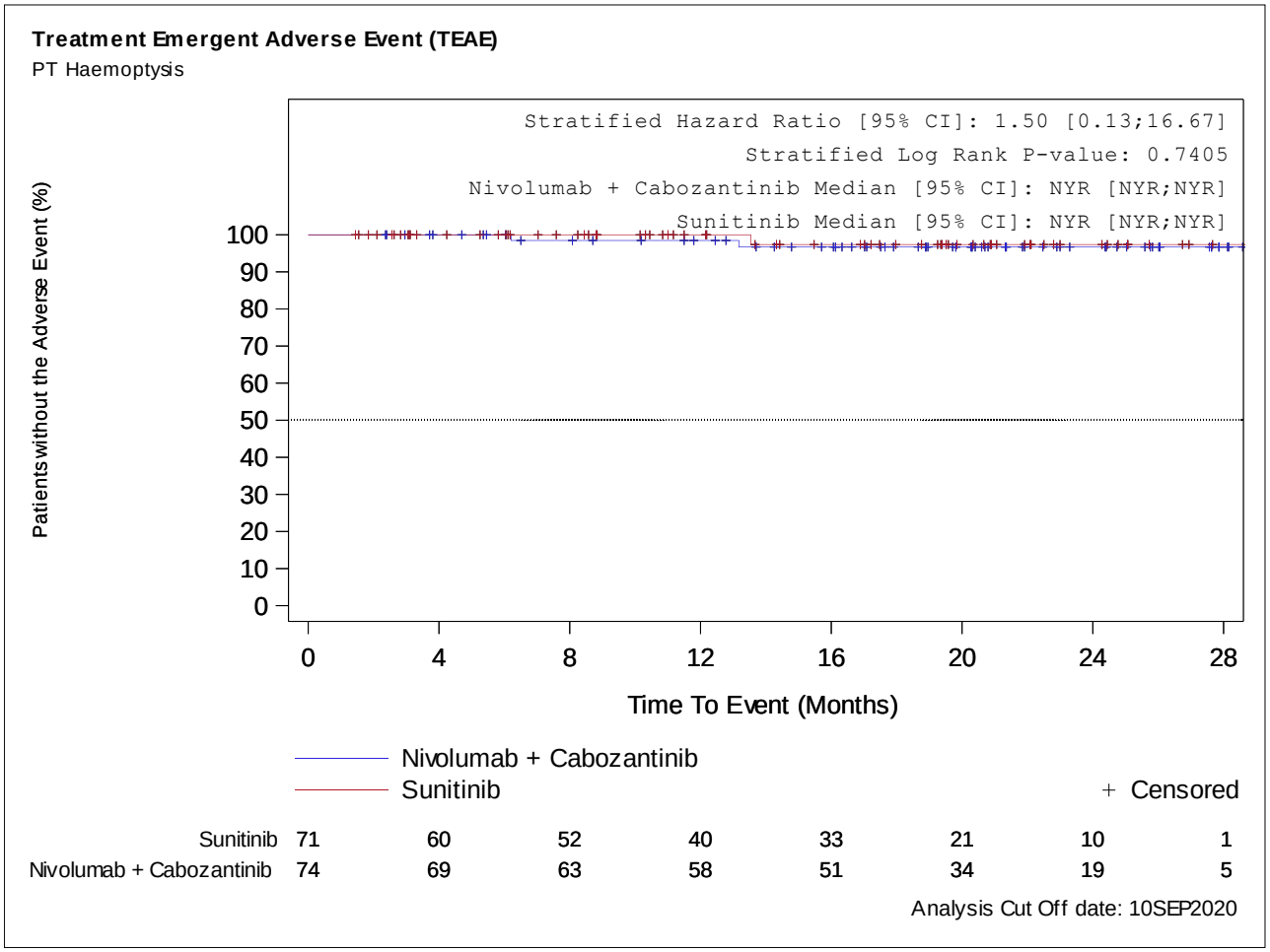
FIGURE 4.1.2.151: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Haemoptysis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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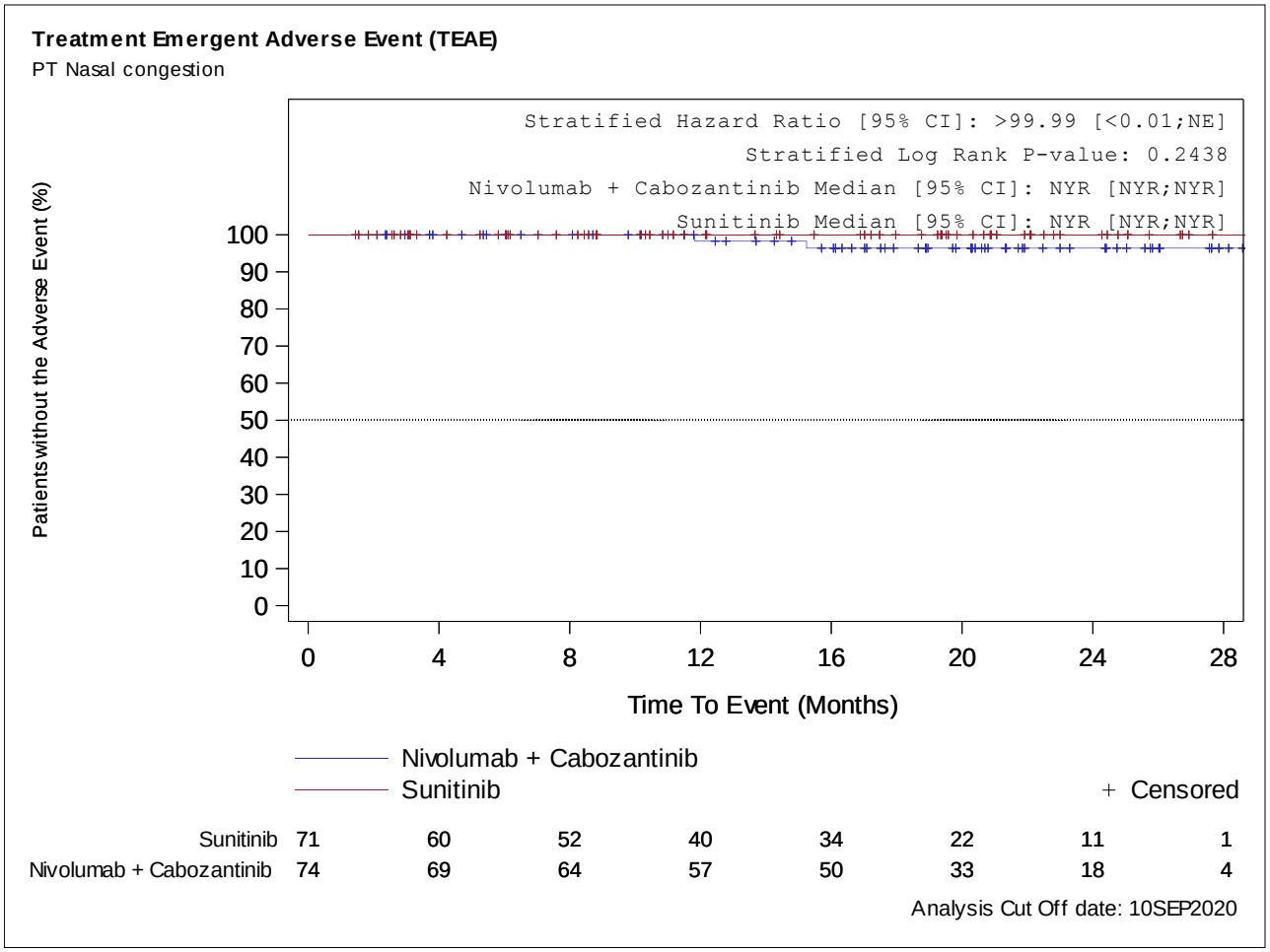
FIGURE 4.1.2.152: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Nasal congestion - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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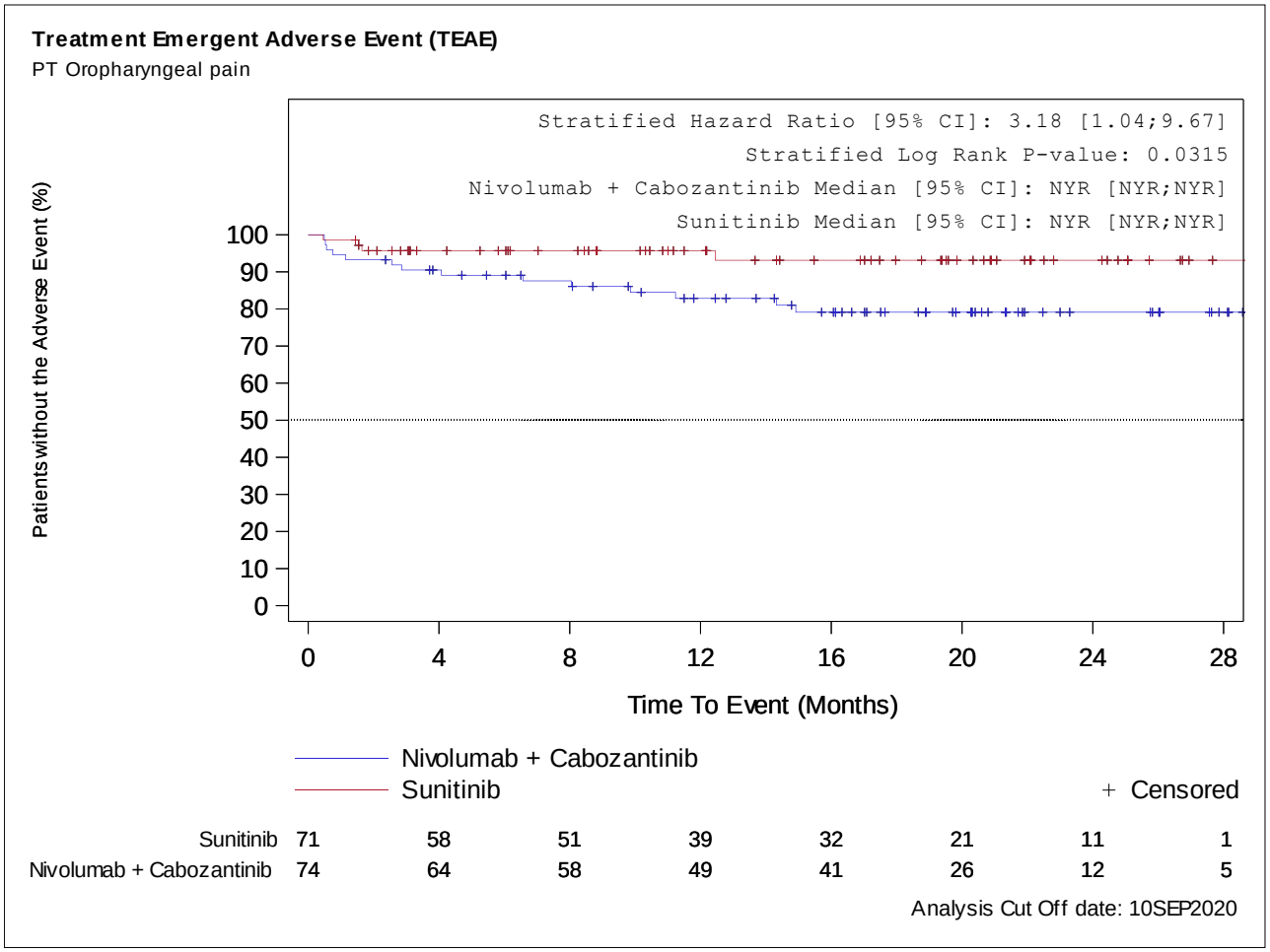
FIGURE 4.1.2.153: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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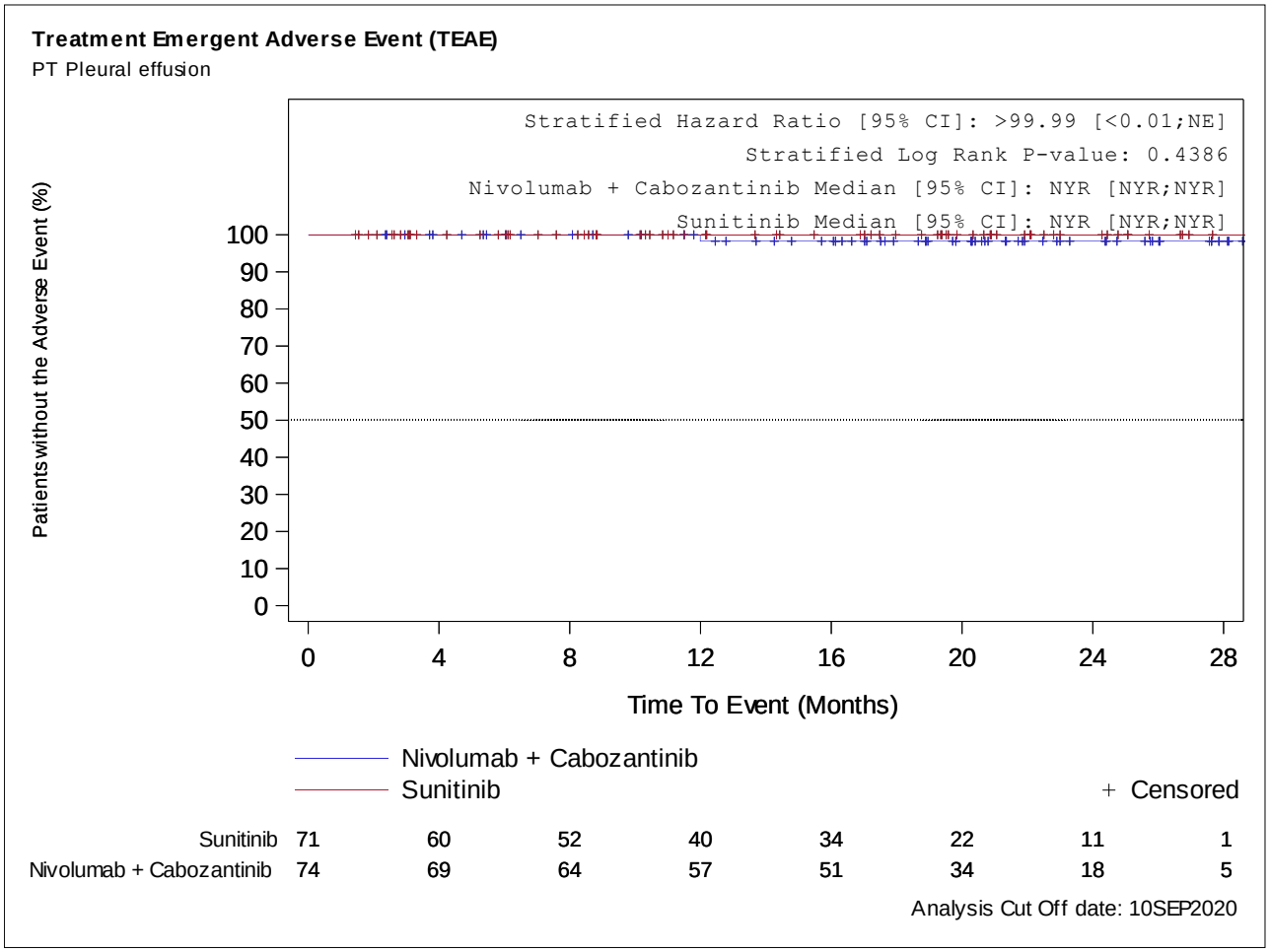
FIGURE 4.1.2.154: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pleural effusion - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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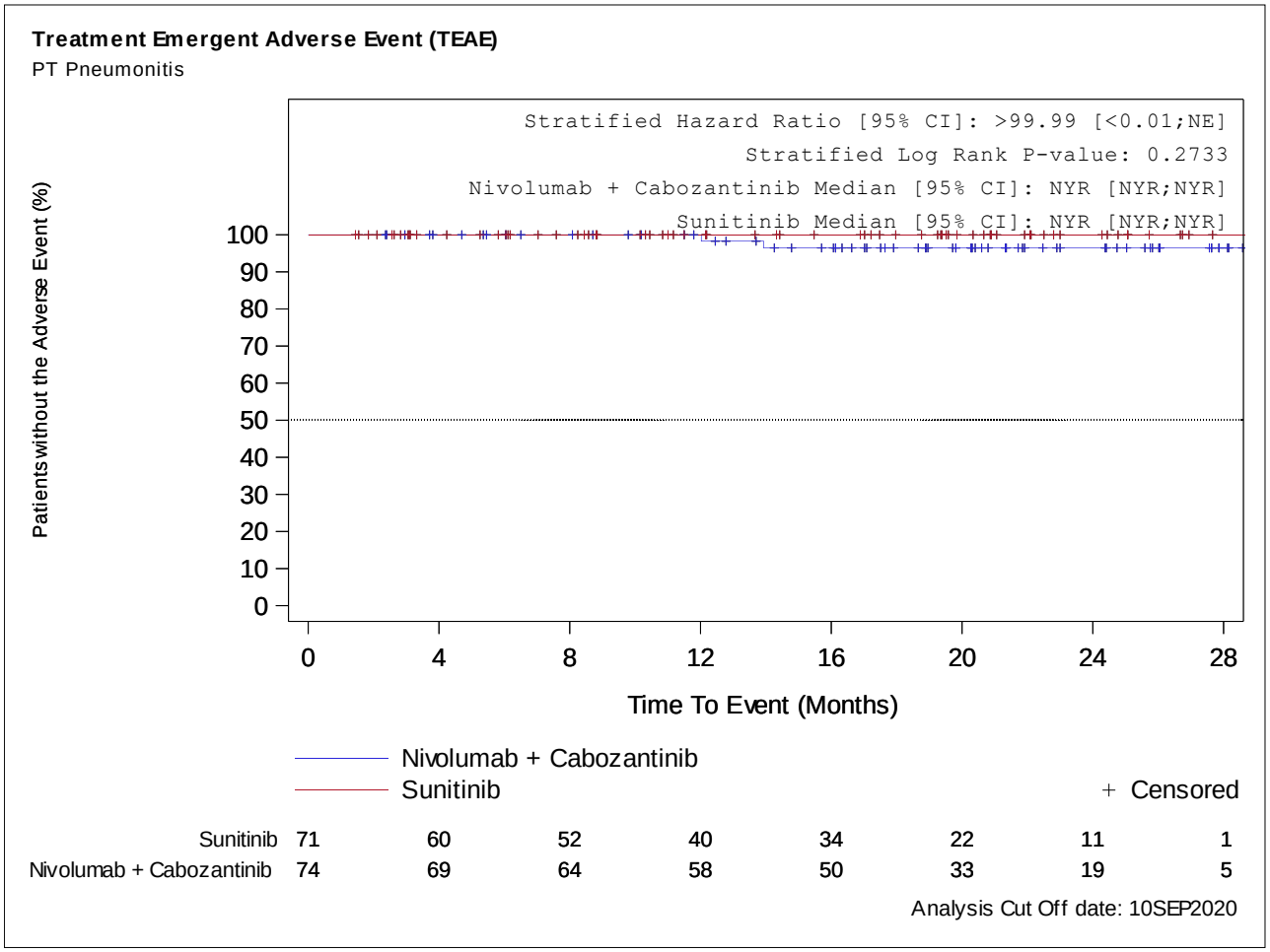
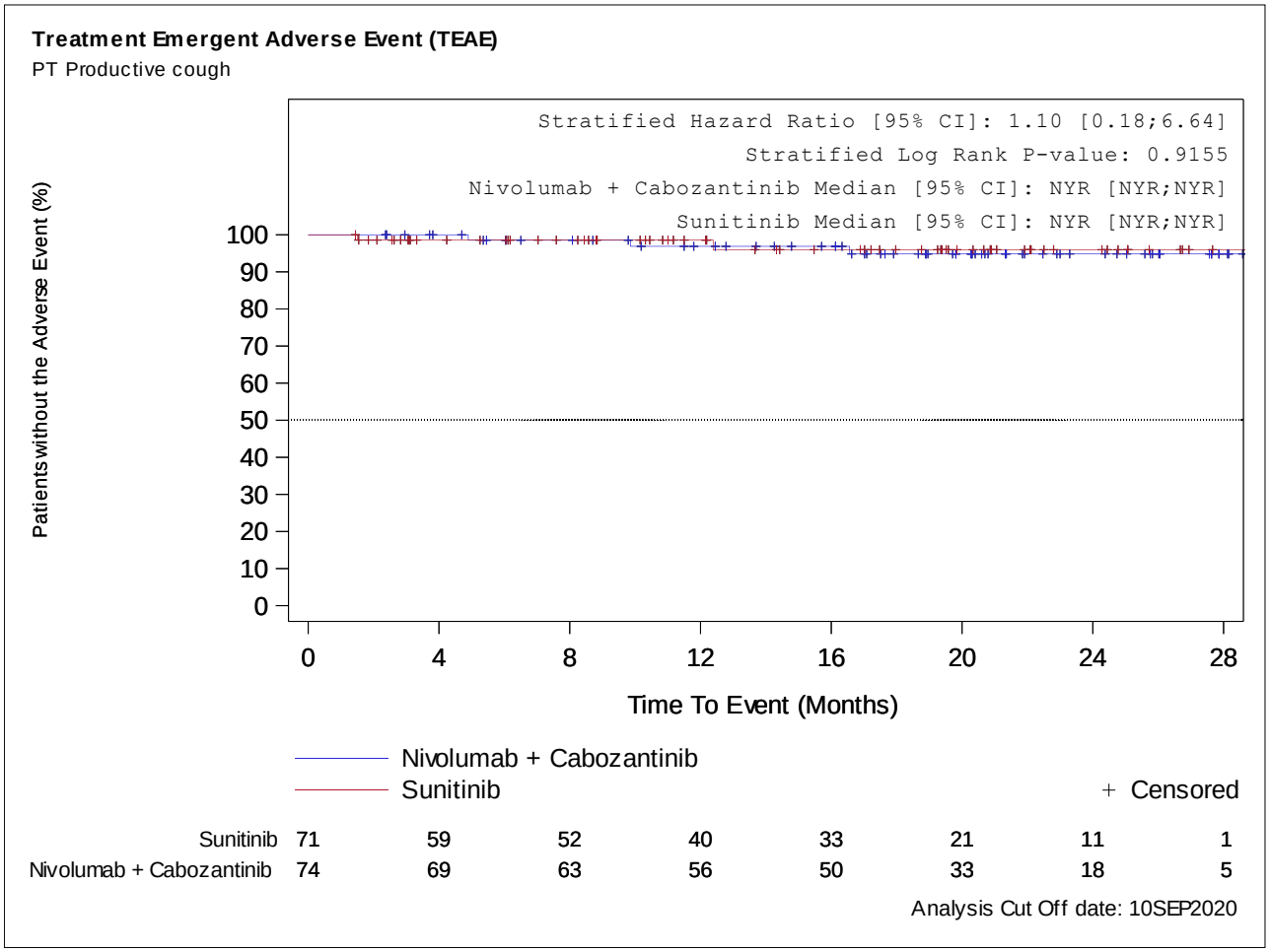
FIGURE 4.1.2.155: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pneumonitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:03:09

FIGURE 4.1.2.156: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Productive cough - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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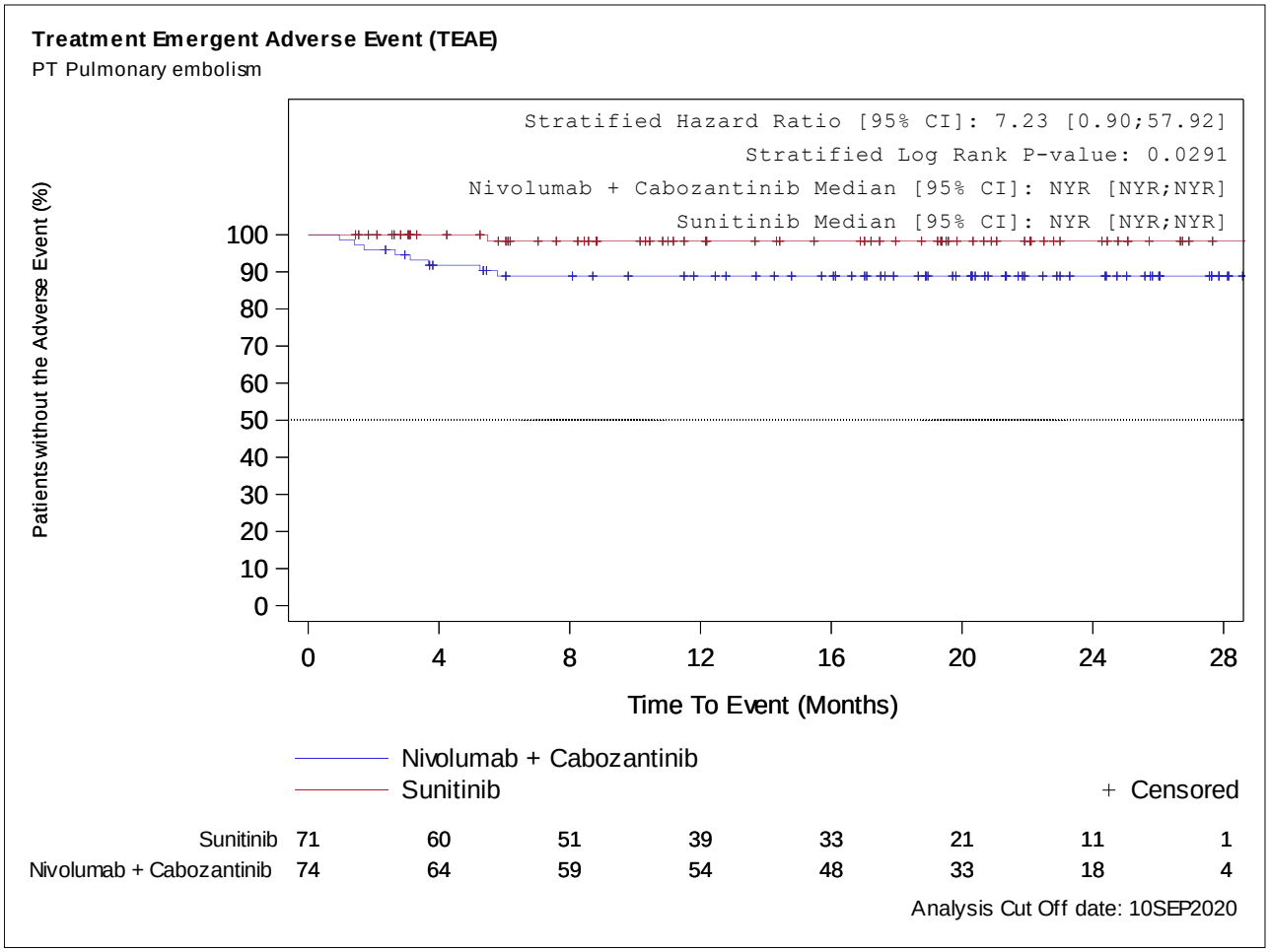
FIGURE 4.1.2.157: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pulmonary embolism - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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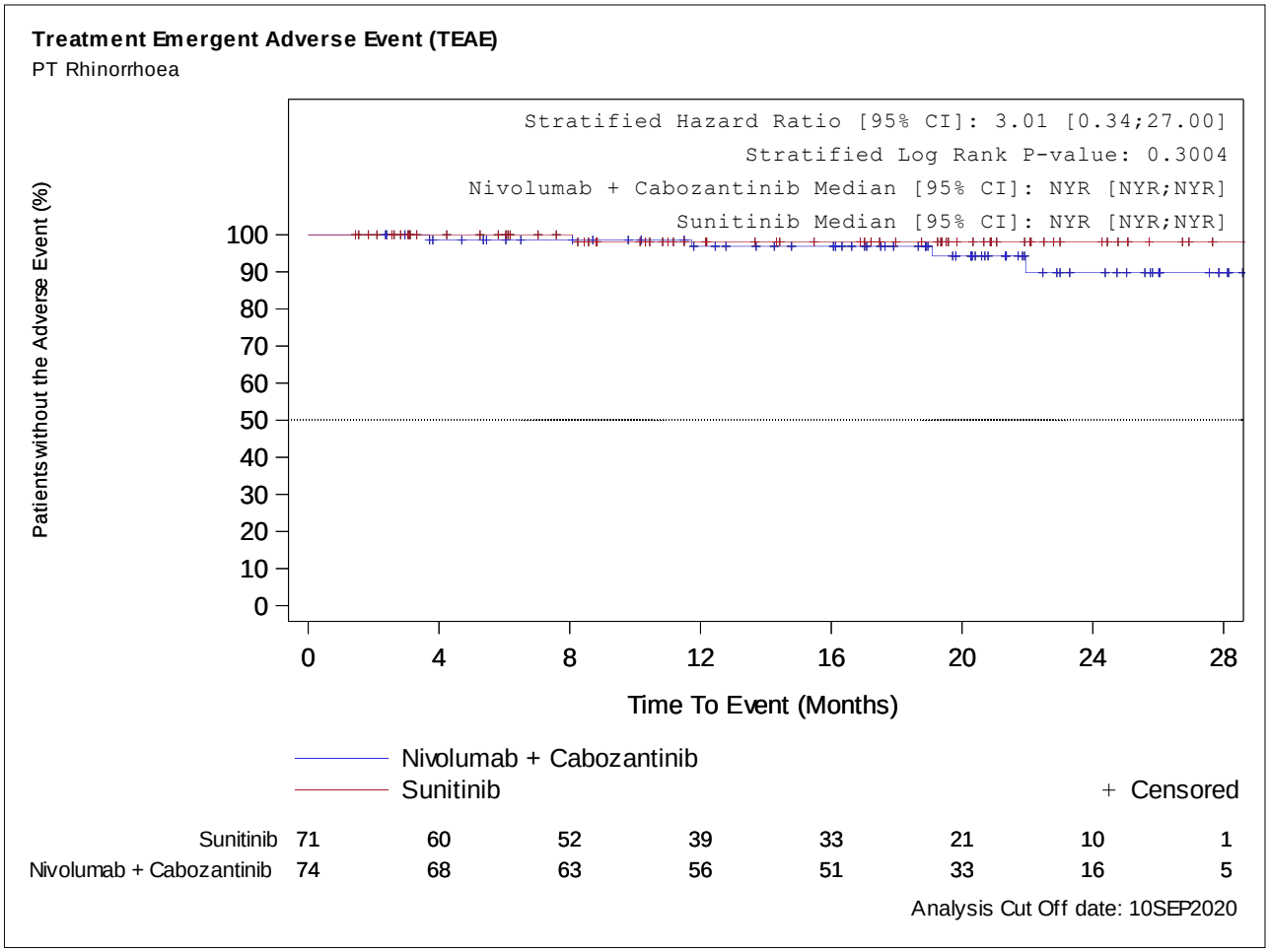
FIGURE 4.1.2.158: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rhinorrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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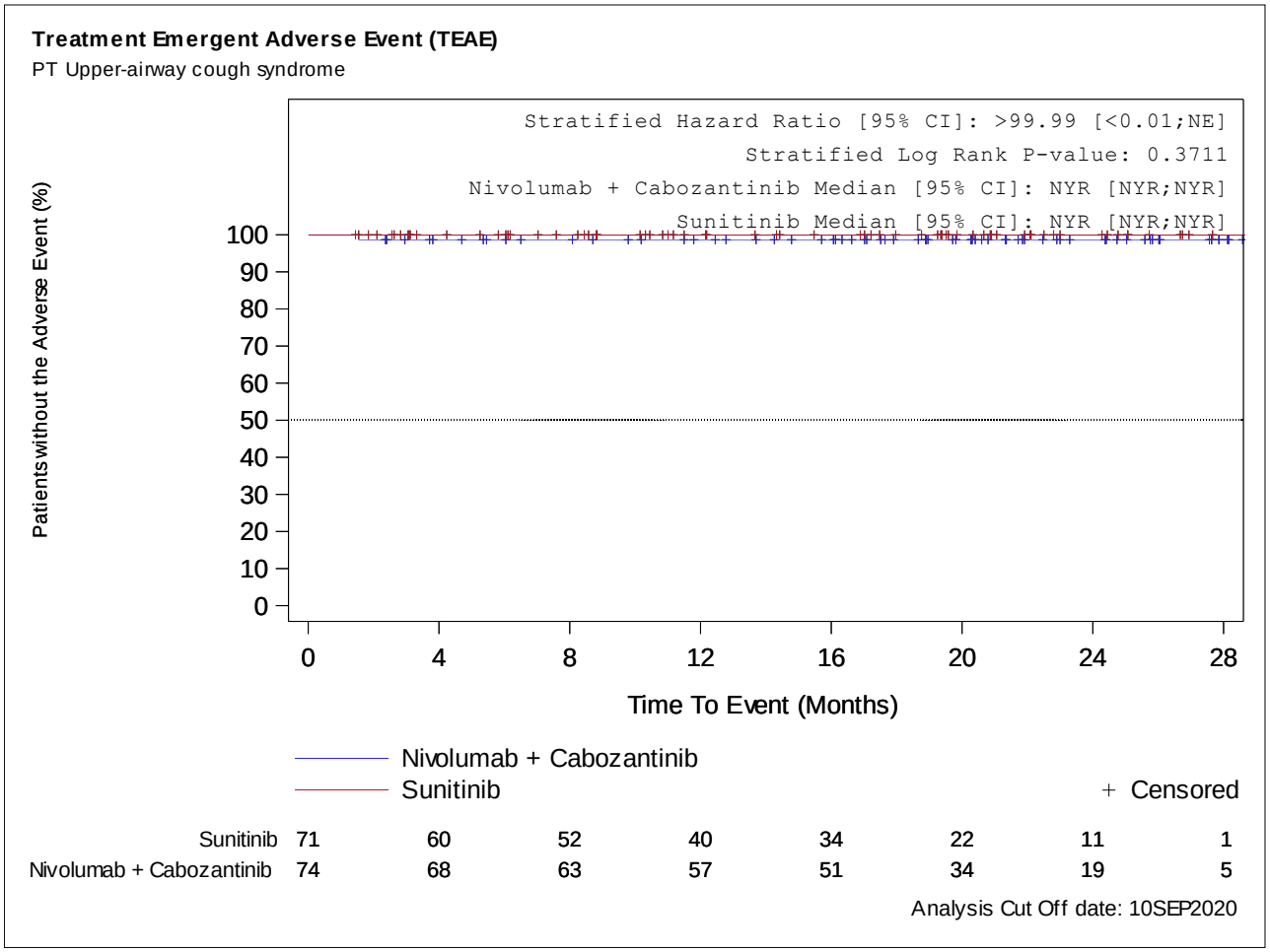
FIGURE 4.1.2.159: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Upper-airway cough syndrome - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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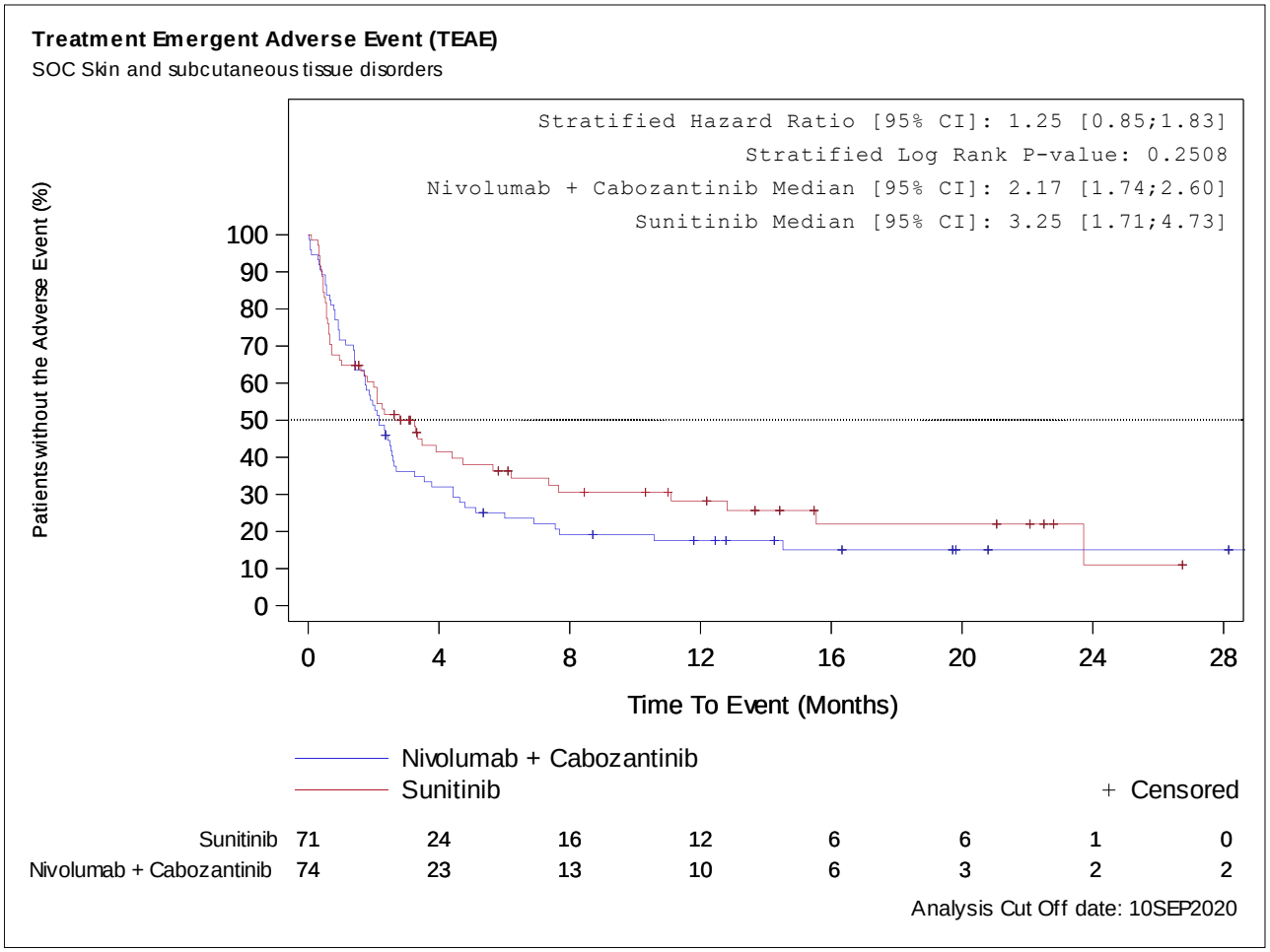
FIGURE 4.1.2.160: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Skin and subcutaneous tissue disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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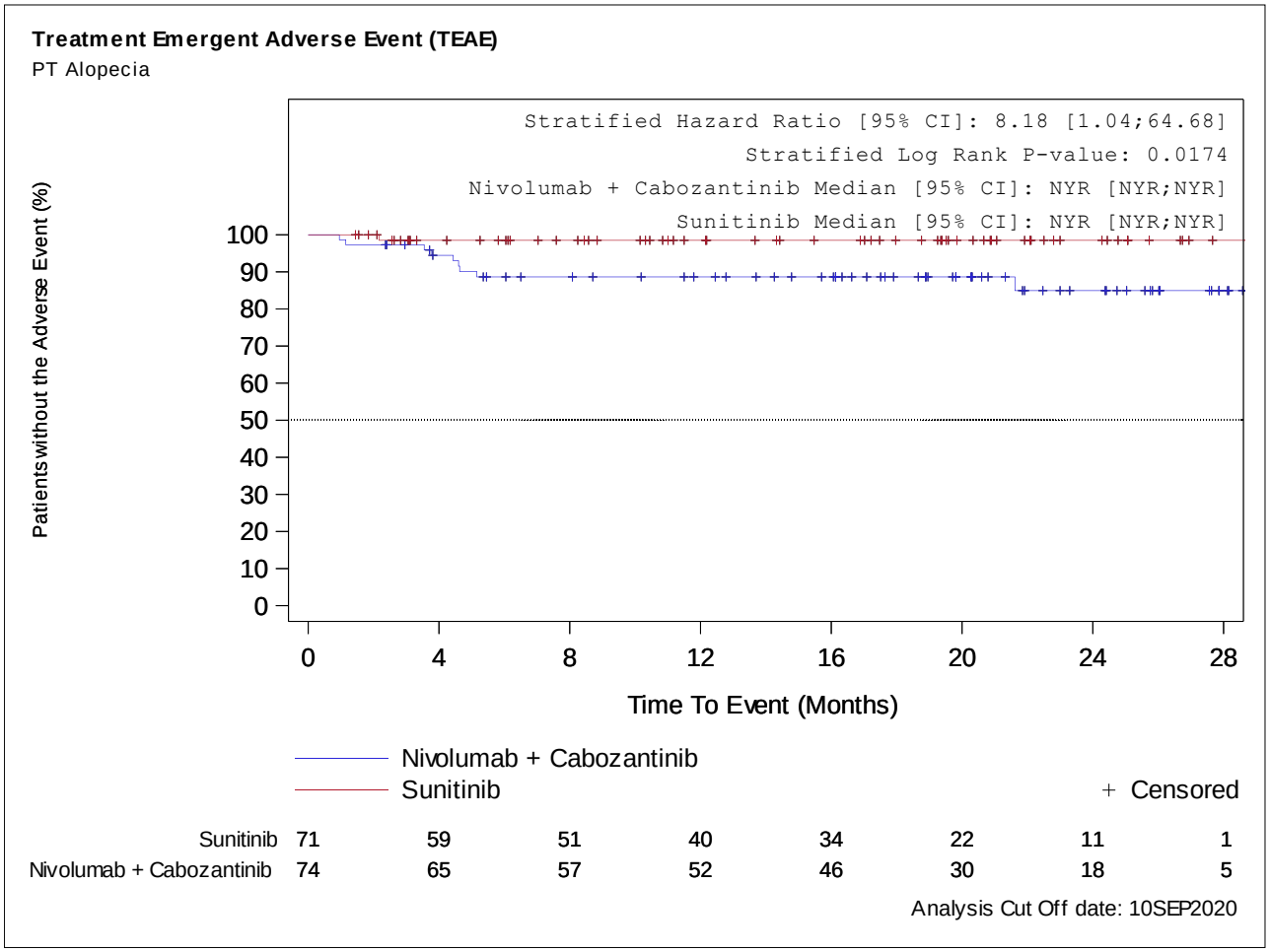
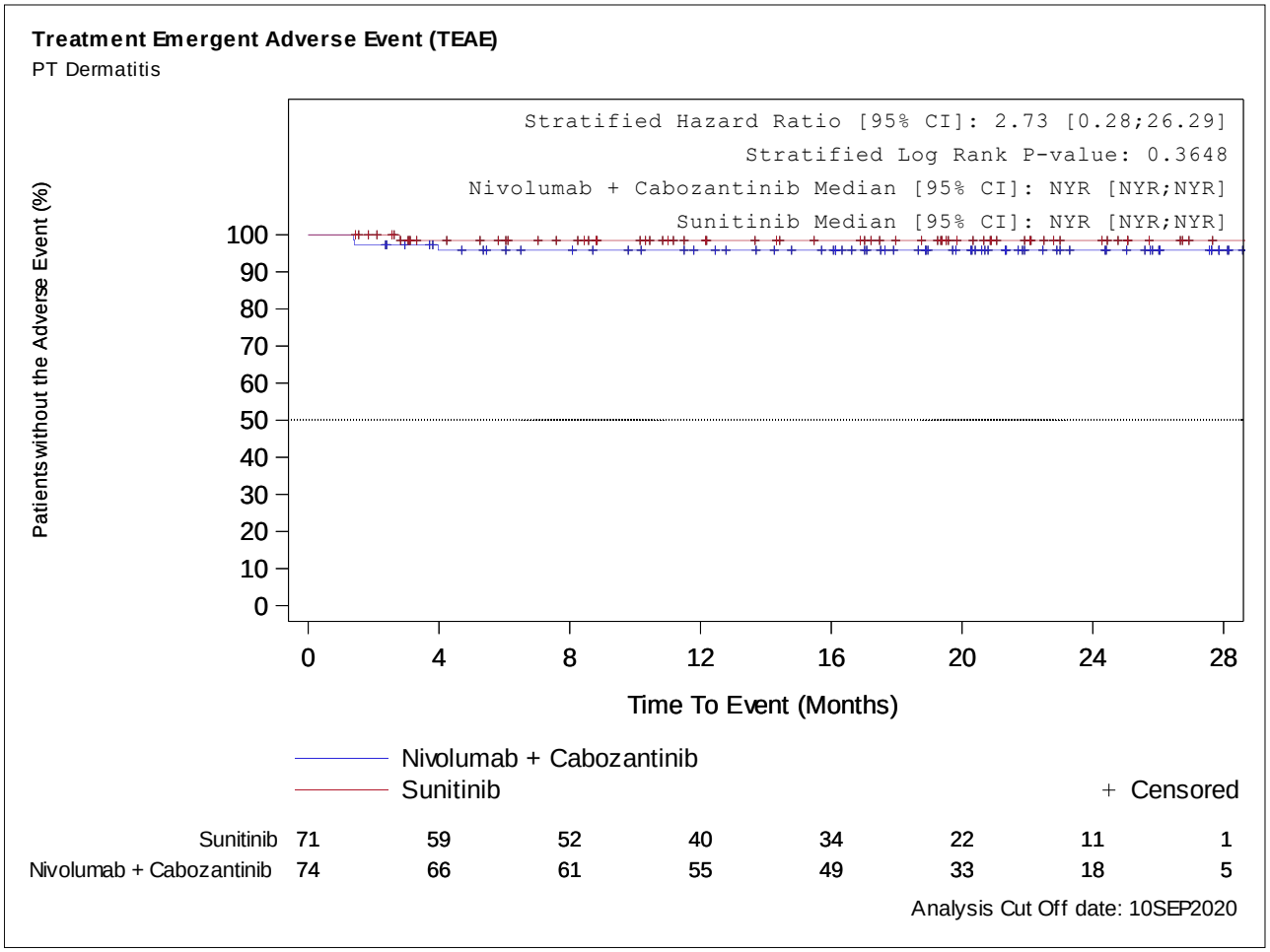
FIGURE 4.1.2.161: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Alopecia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



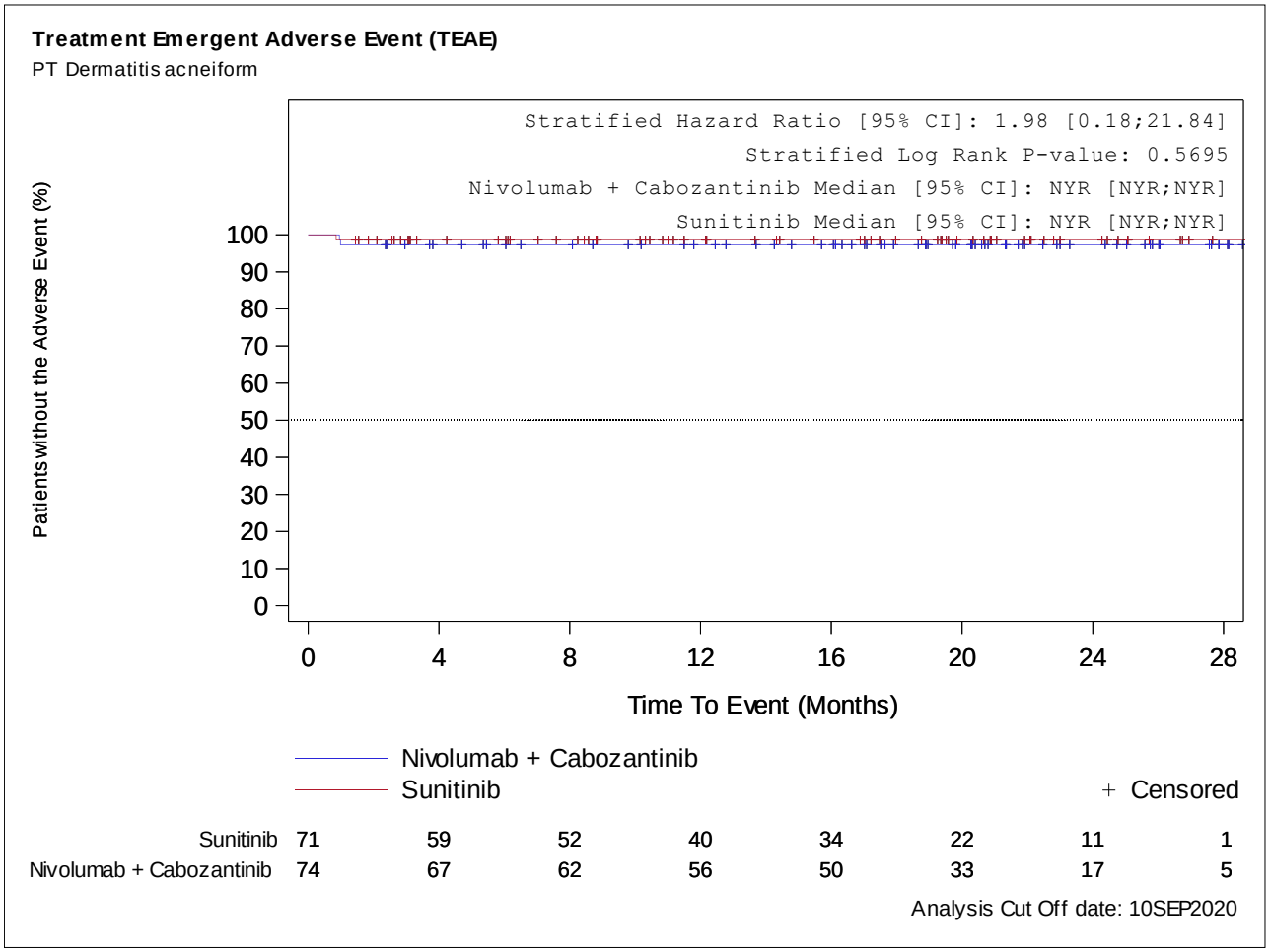

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:03:33

FIGURE 4.1.2.162: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dermatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:03:37

FIGURE 4.1.2.163: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dermatitis acneiform - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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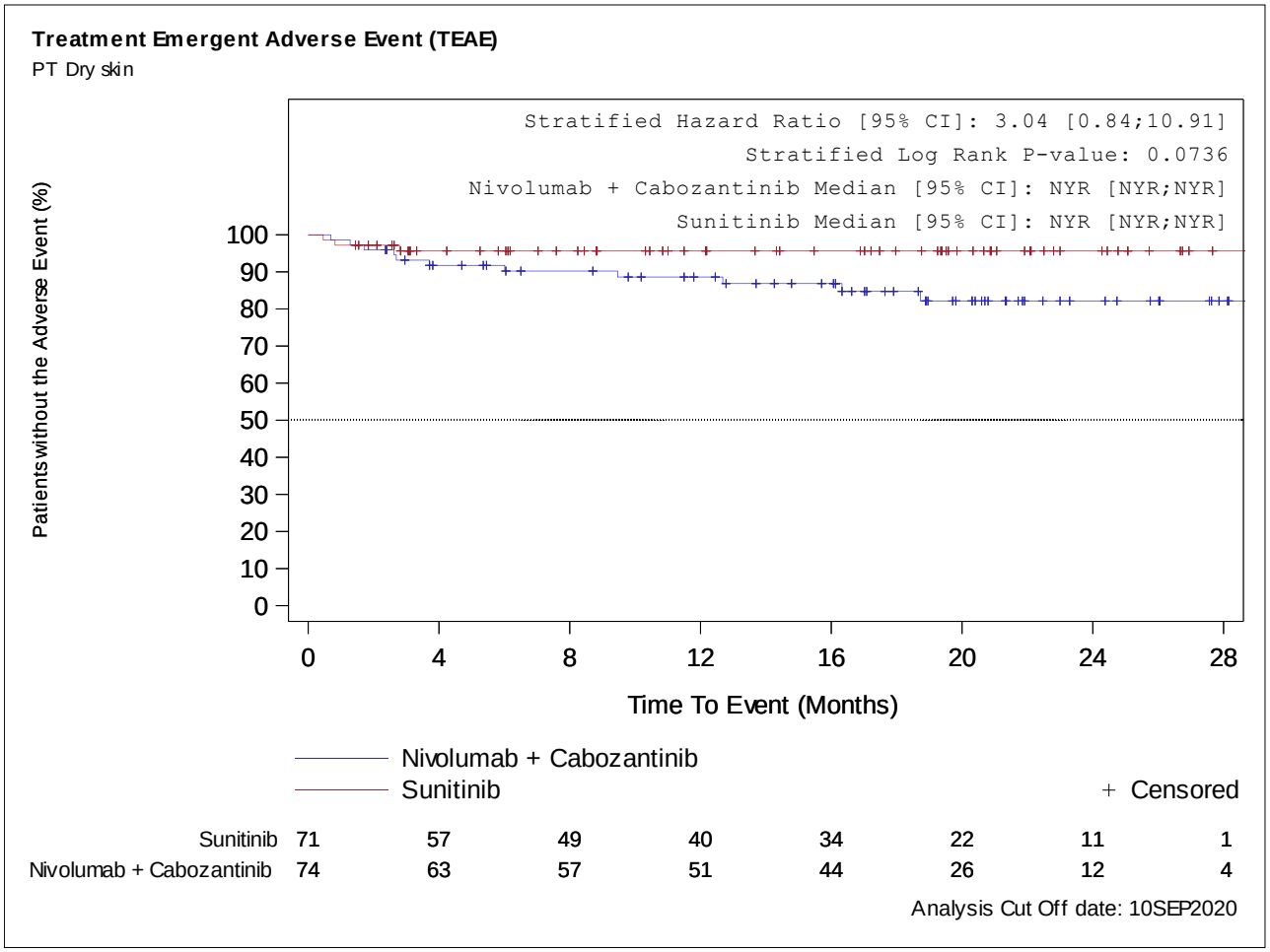
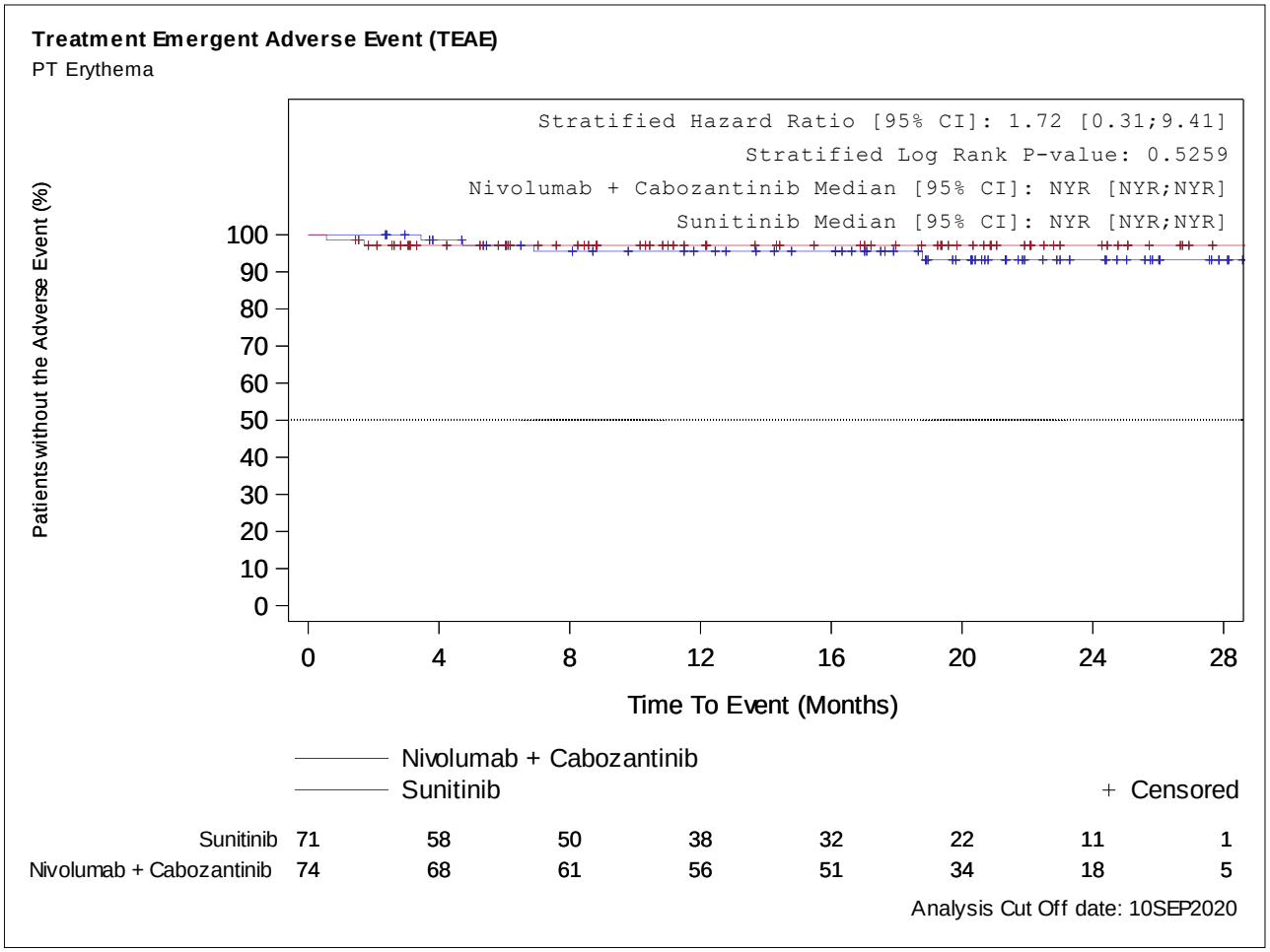
FIGURE 4.1.2.164: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dry skin - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:03:46

FIGURE 4.1.2.165: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Erythema - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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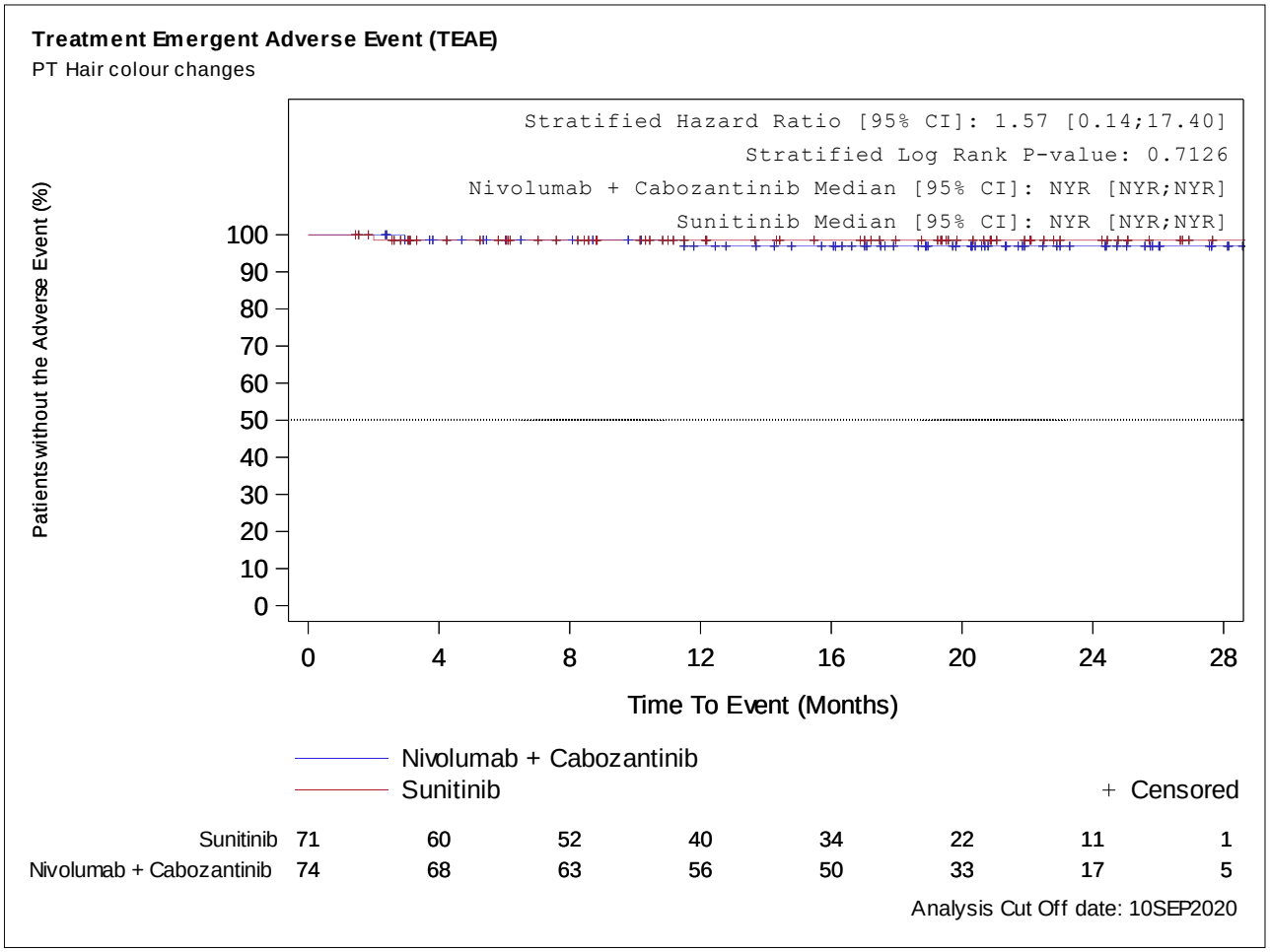
FIGURE 4.1.2.166: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hair colour changes - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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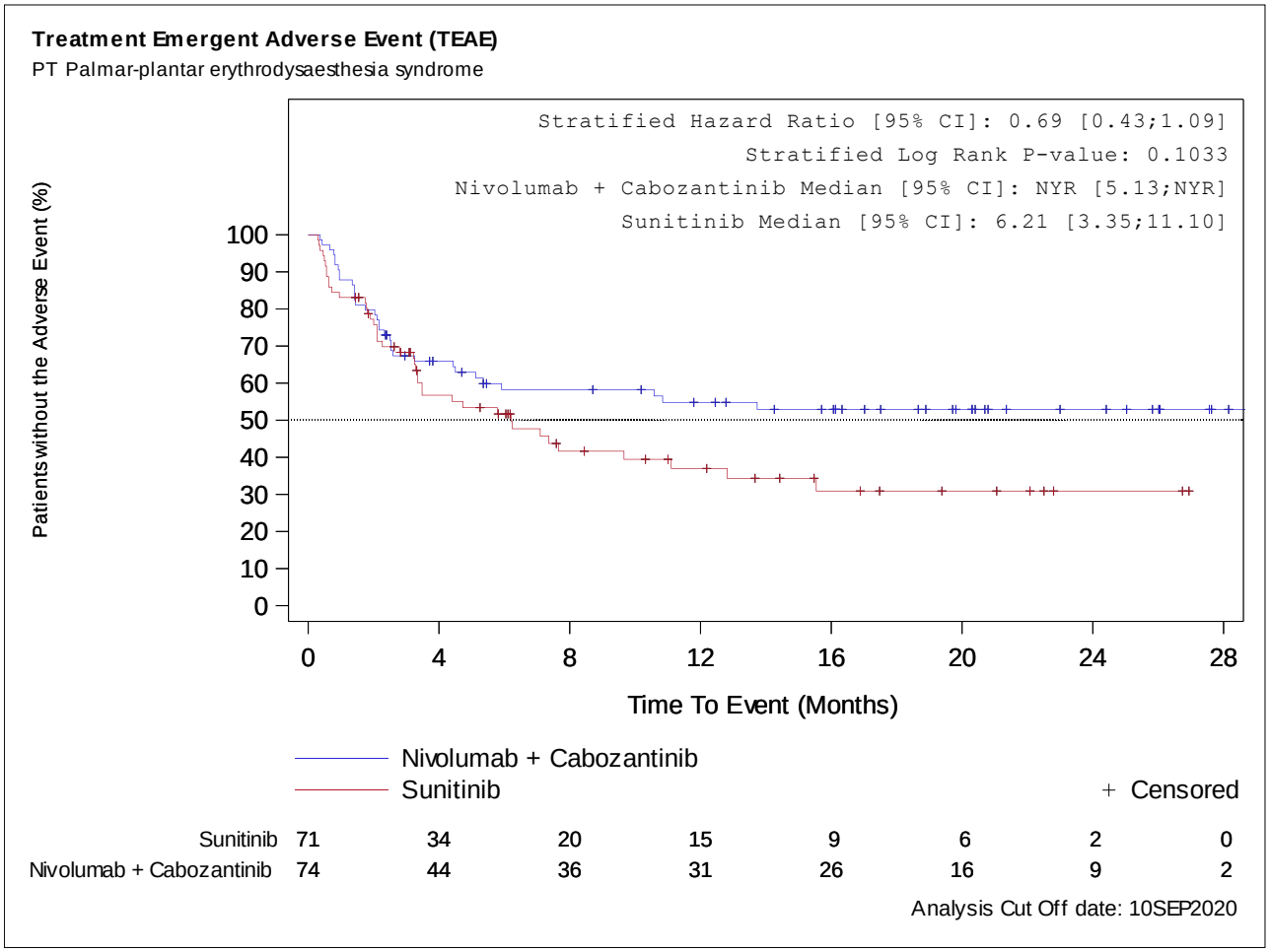
FIGURE 4.1.2.167: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Palmar-plantar erythrodysaesthesia syndrome - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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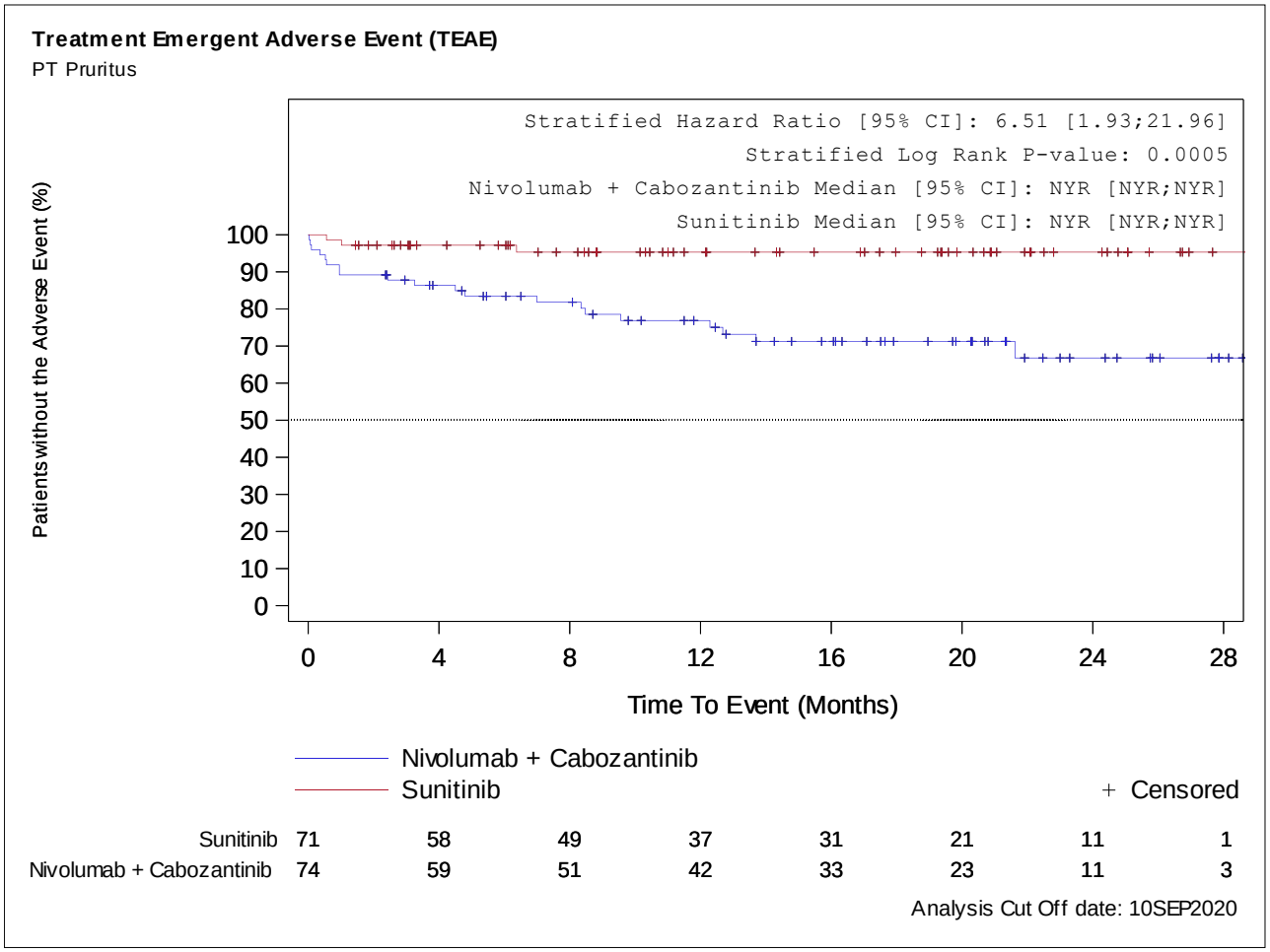
FIGURE 4.1.2.168: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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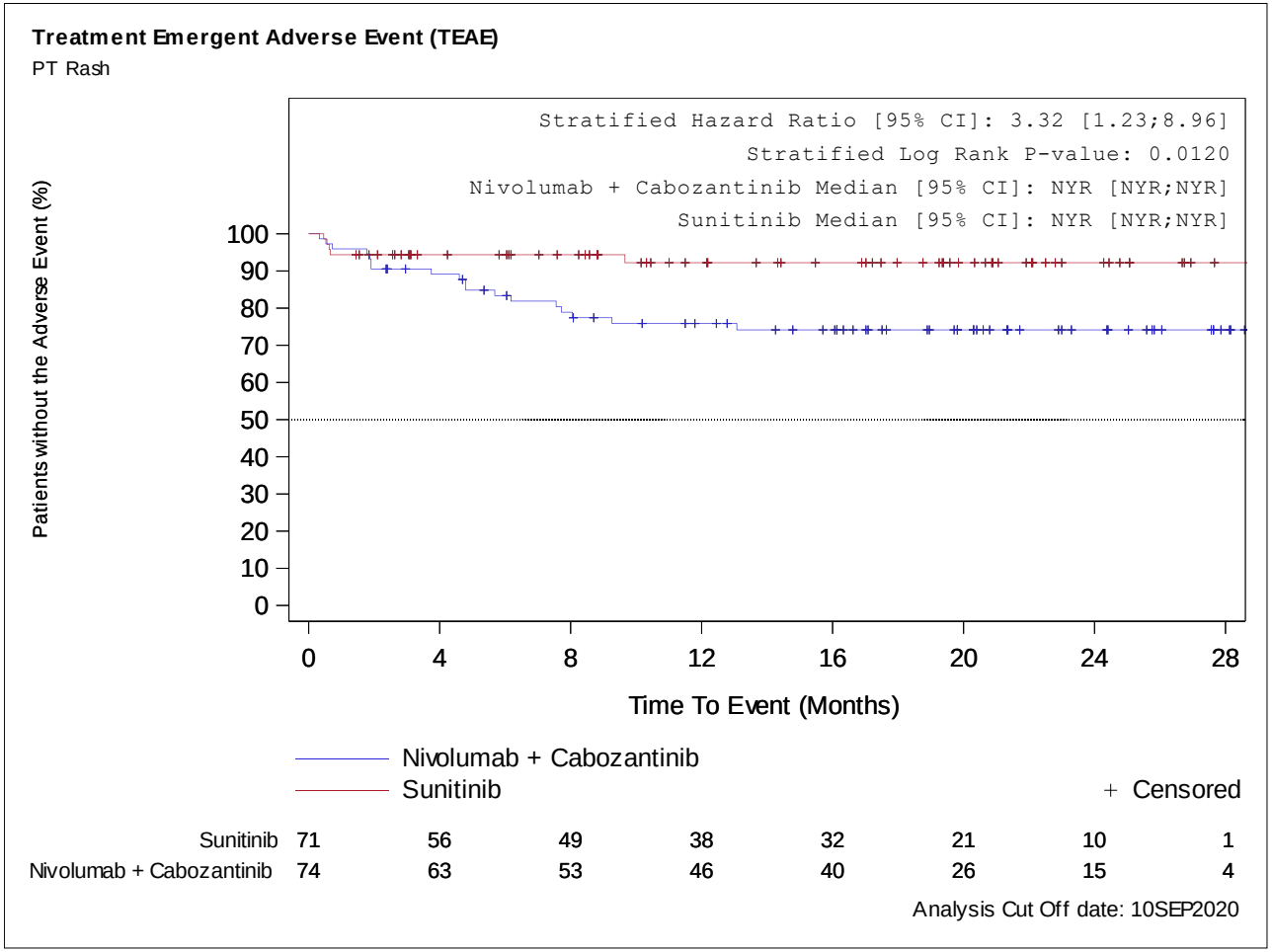
FIGURE 4.1.2.169: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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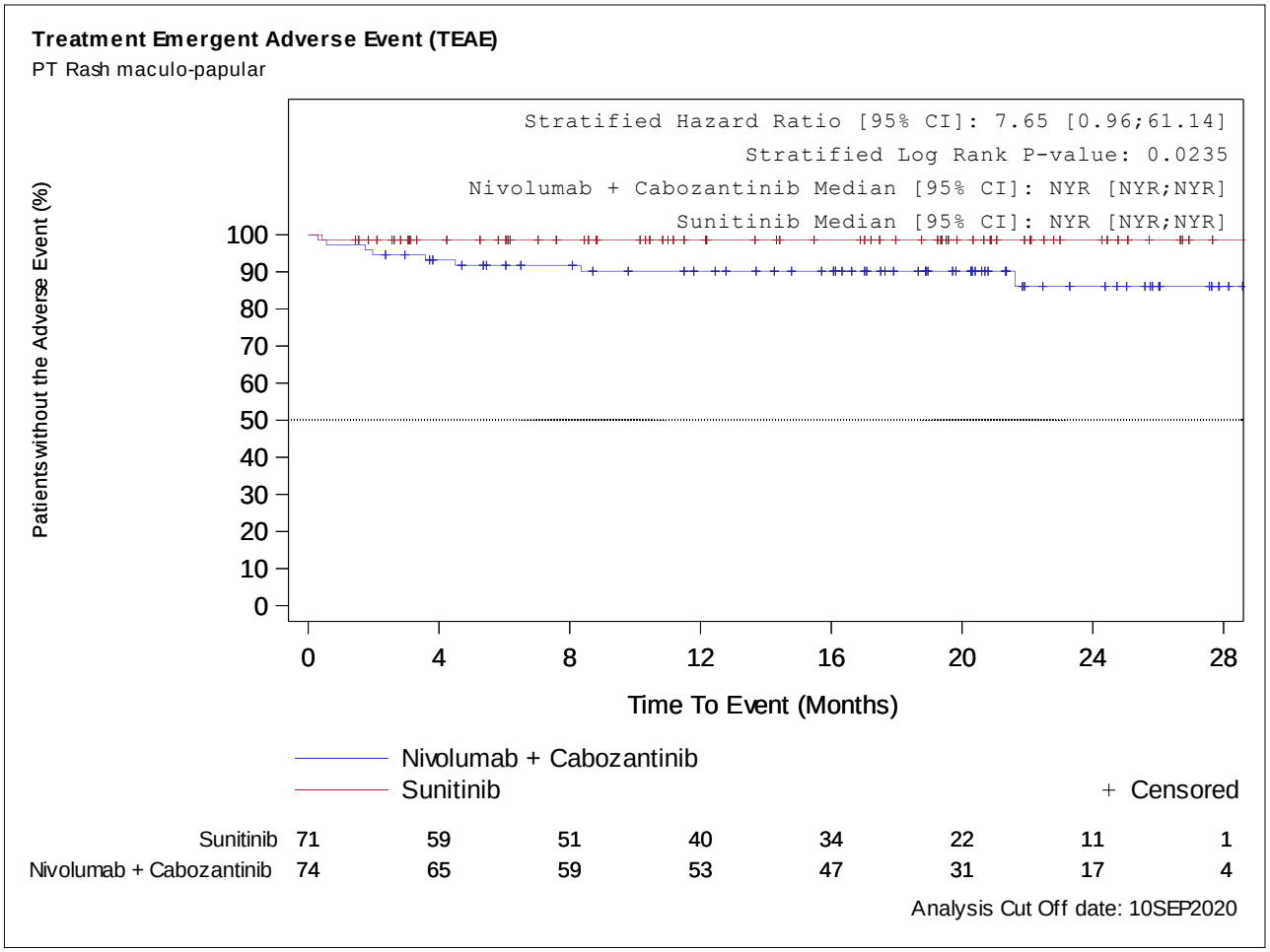
FIGURE 4.1.2.170: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash maculo-papular - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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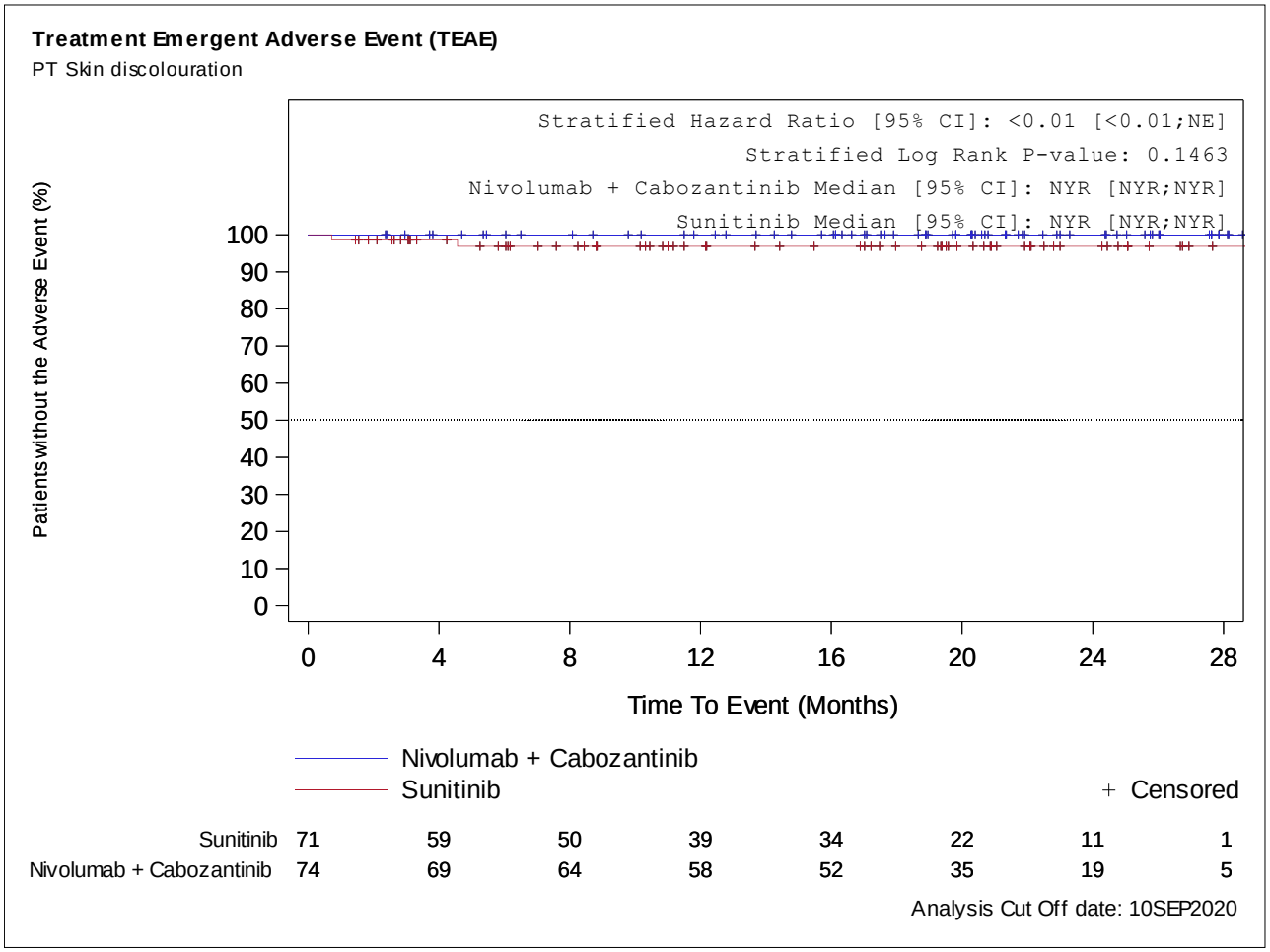
FIGURE 4.1.2.171: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Skin discolouration - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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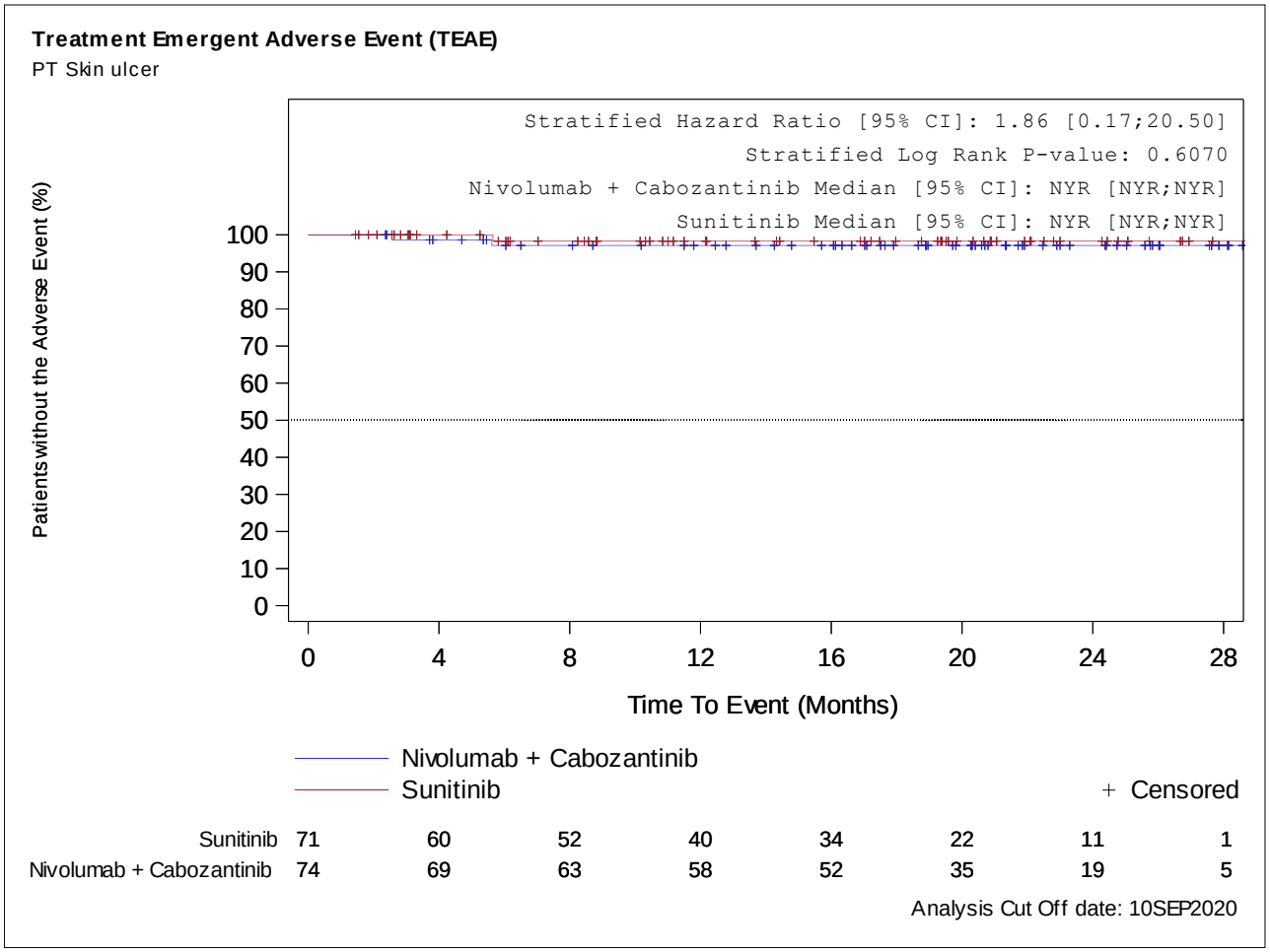
FIGURE 4.1.2.172: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Skin ulcer - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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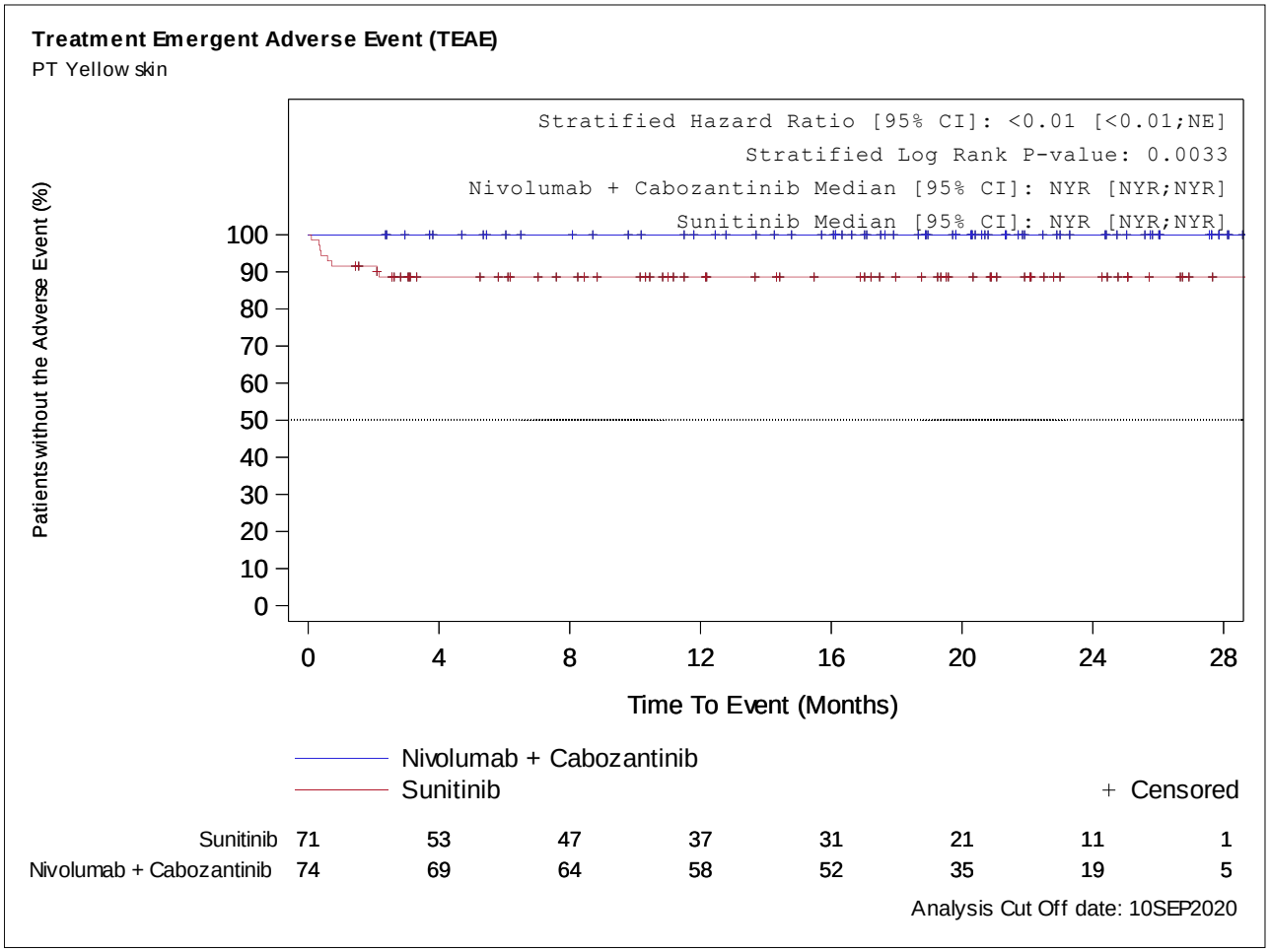
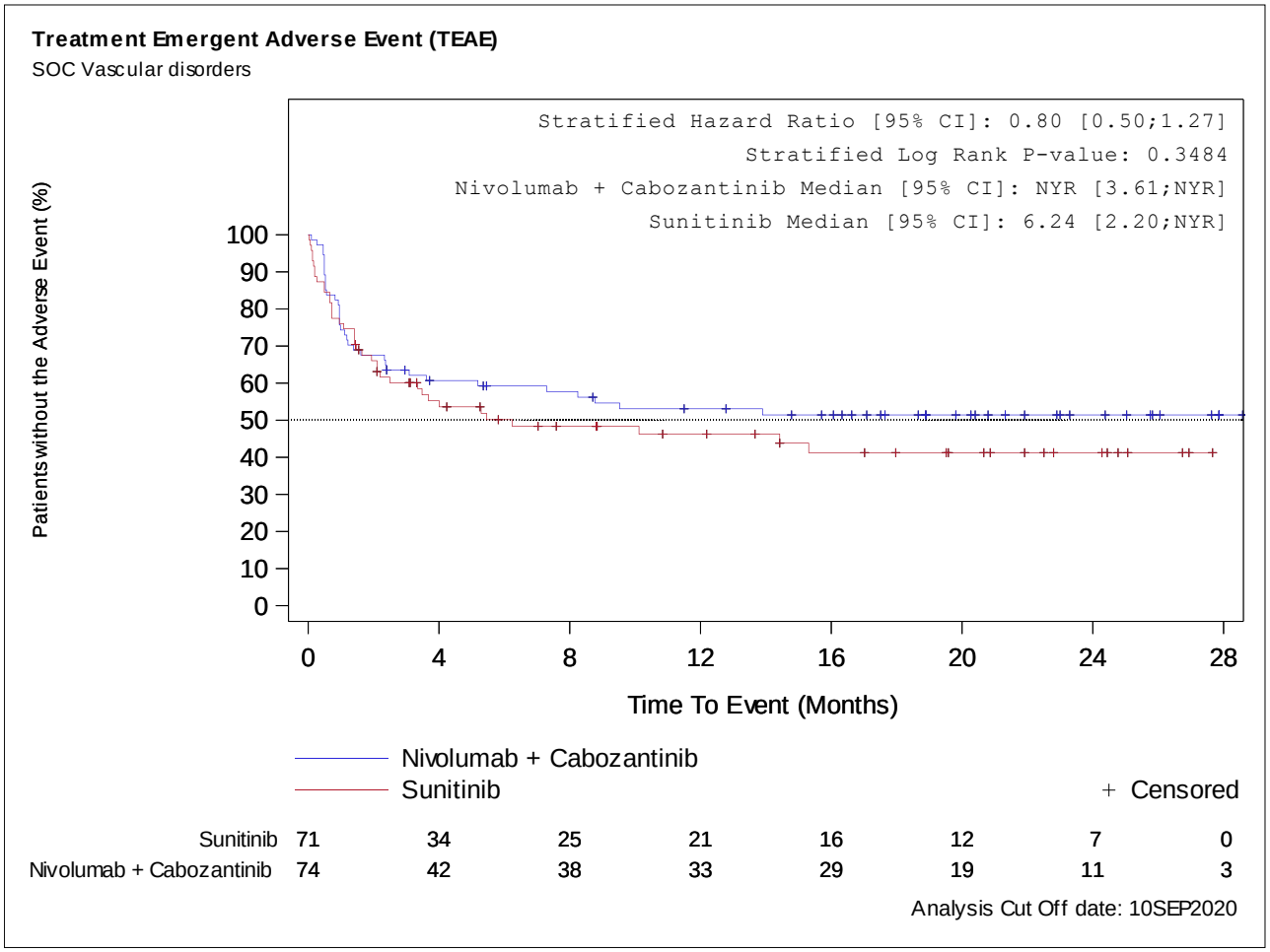
FIGURE 4.1.2.173: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Yellow skin - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:04:24

FIGURE 4.1.2.174: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Vascular disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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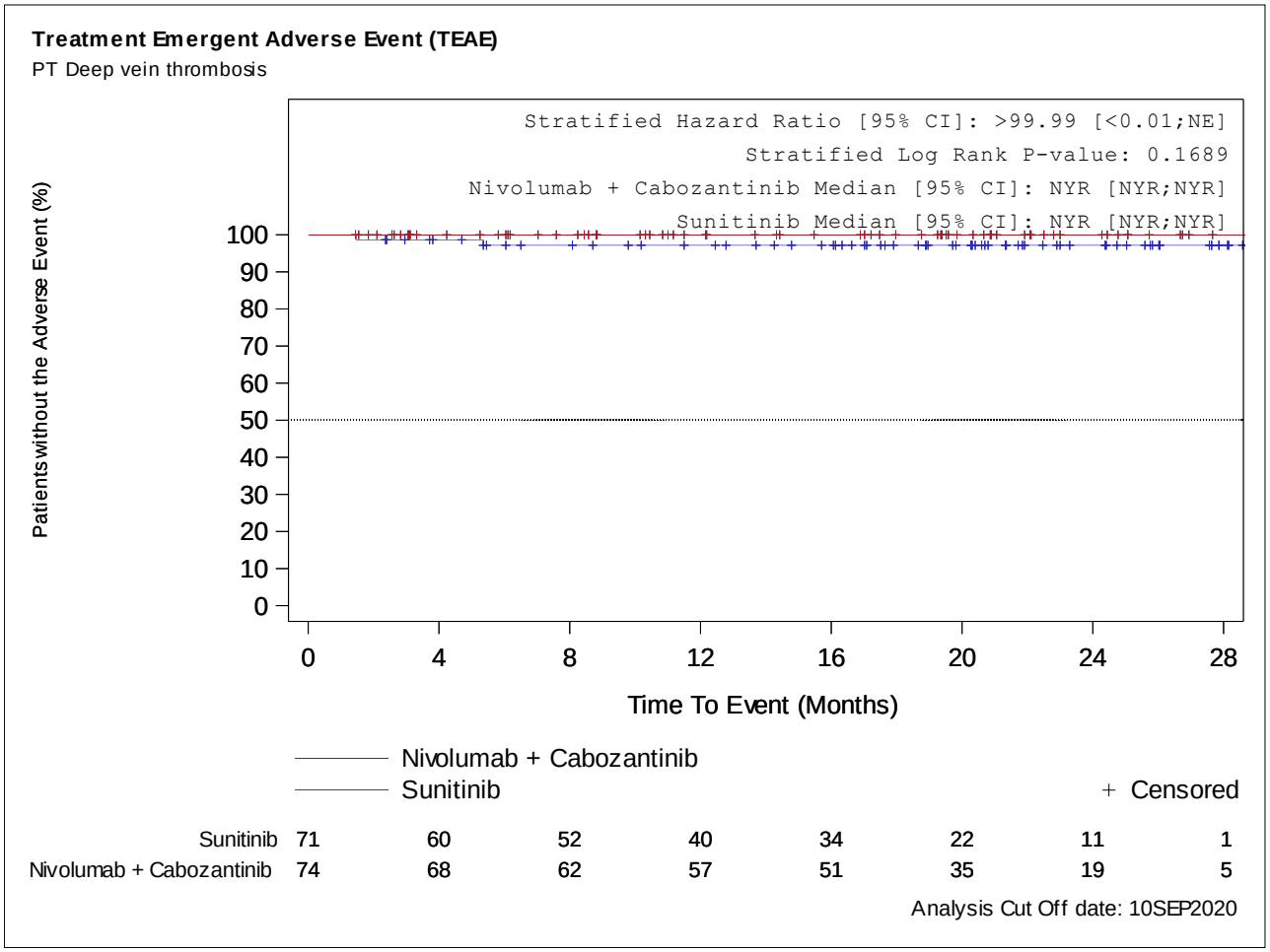
FIGURE 4.1.2.175: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Deep vein thrombosis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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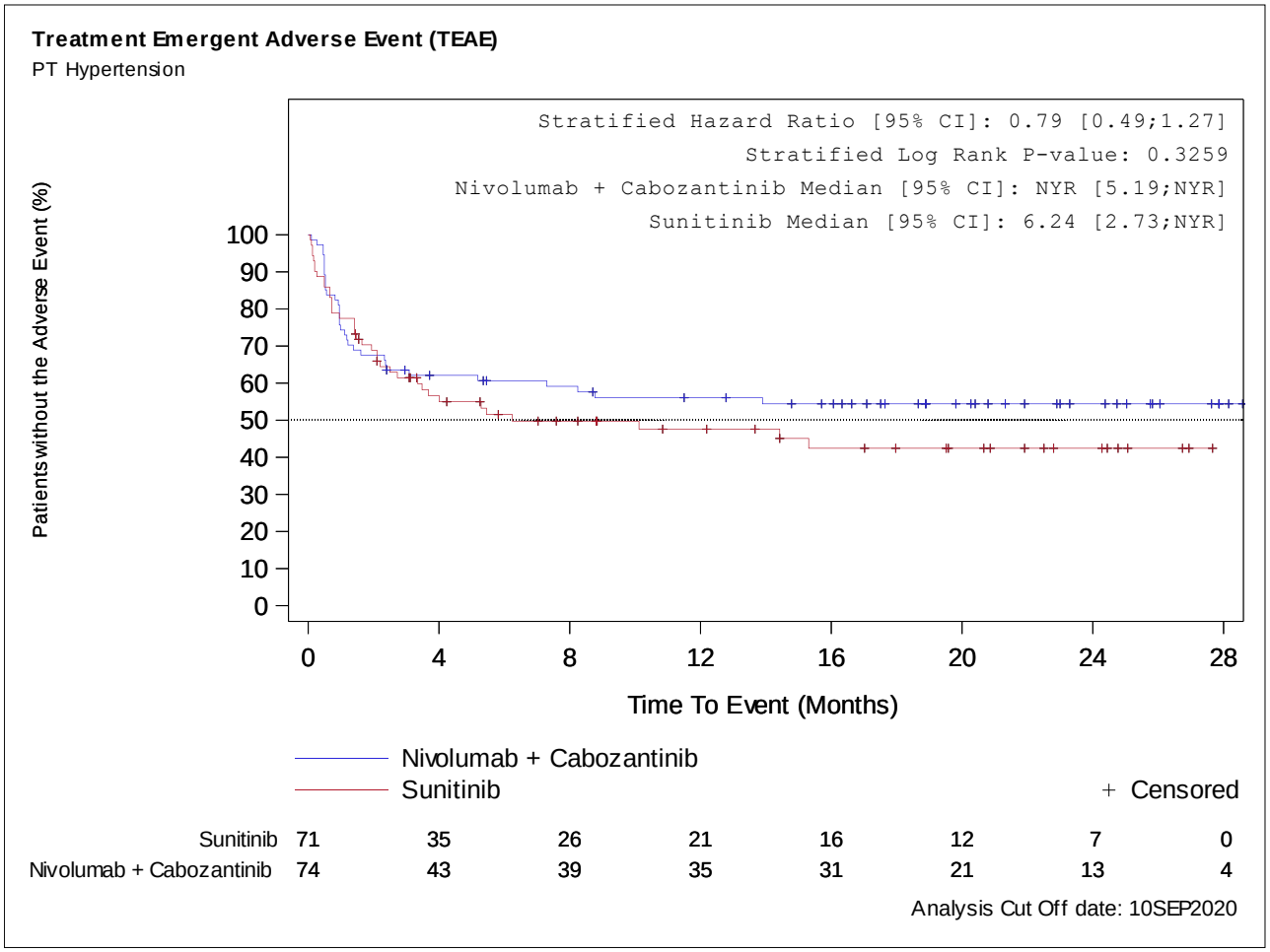
FIGURE 4.1.2.176: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypertension - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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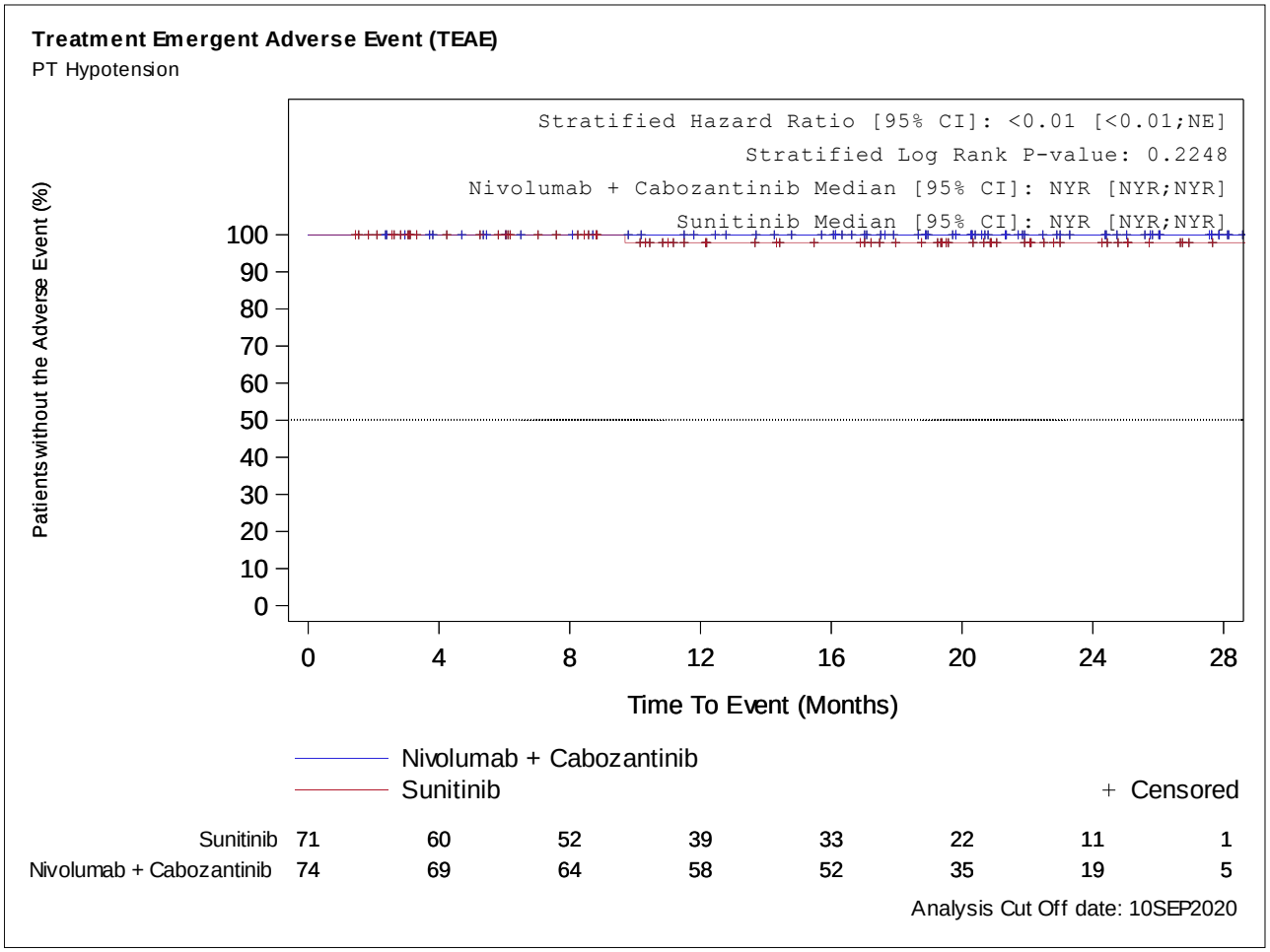
FIGURE 4.1.2.177: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypotension - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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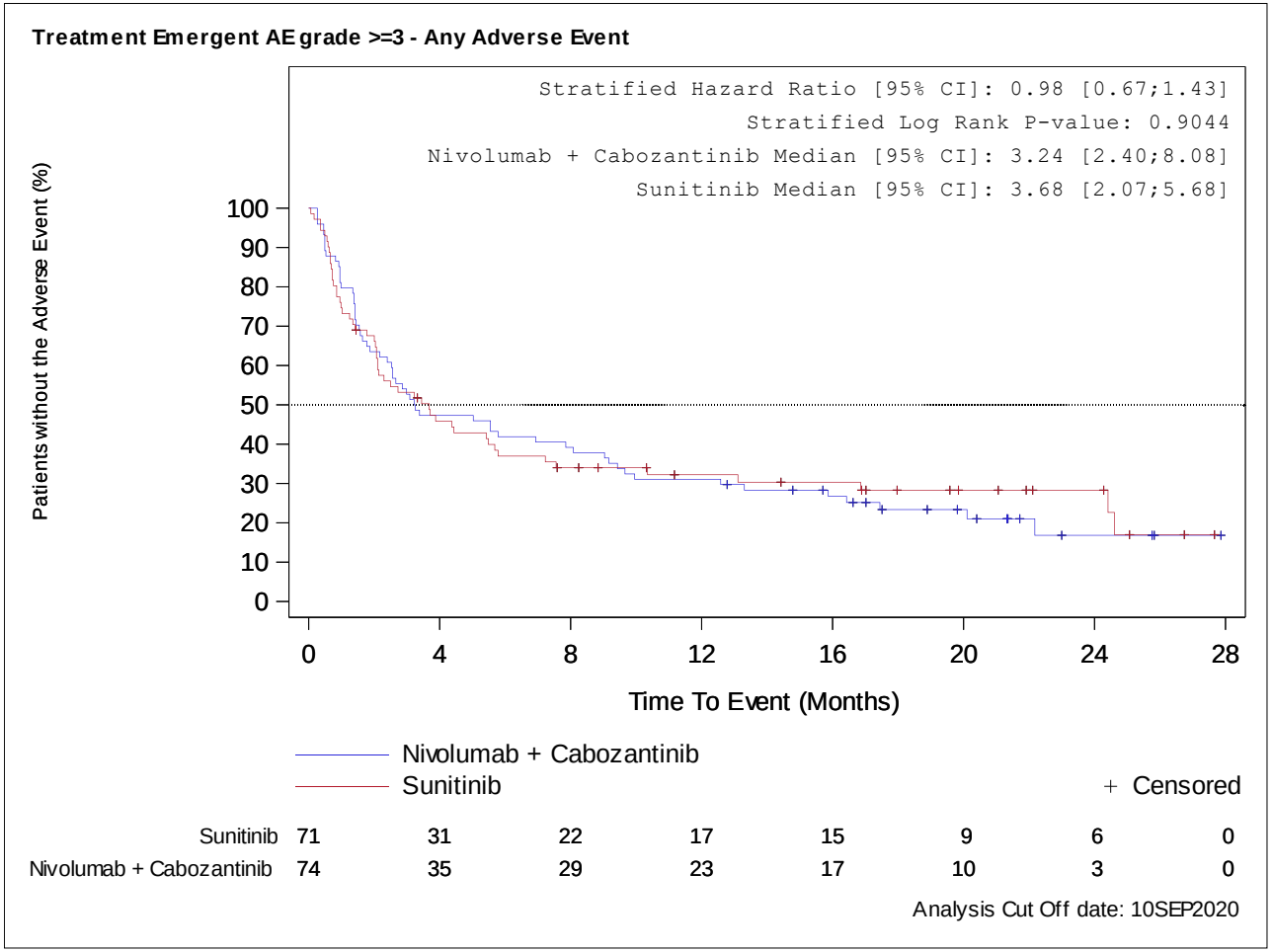
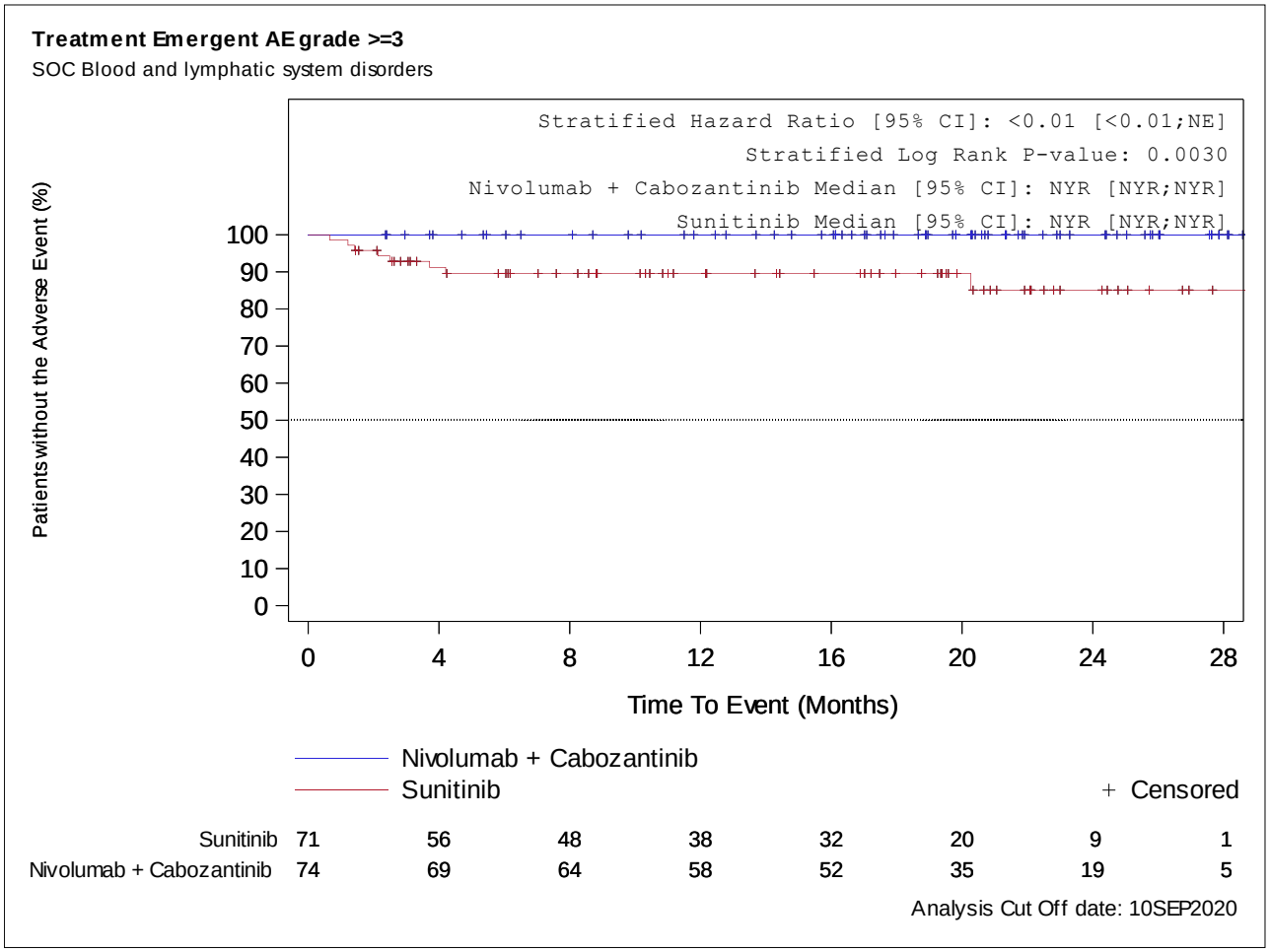
FIGURE 4.2.1: Treatment Emergent AE grade >=3 - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:06:32

FIGURE 4.2.2.1: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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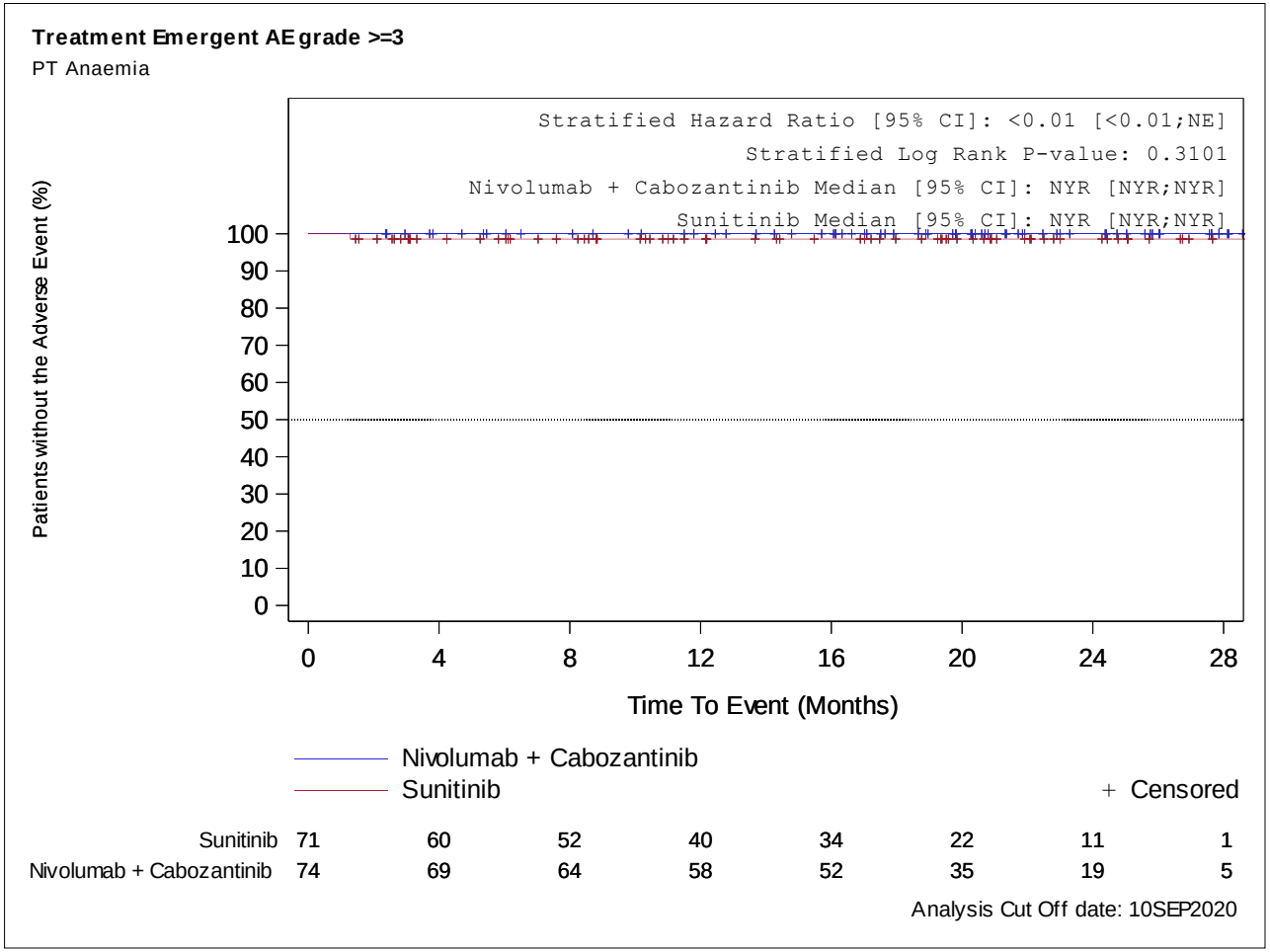
FIGURE 4.2.2.2: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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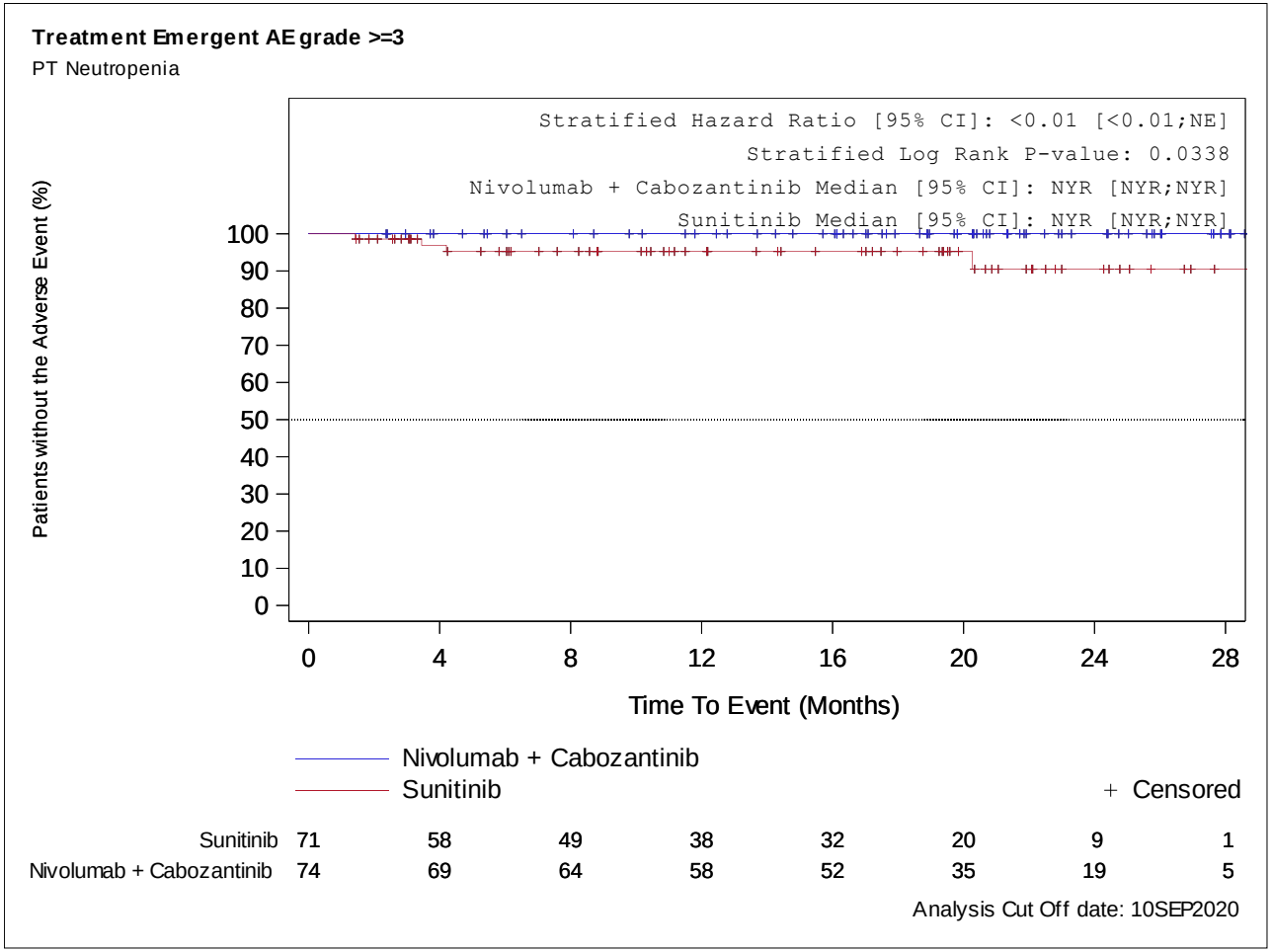
FIGURE 4.2.2.3: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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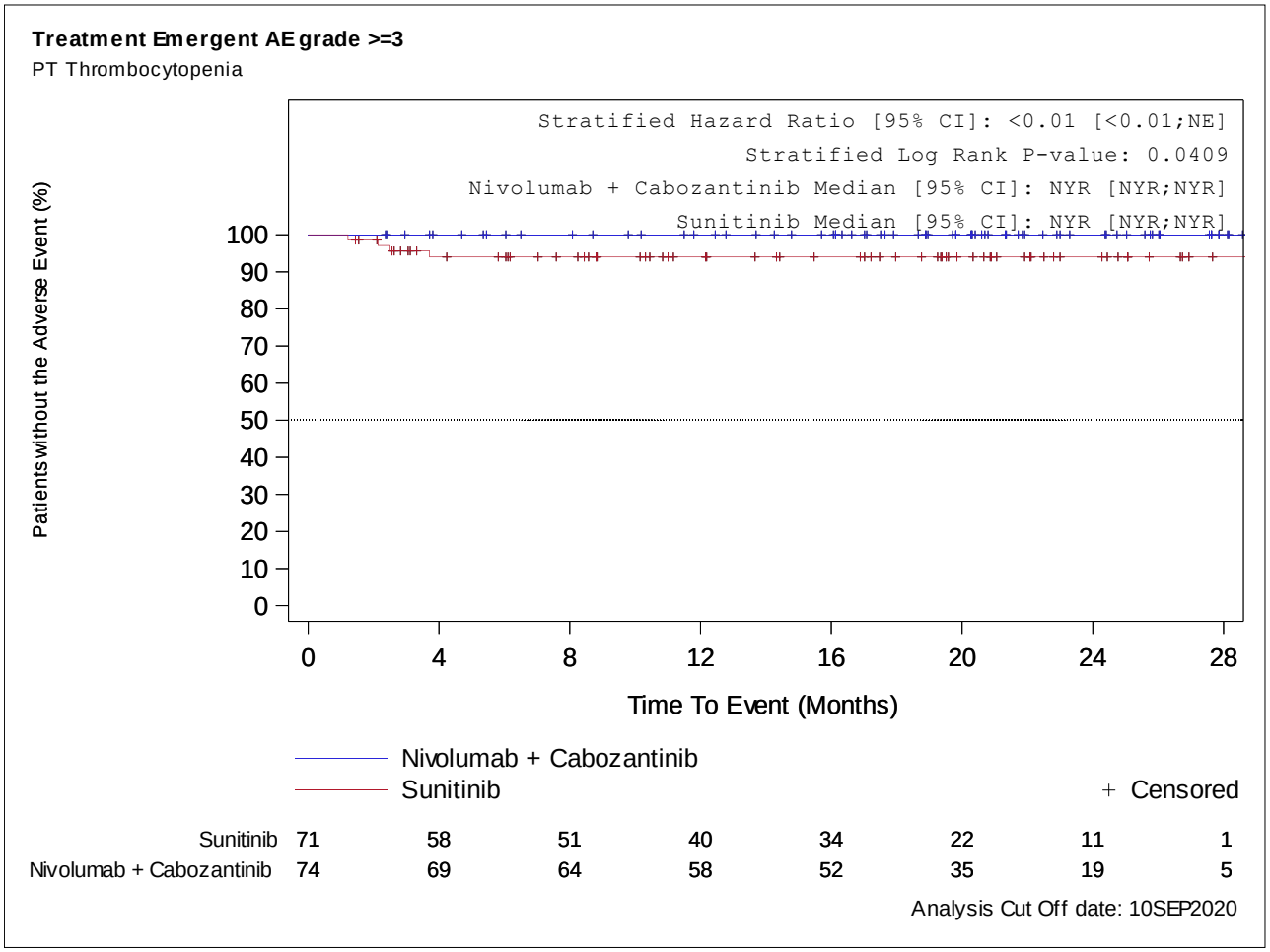
FIGURE 4.2.2.4: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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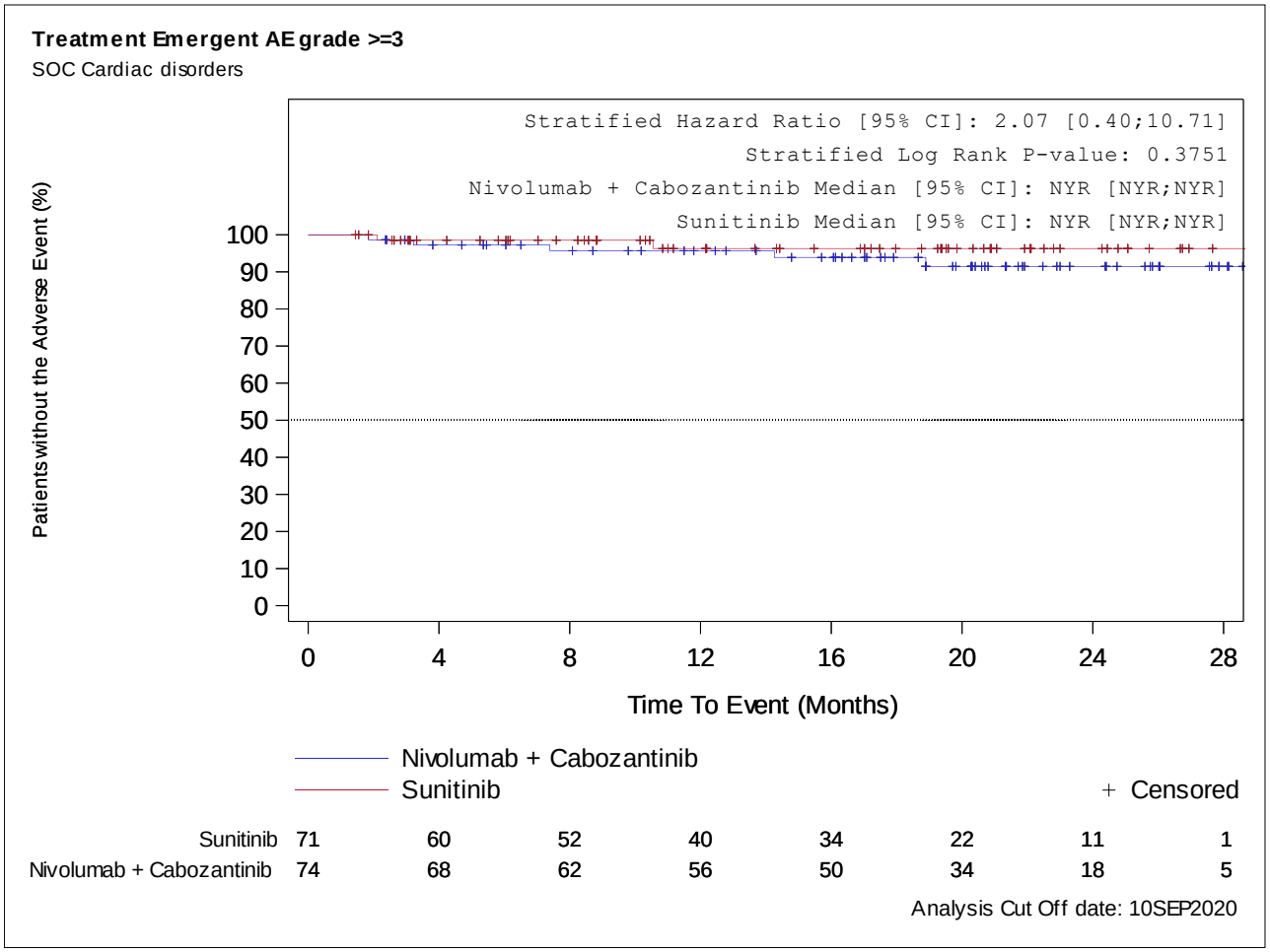
FIGURE 4.2.2.5: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Cardiac disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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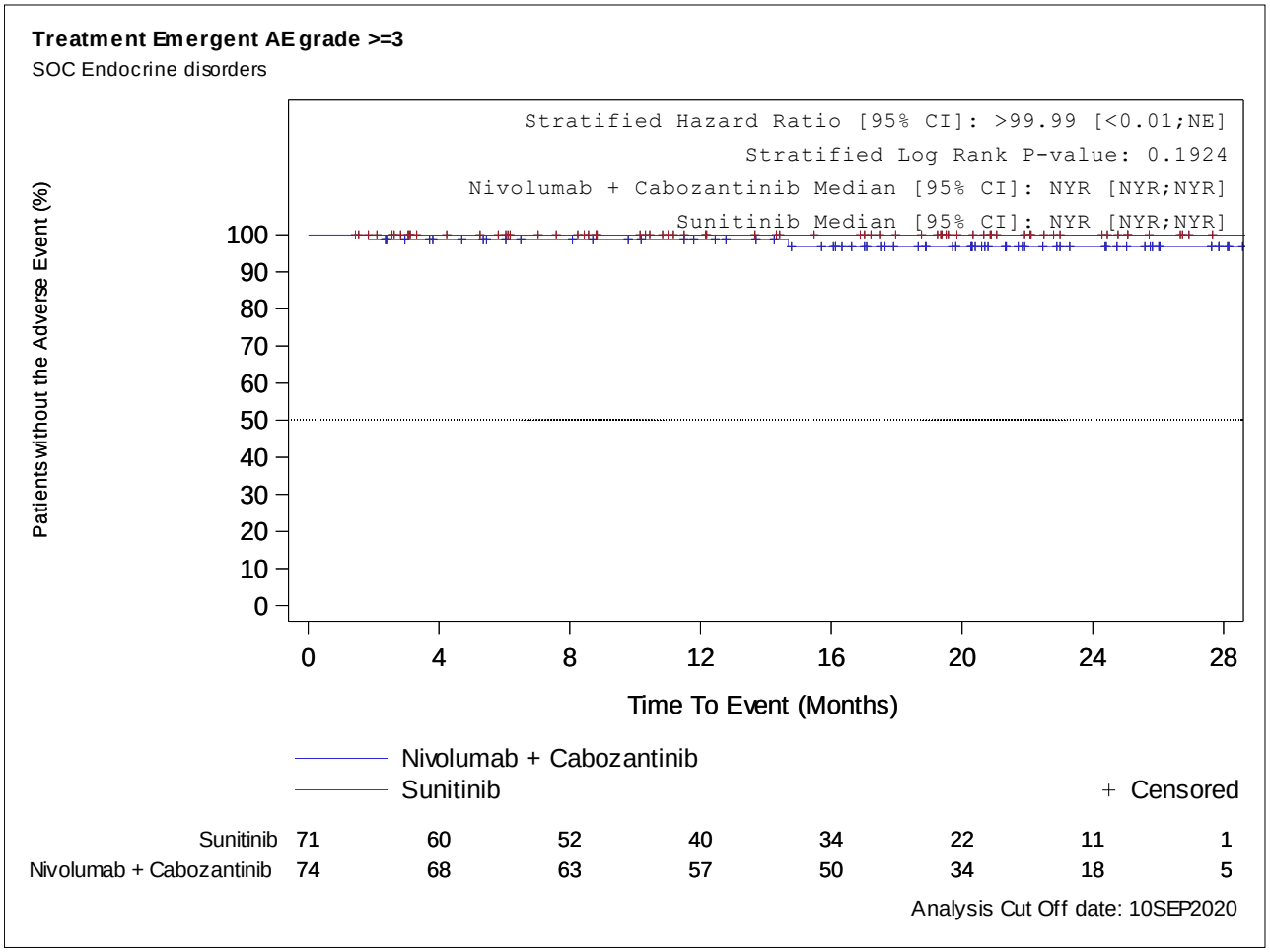
FIGURE 4.2.2.6: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Endocrine disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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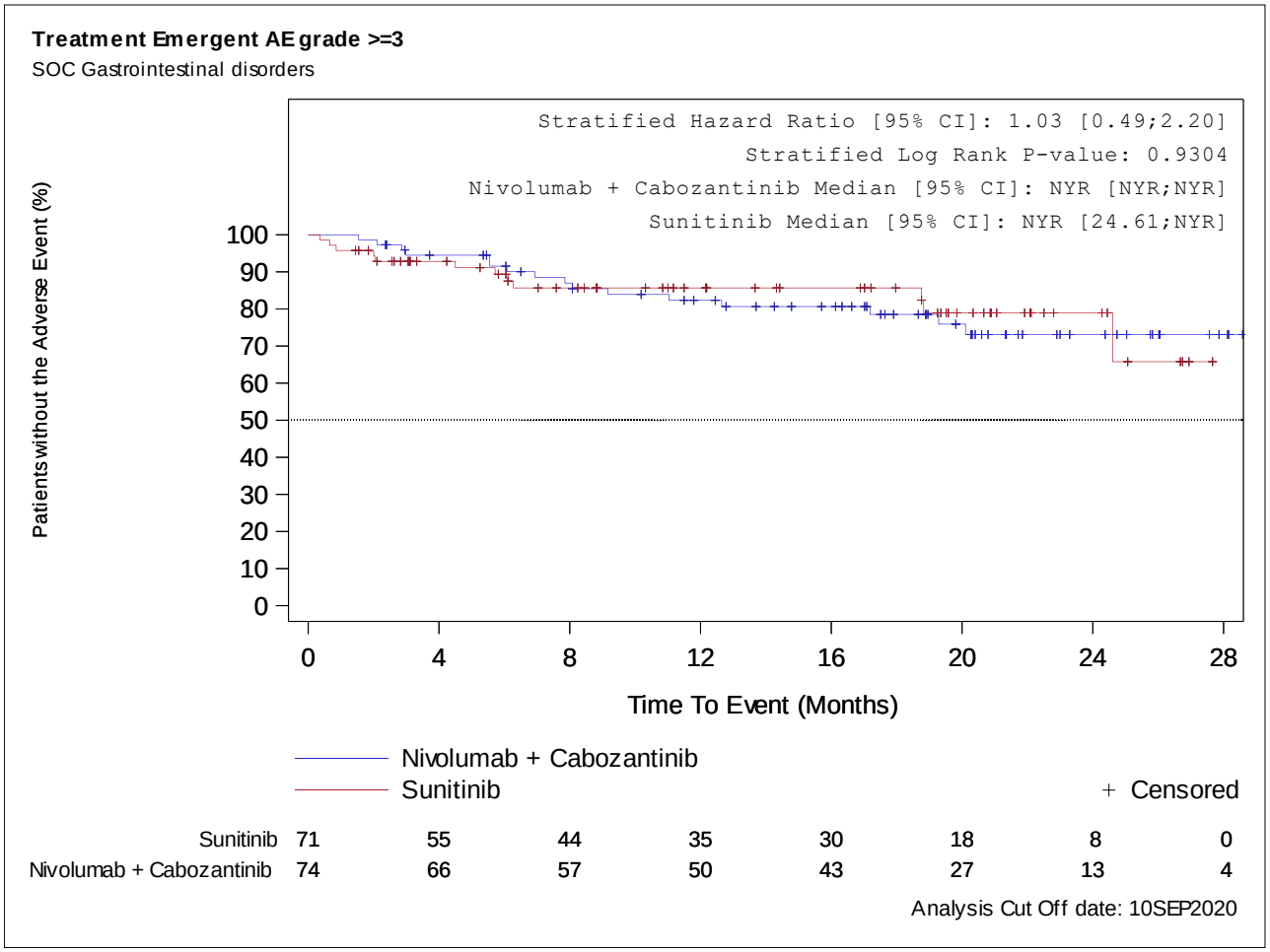
FIGURE 4.2.2.7: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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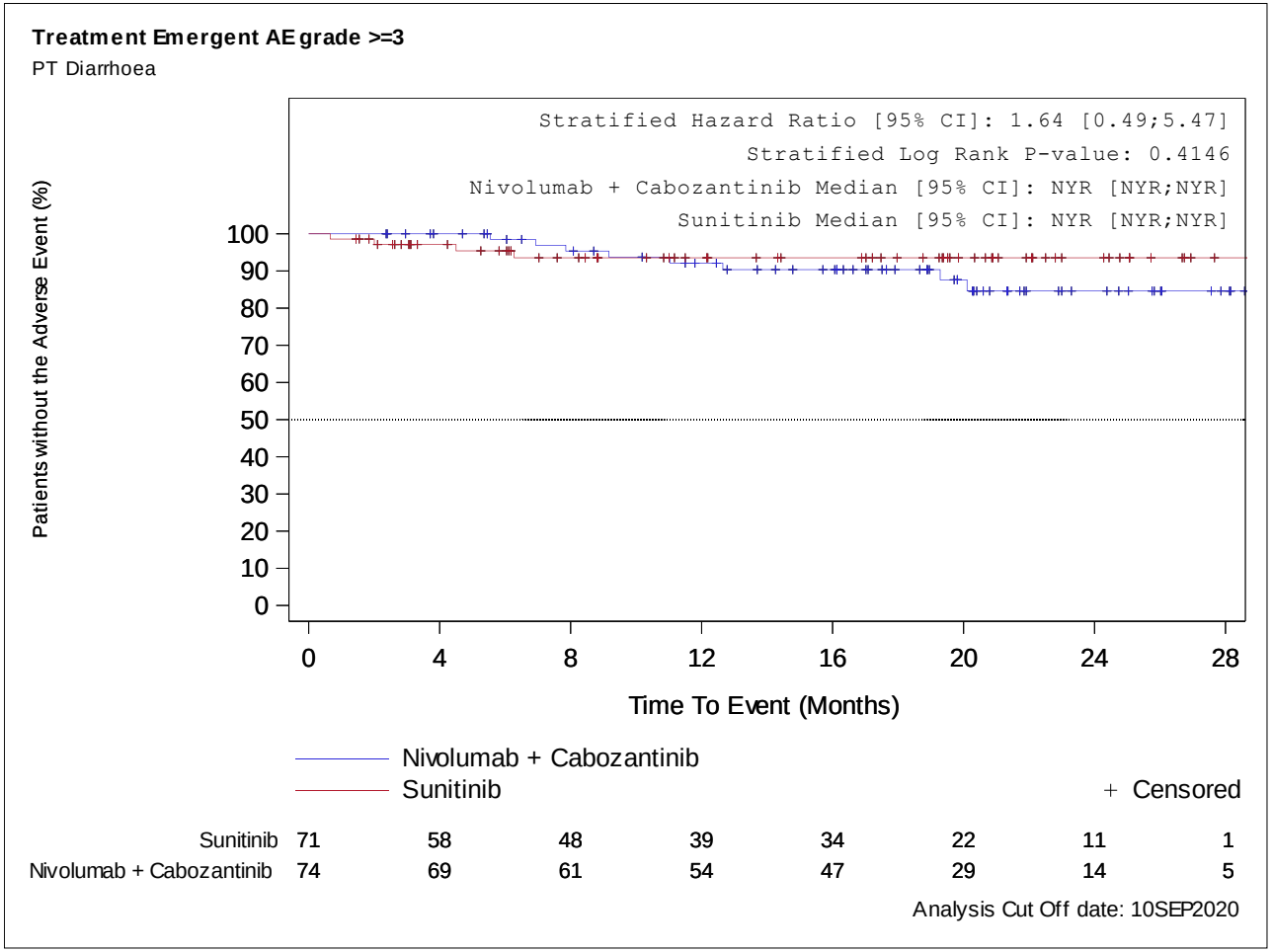
FIGURE 4.2.2.8: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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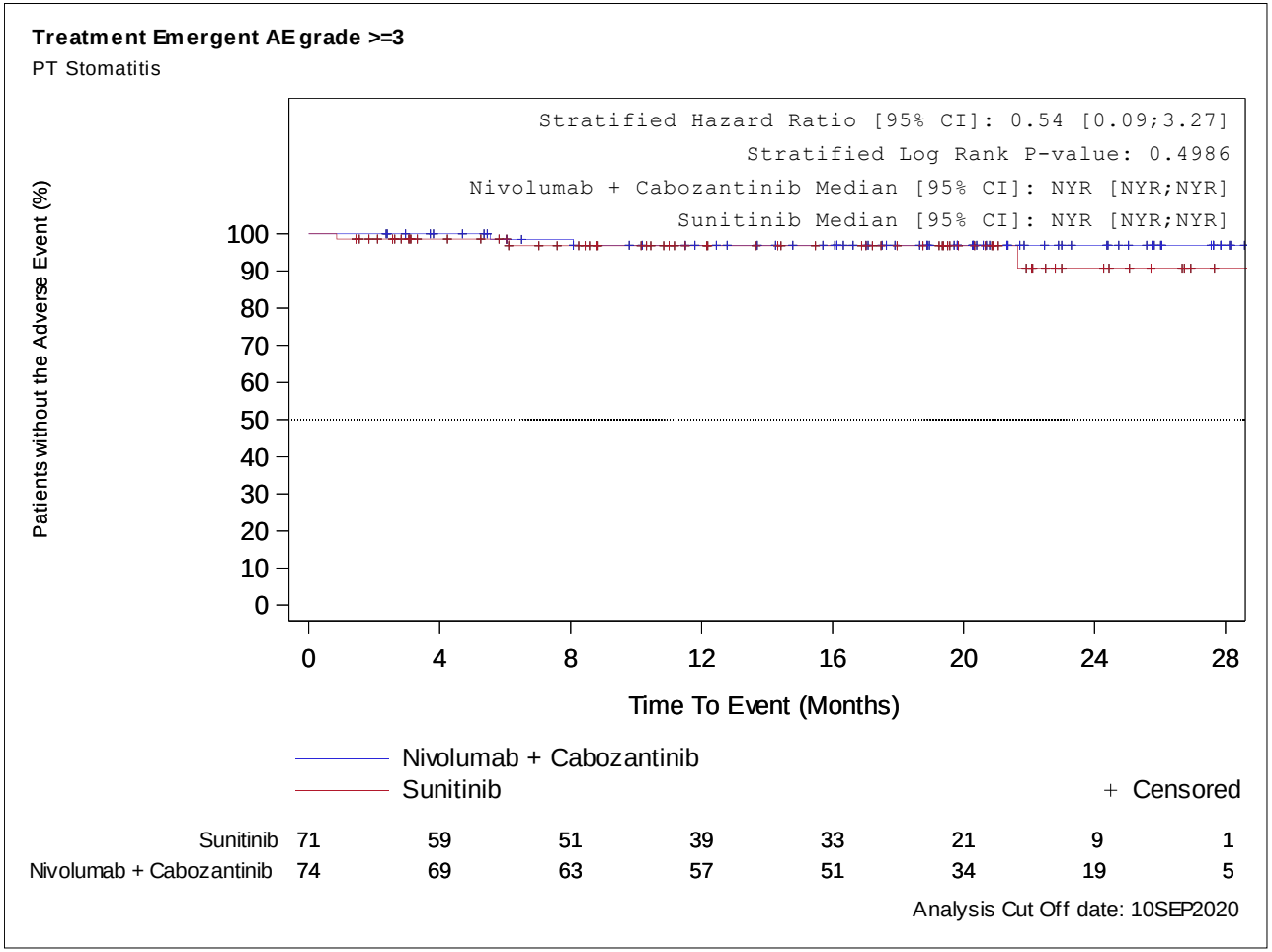
FIGURE 4.2.2.9: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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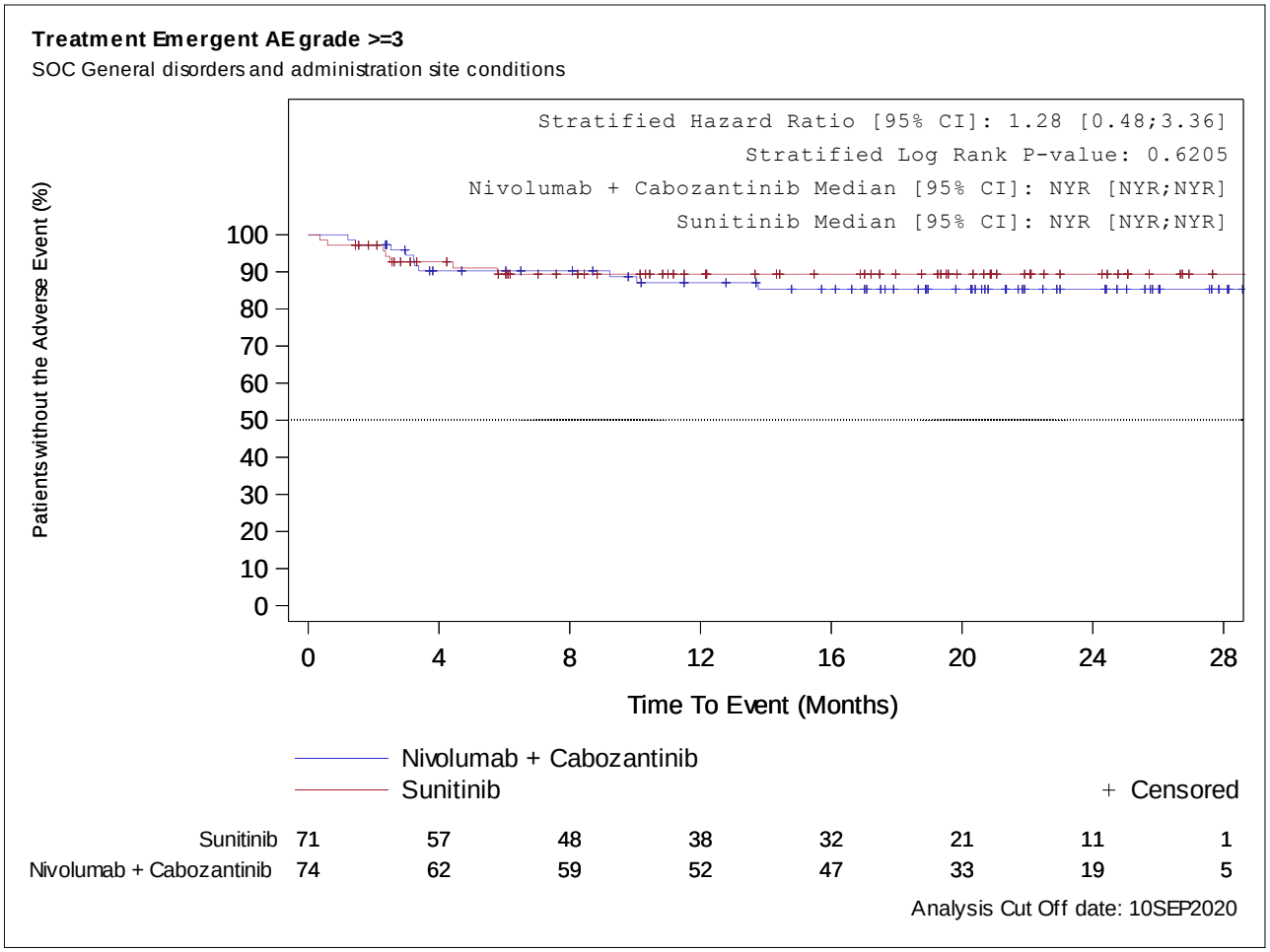
FIGURE 4.2.2.10: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC General disorders and administration site conditions - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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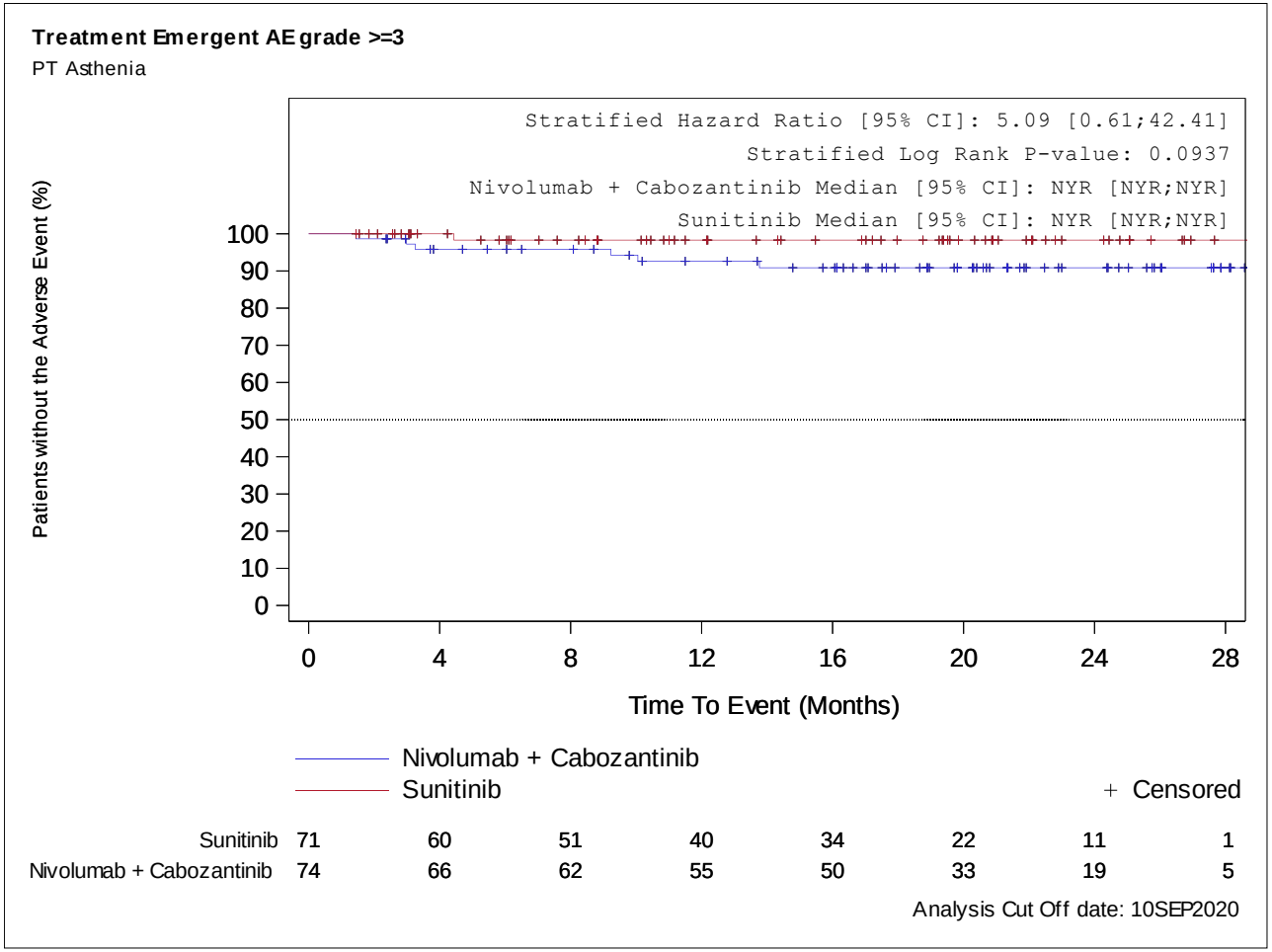
FIGURE 4.2.2.11: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Asthenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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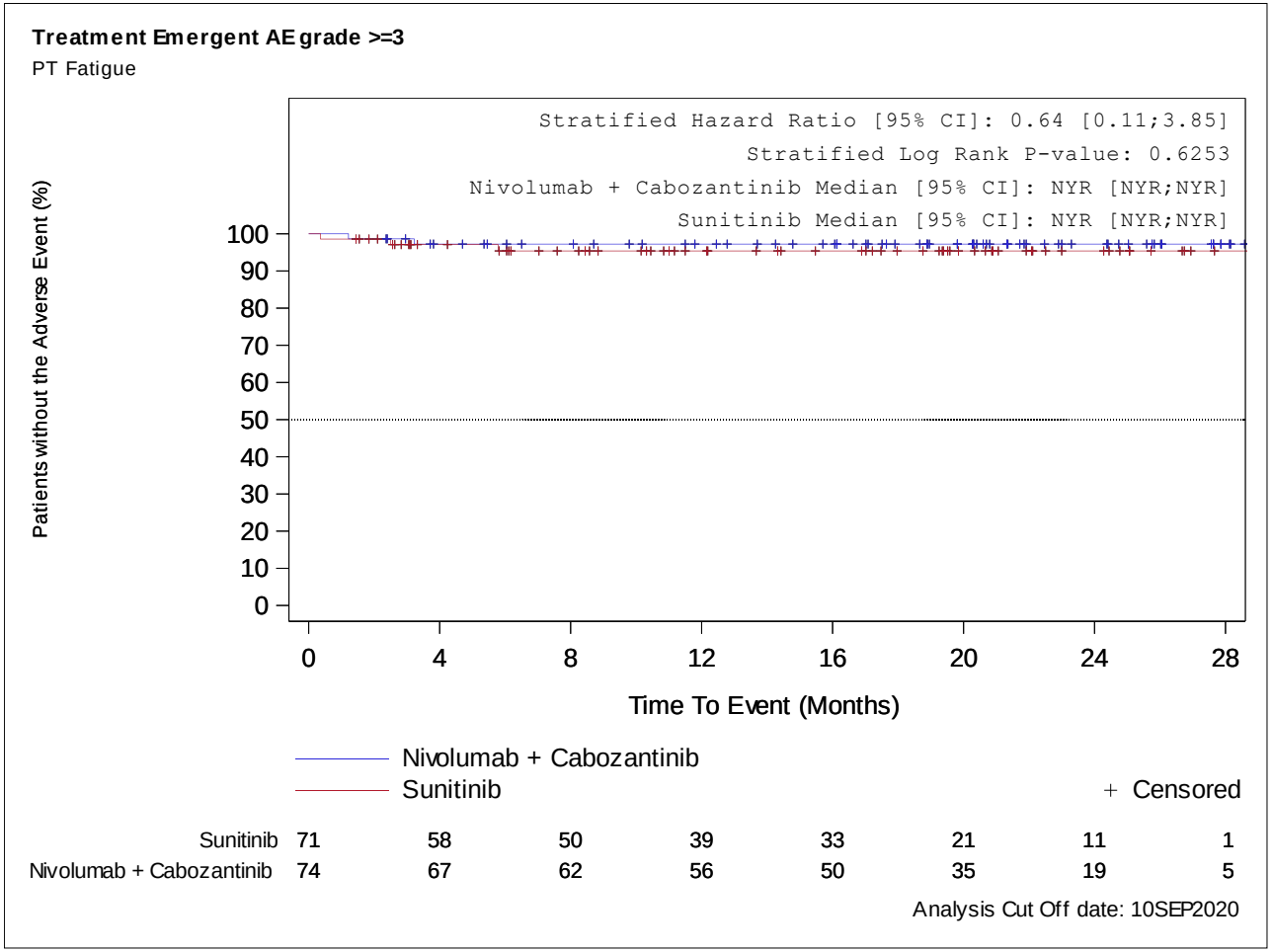
FIGURE 4.2.2.12: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Fatigue - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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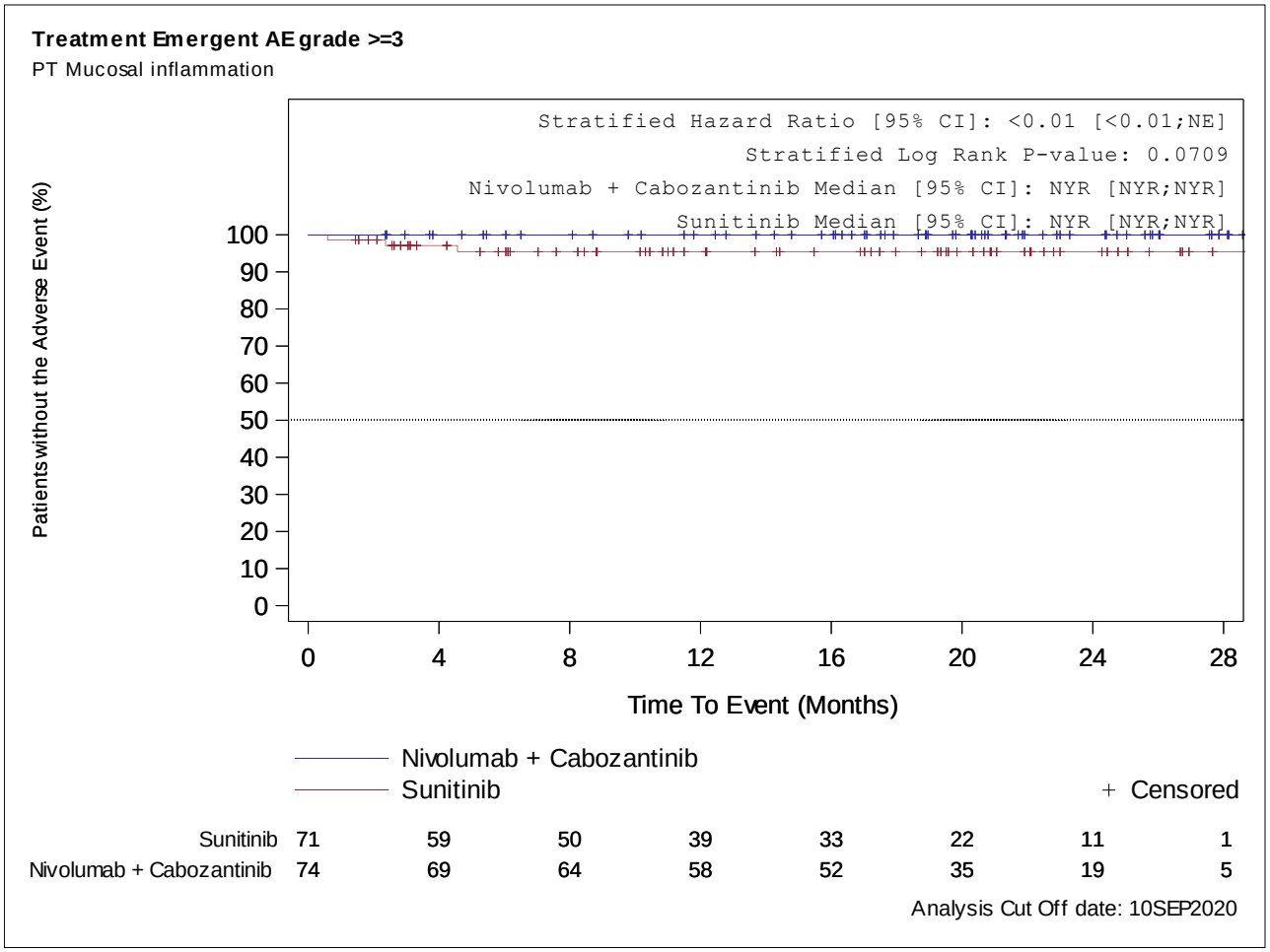
FIGURE 4.2.2.13: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Mucosal inflammation - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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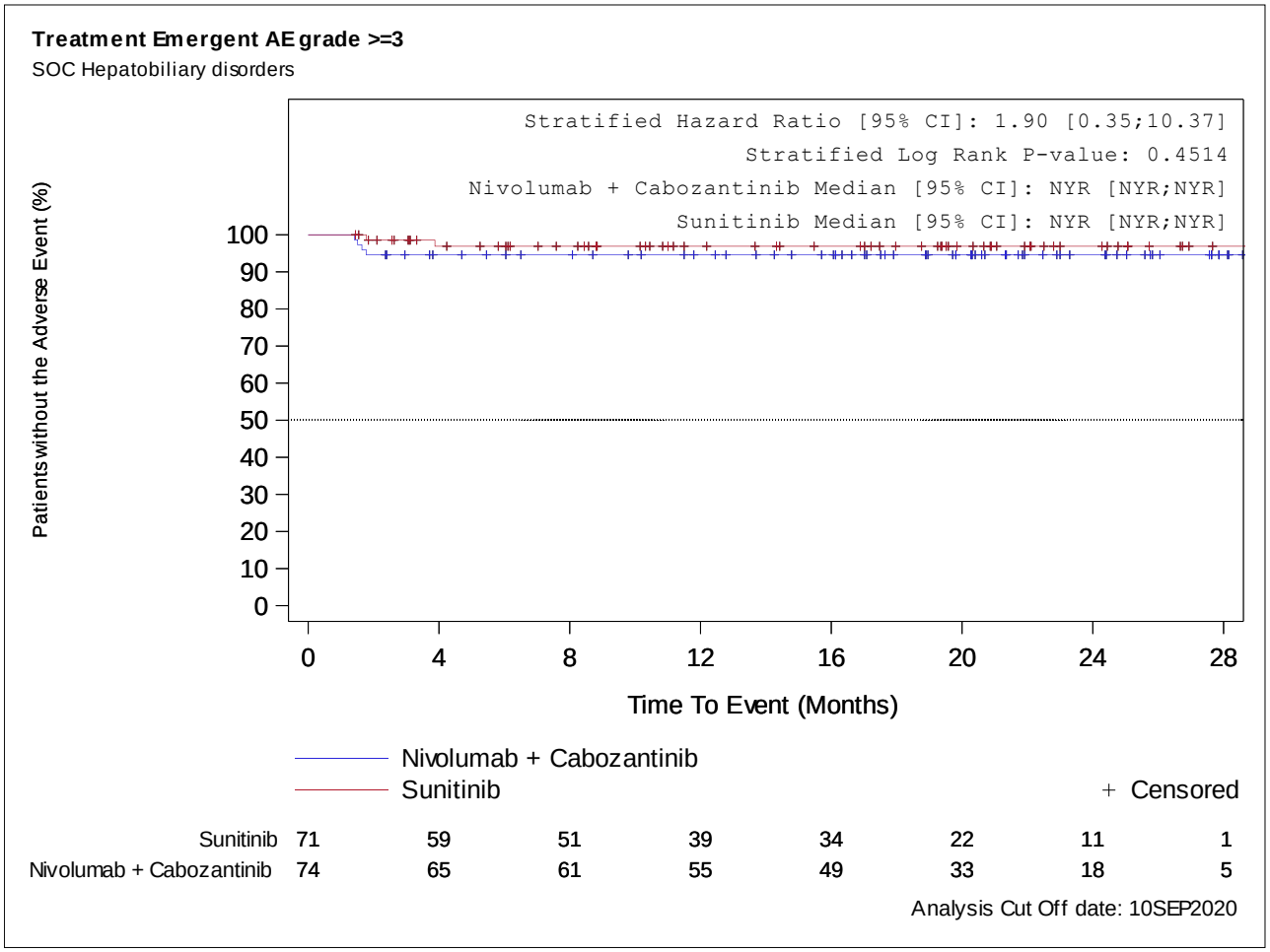
FIGURE 4.2.2.14: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Hepatobiliary disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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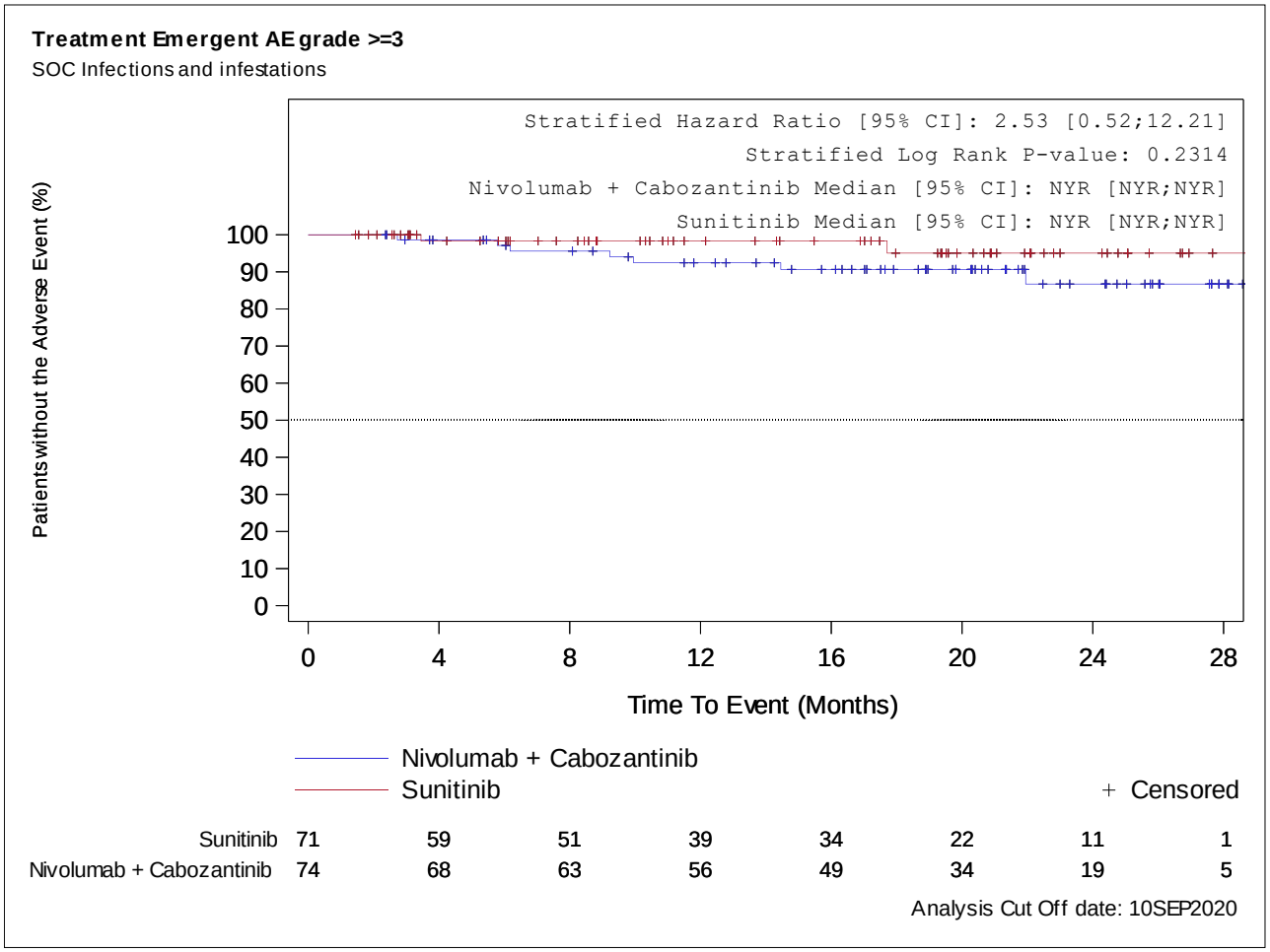
FIGURE 4.2.2.15: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Infections and infestations - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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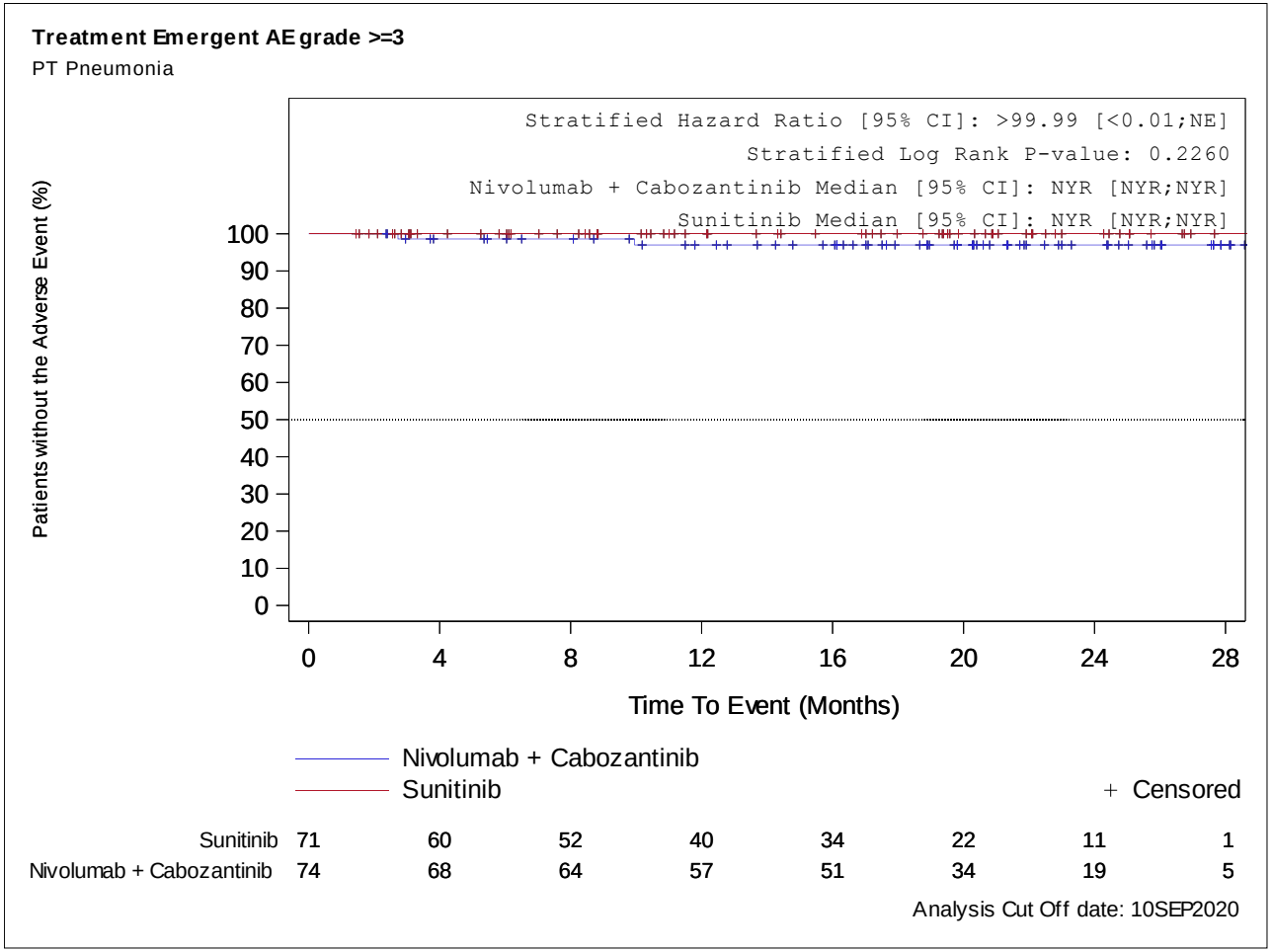
FIGURE 4.2.2.16: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Pneumonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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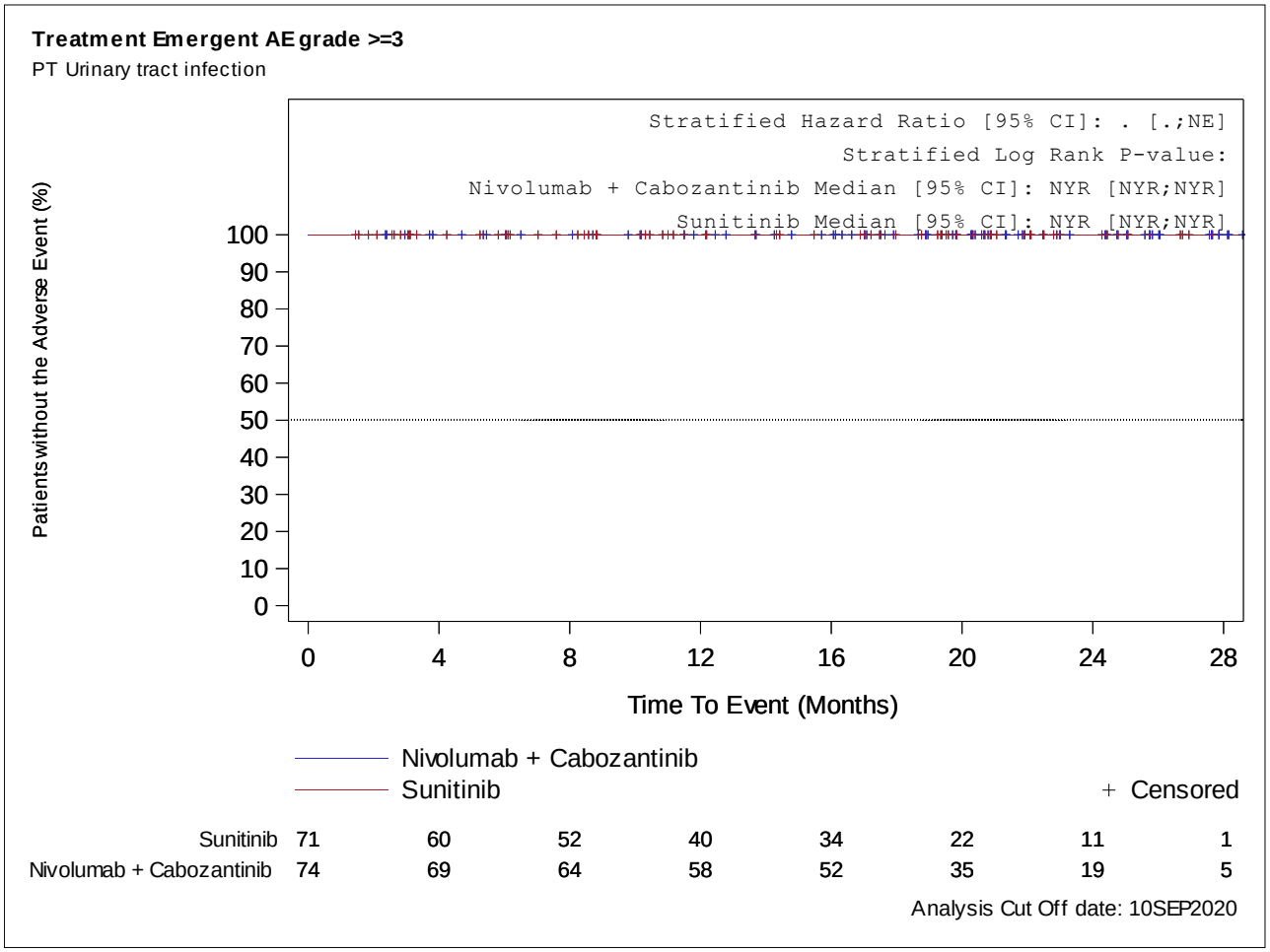
FIGURE 4.2.2.17: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Urinary tract infection - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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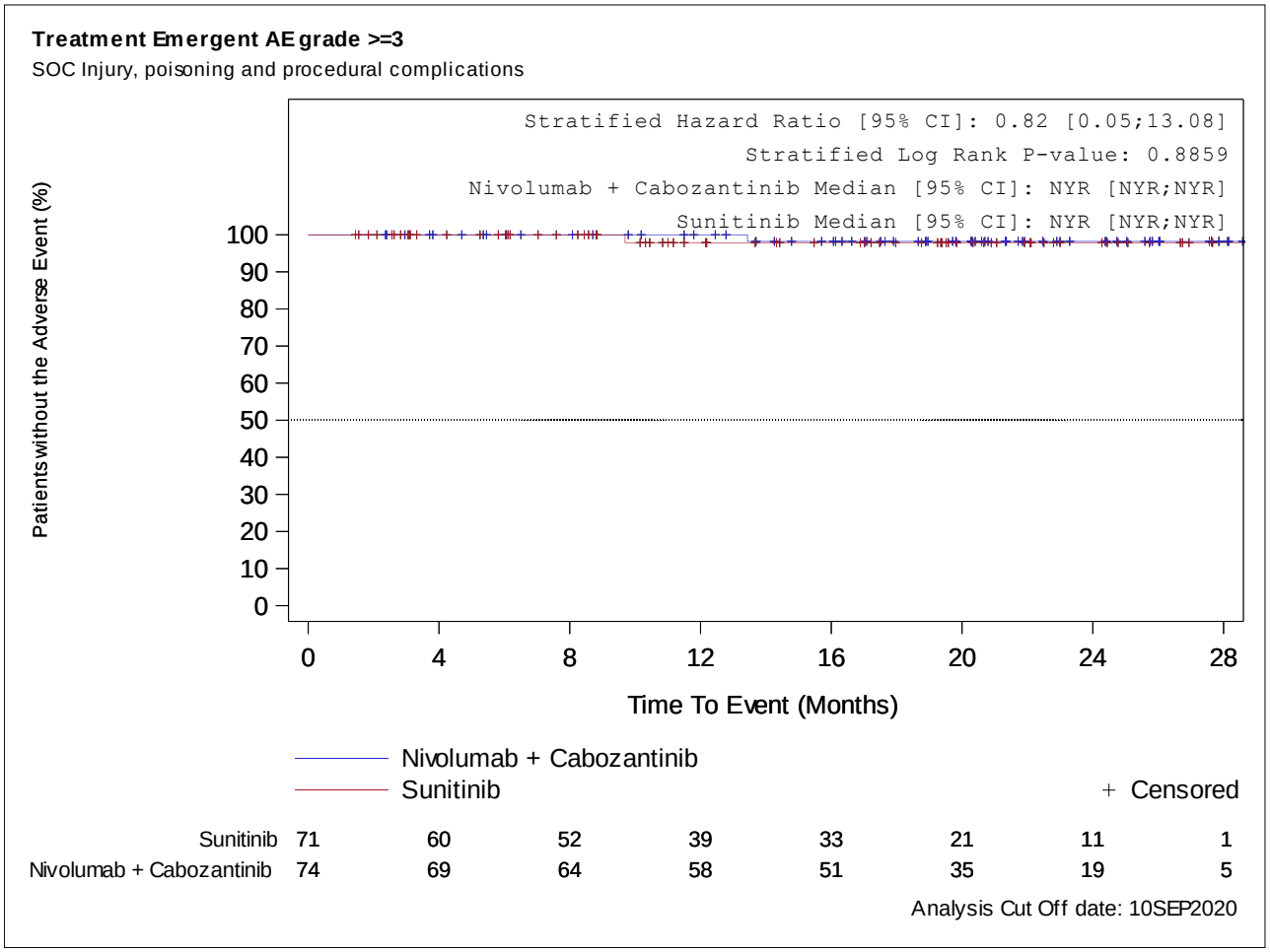
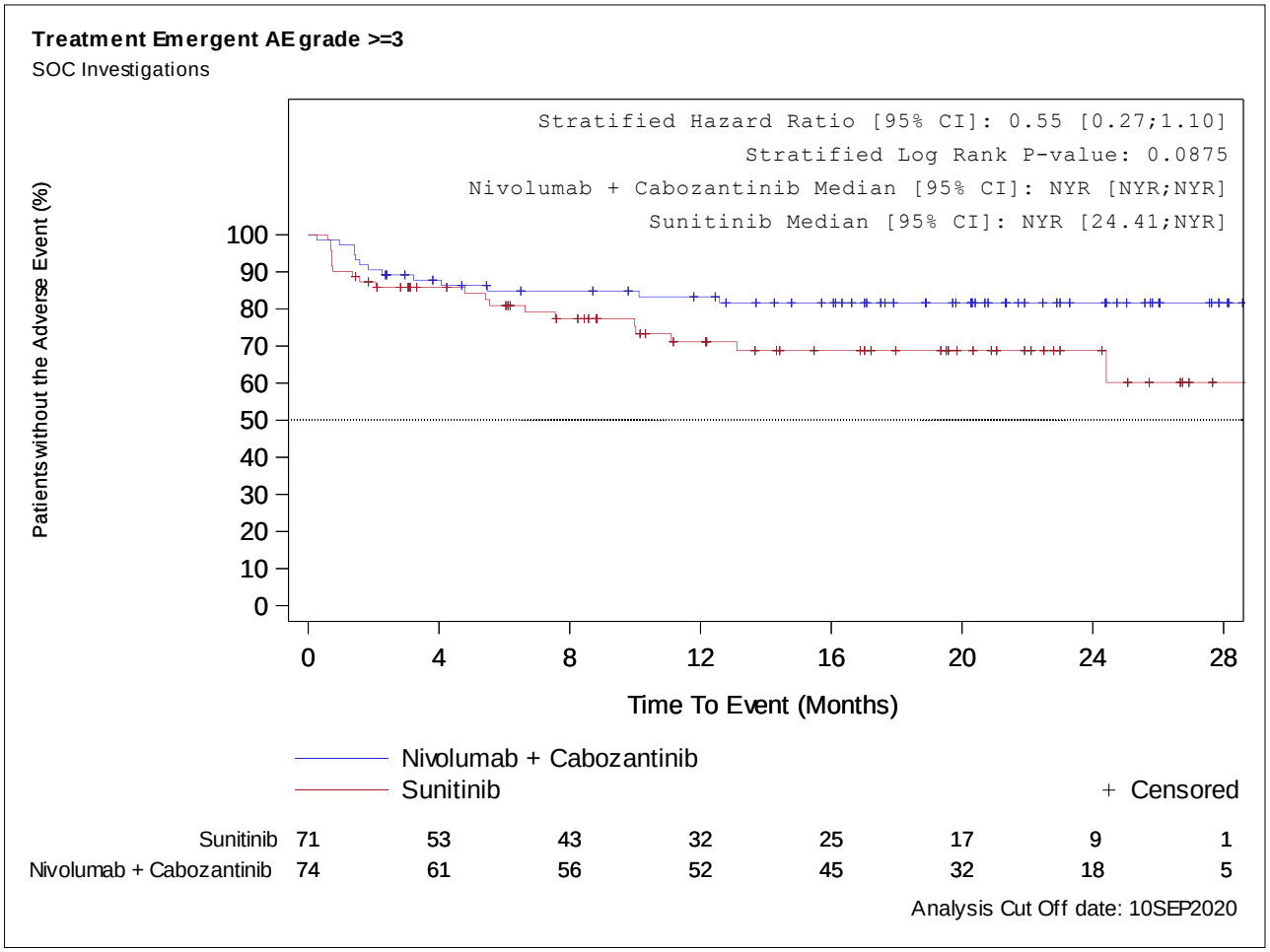
FIGURE 4.2.2.18: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Injury, poisoning and procedural complications - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:07:46

FIGURE 4.2.2.19: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Investigations - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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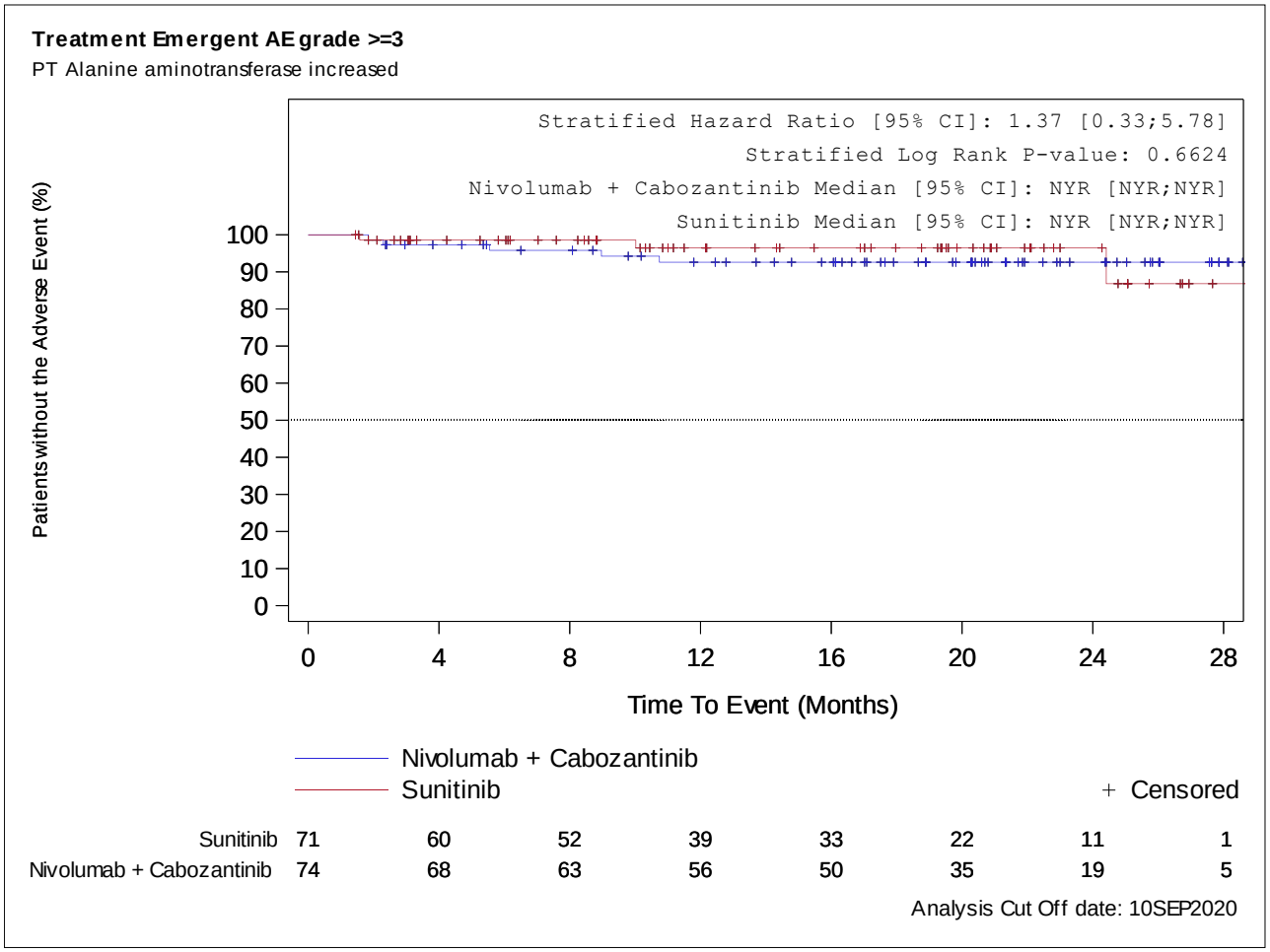
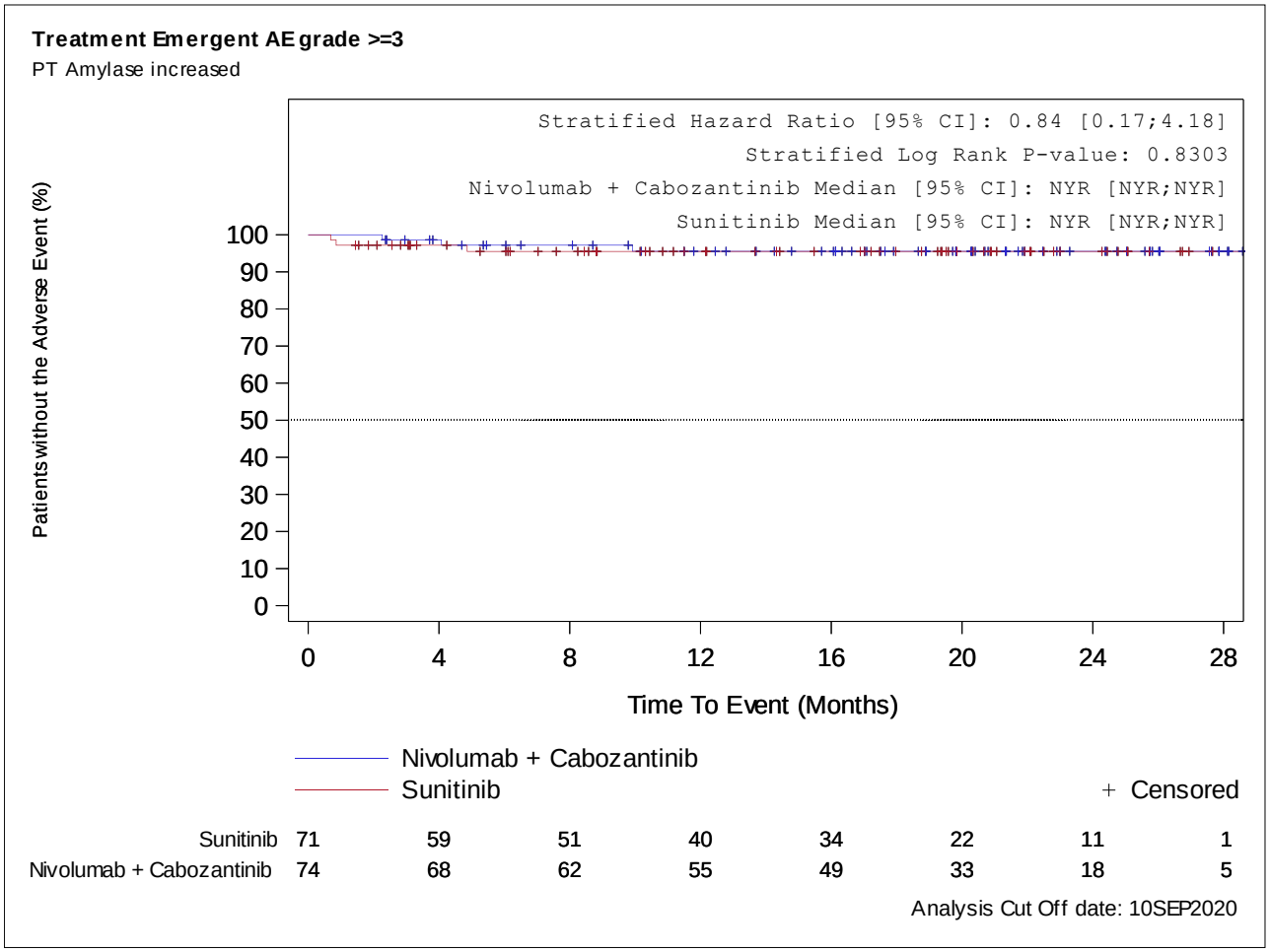
FIGURE 4.2.2.20: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Alanine aminotransferase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



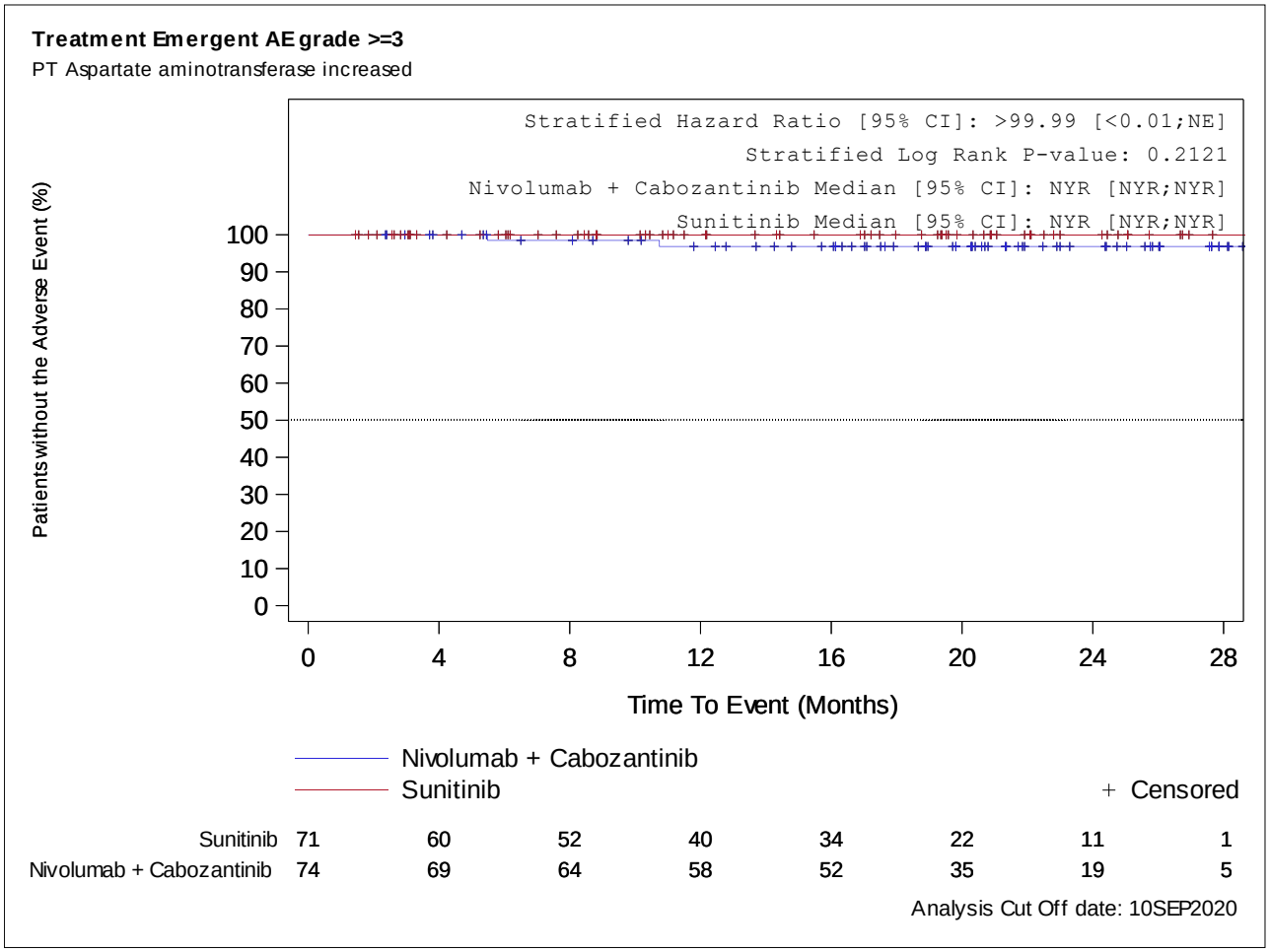

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:07:56

FIGURE 4.2.2.21: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Amylase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



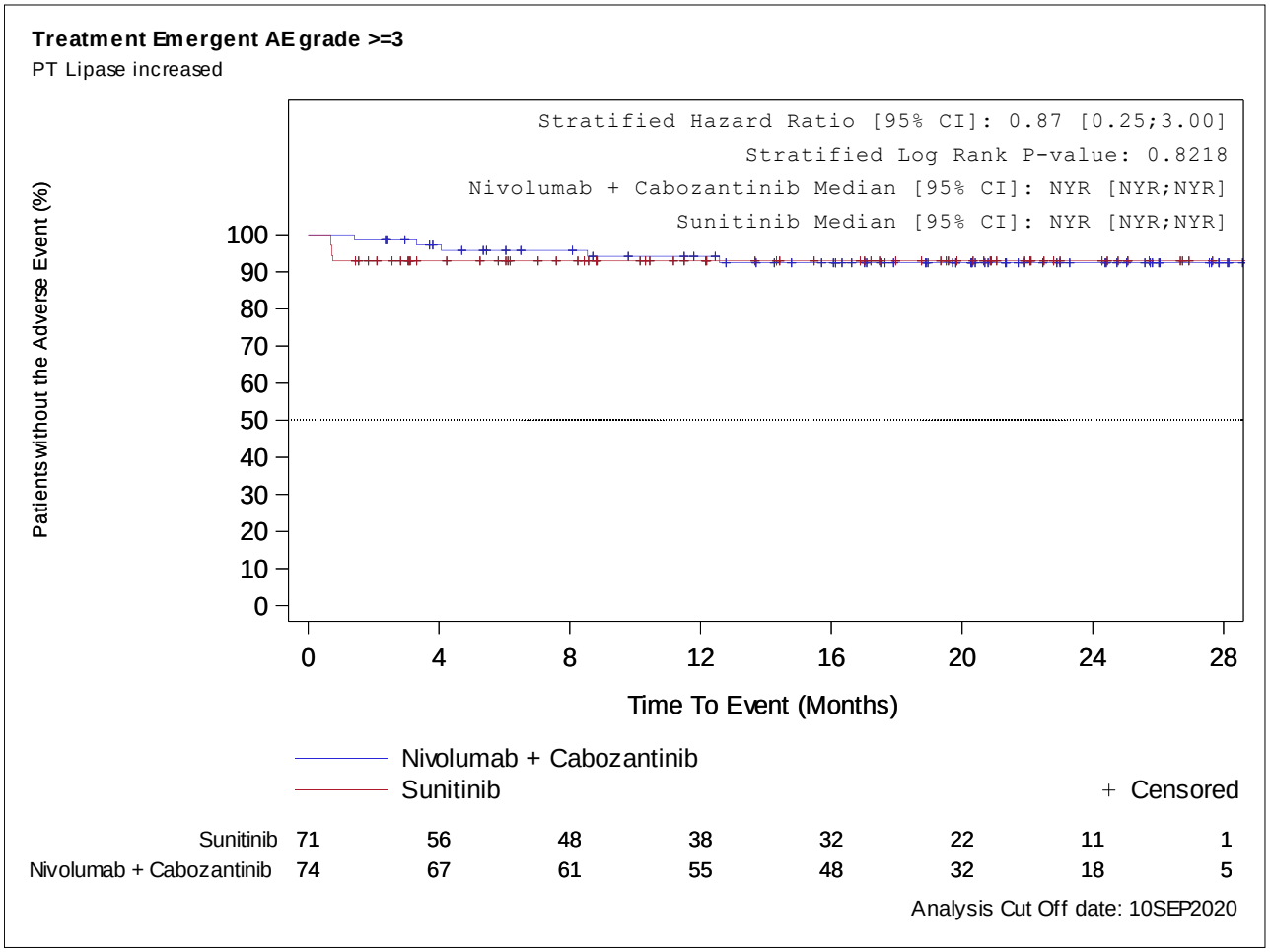

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:08:01

FIGURE 4.2.2.22: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Aspartate aminotransferase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:08:05

FIGURE 4.2.2.23: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Lipase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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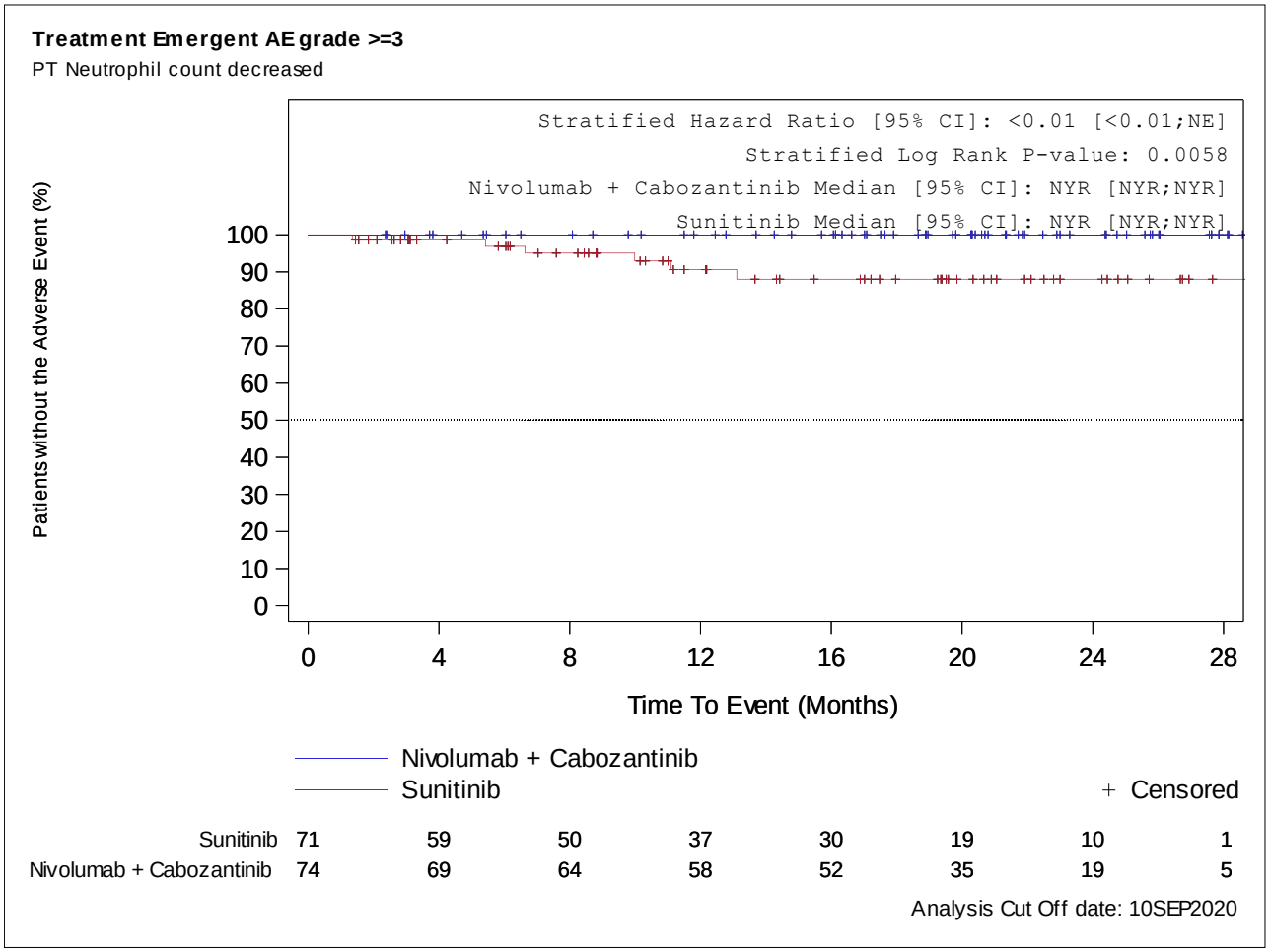
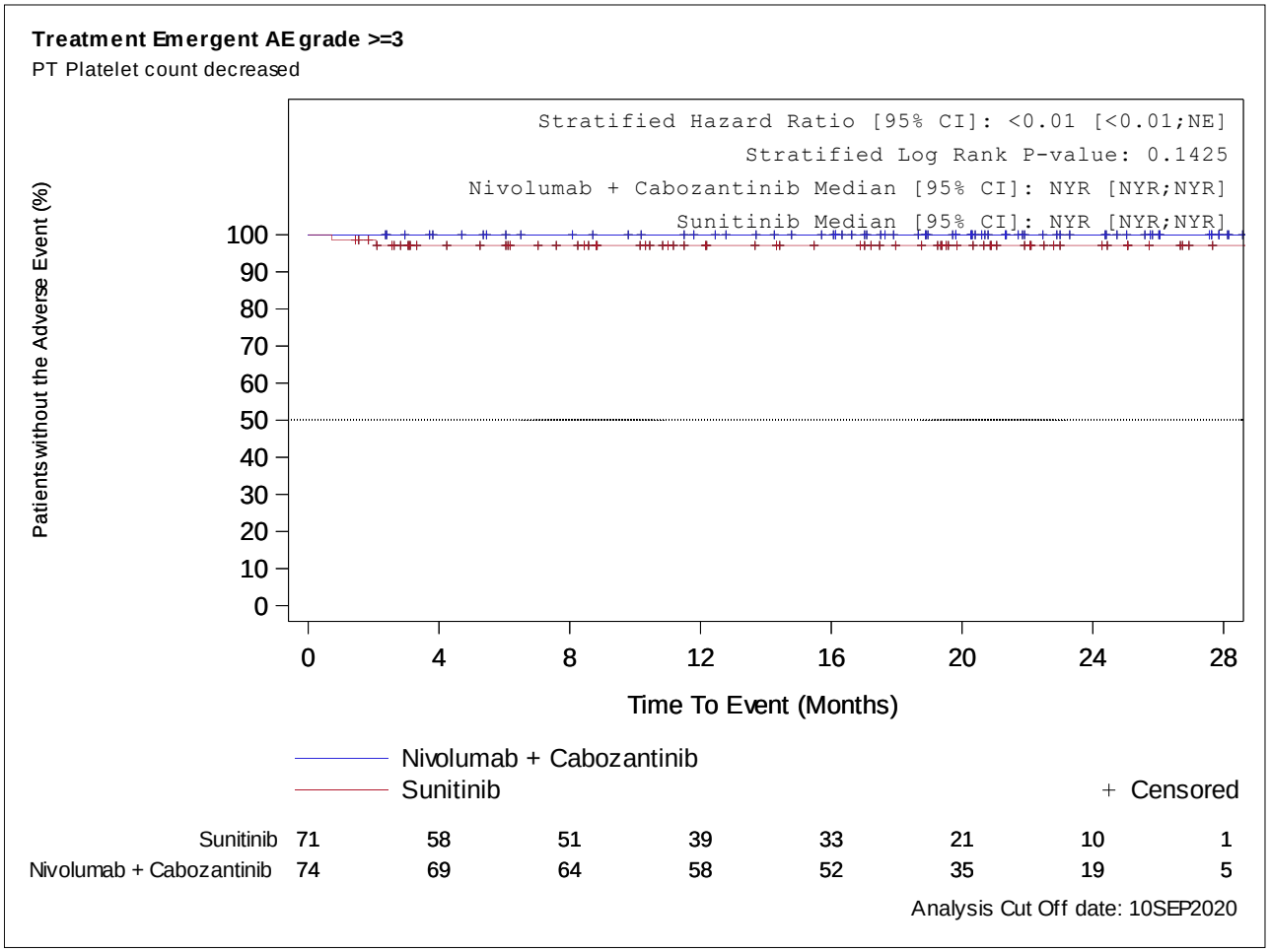
FIGURE 4.2.2.24: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Neutrophil count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:08:13

FIGURE 4.2.2.25: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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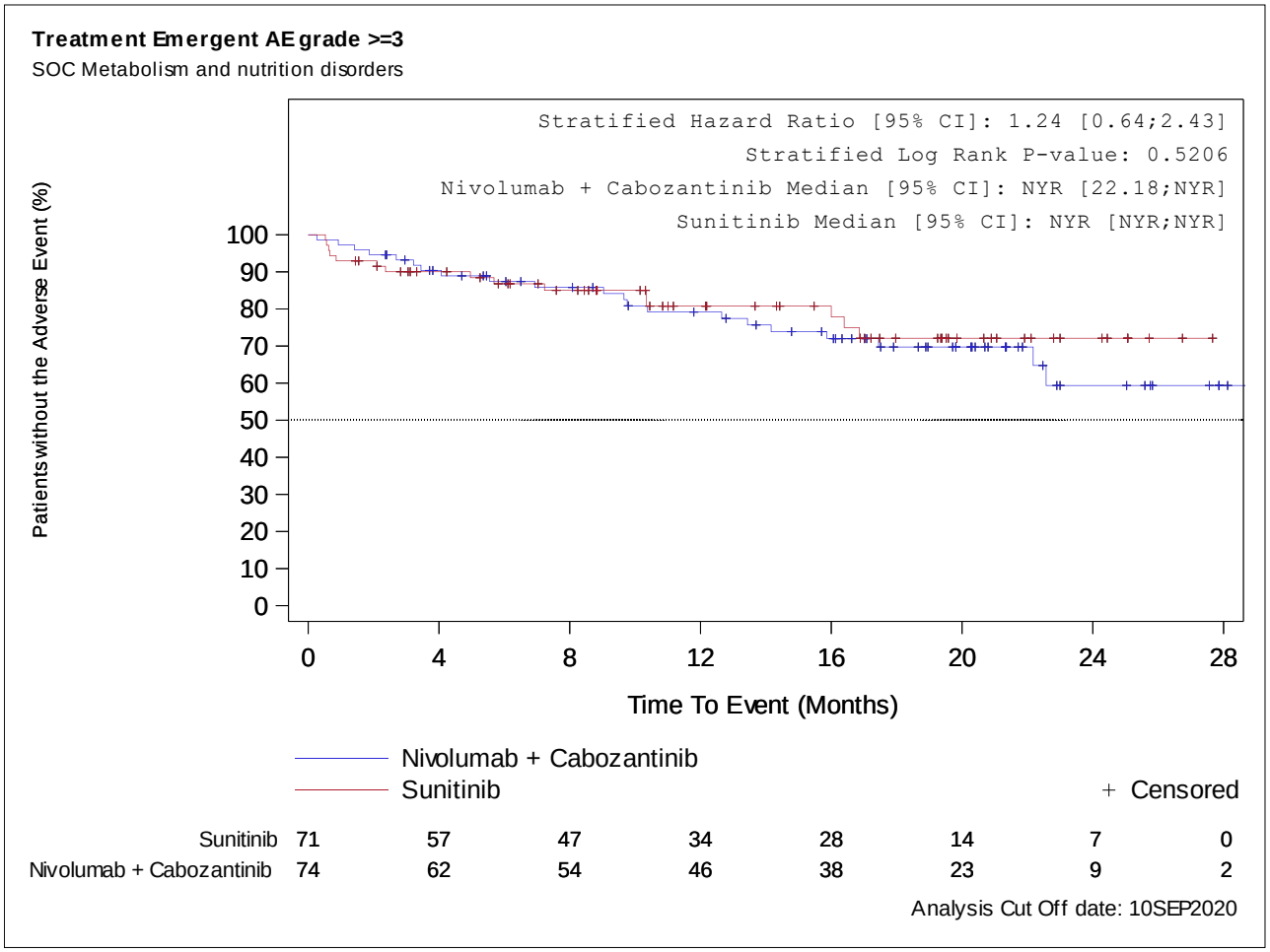
FIGURE 4.2.2.26: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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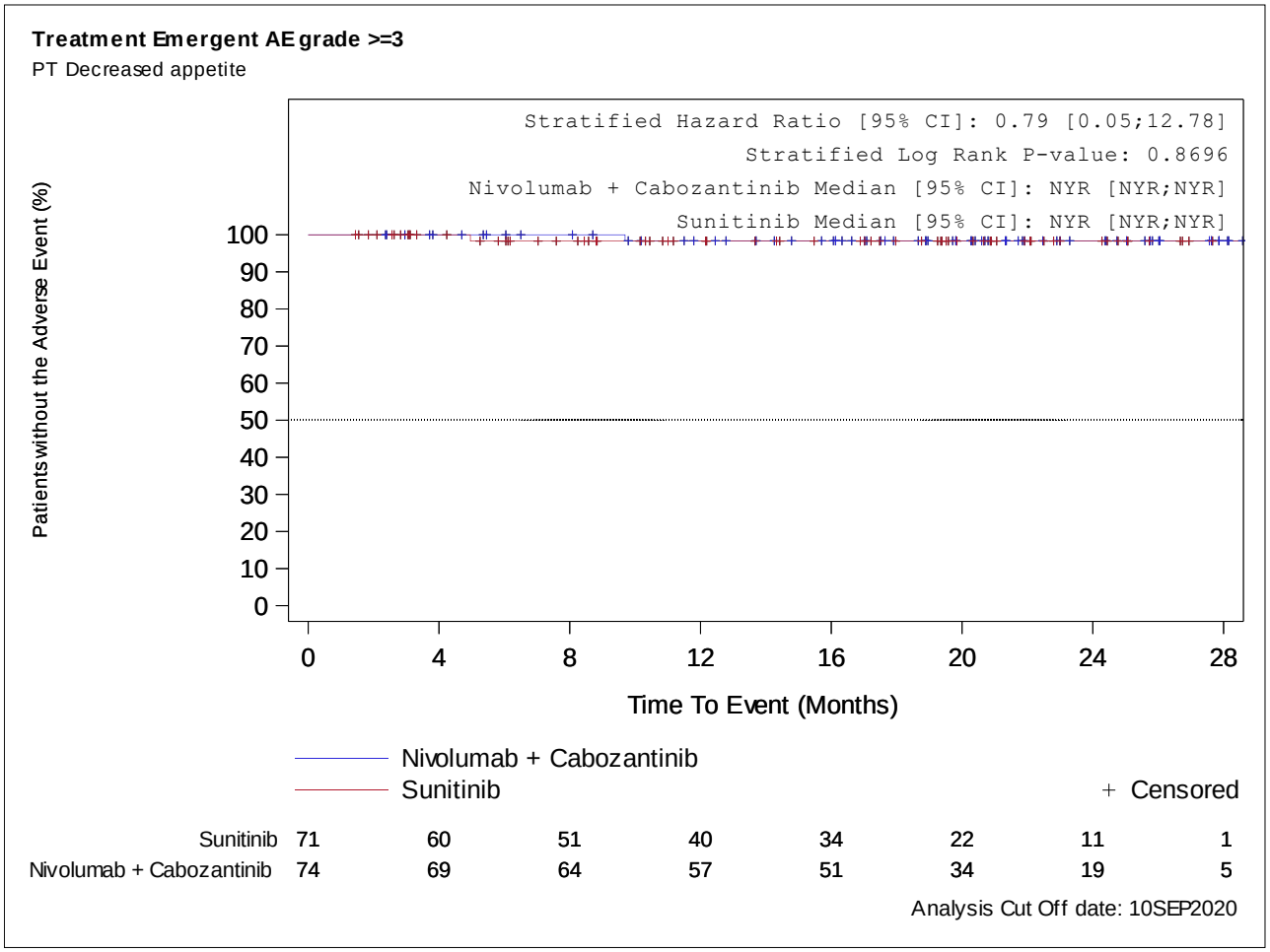
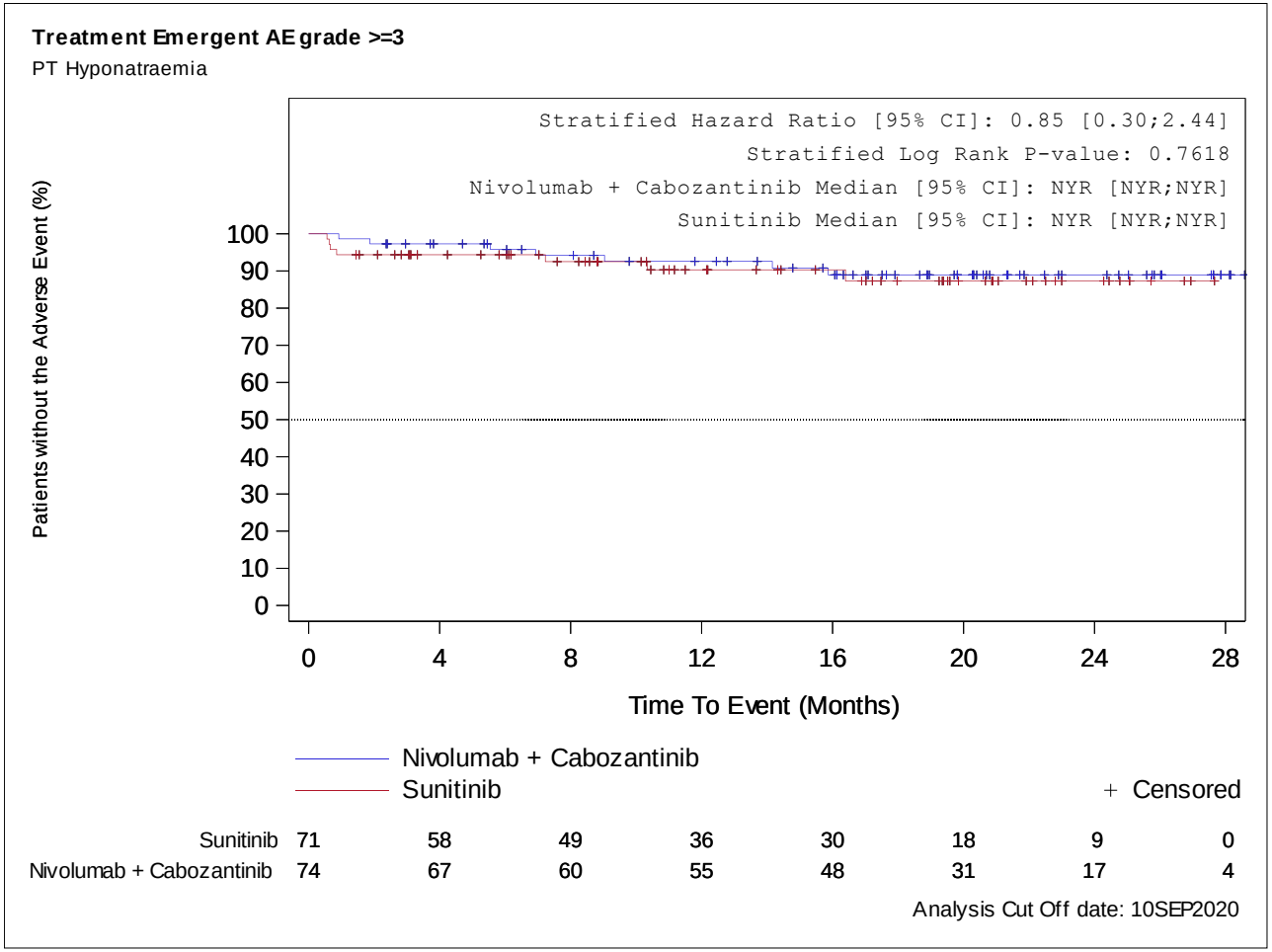
FIGURE 4.2.2.27: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:08:25

FIGURE 4.2.2.28: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Hyponatraemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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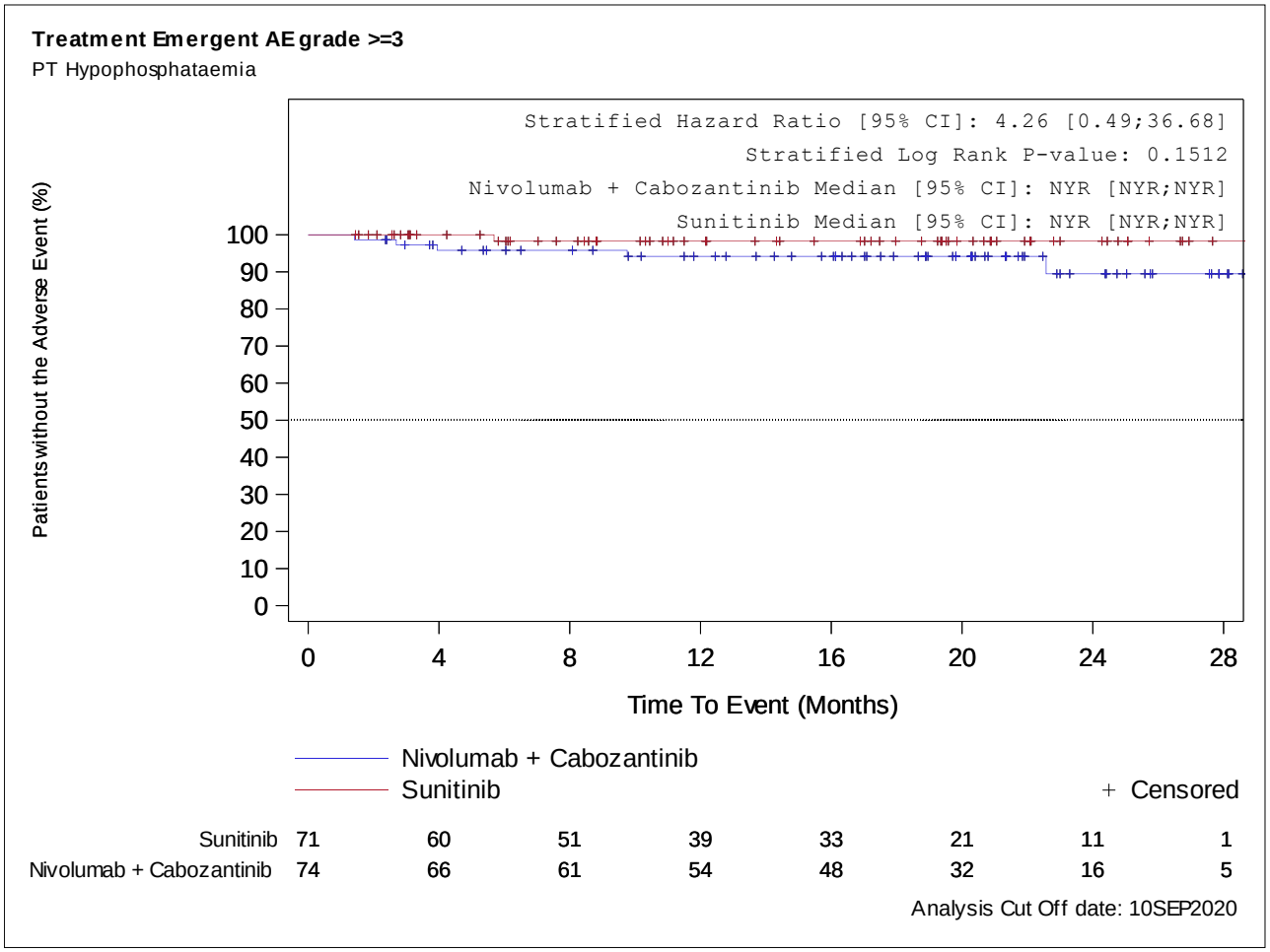
FIGURE 4.2.2.29: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Hypophosphataemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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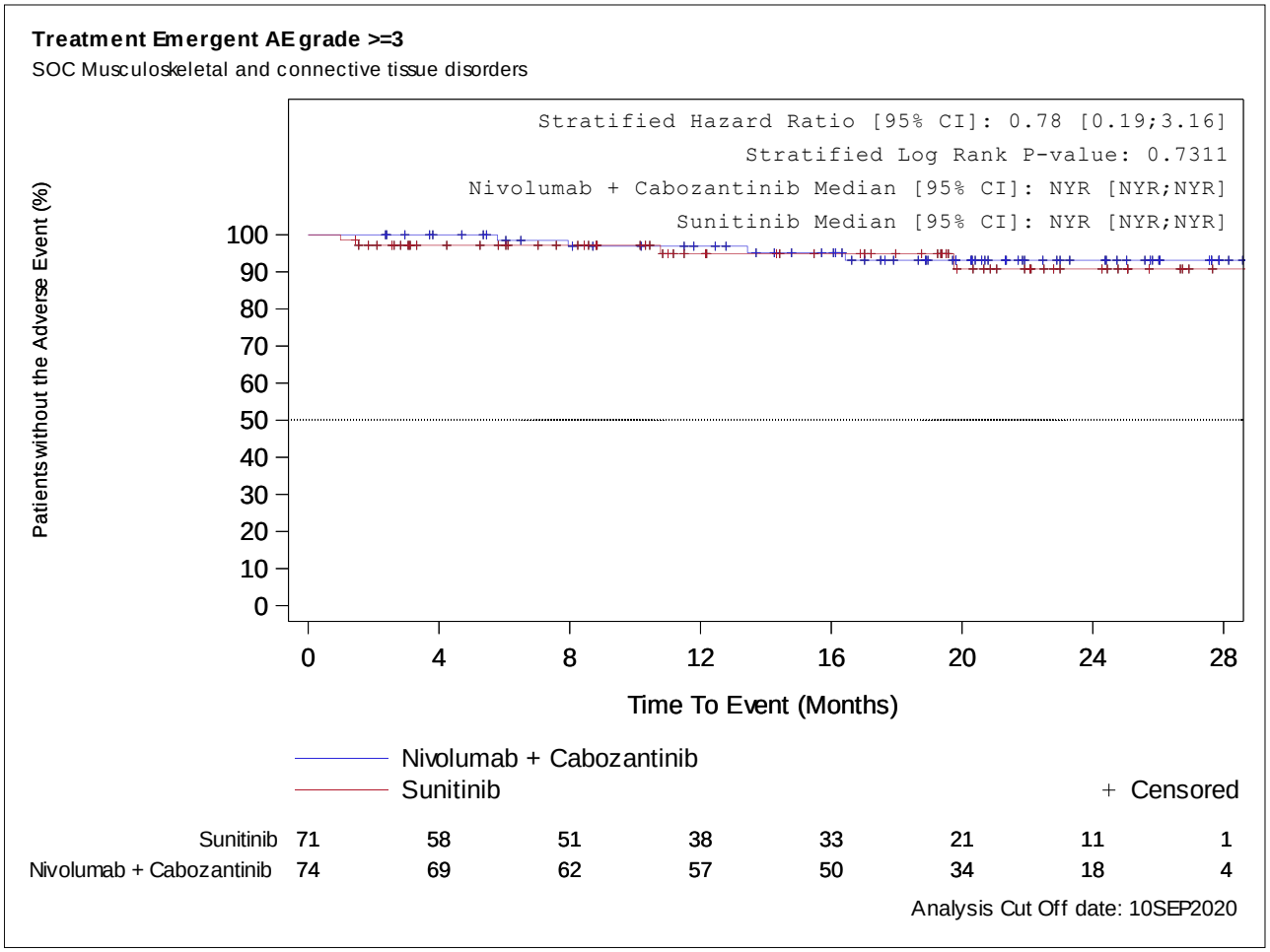
FIGURE 4.2.2.30: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Musculoskeletal and connective tissue disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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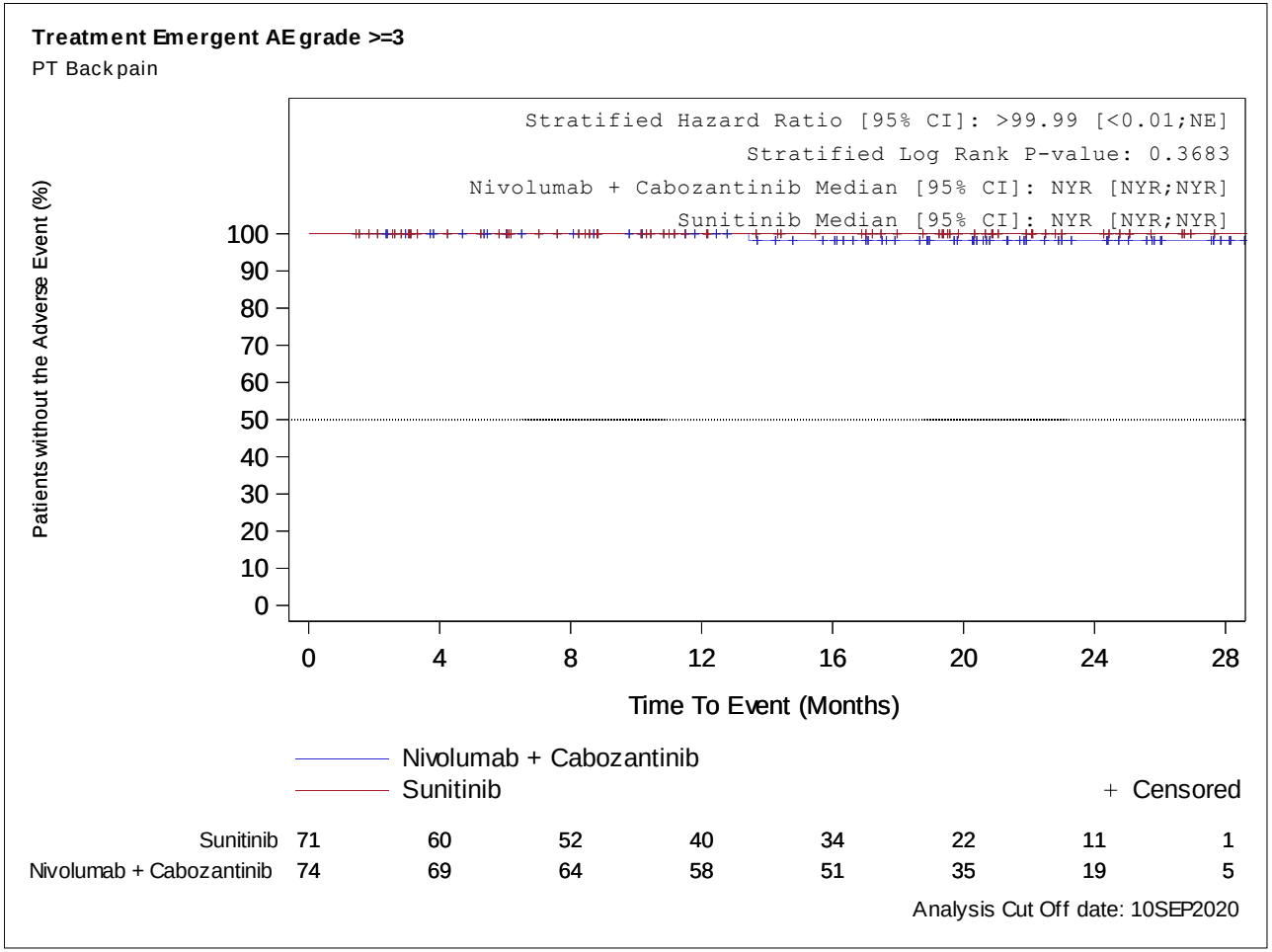
FIGURE 4.2.2.31: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Back pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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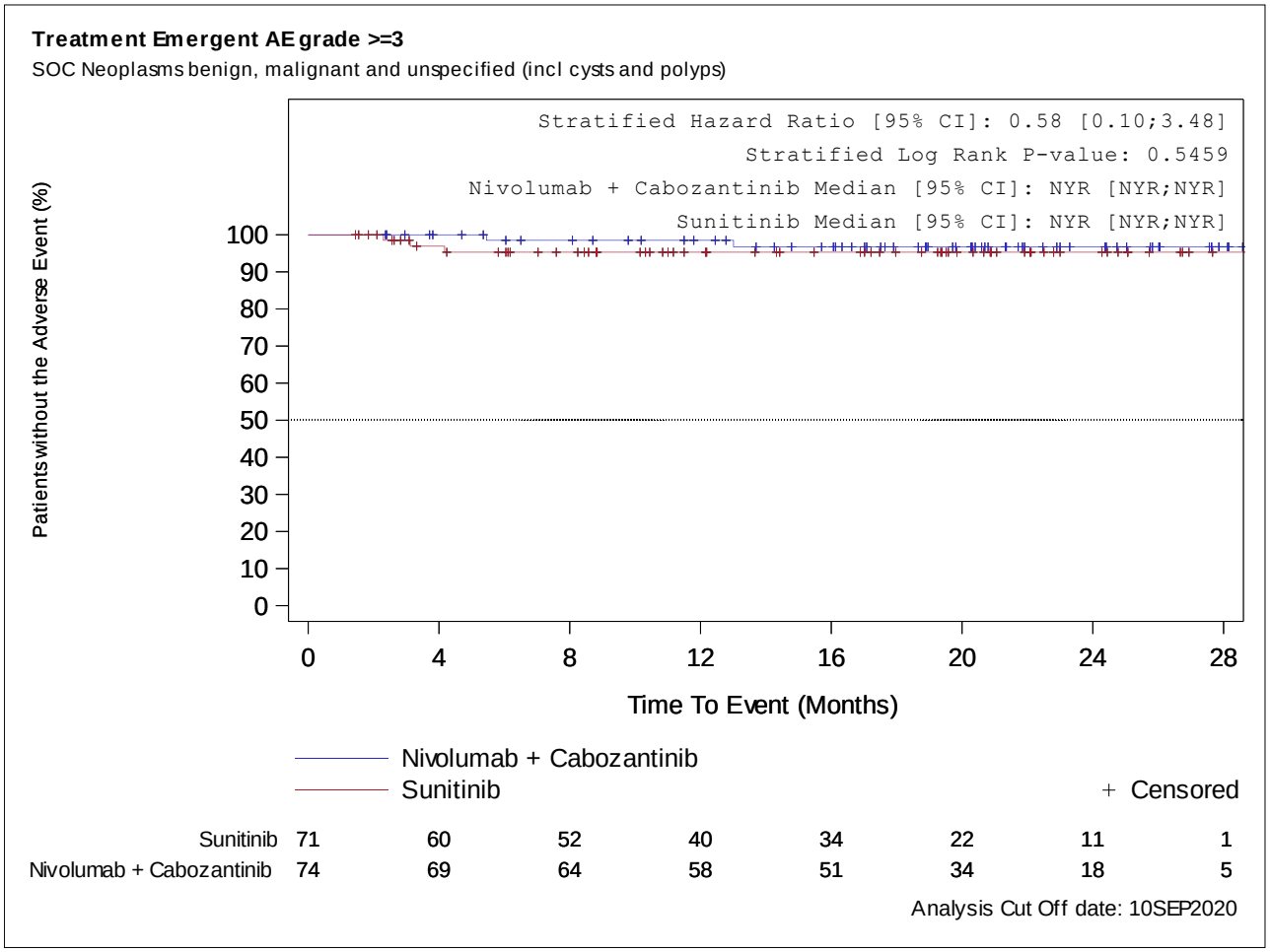
FIGURE 4.2.2.32: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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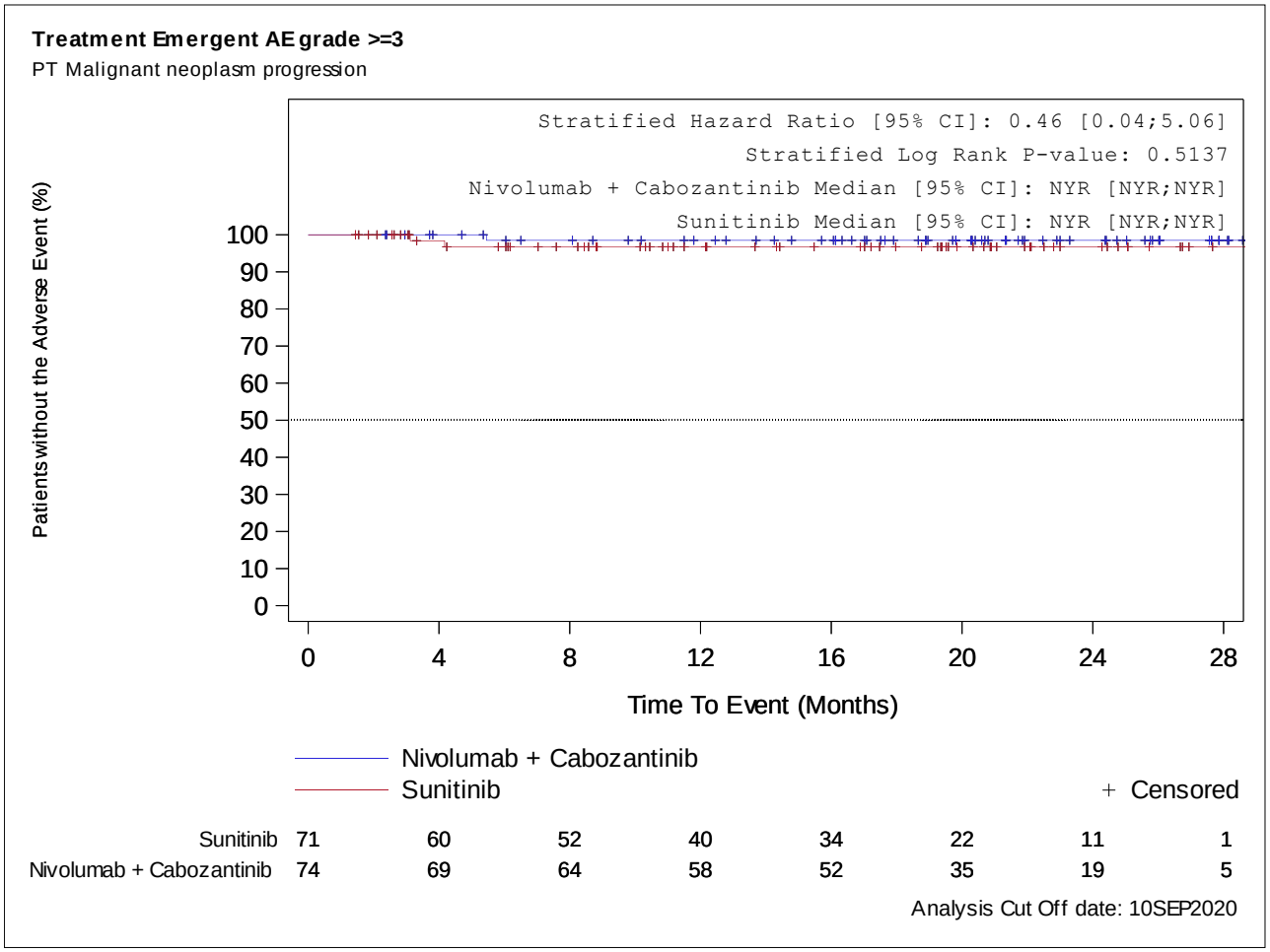
FIGURE 4.2.2.33: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Malignant neoplasm progression - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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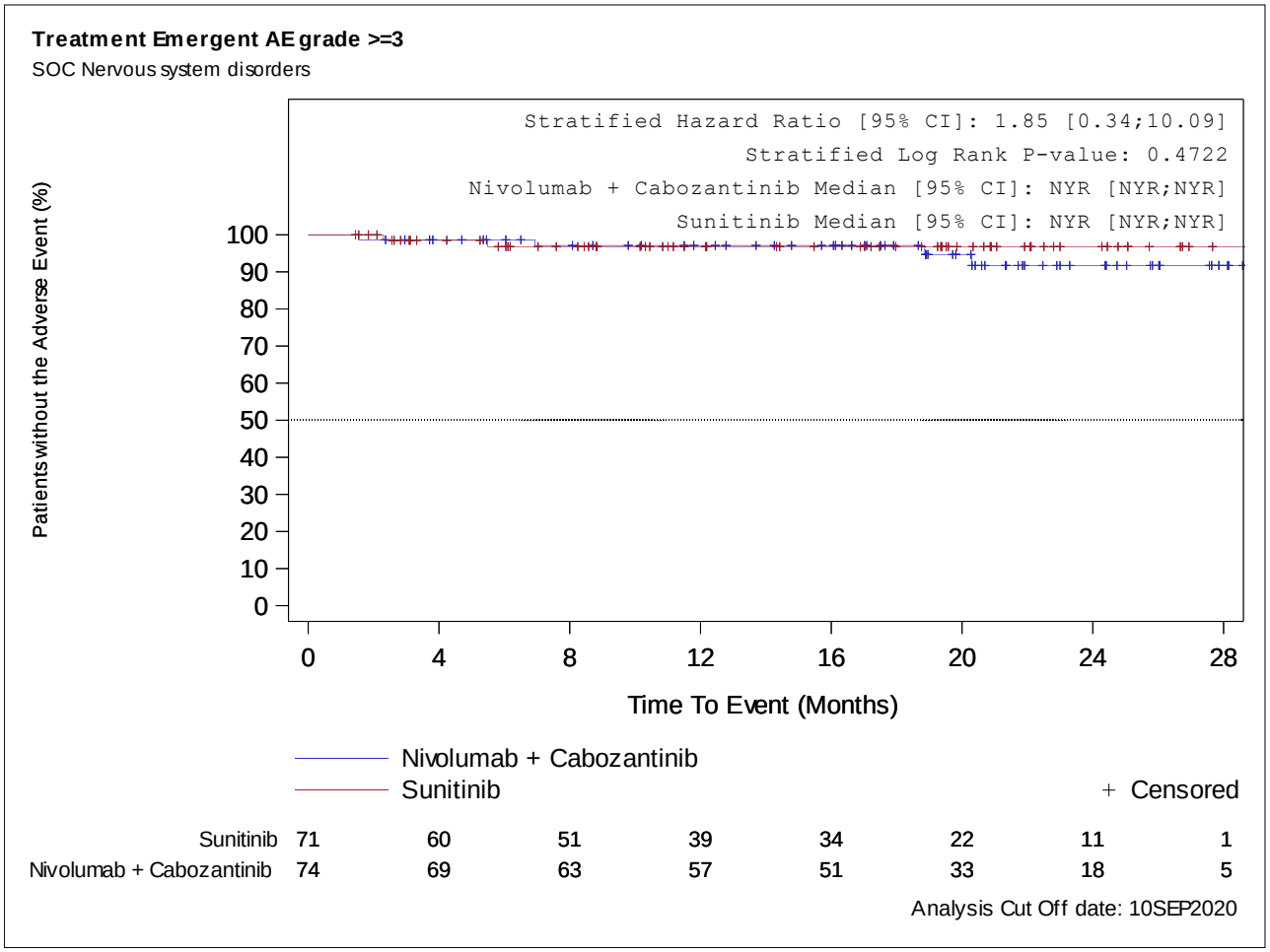
FIGURE 4.2.2.34: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Nervous system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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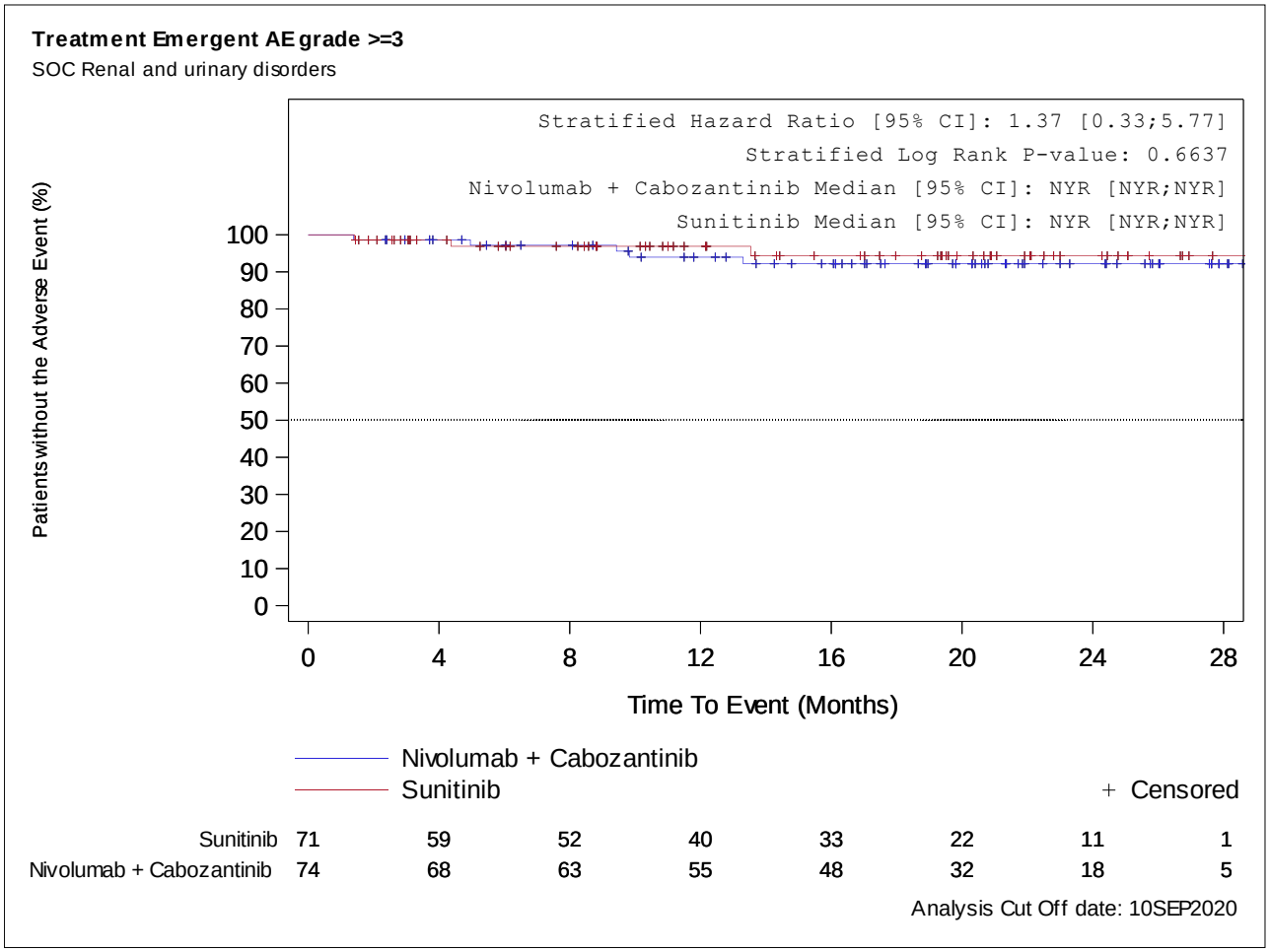
FIGURE 4.2.2.35: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Renal and urinary disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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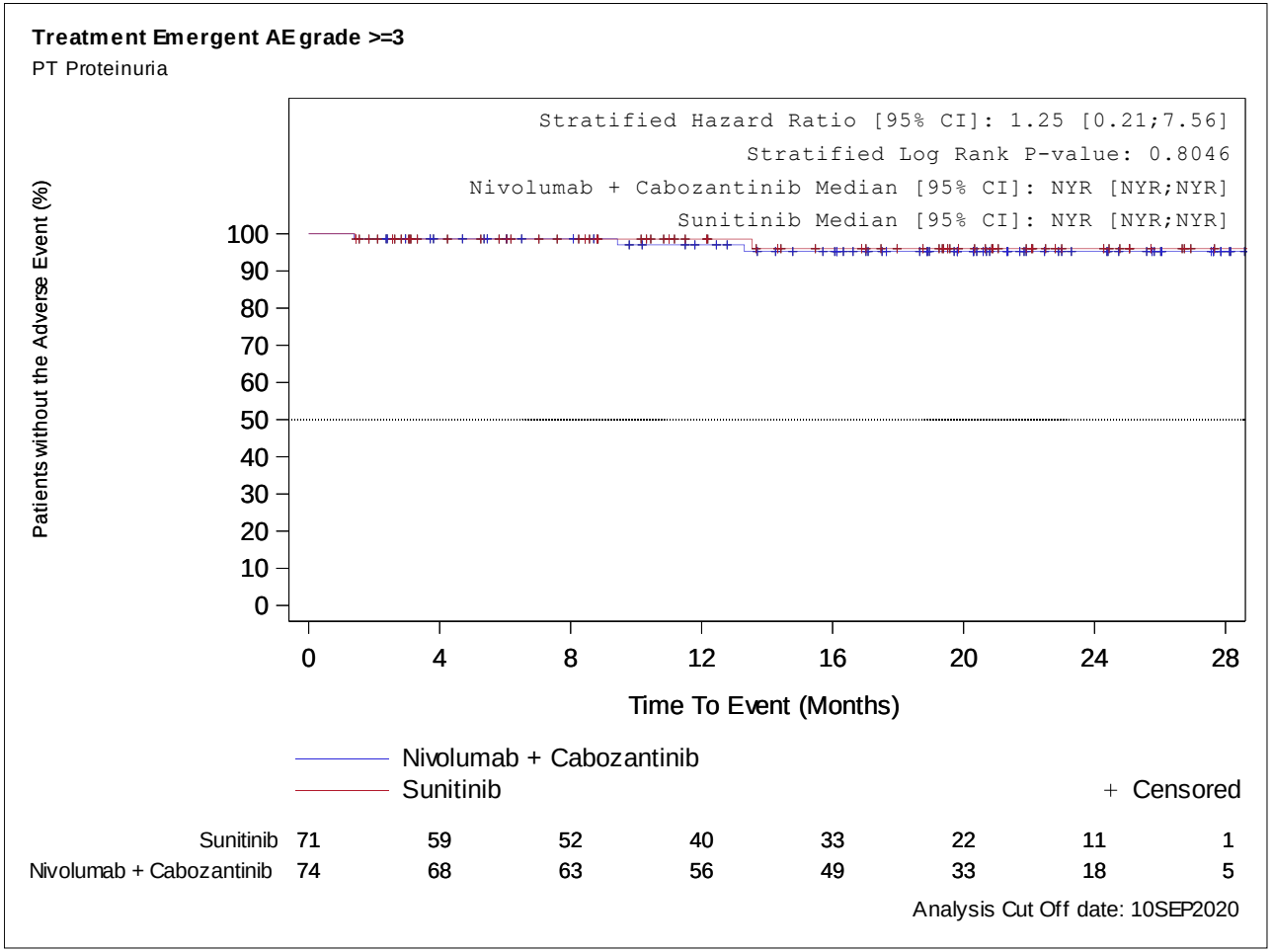
FIGURE 4.2.2.36: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Proteinuria - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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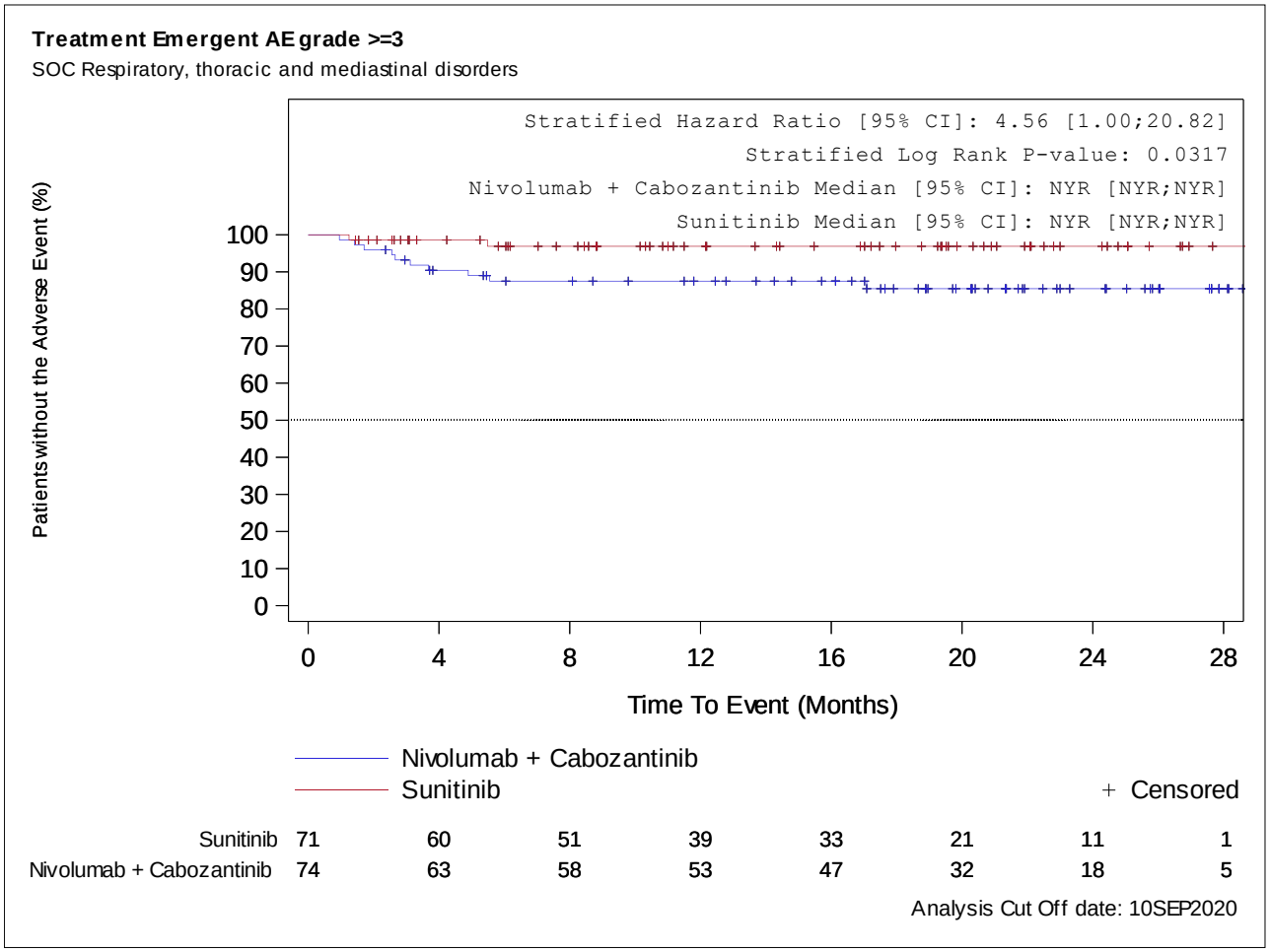
FIGURE 4.2.2.37: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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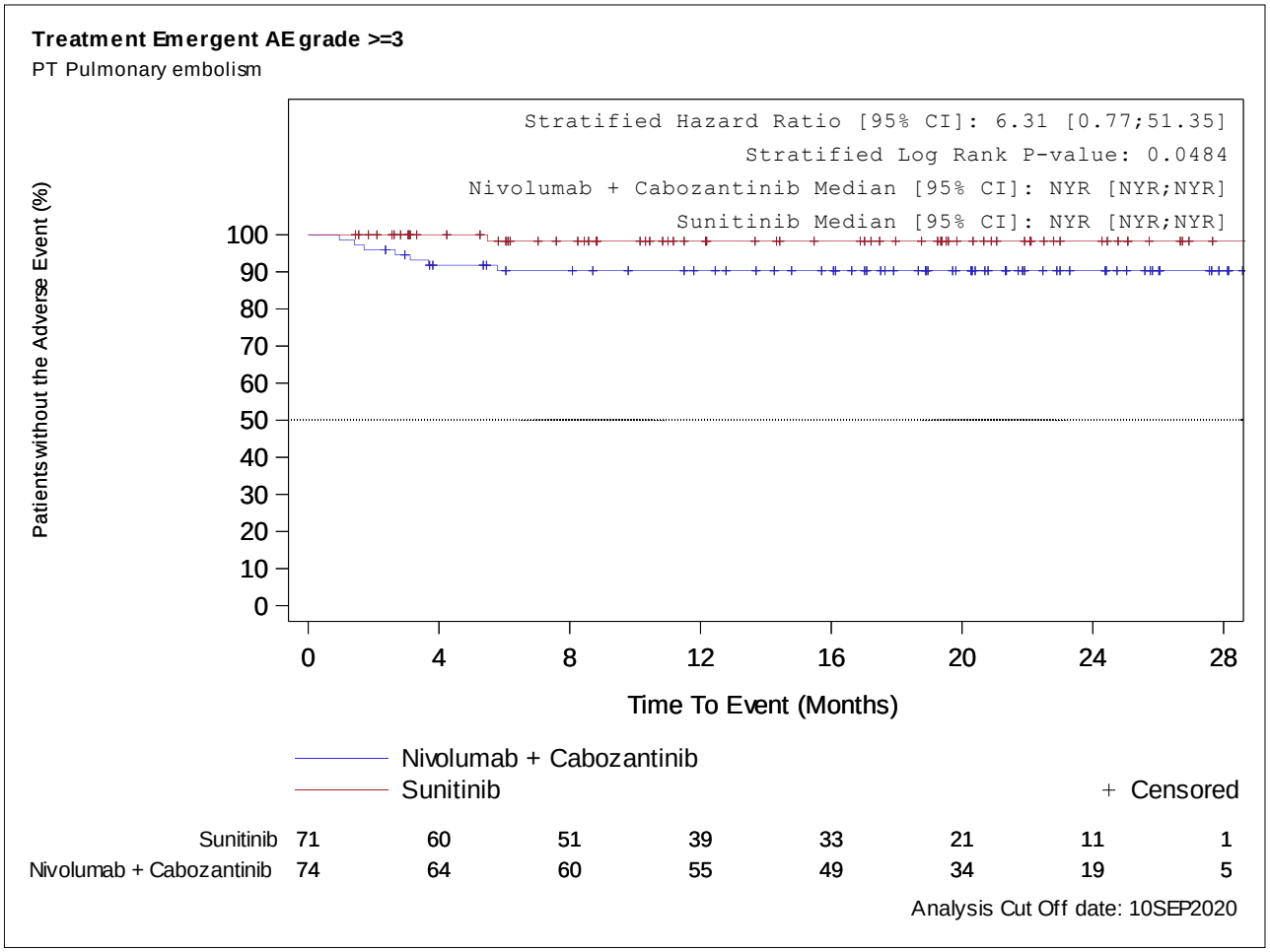
FIGURE 4.2.2.38: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Pulmonary embolism - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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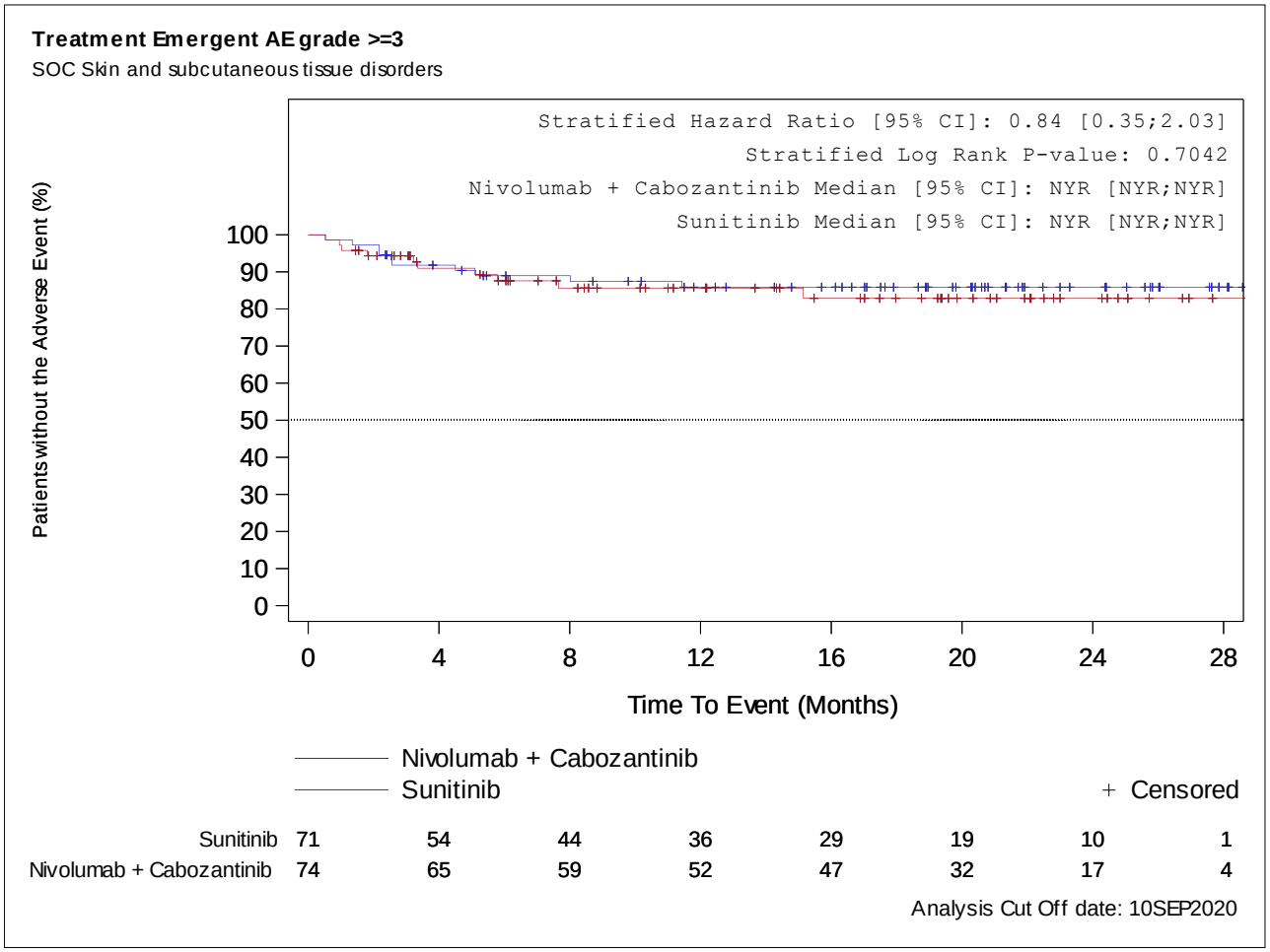
FIGURE 4.2.2.39: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Skin and subcutaneous tissue disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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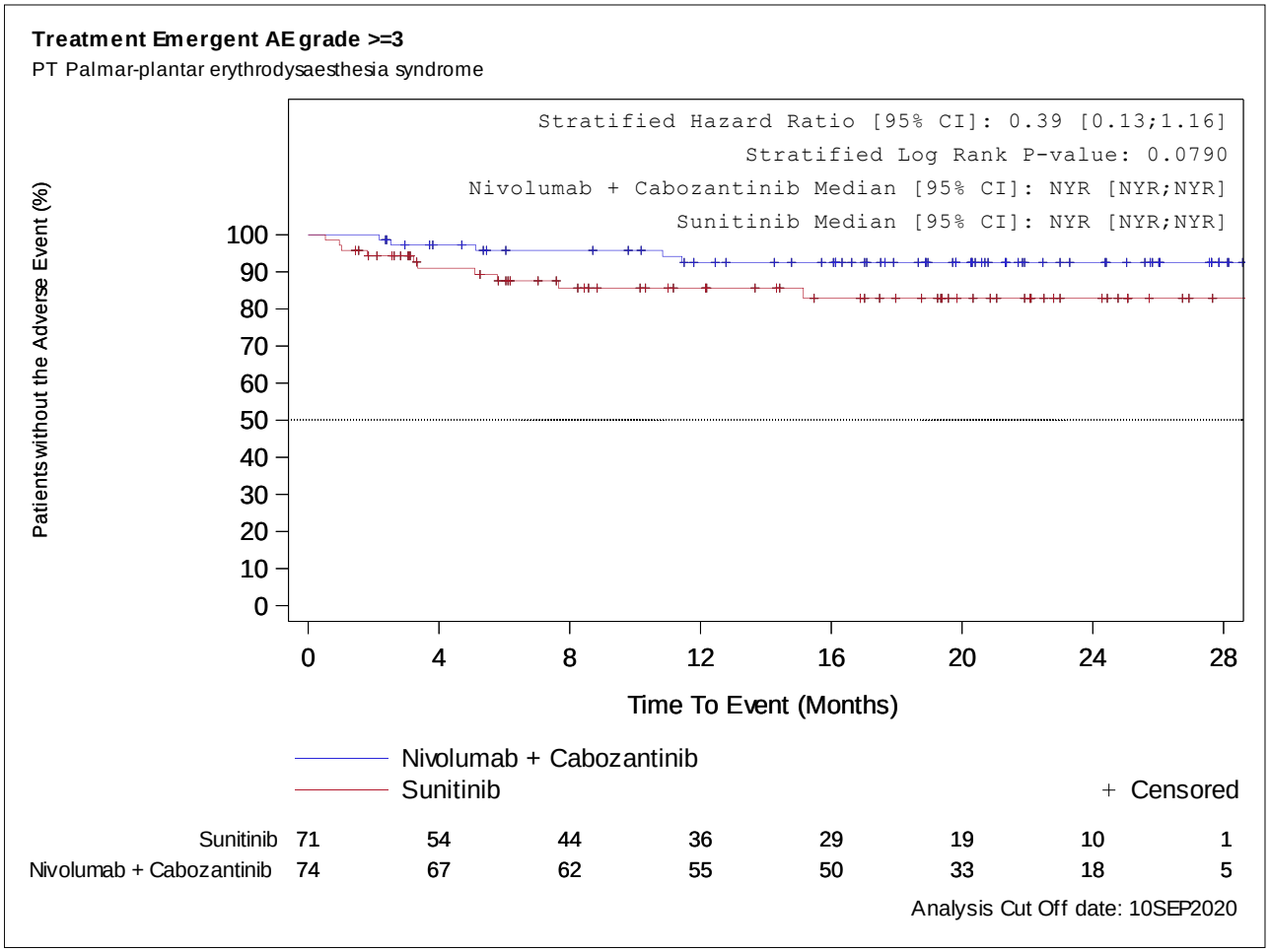
FIGURE 4.2.2.40: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Palmar-plantar erythrodysaesthesia syndrome - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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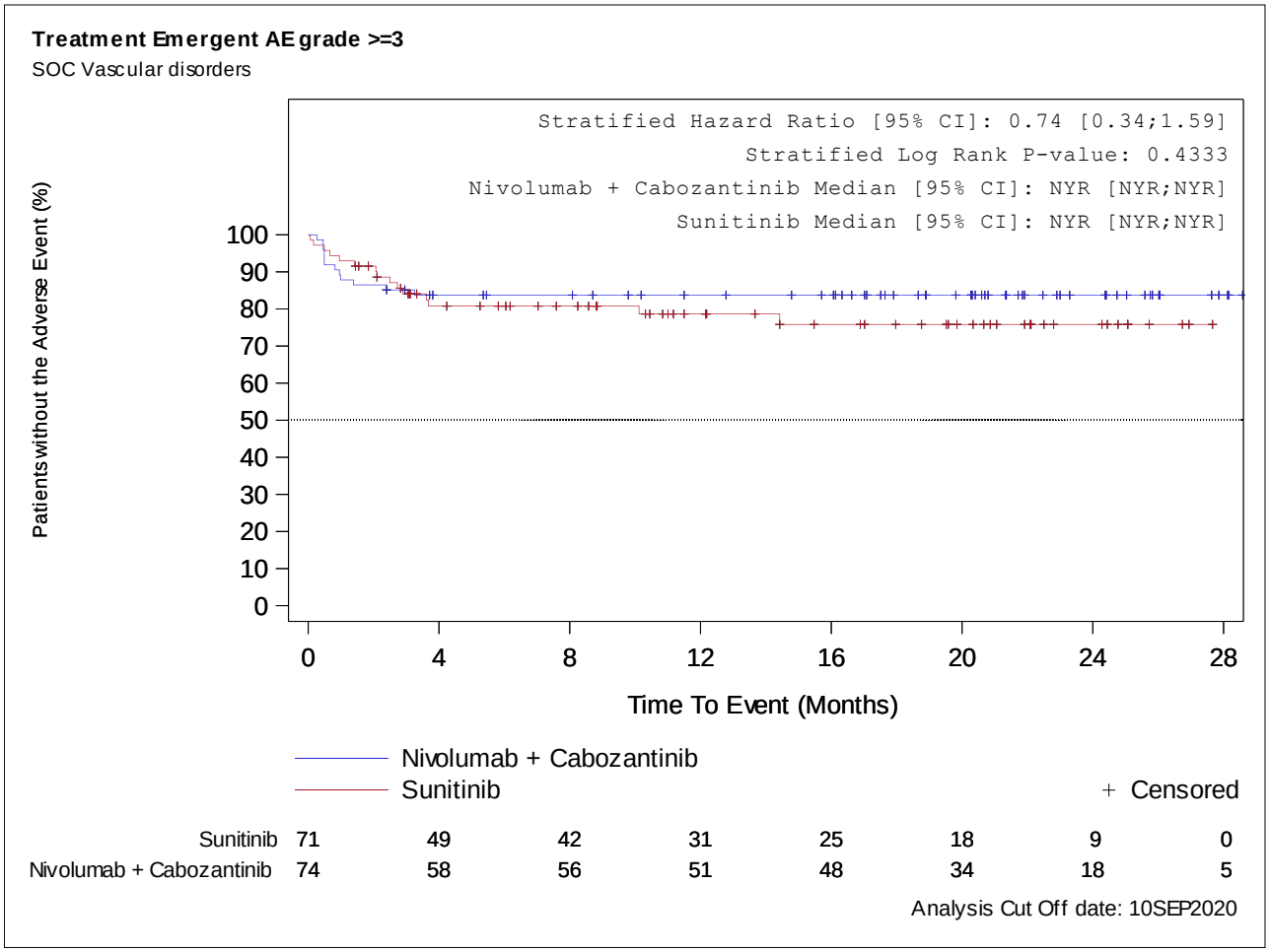
FIGURE 4.2.2.41: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Vascular disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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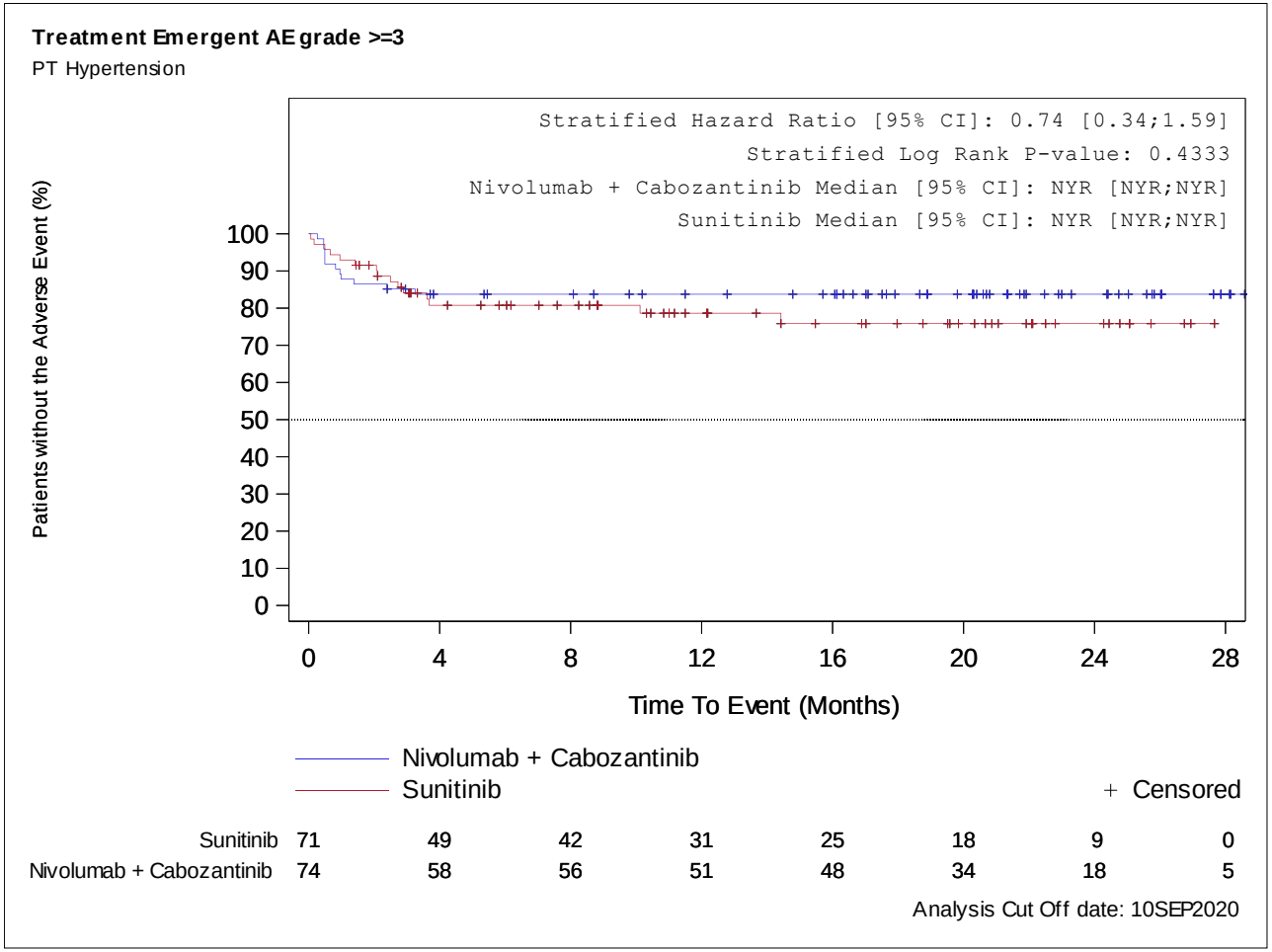
FIGURE 4.2.2.42: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - PT Hypertension - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:09:25

FIGURE 4.3.1: Serious Treatment Emergent Adverse Events - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

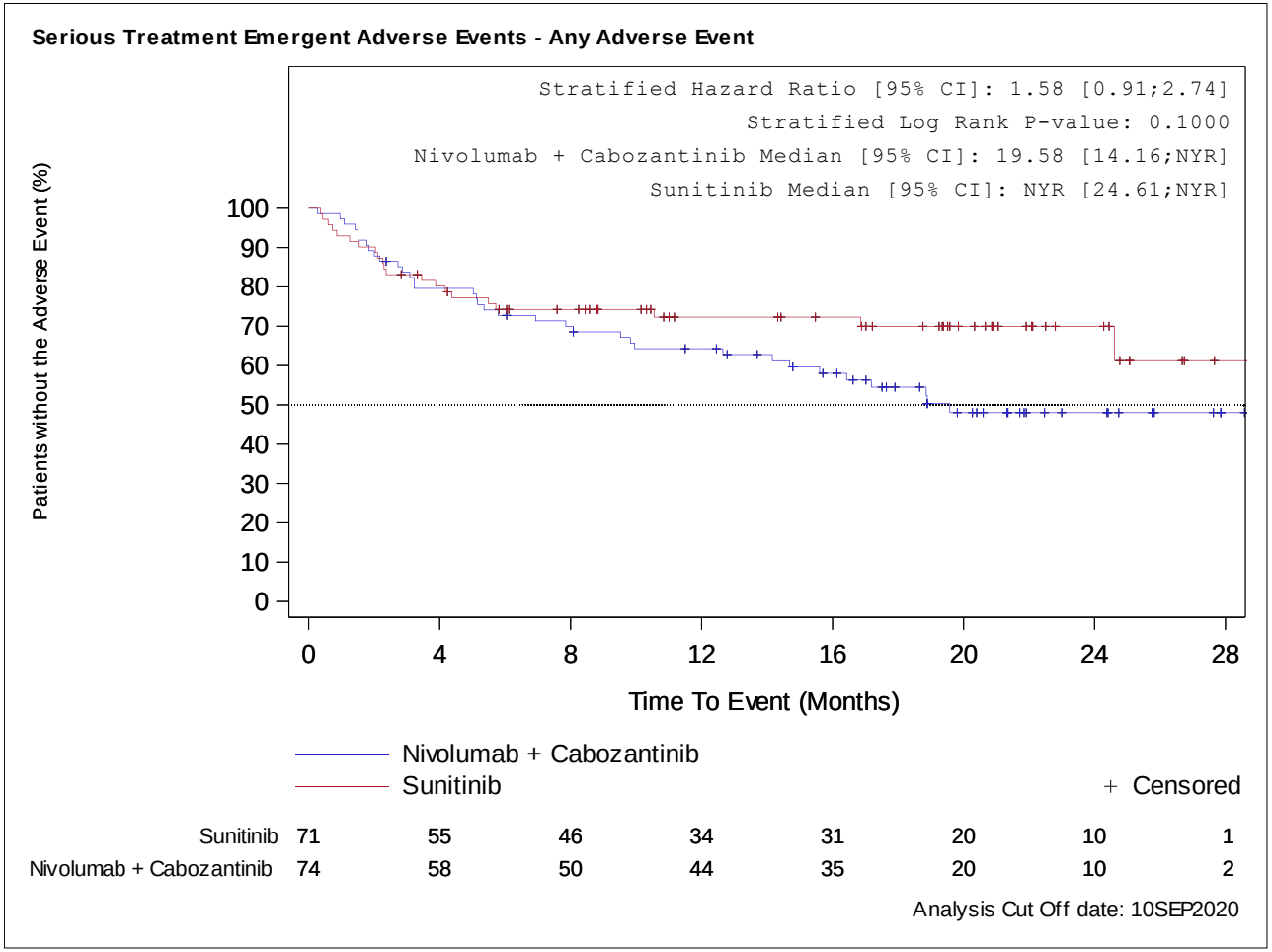



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FIGURE 4.3.2.1: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

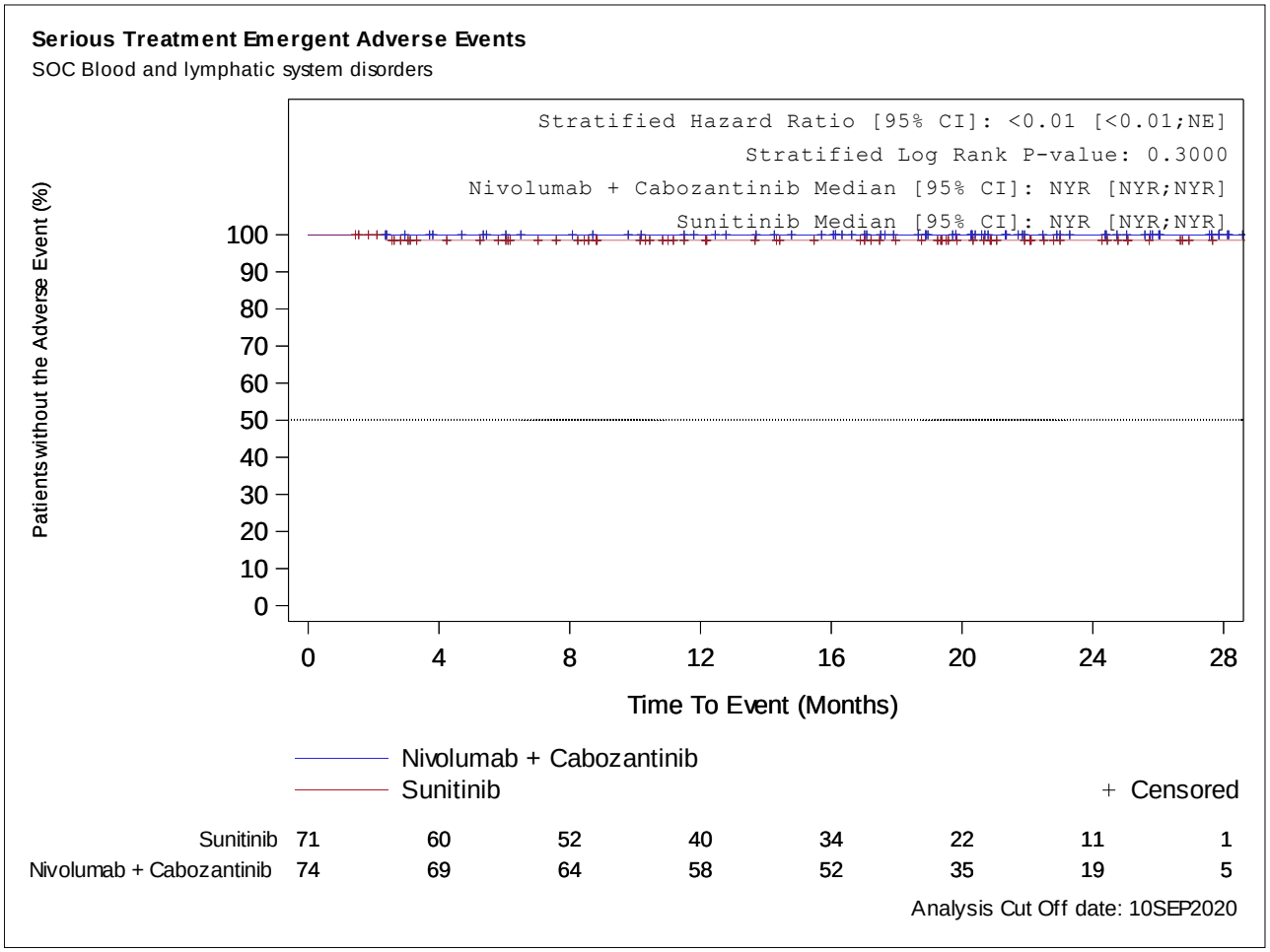


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FIGURE 4.3.2.2: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

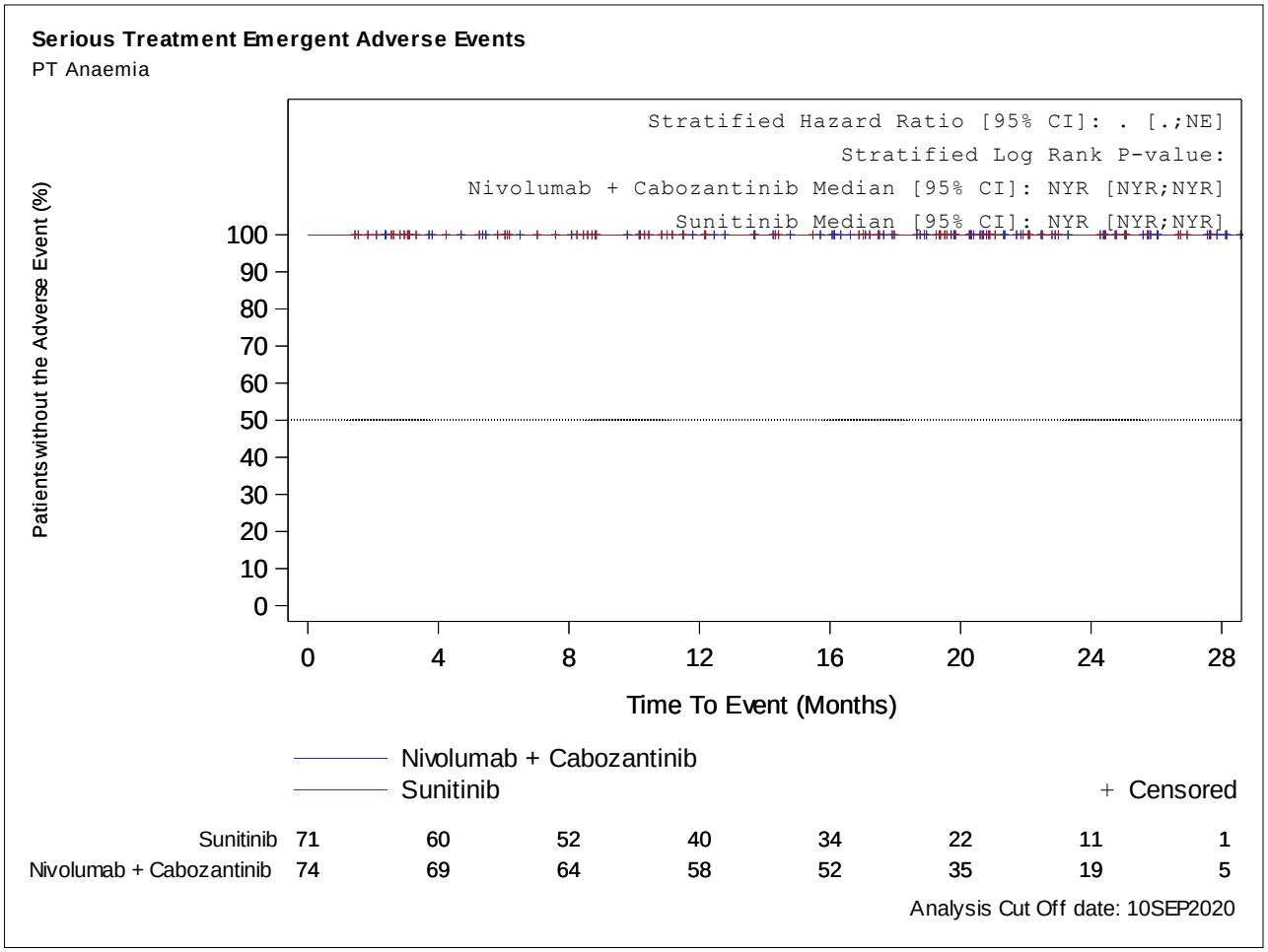


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FIGURE 4.3.2.3: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - SOC Cardiac disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

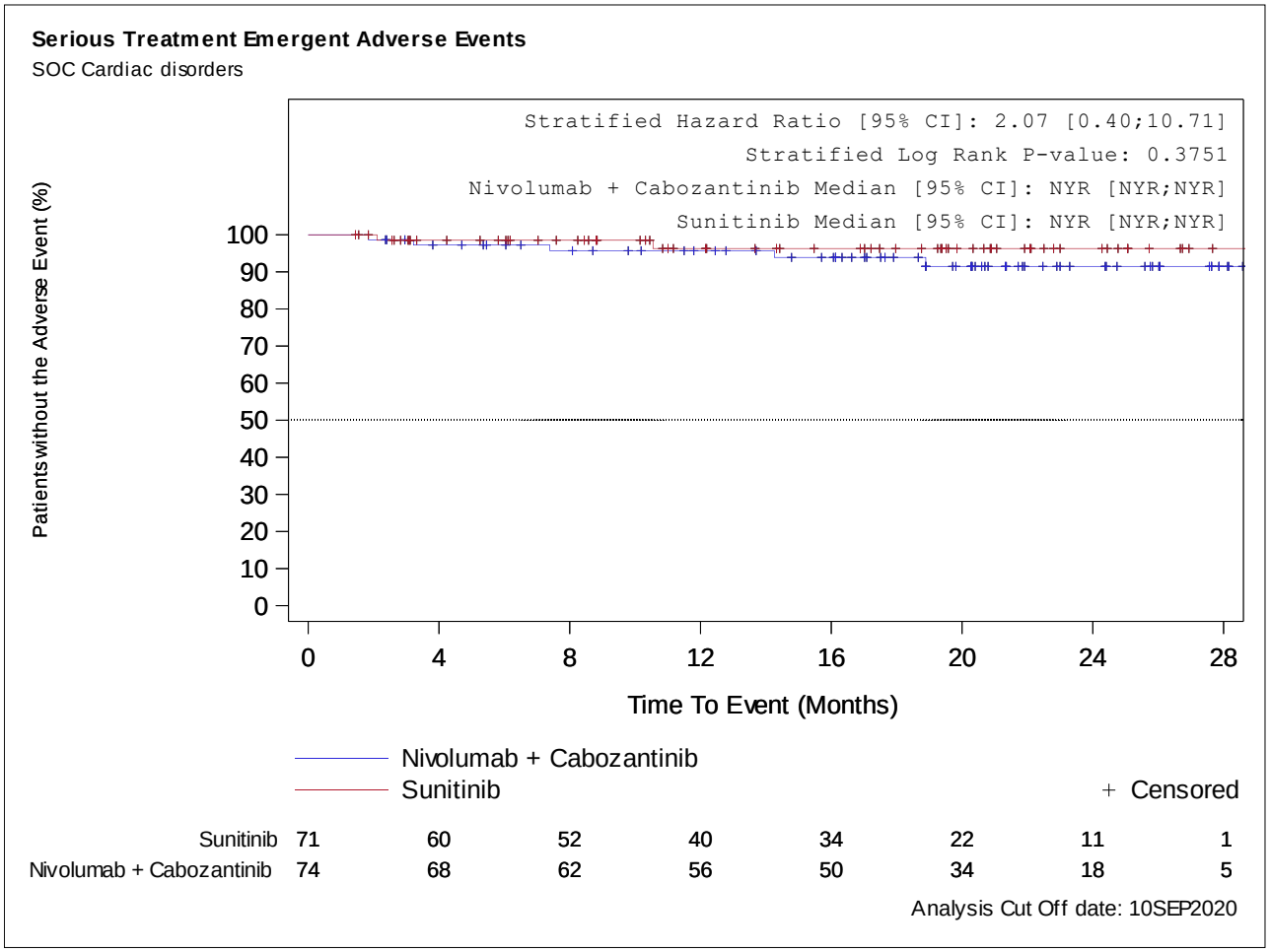


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FIGURE 4.3.2.4: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - SOC Endocrine disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

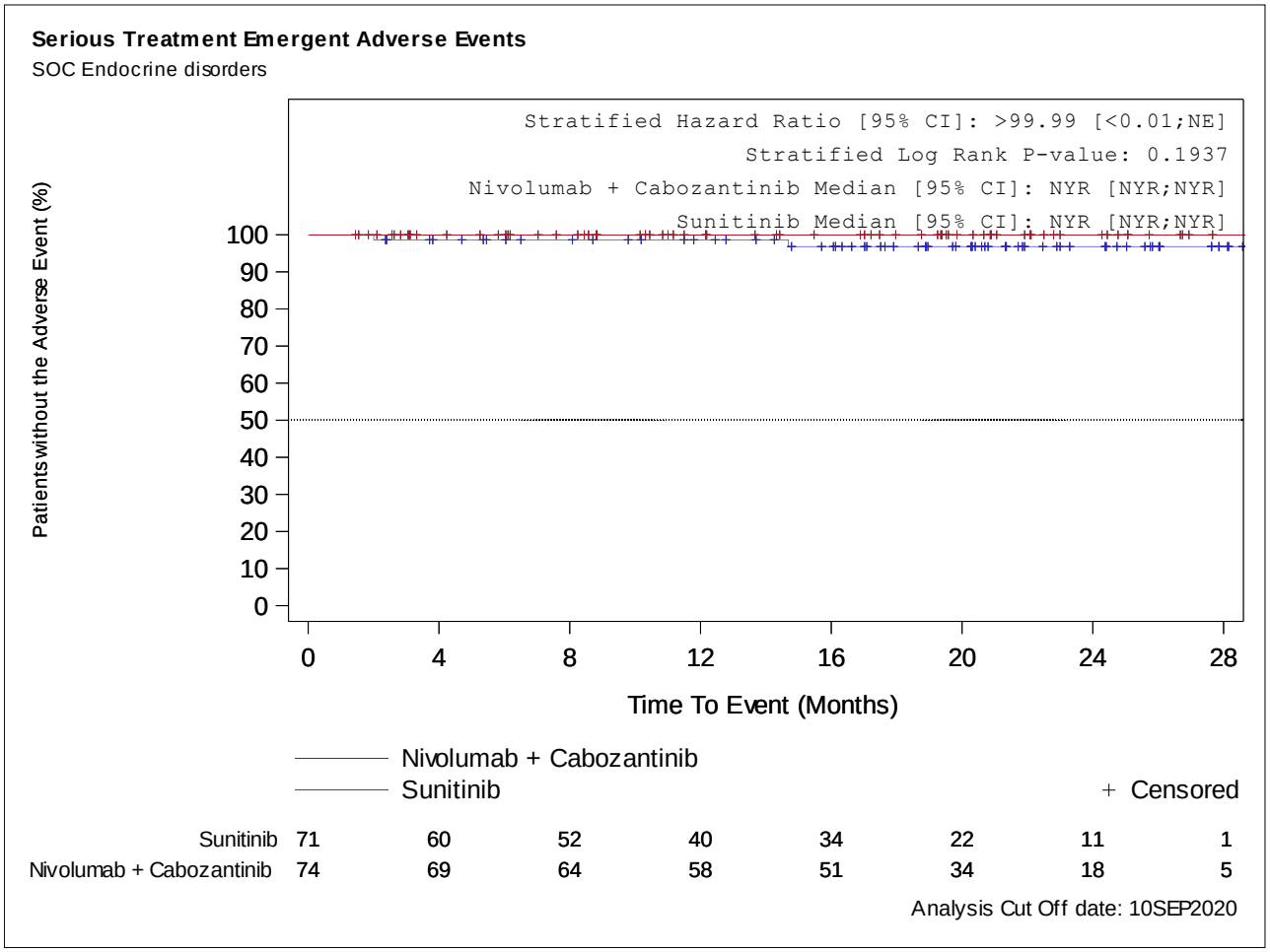


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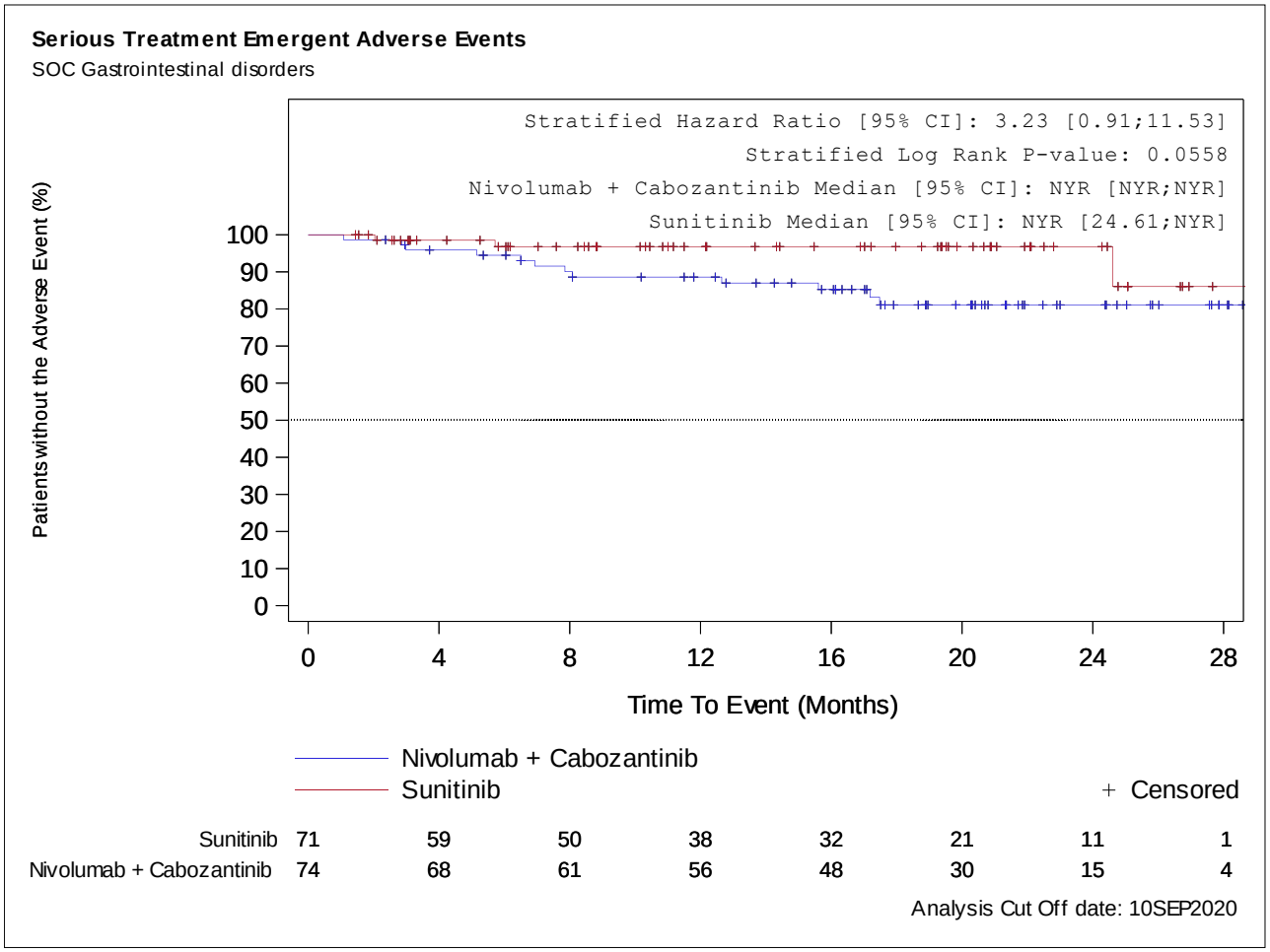
FIGURE 4.3.2.5: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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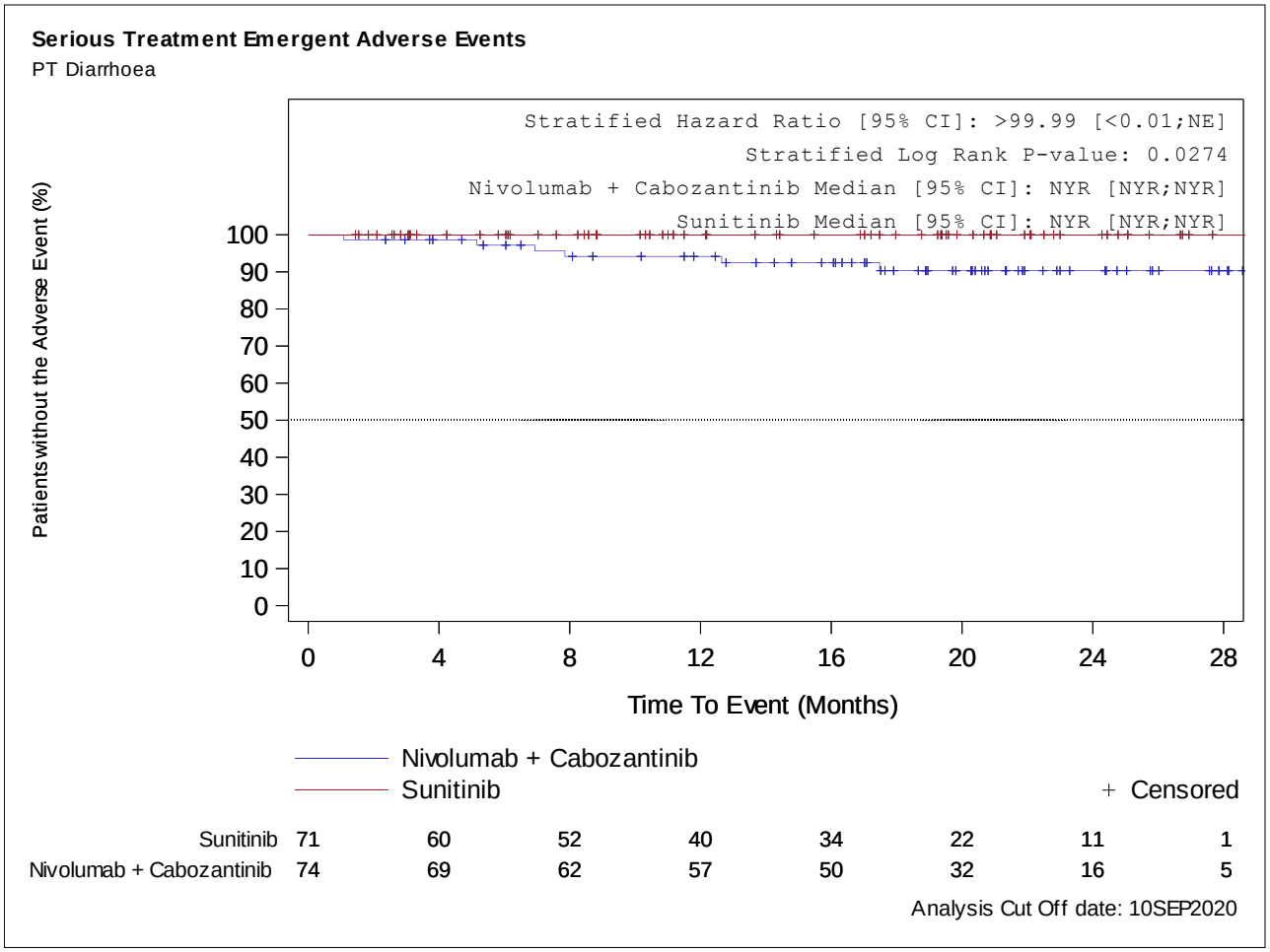
FIGURE 4.3.2.6: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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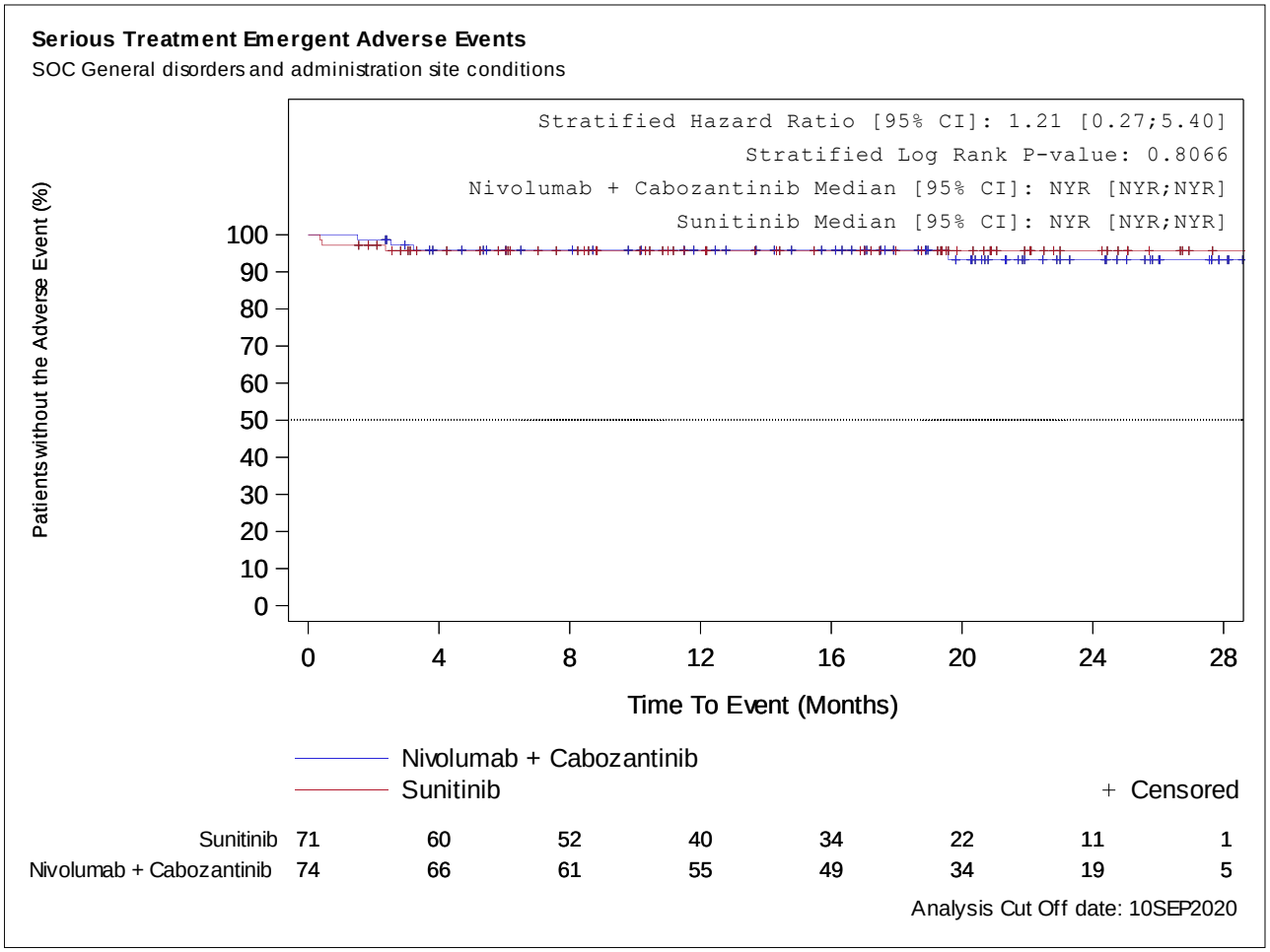
FIGURE 4.3.2.7: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - SOC General disorders and administration site conditions - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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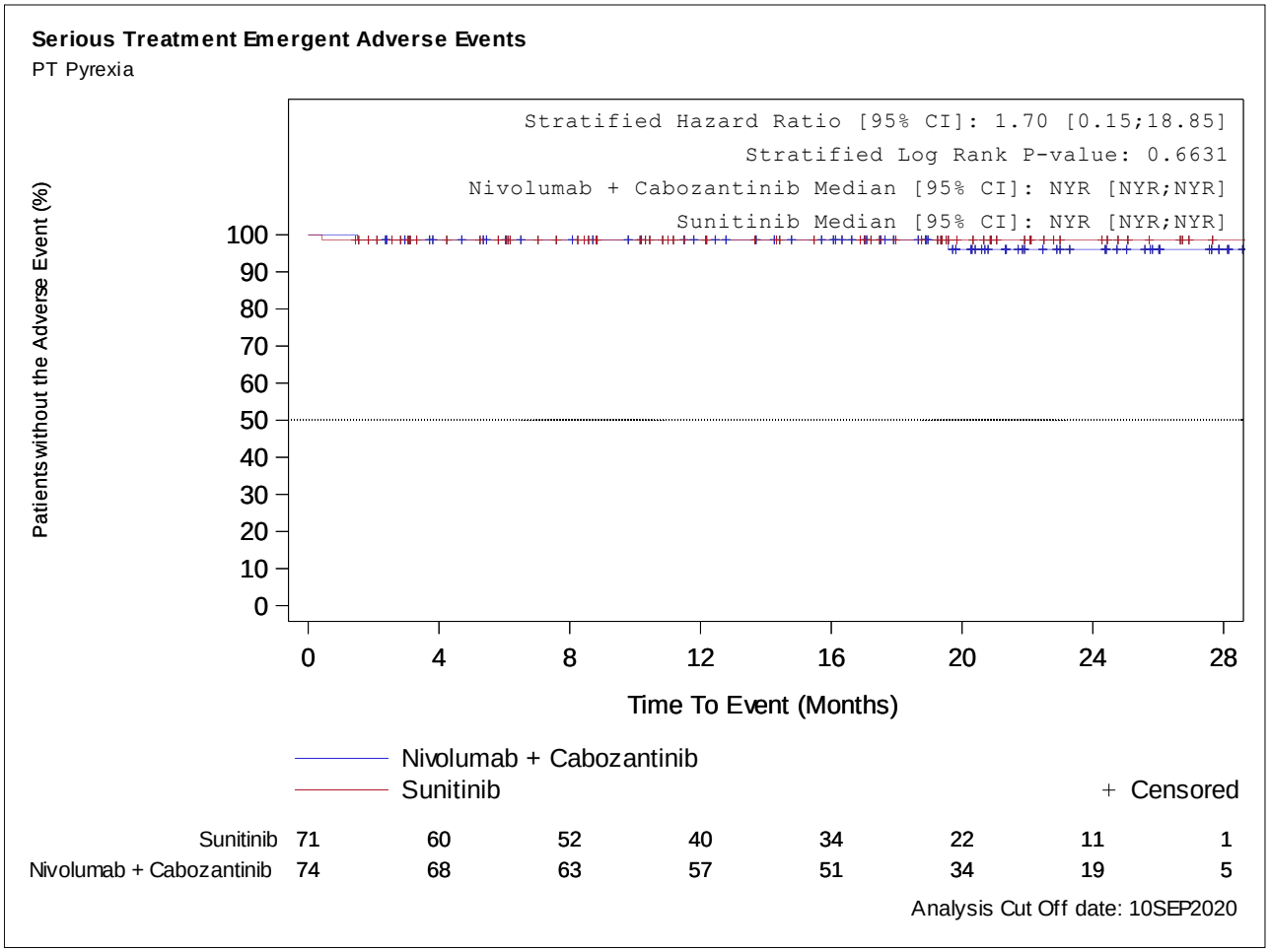
FIGURE 4.3.2.8: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - PT Pyrexia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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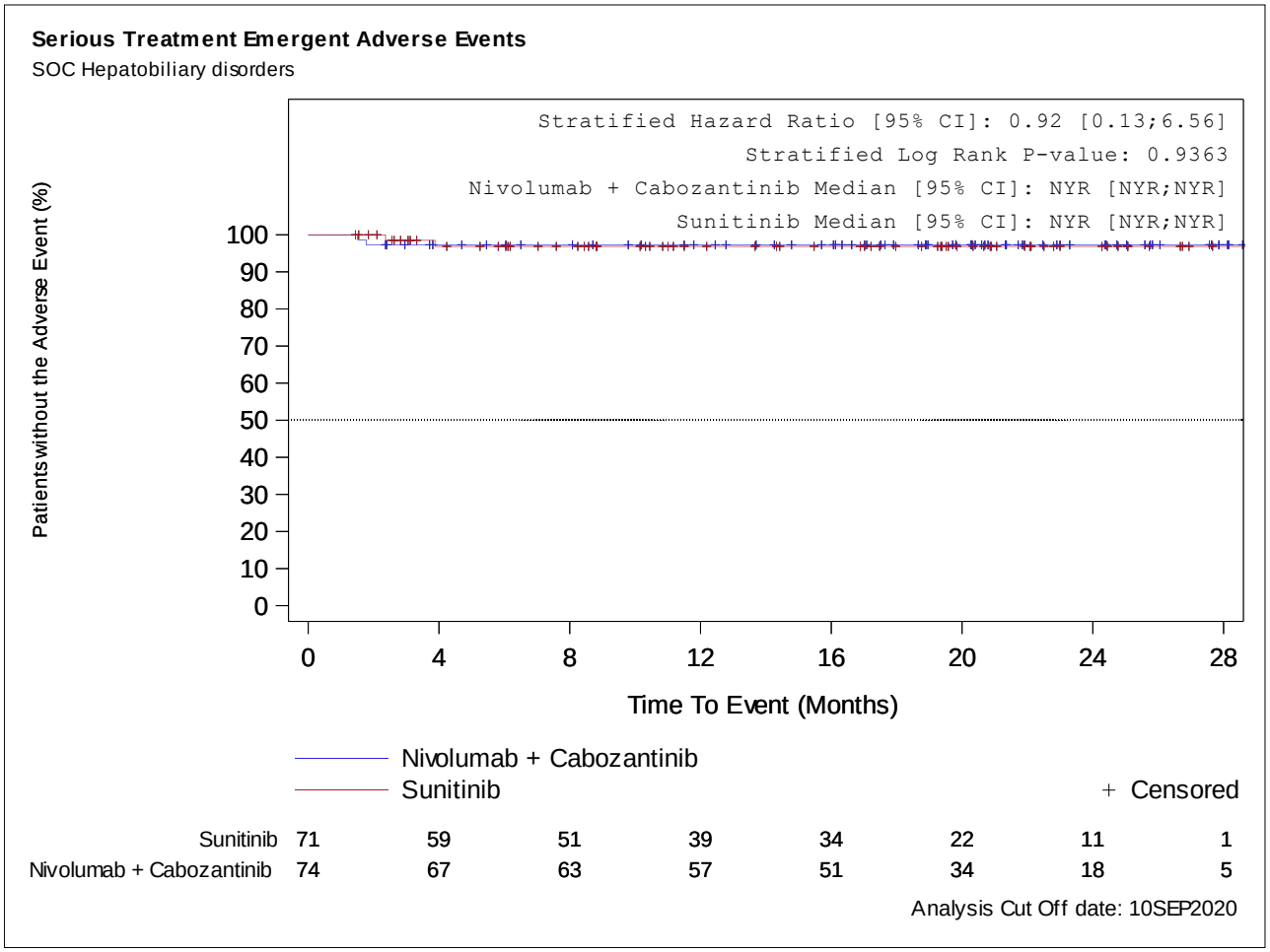
FIGURE 4.3.2.9: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - SOC Hepatobiliary disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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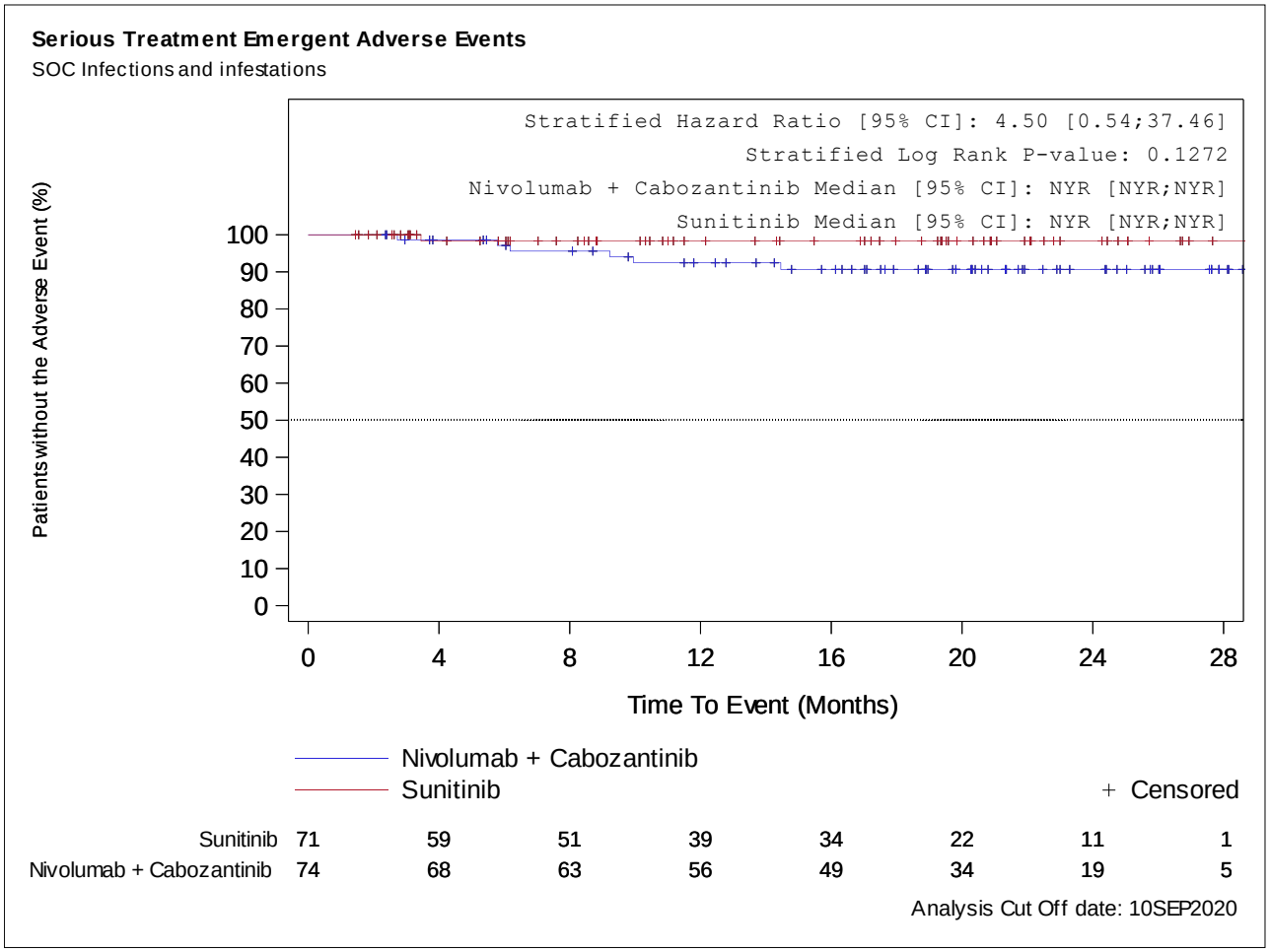
FIGURE 4.3.2.10: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - SOC Infections and infestations - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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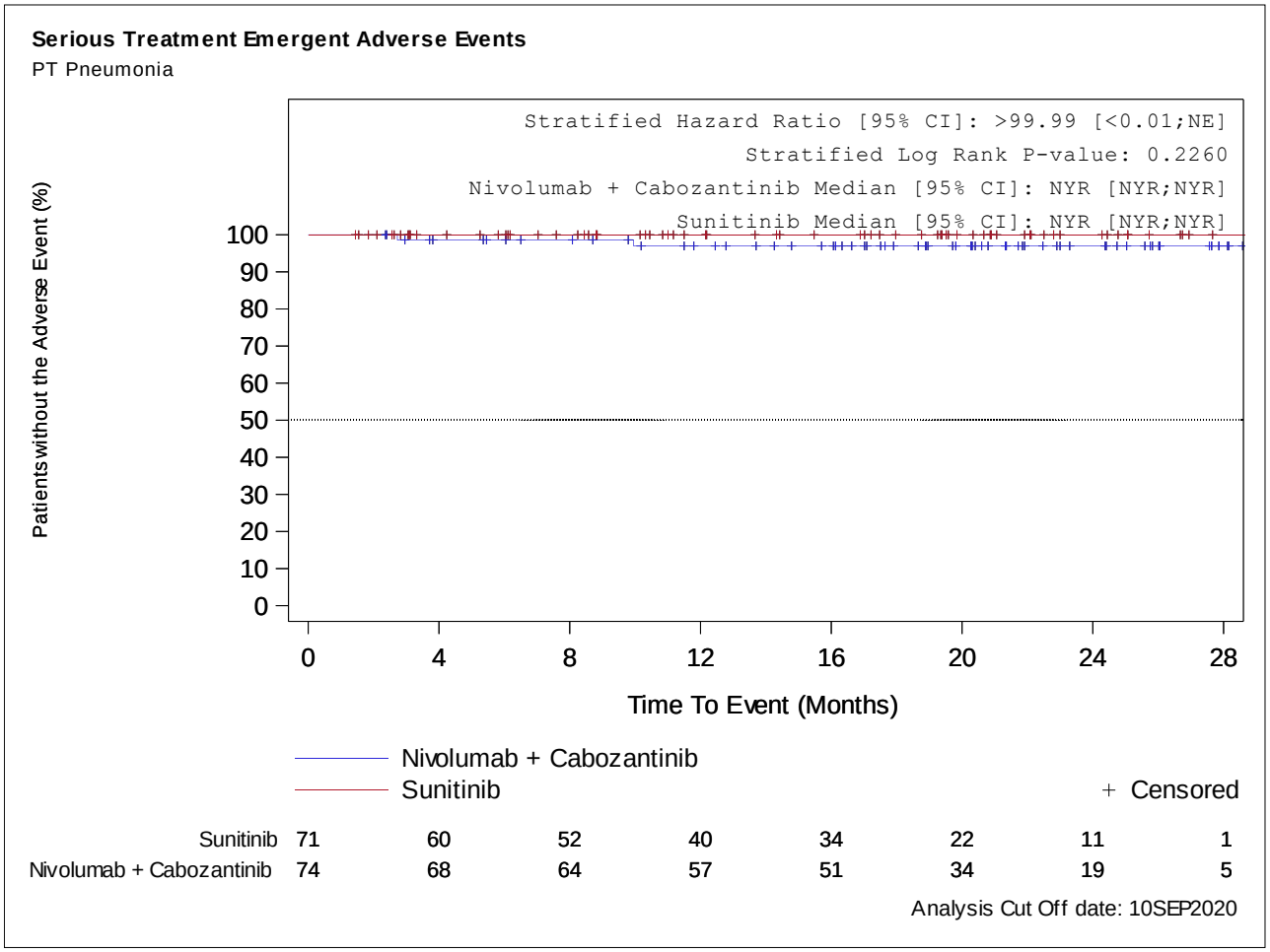
FIGURE 4.3.2.11: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - PT Pneumonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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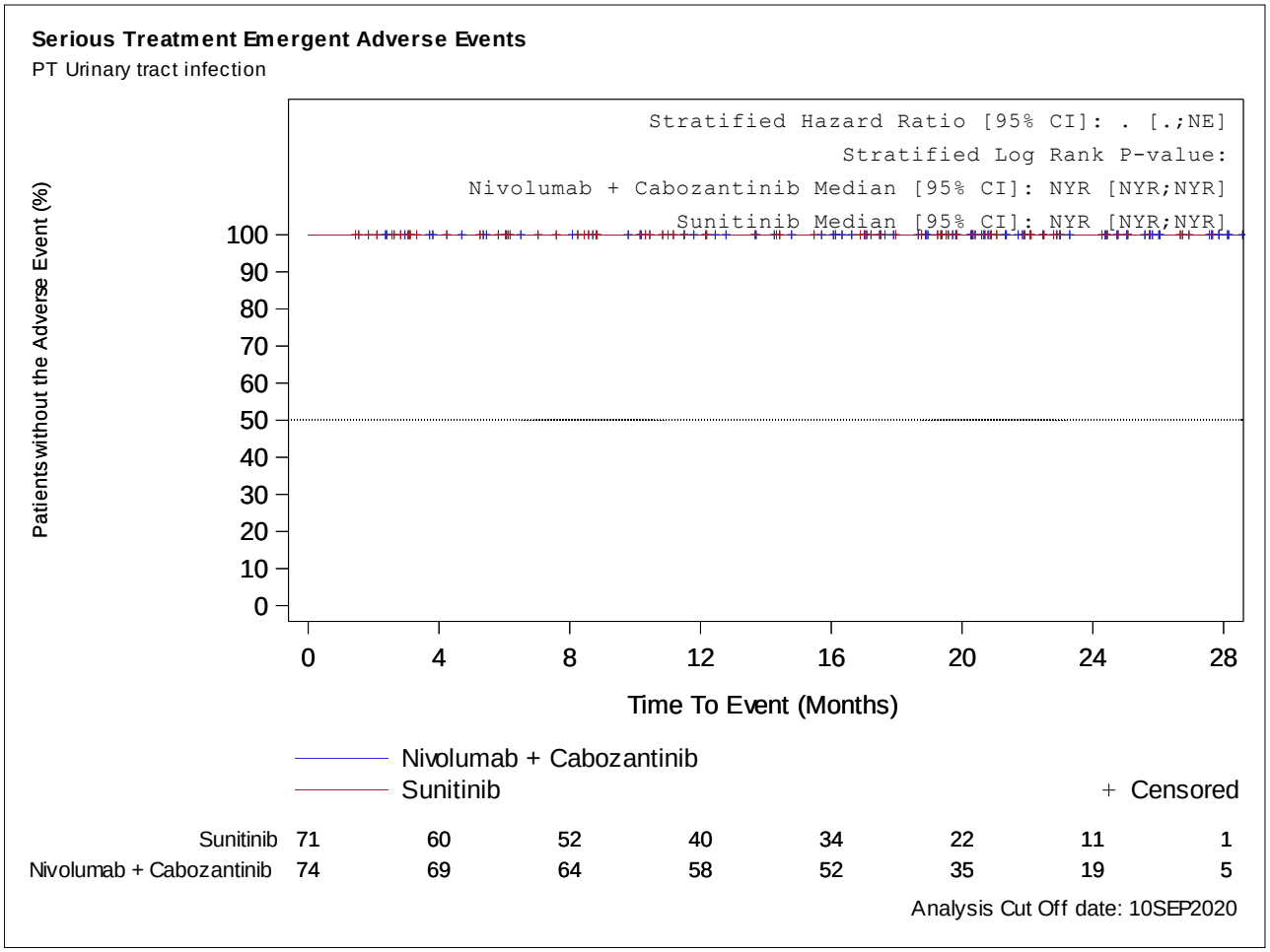
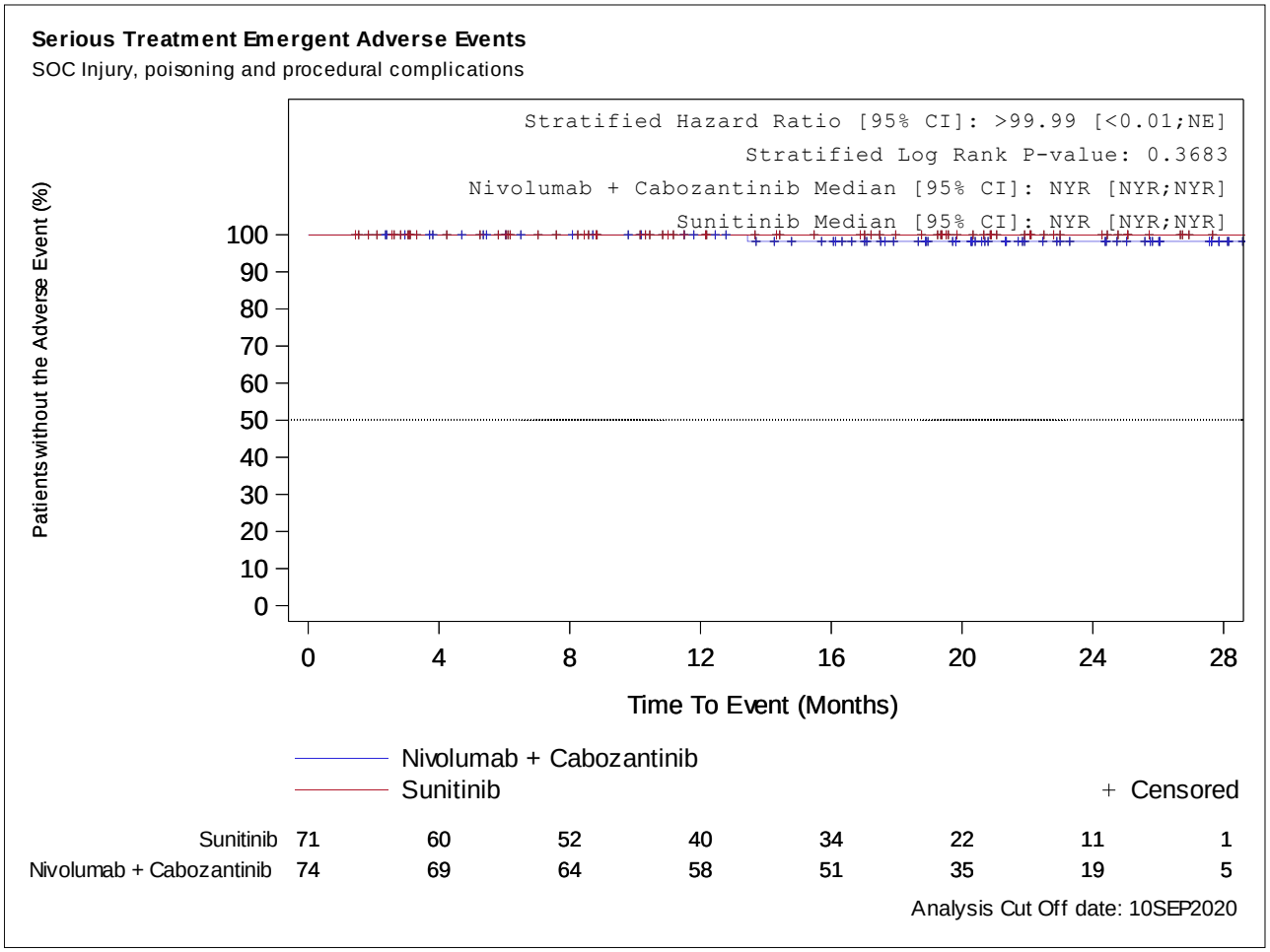
FIGURE 4.3.2.12: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - PT Urinary tract infection - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:11:22

FIGURE 4.3.2.13: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - SOC Injury, poisoning and procedural complications - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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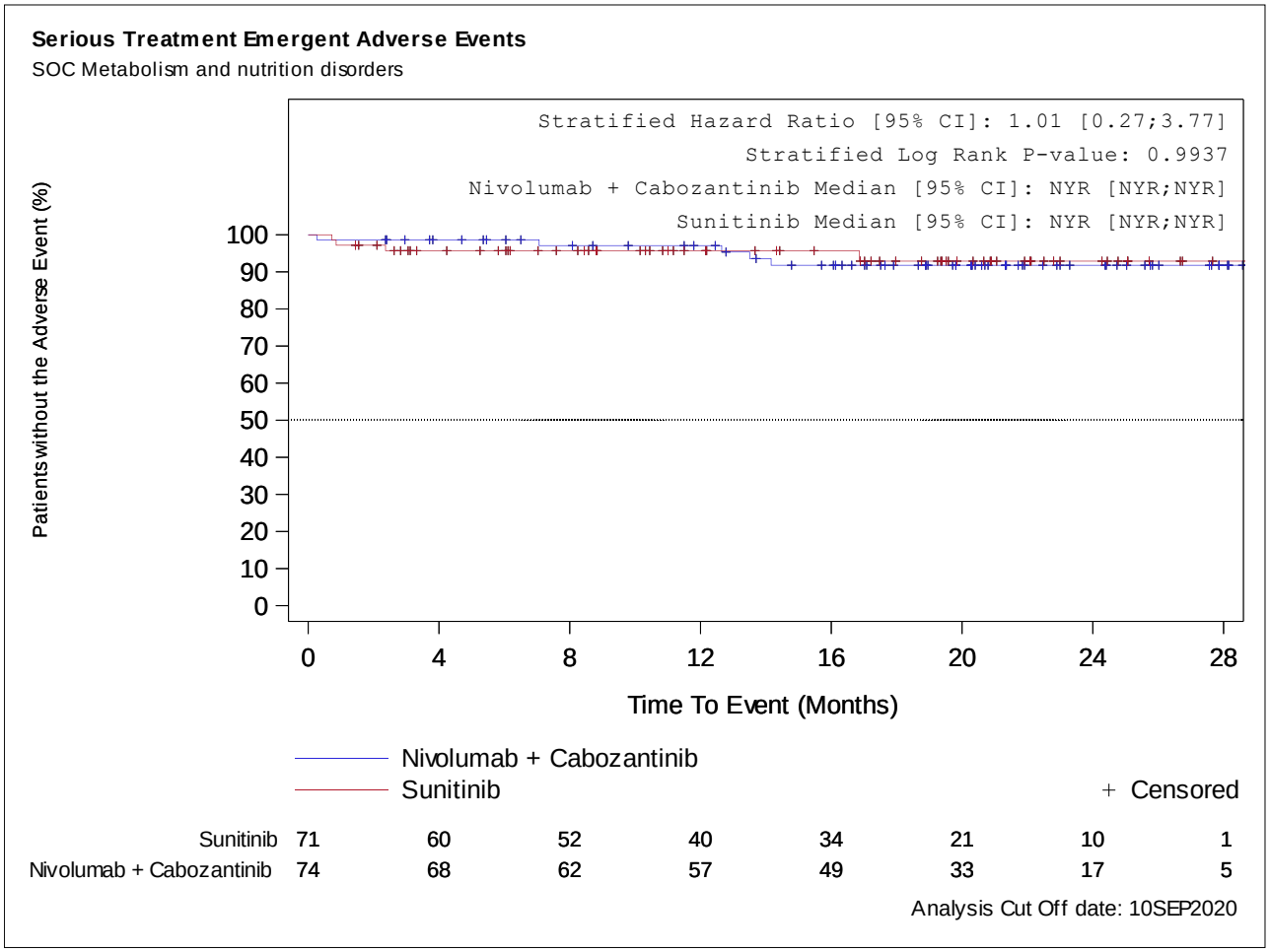
FIGURE 4.3.2.14: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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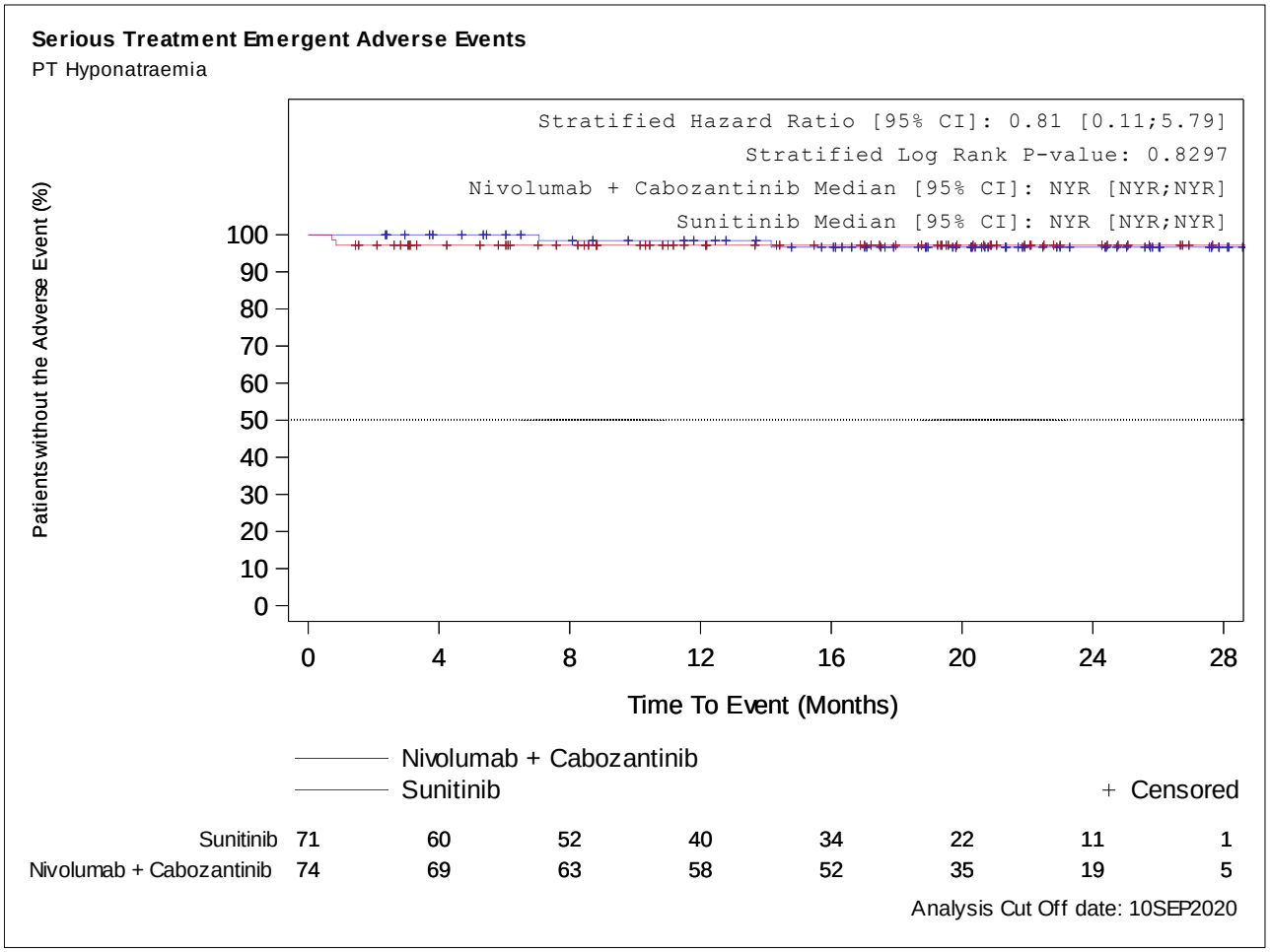
FIGURE 4.3.2.15: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - PT Hyponatraemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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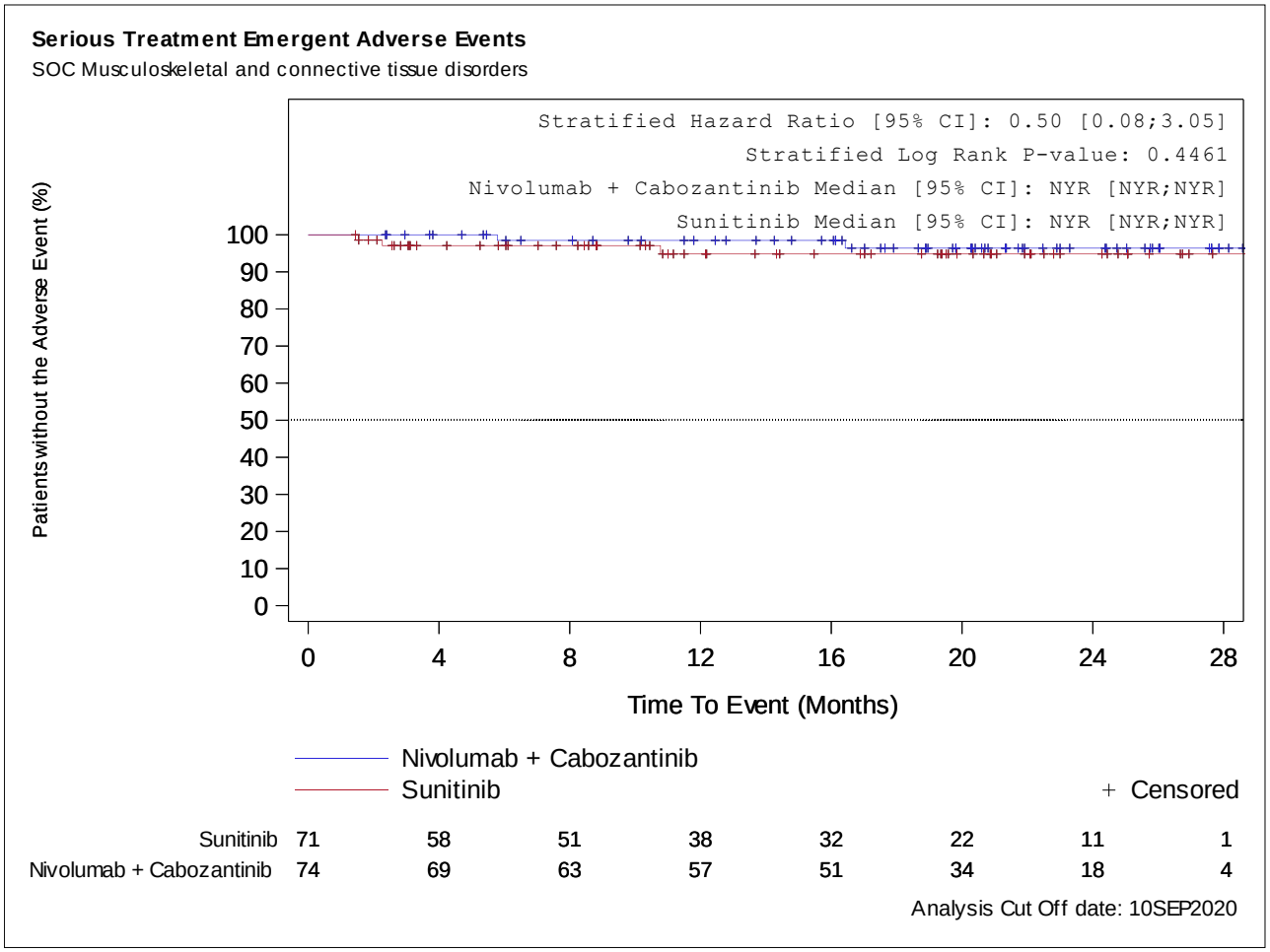
FIGURE 4.3.2.16: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - SOC Musculoskeletal and connective tissue disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.3.2.17: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

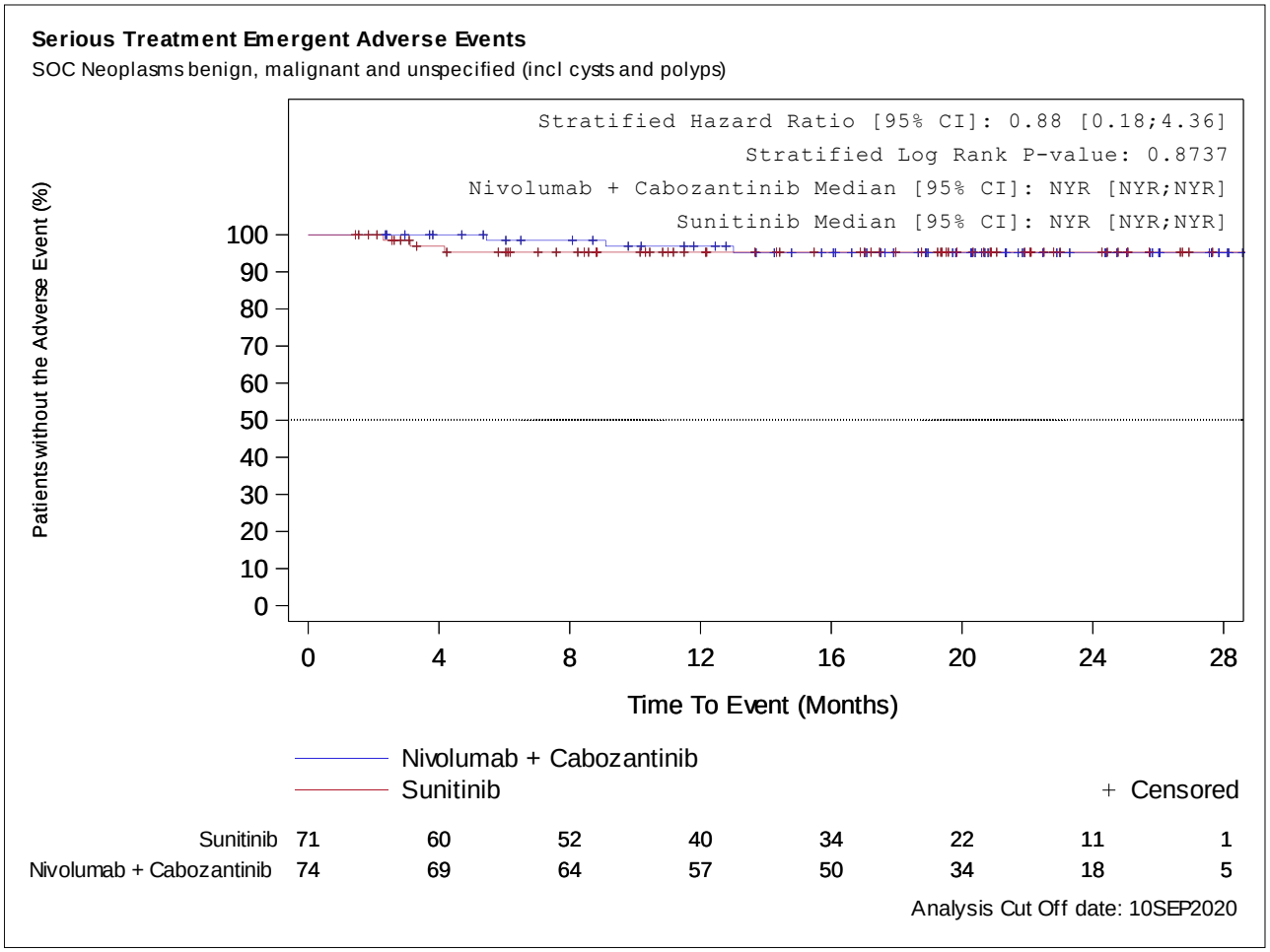


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FIGURE 4.3.2.18: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - PT Malignant neoplasm progression - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

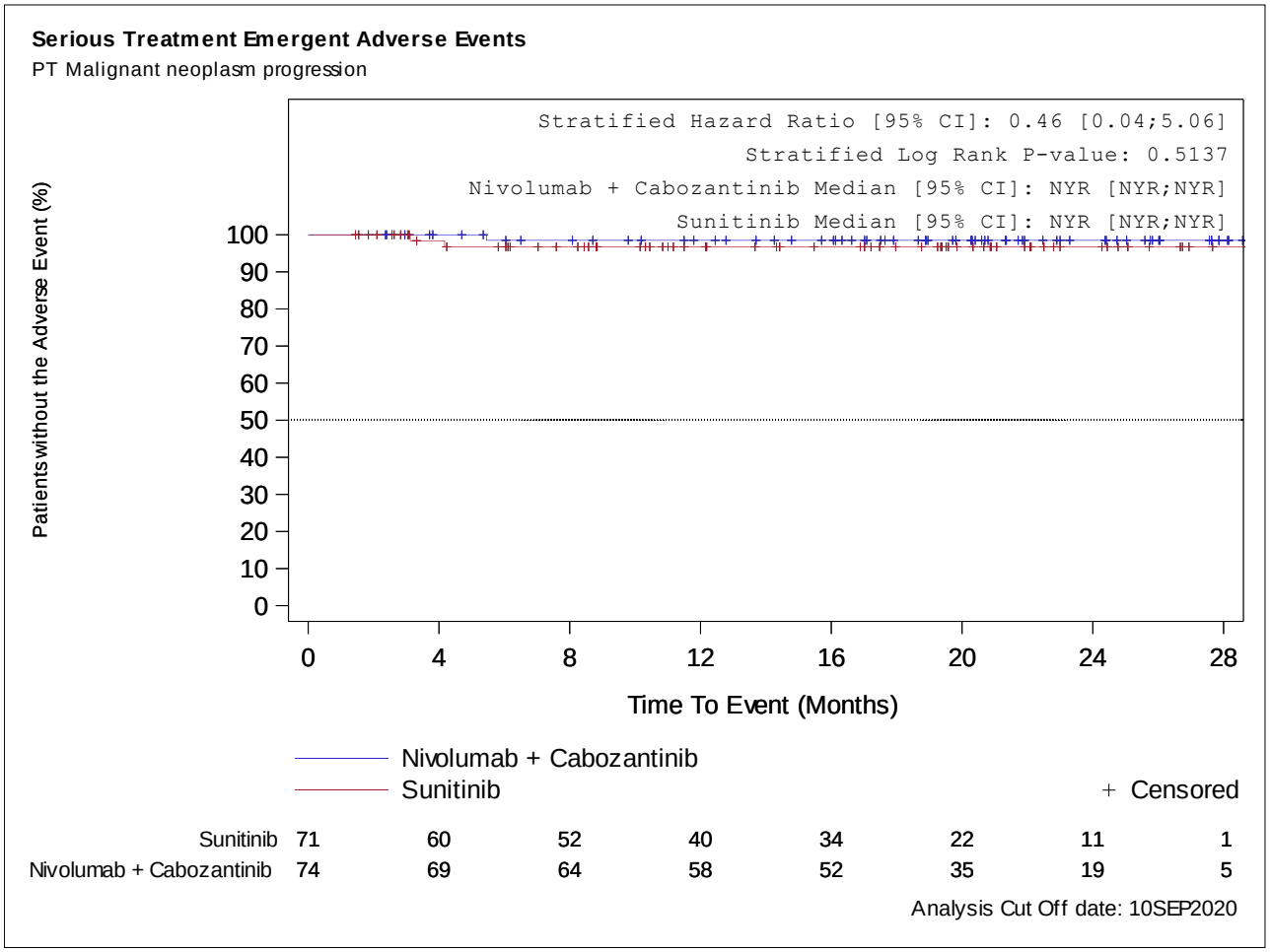


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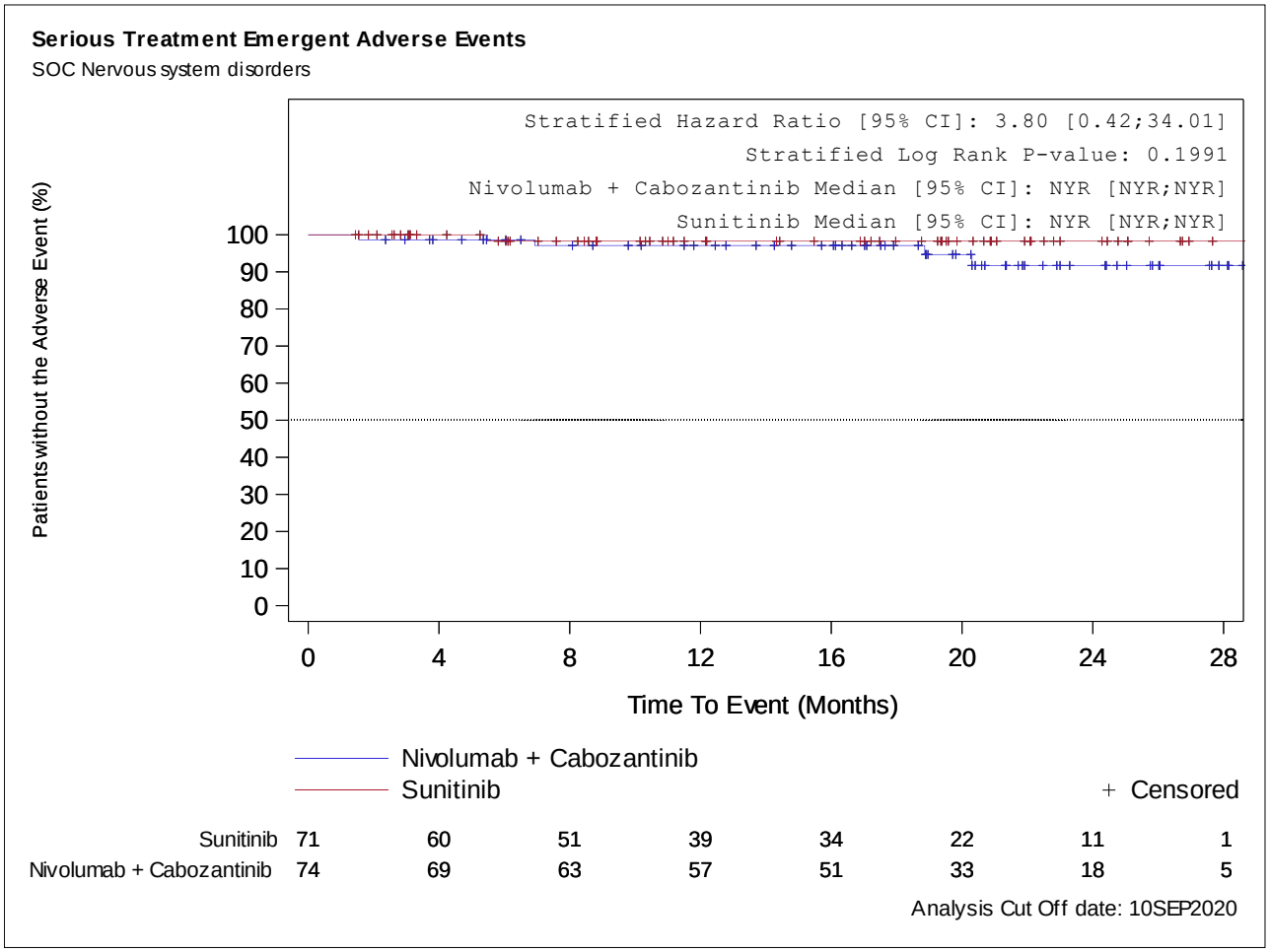
FIGURE 4.3.2.19: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - SOC Nervous system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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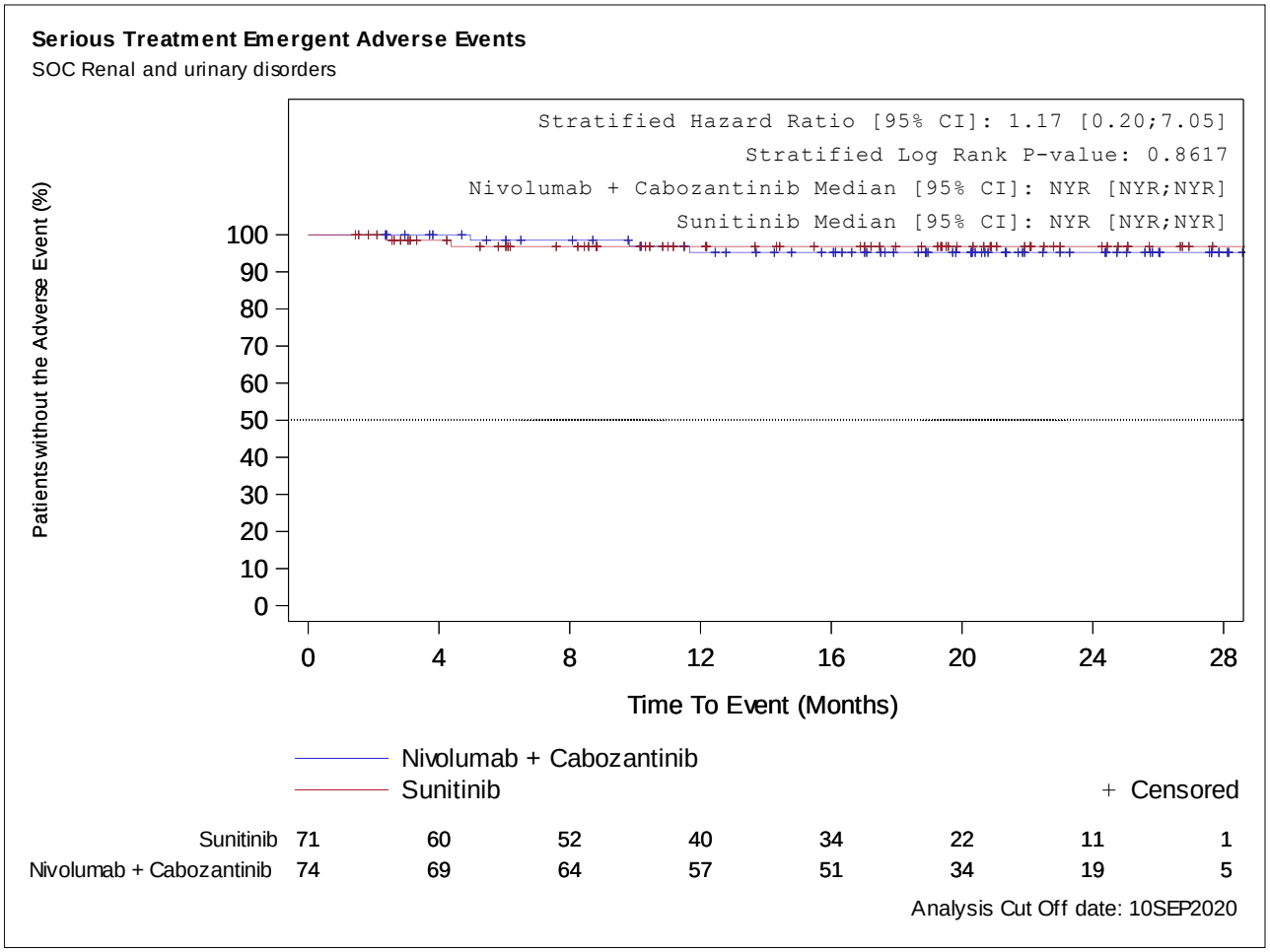
FIGURE 4.3.2.20: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - SOC Renal and urinary disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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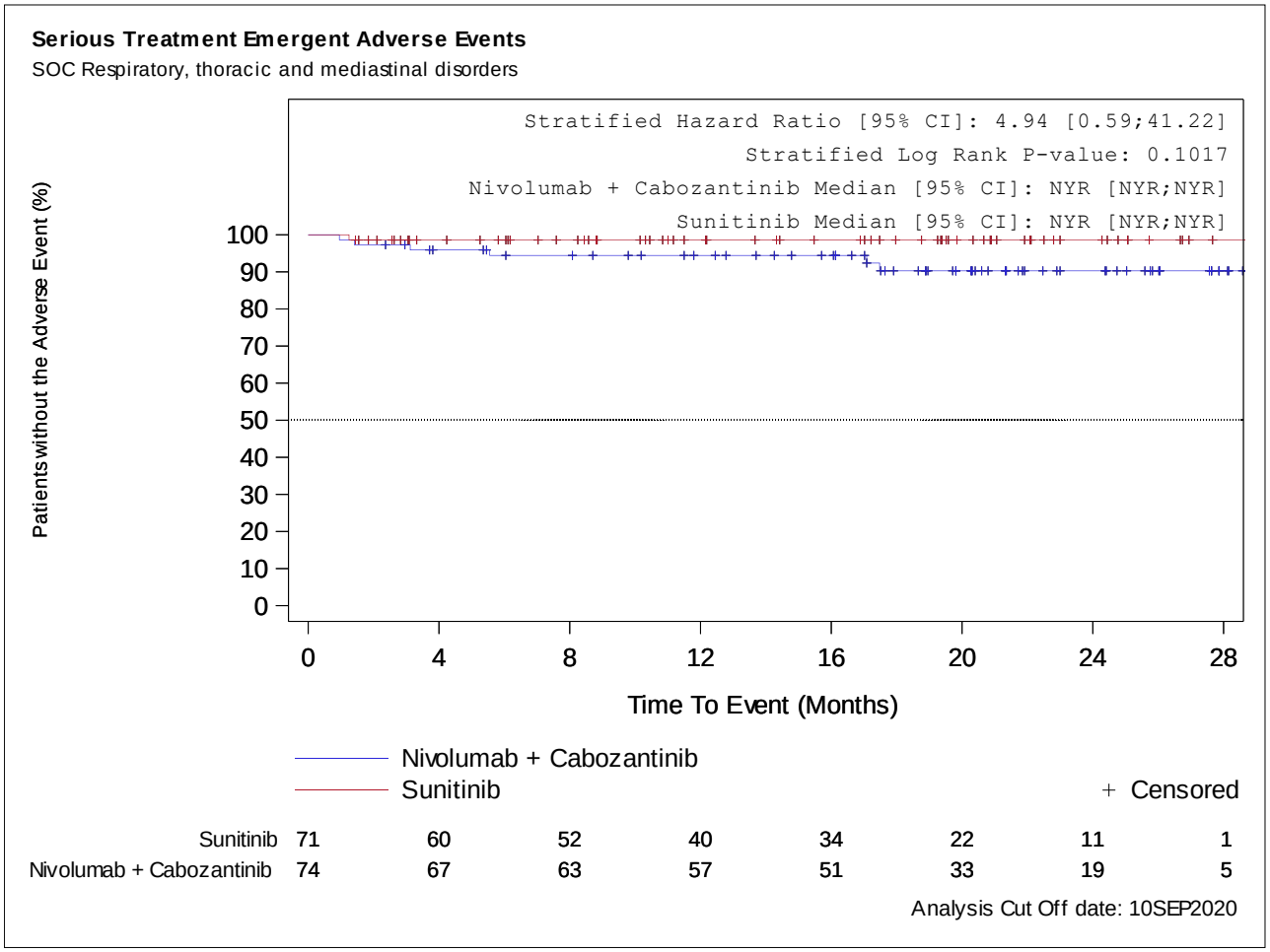
FIGURE 4.3.2.21: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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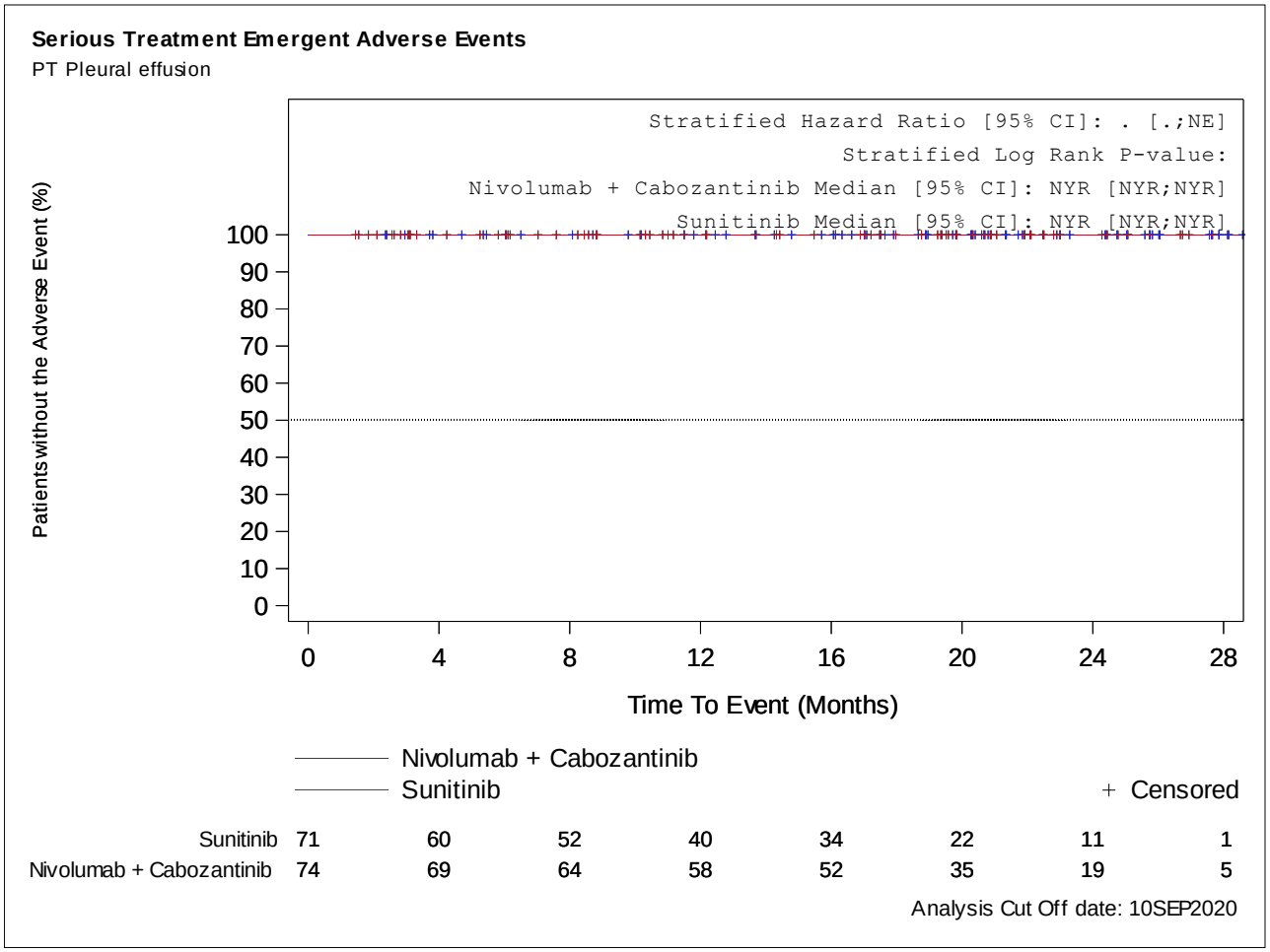
FIGURE 4.3.2.22: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - PT Pleural effusion - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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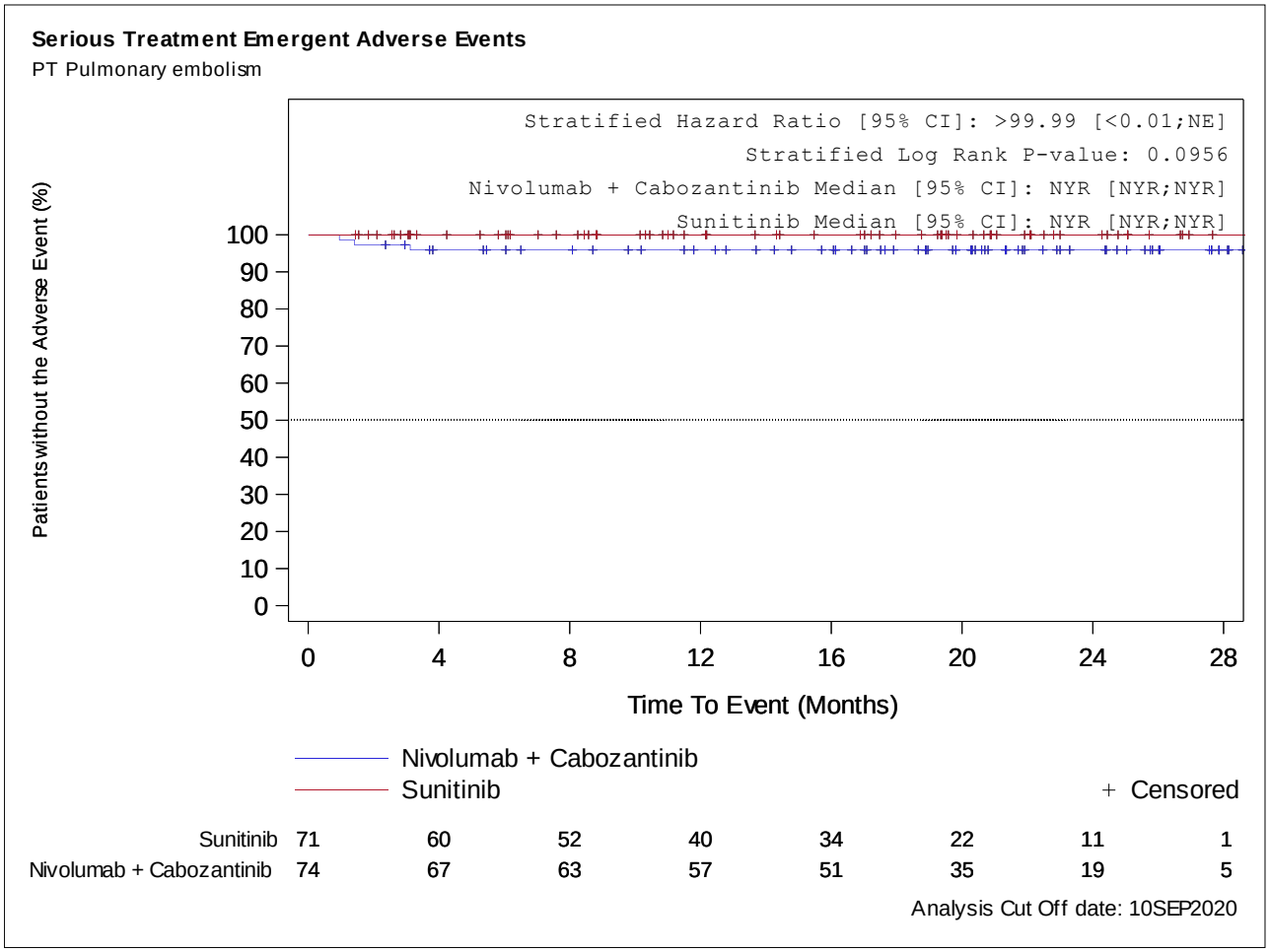
FIGURE 4.3.2.23: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - PT Pulmonary embolism - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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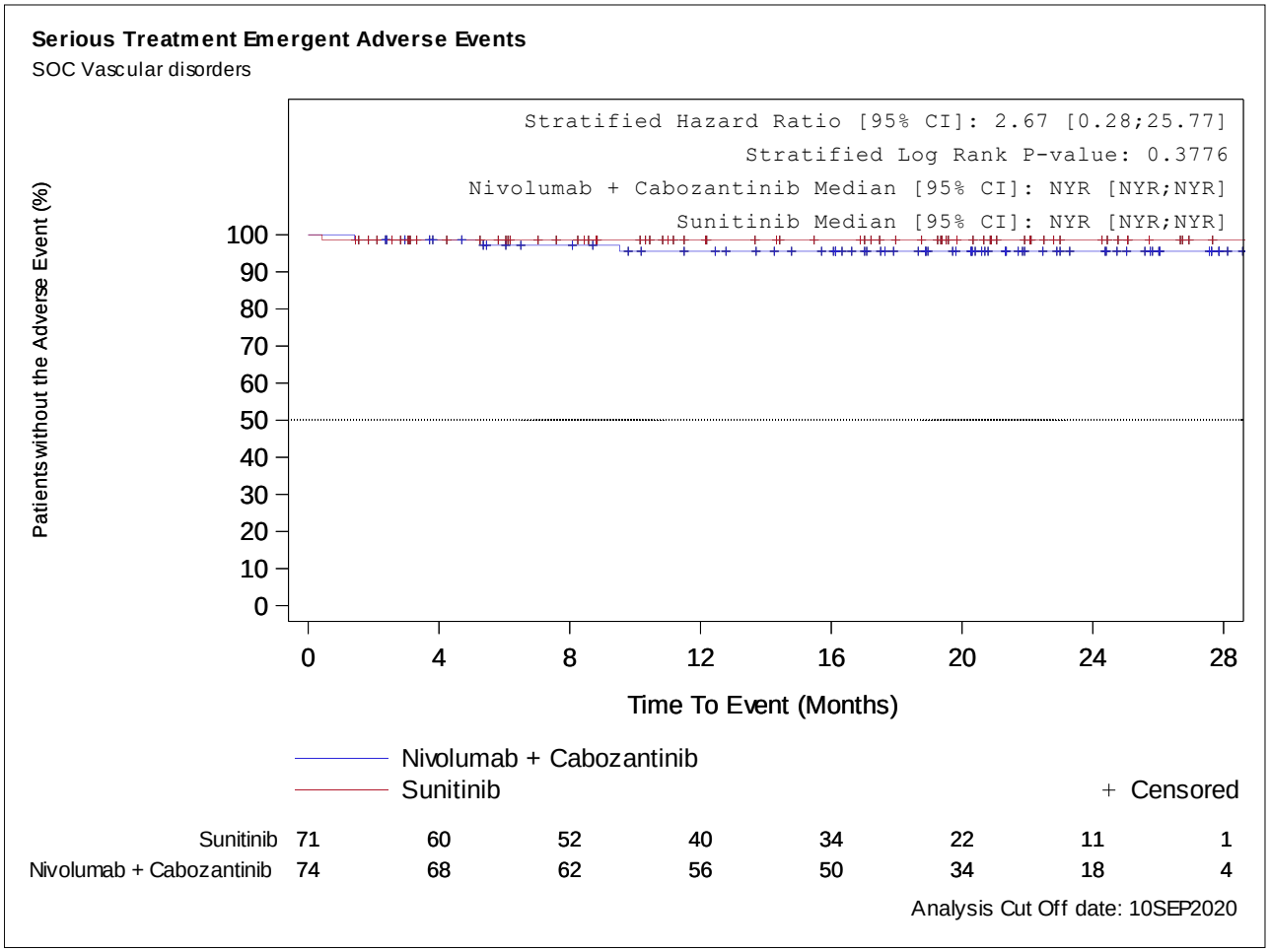
FIGURE 4.3.2.24: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - SOC Vascular disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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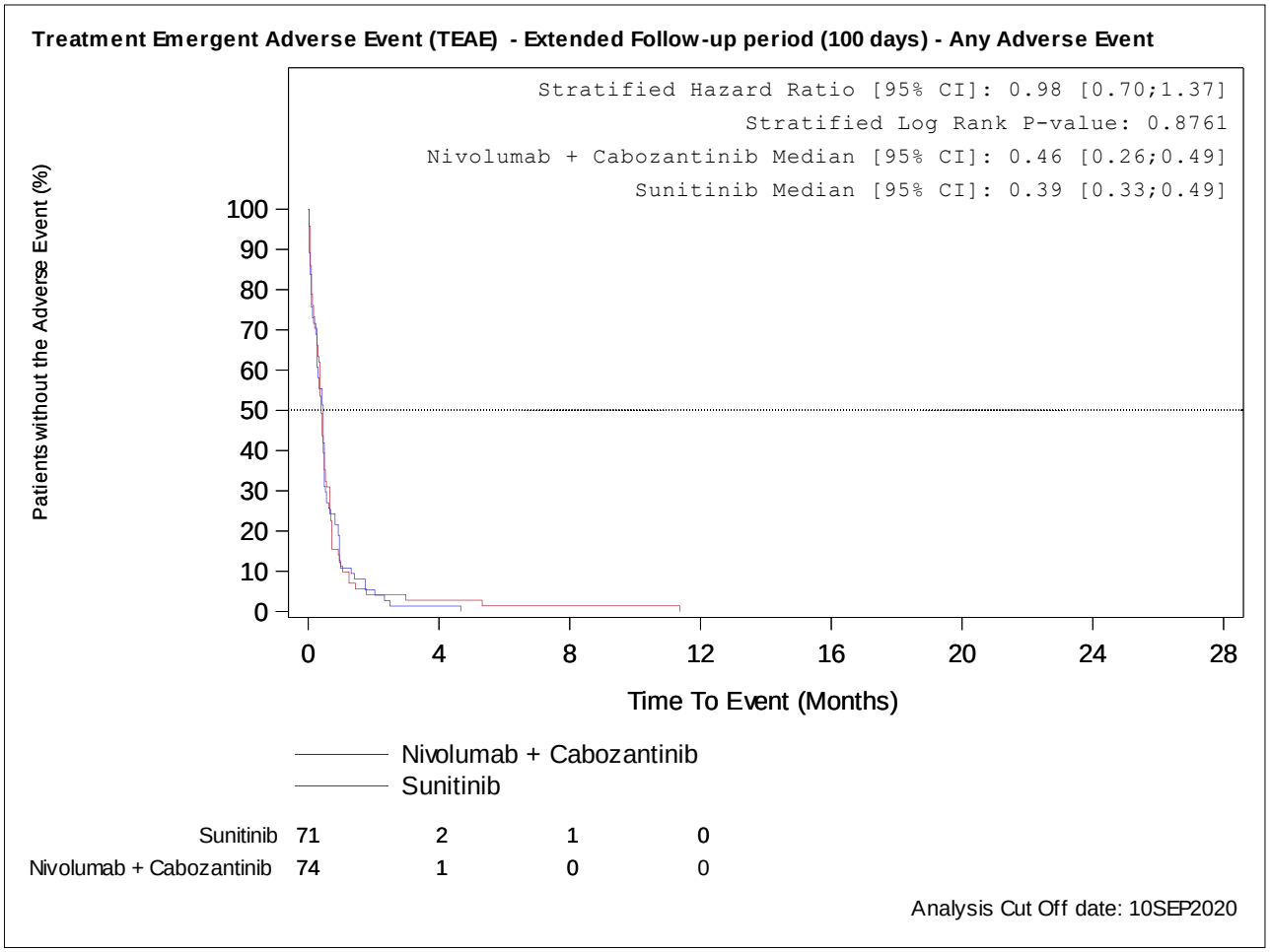
FIGURE 4.4.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.4.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

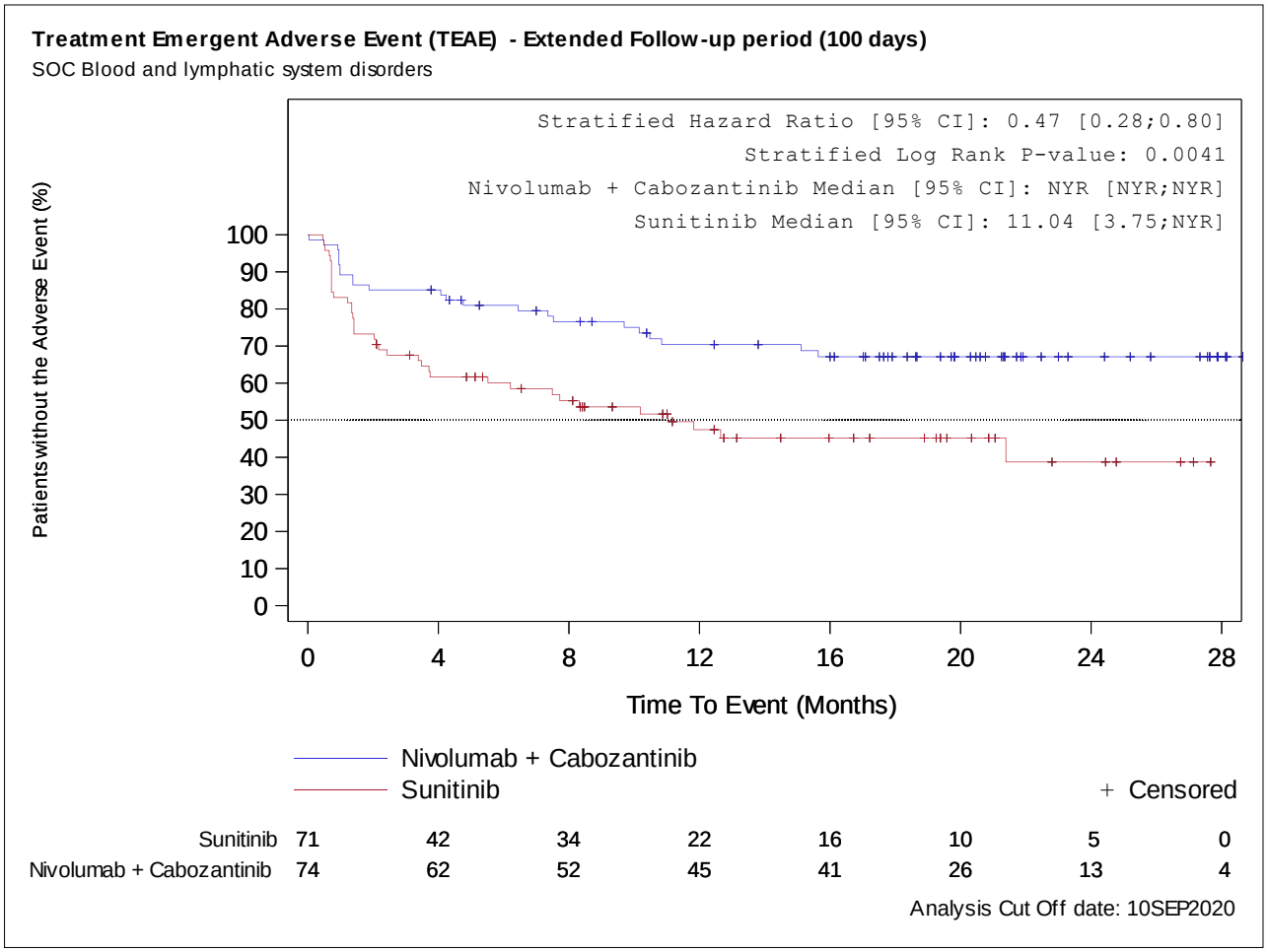


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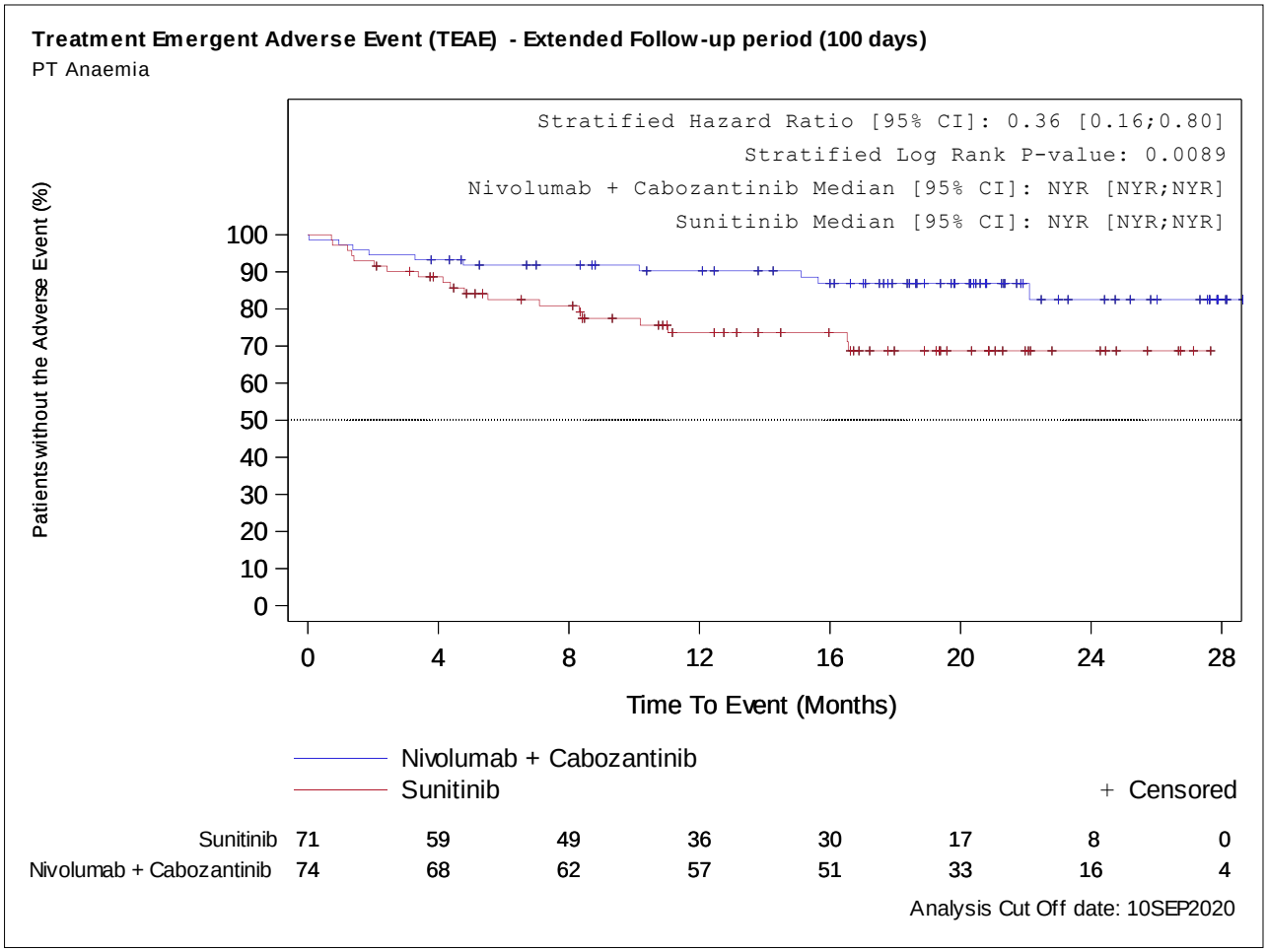
FIGURE 4.4.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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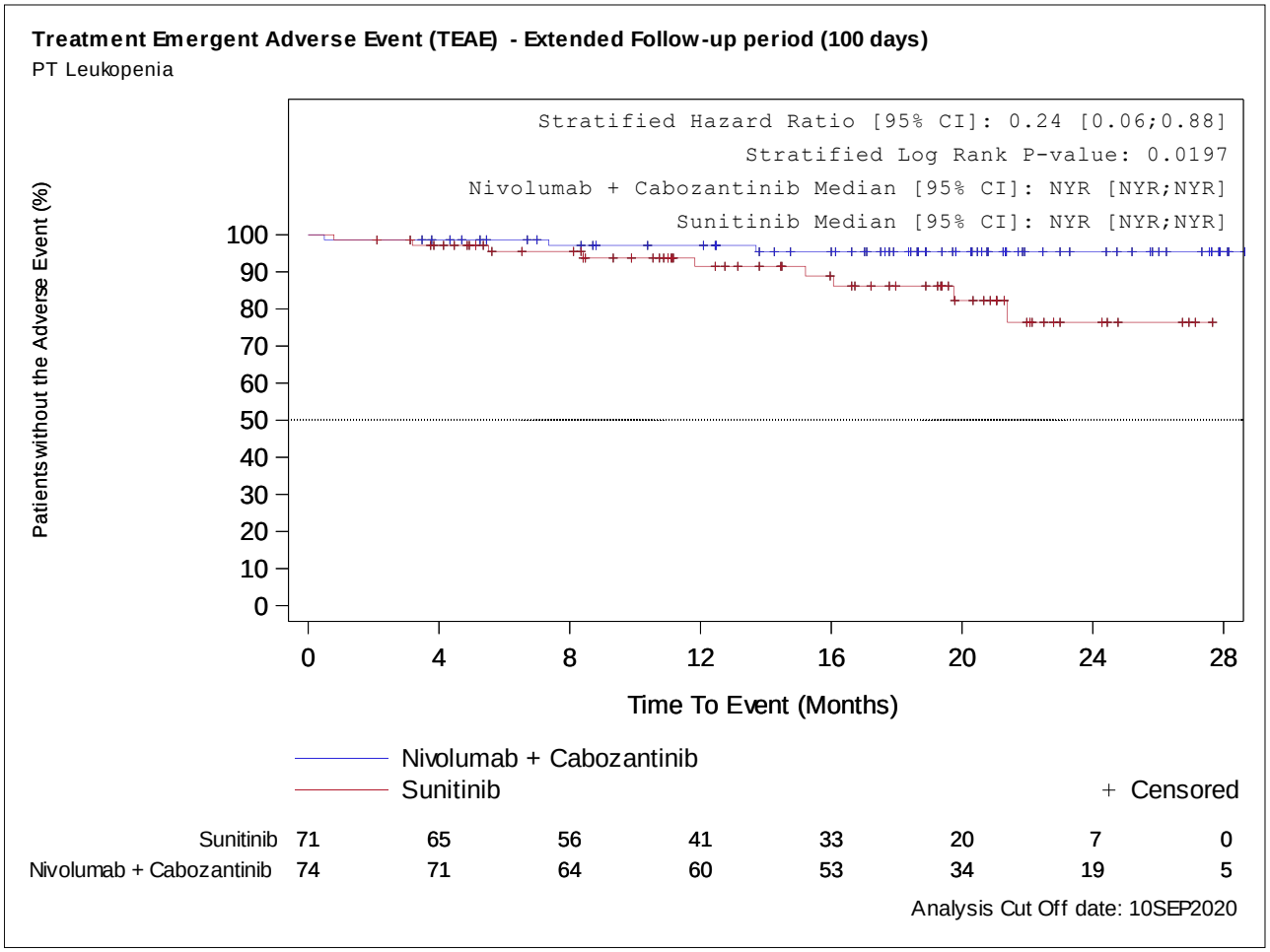
FIGURE 4.4.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Leukopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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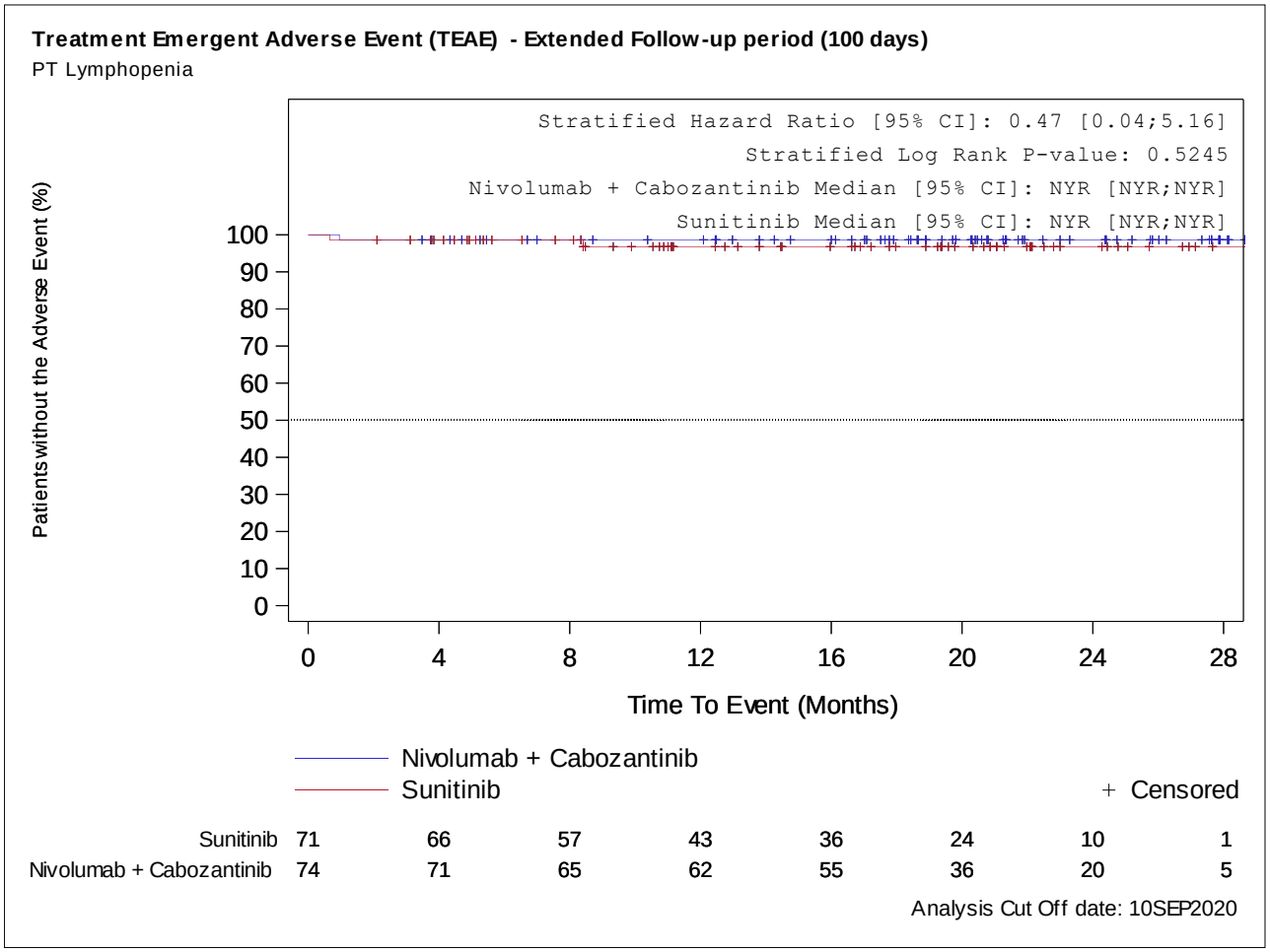
FIGURE 4.4.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Lymphopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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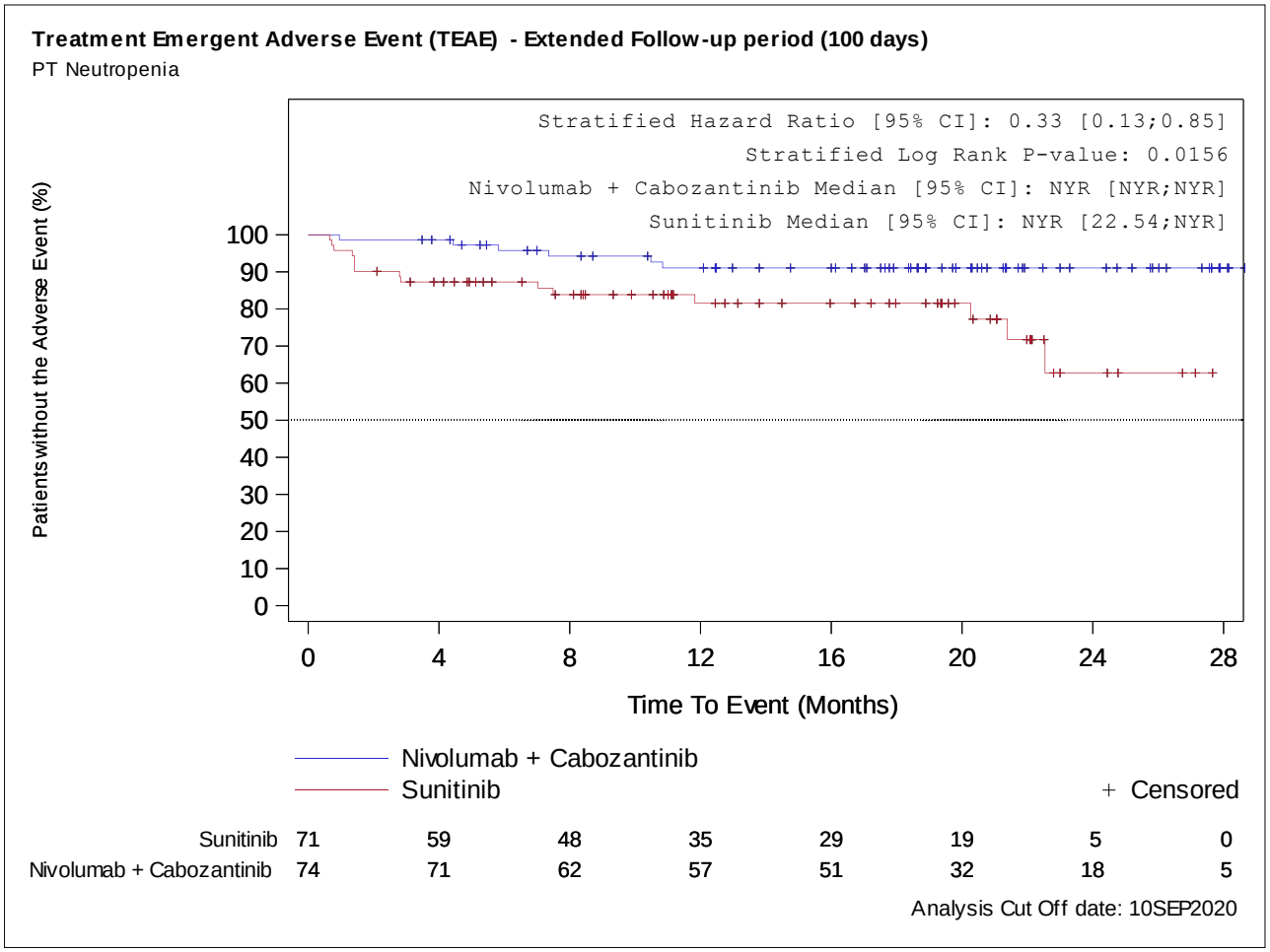
FIGURE 4.4.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.4.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

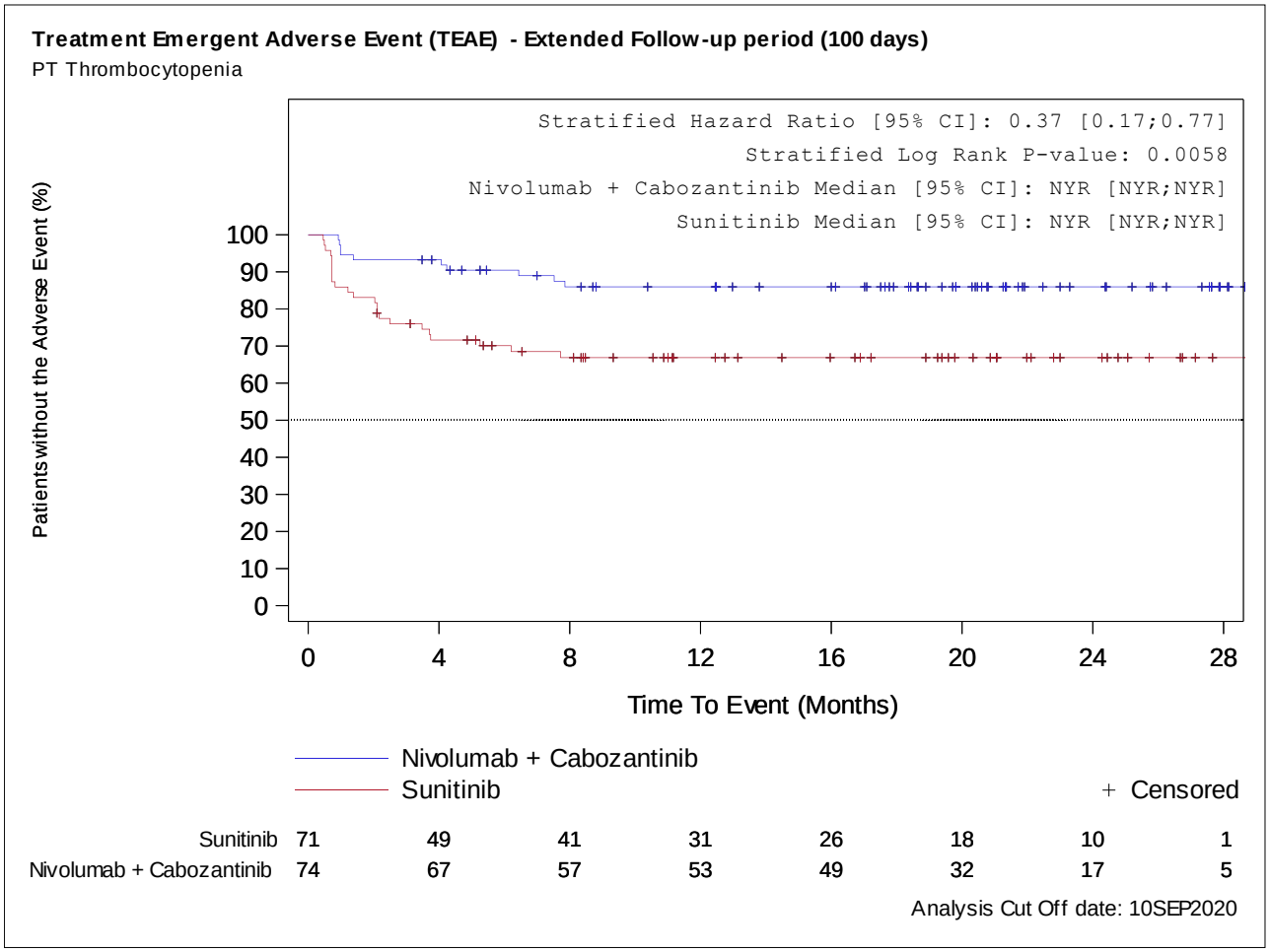


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FIGURE 4.4.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Cardiac disorders - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)

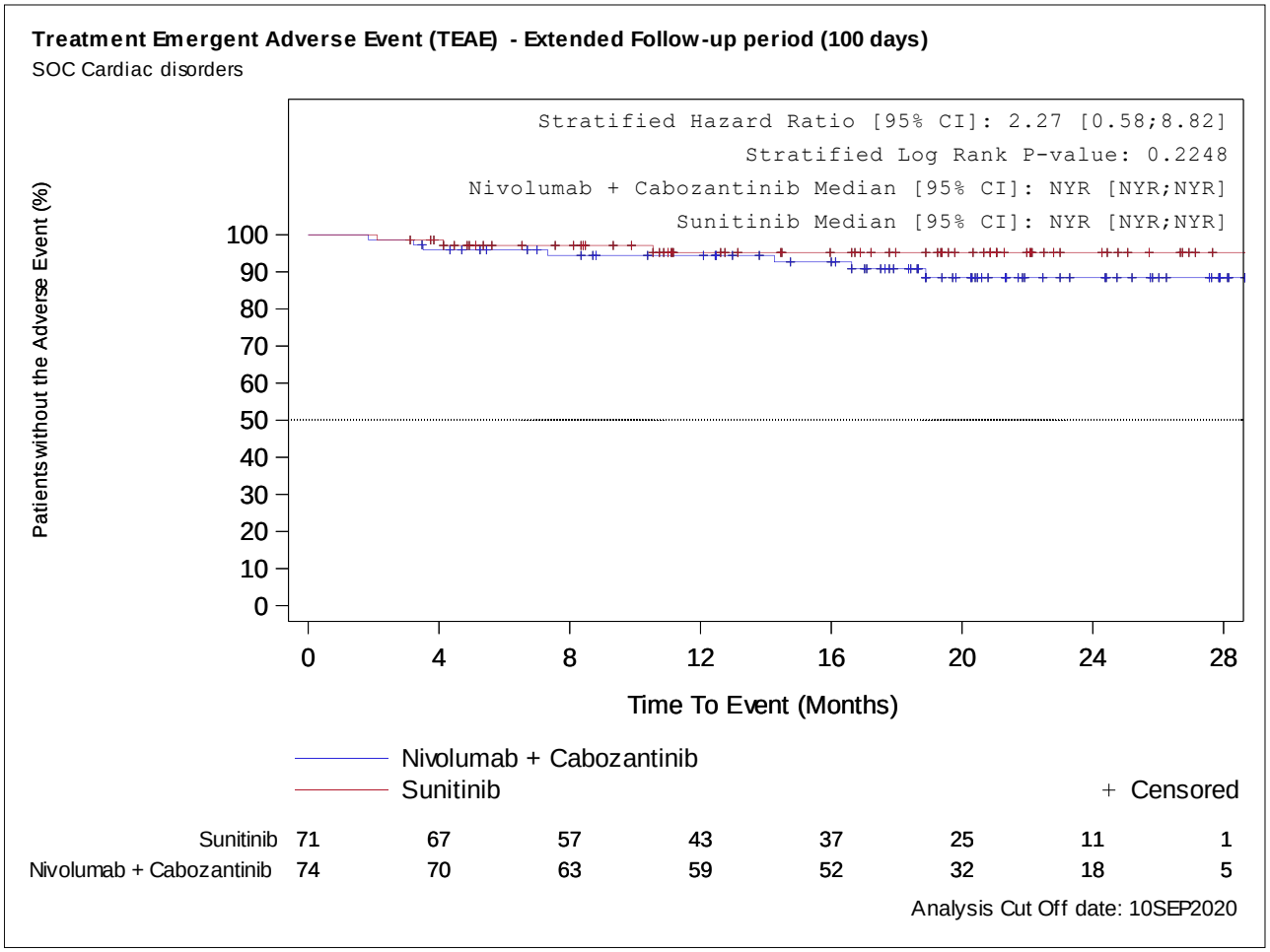


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FIGURE 4.4.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Tachycardia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

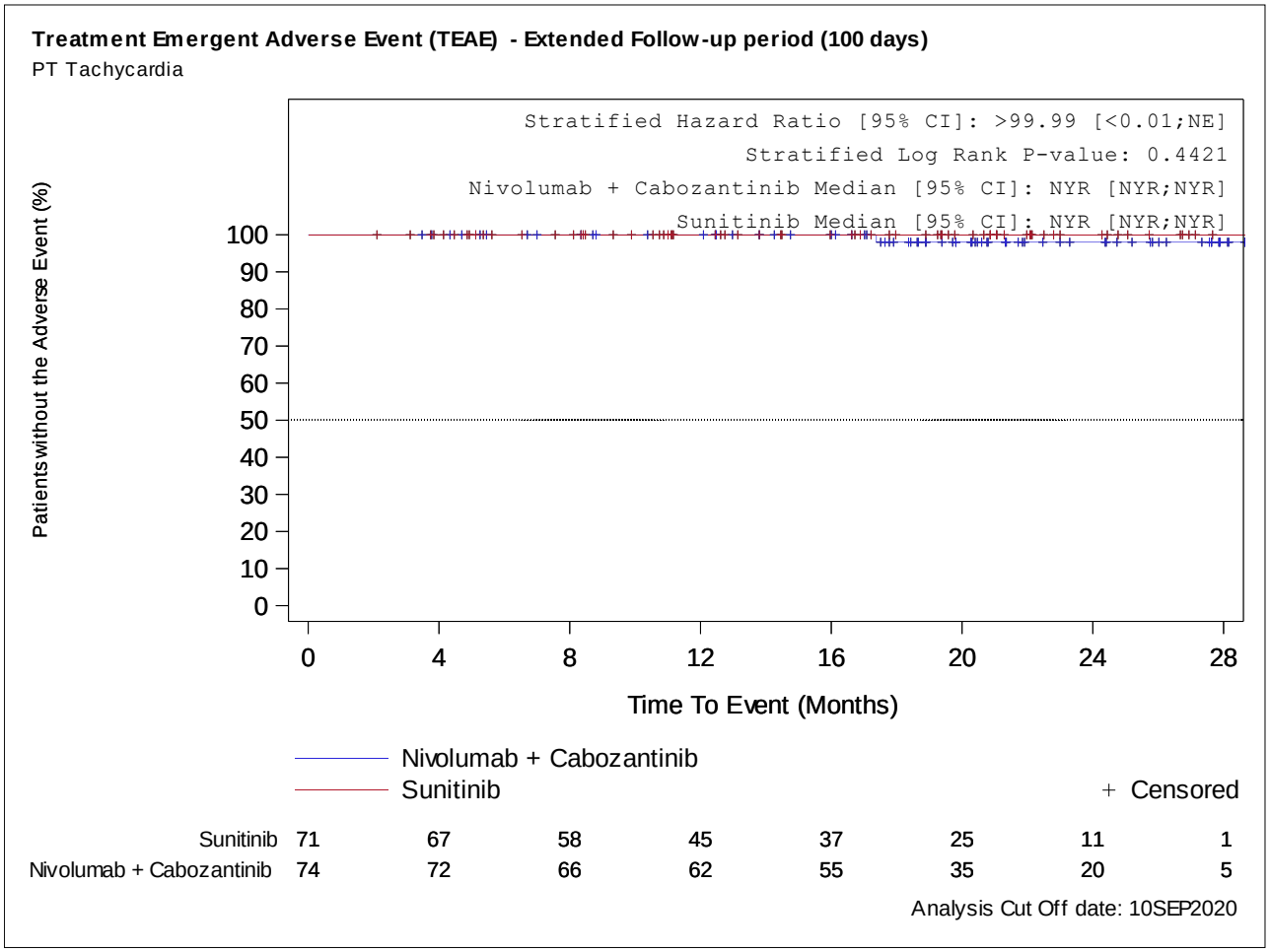


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FIGURE 4.4.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Ear and labyrinth disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

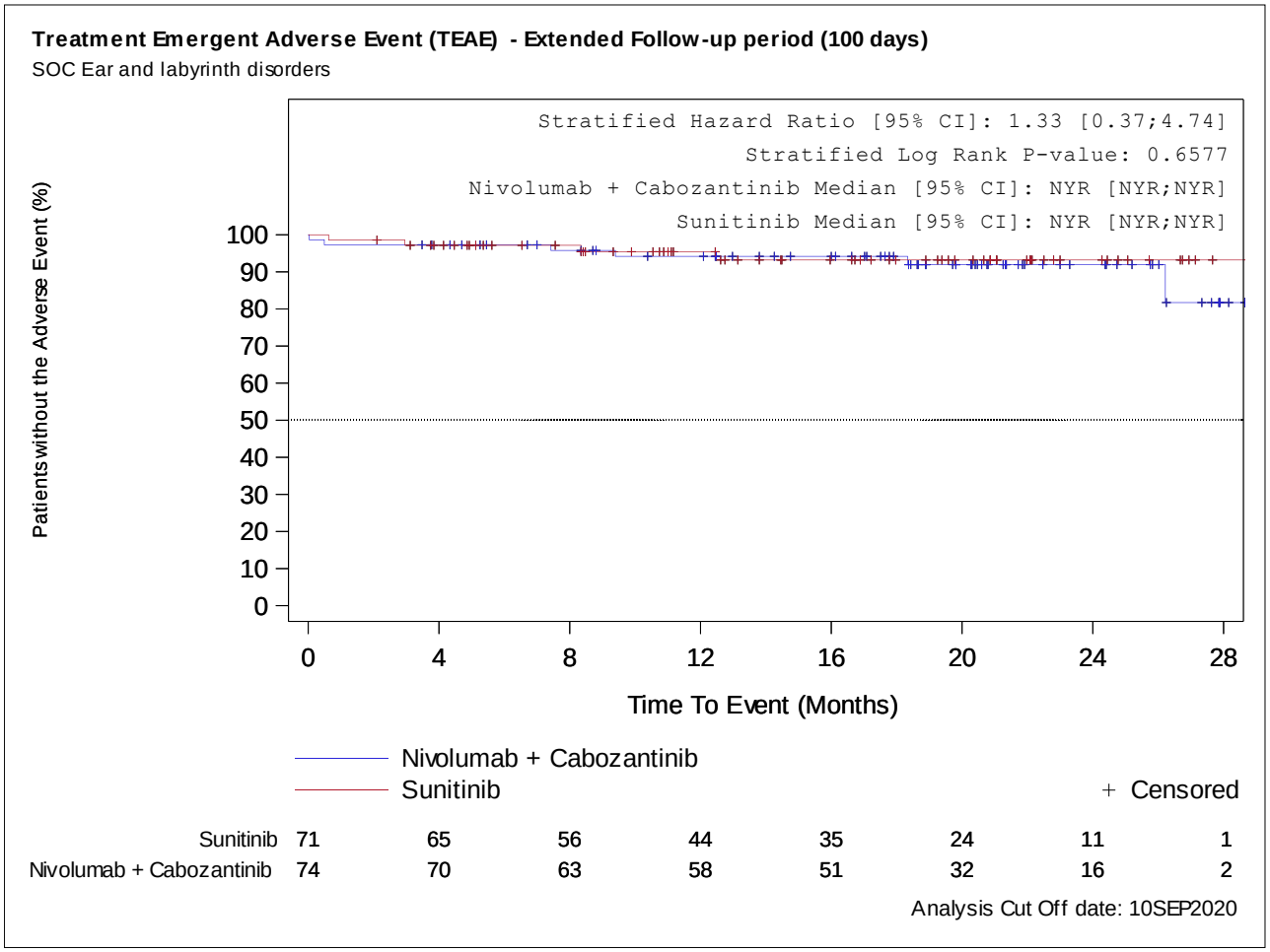


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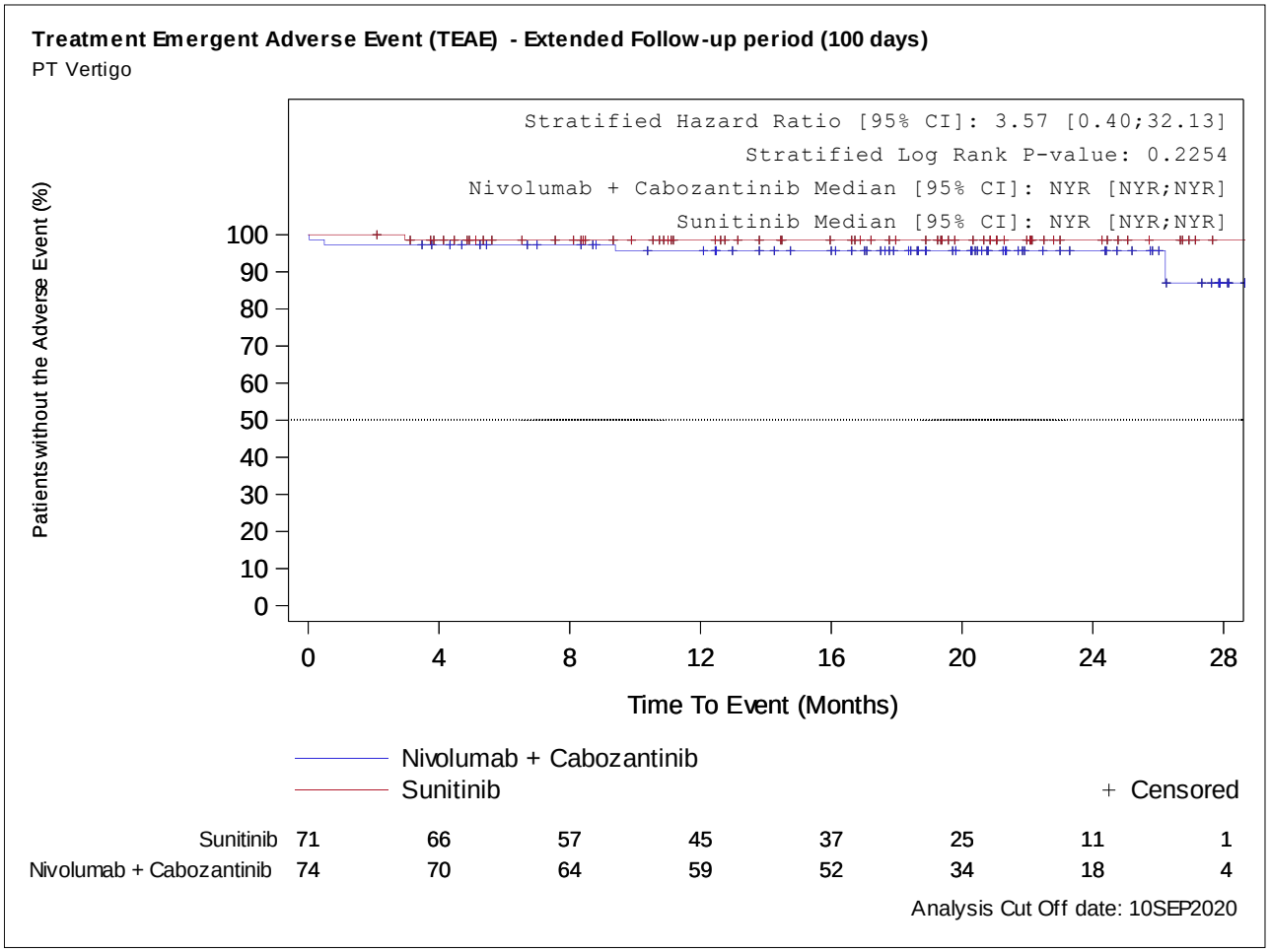
FIGURE 4.4.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Vertigo - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.4.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Endocrine disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

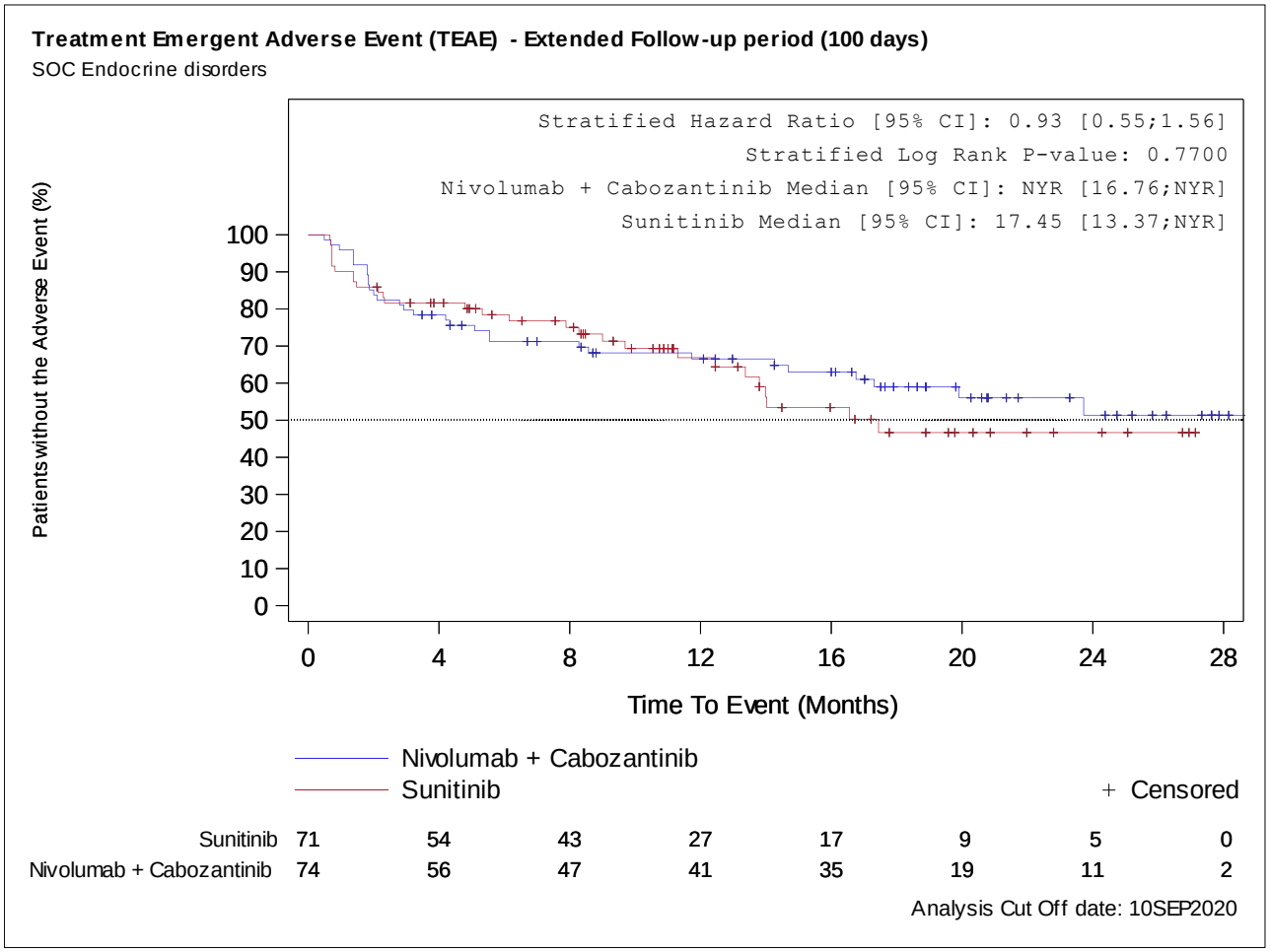


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FIGURE 4.4.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Adrenal insufficiency - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

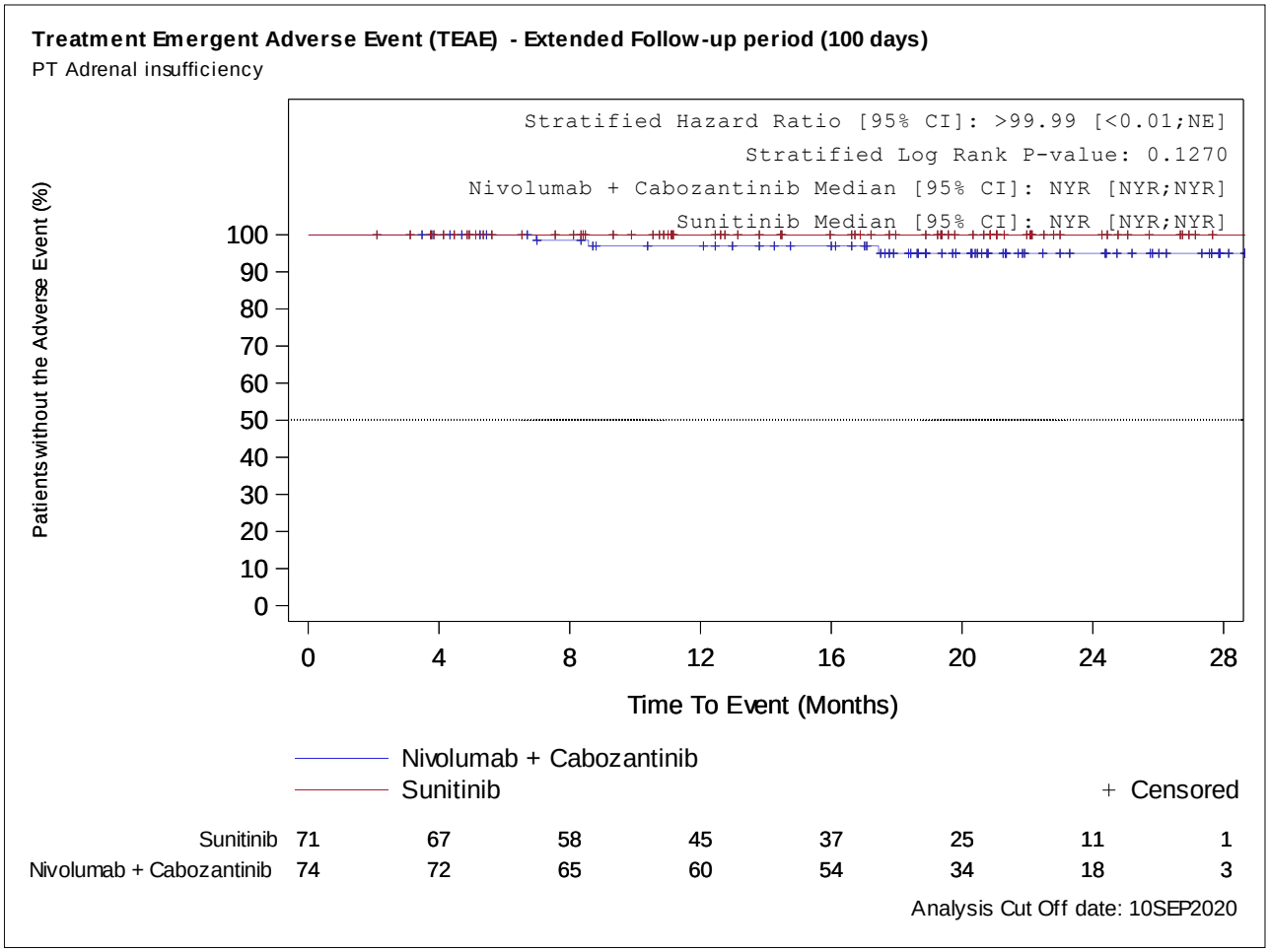


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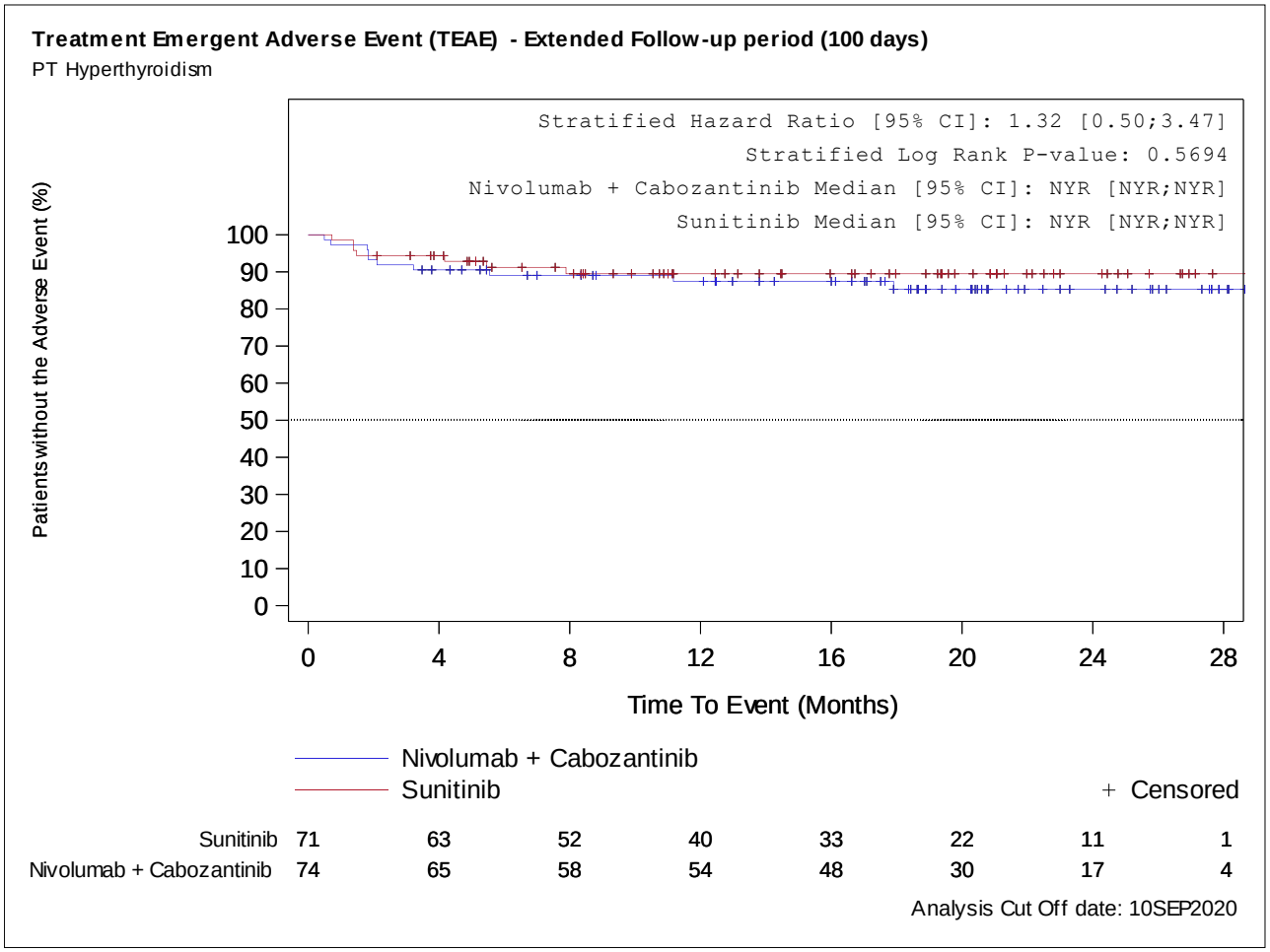
FIGURE 4.4.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hyperthyroidism - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.4.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypothyroidism - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

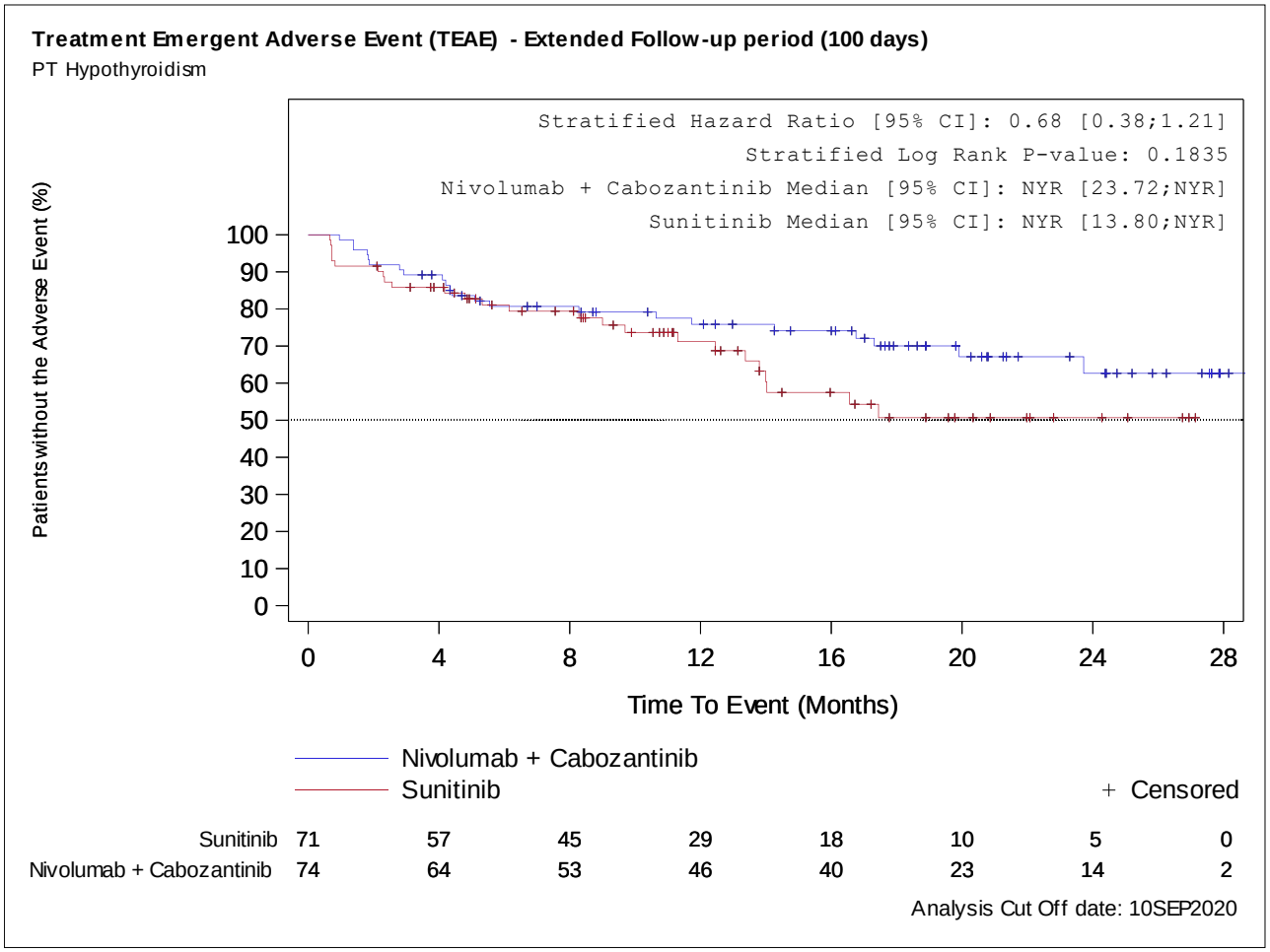


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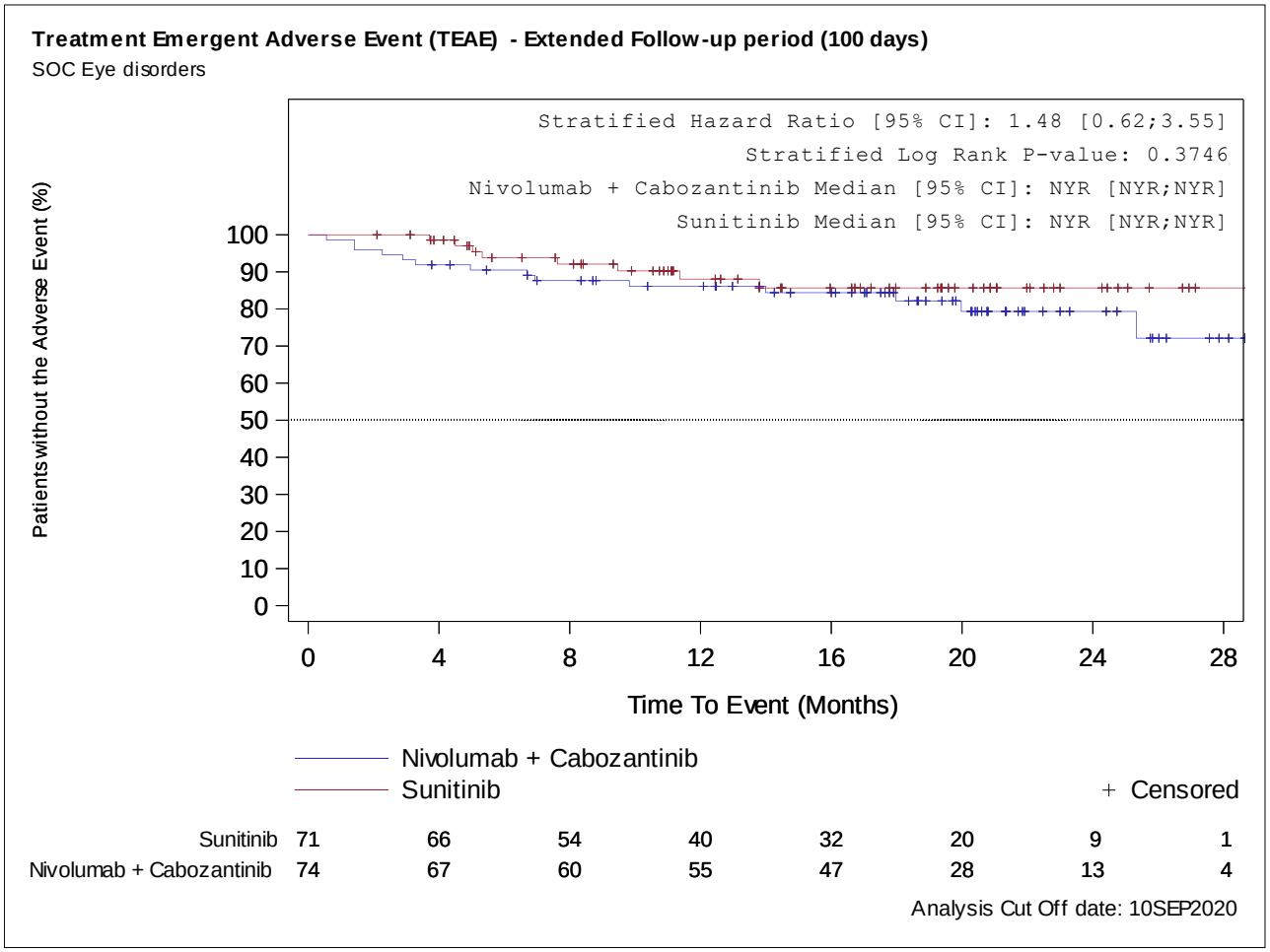
FIGURE 4.4.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Eye disorders - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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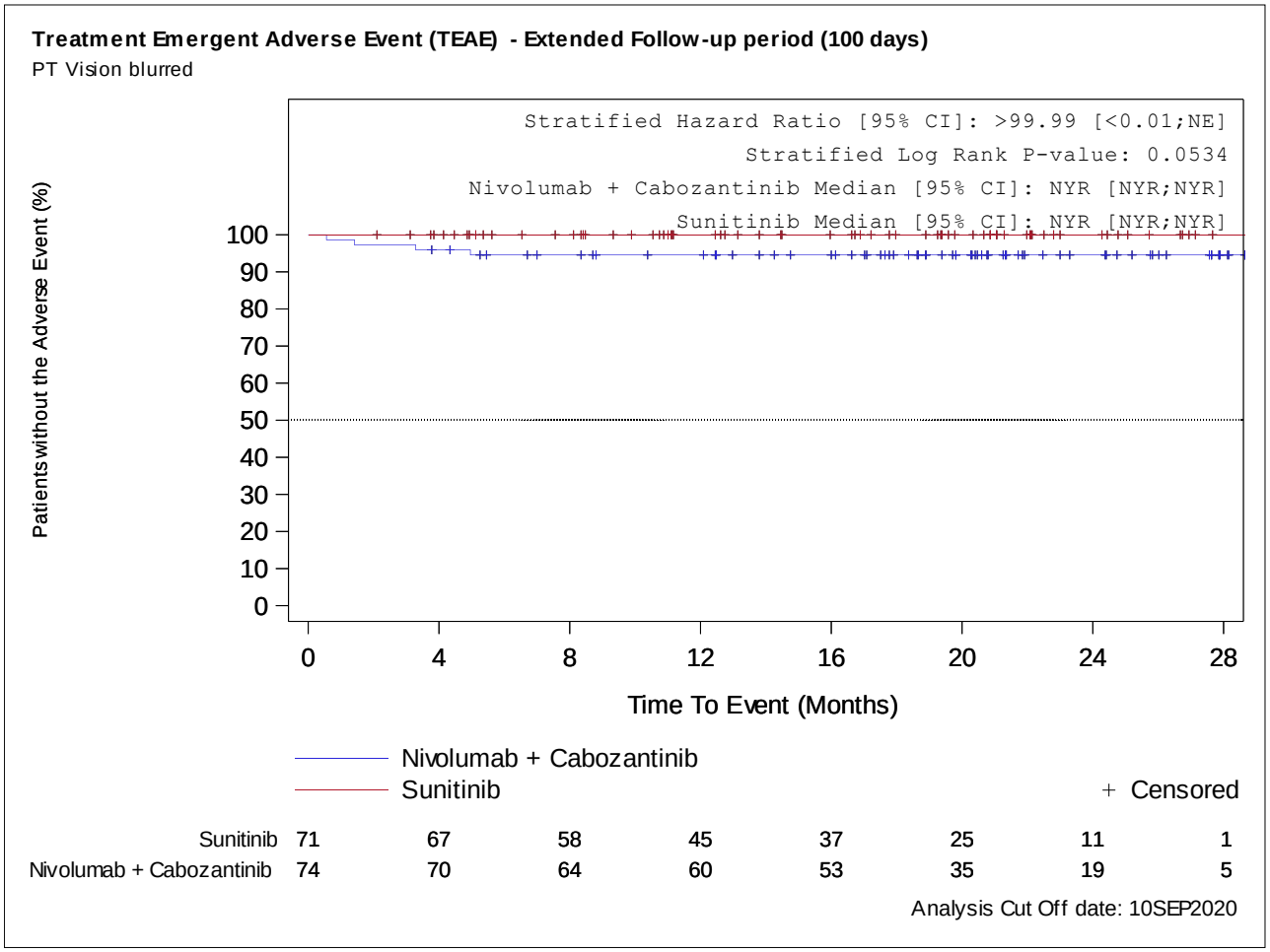
FIGURE 4.4.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Vision blurred - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.4.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

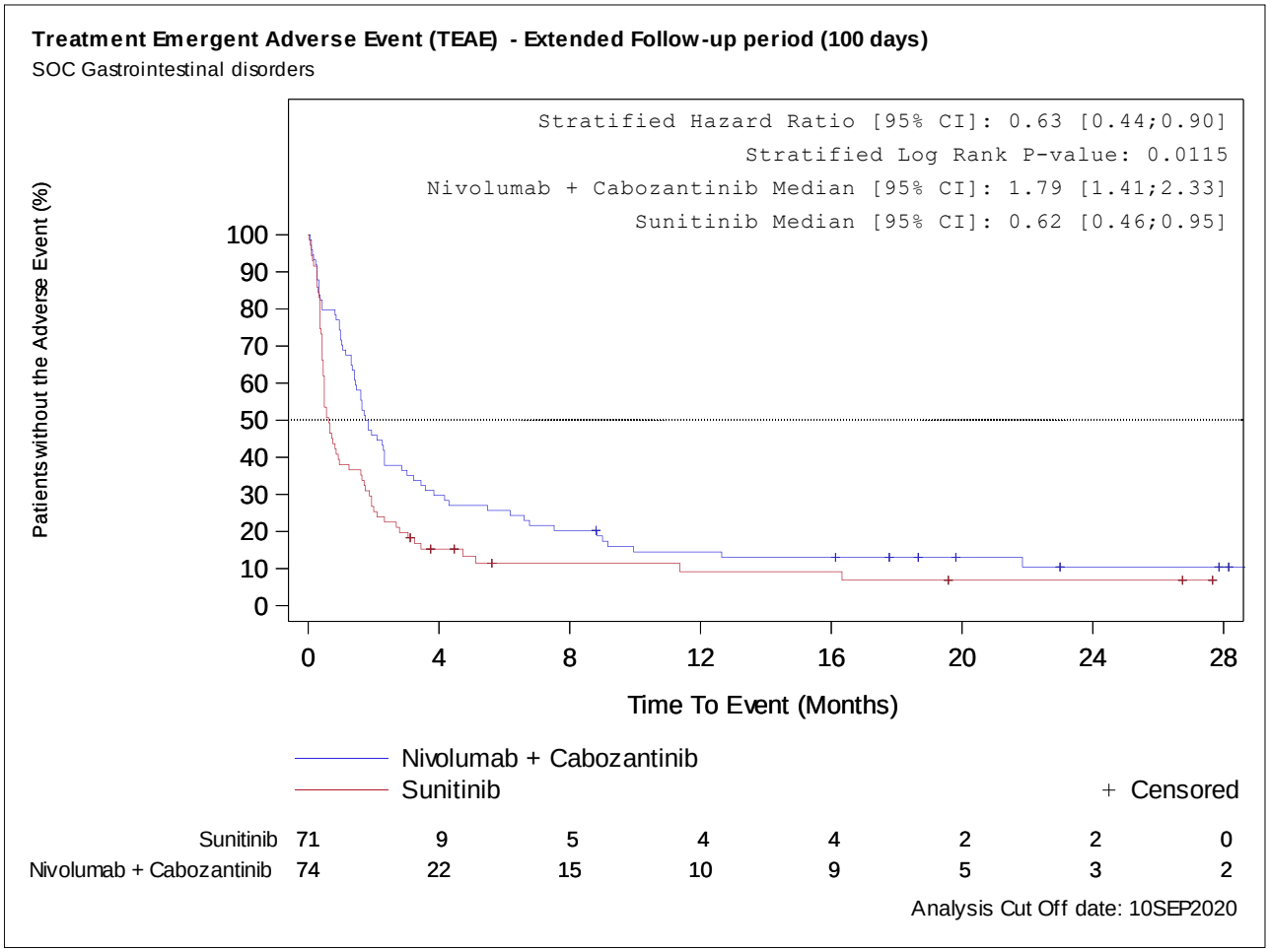


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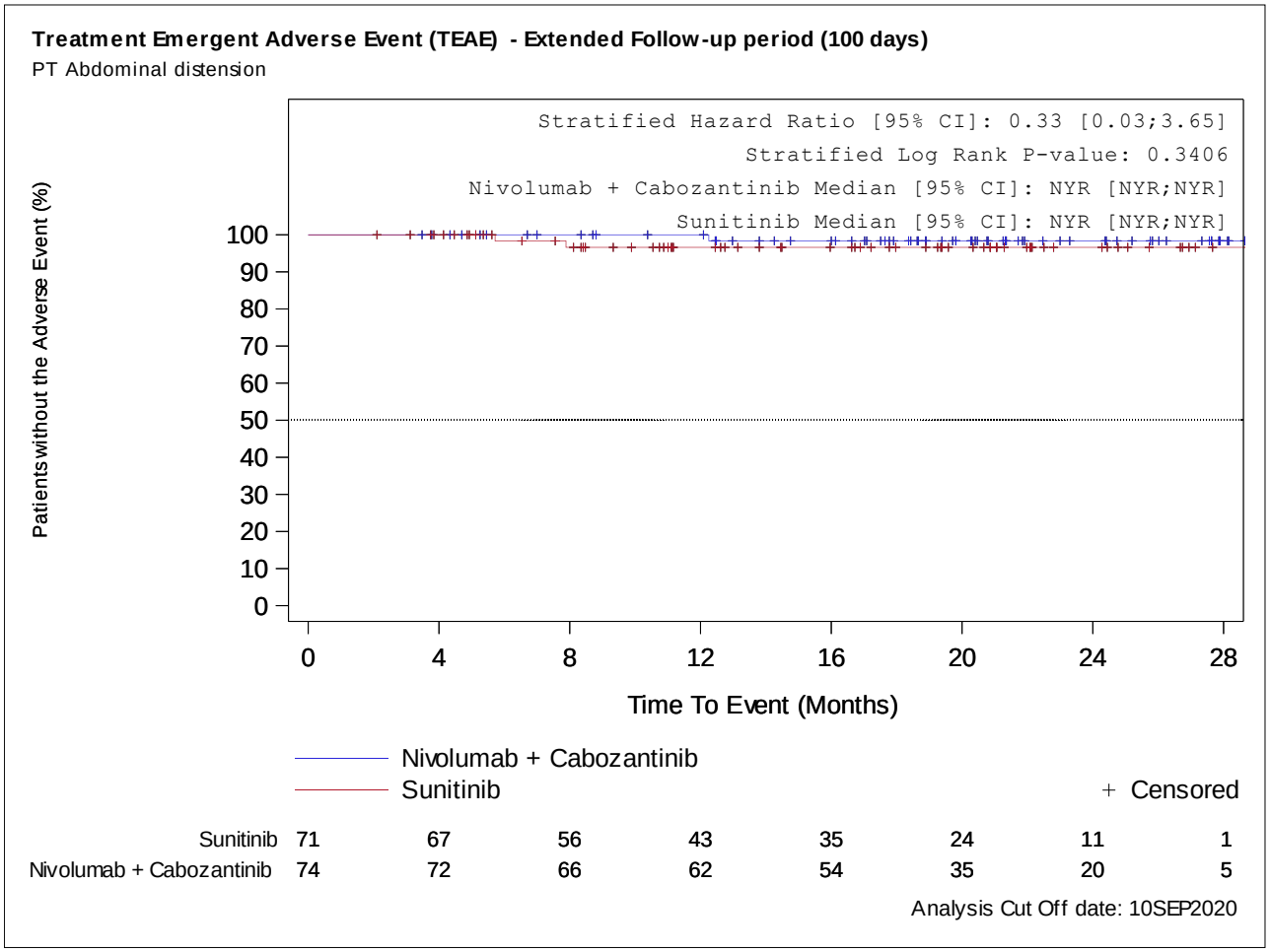
FIGURE 4.4.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Abdominal distension - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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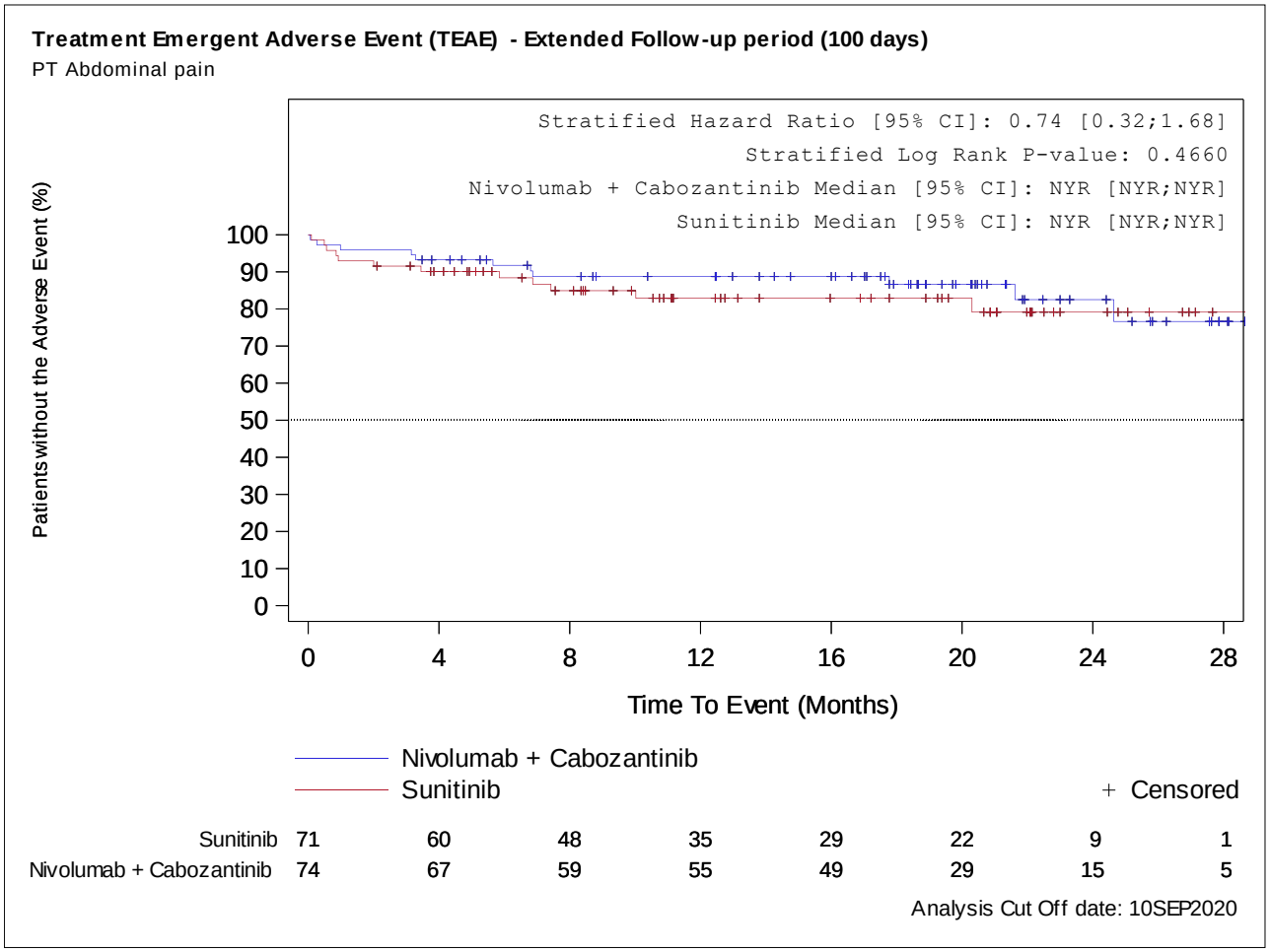
FIGURE 4.4.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Abdominal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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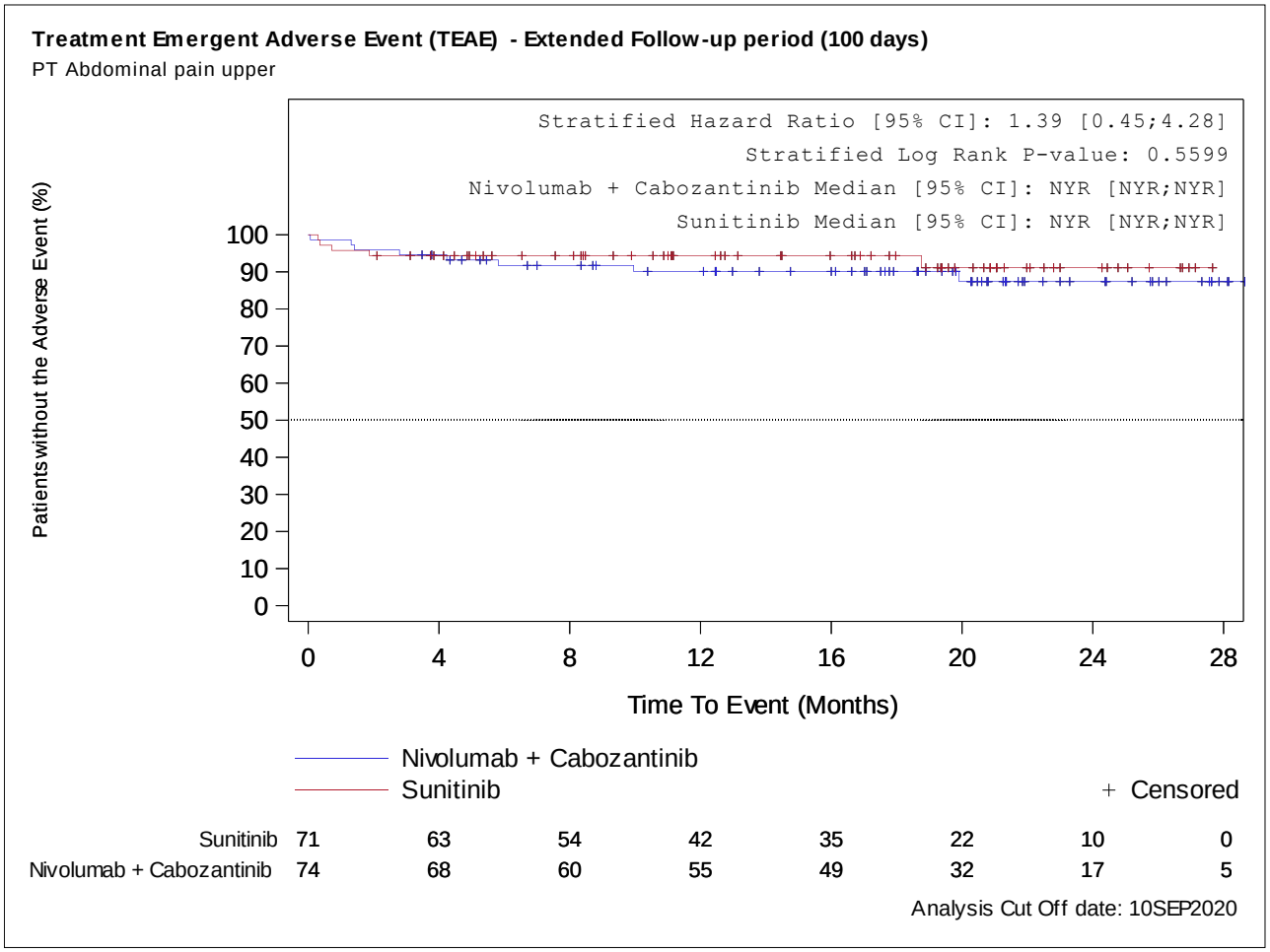
FIGURE 4.4.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Abdominal pain upper - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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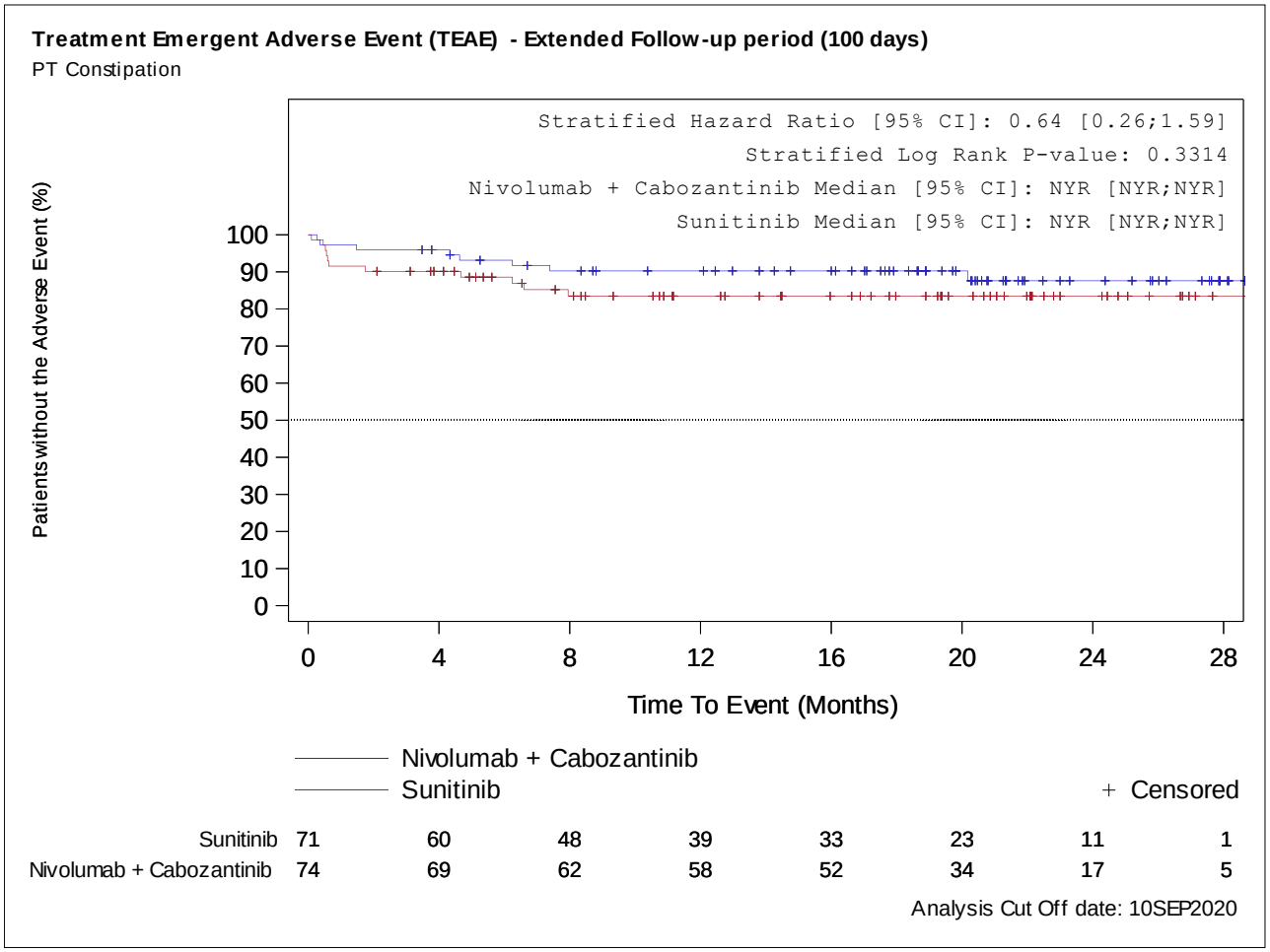
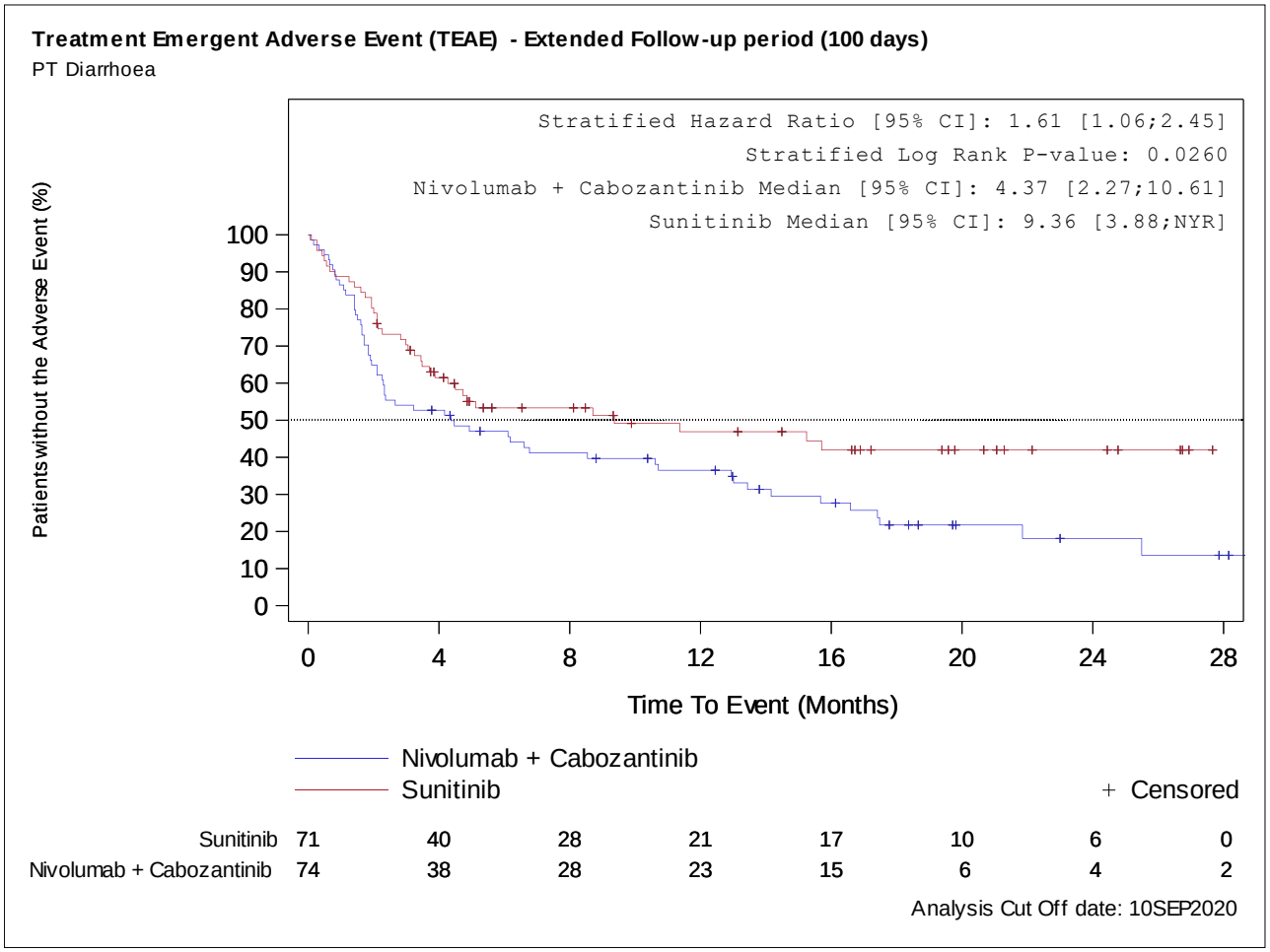
FIGURE 4.4.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Constipation - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:21:03

FIGURE 4.4.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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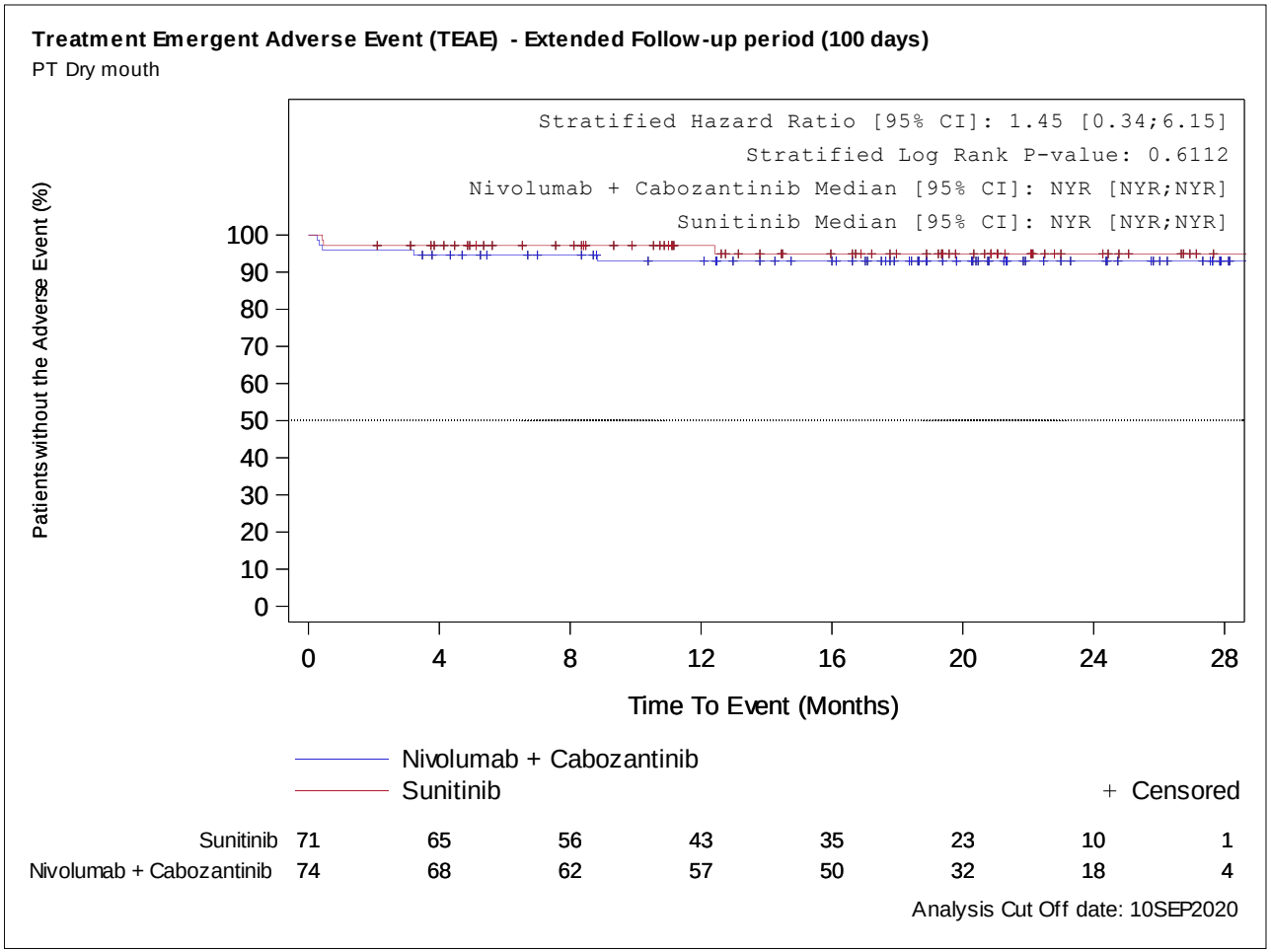
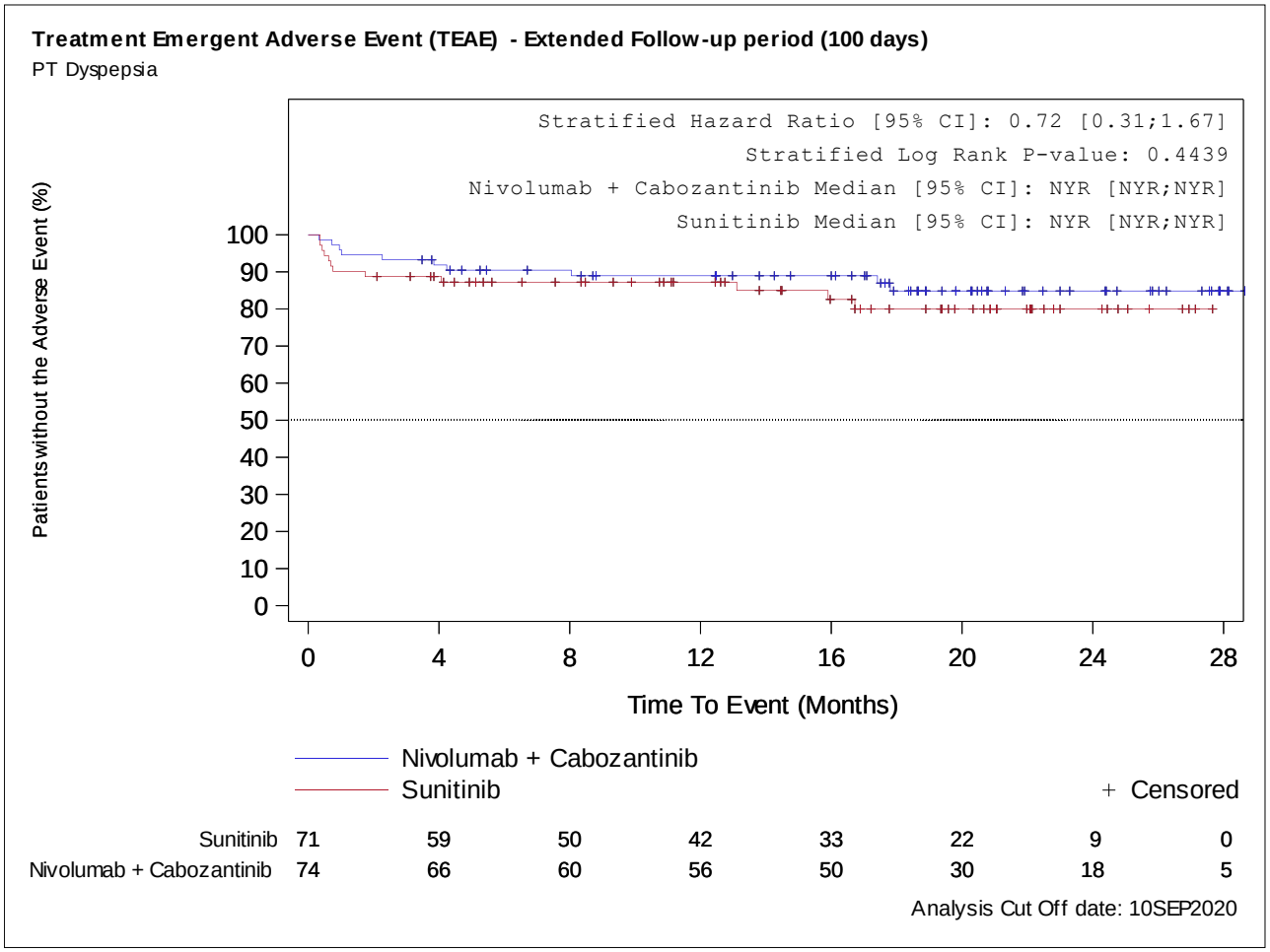
FIGURE 4.4.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dry mouth - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:21:11

FIGURE 4.4.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dyspepsia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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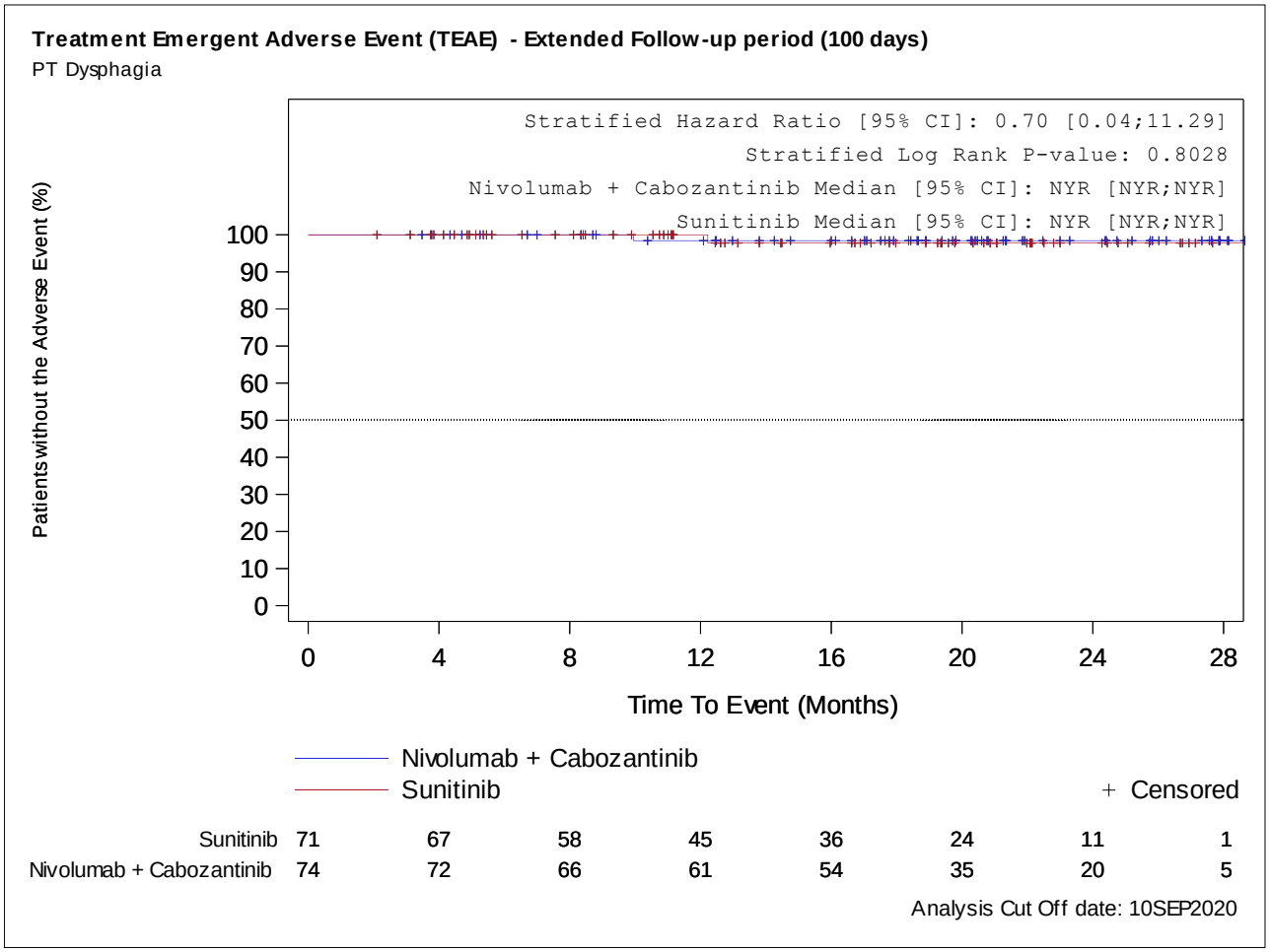
FIGURE 4.4.2.25: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphagia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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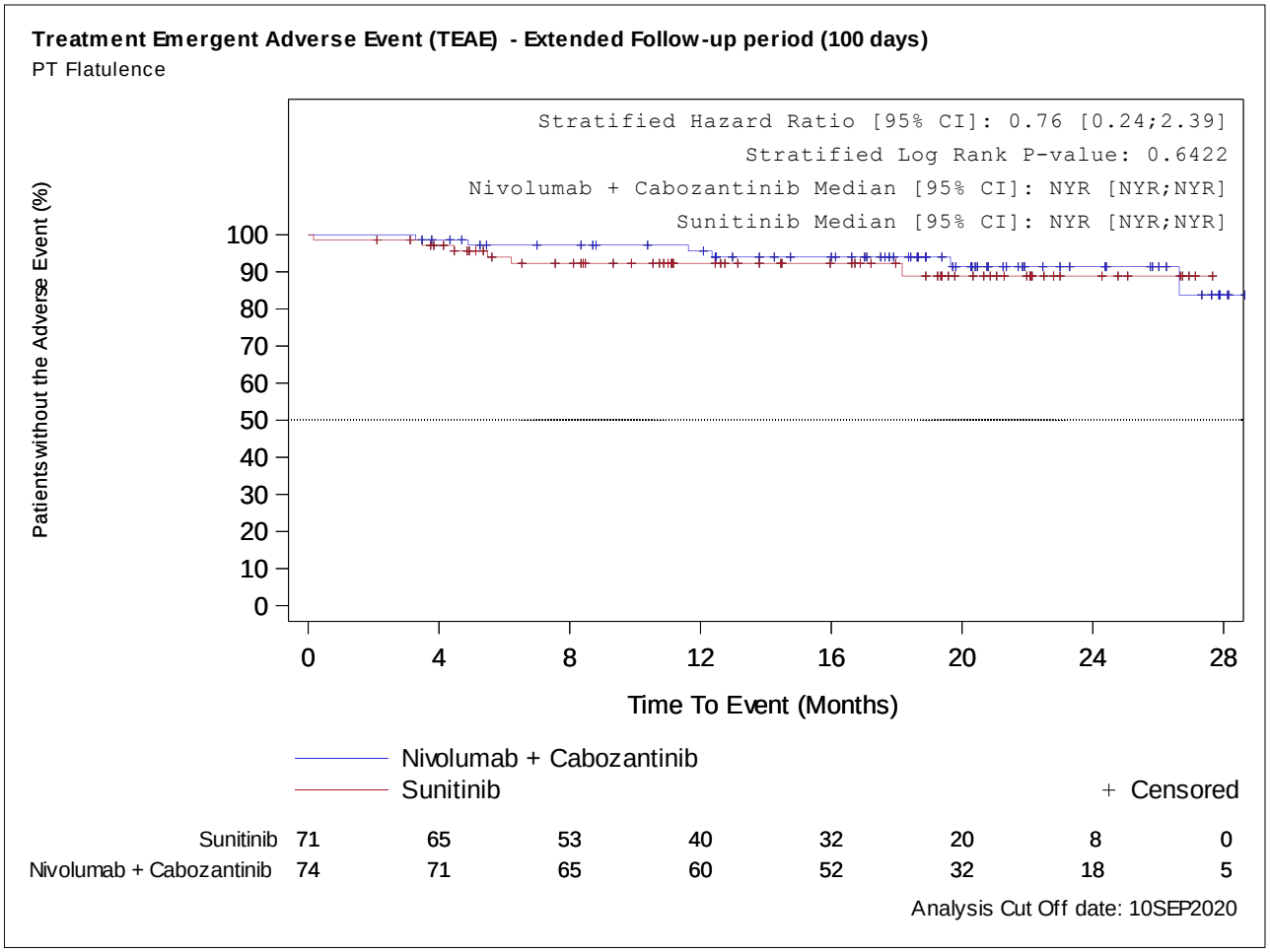
FIGURE 4.4.2.26: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Flatulence - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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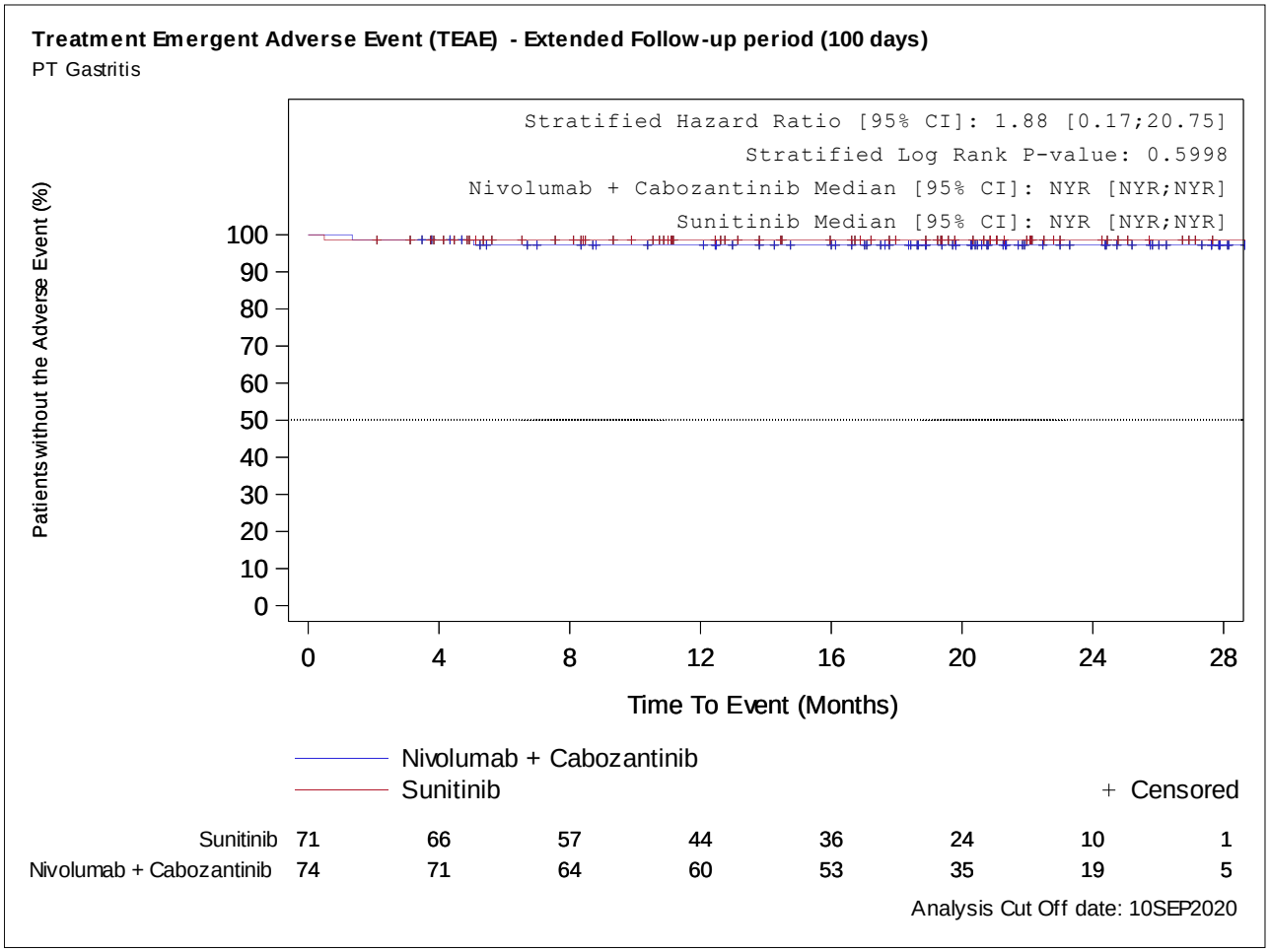
FIGURE 4.4.2.27: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Gastritis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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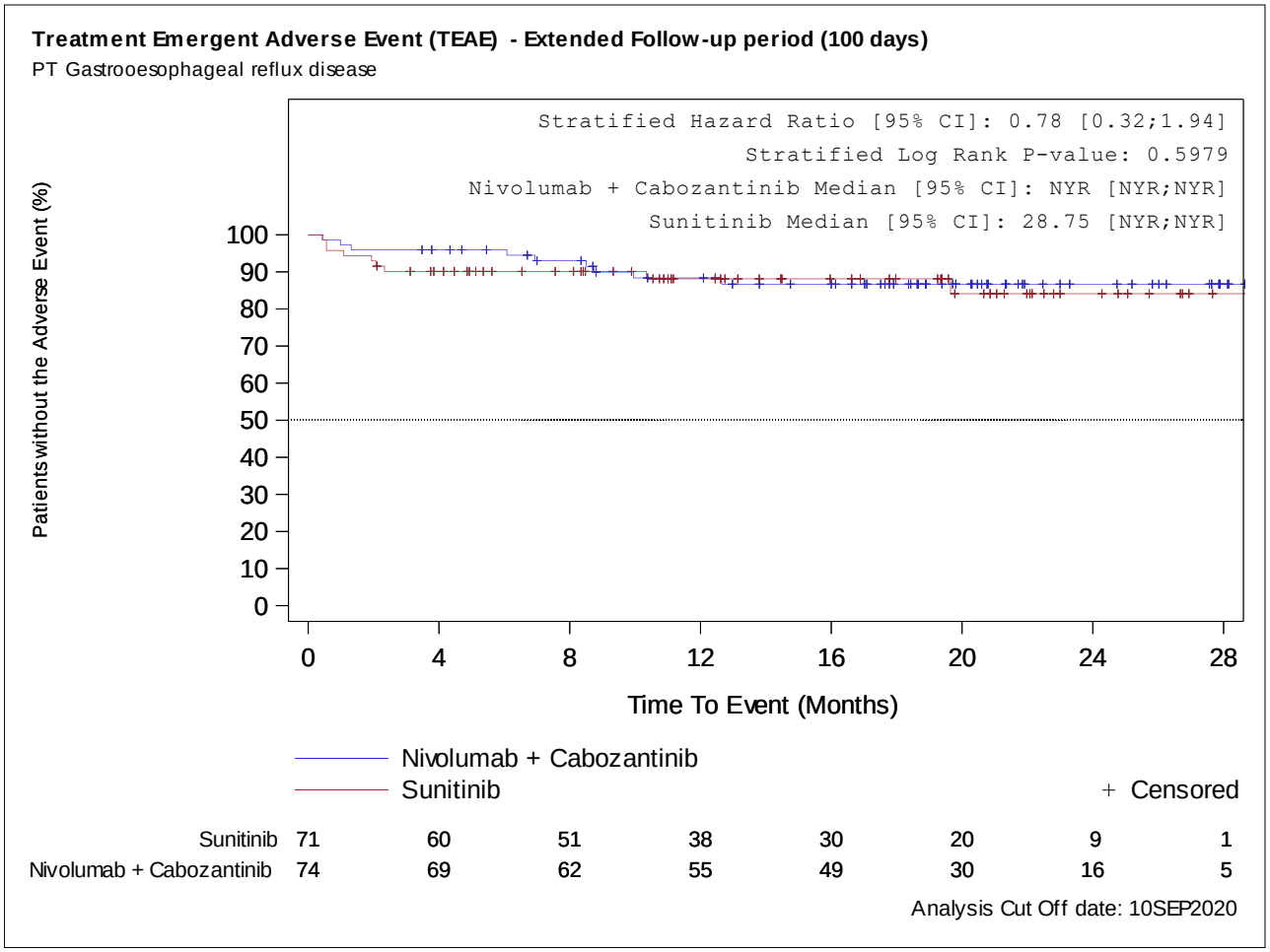
FIGURE 4.4.2.28: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Gastrooesophageal reflux disease - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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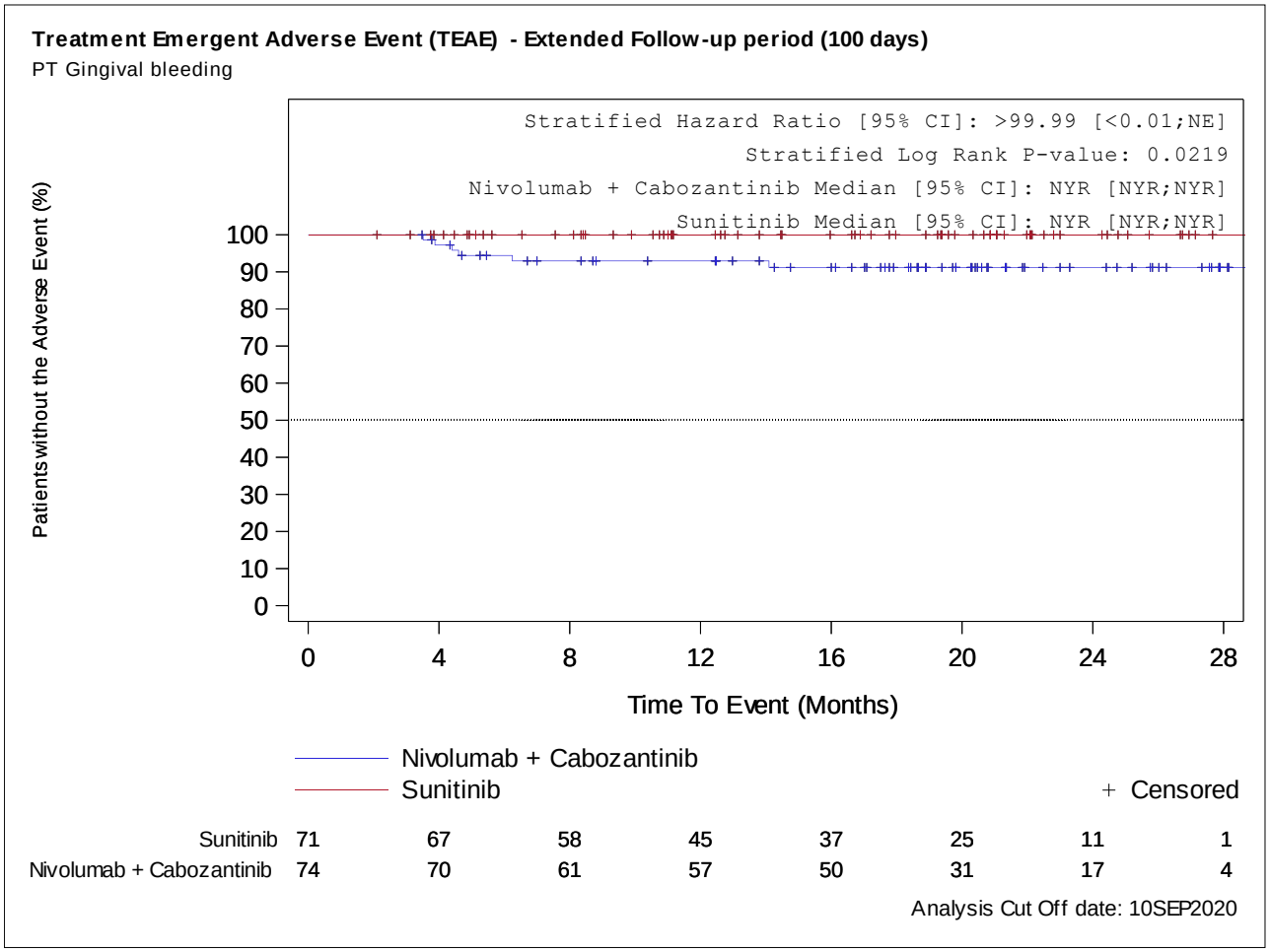
FIGURE 4.4.2.29: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Gingival bleeding - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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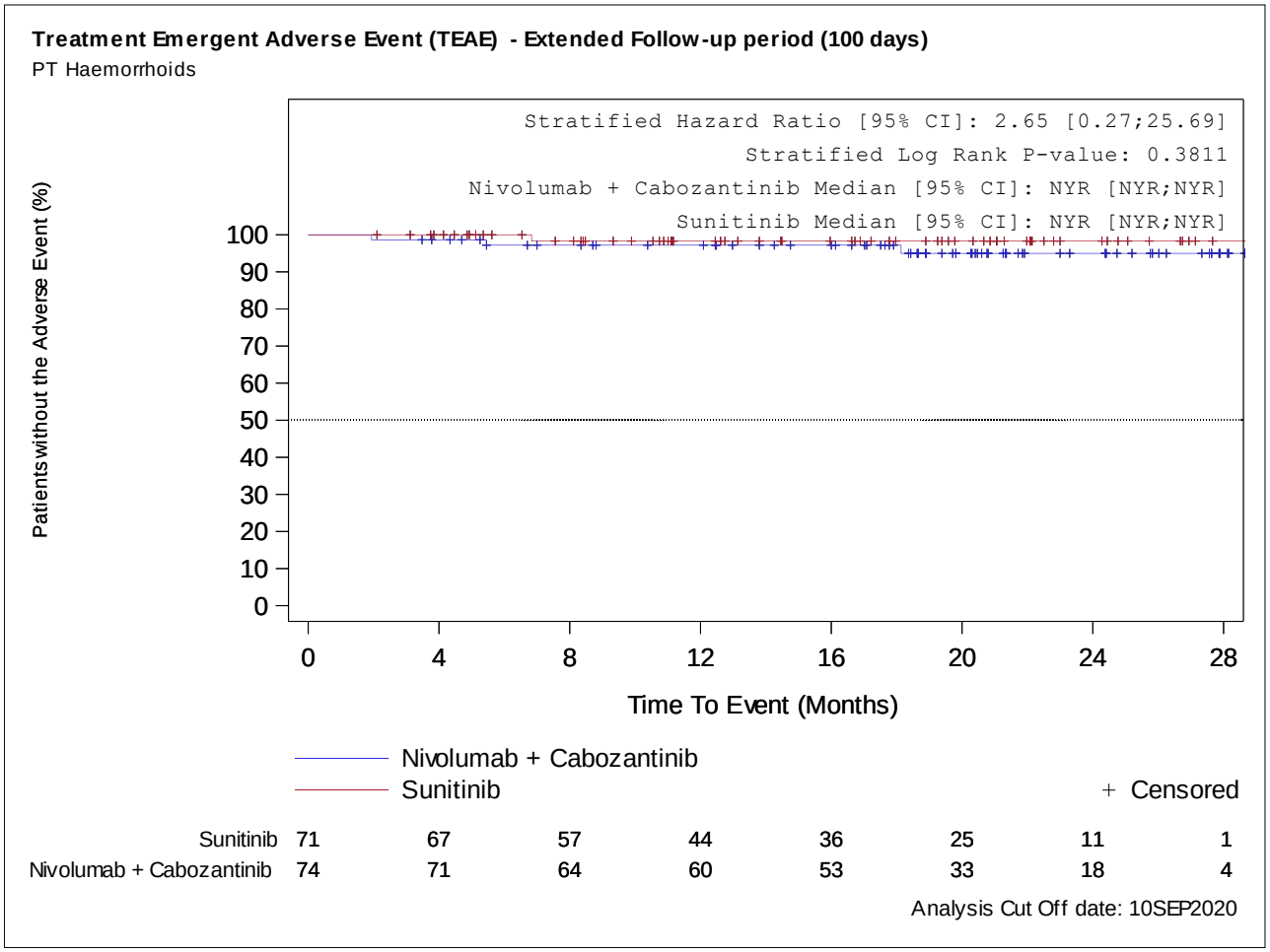
FIGURE 4.4.2.30: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Haemorrhoids - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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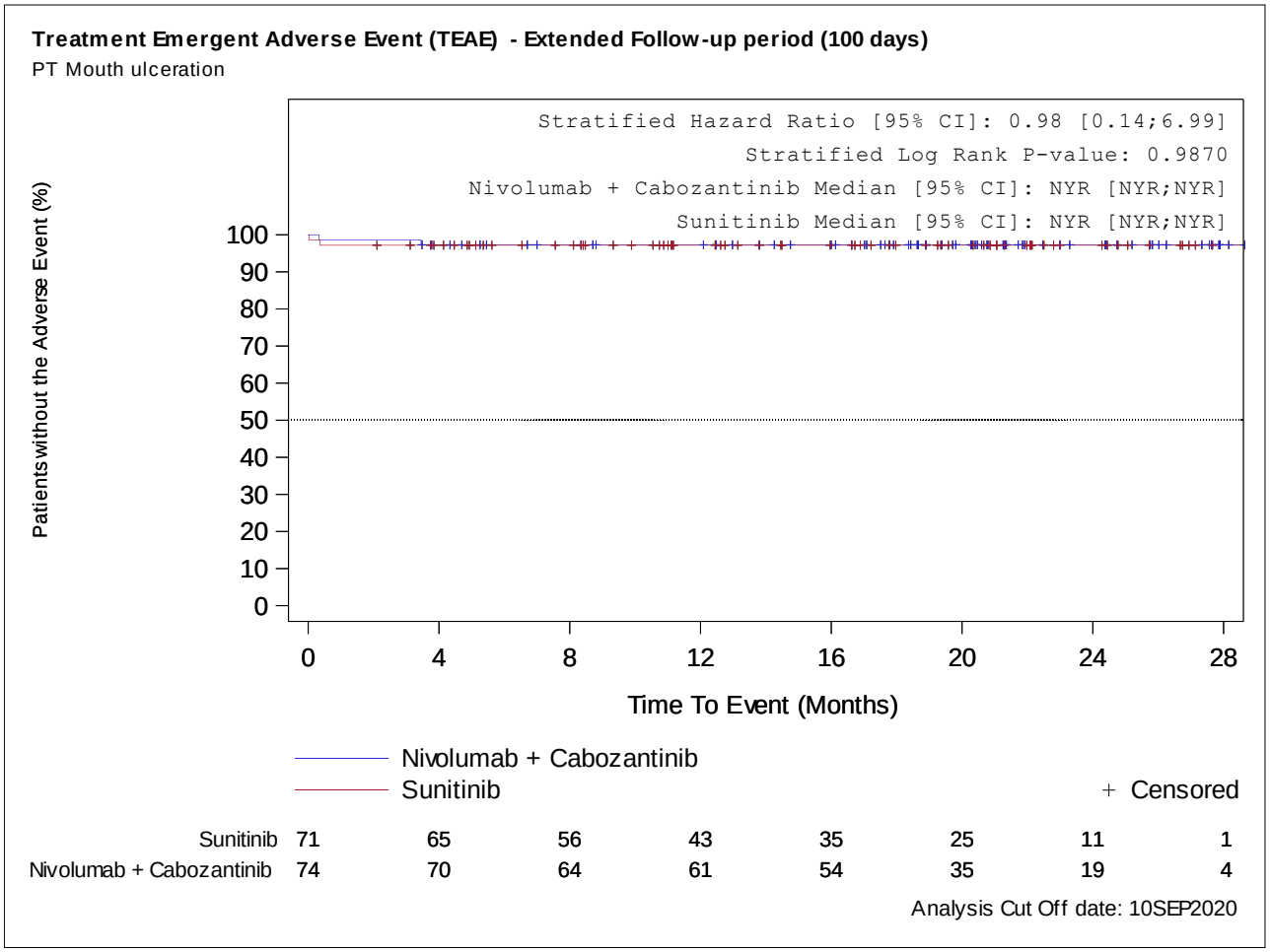
FIGURE 4.4.2.31: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Mouth ulceration - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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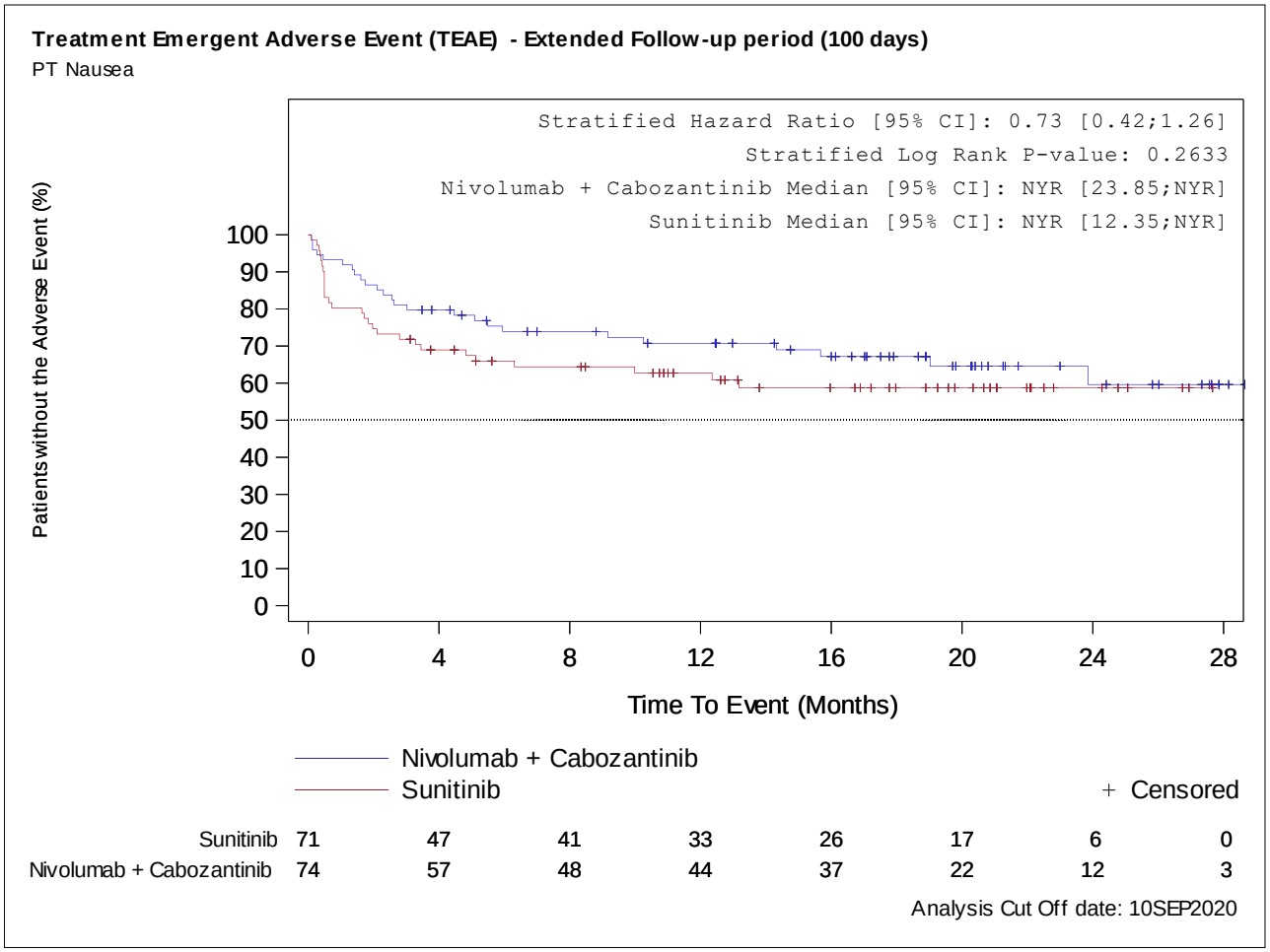
FIGURE 4.4.2.32: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Nausea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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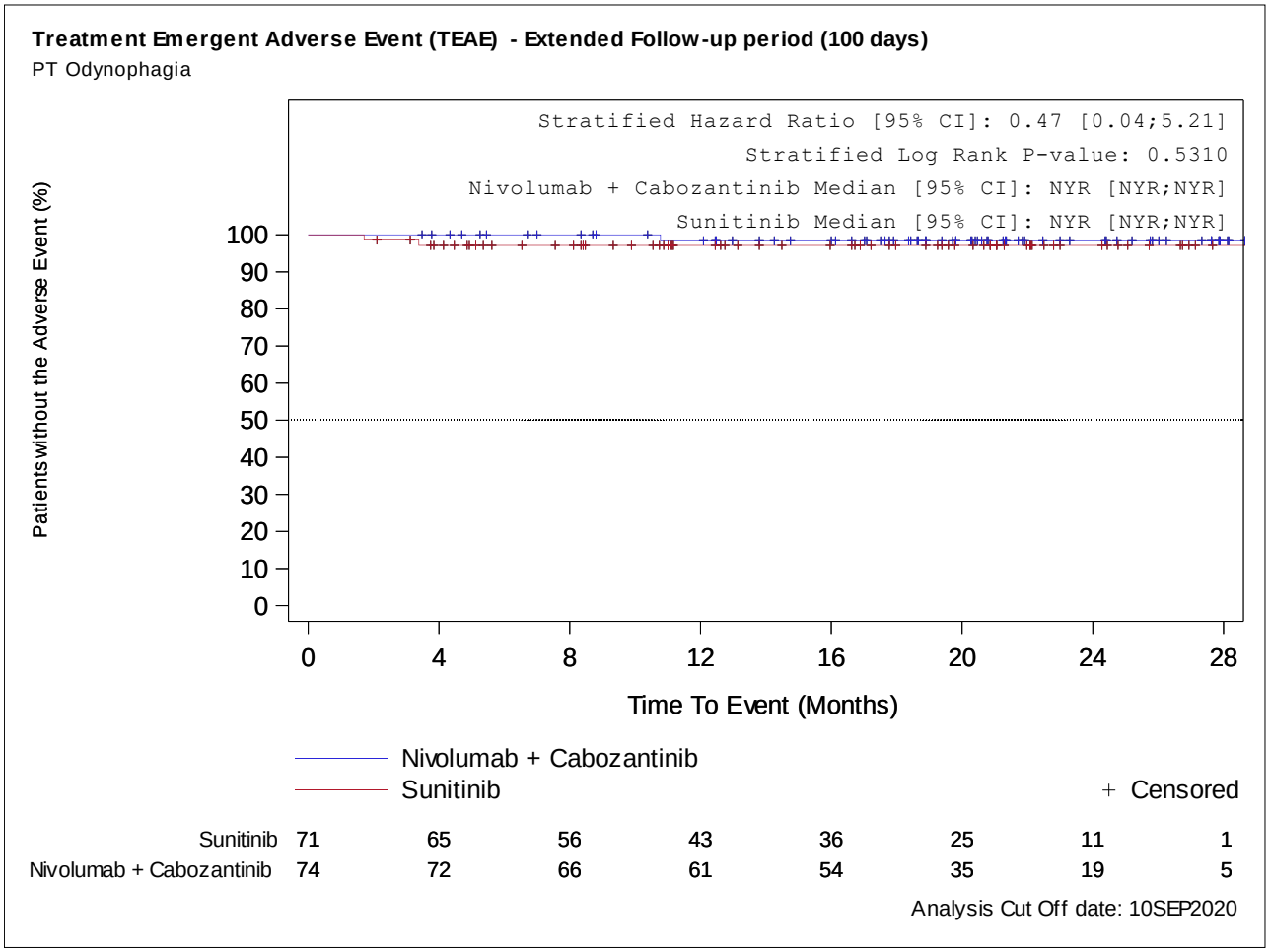
FIGURE 4.4.2.33: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Odynophagia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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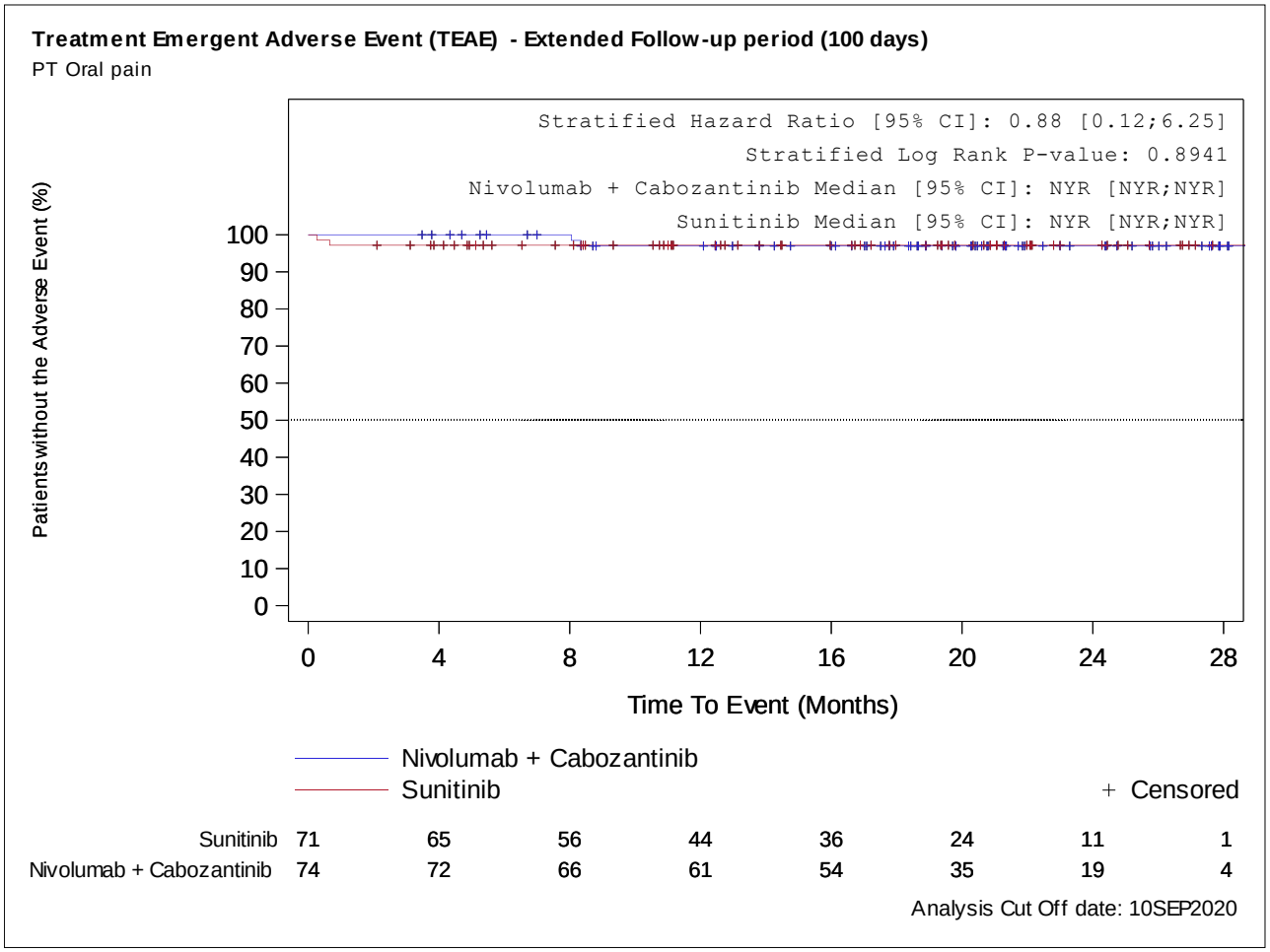
FIGURE 4.4.2.34: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oral pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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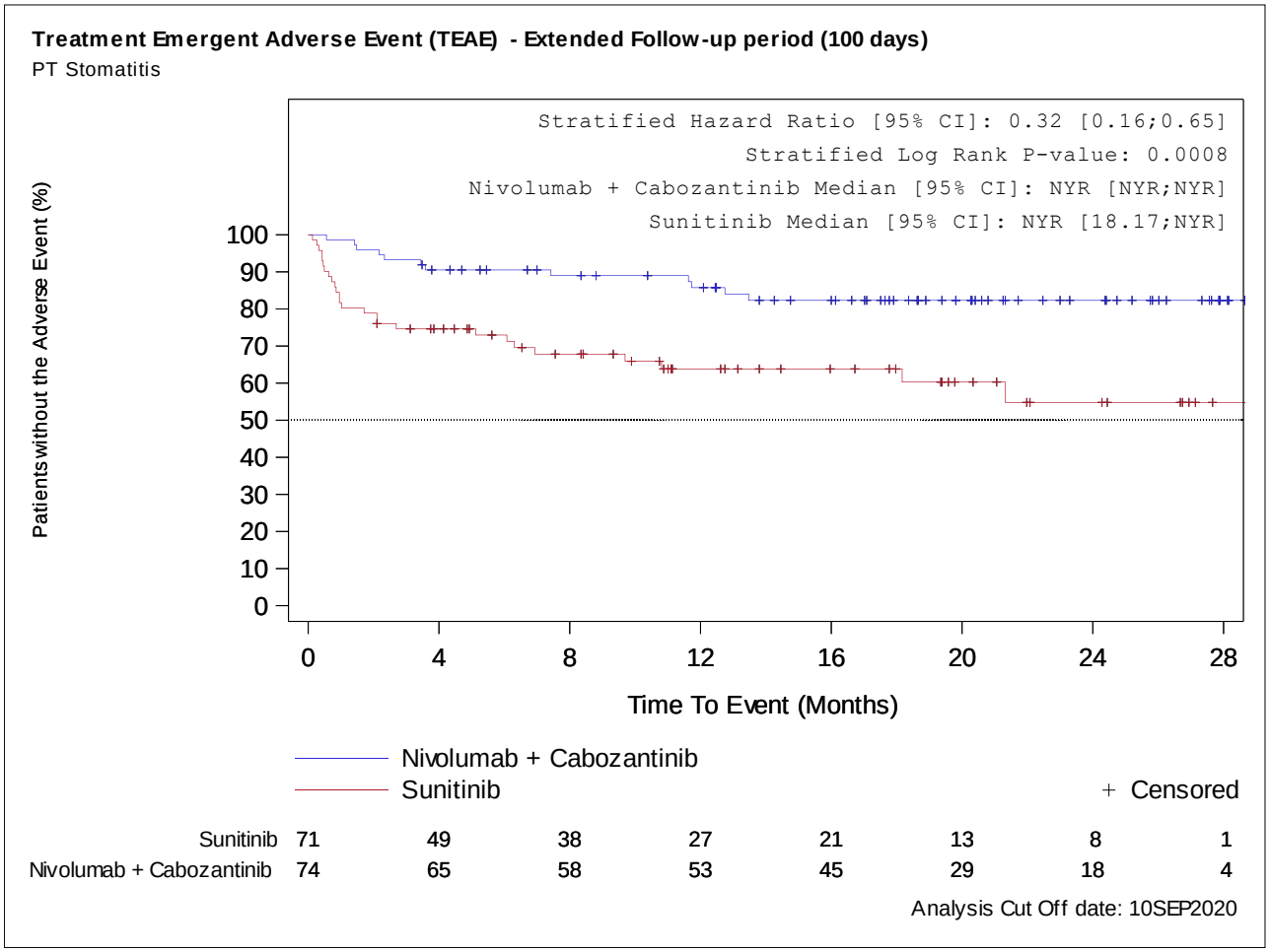
FIGURE 4.4.2.35: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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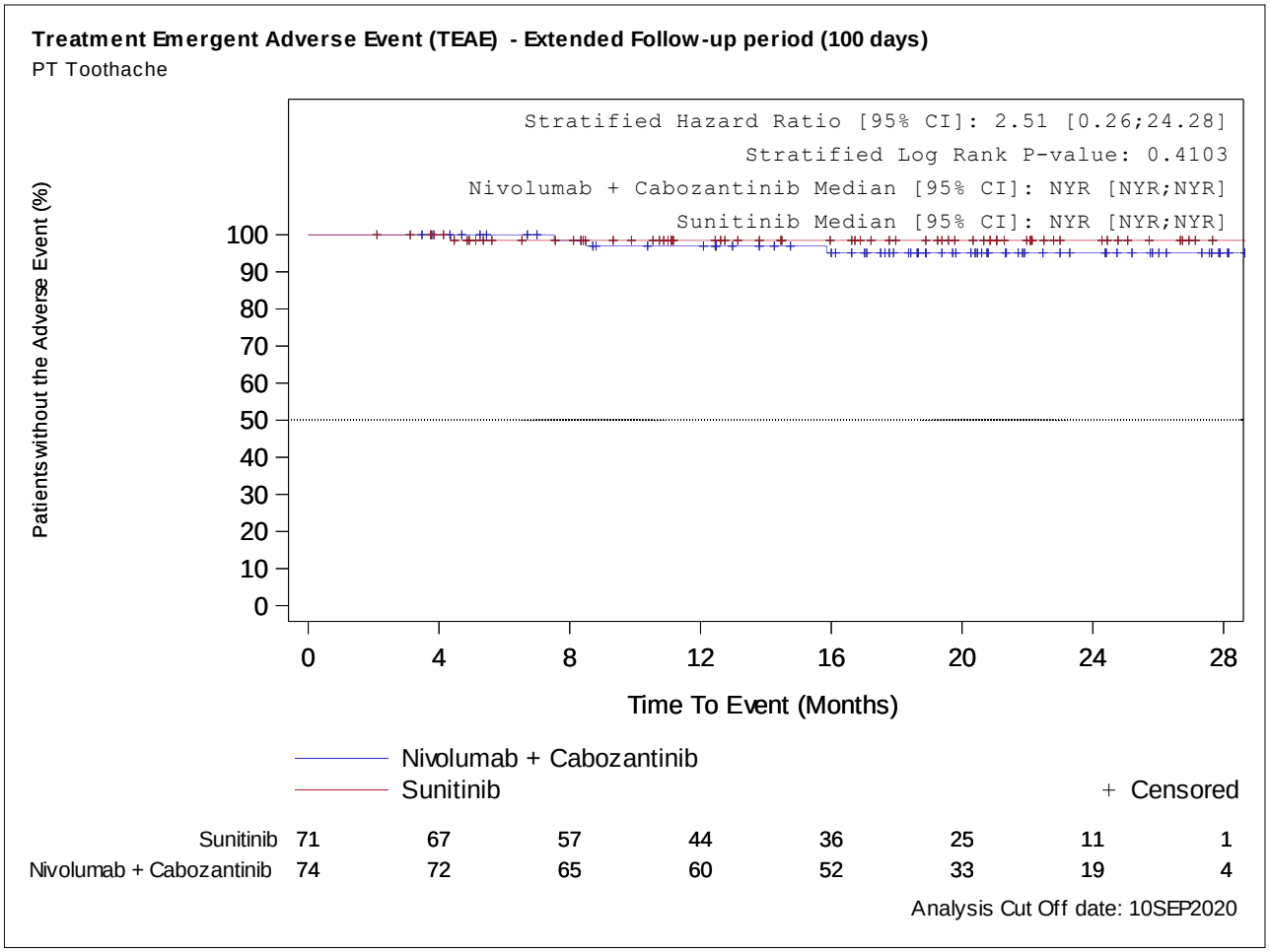
FIGURE 4.4.2.36: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Toothache - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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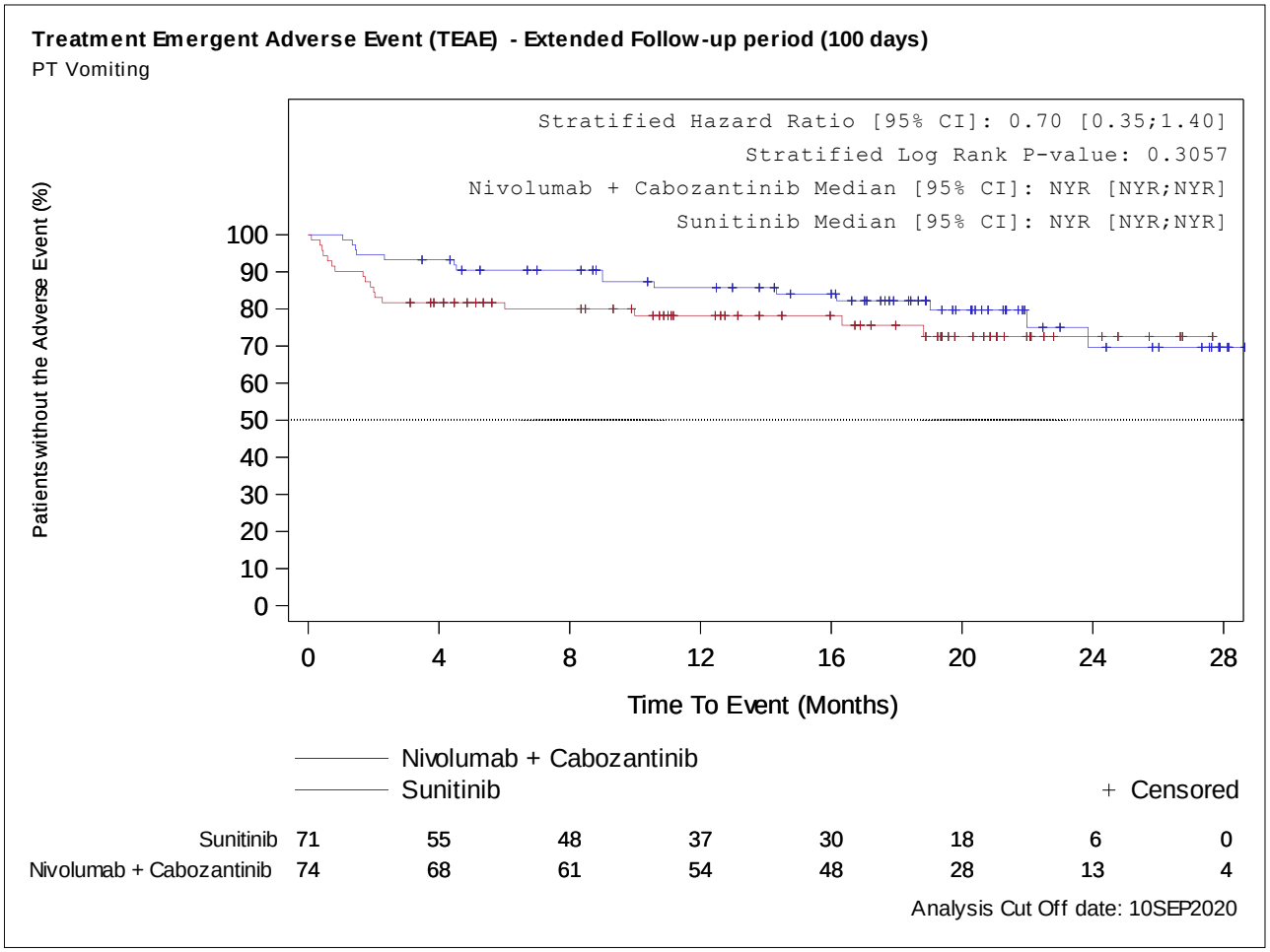
FIGURE 4.4.2.37: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Vomiting - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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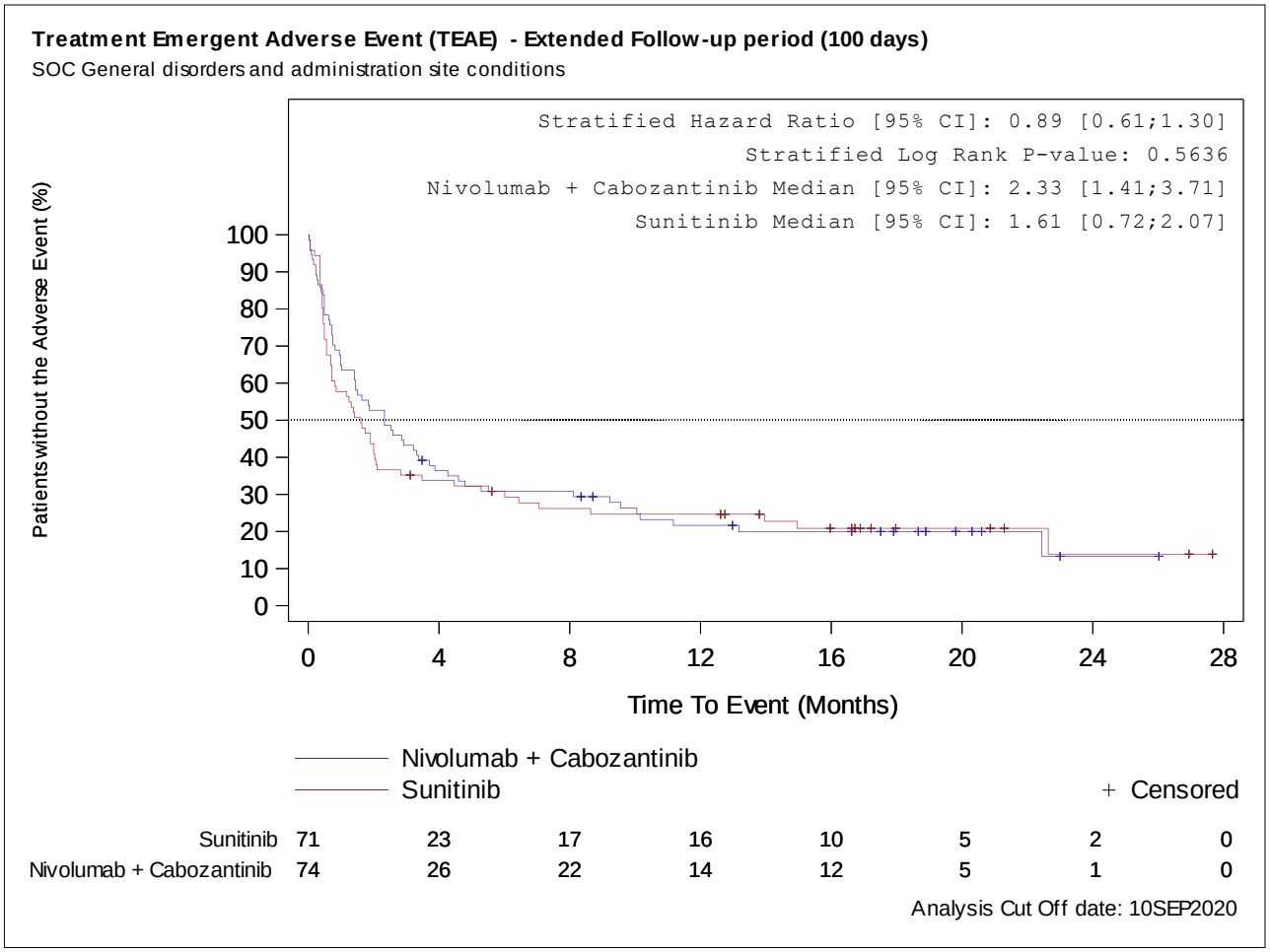
FIGURE 4.4.2.38: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC General disorders and administration site conditions - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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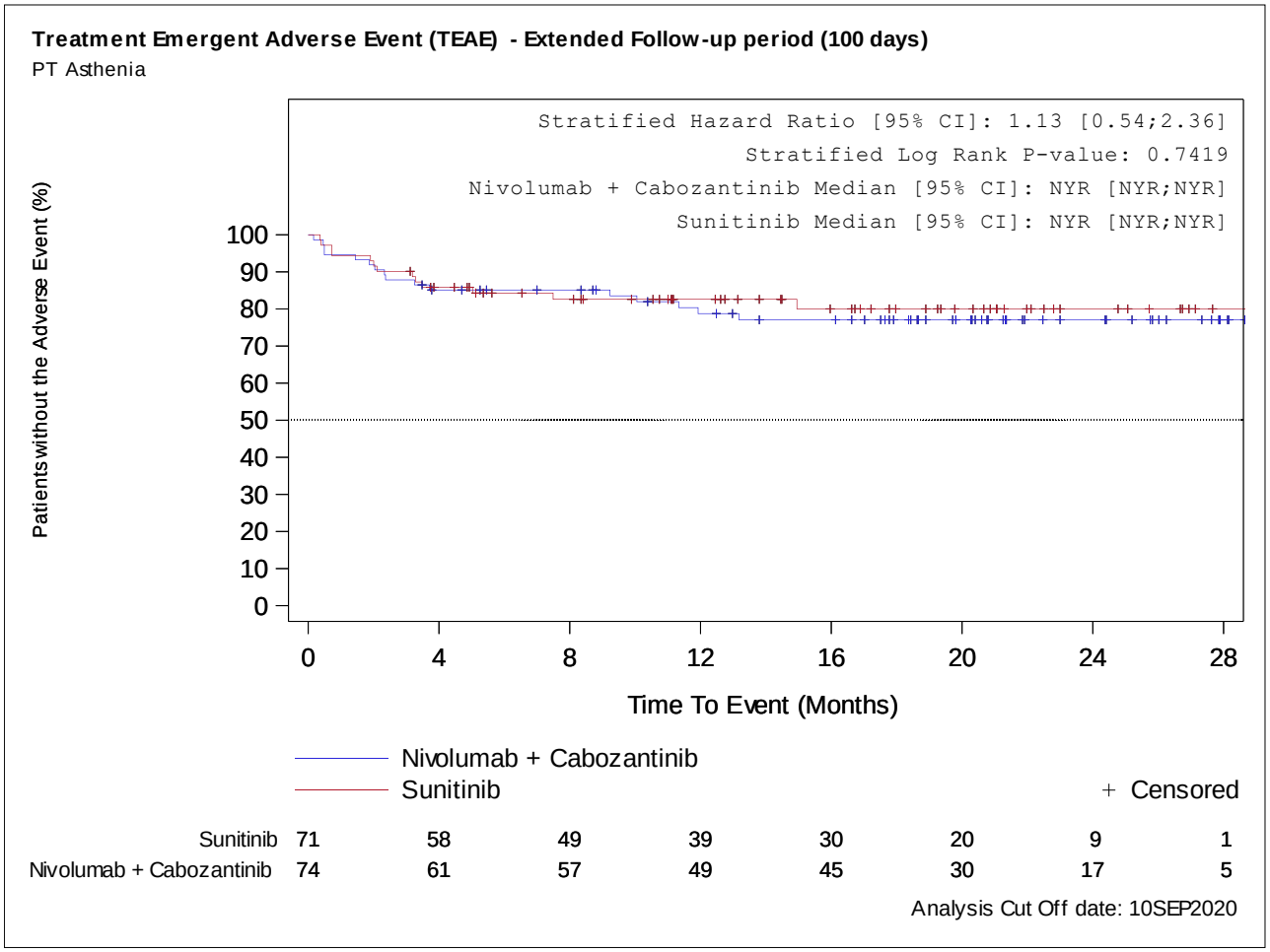
FIGURE 4.4.2.39: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Asthenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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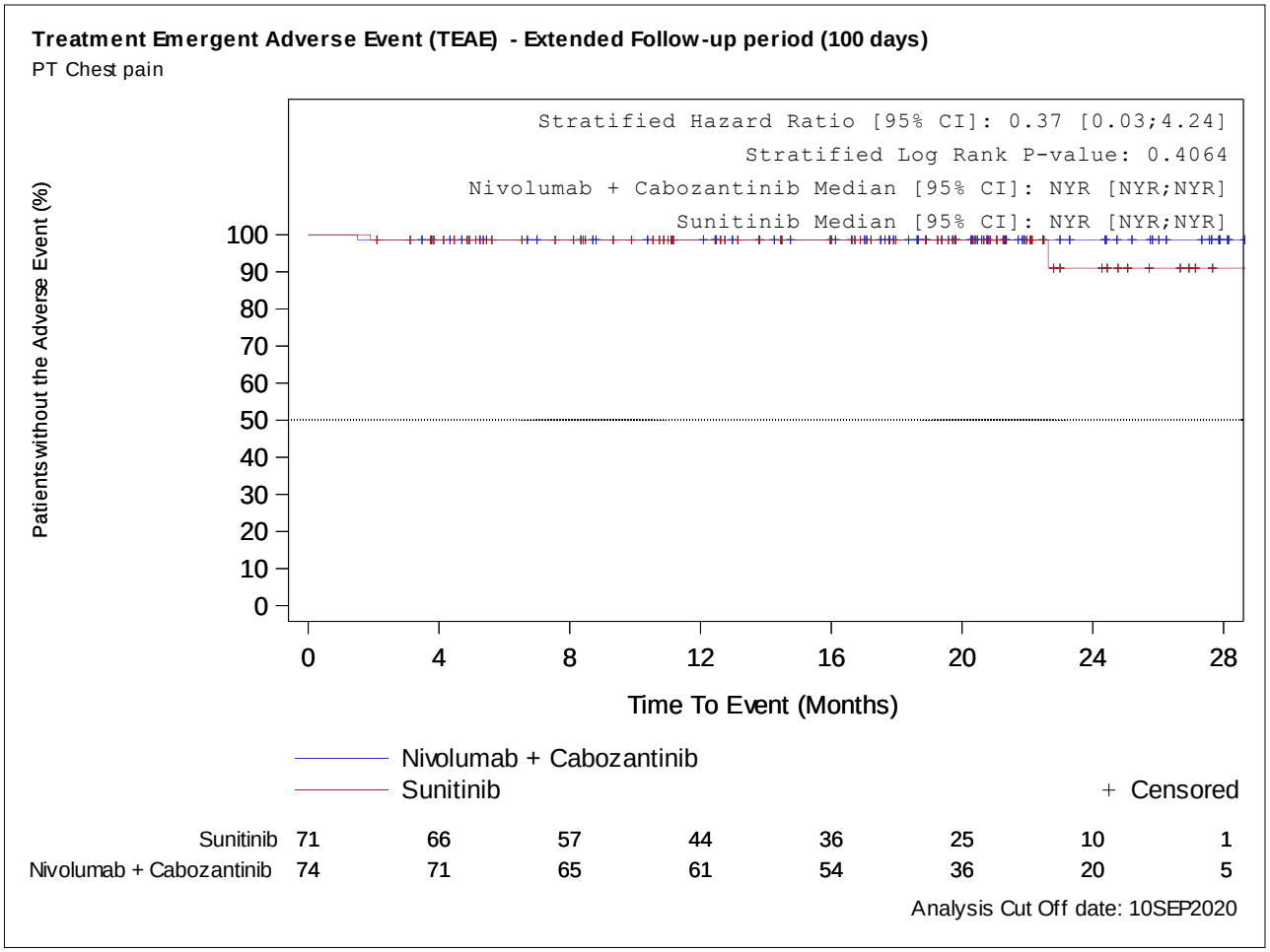
FIGURE 4.4.2.40: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Chest pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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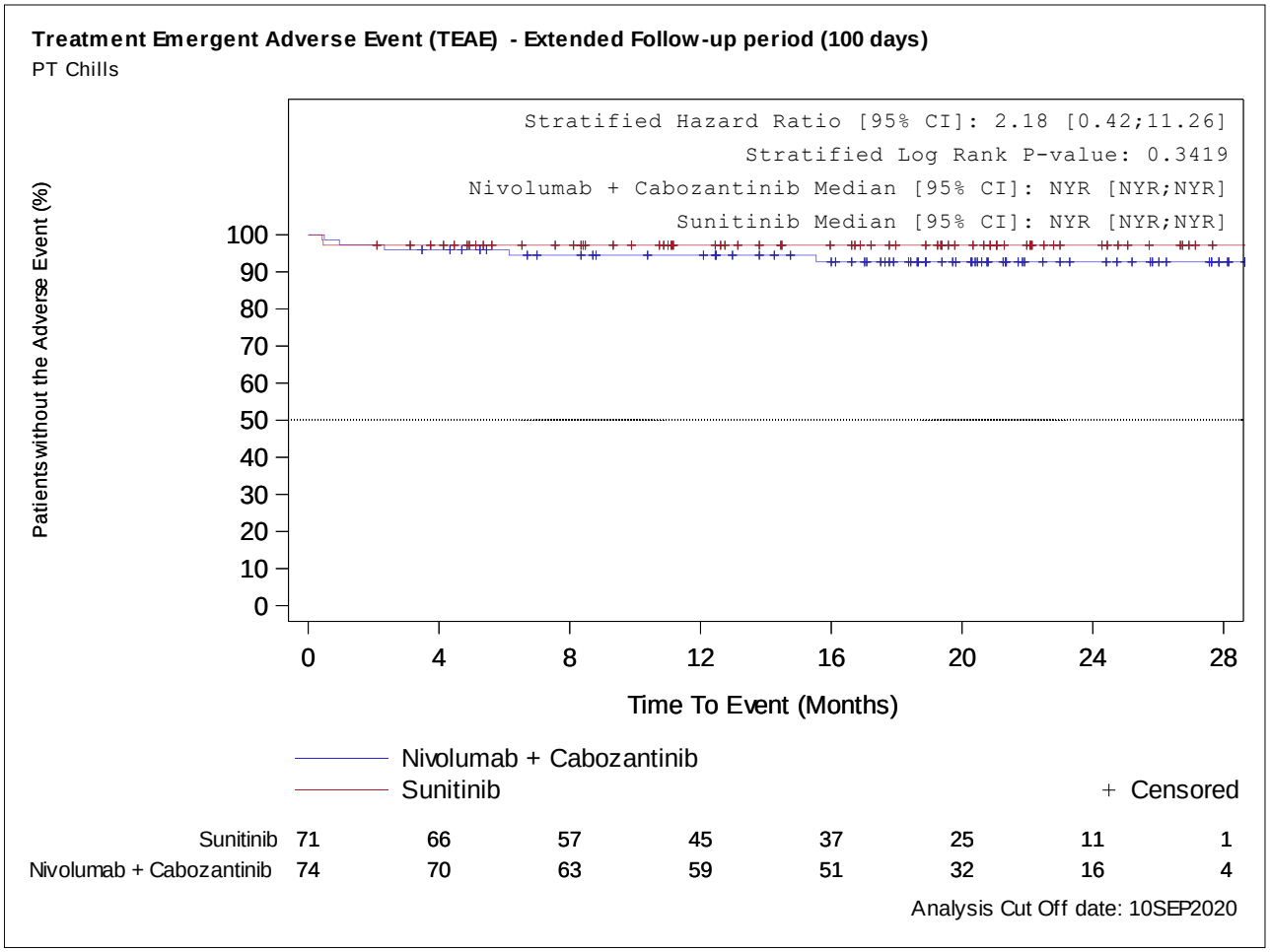
FIGURE 4.4.2.41: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Chills - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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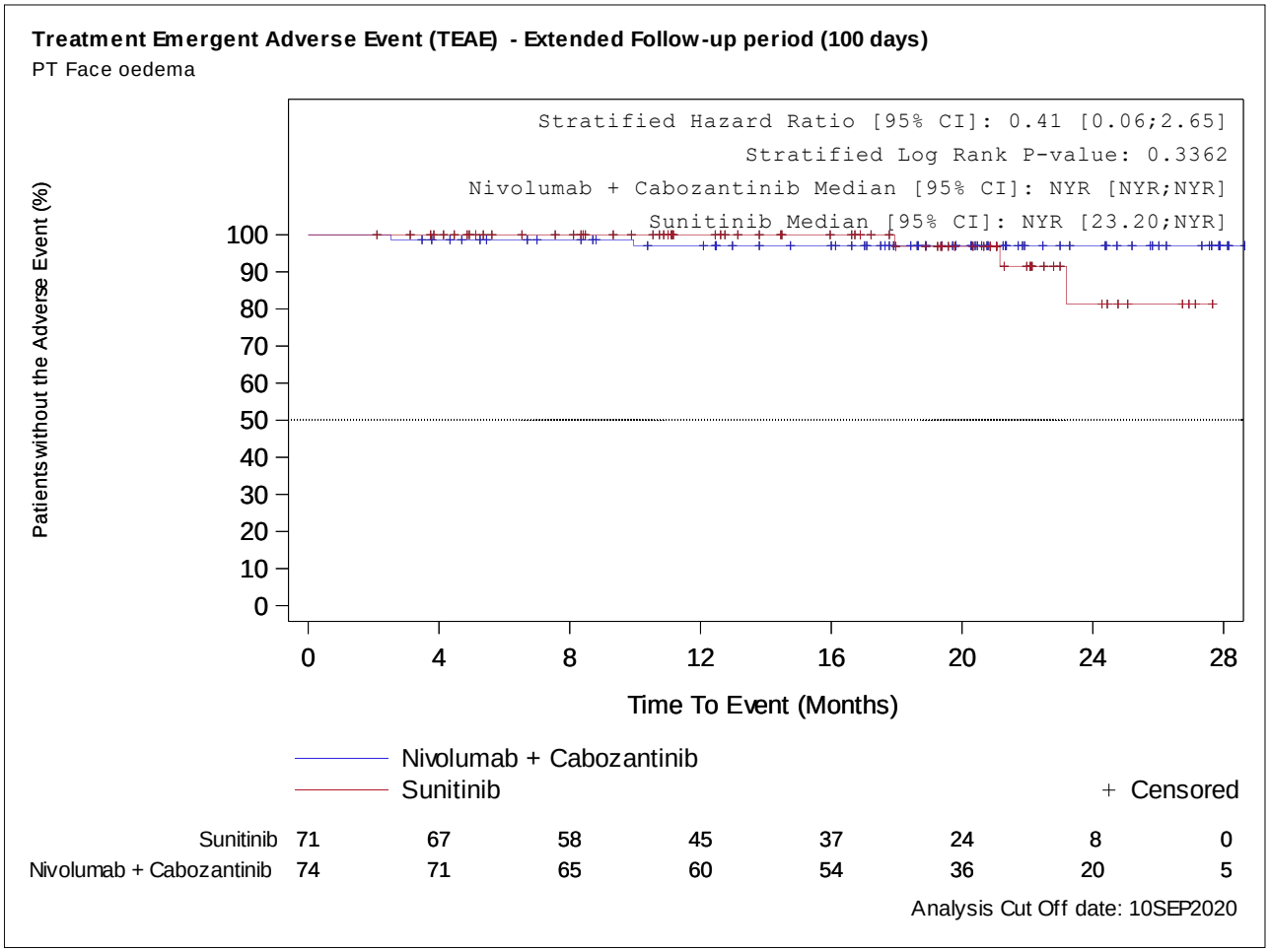
FIGURE 4.4.2.42: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Face oedema - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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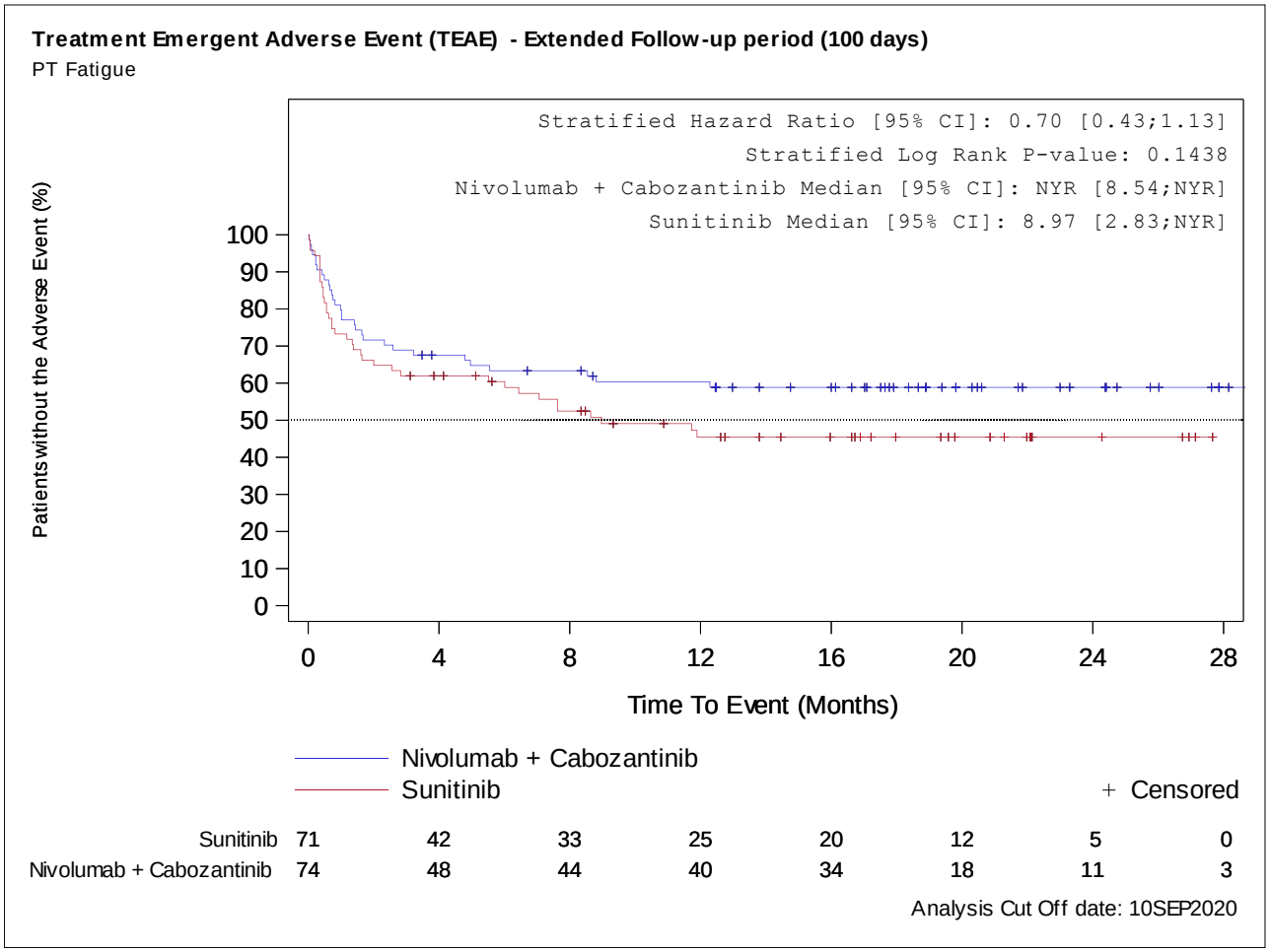
FIGURE 4.4.2.43: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Fatigue - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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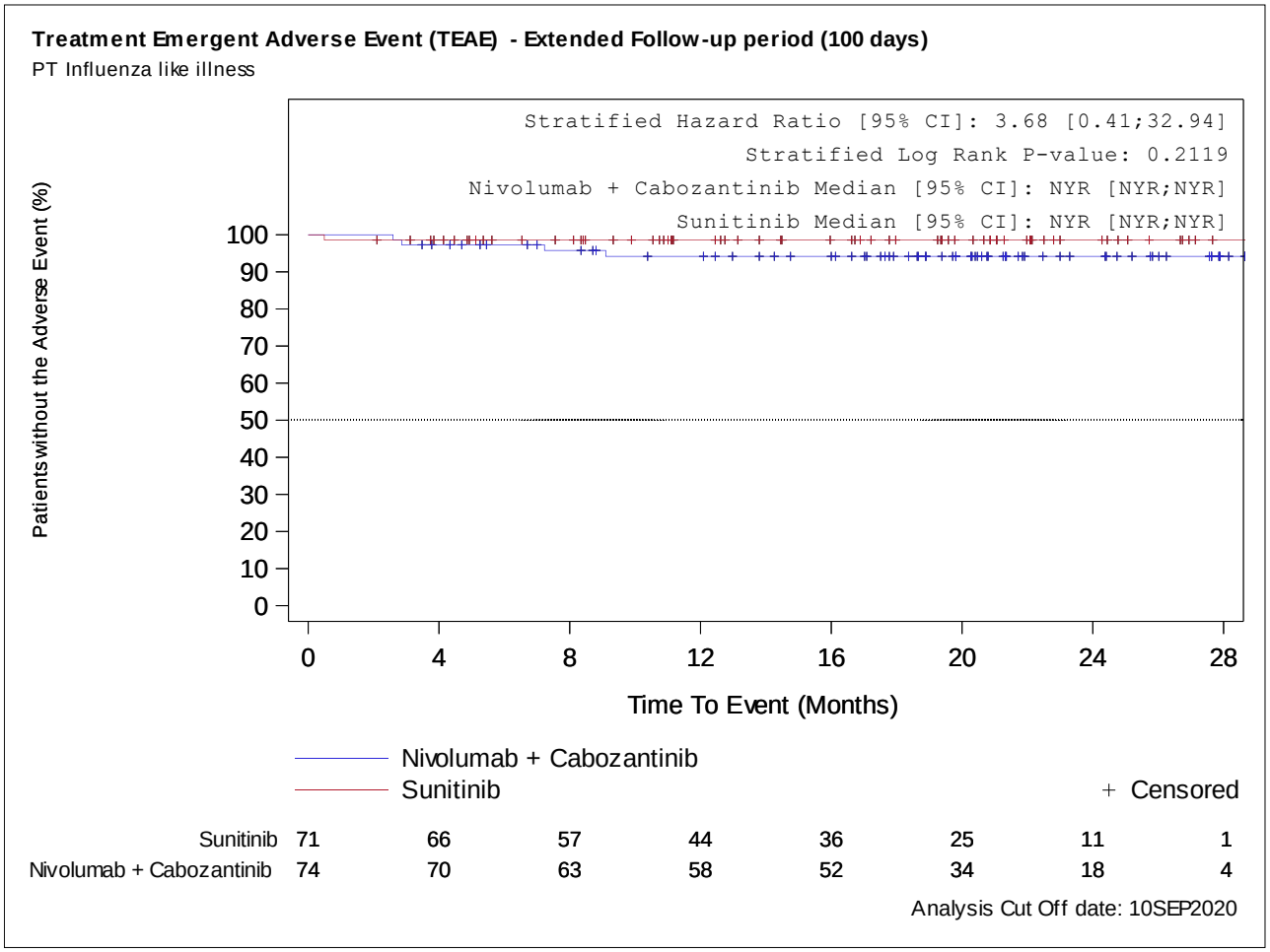
FIGURE 4.4.2.44: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Influenza like illness - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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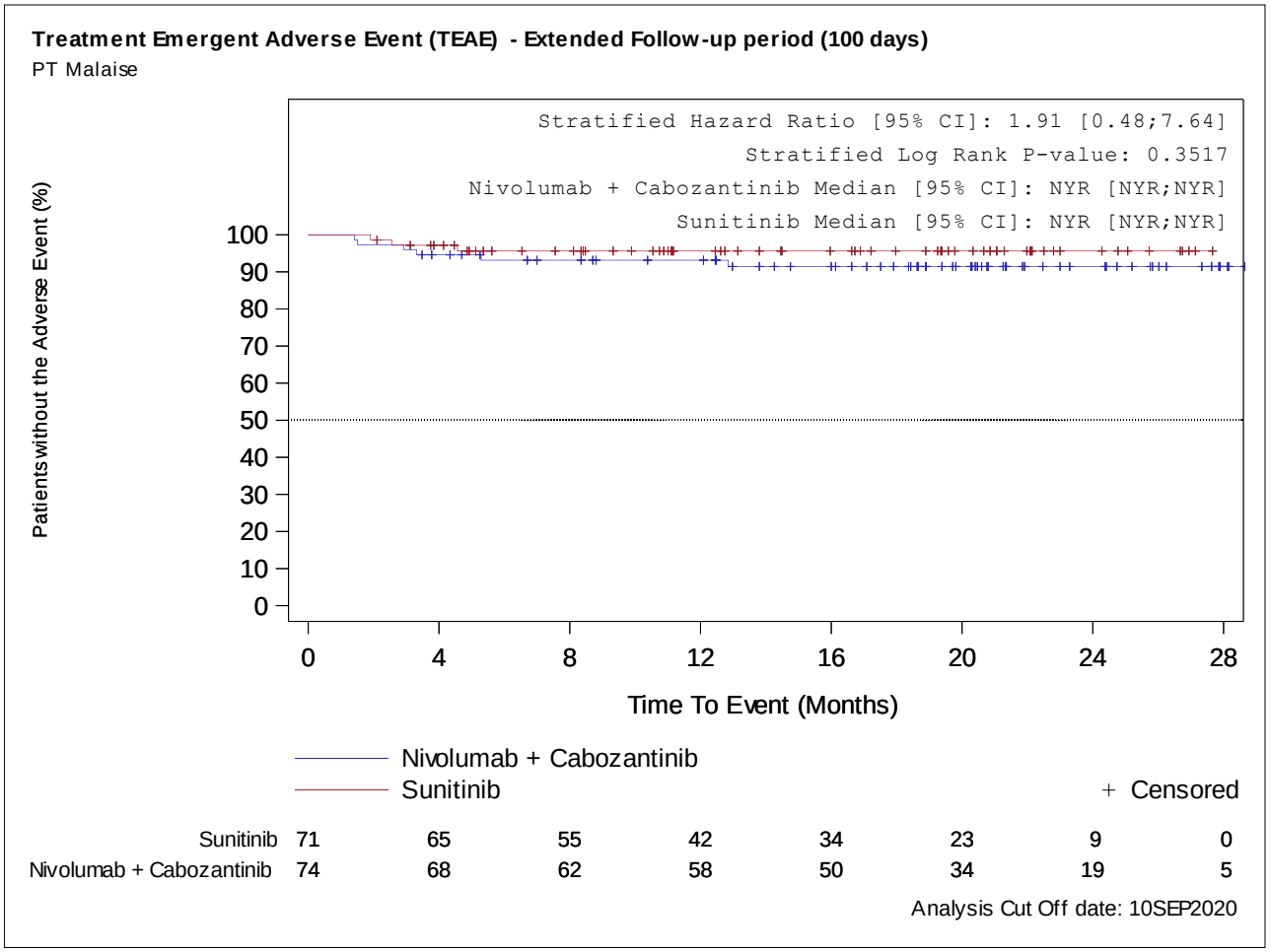
FIGURE 4.4.2.45: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Malaise - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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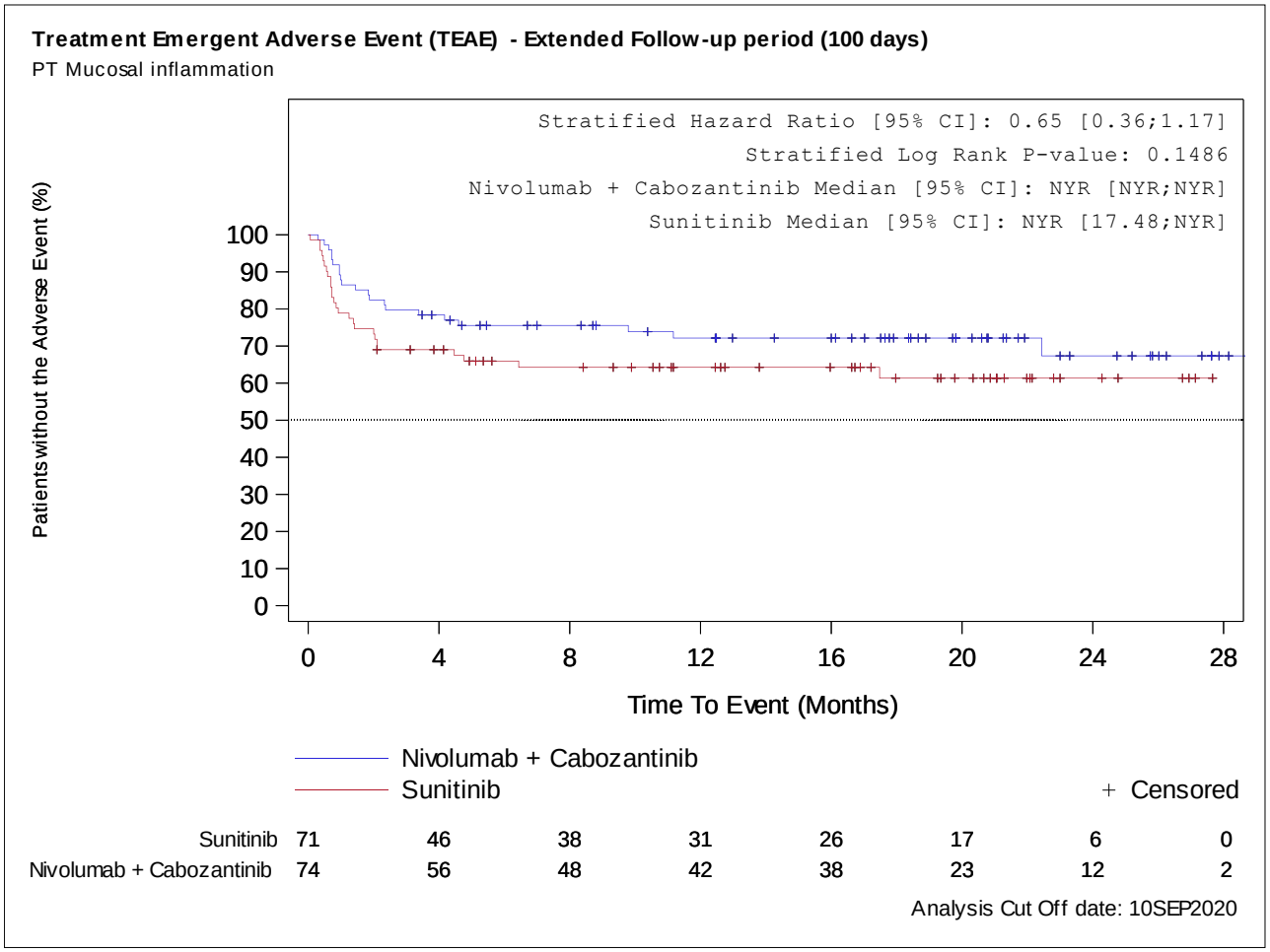
FIGURE 4.4.2.46: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Mucosal inflammation - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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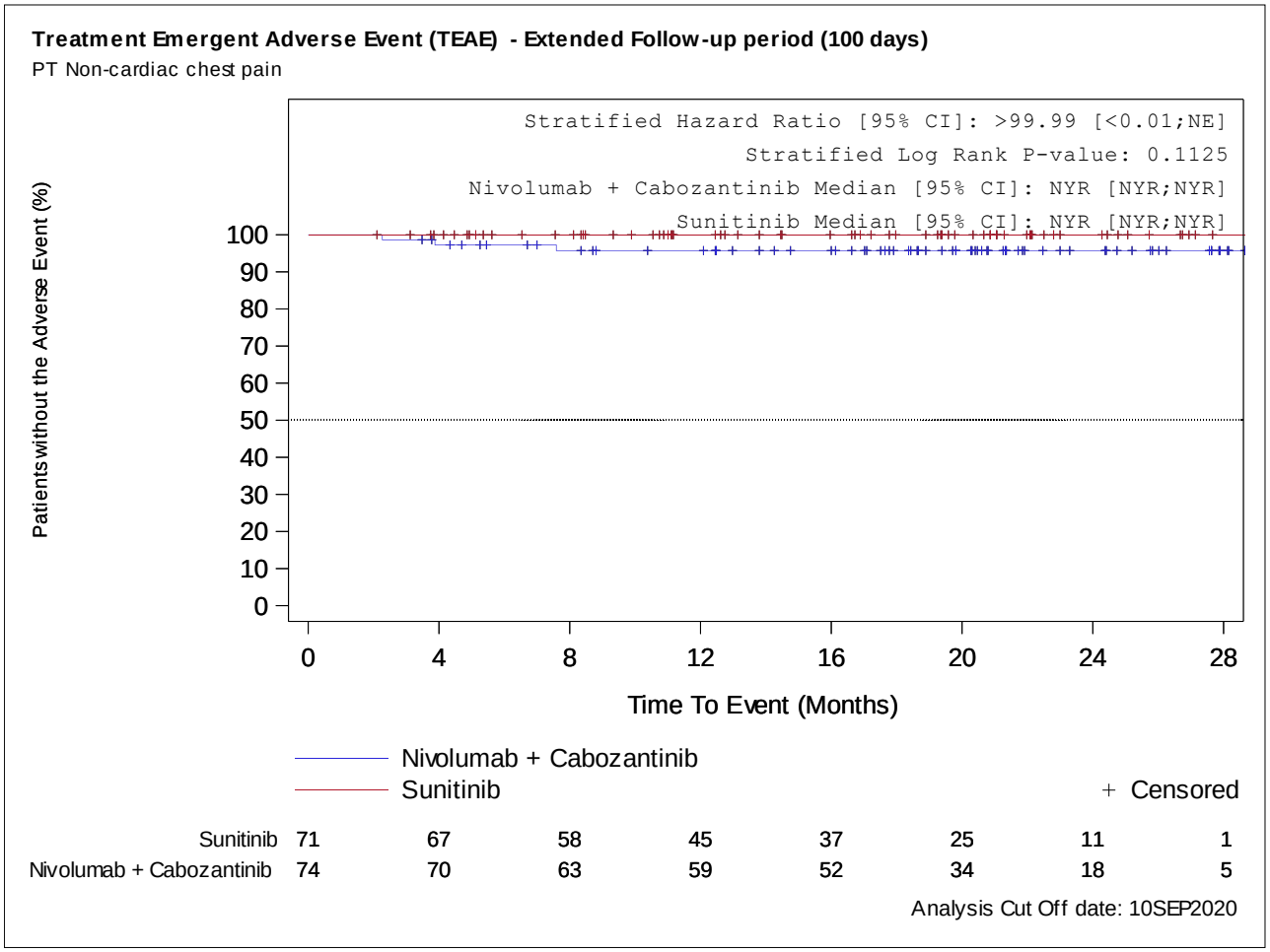
FIGURE 4.4.2.47: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Non-cardiac chest pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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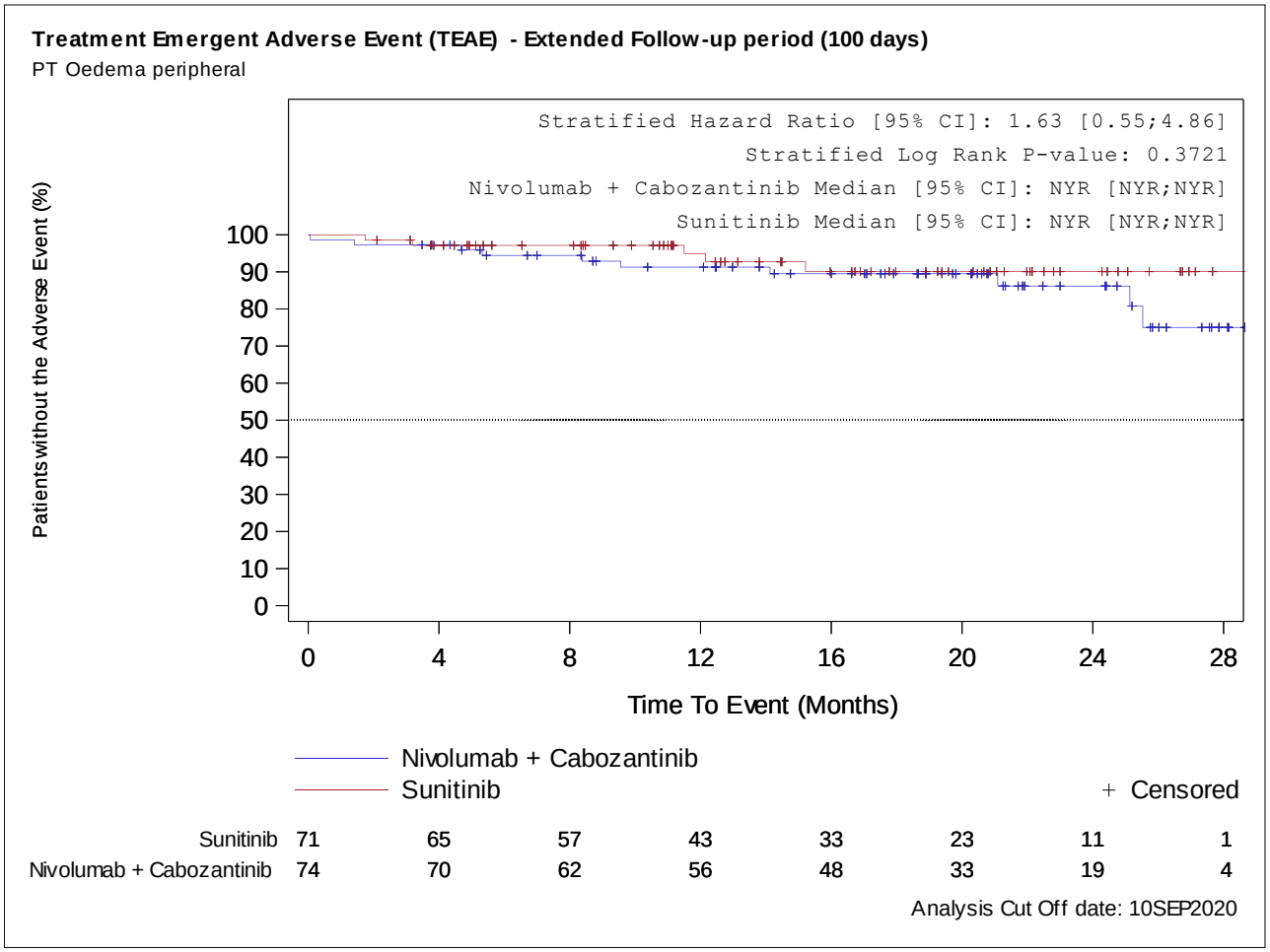
FIGURE 4.4.2.48: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oedema peripheral - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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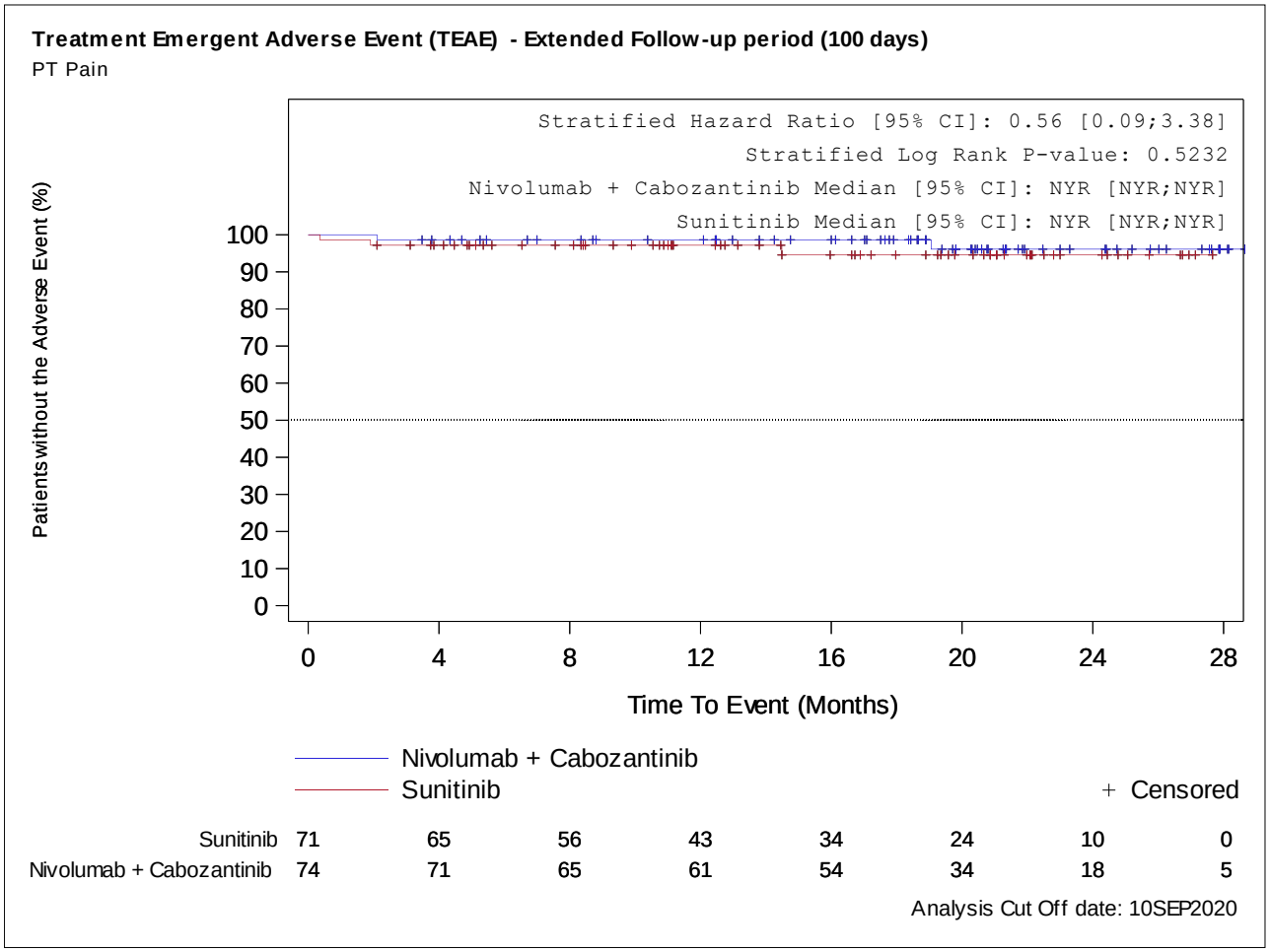
FIGURE 4.4.2.49: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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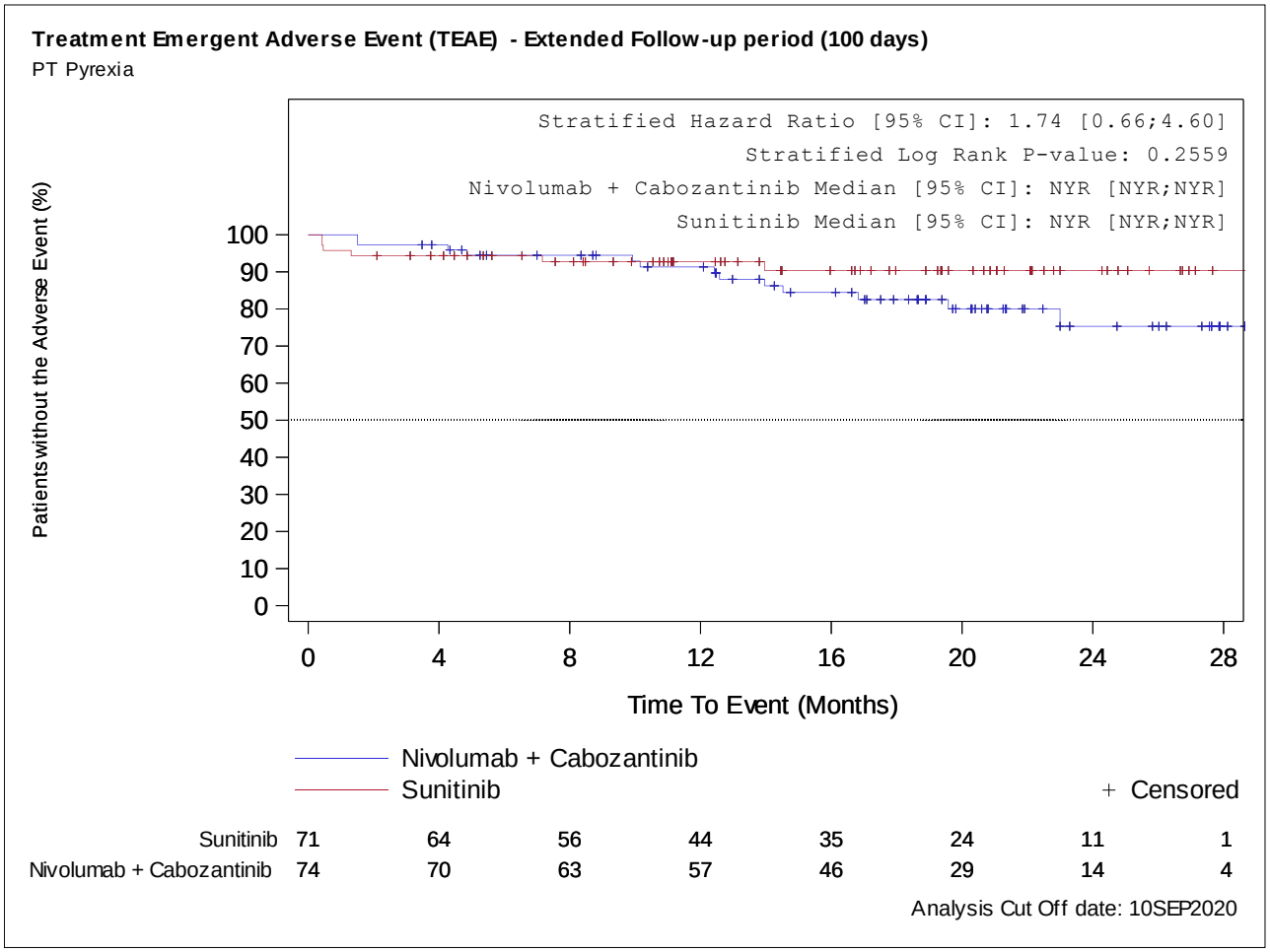
FIGURE 4.4.2.50: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pyrexia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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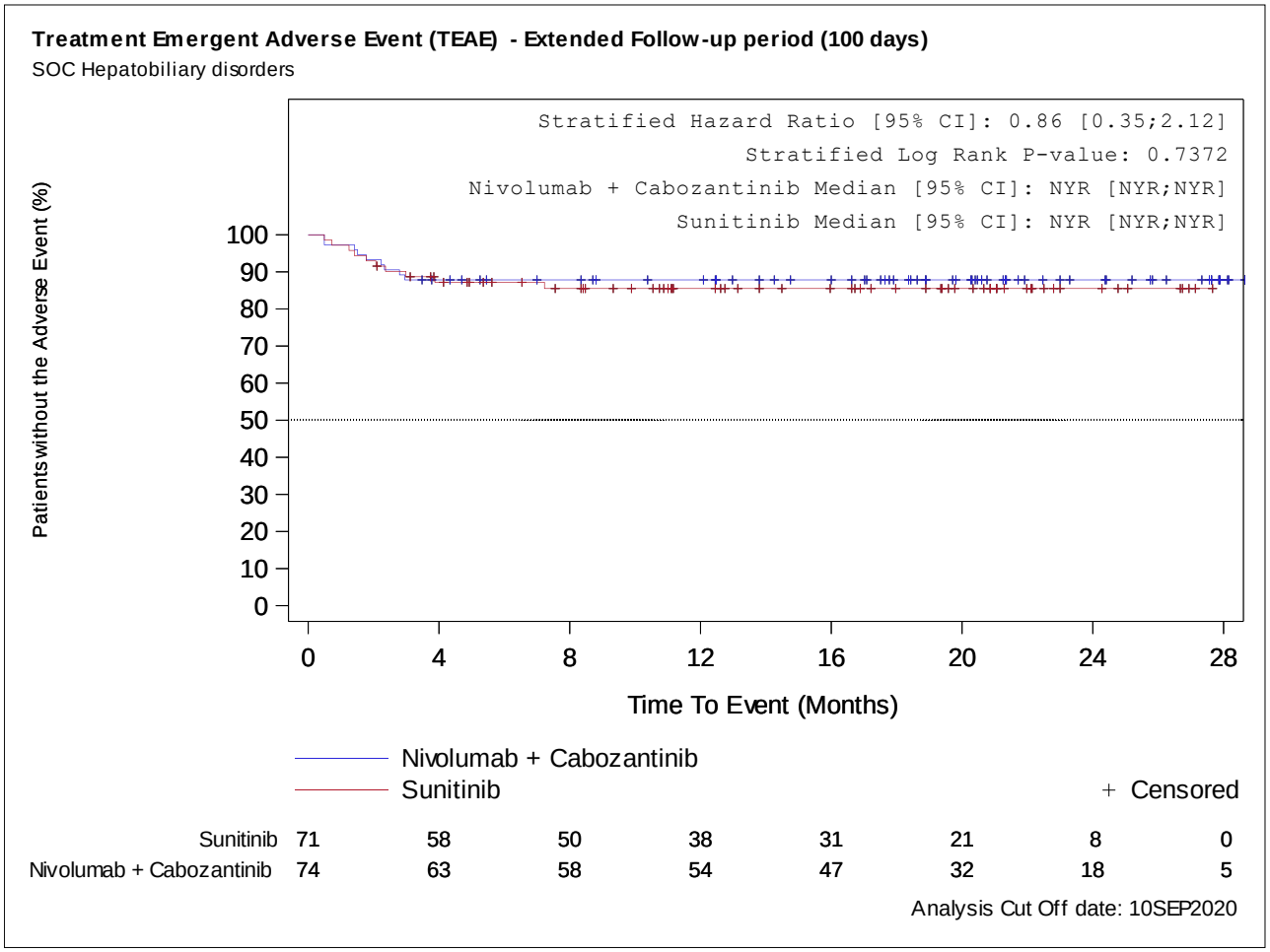
FIGURE 4.4.2.51: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Hepatobiliary disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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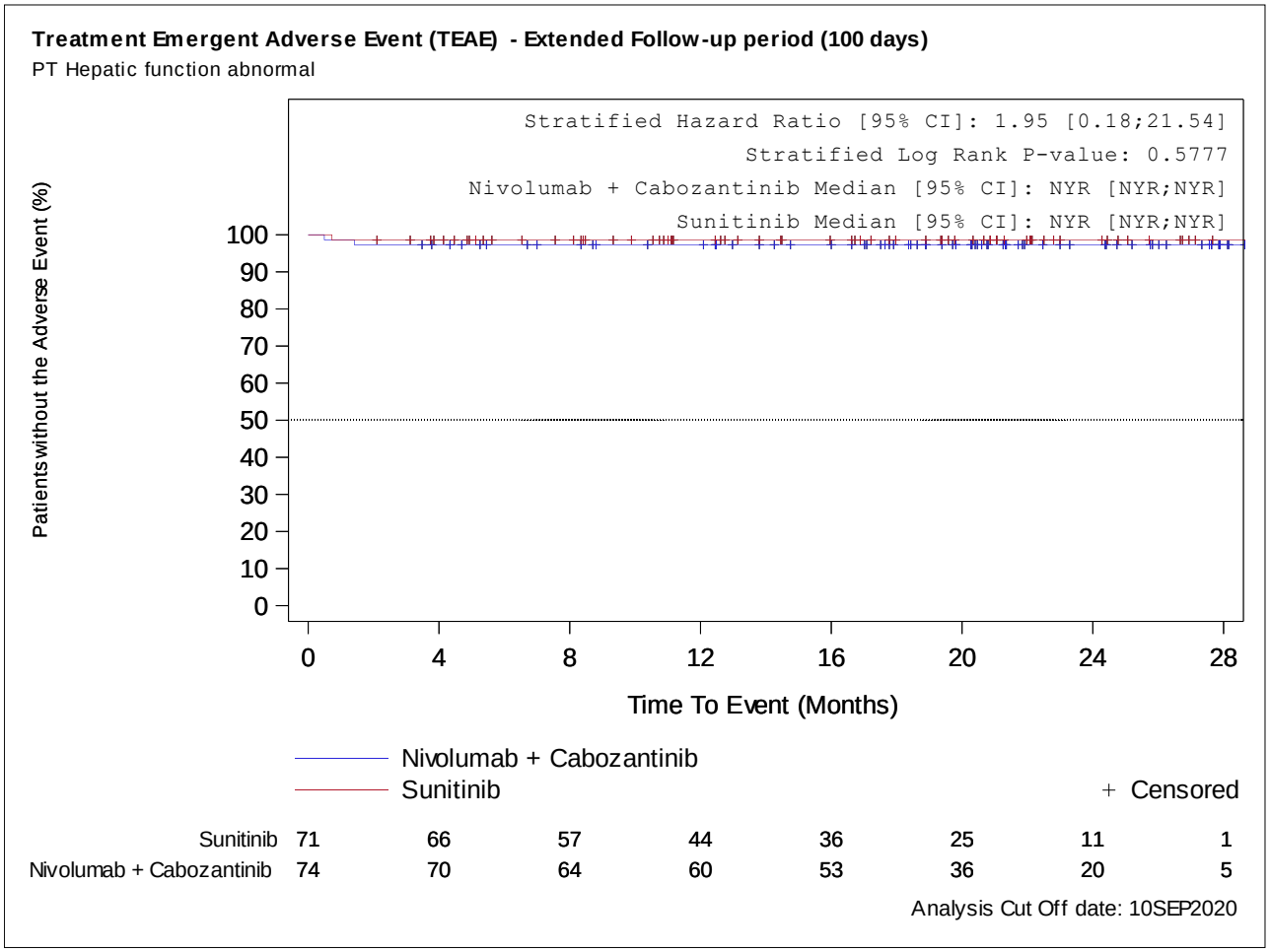
FIGURE 4.4.2.52: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hepatic function abnormal - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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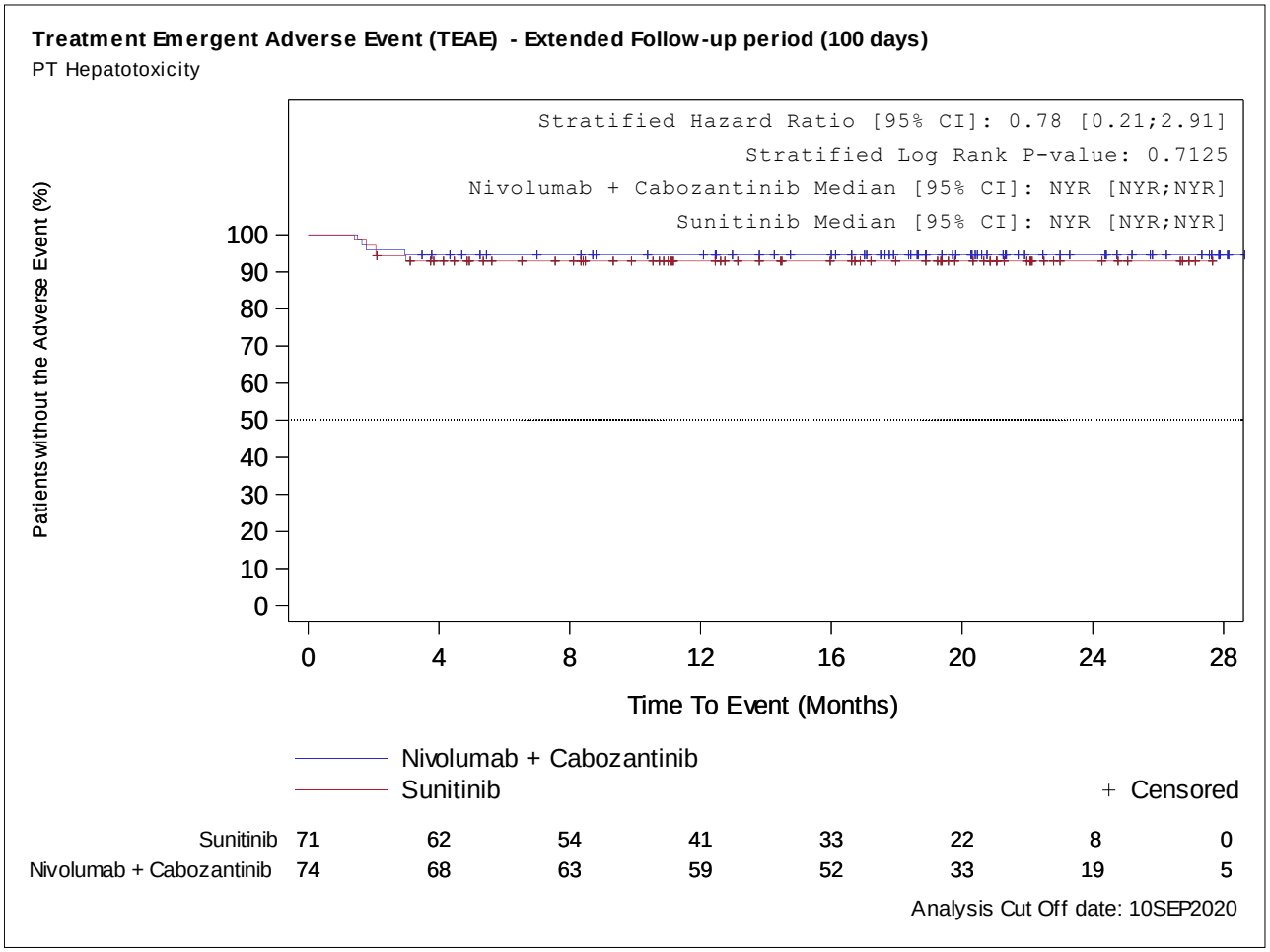
FIGURE 4.4.2.53: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hepatotoxicity - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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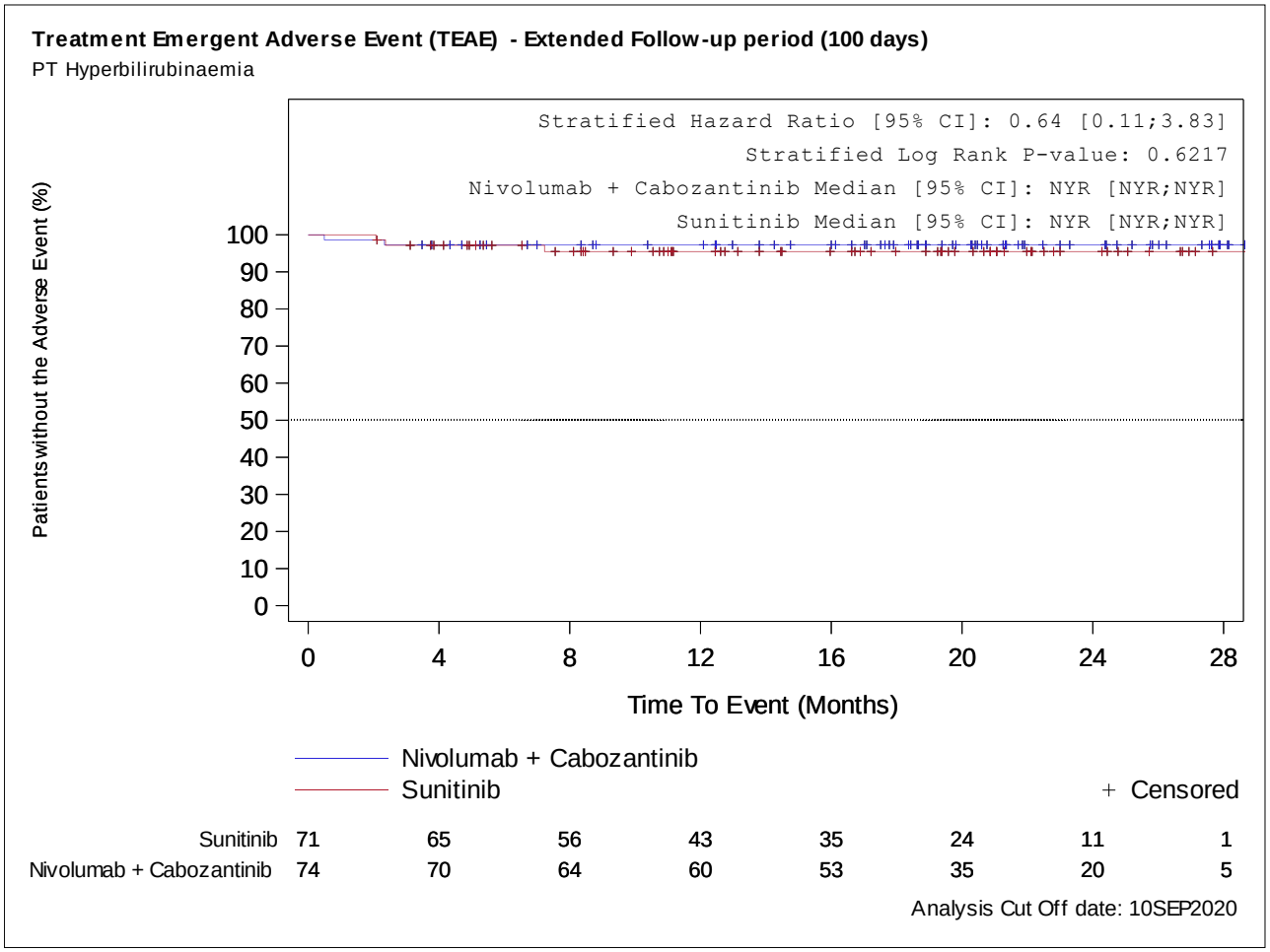
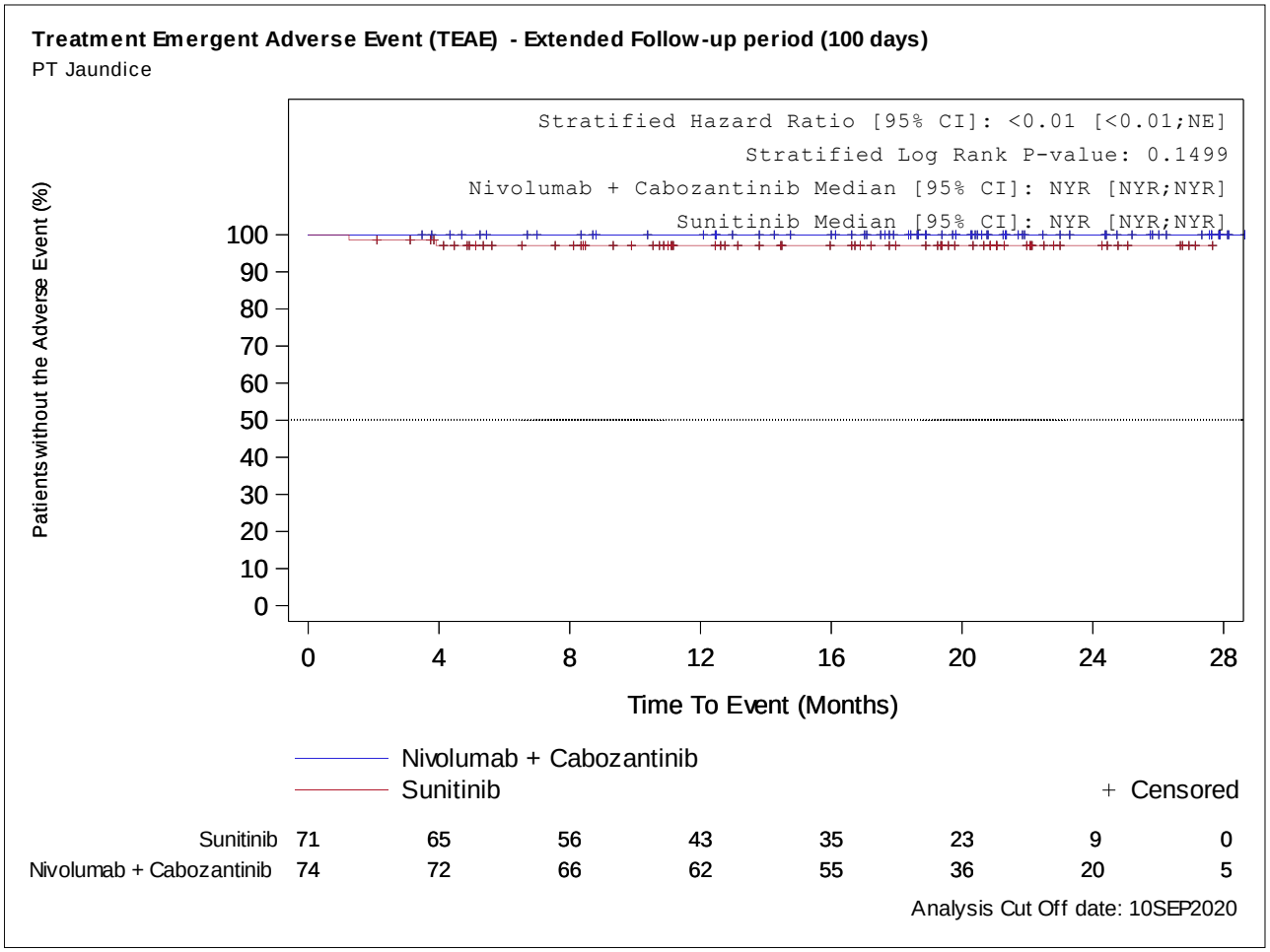
FIGURE 4.4.2.54: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hyperbilirubinaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:23:19

FIGURE 4.4.2.55: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Jaundice - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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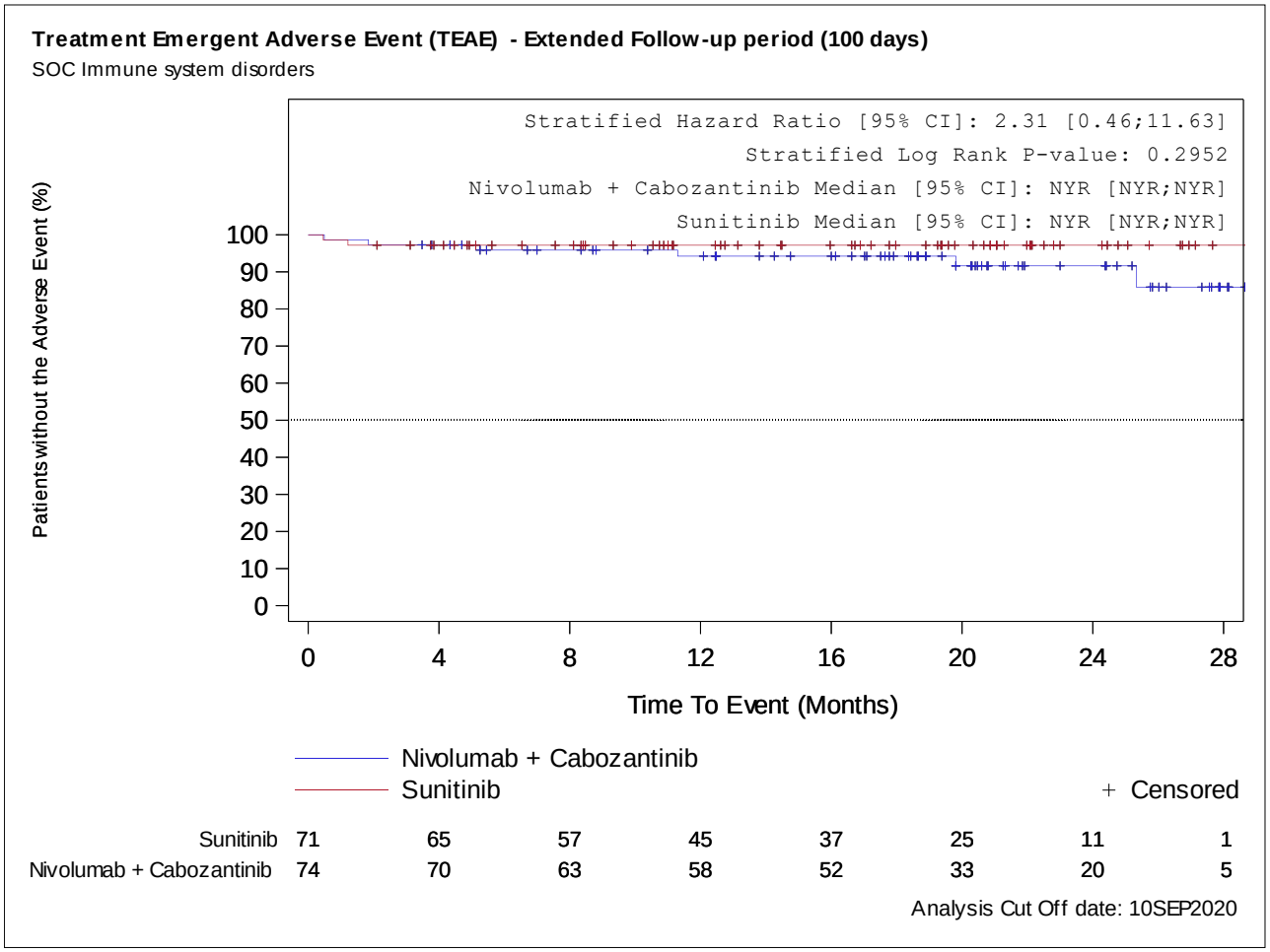
FIGURE 4.4.2.56: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Immune system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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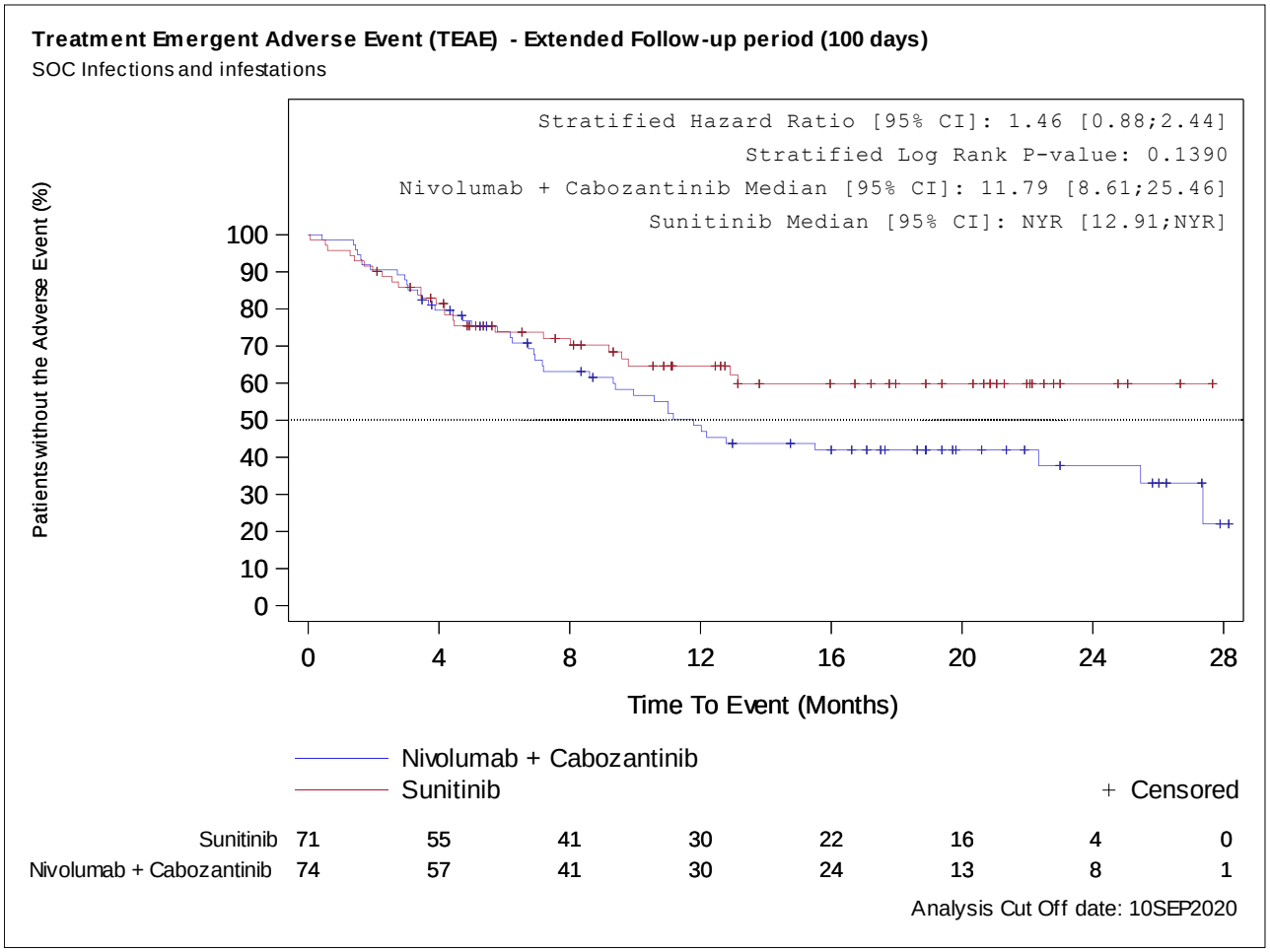
FIGURE 4.4.2.57: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Infections and infestations - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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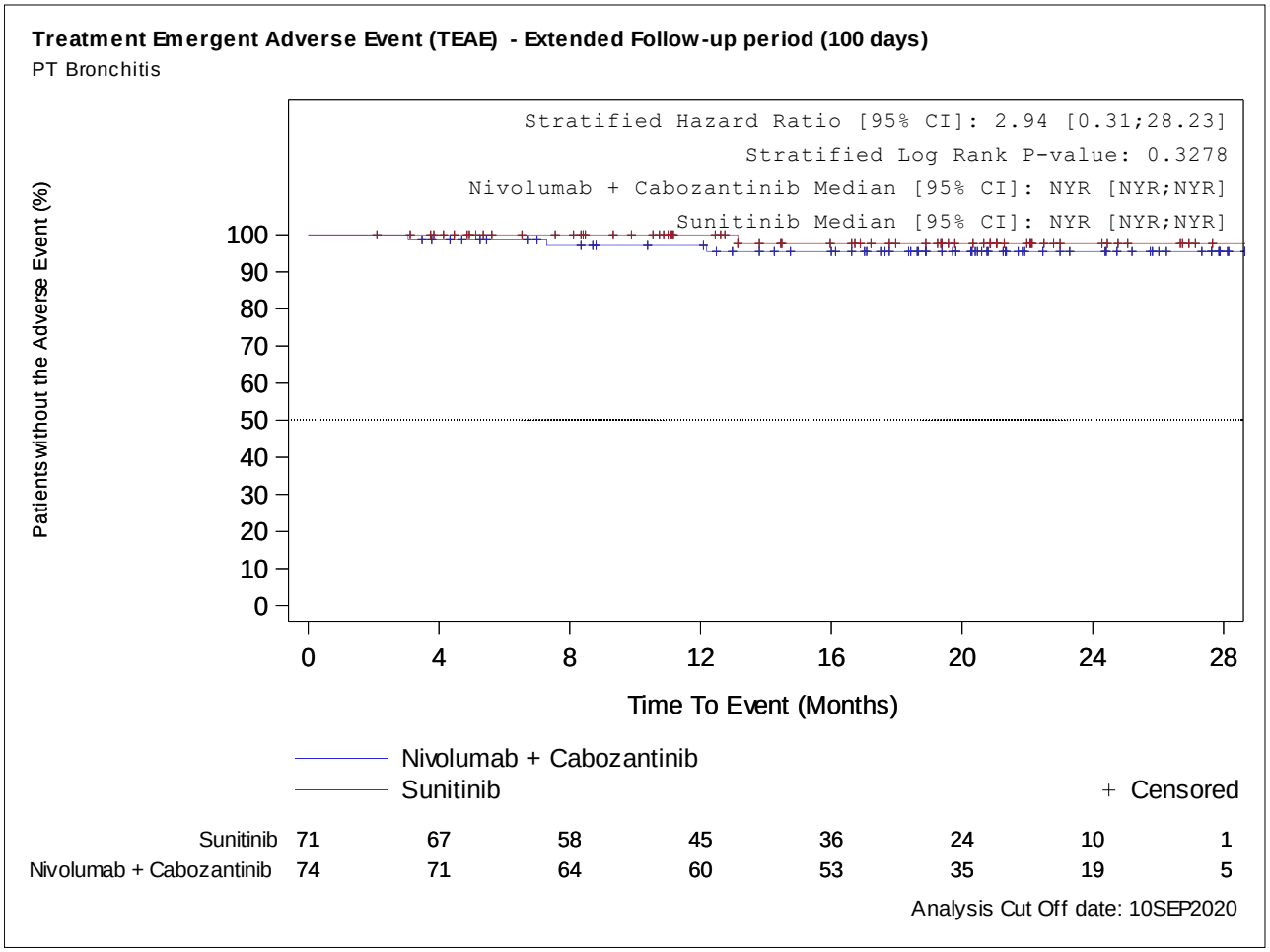
FIGURE 4.4.2.58: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Bronchitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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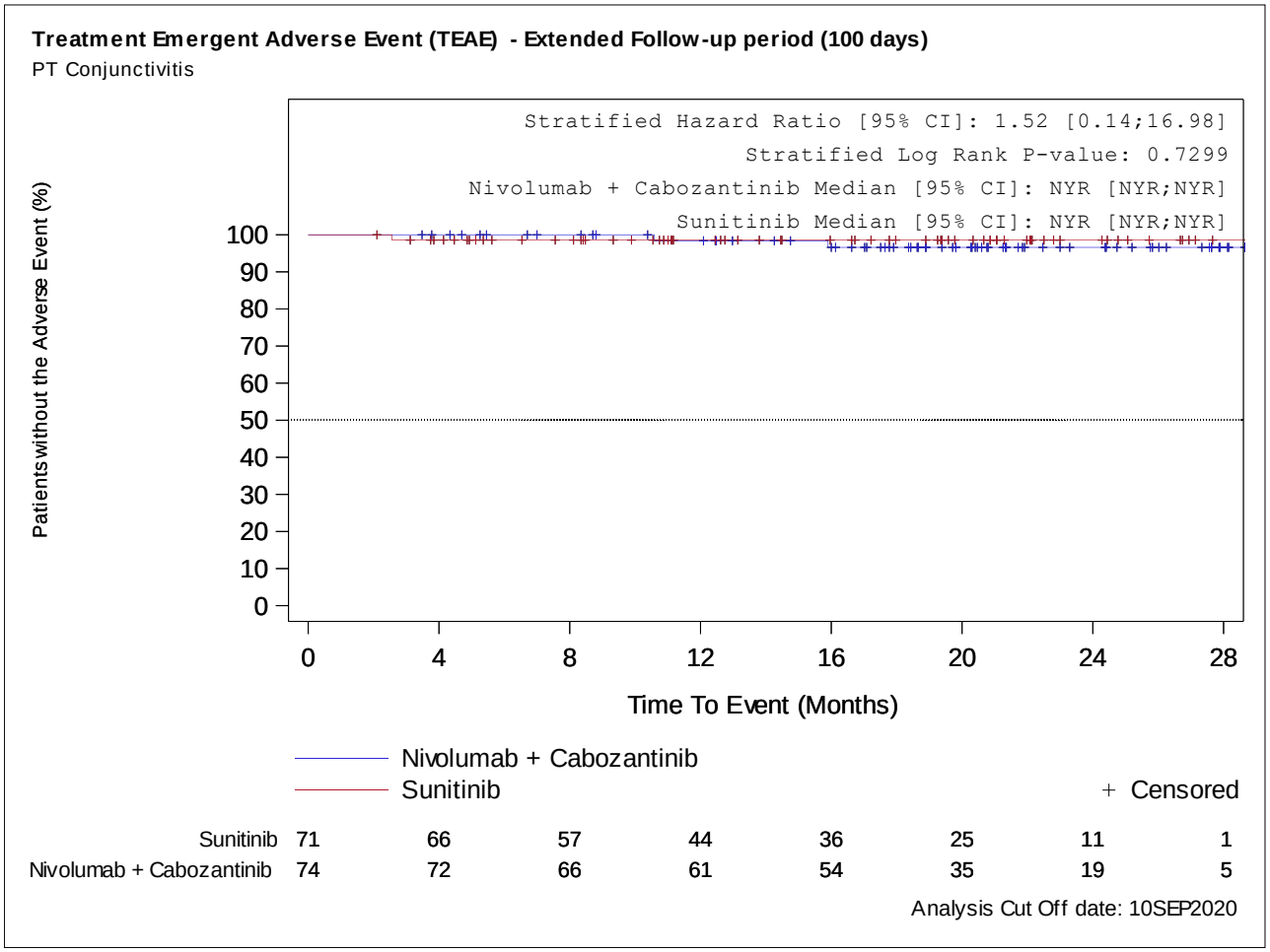
FIGURE 4.4.2.59: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Conjunctivitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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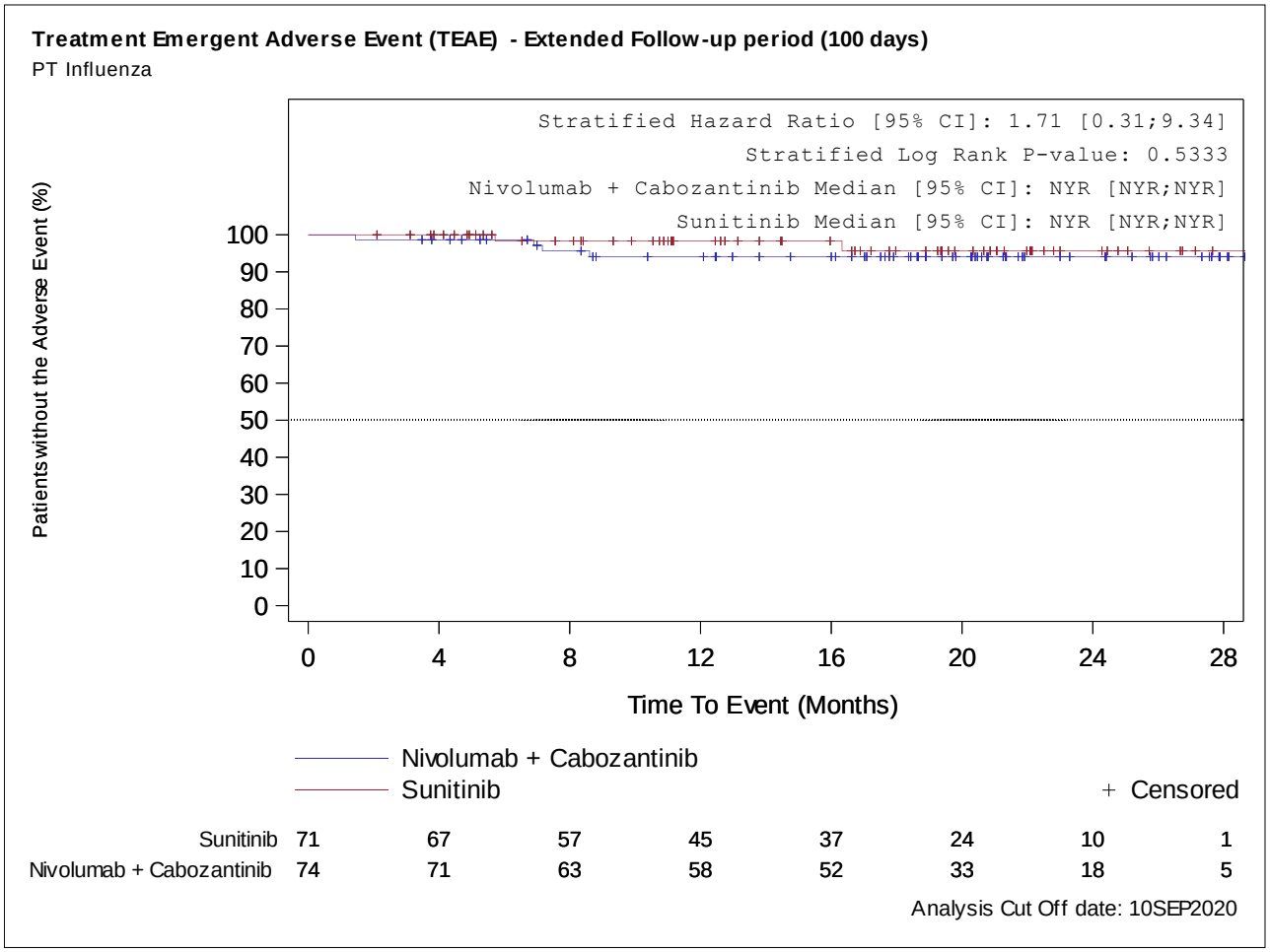
FIGURE 4.4.2.60: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Influenza - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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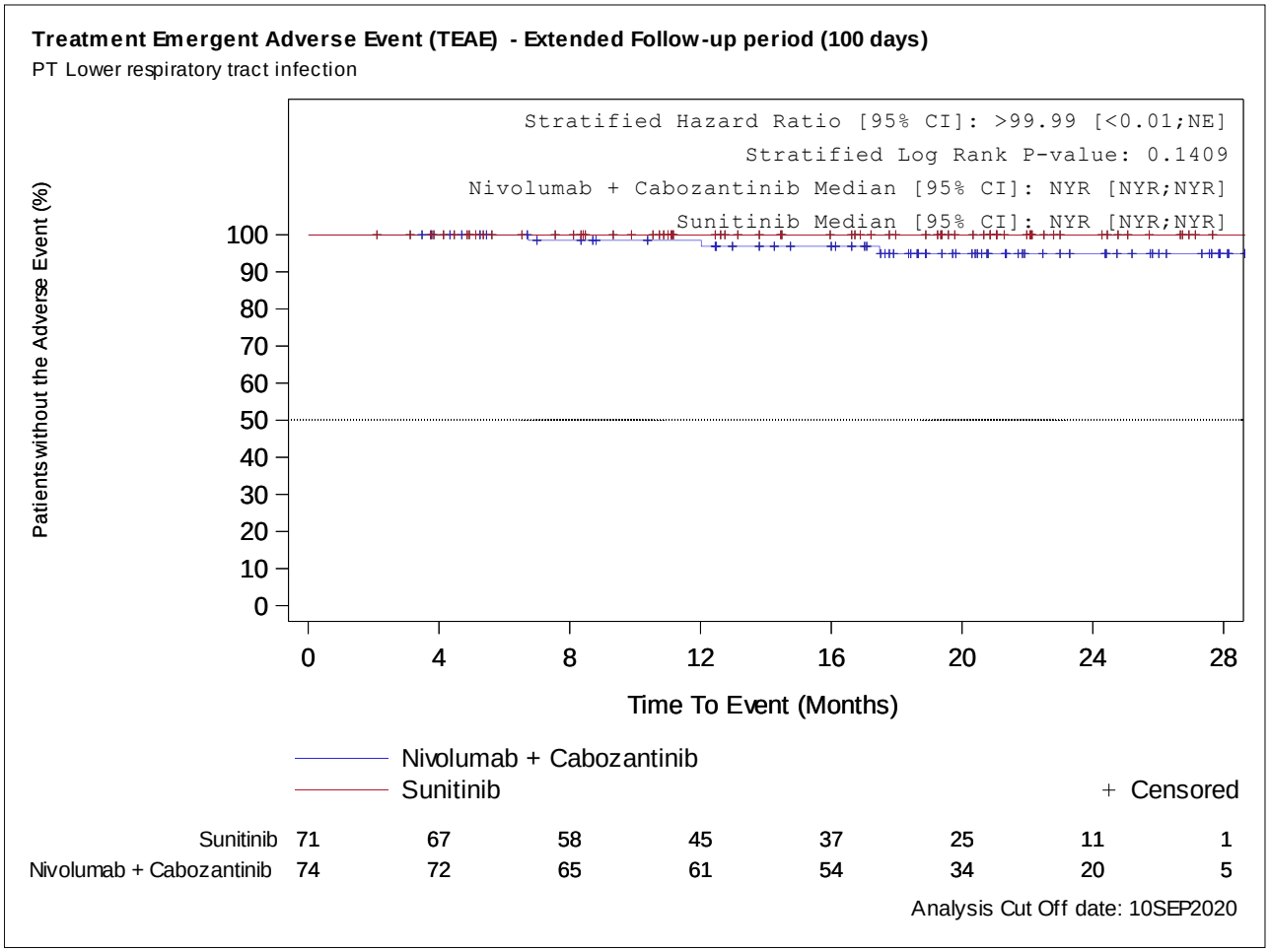
FIGURE 4.4.2.61: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Lower respiratory tract infection - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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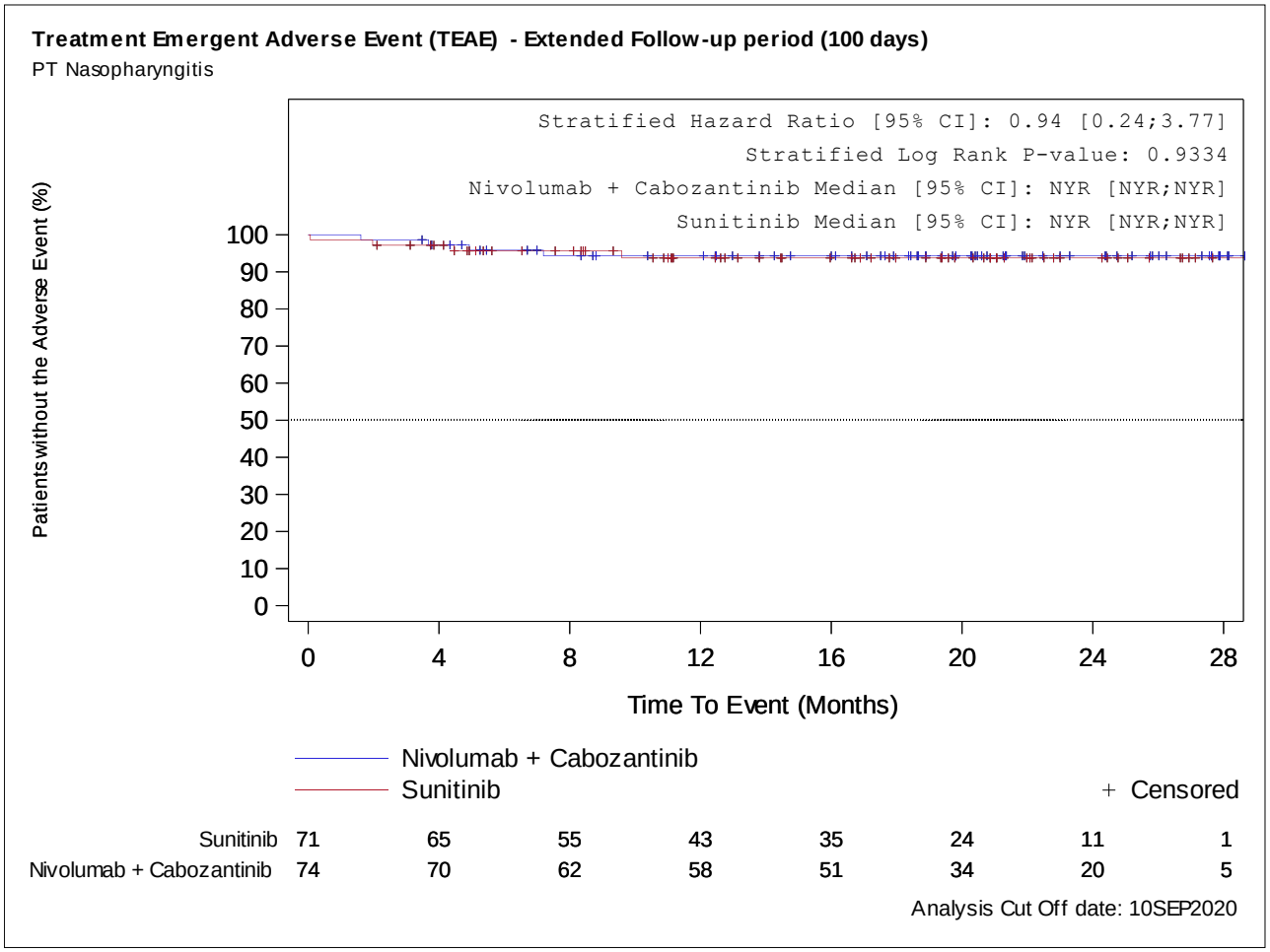
FIGURE 4.4.2.62: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Nasopharyngitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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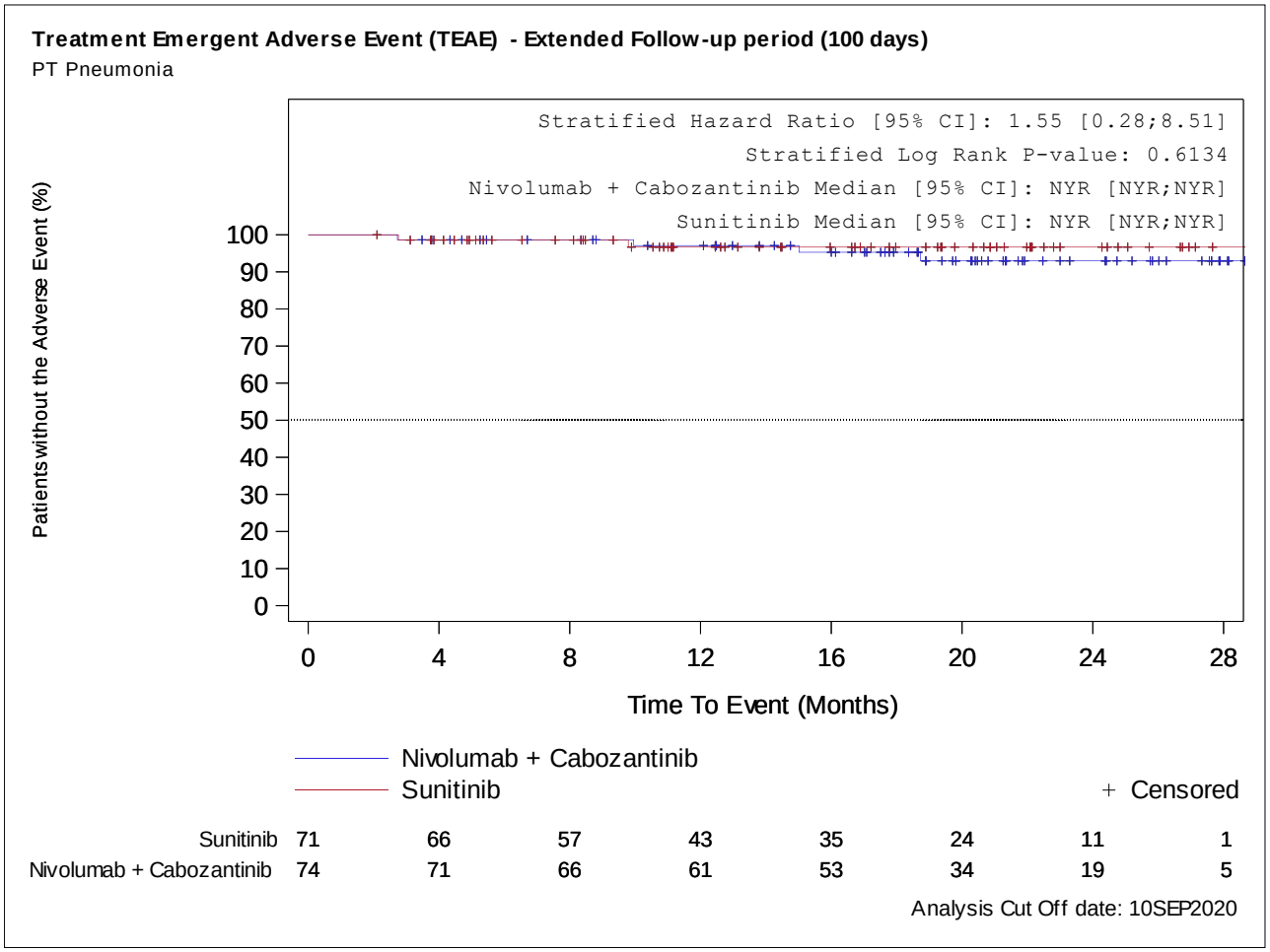
FIGURE 4.4.2.63: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pneumonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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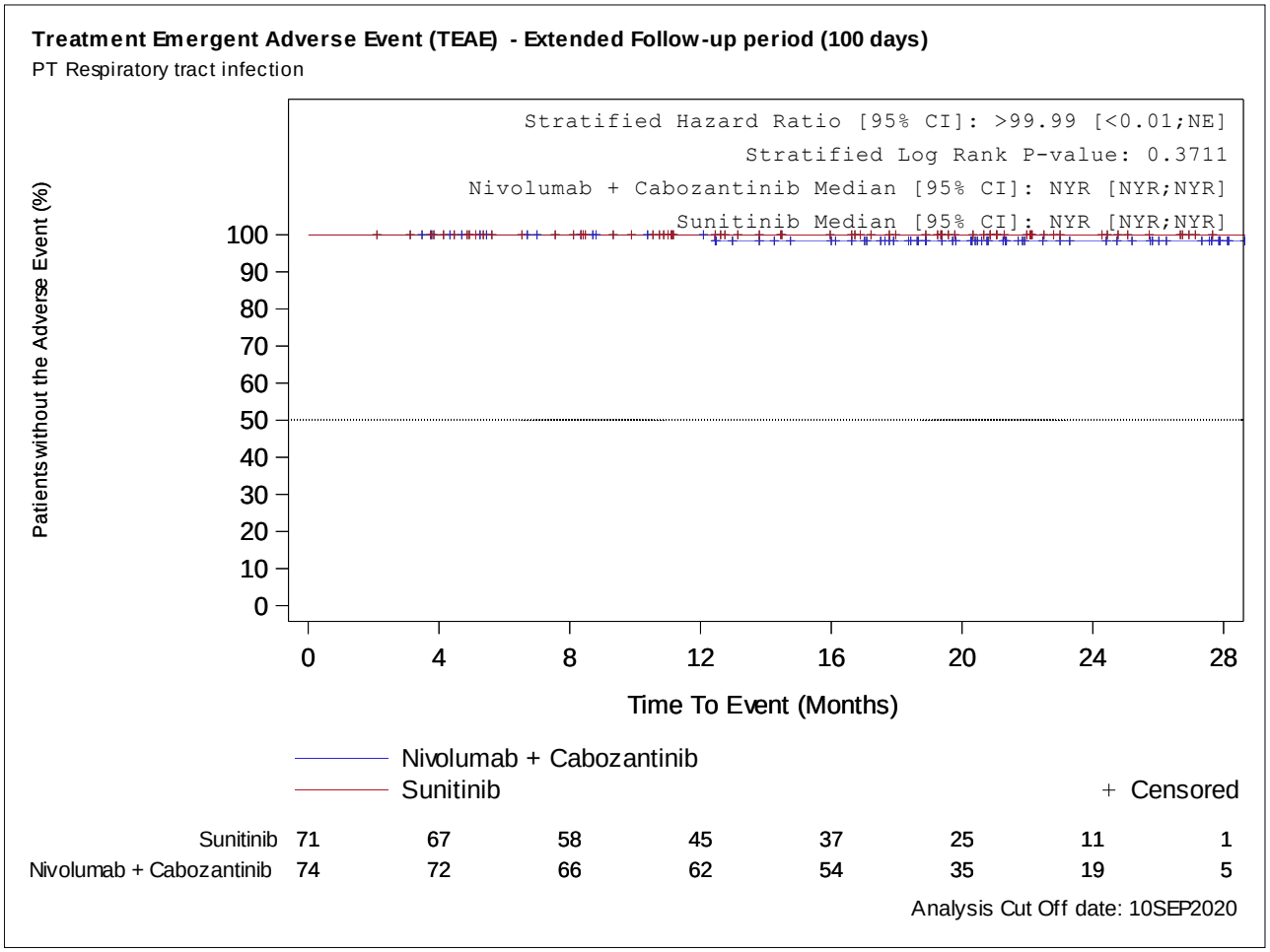
FIGURE 4.4.2.64: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Respiratory tract infection - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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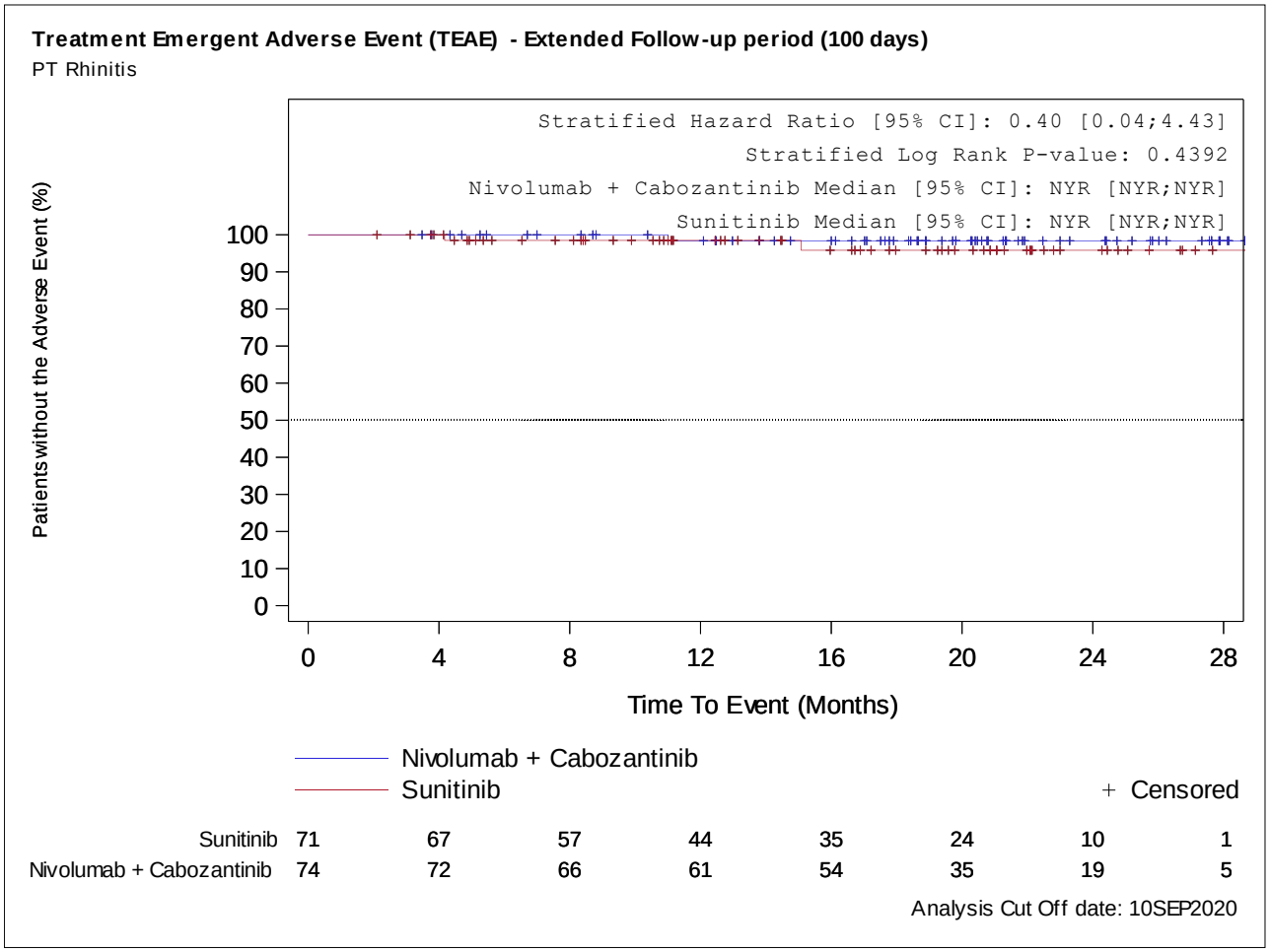
FIGURE 4.4.2.65: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rhinitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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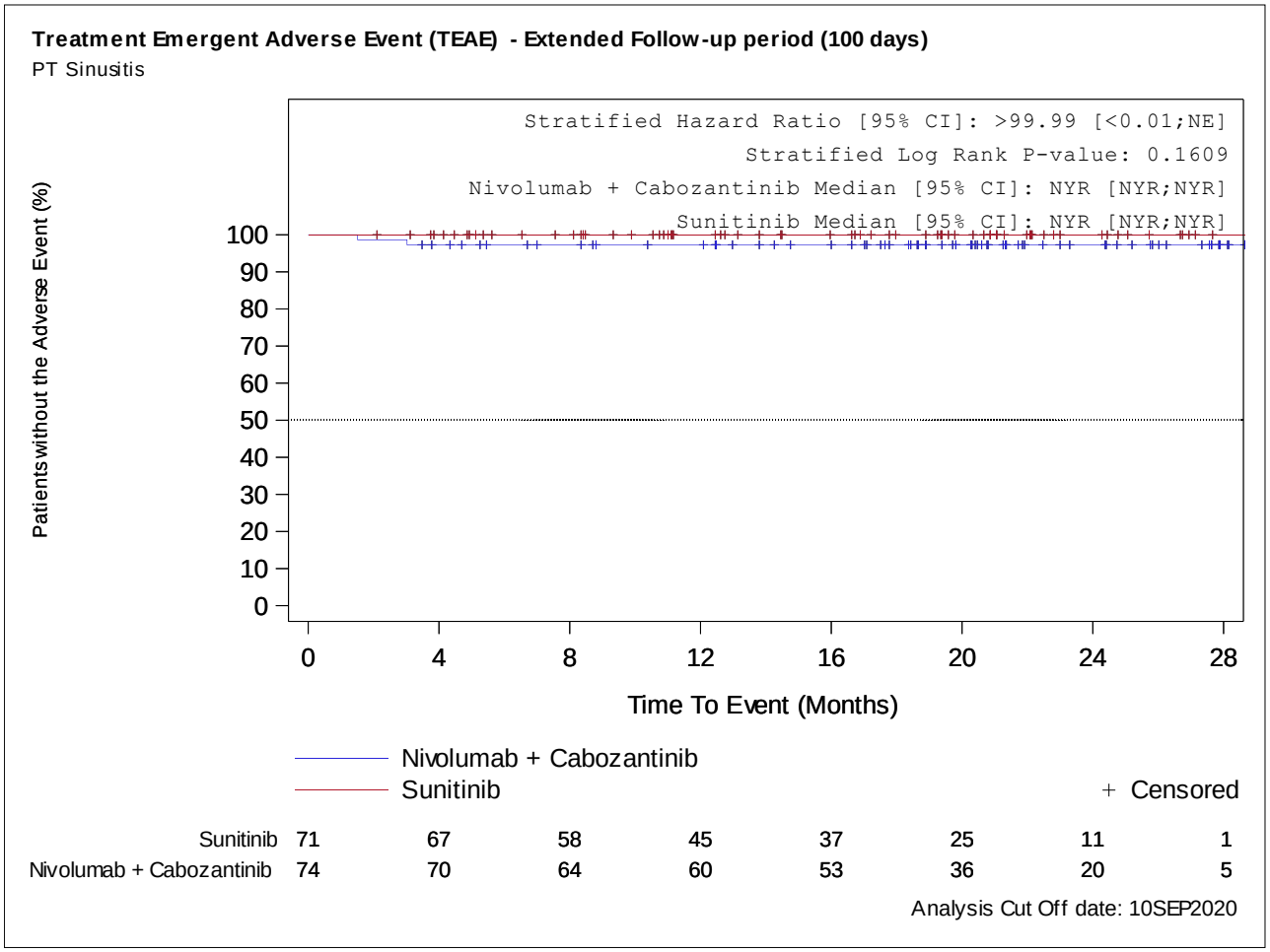
FIGURE 4.4.2.66: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Sinusitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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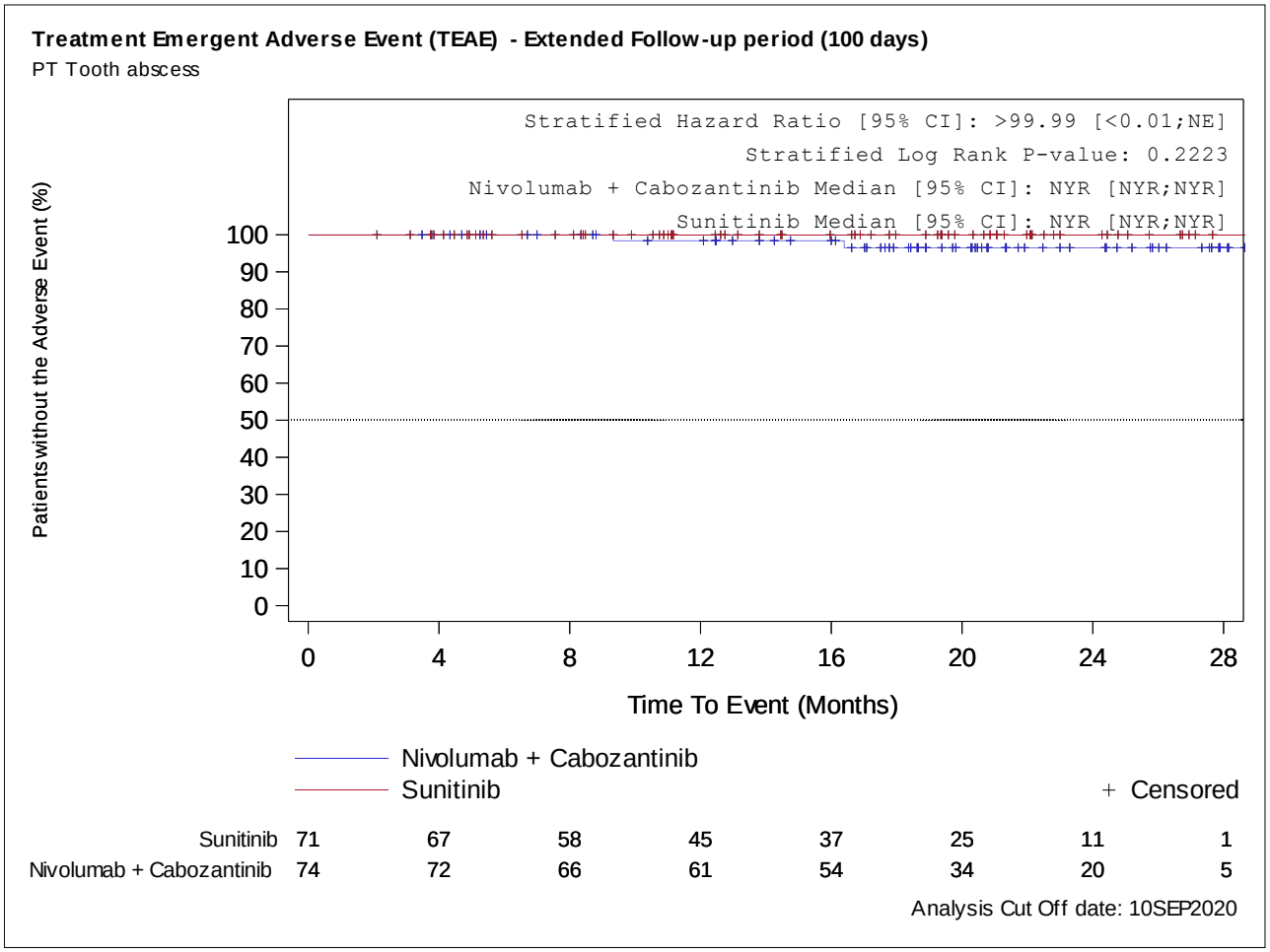
FIGURE 4.4.2.67: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Tooth abscess - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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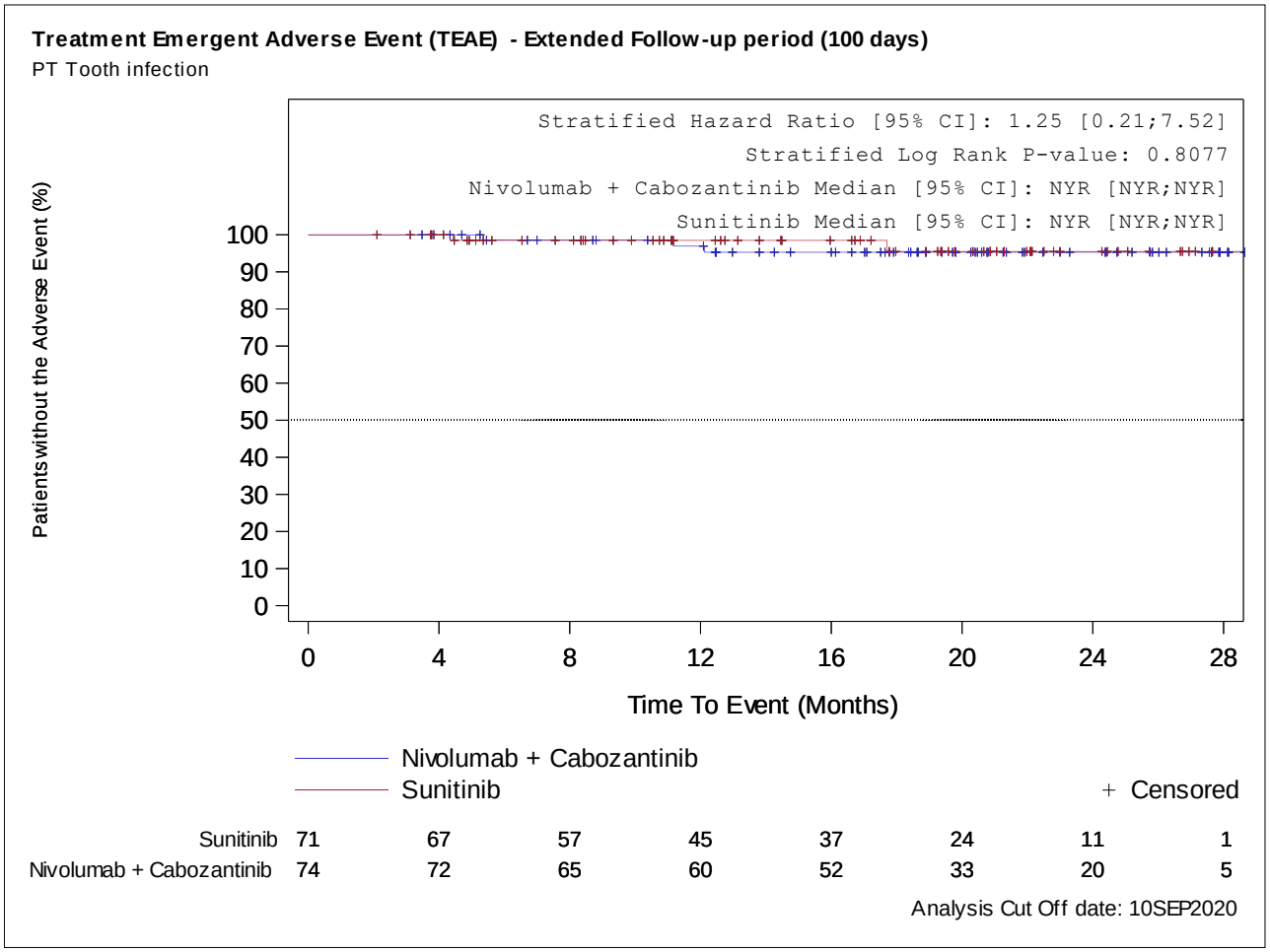
FIGURE 4.4.2.68: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Tooth infection - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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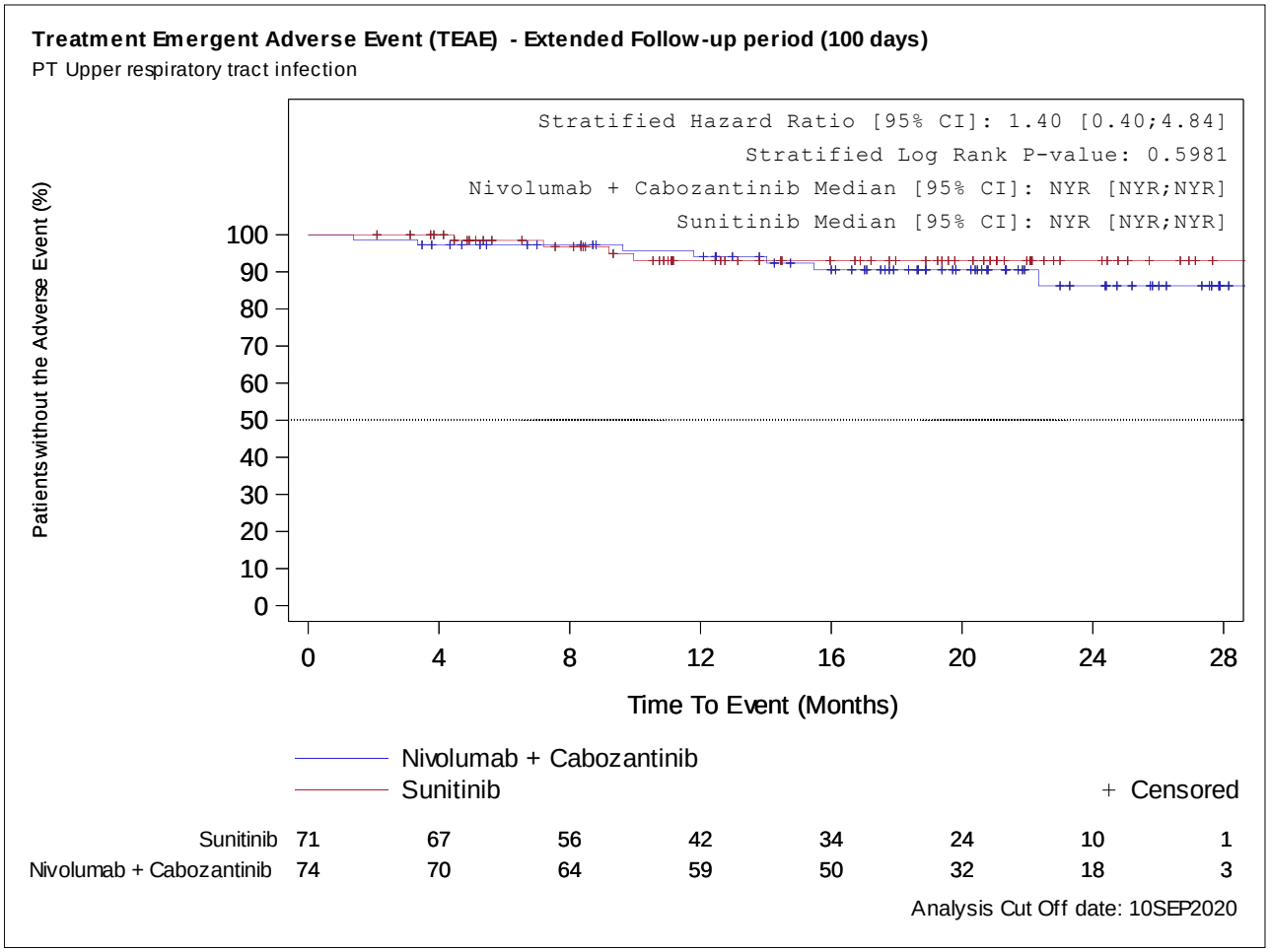
FIGURE 4.4.2.69: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Upper respiratory tract infection - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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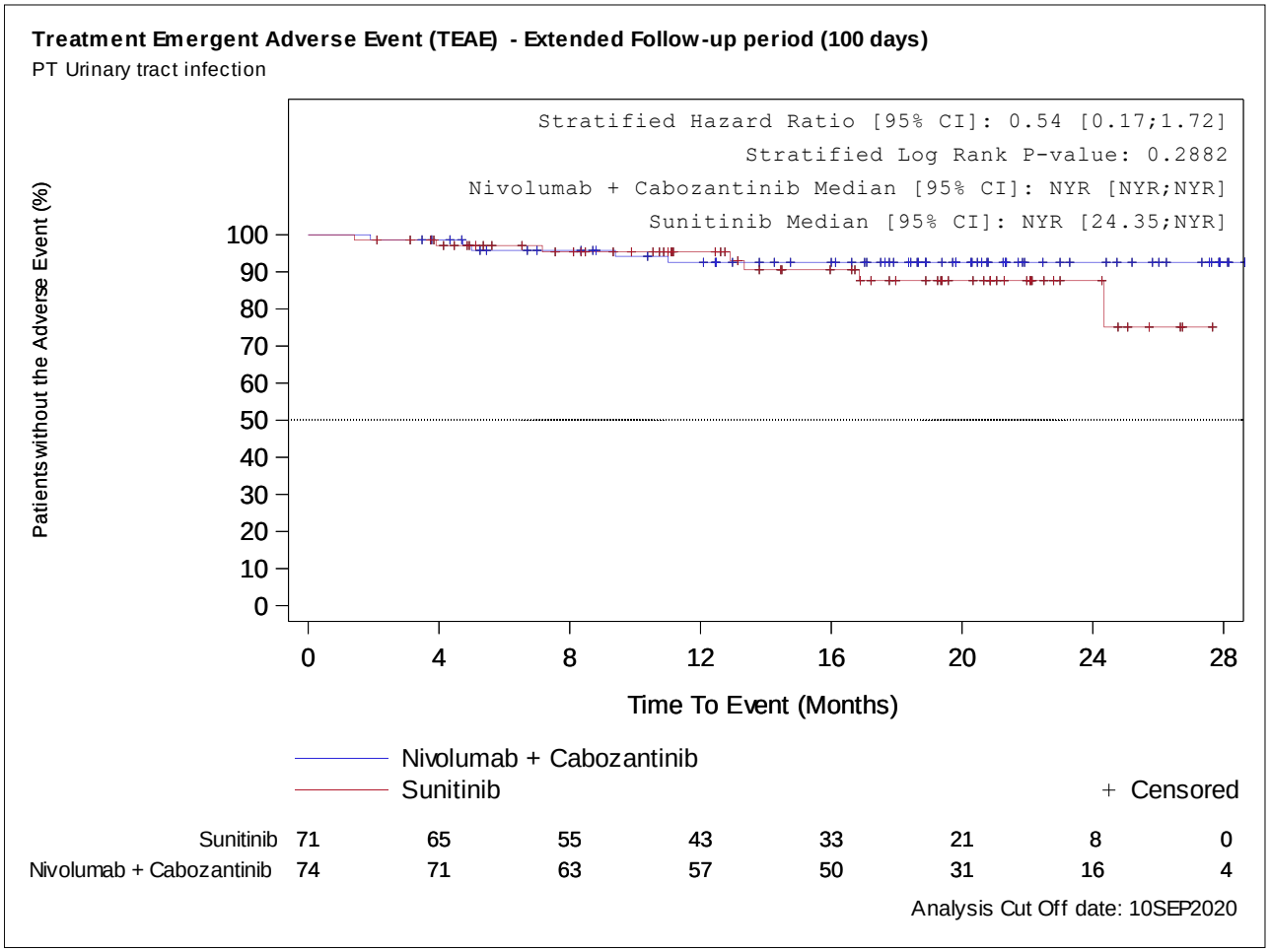
FIGURE 4.4.2.70: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Urinary tract infection - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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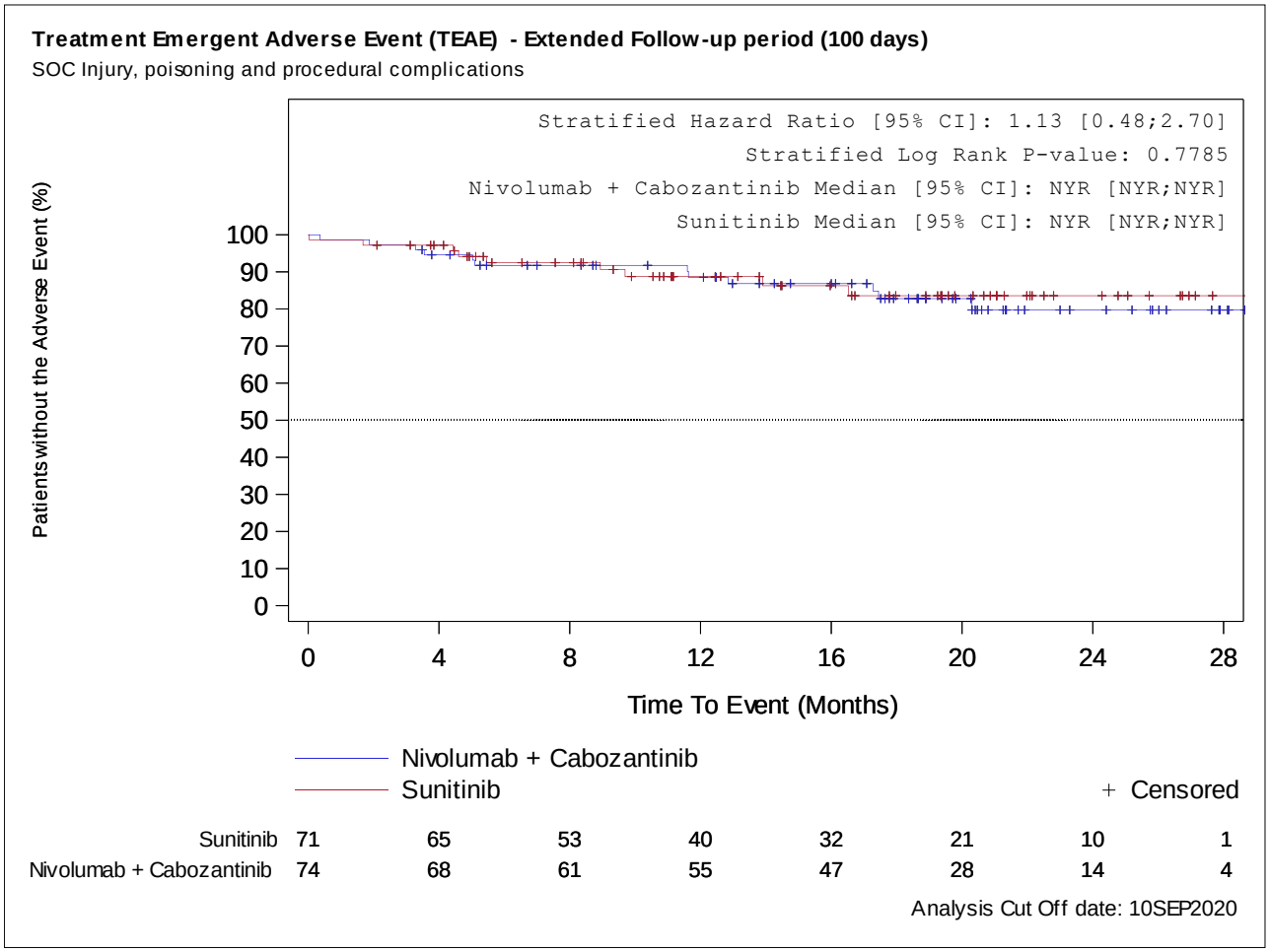
FIGURE 4.4.2.71: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Injury, poisoning and procedural complications - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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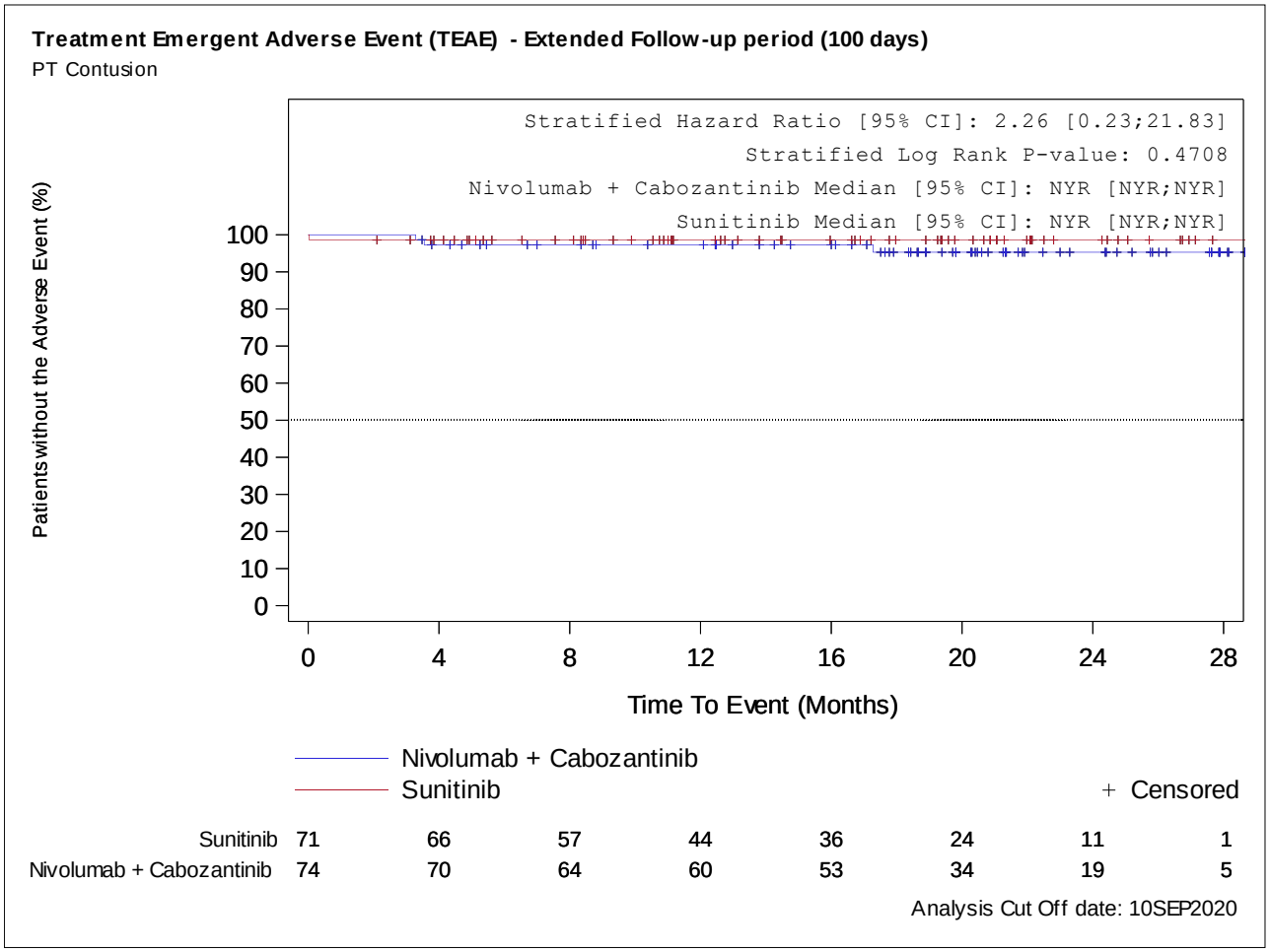
FIGURE 4.4.2.72: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Contusion - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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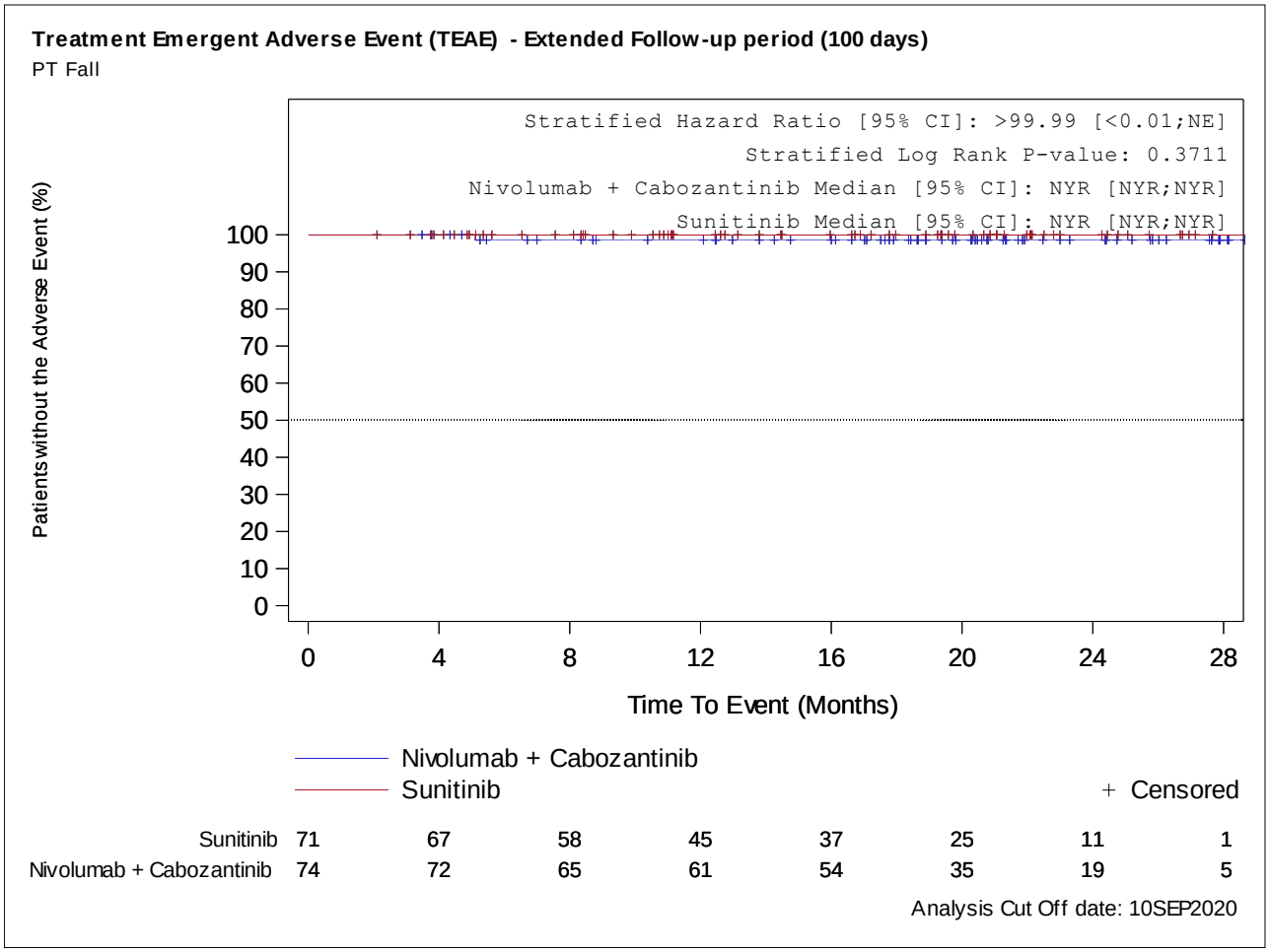
FIGURE 4.4.2.73: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Fall - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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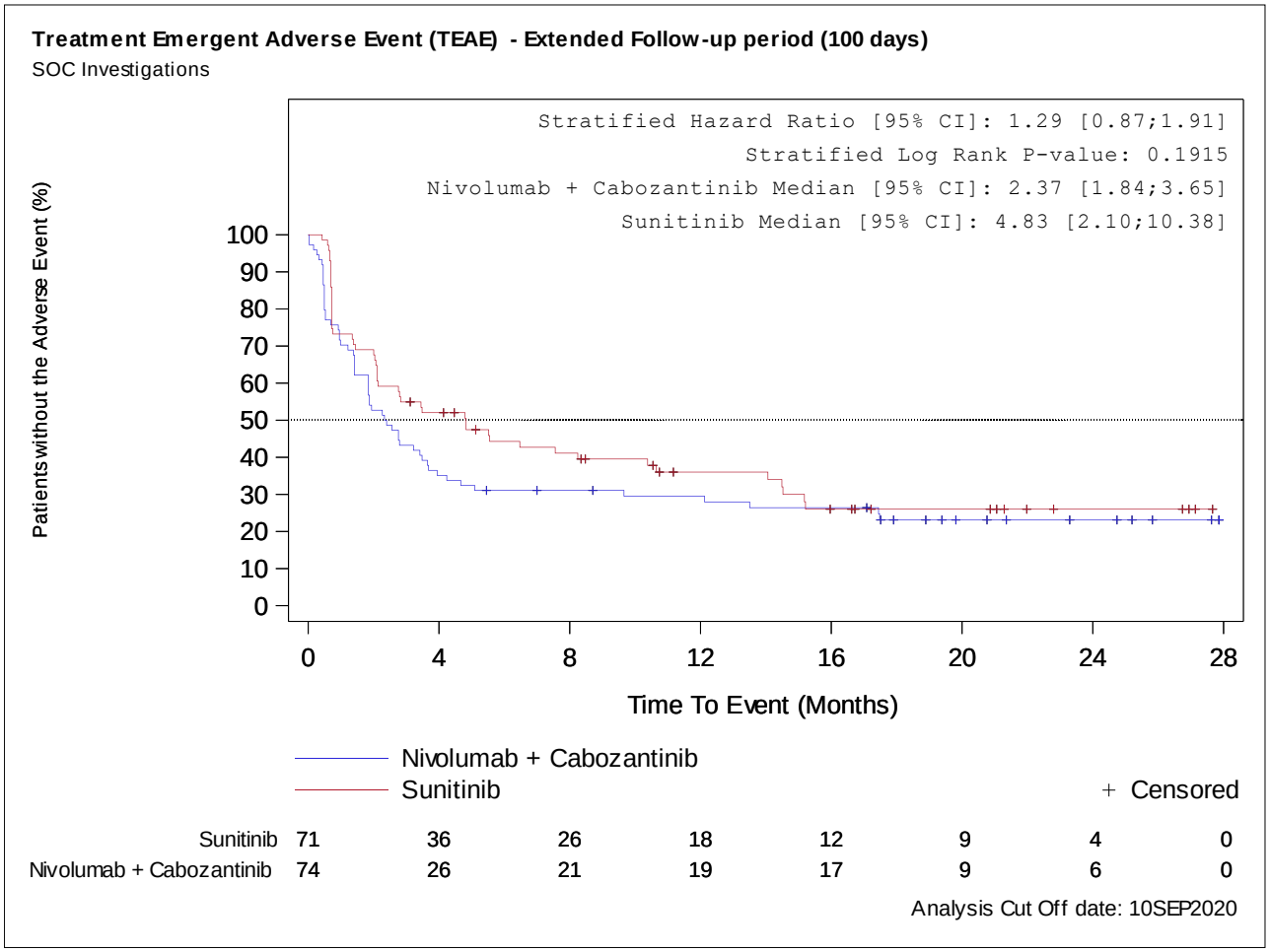
FIGURE 4.4.2.74: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Investigations - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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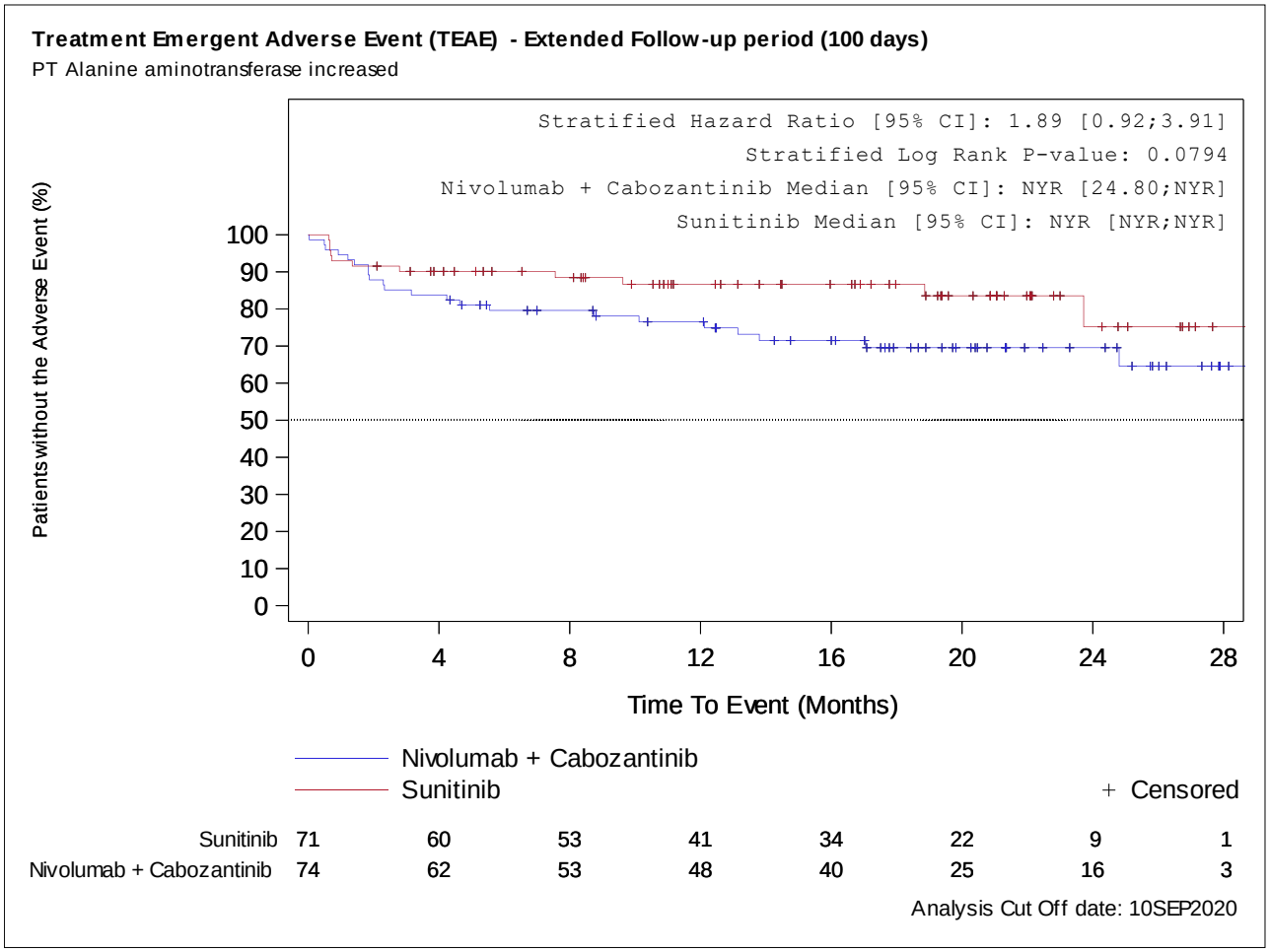
FIGURE 4.4.2.75: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Alanine aminotransferase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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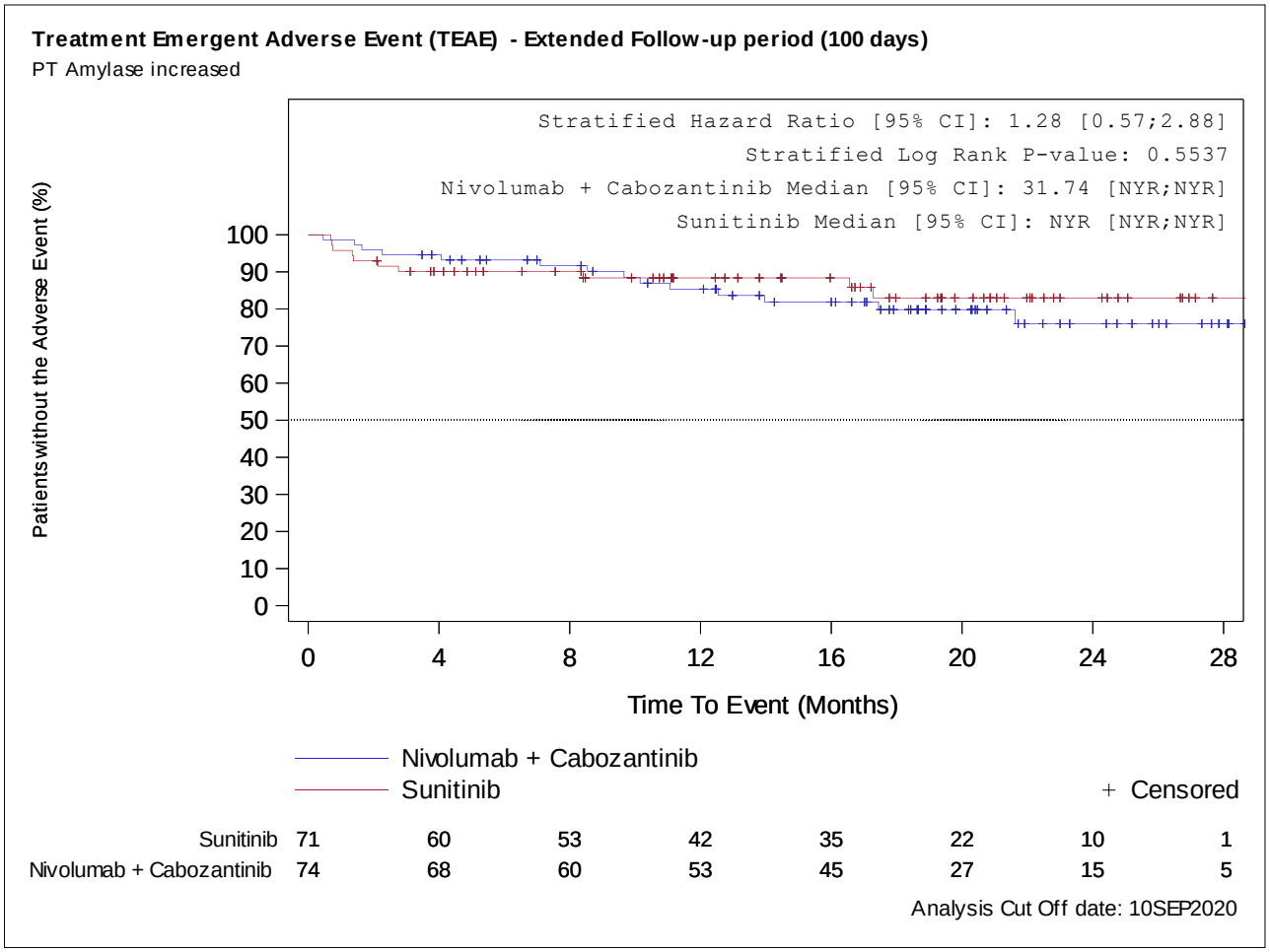
FIGURE 4.4.2.76: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Amylase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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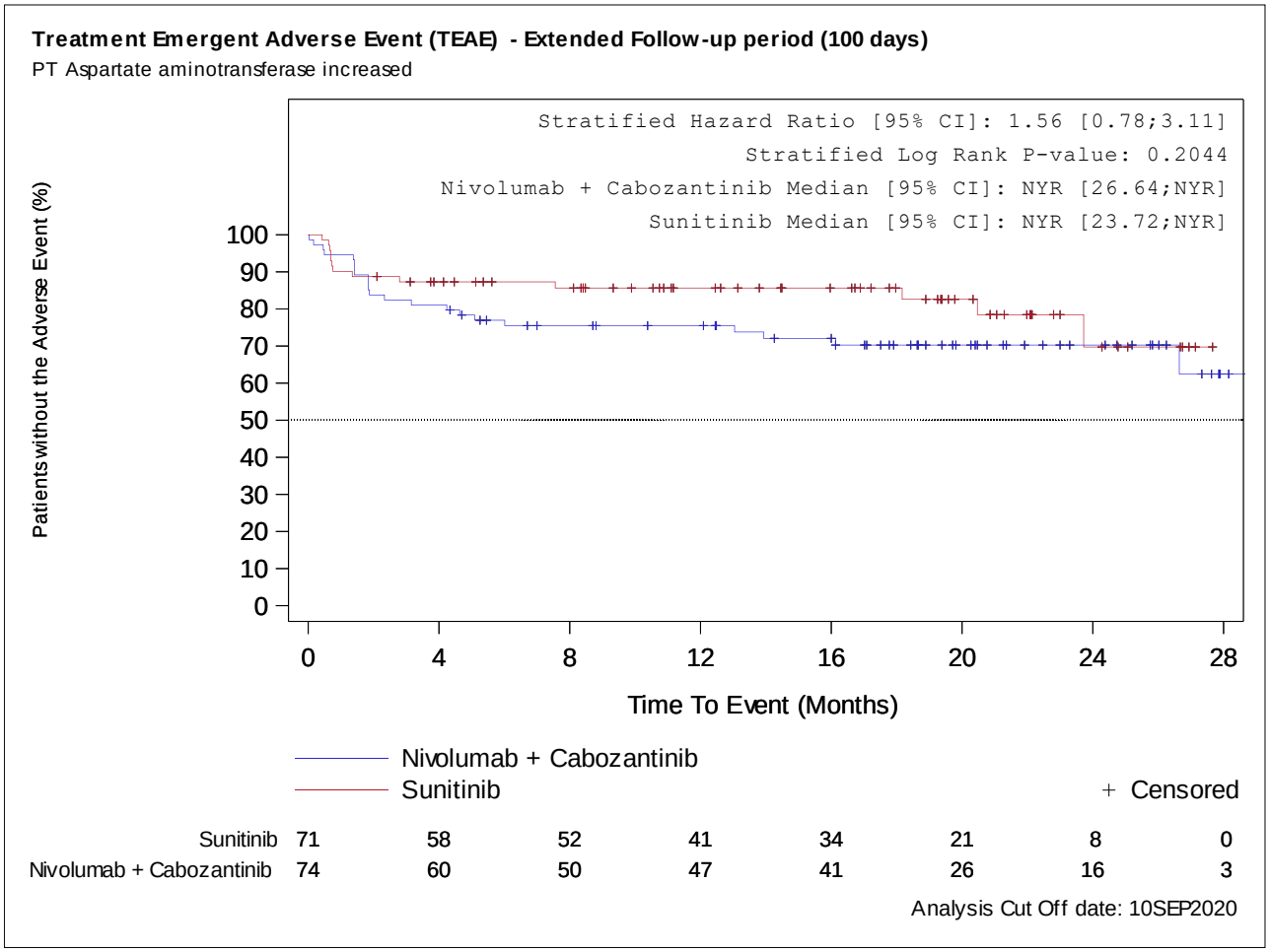
FIGURE 4.4.2.77: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Aspartate aminotransferase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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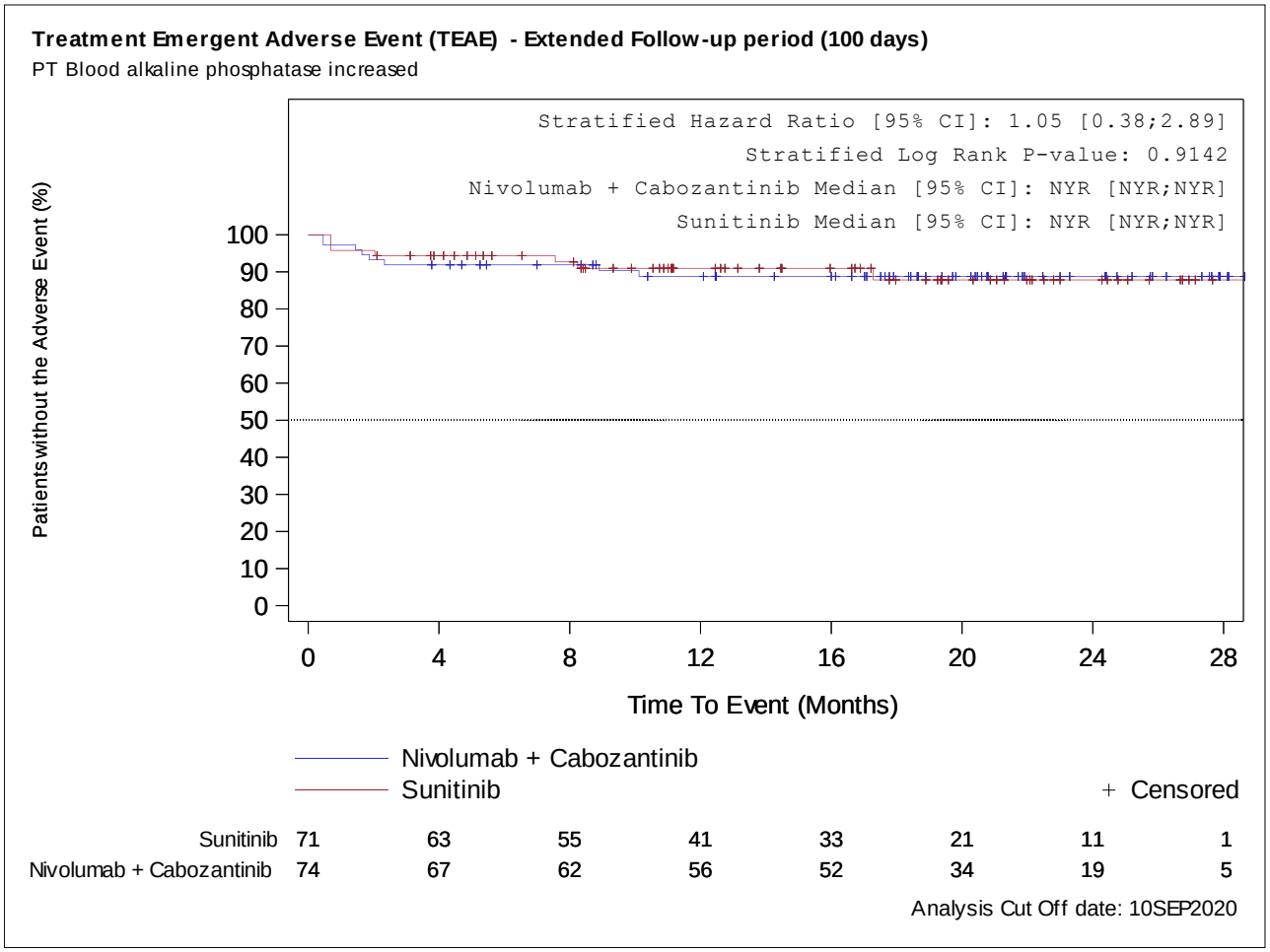
FIGURE 4.4.2.78: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood alkaline phosphatase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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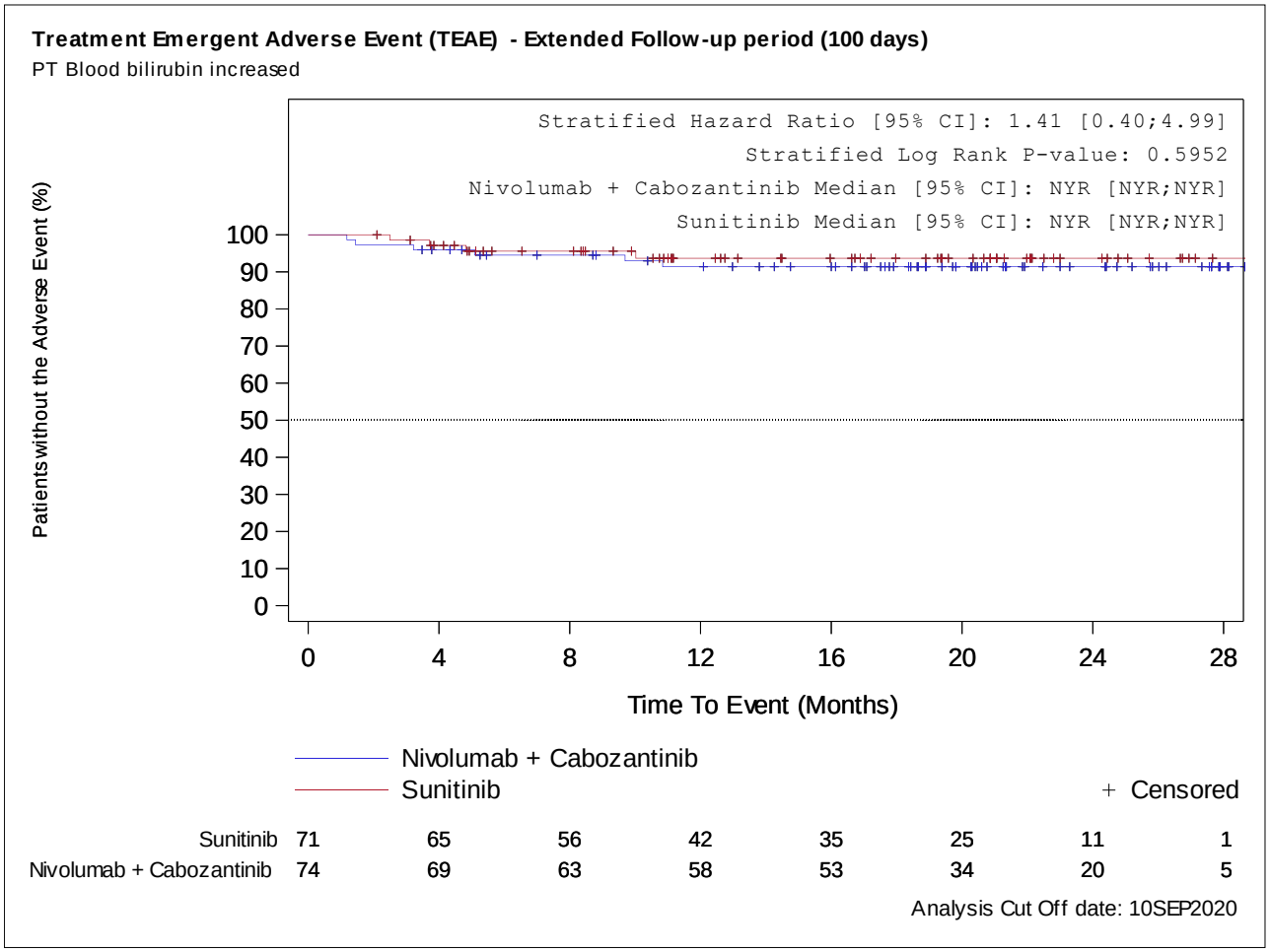
FIGURE 4.4.2.79: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood bilirubin increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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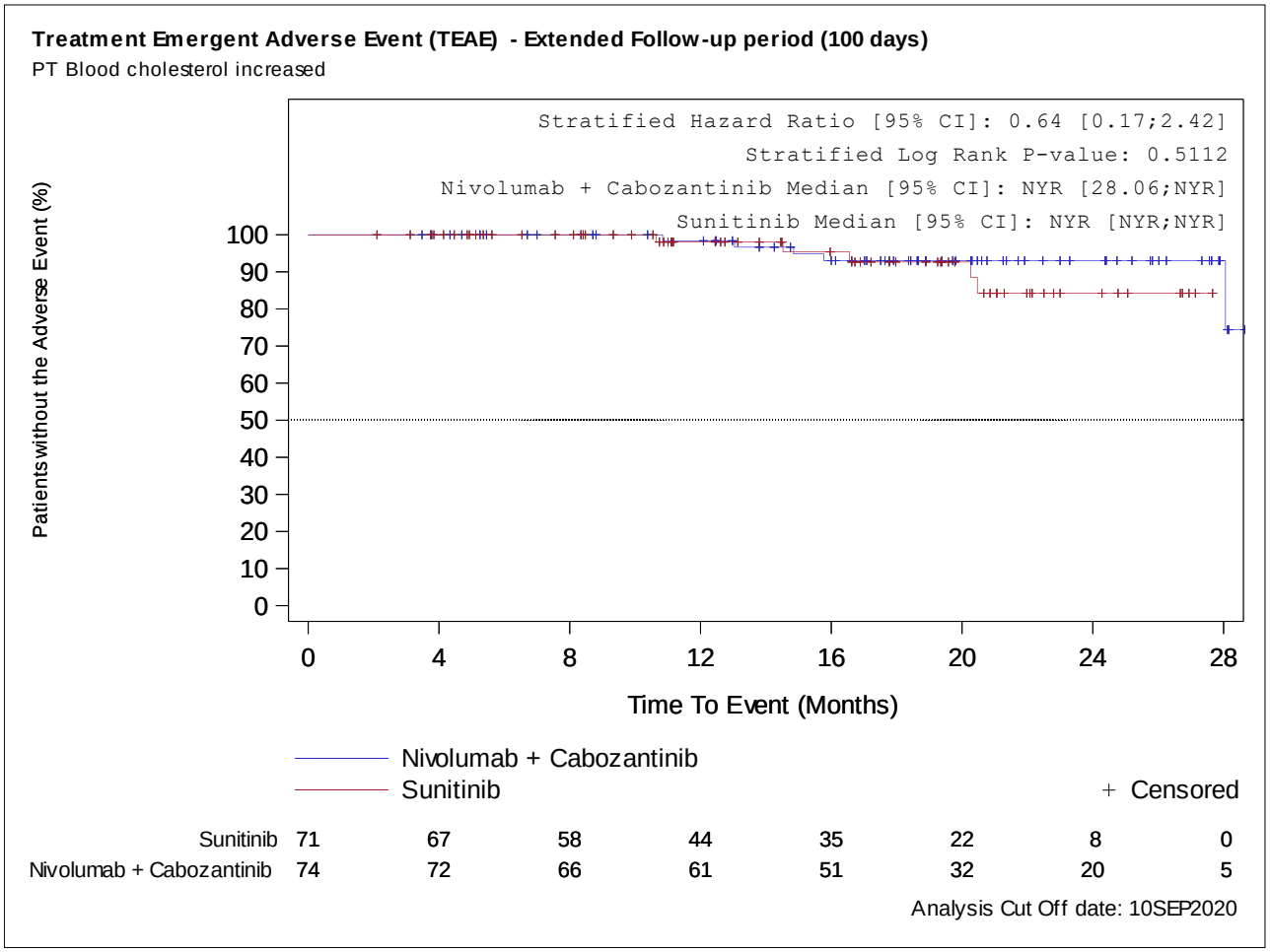
FIGURE 4.4.2.80: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood cholesterol increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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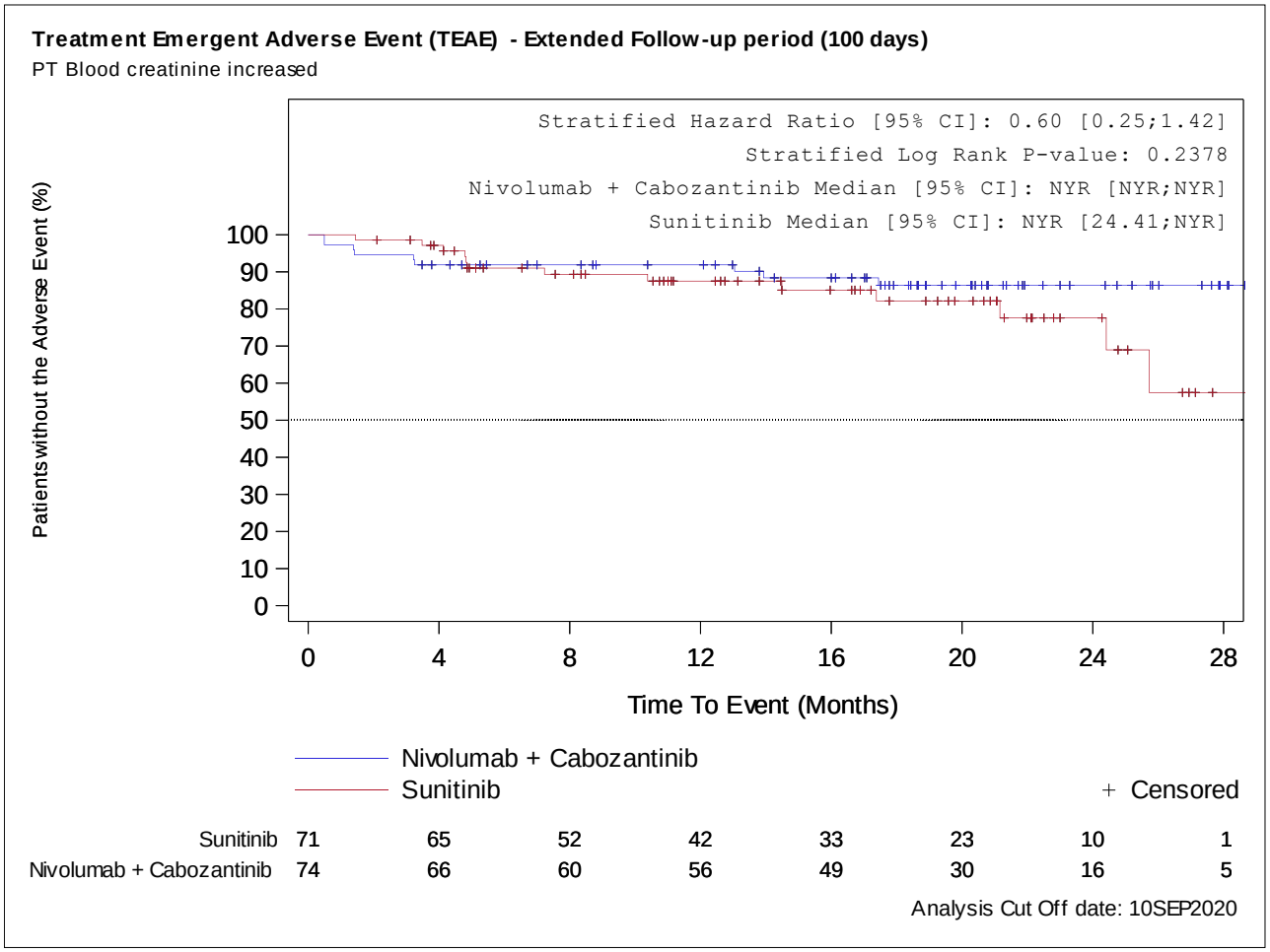
FIGURE 4.4.2.81: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood creatinine increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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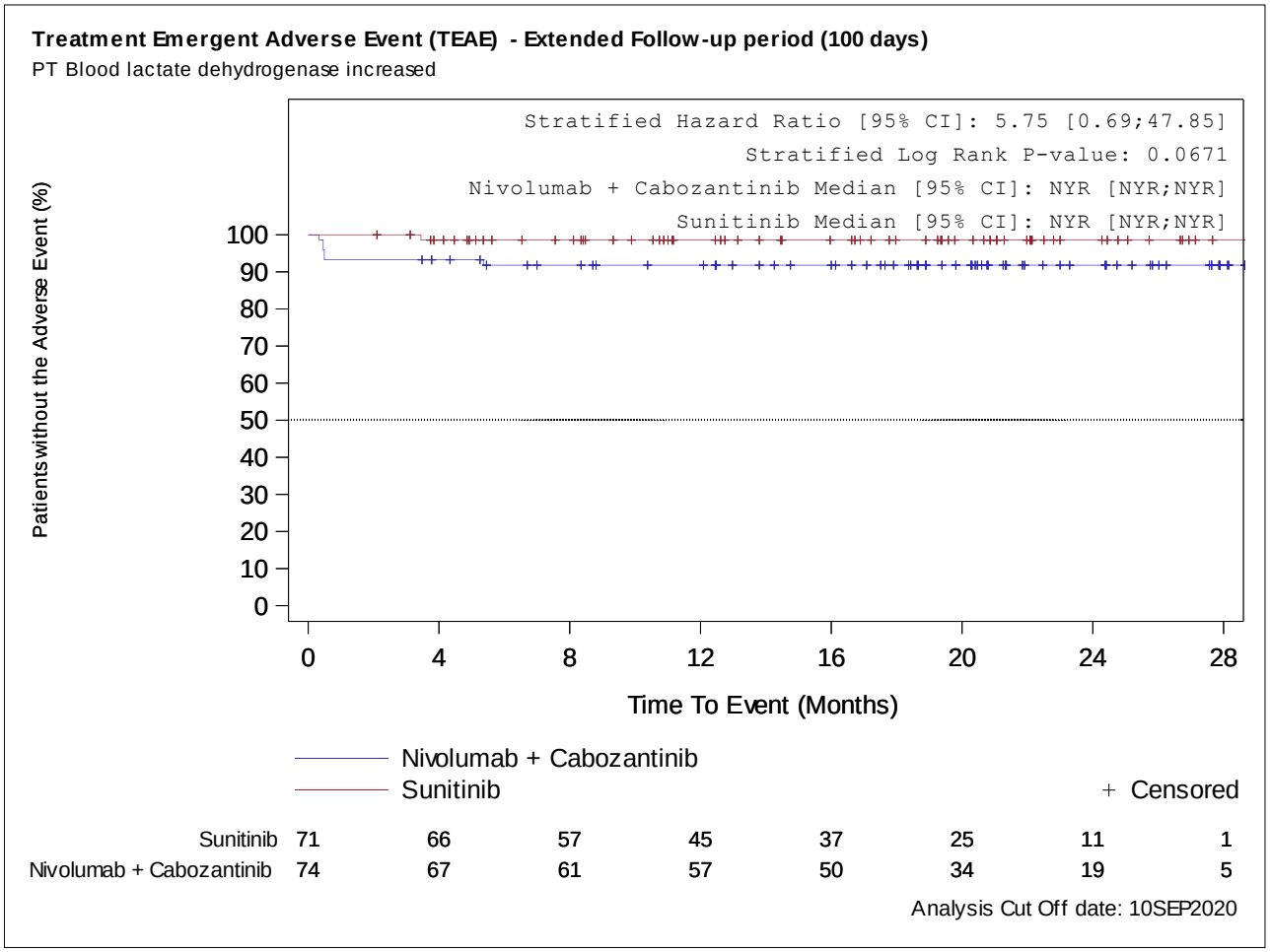
FIGURE 4.4.2.82: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood lactate dehydrogenase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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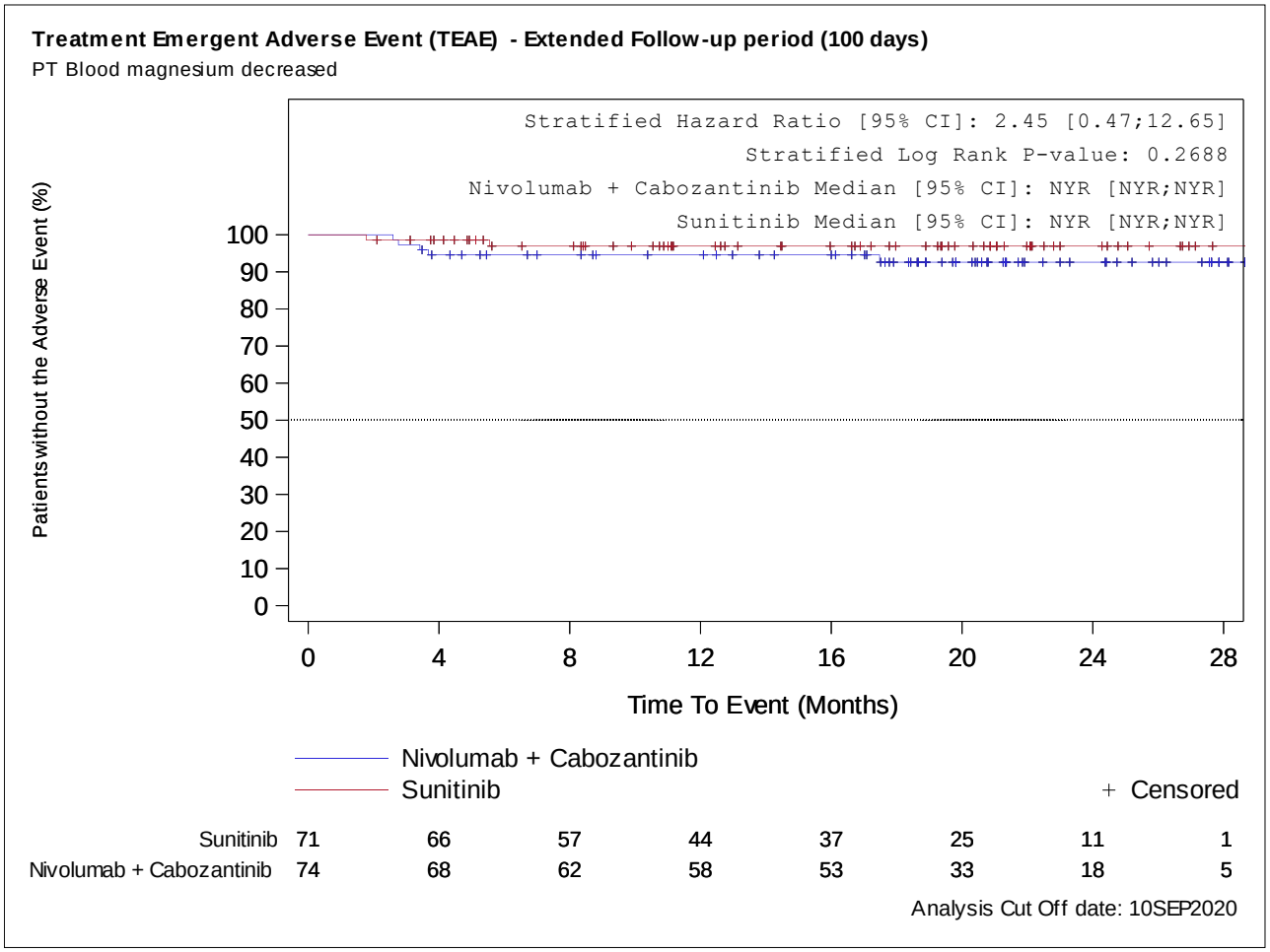
FIGURE 4.4.2.83: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood magnesium decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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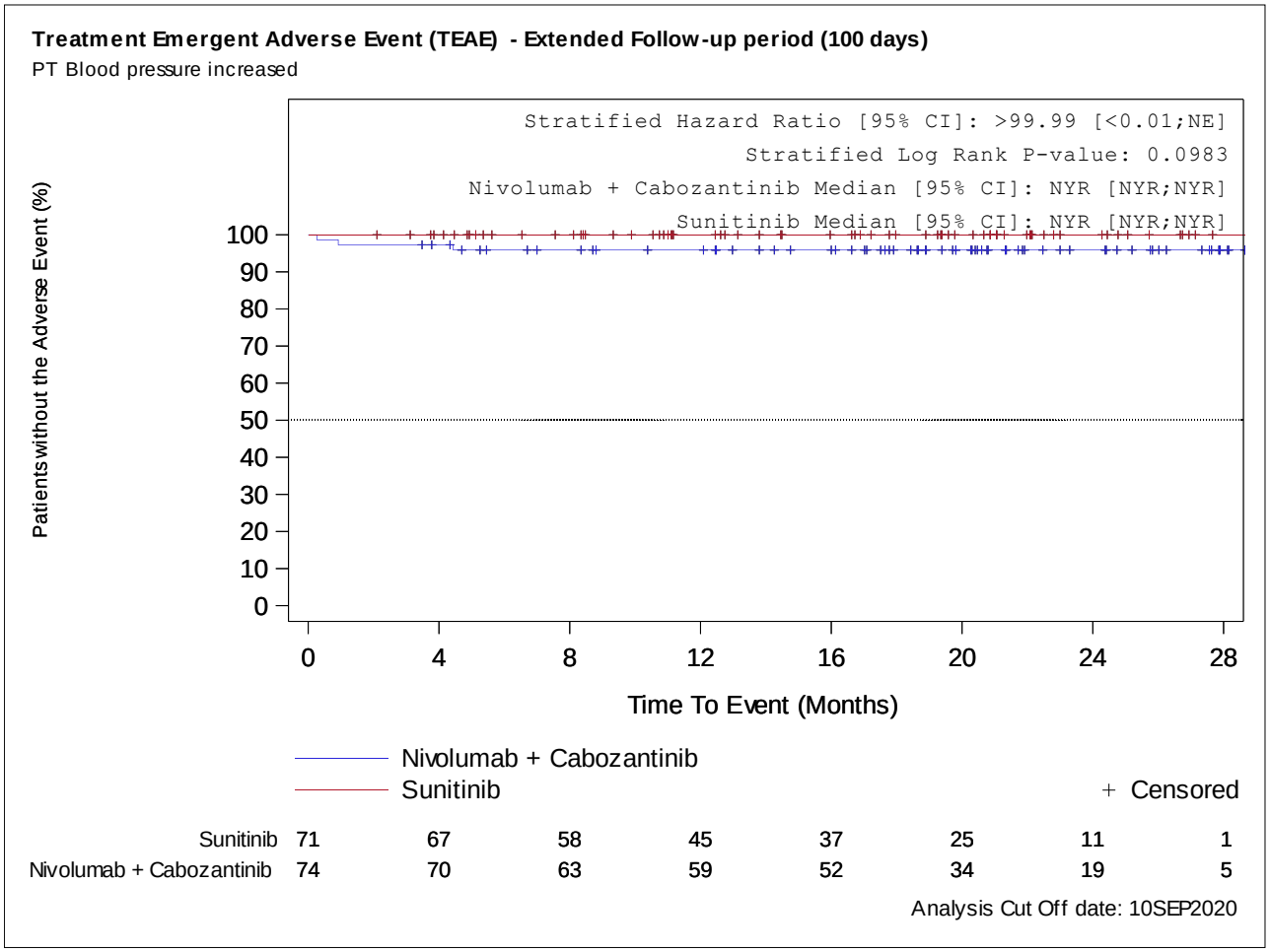
FIGURE 4.4.2.84: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood pressure increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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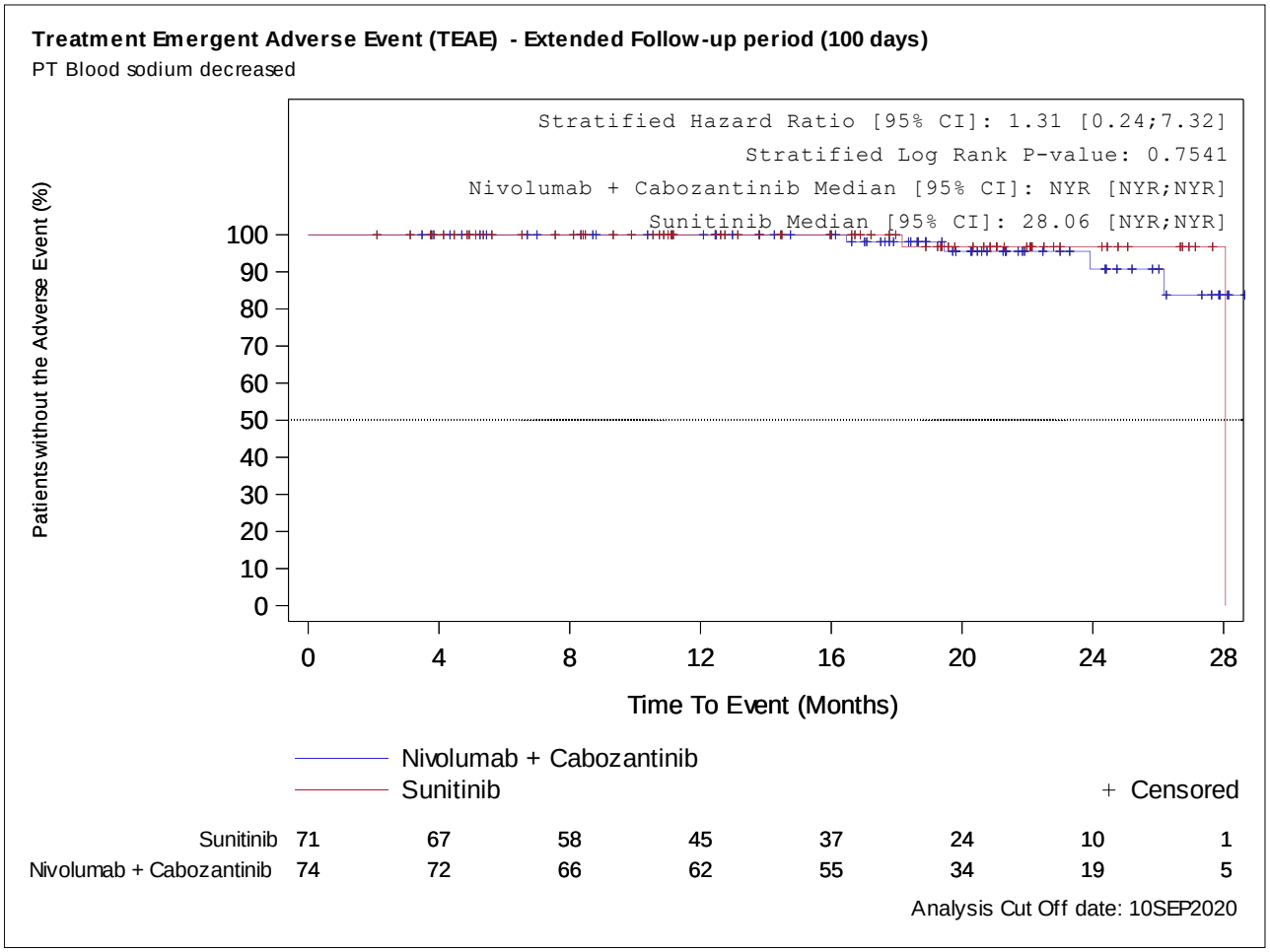
FIGURE 4.4.2.85: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood sodium decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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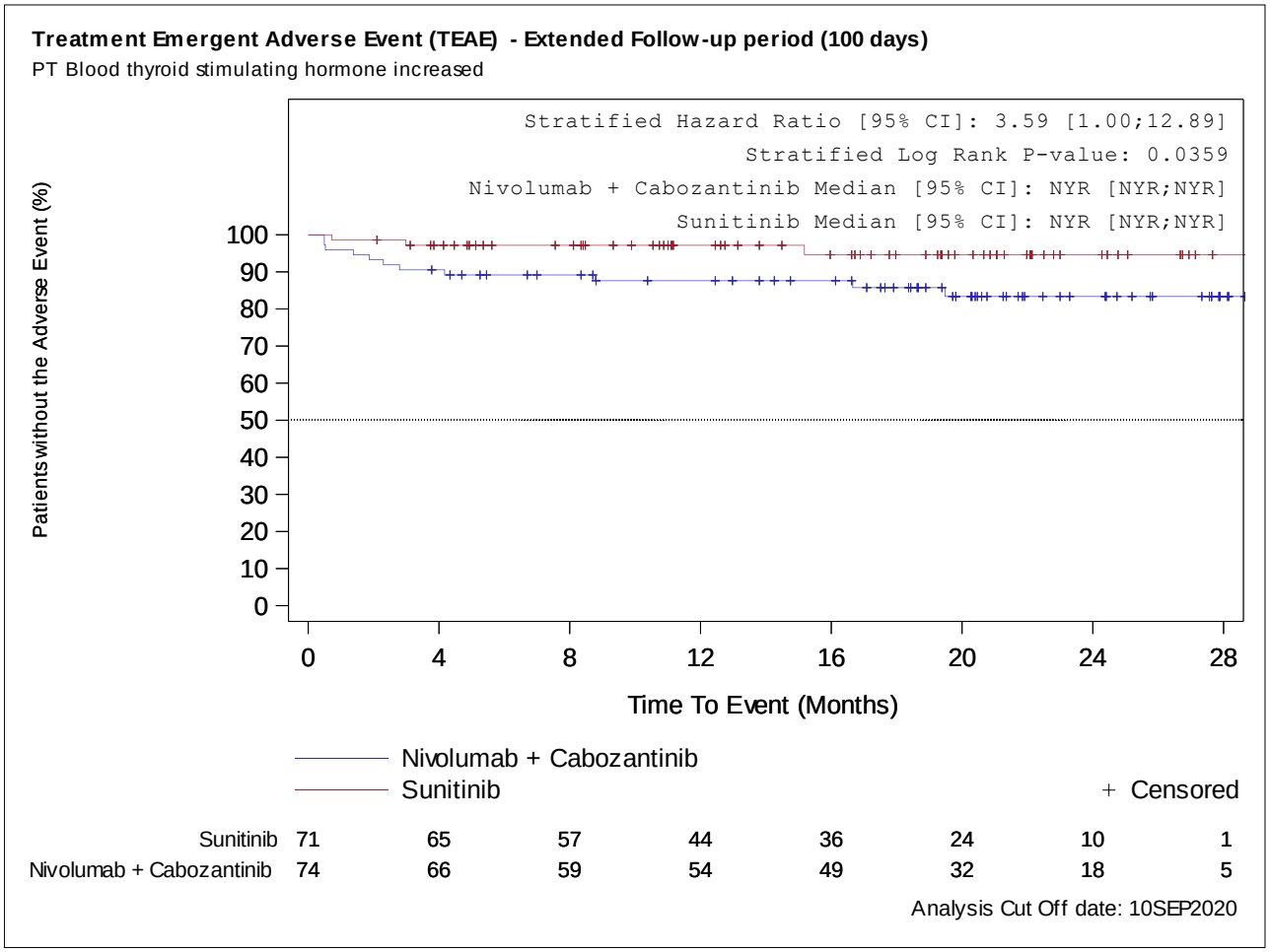
FIGURE 4.4.2.86: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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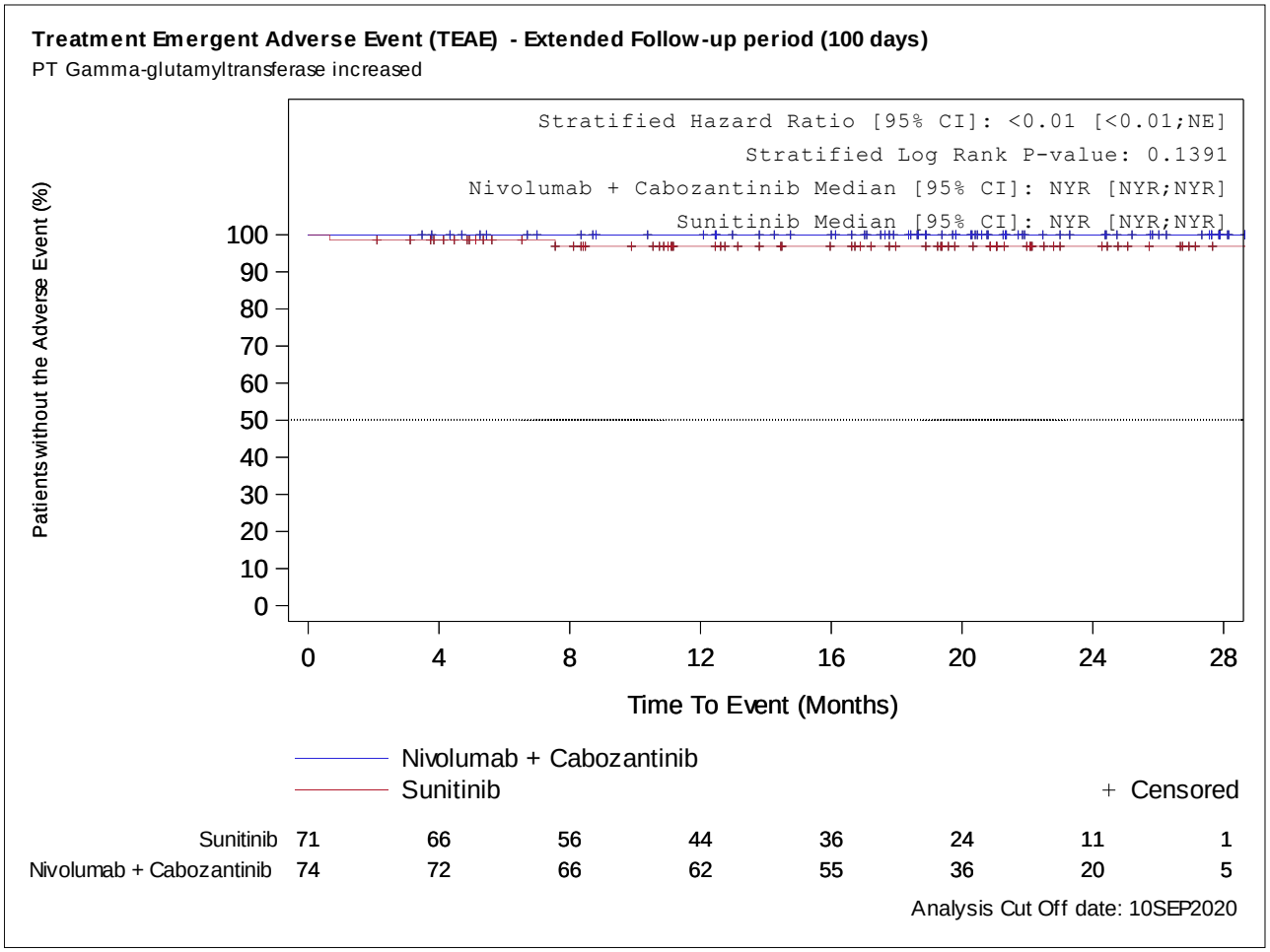
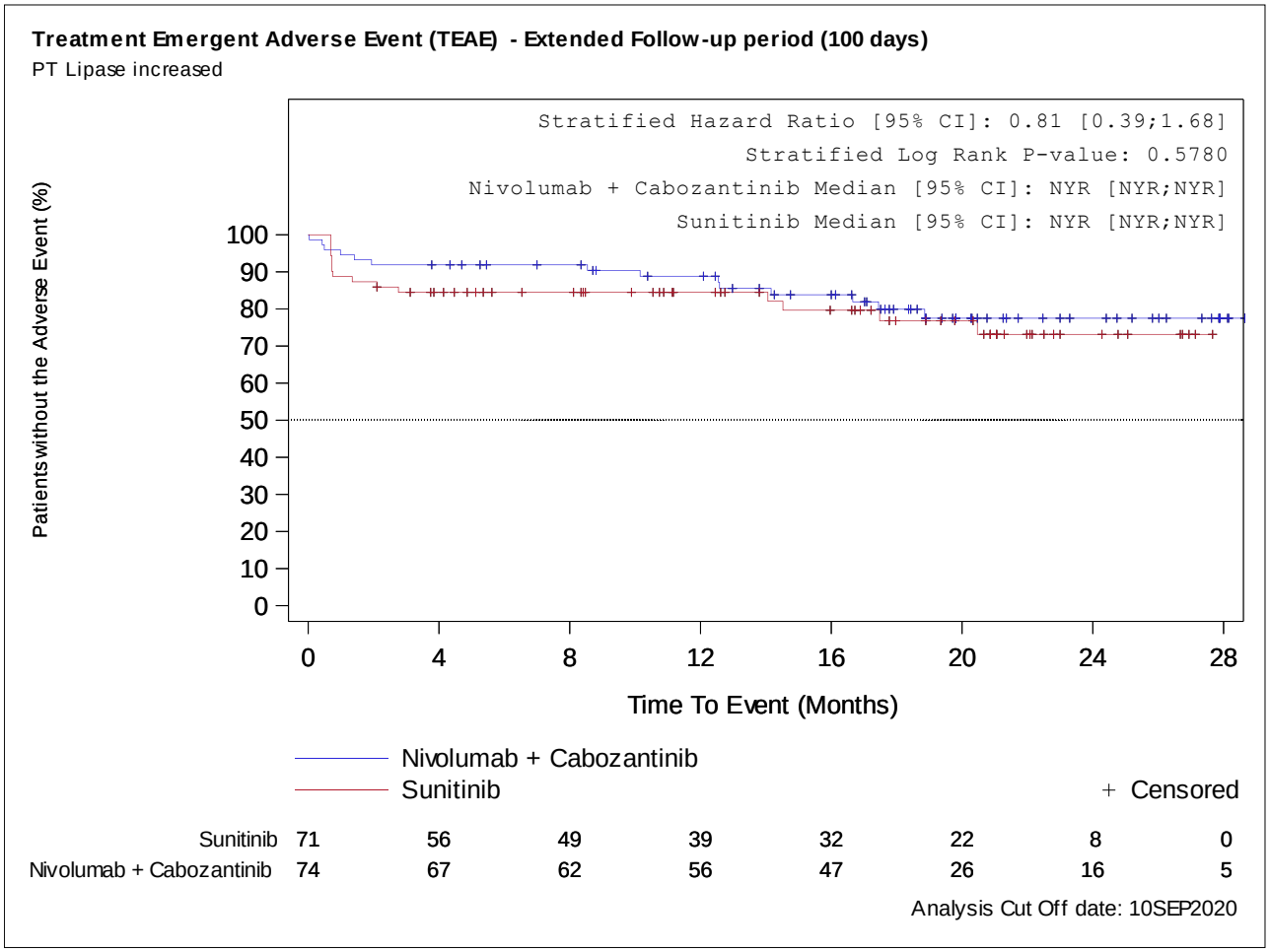
FIGURE 4.4.2.87: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Gamma-glutamyltransferase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:25:38

FIGURE 4.4.2.88: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Lipase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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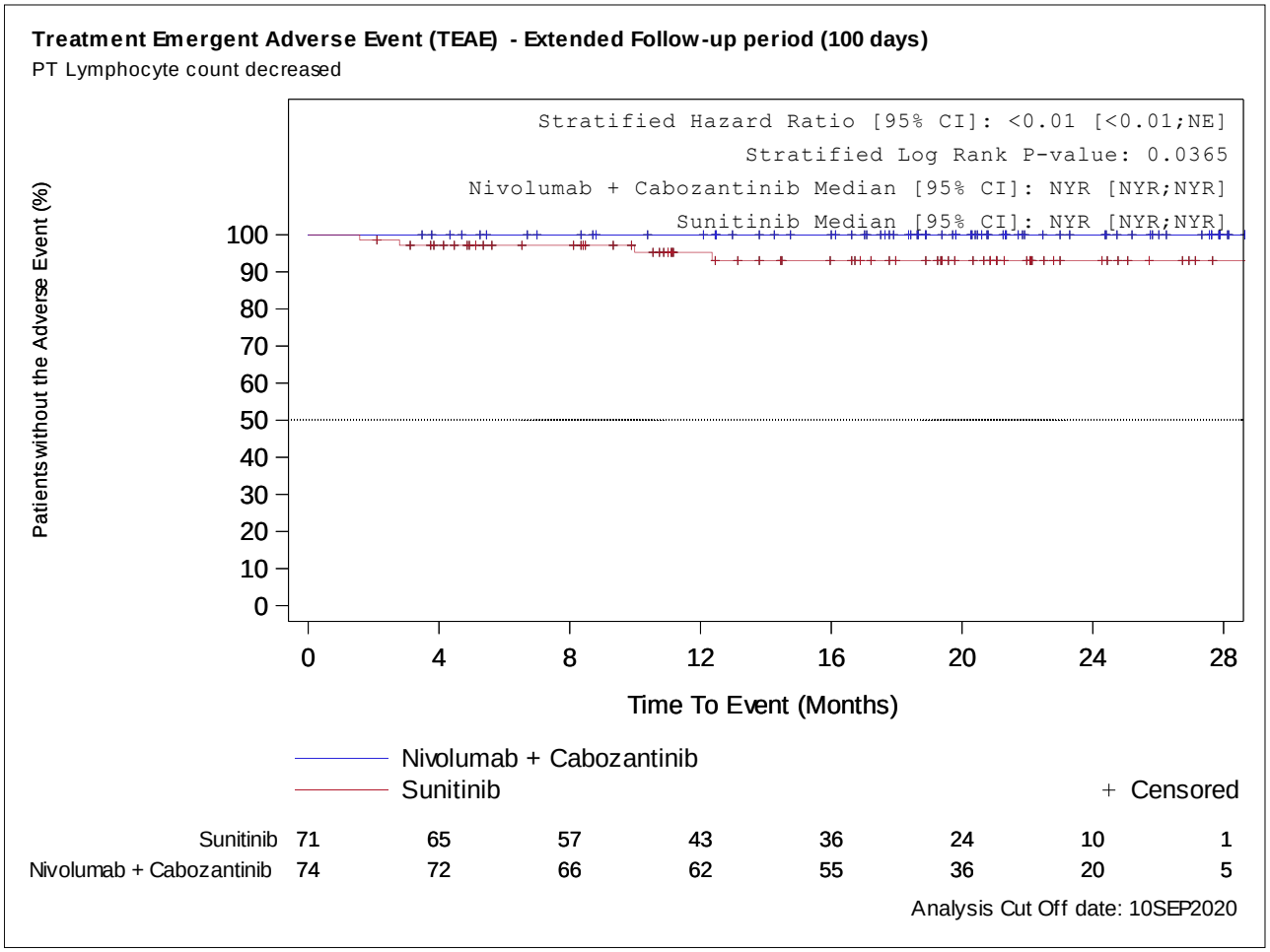
FIGURE 4.4.2.89: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Lymphocyte count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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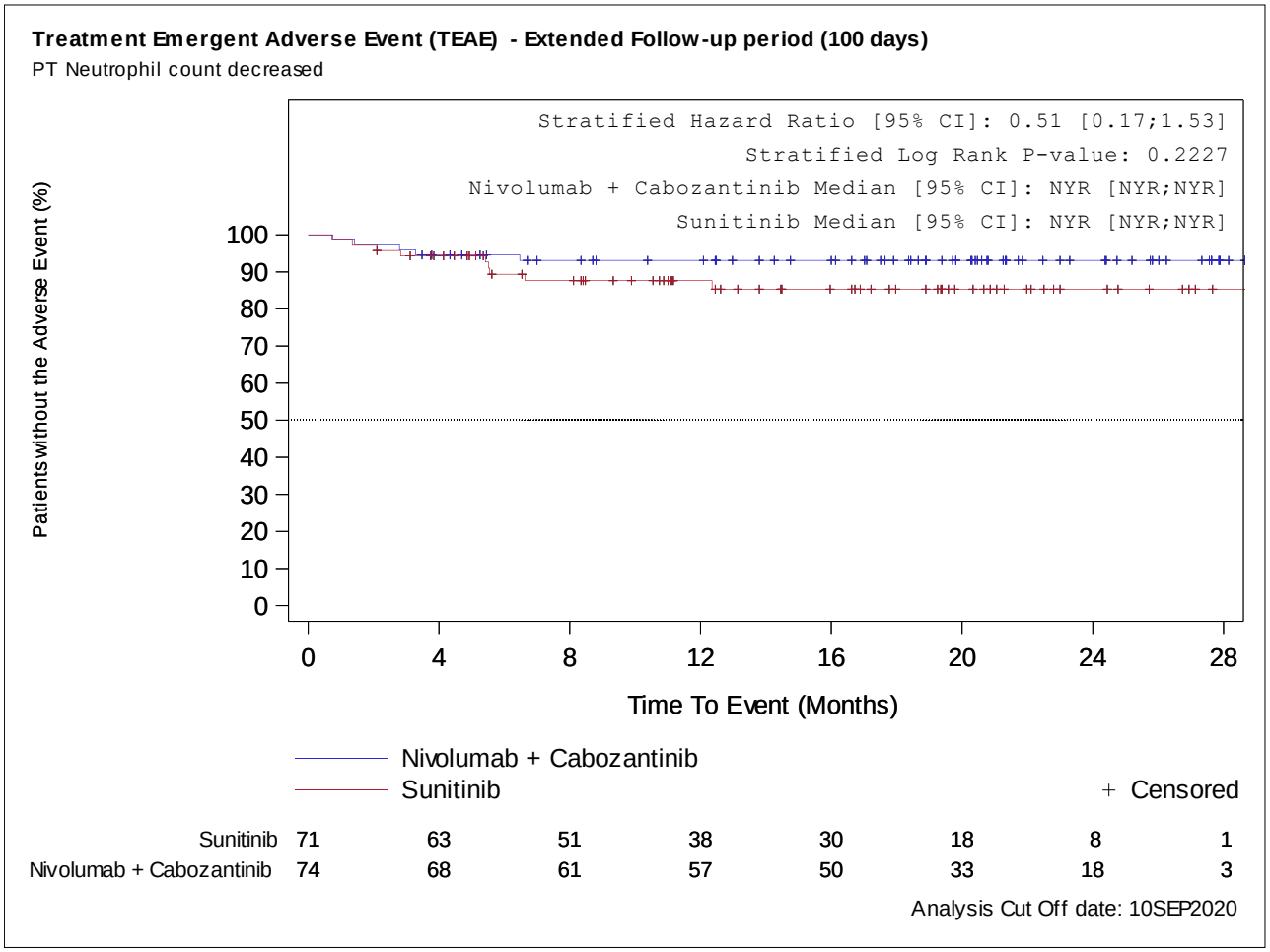
FIGURE 4.4.2.90: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutrophil count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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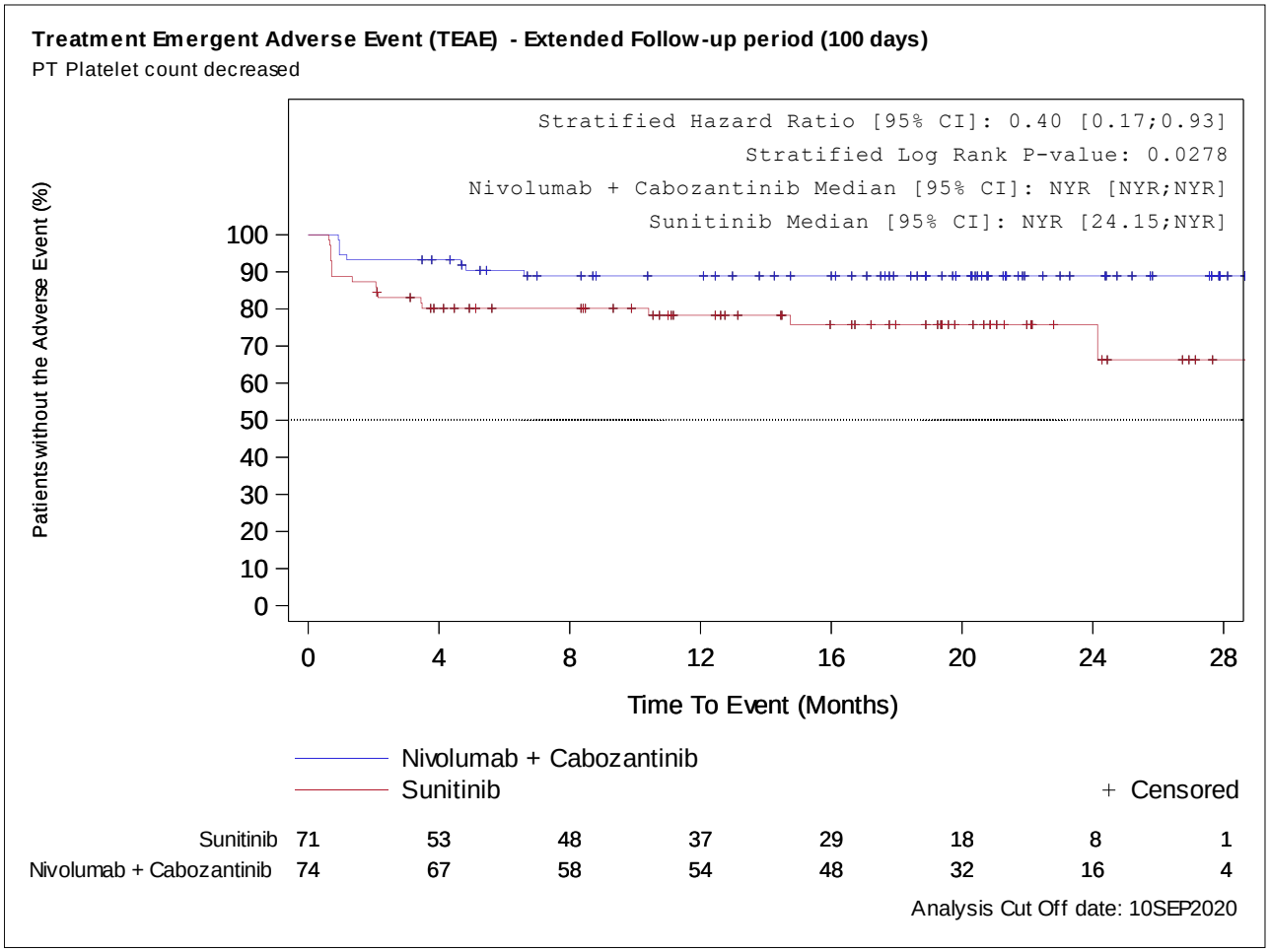
FIGURE 4.4.2.91: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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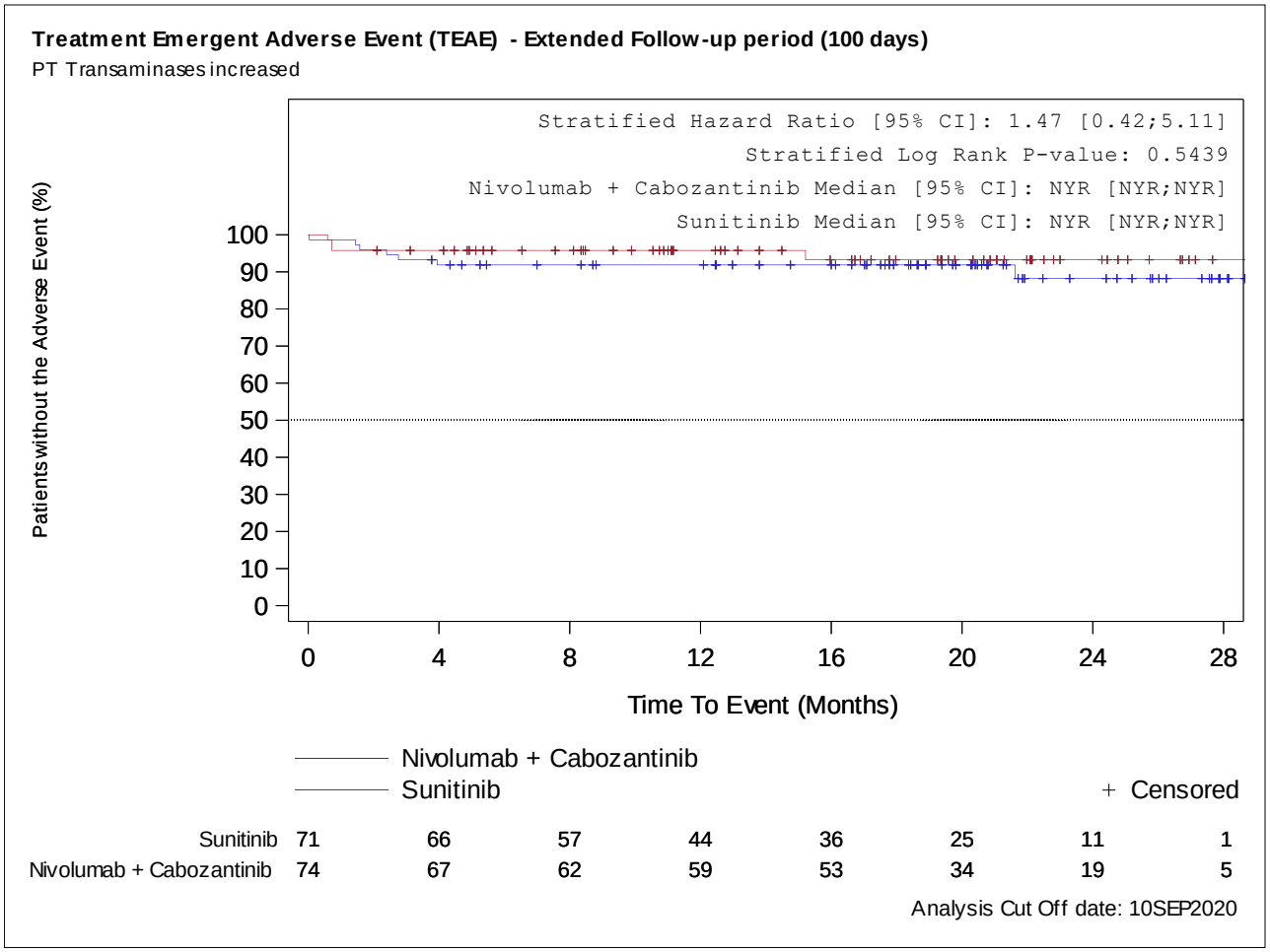
FIGURE 4.4.2.92: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Transaminases increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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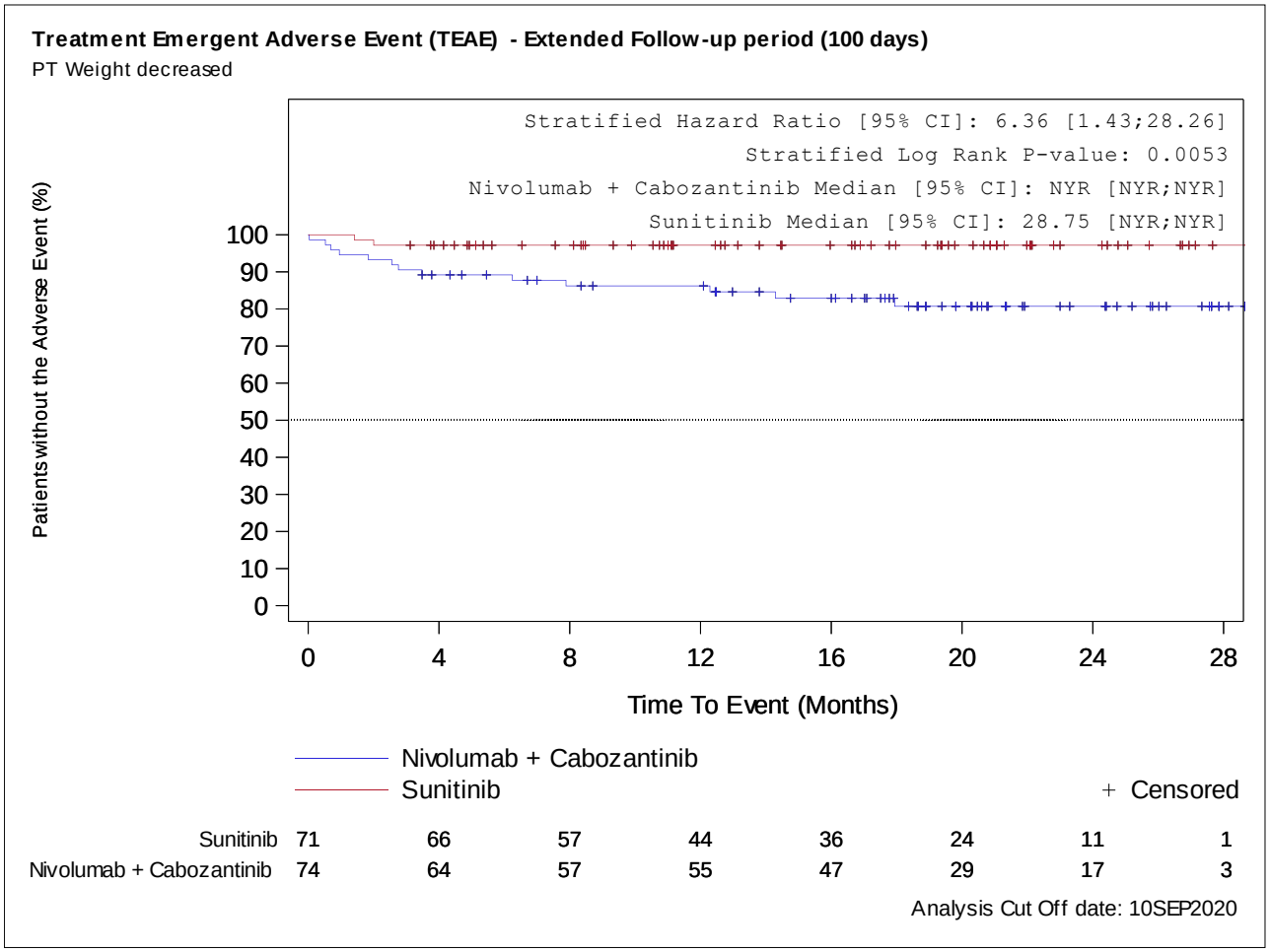
FIGURE 4.4.2.93: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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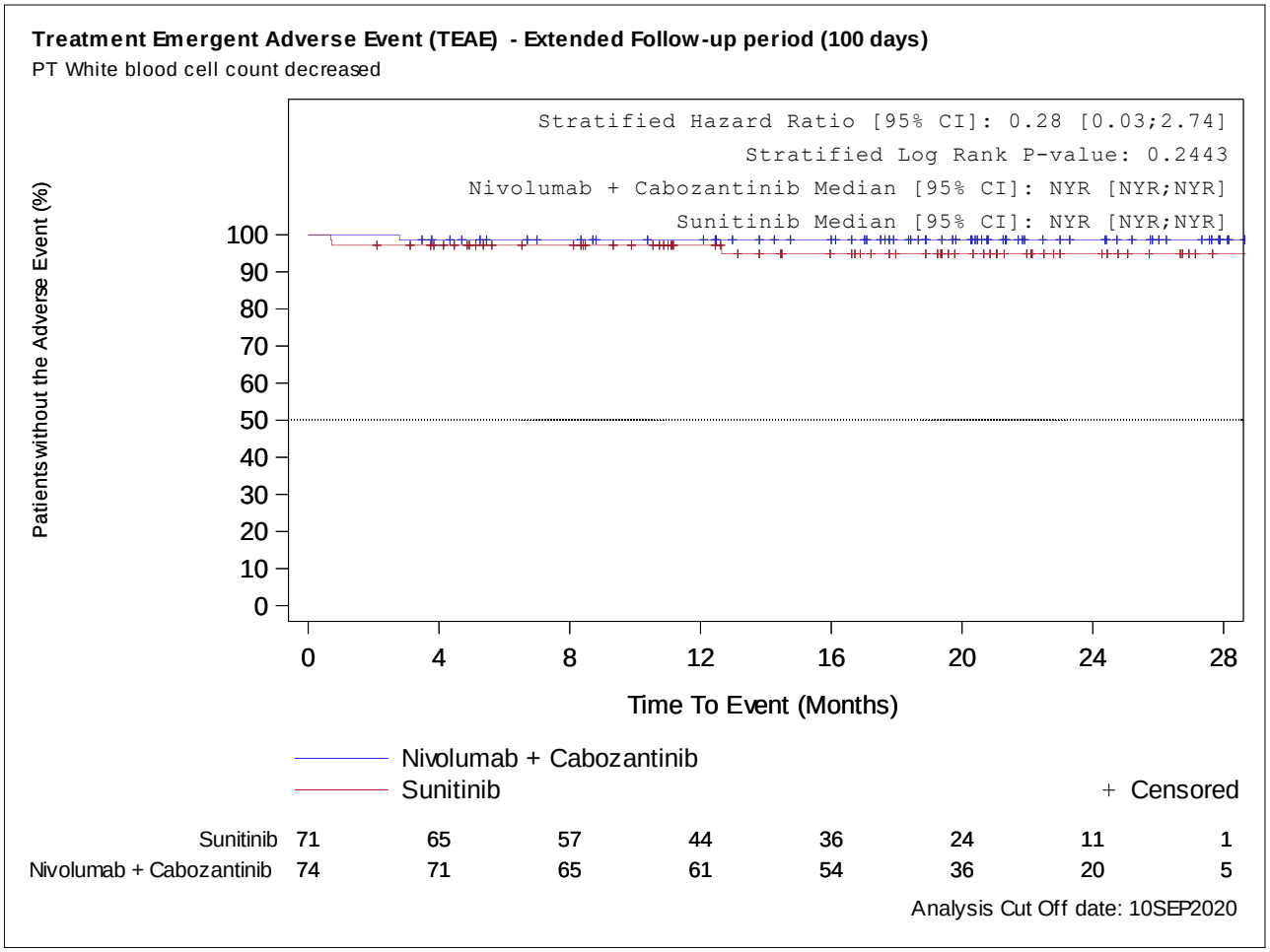
FIGURE 4.4.2.94: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT White blood cell count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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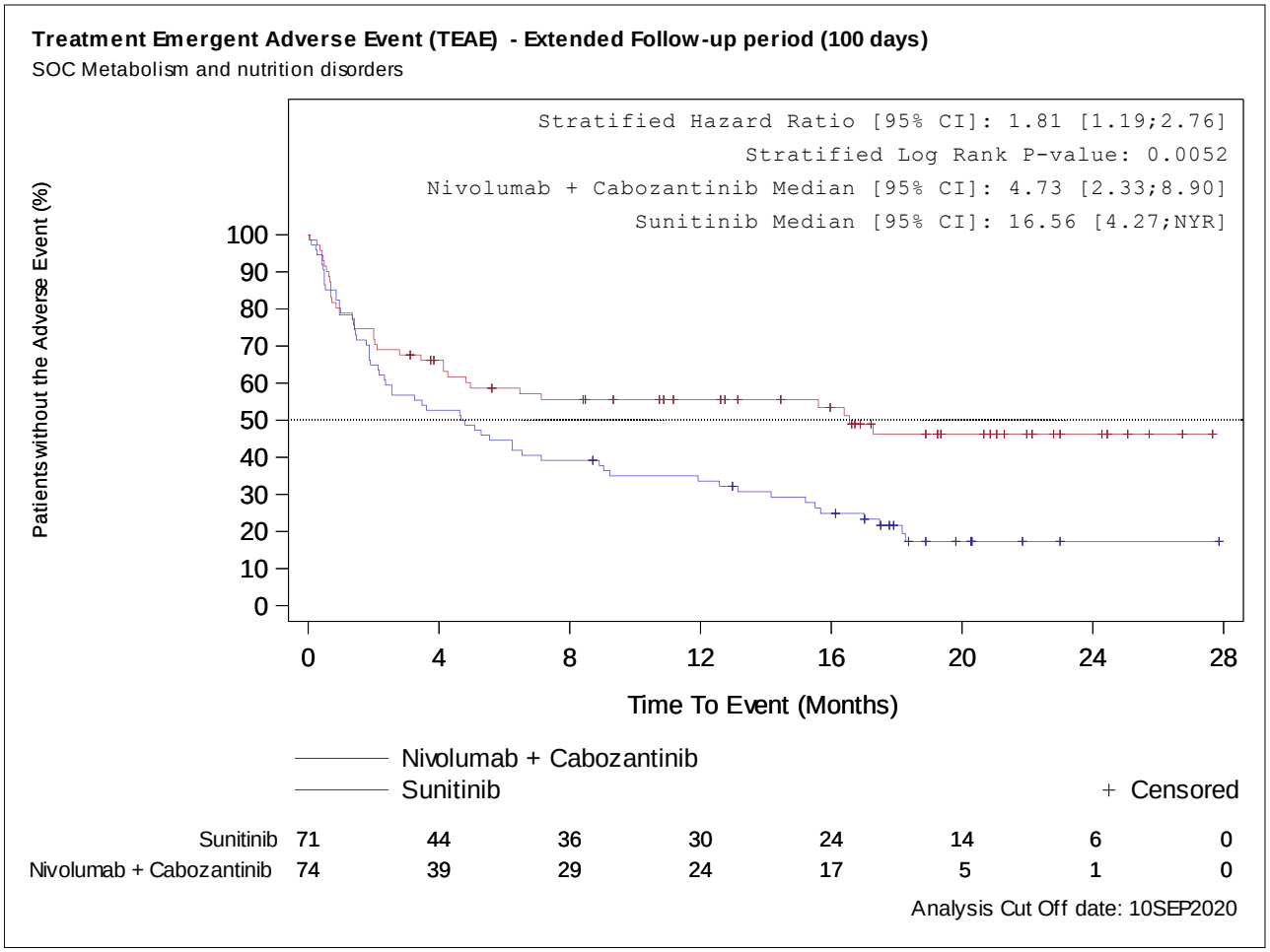
FIGURE 4.4.2.95: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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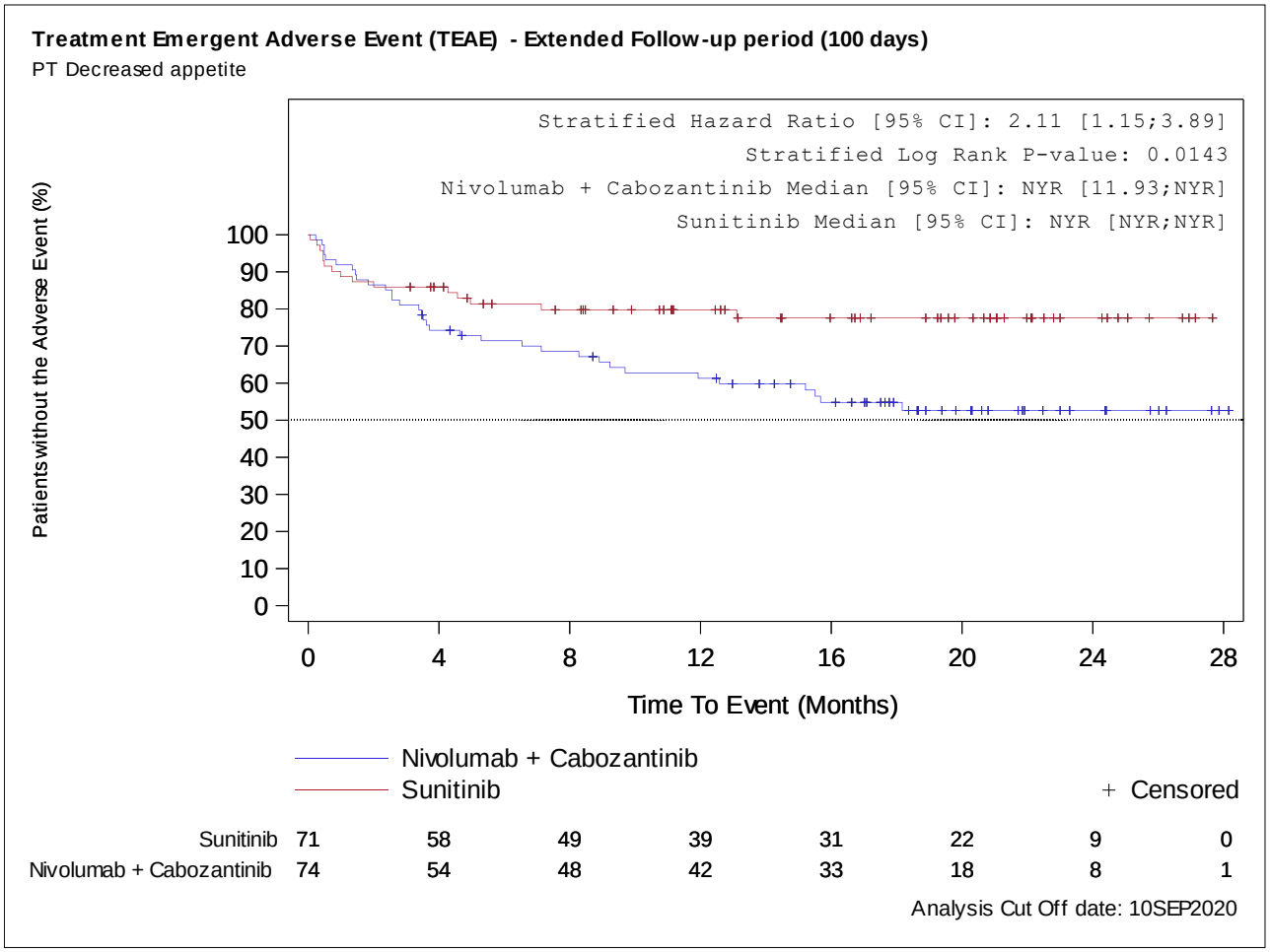
FIGURE 4.4.2.96: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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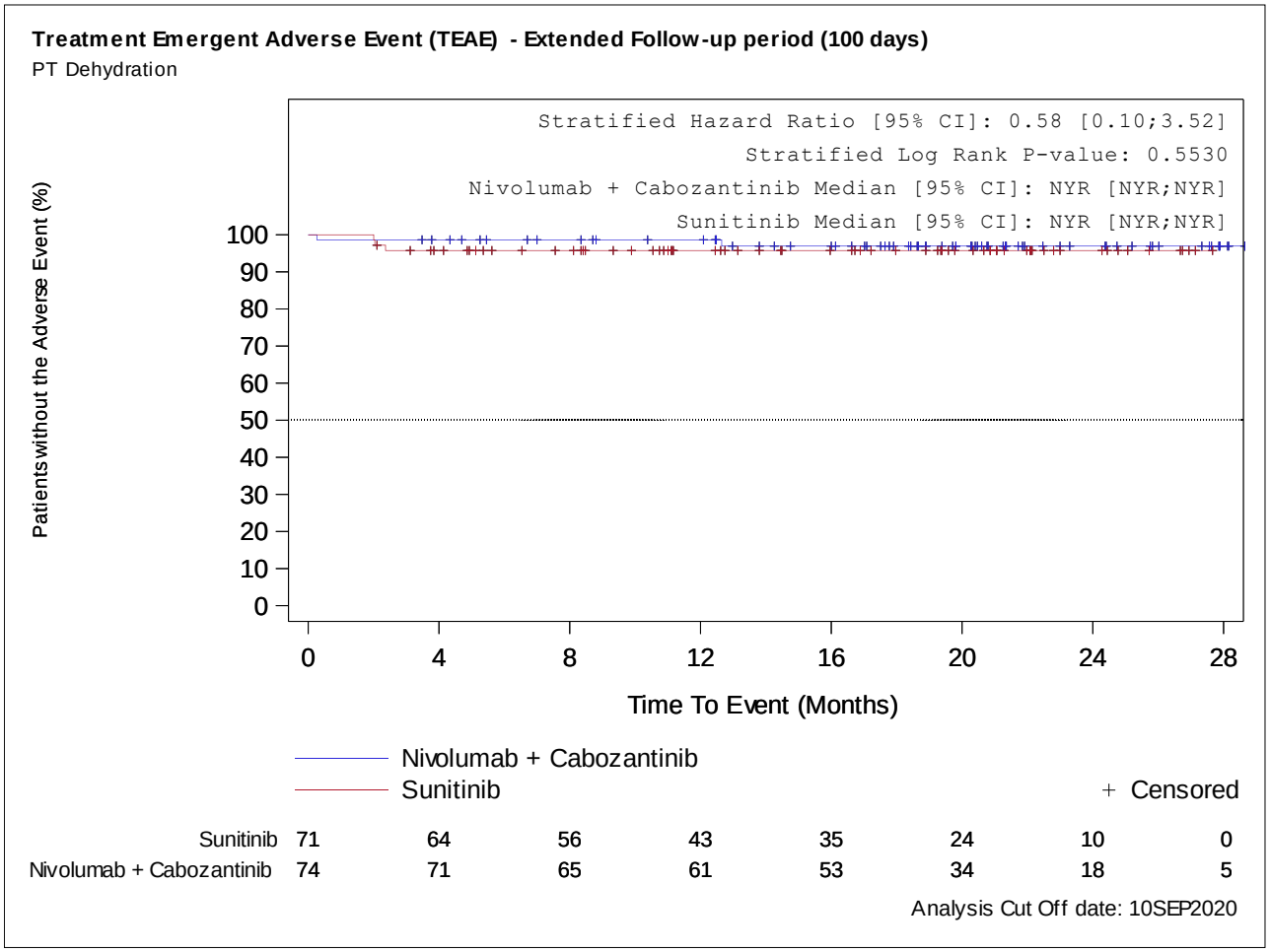
FIGURE 4.4.2.97: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dehydration - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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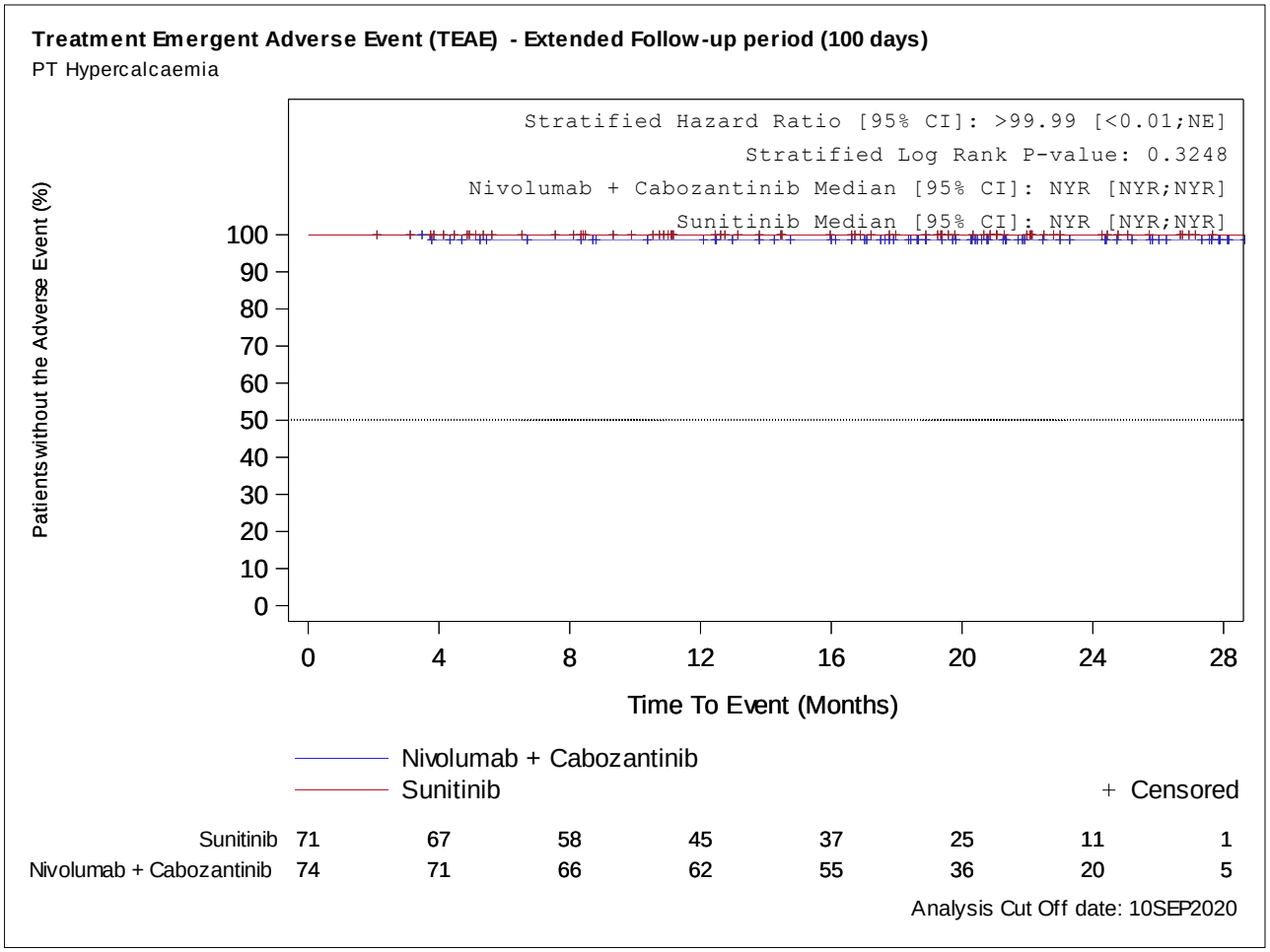
FIGURE 4.4.2.98: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypercalcaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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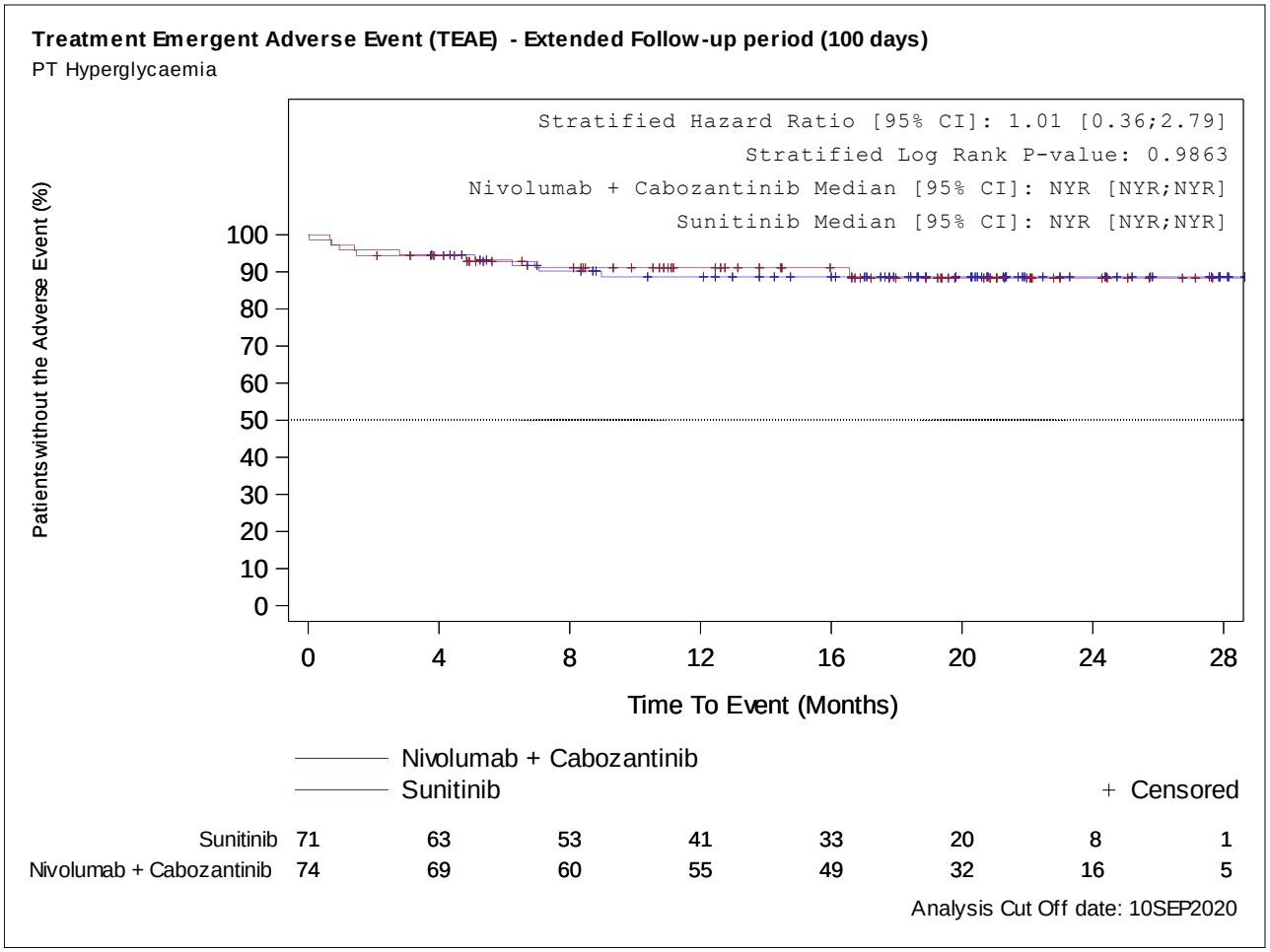
FIGURE 4.4.2.99: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hyperglycaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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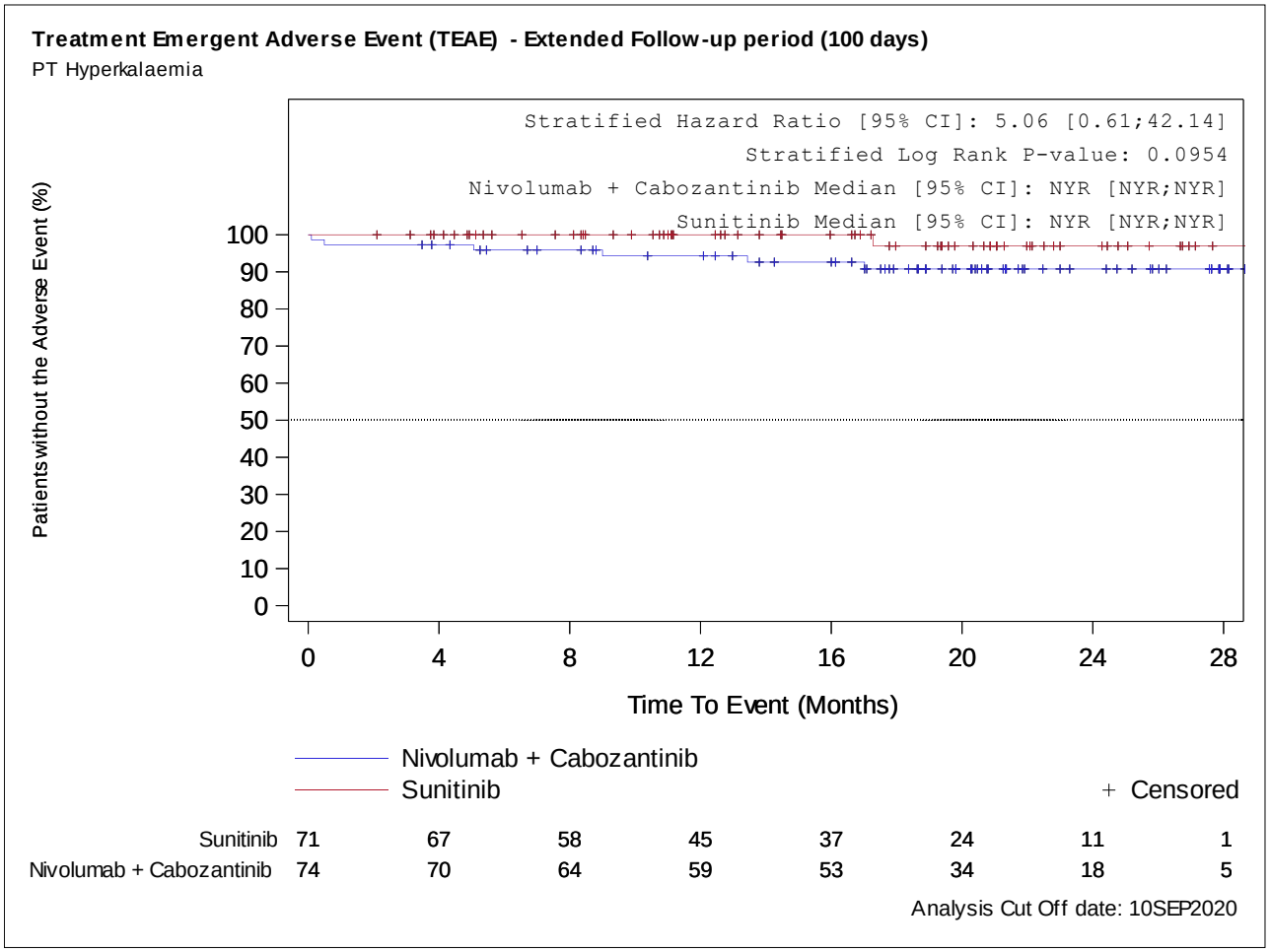
FIGURE 4.4.2.100: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hyperkalaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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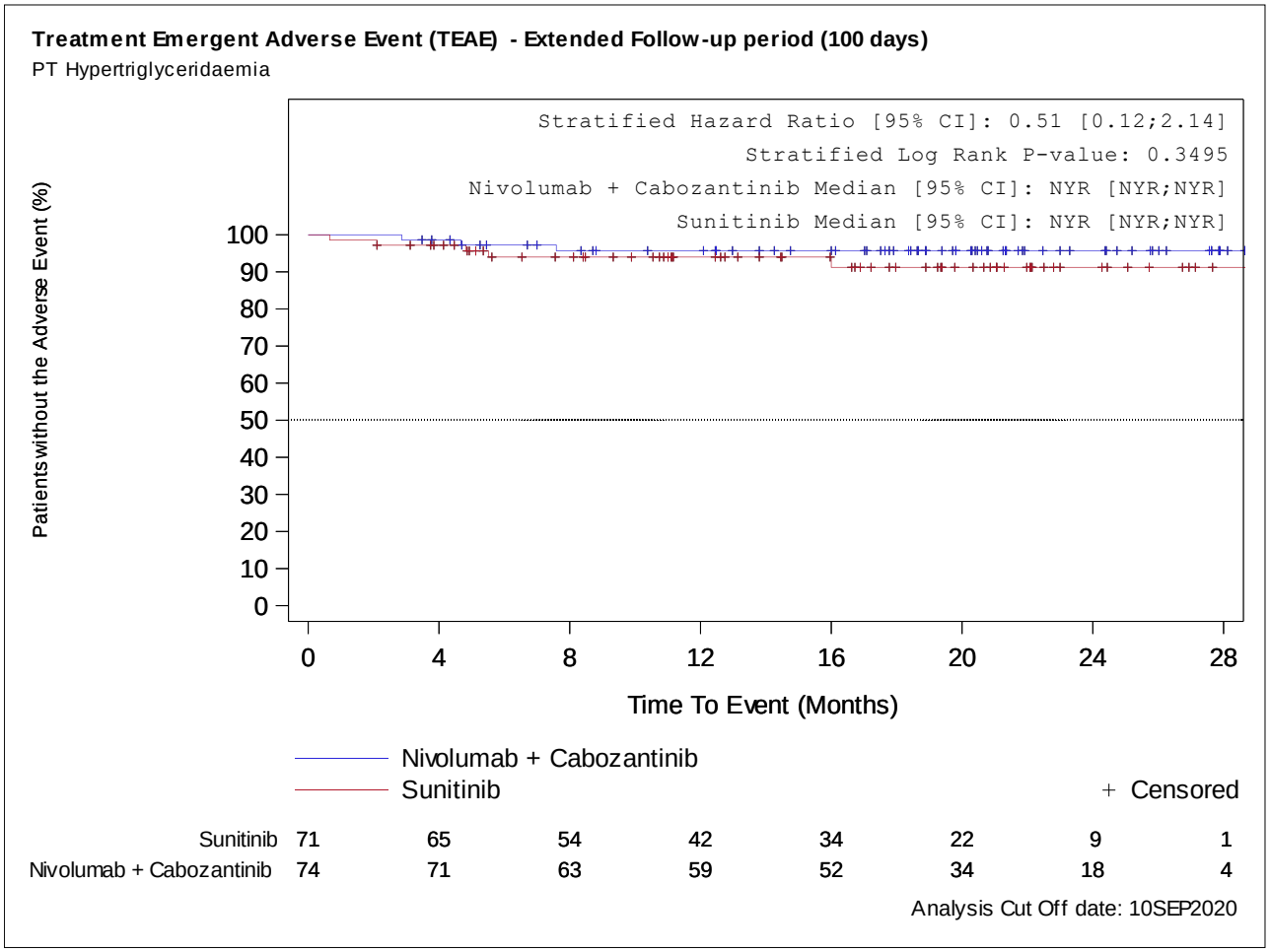
FIGURE 4.4.2.101: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypertriglyceridaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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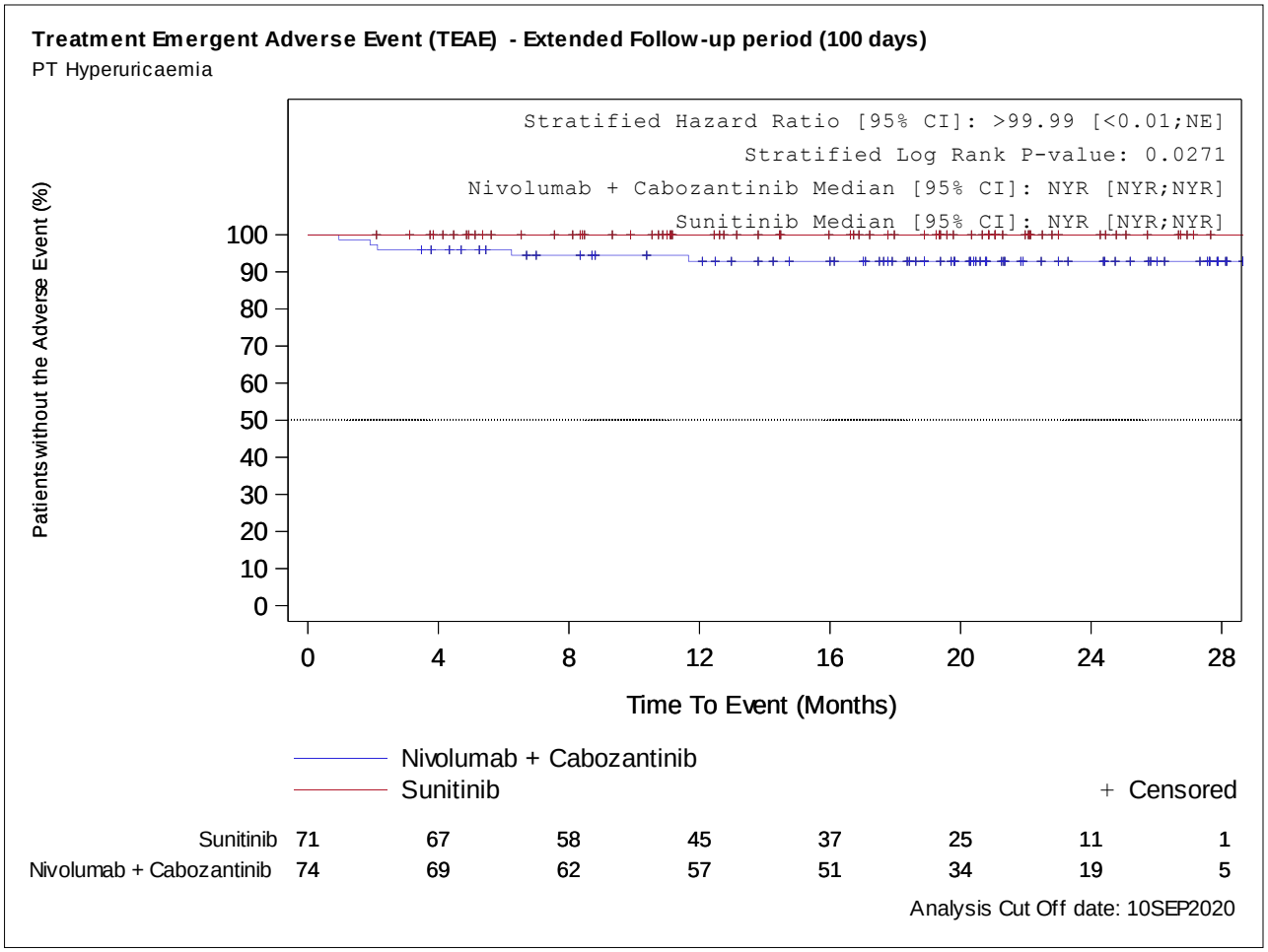
FIGURE 4.4.2.102: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hyperuricaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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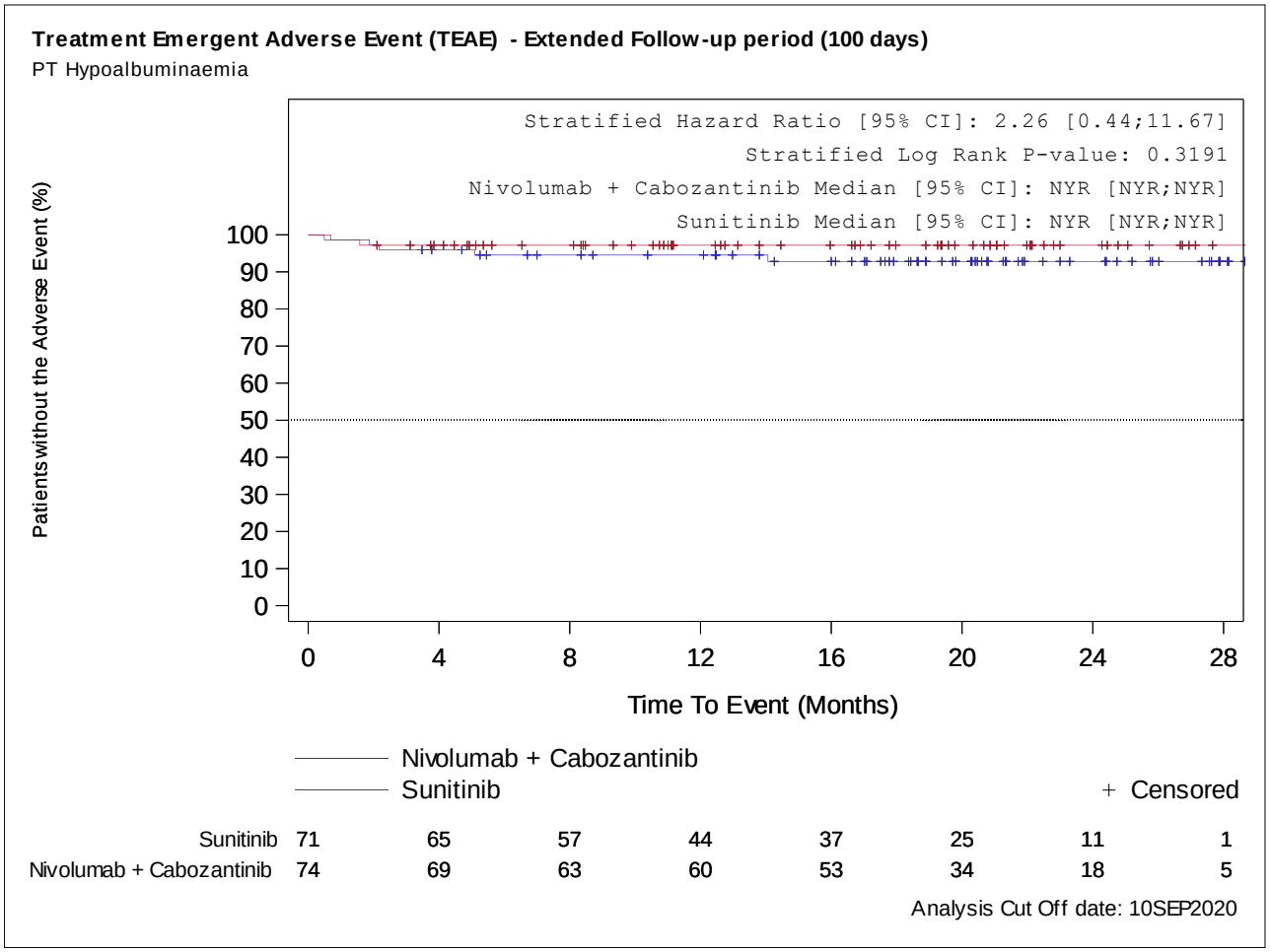
FIGURE 4.4.2.103: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypoalbuminaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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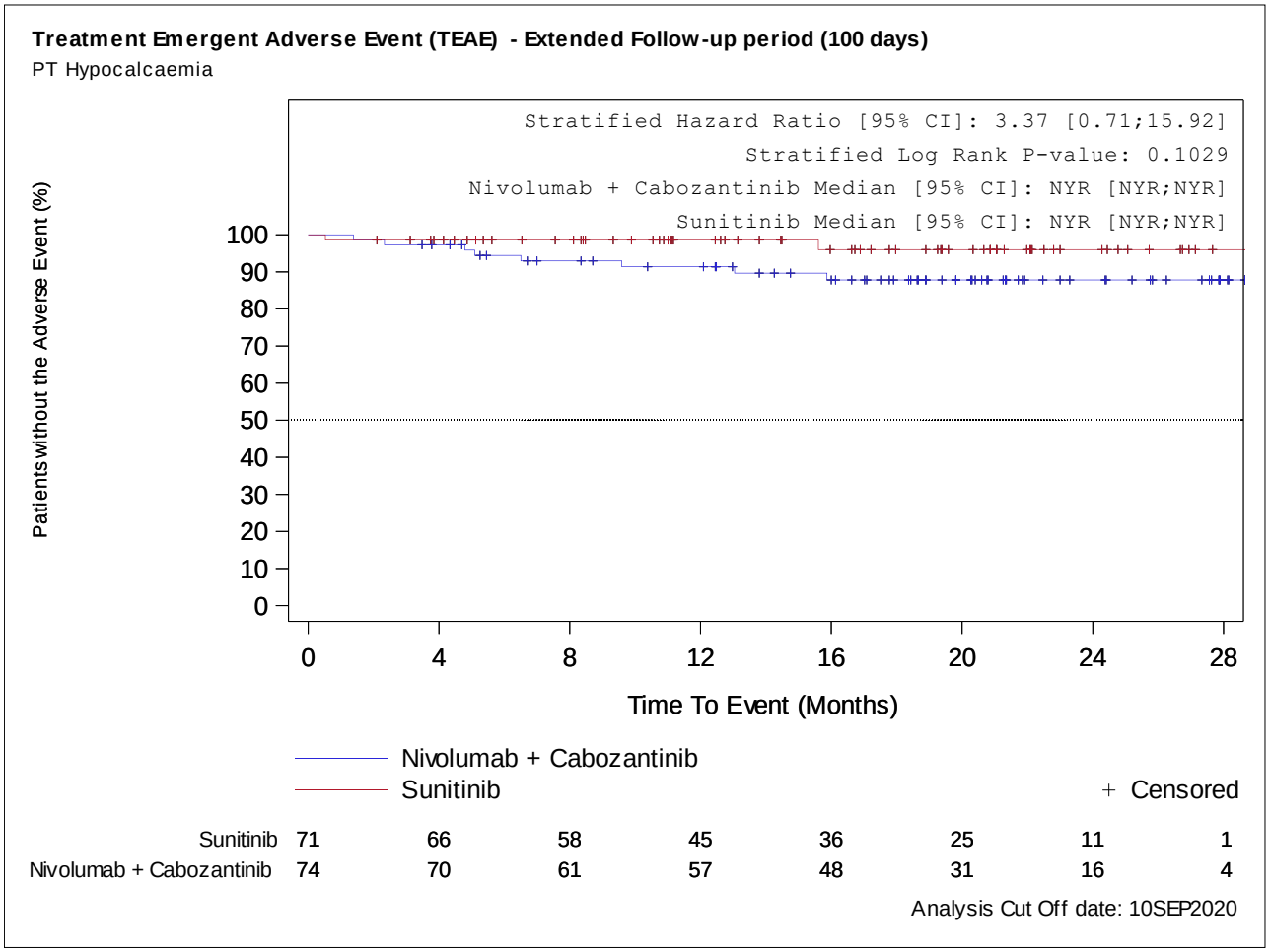
FIGURE 4.4.2.104: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypocalcaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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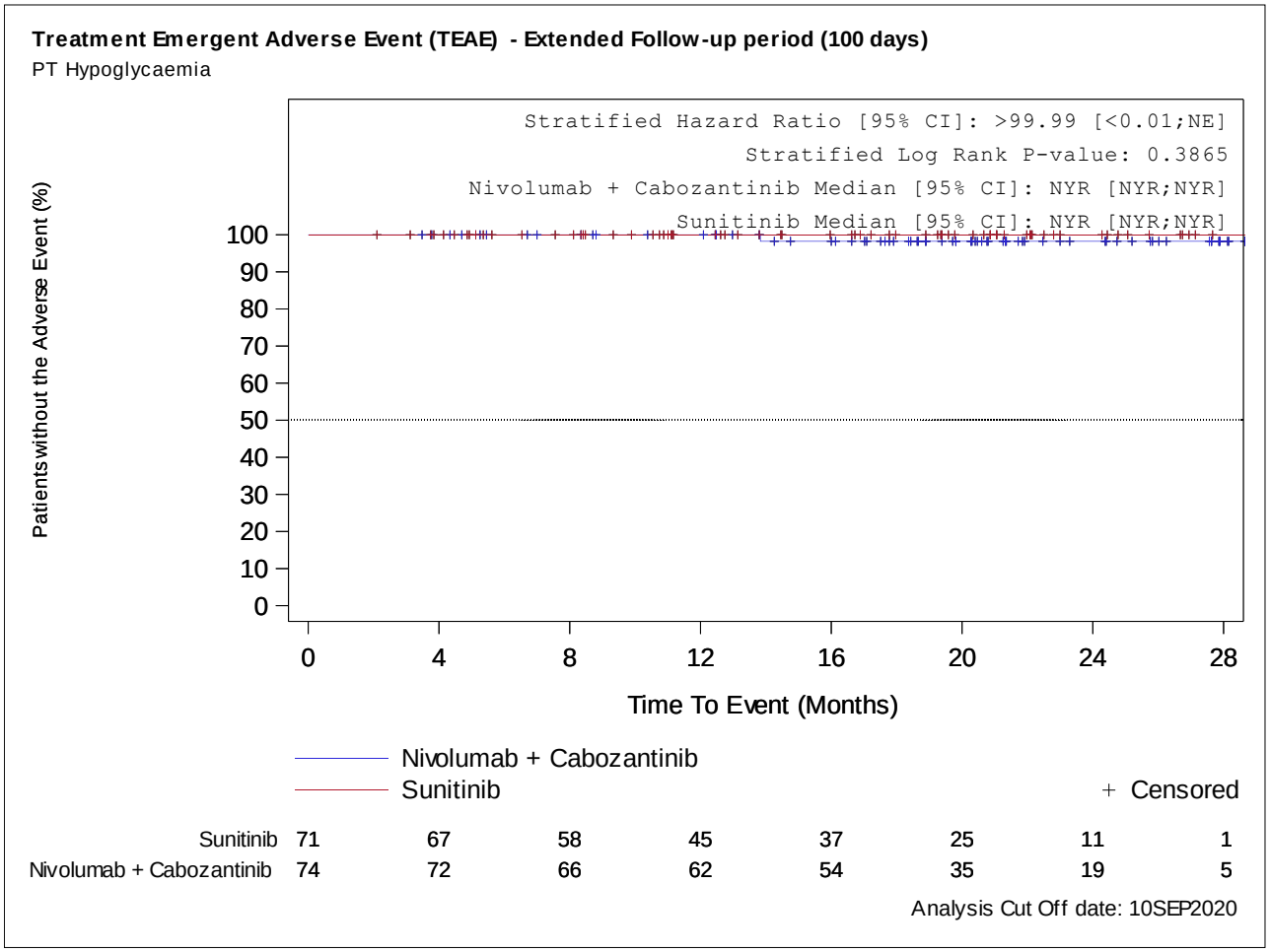
FIGURE 4.4.2.105: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypoglycaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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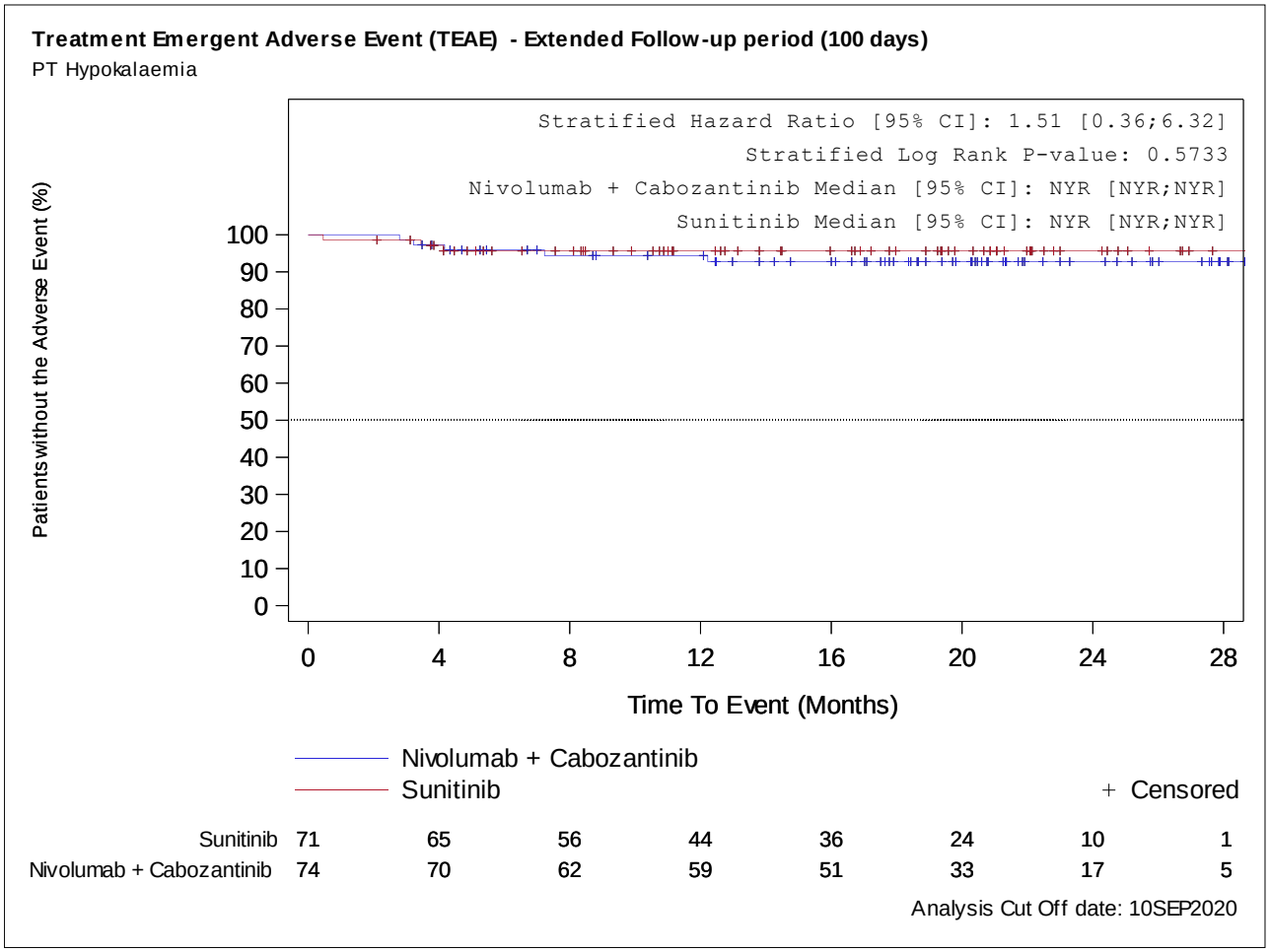
FIGURE 4.4.2.106: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypokalaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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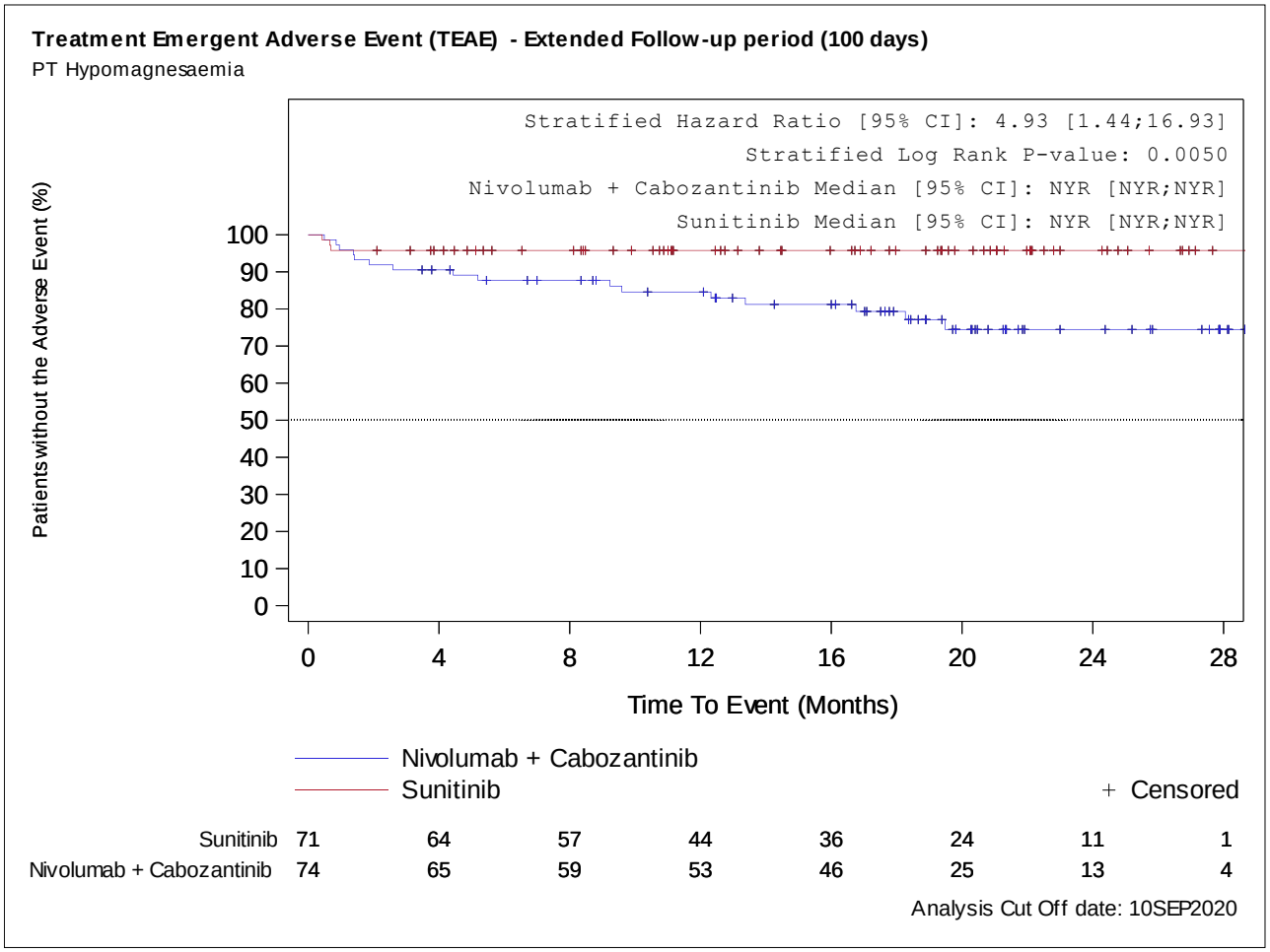
FIGURE 4.4.2.107: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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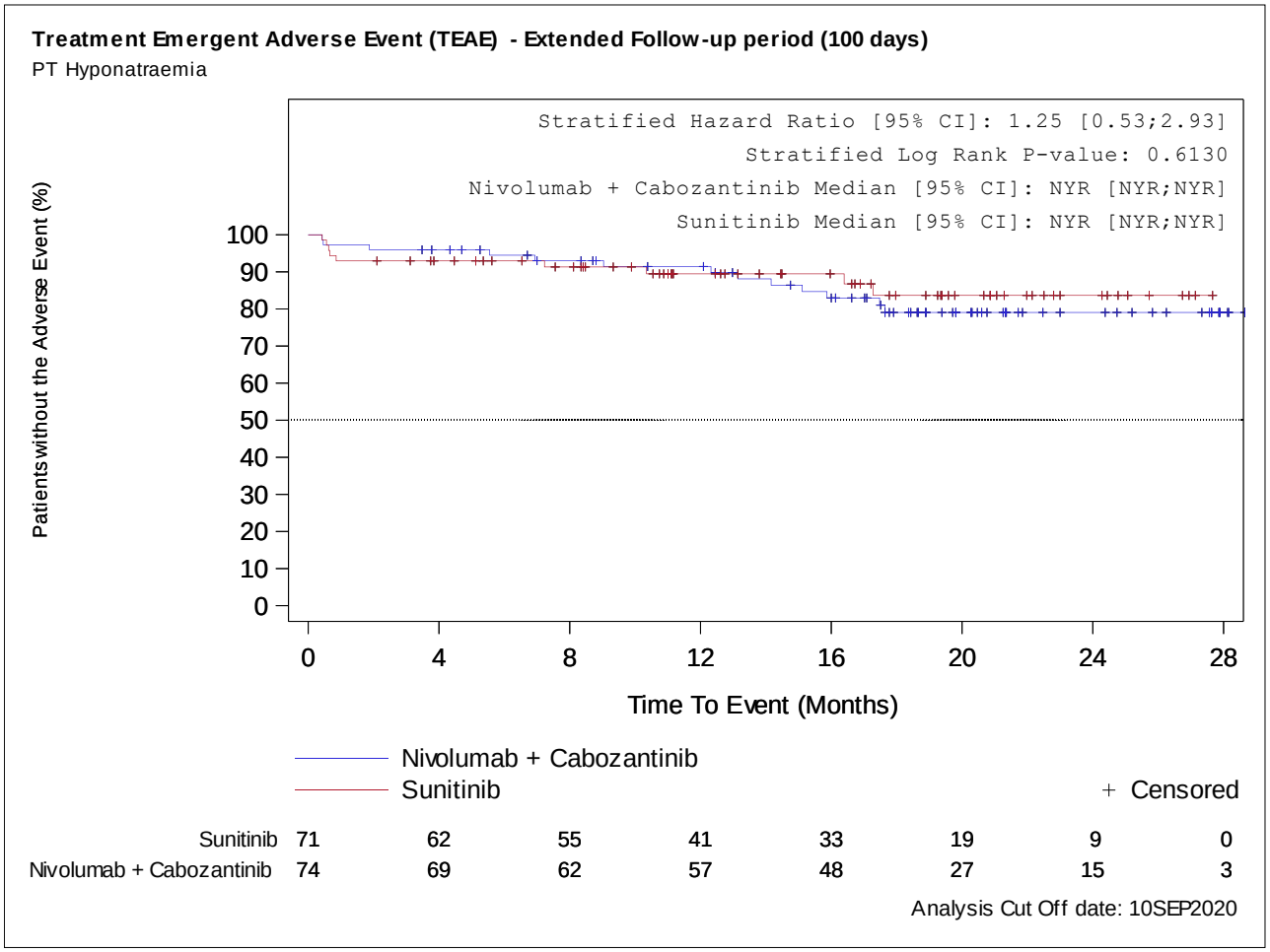
FIGURE 4.4.2.108: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hyponatraemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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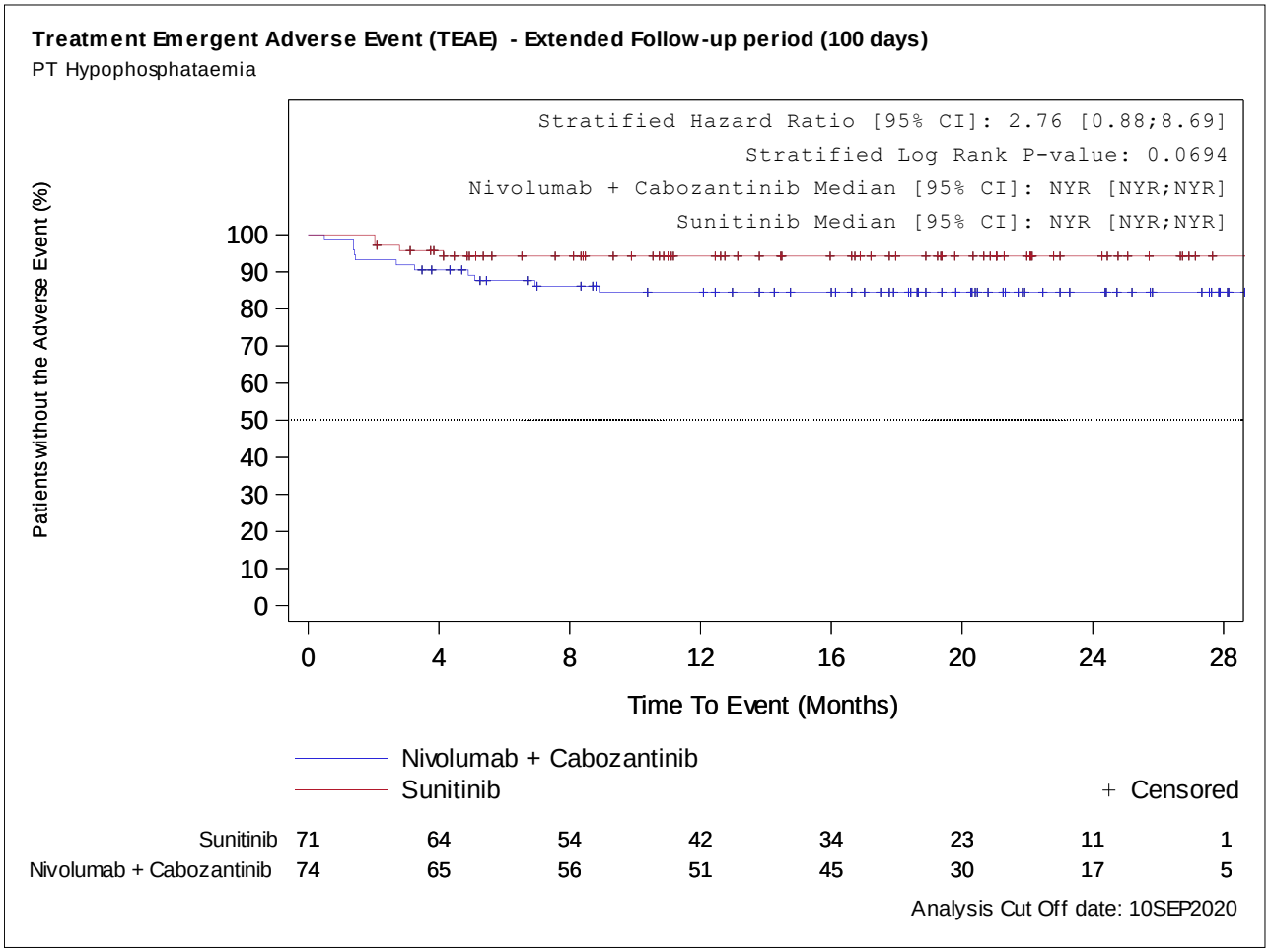
FIGURE 4.4.2.109: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypophosphataemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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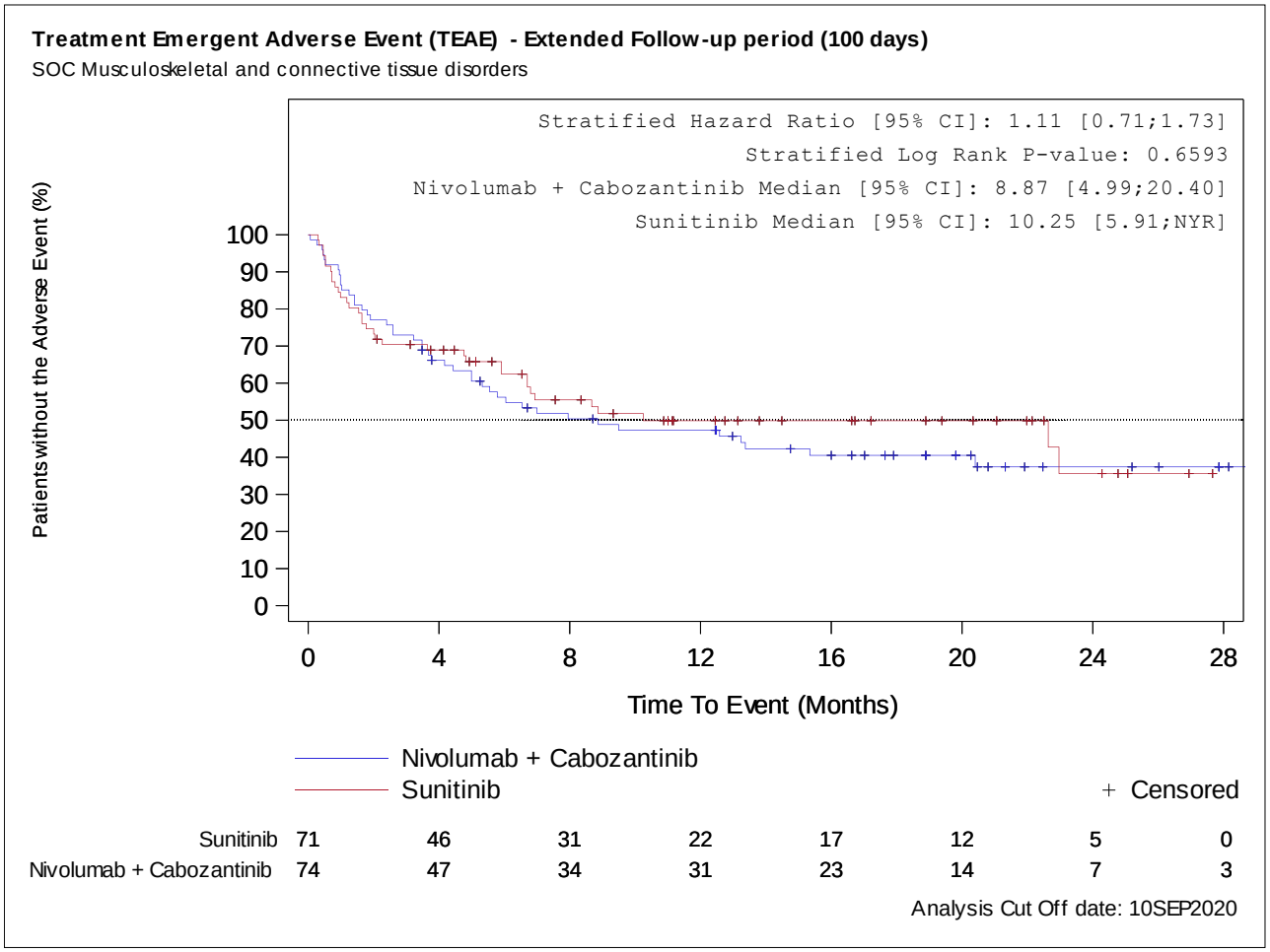
FIGURE 4.4.2.110: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Musculoskeletal and connective tissue disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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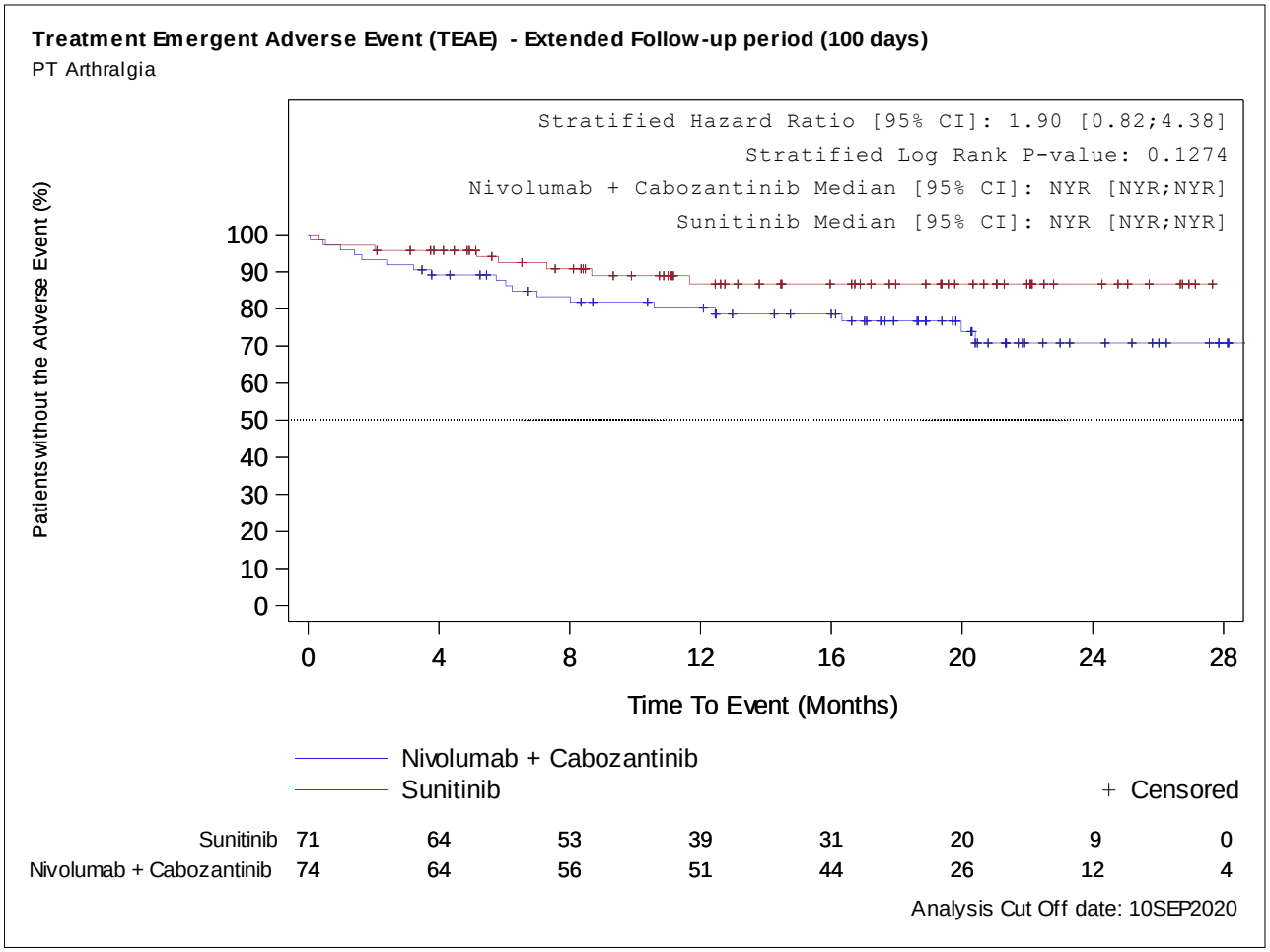
FIGURE 4.4.2.111: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Arthralgia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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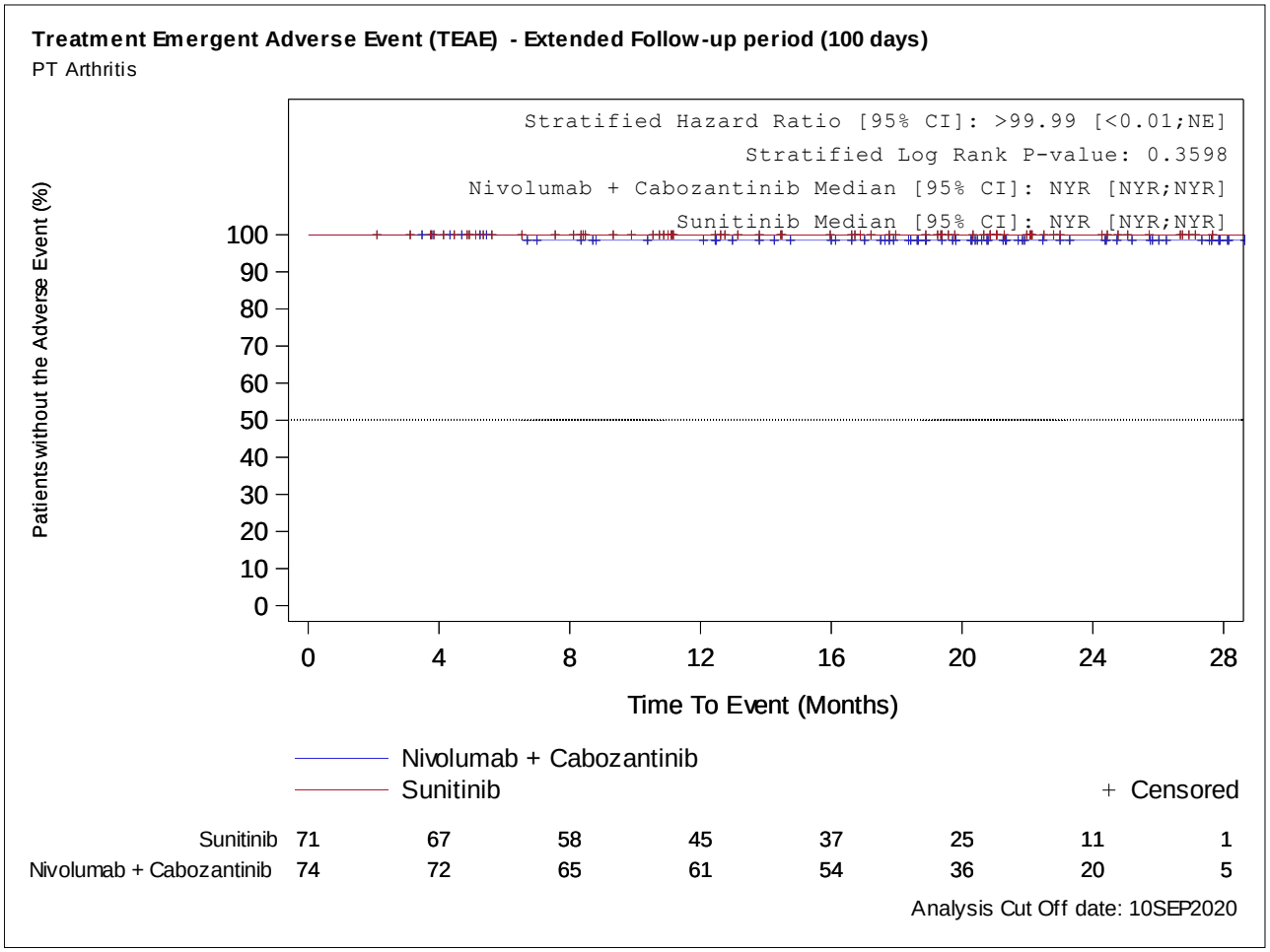
FIGURE 4.4.2.112: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Arthritis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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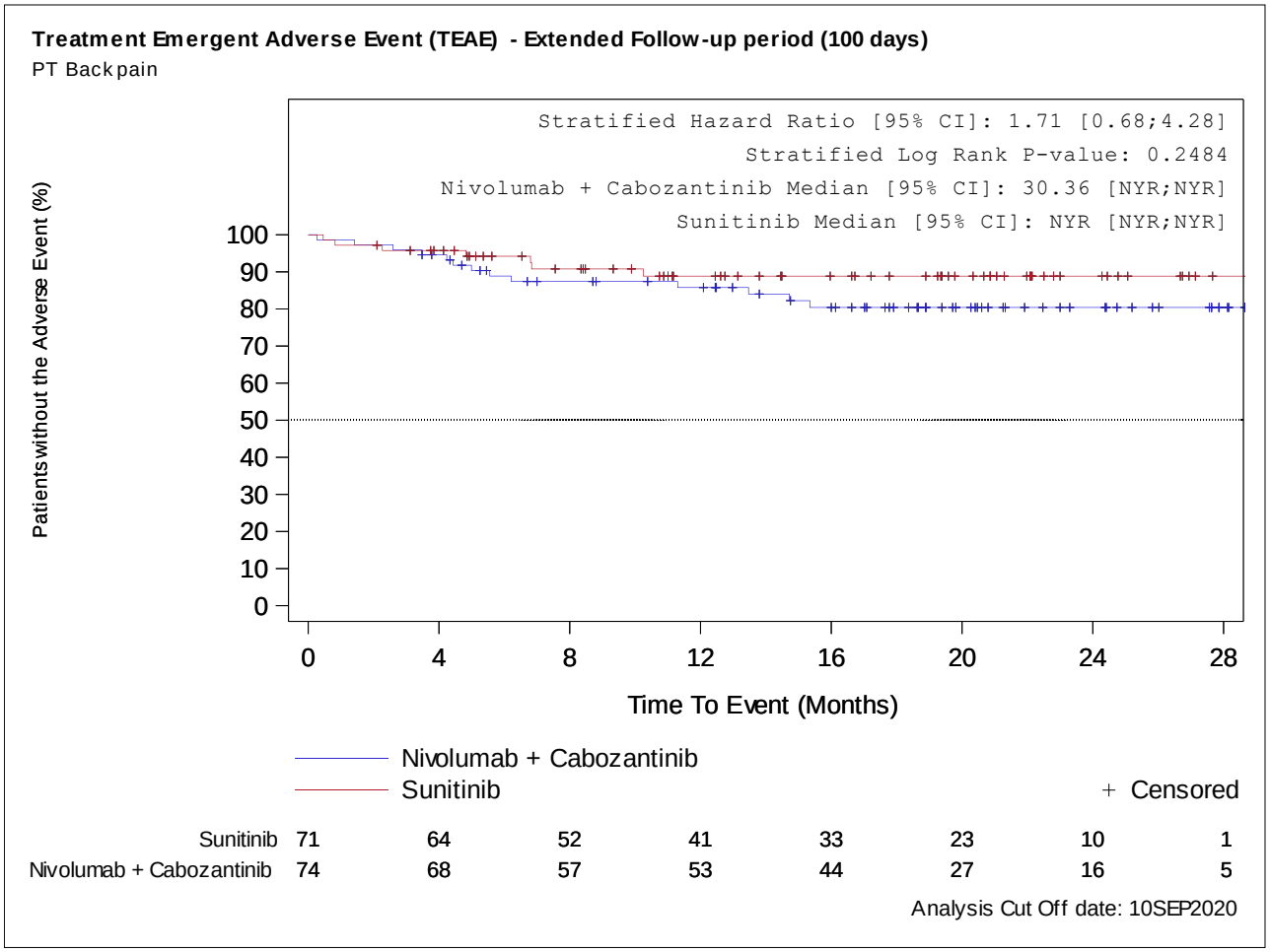
FIGURE 4.4.2.113: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Back pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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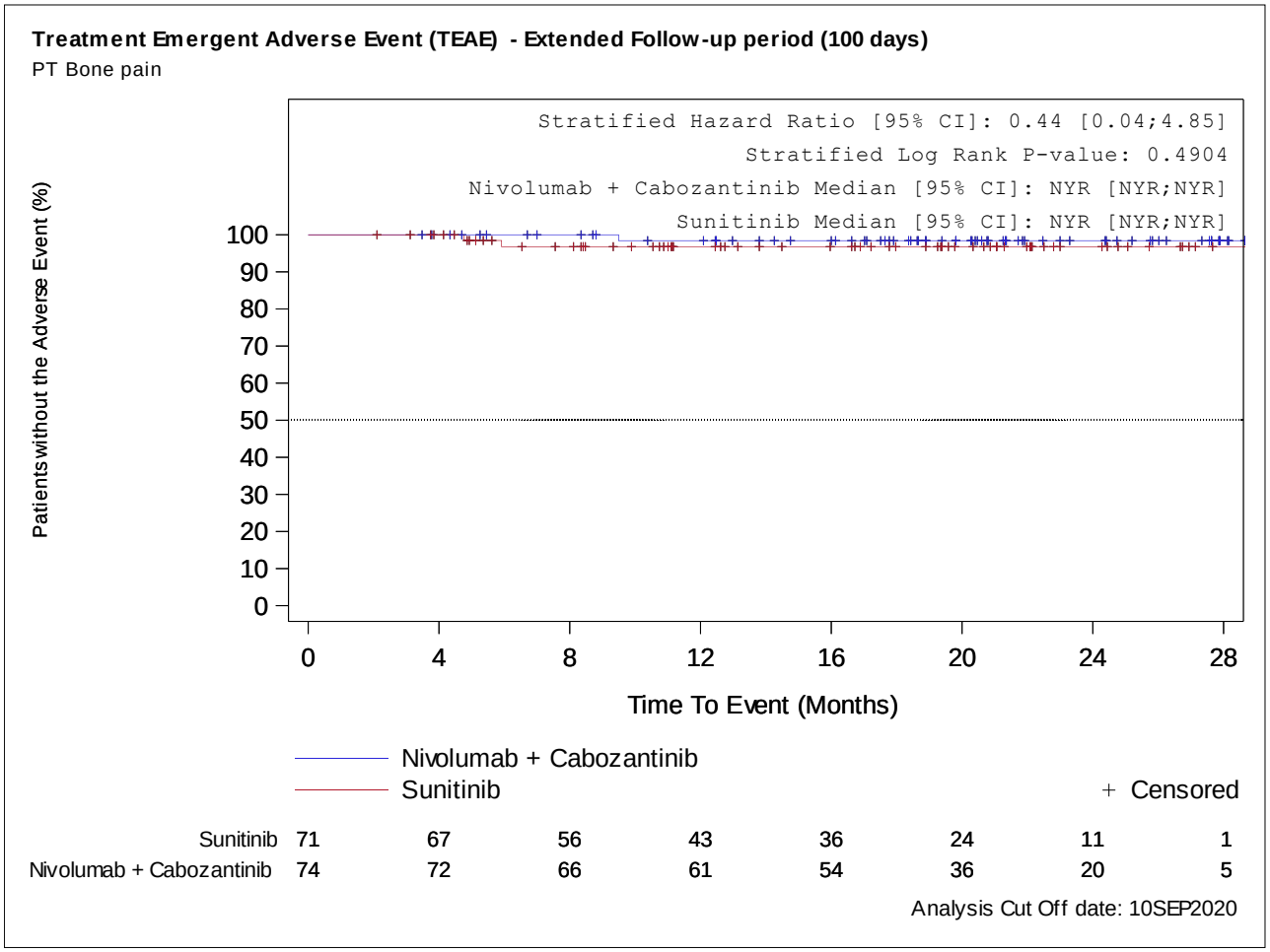
FIGURE 4.4.2.114: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Bone pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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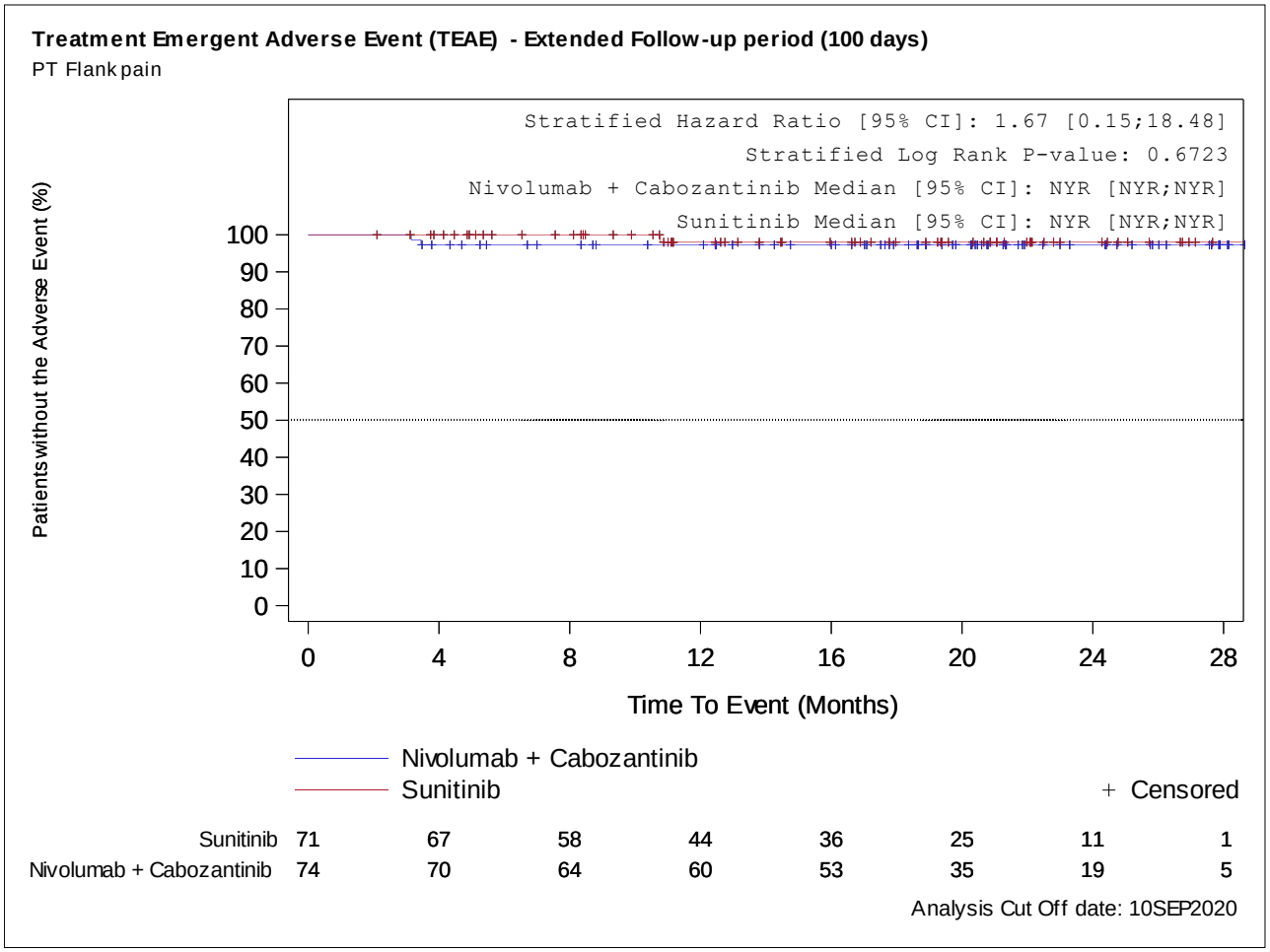
FIGURE 4.4.2.115: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Flank pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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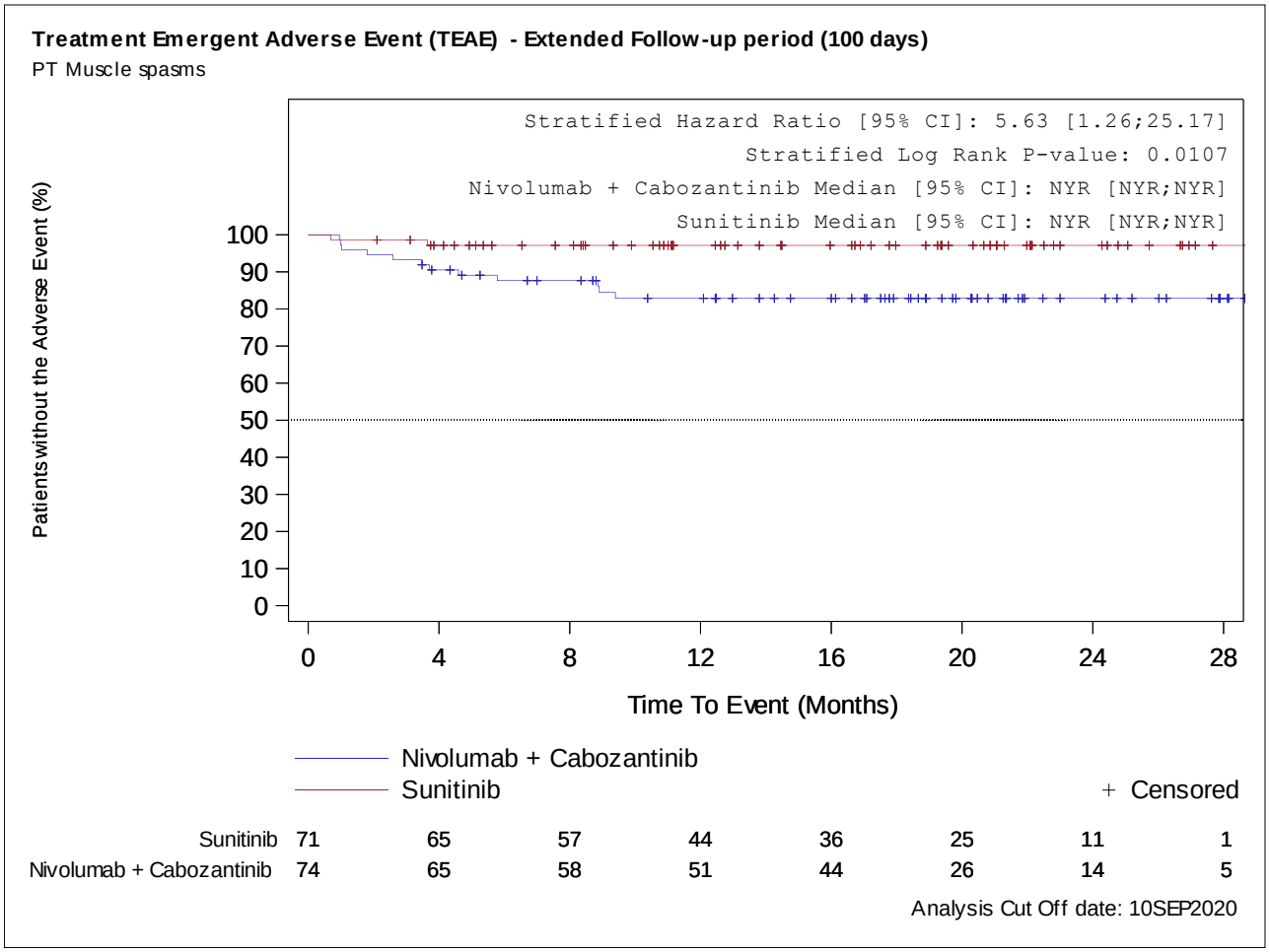
FIGURE 4.4.2.116: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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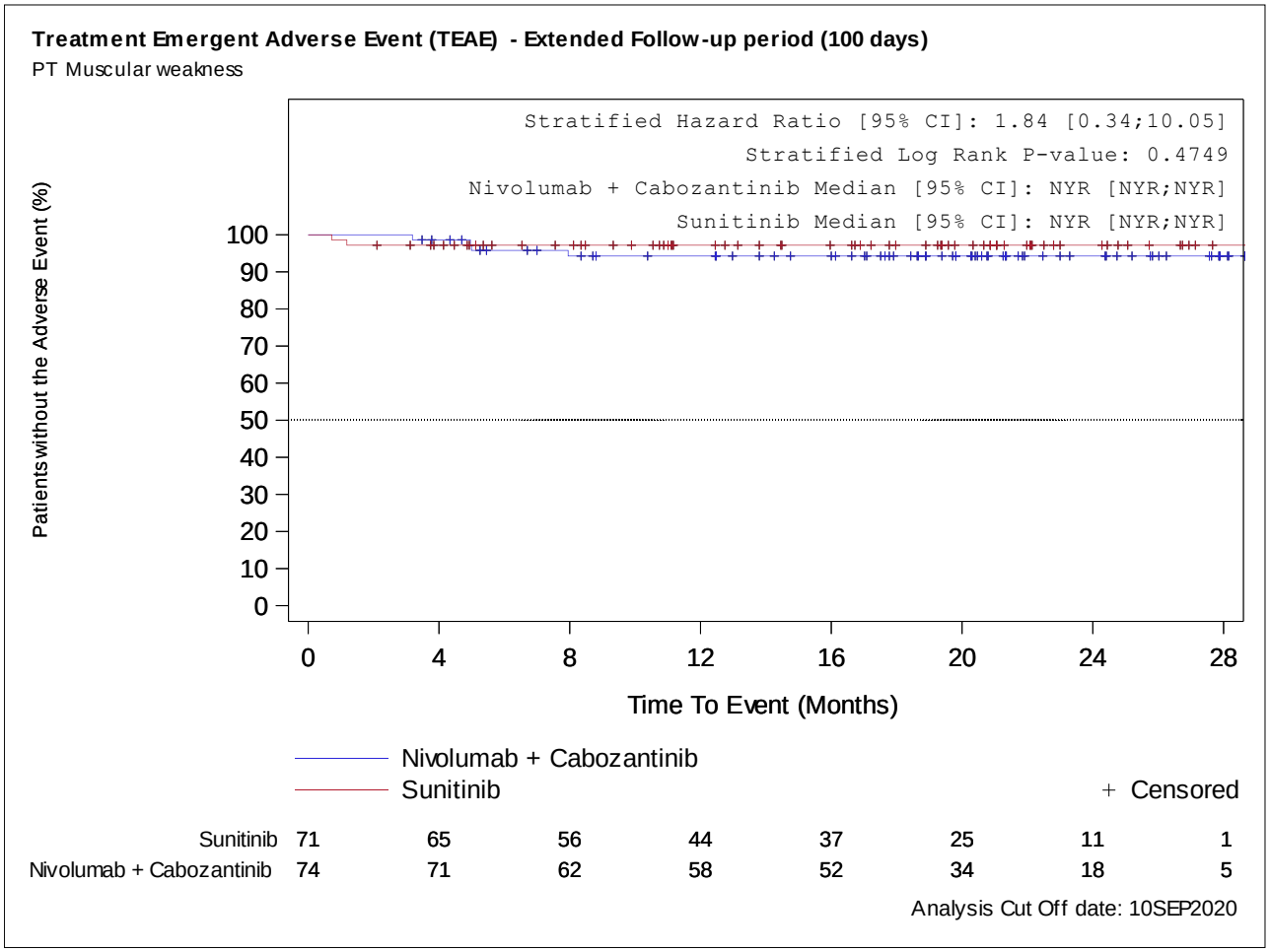
FIGURE 4.4.2.117: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscular weakness - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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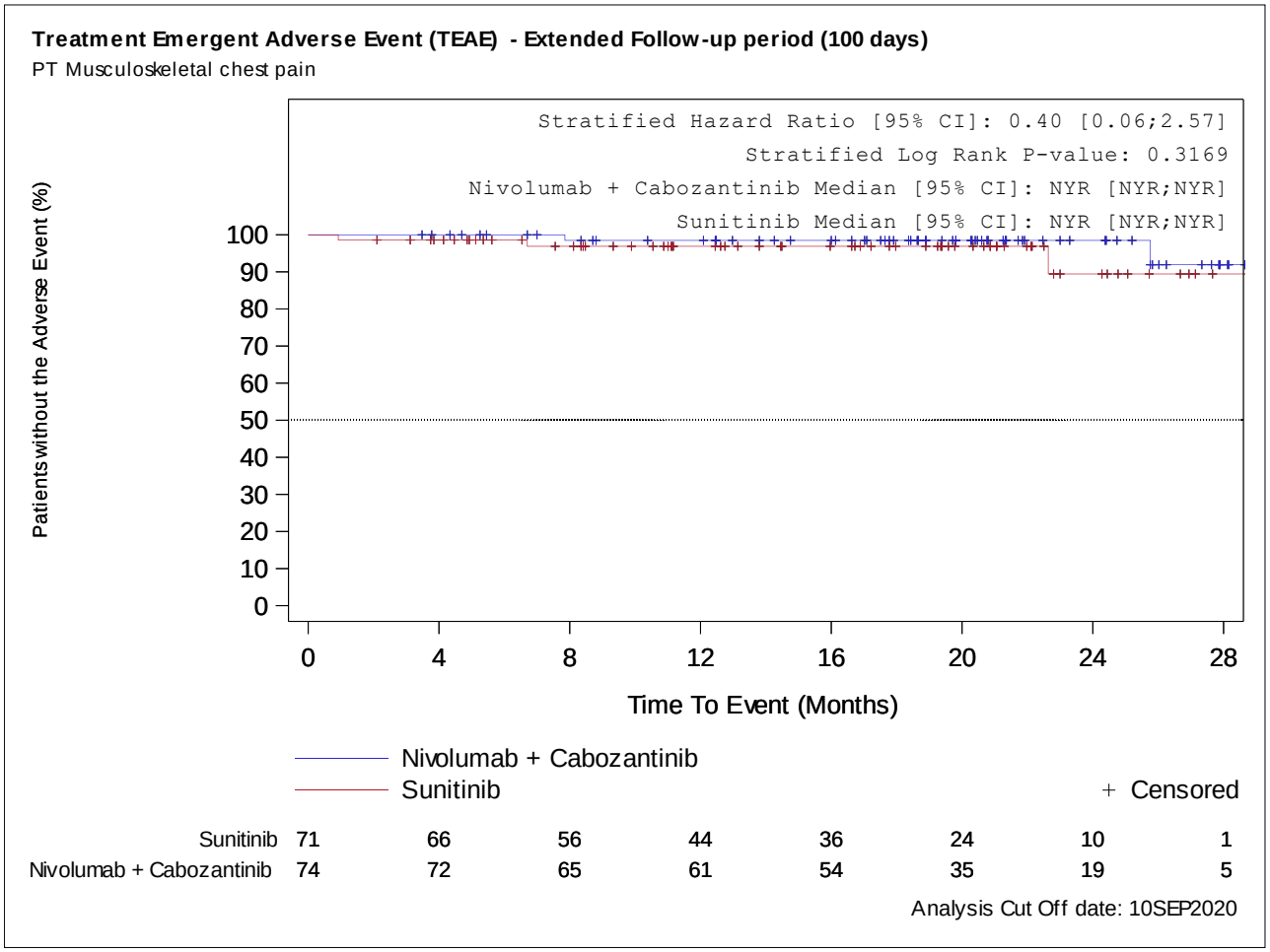
FIGURE 4.4.2.118: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Musculoskeletal chest pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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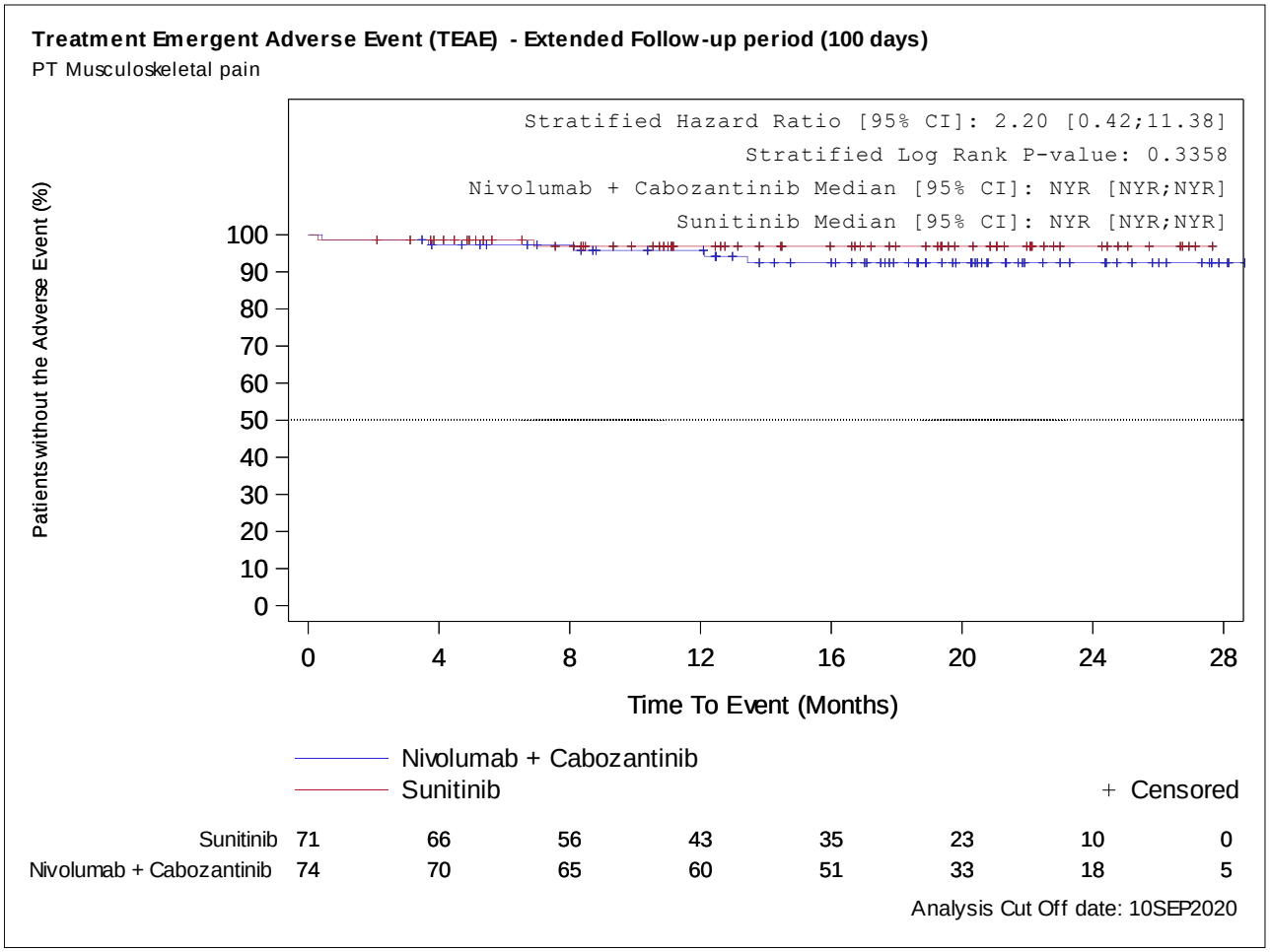
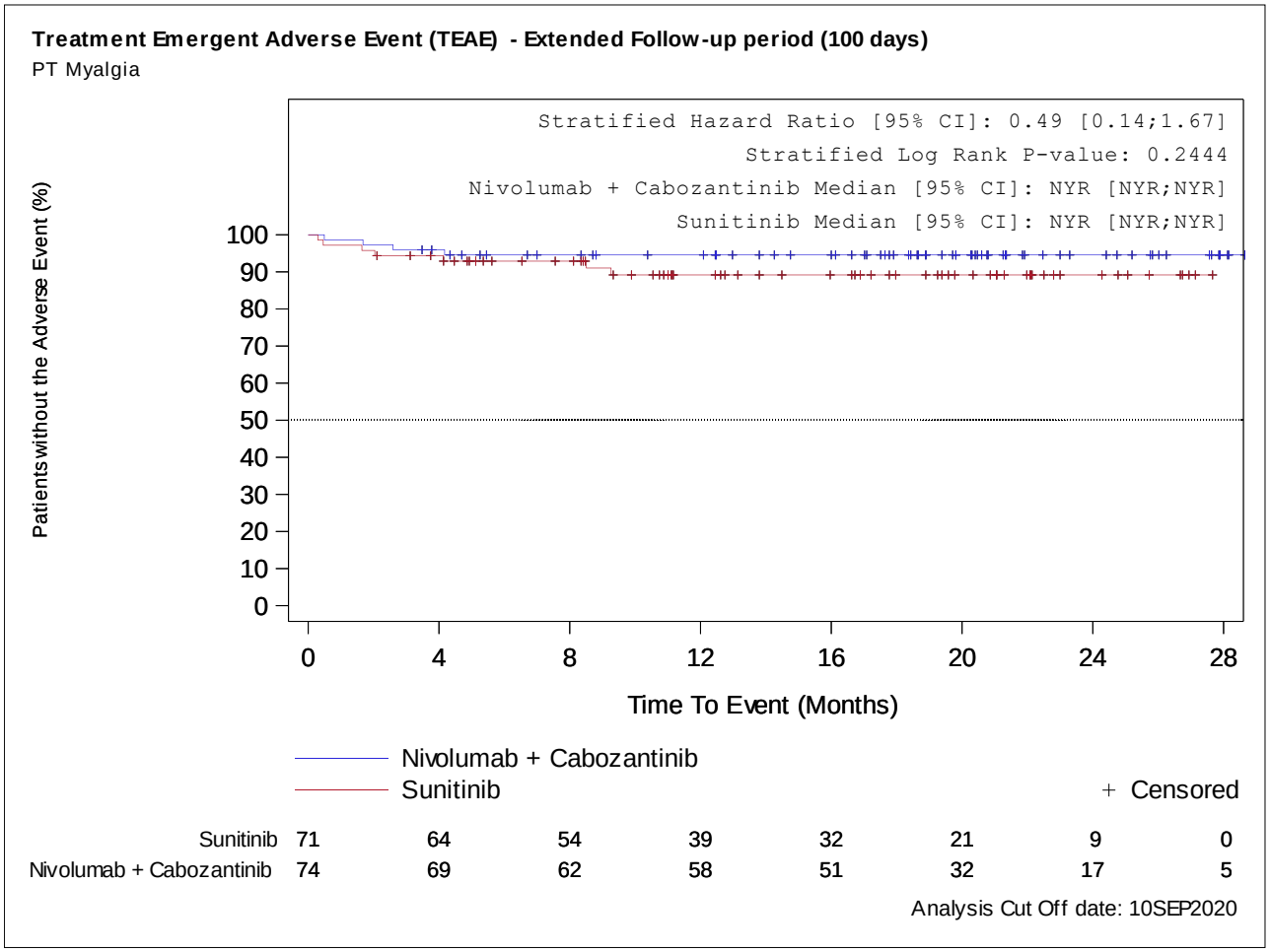
FIGURE 4.4.2.119: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Musculoskeletal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



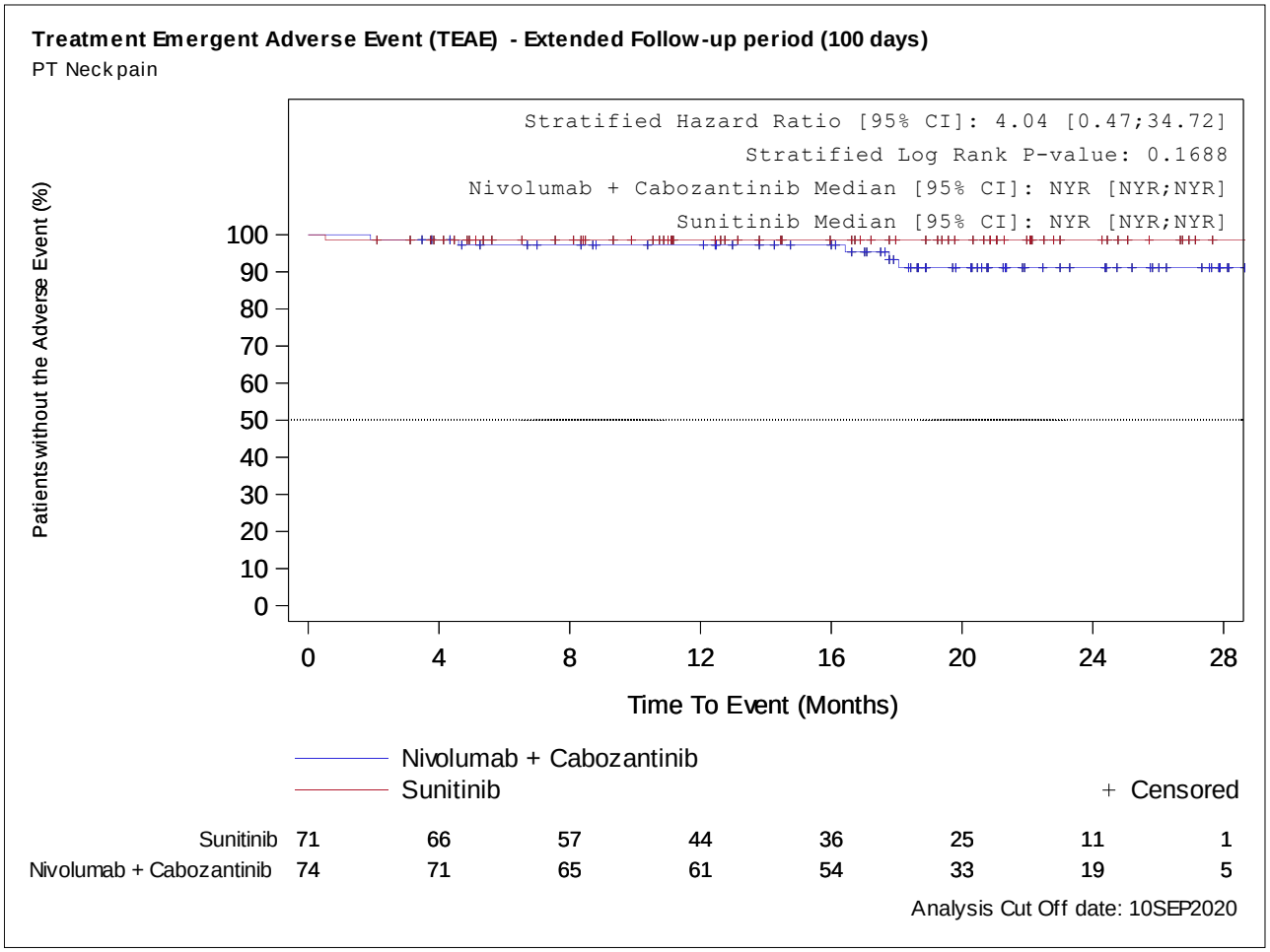

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:27:56

FIGURE 4.4.2.120: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Myalgia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



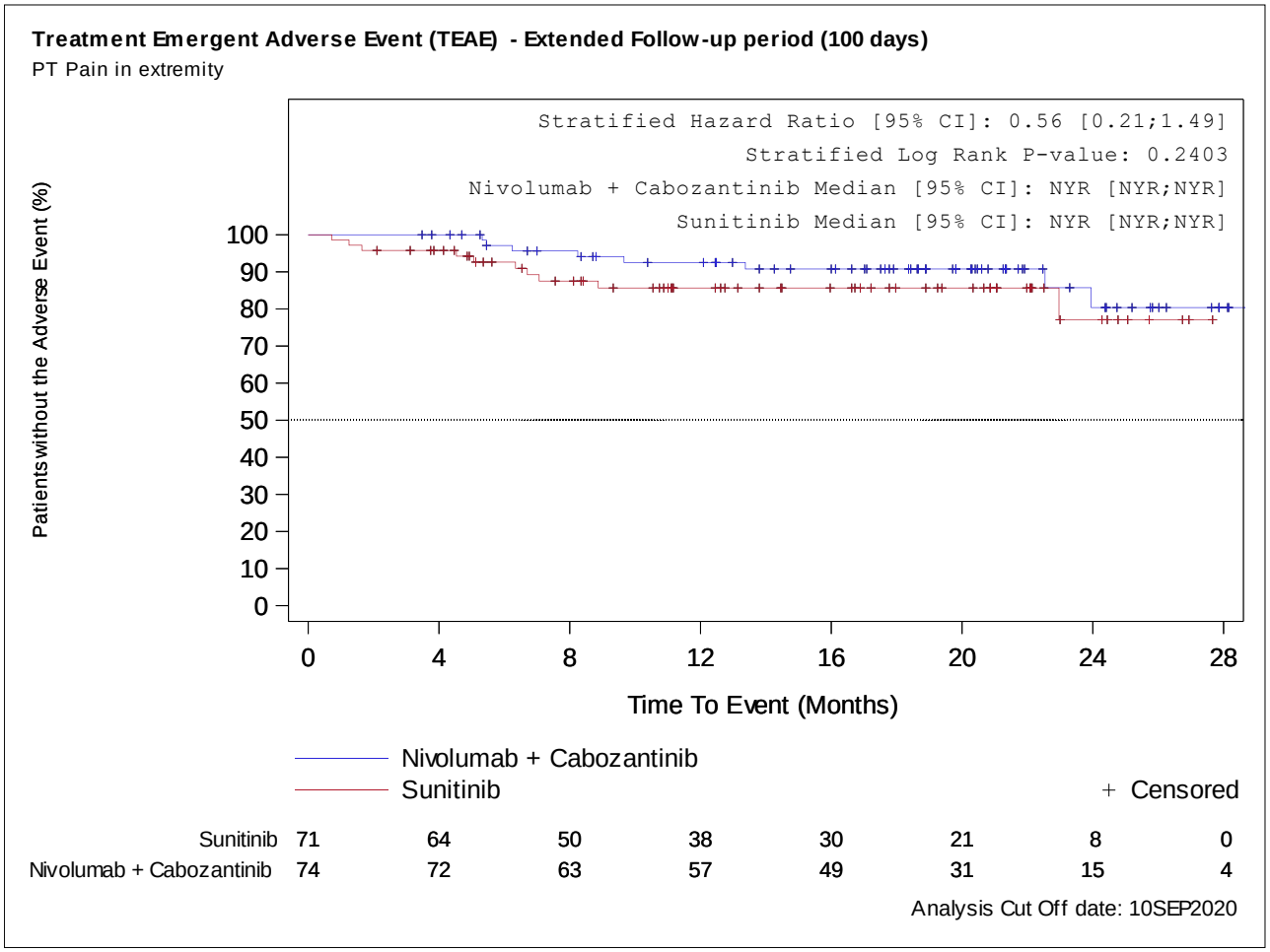

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:28:00

FIGURE 4.4.2.121: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neck pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



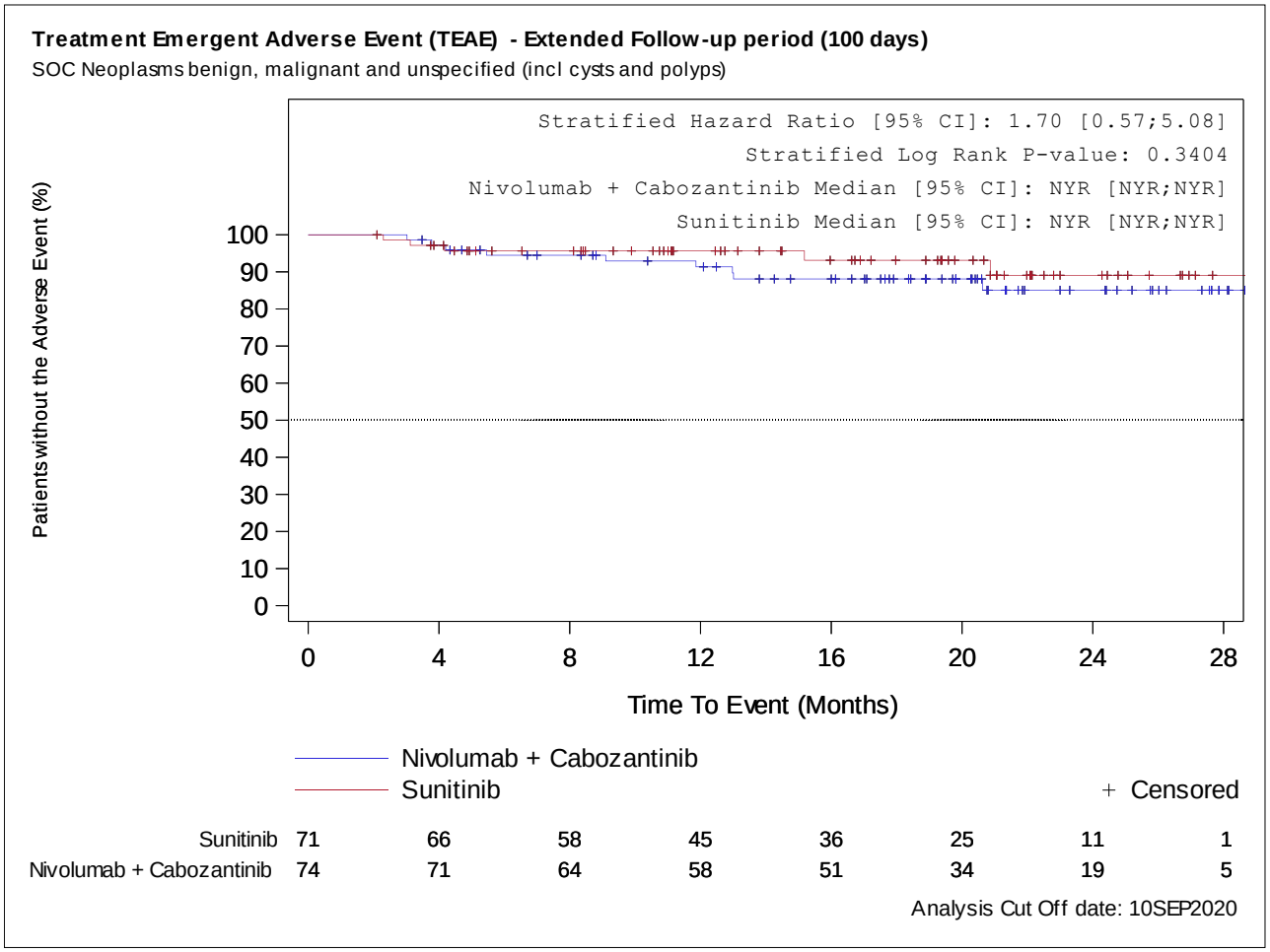

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:28:04

FIGURE 4.4.2.122: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pain in extremity - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



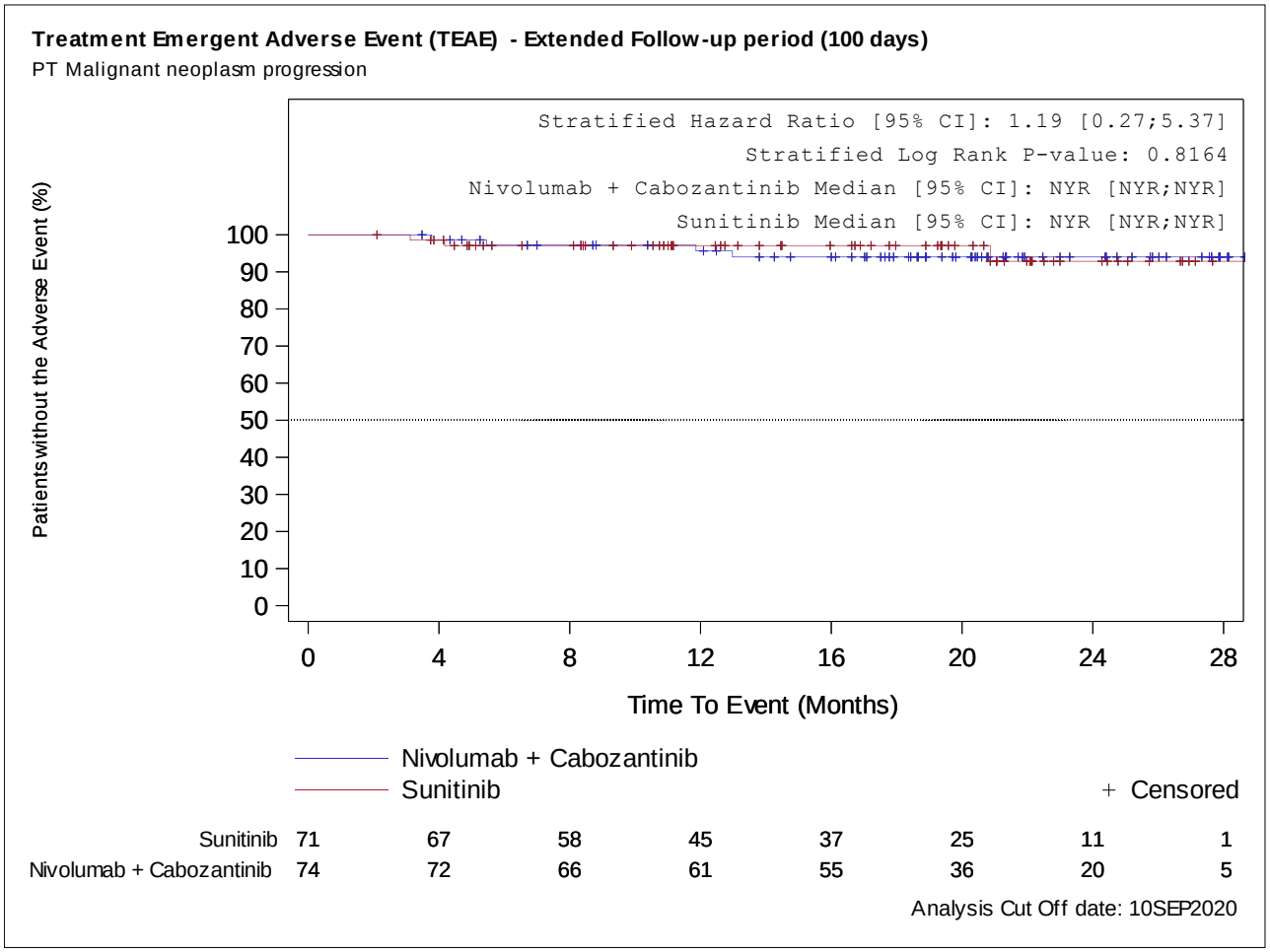

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:28:08

FIGURE 4.4.2.123: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



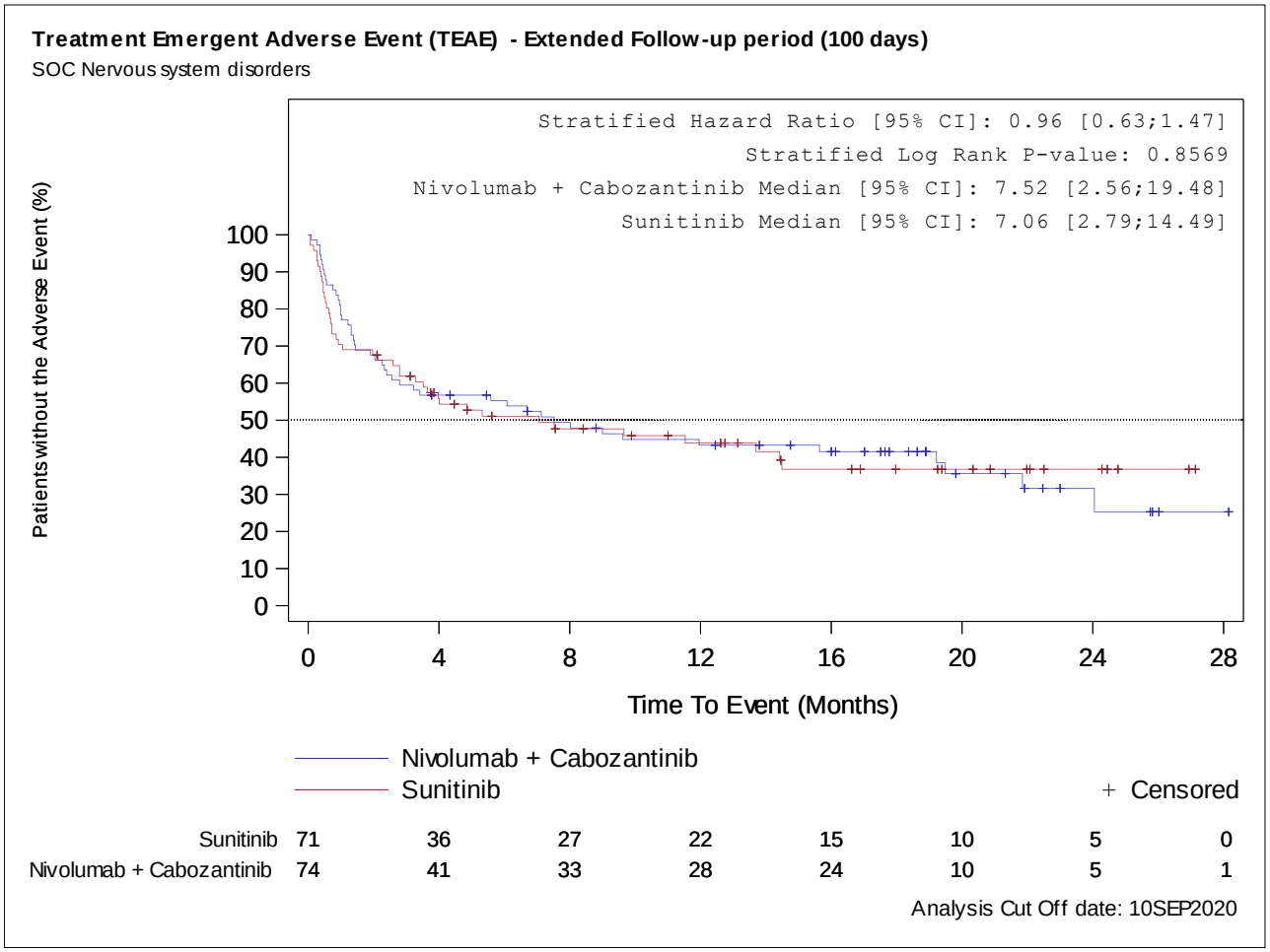

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:28:12

FIGURE 4.4.2.124: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Malignant neoplasm progression - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



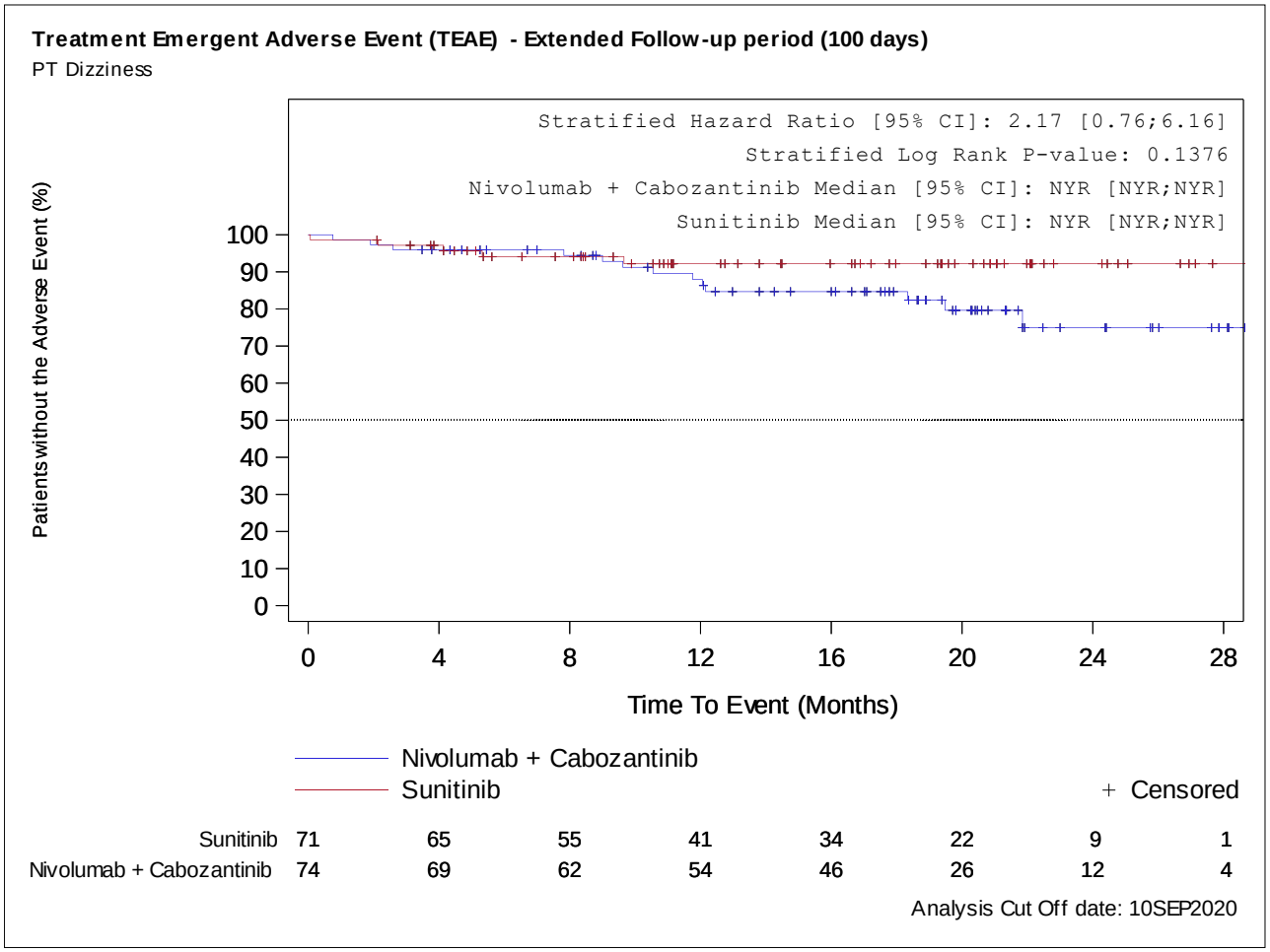

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:28:16

FIGURE 4.4.2.125: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Nervous system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



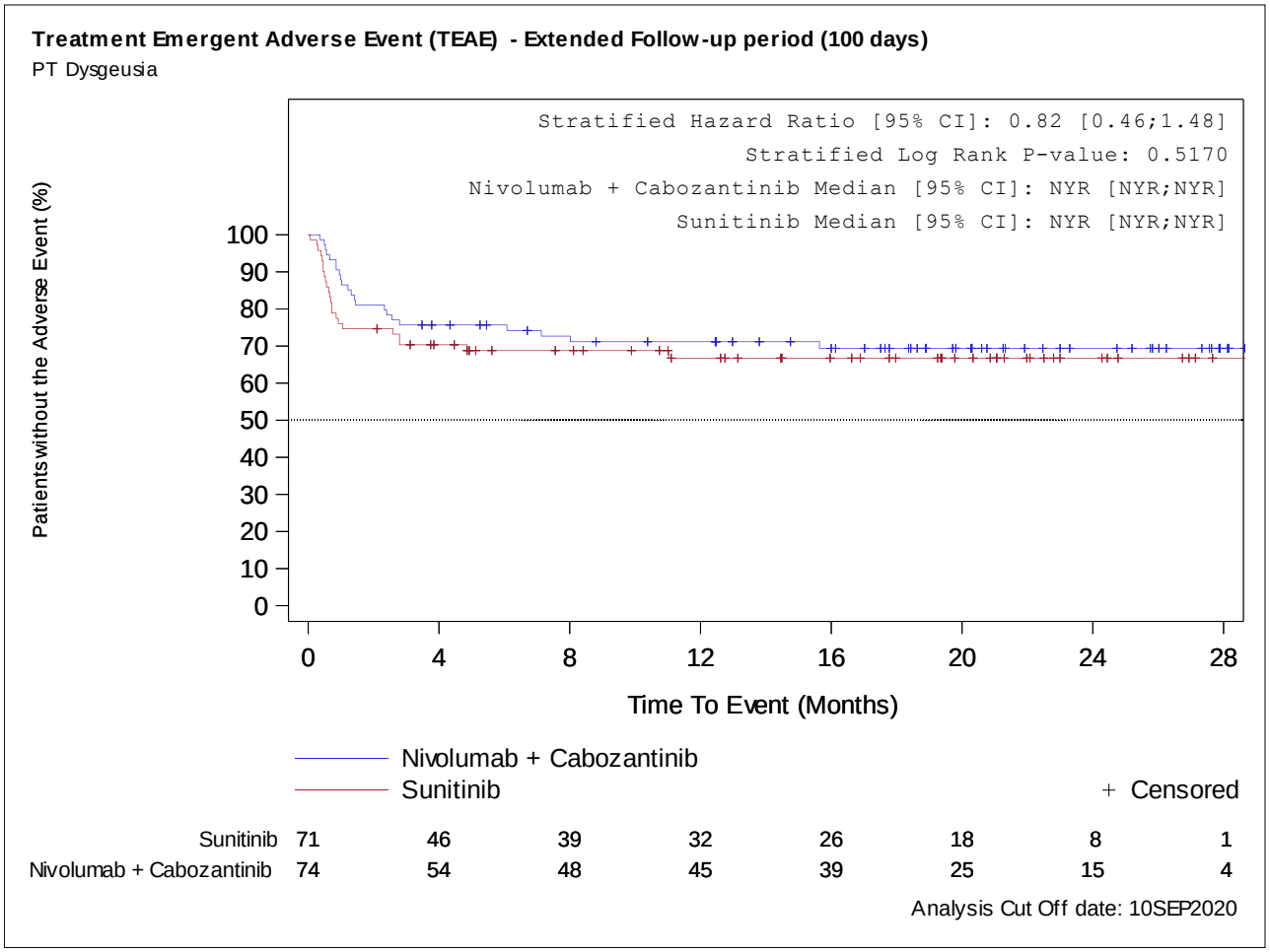

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:28:21

FIGURE 4.4.2.126: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dizziness - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



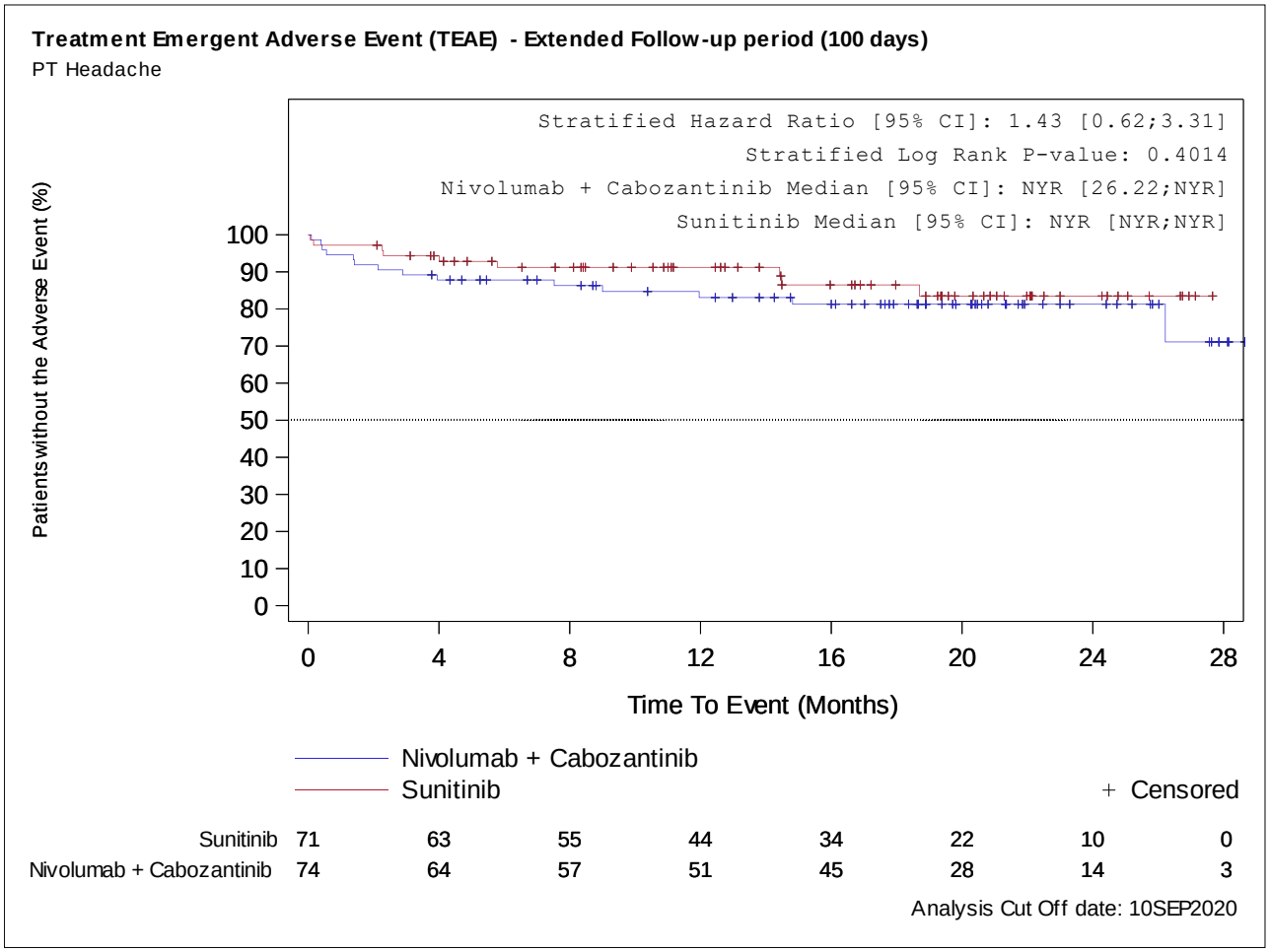

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:28:25

FIGURE 4.4.2.127: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysgeusia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:28:29

FIGURE 4.4.2.128: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Headache - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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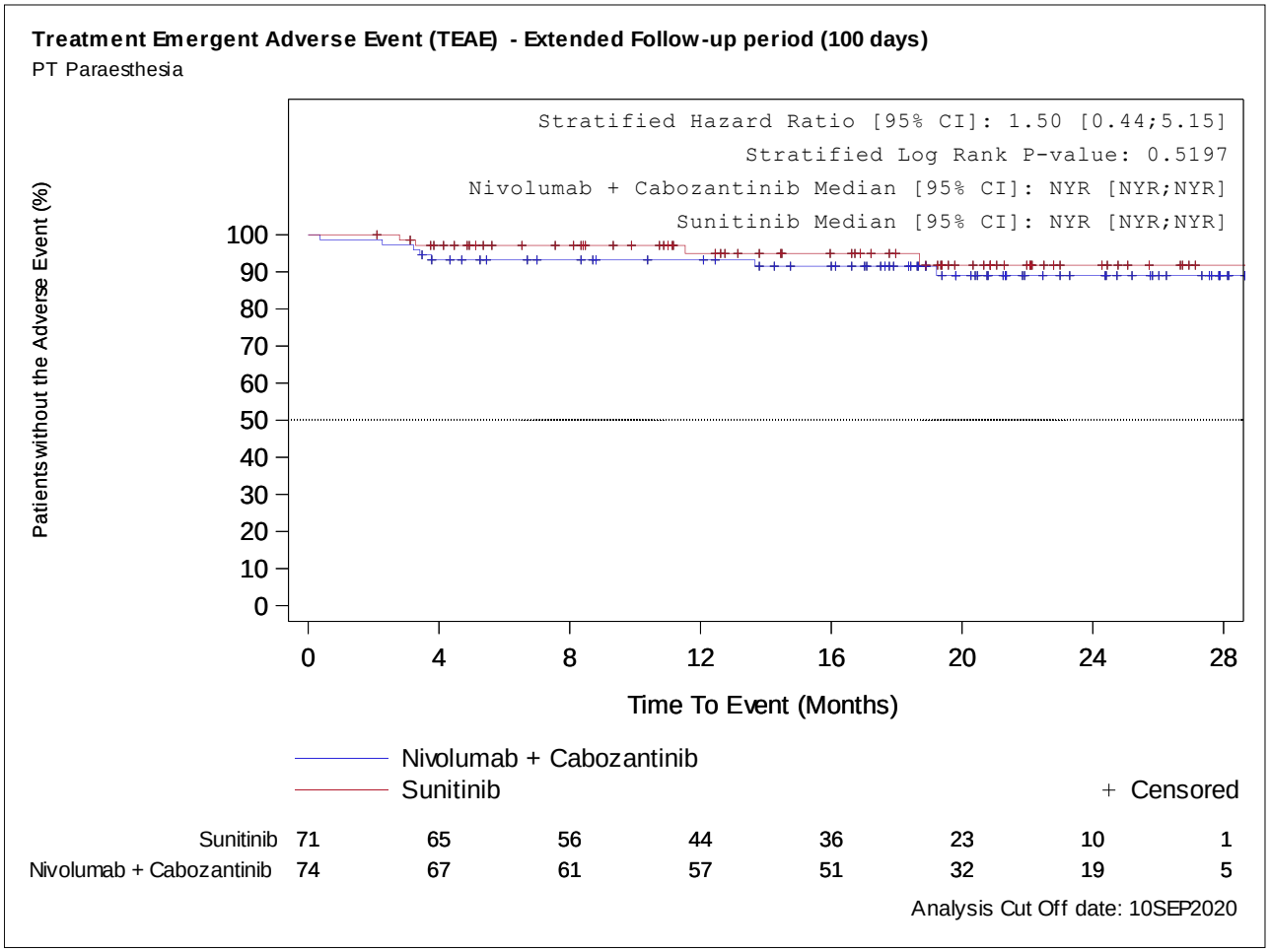
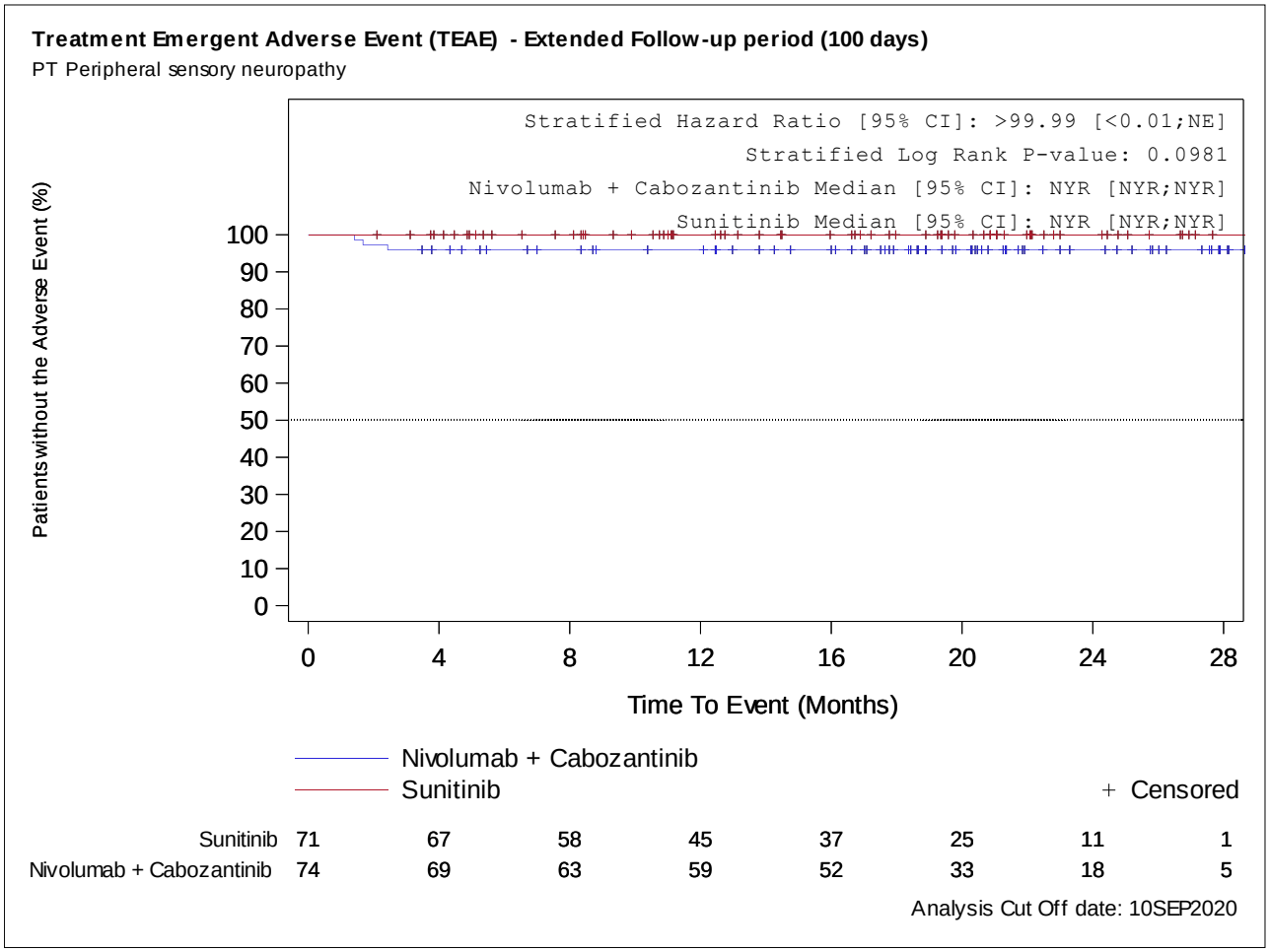
FIGURE 4.4.2.129: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Paraesthesia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



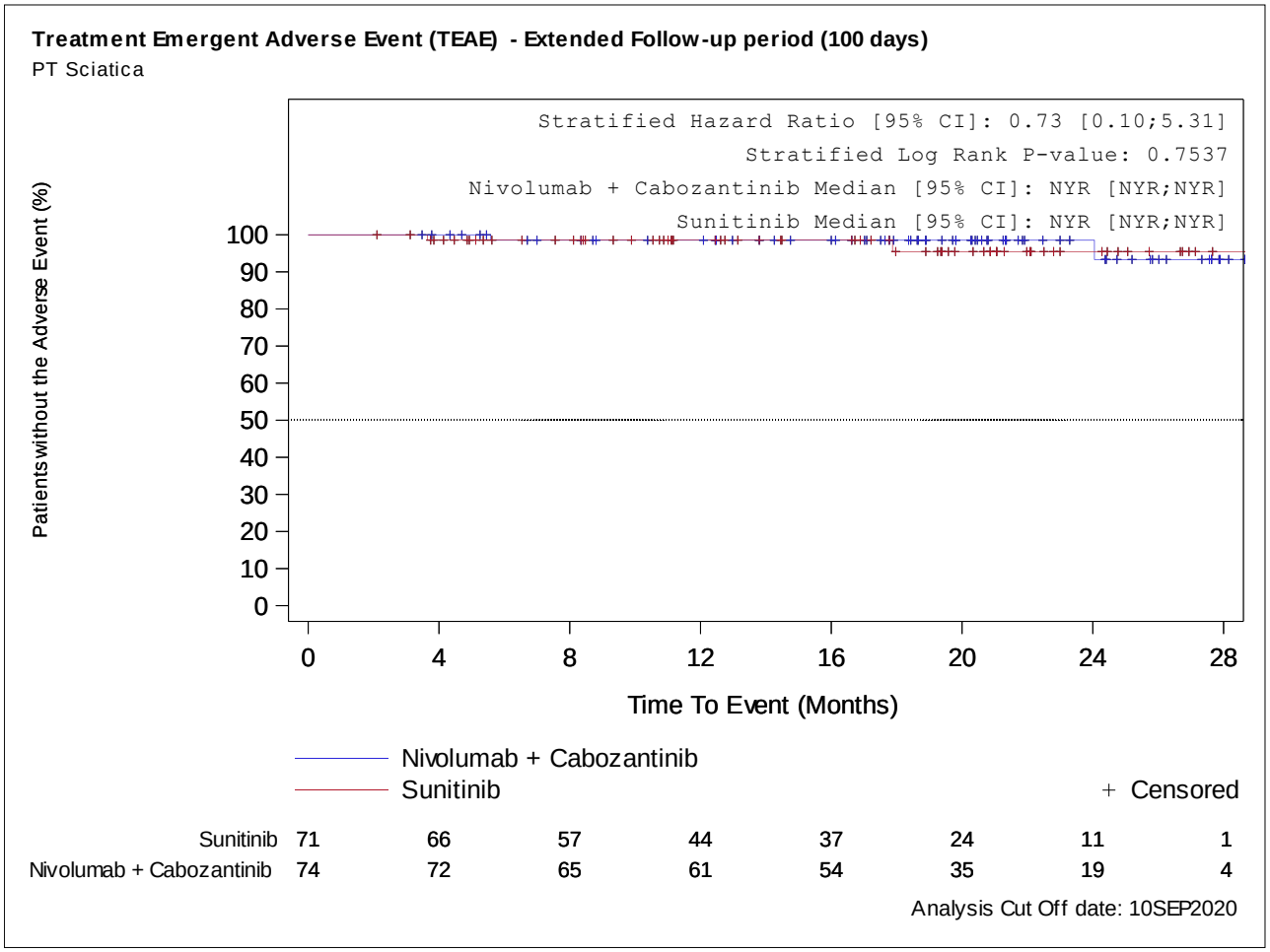

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:28:37

FIGURE 4.4.2.130: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Peripheral sensory neuropathy - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:28:41

FIGURE 4.4.2.131: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Sciatica - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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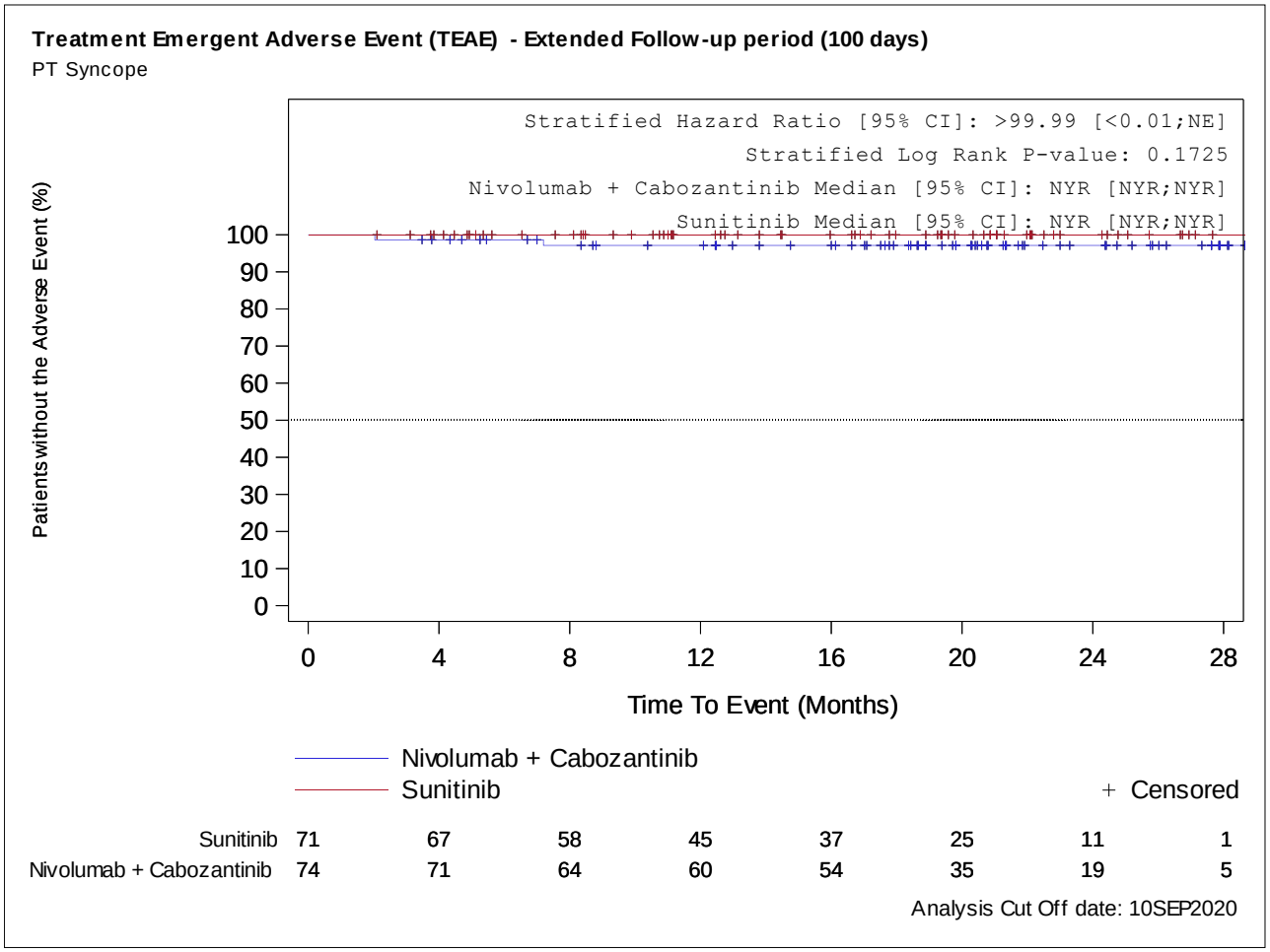
FIGURE 4.4.2.132: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Syncope - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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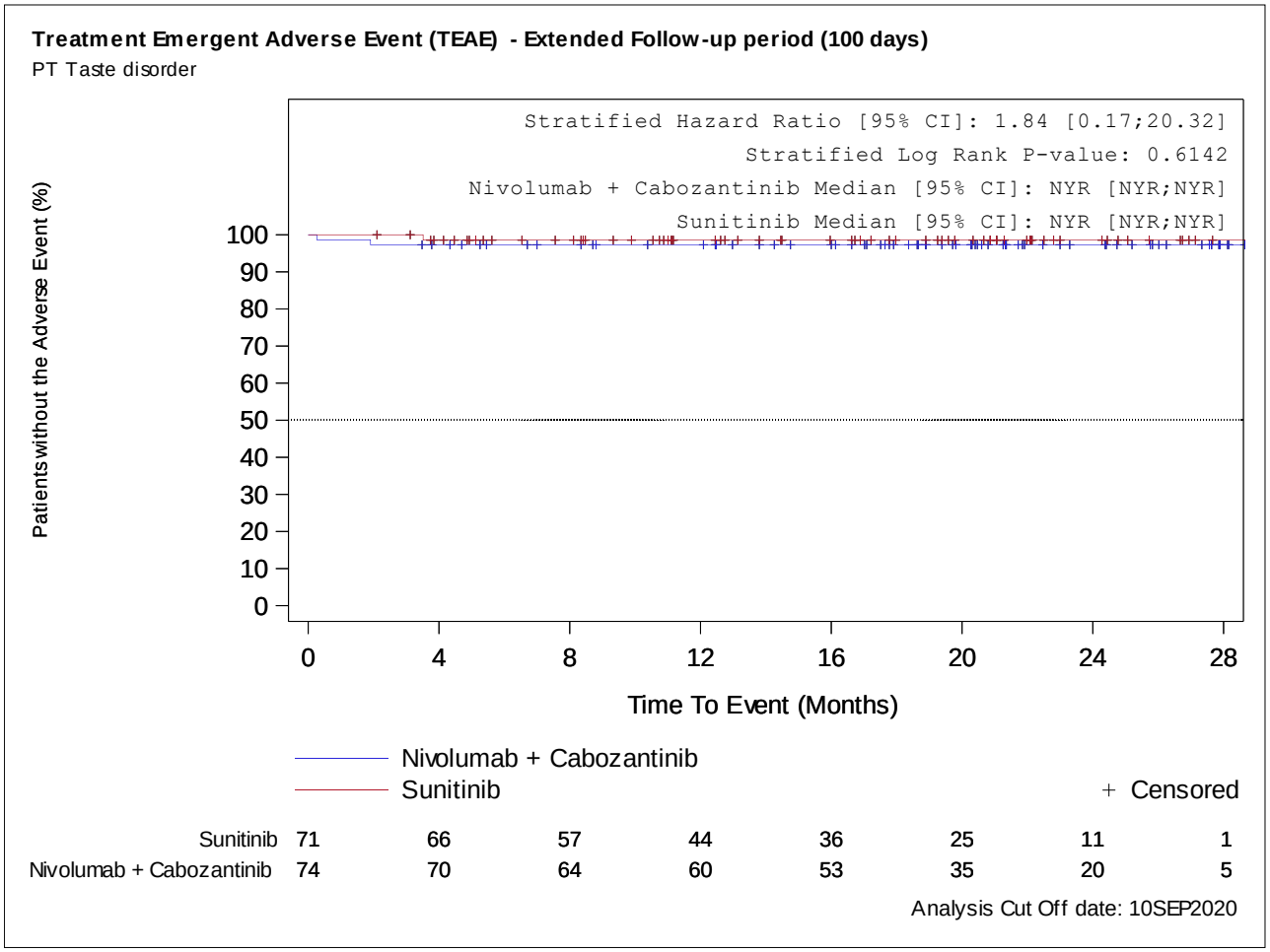
FIGURE 4.4.2.133: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Taste disorder - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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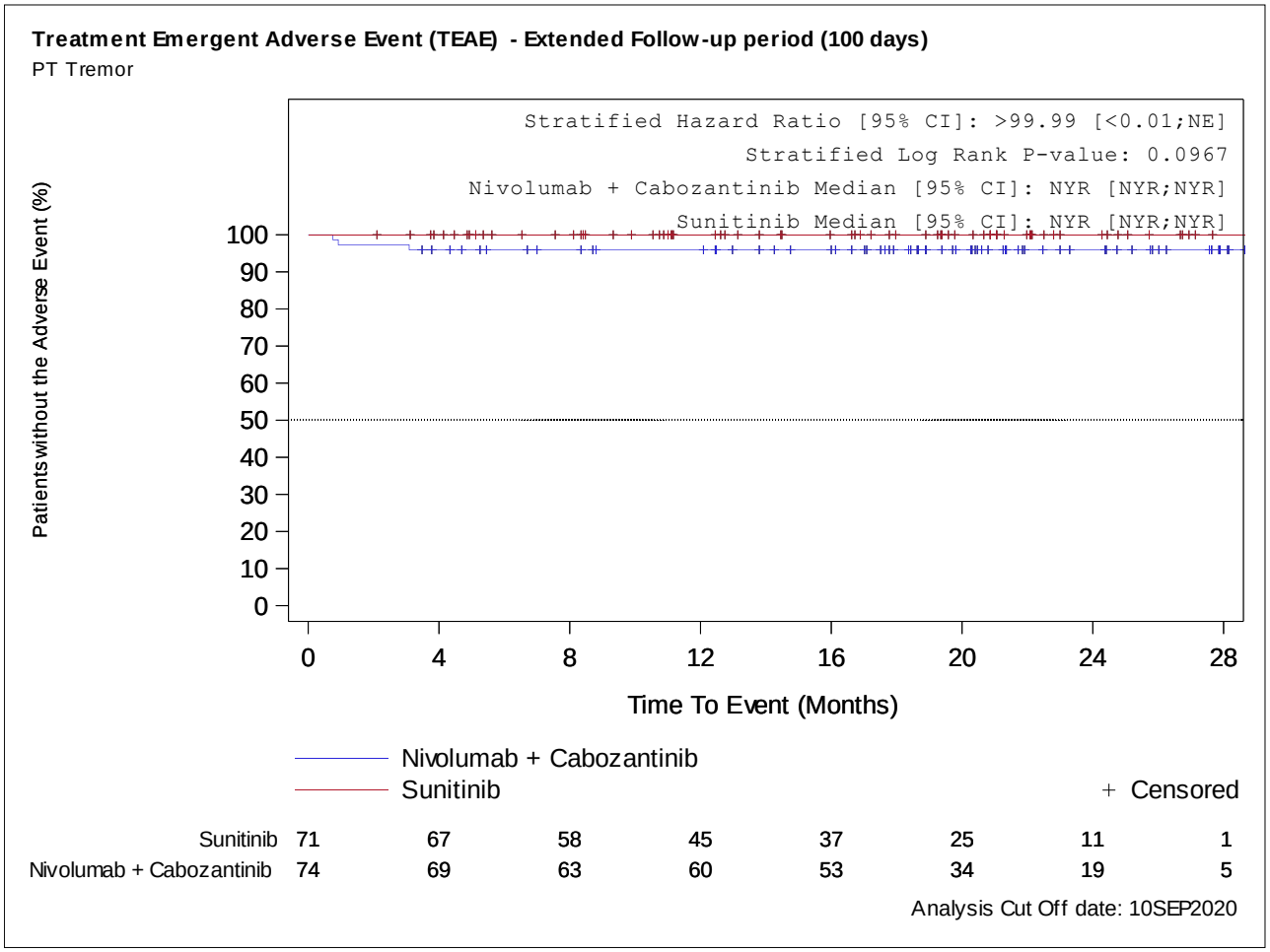
FIGURE 4.4.2.134: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Tremor - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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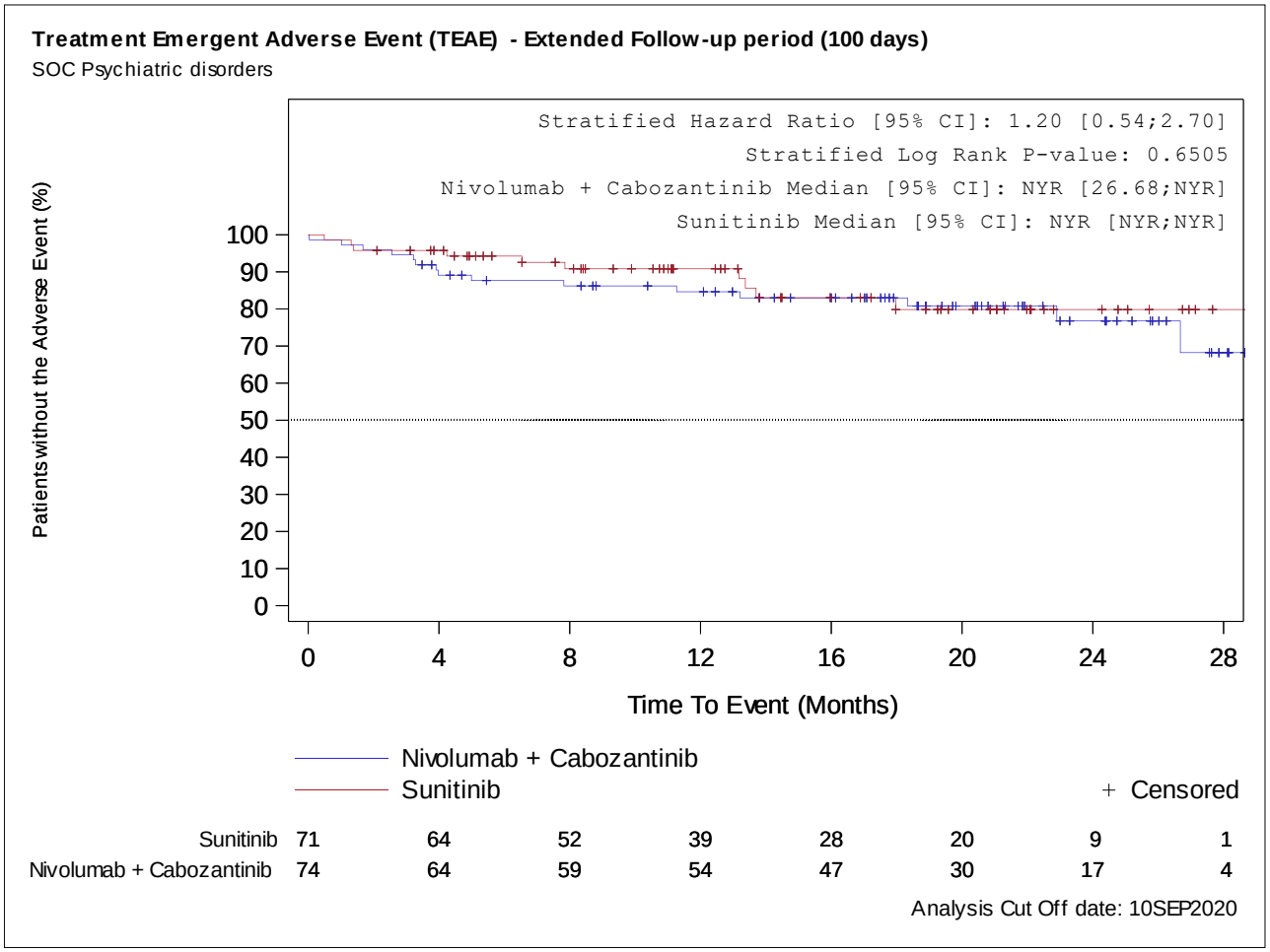
FIGURE 4.4.2.135: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Psychiatric disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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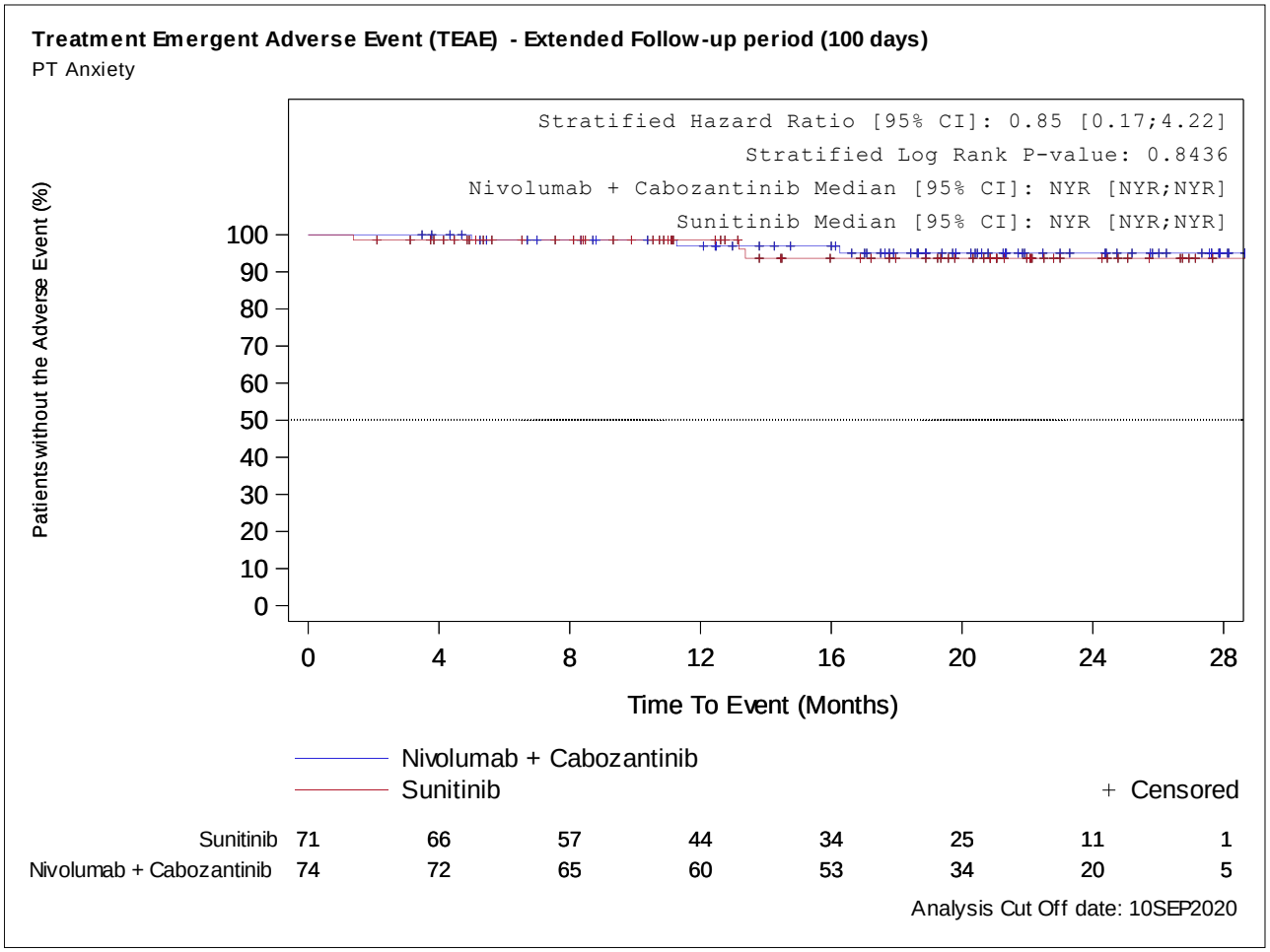
FIGURE 4.4.2.136: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anxiety - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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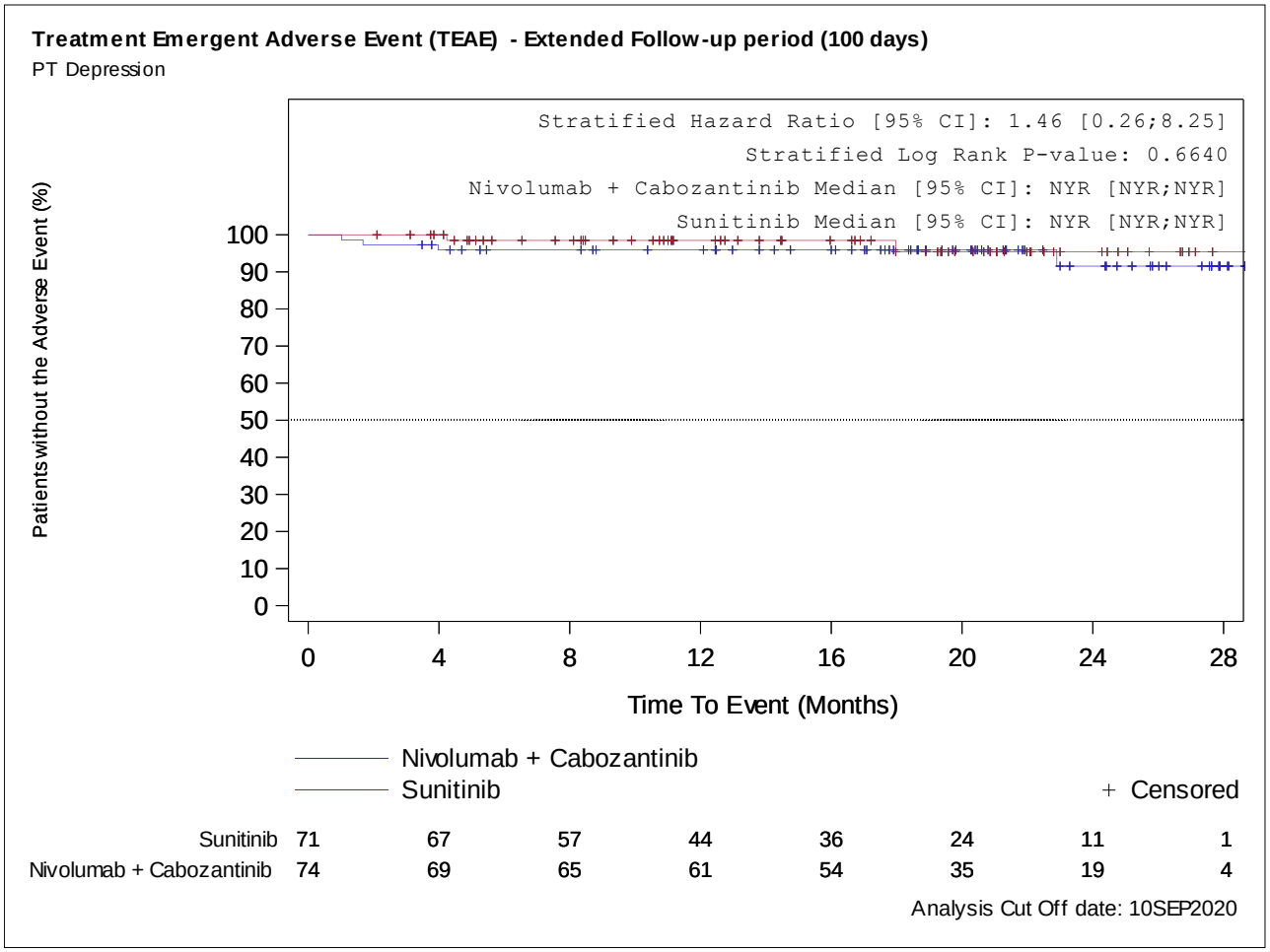
FIGURE 4.4.2.137: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Depression - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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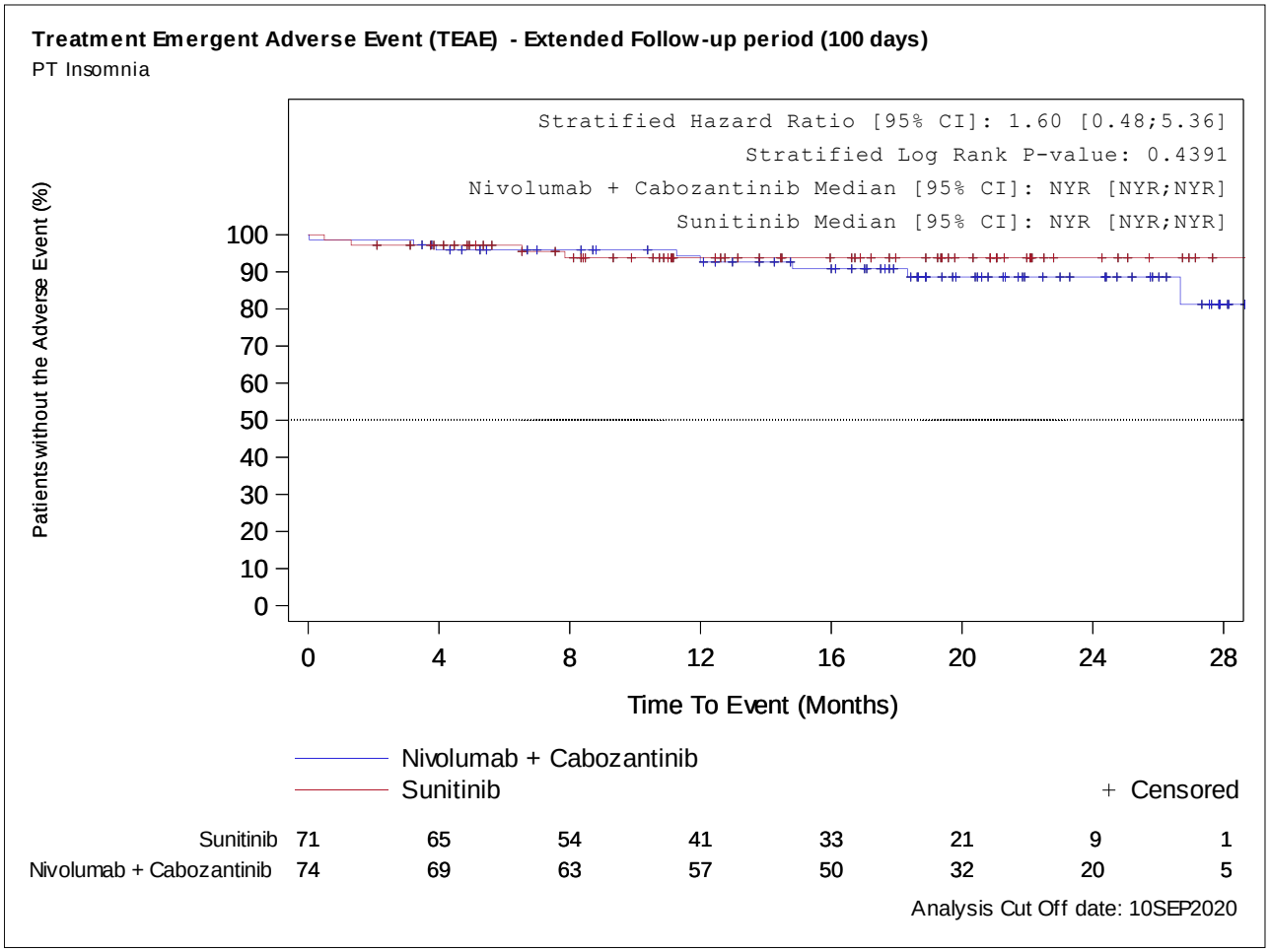
FIGURE 4.4.2.138: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Insomnia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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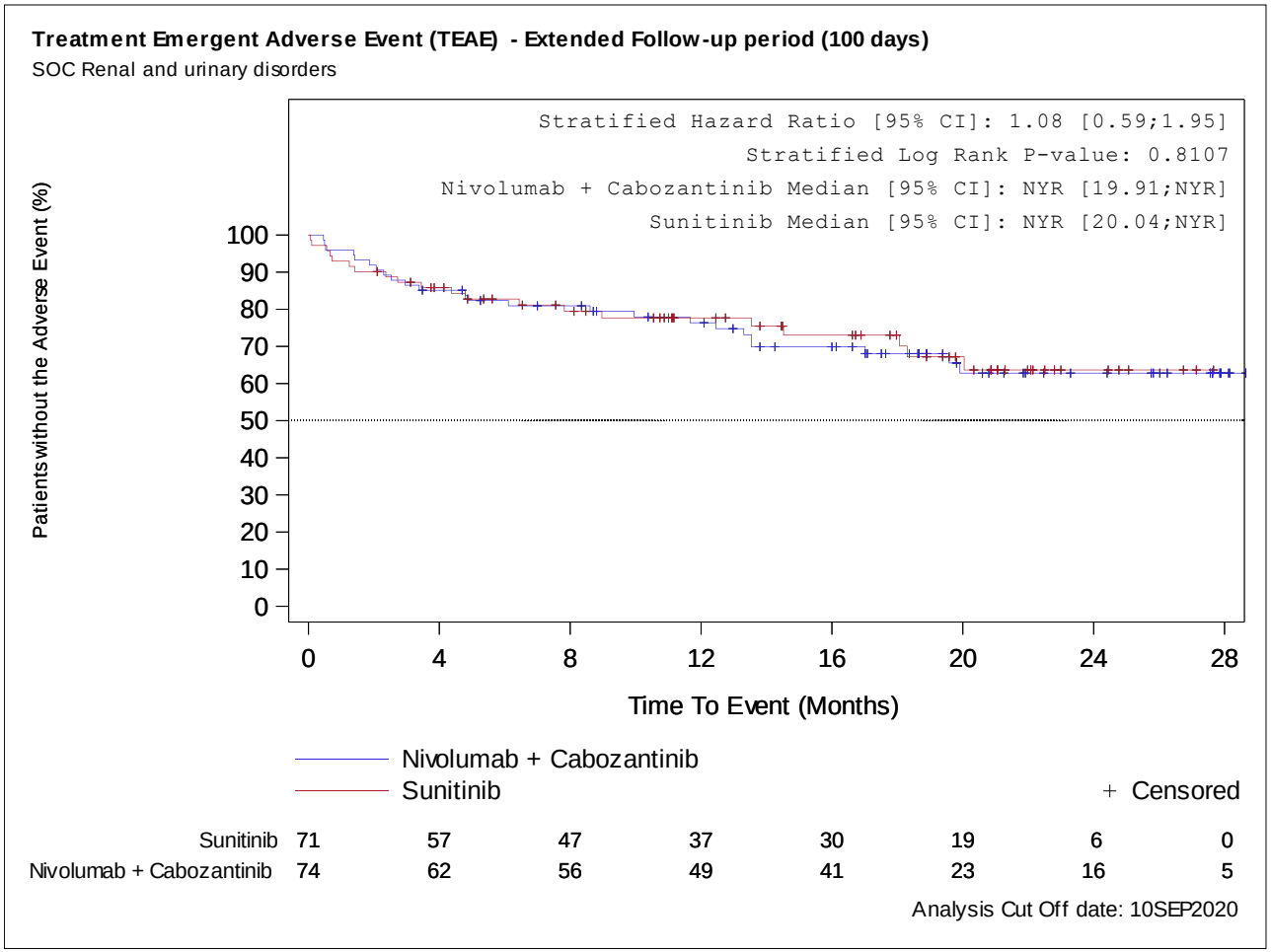
FIGURE 4.4.2.139: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Renal and urinary disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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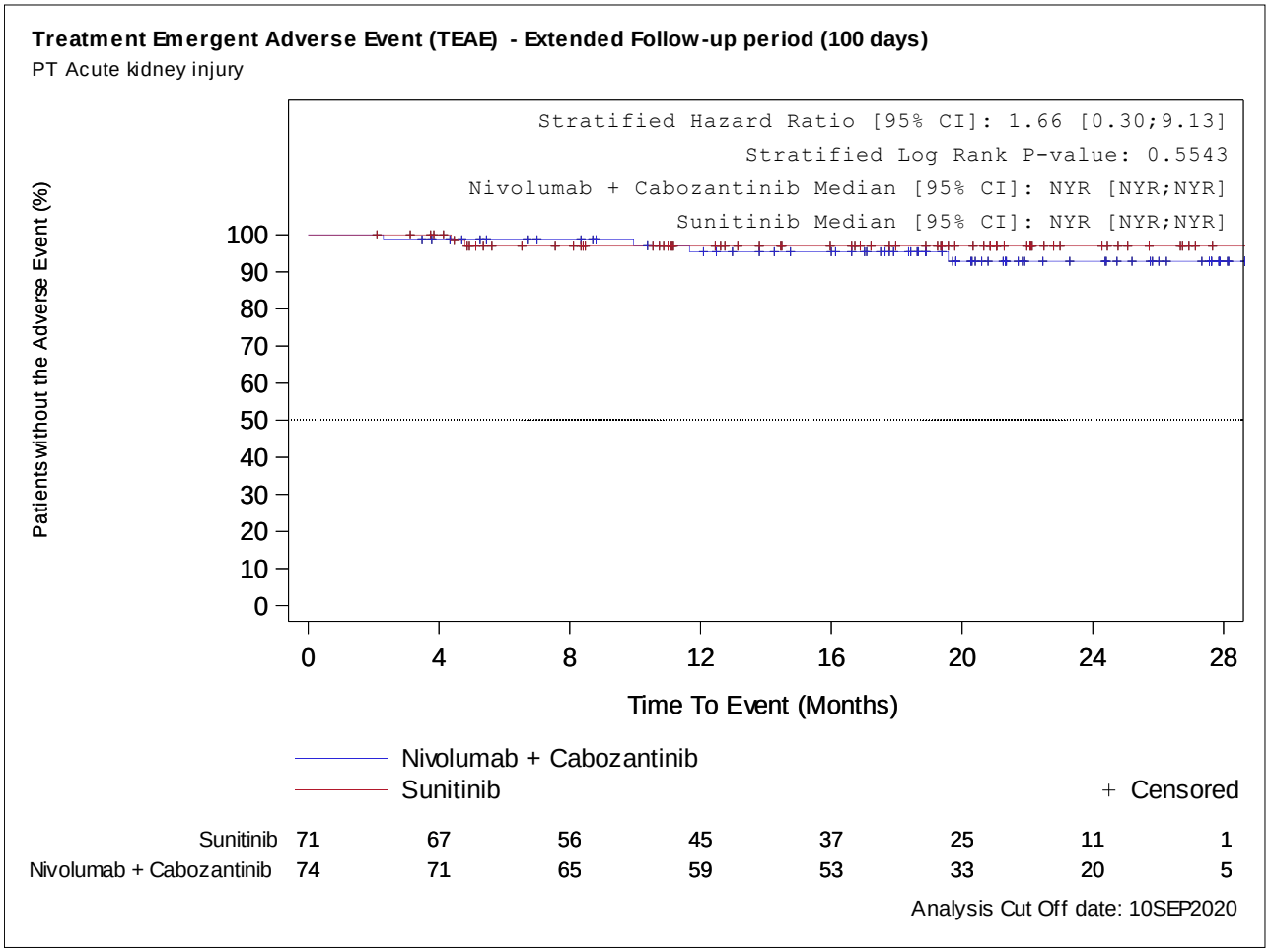
FIGURE 4.4.2.140: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Acute kidney injury - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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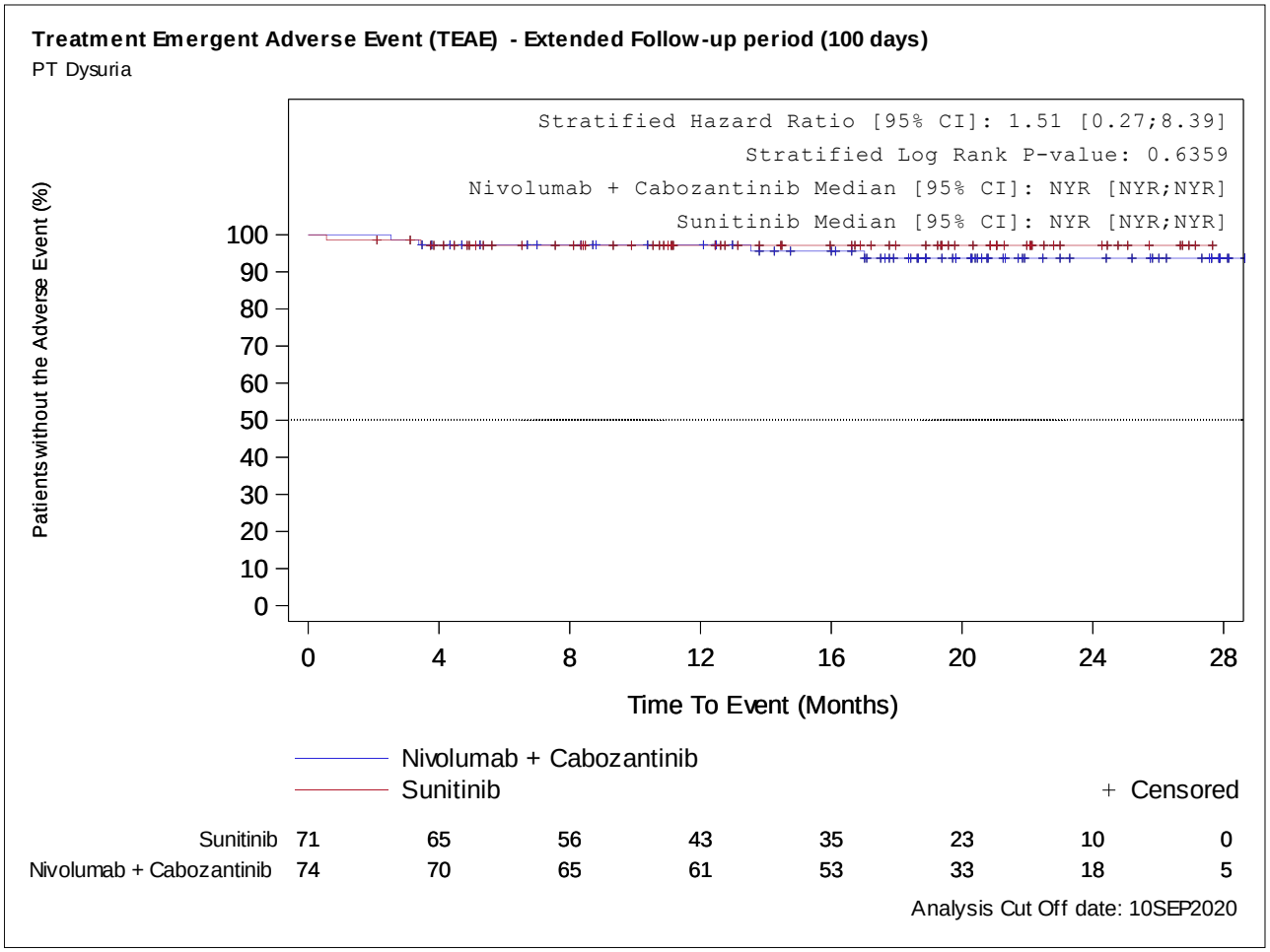
FIGURE 4.4.2.141: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysuria - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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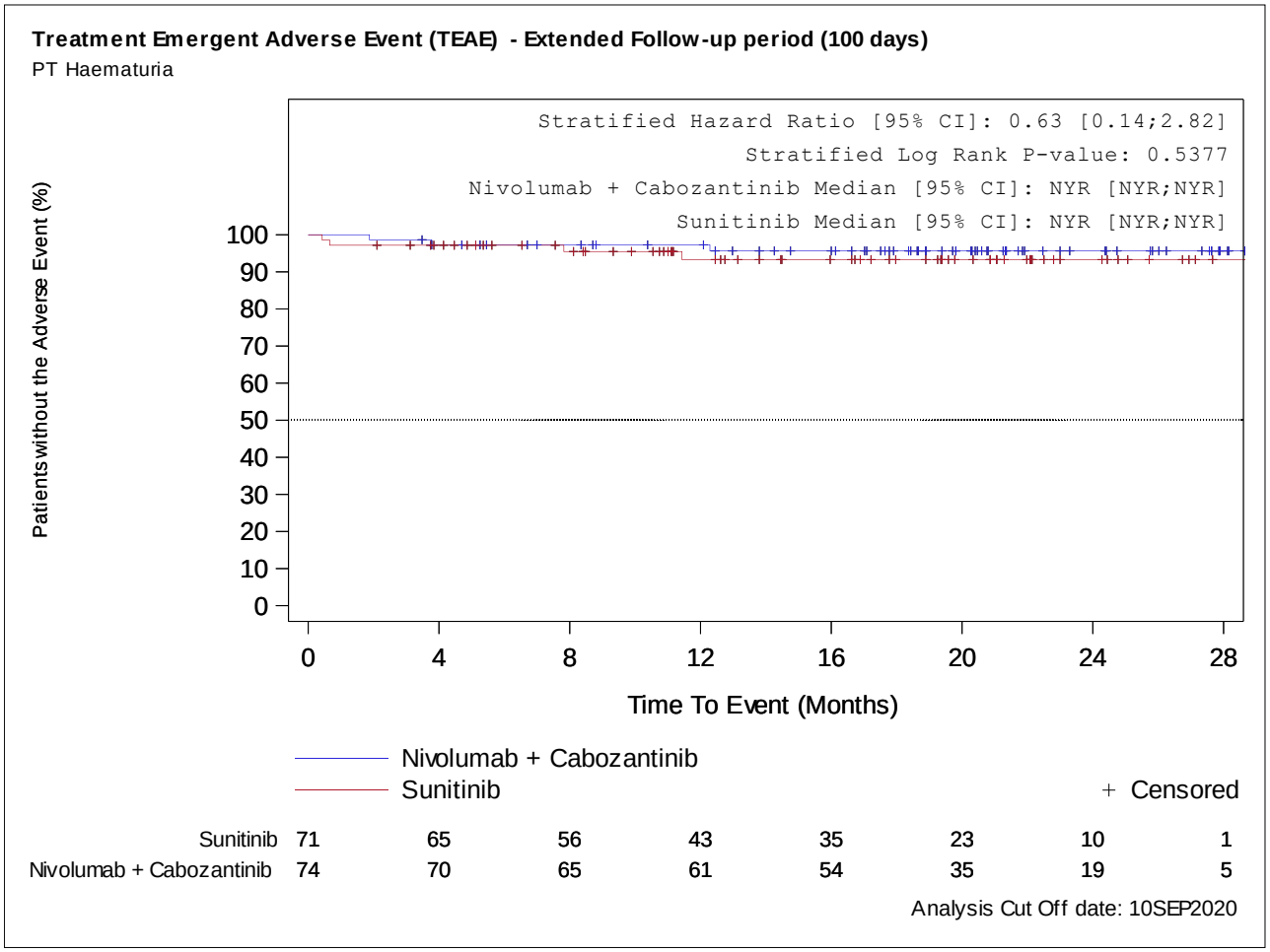
FIGURE 4.4.2.142: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Haematuria - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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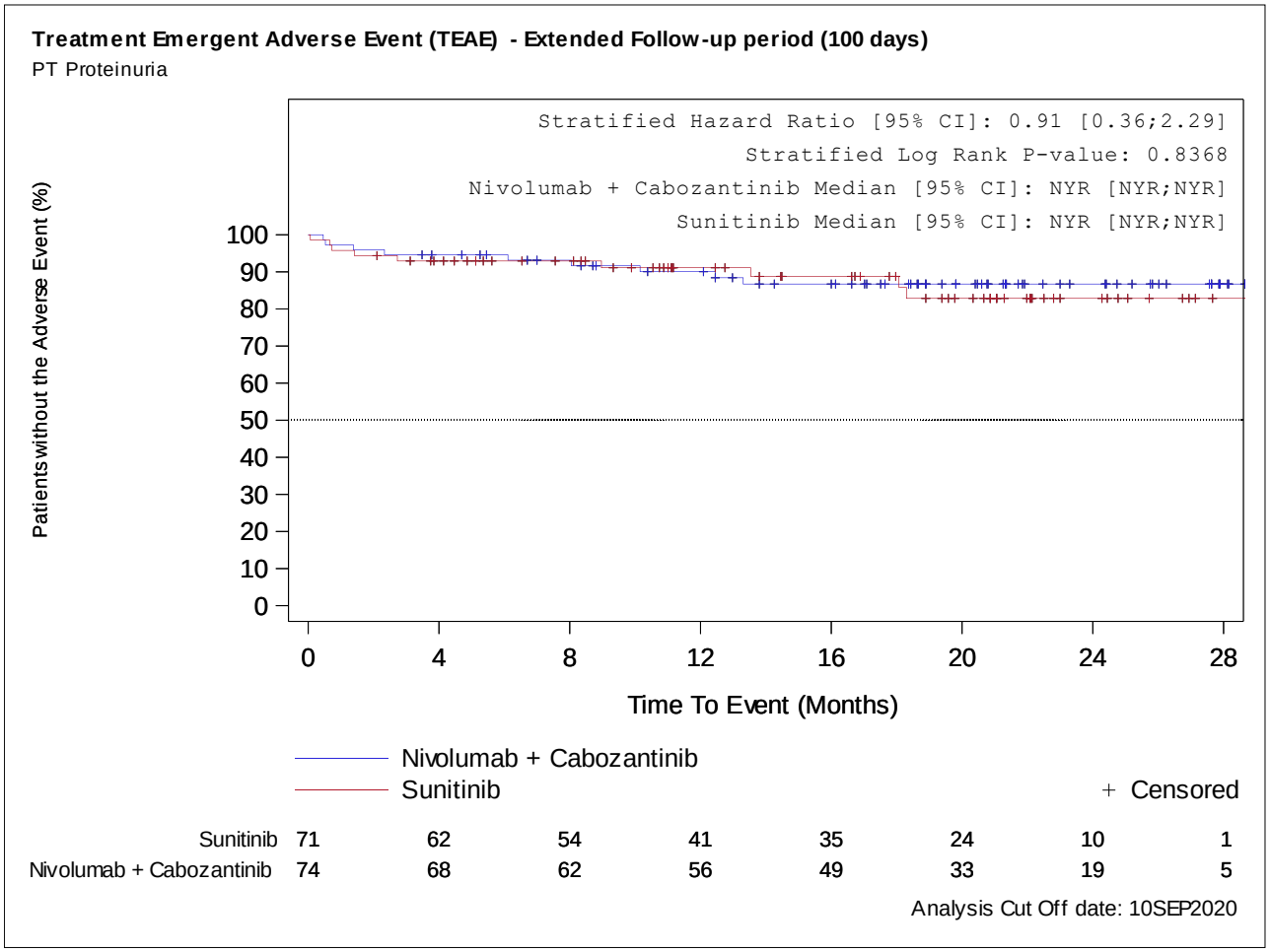
FIGURE 4.4.2.143: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Proteinuria - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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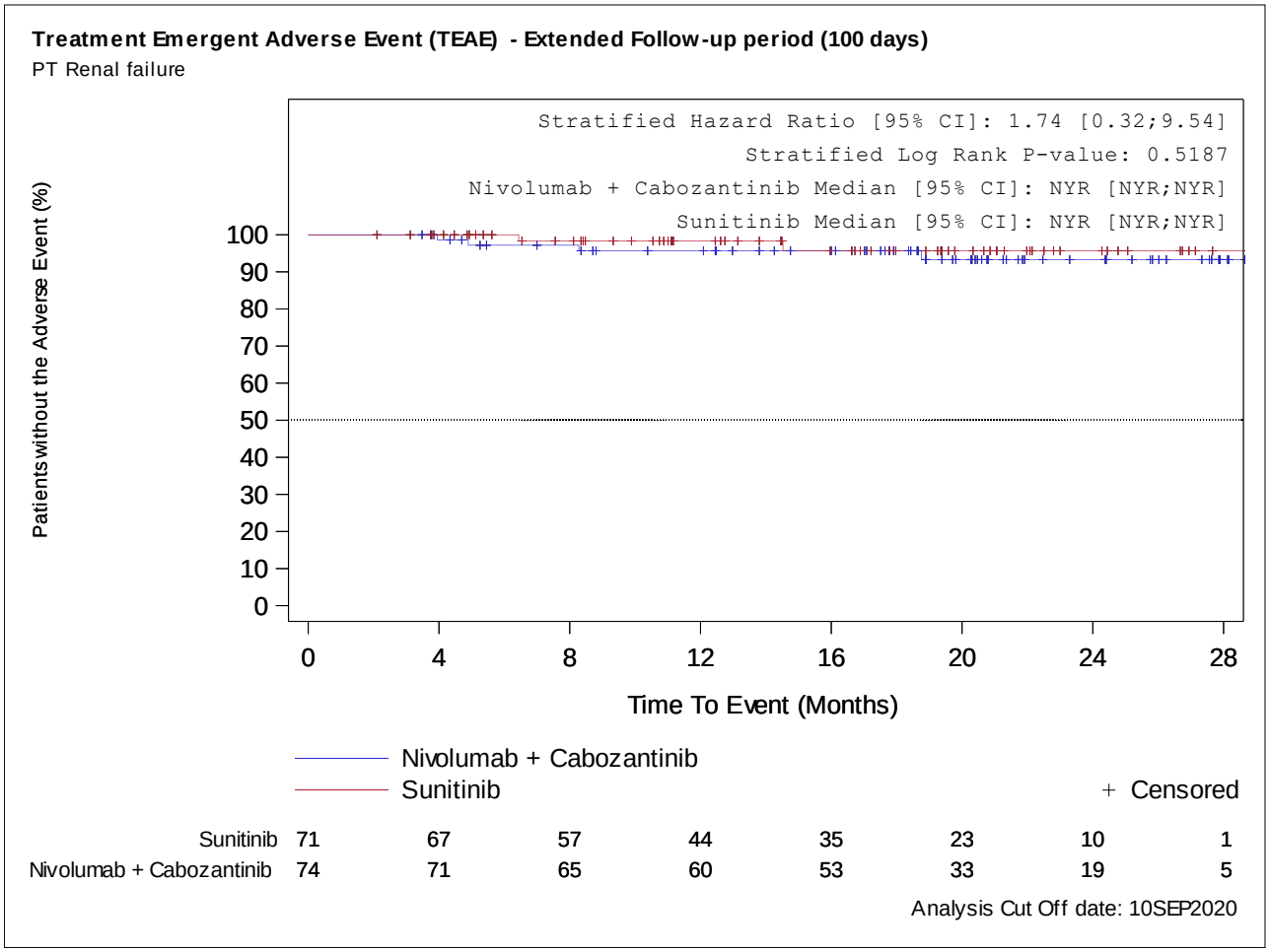
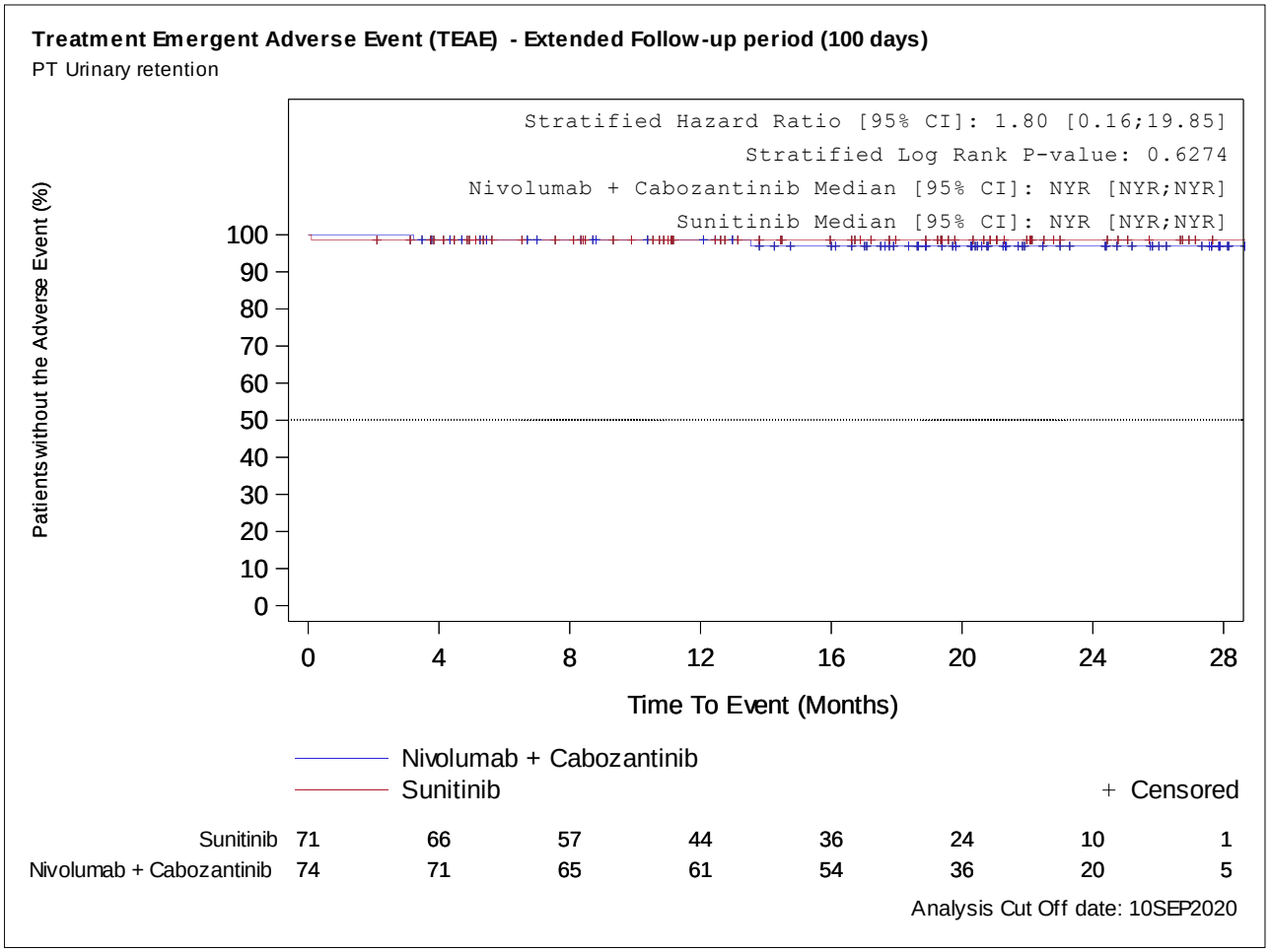
FIGURE 4.4.2.144: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Renal failure - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:29:41

FIGURE 4.4.2.145: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Urinary retention - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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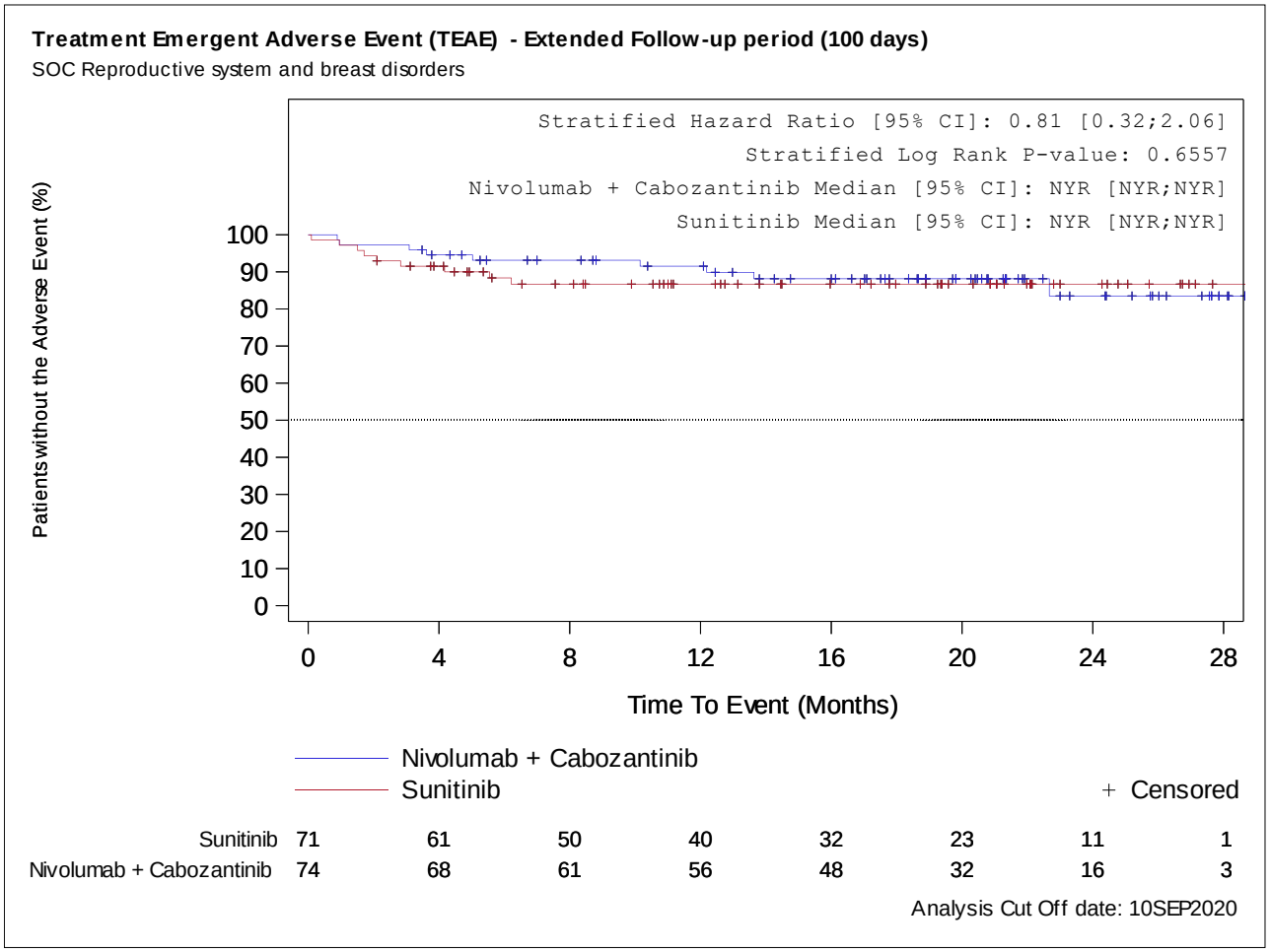
FIGURE 4.4.2.146: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Reproductive system and breast disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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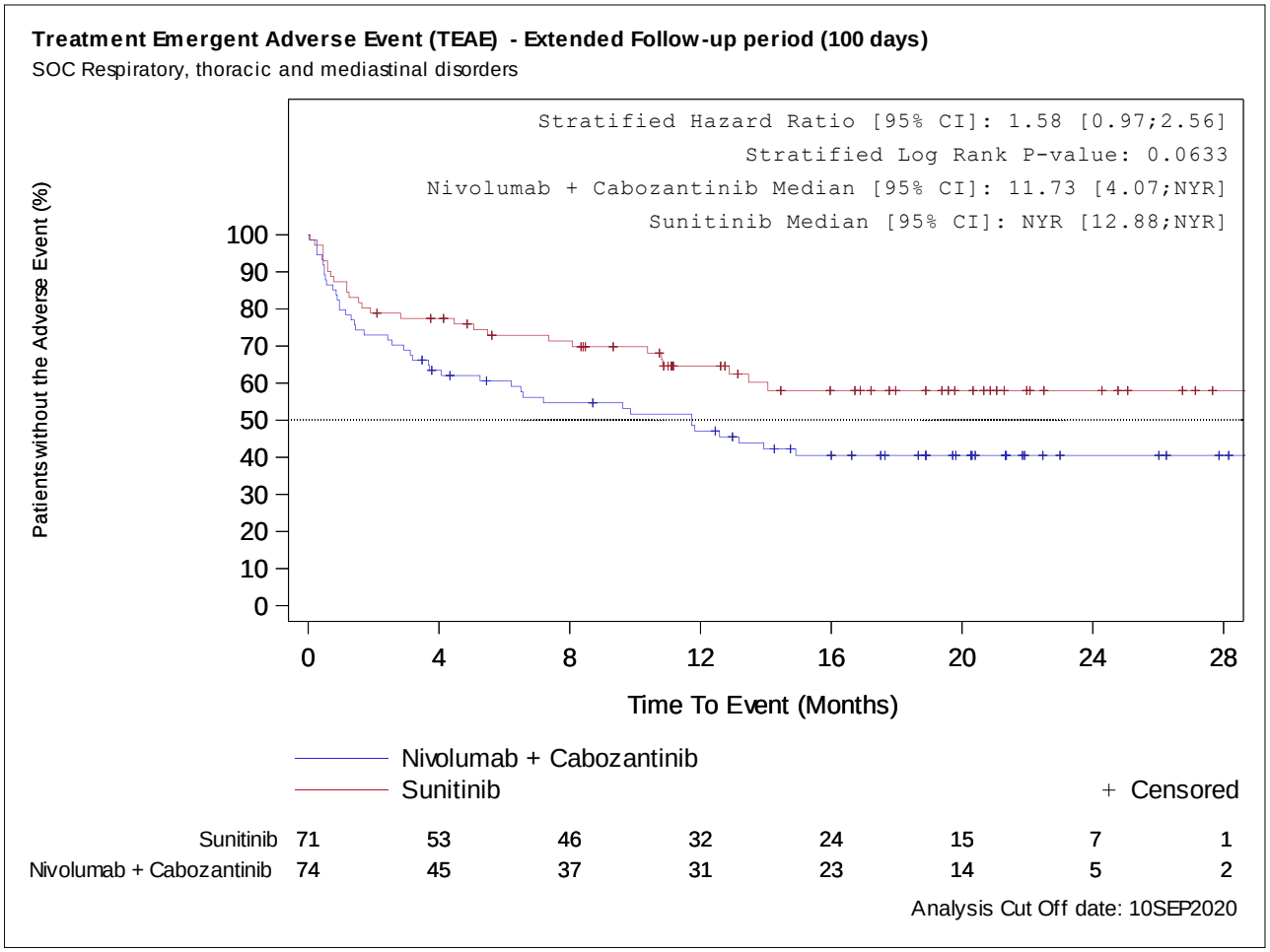
FIGURE 4.4.2.147: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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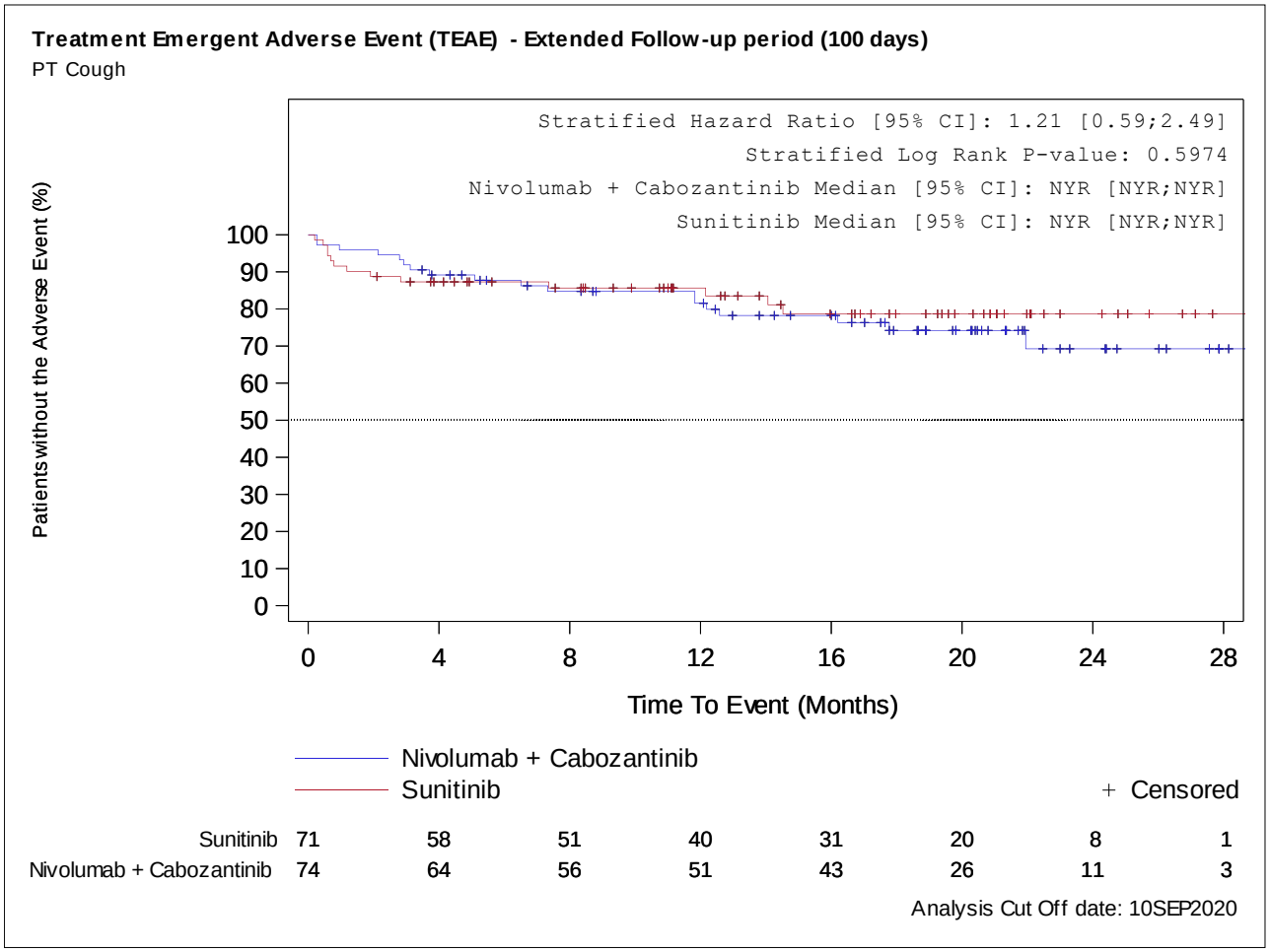
FIGURE 4.4.2.148: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Cough - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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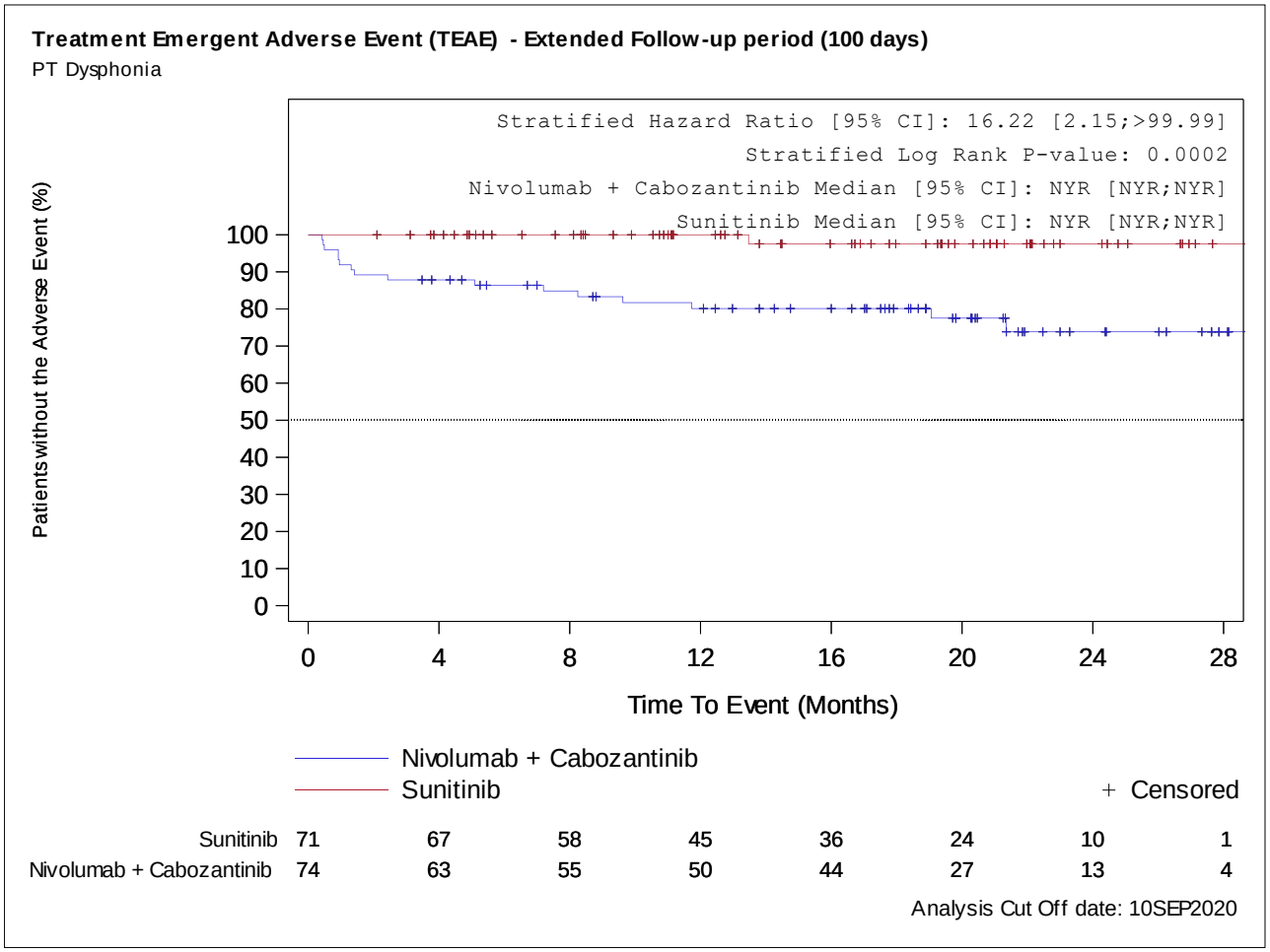
FIGURE 4.4.2.149: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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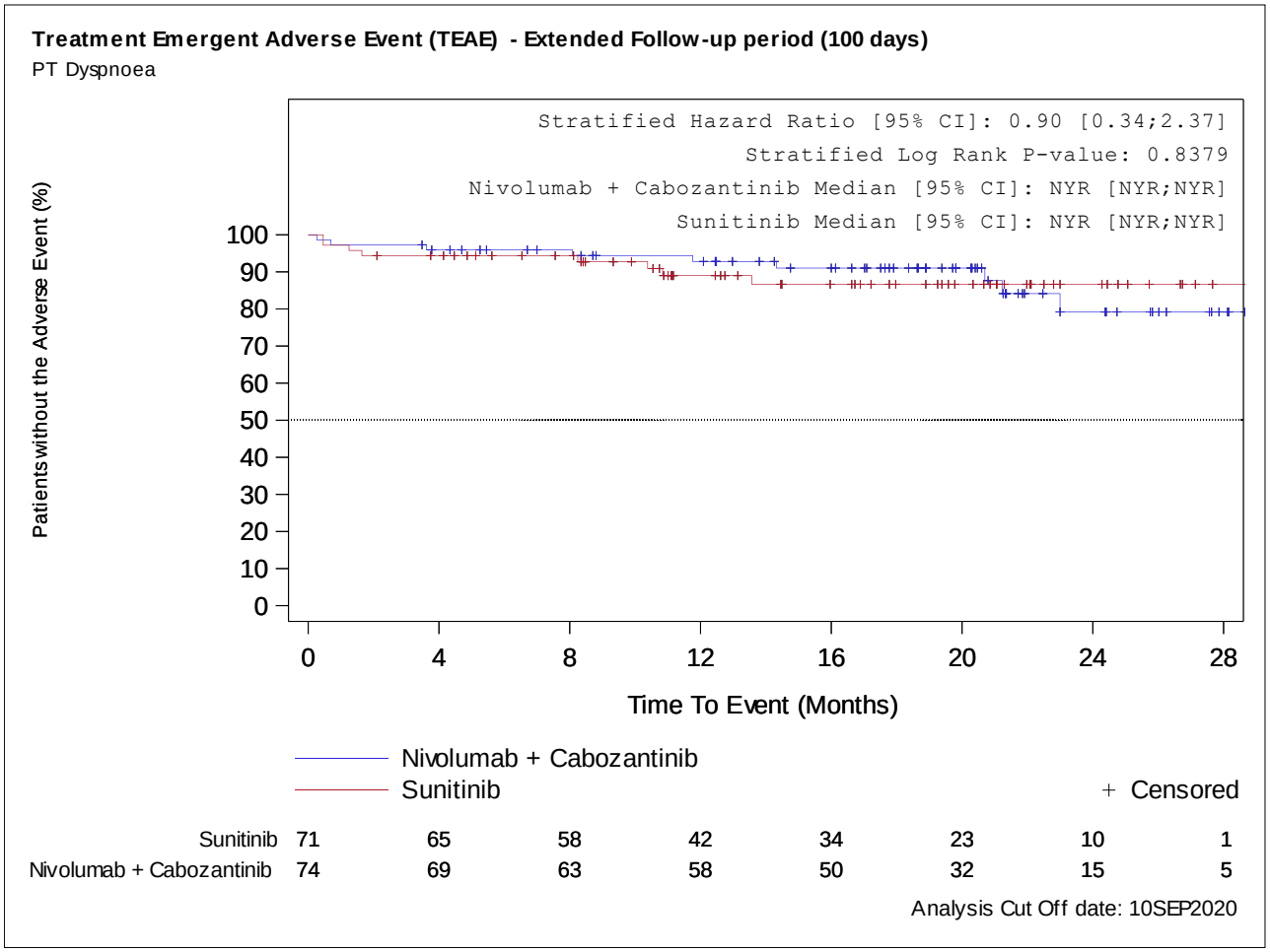
FIGURE 4.4.2.150: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dyspnoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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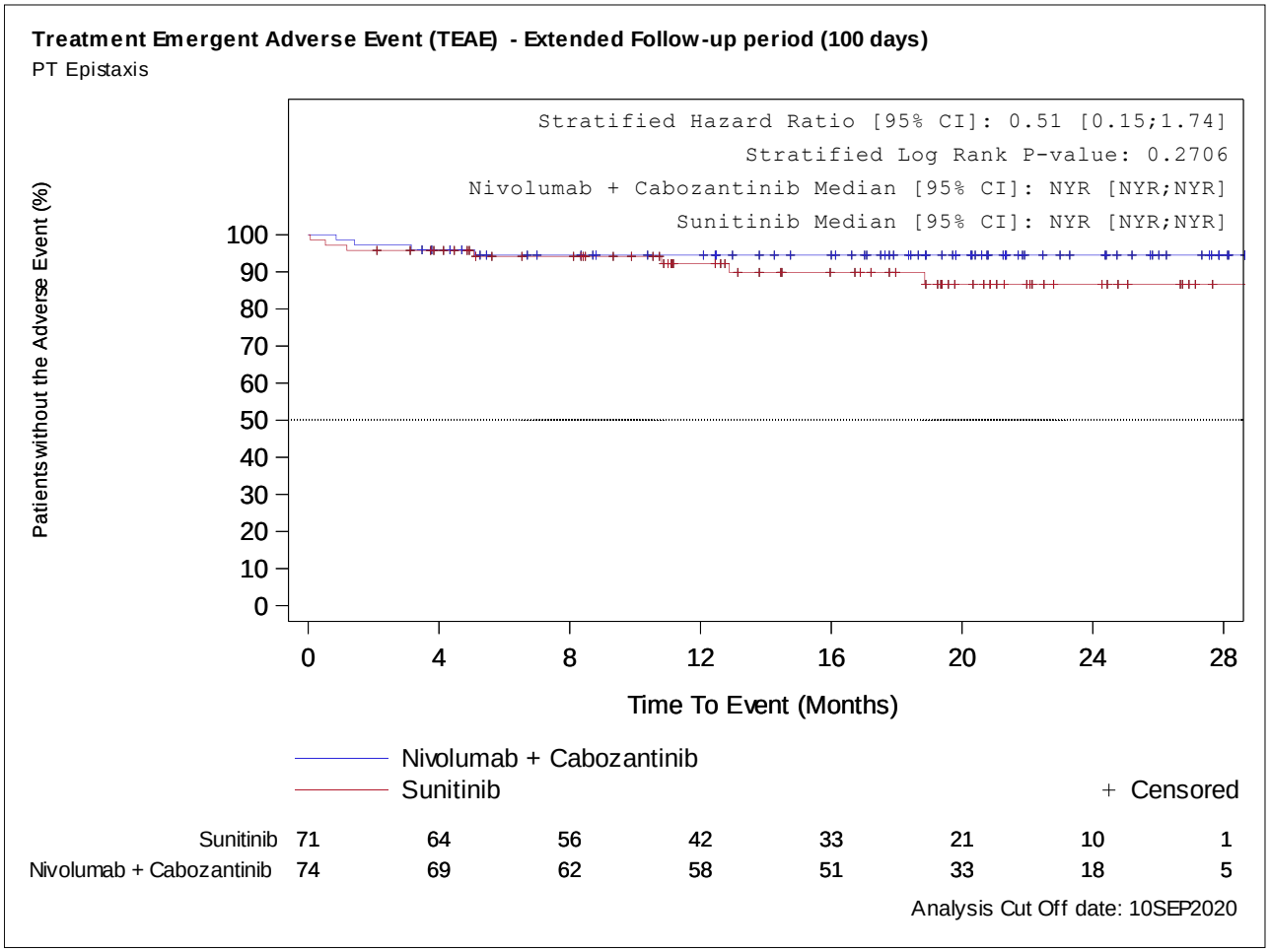
FIGURE 4.4.2.151: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Epistaxis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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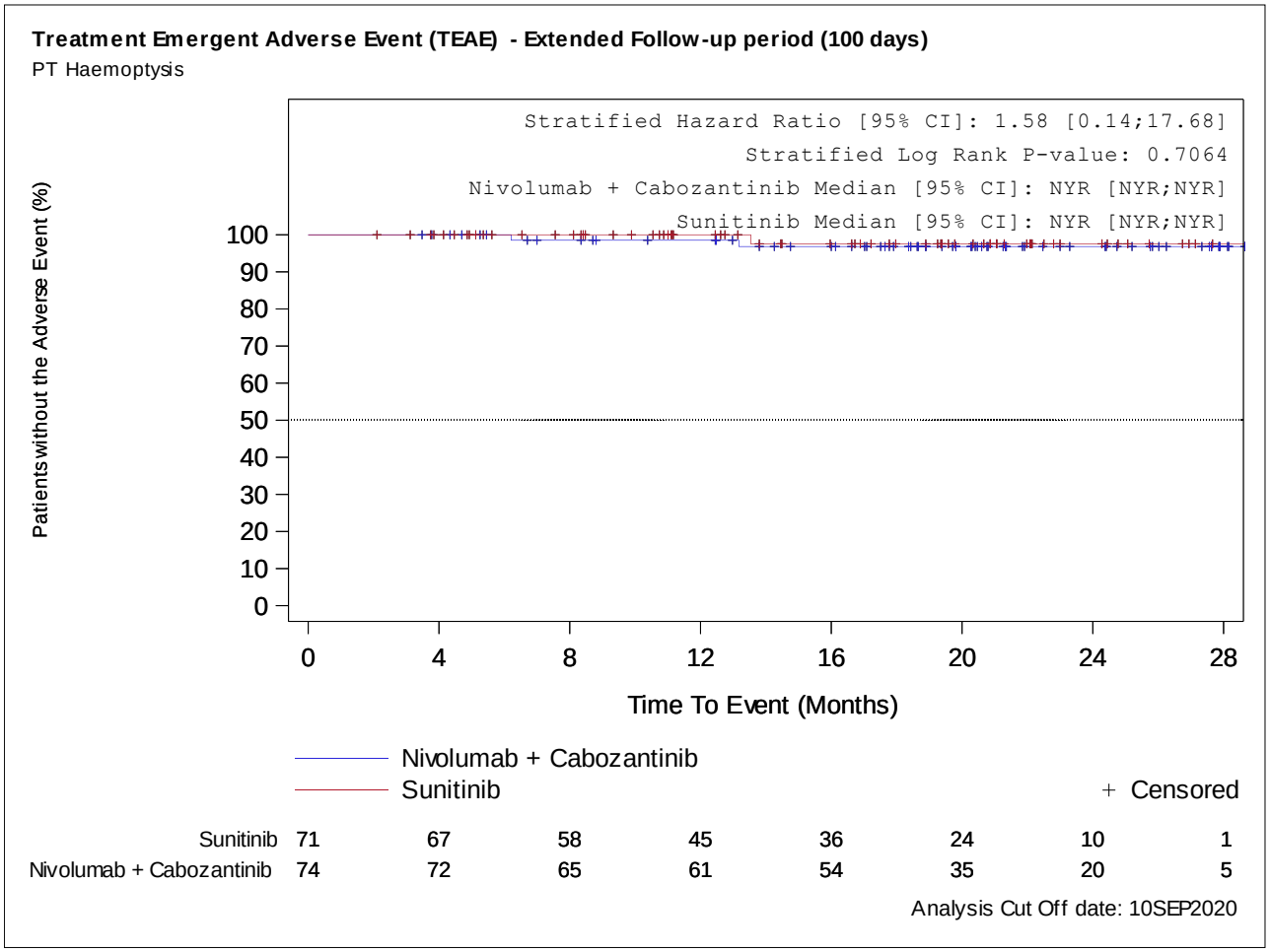
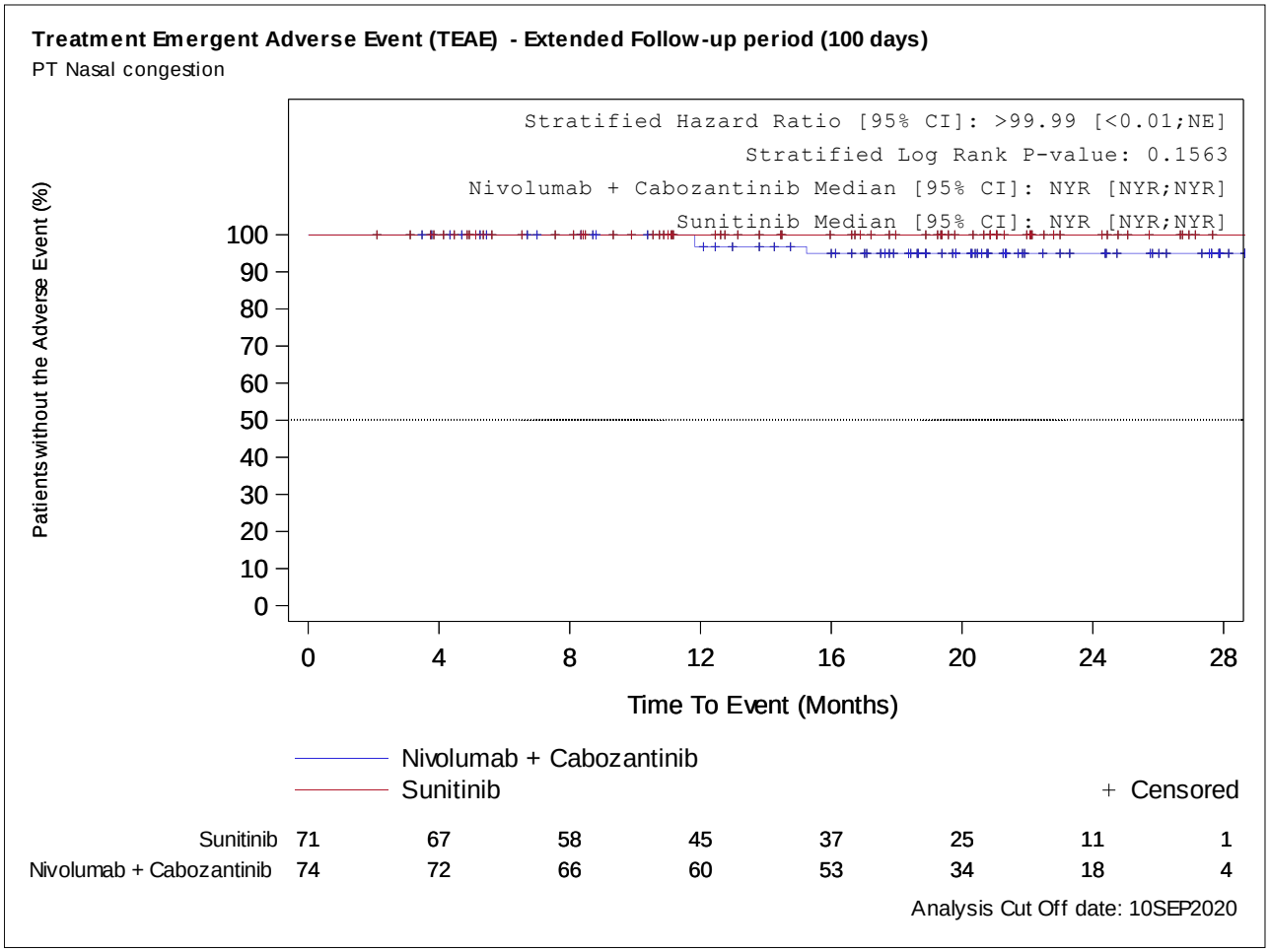
FIGURE 4.4.2.152: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Haemoptysis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



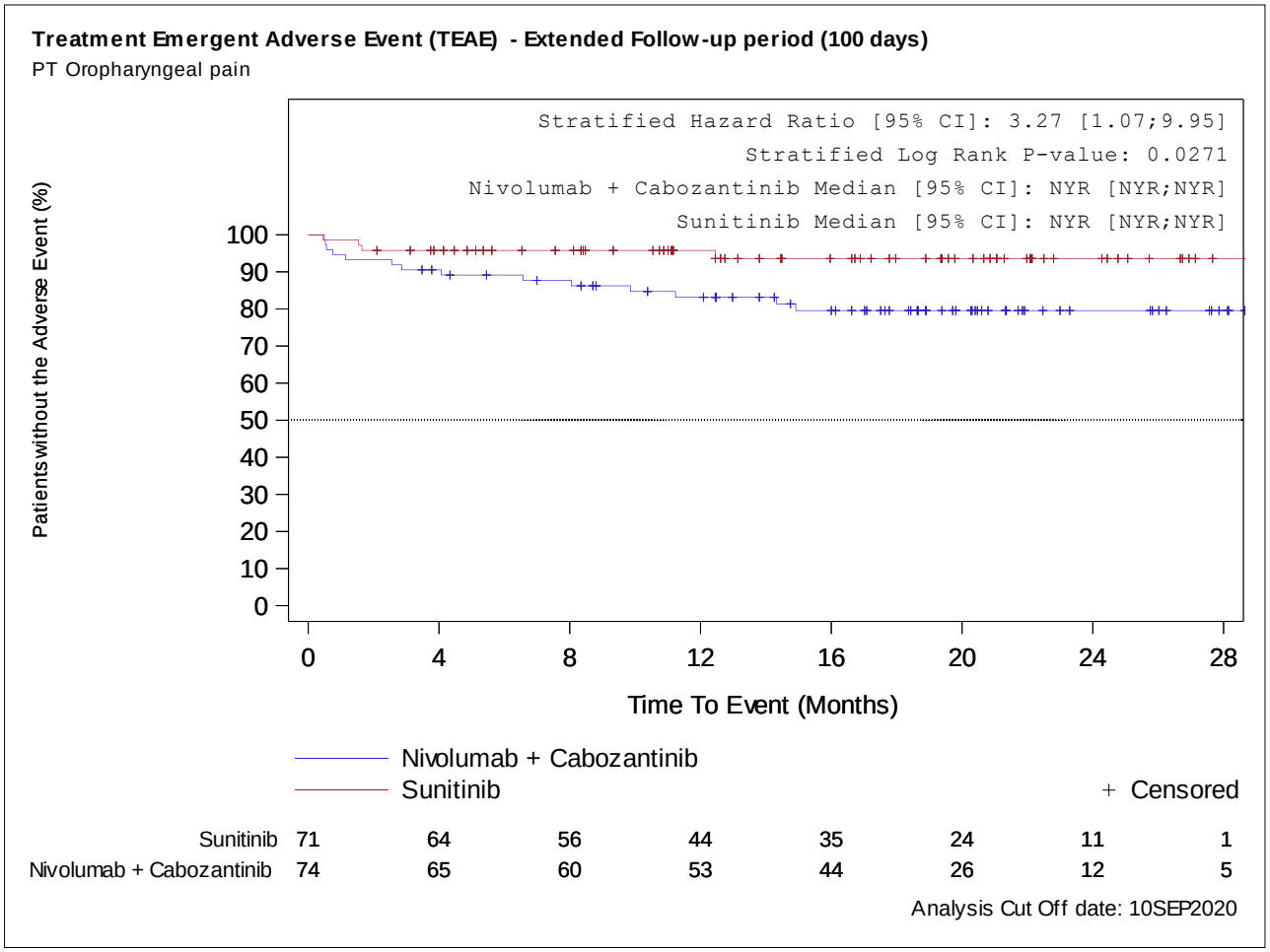

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:30:18

FIGURE 4.4.2.153: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Nasal congestion - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:30:22

FIGURE 4.4.2.154: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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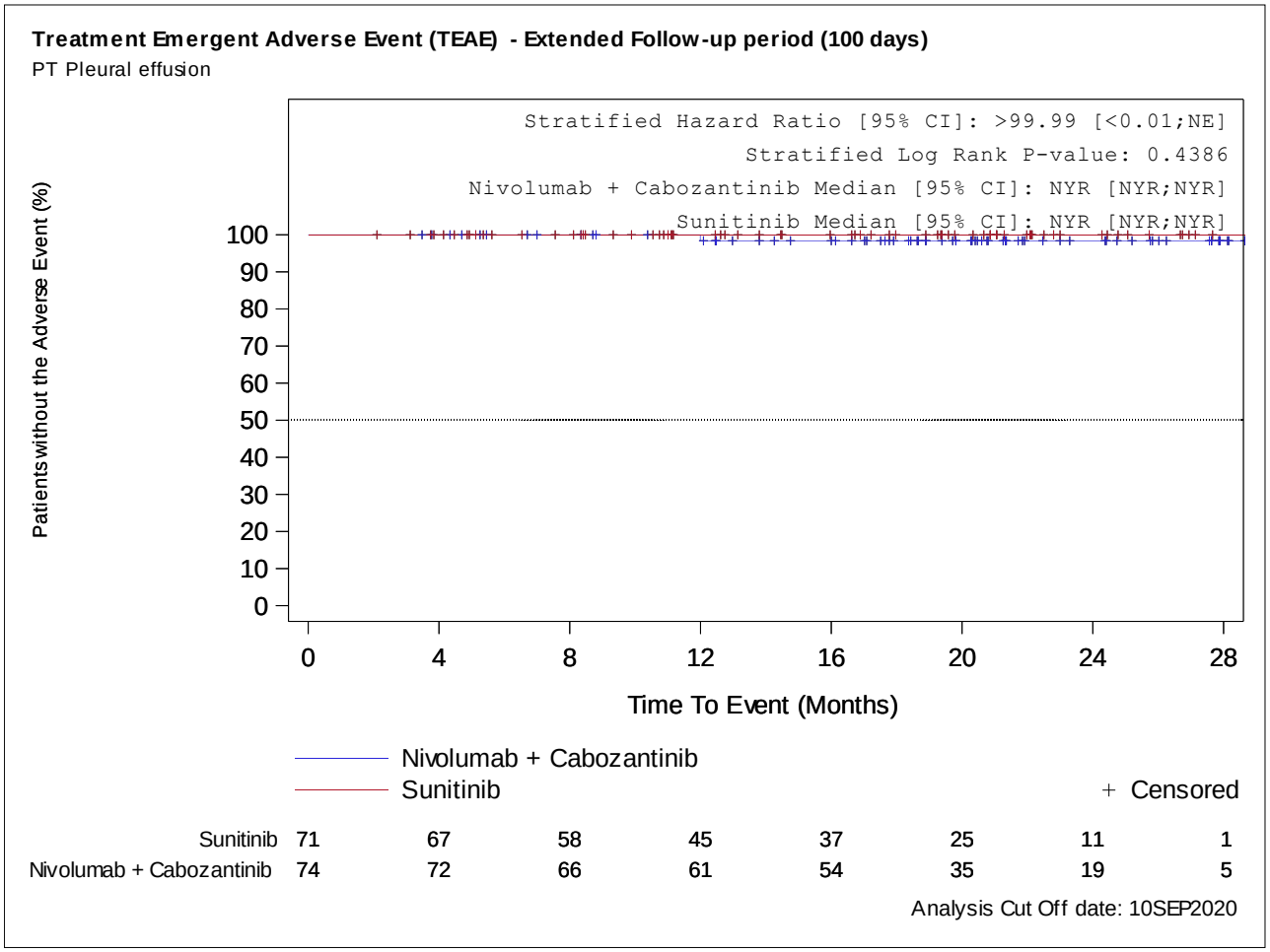
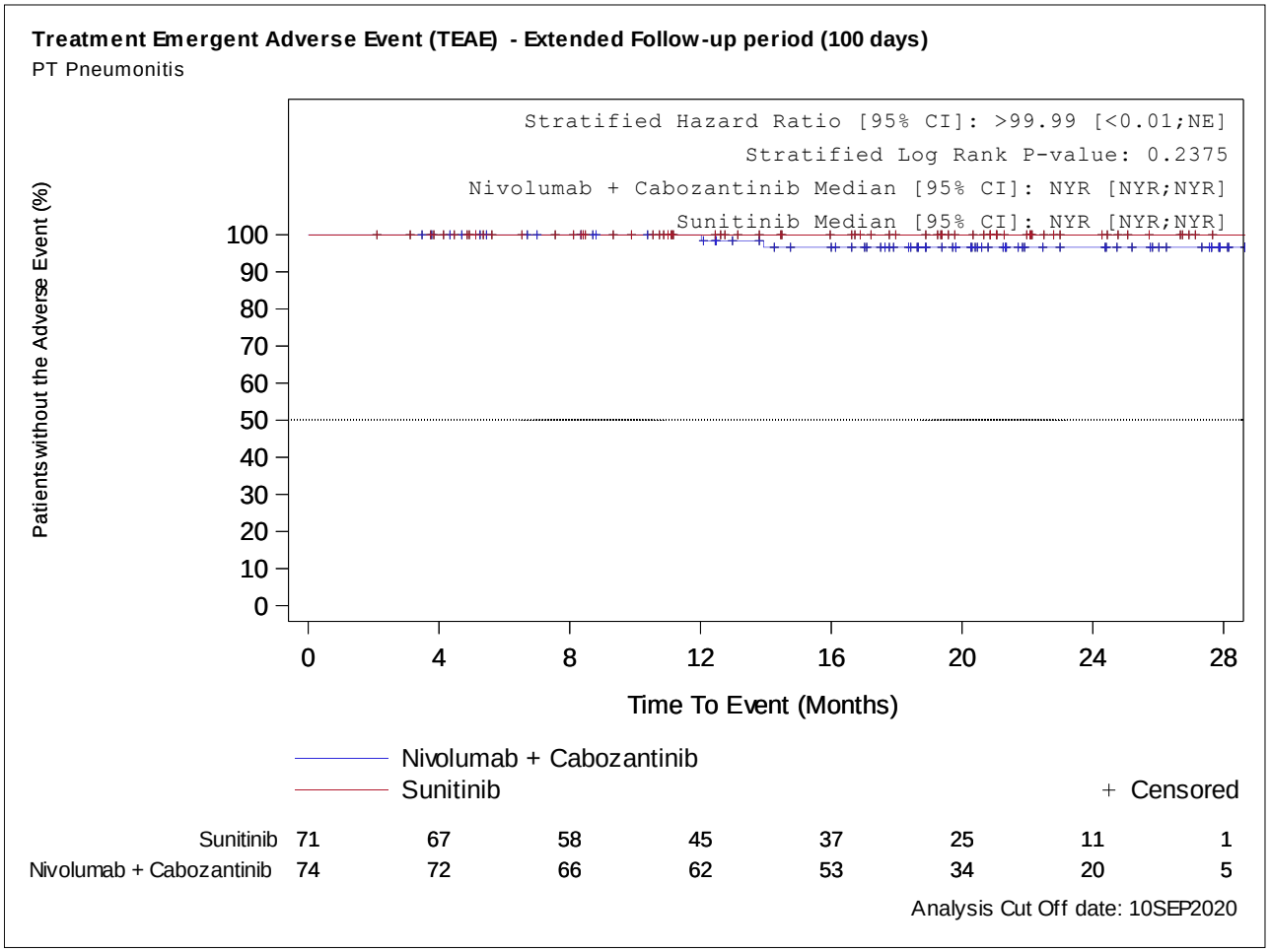
FIGURE 4.4.2.155: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pleural effusion - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



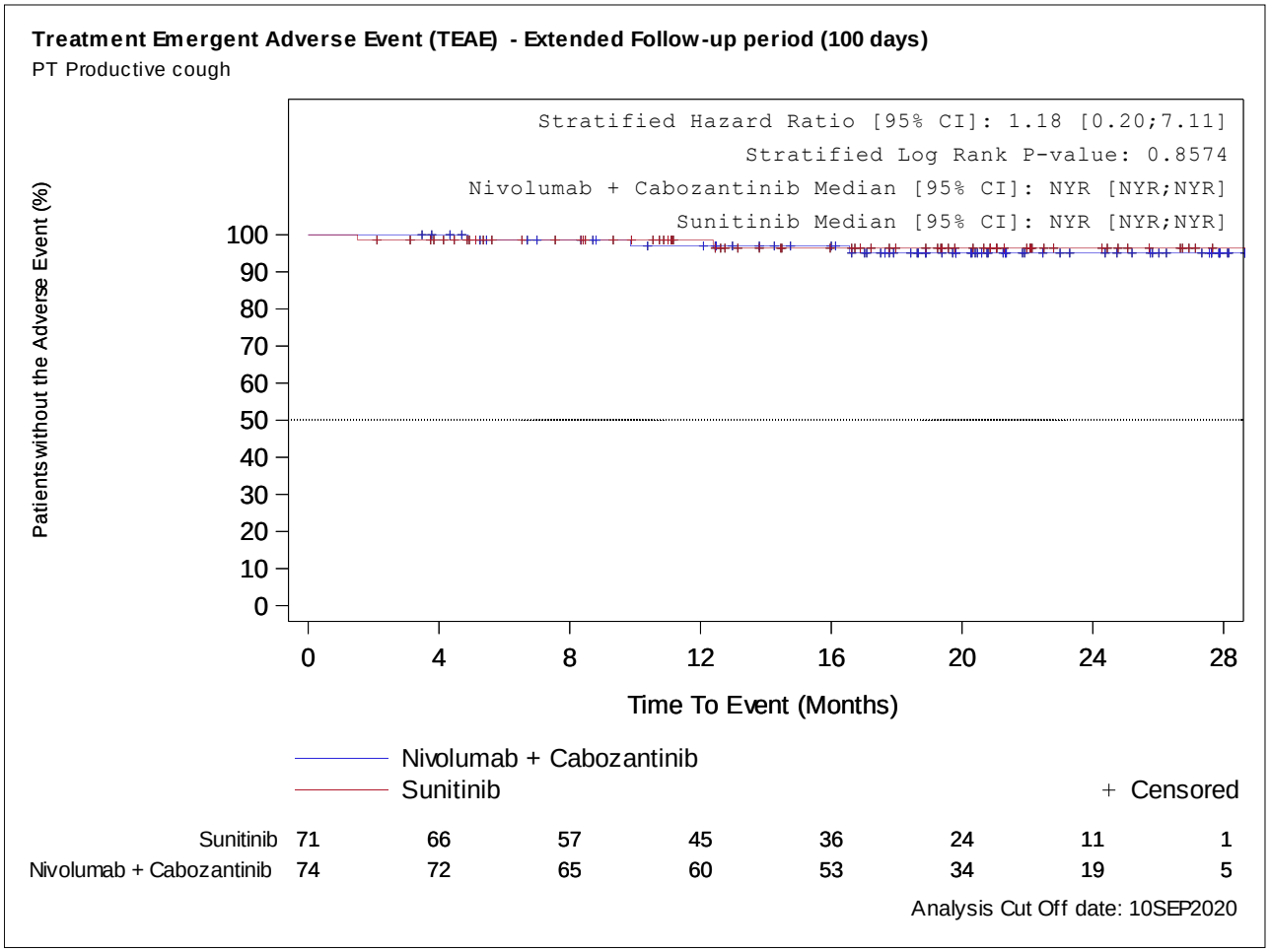

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:30:30

FIGURE 4.4.2.156: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pneumonitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



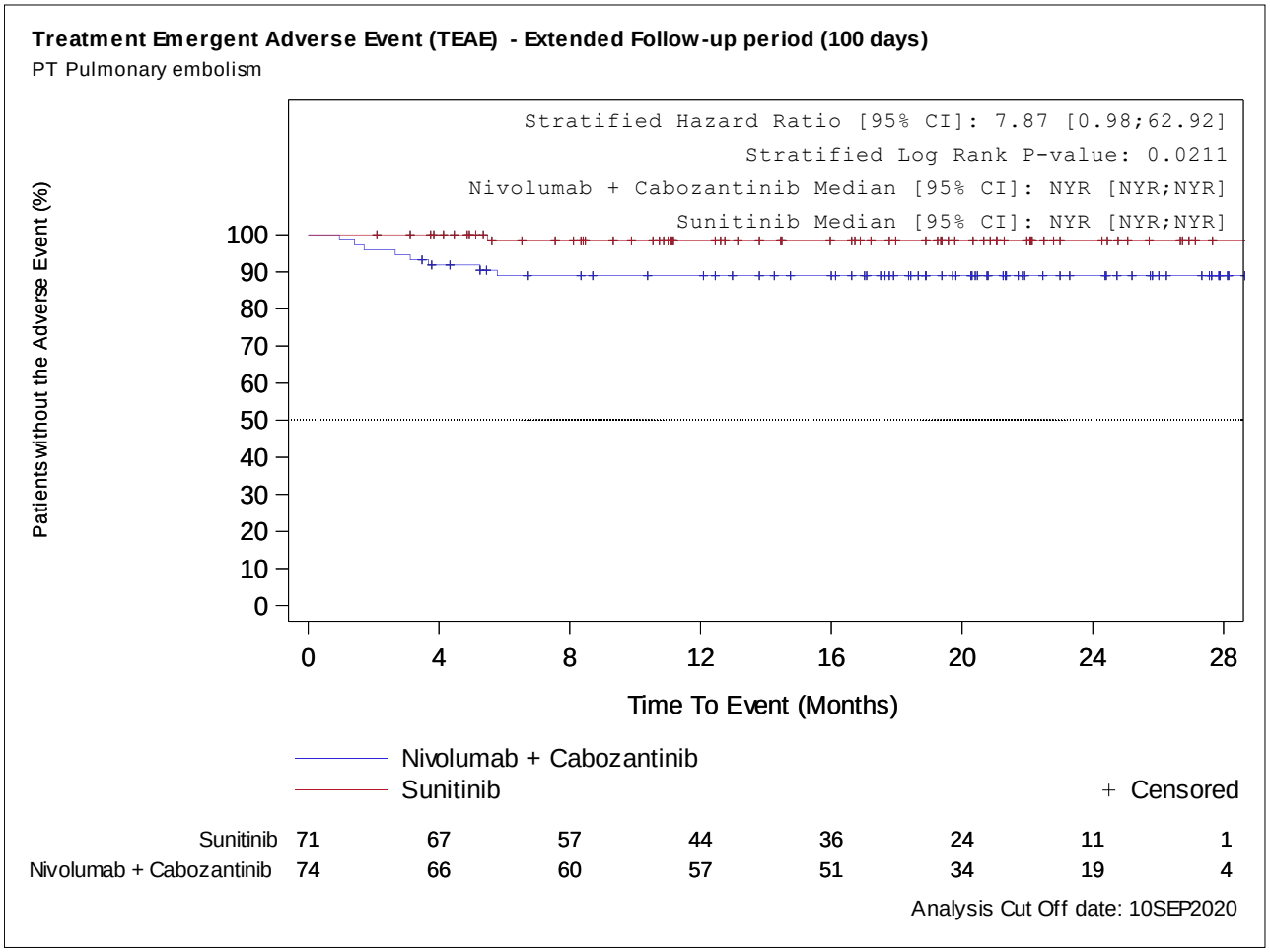

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:30:34

FIGURE 4.4.2.157: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Productive cough - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



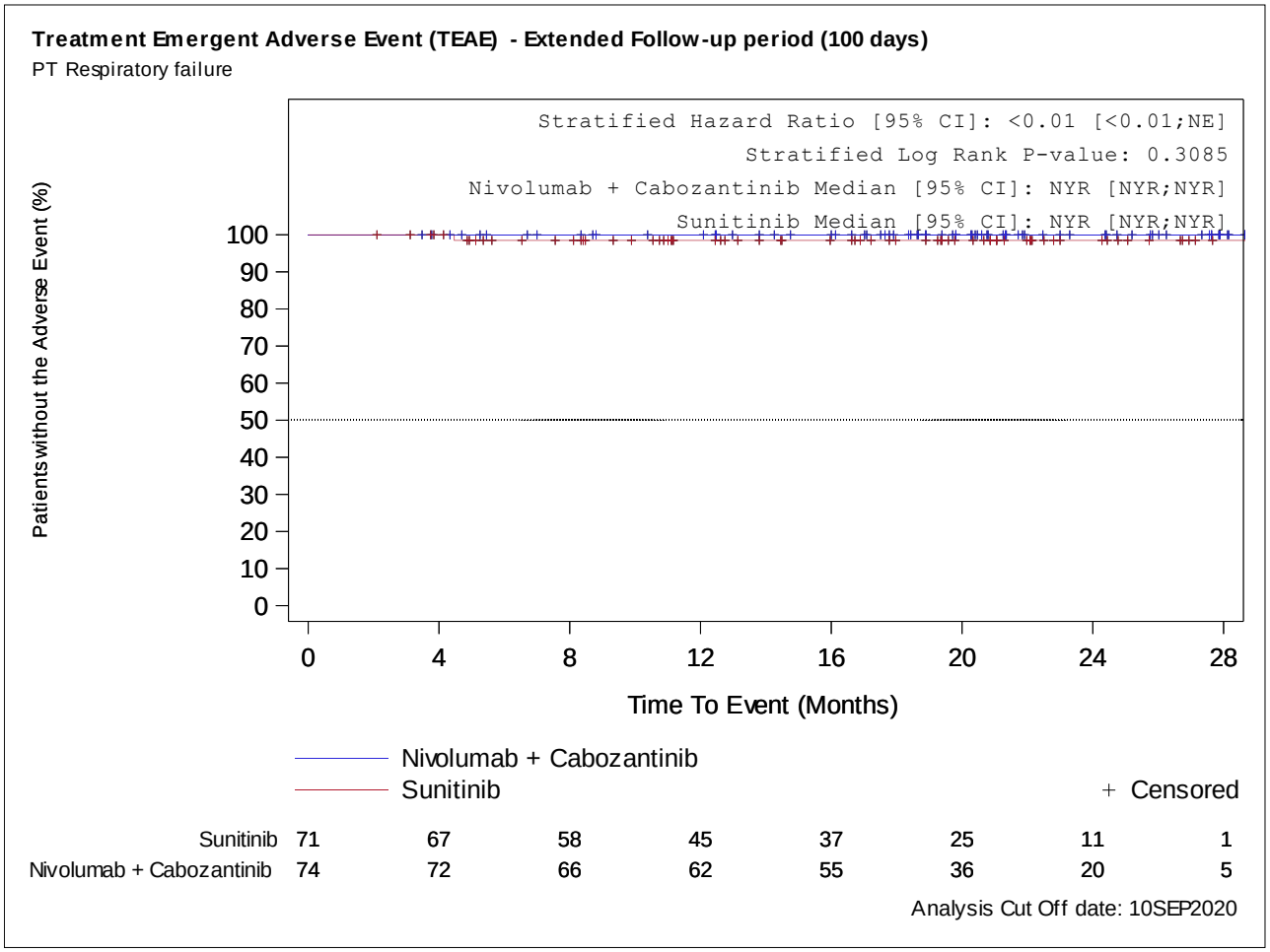

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:30:38

FIGURE 4.4.2.158: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pulmonary embolism - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:30:42

FIGURE 4.4.2.159: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Respiratory failure - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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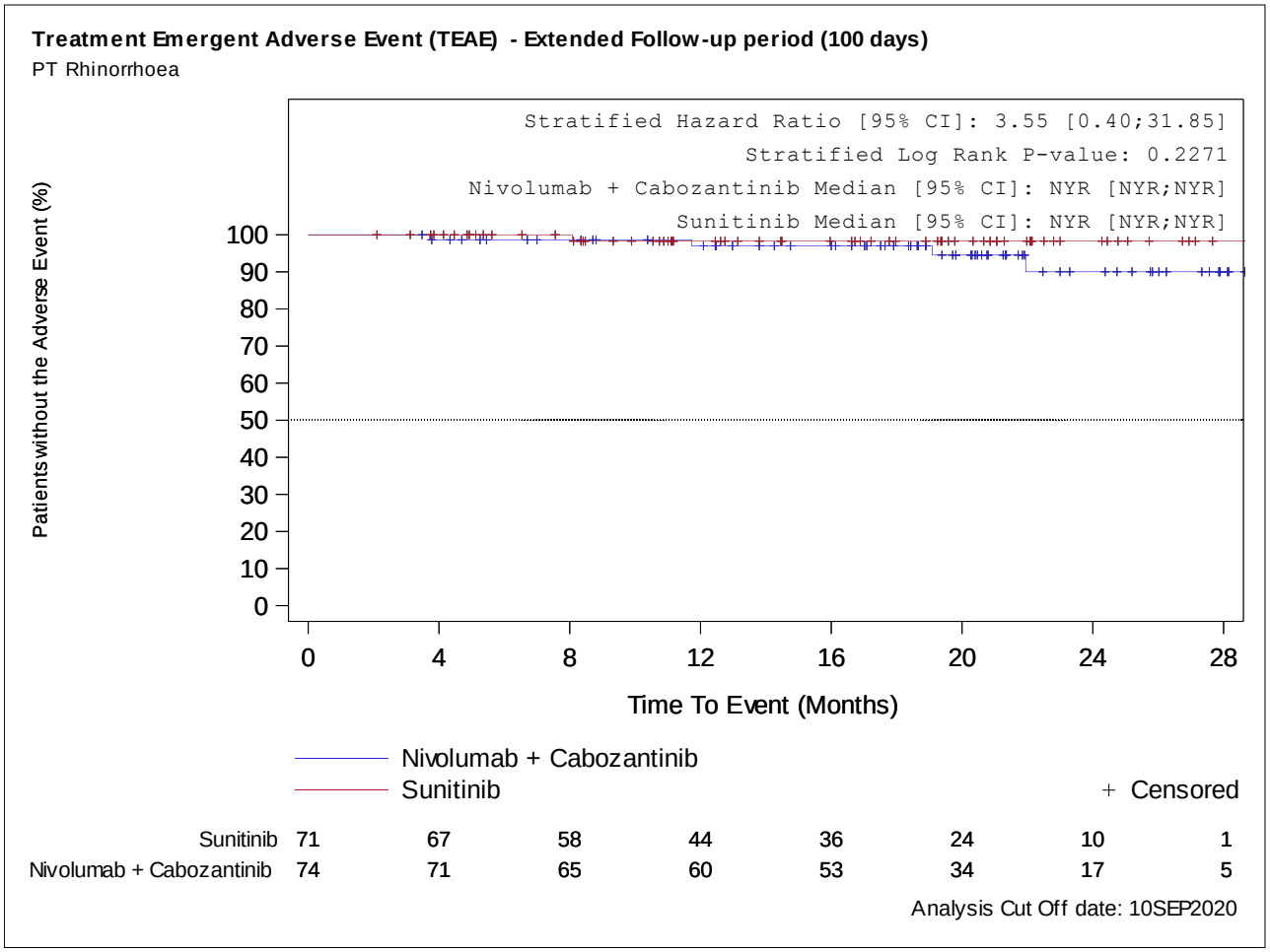
FIGURE 4.4.2.160: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rhinorrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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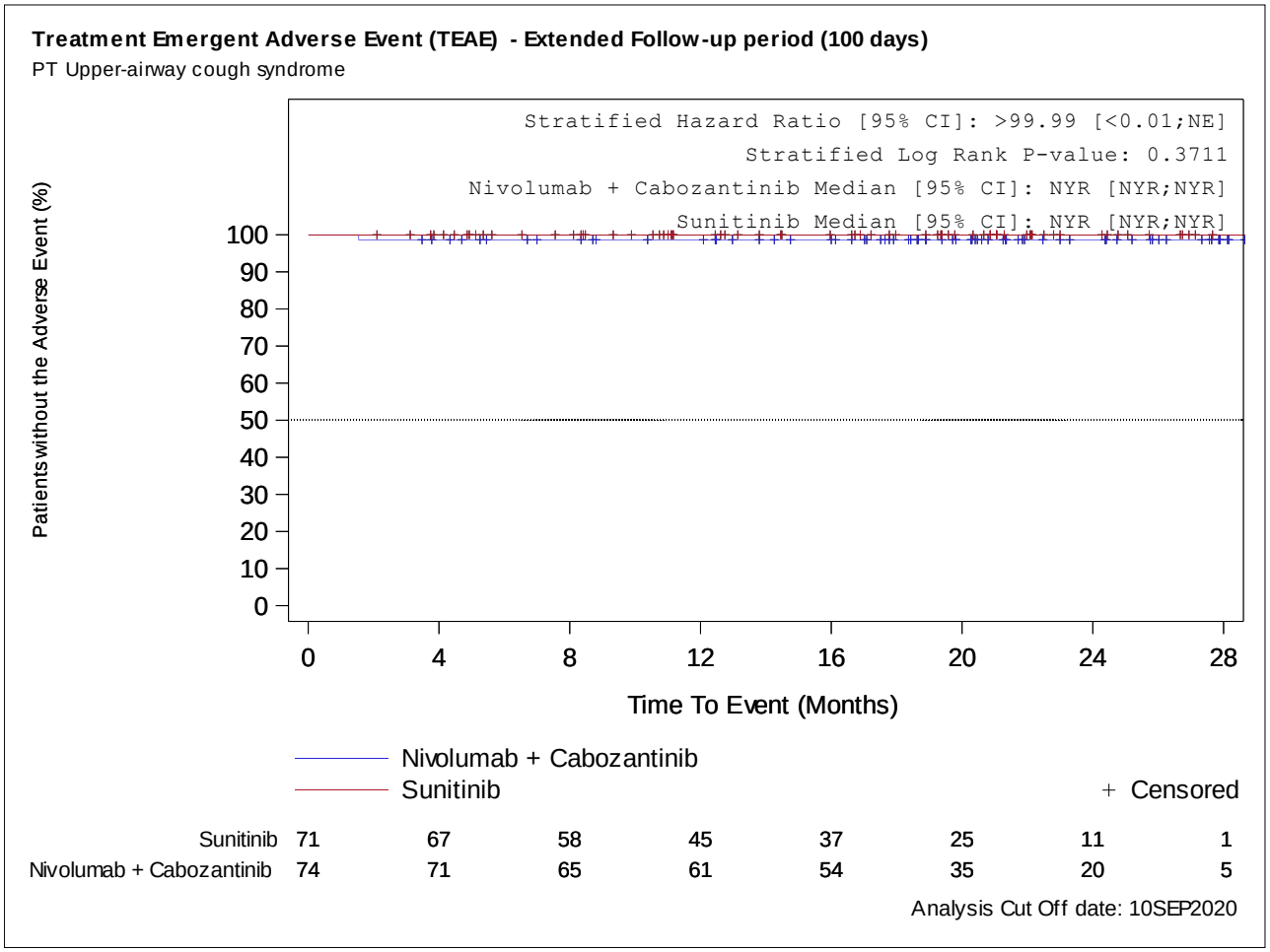
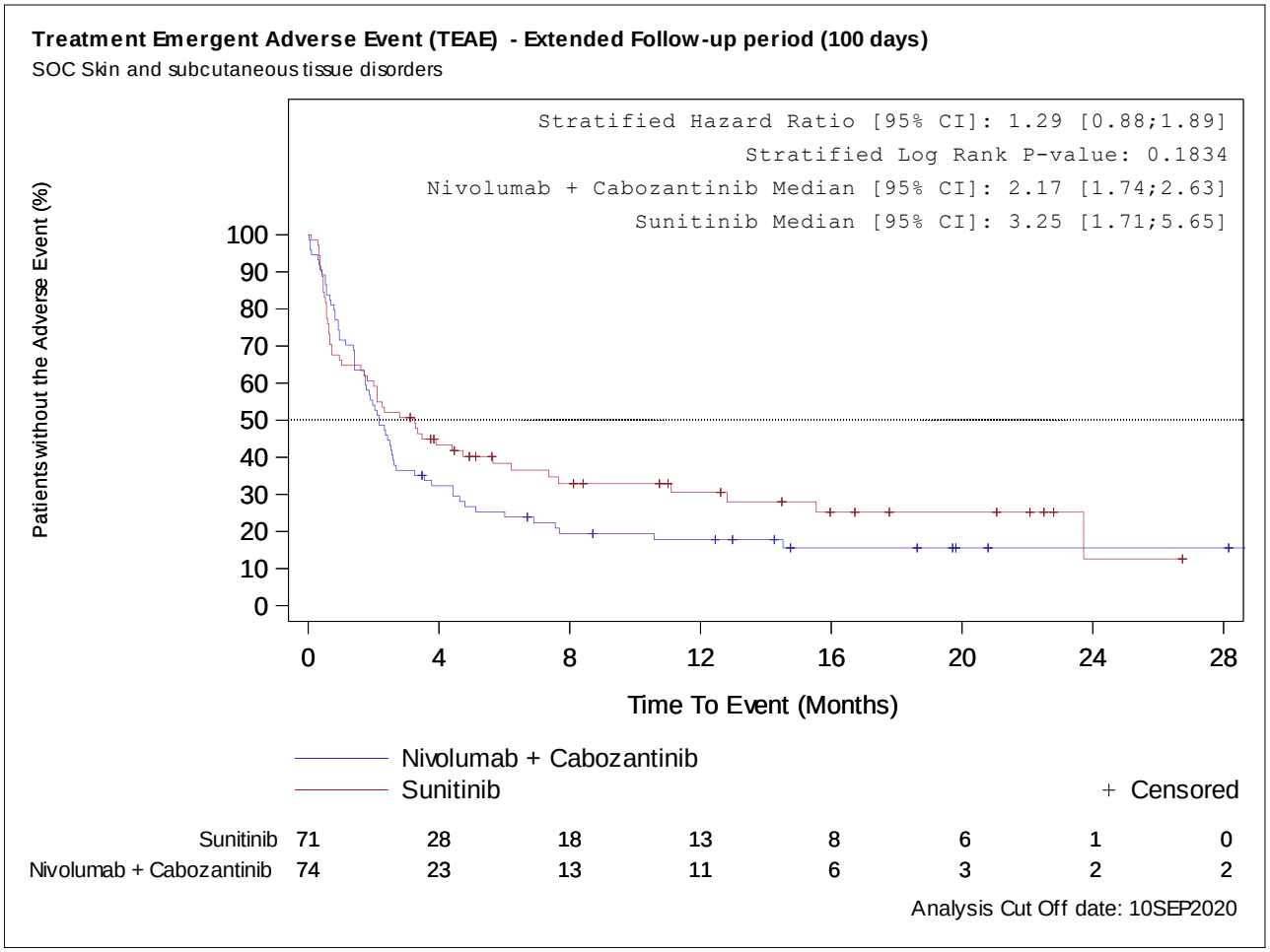
FIGURE 4.4.2.161: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Upper-airway cough syndrome - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



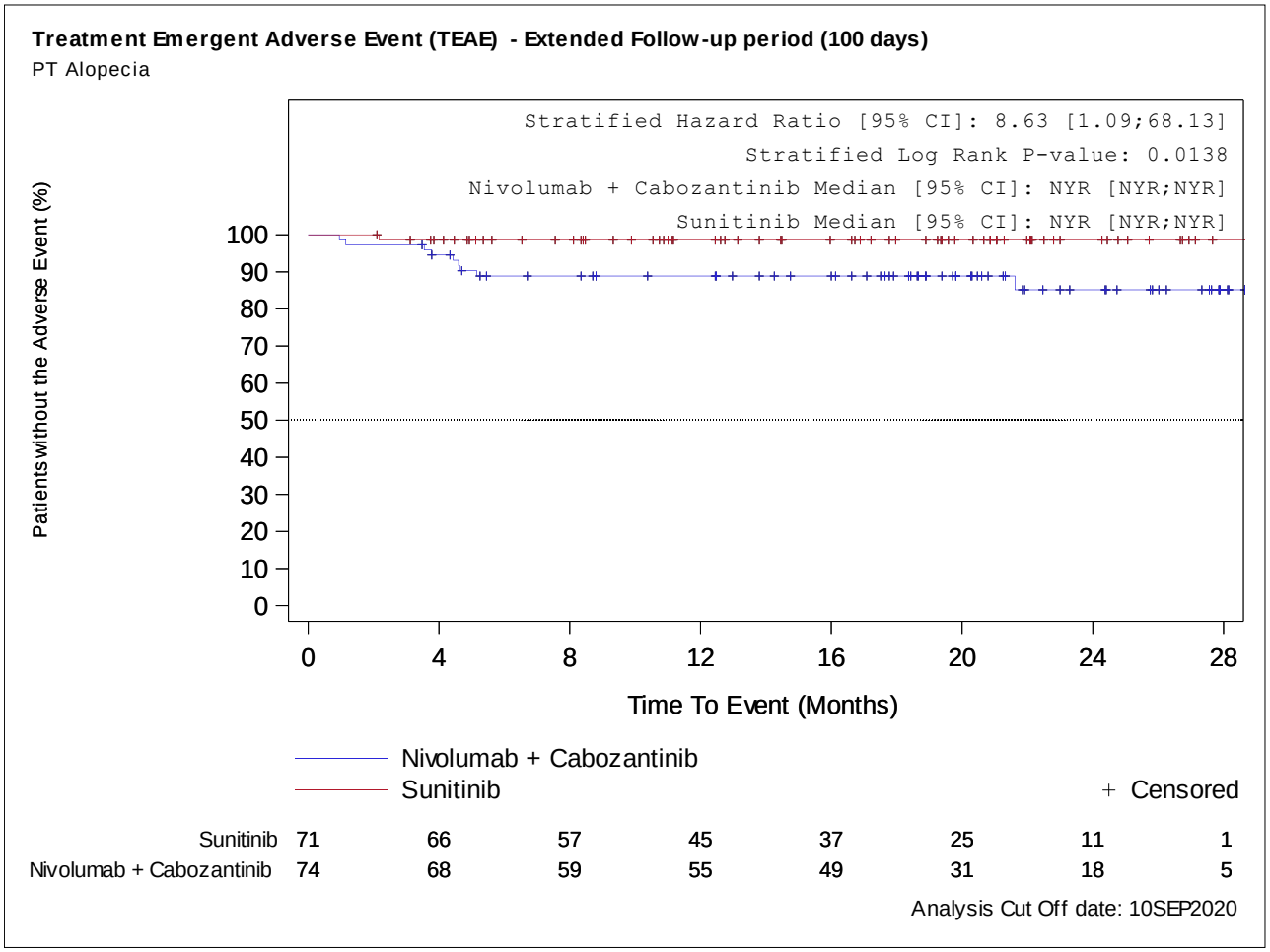

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:30:54

FIGURE 4.4.2.162: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Skin and subcutaneous tissue disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



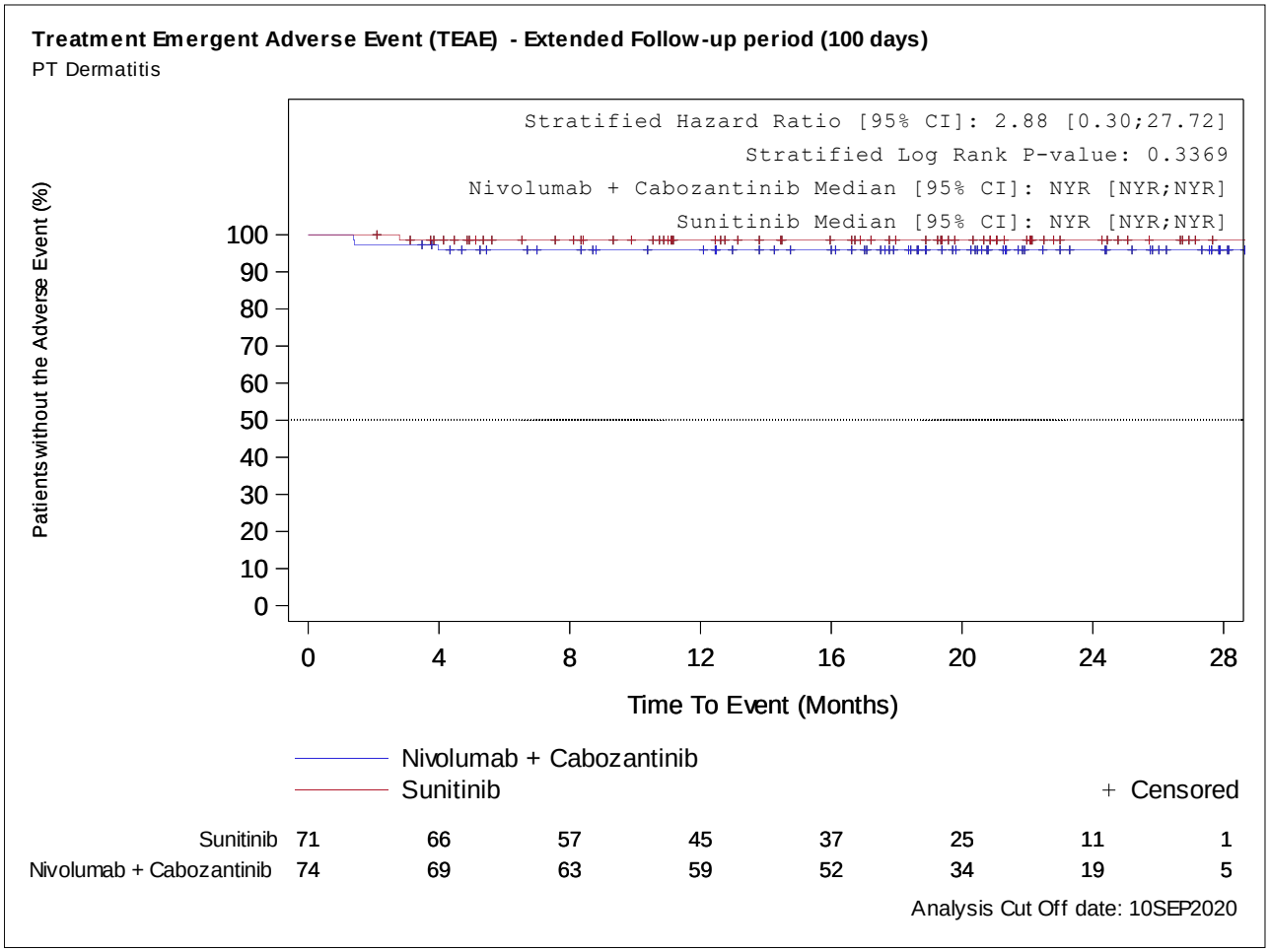

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:30:58

FIGURE 4.4.2.163: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Alopecia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



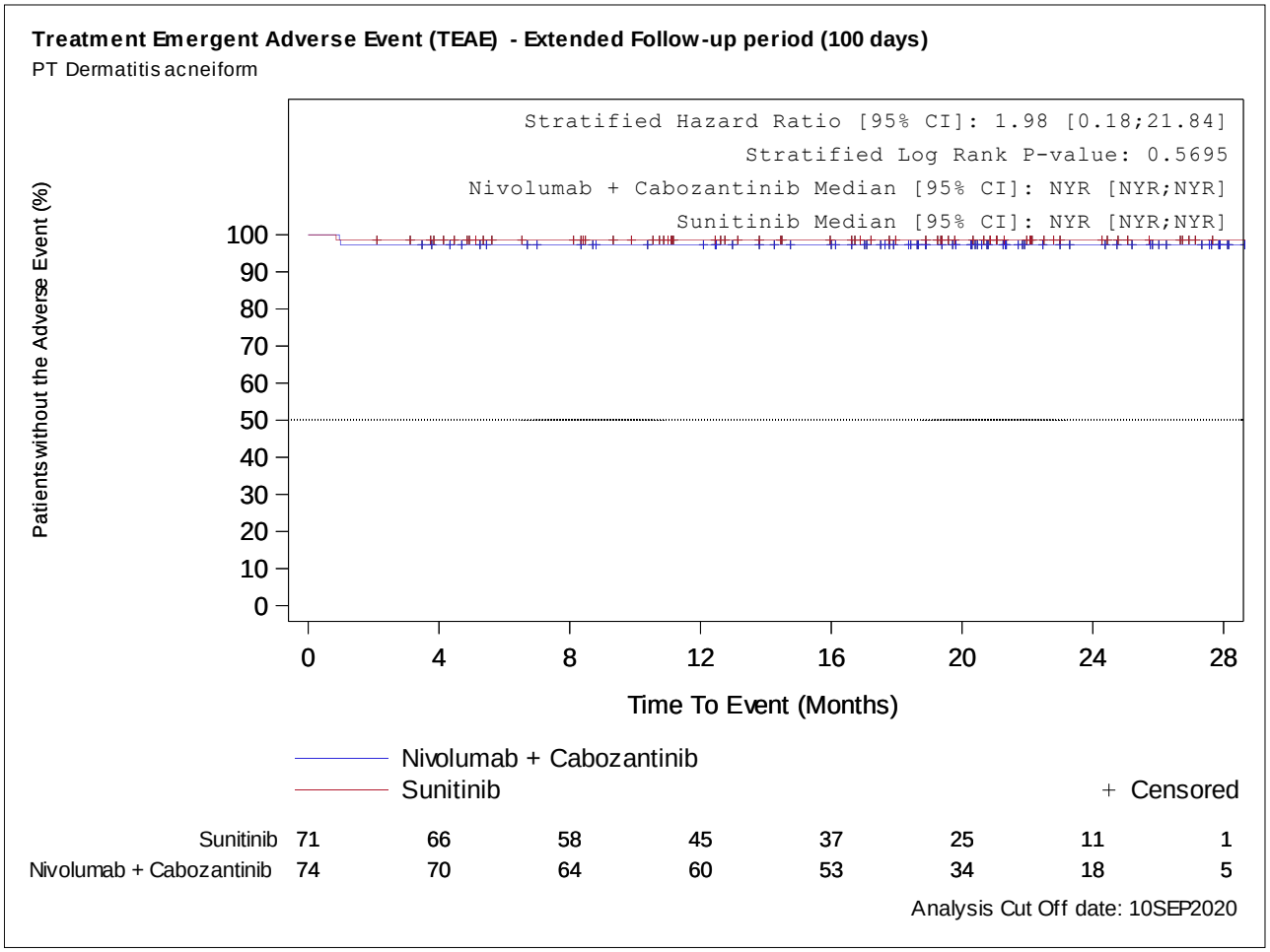

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:31:02

FIGURE 4.4.2.164: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dermatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:31:07

FIGURE 4.4.2.165: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dermatitis acneiform - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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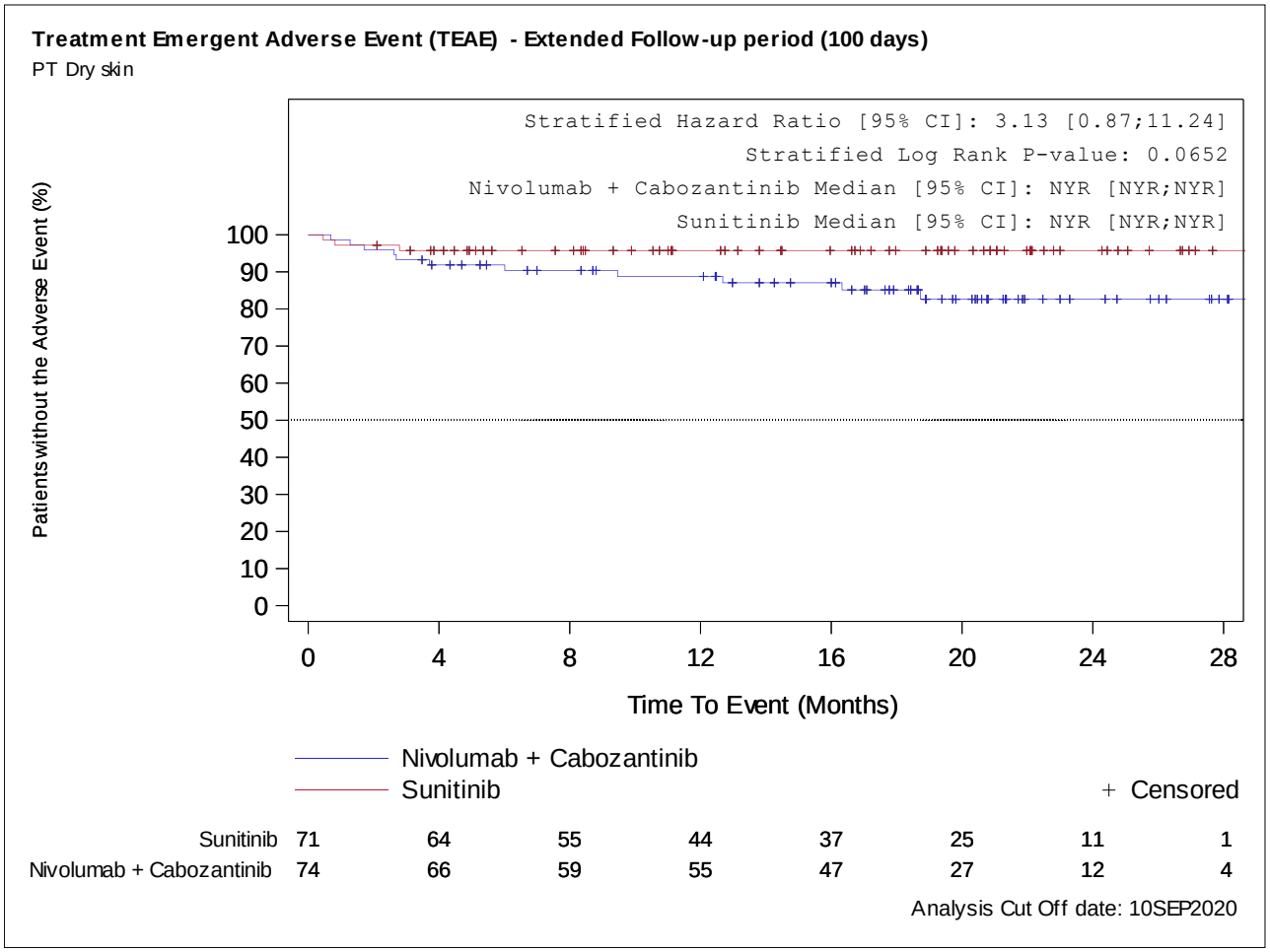
FIGURE 4.4.2.166: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dry skin - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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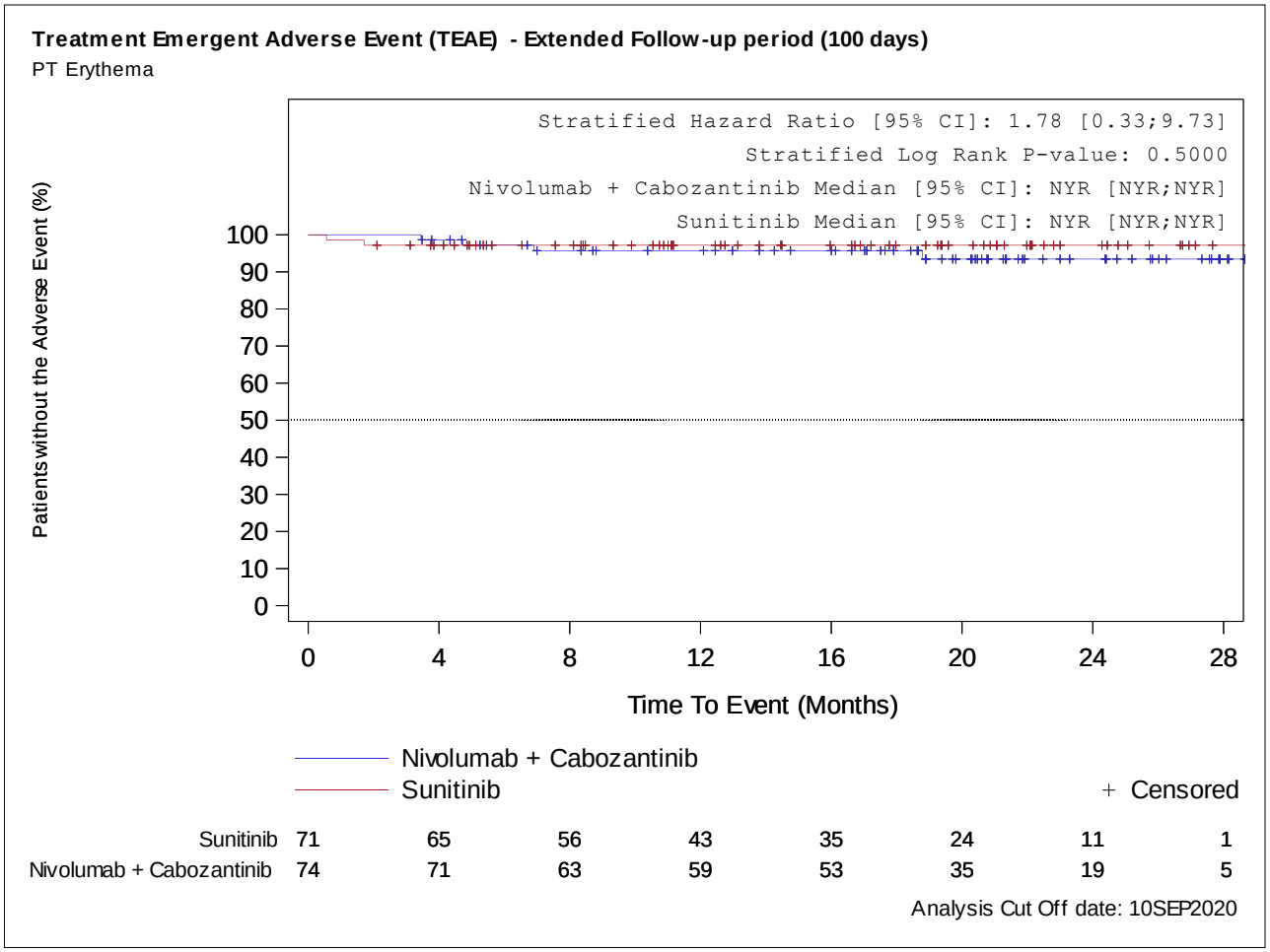
FIGURE 4.4.2.167: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Erythema - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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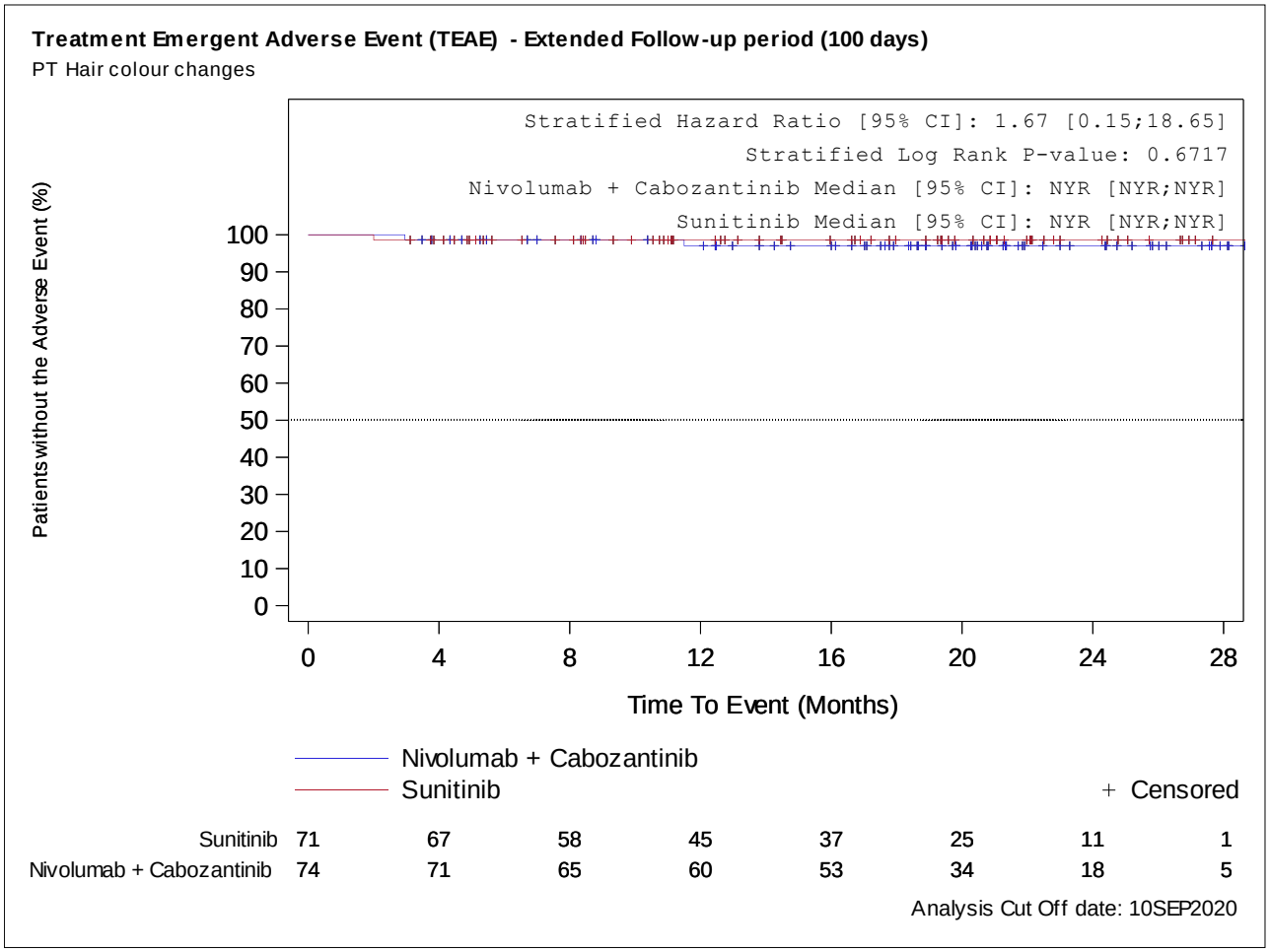
FIGURE 4.4.2.168: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hair colour changes - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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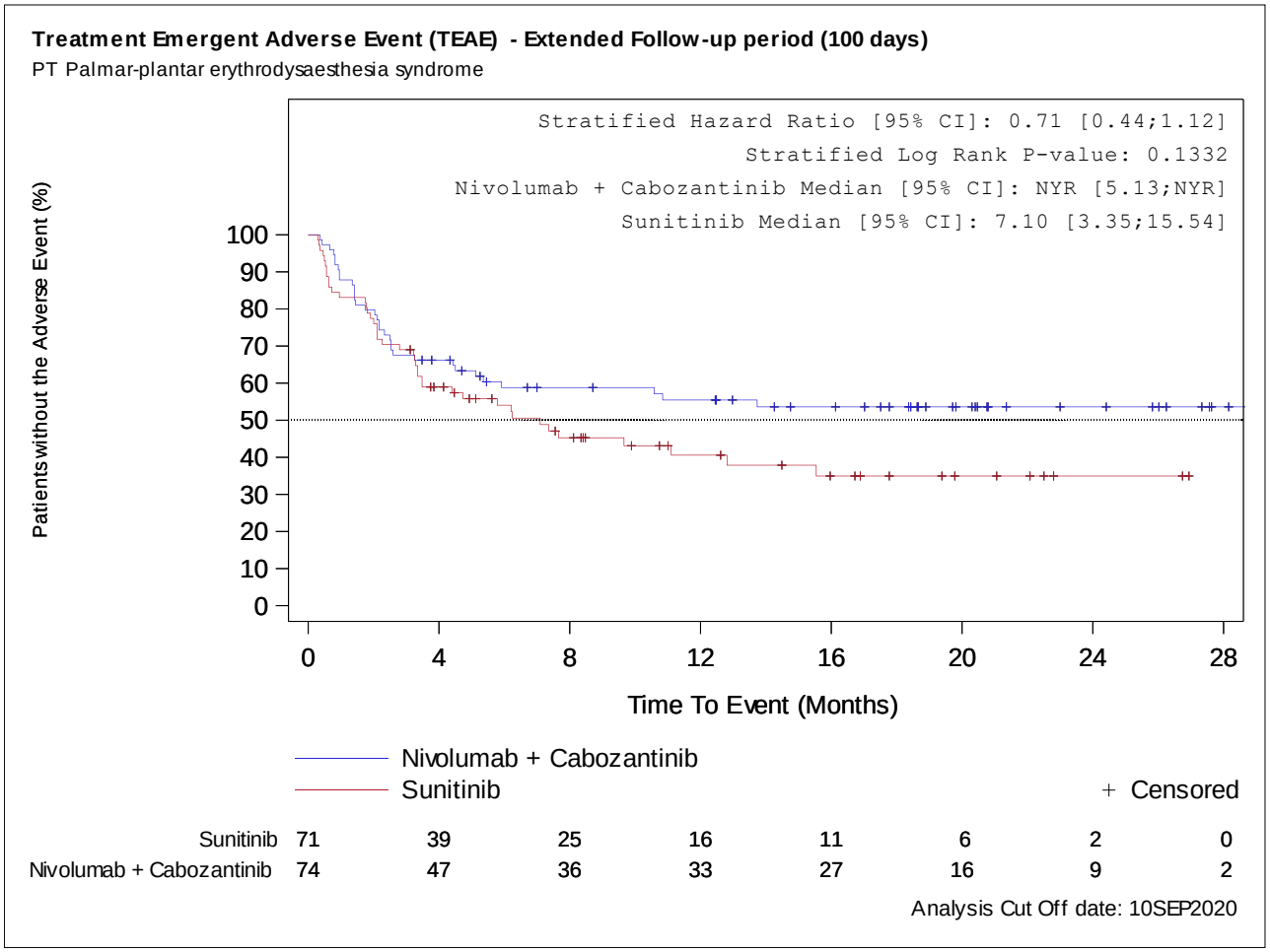
FIGURE 4.4.2.169: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Palmar-plantar erythrodysaesthesia syndrome - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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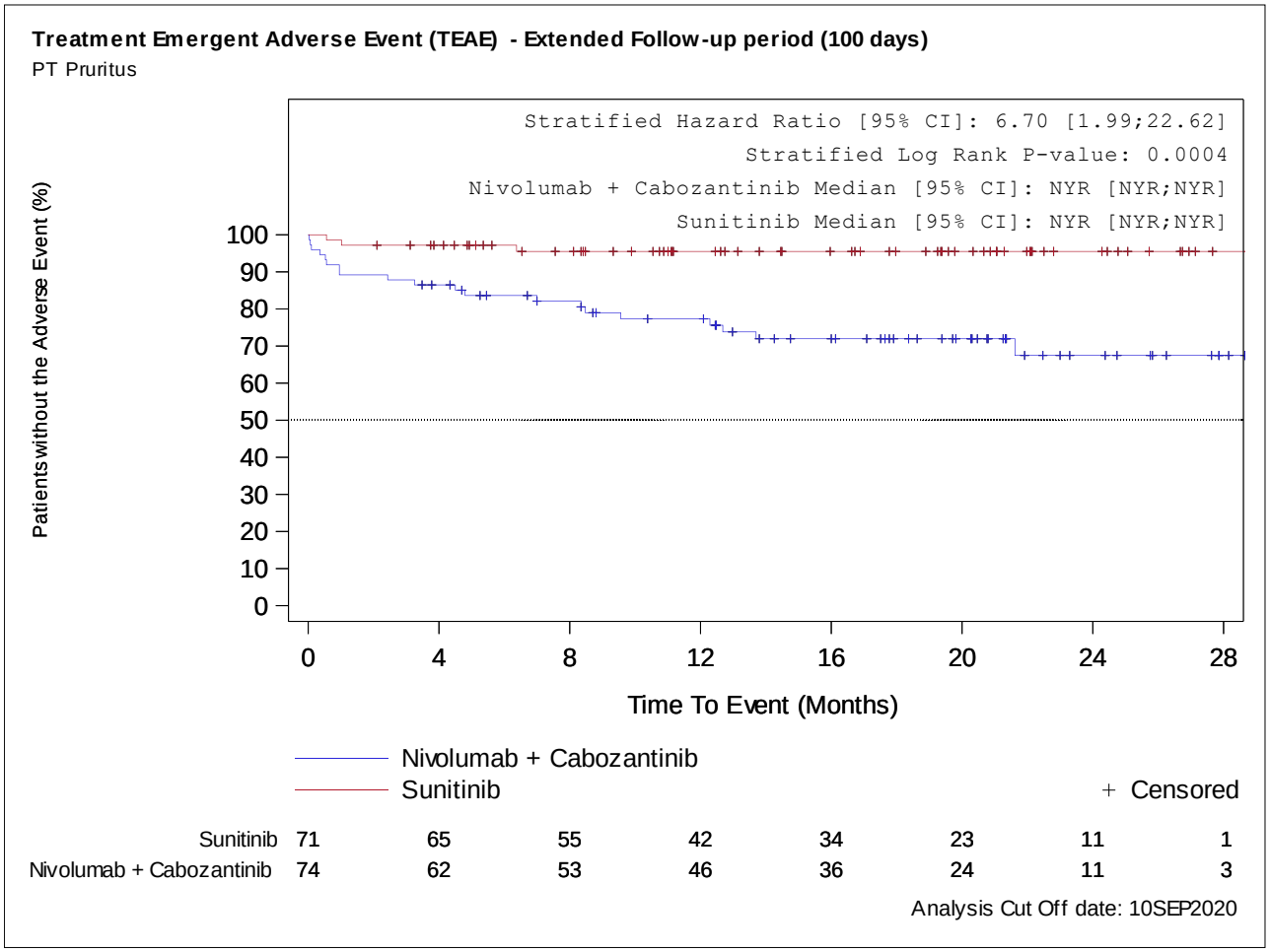
FIGURE 4.4.2.170: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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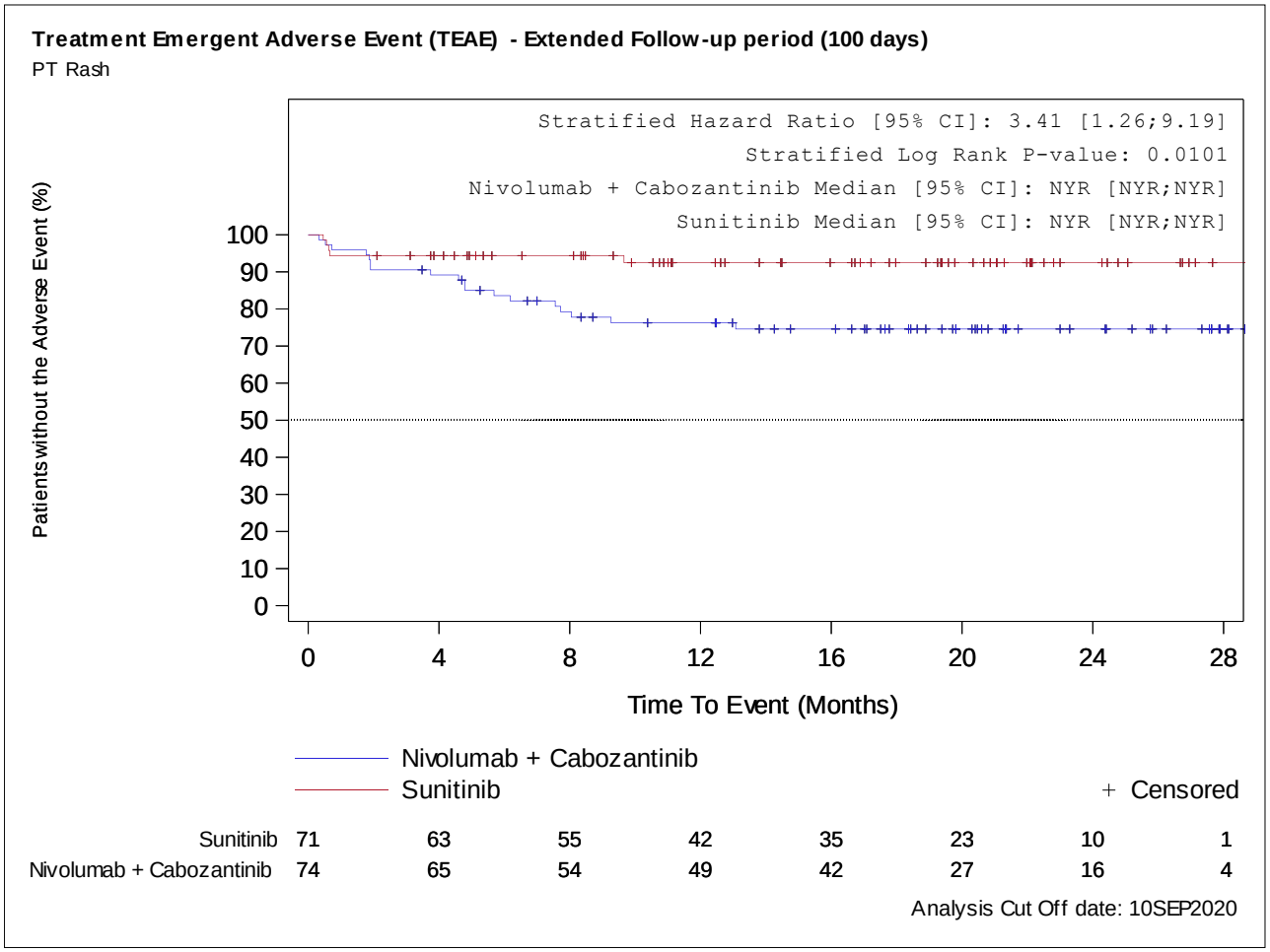
FIGURE 4.4.2.171: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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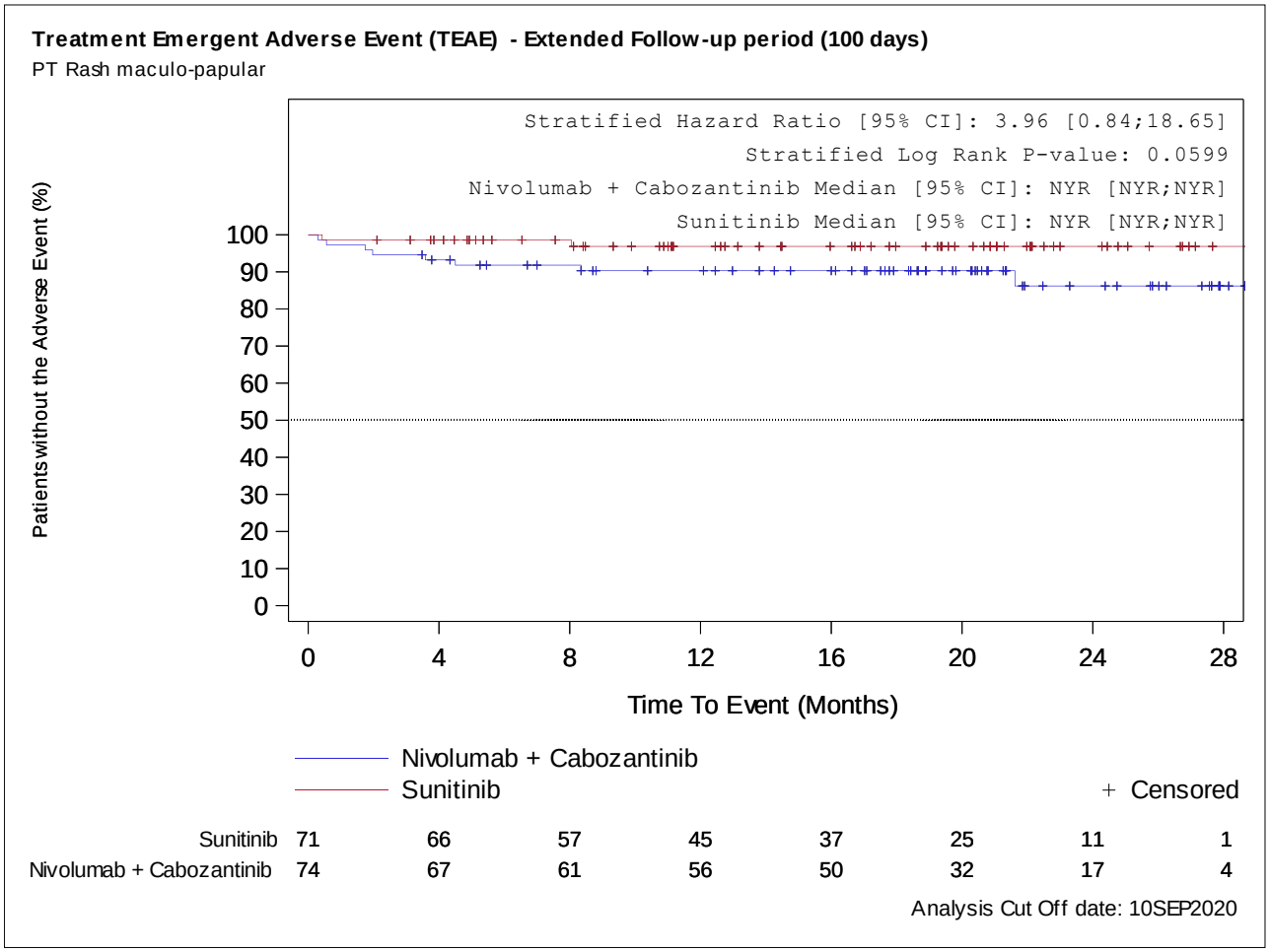
FIGURE 4.4.2.172: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash maculo-papular - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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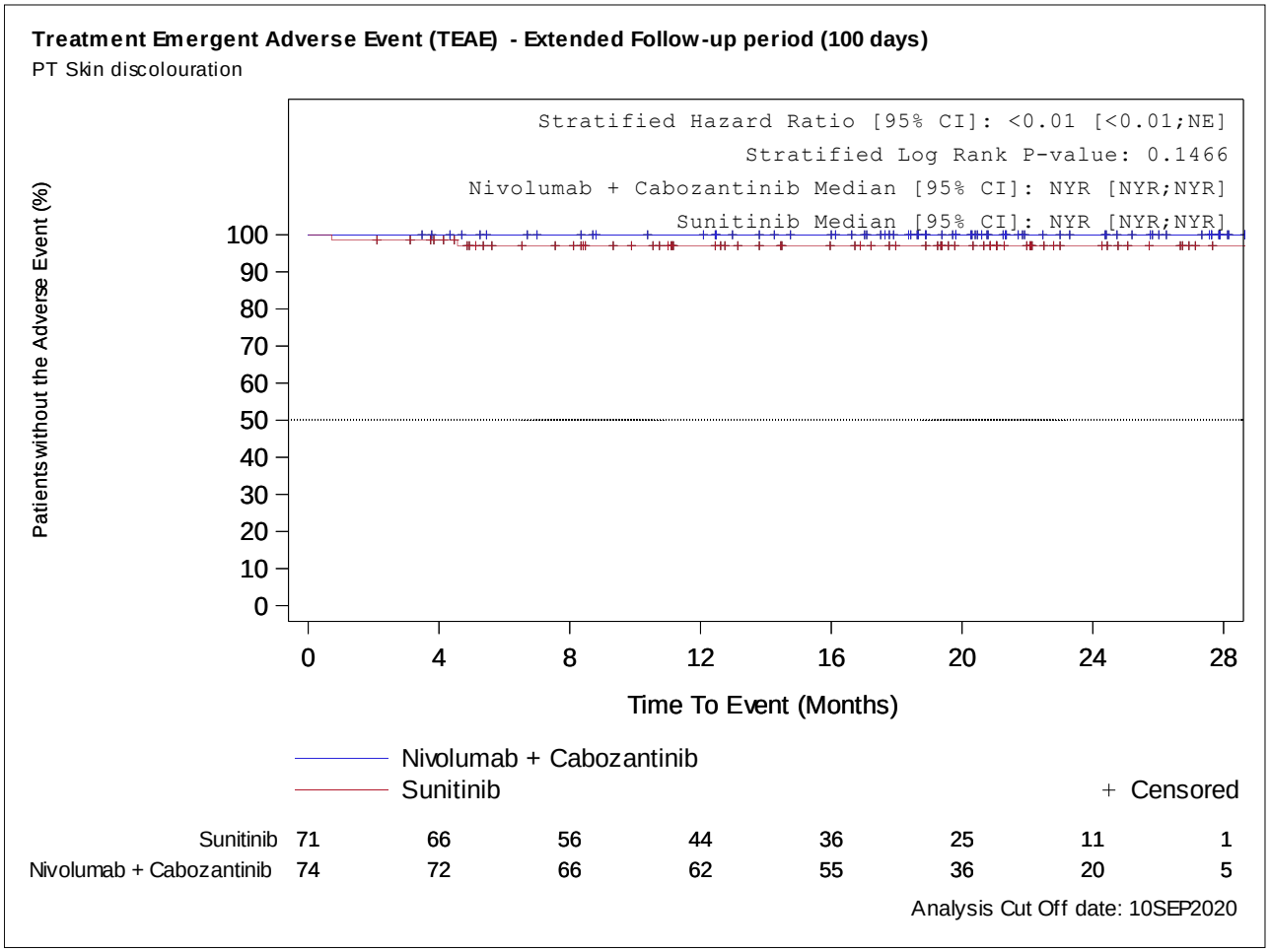
FIGURE 4.4.2.173: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Skin discolouration - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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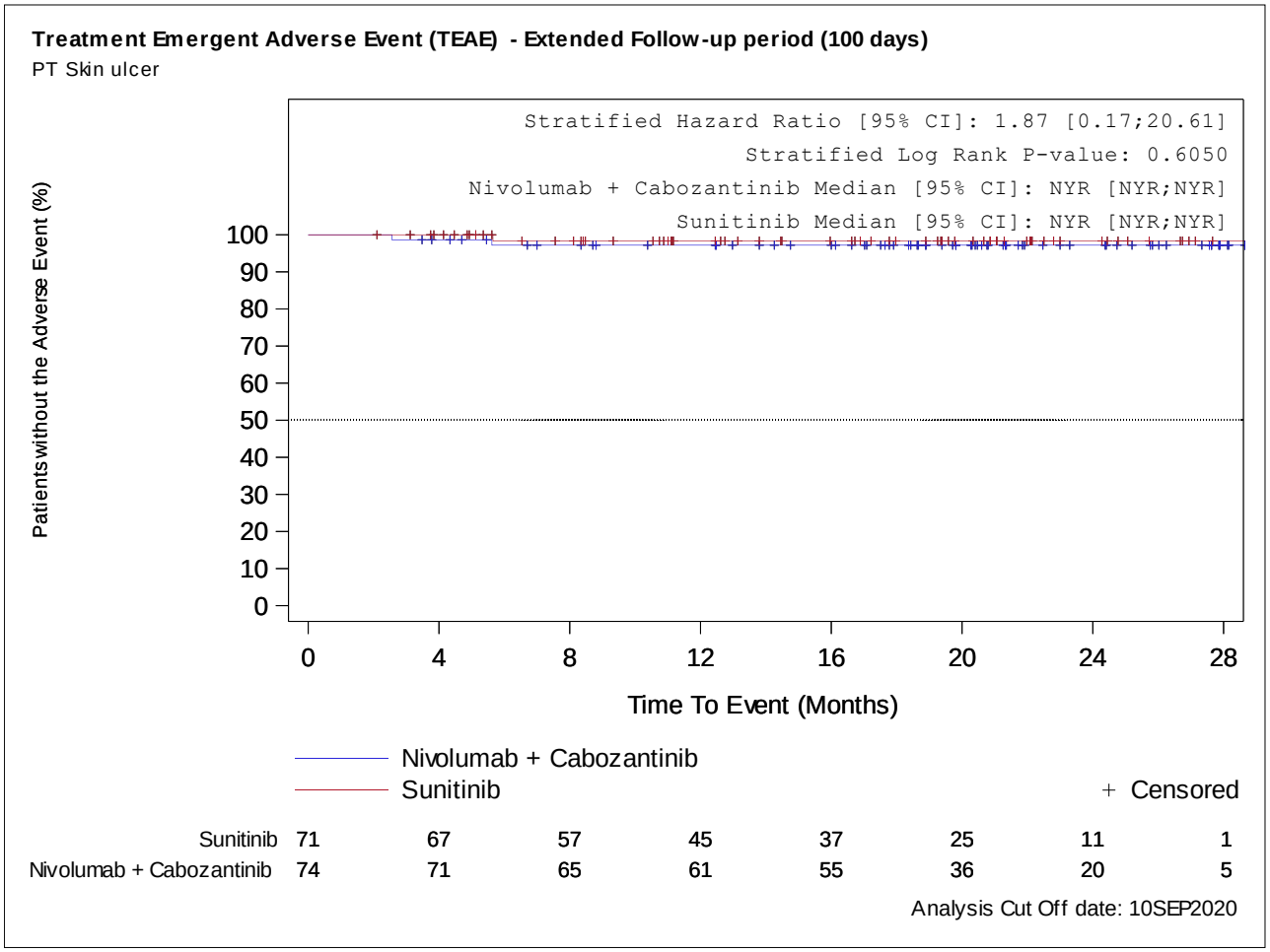
FIGURE 4.4.2.174: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Skin ulcer - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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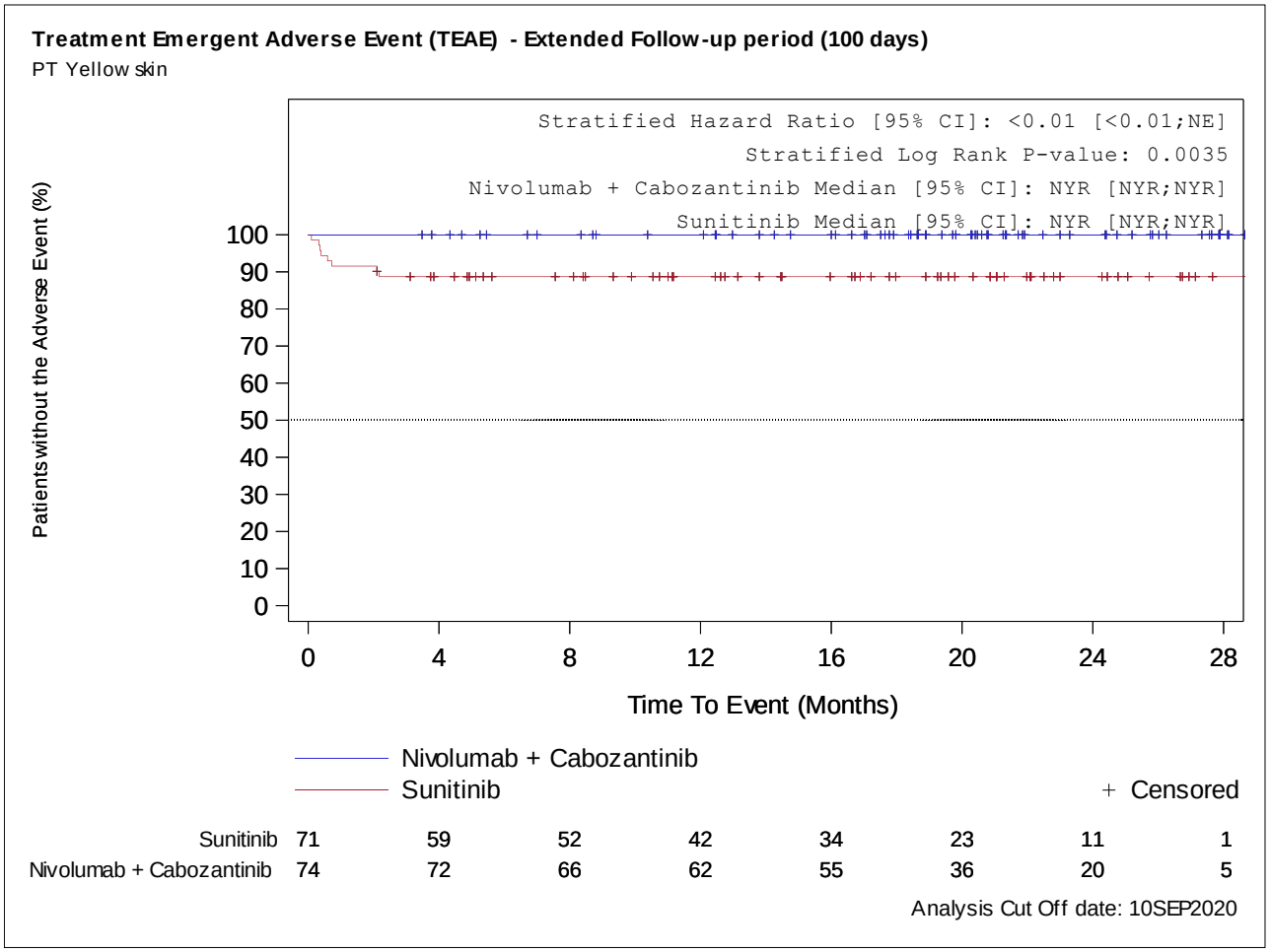
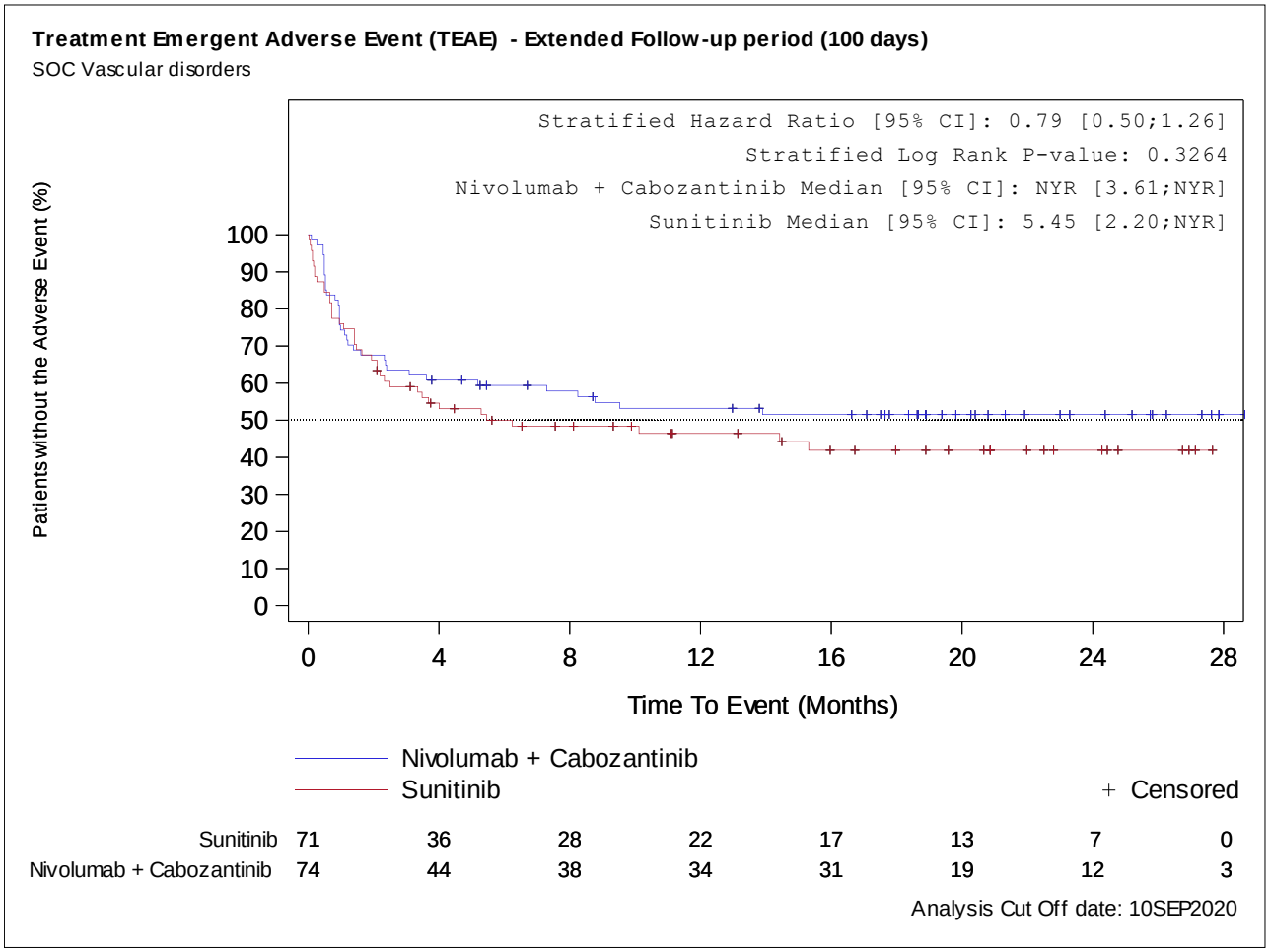
FIGURE 4.4.2.175: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Yellow skin - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:31:51

FIGURE 4.4.2.176: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Vascular disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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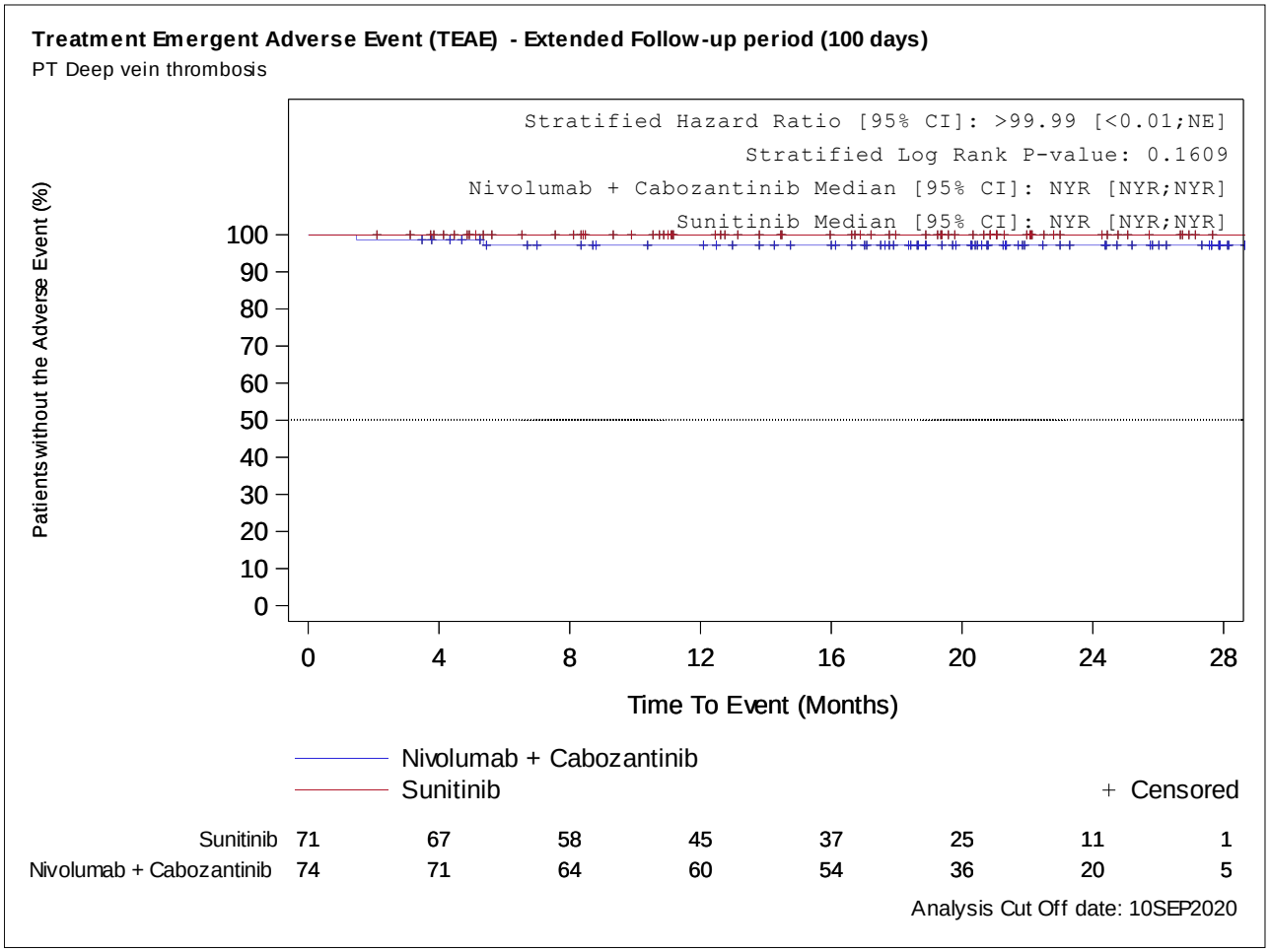
FIGURE 4.4.2.177: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Deep vein thrombosis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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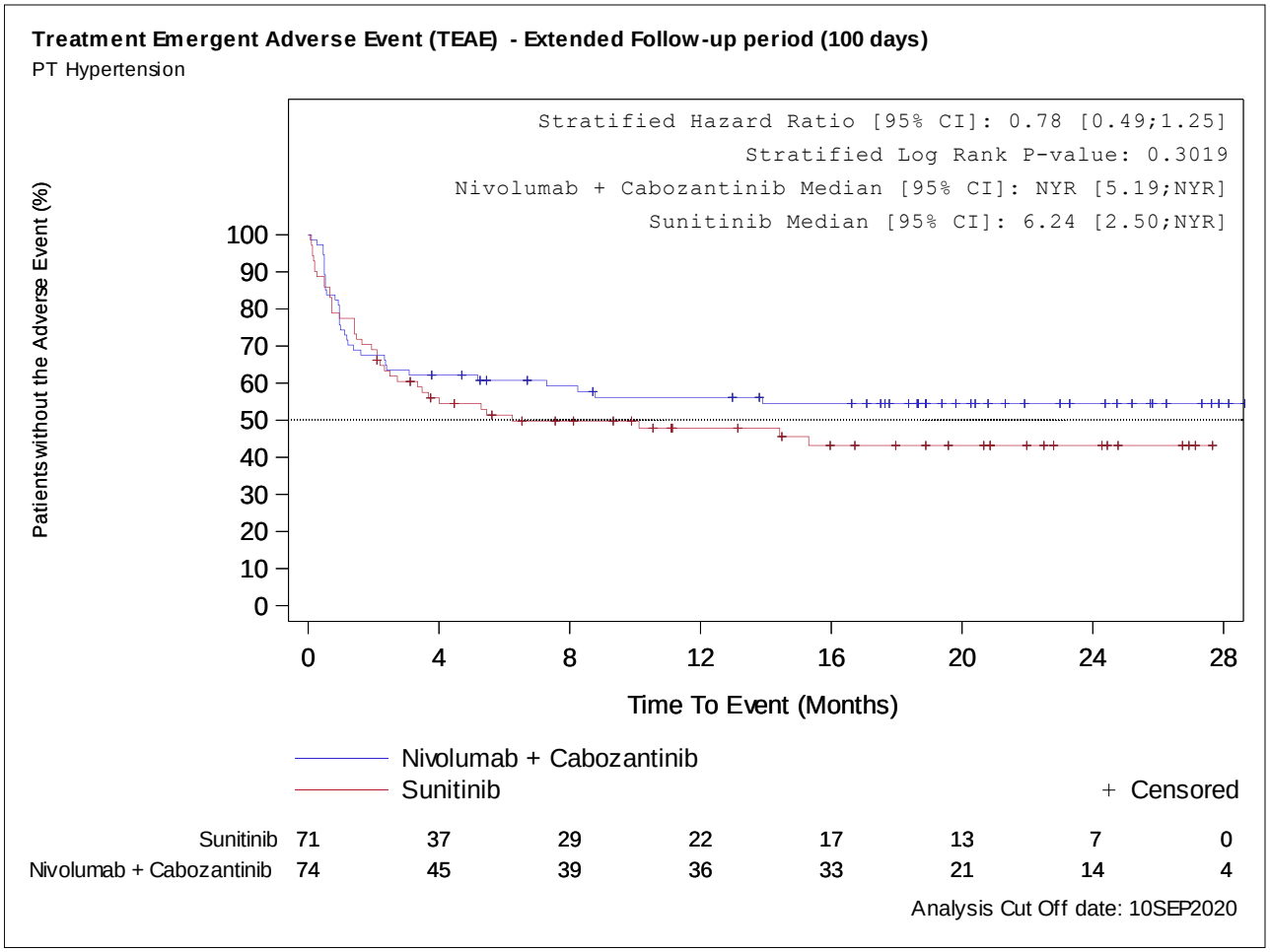
FIGURE 4.4.2.178: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypertension - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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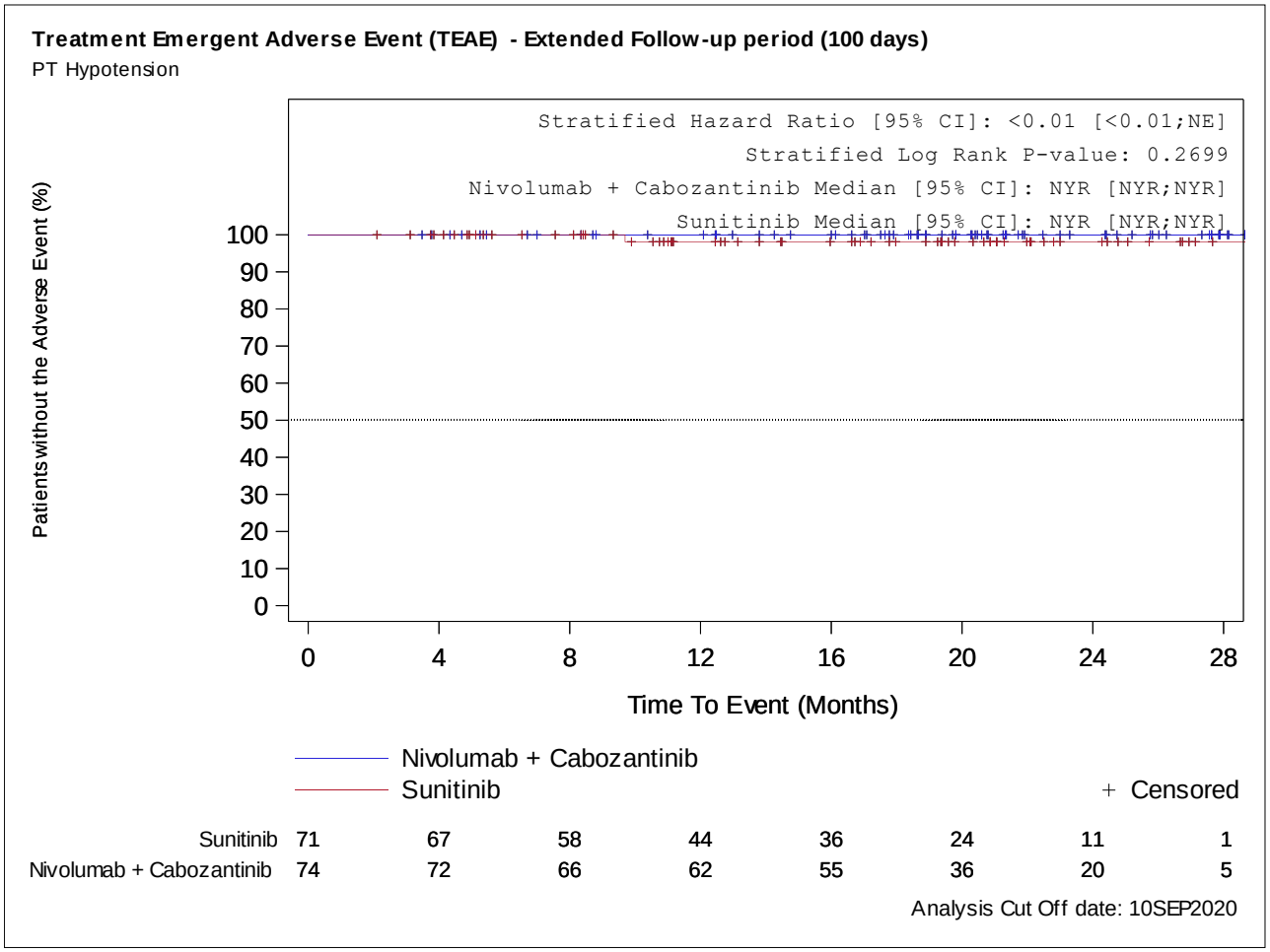
FIGURE 4.4.2.179: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypotension - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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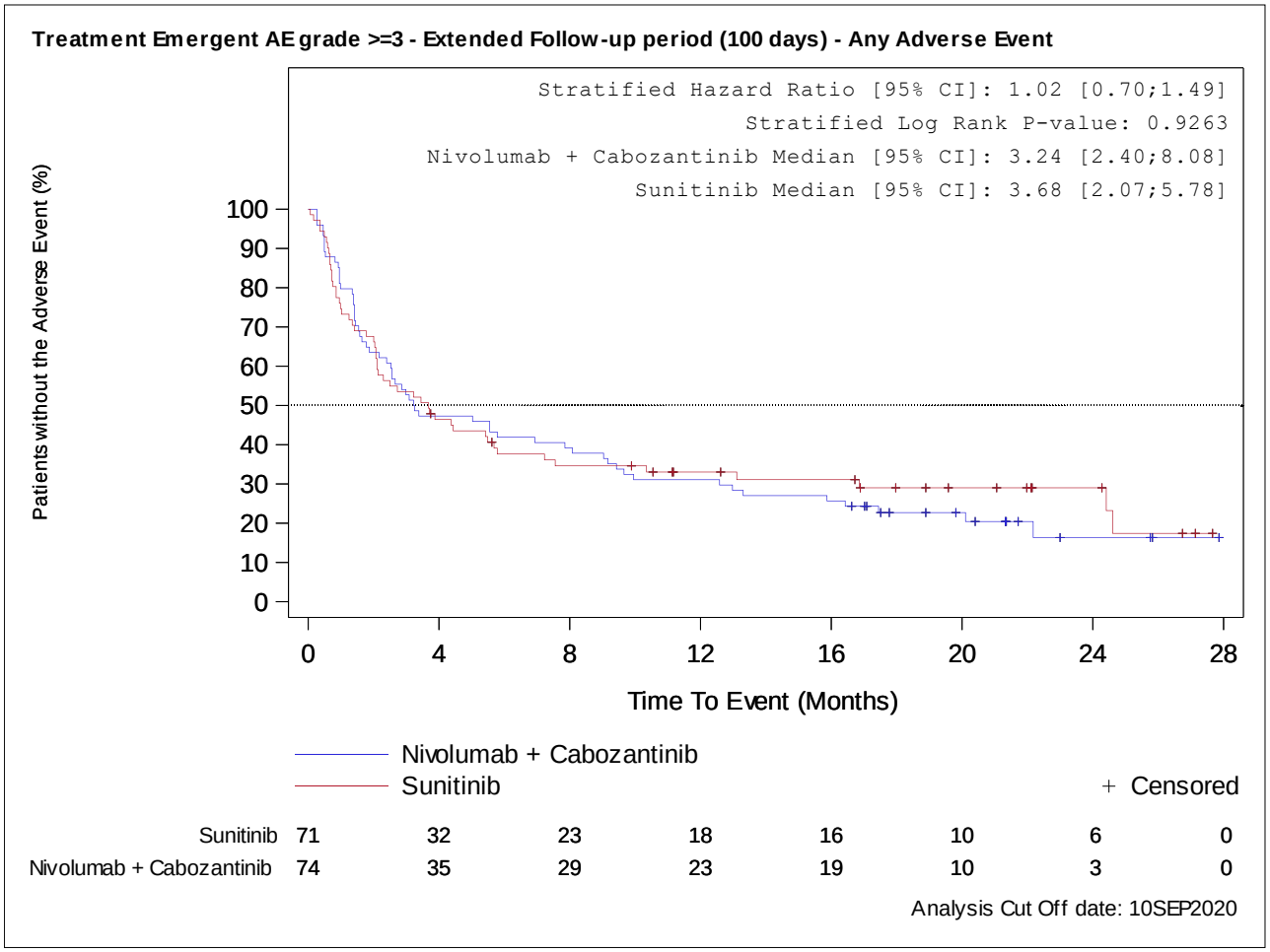
FIGURE 4.5.1: Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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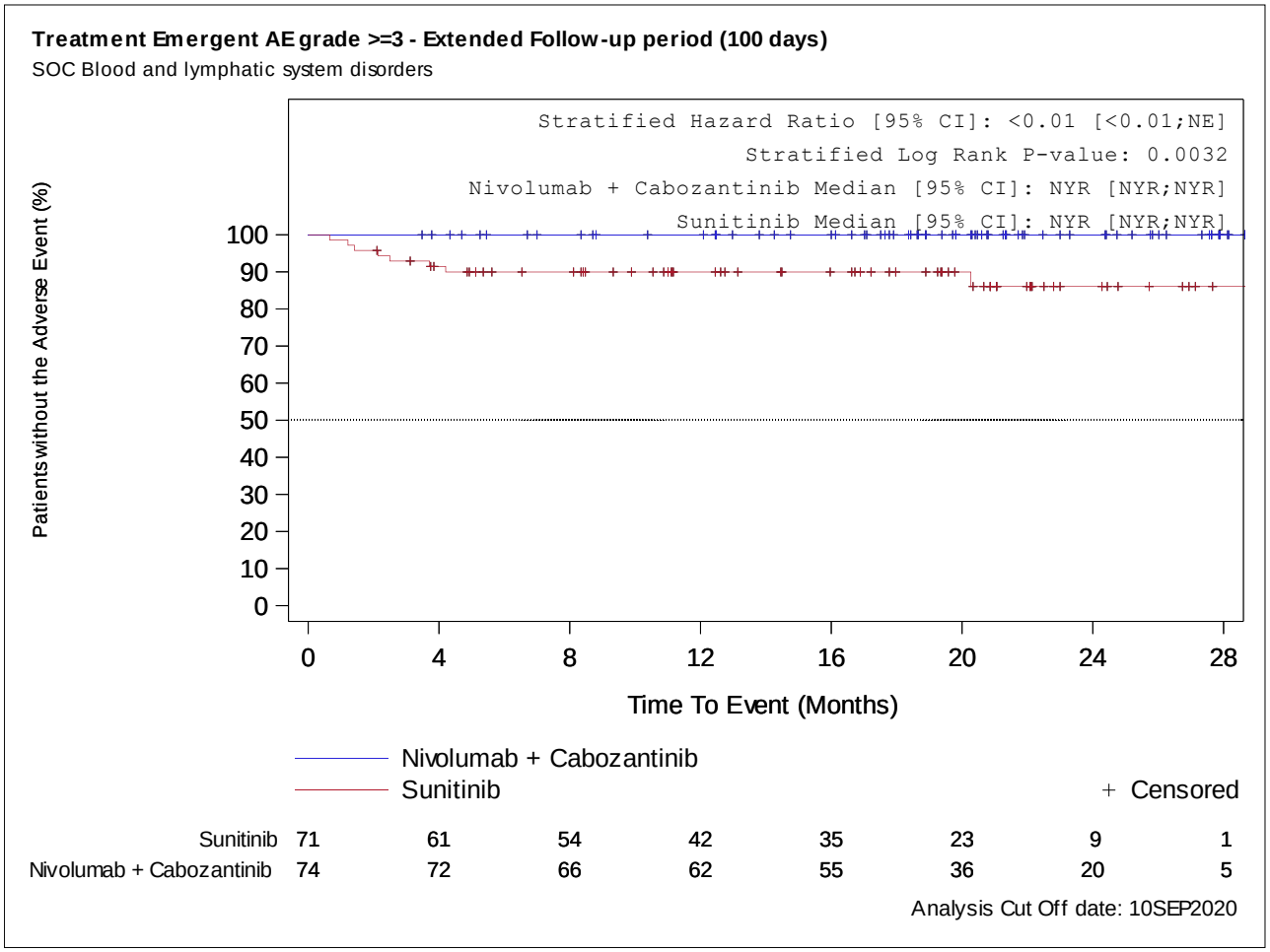
FIGURE 4.5.2.1: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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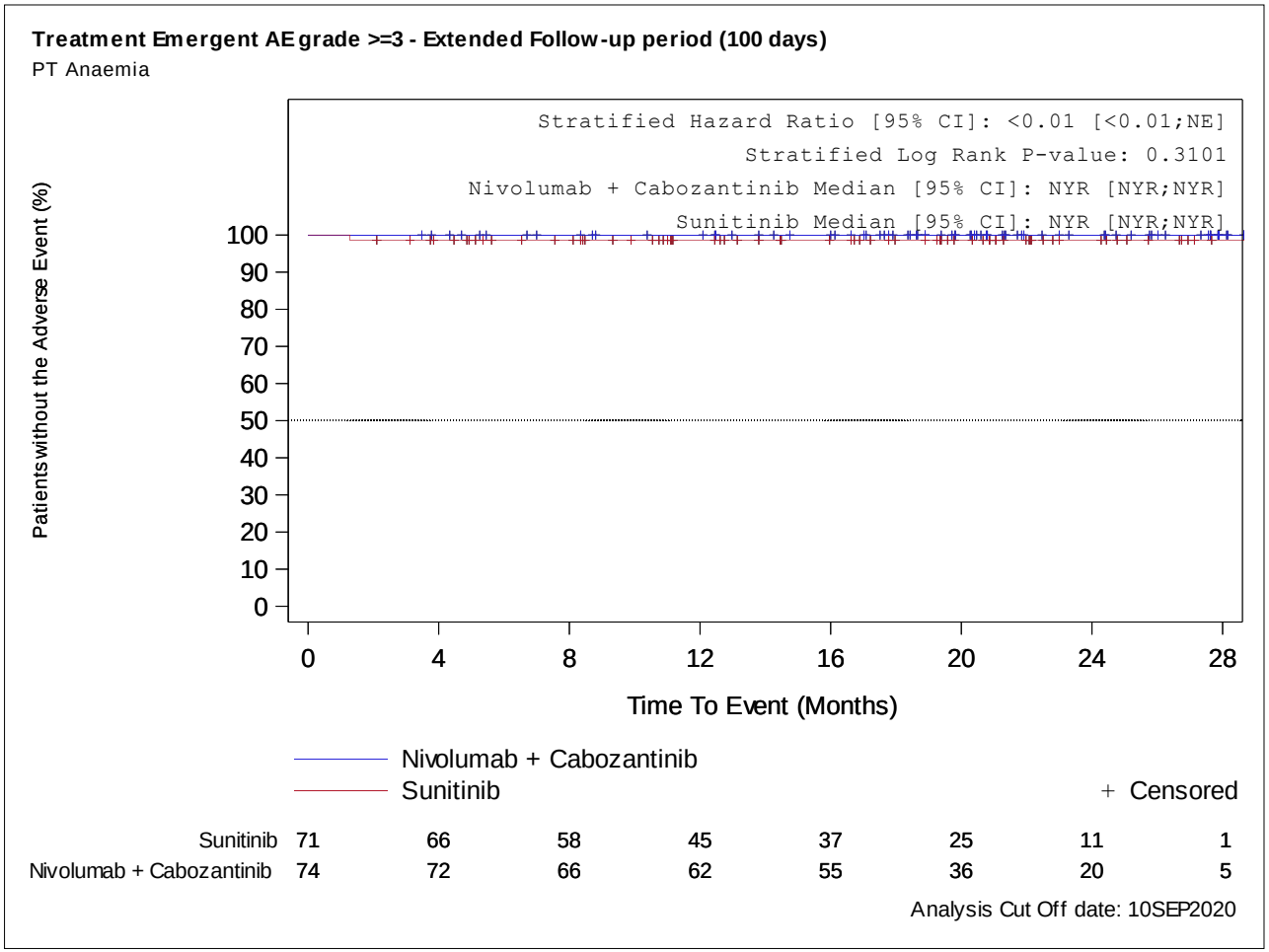
FIGURE 4.5.2.2: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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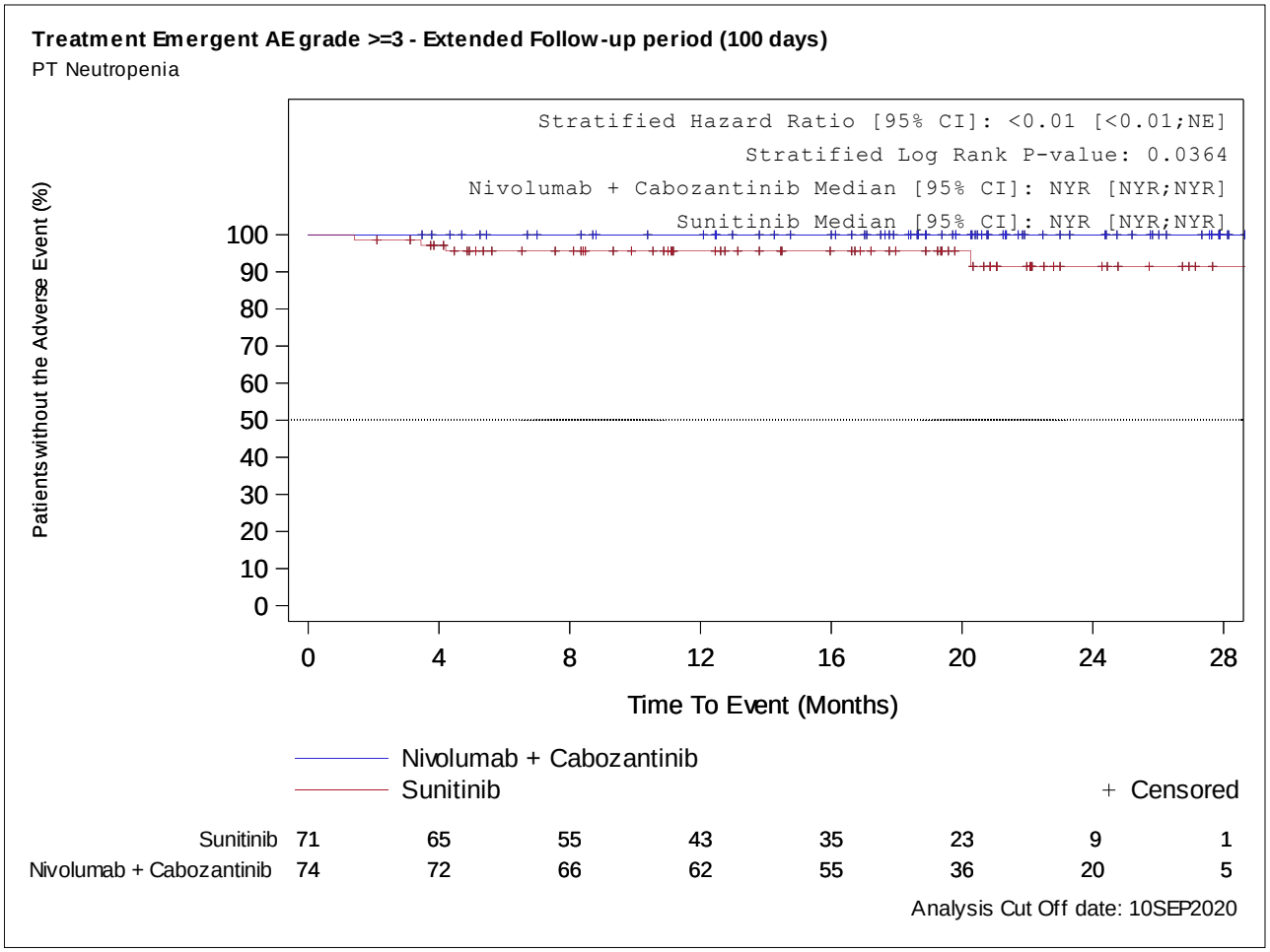
FIGURE 4.5.2.3: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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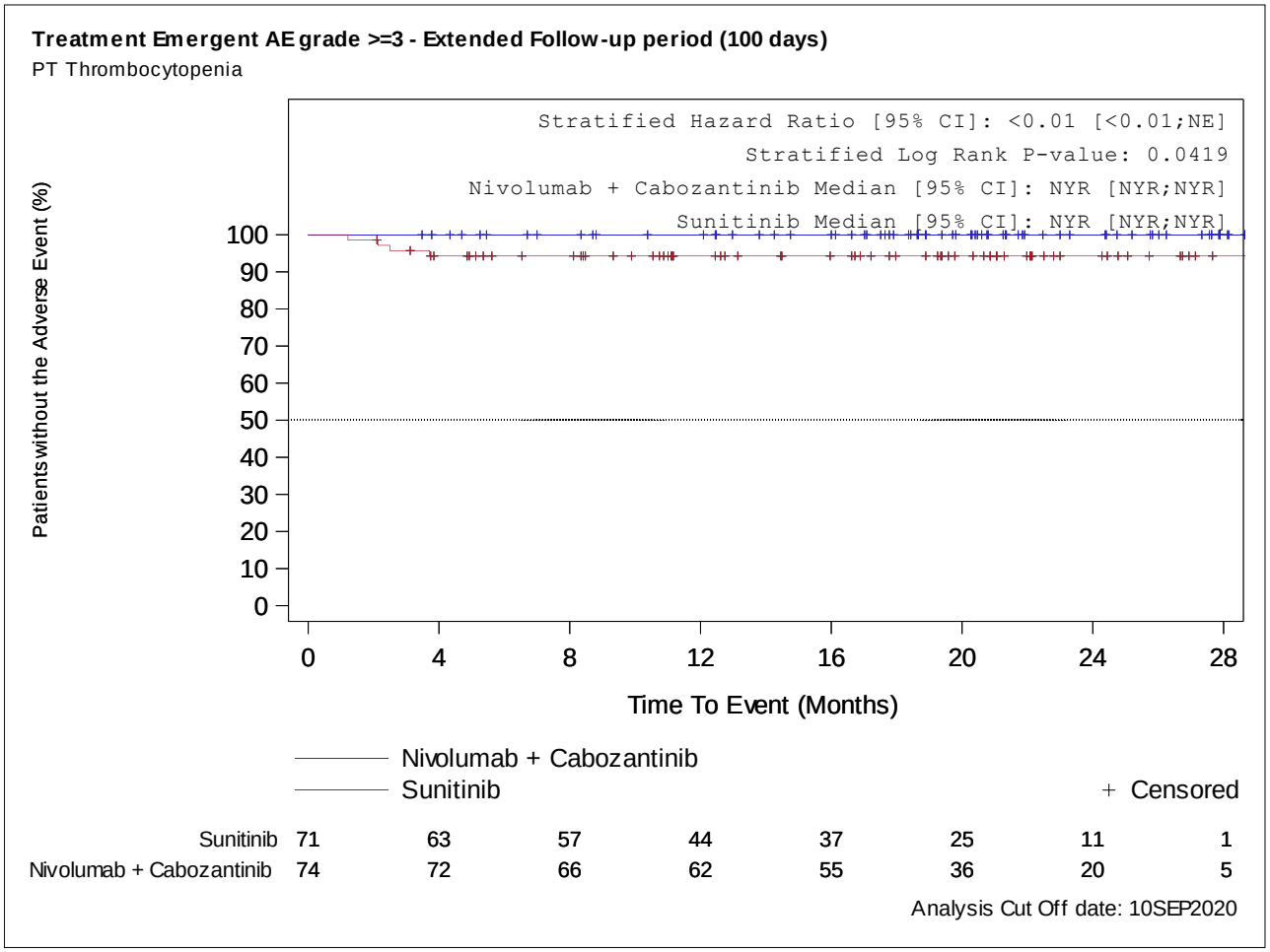
FIGURE 4.5.2.4: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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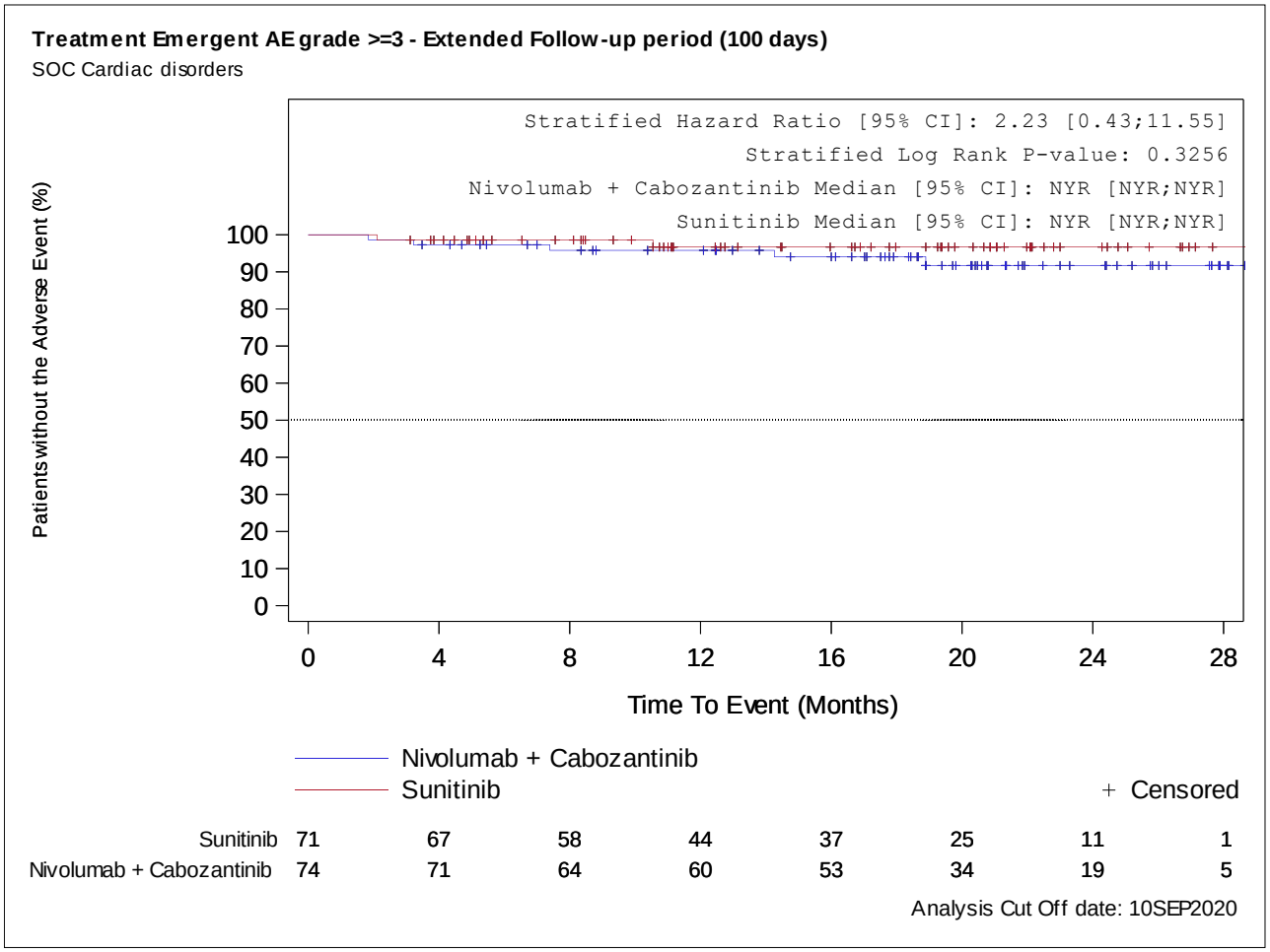
FIGURE 4.5.2.5: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Cardiac disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.5.2.6: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Endocrine disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

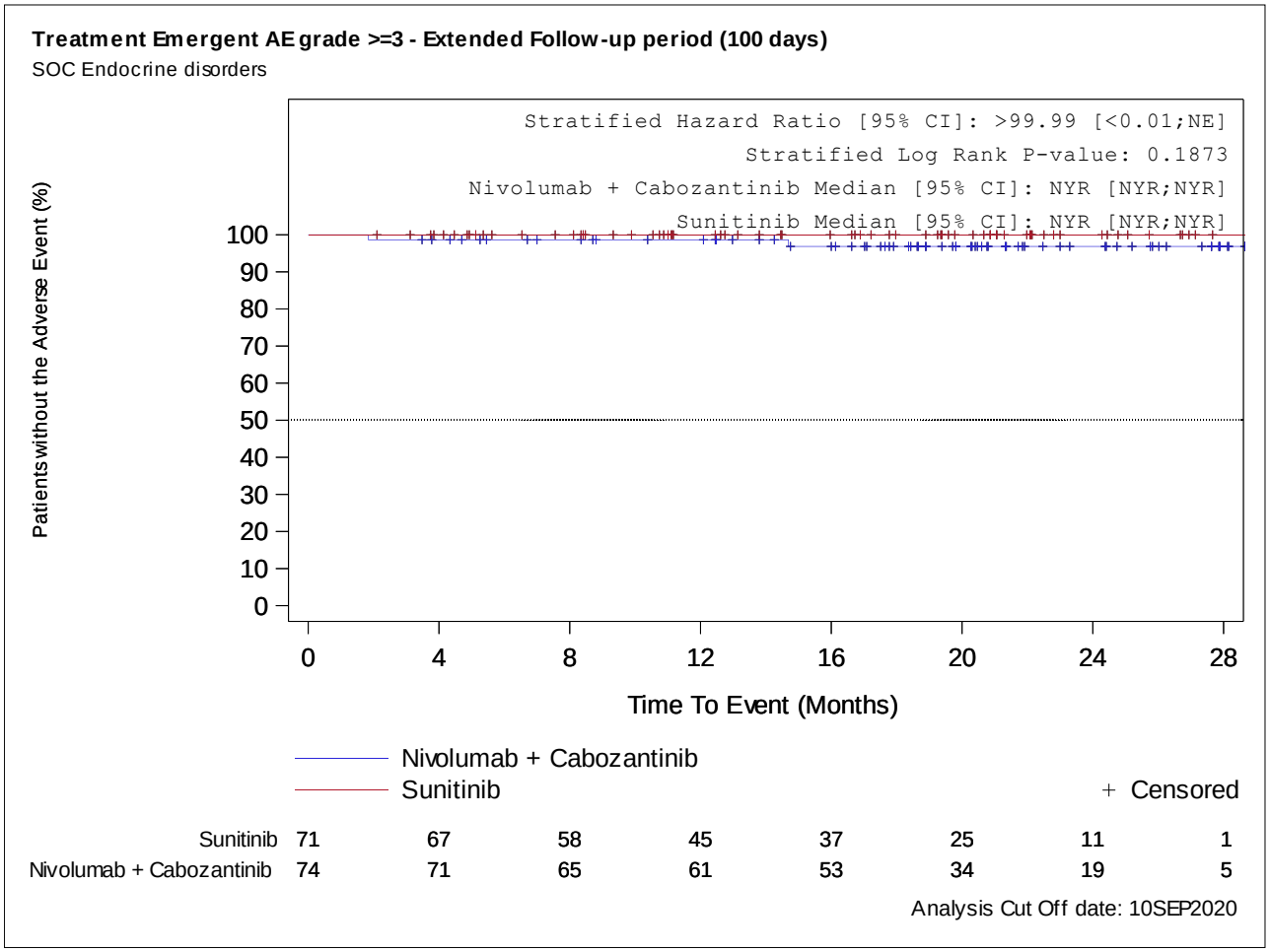


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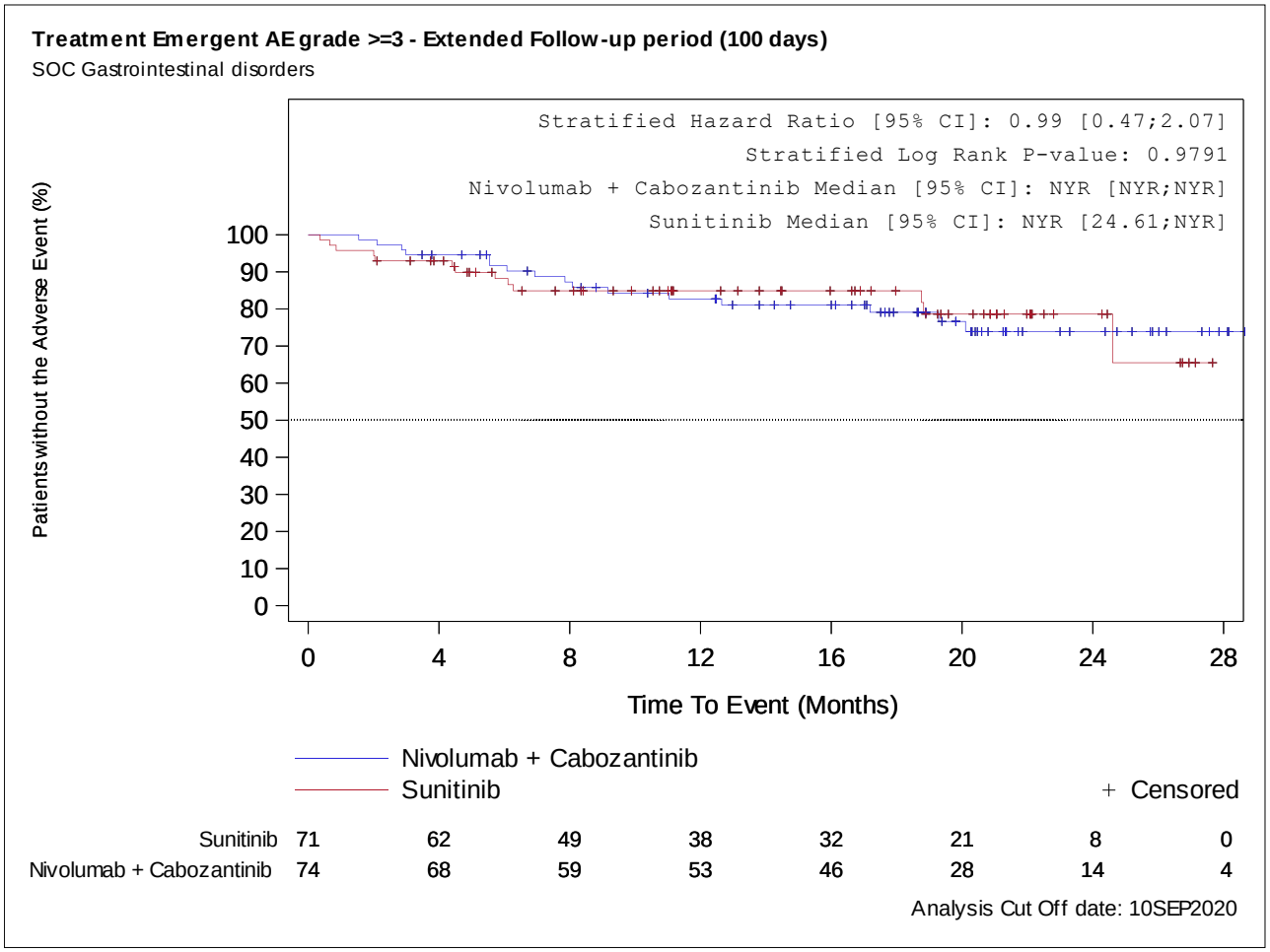
FIGURE 4.5.2.7: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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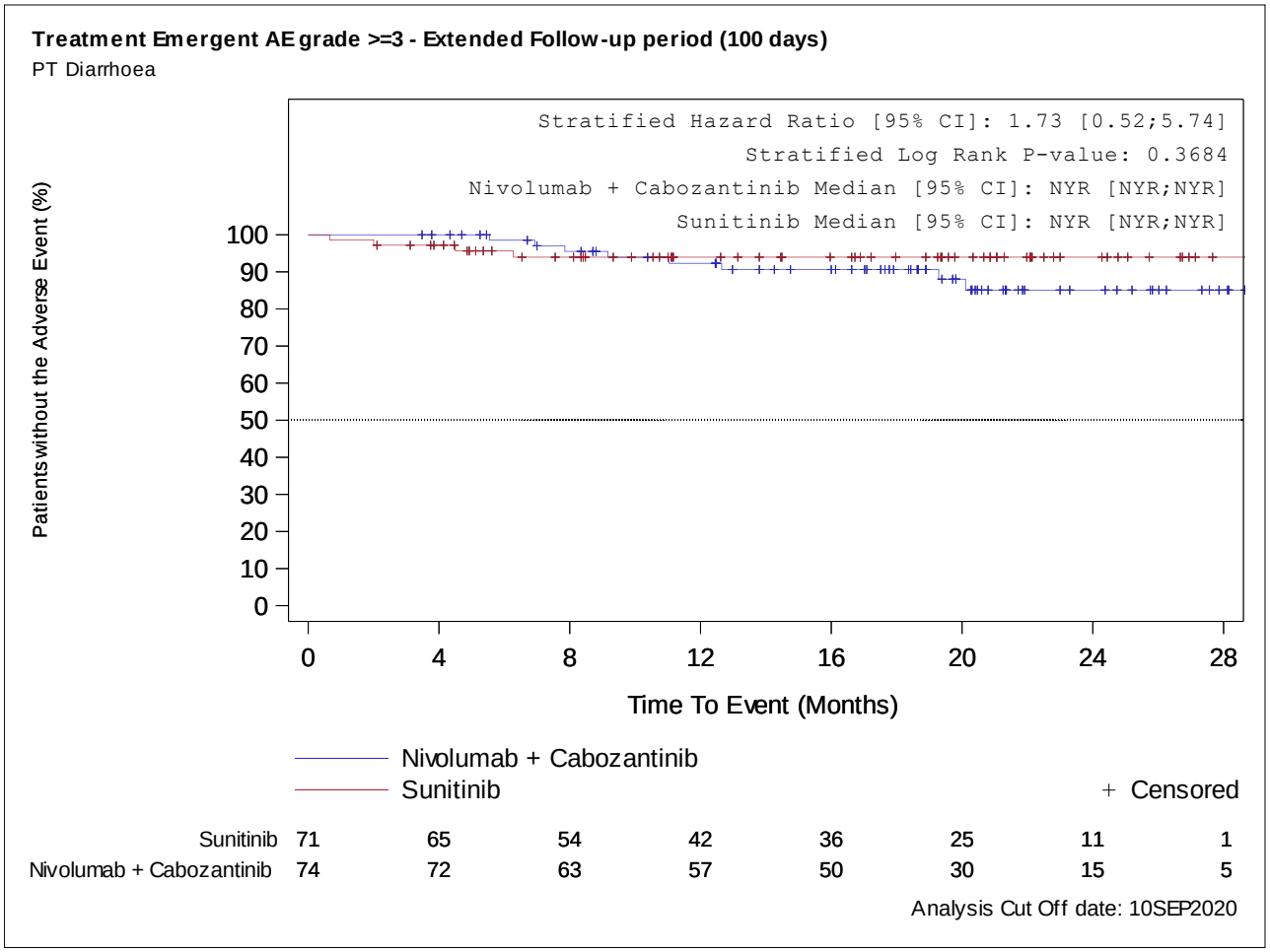
FIGURE 4.5.2.8: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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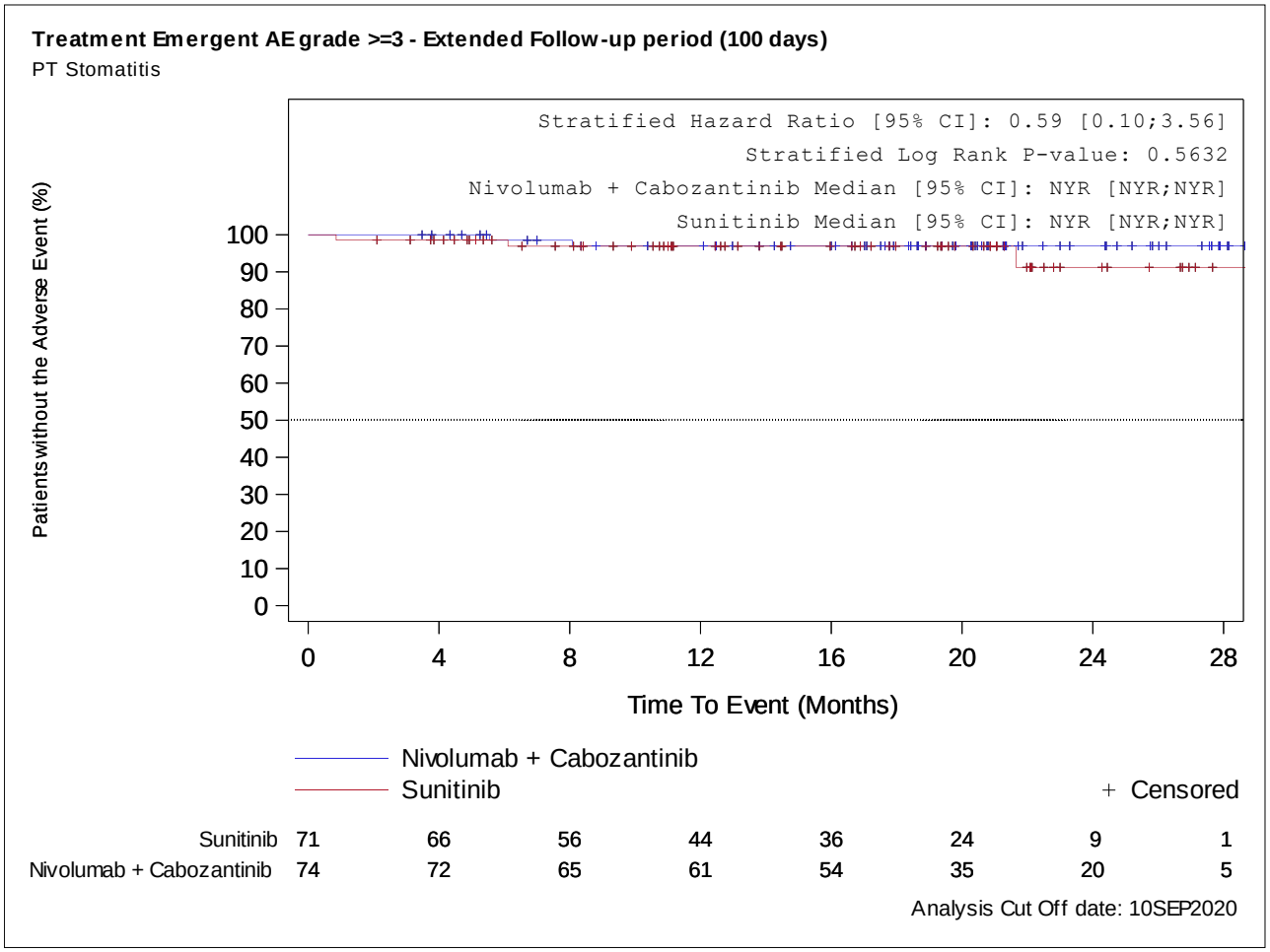
FIGURE 4.5.2.9: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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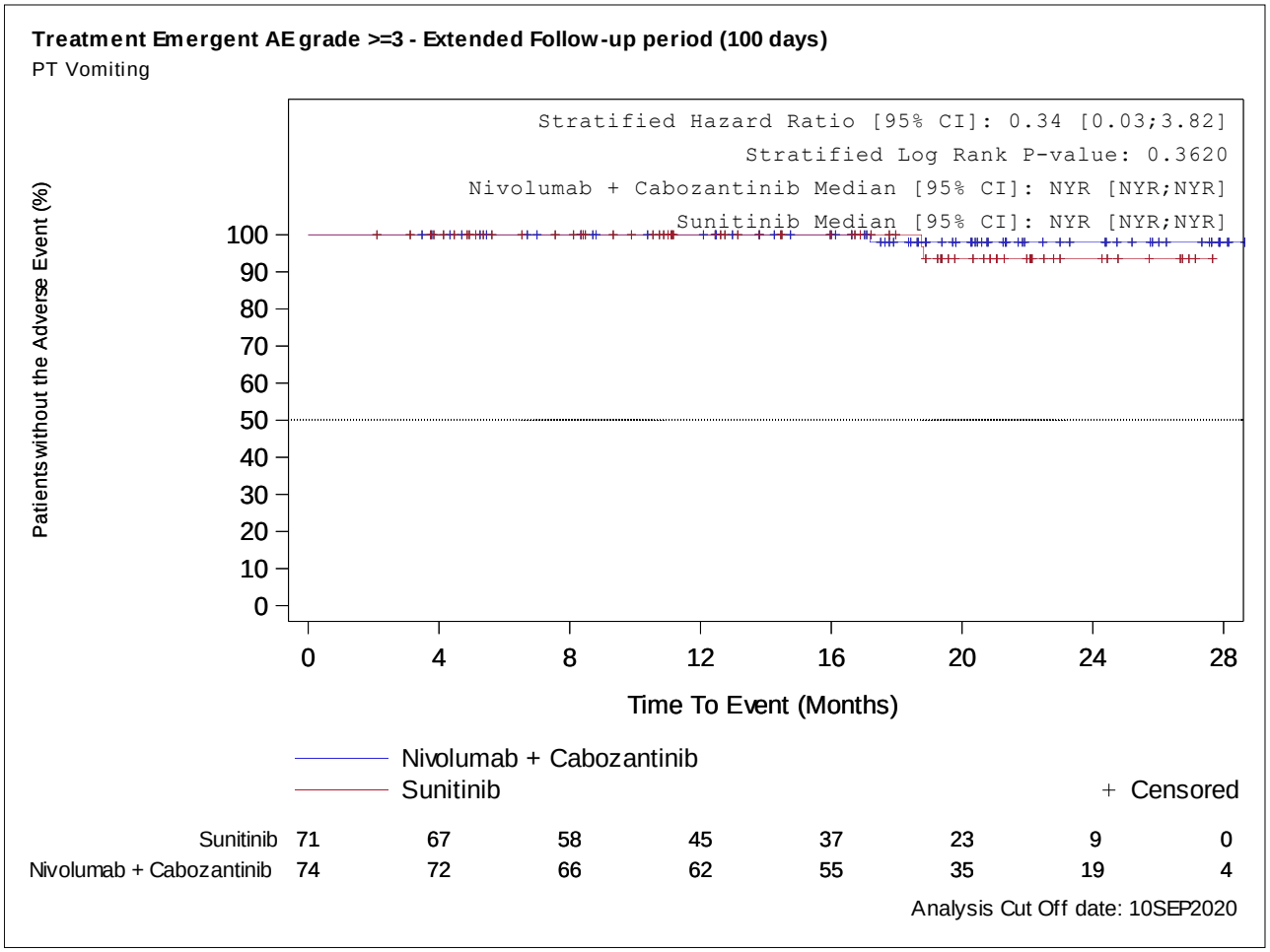
FIGURE 4.5.2.10: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Vomiting - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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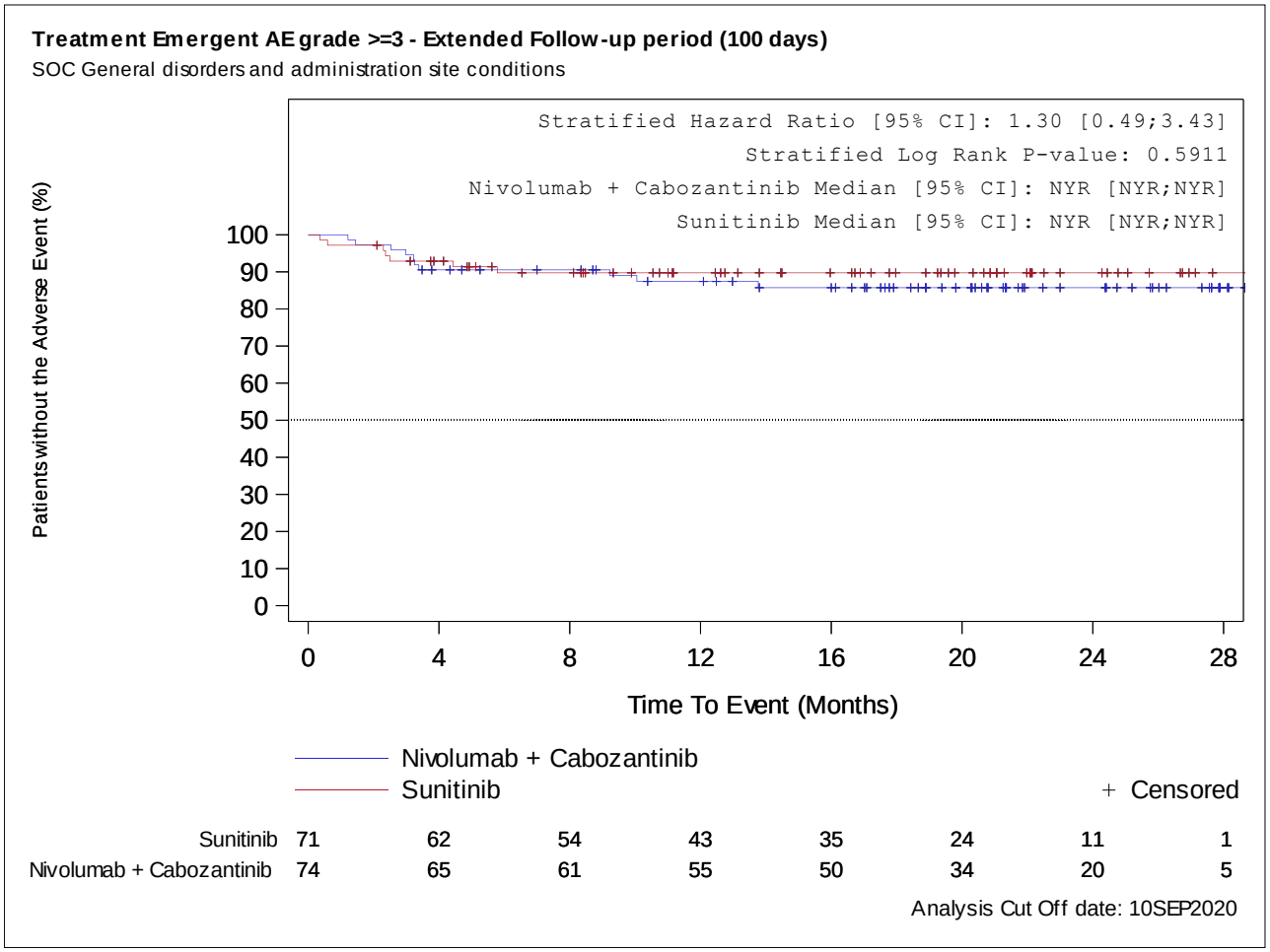
FIGURE 4.5.2.11: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC General disorders and administration site conditions - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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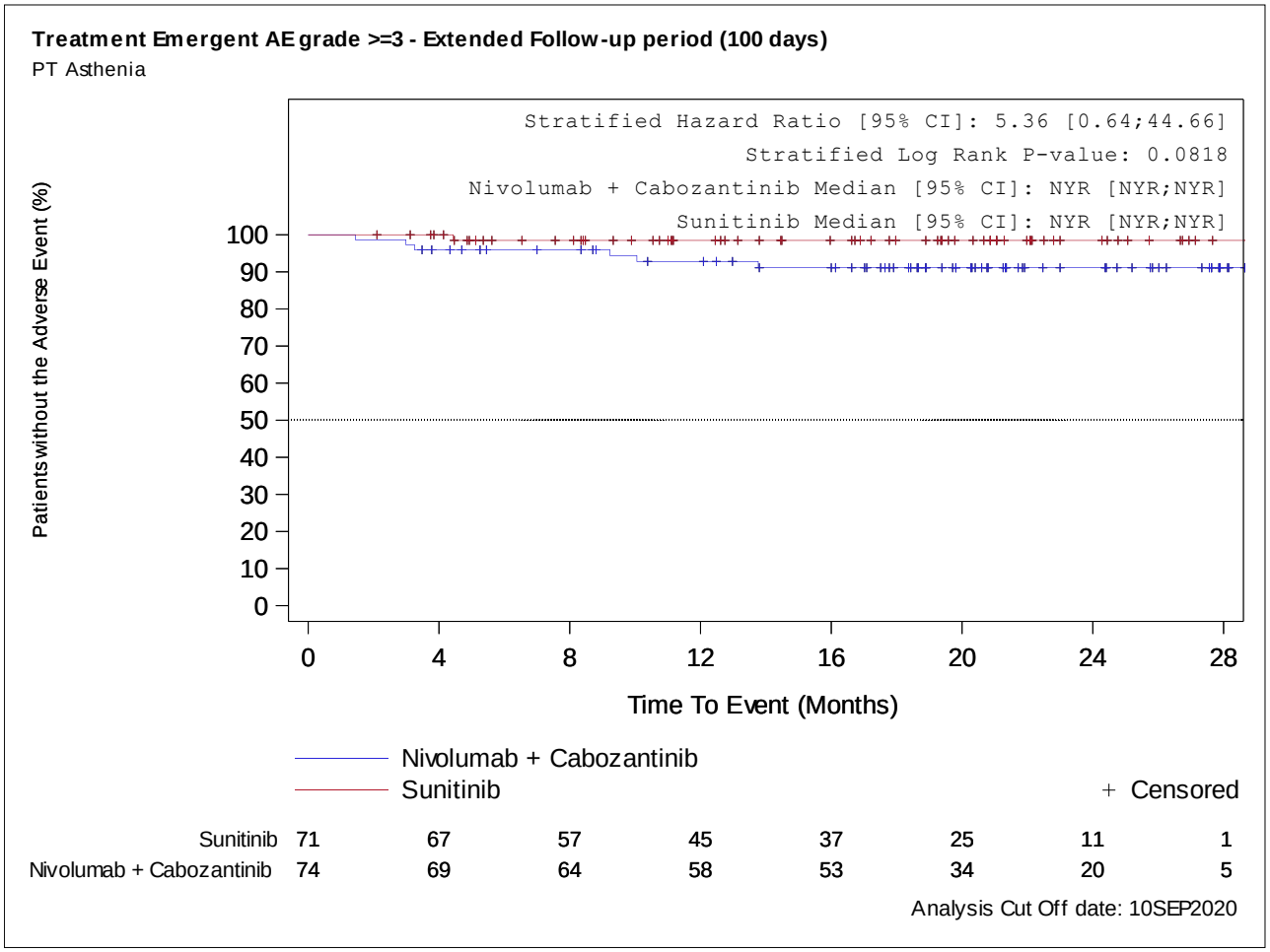
FIGURE 4.5.2.12: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Asthenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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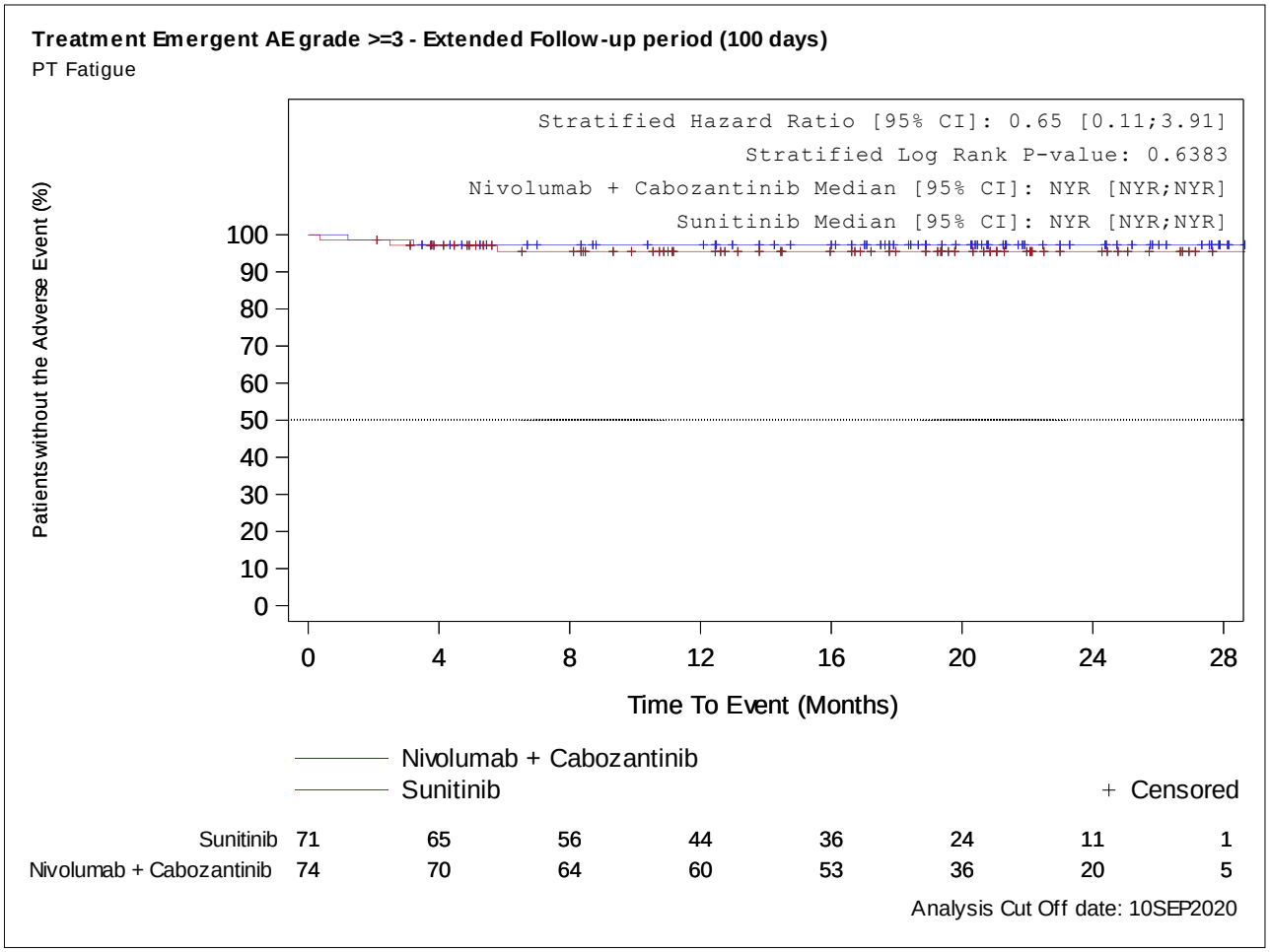
FIGURE 4.5.2.13: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Fatigue - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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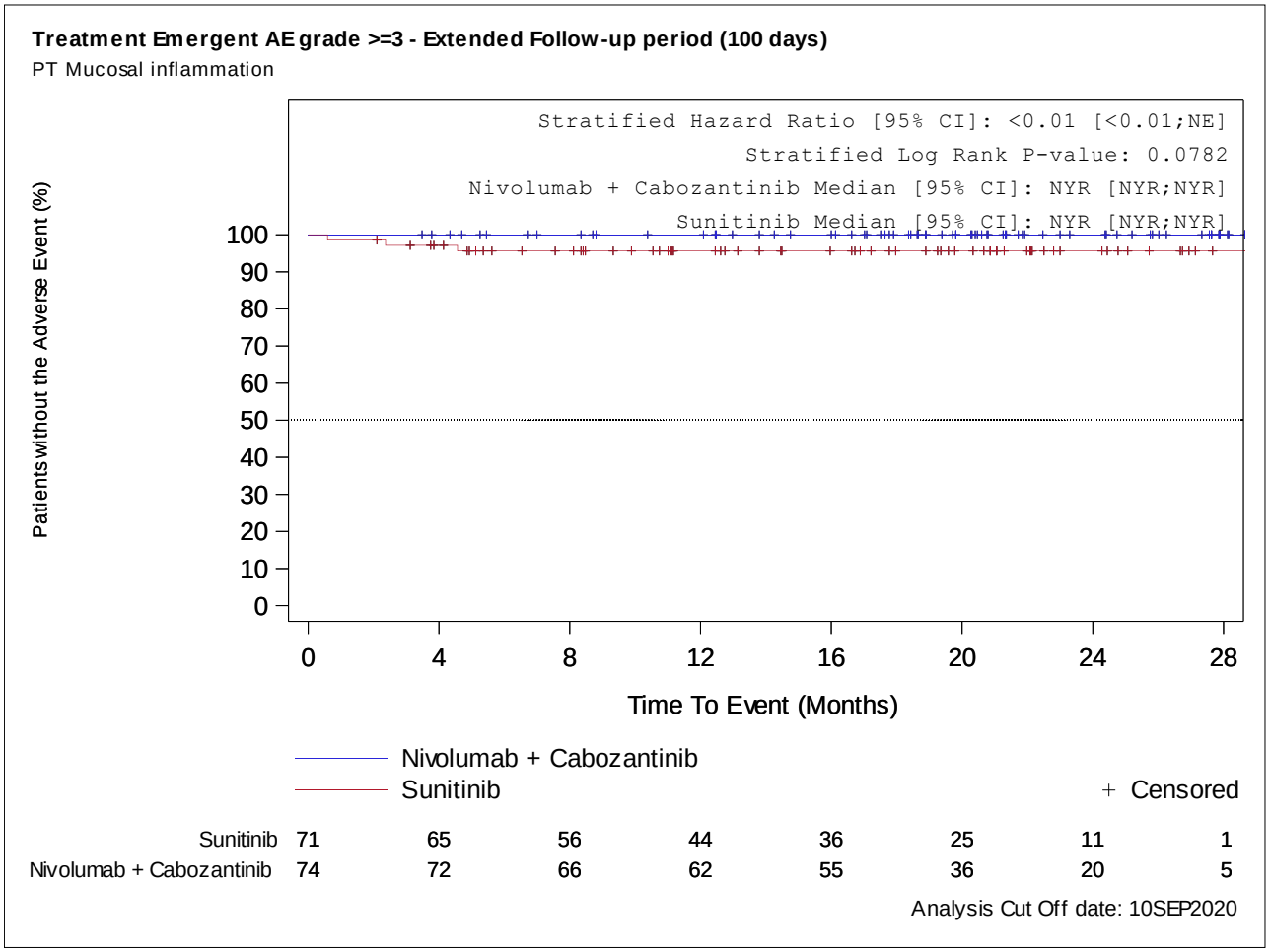
FIGURE 4.5.2.14: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Mucosal inflammation - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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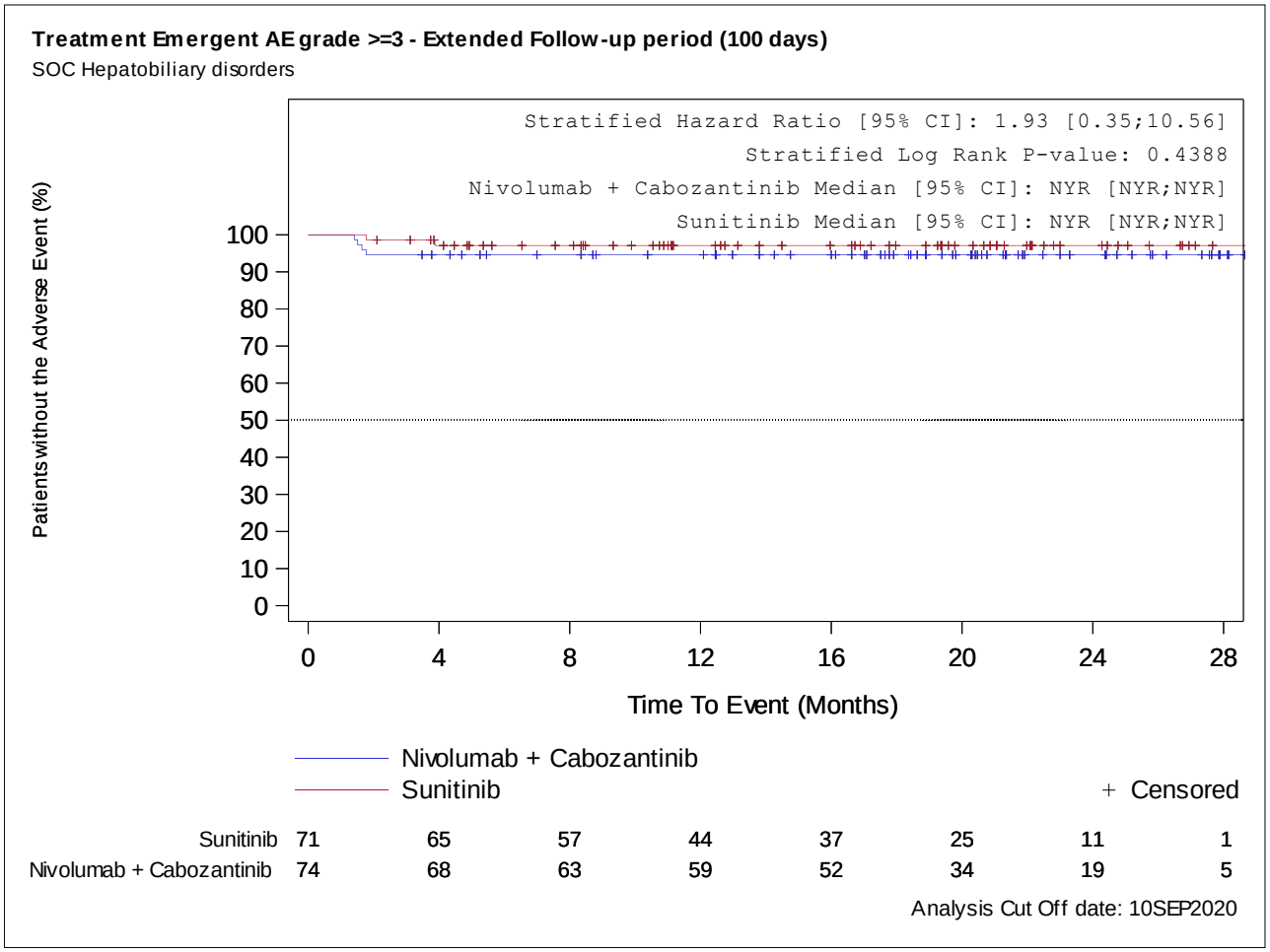
FIGURE 4.5.2.15: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Hepatobiliary disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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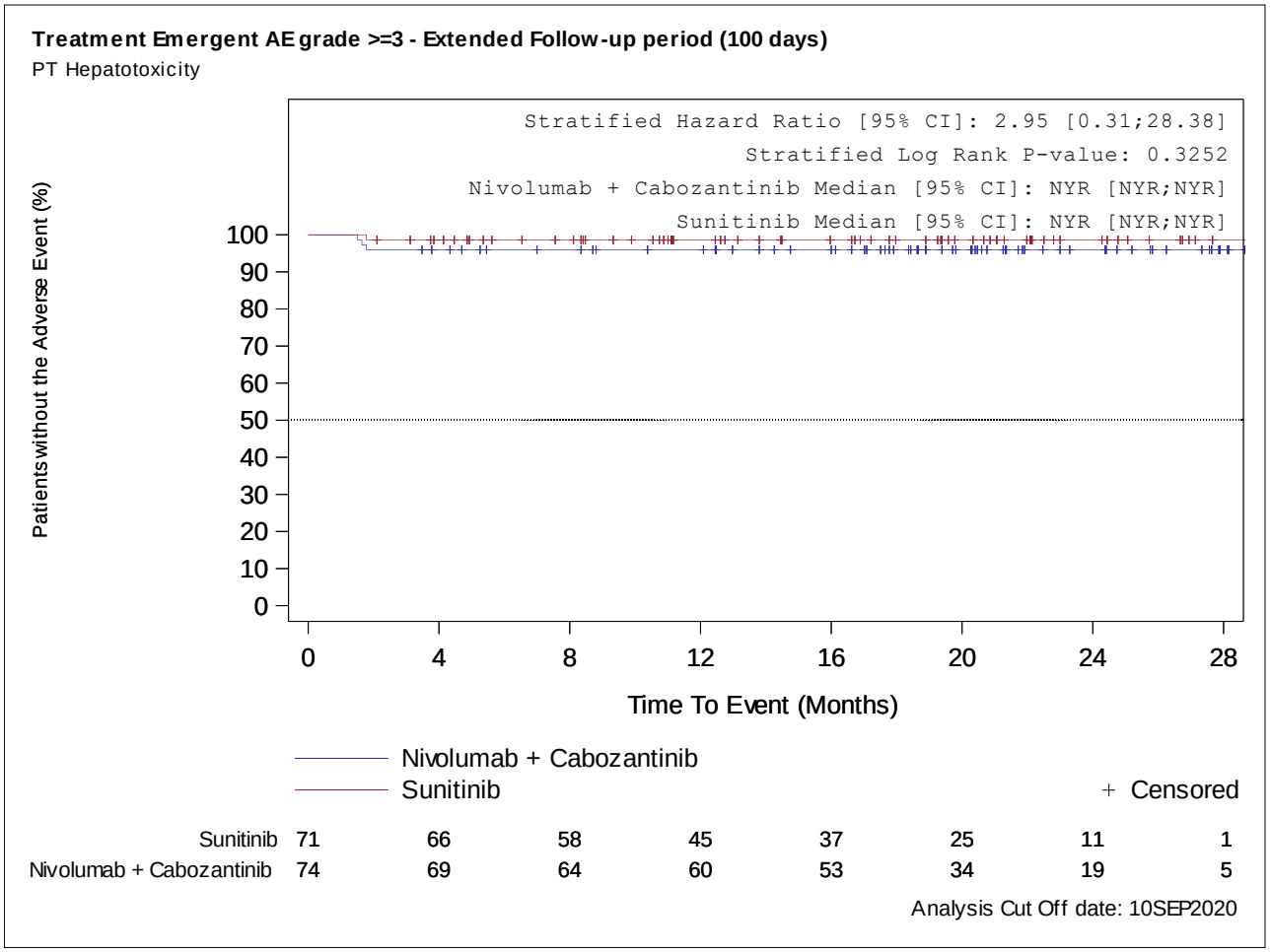
FIGURE 4.5.2.16: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Hepatotoxicity - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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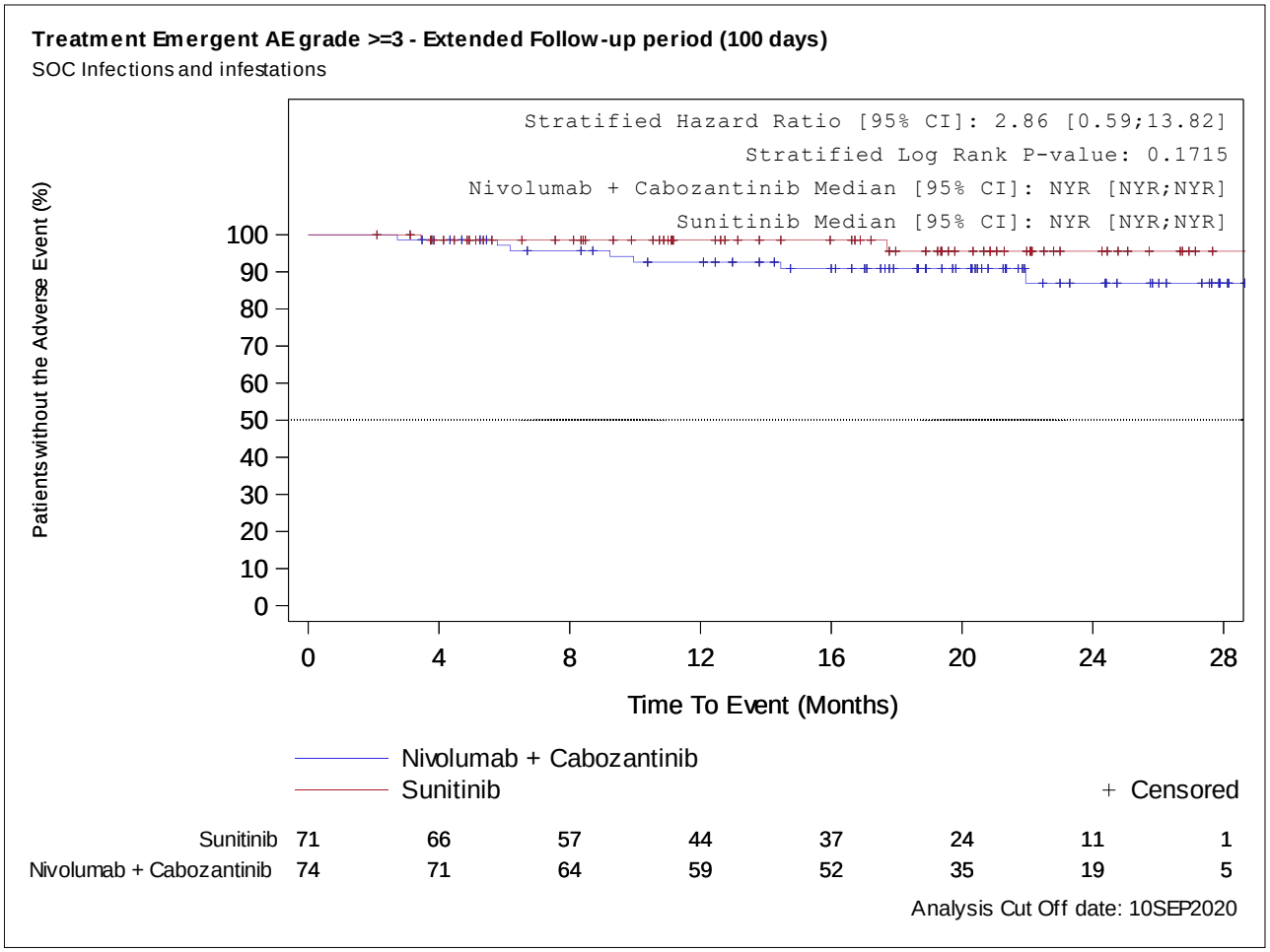
FIGURE 4.5.2.17: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Infections and infestations - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.5.2.18: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Pneumonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

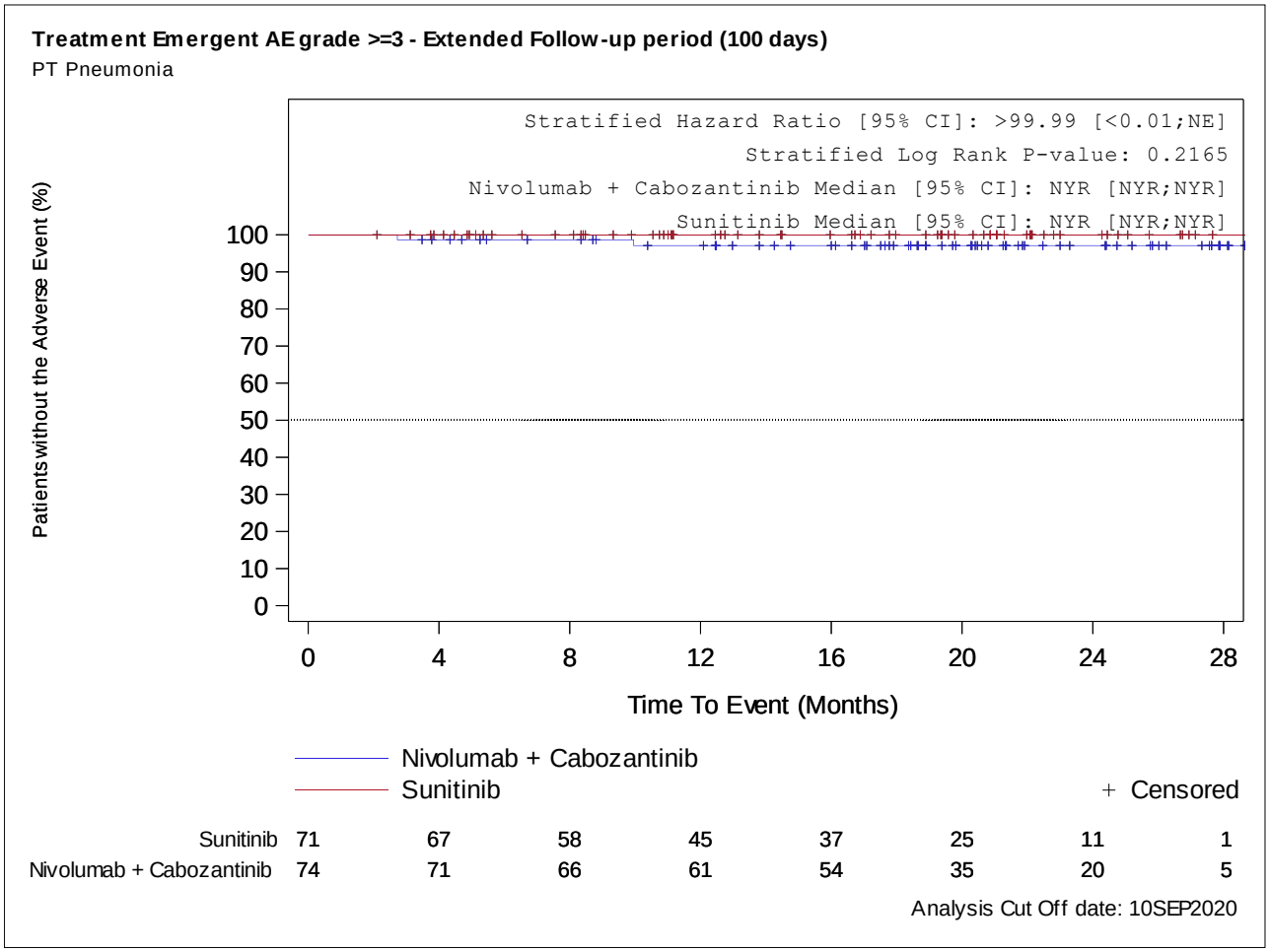


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FIGURE 4.5.2.19: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Urinary tract infection - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

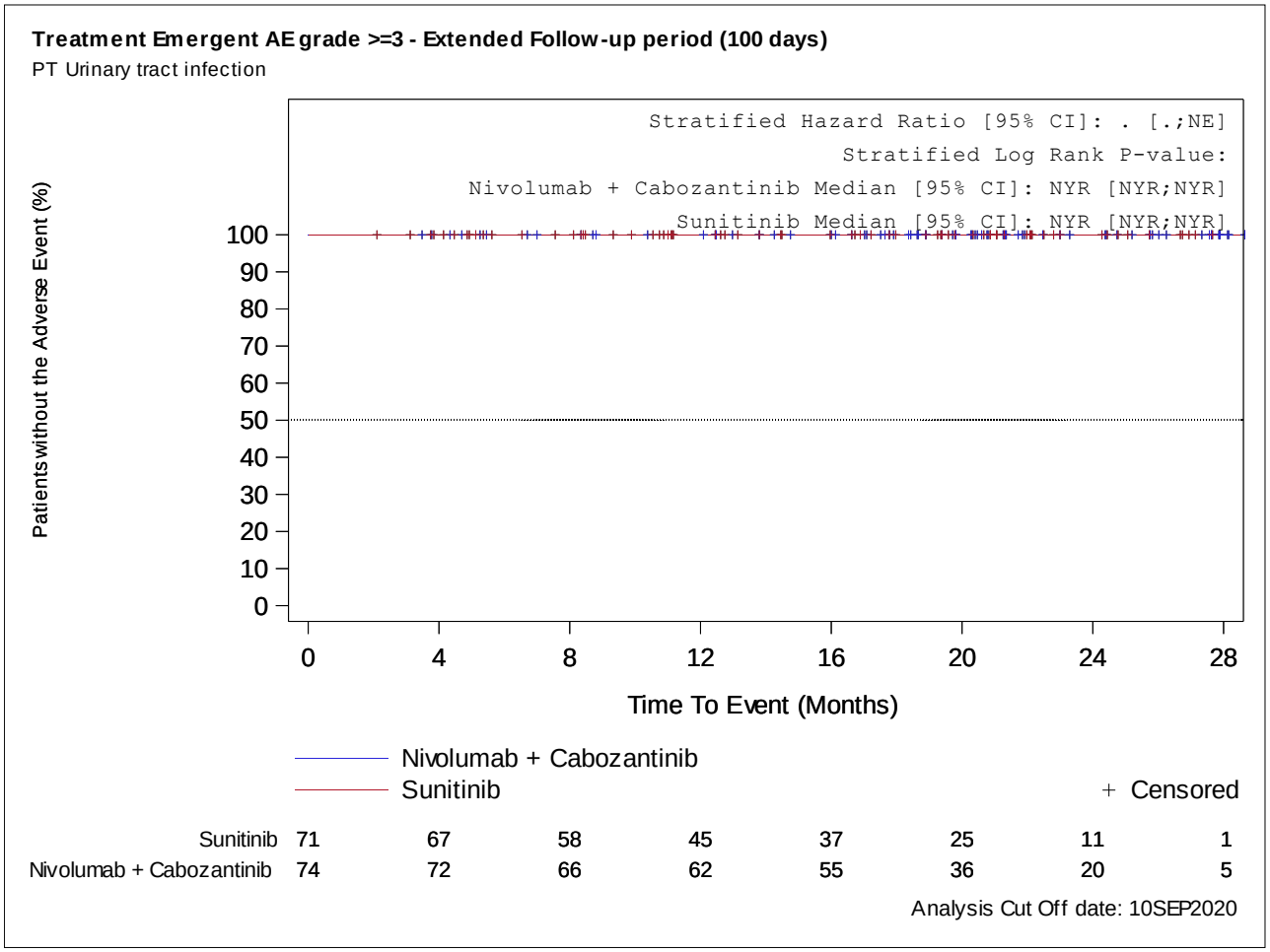


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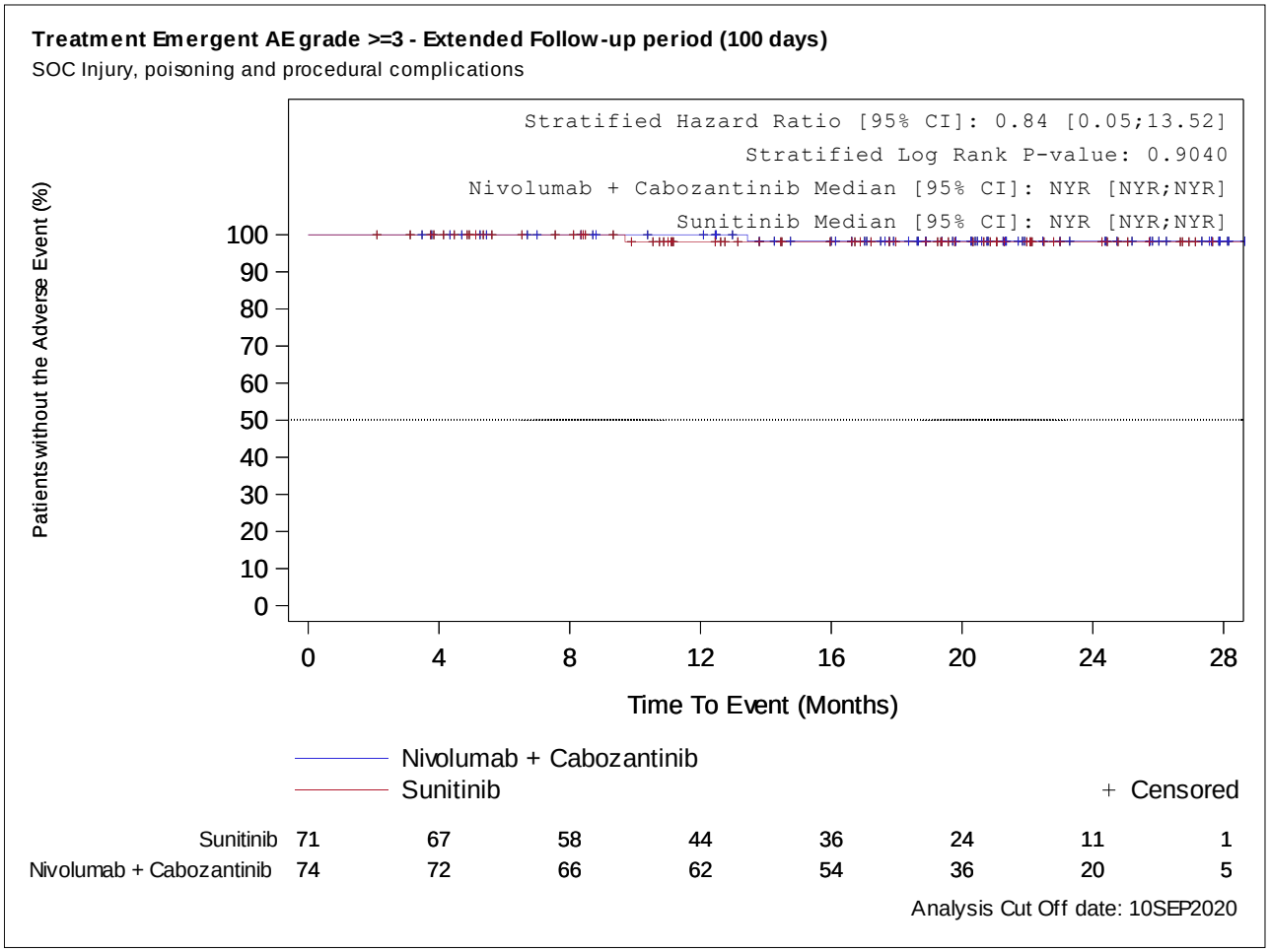
FIGURE 4.5.2.20: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Injury, poisoning and procedural complications - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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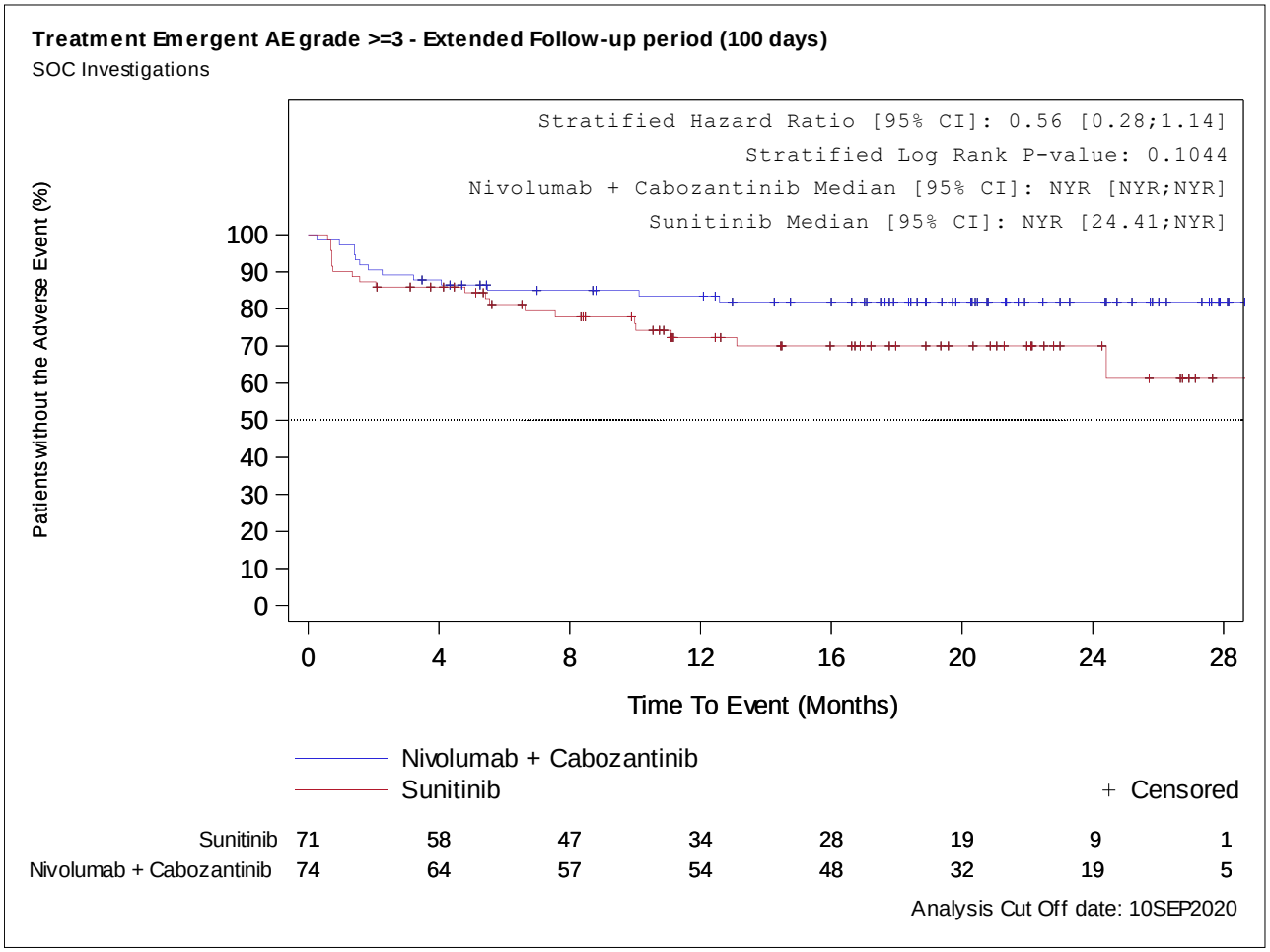
FIGURE 4.5.2.21: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Investigations - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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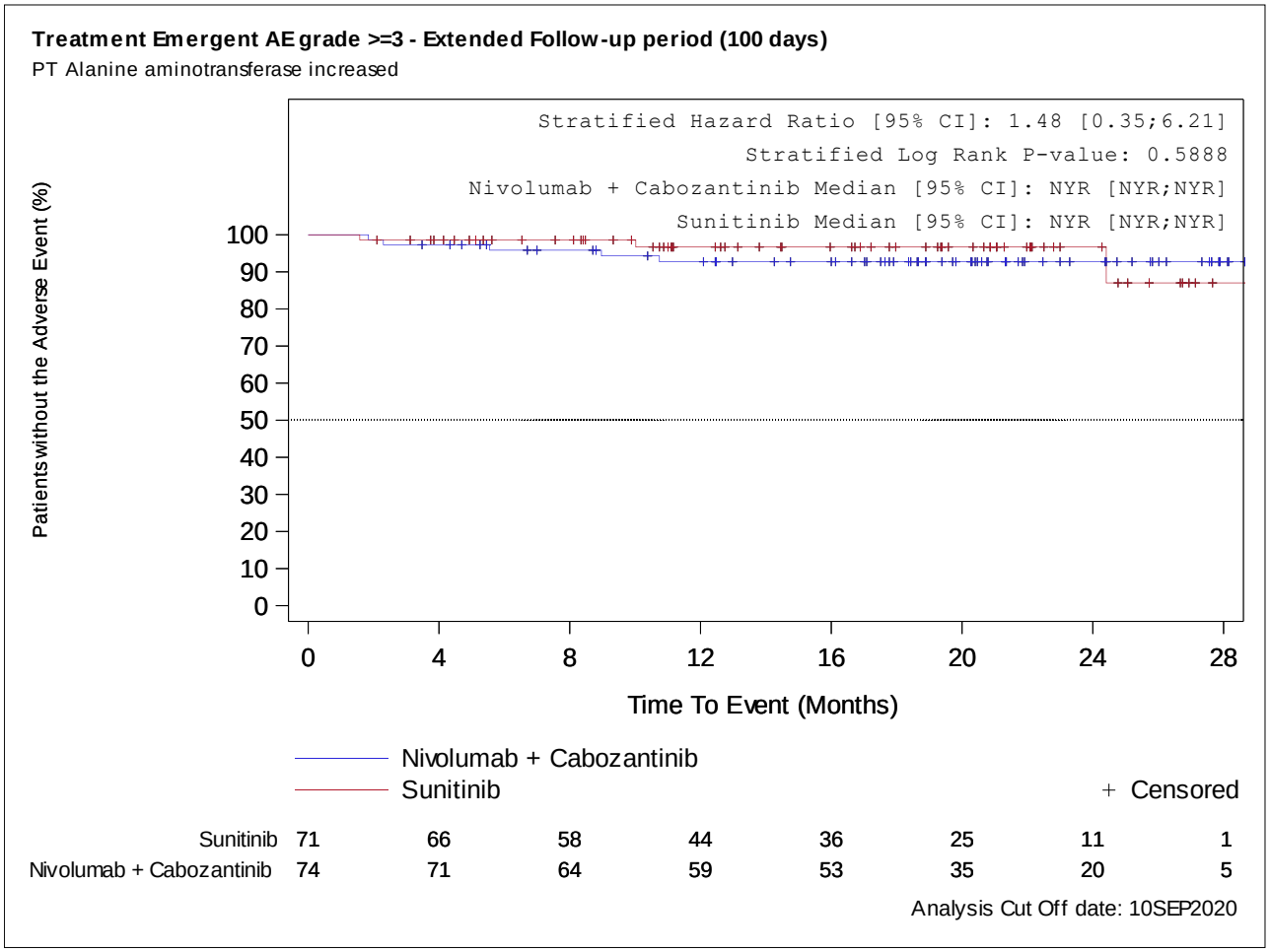
FIGURE 4.5.2.22: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Alanine aminotransferase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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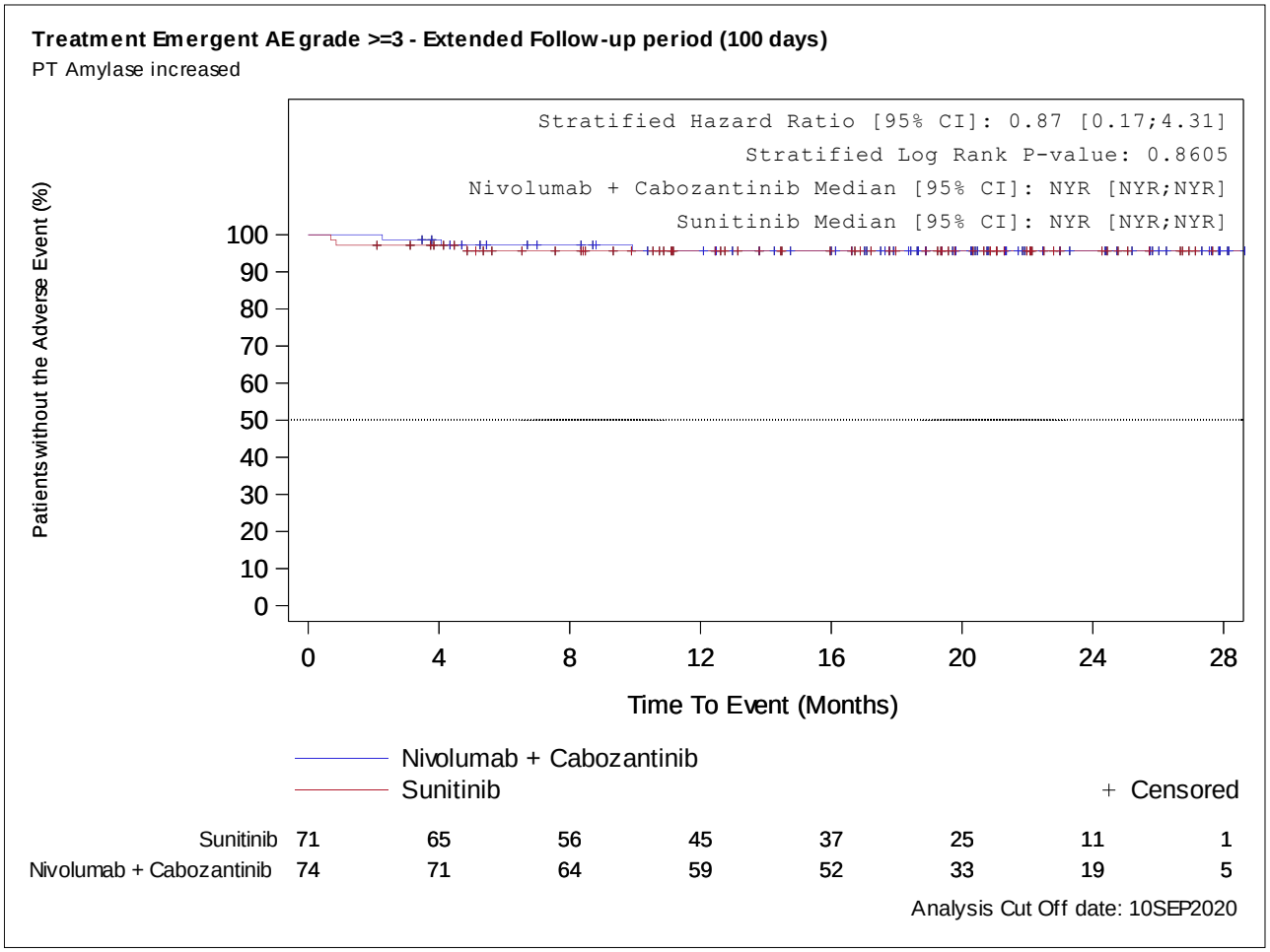
FIGURE 4.5.2.23: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Amylase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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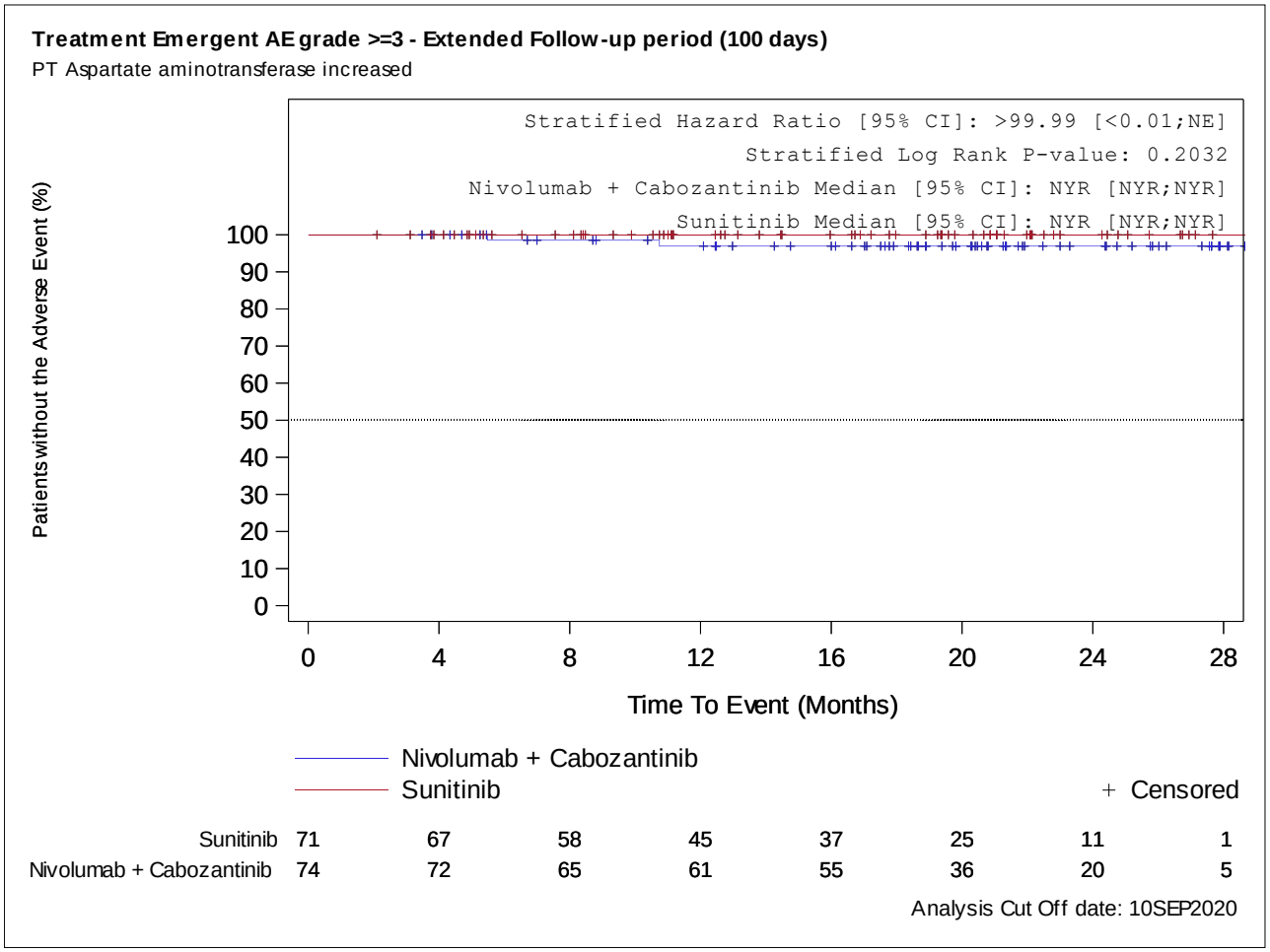
FIGURE 4.5.2.24: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Aspartate aminotransferase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.5.2.25: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Lipase increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

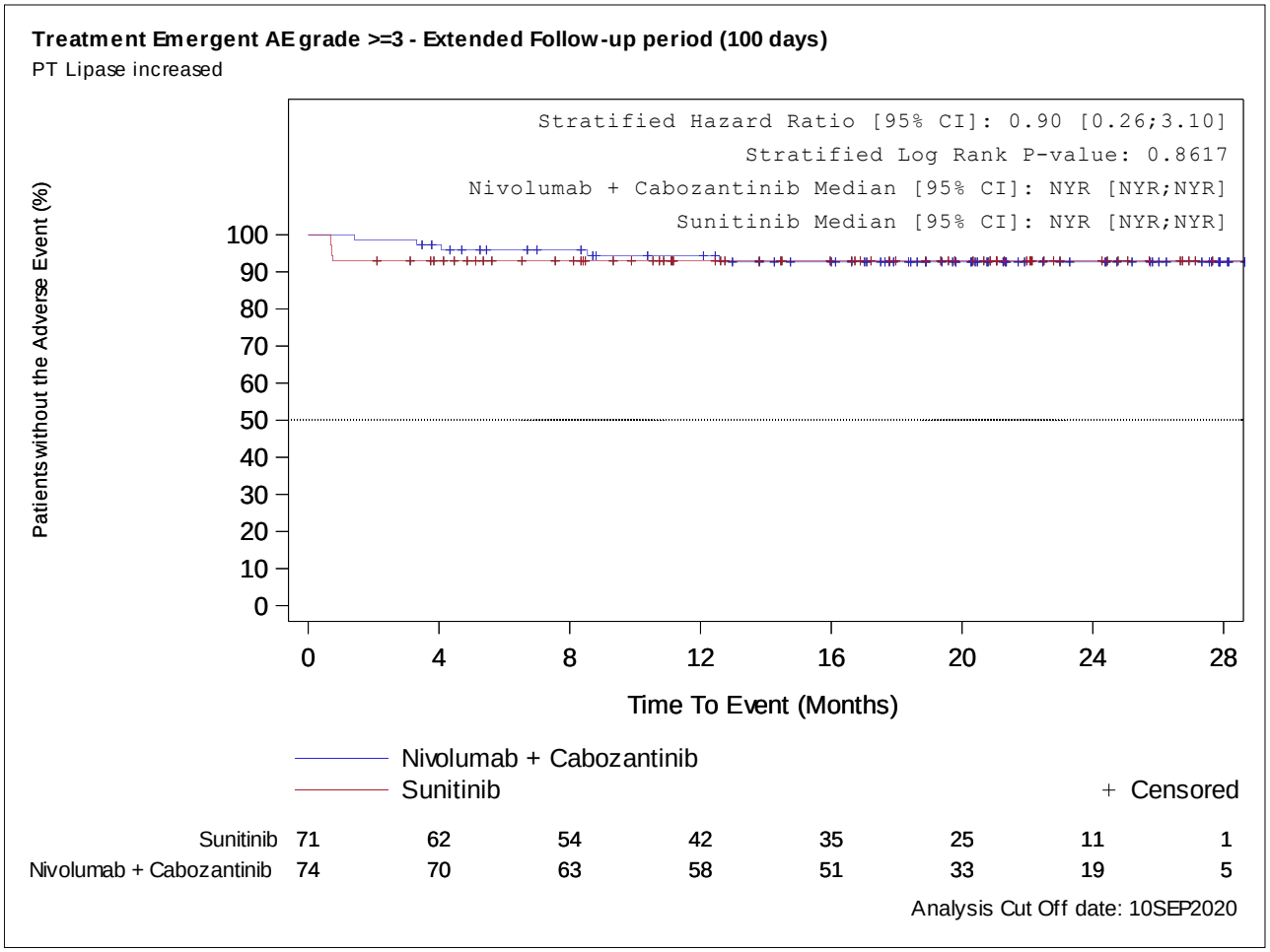


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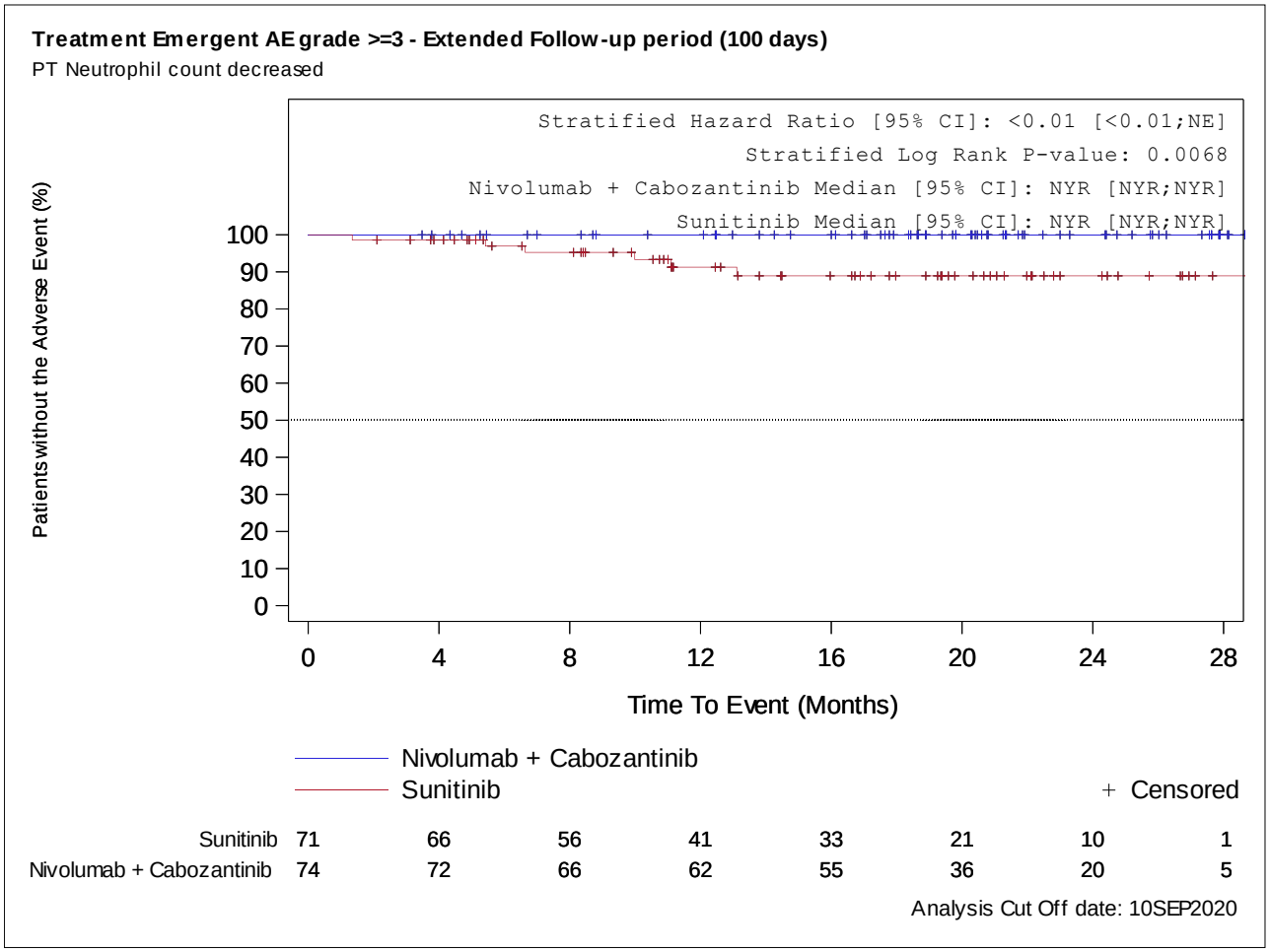
FIGURE 4.5.2.26: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Neutrophil count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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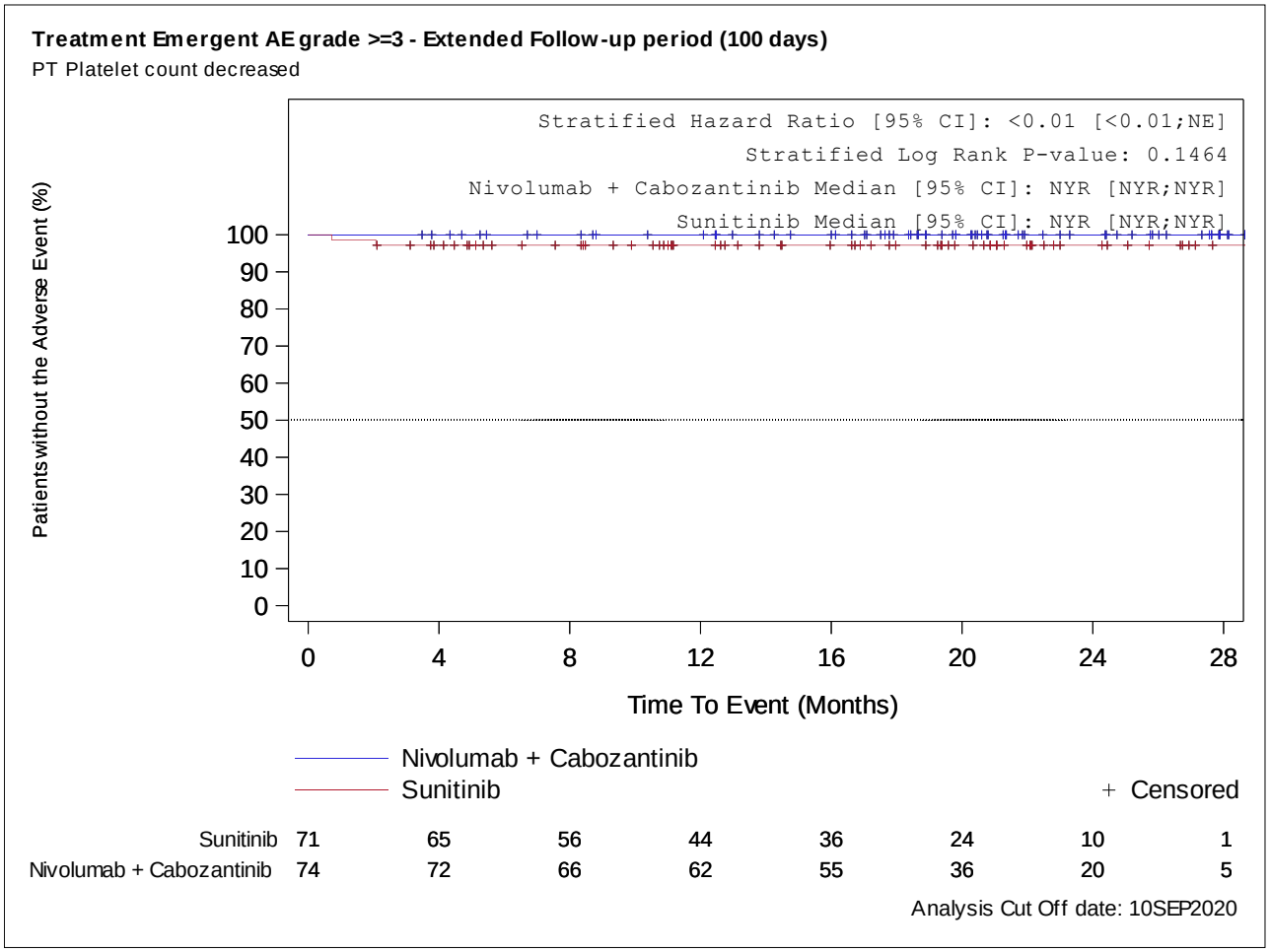
FIGURE 4.5.2.27: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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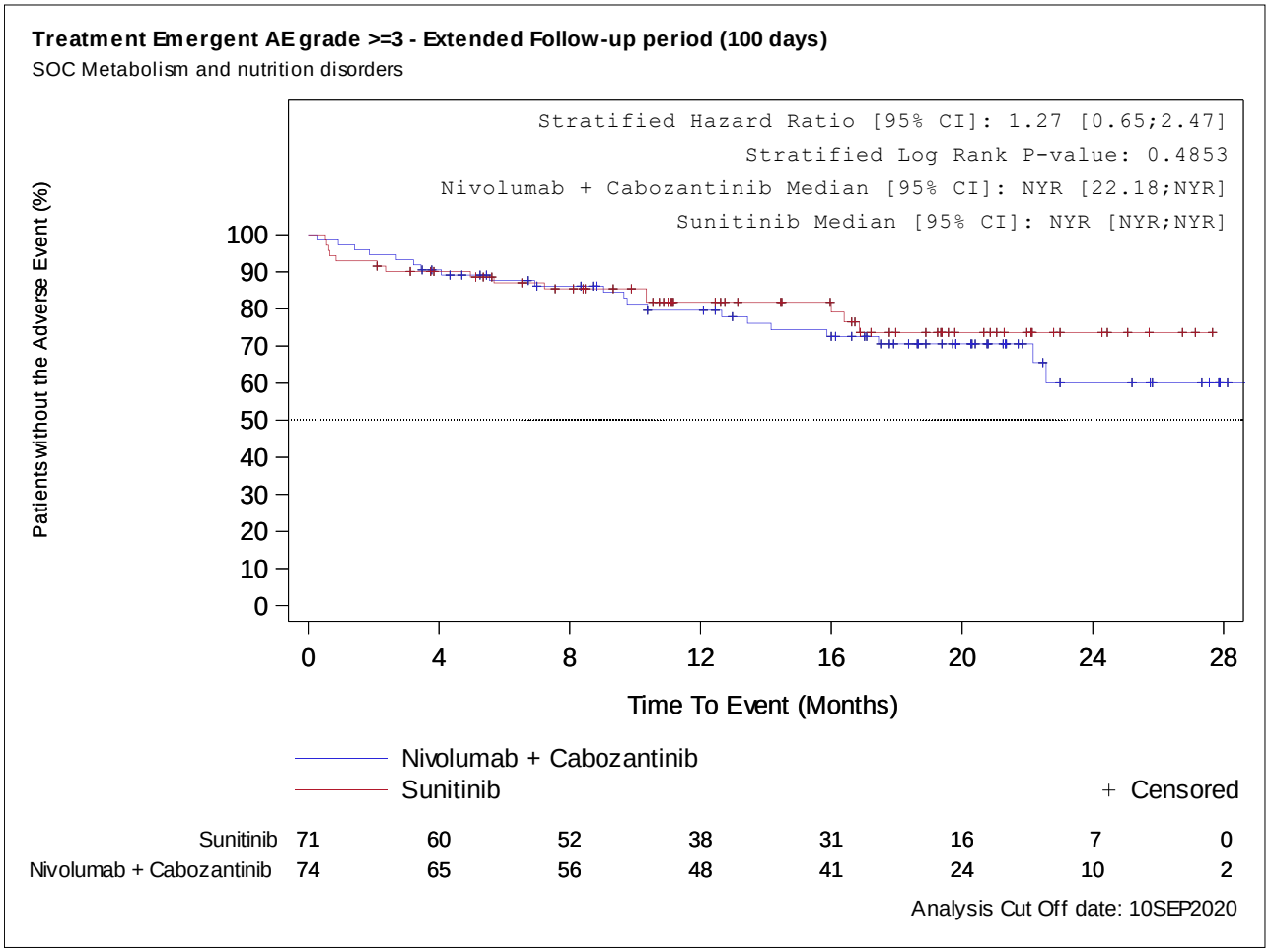
FIGURE 4.5.2.28: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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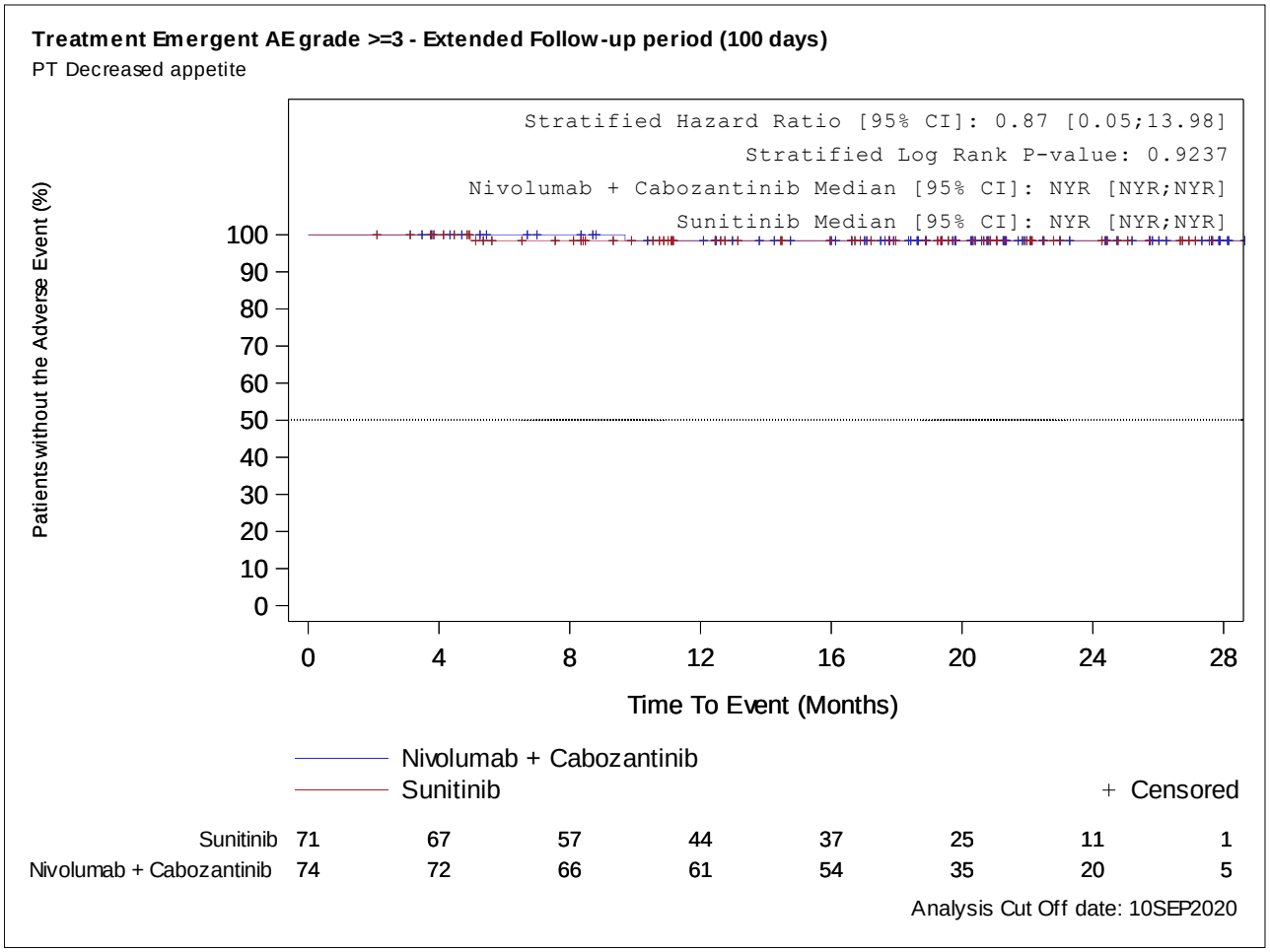
FIGURE 4.5.2.29: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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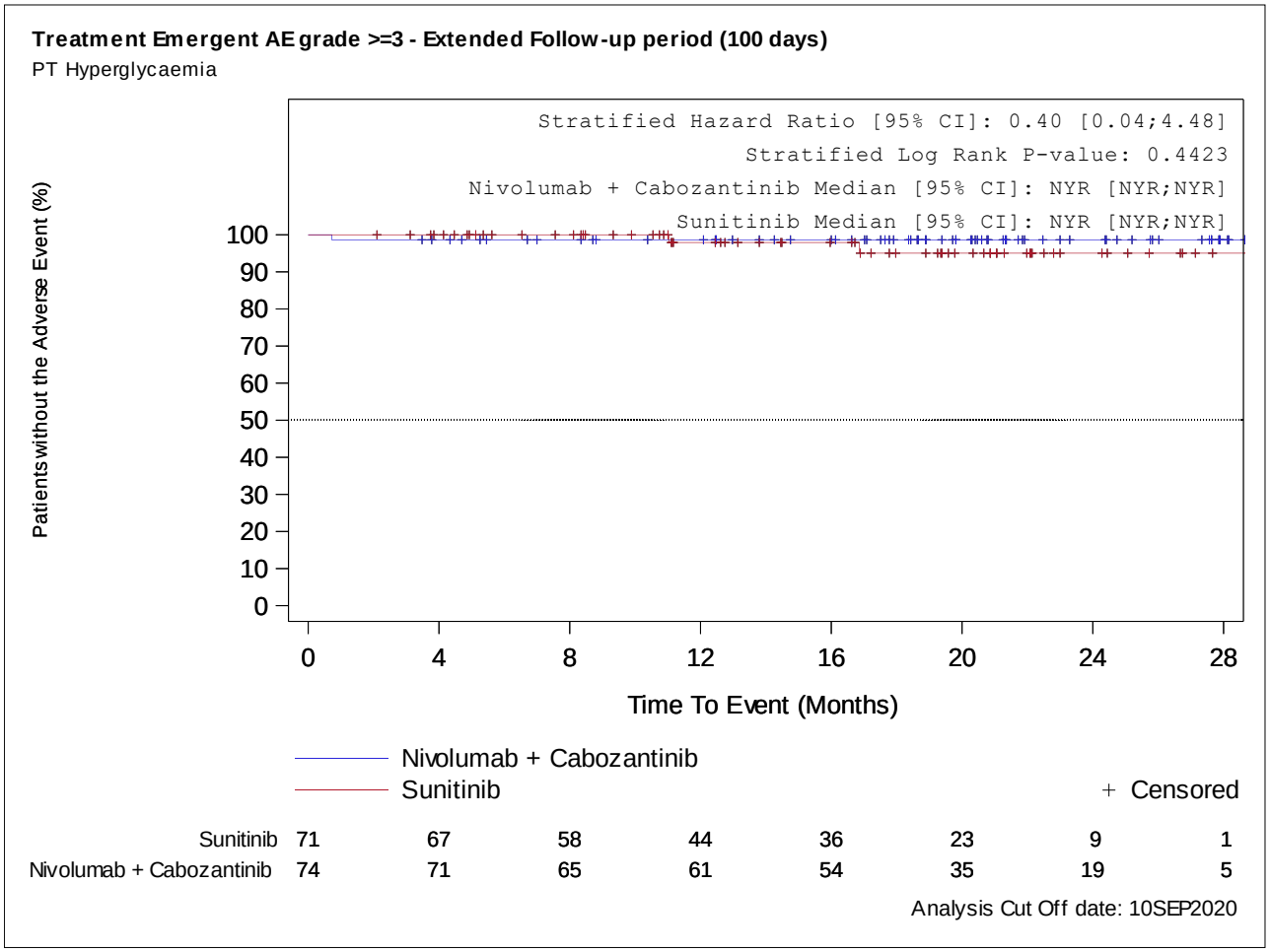
FIGURE 4.5.2.30: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Hyperglycaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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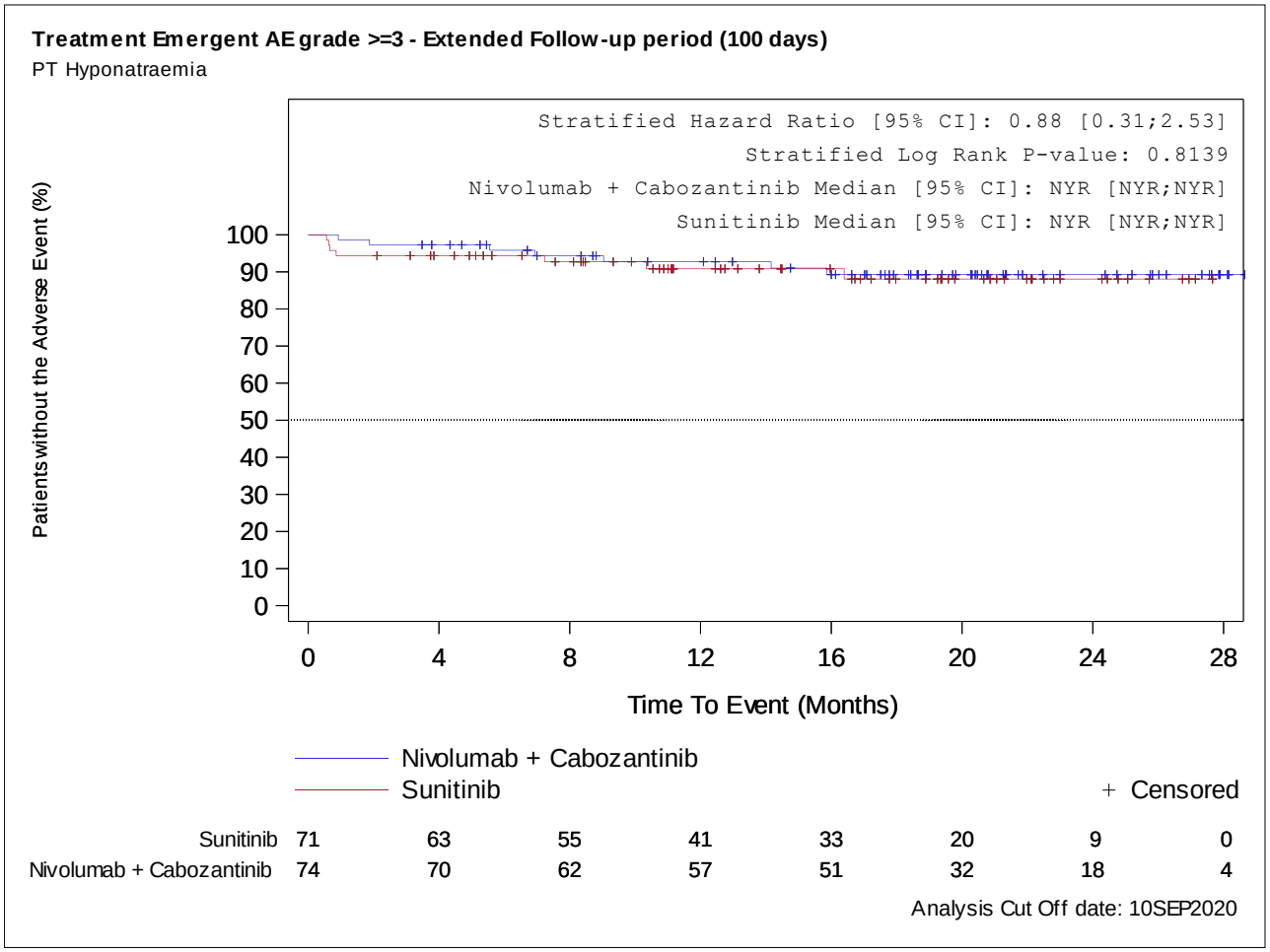
FIGURE 4.5.2.31: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Hyponatraemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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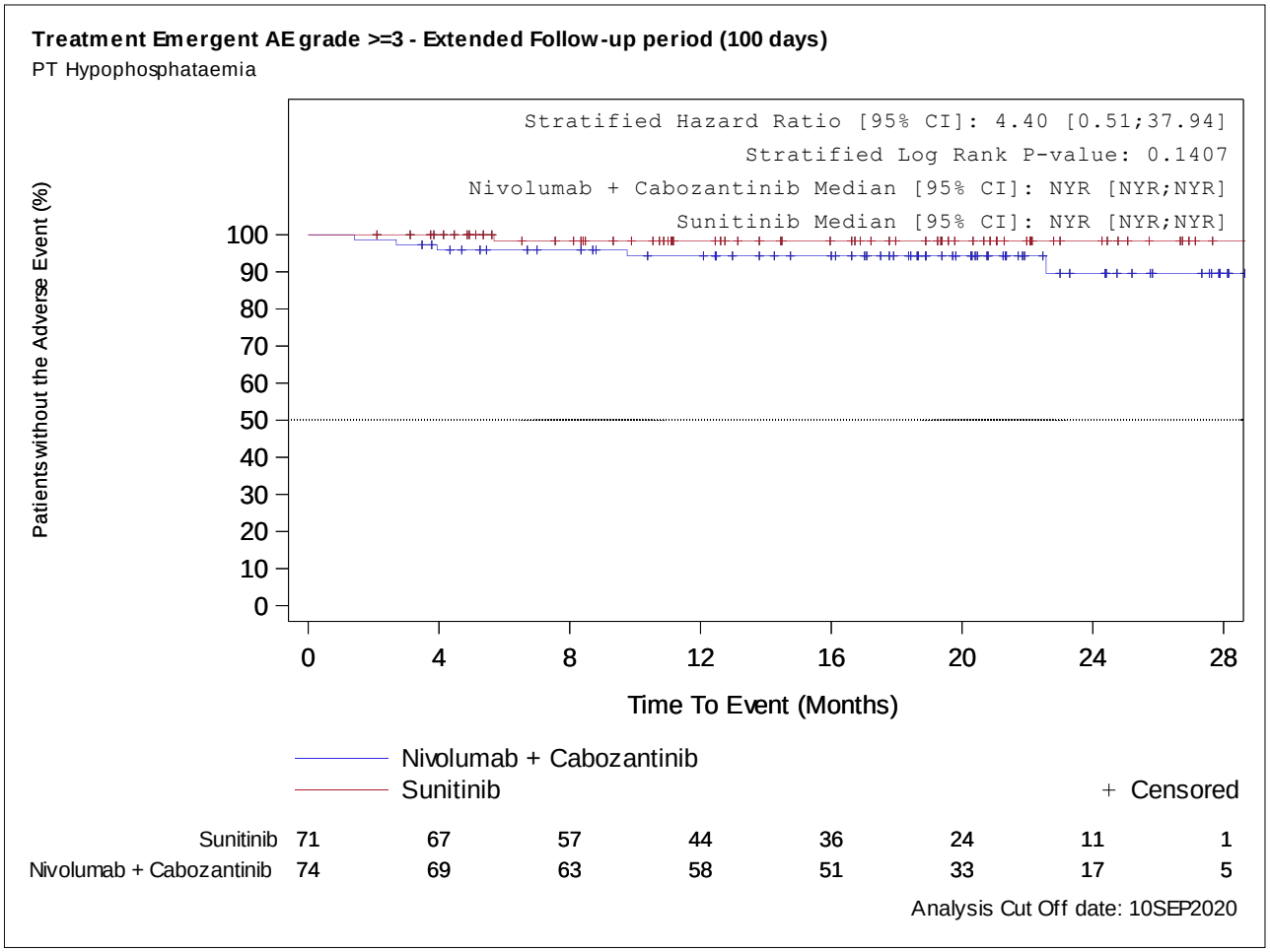
FIGURE 4.5.2.32: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Hypophosphataemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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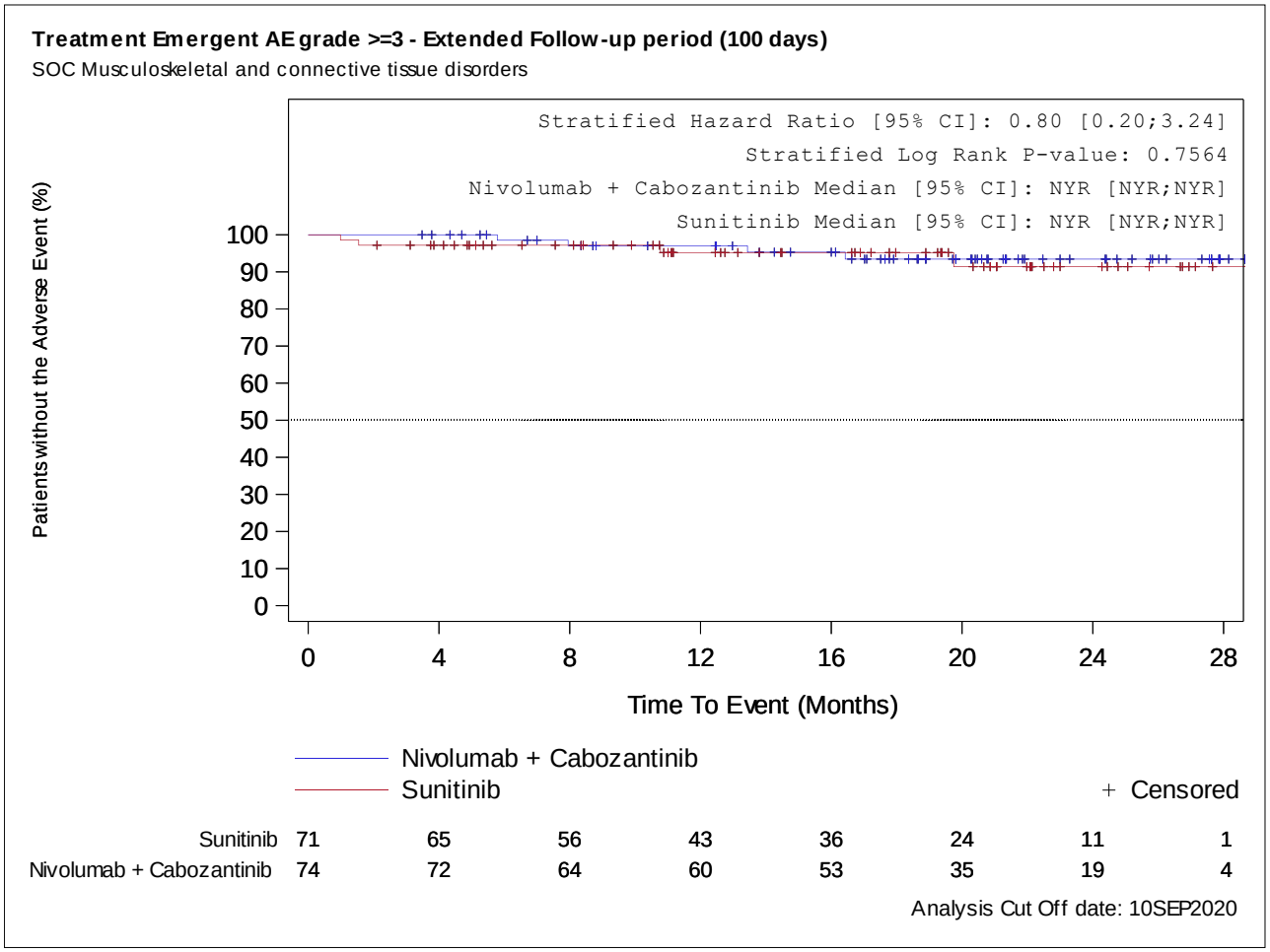
FIGURE 4.5.2.33: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Musculoskeletal and connective tissue disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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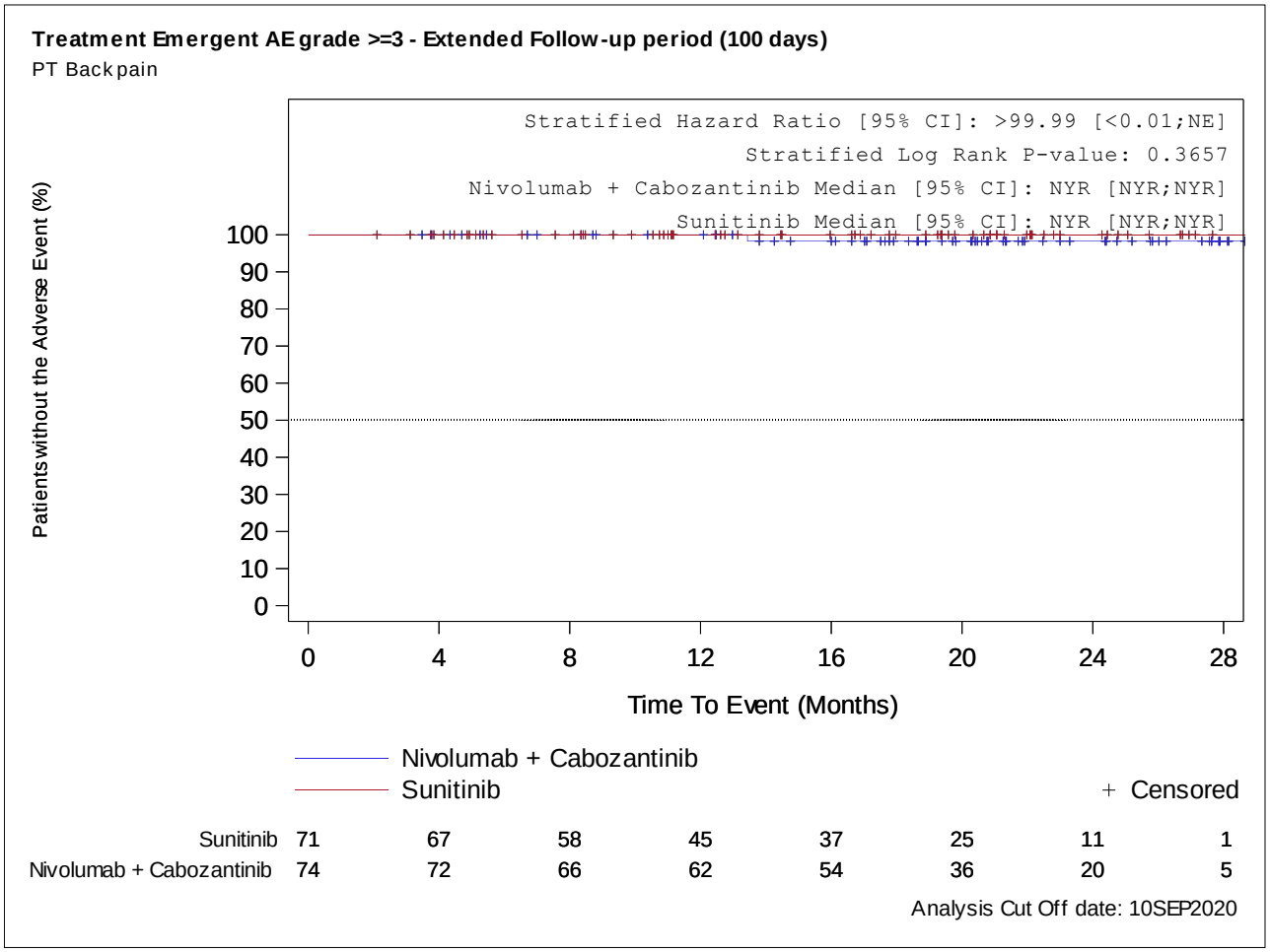
FIGURE 4.5.2.34: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Back pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.5.2.35: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

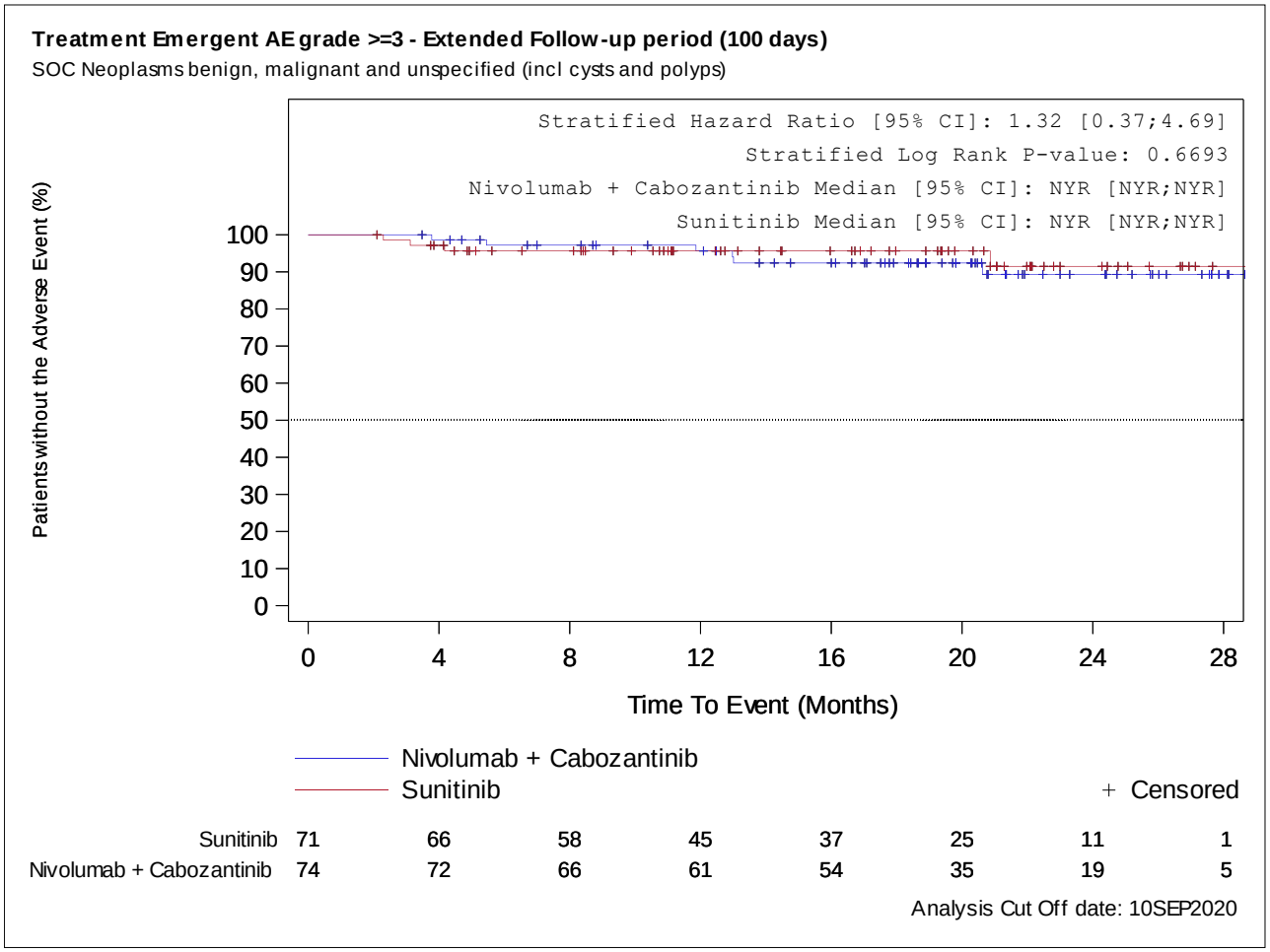


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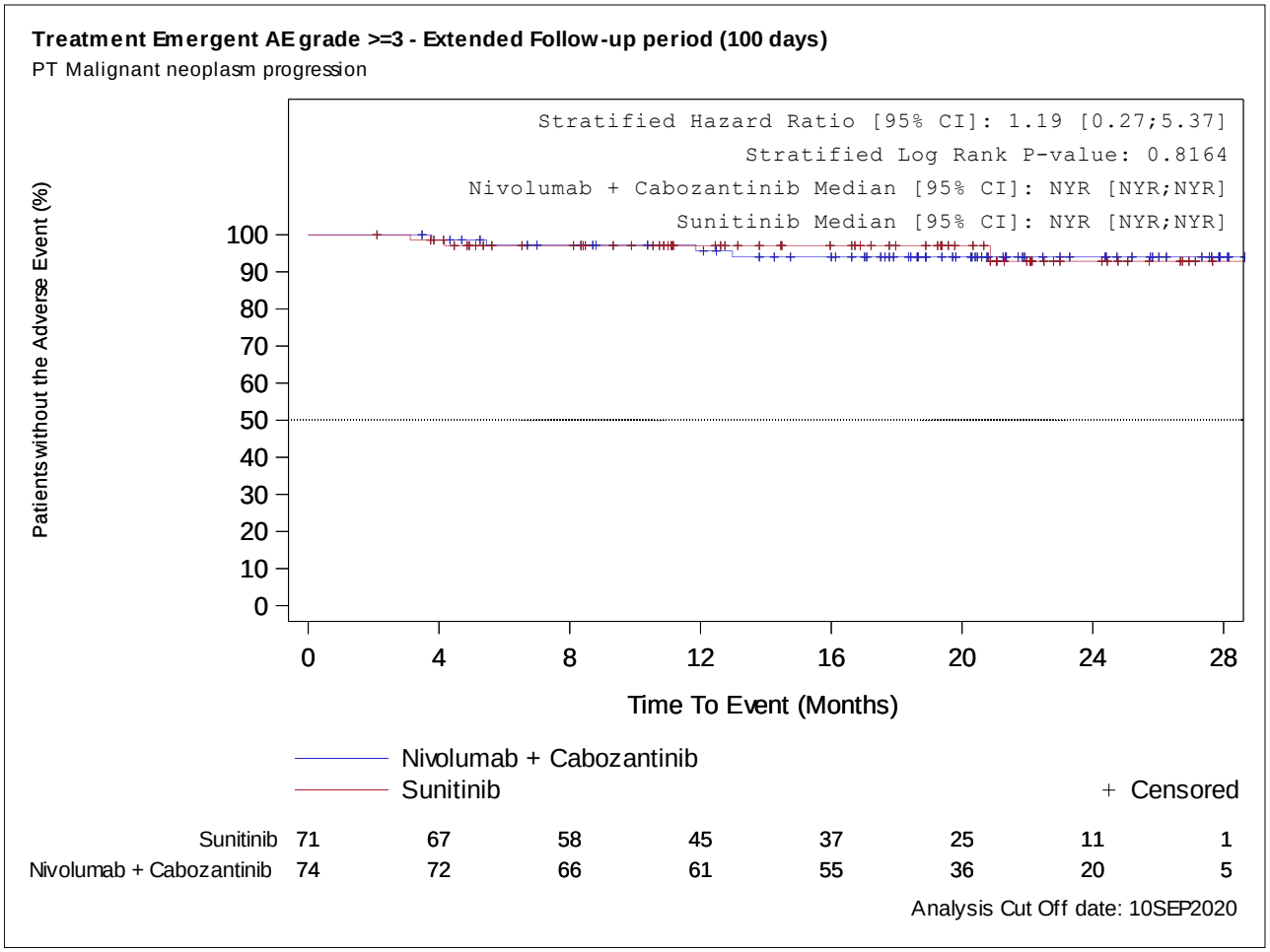
FIGURE 4.5.2.36: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Malignant neoplasm progression - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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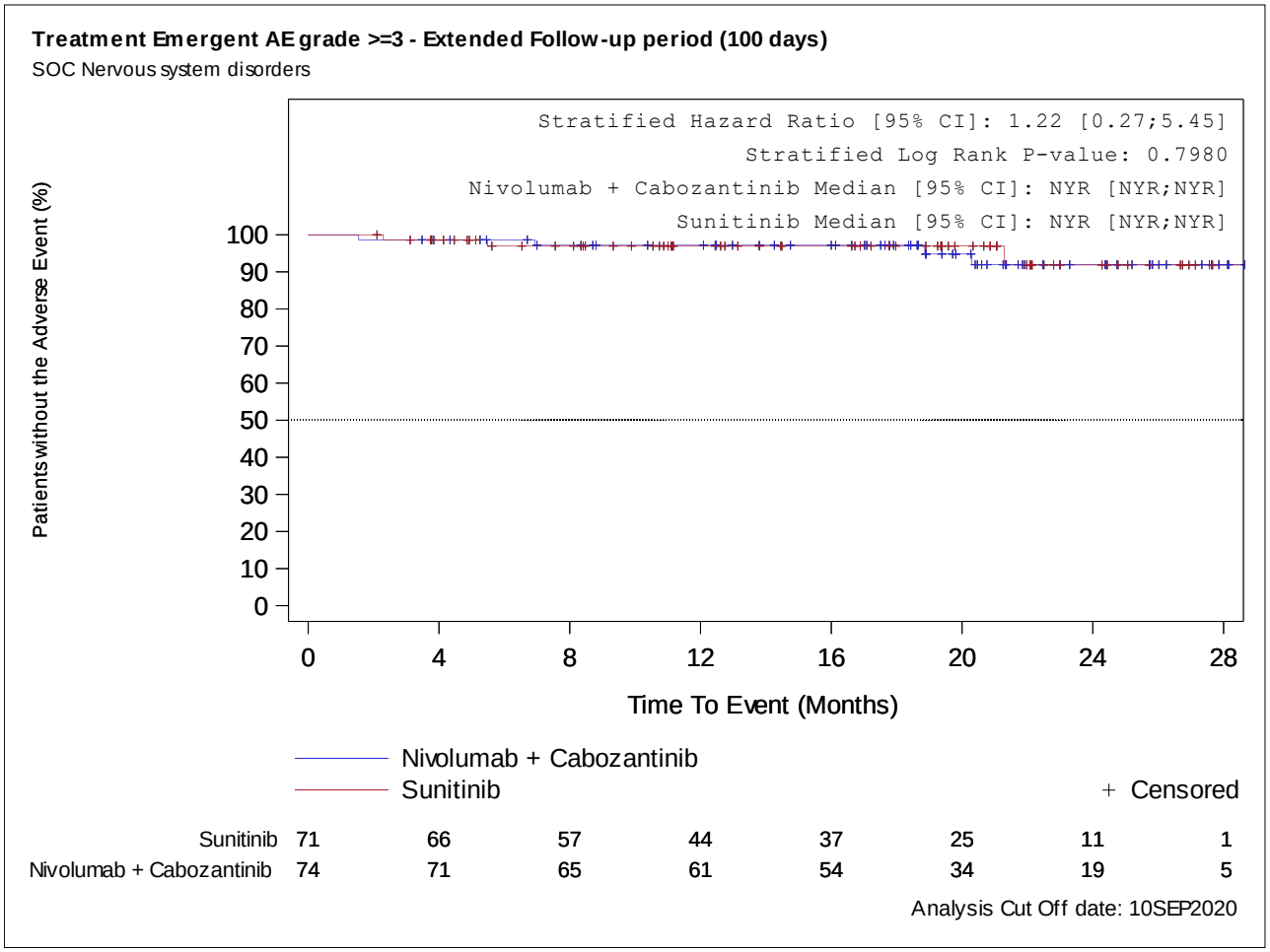
FIGURE 4.5.2.37: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Nervous system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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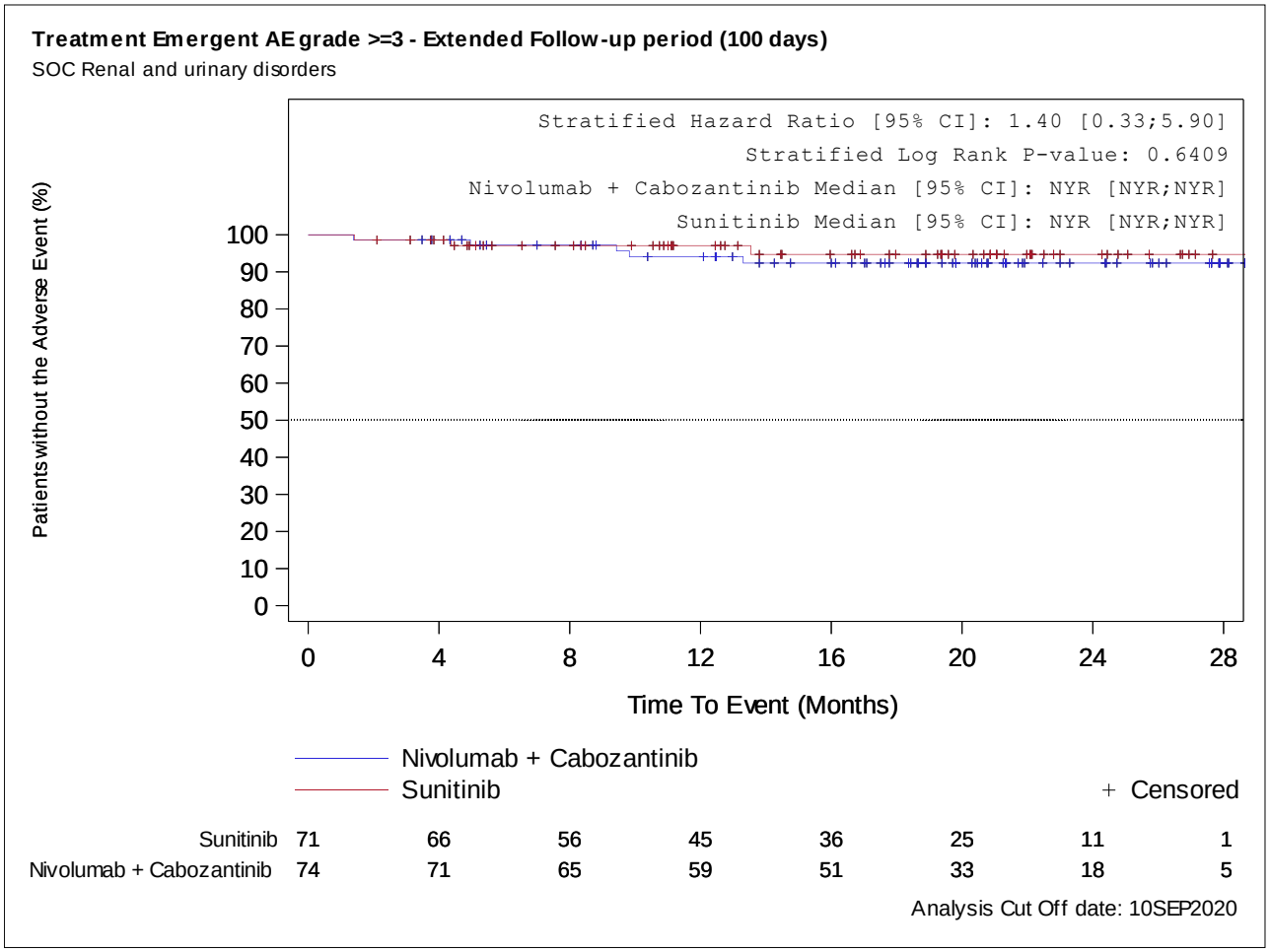
FIGURE 4.5.2.38: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Renal and urinary disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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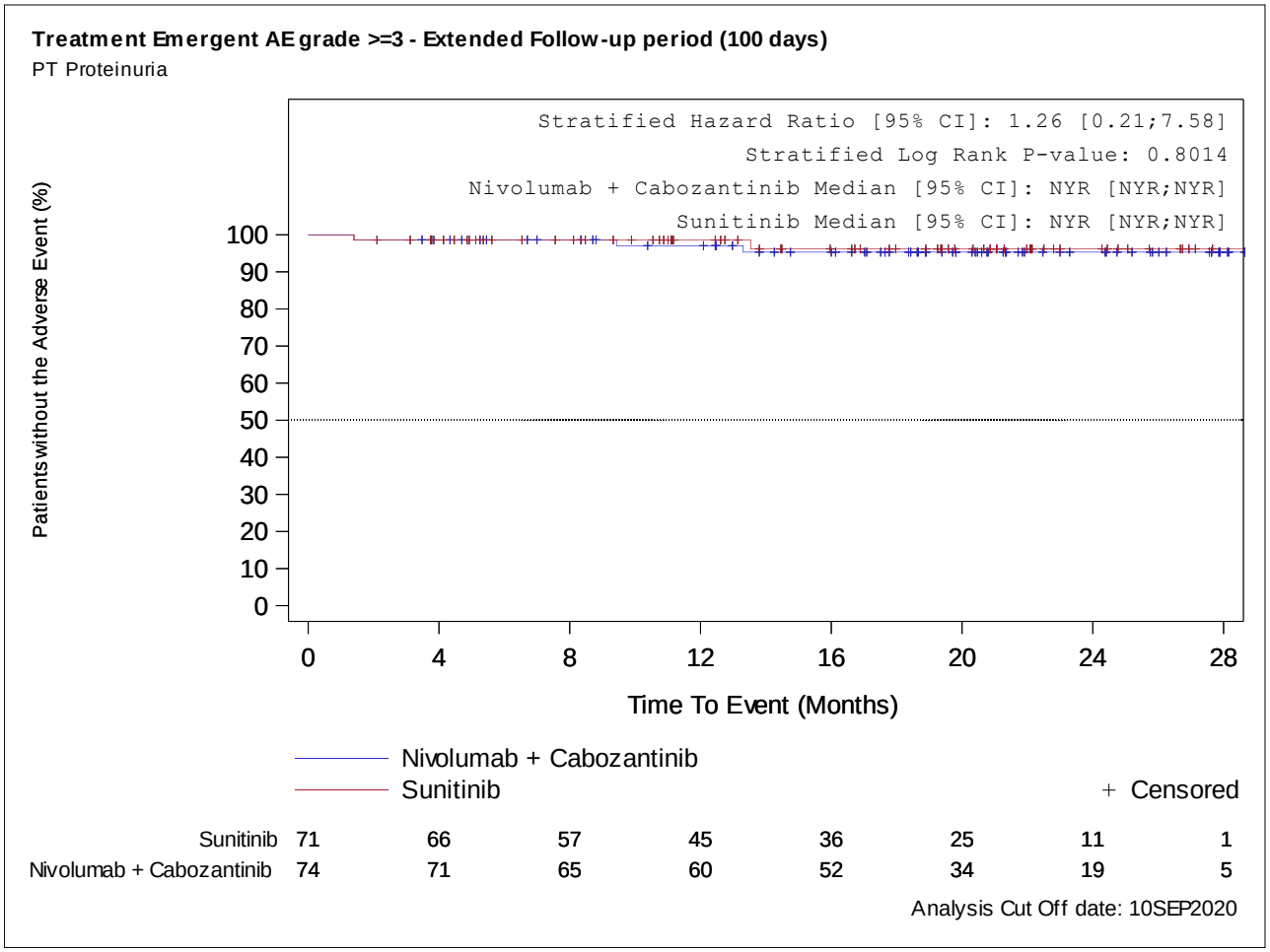
FIGURE 4.5.2.39: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Proteinuria - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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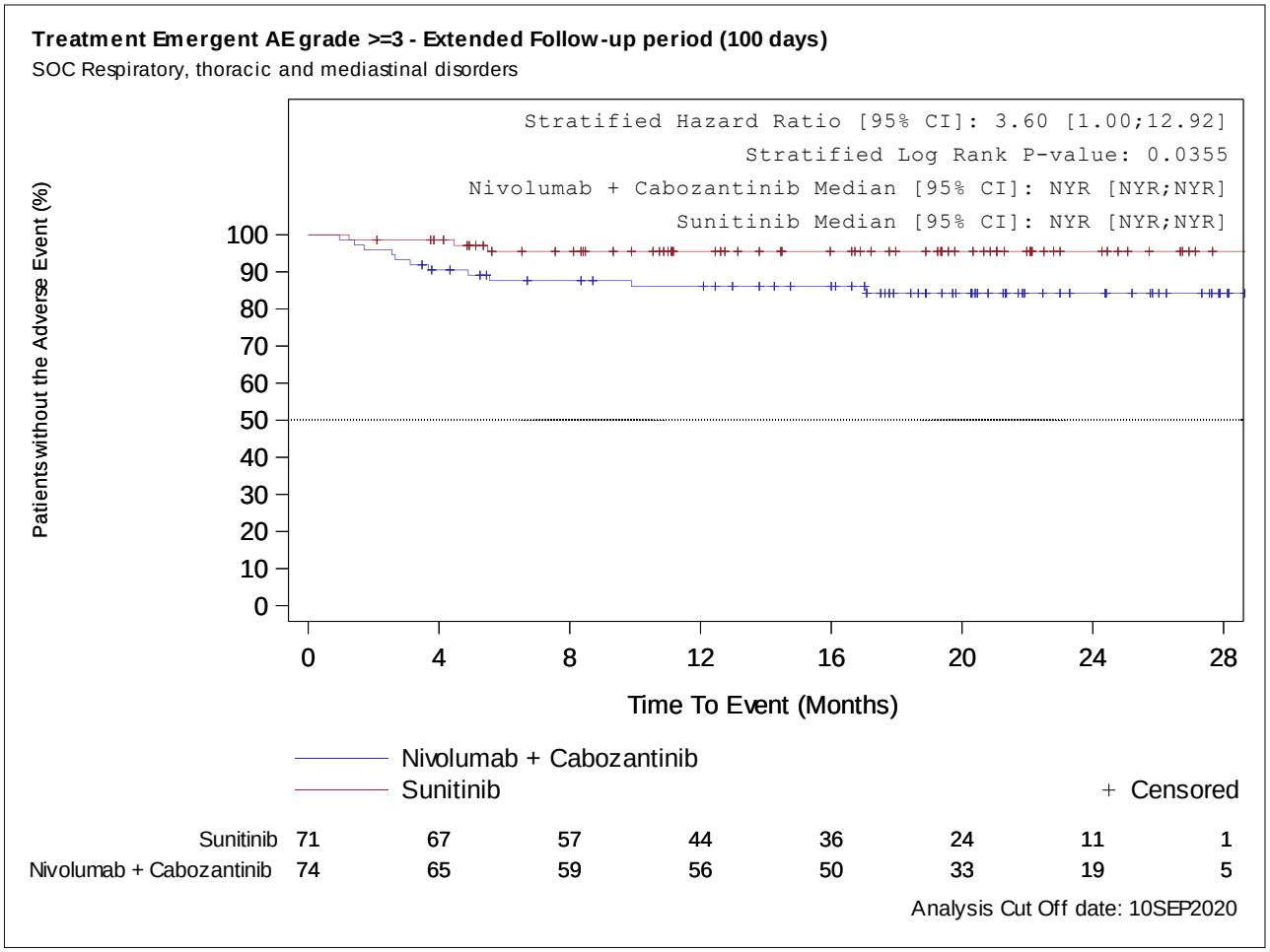
FIGURE 4.5.2.40: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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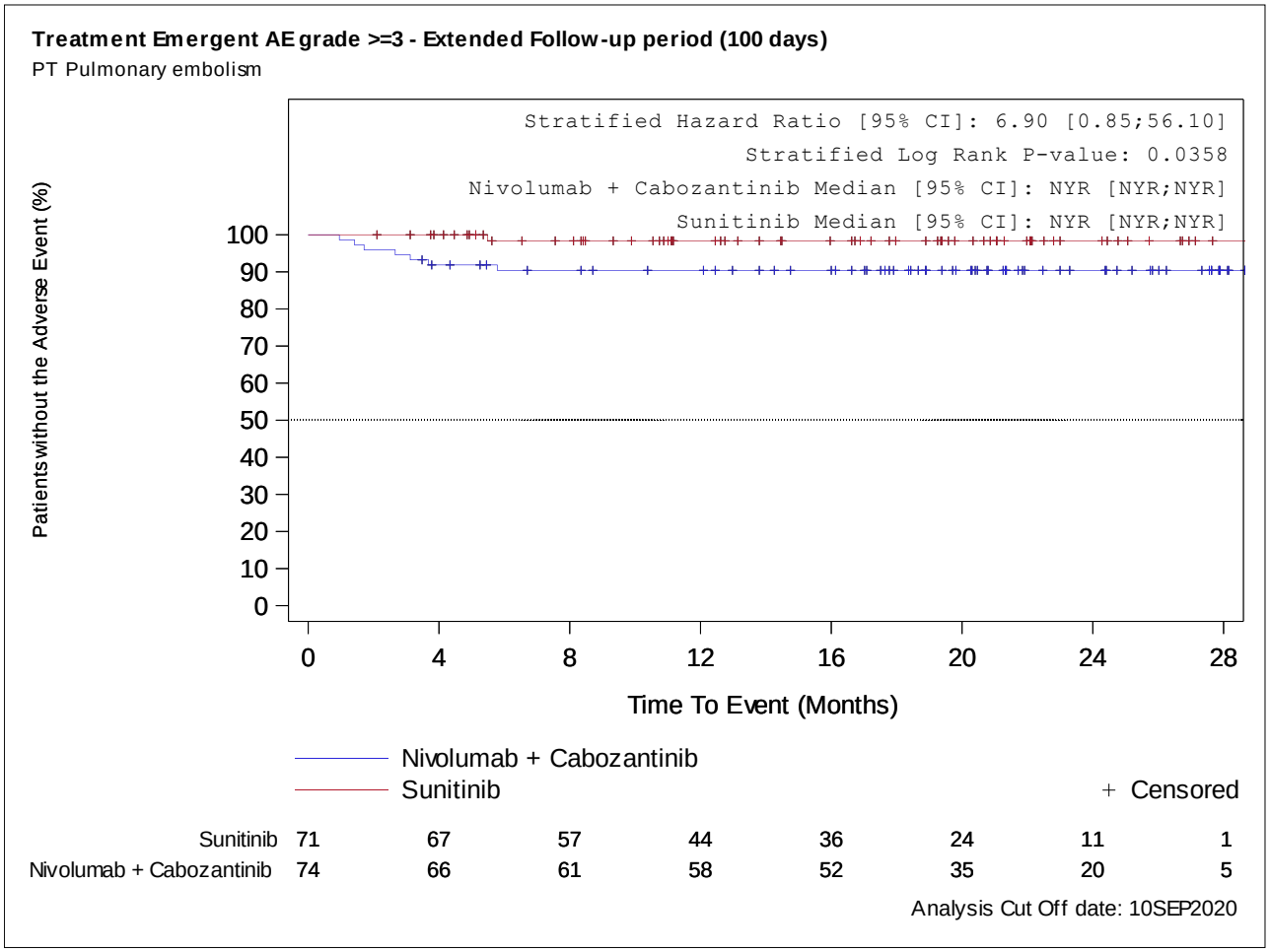
FIGURE 4.5.2.41: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Pulmonary embolism - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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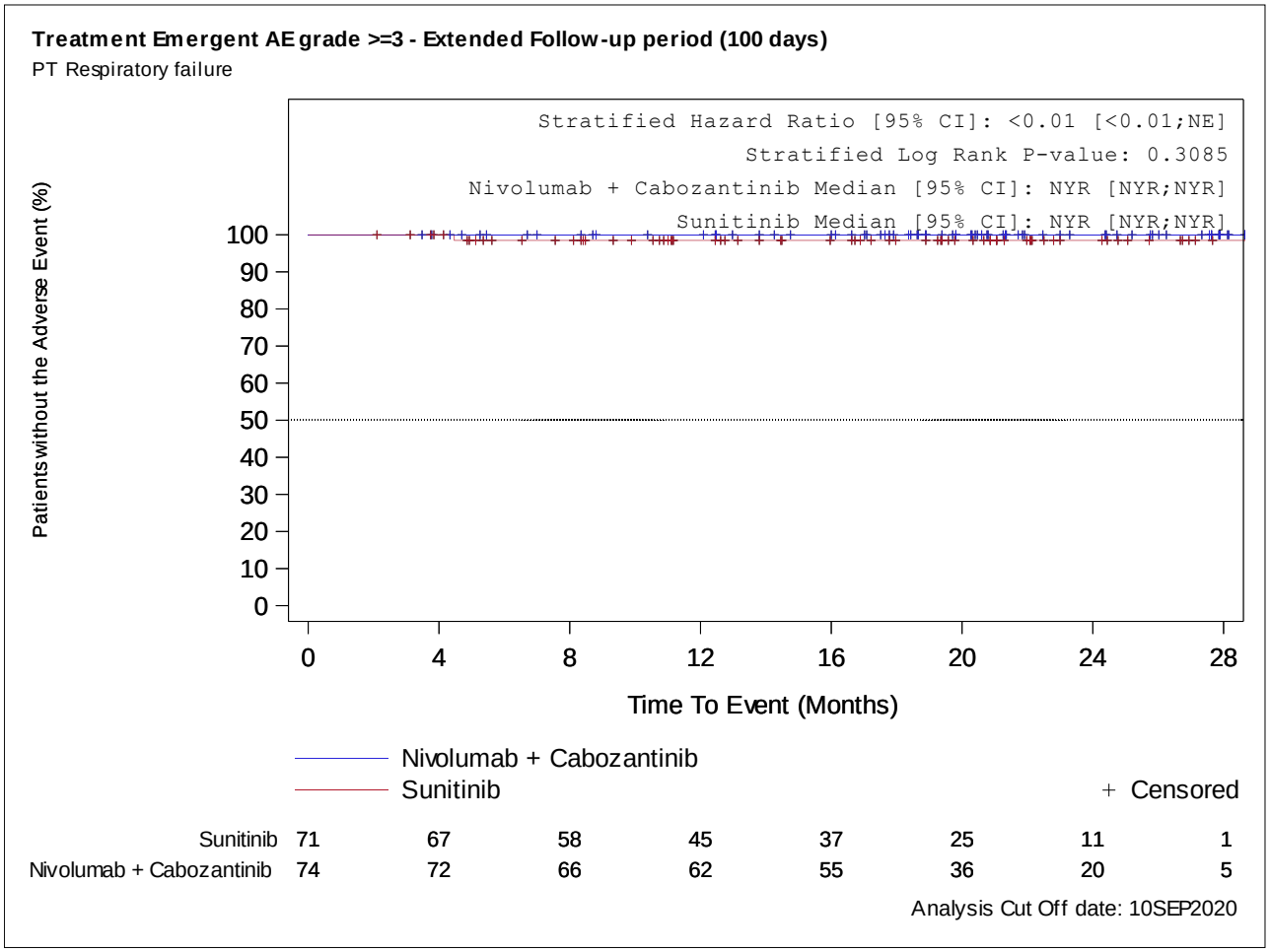
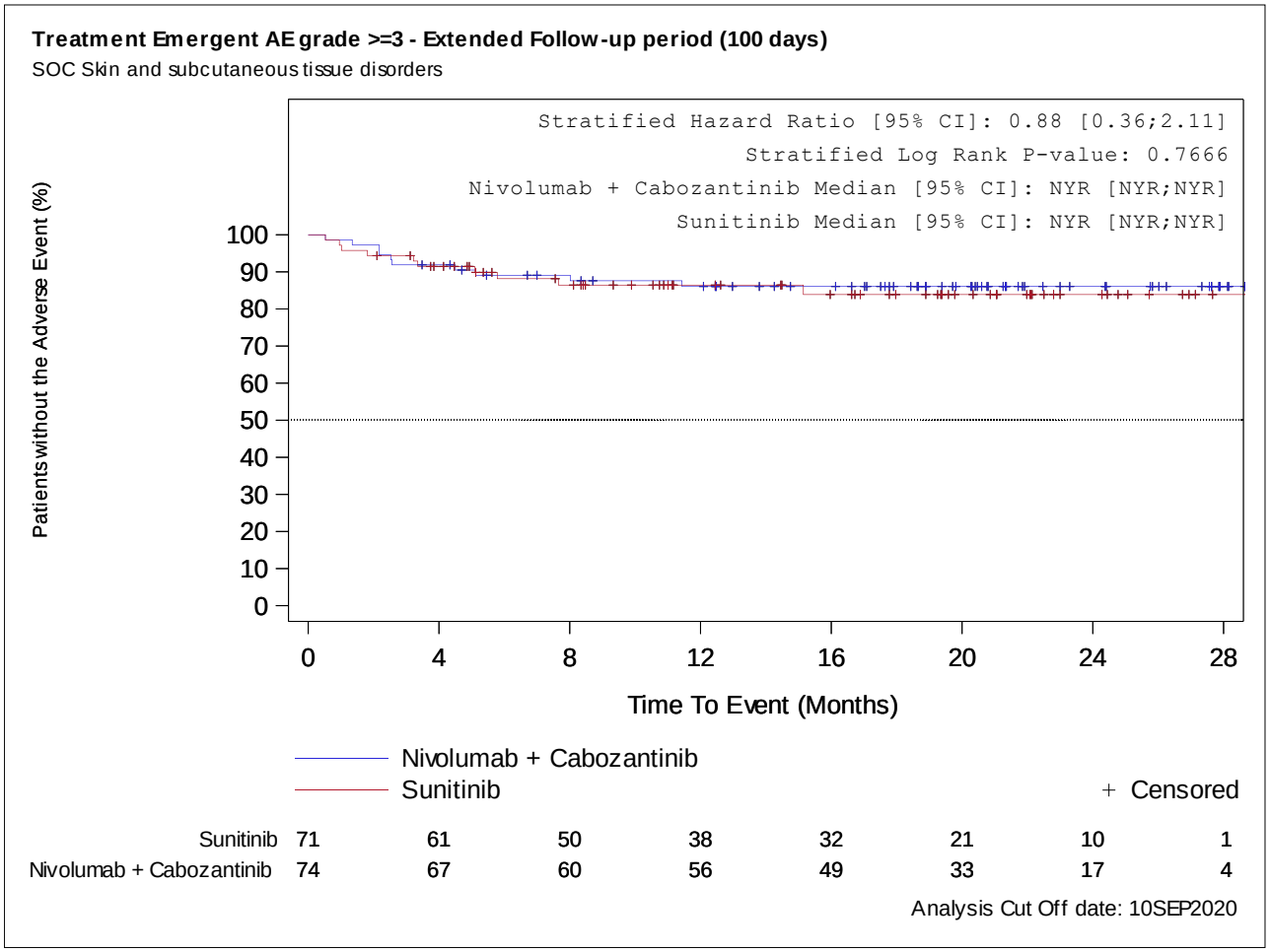
FIGURE 4.5.2.42: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Respiratory failure - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



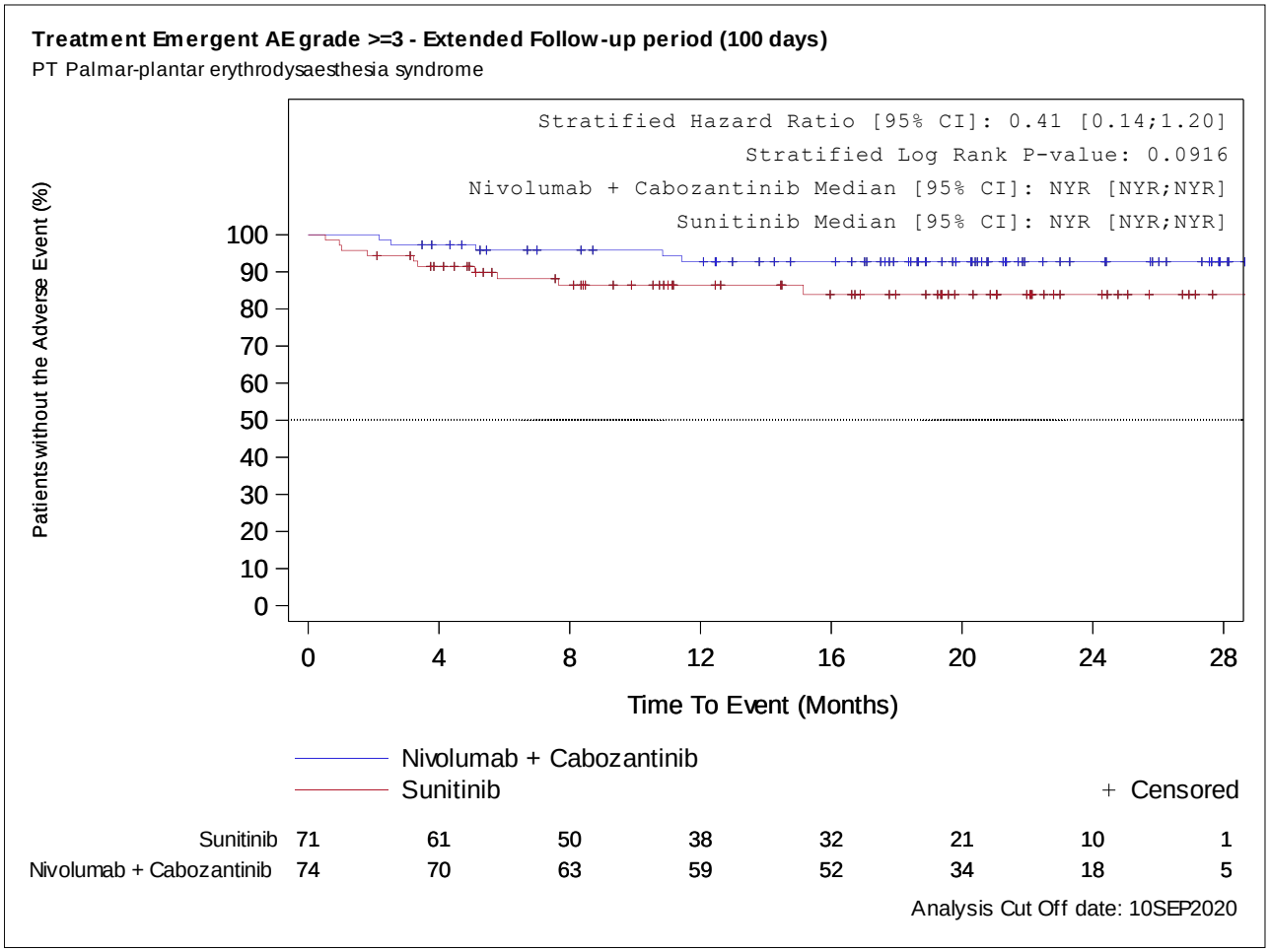

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:36:54

FIGURE 4.5.2.43: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Skin and subcutaneous tissue disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:36:58

FIGURE 4.5.2.44: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Palmar-plantar erythrodysaesthesia syndrome - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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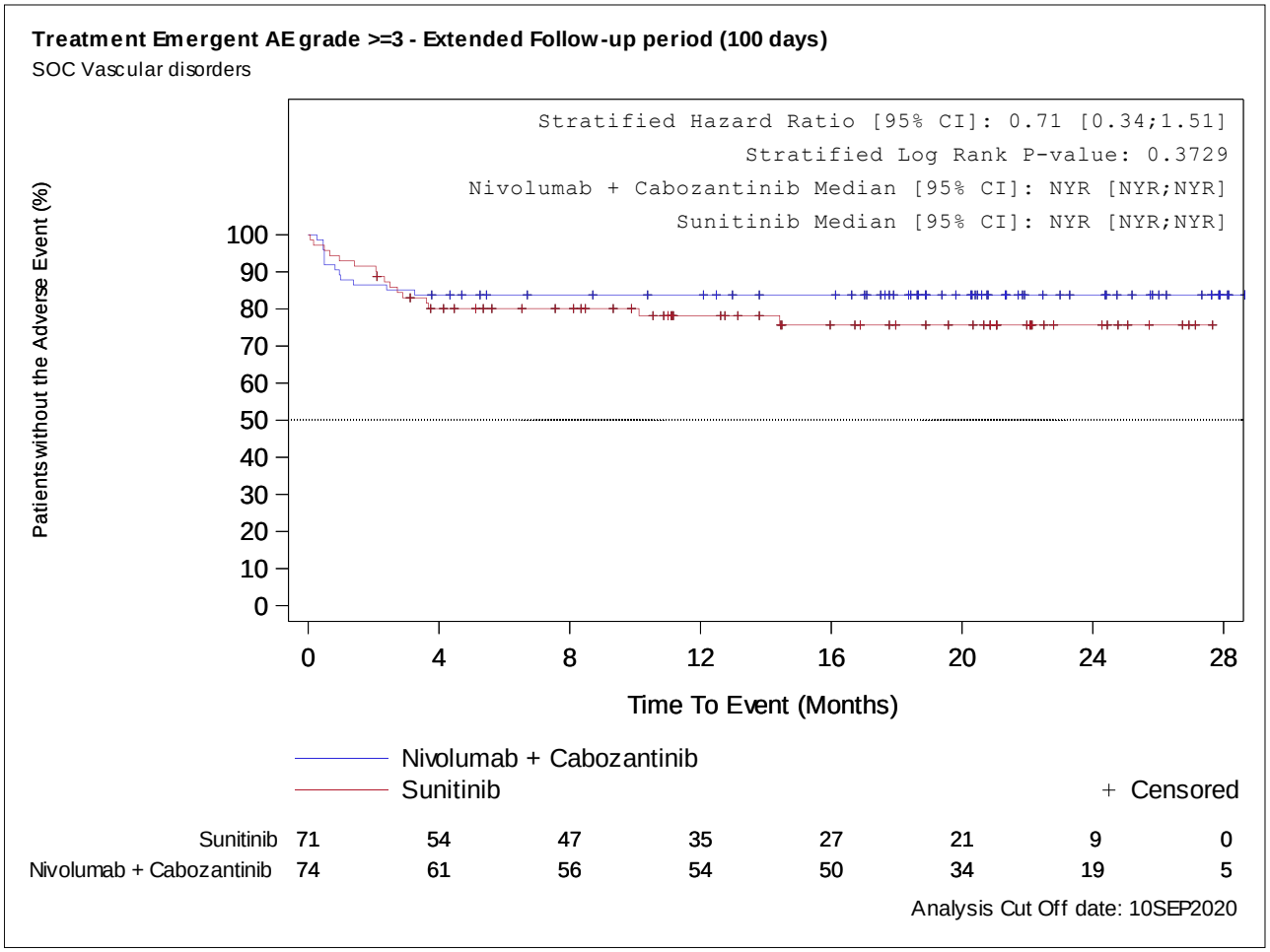
FIGURE 4.5.2.45: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Vascular disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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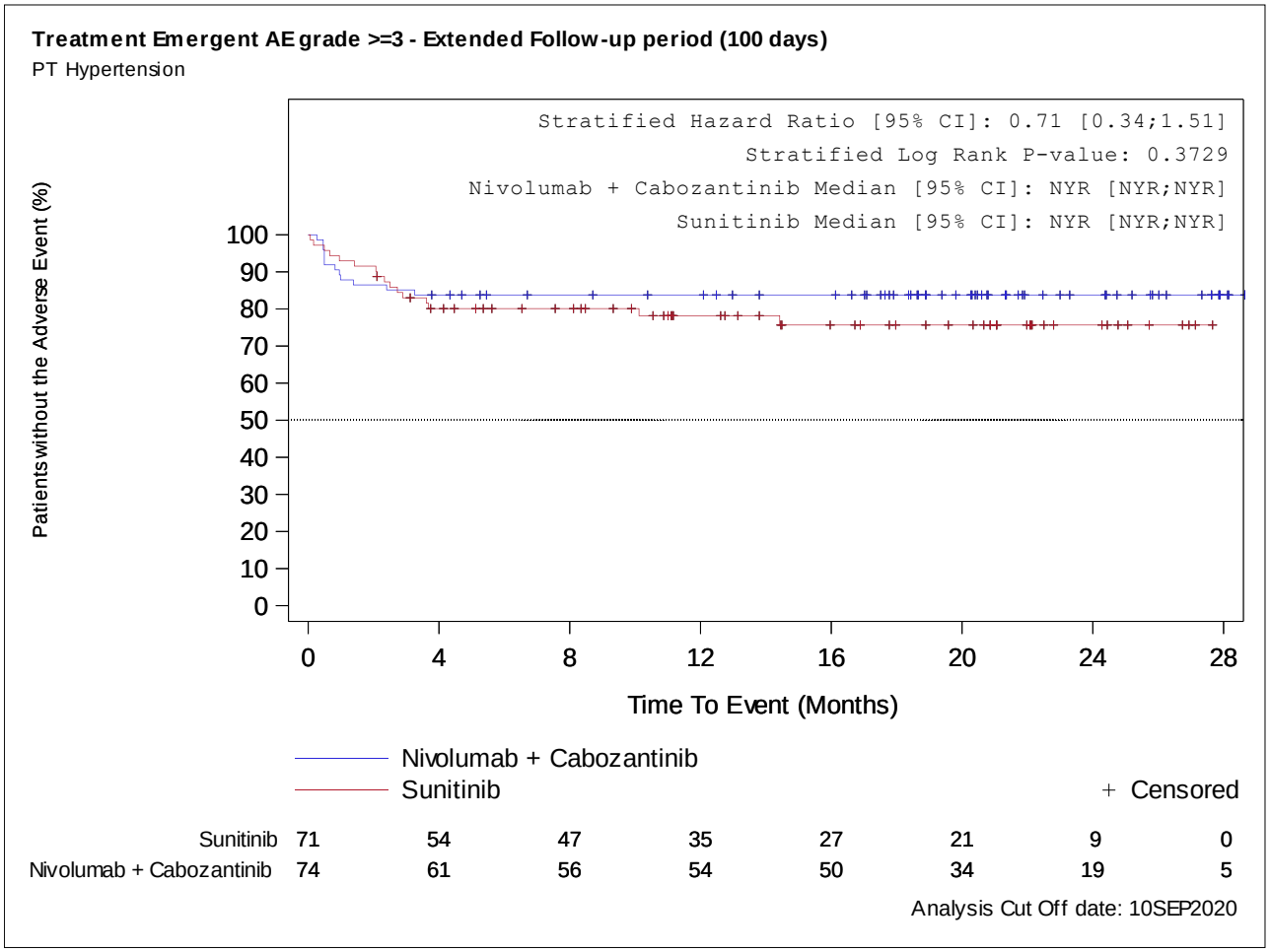
FIGURE 4.5.2.46: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - PT Hypertension - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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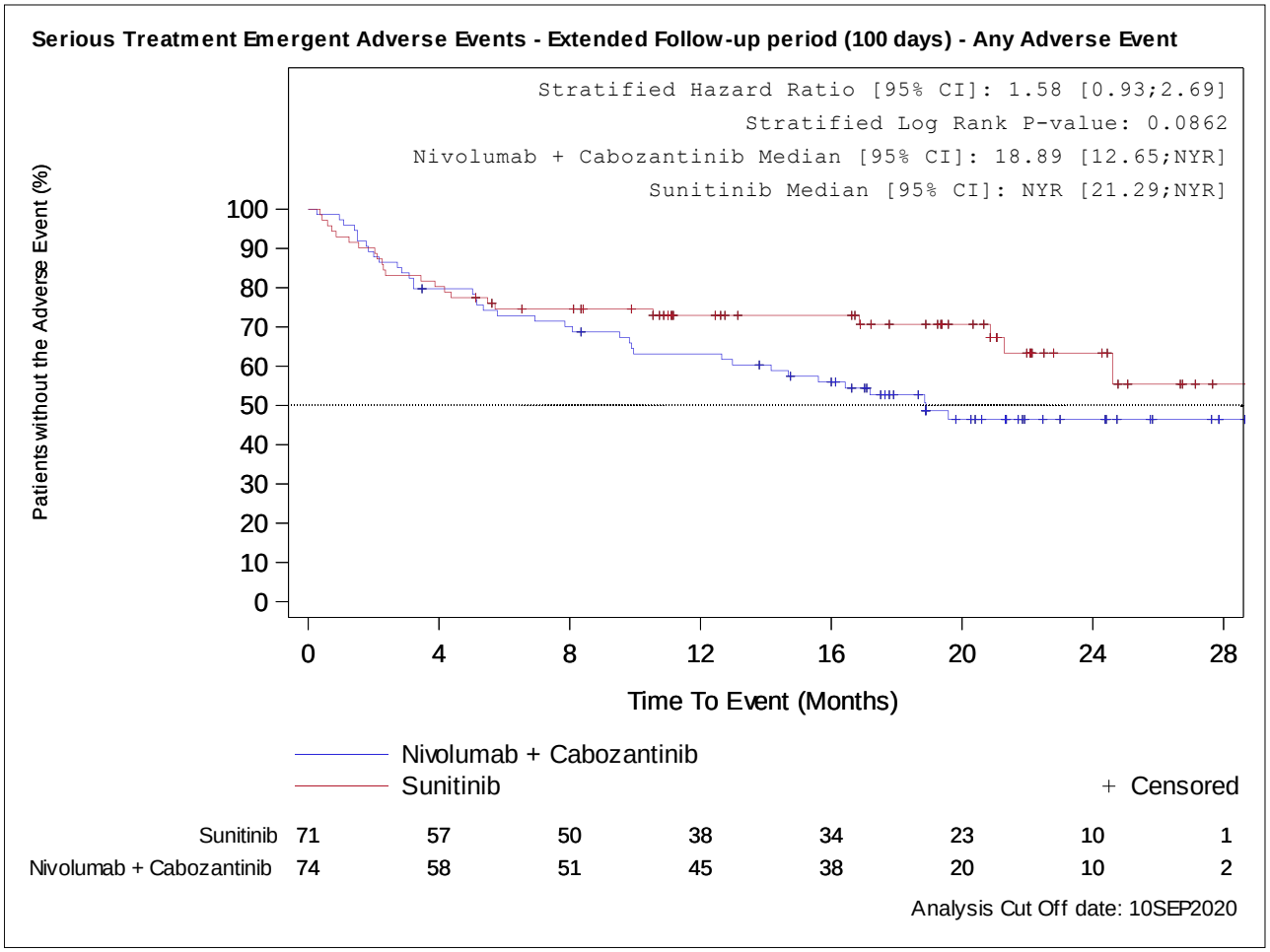
FIGURE 4.6.1: Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - Any Adverse Event - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:38:25

FIGURE 4.6.2.1: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

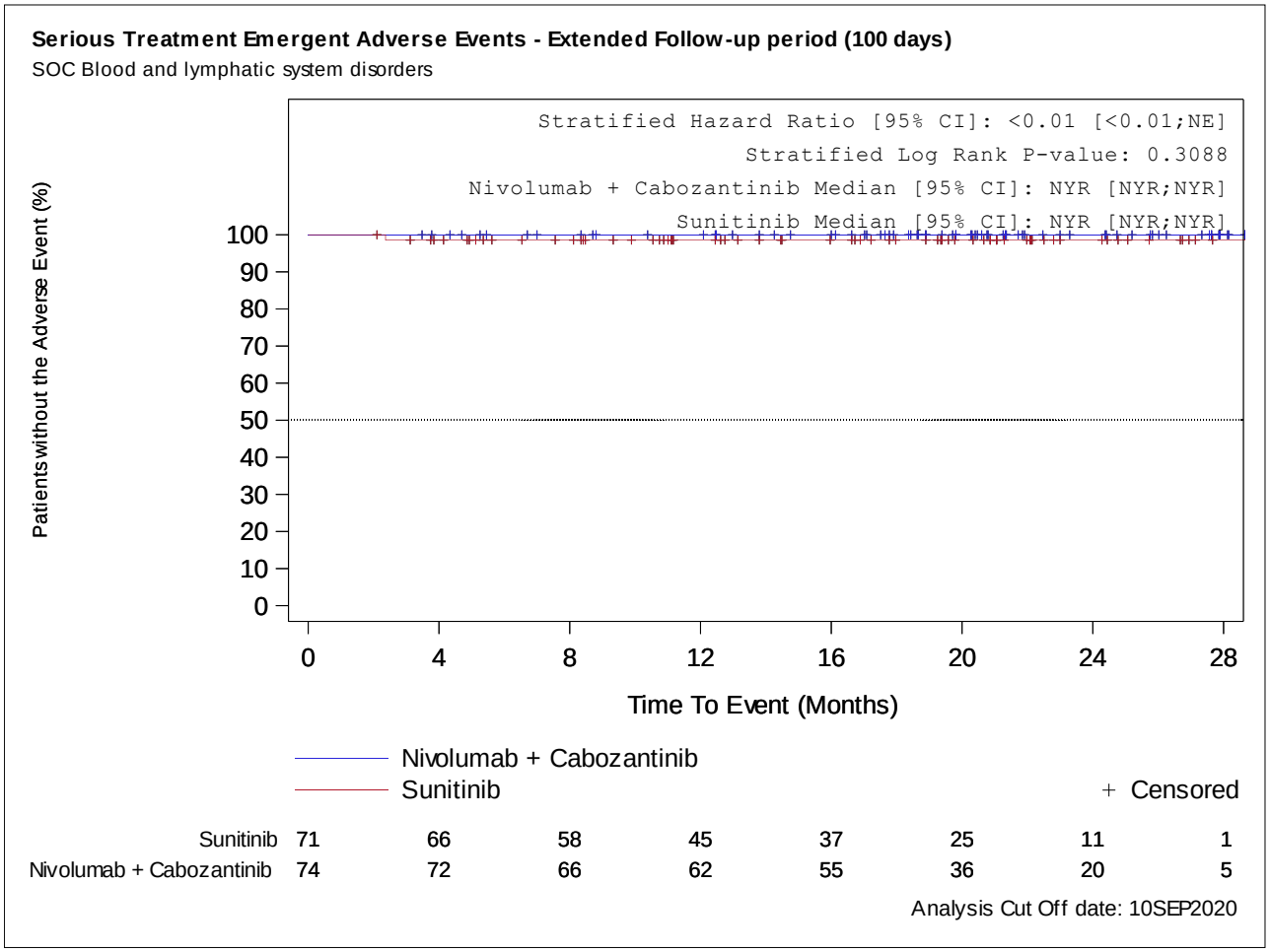



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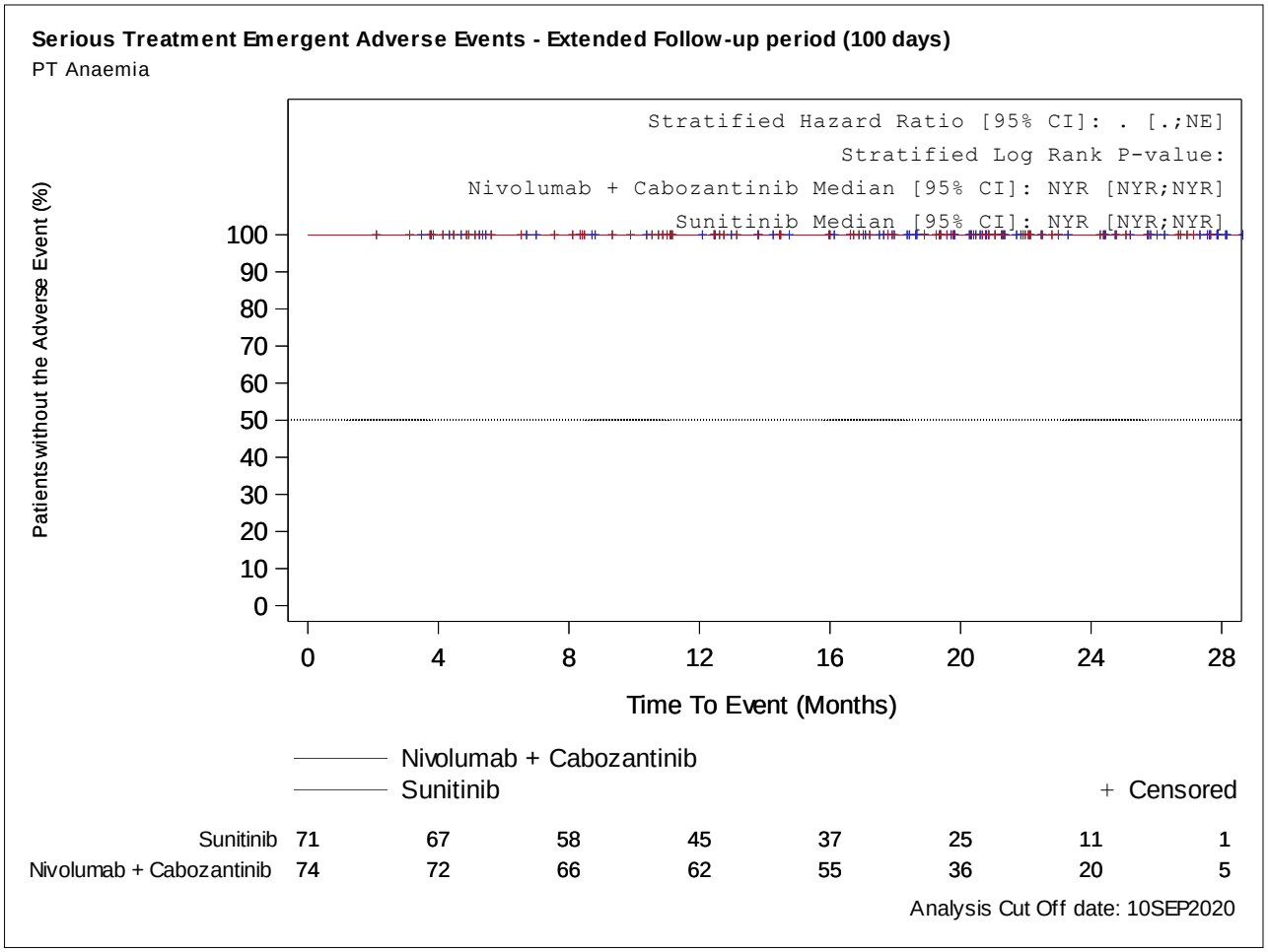
FIGURE 4.6.2.2: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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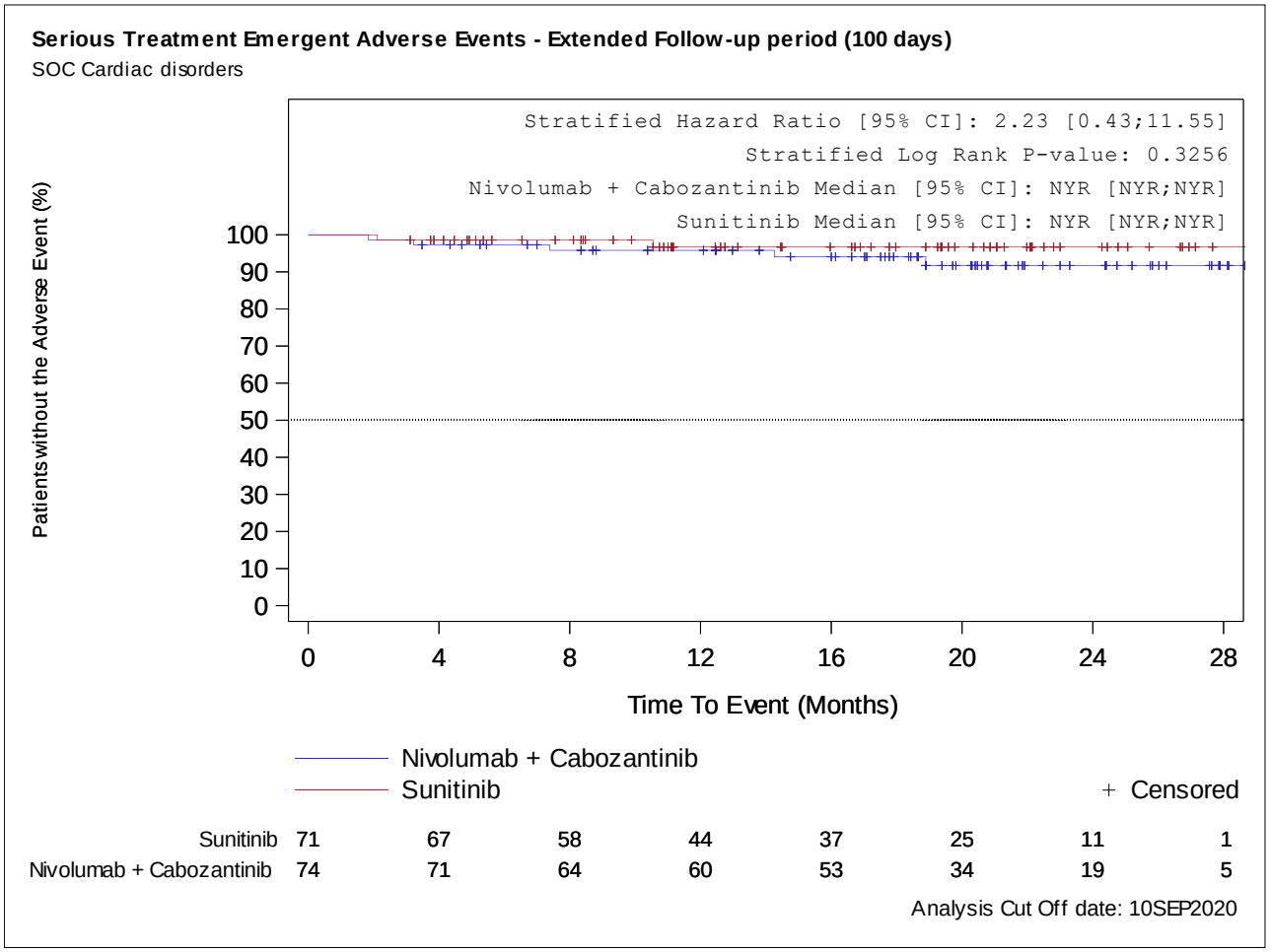
FIGURE 4.6.2.3: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - SOC Cardiac disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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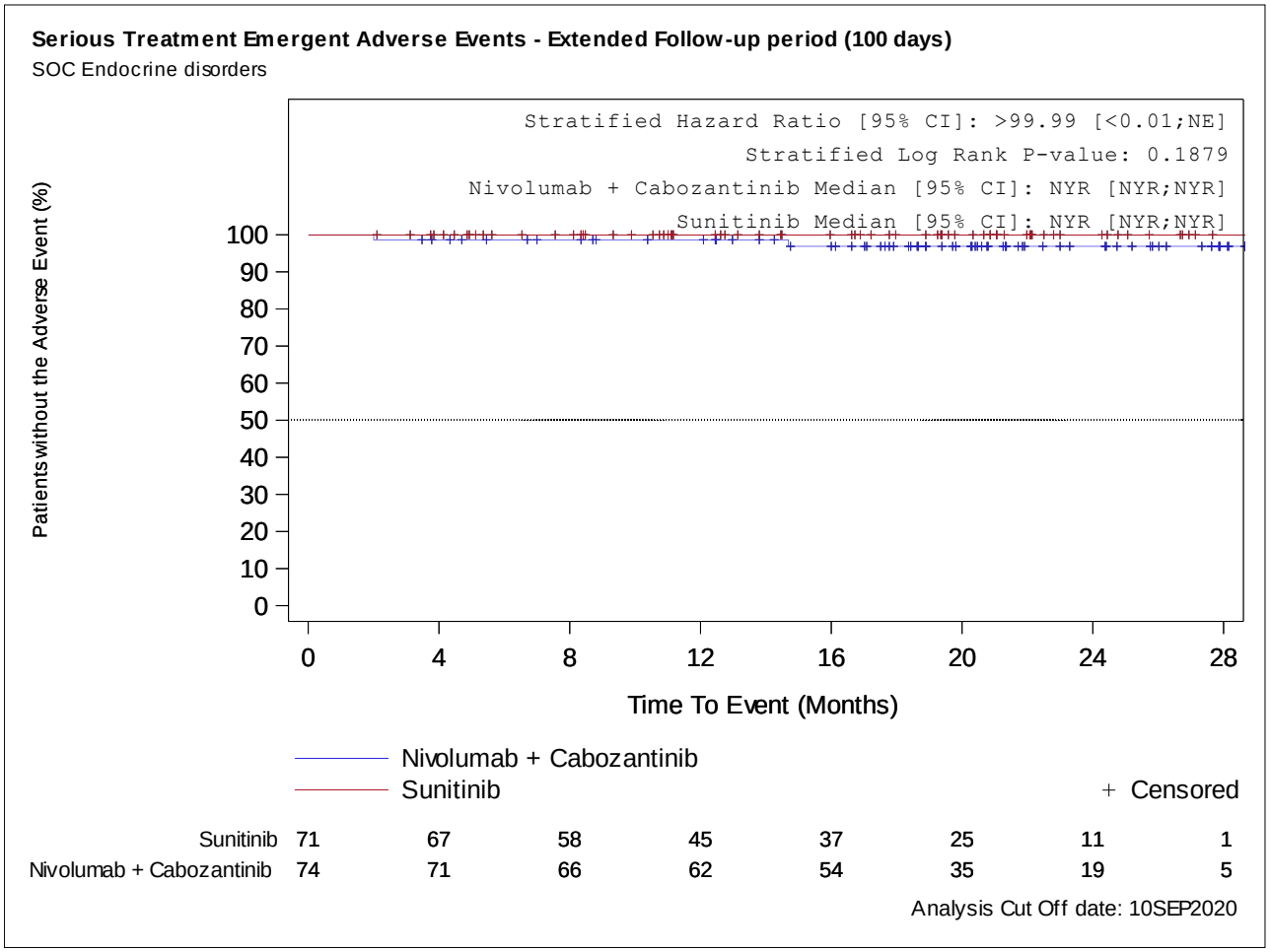
FIGURE 4.6.2.4: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - SOC Endocrine disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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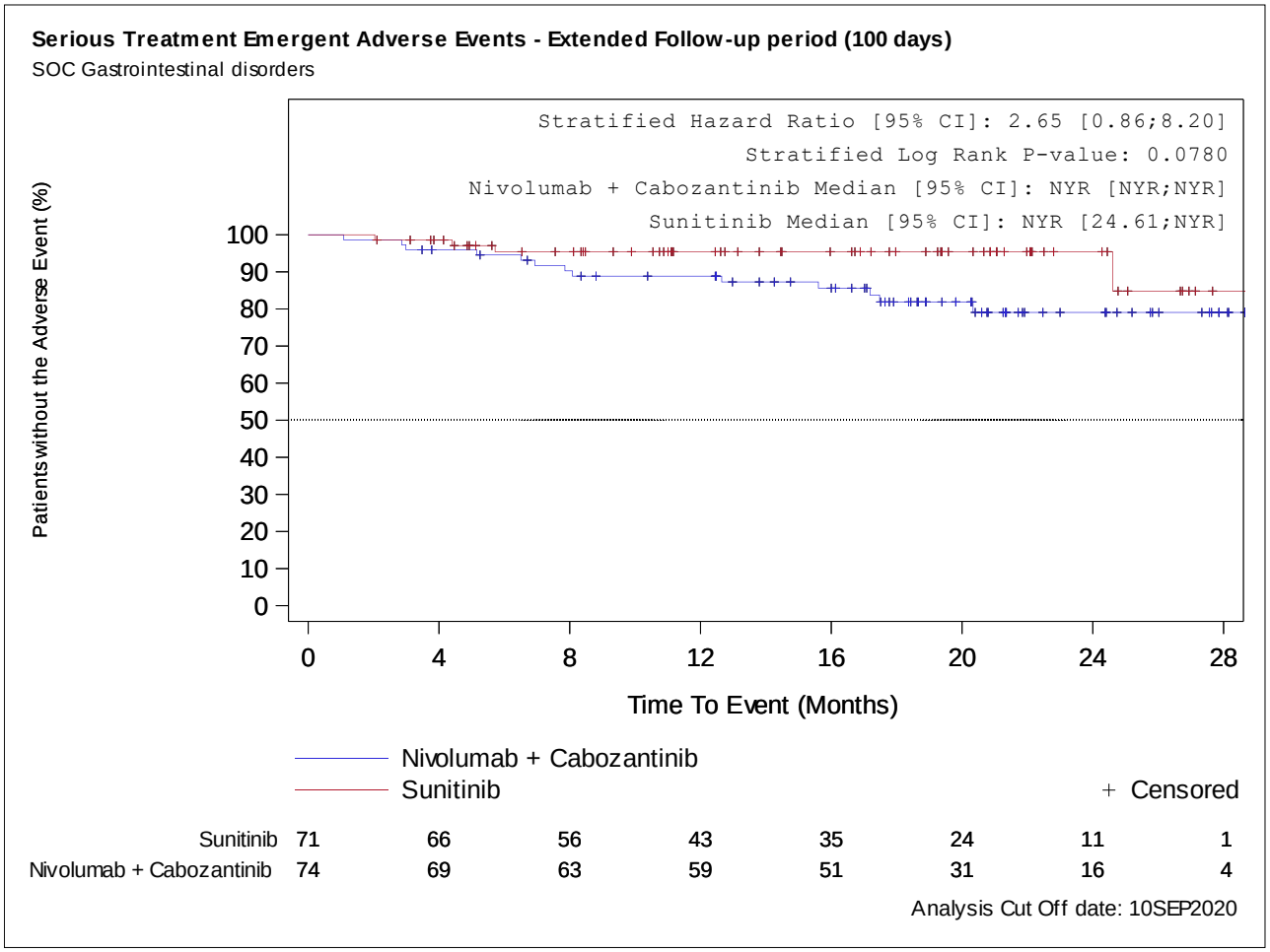
FIGURE 4.6.2.5: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.6.2.6: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

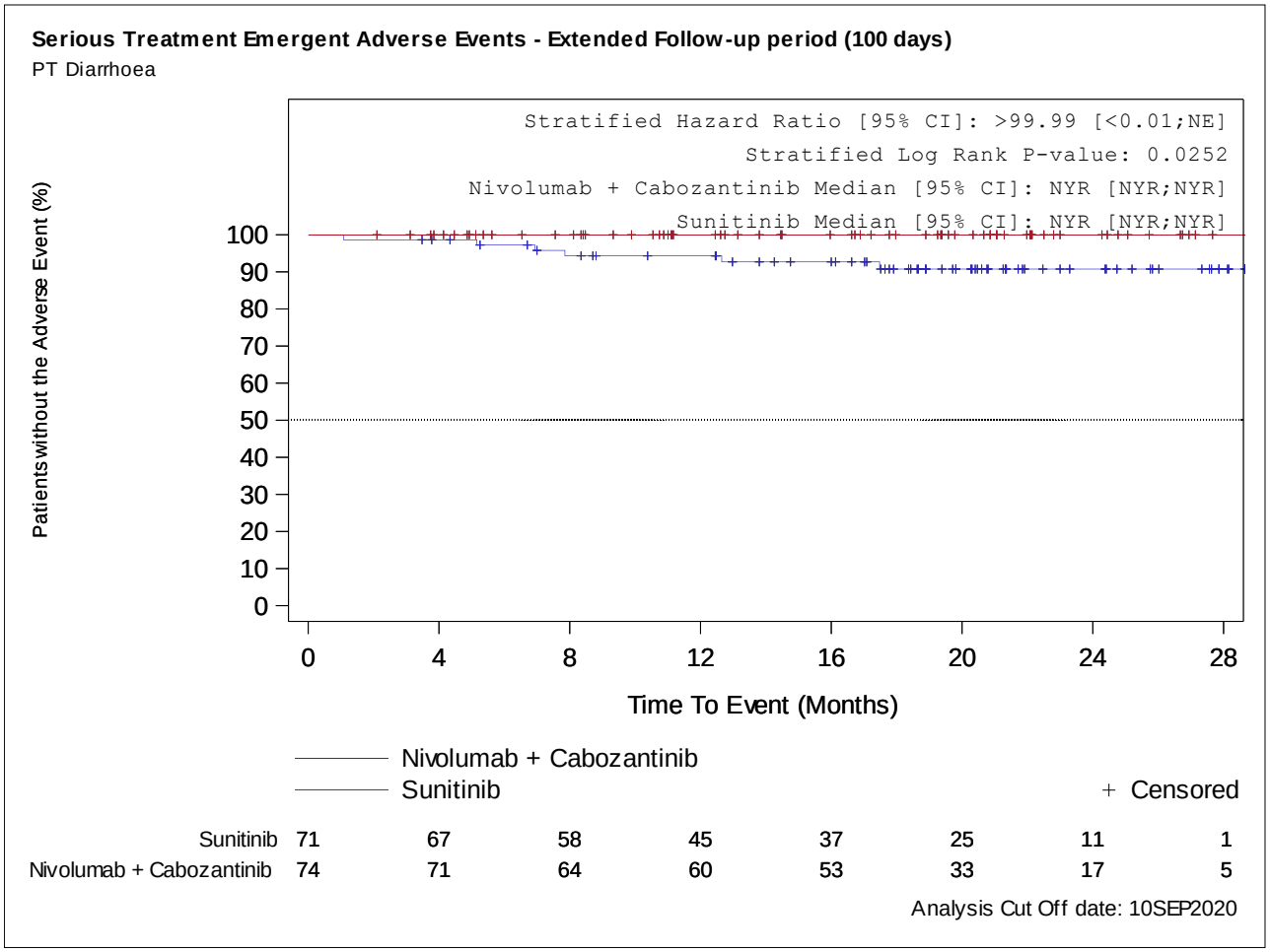


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FIGURE 4.6.2.7: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - SOC General disorders and administration site conditions - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

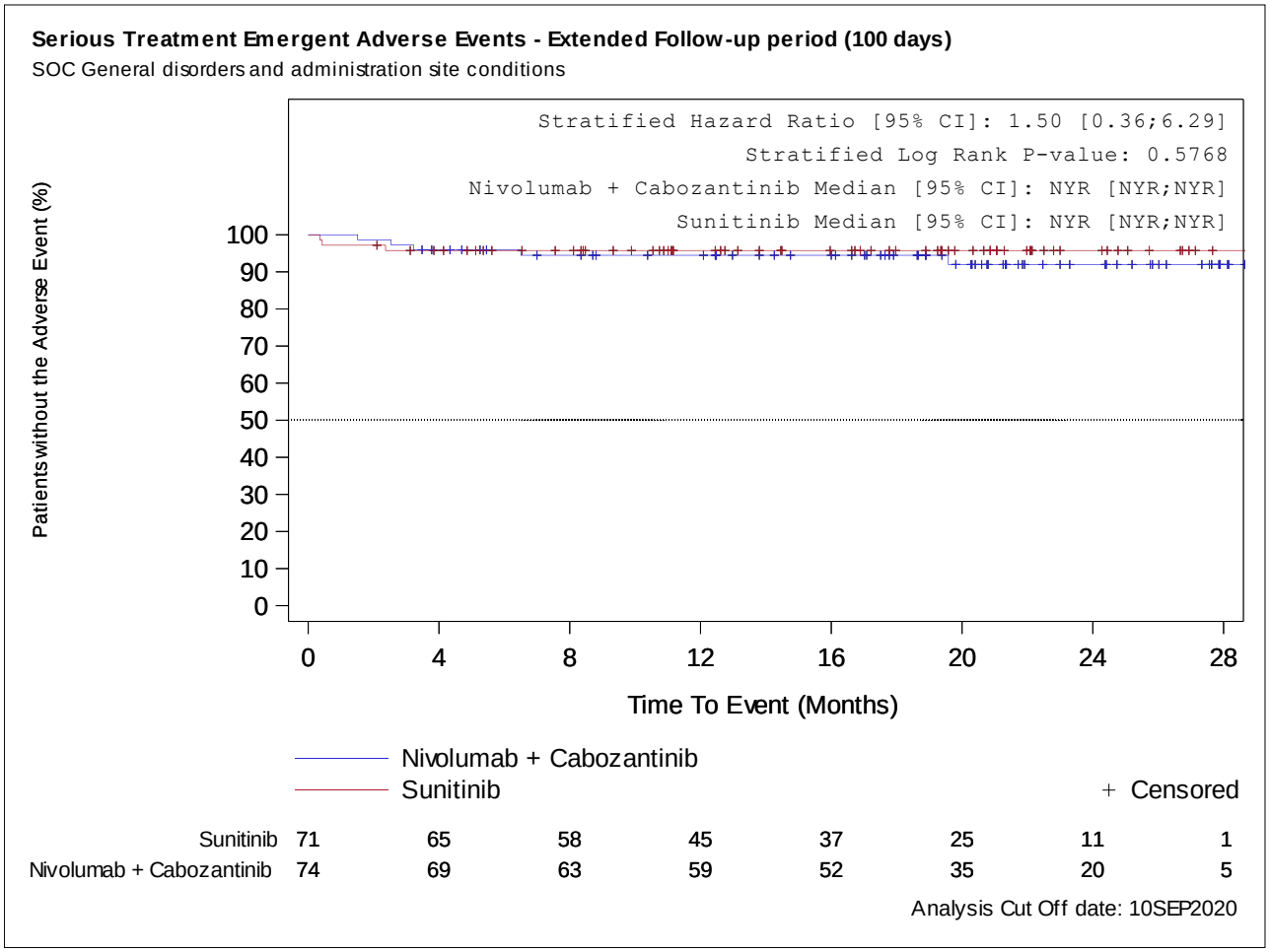


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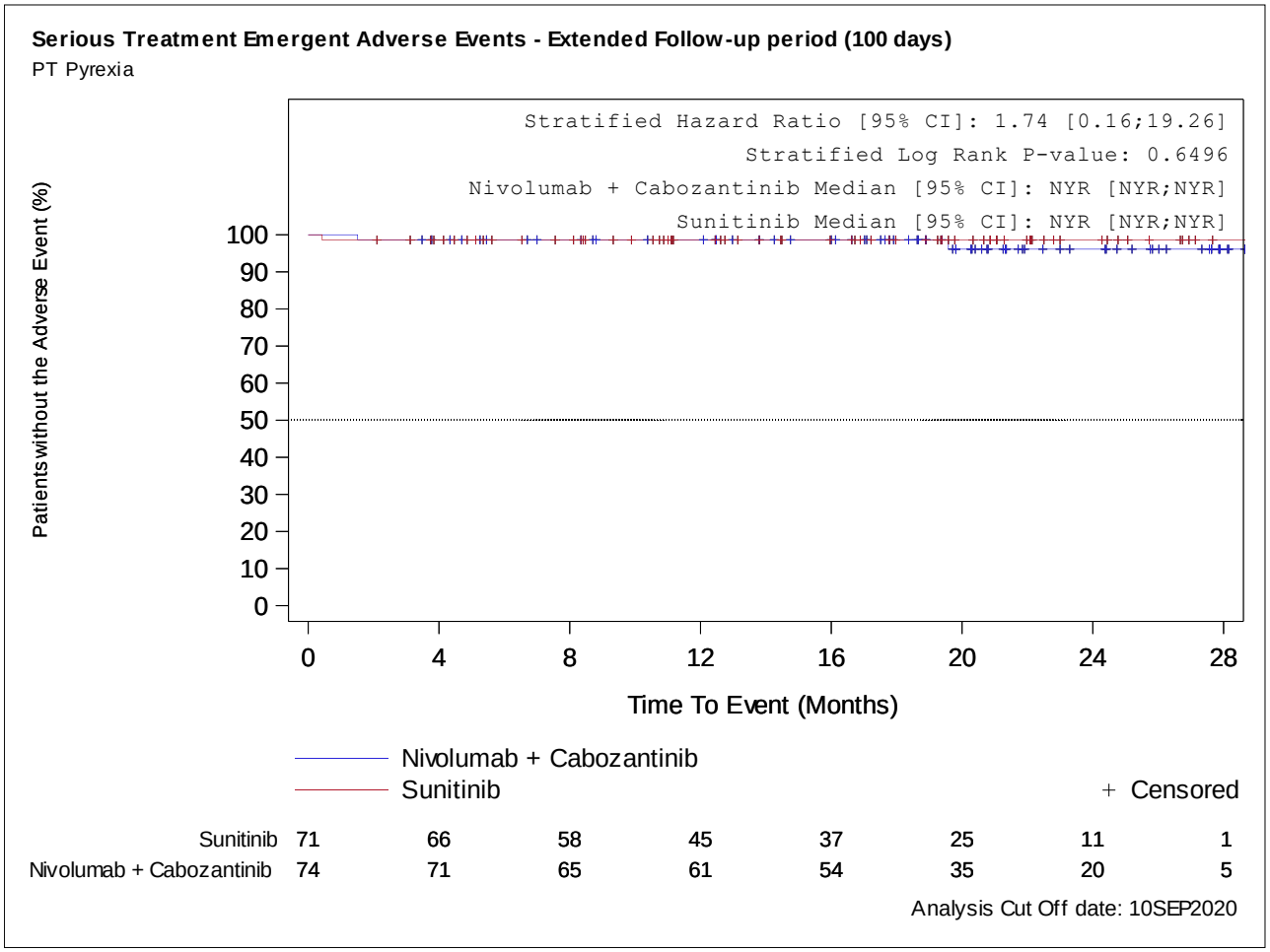
FIGURE 4.6.2.8: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - PT Pyrexia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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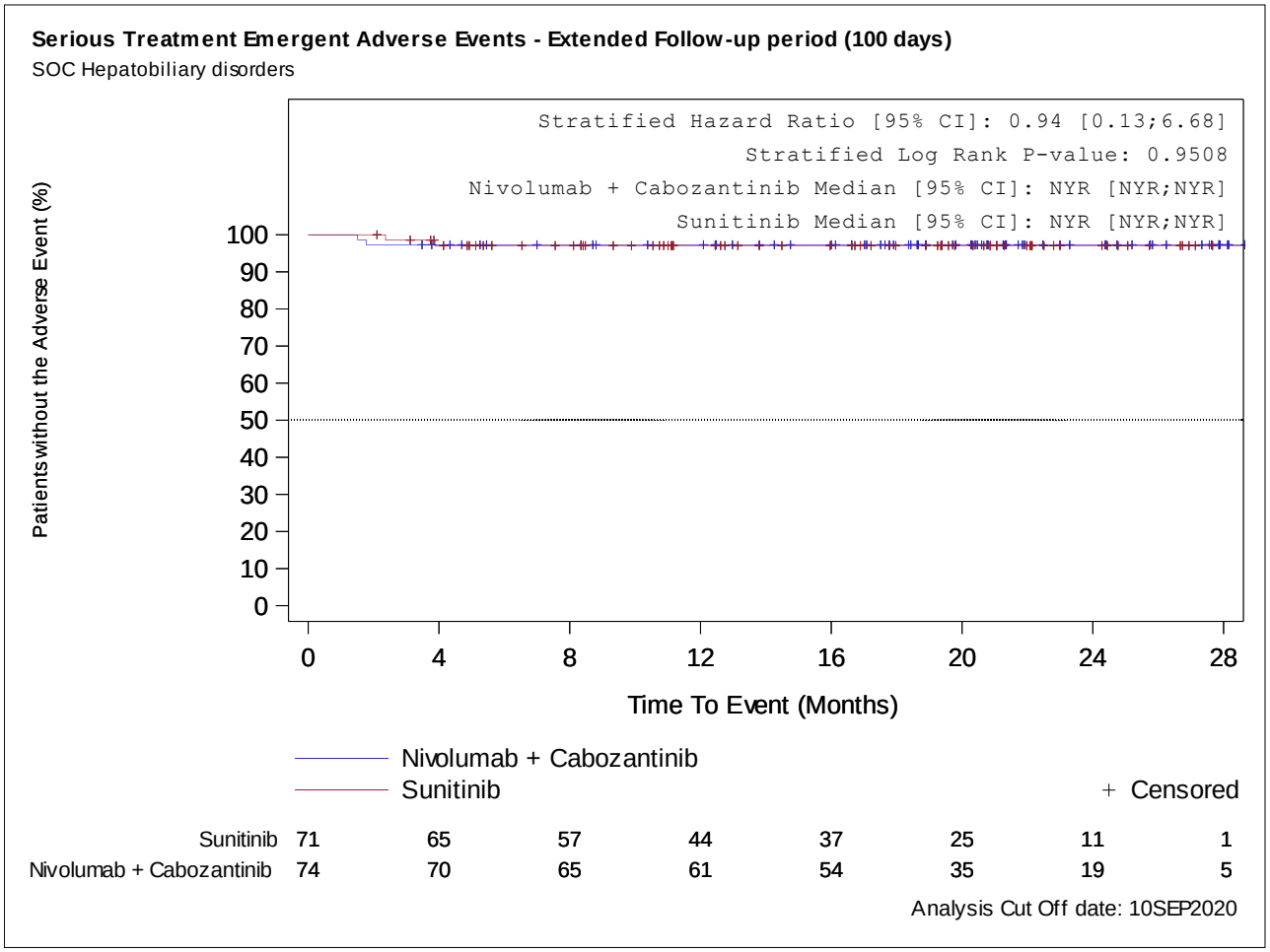
FIGURE 4.6.2.9: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - SOC Hepatobiliary disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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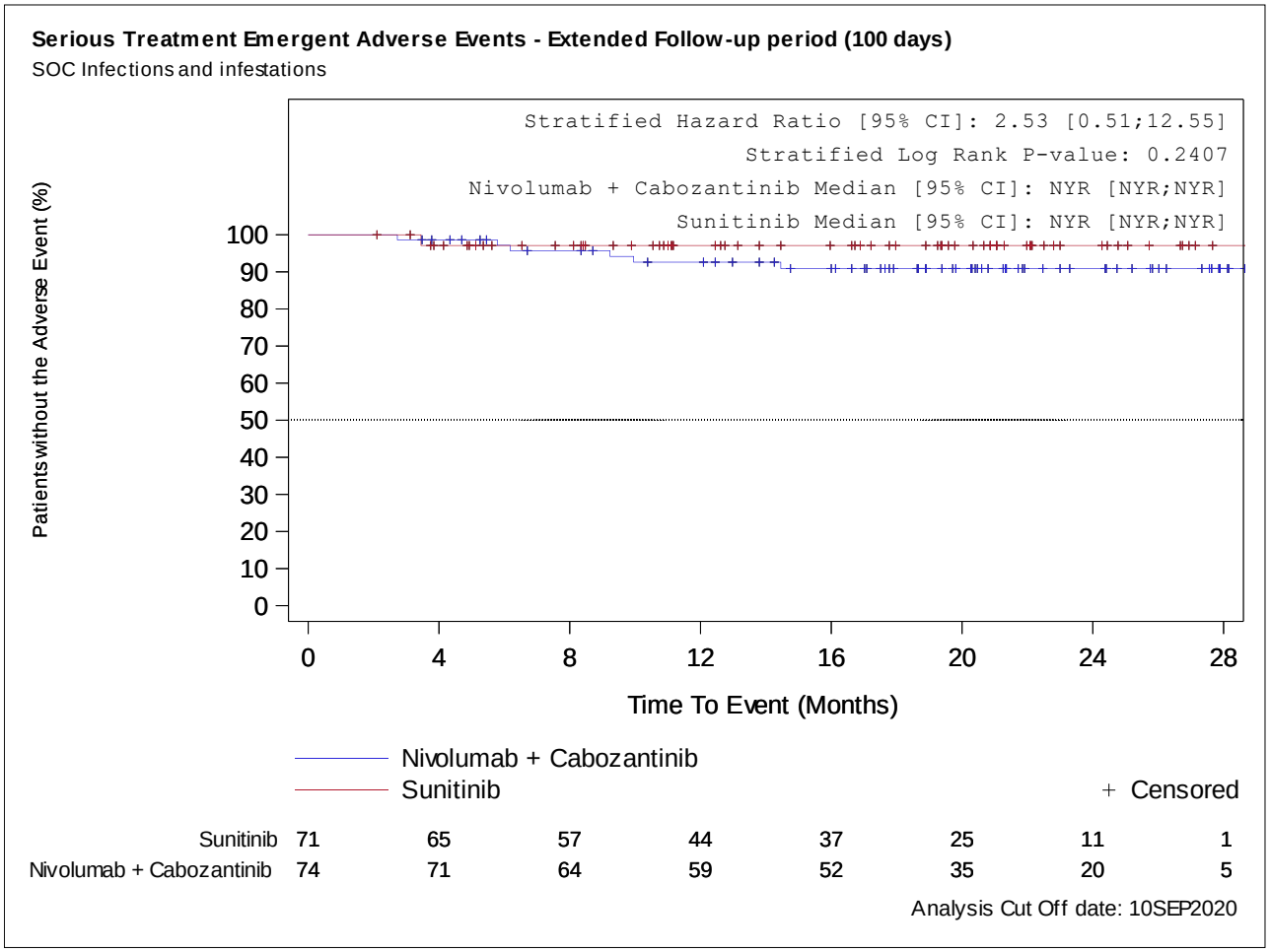
FIGURE 4.6.2.10: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - SOC Infections and infestations - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.6.2.11: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - PT Pneumonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

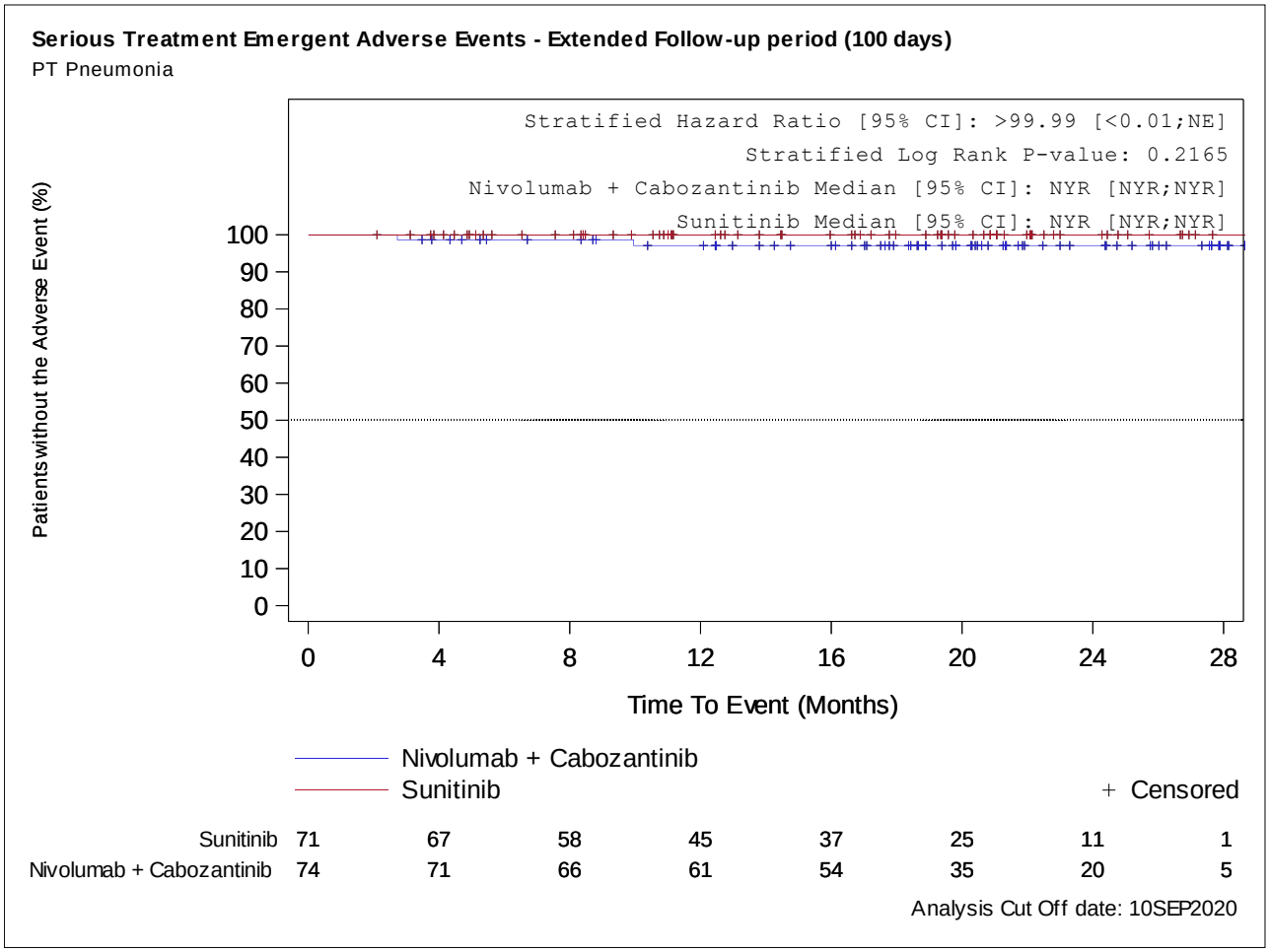


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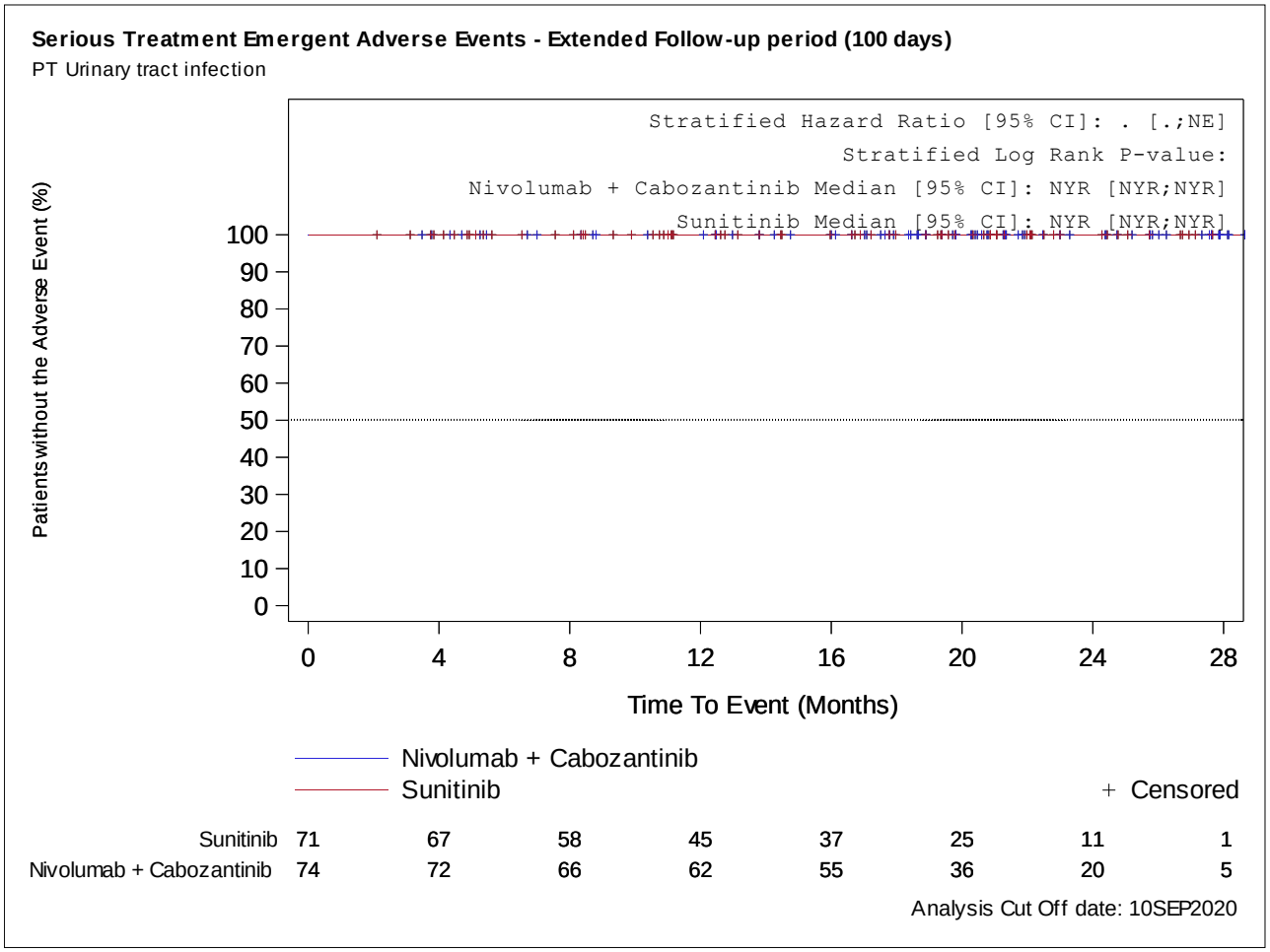
FIGURE 4.6.2.12: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - PT Urinary tract infection - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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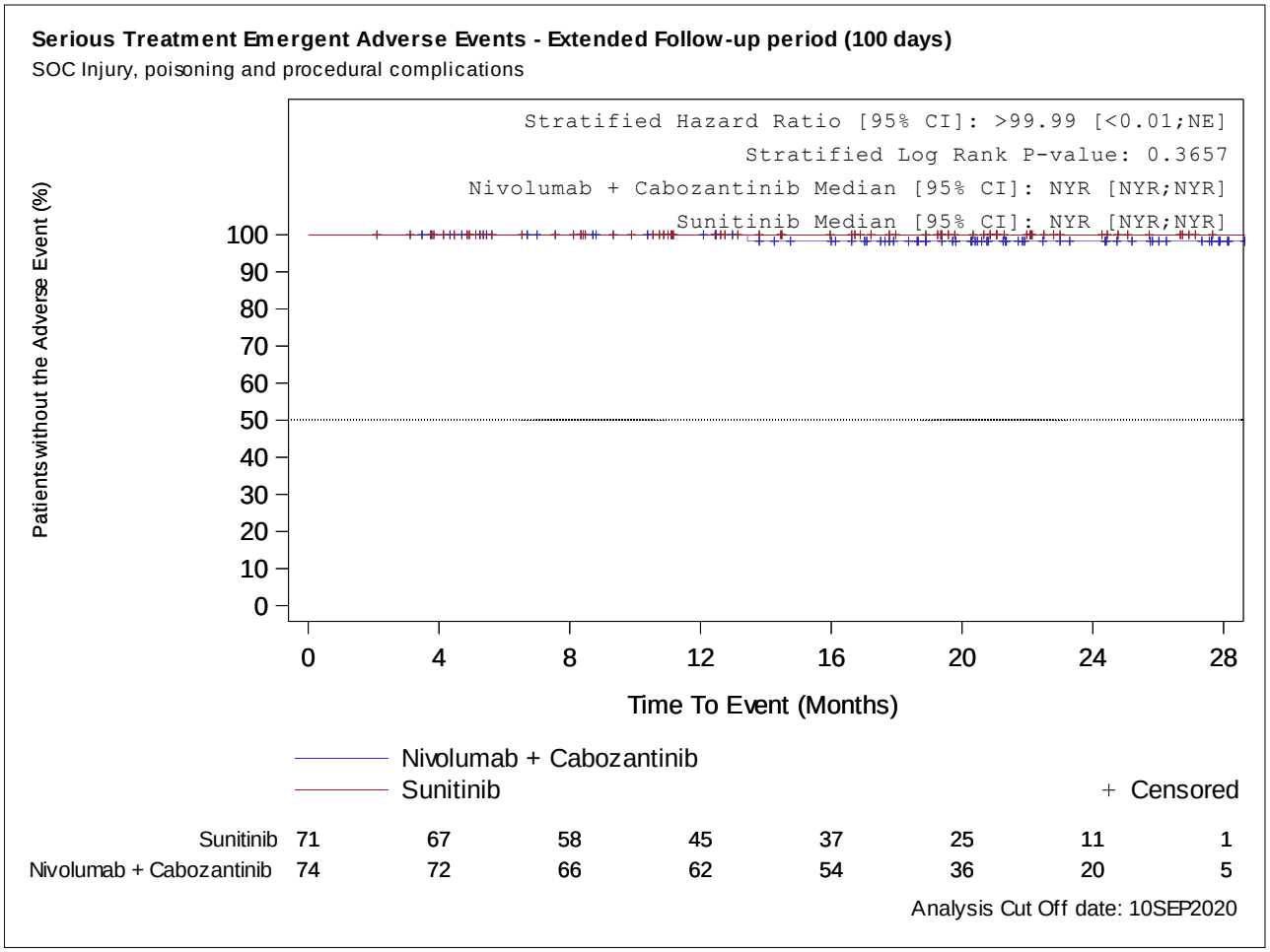
FIGURE 4.6.2.13: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - SOC Injury, poisoning and procedural complications - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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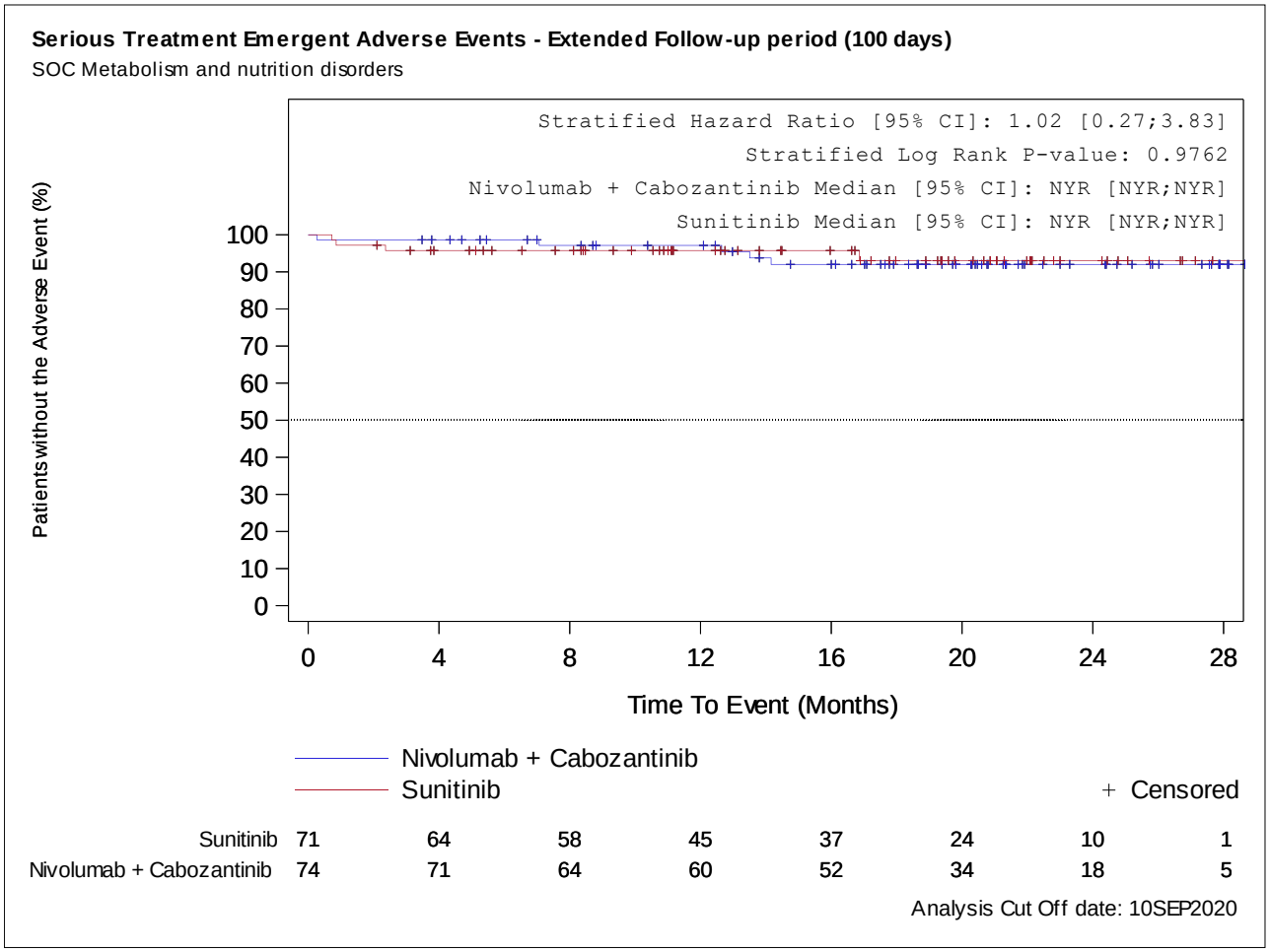
FIGURE 4.6.2.14: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.6.2.15: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - PT Hyponatraemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

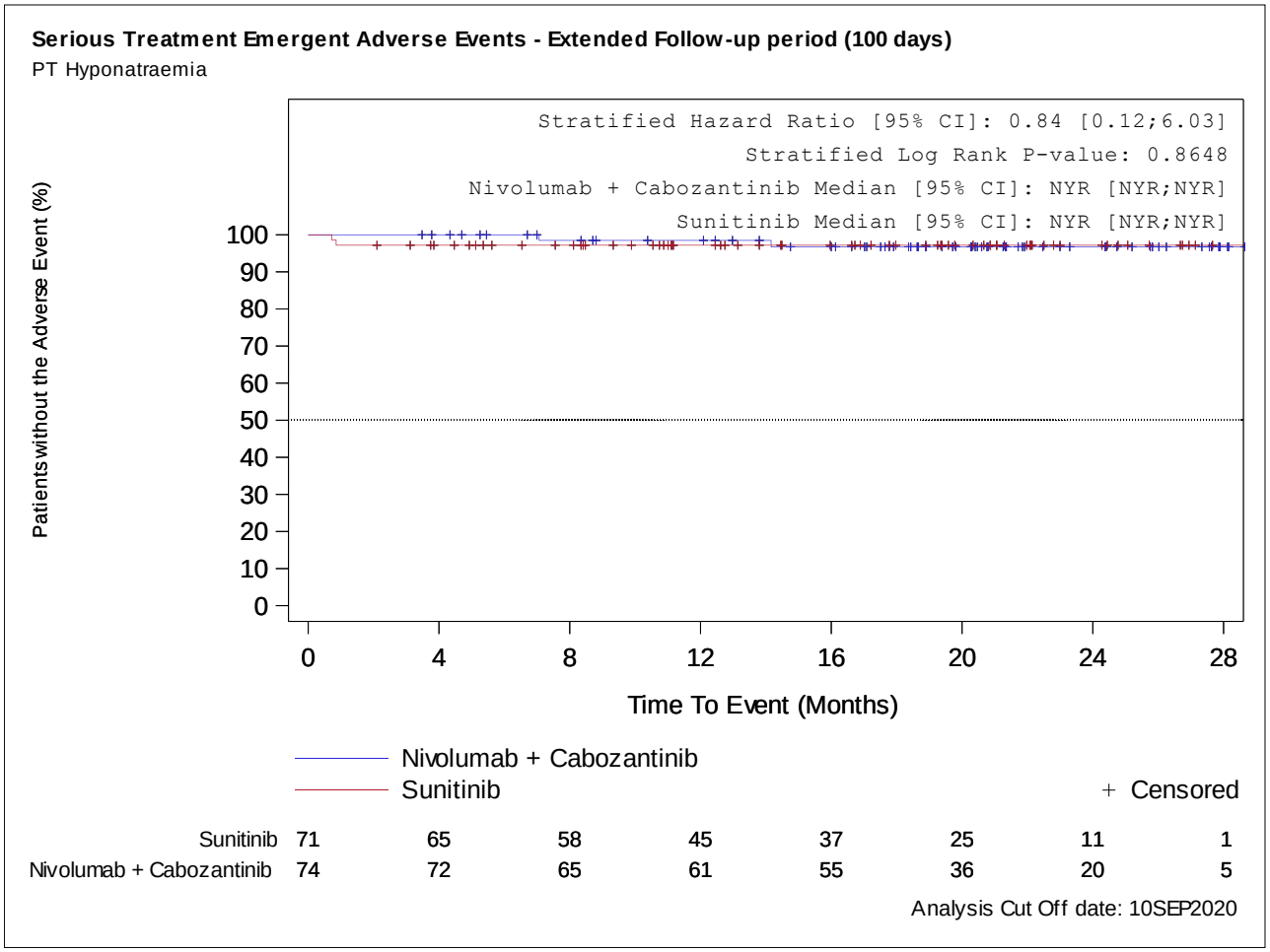


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FIGURE 4.6.2.16: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - SOC Musculoskeletal and connective tissue disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

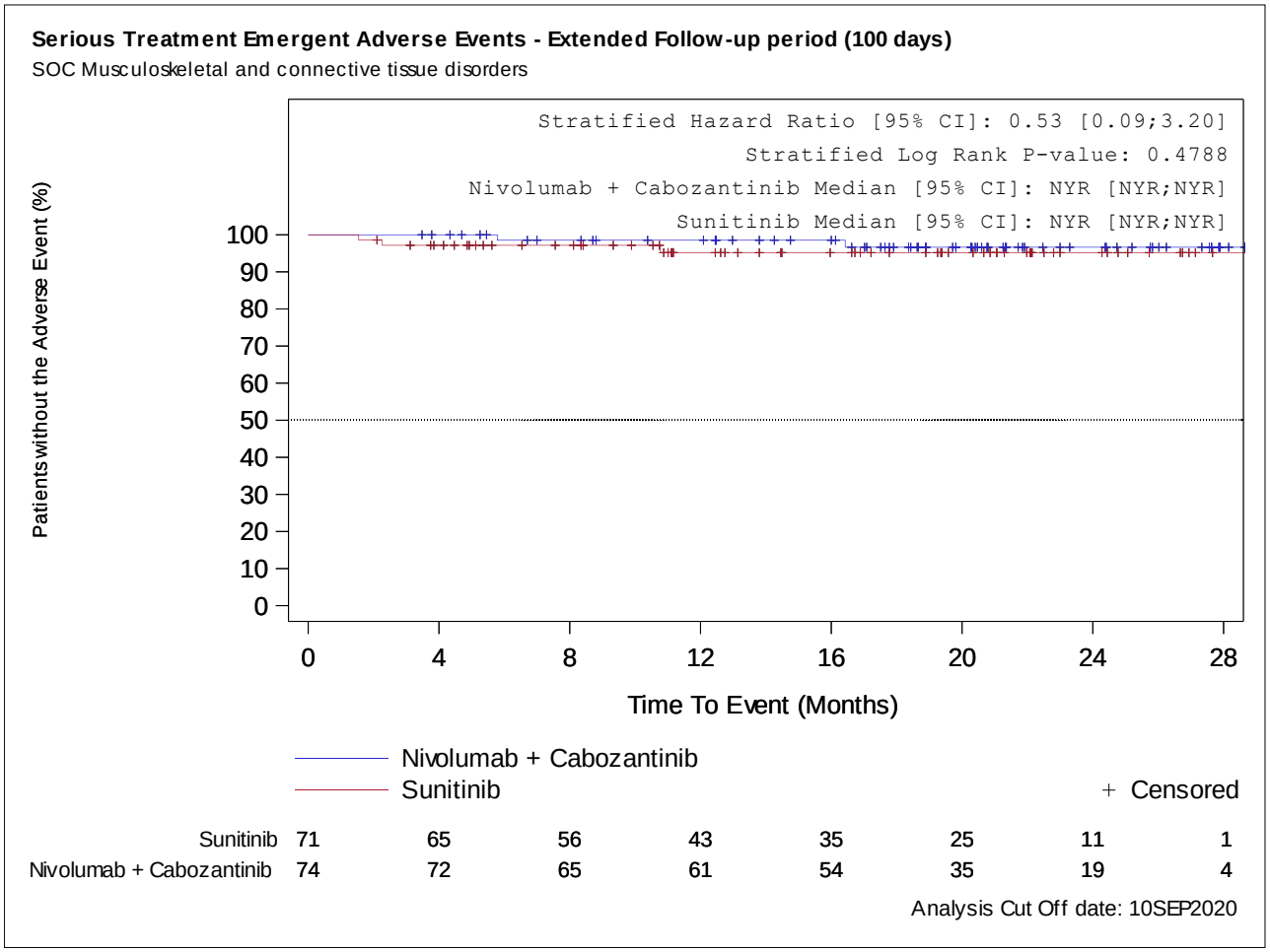


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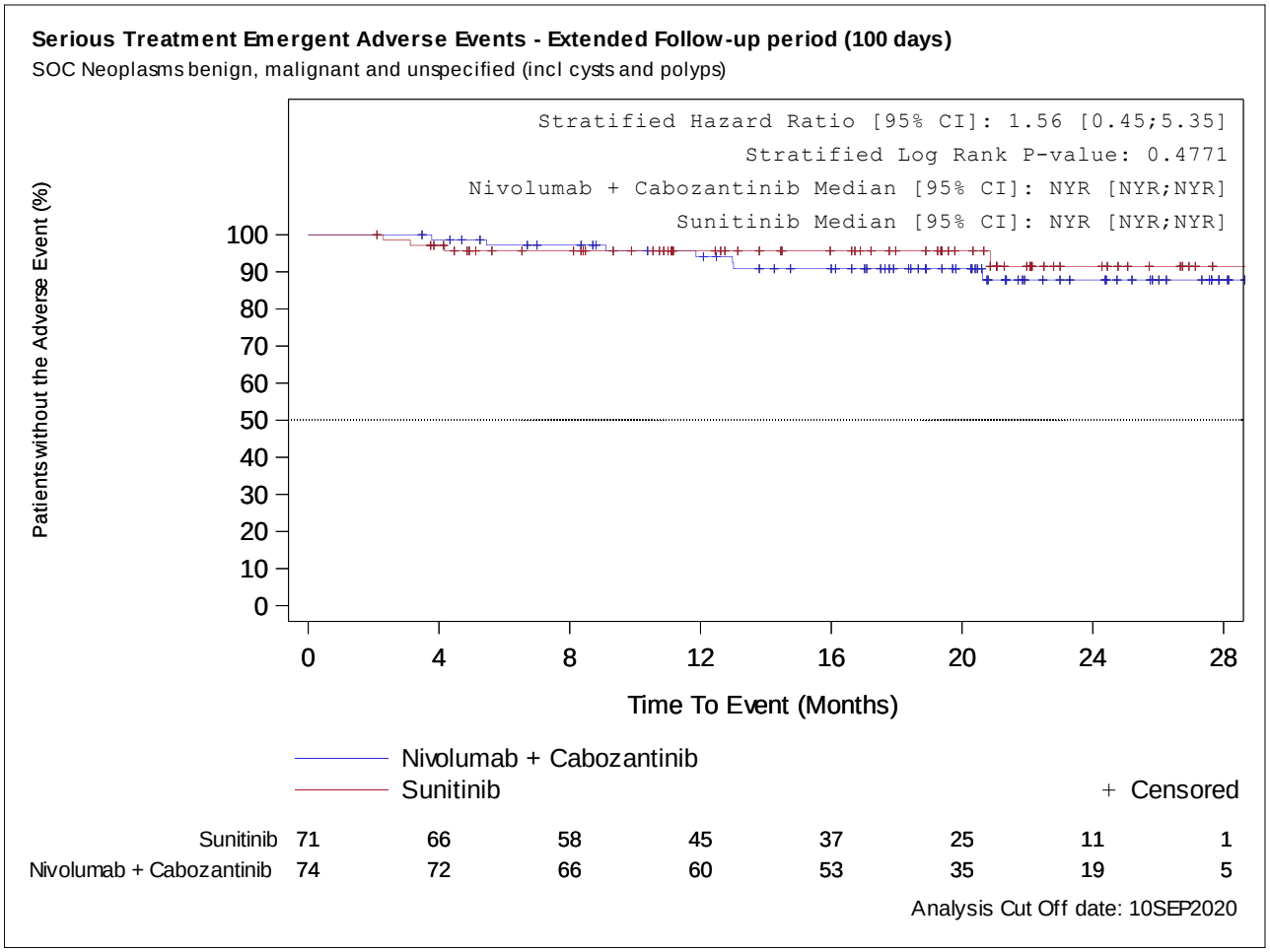
FIGURE 4.6.2.17: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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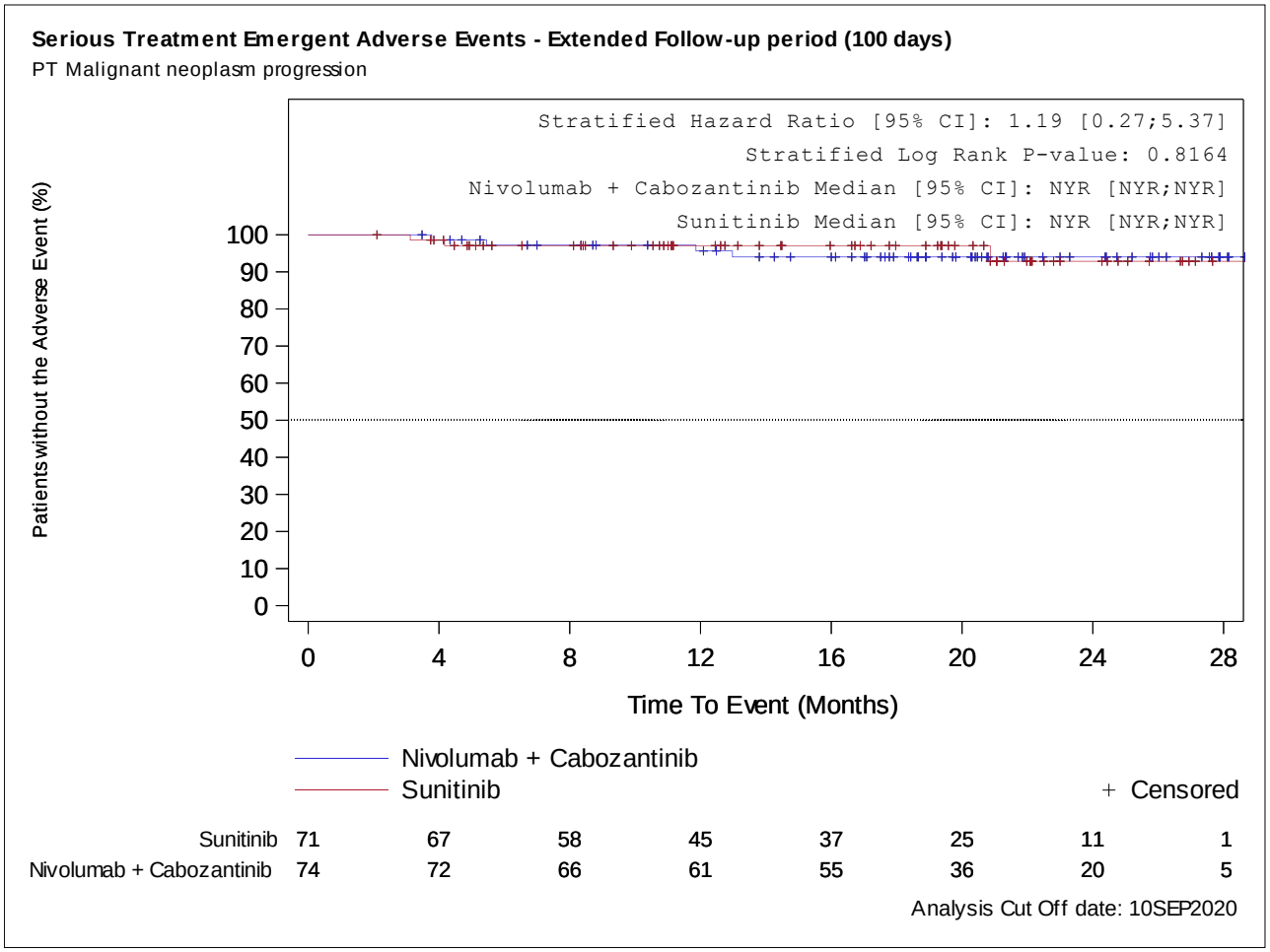
FIGURE 4.6.2.18: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - PT Malignant neoplasm progression - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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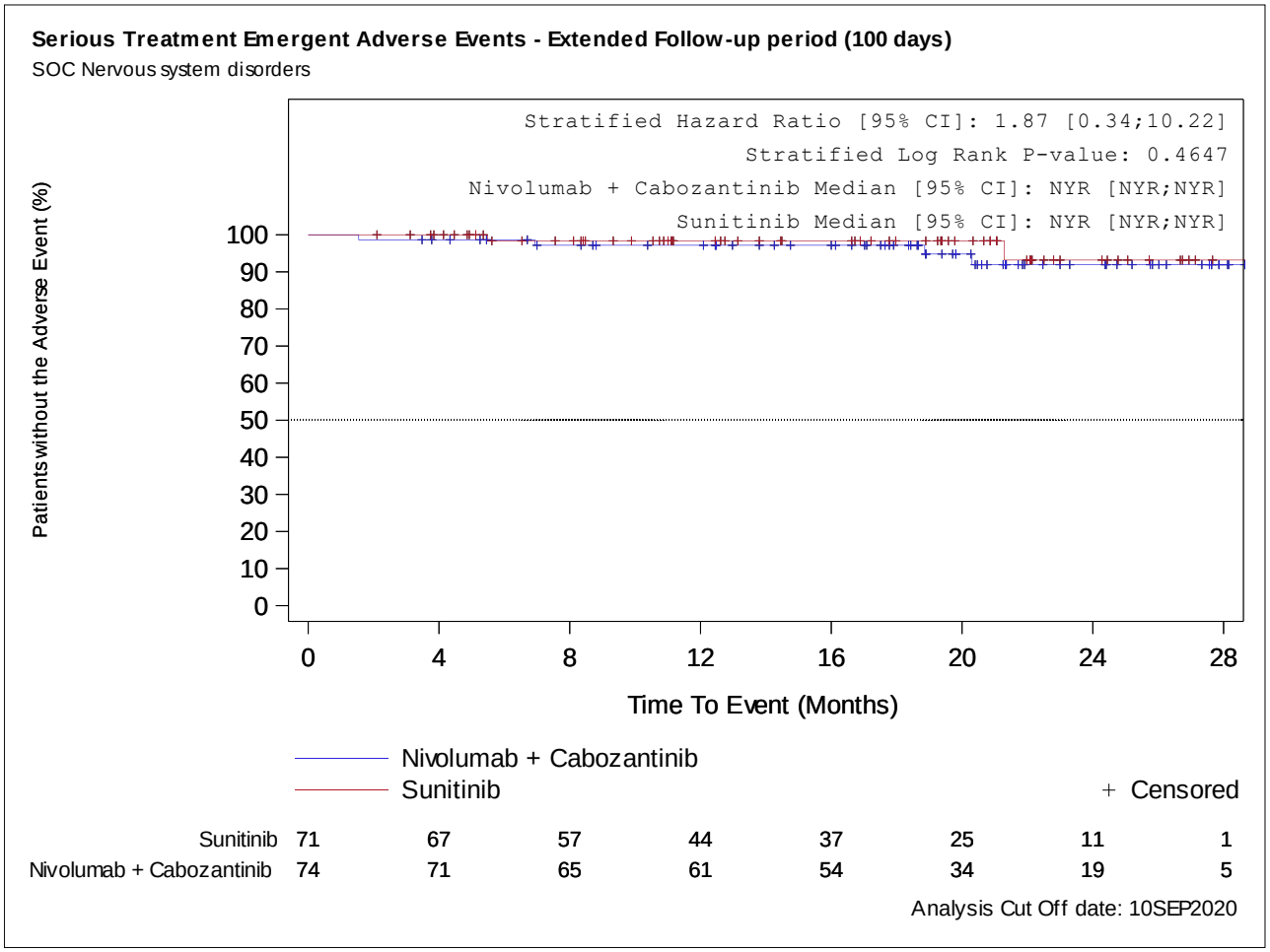
FIGURE 4.6.2.19: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - SOC Nervous system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.6.2.20: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - SOC Renal and urinary disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

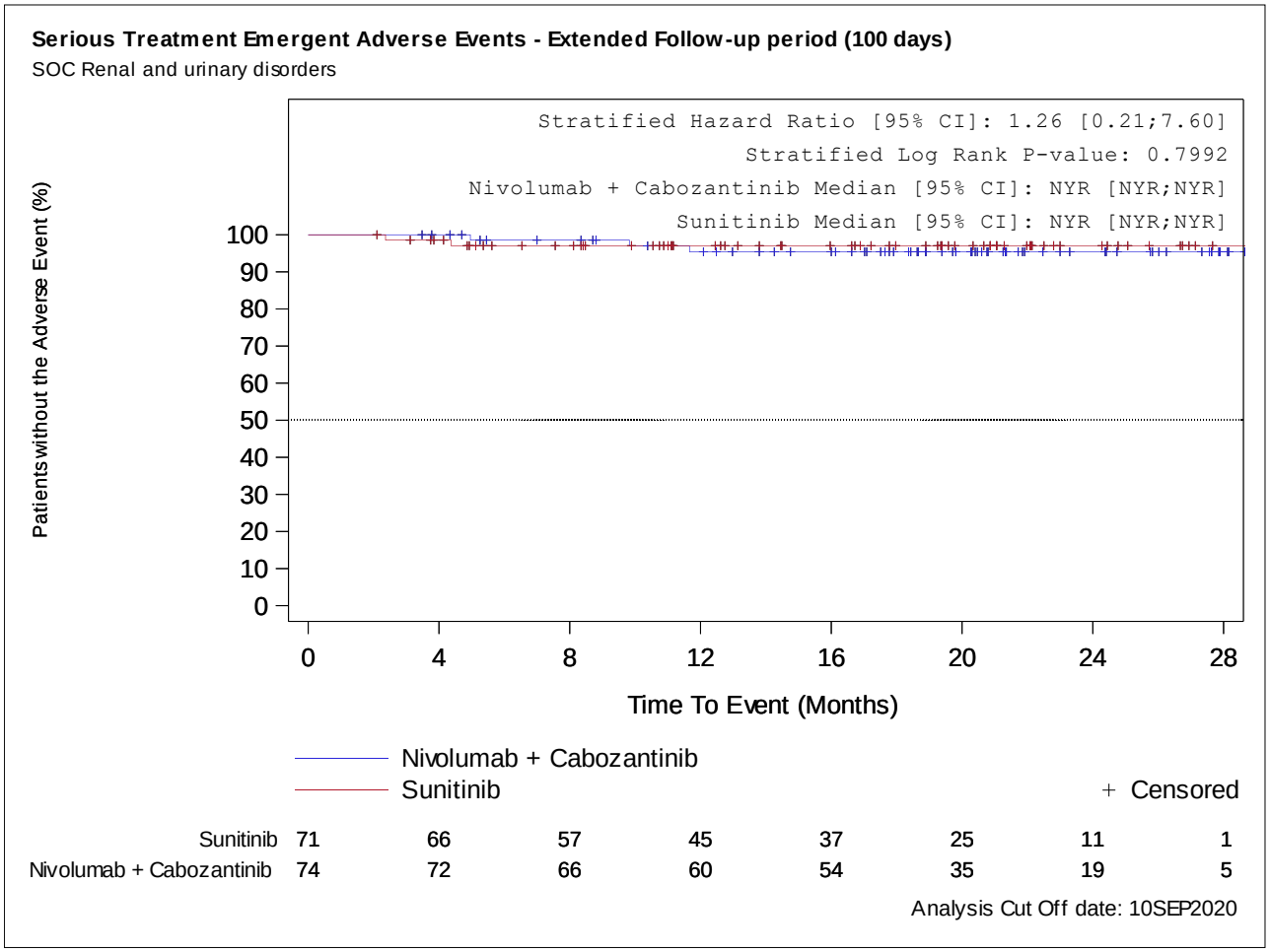


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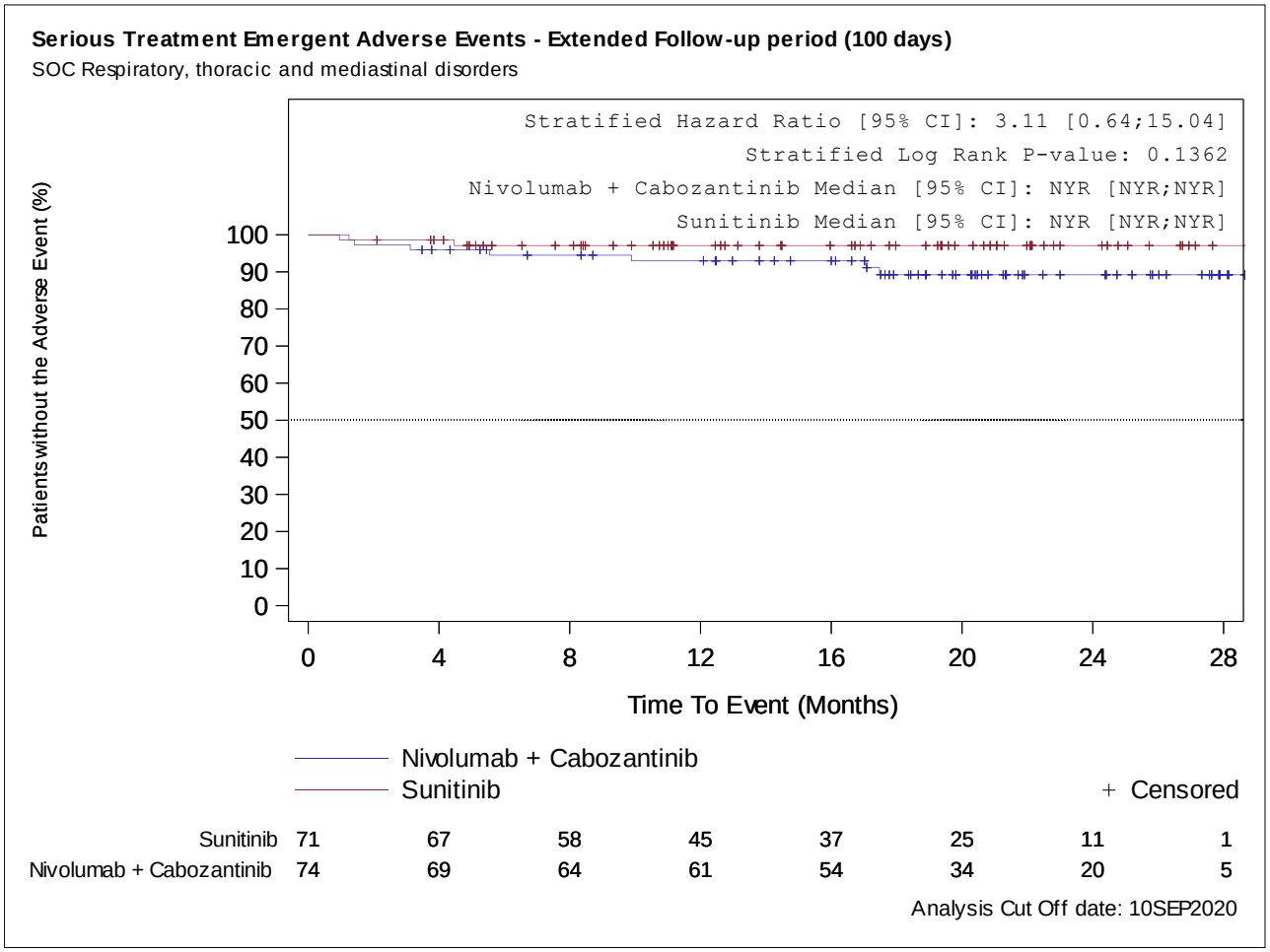
FIGURE 4.6.2.21: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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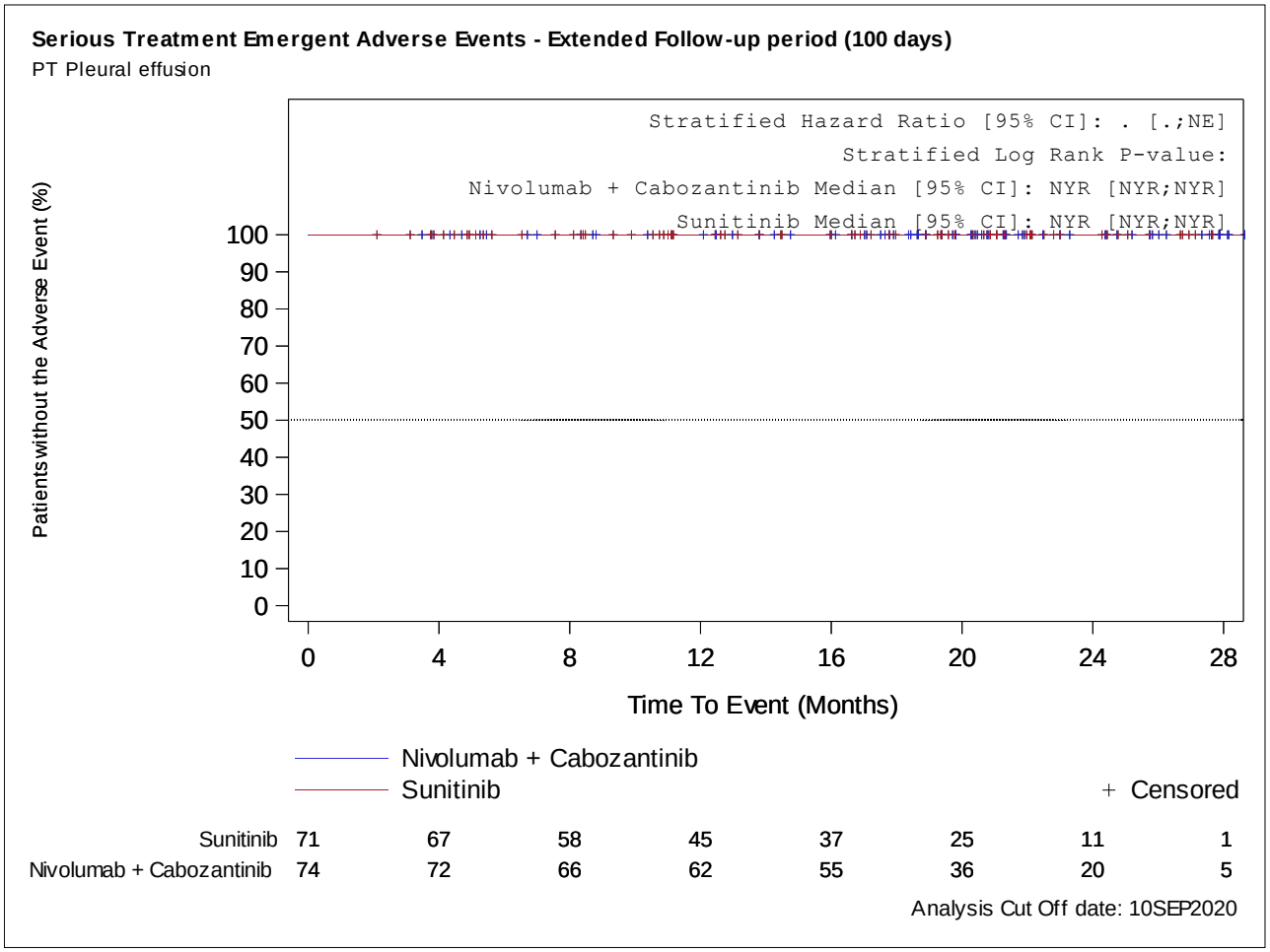
FIGURE 4.6.2.22: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - PT Pleural effusion - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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FIGURE 4.6.2.23: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - PT Pneumonitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

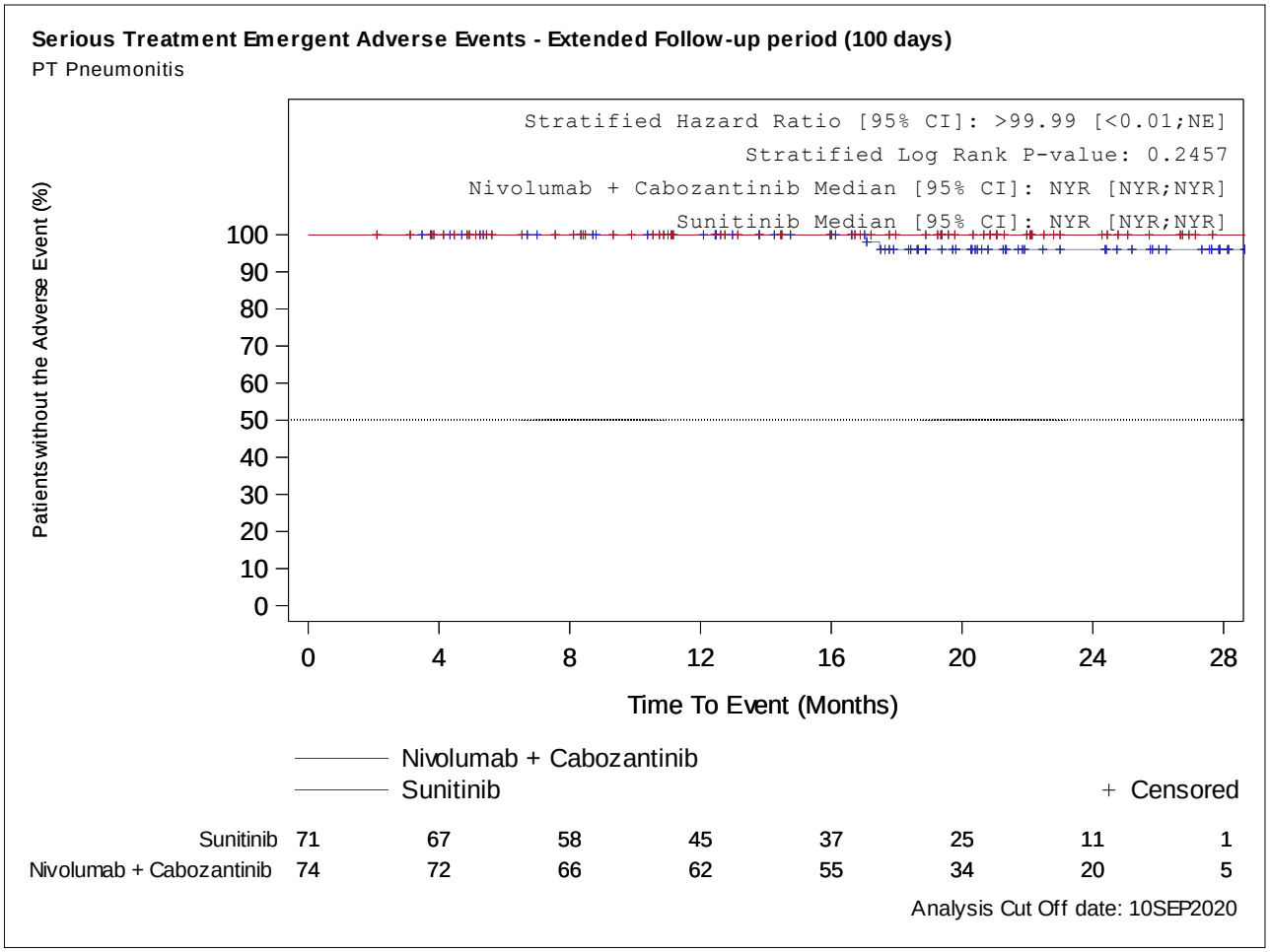


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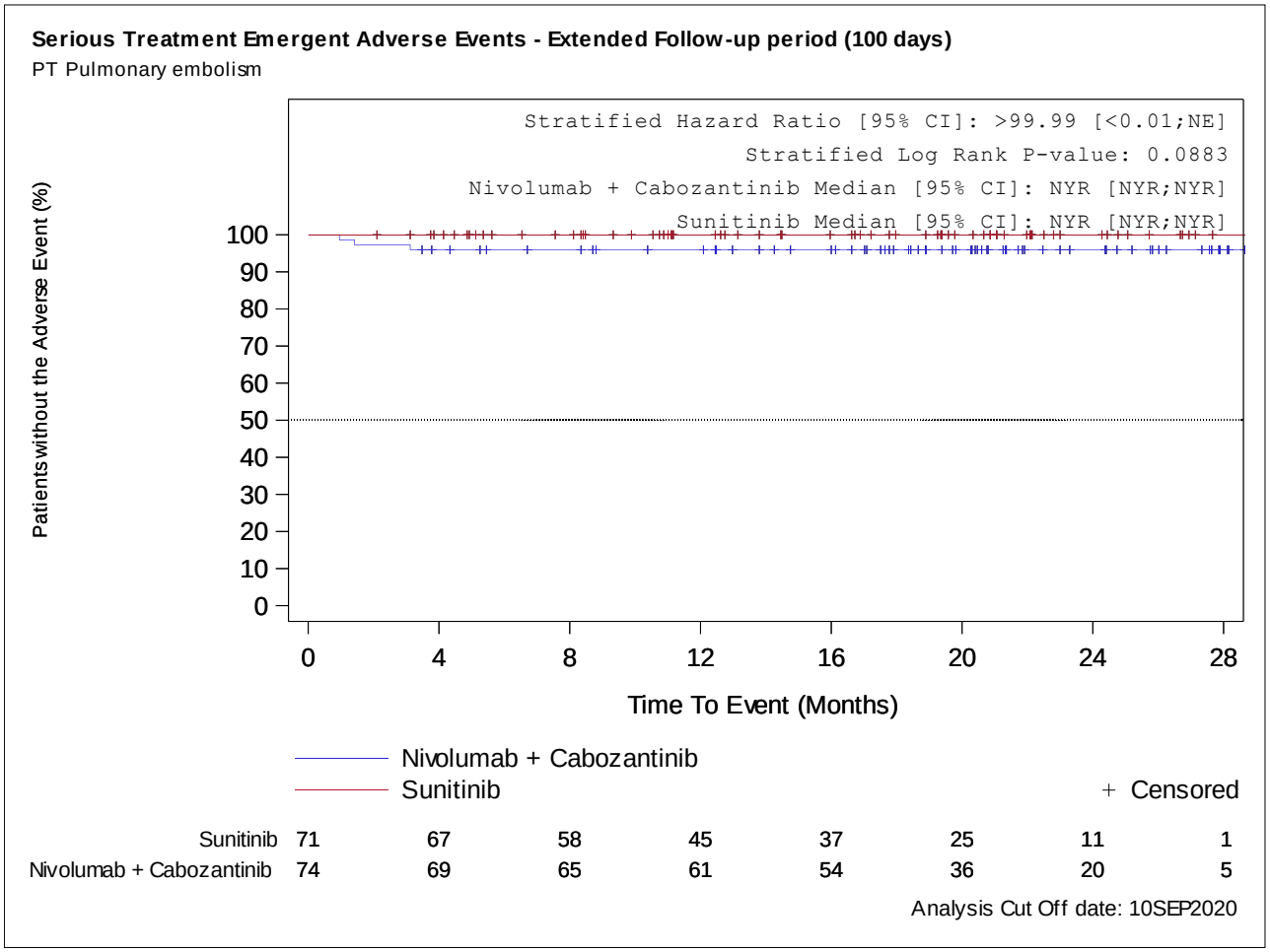
FIGURE 4.6.2.24: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - PT Pulmonary embolism - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

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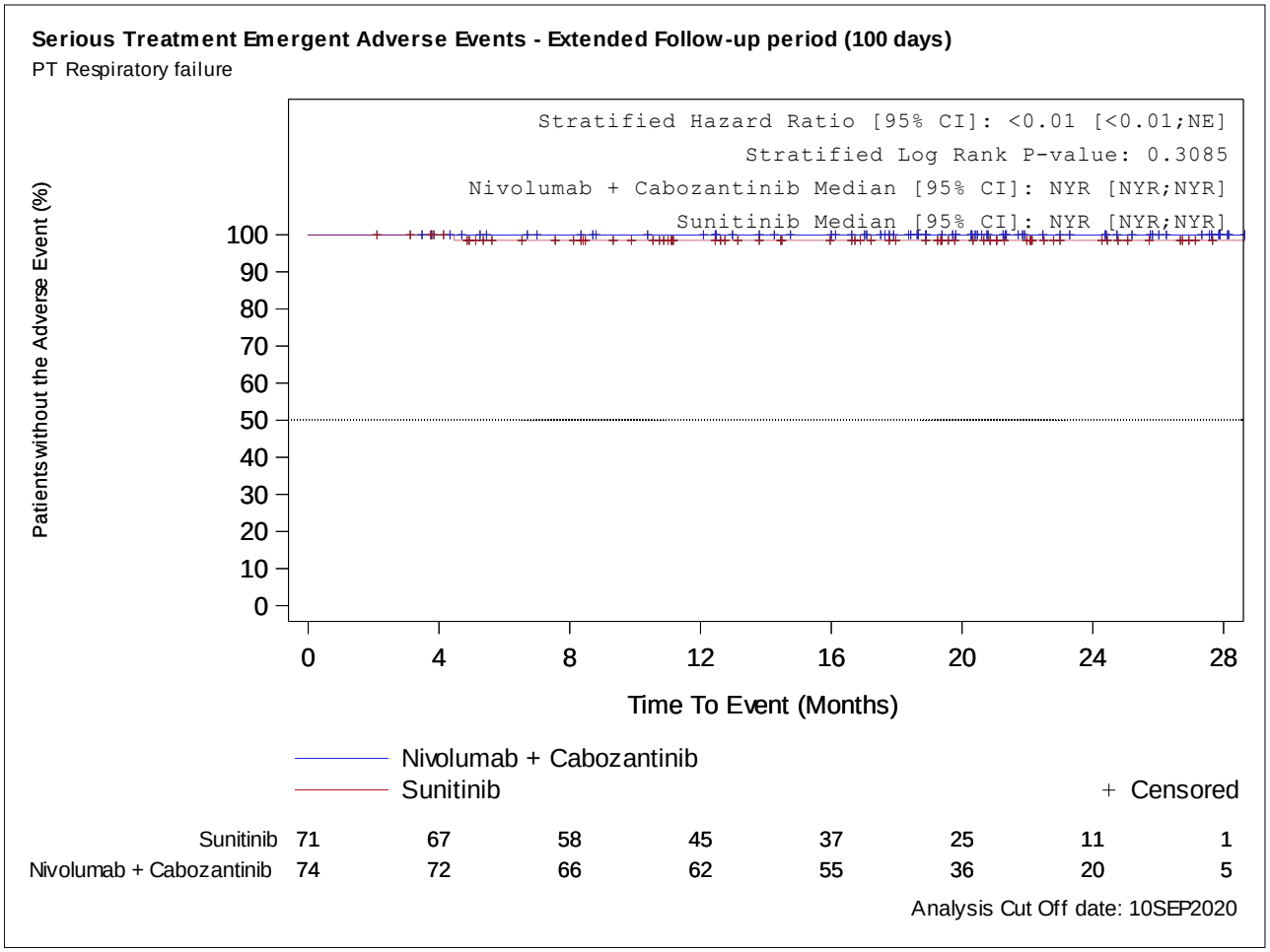
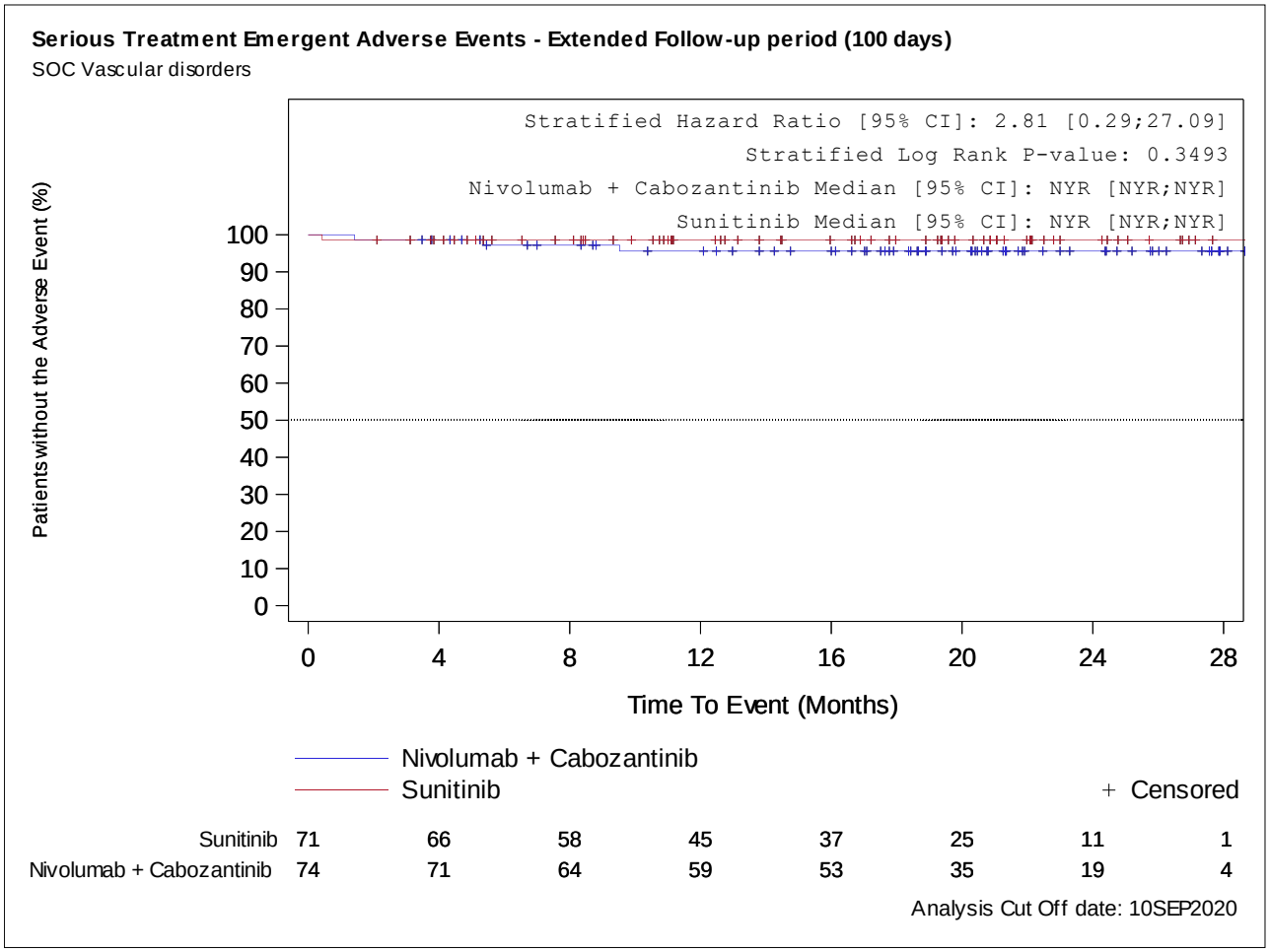
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:40:01

FIGURE 4.6.2.25: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - PT Respiratory failure - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:40:05

FIGURE 4.6.2.26: Kaplan-Meier curve - Serious Treatment Emergent Adverse Events - Extended Follow-up period (100 days) - SOC Vascular disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.04 KM safety by SOCPT.sas] run Tuesday, March 23, 2021 at 16:40:09

TABLE 5.1.1: Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 23 (31.1%) | 36 (50.7%) |
| Number of censored cases | N | 51 (68.9%) | 35 (49.3%) |
| Time to first event (Months) | Mean (SE) | 12.25 (0.67) | 11.71 (1.16) |
| | Q1 [95% CI] | 9.60 [1.87;NYR] | 1.40 [0.72;3.71] |
| | Median [95% CI] | NYR [NYR;NYR] | 11.04 [5.52;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [21.39;NYR] |
| | p-value (a) | 0.0046 | |
| Stratified Cox PH model | HR (b) | 0.47 [0.28;0.80] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:05:24

TABLE 5.1.2: Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 23 (31.1%) | NYR [NYR;NYR] | 71 | 36 (50.7%) | 11.04 [5.52;NYR] | 0.47 [0.28;0.80] | 0.0046 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 10 (24.4%) | NYR [NYR;NYR] | 47 | 22 (46.8%) | 21.39 [6.21;NYR] | 0.41 [0.19;0.87] | 0.0161 | 0.9029 |
| >= 65 | 33 | 13 (39.4%) | NYR [10.15;NYR] | 24 | 14 (58.3%) | 5.52 [1.38;NYR] | 0.40 [0.18;0.86] | 0.0162 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 10 (24.4%) | NYR [NYR;NYR] | 47 | 22 (46.8%) | 21.39 [6.21;NYR] | 0.41 [0.19;0.87] | 0.0161 | 0.6018 |
| >= 65 AND < 75 | 25 | 10 (40.0%) | NYR [6.44;NYR] | 18 | 12 (66.7%) | 3.75 [1.38;7.72] | 0.28 [0.11;0.68] | 0.0029 | |
| >= 75 | 8 | 3 (37.5%) | NYR [0.49;NYR] | 6 | 2 (33.3%) | NYR [0.69;NYR] | 1.01 [0.17;6.11] | 0.9890 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 12 (30.8%) | NYR [NYR;NYR] | 37 | 17 (45.9%) | 12.65 [2.43;NYR] | 0.56 [0.27;1.18] | 0.1234 | 0.6750 |
| Rest of World (ROW) | 35 | 11 (31.4%) | NYR [15.11;NYR] | 34 | 19 (55.9%) | 11.04 [2.17;NYR] | 0.39 [0.19;0.82] | 0.0107 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:05:24

TABLE 5.1.2: Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 21 (32.3%) | NYR [NYR;NYR] | 60 | 32 (53.3%) | 8.31 [3.71;NYR] | 0.44 [0.25;0.77] | 0.0032 | 0.9787 |
| Non-White | 9 | 2 (22.2%) | NYR [1.38;NYR] | 11 | 4 (36.4%) | NYR [0.72;NYR] | 0.48 [0.09;2.64] | 0.3891 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 3 (42.9%) | NYR [0.95;NYR] | 13 | 10 (76.9%) | 2.17 [0.72;8.31] | 0.31 [0.08;1.17] | 0.0683 | 0.7303 |
| Not Hispanic or Latino | 43 | 11 (25.6%) | NYR [NYR;NYR] | 32 | 13 (40.6%) | NYR [2.43;NYR] | 0.53 [0.23;1.18] | 0.1122 | |
| Not Reported | 24 | 9 (37.5%) | NYR [10.84;NYR] | 26 | 13 (50.0%) | 11.83 [3.75;NYR] | 0.55 [0.23;1.29] | 0.1651 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 18 (32.1%) | NYR [NYR;NYR] | 48 | 23 (47.9%) | 12.65 [6.21;NYR] | 0.53 [0.29;0.99] | 0.0443 | 0.3695 |
| Female | 18 | 5 (27.8%) | NYR [10.48;NYR] | 23 | 13 (56.5%) | 10.18 [1.22;NYR] | 0.31 [0.11;0.88] | 0.0212 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 3 (21.4%) | NYR [15.11;NYR] | 19 | 12 (63.2%) | 3.71 [0.79;NYR] | 0.21 [0.06;0.76] | 0.0099 | 0.1378 |
| >= 1 Year | 60 | 20 (33.3%) | NYR [15.64;NYR] | 50 | 24 (48.0%) | 11.83 [6.21;NYR] | 0.55 [0.30;0.99] | 0.0444 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:05:24

TABLE 5.1.2: Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NYR [4.76;NYR] | 12 | 7 (58.3%) | 7.26 [0.72;NYR] | 0.17 [0.03;0.85] | 0.0163 | 0.2013 |
| Yes | 63 | 21 (33.3%) | NYR [15.64;NYR] | 59 | 29 (49.2%) | 11.83 [3.75;NYR] | 0.53 [0.30;0.94] | 0.0270 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 20 (31.3%) | NYR [NYR;NYR] | 65 | 34 (52.3%) | 11.04 [3.71;NYR] | 0.43 [0.25;0.75] | 0.0024 | 0.4716 |
| Yes | 10 | 3 (30.0%) | NYR [0.03;NYR] | 6 | 2 (33.3%) | NYR [1.41;NYR] | 0.79 [0.13;4.76] | 0.7924 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 4 (36.4%) | NYR [0.95;NYR] | 10 | 6 (60.0%) | 11.04 [0.72;NYR] | 0.42 [0.12;1.54] | 0.1799 | 0.9965 |
| < 1% | 61 | 18 (29.5%) | NYR [NYR;NYR] | 60 | 30 (50.0%) | 11.83 [3.71;NYR] | 0.44 [0.25;0.80] | 0.0053 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 5 (27.8%) | NYR [4.07;NYR] | 20 | 11 (55.0%) | 11.04 [1.35;NYR] | 0.37 [0.13;1.07] | 0.0575 | 0.7285 |
| Non-Stage IV | 53 | 17 (32.1%) | NYR [NYR;NYR] | 51 | 25 (49.0%) | 11.83 [3.48;NYR] | 0.48 [0.26;0.90] | 0.0194 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
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Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:05:24

TABLE 5.2.1: Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - PT Anaemia | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 10 (13.5%) | 18 (25.4%) |
| Number of censored cases | N | 64 (86.5%) | 53 (74.6%) |
| Time to first event (Months) | Mean (SE) | 20.03 (0.72) | 13.54 (0.69) |
| | Q1 [95% CI] | NYR [22.11;NYR] | 11.00 [4.80;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0110 | |
| Stratified Cox PH model | HR (b) | 0.36 [0.16;0.82] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:12:13

TABLE 5.2.2: Treatment Emergent Adverse Event (TEAE) - PT Anaemia - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 18 (25.4%) | NYR [NYR;NYR] | 0.36 [0.16;0.82] | 0.0110 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 10 (21.3%) | NYR [NYR;NYR] | 0.48 [0.16;1.41] | 0.1706 | 0.7636 |
| >= 65 | 33 | 5 (15.2%) | NYR [NYR;NYR] | 24 | 8 (33.3%) | NYR [10.18;NYR] | 0.36 [0.12;1.11] | 0.0643 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 10 (21.3%) | NYR [NYR;NYR] | 0.48 [0.16;1.41] | 0.1706 | 0.9421 |
| >= 65 AND < 75 | 25 | 4 (16.0%) | NYR [NYR;NYR] | 18 | 6 (33.3%) | NYR [5.52;NYR] | 0.38 [0.11;1.37] | 0.1255 | |
| >= 75 | 8 | 1 (12.5%) | NYR [3.29;NYR] | 6 | 2 (33.3%) | NYR [1.22;NYR] | 0.40 [0.04;4.49] | 0.4459 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NYR [NYR;NYR] | 37 | 10 (27.0%) | NYR [16.53;NYR] | 0.40 [0.13;1.16] | 0.0815 | 0.6812 |
| Rest of World (ROW) | 35 | 5 (14.3%) | NYR [22.11;NYR] | 34 | 8 (23.5%) | NYR [NYR;NYR] | 0.48 [0.16;1.47] | 0.1886 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:12:13

TABLE 5.2.2: Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 9 (13.8%) | NYR [NYR;NYR] | 60 | 16 (26.7%) | NYR [16.56;NYR] | 0.42 [0.19;0.96] | 0.0349 | 0.9440 |
| Non-White | 9 | 1 (11.1%) | NYR [22.11;NYR] | 11 | 2 (18.2%) | NYR [1.41;NYR] | 0.48 [0.04;5.38] | 0.5418 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NC | 13 | 4 (30.8%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 4 (9.3%) | NC | 32 | 7 (21.9%) | NC | NC | NC | |
| Not Reported | 24 | 5 (20.8%) | NC | 26 | 7 (26.9%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 7 (12.5%) | NC | 48 | 9 (18.8%) | NC | NC | NC | NC |
| Female | 18 | 3 (16.7%) | NC | 23 | 9 (39.1%) | NC | NC | NC | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [15.11;NYR] | 19 | 6 (31.6%) | NYR [8.31;NYR] | 0.34 [0.07;1.70] | 0.1704 | 0.7928 |
| >= 1 Year | 60 | 8 (13.3%) | NYR [NYR;NYR] | 50 | 12 (24.0%) | NYR [NYR;NYR] | 0.46 [0.19;1.12] | 0.0795 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.2.2: Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NYR [4.76;NYR] | 12 | 4 (33.3%) | NYR [4.80;NYR] | 0.45 [0.08;2.47] | 0.3425 | 0.9121 |
| Yes | 63 | 8 (12.7%) | NYR [NYR;NYR] | 59 | 14 (23.7%) | NYR [NYR;NYR] | 0.44 [0.18;1.05] | 0.0566 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 8 (12.5%) | NYR [NYR;NYR] | 65 | 17 (26.2%) | NYR [NYR;NYR] | 0.37 [0.16;0.87] | 0.0175 | 0.3694 |
| Yes | 10 | 2 (20.0%) | NYR [0.03;NYR] | 6 | 1 (16.7%) | NYR [10.18;NYR] | 1.32 [0.12;14.56] | 0.8210 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 3 (27.3%) | NYR [15.11;NYR] | 10 | 5 (50.0%) | 11.04 [1.35;NYR] | 0.29 [0.07;1.26] | 0.0803 | 0.9634 |
| < 1% | 61 | 7 (11.5%) | NYR [NYR;NYR] | 60 | 13 (21.7%) | NYR [NYR;NYR] | 0.45 [0.18;1.14] | 0.0838 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 2 (11.1%) | NYR [NYR;NYR] | 20 | 7 (35.0%) | NYR [8.31;NYR] | 0.25 [0.05;1.23] | 0.0668 | 0.5102 |
| Non-Stage IV | 53 | 7 (13.2%) | NYR [NYR;NYR] | 51 | 11 (21.6%) | NYR [NYR;NYR] | 0.49 [0.19;1.26] | 0.1292 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:12:13

TABLE 5.3.1: Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - PT Neutropenia | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 6 (8.1%) | 15 (21.1%) |
| Number of censored cases | N | 68 (91.9%) | 56 (78.9%) |
| Time to first event (Months) | Mean (SE) | 10.48 (0.20) | 18.78 (0.97) |
| | Q1 [95% CI] | NYR [NYR;NYR] | 21.40 [7.03;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [22.54;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0121 | |
| Stratified Cox PH model | HR (b) | 0.31 [0.12;0.81] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:18:32

TABLE 5.3.2: Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)


| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 15 (21.1%) | NYR [22.54;NYR] | 0.31 [0.12;0.81] | 0.0121 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 3 (7.3%) | NYR [NYR;NYR] | 47 | 10 (21.3%) | NYR [22.54;NYR] | 0.27 [0.07;0.99] | 0.0353 | 0.8863 |
| >= 65 | 33 | 3 (9.1%) | NYR [NYR;NYR] | 24 | 5 (20.8%) | NYR [20.27;NYR] | 0.33 [0.08;1.38] | 0.1120 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 3 (7.3%) | NYR [NYR;NYR] | 47 | 10 (21.3%) | NYR [22.54;NYR] | 0.27 [0.07;0.99] | 0.0353 | 0.9542 |
| >= 65 AND < 75 | 25 | 2 (8.0%) | NYR [NYR;NYR] | 18 | 5 (27.8%) | NYR [20.27;NYR] | 0.21 [0.04;1.09] | 0.0417 | |
| >= 75 | 8 | 1 (12.5%) | NYR [10.48;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.5637 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 2 (5.1%) | NYR [NYR;NYR] | 37 | 4 (10.8%) | NYR [NYR;NYR] | 0.42 [0.08;2.27] | 0.2971 | 0.8007 |
| Rest of World (ROW) | 35 | 4 (11.4%) | NYR [NYR;NYR] | 34 | 11 (32.4%) | 22.54 [20.27;NYR] | 0.27 [0.09;0.86] | 0.0172 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:18:32

TABLE 5.3.2: Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 5 (7.7%) | NYR [NYR;NYR] | 60 | 13 (21.7%) | NYR [21.39;NYR] | 0.28 [0.10;0.78] | 0.0095 | 0.6874 |
| Non-White | 9 | 1 (11.1%) | NYR [7.36;NYR] | 11 | 2 (18.2%) | NYR [11.83;NYR] | 0.46 [0.04;5.09] | 0.5129 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NC | 13 | 4 (30.8%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NC | 32 | 4 (12.5%) | NC | NC | NC | |
| Not Reported | 24 | 3 (12.5%) | NC | 26 | 7 (26.9%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 4 (7.1%) | NC | 48 | 9 (18.8%) | NC | NC | NC | NC |
| Female | 18 | 2 (11.1%) | NC | 23 | 6 (26.1%) | NC | NC | NC | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 5 (26.3%) | NYR [7.03;NYR] | 0.21 [0.02;1.82] | 0.1191 | 0.5707 |
| >= 1 Year | 60 | 5 (8.3%) | NYR [NYR;NYR] | 50 | 10 (20.0%) | NYR [21.39;NYR] | 0.33 [0.11;0.96] | 0.0324 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:18:32

TABLE 5.3.2: Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 2 (16.7%) | NYR [7.03;NYR] | <0.01 [<0.01;NE] | 0.1283 | 0.9922 |
| Yes | 63 | 6 (9.5%) | NYR [NYR;NYR] | 59 | 13 (22.0%) | NYR [21.39;NYR] | 0.33 [0.13;0.88] | 0.0204 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 5 (7.8%) | NYR [NYR;NYR] | 65 | 14 (21.5%) | NYR [21.39;NYR] | 0.28 [0.10;0.78] | 0.0097 | 0.7655 |
| Yes | 10 | 1 (10.0%) | NYR [10.84;NYR] | 6 | 1 (16.7%) | NYR [1.41;NYR] | 0.51 [0.03;8.19] | 0.6259 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [7.36;NYR] | 10 | 2 (20.0%) | NYR [2.79;NYR] | 0.72 [0.10;5.24] | 0.7470 | 0.6199 |
| < 1% | 61 | 4 (6.6%) | NYR [NYR;NYR] | 60 | 13 (21.7%) | NYR [21.39;NYR] | 0.23 [0.08;0.72] | 0.0060 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 4 (20.0%) | 22.54 [22.54;NYR] | 0.21 [0.02;1.92] | 0.1298 | 0.7729 |
| Non-Stage IV | 53 | 5 (9.4%) | NYR [NYR;NYR] | 51 | 11 (21.6%) | NYR [21.39;NYR] | 0.33 [0.11;0.96] | 0.0327 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.4.1: Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 10 (13.5%) | 23 (32.4%) |
| Number of censored cases | N | 64 (86.5%) | 48 (67.6%) |
| Time to first event (Months) | Mean (SE) | 7.26 (0.22) | 5.89 (0.34) |
| | Q1 [95% CI] | NYR [7.85;NYR] | 3.40 [1.22;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0045 | |
| Stratified Cox PH model | HR (b) | 0.36 [0.17;0.75] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:24:56

TABLE 5.4.2: Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 23 (32.4%) | NYR [NYR;NYR] | 0.36 [0.17;0.75] | 0.0045 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 13 (27.7%) | NYR [NYR;NYR] | 0.37 [0.13;1.05] | 0.0526 | 0.7465 |
| >= 65 | 33 | 5 (15.2%) | NYR [NYR;NYR] | 24 | 10 (41.7%) | NYR [3.71;NYR] | 0.28 [0.10;0.83] | 0.0141 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 13 (27.7%) | NYR [NYR;NYR] | 0.37 [0.13;1.05] | 0.0526 | 0.9993 |
| >= 65 AND < 75 | 25 | 5 (20.0%) | NYR [NYR;NYR] | 18 | 8 (44.4%) | 7.72 [3.71;NYR] | 0.33 [0.11;1.03] | 0.0451 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 2 (33.3%) | NYR [0.69;NYR] | <0.01 [<0.01;NE] | 0.0872 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 7 (17.9%) | NYR [NYR;NYR] | 37 | 11 (29.7%) | NYR [7.72;NYR] | 0.52 [0.20;1.35] | 0.1729 | 0.2211 |
| Rest of World (ROW) | 35 | 3 (8.6%) | NYR [NYR;NYR] | 34 | 12 (35.3%) | NYR [3.71;NYR] | 0.19 [0.05;0.69] | 0.0048 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
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Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:24:56

TABLE 5.4.2: Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 9 (13.8%) | NYR [NYR;NYR] | 60 | 22 (36.7%) | NYR [6.21;NYR] | 0.30 [0.14;0.66] | 0.0014 | 0.3502 |
| Non-White | 9 | 1 (11.1%) | NYR [1.38;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 1.30 [0.08;20.75] | 0.8540 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NC | 13 | 6 (46.2%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 7 (16.3%) | NC | 32 | 8 (25.0%) | NC | NC | NC | |
| Not Reported | 24 | 2 (8.3%) | NC | 26 | 9 (34.6%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 9 (16.1%) | NYR [NYR;NYR] | 48 | 14 (29.2%) | NYR [NYR;NYR] | 0.48 [0.21;1.10] | 0.0754 | 0.1667 |
| Female | 18 | 1 (5.6%) | NYR [NYR;NYR] | 23 | 9 (39.1%) | NYR [1.38;NYR] | 0.12 [0.01;0.91] | 0.0136 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 8 (42.1%) | NYR [2.04;NYR] | 0.13 [0.02;1.06] | 0.0253 | 0.2565 |
| >= 1 Year | 60 | 9 (15.0%) | NYR [NYR;NYR] | 50 | 15 (30.0%) | NYR [NYR;NYR] | 0.43 [0.19;0.99] | 0.0402 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.4.2: Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [7.85;NYR] | 12 | 4 (33.3%) | NYR [0.72;NYR] | 0.17 [0.02;1.59] | 0.0824 | 0.5686 |
| Yes | 63 | 9 (14.3%) | NYR [NYR;NYR] | 59 | 19 (32.2%) | NYR [NYR;NYR] | 0.38 [0.17;0.85] | 0.0138 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 10 (15.6%) | NYR [NYR;NYR] | 65 | 22 (33.8%) | NYR [NYR;NYR] | 0.38 [0.18;0.80] | 0.0084 | 0.9912 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 1 (16.7%) | NYR [5.26;NYR] | <0.01 [<0.01;NE] | 0.2059 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 2 (20.0%) | NYR [0.72;NYR] | <0.01 [<0.01;NE] | 0.1277 | 0.9999 |
| < 1% | 61 | 10 (16.4%) | NYR [NYR;NYR] | 60 | 21 (35.0%) | NYR [7.72;NYR] | 0.39 [0.18;0.82] | 0.0108 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 4 (22.2%) | NYR [7.85;NYR] | 20 | 7 (35.0%) | NYR [2.50;NYR] | 0.52 [0.15;1.79] | 0.2970 | 0.4568 |
| Non-Stage IV | 53 | 6 (11.3%) | NYR [NYR;NYR] | 51 | 16 (31.4%) | NYR [NYR;NYR] | 0.30 [0.12;0.77] | 0.0076 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:24:56

TABLE 5.5.1: Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 65 (87.8%) | 64 (90.1%) |
| Number of censored cases | N | 9 (12.2%) | 7 (9.9%) |
| Time to first event (Months) | Mean (SE) | 5.06 (0.82) | 2.53 (0.56) |
| | Q1 [95% CI] | 1.00 [0.33;1.31] | 0.40 [0.30;0.46] |
| | Median [95% CI] | 1.79 [1.41;2.33] | 0.62 [0.46;0.95] |
| | Q3 [95% CI] | 6.20 [3.02;9.95] | 2.00 [1.61;3.45] |
| | p-value (a) | 0.0067 | |
| Stratified Cox PH model | HR (b) | 0.61 [0.43;0.87] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:31:28

TABLE 5.5.2: Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 65 (87.8%) | 1.79 [1.41;2.33] | 71 | 64 (90.1%) | 0.62 [0.46;0.95] | 0.61 [0.43;0.87] | 0.0067 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 38 (92.7%) | 1.71 [0.95;2.33] | 47 | 42 (89.4%) | 0.76 [0.46;1.61] | 0.76 [0.49;1.18] | 0.2125 | 0.1385 |
| >= 65 | 33 | 27 (81.8%) | 1.84 [1.31;3.58] | 24 | 22 (91.7%) | 0.49 [0.36;1.64] | 0.43 [0.24;0.78] | 0.0045 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 38 (92.7%) | 1.71 [0.95;2.33] | 47 | 42 (89.4%) | 0.76 [0.46;1.61] | 0.76 [0.49;1.18] | 0.2125 | 0.0451 |
| >= 65 AND < 75 | 25 | 22 (88.0%) | 1.74 [1.31;4.17] | 18 | 16 (88.9%) | 0.49 [0.36;1.74] | 0.59 [0.31;1.14] | 0.1198 | |
| >= 75 | 8 | 5 (62.5%) | 2.71 [0.26;NYR] | 6 | 6 (100.0%) | 0.49 [0.26;0.66] | 0.07 [0.01;0.59] | 0.0021 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 37 (94.9%) | 1.84 [1.41;2.33] | 37 | 33 (89.2%) | 0.49 [0.43;1.74] | 0.76 [0.48;1.23] | 0.2676 | 0.1568 |
| Rest of World (ROW) | 35 | 28 (80.0%) | 1.74 [0.99;4.30] | 34 | 31 (91.2%) | 0.64 [0.43;1.61] | 0.46 [0.26;0.80] | 0.0055 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:31:28

TABLE 5.5.2: Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)


| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 59 (90.8%) | 1.74 [1.41;2.33] | 60 | 53 (88.3%) | 0.69 [0.49;1.71] | 0.69 [0.47;1.00] | 0.0497 | 0.0523 |
| Non-White | 9 | 6 (66.7%) | 2.33 [0.23;NYR] | 11 | 11 (100.0%) | 0.43 [0.26;1.61] | 0.34 [0.11;1.04] | 0.0513 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 5 (71.4%) | 2.30 [0.26;NYR] | 13 | 11 (84.6%) | 1.61 [0.36;1.87] | 0.48 [0.16;1.44] | 0.1795 | 0.6071 |
| Not Hispanic or Latino | 43 | 41 (95.3%) | 1.71 [1.31;2.33] | 32 | 29 (90.6%) | 0.49 [0.39;0.85] | 0.69 [0.43;1.12] | 0.1343 | |
| Not Reported | 24 | 19 (79.2%) | 1.69 [1.02;9.00] | 26 | 24 (92.3%) | 0.66 [0.43;1.94] | 0.49 [0.26;0.92] | 0.0249 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 50 (89.3%) | 1.74 [1.31;2.33] | 48 | 43 (89.6%) | 0.66 [0.43;1.87] | 0.68 [0.45;1.03] | 0.0699 | 0.2857 |
| Female | 18 | 15 (83.3%) | 1.79 [1.31;4.17] | 23 | 21 (91.3%) | 0.49 [0.43;1.25] | 0.43 [0.22;0.87] | 0.0173 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 13 (92.9%) | 2.32 [0.33;7.52] | 19 | 18 (94.7%) | 0.49 [0.30;1.71] | 0.37 [0.16;0.86] | 0.0170 | 0.3628 |
| >= 1 Year | 60 | 52 (86.7%) | 1.68 [1.35;2.33] | 50 | 44 (88.0%) | 0.69 [0.46;1.61] | 0.65 [0.43;0.98] | 0.0374 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:31:28

TABLE 5.5.2: Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)


| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 11 (100.0%) | 1.61 [0.33;3.84] | 12 | 11 (91.7%) | 0.71 [0.26;3.25] | 0.68 [0.27;1.72] | 0.4231 | 0.2889 |
| Yes | 63 | 54 (85.7%) | 1.94 [1.41;2.86] | 59 | 53 (89.8%) | 0.62 [0.46;0.95] | 0.58 [0.40;0.85] | 0.0055 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 55 (85.9%) | 1.84 [1.41;2.33] | 65 | 58 (89.2%) | 0.66 [0.49;1.61] | 0.59 [0.41;0.86] | 0.0062 | 0.8438 |
| Yes | 10 | 10 (100.0%) | 1.30 [0.16;3.02] | 6 | 6 (100.0%) | 0.44 [0.13;11.37] | 0.73 [0.24;2.23] | 0.5737 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 9 (81.8%) | 2.27 [0.26;9.17] | 10 | 8 (80.0%) | 0.62 [0.13;1.71] | 0.57 [0.22;1.52] | 0.2602 | 0.3630 |
| < 1% | 61 | 54 (88.5%) | 1.84 [1.41;2.33] | 60 | 55 (91.7%) | 0.59 [0.46;0.95] | 0.59 [0.40;0.87] | 0.0068 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 17 (94.4%) | 1.79 [1.15;4.17] | 20 | 18 (90.0%) | 0.74 [0.30;2.33] | 0.59 [0.30;1.18] | 0.1346 | 0.7399 |
| Non-Stage IV | 53 | 45 (84.9%) | 1.94 [1.31;3.02] | 51 | 46 (90.2%) | 0.49 [0.43;0.95] | 0.59 [0.39;0.89] | 0.0130 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:31:28

TABLE 5.6.1: Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 56 (75.7%) | 37 (52.1%) |
| Number of censored cases | N | 18 (24.3%) | 34 (47.9%) |
| Time to first event (Months) | Mean (SE) | 9.30 (1.14) | 8.72 (0.83) |
| | Q1 [95% CI] | 1.60 [1.08;1.94] | 2.20 [1.61;3.45] |
| | Median [95% CI] | 4.37 [2.27;10.61] | 8.71 [3.48;NYR] |
| | Q3 [95% CI] | 16.60 [12.94;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0434 | |
| Stratified Cox PH model | HR (b) | 1.54 [1.01;2.34] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:38:25

TABLE 5.6.2: Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 56 (75.7%) | 4.37 [2.27;10.61] | 71 | 37 (52.1%) | 8.71 [3.48;NYR] | 1.54 [1.01;2.34] | 0.0434 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 36 (87.8%) | 2.33 [1.71;6.60] | 47 | 27 (57.4%) | 8.71 [3.48;15.70] | 1.79 [1.09;2.95] | 0.0208 | 0.5013 |
| >= 65 | 33 | 20 (60.6%) | 6.77 [2.30;16.59] | 24 | 10 (41.7%) | NYR [2.14;NYR] | 1.31 [0.61;2.82] | 0.4827 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 36 (87.8%) | 2.33 [1.71;6.60] | 47 | 27 (57.4%) | 8.71 [3.48;15.70] | 1.79 [1.09;2.95] | 0.0208 | 0.2087 |
| >= 65 AND < 75 | 25 | 17 (68.0%) | 6.77 [2.27;12.94] | 18 | 7 (38.9%) | NYR [2.14;NYR] | 1.80 [0.74;4.37] | 0.1883 | |
| >= 75 | 8 | 3 (37.5%) | NYR [1.51;NYR] | 6 | 3 (50.0%) | 2.83 [0.56;NYR] | 0.55 [0.11;2.73] | 0.4555 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 33 (84.6%) | 2.27 [1.61;6.18] | 37 | 17 (45.9%) | 9.36 [3.48;NYR] | 2.28 [1.27;4.10] | 0.0045 | 0.0509 |
| Rest of World (ROW) | 35 | 23 (65.7%) | 8.54 [2.66;17.41] | 34 | 20 (58.8%) | 5.13 [2.99;NYR] | 0.99 [0.54;1.80] | 0.9651 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:38:26

TABLE 5.6.2: Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 50 (76.9%) | 4.17 [1.94;8.54] | 60 | 30 (50.0%) | 9.36 [3.71;NYR] | 1.71 [1.09;2.69] | 0.0187 | 0.2117 |
| Non-White | 9 | 6 (66.7%) | 13.01 [0.33;NYR] | 11 | 7 (63.6%) | 3.45 [0.43;NYR] | 0.81 [0.27;2.42] | 0.7018 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 4 (57.1%) | 4.93 [2.27;NYR] | 13 | 8 (61.5%) | 4.86 [1.61;15.70] | 0.64 [0.19;2.15] | 0.4701 | 0.2047 |
| Not Hispanic or Latino | 43 | 35 (81.4%) | 2.33 [1.71;6.77] | 32 | 15 (46.9%) | 4.73 [3.25;NYR] | 2.12 [1.16;3.89] | 0.0128 | |
| Not Reported | 24 | 17 (70.8%) | 9.58 [1.71;16.59] | 26 | 14 (53.8%) | 9.36 [2.14;NYR] | 1.28 [0.63;2.60] | 0.4921 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 44 (78.6%) | 2.50 [1.84;8.54] | 48 | 26 (54.2%) | 9.36 [3.88;NYR] | 1.76 [1.08;2.86] | 0.0208 | 0.2474 |
| Female | 18 | 12 (66.7%) | 6.11 [2.37;17.41] | 23 | 11 (47.8%) | 3.71 [2.10;NYR] | 0.94 [0.41;2.15] | 0.8718 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 11 (78.6%) | 11.78 [1.71;14.16] | 19 | 10 (52.6%) | 15.24 [3.48;NYR] | 1.64 [0.69;3.92] | 0.2608 | 0.9259 |
| >= 1 Year | 60 | 45 (75.0%) | 3.22 [1.91;6.77] | 50 | 25 (50.0%) | 4.73 [2.83;NYR] | 1.59 [0.97;2.59] | 0.0608 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:38:26

TABLE 5.6.2: Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 10 (90.9%) | 2.66 [1.61;4.93] | 12 | 7 (58.3%) | 4.86 [2.83;NYR] | 2.34 [0.88;6.18] | 0.0787 | 0.4347 |
| Yes | 63 | 46 (73.0%) | 6.18 [2.27;12.94] | 59 | 30 (50.8%) | 8.71 [3.71;NYR] | 1.44 [0.91;2.28] | 0.1167 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 49 (76.6%) | 2.94 [1.94;6.77] | 65 | 33 (50.8%) | 8.71 [3.48;NYR] | 1.65 [1.06;2.56] | 0.0256 | 0.3415 |
| Yes | 10 | 7 (70.0%) | 16.59 [0.16;25.49] | 6 | 4 (66.7%) | 3.88 [2.14;NYR] | 0.65 [0.18;2.36] | 0.5084 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 8 (72.7%) | 10.71 [1.71;25.49] | 10 | 6 (60.0%) | 2.81 [0.26;NYR] | 0.79 [0.27;2.33] | 0.6703 | 0.4446 |
| < 1% | 61 | 47 (77.0%) | 3.22 [1.94;6.77] | 60 | 30 (50.0%) | 8.71 [3.88;NYR] | 1.73 [1.09;2.73] | 0.0183 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 12 (66.7%) | 12.94 [1.84;15.67] | 20 | 13 (65.0%) | 3.48 [0.82;15.70] | 0.88 [0.40;1.93] | 0.7446 | 0.1172 |
| Non-Stage IV | 53 | 41 (77.4%) | 4.37 [2.10;6.77] | 51 | 24 (47.1%) | 11.37 [3.88;NYR] | 1.82 [1.10;3.01] | 0.0183 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.7.1: Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - PT Stomatitis | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 12 (16.2%) | 25 (35.2%) |
| Number of censored cases | N | 62 (83.8%) | 46 (64.8%) |
| Time to first event (Months) | Mean (SE) | 12.22 (0.42) | 14.60 (1.14) |
| | Q1 [95% CI] | NYR [11.73;NYR] | 2.60 [0.85;10.81] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [18.17;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0010 | |
| Stratified Cox PH model | HR (b) | 0.33 [0.16;0.66] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:45:24

TABLE 5.7.2: Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 12 (16.2%) | NYR [NYR;NYR] | 71 | 25 (35.2%) | NYR [18.17;NYR] | 0.33 [0.16;0.66] | 0.0010 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 8 (19.5%) | NYR [NYR;NYR] | 47 | 19 (40.4%) | 21.32 [9.69;NYR] | 0.34 [0.15;0.77] | 0.0071 | 0.9486 |
| >= 65 | 33 | 4 (12.1%) | NYR [NYR;NYR] | 24 | 6 (25.0%) | NYR [6.08;NYR] | 0.38 [0.11;1.35] | 0.1204 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 8 (19.5%) | NYR [NYR;NYR] | 47 | 19 (40.4%) | 21.32 [9.69;NYR] | 0.34 [0.15;0.77] | 0.0071 | 0.7284 |
| >= 65 AND < 75 | 25 | 2 (8.0%) | NYR [NYR;NYR] | 18 | 6 (33.3%) | NYR [2.10;NYR] | 0.16 [0.03;0.81] | 0.0121 | |
| >= 75 | 8 | 2 (25.0%) | NYR [0.56;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2084 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 7 (17.9%) | NYR [NYR;NYR] | 37 | 12 (32.4%) | NYR [6.93;NYR] | 0.41 [0.16;1.04] | 0.0534 | 0.5324 |
| Rest of World (ROW) | 35 | 5 (14.3%) | NYR [NYR;NYR] | 34 | 13 (38.2%) | 21.32 [9.69;NYR] | 0.27 [0.10;0.76] | 0.0082 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:45:24

TABLE 5.7.2: Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 11 (16.9%) | NYR [NYR;NYR] | 60 | 20 (33.3%) | NYR [18.17;NYR] | 0.38 [0.18;0.80] | 0.0086 | 0.3588 |
| Non-White | 9 | 1 (11.1%) | NYR [11.73;NYR] | 11 | 5 (45.5%) | NYR [0.43;NYR] | 0.13 [0.01;1.22] | 0.0419 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 2 (28.6%) | NYR [2.17;NYR] | 13 | 4 (30.8%) | 18.17 [6.31;NYR] | 0.72 [0.13;3.94] | 0.6990 | 0.4389 |
| Not Hispanic or Latino | 43 | 6 (14.0%) | NYR [NYR;NYR] | 32 | 9 (28.1%) | NYR [21.32;NYR] | 0.41 [0.14;1.15] | 0.0799 | |
| Not Reported | 24 | 4 (16.7%) | NYR [NYR;NYR] | 26 | 12 (46.2%) | 10.81 [1.71;NYR] | 0.23 [0.07;0.72] | 0.0059 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 10 (17.9%) | NYR [NYR;NYR] | 48 | 20 (41.7%) | 21.32 [6.93;NYR] | 0.31 [0.15;0.67] | 0.0017 | 0.8599 |
| Female | 18 | 2 (11.1%) | NYR [NYR;NYR] | 23 | 5 (21.7%) | NYR [NYR;NYR] | 0.38 [0.07;1.97] | 0.2291 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 5 (35.7%) | NYR [7.43;NYR] | 19 | 7 (36.8%) | NYR [2.69;NYR] | 0.63 [0.20;2.02] | 0.4328 | 0.1575 |
| >= 1 Year | 60 | 7 (11.7%) | NYR [NYR;NYR] | 50 | 17 (34.0%) | NYR [18.17;NYR] | 0.26 [0.11;0.63] | 0.0014 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Analysis Cut Off date: 10SEP2020
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TABLE 5.7.2: Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 4 (33.3%) | NYR [0.85;NYR] | 0.21 [0.02;1.90] | 0.1258 | 0.5608 |
| Yes | 63 | 11 (17.5%) | NYR [NYR;NYR] | 59 | 21 (35.6%) | NYR [10.81;NYR] | 0.36 [0.17;0.76] | 0.0049 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 10 (15.6%) | NYR [NYR;NYR] | 65 | 21 (32.3%) | NYR [18.17;NYR] | 0.35 [0.17;0.75] | 0.0049 | 0.2539 |
| Yes | 10 | 2 (20.0%) | NYR [1.48;NYR] | 6 | 4 (66.7%) | 0.71 [0.13;NYR] | 0.17 [0.03;0.94] | 0.0222 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 3 (27.3%) | NYR [3.45;NYR] | 10 | 3 (30.0%) | NYR [0.13;NYR] | 0.75 [0.15;3.71] | 0.7201 | 0.4350 |
| < 1% | 61 | 8 (13.1%) | NYR [NYR;NYR] | 60 | 21 (35.0%) | NYR [10.81;NYR] | 0.26 [0.11;0.59] | 0.0005 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 4 (22.2%) | NYR [11.73;NYR] | 20 | 5 (25.0%) | NYR [9.69;NYR] | 0.68 [0.18;2.56] | 0.5667 | 0.1349 |
| Non-Stage IV | 53 | 7 (13.2%) | NYR [NYR;NYR] | 51 | 20 (39.2%) | 21.32 [6.31;NYR] | 0.24 [0.10;0.56] | 0.0004 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Analysis Cut Off date: 10SEP2020
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TABLE 5.8.1: Treatment Emergent Adverse Event (TEAE) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - PT Blood thyroid stimulating hormone increased | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 11 (14.9%) | 3 (4.2%) |
| Number of censored cases | N | 63 (85.1%) | 68 (95.8%) |
| Time to first event (Months) | Mean (SE) | 17.32 (0.69) | 14.78 (0.34) |
| | Q1 [95% CI] | NYR [16.66;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0401 | |
| Stratified Cox PH model | HR (b) | 3.51 [0.98;12.59] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:51:42

TABLE 5.8.2: Treatment Emergent Adverse Event (TEAE) - PT Blood thyroid stimulating hormone increased - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 11 (14.9%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 3.51 [0.98;12.59] | 0.0401 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NC | 47 | 2 (4.3%) | NC | NC | NC | NC |
| >= 65 | 33 | 6 (18.2%) | NC | 24 | 1 (4.2%) | NC | NC | NC | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NC | 47 | 2 (4.3%) | NC | NC | NC | NC |
| >= 65 AND < 75 | 25 | 6 (24.0%) | NC | 18 | 1 (5.6%) | NC | NC | NC | |
| >= 75 | 8 | 0 (0.0%) | NC | 6 | 0 (0.0%) | NC | NC | NC | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NC | 37 | 0 (0.0%) | NC | NC | NC | NC |
| Rest of World (ROW) | 35 | 6 (17.1%) | NC | 34 | 3 (8.8%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
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Analysis Cut Off date: 10SEP2020
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TABLE 5.8.2: Treatment Emergent Adverse Event (TEAE) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 8 (12.3%) | NC | 60 | 2 (3.3%) | NC | NC | NC | NC |
| Non-White | 9 | 3 (33.3%) | NC | 11 | 1 (9.1%) | NC | NC | NC | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NC | 13 | 2 (15.4%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 4 (9.3%) | NC | 32 | 1 (3.1%) | NC | NC | NC | |
| Not Reported | 24 | 6 (25.0%) | NC | 26 | 0 (0.0%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 7 (12.5%) | NC | 48 | 1 (2.1%) | NC | NC | NC | NC |
| Female | 18 | 4 (22.2%) | NC | 23 | 2 (8.7%) | NC | NC | NC | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9998 |
| >= 1 Year | 60 | 11 (18.3%) | NYR [NYR;NYR] | 50 | 3 (6.0%) | NYR [NYR;NYR] | 2.89 [0.81;10.39] | 0.0880 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:51:42

TABLE 5.8.2: Treatment Emergent Adverse Event (TEAE) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NC | 12 | 0 (0.0%) | NC | NC | NC | NC |
| Yes | 63 | 9 (14.3%) | NC | 59 | 3 (5.1%) | NC | NC | NC | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 9 (14.1%) | NC | 65 | 3 (4.6%) | NC | NC | NC | NC |
| Yes | 10 | 2 (20.0%) | NC | 6 | 0 (0.0%) | NC | NC | NC | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 1 (10.0%) | NYR [0.72;NYR] | <0.01 [<0.01;NE] | 0.2943 | 1.0000 |
| < 1% | 61 | 11 (18.0%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 5.16 [1.14;23.29] | 0.0174 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NC | 20 | 1 (5.0%) | NC | NC | NC | NC |
| Non-Stage IV | 53 | 9 (17.0%) | NC | 51 | 2 (3.9%) | NC | NC | NC | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:51:42

TABLE 5.9.1: Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 8 (10.8%) | 17 (23.9%) |
| Number of censored cases | N | 66 (89.2%) | 54 (76.1%) |
| Time to first event (Months) | Mean (SE) | 6.17 (0.18) | 18.97 (1.17) |
| | Q1 [95% CI] | NYR [NYR;NYR] | 14.80 [2.10;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [24.15;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0234 | |
| Stratified Cox PH model | HR (b) | 0.39 [0.17;0.90] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:55:46

TABLE 5.9.2: Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 17 (23.9%) | NYR [24.15;NYR] | 0.39 [0.17;0.90] | 0.0234 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 3 (7.3%) | NC | 47 | 8 (17.0%) | NC | NC | NC | NC |
| >= 65 | 33 | 5 (15.2%) | NC | 24 | 9 (37.5%) | NC | NC | NC | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 3 (7.3%) | NC | 47 | 8 (17.0%) | NC | NC | NC | NC |
| >= 65 AND < 75 | 25 | 3 (12.0%) | NC | 18 | 9 (50.0%) | NC | NC | NC | |
| >= 75 | 8 | 2 (25.0%) | NC | 6 | 0 (0.0%) | NC | NC | NC | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NYR [NYR;NYR] | 37 | 7 (18.9%) | NYR [NYR;NYR] | 0.60 [0.19;1.89] | 0.3768 | 0.3074 |
| Rest of World (ROW) | 35 | 3 (8.6%) | NYR [NYR;NYR] | 34 | 10 (29.4%) | 24.15 [24.15;NYR] | 0.24 [0.06;0.87] | 0.0184 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.9.2: Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 6 (9.2%) | NYR [NYR;NYR] | 60 | 14 (23.3%) | NYR [24.15;NYR] | 0.33 [0.13;0.87] | 0.0180 | 0.4623 |
| Non-White | 9 | 2 (22.2%) | NYR [0.92;NYR] | 11 | 3 (27.3%) | NYR [0.72;NYR] | 0.76 [0.13;4.57] | 0.7659 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NC | 13 | 4 (30.8%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 3 (7.0%) | NC | 32 | 6 (18.8%) | NC | NC | NC | |
| Not Reported | 24 | 4 (16.7%) | NC | 26 | 7 (26.9%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 5 (8.9%) | NYR [NYR;NYR] | 48 | 10 (20.8%) | NYR [24.15;NYR] | 0.37 [0.13;1.09] | 0.0615 | 0.8627 |
| Female | 18 | 3 (16.7%) | NYR [NYR;NYR] | 23 | 7 (30.4%) | NYR [3.45;NYR] | 0.44 [0.11;1.73] | 0.2303 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 5 (26.3%) | NYR [2.14;NYR] | <0.01 [<0.01;NE] | 0.0404 | 0.9897 |
| >= 1 Year | 60 | 8 (13.3%) | NYR [NYR;NYR] | 50 | 12 (24.0%) | NYR [24.15;NYR] | 0.49 [0.20;1.19] | 0.1063 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.9.2: Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3384 | 0.9920 |
| Yes | 63 | 8 (12.7%) | NYR [NYR;NYR] | 59 | 16 (27.1%) | NYR [24.15;NYR] | 0.40 [0.17;0.94] | 0.0288 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 7 (10.9%) | NYR [NYR;NYR] | 65 | 15 (23.1%) | NYR [24.15;NYR] | 0.40 [0.16;0.99] | 0.0394 | 0.6440 |
| Yes | 10 | 1 (10.0%) | NYR [1.18;NYR] | 6 | 2 (33.3%) | NYR [0.62;NYR] | 0.25 [0.02;2.73] | 0.2159 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [NYR;NYR] | 10 | 4 (40.0%) | NYR [0.69;NYR] | 0.18 [0.02;1.63] | 0.0877 | 0.6906 |
| < 1% | 61 | 7 (11.5%) | NYR [NYR;NYR] | 60 | 13 (21.7%) | NYR [24.15;NYR] | 0.46 [0.18;1.14] | 0.0861 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 4 (20.0%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.0416 | 0.9889 |
| Non-Stage IV | 53 | 8 (15.1%) | NYR [NYR;NYR] | 51 | 13 (25.5%) | NYR [24.15;NYR] | 0.50 [0.21;1.21] | 0.1163 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.10.1: Treatment Emergent Adverse Event (TEAE) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - PT Weight decreased | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 13 (17.6%) | 3 (4.2%) |
| Number of censored cases | N | 61 (82.4%) | 68 (95.8%) |
| Time to first event (Months) | Mean (SE) | 15.66 (0.66) | 27.97 (0.66) |
| | Q1 [95% CI] | NYR [12.29;NYR] | 28.80 [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | 28.75 [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | 28.80 [NYR;NYR] |
| | p-value (a) | 0.0063 | |
| Stratified Cox PH model | HR (b) | 6.18 [1.39;27.46] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

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TABLE 5.10.2: Treatment Emergent Adverse Event (TEAE) - PT Weight decreased - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 13 (17.6%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | 28.75 [NYR;NYR] | 6.18 [1.39;27.46] | 0.0063 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 6 (14.6%) | NC | 47 | 3 (6.4%) | NC | NC | NC | NC |
| >= 65 | 33 | 7 (21.2%) | NC | 24 | 0 (0.0%) | NC | NC | NC | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 6 (14.6%) | NC | 47 | 3 (6.4%) | NC | NC | NC | NC |
| >= 65 AND < 75 | 25 | 4 (16.0%) | NC | 18 | 0 (0.0%) | NC | NC | NC | |
| >= 75 | 8 | 3 (37.5%) | NC | 6 | 0 (0.0%) | NC | NC | NC | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 3 (7.7%) | NYR [NYR;NYR] | 37 | 2 (5.4%) | NYR [NYR;NYR] | 1.18 [0.19;7.13] | 0.8586 | 0.0708 |
| Rest of World (ROW) | 35 | 10 (28.6%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | 28.75 [NYR;NYR] | >99.99 [<0.01;NE] | 0.0013 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.10.2: Treatment Emergent Adverse Event (TEAE) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 13 (20.0%) | NYR [NYR;NYR] | 60 | 3 (5.0%) | 28.75 [NYR;NYR] | 5.82 [1.31;25.79] | 0.0086 | 0.9992 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 2 (28.6%) | NC | 13 | 0 (0.0%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 6 (14.0%) | NC | 32 | 1 (3.1%) | NC | NC | NC | |
| Not Reported | 24 | 5 (20.8%) | NC | 26 | 2 (7.7%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 10 (17.9%) | NYR [NYR;NYR] | 48 | 2 (4.2%) | NYR [NYR;NYR] | 4.12 [0.90;18.83] | 0.0474 | 0.9085 |
| Female | 18 | 3 (16.7%) | NYR [NYR;NYR] | 23 | 1 (4.3%) | 28.75 [NYR;NYR] | 3.52 [0.36;33.92] | 0.2460 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 5 (35.7%) | NC | 19 | 1 (5.3%) | NC | NC | NC | NC |
| >= 1 Year | 60 | 8 (13.3%) | NC | 50 | 2 (4.0%) | NC | NC | NC | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:01:30

TABLE 5.10.2: Treatment Emergent Adverse Event (TEAE) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 4 (36.4%) | NC | 12 | 0 (0.0%) | NC | NC | NC | NC |
| Yes | 63 | 9 (14.3%) | NC | 59 | 3 (5.1%) | NC | NC | NC | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 11 (17.2%) | NYR [NYR;NYR] | 65 | 3 (4.6%) | 28.75 [NYR;NYR] | 3.52 [0.98;12.65] | 0.0393 | 0.9928 |
| Yes | 10 | 2 (20.0%) | NYR [2.56;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2824 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NC | 10 | 1 (10.0%) | NC | NC | NC | NC |
| < 1% | 61 | 9 (14.8%) | NC | 60 | 2 (3.3%) | NC | NC | NC | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 6 (33.3%) | NC | 20 | 2 (10.0%) | NC | NC | NC | NC |
| Non-Stage IV | 53 | 7 (13.2%) | NC | 51 | 1 (2.0%) | NC | NC | NC | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:01:30
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:01:30

TABLE 5.11.1: Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 59 (79.7%) | 35 (49.3%) |
| Number of censored cases | N | 15 (20.3%) | 36 (50.7%) |
| Time to first event (Months) | Mean (SE) | 7.73 (0.84) | 10.36 (0.93) |
| | Q1 [95% CI] | 1.40 [0.53;1.91] | 1.40 [0.69;4.14] |
| | Median [95% CI] | 4.73 [2.33;8.90] | 16.56 [4.27;NYR] |
| | Q3 [95% CI] | 15.60 [9.23;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0078 | |
| Stratified Cox PH model | HR (b) | 1.76 [1.15;2.69] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:06:56

TABLE 5.11.2: Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 59 (79.7%) | 4.73 [2.33;8.90] | 71 | 35 (49.3%) | 16.56 [4.27;NYR] | 1.76 [1.15;2.69] | 0.0078 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 34 (82.9%) | 4.63 [1.87;9.03] | 47 | 19 (40.4%) | NYR [4.83;NYR] | 2.45 [1.40;4.30] | 0.0012 | 0.0512 |
| >= 65 | 33 | 25 (75.8%) | 5.55 [1.87;11.93] | 24 | 16 (66.7%) | 4.27 [0.62;16.56] | 1.06 [0.56;2.00] | 0.8592 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 34 (82.9%) | 4.63 [1.87;9.03] | 47 | 19 (40.4%) | NYR [4.83;NYR] | 2.45 [1.40;4.30] | 0.0012 | 0.1513 |
| >= 65 AND < 75 | 25 | 19 (76.0%) | 5.55 [1.77;12.58] | 18 | 13 (72.2%) | 4.27 [0.49;16.56] | 1.04 [0.51;2.13] | 0.9148 | |
| >= 75 | 8 | 6 (75.0%) | 5.45 [0.49;NYR] | 6 | 3 (50.0%) | NYR [0.56;NYR] | 1.22 [0.30;4.93] | 0.7760 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 33 (84.6%) | 2.33 [1.41;5.29] | 37 | 19 (51.4%) | 15.61 [2.79;NYR] | 2.05 [1.17;3.62] | 0.0106 | 0.4909 |
| Rest of World (ROW) | 35 | 26 (74.3%) | 7.13 [2.56;13.14] | 34 | 16 (47.1%) | 17.28 [2.10;NYR] | 1.58 [0.84;2.94] | 0.1510 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:06:56

TABLE 5.11.2: Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 54 (83.1%) | 3.48 [1.87;6.54] | 60 | 28 (46.7%) | 16.56 [4.96;NYR] | 2.18 [1.38;3.45] | 0.0006 | 0.0274 |
| Non-White | 9 | 5 (55.6%) | 17.02 [2.37;NYR] | 11 | 7 (63.6%) | 3.45 [0.49;NYR] | 0.53 [0.17;1.68] | 0.2699 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 5 (71.4%) | 0.95 [0.23;NYR] | 13 | 9 (69.2%) | 3.45 [0.46;NYR] | 1.22 [0.41;3.66] | 0.7222 | 0.0636 |
| Not Hispanic or Latino | 43 | 38 (88.4%) | 2.14 [1.45;3.61] | 32 | 13 (40.6%) | NYR [4.14;NYR] | 3.15 [1.67;5.94] | 0.0002 | |
| Not Reported | 24 | 16 (66.7%) | 12.53 [6.54;18.17] | 26 | 13 (50.0%) | 16.56 [2.04;NYR] | 1.09 [0.52;2.27] | 0.8171 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 45 (80.4%) | 2.91 [1.87;8.90] | 48 | 20 (41.7%) | NYR [6.47;NYR] | 2.48 [1.46;4.21] | 0.0005 | 0.0220 |
| Female | 18 | 14 (77.8%) | 6.39 [3.61;17.02] | 23 | 15 (65.2%) | 4.14 [0.85;16.56] | 0.90 [0.43;1.88] | 0.7696 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 10 (71.4%) | 9.23 [5.29;18.27] | 19 | 11 (57.9%) | 15.61 [0.69;NYR] | 0.98 [0.42;2.32] | 0.9758 | 0.1136 |
| >= 1 Year | 60 | 49 (81.7%) | 2.91 [1.77;6.24] | 50 | 23 (46.0%) | 16.56 [4.14;NYR] | 2.14 [1.30;3.52] | 0.0021 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:06:56

TABLE 5.11.2: Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 10 (90.9%) | 5.09 [0.95;18.17] | 12 | 6 (50.0%) | 15.61 [2.04;NYR] | 2.00 [0.73;5.53] | 0.1714 | 0.8314 |
| Yes | 63 | 49 (77.8%) | 4.67 [2.14;8.90] | 59 | 29 (49.2%) | 16.56 [4.14;NYR] | 1.73 [1.09;2.74] | 0.0180 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 50 (78.1%) | 5.19 [2.33;9.03] | 65 | 31 (47.7%) | 17.28 [4.14;NYR] | 1.76 [1.12;2.75] | 0.0124 | 0.9107 |
| Yes | 10 | 9 (90.0%) | 2.22 [0.26;13.14] | 6 | 4 (66.7%) | 11.43 [0.62;NYR] | 1.89 [0.57;6.25] | 0.2898 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 10 (90.9%) | 6.24 [0.53;15.51] | 10 | 5 (50.0%) | 16.39 [0.36;NYR] | 2.35 [0.78;7.11] | 0.1213 | 0.9396 |
| < 1% | 61 | 47 (77.0%) | 4.67 [2.14;9.23] | 60 | 30 (50.0%) | 16.56 [4.14;NYR] | 1.66 [1.05;2.62] | 0.0291 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 14 (77.8%) | 8.02 [2.17;14.16] | 20 | 13 (65.0%) | 4.96 [2.00;17.28] | 1.00 [0.47;2.12] | 0.9912 | 0.1103 |
| Non-Stage IV | 53 | 42 (79.2%) | 4.63 [1.87;9.03] | 51 | 22 (43.1%) | NYR [4.14;NYR] | 2.14 [1.27;3.59] | 0.0033 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.12.1: Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 33 (44.6%) | 15 (21.1%) |
| Number of censored cases | N | 41 (55.4%) | 56 (78.9%) |
| Time to first event (Months) | Mean (SE) | 12.41 (0.85) | 10.84 (0.57) |
| | Q1 [95% CI] | 3.80 [2.37;9.23] | NYR [4.27;NYR] |
| | Median [95% CI] | NYR [11.93;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0225 | |
| Stratified Cox PH model | HR (b) | 2.01 [1.09;3.71] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:13:56

TABLE 5.12.2: Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 33 (44.6%) | NYR [11.93;NYR] | 71 | 15 (21.1%) | NYR [NYR;NYR] | 2.01 [1.09;3.71] | 0.0225 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 18 (43.9%) | NYR [9.69;NYR] | 47 | 6 (12.8%) | NYR [NYR;NYR] | 3.52 [1.40;8.88] | 0.0044 | 0.0465 |
| >= 65 | 33 | 15 (45.5%) | NYR [6.54;NYR] | 24 | 9 (37.5%) | NYR [4.27;NYR] | 0.98 [0.43;2.25] | 0.9707 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 18 (43.9%) | NYR [9.69;NYR] | 47 | 6 (12.8%) | NYR [NYR;NYR] | 3.52 [1.40;8.88] | 0.0044 | 0.0393 |
| >= 65 AND < 75 | 25 | 11 (44.0%) | NYR [8.28;NYR] | 18 | 9 (50.0%) | 7.13 [0.49;NYR] | 0.66 [0.27;1.60] | 0.3613 | |
| >= 75 | 8 | 4 (50.0%) | NYR [0.49;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0785 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 18 (46.2%) | 18.17 [9.69;NYR] | 37 | 7 (18.9%) | NYR [NYR;NYR] | 2.33 [0.97;5.59] | 0.0503 | 0.6902 |
| Rest of World (ROW) | 35 | 15 (42.9%) | NYR [7.13;NYR] | 34 | 8 (23.5%) | NYR [NYR;NYR] | 1.80 [0.76;4.26] | 0.1723 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:13:56

TABLE 5.12.2: Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 30 (46.2%) | NYR [9.23;NYR] | 60 | 12 (20.0%) | NYR [NYR;NYR] | 2.34 [1.20;4.57] | 0.0105 | 0.3171 |
| Non-White | 9 | 3 (33.3%) | NYR [2.37;NYR] | 11 | 3 (27.3%) | NYR [0.49;NYR] | 0.98 [0.20;4.86] | 0.9762 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 5 (71.4%) | 2.37 [0.23;NYR] | 13 | 7 (53.8%) | 4.96 [0.46;NYR] | 1.29 [0.41;4.08] | 0.6551 | 0.2399 |
| Not Hispanic or Latino | 43 | 20 (46.5%) | 15.67 [5.29;NYR] | 32 | 3 (9.4%) | NYR [NYR;NYR] | 5.35 [1.59;18.03] | 0.0024 | |
| Not Reported | 24 | 8 (33.3%) | NYR [11.93;NYR] | 26 | 5 (19.2%) | NYR [NYR;NYR] | 1.53 [0.50;4.69] | 0.4493 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 24 (42.9%) | NYR [11.93;NYR] | 48 | 10 (20.8%) | NYR [NYR;NYR] | 2.14 [1.02;4.47] | 0.0390 | 0.9068 |
| Female | 18 | 9 (50.0%) | NYR [3.61;NYR] | 23 | 5 (21.7%) | NYR [13.11;NYR] | 1.96 [0.66;5.86] | 0.2192 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 5 (35.7%) | NYR [8.90;NYR] | 19 | 3 (15.8%) | NYR [NYR;NYR] | 1.85 [0.44;7.74] | 0.3950 | 0.9738 |
| >= 1 Year | 60 | 28 (46.7%) | NYR [8.28;NYR] | 50 | 12 (24.0%) | NYR [NYR;NYR] | 1.90 [0.97;3.74] | 0.0581 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:13:56

TABLE 5.12.2: Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 6 (54.5%) | 18.17 [2.56;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | 6.77 [0.81;56.44] | 0.0410 | 0.2386 |
| Yes | 63 | 27 (42.9%) | NYR [9.69;NYR] | 59 | 14 (23.7%) | NYR [NYR;NYR] | 1.74 [0.91;3.32] | 0.0877 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 27 (42.2%) | NYR [11.93;NYR] | 65 | 15 (23.1%) | NYR [NYR;NYR] | 1.72 [0.91;3.23] | 0.0884 | 0.9850 |
| Yes | 10 | 6 (60.0%) | 4.63 [1.35;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0347 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 6 (54.5%) | 15.51 [0.53;NYR] | 10 | 2 (20.0%) | NYR [0.36;NYR] | 2.75 [0.55;13.63] | 0.1967 | 0.8687 |
| < 1% | 61 | 25 (41.0%) | NYR [12.58;NYR] | 60 | 13 (21.7%) | NYR [NYR;NYR] | 1.78 [0.91;3.49] | 0.0856 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 10 (55.6%) | 12.58 [7.13;NYR] | 20 | 4 (20.0%) | NYR [13.11;NYR] | 2.86 [0.90;9.11] | 0.0630 | 0.4410 |
| Non-Stage IV | 53 | 21 (39.6%) | NYR [15.21;NYR] | 51 | 11 (21.6%) | NYR [NYR;NYR] | 1.70 [0.82;3.53] | 0.1492 | |
| Not Reported | 3 | 2 (66.7%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:13:56

TABLE 5.13.1: Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 16 (21.6%) | 3 (4.2%) |
| Number of censored cases | N | 58 (78.4%) | 68 (95.8%) |
| Time to first event (Months) | Mean (SE) | 16.71 (0.72) | 0.69 (0.00) |
| | Q1 [95% CI] | 19.40 [9.59;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0062 | |
| Stratified Cox PH model | HR (b) | 4.77 [1.39;16.39] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:20:56

TABLE 5.13.2: Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 16 (21.6%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 4.77 [1.39;16.39] | 0.0062 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 13 (31.7%) | NYR [19.48;NYR] | 47 | 2 (4.3%) | NYR [NYR;NYR] | 6.85 [1.54;30.41] | 0.0033 | 0.3718 |
| >= 65 | 33 | 3 (9.1%) | NYR [NYR;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 1.99 [0.21;19.14] | 0.5442 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 13 (31.7%) | NYR [19.48;NYR] | 47 | 2 (4.3%) | NYR [NYR;NYR] | 6.85 [1.54;30.41] | 0.0033 | 0.5368 |
| >= 65 AND < 75 | 25 | 2 (8.0%) | NYR [NYR;NYR] | 18 | 1 (5.6%) | NYR [NYR;NYR] | 1.34 [0.12;14.78] | 0.8112 | |
| >= 75 | 8 | 1 (12.5%) | NYR [2.60;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4292 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 10 (25.6%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 9.22 [1.18;72.06] | 0.0099 | 0.3396 |
| Rest of World (ROW) | 35 | 6 (17.1%) | NYR [NYR;NYR] | 34 | 2 (5.9%) | NYR [NYR;NYR] | 2.53 [0.51;12.55] | 0.2400 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:20:56

TABLE 5.13.2: Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 15 (23.1%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 6.65 [1.52;29.08] | 0.0036 | 0.2285 |
| Non-White | 9 | 1 (11.1%) | NYR [16.76;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 1.01 [0.06;16.34] | 0.9948 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 1 (7.7%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.4631 | 0.5401 |
| Not Hispanic or Latino | 43 | 14 (32.6%) | NYR [16.76;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 10.83 [1.42;82.34] | 0.0039 | |
| Not Reported | 24 | 2 (8.3%) | NYR [NYR;NYR] | 26 | 1 (3.8%) | NYR [NYR;NYR] | 1.68 [0.15;18.71] | 0.6715 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 14 (25.0%) | NYR [NYR;NYR] | 48 | 3 (6.3%) | NYR [NYR;NYR] | 3.86 [1.11;13.43] | 0.0223 | 0.9912 |
| Female | 18 | 2 (11.1%) | NYR [16.76;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1583 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 4 (28.6%) | NYR [16.76;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | 4.95 [0.55;44.30] | 0.1127 | 0.6725 |
| >= 1 Year | 60 | 12 (20.0%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 9.43 [1.23;72.57] | 0.0084 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
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Analysis Cut Off date: 10SEP2020
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TABLE 5.13.2: Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 3 (27.3%) | NYR [9.23;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1089 | 0.9929 |
| Yes | 63 | 13 (20.6%) | NYR [NYR;NYR] | 59 | 3 (5.1%) | NYR [NYR;NYR] | 3.83 [1.09;13.44] | 0.0241 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 13 (20.3%) | NYR [NYR;NYR] | 65 | 2 (3.1%) | NYR [NYR;NYR] | 6.06 [1.37;26.88] | 0.0068 | 0.3487 |
| Yes | 10 | 3 (30.0%) | NYR [0.49;NYR] | 6 | 1 (16.7%) | NYR [0.66;NYR] | 1.70 [0.18;16.45] | 0.6415 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 3 (27.3%) | NYR [12.32;NYR] | 10 | 1 (10.0%) | NYR [0.69;NYR] | 2.29 [0.24;22.11] | 0.4619 | 0.8433 |
| < 1% | 61 | 12 (19.7%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 5.59 [1.25;24.99] | 0.0110 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 5 (27.8%) | NYR [9.59;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | 5.25 [0.61;44.90] | 0.0906 | 0.8862 |
| Non-Stage IV | 53 | 10 (18.9%) | NYR [NYR;NYR] | 51 | 2 (3.9%) | NYR [NYR;NYR] | 4.39 [0.96;20.07] | 0.0369 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
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Analysis Cut Off date: 10SEP2020
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TABLE 5.14.1: Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 12 (16.2%) | 2 (2.8%) |
| Number of censored cases | N | 62 (83.8%) | 69 (97.2%) |
| Time to first event (Months) | Mean (SE) | 8.55 (0.28) | 3.61 (0.06) |
| | Q1 [95% CI] | NYR [8.90;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0120 | |
| Stratified Cox PH model | HR (b) | 5.50 [1.23;24.61] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:27:23

TABLE 5.14.2: Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 12 (16.2%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 5.50 [1.23;24.61] | 0.0120 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NC | 47 | 1 (2.1%) | NC | NC | NC | NC |
| >= 65 | 33 | 5 (15.2%) | NC | 24 | 1 (4.2%) | NC | NC | NC | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NC | 47 | 1 (2.1%) | NC | NC | NC | NC |
| >= 65 AND < 75 | 25 | 4 (16.0%) | NC | 18 | 1 (5.6%) | NC | NC | NC | |
| >= 75 | 8 | 1 (12.5%) | NC | 6 | 0 (0.0%) | NC | NC | NC | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 6 (15.4%) | NC | 37 | 2 (5.4%) | NC | NC | NC | NC |
| Rest of World (ROW) | 35 | 6 (17.1%) | NC | 34 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
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Analysis Cut Off date: 10SEP2020
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TABLE 5.14.2: Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 12 (18.5%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 5.41 [1.21;24.18] | 0.0130 | 0.9995 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 2 (28.6%) | NC | 13 | 0 (0.0%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 6 (14.0%) | NC | 32 | 2 (6.3%) | NC | NC | NC | |
| Not Reported | 24 | 4 (16.7%) | NC | 26 | 0 (0.0%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 9 (16.1%) | NC | 48 | 1 (2.1%) | NC | NC | NC | NC |
| Female | 18 | 3 (16.7%) | NC | 23 | 1 (4.3%) | NC | NC | NC | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [NYR;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | 2.57 [0.23;28.30] | 0.4249 | 0.4659 |
| >= 1 Year | 60 | 10 (16.7%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 8.11 [1.04;63.35] | 0.0173 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |
| **Karnofsky Performance Status Subgroups** | | | | | | | | | |
| 100 - 90 | 67 | 12 (17.9%) | NYR [NYR;NYR] | 58 | 1 (1.7%) | NYR [NYR;NYR] | 10.60 [1.38;81.51] | 0.0046 | 0.9912 |
| < 90 | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 1 (7.7%) | NYR [3.65;NYR] | <0.01 [<0.01;NE] | 0.3173 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:27:24

TABLE 5.14.2: Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NYR [3.71;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | 2.13 [0.19;23.45] | 0.5284 | 0.3409 |
| Yes | 63 | 10 (15.9%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 9.20 [1.18;71.91] | 0.0099 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 10 (15.6%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 9.59 [1.23;74.96] | 0.0082 | 0.2147 |
| Yes | 10 | 2 (20.0%) | NYR [0.99;NYR] | 6 | 1 (16.7%) | NYR [0.69;NYR] | 1.15 [0.10;12.68] | 0.9111 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 3 (27.3%) | NC | 10 | 0 (0.0%) | NC | NC | NC | NC |
| < 1% | 61 | 9 (14.8%) | NC | 60 | 2 (3.3%) | NC | NC | NC | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3311 | 0.9907 |
| Non-Stage IV | 53 | 11 (20.8%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 10.08 [1.30;78.07] | 0.0062 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.15.1: Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - PT Dysphonia | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 16 (21.6%) | 1 (1.4%) |
| Number of censored cases | N | 58 (78.4%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 17.80 (0.88) | 13.47 (.) |
| | Q1 [95% CI] | 21.40 [7.20;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0003 | |
| Stratified Cox PH model | HR (b) | 15.70 [2.08;>99.99] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:32:29

TABLE 5.15.2: Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 16 (21.6%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 15.70 [2.08;>99.99] | 0.0003 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 9 (22.0%) | NC | 47 | 1 (2.1%) | NC | NC | NC | NC |
| >= 65 | 33 | 7 (21.2%) | NC | 24 | 0 (0.0%) | NC | NC | NC | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 9 (22.0%) | NC | 47 | 1 (2.1%) | NC | NC | NC | NC |
| >= 65 AND < 75 | 25 | 6 (24.0%) | NC | 18 | 0 (0.0%) | NC | NC | NC | |
| >= 75 | 8 | 1 (12.5%) | NC | 6 | 0 (0.0%) | NC | NC | NC | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 8 (20.5%) | NC | 37 | 0 (0.0%) | NC | NC | NC | NC |
| Rest of World (ROW) | 35 | 8 (22.9%) | NC | 34 | 1 (2.9%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.15.2: Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 14 (21.5%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 13.12 [1.72;99.74] | 0.0012 | 0.9944 |
| Non-White | 9 | 2 (22.2%) | NYR [2.43;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1736 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 1 (7.7%) | NYR [13.47;NYR] | <0.01 [<0.01;NE] | 0.3865 | 1.0000 |
| Not Hispanic or Latino | 43 | 11 (25.6%) | NYR [21.36;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0032 | |
| Not Reported | 24 | 5 (20.8%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0242 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 13 (23.2%) | NYR [NYR;NYR] | 48 | 1 (2.1%) | NYR [NYR;NYR] | 11.29 [1.48;86.35] | 0.0032 | 0.9923 |
| Female | 18 | 3 (16.7%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0671 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2850 | 0.9937 |
| >= 1 Year | 60 | 15 (25.0%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 12.85 [1.70;97.26] | 0.0014 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.15.2: Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2963 | 0.9948 |
| Yes | 63 | 15 (23.8%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 14.20 [1.88;>99.99] | 0.0007 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 12 (18.8%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 11.83 [1.54;91.02] | 0.0025 | 0.9925 |
| Yes | 10 | 4 (40.0%) | 21.36 [0.92;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1341 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 3 (27.3%) | NYR [1.31;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1171 | 1.0000 |
| < 1% | 61 | 13 (21.3%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 12.71 [1.66;97.17] | 0.0016 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3329 | 0.9948 |
| Non-Stage IV | 53 | 14 (26.4%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 13.22 [1.74;>99.99] | 0.0012 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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TABLE 5.16.1: Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 14 (18.9%) | 4 (5.6%) |
| Number of censored cases | N | 60 (81.1%) | 67 (94.4%) |
| Time to first event (Months) | Mean (SE) | 13.09 (0.52) | 11.97 (0.31) |
| | Q1 [95% CI] | NYR [9.86;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0315 | |
| Stratified Cox PH model | HR (b) | 3.18 [1.04;9.67] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:38:41

TABLE 5.16.2: Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 14 (18.9%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 3.18 [1.04;9.67] | 0.0315 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 10 (24.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 11.42 [1.46;89.25] | 0.0033 | 0.0482 |
| >= 65 | 33 | 4 (12.1%) | NYR [NYR;NYR] | 24 | 3 (12.5%) | NYR [NYR;NYR] | 0.85 [0.19;3.82] | 0.8352 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 10 (24.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 11.42 [1.46;89.25] | 0.0033 | 0.1305 |
| >= 65 AND < 75 | 25 | 3 (12.0%) | NYR [NYR;NYR] | 18 | 2 (11.1%) | NYR [NYR;NYR] | 1.06 [0.18;6.37] | 0.9450 | |
| >= 75 | 8 | 1 (12.5%) | NYR [2.56;NYR] | 6 | 1 (16.7%) | NYR [1.64;NYR] | 0.61 [0.04;9.93] | 0.7276 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 10 (25.6%) | NYR [NYR;NYR] | 37 | 3 (8.1%) | NYR [NYR;NYR] | 2.91 [0.80;10.61] | 0.0888 | 0.8751 |
| Rest of World (ROW) | 35 | 4 (11.4%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | NYR [NYR;NYR] | 3.68 [0.41;32.94] | 0.2124 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
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TABLE 5.16.2: Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 11 (16.9%) | NYR [NYR;NYR] | 60 | 3 (5.0%) | NYR [NYR;NYR] | 3.23 [0.90;11.57] | 0.0572 | 0.9984 |
| Non-White | 9 | 3 (33.3%) | NYR [0.76;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 3.05 [0.31;29.81] | 0.3129 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NC | 13 | 1 (7.7%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 9 (20.9%) | NC | 32 | 2 (6.3%) | NC | NC | NC | |
| Not Reported | 24 | 4 (16.7%) | NC | 26 | 1 (3.8%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 13 (23.2%) | NYR [NYR;NYR] | 48 | 2 (4.2%) | NYR [NYR;NYR] | 5.45 [1.23;24.16] | 0.0121 | 0.1117 |
| Female | 18 | 1 (5.6%) | NYR [NYR;NYR] | 23 | 2 (8.7%) | NYR [NYR;NYR] | 0.54 [0.05;6.07] | 0.6160 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [NYR;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | 2.33 [0.21;25.79] | 0.4772 | 0.8607 |
| >= 1 Year | 60 | 12 (20.0%) | NYR [NYR;NYR] | 50 | 3 (6.0%) | NYR [NYR;NYR] | 3.11 [0.88;11.03] | 0.0643 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
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TABLE 5.16.2: Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NYR [9.86;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | 1.84 [0.17;20.39] | 0.6139 | 0.6596 |
| Yes | 63 | 12 (19.0%) | NYR [NYR;NYR] | 59 | 3 (5.1%) | NYR [NYR;NYR] | 3.54 [1.00;12.57] | 0.0365 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 11 (17.2%) | NYR [NYR;NYR] | 65 | 4 (6.2%) | NYR [NYR;NYR] | 2.61 [0.83;8.22] | 0.0877 | 0.9919 |
| Yes | 10 | 3 (30.0%) | NYR [2.56;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1786 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 4 (36.4%) | NC | 10 | 1 (10.0%) | NC | NC | NC | NC |
| < 1% | 61 | 9 (14.8%) | NC | 60 | 3 (5.0%) | NC | NC | NC | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 3 (16.7%) | NYR [NYR;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | 3.36 [0.35;32.30] | 0.2651 | 0.9320 |
| Non-Stage IV | 53 | 10 (18.9%) | NYR [NYR;NYR] | 51 | 3 (5.9%) | NYR [NYR;NYR] | 2.85 [0.78;10.39] | 0.0966 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:38:41

TABLE 5.17.1: Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - PT Pruritus | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 20 (27.0%) | 3 (4.2%) |
| Number of censored cases | N | 54 (73.0%) | 68 (95.8%) |
| Time to first event (Months) | Mean (SE) | 16.94 (0.96) | 6.22 (0.13) |
| | Q1 [95% CI] | 12.60 [4.50;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0005 | |
| Stratified Cox PH model | HR (b) | 6.51 [1.93;21.96] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:45:09

TABLE 5.17.2: Treatment Emergent Adverse Event (TEAE) - PT Pruritus - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 20 (27.0%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 6.51 [1.93;21.96] | 0.0005 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 11 (26.8%) | NYR [21.62;NYR] | 47 | 2 (4.3%) | NYR [NYR;NYR] | 6.12 [1.36;27.66] | 0.0072 | 0.9588 |
| >= 65 | 33 | 9 (27.3%) | NYR [12.68;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 6.41 [0.81;50.65] | 0.0427 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 11 (26.8%) | NYR [21.62;NYR] | 47 | 2 (4.3%) | NYR [NYR;NYR] | 6.12 [1.36;27.66] | 0.0072 | 0.9622 |
| >= 65 AND < 75 | 25 | 6 (24.0%) | NYR [12.68;NYR] | 18 | 1 (5.6%) | NYR [NYR;NYR] | 4.03 [0.48;33.61] | 0.1627 | |
| >= 75 | 8 | 3 (37.5%) | NYR [0.53;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1069 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 9 (23.1%) | NYR [21.62;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 7.99 [1.01;63.22] | 0.0192 | 0.7969 |
| Rest of World (ROW) | 35 | 11 (31.4%) | NYR [12.29;NYR] | 34 | 2 (5.9%) | NYR [NYR;NYR] | 5.76 [1.28;25.99] | 0.0098 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:45:09

TABLE 5.17.2: Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 17 (26.2%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 8.18 [1.89;35.42] | 0.0008 | 0.4865 |
| Non-White | 9 | 3 (33.3%) | NYR [0.53;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 2.91 [0.30;28.59] | 0.3381 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [12.68;NYR] | 13 | 1 (7.7%) | NYR [6.37;NYR] | 1.15 [0.07;18.59] | 0.9191 | 0.5043 |
| Not Hispanic or Latino | 43 | 9 (20.9%) | NYR [21.62;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 6.59 [0.83;52.07] | 0.0392 | |
| Not Reported | 24 | 10 (41.7%) | NYR [7.00;NYR] | 26 | 1 (3.8%) | NYR [NYR;NYR] | 11.84 [1.51;92.51] | 0.0027 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 16 (28.6%) | NYR [21.62;NYR] | 48 | 2 (4.2%) | NYR [NYR;NYR] | 7.36 [1.69;32.01] | 0.0018 | 0.7267 |
| Female | 18 | 4 (22.2%) | NYR [12.29;NYR] | 23 | 1 (4.3%) | NYR [NYR;NYR] | 4.47 [0.50;40.16] | 0.1433 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 4 (28.6%) | NYR [8.48;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | 4.50 [0.50;40.32] | 0.1409 | 0.8138 |
| >= 1 Year | 60 | 16 (26.7%) | NYR [21.62;NYR] | 50 | 2 (4.0%) | NYR [NYR;NYR] | 6.89 [1.58;29.98] | 0.0028 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:45:09

TABLE 5.17.2: Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NYR [8.35;NYR] | 12 | 1 (8.3%) | NYR [6.37;NYR] | 1.34 [0.12;14.87] | 0.8097 | 0.2752 |
| Yes | 63 | 18 (28.6%) | NYR [21.62;NYR] | 59 | 2 (3.4%) | NYR [NYR;NYR] | 8.85 [2.05;38.14] | 0.0004 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 19 (29.7%) | NYR [NYR;NYR] | 65 | 3 (4.6%) | NYR [NYR;NYR] | 6.58 [1.95;22.23] | 0.0005 | 0.9926 |
| Yes | 10 | 1 (10.0%) | NYR [21.62;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 3 (27.3%) | NYR [8.48;NYR] | 10 | 1 (10.0%) | NYR [1.02;NYR] | 1.90 [0.19;18.44] | 0.5755 | 0.6187 |
| < 1% | 61 | 16 (26.2%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 8.14 [1.87;35.42] | 0.0009 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 3 (16.7%) | NYR [NYR;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | 3.08 [0.32;29.64] | 0.3050 | 0.5030 |
| Non-Stage IV | 53 | 17 (32.1%) | NYR [21.62;NYR] | 51 | 2 (3.9%) | NYR [NYR;NYR] | 8.28 [1.91;35.85] | 0.0007 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:45:09

TABLE 5.18.1: Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - PT Rash | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 18 (24.3%) | 5 (7.0%) |
| Number of censored cases | N | 56 (75.7%) | 66 (93.0%) |
| Time to first event (Months) | Mean (SE) | 10.96 (0.48) | 9.15 (0.28) |
| | Q1 [95% CI] | 13.00 [4.80;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0120 | |
| Stratified Cox PH model | HR (b) | 3.32 [1.23;8.96] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:52:00

TABLE 5.18.2: Treatment Emergent Adverse Event (TEAE) - PT Rash - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 18 (24.3%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 3.32 [1.23;8.96] | 0.0120 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NYR [NYR;NYR] | 47 | 4 (8.5%) | NYR [NYR;NYR] | 1.81 [0.53;6.19] | 0.3370 | 0.2301 |
| >= 65 | 33 | 11 (33.3%) | NYR [7.72;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 7.95 [1.03;61.60] | 0.0184 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NYR [NYR;NYR] | 47 | 4 (8.5%) | NYR [NYR;NYR] | 1.81 [0.53;6.19] | 0.3370 | 0.7818 |
| >= 65 AND < 75 | 25 | 10 (40.0%) | NYR [4.80;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0062 | |
| >= 75 | 8 | 1 (12.5%) | NYR [0.72;NYR] | 6 | 1 (16.7%) | NYR [0.66;NYR] | 0.68 [0.04;10.98] | 0.7878 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 7 (17.9%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 6.10 [0.75;49.59] | 0.0537 | 0.5010 |
| Rest of World (ROW) | 35 | 11 (31.4%) | NYR [13.08;NYR] | 34 | 4 (11.8%) | NYR [NYR;NYR] | 2.66 [0.85;8.36] | 0.0821 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:52:00

TABLE 5.18.2: Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 15 (23.1%) | NYR [NYR;NYR] | 60 | 5 (8.3%) | NYR [NYR;NYR] | 2.59 [0.94;7.13] | 0.0556 | 0.9917 |
| Non-White | 9 | 3 (33.3%) | NYR [0.72;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0450 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 3 (42.9%) | NC | 13 | 2 (15.4%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 7 (16.3%) | NC | 32 | 3 (9.4%) | NC | NC | NC | |
| Not Reported | 24 | 8 (33.3%) | NC | 26 | 0 (0.0%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 12 (21.4%) | NYR [NYR;NYR] | 48 | 5 (10.4%) | NYR [NYR;NYR] | 1.98 [0.70;5.61] | 0.1920 | 0.9890 |
| Female | 18 | 6 (33.3%) | NYR [7.56;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0061 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 4 (28.6%) | NYR [7.72;NYR] | 19 | 2 (10.5%) | NYR [NYR;NYR] | 2.48 [0.45;13.60] | 0.2782 | 0.6962 |
| >= 1 Year | 60 | 14 (23.3%) | NYR [NYR;NYR] | 50 | 3 (6.0%) | NYR [NYR;NYR] | 3.76 [1.08;13.09] | 0.0253 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:52:00

TABLE 5.18.2: Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 3 (27.3%) | NYR [4.60;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | 2.89 [0.30;27.88] | 0.3364 | 0.8922 |
| Yes | 63 | 15 (23.8%) | NYR [NYR;NYR] | 59 | 4 (6.8%) | NYR [NYR;NYR] | 3.42 [1.14;10.32] | 0.0200 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 15 (23.4%) | NYR [NYR;NYR] | 65 | 5 (7.7%) | NYR [NYR;NYR] | 2.86 [1.04;7.87] | 0.0334 | 0.9906 |
| Yes | 10 | 3 (30.0%) | NYR [1.87;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1595 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 4 (36.4%) | NYR [3.75;NYR] | 10 | 1 (10.0%) | NYR [0.46;NYR] | 3.40 [0.38;30.49] | 0.2453 | 0.9981 |
| < 1% | 61 | 14 (23.0%) | NYR [NYR;NYR] | 60 | 4 (6.7%) | NYR [NYR;NYR] | 3.25 [1.07;9.88] | 0.0279 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 7 (38.9%) | NYR [7.72;NYR] | 20 | 2 (10.0%) | NYR [NYR;NYR] | 3.95 [0.82;19.01] | 0.0642 | 0.7618 |
| Non-Stage IV | 53 | 10 (18.9%) | NYR [NYR;NYR] | 51 | 3 (5.9%) | NYR [NYR;NYR] | 2.92 [0.80;10.60] | 0.0891 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:52:00

TABLE 5.19.1: Treatment Emergent AE grade >=3 - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent AE grade >=3 - SOC Respiratory, thoracic and mediastinal disorders | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 10 (13.5%) | 2 (2.8%) |
| Number of censored cases | N | 64 (86.5%) | 69 (97.2%) |
| Time to first event (Months) | Mean (SE) | 15.32 (0.58) | 5.43 (0.08) |
| | Q1 [95% CI] | NYR [17.08;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0317 | |
| Stratified Cox PH model | HR (b) | 4.56 [1.00;20.82] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:57:37

TABLE 5.19.2: Treatment Emergent AE grade >=3 - SOC Respiratory, thoracic and mediastinal disorders - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 4.56 [1.00;20.82] | 0.0317 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 4 (9.8%) | NC | 47 | 2 (4.3%) | NC | NC | NC | NC |
| >= 65 | 33 | 6 (18.2%) | NC | 24 | 0 (0.0%) | NC | NC | NC | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 4 (9.8%) | NC | 47 | 2 (4.3%) | NC | NC | NC | NC |
| >= 65 AND < 75 | 25 | 5 (20.0%) | NC | 18 | 0 (0.0%) | NC | NC | NC | |
| >= 75 | 8 | 1 (12.5%) | NC | 6 | 0 (0.0%) | NC | NC | NC | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 7 (17.9%) | NC | 37 | 0 (0.0%) | NC | NC | NC | NC |
| Rest of World (ROW) | 35 | 3 (8.6%) | NC | 34 | 2 (5.9%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:57:37

TABLE 5.19.2: Treatment Emergent AE grade >=3 - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 10 (15.4%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 8.86 [1.13;69.26] | 0.0118 | 0.9907 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 1 (9.1%) | NYR [5.49;NYR] | <0.01 [<0.01;NE] | 0.3428 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NC | 13 | 1 (7.7%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 9 (20.9%) | NC | 32 | 0 (0.0%) | NC | NC | NC | |
| Not Reported | 24 | 0 (0.0%) | NC | 26 | 1 (3.8%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 8 (14.3%) | NC | 48 | 2 (4.2%) | NC | NC | NC | NC |
| Female | 18 | 2 (11.1%) | NC | 23 | 0 (0.0%) | NC | NC | NC | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NC | 19 | 1 (5.3%) | NC | NC | NC | NC |
| >= 1 Year | 60 | 9 (15.0%) | NC | 50 | 0 (0.0%) | NC | NC | NC | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:57:37

TABLE 5.19.2: Treatment Emergent AE grade >=3 - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3384 | 0.9935 |
| Yes | 63 | 10 (15.9%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 9.07 [1.16;70.86] | 0.0107 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 9 (14.1%) | NC | 65 | 1 (1.5%) | NC | NC | NC | NC |
| Yes | 10 | 1 (10.0%) | NC | 6 | 1 (16.7%) | NC | NC | NC | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NC | 10 | 1 (10.0%) | NC | NC | NC | NC |
| < 1% | 61 | 8 (13.1%) | NC | 60 | 1 (1.7%) | NC | NC | NC | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NC | 20 | 1 (5.0%) | NC | NC | NC | NC |
| Non-Stage IV | 53 | 7 (13.2%) | NC | 51 | 1 (2.0%) | NC | NC | NC | |
| Not Reported | 3 | 2 (66.7%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:57:37

TABLE 5.20.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 23 (31.1%) | 37 (52.1%) |
| Number of censored cases | N | 51 (68.9%) | 34 (47.9%) |
| Time to first event (Months) | Mean (SE) | 12.28 (0.67) | 11.78 (1.14) |
| | Q1 [95% CI] | 10.20 [1.87;NYR] | 1.40 [0.72;3.48] |
| | Median [95% CI] | NYR [NYR;NYR] | 11.04 [3.75;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [21.39;NYR] |
| | p-value (a) | 0.0041 | |
| Stratified Cox PH model | HR (b) | 0.47 [0.28;0.80] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:01:21

TABLE 5.20.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 23 (31.1%) | NYR [NYR;NYR] | 71 | 37 (52.1%) | 11.04 [3.75;NYR] | 0.47 [0.28;0.80] | 0.0041 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 10 (24.4%) | NYR [NYR;NYR] | 47 | 22 (46.8%) | 21.39 [7.49;NYR] | 0.42 [0.20;0.88] | 0.0188 | 0.9486 |
| >= 65 | 33 | 13 (39.4%) | NYR [10.15;NYR] | 24 | 15 (62.5%) | 4.63 [1.38;NYR] | 0.40 [0.19;0.85] | 0.0139 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 10 (24.4%) | NYR [NYR;NYR] | 47 | 22 (46.8%) | 21.39 [7.49;NYR] | 0.42 [0.20;0.88] | 0.0188 | 0.5411 |
| >= 65 AND < 75 | 25 | 10 (40.0%) | NYR [6.44;NYR] | 18 | 13 (72.2%) | 3.73 [1.38;7.72] | 0.29 [0.12;0.69] | 0.0031 | |
| >= 75 | 8 | 3 (37.5%) | NYR [0.49;NYR] | 6 | 2 (33.3%) | NYR [0.69;NYR] | 1.10 [0.18;6.58] | 0.9203 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 12 (30.8%) | NYR [NYR;NYR] | 37 | 18 (48.6%) | 12.65 [2.43;NYR] | 0.55 [0.26;1.14] | 0.1008 | 0.7256 |
| Rest of World (ROW) | 35 | 11 (31.4%) | NYR [15.64;NYR] | 34 | 19 (55.9%) | 11.04 [2.17;NYR] | 0.40 [0.19;0.85] | 0.0133 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:01:21

TABLE 5.20.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 21 (32.3%) | NYR [NYR;NYR] | 60 | 33 (55.0%) | 8.31 [3.48;NYR] | 0.44 [0.26;0.77] | 0.0030 | 0.9315 |
| Non-White | 9 | 2 (22.2%) | NYR [1.38;NYR] | 11 | 4 (36.4%) | NYR [0.72;NYR] | 0.51 [0.09;2.79] | 0.4292 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 3 (42.9%) | NYR [0.95;NYR] | 13 | 10 (76.9%) | 2.17 [0.72;21.39] | 0.34 [0.09;1.27] | 0.0917 | 0.7850 |
| Not Hispanic or Latino | 43 | 11 (25.6%) | NYR [NYR;NYR] | 32 | 13 (40.6%) | NYR [2.43;NYR] | 0.54 [0.24;1.20] | 0.1263 | |
| Not Reported | 24 | 9 (37.5%) | NYR [10.84;NYR] | 26 | 14 (53.8%) | 11.04 [3.48;NYR] | 0.54 [0.23;1.24] | 0.1411 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 18 (32.1%) | NYR [NYR;NYR] | 48 | 24 (50.0%) | 12.65 [3.75;NYR] | 0.53 [0.29;0.98] | 0.0385 | 0.3967 |
| Female | 18 | 5 (27.8%) | NYR [10.48;NYR] | 23 | 13 (56.5%) | 10.18 [1.22;NYR] | 0.32 [0.11;0.89] | 0.0224 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 3 (21.4%) | NYR [15.11;NYR] | 19 | 12 (63.2%) | 3.71 [0.79;NYR] | 0.22 [0.06;0.78] | 0.0115 | 0.1474 |
| >= 1 Year | 60 | 20 (33.3%) | NYR [NYR;NYR] | 50 | 25 (50.0%) | 11.83 [5.52;NYR] | 0.55 [0.30;0.99] | 0.0431 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:01:21

TABLE 5.20.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NYR [4.76;NYR] | 12 | 7 (58.3%) | 8.31 [0.72;NYR] | 0.20 [0.04;0.99] | 0.0308 | 0.2382 |
| Yes | 63 | 21 (33.3%) | NYR [NYR;NYR] | 59 | 30 (50.8%) | 11.83 [3.71;NYR] | 0.53 [0.30;0.92] | 0.0233 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 20 (31.3%) | NYR [NYR;NYR] | 65 | 35 (53.8%) | 11.04 [3.48;NYR] | 0.43 [0.25;0.75] | 0.0023 | 0.4403 |
| Yes | 10 | 3 (30.0%) | NYR [0.03;NYR] | 6 | 2 (33.3%) | NYR [1.41;NYR] | 0.91 [0.15;5.48] | 0.9213 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 4 (36.4%) | NYR [0.95;NYR] | 10 | 6 (60.0%) | 11.04 [0.72;NYR] | 0.42 [0.12;1.54] | 0.1799 | 0.9939 |
| < 1% | 61 | 18 (29.5%) | NYR [NYR;NYR] | 60 | 31 (51.7%) | 11.83 [3.48;NYR] | 0.44 [0.25;0.79] | 0.0050 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 5 (27.8%) | NYR [15.11;NYR] | 20 | 11 (55.0%) | 11.04 [1.35;NYR] | 0.37 [0.13;1.08] | 0.0591 | 0.7382 |
| Non-Stage IV | 53 | 17 (32.1%) | NYR [NYR;NYR] | 51 | 26 (51.0%) | 11.83 [3.38;NYR] | 0.48 [0.26;0.90] | 0.0187 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.21.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 10 (13.5%) | 19 (26.8%) |
| Number of censored cases | N | 64 (86.5%) | 52 (73.2%) |
| Time to first event (Months) | Mean (SE) | 20.06 (0.71) | 13.48 (0.68) |
| | Q1 [95% CI] | NYR [22.11;NYR] | 11.00 [4.37;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0089 | |
| Stratified Cox PH model | HR (b) | 0.36 [0.16;0.80] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:08:19

TABLE 5.21.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 19 (26.8%) | NYR [NYR;NYR] | 0.36 [0.16;0.80] | 0.0089 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 10 (21.3%) | NYR [NYR;NYR] | 0.49 [0.17;1.45] | 0.1879 | 0.6328 |
| >= 65 | 33 | 5 (15.2%) | NYR [NYR;NYR] | 24 | 9 (37.5%) | NYR [10.18;NYR] | 0.32 [0.11;0.96] | 0.0322 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 10 (21.3%) | NYR [NYR;NYR] | 0.49 [0.17;1.45] | 0.1879 | 0.8891 |
| >= 65 AND < 75 | 25 | 4 (16.0%) | NYR [NYR;NYR] | 18 | 7 (38.9%) | 16.56 [5.52;NYR] | 0.32 [0.09;1.10] | 0.0578 | |
| >= 75 | 8 | 1 (12.5%) | NYR [3.29;NYR] | 6 | 2 (33.3%) | NYR [1.22;NYR] | 0.35 [0.03;3.83] | 0.3656 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NYR [NYR;NYR] | 37 | 11 (29.7%) | NYR [16.53;NYR] | 0.37 [0.13;1.08] | 0.0586 | 0.6238 |
| Rest of World (ROW) | 35 | 5 (14.3%) | NYR [22.11;NYR] | 34 | 8 (23.5%) | NYR [NYR;NYR] | 0.49 [0.16;1.50] | 0.1999 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:08:19

TABLE 5.21.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 9 (13.8%) | NYR [NYR;NYR] | 60 | 17 (28.3%) | NYR [NYR;NYR] | 0.42 [0.18;0.93] | 0.0285 | 0.9253 |
| Non-White | 9 | 1 (11.1%) | NYR [22.11;NYR] | 11 | 2 (18.2%) | NYR [1.41;NYR] | 0.48 [0.04;5.38] | 0.5418 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NC | 13 | 4 (30.8%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 4 (9.3%) | NC | 32 | 7 (21.9%) | NC | NC | NC | |
| Not Reported | 24 | 5 (20.8%) | NC | 26 | 8 (30.8%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 7 (12.5%) | NYR [NYR;NYR] | 48 | 10 (20.8%) | NYR [NYR;NYR] | 0.56 [0.21;1.47] | 0.2316 | 0.4917 |
| Female | 18 | 3 (16.7%) | NYR [22.11;NYR] | 23 | 9 (39.1%) | 16.56 [5.52;NYR] | 0.27 [0.07;1.00] | 0.0370 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [15.11;NYR] | 19 | 6 (31.6%) | NYR [8.31;NYR] | 0.34 [0.07;1.71] | 0.1713 | 0.8368 |
| >= 1 Year | 60 | 8 (13.3%) | NYR [NYR;NYR] | 50 | 13 (26.0%) | NYR [NYR;NYR] | 0.44 [0.18;1.06] | 0.0607 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.21.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NYR [4.76;NYR] | 12 | 4 (33.3%) | NYR [4.80;NYR] | 0.51 [0.09;2.79] | 0.4277 | 0.9978 |
| Yes | 63 | 8 (12.7%) | NYR [NYR;NYR] | 59 | 15 (25.4%) | NYR [NYR;NYR] | 0.42 [0.18;1.00] | 0.0431 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 8 (12.5%) | NYR [NYR;NYR] | 65 | 18 (27.7%) | NYR [NYR;NYR] | 0.37 [0.16;0.84] | 0.0138 | 0.3359 |
| Yes | 10 | 2 (20.0%) | NYR [0.03;NYR] | 6 | 1 (16.7%) | NYR [10.18;NYR] | 1.45 [0.13;16.03] | 0.7621 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 3 (27.3%) | NYR [15.11;NYR] | 10 | 5 (50.0%) | 11.04 [1.35;NYR] | 0.30 [0.07;1.31] | 0.0920 | 0.9803 |
| < 1% | 61 | 7 (11.5%) | NYR [NYR;NYR] | 60 | 14 (23.3%) | NYR [NYR;NYR] | 0.43 [0.17;1.08] | 0.0641 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 2 (11.1%) | NYR [NYR;NYR] | 20 | 7 (35.0%) | NYR [8.31;NYR] | 0.25 [0.05;1.23] | 0.0657 | 0.5314 |
| Non-Stage IV | 53 | 7 (13.2%) | NYR [NYR;NYR] | 51 | 12 (23.5%) | NYR [NYR;NYR] | 0.47 [0.18;1.19] | 0.1034 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
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TABLE 5.22.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 6 (8.1%) | 15 (21.1%) |
| Number of censored cases | N | 68 (91.9%) | 56 (78.9%) |
| Time to first event (Months) | Mean (SE) | 10.49 (0.20) | 18.93 (0.94) |
| | Q1 [95% CI] | NYR [NYR;NYR] | 21.40 [7.03;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [22.54;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0156 | |
| Stratified Cox PH model | HR (b) | 0.33 [0.13;0.85] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:14:52

TABLE 5.22.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 6 (8.1%) | NYR [NYR;NYR] | 71 | 15 (21.1%) | NYR [22.54;NYR] | 0.33 [0.13;0.85] | 0.0156 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 3 (7.3%) | NYR [NYR;NYR] | 47 | 10 (21.3%) | NYR [22.54;NYR] | 0.28 [0.08;1.02] | 0.0403 | 0.8612 |
| >= 65 | 33 | 3 (9.1%) | NYR [NYR;NYR] | 24 | 5 (20.8%) | NYR [20.27;NYR] | 0.34 [0.08;1.44] | 0.1260 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 3 (7.3%) | NYR [NYR;NYR] | 47 | 10 (21.3%) | NYR [22.54;NYR] | 0.28 [0.08;1.02] | 0.0403 | 0.9582 |
| >= 65 AND < 75 | 25 | 2 (8.0%) | NYR [NYR;NYR] | 18 | 5 (27.8%) | NYR [20.27;NYR] | 0.22 [0.04;1.14] | 0.0489 | |
| >= 75 | 8 | 1 (12.5%) | NYR [10.48;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.4795 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 2 (5.1%) | NYR [NYR;NYR] | 37 | 4 (10.8%) | NYR [NYR;NYR] | 0.43 [0.08;2.34] | 0.3152 | 0.7960 |
| Rest of World (ROW) | 35 | 4 (11.4%) | NYR [NYR;NYR] | 34 | 11 (32.4%) | 22.54 [20.27;NYR] | 0.28 [0.09;0.89] | 0.0213 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:14:52

TABLE 5.22.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 5 (7.7%) | NYR [NYR;NYR] | 60 | 13 (21.7%) | NYR [22.54;NYR] | 0.29 [0.10;0.81] | 0.0122 | 0.6786 |
| Non-White | 9 | 1 (11.1%) | NYR [7.36;NYR] | 11 | 2 (18.2%) | NYR [11.83;NYR] | 0.48 [0.04;5.38] | 0.5451 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NC | 13 | 4 (30.8%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 2 (4.7%) | NC | 32 | 4 (12.5%) | NC | NC | NC | |
| Not Reported | 24 | 3 (12.5%) | NC | 26 | 7 (26.9%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 4 (7.1%) | NC | 48 | 9 (18.8%) | NC | NC | NC | NC |
| Female | 18 | 2 (11.1%) | NC | 23 | 6 (26.1%) | NC | NC | NC | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 5 (26.3%) | NYR [7.03;NYR] | 0.22 [0.03;1.88] | 0.1281 | 0.5498 |
| >= 1 Year | 60 | 5 (8.3%) | NYR [NYR;NYR] | 50 | 10 (20.0%) | NYR [21.39;NYR] | 0.35 [0.12;1.03] | 0.0462 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:14:52

TABLE 5.22.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 2 (16.7%) | NYR [7.03;NYR] | <0.01 [<0.01;NE] | 0.1663 | 0.9923 |
| Yes | 63 | 6 (9.5%) | NYR [NYR;NYR] | 59 | 13 (22.0%) | NYR [21.39;NYR] | 0.35 [0.13;0.92] | 0.0270 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 5 (7.8%) | NYR [NYR;NYR] | 65 | 14 (21.5%) | NYR [22.54;NYR] | 0.29 [0.10;0.81] | 0.0125 | 0.7328 |
| Yes | 10 | 1 (10.0%) | NYR [10.84;NYR] | 6 | 1 (16.7%) | NYR [1.41;NYR] | 0.59 [0.04;9.36] | 0.7017 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NYR [7.36;NYR] | 10 | 2 (20.0%) | NYR [2.79;NYR] | 0.75 [0.10;5.43] | 0.7765 | 0.6191 |
| < 1% | 61 | 4 (6.6%) | NYR [NYR;NYR] | 60 | 13 (21.7%) | NYR [21.39;NYR] | 0.25 [0.08;0.76] | 0.0082 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 4 (20.0%) | 22.54 [22.54;NYR] | 0.22 [0.02;2.00] | 0.1416 | 0.7543 |
| Non-Stage IV | 53 | 5 (9.4%) | NYR [NYR;NYR] | 51 | 11 (21.6%) | NYR [21.39;NYR] | 0.35 [0.12;1.02] | 0.0452 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:14:52

TABLE 5.23.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 10 (13.5%) | 23 (32.4%) |
| Number of censored cases | N | 64 (86.5%) | 48 (67.6%) |
| Time to first event (Months) | Mean (SE) | 7.26 (0.22) | 5.91 (0.34) |
| | Q1 [95% CI] | NYR [NYR;NYR] | 3.40 [1.22;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0058 | |
| Stratified Cox PH model | HR (b) | 0.37 [0.17;0.77] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:21:15

TABLE 5.23.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 10 (13.5%) | NYR [NYR;NYR] | 71 | 23 (32.4%) | NYR [NYR;NYR] | 0.37 [0.17;0.77] | 0.0058 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 13 (27.7%) | NYR [NYR;NYR] | 0.38 [0.13;1.06] | 0.0548 | 0.7880 |
| >= 65 | 33 | 5 (15.2%) | NYR [NYR;NYR] | 24 | 10 (41.7%) | NYR [3.71;NYR] | 0.30 [0.10;0.89] | 0.0212 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NYR [NYR;NYR] | 47 | 13 (27.7%) | NYR [NYR;NYR] | 0.38 [0.13;1.06] | 0.0548 | 0.9991 |
| >= 65 AND < 75 | 25 | 5 (20.0%) | NYR [NYR;NYR] | 18 | 8 (44.4%) | NYR [3.71;NYR] | 0.38 [0.12;1.16] | 0.0762 | |
| >= 75 | 8 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 2 (33.3%) | NYR [0.69;NYR] | <0.01 [<0.01;NE] | 0.0872 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 7 (17.9%) | NYR [NYR;NYR] | 37 | 11 (29.7%) | NYR [NYR;NYR] | 0.54 [0.21;1.40] | 0.1981 | 0.2136 |
| Rest of World (ROW) | 35 | 3 (8.6%) | NYR [NYR;NYR] | 34 | 12 (35.3%) | NYR [3.71;NYR] | 0.20 [0.06;0.70] | 0.0054 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
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TABLE 5.23.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 9 (13.8%) | NYR [NYR;NYR] | 60 | 22 (36.7%) | NYR [7.72;NYR] | 0.31 [0.14;0.67] | 0.0017 | 0.3462 |
| Non-White | 9 | 1 (11.1%) | NYR [1.38;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 1.30 [0.08;20.75] | 0.8540 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NC | 13 | 6 (46.2%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 7 (16.3%) | NC | 32 | 8 (25.0%) | NC | NC | NC | |
| Not Reported | 24 | 2 (8.3%) | NC | 26 | 9 (34.6%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 9 (16.1%) | NYR [NYR;NYR] | 48 | 14 (29.2%) | NYR [NYR;NYR] | 0.48 [0.21;1.12] | 0.0834 | 0.1739 |
| Female | 18 | 1 (5.6%) | NYR [NYR;NYR] | 23 | 9 (39.1%) | NYR [1.38;NYR] | 0.12 [0.01;0.91] | 0.0136 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 8 (42.1%) | NYR [2.04;NYR] | 0.13 [0.02;1.08] | 0.0266 | 0.2578 |
| >= 1 Year | 60 | 9 (15.0%) | NYR [NYR;NYR] | 50 | 15 (30.0%) | NYR [NYR;NYR] | 0.44 [0.19;1.02] | 0.0485 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
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TABLE 5.23.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [7.85;NYR] | 12 | 4 (33.3%) | NYR [0.72;NYR] | 0.22 [0.02;1.98] | 0.1391 | 0.6056 |
| Yes | 63 | 9 (14.3%) | NYR [NYR;NYR] | 59 | 19 (32.2%) | NYR [NYR;NYR] | 0.39 [0.17;0.85] | 0.0150 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 10 (15.6%) | NYR [NYR;NYR] | 65 | 22 (33.8%) | NYR [NYR;NYR] | 0.39 [0.18;0.82] | 0.0102 | 0.9911 |
| Yes | 10 | 0 (0.0%) | NYR [NYR;NYR] | 6 | 1 (16.7%) | NYR [5.26;NYR] | <0.01 [<0.01;NE] | 0.1797 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 2 (20.0%) | NYR [0.72;NYR] | <0.01 [<0.01;NE] | 0.1277 | 0.9999 |
| < 1% | 61 | 10 (16.4%) | NYR [NYR;NYR] | 60 | 21 (35.0%) | NYR [NYR;NYR] | 0.40 [0.19;0.85] | 0.0135 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 4 (22.2%) | NYR [7.85;NYR] | 20 | 7 (35.0%) | NYR [2.50;NYR] | 0.52 [0.15;1.76] | 0.2848 | 0.4796 |
| Non-Stage IV | 53 | 6 (11.3%) | NYR [NYR;NYR] | 51 | 16 (31.4%) | NYR [NYR;NYR] | 0.31 [0.12;0.79] | 0.0095 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.24.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 65 (87.8%) | 64 (90.1%) |
| Number of censored cases | N | 9 (12.2%) | 7 (9.9%) |
| Time to first event (Months) | Mean (SE) | 5.09 (0.82) | 2.72 (0.58) |
| | Q1 [95% CI] | 1.00 [0.33;1.31] | 0.40 [0.30;0.46] |
| | Median [95% CI] | 1.79 [1.41;2.33] | 0.62 [0.46;0.95] |
| | Q3 [95% CI] | 6.20 [3.02;9.95] | 2.20 [1.61;3.45] |
| | p-value (a) | 0.0115 | |
| Stratified Cox PH model | HR (b) | 0.63 [0.44;0.90] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:27:55

TABLE 5.24.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 65 (87.8%) | 1.79 [1.41;2.33] | 71 | 64 (90.1%) | 0.62 [0.46;0.95] | 0.63 [0.44;0.90] | 0.0115 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 38 (92.7%) | 1.71 [0.95;2.33] | 47 | 42 (89.4%) | 0.76 [0.46;1.61] | 0.77 [0.49;1.20] | 0.2443 | 0.1573 |
| >= 65 | 33 | 27 (81.8%) | 1.84 [1.31;3.58] | 24 | 22 (91.7%) | 0.49 [0.36;1.64] | 0.46 [0.26;0.82] | 0.0085 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 38 (92.7%) | 1.71 [0.95;2.33] | 47 | 42 (89.4%) | 0.76 [0.46;1.61] | 0.77 [0.49;1.20] | 0.2443 | 0.0455 |
| >= 65 AND < 75 | 25 | 22 (88.0%) | 1.74 [1.31;4.17] | 18 | 16 (88.9%) | 0.49 [0.36;1.74] | 0.63 [0.33;1.21] | 0.1656 | |
| >= 75 | 8 | 5 (62.5%) | 2.71 [0.26;NYR] | 6 | 6 (100.0%) | 0.49 [0.26;0.66] | 0.07 [0.01;0.59] | 0.0021 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 37 (94.9%) | 1.84 [1.41;2.33] | 37 | 33 (89.2%) | 0.49 [0.43;1.74] | 0.77 [0.48;1.24] | 0.2893 | 0.1970 |
| Rest of World (ROW) | 35 | 28 (80.0%) | 1.74 [0.99;4.30] | 34 | 31 (91.2%) | 0.64 [0.43;1.61] | 0.49 [0.28;0.85] | 0.0104 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:27:55

TABLE 5.24.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 59 (90.8%) | 1.74 [1.41;2.33] | 60 | 53 (88.3%) | 0.69 [0.49;1.71] | 0.71 [0.49;1.03] | 0.0729 | 0.0473 |
| Non-White | 9 | 6 (66.7%) | 2.33 [0.23;NYR] | 11 | 11 (100.0%) | 0.43 [0.26;1.61] | 0.34 [0.11;1.04] | 0.0513 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 5 (71.4%) | 2.30 [0.26;NYR] | 13 | 11 (84.6%) | 1.61 [0.36;1.87] | 0.51 [0.17;1.50] | 0.2092 | 0.6873 |
| Not Hispanic or Latino | 43 | 41 (95.3%) | 1.71 [1.31;2.33] | 32 | 29 (90.6%) | 0.49 [0.39;0.85] | 0.69 [0.43;1.12] | 0.1343 | |
| Not Reported | 24 | 19 (79.2%) | 1.69 [1.02;9.00] | 26 | 24 (92.3%) | 0.66 [0.43;1.94] | 0.52 [0.28;0.96] | 0.0368 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 50 (89.3%) | 1.74 [1.31;2.33] | 48 | 43 (89.6%) | 0.66 [0.43;1.87] | 0.69 [0.46;1.04] | 0.0756 | 0.3722 |
| Female | 18 | 15 (83.3%) | 1.79 [1.31;4.17] | 23 | 21 (91.3%) | 0.49 [0.43;1.25] | 0.49 [0.25;0.96] | 0.0381 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 13 (92.9%) | 2.32 [0.33;7.52] | 19 | 18 (94.7%) | 0.49 [0.30;1.71] | 0.37 [0.16;0.86] | 0.0170 | 0.3352 |
| >= 1 Year | 60 | 52 (86.7%) | 1.68 [1.35;2.33] | 50 | 44 (88.0%) | 0.69 [0.46;1.61] | 0.67 [0.45;1.01] | 0.0563 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.24.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 11 (100.0%) | 1.61 [0.33;3.84] | 12 | 11 (91.7%) | 0.71 [0.26;3.25] | 0.68 [0.27;1.72] | 0.4231 | 0.3181 |
| Yes | 63 | 54 (85.7%) | 1.94 [1.41;2.86] | 59 | 53 (89.8%) | 0.62 [0.46;0.95] | 0.60 [0.41;0.88] | 0.0082 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 55 (85.9%) | 1.84 [1.41;2.33] | 65 | 58 (89.2%) | 0.66 [0.49;1.61] | 0.61 [0.42;0.89] | 0.0104 | 0.8919 |
| Yes | 10 | 10 (100.0%) | 1.30 [0.16;3.02] | 6 | 6 (100.0%) | 0.44 [0.13;11.37] | 0.73 [0.24;2.23] | 0.5737 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 9 (81.8%) | 2.27 [0.26;9.17] | 10 | 8 (80.0%) | 0.62 [0.13;1.71] | 0.57 [0.22;1.52] | 0.2602 | 0.3749 |
| < 1% | 61 | 54 (88.5%) | 1.84 [1.41;2.33] | 60 | 55 (91.7%) | 0.59 [0.46;0.95] | 0.61 [0.42;0.90] | 0.0118 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 17 (94.4%) | 1.79 [1.15;4.17] | 20 | 18 (90.0%) | 0.74 [0.30;2.33] | 0.59 [0.30;1.18] | 0.1346 | 0.8014 |
| Non-Stage IV | 53 | 45 (84.9%) | 1.94 [1.31;3.02] | 51 | 46 (90.2%) | 0.49 [0.43;0.95] | 0.61 [0.40;0.92] | 0.0200 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:27:55

TABLE 5.25.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 56 (75.7%) | 37 (52.1%) |
| Number of censored cases | N | 18 (24.3%) | 34 (47.9%) |
| Time to first event (Months) | Mean (SE) | 9.46 (1.15) | 9.10 (0.81) |
| | Q1 [95% CI] | 1.60 [1.08;1.94] | 2.20 [1.61;3.48] |
| | Median [95% CI] | 4.37 [2.27;10.61] | 9.36 [3.88;NYR] |
| | Q3 [95% CI] | 17.40 [12.94;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0260 | |
| Stratified Cox PH model | HR (b) | 1.61 [1.06;2.45] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:35:00

TABLE 5.25.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 56 (75.7%) | 4.37 [2.27;10.61] | 71 | 37 (52.1%) | 9.36 [3.88;NYR] | 1.61 [1.06;2.45] | 0.0260 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 36 (87.8%) | 2.33 [1.71;6.60] | 47 | 27 (57.4%) | 8.71 [3.48;NYR] | 1.85 [1.12;3.05] | 0.0144 | 0.5657 |
| >= 65 | 33 | 20 (60.6%) | 6.77 [2.30;NYR] | 24 | 10 (41.7%) | NYR [2.14;NYR] | 1.39 [0.65;2.98] | 0.3910 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 36 (87.8%) | 2.33 [1.71;6.60] | 47 | 27 (57.4%) | 8.71 [3.48;NYR] | 1.85 [1.12;3.05] | 0.0144 | 0.2432 |
| >= 65 AND < 75 | 25 | 17 (68.0%) | 6.77 [2.27;16.59] | 18 | 7 (38.9%) | NYR [2.14;NYR] | 1.88 [0.78;4.54] | 0.1550 | |
| >= 75 | 8 | 3 (37.5%) | NYR [1.51;NYR] | 6 | 3 (50.0%) | NYR [0.56;NYR] | 0.57 [0.11;2.87] | 0.4935 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 33 (84.6%) | 2.27 [1.61;6.18] | 37 | 17 (45.9%) | 11.37 [3.71;NYR] | 2.43 [1.35;4.38] | 0.0022 | 0.0404 |
| Rest of World (ROW) | 35 | 23 (65.7%) | 10.61 [2.66;17.41] | 34 | 20 (58.8%) | 5.13 [2.99;NYR] | 1.00 [0.55;1.83] | 0.9892 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:35:00

TABLE 5.25.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 50 (76.9%) | 4.17 [1.94;8.54] | 60 | 30 (50.0%) | 11.37 [4.27;NYR] | 1.79 [1.14;2.82] | 0.0104 | 0.1880 |
| Non-White | 9 | 6 (66.7%) | 13.01 [0.33;NYR] | 11 | 7 (63.6%) | 3.45 [0.43;NYR] | 0.82 [0.27;2.46] | 0.7249 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 4 (57.1%) | 4.93 [2.27;NYR] | 13 | 8 (61.5%) | 4.86 [1.61;NYR] | 0.74 [0.22;2.45] | 0.6156 | 0.2211 |
| Not Hispanic or Latino | 43 | 35 (81.4%) | 2.33 [1.71;6.77] | 32 | 15 (46.9%) | NYR [3.25;NYR] | 2.21 [1.21;4.06] | 0.0084 | |
| Not Reported | 24 | 17 (70.8%) | 9.58 [1.71;17.41] | 26 | 14 (53.8%) | 11.37 [2.99;NYR] | 1.32 [0.65;2.69] | 0.4372 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 44 (78.6%) | 2.50 [1.84;8.54] | 48 | 26 (54.2%) | 9.36 [3.88;NYR] | 1.79 [1.10;2.91] | 0.0174 | 0.3455 |
| Female | 18 | 12 (66.7%) | 6.11 [2.37;17.41] | 23 | 11 (47.8%) | NYR [2.14;NYR] | 1.09 [0.48;2.48] | 0.8409 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 11 (78.6%) | 11.78 [1.71;14.16] | 19 | 10 (52.6%) | 15.24 [3.48;NYR] | 1.71 [0.71;4.07] | 0.2235 | 0.8713 |
| >= 1 Year | 60 | 45 (75.0%) | 3.70 [1.91;6.77] | 50 | 25 (50.0%) | 8.71 [3.06;NYR] | 1.67 [1.03;2.73] | 0.0370 | |
| Not Reported | 0 | 0/0 | NC | 2 | 2 (100.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.25.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 10 (90.9%) | 2.66 [1.61;4.93] | 12 | 7 (58.3%) | 4.86 [2.83;NYR] | 2.34 [0.88;6.18] | 0.0787 | 0.4852 |
| Yes | 63 | 46 (73.0%) | 6.18 [2.27;12.94] | 59 | 30 (50.8%) | 9.36 [3.88;NYR] | 1.50 [0.95;2.38] | 0.0814 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 49 (76.6%) | 2.94 [1.94;6.77] | 65 | 33 (50.8%) | 9.36 [3.71;NYR] | 1.73 [1.11;2.69] | 0.0140 | 0.3283 |
| Yes | 10 | 7 (70.0%) | 16.59 [0.16;25.49] | 6 | 4 (66.7%) | 7.62 [2.14;NYR] | 0.65 [0.18;2.35] | 0.5044 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 8 (72.7%) | 10.71 [1.71;25.49] | 10 | 6 (60.0%) | 2.81 [0.26;NYR] | 0.83 [0.28;2.42] | 0.7283 | 0.3999 |
| < 1% | 61 | 47 (77.0%) | 3.22 [1.94;6.77] | 60 | 30 (50.0%) | 15.24 [4.27;NYR] | 1.82 [1.15;2.88] | 0.0094 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 12 (66.7%) | 12.94 [1.84;15.67] | 20 | 13 (65.0%) | 3.48 [0.82;15.70] | 0.88 [0.40;1.93] | 0.7462 | 0.0855 |
| Non-Stage IV | 53 | 41 (77.4%) | 4.37 [2.10;8.54] | 51 | 24 (47.1%) | 15.24 [4.27;NYR] | 1.93 [1.17;3.20] | 0.0092 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.26.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 12 (16.2%) | 26 (36.6%) |
| Number of censored cases | N | 62 (83.8%) | 45 (63.4%) |
| Time to first event (Months) | Mean (SE) | 12.23 (0.41) | 14.57 (1.12) |
| | Q1 [95% CI] | NYR [12.75;NYR] | 2.60 [0.85;10.81] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [18.17;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0008 | |
| Stratified Cox PH model | HR (b) | 0.32 [0.16;0.65] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:41:54

TABLE 5.26.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 12 (16.2%) | NYR [NYR;NYR] | 71 | 26 (36.6%) | NYR [18.17;NYR] | 0.32 [0.16;0.65] | 0.0008 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 8 (19.5%) | NYR [NYR;NYR] | 47 | 19 (40.4%) | NYR [9.69;NYR] | 0.35 [0.15;0.79] | 0.0088 | 0.9236 |
| >= 65 | 33 | 4 (12.1%) | NYR [NYR;NYR] | 24 | 7 (29.2%) | NYR [6.08;NYR] | 0.35 [0.10;1.20] | 0.0809 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 8 (19.5%) | NYR [NYR;NYR] | 47 | 19 (40.4%) | NYR [9.69;NYR] | 0.35 [0.15;0.79] | 0.0088 | 0.6260 |
| >= 65 AND < 75 | 25 | 2 (8.0%) | NYR [NYR;NYR] | 18 | 7 (38.9%) | NYR [2.10;NYR] | 0.15 [0.03;0.72] | 0.0063 | |
| >= 75 | 8 | 2 (25.0%) | NYR [0.56;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2051 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 7 (17.9%) | NYR [NYR;NYR] | 37 | 13 (35.1%) | NYR [6.93;NYR] | 0.38 [0.15;0.97] | 0.0356 | 0.6358 |
| Rest of World (ROW) | 35 | 5 (14.3%) | NYR [NYR;NYR] | 34 | 13 (38.2%) | 21.32 [9.69;NYR] | 0.28 [0.10;0.79] | 0.0104 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:41:54

TABLE 5.26.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 11 (16.9%) | NYR [NYR;NYR] | 60 | 21 (35.0%) | NYR [18.17;NYR] | 0.38 [0.18;0.79] | 0.0071 | 0.4004 |
| Non-White | 9 | 1 (11.1%) | NYR [11.73;NYR] | 11 | 5 (45.5%) | NYR [0.43;NYR] | 0.15 [0.02;1.38] | 0.0585 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 2 (28.6%) | NYR [2.17;NYR] | 13 | 5 (38.5%) | 18.17 [5.13;NYR] | 0.60 [0.12;3.12] | 0.5389 | 0.5551 |
| Not Hispanic or Latino | 43 | 6 (14.0%) | NYR [NYR;NYR] | 32 | 9 (28.1%) | NYR [21.32;NYR] | 0.42 [0.15;1.17] | 0.0870 | |
| Not Reported | 24 | 4 (16.7%) | NYR [NYR;NYR] | 26 | 12 (46.2%) | NYR [1.71;NYR] | 0.24 [0.08;0.76] | 0.0086 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 10 (17.9%) | NYR [NYR;NYR] | 48 | 21 (43.8%) | 21.32 [6.93;NYR] | 0.31 [0.14;0.65] | 0.0012 | 0.7916 |
| Female | 18 | 2 (11.1%) | NYR [NYR;NYR] | 23 | 5 (21.7%) | NYR [NYR;NYR] | 0.40 [0.08;2.08] | 0.2596 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 5 (35.7%) | NYR [7.43;NYR] | 19 | 7 (36.8%) | NYR [2.69;NYR] | 0.69 [0.22;2.19] | 0.5292 | 0.1320 |
| >= 1 Year | 60 | 7 (11.7%) | NYR [NYR;NYR] | 50 | 18 (36.0%) | NYR [18.17;NYR] | 0.25 [0.10;0.60] | 0.0009 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:41:54

TABLE 5.26.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 4 (33.3%) | NYR [0.85;NYR] | 0.22 [0.02;1.97] | 0.1374 | 0.5982 |
| Yes | 63 | 11 (17.5%) | NYR [NYR;NYR] | 59 | 22 (37.3%) | NYR [10.81;NYR] | 0.36 [0.17;0.74] | 0.0040 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 10 (15.6%) | NYR [NYR;NYR] | 65 | 22 (33.8%) | NYR [18.17;NYR] | 0.35 [0.17;0.75] | 0.0044 | 0.2717 |
| Yes | 10 | 2 (20.0%) | NYR [1.48;NYR] | 6 | 4 (66.7%) | 0.71 [0.13;NYR] | 0.17 [0.03;0.94] | 0.0222 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 3 (27.3%) | NYR [3.45;NYR] | 10 | 3 (30.0%) | NYR [0.13;NYR] | 0.75 [0.15;3.71] | 0.7201 | 0.4394 |
| < 1% | 61 | 8 (13.1%) | NYR [NYR;NYR] | 60 | 22 (36.7%) | NYR [10.81;NYR] | 0.26 [0.11;0.58] | 0.0004 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 1 (100.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 4 (22.2%) | NYR [11.73;NYR] | 20 | 5 (25.0%) | NYR [9.69;NYR] | 0.74 [0.20;2.76] | 0.6514 | 0.1161 |
| Non-Stage IV | 53 | 7 (13.2%) | NYR [NYR;NYR] | 51 | 21 (41.2%) | 21.32 [6.31;NYR] | 0.23 [0.10;0.54] | 0.0003 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:41:54

TABLE 5.27.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood thyroid stimulating hormone increased | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 11 (14.9%) | 3 (4.2%) |
| Number of censored cases | N | 63 (85.1%) | 68 (95.8%) |
| Time to first event (Months) | Mean (SE) | 17.34 (0.69) | 14.80 (0.32) |
| | Q1 [95% CI] | NYR [16.66;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0359 | |
| Stratified Cox PH model | HR (b) | 3.59 [1.00;12.89] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:48:05

TABLE 5.27.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood thyroid stimulating hormone increased - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 11 (14.9%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 3.59 [1.00;12.89] | 0.0359 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NC | 47 | 2 (4.3%) | NC | NC | NC | NC |
| >= 65 | 33 | 6 (18.2%) | NC | 24 | 1 (4.2%) | NC | NC | NC | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 5 (12.2%) | NC | 47 | 2 (4.3%) | NC | NC | NC | NC |
| >= 65 AND < 75 | 25 | 6 (24.0%) | NC | 18 | 1 (5.6%) | NC | NC | NC | |
| >= 75 | 8 | 0 (0.0%) | NC | 6 | 0 (0.0%) | NC | NC | NC | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NC | 37 | 0 (0.0%) | NC | NC | NC | NC |
| Rest of World (ROW) | 35 | 6 (17.1%) | NC | 34 | 3 (8.8%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:48:05

TABLE 5.27.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 8 (12.3%) | NC | 60 | 2 (3.3%) | NC | NC | NC | NC |
| Non-White | 9 | 3 (33.3%) | NC | 11 | 1 (9.1%) | NC | NC | NC | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NC | 13 | 2 (15.4%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 4 (9.3%) | NC | 32 | 1 (3.1%) | NC | NC | NC | |
| Not Reported | 24 | 6 (25.0%) | NC | 26 | 0 (0.0%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 7 (12.5%) | NC | 48 | 1 (2.1%) | NC | NC | NC | NC |
| Female | 18 | 4 (22.2%) | NC | 23 | 2 (8.7%) | NC | NC | NC | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | 0.9998 |
| >= 1 Year | 60 | 11 (18.3%) | NYR [NYR;NYR] | 50 | 3 (6.0%) | NYR [NYR;NYR] | 3.00 [0.84;10.79] | 0.0764 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:48:05

TABLE 5.27.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NC | 12 | 0 (0.0%) | NC | NC | NC | NC |
| Yes | 63 | 9 (14.3%) | NC | 59 | 3 (5.1%) | NC | NC | NC | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 9 (14.1%) | NC | 65 | 3 (4.6%) | NC | NC | NC | NC |
| Yes | 10 | 2 (20.0%) | NC | 6 | 0 (0.0%) | NC | NC | NC | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 0 (0.0%) | NYR [NYR;NYR] | 10 | 1 (10.0%) | NYR [0.72;NYR] | <0.01 [<0.01;NE] | 0.2943 | 1.0000 |
| < 1% | 61 | 11 (18.0%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 5.36 [1.19;24.20] | 0.0145 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NC | 20 | 1 (5.0%) | NC | NC | NC | NC |
| Non-Stage IV | 53 | 9 (17.0%) | NC | 51 | 2 (3.9%) | NC | NC | NC | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.28.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 8 (10.8%) | 17 (23.9%) |
| Number of censored cases | N | 66 (89.2%) | 54 (76.1%) |
| Time to first event (Months) | Mean (SE) | 6.17 (0.18) | 19.15 (1.14) |
| | Q1 [95% CI] | NYR [NYR;NYR] | 24.20 [2.10;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [24.15;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0278 | |
| Stratified Cox PH model | HR (b) | 0.40 [0.17;0.93] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:52:13

TABLE 5.28.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 8 (10.8%) | NYR [NYR;NYR] | 71 | 17 (23.9%) | NYR [24.15;NYR] | 0.40 [0.17;0.93] | 0.0278 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 3 (7.3%) | NC | 47 | 8 (17.0%) | NC | NC | NC | NC |
| >= 65 | 33 | 5 (15.2%) | NC | 24 | 9 (37.5%) | NC | NC | NC | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 3 (7.3%) | NC | 47 | 8 (17.0%) | NC | NC | NC | NC |
| >= 65 AND < 75 | 25 | 3 (12.0%) | NC | 18 | 9 (50.0%) | NC | NC | NC | |
| >= 75 | 8 | 2 (25.0%) | NC | 6 | 0 (0.0%) | NC | NC | NC | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 5 (12.8%) | NYR [NYR;NYR] | 37 | 7 (18.9%) | NYR [NYR;NYR] | 0.63 [0.20;1.98] | 0.4226 | 0.3016 |
| Rest of World (ROW) | 35 | 3 (8.6%) | NYR [NYR;NYR] | 34 | 10 (29.4%) | 24.15 [24.15;NYR] | 0.24 [0.07;0.87] | 0.0192 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.28.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 6 (9.2%) | NYR [NYR;NYR] | 60 | 14 (23.3%) | NYR [24.15;NYR] | 0.34 [0.13;0.89] | 0.0213 | 0.4863 |
| Non-White | 9 | 2 (22.2%) | NYR [0.92;NYR] | 11 | 3 (27.3%) | NYR [0.72;NYR] | 0.76 [0.13;4.57] | 0.7659 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NC | 13 | 4 (30.8%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 3 (7.0%) | NC | 32 | 6 (18.8%) | NC | NC | NC | |
| Not Reported | 24 | 4 (16.7%) | NC | 26 | 7 (26.9%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 5 (8.9%) | NYR [NYR;NYR] | 48 | 10 (20.8%) | NYR [24.15;NYR] | 0.37 [0.13;1.10] | 0.0628 | 0.8378 |
| Female | 18 | 3 (16.7%) | NYR [NYR;NYR] | 23 | 7 (30.4%) | NYR [14.75;NYR] | 0.46 [0.12;1.77] | 0.2456 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 0 (0.0%) | NYR [NYR;NYR] | 19 | 5 (26.3%) | NYR [2.14;NYR] | <0.01 [<0.01;NE] | 0.0404 | 0.9898 |
| >= 1 Year | 60 | 8 (13.3%) | NYR [NYR;NYR] | 50 | 12 (24.0%) | NYR [24.15;NYR] | 0.50 [0.20;1.22] | 0.1182 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:52:13

TABLE 5.28.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3384 | 0.9920 |
| Yes | 63 | 8 (12.7%) | NYR [NYR;NYR] | 59 | 16 (27.1%) | NYR [24.15;NYR] | 0.41 [0.17;0.96] | 0.0328 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 7 (10.9%) | NYR [NYR;NYR] | 65 | 15 (23.1%) | NYR [24.15;NYR] | 0.41 [0.17;1.01] | 0.0460 | 0.6208 |
| Yes | 10 | 1 (10.0%) | NYR [1.18;NYR] | 6 | 2 (33.3%) | NYR [0.62;NYR] | 0.25 [0.02;2.73] | 0.2159 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 1 (9.1%) | NYR [NYR;NYR] | 10 | 4 (40.0%) | NYR [0.69;NYR] | 0.18 [0.02;1.63] | 0.0877 | 0.6660 |
| < 1% | 61 | 7 (11.5%) | NYR [NYR;NYR] | 60 | 13 (21.7%) | NYR [24.15;NYR] | 0.47 [0.19;1.18] | 0.0995 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 4 (20.0%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.0439 | 0.9889 |
| Non-Stage IV | 53 | 8 (15.1%) | NYR [NYR;NYR] | 51 | 13 (25.5%) | NYR [24.15;NYR] | 0.52 [0.21;1.25] | 0.1348 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:52:13

TABLE 5.29.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Weight decreased | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 13 (17.6%) | 3 (4.2%) |
| Number of censored cases | N | 61 (82.4%) | 68 (95.8%) |
| Time to first event (Months) | Mean (SE) | 15.70 (0.65) | 27.99 (0.65) |
| | Q1 [95% CI] | NYR [12.29;NYR] | 28.80 [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | 28.75 [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | 28.80 [NYR;NYR] |
| | p-value (a) | 0.0053 | |
| Stratified Cox PH model | HR (b) | 6.36 [1.43;28.26] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:57:56

TABLE 5.29.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Weight decreased - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 13 (17.6%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | 28.75 [NYR;NYR] | 6.36 [1.43;28.26] | 0.0053 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 6 (14.6%) | NC | 47 | 3 (6.4%) | NC | NC | NC | NC |
| >= 65 | 33 | 7 (21.2%) | NC | 24 | 0 (0.0%) | NC | NC | NC | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 6 (14.6%) | NC | 47 | 3 (6.4%) | NC | NC | NC | NC |
| >= 65 AND < 75 | 25 | 4 (16.0%) | NC | 18 | 0 (0.0%) | NC | NC | NC | |
| >= 75 | 8 | 3 (37.5%) | NC | 6 | 0 (0.0%) | NC | NC | NC | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 3 (7.7%) | NYR [NYR;NYR] | 37 | 2 (5.4%) | NYR [NYR;NYR] | 1.21 [0.20;7.33] | 0.8324 | 0.0715 |
| Rest of World (ROW) | 35 | 10 (28.6%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | 28.75 [NYR;NYR] | >99.99 [<0.01;NE] | 0.0010 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:57:56

TABLE 5.29.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 13 (20.0%) | NYR [NYR;NYR] | 60 | 3 (5.0%) | 28.75 [NYR;NYR] | 6.03 [1.36;26.75] | 0.0070 | 0.9992 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 2 (28.6%) | NC | 13 | 0 (0.0%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 6 (14.0%) | NC | 32 | 1 (3.1%) | NC | NC | NC | |
| Not Reported | 24 | 5 (20.8%) | NC | 26 | 2 (7.7%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 10 (17.9%) | NYR [NYR;NYR] | 48 | 2 (4.2%) | NYR [NYR;NYR] | 4.20 [0.92;19.17] | 0.0441 | 0.9269 |
| Female | 18 | 3 (16.7%) | NYR [NYR;NYR] | 23 | 1 (4.3%) | 28.75 [NYR;NYR] | 3.64 [0.38;35.04] | 0.2321 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 5 (35.7%) | NC | 19 | 1 (5.3%) | NC | NC | NC | NC |
| >= 1 Year | 60 | 8 (13.3%) | NC | 50 | 2 (4.0%) | NC | NC | NC | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:57:56

TABLE 5.29.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 4 (36.4%) | NC | 12 | 0 (0.0%) | NC | NC | NC | NC |
| Yes | 63 | 9 (14.3%) | NC | 59 | 3 (5.1%) | NC | NC | NC | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 11 (17.2%) | NYR [NYR;NYR] | 65 | 3 (4.6%) | 28.75 [NYR;NYR] | 3.63 [1.01;13.04] | 0.0341 | 0.9928 |
| Yes | 10 | 2 (20.0%) | NYR [2.56;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2605 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NC | 10 | 1 (10.0%) | NC | NC | NC | NC |
| < 1% | 61 | 9 (14.8%) | NC | 60 | 2 (3.3%) | NC | NC | NC | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 6 (33.3%) | NC | 20 | 2 (10.0%) | NC | NC | NC | NC |
| Non-Stage IV | 53 | 7 (13.2%) | NC | 51 | 1 (2.0%) | NC | NC | NC | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:57:56

TABLE 5.30.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 59 (79.7%) | 35 (49.3%) |
| Number of censored cases | N | 15 (20.3%) | 36 (50.7%) |
| Time to first event (Months) | Mean (SE) | 7.74 (0.84) | 10.46 (0.92) |
| | Q1 [95% CI] | 1.40 [0.53;1.91] | 1.40 [0.69;4.14] |
| | Median [95% CI] | 4.73 [2.33;8.90] | 16.56 [4.27;NYR] |
| | Q3 [95% CI] | 15.60 [9.23;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0052 | |
| Stratified Cox PH model | HR (b) | 1.81 [1.19;2.76] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:03:22

TABLE 5.30.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 59 (79.7%) | 4.73 [2.33;8.90] | 71 | 35 (49.3%) | 16.56 [4.27;NYR] | 1.81 [1.19;2.76] | 0.0052 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 34 (82.9%) | 4.63 [1.87;9.03] | 47 | 19 (40.4%) | NYR [4.83;NYR] | 2.55 [1.45;4.47] | 0.0007 | 0.0424 |
| >= 65 | 33 | 25 (75.8%) | 5.55 [1.87;11.93] | 24 | 16 (66.7%) | 4.62 [0.62;16.56] | 1.07 [0.57;2.01] | 0.8331 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 34 (82.9%) | 4.63 [1.87;9.03] | 47 | 19 (40.4%) | NYR [4.83;NYR] | 2.55 [1.45;4.47] | 0.0007 | 0.1266 |
| >= 65 AND < 75 | 25 | 19 (76.0%) | 5.55 [1.77;12.58] | 18 | 13 (72.2%) | 4.62 [0.49;16.56] | 1.02 [0.50;2.07] | 0.9616 | |
| >= 75 | 8 | 6 (75.0%) | 5.45 [0.49;NYR] | 6 | 3 (50.0%) | NYR [0.56;NYR] | 1.34 [0.33;5.42] | 0.6773 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 33 (84.6%) | 2.33 [1.41;5.29] | 37 | 19 (51.4%) | 15.61 [4.14;NYR] | 2.13 [1.21;3.75] | 0.0074 | 0.4732 |
| Rest of World (ROW) | 35 | 26 (74.3%) | 7.13 [2.56;13.14] | 34 | 16 (47.1%) | 17.28 [2.10;NYR] | 1.60 [0.86;2.98] | 0.1396 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:03:22

TABLE 5.30.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 54 (83.1%) | 3.48 [1.87;6.54] | 60 | 28 (46.7%) | 17.28 [4.96;NYR] | 2.25 [1.42;3.56] | 0.0004 | 0.0231 |
| Non-White | 9 | 5 (55.6%) | 17.02 [2.37;NYR] | 11 | 7 (63.6%) | 3.45 [0.49;NYR] | 0.51 [0.16;1.64] | 0.2518 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 5 (71.4%) | 0.95 [0.23;NYR] | 13 | 9 (69.2%) | 3.45 [0.46;NYR] | 1.22 [0.41;3.66] | 0.7222 | 0.0673 |
| Not Hispanic or Latino | 43 | 38 (88.4%) | 2.14 [1.45;3.61] | 32 | 13 (40.6%) | NYR [4.14;NYR] | 3.23 [1.72;6.10] | 0.0001 | |
| Not Reported | 24 | 16 (66.7%) | 12.53 [6.54;18.17] | 26 | 13 (50.0%) | 16.56 [2.04;NYR] | 1.11 [0.53;2.32] | 0.7732 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 45 (80.4%) | 2.91 [1.87;8.90] | 48 | 20 (41.7%) | NYR [6.47;NYR] | 2.55 [1.50;4.33] | 0.0003 | 0.0211 |
| Female | 18 | 14 (77.8%) | 6.39 [3.61;17.02] | 23 | 15 (65.2%) | 4.14 [0.85;16.56] | 0.87 [0.42;1.81] | 0.6959 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 10 (71.4%) | 9.23 [5.29;18.27] | 19 | 11 (57.9%) | 15.61 [0.69;NYR] | 1.02 [0.43;2.42] | 0.9493 | 0.1106 |
| >= 1 Year | 60 | 49 (81.7%) | 2.91 [1.77;6.24] | 50 | 23 (46.0%) | NYR [4.14;NYR] | 2.20 [1.34;3.62] | 0.0014 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:03:22

TABLE 5.30.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 10 (90.9%) | 5.09 [0.95;18.17] | 12 | 6 (50.0%) | 15.61 [2.04;NYR] | 2.07 [0.75;5.73] | 0.1500 | 0.8282 |
| Yes | 63 | 49 (77.8%) | 4.67 [2.14;8.90] | 59 | 29 (49.2%) | 16.56 [4.14;NYR] | 1.77 [1.12;2.80] | 0.0136 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 50 (78.1%) | 5.19 [2.33;9.03] | 65 | 31 (47.7%) | 17.28 [4.14;NYR] | 1.80 [1.15;2.82] | 0.0090 | 0.9120 |
| Yes | 10 | 9 (90.0%) | 2.22 [0.26;13.14] | 6 | 4 (66.7%) | 11.43 [0.62;NYR] | 1.96 [0.59;6.50] | 0.2640 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 10 (90.9%) | 6.24 [0.53;15.51] | 10 | 5 (50.0%) | 16.39 [0.36;NYR] | 2.35 [0.78;7.11] | 0.1213 | 0.9530 |
| < 1% | 61 | 47 (77.0%) | 4.67 [2.14;9.23] | 60 | 30 (50.0%) | 16.56 [4.14;NYR] | 1.70 [1.08;2.69] | 0.0215 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 14 (77.8%) | 8.02 [2.17;14.16] | 20 | 13 (65.0%) | 4.96 [2.00;17.28] | 1.05 [0.49;2.23] | 0.8904 | 0.1121 |
| Non-Stage IV | 53 | 42 (79.2%) | 4.63 [1.87;9.03] | 51 | 22 (43.1%) | NYR [4.14;NYR] | 2.17 [1.29;3.65] | 0.0026 | |
| Not Reported | 3 | 3 (100.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:03:22

TABLE 5.31.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 33 (44.6%) | 15 (21.1%) |
| Number of censored cases | N | 41 (55.4%) | 56 (78.9%) |
| Time to first event (Months) | Mean (SE) | 12.46 (0.84) | 10.88 (0.56) |
| | Q1 [95% CI] | 3.80 [2.37;9.23] | NYR [4.27;NYR] |
| | Median [95% CI] | NYR [11.93;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0143 | |
| Stratified Cox PH model | HR (b) | 2.11 [1.15;3.89] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:10:19

TABLE 5.31.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 33 (44.6%) | NYR [11.93;NYR] | 71 | 15 (21.1%) | NYR [NYR;NYR] | 2.11 [1.15;3.89] | 0.0143 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 18 (43.9%) | NYR [9.69;NYR] | 47 | 6 (12.8%) | NYR [NYR;NYR] | 3.62 [1.44;9.12] | 0.0035 | 0.0537 |
| >= 65 | 33 | 15 (45.5%) | NYR [8.28;NYR] | 24 | 9 (37.5%) | NYR [4.27;NYR] | 1.06 [0.46;2.43] | 0.8797 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 18 (43.9%) | NYR [9.69;NYR] | 47 | 6 (12.8%) | NYR [NYR;NYR] | 3.62 [1.44;9.12] | 0.0035 | 0.0419 |
| >= 65 AND < 75 | 25 | 11 (44.0%) | NYR [8.28;NYR] | 18 | 9 (50.0%) | 7.13 [0.49;NYR] | 0.68 [0.28;1.66] | 0.4016 | |
| >= 75 | 8 | 4 (50.0%) | NYR [0.49;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0579 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 18 (46.2%) | 18.17 [9.69;NYR] | 37 | 7 (18.9%) | NYR [NYR;NYR] | 2.47 [1.03;5.91] | 0.0360 | 0.6670 |
| Rest of World (ROW) | 35 | 15 (42.9%) | NYR [7.13;NYR] | 34 | 8 (23.5%) | NYR [NYR;NYR] | 1.86 [0.79;4.40] | 0.1494 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:10:19

TABLE 5.31.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 30 (46.2%) | NYR [9.23;NYR] | 60 | 12 (20.0%) | NYR [NYR;NYR] | 2.44 [1.25;4.77] | 0.0069 | 0.3109 |
| Non-White | 9 | 3 (33.3%) | NYR [2.37;NYR] | 11 | 3 (27.3%) | NYR [0.49;NYR] | 0.98 [0.20;4.86] | 0.9762 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 5 (71.4%) | 2.37 [0.23;NYR] | 13 | 7 (53.8%) | 4.96 [0.46;NYR] | 1.29 [0.41;4.08] | 0.6551 | 0.2352 |
| Not Hispanic or Latino | 43 | 20 (46.5%) | 15.67 [8.28;NYR] | 32 | 3 (9.4%) | NYR [NYR;NYR] | 5.59 [1.66;18.82] | 0.0017 | |
| Not Reported | 24 | 8 (33.3%) | NYR [11.93;NYR] | 26 | 5 (19.2%) | NYR [NYR;NYR] | 1.58 [0.52;4.85] | 0.4144 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 24 (42.9%) | NYR [11.93;NYR] | 48 | 10 (20.8%) | NYR [NYR;NYR] | 2.18 [1.04;4.56] | 0.0339 | 0.9881 |
| Female | 18 | 9 (50.0%) | NYR [3.61;NYR] | 23 | 5 (21.7%) | NYR [13.11;NYR] | 2.14 [0.72;6.40] | 0.1614 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 5 (35.7%) | NYR [8.90;NYR] | 19 | 3 (15.8%) | NYR [NYR;NYR] | 2.02 [0.48;8.44] | 0.3277 | 0.9711 |
| >= 1 Year | 60 | 28 (46.7%) | NYR [8.28;NYR] | 50 | 12 (24.0%) | NYR [NYR;NYR] | 1.98 [1.01;3.89] | 0.0438 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:10:19

TABLE 5.31.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 6 (54.5%) | 18.17 [2.56;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | 7.05 [0.85;58.69] | 0.0353 | 0.2398 |
| Yes | 63 | 27 (42.9%) | NYR [9.69;NYR] | 59 | 14 (23.7%) | NYR [NYR;NYR] | 1.81 [0.95;3.46] | 0.0662 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 27 (42.2%) | NYR [12.58;NYR] | 65 | 15 (23.1%) | NYR [NYR;NYR] | 1.79 [0.95;3.36] | 0.0666 | 0.9849 |
| Yes | 10 | 6 (60.0%) | 4.63 [1.35;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0252 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 6 (54.5%) | 15.51 [0.53;NYR] | 10 | 2 (20.0%) | NYR [0.36;NYR] | 2.86 [0.58;14.22] | 0.1780 | 0.8637 |
| < 1% | 61 | 25 (41.0%) | NYR [12.58;NYR] | 60 | 13 (21.7%) | NYR [NYR;NYR] | 1.86 [0.95;3.64] | 0.0646 | |
| Not Reported | 2 | 2 (100.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 10 (55.6%) | 15.38 [7.13;NYR] | 20 | 4 (20.0%) | NYR [13.11;NYR] | 3.07 [0.96;9.79] | 0.0459 | 0.4620 |
| Non-Stage IV | 53 | 21 (39.6%) | NYR [15.21;NYR] | 51 | 11 (21.6%) | NYR [NYR;NYR] | 1.77 [0.86;3.68] | 0.1177 | |
| Not Reported | 3 | 2 (66.7%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
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Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:10:20

TABLE 5.32.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 16 (21.6%) | 3 (4.2%) |
| Number of censored cases | N | 58 (78.4%) | 68 (95.8%) |
| Time to first event (Months) | Mean (SE) | 16.74 (0.72) | 0.69 (0.00) |
| | Q1 [95% CI] | 19.40 [9.59;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0050 | |
| Stratified Cox PH model | HR (b) | 4.93 [1.44;16.93] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:17:11

TABLE 5.32.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 16 (21.6%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 4.93 [1.44;16.93] | 0.0050 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 13 (31.7%) | NYR [19.48;NYR] | 47 | 2 (4.3%) | NYR [NYR;NYR] | 7.05 [1.59;31.30] | 0.0027 | 0.3696 |
| >= 65 | 33 | 3 (9.1%) | NYR [NYR;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 2.05 [0.21;19.77] | 0.5243 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 13 (31.7%) | NYR [19.48;NYR] | 47 | 2 (4.3%) | NYR [NYR;NYR] | 7.05 [1.59;31.30] | 0.0027 | 0.5316 |
| >= 65 AND < 75 | 25 | 2 (8.0%) | NYR [NYR;NYR] | 18 | 1 (5.6%) | NYR [NYR;NYR] | 1.32 [0.12;14.54] | 0.8224 | |
| >= 75 | 8 | 1 (12.5%) | NYR [2.60;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3865 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 10 (25.6%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 9.45 [1.21;73.90] | 0.0088 | 0.3375 |
| Rest of World (ROW) | 35 | 6 (17.1%) | NYR [NYR;NYR] | 34 | 2 (5.9%) | NYR [NYR;NYR] | 2.63 [0.53;13.08] | 0.2180 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:17:11

TABLE 5.32.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 15 (23.1%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 6.90 [1.58;30.19] | 0.0028 | 0.2317 |
| Non-White | 9 | 1 (11.1%) | NYR [16.76;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 0.93 [0.06;15.32] | 0.9620 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 1 (7.7%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.4631 | 0.5372 |
| Not Hispanic or Latino | 43 | 14 (32.6%) | NYR [16.76;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 11.00 [1.45;83.71] | 0.0036 | |
| Not Reported | 24 | 2 (8.3%) | NYR [NYR;NYR] | 26 | 1 (3.8%) | NYR [NYR;NYR] | 1.70 [0.15;18.94] | 0.6627 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 14 (25.0%) | NYR [NYR;NYR] | 48 | 3 (6.3%) | NYR [NYR;NYR] | 3.96 [1.14;13.78] | 0.0195 | 0.9911 |
| Female | 18 | 2 (11.1%) | NYR [16.76;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1746 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 4 (28.6%) | NYR [16.76;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | 5.24 [0.59;46.89] | 0.0978 | 0.6830 |
| >= 1 Year | 60 | 12 (20.0%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 9.87 [1.28;75.95] | 0.0067 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:17:11

TABLE 5.32.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 3 (27.3%) | NYR [9.23;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0992 | 0.9928 |
| Yes | 63 | 13 (20.6%) | NYR [NYR;NYR] | 59 | 3 (5.1%) | NYR [NYR;NYR] | 3.94 [1.12;13.84] | 0.0207 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 13 (20.3%) | NYR [NYR;NYR] | 65 | 2 (3.1%) | NYR [NYR;NYR] | 6.23 [1.41;27.63] | 0.0058 | 0.3631 |
| Yes | 10 | 3 (30.0%) | NYR [0.49;NYR] | 6 | 1 (16.7%) | NYR [0.66;NYR] | 1.90 [0.20;18.28] | 0.5728 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 3 (27.3%) | NYR [12.32;NYR] | 10 | 1 (10.0%) | NYR [0.69;NYR] | 2.55 [0.26;24.60] | 0.4013 | 0.8462 |
| < 1% | 61 | 12 (19.7%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 5.70 [1.28;25.50] | 0.0099 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 5 (27.8%) | NYR [9.59;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | 5.36 [0.63;45.89] | 0.0856 | 0.8751 |
| Non-Stage IV | 53 | 10 (18.9%) | NYR [NYR;NYR] | 51 | 2 (3.9%) | NYR [NYR;NYR] | 4.44 [0.97;20.29] | 0.0353 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.33.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 12 (16.2%) | 2 (2.8%) |
| Number of censored cases | N | 62 (83.8%) | 69 (97.2%) |
| Time to first event (Months) | Mean (SE) | 8.57 (0.27) | 3.61 (0.06) |
| | Q1 [95% CI] | NYR [8.90;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0107 | |
| Stratified Cox PH model | HR (b) | 5.63 [1.26;25.17] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:23:38

TABLE 5.33.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 12 (16.2%) | NYR [NYR;NYR] | 71 | 2 (2.8%) | NYR [NYR;NYR] | 5.63 [1.26;25.17] | 0.0107 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NC | 47 | 1 (2.1%) | NC | NC | NC | NC |
| >= 65 | 33 | 5 (15.2%) | NC | 24 | 1 (4.2%) | NC | NC | NC | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NC | 47 | 1 (2.1%) | NC | NC | NC | NC |
| >= 65 AND < 75 | 25 | 4 (16.0%) | NC | 18 | 1 (5.6%) | NC | NC | NC | |
| >= 75 | 8 | 1 (12.5%) | NC | 6 | 0 (0.0%) | NC | NC | NC | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 6 (15.4%) | NC | 37 | 2 (5.4%) | NC | NC | NC | NC |
| Rest of World (ROW) | 35 | 6 (17.1%) | NC | 34 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.33.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 12 (18.5%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 5.68 [1.27;25.39] | 0.0101 | 0.9995 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 2 (28.6%) | NC | 13 | 0 (0.0%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 6 (14.0%) | NC | 32 | 2 (6.3%) | NC | NC | NC | |
| Not Reported | 24 | 4 (16.7%) | NC | 26 | 0 (0.0%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 9 (16.1%) | NC | 48 | 1 (2.1%) | NC | NC | NC | NC |
| Female | 18 | 3 (16.7%) | NC | 23 | 1 (4.3%) | NC | NC | NC | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [NYR;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | 2.67 [0.24;29.48] | 0.4038 | 0.4659 |
| >= 1 Year | 60 | 10 (16.7%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 8.51 [1.09;66.45] | 0.0141 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.33.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NYR [3.71;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | 2.13 [0.19;23.45] | 0.5284 | 0.3319 |
| Yes | 63 | 10 (15.9%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 9.66 [1.24;75.47] | 0.0079 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 10 (15.6%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 10.24 [1.31;79.96] | 0.0059 | 0.1934 |
| Yes | 10 | 2 (20.0%) | NYR [0.99;NYR] | 6 | 1 (16.7%) | NYR [0.69;NYR] | 1.10 [0.10;12.17] | 0.9370 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 3 (27.3%) | NC | 10 | 0 (0.0%) | NC | NC | NC | NC |
| < 1% | 61 | 9 (14.8%) | NC | 60 | 2 (3.3%) | NC | NC | NC | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 0 (0.0%) | NYR [NYR;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3173 | 0.9903 |
| Non-Stage IV | 53 | 11 (20.8%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 10.85 [1.40;84.05] | 0.0042 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.34.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 16 (21.6%) | 1 (1.4%) |
| Number of censored cases | N | 58 (78.4%) | 70 (98.6%) |
| Time to first event (Months) | Mean (SE) | 17.83 (0.87) | 13.47 (.) |
| | Q1 [95% CI] | 21.40 [7.20;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0002 | |
| Stratified Cox PH model | HR (b) | 16.22 [2.15;>99.99] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:28:37

TABLE 5.34.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 16 (21.6%) | NYR [NYR;NYR] | 71 | 1 (1.4%) | NYR [NYR;NYR] | 16.22 [2.15;>99.99] | 0.0002 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 9 (22.0%) | NC | 47 | 1 (2.1%) | NC | NC | NC | NC |
| >= 65 | 33 | 7 (21.2%) | NC | 24 | 0 (0.0%) | NC | NC | NC | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 9 (22.0%) | NC | 47 | 1 (2.1%) | NC | NC | NC | NC |
| >= 65 AND < 75 | 25 | 6 (24.0%) | NC | 18 | 0 (0.0%) | NC | NC | NC | |
| >= 75 | 8 | 1 (12.5%) | NC | 6 | 0 (0.0%) | NC | NC | NC | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 8 (20.5%) | NC | 37 | 0 (0.0%) | NC | NC | NC | NC |
| Rest of World (ROW) | 35 | 8 (22.9%) | NC | 34 | 1 (2.9%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.34.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 14 (21.5%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 13.50 [1.78;>99.99] | 0.0010 | 0.9944 |
| Non-White | 9 | 2 (22.2%) | NYR [2.43;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1736 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 0 (0.0%) | NYR [NYR;NYR] | 13 | 1 (7.7%) | NYR [13.47;NYR] | <0.01 [<0.01;NE] | 0.4386 | 1.0000 |
| Not Hispanic or Latino | 43 | 11 (25.6%) | NYR [21.36;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0028 | |
| Not Reported | 24 | 5 (20.8%) | NYR [NYR;NYR] | 26 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0212 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 13 (23.2%) | NYR [NYR;NYR] | 48 | 1 (2.1%) | NYR [NYR;NYR] | 11.59 [1.52;88.67] | 0.0028 | 0.9922 |
| Female | 18 | 3 (16.7%) | NYR [NYR;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0636 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2705 | 0.9937 |
| >= 1 Year | 60 | 15 (25.0%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 13.26 [1.75;>99.99] | 0.0011 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:28:37

TABLE 5.34.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 1 (9.1%) | NYR [NYR;NYR] | 12 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.2963 | 0.9947 |
| Yes | 63 | 15 (23.8%) | NYR [NYR;NYR] | 59 | 1 (1.7%) | NYR [NYR;NYR] | 14.59 [1.93;>99.99] | 0.0006 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 12 (18.8%) | NYR [NYR;NYR] | 65 | 1 (1.5%) | NYR [NYR;NYR] | 12.16 [1.58;93.57] | 0.0021 | 0.9926 |
| Yes | 10 | 4 (40.0%) | 21.36 [0.92;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1341 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 3 (27.3%) | NYR [1.31;NYR] | 10 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1171 | 1.0000 |
| < 1% | 61 | 13 (21.3%) | NYR [NYR;NYR] | 60 | 1 (1.7%) | NYR [NYR;NYR] | 13.18 [1.72;>99.99] | 0.0012 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NYR [NYR;NYR] | 20 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.3026 | 0.9946 |
| Non-Stage IV | 53 | 14 (26.4%) | NYR [NYR;NYR] | 51 | 1 (2.0%) | NYR [NYR;NYR] | 13.68 [1.80;>99.99] | 0.0009 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
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Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:28:37

TABLE 5.35.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 14 (18.9%) | 4 (5.6%) |
| Number of censored cases | N | 60 (81.1%) | 67 (94.4%) |
| Time to first event (Months) | Mean (SE) | 13.11 (0.52) | 11.98 (0.31) |
| | Q1 [95% CI] | NYR [9.86;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0271 | |
| Stratified Cox PH model | HR (b) | 3.27 [1.07;9.95] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:34:47

TABLE 5.35.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 14 (18.9%) | NYR [NYR;NYR] | 71 | 4 (5.6%) | NYR [NYR;NYR] | 3.27 [1.07;9.95] | 0.0271 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 10 (24.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 11.80 [1.51;92.18] | 0.0027 | 0.0473 |
| >= 65 | 33 | 4 (12.1%) | NYR [NYR;NYR] | 24 | 3 (12.5%) | NYR [NYR;NYR] | 0.87 [0.20;3.91] | 0.8599 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 10 (24.4%) | NYR [NYR;NYR] | 47 | 1 (2.1%) | NYR [NYR;NYR] | 11.80 [1.51;92.18] | 0.0027 | 0.1336 |
| >= 65 AND < 75 | 25 | 3 (12.0%) | NYR [NYR;NYR] | 18 | 2 (11.1%) | NYR [NYR;NYR] | 1.02 [0.17;6.08] | 0.9861 | |
| >= 75 | 8 | 1 (12.5%) | NYR [2.56;NYR] | 6 | 1 (16.7%) | NYR [1.64;NYR] | 0.68 [0.04;10.98] | 0.7878 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 10 (25.6%) | NYR [NYR;NYR] | 37 | 3 (8.1%) | NYR [NYR;NYR] | 3.03 [0.83;11.03] | 0.0766 | 0.8767 |
| Rest of World (ROW) | 35 | 4 (11.4%) | NYR [NYR;NYR] | 34 | 1 (2.9%) | NYR [NYR;NYR] | 3.78 [0.42;33.88] | 0.2012 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:34:47

TABLE 5.35.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 11 (16.9%) | NYR [NYR;NYR] | 60 | 3 (5.0%) | NYR [NYR;NYR] | 3.35 [0.93;12.01] | 0.0487 | 0.9995 |
| Non-White | 9 | 3 (33.3%) | NYR [0.76;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 3.05 [0.31;29.81] | 0.3129 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NC | 13 | 1 (7.7%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 9 (20.9%) | NC | 32 | 2 (6.3%) | NC | NC | NC | |
| Not Reported | 24 | 4 (16.7%) | NC | 26 | 1 (3.8%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 13 (23.2%) | NYR [NYR;NYR] | 48 | 2 (4.2%) | NYR [NYR;NYR] | 5.61 [1.27;24.86] | 0.0104 | 0.1133 |
| Female | 18 | 1 (5.6%) | NYR [NYR;NYR] | 23 | 2 (8.7%) | NYR [NYR;NYR] | 0.58 [0.05;6.45] | 0.6539 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 2 (14.3%) | NYR [NYR;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | 2.44 [0.22;26.94] | 0.4521 | 0.8569 |
| >= 1 Year | 60 | 12 (20.0%) | NYR [NYR;NYR] | 50 | 3 (6.0%) | NYR [NYR;NYR] | 3.21 [0.90;11.37] | 0.0566 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:34:47

TABLE 5.35.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NYR [9.86;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | 1.84 [0.17;20.39] | 0.6139 | 0.6565 |
| Yes | 63 | 12 (19.0%) | NYR [NYR;NYR] | 59 | 3 (5.1%) | NYR [NYR;NYR] | 3.65 [1.03;12.92] | 0.0319 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 11 (17.2%) | NYR [NYR;NYR] | 65 | 4 (6.2%) | NYR [NYR;NYR] | 2.69 [0.86;8.47] | 0.0775 | 0.9917 |
| Yes | 10 | 3 (30.0%) | NYR [2.56;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1595 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 4 (36.4%) | NC | 10 | 1 (10.0%) | NC | NC | NC | NC |
| < 1% | 61 | 9 (14.8%) | NC | 60 | 3 (5.0%) | NC | NC | NC | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 3 (16.7%) | NYR [NYR;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | 3.36 [0.35;32.30] | 0.2651 | 0.9418 |
| Non-Stage IV | 53 | 10 (18.9%) | NYR [NYR;NYR] | 51 | 3 (5.9%) | NYR [NYR;NYR] | 2.95 [0.81;10.74] | 0.0851 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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TABLE 5.36.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 20 (27.0%) | 3 (4.2%) |
| Number of censored cases | N | 54 (73.0%) | 68 (95.8%) |
| Time to first event (Months) | Mean (SE) | 17.04 (0.95) | 6.22 (0.13) |
| | Q1 [95% CI] | 12.60 [4.50;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0004 | |
| Stratified Cox PH model | HR (b) | 6.70 [1.99;22.62] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:41:12

TABLE 5.36.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 20 (27.0%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 6.70 [1.99;22.62] | 0.0004 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 11 (26.8%) | NYR [21.62;NYR] | 47 | 2 (4.3%) | NYR [NYR;NYR] | 6.34 [1.40;28.60] | 0.0059 | 0.9378 |
| >= 65 | 33 | 9 (27.3%) | NYR [12.68;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 6.98 [0.88;55.13] | 0.0319 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 11 (26.8%) | NYR [21.62;NYR] | 47 | 2 (4.3%) | NYR [NYR;NYR] | 6.34 [1.40;28.60] | 0.0059 | 0.9670 |
| >= 65 AND < 75 | 25 | 6 (24.0%) | NYR [12.68;NYR] | 18 | 1 (5.6%) | NYR [NYR;NYR] | 4.49 [0.54;37.39] | 0.1275 | |
| >= 75 | 8 | 3 (37.5%) | NYR [0.53;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1069 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 9 (23.1%) | NYR [21.62;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 8.40 [1.06;66.36] | 0.0157 | 0.7832 |
| Rest of World (ROW) | 35 | 11 (31.4%) | NYR [12.29;NYR] | 34 | 2 (5.9%) | NYR [NYR;NYR] | 5.92 [1.31;26.71] | 0.0085 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:41:12

TABLE 5.36.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 17 (26.2%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 8.43 [1.95;36.48] | 0.0006 | 0.5051 |
| Non-White | 9 | 3 (33.3%) | NYR [0.53;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | 3.03 [0.31;29.64] | 0.3170 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [12.68;NYR] | 13 | 1 (7.7%) | NYR [6.37;NYR] | 1.41 [0.09;22.64] | 0.8055 | 0.5223 |
| Not Hispanic or Latino | 43 | 9 (20.9%) | NYR [21.62;NYR] | 32 | 1 (3.1%) | NYR [NYR;NYR] | 6.81 [0.86;53.81] | 0.0348 | |
| Not Reported | 24 | 10 (41.7%) | NYR [7.00;NYR] | 26 | 1 (3.8%) | NYR [NYR;NYR] | 12.11 [1.55;94.63] | 0.0023 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 16 (28.6%) | NYR [21.62;NYR] | 48 | 2 (4.2%) | NYR [NYR;NYR] | 7.54 [1.73;32.79] | 0.0015 | 0.7433 |
| Female | 18 | 4 (22.2%) | NYR [12.29;NYR] | 23 | 1 (4.3%) | NYR [NYR;NYR] | 4.61 [0.51;41.39] | 0.1332 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 4 (28.6%) | NYR [8.48;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | 4.96 [0.55;44.41] | 0.1123 | 0.8270 |
| >= 1 Year | 60 | 16 (26.7%) | NYR [21.62;NYR] | 50 | 2 (4.0%) | NYR [NYR;NYR] | 7.14 [1.64;31.06] | 0.0022 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:41:12

TABLE 5.36.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 2 (18.2%) | NYR [8.35;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | 1.72 [0.15;19.45] | 0.6555 | 0.2857 |
| Yes | 63 | 18 (28.6%) | NYR [21.62;NYR] | 59 | 2 (3.4%) | NYR [NYR;NYR] | 9.14 [2.12;39.42] | 0.0003 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 19 (29.7%) | NYR [NYR;NYR] | 65 | 3 (4.6%) | NYR [NYR;NYR] | 6.82 [2.02;23.03] | 0.0003 | 0.9927 |
| Yes | 10 | 1 (10.0%) | NYR [21.62;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | NE [NE;NE] | . | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 3 (27.3%) | NYR [12.68;NYR] | 10 | 1 (10.0%) | NYR [1.02;NYR] | 1.94 [0.20;18.85] | 0.5618 | 0.6205 |
| < 1% | 61 | 16 (26.2%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 8.46 [1.94;36.80] | 0.0006 | |
| Not Reported | 2 | 1 (50.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 3 (16.7%) | NYR [NYR;NYR] | 20 | 1 (5.0%) | NYR [NYR;NYR] | 3.33 [0.35;32.08] | 0.2683 | 0.5003 |
| Non-Stage IV | 53 | 17 (32.1%) | NYR [21.62;NYR] | 51 | 2 (3.9%) | NYR [NYR;NYR] | 8.64 [1.99;37.39] | 0.0005 | |
| Not Reported | 3 | 0 (0.0%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:41:12

TABLE 5.37.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 18 (24.3%) | 5 (7.0%) |
| Number of censored cases | N | 56 (75.7%) | 66 (93.0%) |
| Time to first event (Months) | Mean (SE) | 10.99 (0.48) | 9.15 (0.28) |
| | Q1 [95% CI] | 13.00 [4.80;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0101 | |
| Stratified Cox PH model | HR (b) | 3.41 [1.26;9.19] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:48:04

TABLE 5.37.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 18 (24.3%) | NYR [NYR;NYR] | 71 | 5 (7.0%) | NYR [NYR;NYR] | 3.41 [1.26;9.19] | 0.0101 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NYR [NYR;NYR] | 47 | 4 (8.5%) | NYR [NYR;NYR] | 1.86 [0.54;6.36] | 0.3143 | 0.2163 |
| >= 65 | 33 | 11 (33.3%) | NYR [7.72;NYR] | 24 | 1 (4.2%) | NYR [NYR;NYR] | 8.44 [1.09;65.40] | 0.0143 | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 7 (17.1%) | NYR [NYR;NYR] | 47 | 4 (8.5%) | NYR [NYR;NYR] | 1.86 [0.54;6.36] | 0.3143 | 0.8004 |
| >= 65 AND < 75 | 25 | 10 (40.0%) | NYR [4.80;NYR] | 18 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0052 | |
| >= 75 | 8 | 1 (12.5%) | NYR [0.72;NYR] | 6 | 1 (16.7%) | NYR [0.66;NYR] | 0.68 [0.04;10.98] | 0.7878 | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 7 (17.9%) | NYR [NYR;NYR] | 37 | 1 (2.7%) | NYR [NYR;NYR] | 6.35 [0.78;51.62] | 0.0472 | 0.4851 |
| Rest of World (ROW) | 35 | 11 (31.4%) | NYR [13.08;NYR] | 34 | 4 (11.8%) | NYR [NYR;NYR] | 2.72 [0.86;8.53] | 0.0754 | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:48:04

TABLE 5.37.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 15 (23.1%) | NYR [NYR;NYR] | 60 | 5 (8.3%) | NYR [NYR;NYR] | 2.71 [0.98;7.45] | 0.0446 | 0.9917 |
| Non-White | 9 | 3 (33.3%) | NYR [0.72;NYR] | 11 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0415 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 3 (42.9%) | NC | 13 | 2 (15.4%) | NC | NC | NC | NC |
| Not Hispanic or Latino | 43 | 7 (16.3%) | NC | 32 | 3 (9.4%) | NC | NC | NC | |
| Not Reported | 24 | 8 (33.3%) | NC | 26 | 0 (0.0%) | NC | NC | NC | |
| **Gender** | | | | | | | | | |
| Male | 56 | 12 (21.4%) | NYR [NYR;NYR] | 48 | 5 (10.4%) | NYR [NYR;NYR] | 2.03 [0.72;5.77] | 0.1738 | 0.9887 |
| Female | 18 | 6 (33.3%) | NYR [7.56;NYR] | 23 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0043 | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 4 (28.6%) | NYR [7.72;NYR] | 19 | 2 (10.5%) | NYR [NYR;NYR] | 2.63 [0.48;14.36] | 0.2471 | 0.6890 |
| >= 1 Year | 60 | 14 (23.3%) | NYR [NYR;NYR] | 50 | 3 (6.0%) | NYR [NYR;NYR] | 3.99 [1.15;13.90] | 0.0186 | |
| Not Reported | 0 | 0/0 | NC | 2 | 0 (0.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.37.2: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 3 (27.3%) | NYR [4.60;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | 3.15 [0.33;30.29] | 0.2943 | 0.9123 |
| Yes | 63 | 15 (23.8%) | NYR [NYR;NYR] | 59 | 4 (6.8%) | NYR [NYR;NYR] | 3.56 [1.18;10.74] | 0.0158 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 15 (23.4%) | NYR [NYR;NYR] | 65 | 5 (7.7%) | NYR [NYR;NYR] | 3.01 [1.09;8.28] | 0.0251 | 0.9907 |
| Yes | 10 | 3 (30.0%) | NYR [1.87;NYR] | 6 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.1595 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 4 (36.4%) | NYR [3.75;NYR] | 10 | 1 (10.0%) | NYR [0.46;NYR] | 3.48 [0.39;31.21] | 0.2344 | 0.9990 |
| < 1% | 61 | 14 (23.0%) | NYR [NYR;NYR] | 60 | 4 (6.7%) | NYR [NYR;NYR] | 3.42 [1.13;10.40] | 0.0211 | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 7 (38.9%) | NYR [7.72;NYR] | 20 | 2 (10.0%) | NYR [NYR;NYR] | 4.13 [0.86;19.88] | 0.0549 | 0.7957 |
| Non-Stage IV | 53 | 10 (18.9%) | NYR [NYR;NYR] | 51 | 3 (5.9%) | NYR [NYR;NYR] | 3.16 [0.87;11.49] | 0.0652 | |
| Not Reported | 3 | 1 (33.3%) | NC | 0 | 0/0 | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:48:04

TABLE 5.38.1: Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| Parameter | Measure | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|---|
| Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders | | | |
| Total number of subjects | N | 74 | 71 |
| Number of subjects with events | N | 11 (14.9%) | 3 (4.2%) |
| Number of censored cases | N | 63 (85.1%) | 68 (95.8%) |
| Time to first event (Months) | Mean (SE) | 15.23 (0.58) | 5.41 (0.07) |
| | Q1 [95% CI] | NYR [17.08;NYR] | NYR [NYR;NYR] |
| | Median [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | Q3 [95% CI] | NYR [NYR;NYR] | NYR [NYR;NYR] |
| | p-value (a) | 0.0355 | |
| Stratified Cox PH model | HR (b) | 3.60 [1.00;12.92] | |

a: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT.
b: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by factors defined above, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
NYR: (Median) Not Yet Reached.

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:54:08

TABLE 5.38.2: Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - by subgroups - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Safety Population A: Favorable risk (IMDC prognostic risk score = 0)** | | | | | | | | | |
| Overall | 74 | 11 (14.9%) | NYR [NYR;NYR] | 71 | 3 (4.2%) | NYR [NYR;NYR] | 3.60 [1.00;12.92] | 0.0355 | -- |
| **Age Categorization 1** | | | | | | | | | |
| < 65 | 41 | 4 (9.8%) | NC | 47 | 2 (4.3%) | NC | NC | NC | NC |
| >= 65 | 33 | 7 (21.2%) | NC | 24 | 1 (4.2%) | NC | NC | NC | |
| **Age Categorization 2** | | | | | | | | | |
| < 65 | 41 | 4 (9.8%) | NC | 47 | 2 (4.3%) | NC | NC | NC | NC |
| >= 65 AND < 75 | 25 | 6 (24.0%) | NC | 18 | 1 (5.6%) | NC | NC | NC | |
| >= 75 | 8 | 1 (12.5%) | NC | 6 | 0 (0.0%) | NC | NC | NC | |
| **Geographic Region (IRT)** | | | | | | | | | |
| US/Canada/Western Europe/Northern Europe | 39 | 7 (17.9%) | NC | 37 | 0 (0.0%) | NC | NC | NC | NC |
| Rest of World (ROW) | 35 | 4 (11.4%) | NC | 34 | 3 (8.8%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
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Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 5.38.2: Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Race subgroups** | | | | | | | | | |
| White | 65 | 11 (16.9%) | NYR [NYR;NYR] | 60 | 2 (3.3%) | NYR [NYR;NYR] | 5.13 [1.14;23.15] | 0.0177 | 0.9901 |
| Non-White | 9 | 0 (0.0%) | NYR [NYR;NYR] | 11 | 1 (9.1%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3657 | |
| **Ethnicity** | | | | | | | | | |
| Hispanic or Latino | 7 | 1 (14.3%) | NYR [5.55;NYR] | 13 | 2 (15.4%) | NYR [NYR;NYR] | 0.84 [0.08;9.29] | 0.8875 | 1.0000 |
| Not Hispanic or Latino | 43 | 10 (23.3%) | NYR [NYR;NYR] | 32 | 0 (0.0%) | NYR [NYR;NYR] | >99.99 [<0.01;NE] | 0.0053 | |
| Not Reported | 24 | 0 (0.0%) | NYR [NYR;NYR] | 26 | 1 (3.8%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3173 | |
| **Gender** | | | | | | | | | |
| Male | 56 | 8 (14.3%) | NC | 48 | 2 (4.2%) | NC | NC | NC | NC |
| Female | 18 | 3 (16.7%) | NC | 23 | 1 (4.3%) | NC | NC | NC | |
| **Time from Initial Diagnosis to Randomization (Year)** | | | | | | | | | |
| < 1 Year | 14 | 1 (7.1%) | NYR [NYR;NYR] | 19 | 1 (5.3%) | NYR [NYR;NYR] | 1.41 [0.09;22.53] | 0.8078 | 0.2862 |
| >= 1 Year | 60 | 10 (16.7%) | NYR [NYR;NYR] | 50 | 1 (2.0%) | NYR [NYR;NYR] | 8.50 [1.09;66.47] | 0.0143 | |
| Not Reported | 0 | 0/0 | NC | 2 | 1 (50.0%) | NC | NC | NC | |

a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:54:08

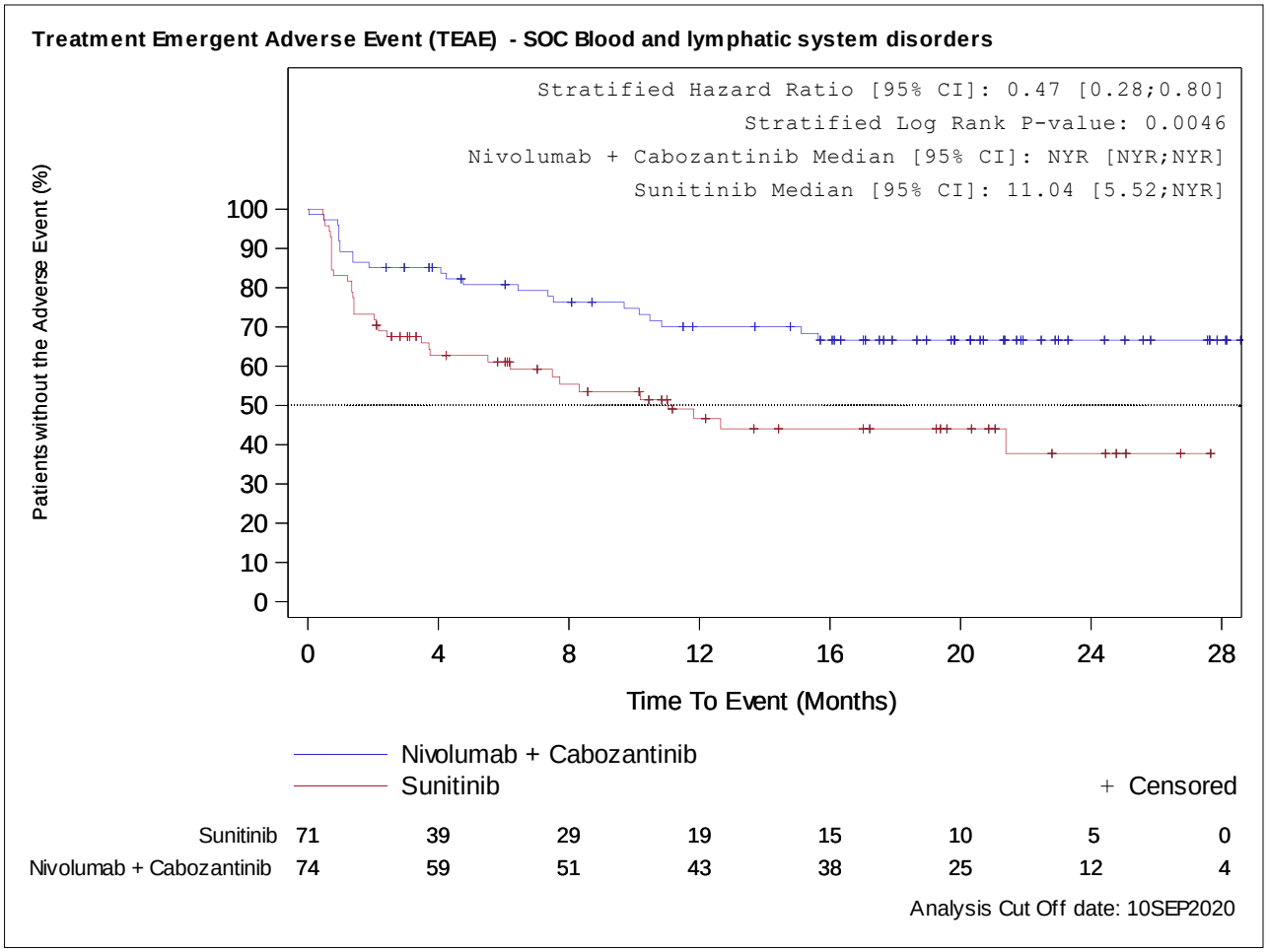
TABLE 5.38.2: Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| | Nivolumab + Cabozantinib | | | Sunitinib | | | Nivolumab + Cabozantinib vs. Sunitinib | | |
|---|---|---|---|---|---|---|---|---|---|
| Subgroup Value | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | N[a] | Subjects with events n (%) | Median [95% CI][b] (Months) | Hazard Ratio [95% CI][c] | p-value[d] | Interaction p[e] |
| **Prior nephrectomy** | | | | | | | | | |
| No | 11 | 0 (0.0%) | NYR [NYR;NYR] | 12 | 1 (8.3%) | NYR [NYR;NYR] | <0.01 [<0.01;NE] | 0.3384 | 0.9931 |
| Yes | 63 | 11 (17.5%) | NYR [NYR;NYR] | 59 | 2 (3.4%) | NYR [NYR;NYR] | 5.27 [1.17;23.78] | 0.0156 | |
| **Prior radiotherapy** | | | | | | | | | |
| No | 64 | 10 (15.6%) | NYR [NYR;NYR] | 65 | 2 (3.1%) | NYR [NYR;NYR] | 5.21 [1.14;23.79] | 0.0172 | 0.1764 |
| Yes | 10 | 1 (10.0%) | NYR [17.08;NYR] | 6 | 1 (16.7%) | NYR [5.49;NYR] | 0.45 [0.03;7.77] | 0.5755 | |
| **PD-L1+ Status Based on a 1% Cut Off** | | | | | | | | | |
| >= 1% | 11 | 2 (18.2%) | NC | 10 | 1 (10.0%) | NC | NC | NC | NC |
| < 1% | 61 | 9 (14.8%) | NC | 60 | 2 (3.3%) | NC | NC | NC | |
| Not Reported | 2 | 0 (0.0%) | NC | 1 | 0 (0.0%) | NC | NC | NC | |
| **Stage at Initial Diagnosis** | | | | | | | | | |
| Stage IV | 18 | 1 (5.6%) | NC | 20 | 1 (5.0%) | NC | NC | NC | NC |
| Non-Stage IV | 53 | 8 (15.1%) | NC | 51 | 2 (3.9%) | NC | NC | NC | |
| Not Reported | 3 | 2 (66.7%) | NC | 0 | 0/0 | NC | NC | NC | |

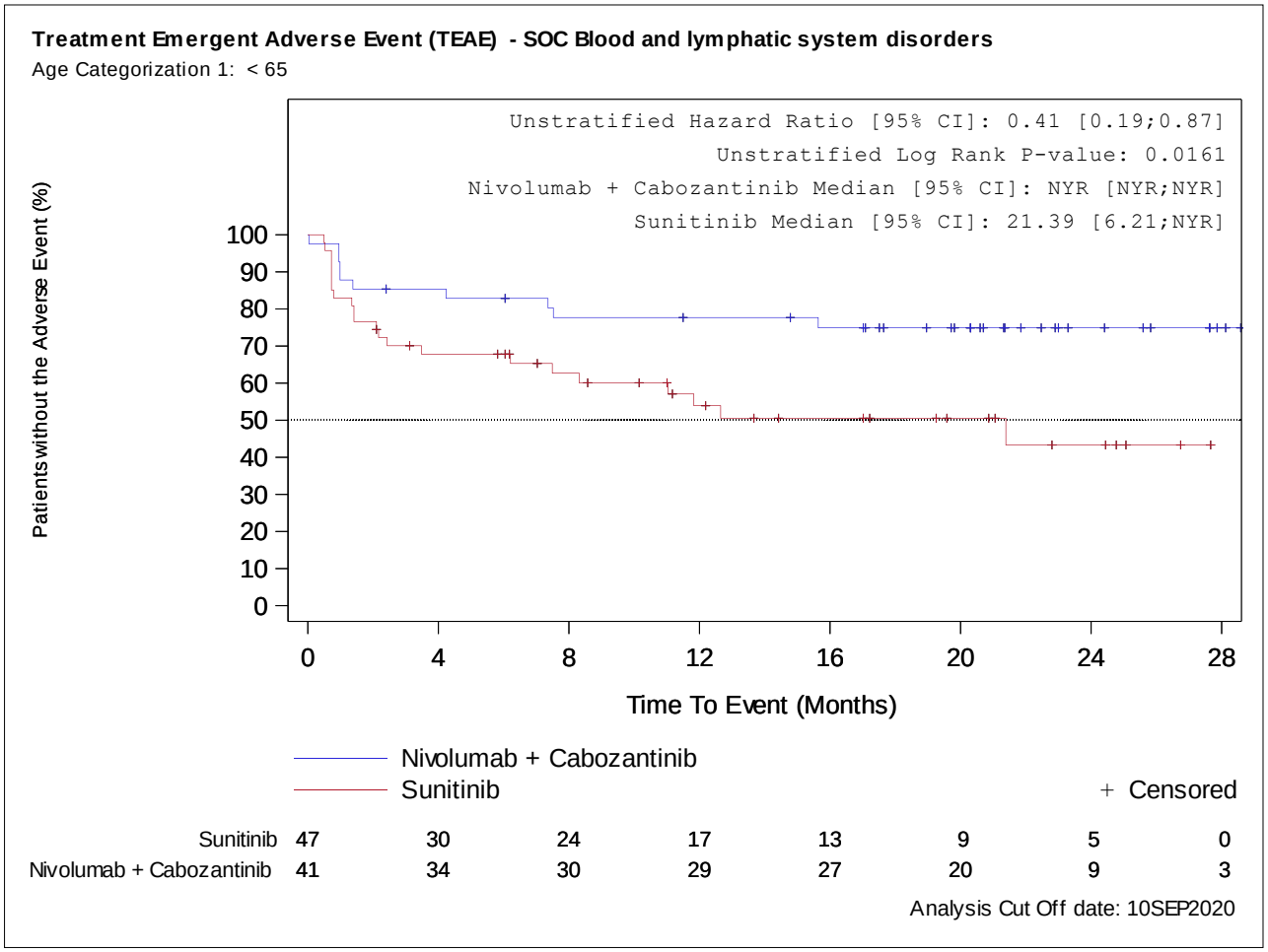
a: Number of patients in the Safety Population A: Favorable risk (IMDC prognostic risk score = 0).
b: Median and 95% CI were calculated using an unstratified product-limit estimator survival model.
c: The Hazard ratio was based on a Cox regression model (with treatment as the only covariate) stratified by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, and an unstratified model for subgroups, and was relative to the sunitinib group with <1 favoring the cabozantinib+nivolumab group.
d: P-value was based on a stratified log-rank test by PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, for the overall population, and unstratified for subgroups.
Subgroup analyses are only performed on SOC/PT for which the overall treatment was significant (Log Rank p-value <0.05) and if in at least one subgroup in one study arm 10 or more patients with event is presented
Subgroup analyses are only performed on the subjects for which the subgroup variable value is known and for which there are at least 10 subjects.
CI: Confidence Interval; NC: Not Calculated; NE: Not Estimable; NYR: (Median) Not Yet Reached; PT: Preferred Term; SOC: System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:54:08

FIGURE 5.1.1: Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:05:28

FIGURE 5.1.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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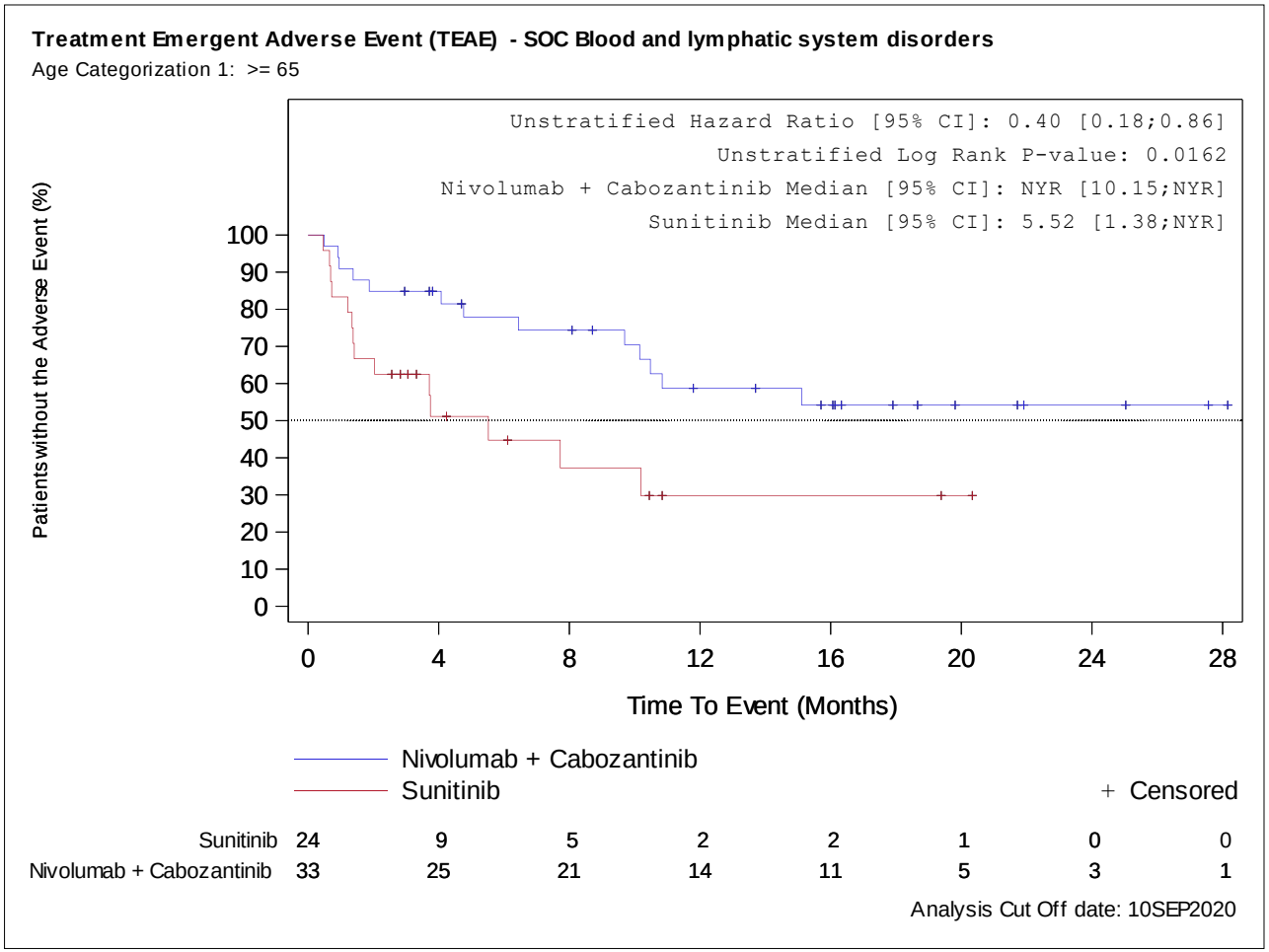
FIGURE 5.1.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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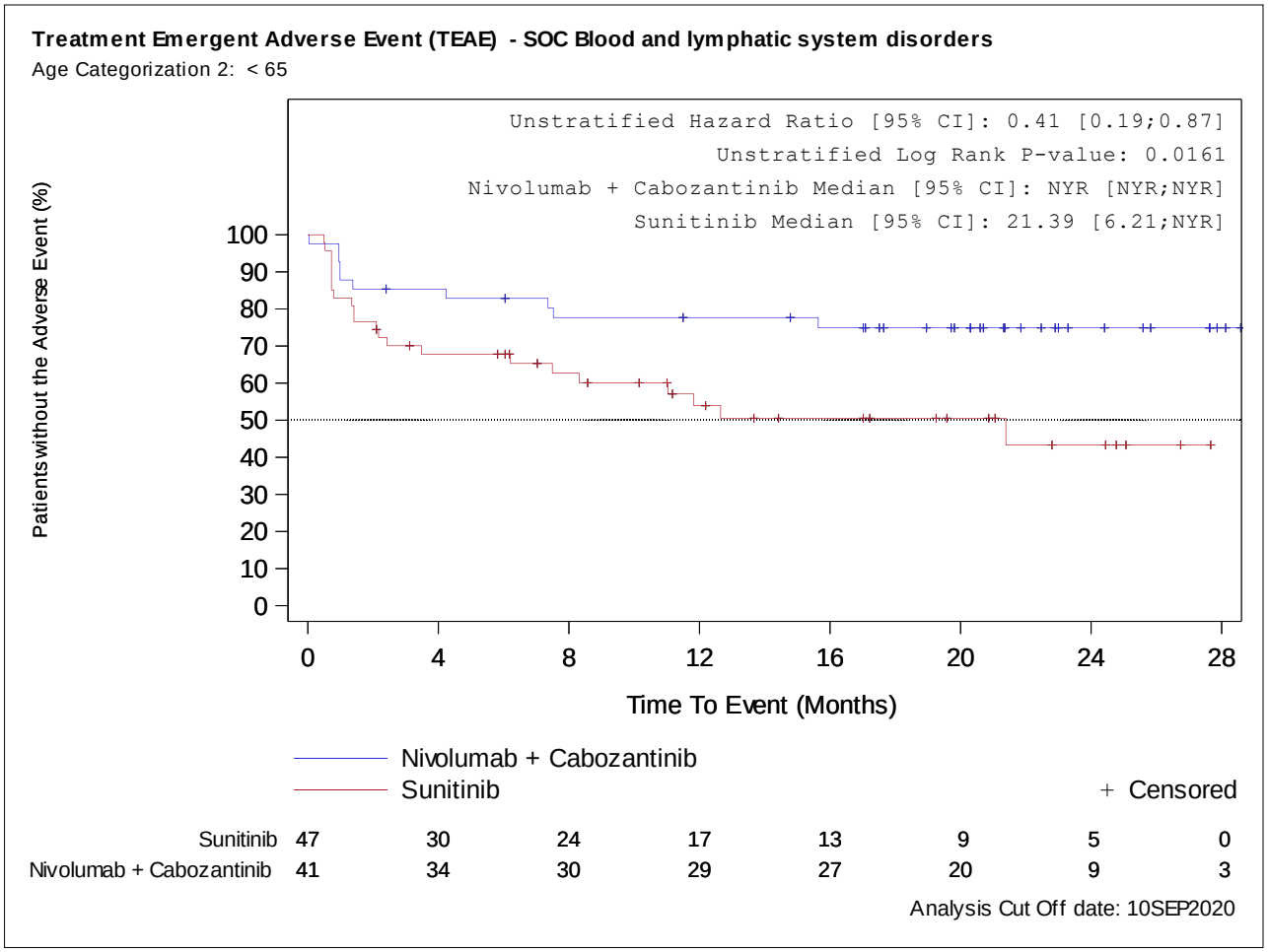
FIGURE 5.1.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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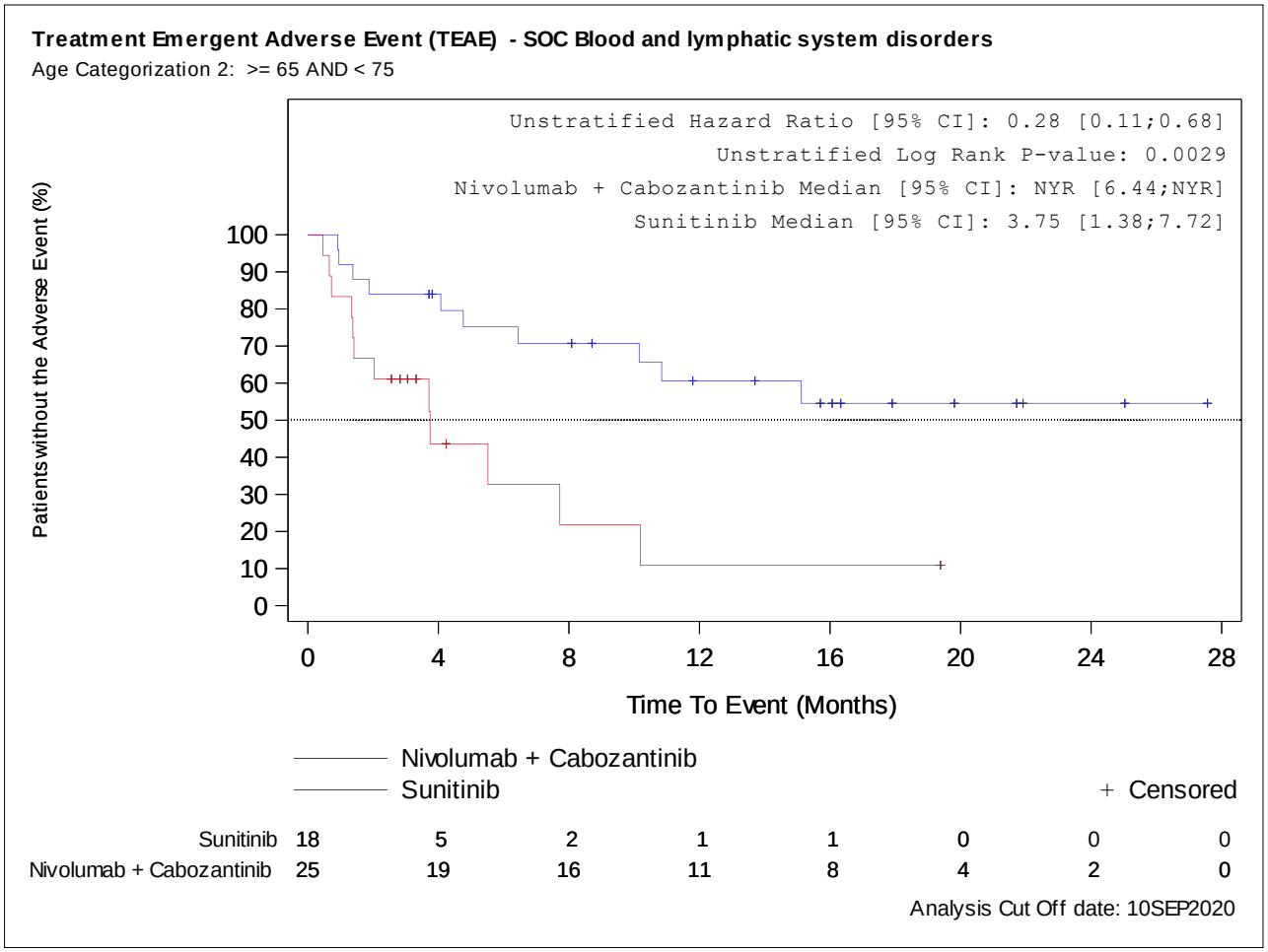
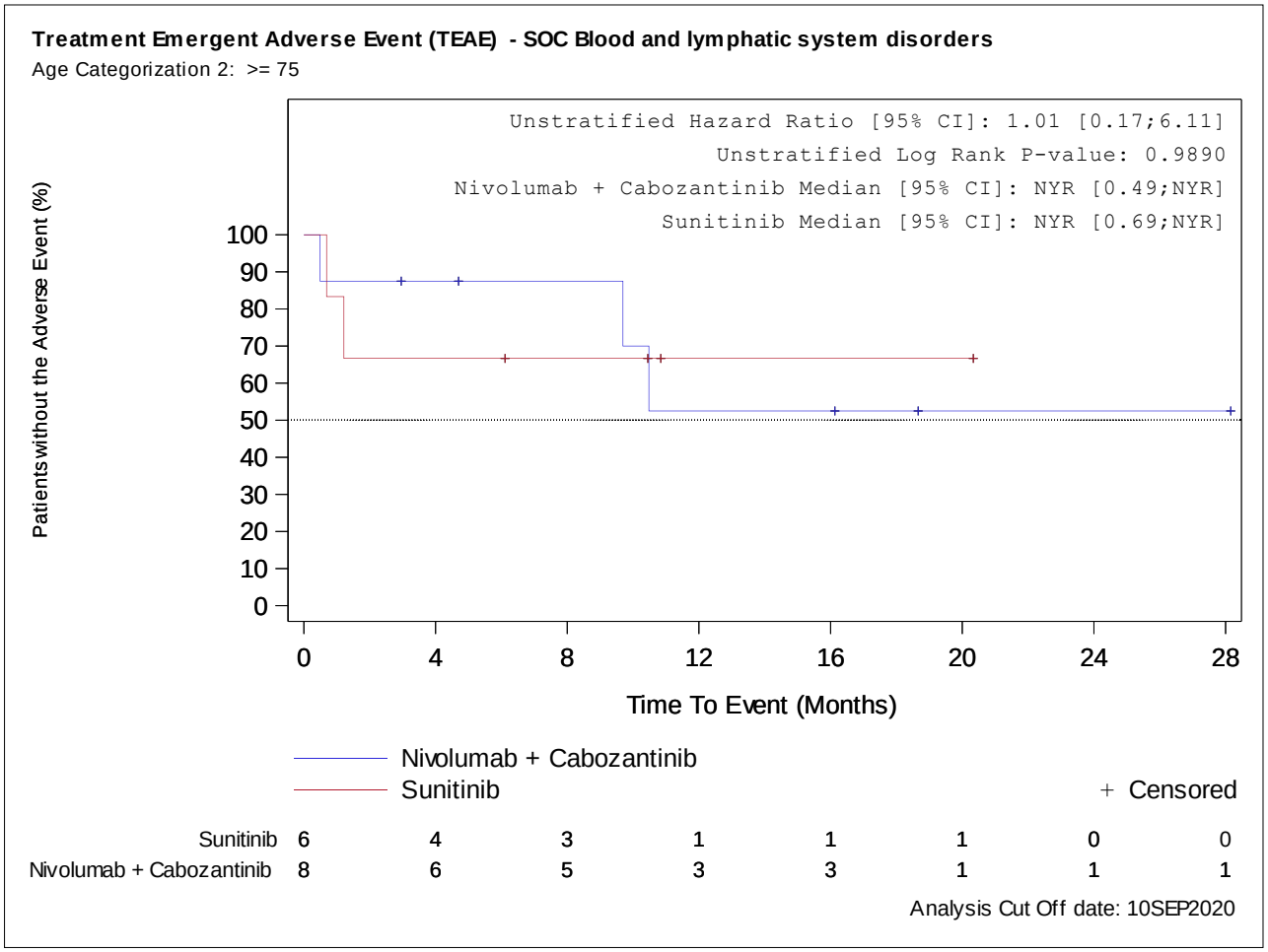
FIGURE 5.1.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:05:49

FIGURE 5.1.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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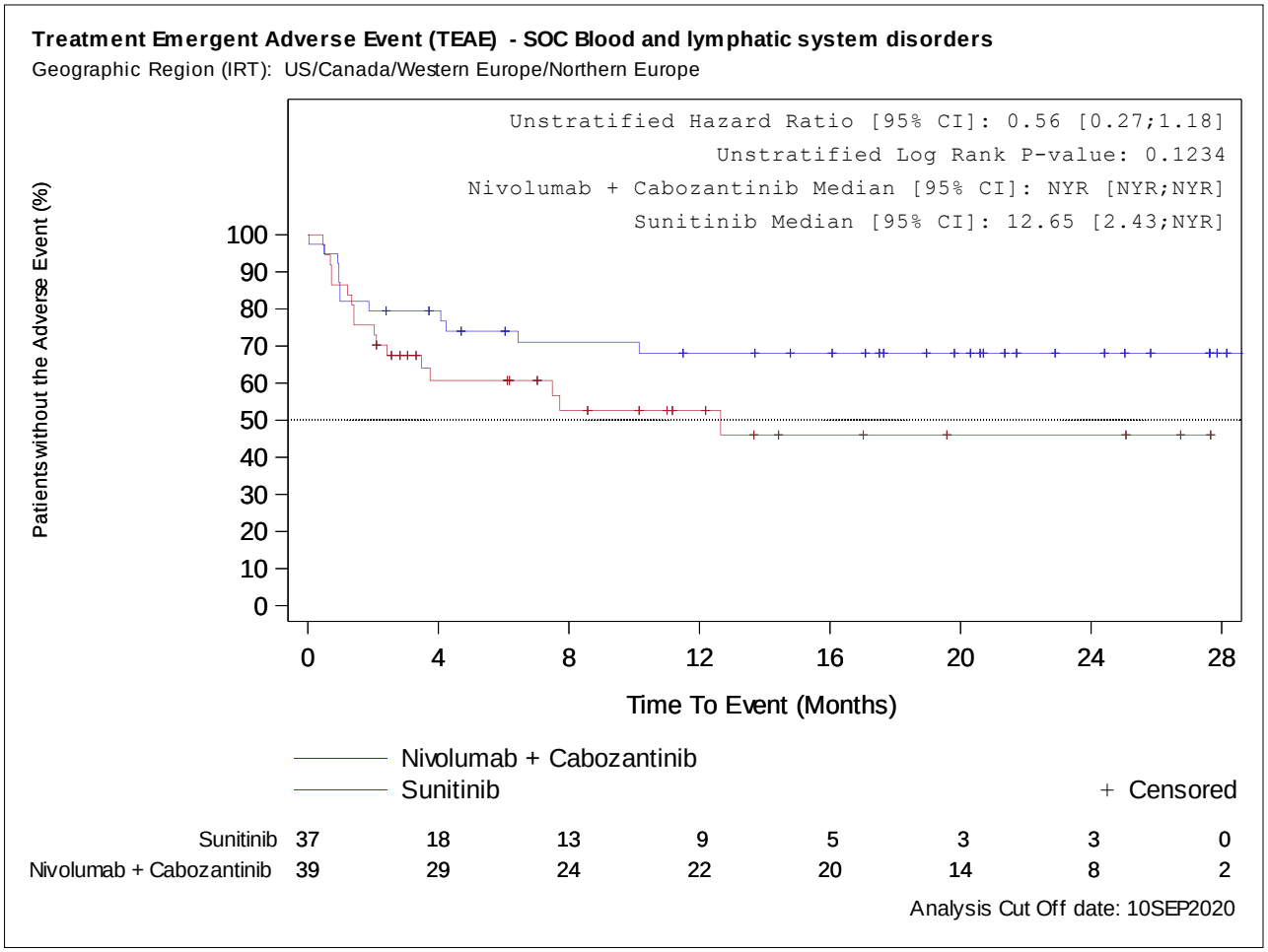
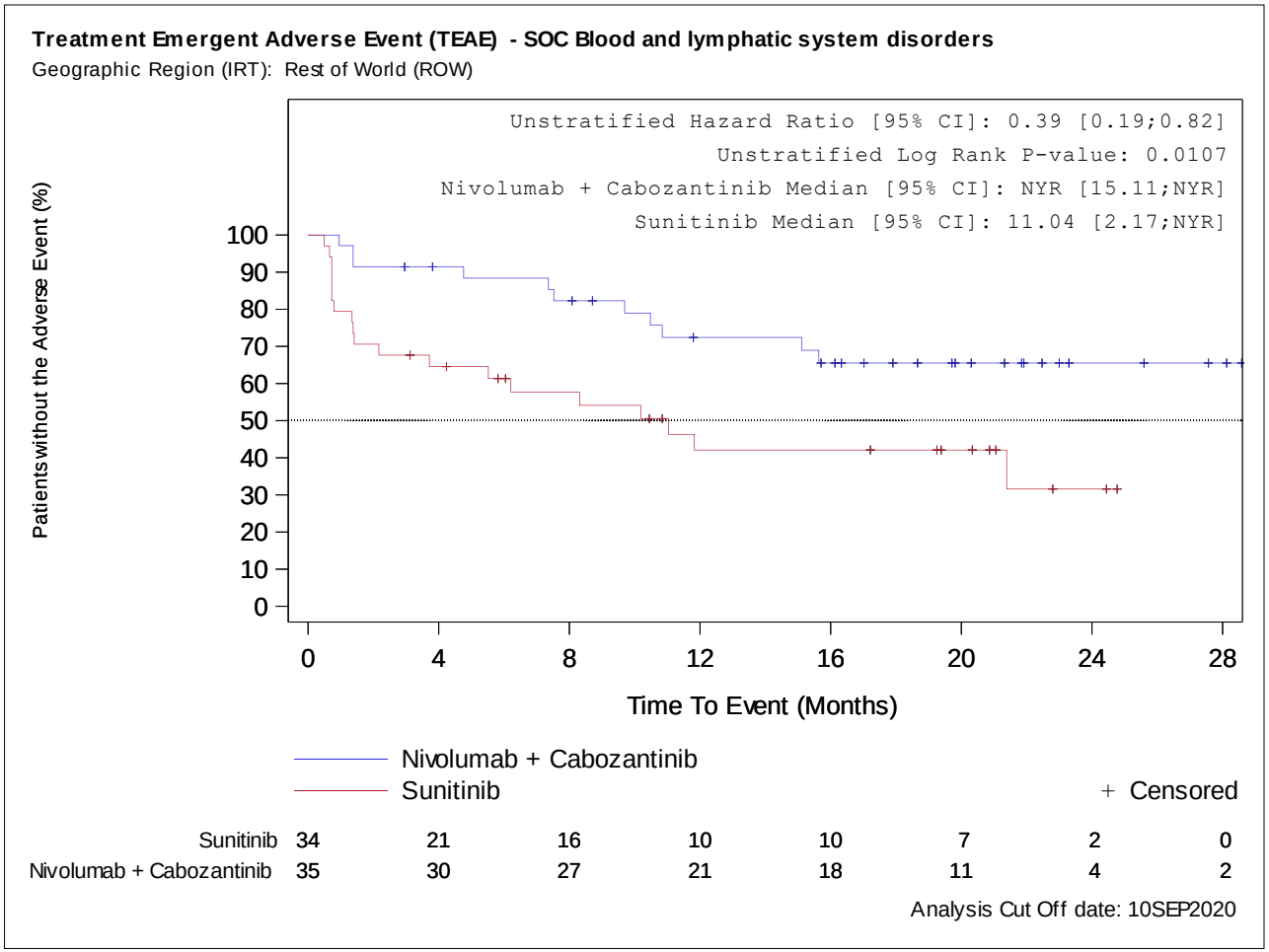
FIGURE 5.1.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:06:02

FIGURE 5.1.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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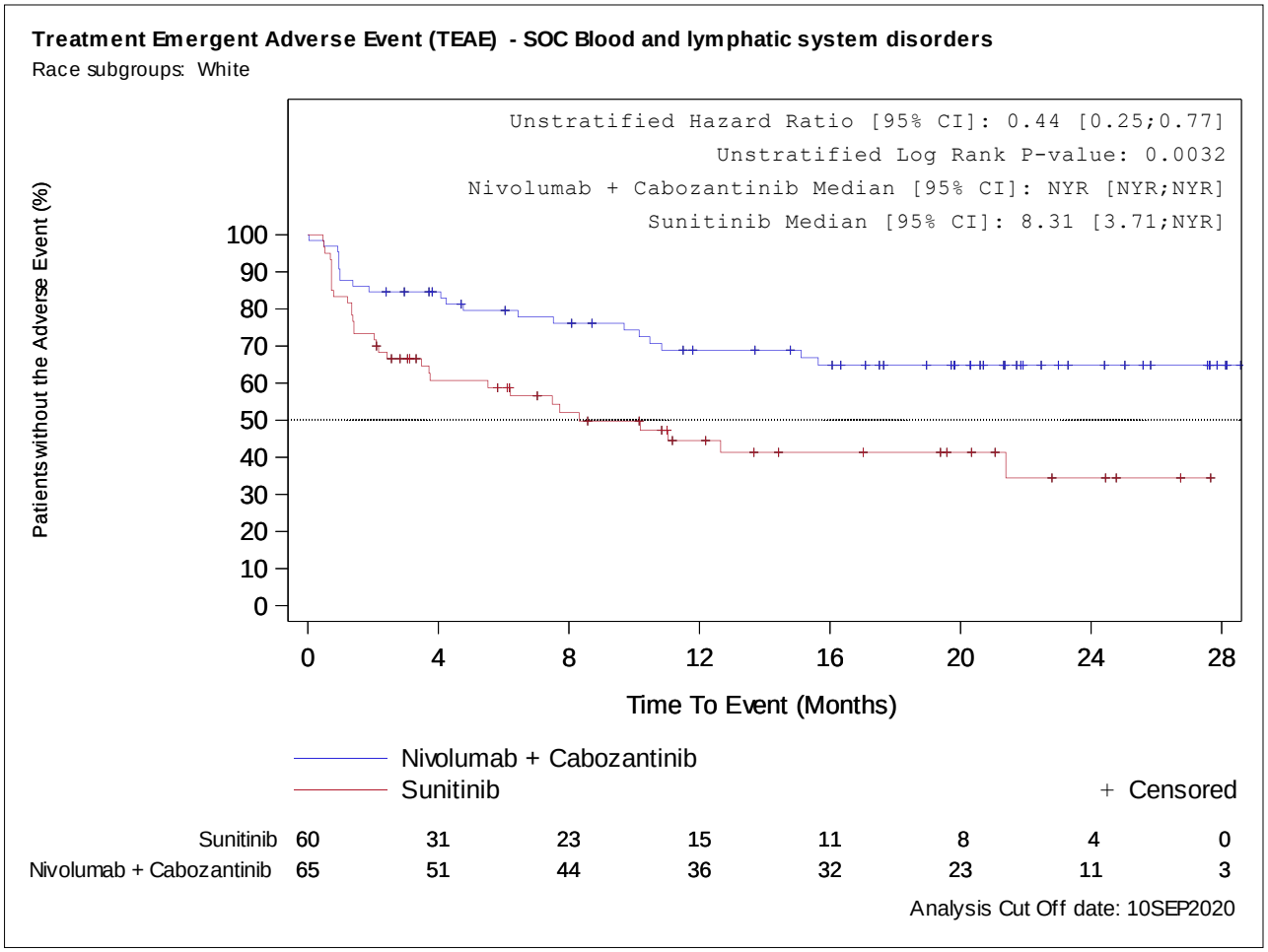
FIGURE 5.1.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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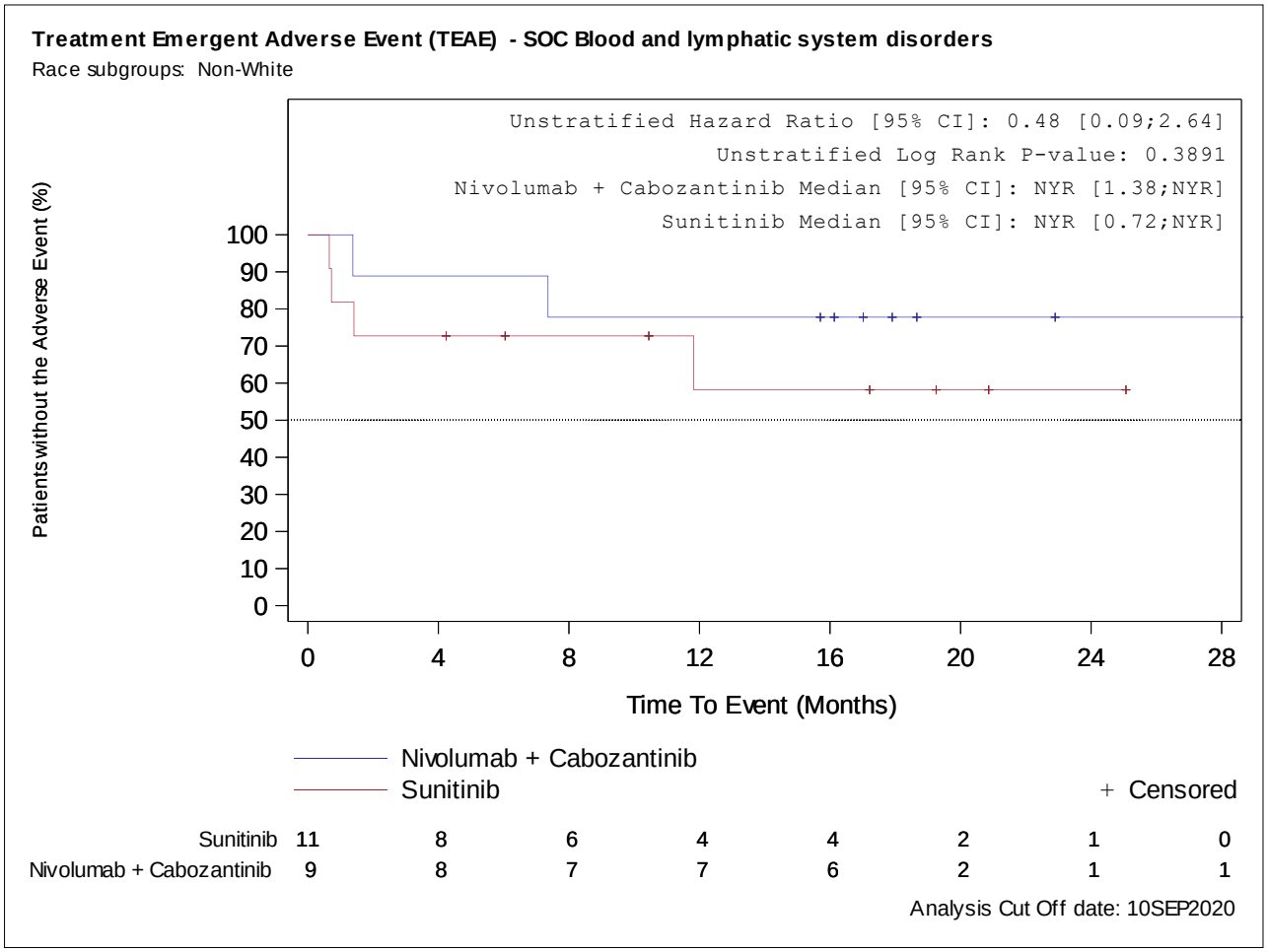
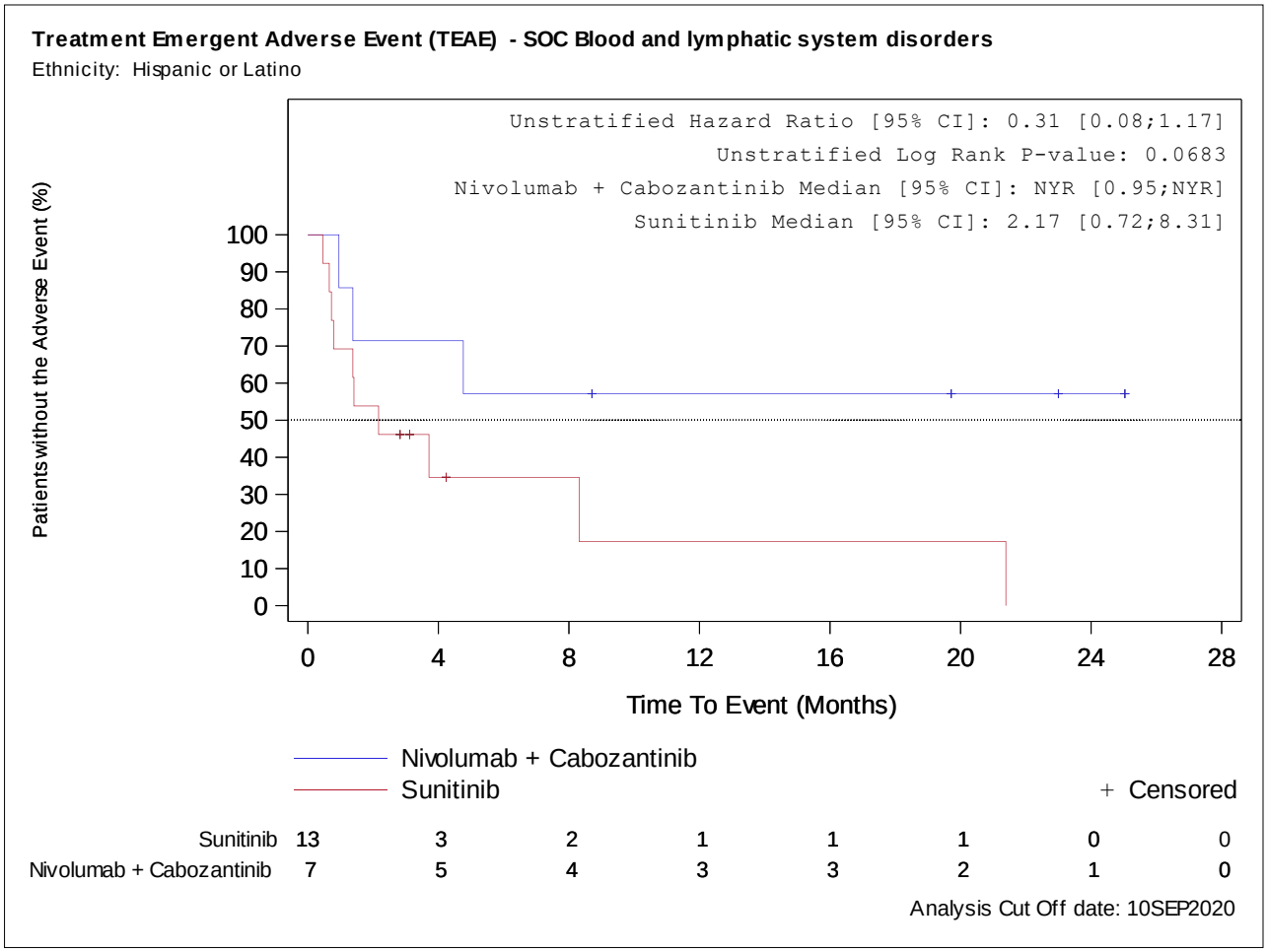
FIGURE 5.1.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



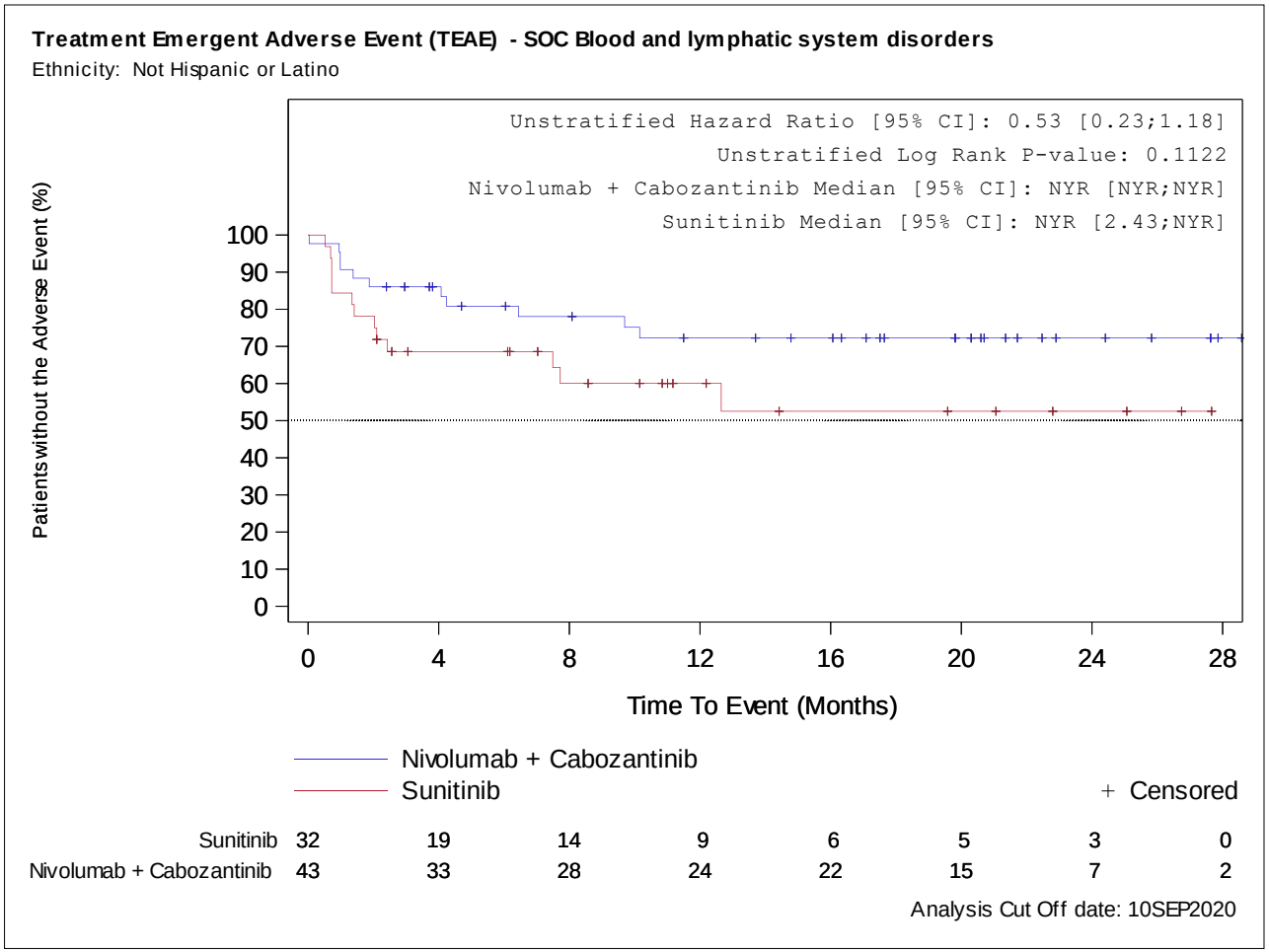

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:06:19

FIGURE 5.1.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:06:25

FIGURE 5.1.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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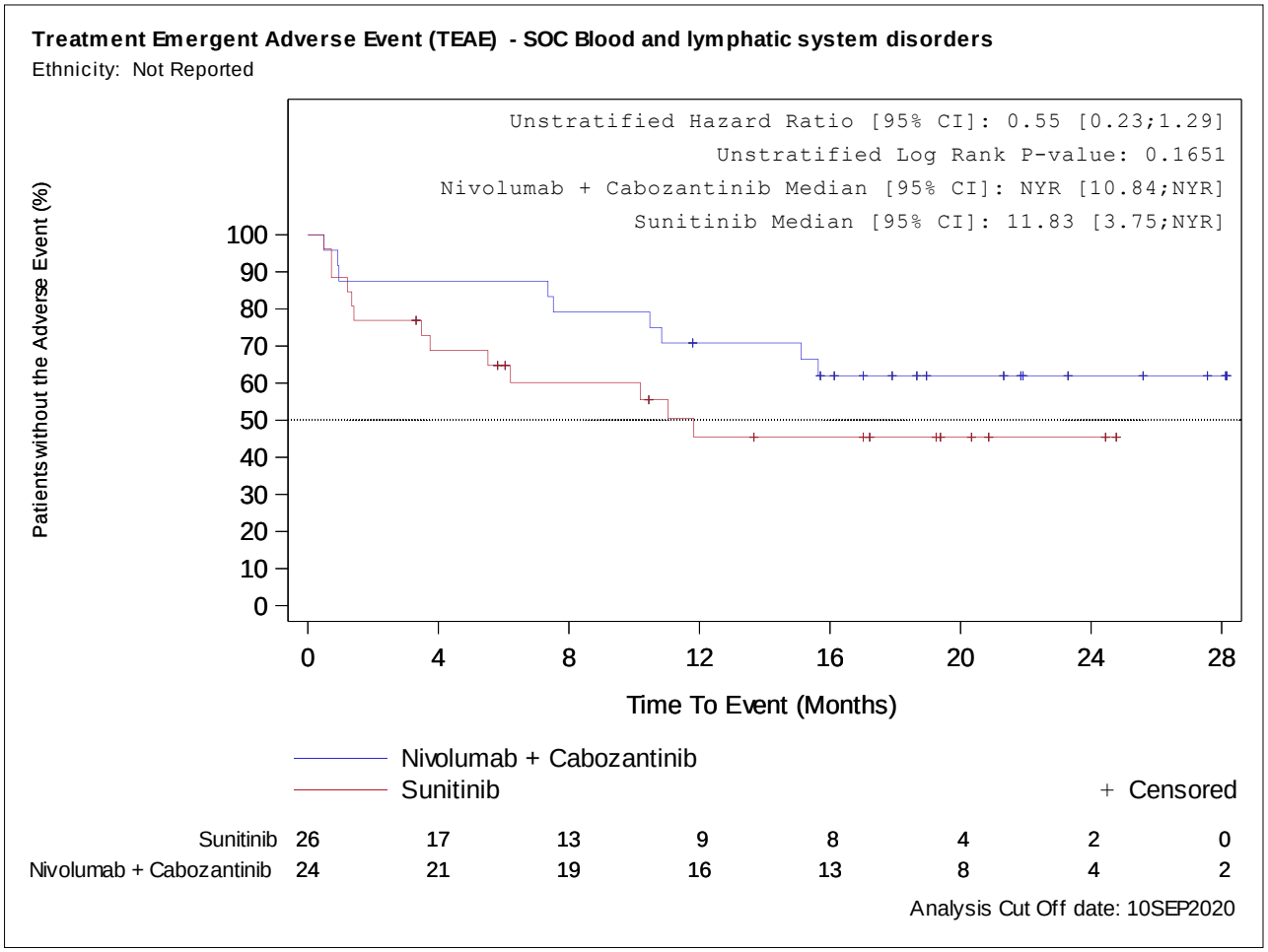
FIGURE 5.1.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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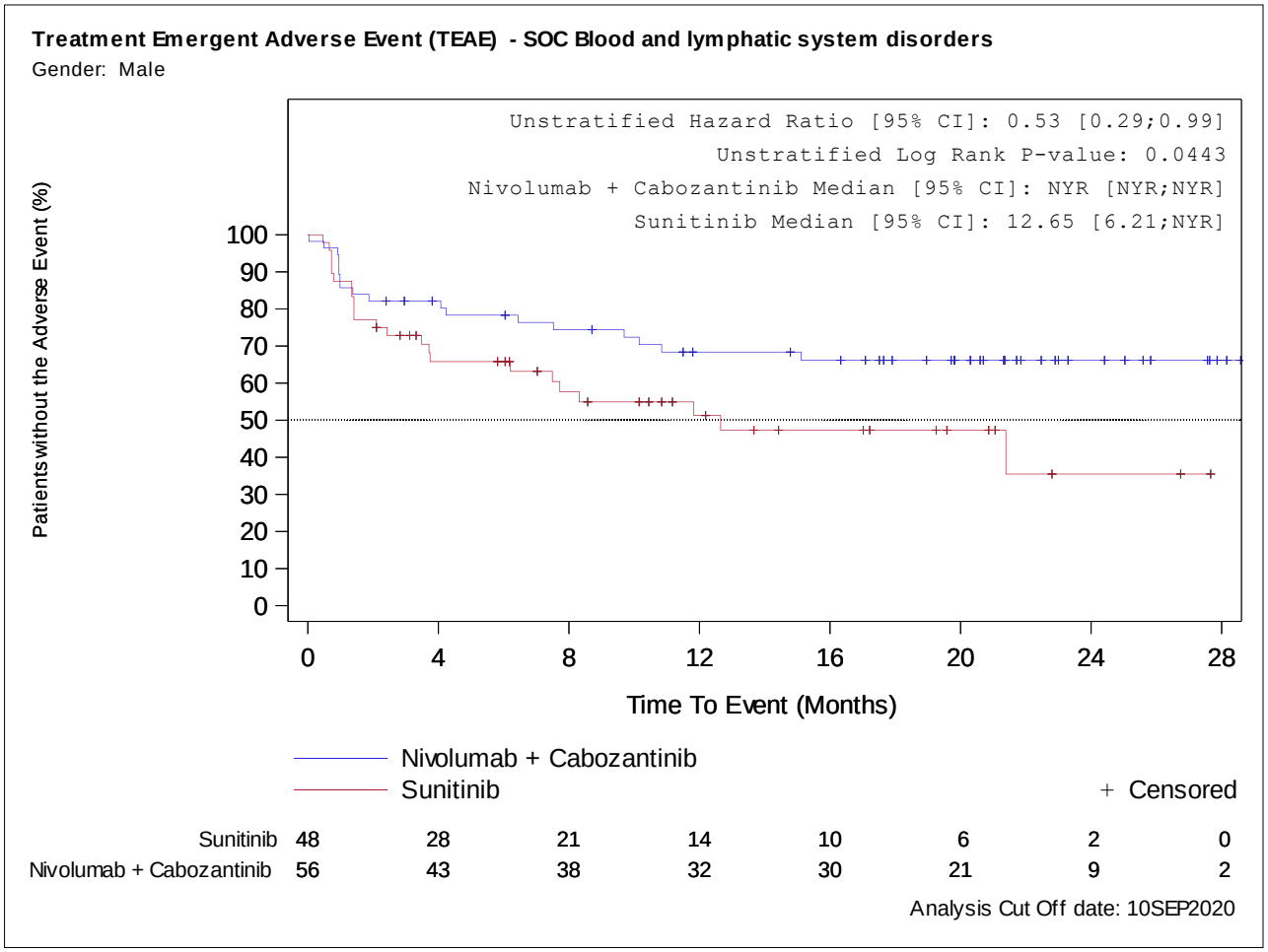
FIGURE 5.1.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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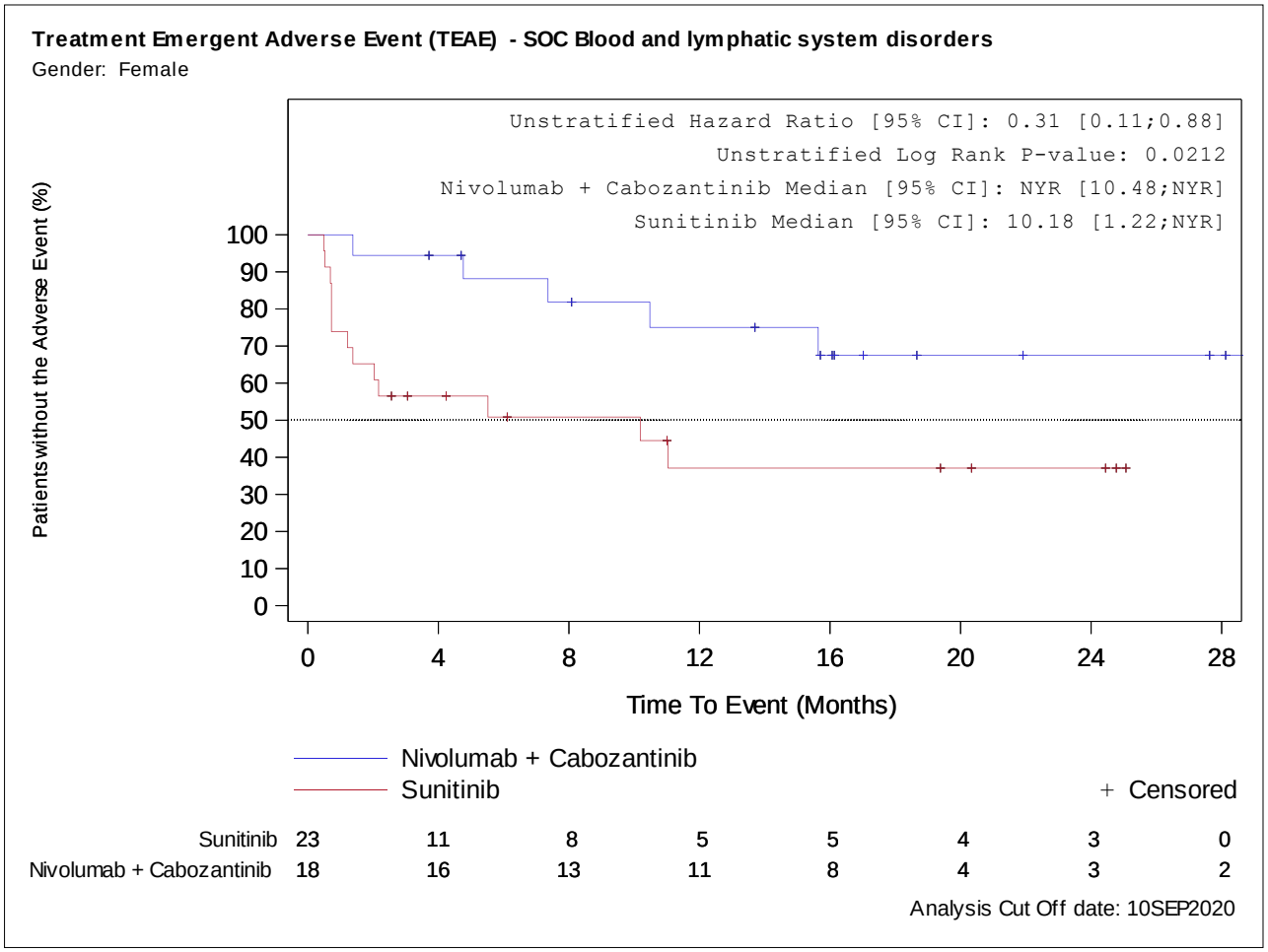
FIGURE 5.1.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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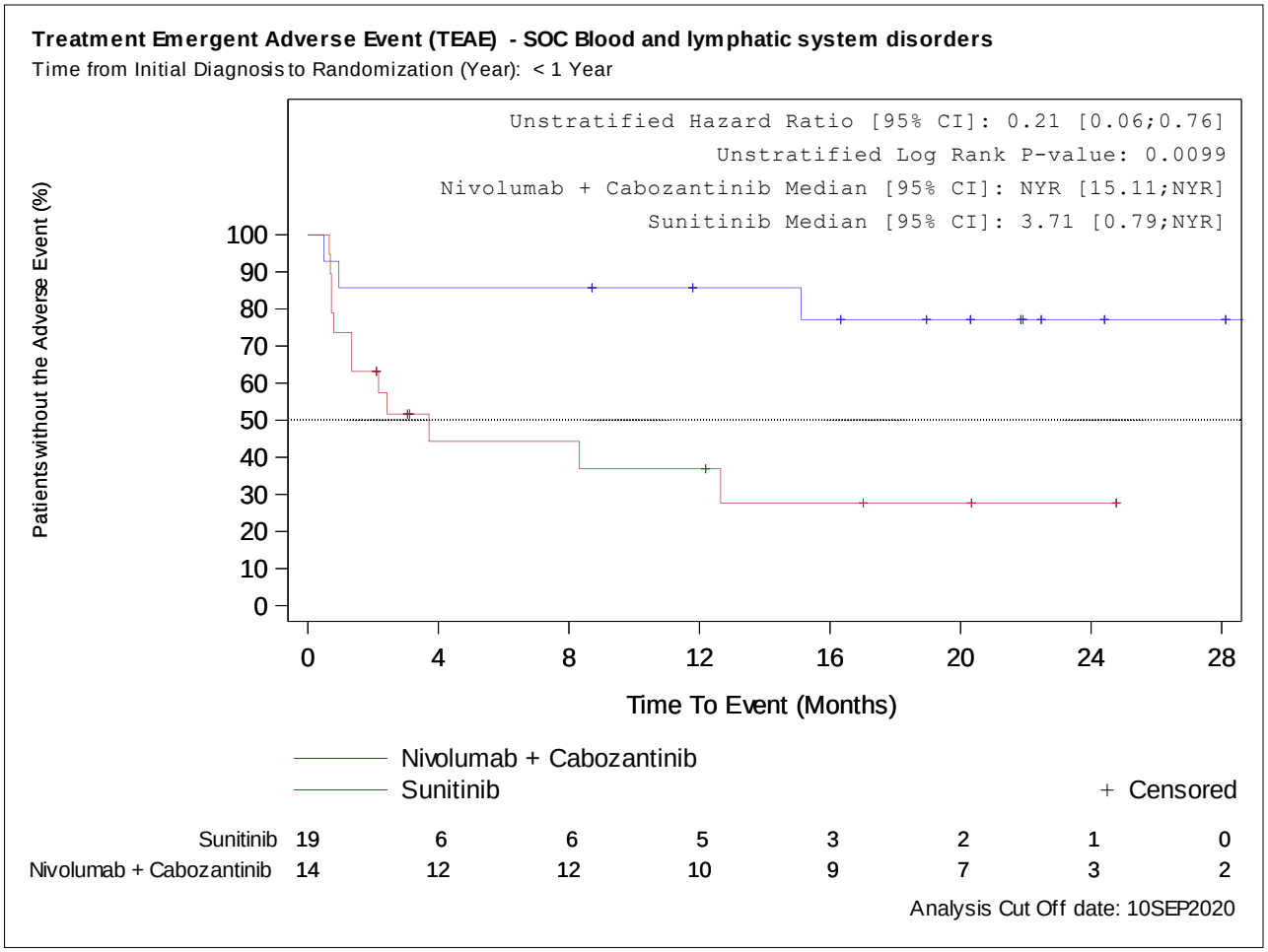
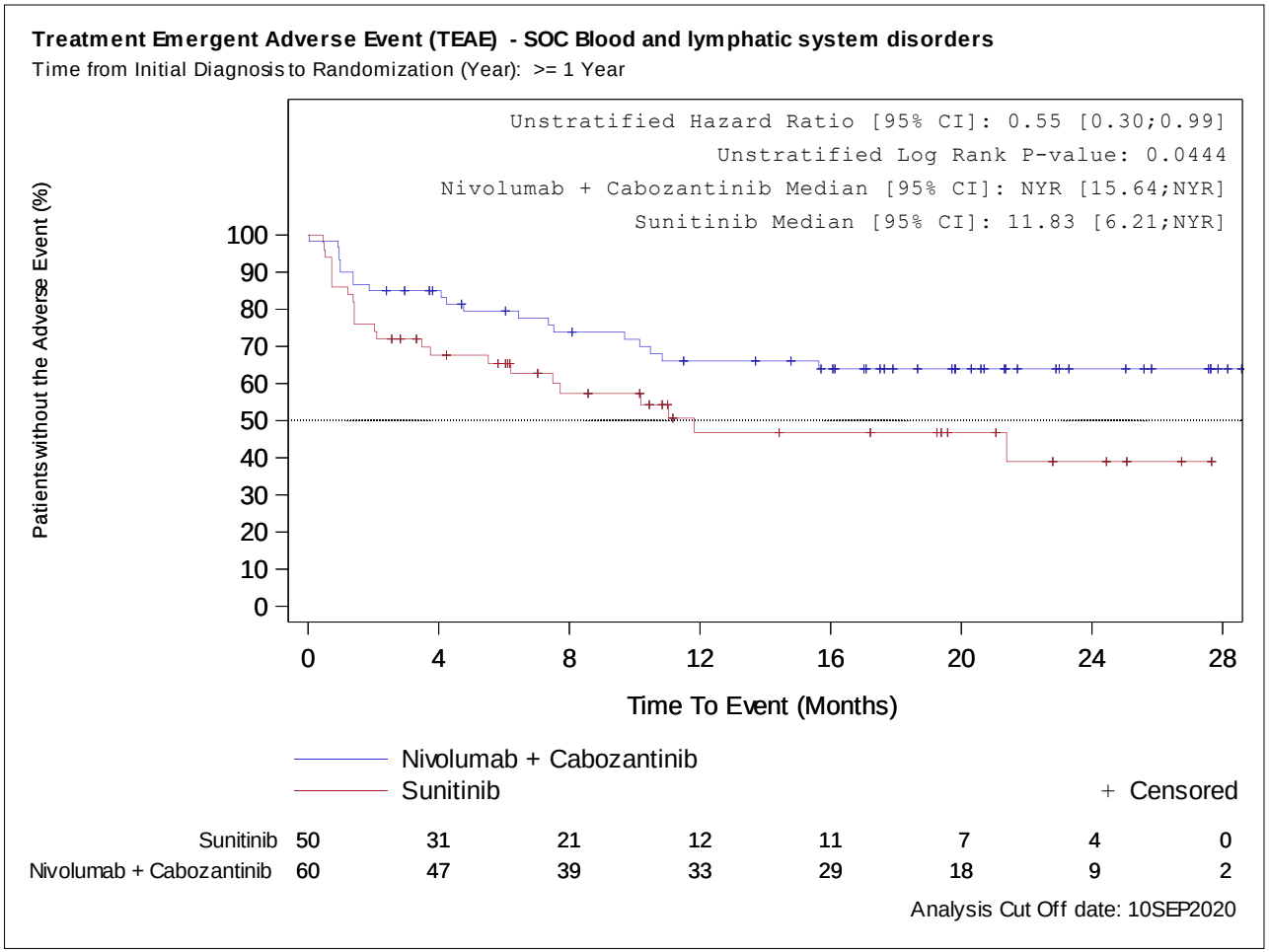
FIGURE 5.1.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



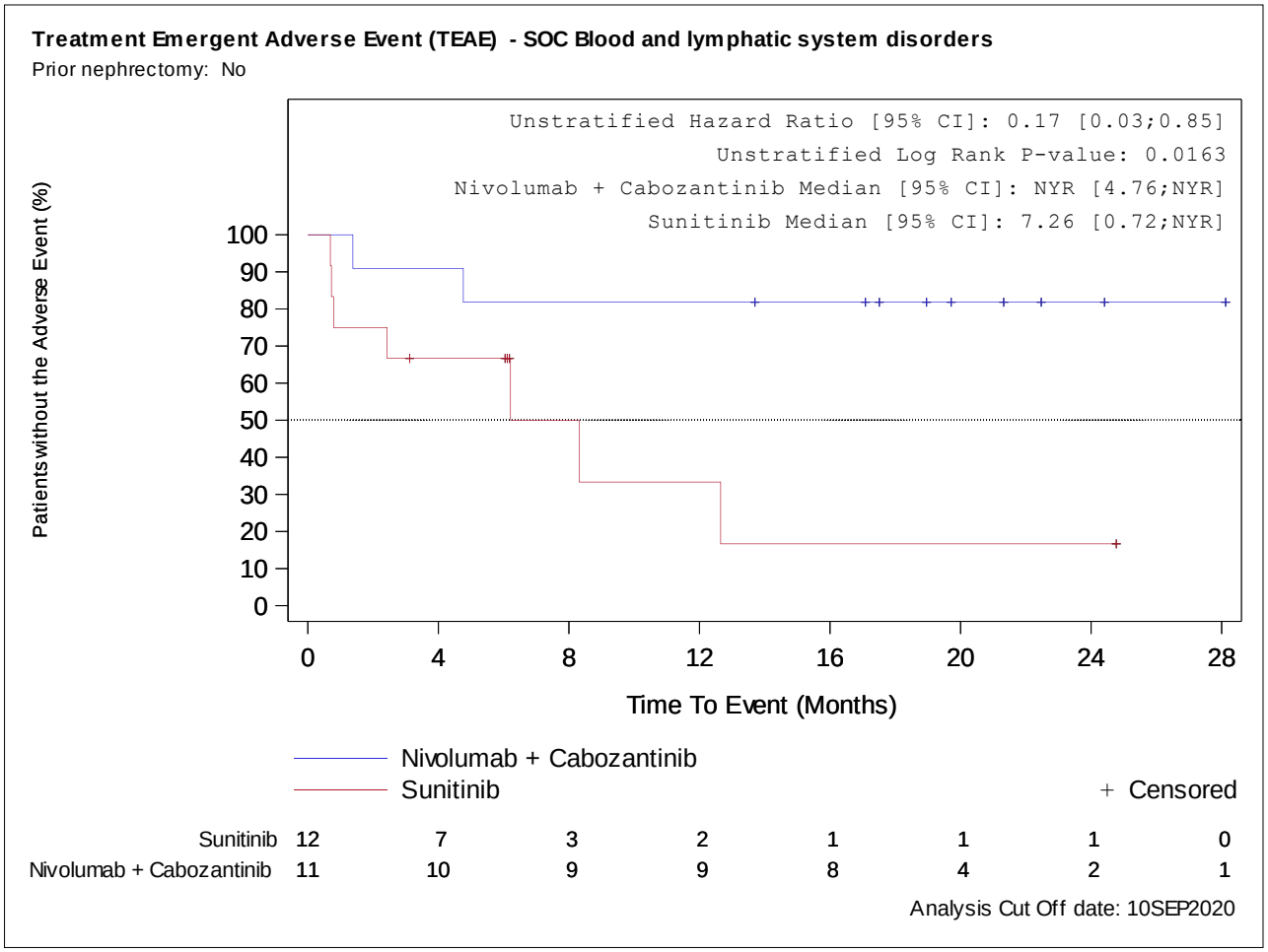

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:07:06

FIGURE 5.1.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



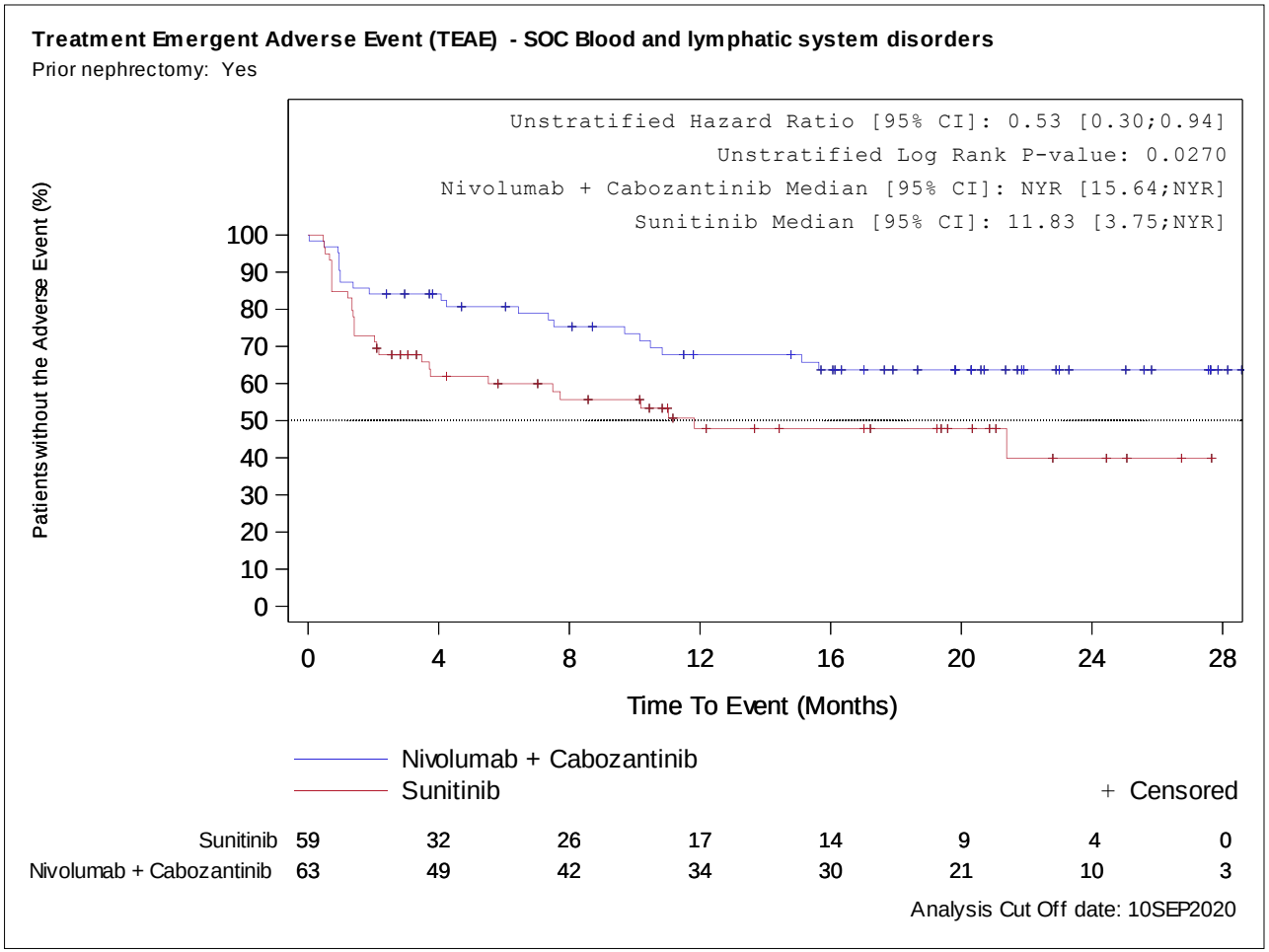

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:07:11

FIGURE 5.1.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



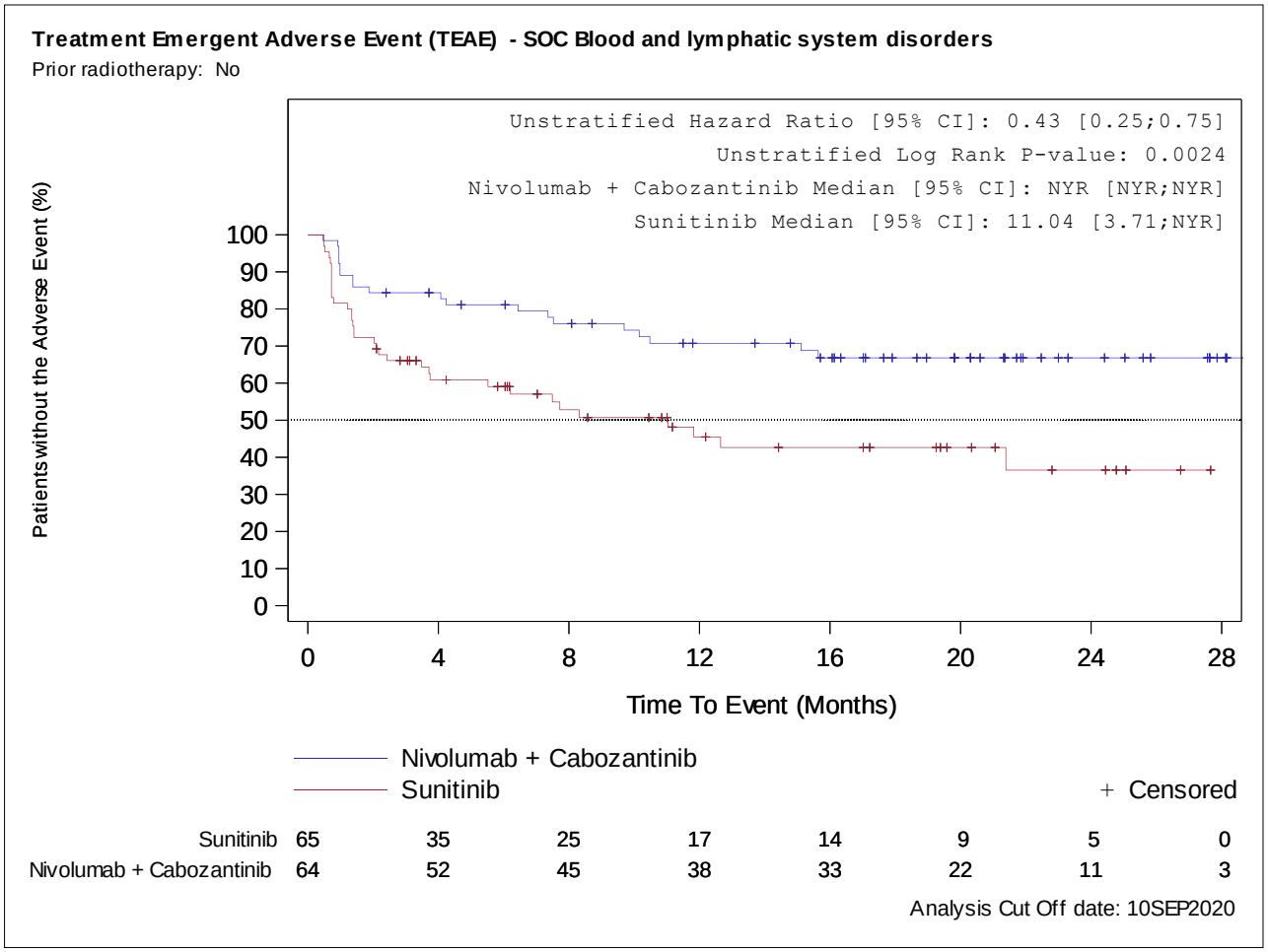

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:08:04

FIGURE 5.1.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



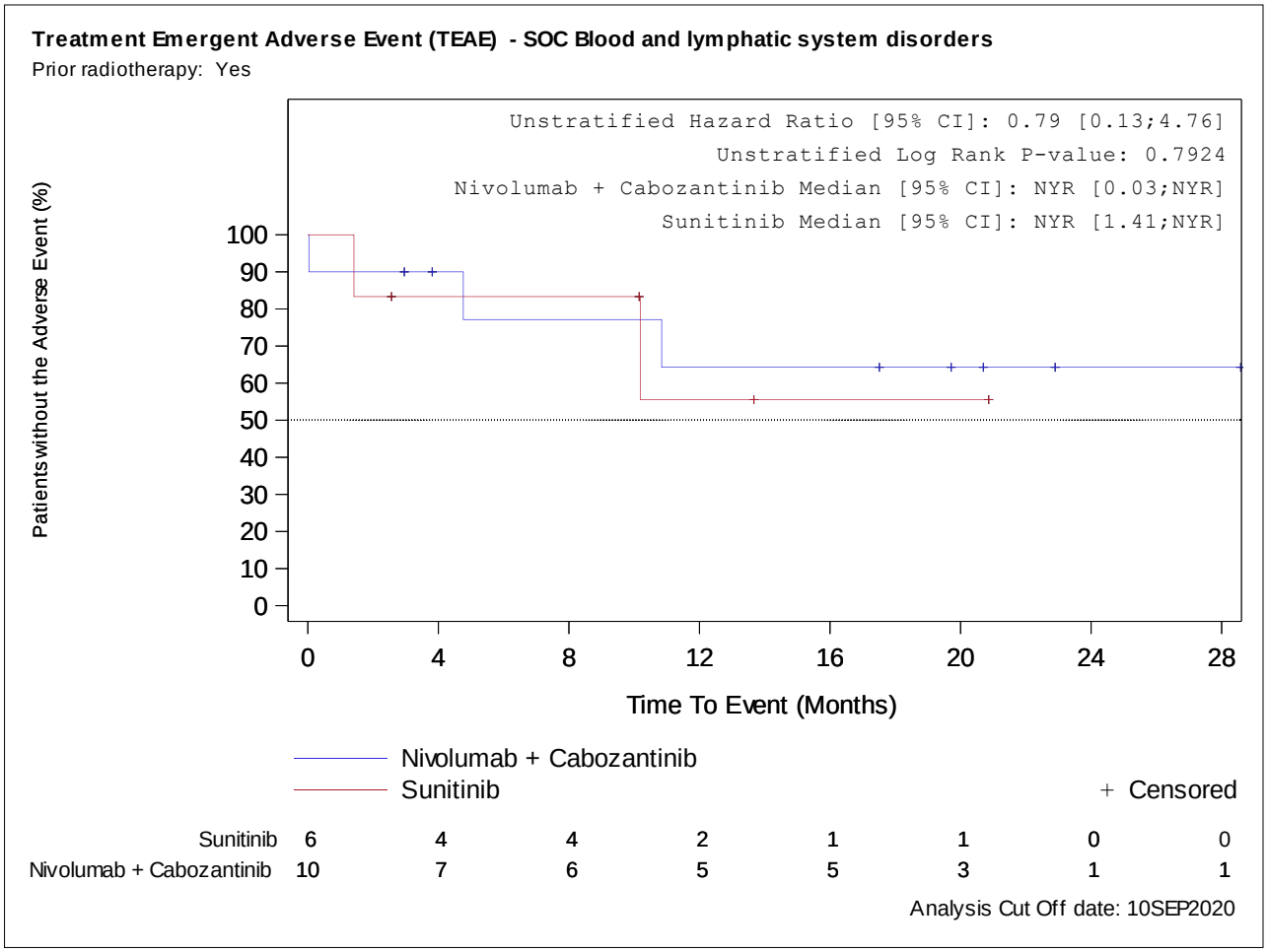

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:08:10

FIGURE 5.1.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



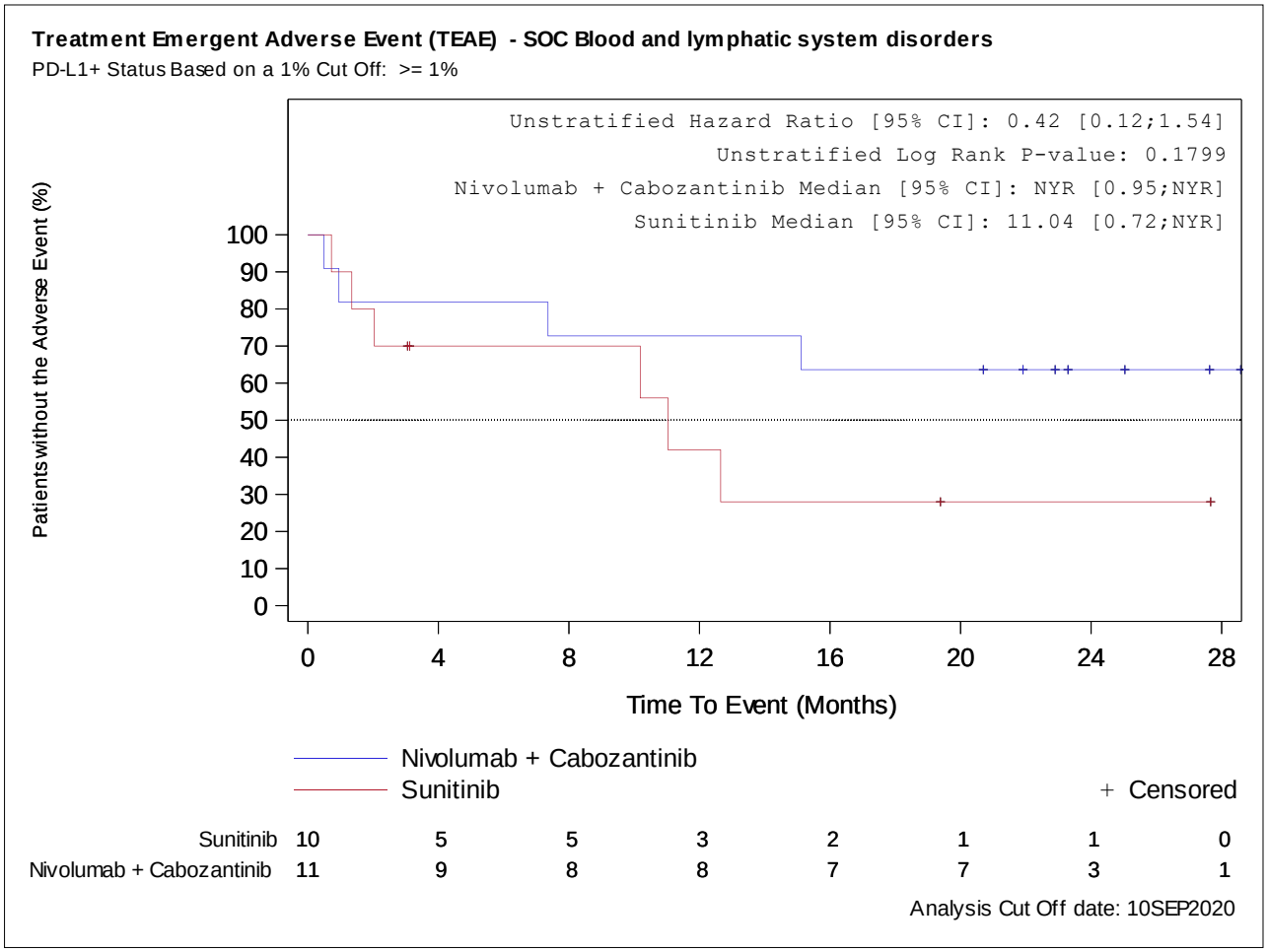

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:08:16

FIGURE 5.1.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:08:22

FIGURE 5.1.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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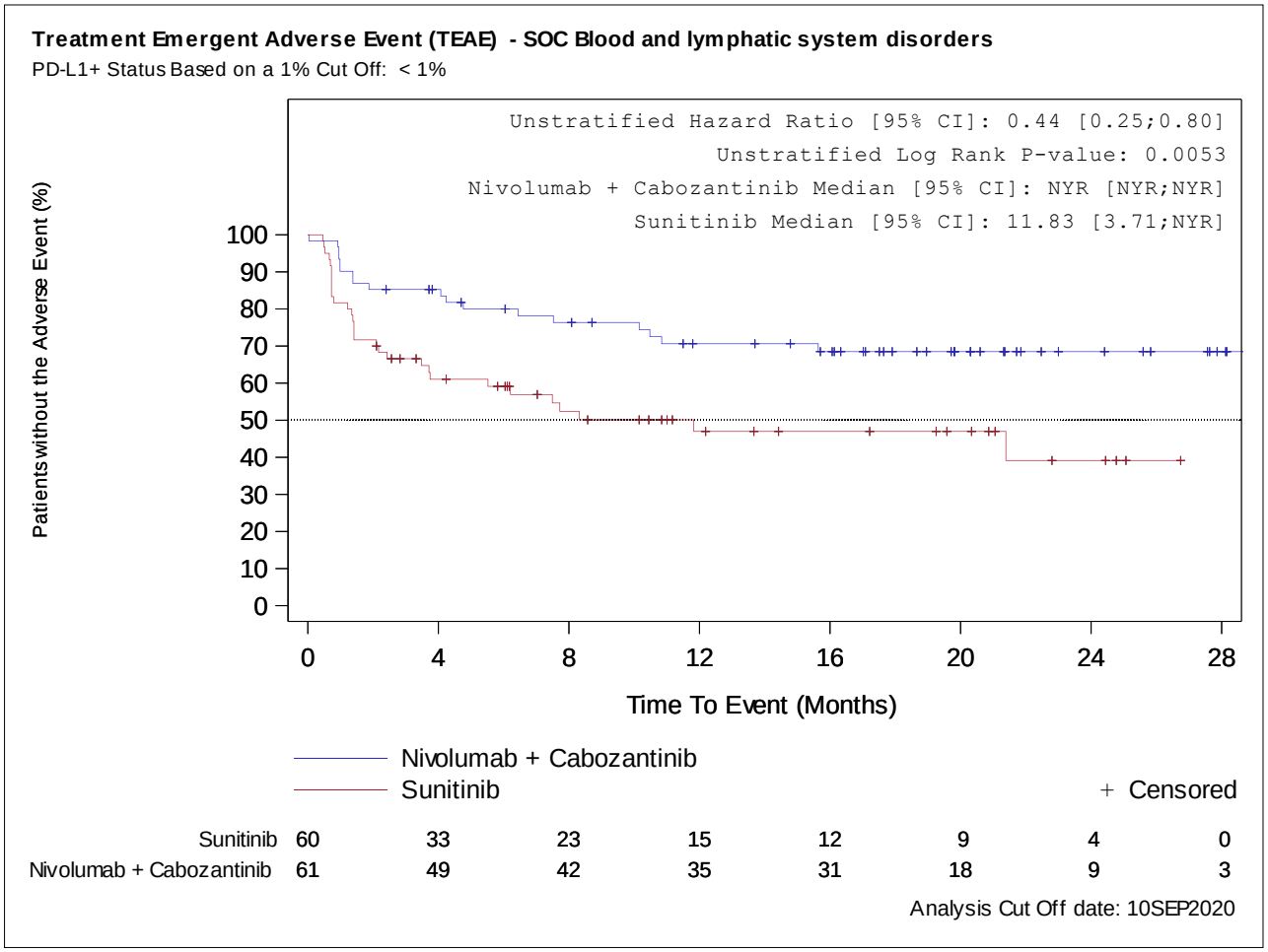
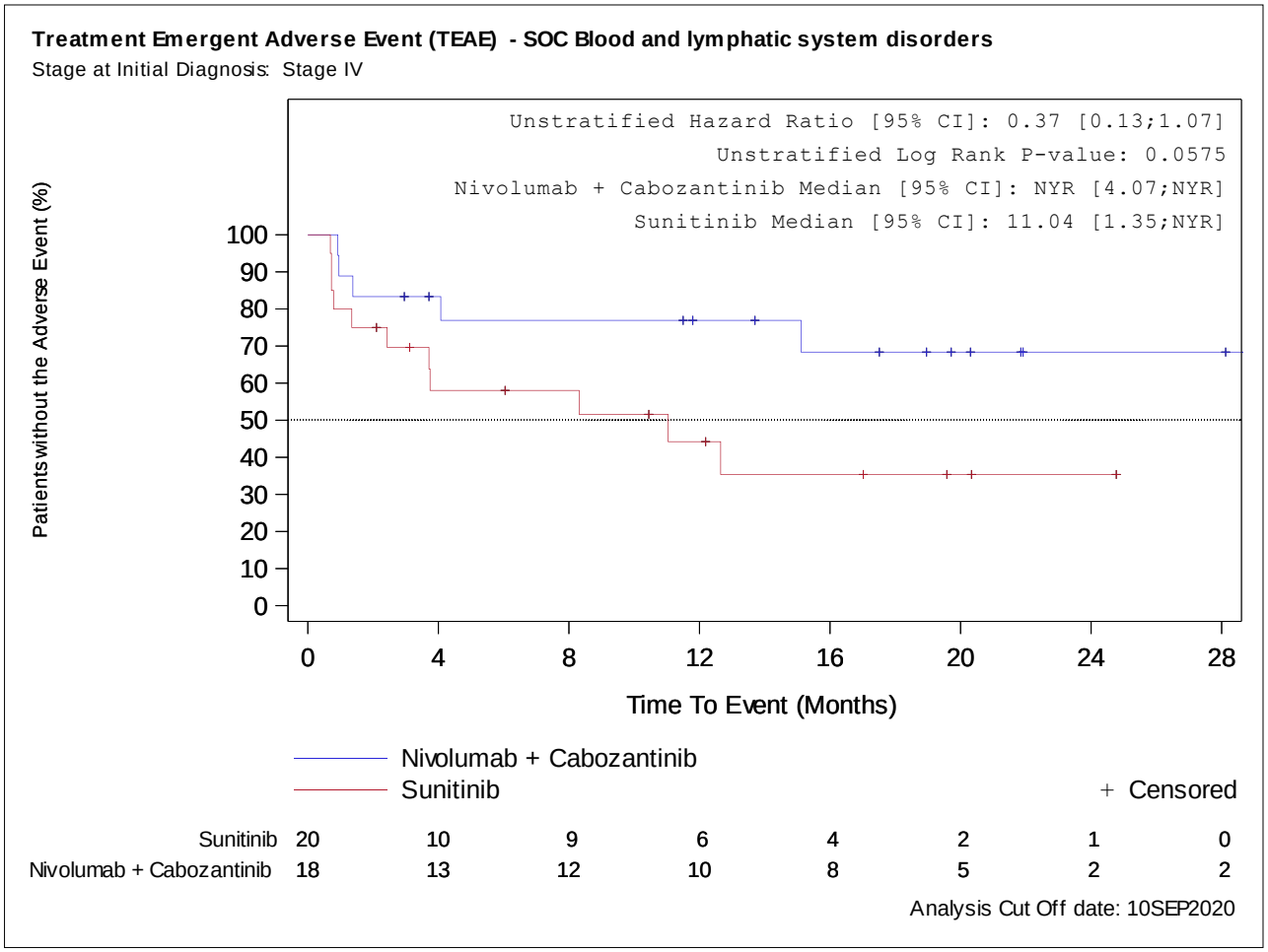
FIGURE 5.1.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



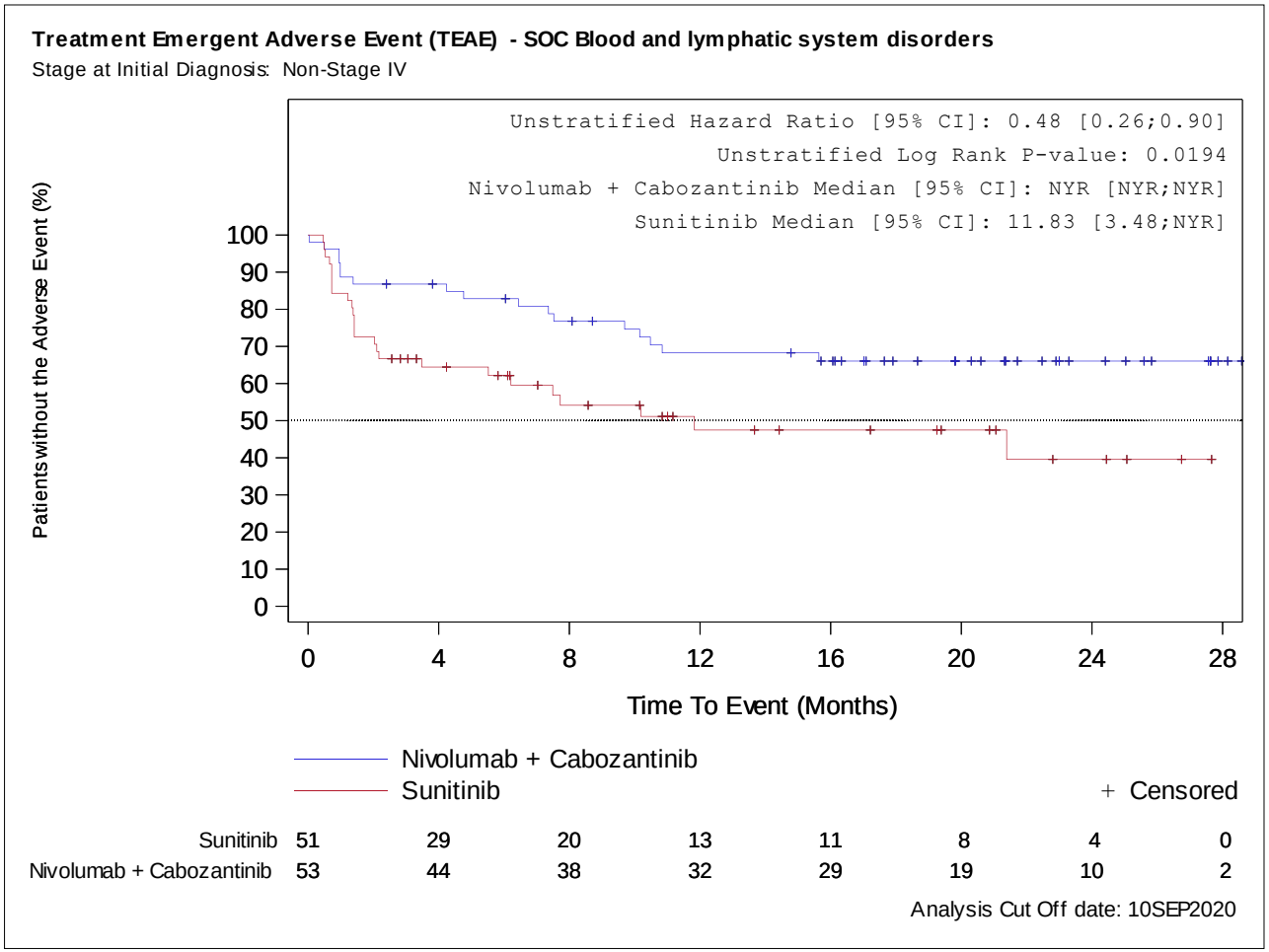

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:08:34

FIGURE 5.1.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



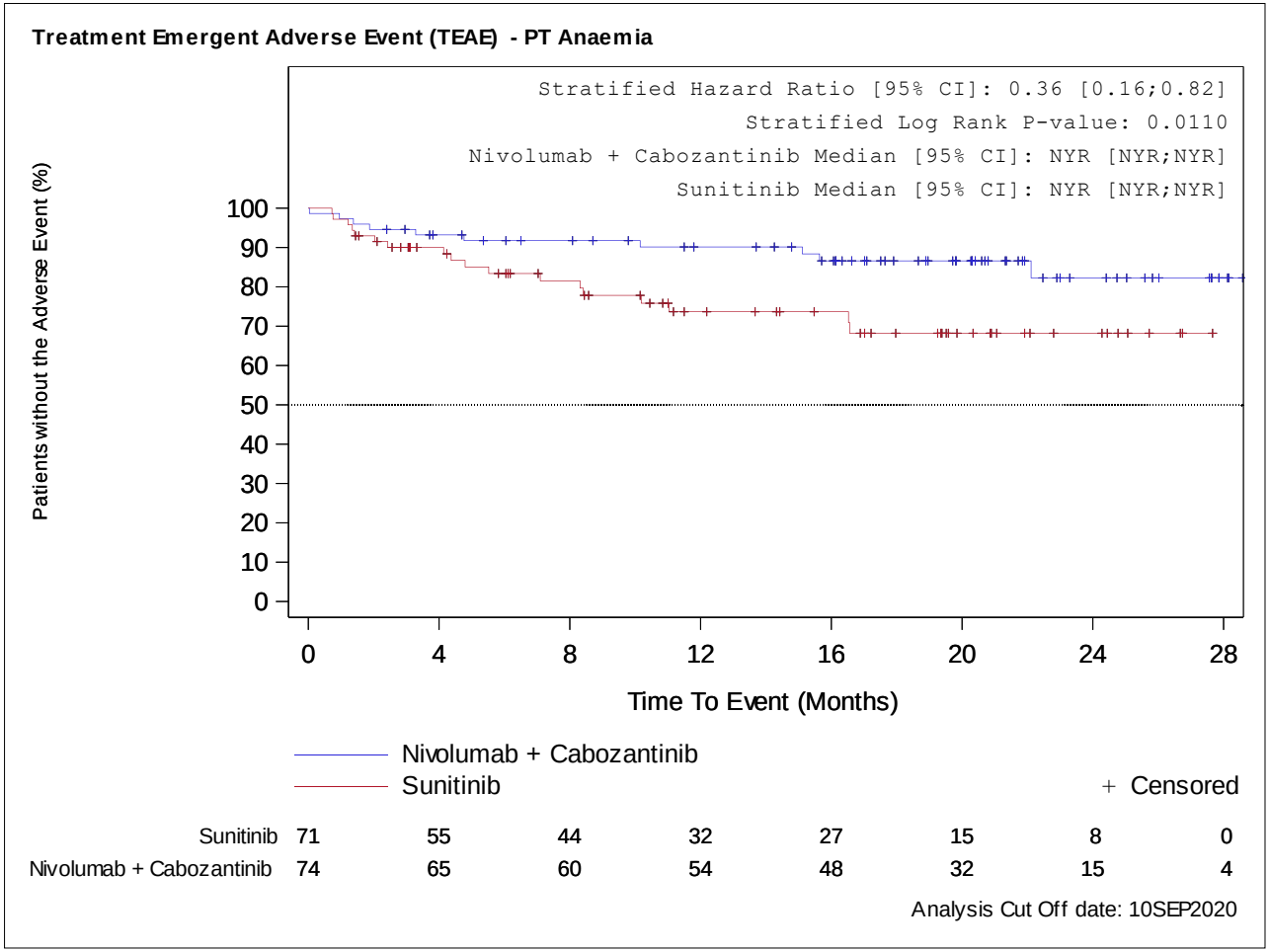

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:09:04

FIGURE 5.1.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



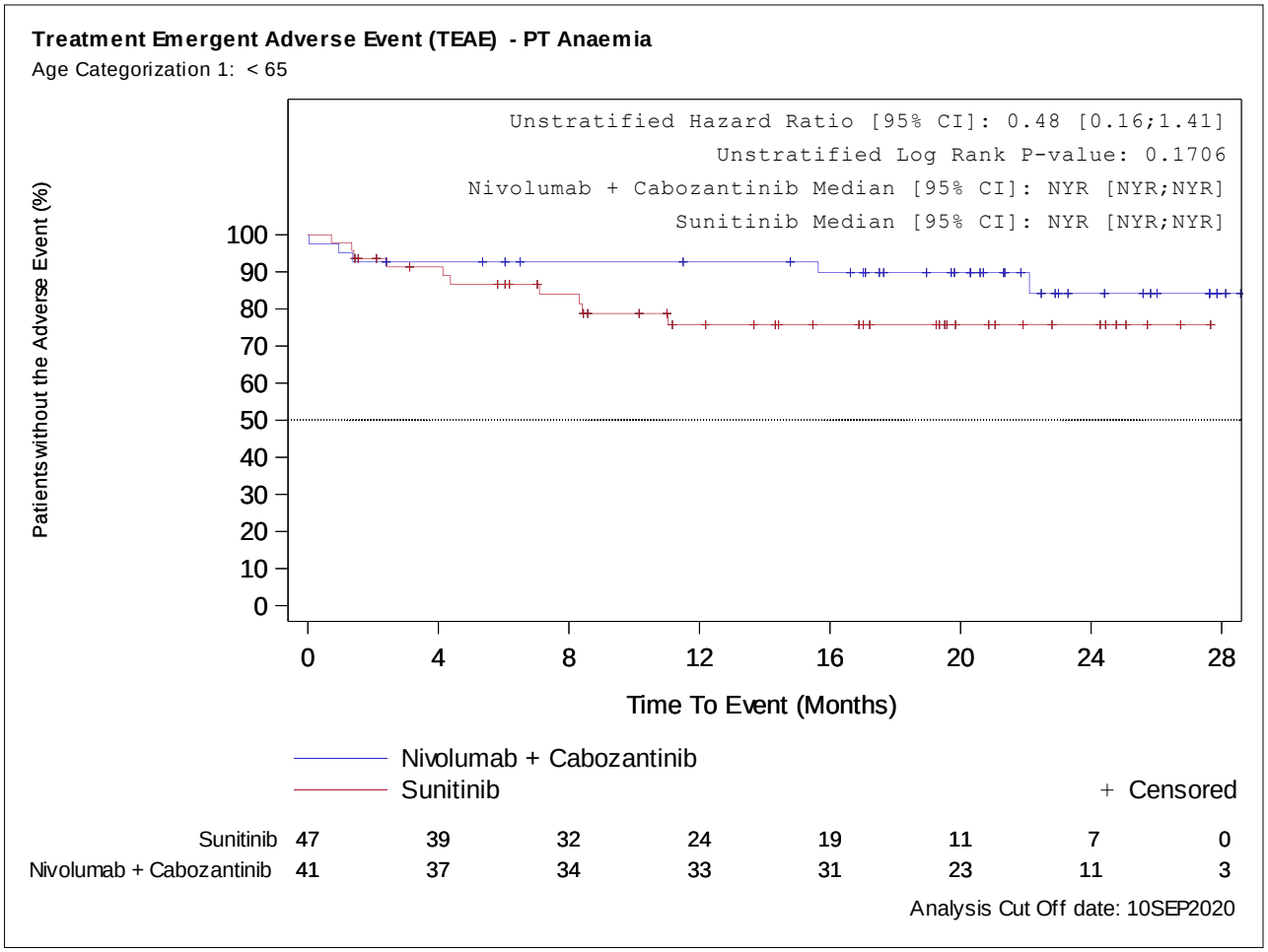

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:09:10

FIGURE 5.2.1: Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



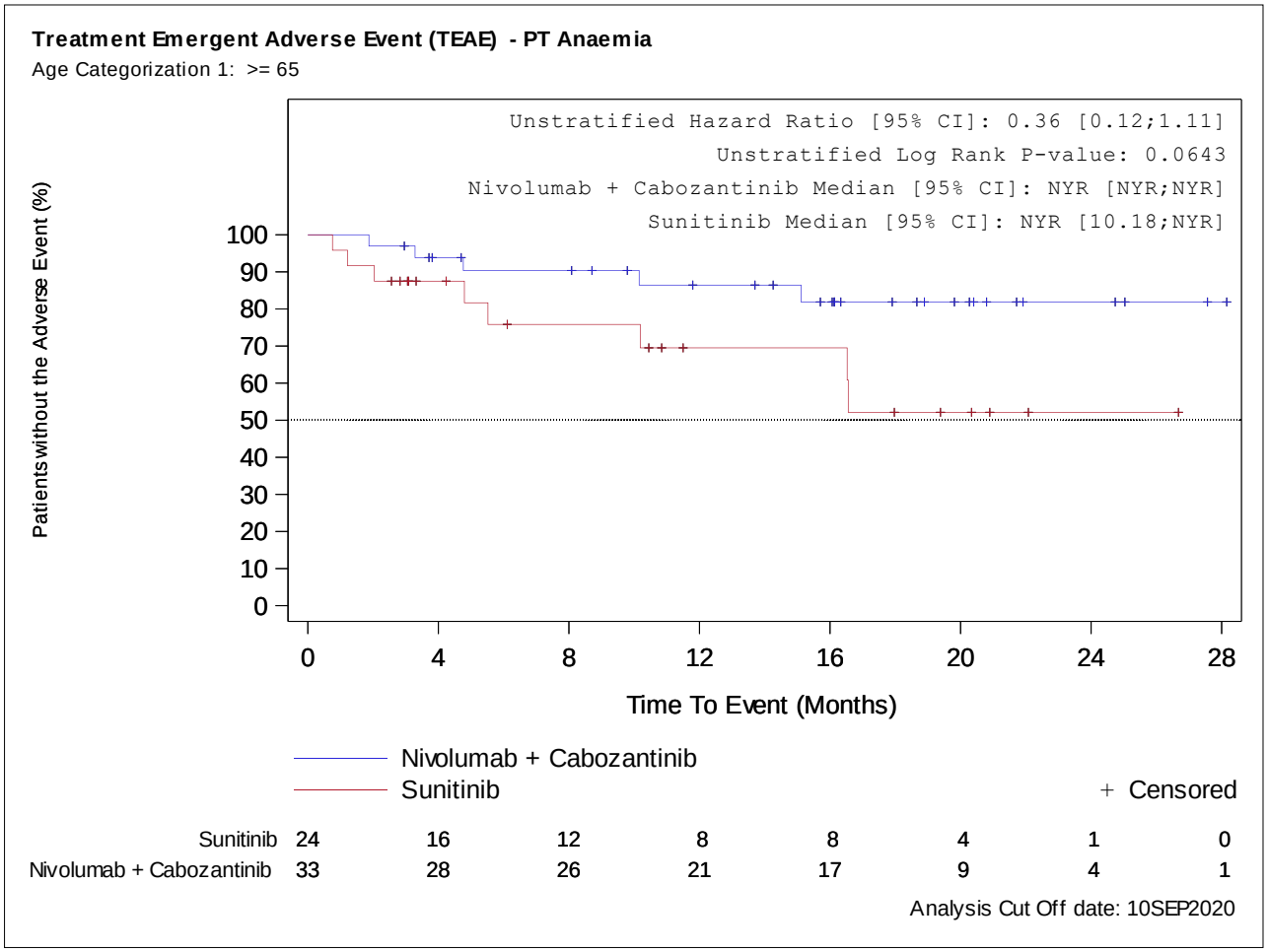

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:12:17

FIGURE 5.2.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:12:20

FIGURE 5.2.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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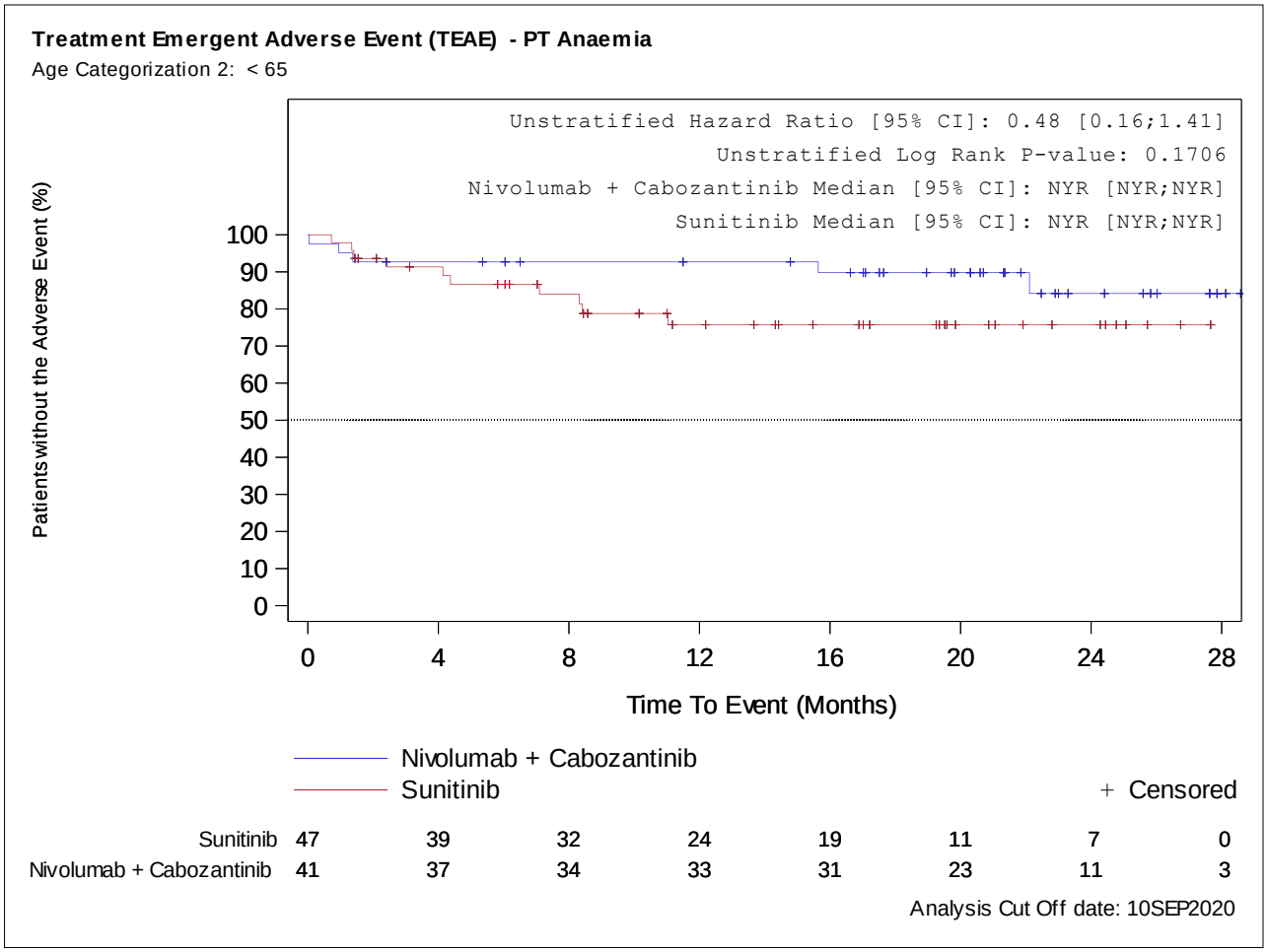
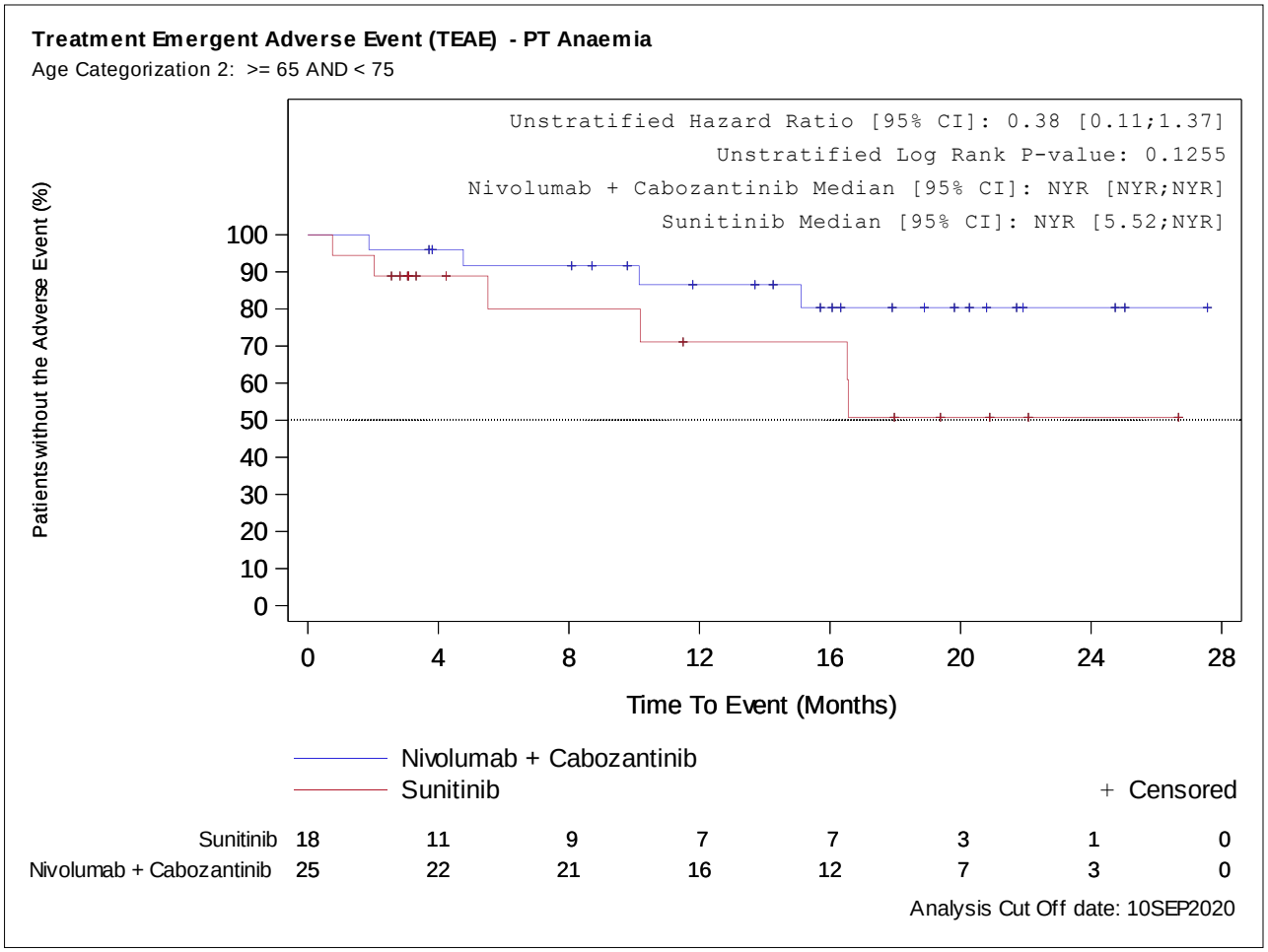
FIGURE 5.2.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



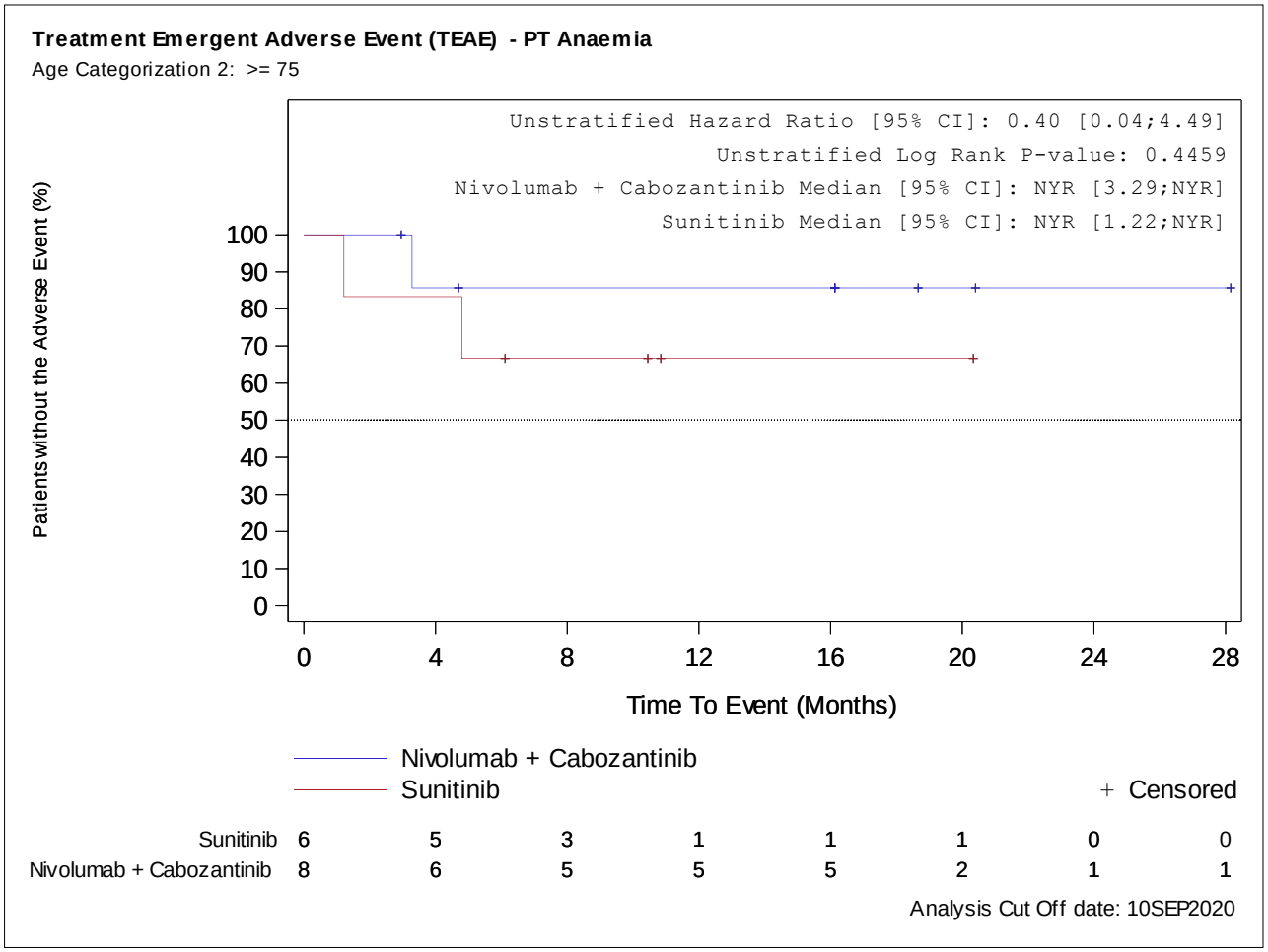

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:12:31

FIGURE 5.2.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



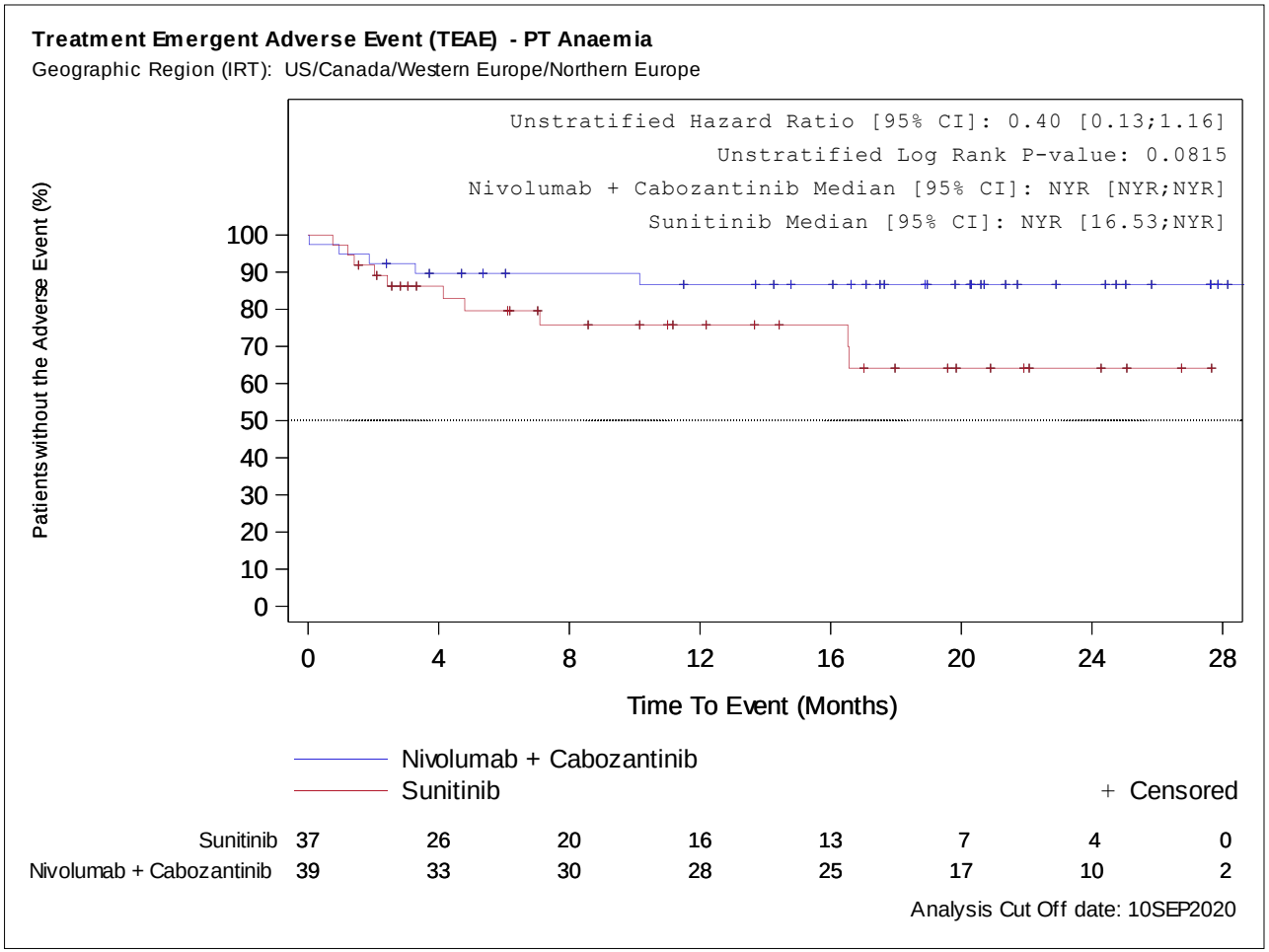

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:12:37

FIGURE 5.2.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



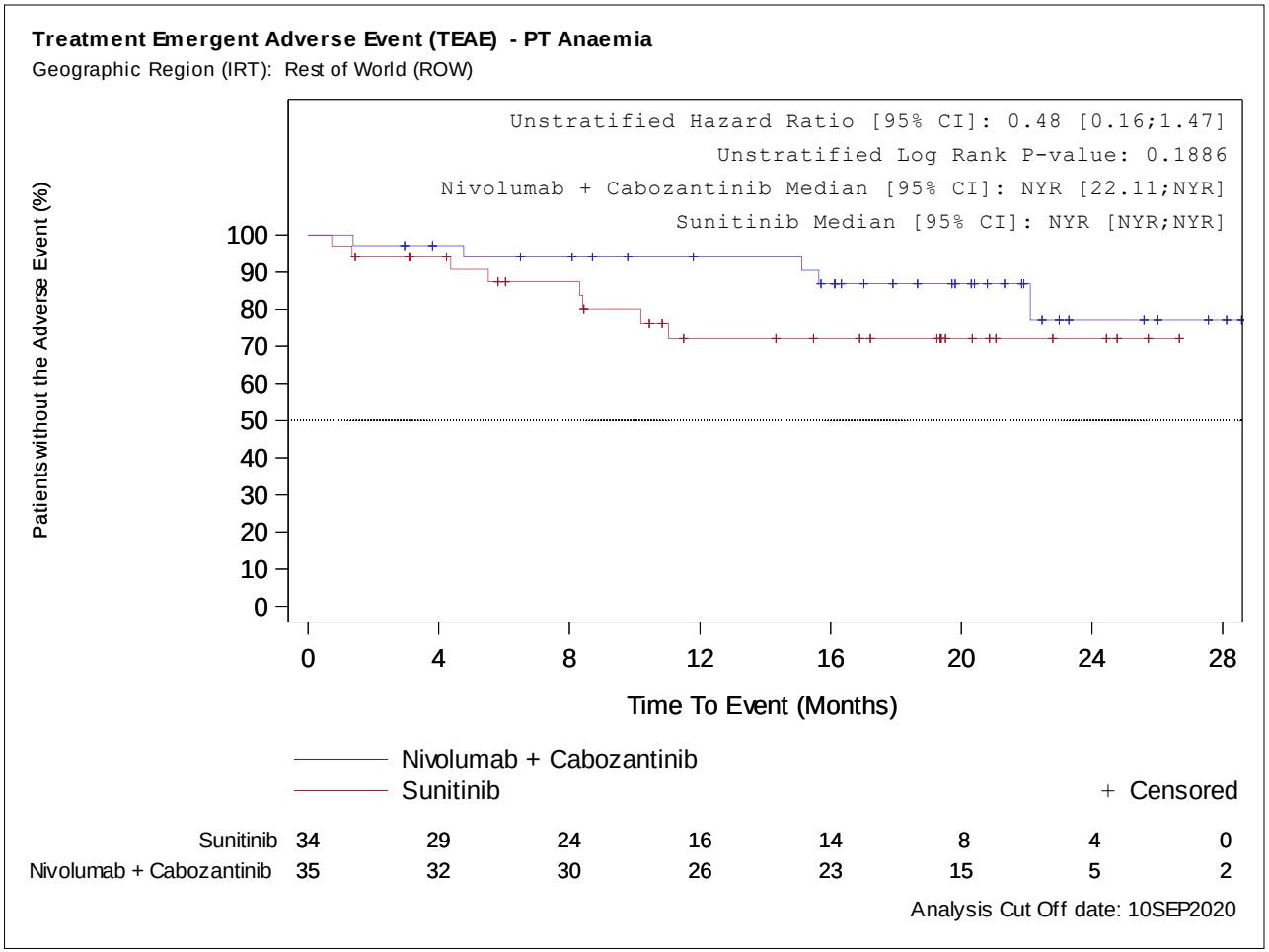

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:12:43

FIGURE 5.2.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



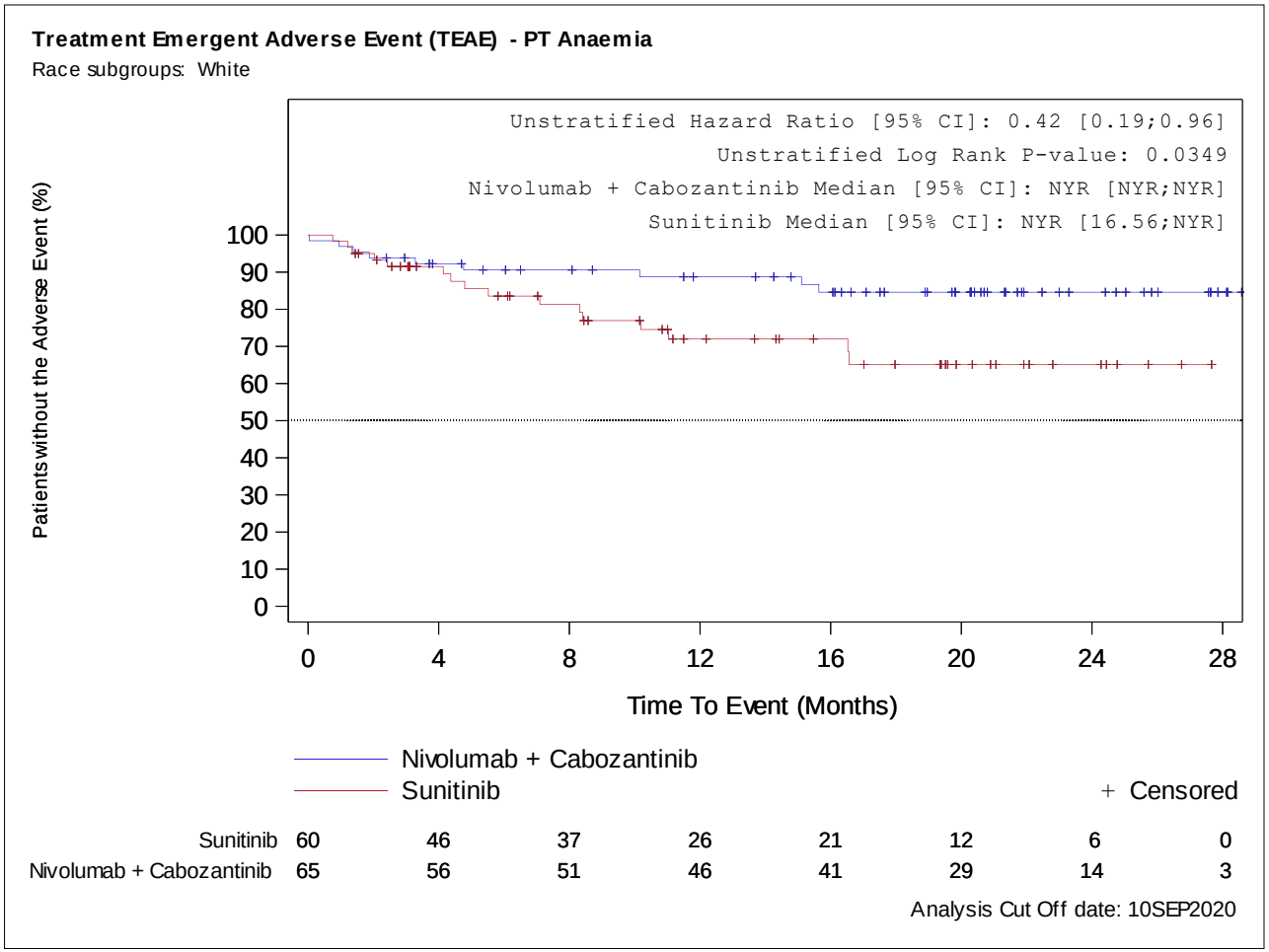

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:12:49

FIGURE 5.2.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



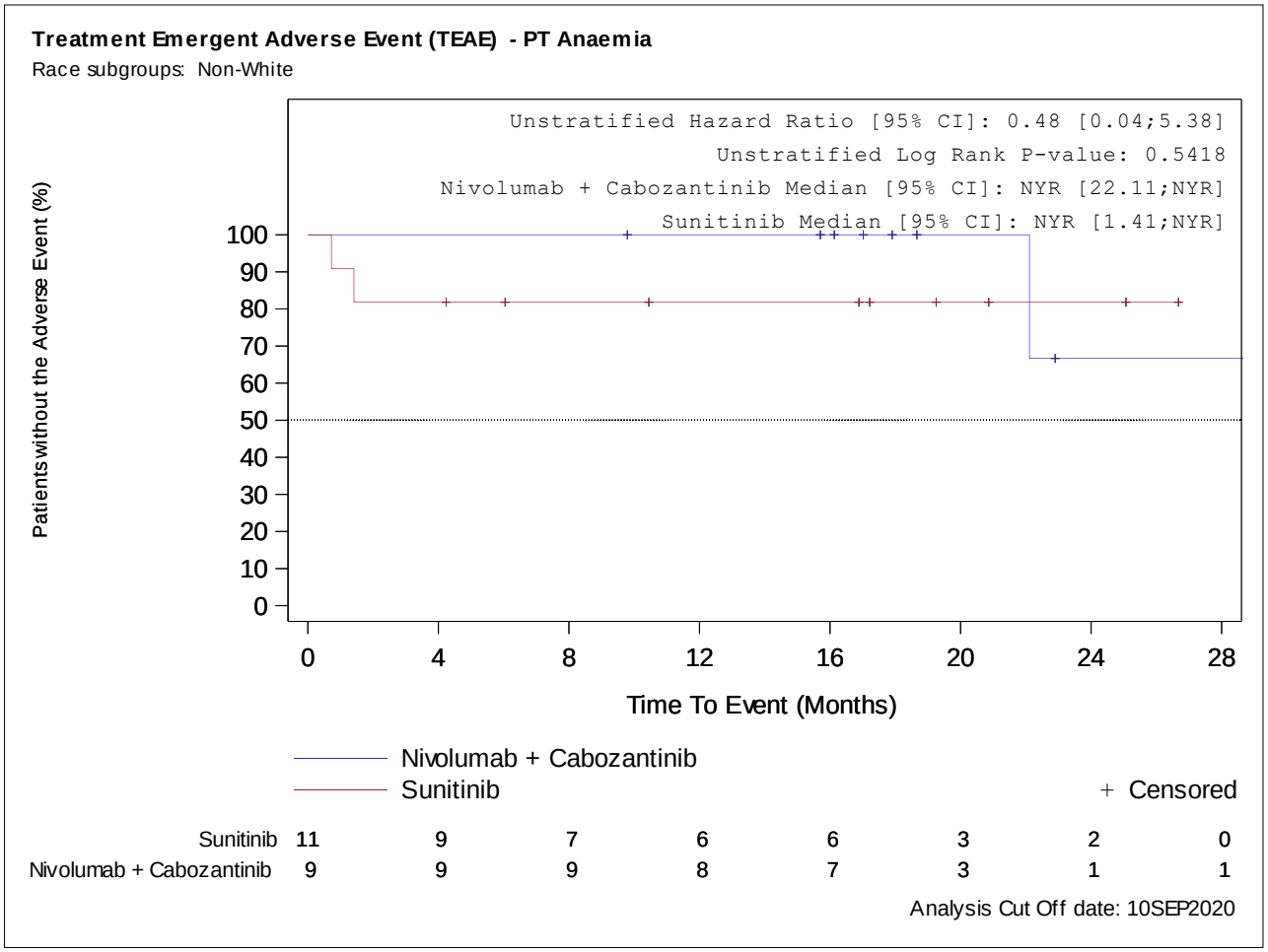

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:12:55

FIGURE 5.2.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:13:01

FIGURE 5.2.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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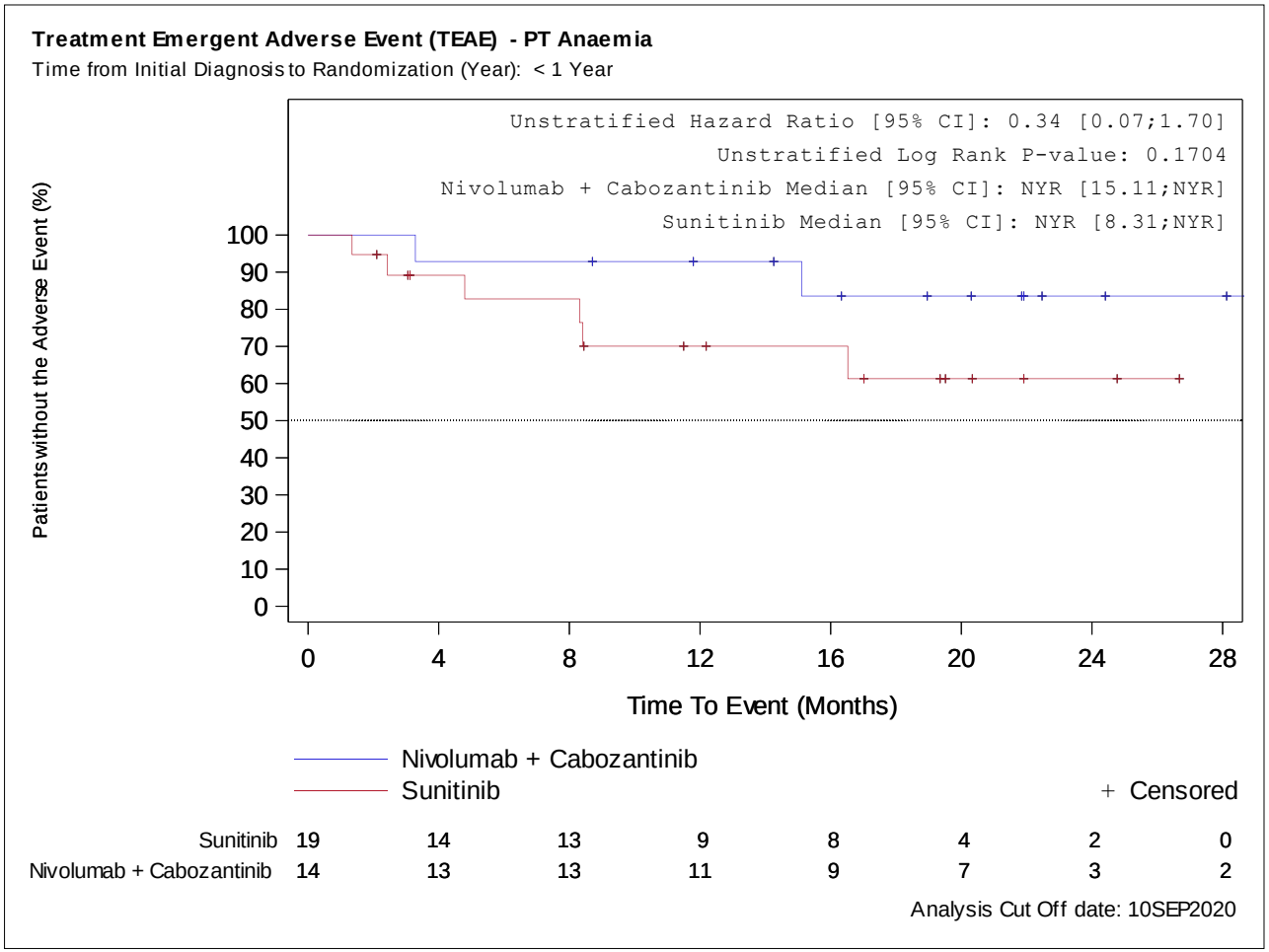
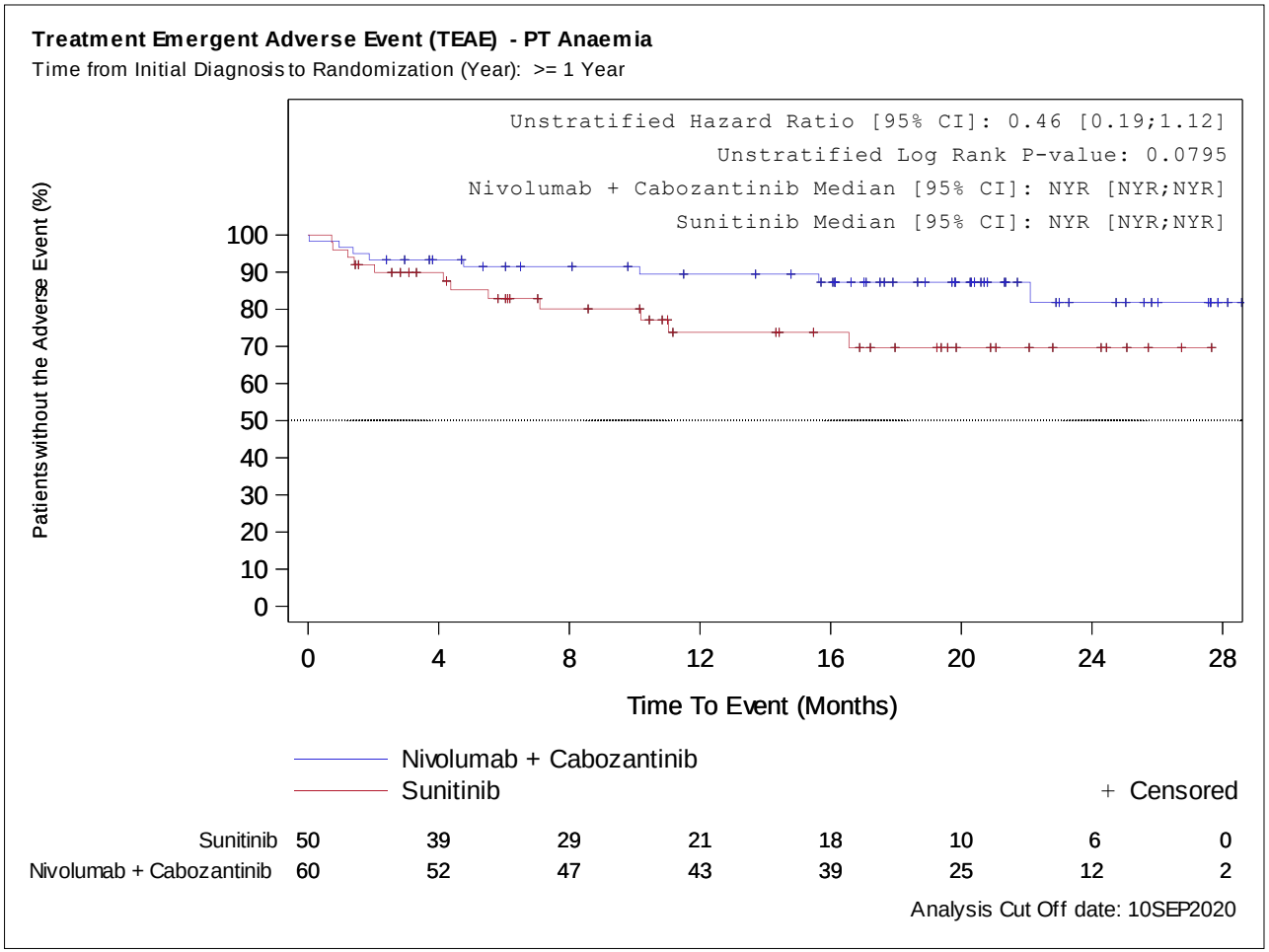
FIGURE 5.2.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:13:22

FIGURE 5.2.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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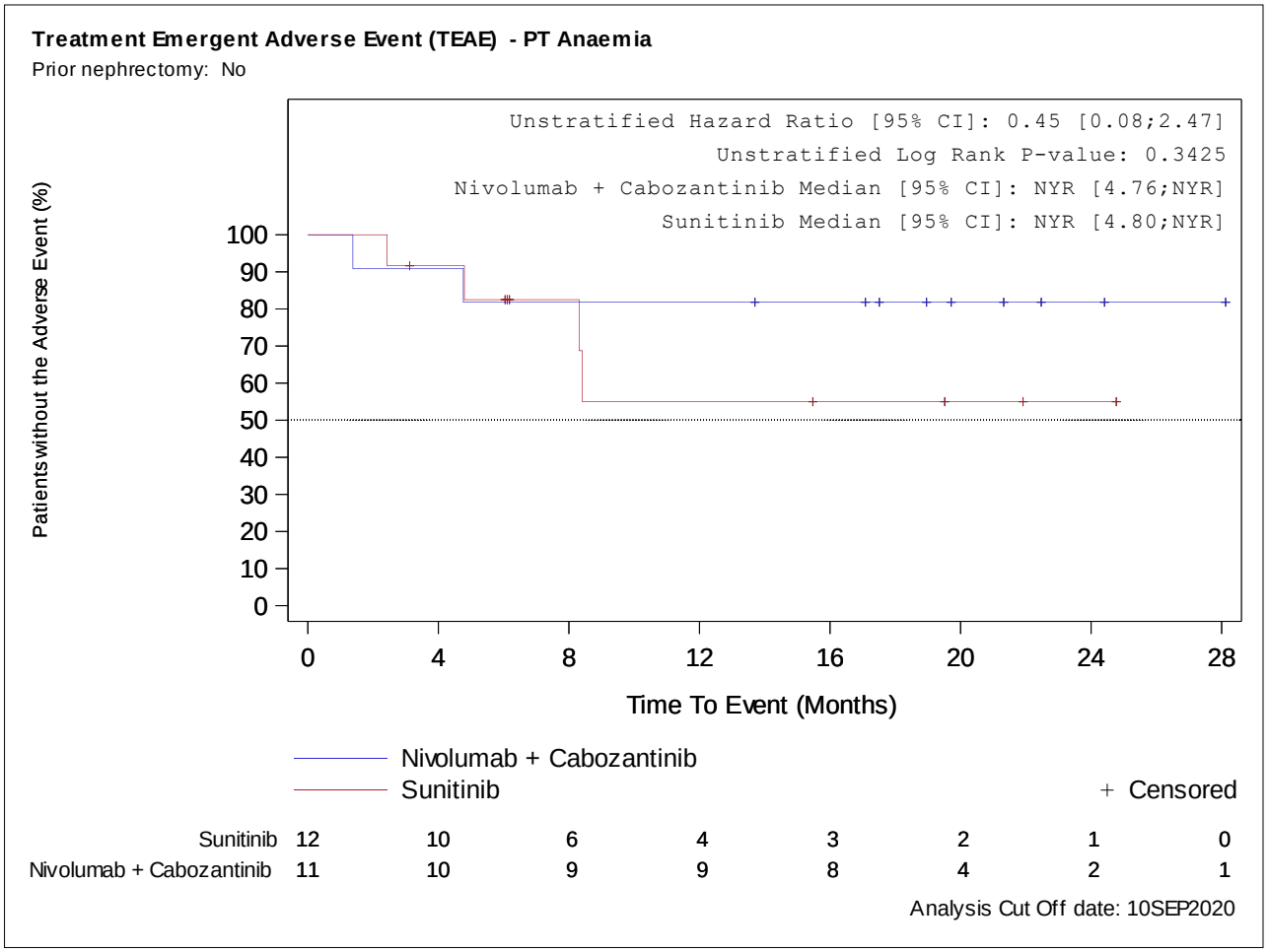
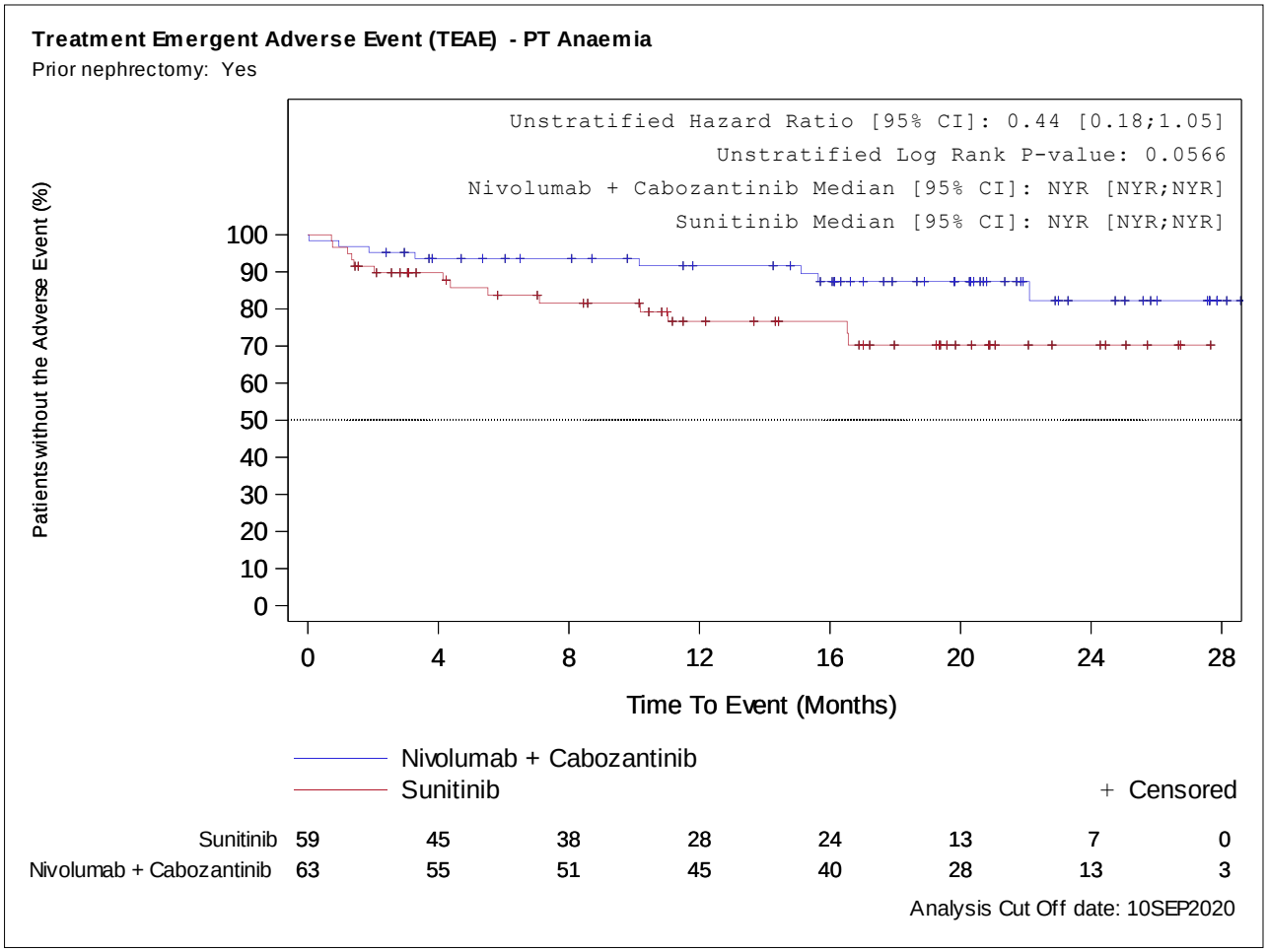
FIGURE 5.2.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:14:20

FIGURE 5.2.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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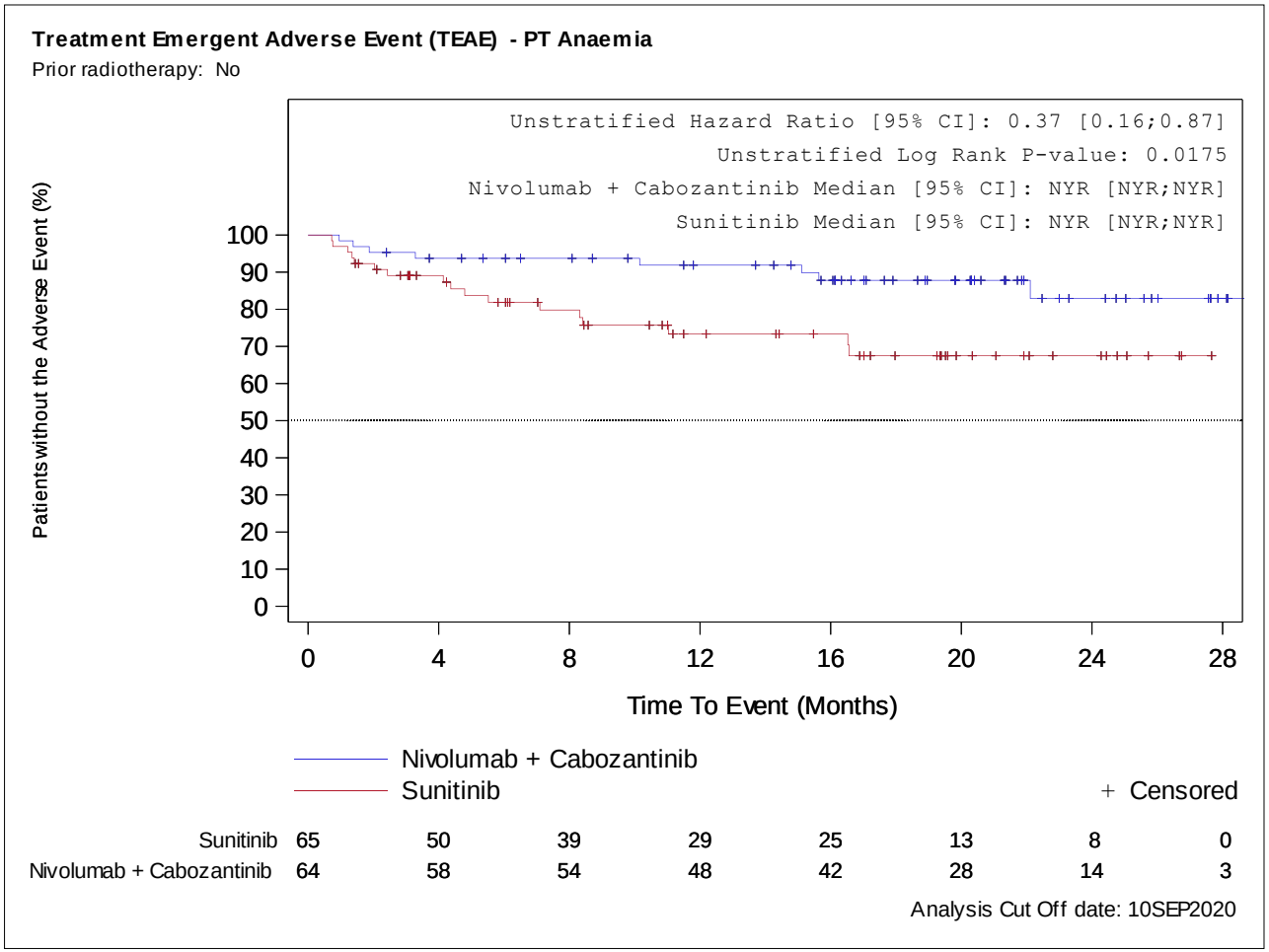
FIGURE 5.2.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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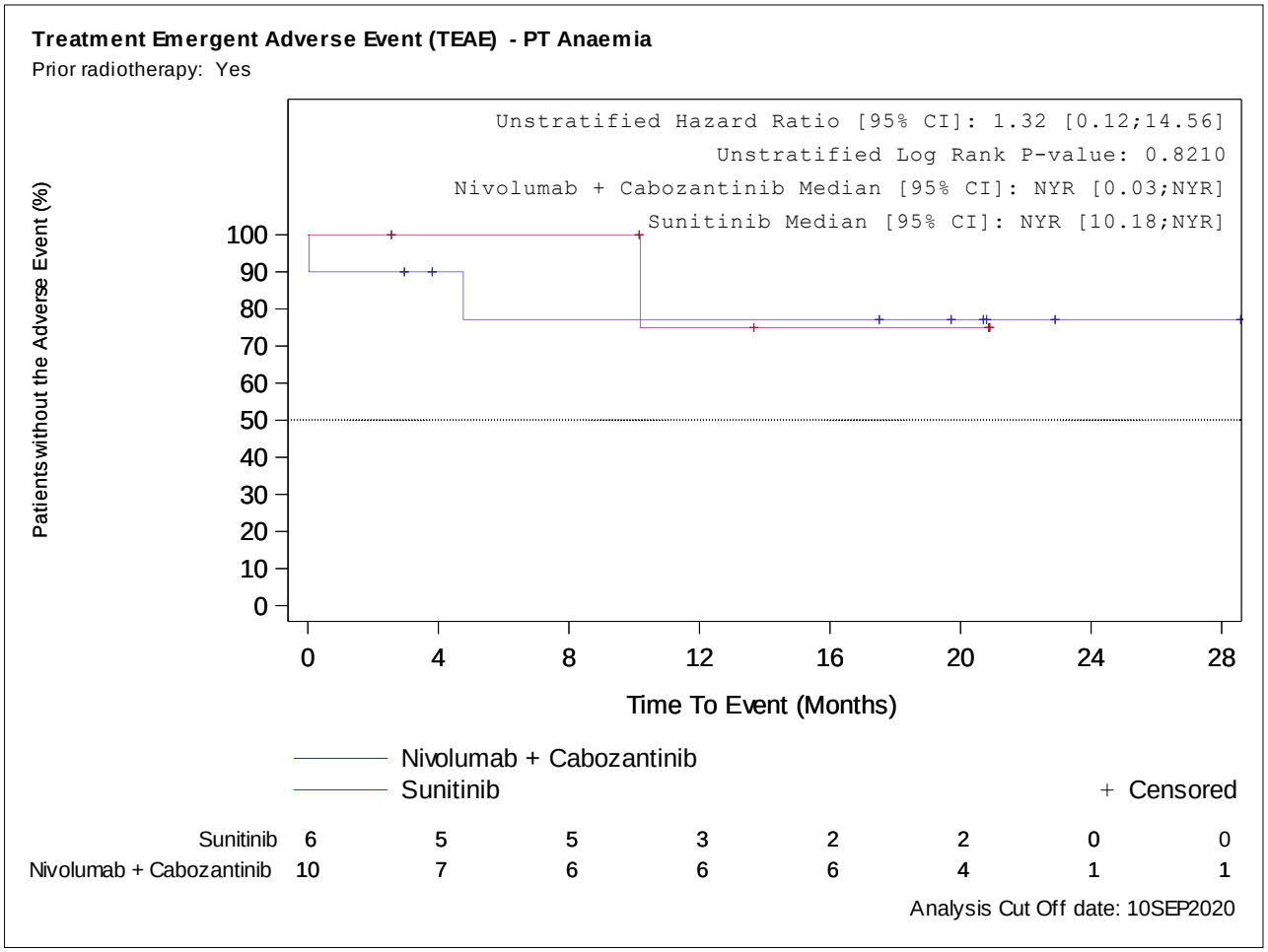
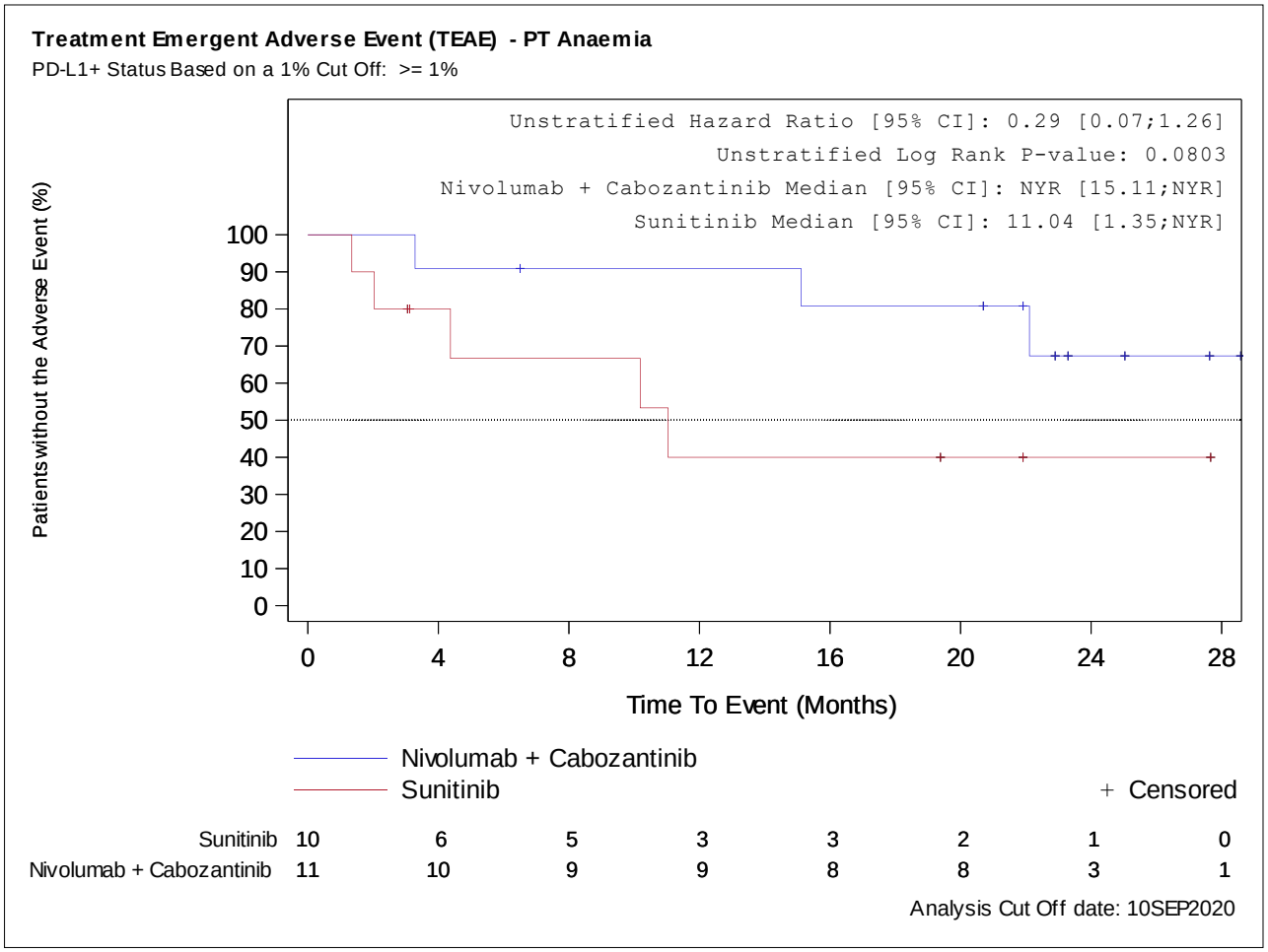
FIGURE 5.2.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



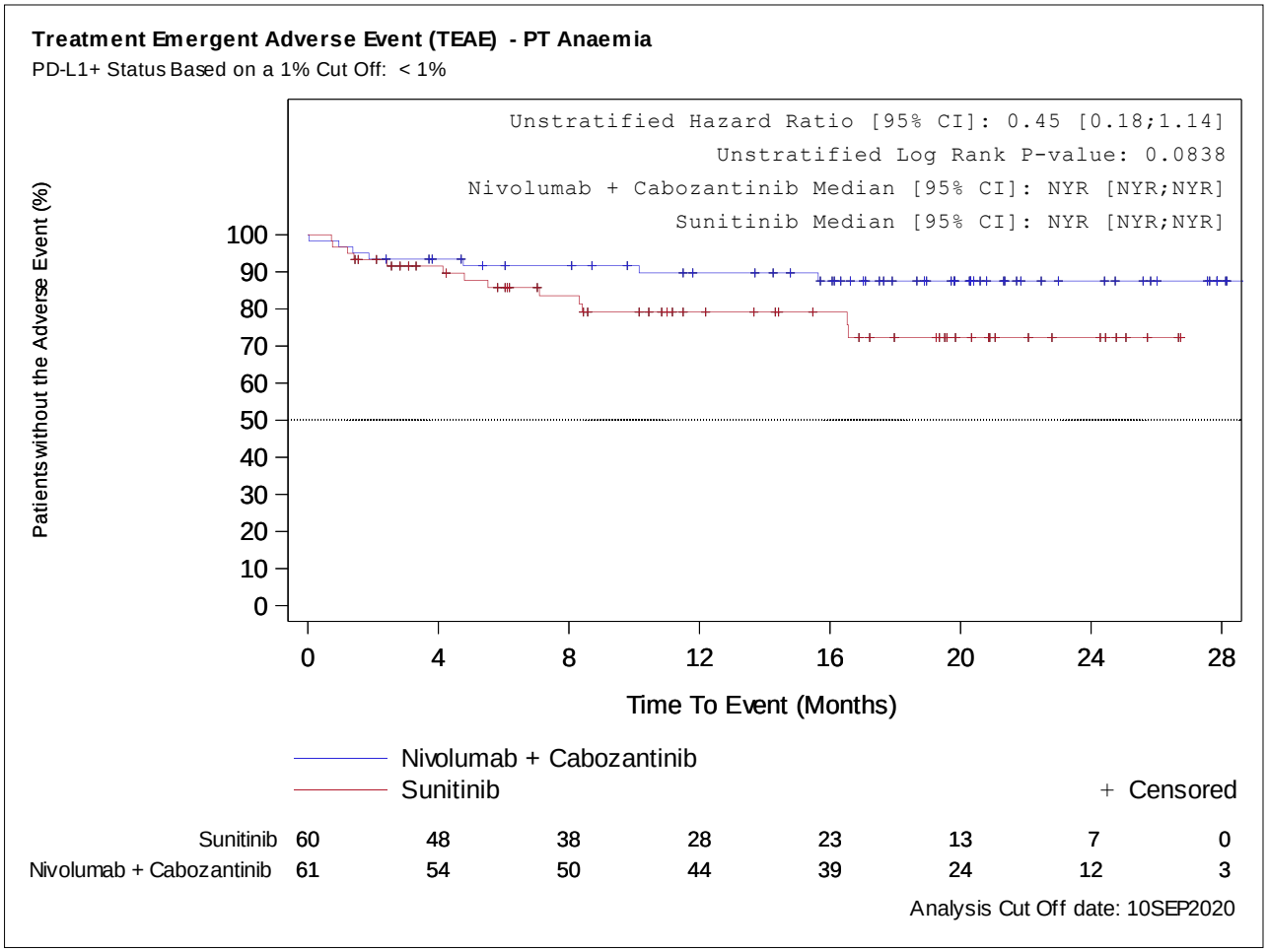

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:14:37

FIGURE 5.2.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



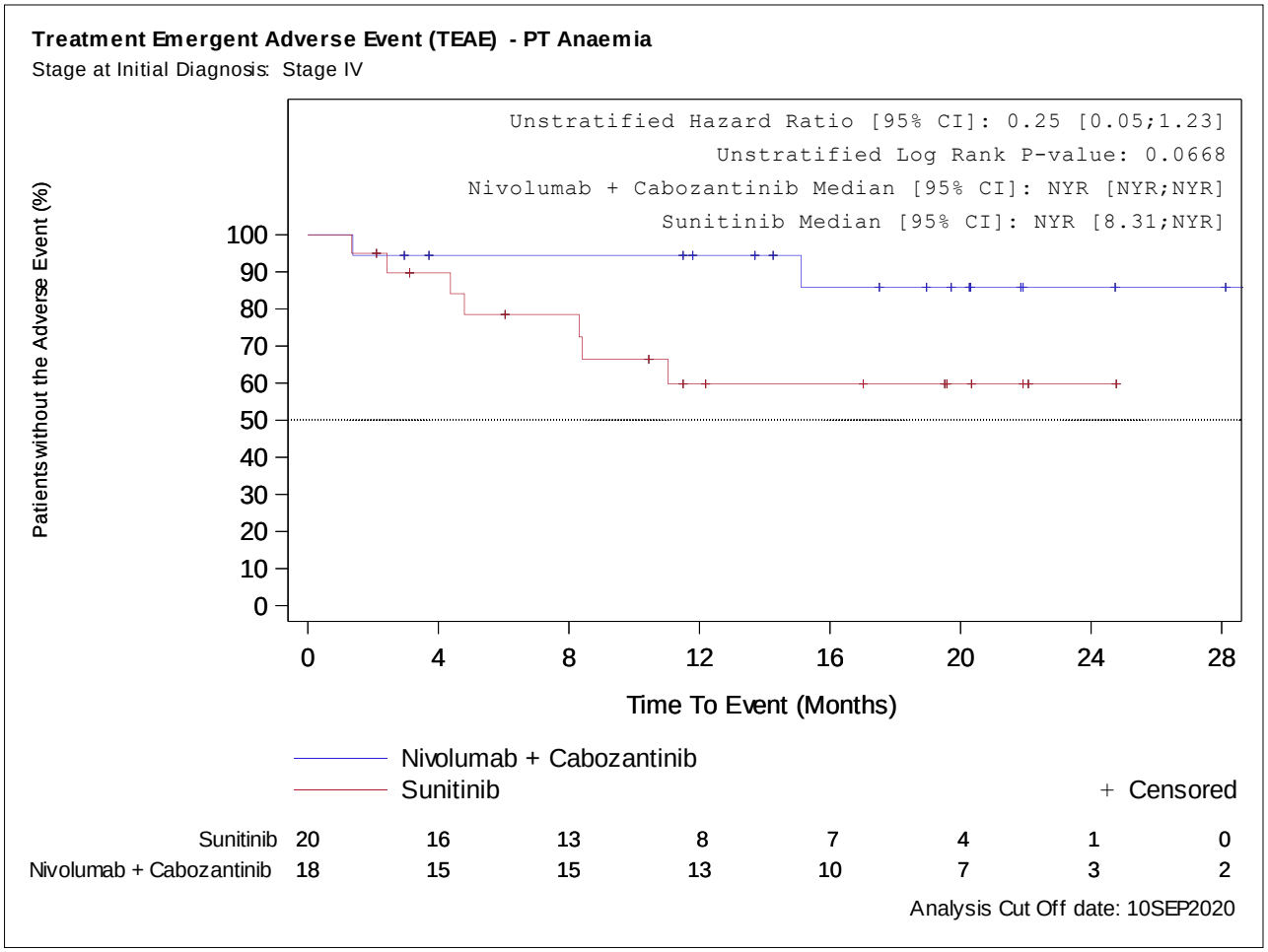

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:14:43

FIGURE 5.2.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



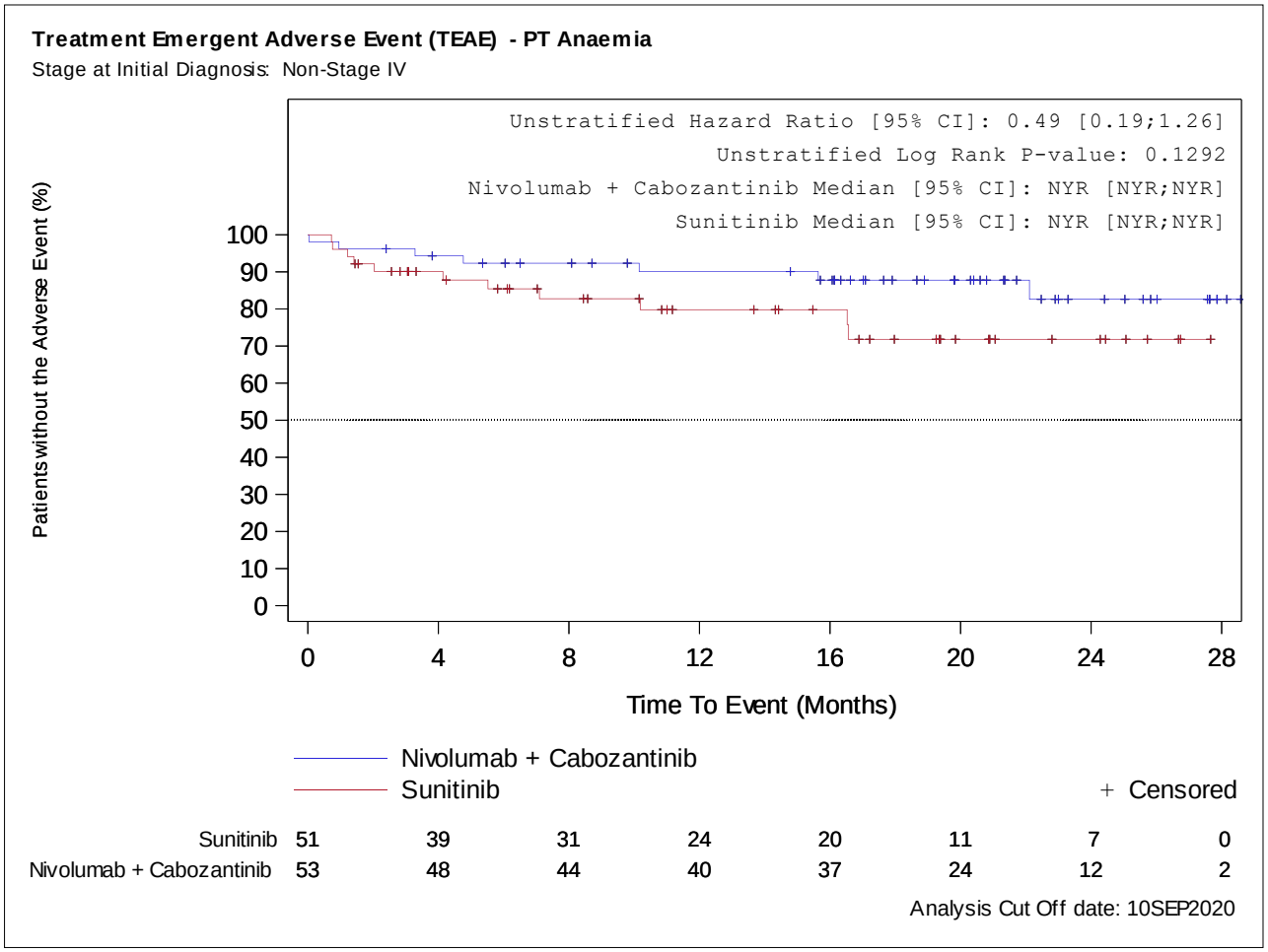

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:14:49

FIGURE 5.2.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



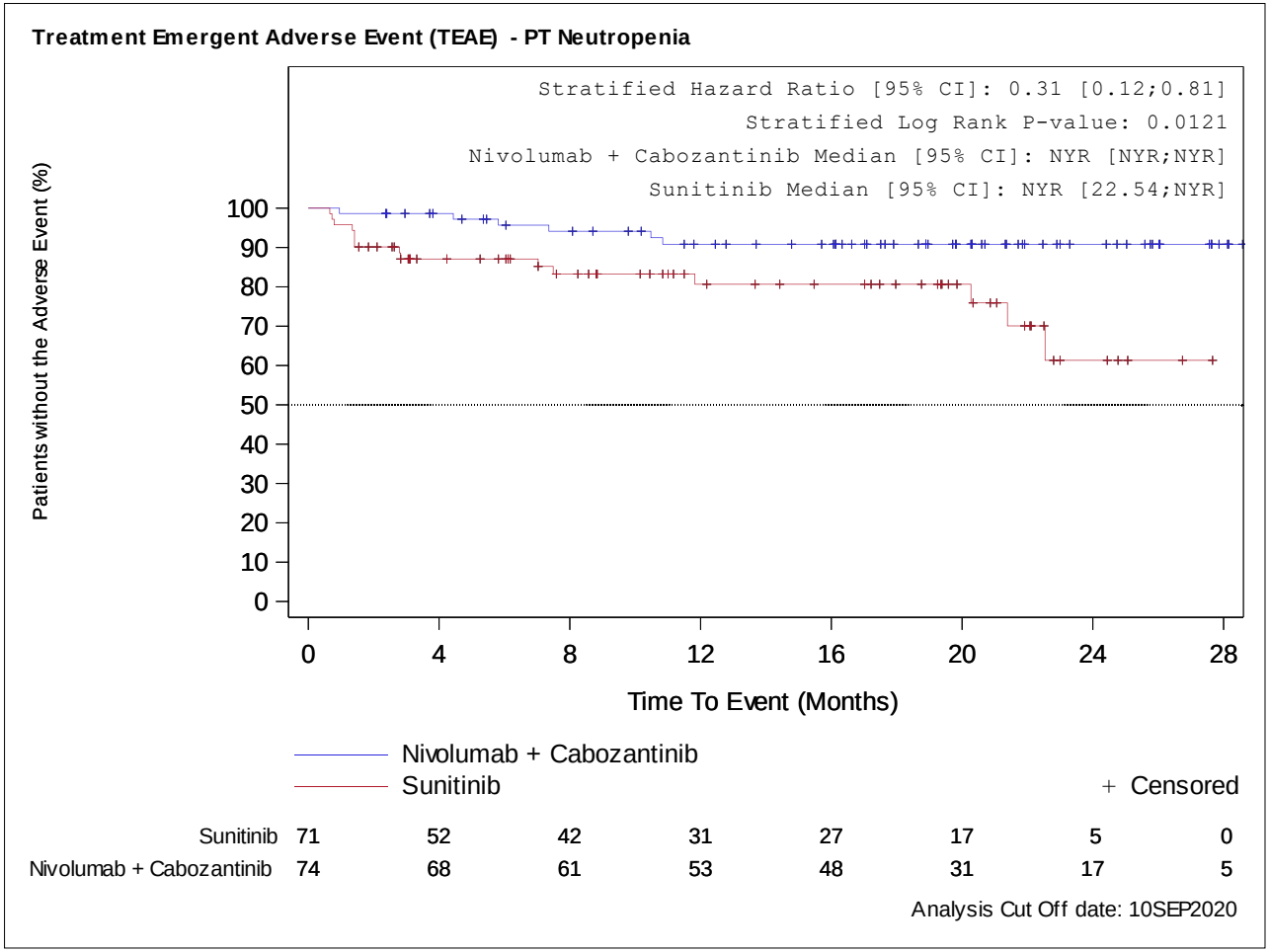

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:15:19

FIGURE 5.2.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:15:24

FIGURE 5.3.1: Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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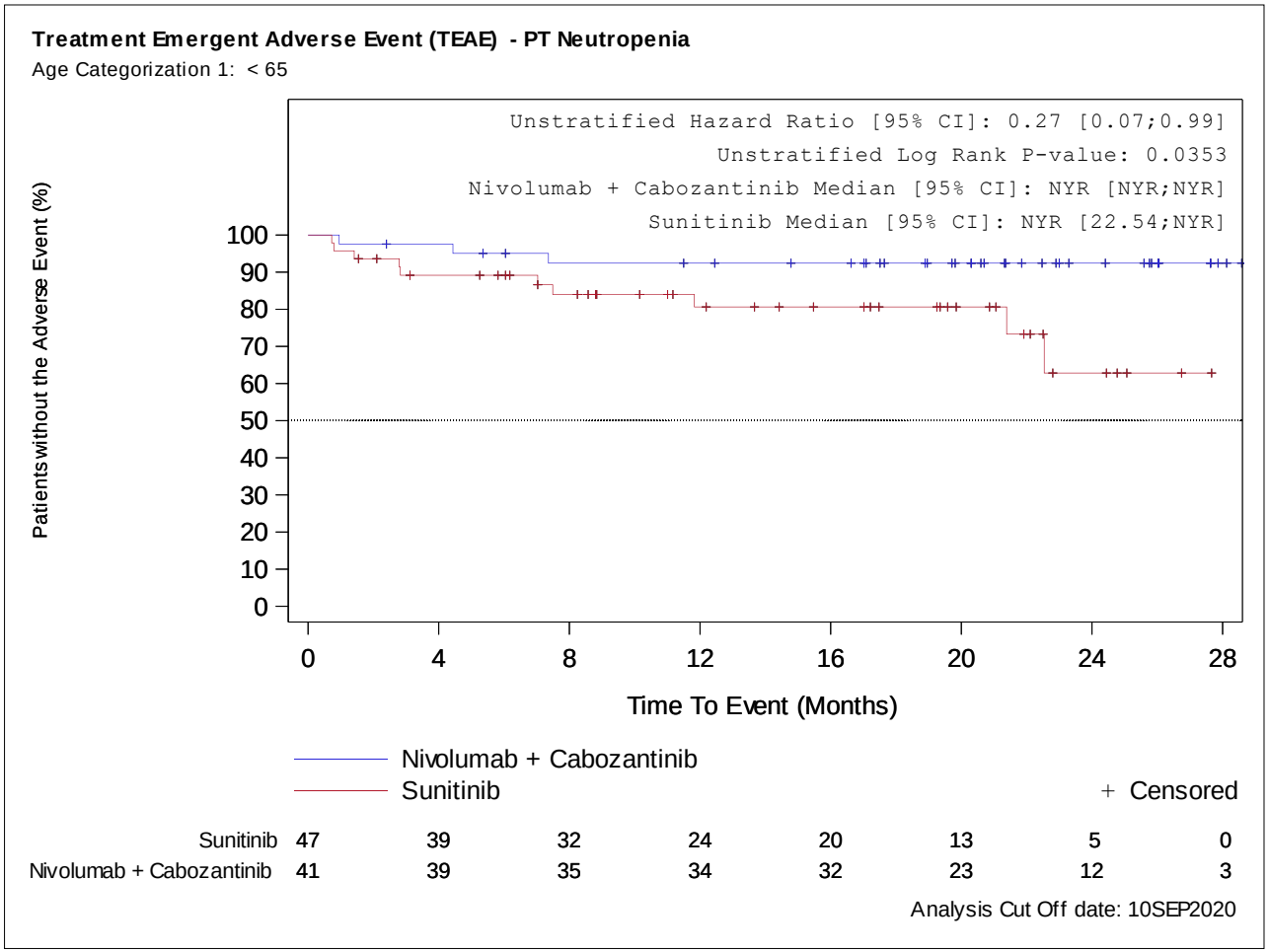
FIGURE 5.3.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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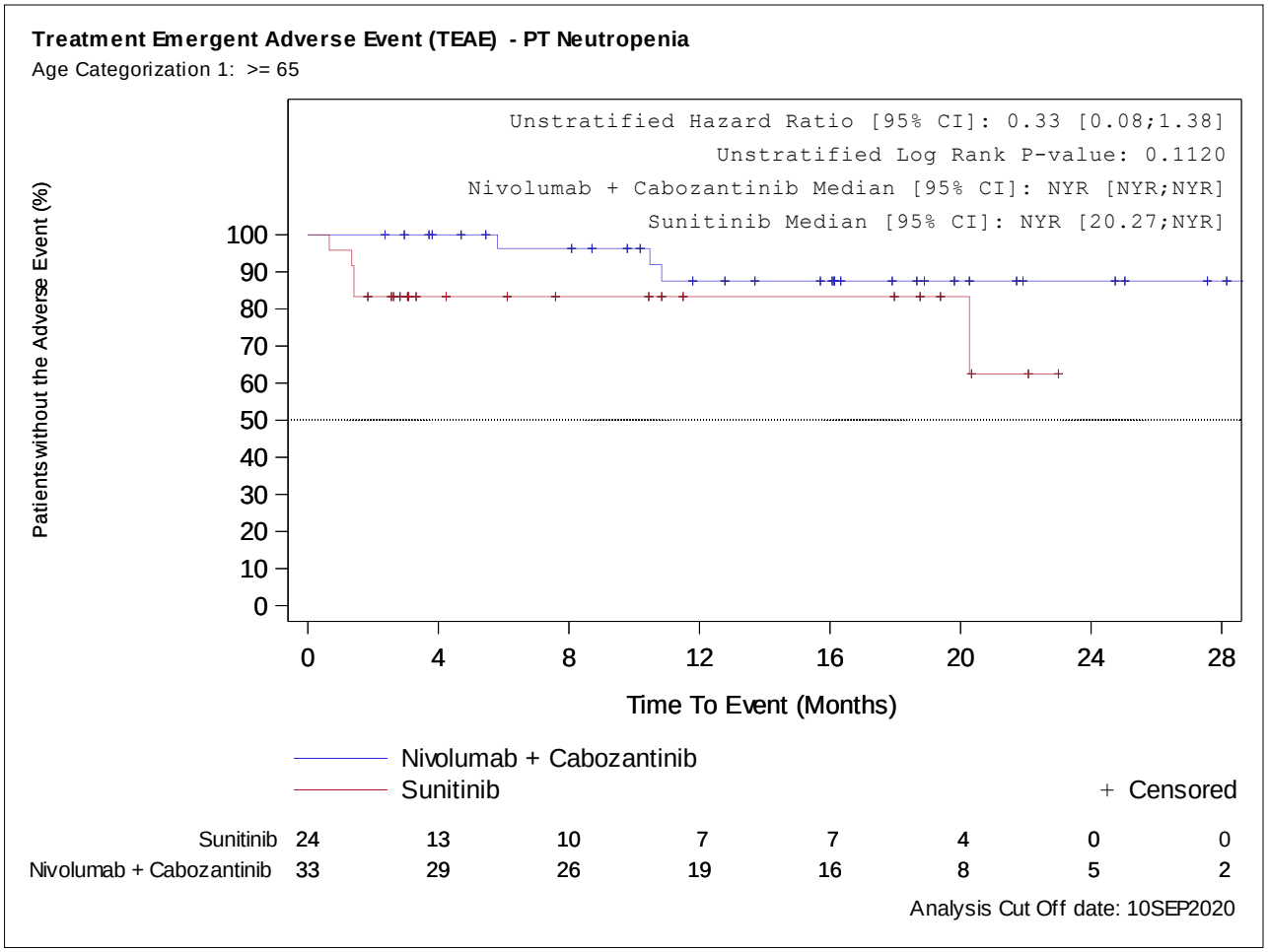
FIGURE 5.3.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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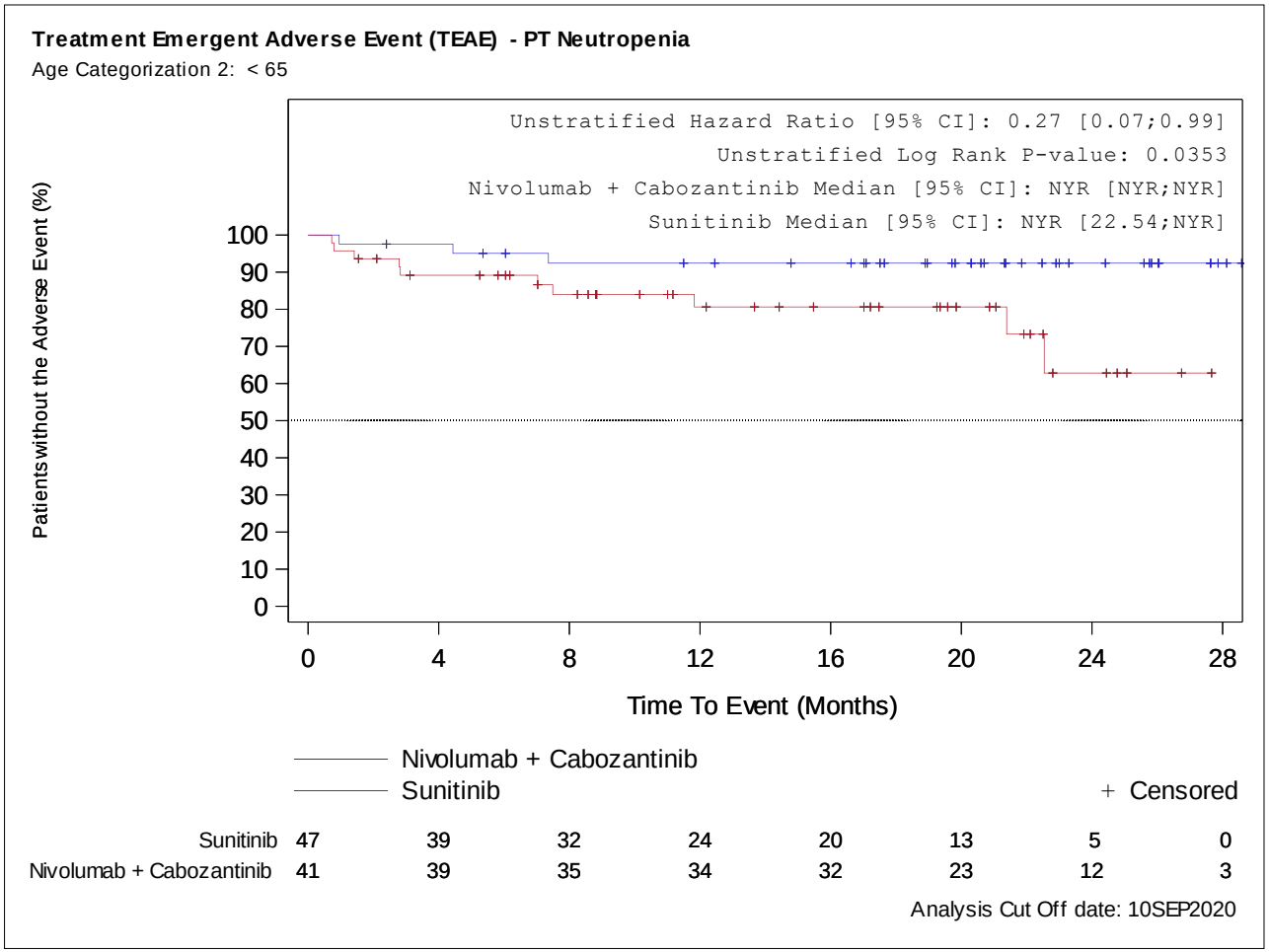
FIGURE 5.3.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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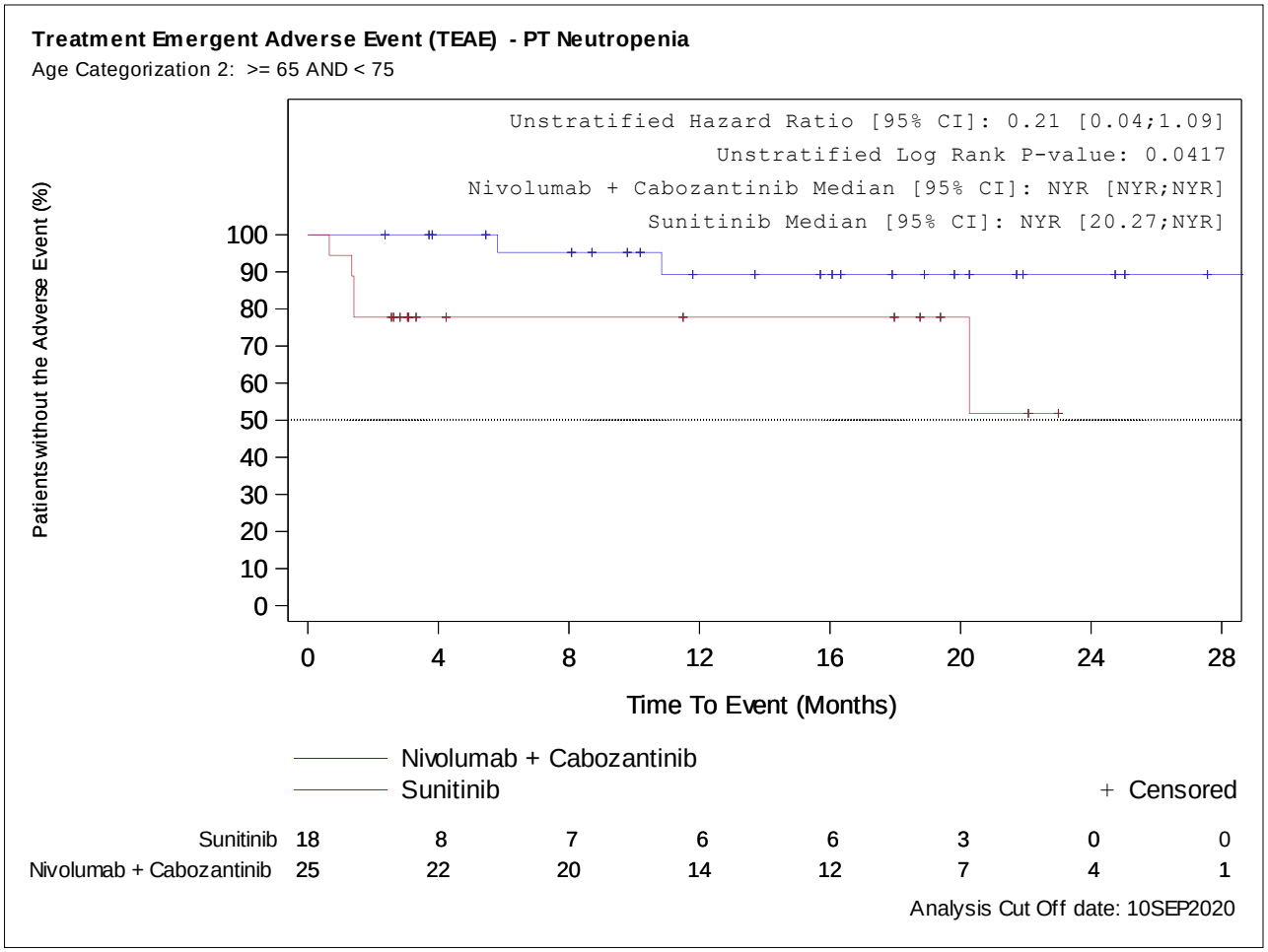
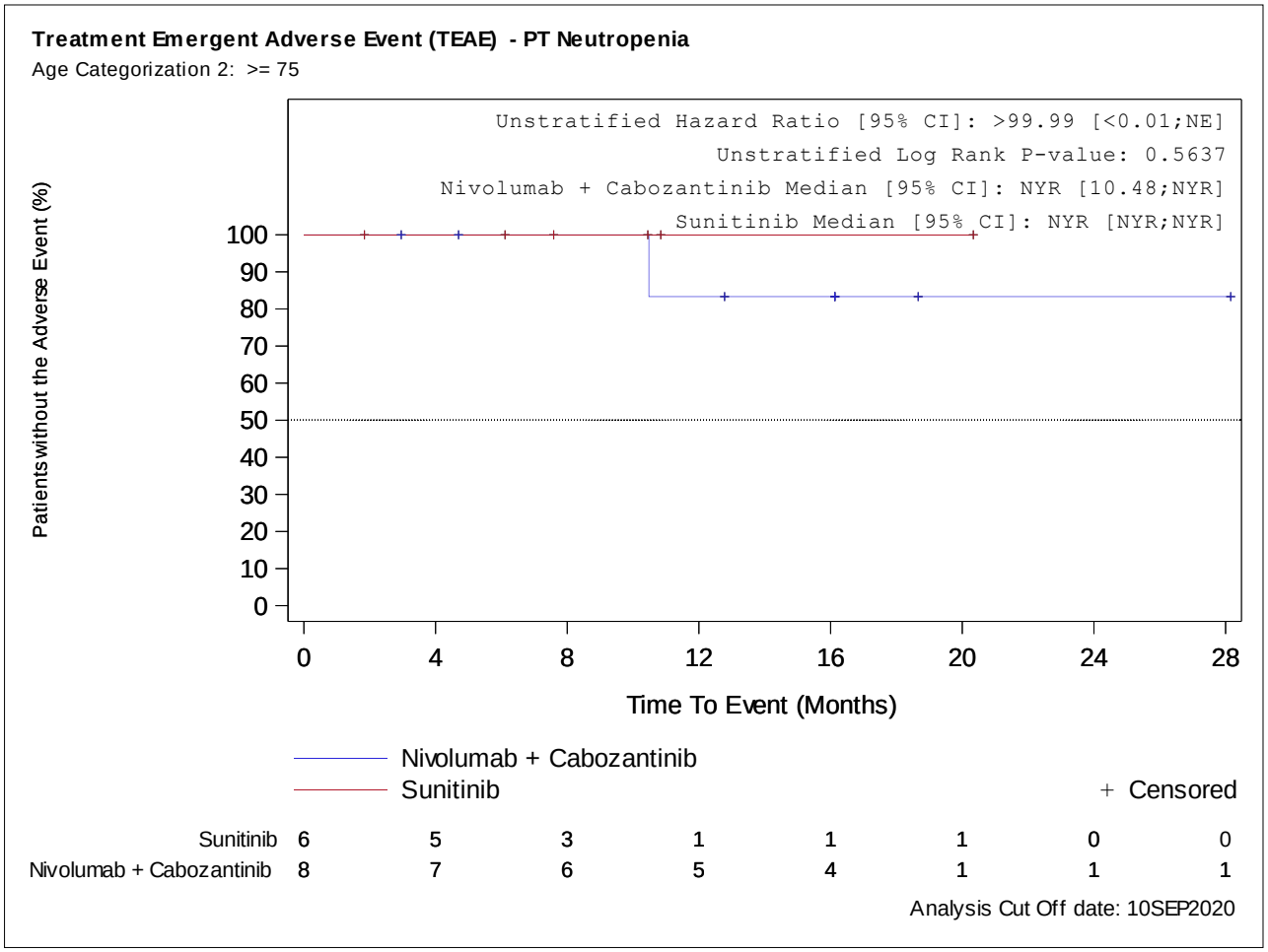
FIGURE 5.3.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:18:56

FIGURE 5.3.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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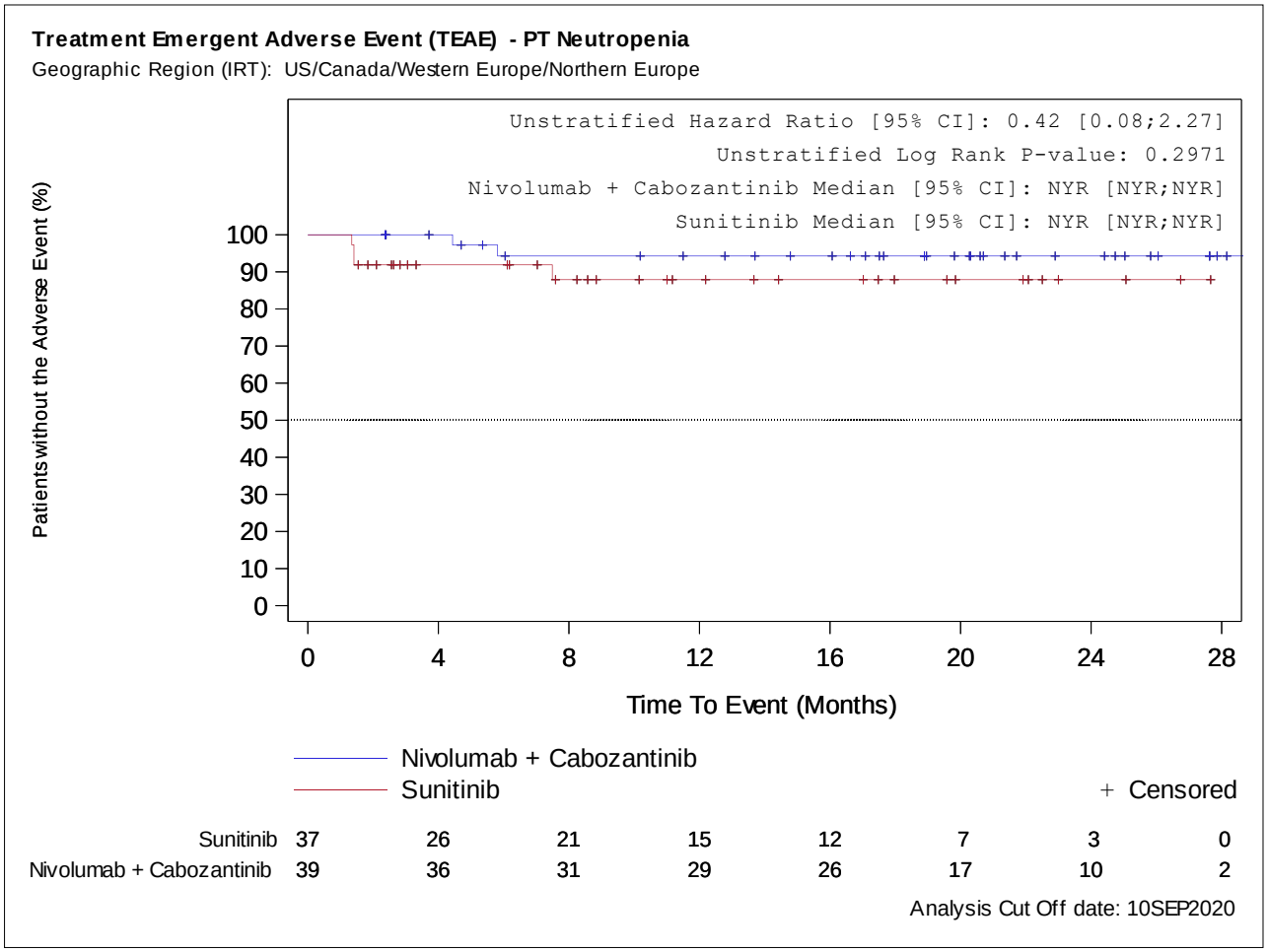
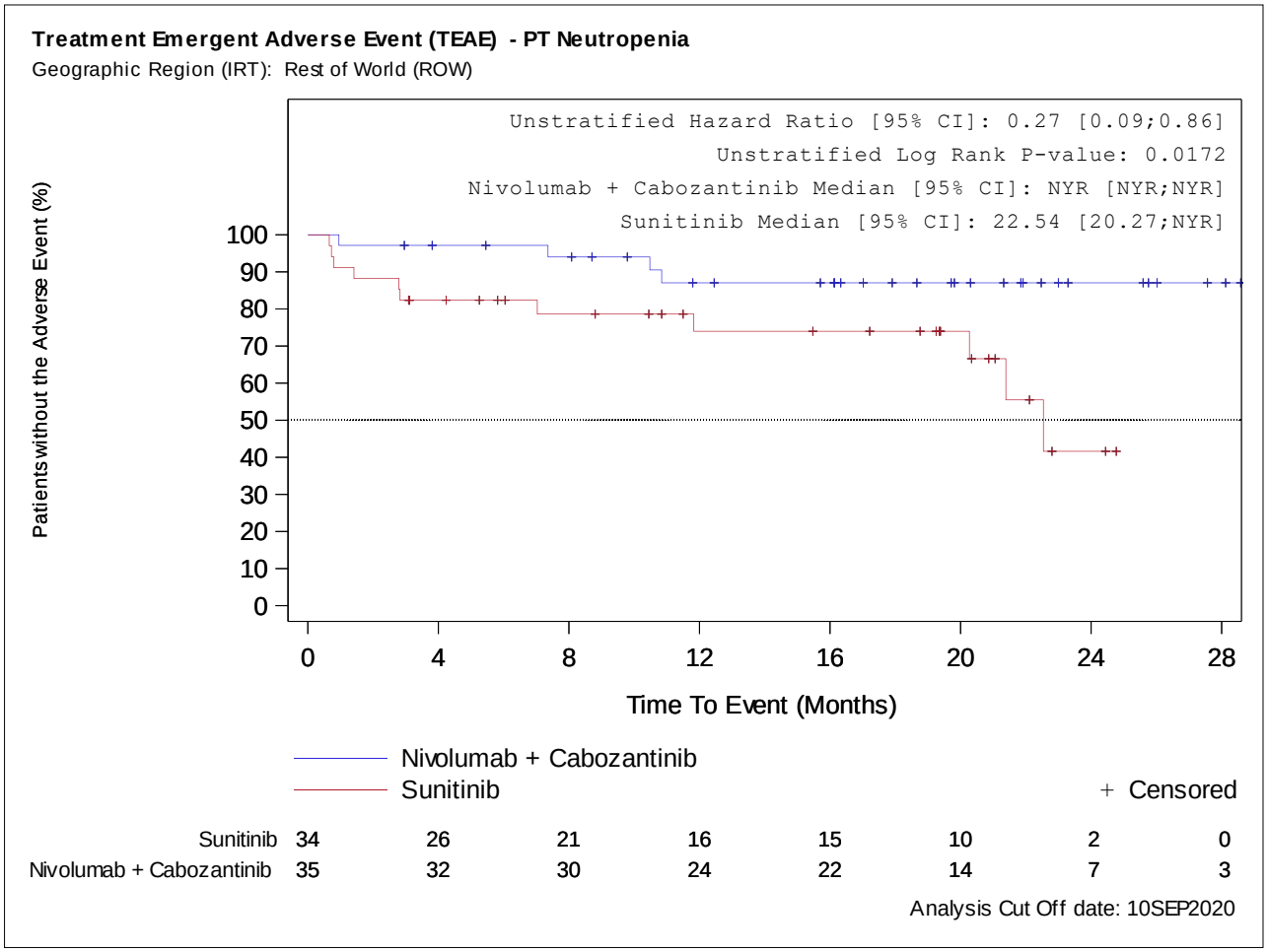
FIGURE 5.3.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



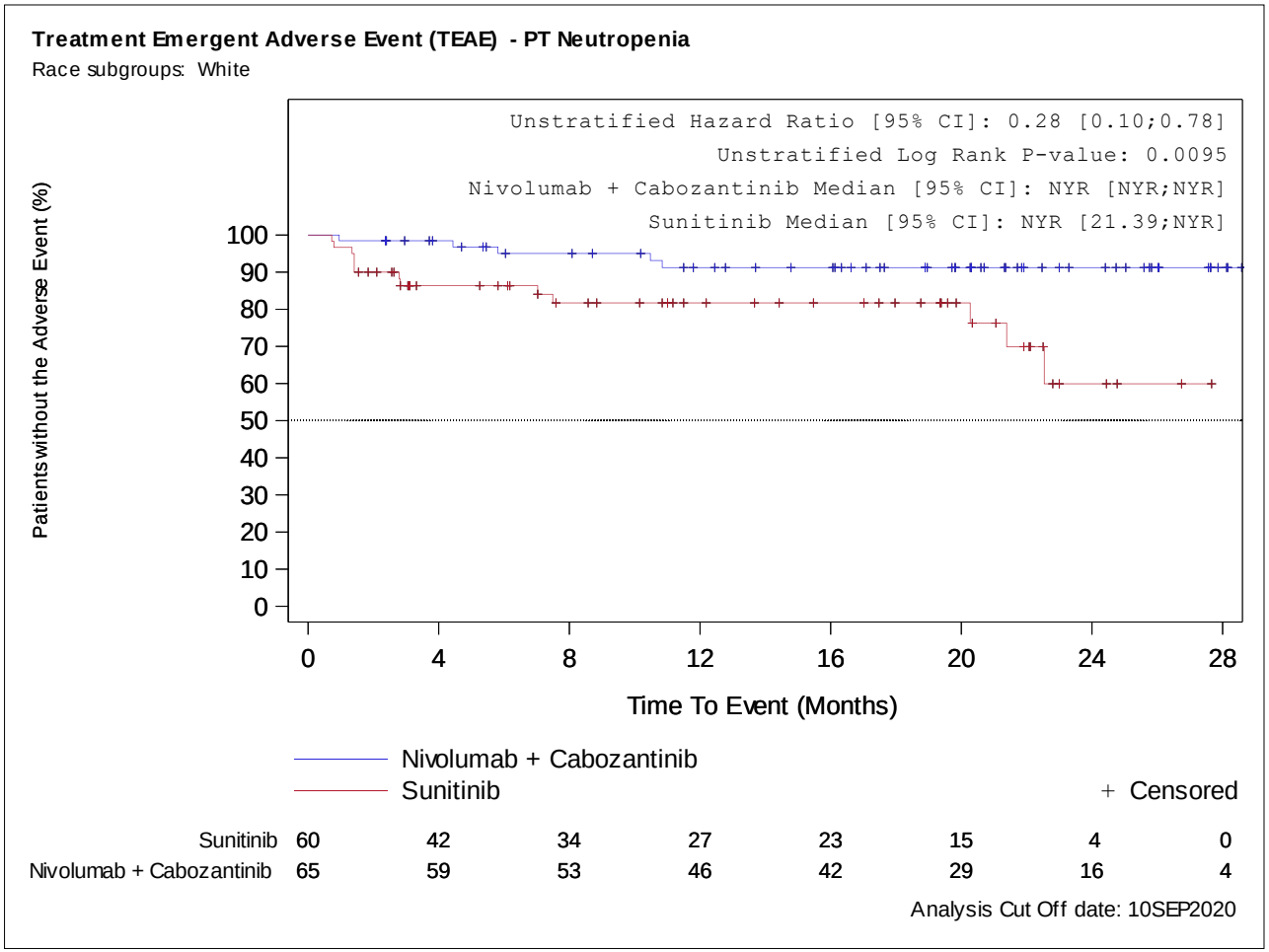

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:19:07

FIGURE 5.3.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



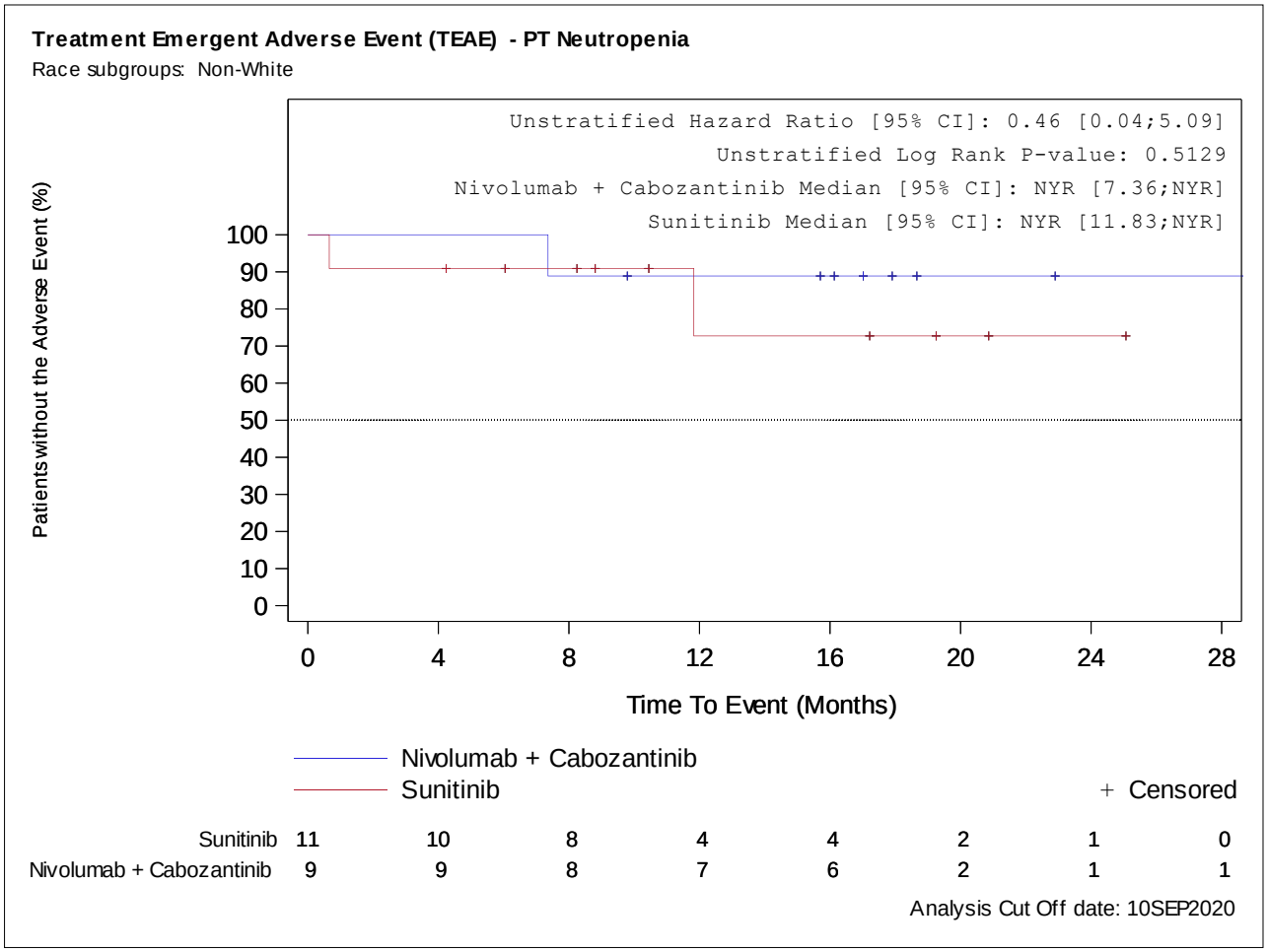

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:19:13

FIGURE 5.3.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:19:19

FIGURE 5.3.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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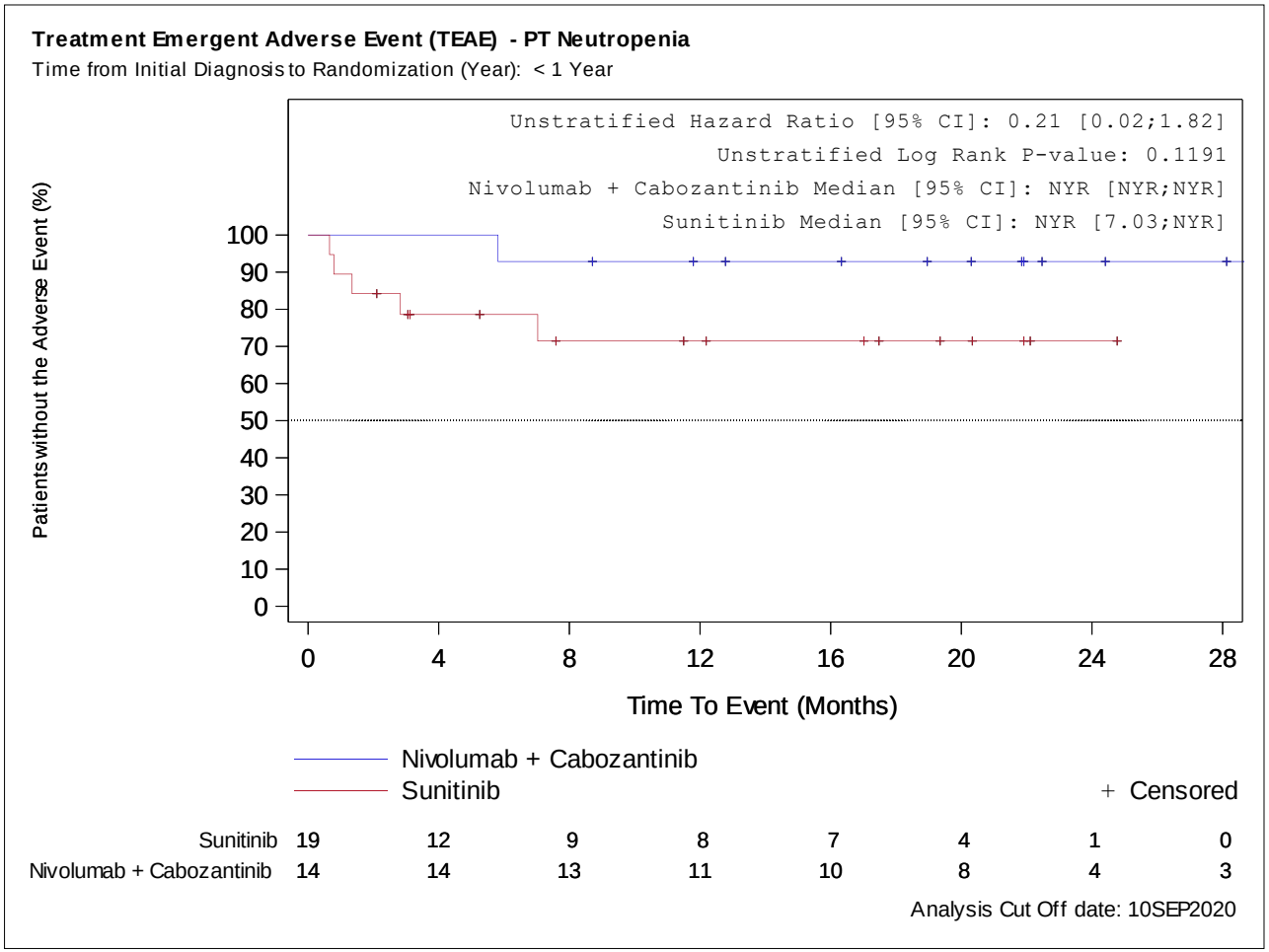
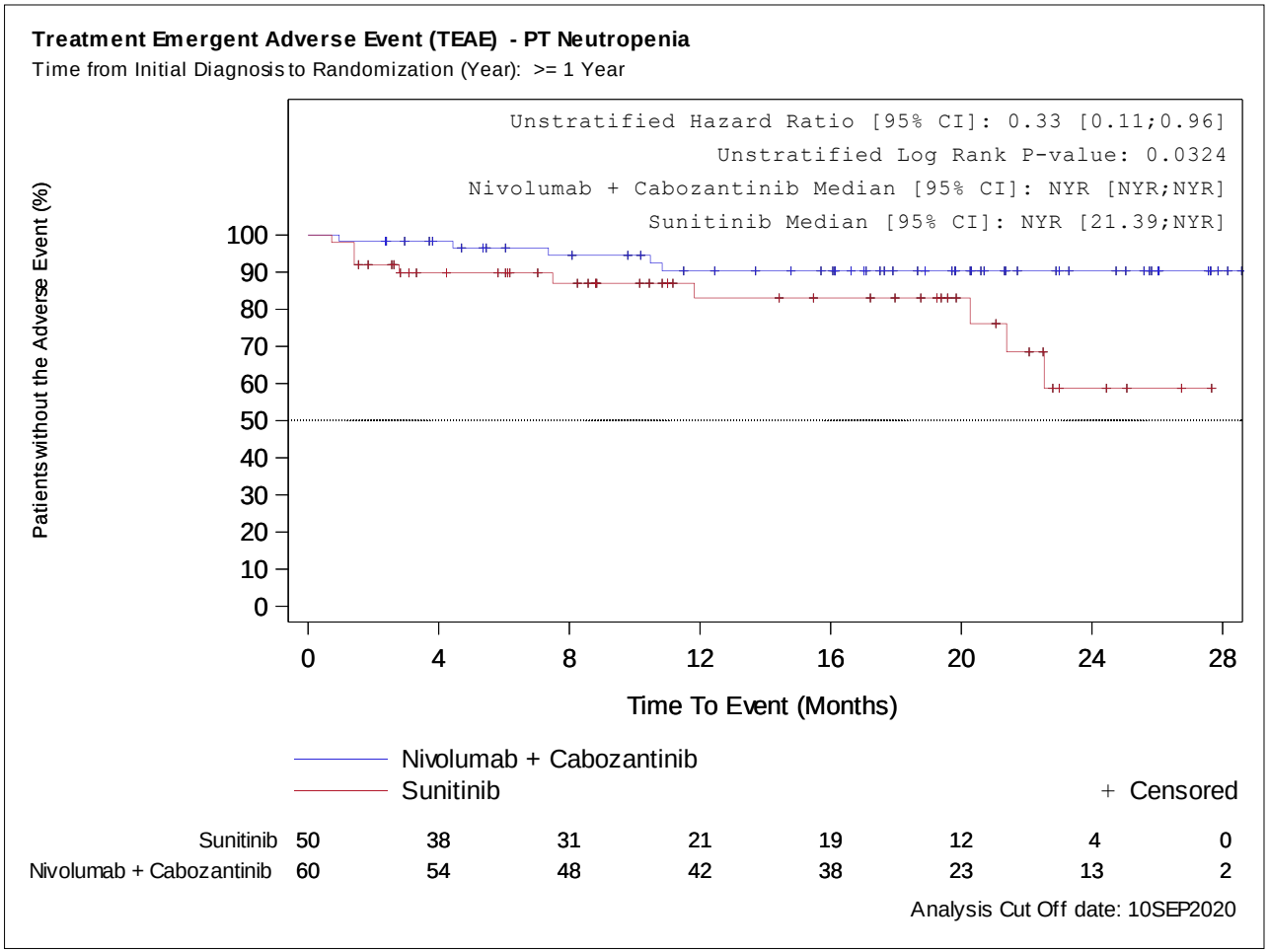
FIGURE 5.3.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



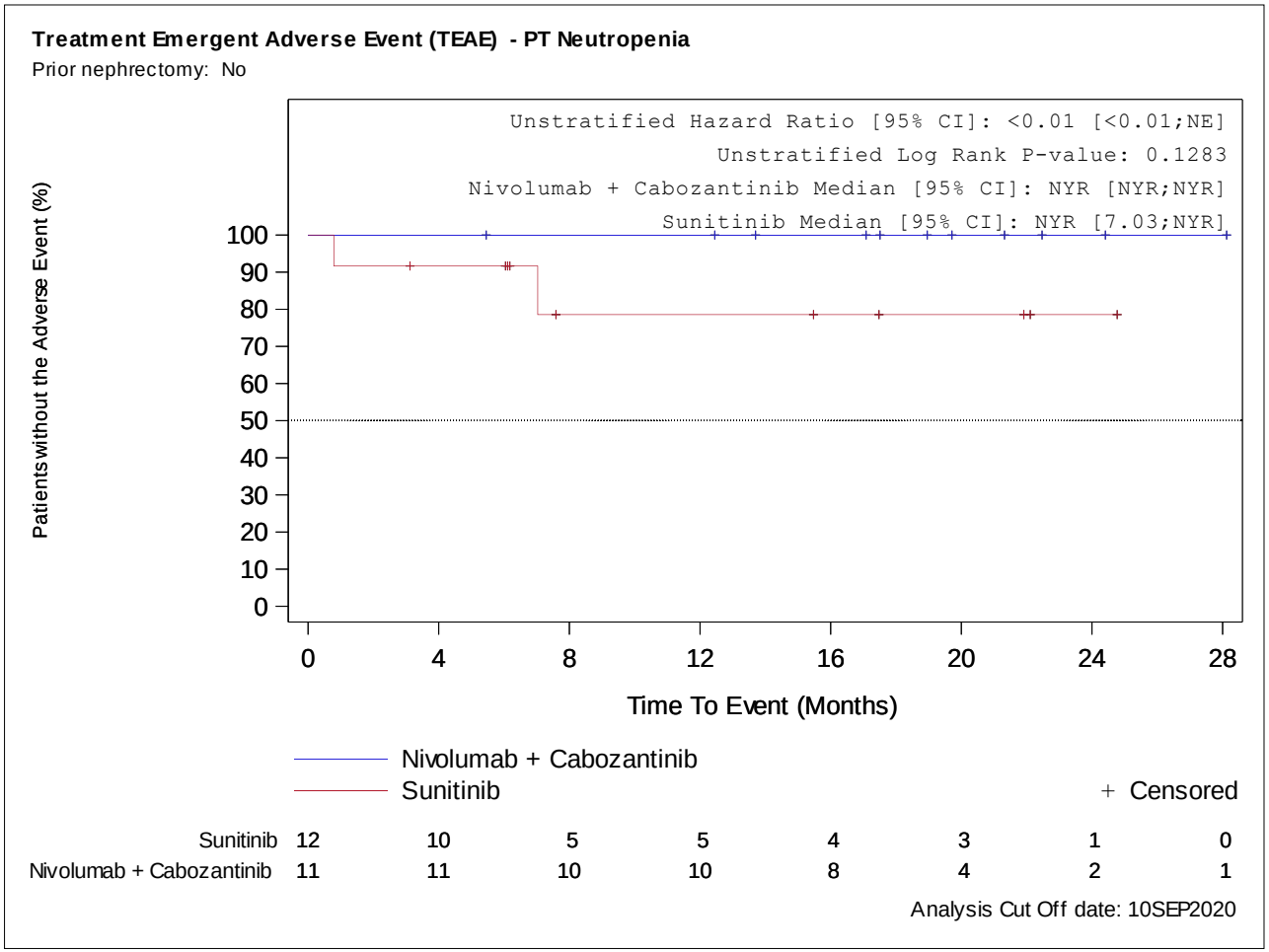

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:19:43

FIGURE 5.3.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:19:49

FIGURE 5.3.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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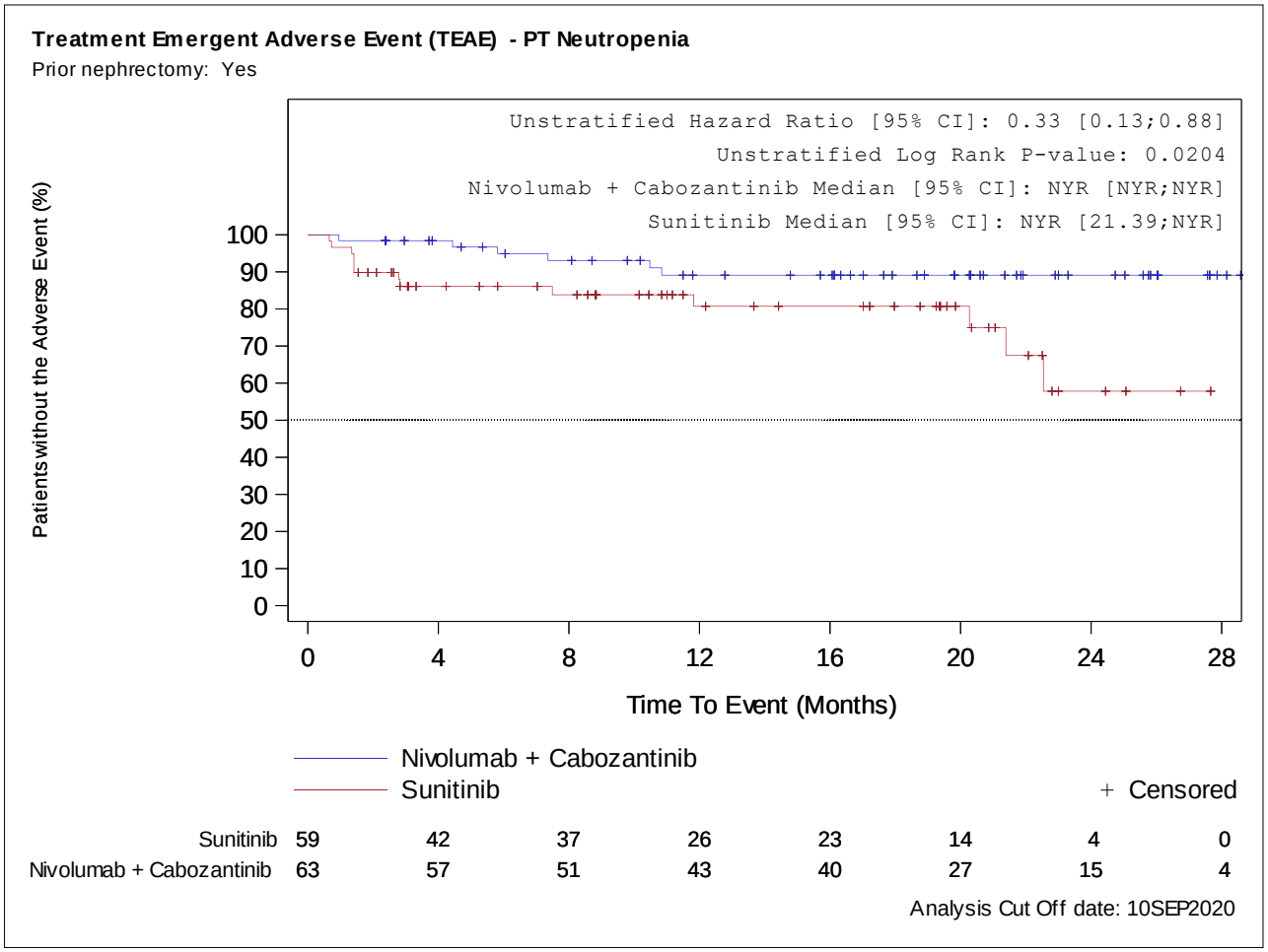
FIGURE 5.3.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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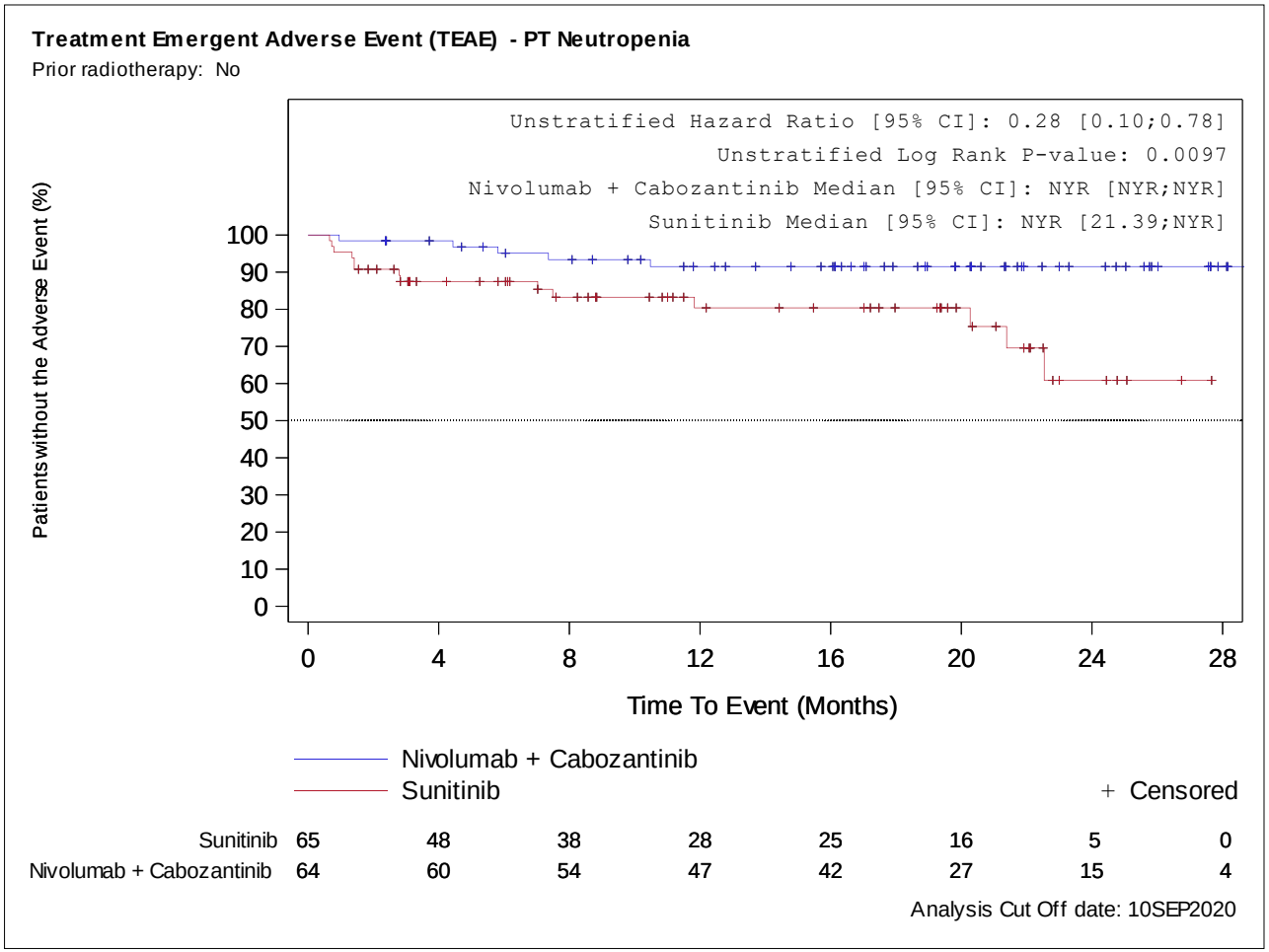
FIGURE 5.3.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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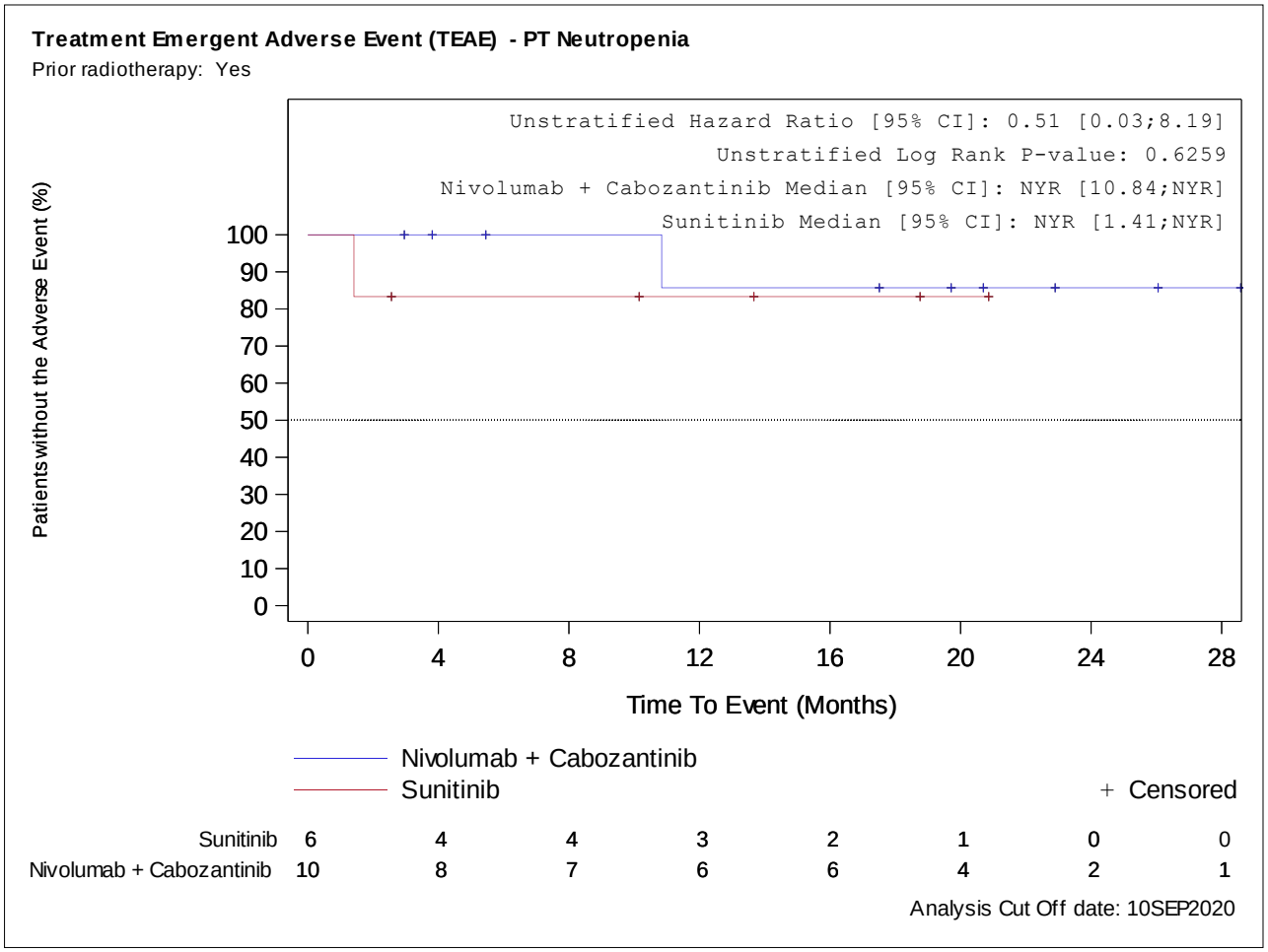
FIGURE 5.3.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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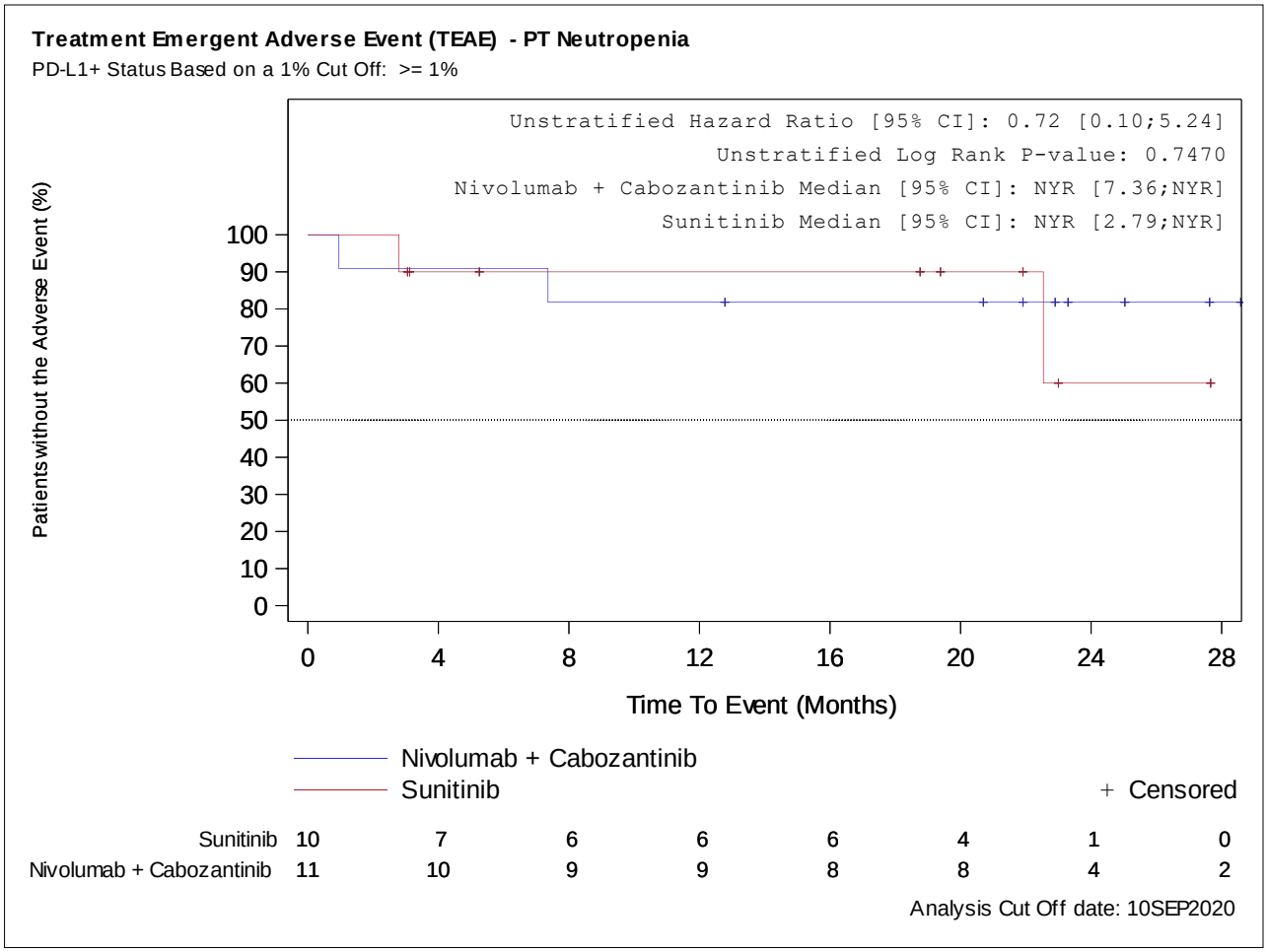
FIGURE 5.3.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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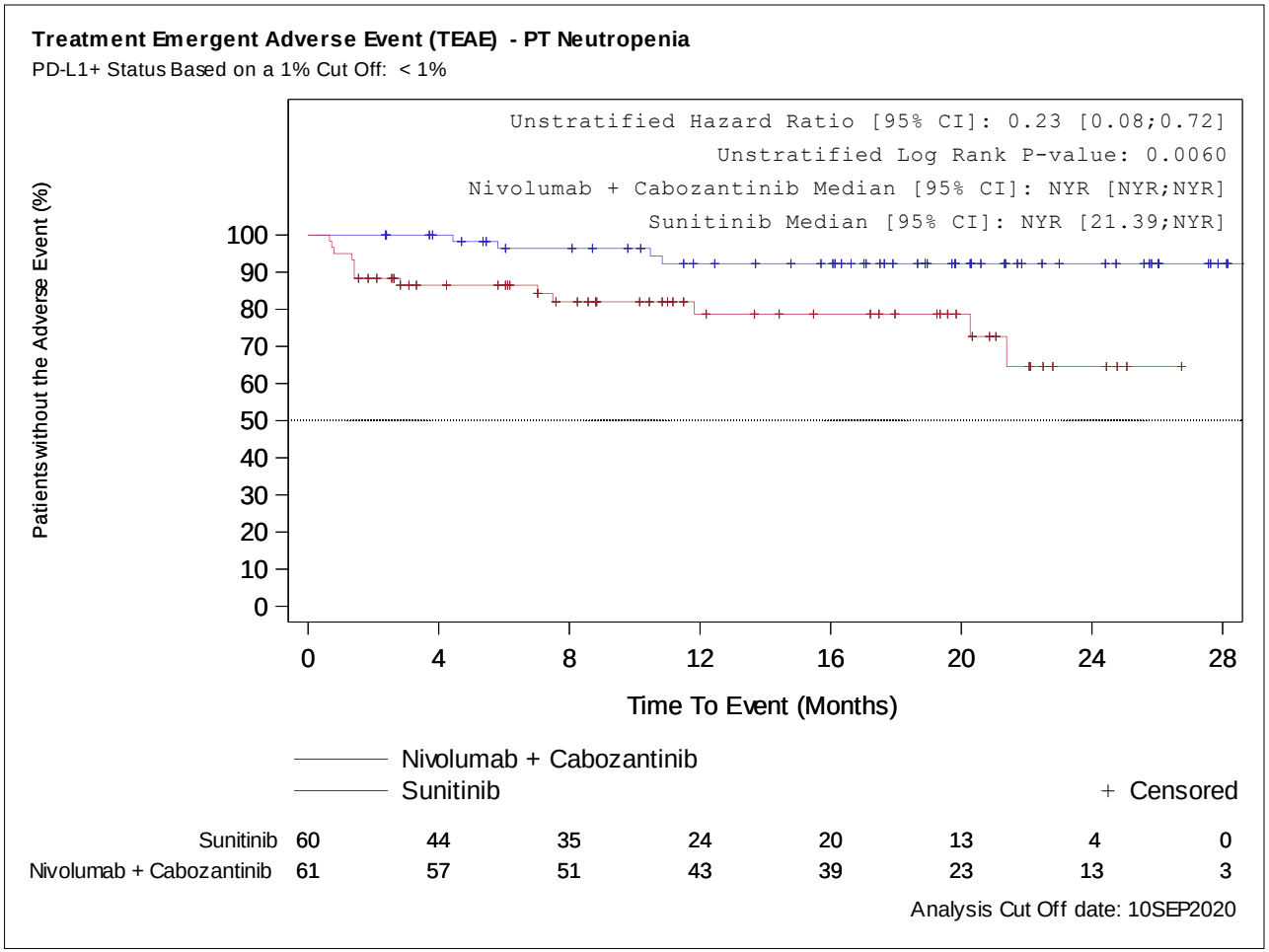
FIGURE 5.3.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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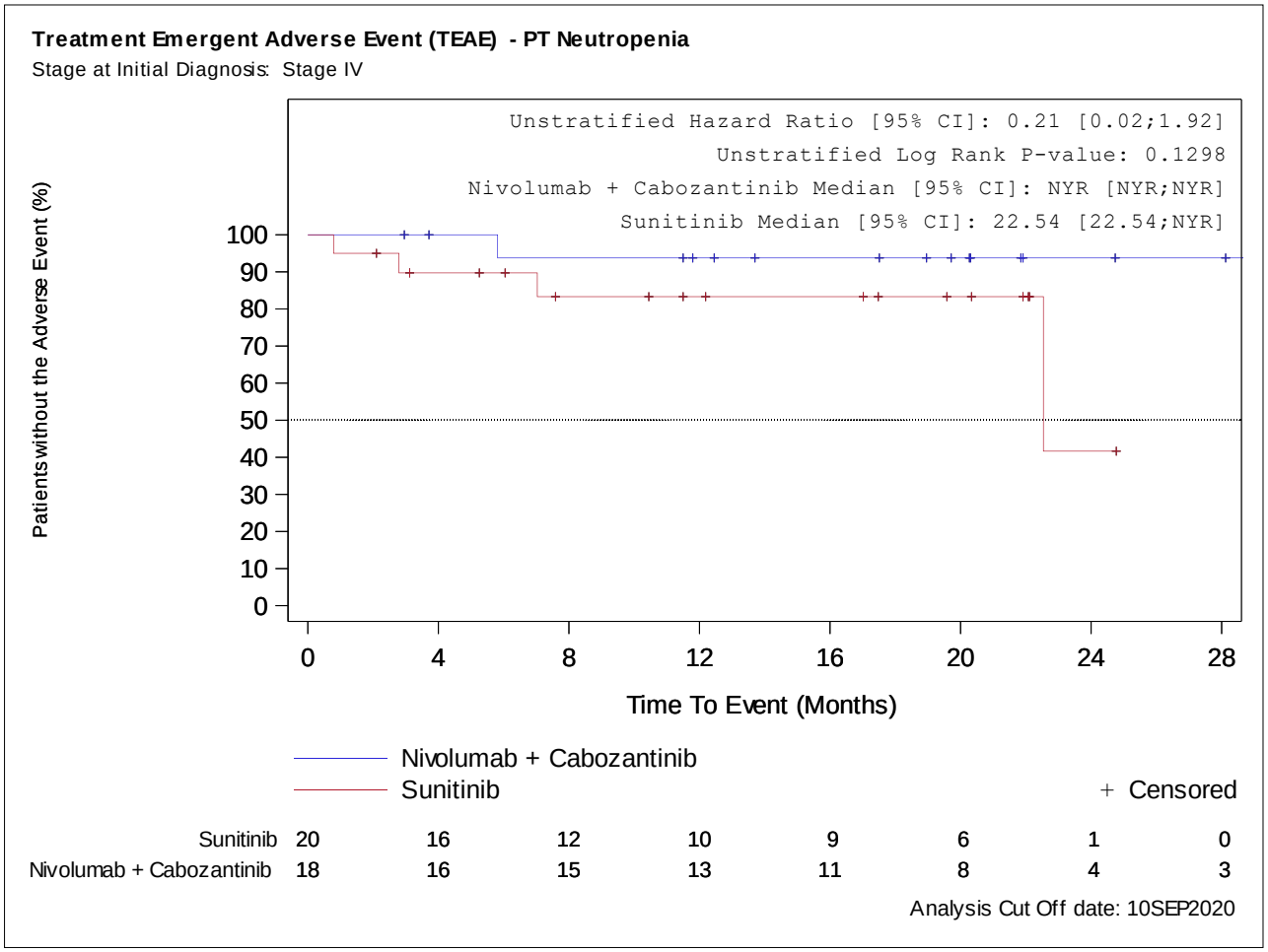
FIGURE 5.3.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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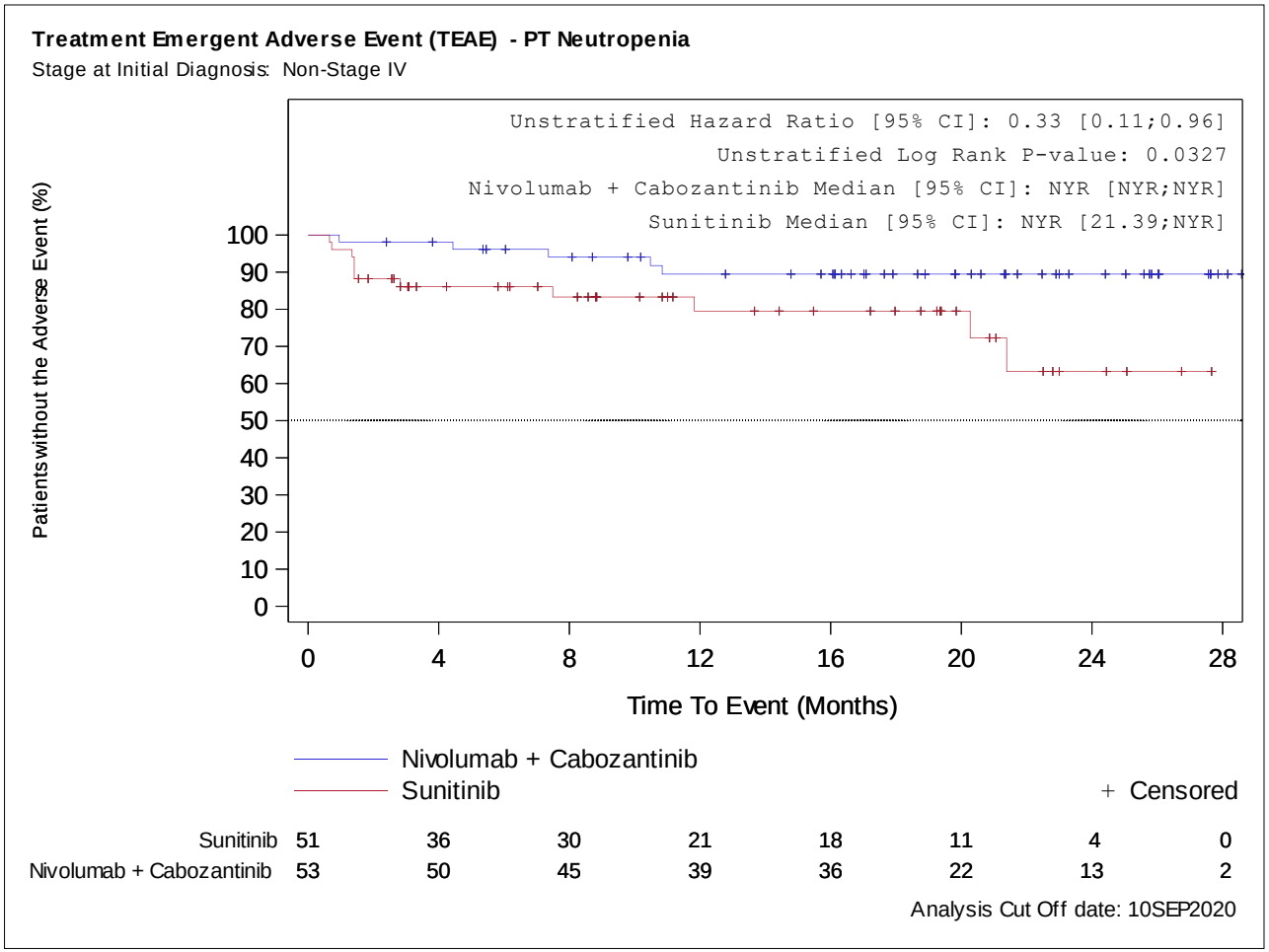
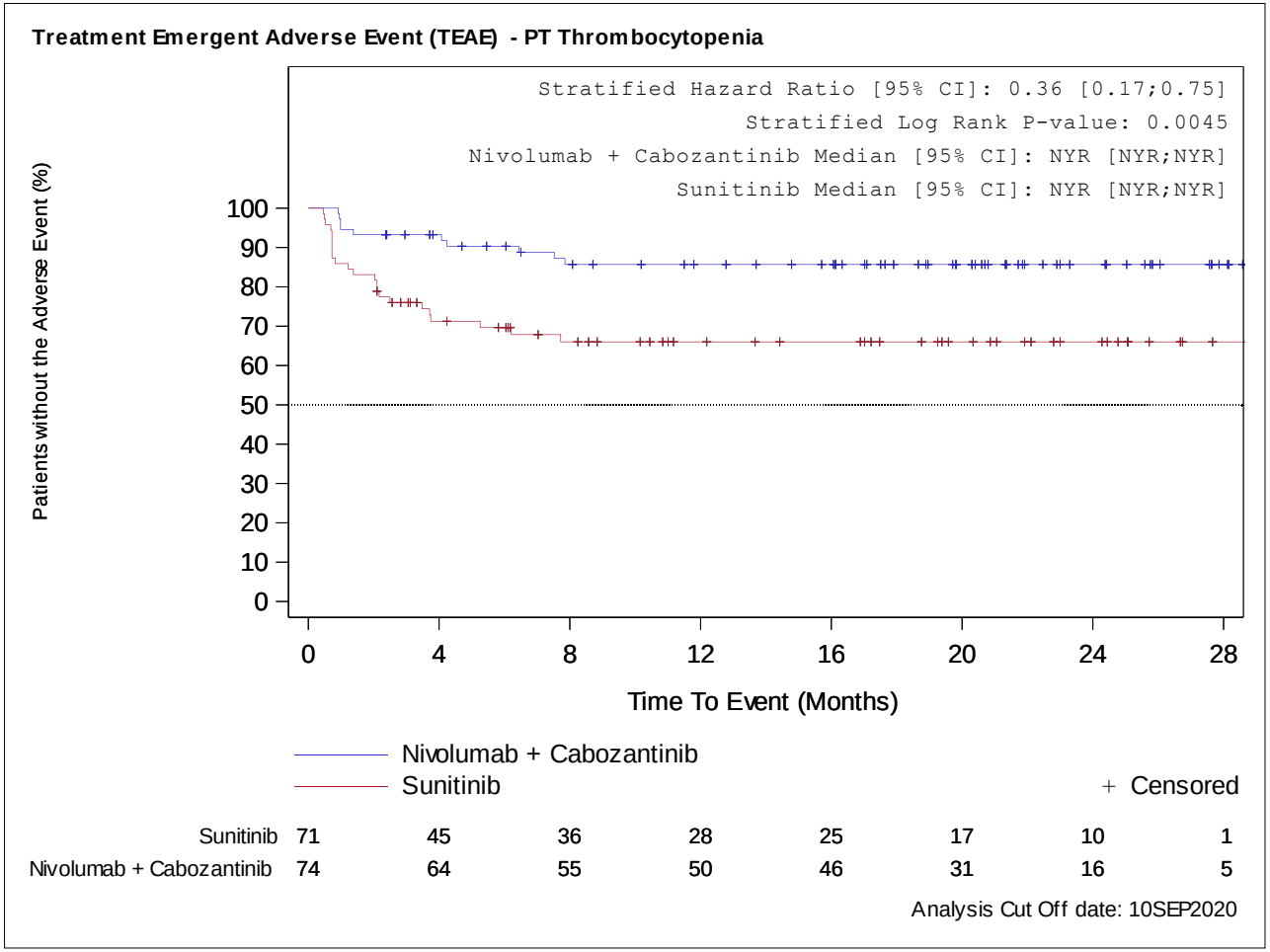
FIGURE 5.3.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



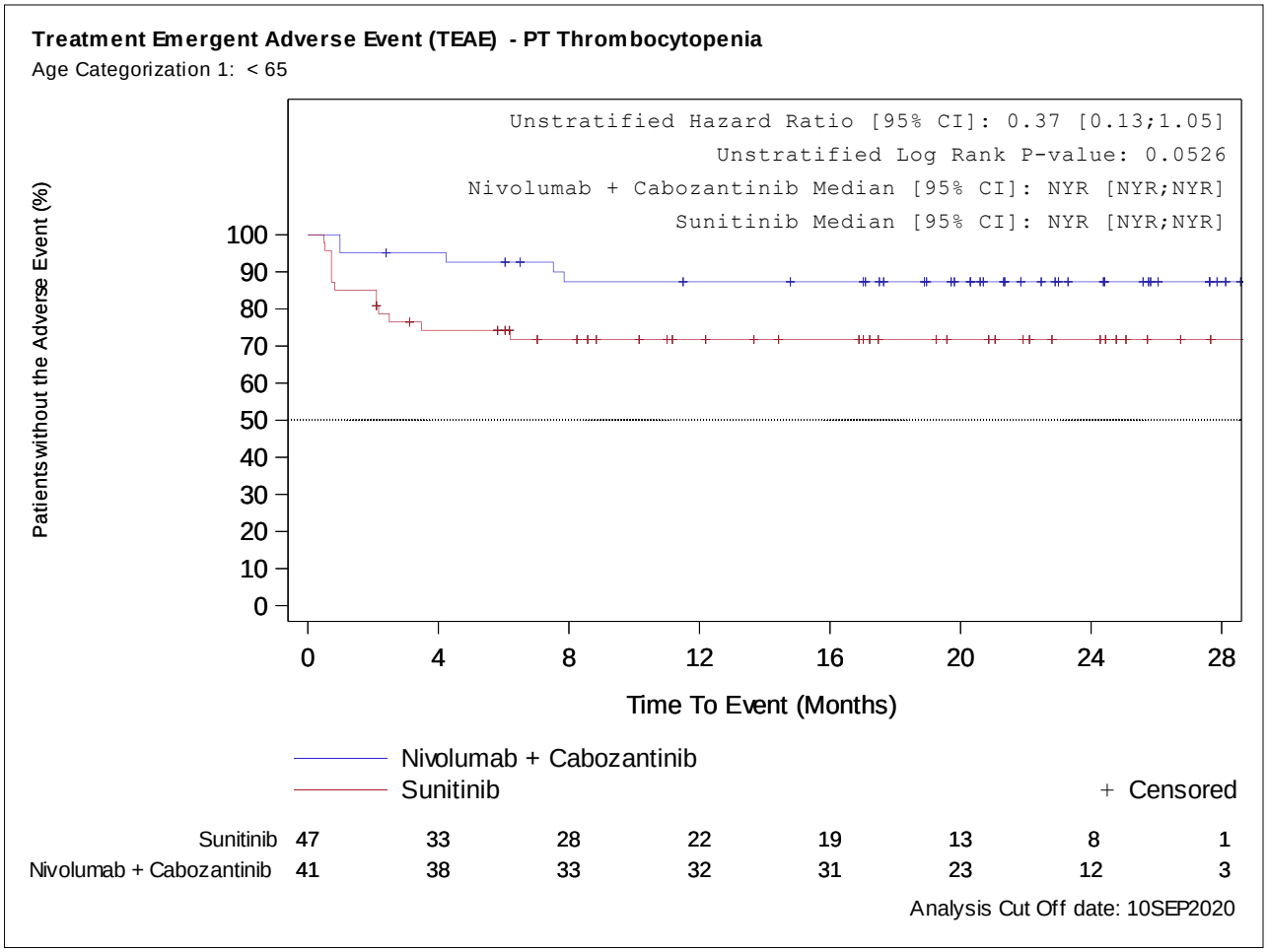

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:21:44

FIGURE 5.4.1: Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



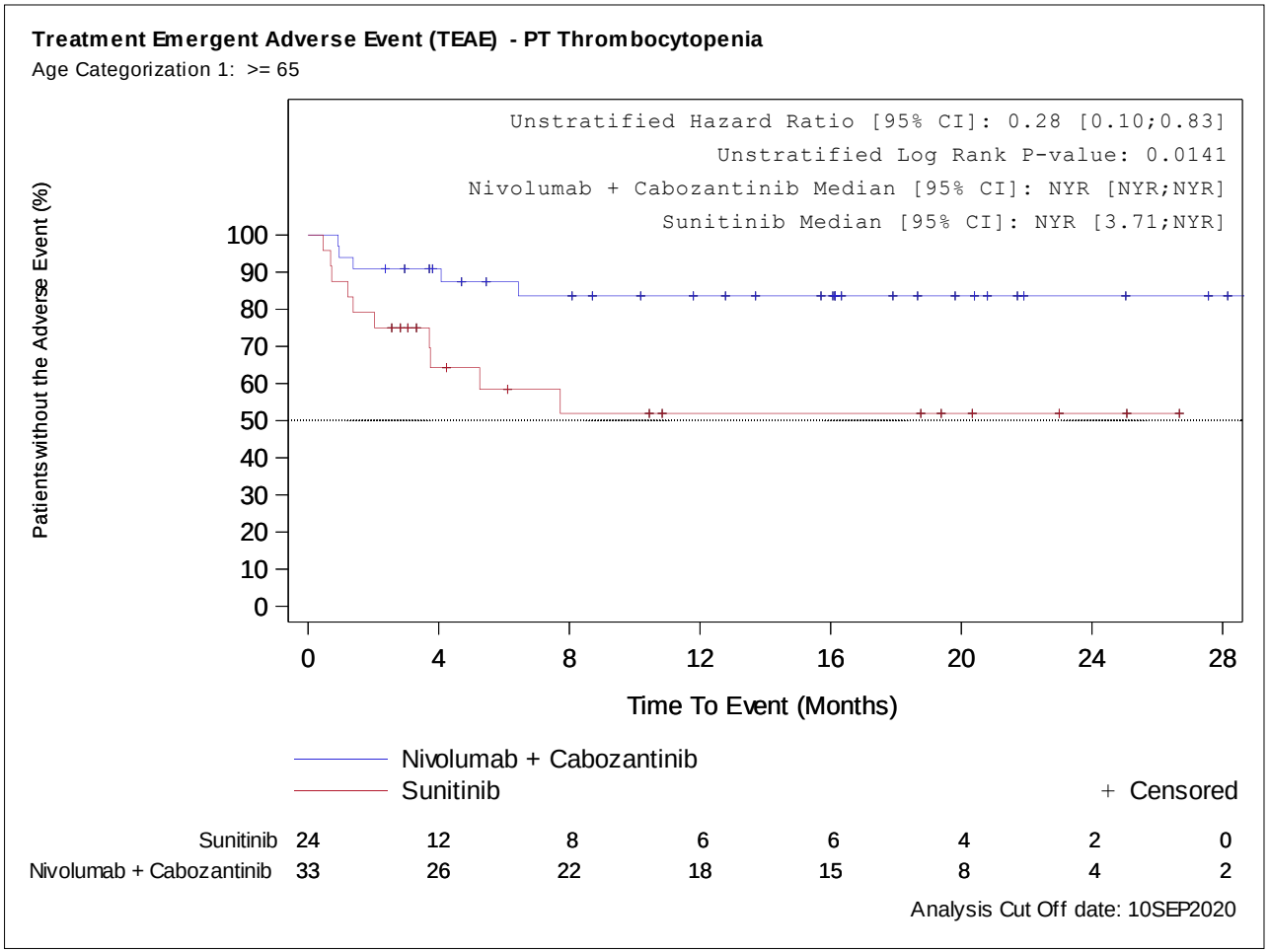

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:25:00

FIGURE 5.4.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



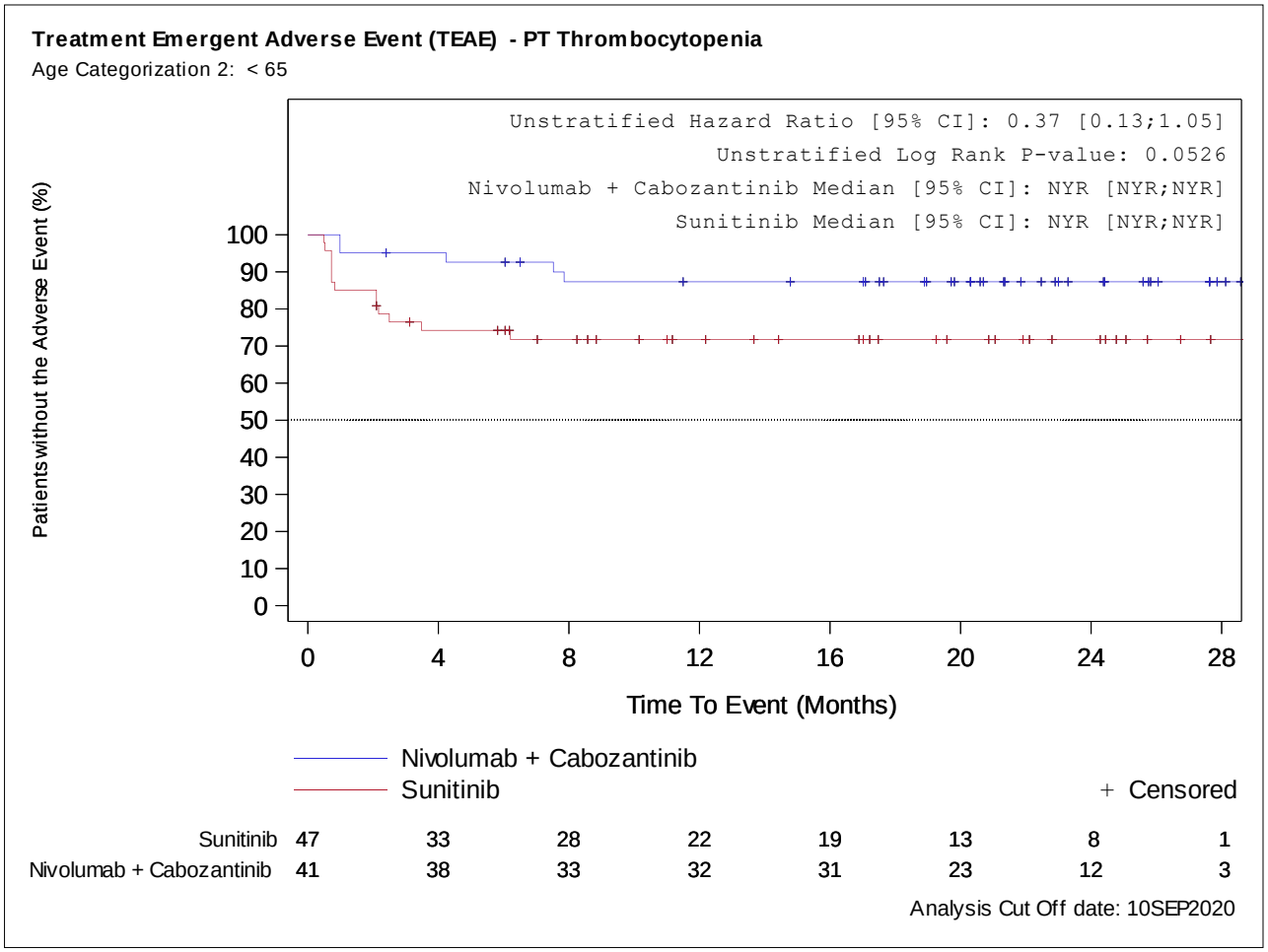

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:25:03

FIGURE 5.4.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



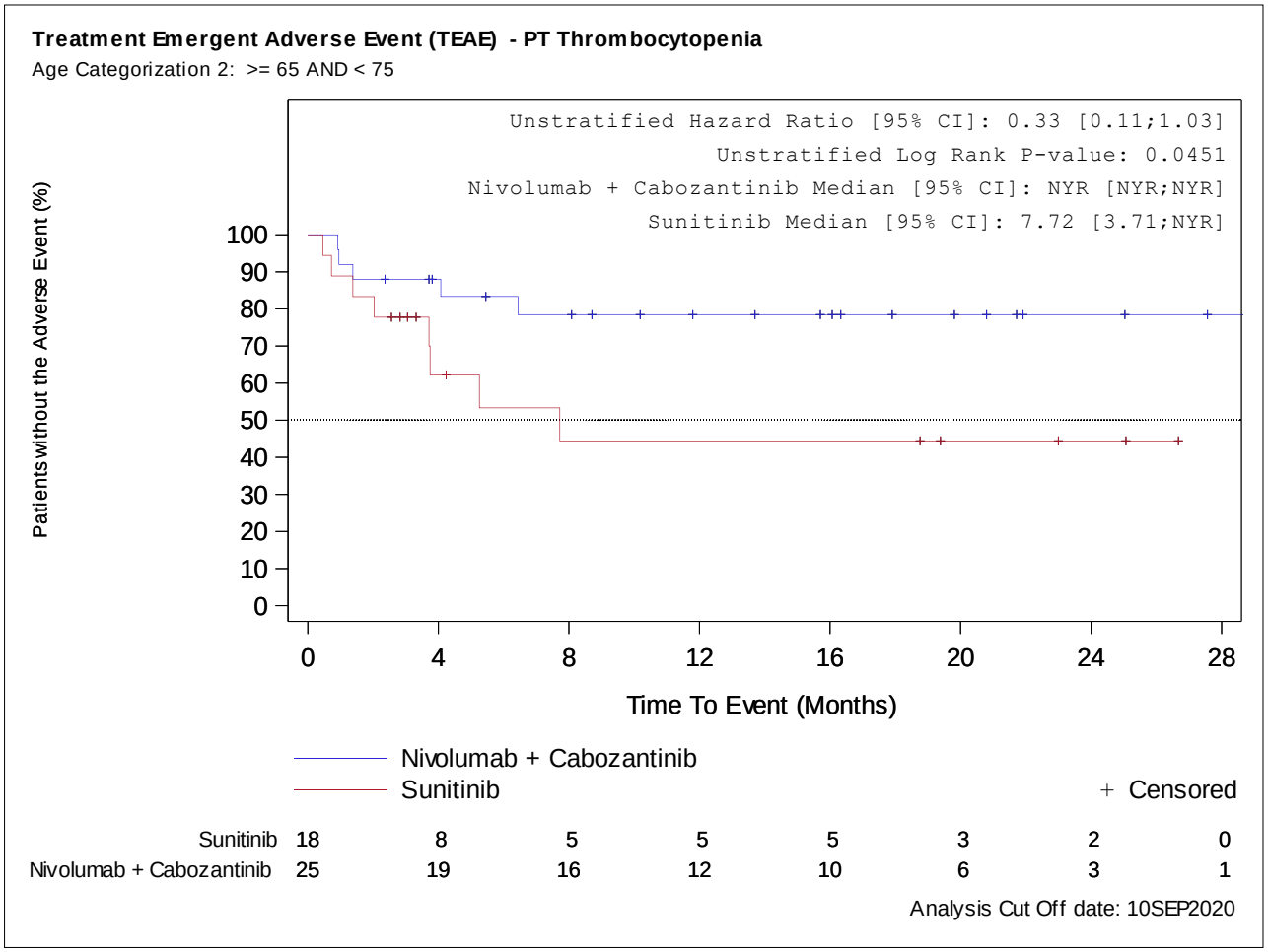

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:25:09

FIGURE 5.4.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:25:15

FIGURE 5.4.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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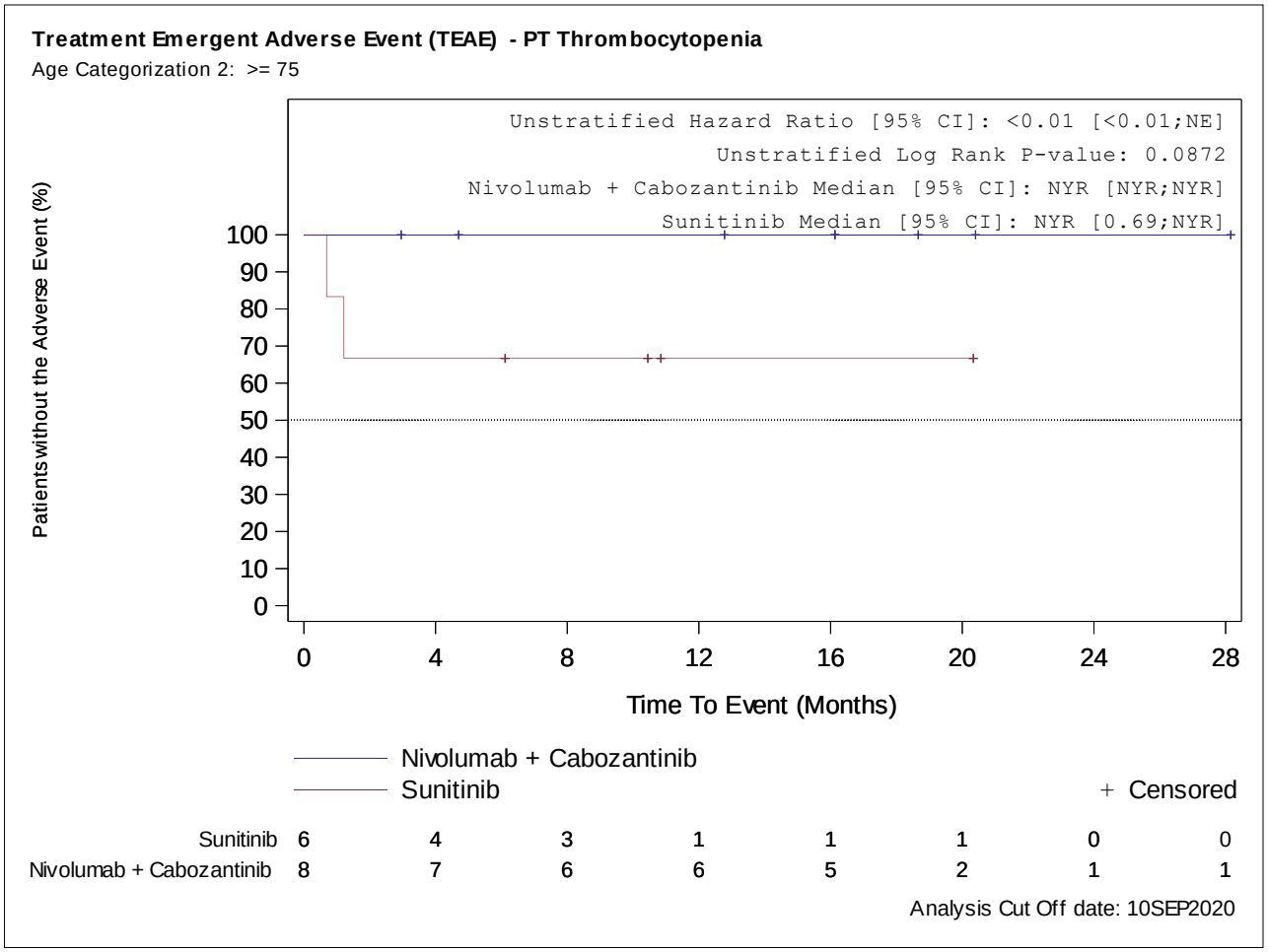
FIGURE 5.4.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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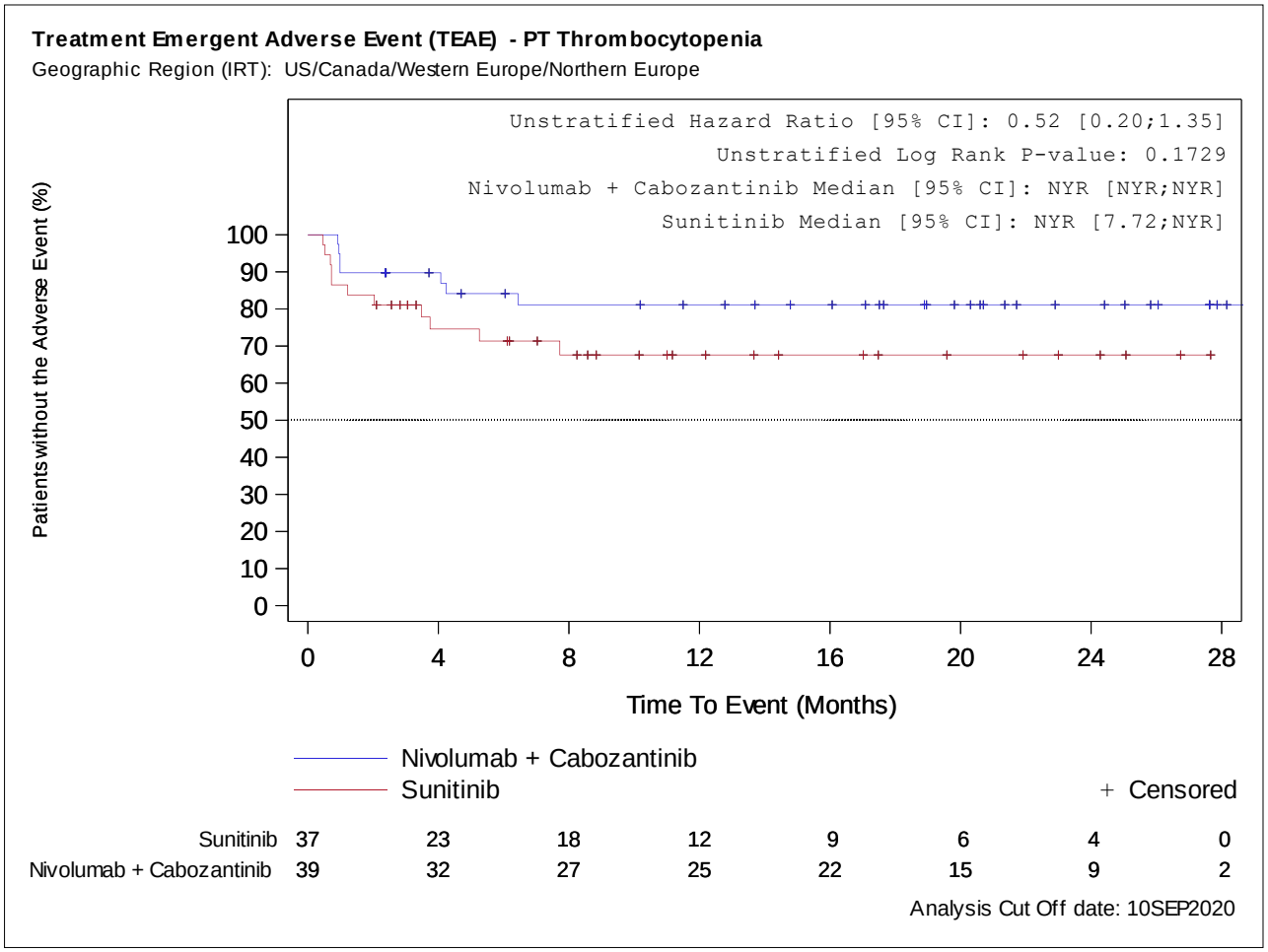
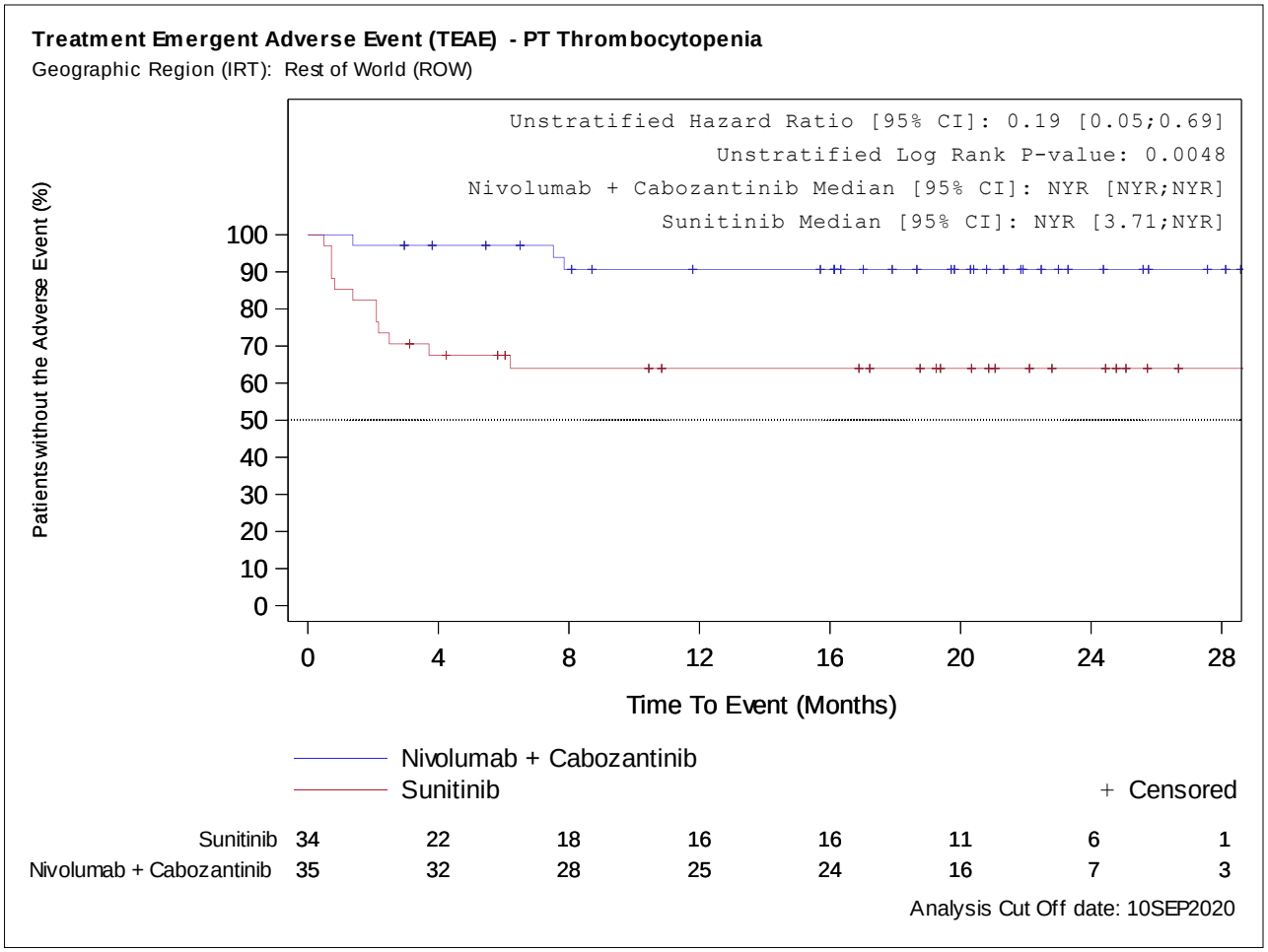
FIGURE 5.4.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:25:32

FIGURE 5.4.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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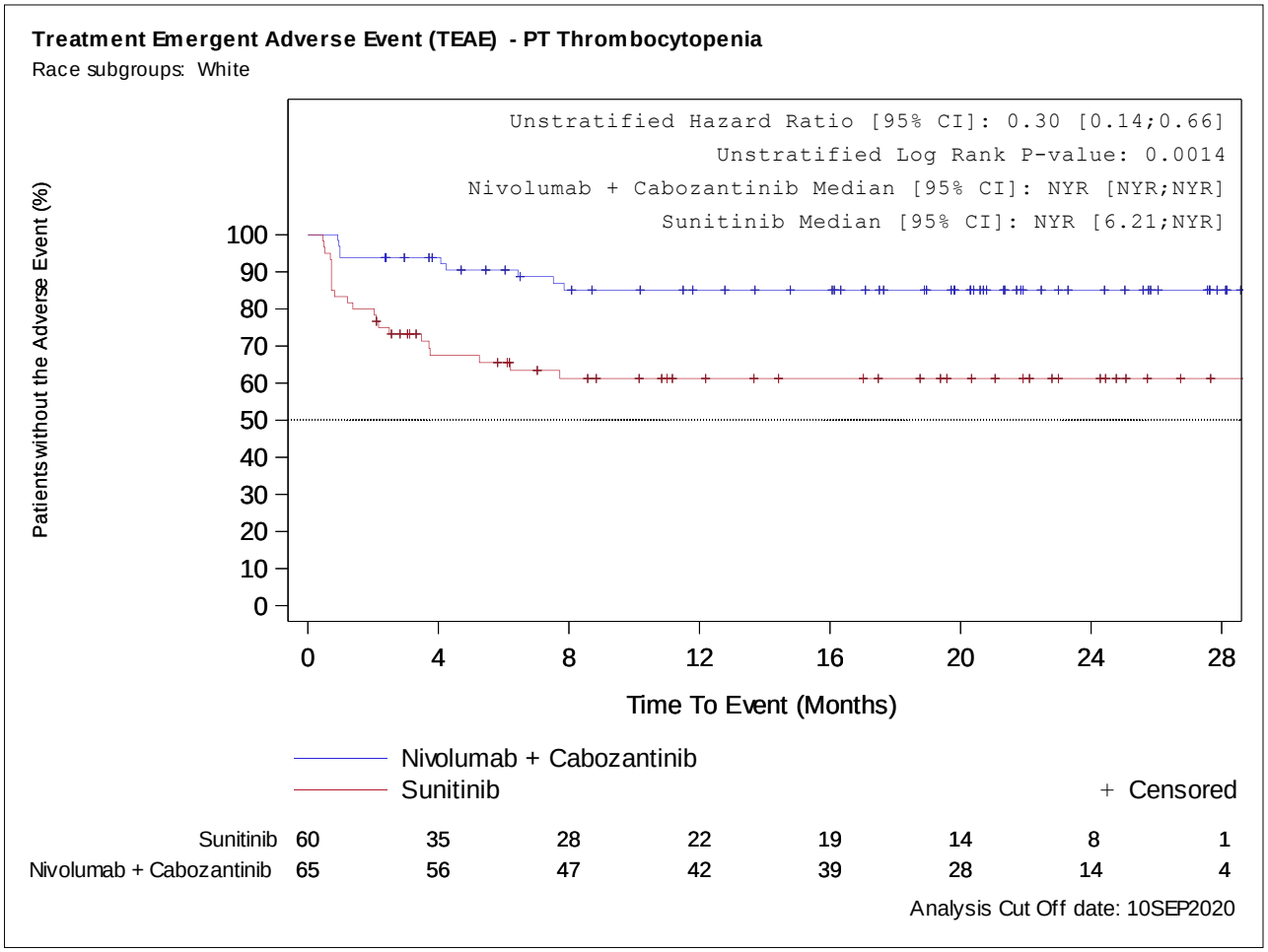
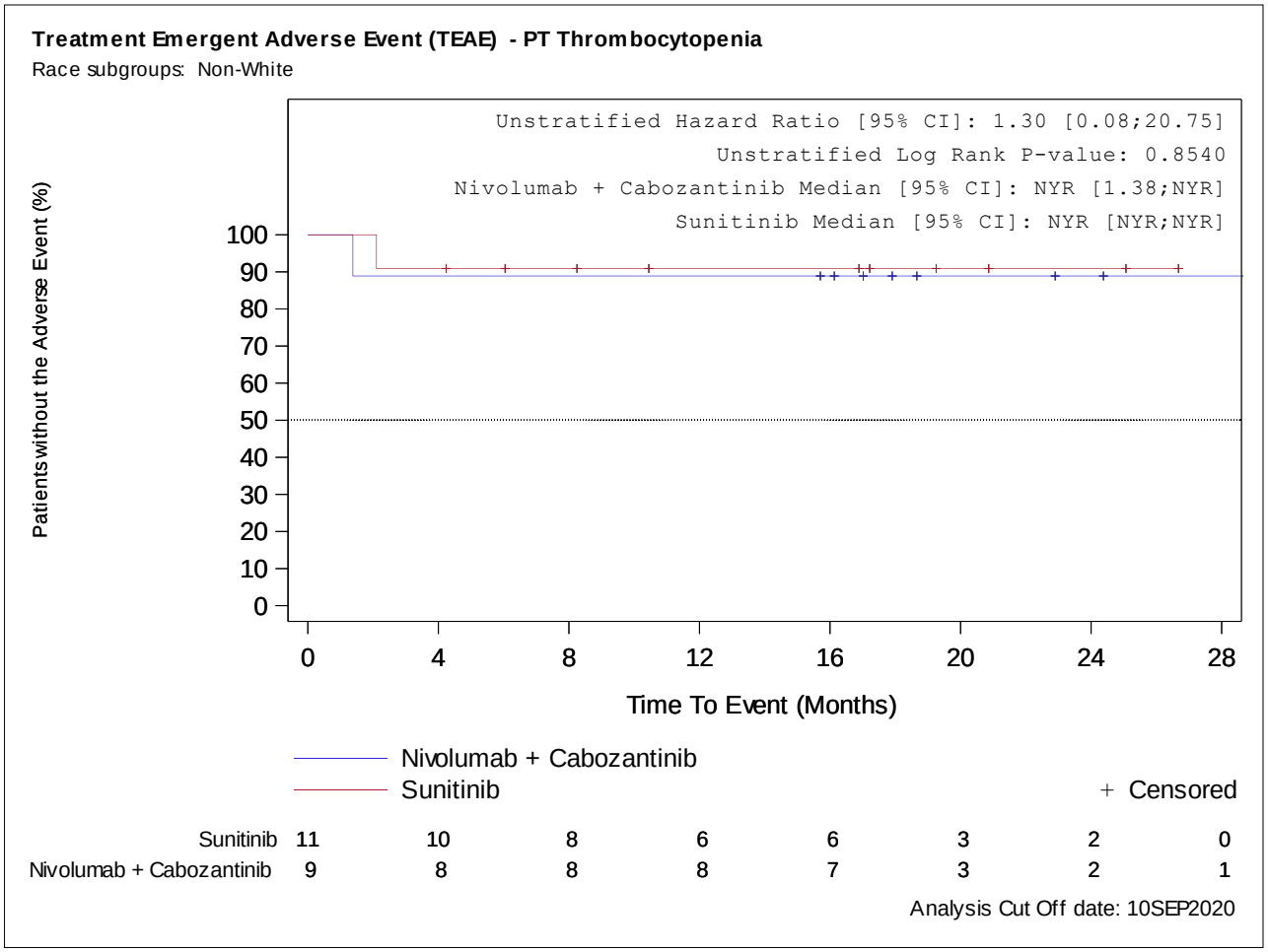
FIGURE 5.4.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



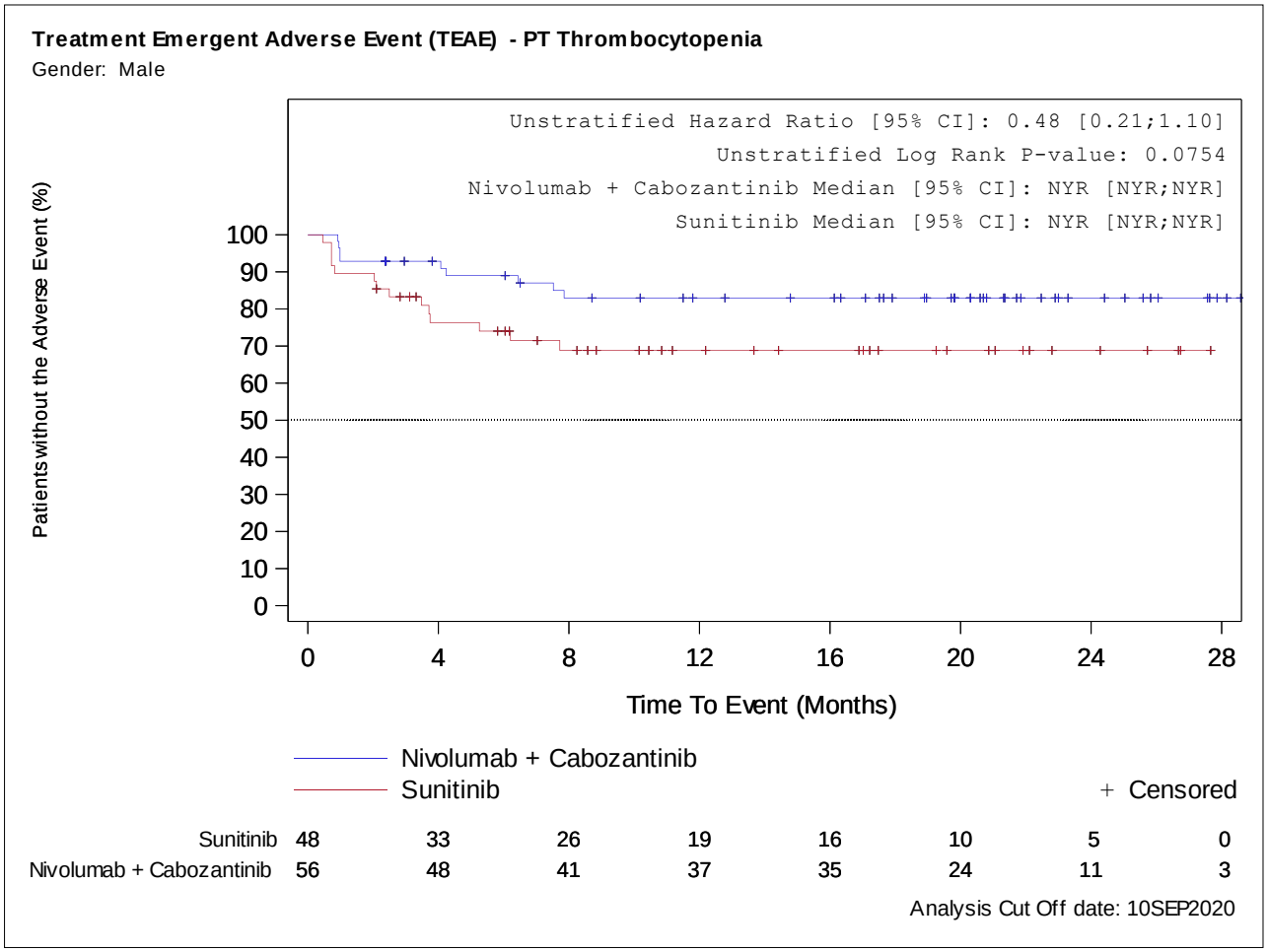

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:25:43

FIGURE 5.4.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:25:48

FIGURE 5.4.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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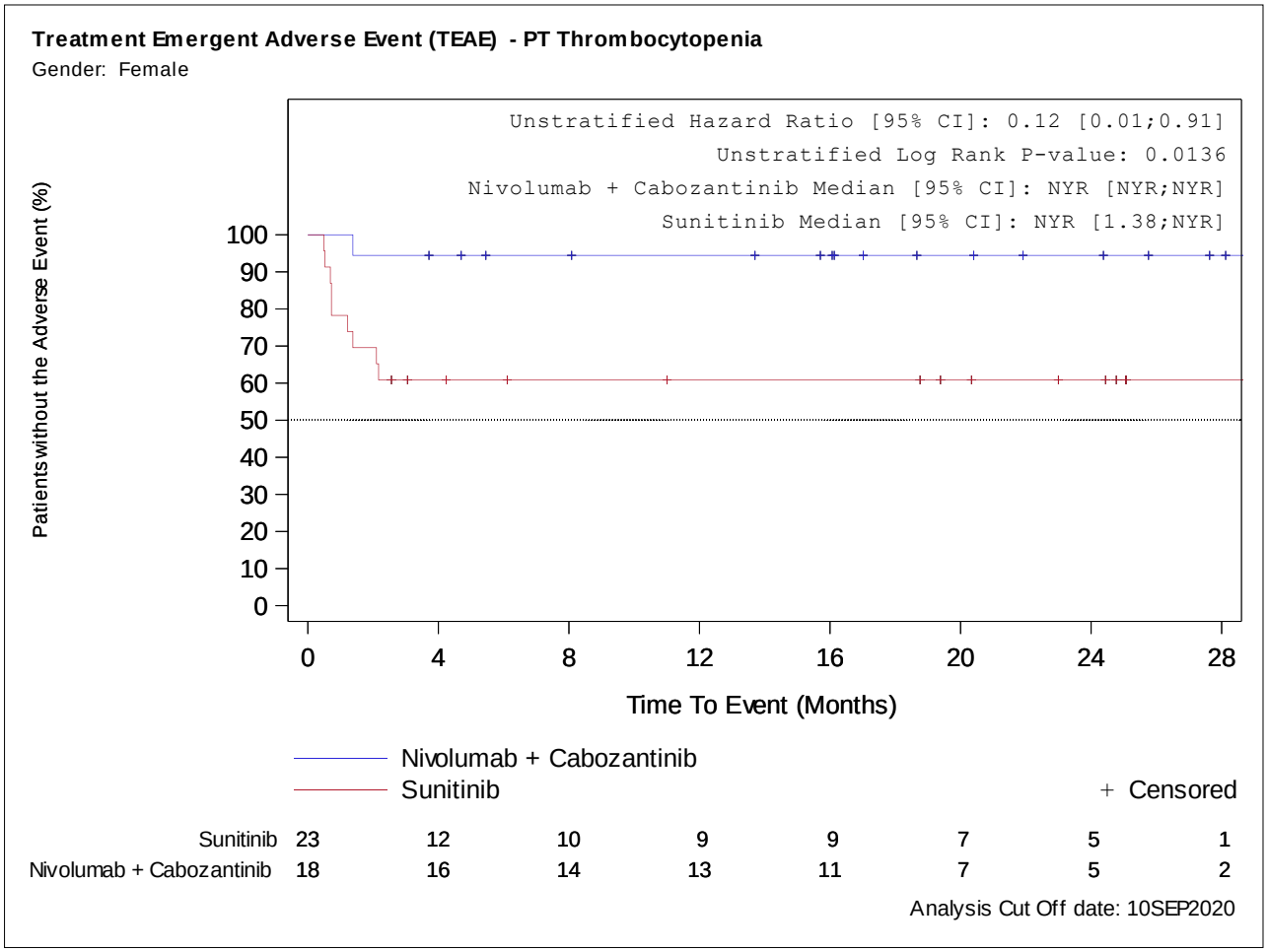
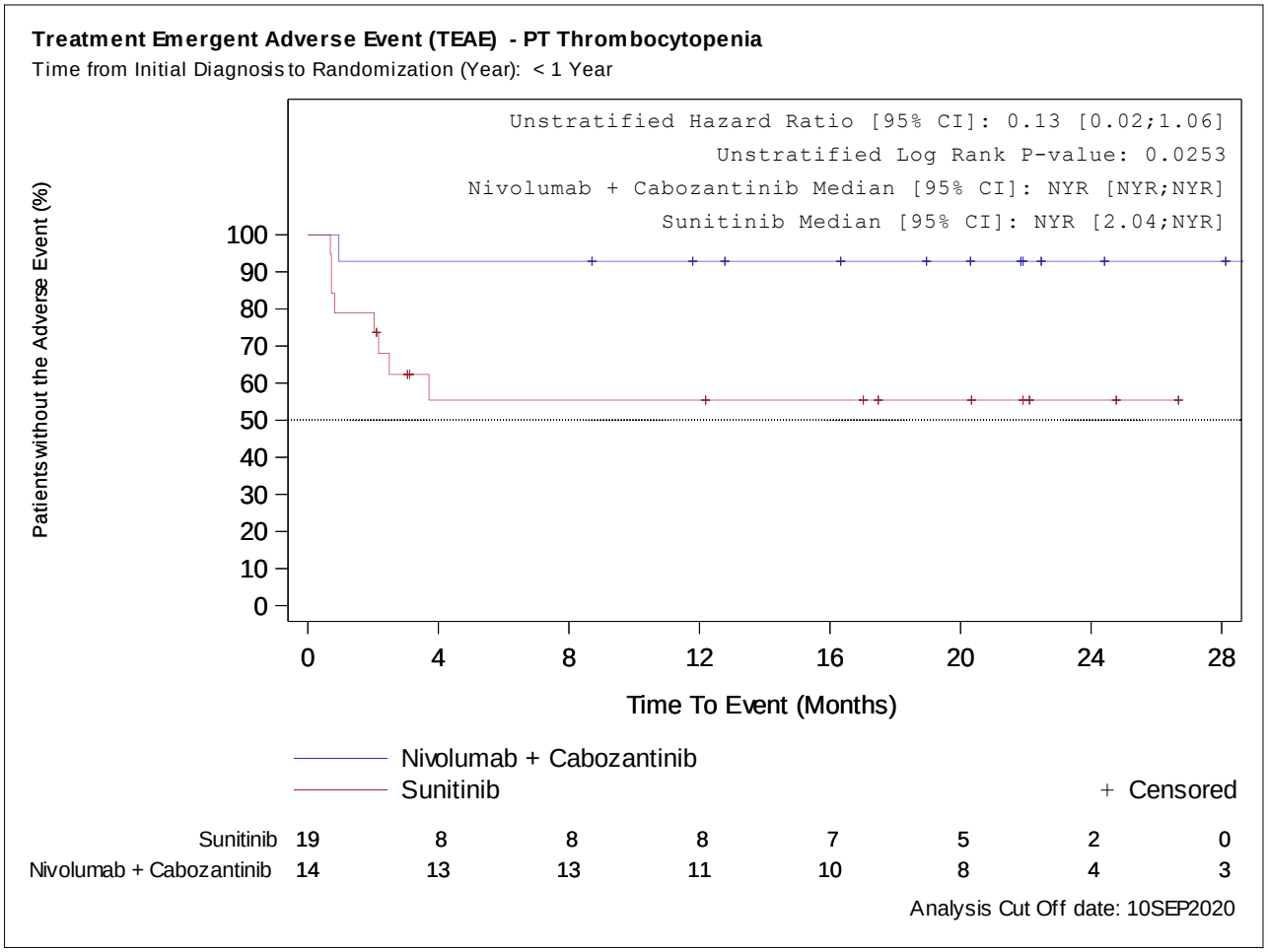
FIGURE 5.4.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:26:00

FIGURE 5.4.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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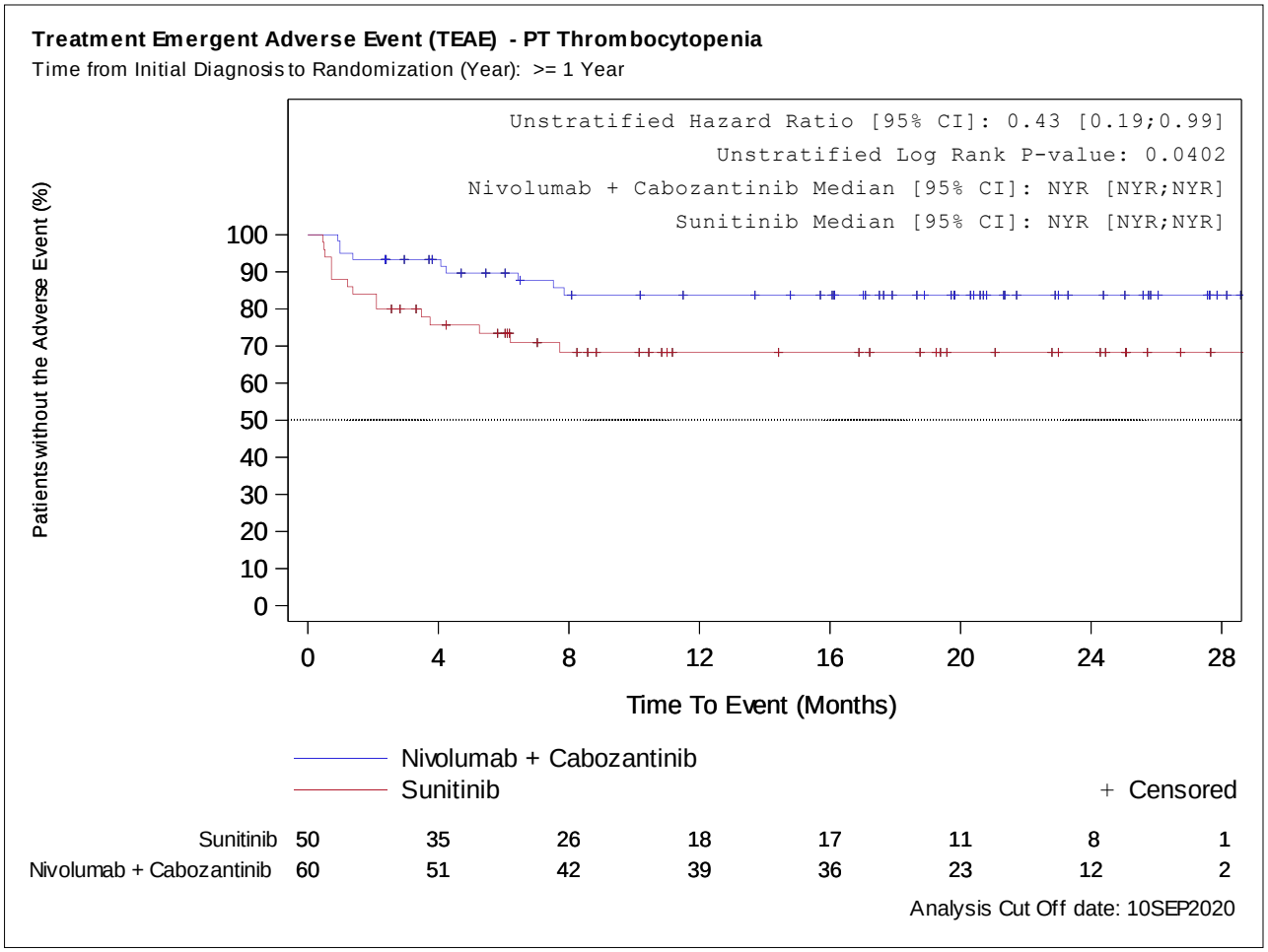
FIGURE 5.4.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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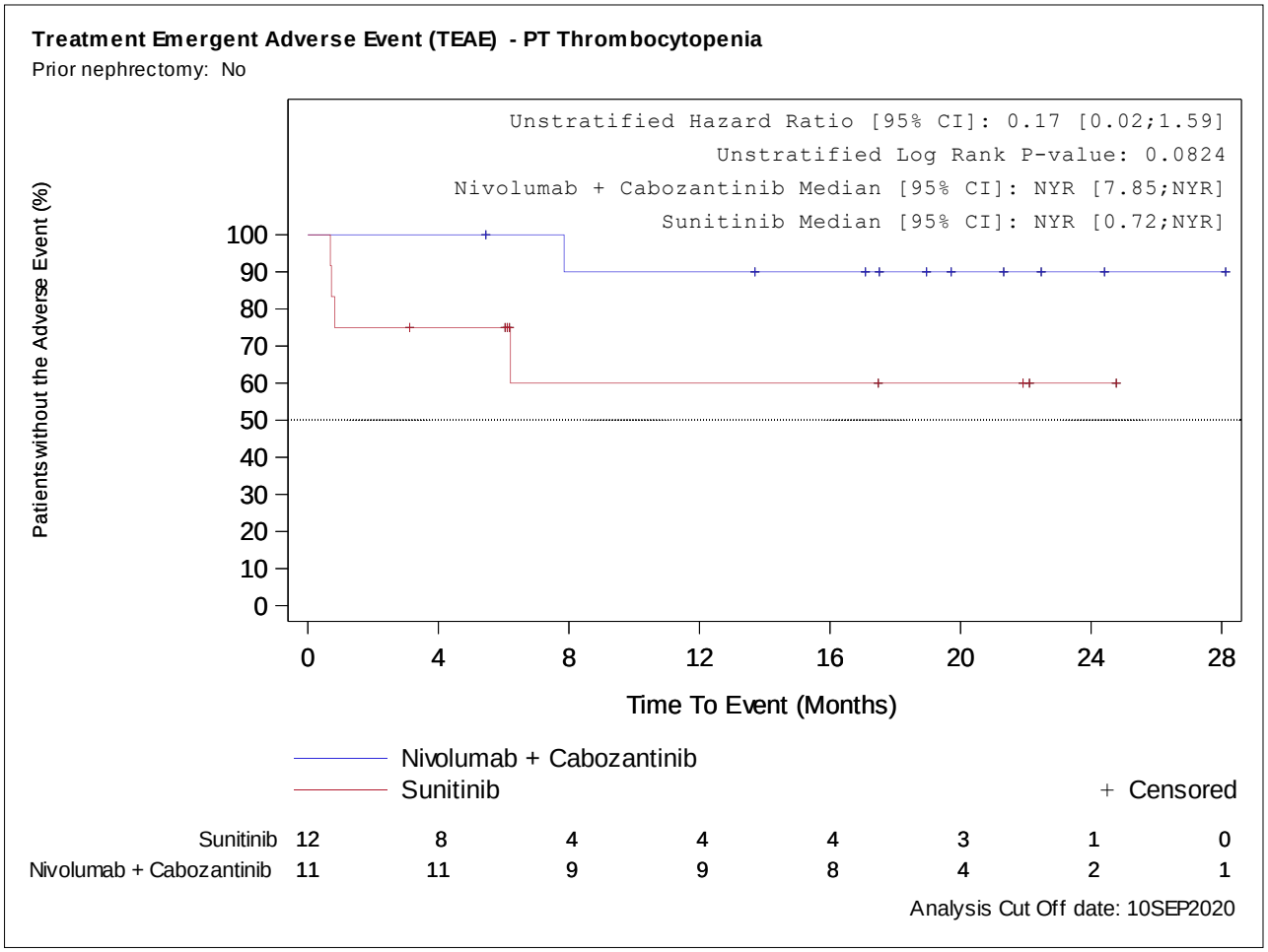
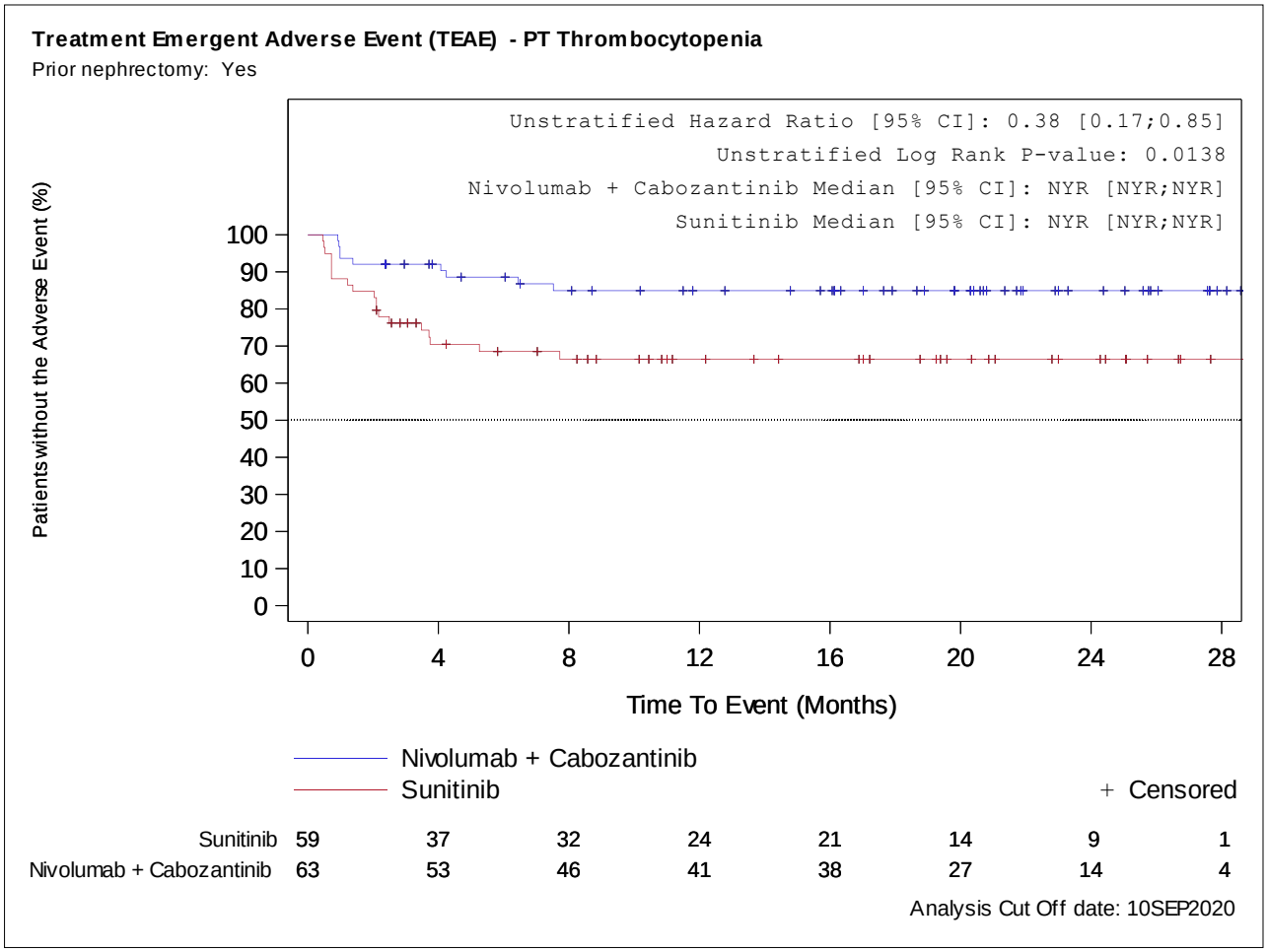
FIGURE 5.4.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:27:17

FIGURE 5.4.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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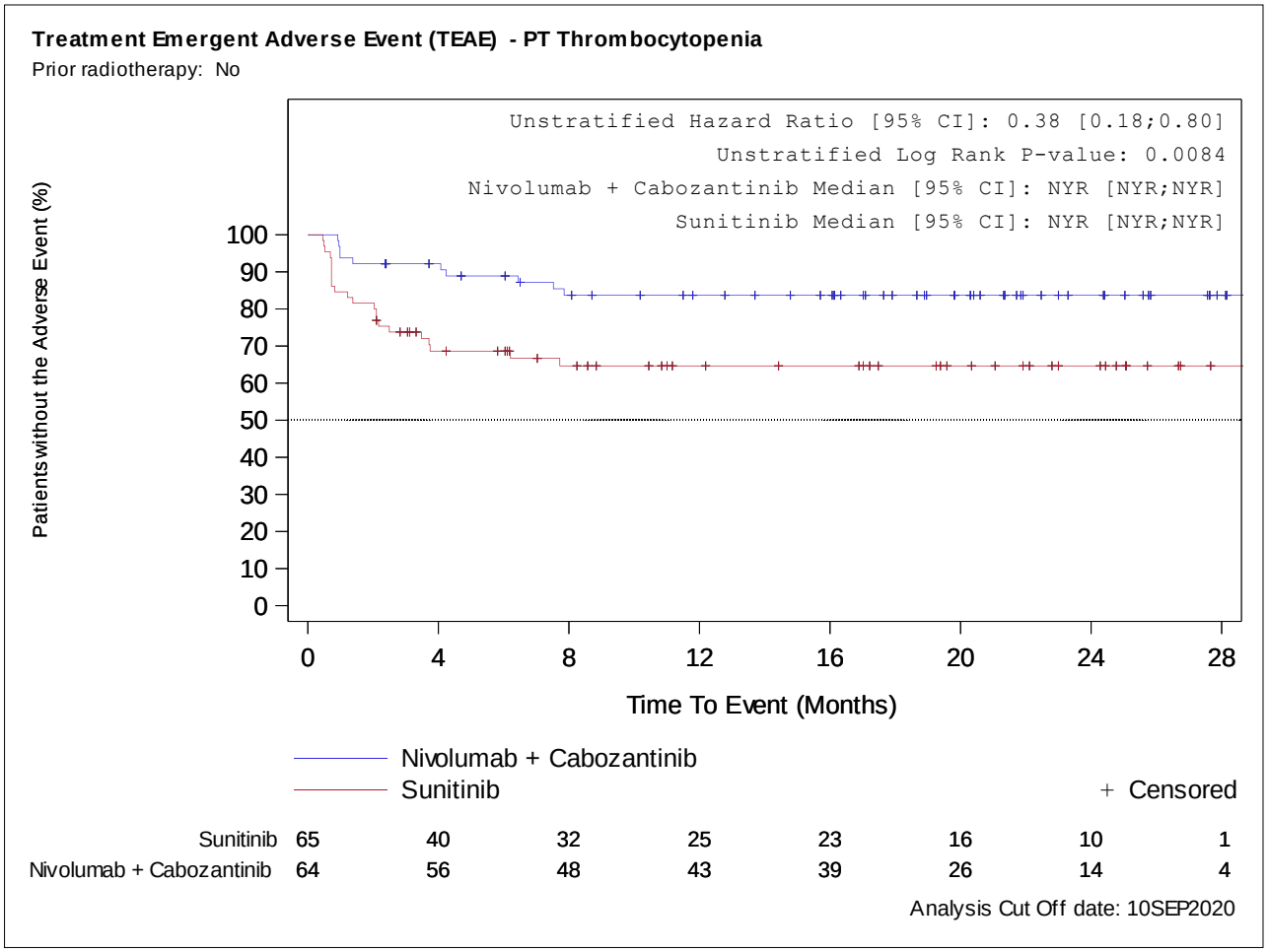
FIGURE 5.4.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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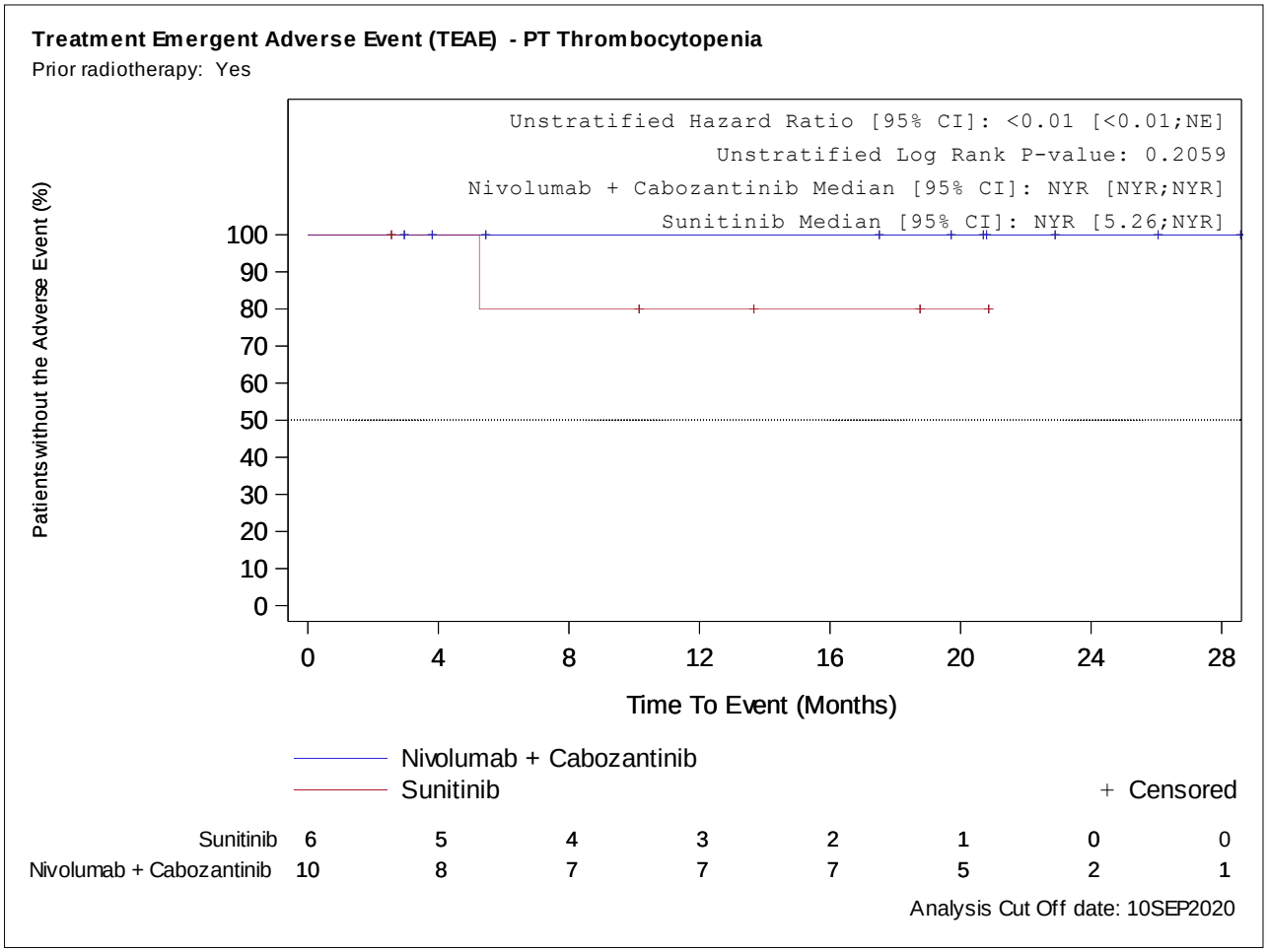
FIGURE 5.4.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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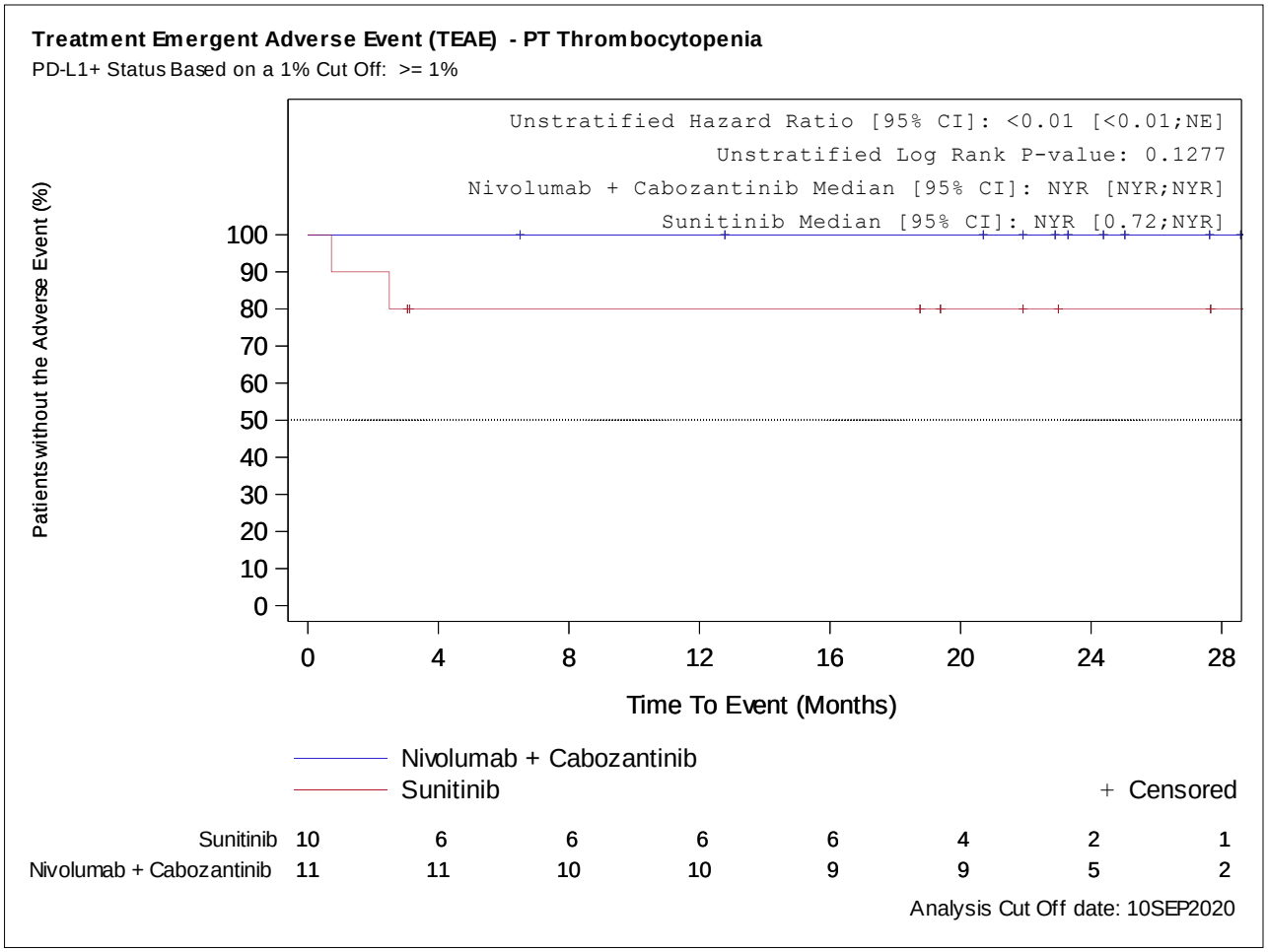
FIGURE 5.4.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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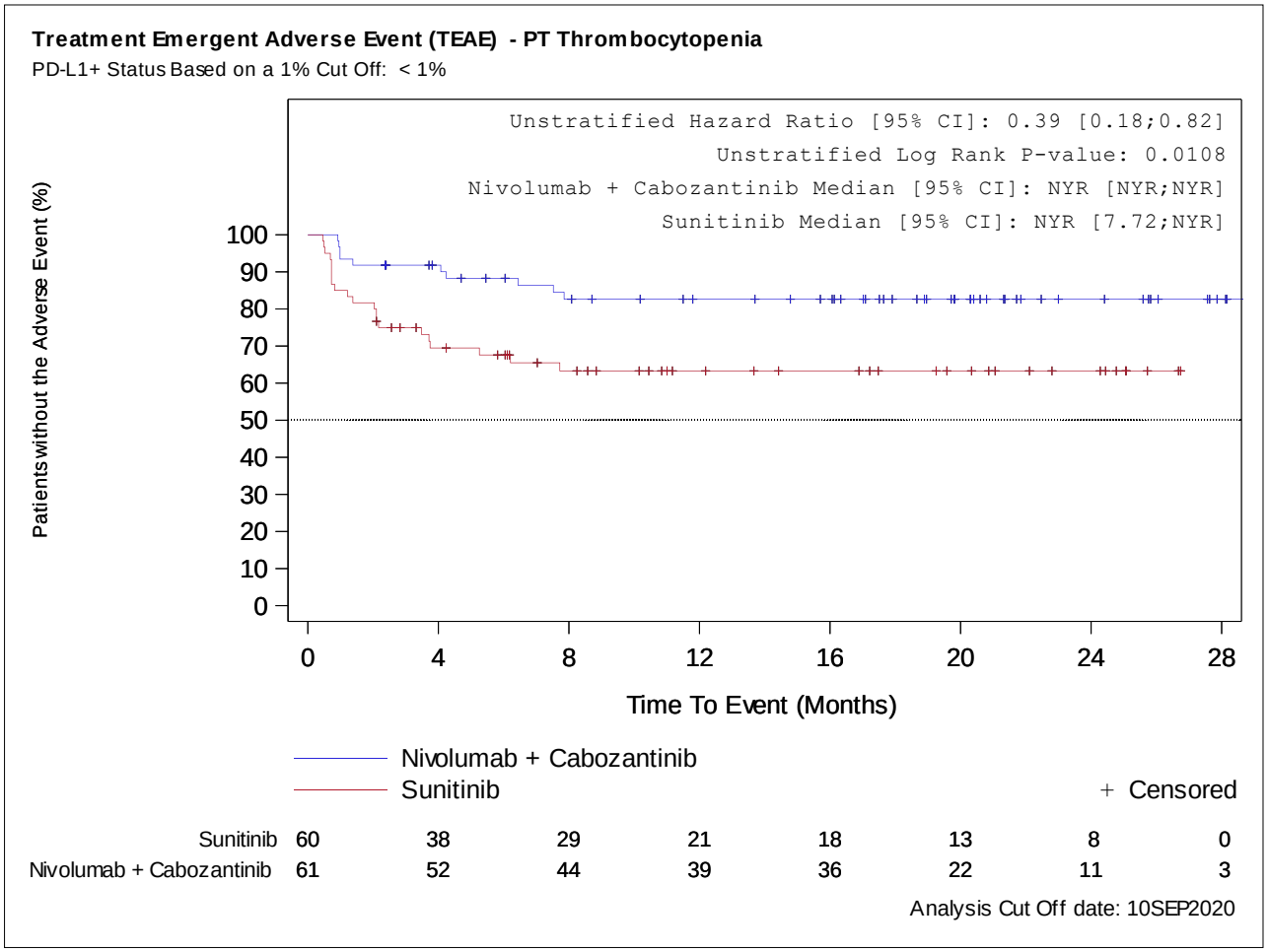
FIGURE 5.4.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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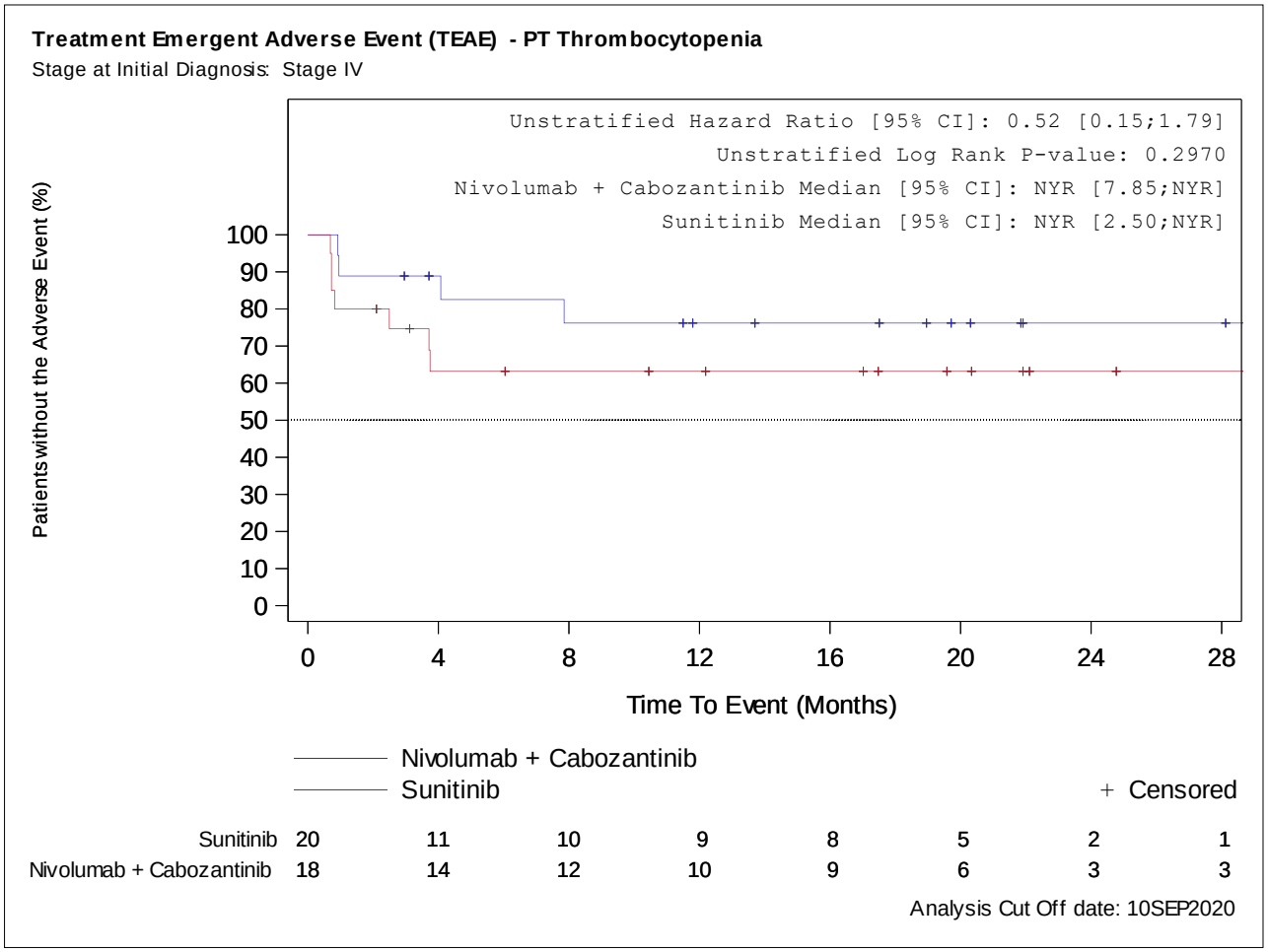
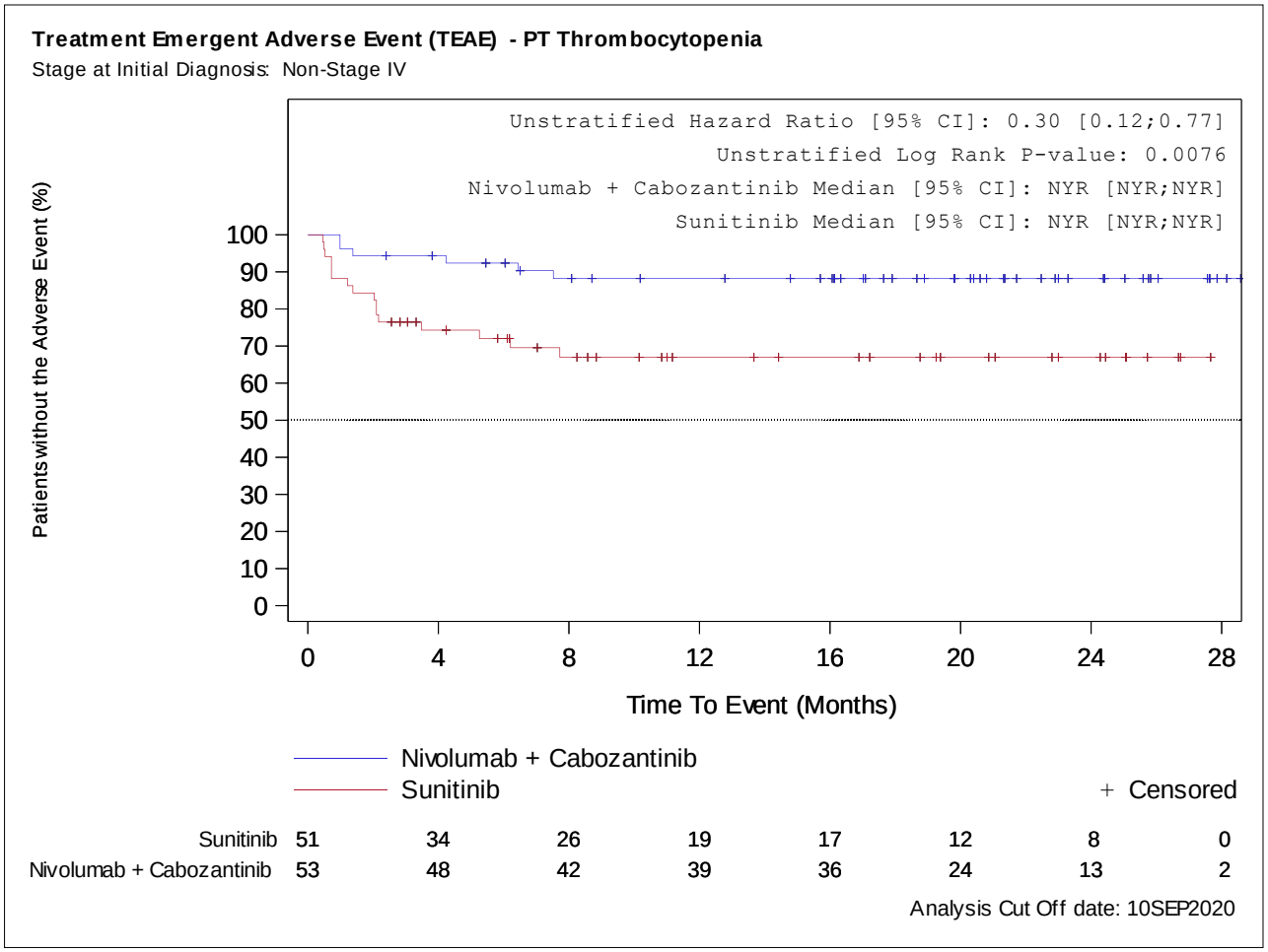
FIGURE 5.4.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:28:13

FIGURE 5.4.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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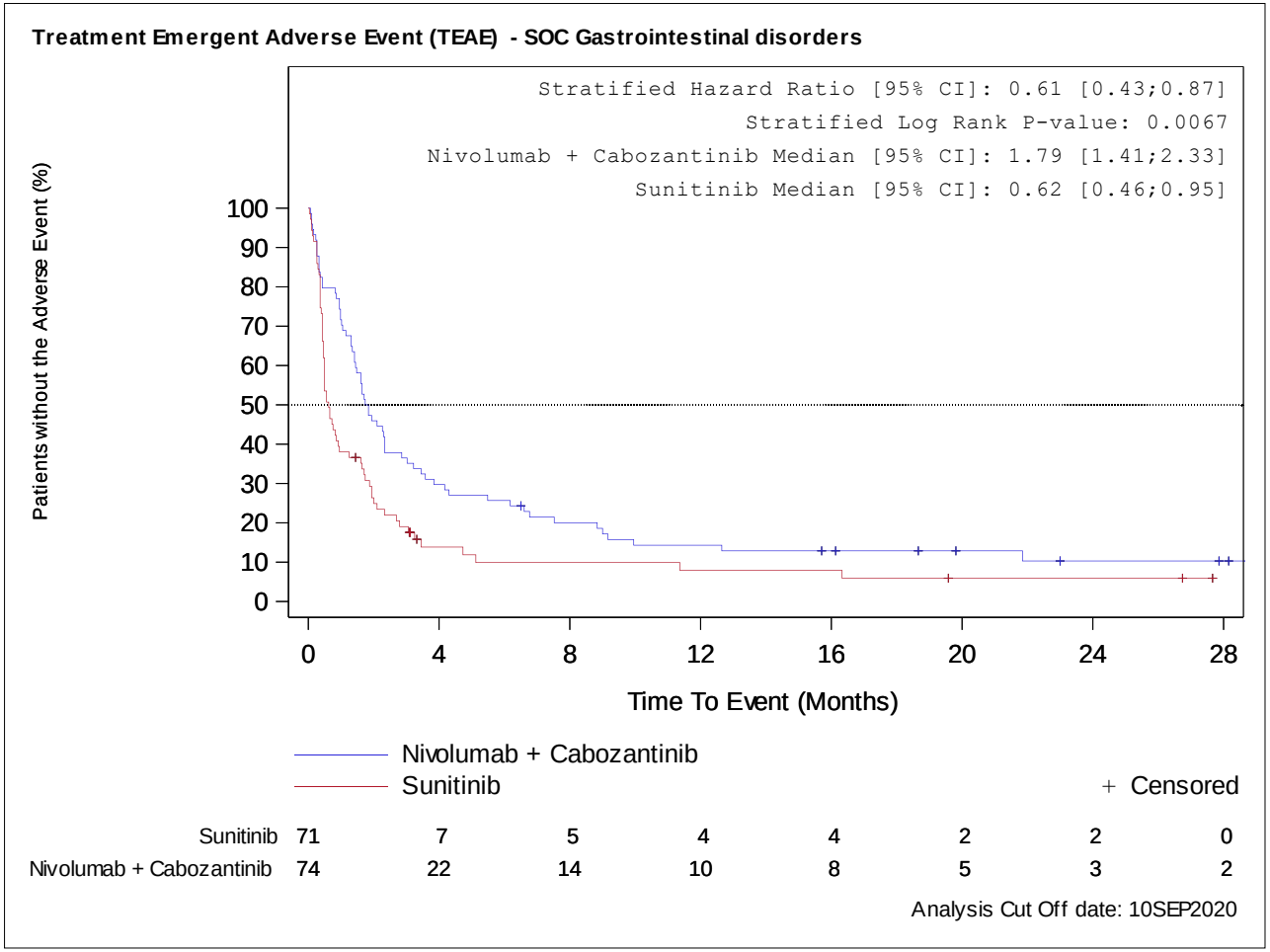
FIGURE 5.5.1: Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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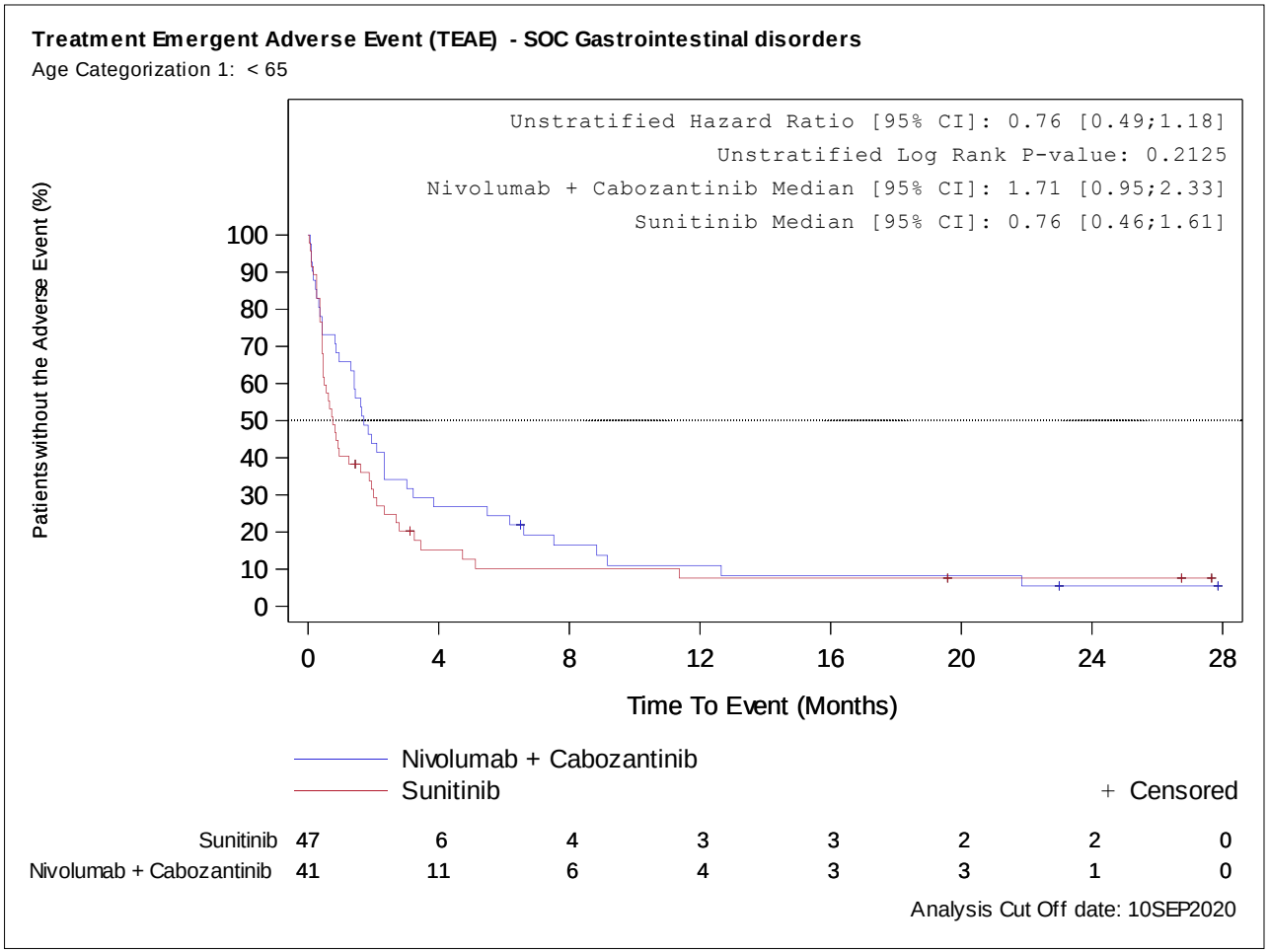
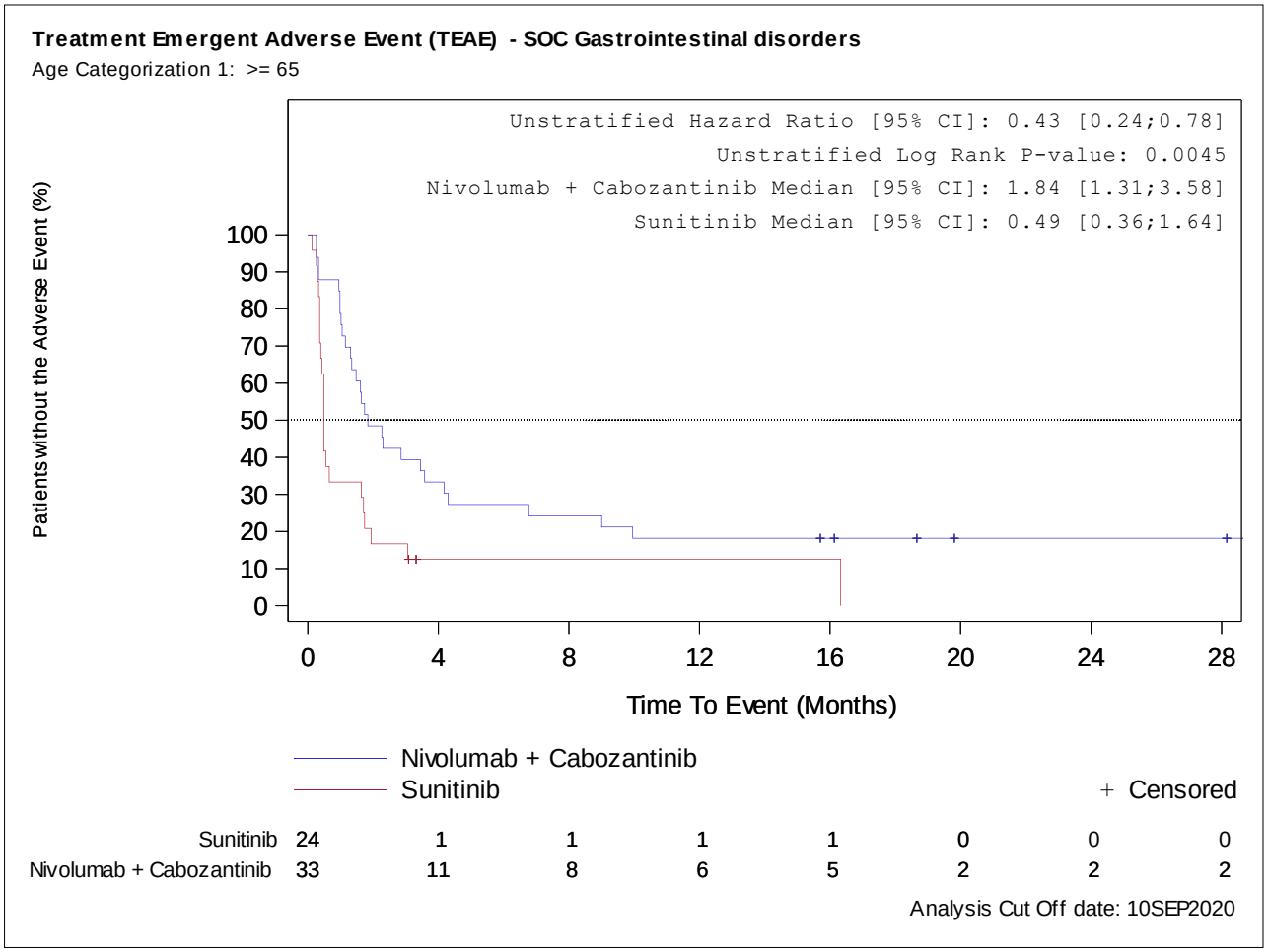
FIGURE 5.5.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:31:34

FIGURE 5.5.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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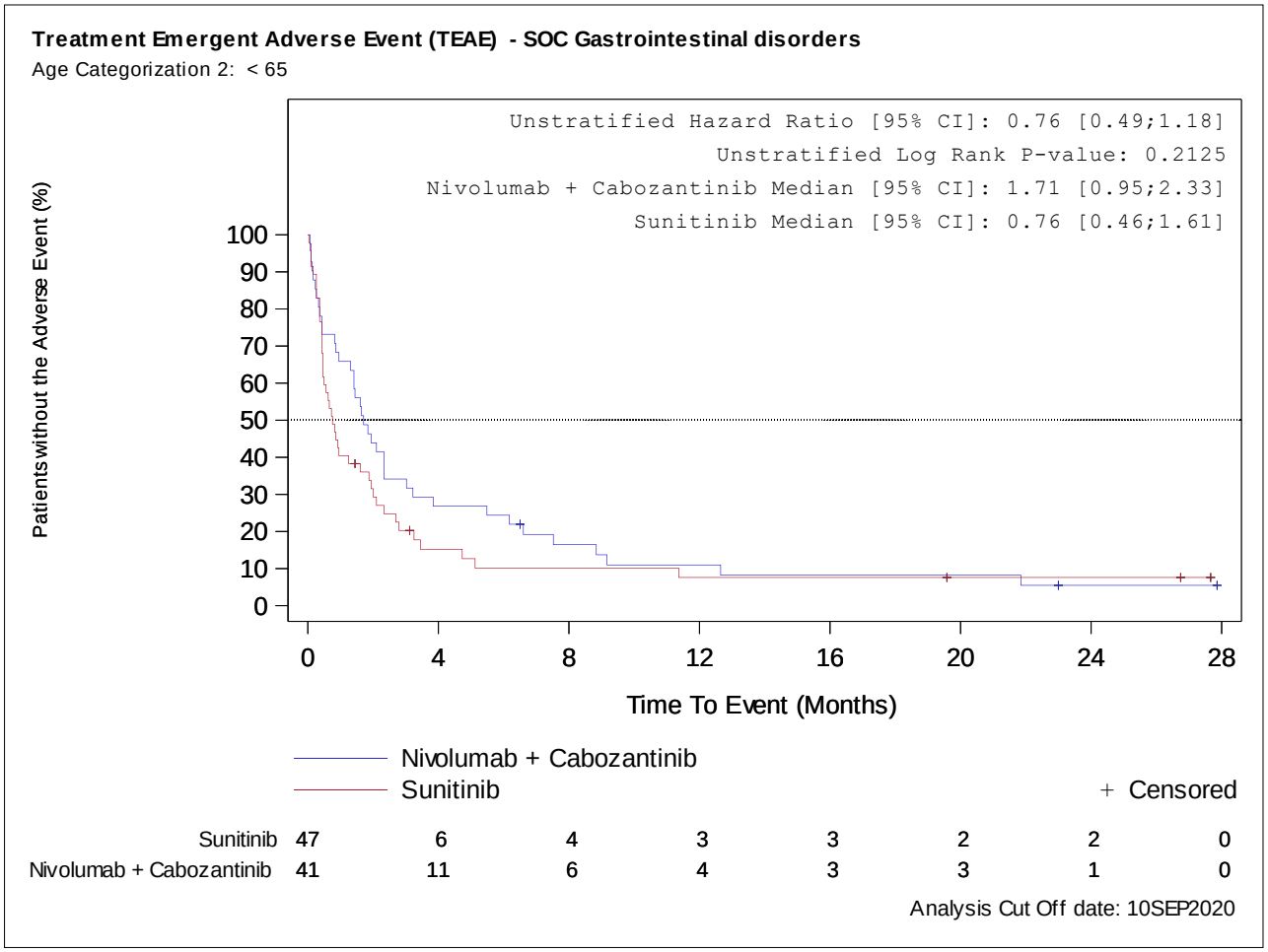
FIGURE 5.5.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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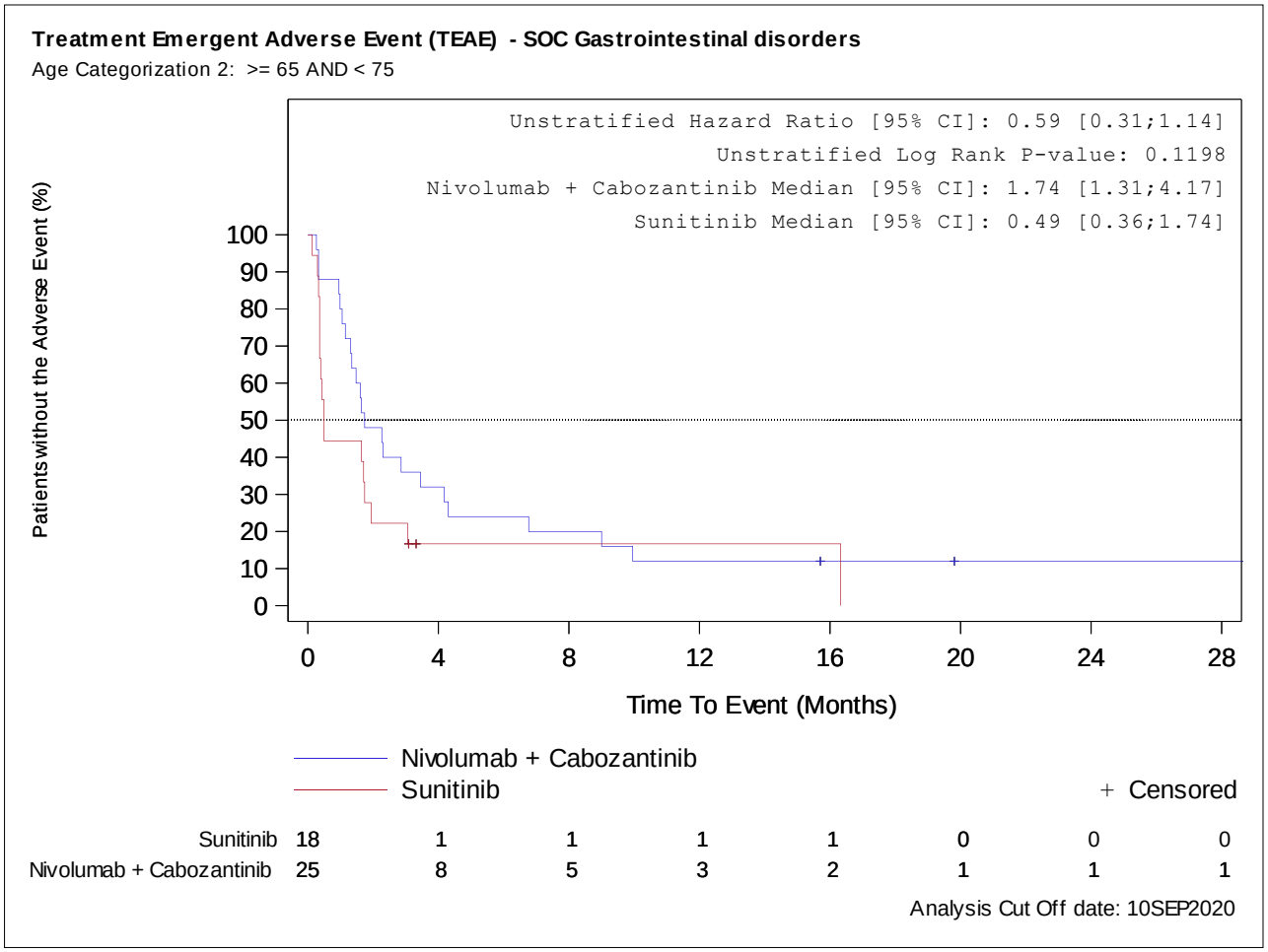
FIGURE 5.5.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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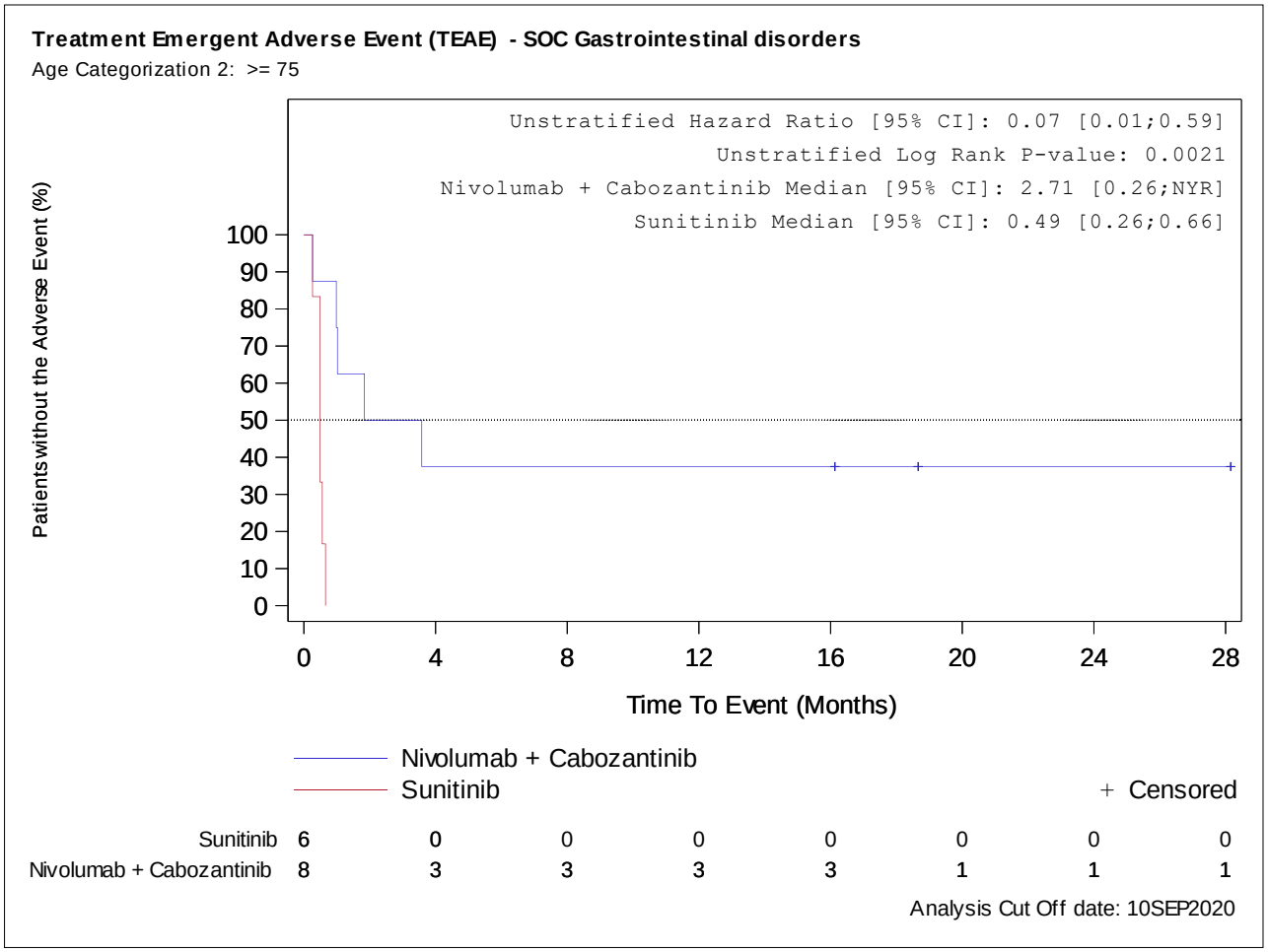
FIGURE 5.5.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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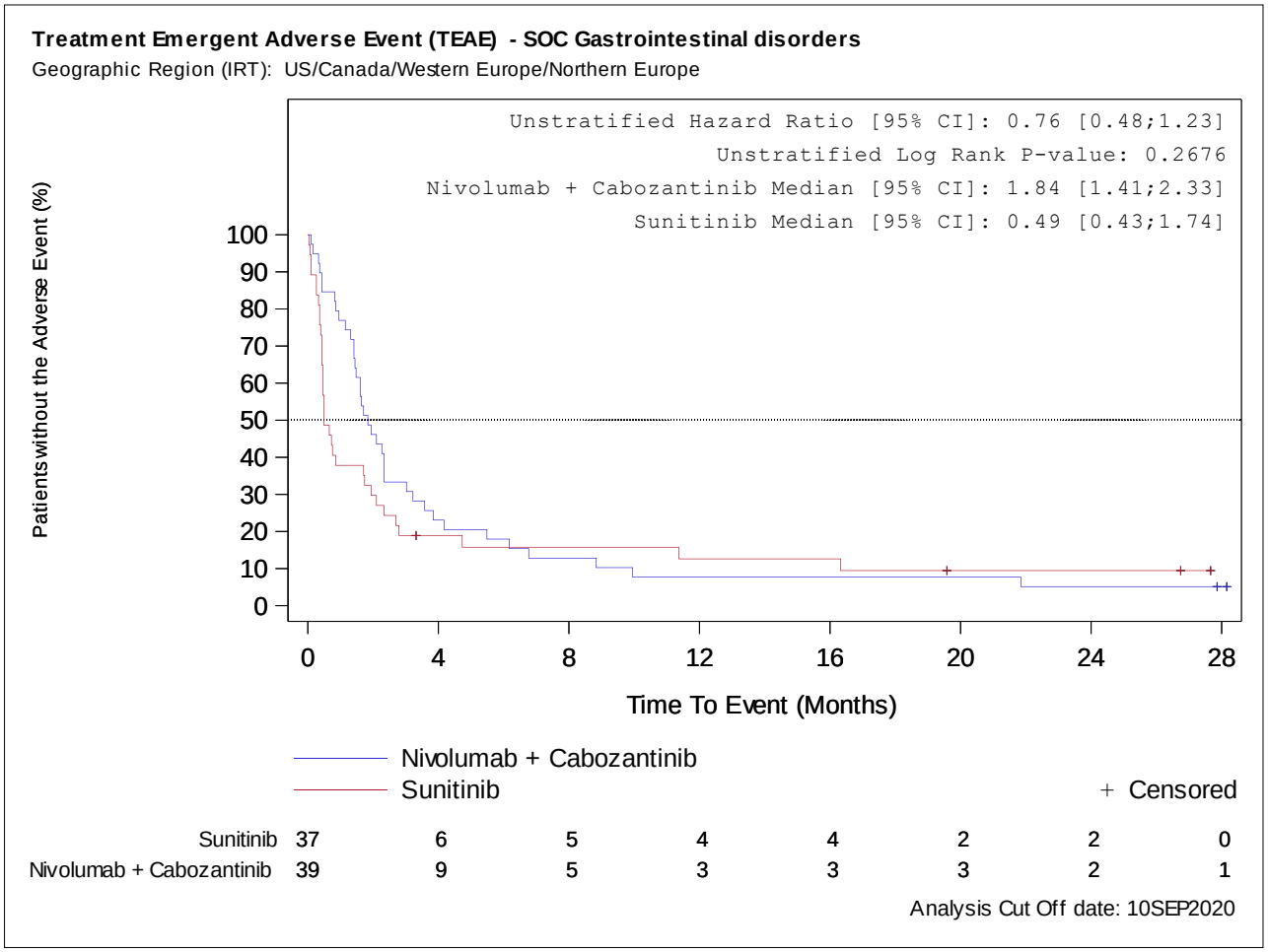
FIGURE 5.5.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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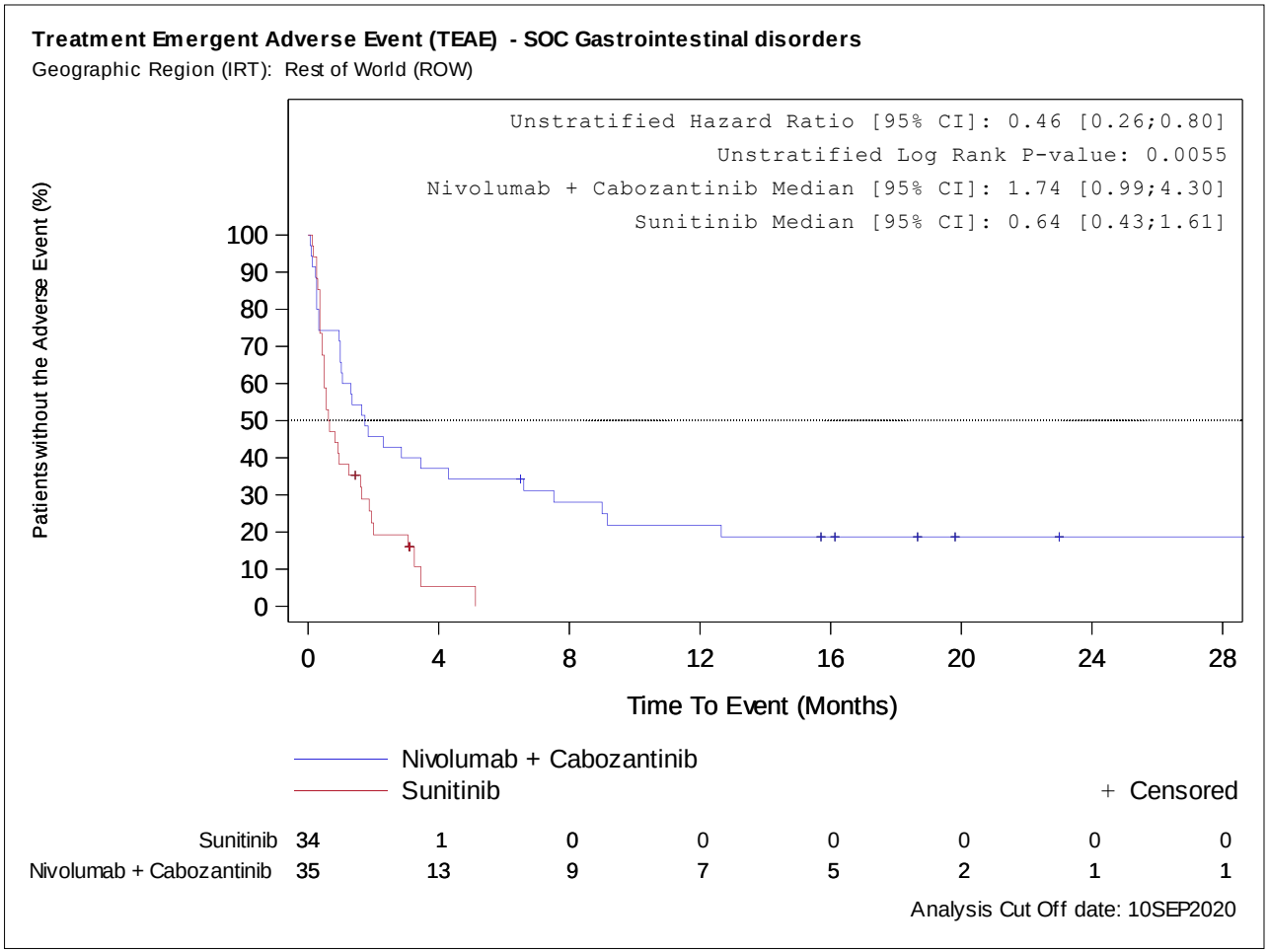
FIGURE 5.5.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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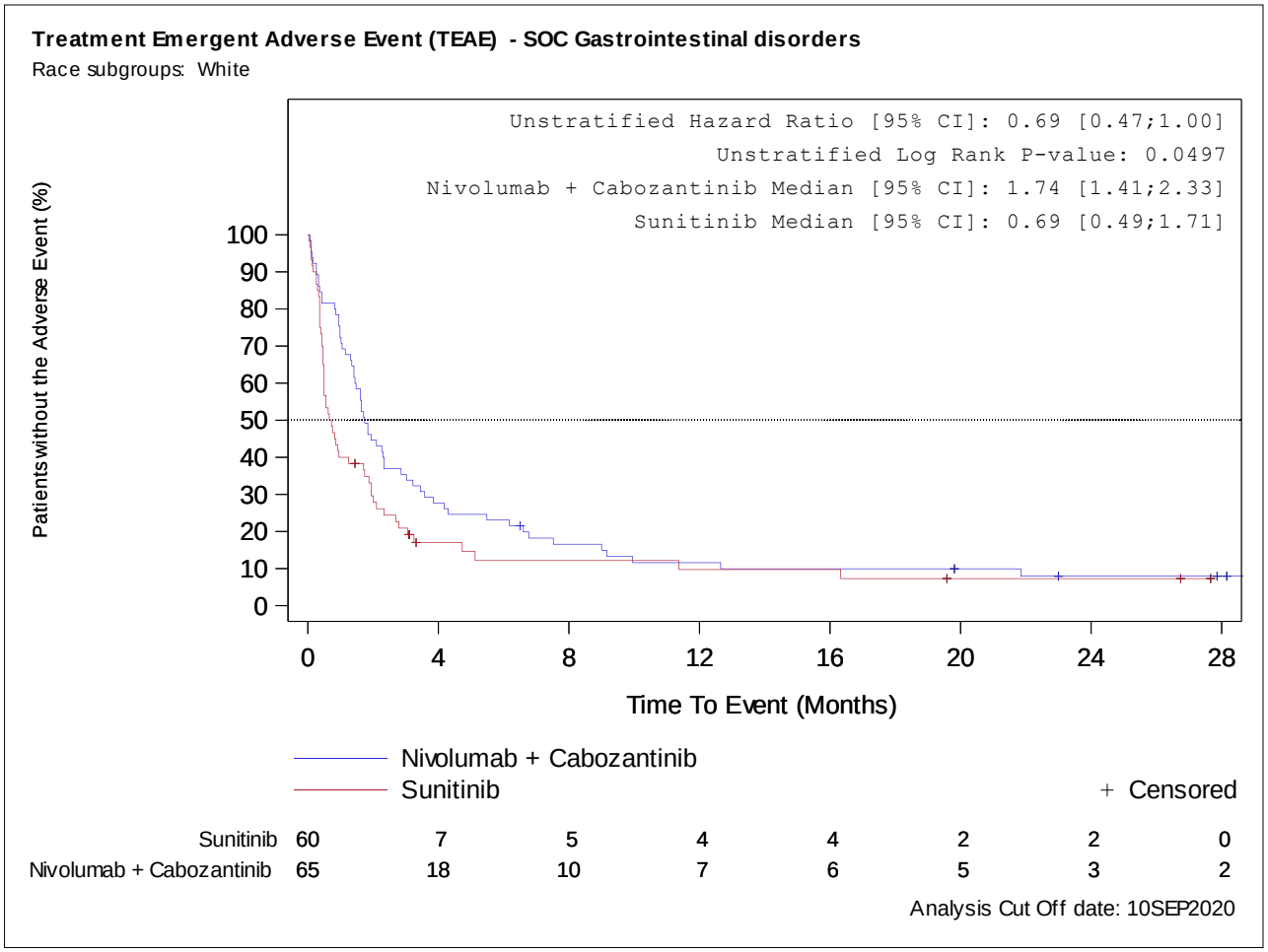
FIGURE 5.5.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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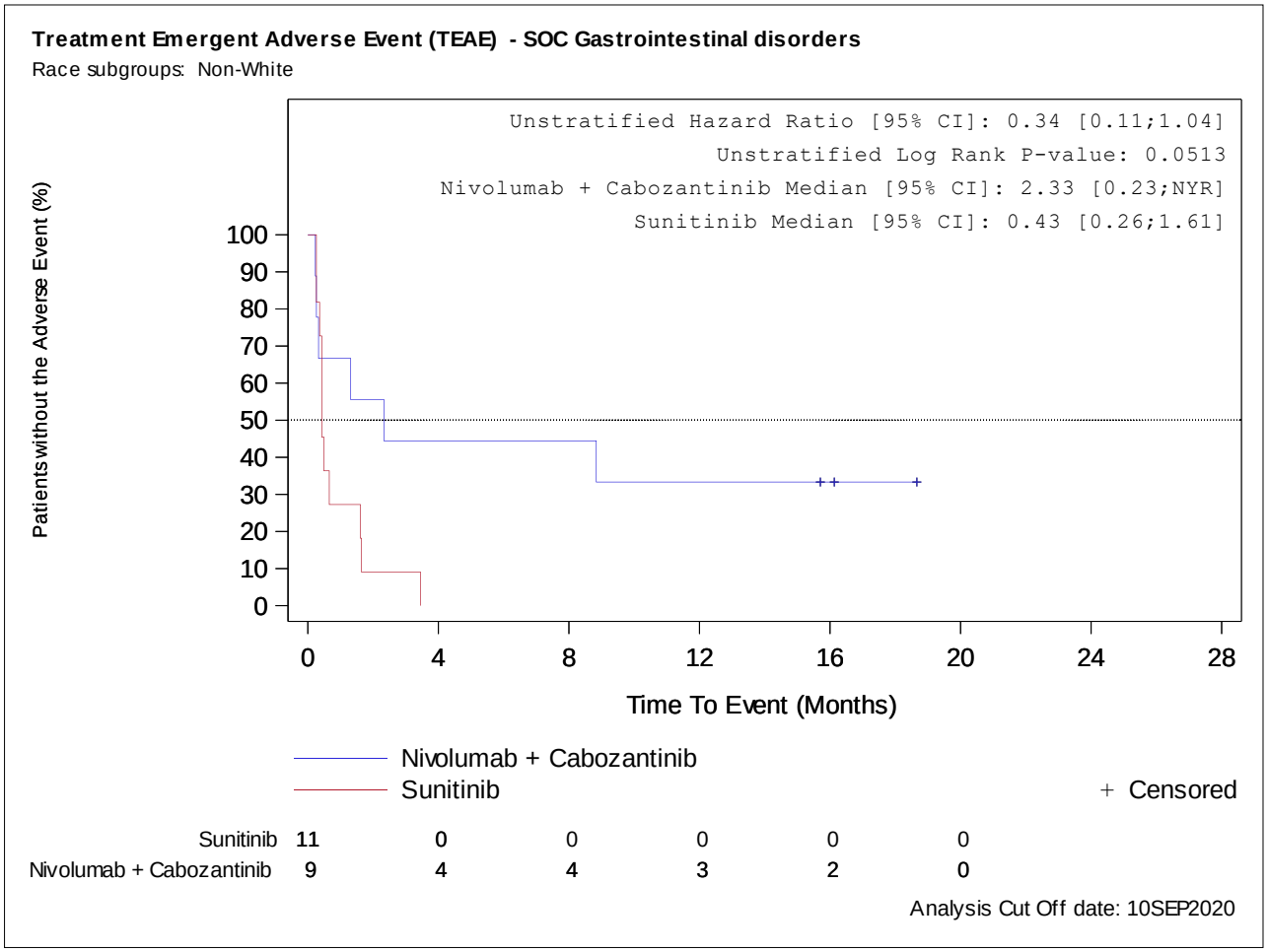
FIGURE 5.5.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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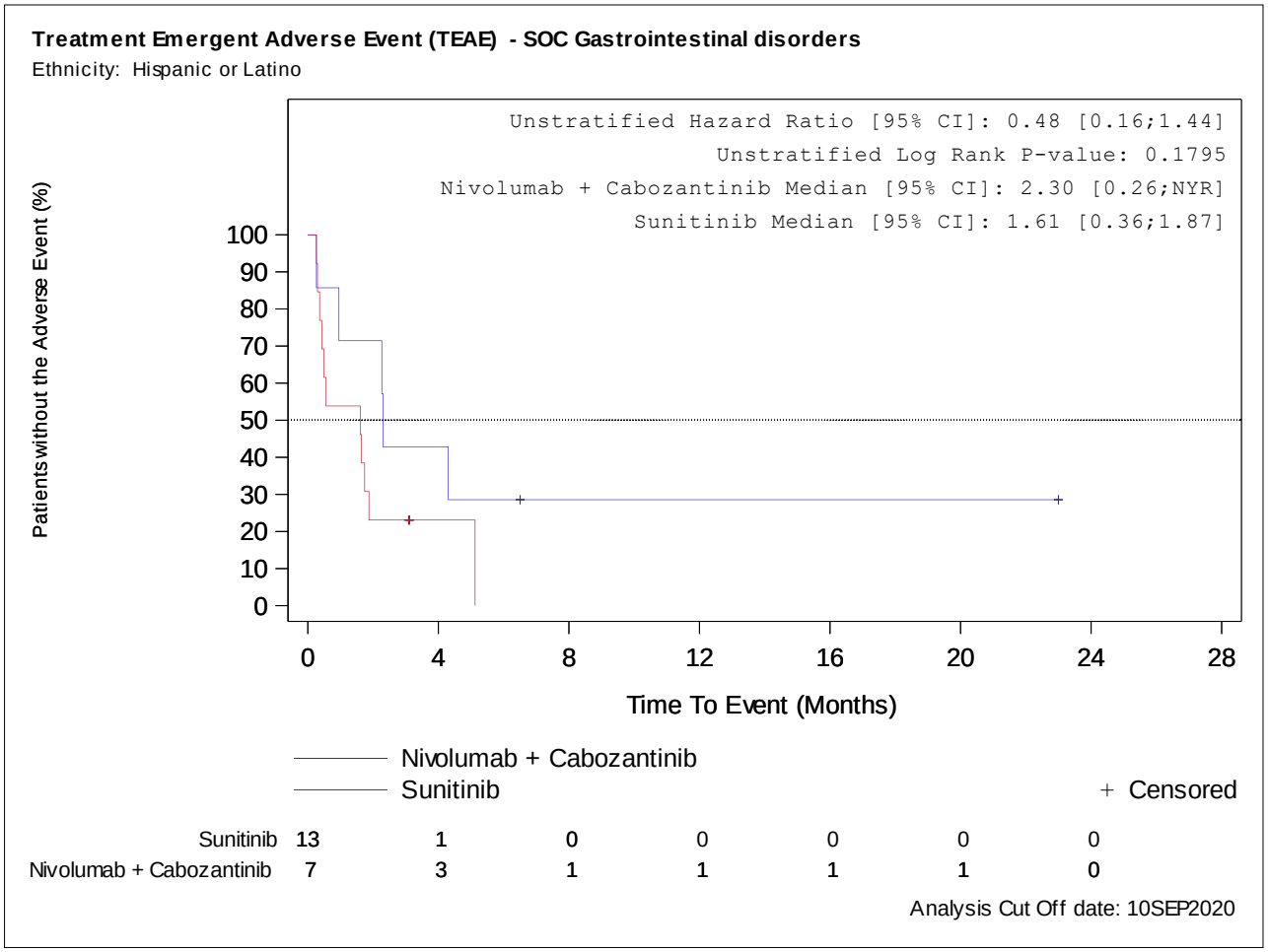
FIGURE 5.5.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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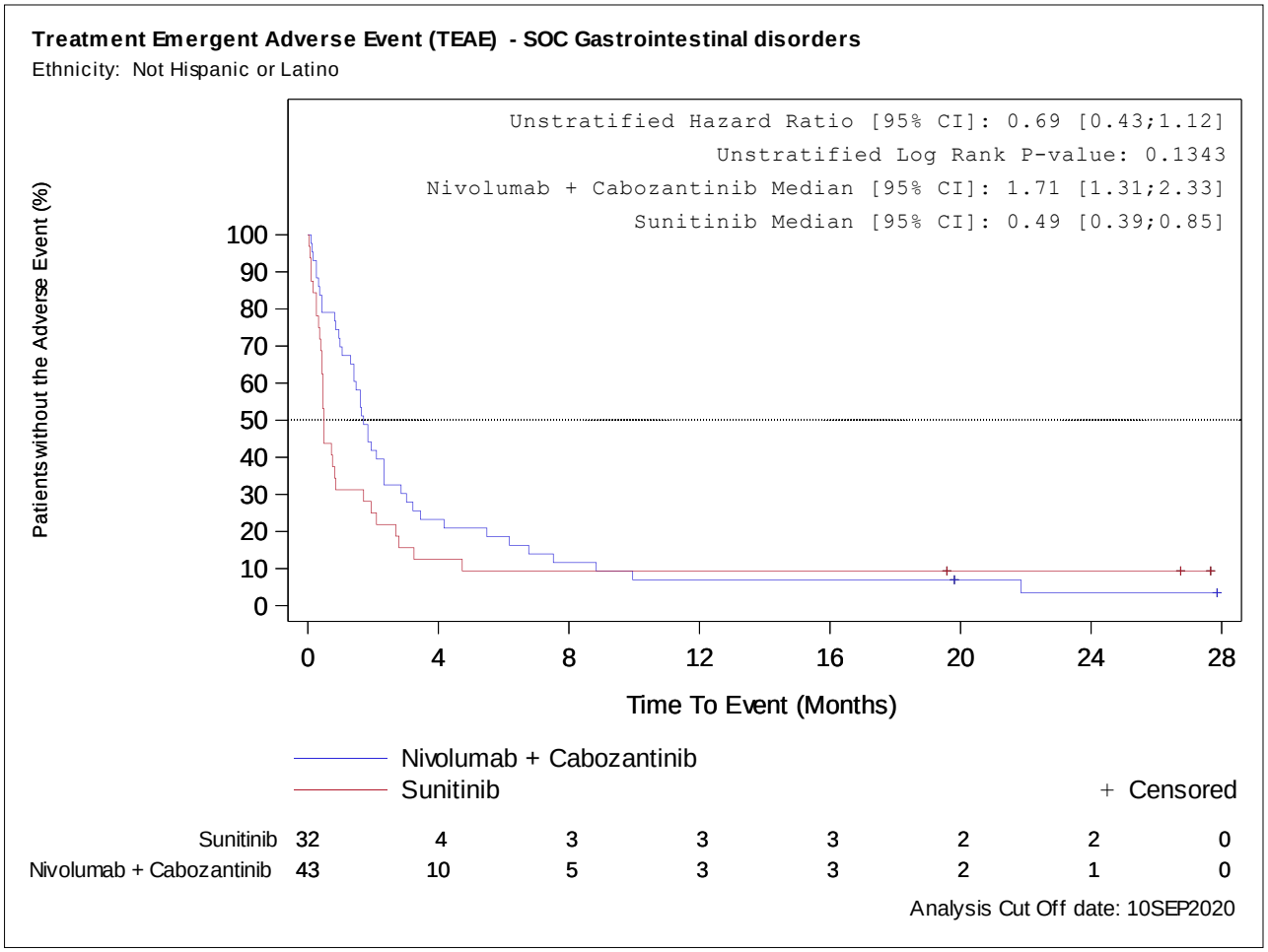
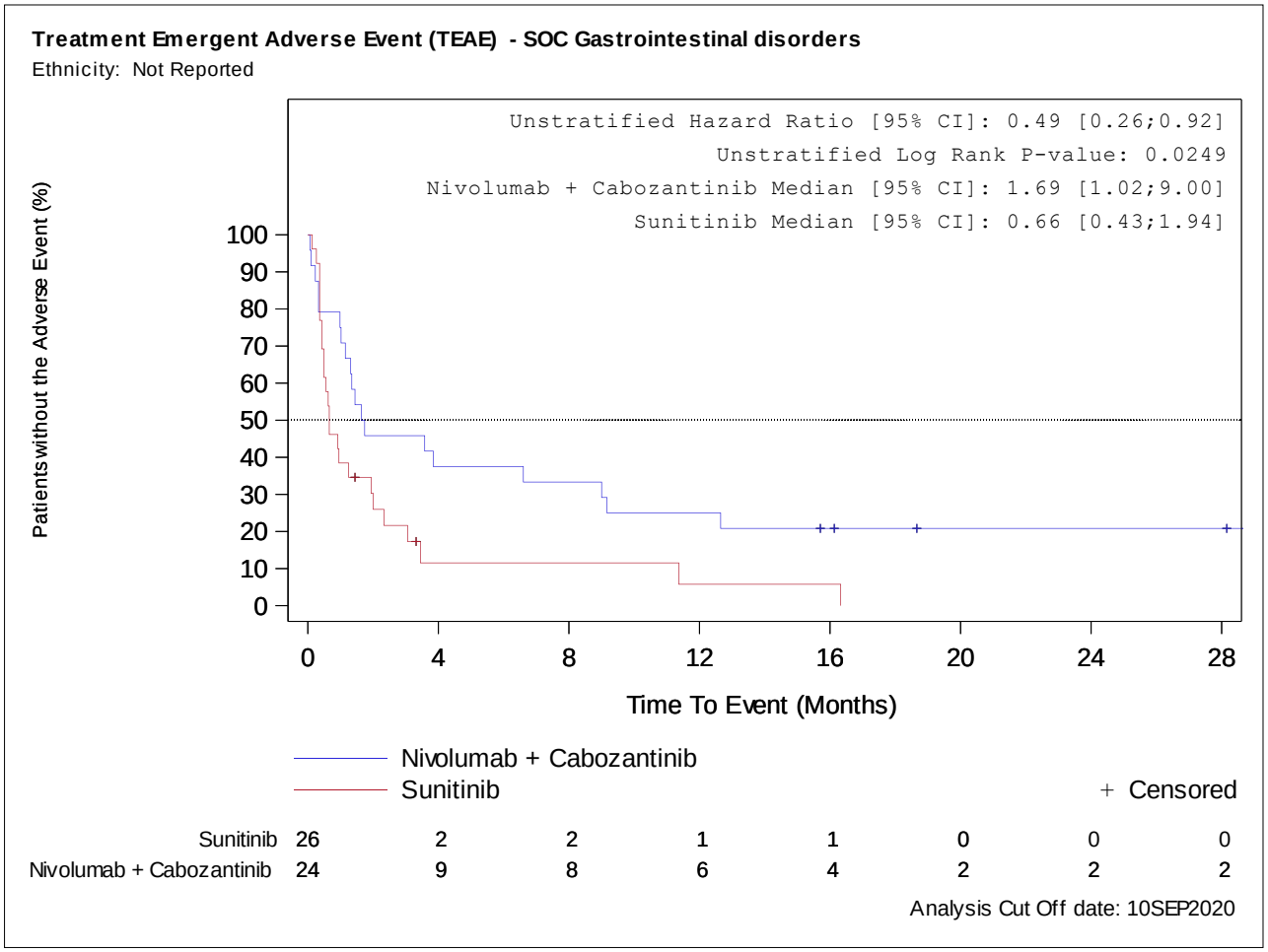
FIGURE 5.5.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



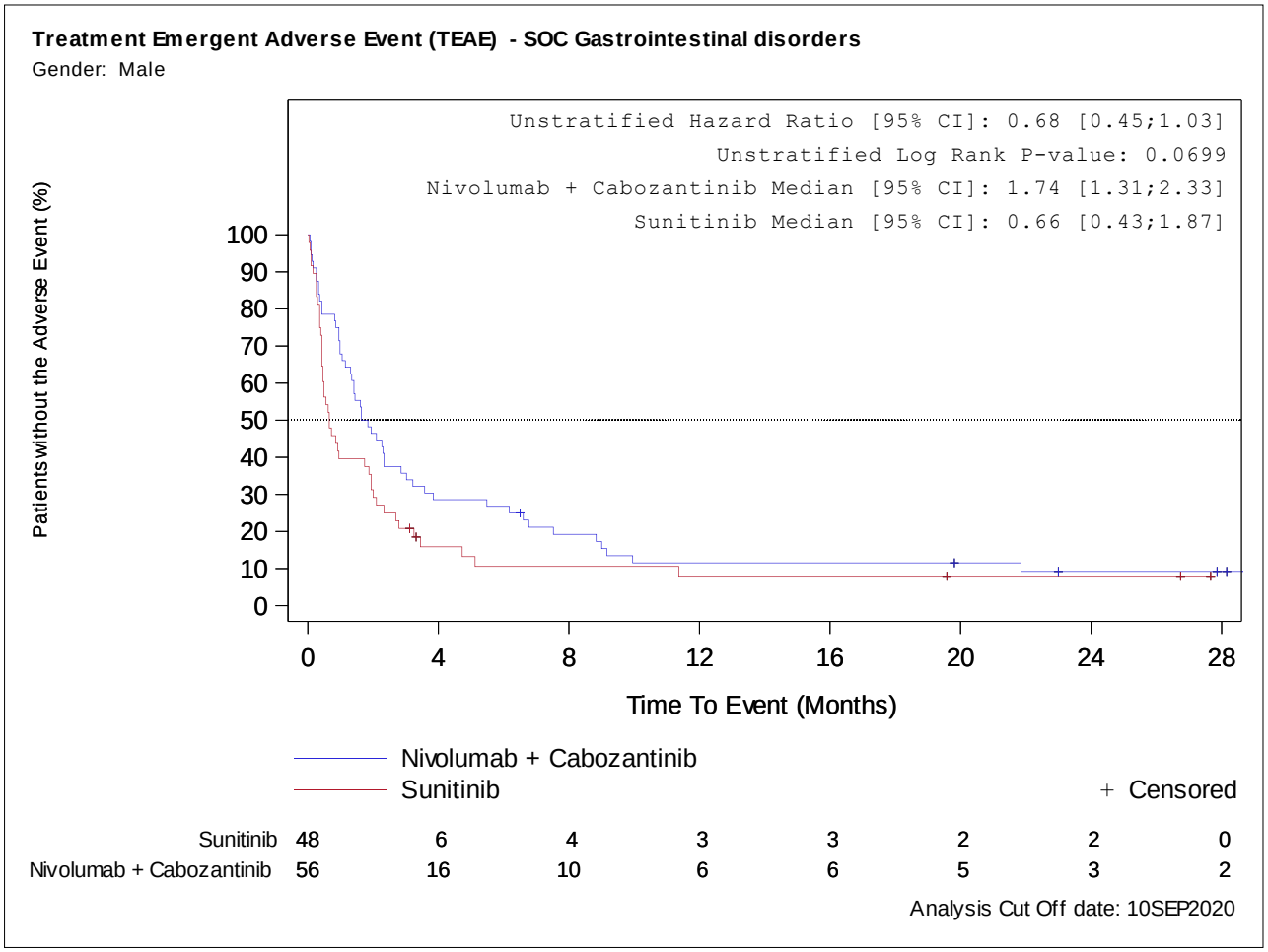

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:32:32

FIGURE 5.5.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:32:38

FIGURE 5.5.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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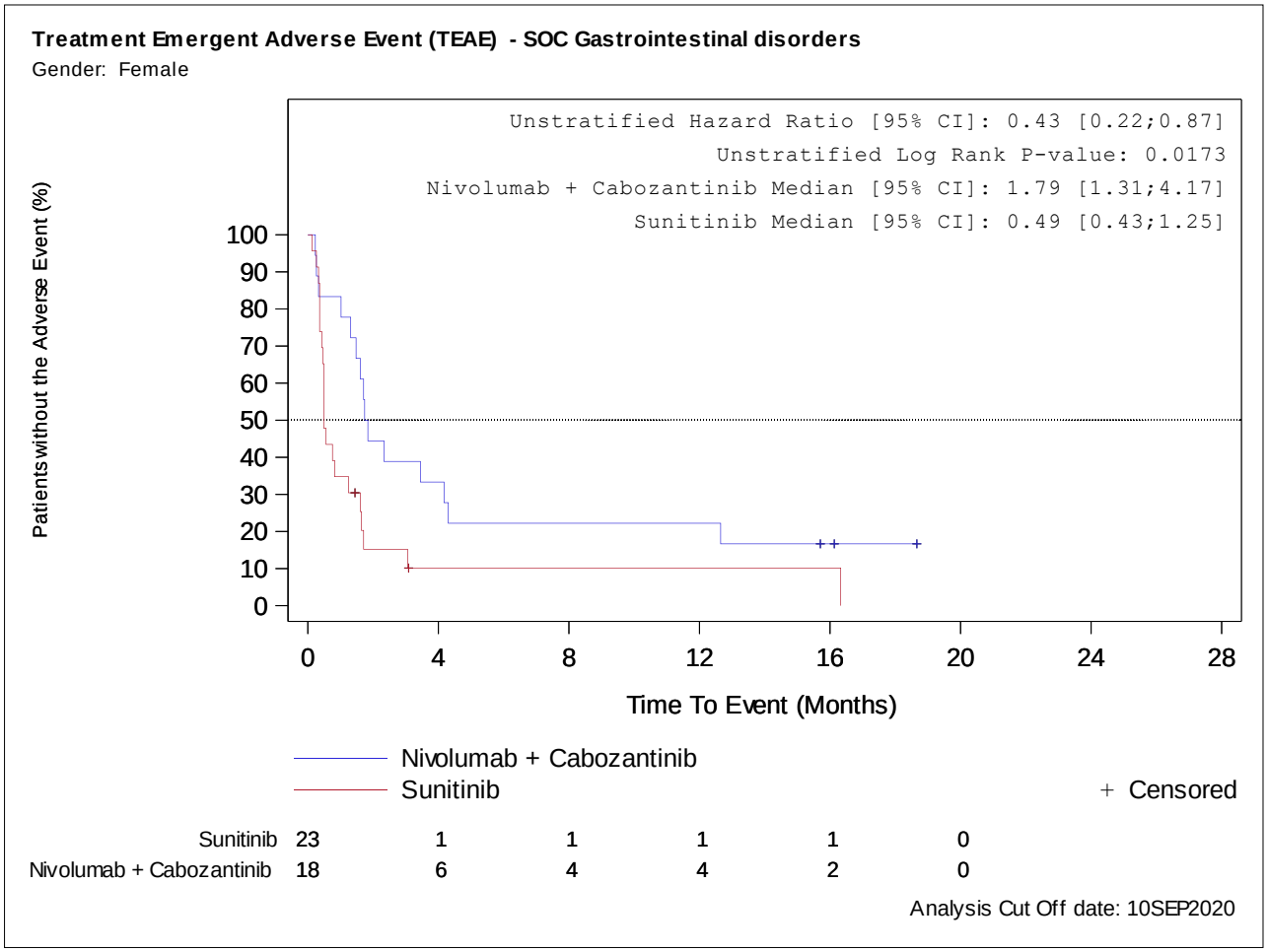
FIGURE 5.5.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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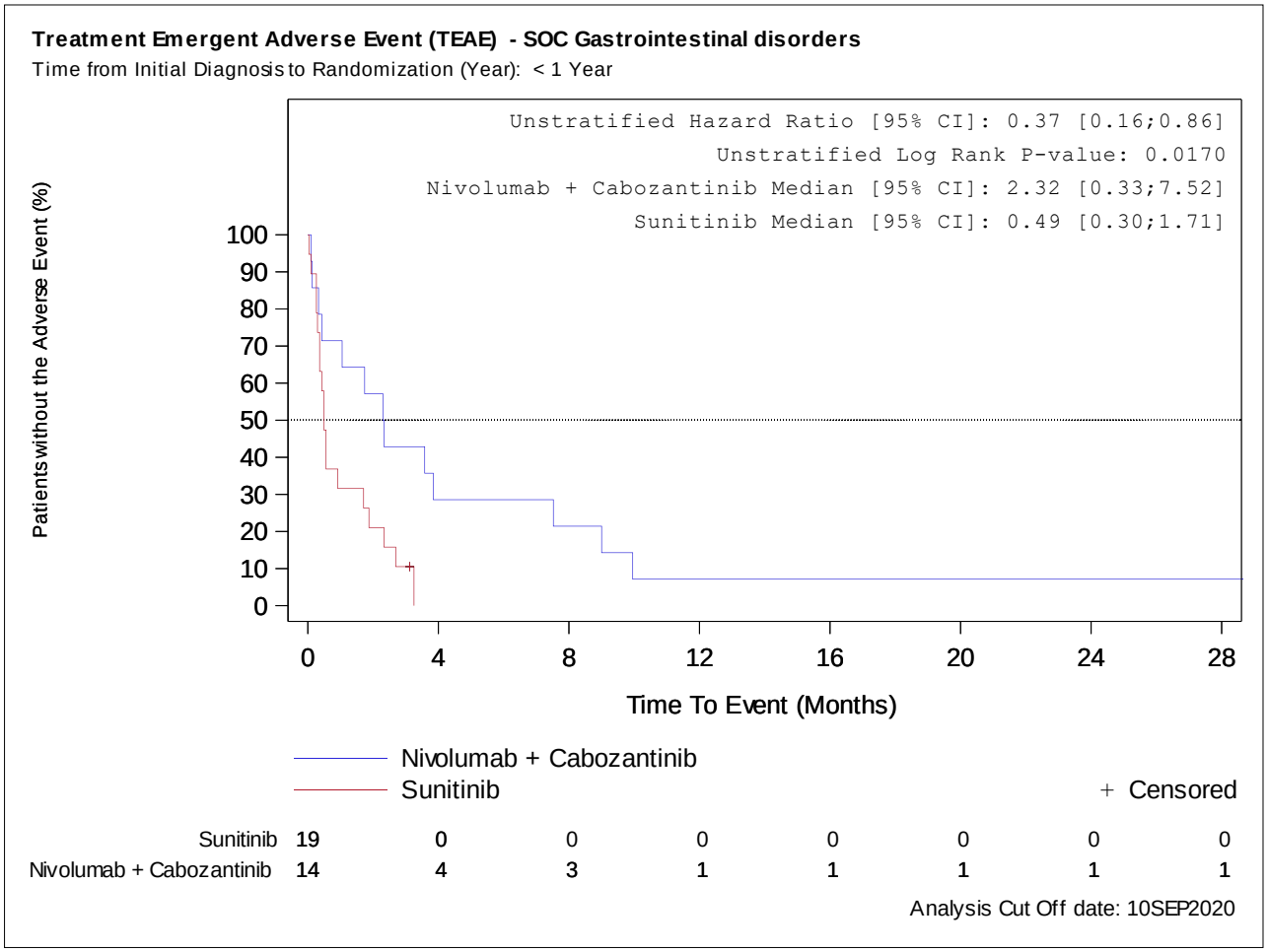
FIGURE 5.5.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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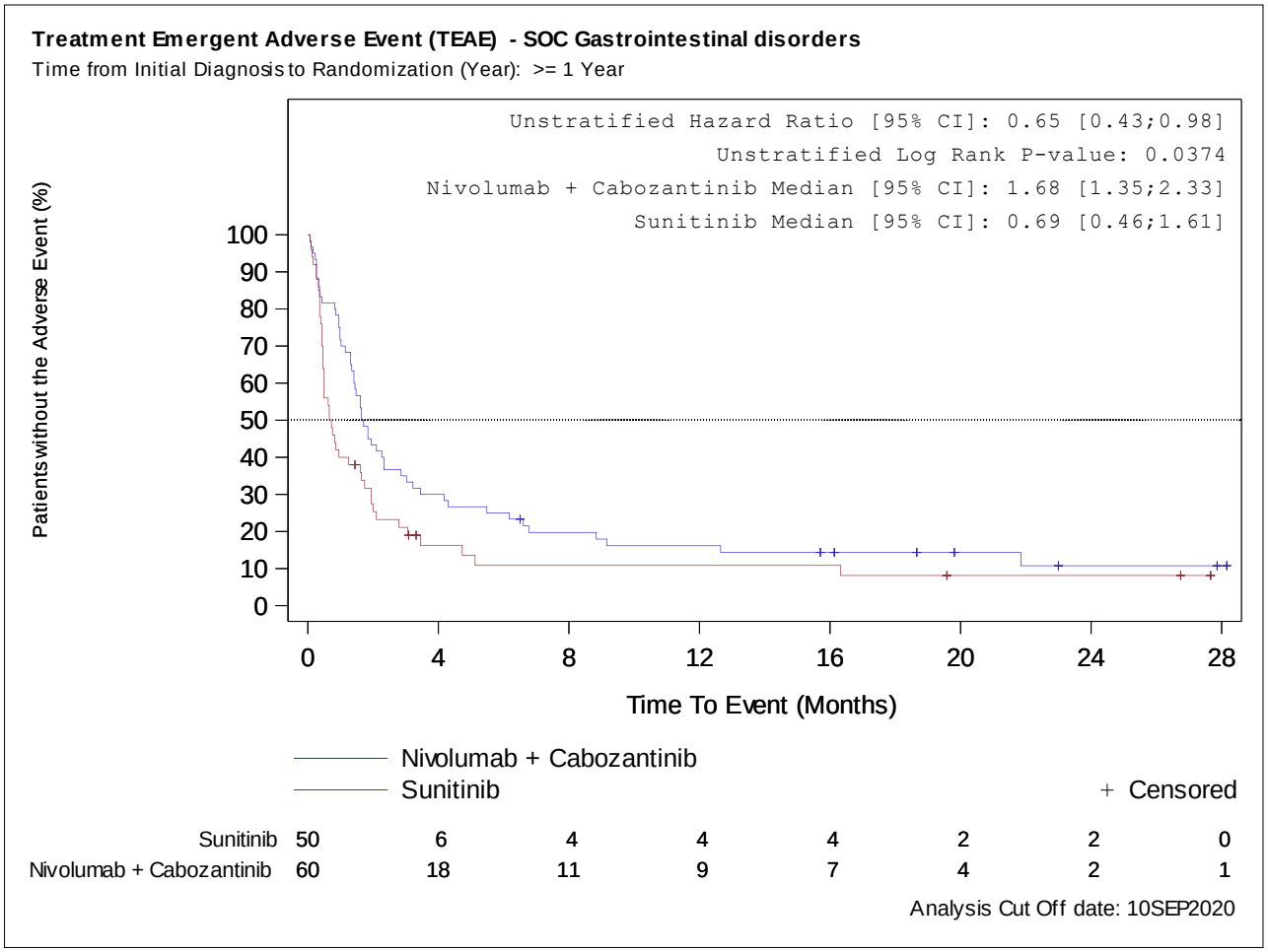
FIGURE 5.5.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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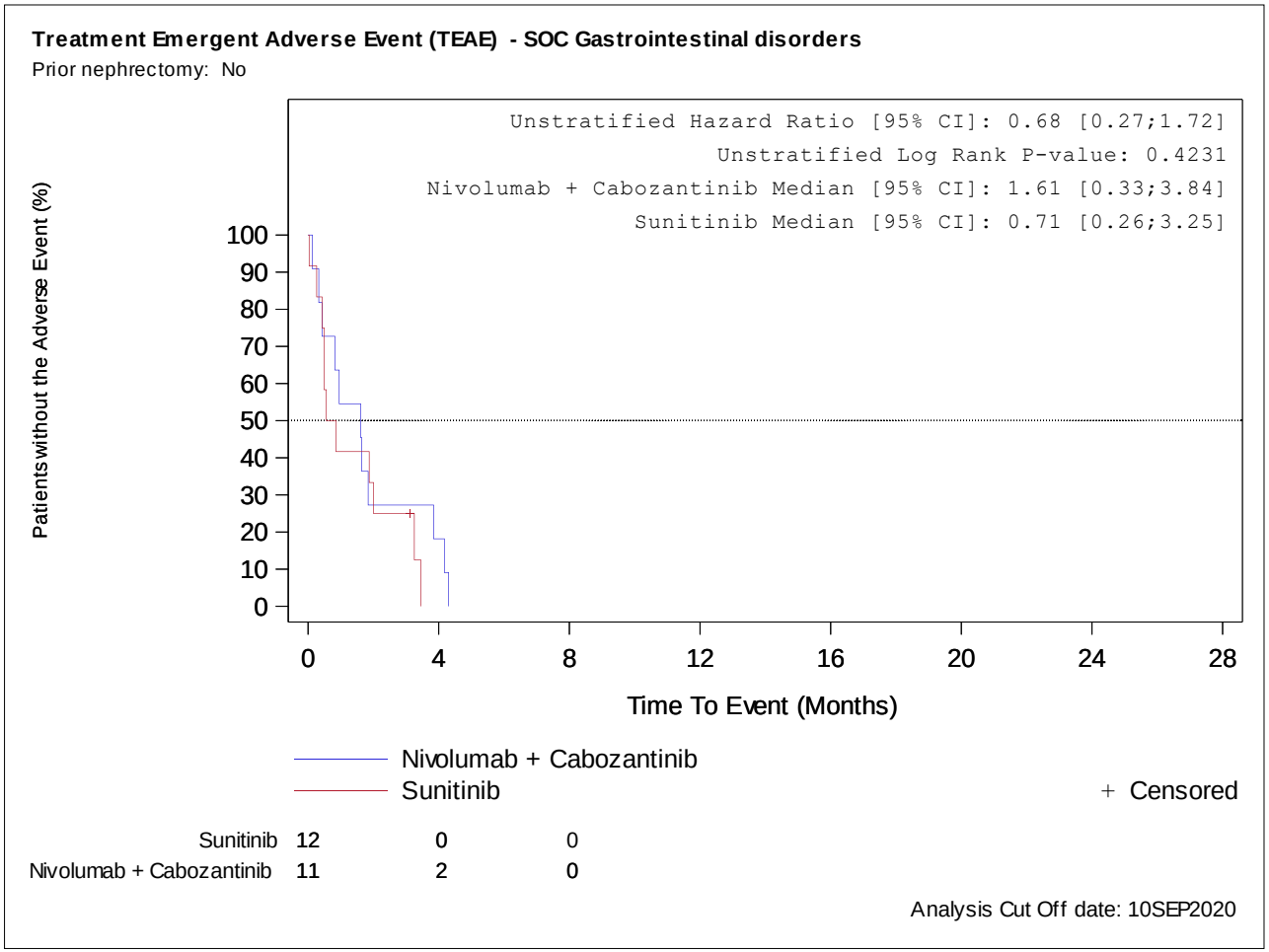
FIGURE 5.5.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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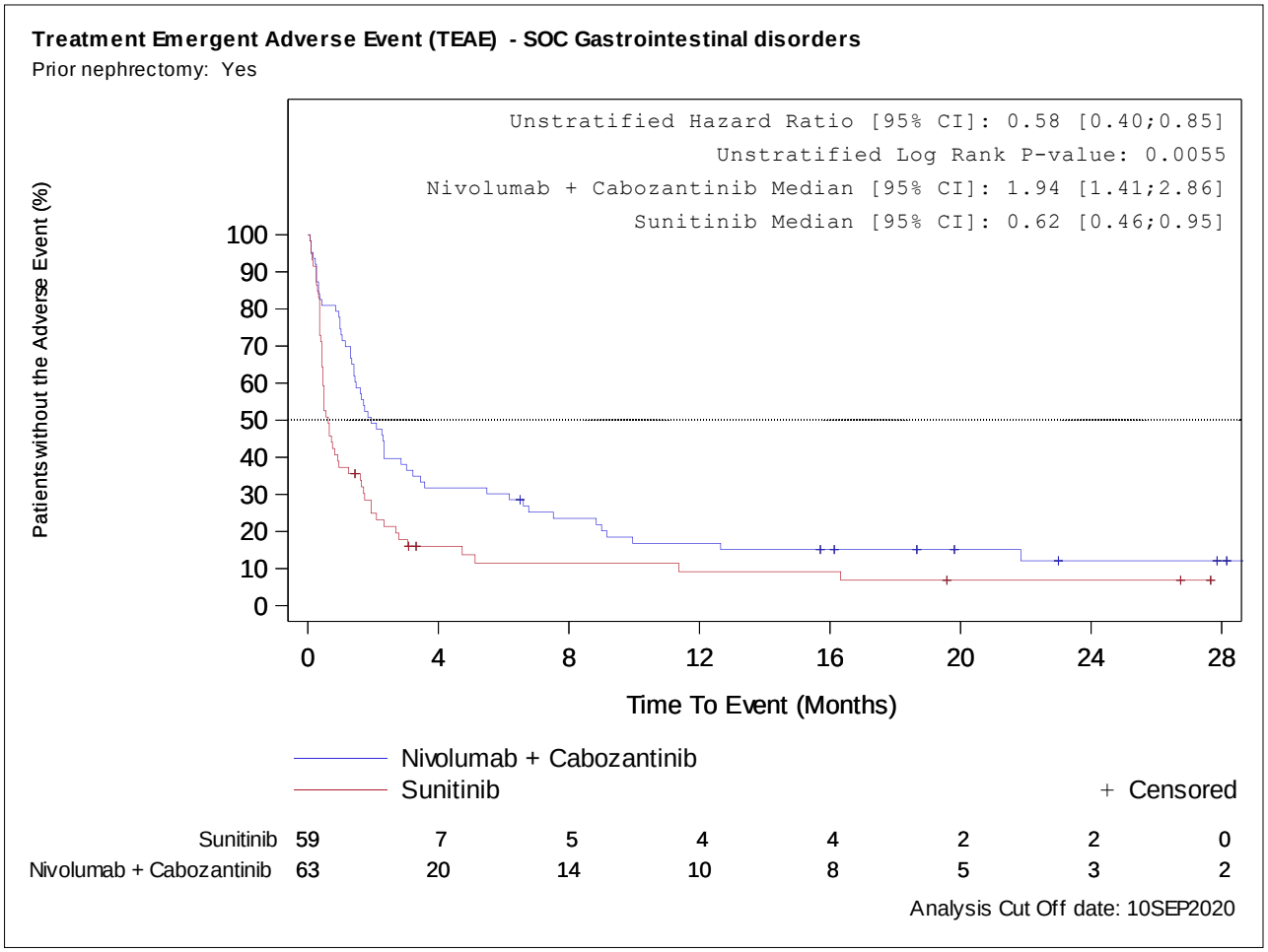
FIGURE 5.5.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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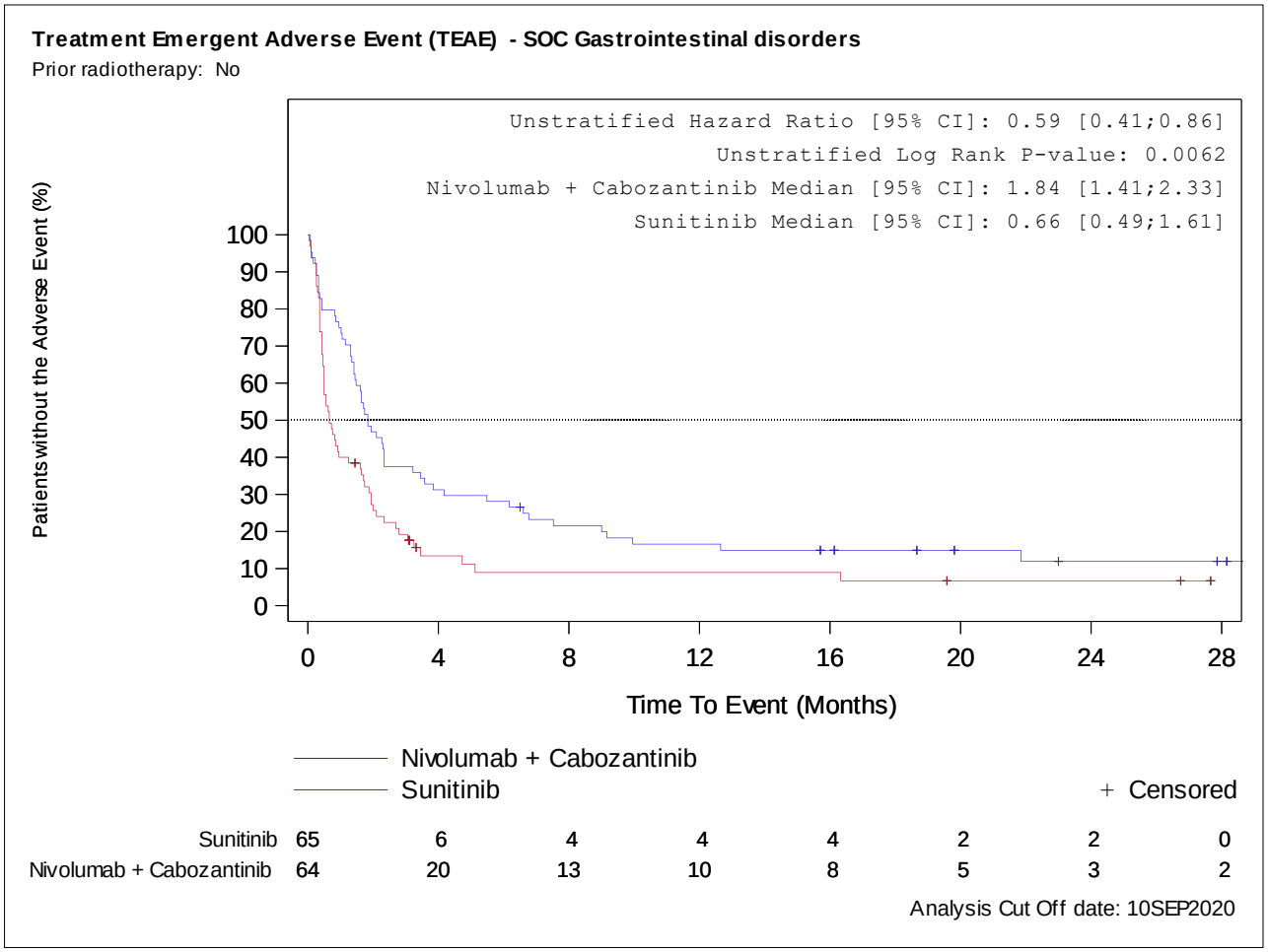
FIGURE 5.5.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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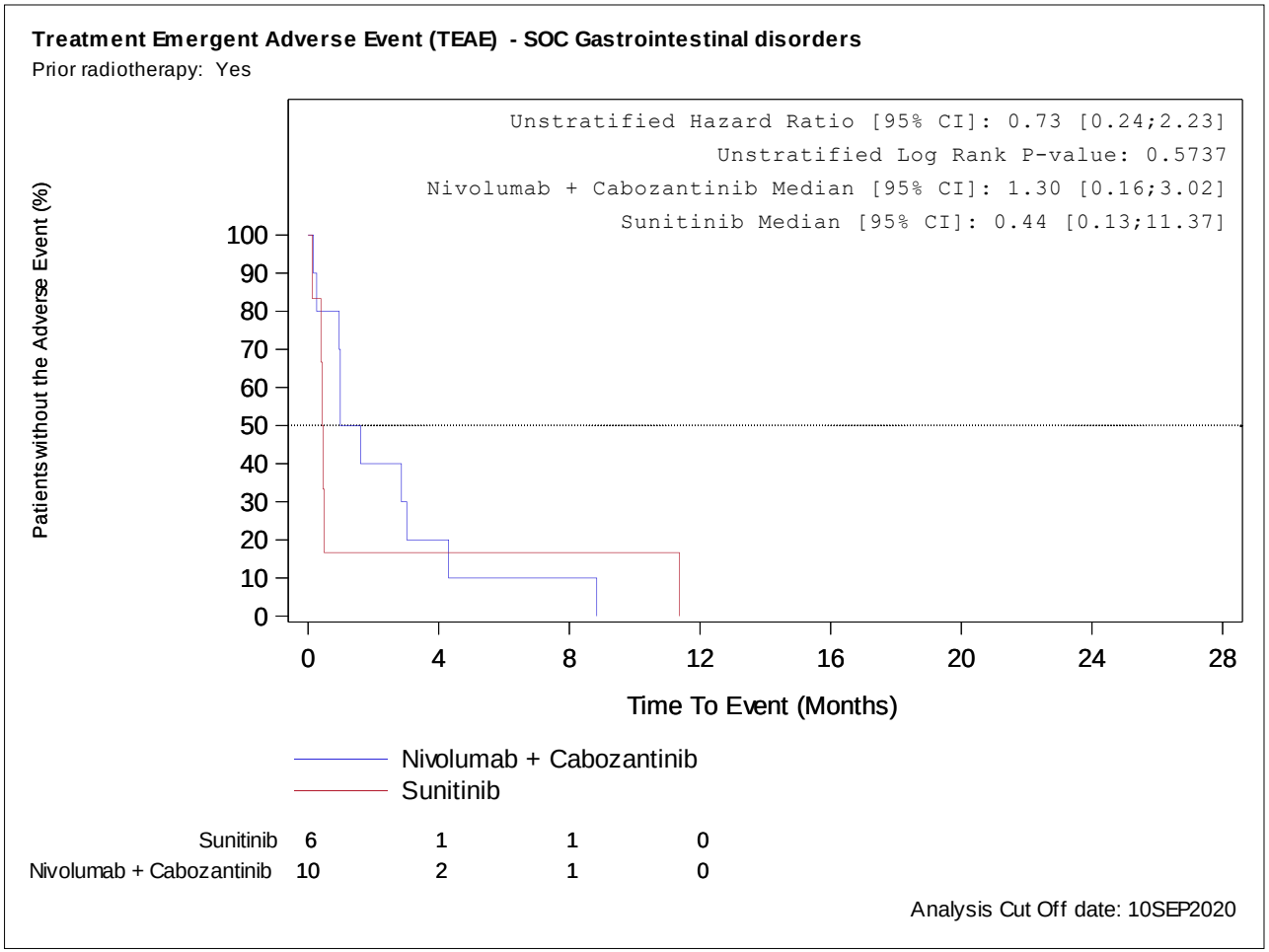
FIGURE 5.5.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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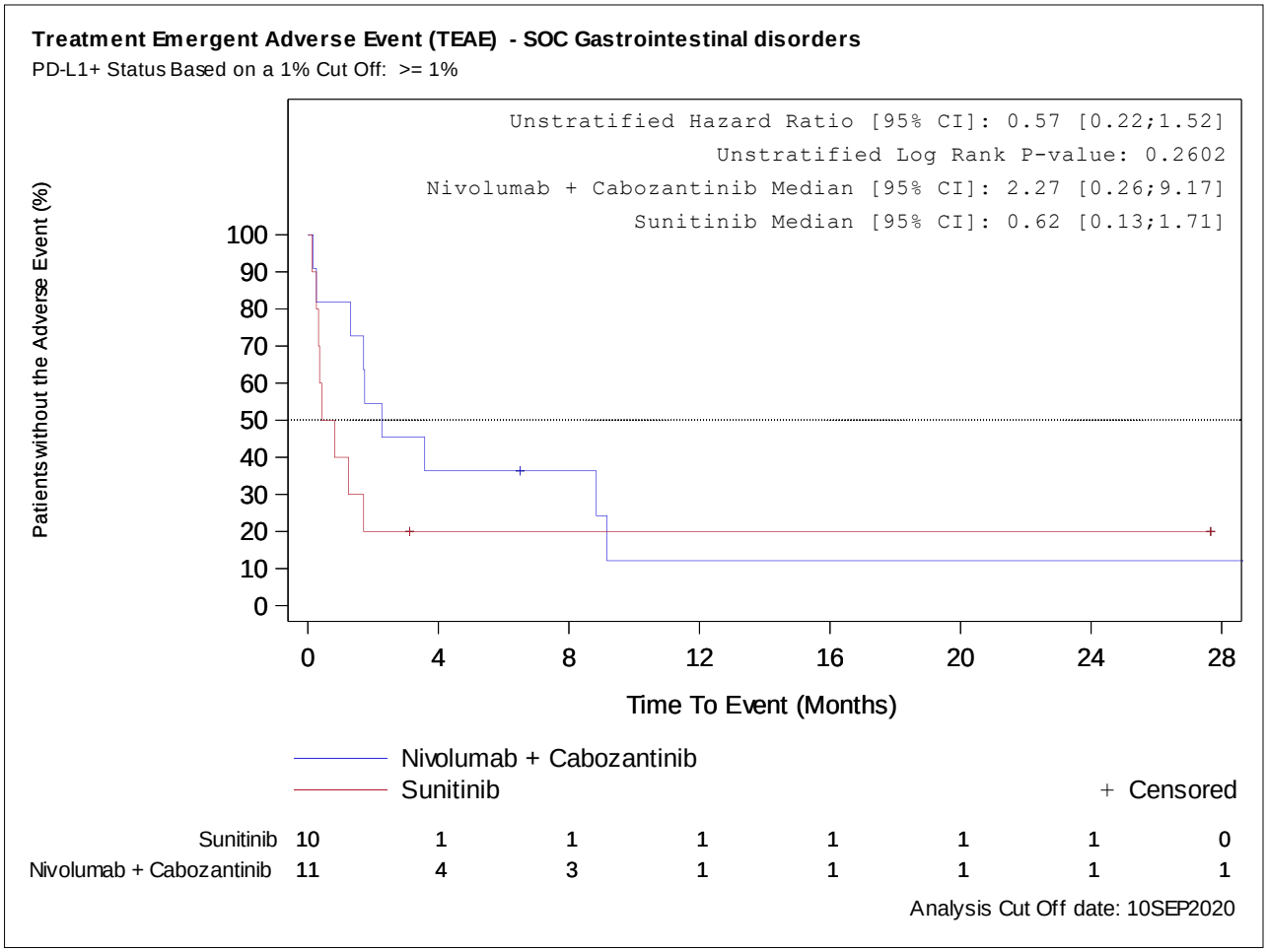
FIGURE 5.5.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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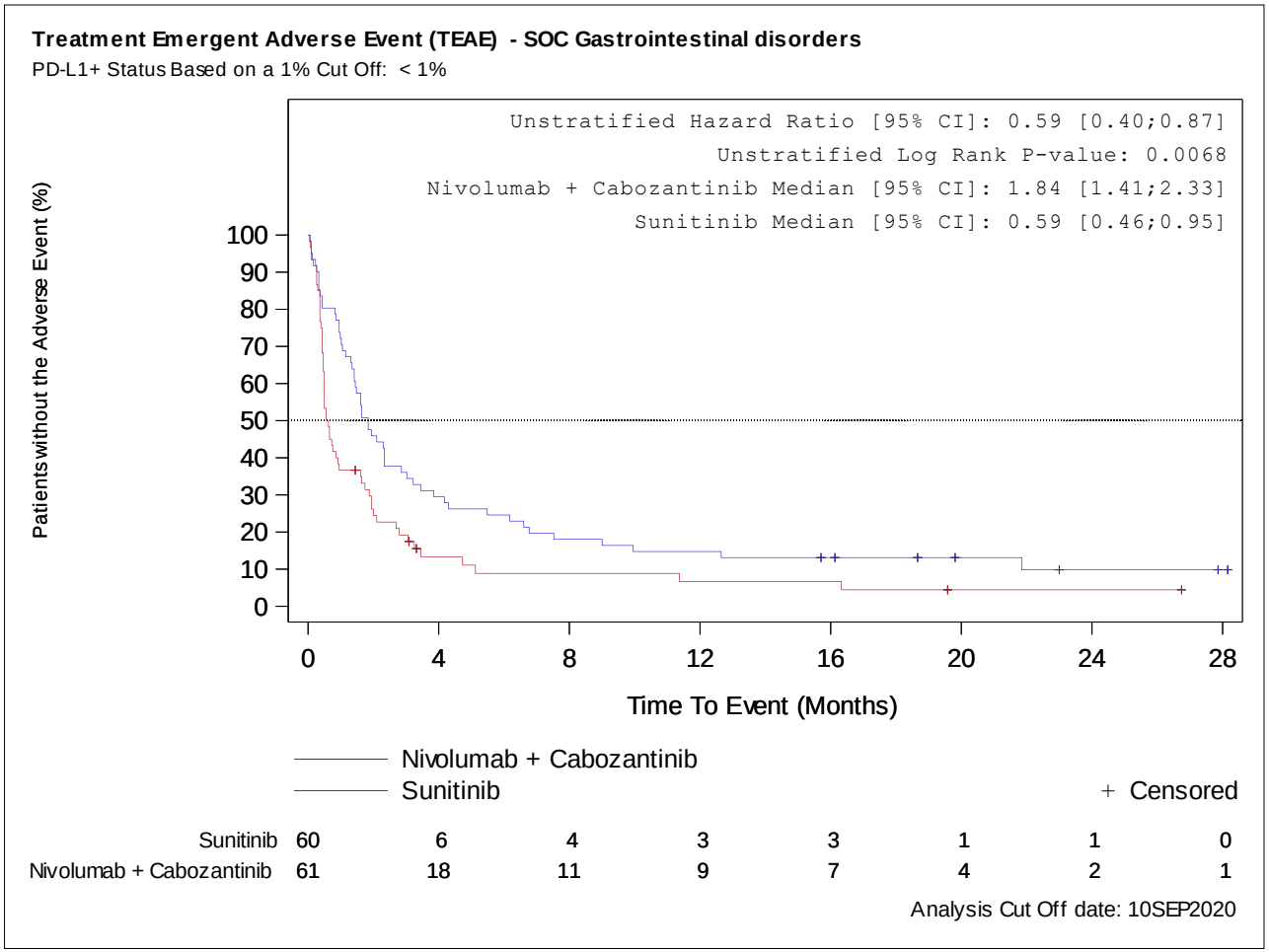
FIGURE 5.5.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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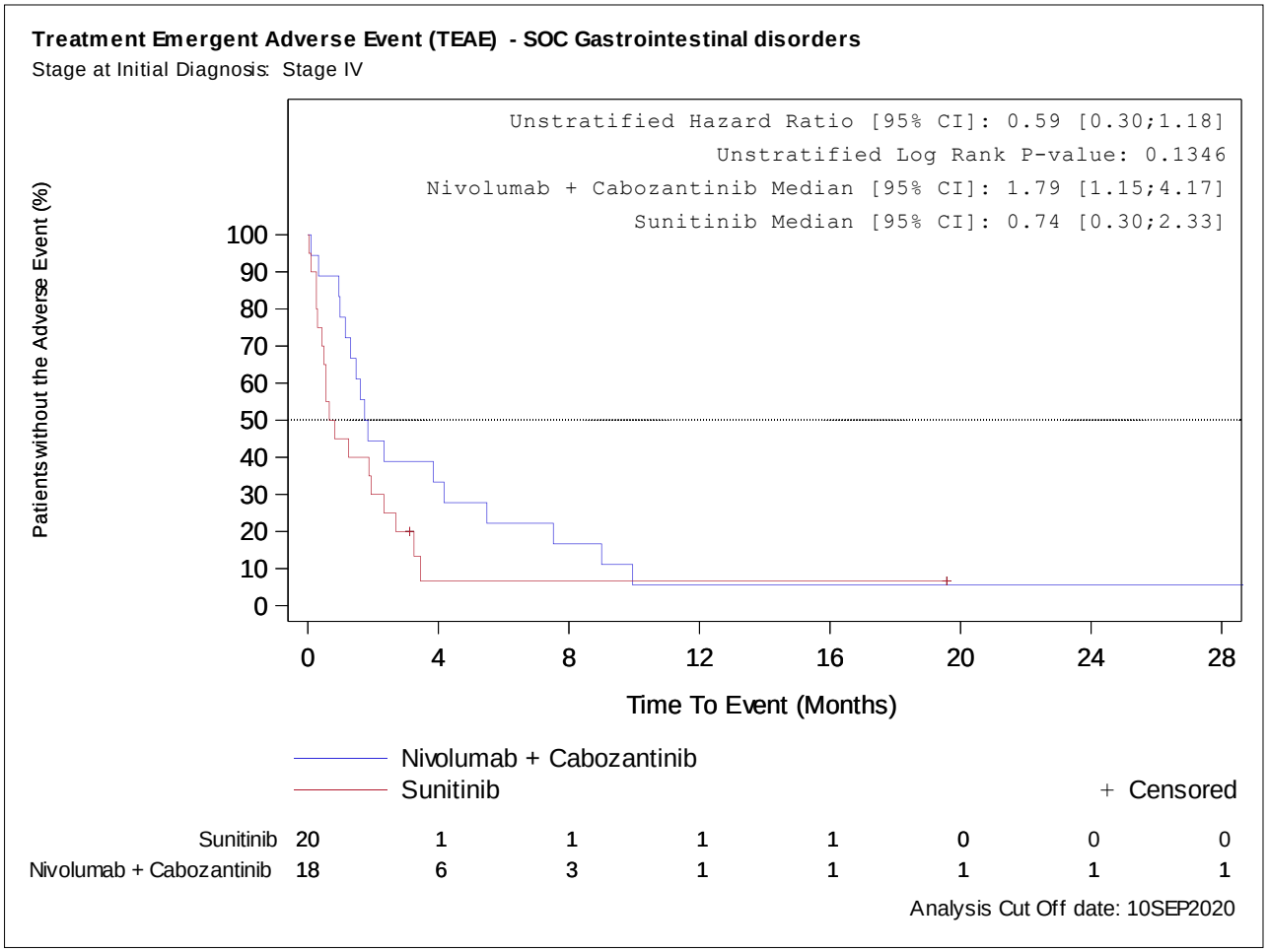
FIGURE 5.5.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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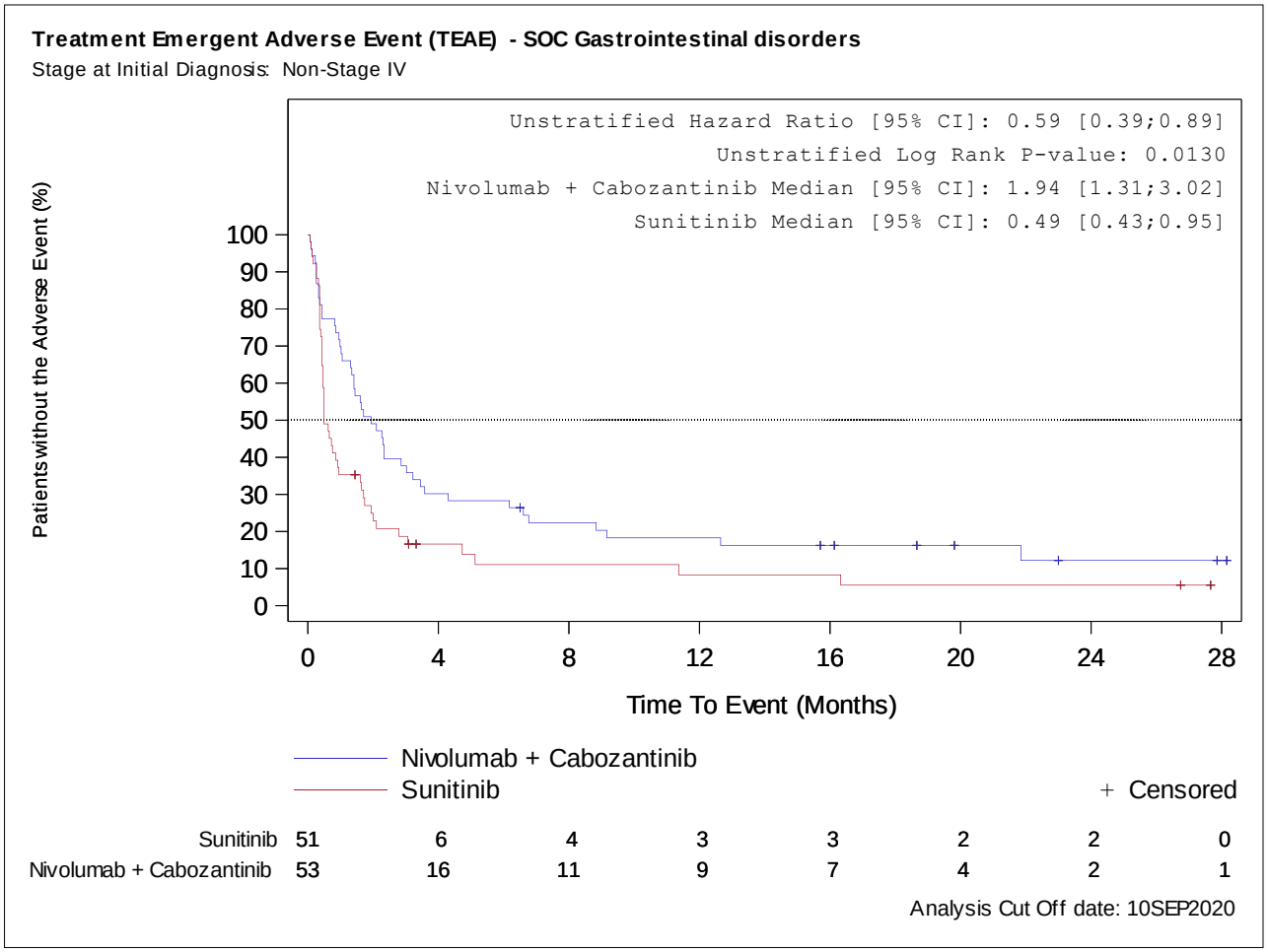
FIGURE 5.5.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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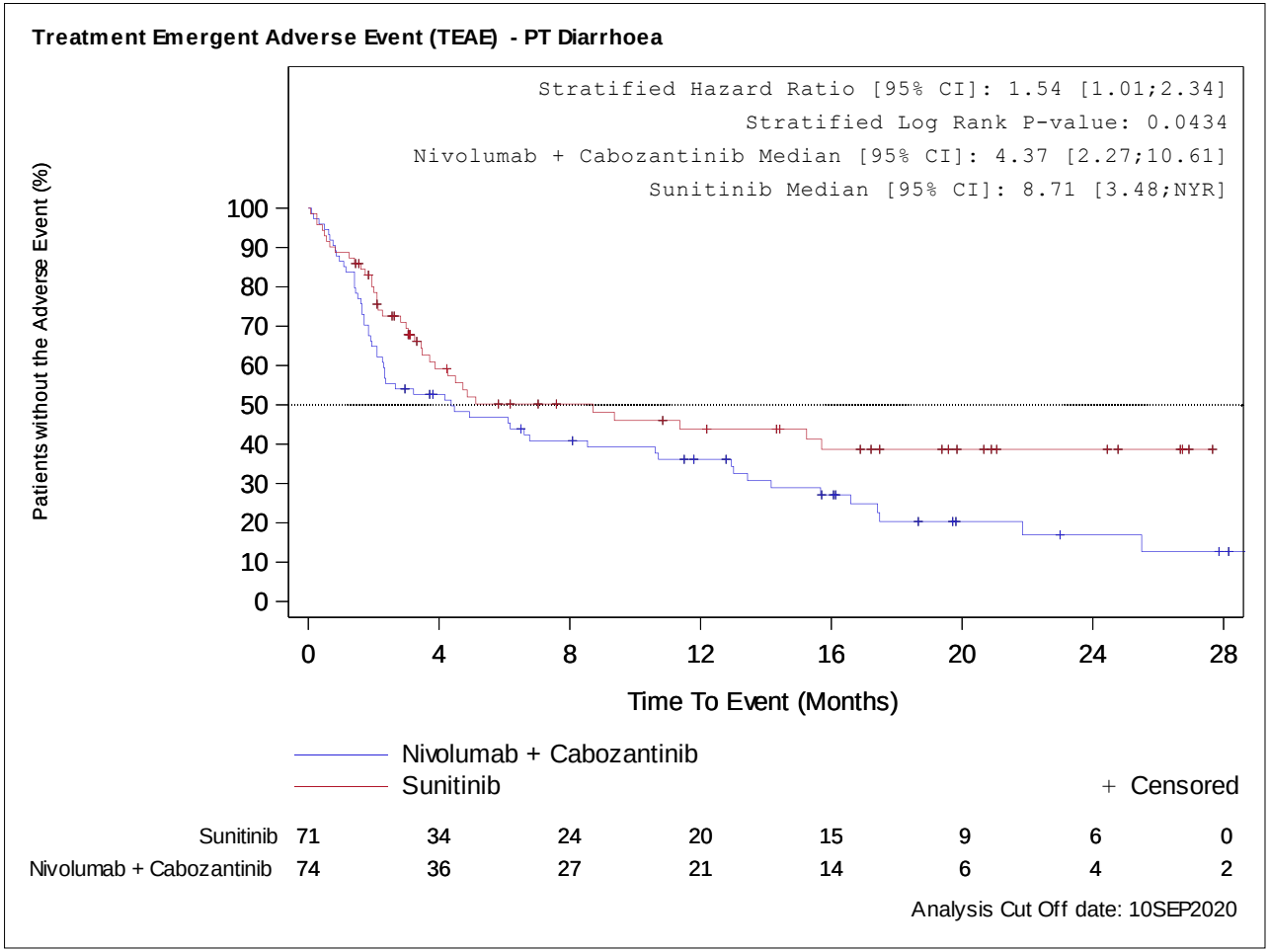
FIGURE 5.6.1: Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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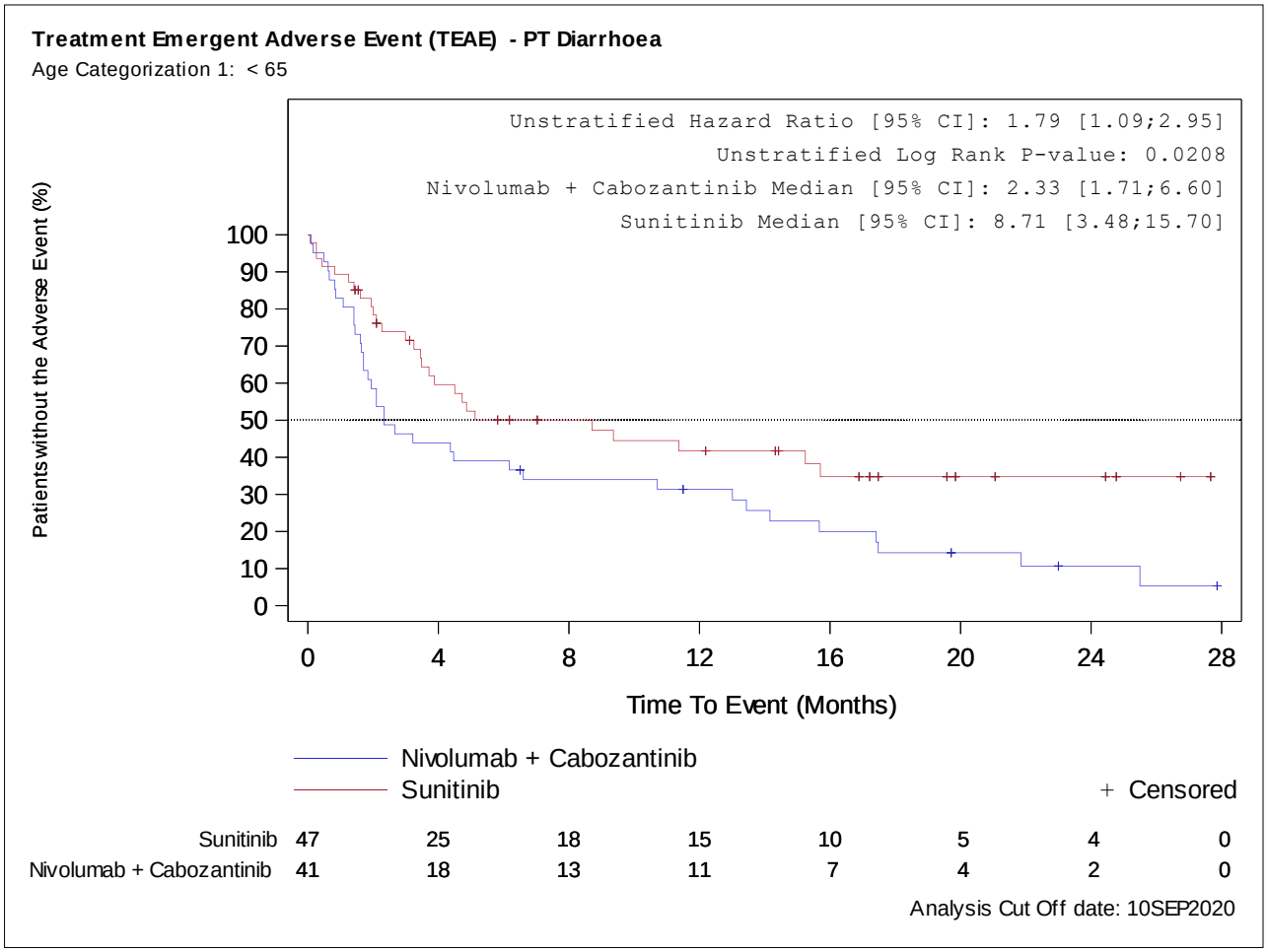
FIGURE 5.6.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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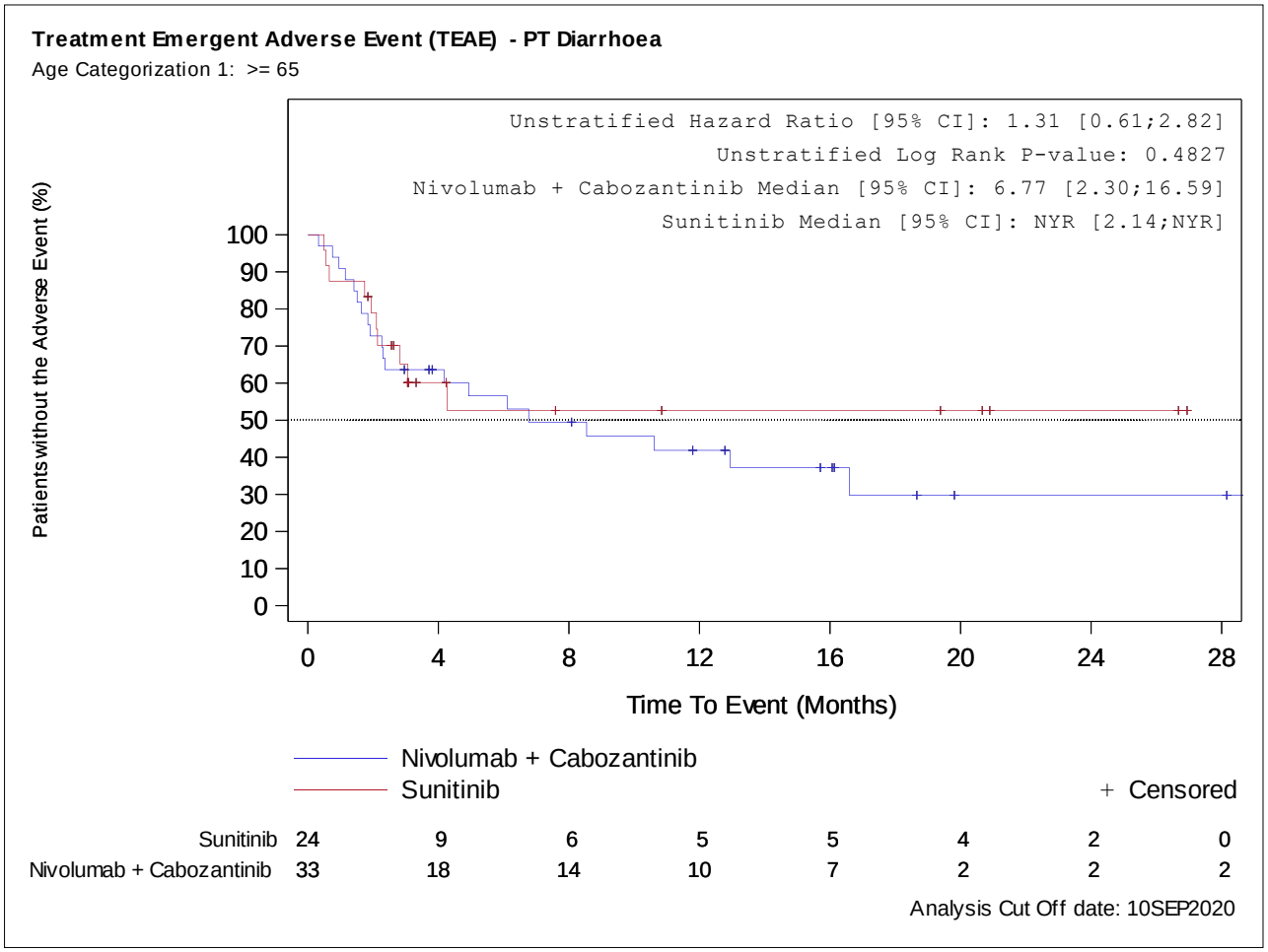
FIGURE 5.6.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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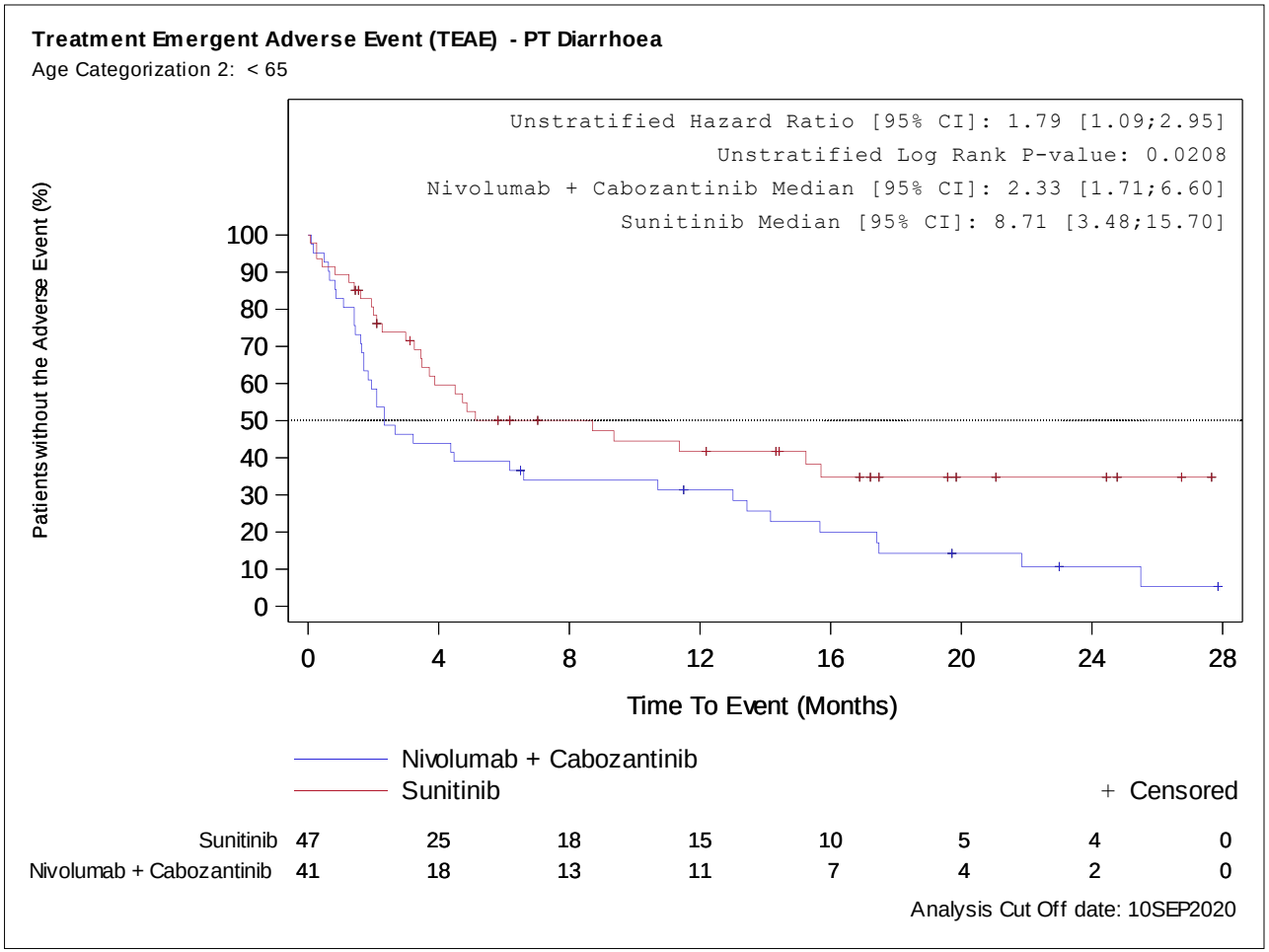
FIGURE 5.6.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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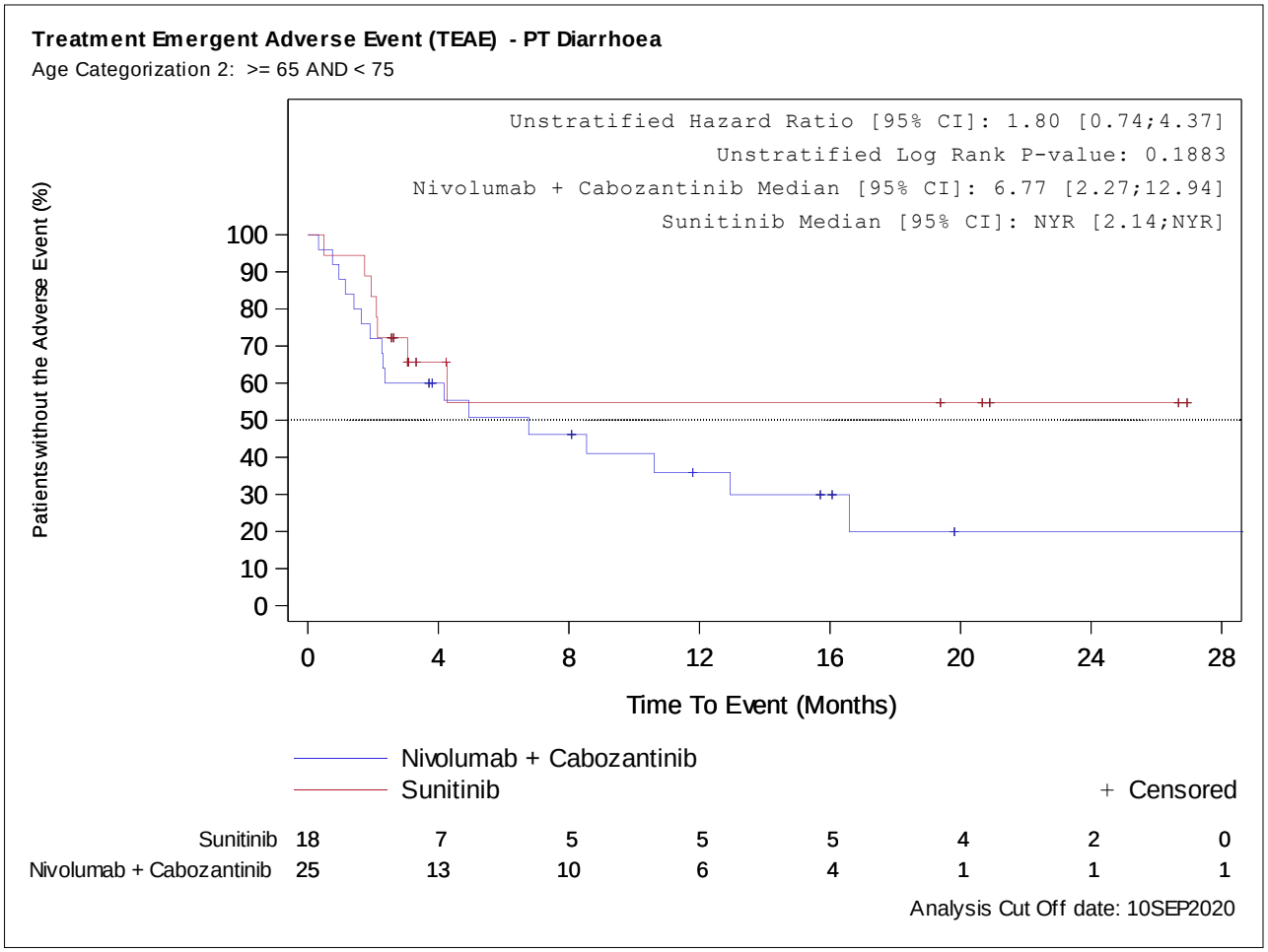
FIGURE 5.6.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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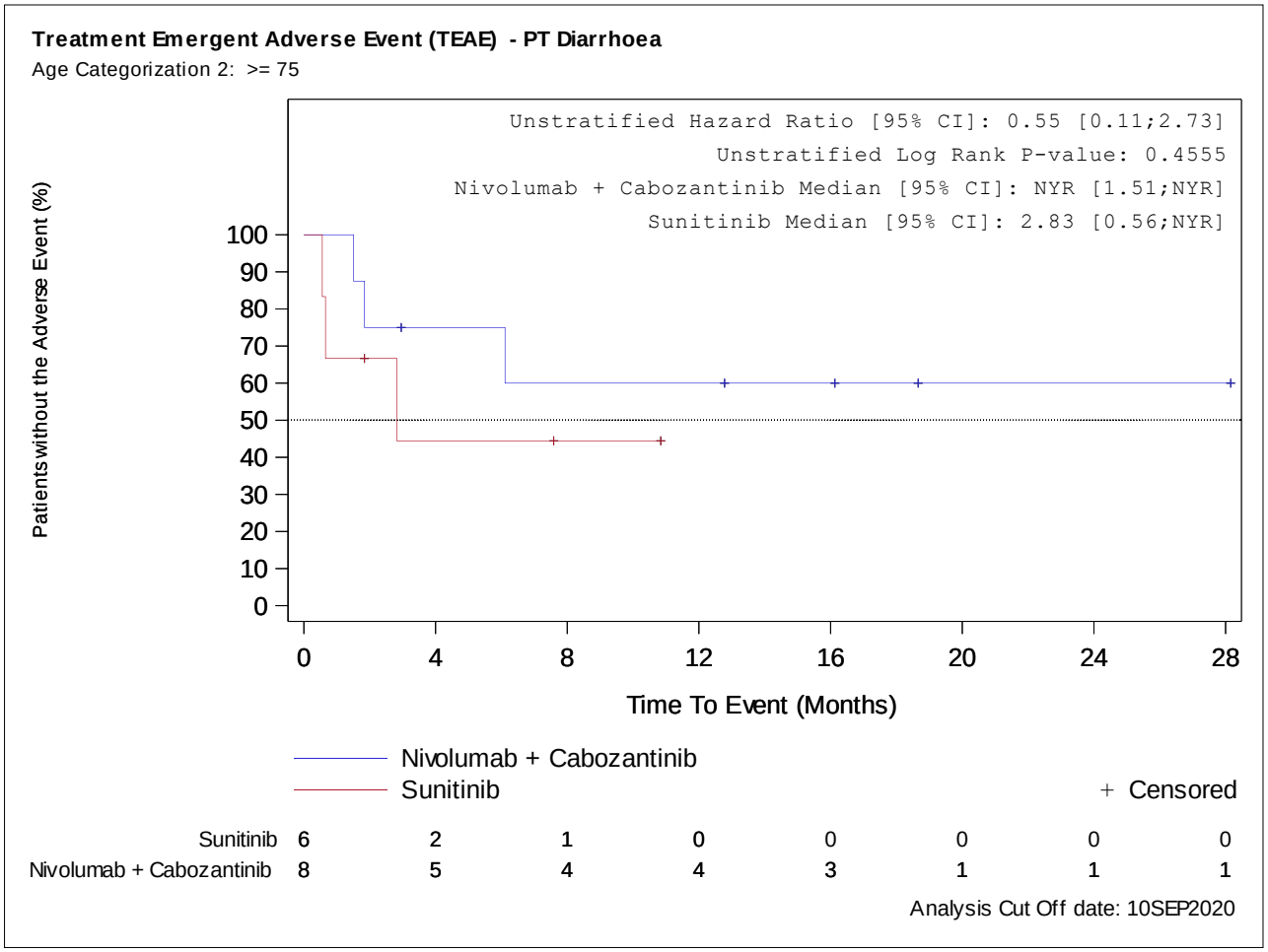
FIGURE 5.6.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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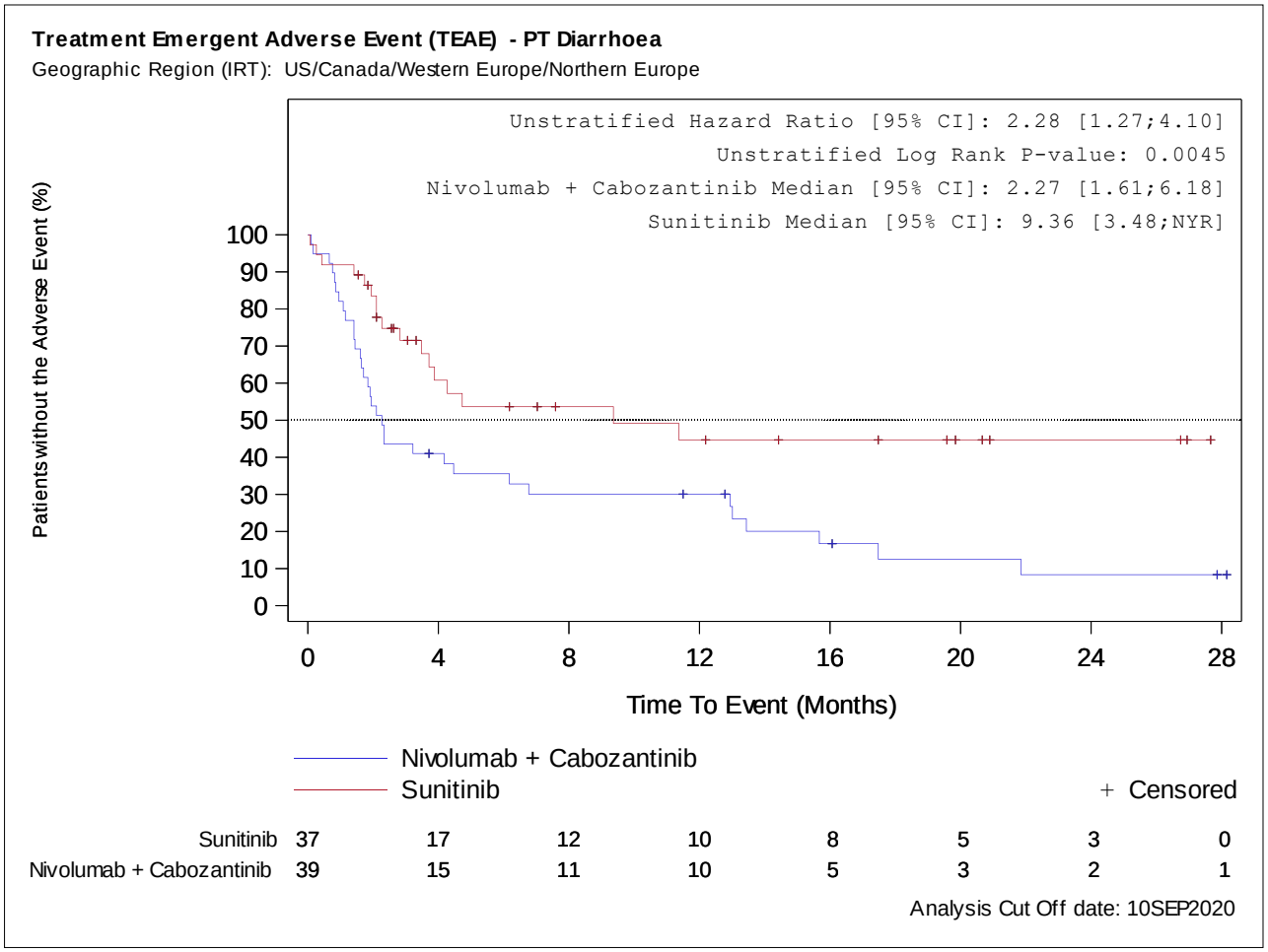
FIGURE 5.6.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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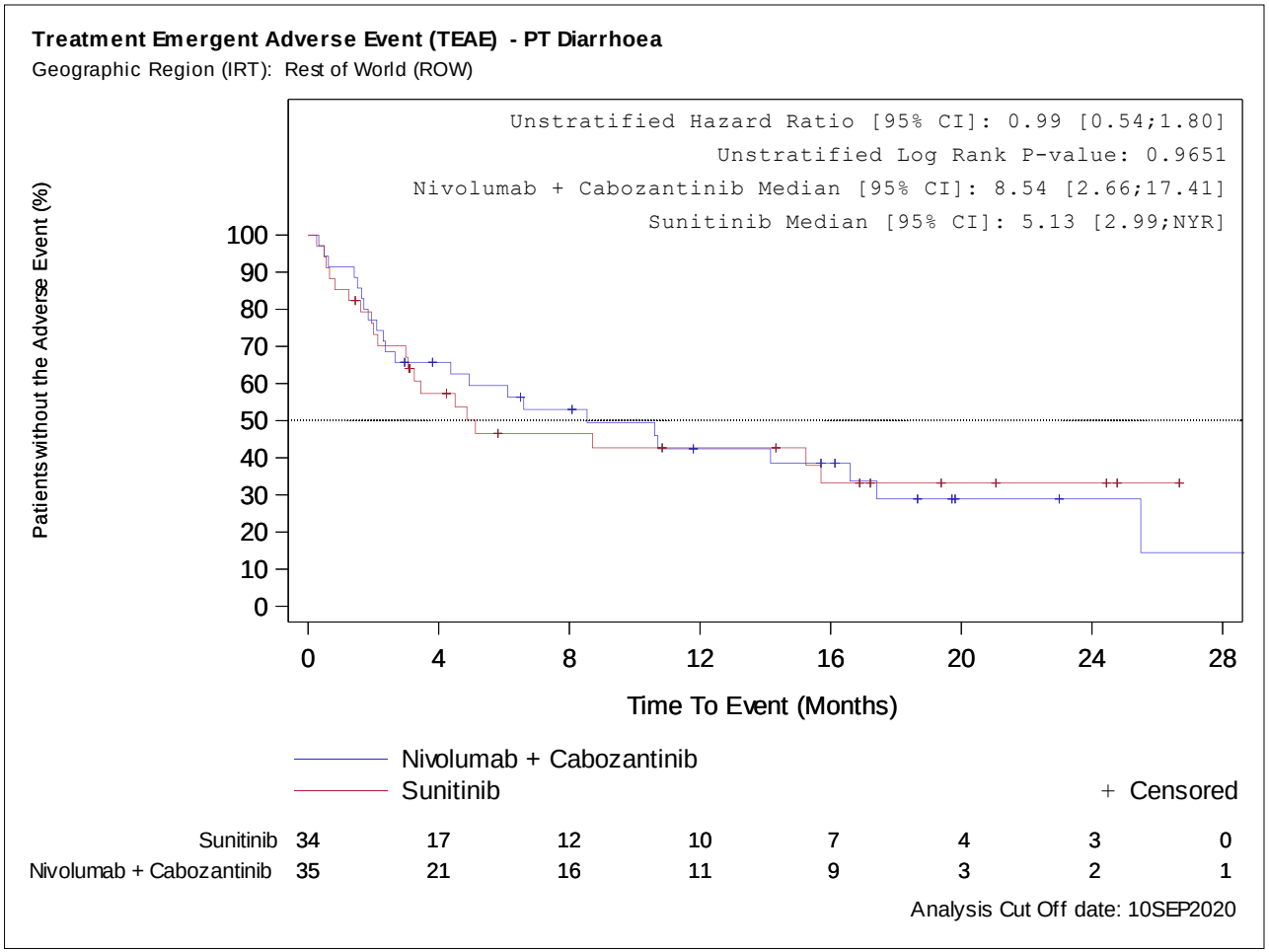
FIGURE 5.6.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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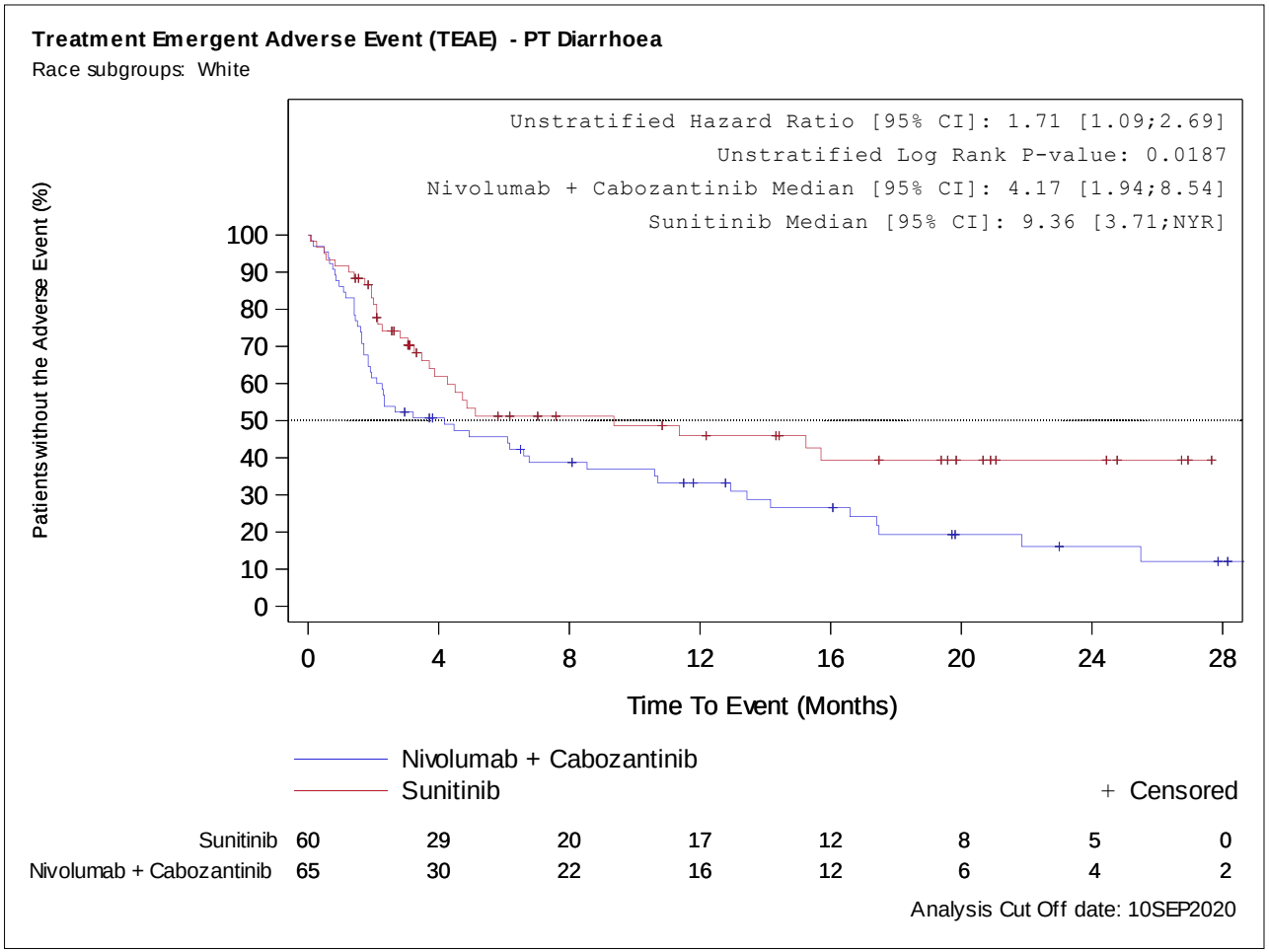
FIGURE 5.6.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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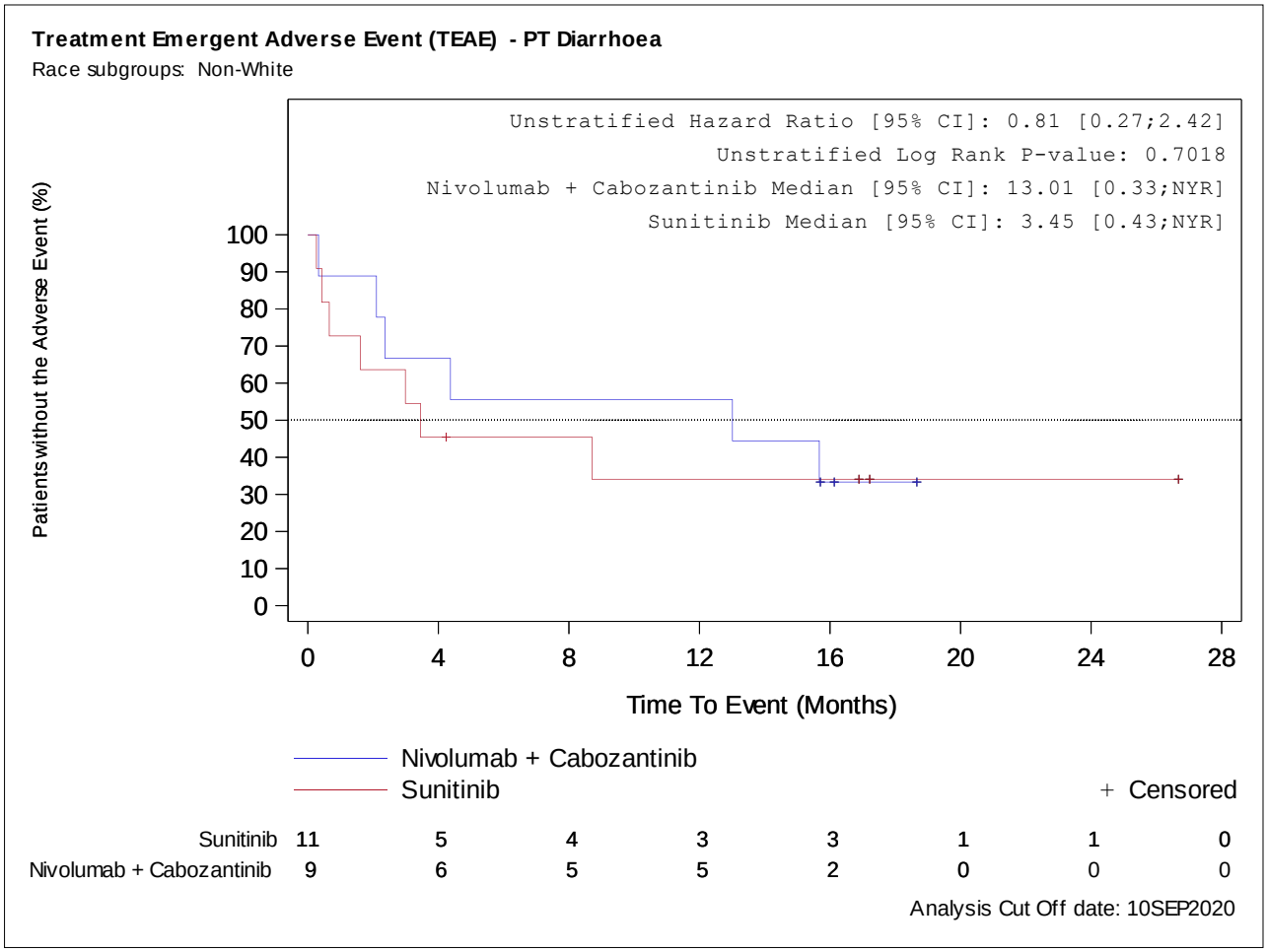
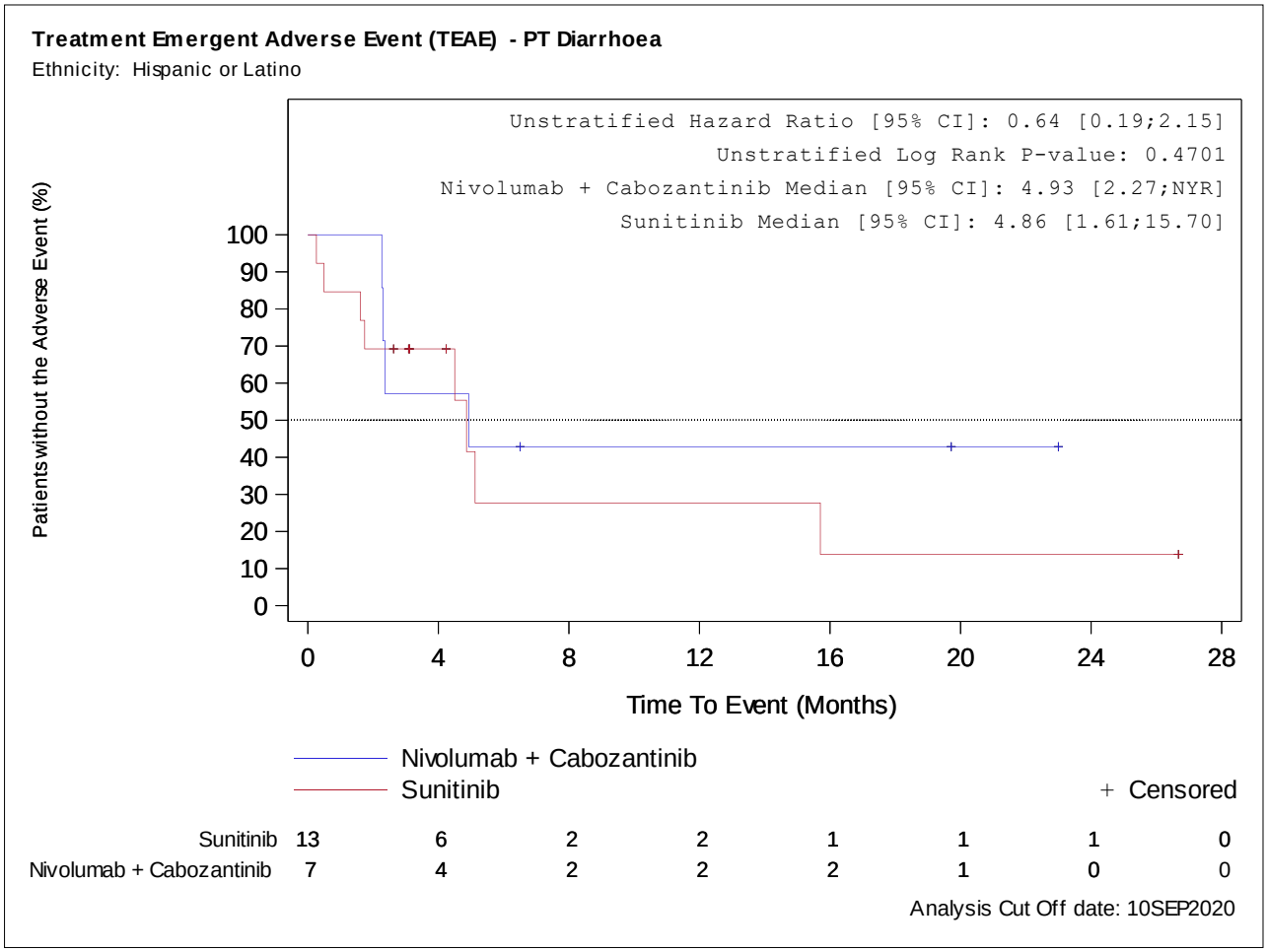
FIGURE 5.6.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



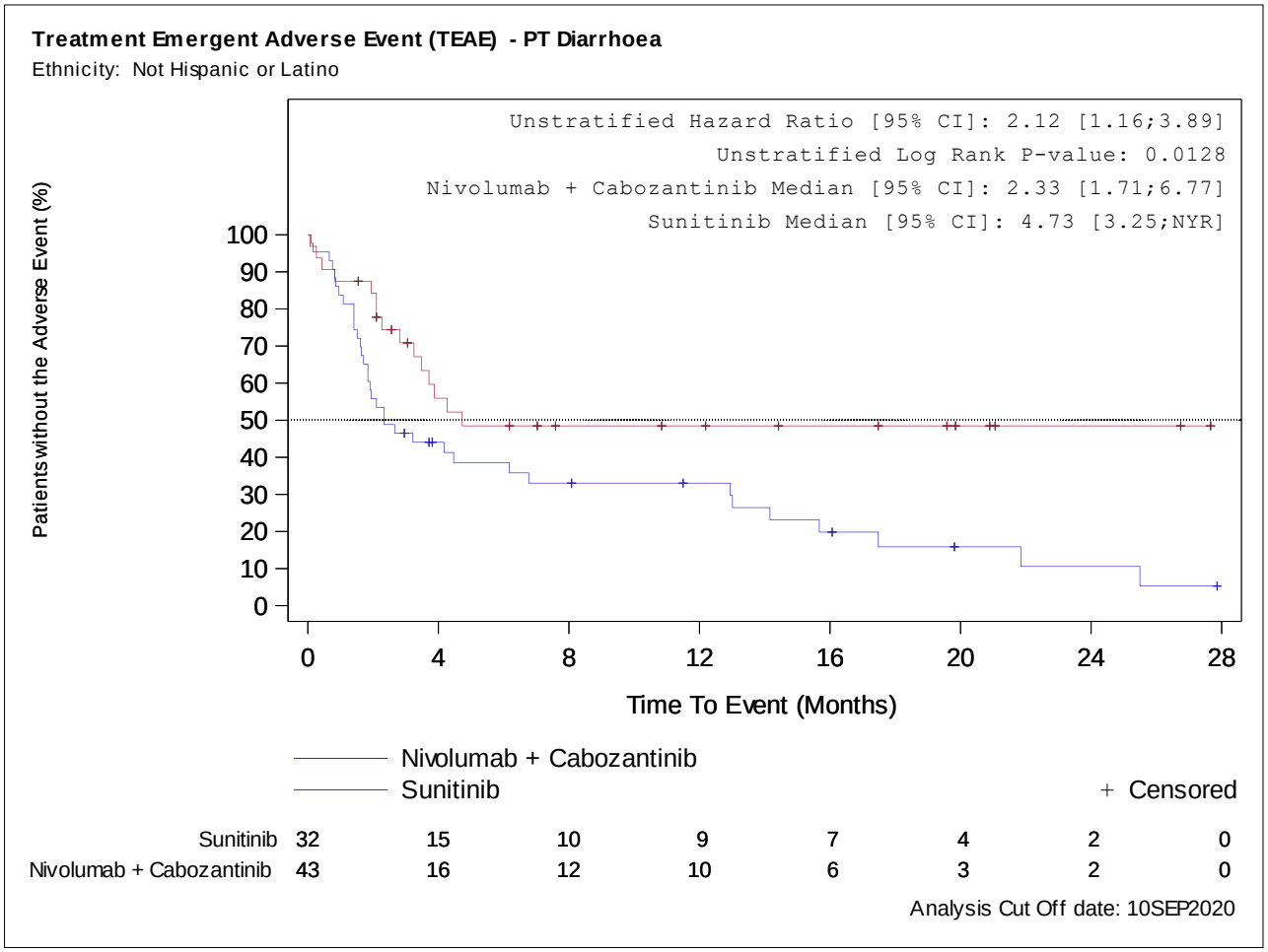

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:39:16

FIGURE 5.6.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



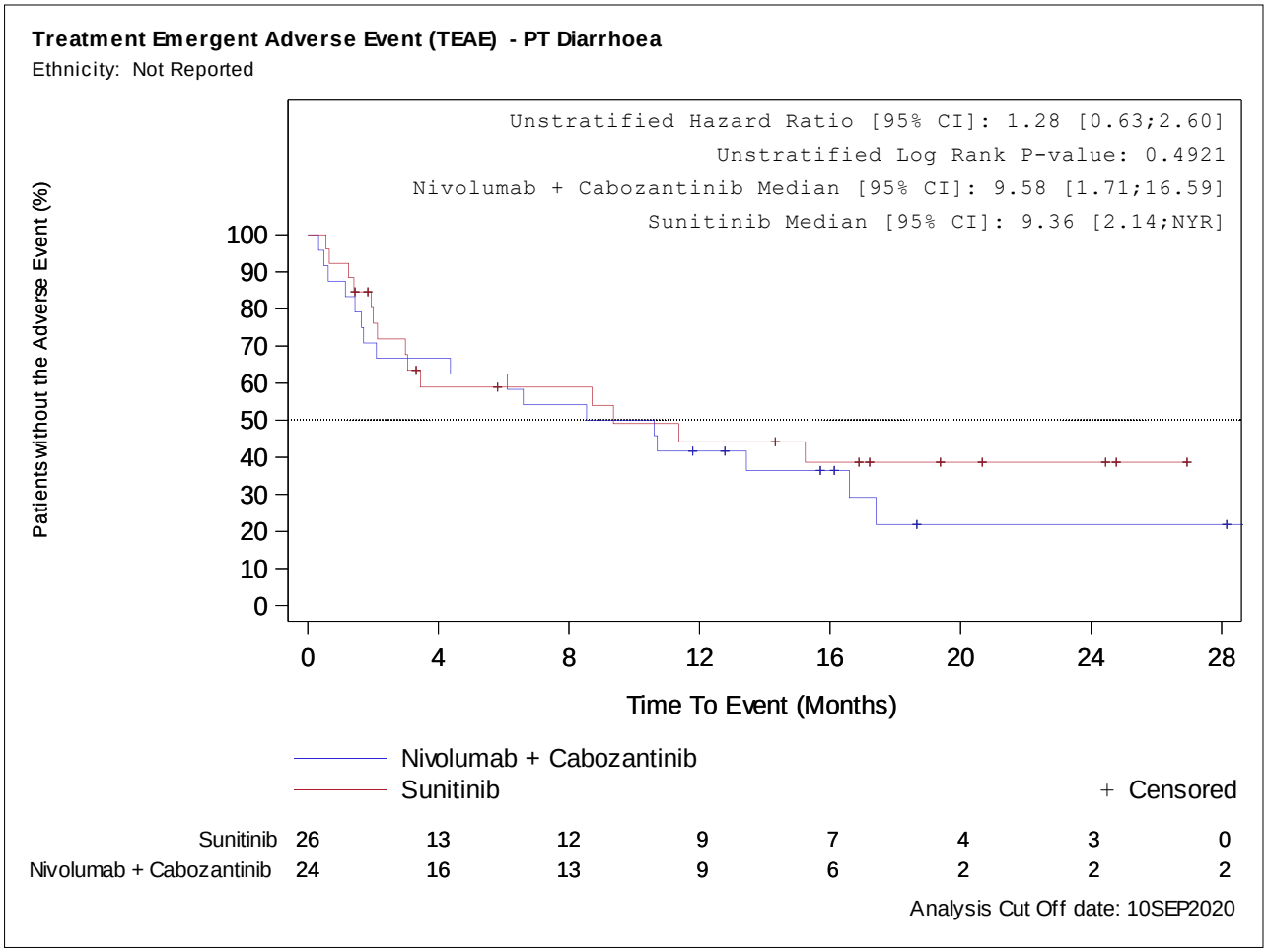

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:39:22

FIGURE 5.6.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:39:28

FIGURE 5.6.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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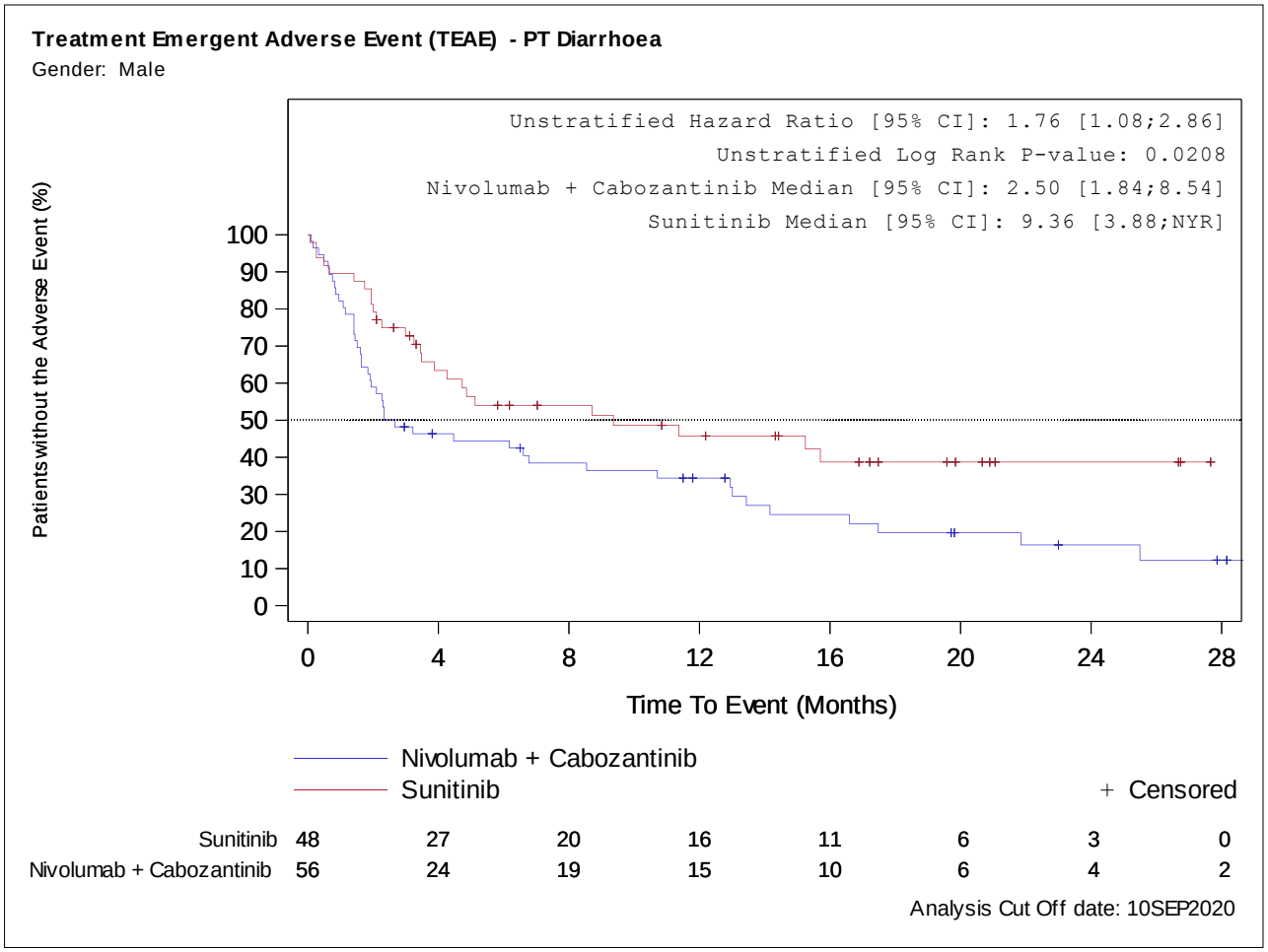
FIGURE 5.6.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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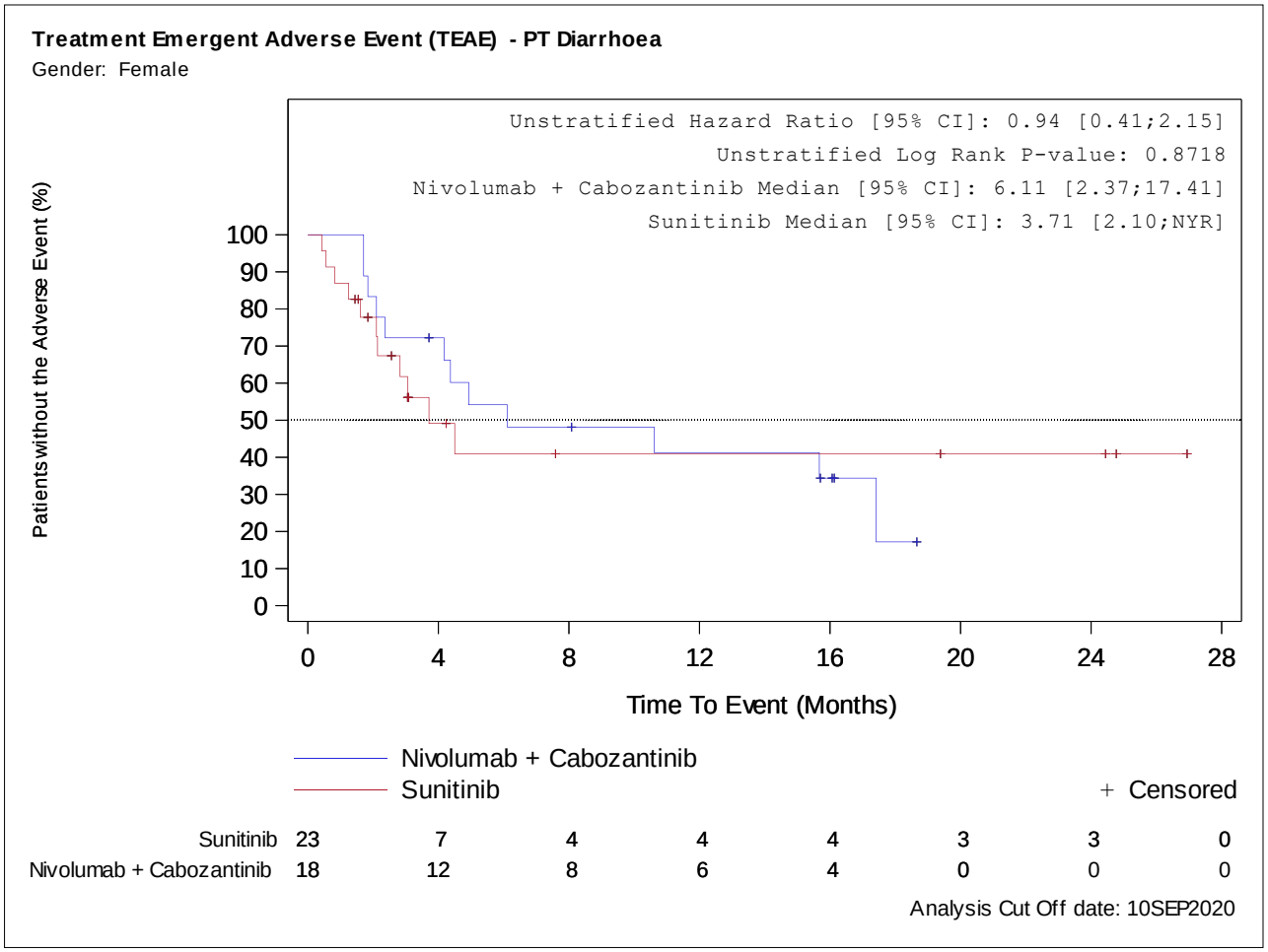
FIGURE 5.6.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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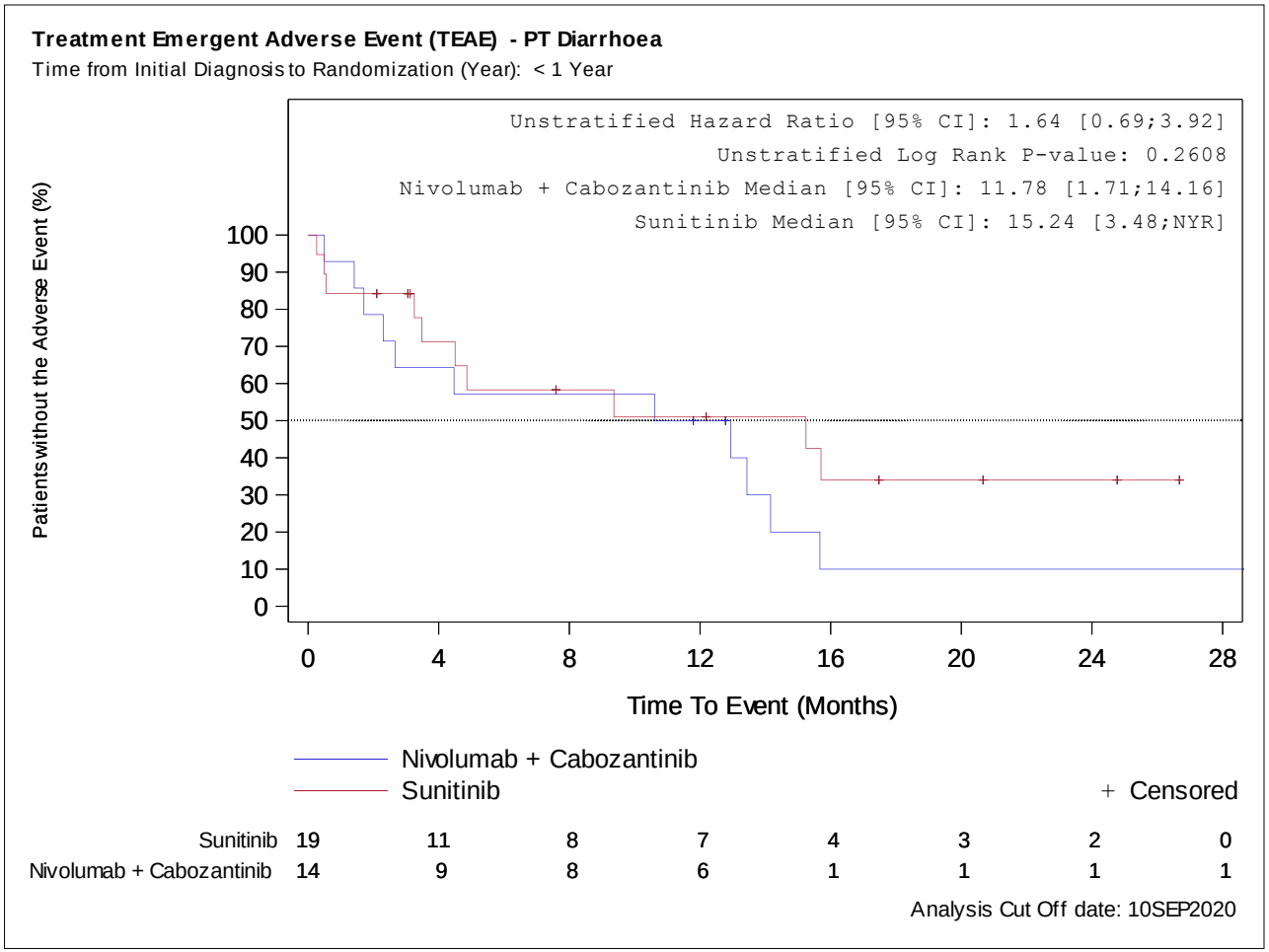
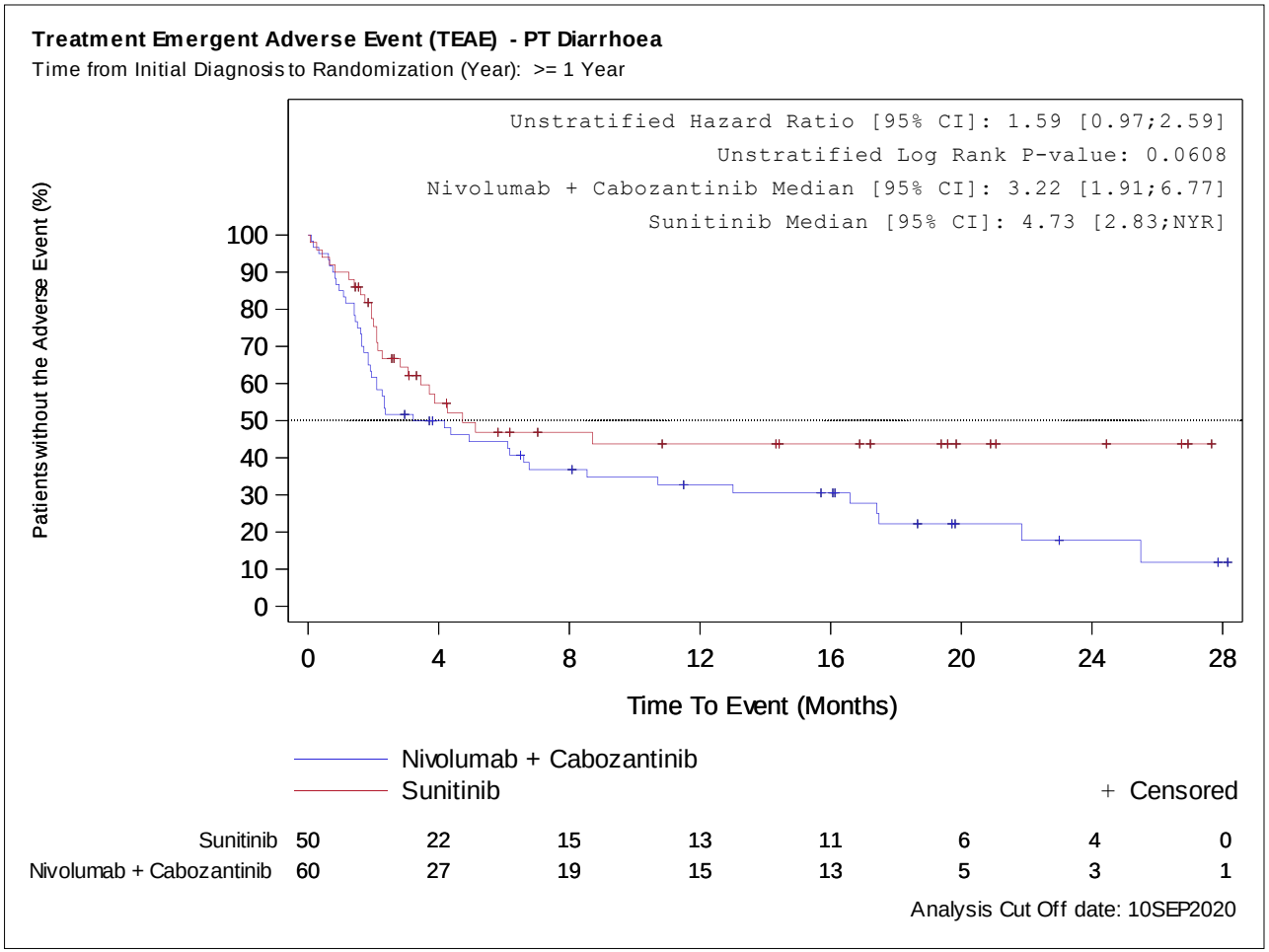
FIGURE 5.6.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



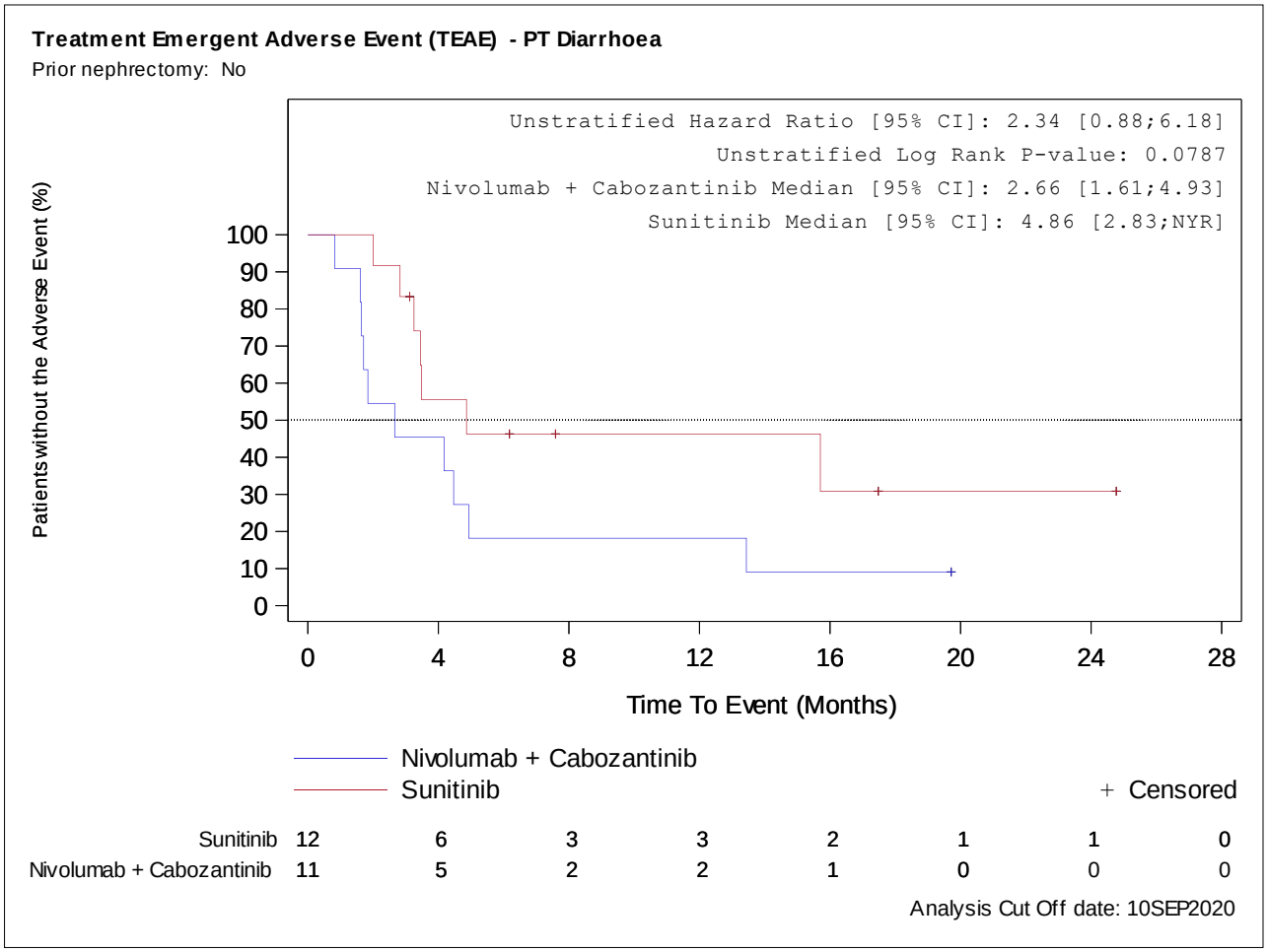

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:40:02

FIGURE 5.6.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:40:08

FIGURE 5.6.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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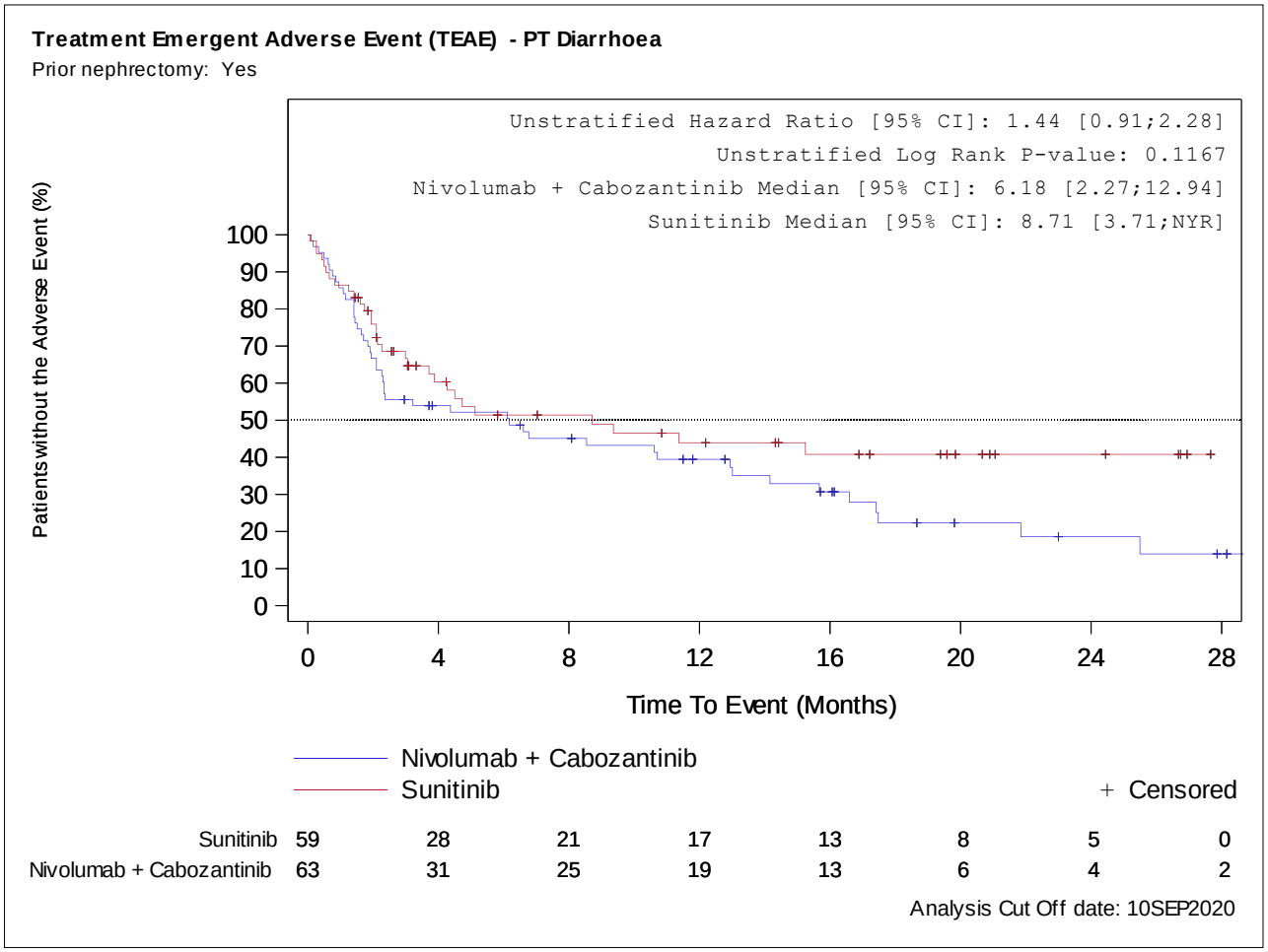
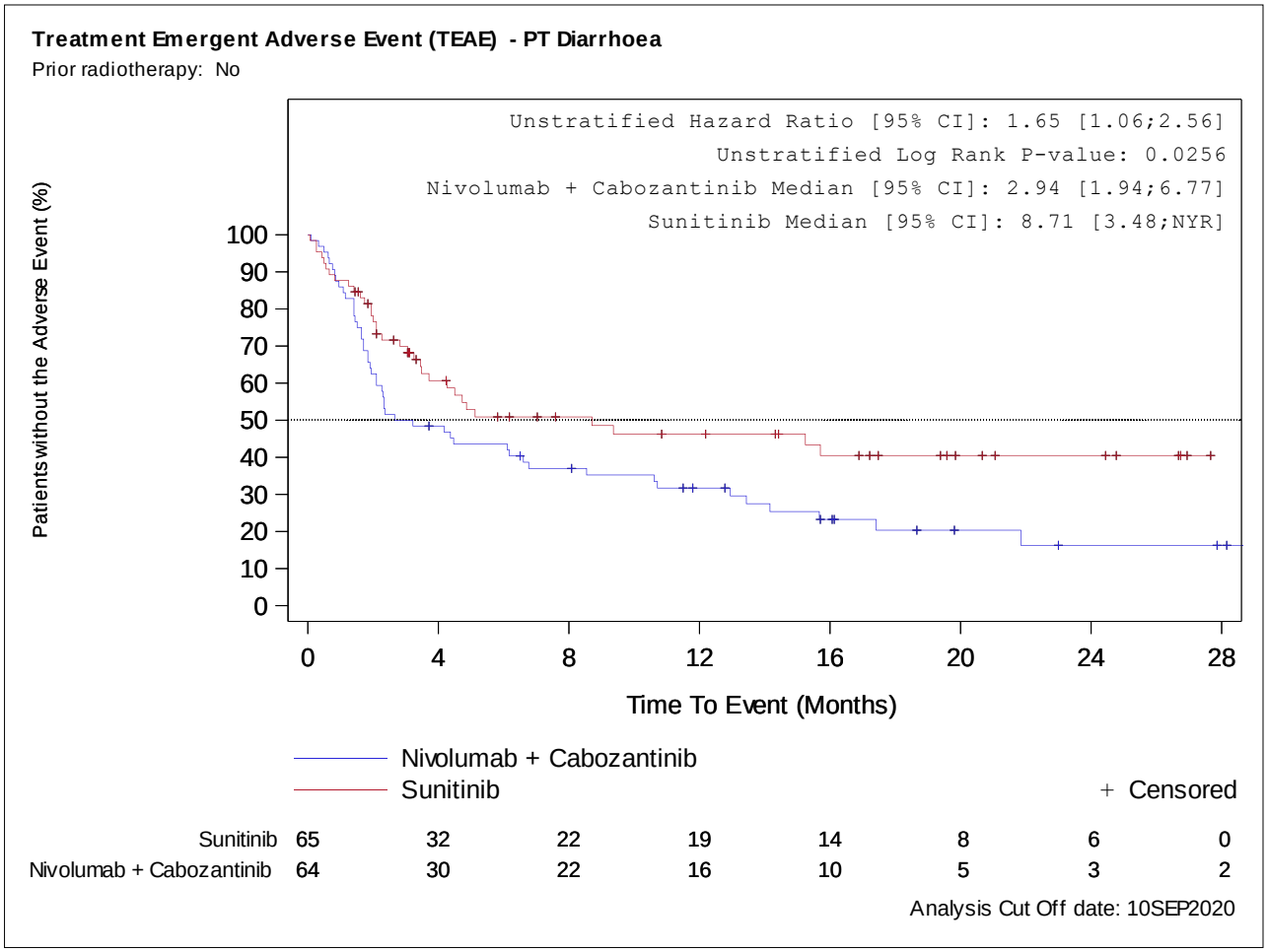
FIGURE 5.6.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



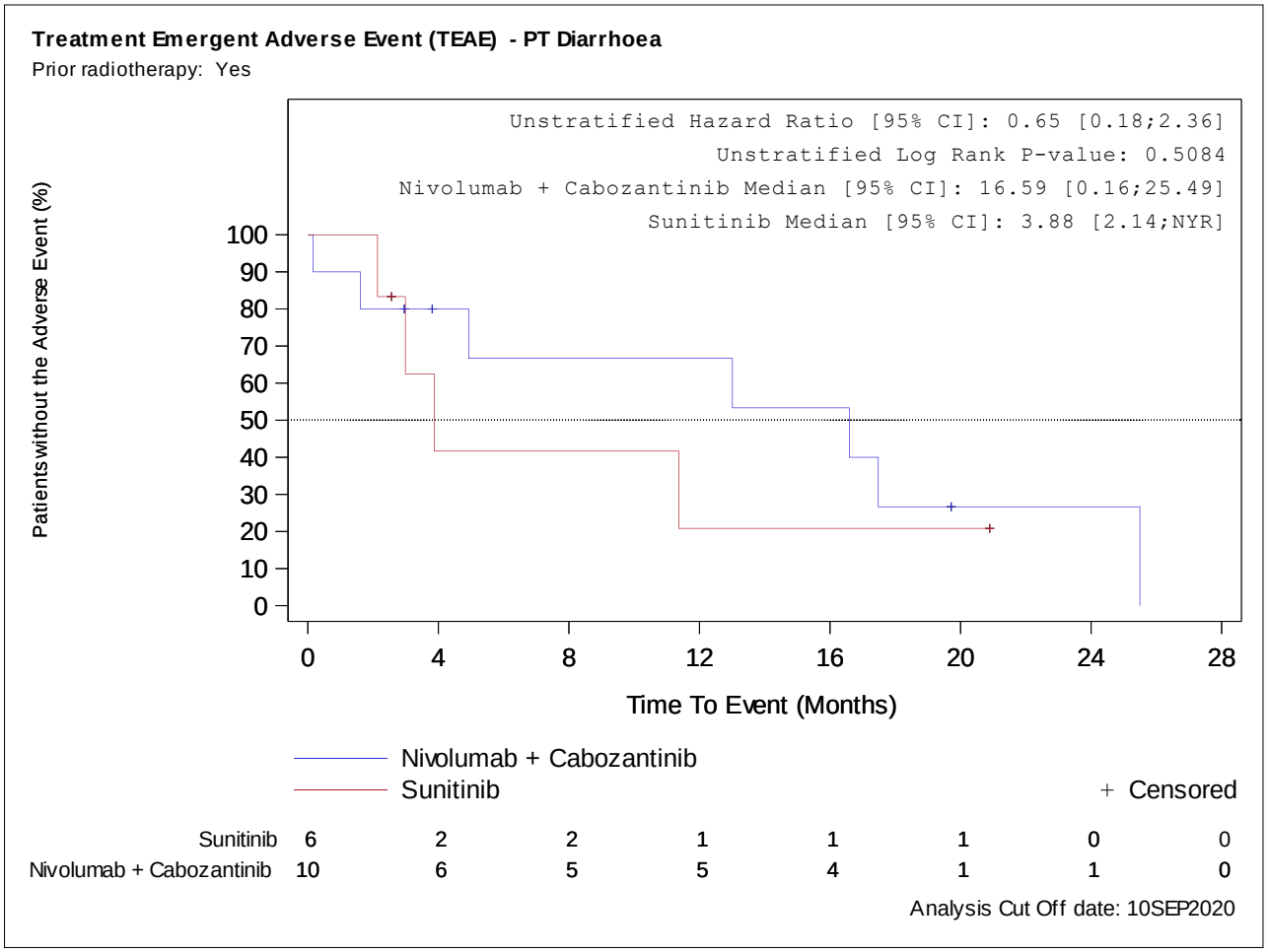

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:41:04

FIGURE 5.6.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



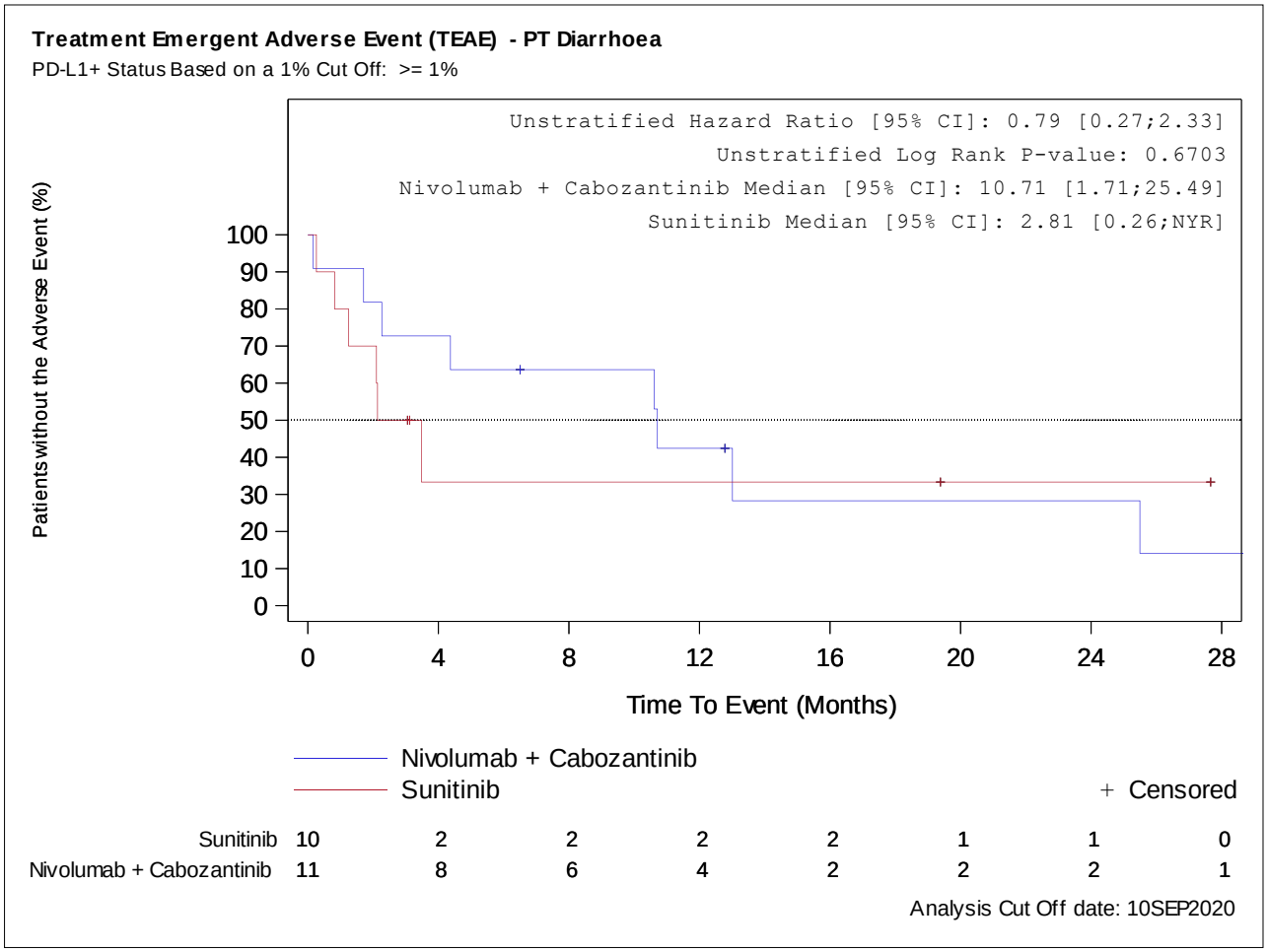

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:41:10

FIGURE 5.6.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



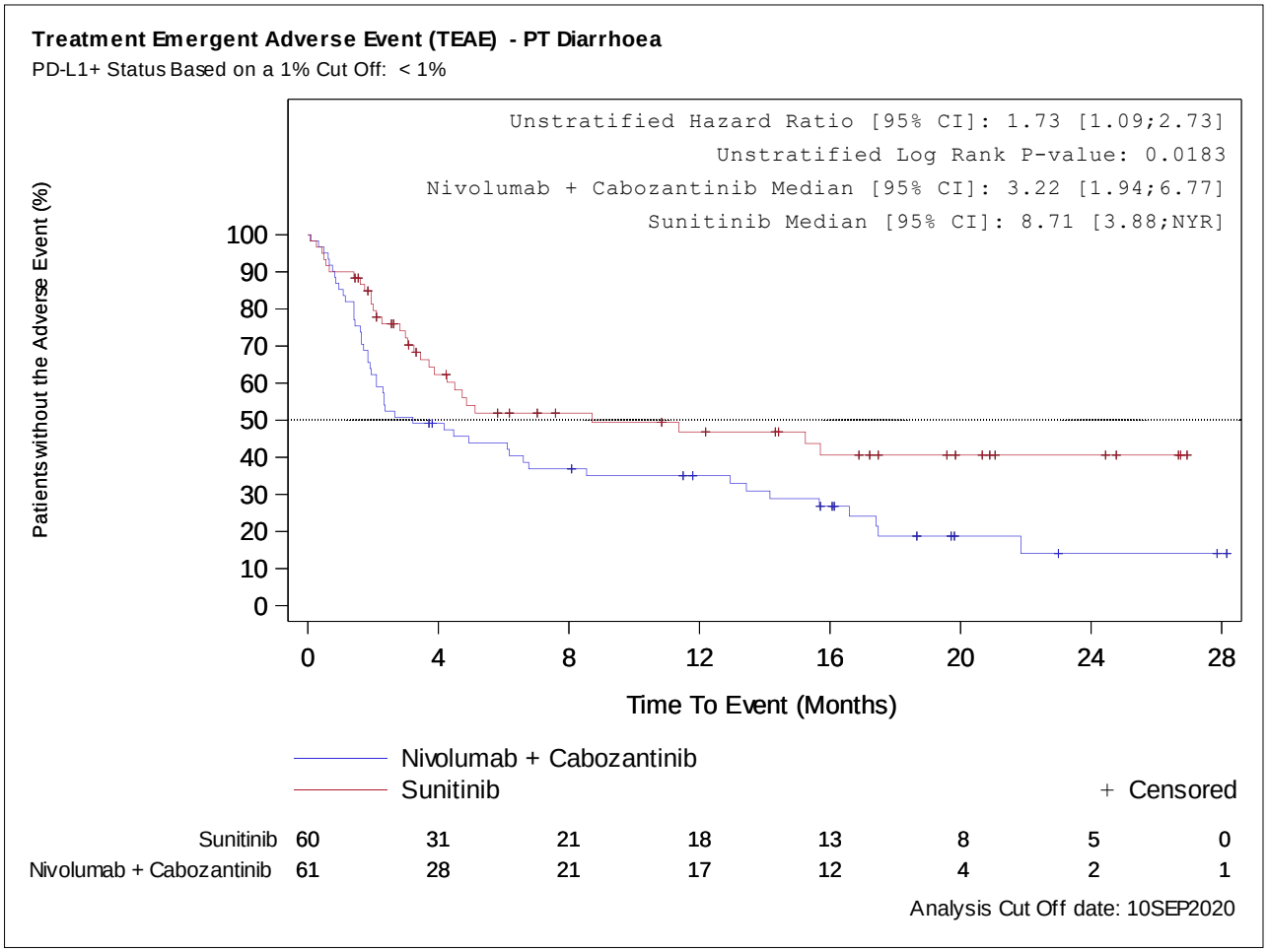

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:41:15

FIGURE 5.6.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



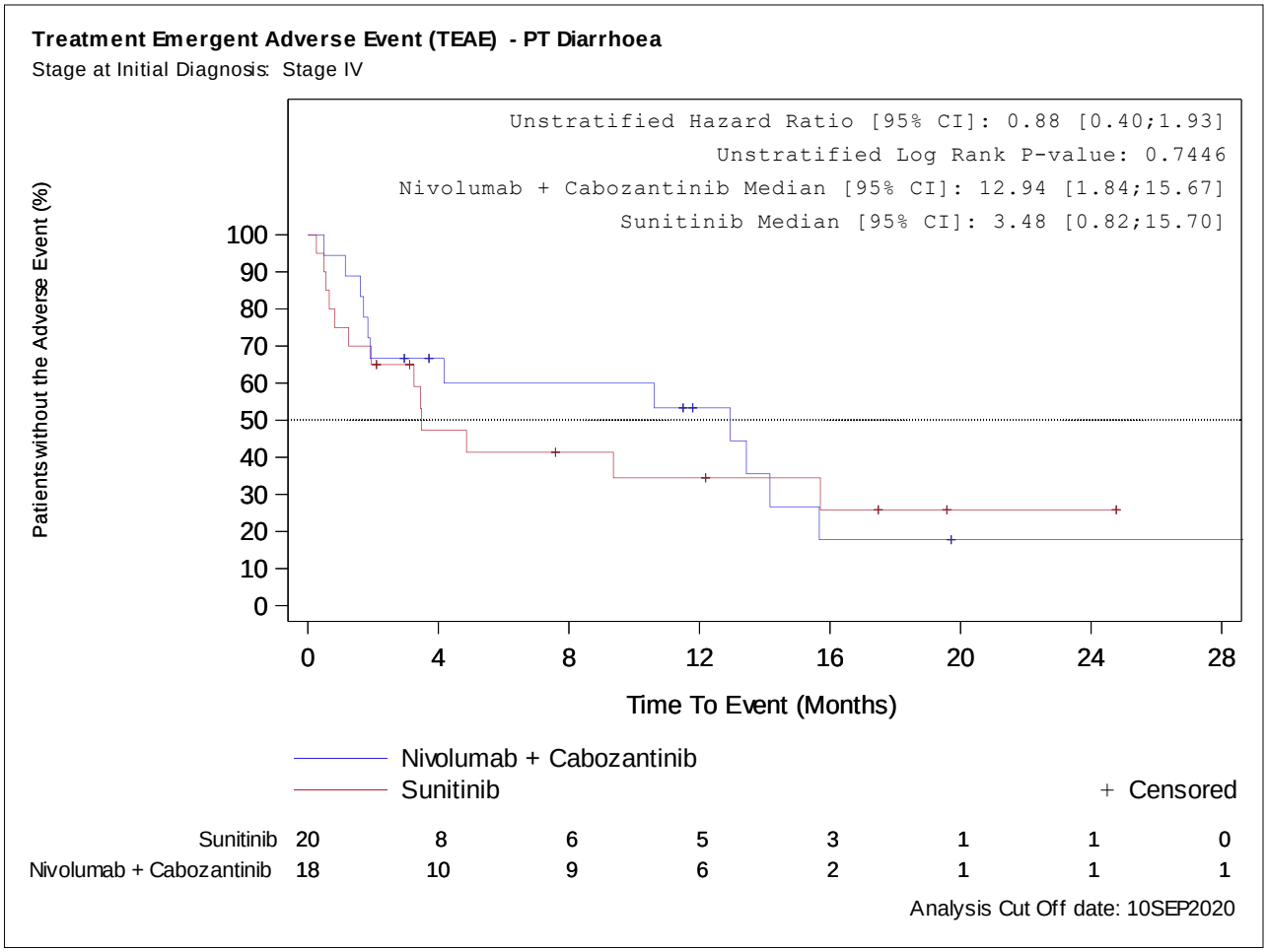

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:41:21

FIGURE 5.6.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



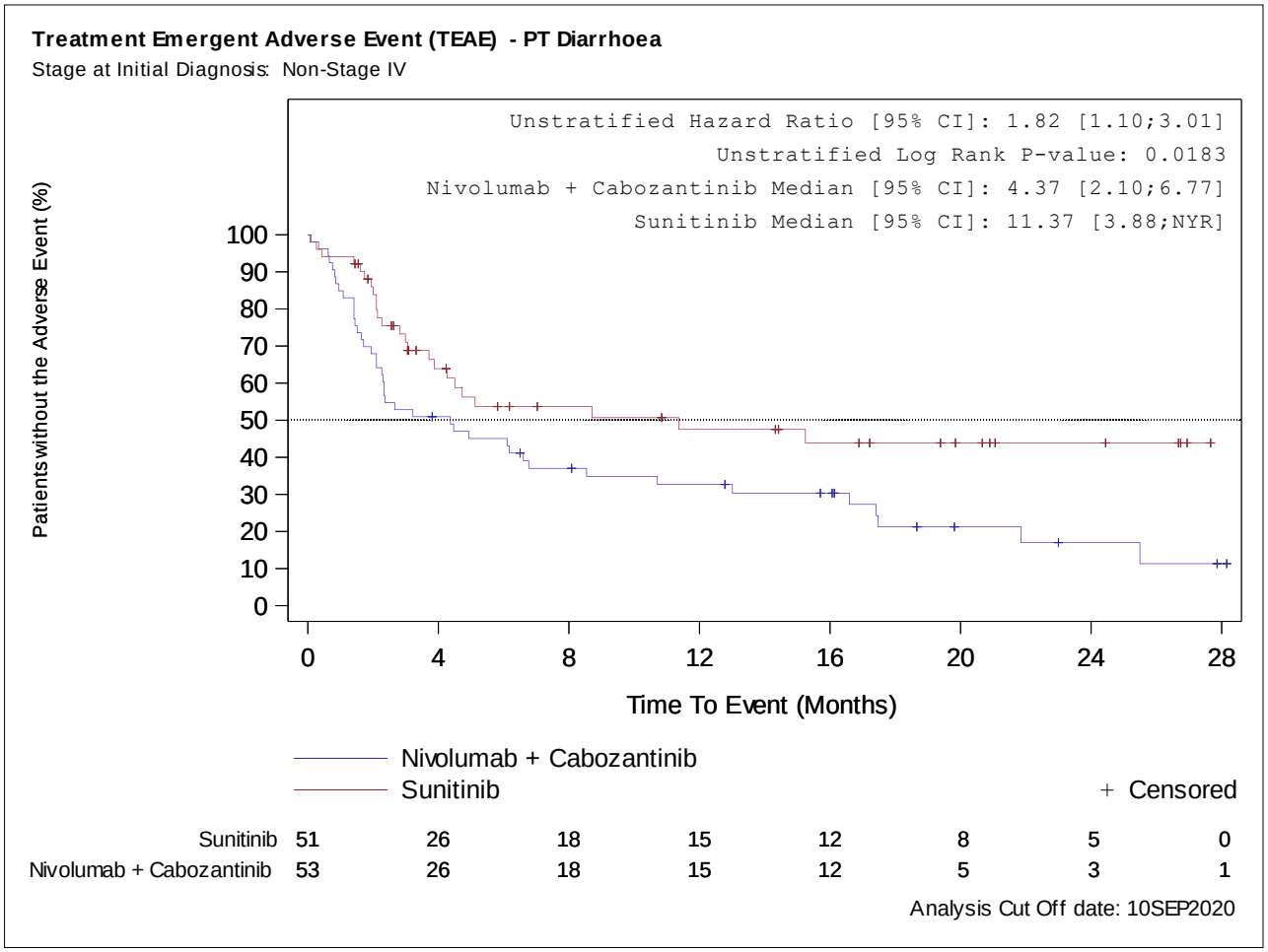

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:41:27

FIGURE 5.6.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



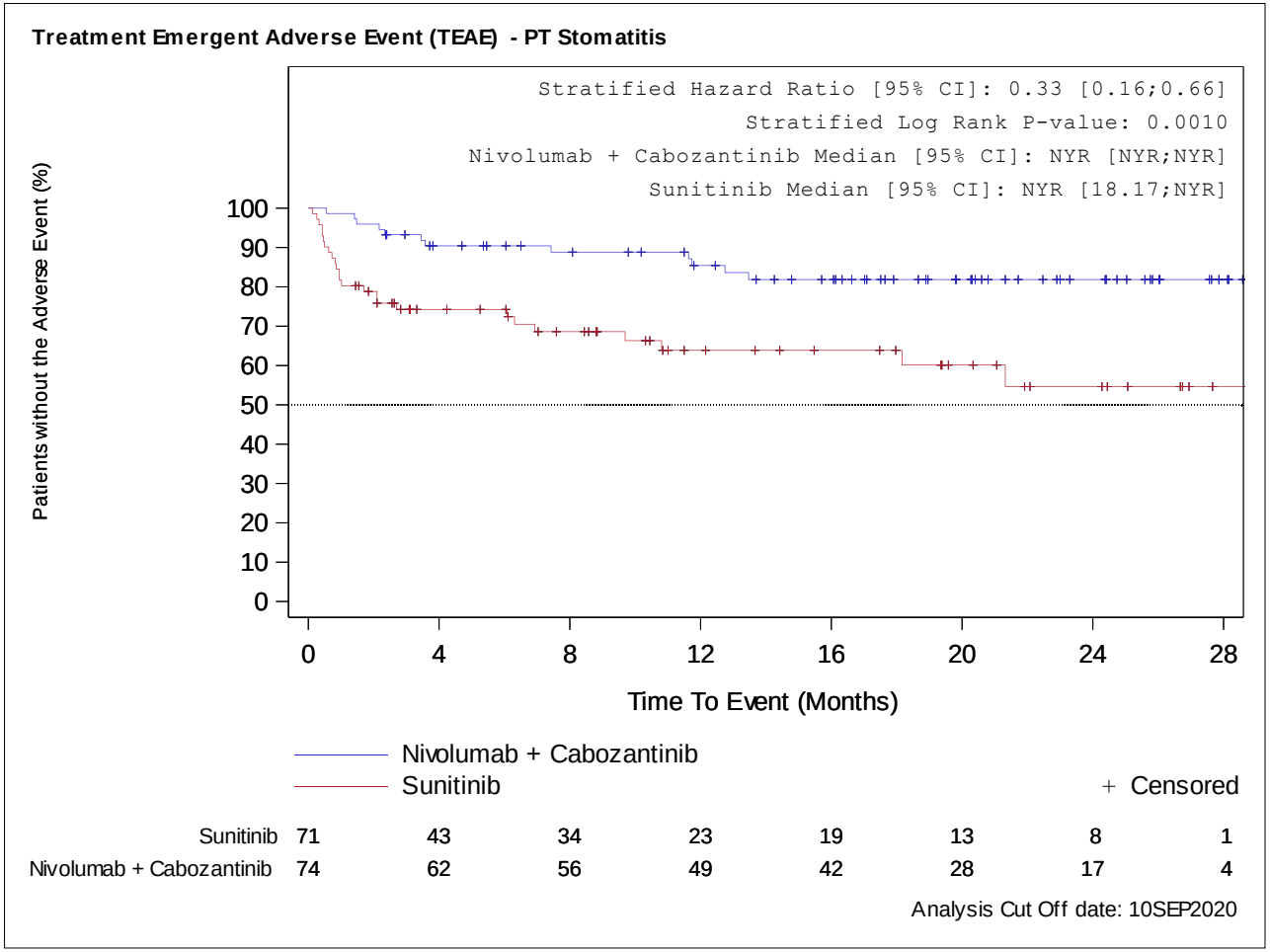

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:41:55

FIGURE 5.6.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



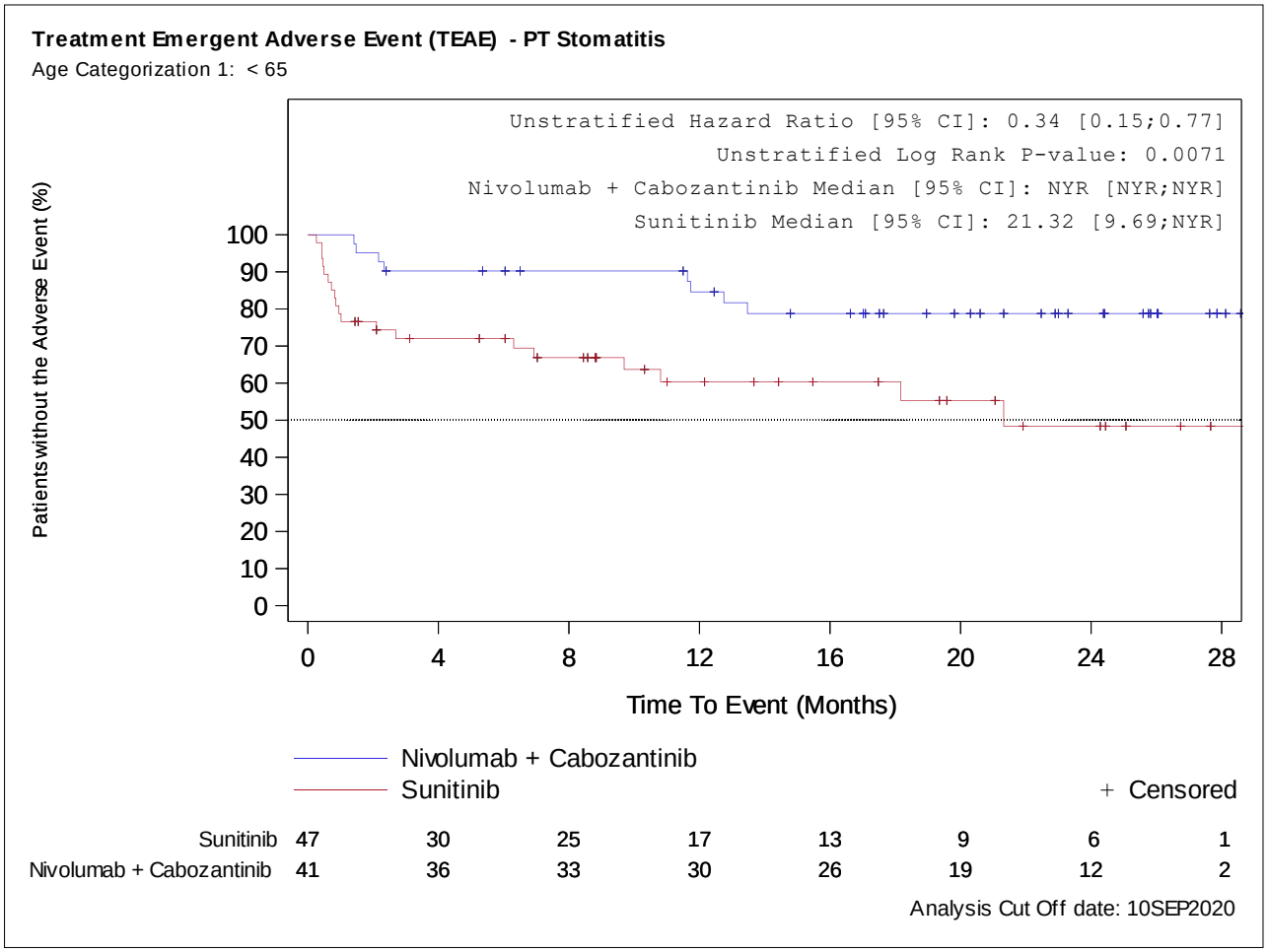

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:42:01

FIGURE 5.7.1: Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



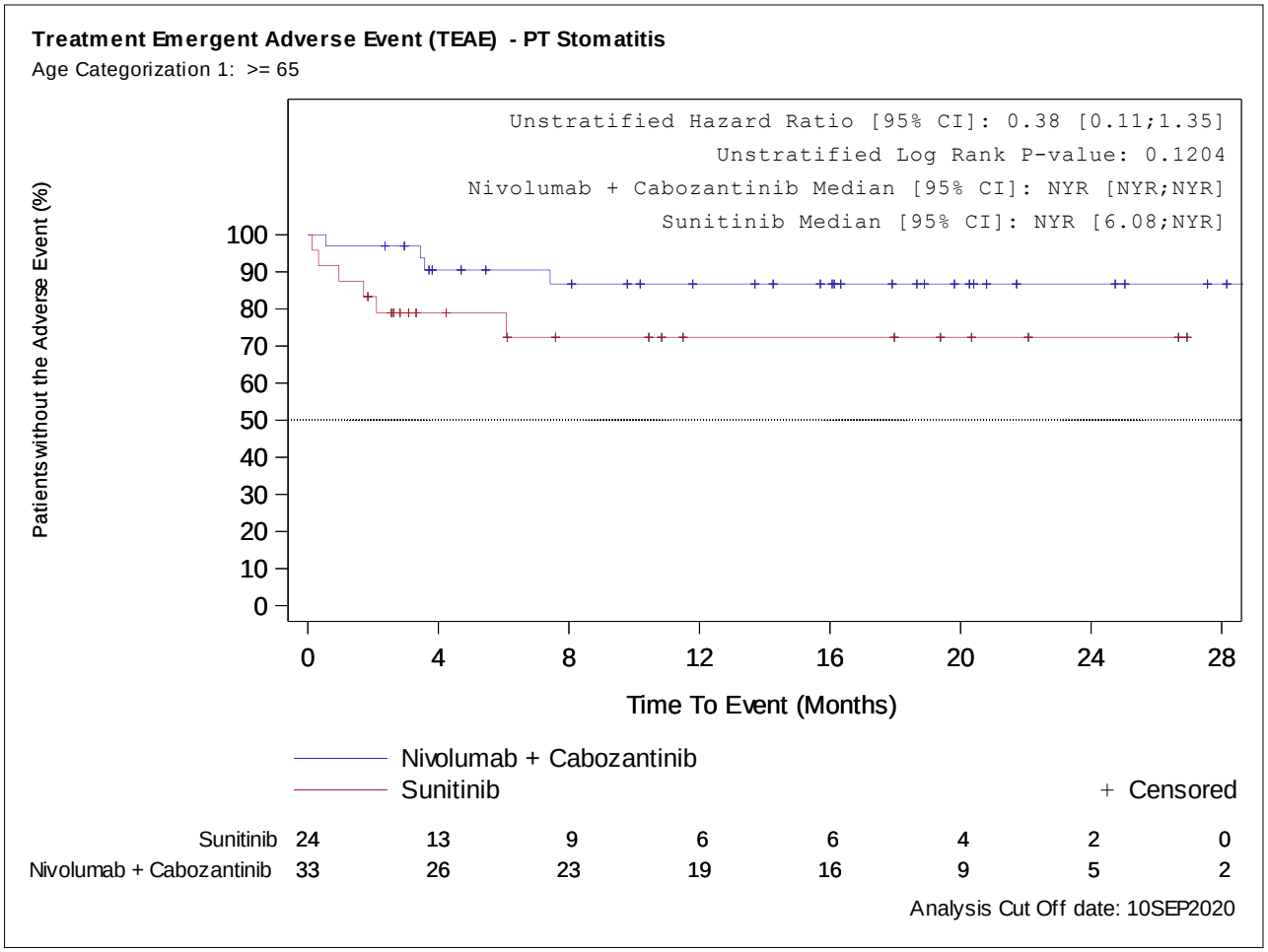

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:45:27

FIGURE 5.7.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:45:31

FIGURE 5.7.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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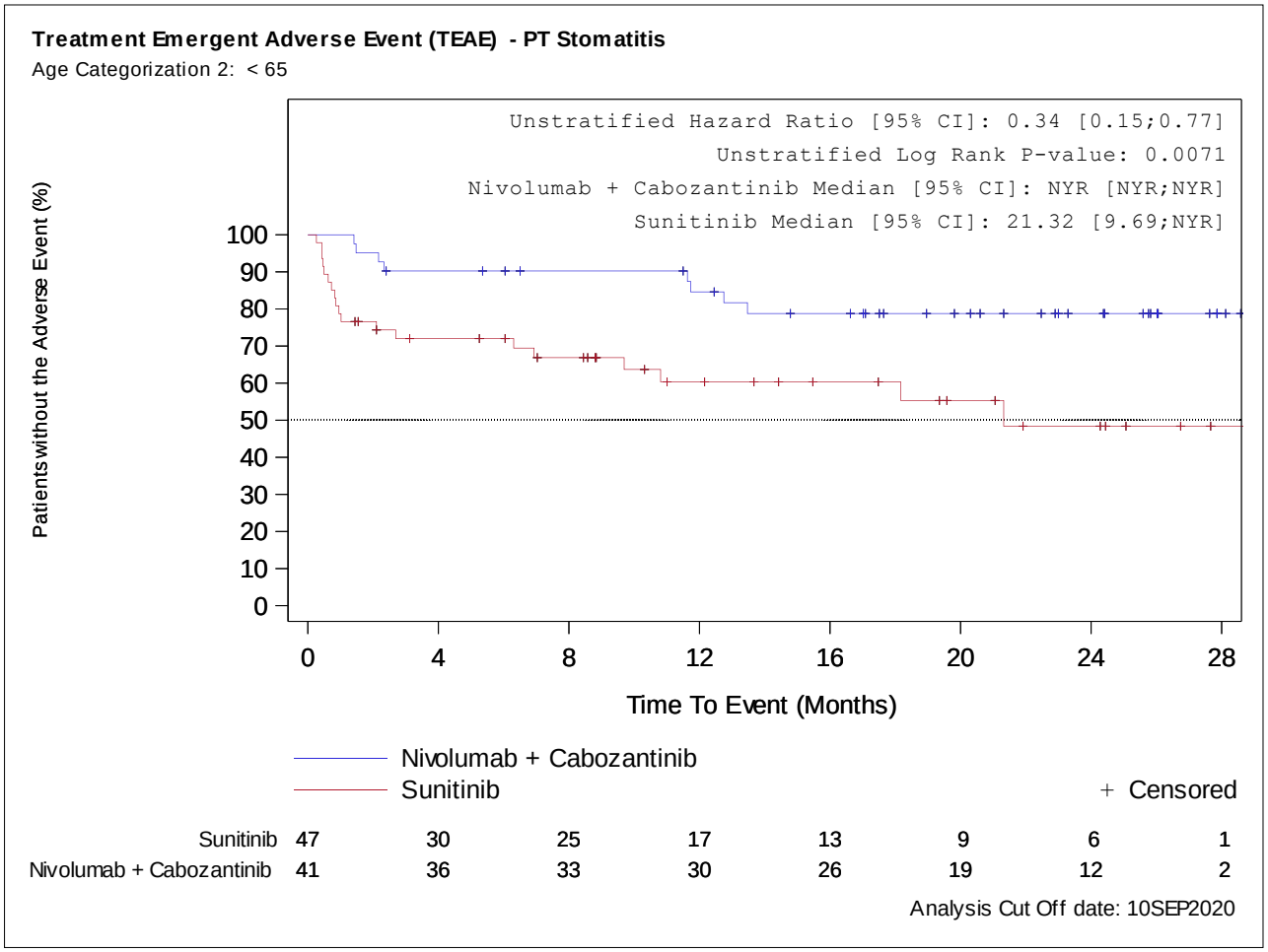
FIGURE 5.7.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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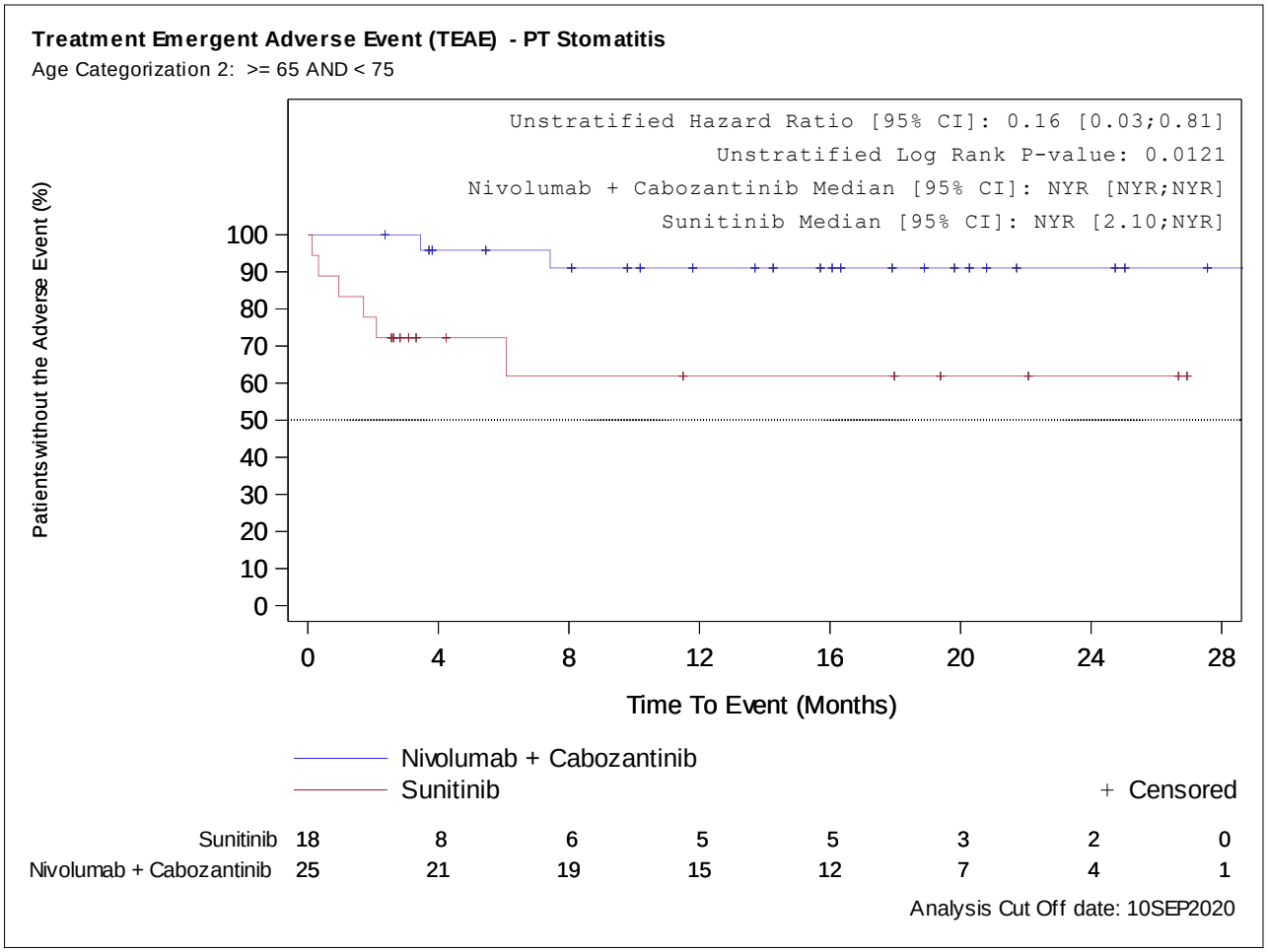
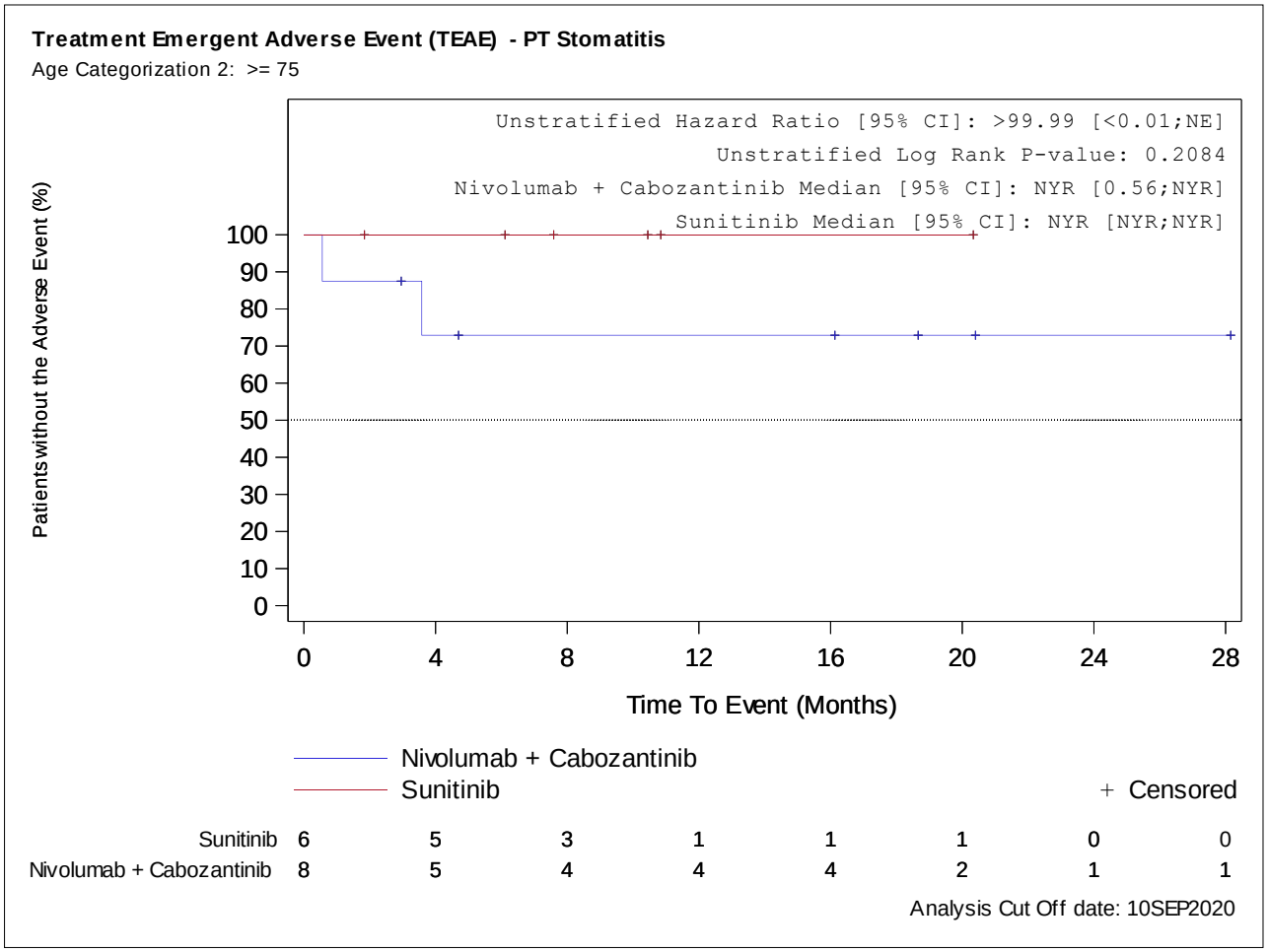
FIGURE 5.7.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



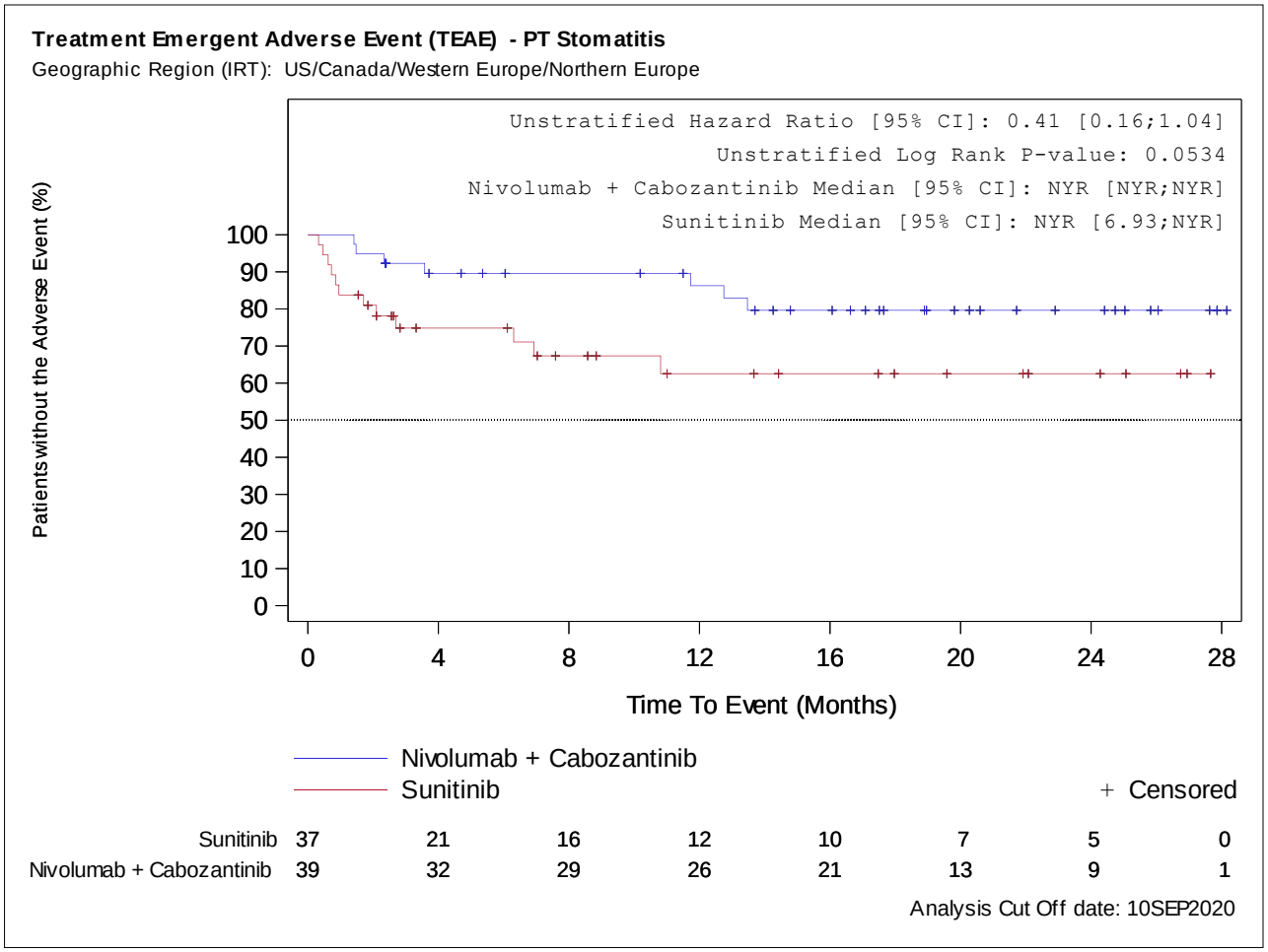

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:45:50

FIGURE 5.7.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



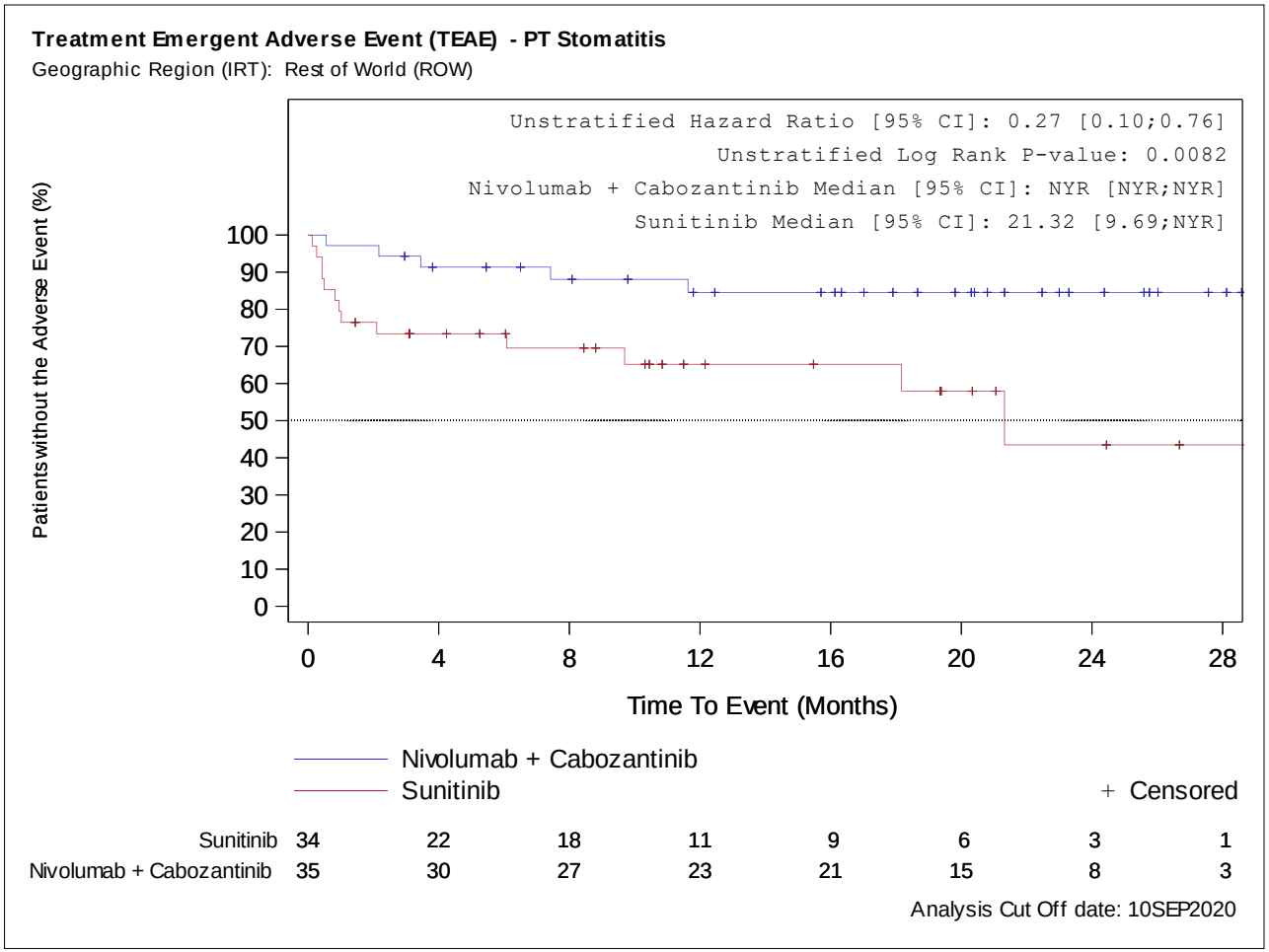

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:45:55

FIGURE 5.7.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



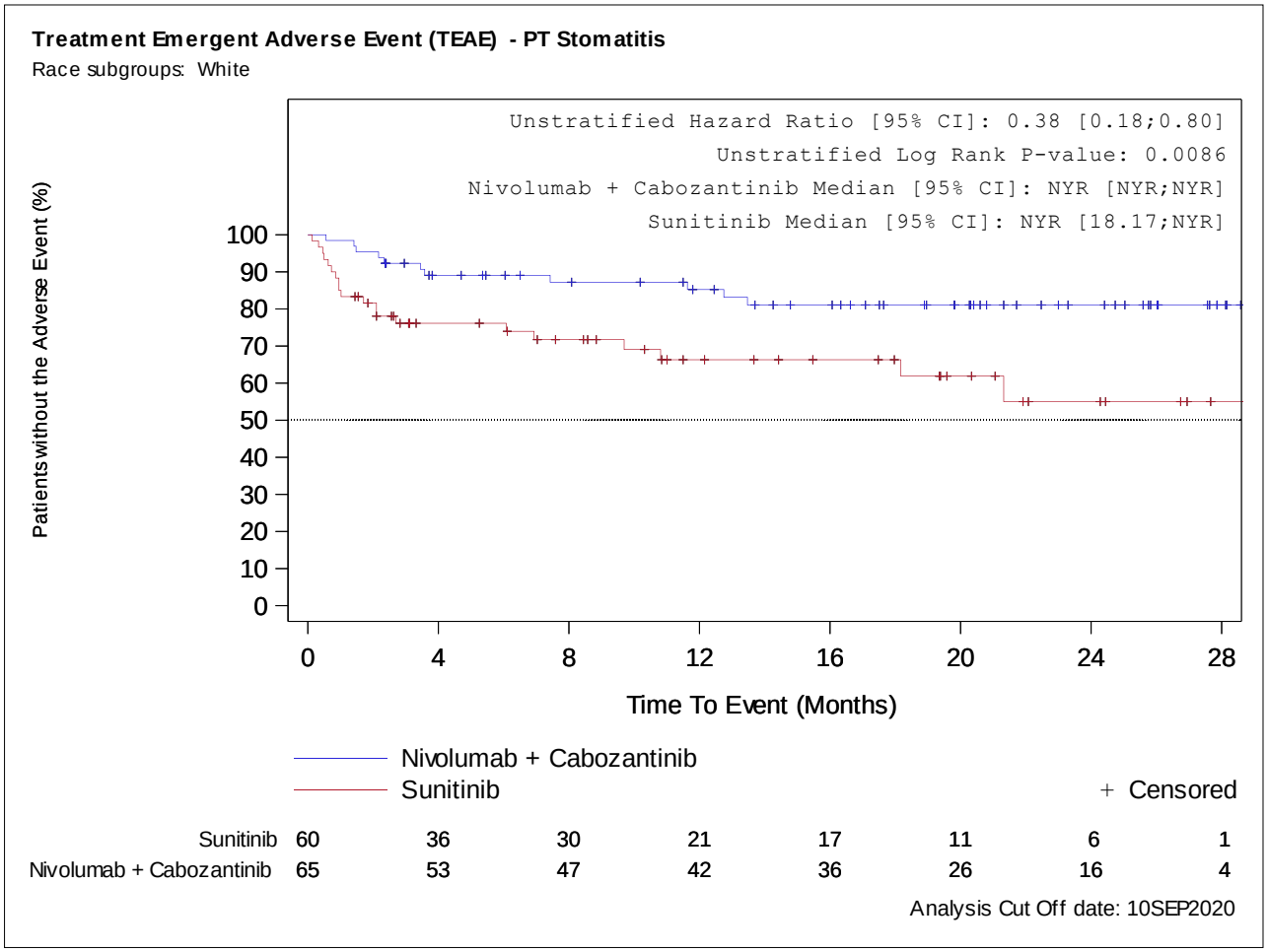

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:46:01

FIGURE 5.7.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



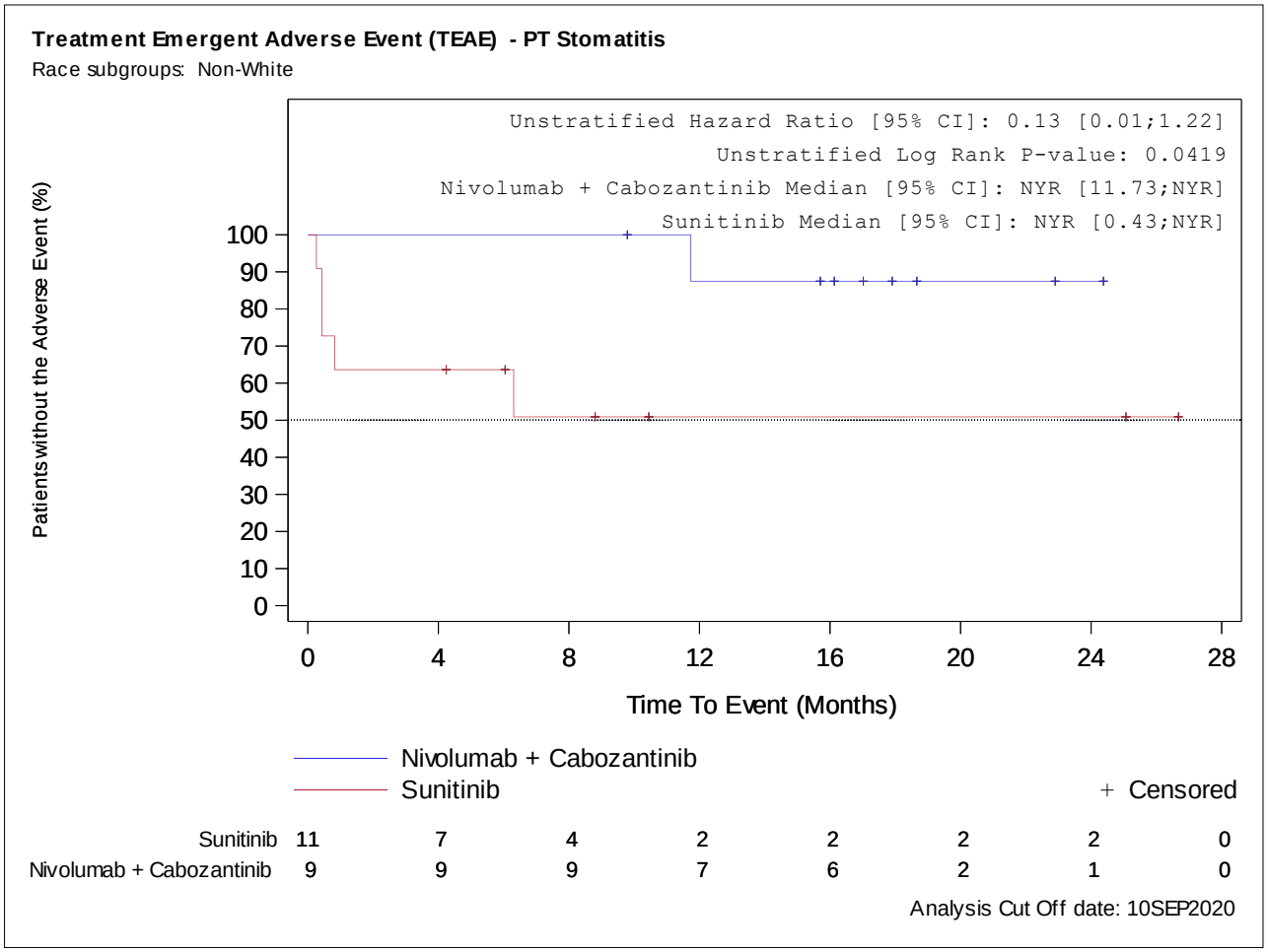

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:46:08

FIGURE 5.7.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



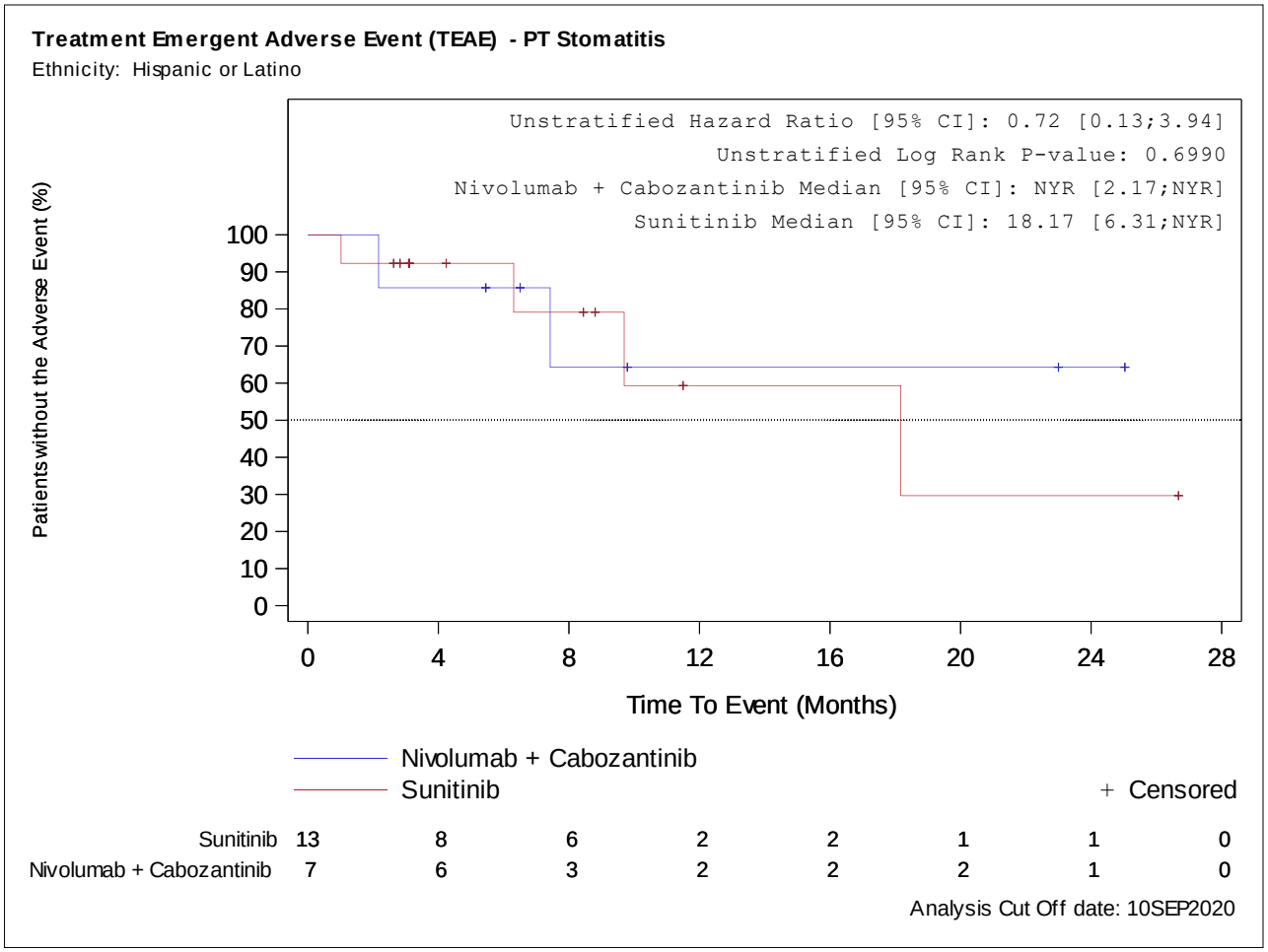

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:46:14

FIGURE 5.7.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:46:20

FIGURE 5.7.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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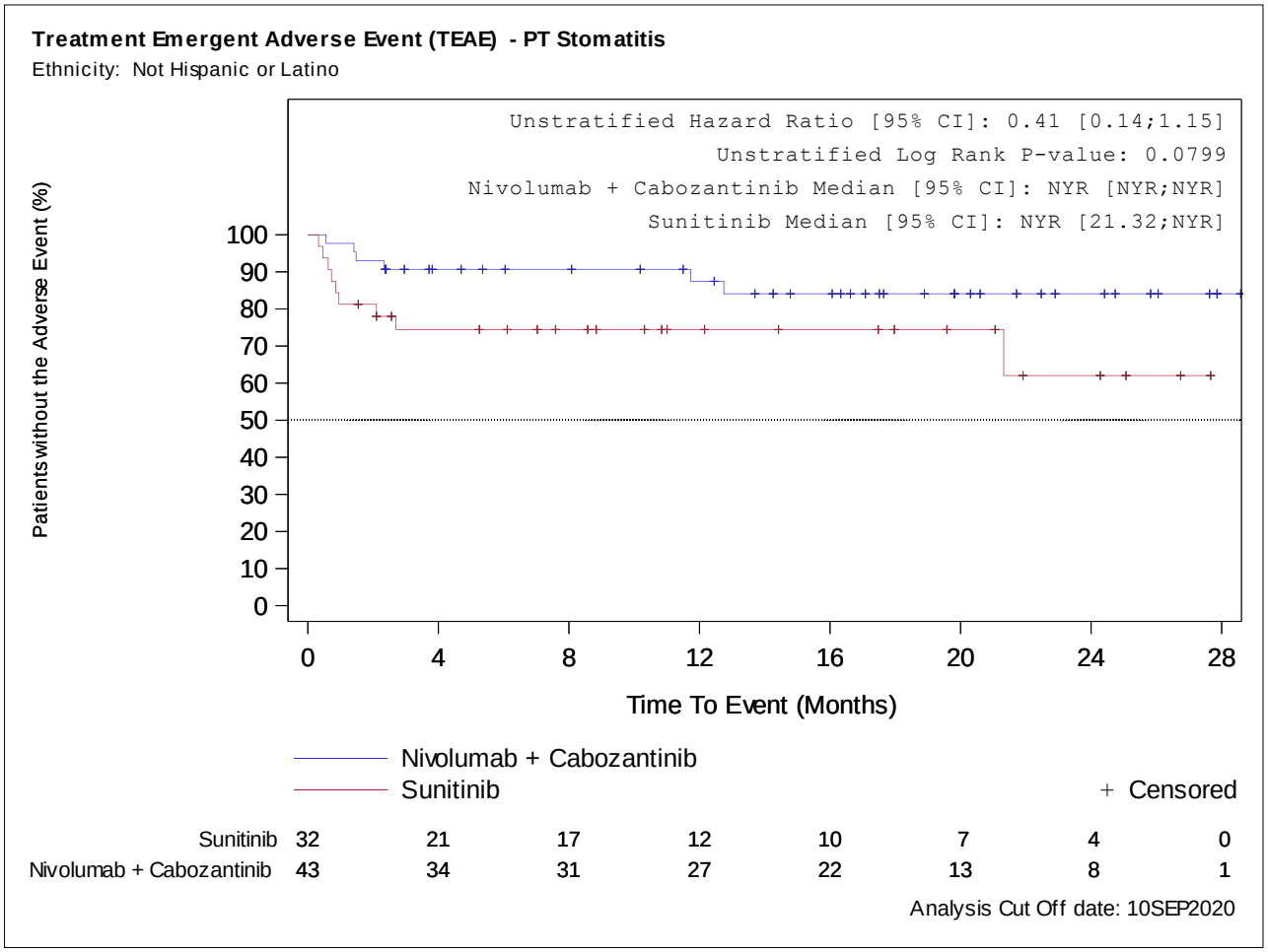
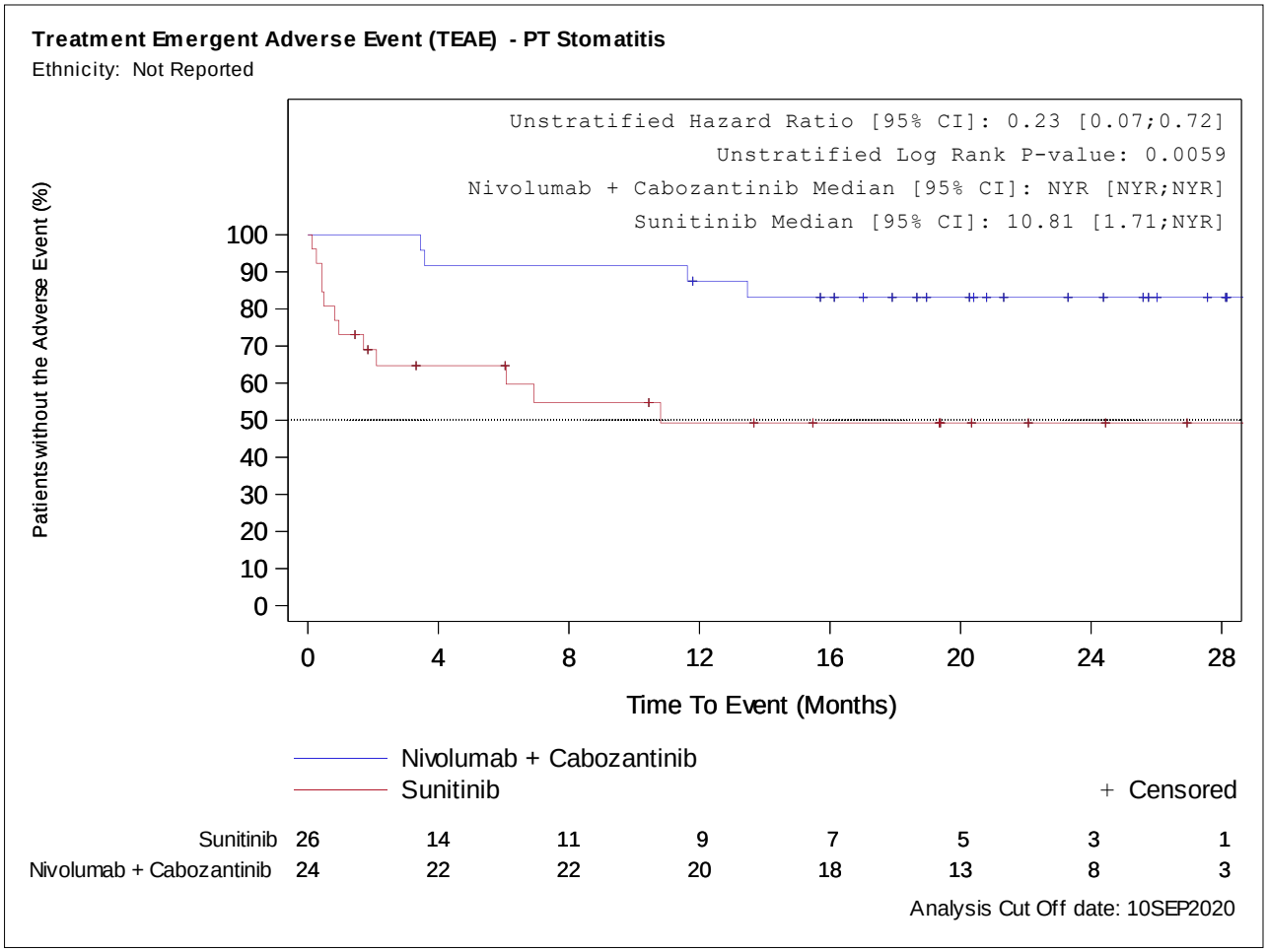
FIGURE 5.7.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



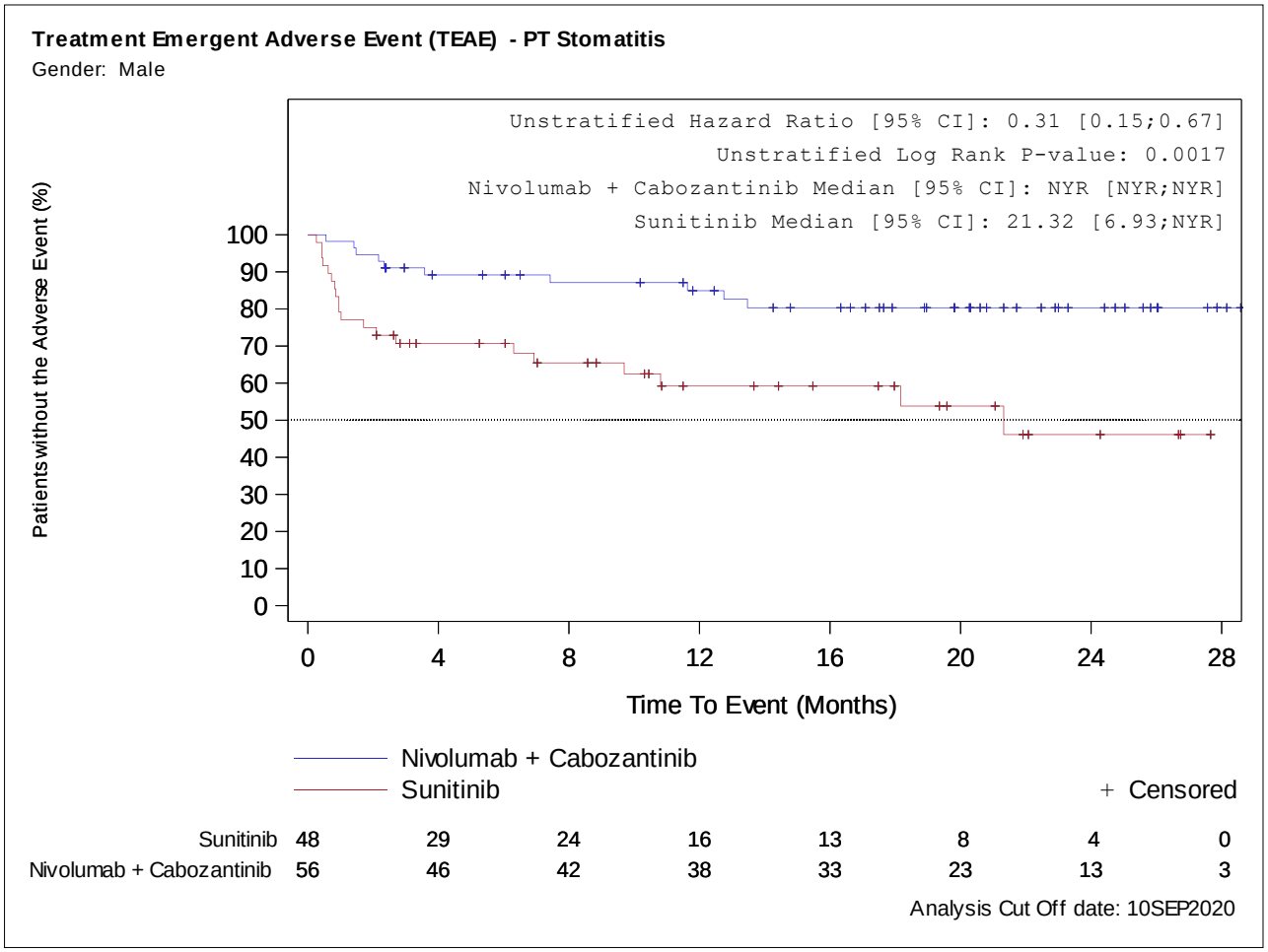

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:46:32

FIGURE 5.7.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:46:39

FIGURE 5.7.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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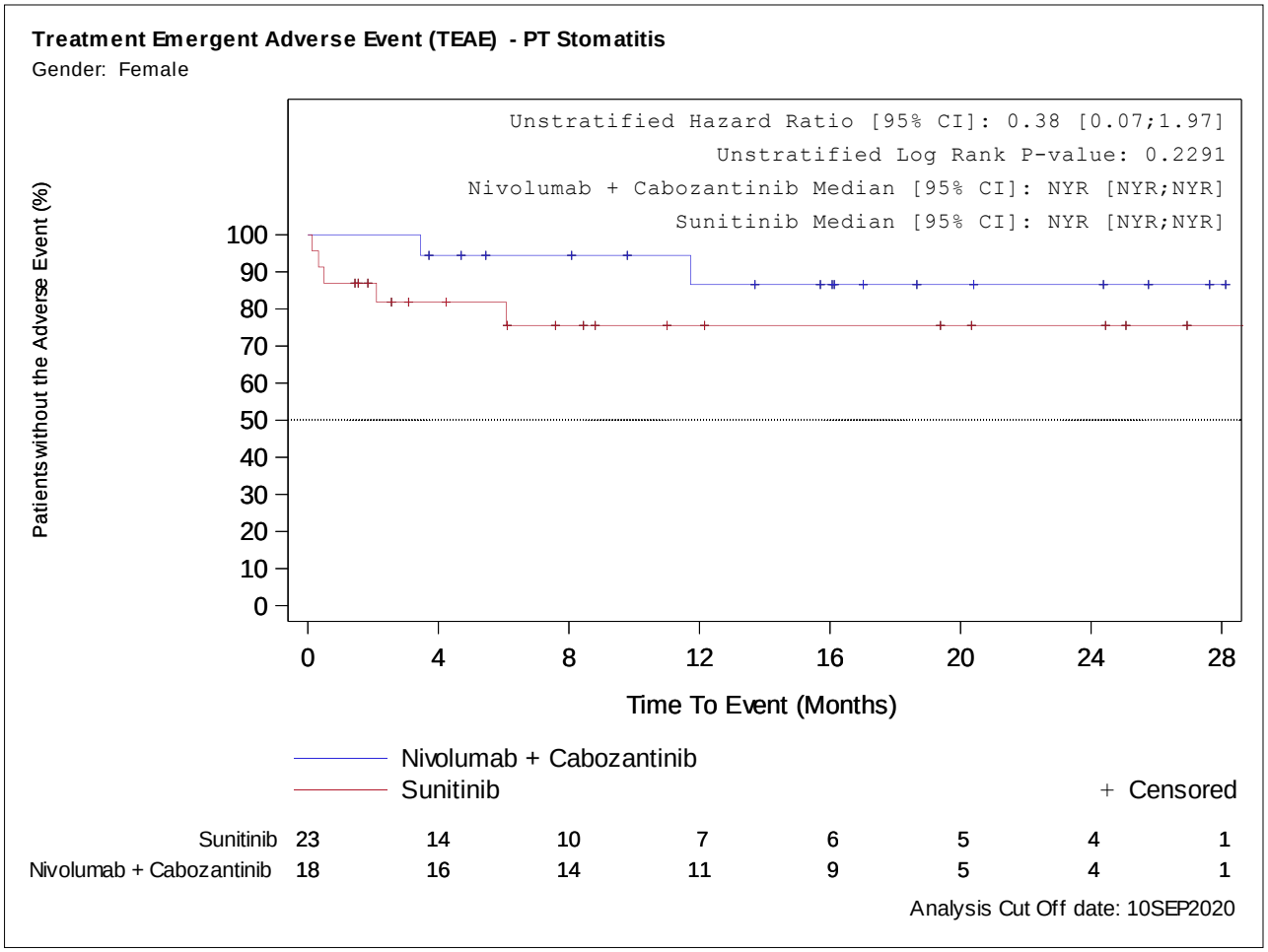
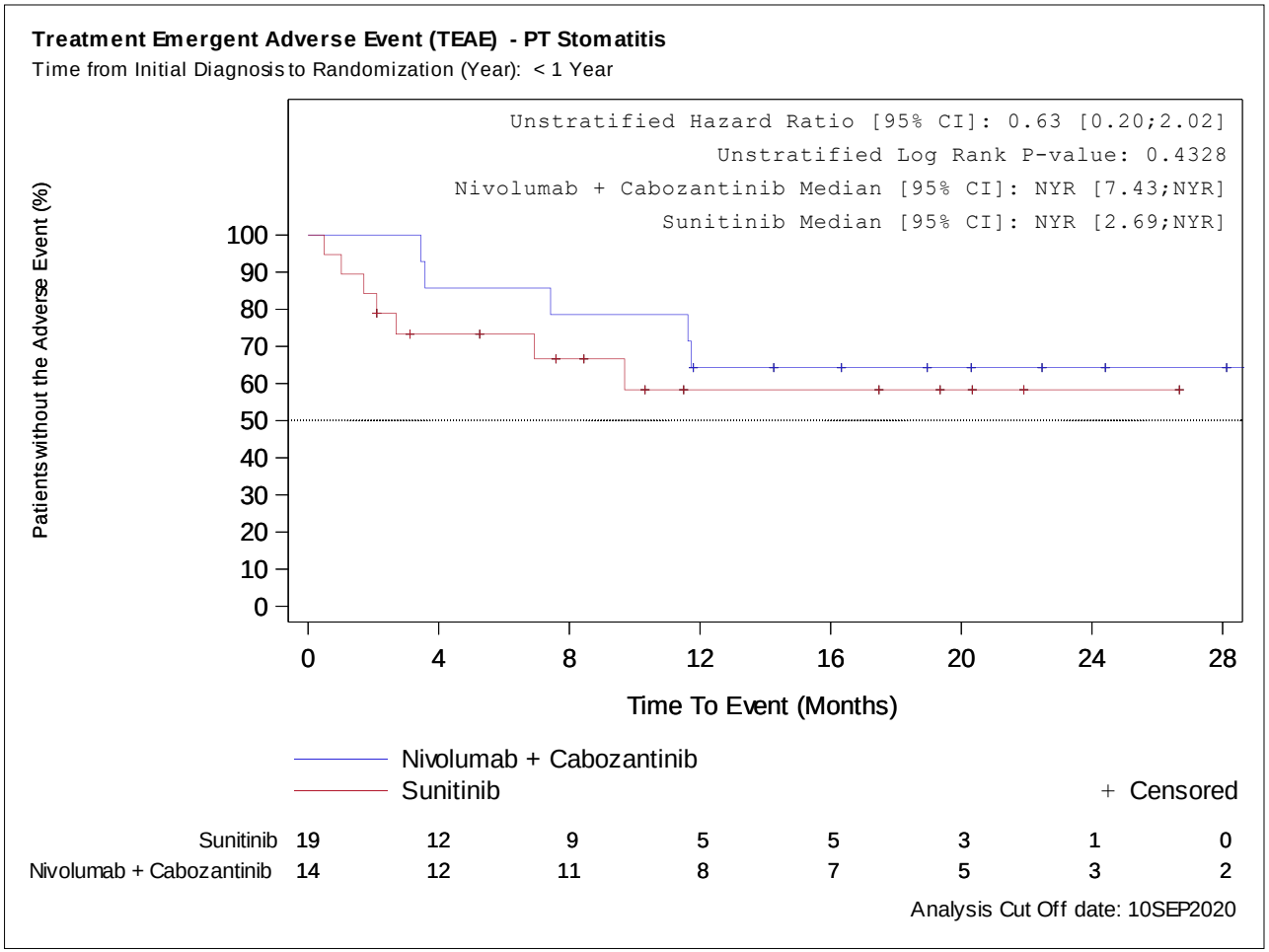
FIGURE 5.7.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:46:50

FIGURE 5.7.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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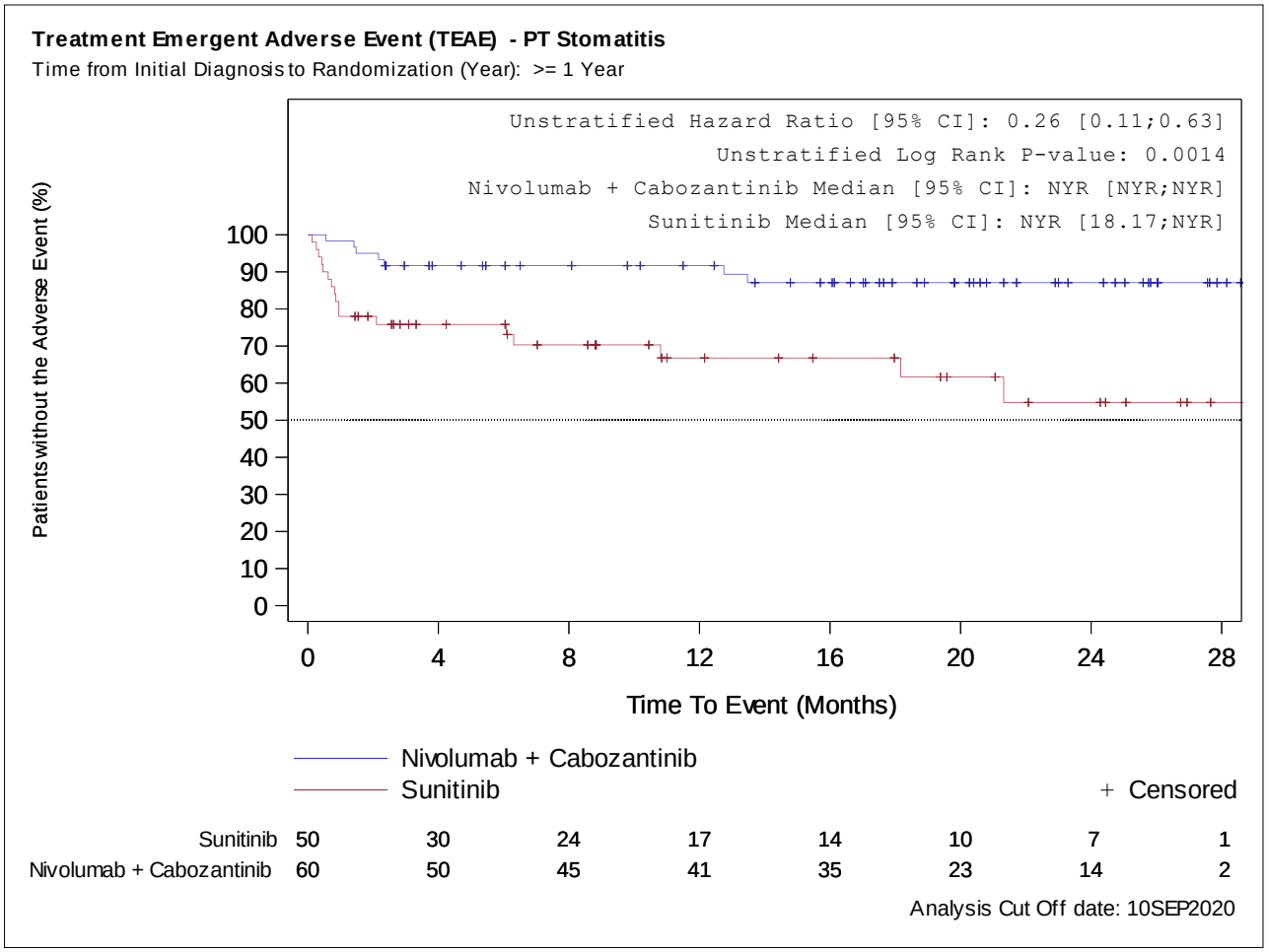
FIGURE 5.7.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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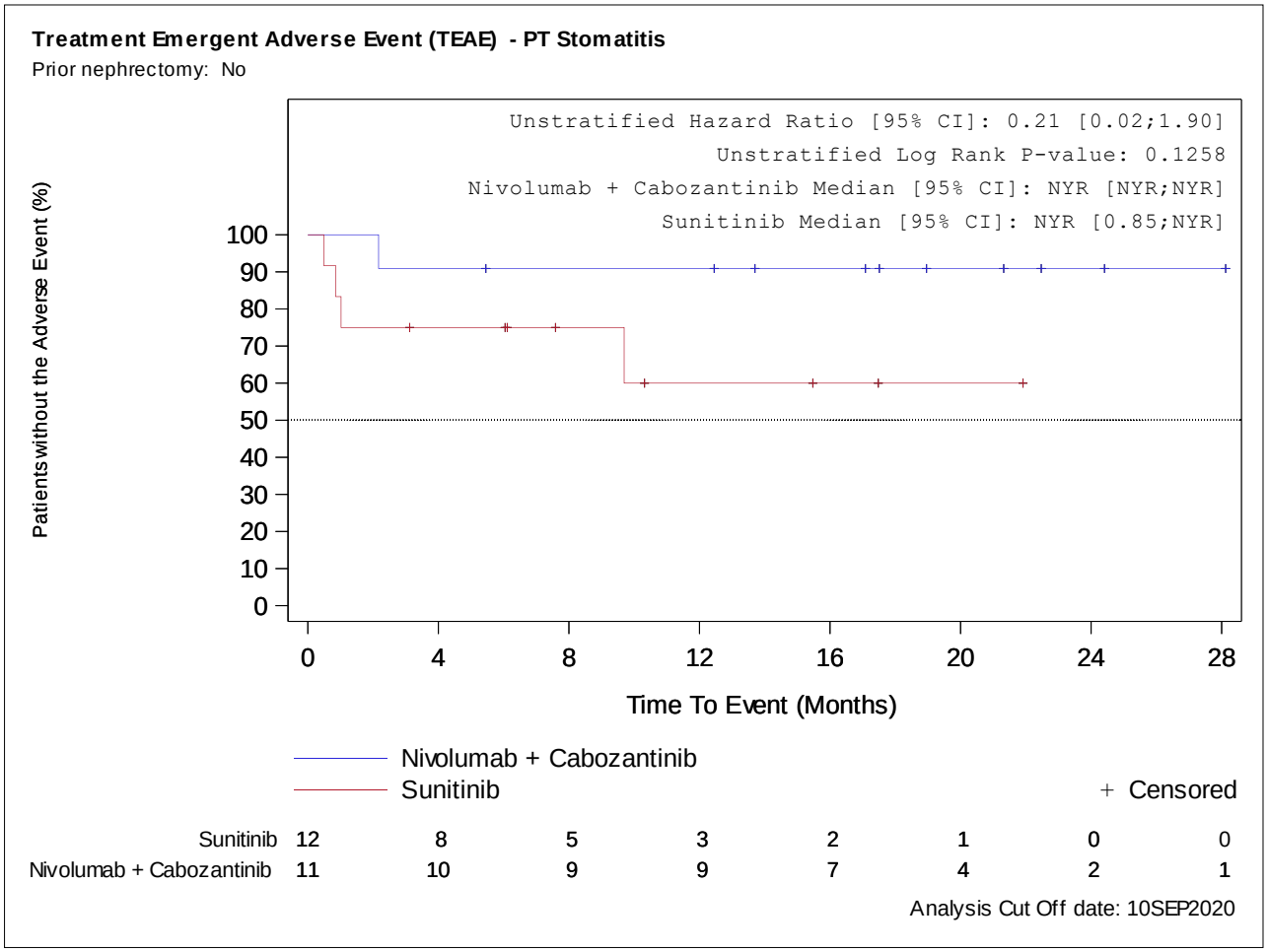
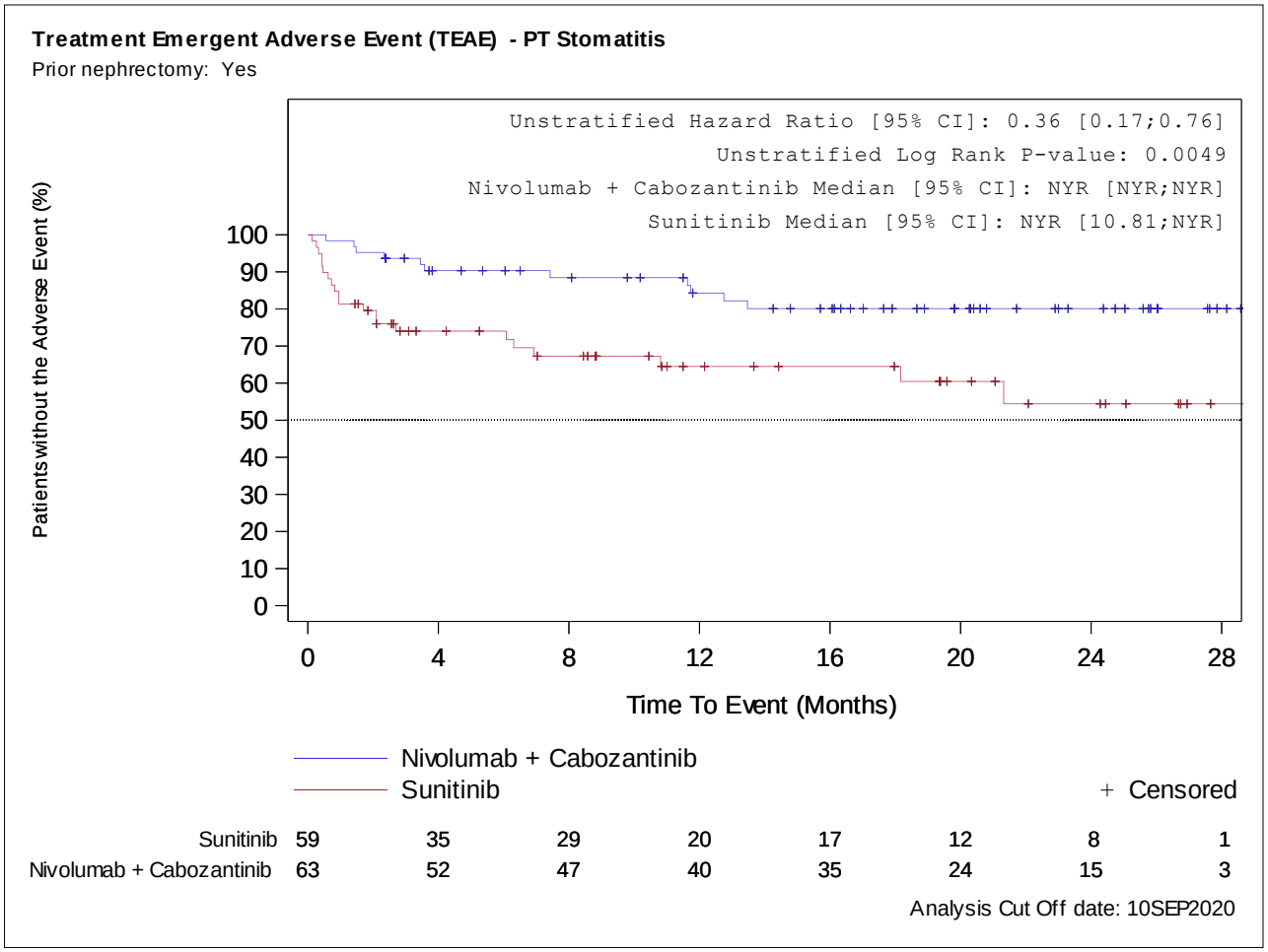
FIGURE 5.7.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



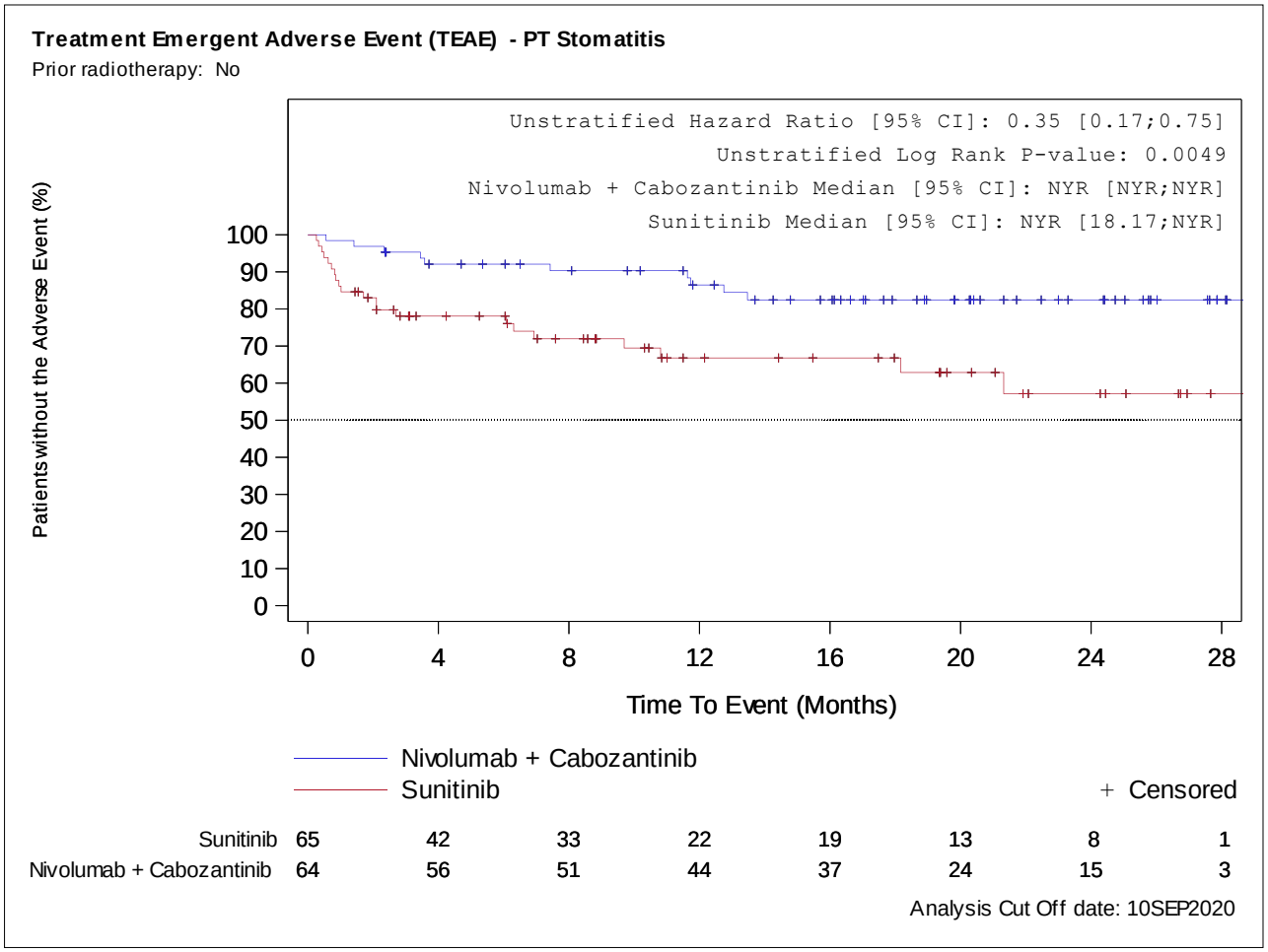

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:48:07

FIGURE 5.7.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:48:13

FIGURE 5.7.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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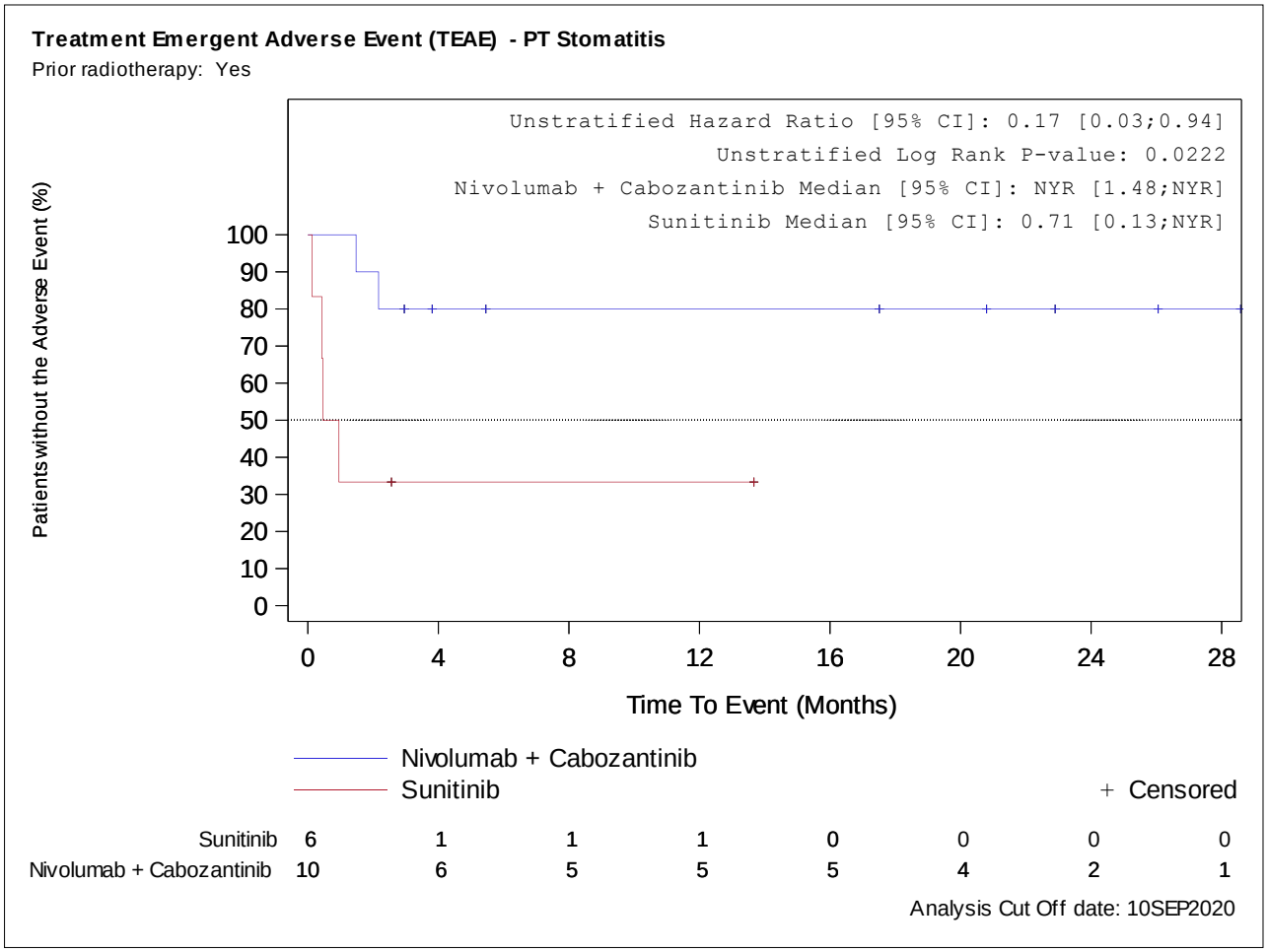
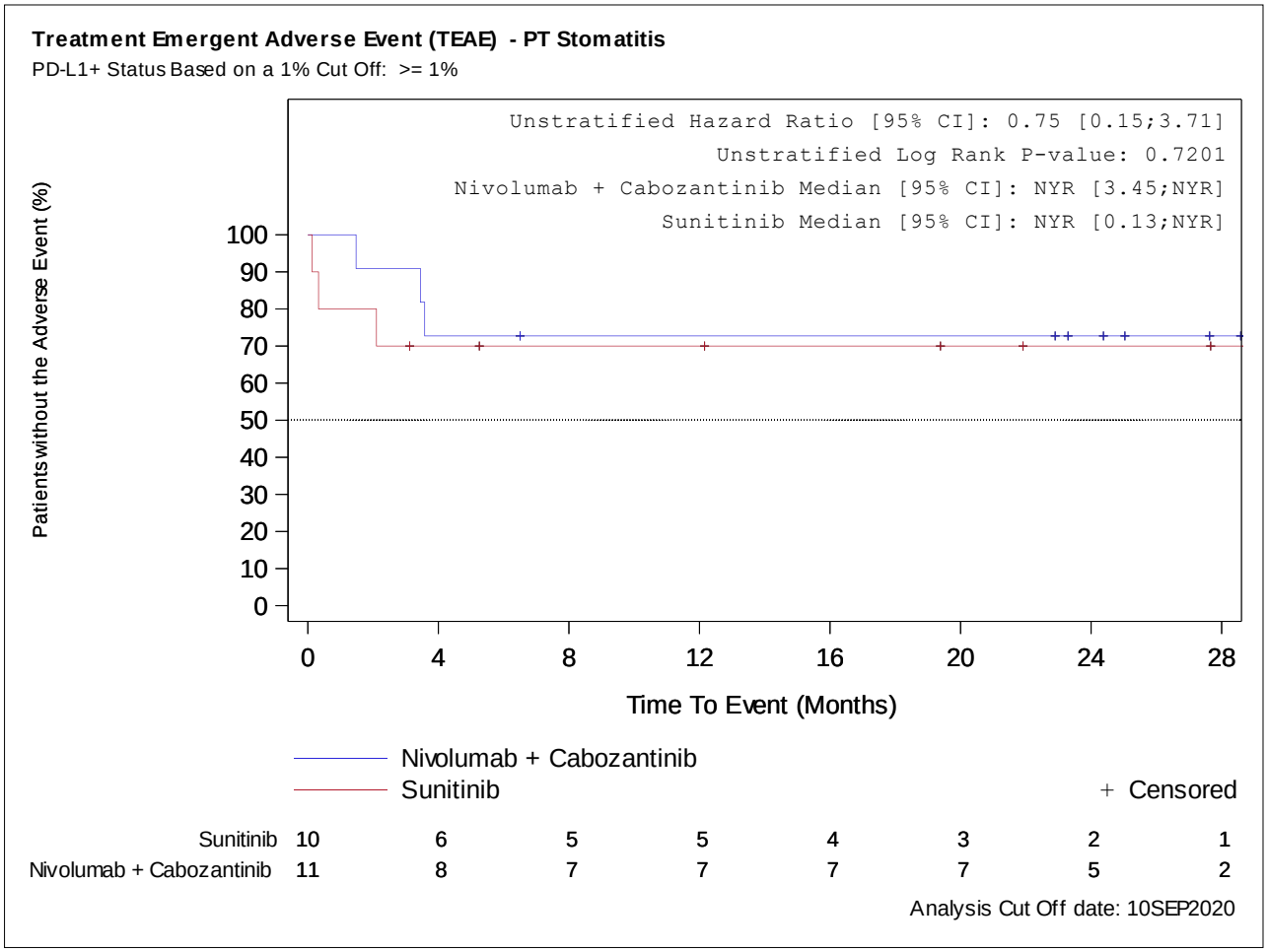
FIGURE 5.7.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



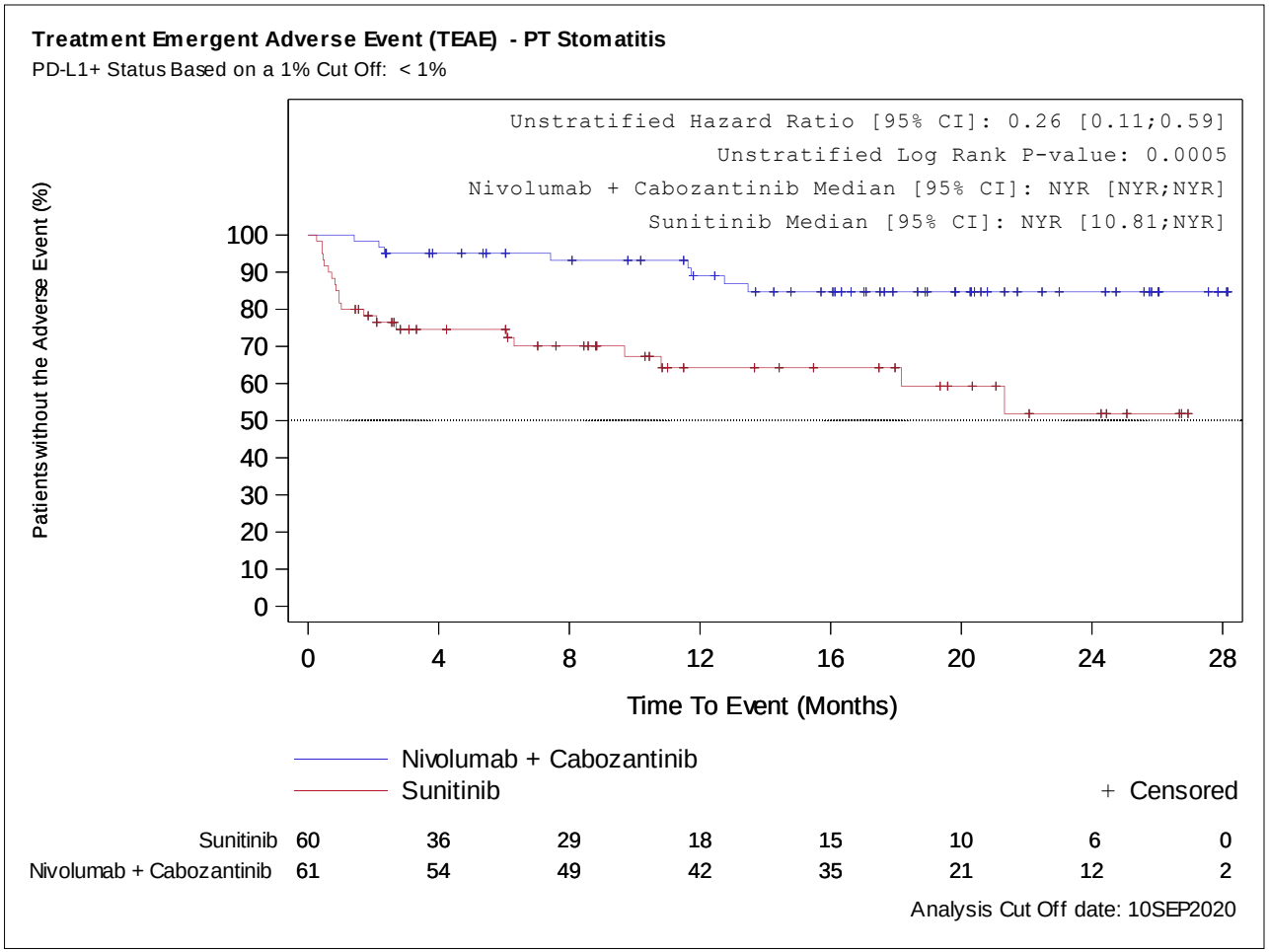

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:48:26

FIGURE 5.7.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



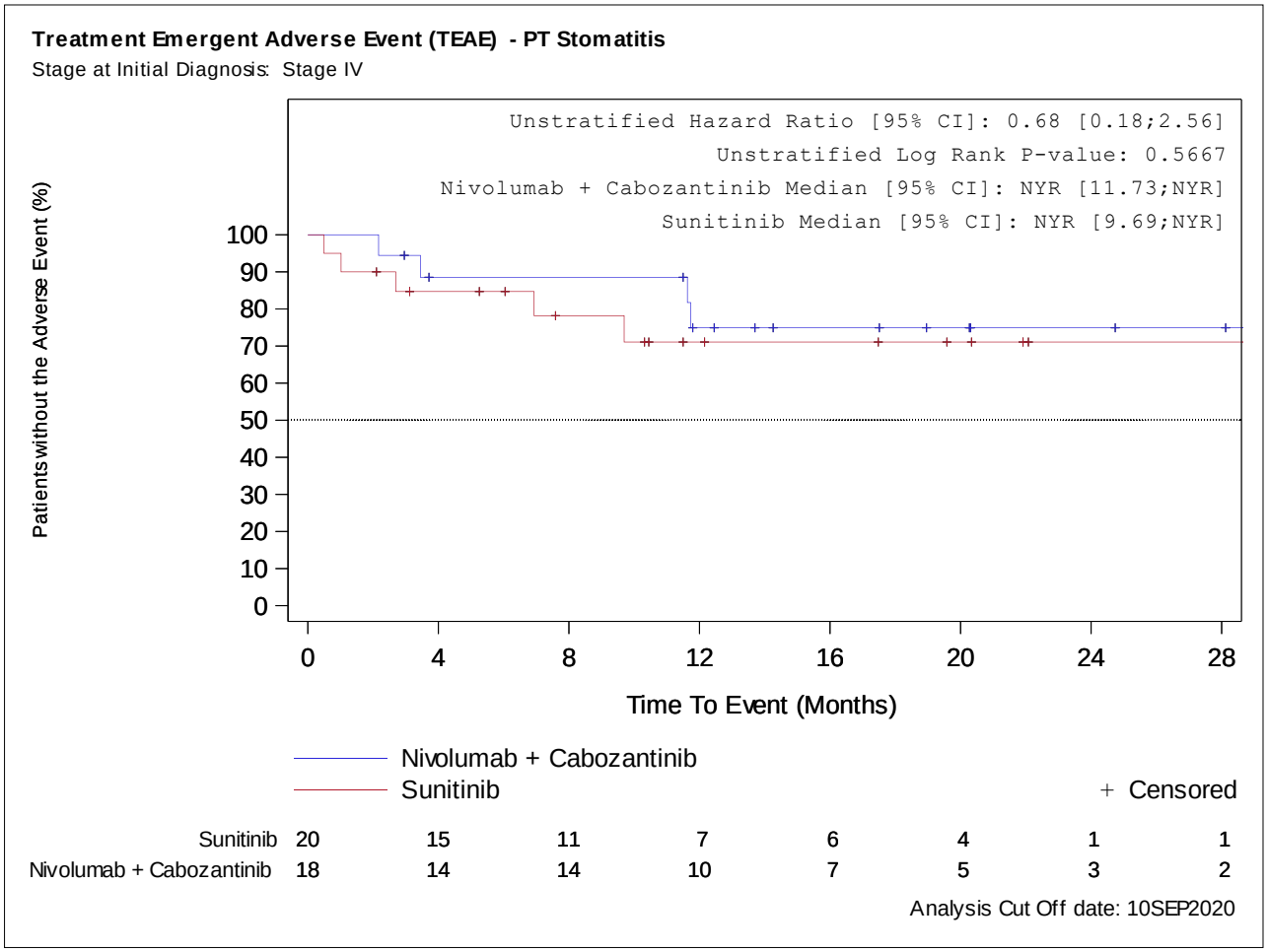

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:48:31

FIGURE 5.7.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



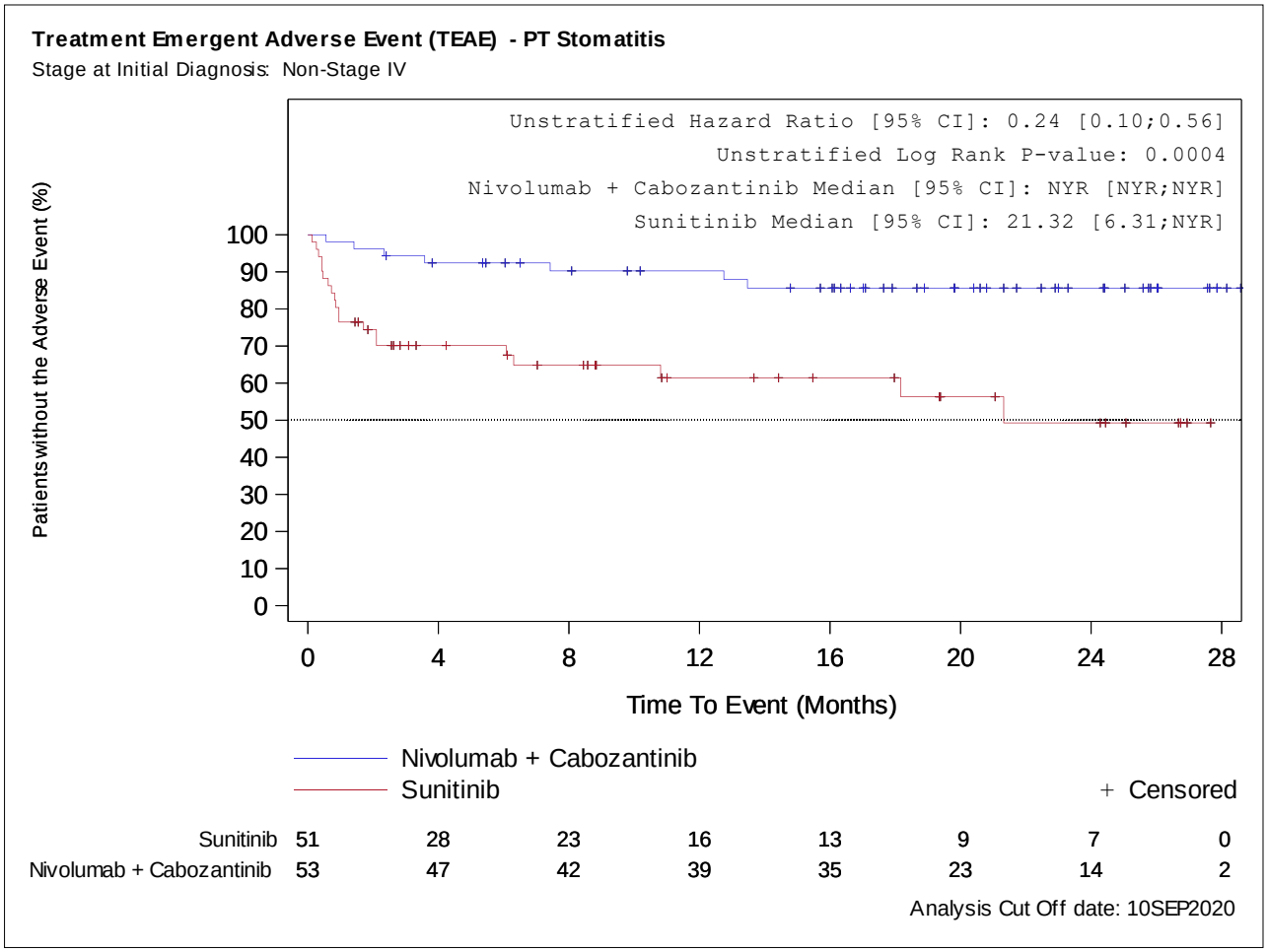

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:48:37

FIGURE 5.7.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



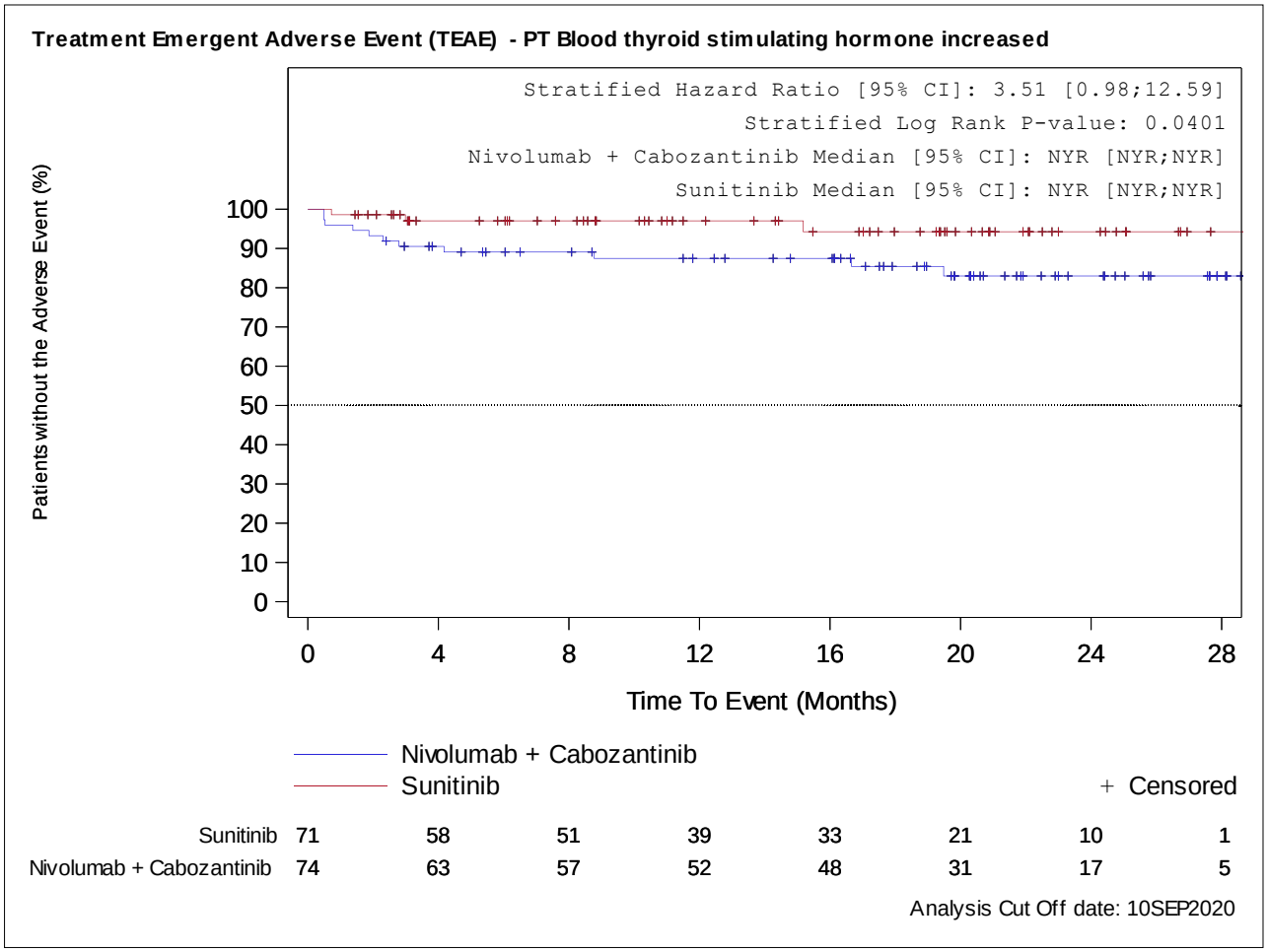

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:49:06

FIGURE 5.7.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



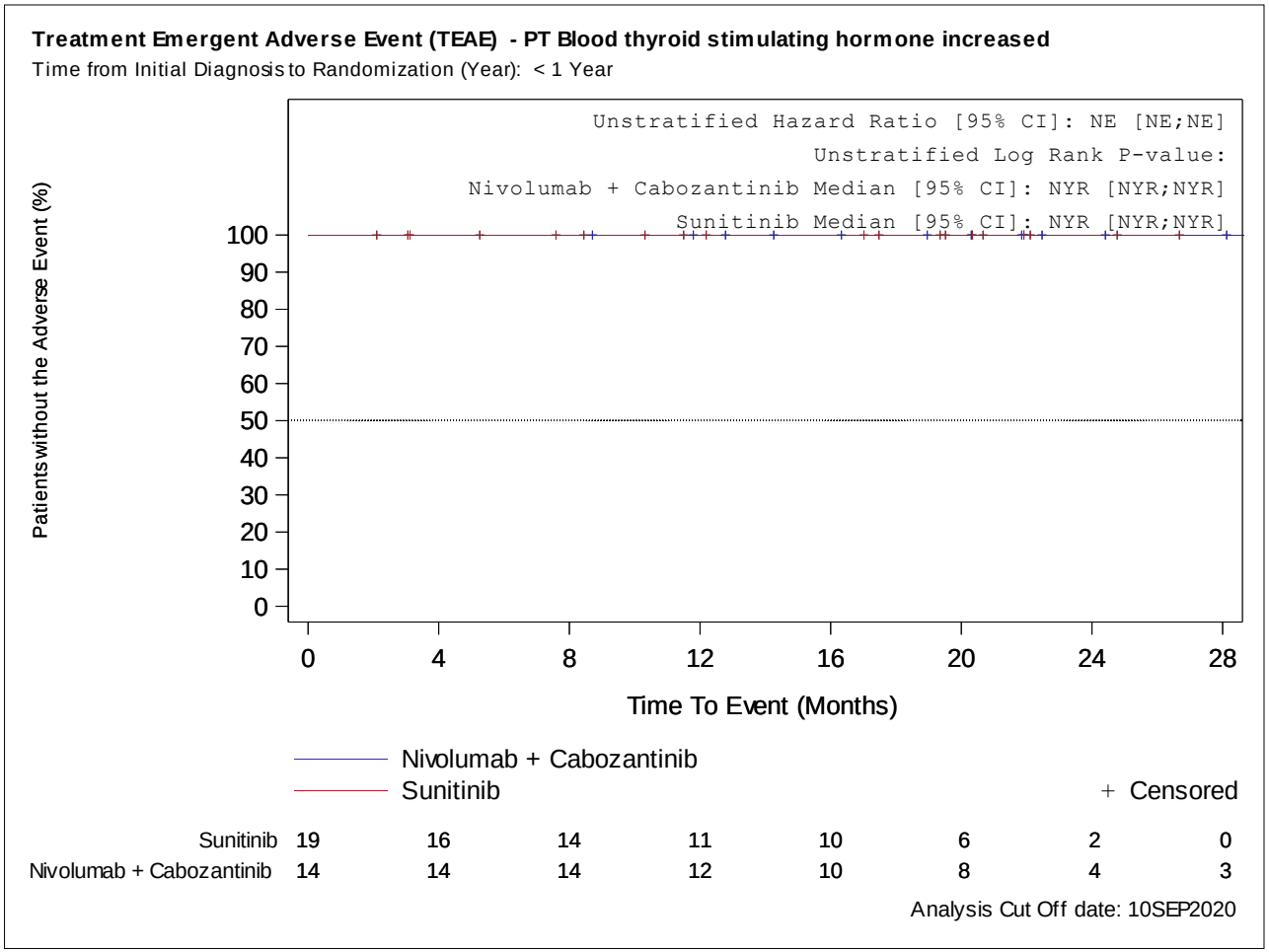

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:49:13

FIGURE 5.8.1: Treatment Emergent Adverse Event (TEAE) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



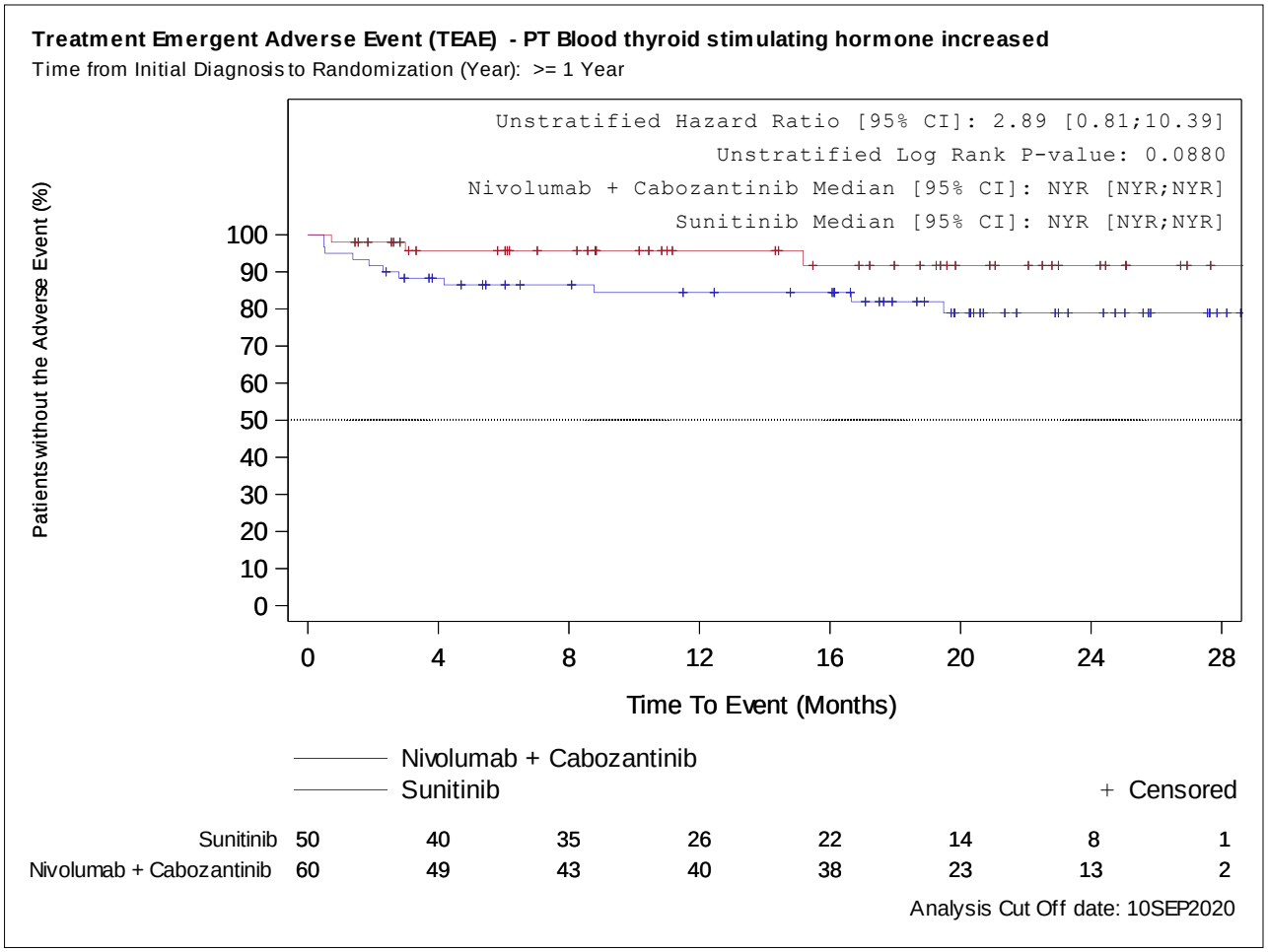

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:51:45

FIGURE 5.8.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



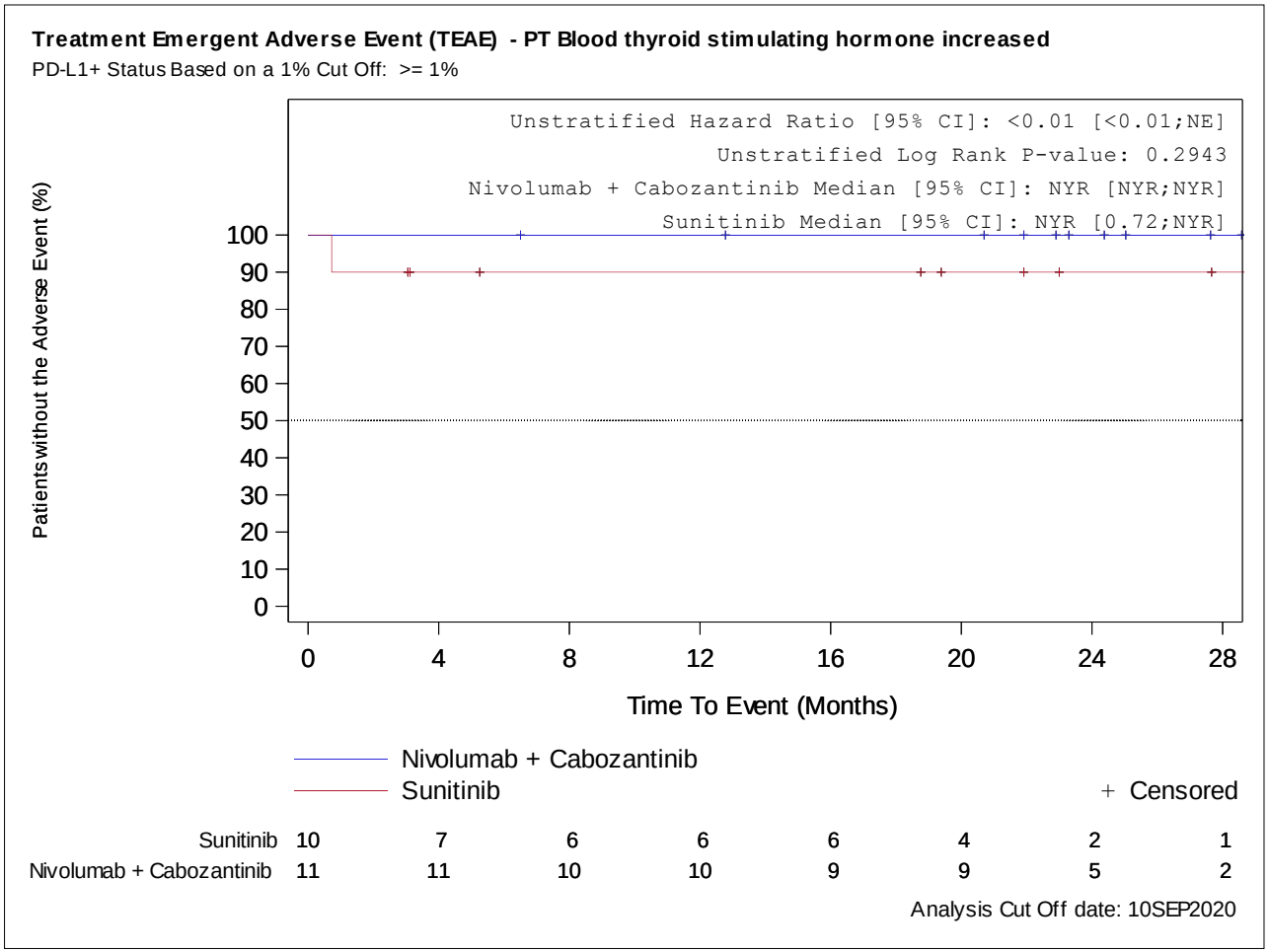

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:51:49

FIGURE 5.8.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:51:55

FIGURE 5.8.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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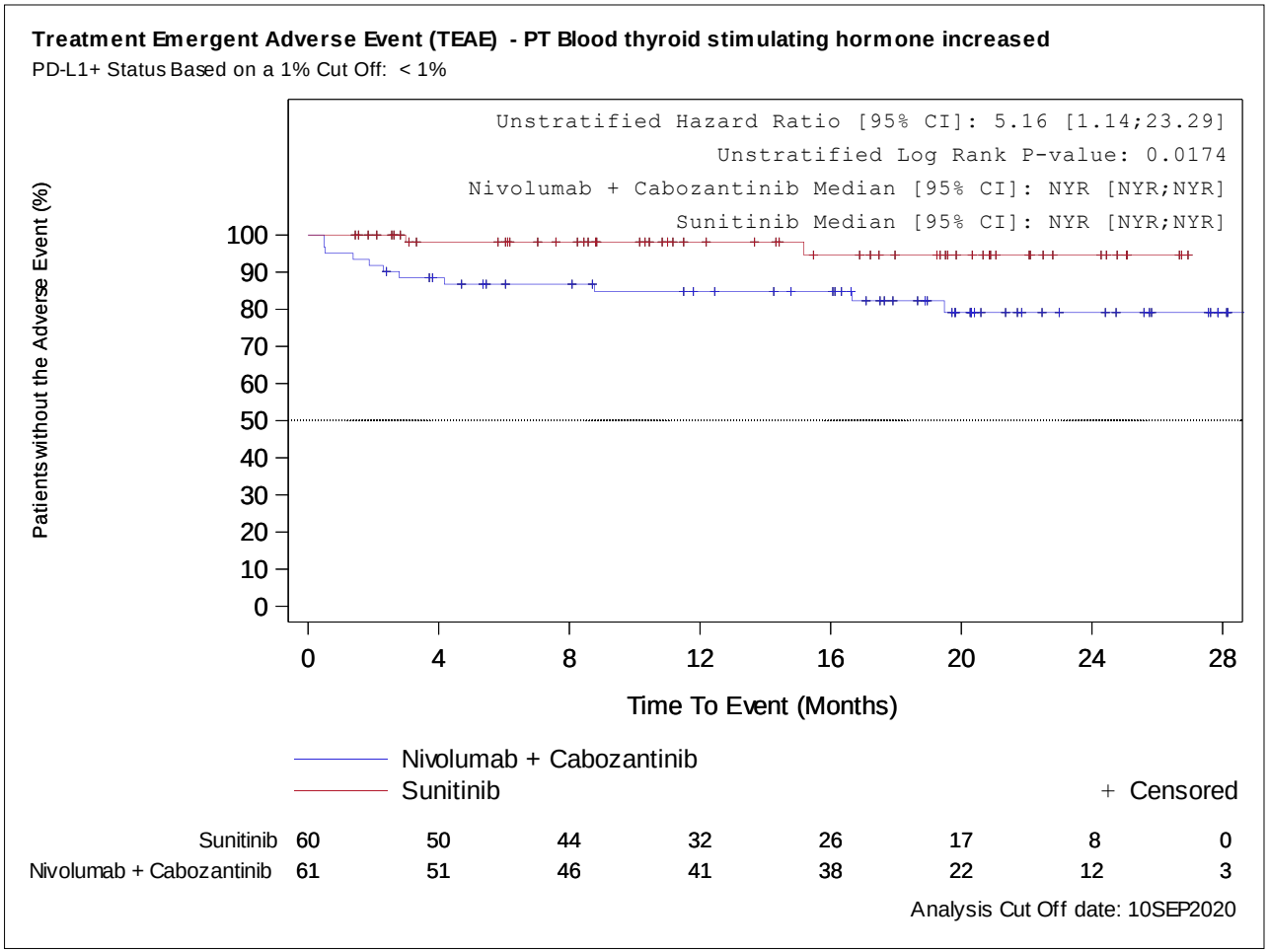
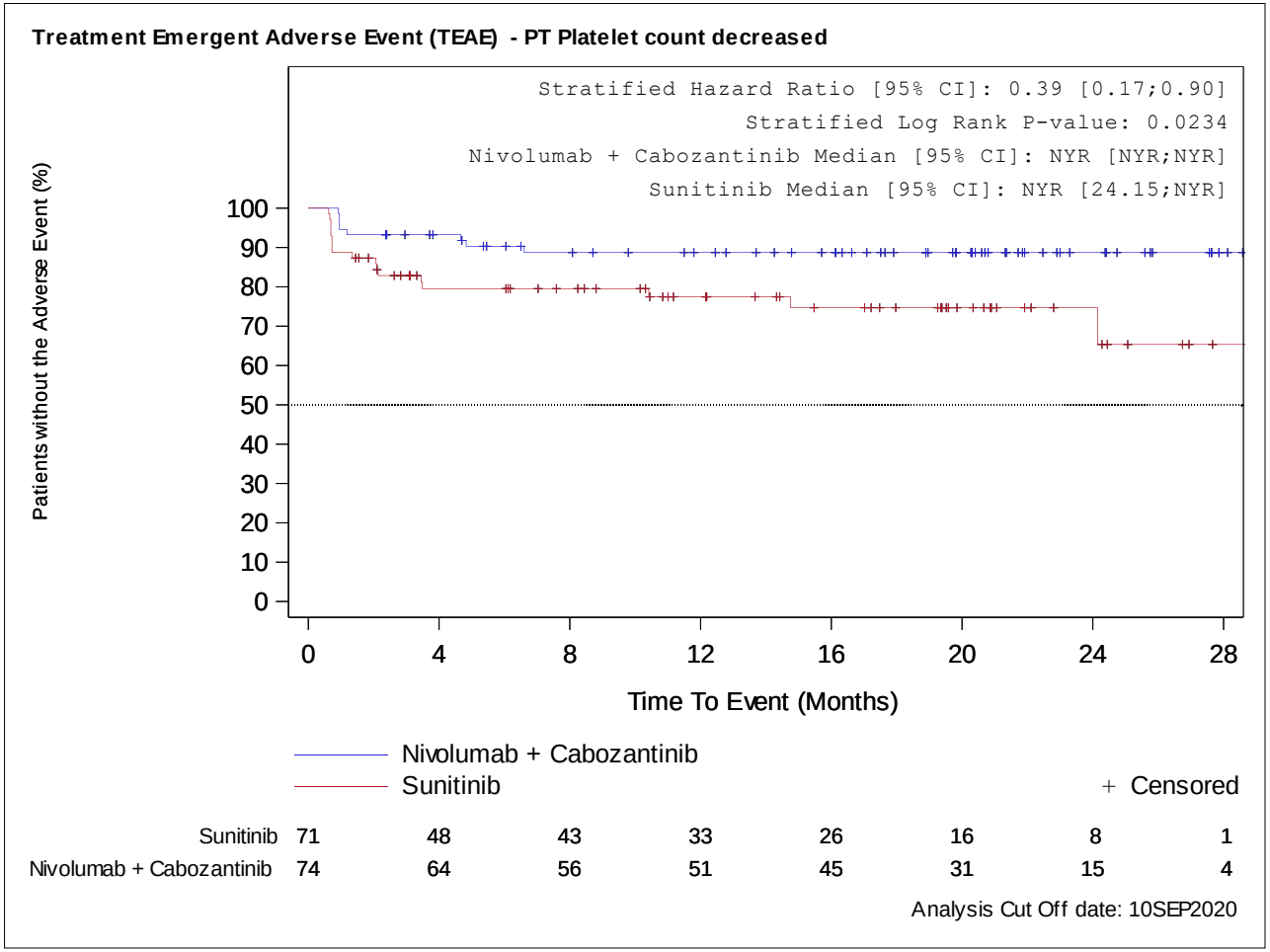
FIGURE 5.8.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



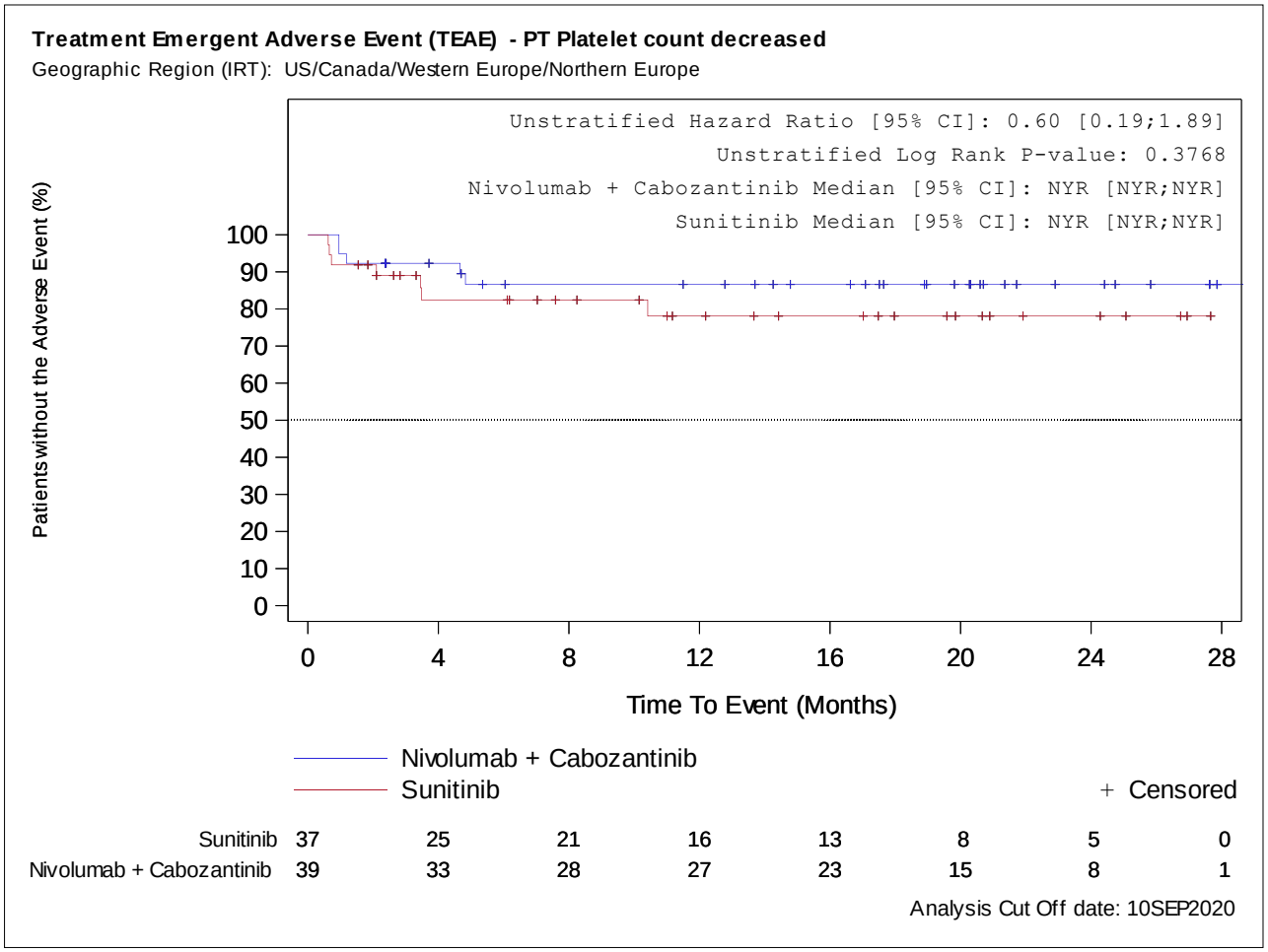

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:52:42

FIGURE 5.9.1: Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



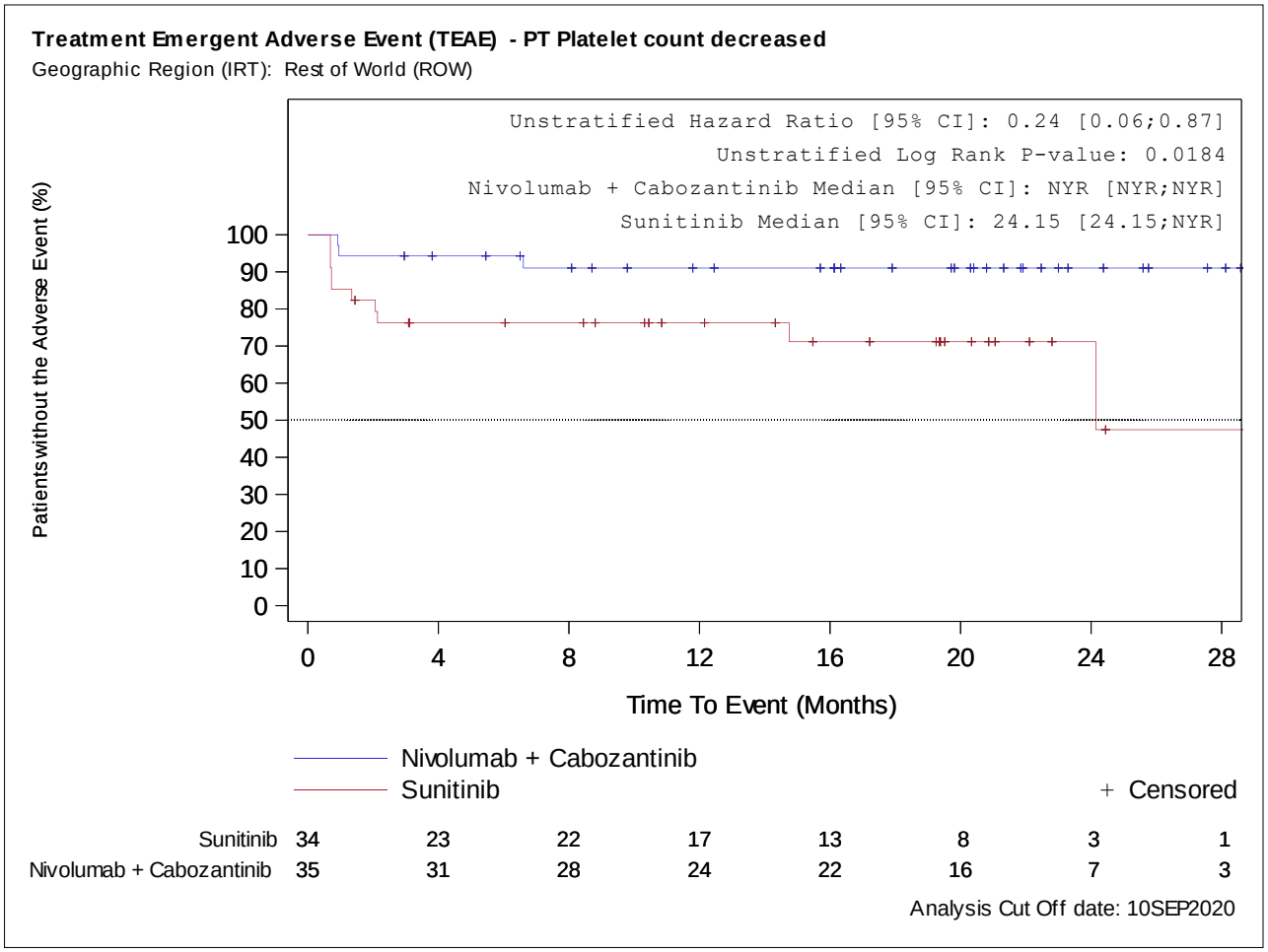

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:55:50

FIGURE 5.9.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



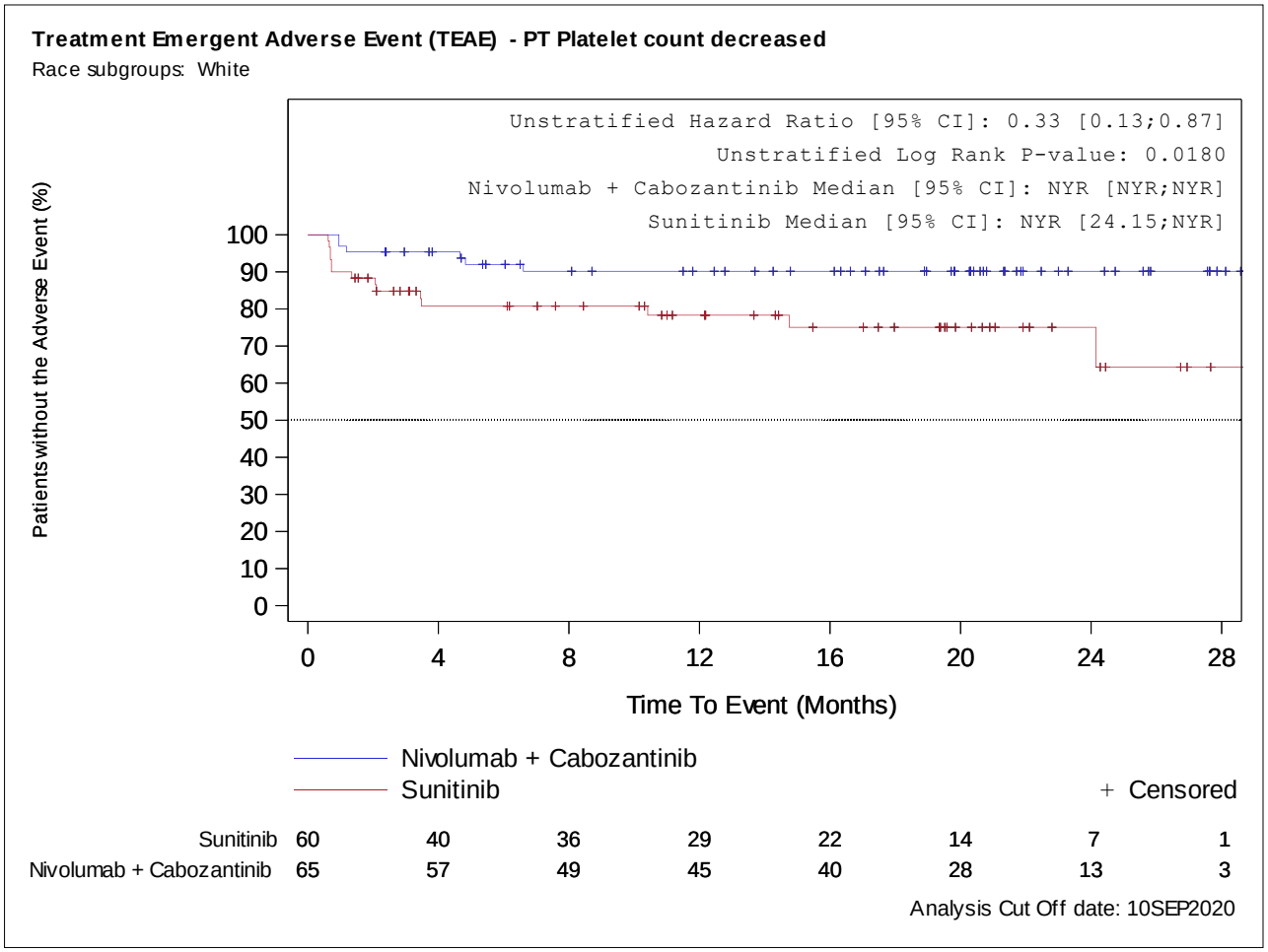

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:55:53

FIGURE 5.9.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:55:59

FIGURE 5.9.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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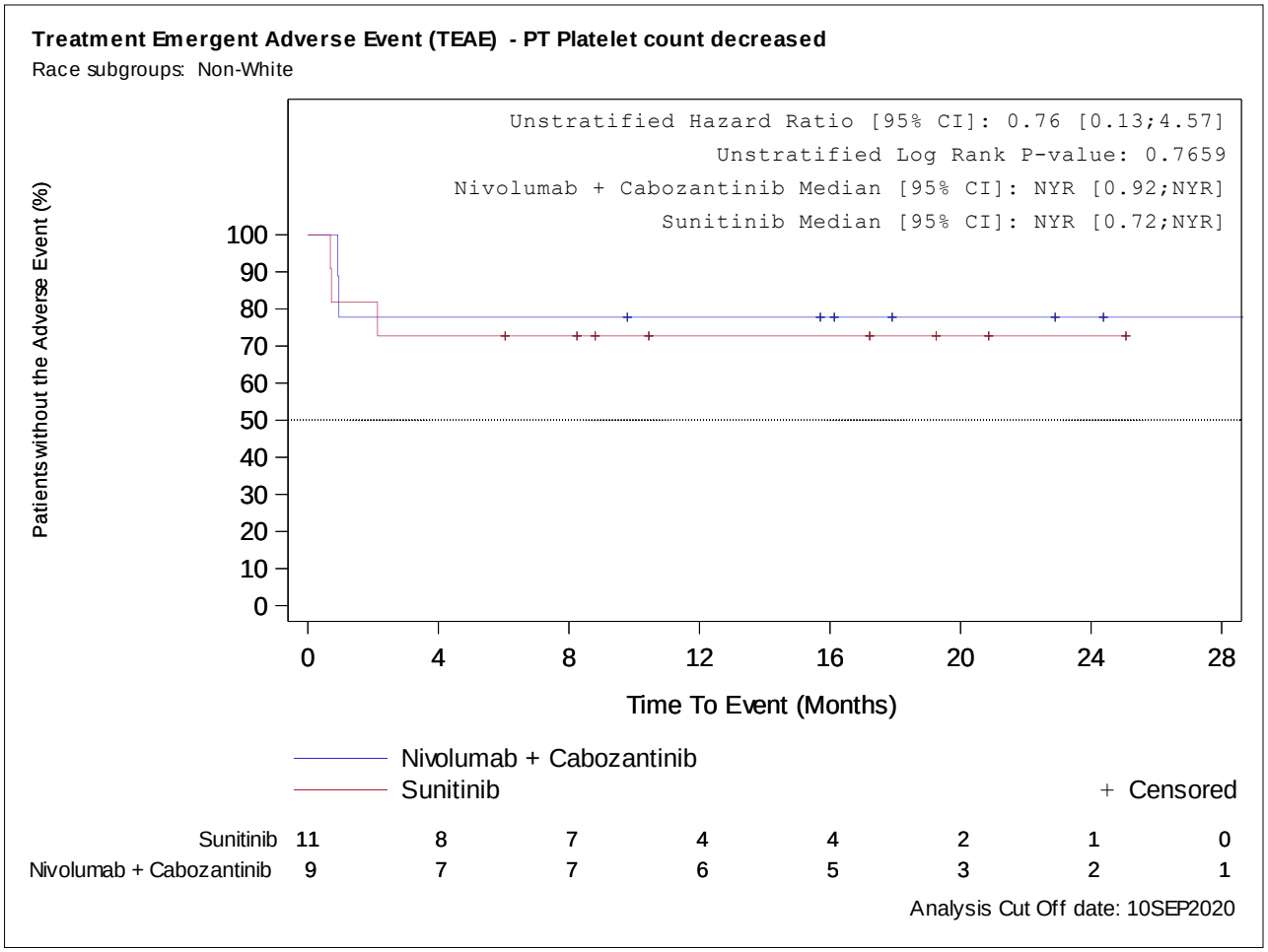
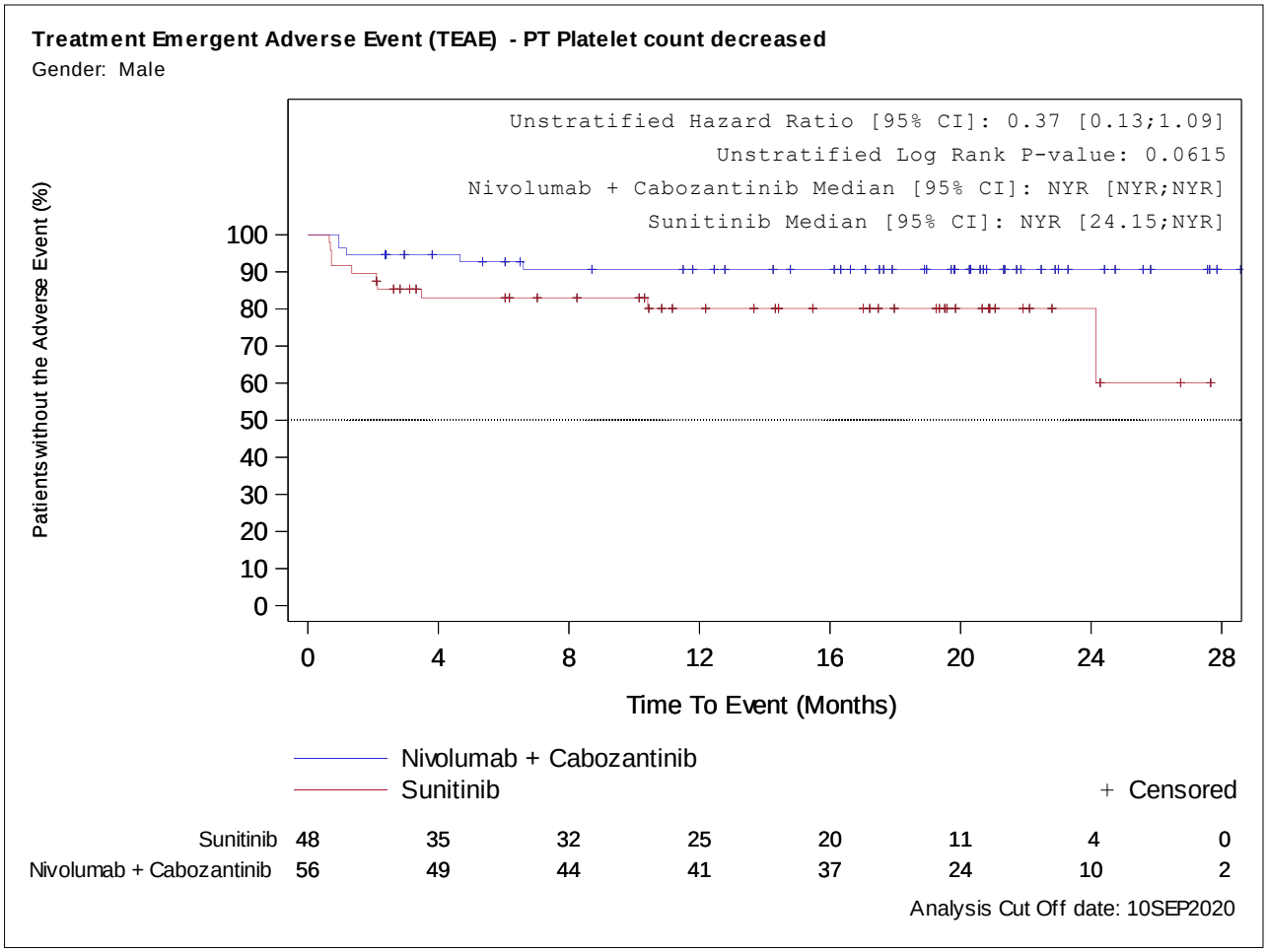
FIGURE 5.9.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:56:12

FIGURE 5.9.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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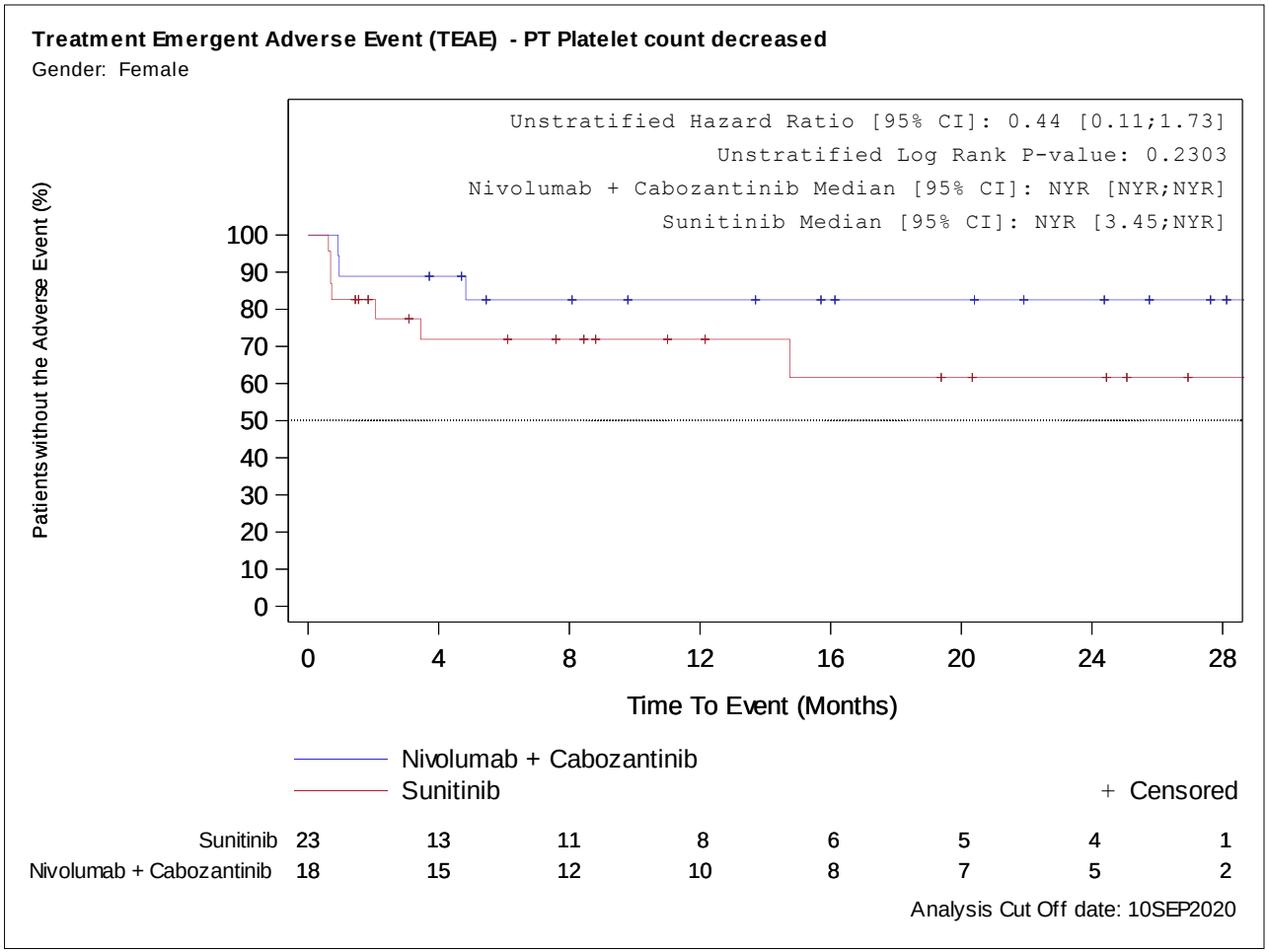
FIGURE 5.9.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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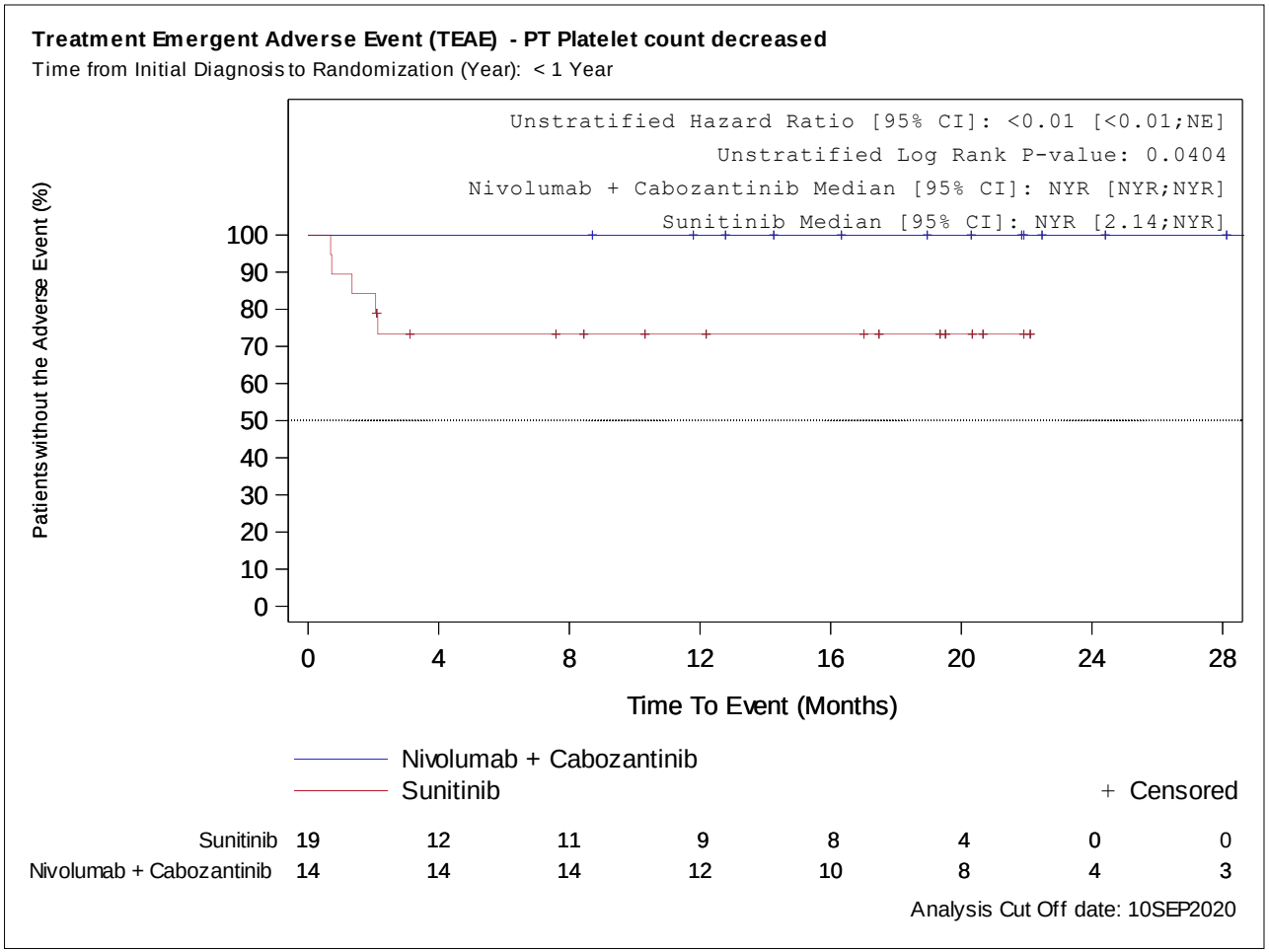
FIGURE 5.9.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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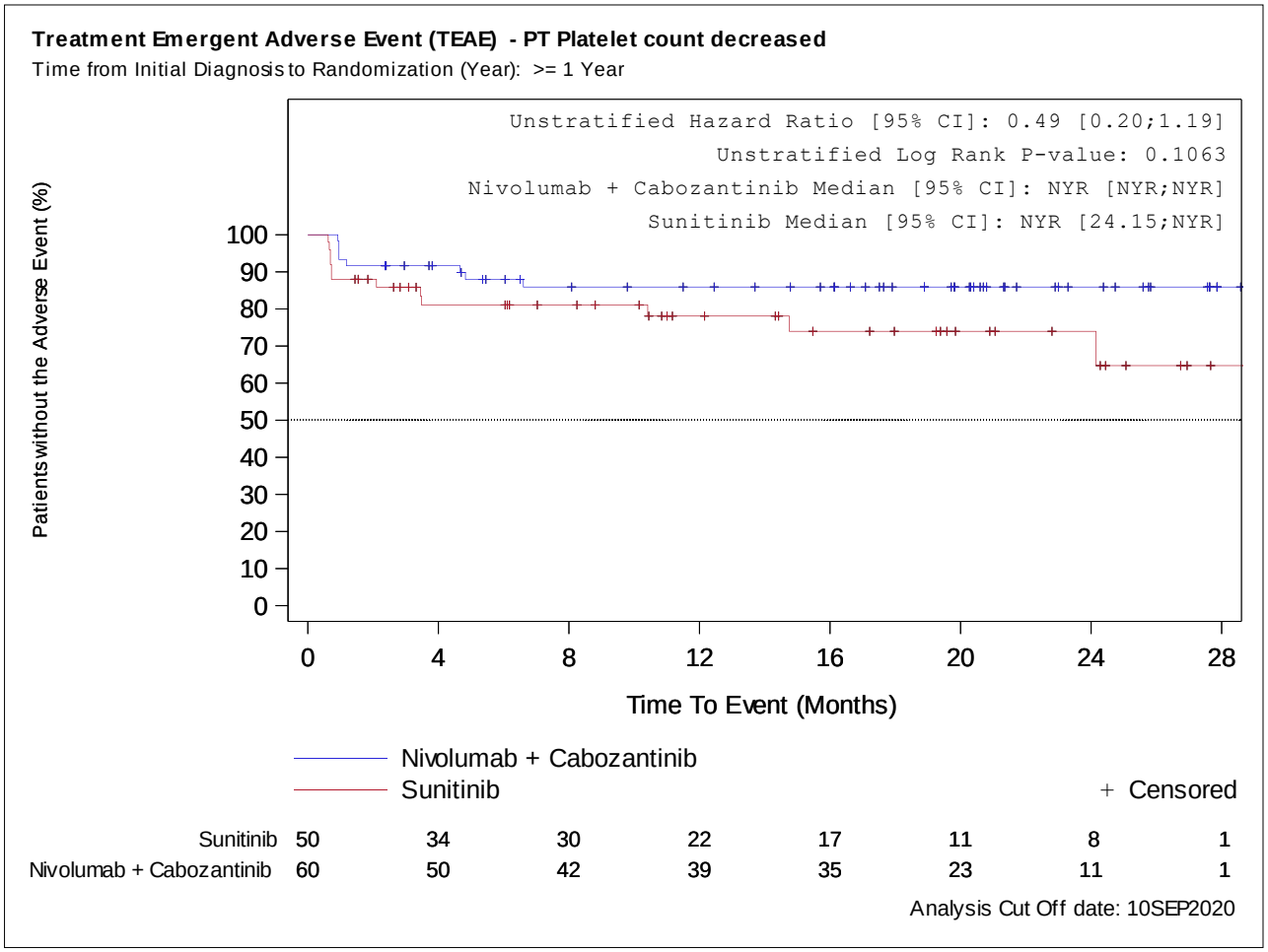
FIGURE 5.9.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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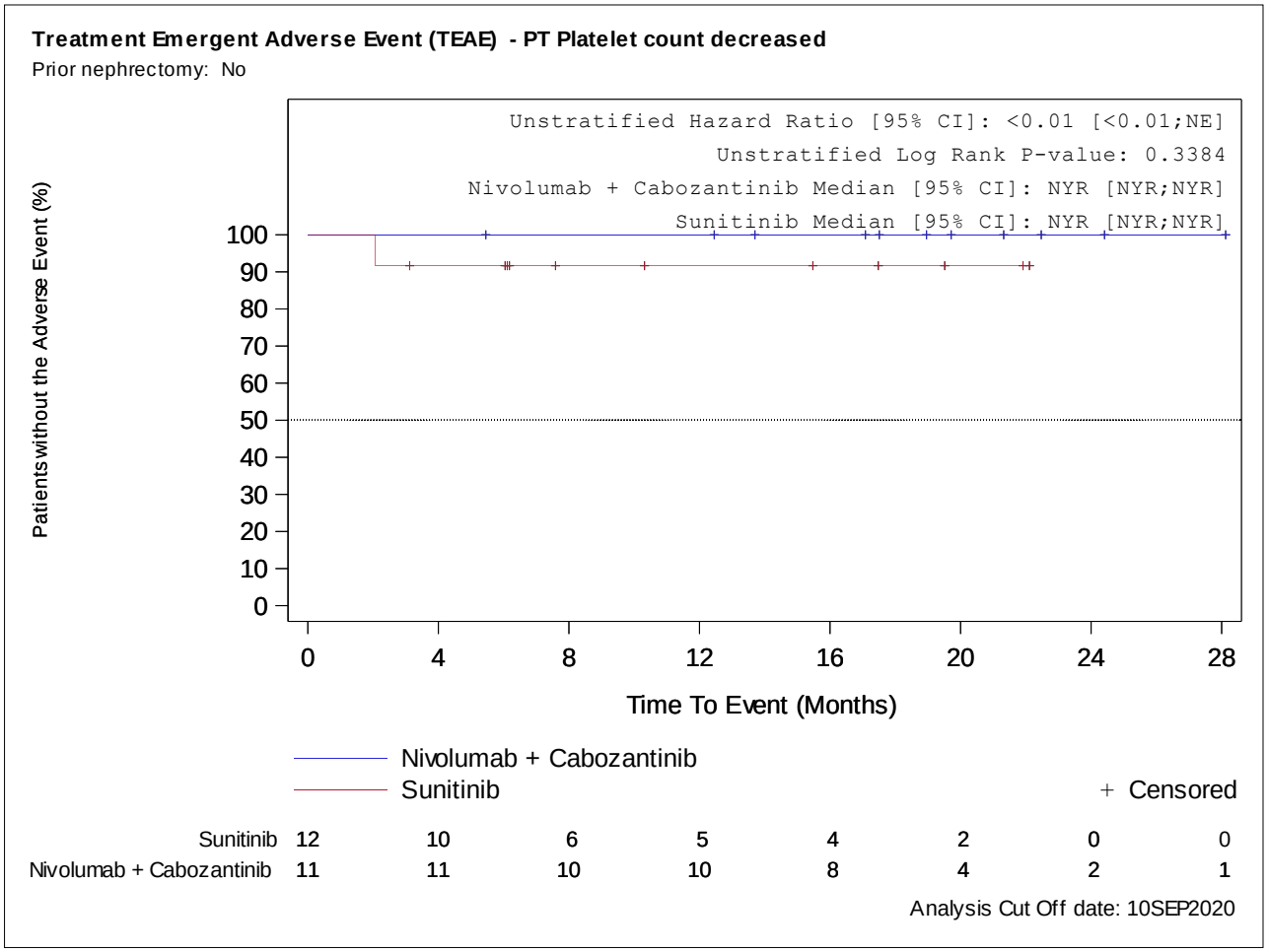
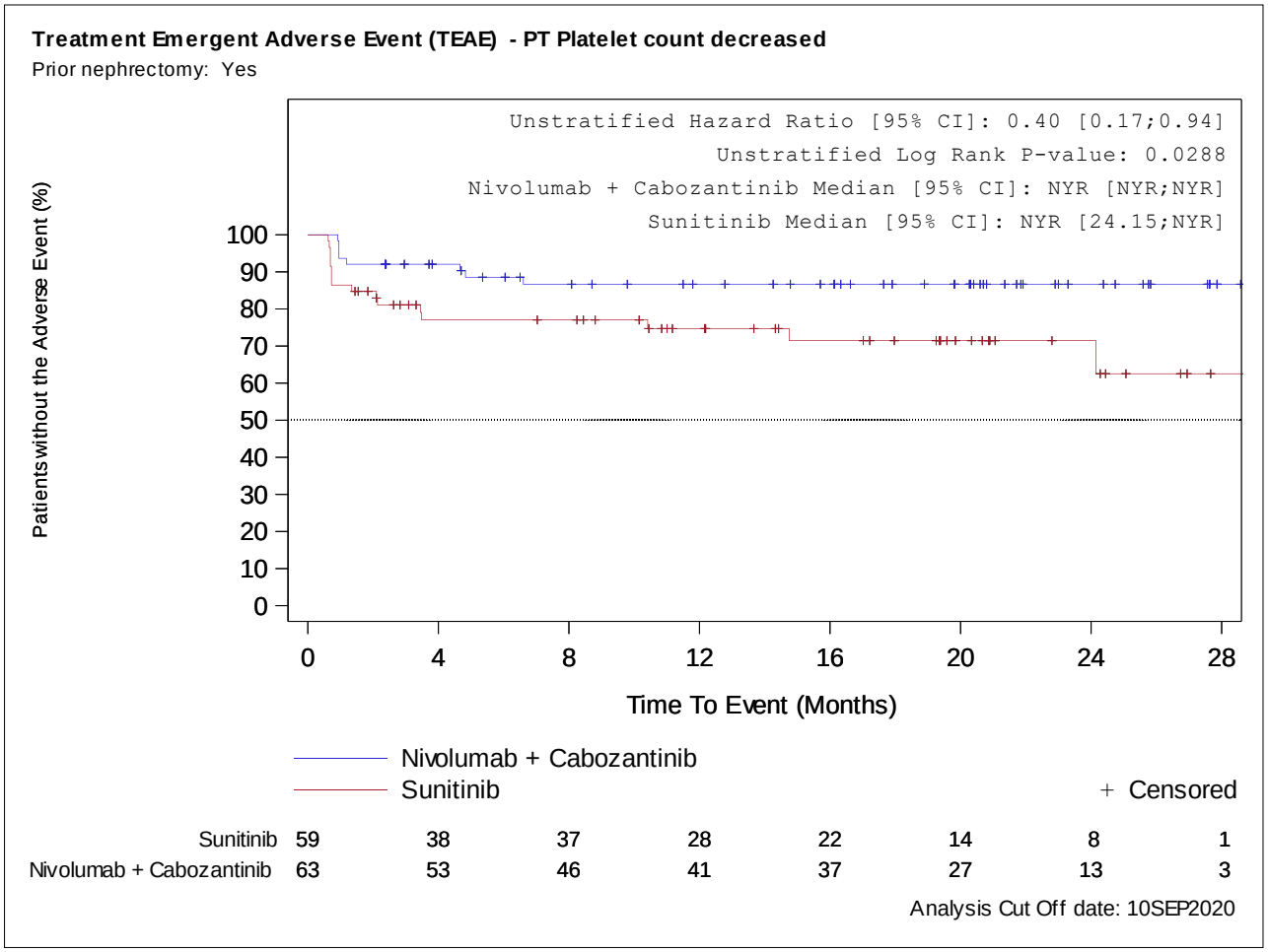
FIGURE 5.9.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:57:39

FIGURE 5.9.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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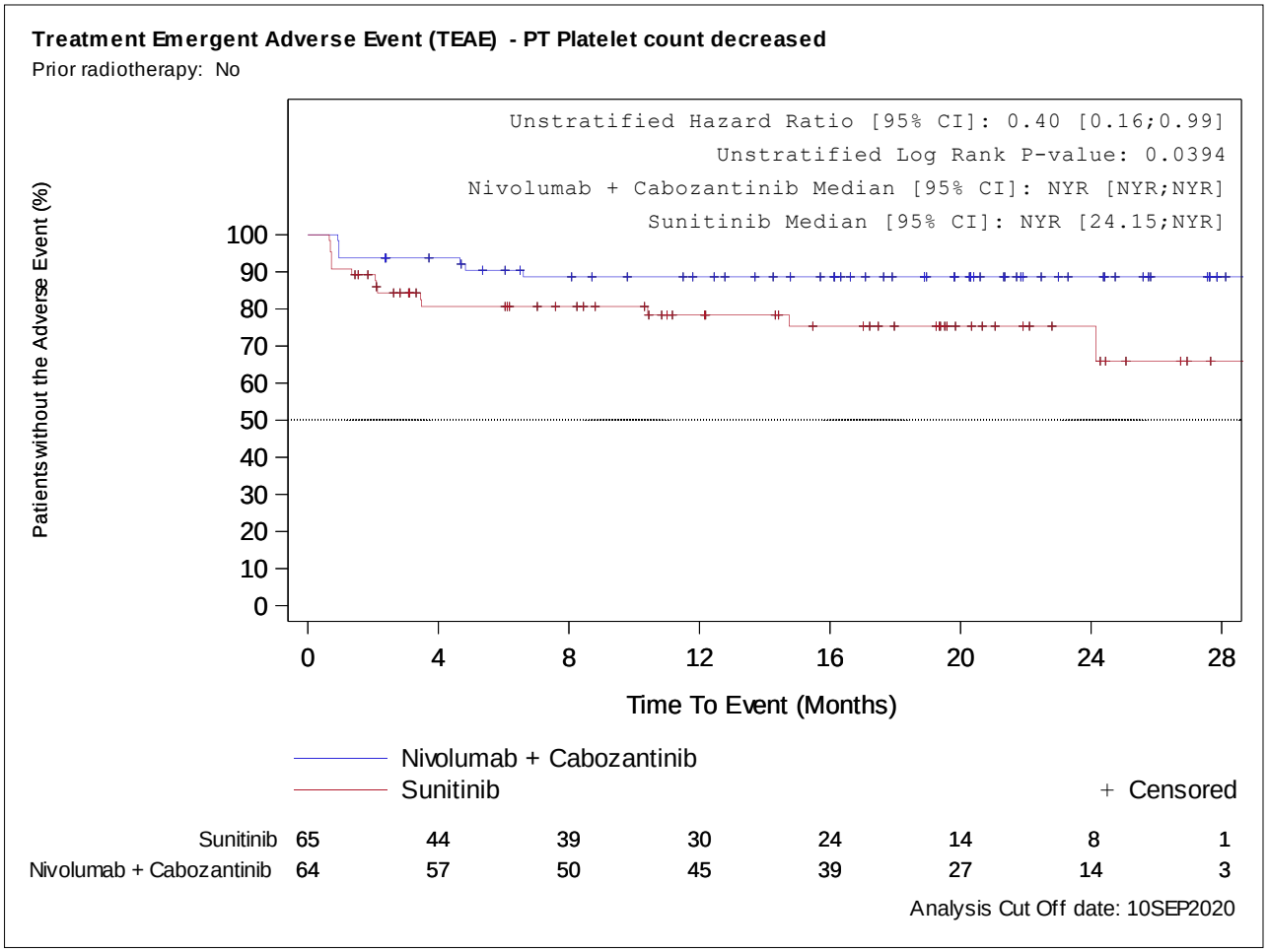
FIGURE 5.9.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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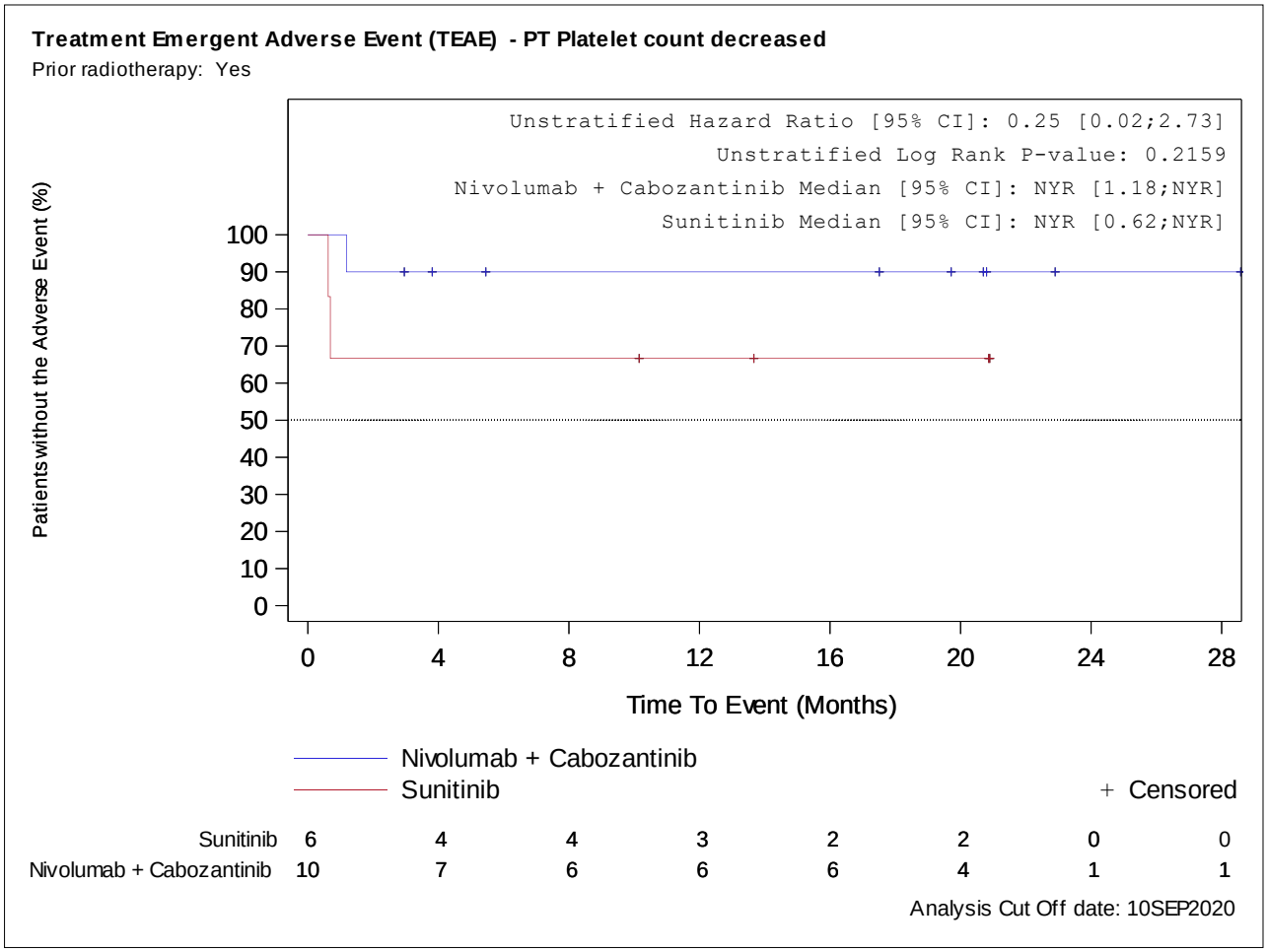
FIGURE 5.9.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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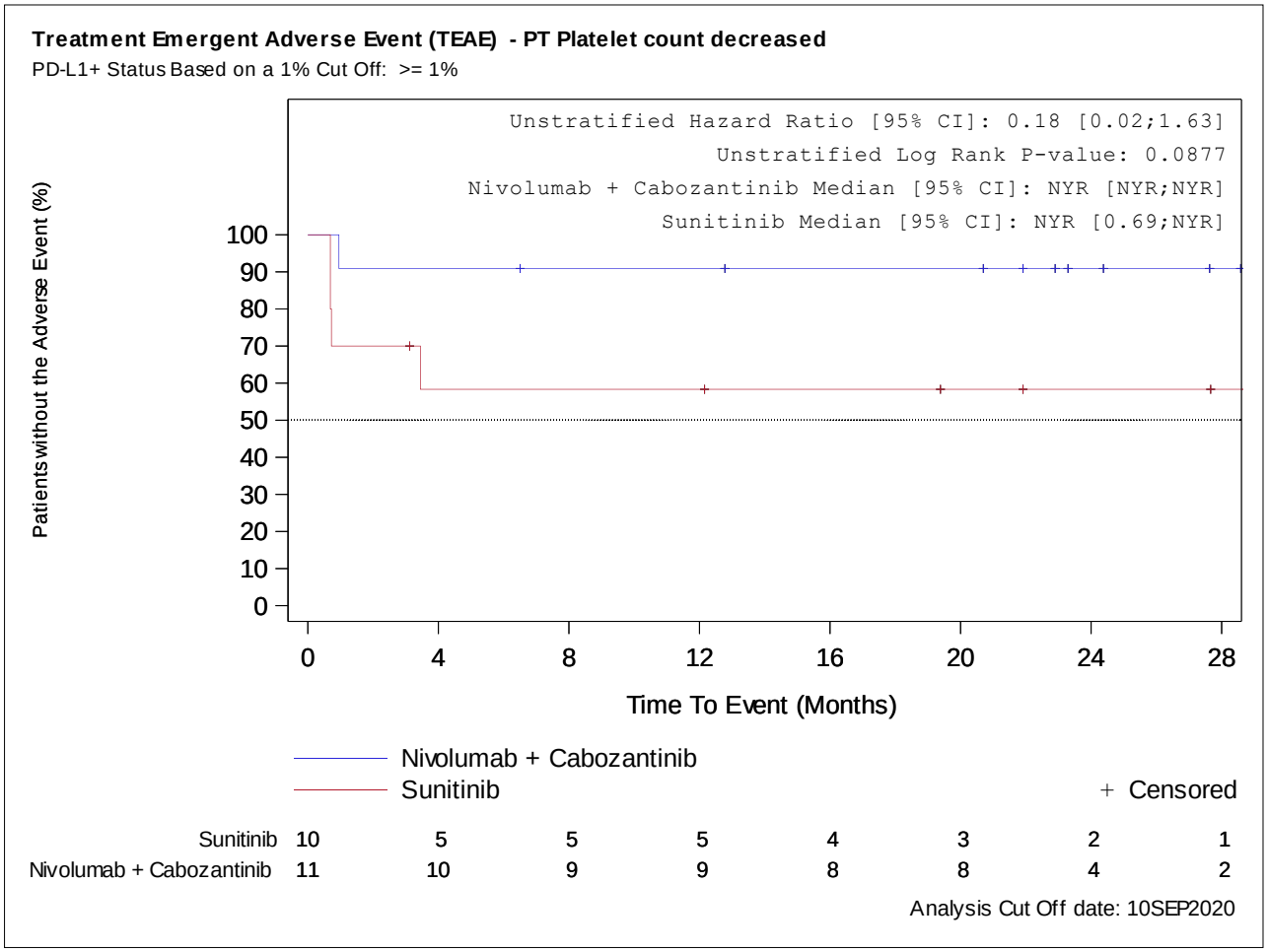
FIGURE 5.9.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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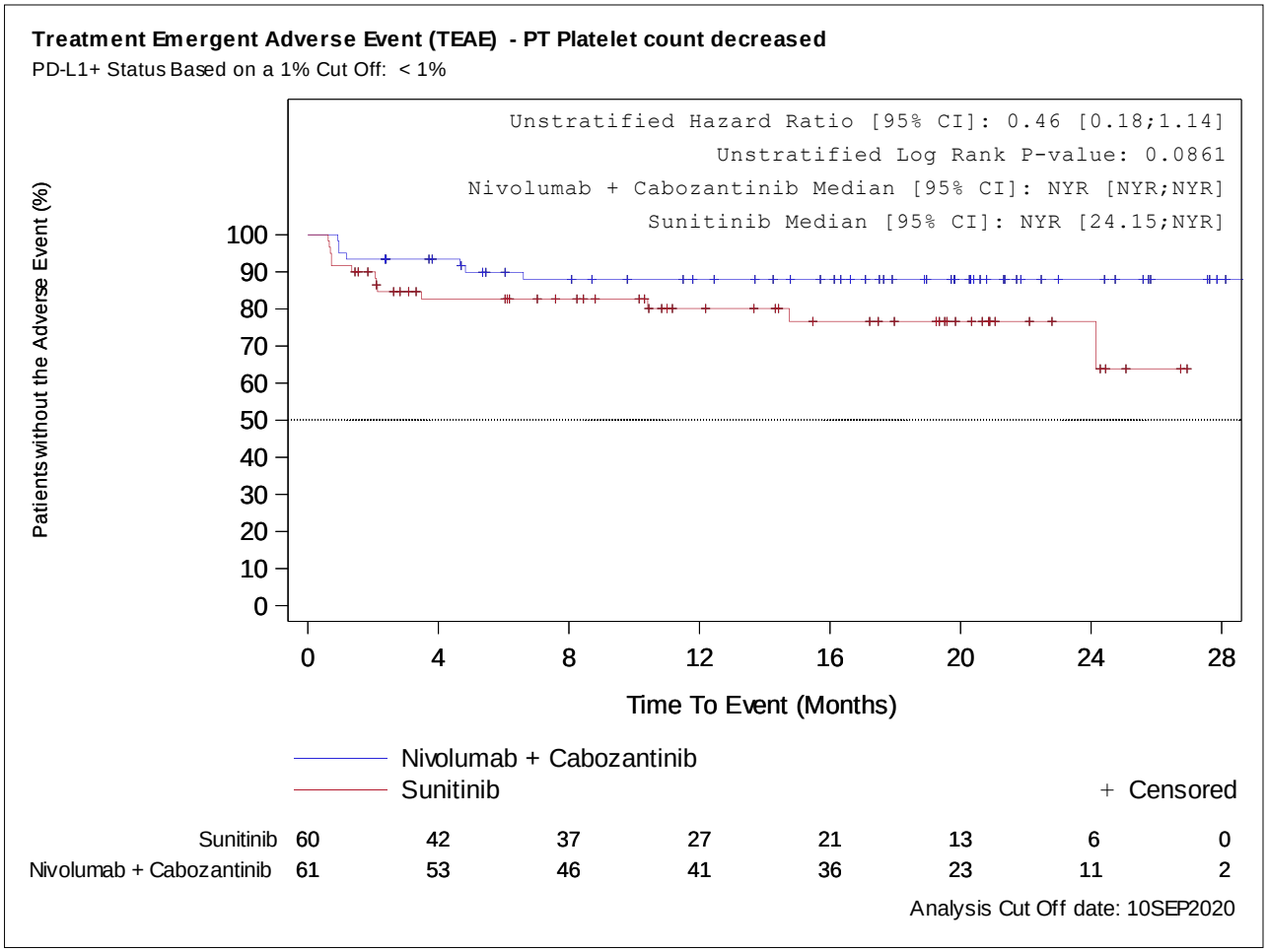
FIGURE 5.9.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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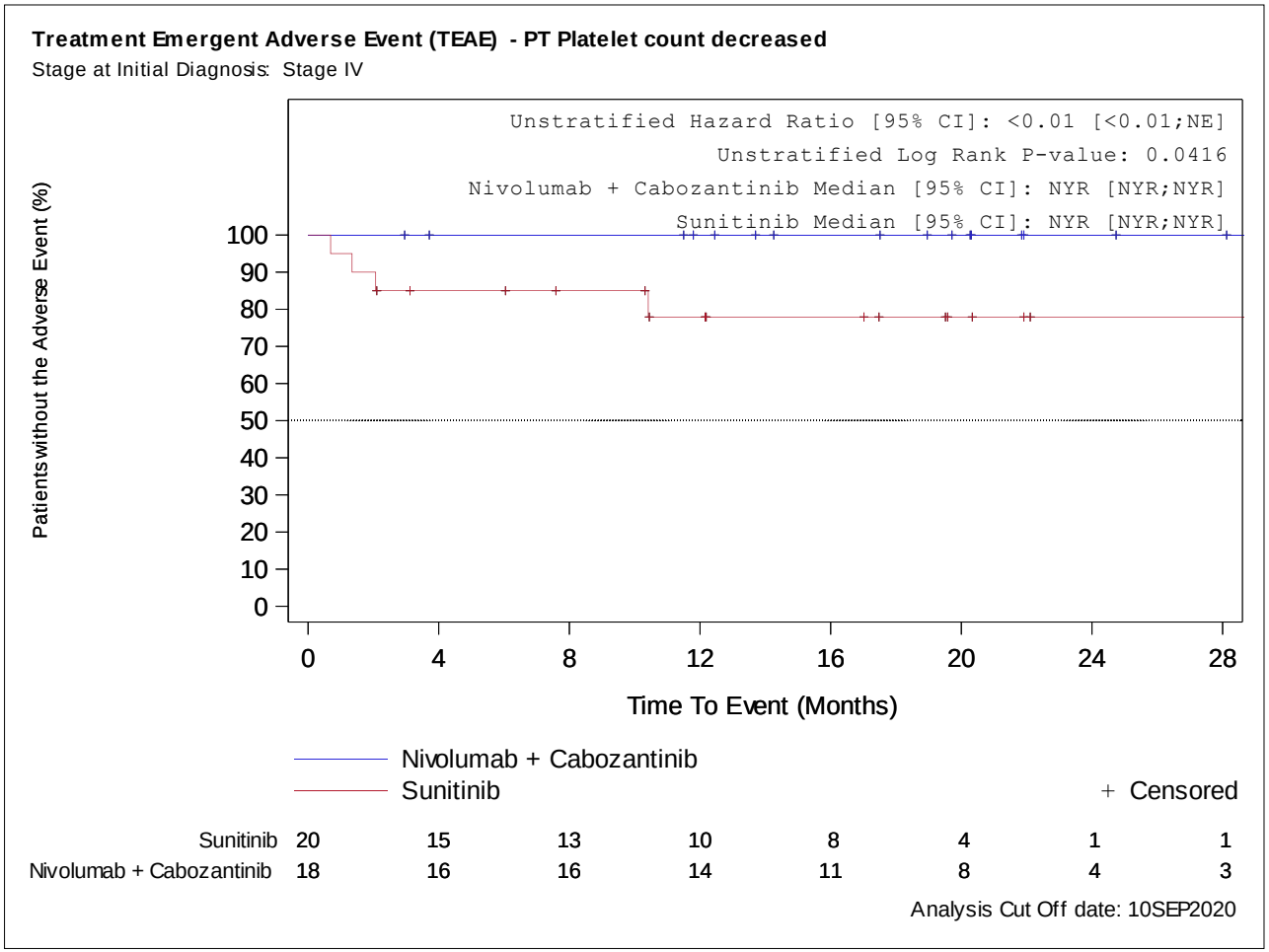
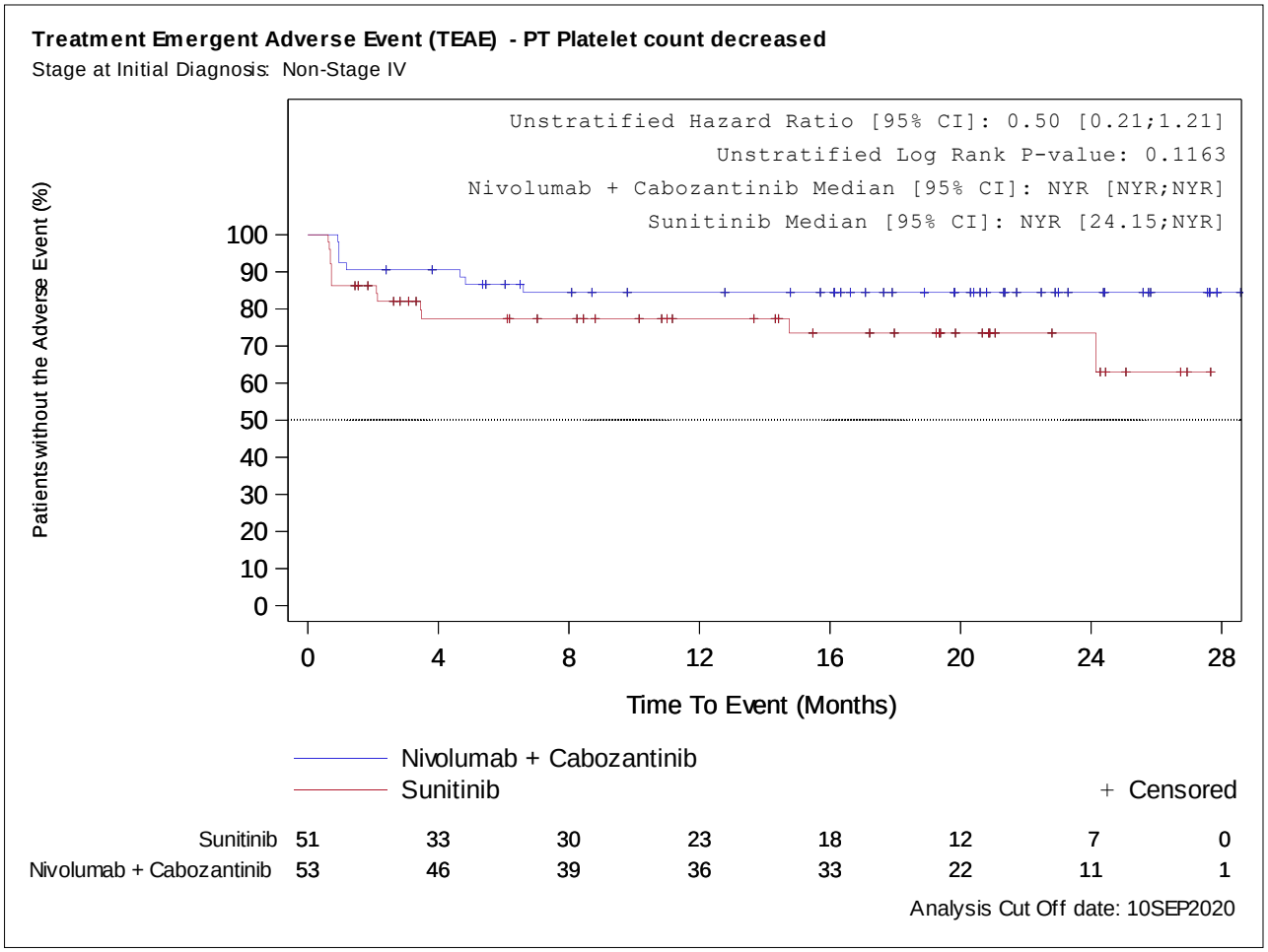
FIGURE 5.9.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



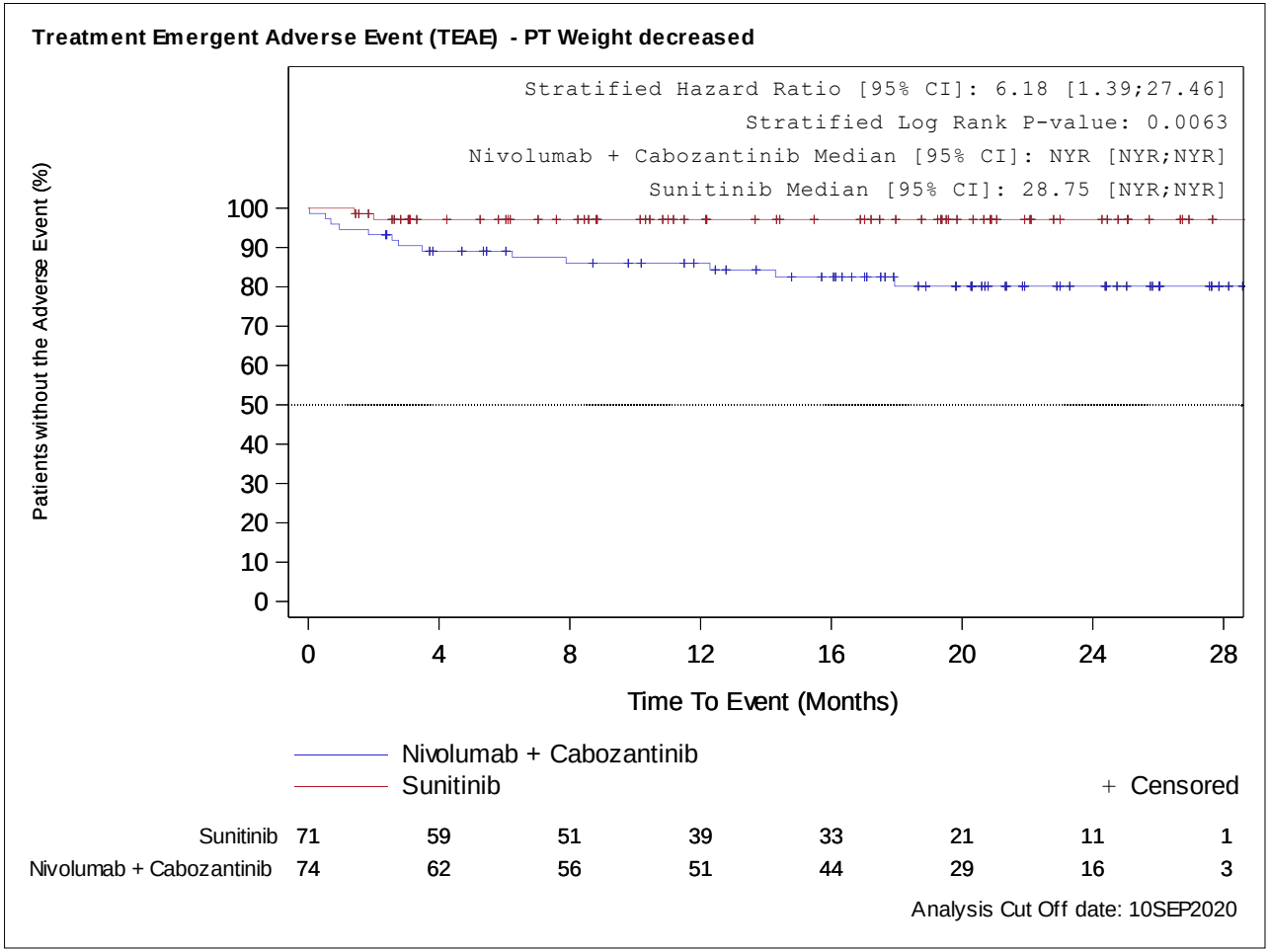

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:58:37

FIGURE 5.9.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 16:58:44

FIGURE 5.10.1: Treatment Emergent Adverse Event (TEAE) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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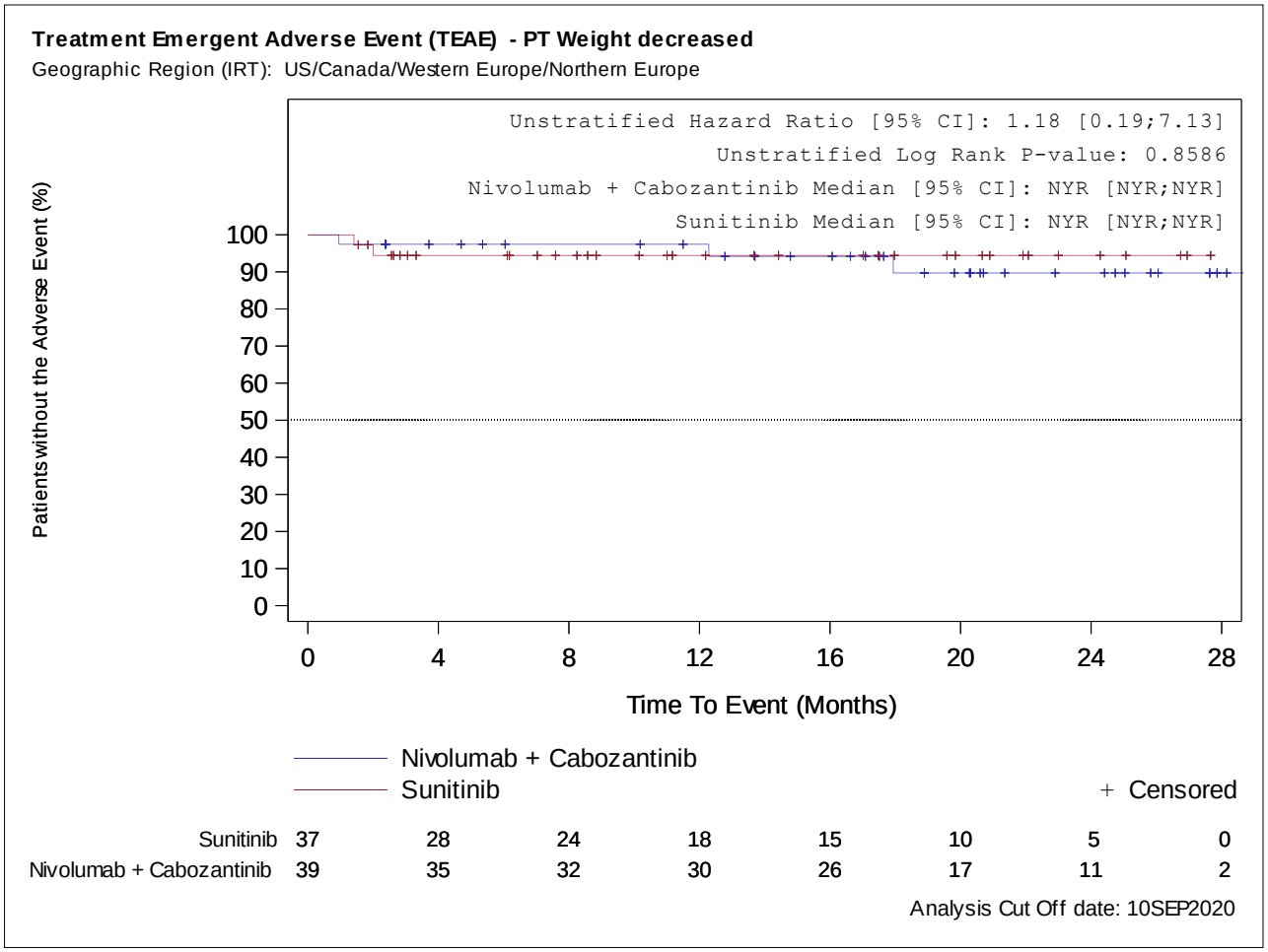
FIGURE 5.10.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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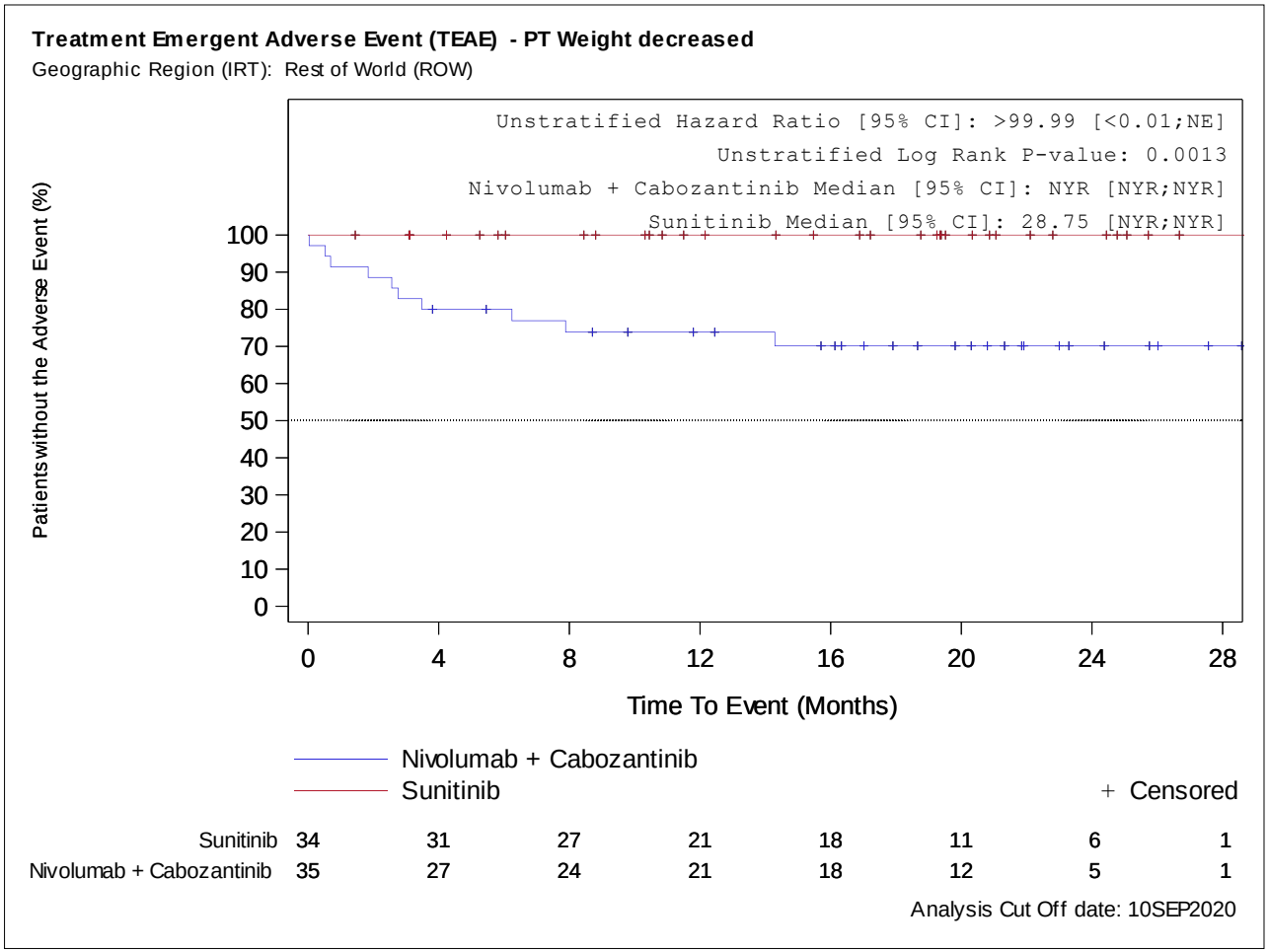
FIGURE 5.10.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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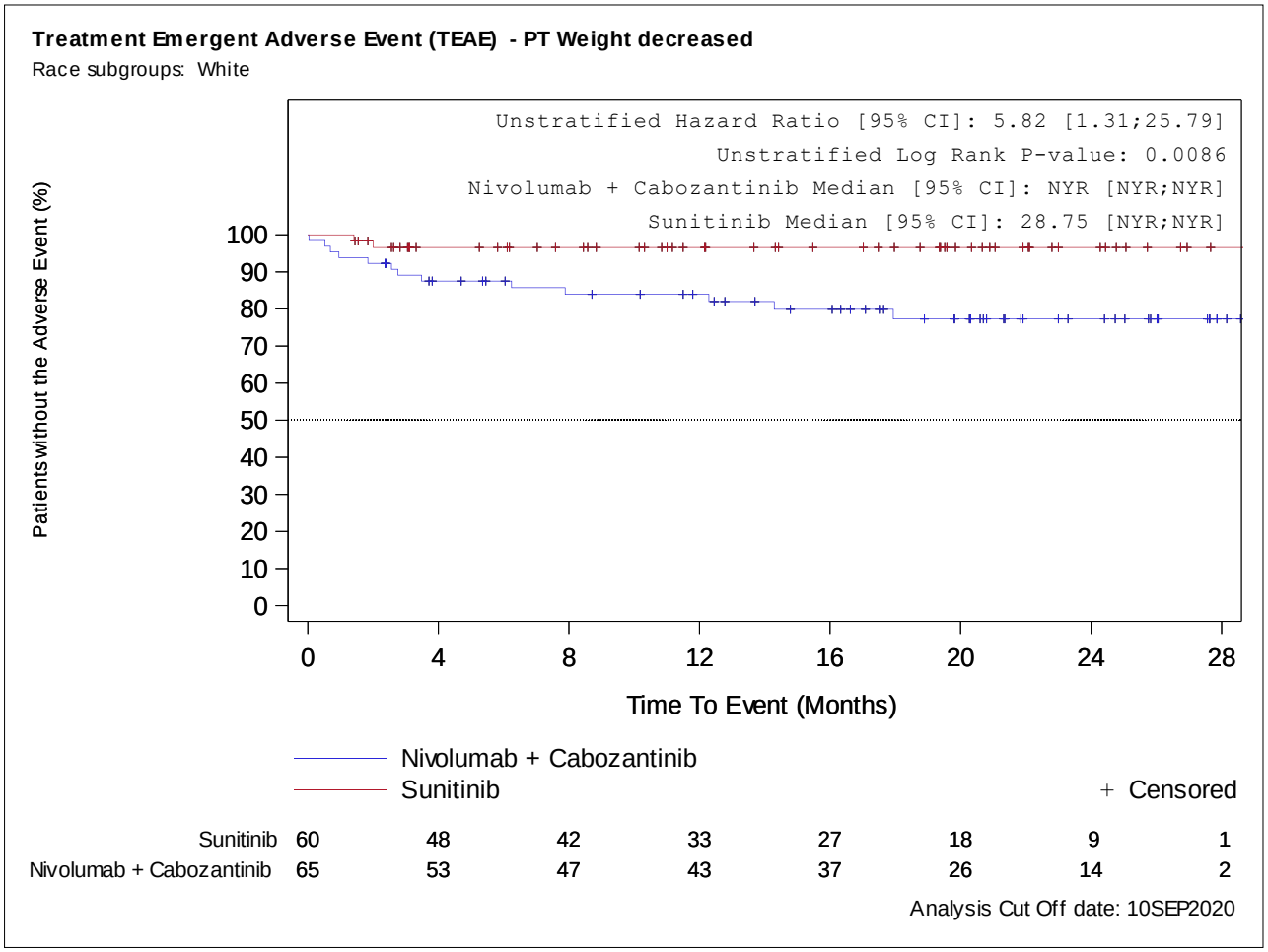
FIGURE 5.10.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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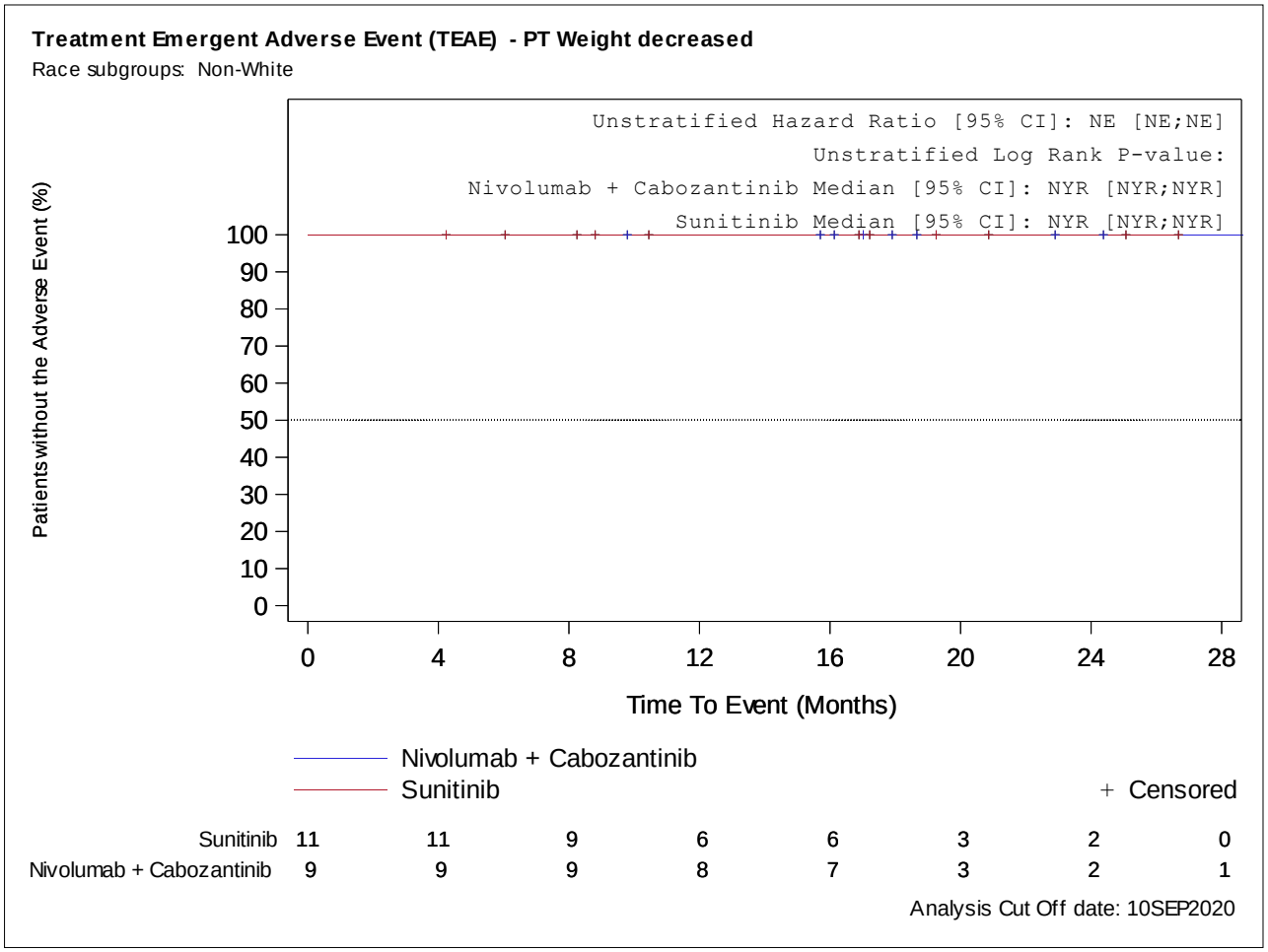
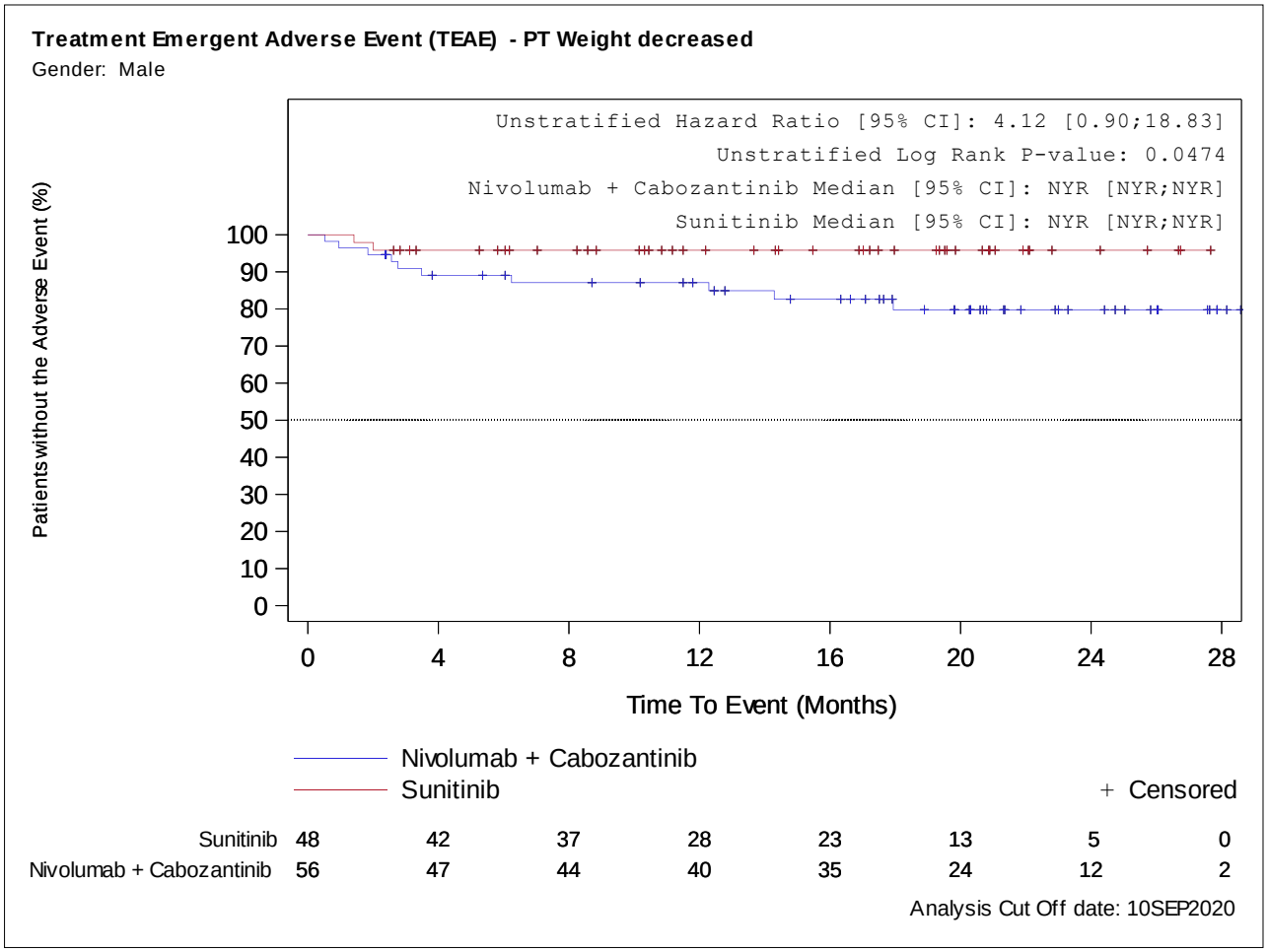
FIGURE 5.10.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



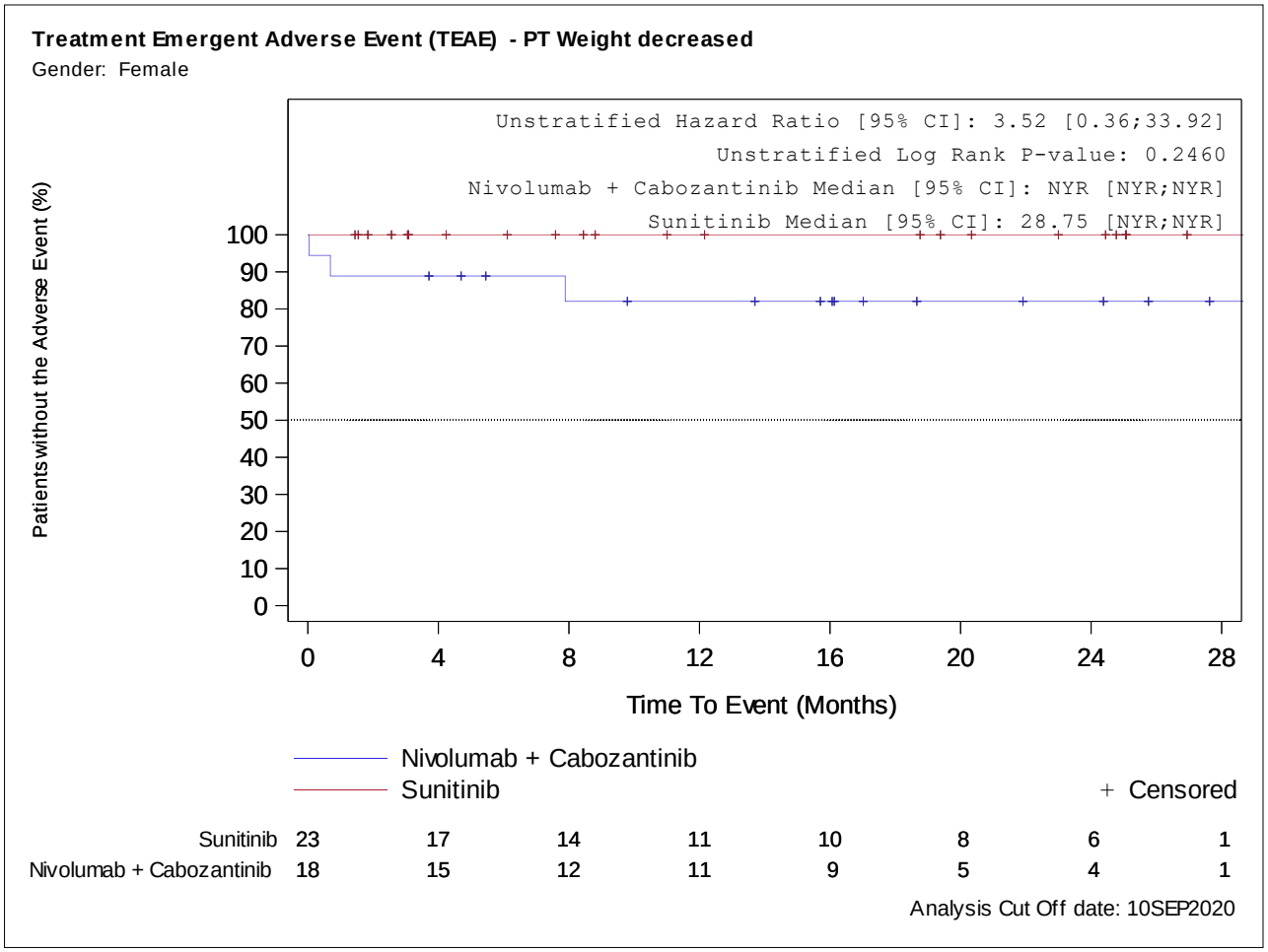

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:01:55

FIGURE 5.10.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



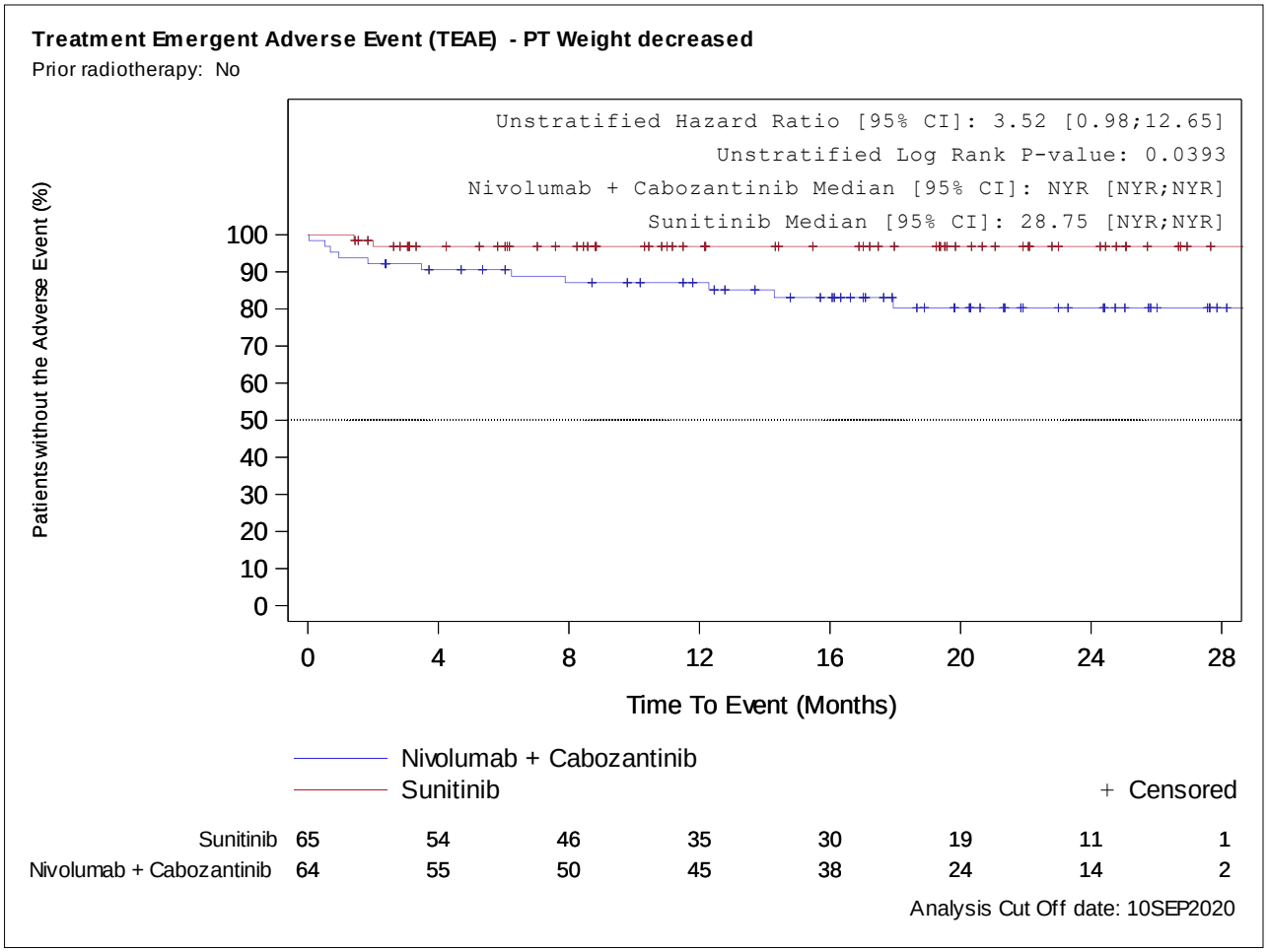

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:02:00

FIGURE 5.10.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:02:06

FIGURE 5.10.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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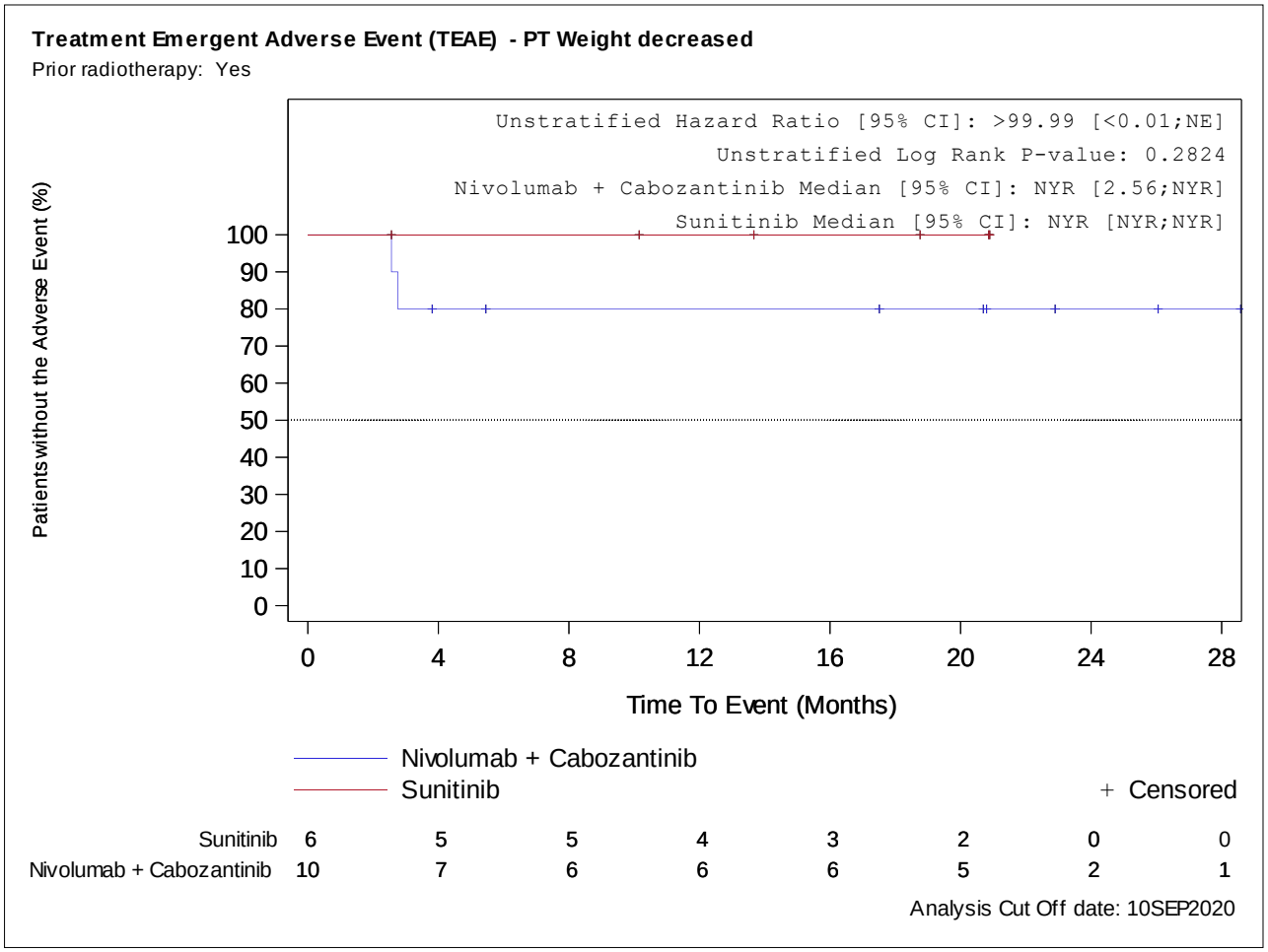
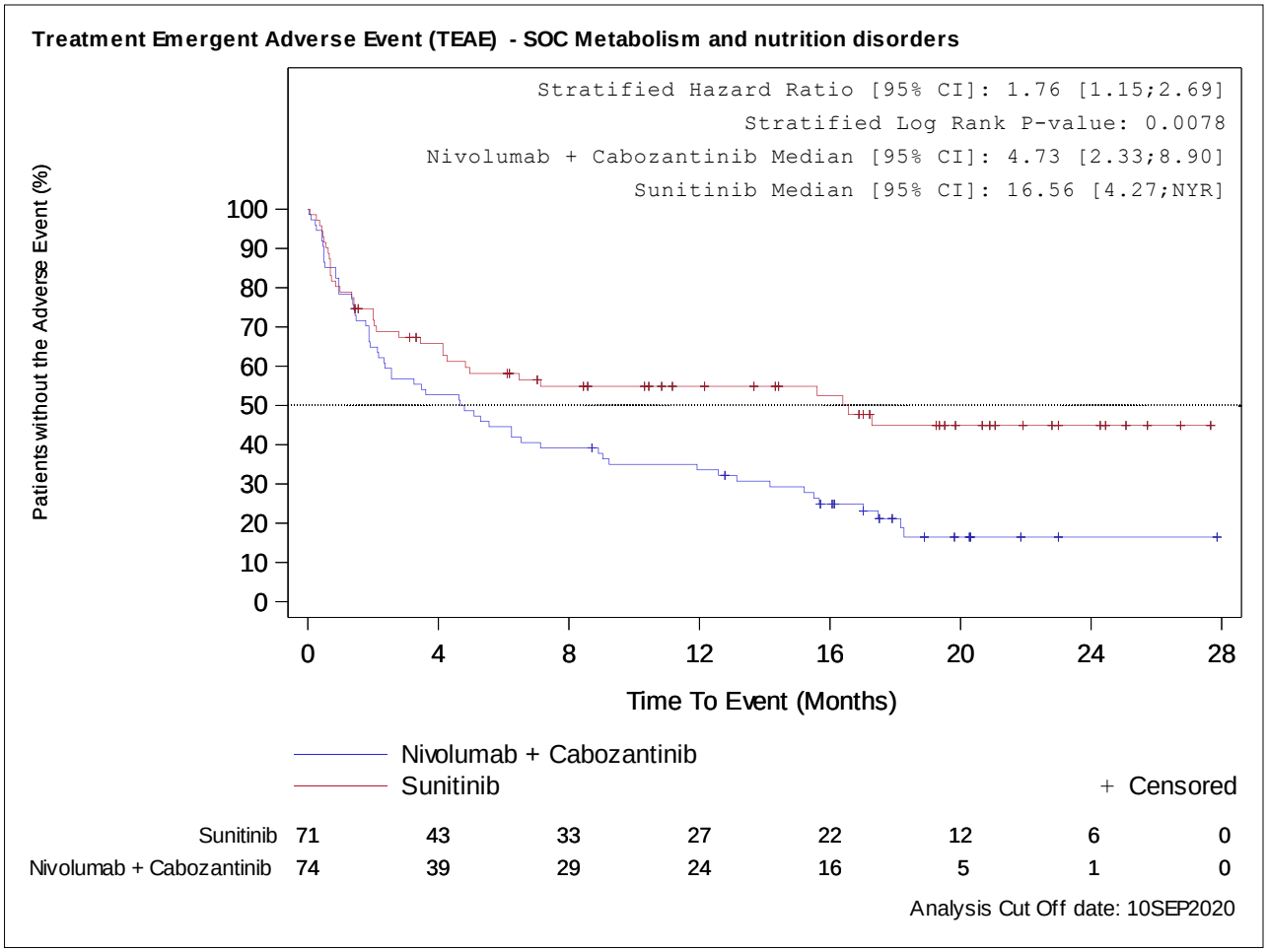
FIGURE 5.10.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:03:16

FIGURE 5.11.1: Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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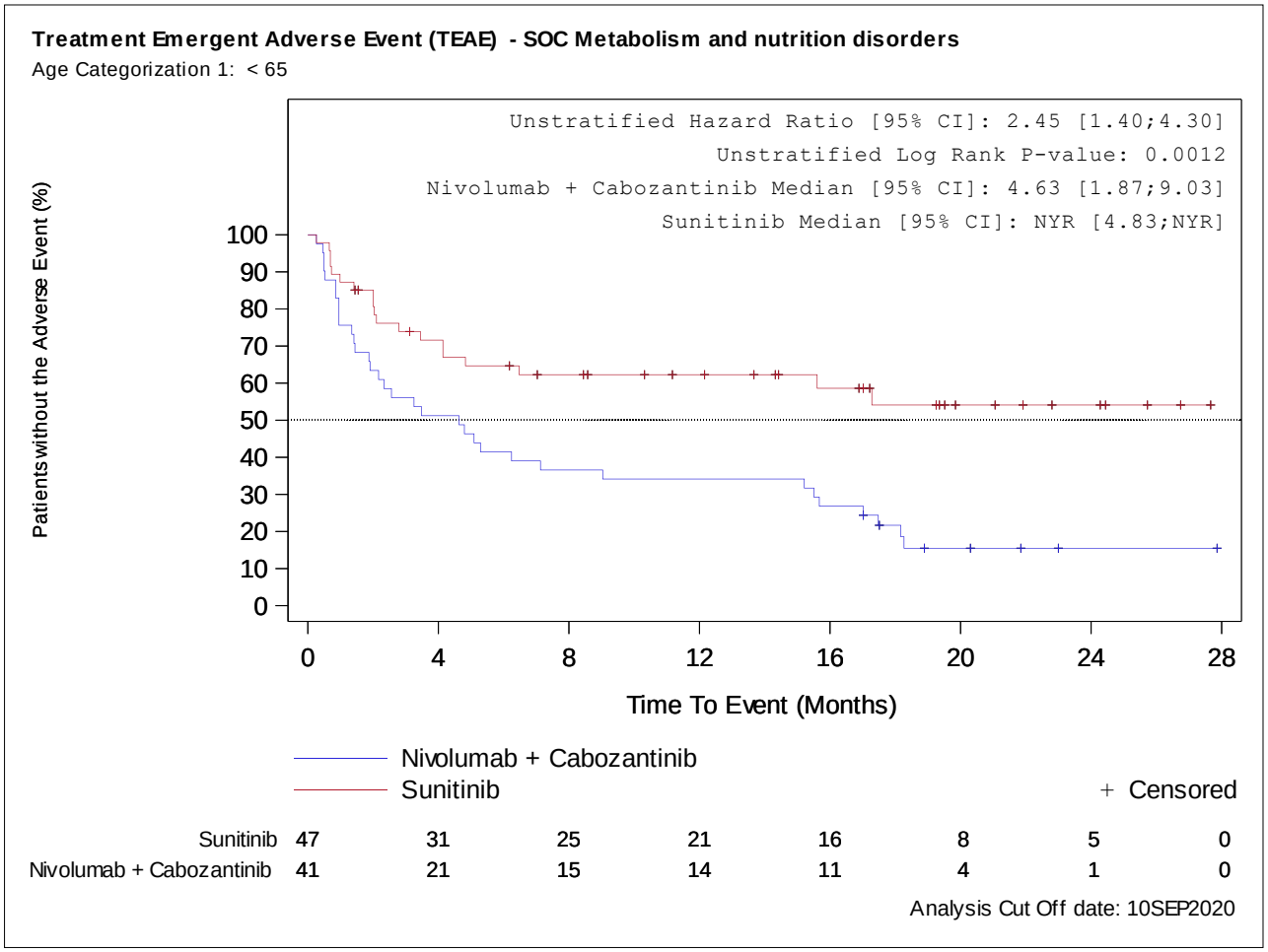
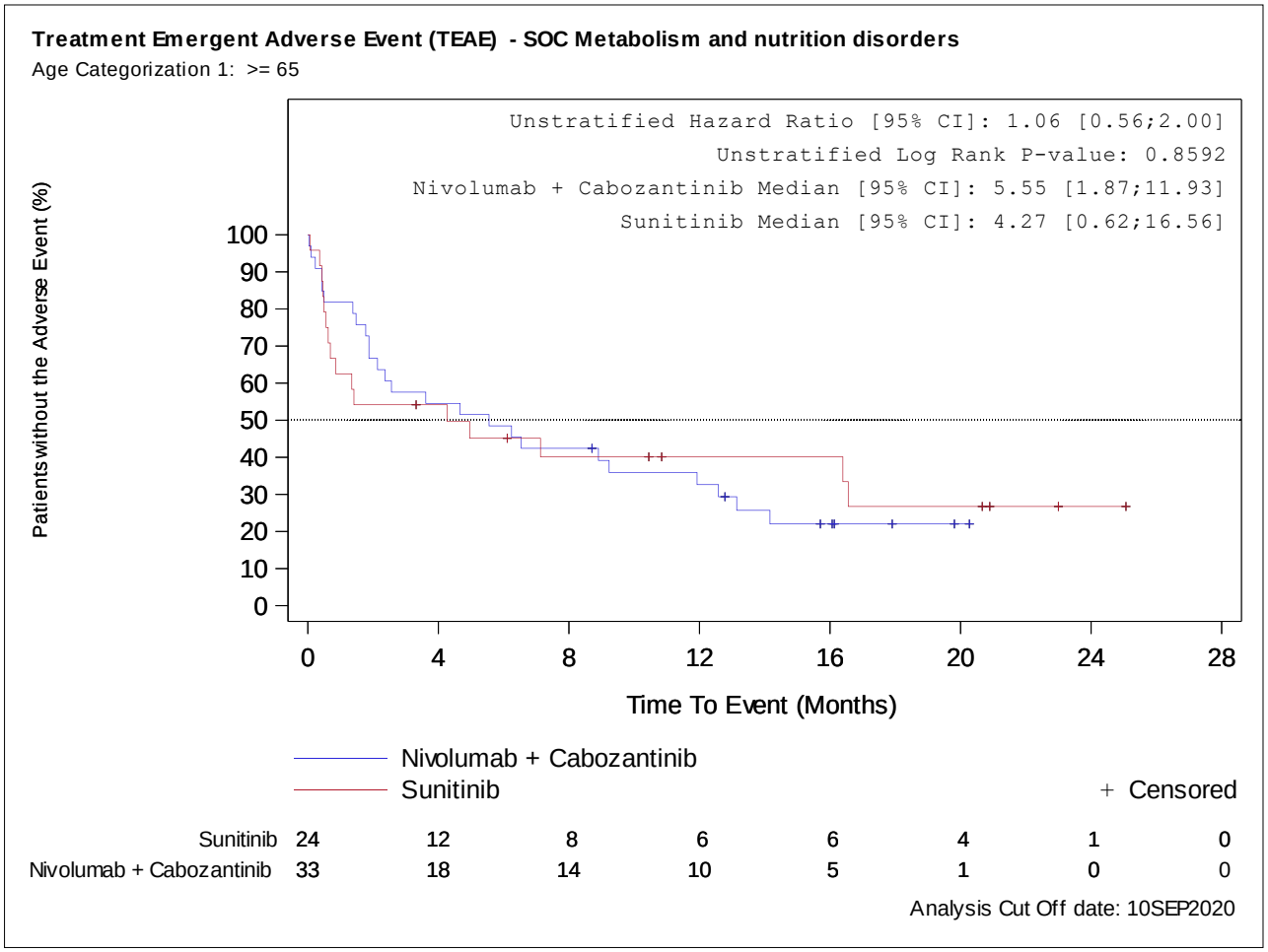
FIGURE 5.11.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:07:02

FIGURE 5.11.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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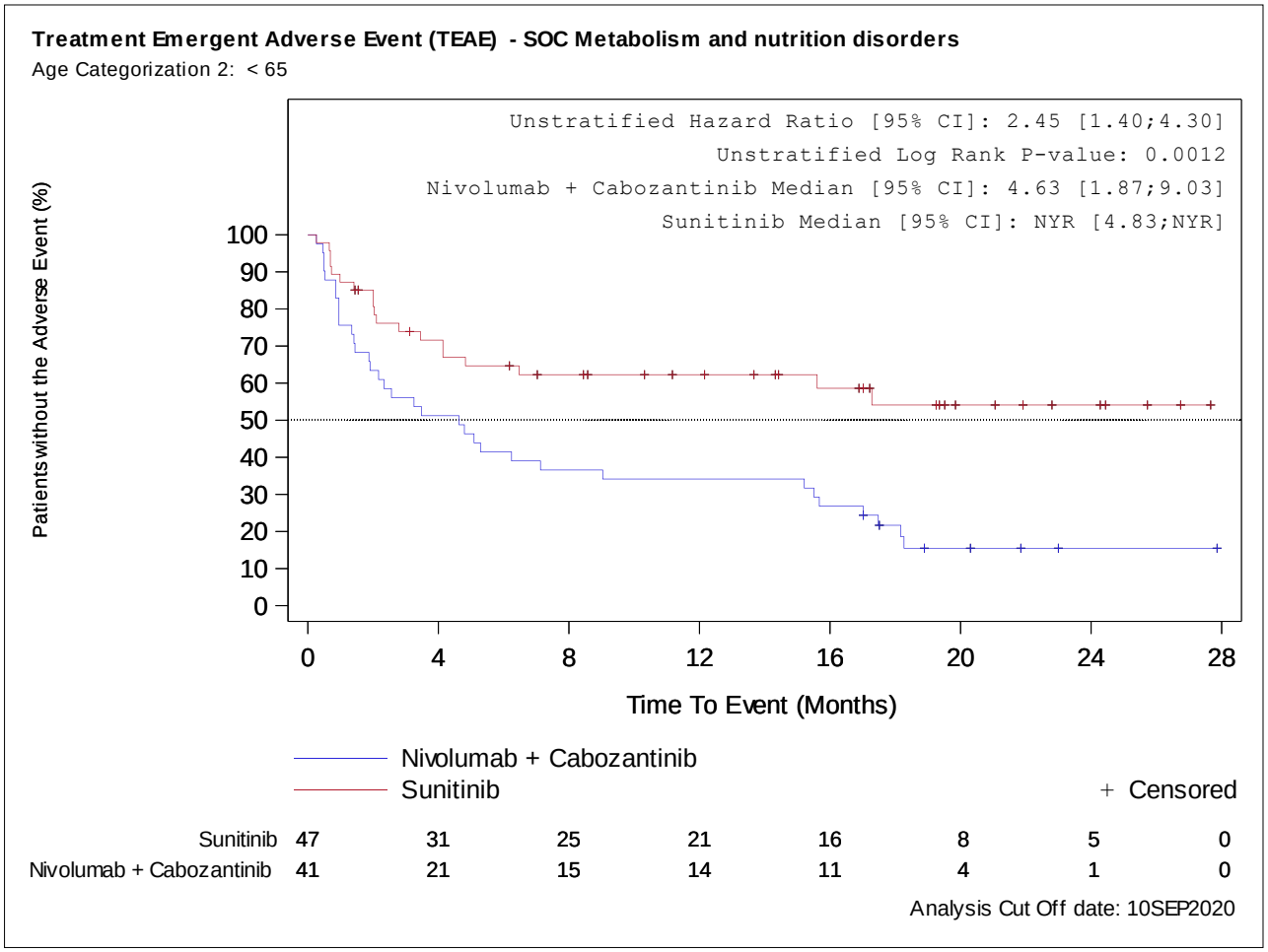
FIGURE 5.11.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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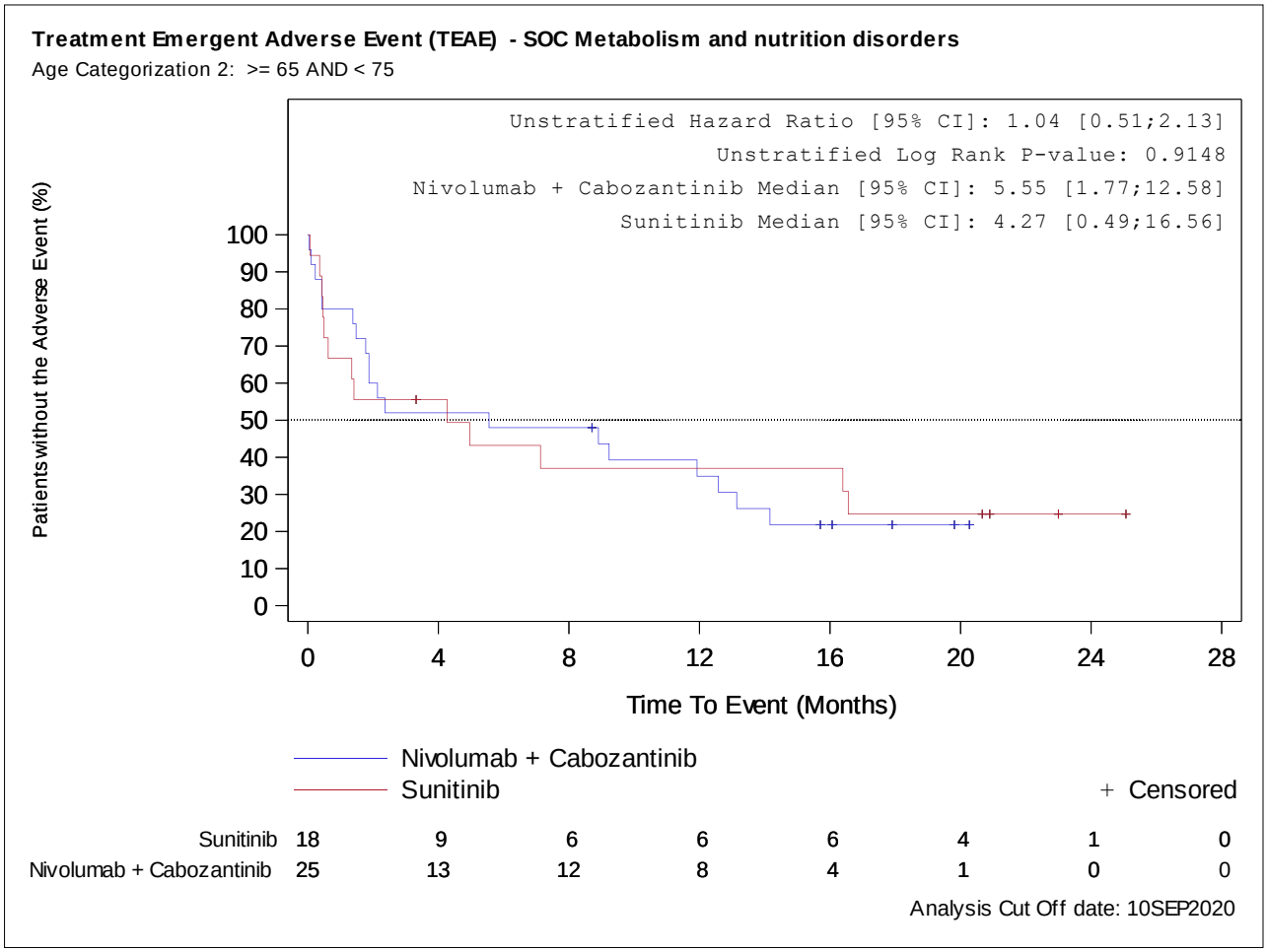
FIGURE 5.11.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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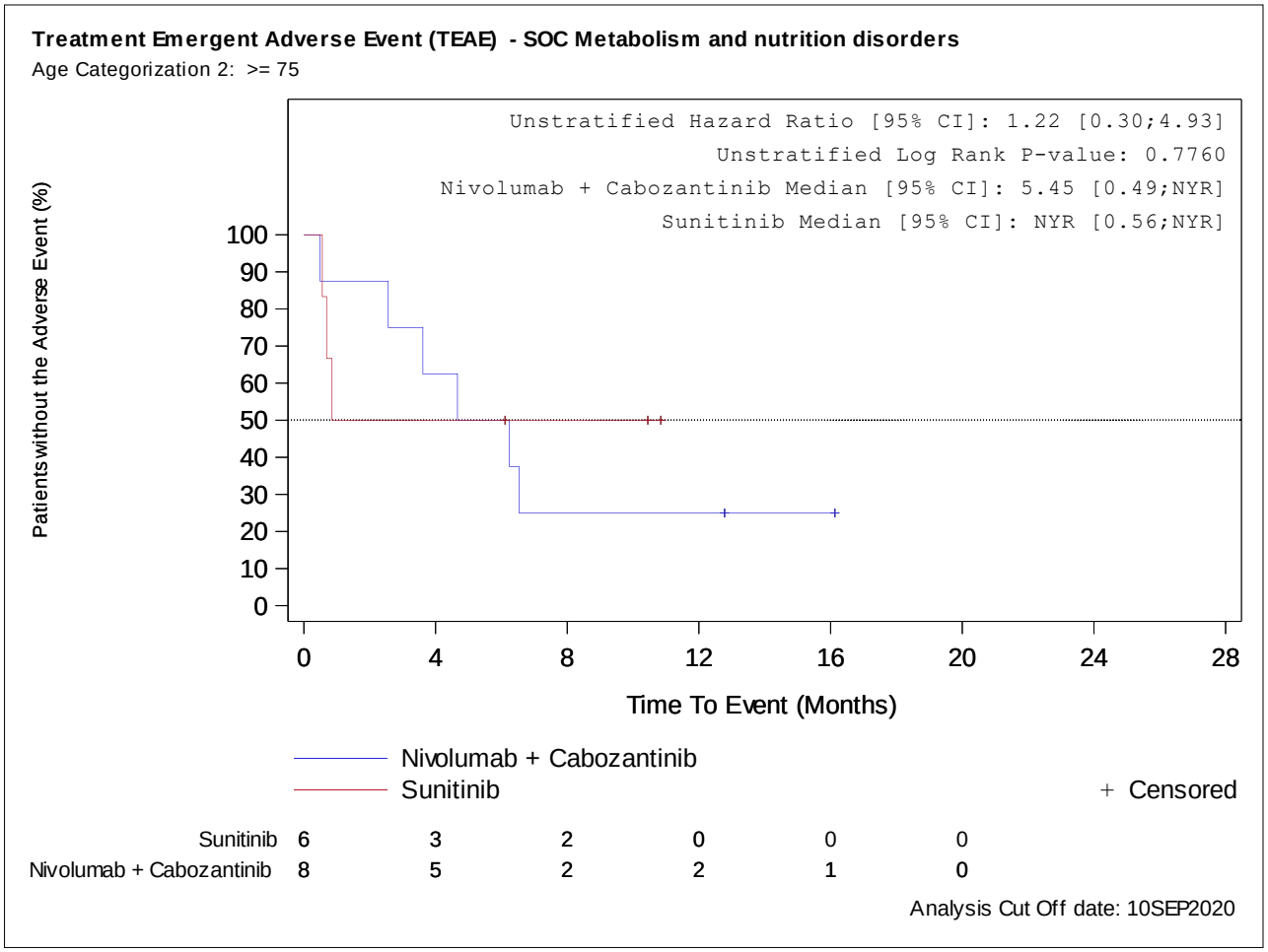
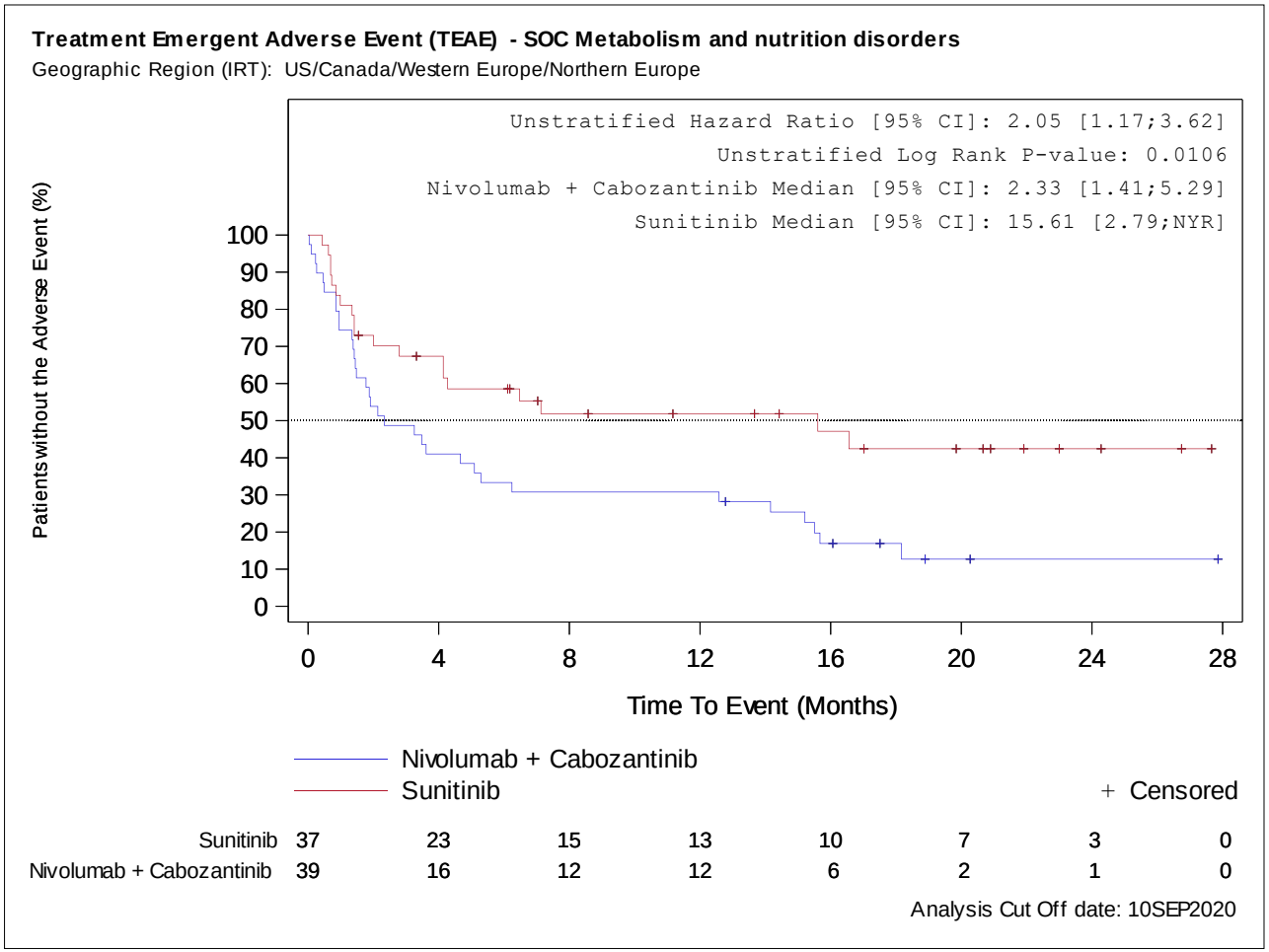
FIGURE 5.11.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



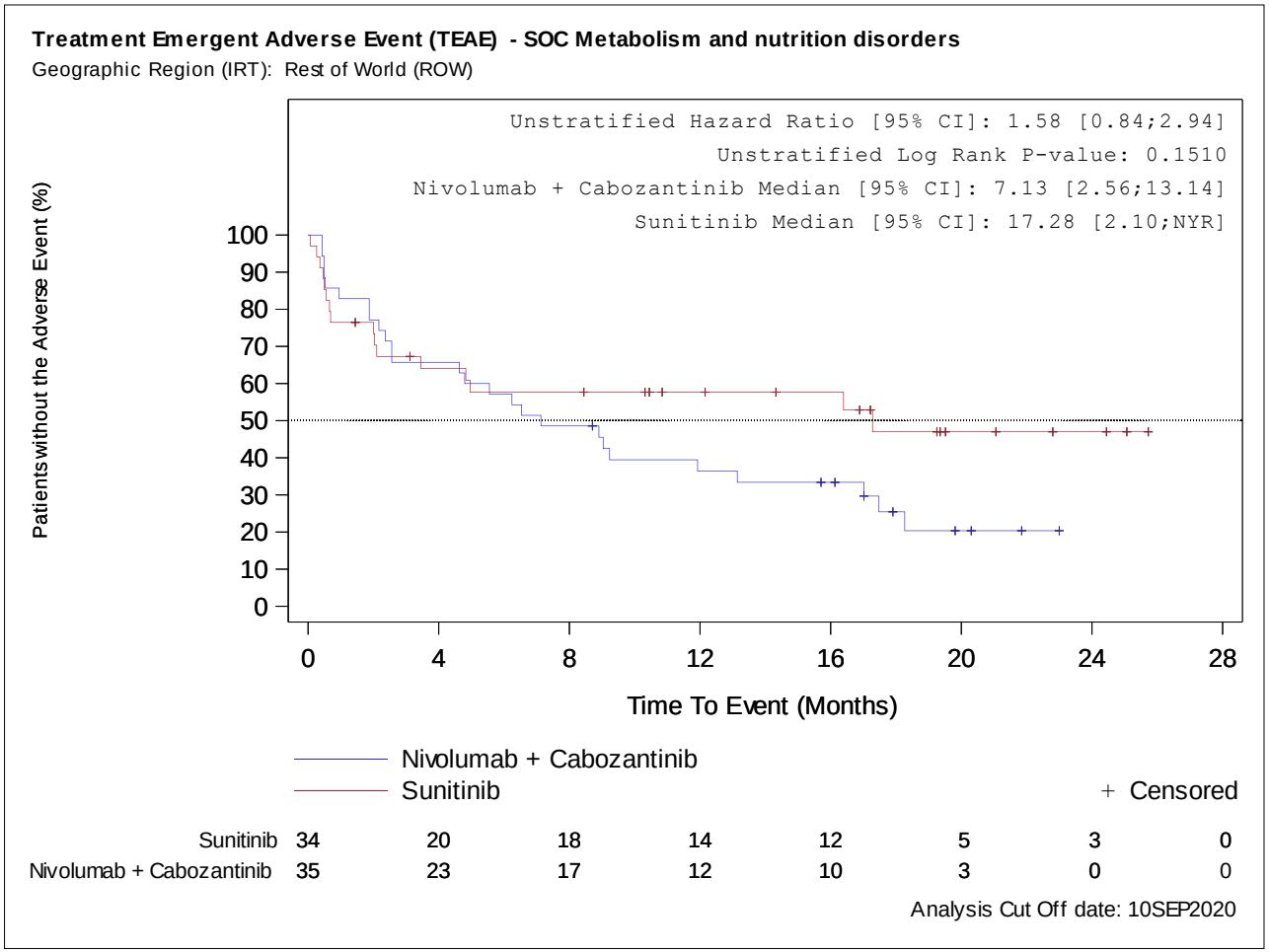

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:07:25

FIGURE 5.11.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:07:31

FIGURE 5.11.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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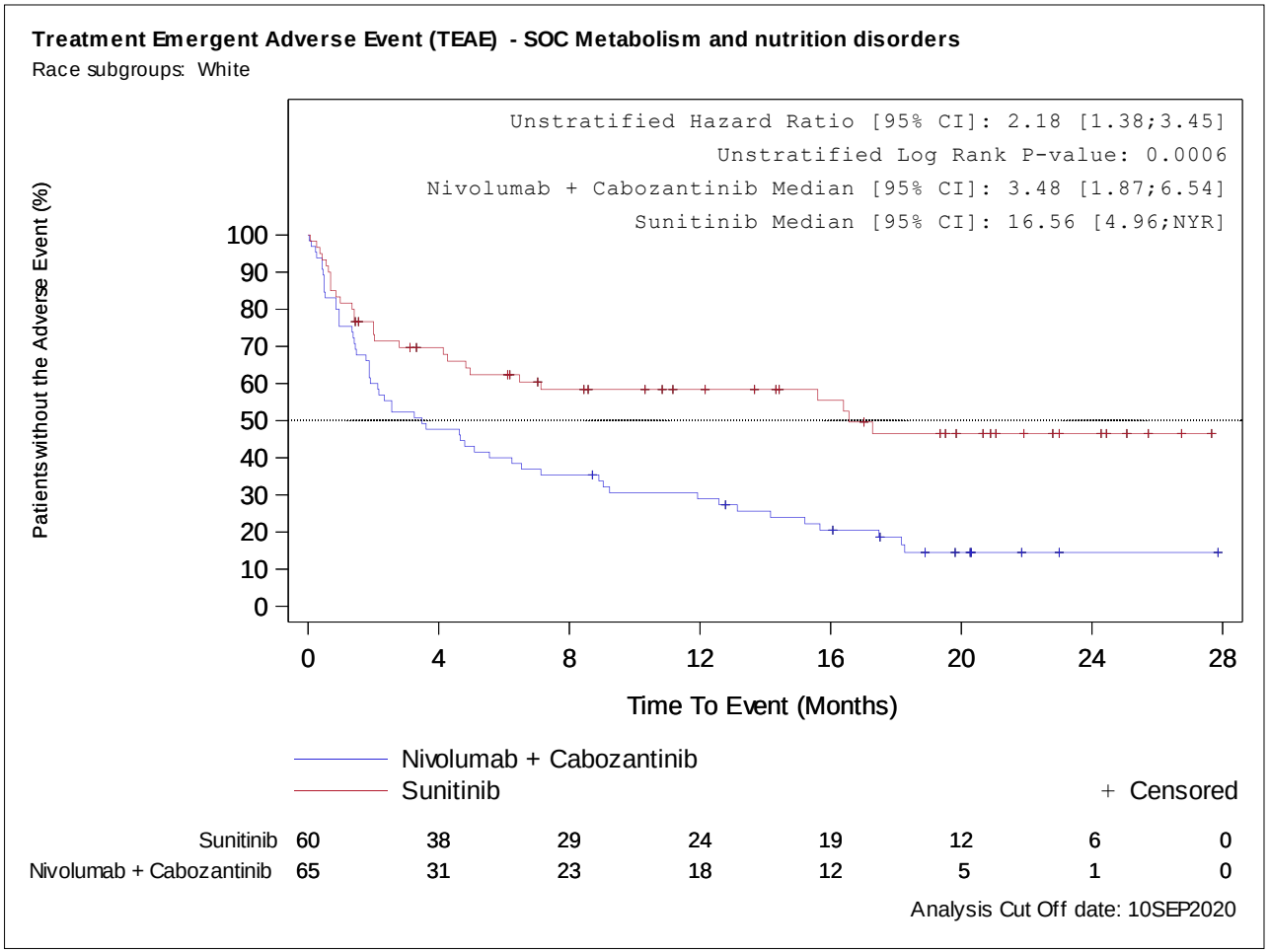
FIGURE 5.11.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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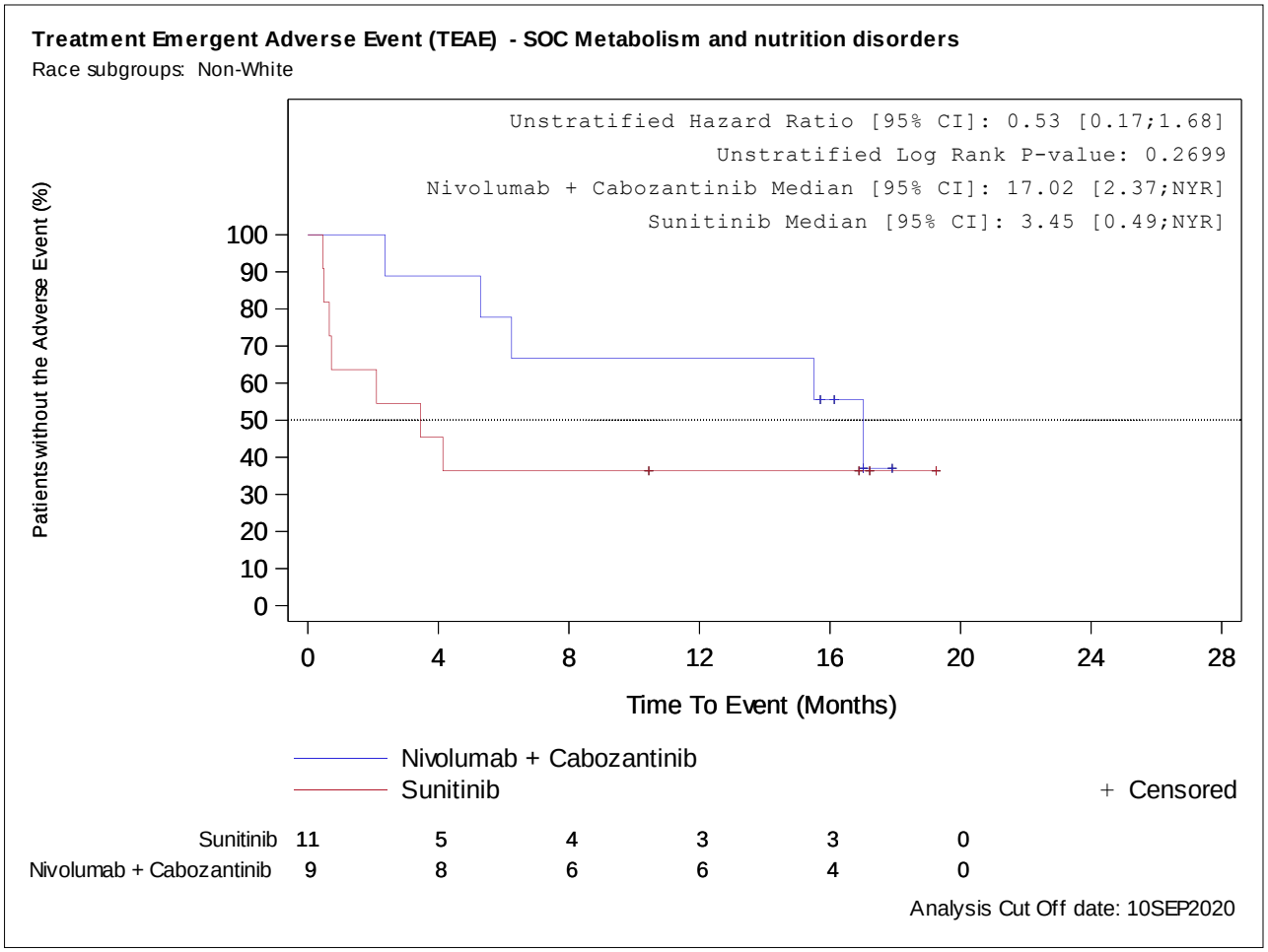
FIGURE 5.11.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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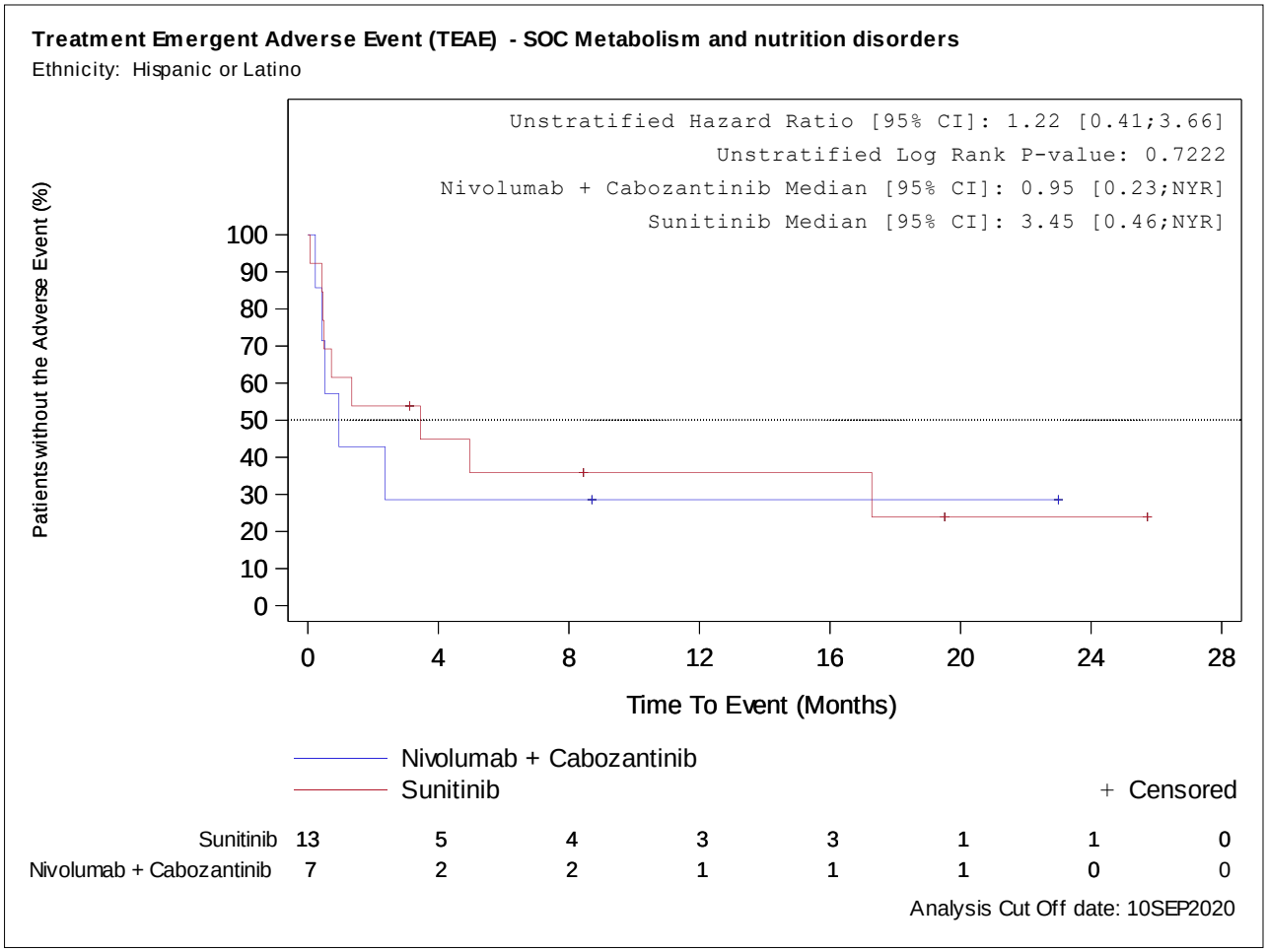
FIGURE 5.11.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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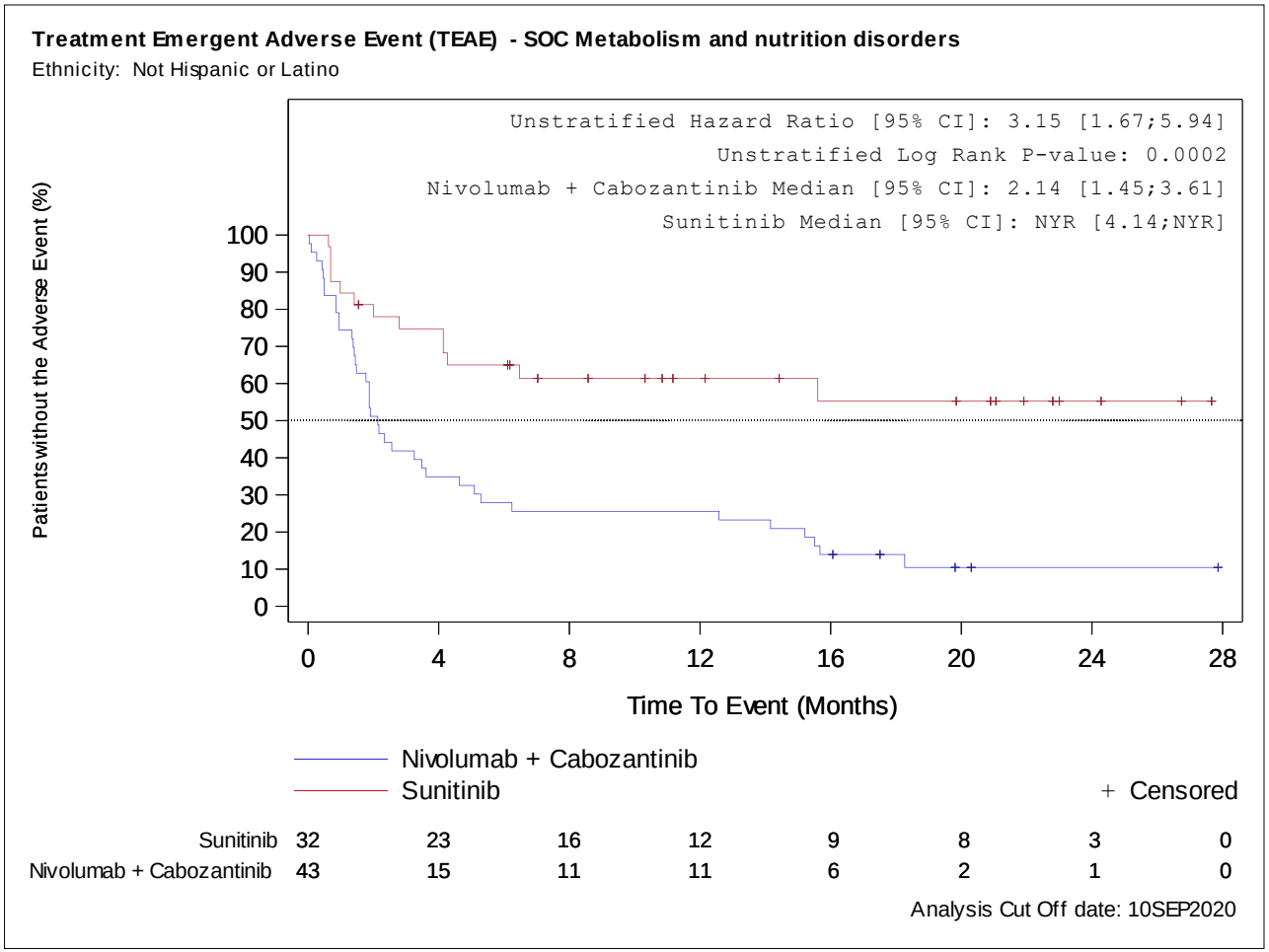
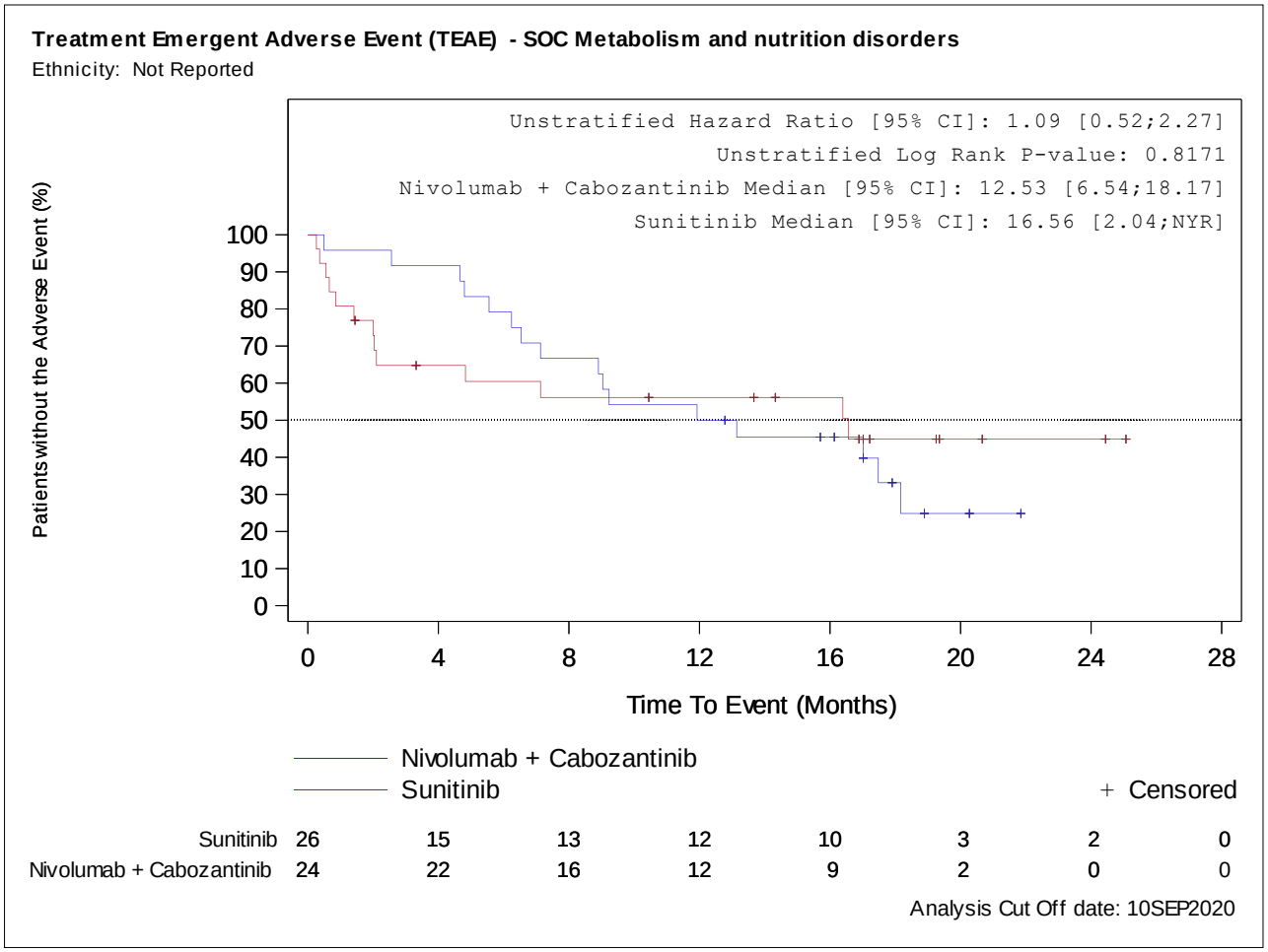
FIGURE 5.11.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



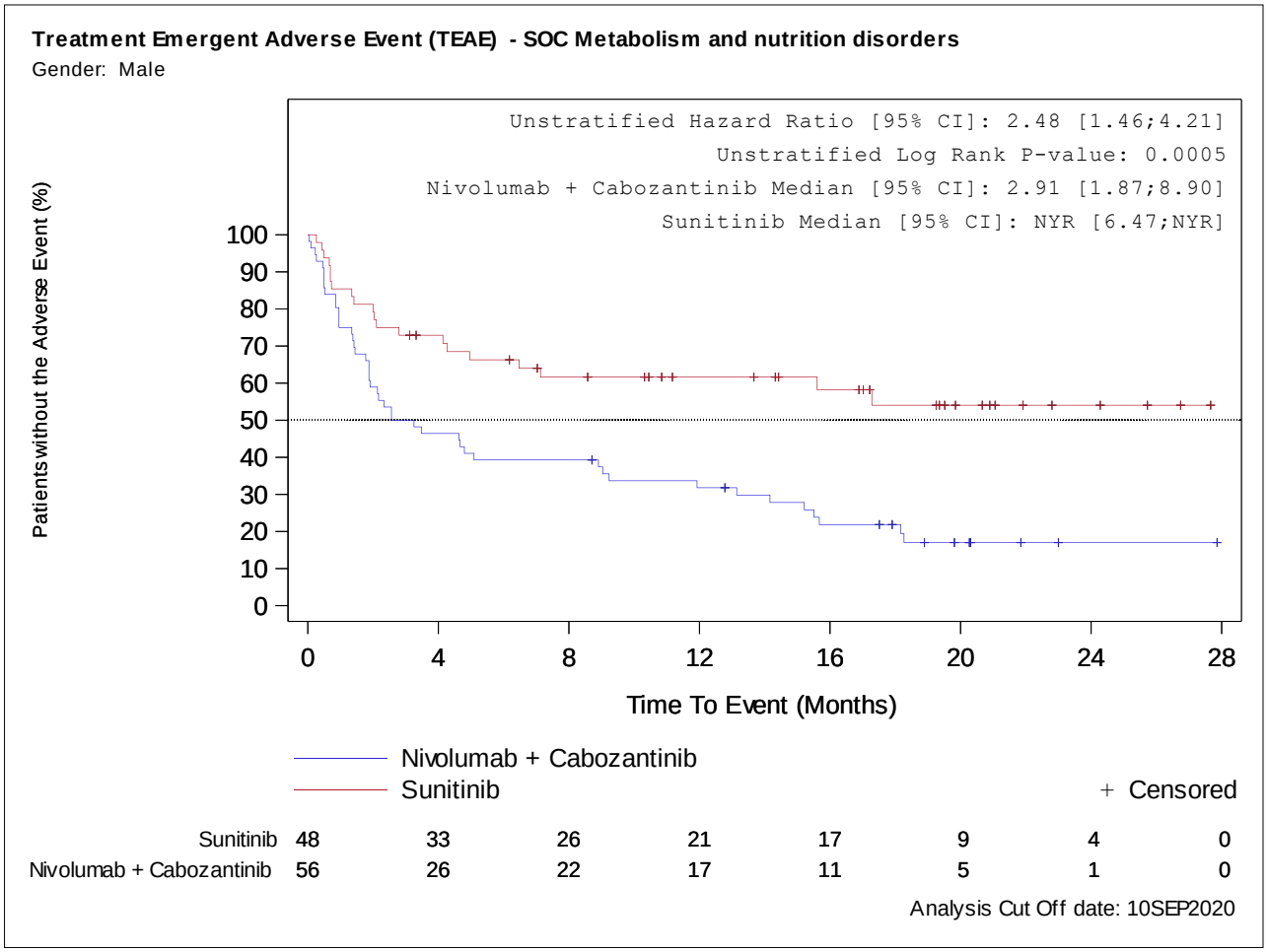

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:08:00

FIGURE 5.11.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:08:06

FIGURE 5.11.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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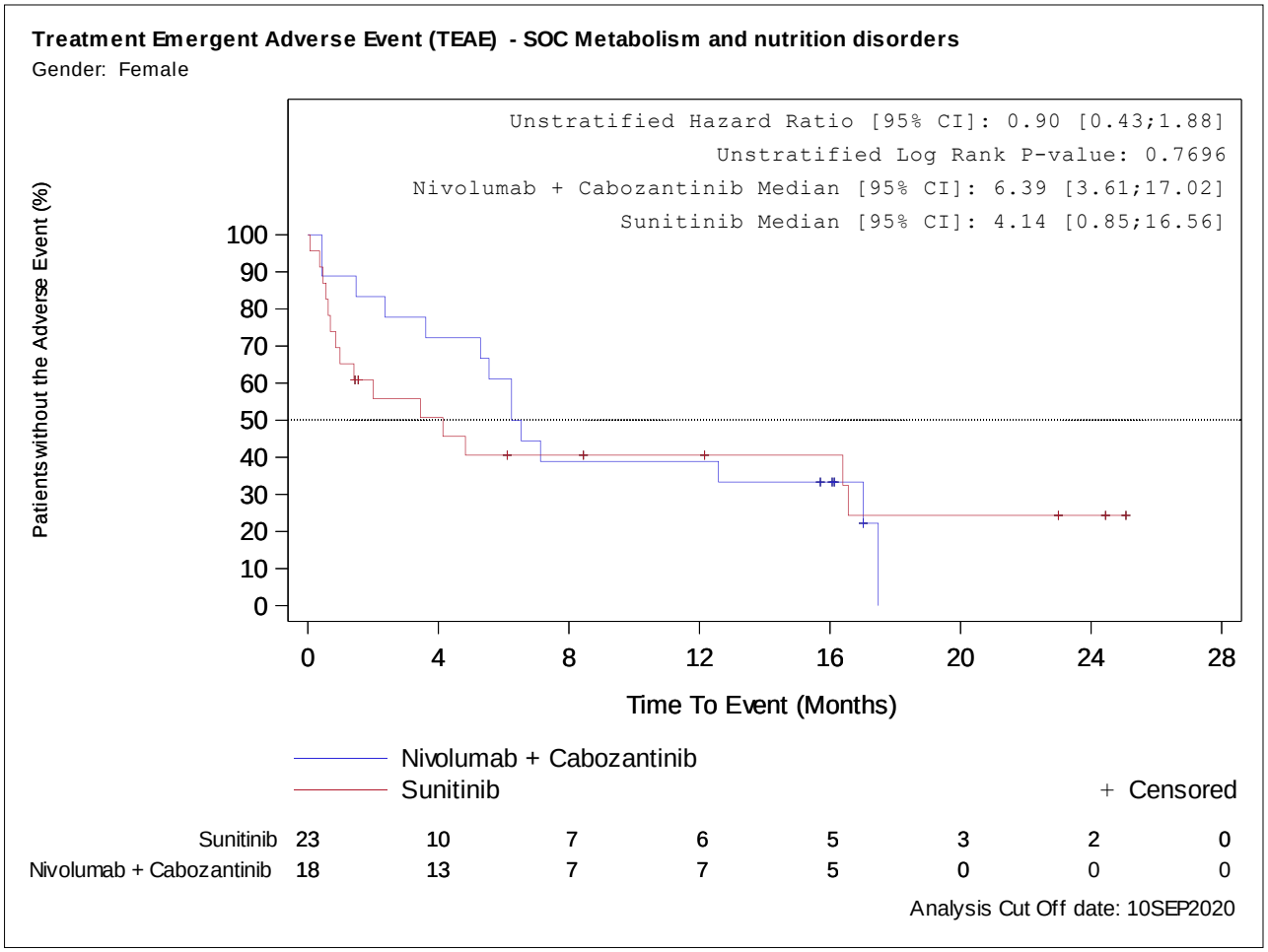
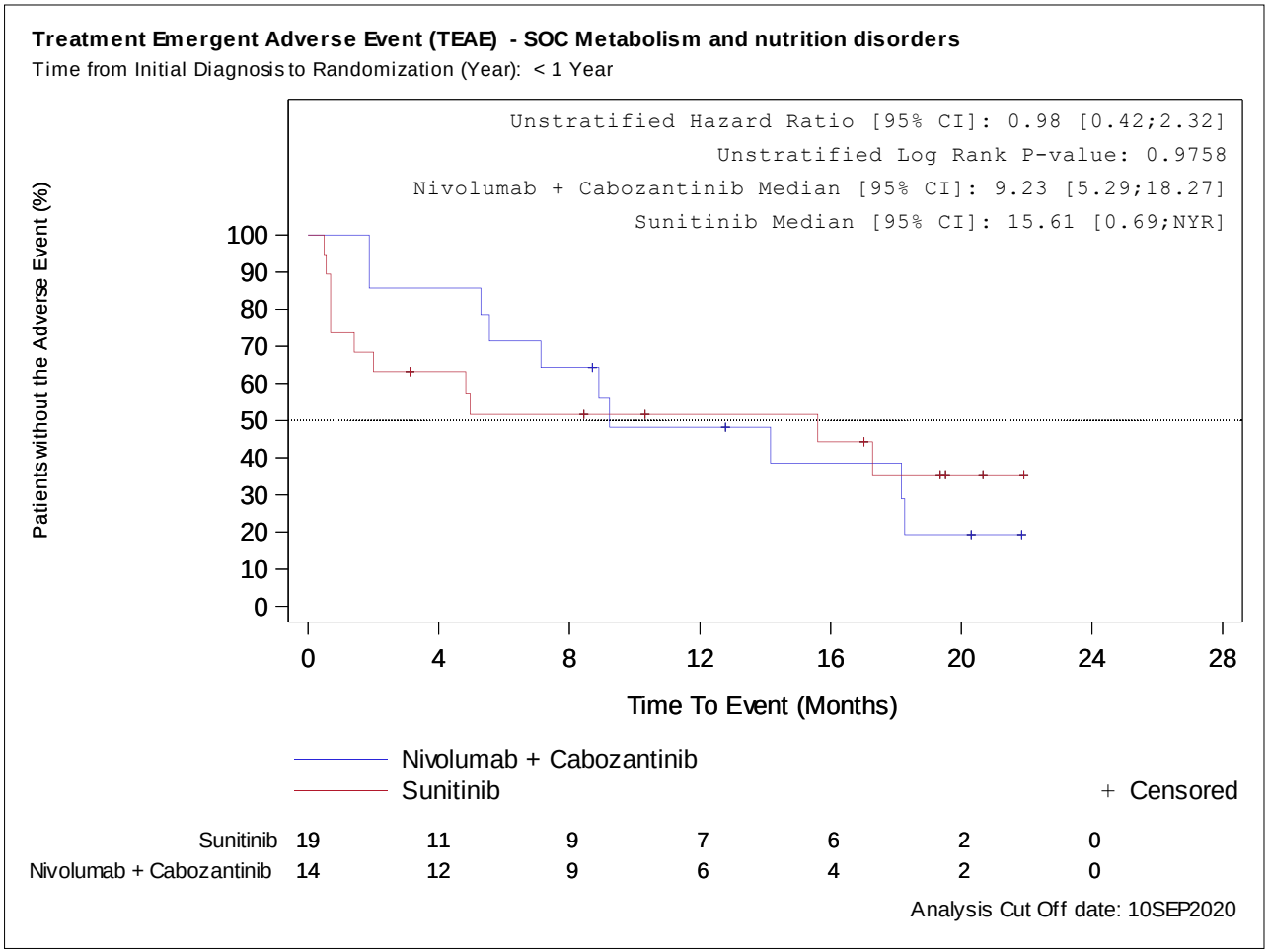
FIGURE 5.11.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



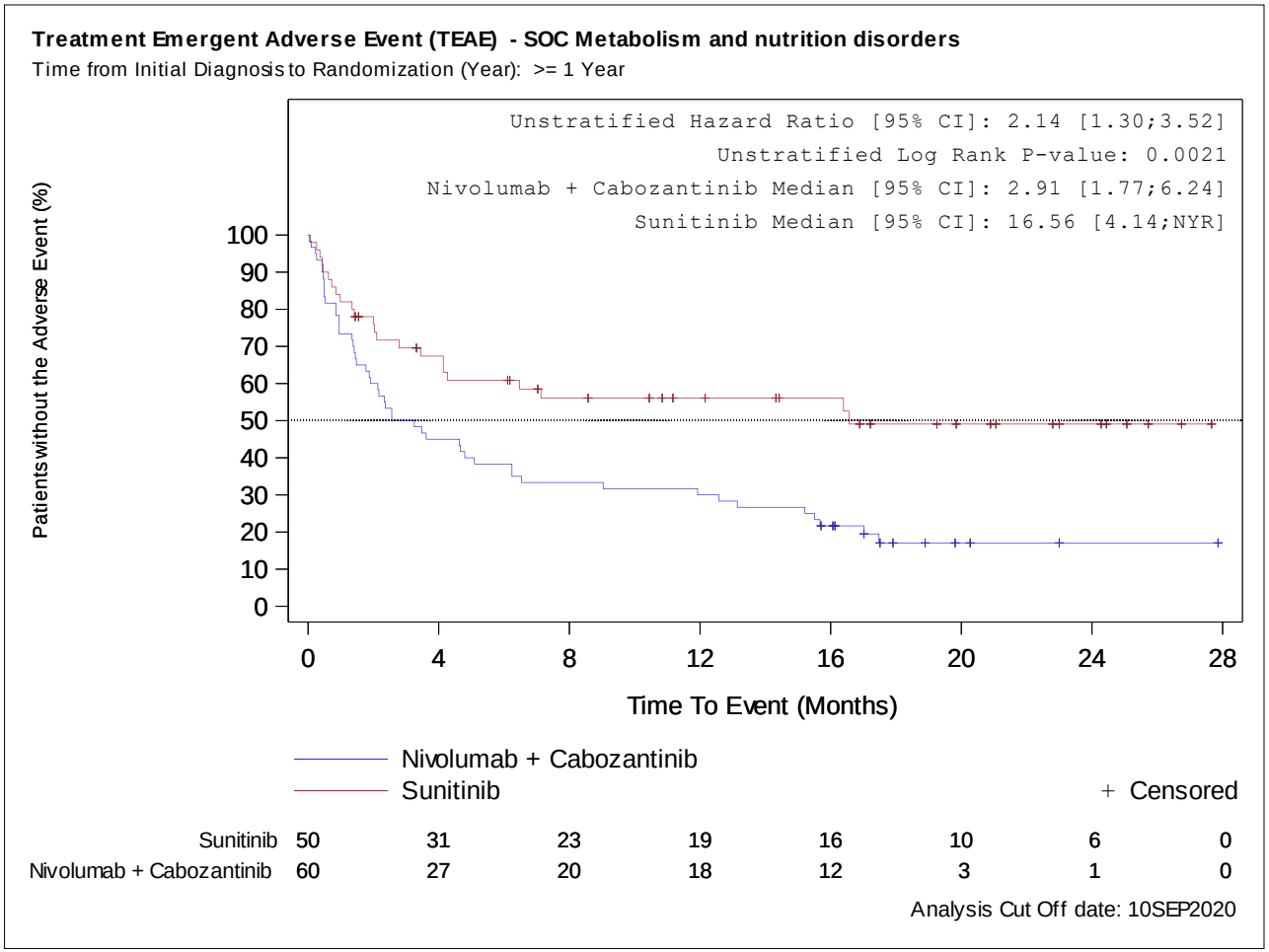

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:08:17

FIGURE 5.11.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



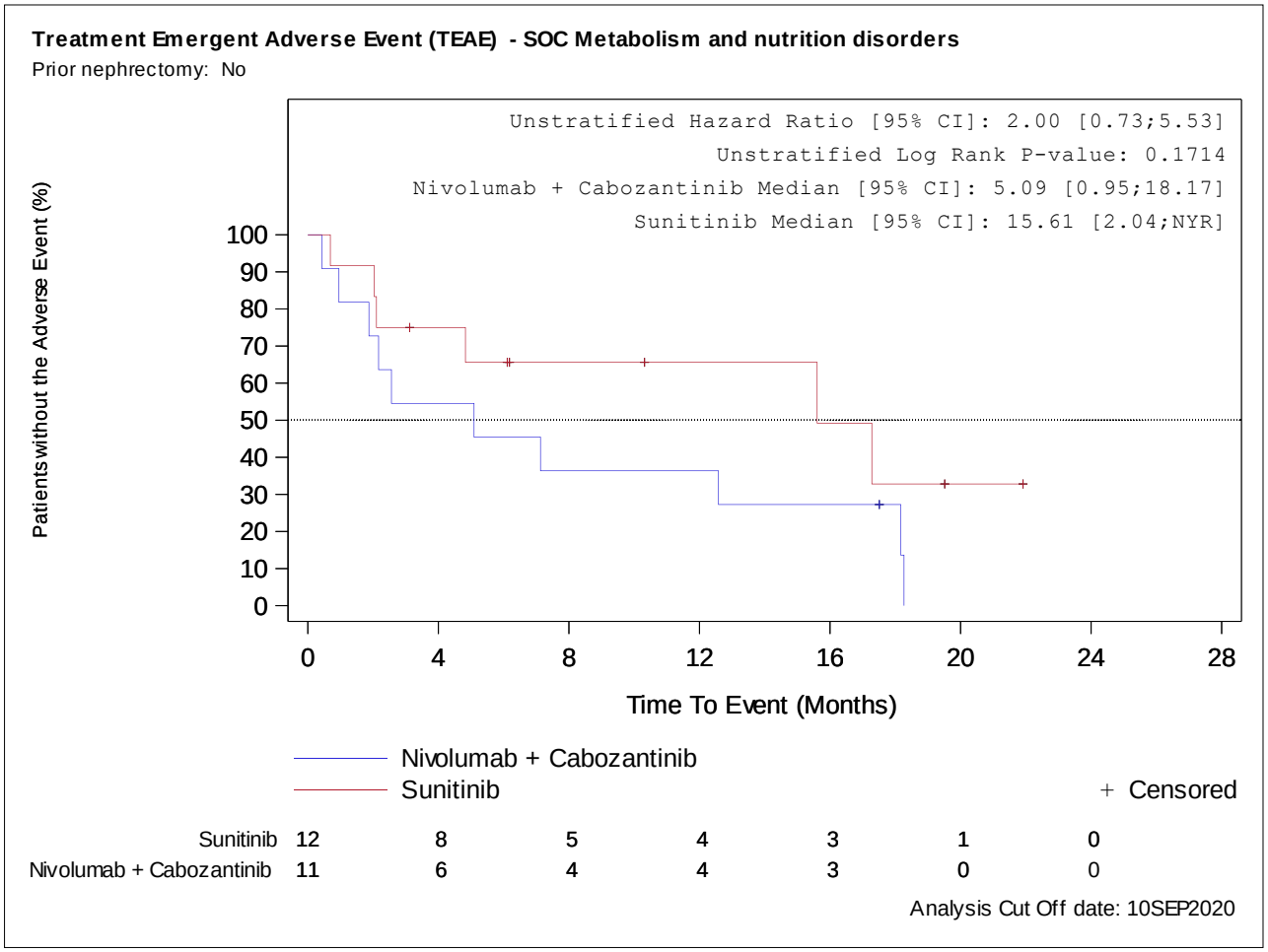

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:08:35

FIGURE 5.11.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



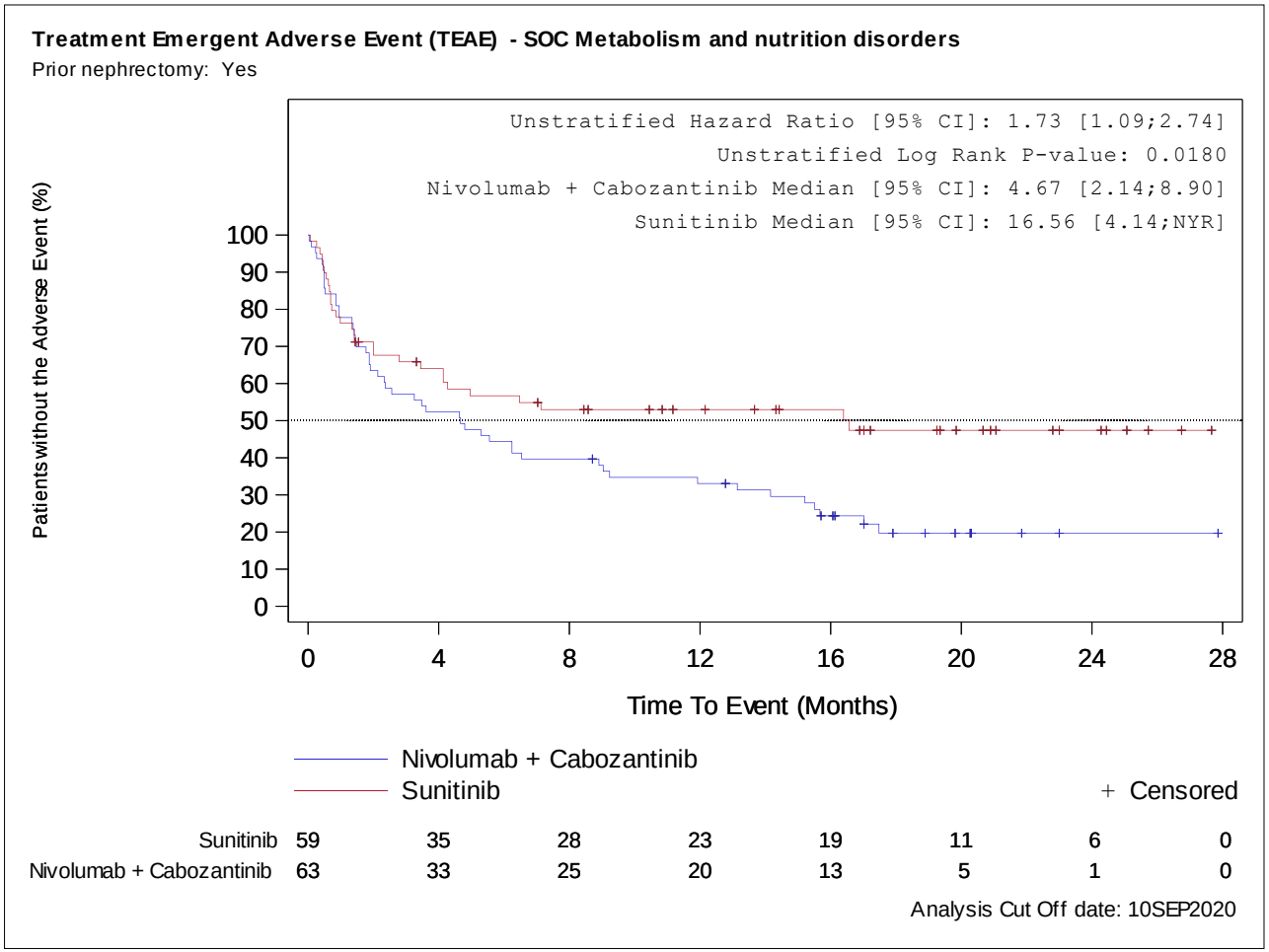

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:08:41

FIGURE 5.11.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



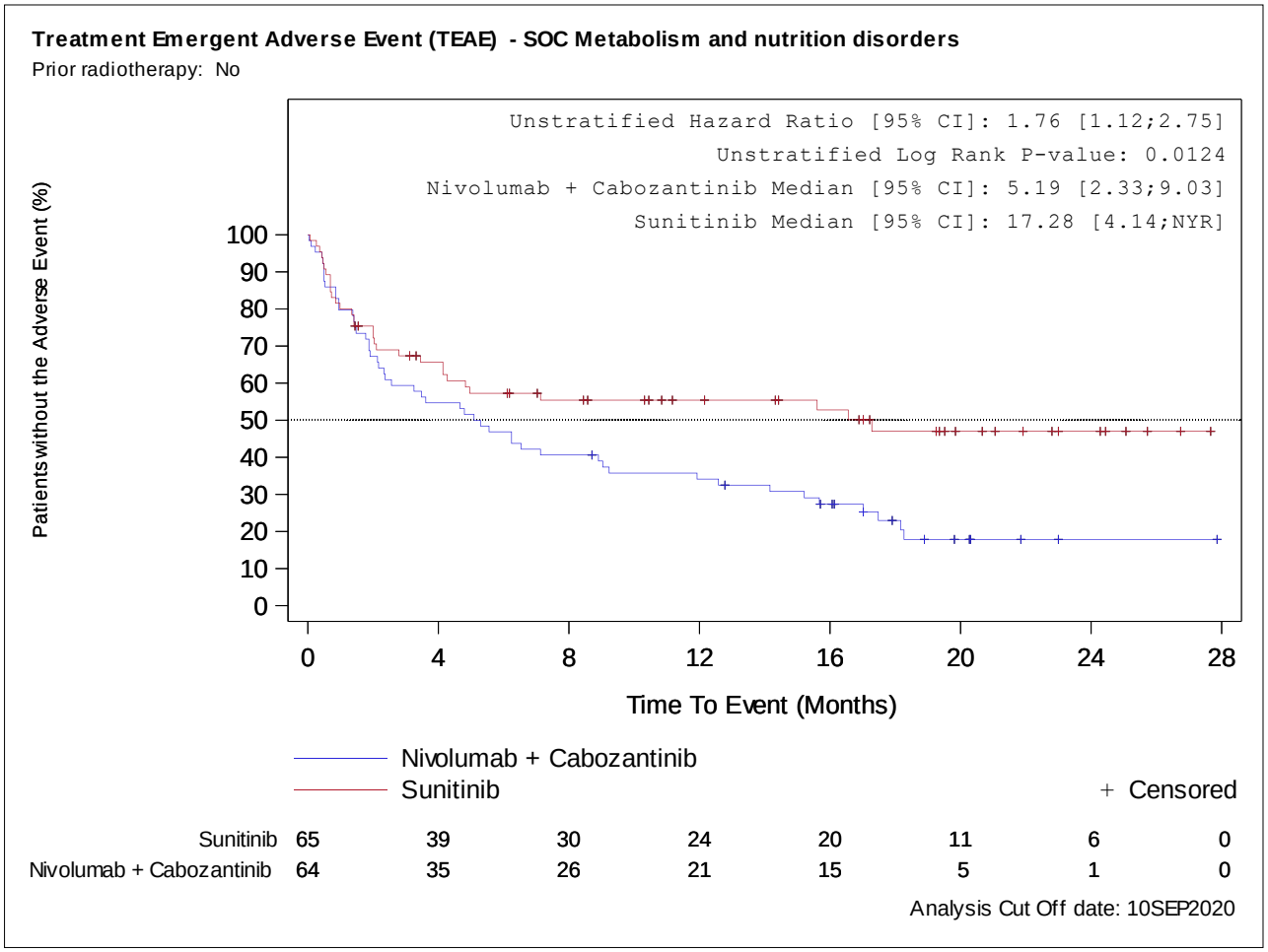

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:09:35

FIGURE 5.11.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



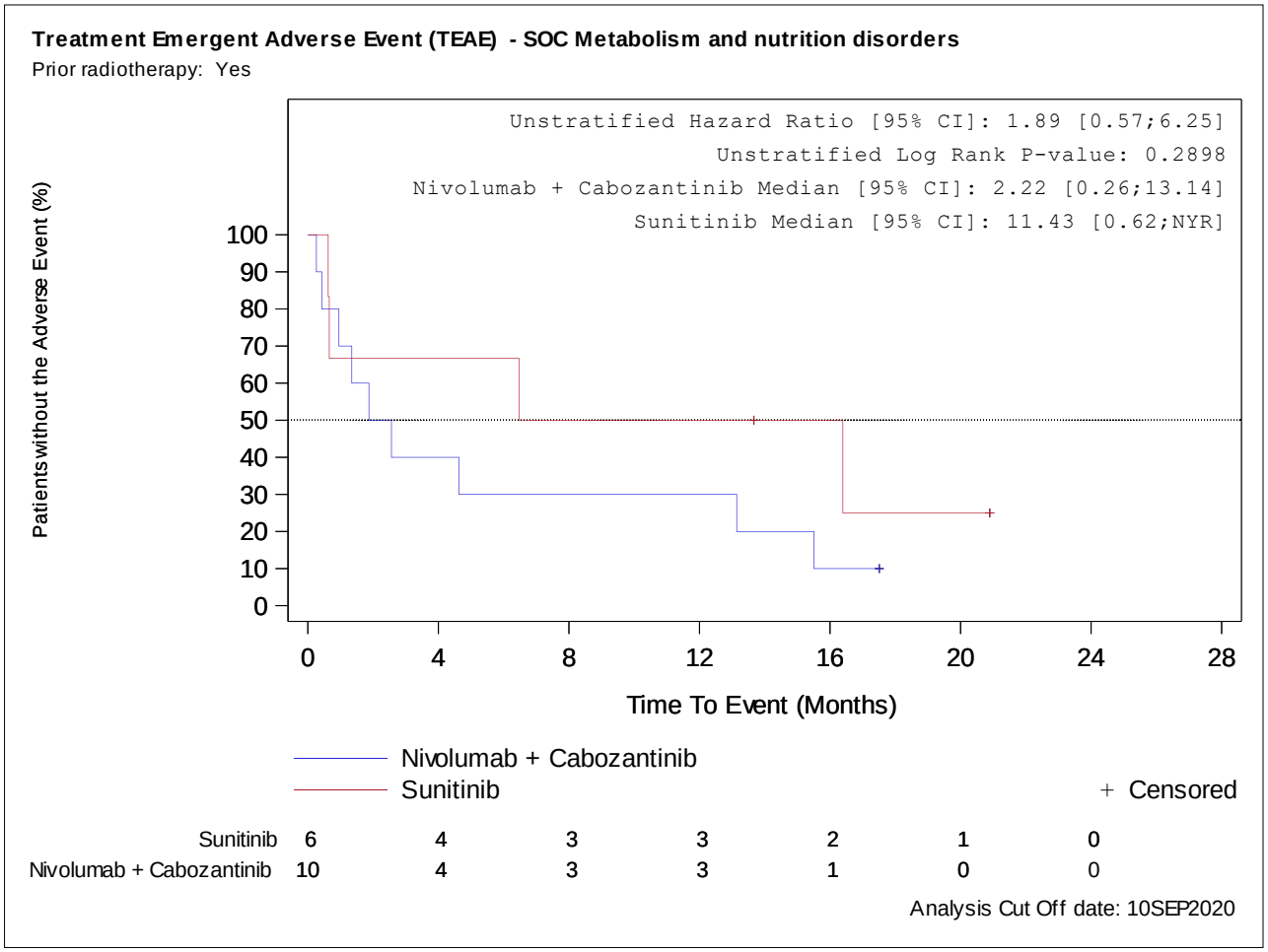

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:09:41

FIGURE 5.11.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:09:47

FIGURE 5.11.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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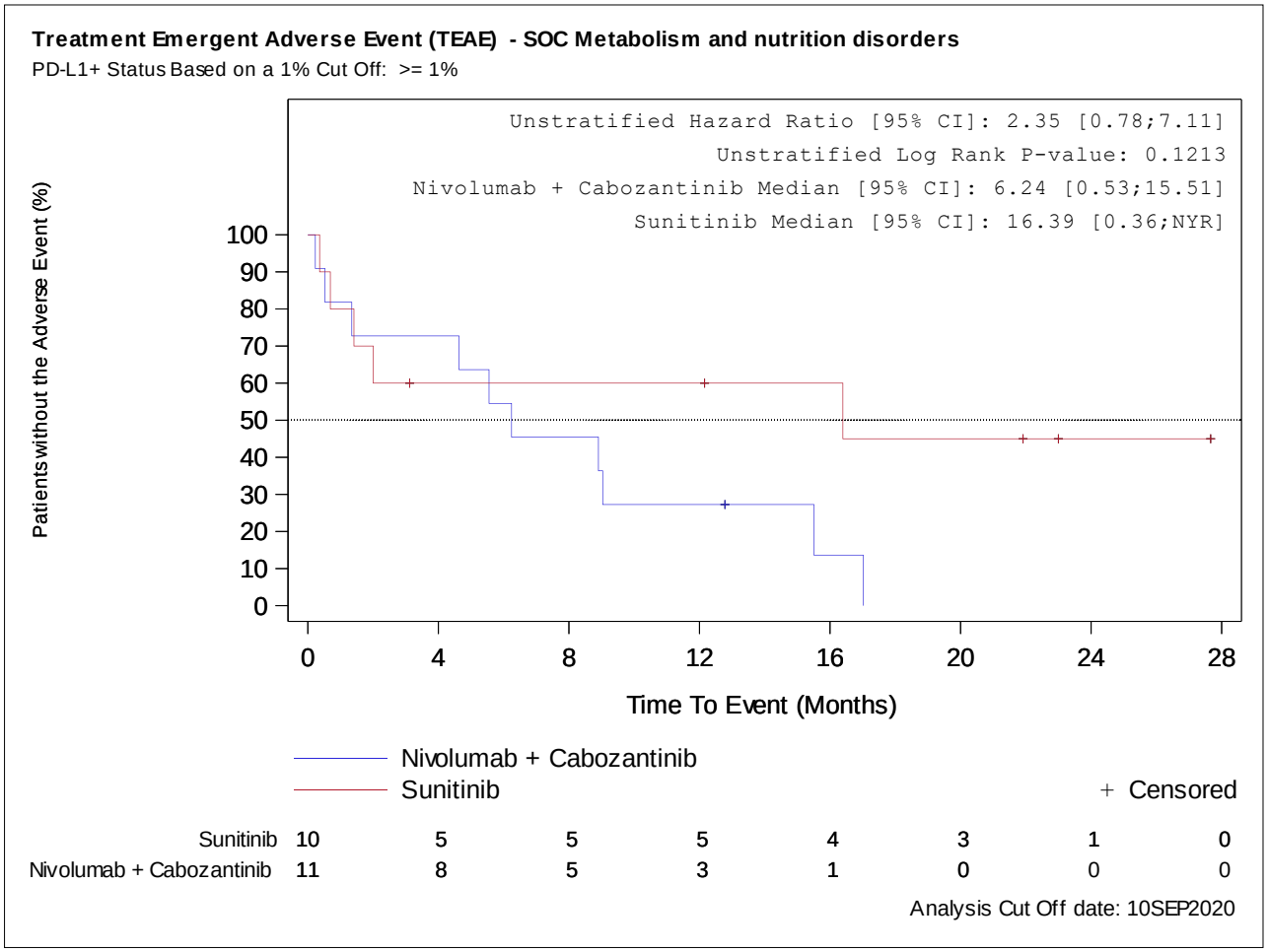
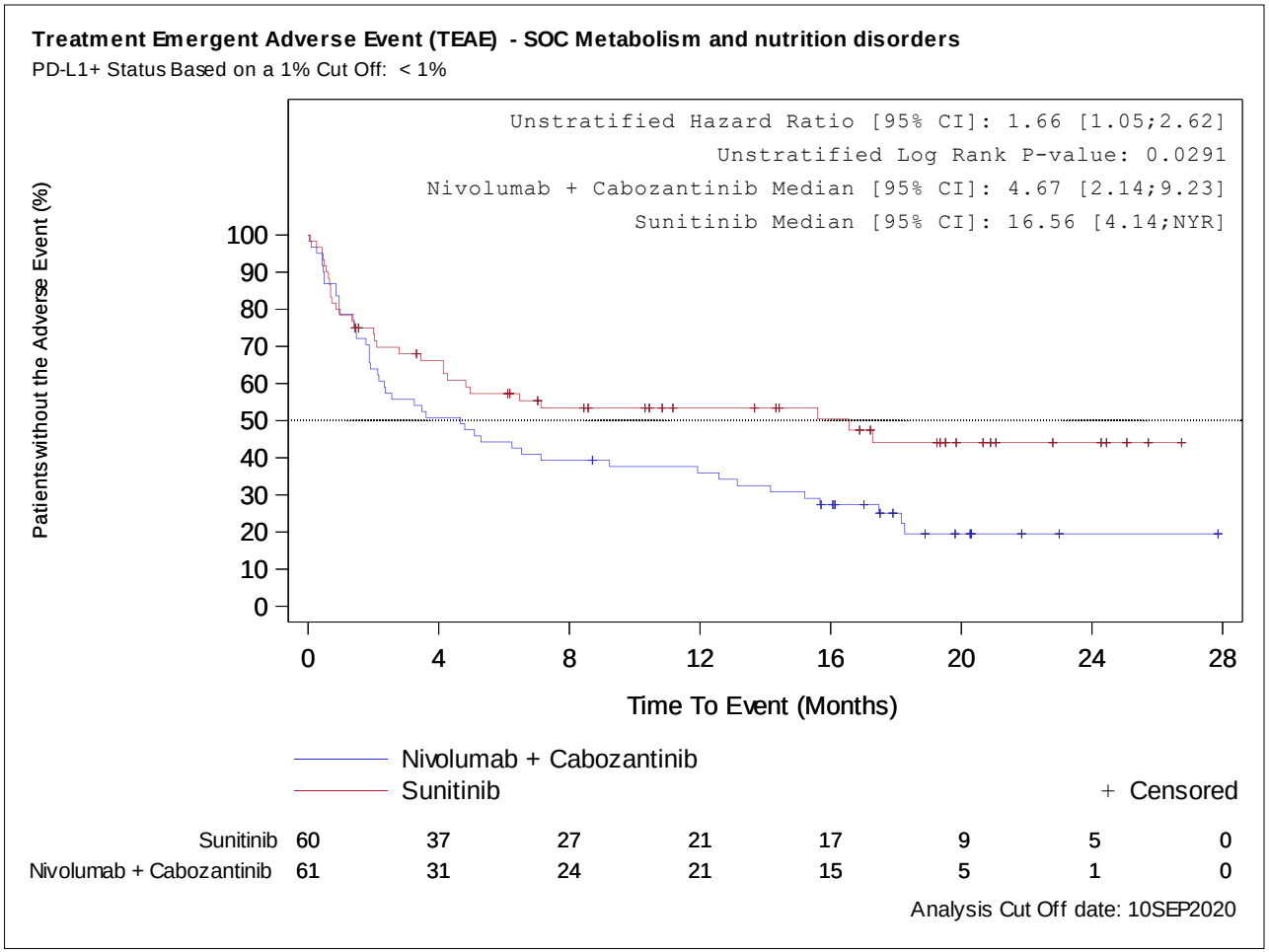
FIGURE 5.11.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



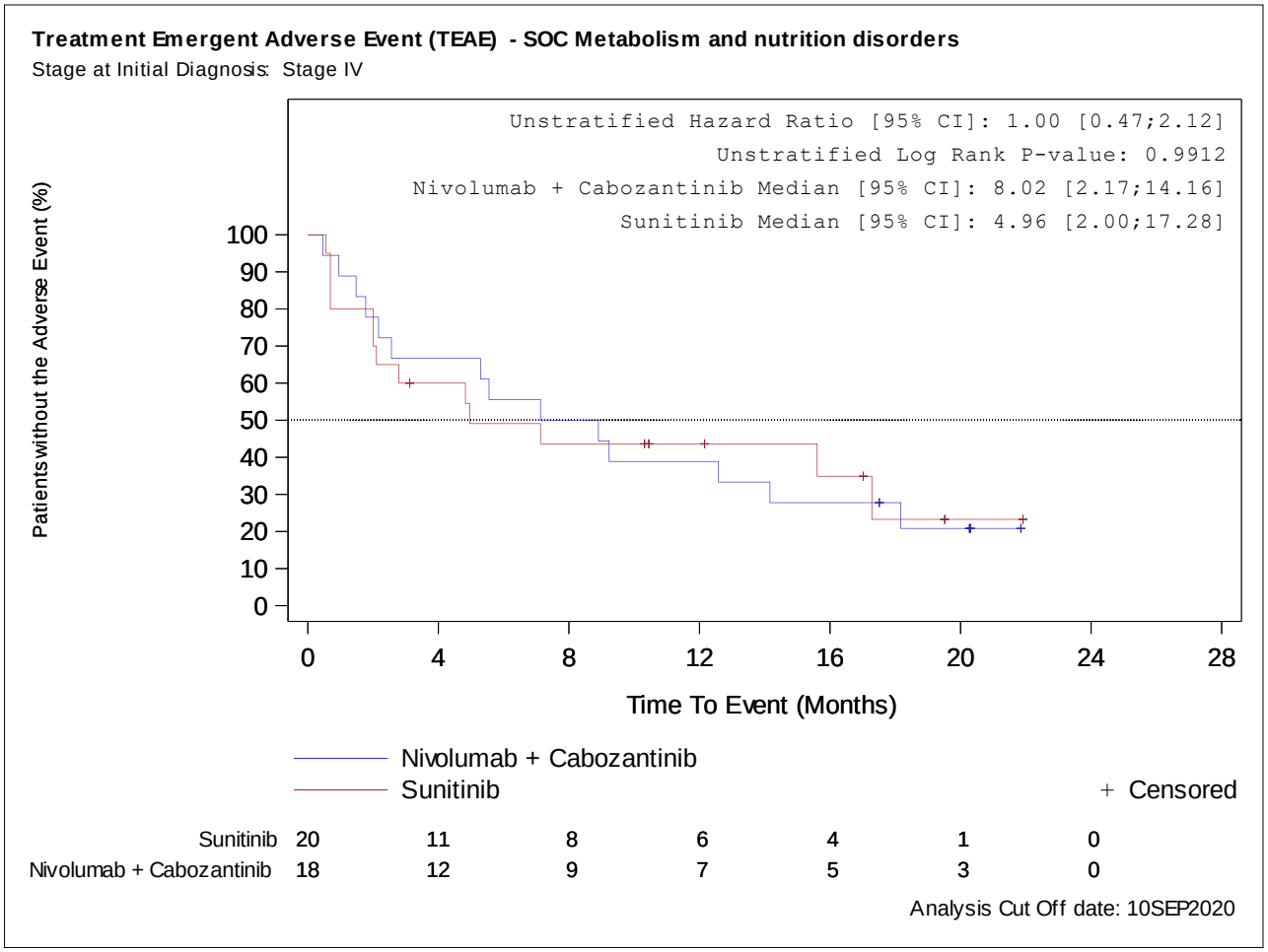

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:09:59

FIGURE 5.11.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



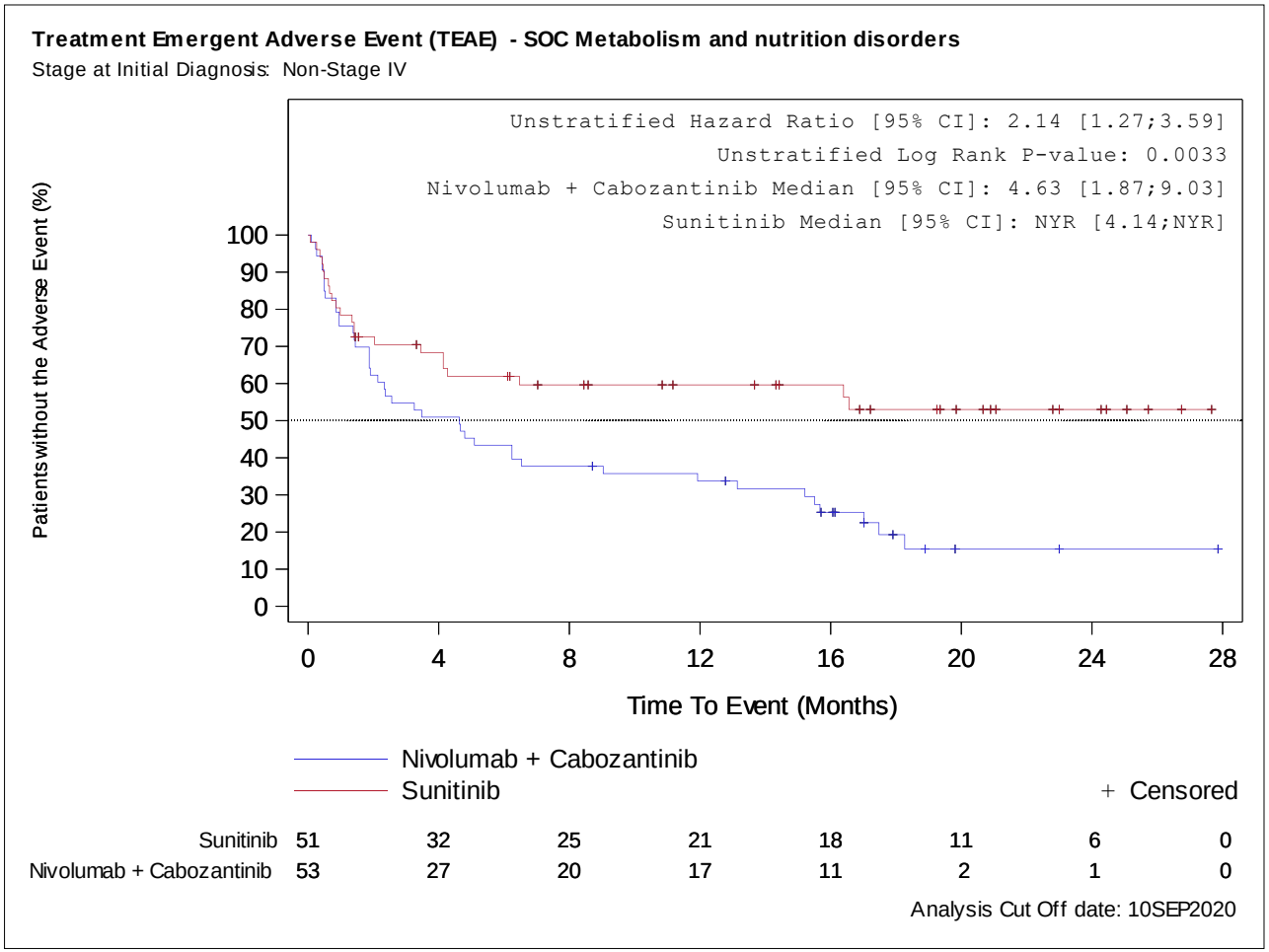

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:10:05

FIGURE 5.11.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



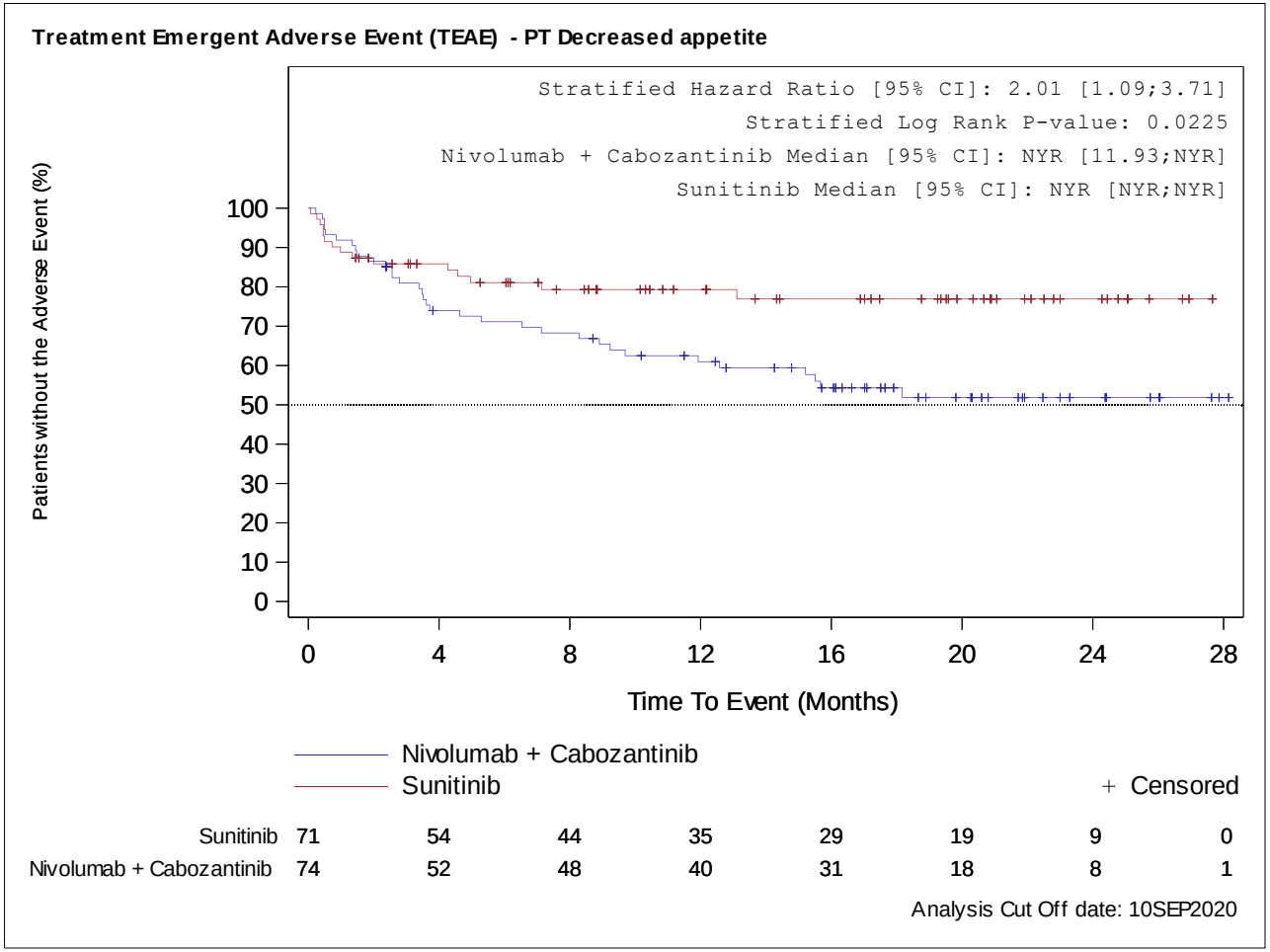

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:10:35

FIGURE 5.11.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



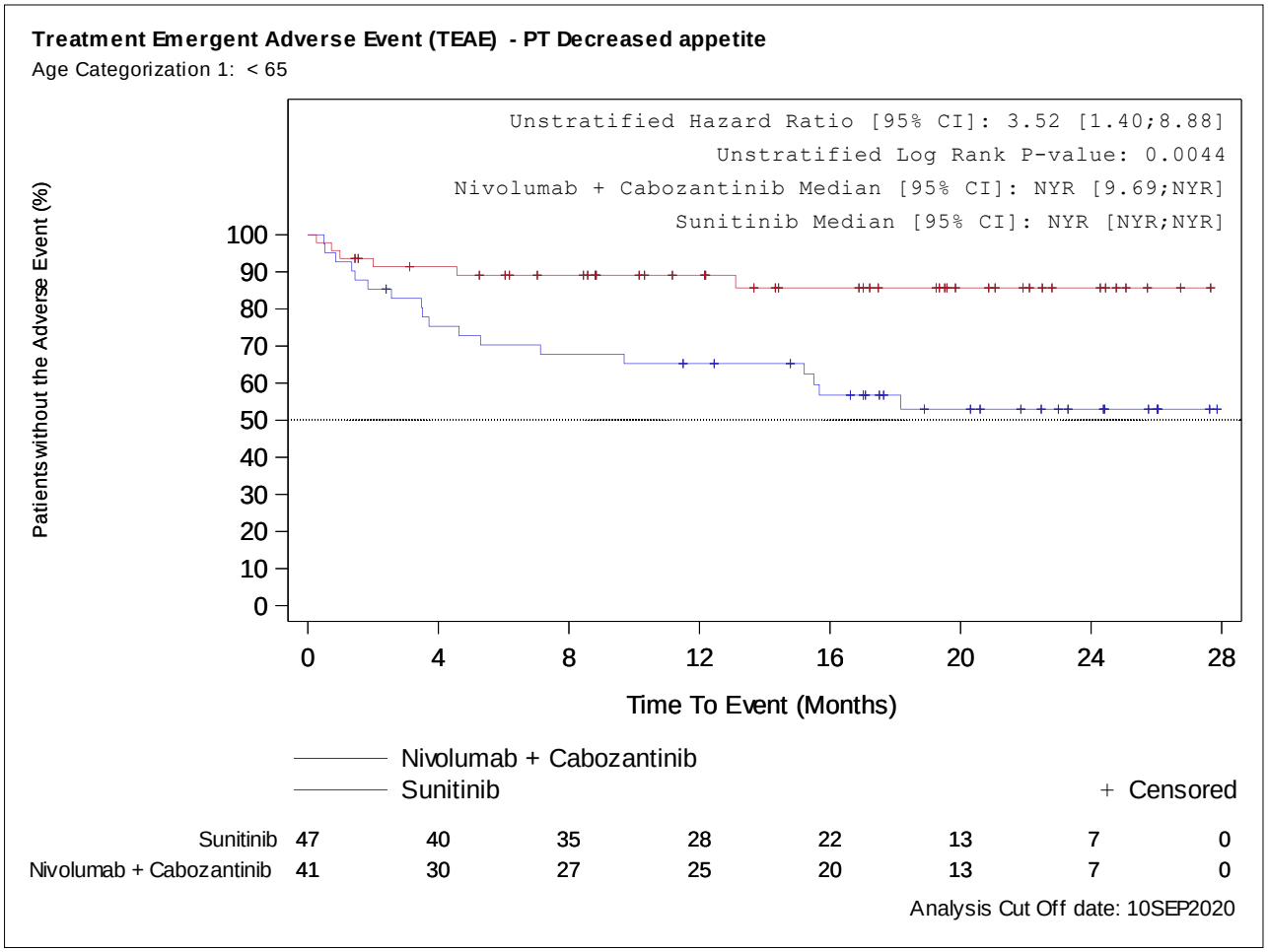

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:10:41

FIGURE 5.12.1: Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:13:59

FIGURE 5.12.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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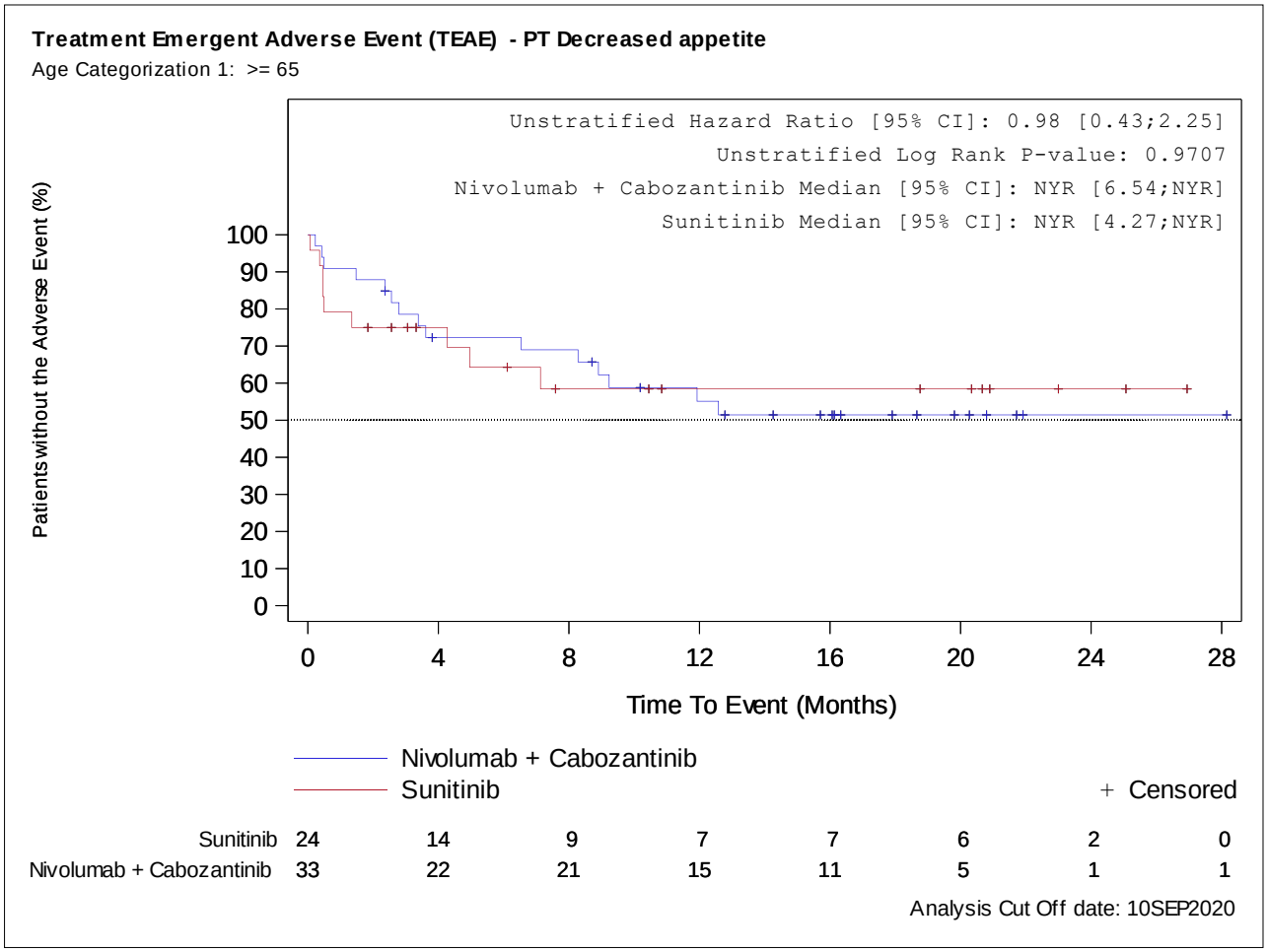
FIGURE 5.12.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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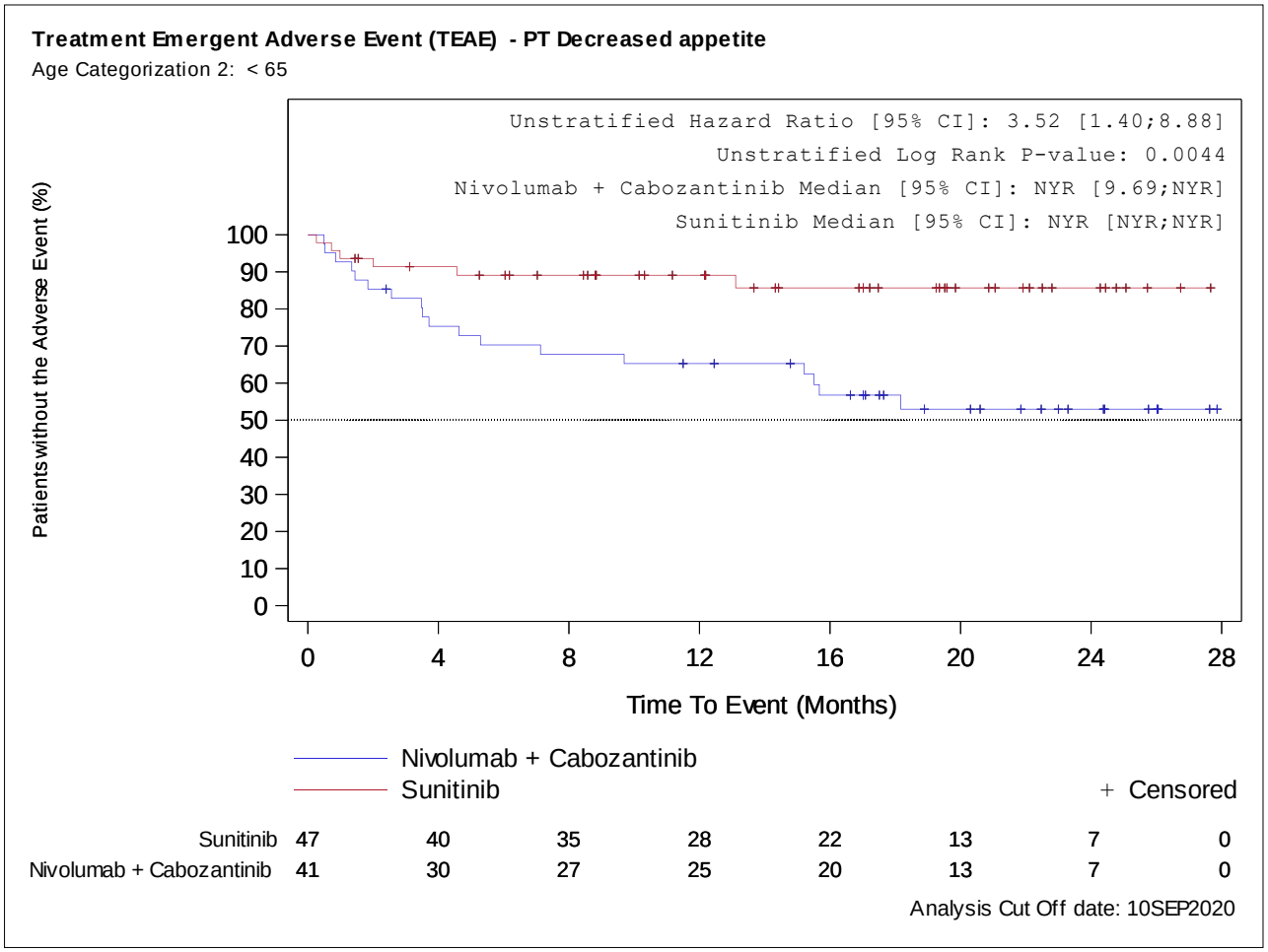
FIGURE 5.12.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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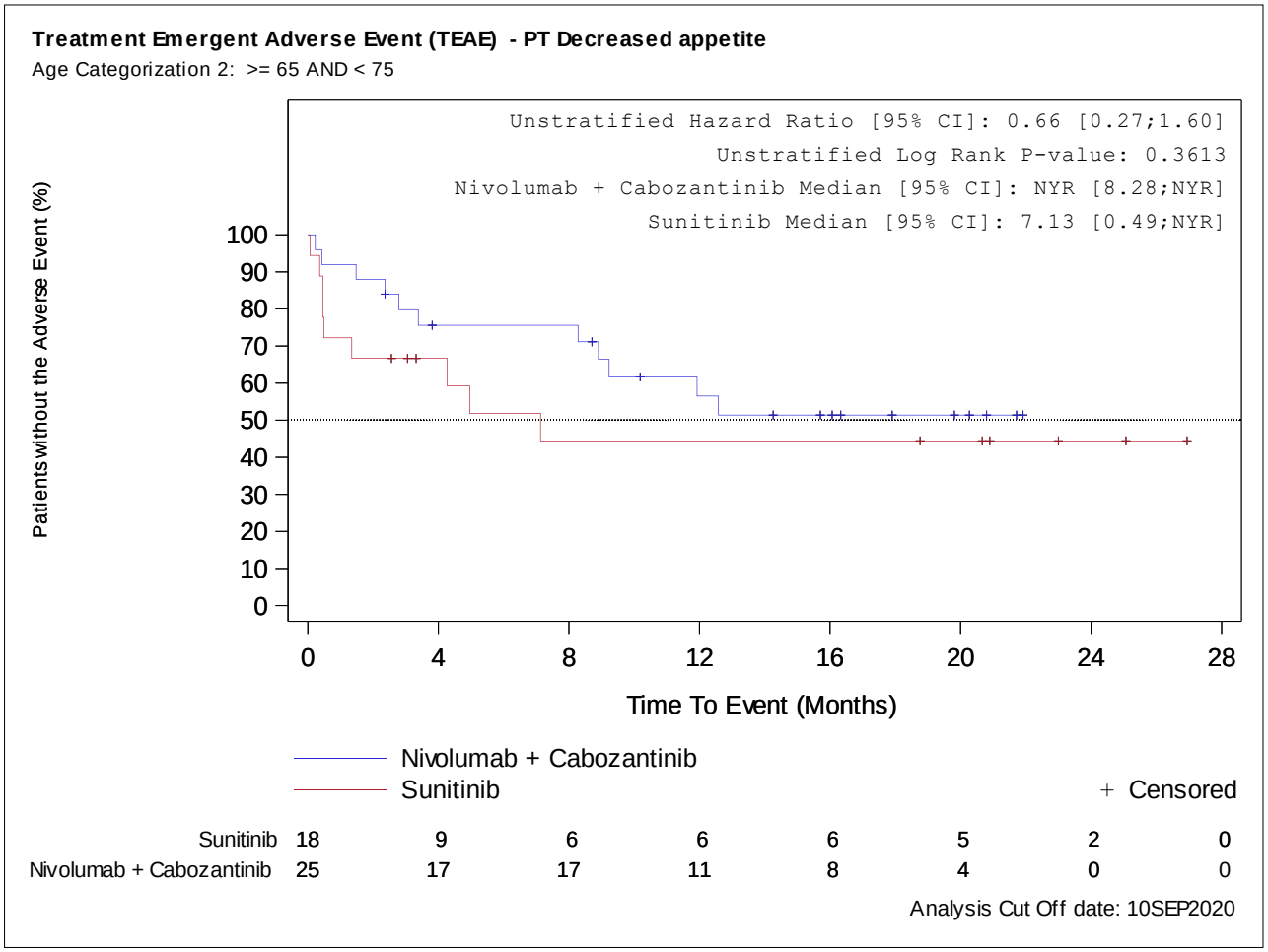
FIGURE 5.12.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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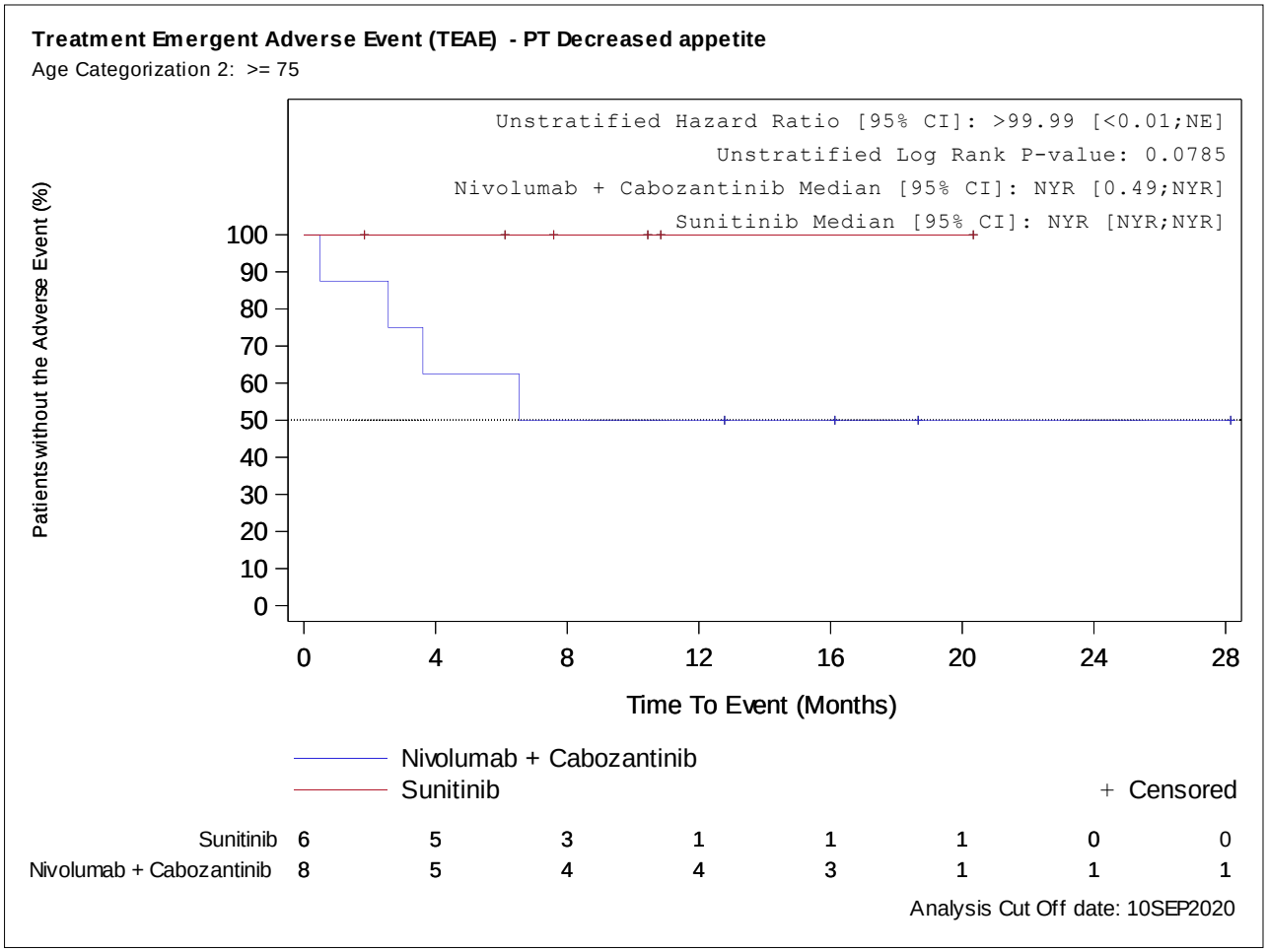
FIGURE 5.12.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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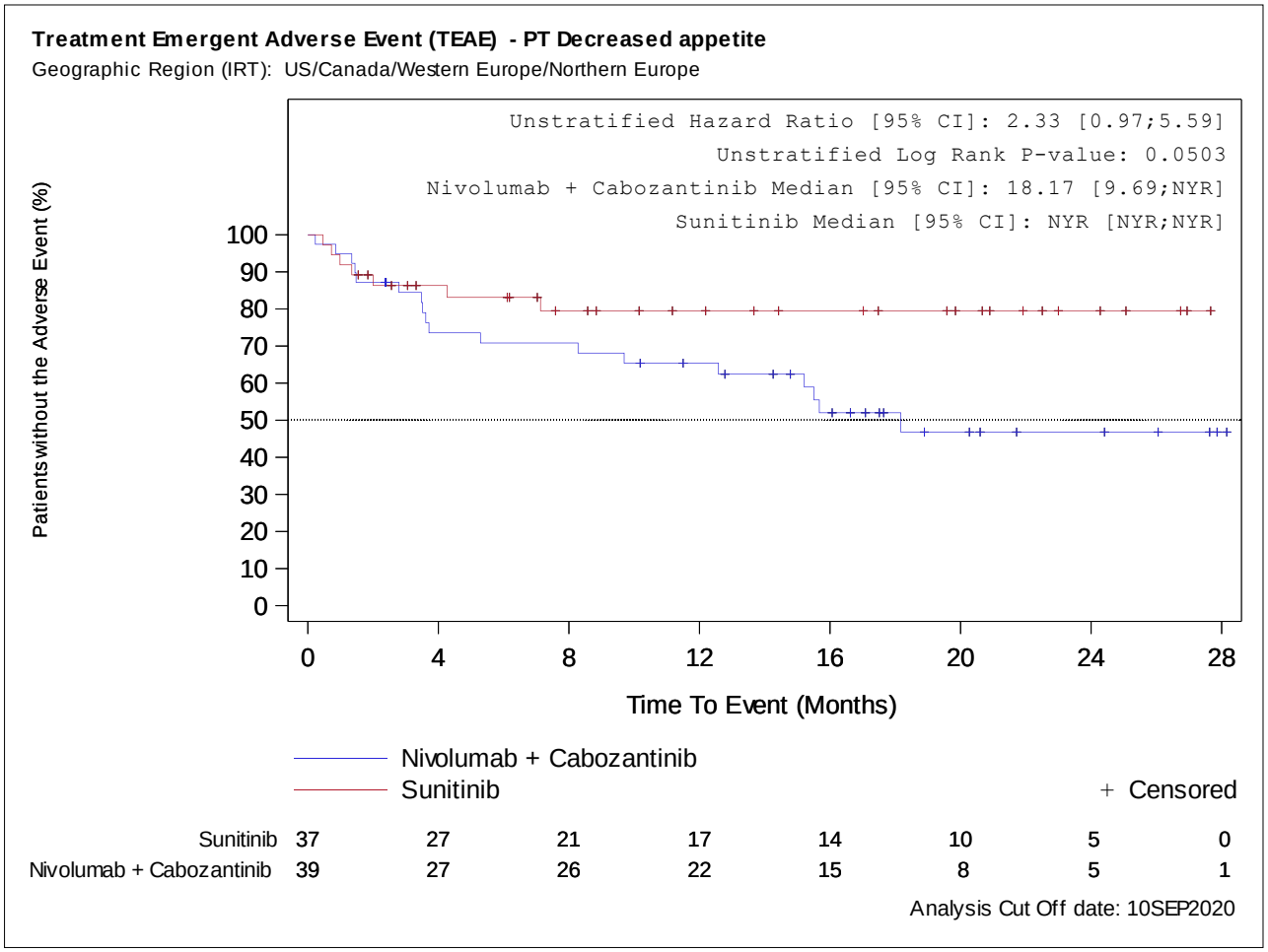
FIGURE 5.12.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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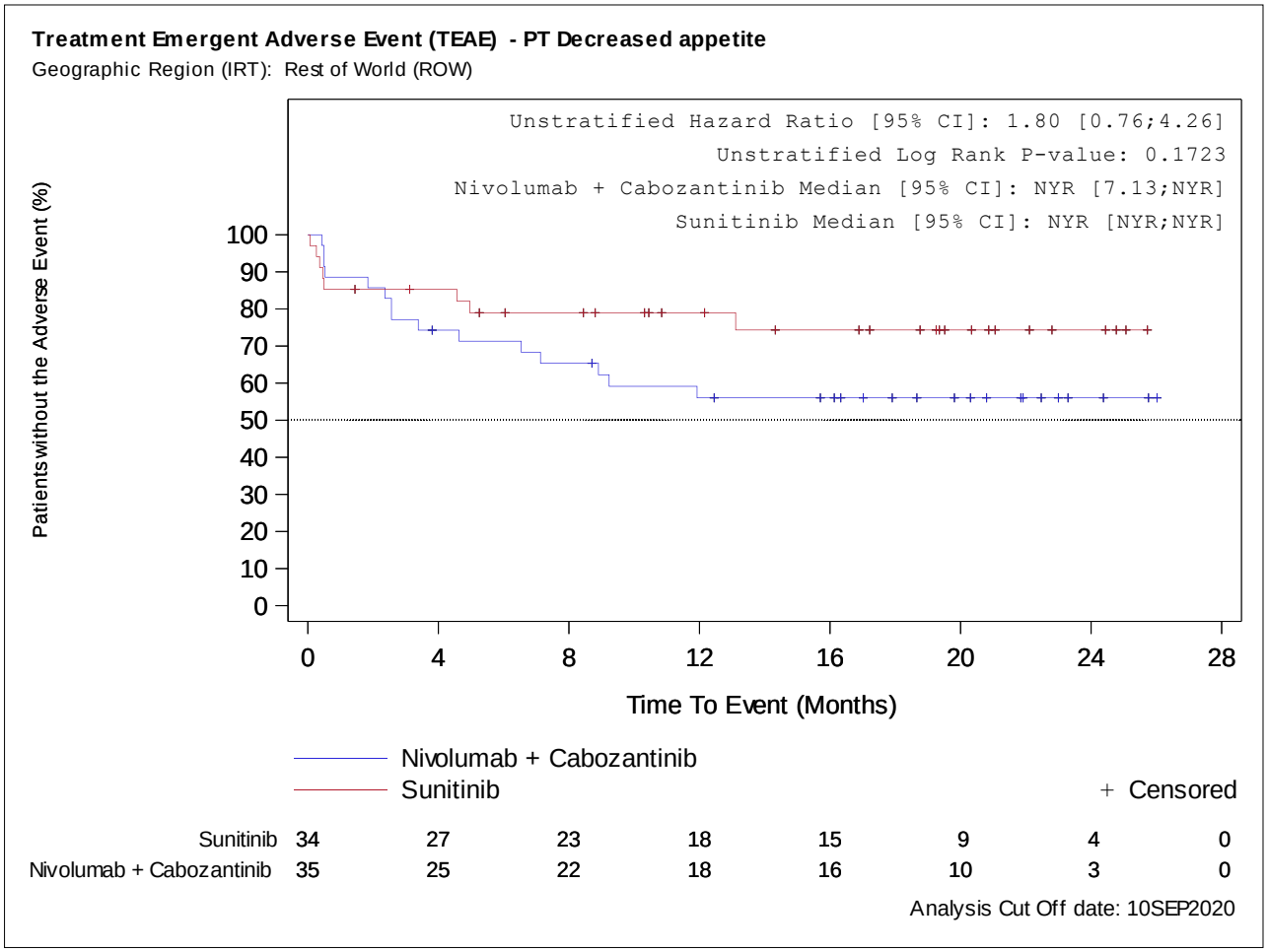
FIGURE 5.12.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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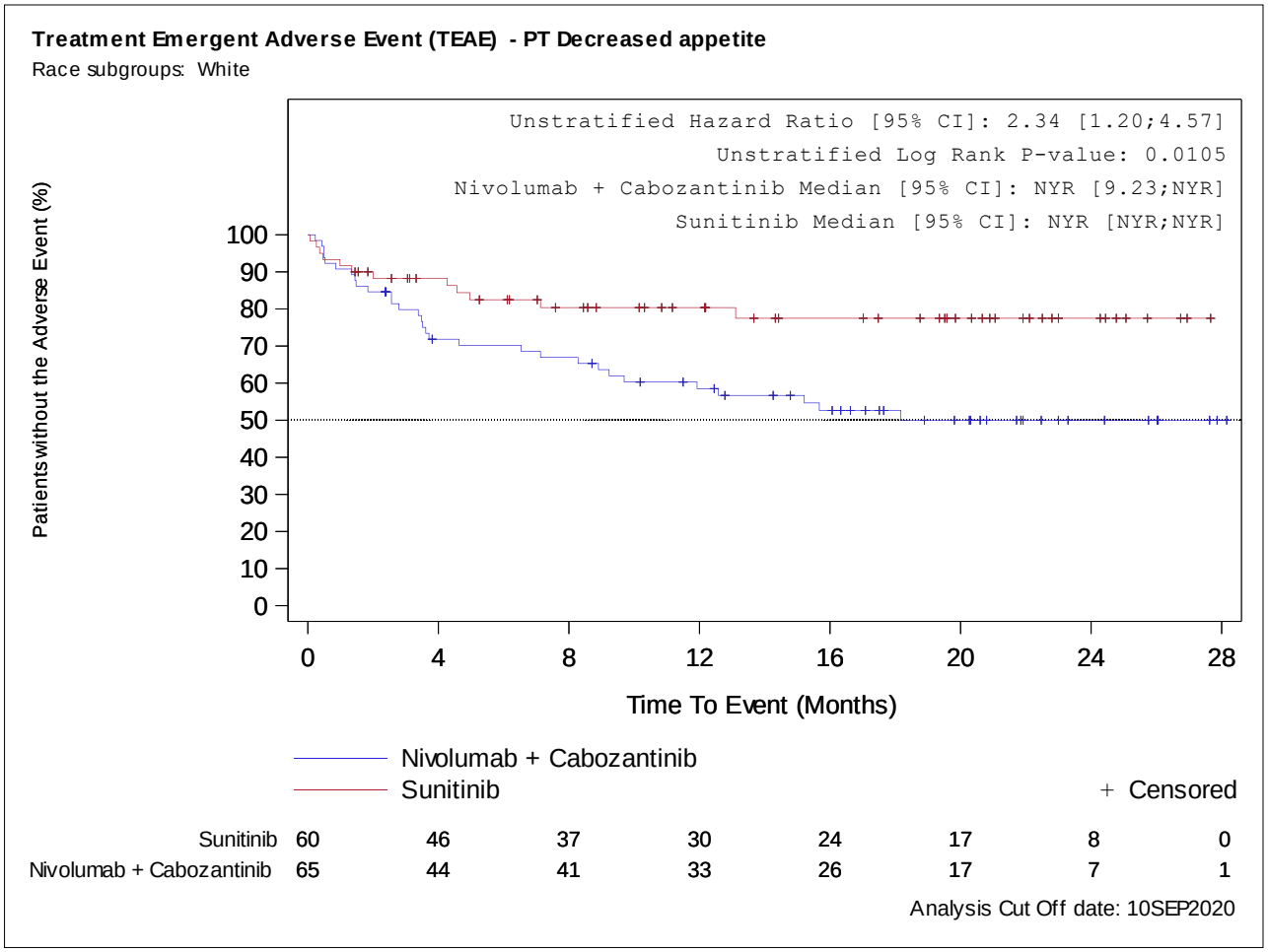
FIGURE 5.12.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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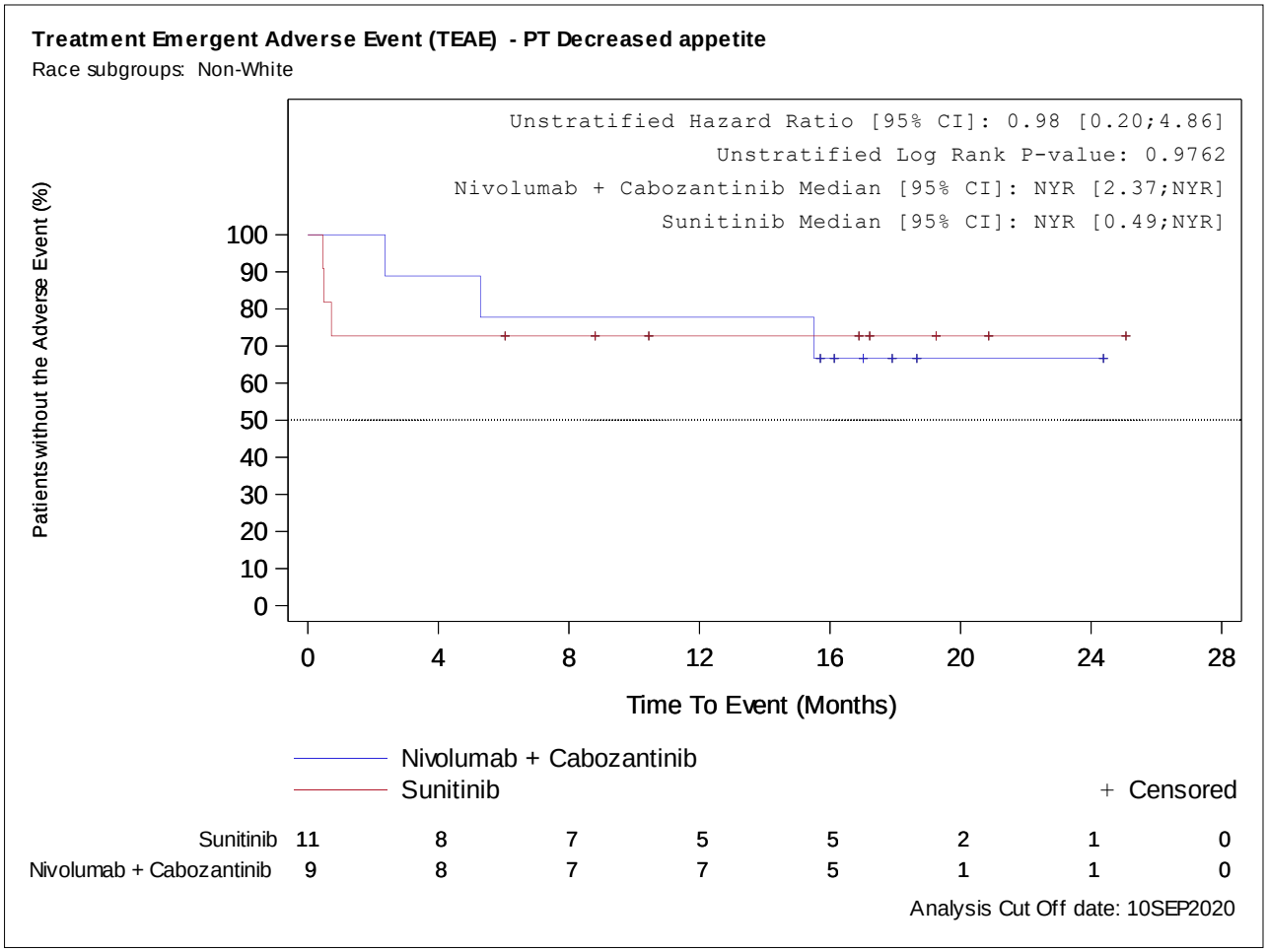
FIGURE 5.12.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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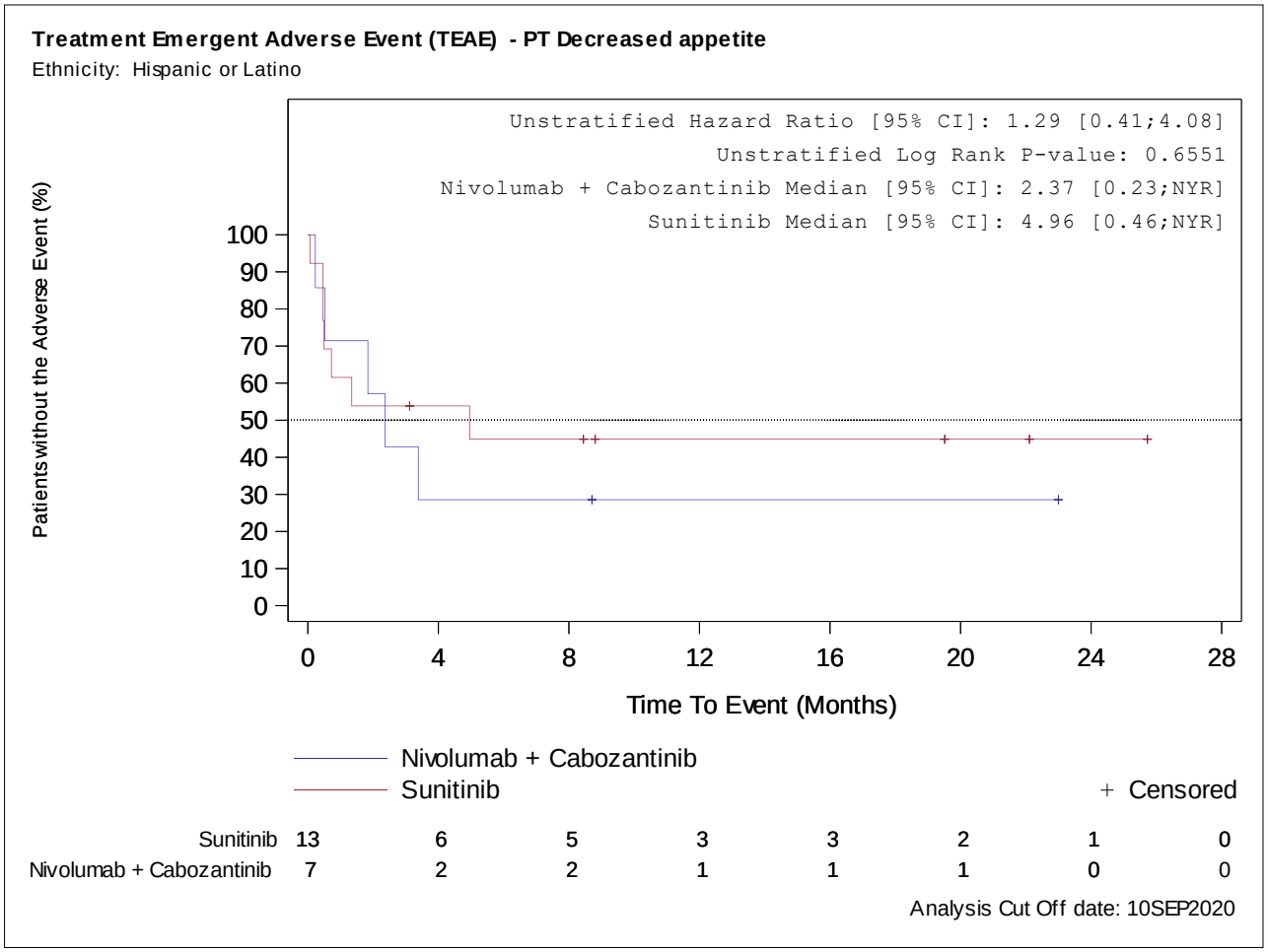
FIGURE 5.12.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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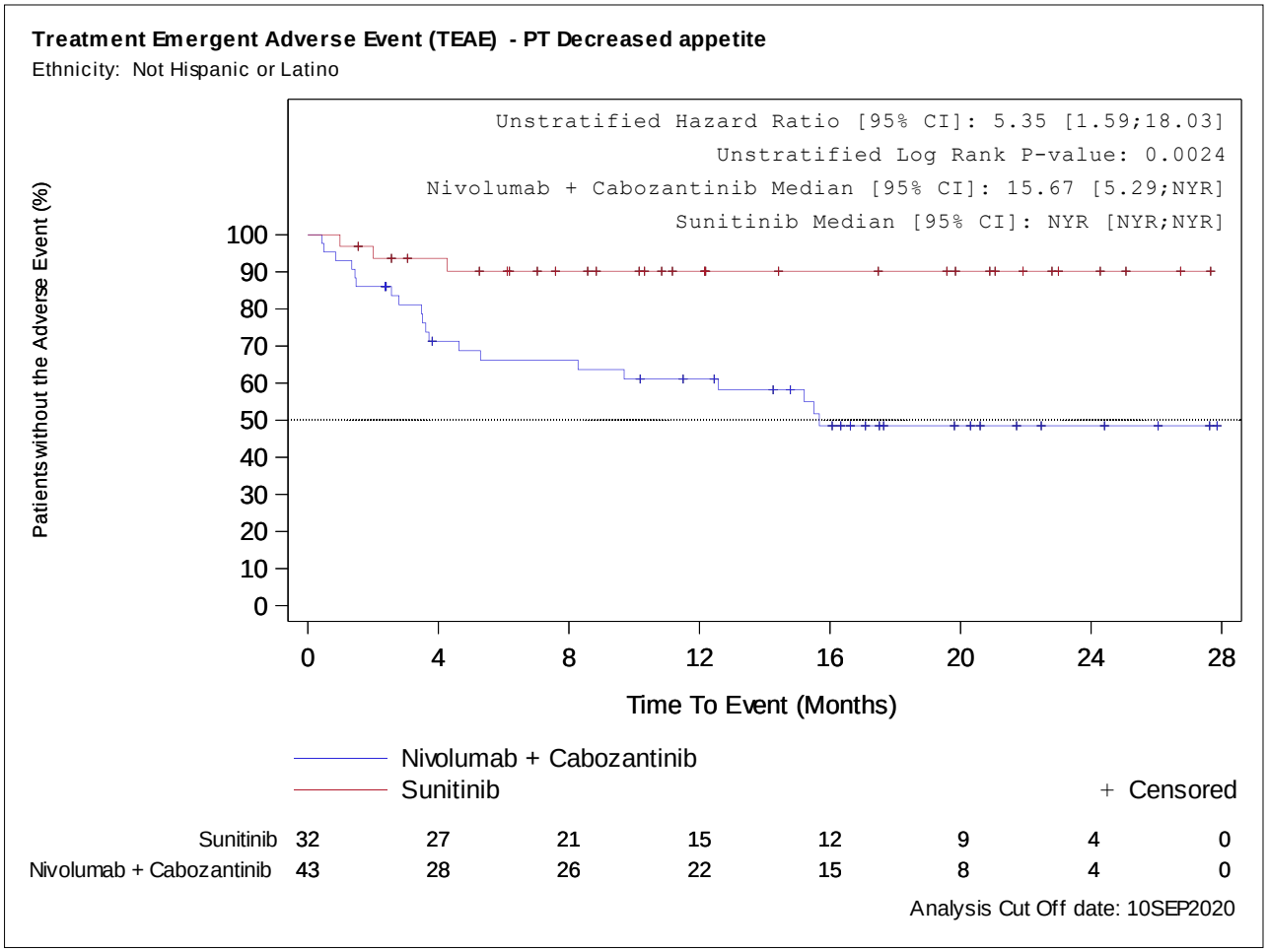
FIGURE 5.12.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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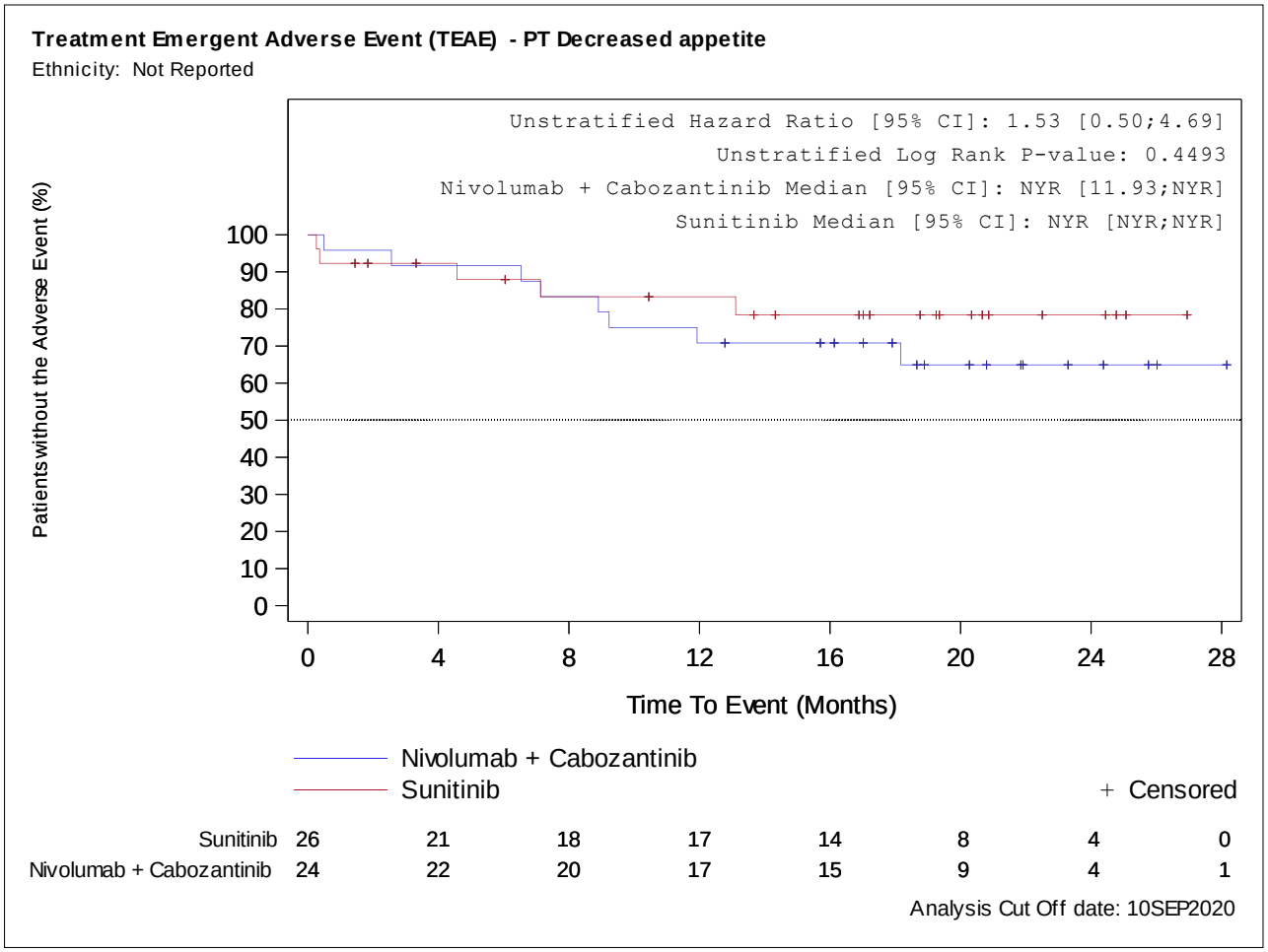
FIGURE 5.12.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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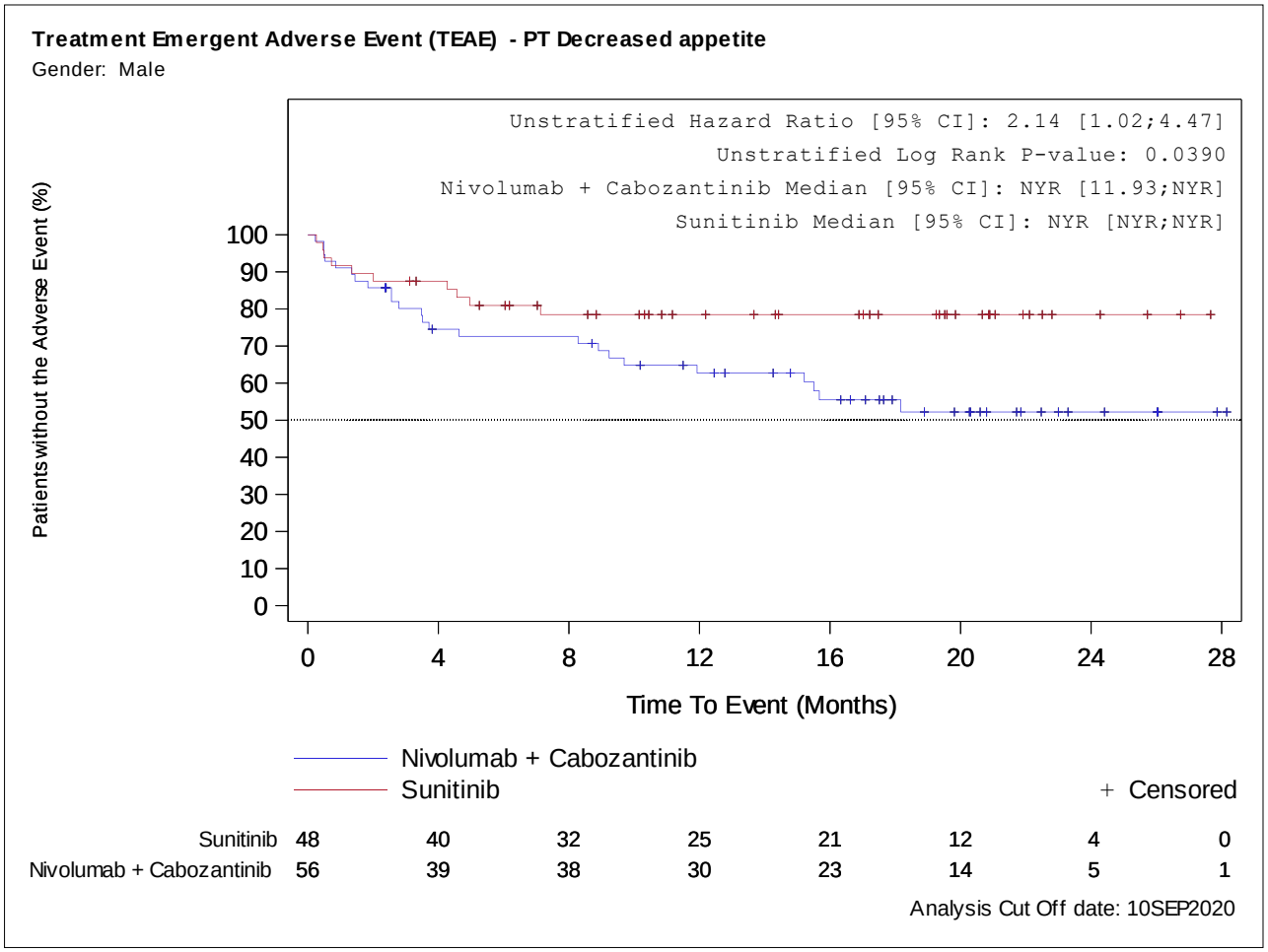
FIGURE 5.12.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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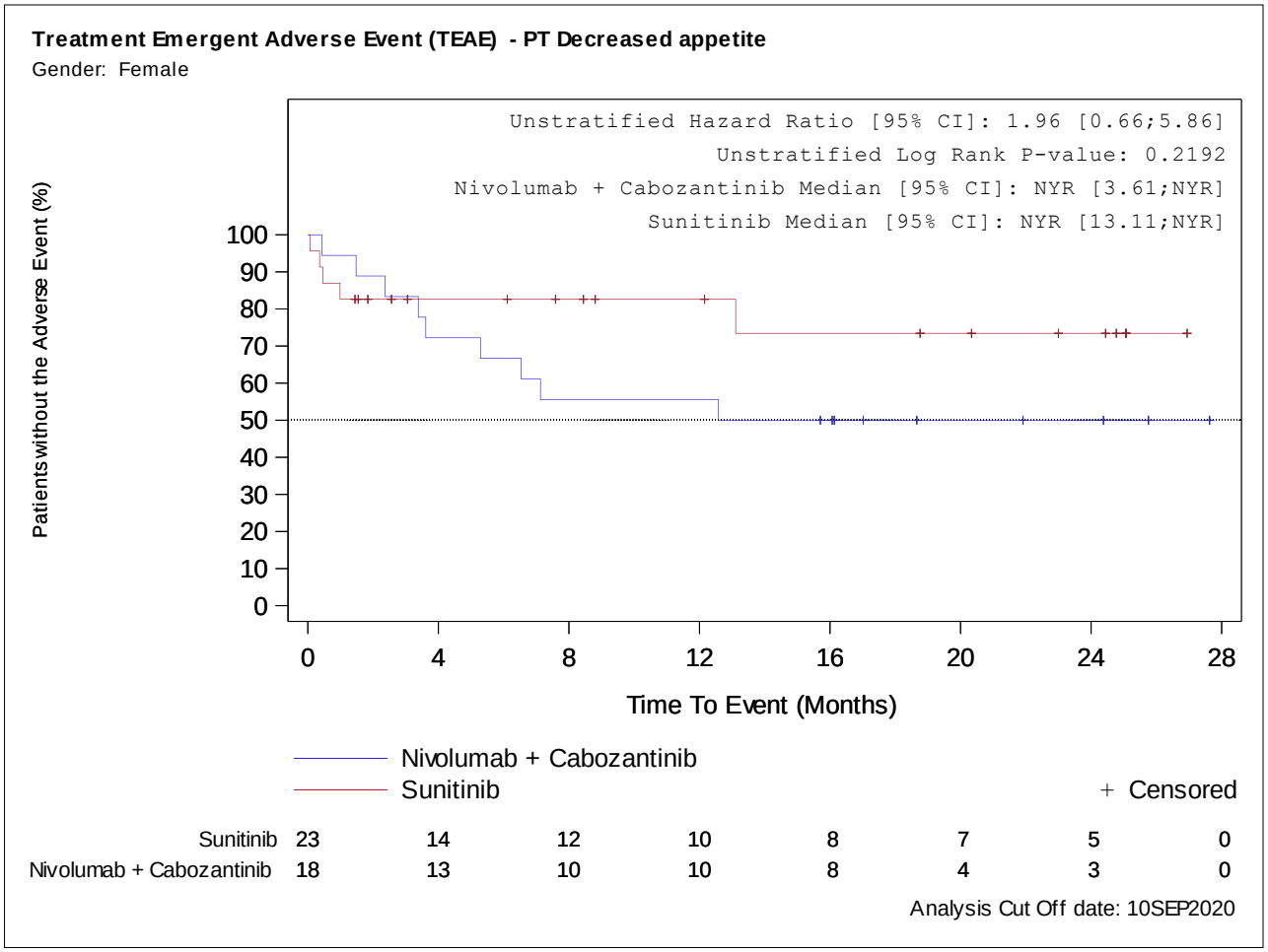
FIGURE 5.12.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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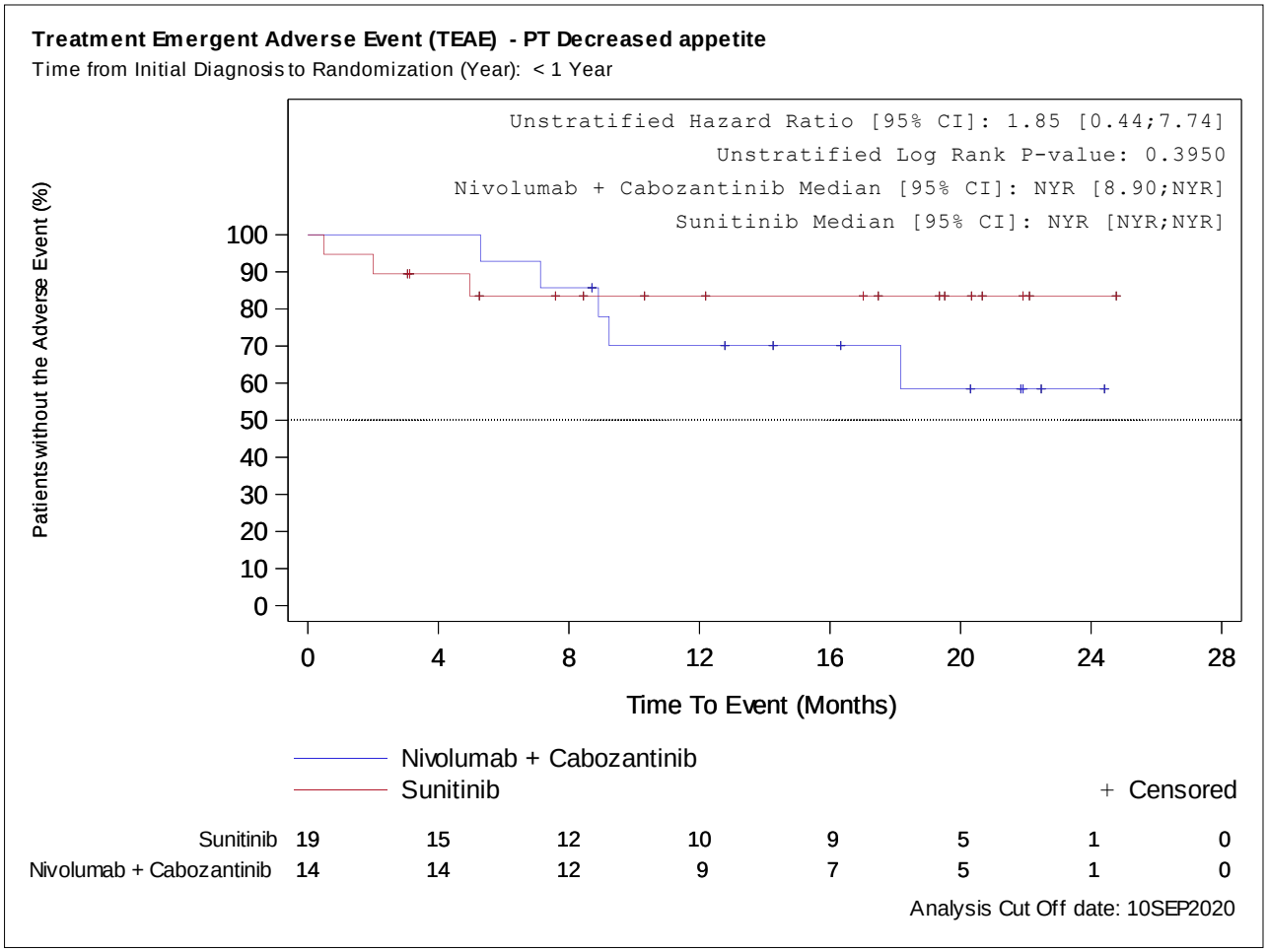
FIGURE 5.12.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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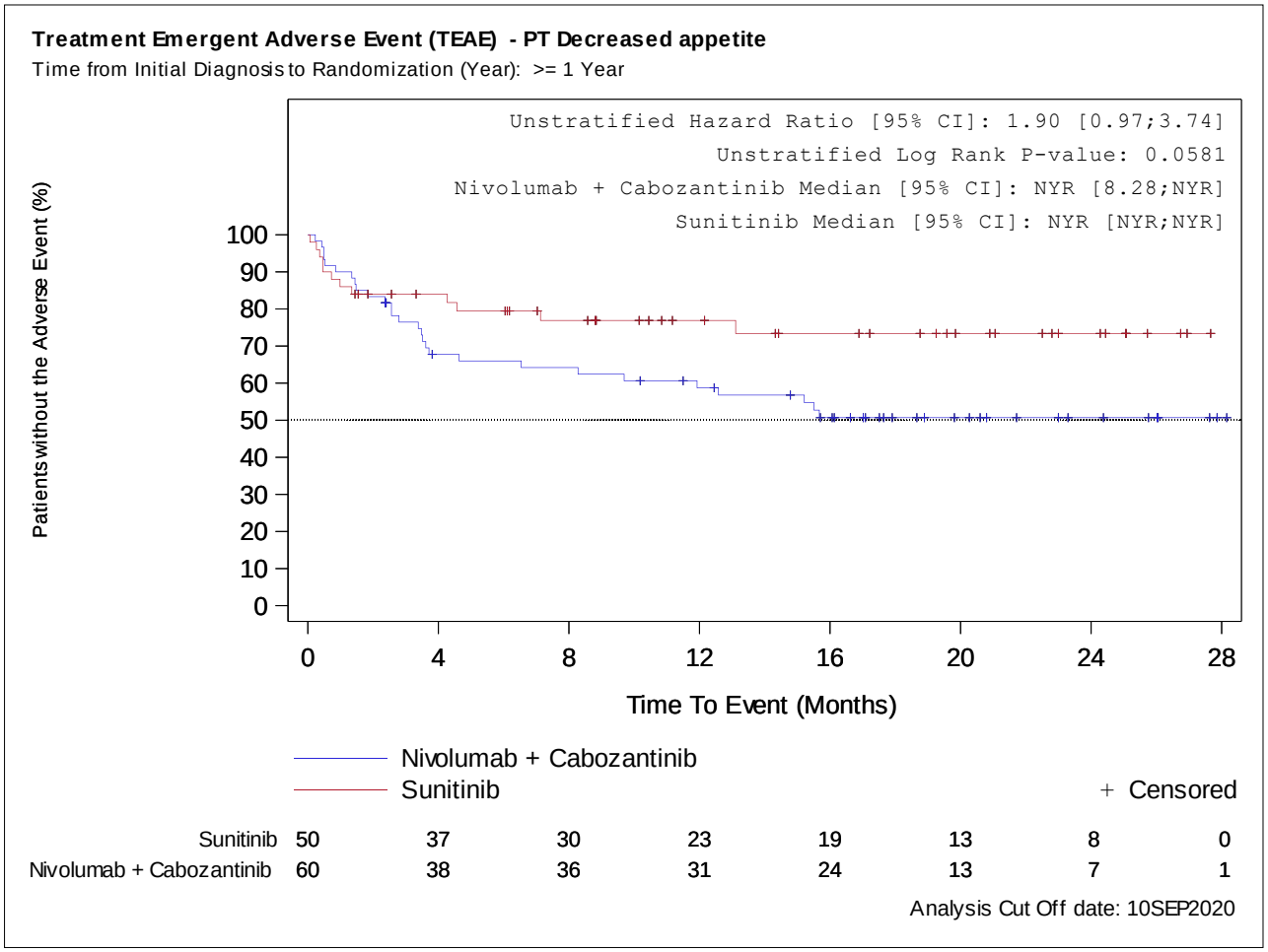
FIGURE 5.12.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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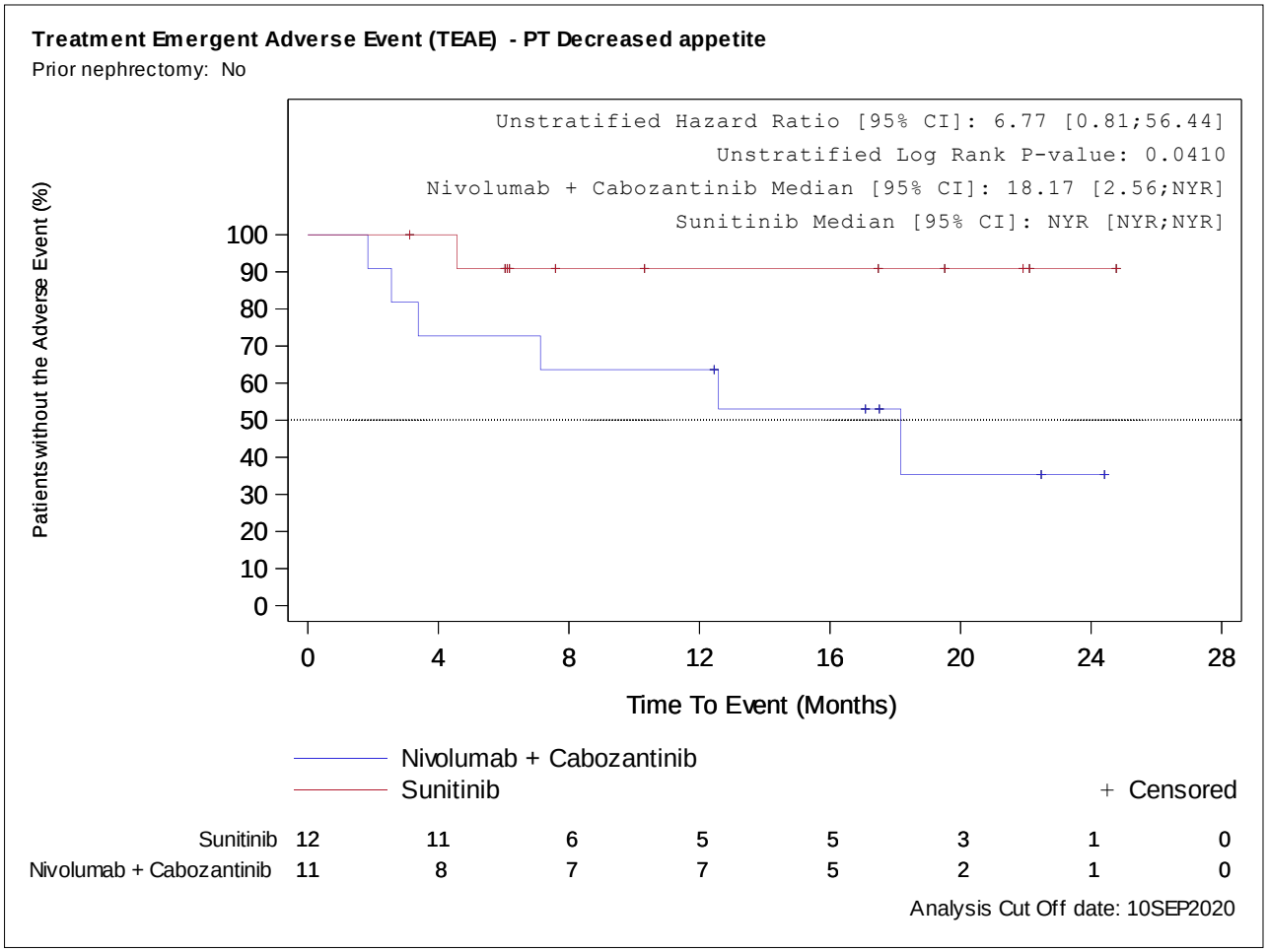
FIGURE 5.12.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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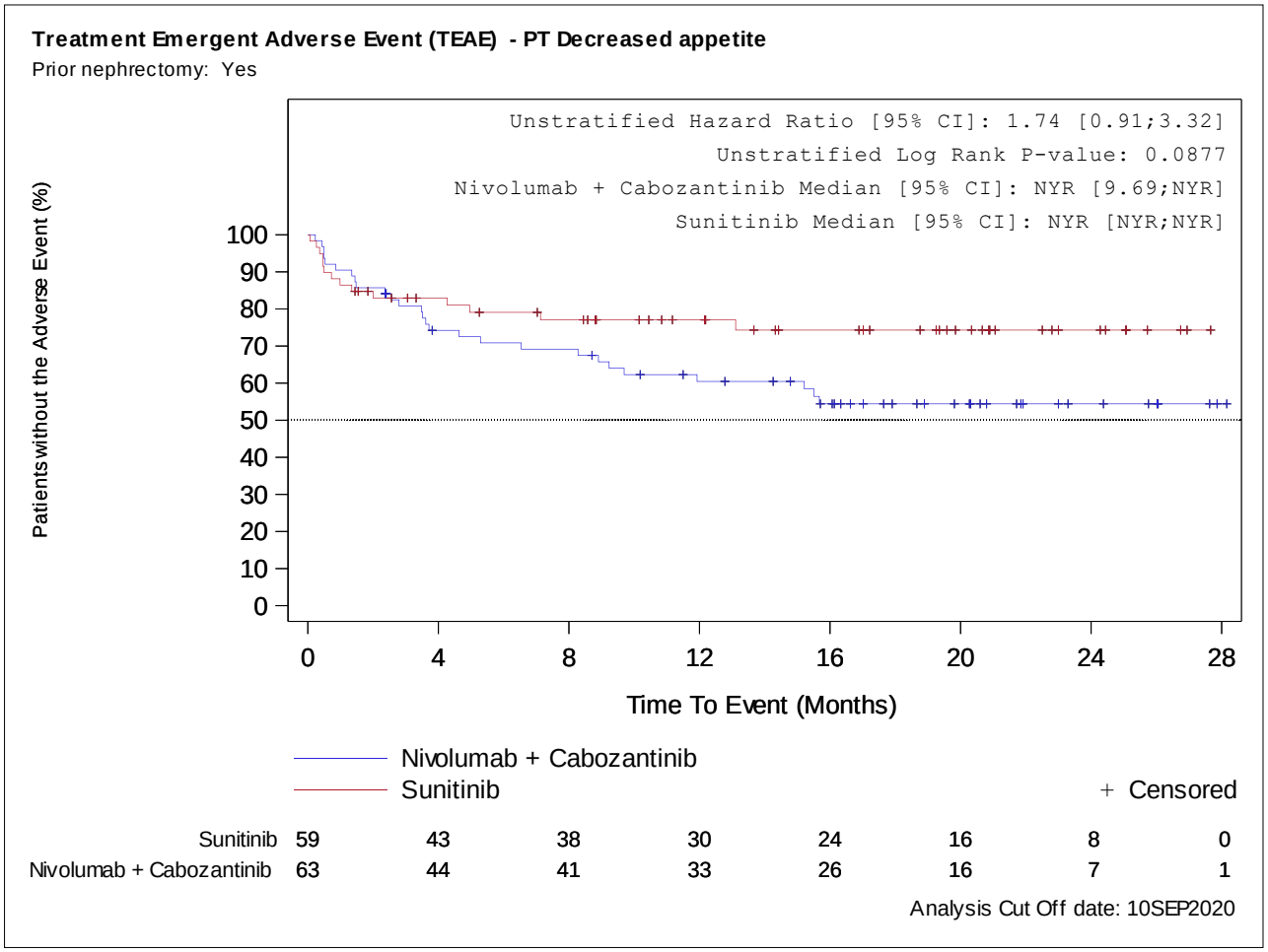
FIGURE 5.12.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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FIGURE 5.12.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No

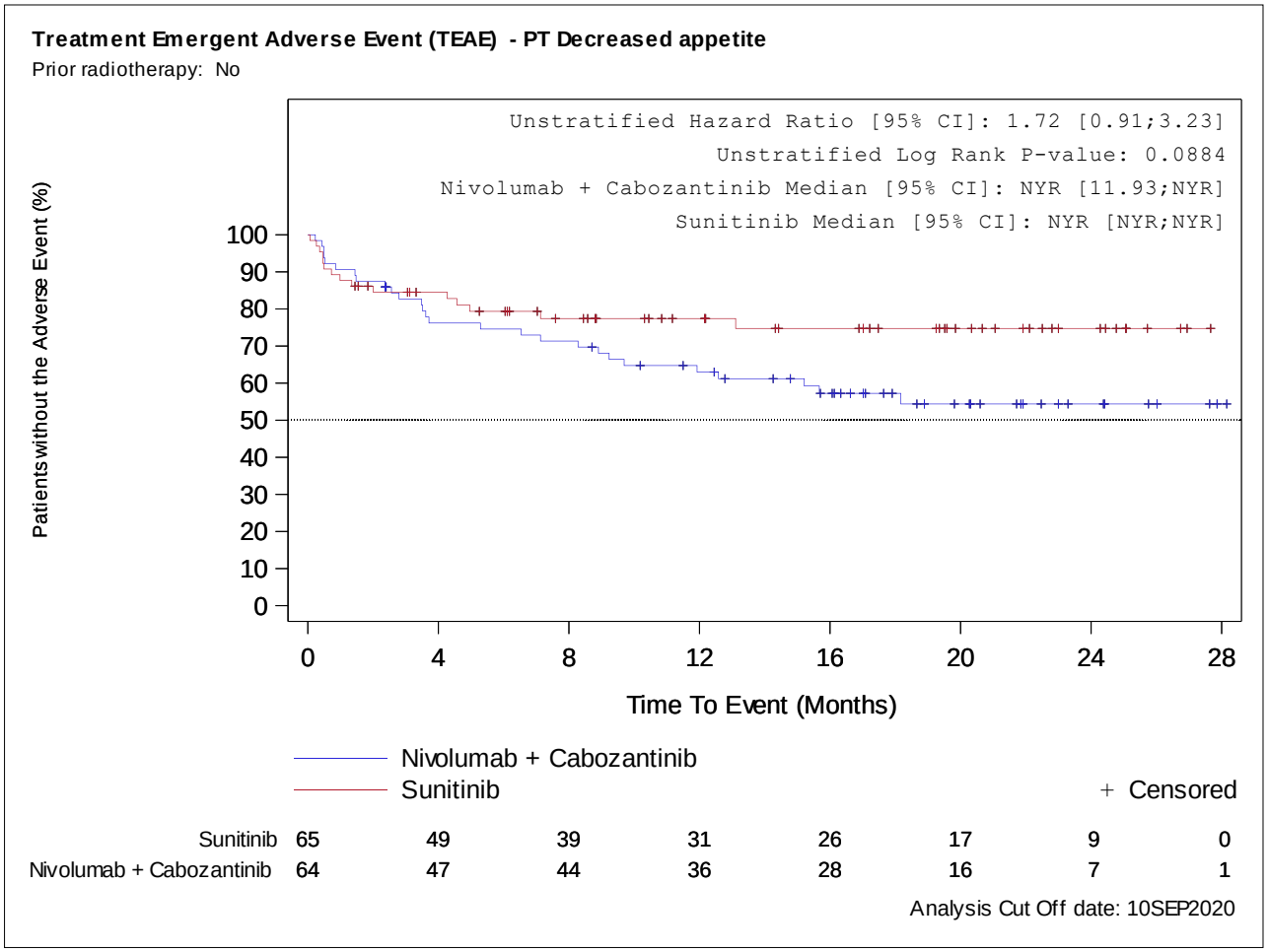


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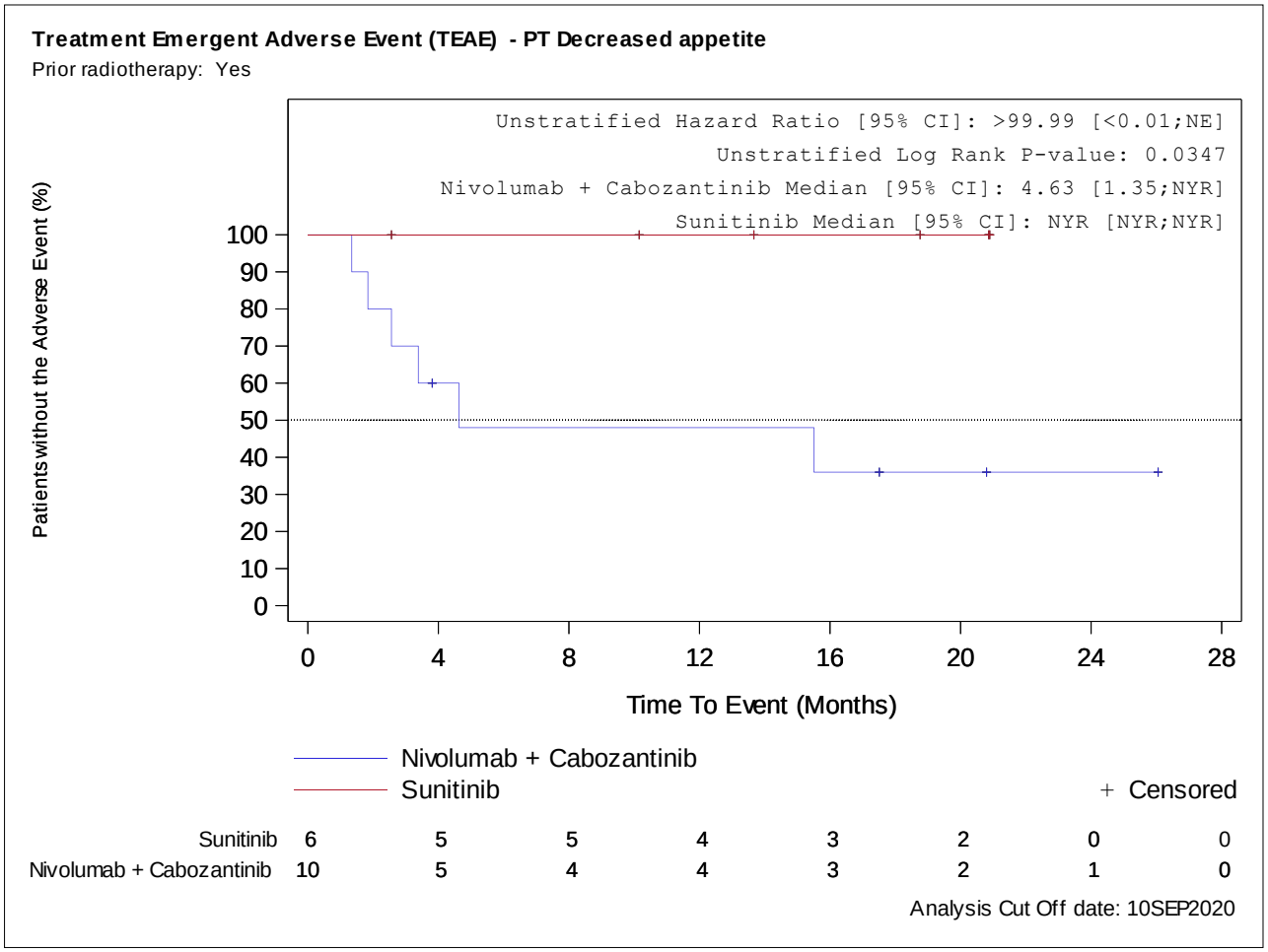
FIGURE 5.12.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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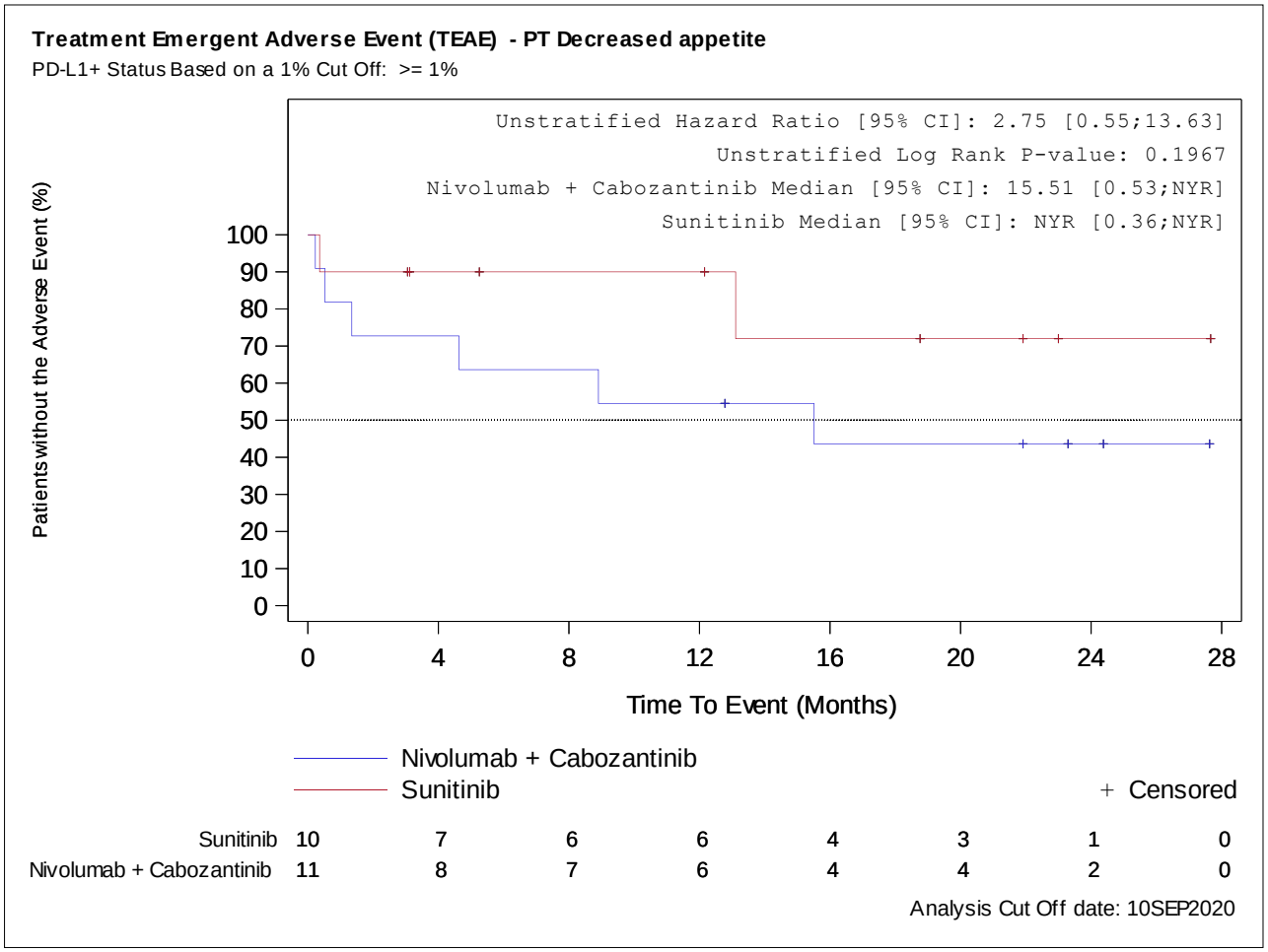
FIGURE 5.12.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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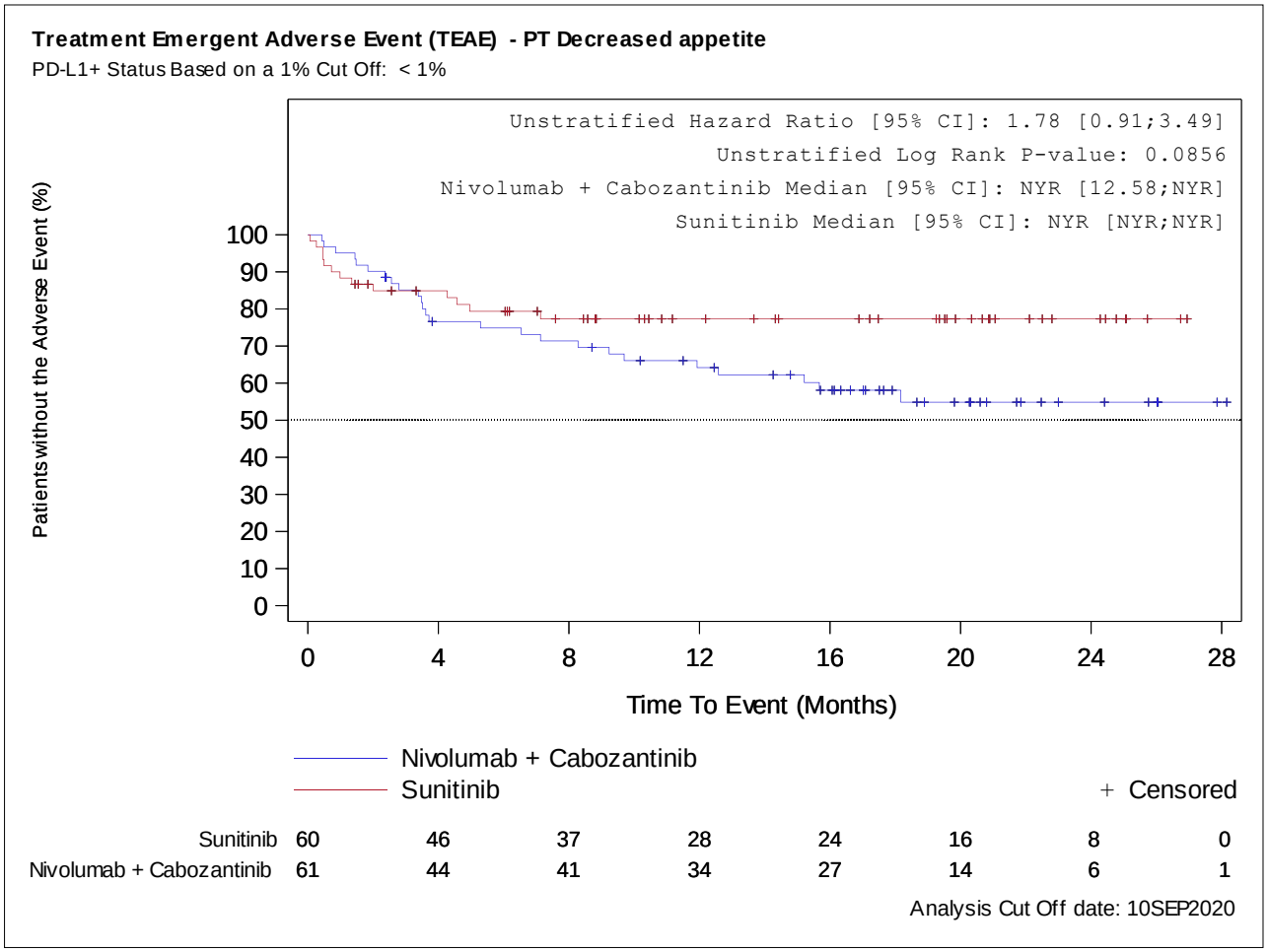
FIGURE 5.12.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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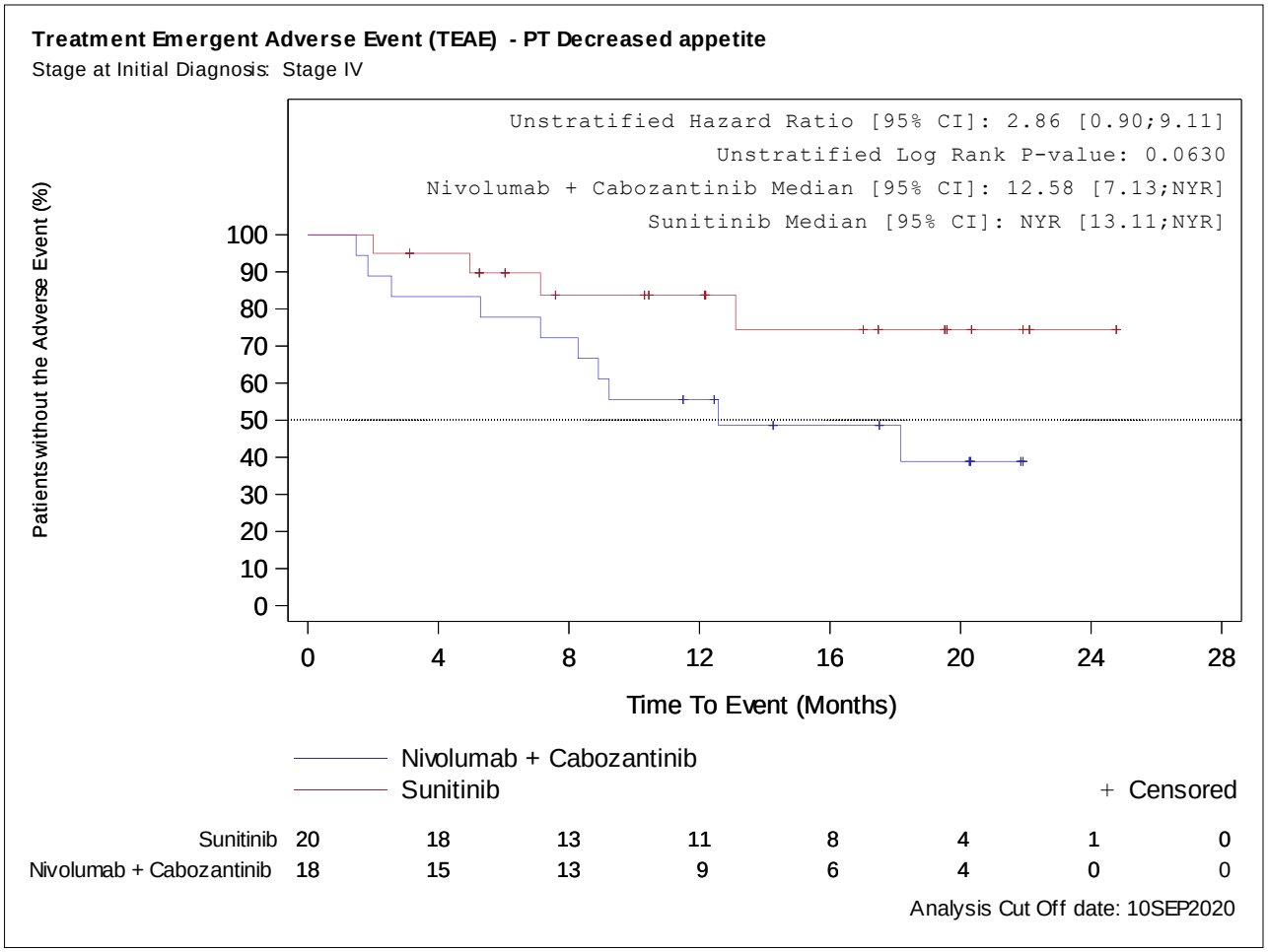
FIGURE 5.12.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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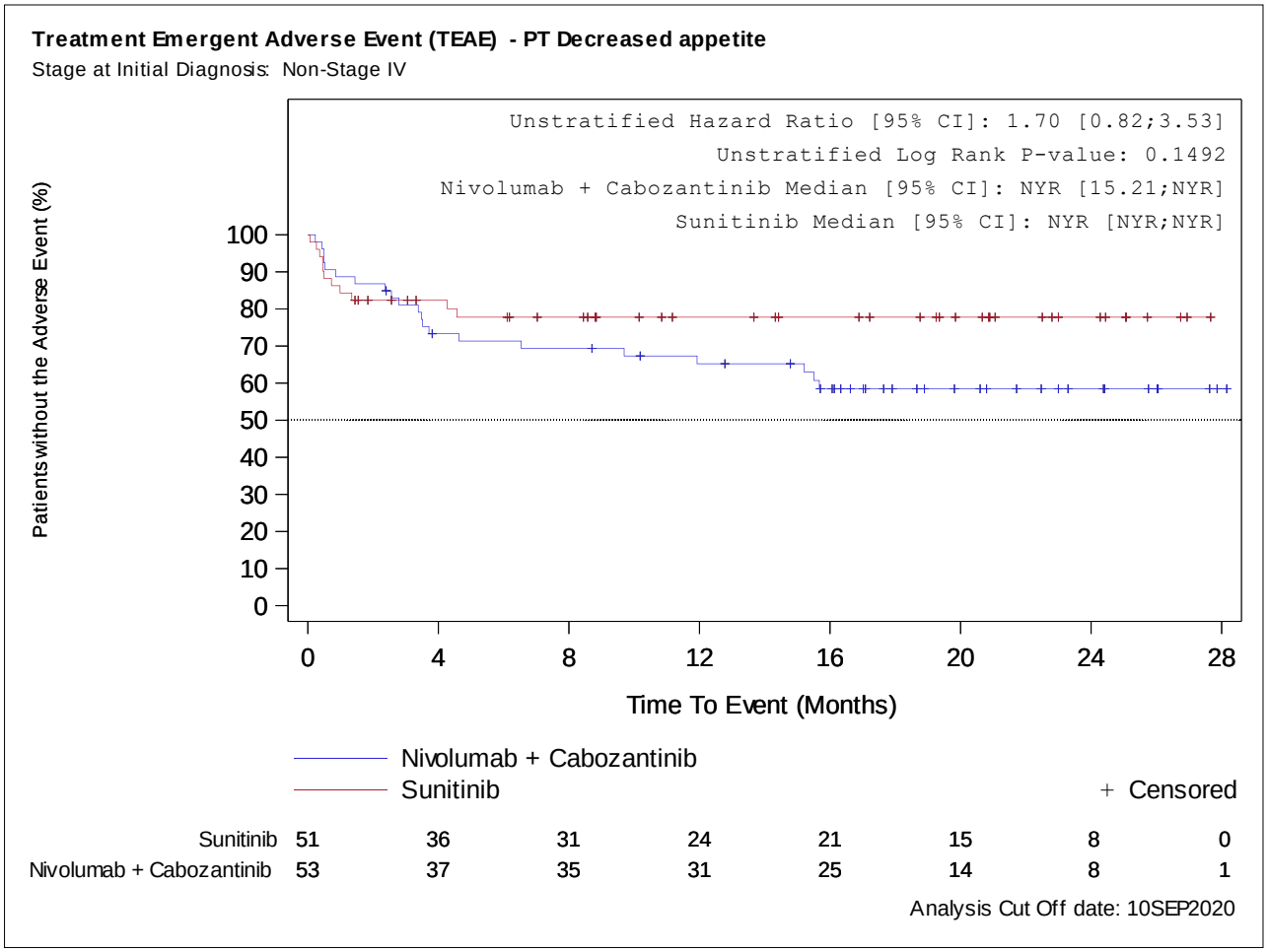
FIGURE 5.12.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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FIGURE 5.13.1: Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)

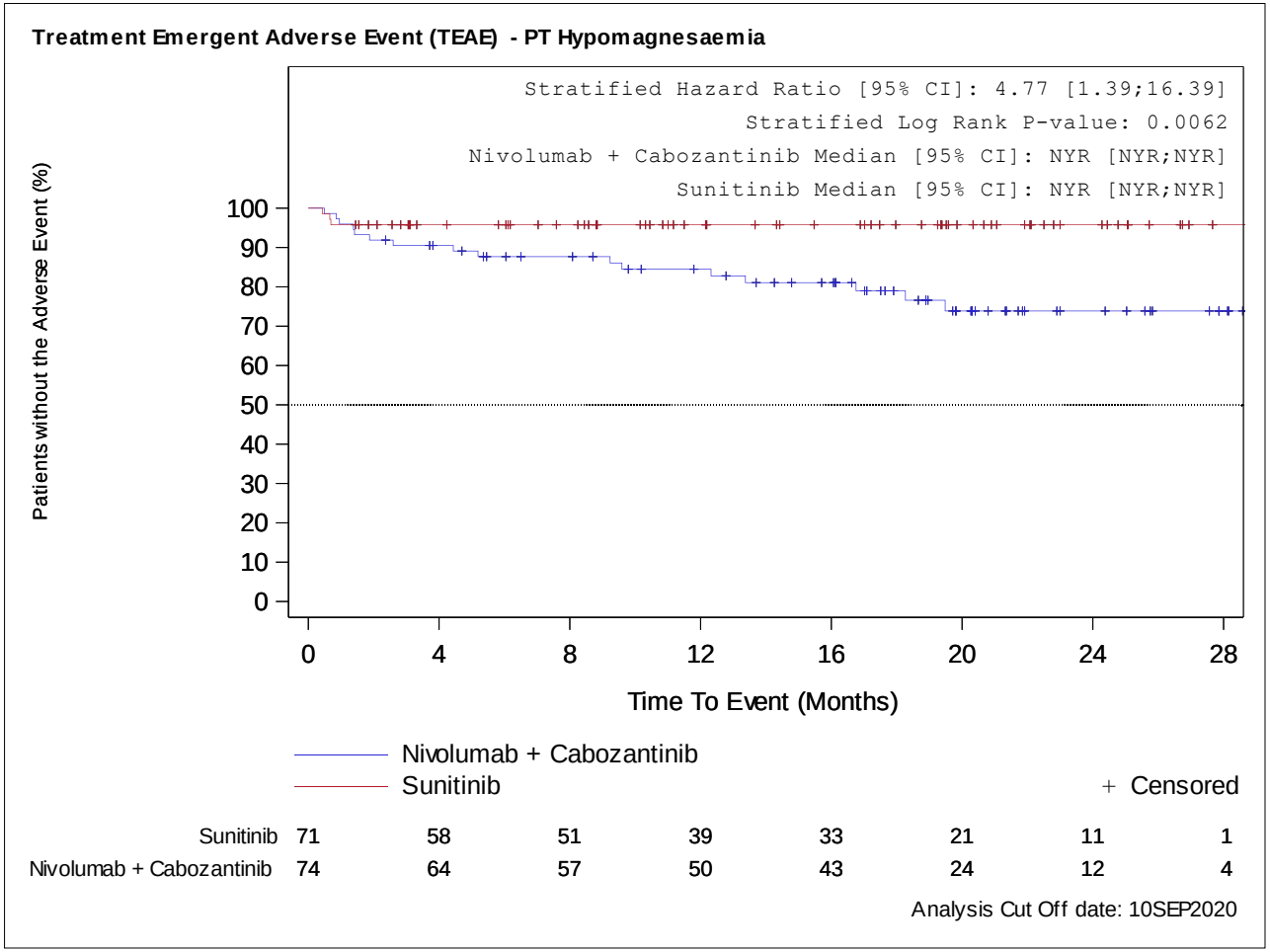


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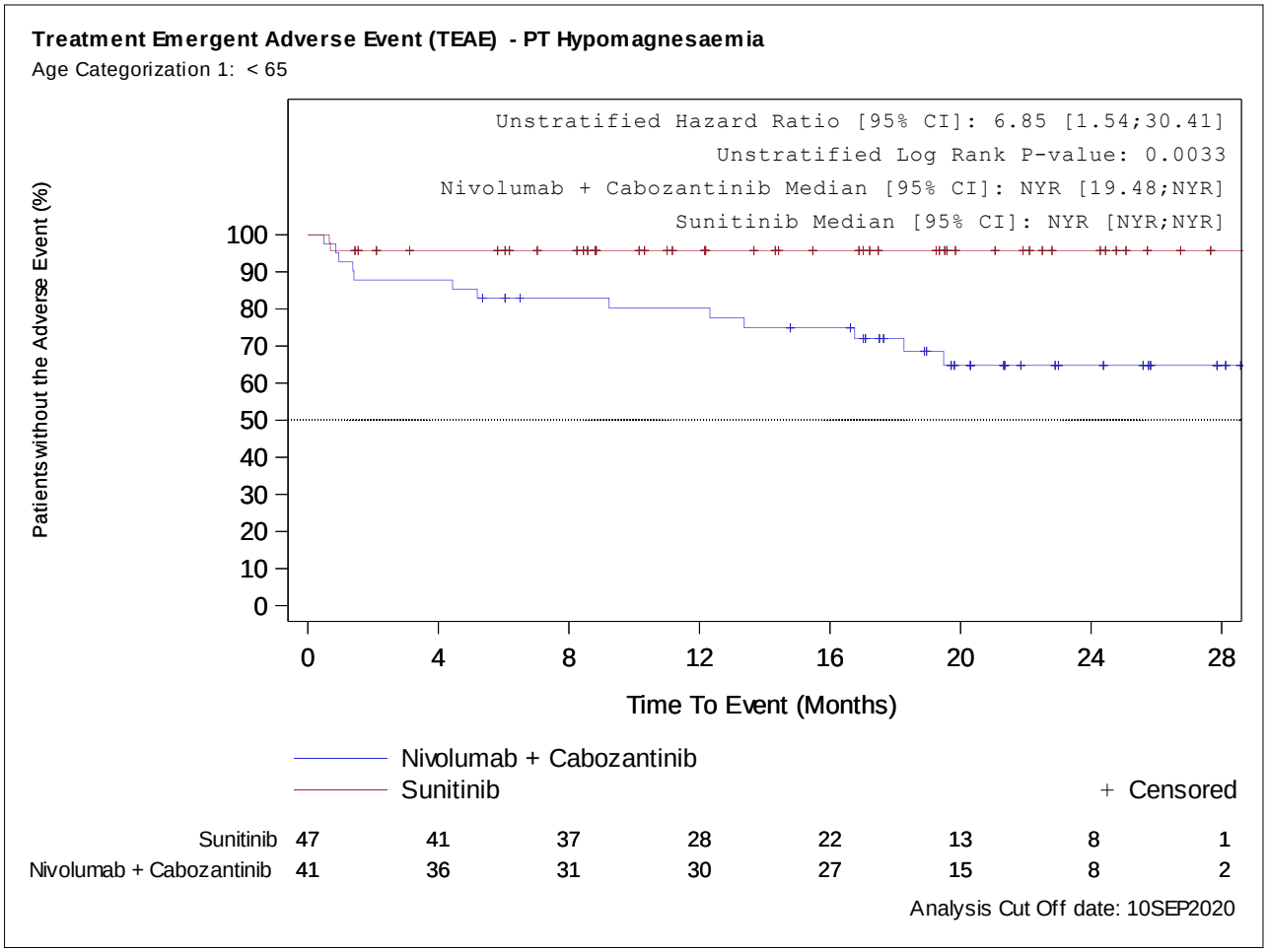
FIGURE 5.13.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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FIGURE 5.13.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65

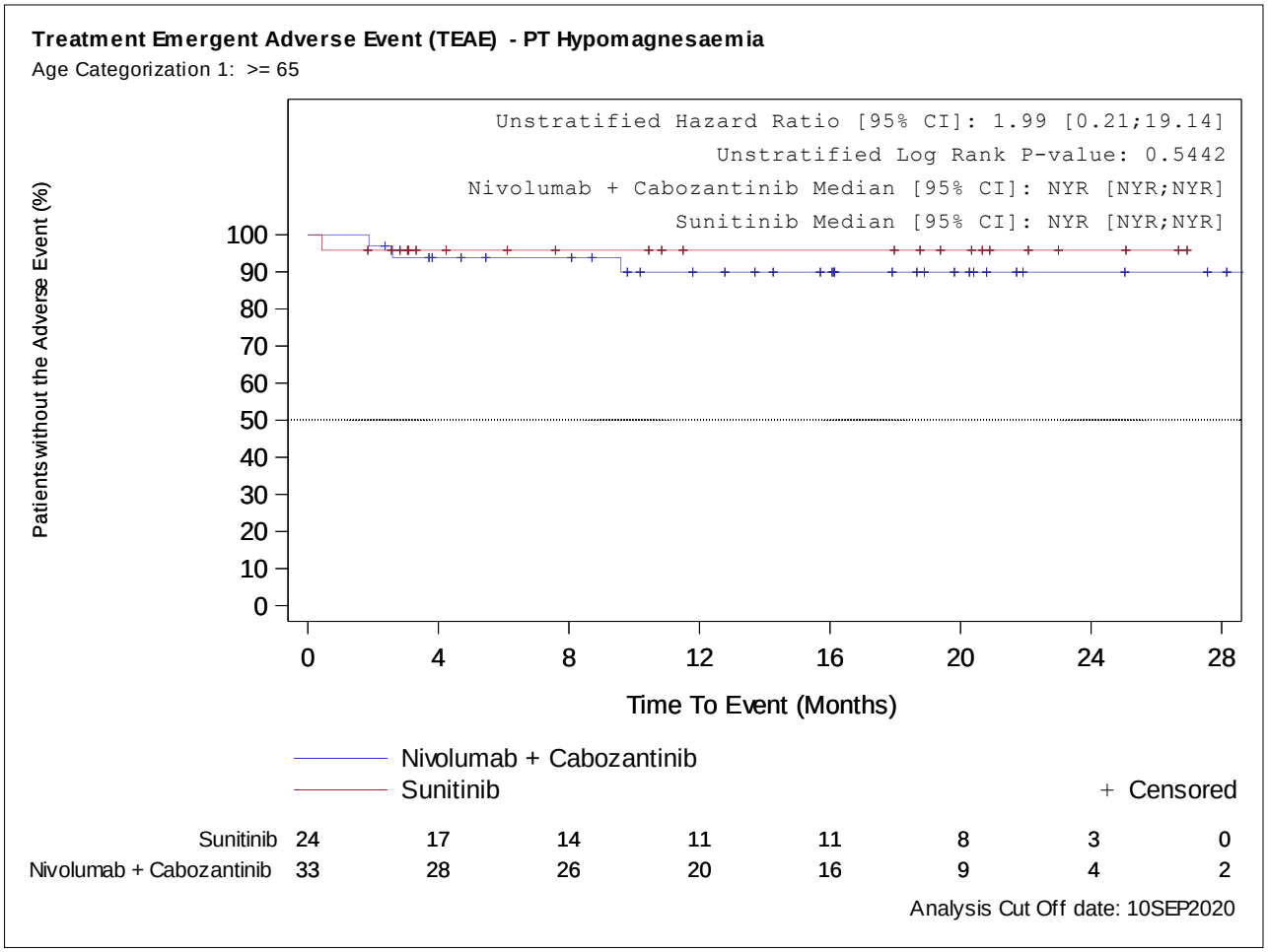


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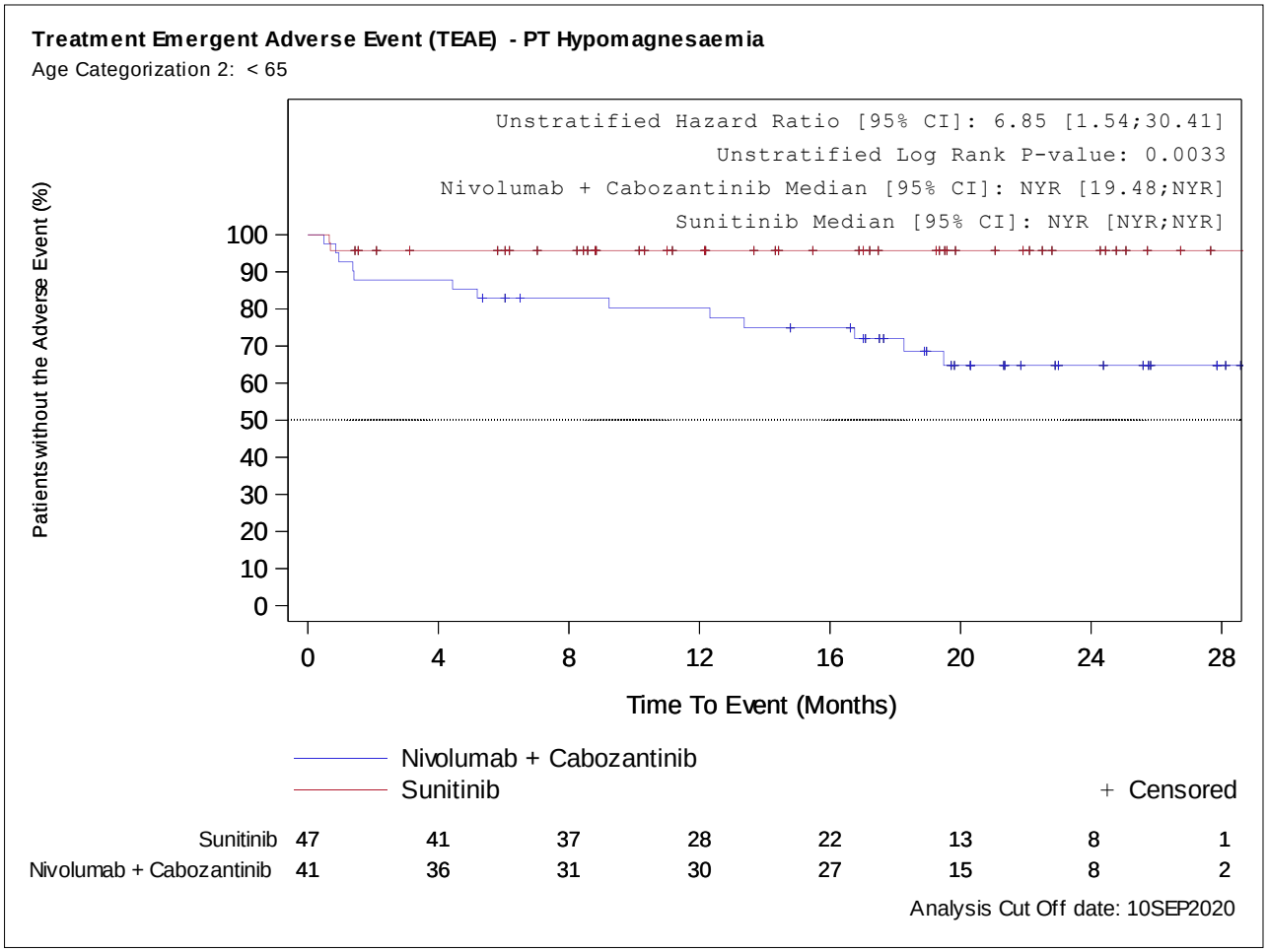
FIGURE 5.13.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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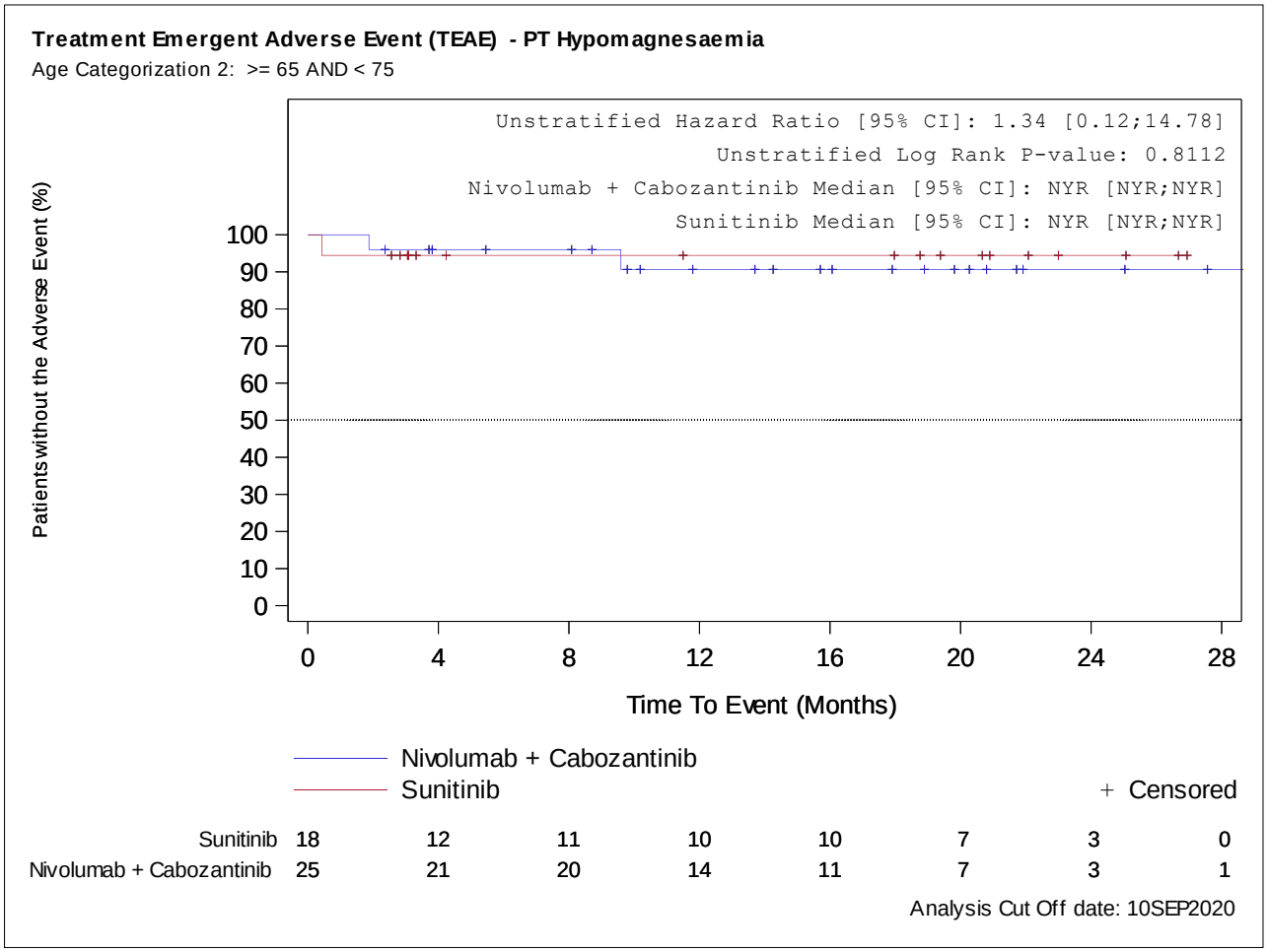
FIGURE 5.13.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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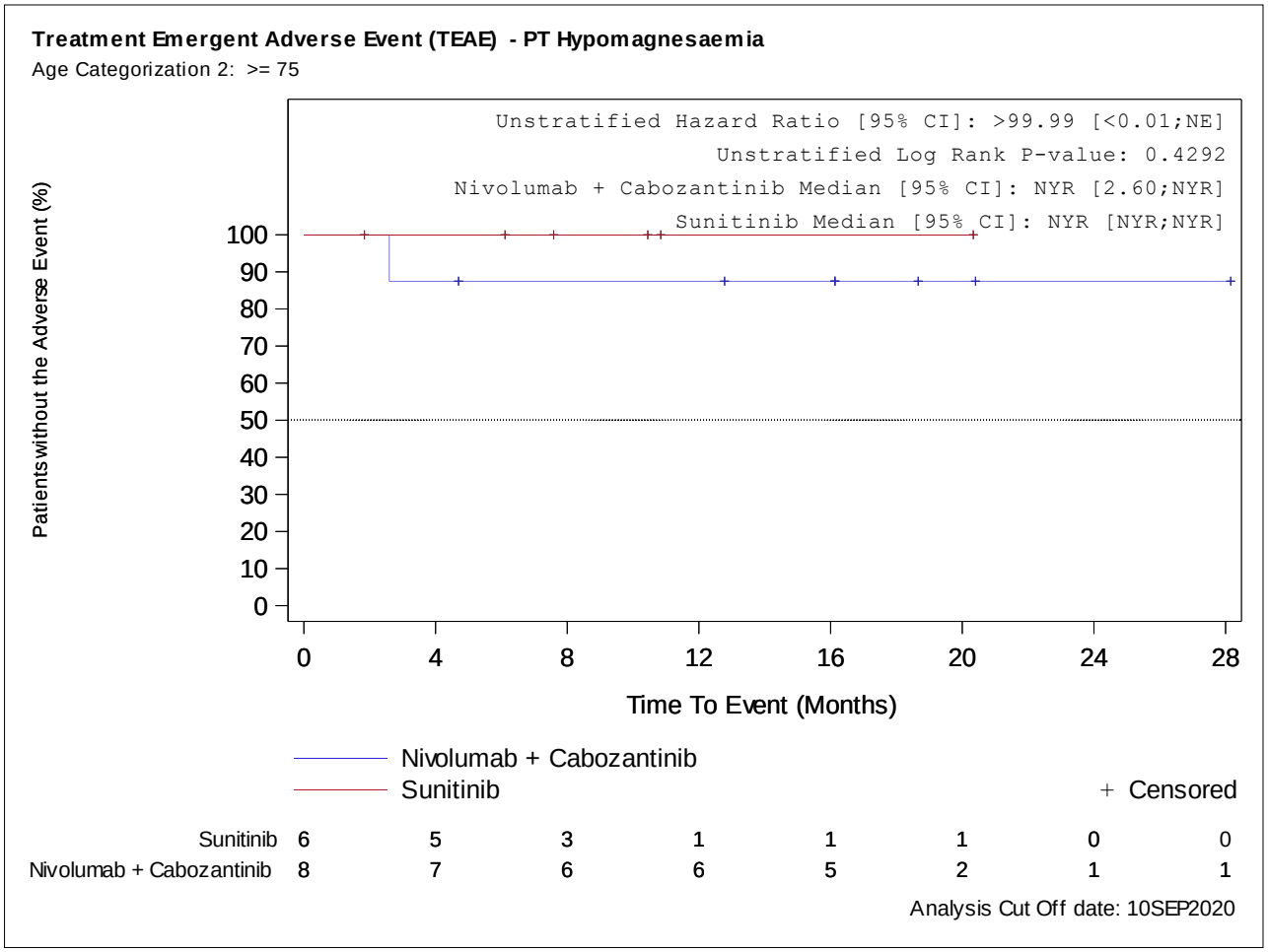
FIGURE 5.13.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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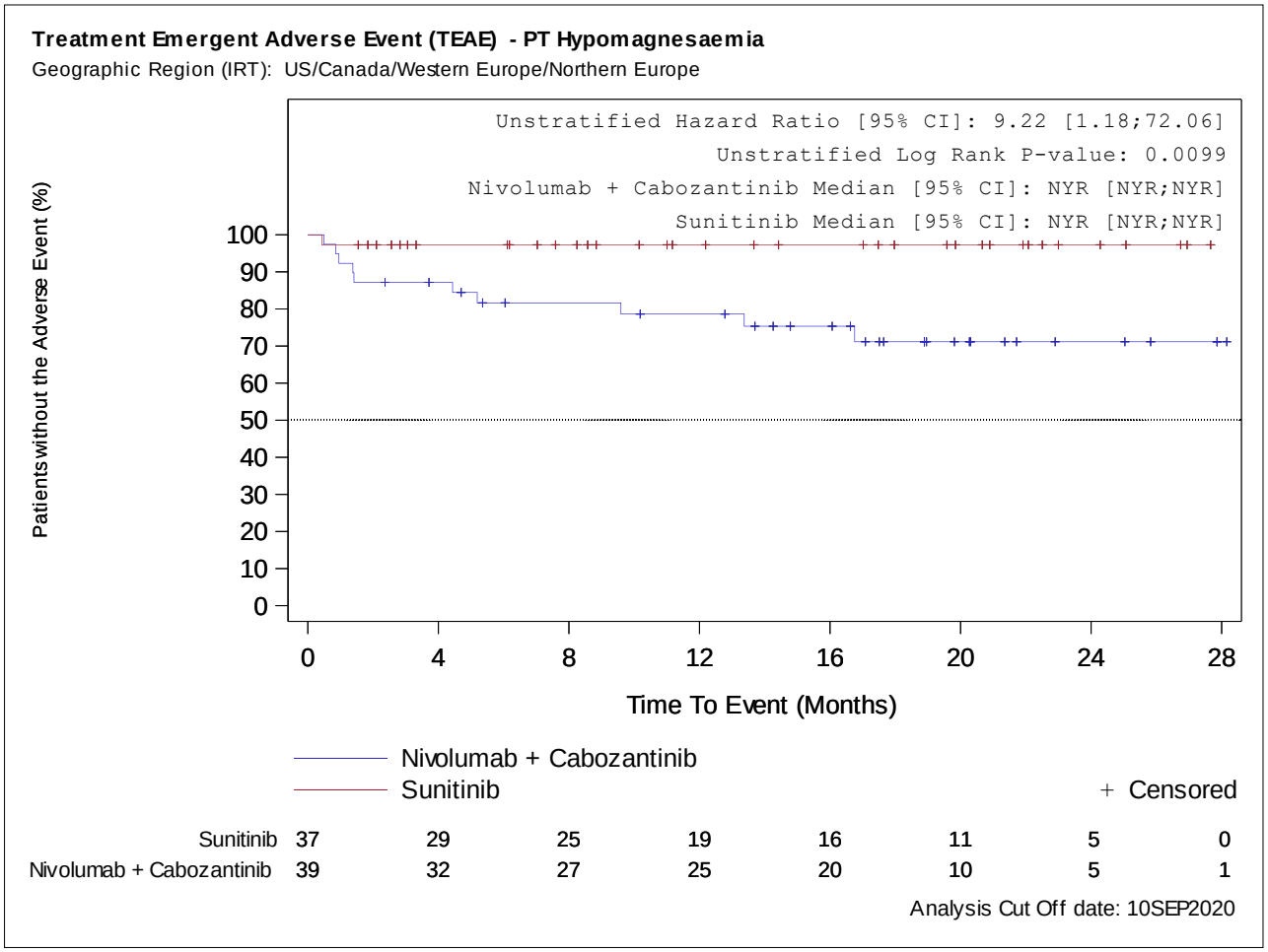
FIGURE 5.13.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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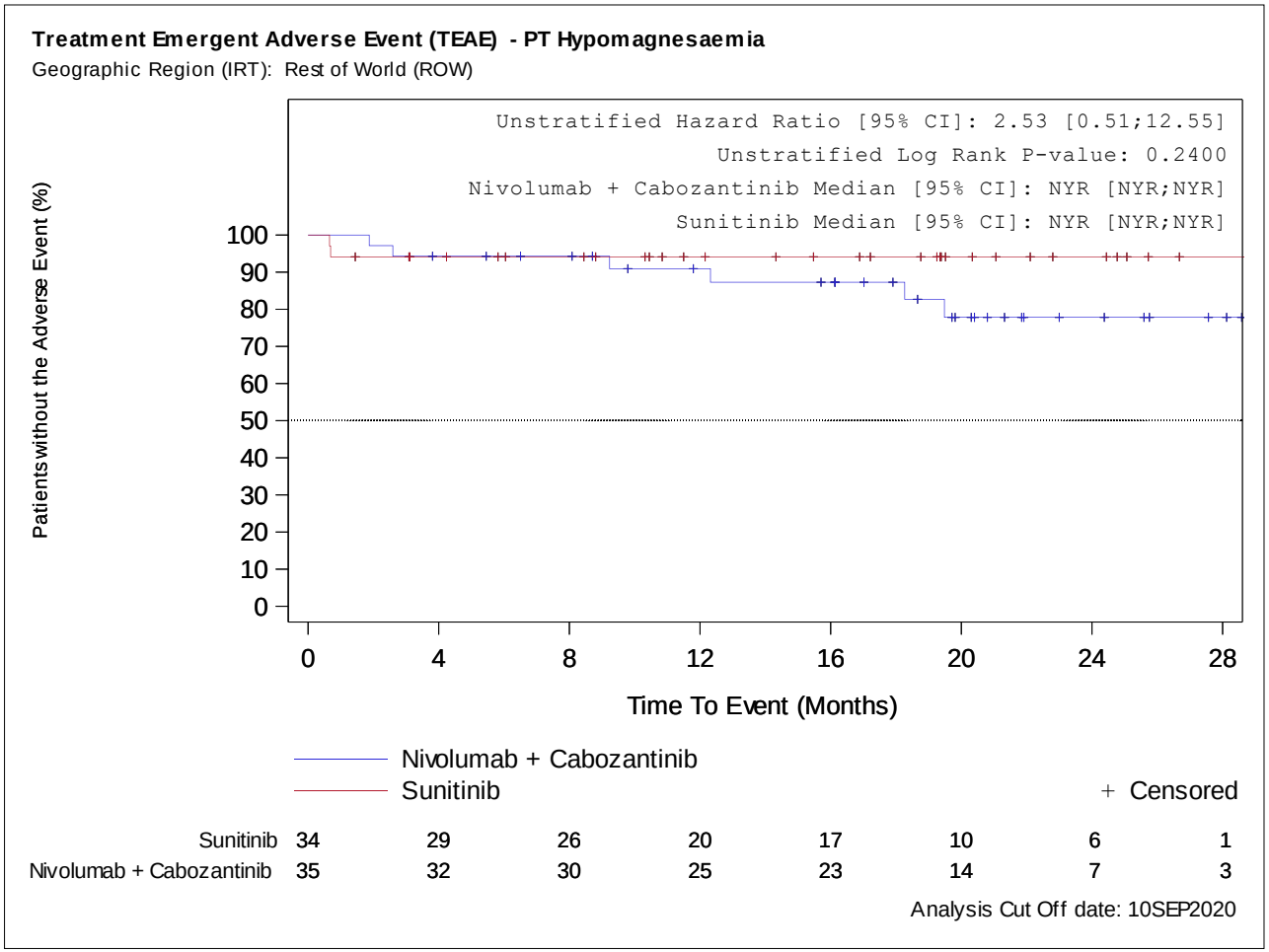
FIGURE 5.13.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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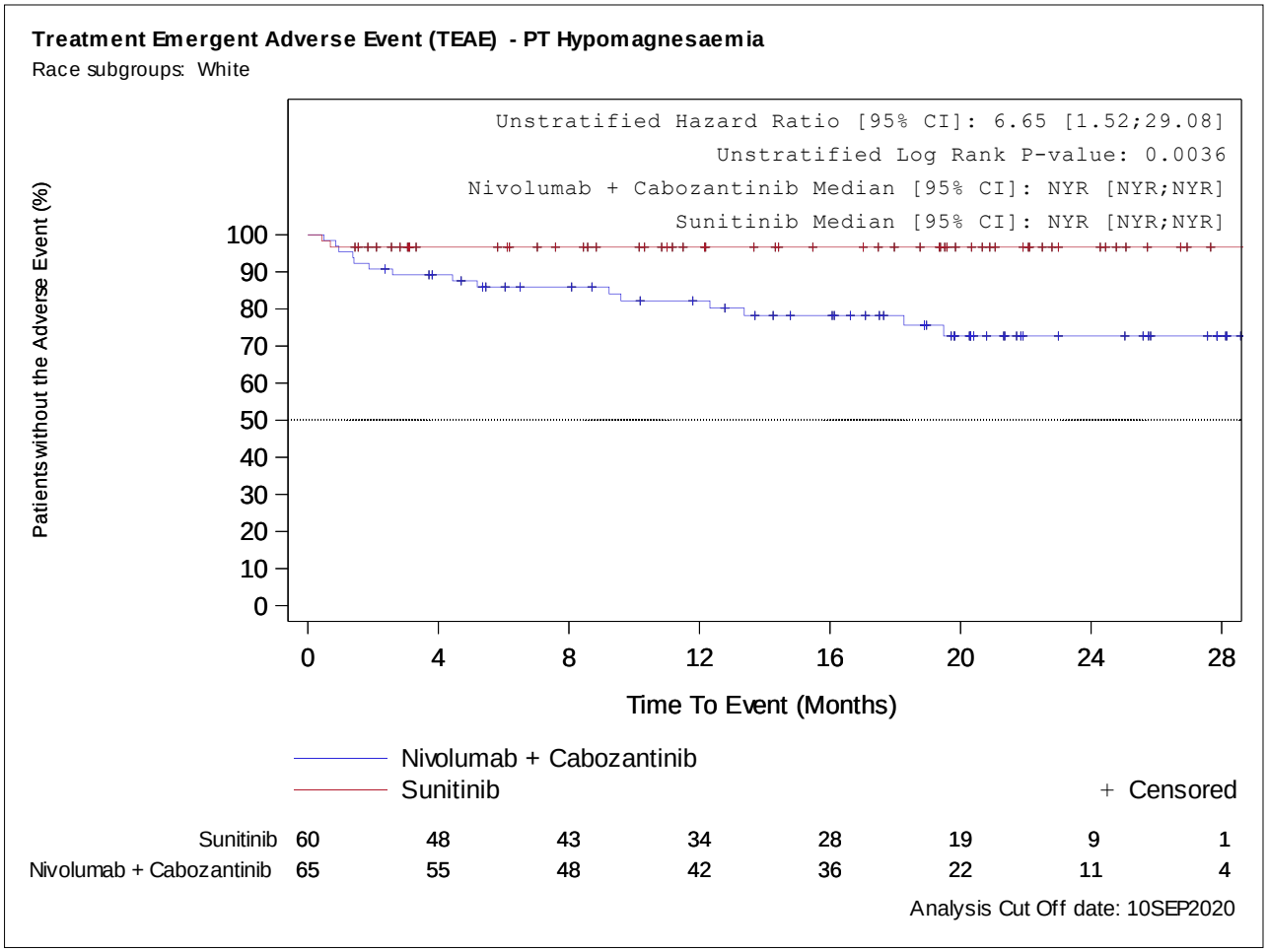
FIGURE 5.13.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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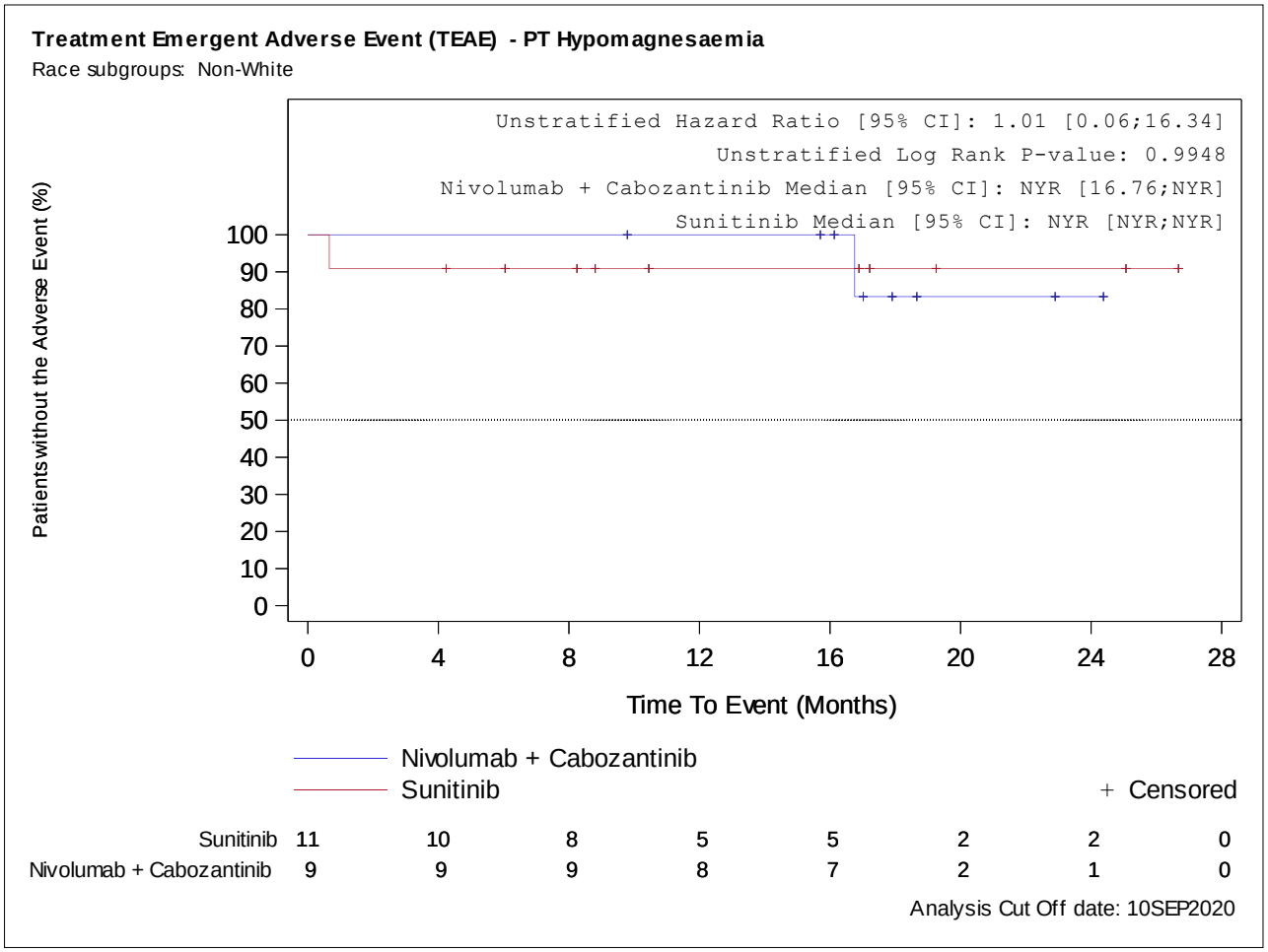
FIGURE 5.13.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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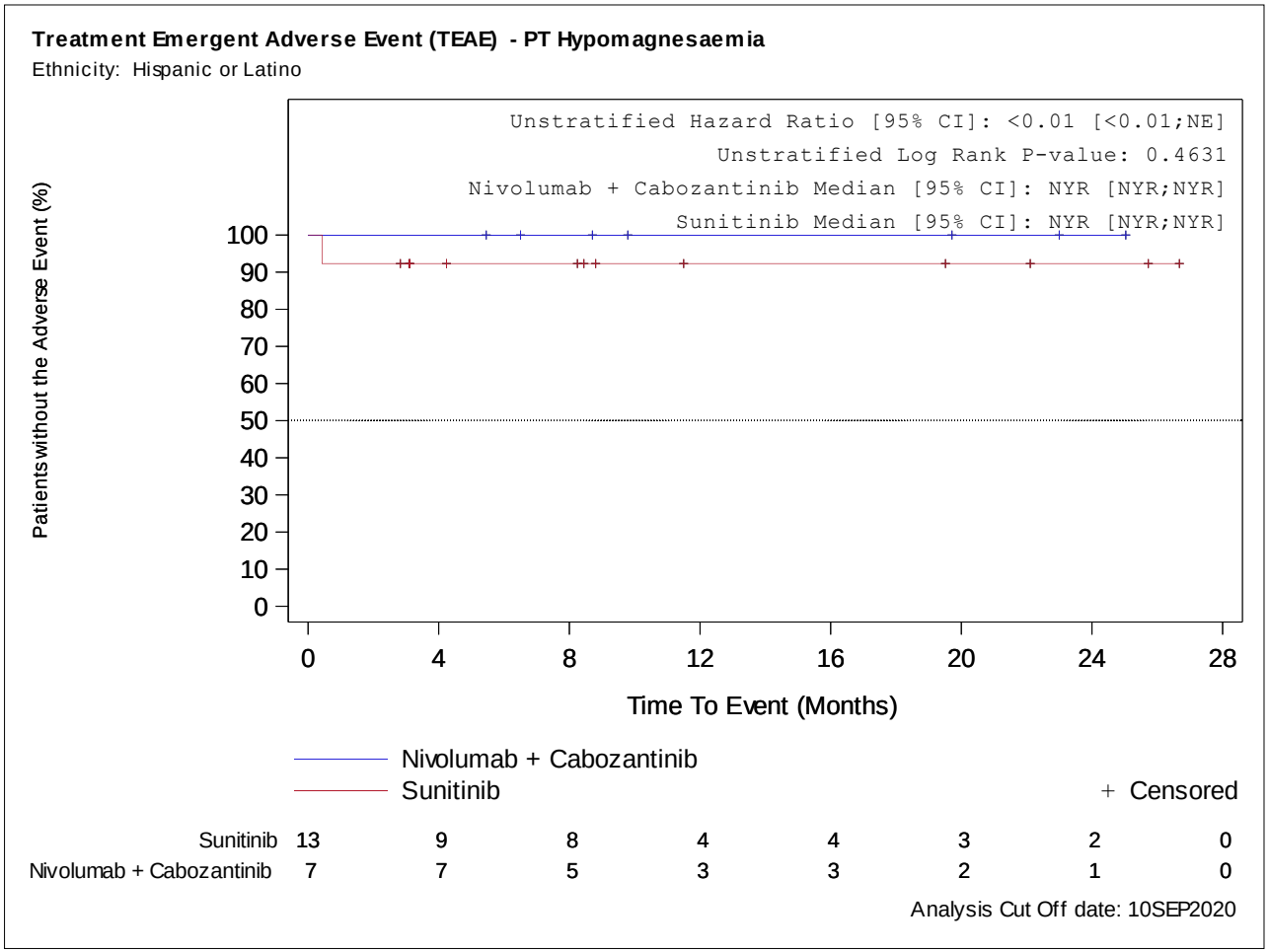
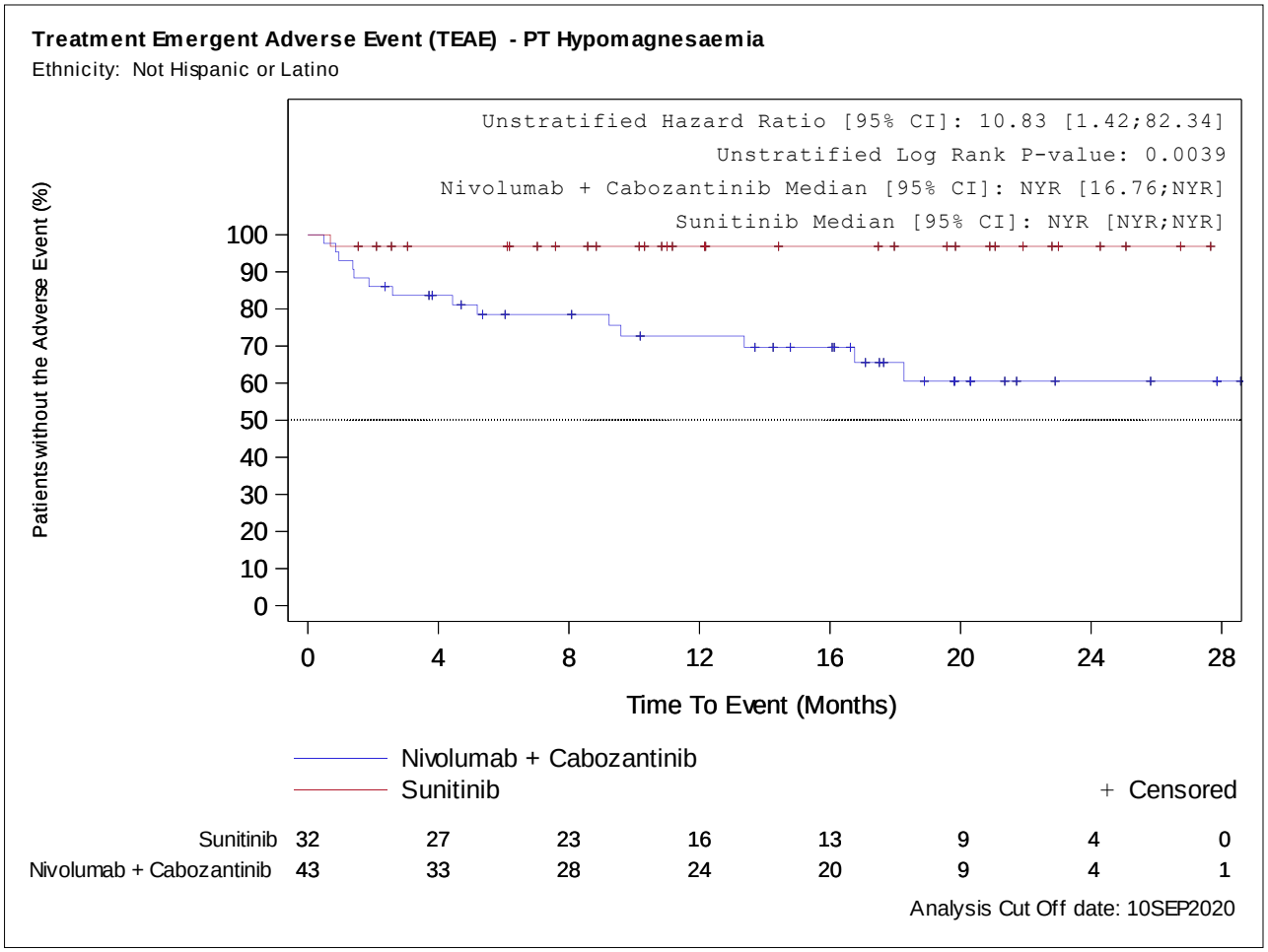
FIGURE 5.13.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



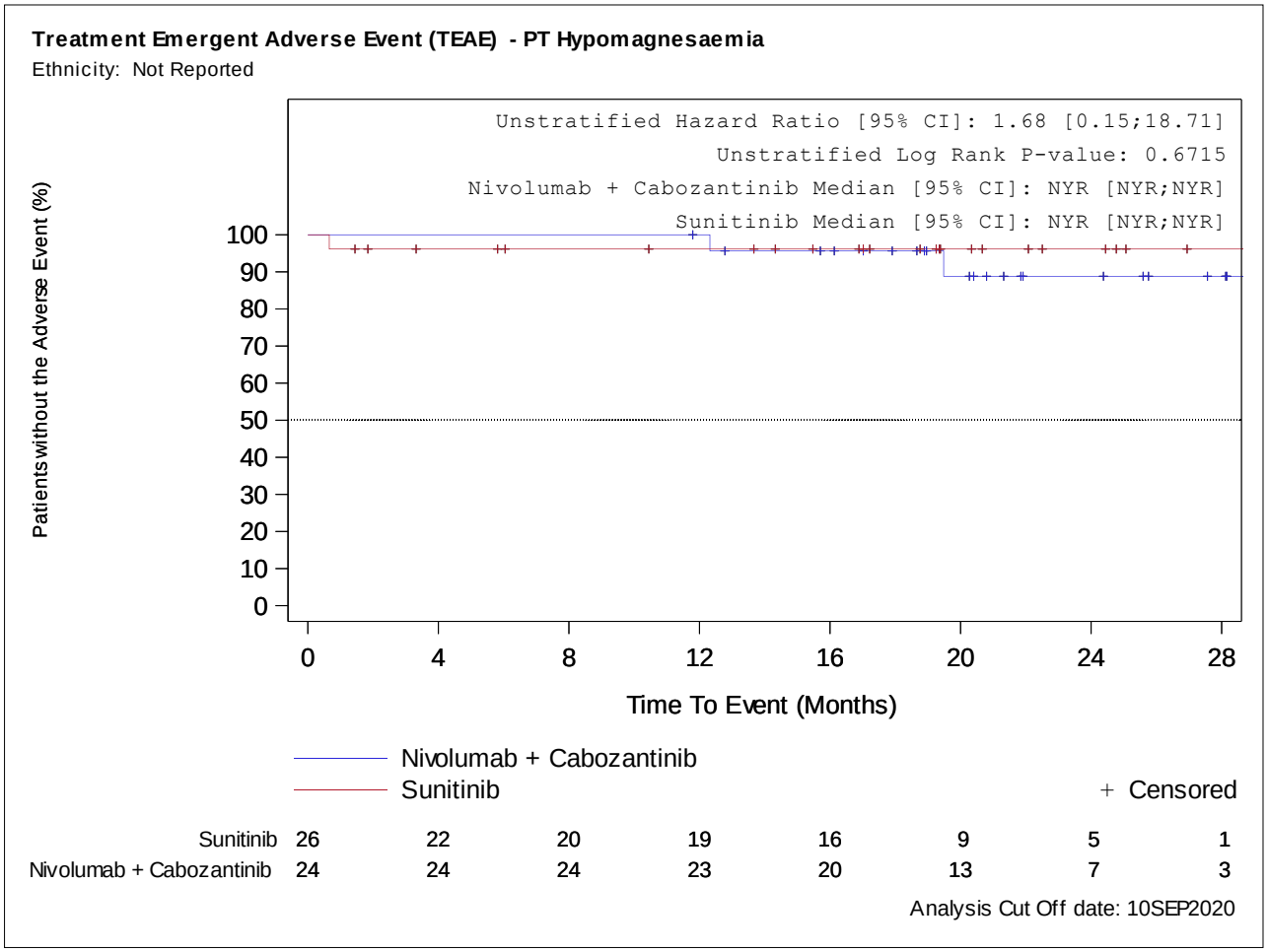

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:21:55

FIGURE 5.13.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



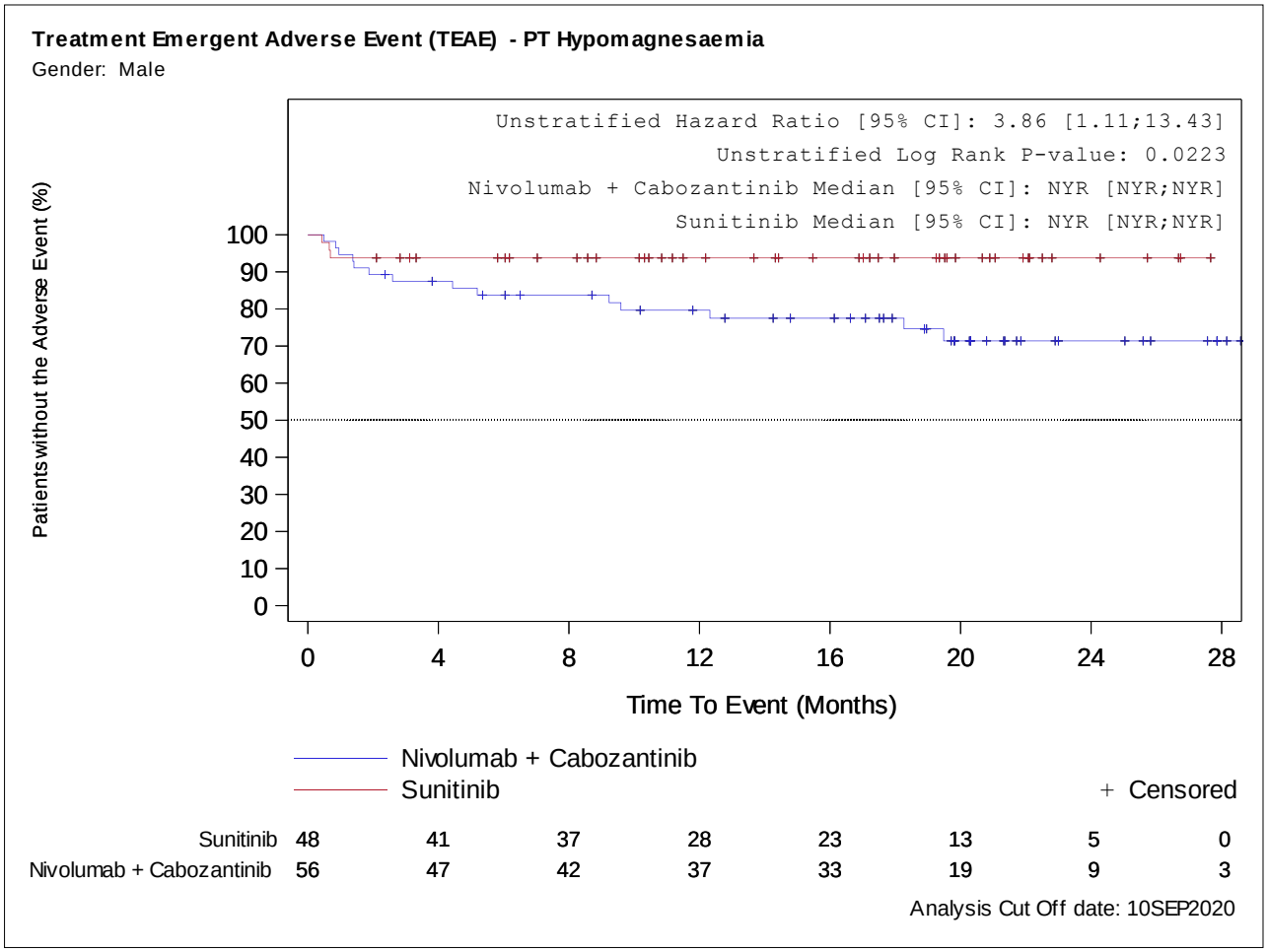

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:22:00

FIGURE 5.13.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



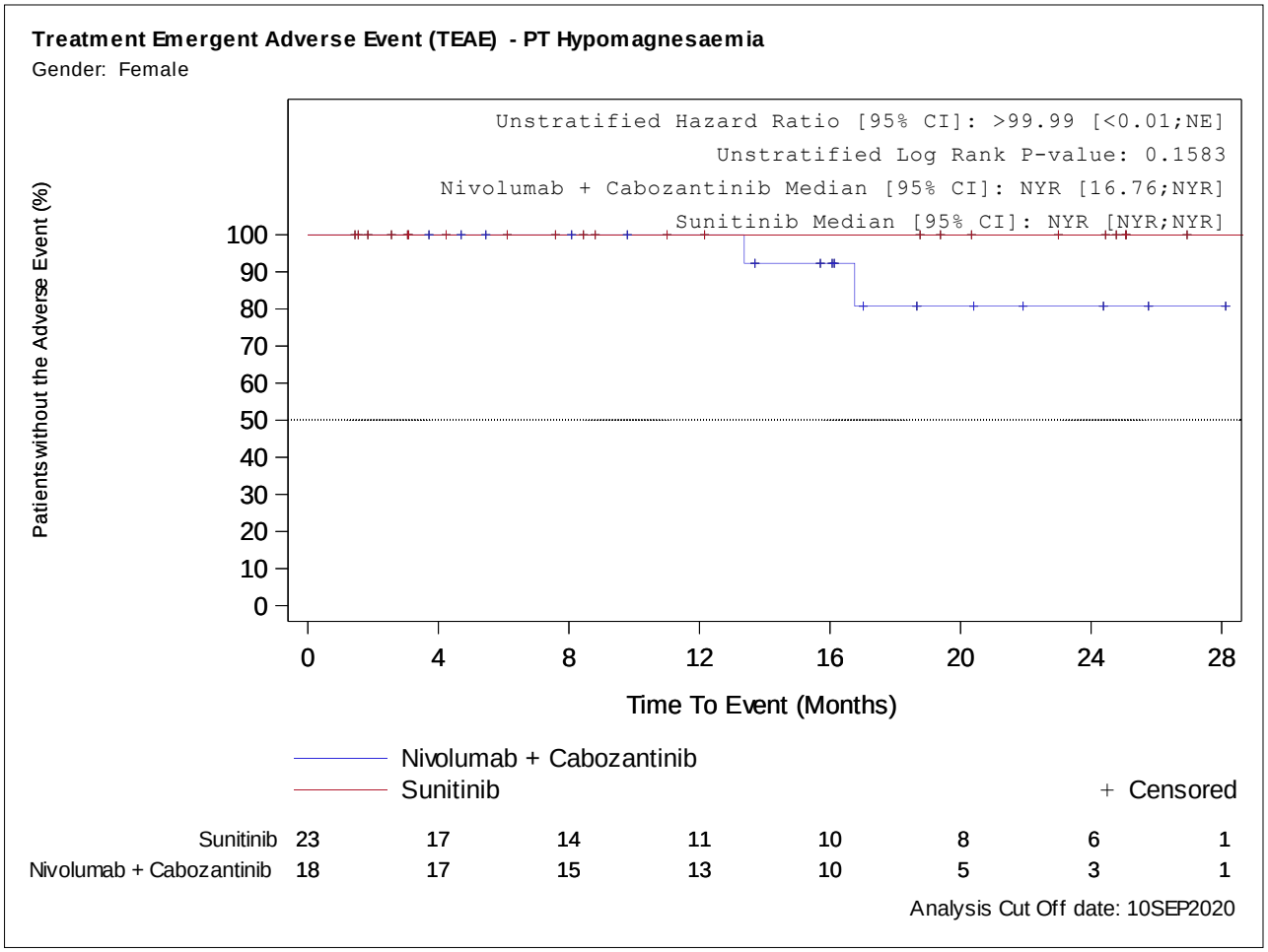

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:22:06

FIGURE 5.13.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



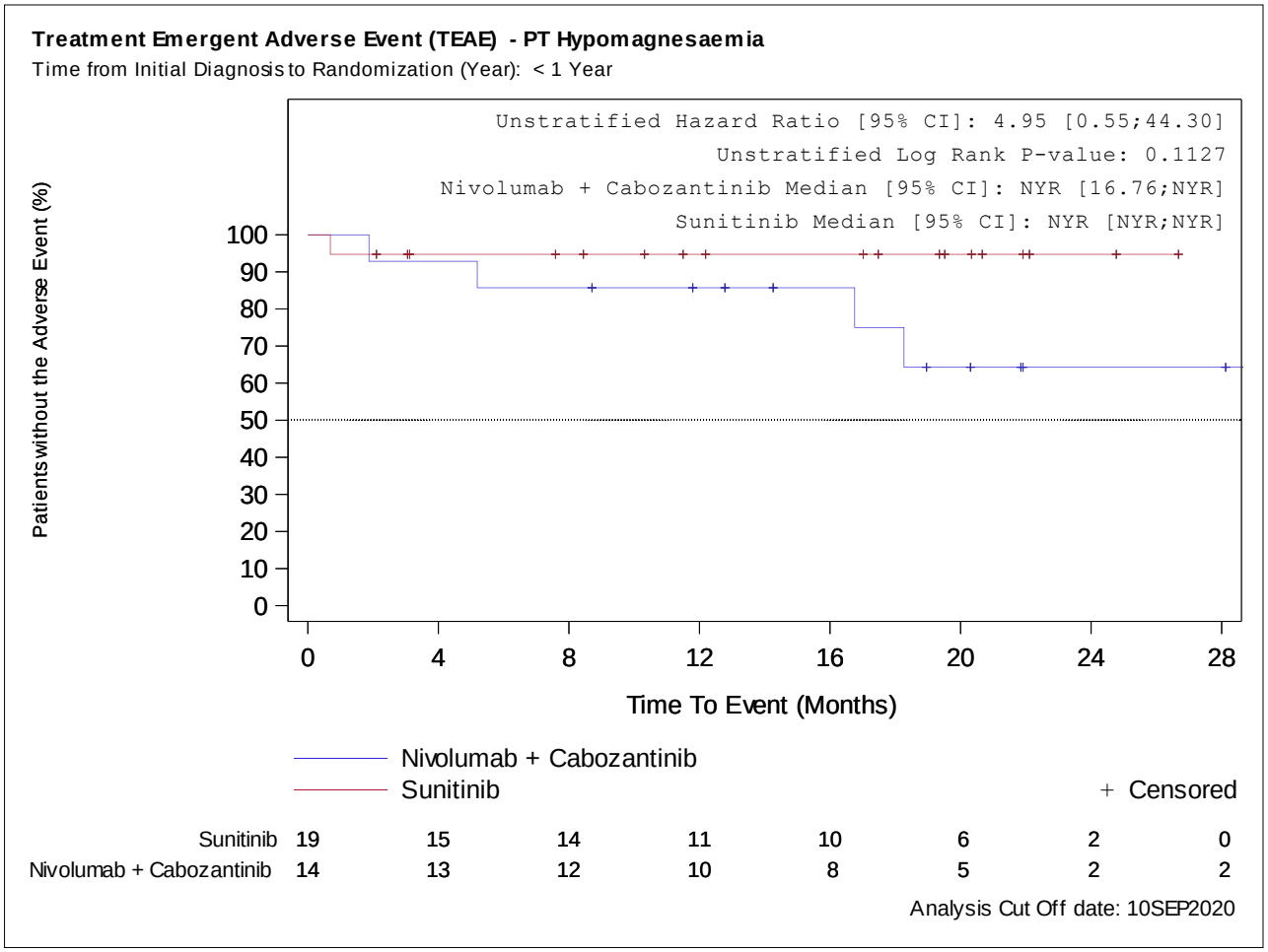

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:22:12

FIGURE 5.13.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



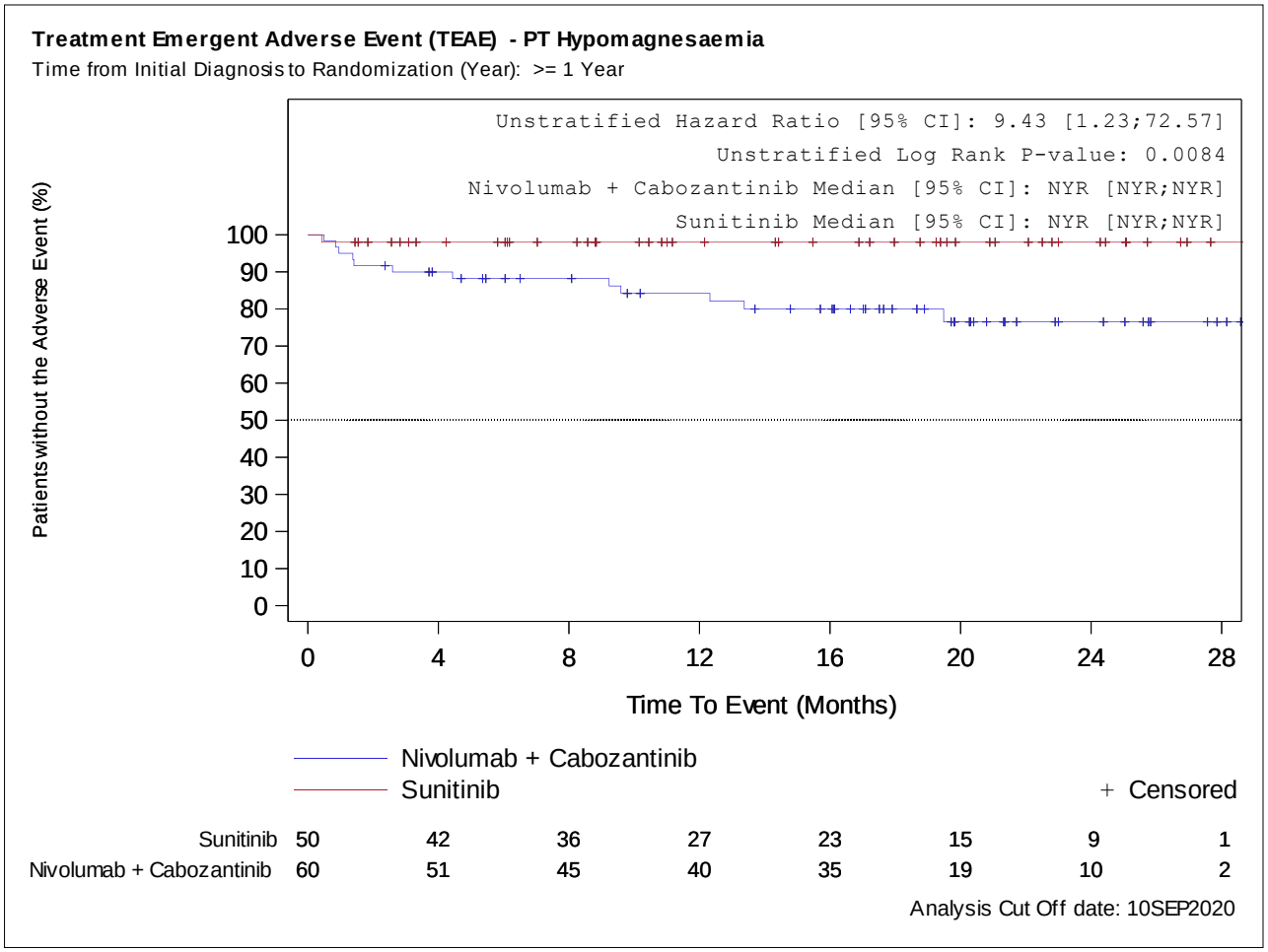

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:22:18

FIGURE 5.13.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



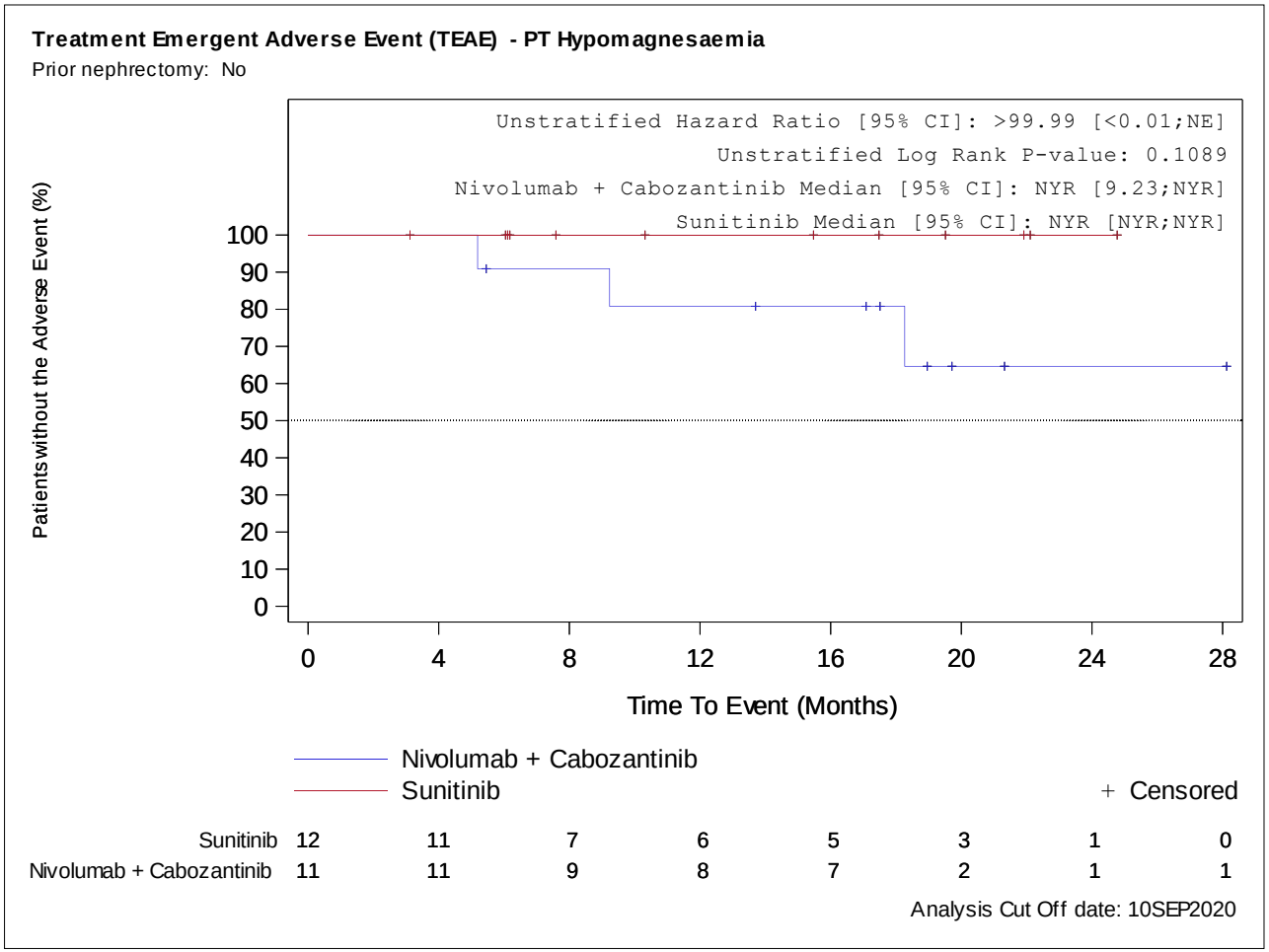

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:22:36

FIGURE 5.13.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



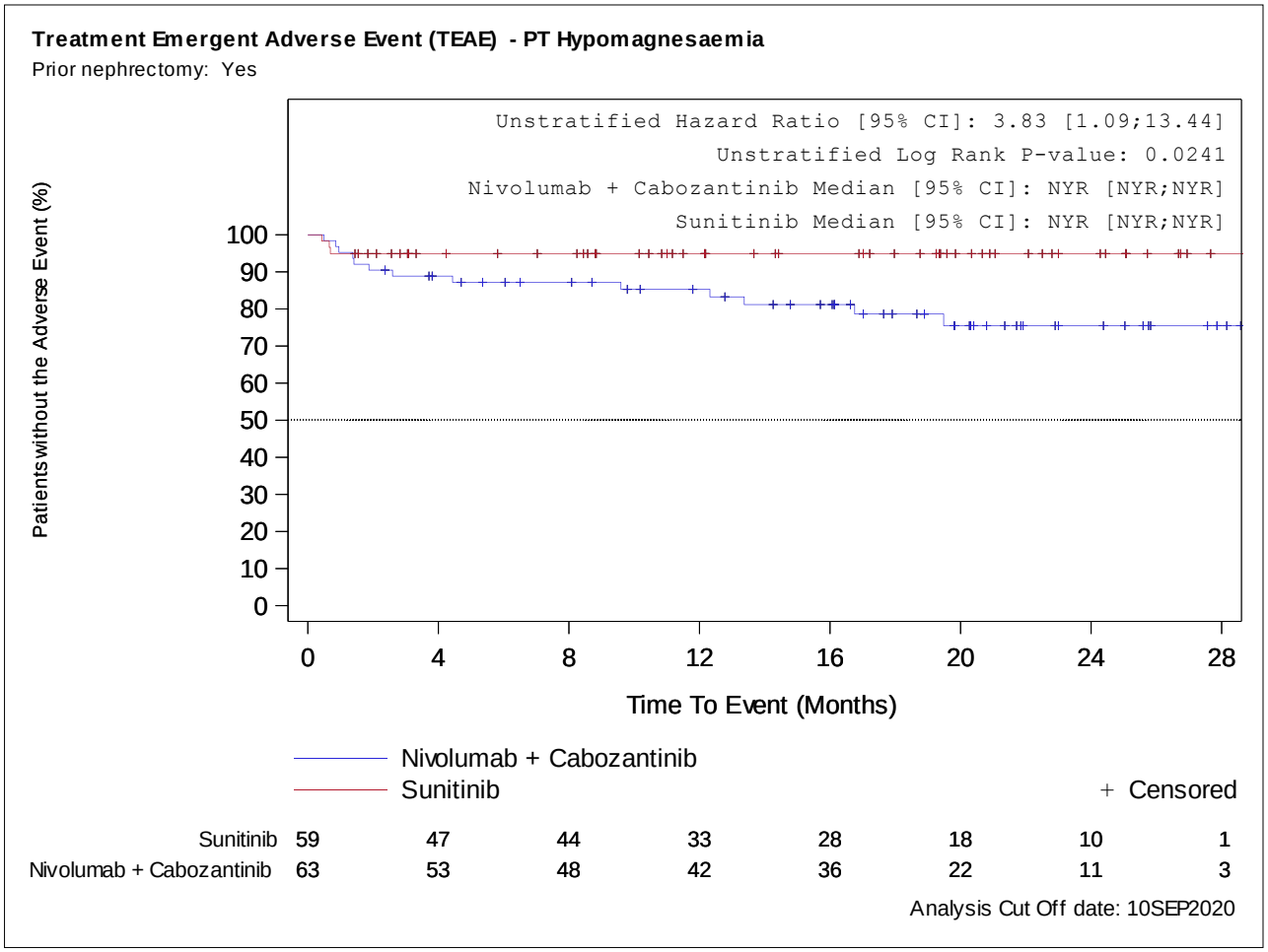

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:22:41

FIGURE 5.13.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



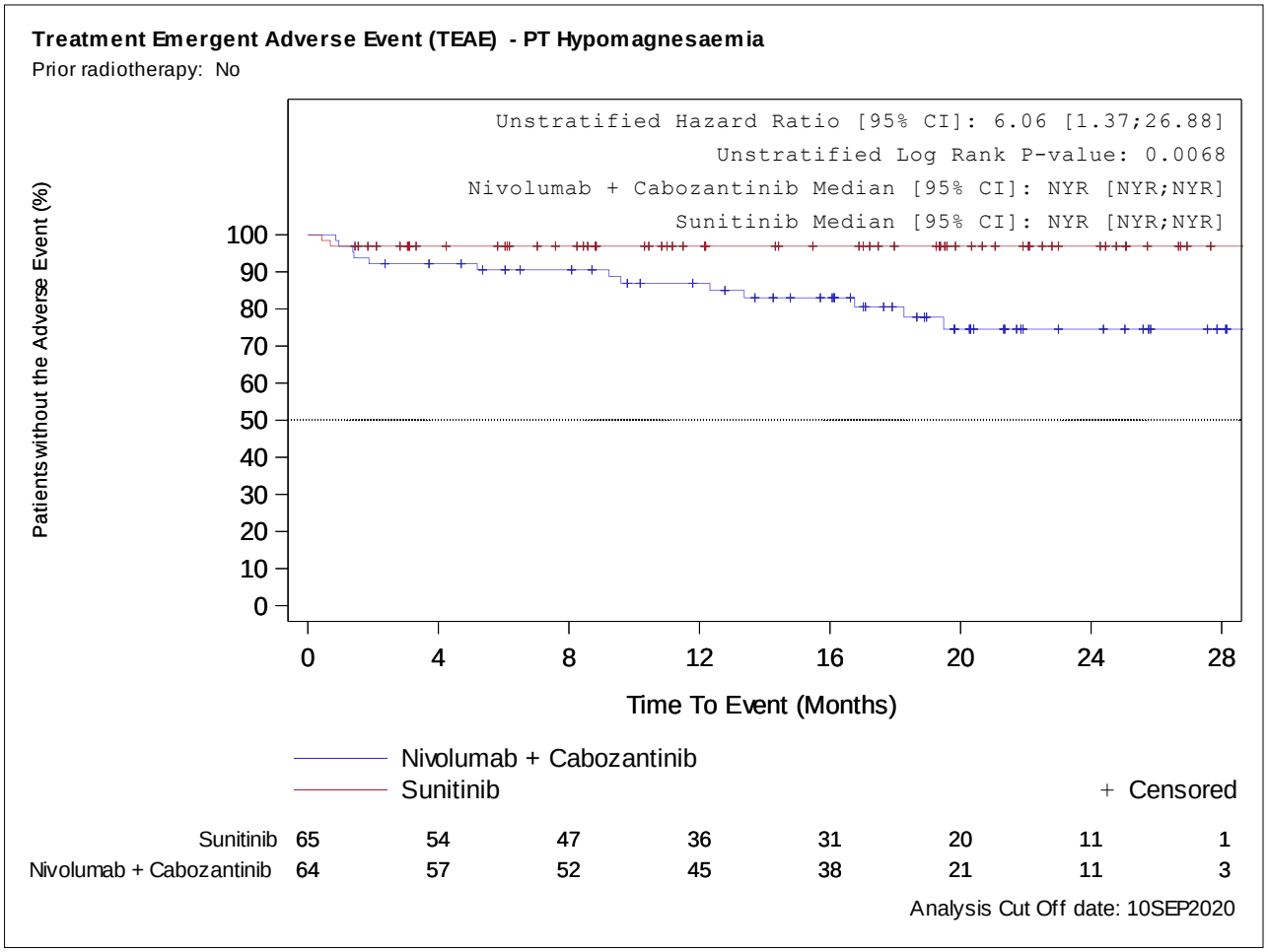

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:23:34

FIGURE 5.13.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



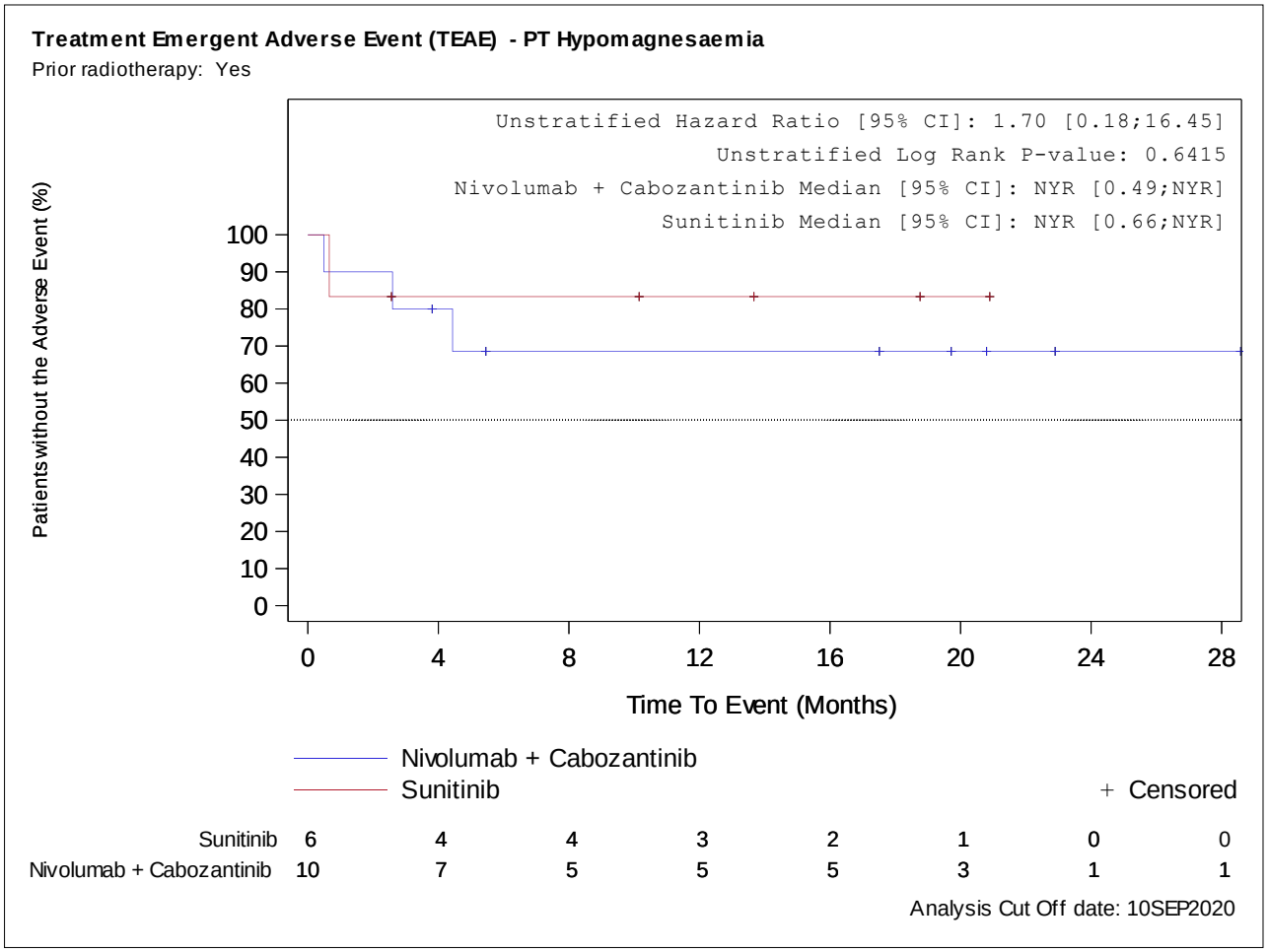

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:23:40

FIGURE 5.13.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



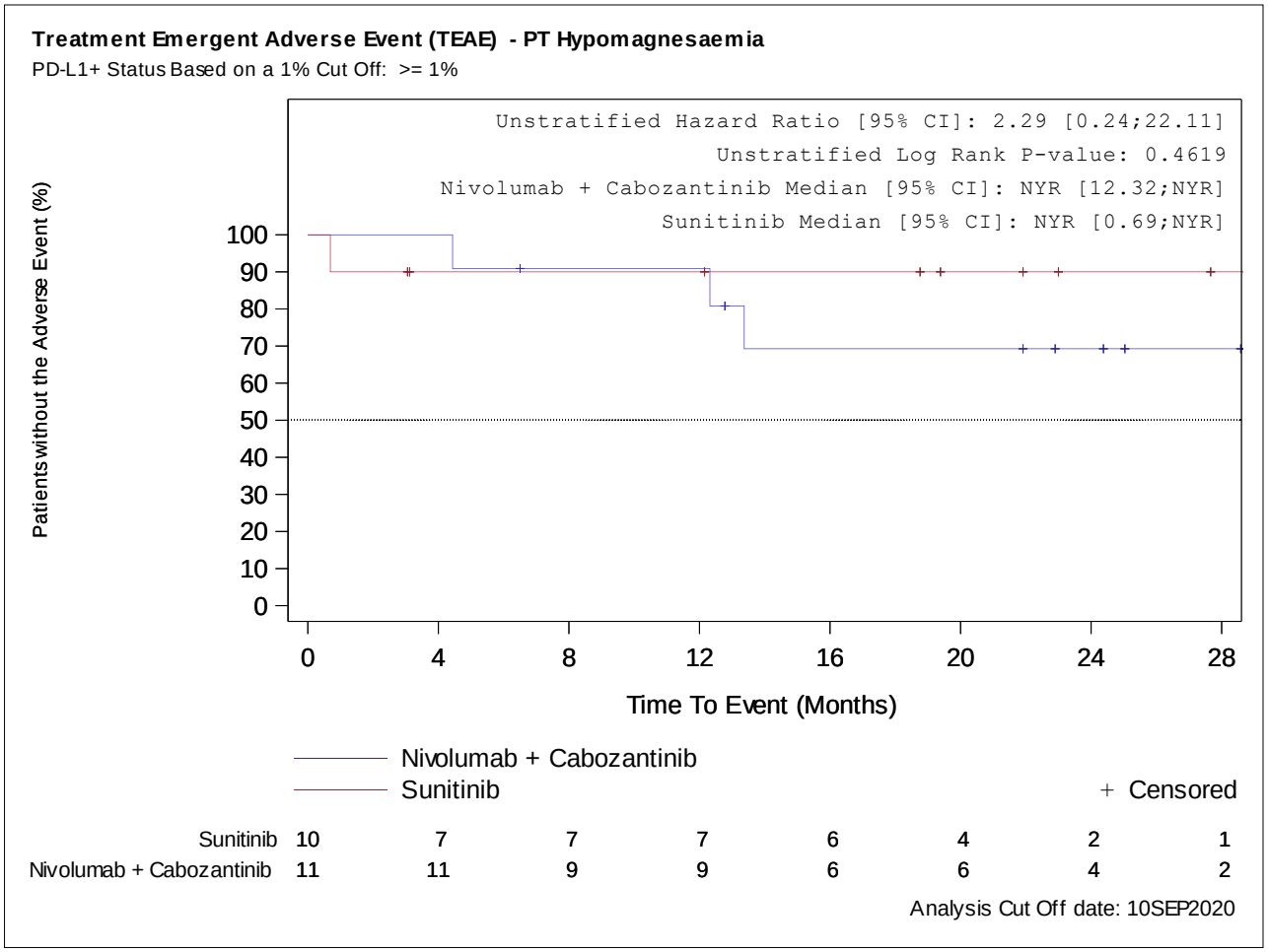

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:23:46

FIGURE 5.13.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



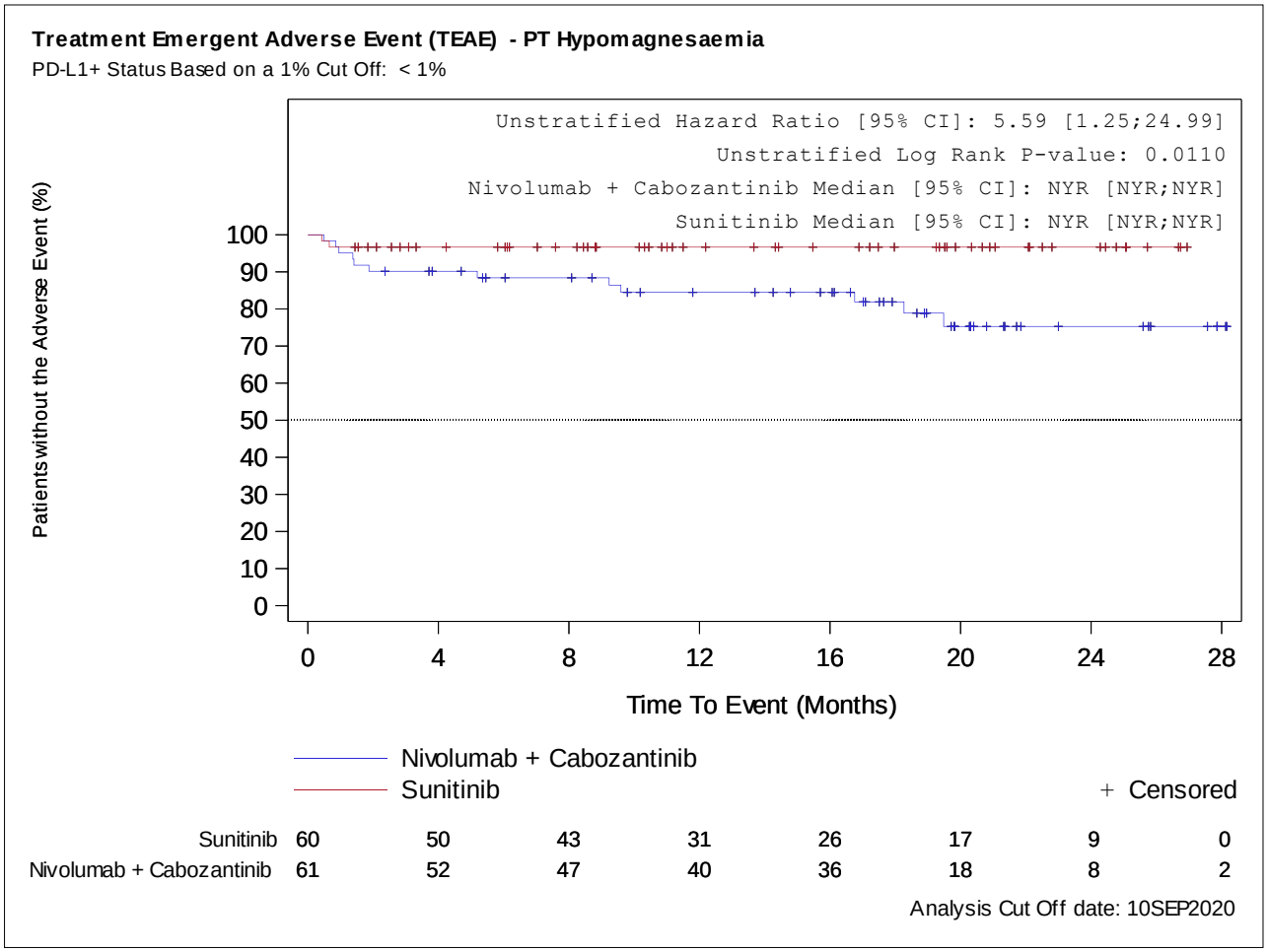

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:23:52

FIGURE 5.13.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



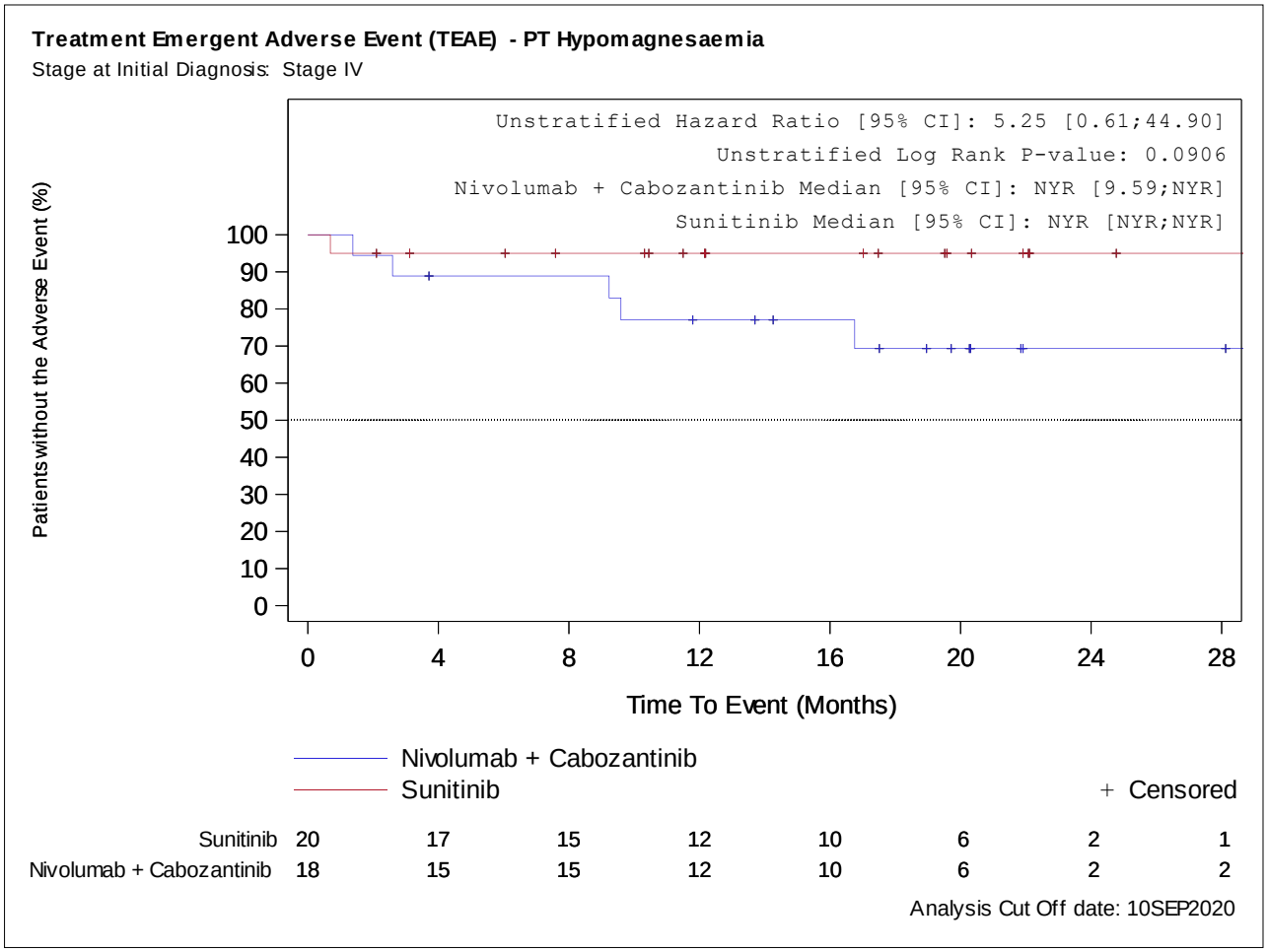

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:23:58

FIGURE 5.13.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



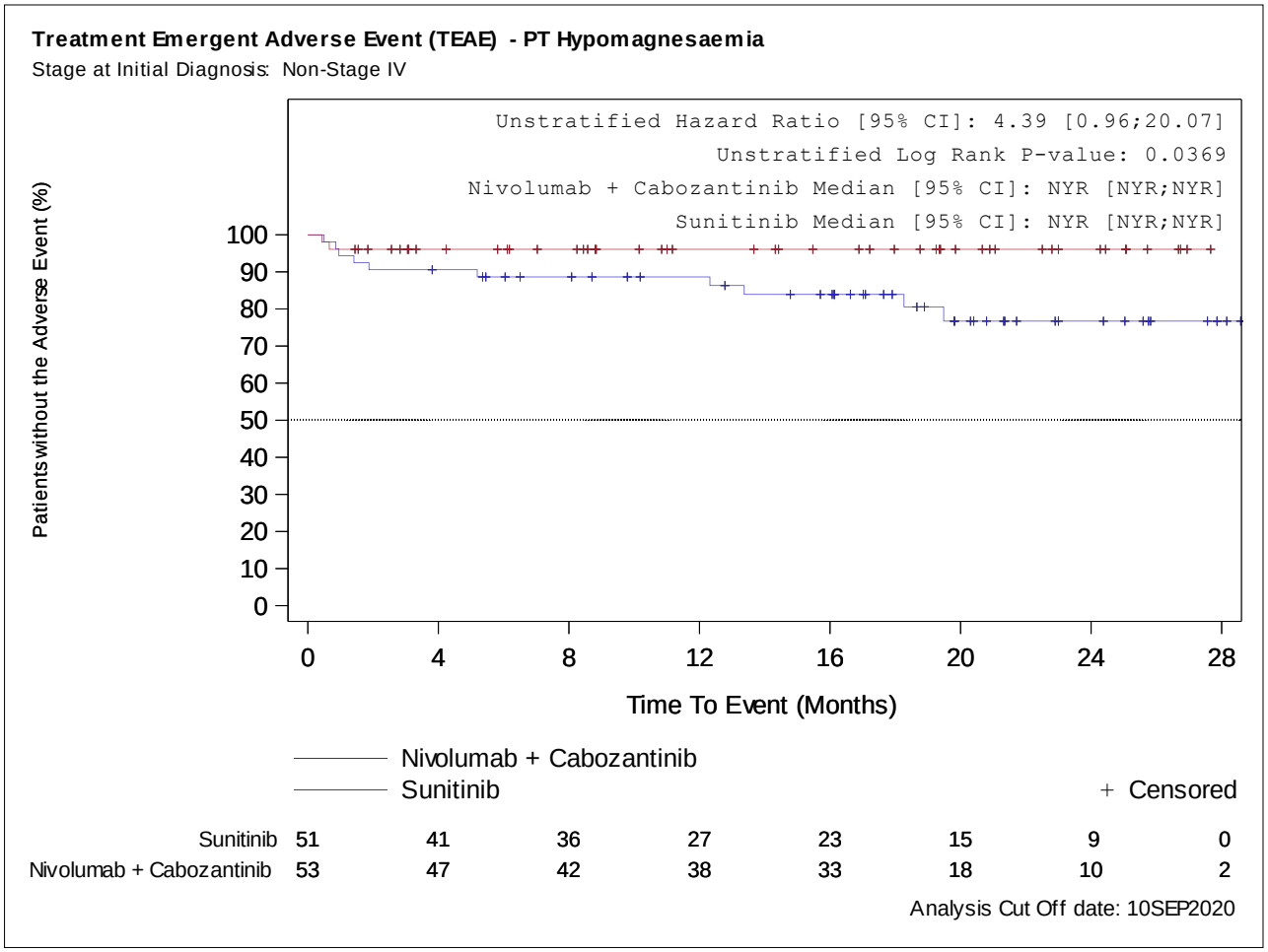

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:24:04

FIGURE 5.13.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:24:33

FIGURE 5.13.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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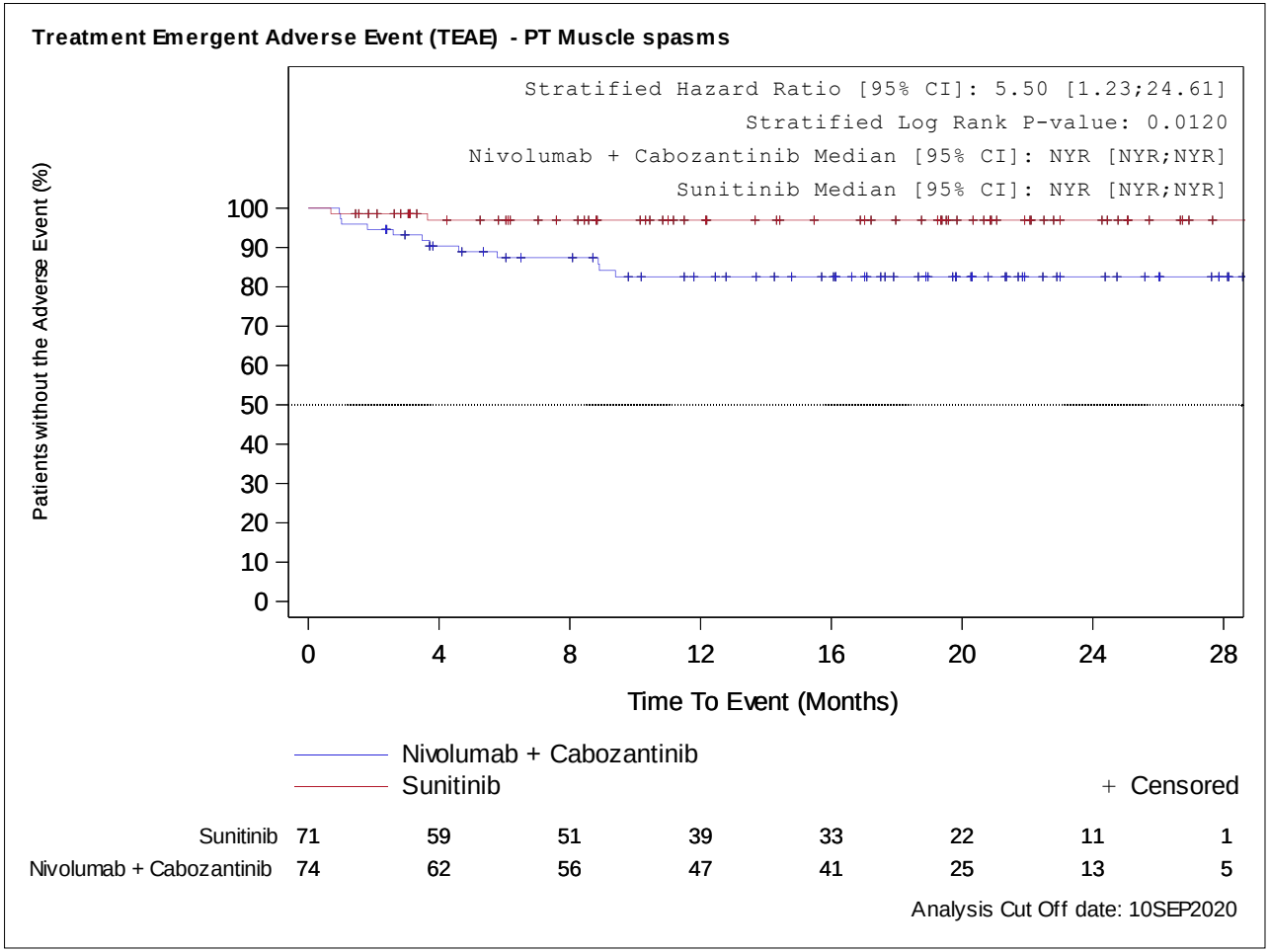
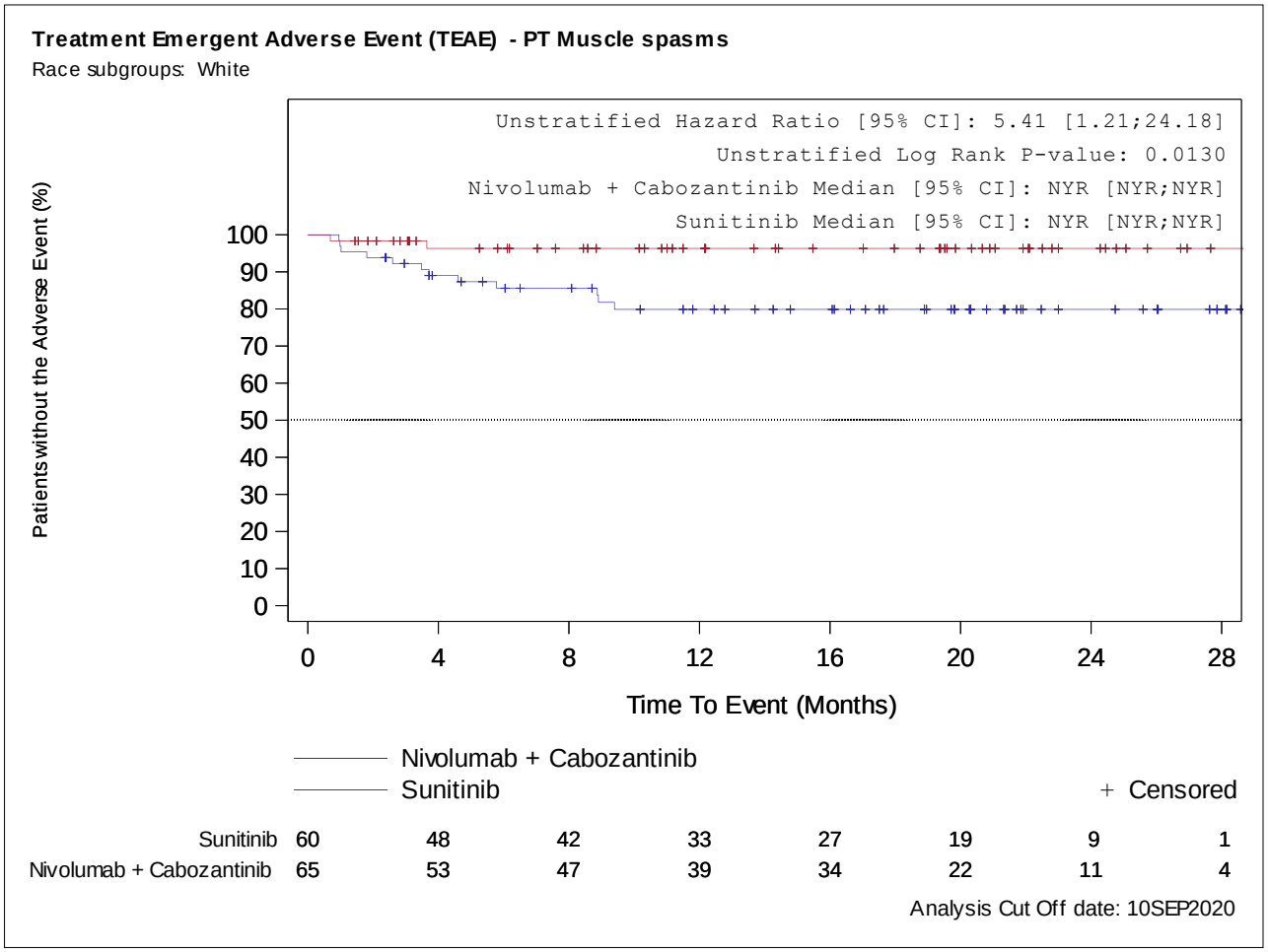
FIGURE 5.14.1: Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



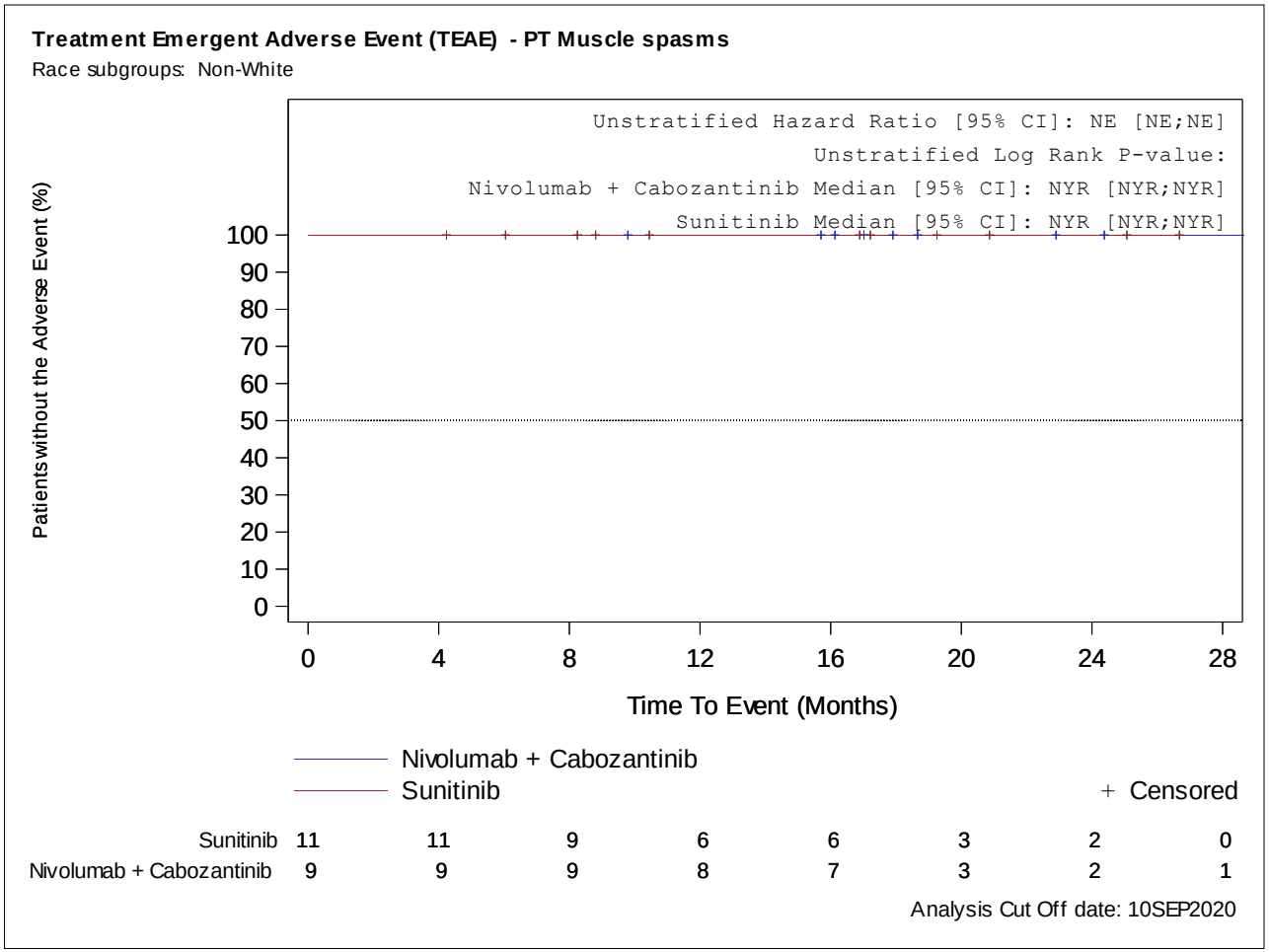

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:27:27

FIGURE 5.14.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



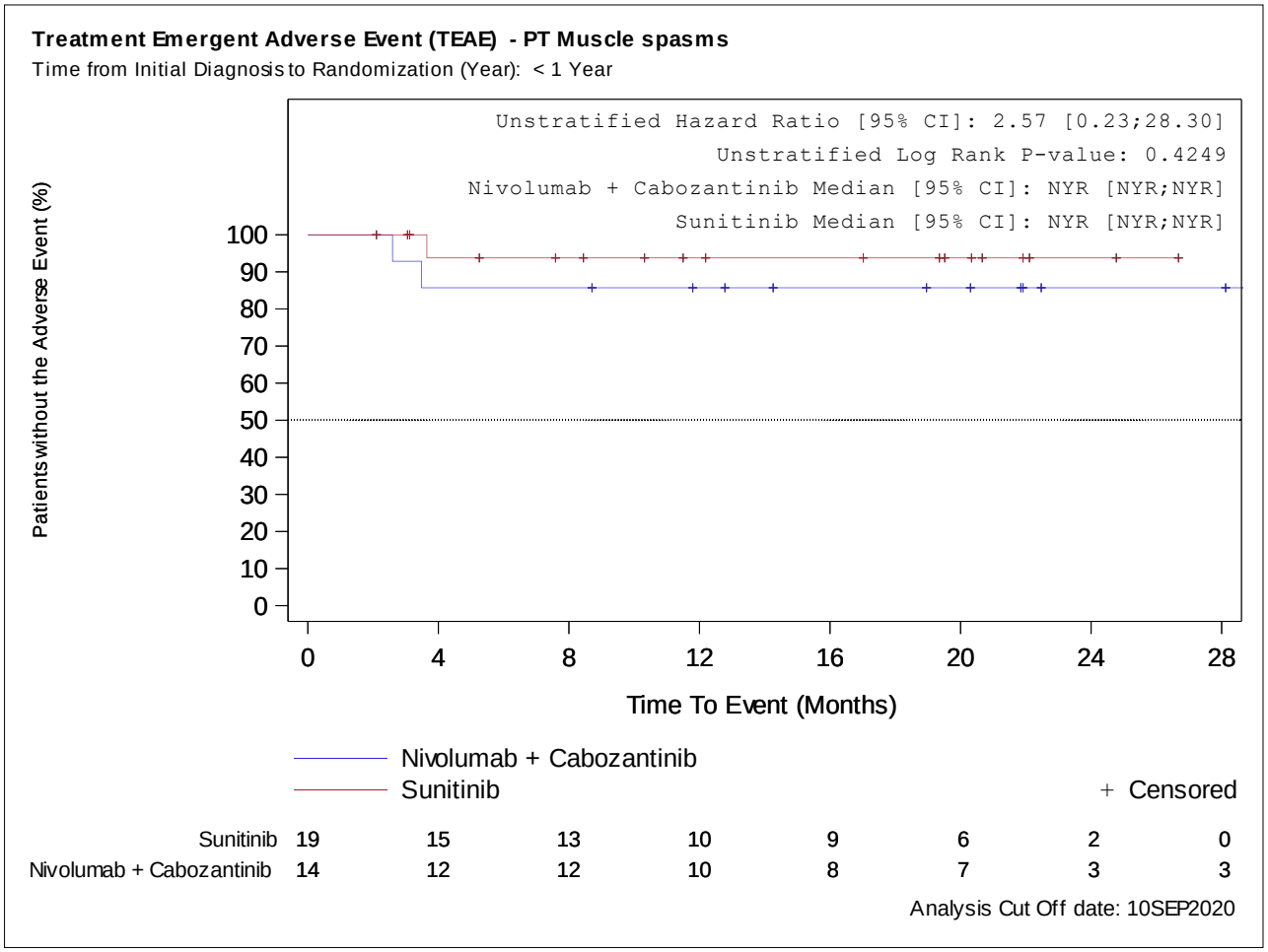

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:27:30

FIGURE 5.14.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



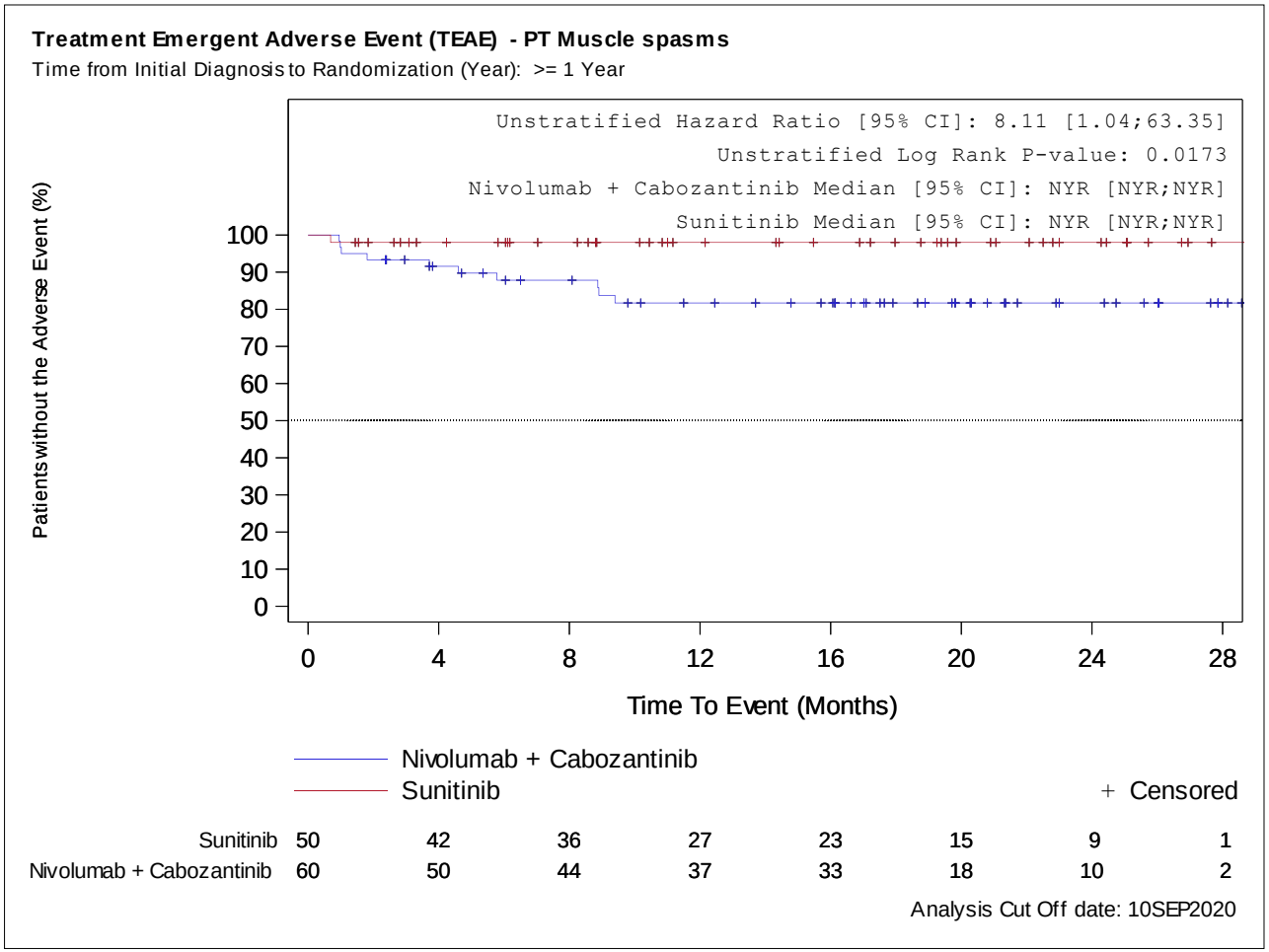

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:27:36

FIGURE 5.14.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



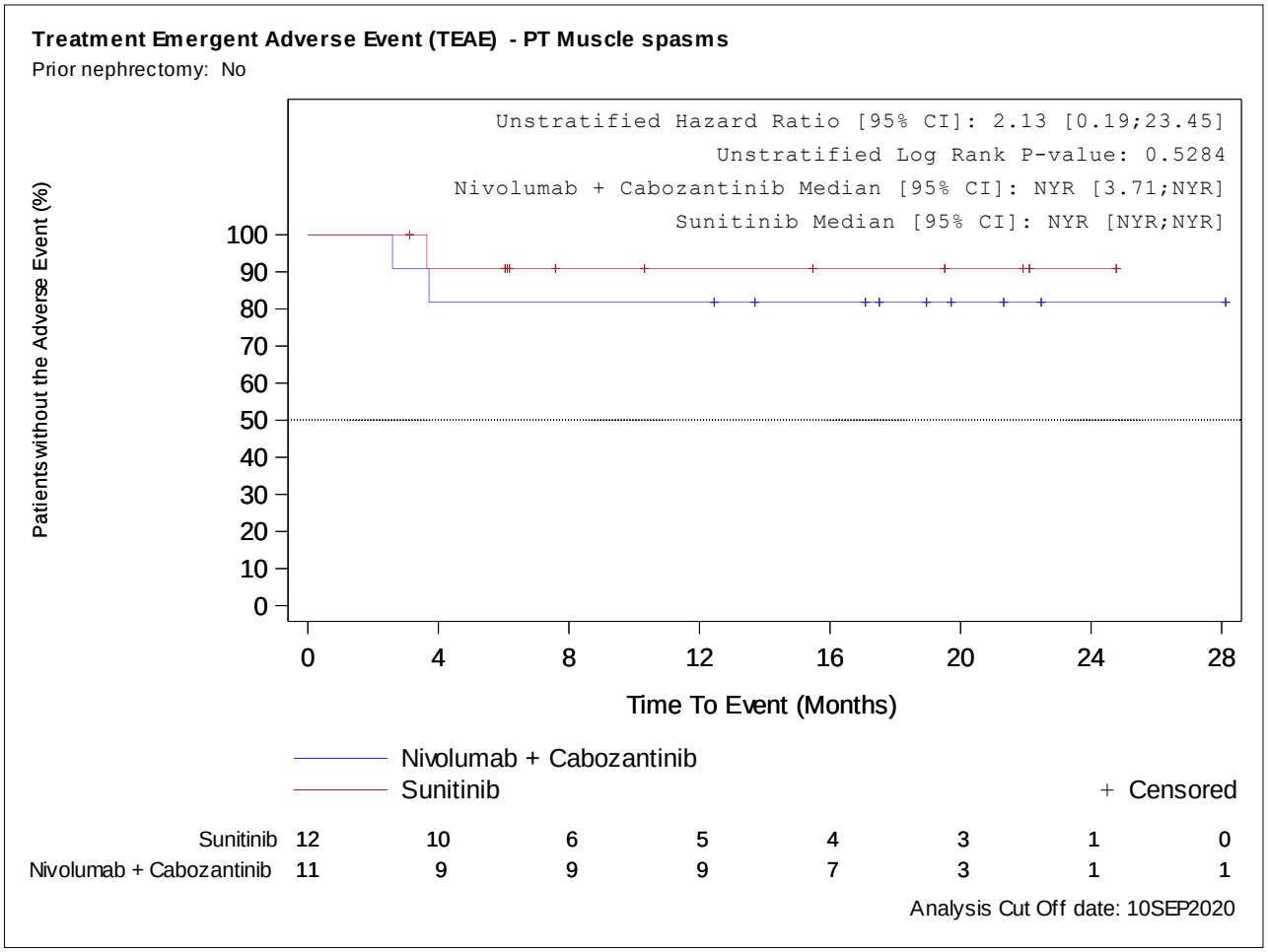

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:27:54

FIGURE 5.14.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



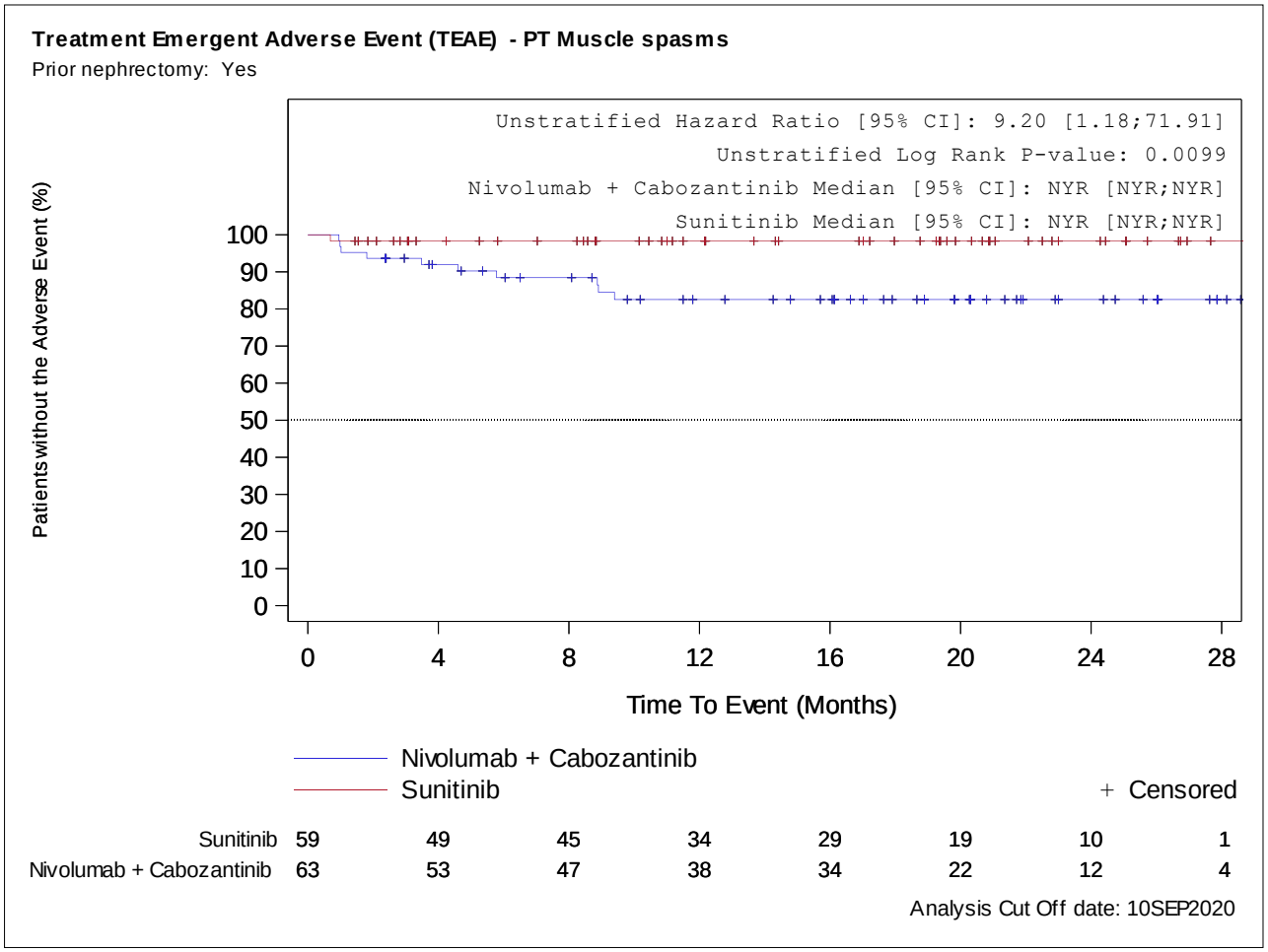

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:28:00

FIGURE 5.14.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



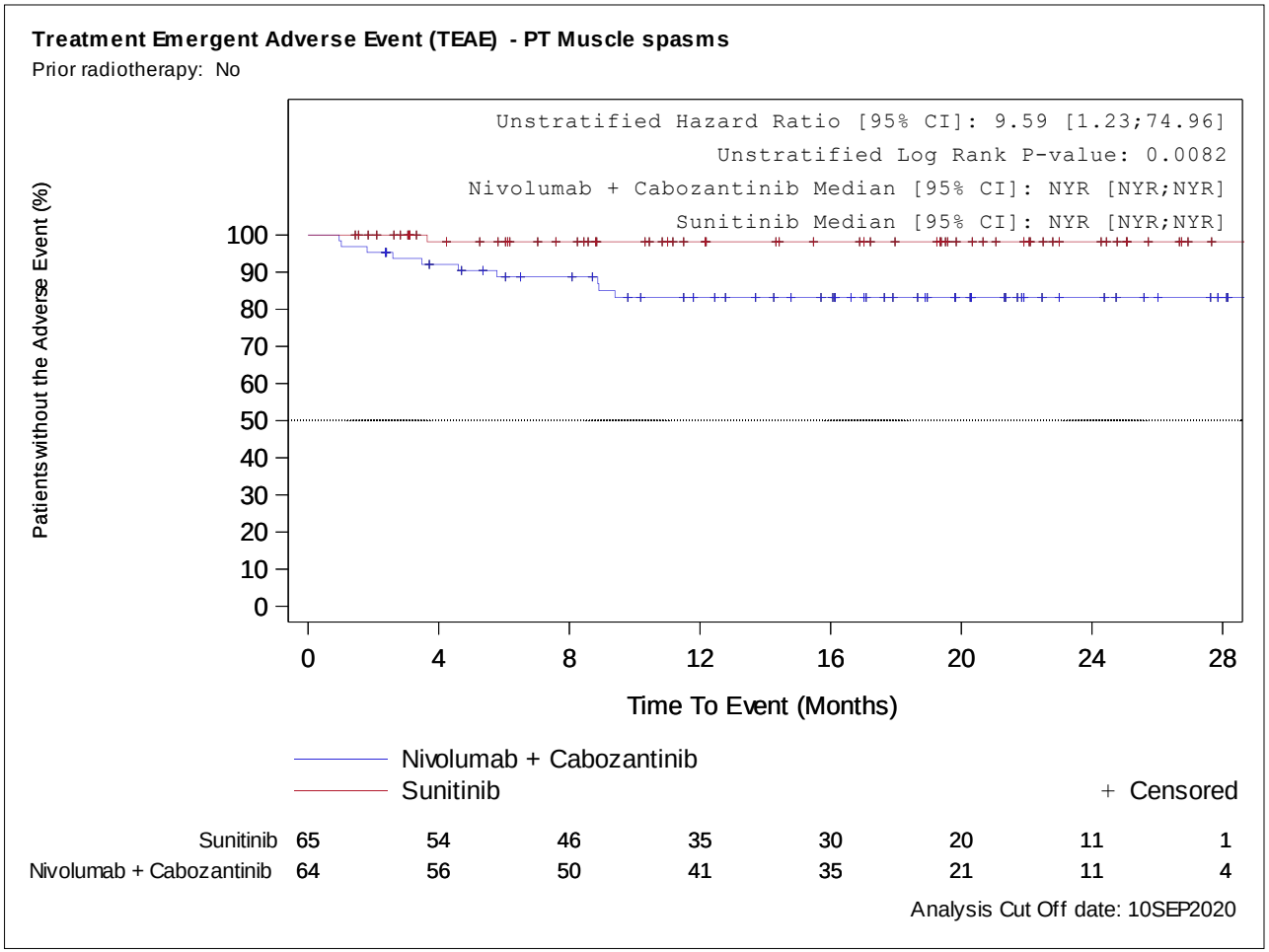

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:28:43

FIGURE 5.14.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



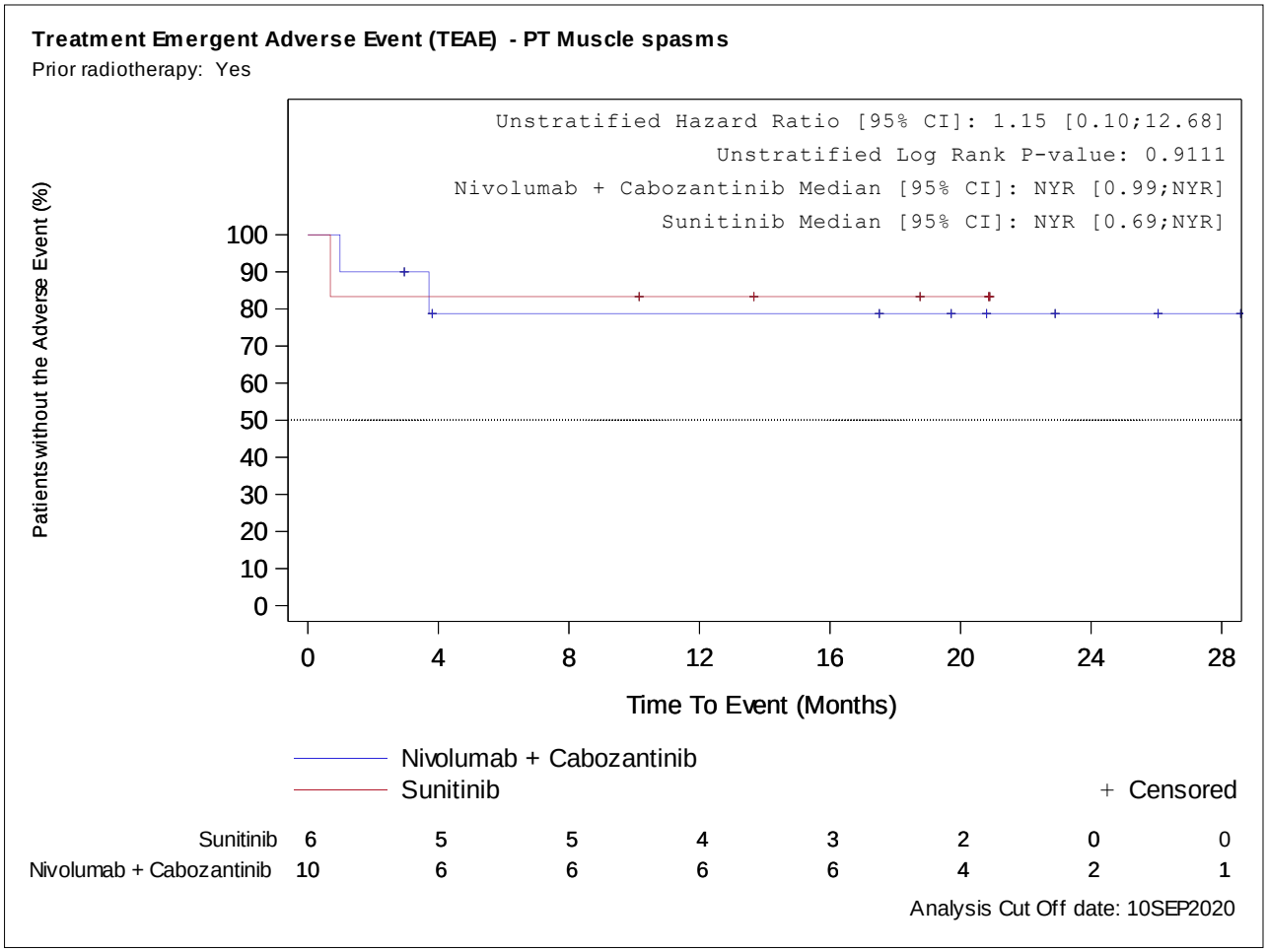

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:28:49

FIGURE 5.14.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



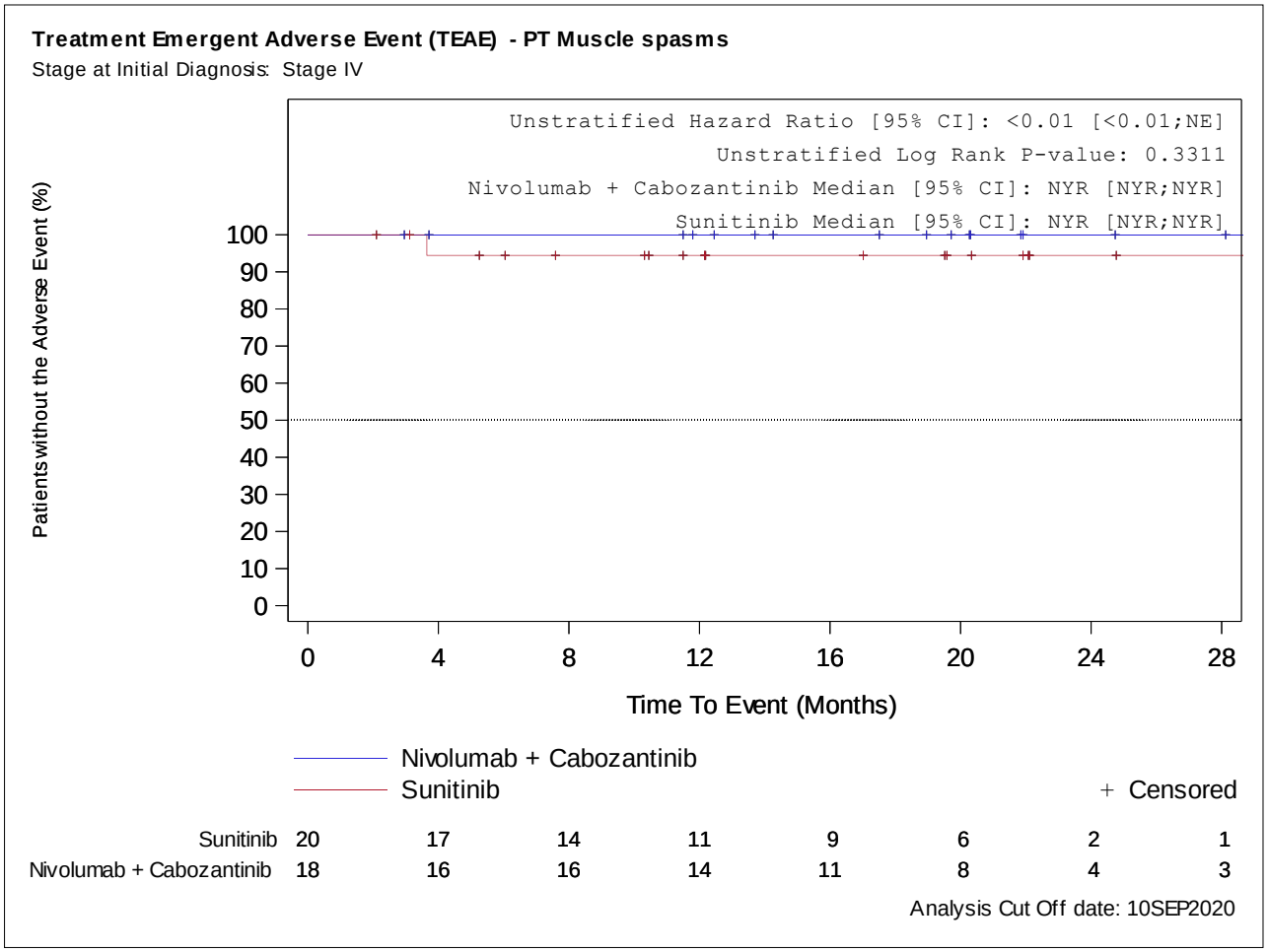

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:28:55

FIGURE 5.14.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



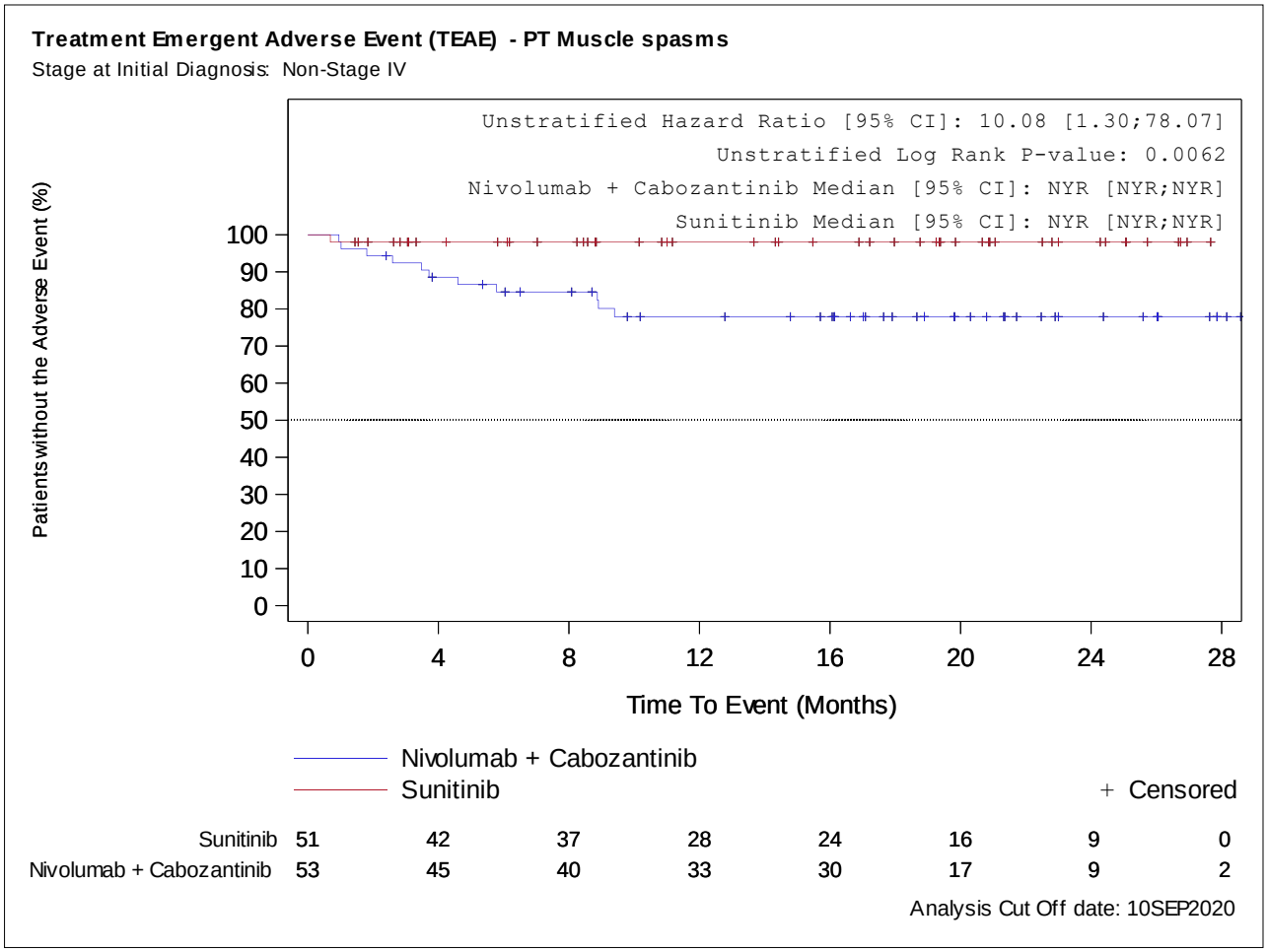

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:29:01

FIGURE 5.14.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



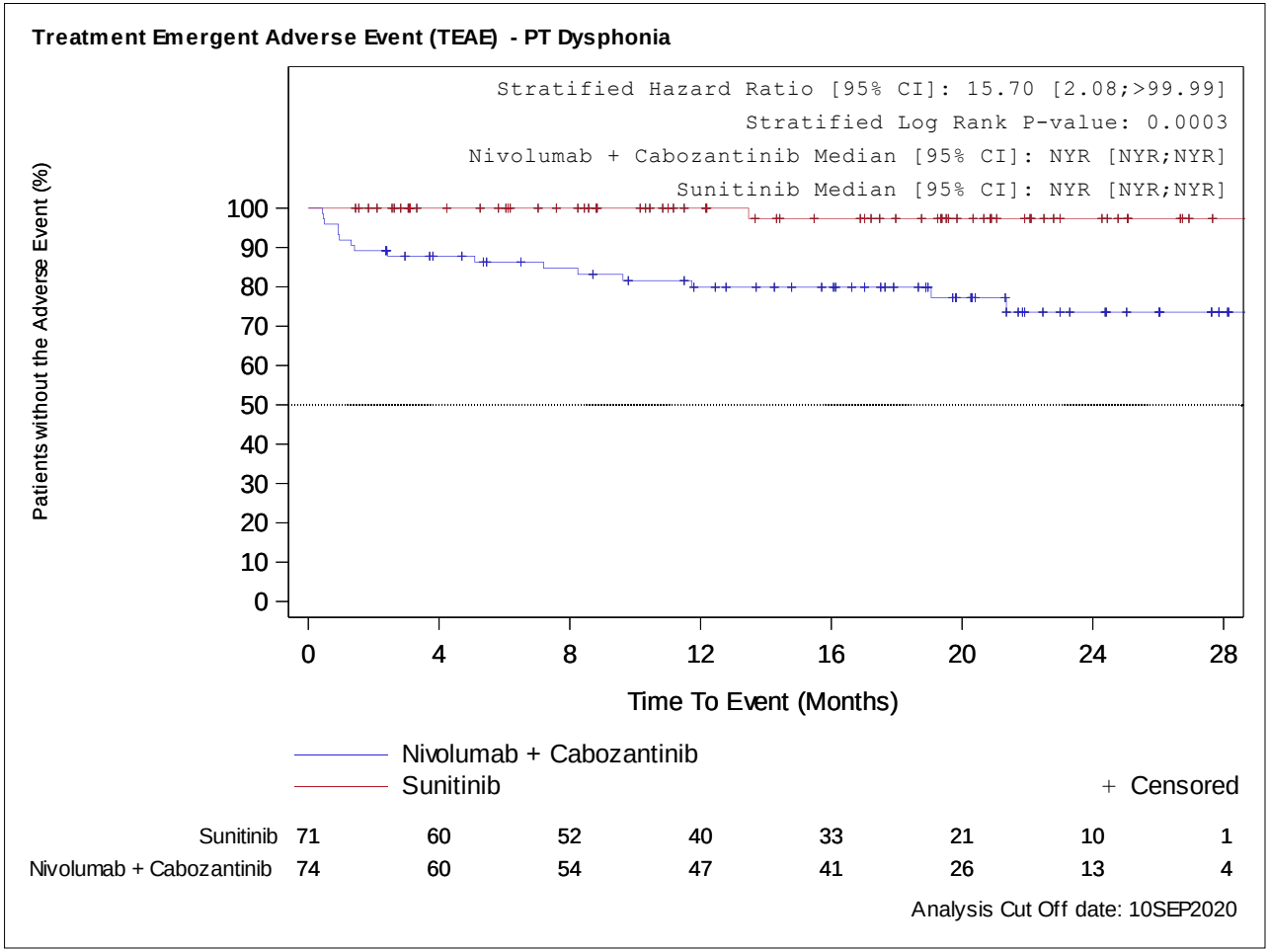

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:29:31

FIGURE 5.14.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



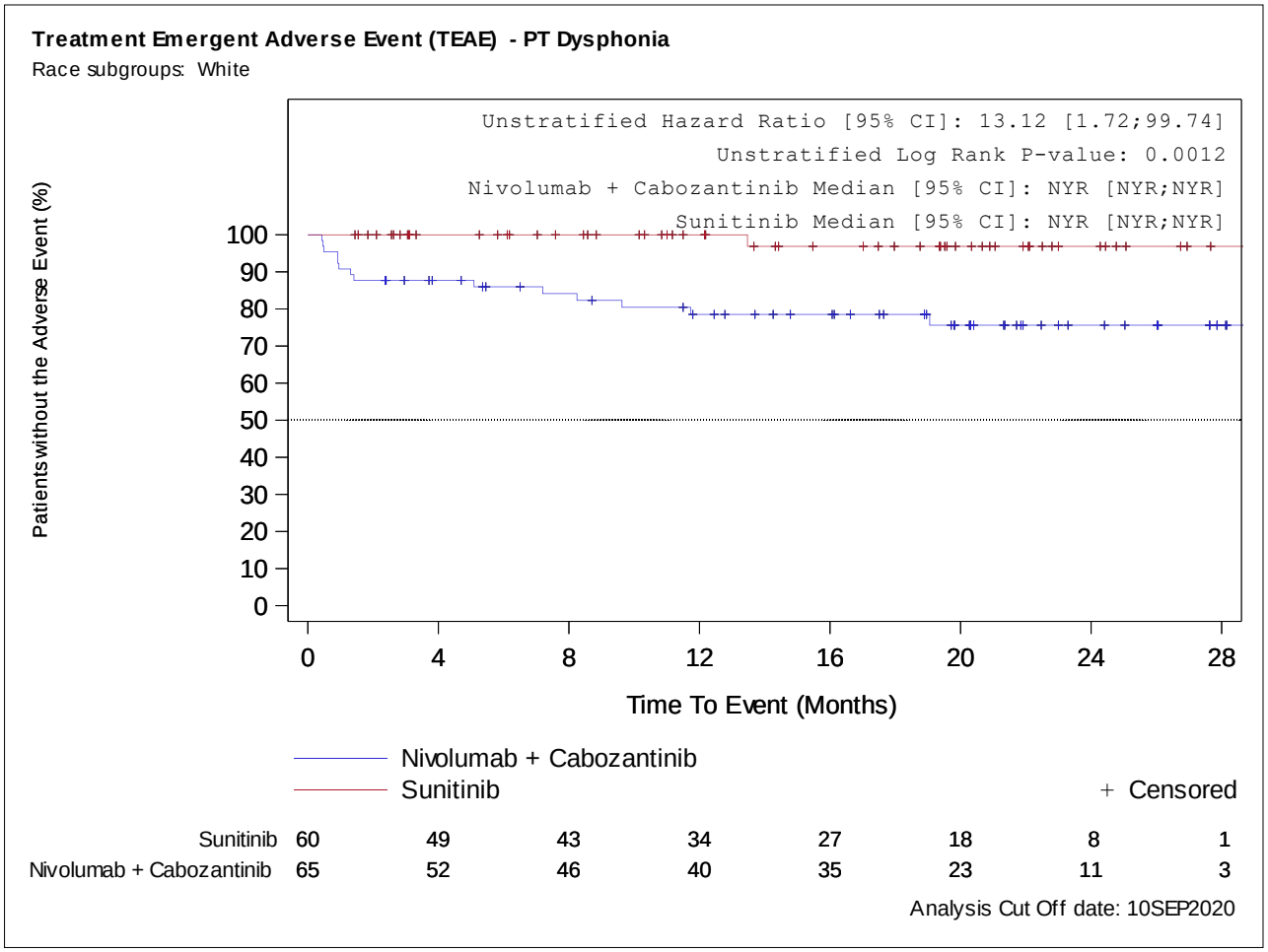

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:29:37

FIGURE 5.15.1: Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



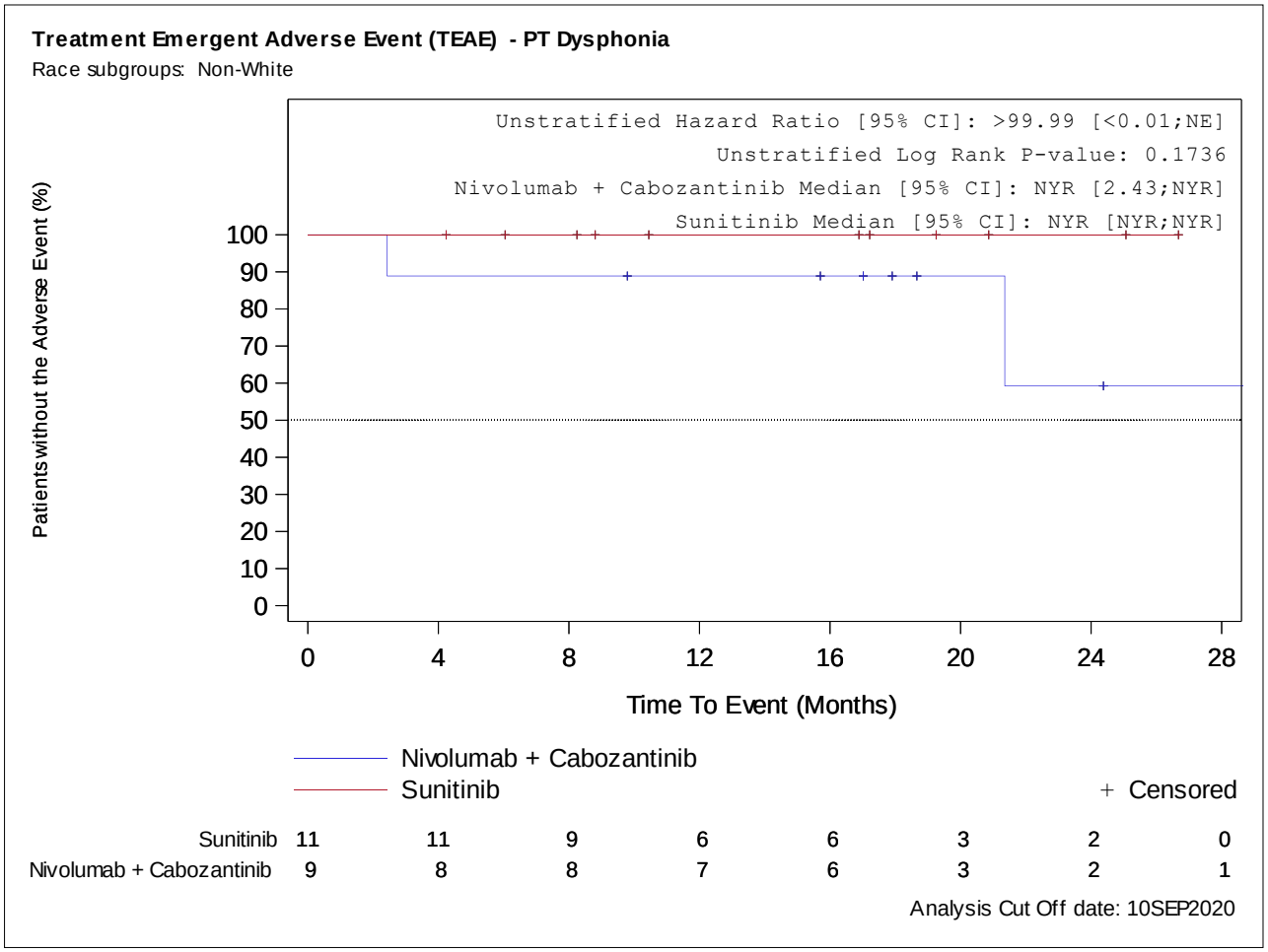

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:32:32

FIGURE 5.15.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:32:36

FIGURE 5.15.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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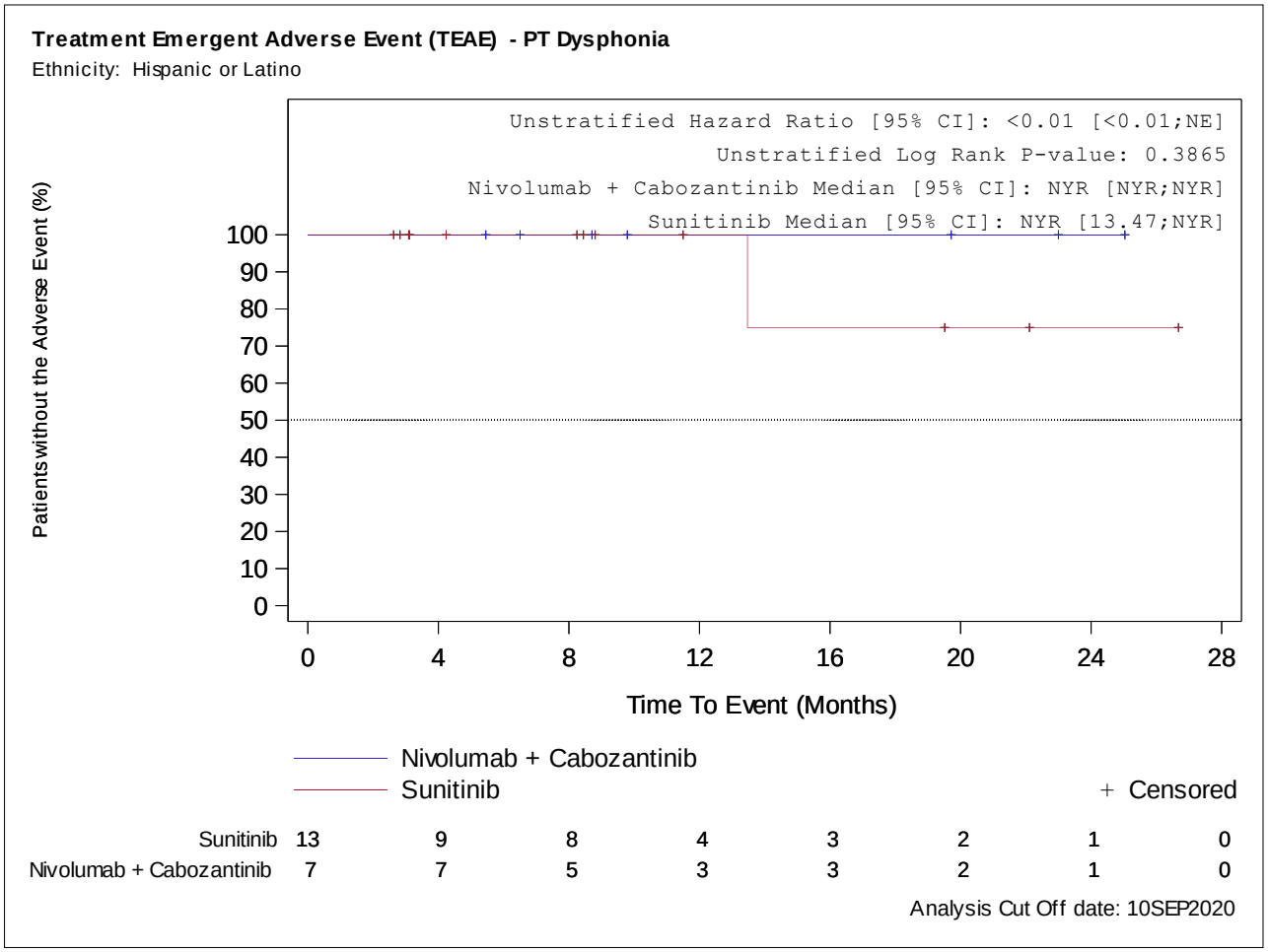
FIGURE 5.15.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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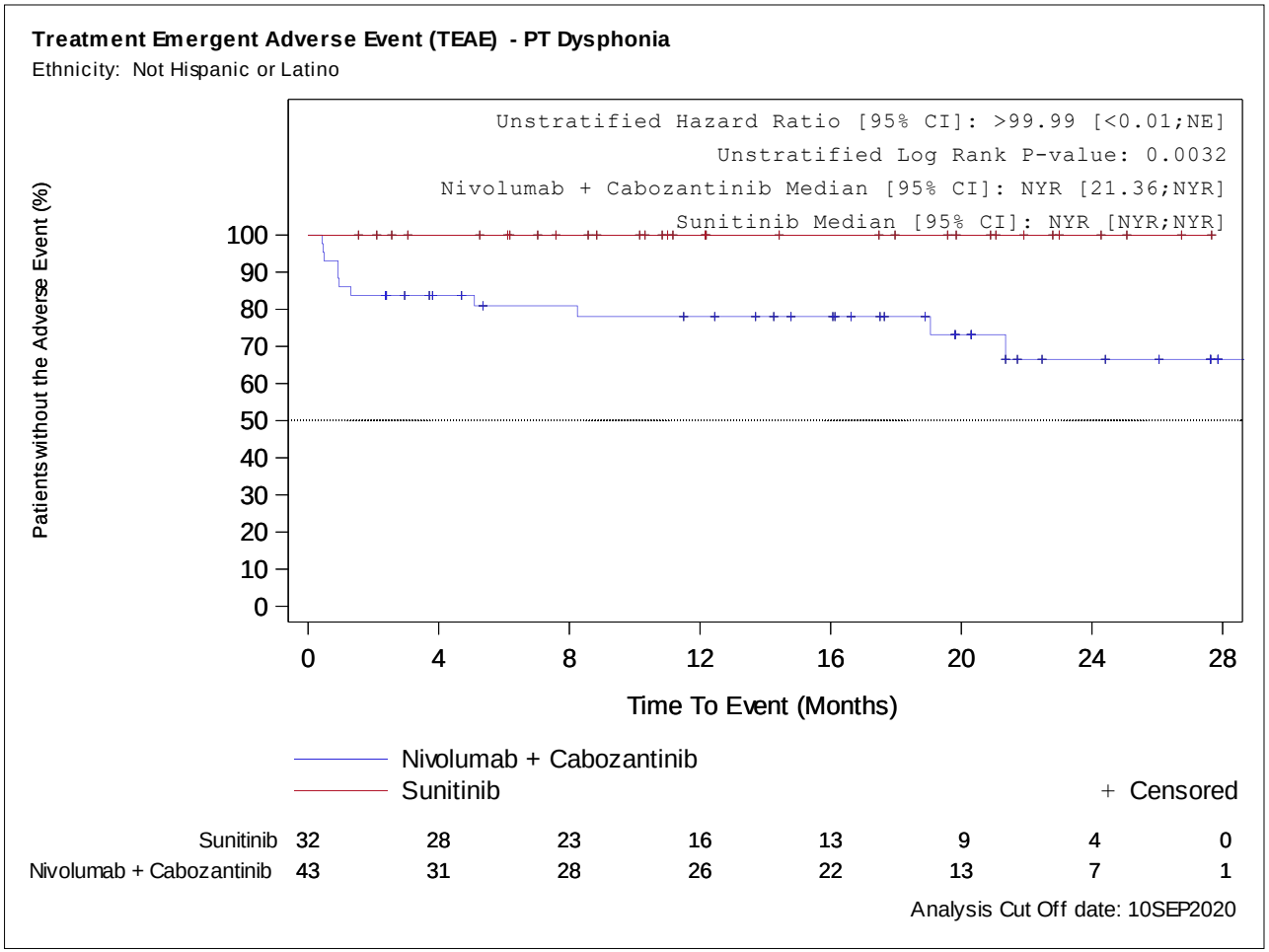
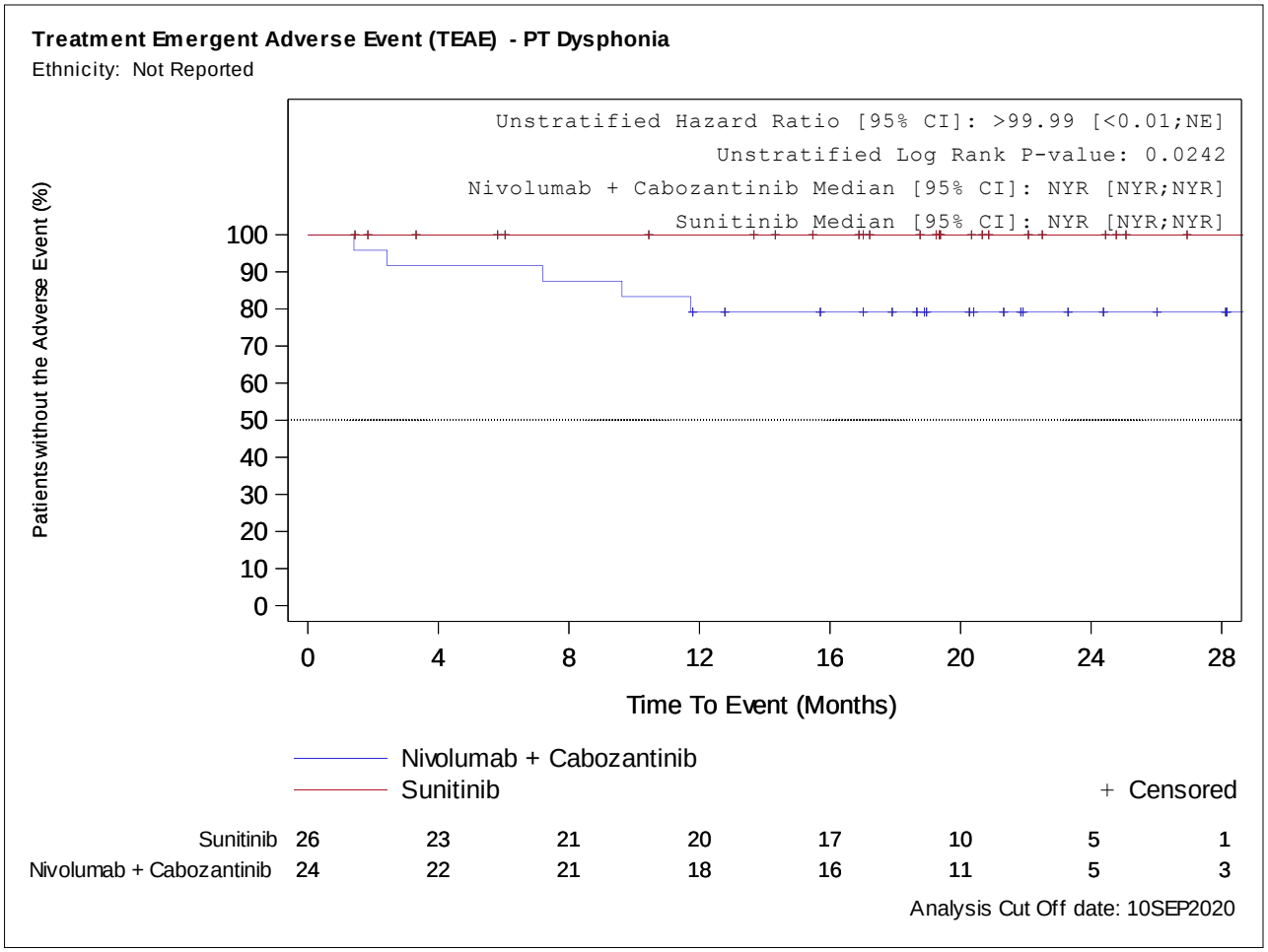
FIGURE 5.15.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:32:53

FIGURE 5.15.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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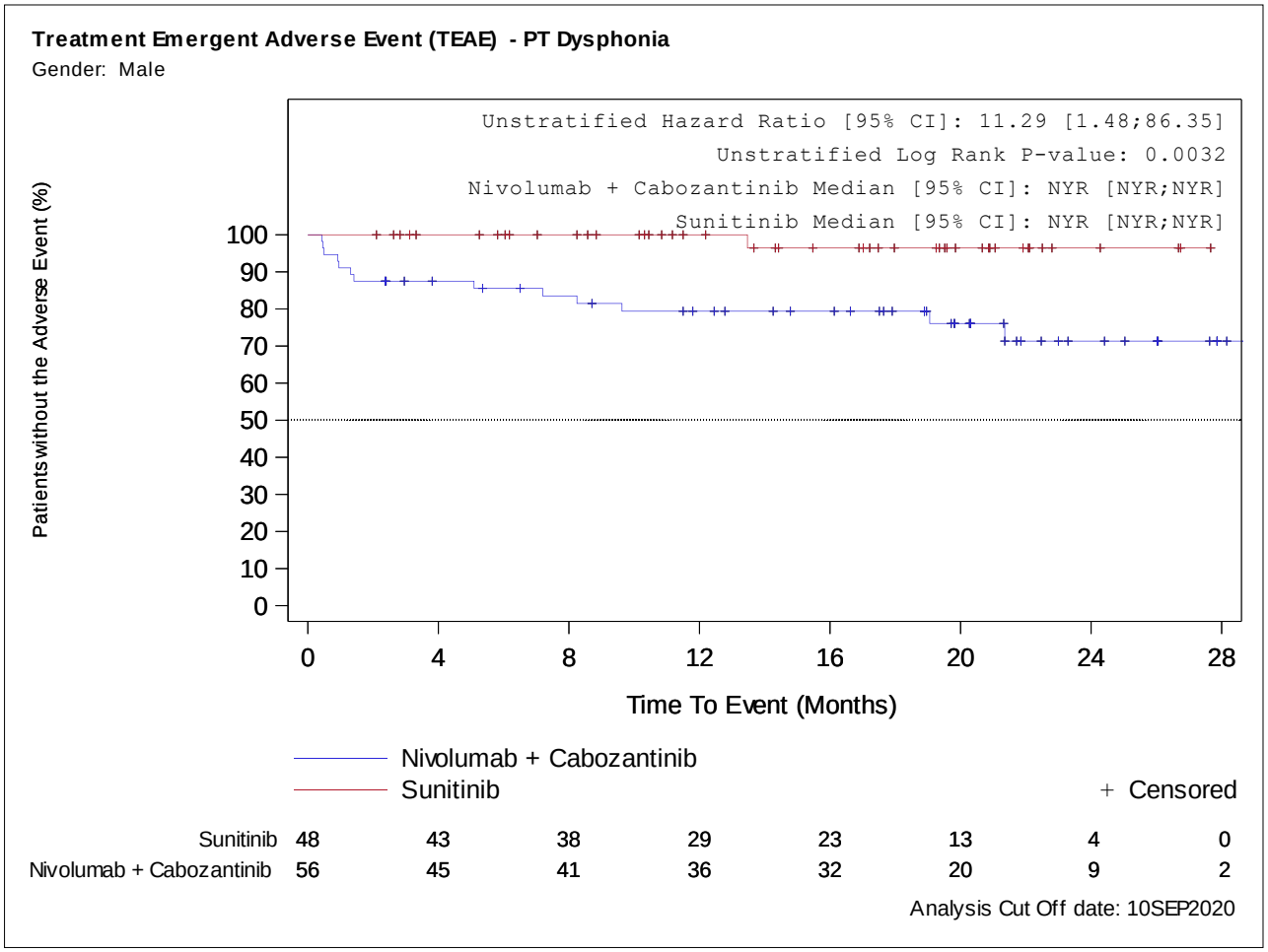
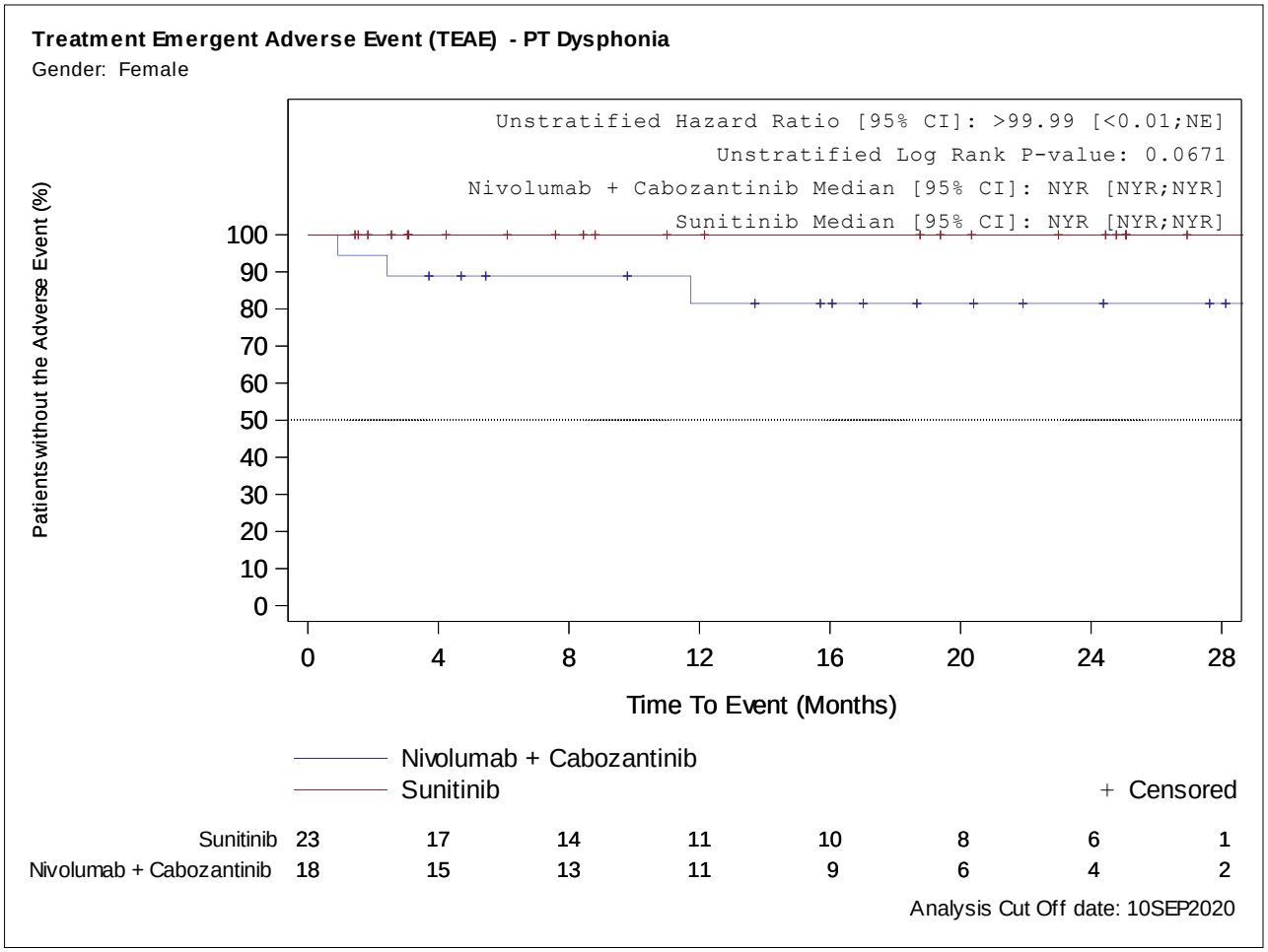
FIGURE 5.15.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



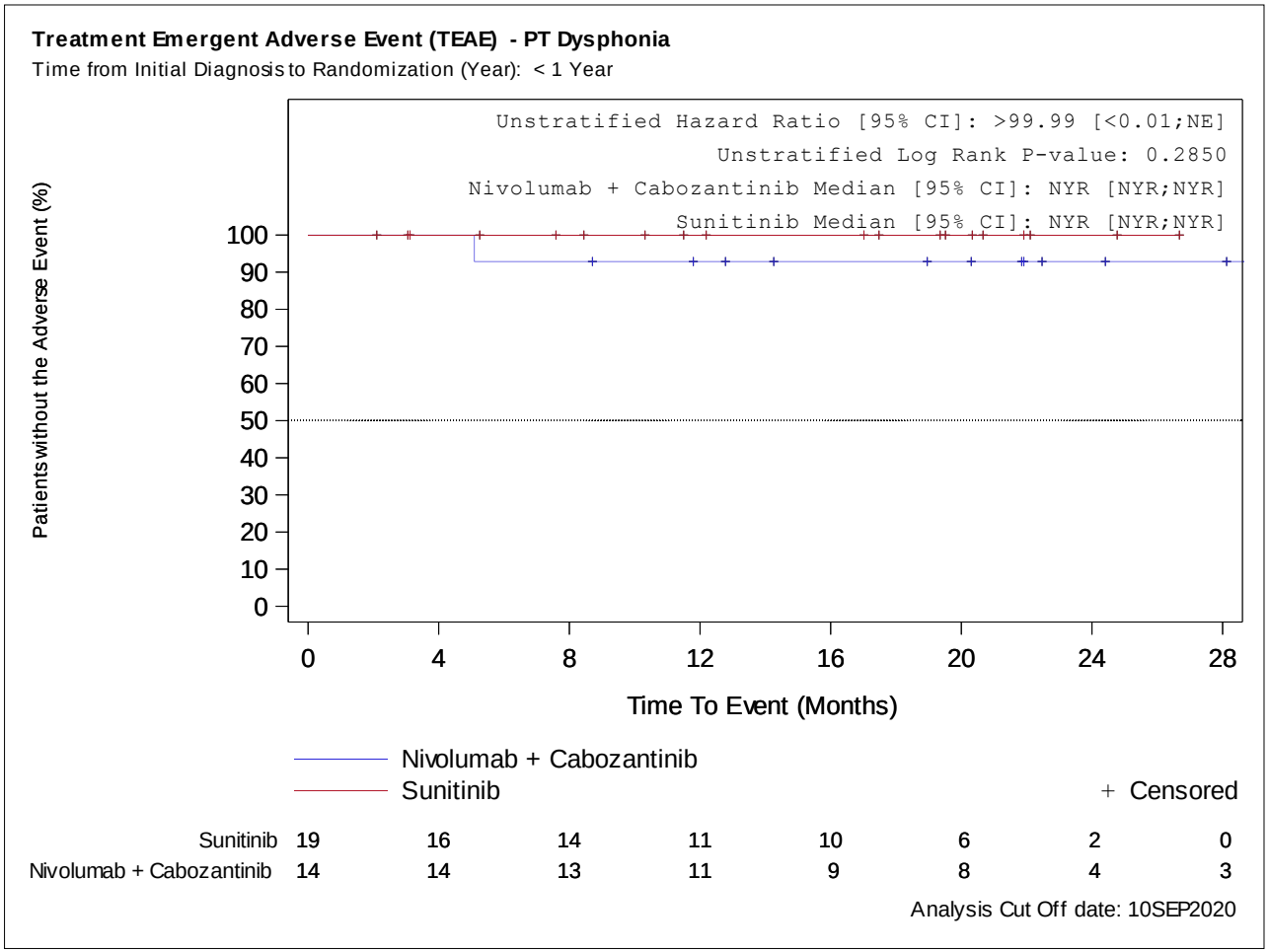

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:33:04

FIGURE 5.15.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:33:10

FIGURE 5.15.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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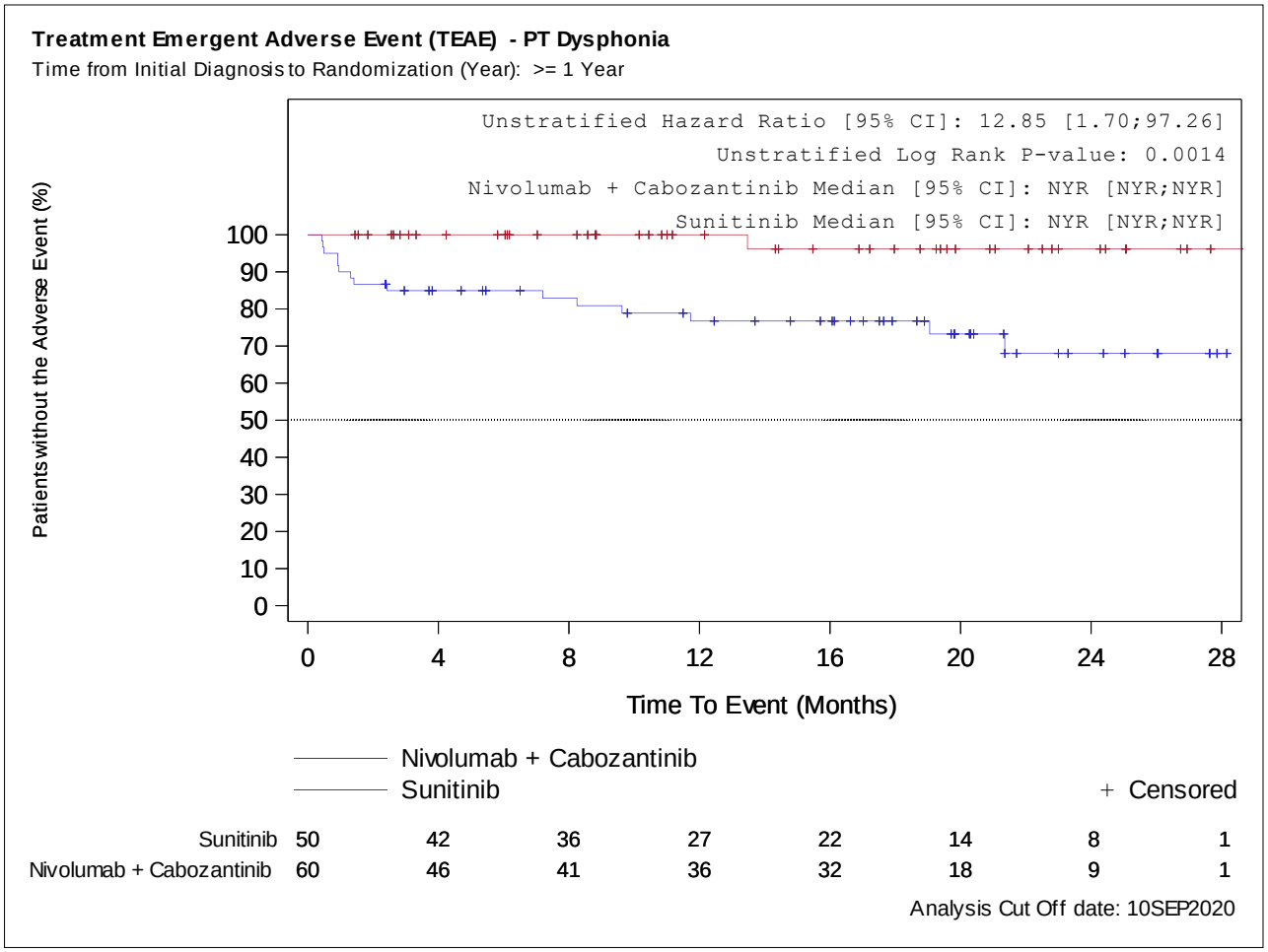
FIGURE 5.15.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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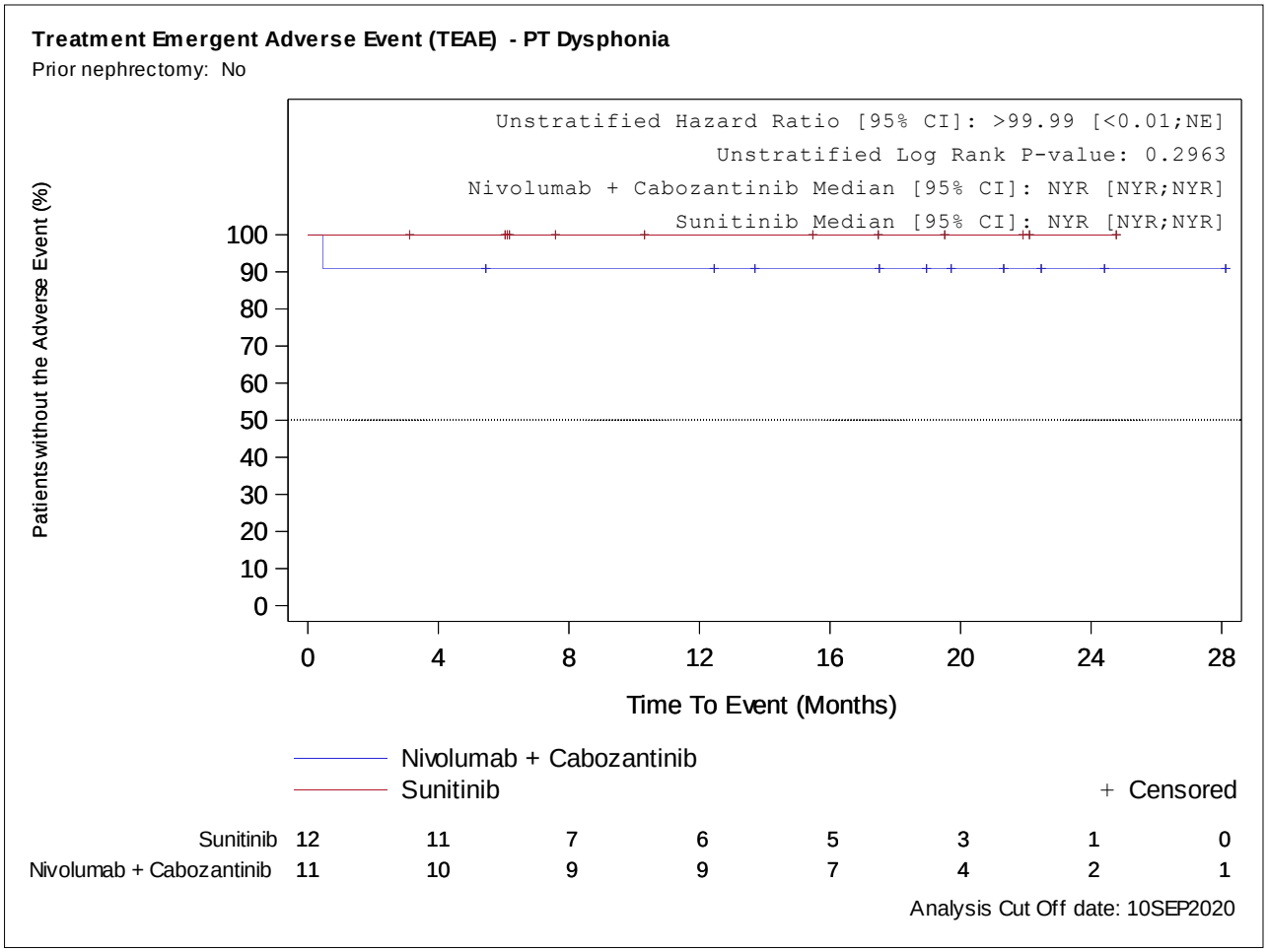
FIGURE 5.15.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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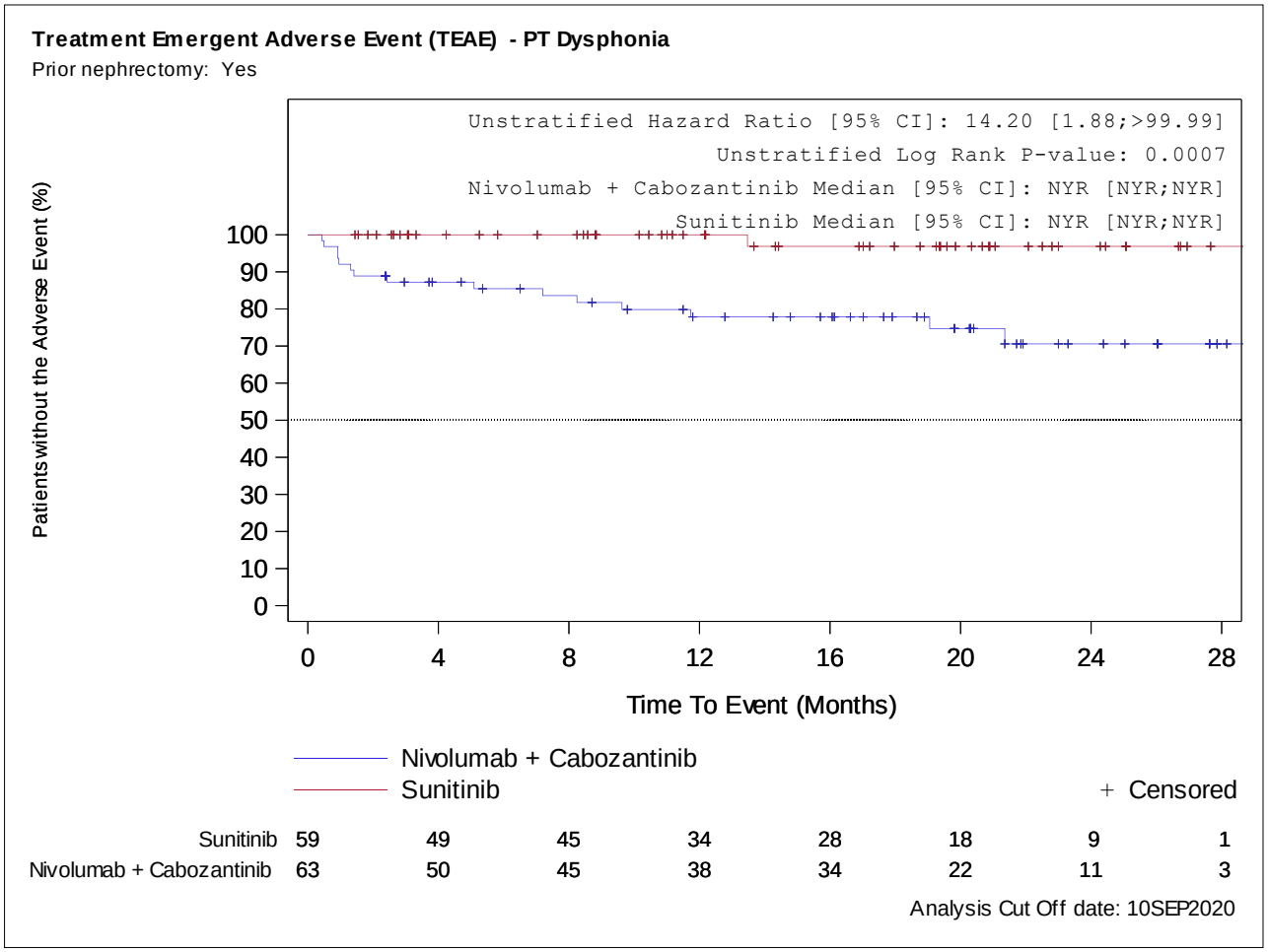
FIGURE 5.15.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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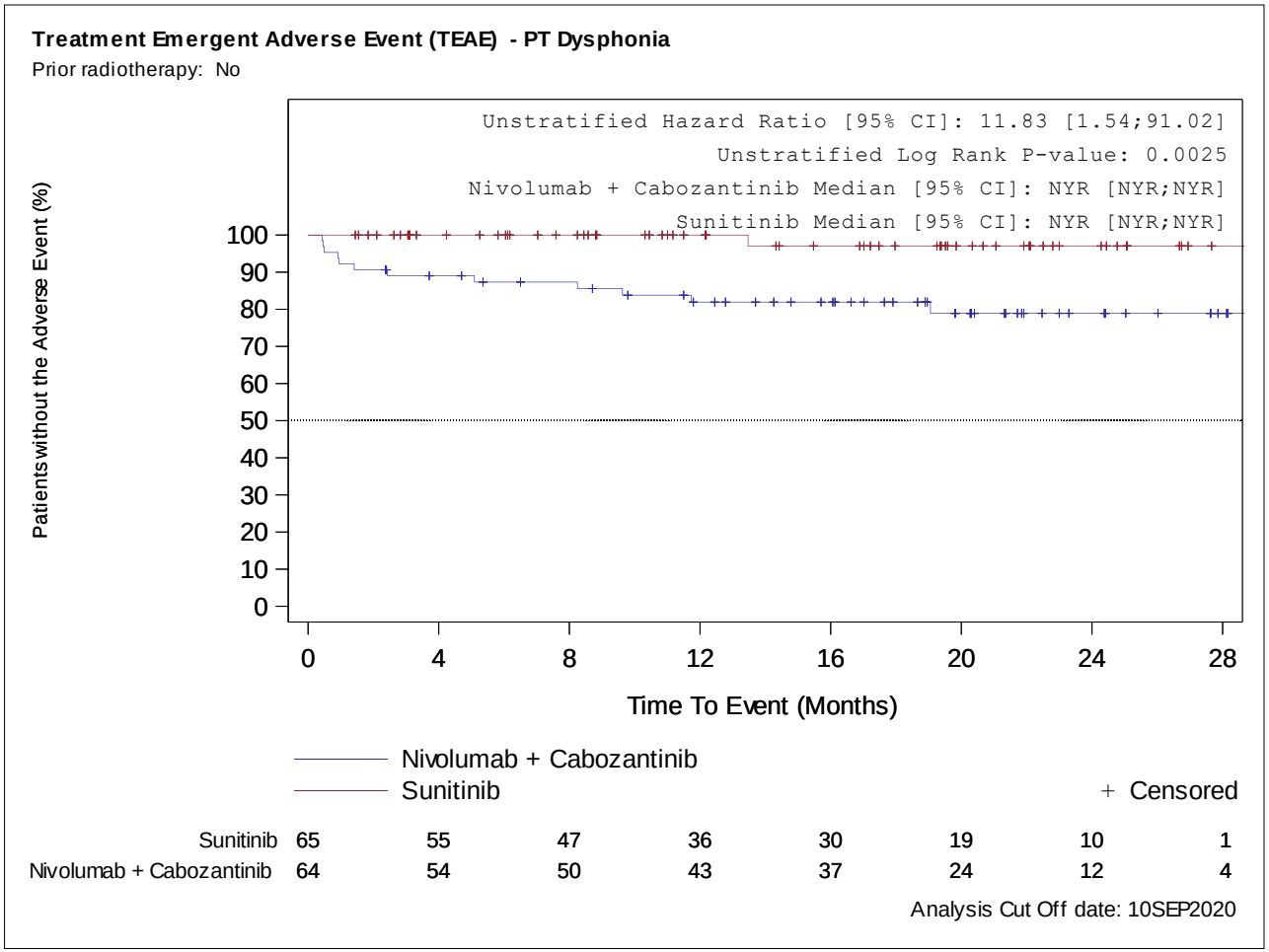
FIGURE 5.15.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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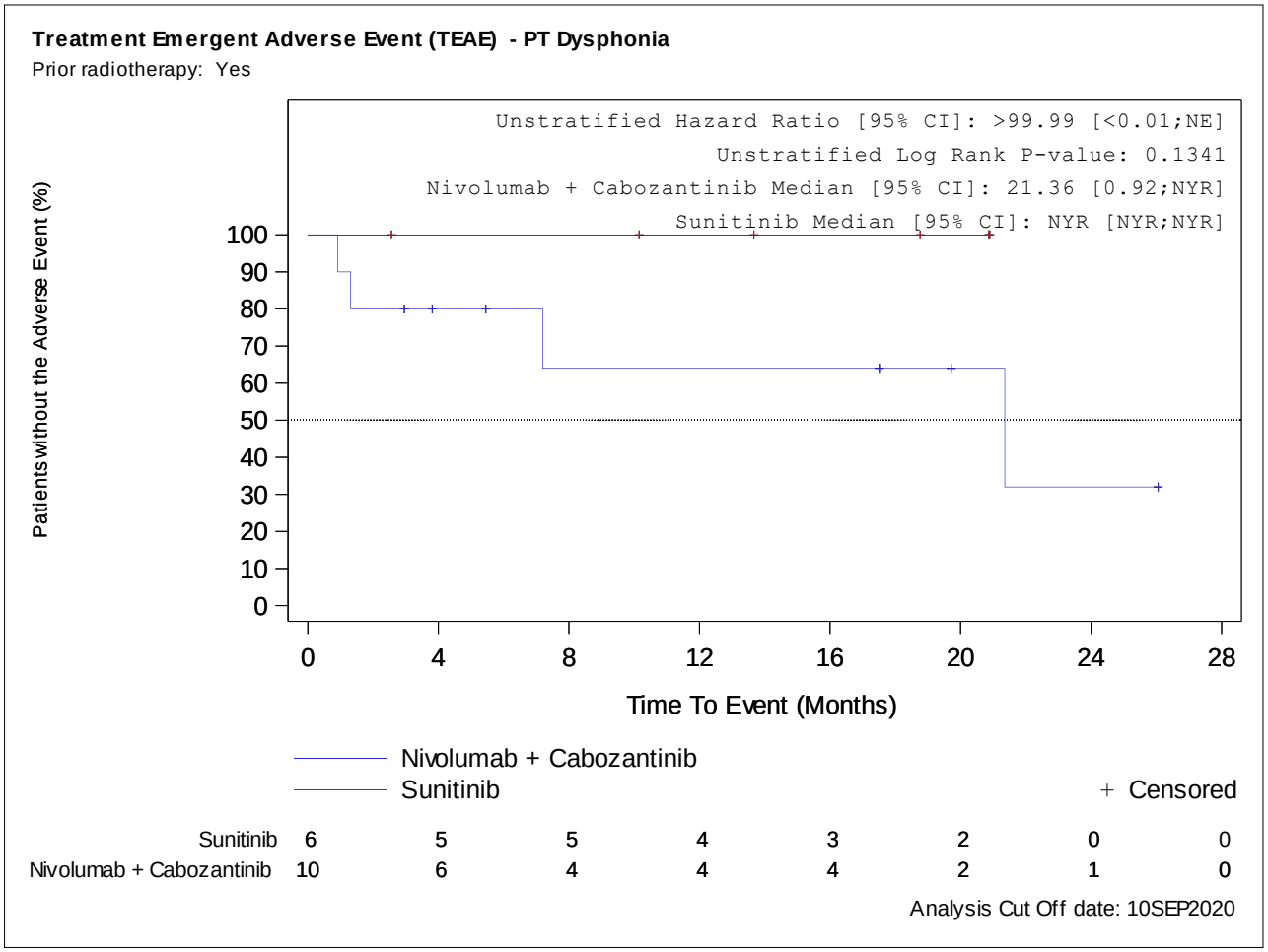
FIGURE 5.15.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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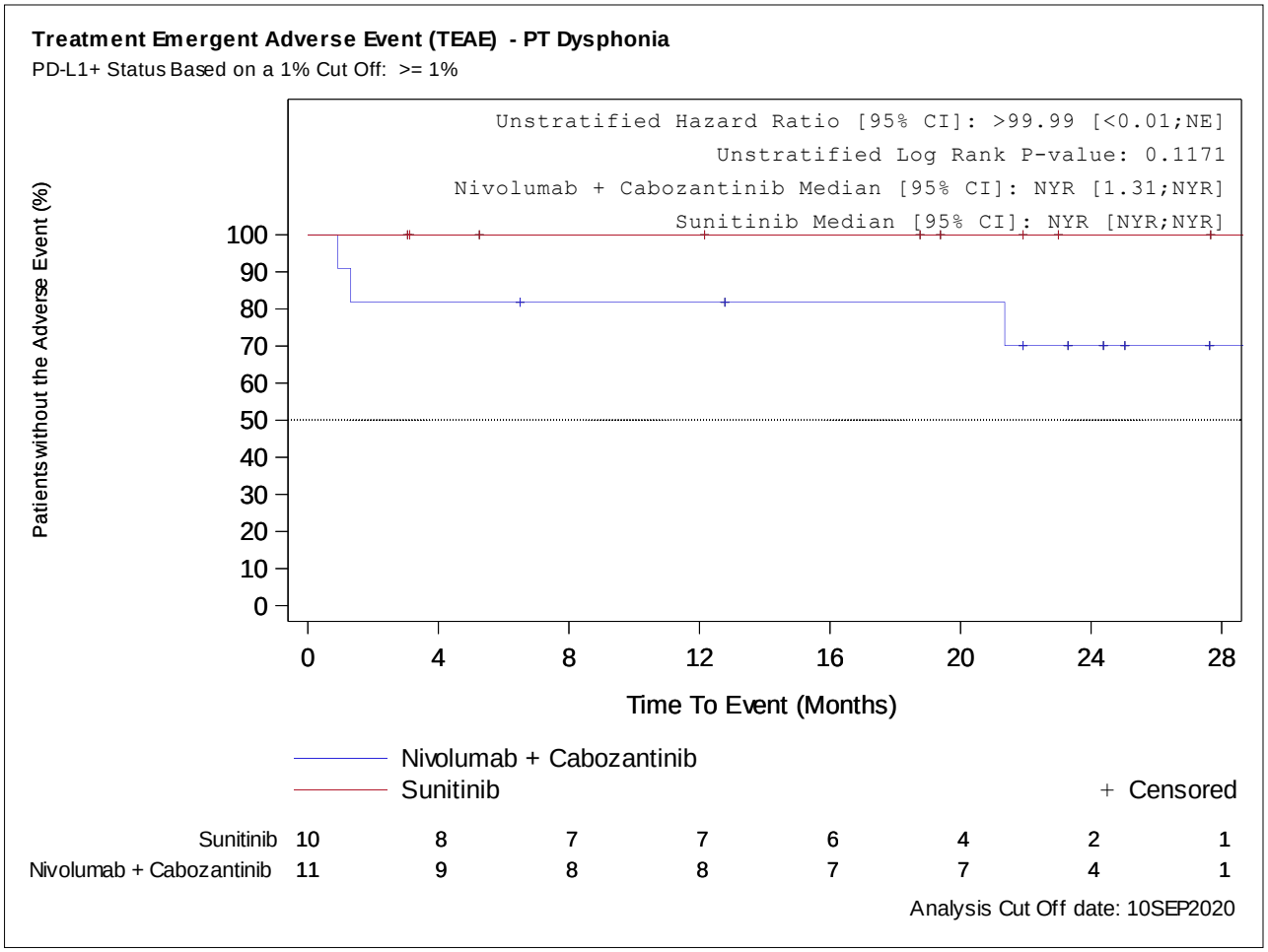
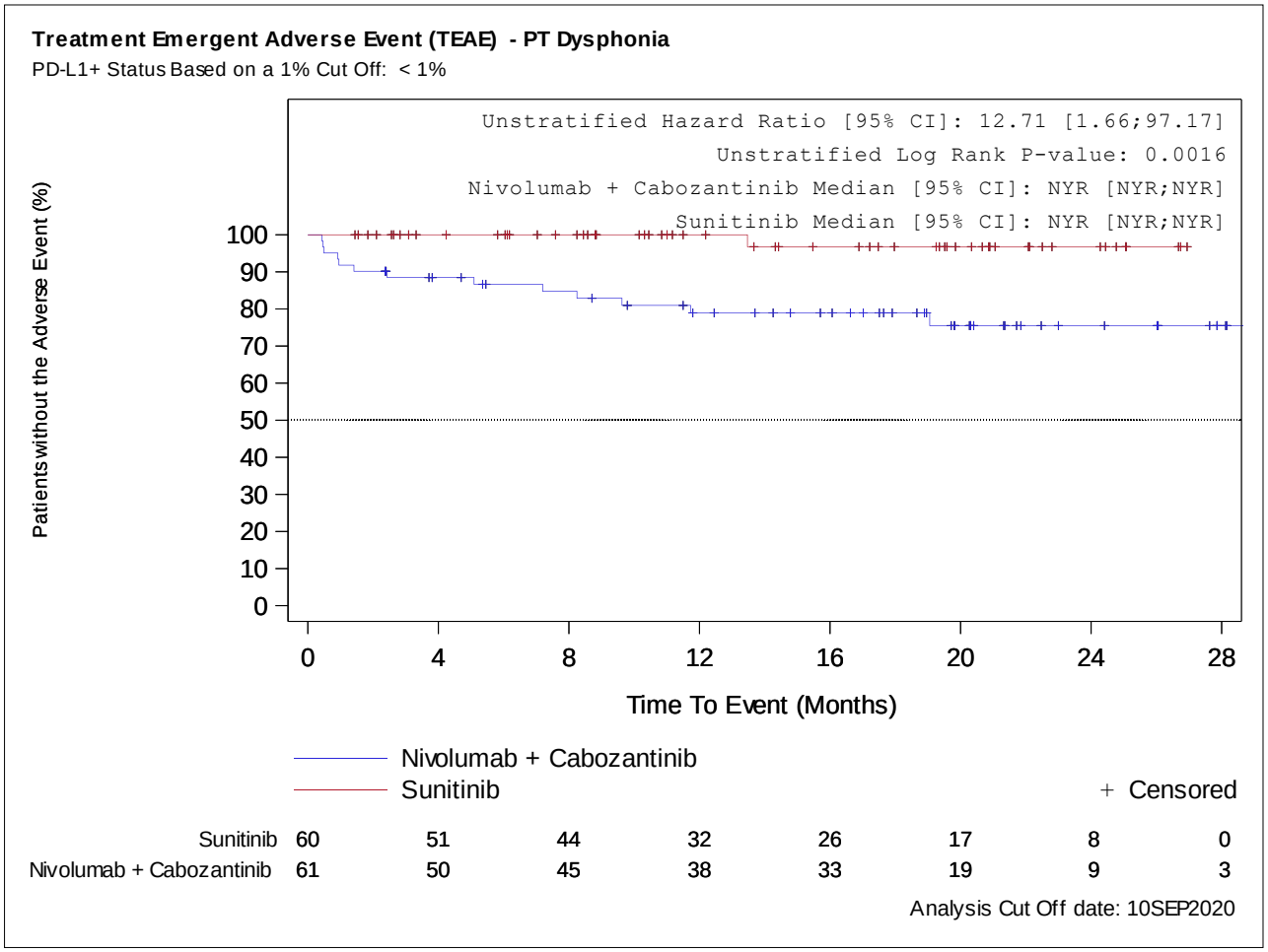
FIGURE 5.15.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:34:51

FIGURE 5.15.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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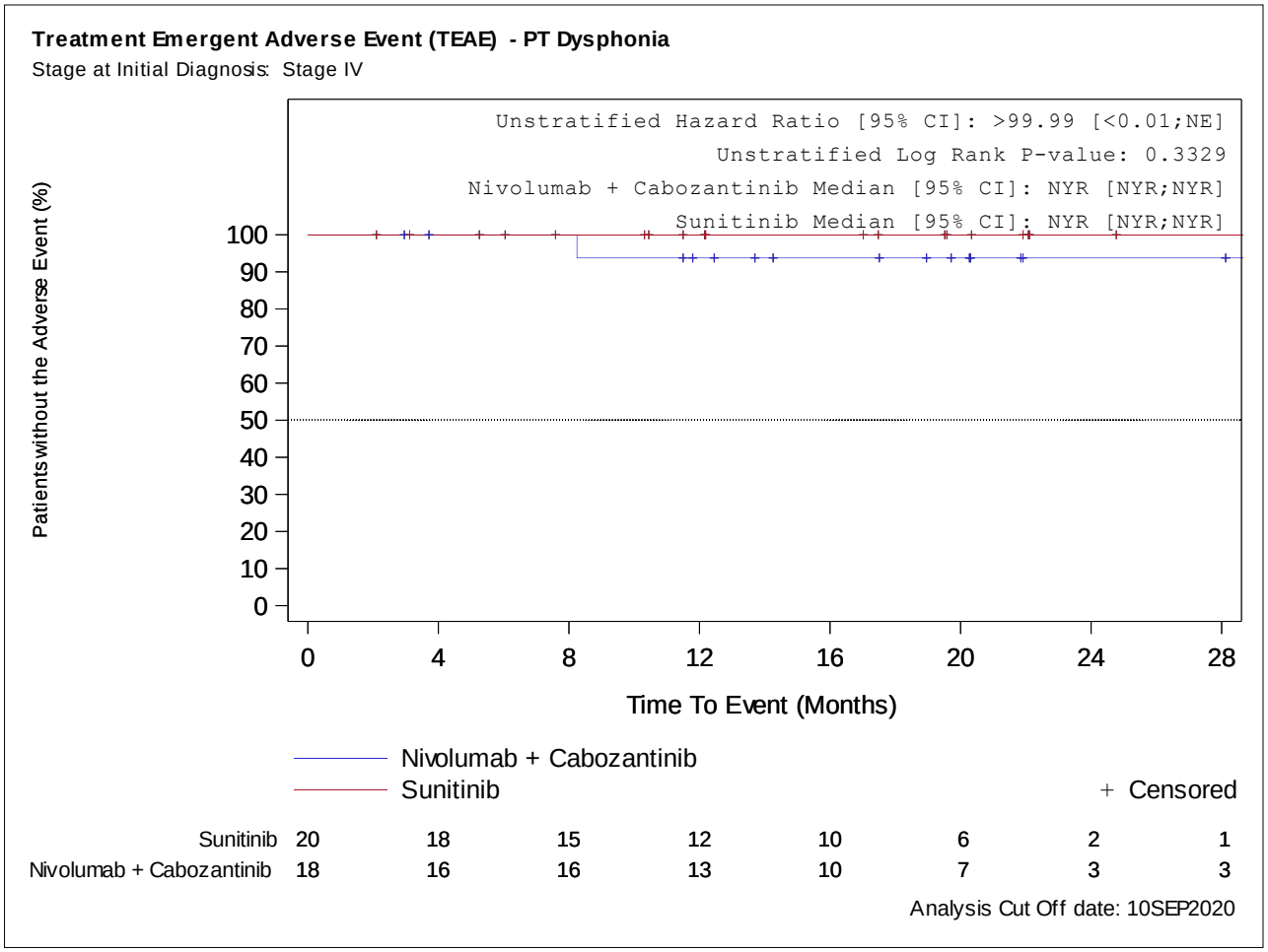
FIGURE 5.15.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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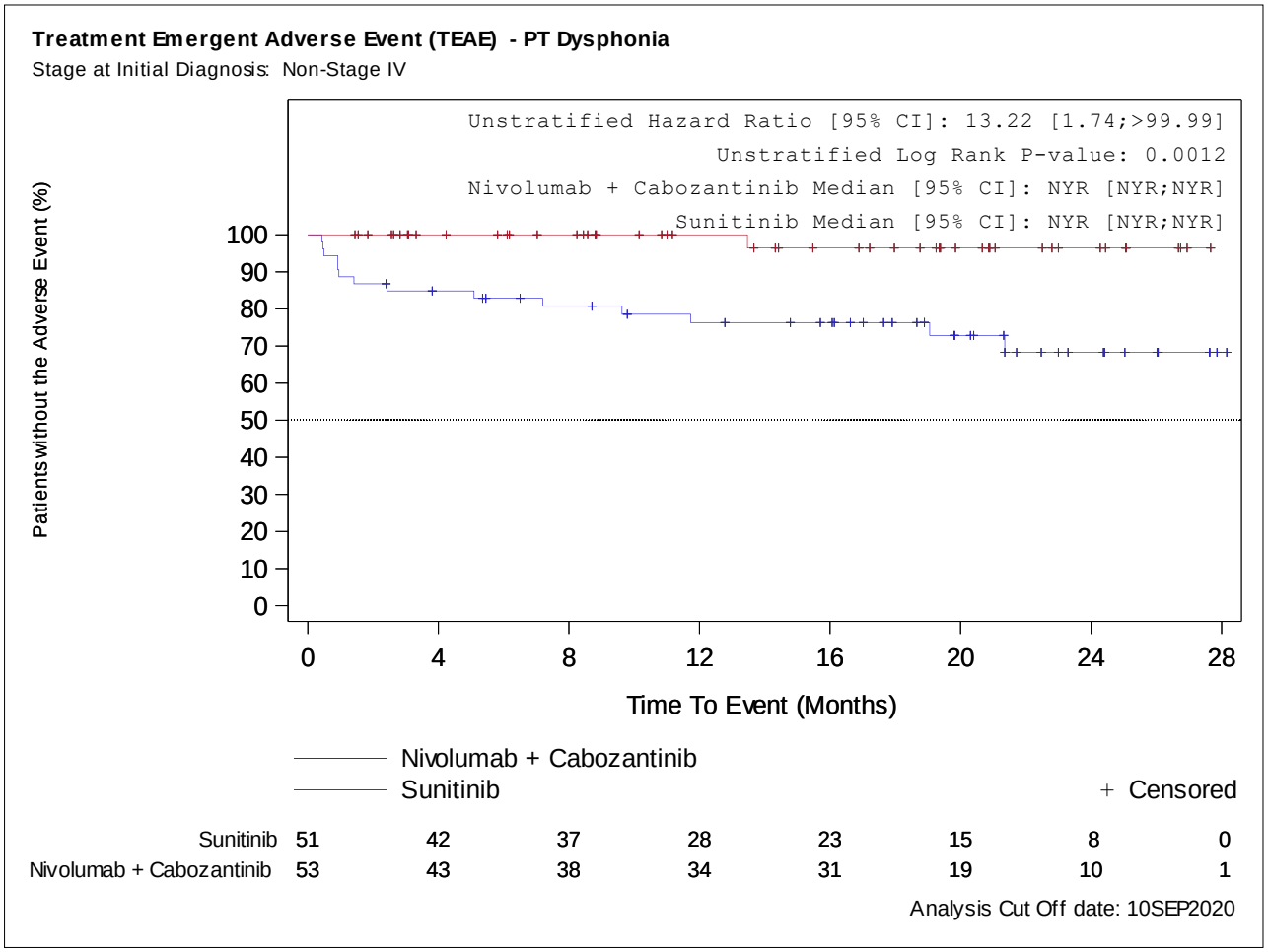
FIGURE 5.15.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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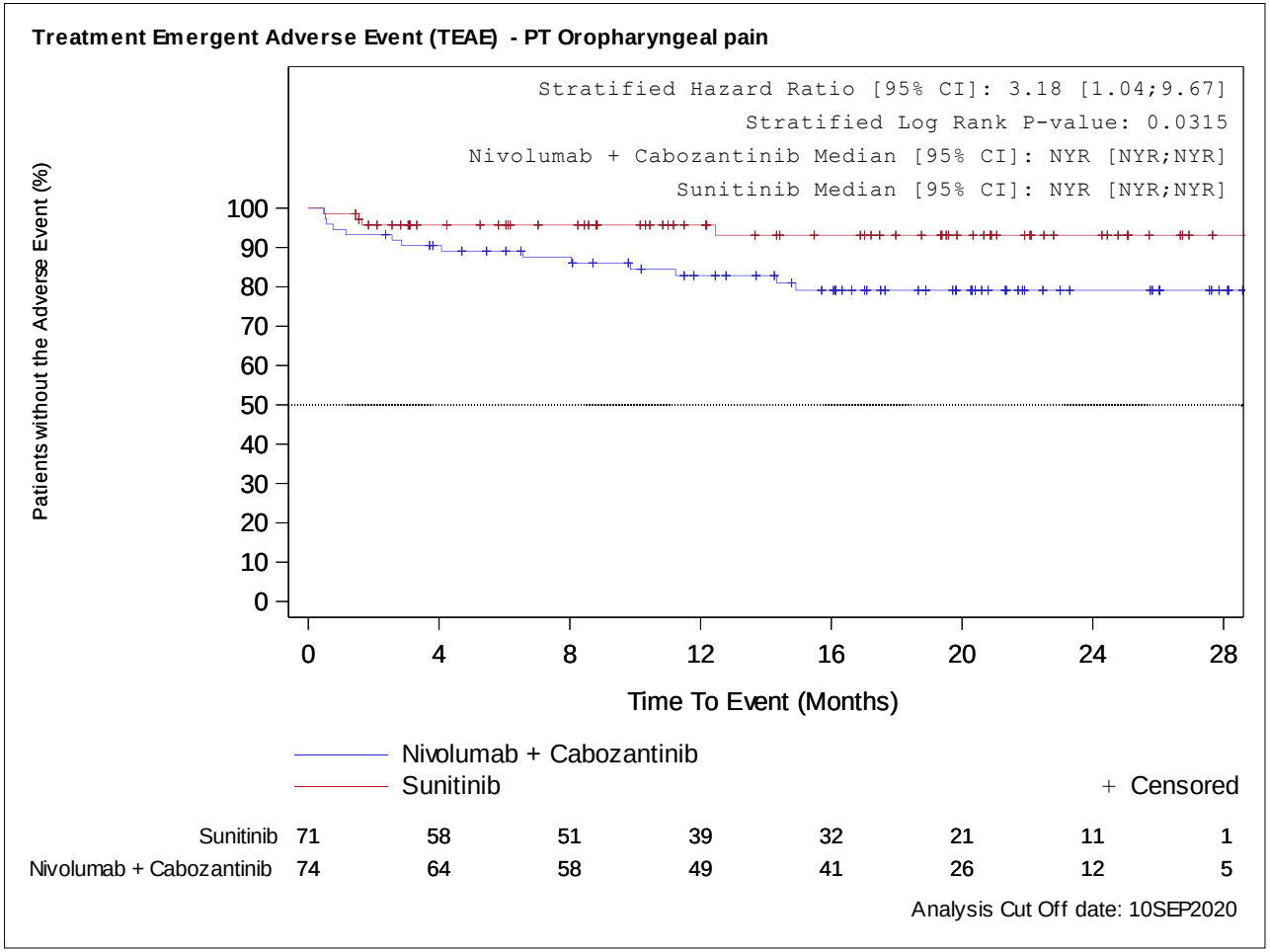
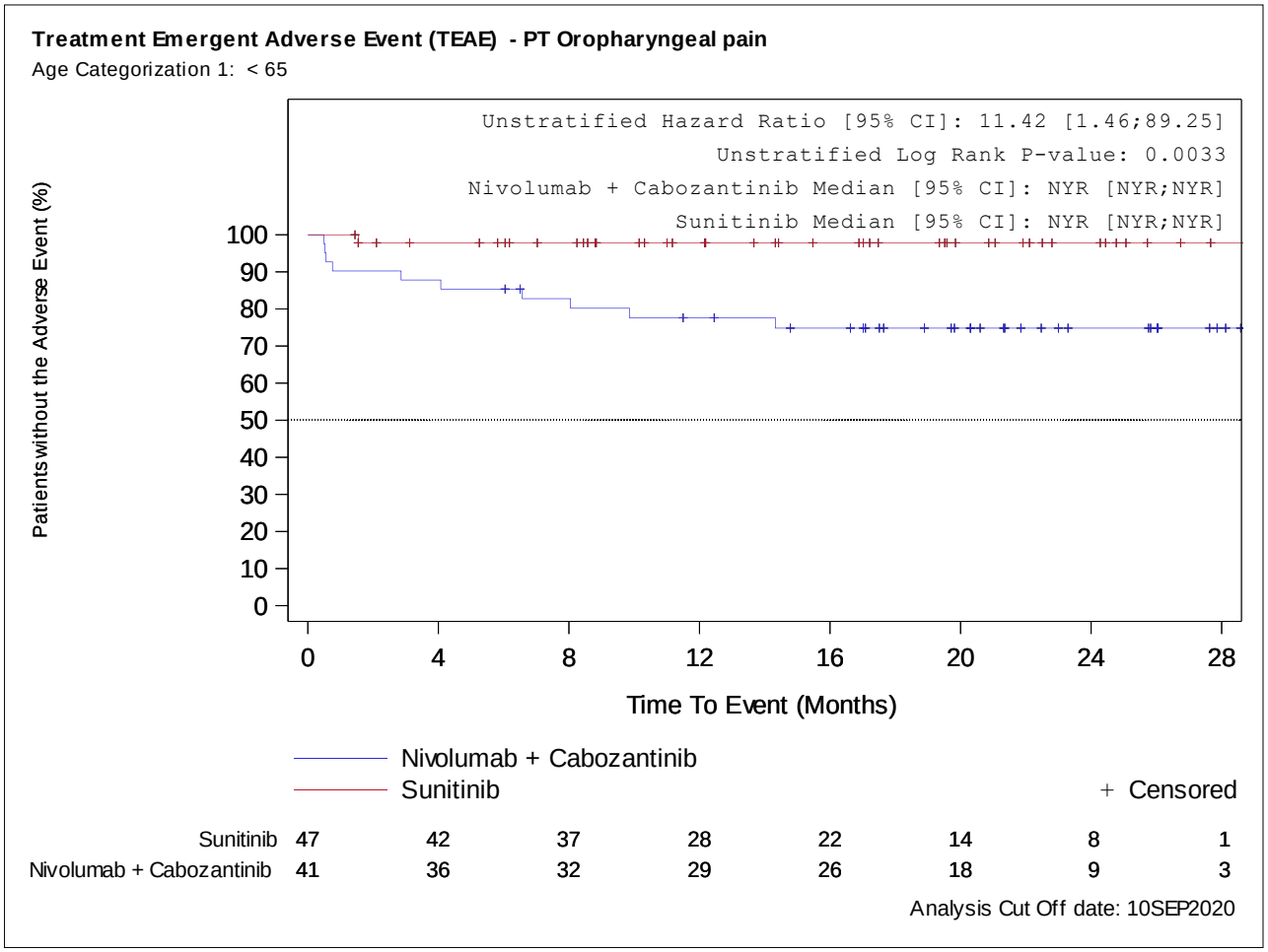
FIGURE 5.16.1: Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:38:44

FIGURE 5.16.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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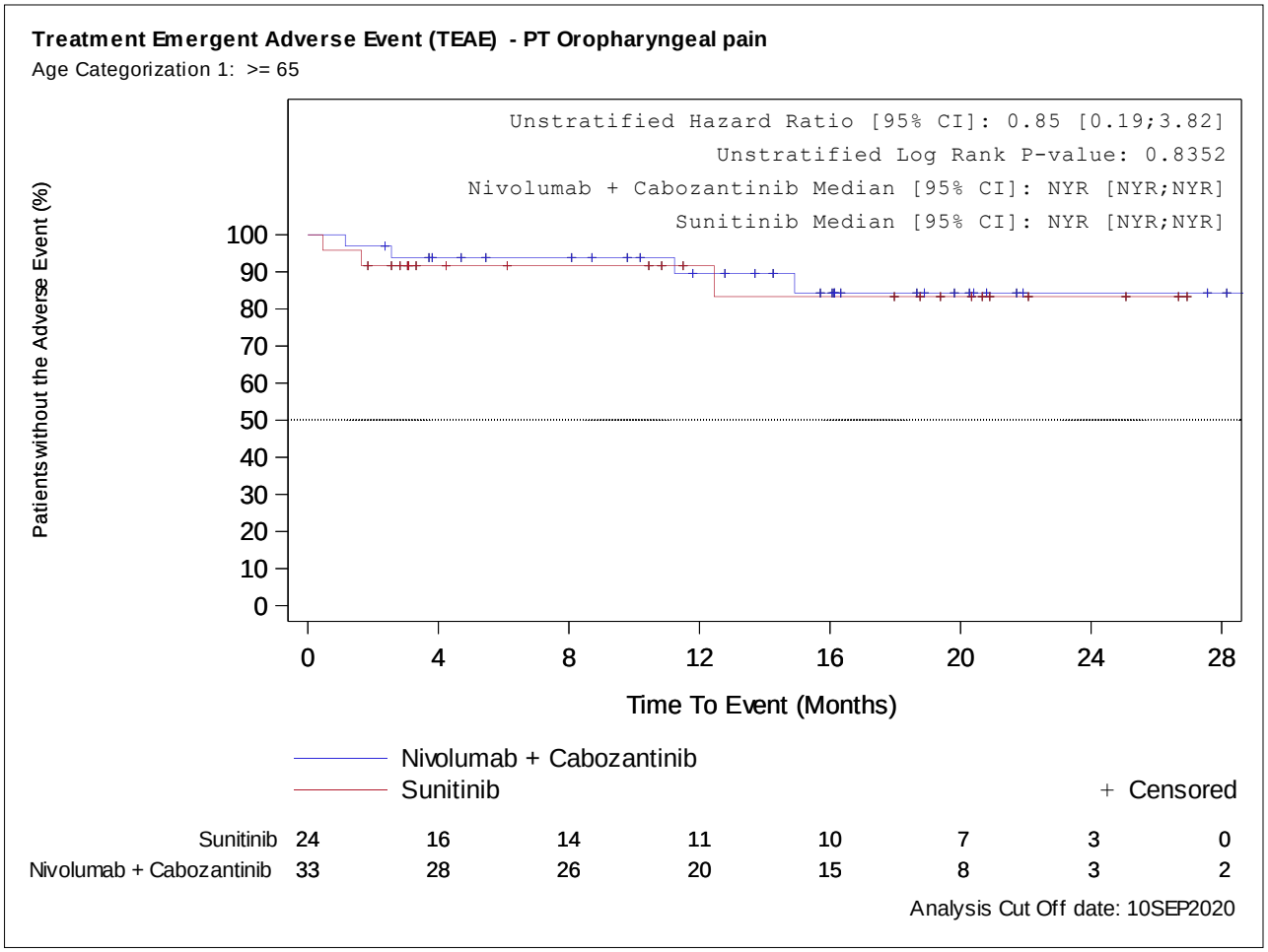
FIGURE 5.16.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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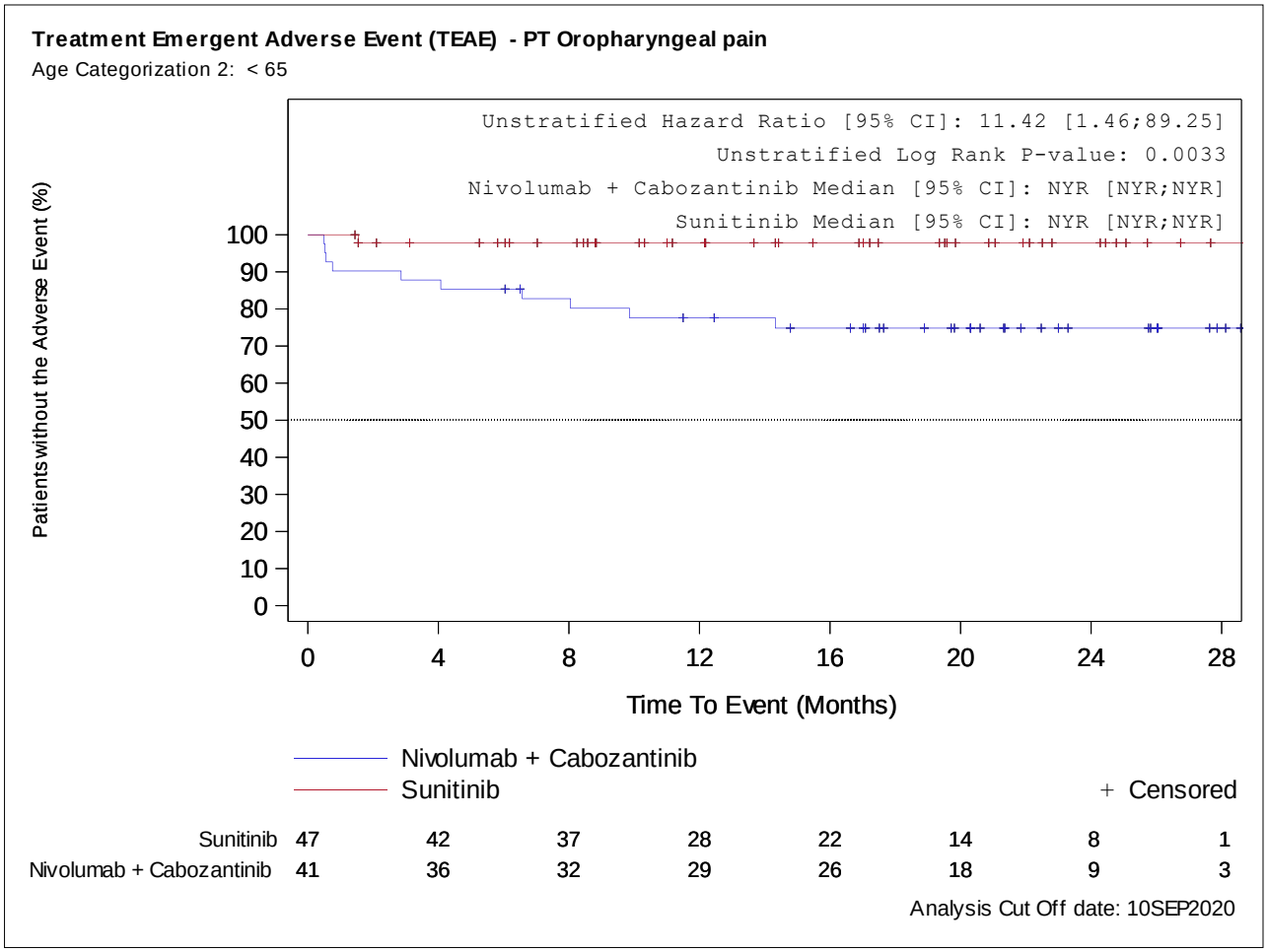
FIGURE 5.16.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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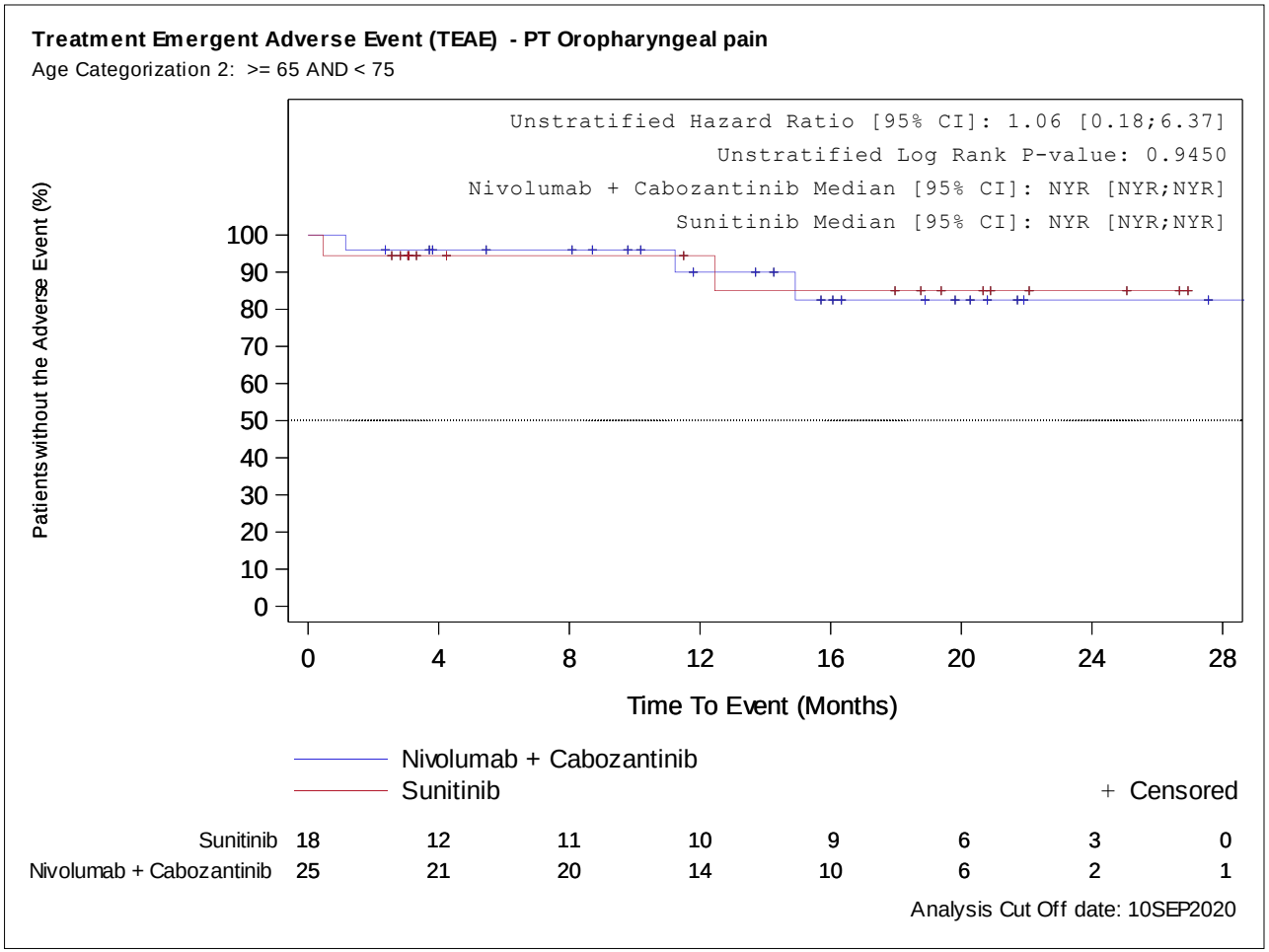
FIGURE 5.16.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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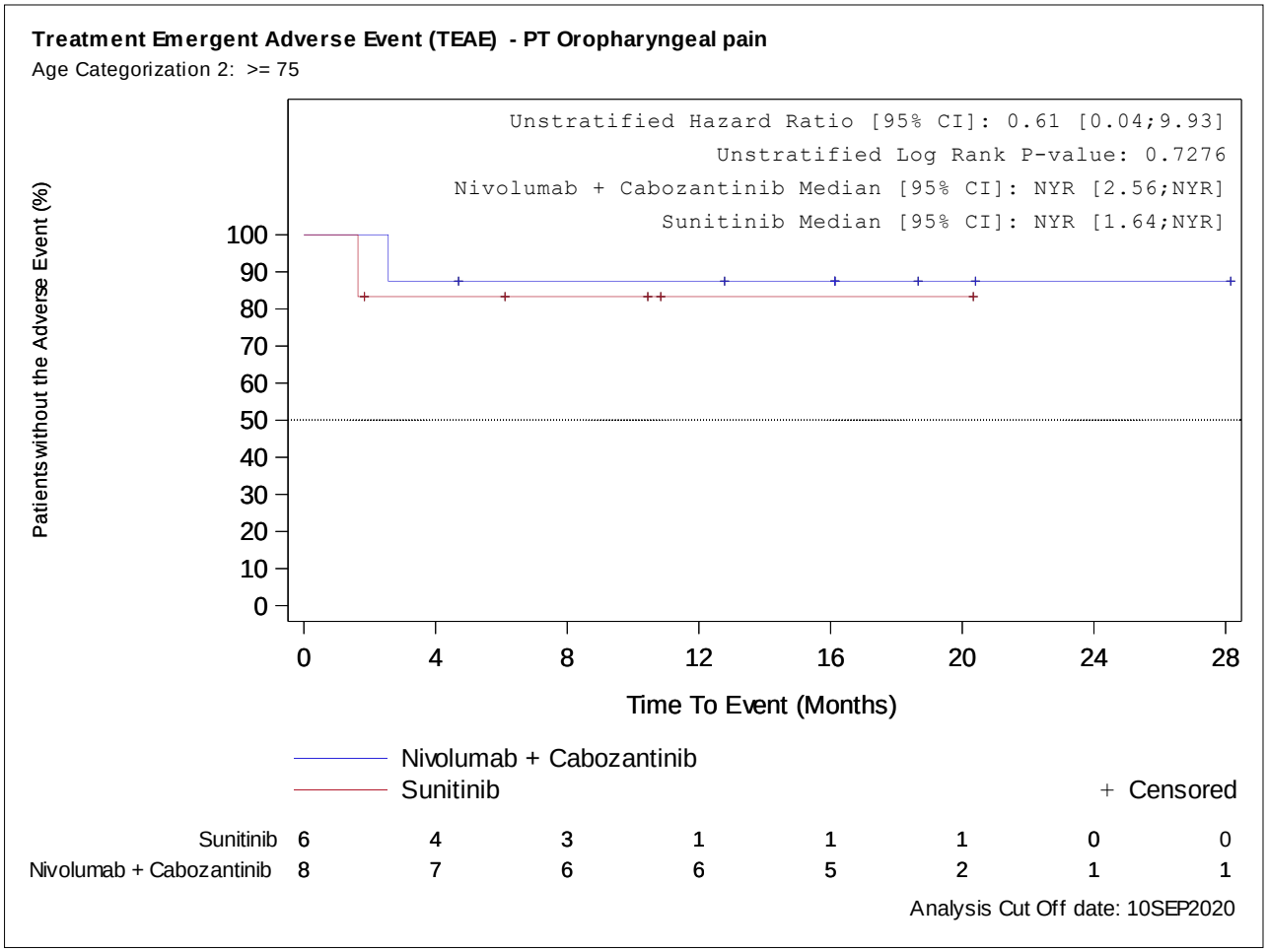
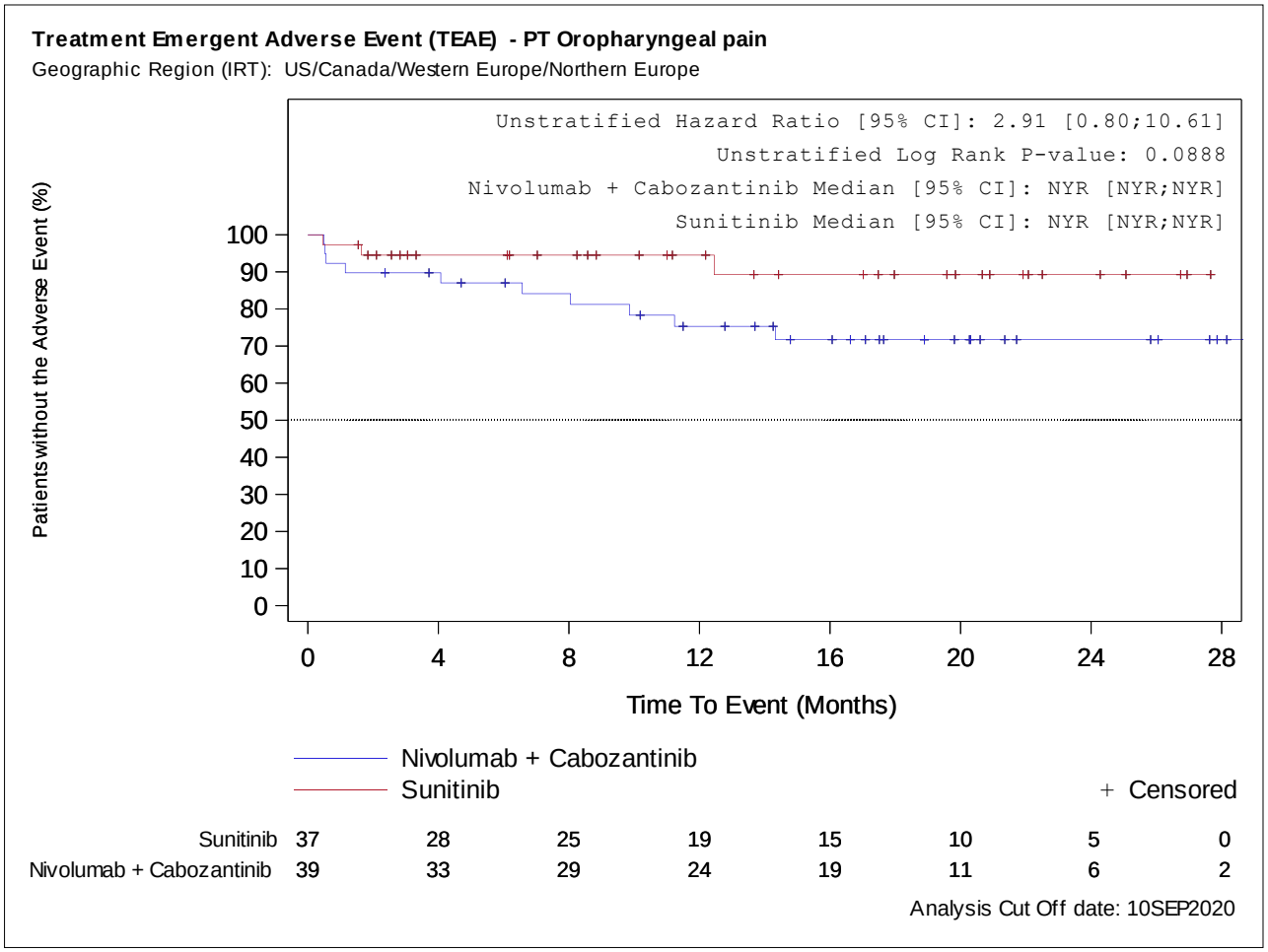
FIGURE 5.16.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



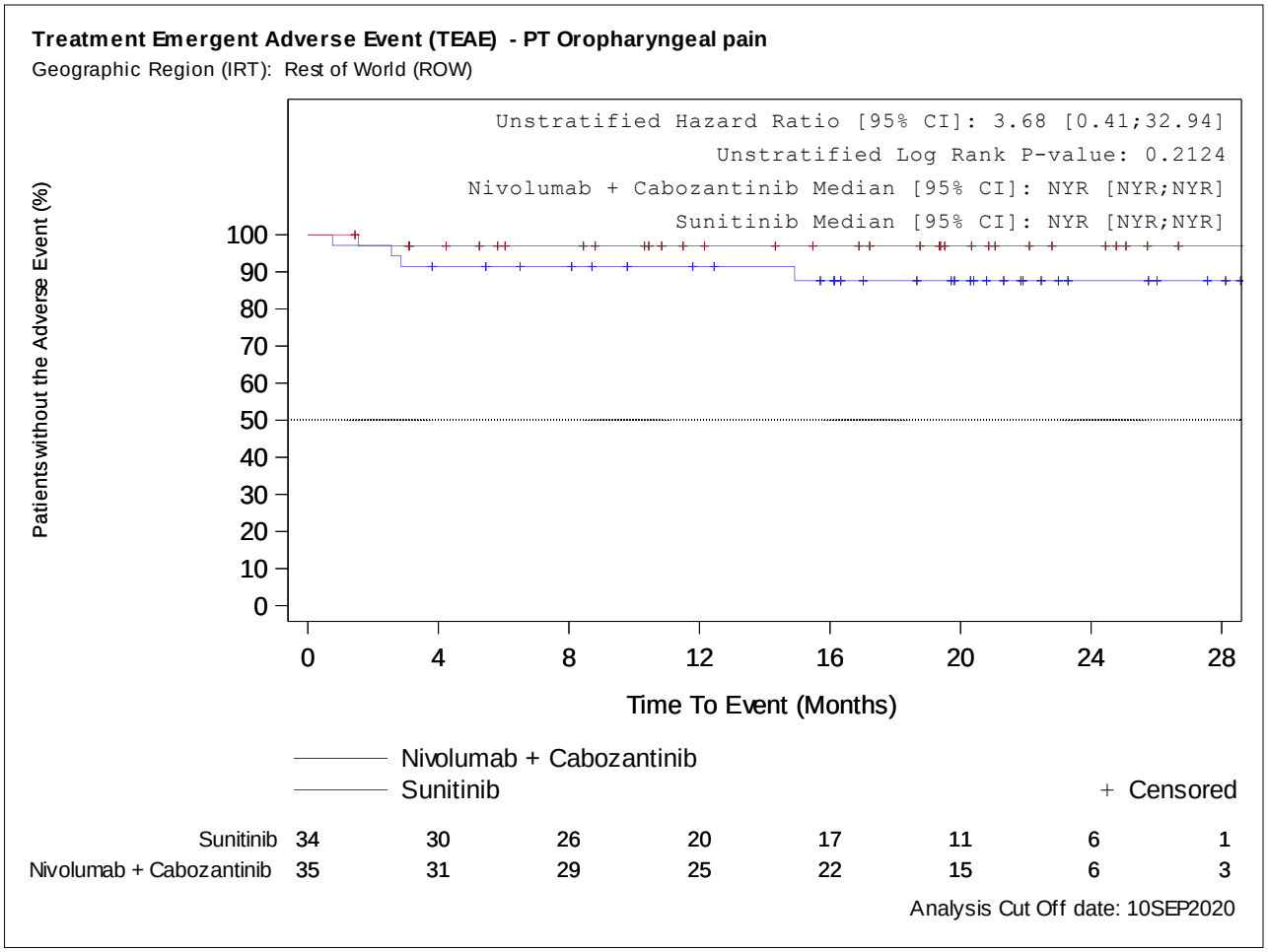

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:39:11

FIGURE 5.16.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:39:17

FIGURE 5.16.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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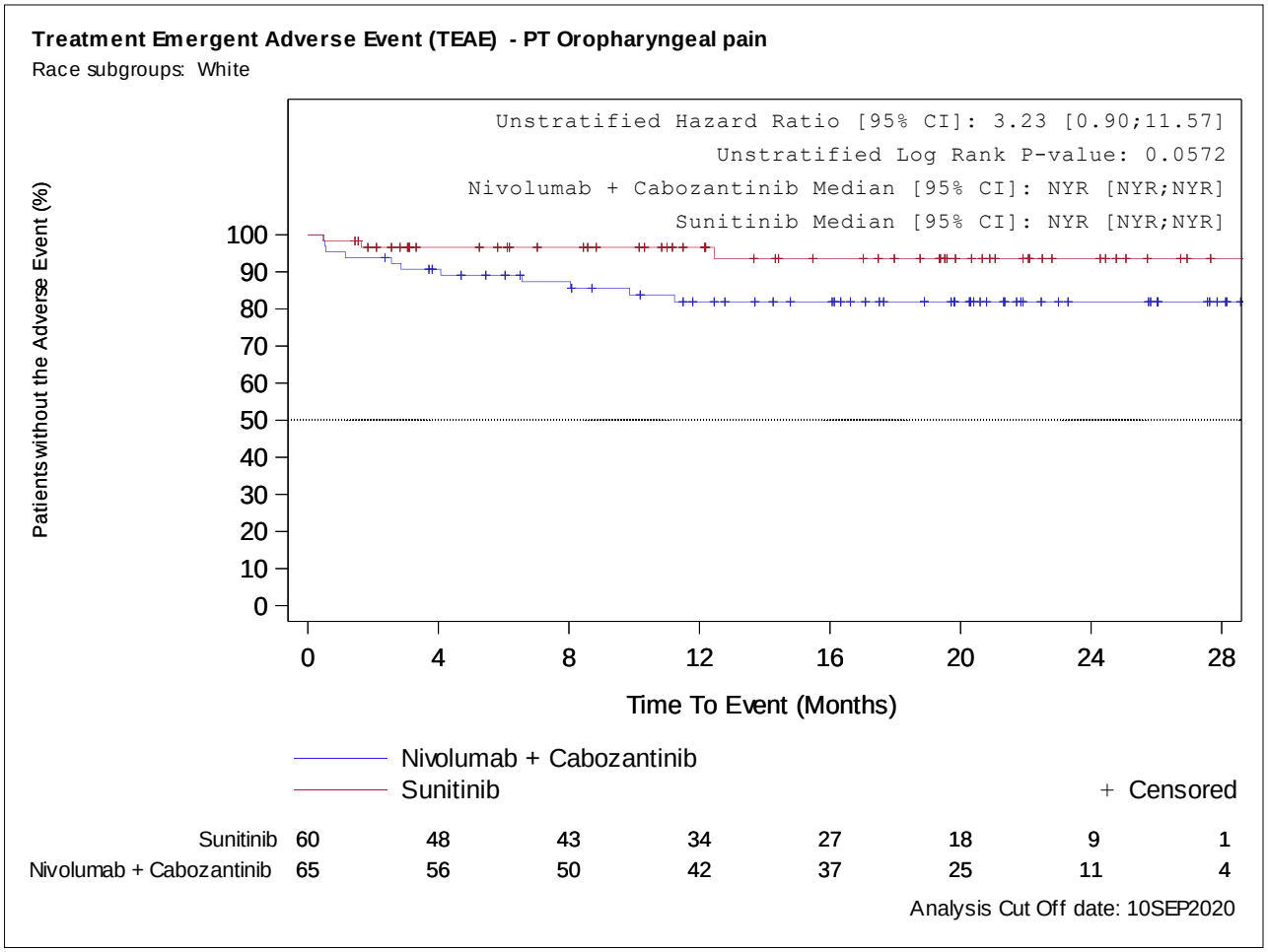
FIGURE 5.16.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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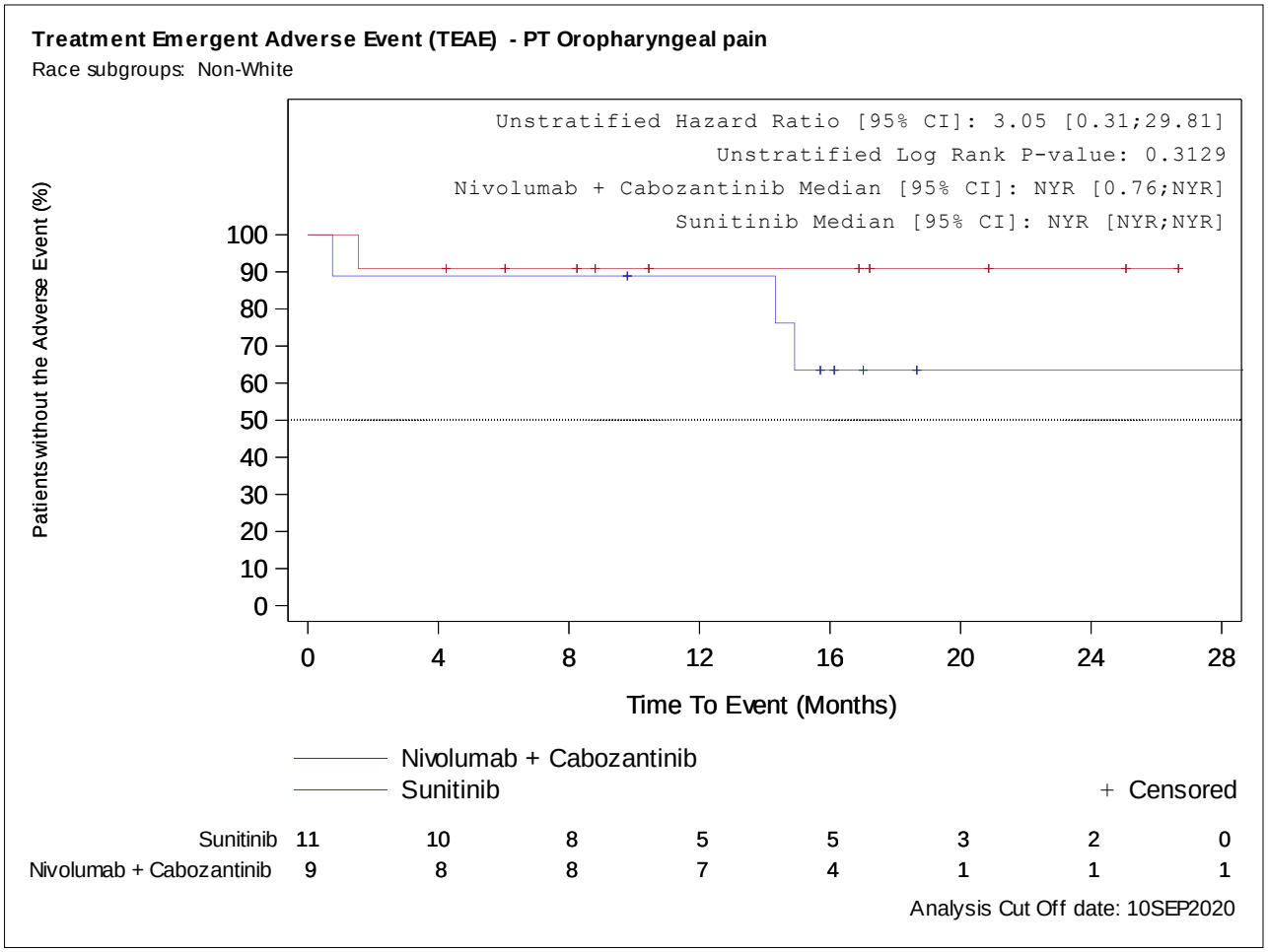
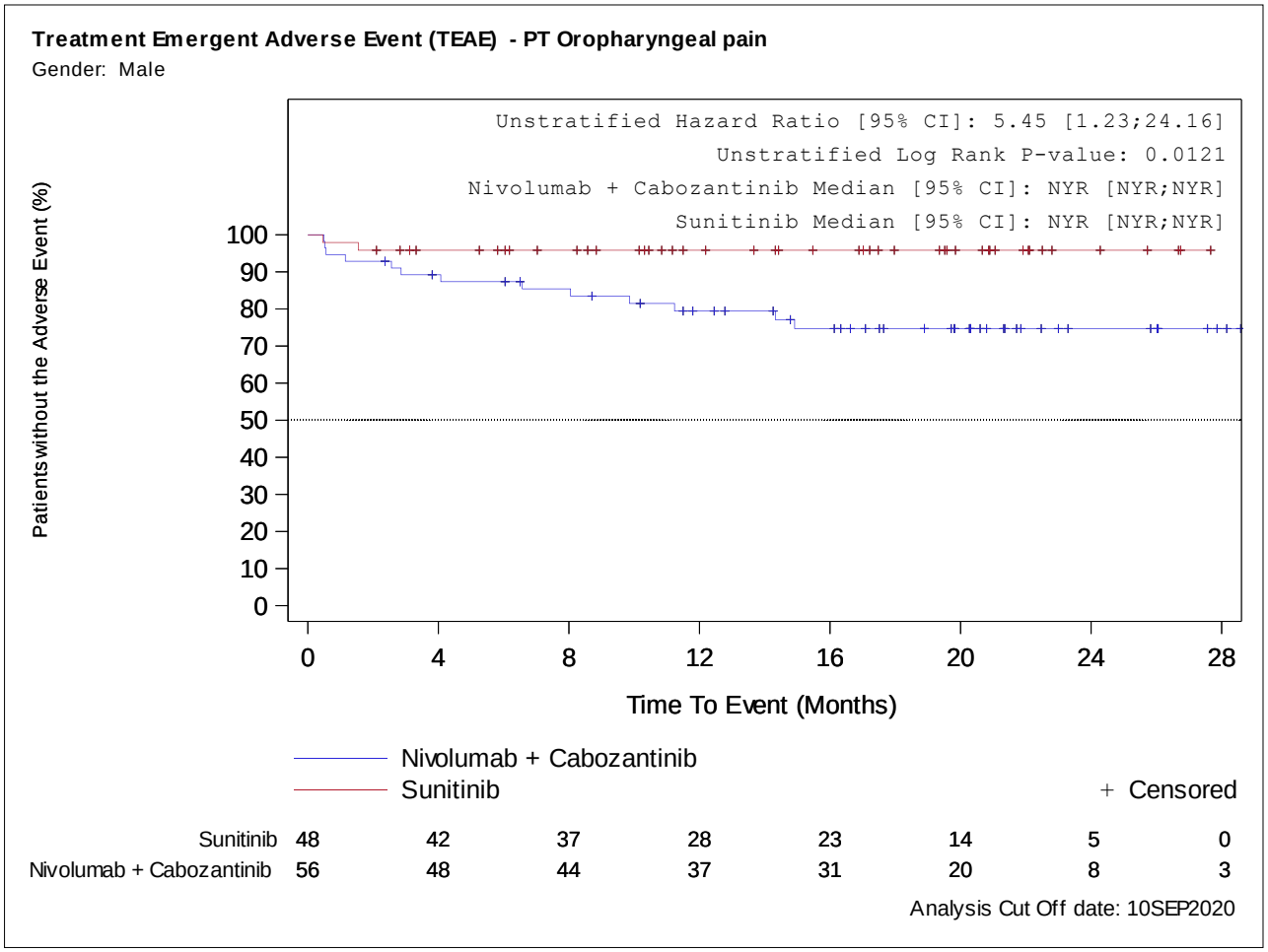
FIGURE 5.16.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:39:34

FIGURE 5.16.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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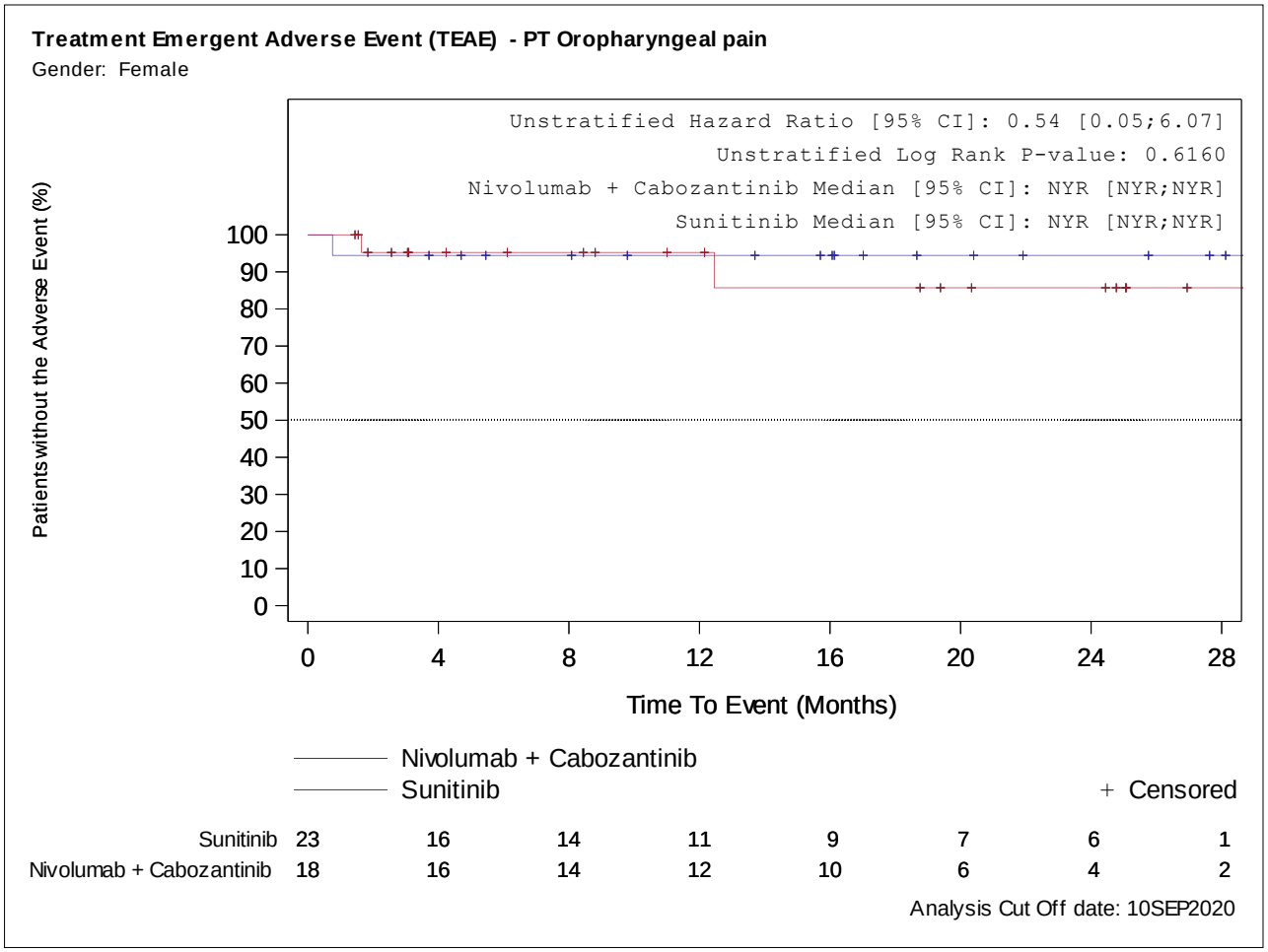
FIGURE 5.16.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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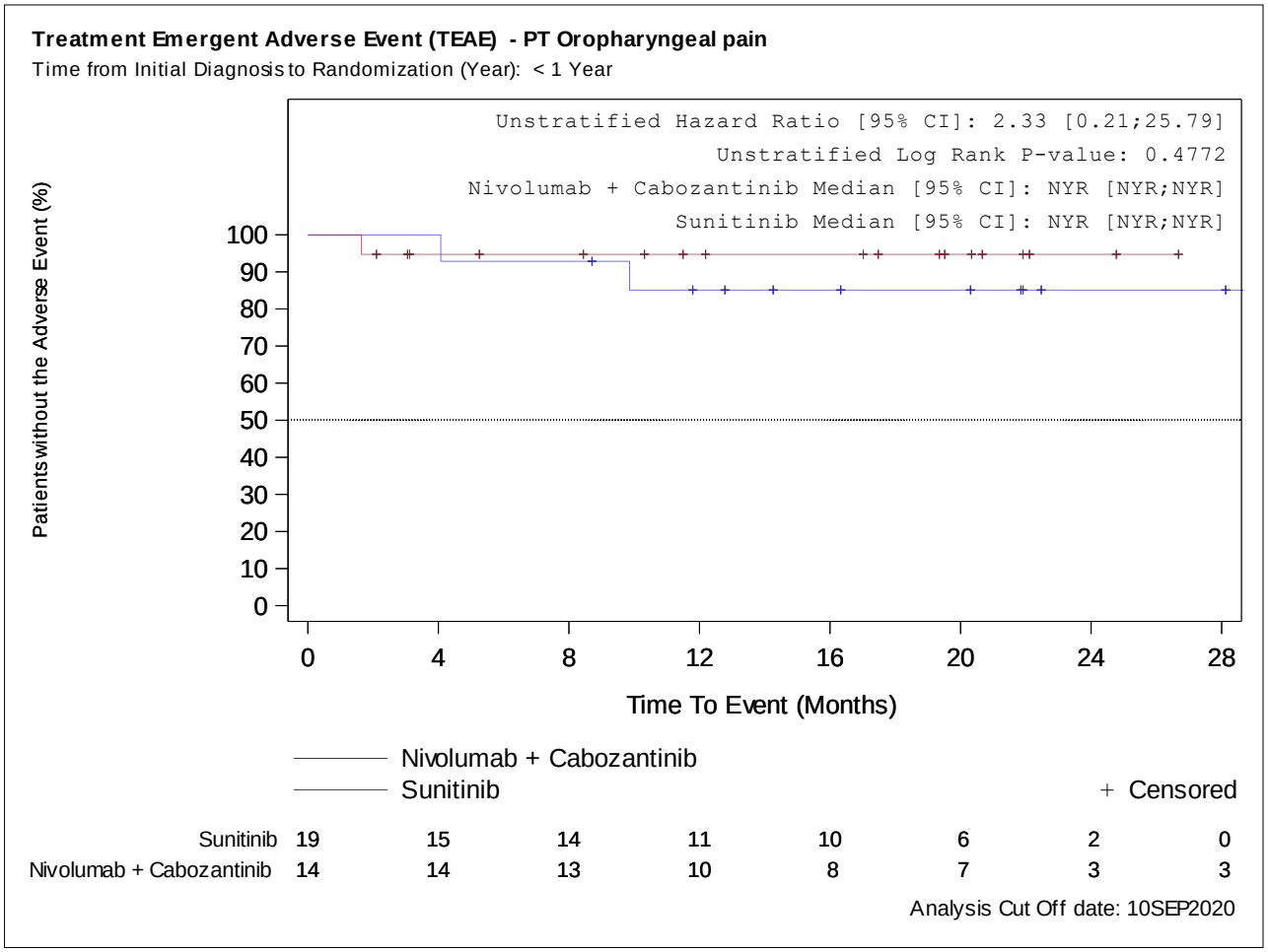
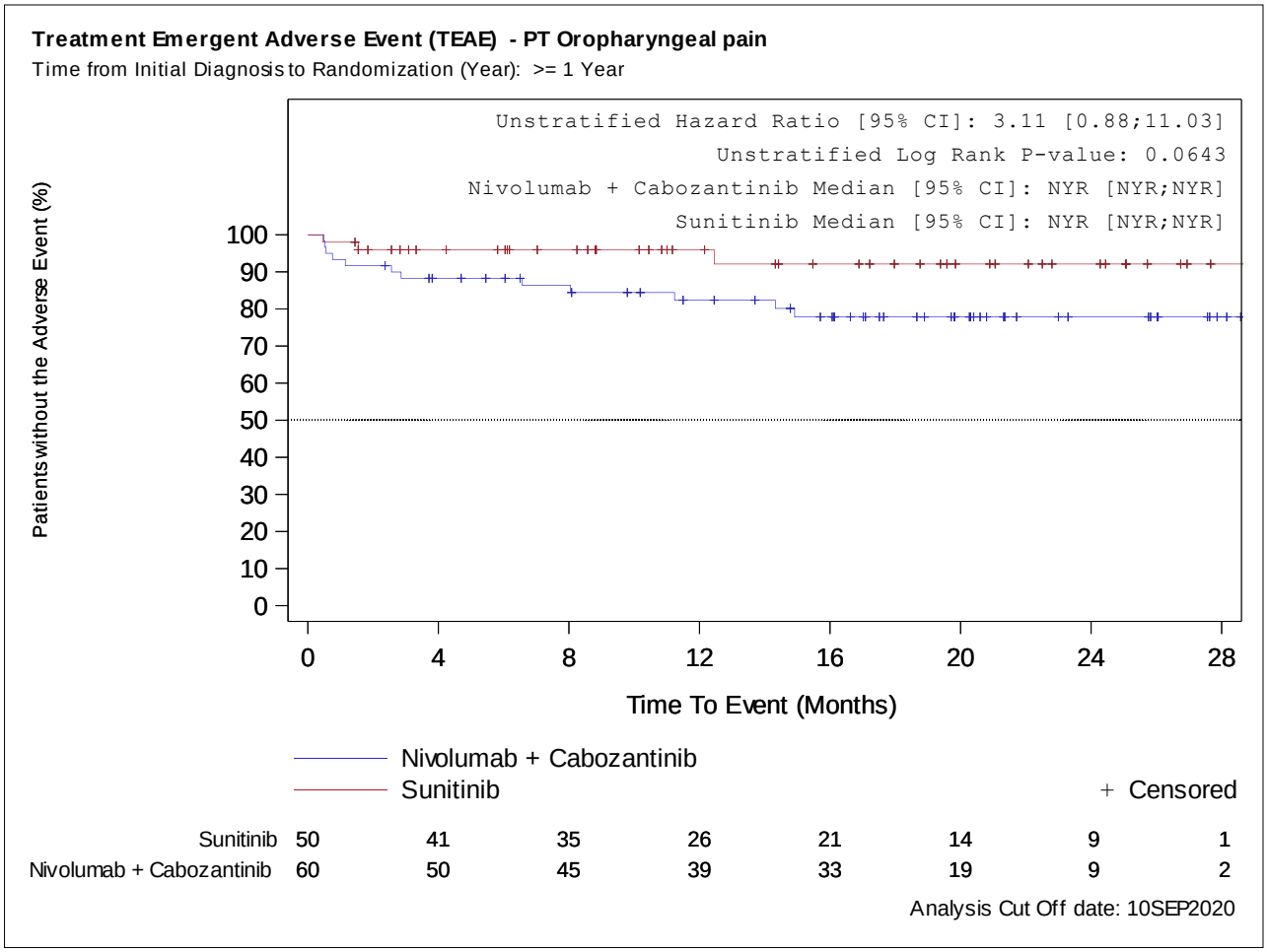
FIGURE 5.16.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



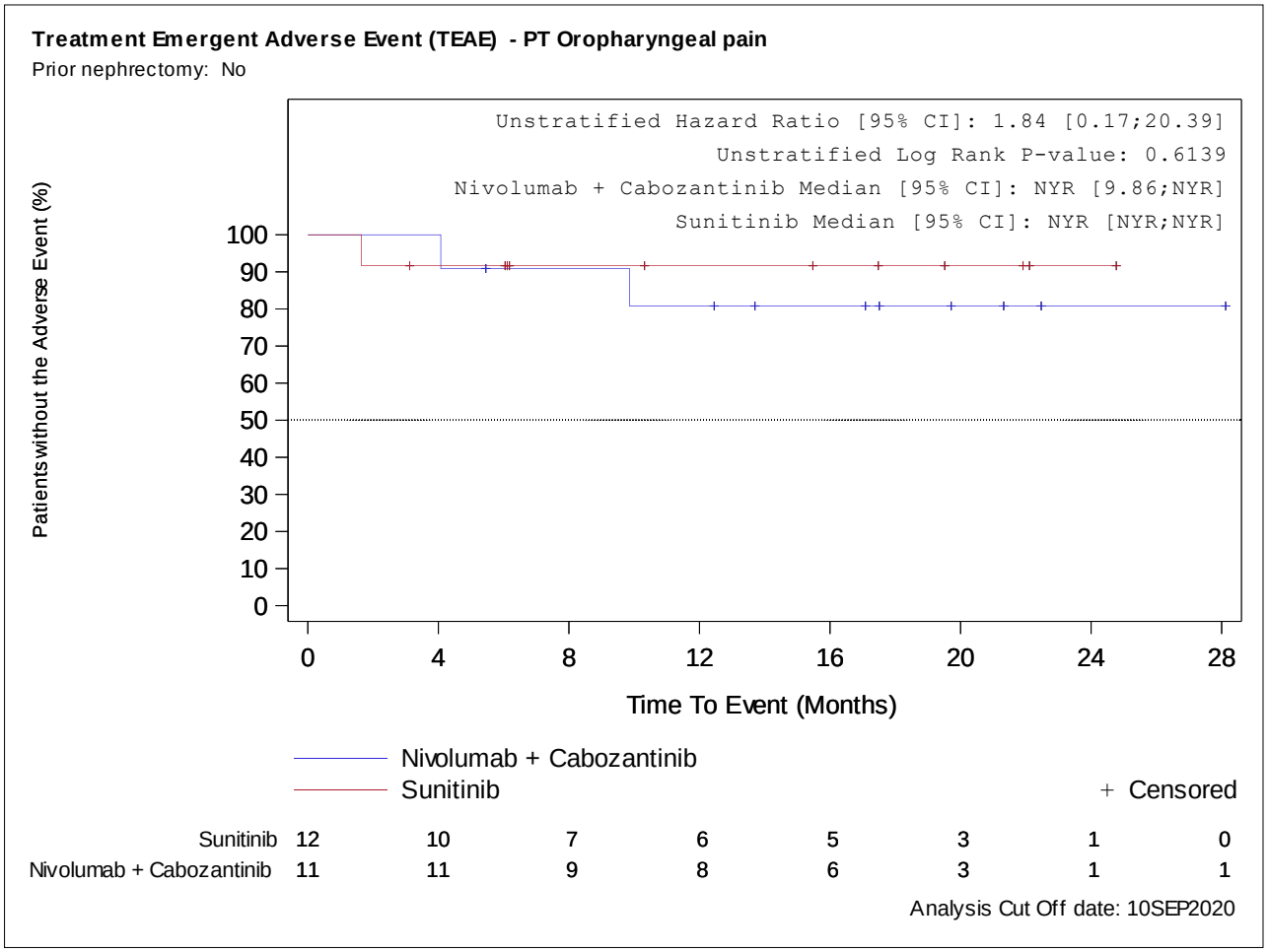

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:40:02

FIGURE 5.16.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:40:08

FIGURE 5.16.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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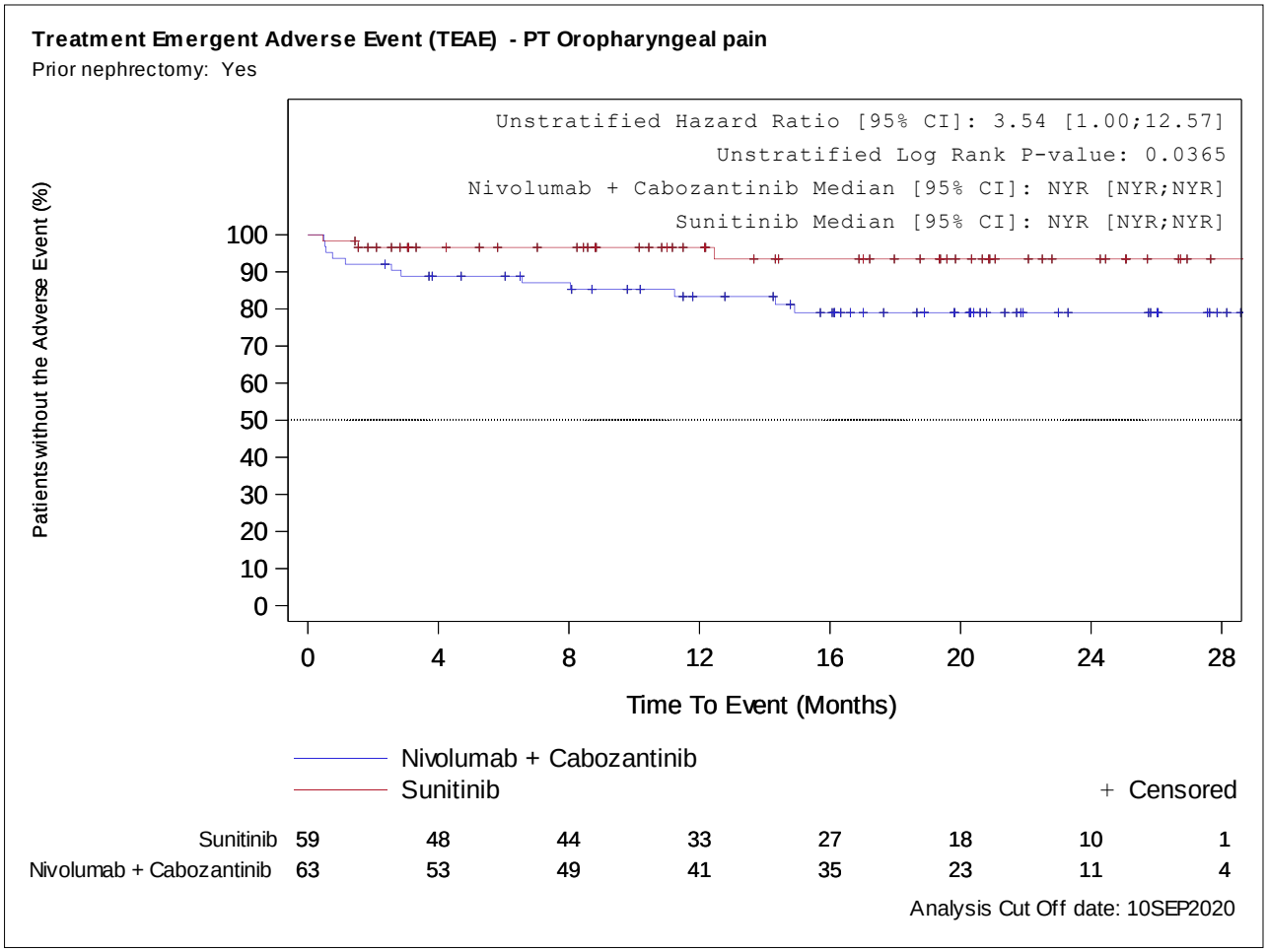
FIGURE 5.16.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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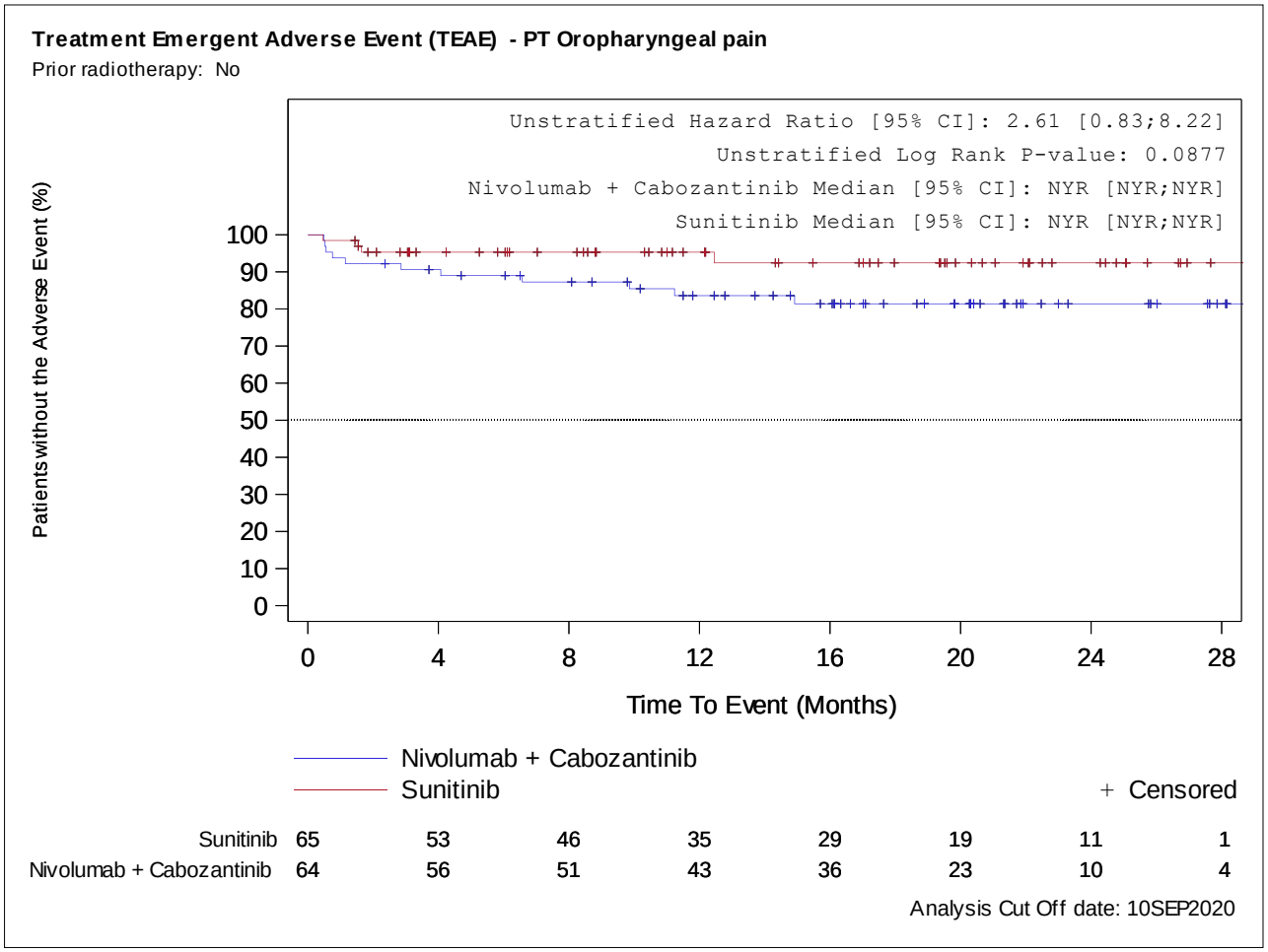
FIGURE 5.16.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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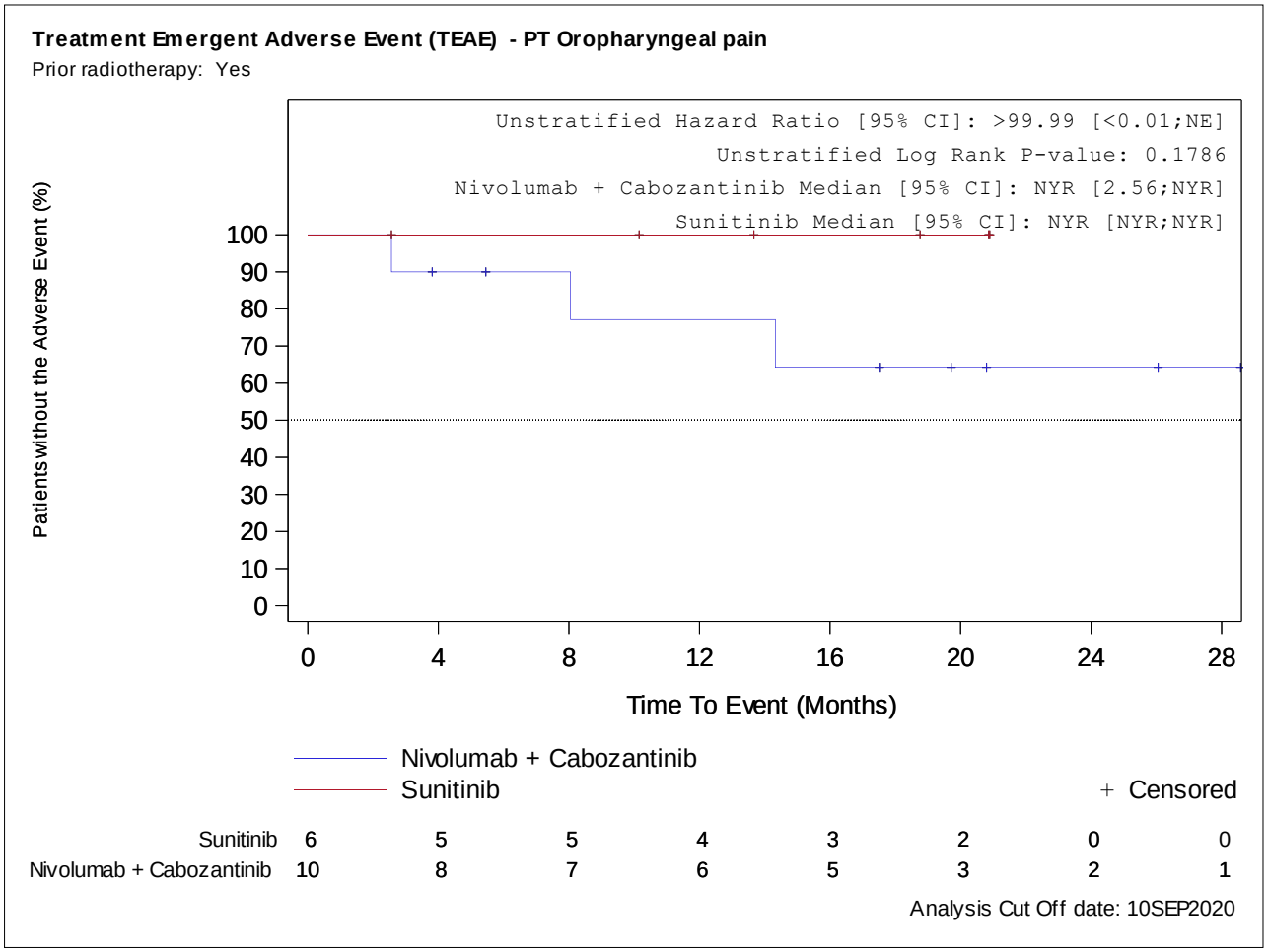
FIGURE 5.16.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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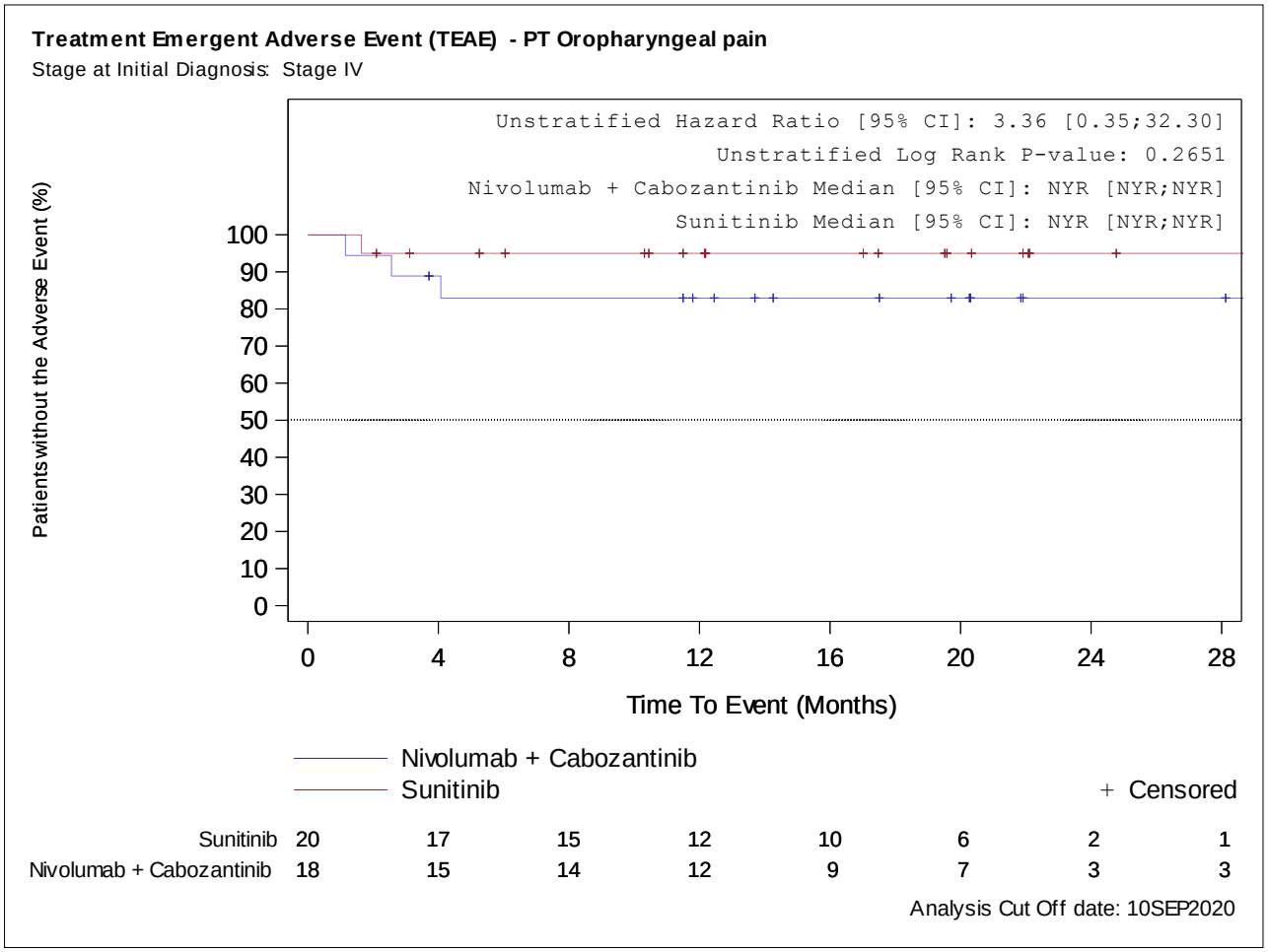
FIGURE 5.16.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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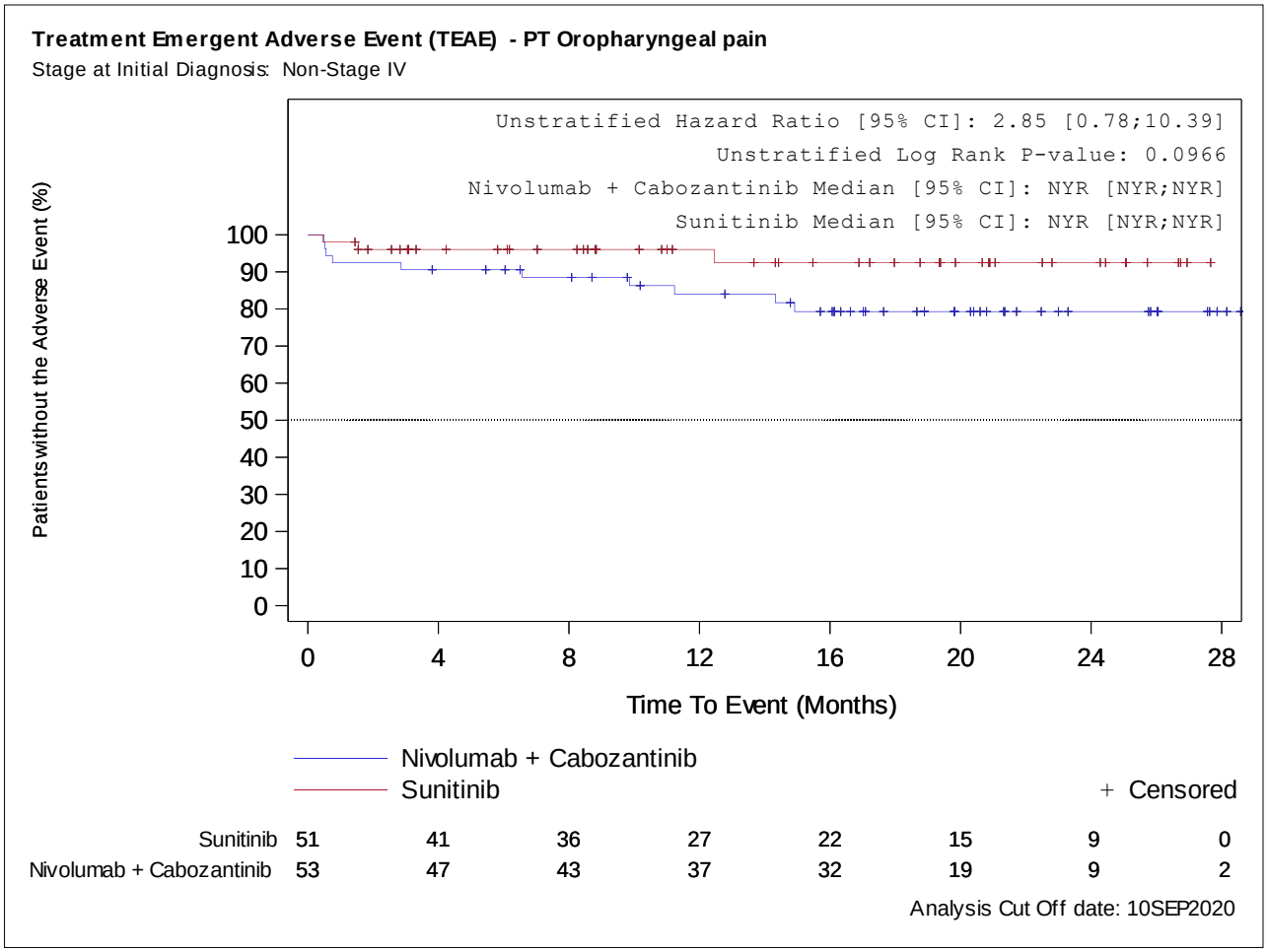
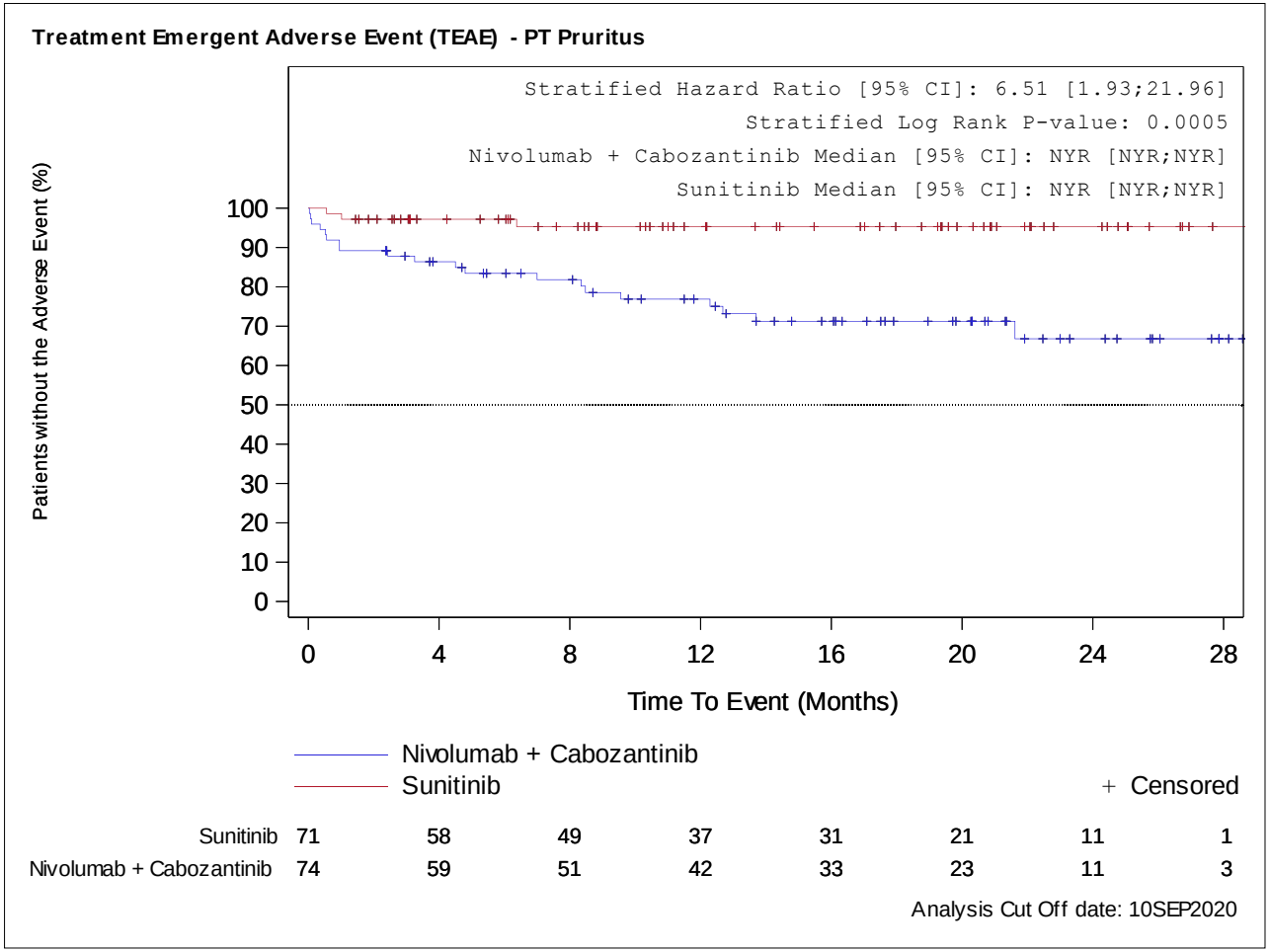
FIGURE 5.16.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:41:56

FIGURE 5.17.1: Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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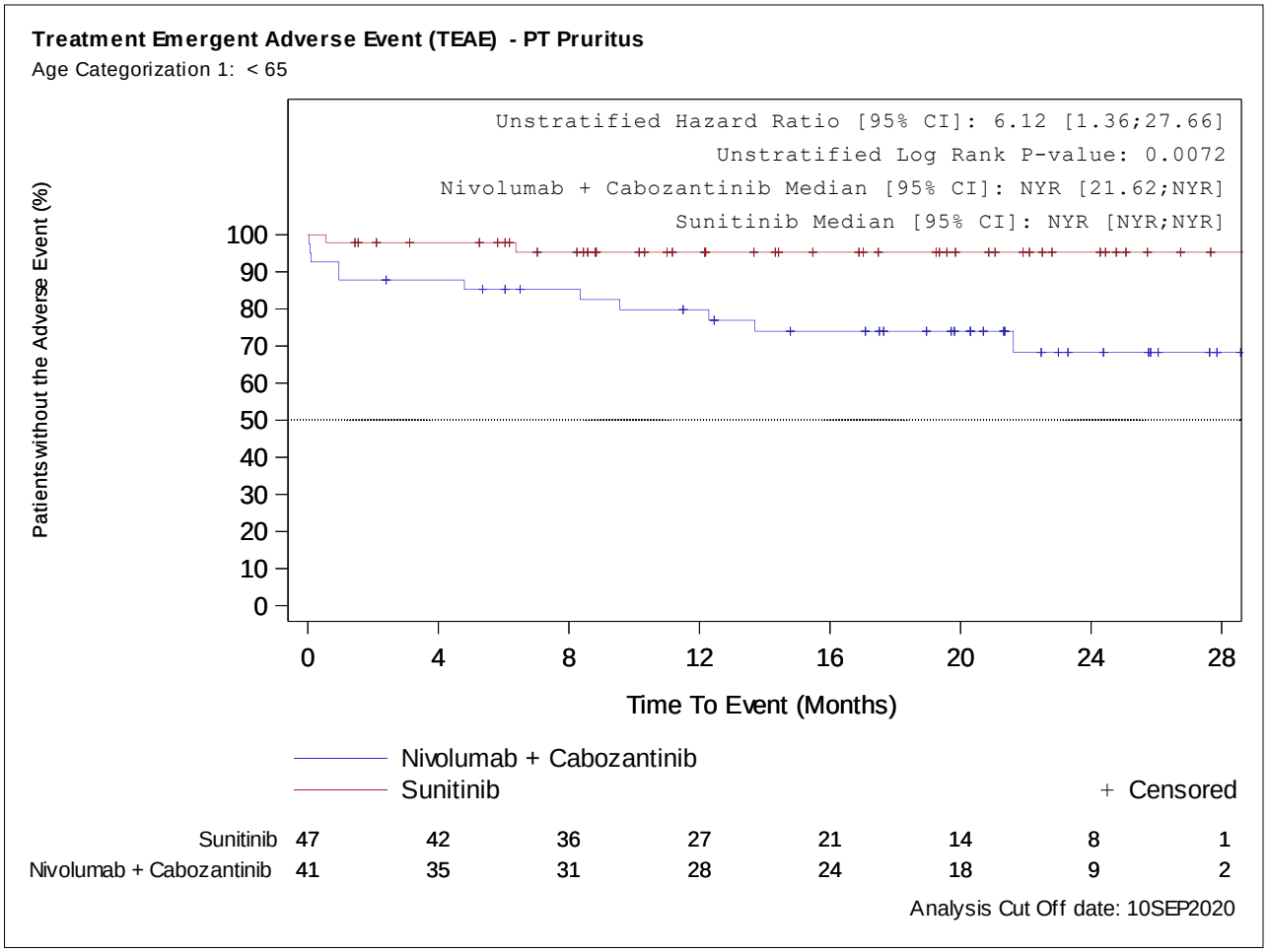
FIGURE 5.17.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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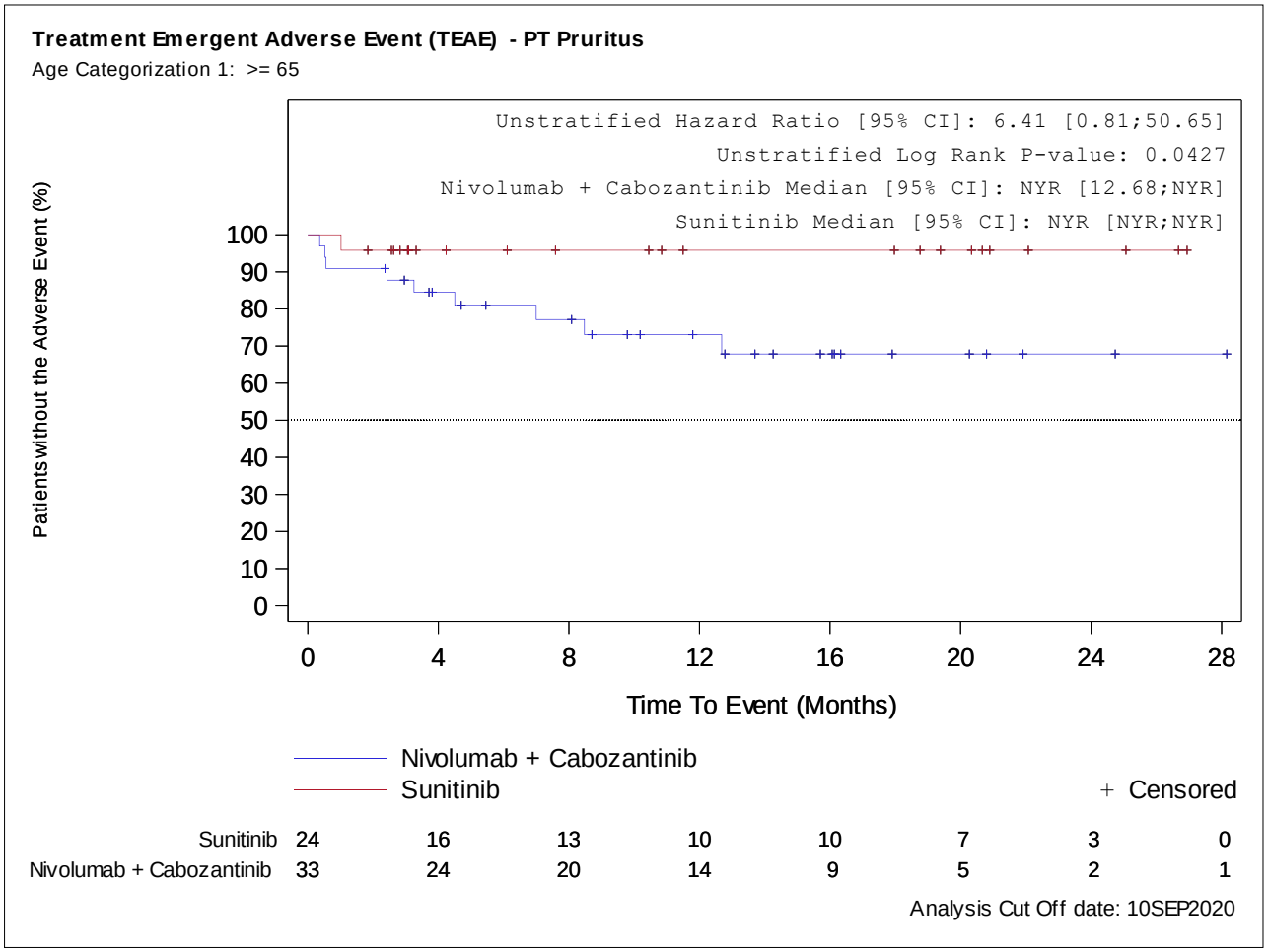
FIGURE 5.17.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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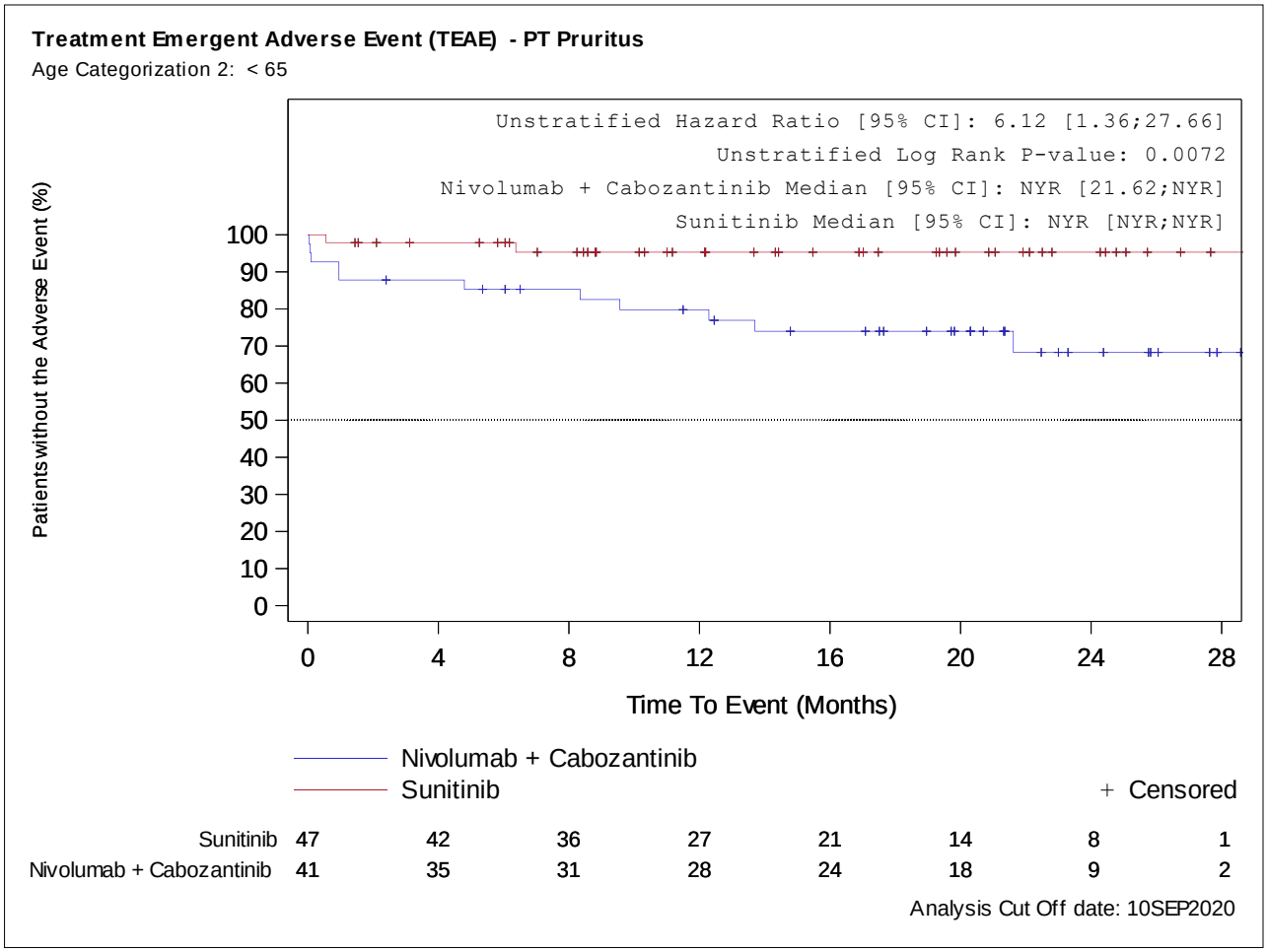
FIGURE 5.17.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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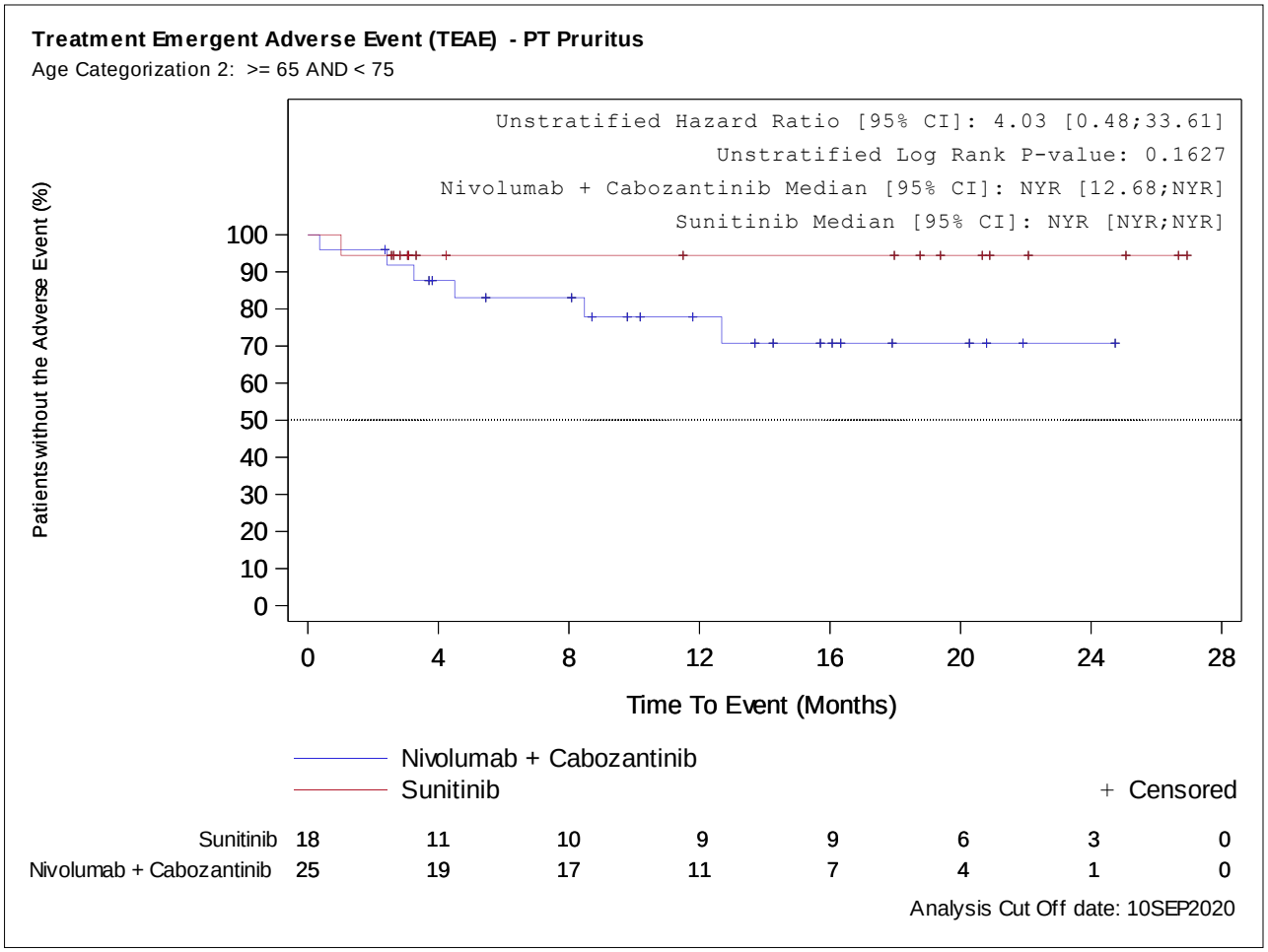
FIGURE 5.17.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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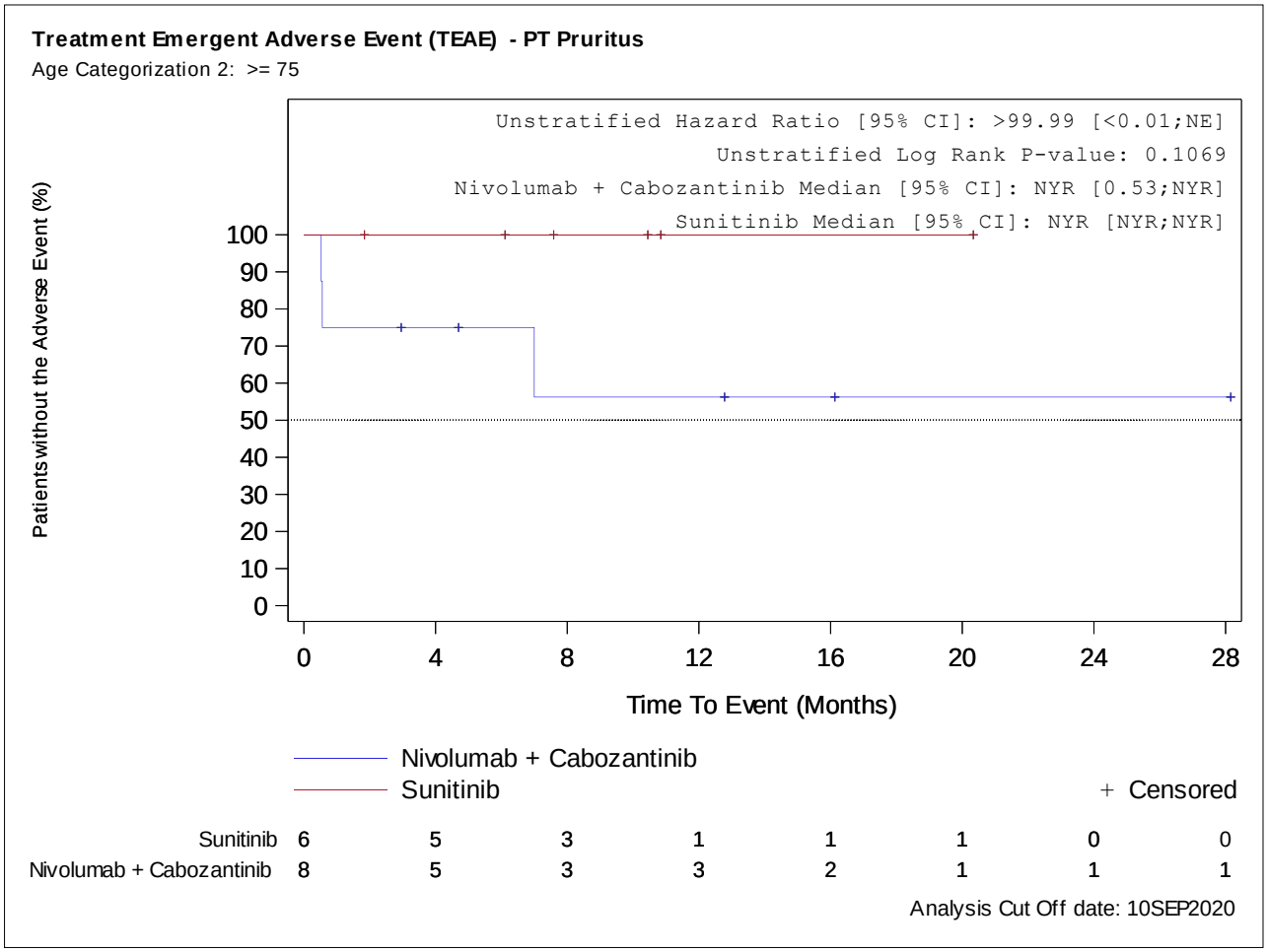
FIGURE 5.17.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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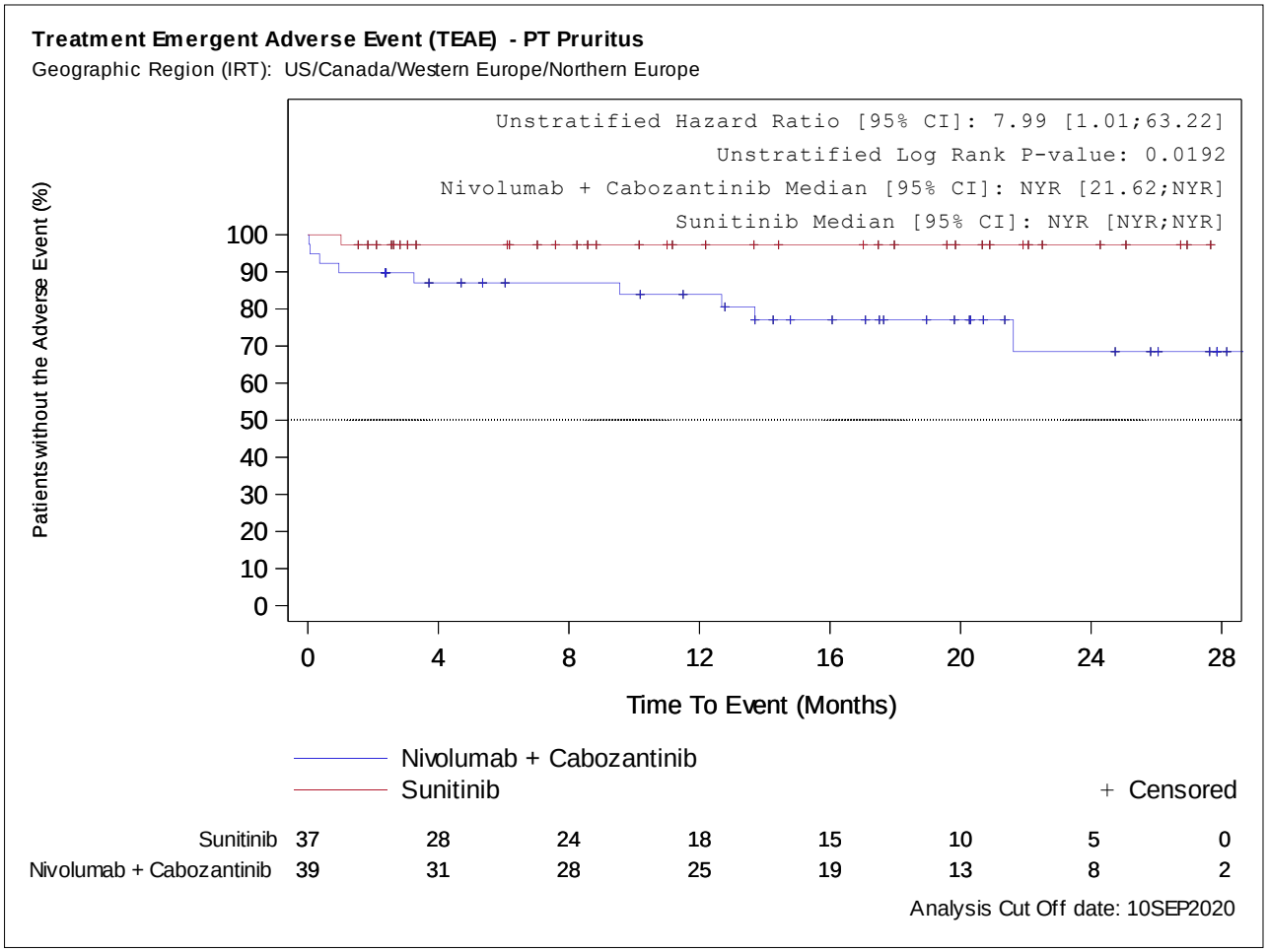
FIGURE 5.17.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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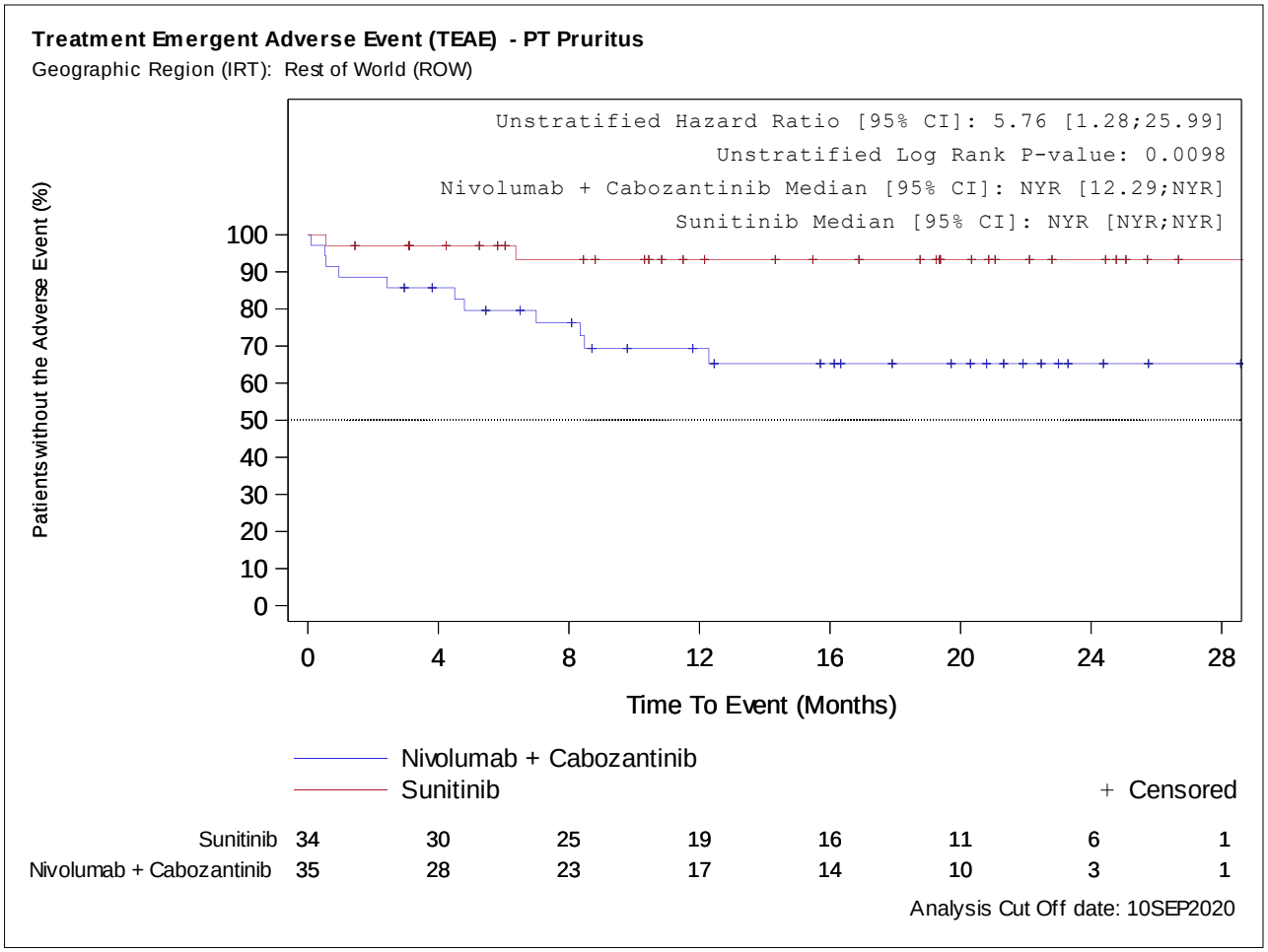
FIGURE 5.17.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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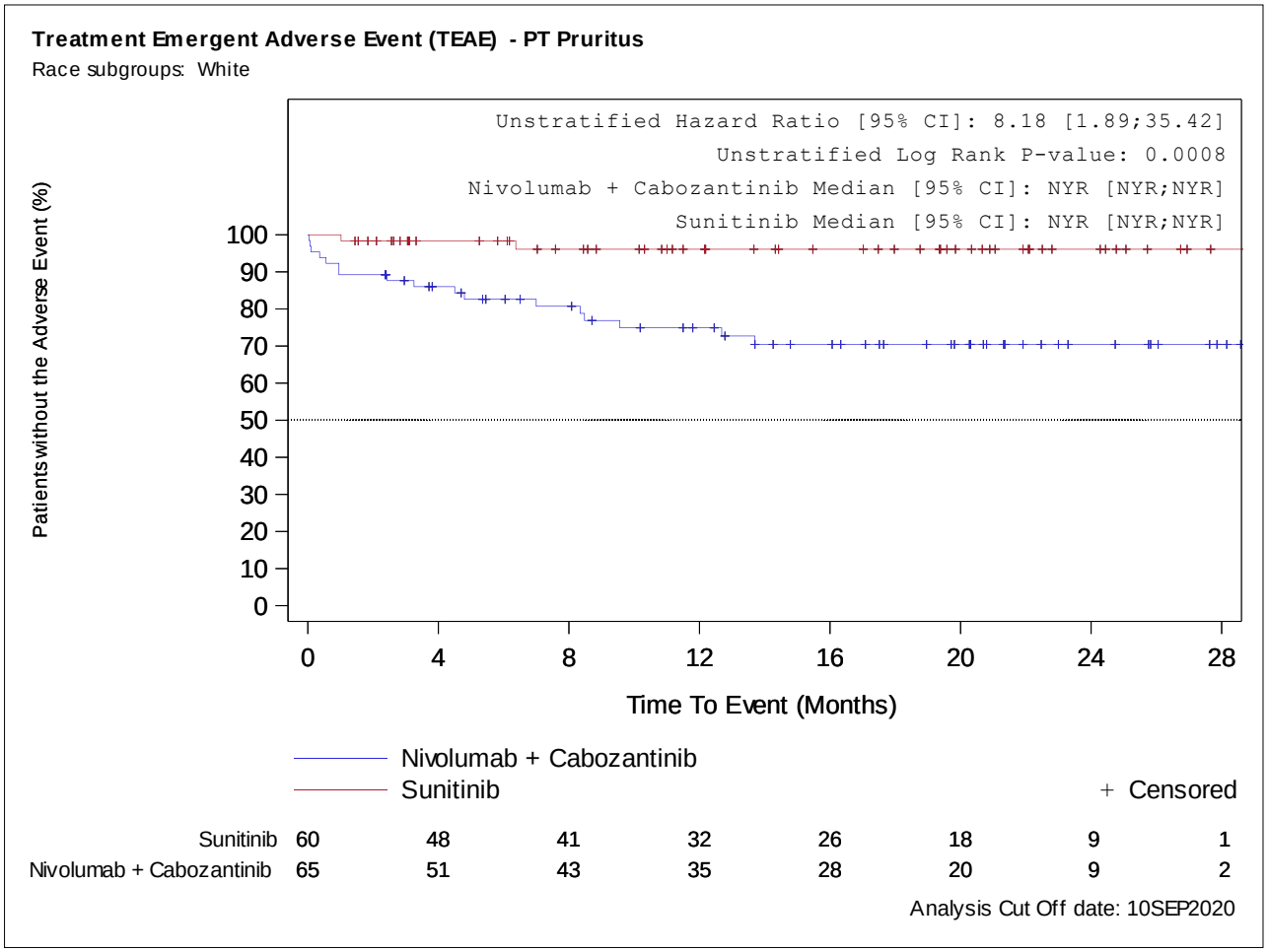
FIGURE 5.17.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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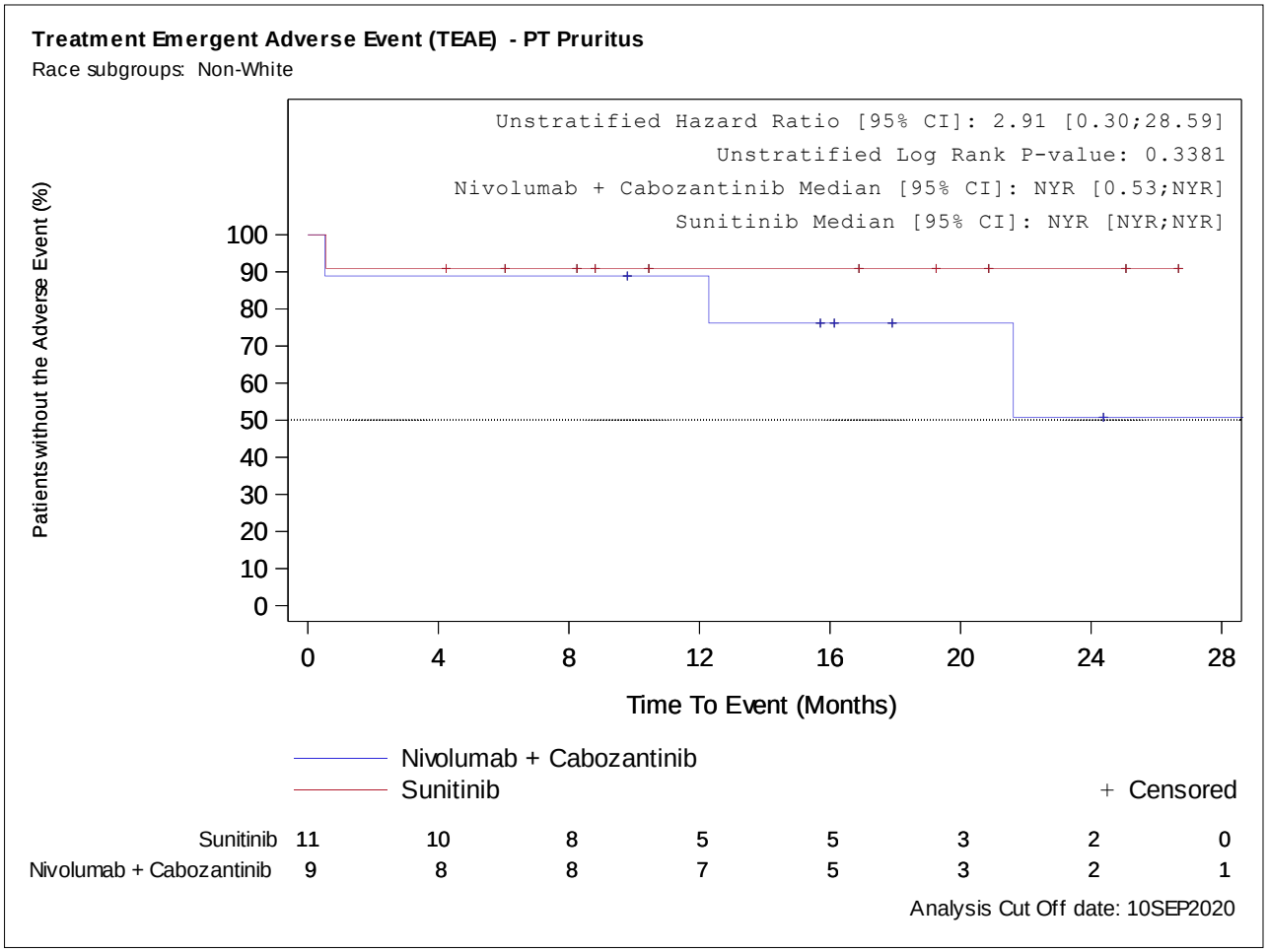
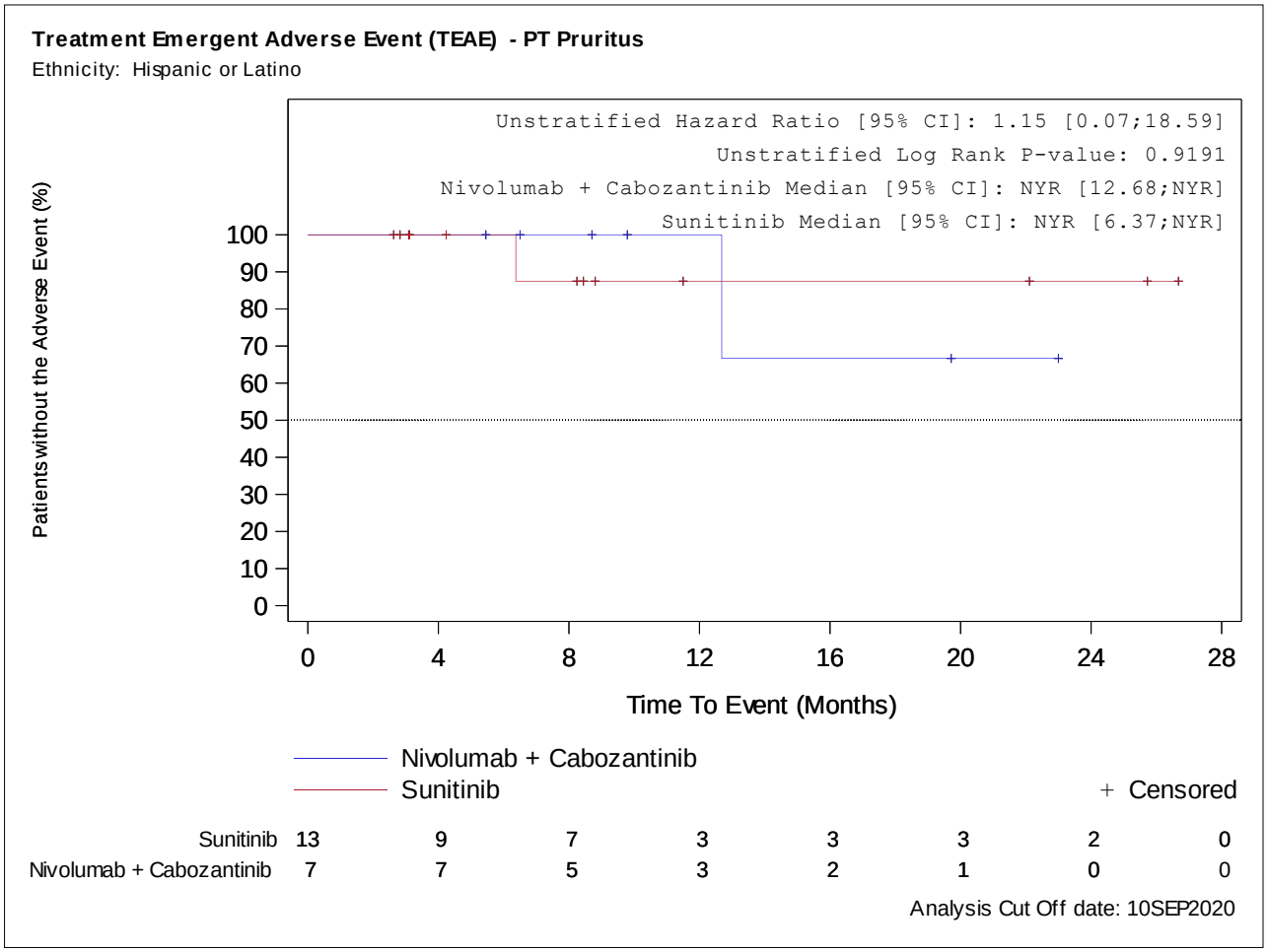
FIGURE 5.17.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:46:02

FIGURE 5.17.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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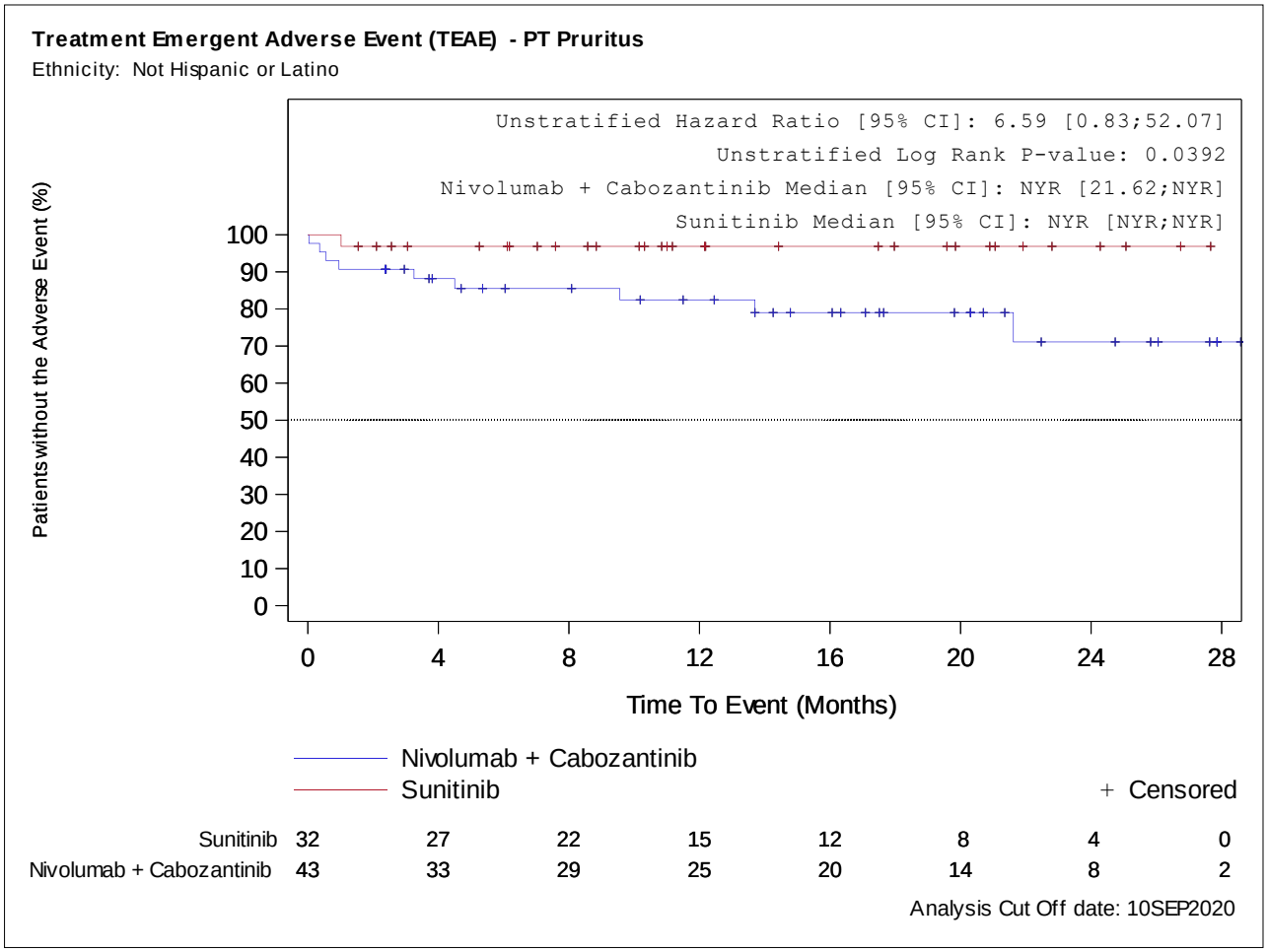
FIGURE 5.17.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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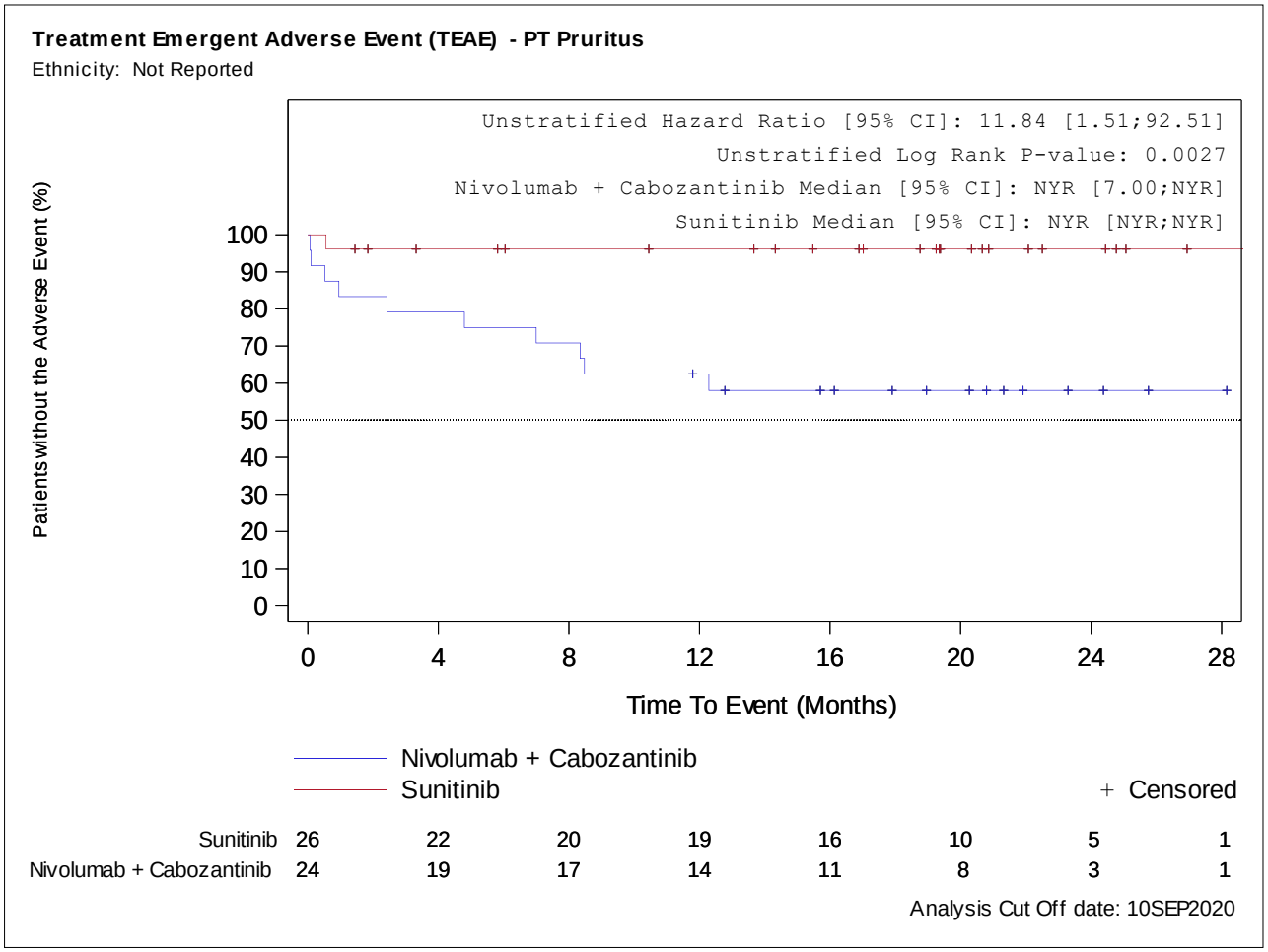
FIGURE 5.17.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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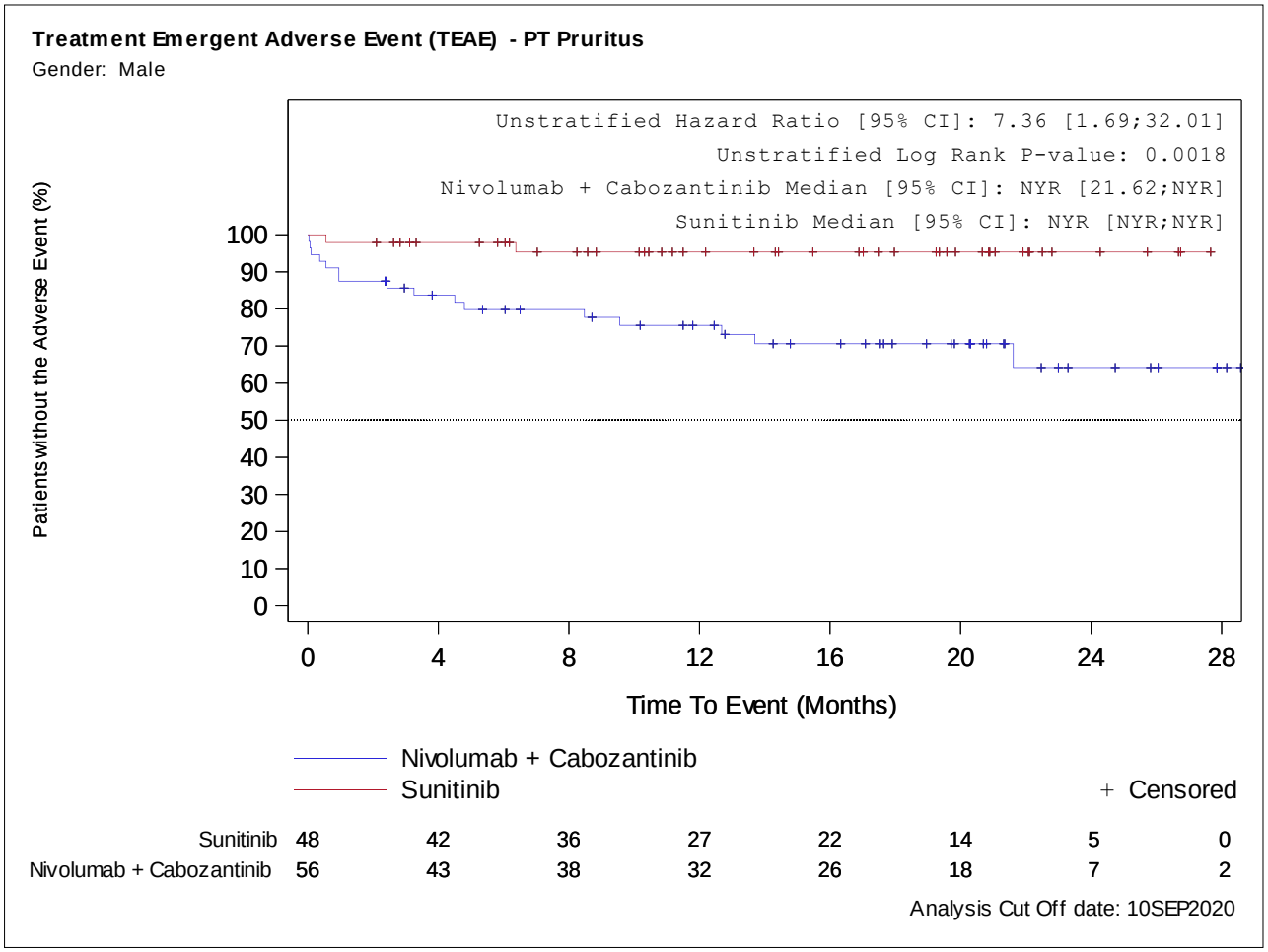
FIGURE 5.17.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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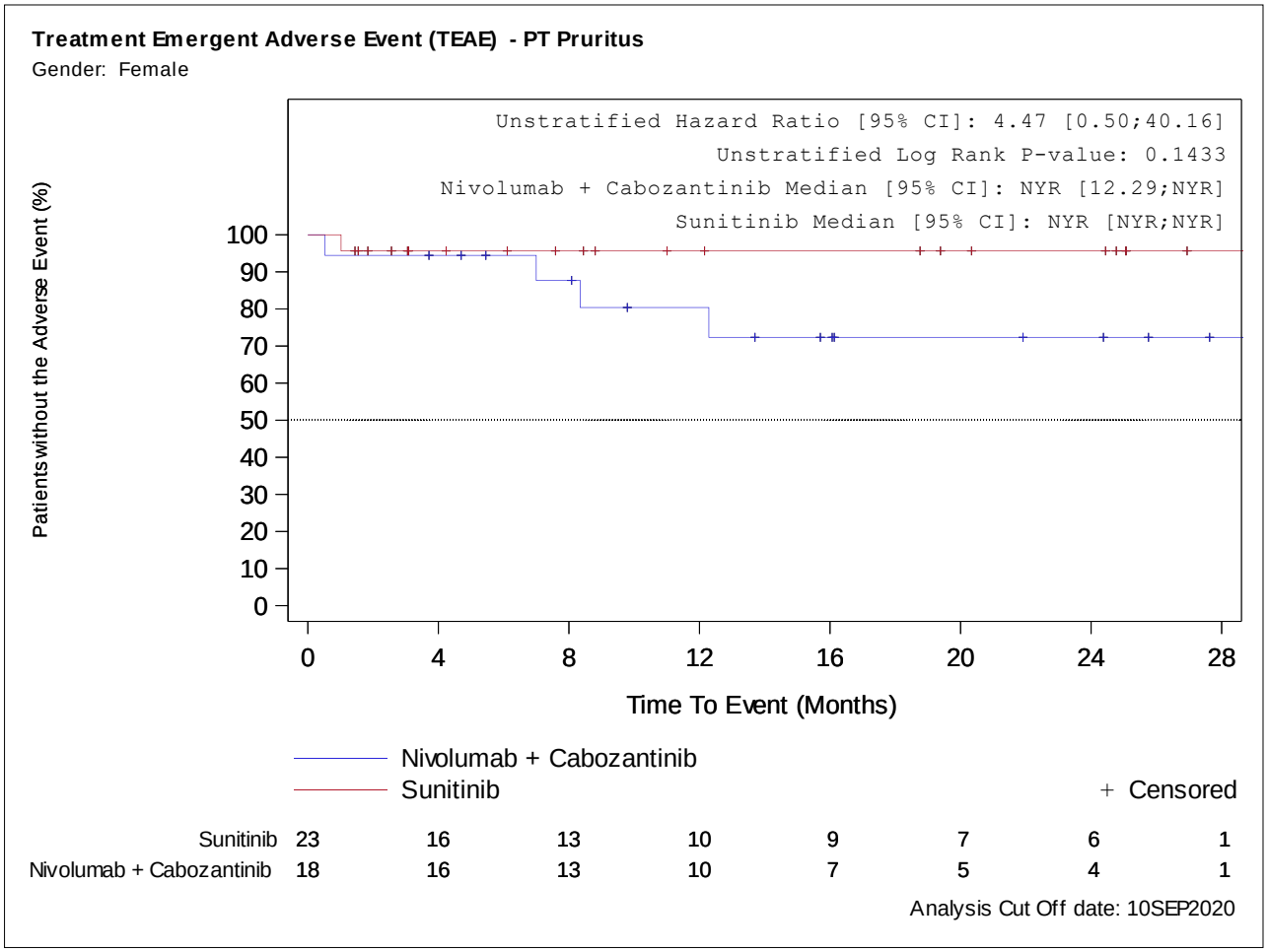
FIGURE 5.17.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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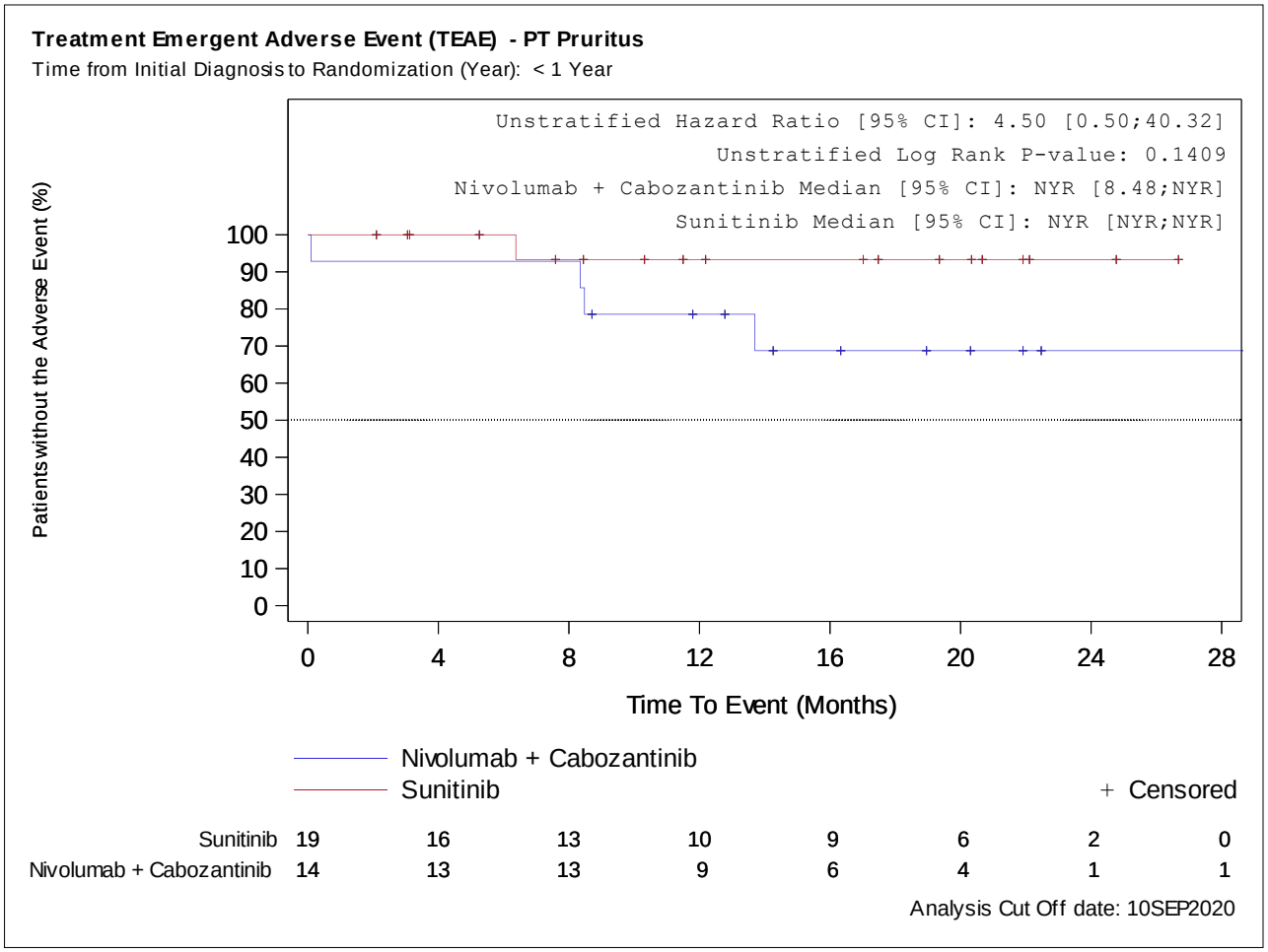
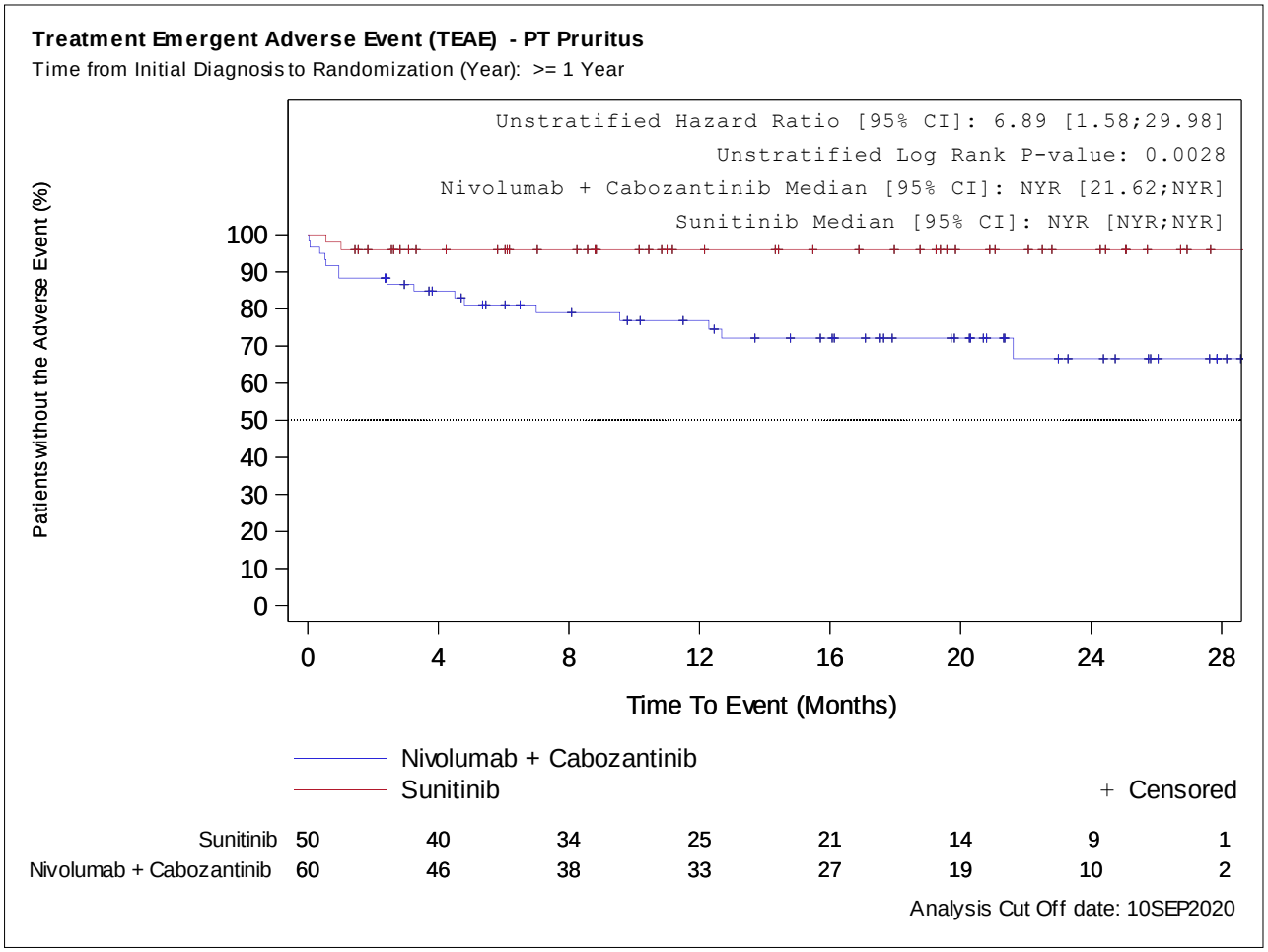
FIGURE 5.17.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:46:47

FIGURE 5.17.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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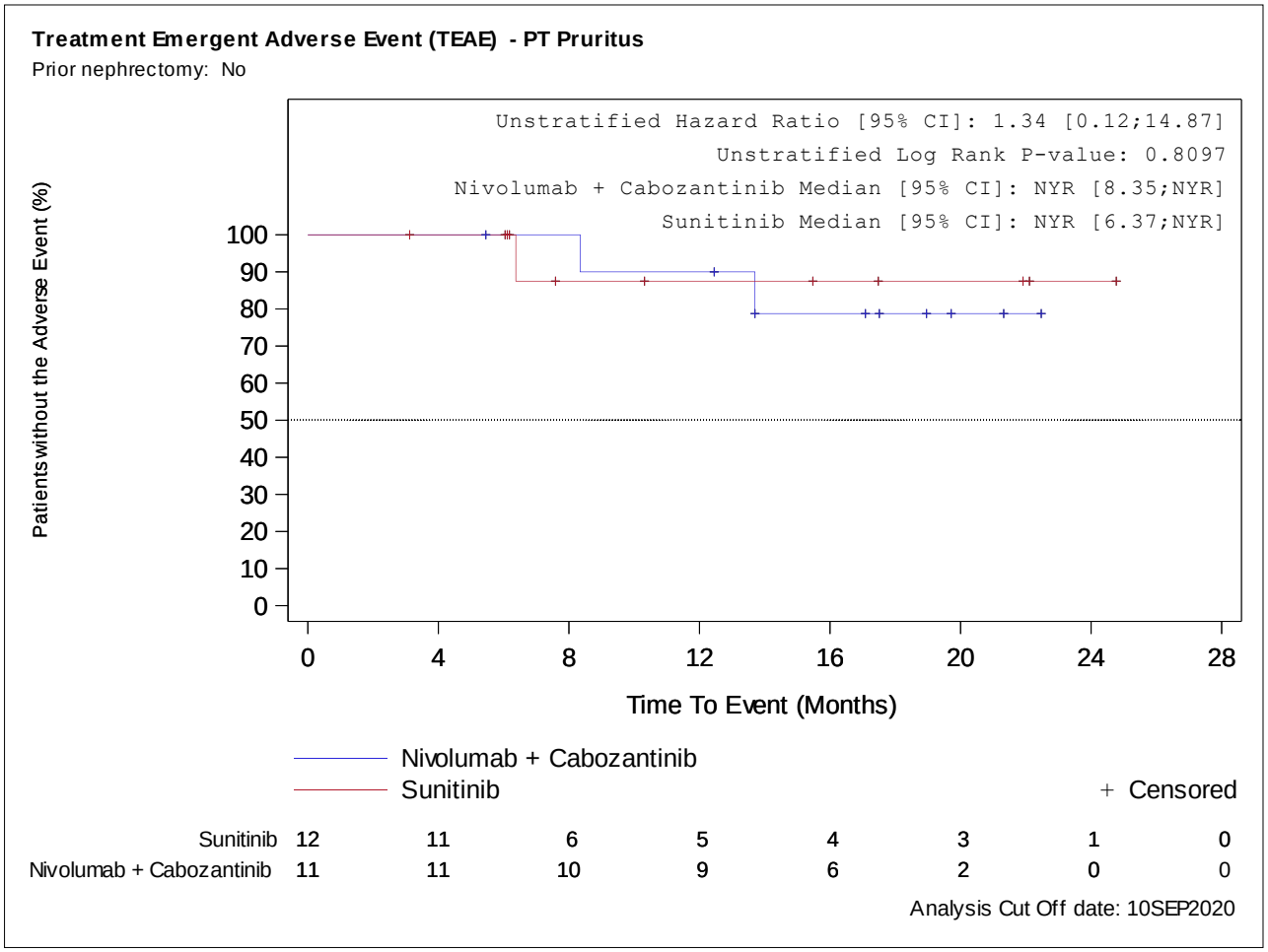
FIGURE 5.17.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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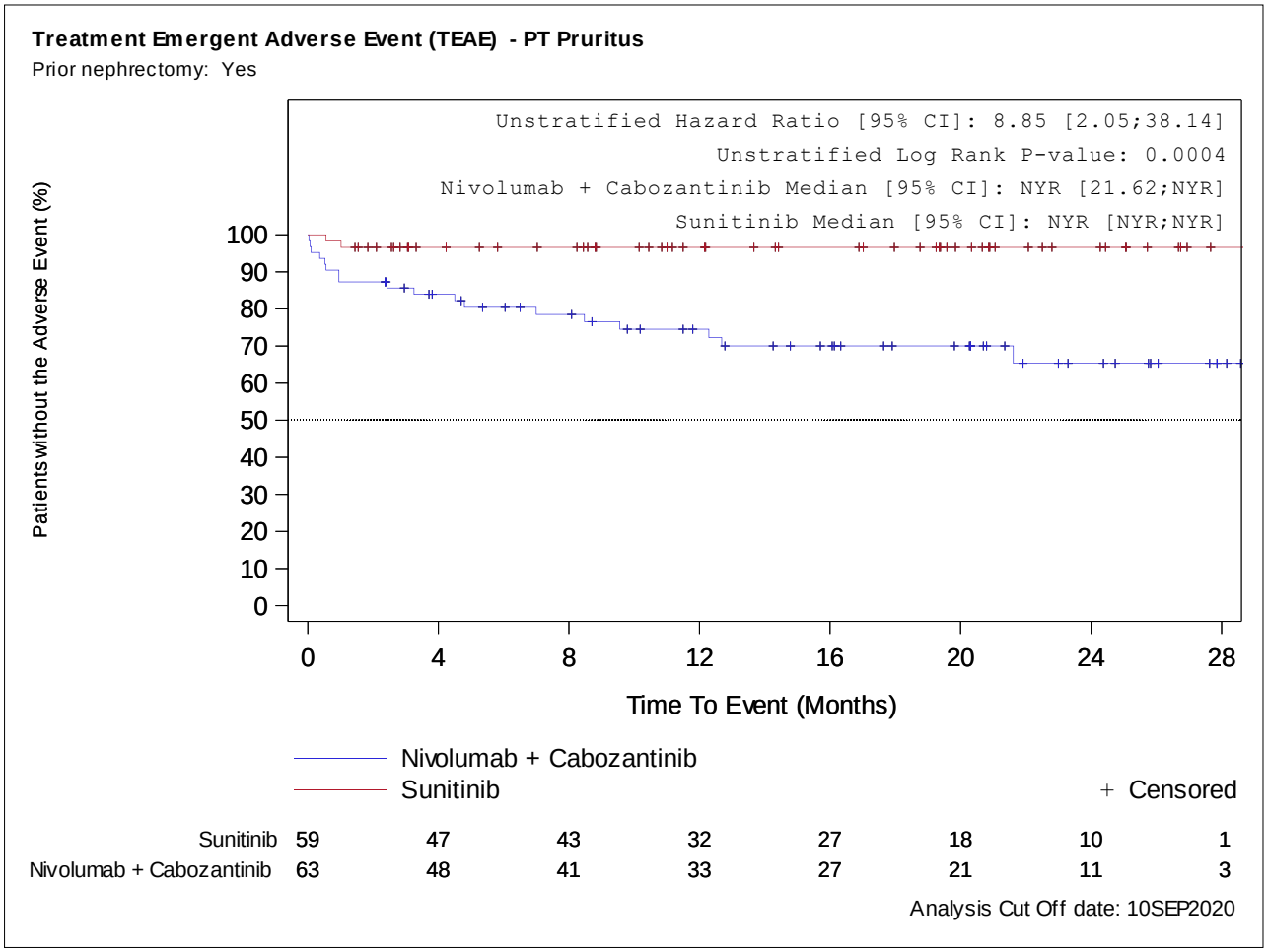
FIGURE 5.17.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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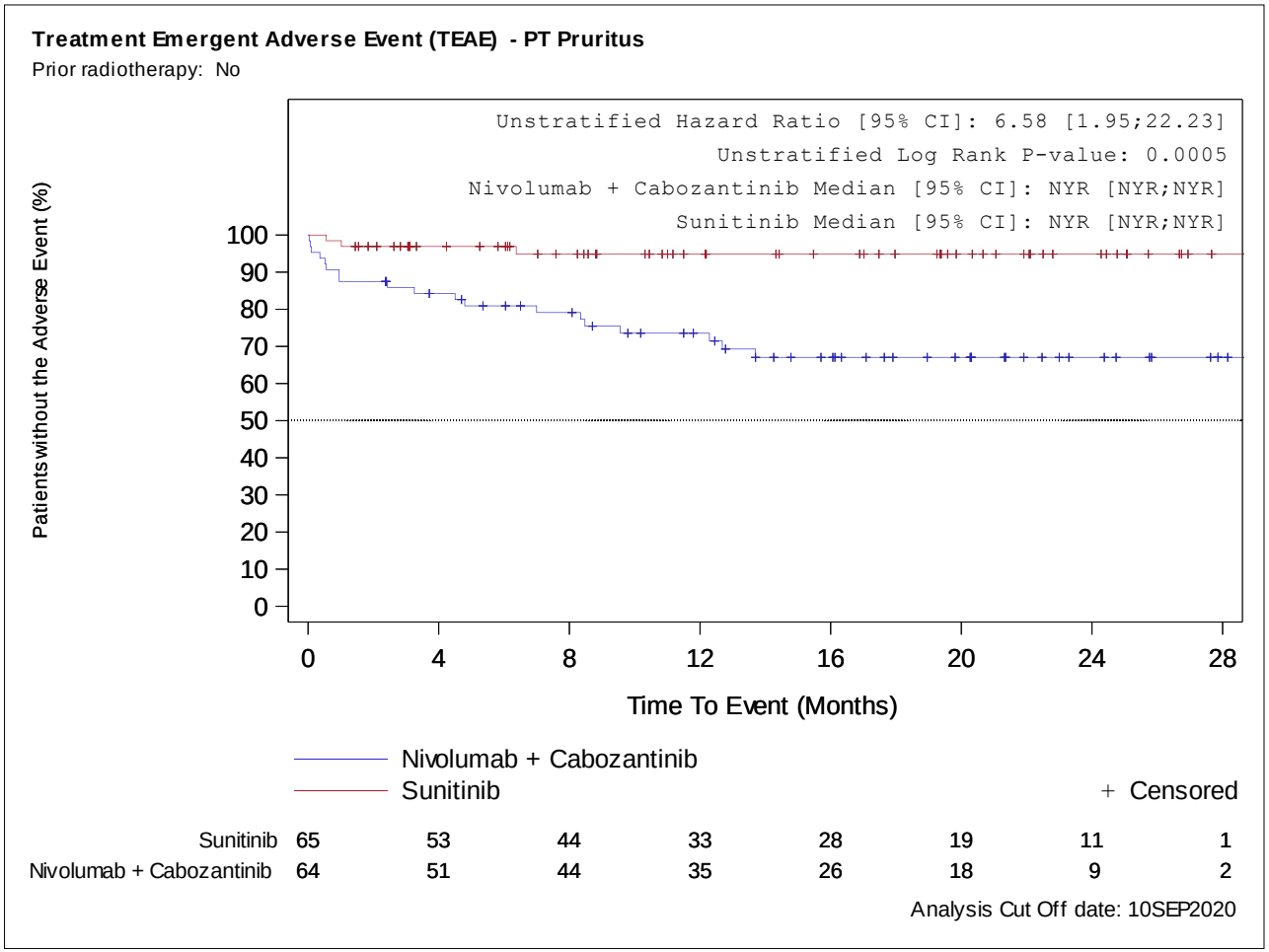
FIGURE 5.17.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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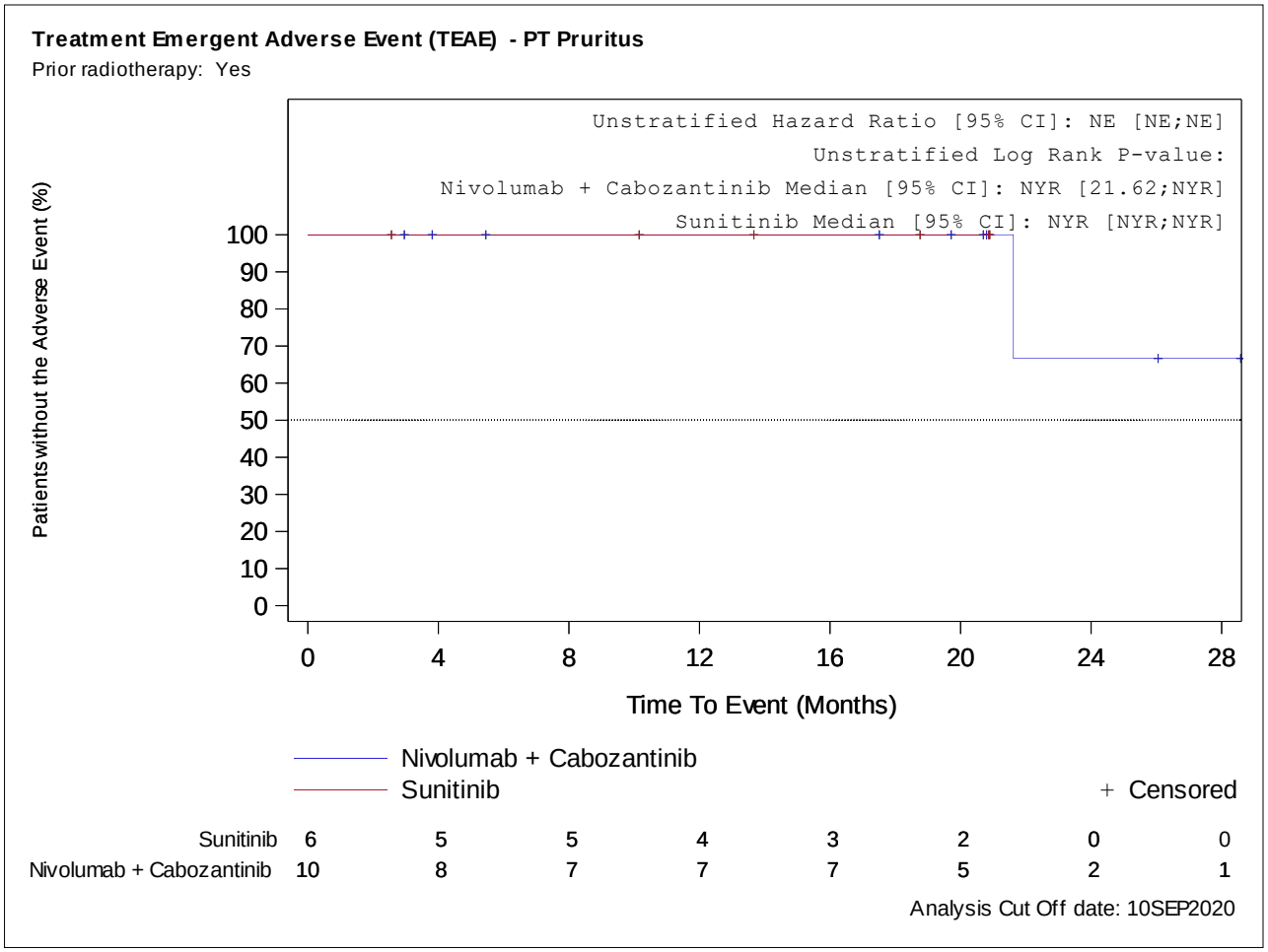
FIGURE 5.17.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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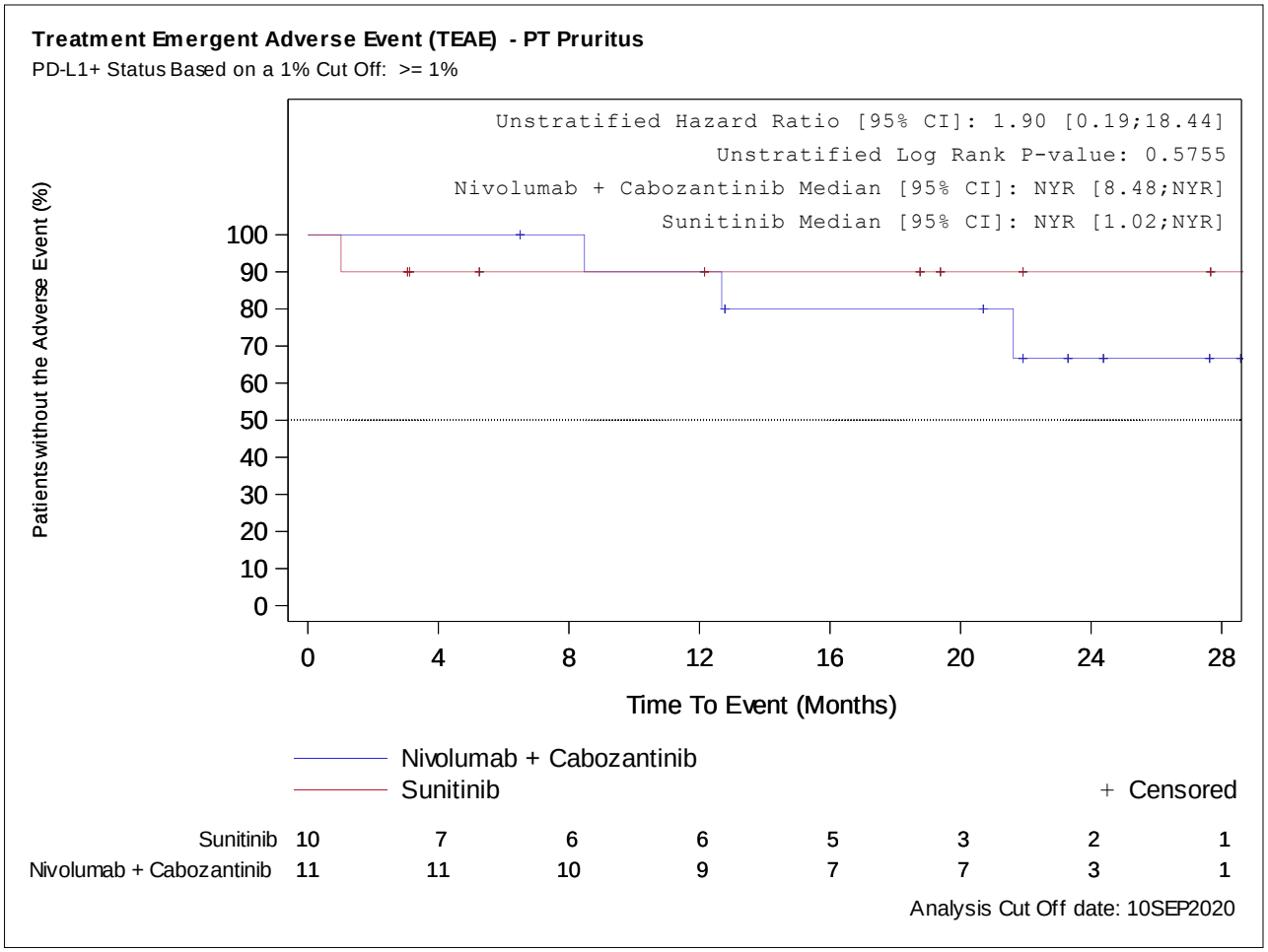
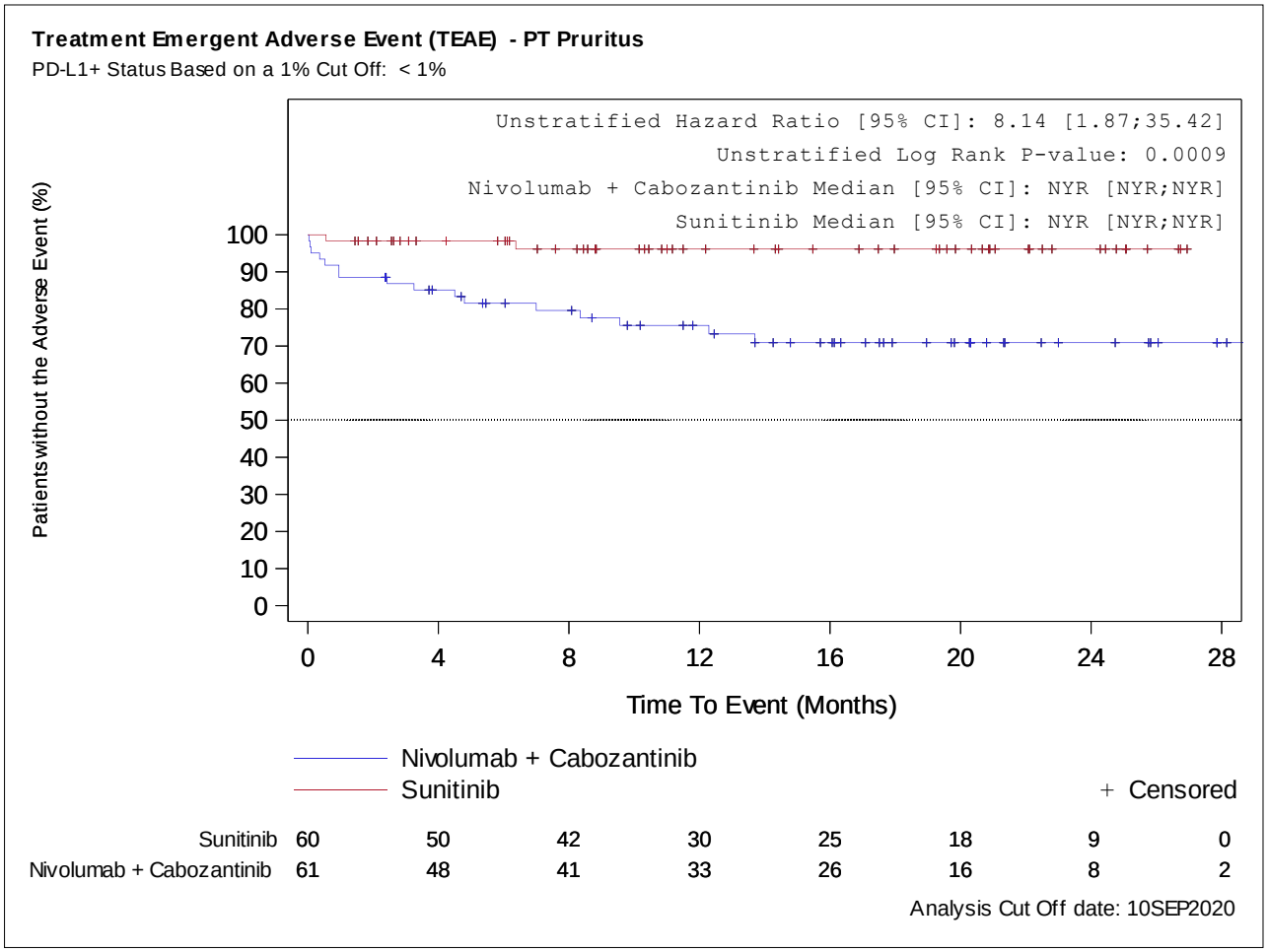
FIGURE 5.17.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:48:10

FIGURE 5.17.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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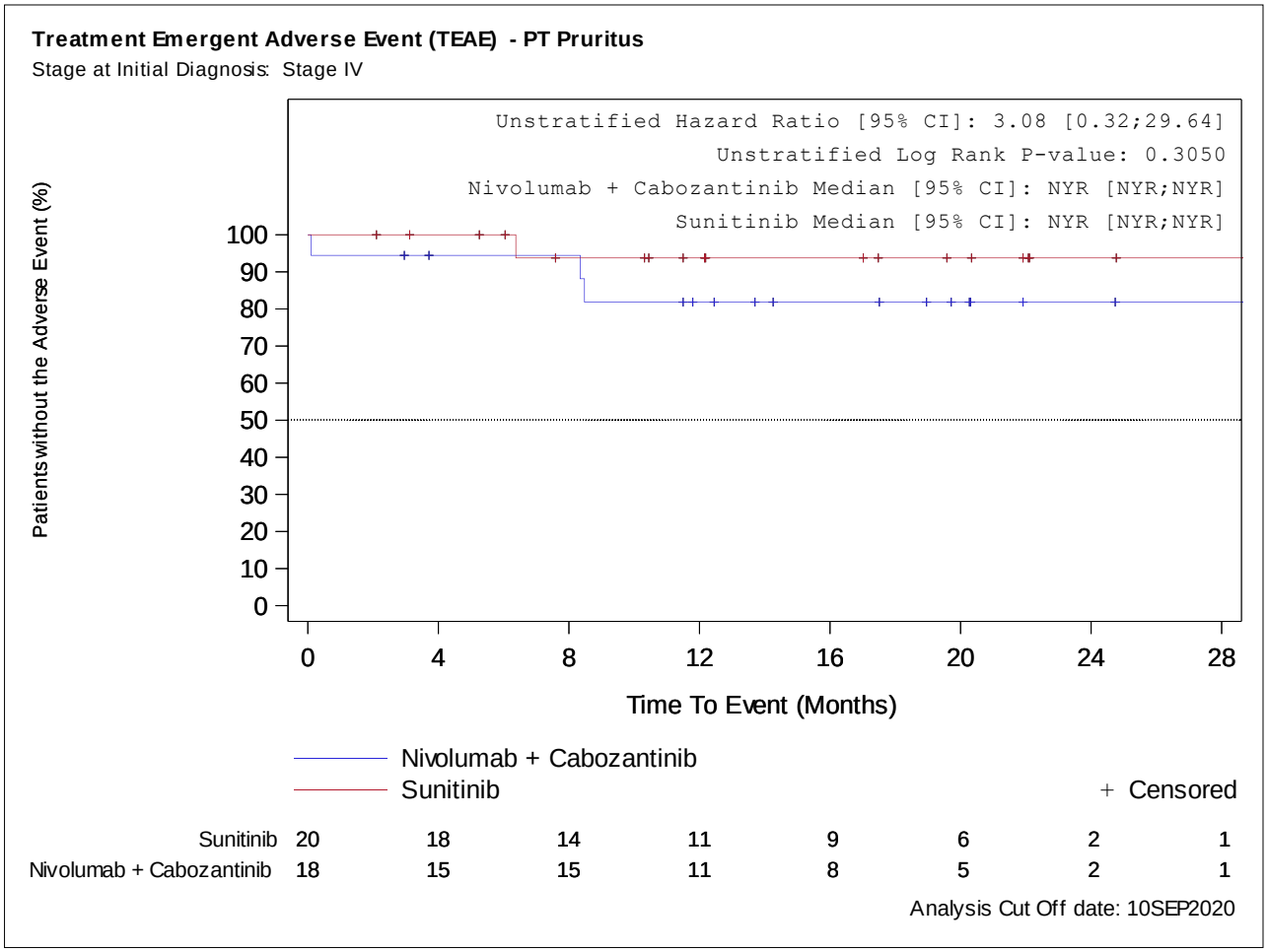
FIGURE 5.17.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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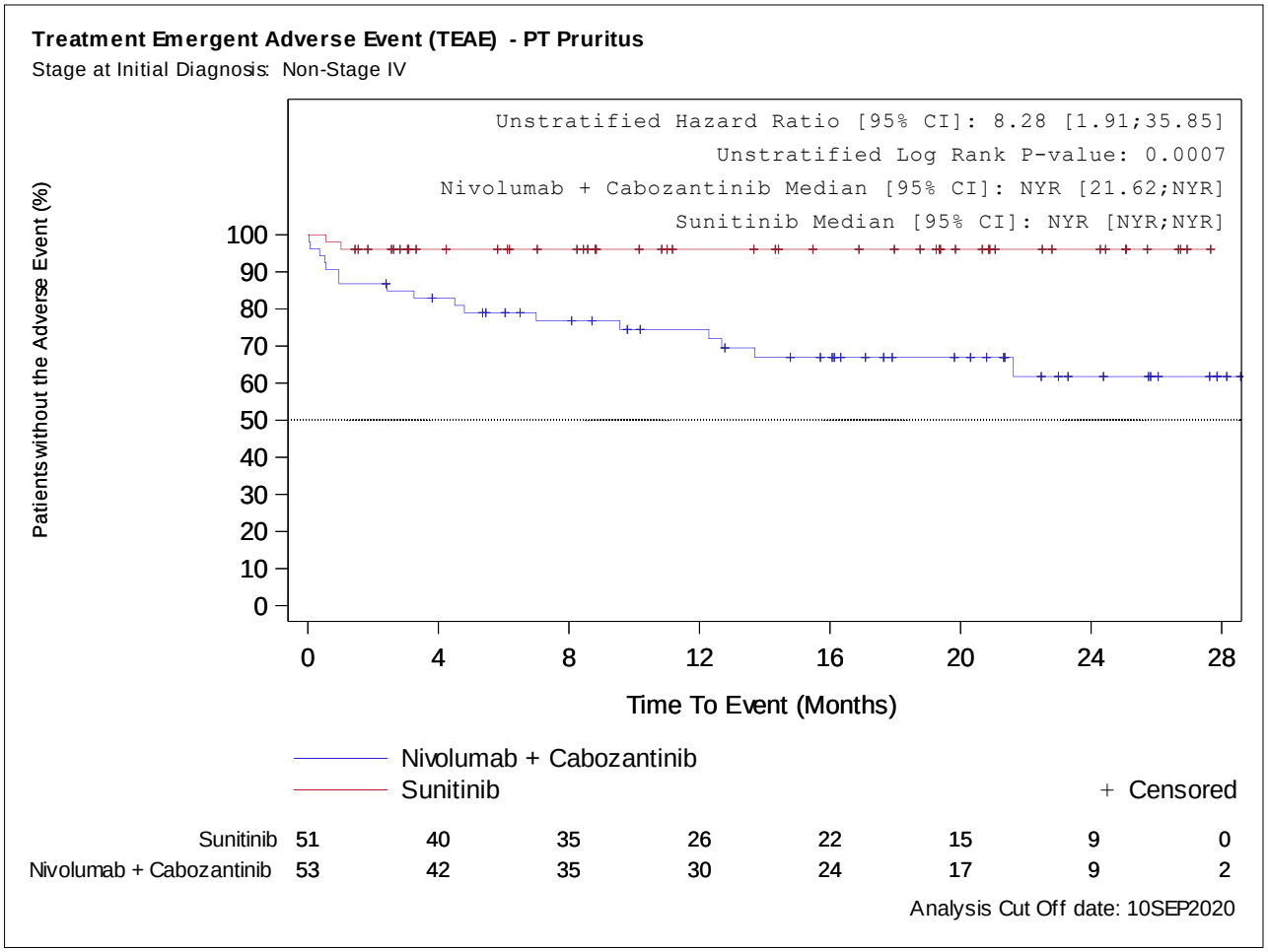
FIGURE 5.17.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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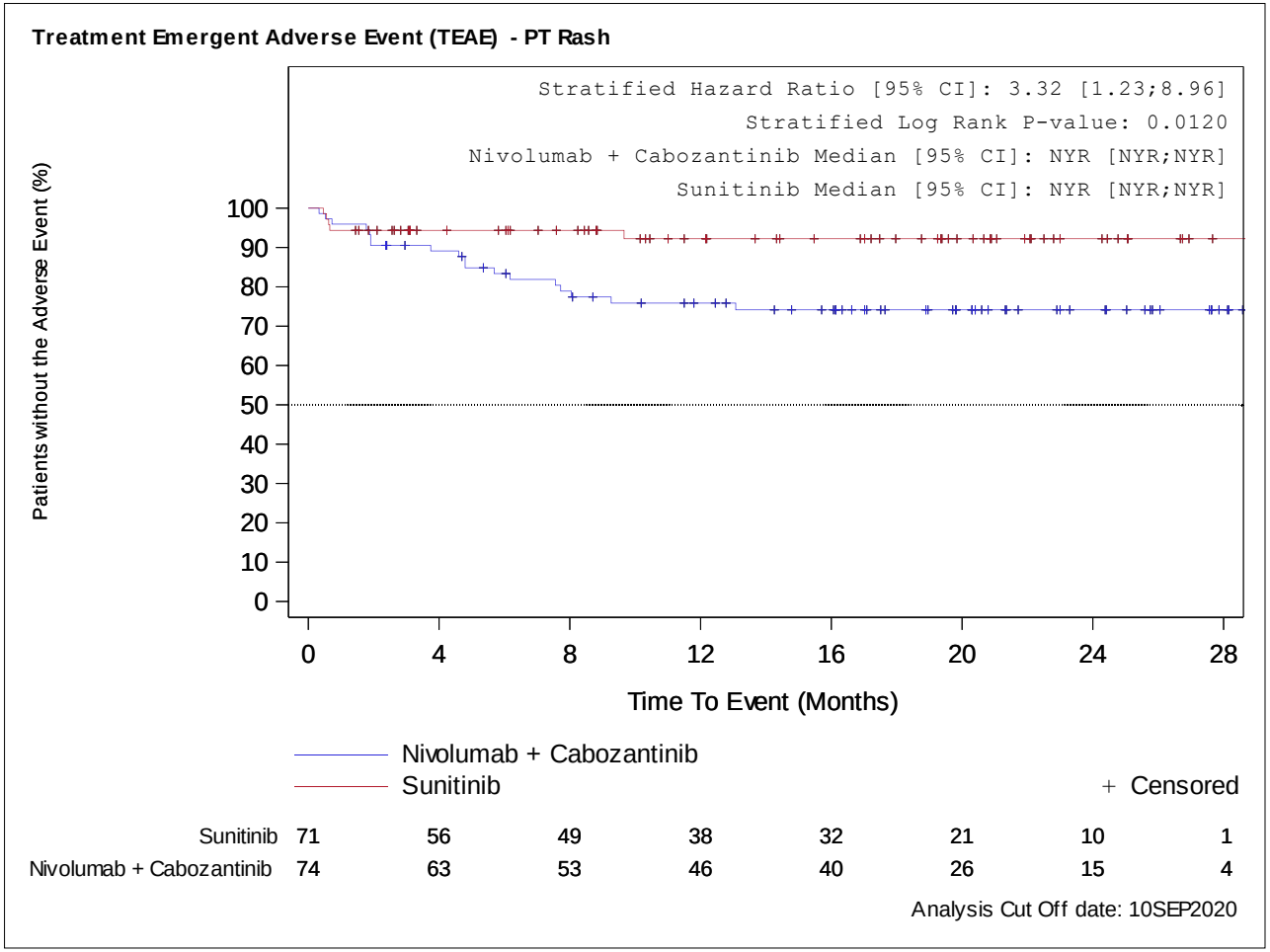
FIGURE 5.18.1: Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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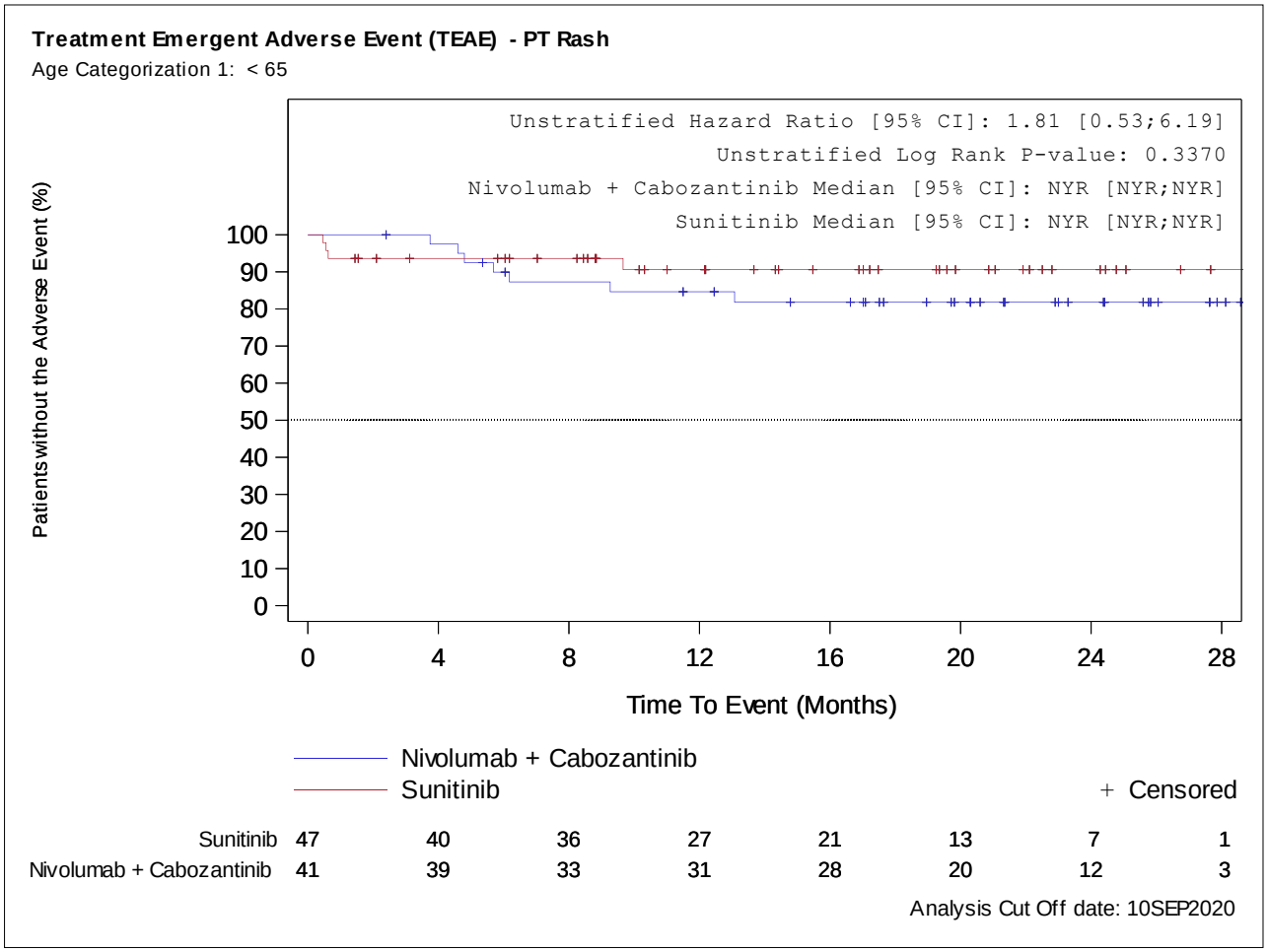
FIGURE 5.18.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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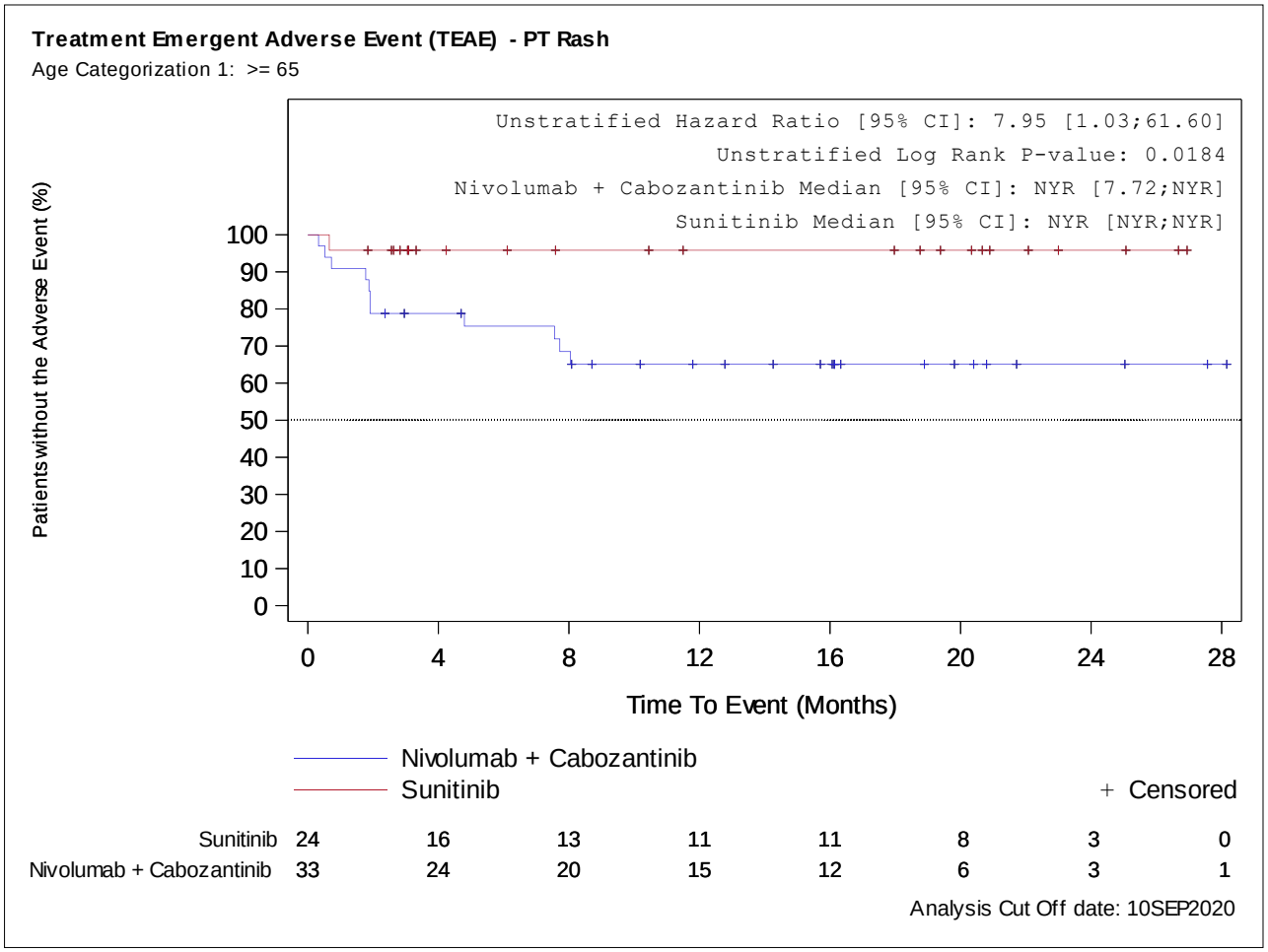
FIGURE 5.18.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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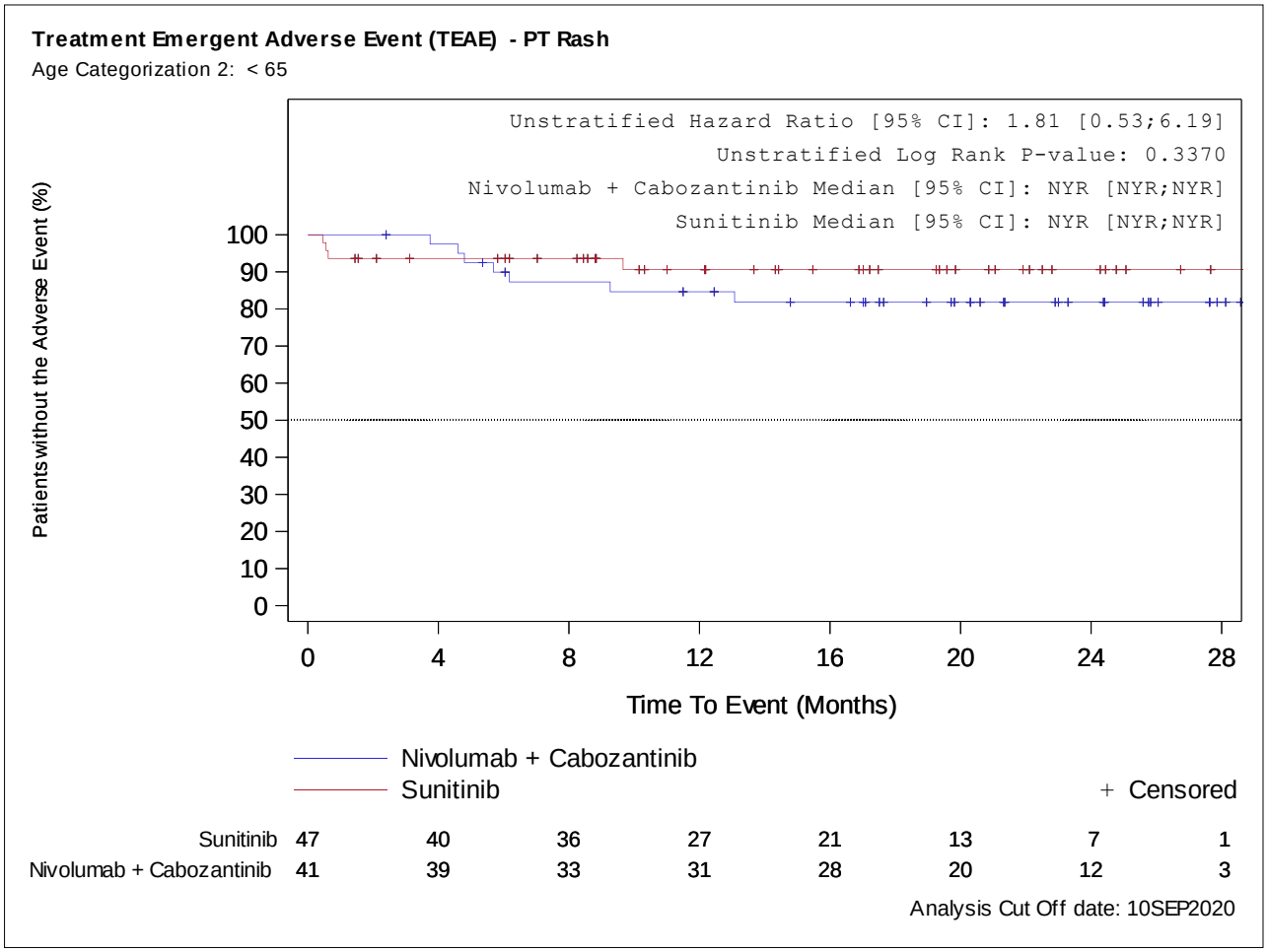
FIGURE 5.18.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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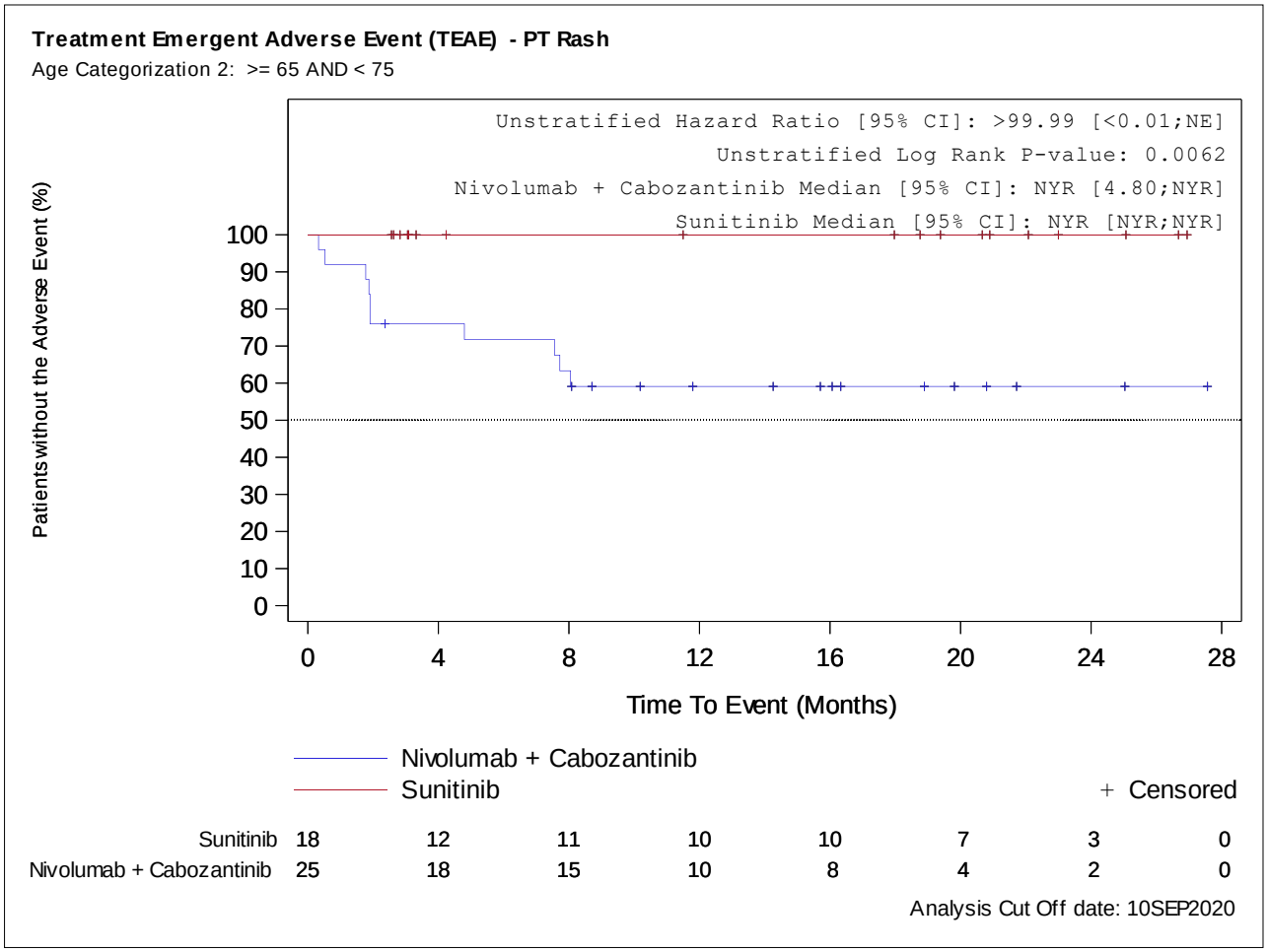
FIGURE 5.18.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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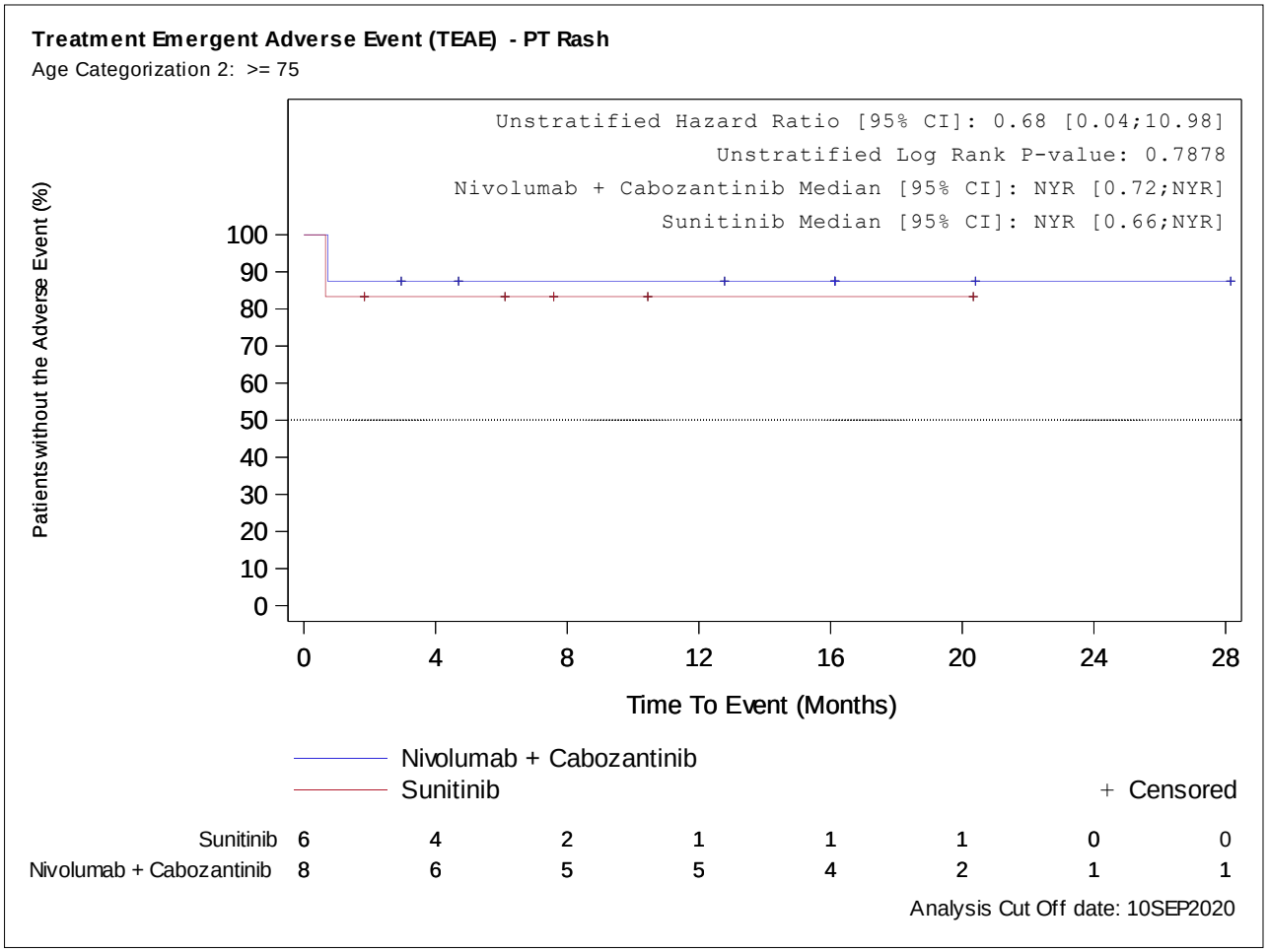
FIGURE 5.18.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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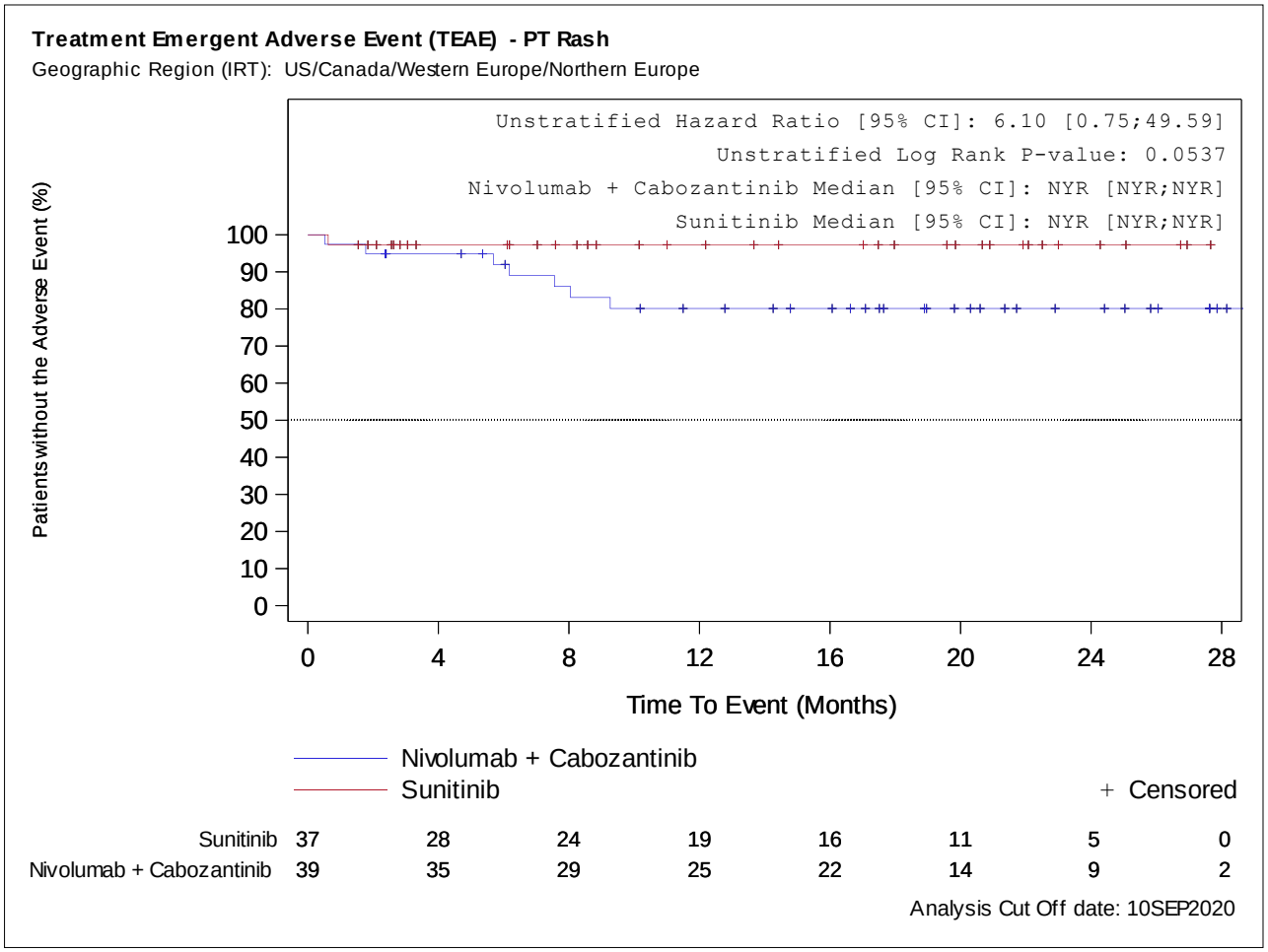
FIGURE 5.18.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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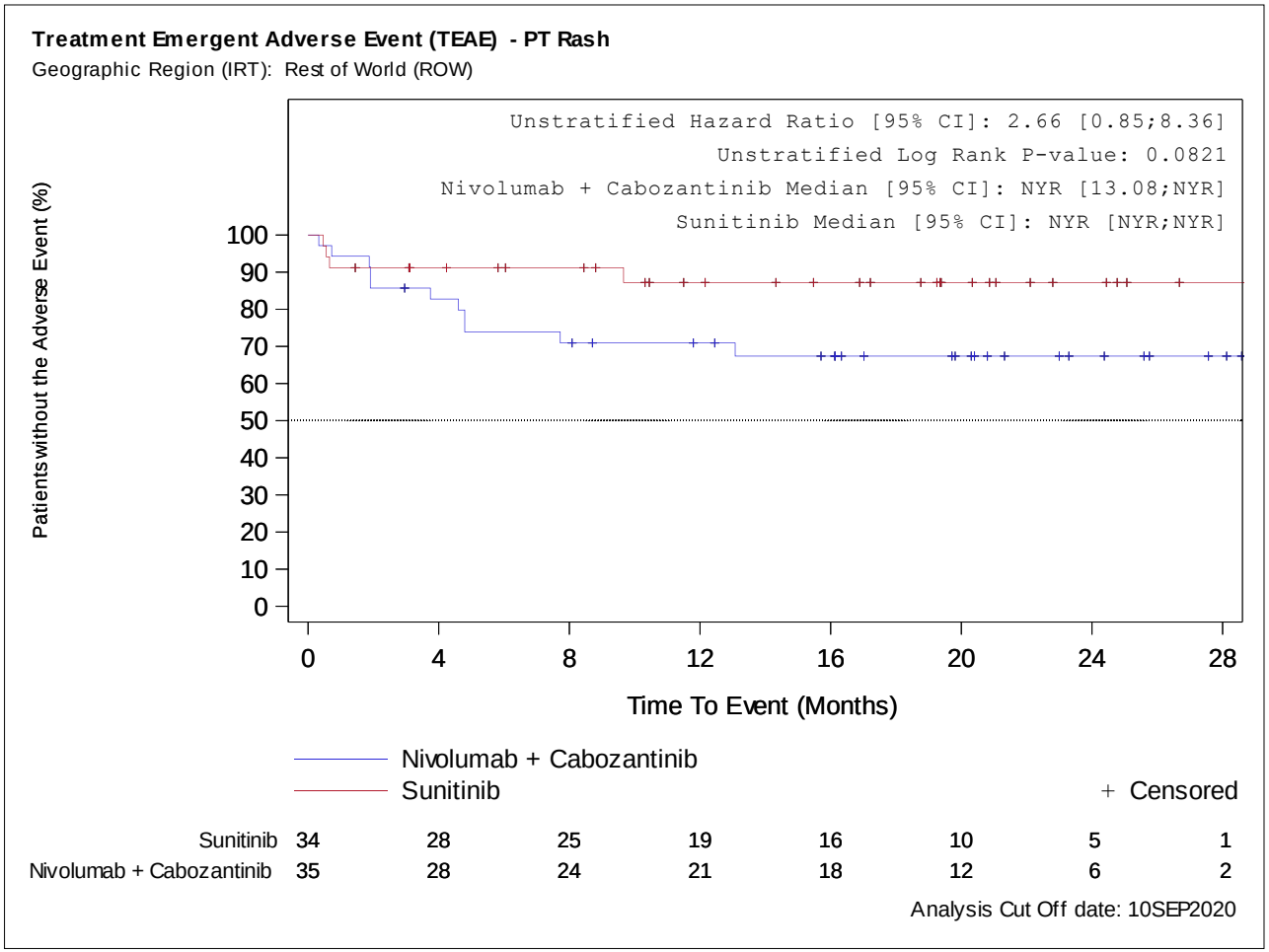
FIGURE 5.18.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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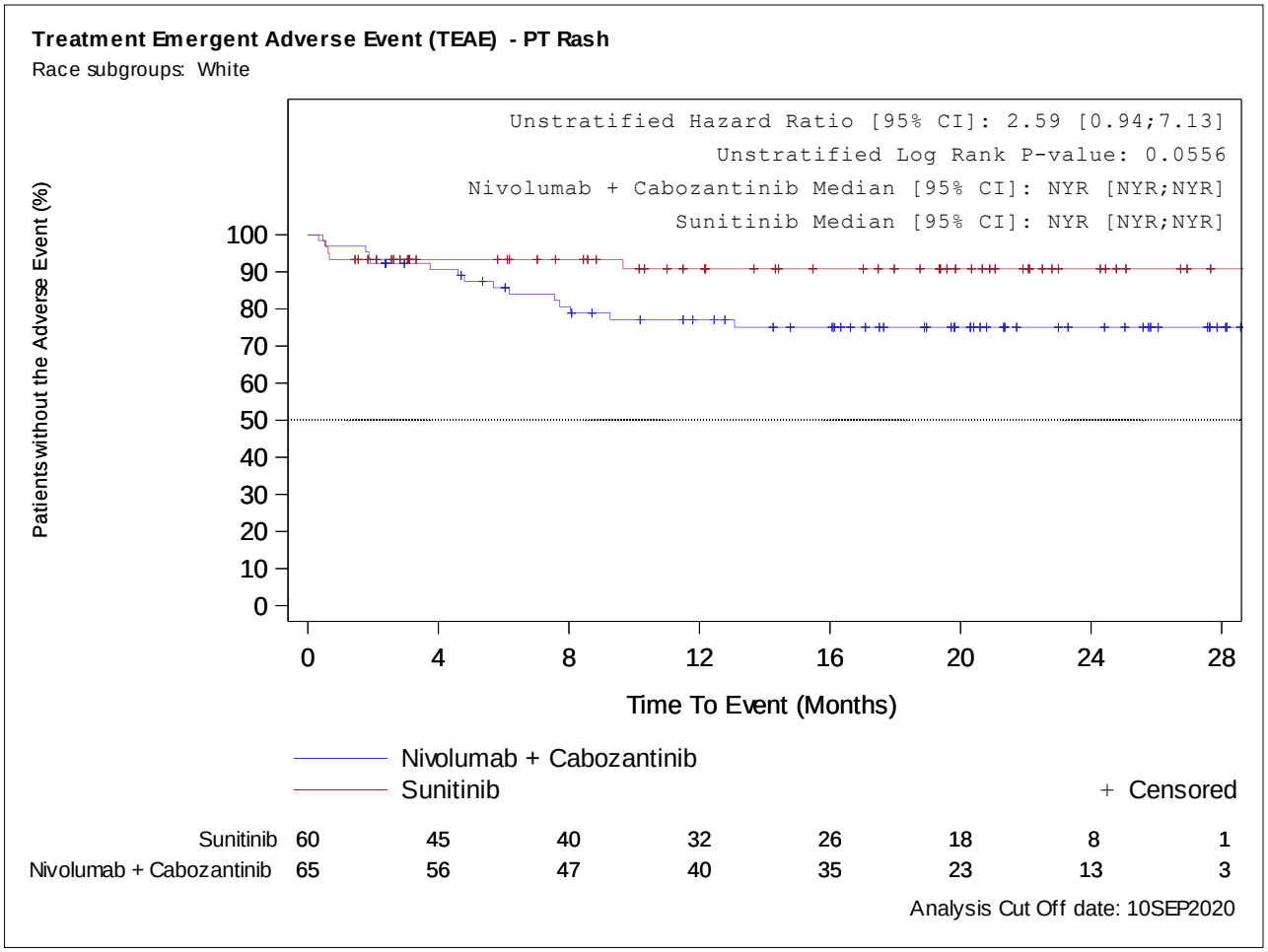
FIGURE 5.18.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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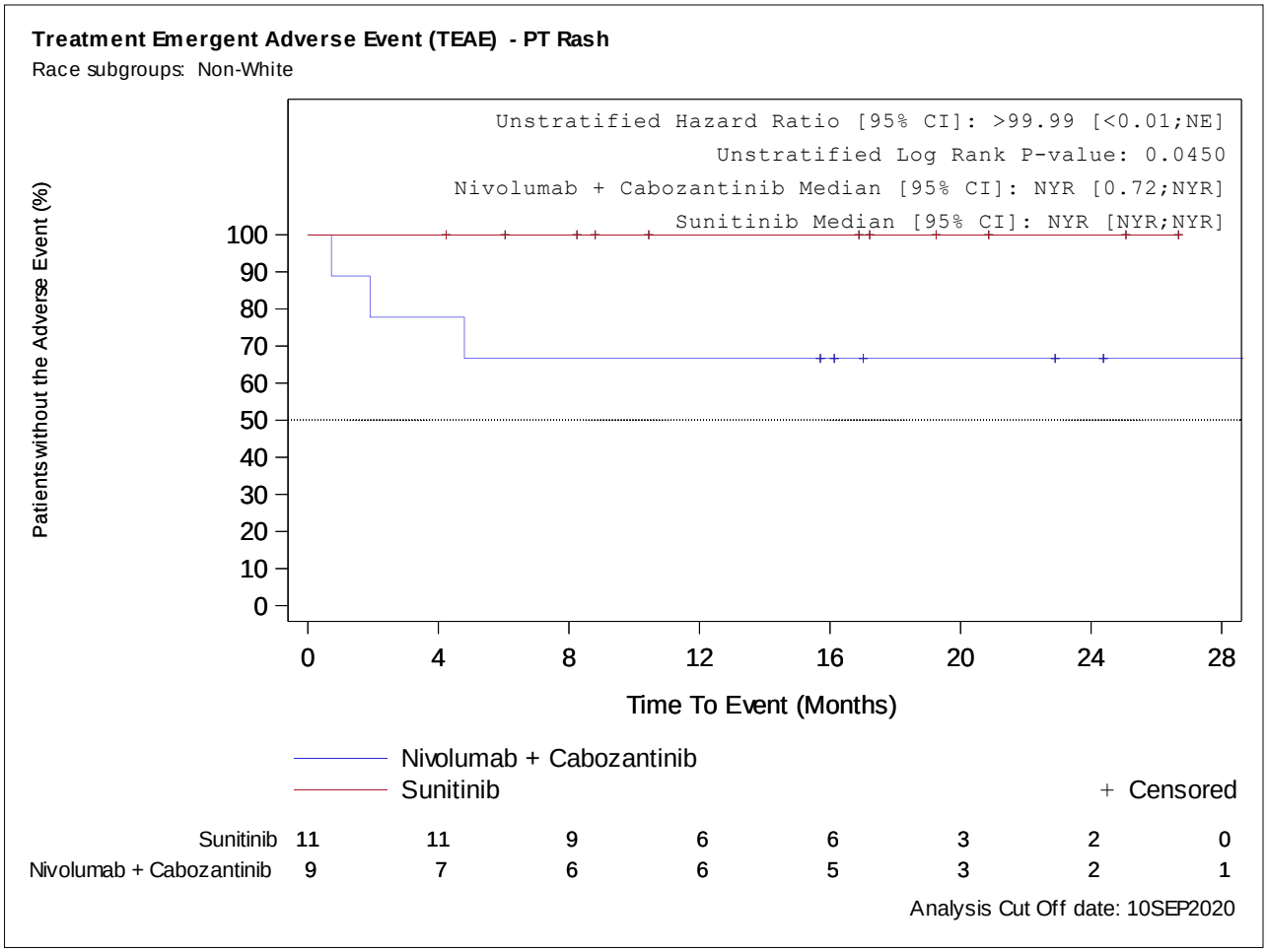
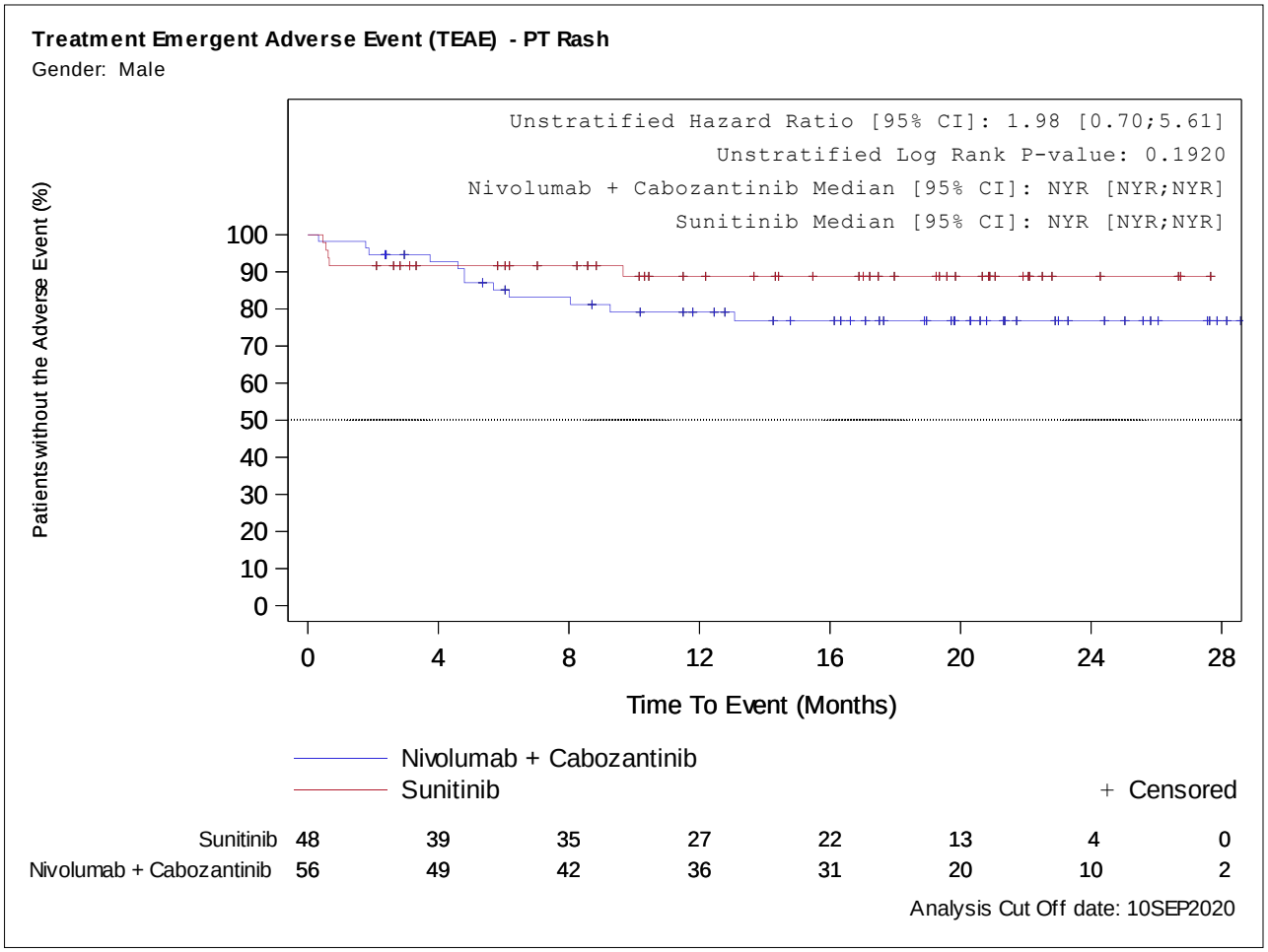
FIGURE 5.18.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



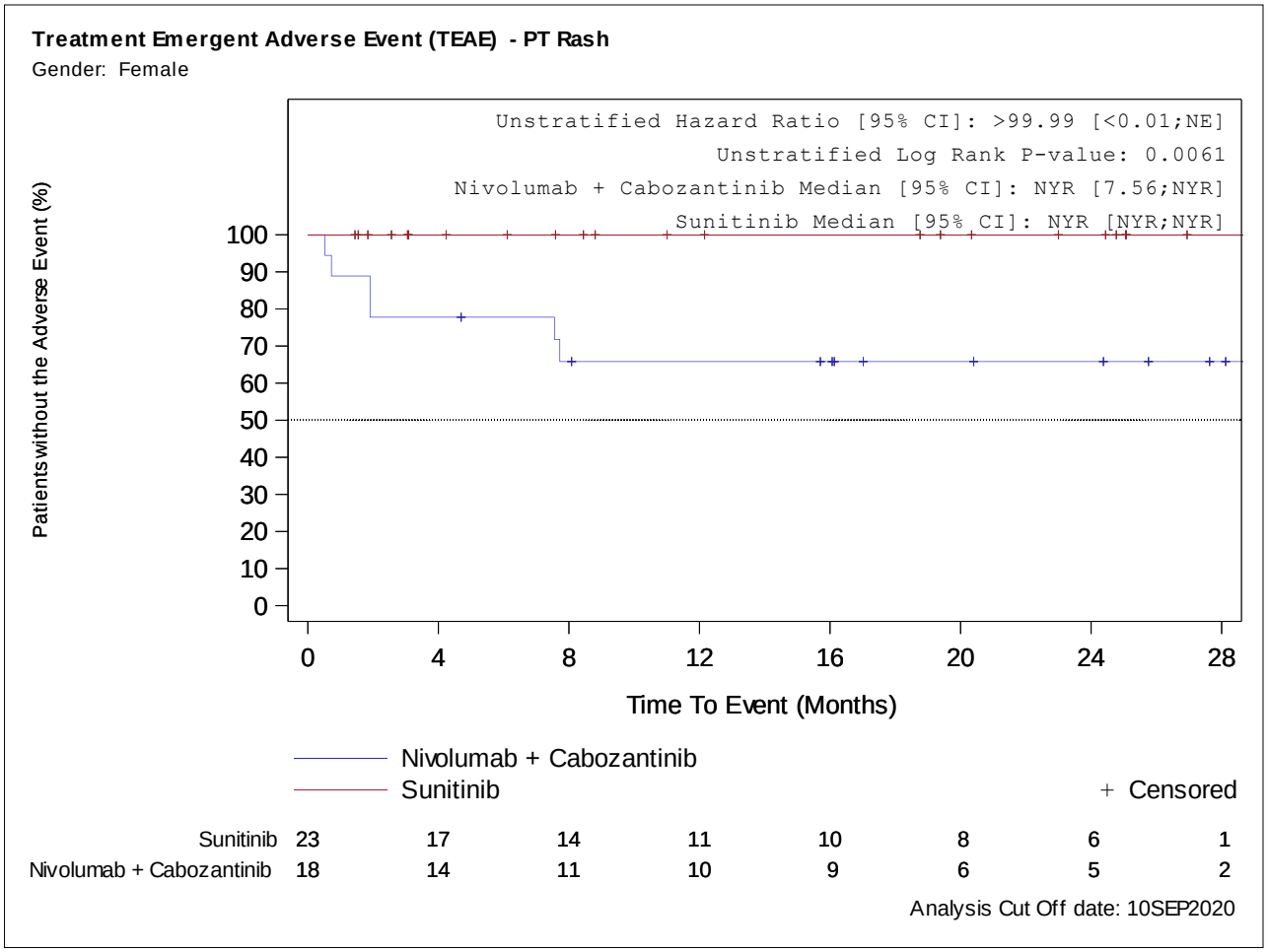

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:52:53

FIGURE 5.18.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



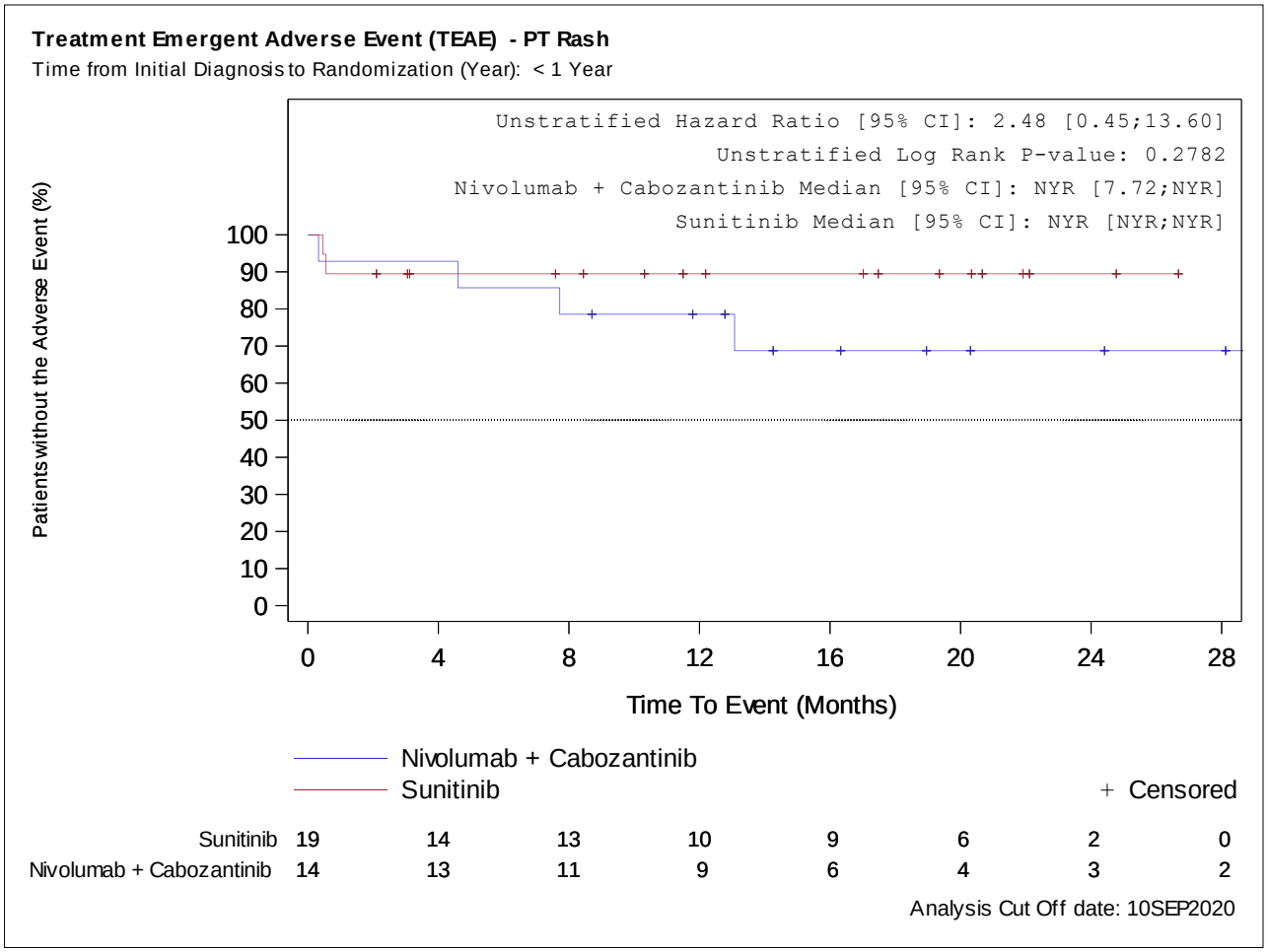

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:52:58

FIGURE 5.18.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



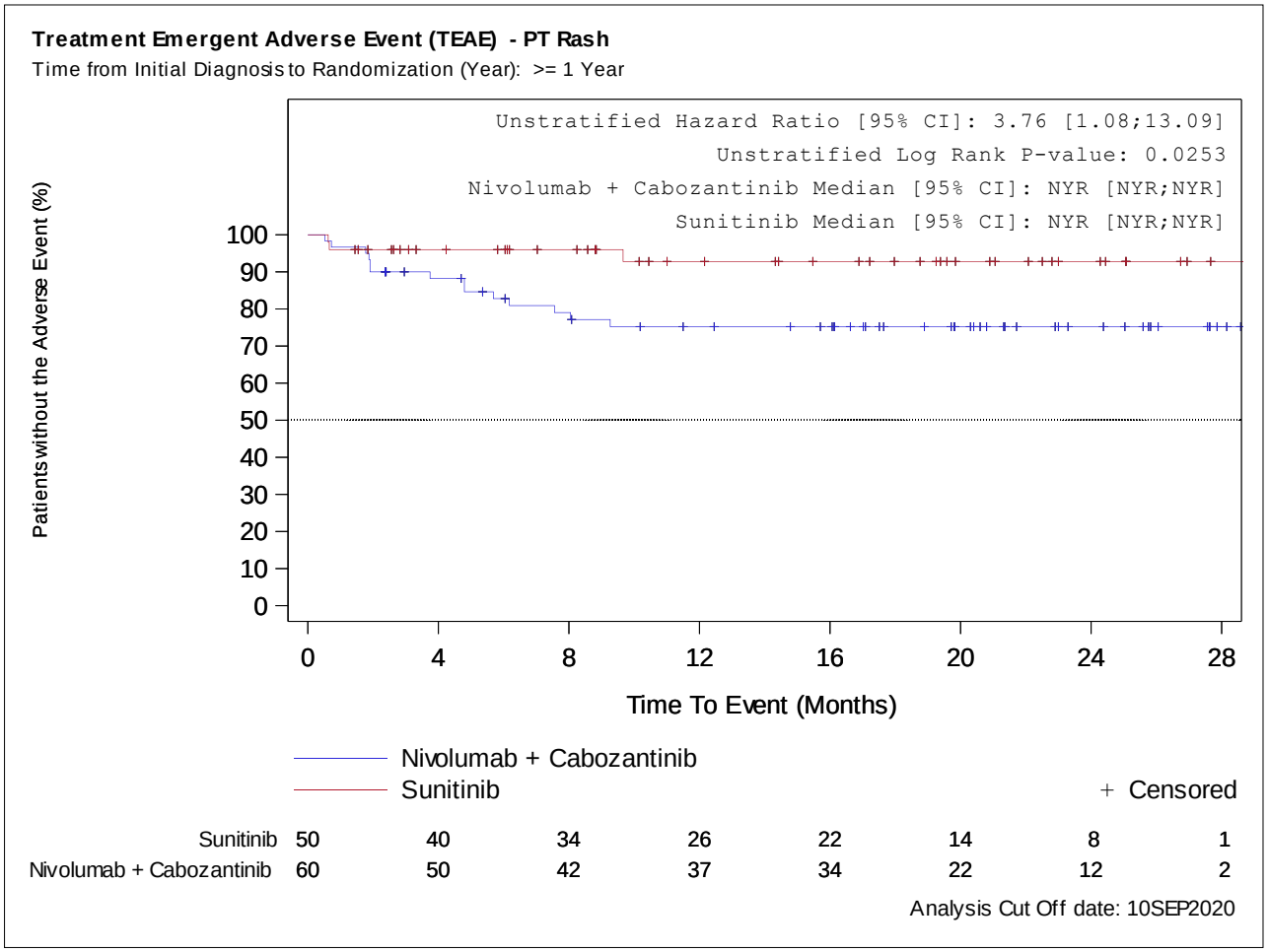

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:53:04

FIGURE 5.18.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:53:21

FIGURE 5.18.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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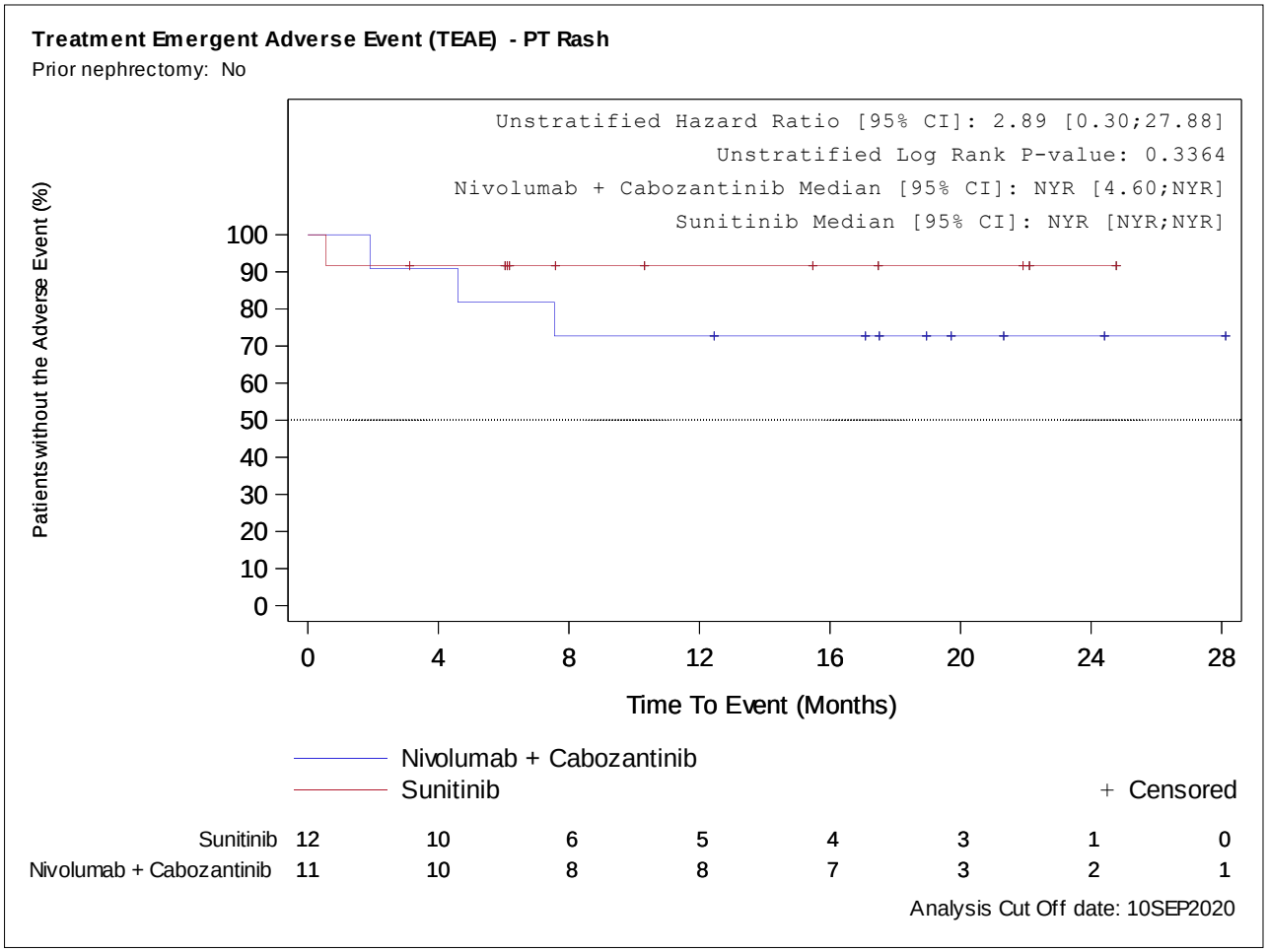
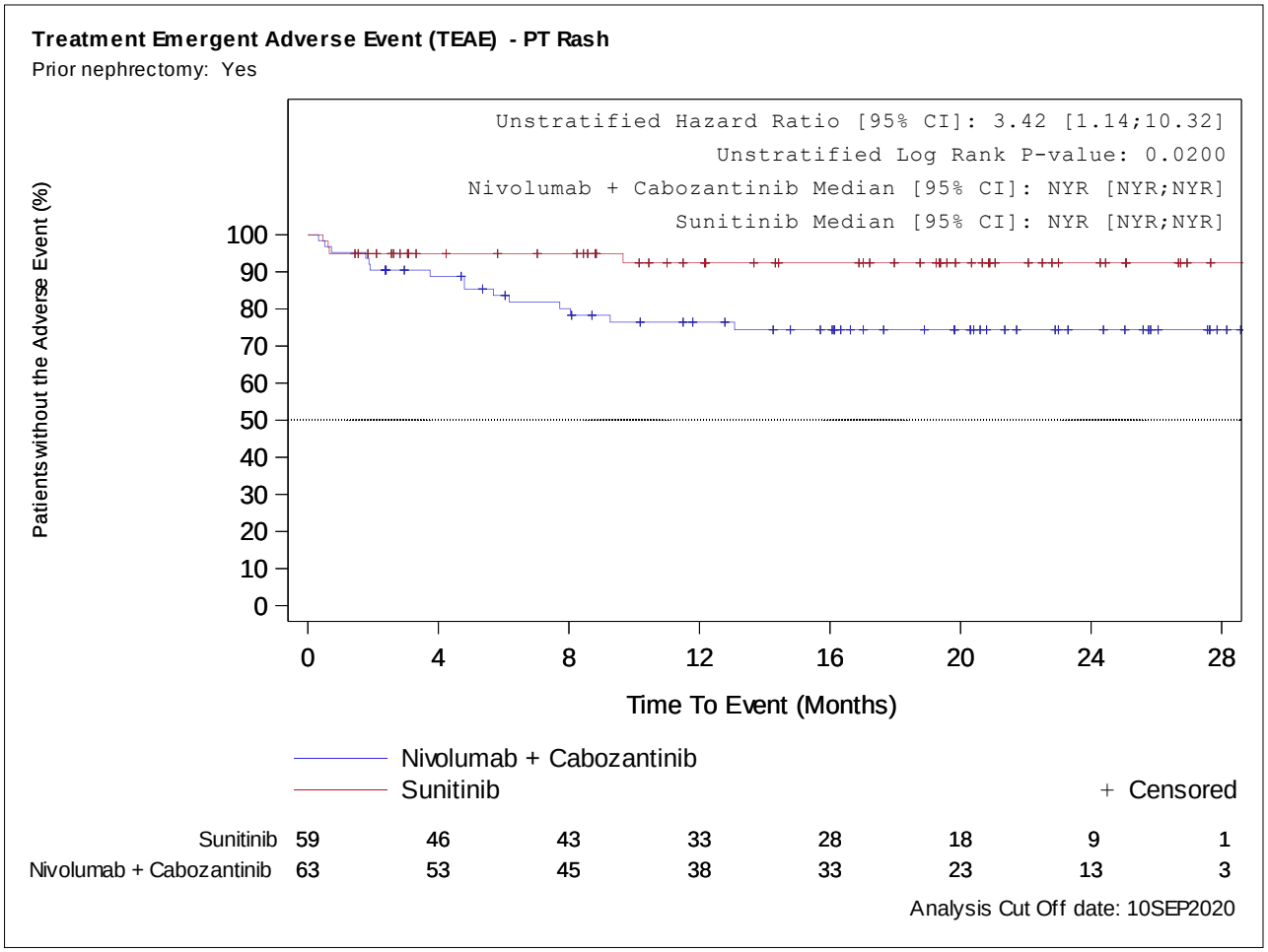
FIGURE 5.18.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



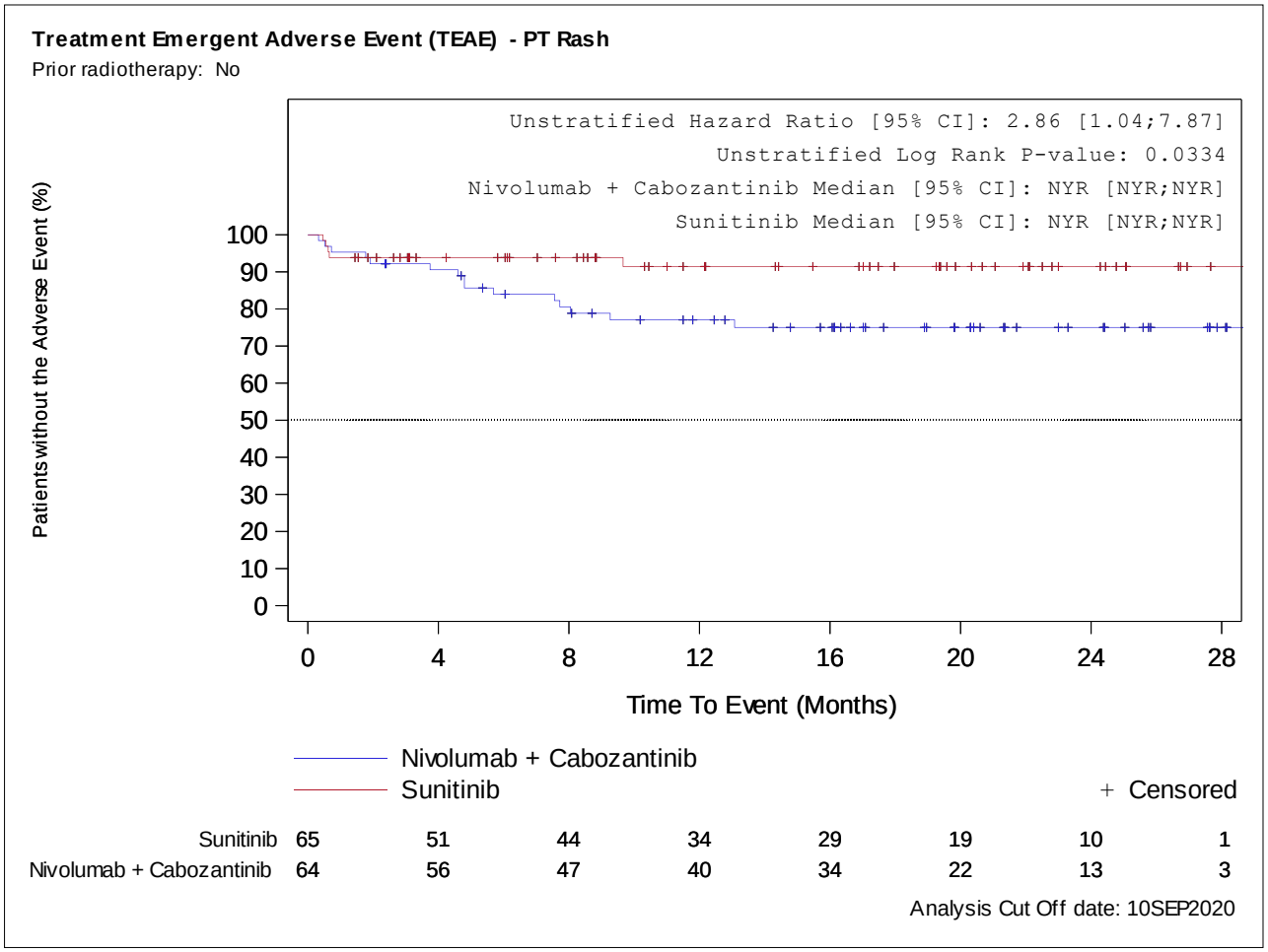

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:54:17

FIGURE 5.18.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



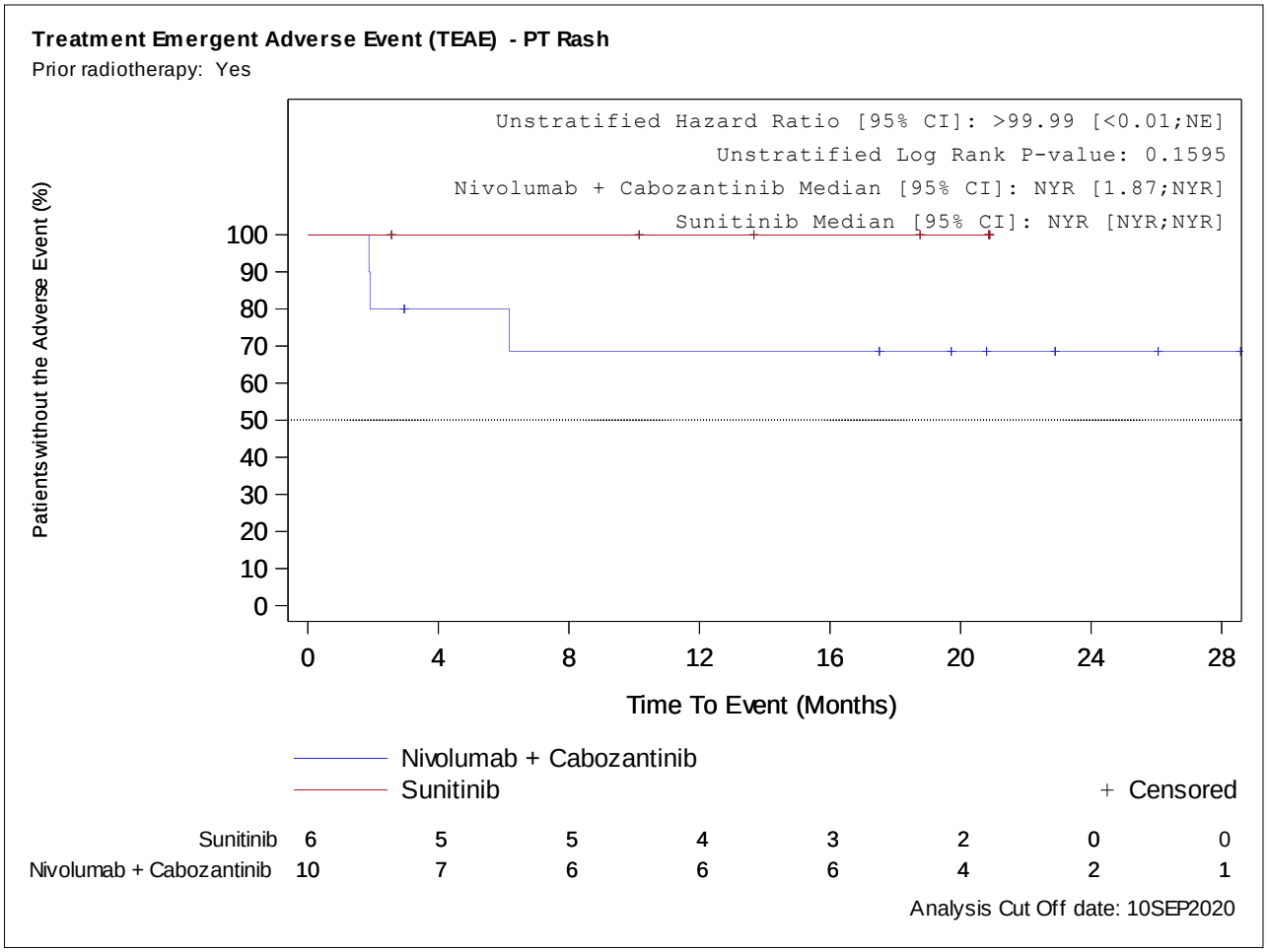

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:54:24

FIGURE 5.18.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



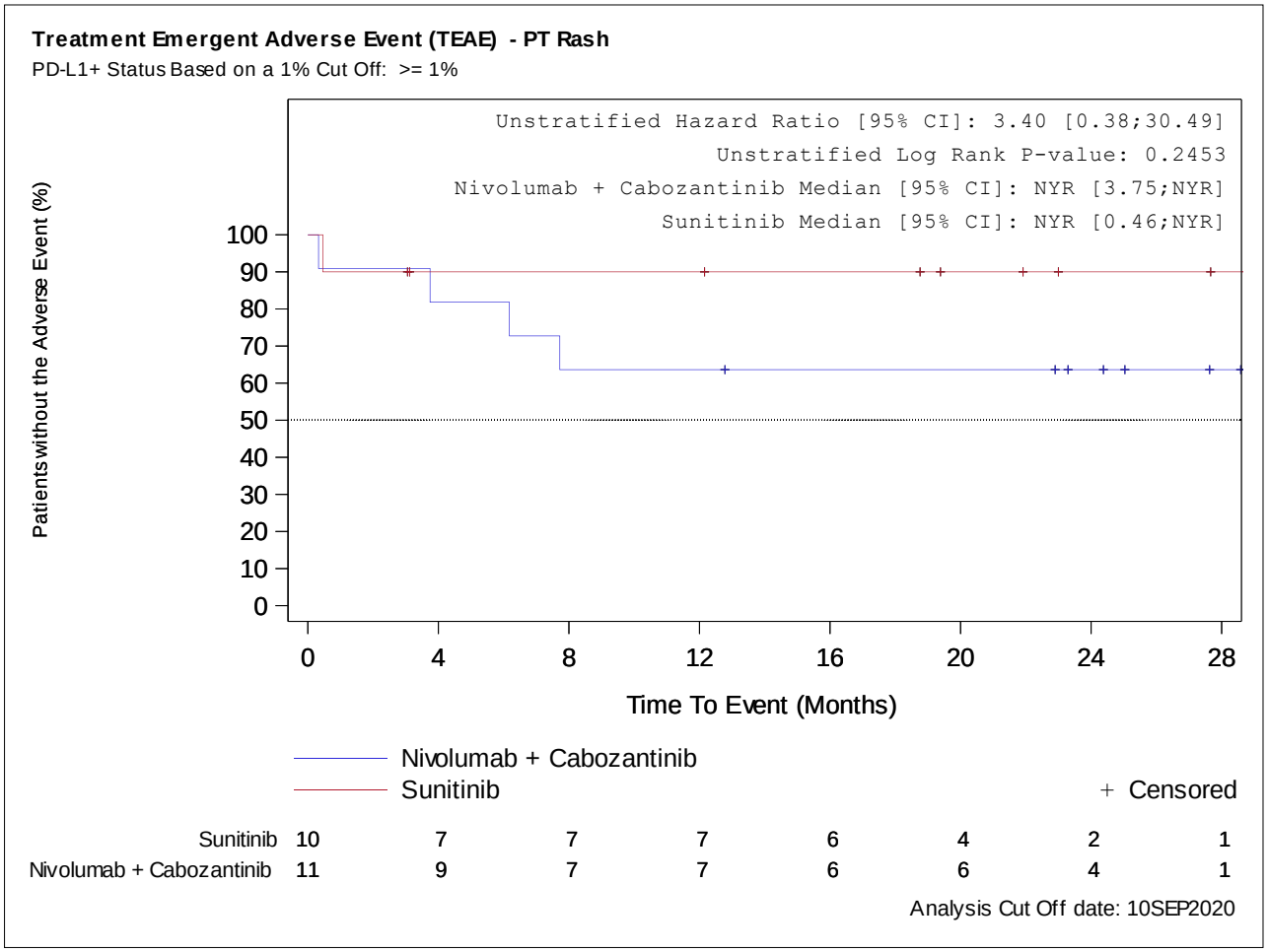

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:54:29

FIGURE 5.18.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



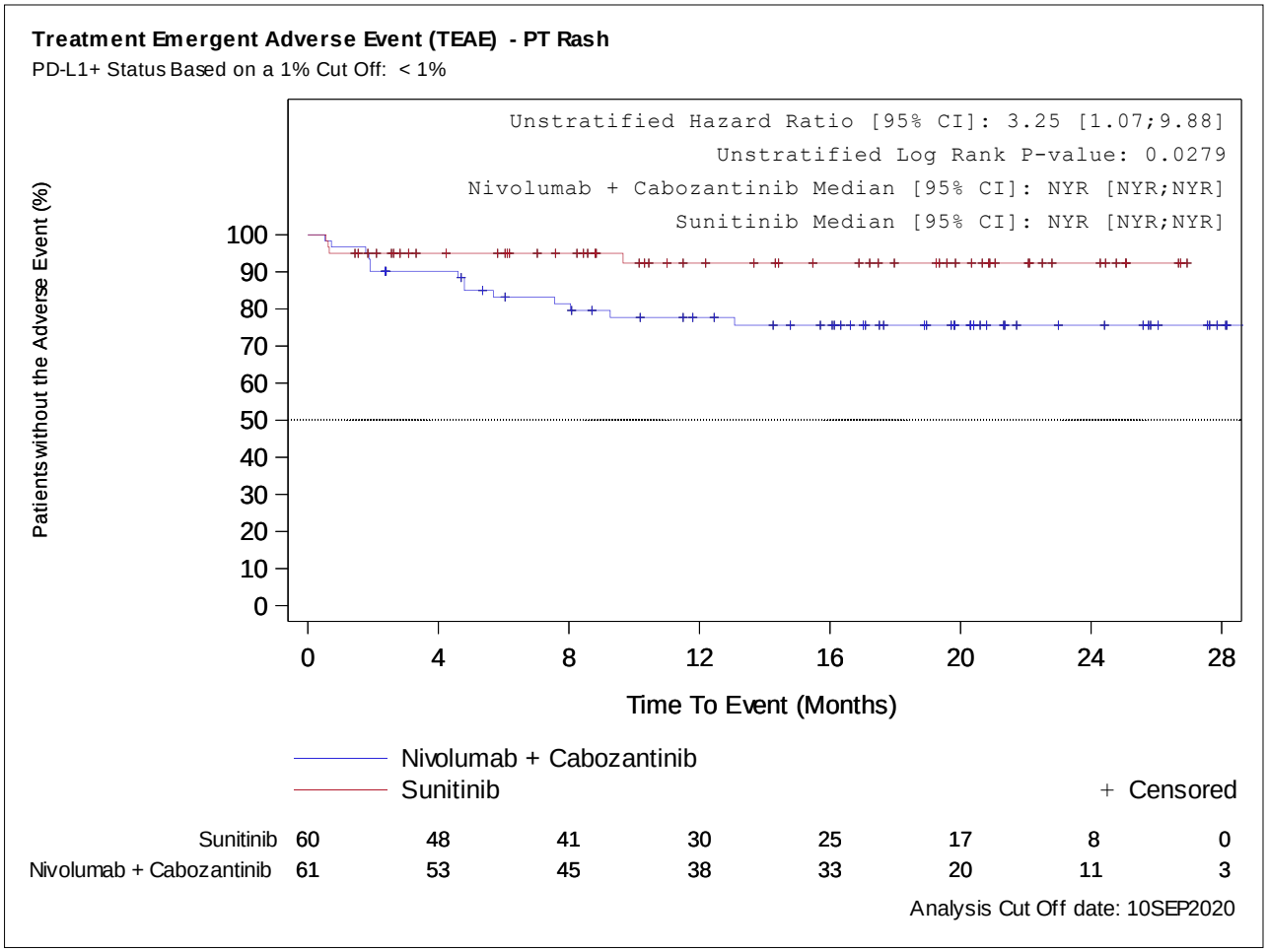

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:54:35

FIGURE 5.18.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



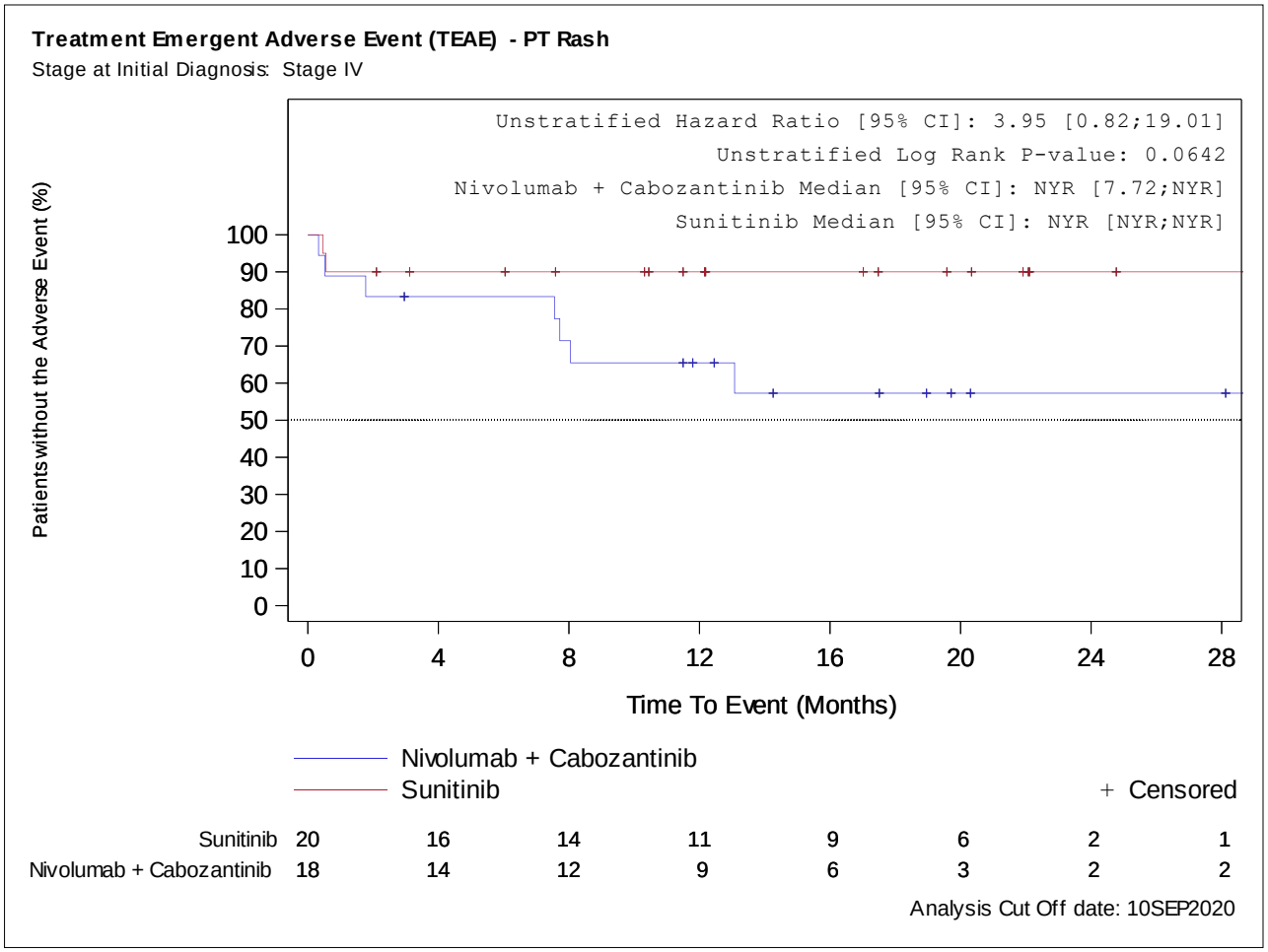

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:54:41

FIGURE 5.18.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 17:54:46

FIGURE 5.18.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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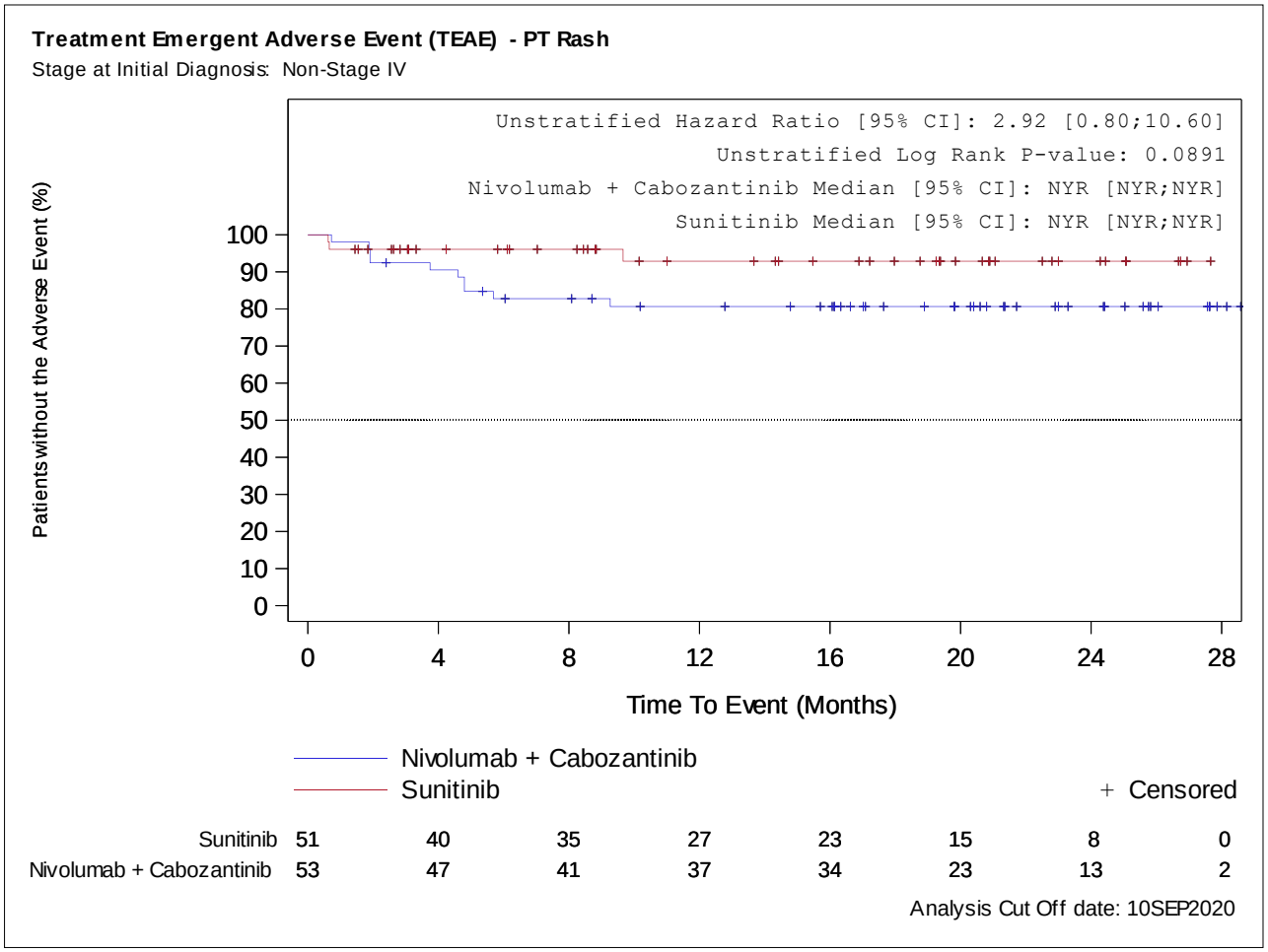
FIGURE 5.18.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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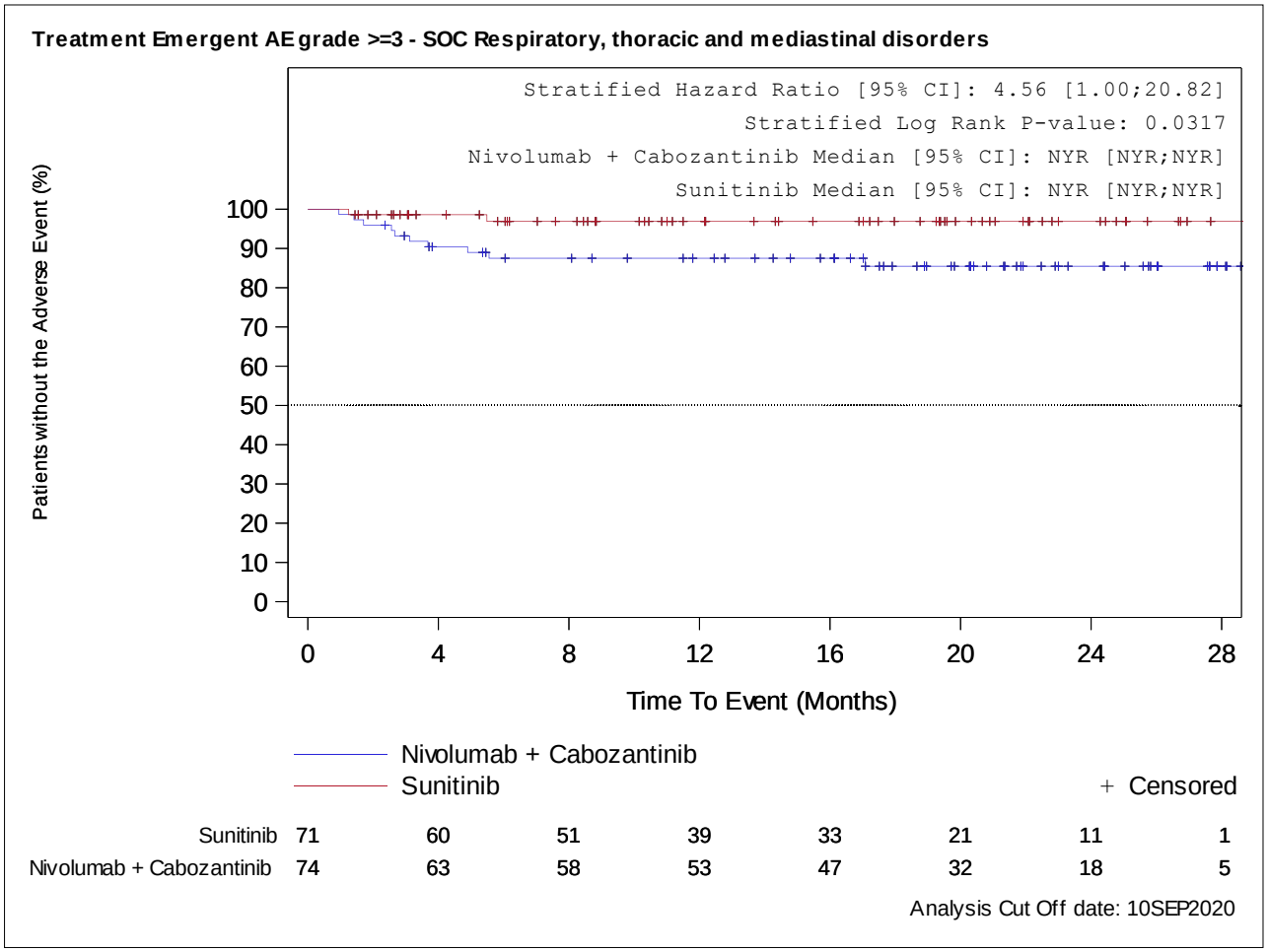
FIGURE 5.19.1: Treatment Emergent AE grade >=3 - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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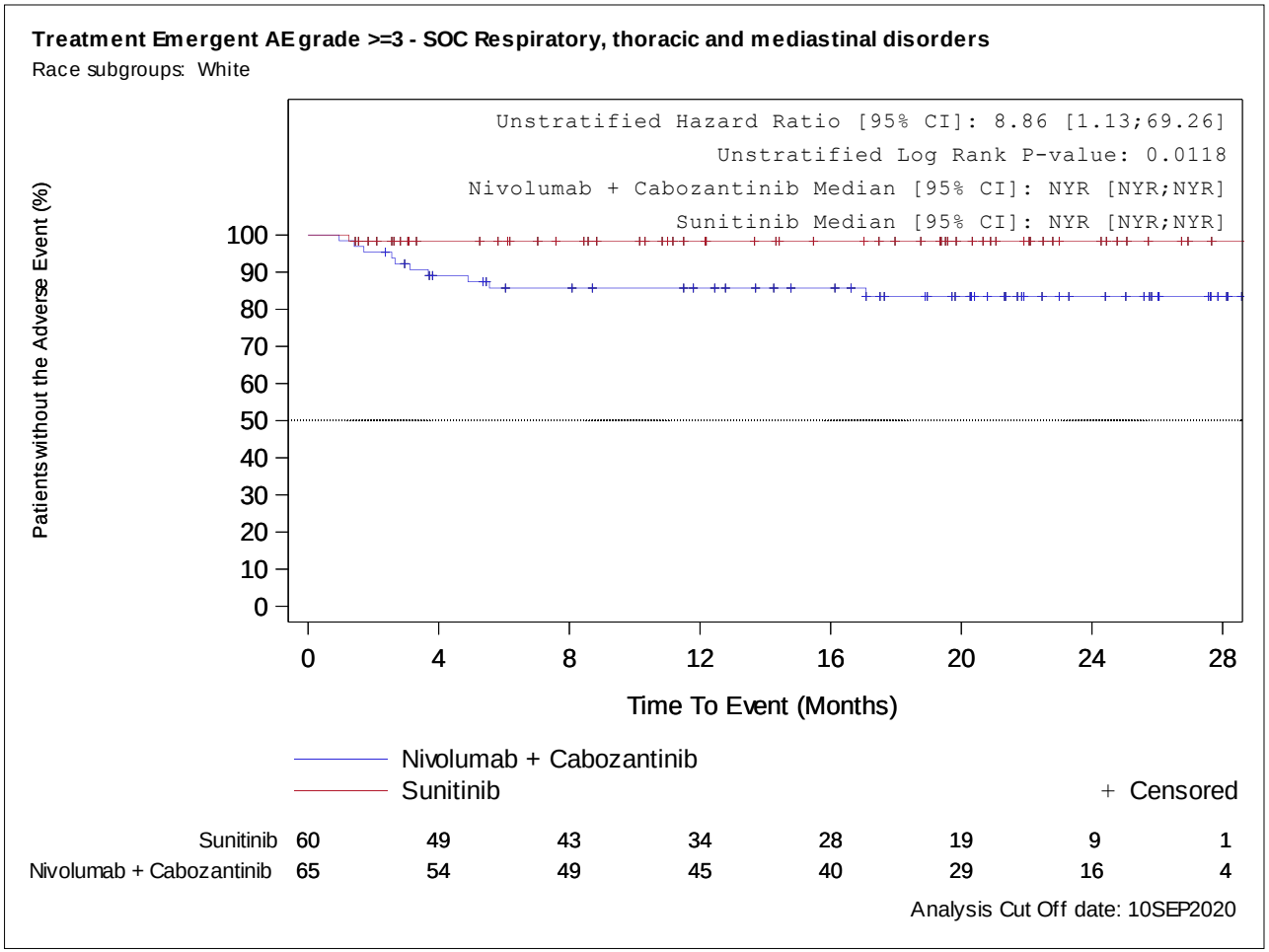
FIGURE 5.19.2.1: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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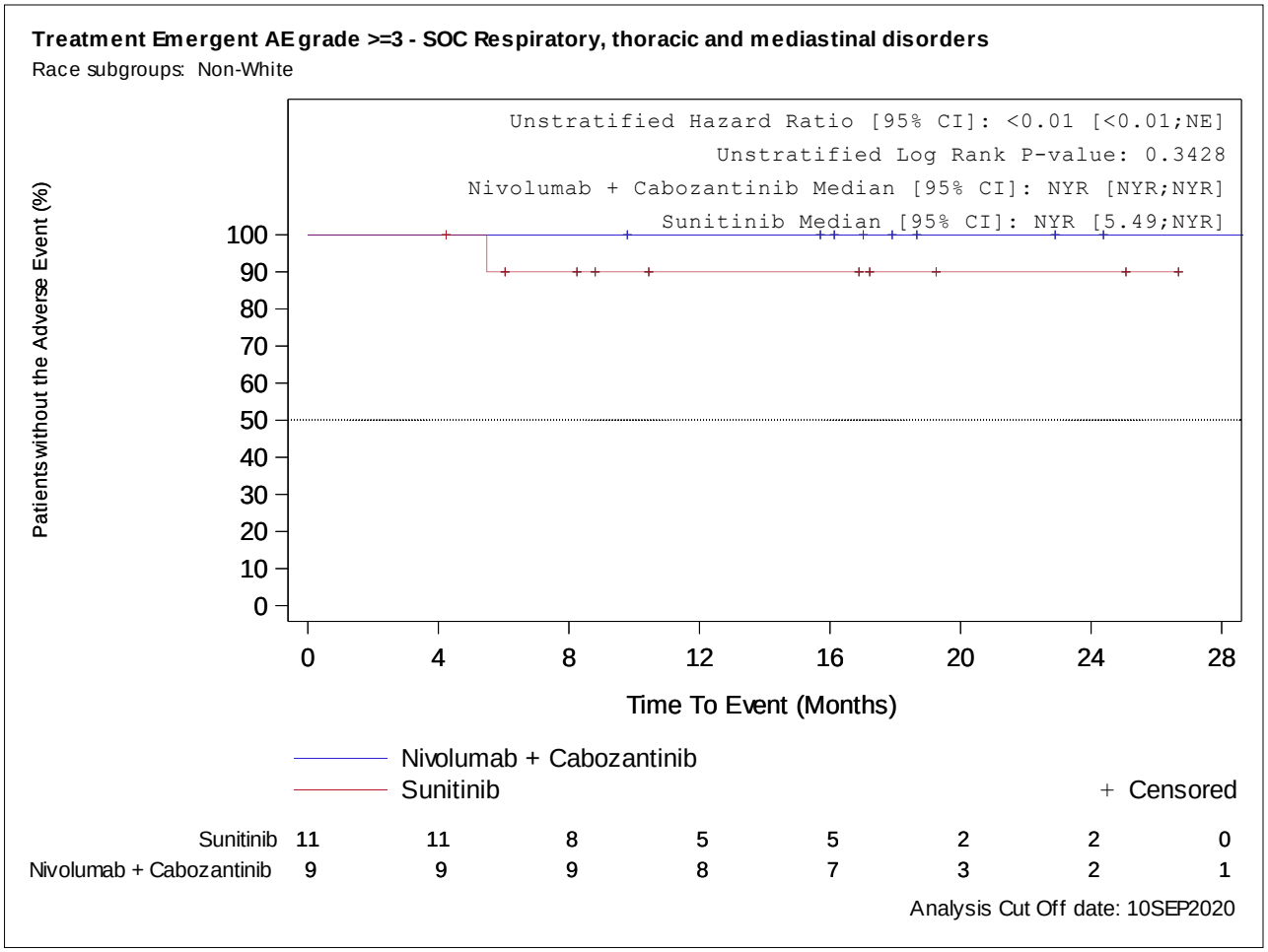
FIGURE 5.19.2.2: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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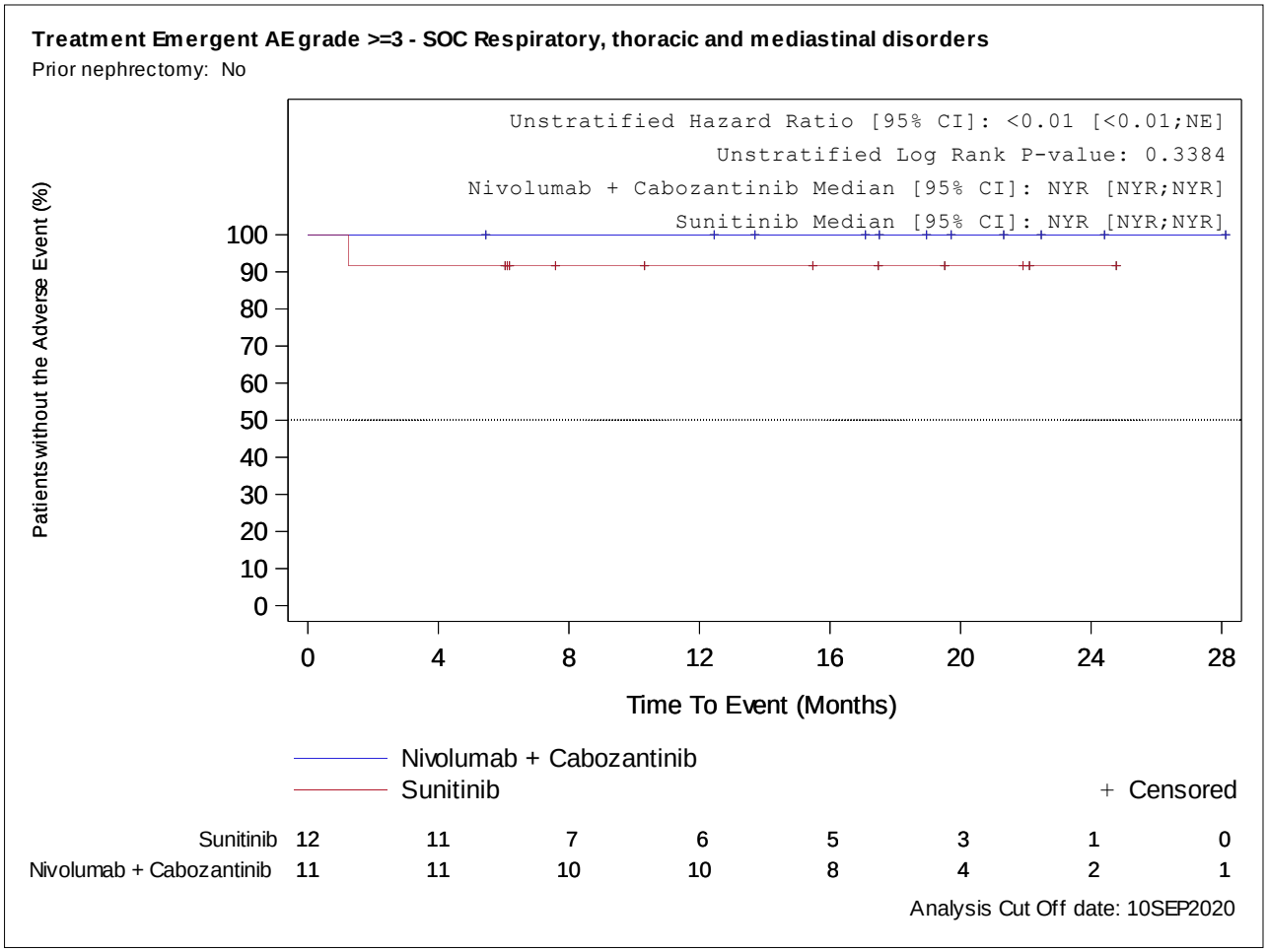
FIGURE 5.19.2.3: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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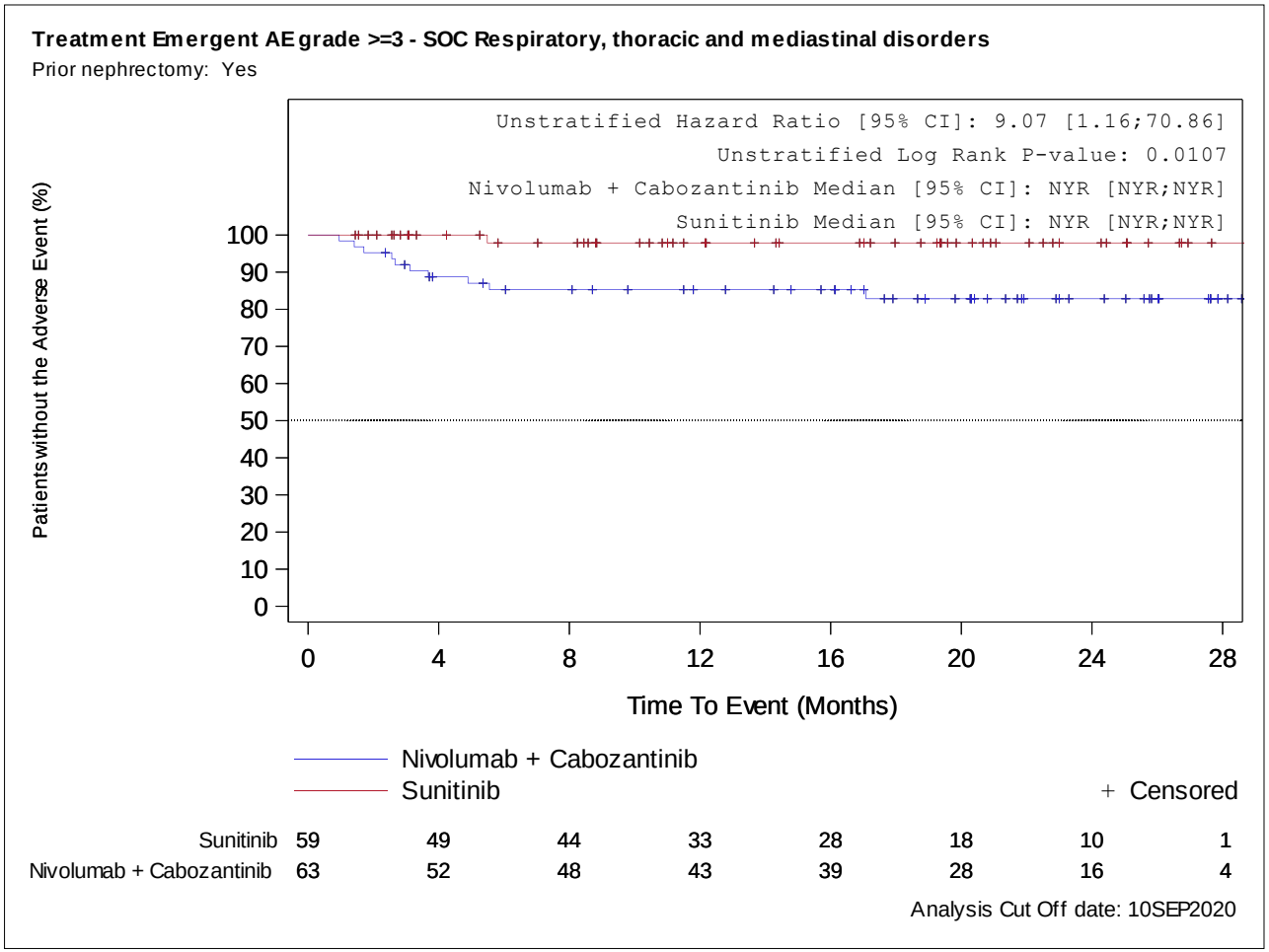
FIGURE 5.19.2.4: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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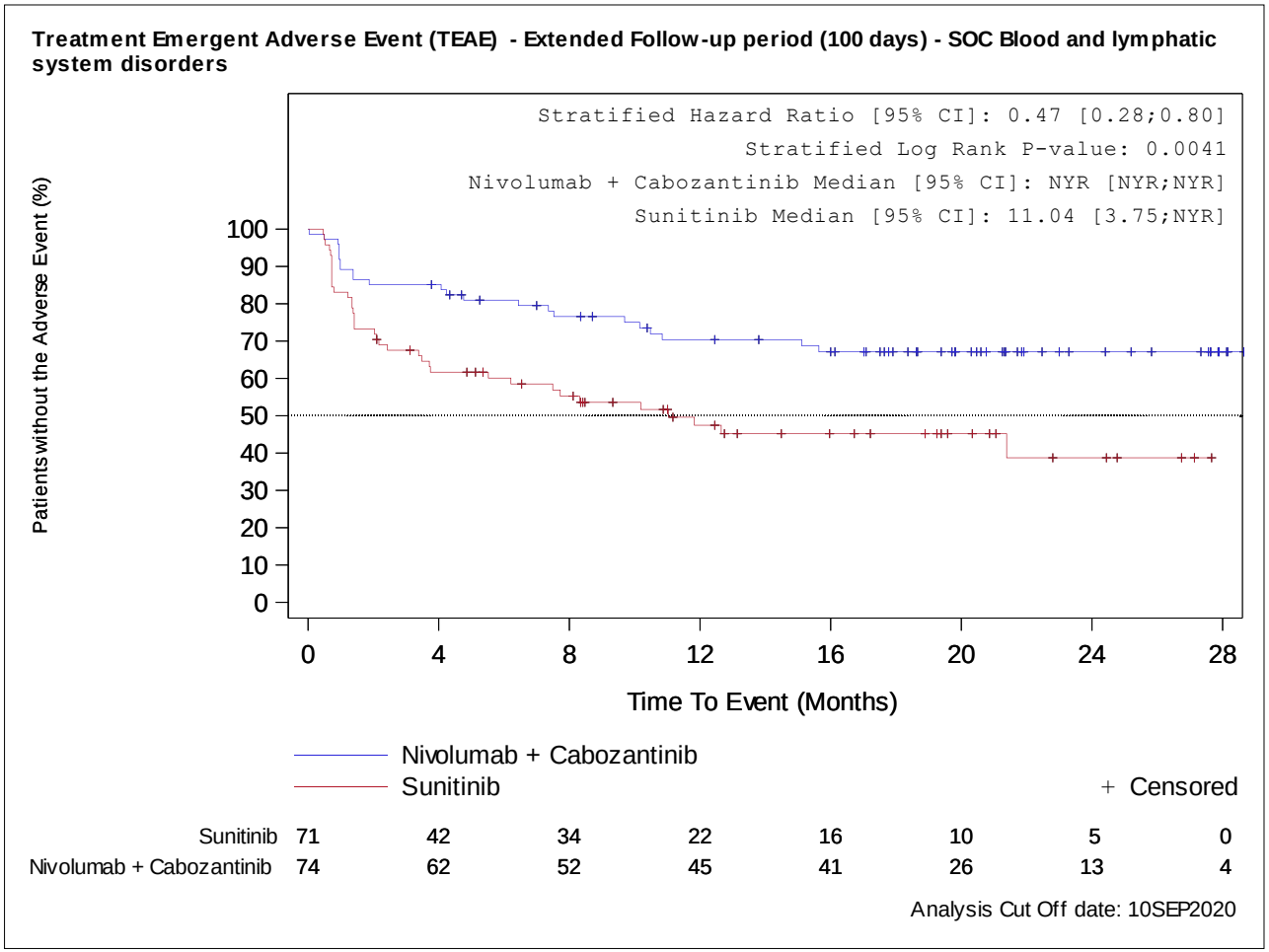
FIGURE 5.20.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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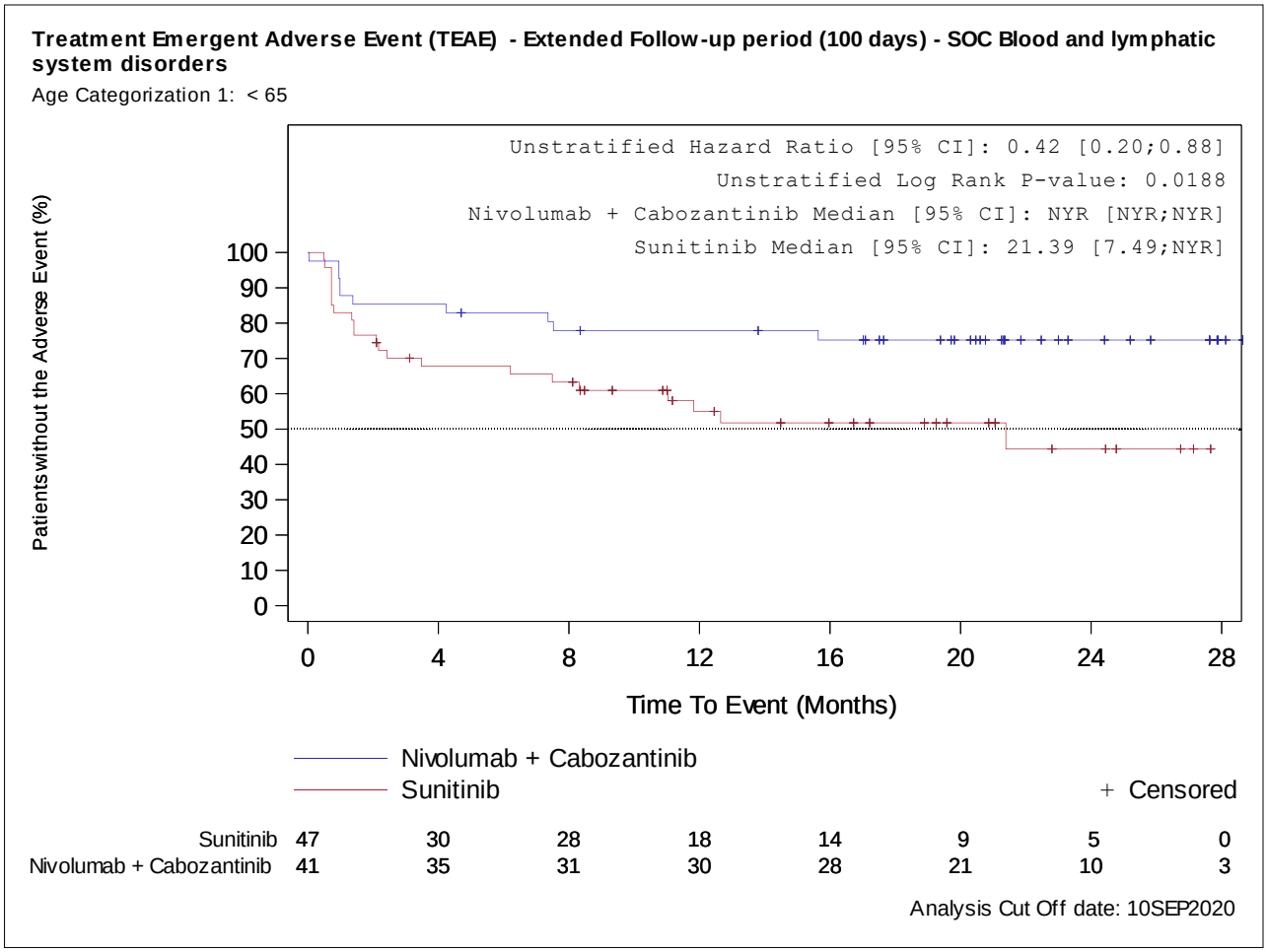
FIGURE 5.20.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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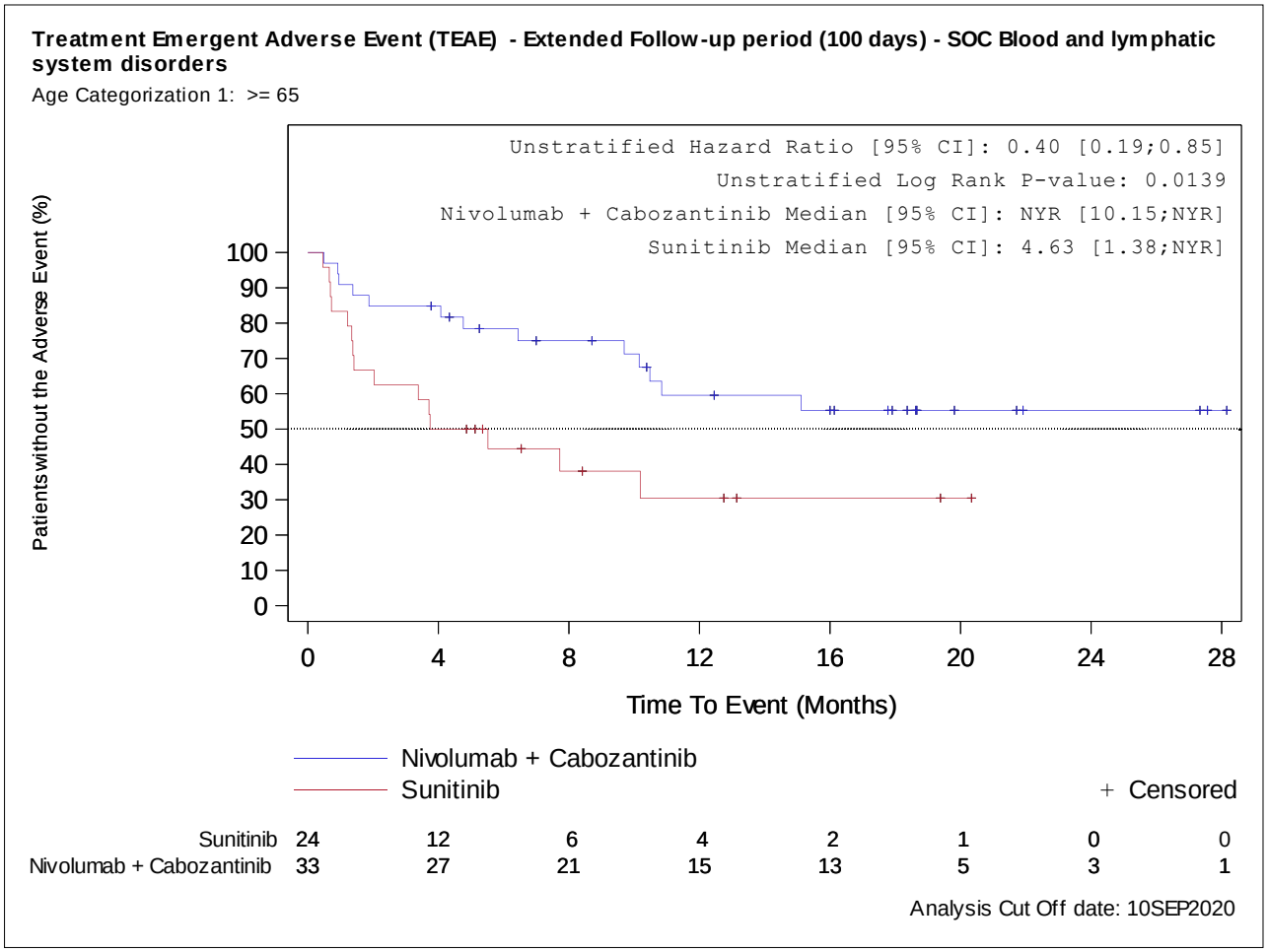
FIGURE 5.20.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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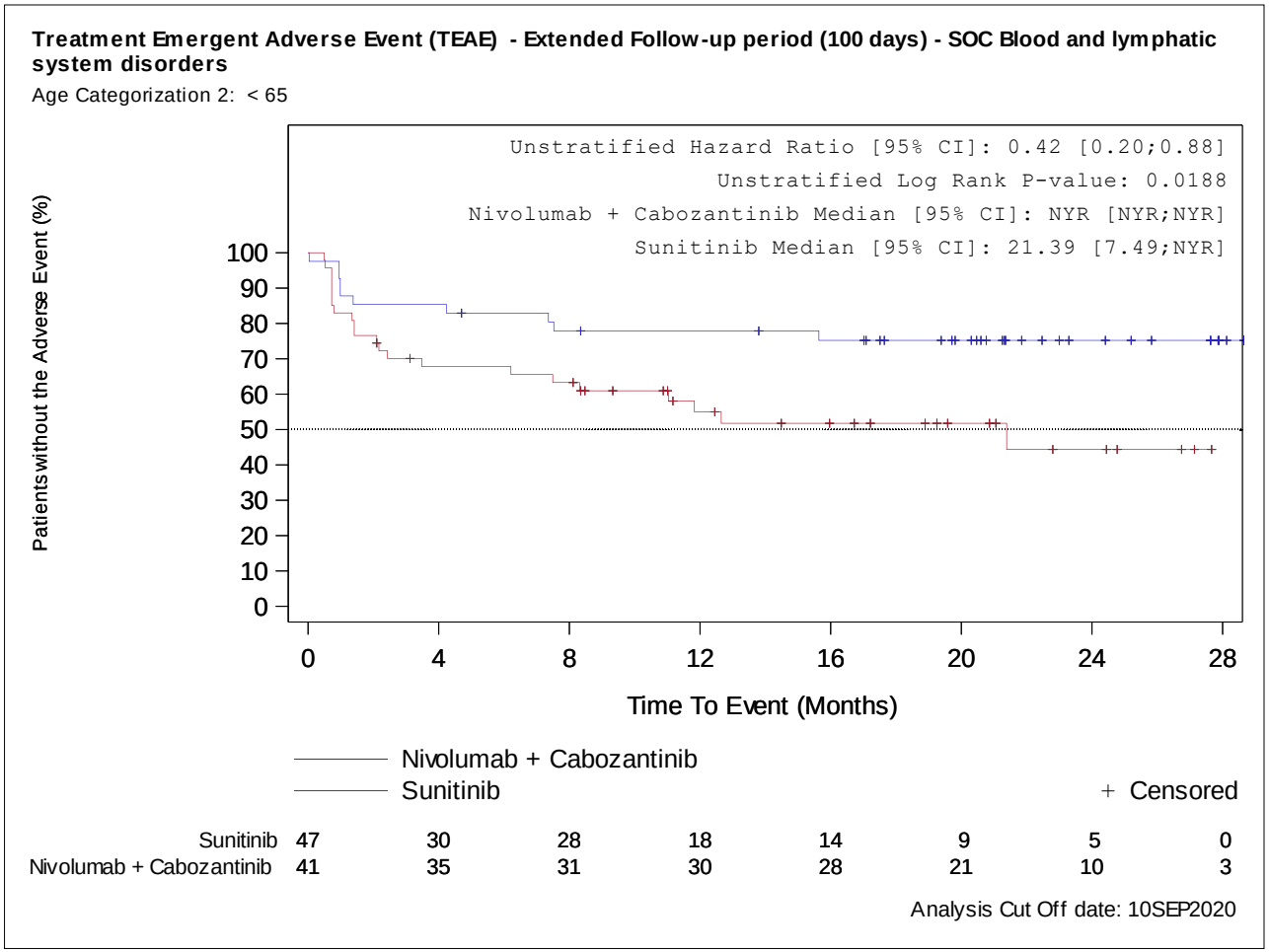
FIGURE 5.20.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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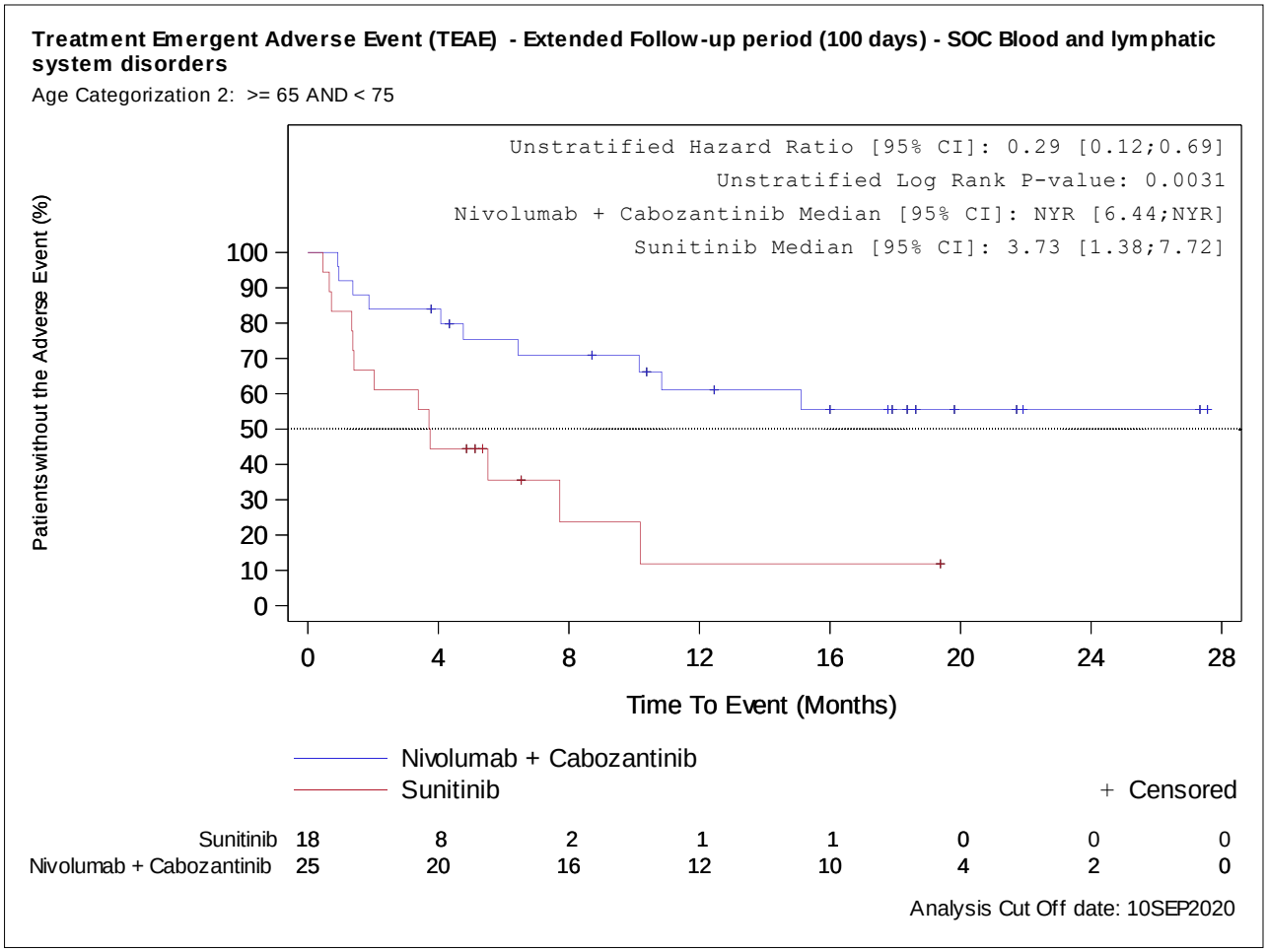
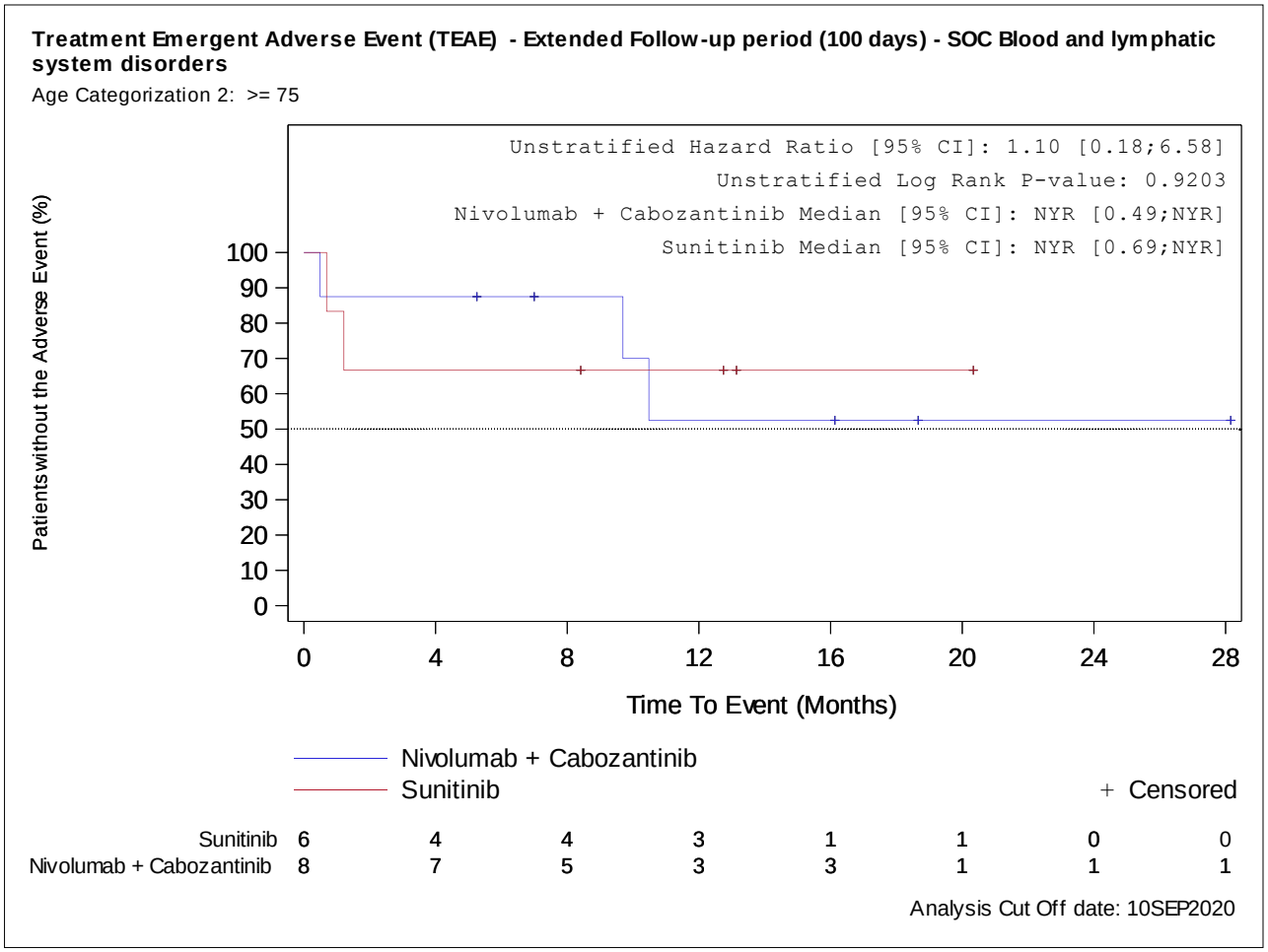
FIGURE 5.20.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:01:46

FIGURE 5.20.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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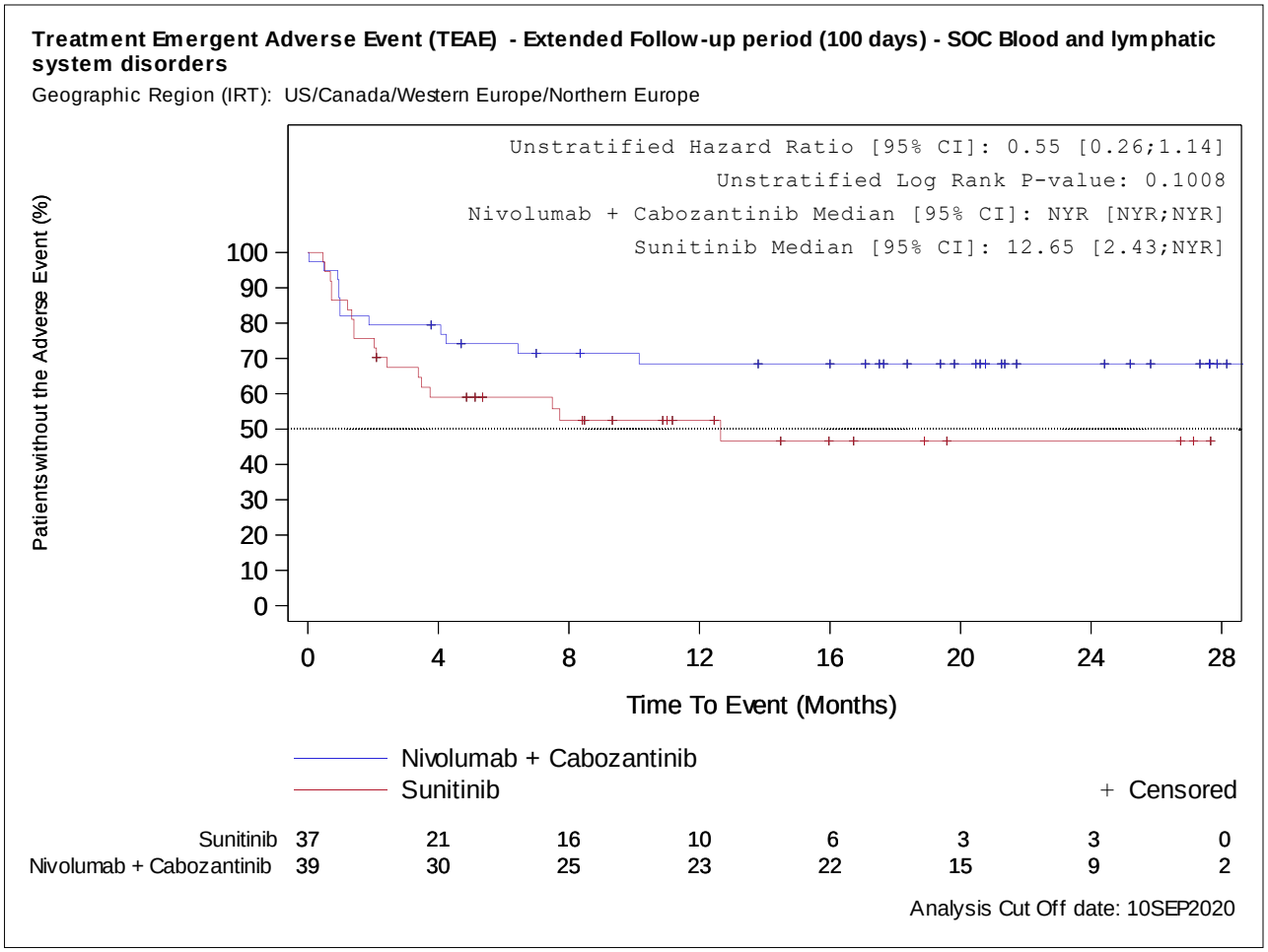
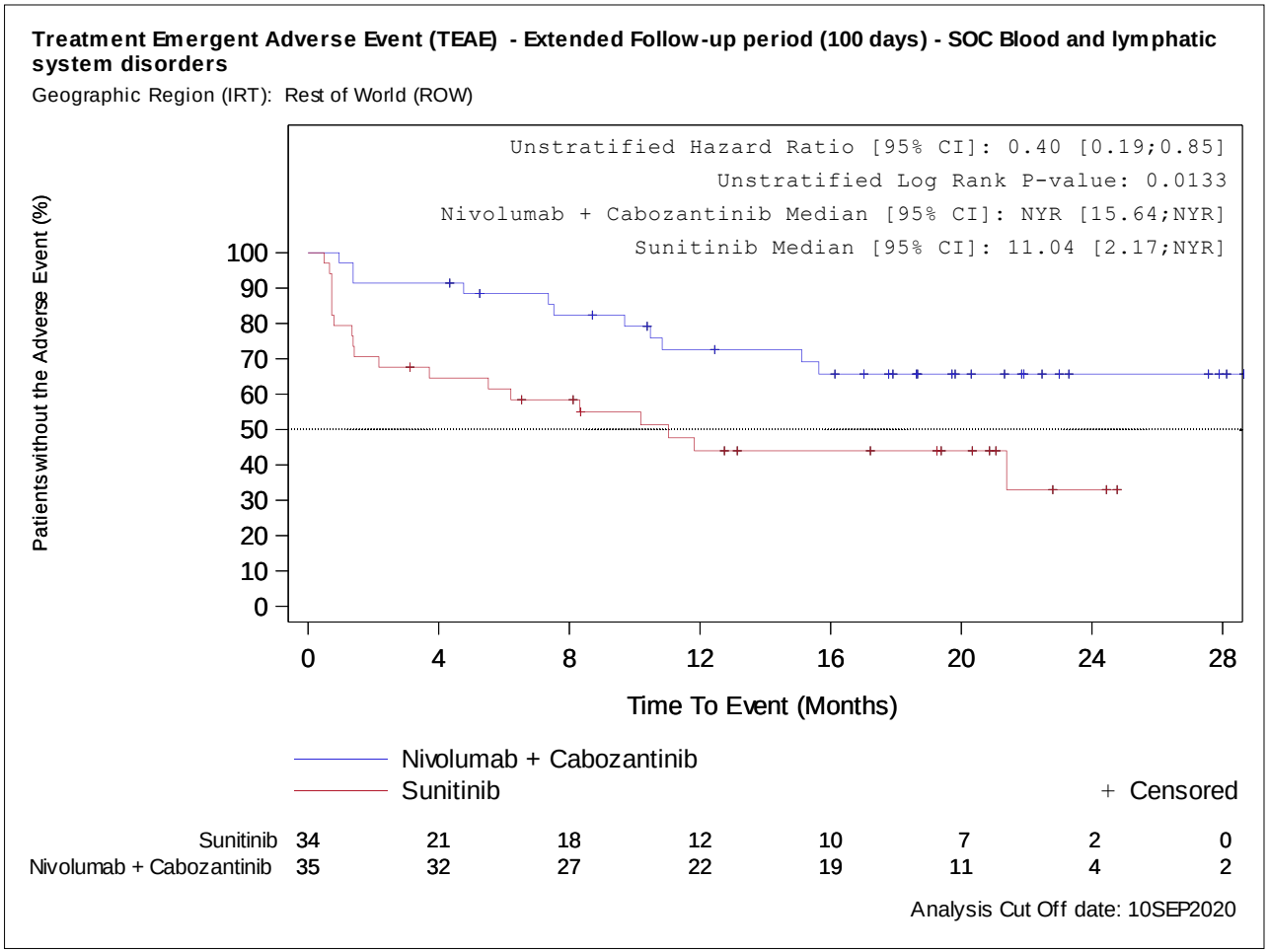
FIGURE 5.20.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:01:57

FIGURE 5.20.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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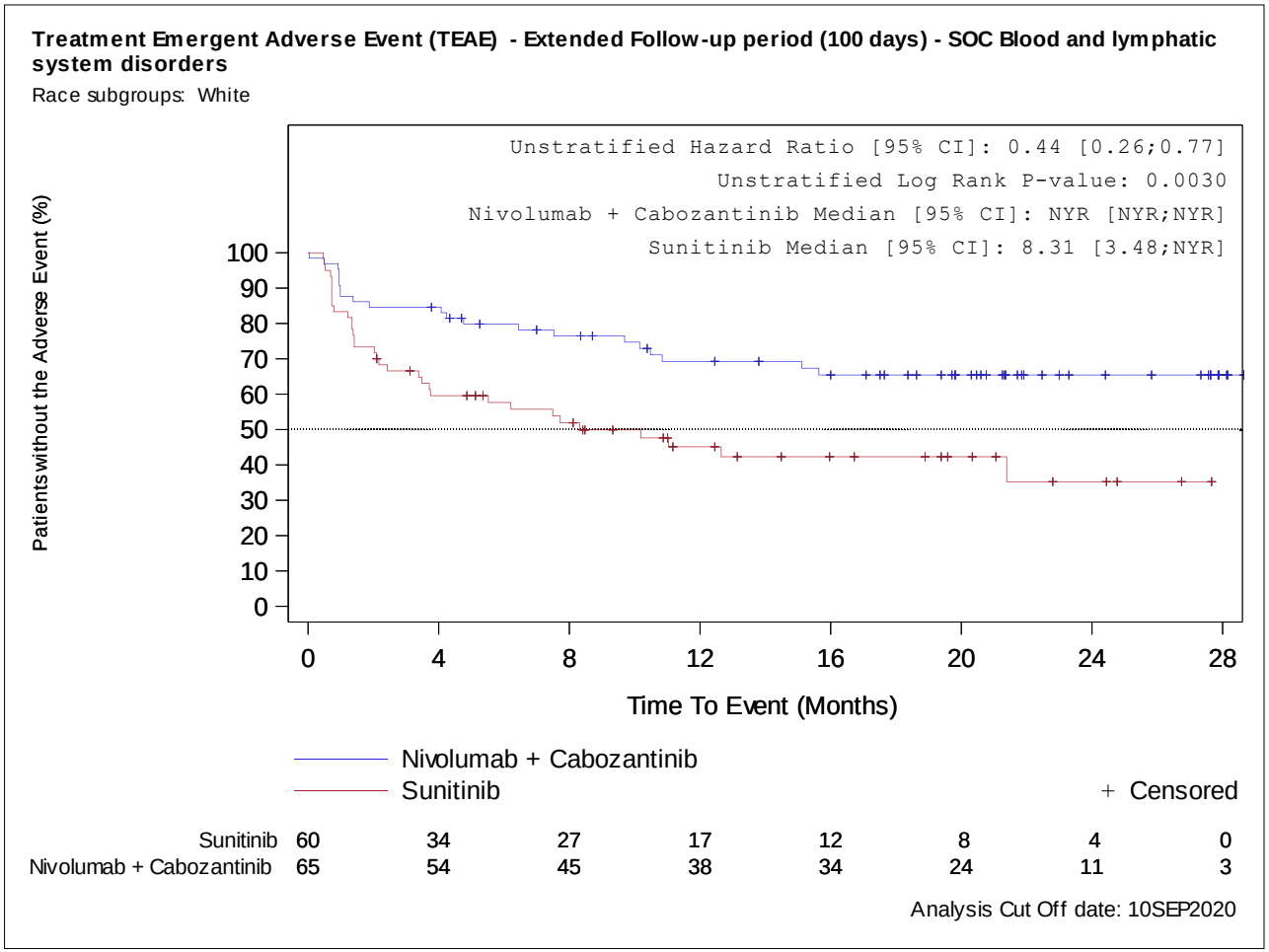
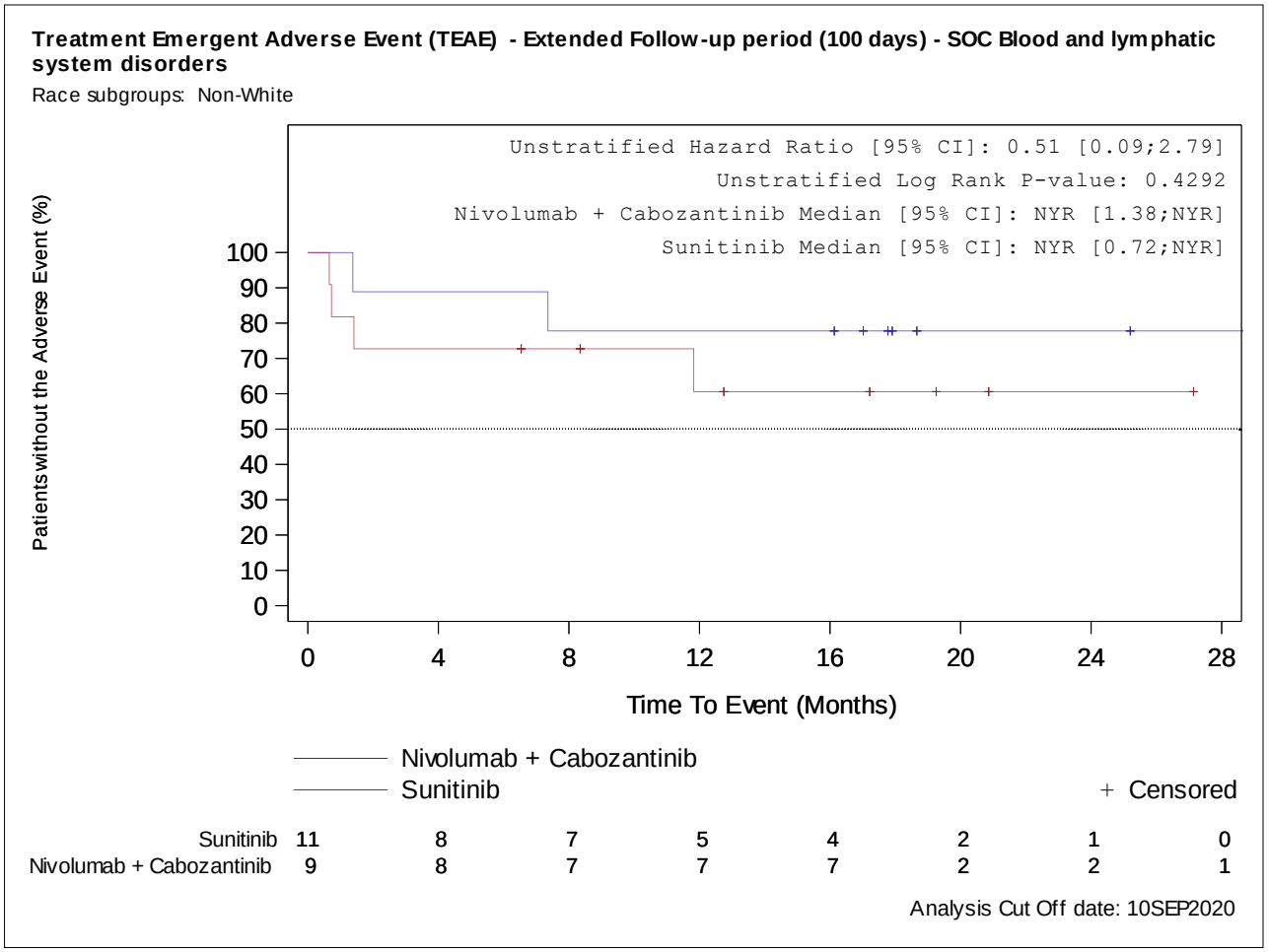
FIGURE 5.20.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:02:09

FIGURE 5.20.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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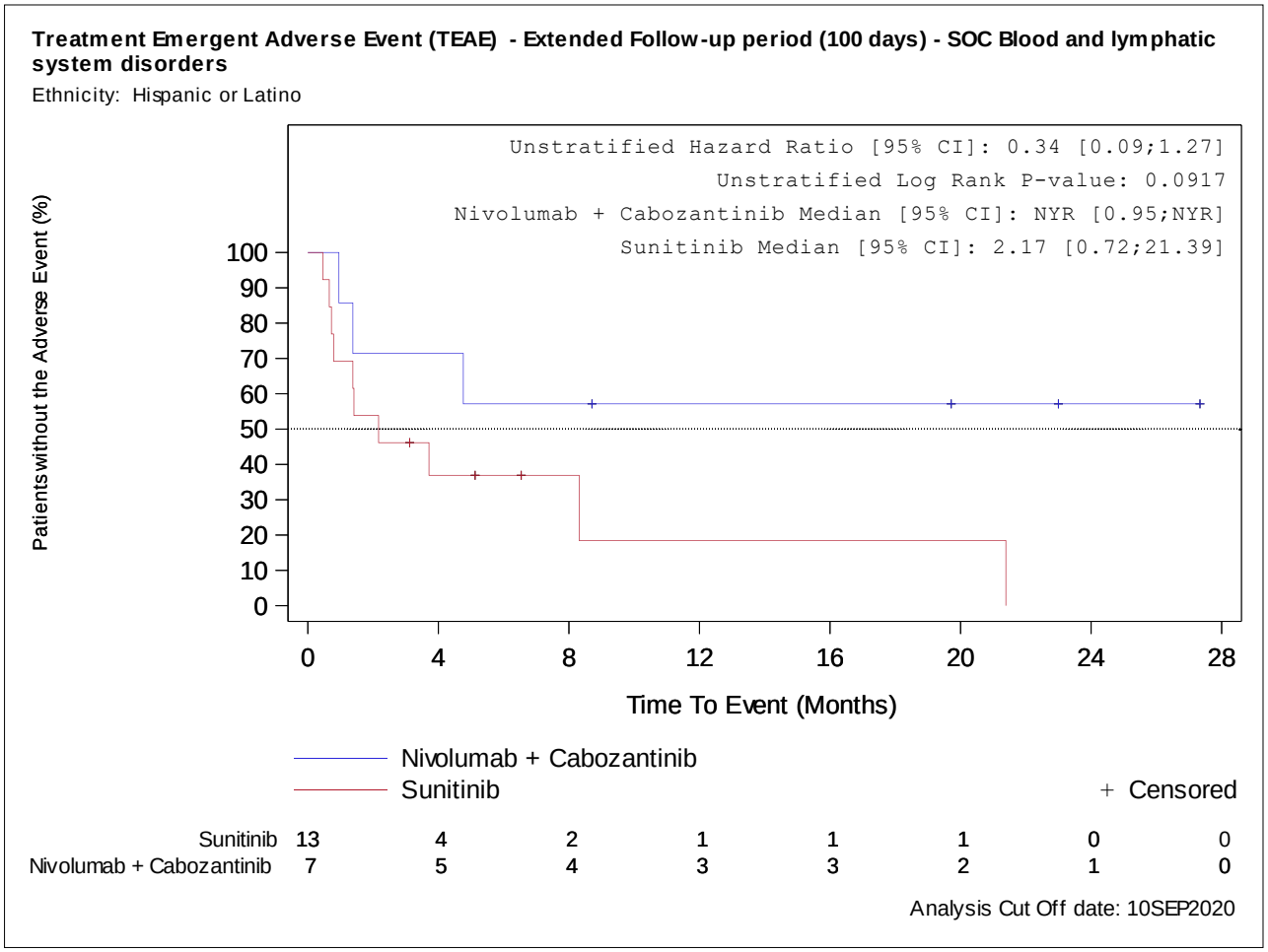
FIGURE 5.20.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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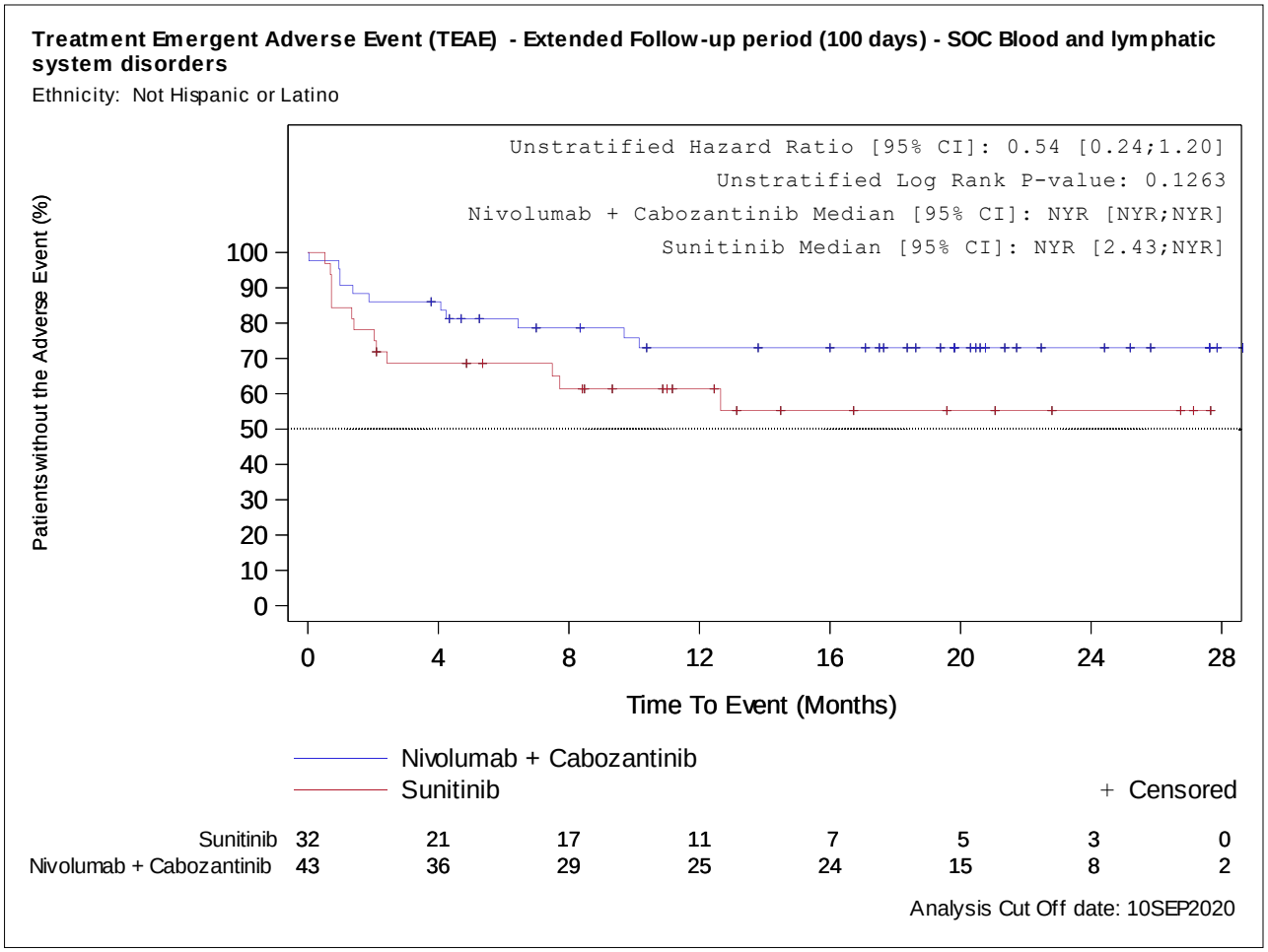
FIGURE 5.20.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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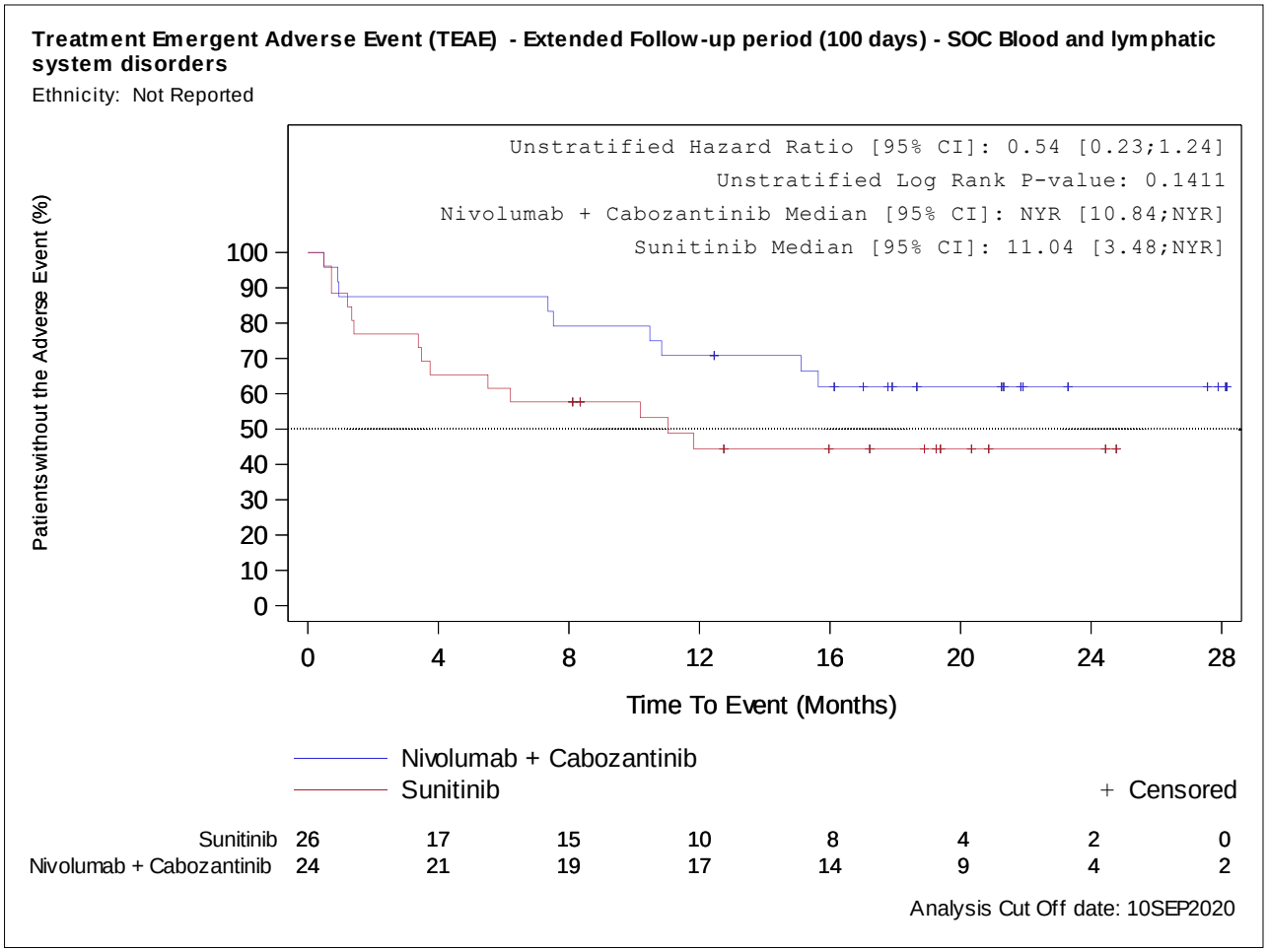
FIGURE 5.20.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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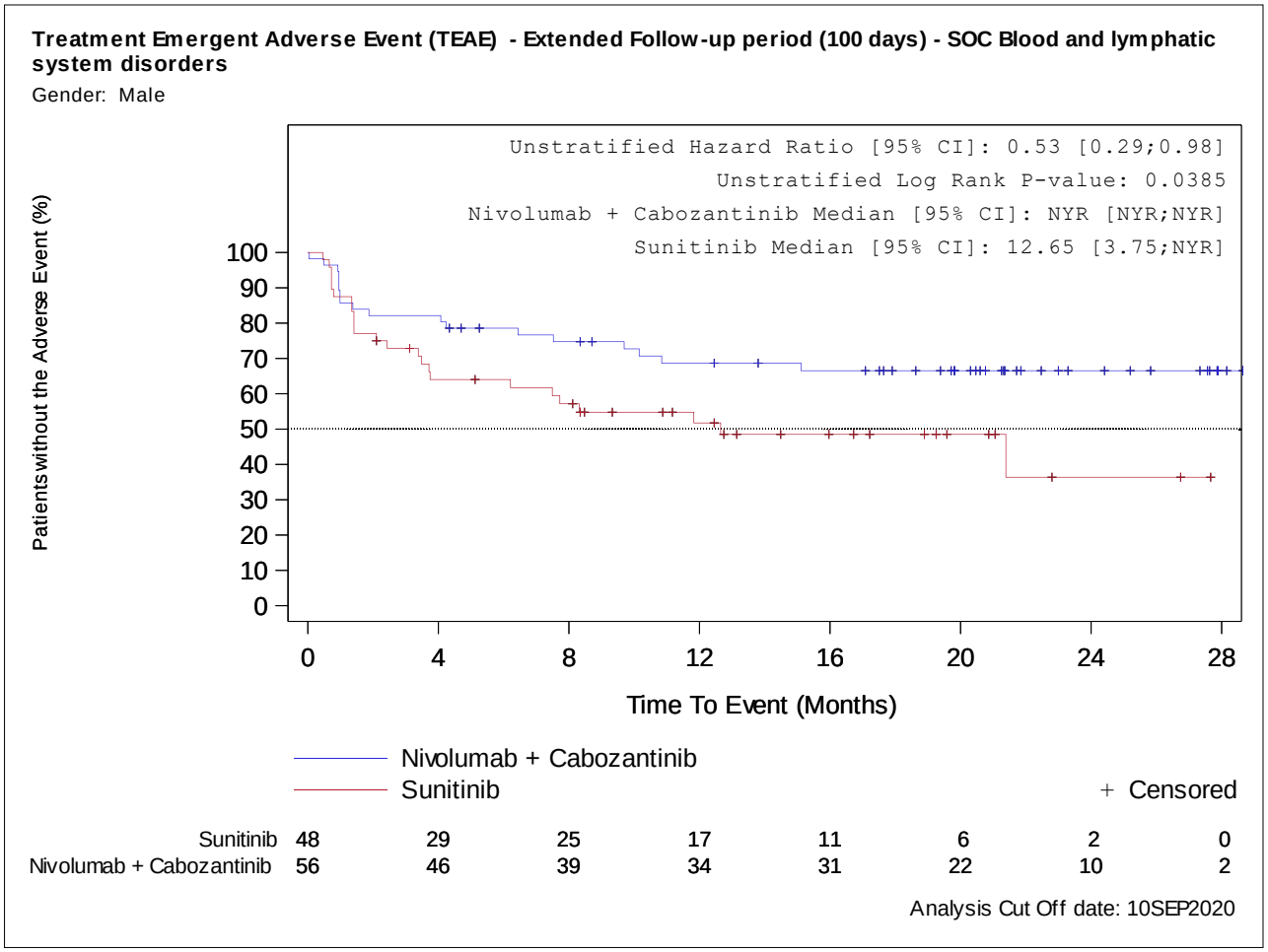
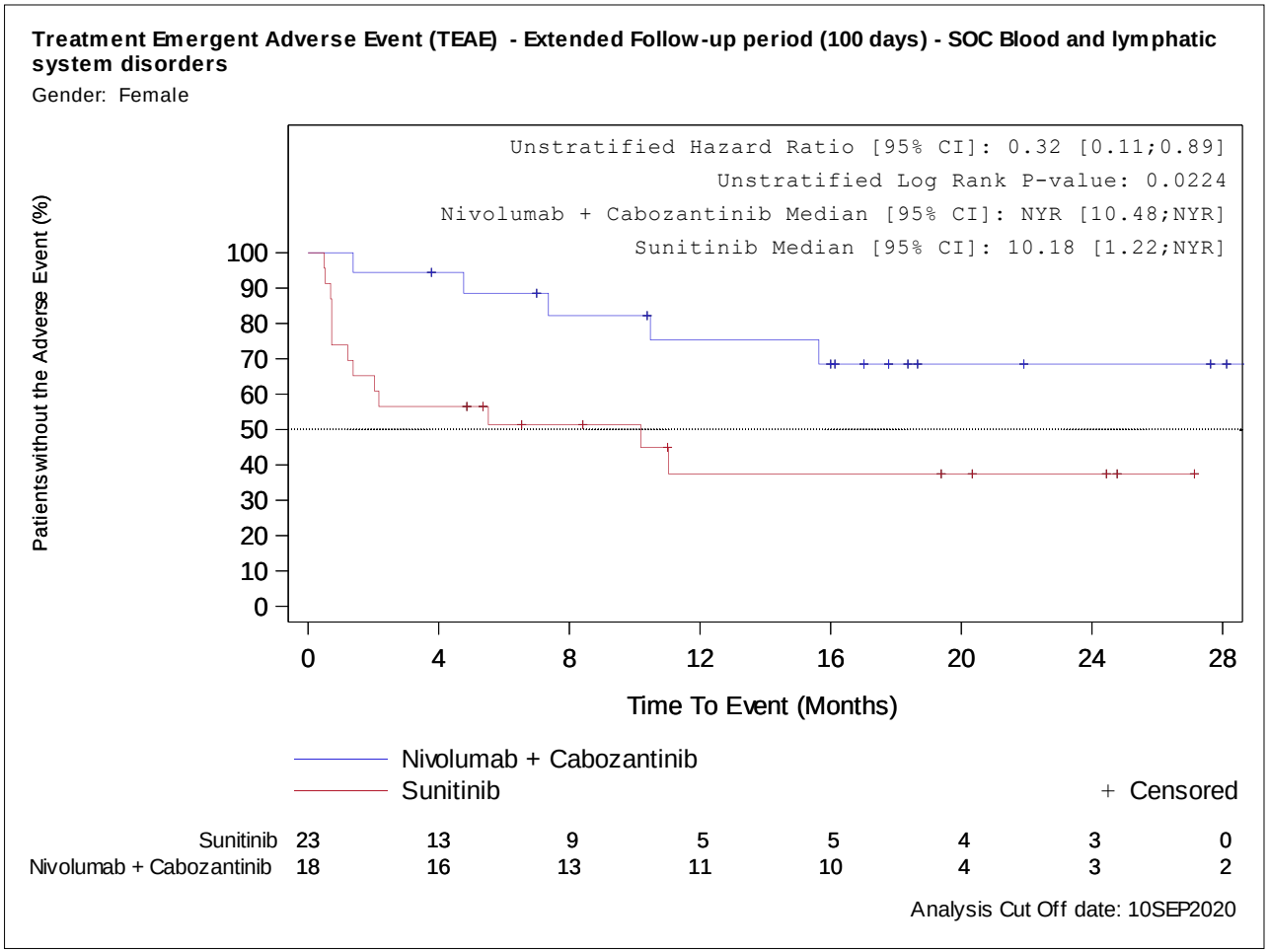
FIGURE 5.20.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:02:38

FIGURE 5.20.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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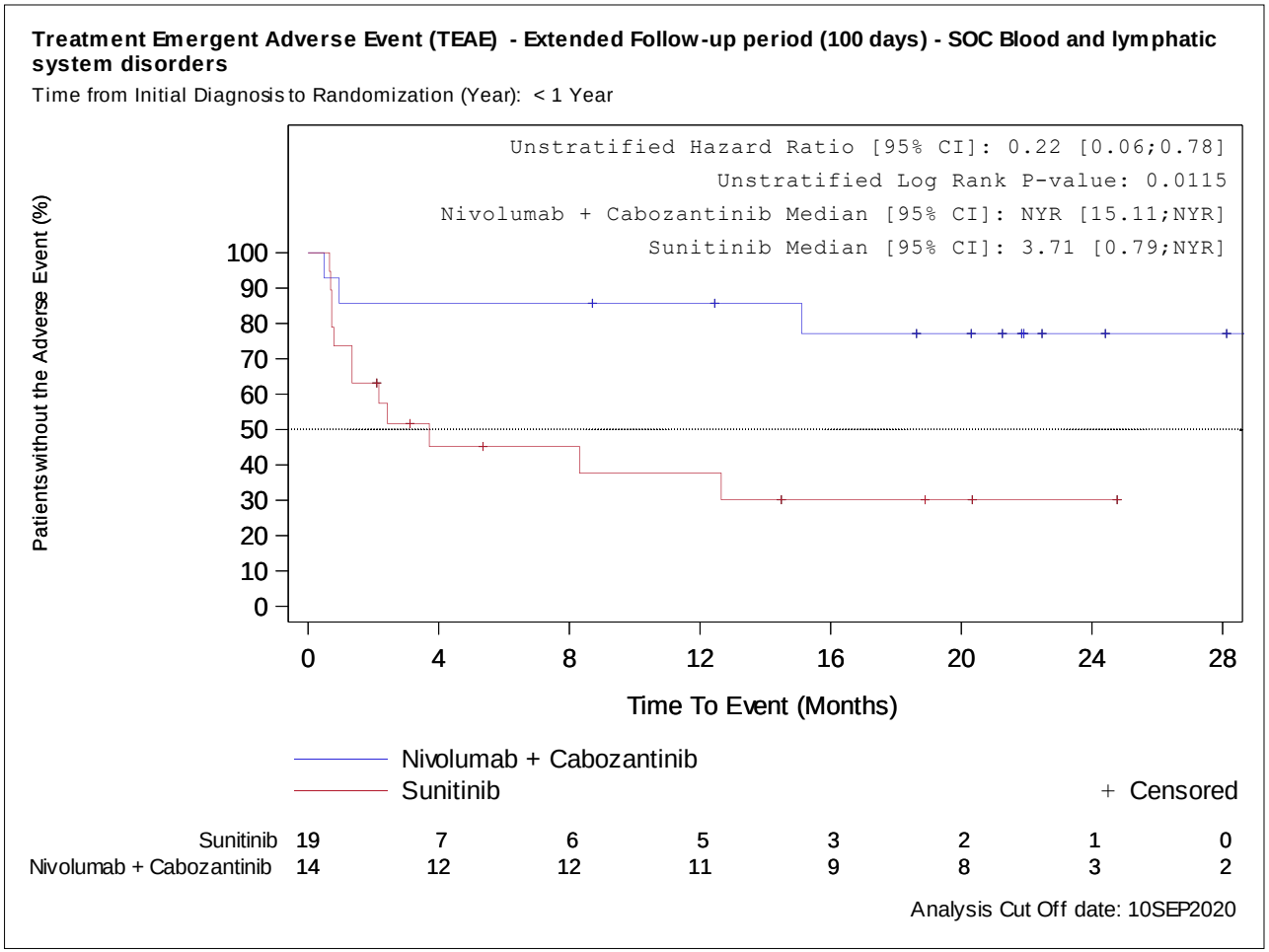
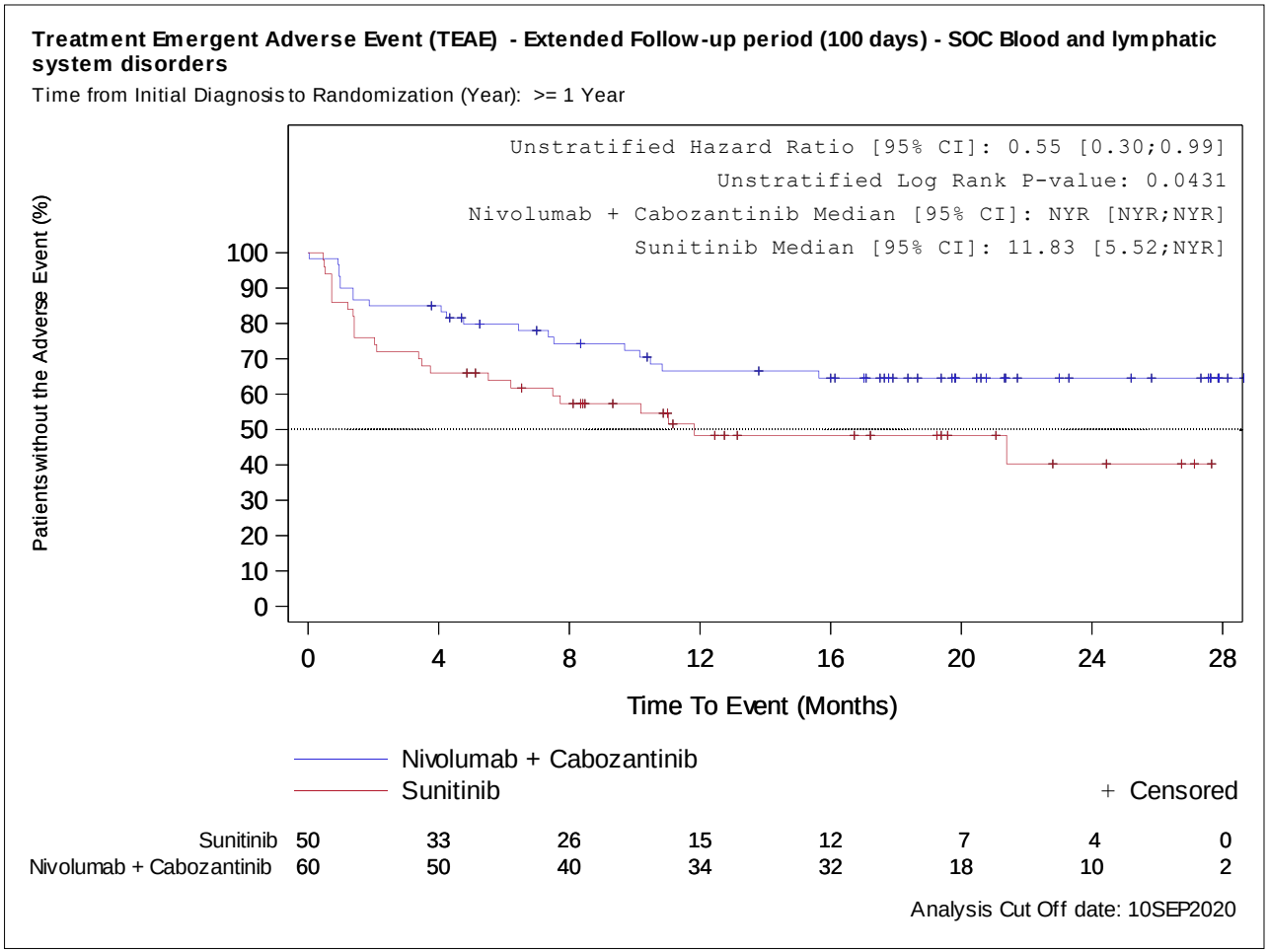
FIGURE 5.20.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



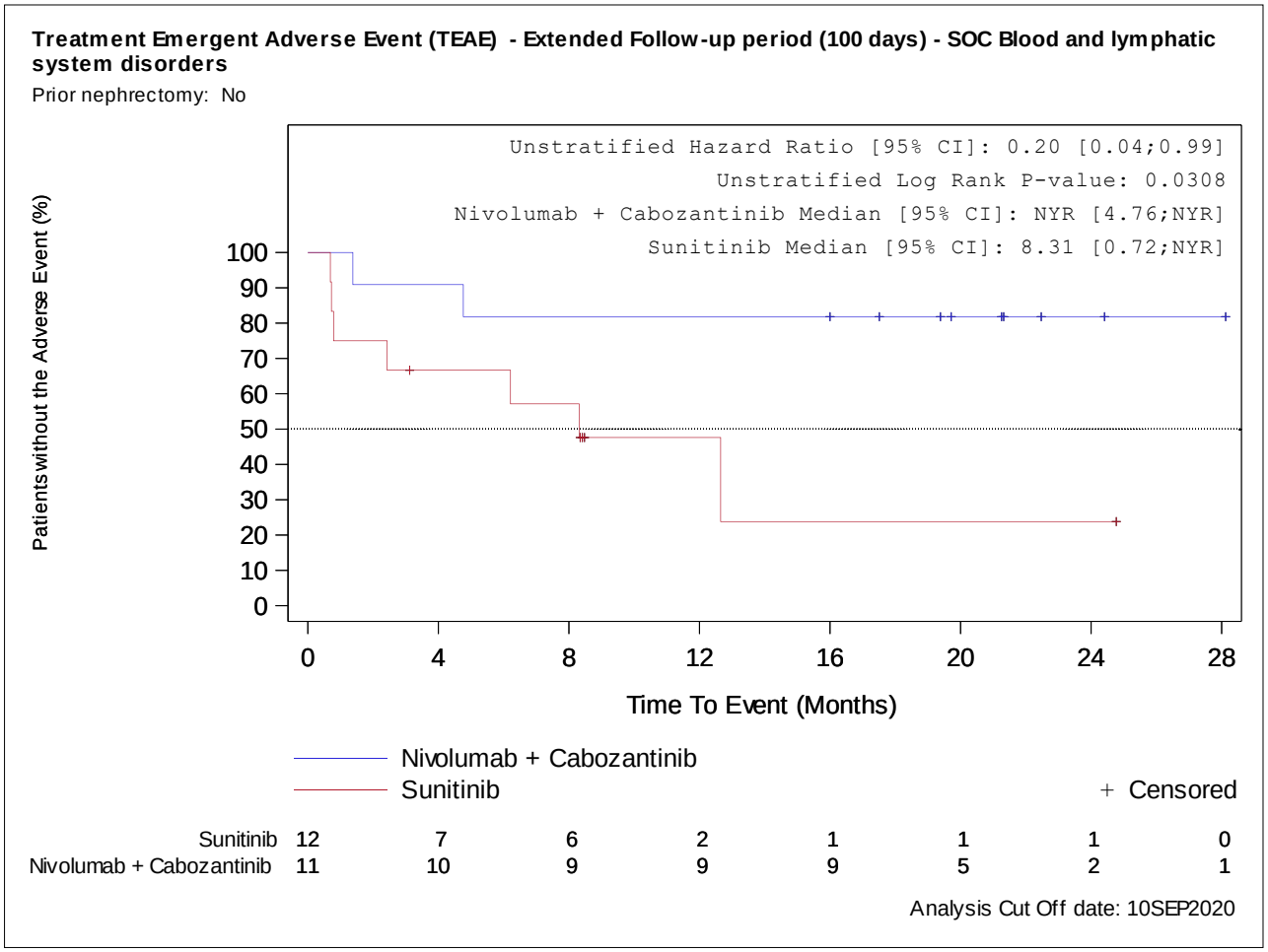

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:03:01

FIGURE 5.20.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



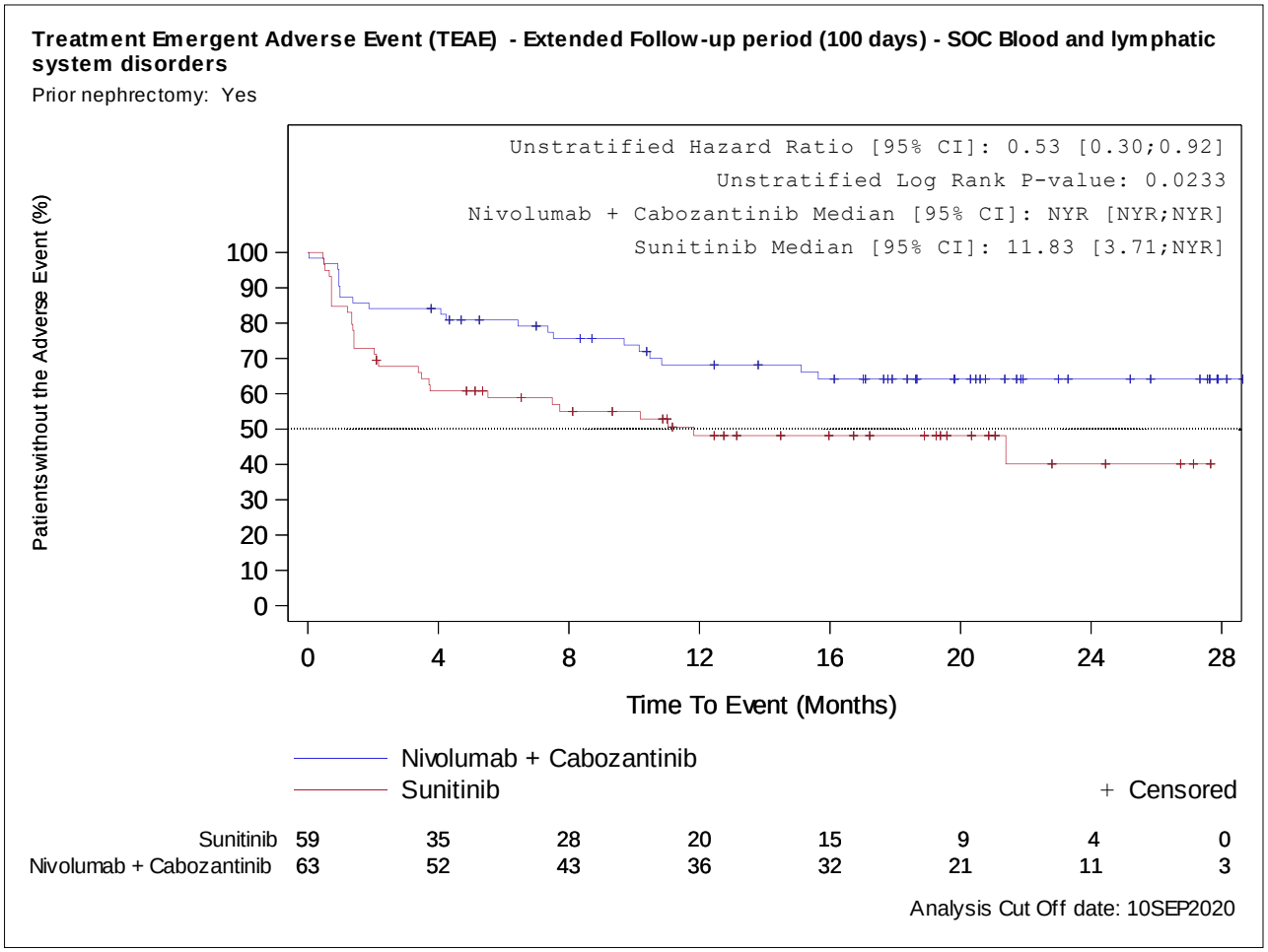

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:03:07

FIGURE 5.20.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:04:00

FIGURE 5.20.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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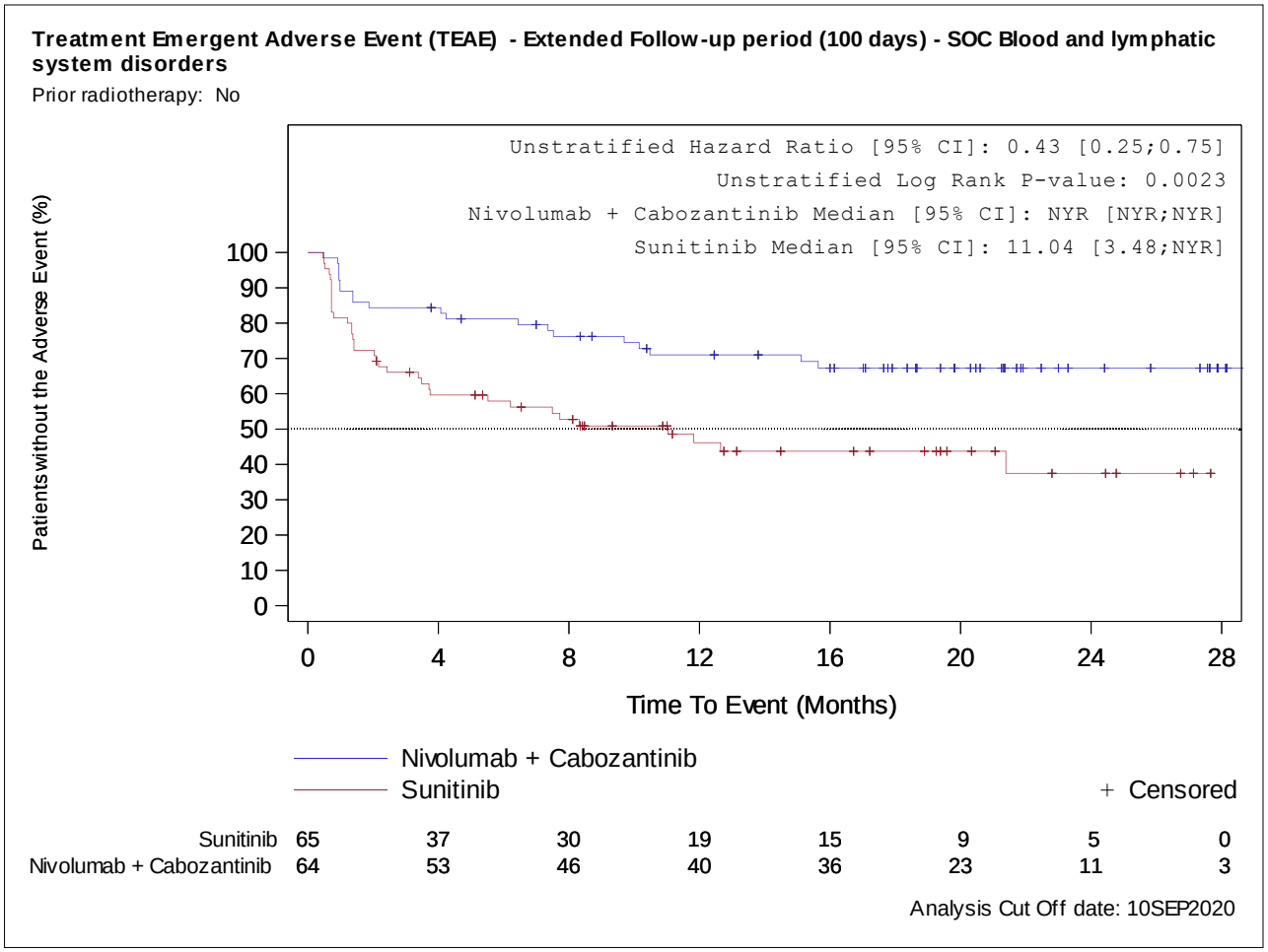
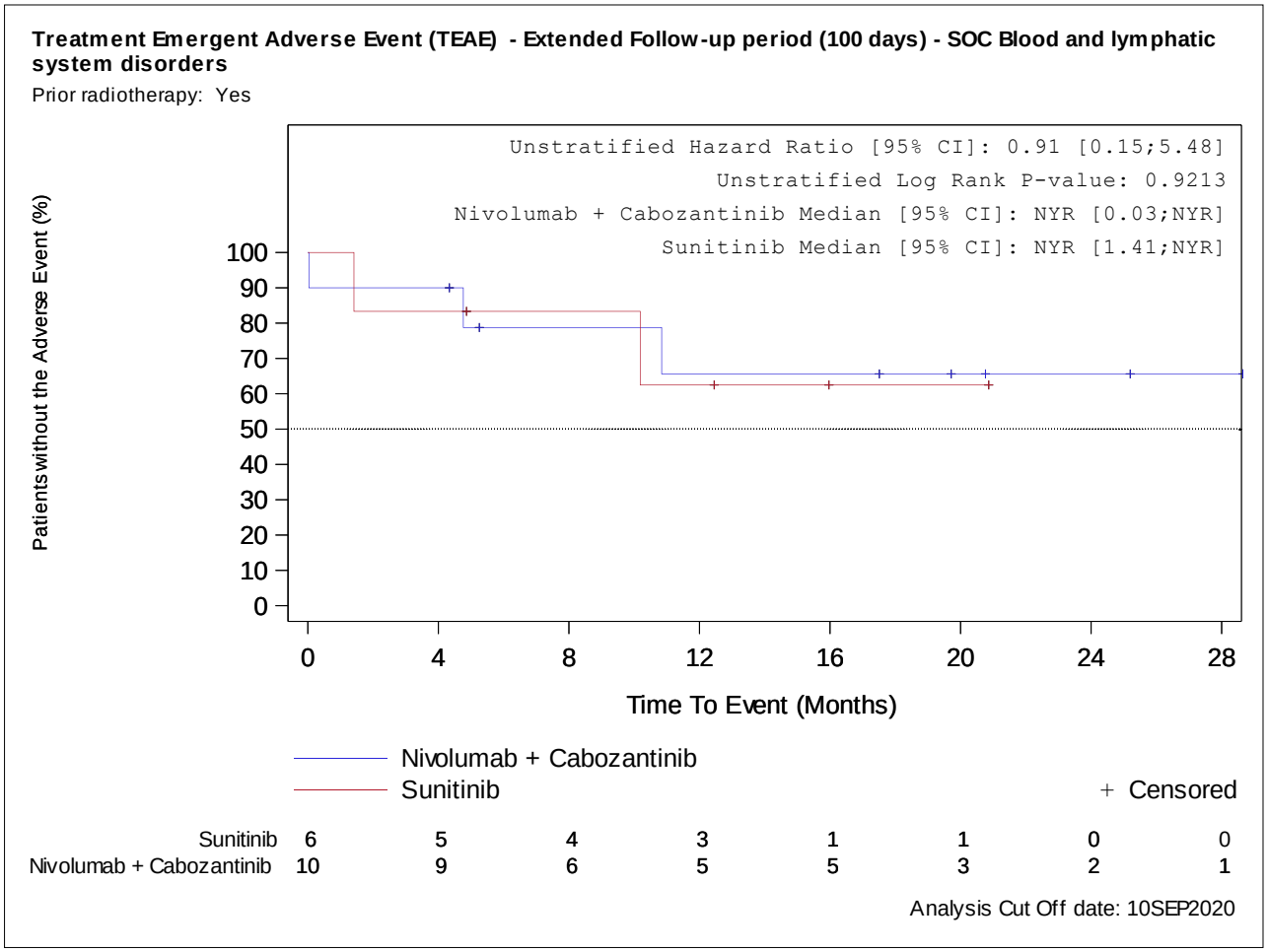
FIGURE 5.20.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



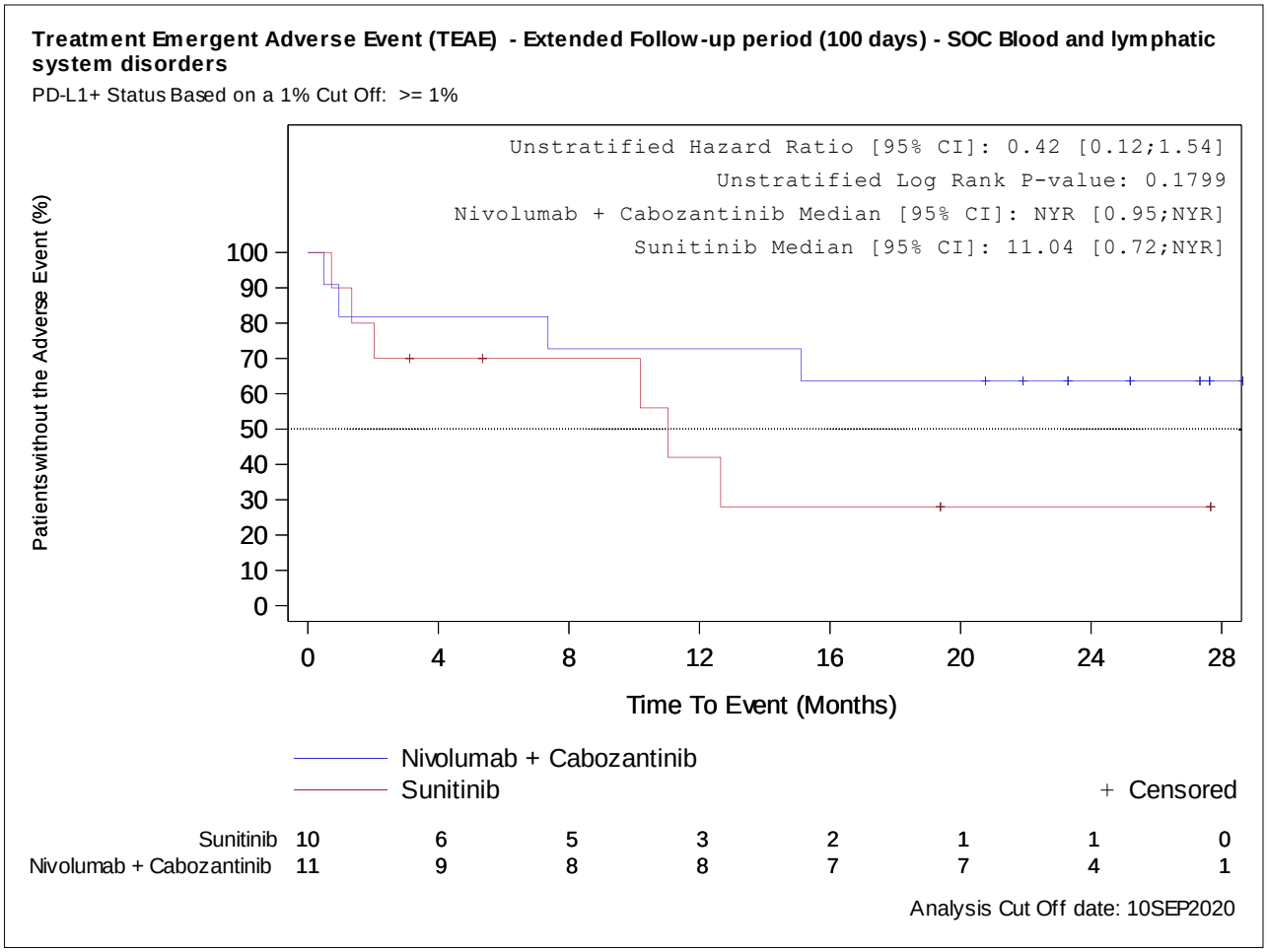

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:04:11

FIGURE 5.20.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



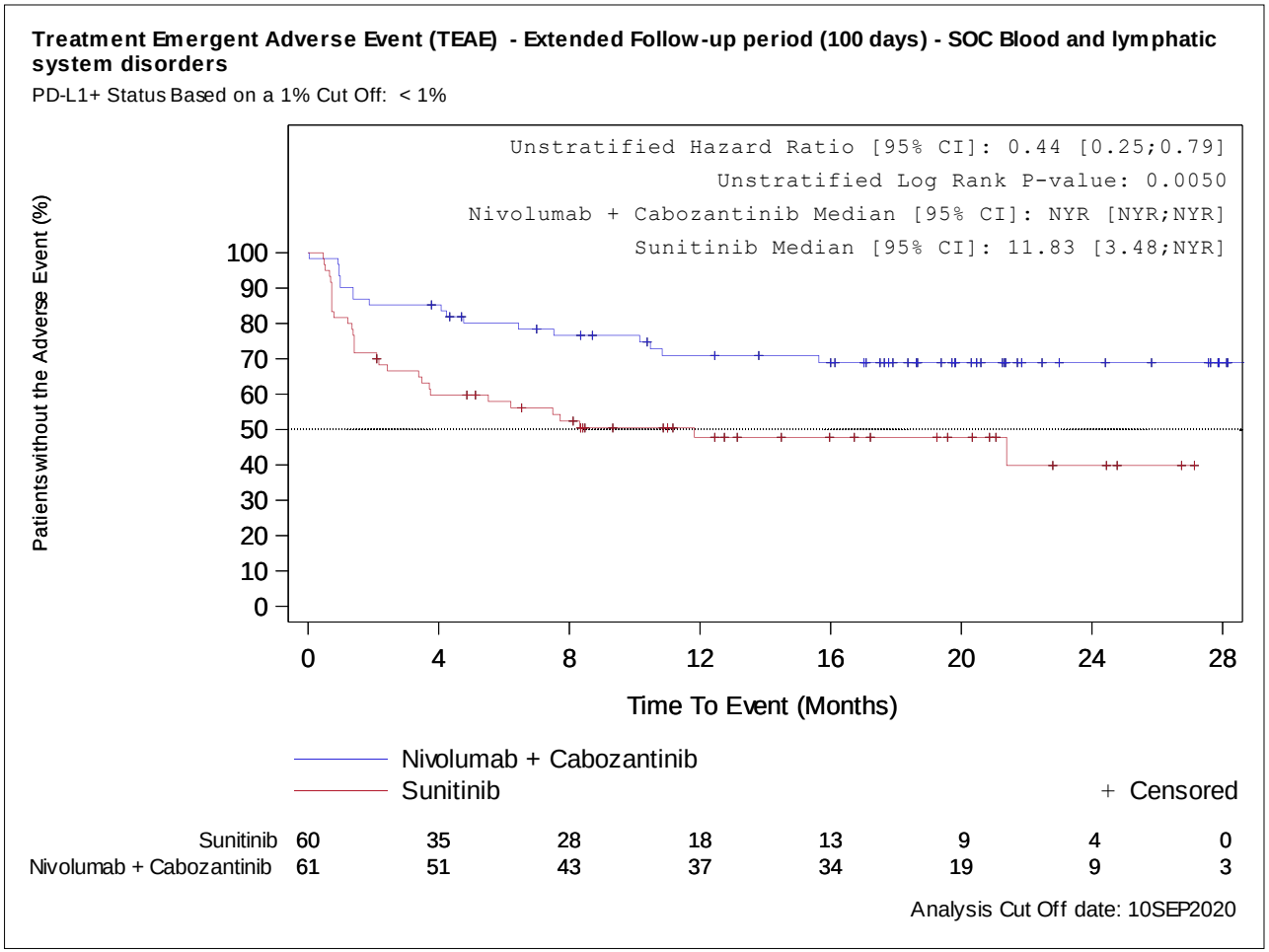

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:04:17

FIGURE 5.20.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



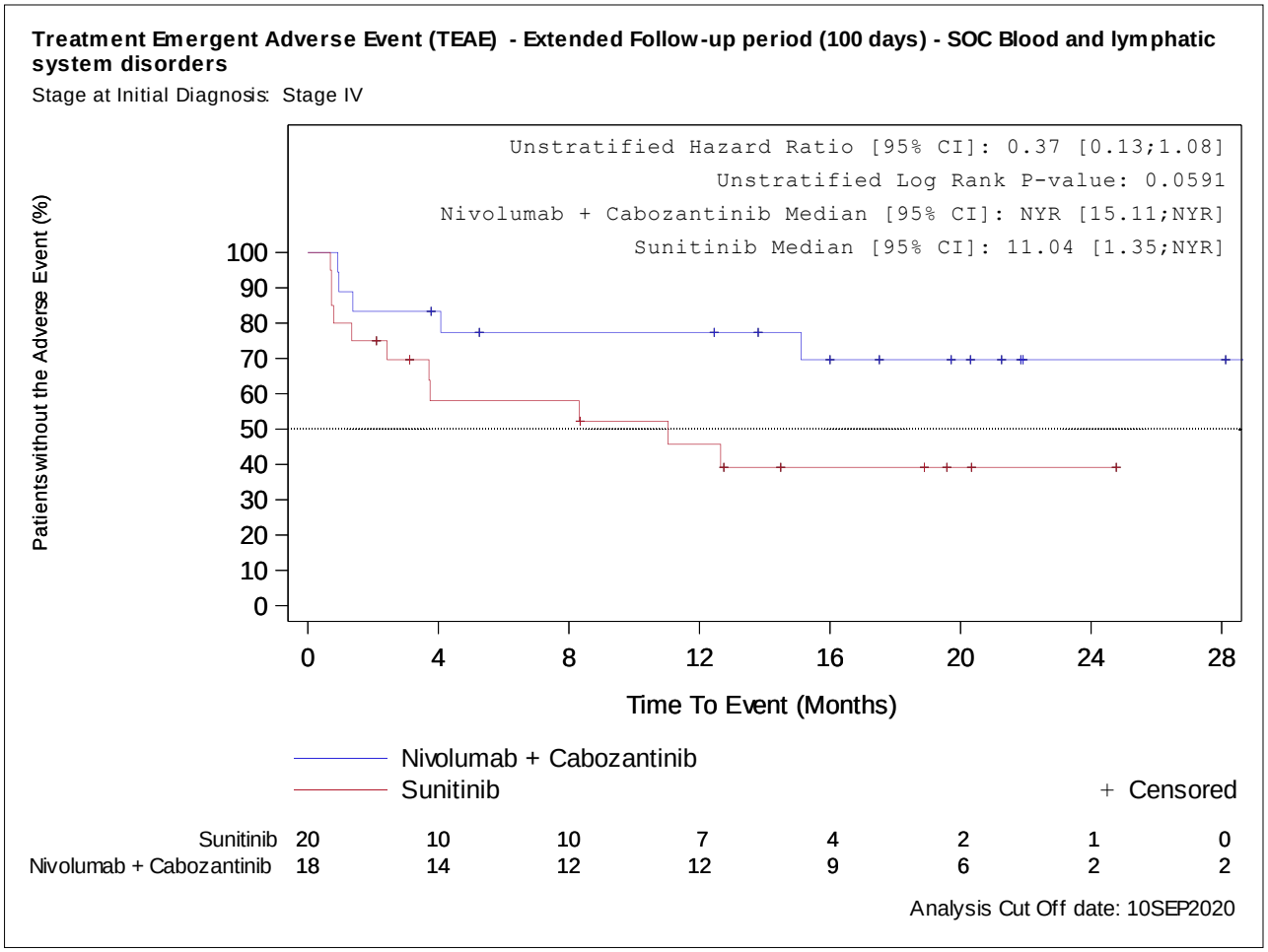

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:04:23

FIGURE 5.20.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



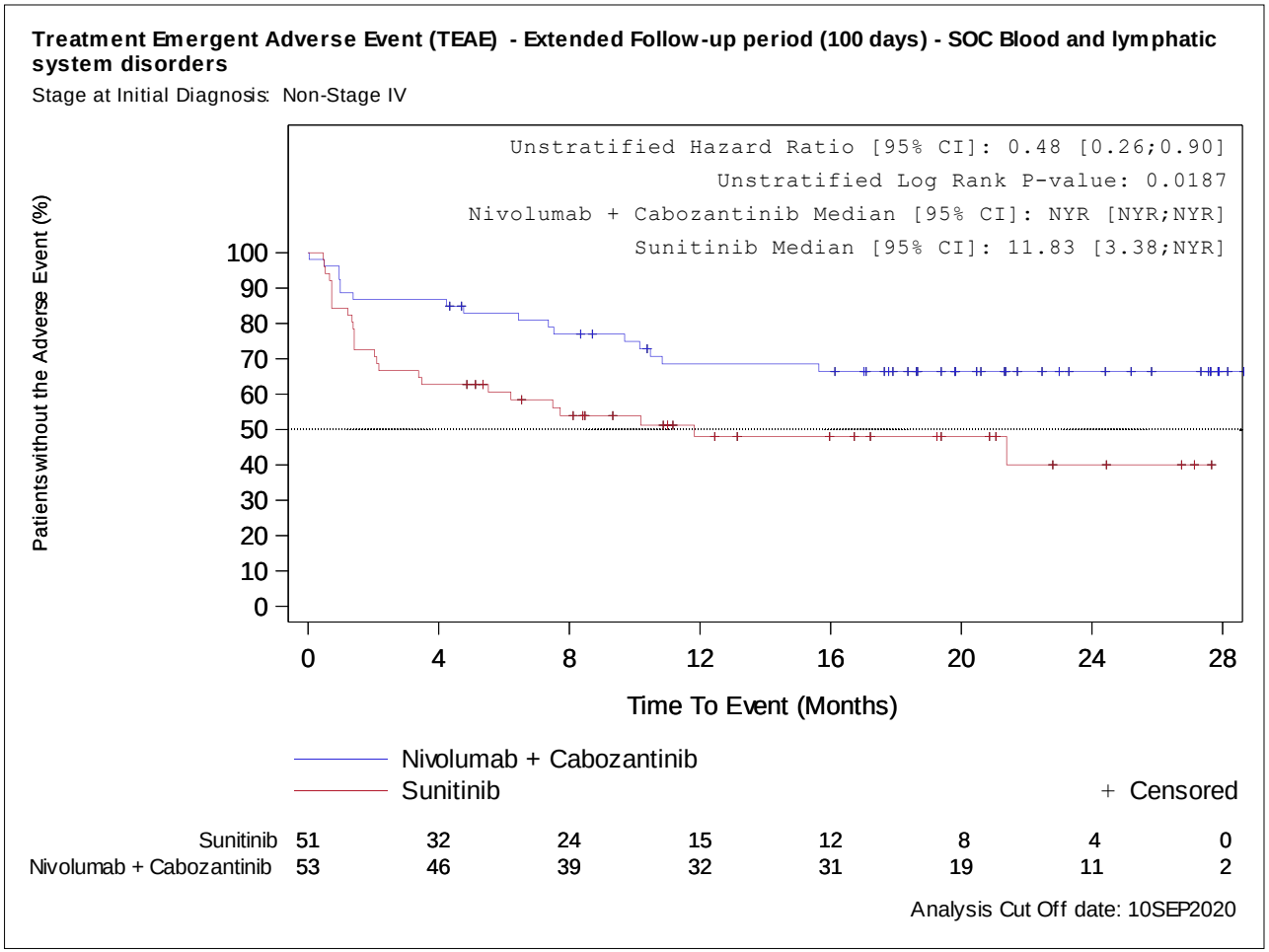

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:04:30

FIGURE 5.20.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



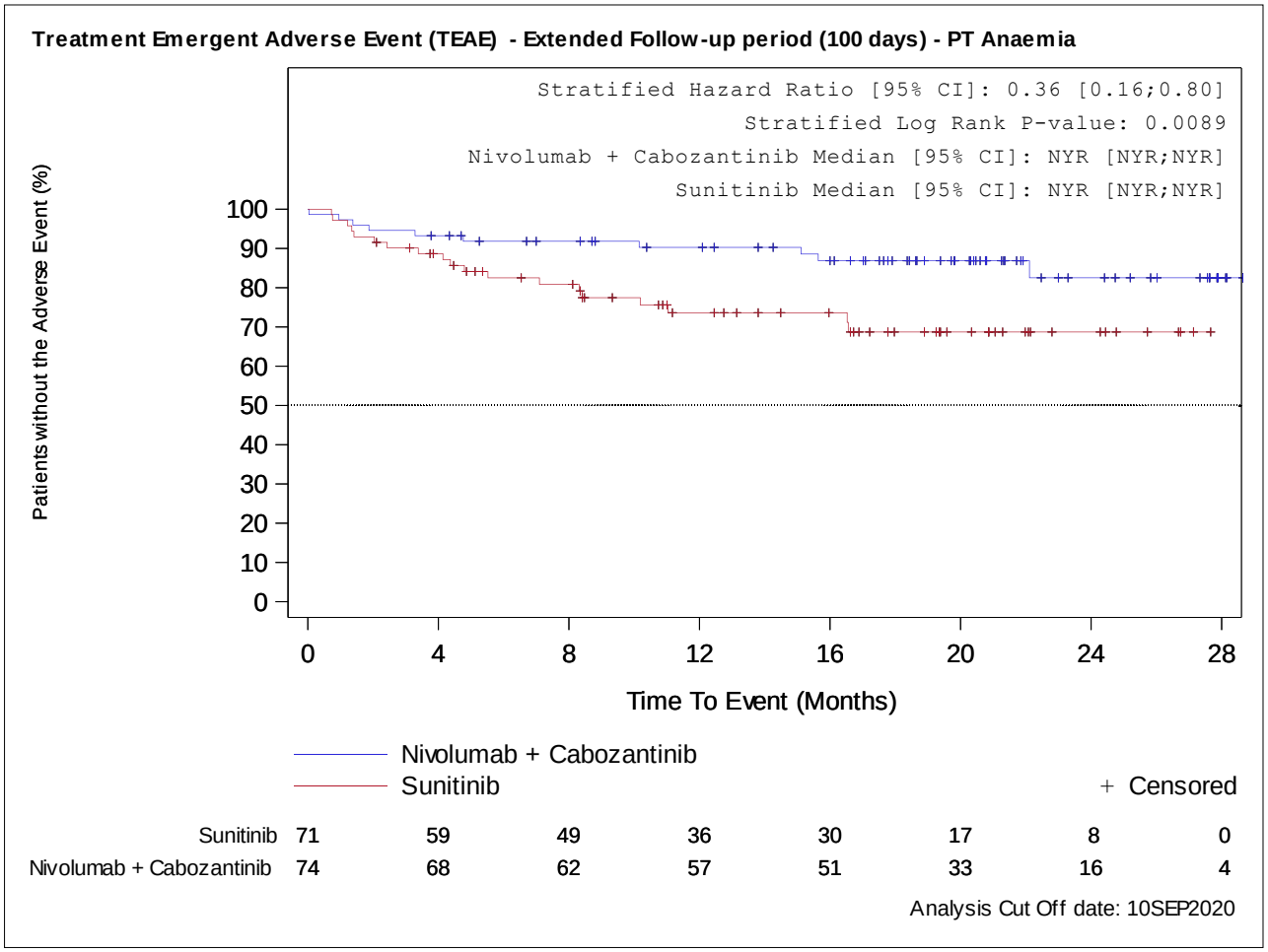

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:04:59

FIGURE 5.20.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Blood and lymphatic system disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



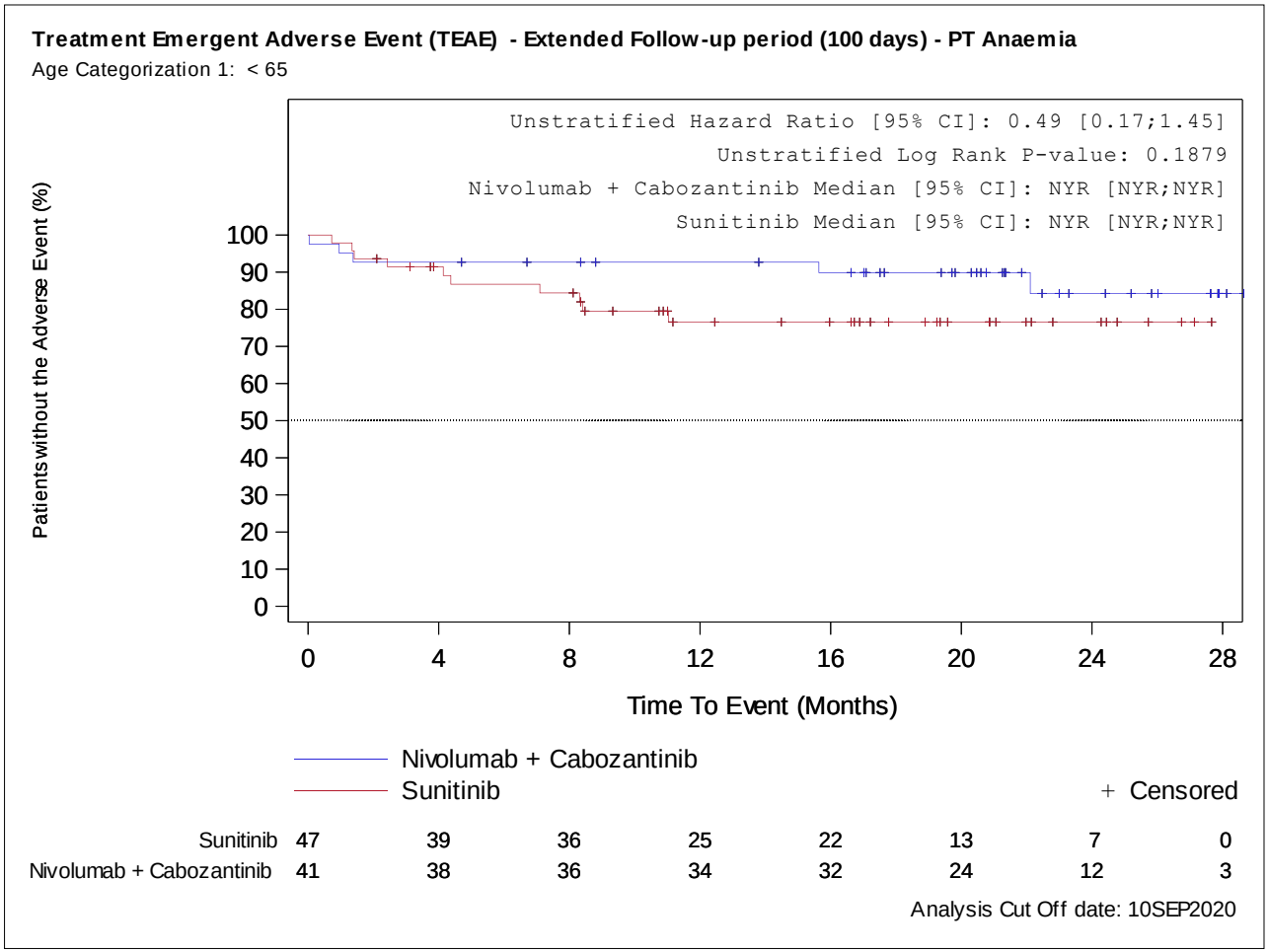

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:05:05

FIGURE 5.21.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:08:23

FIGURE 5.21.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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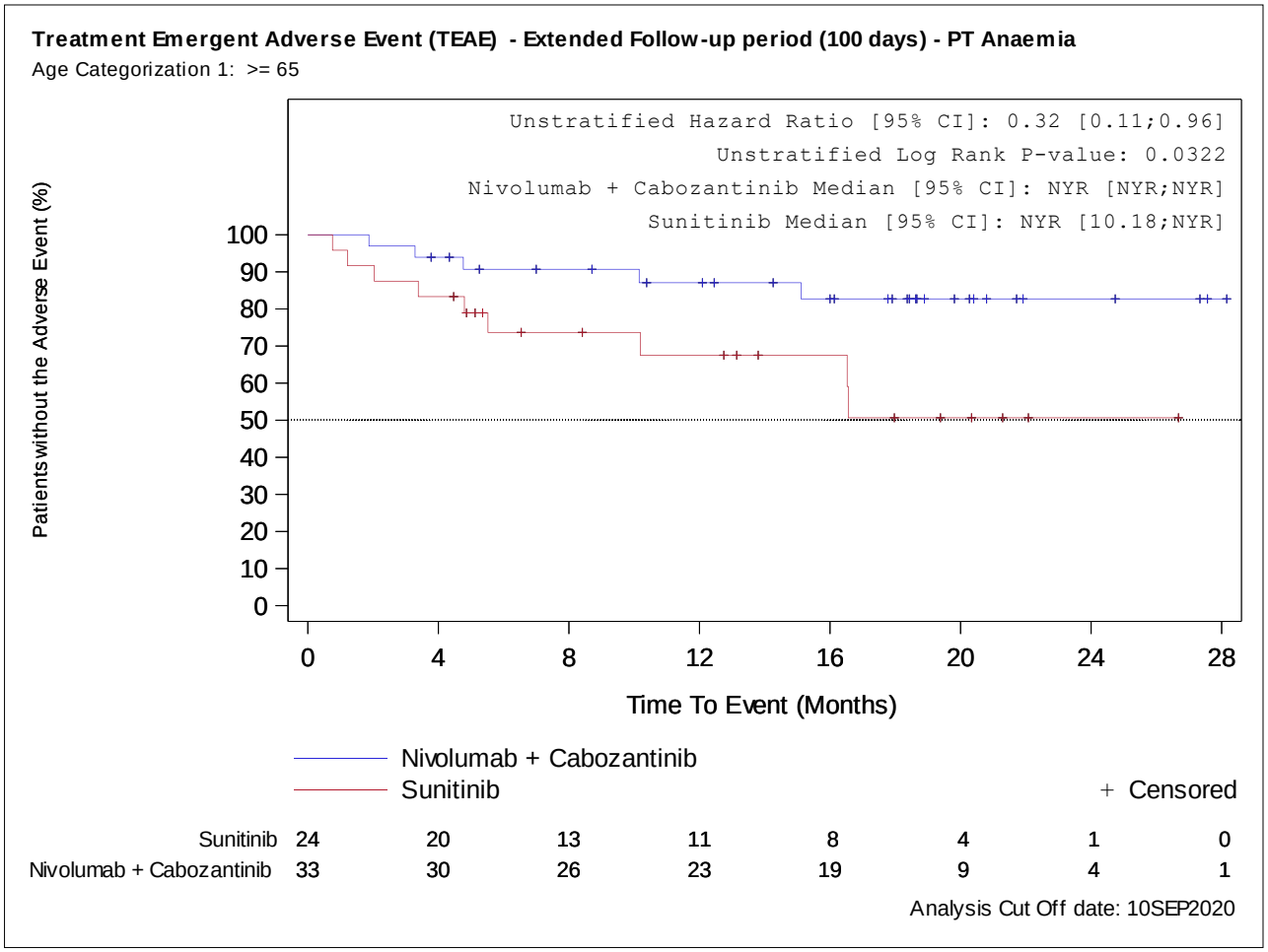
FIGURE 5.21.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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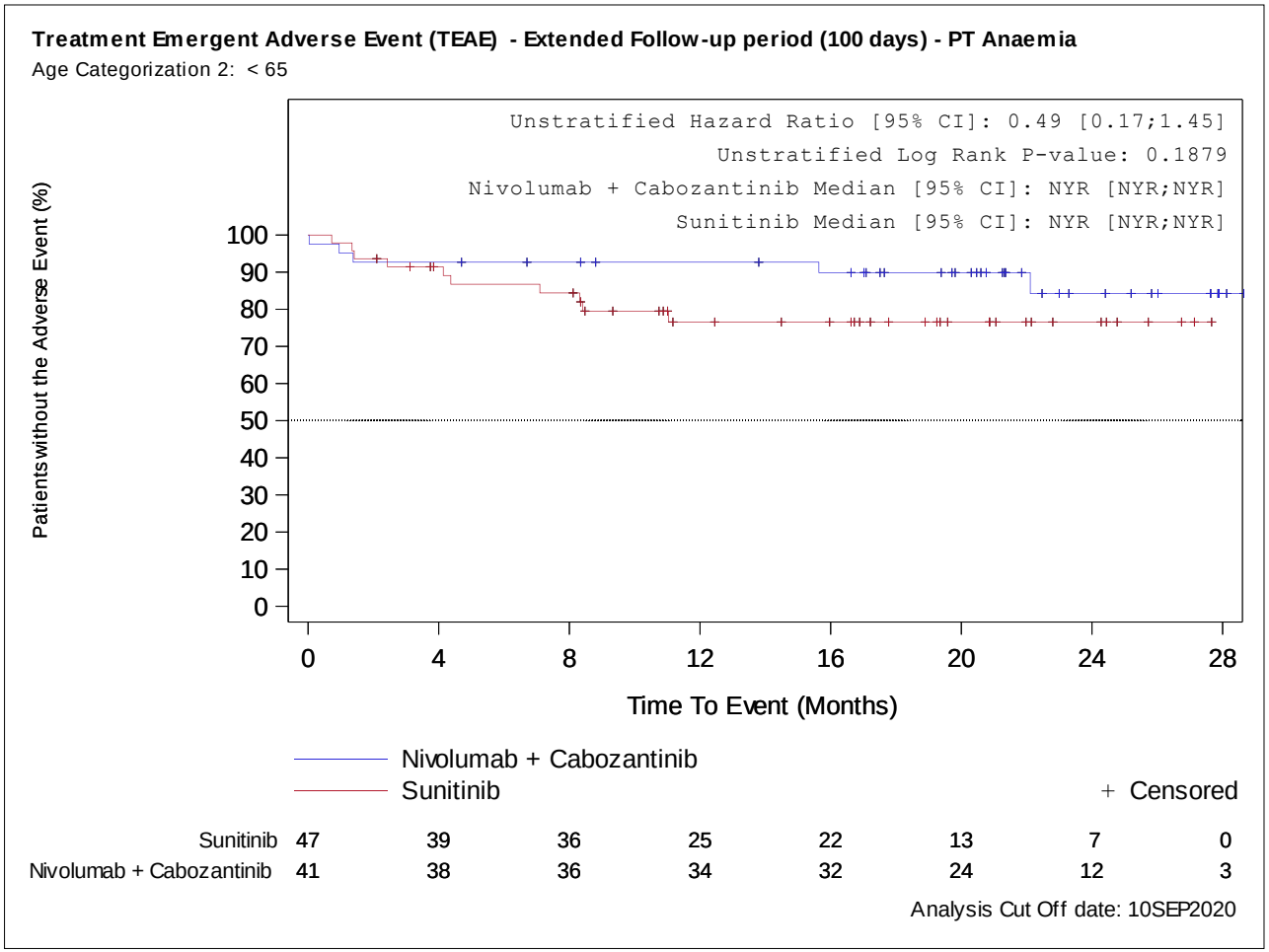
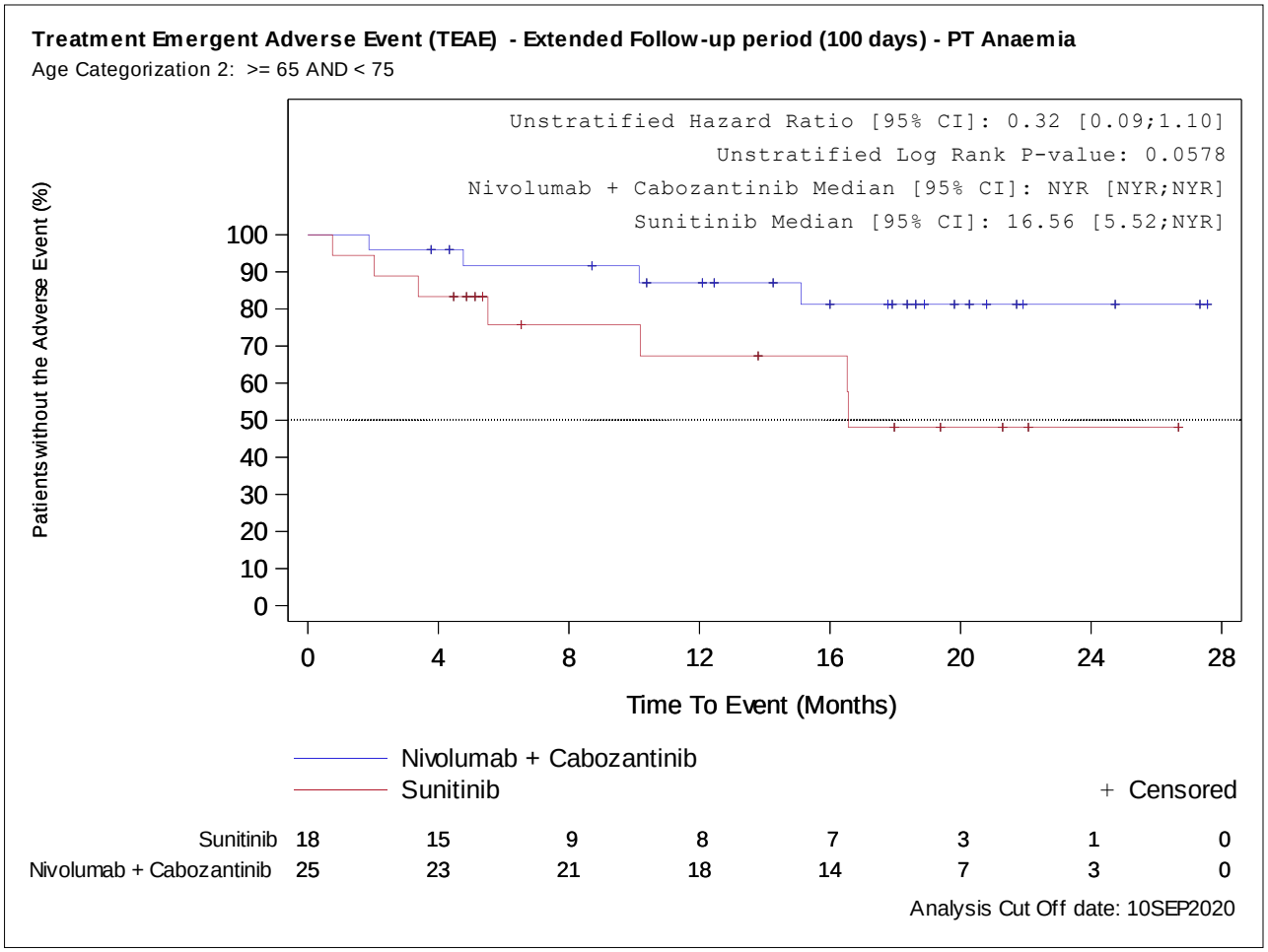
FIGURE 5.21.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



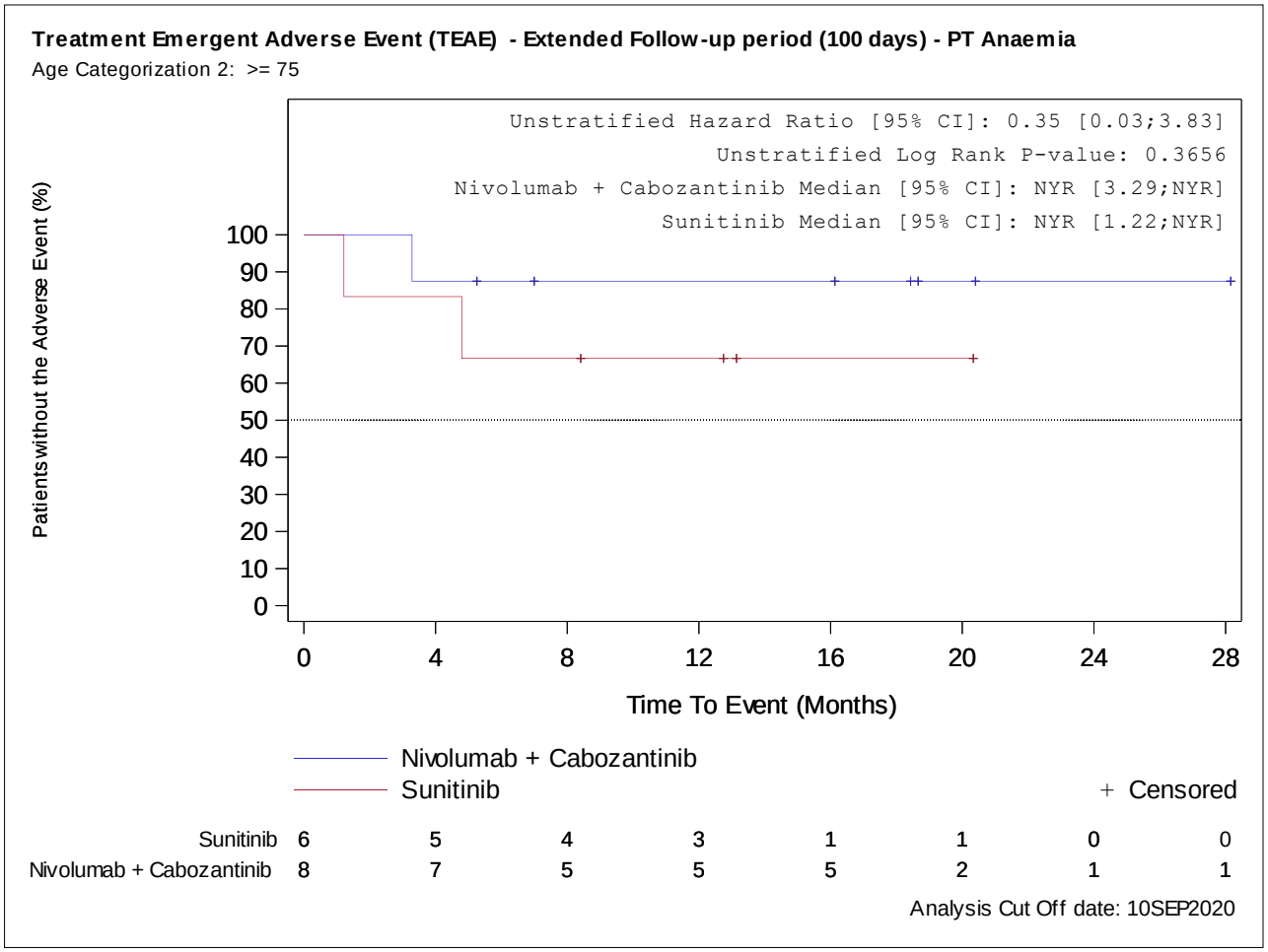

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:08:38

FIGURE 5.21.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



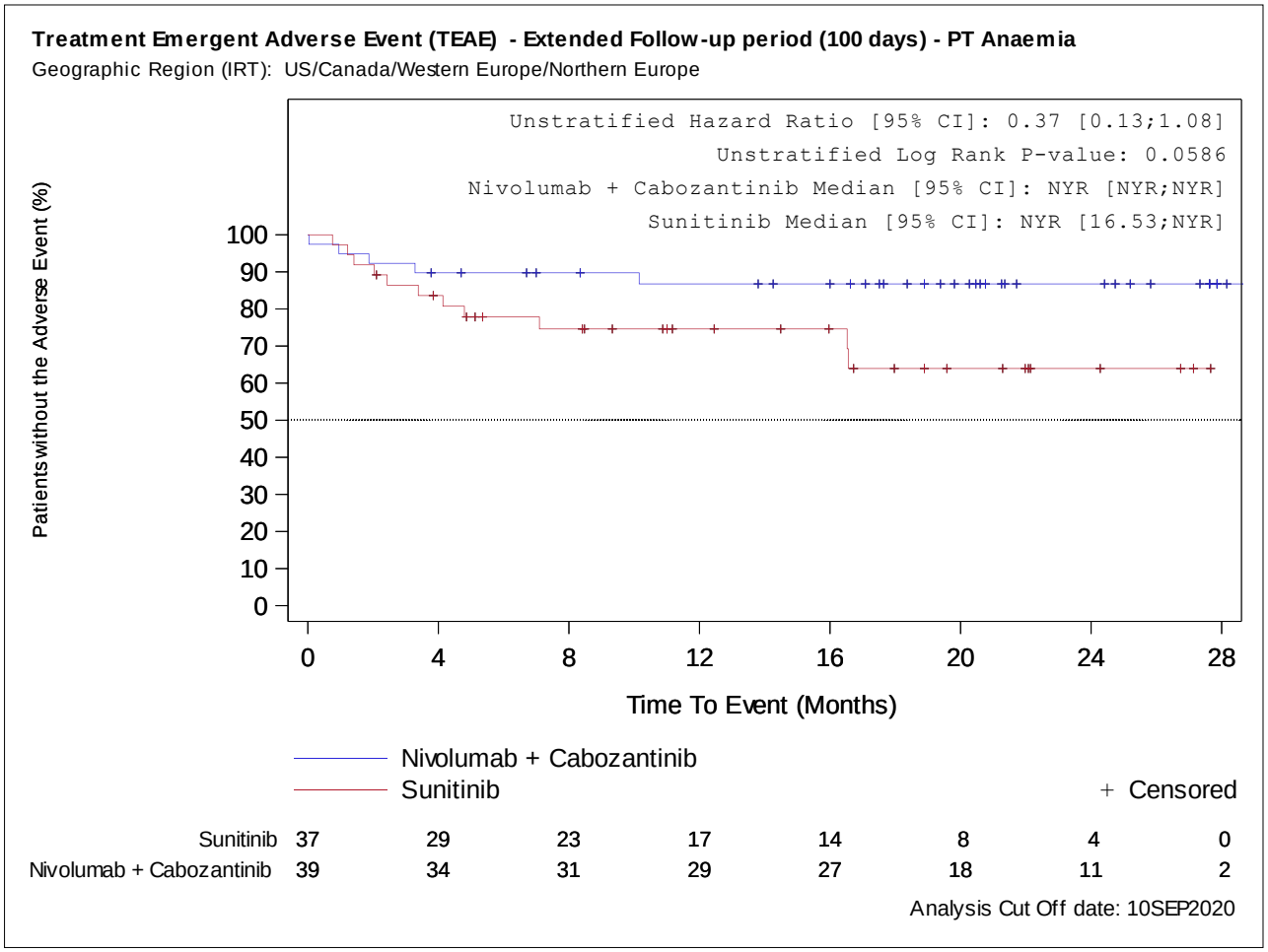

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:08:44

FIGURE 5.21.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



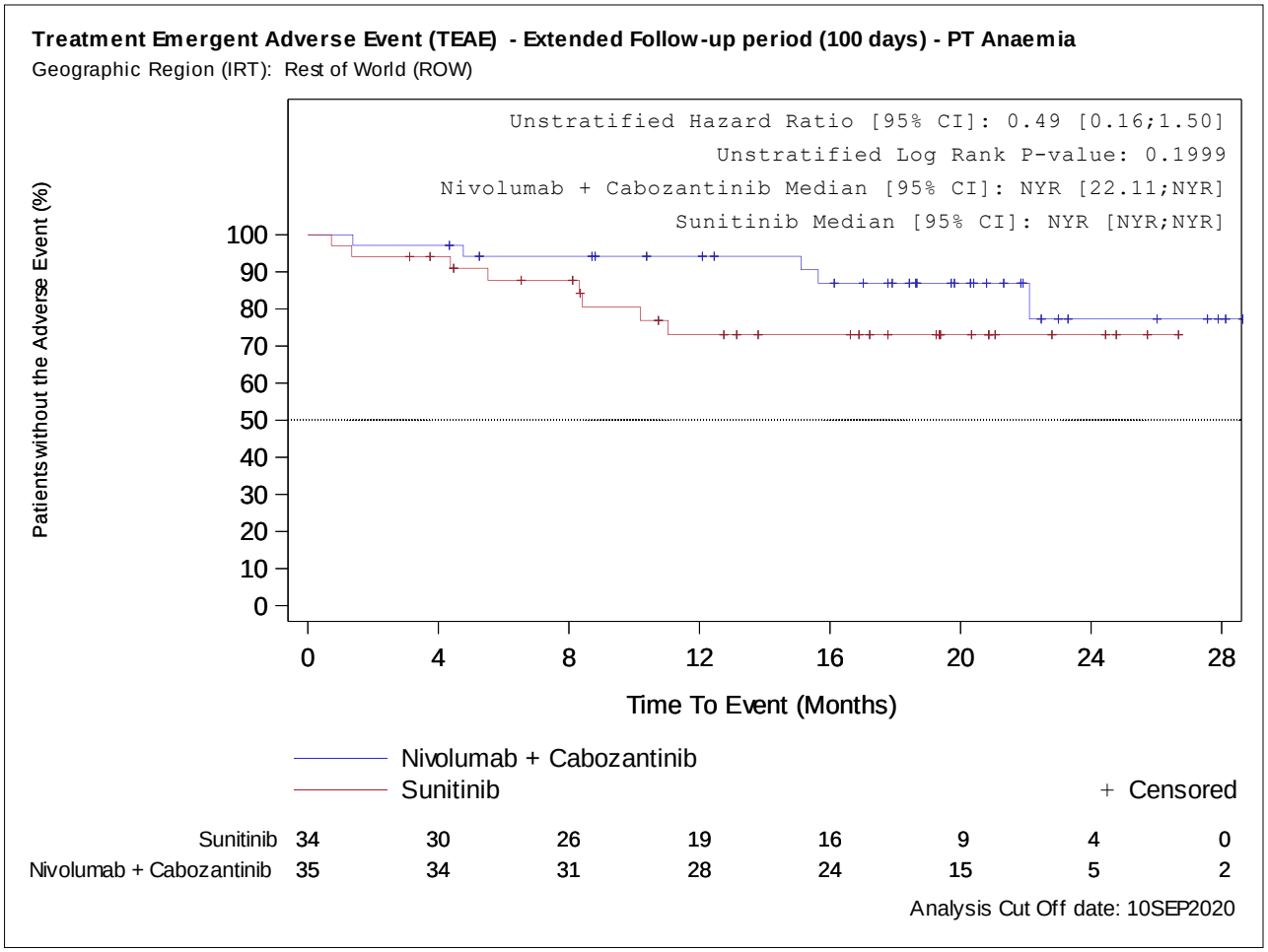

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:08:49

FIGURE 5.21.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



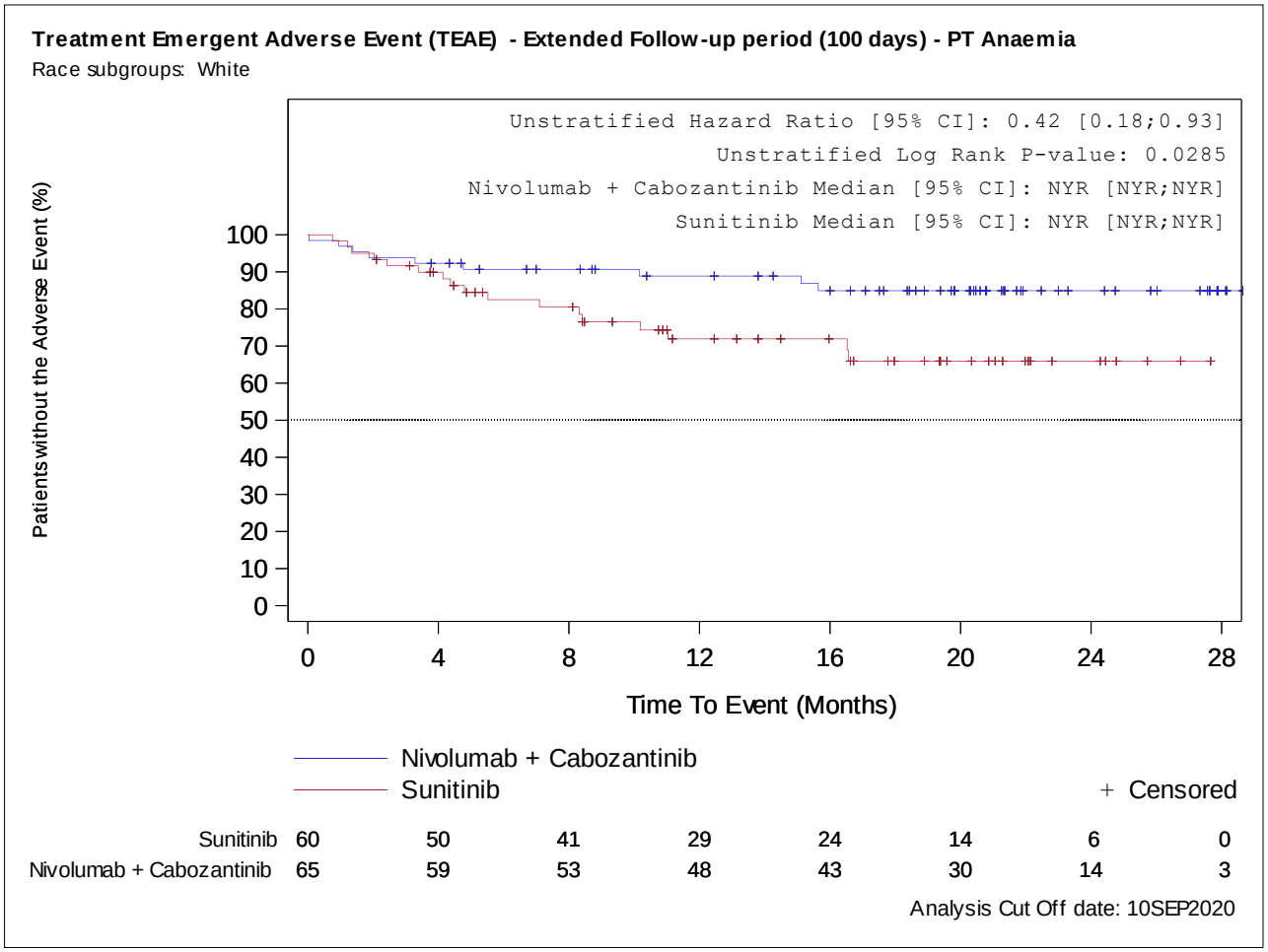

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:08:55

FIGURE 5.21.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



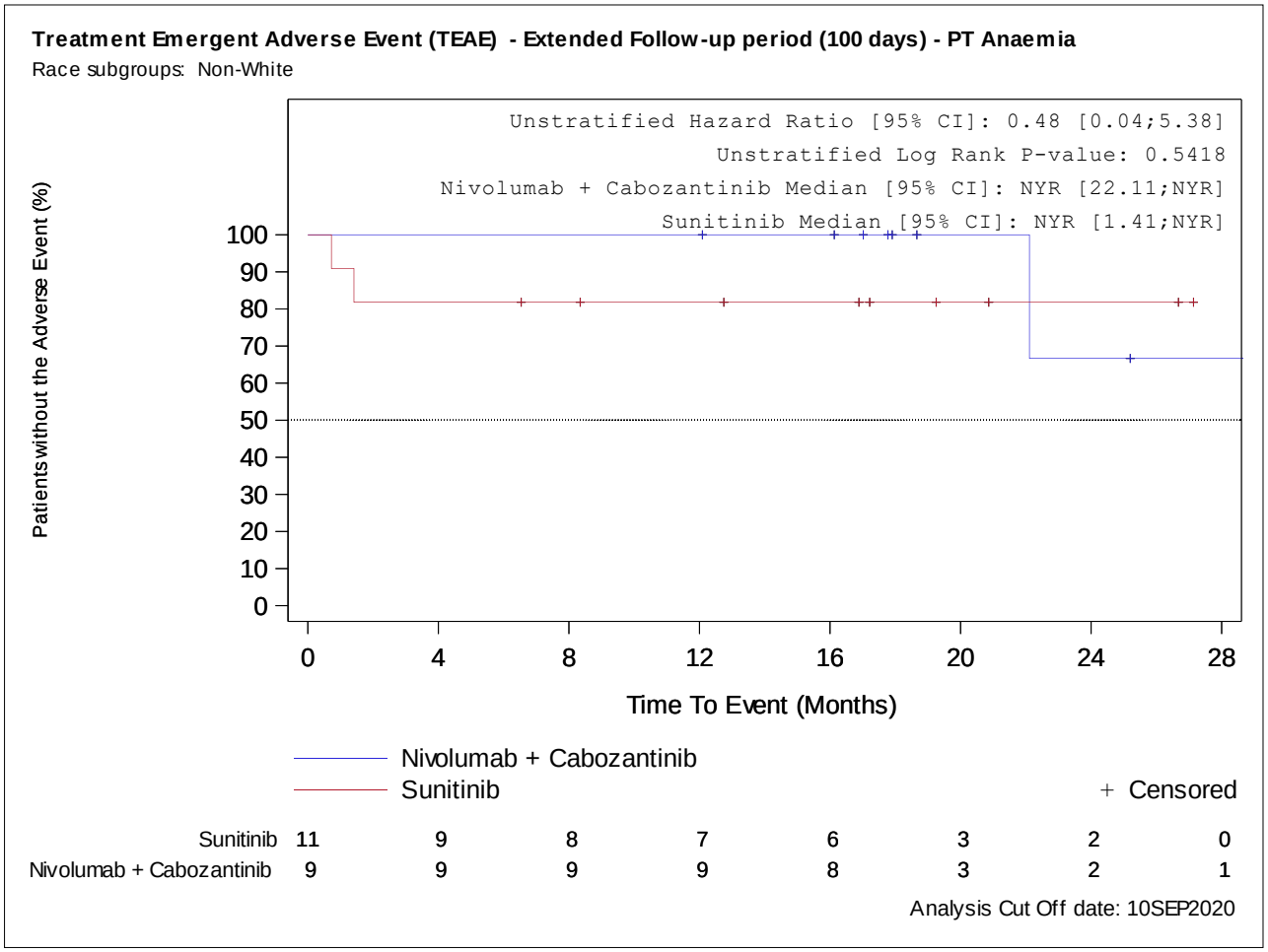

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:09:00

FIGURE 5.21.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



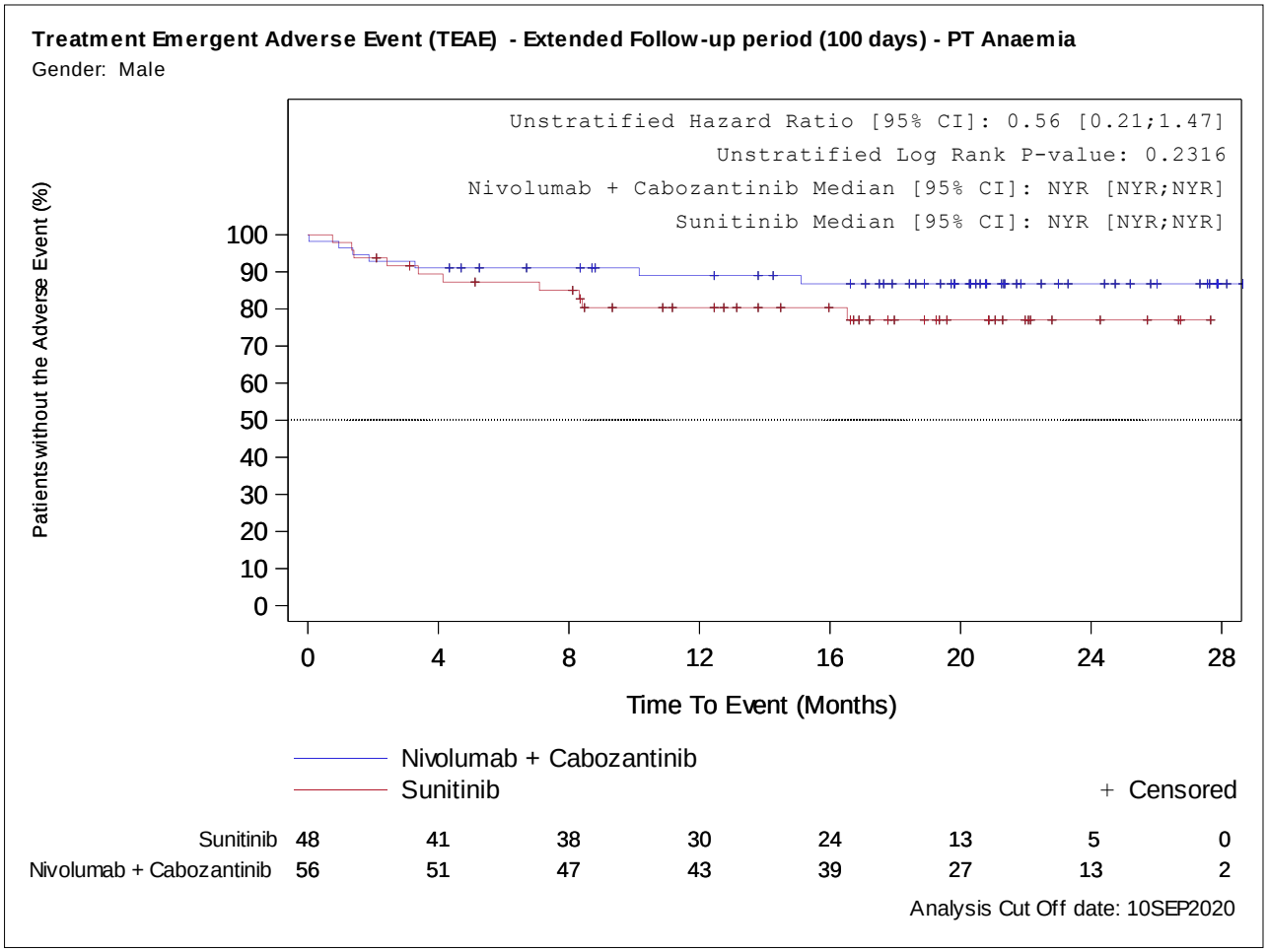

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:09:06

FIGURE 5.21.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



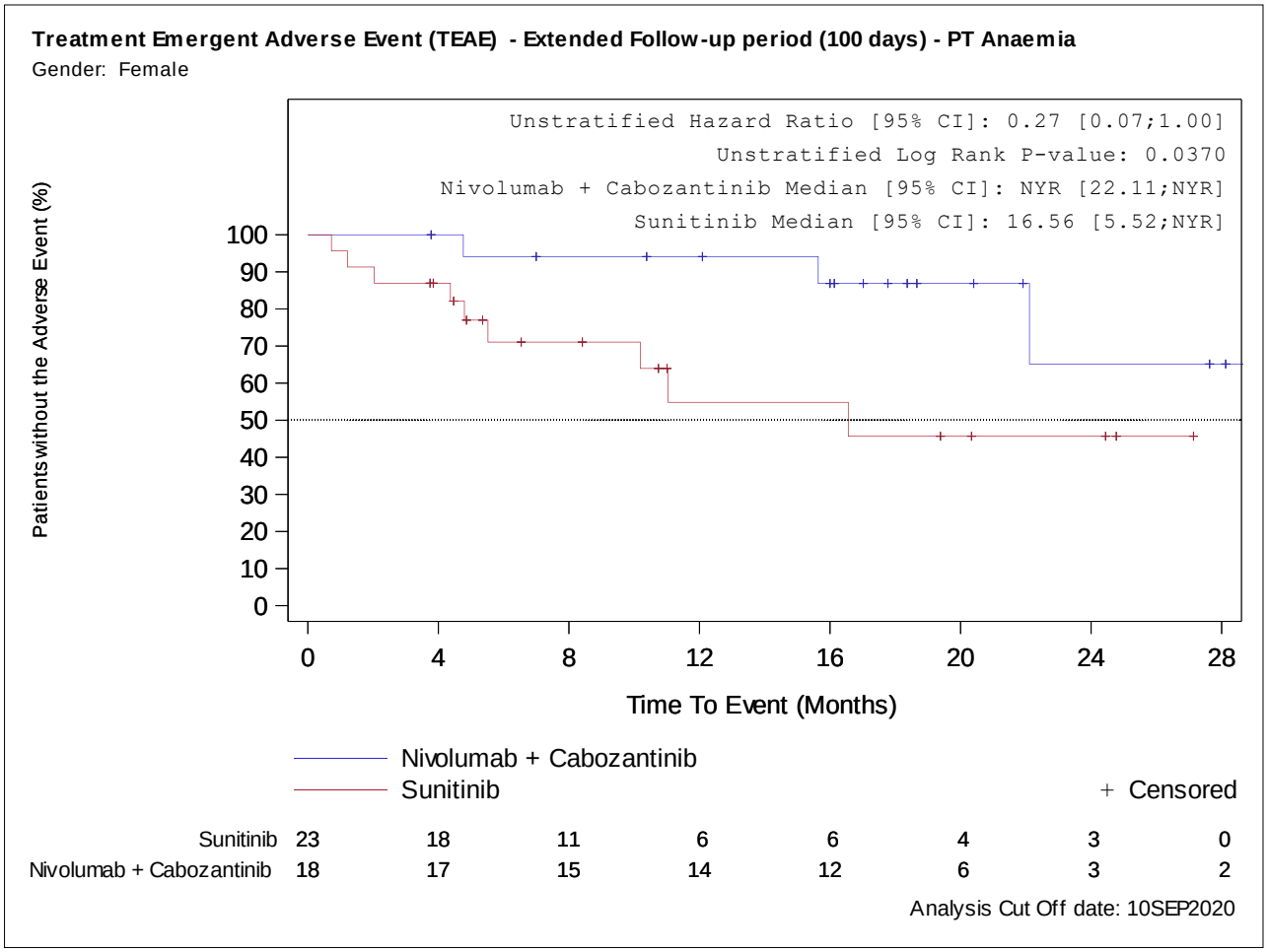

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:09:12

FIGURE 5.21.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



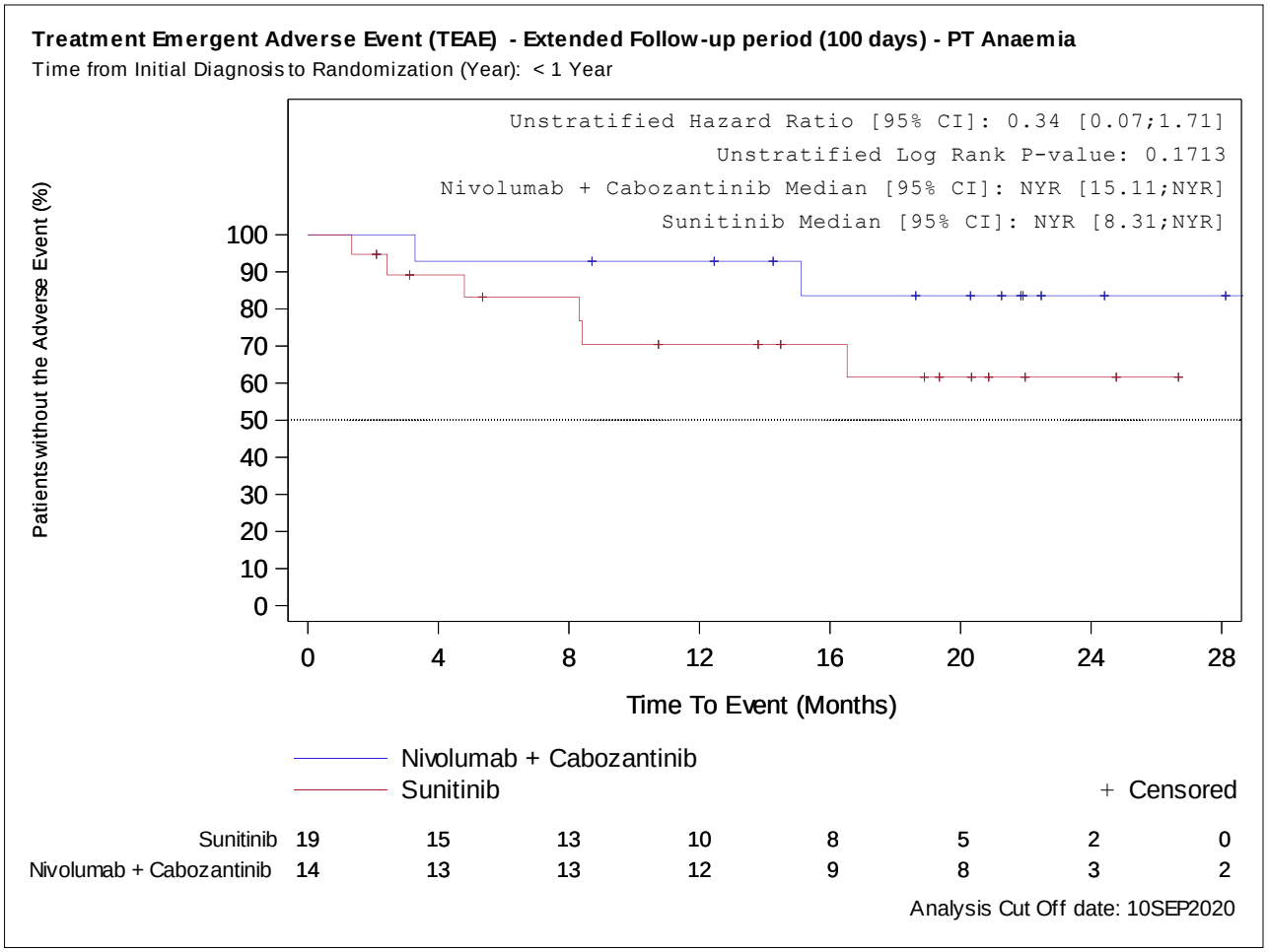

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:09:17

FIGURE 5.21.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



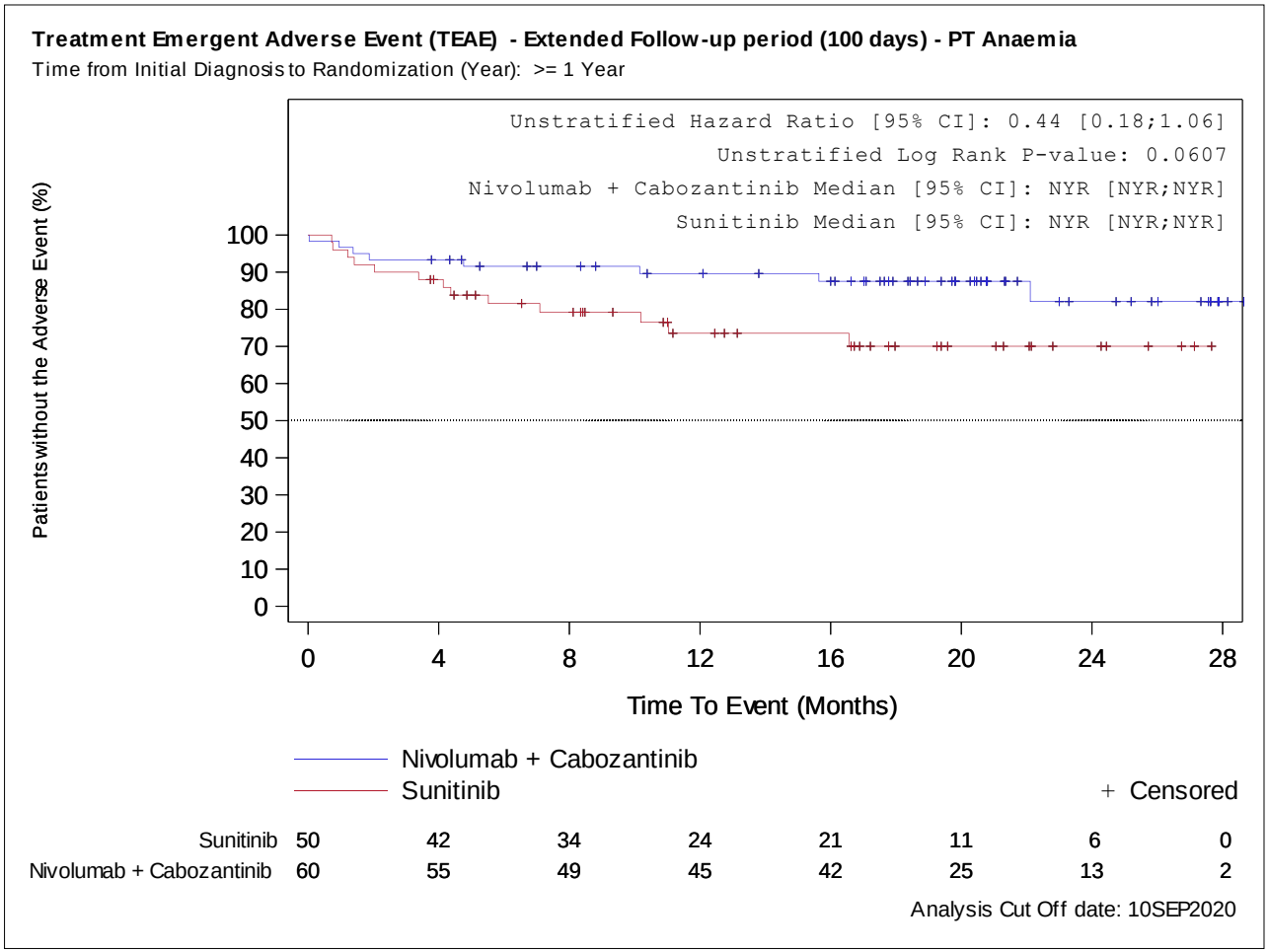

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:09:23

FIGURE 5.21.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



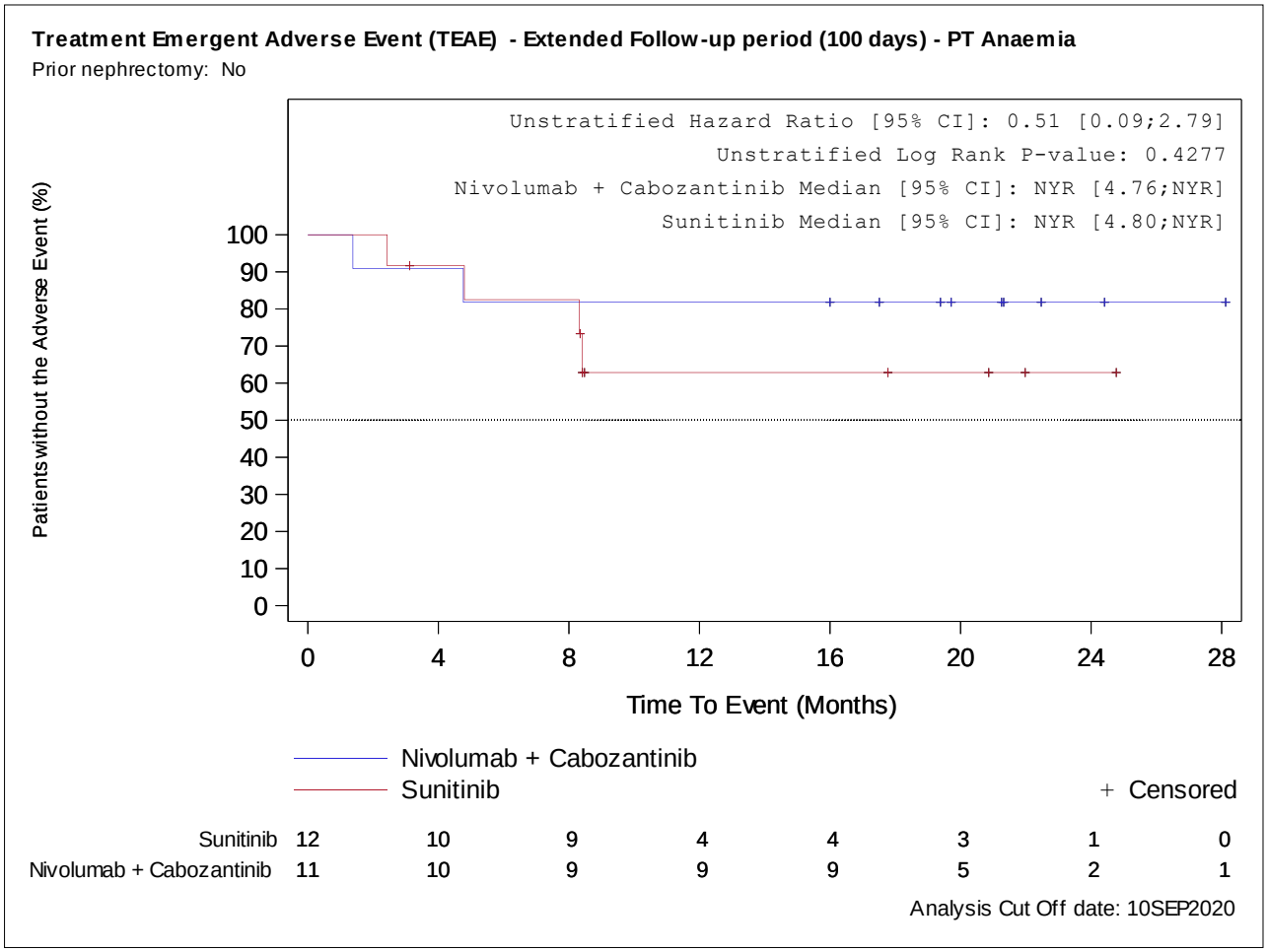

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:09:41

FIGURE 5.21.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



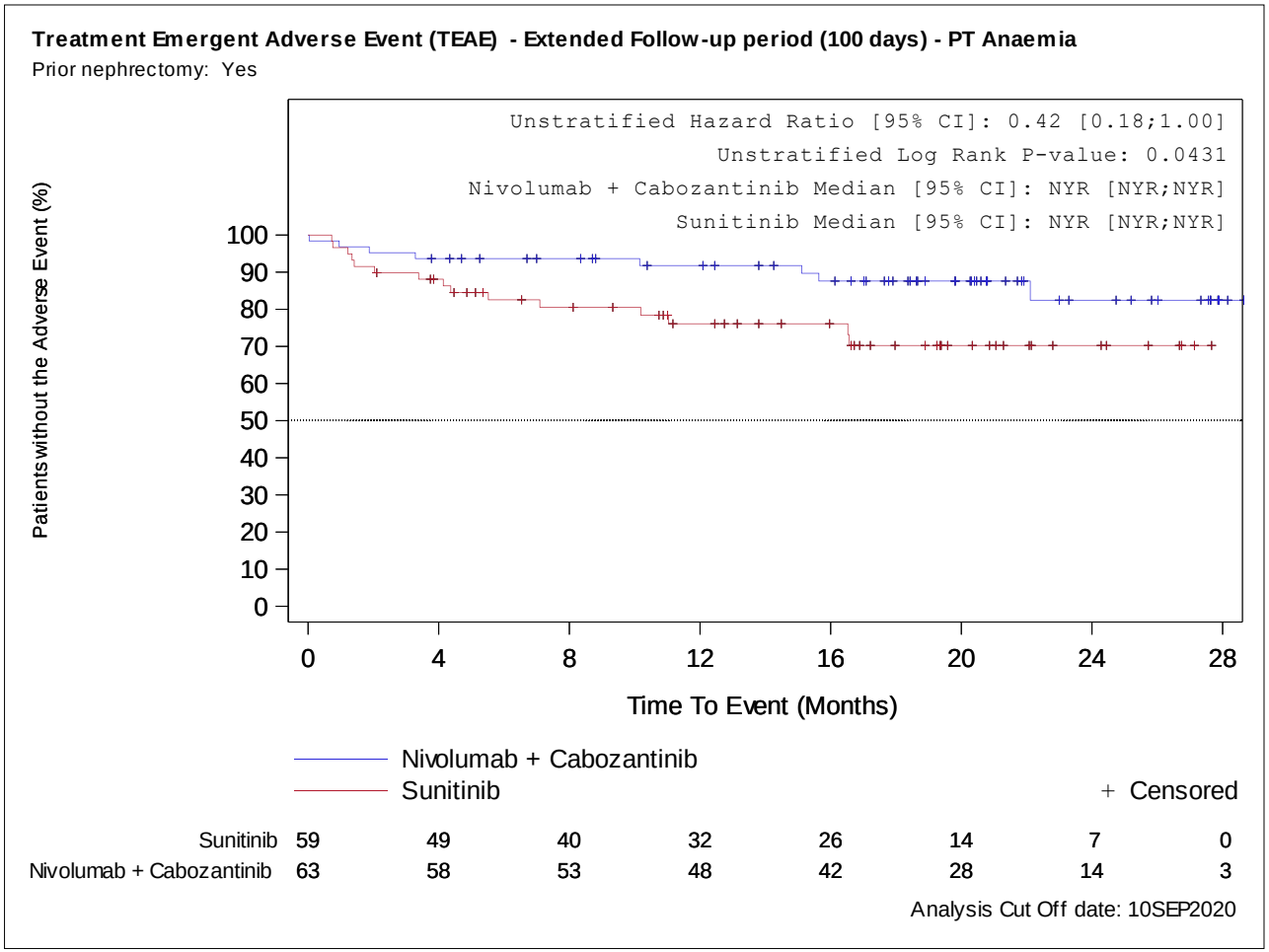

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:09:46

FIGURE 5.21.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:10:39

FIGURE 5.21.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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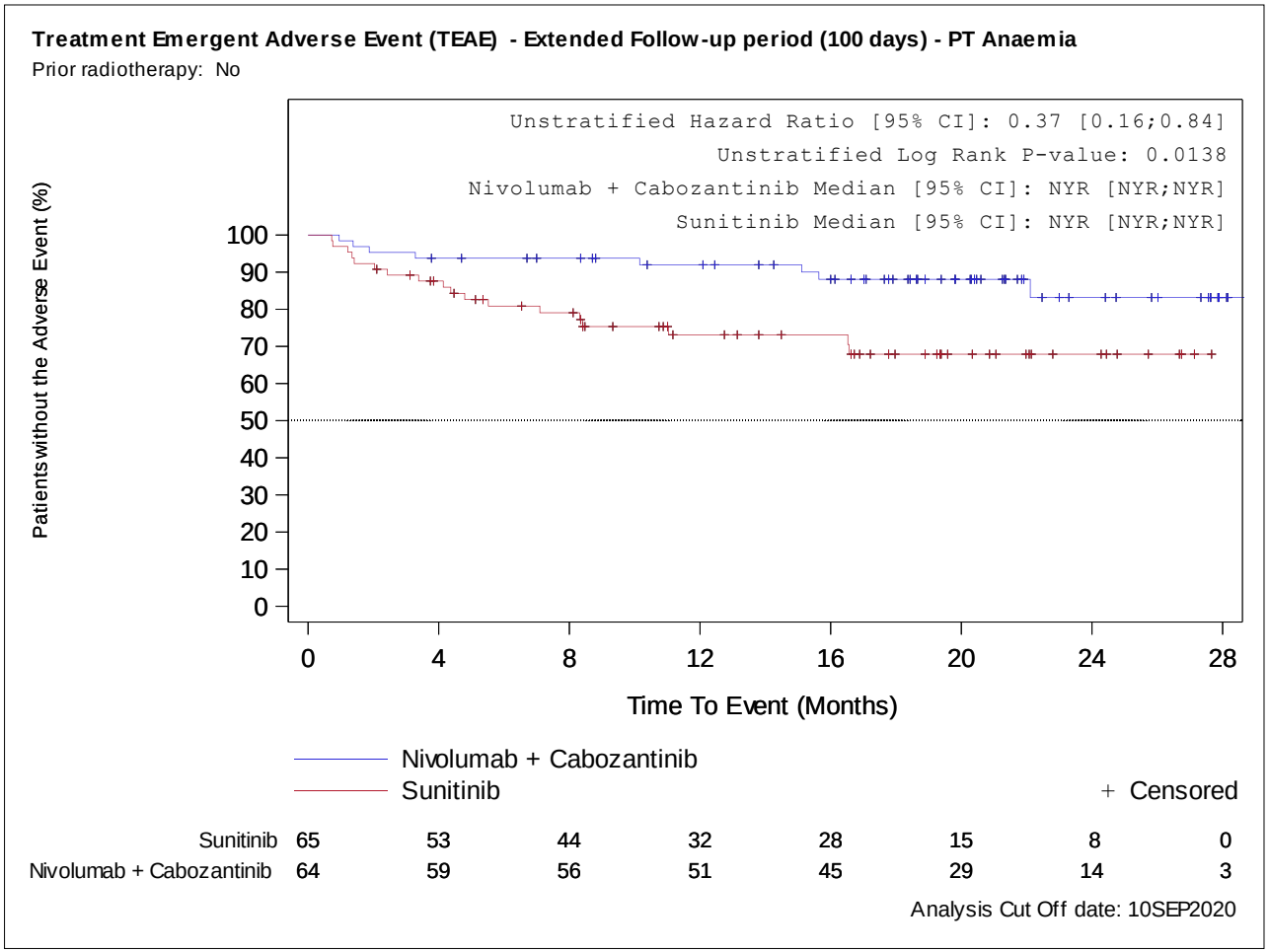
FIGURE 5.21.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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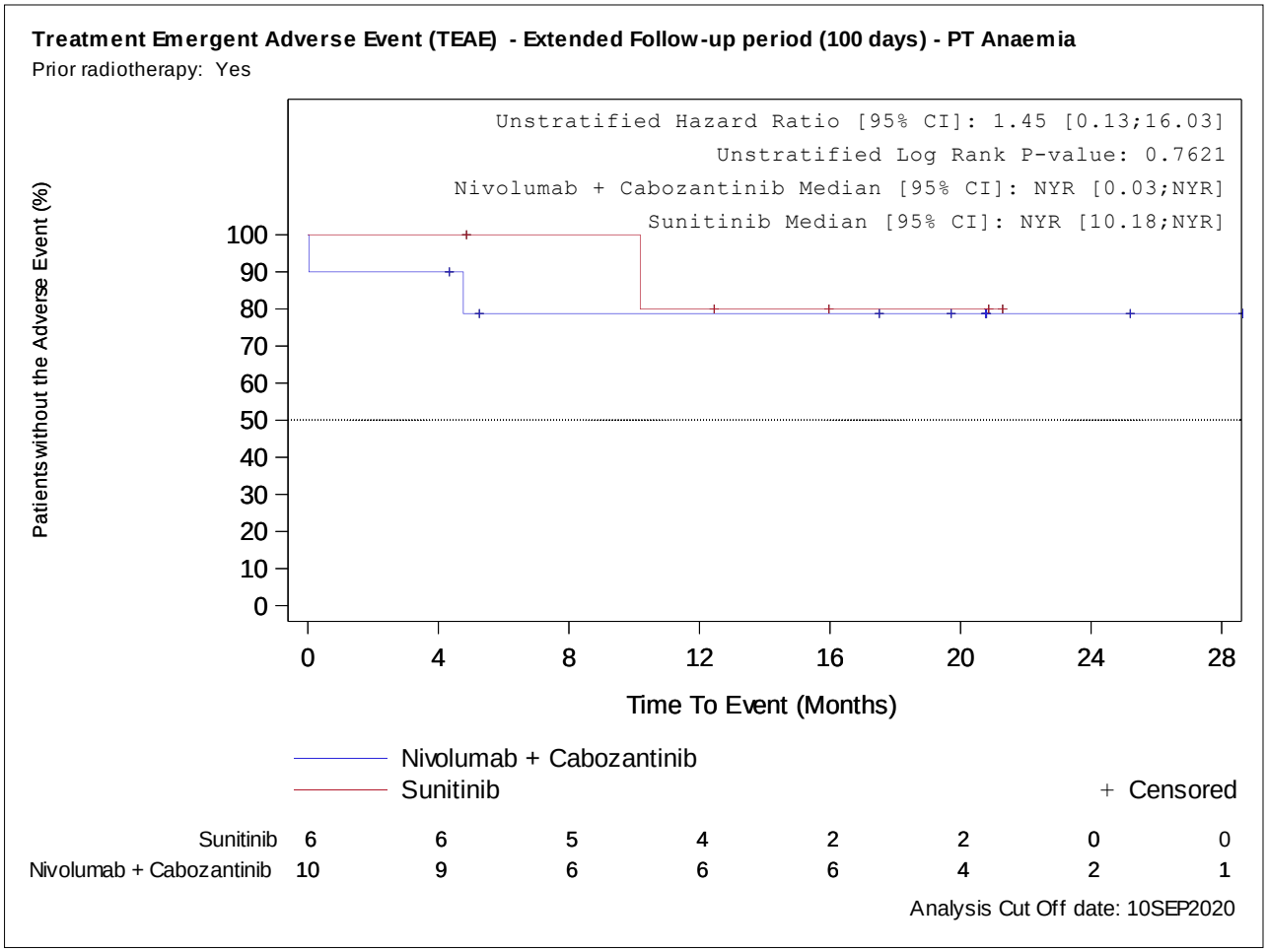
FIGURE 5.21.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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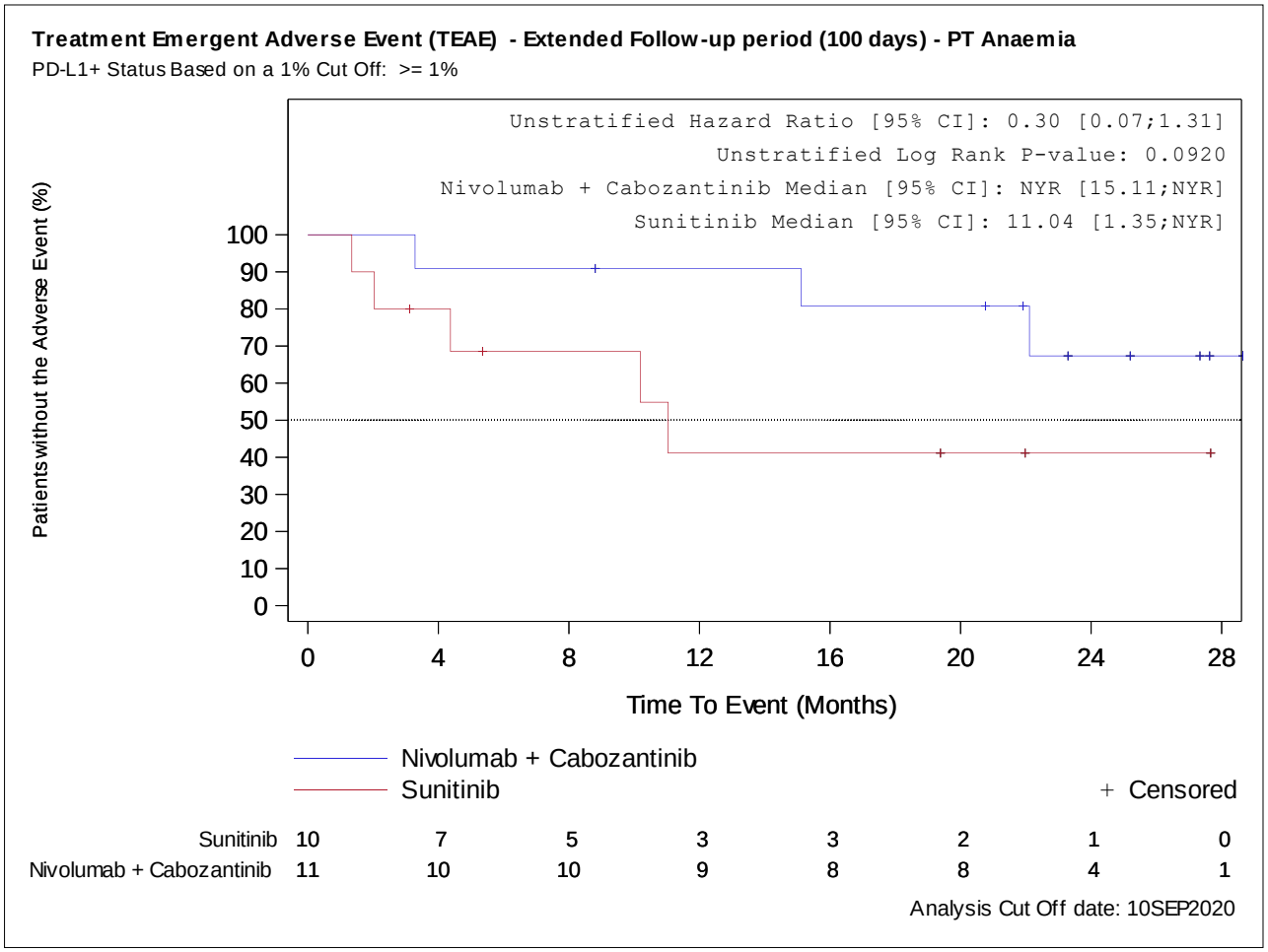
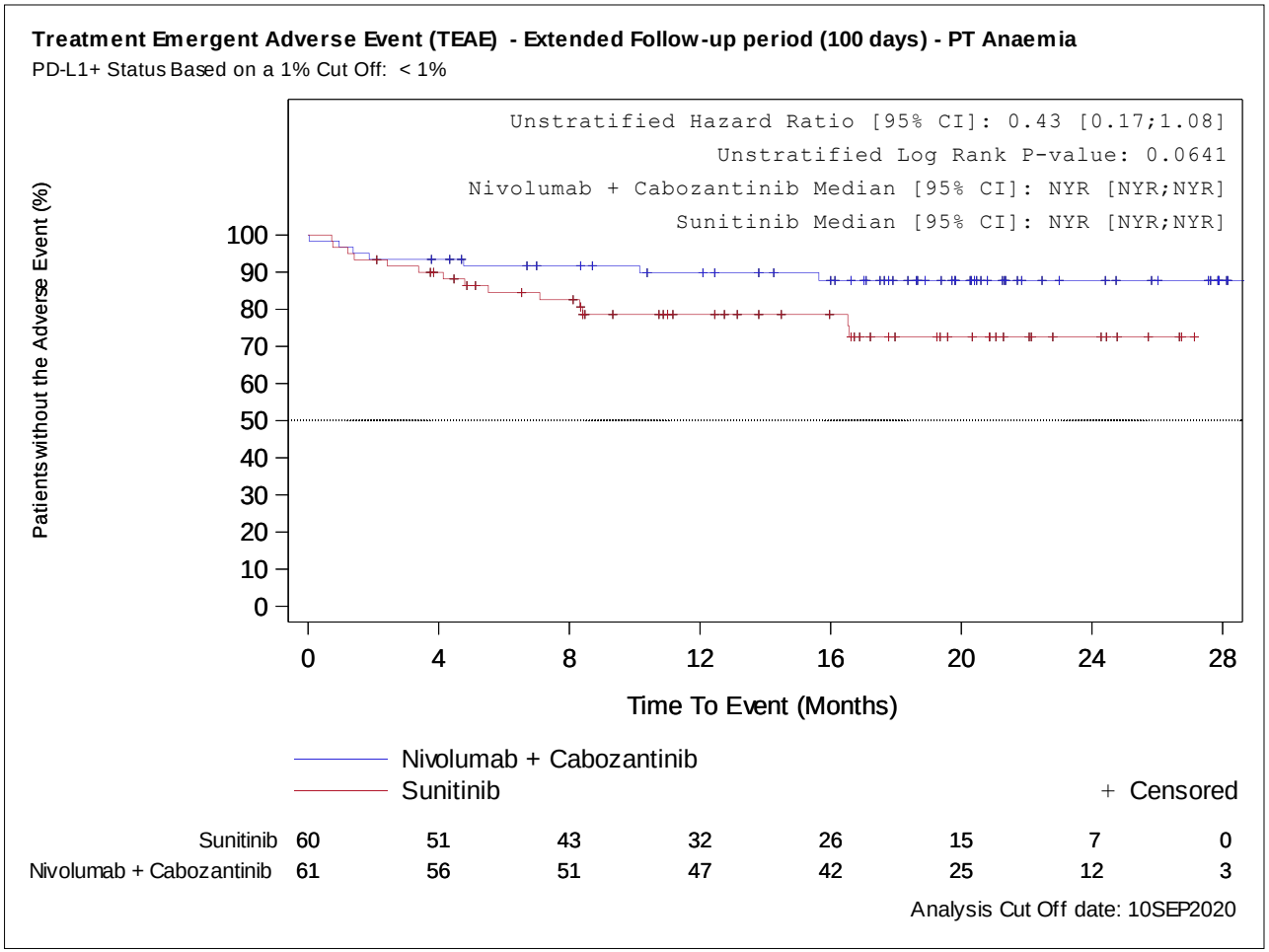
FIGURE 5.21.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



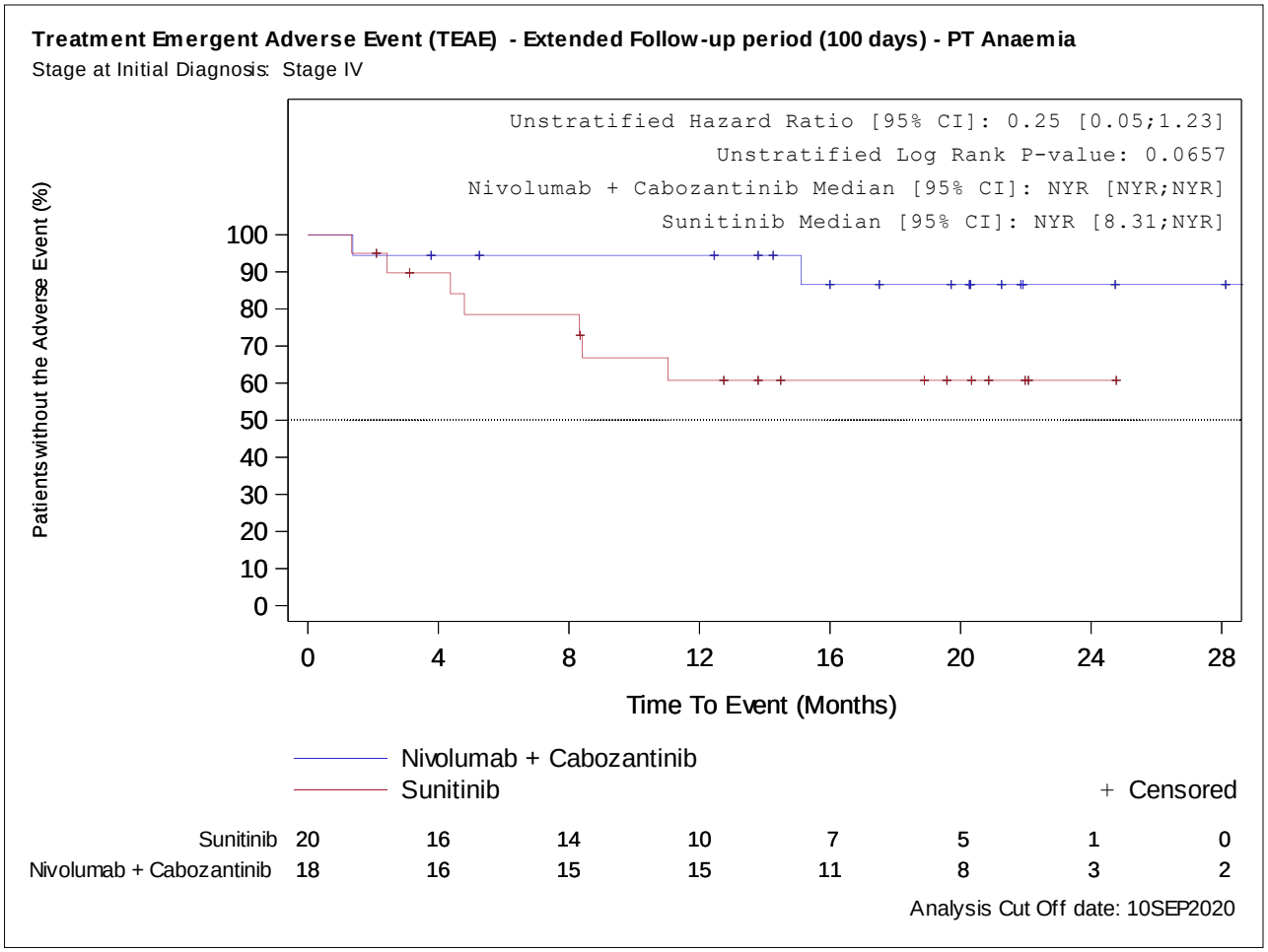

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:11:03

FIGURE 5.21.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:11:09

FIGURE 5.21.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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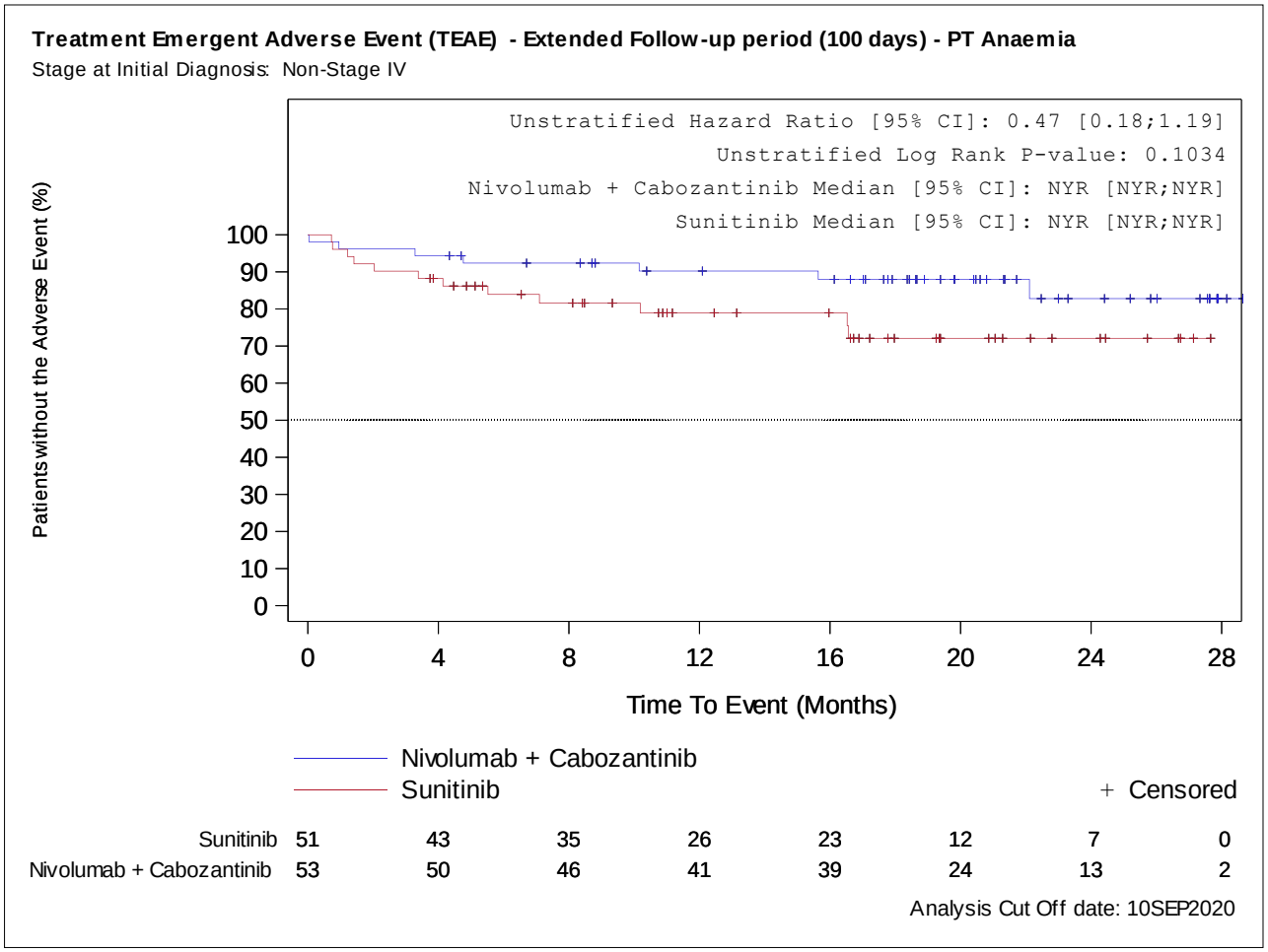
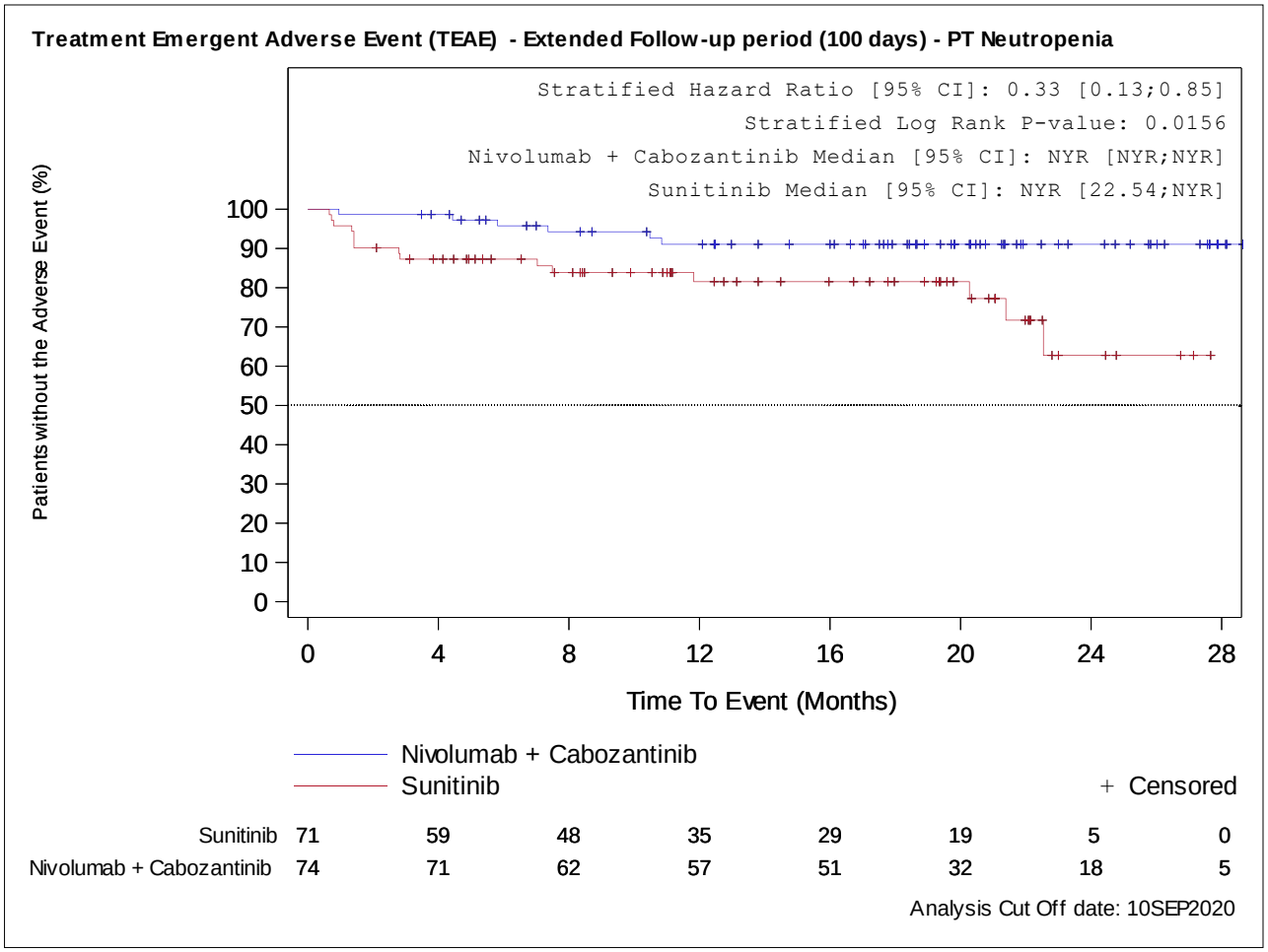
FIGURE 5.21.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Anaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



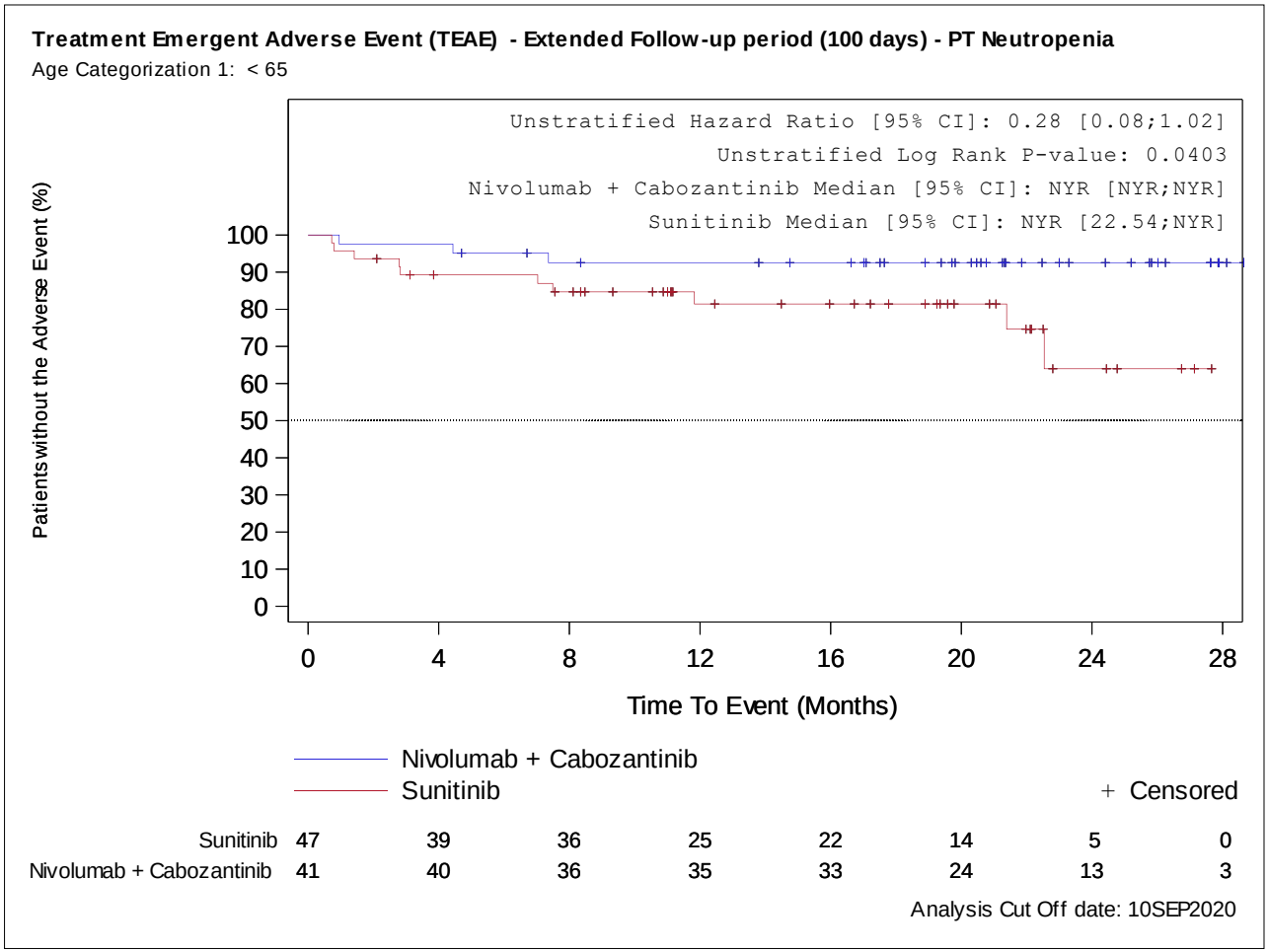

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:11:45

FIGURE 5.22.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



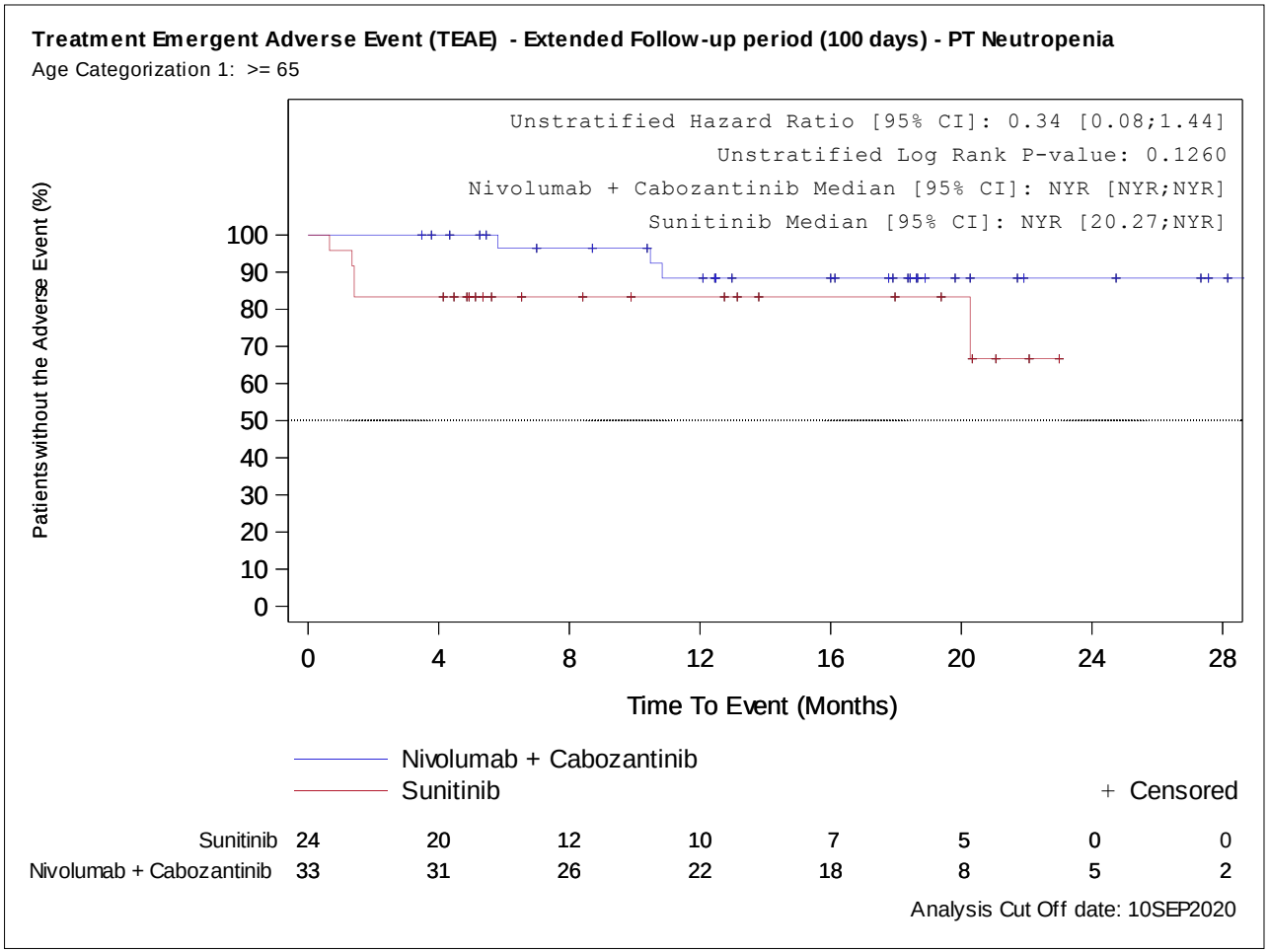

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:14:55

FIGURE 5.22.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:14:58

FIGURE 5.22.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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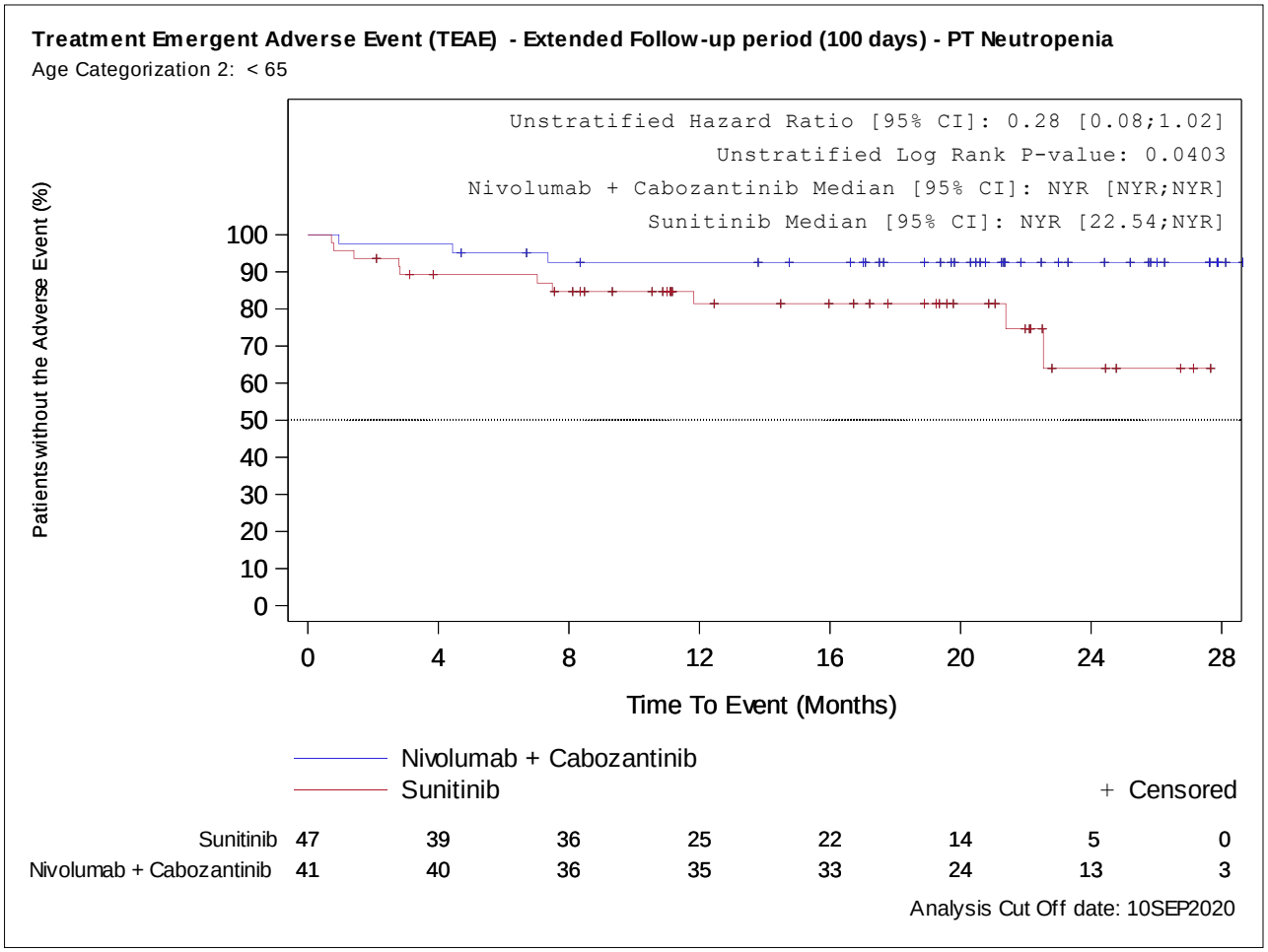
FIGURE 5.22.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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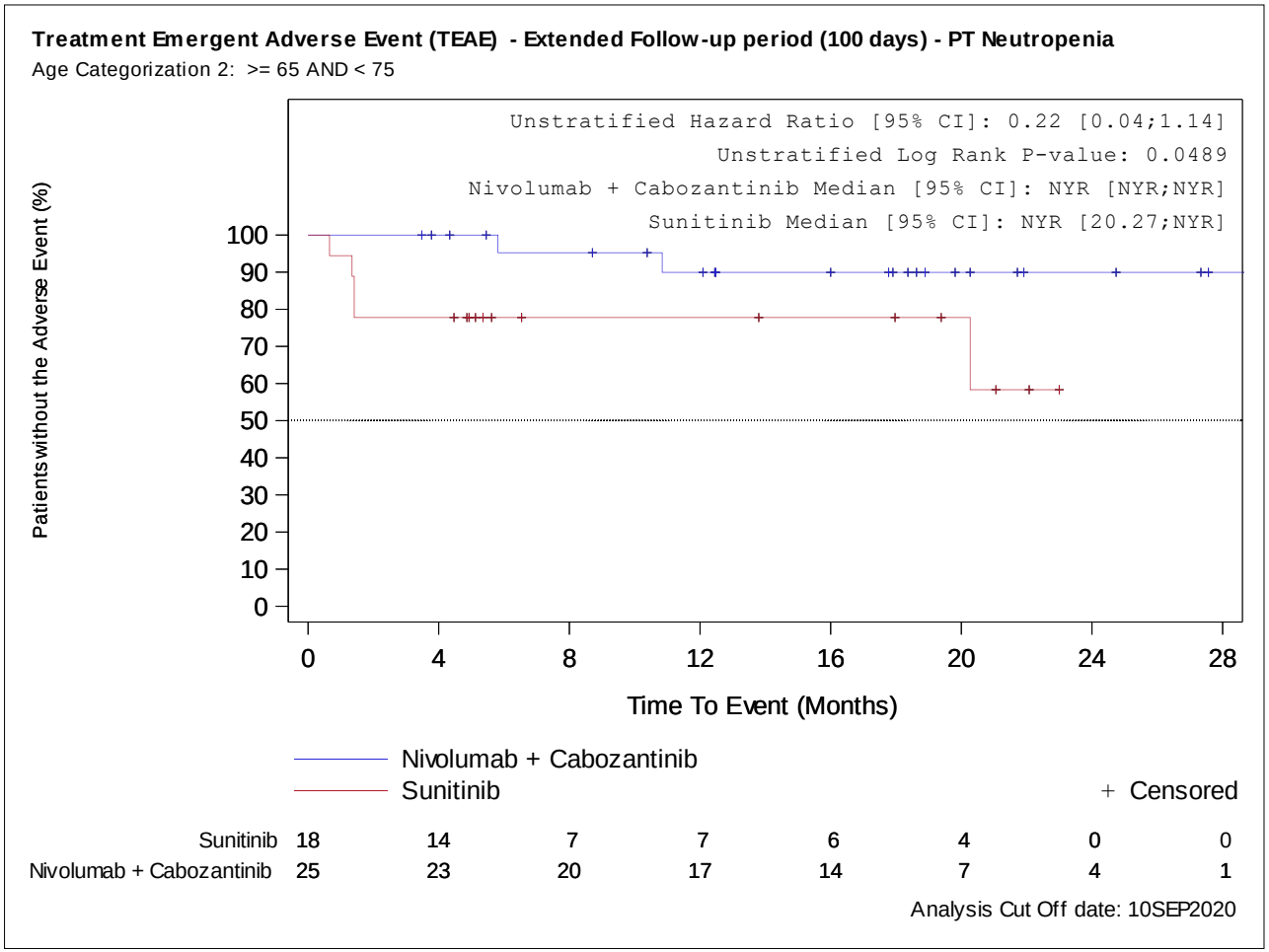
FIGURE 5.22.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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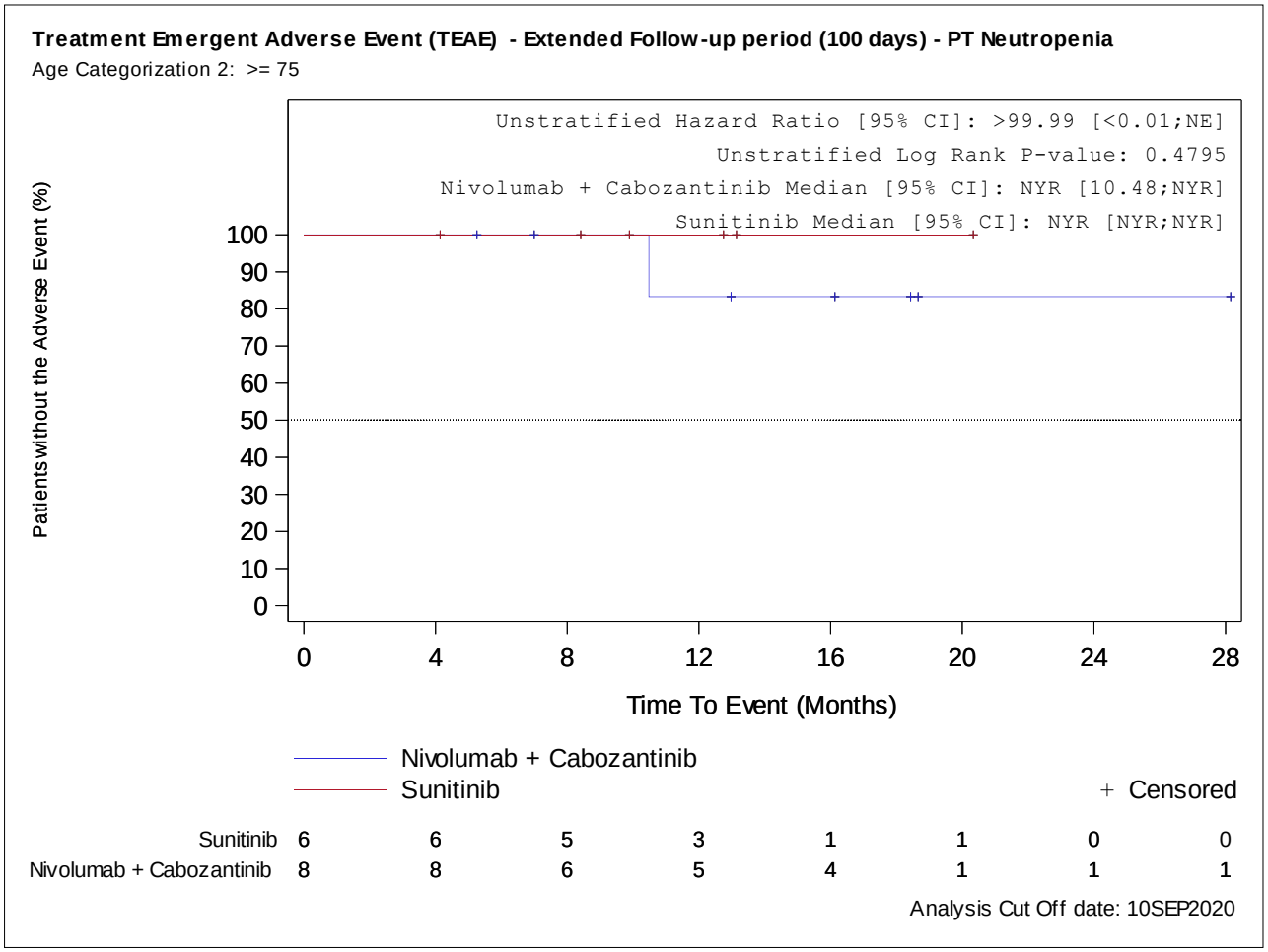
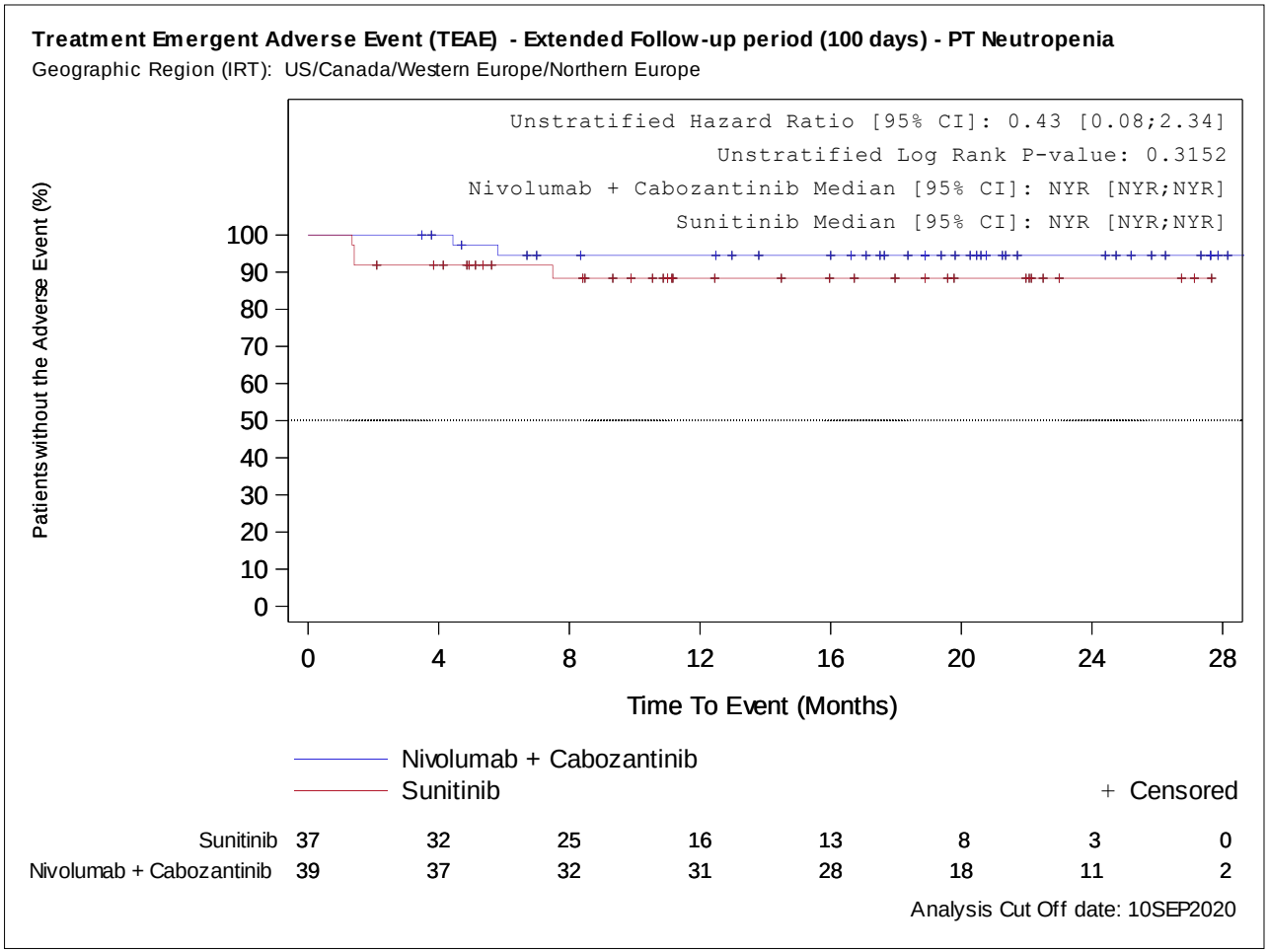
FIGURE 5.22.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



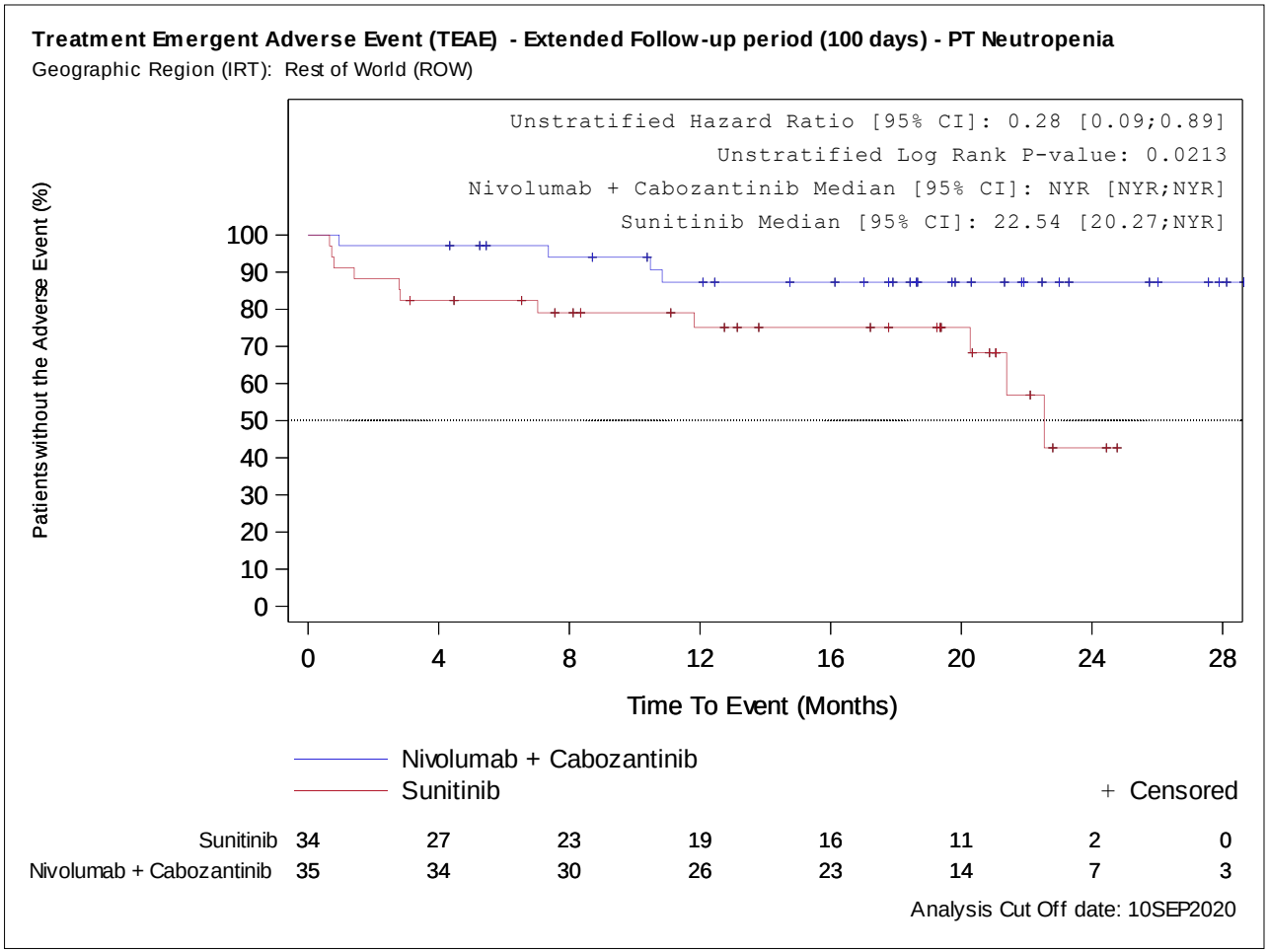

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:15:21

FIGURE 5.22.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



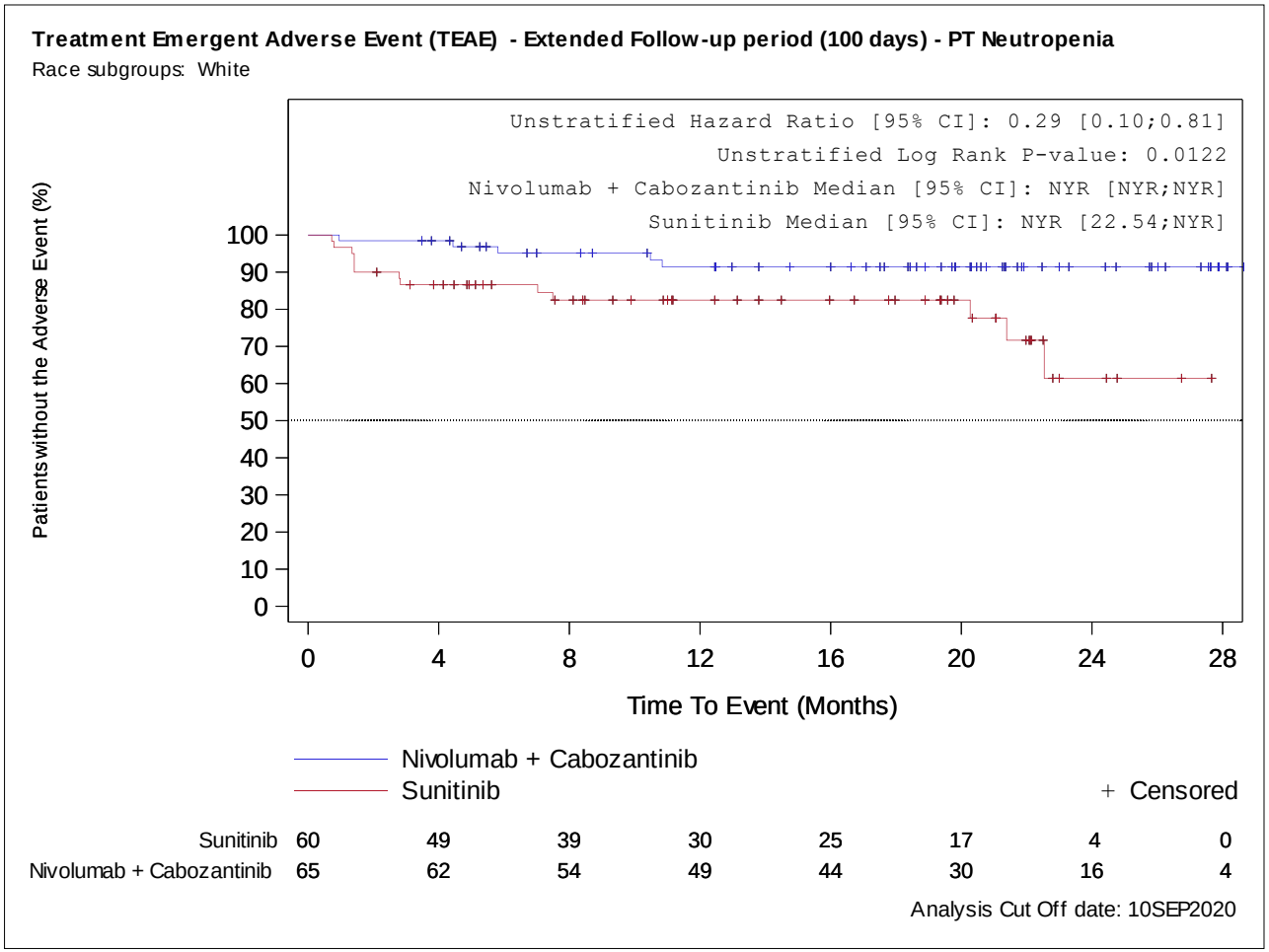

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:15:28

FIGURE 5.22.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



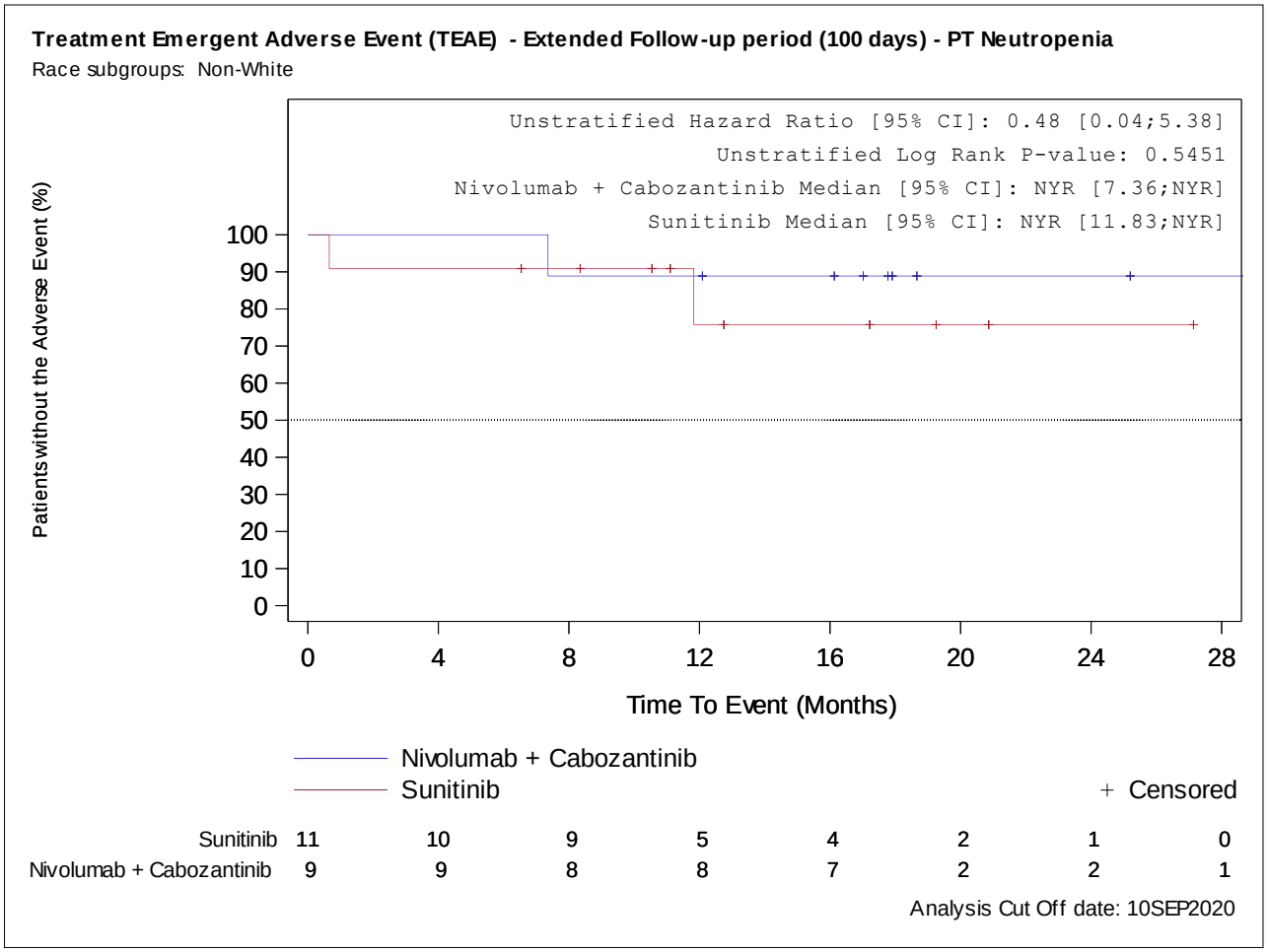

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:15:33

FIGURE 5.22.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:15:39

FIGURE 5.22.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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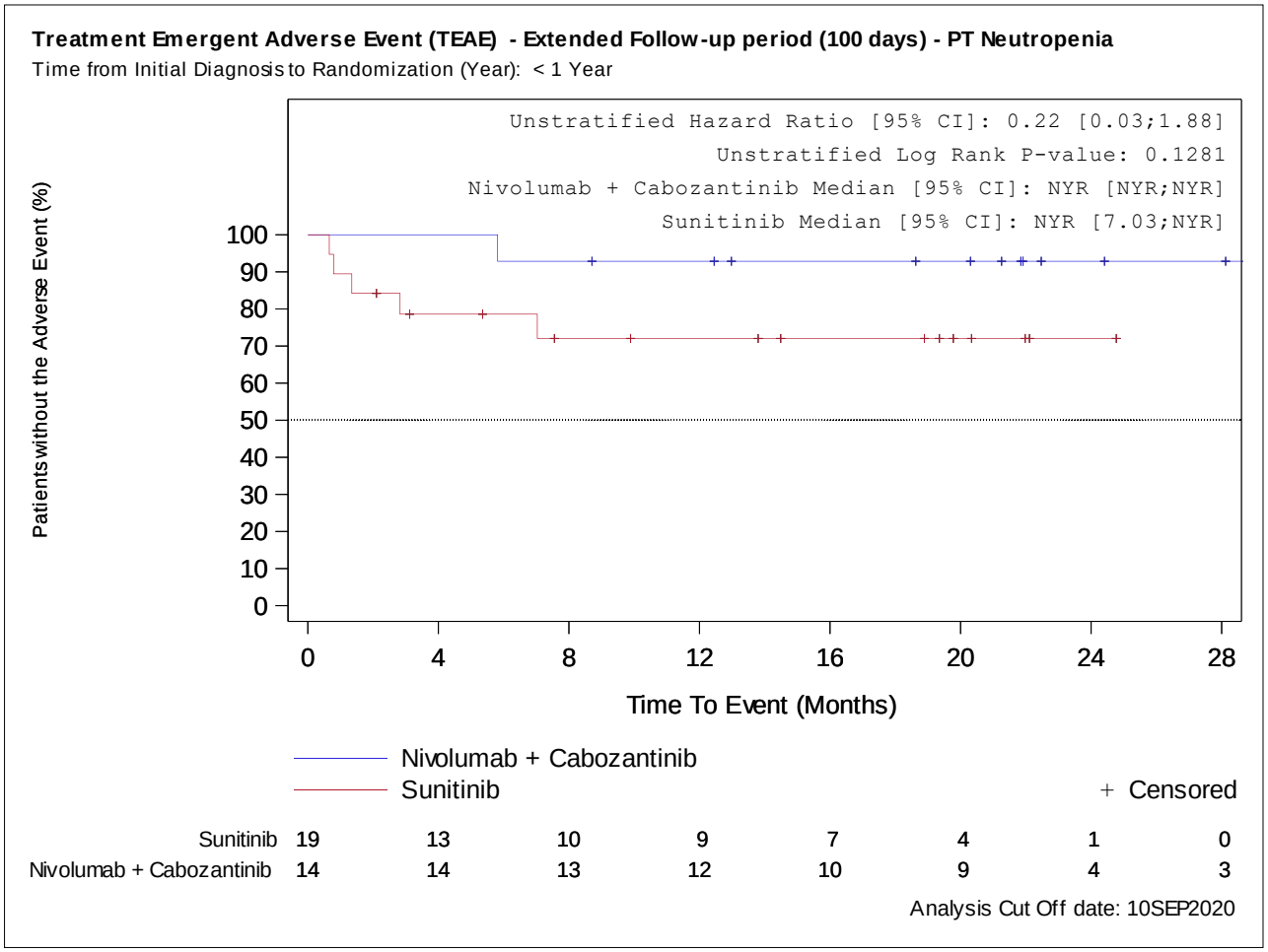
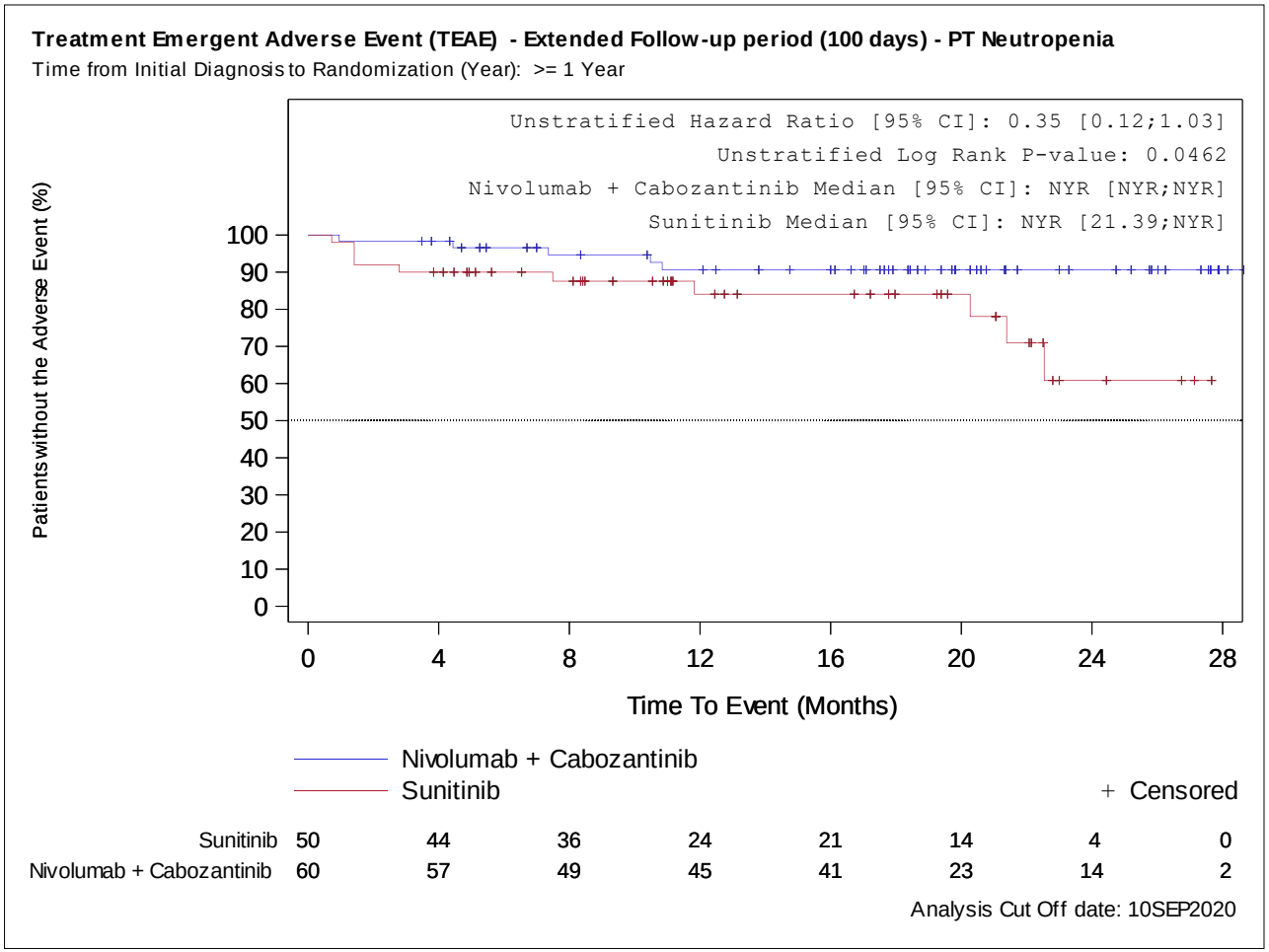
FIGURE 5.22.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



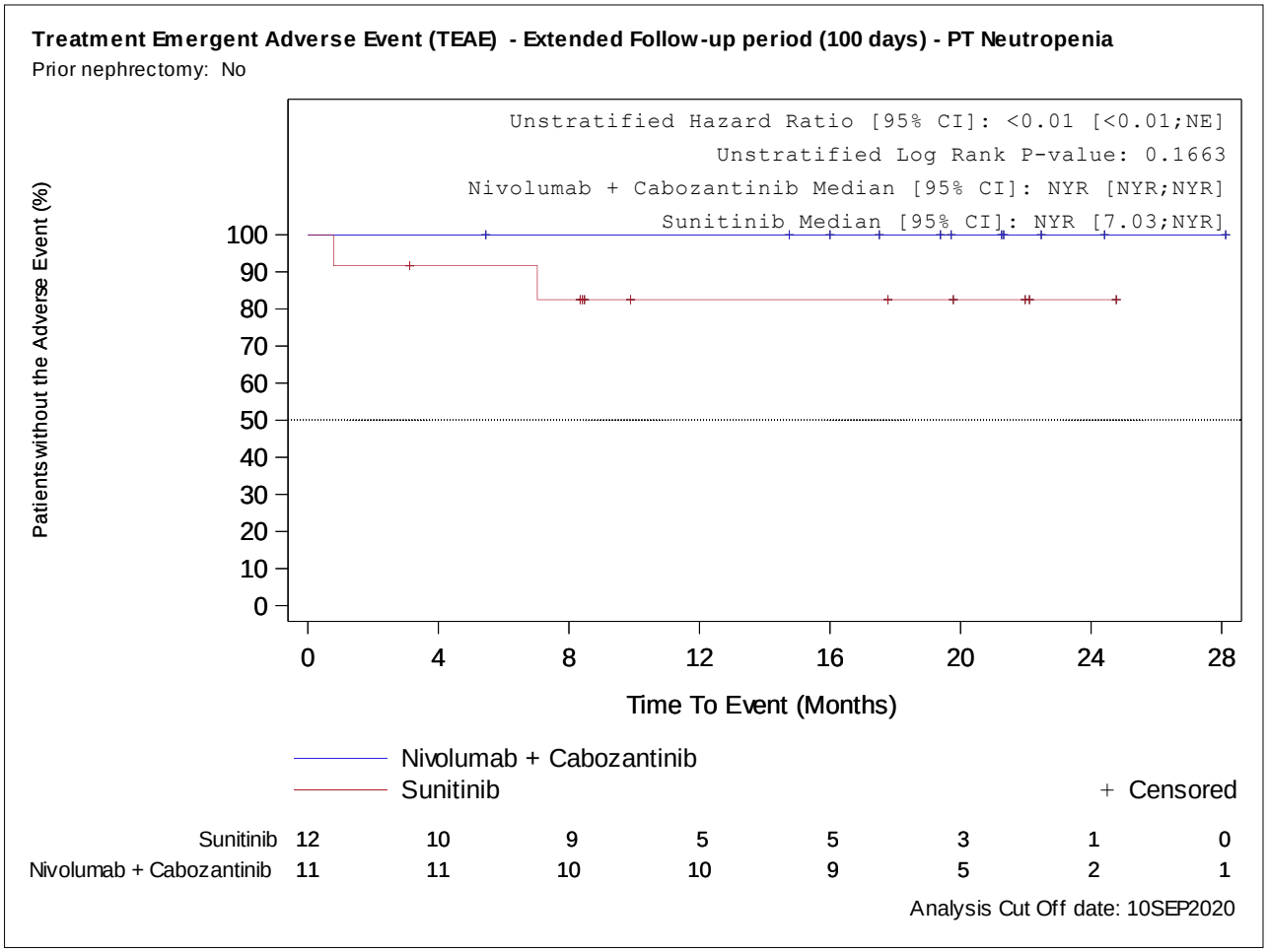

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:16:02

FIGURE 5.22.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:16:08

FIGURE 5.22.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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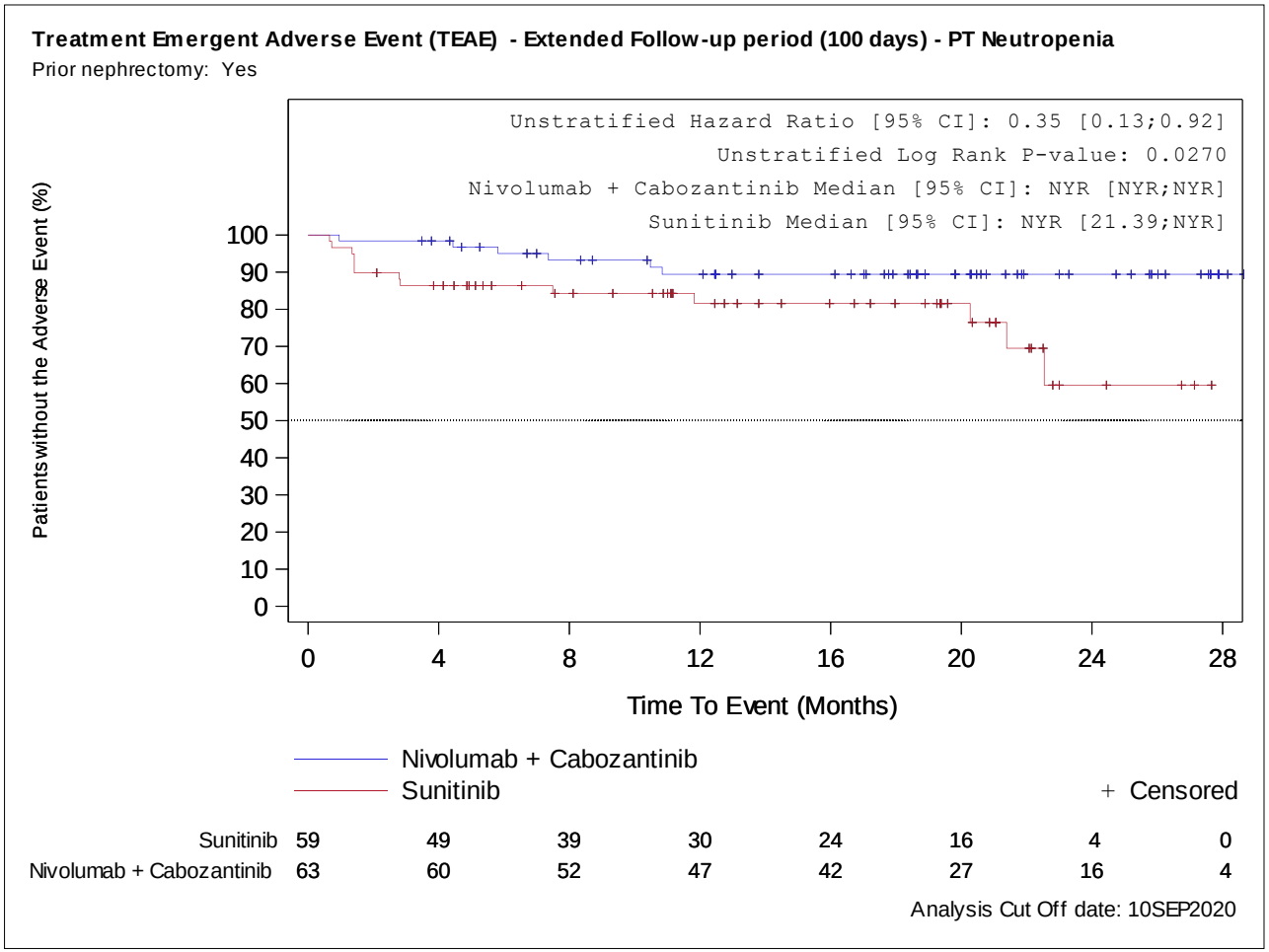
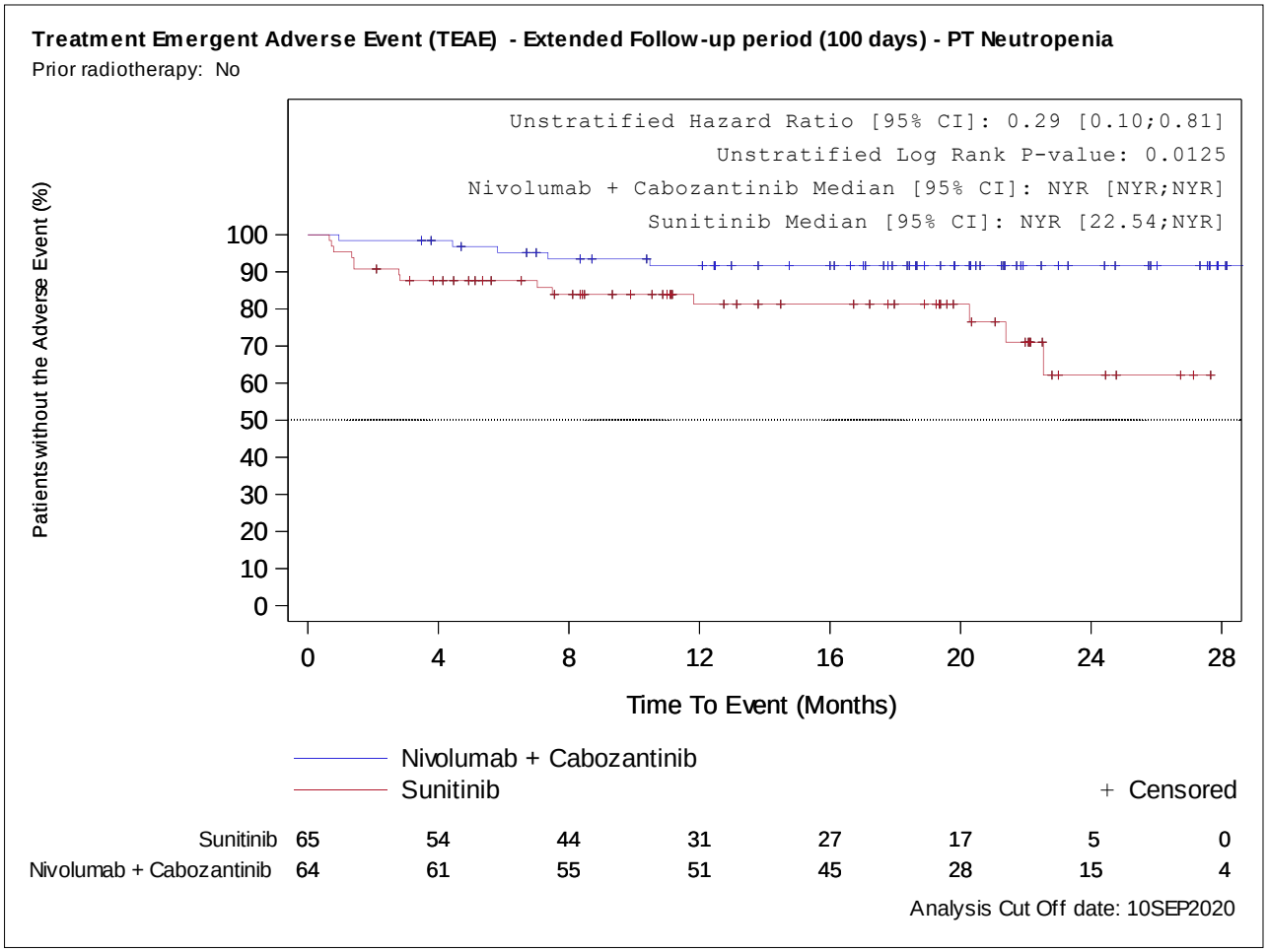
FIGURE 5.22.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:17:06

FIGURE 5.22.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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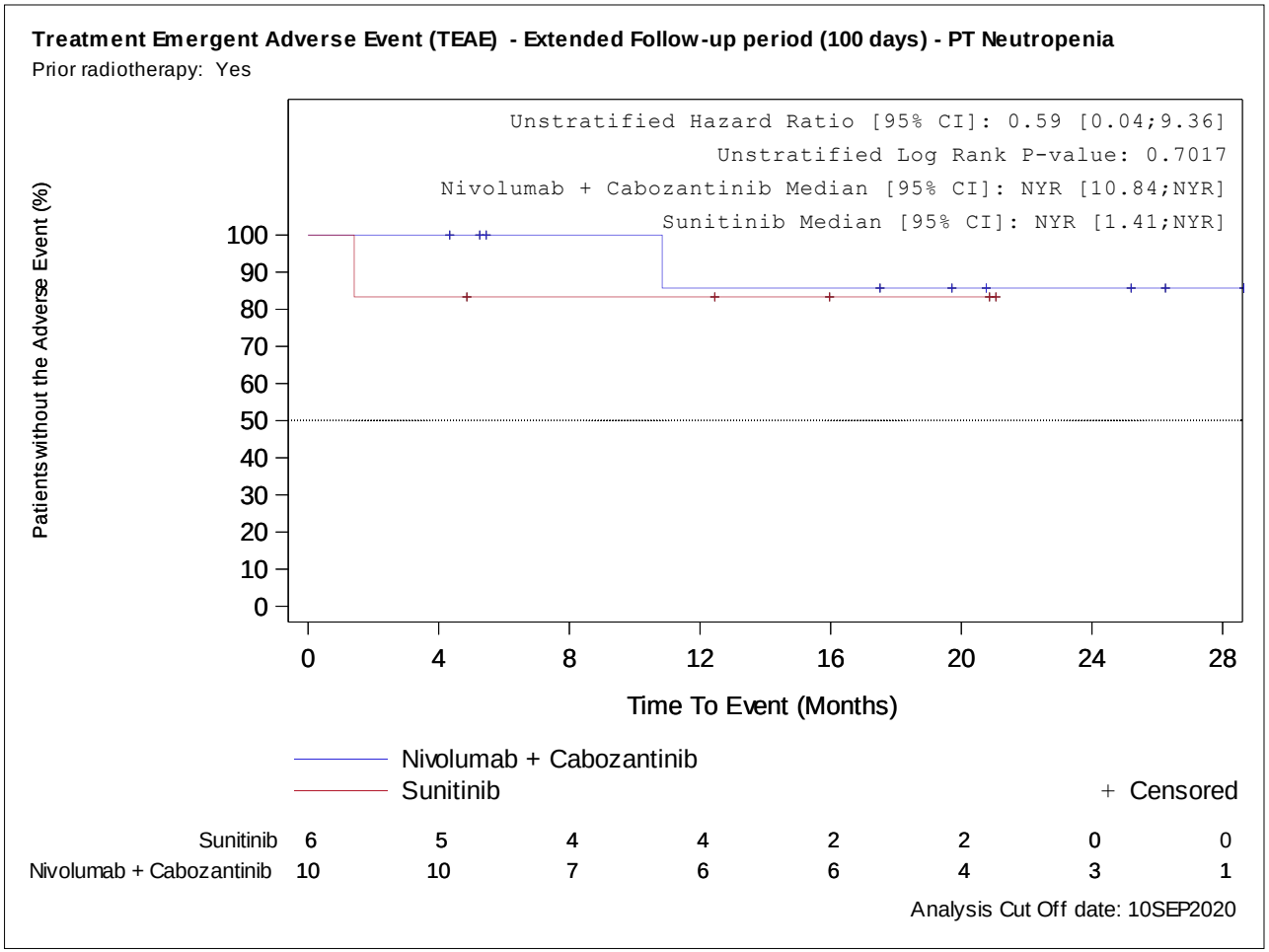
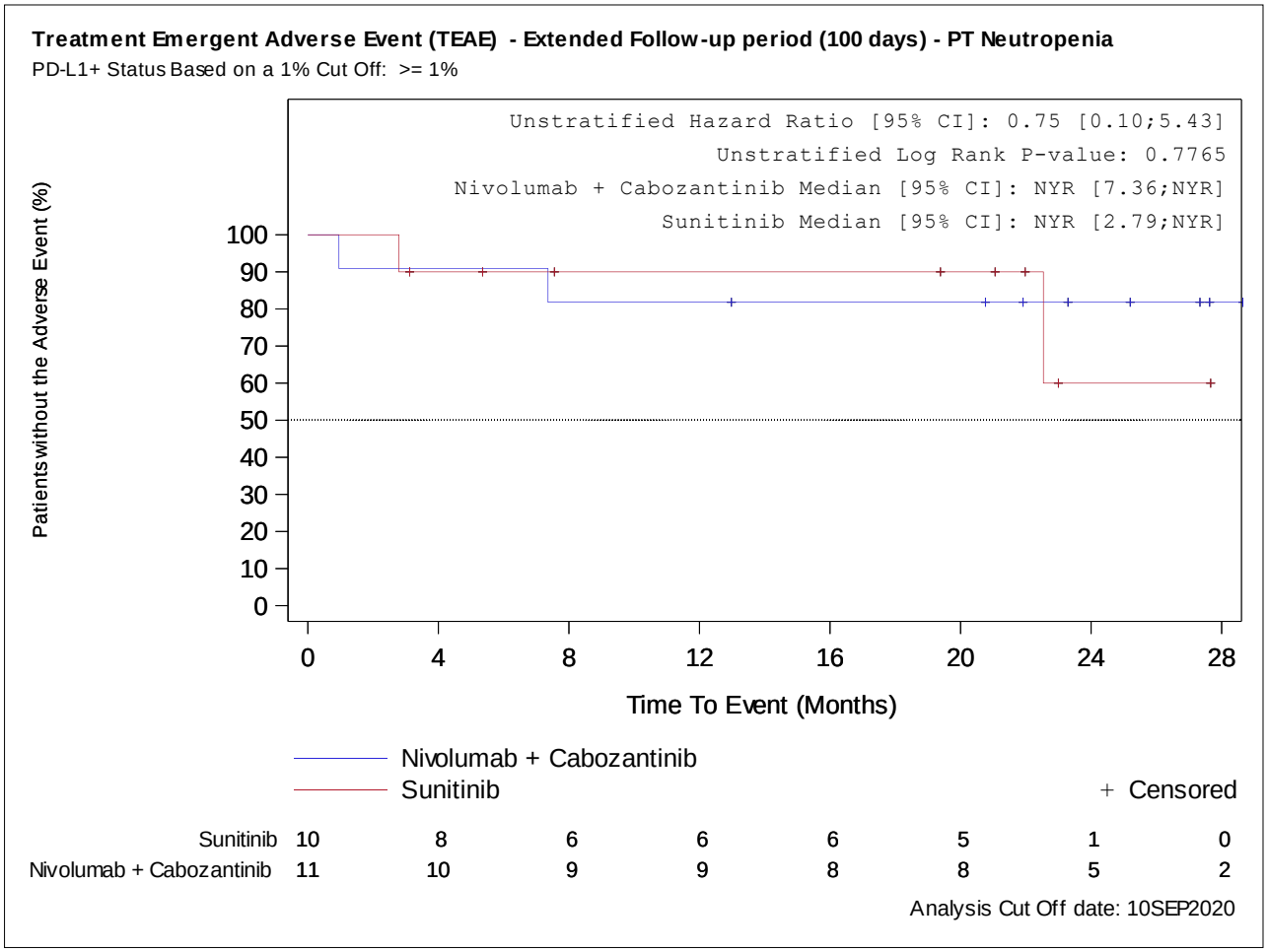
FIGURE 5.22.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



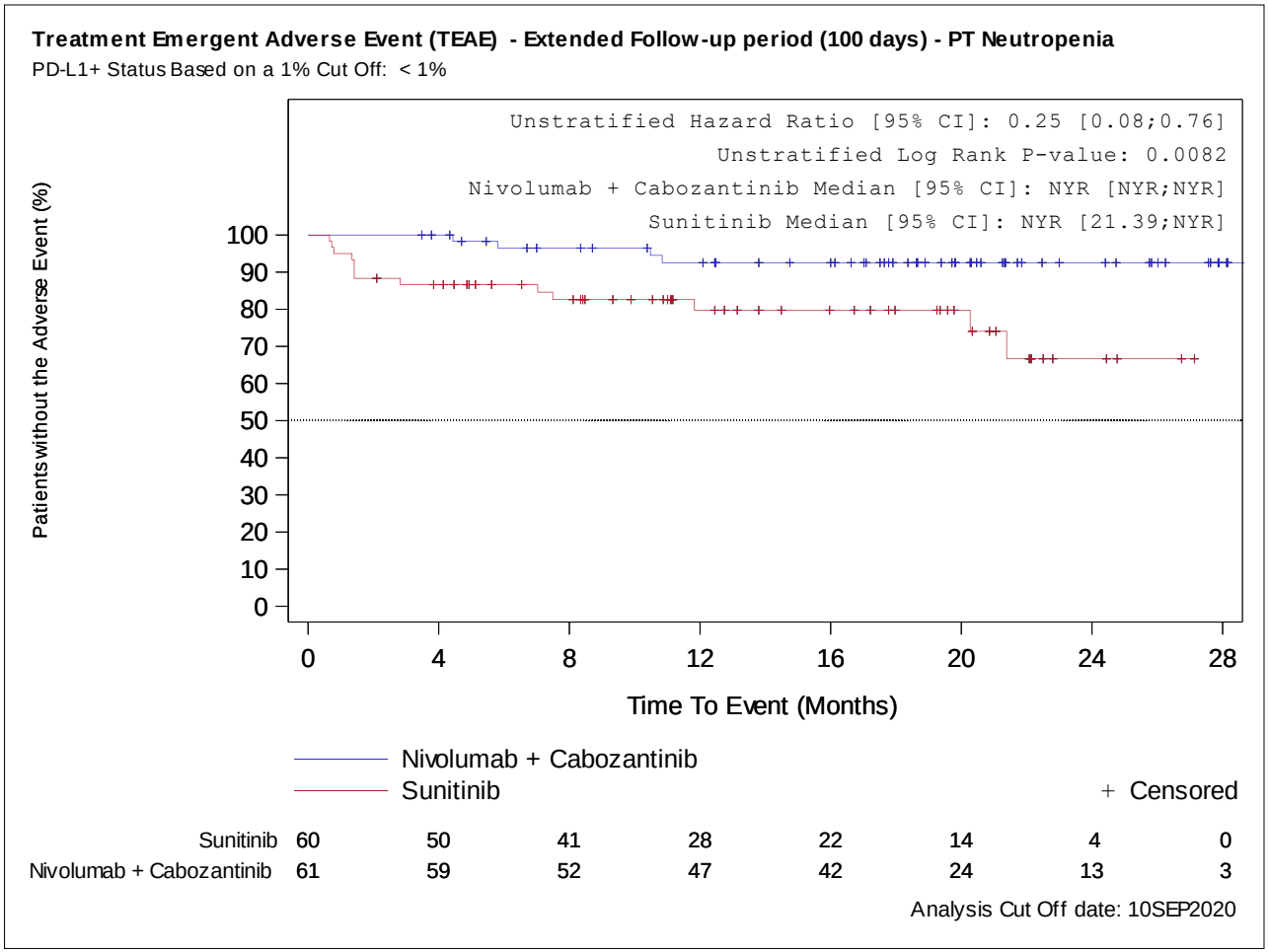

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:17:18

FIGURE 5.22.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



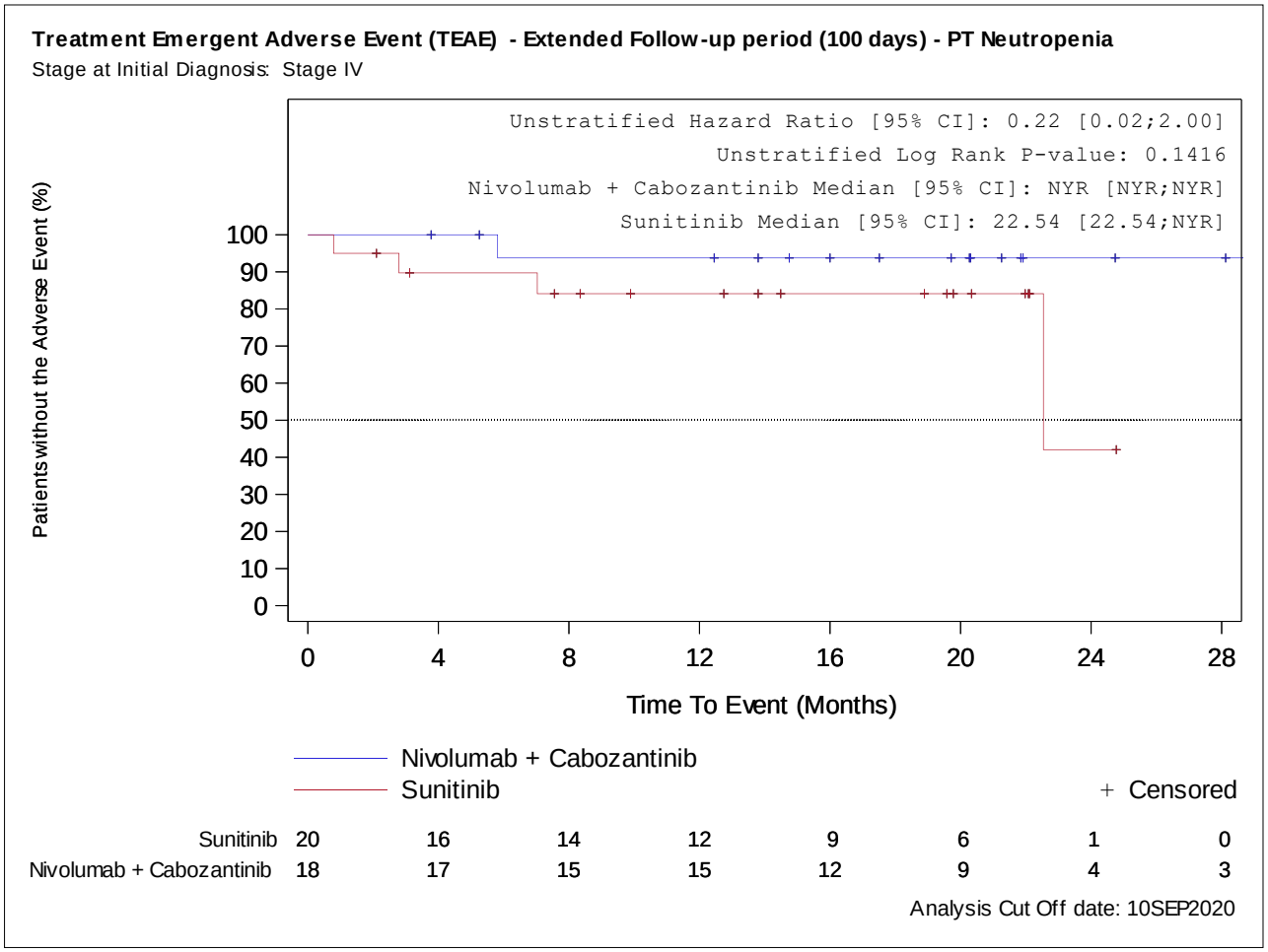

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:17:24

FIGURE 5.22.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



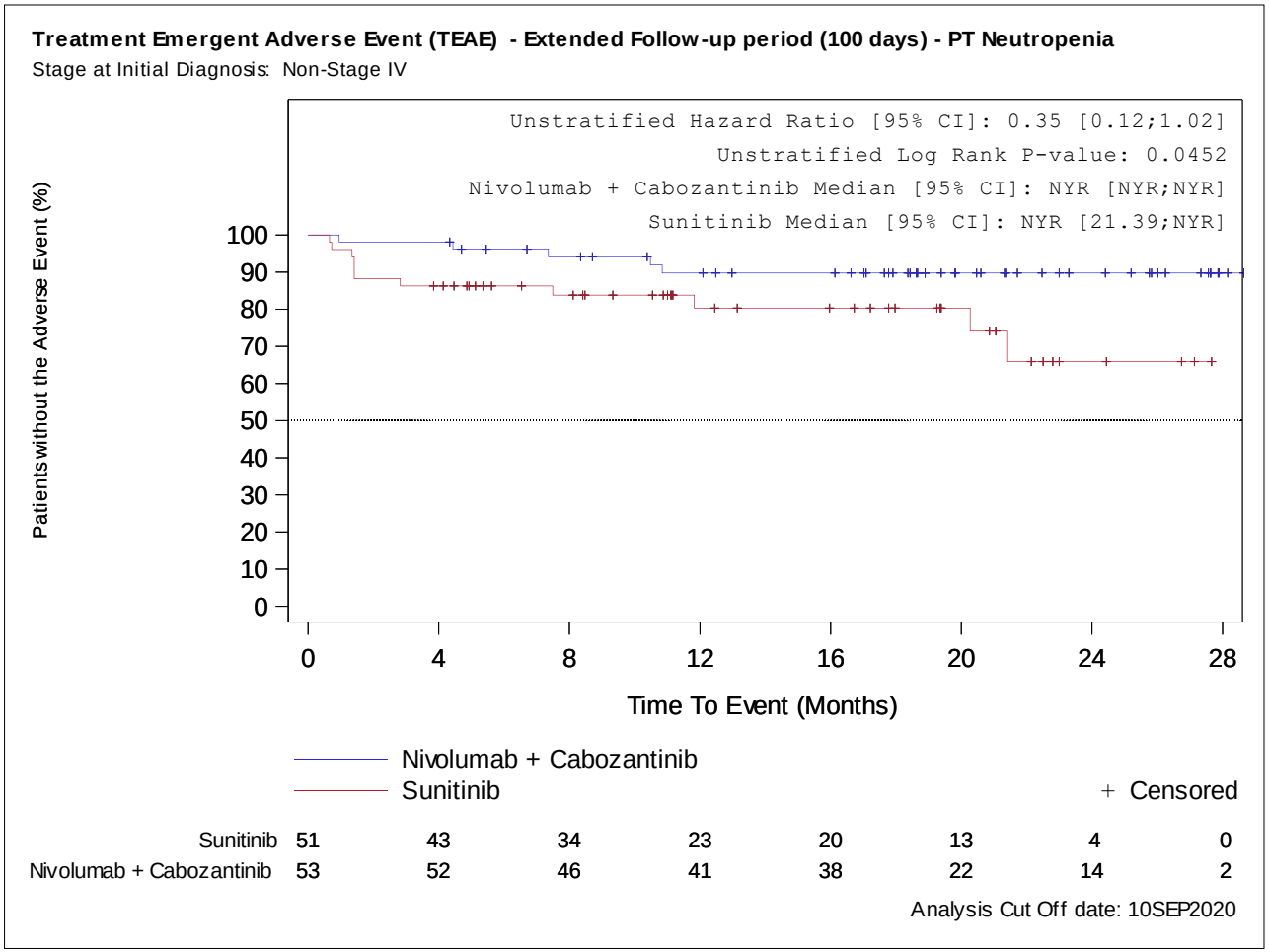

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:17:30

FIGURE 5.22.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



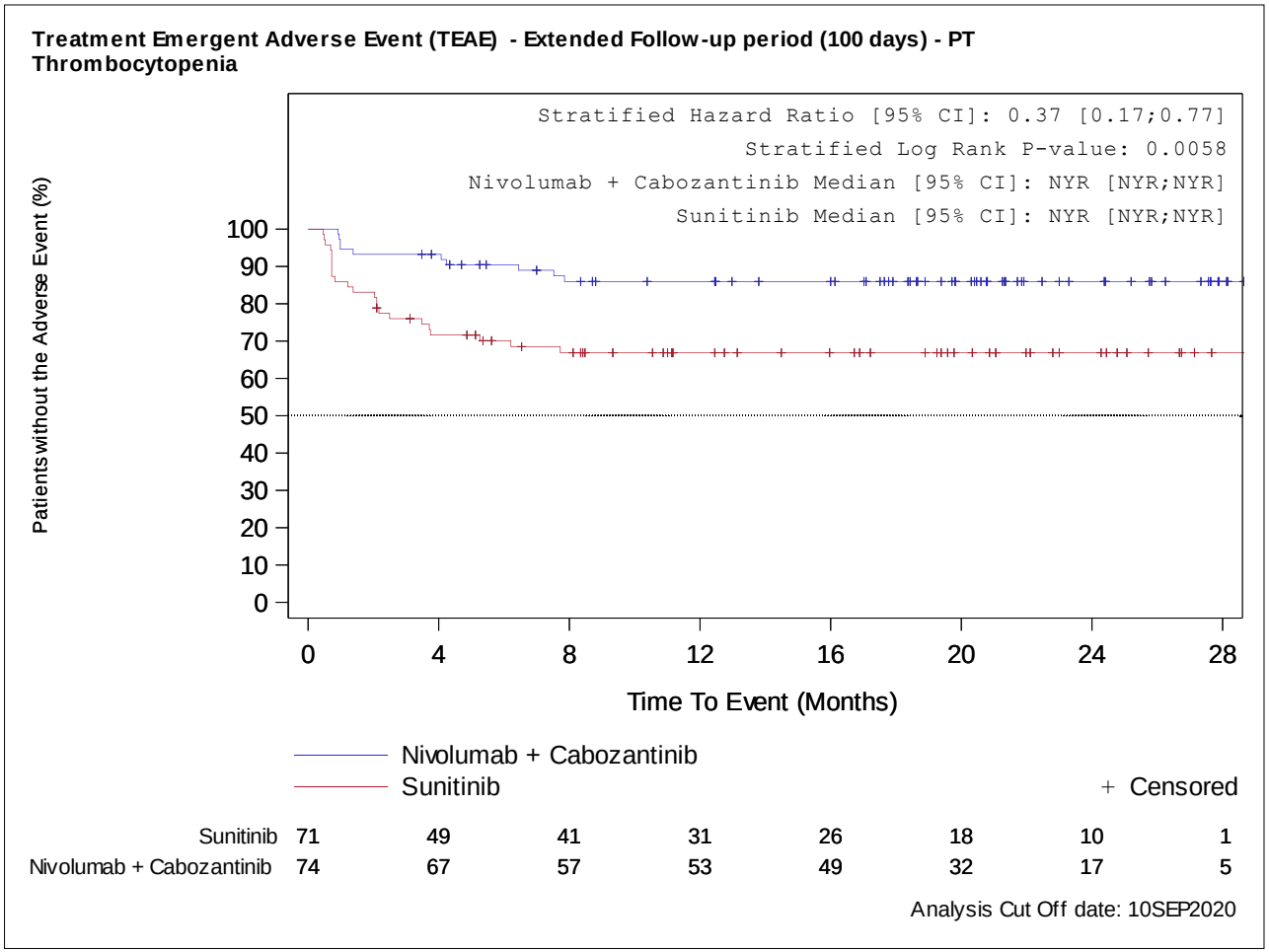

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:17:59

FIGURE 5.22.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Neutropenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:18:05

FIGURE 5.23.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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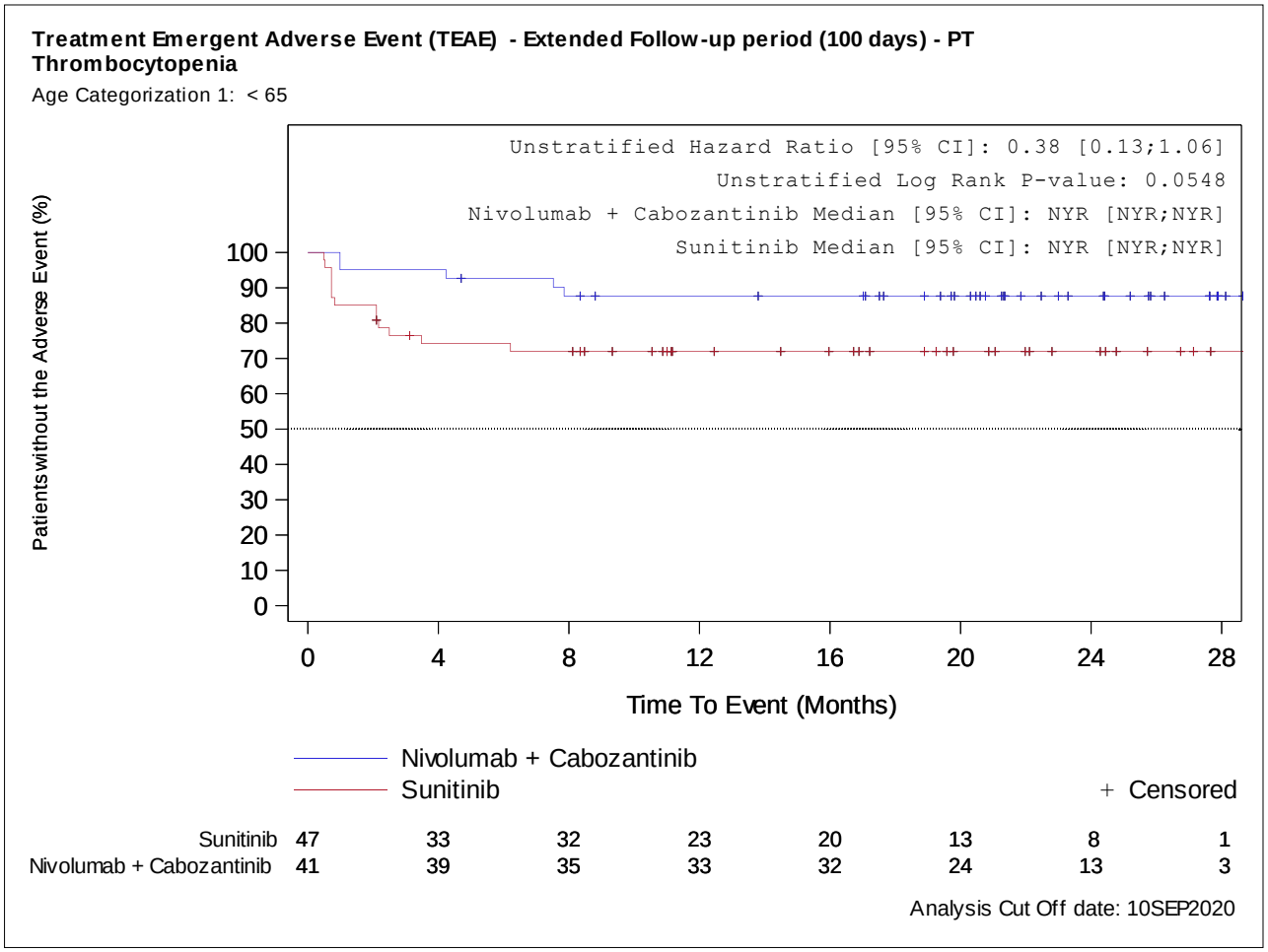
FIGURE 5.23.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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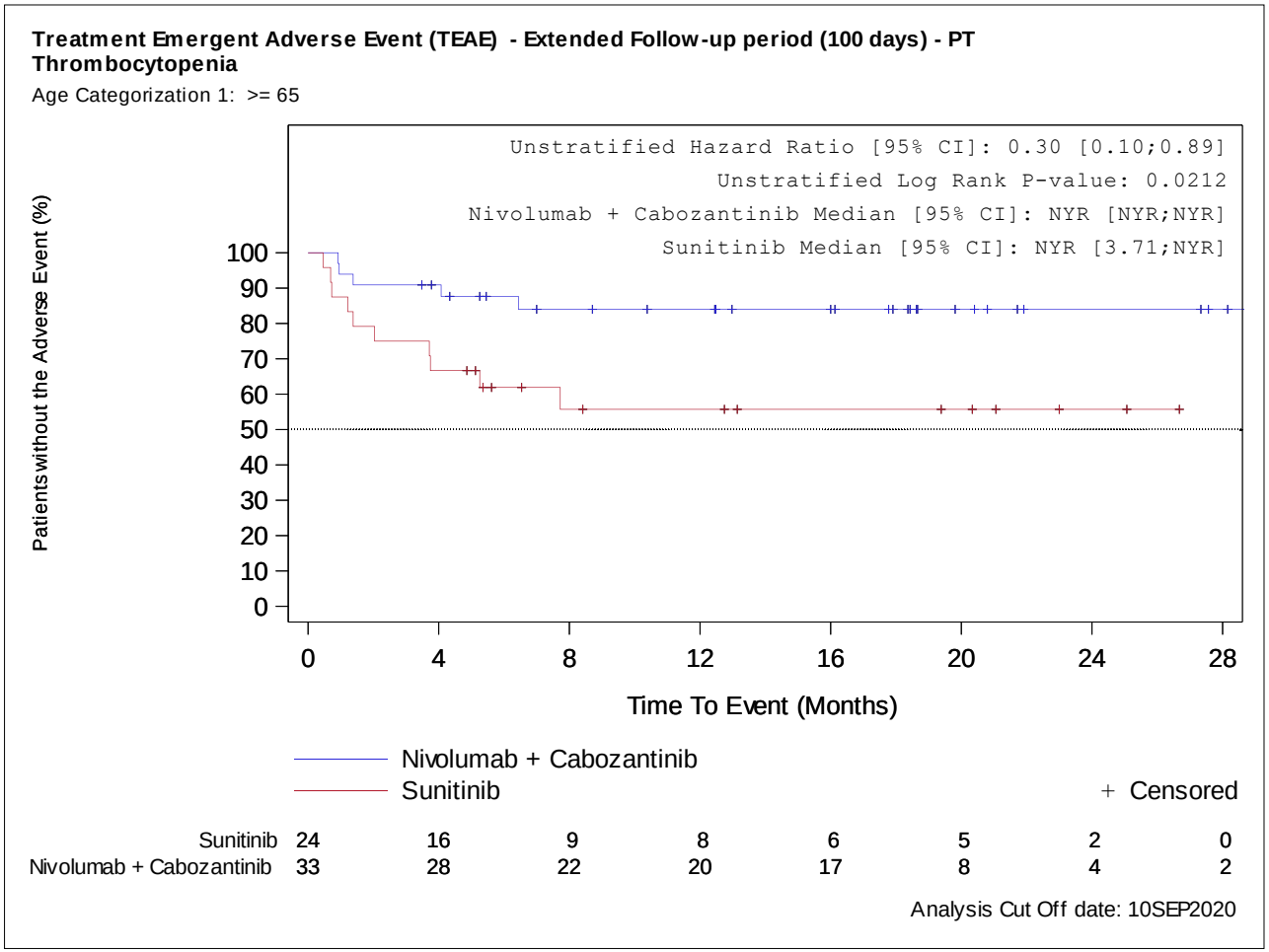
FIGURE 5.23.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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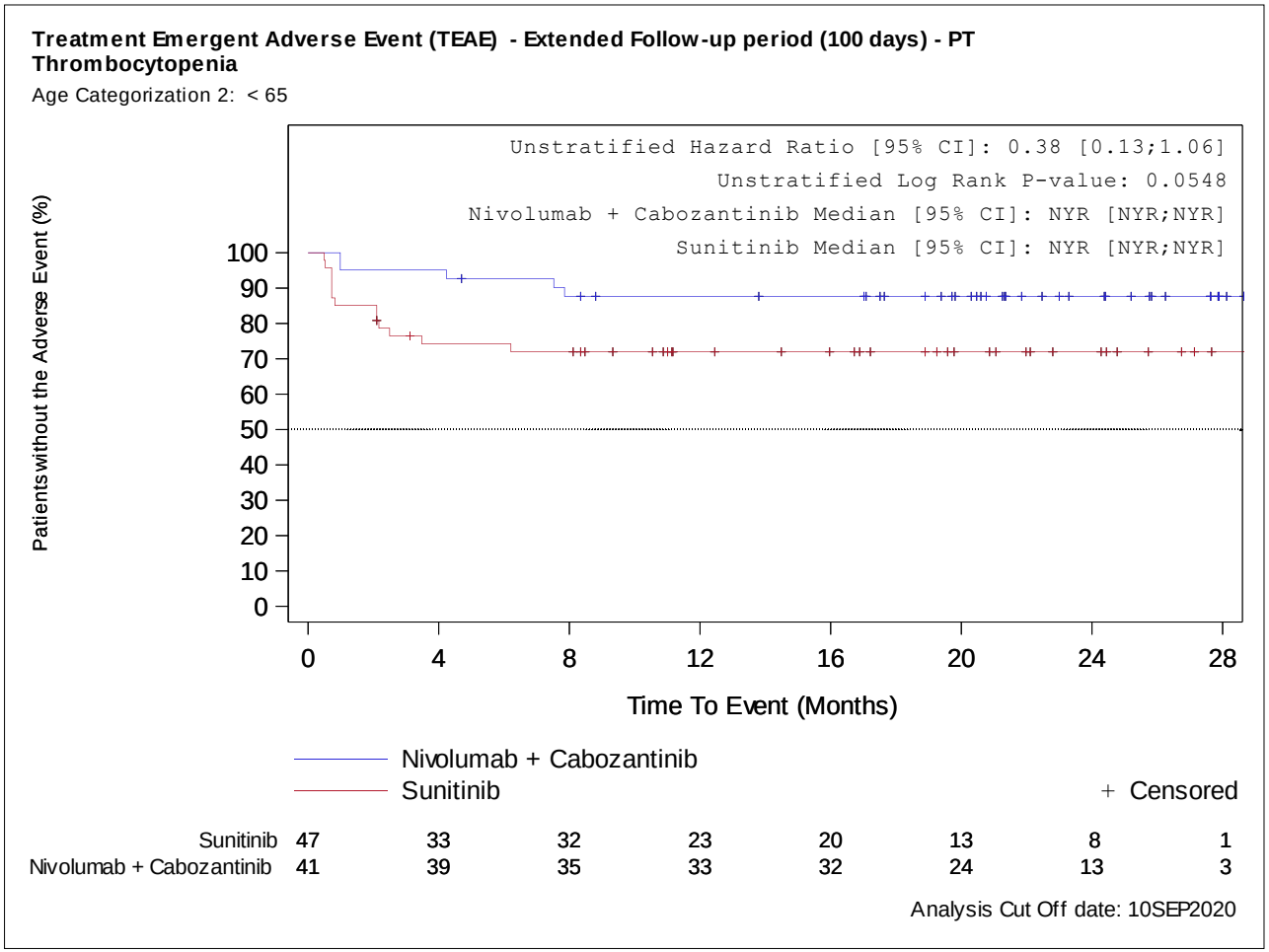
FIGURE 5.23.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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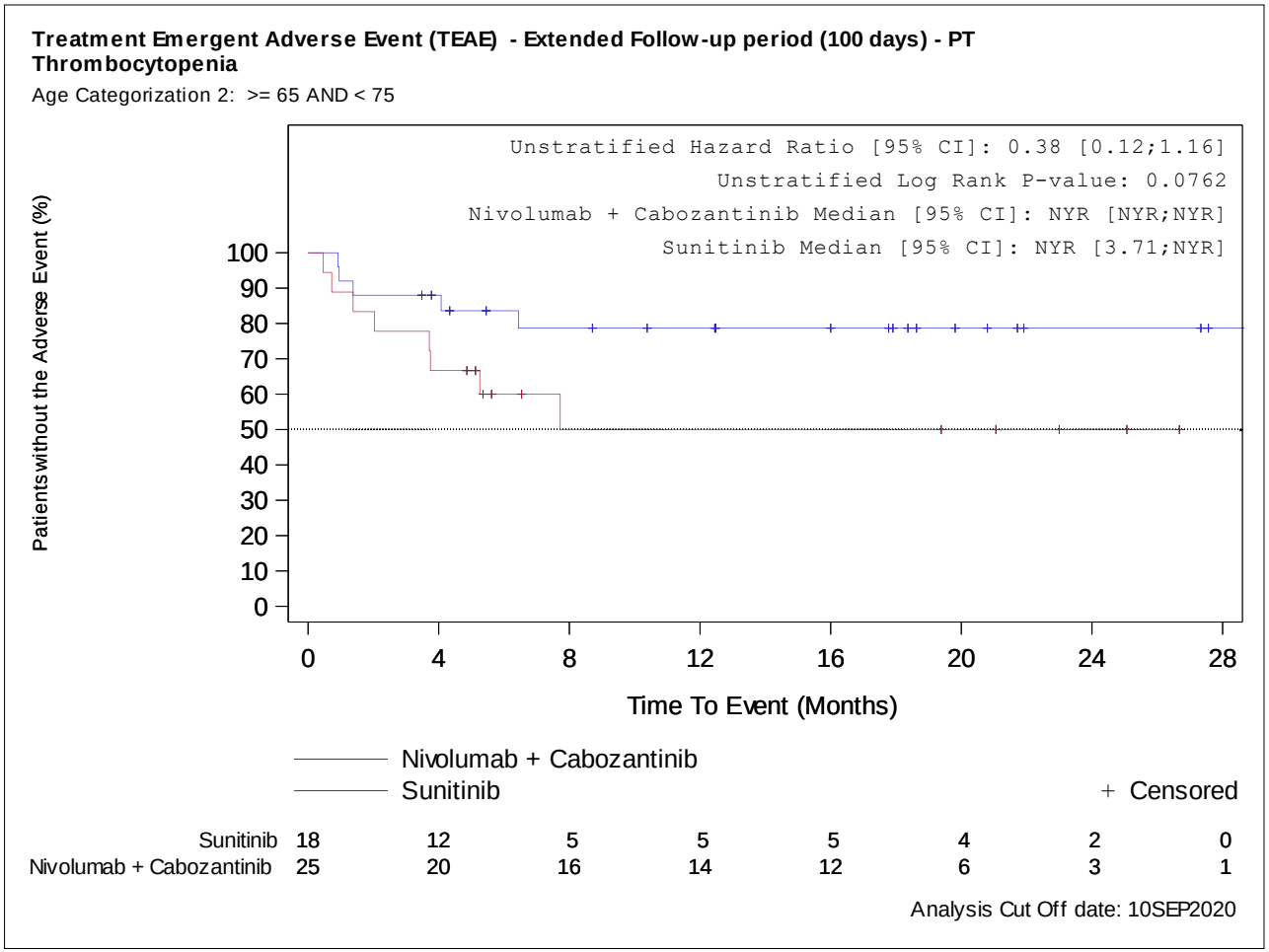
FIGURE 5.23.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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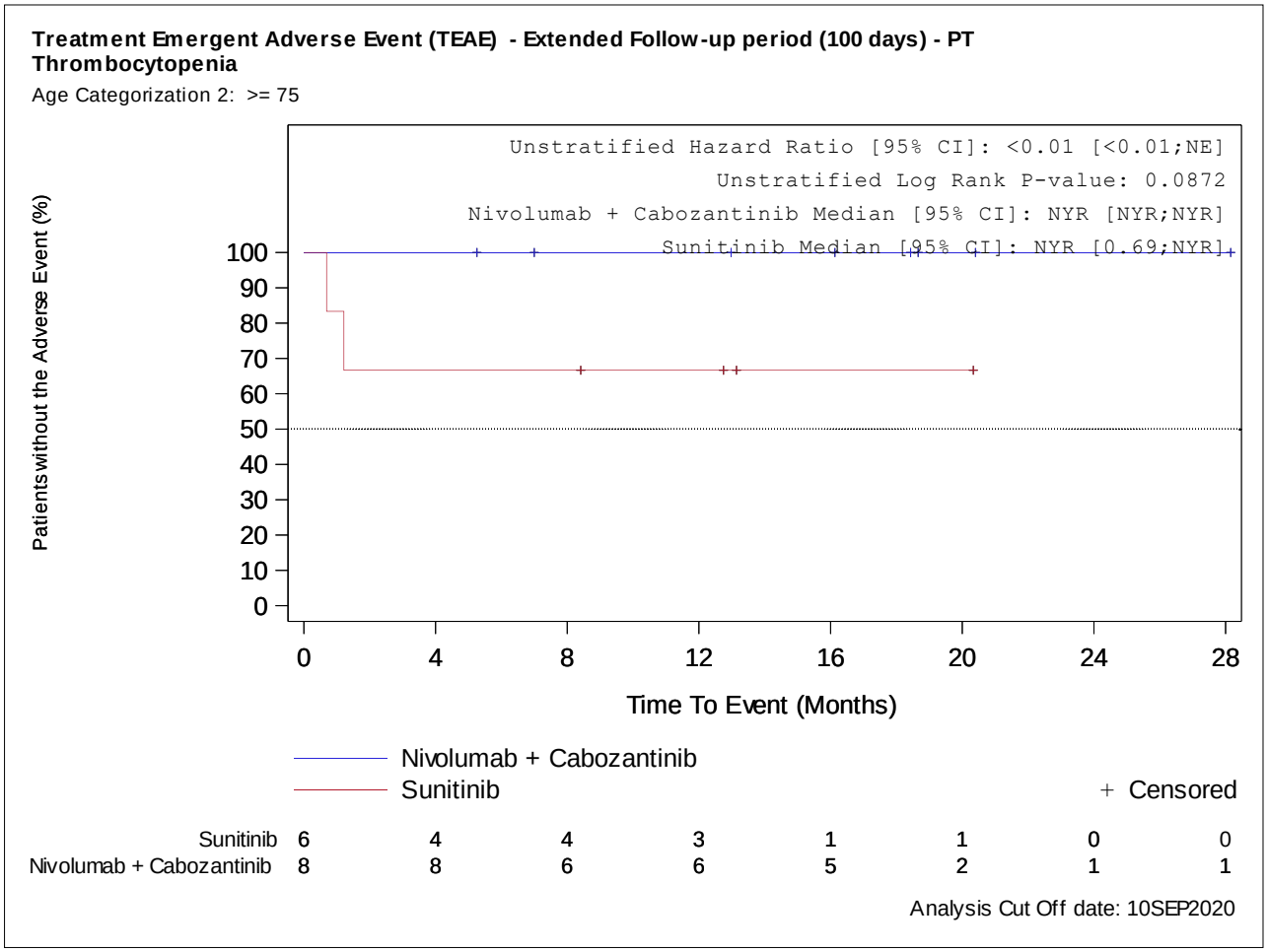
FIGURE 5.23.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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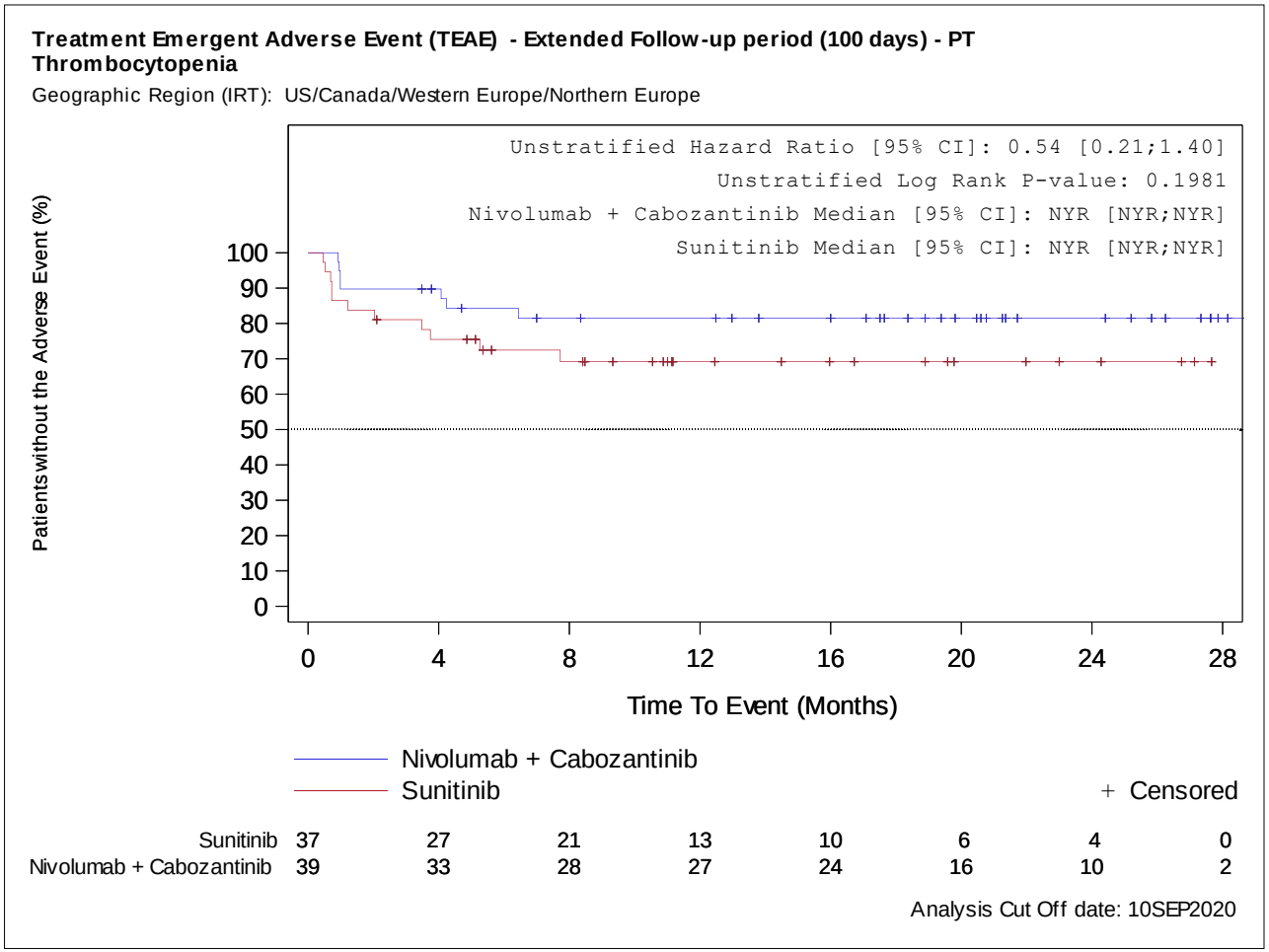
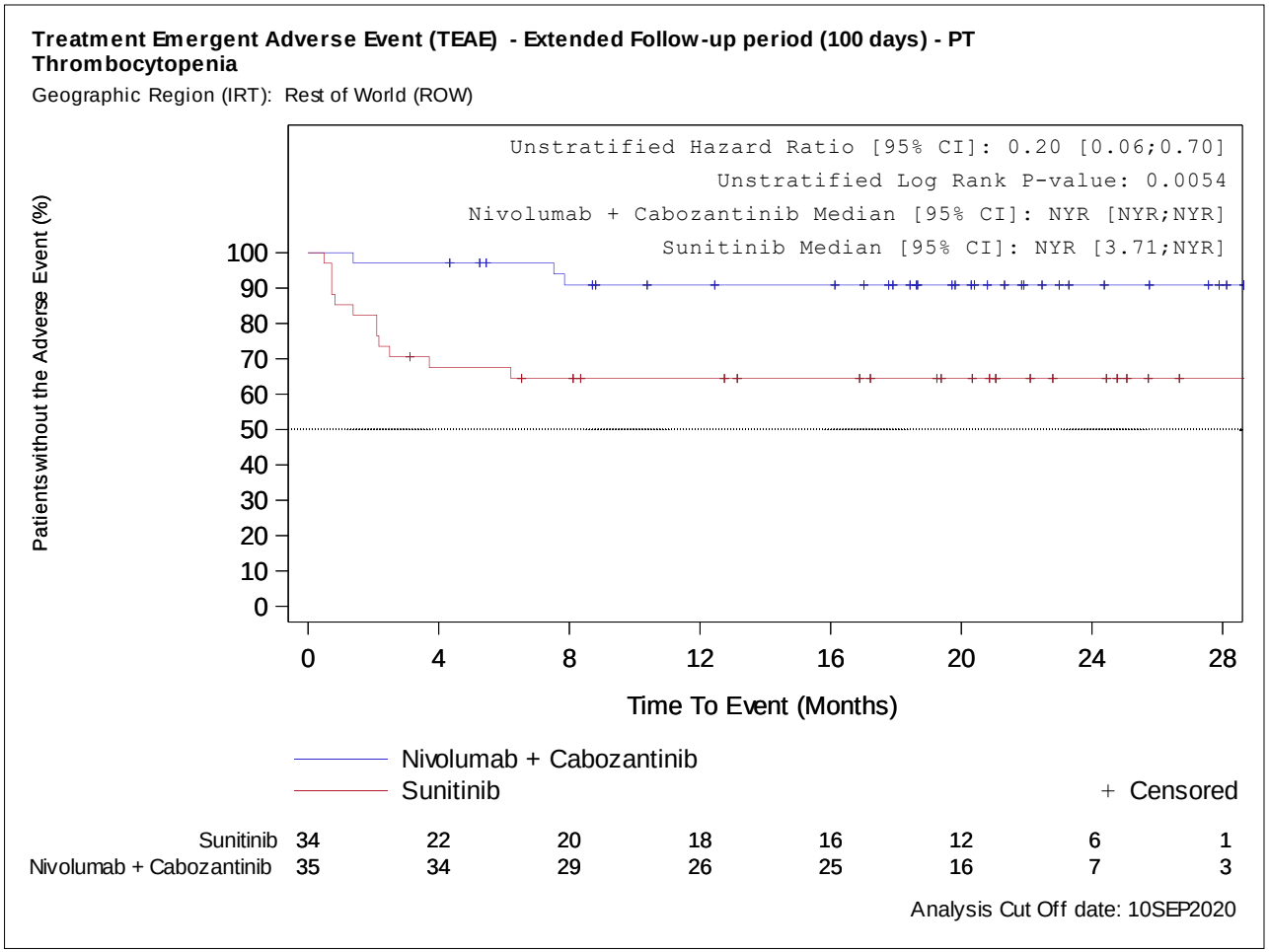
FIGURE 5.23.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:21:51

FIGURE 5.23.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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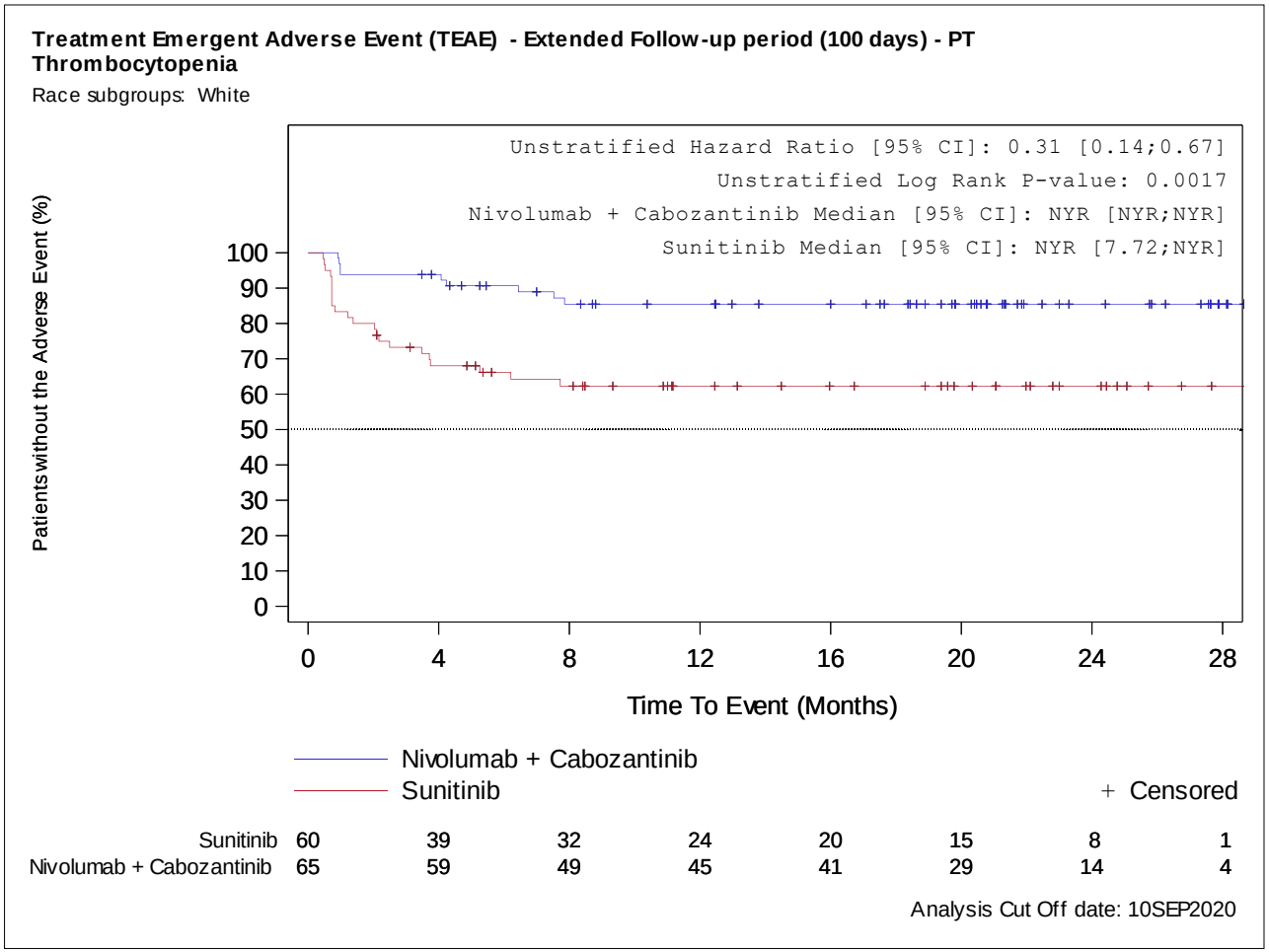
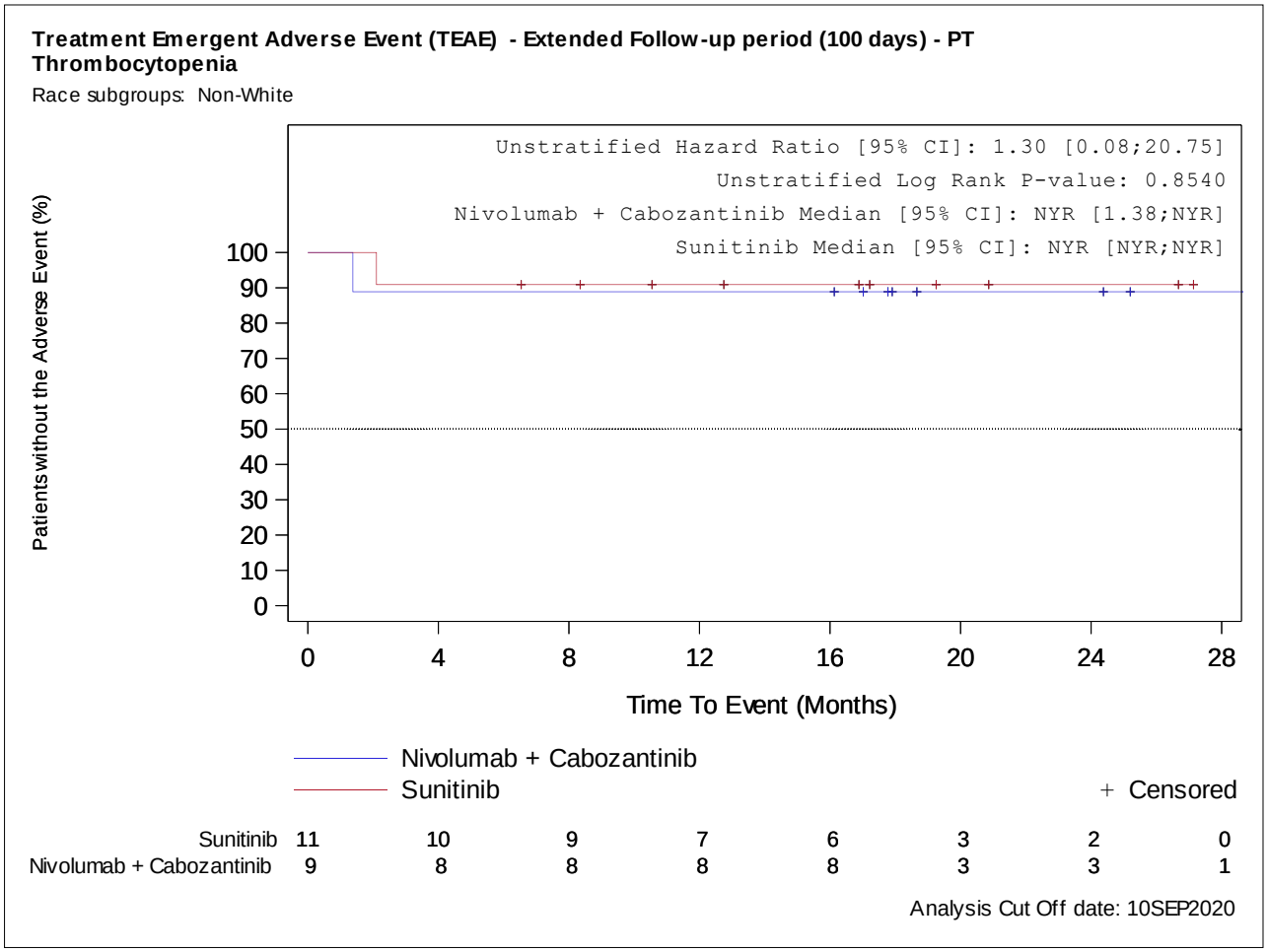
FIGURE 5.23.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



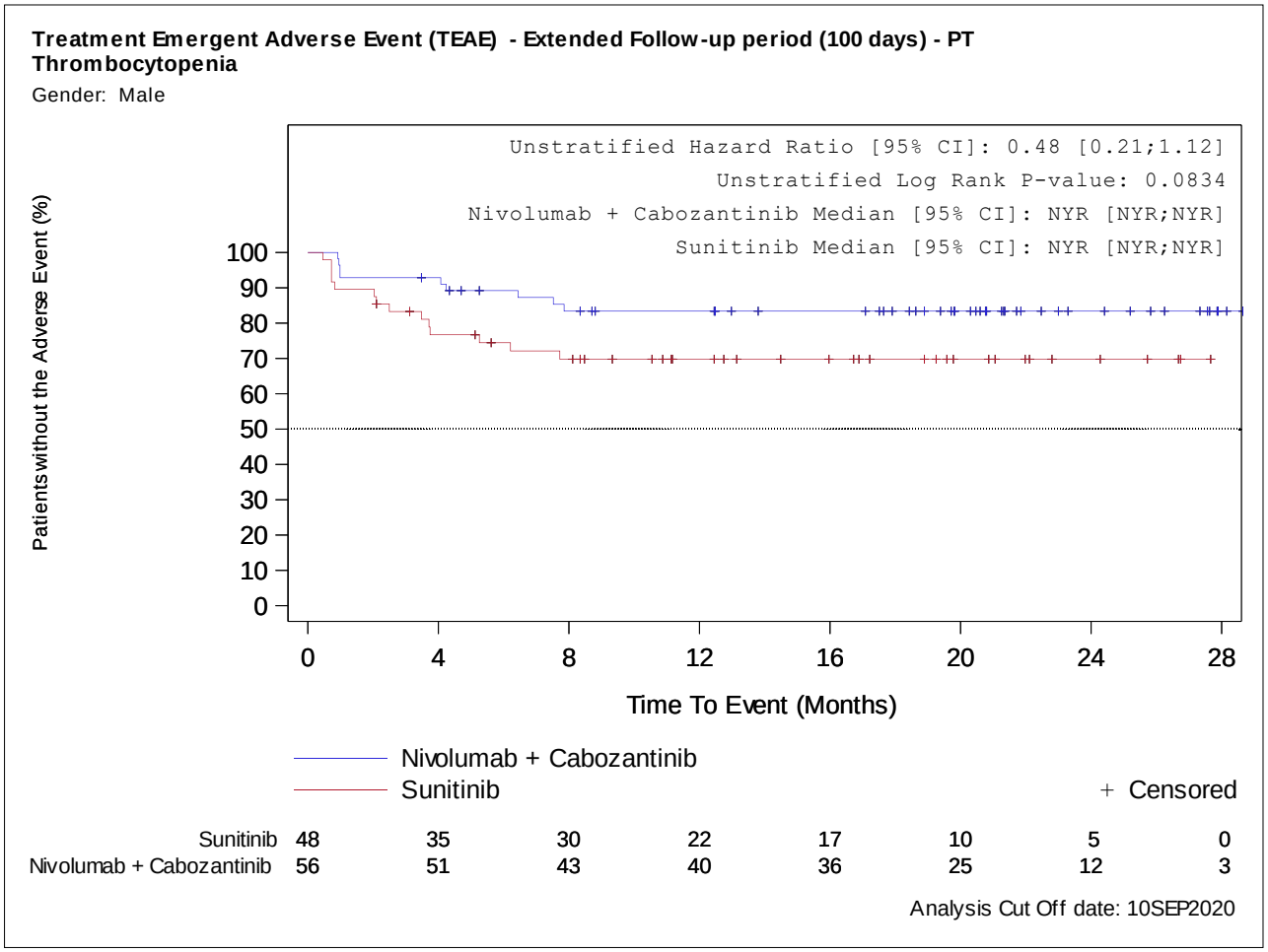

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:22:02

FIGURE 5.23.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



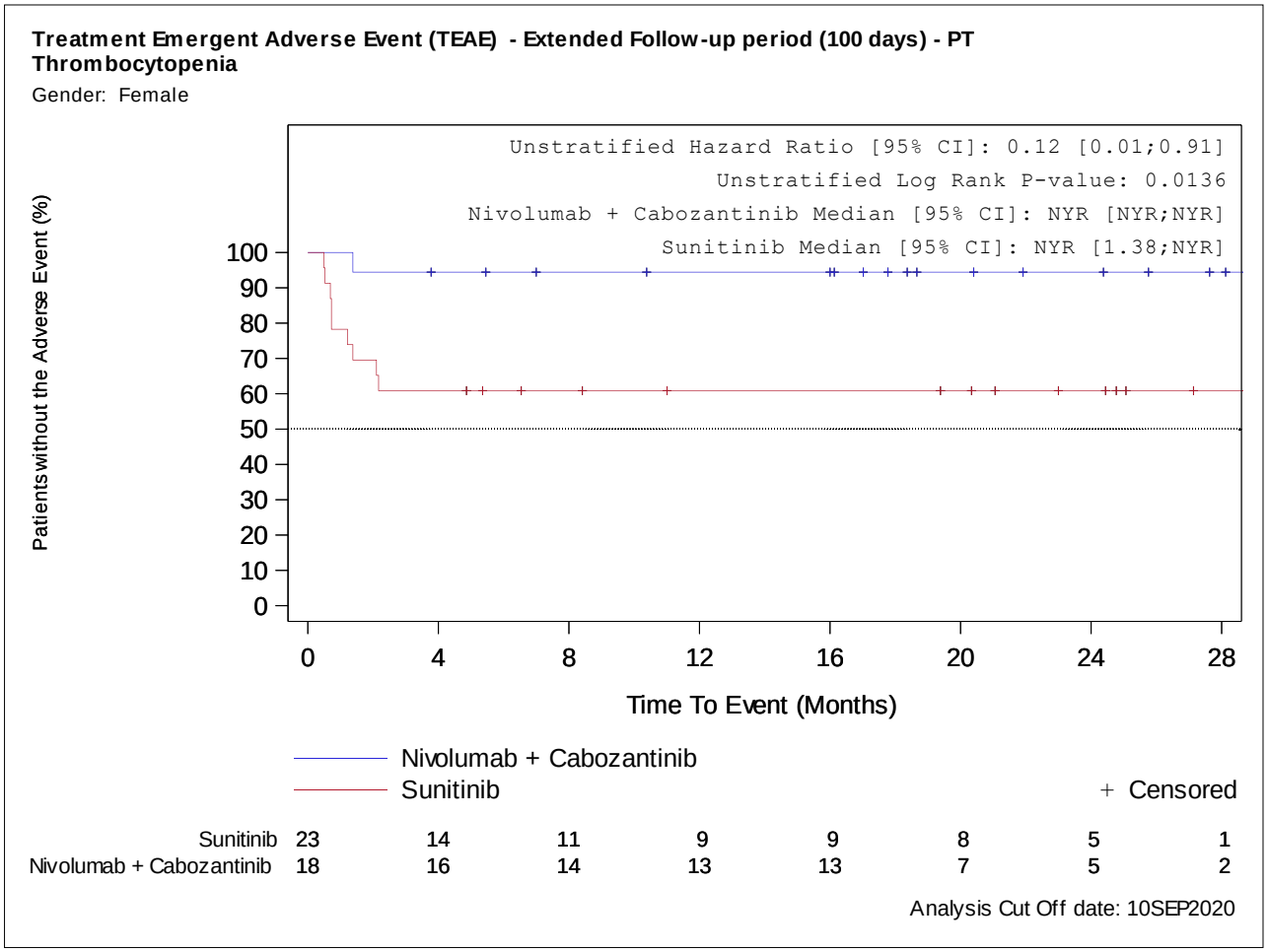

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:22:07

FIGURE 5.23.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



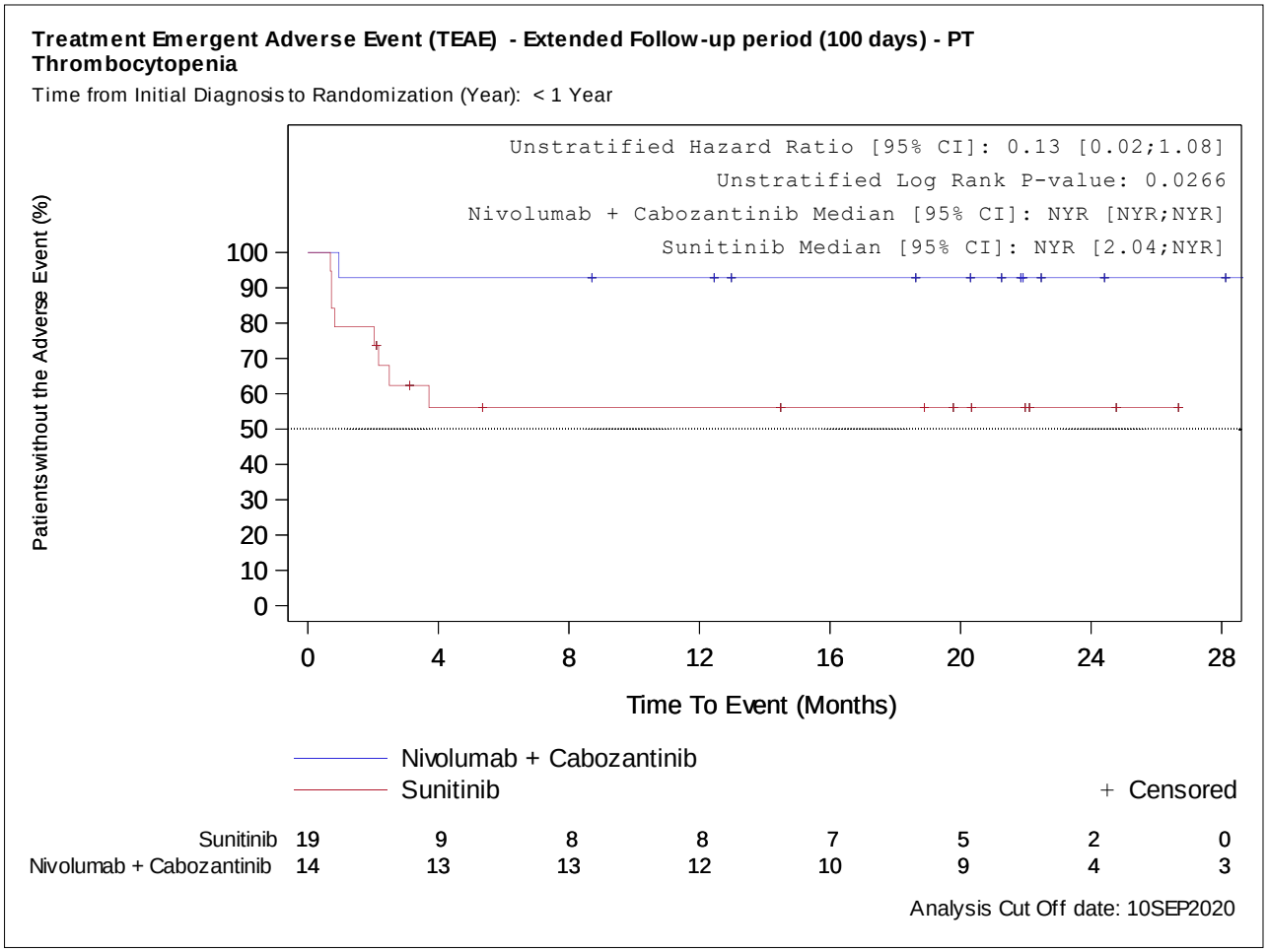

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:22:13

FIGURE 5.23.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:22:18

FIGURE 5.23.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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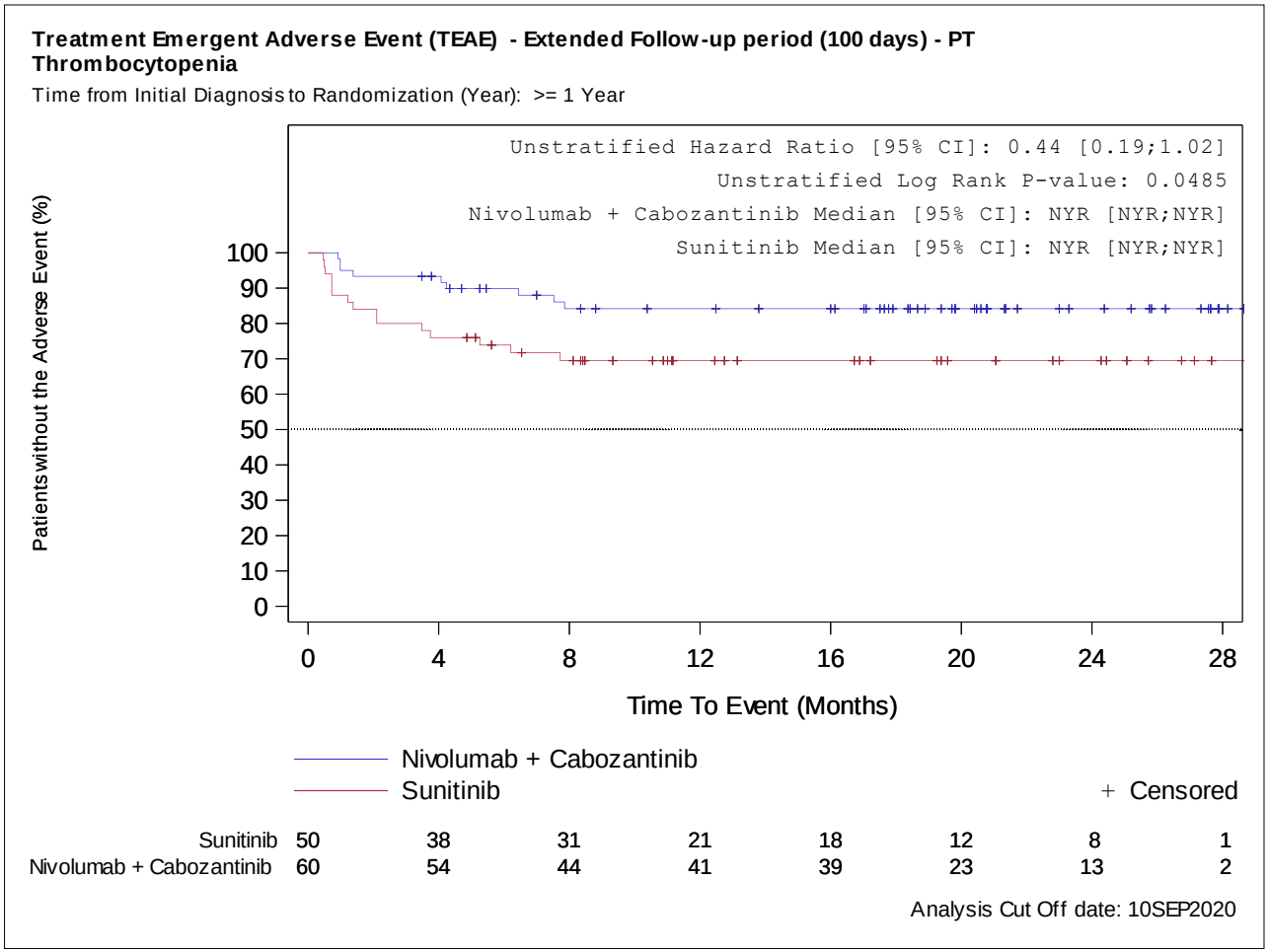
FIGURE 5.23.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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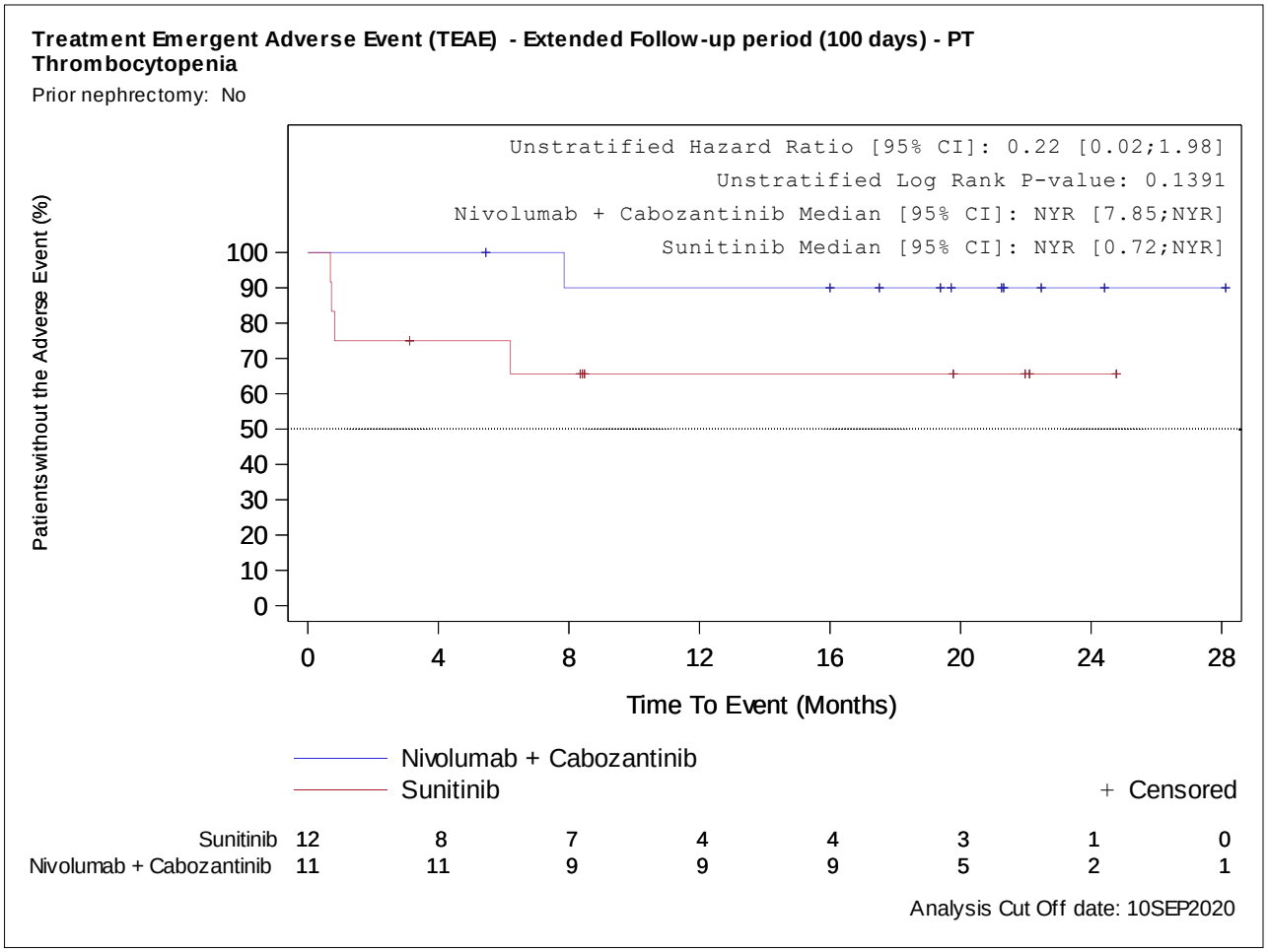
FIGURE 5.23.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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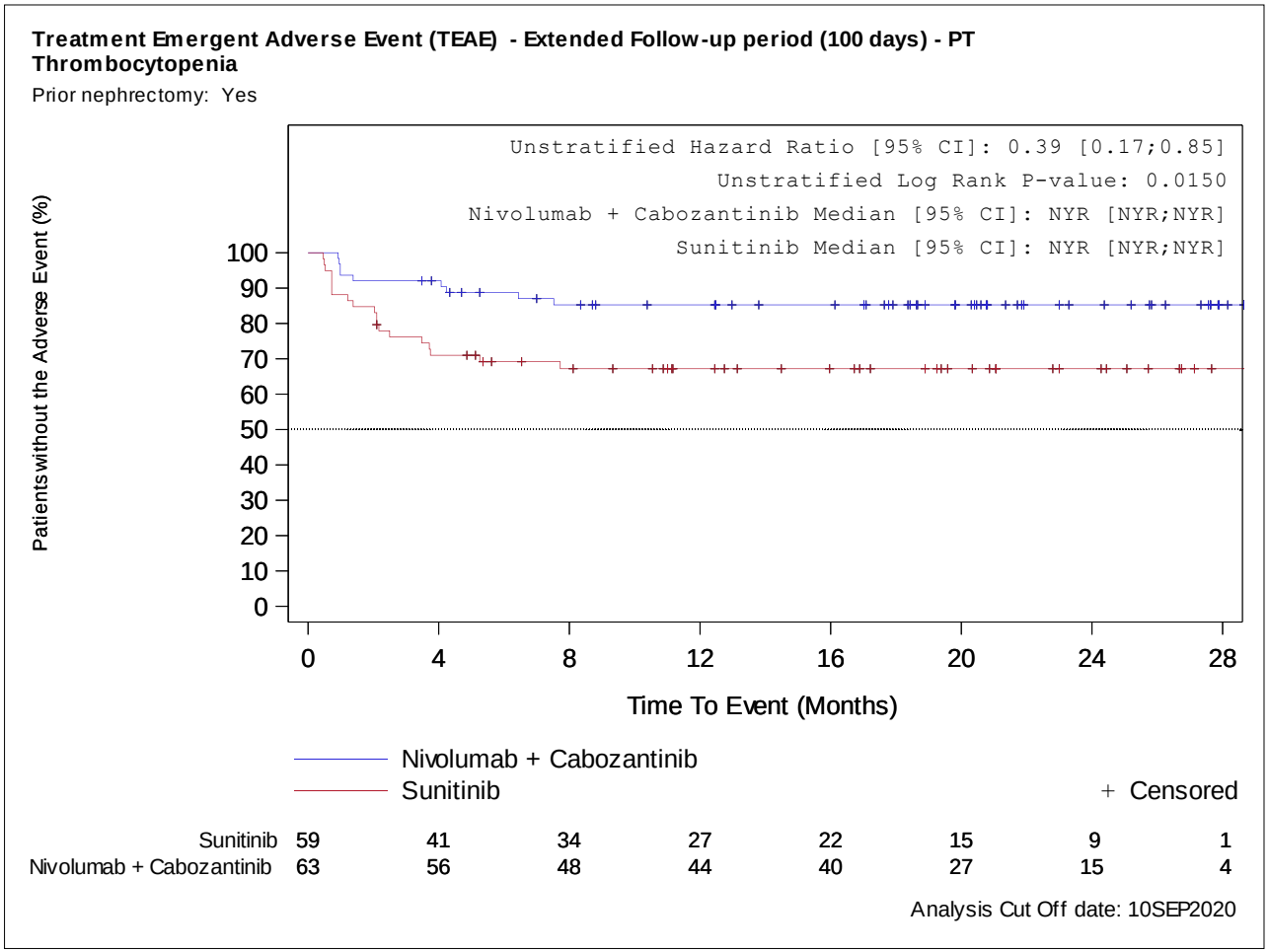
FIGURE 5.23.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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FIGURE 5.23.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No

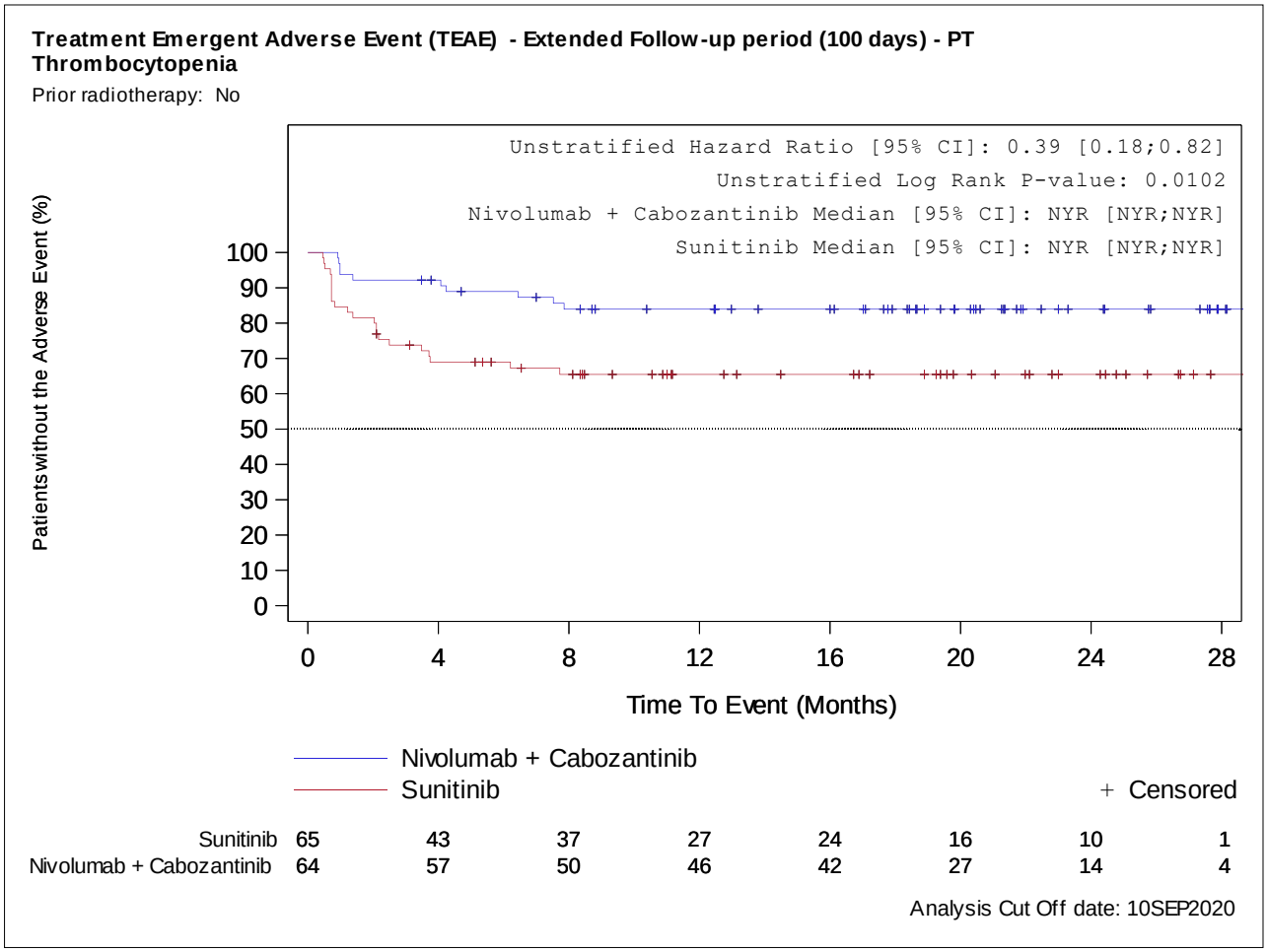


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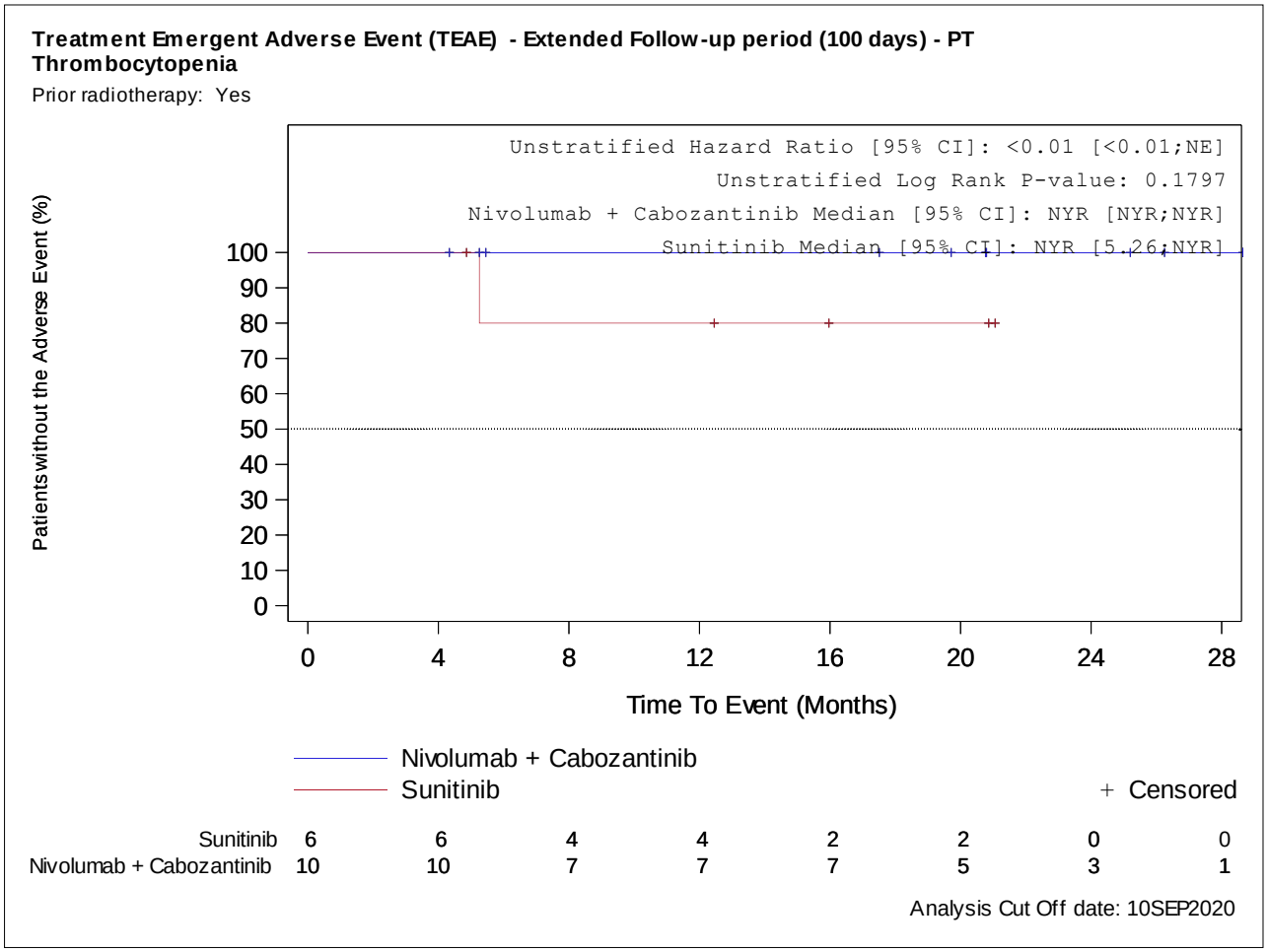
FIGURE 5.23.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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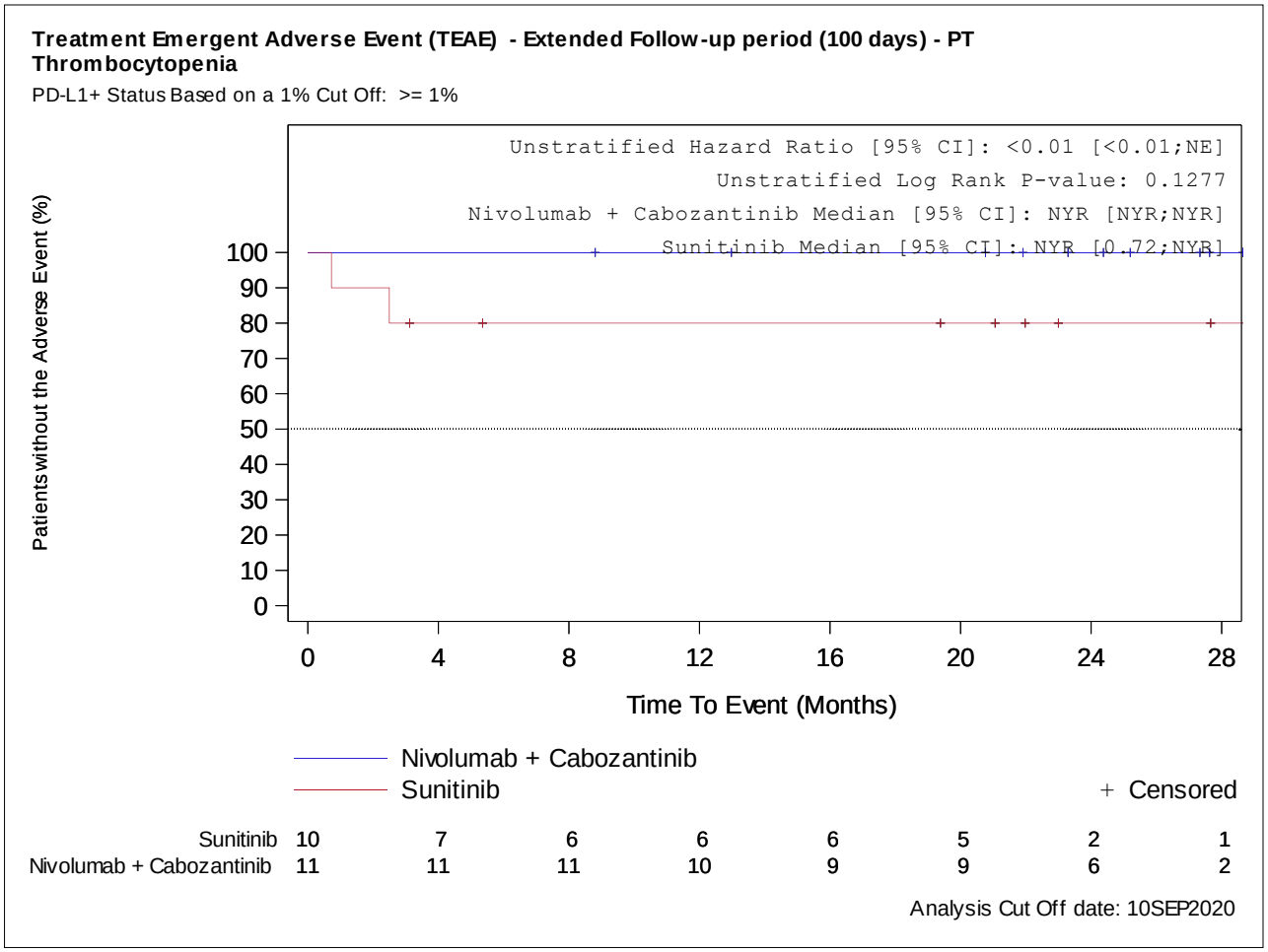
FIGURE 5.23.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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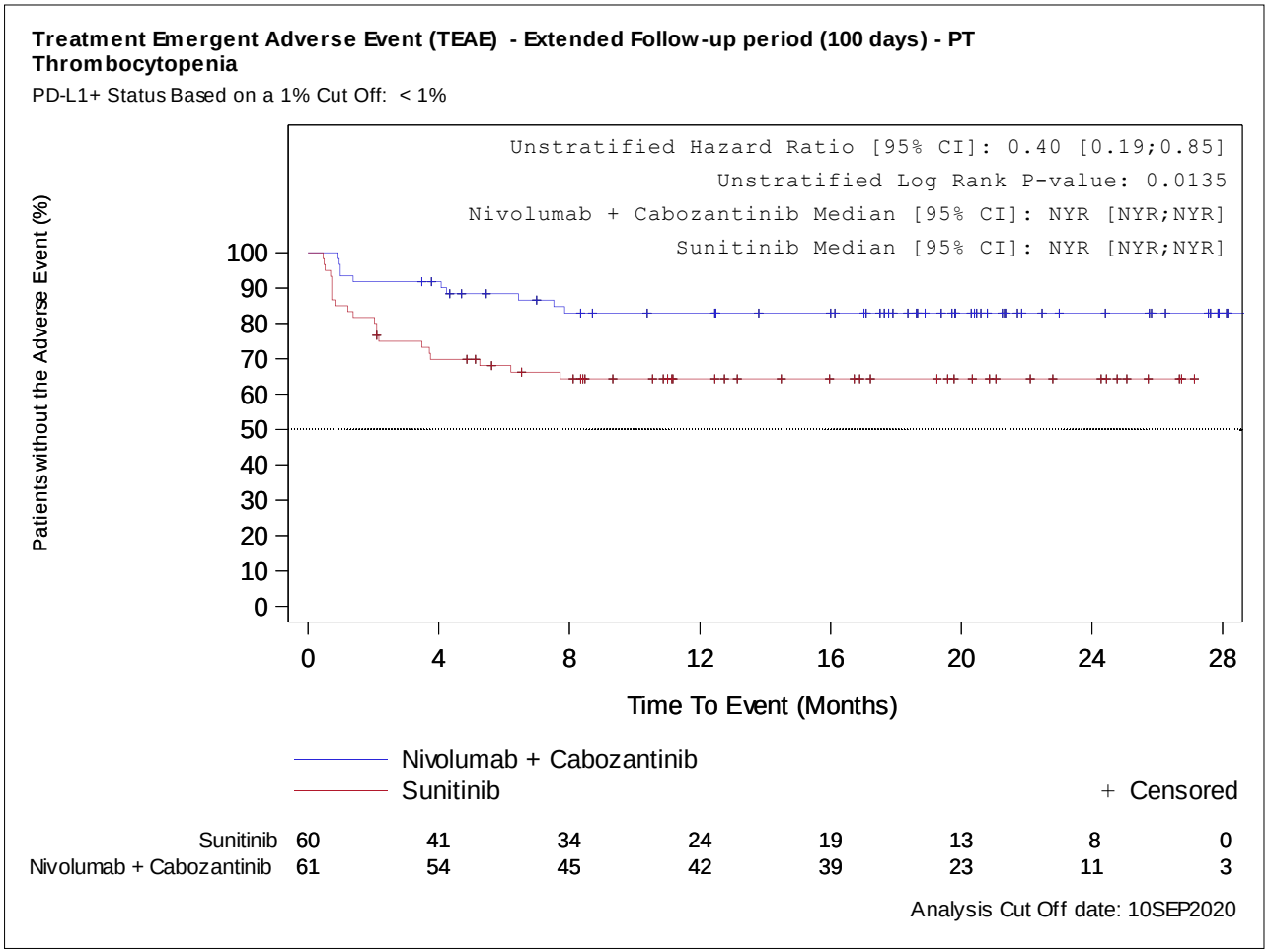
FIGURE 5.23.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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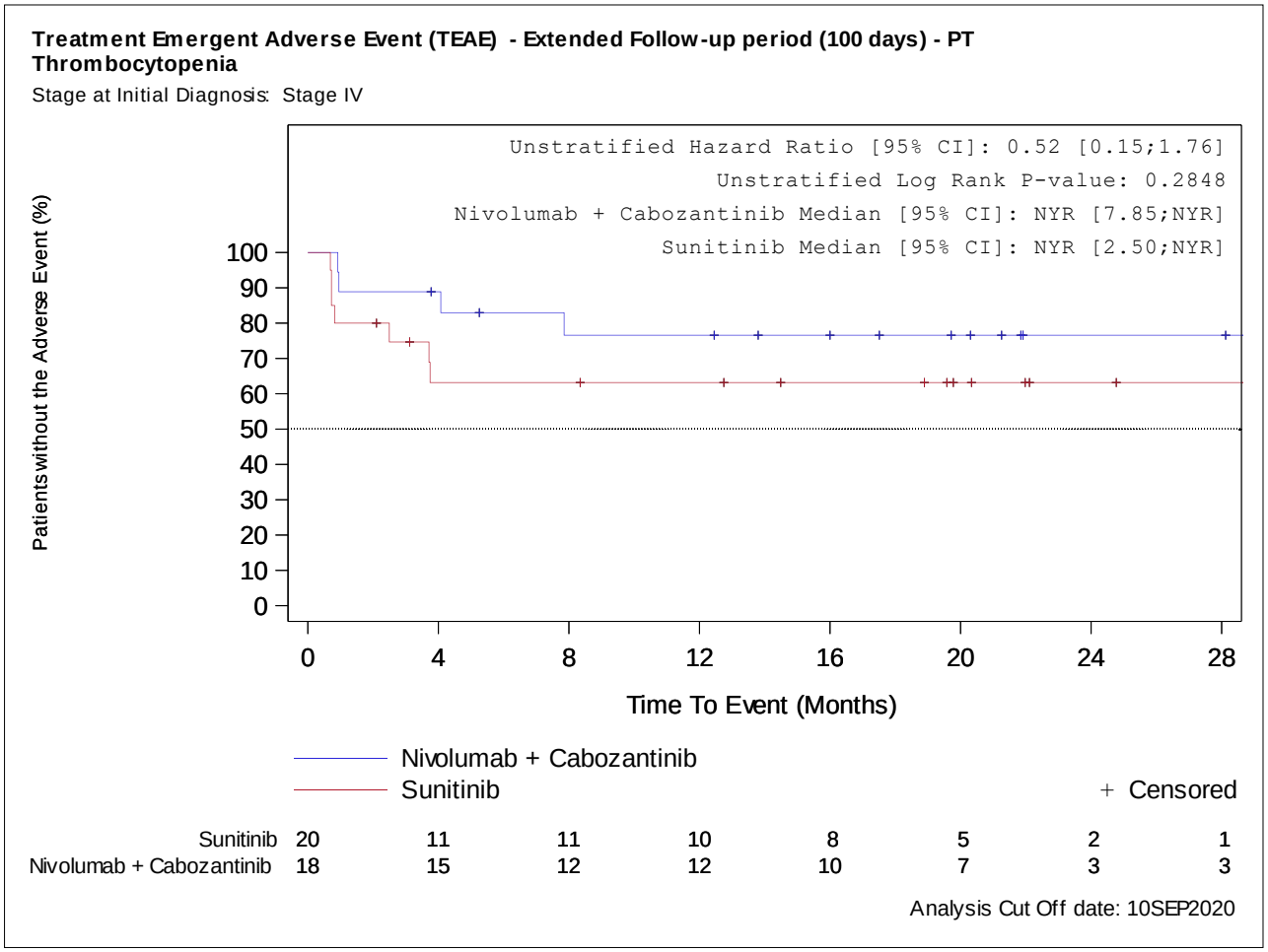
FIGURE 5.23.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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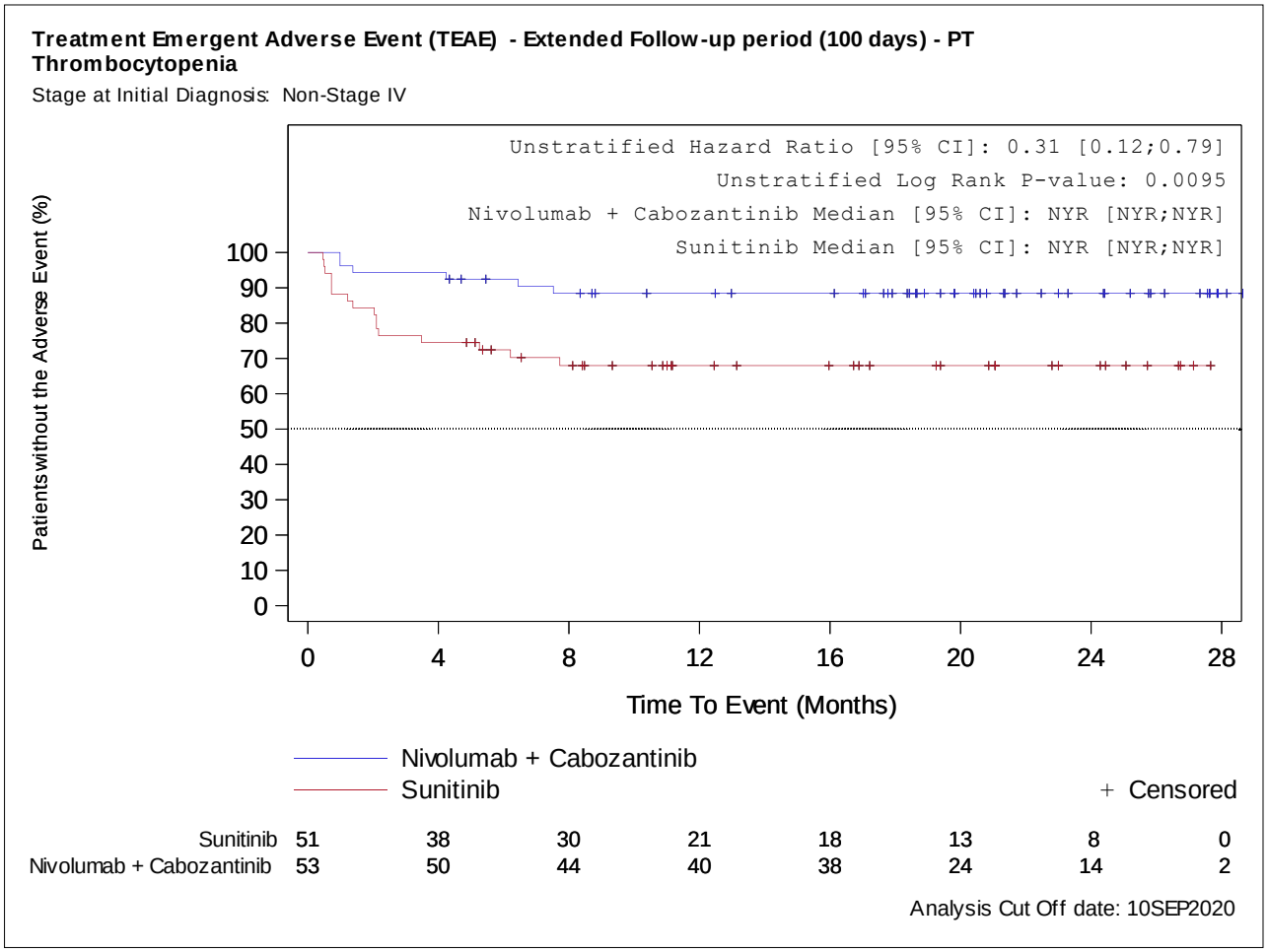
FIGURE 5.23.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Thrombocytopenia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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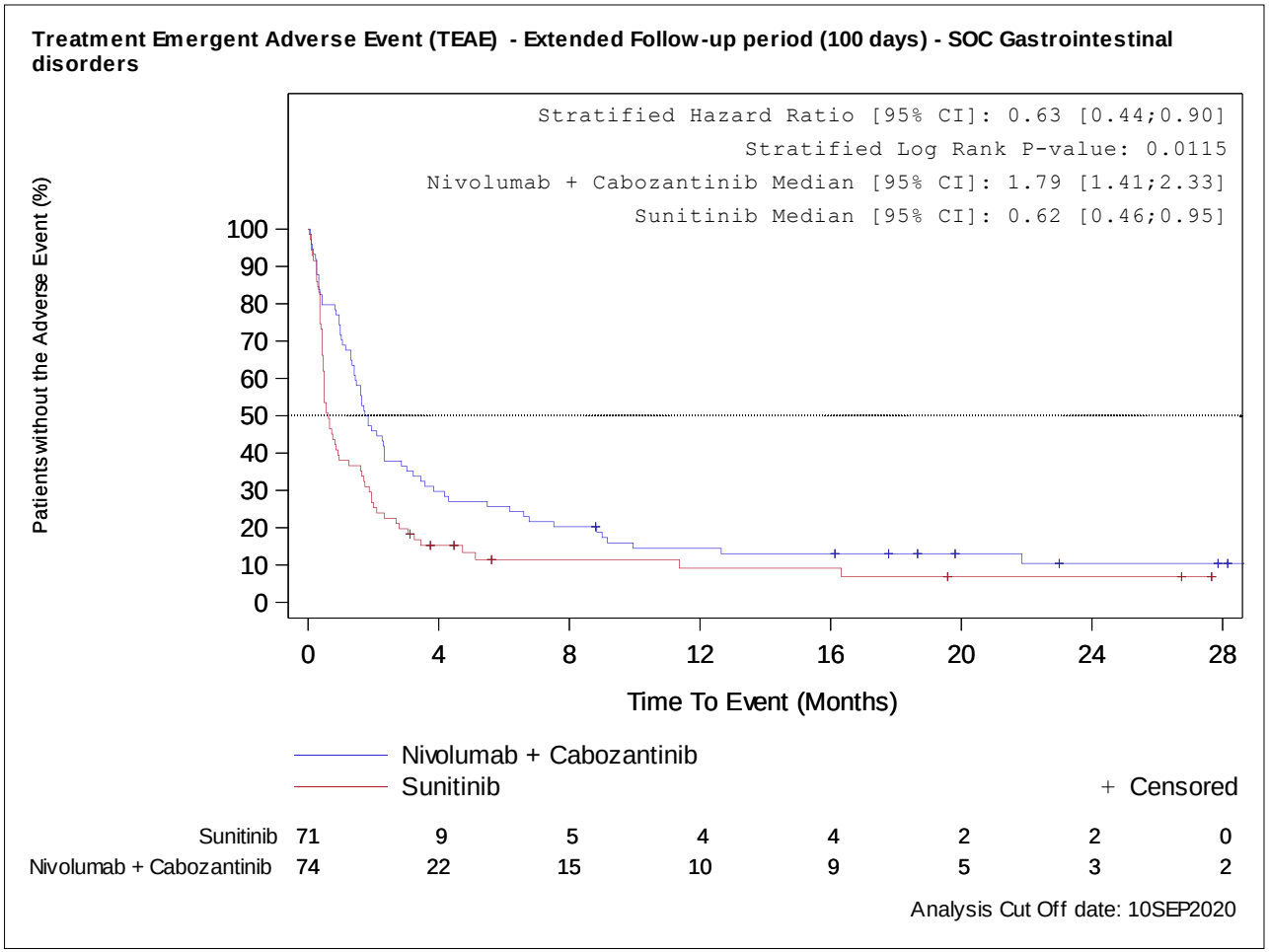
FIGURE 5.24.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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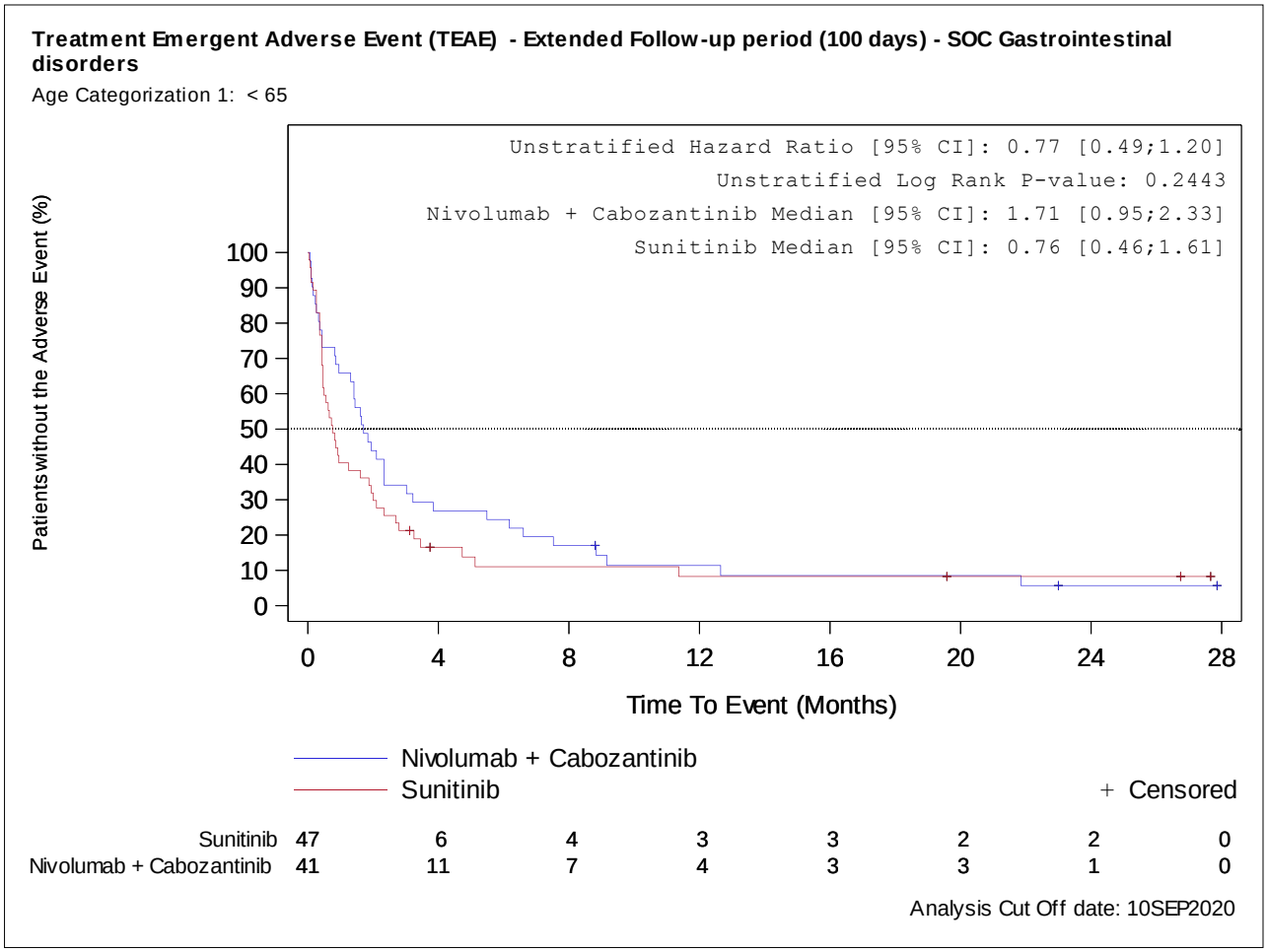
FIGURE 5.24.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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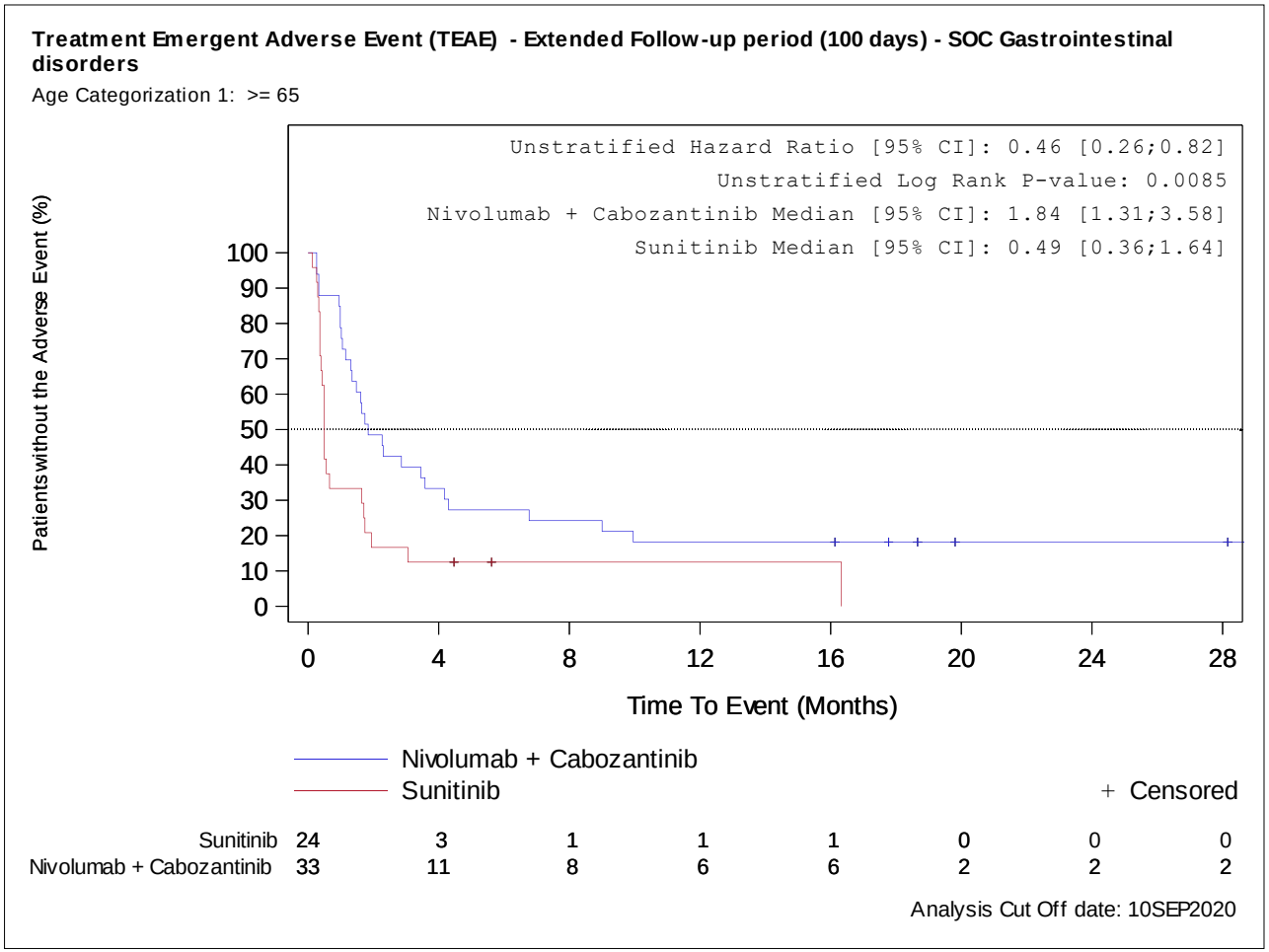
FIGURE 5.24.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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FIGURE 5.24.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65

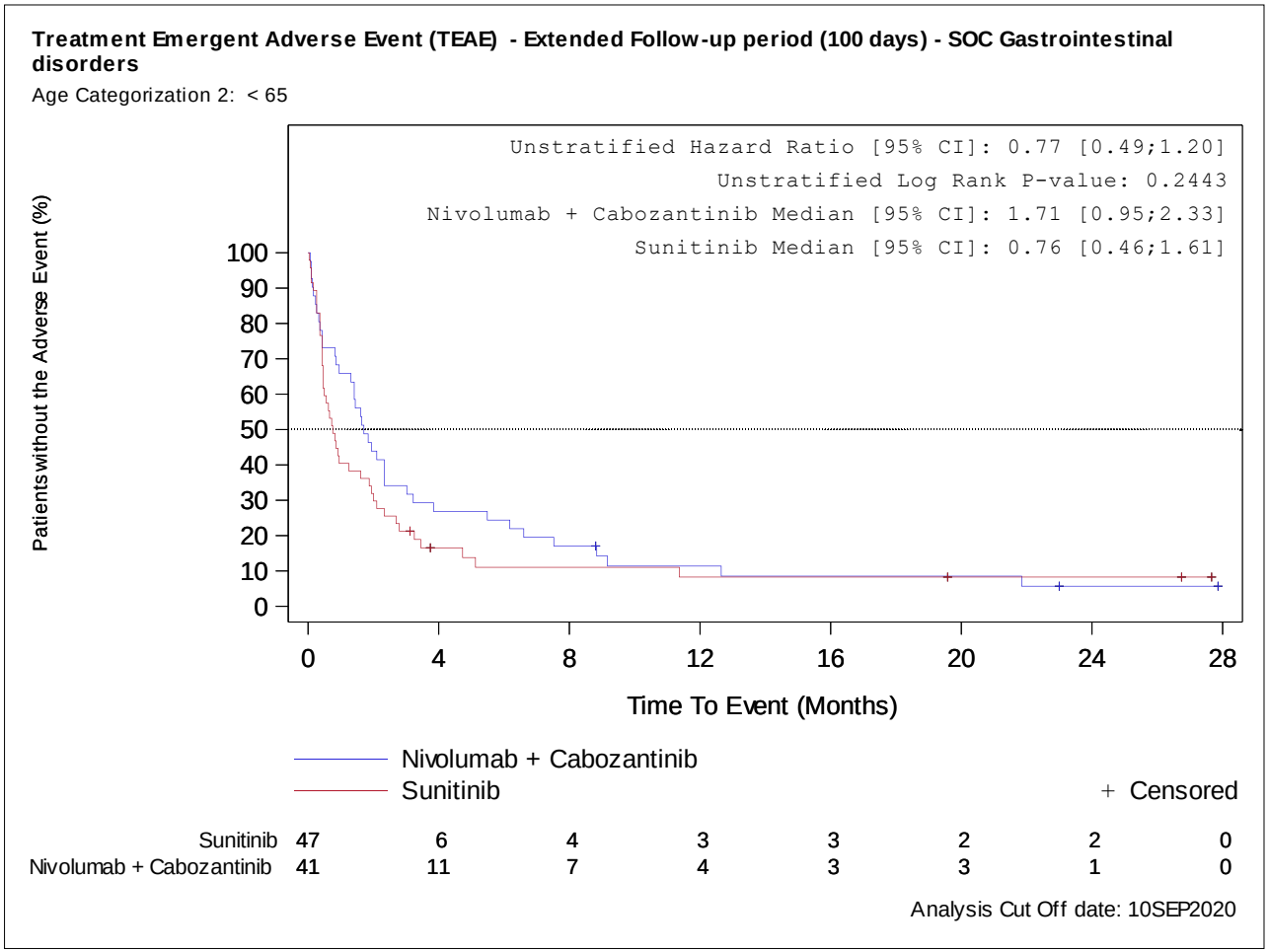


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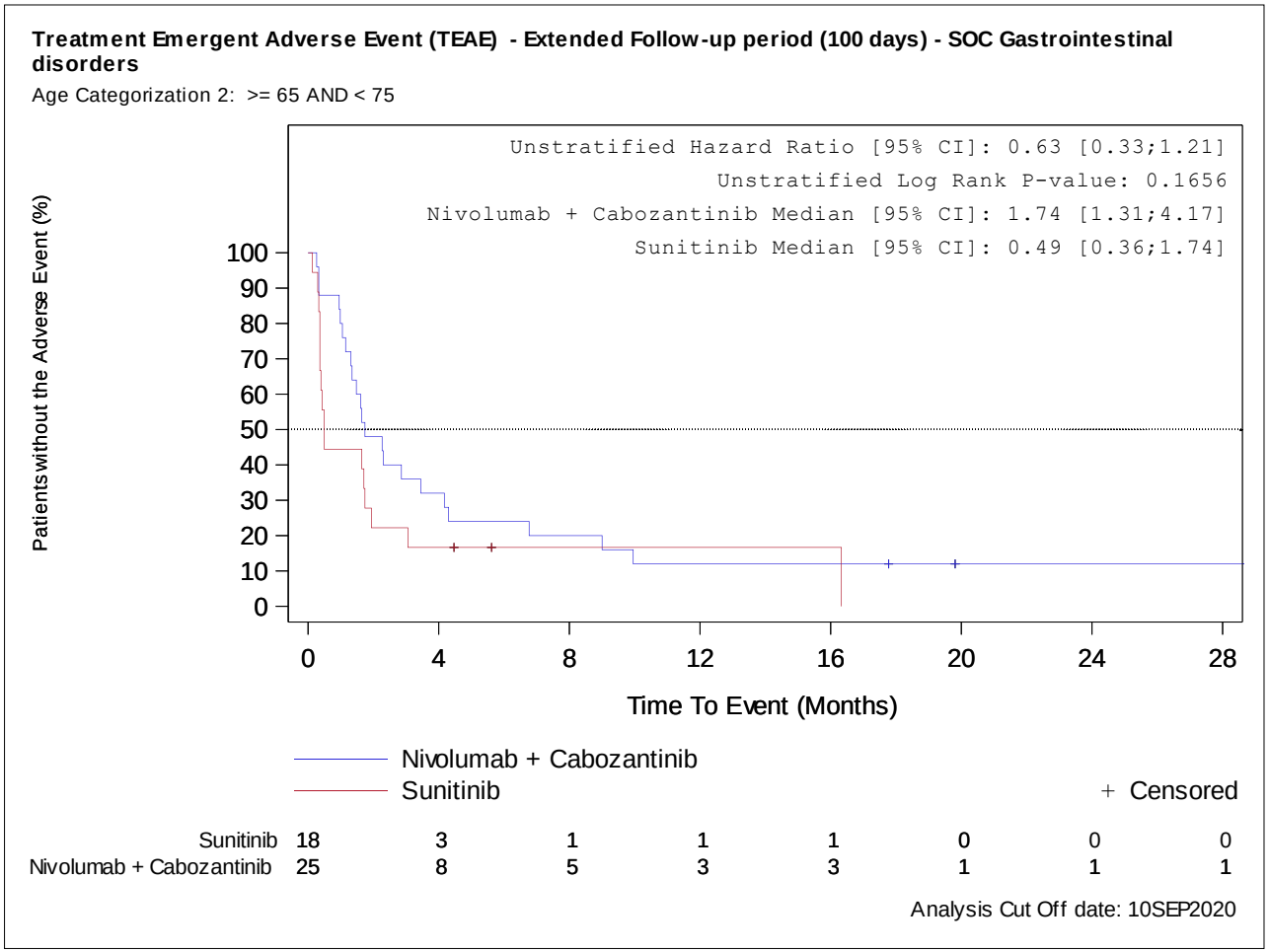
FIGURE 5.24.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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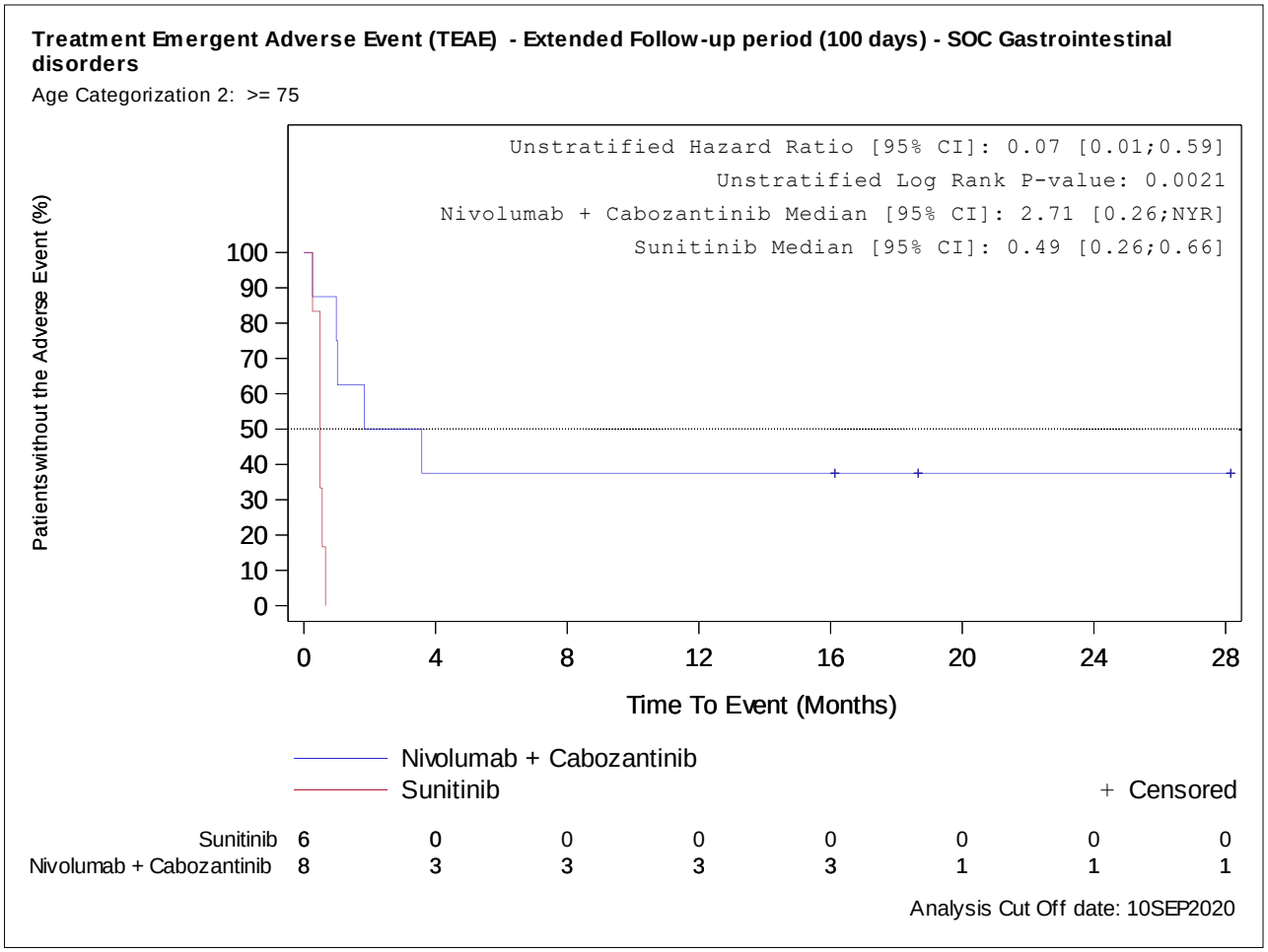
FIGURE 5.24.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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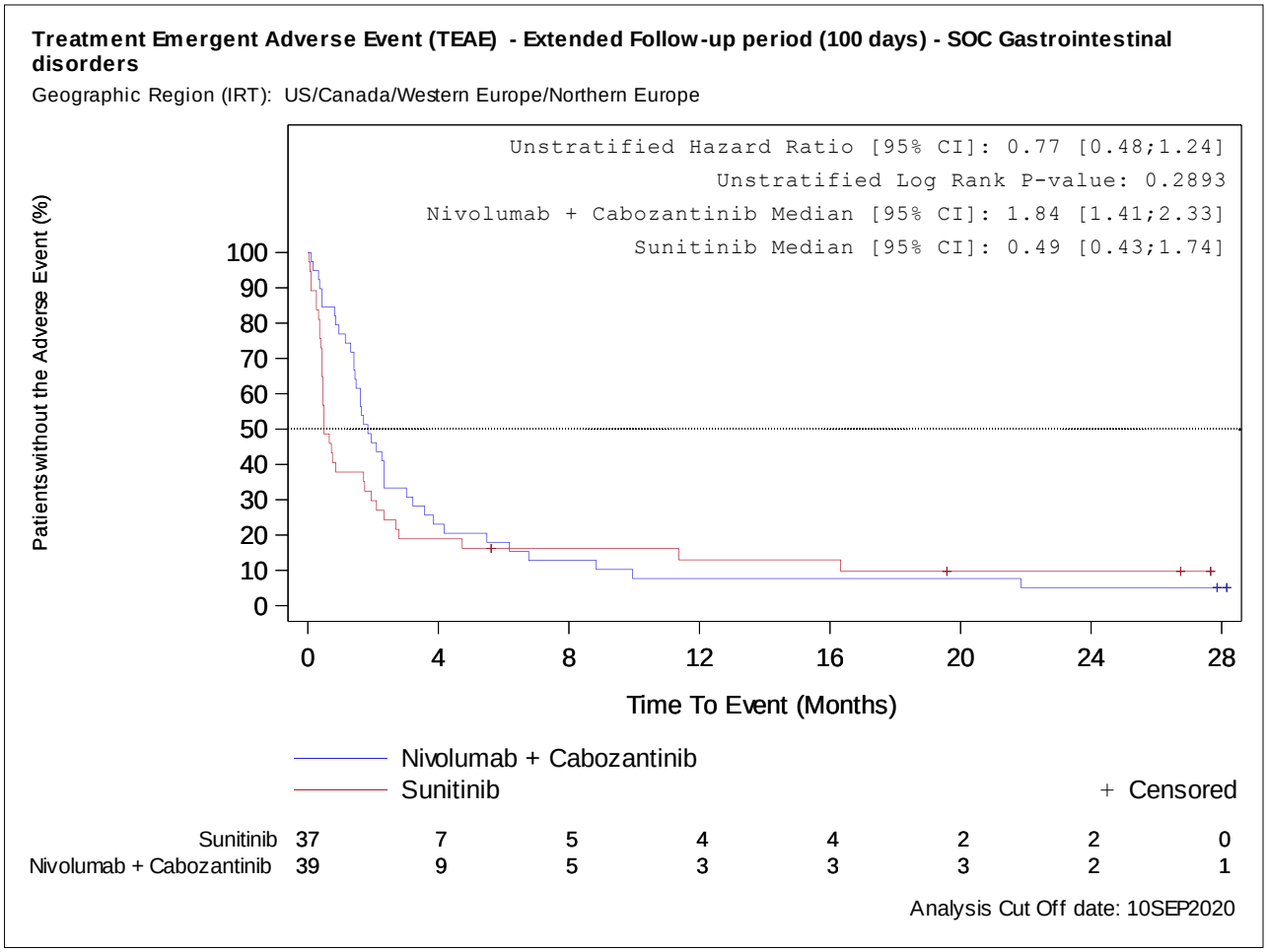
FIGURE 5.24.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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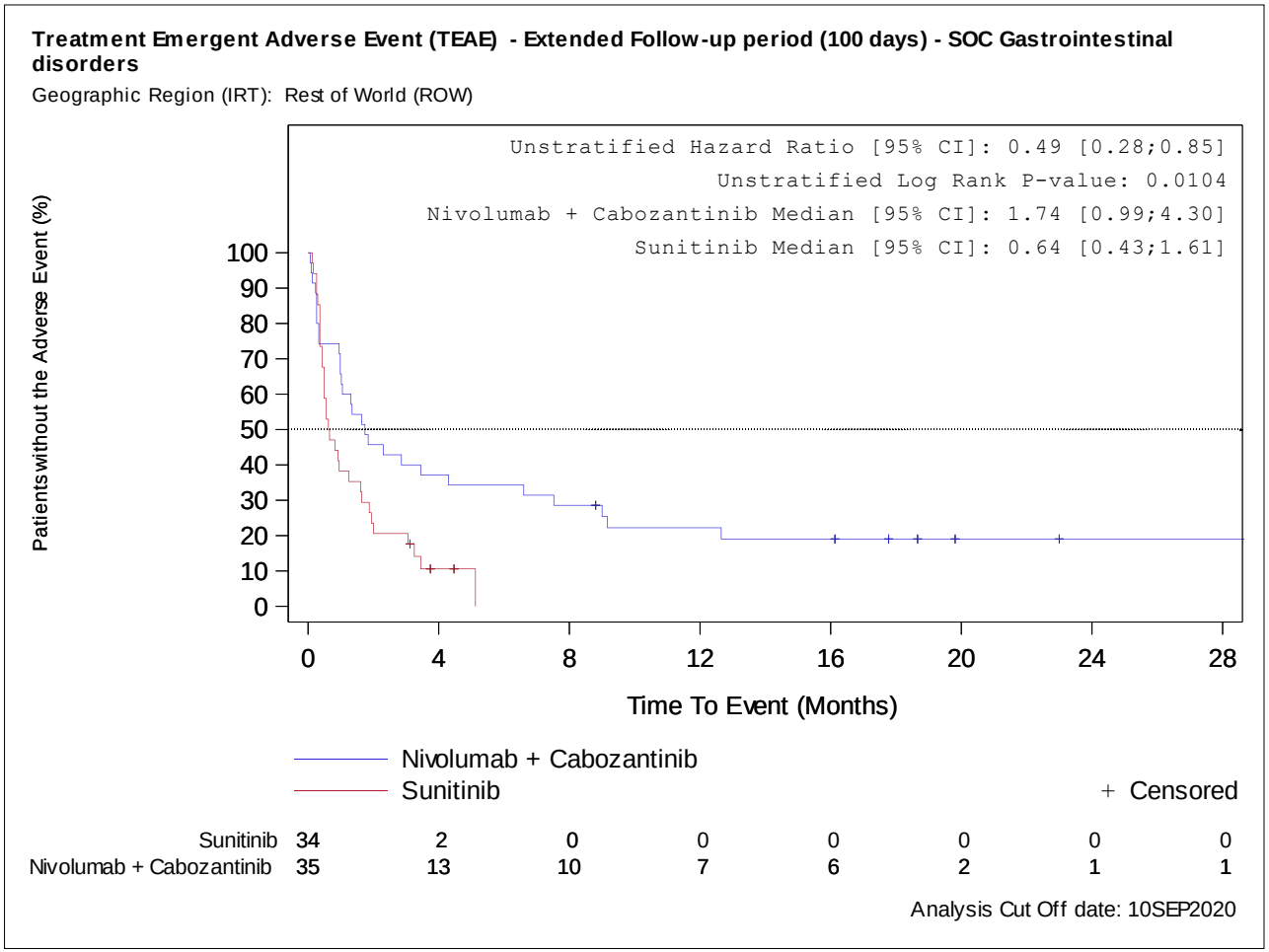
FIGURE 5.24.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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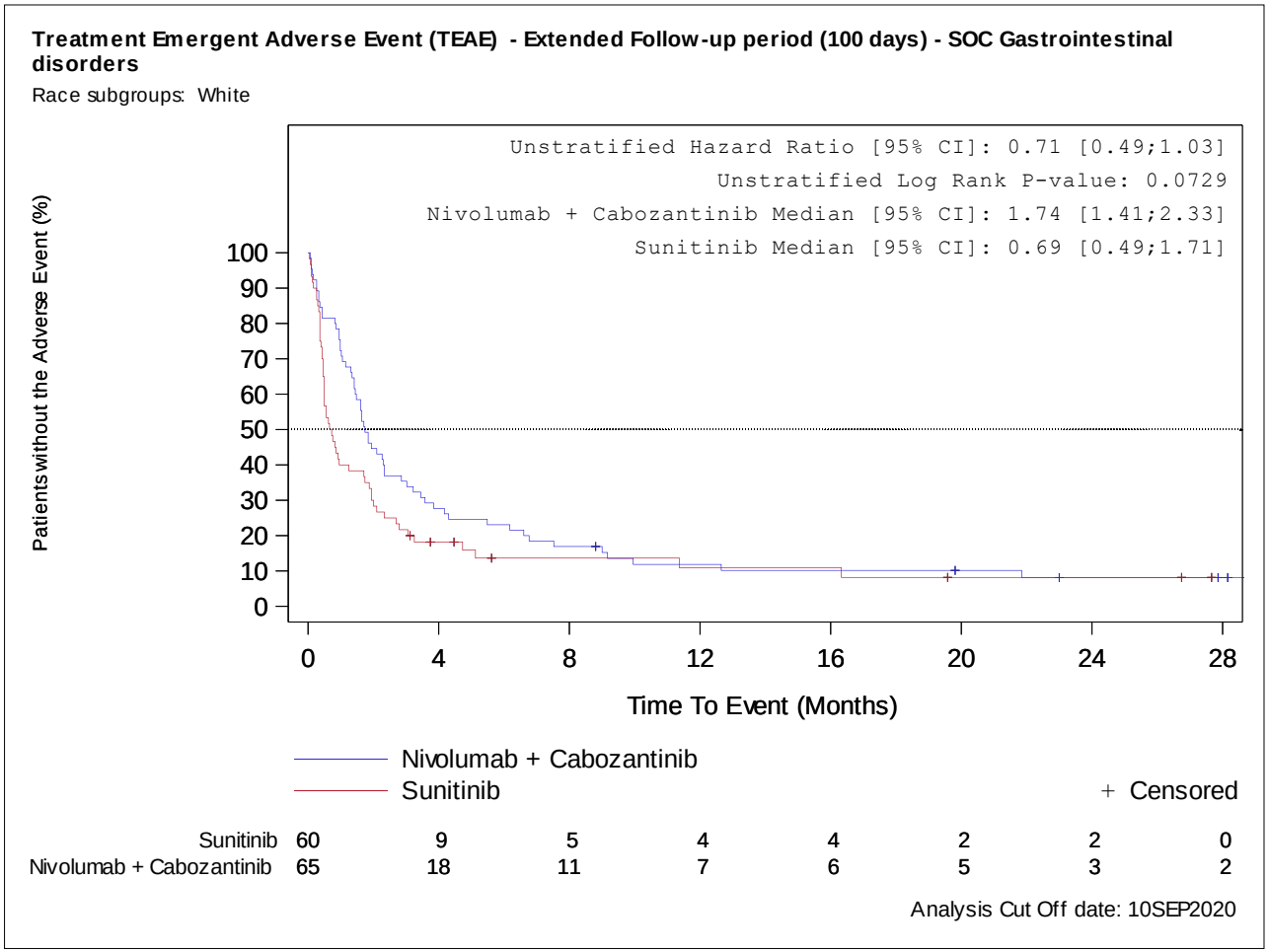
FIGURE 5.24.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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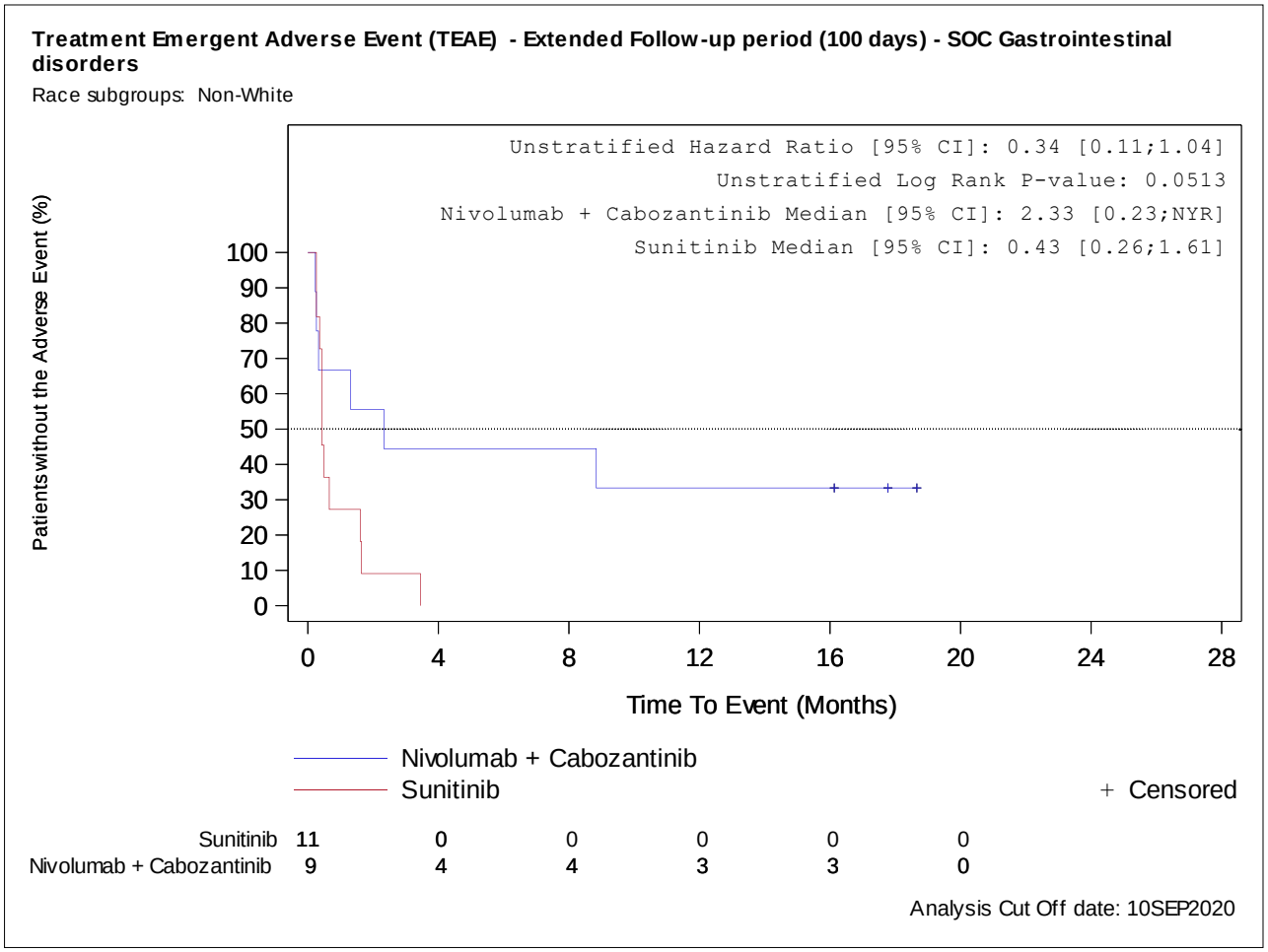
FIGURE 5.24.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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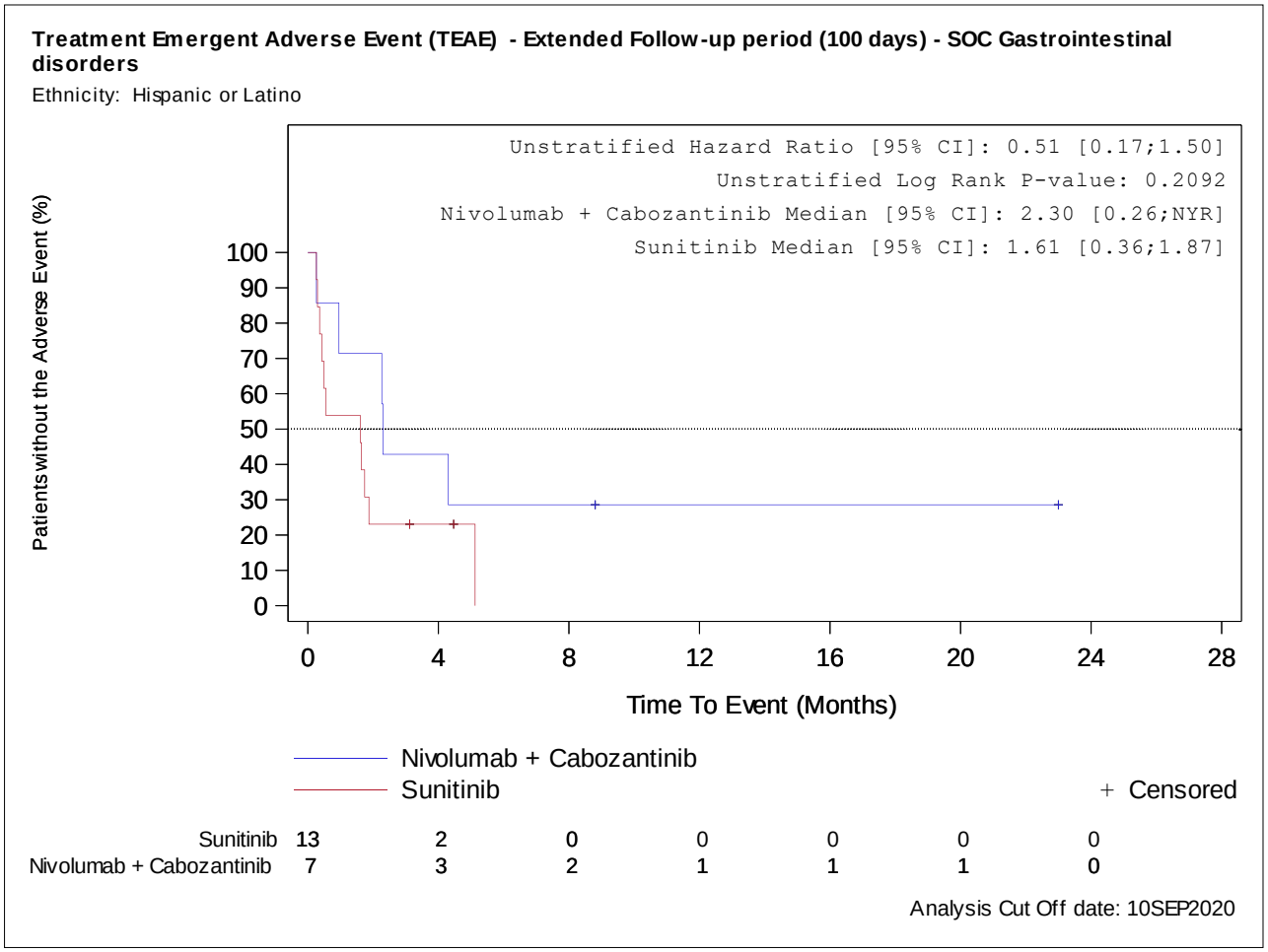
FIGURE 5.24.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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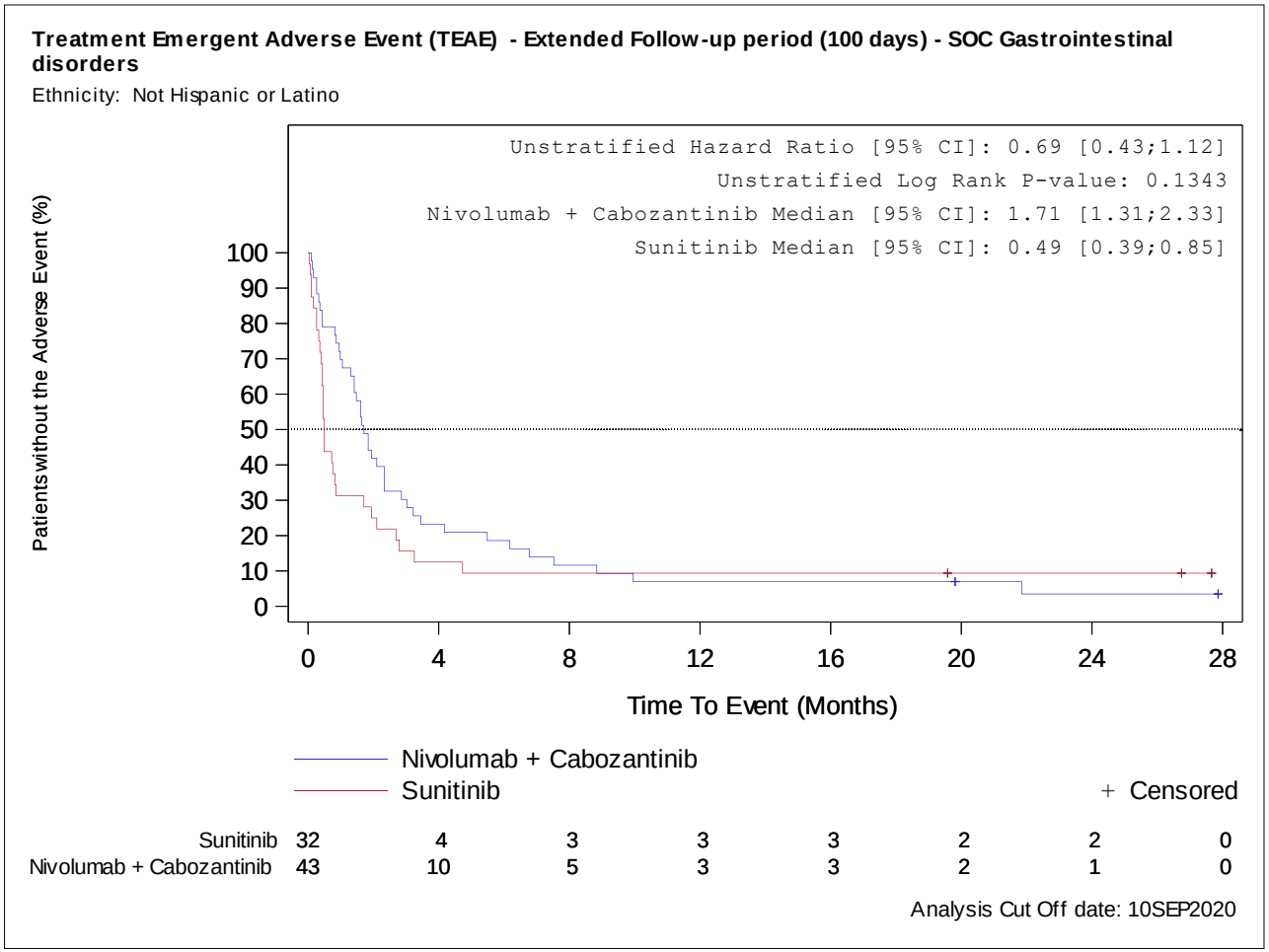
FIGURE 5.24.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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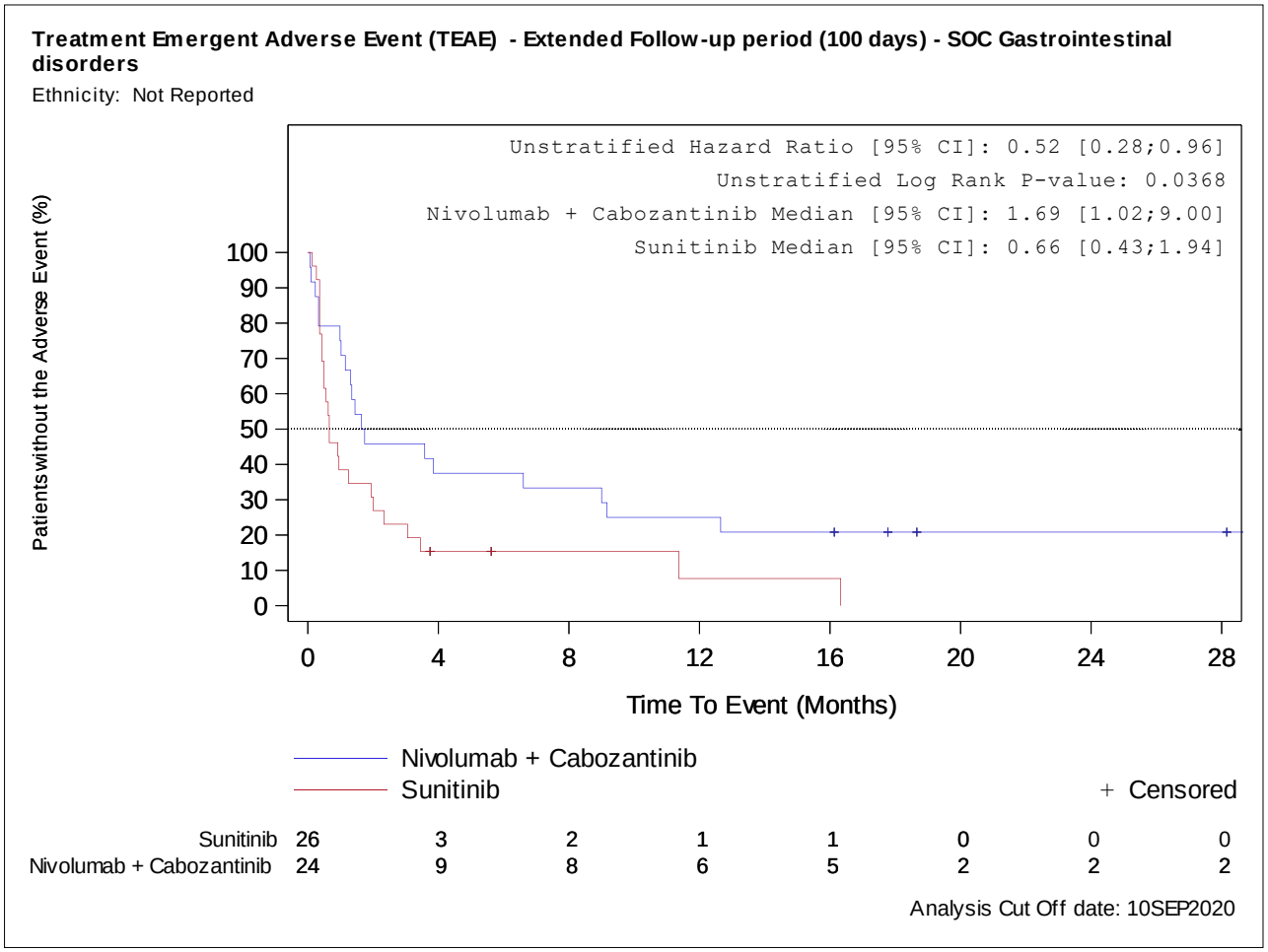
FIGURE 5.24.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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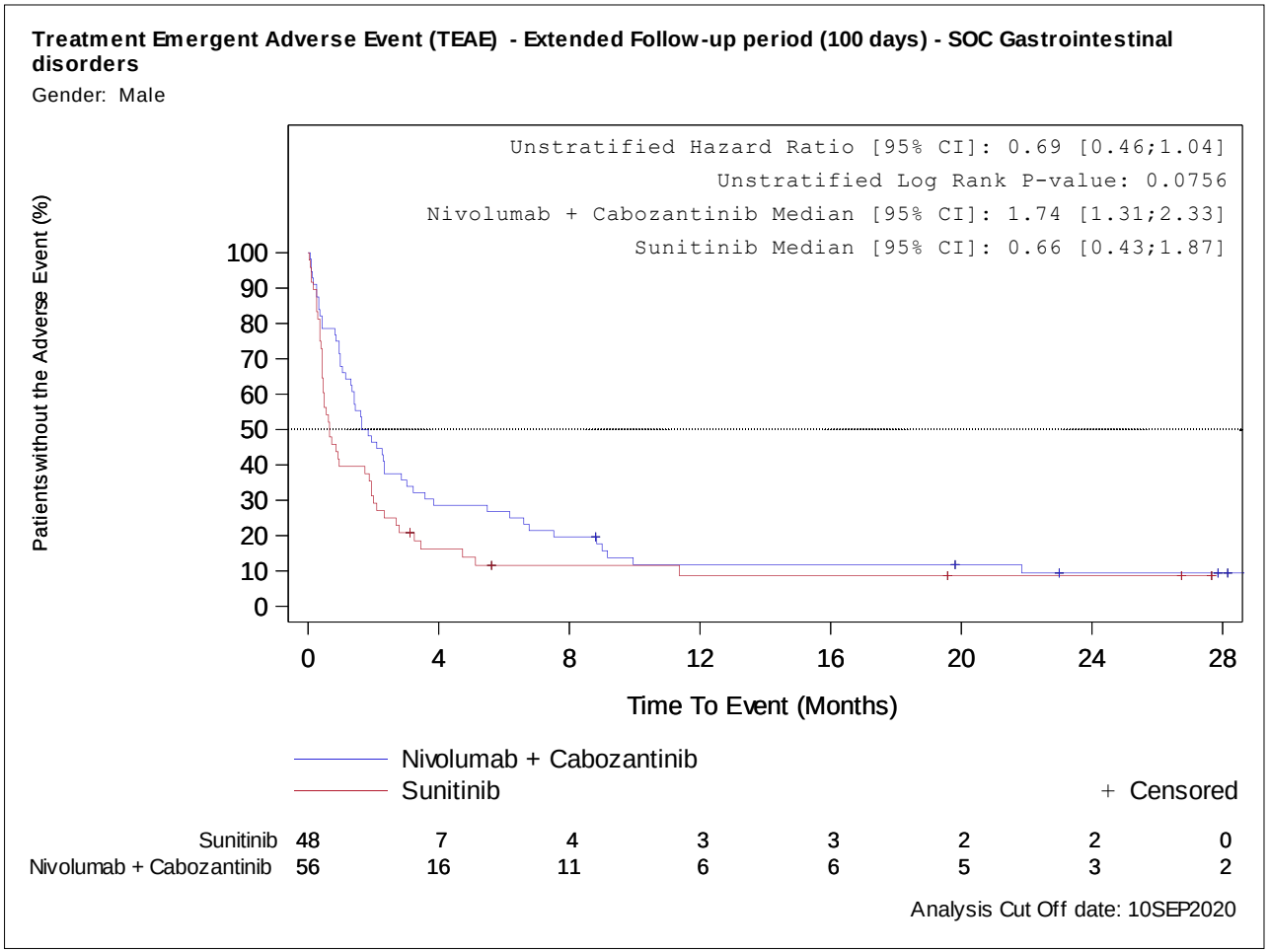
FIGURE 5.24.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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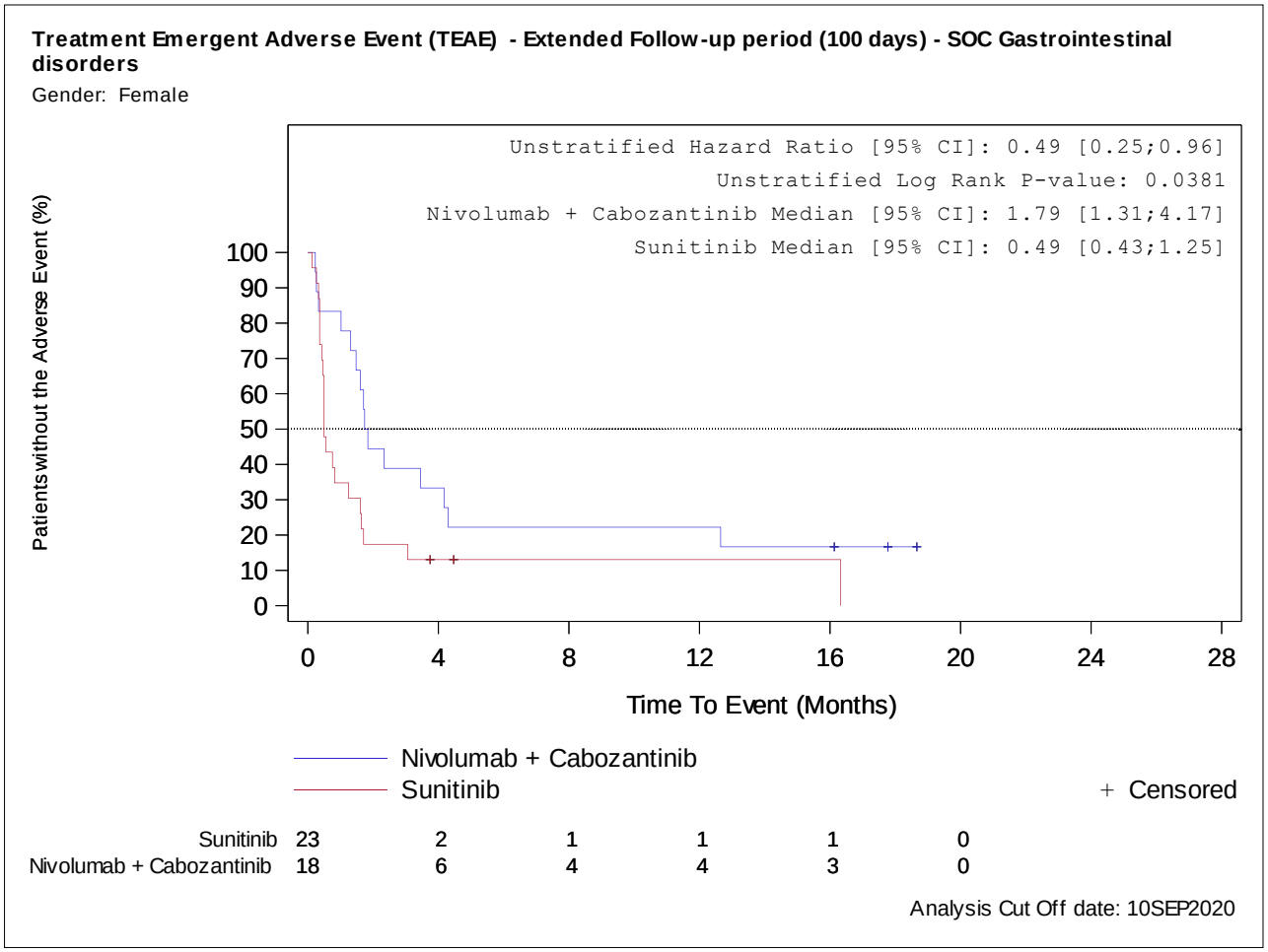
FIGURE 5.24.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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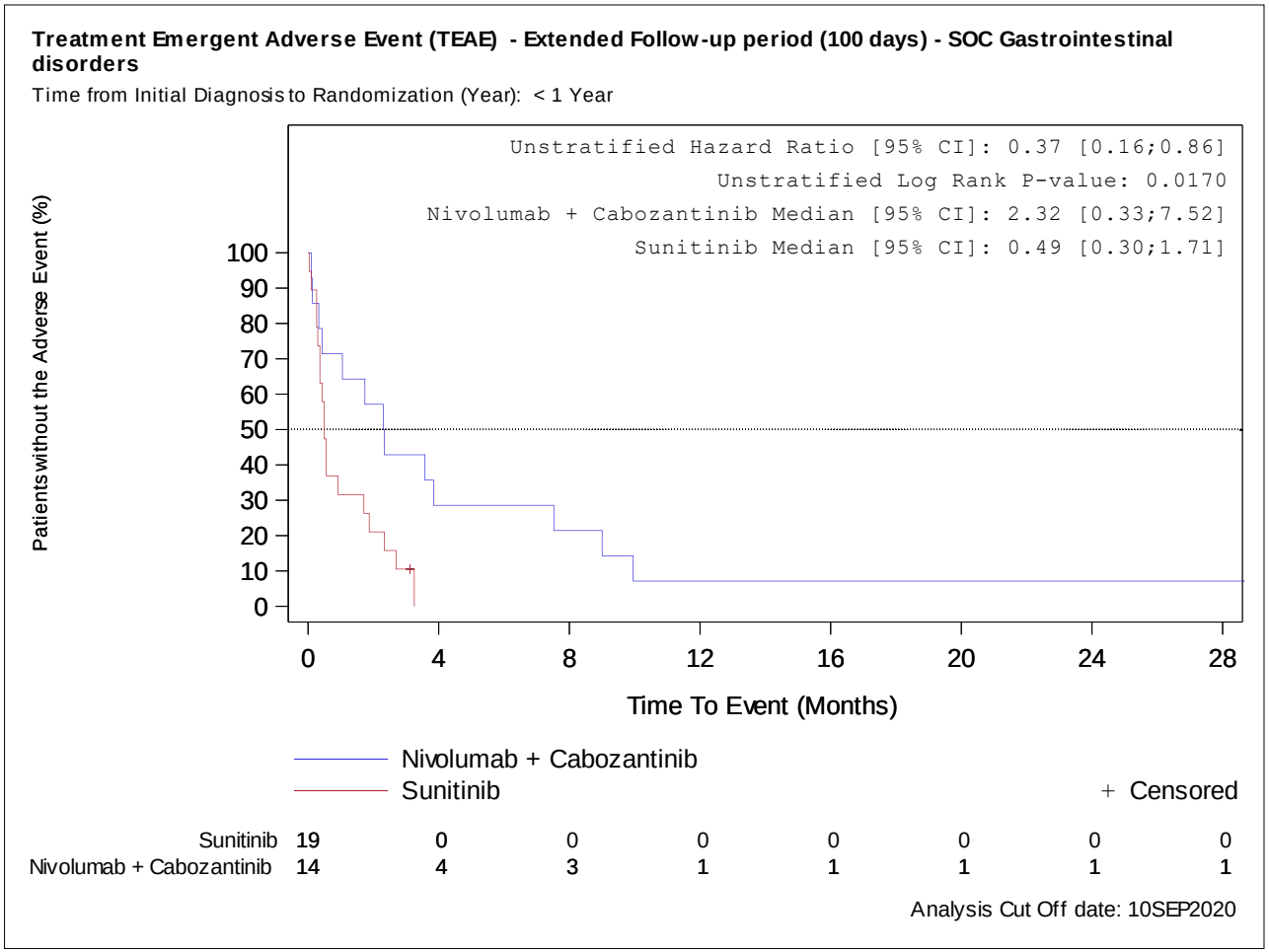
FIGURE 5.24.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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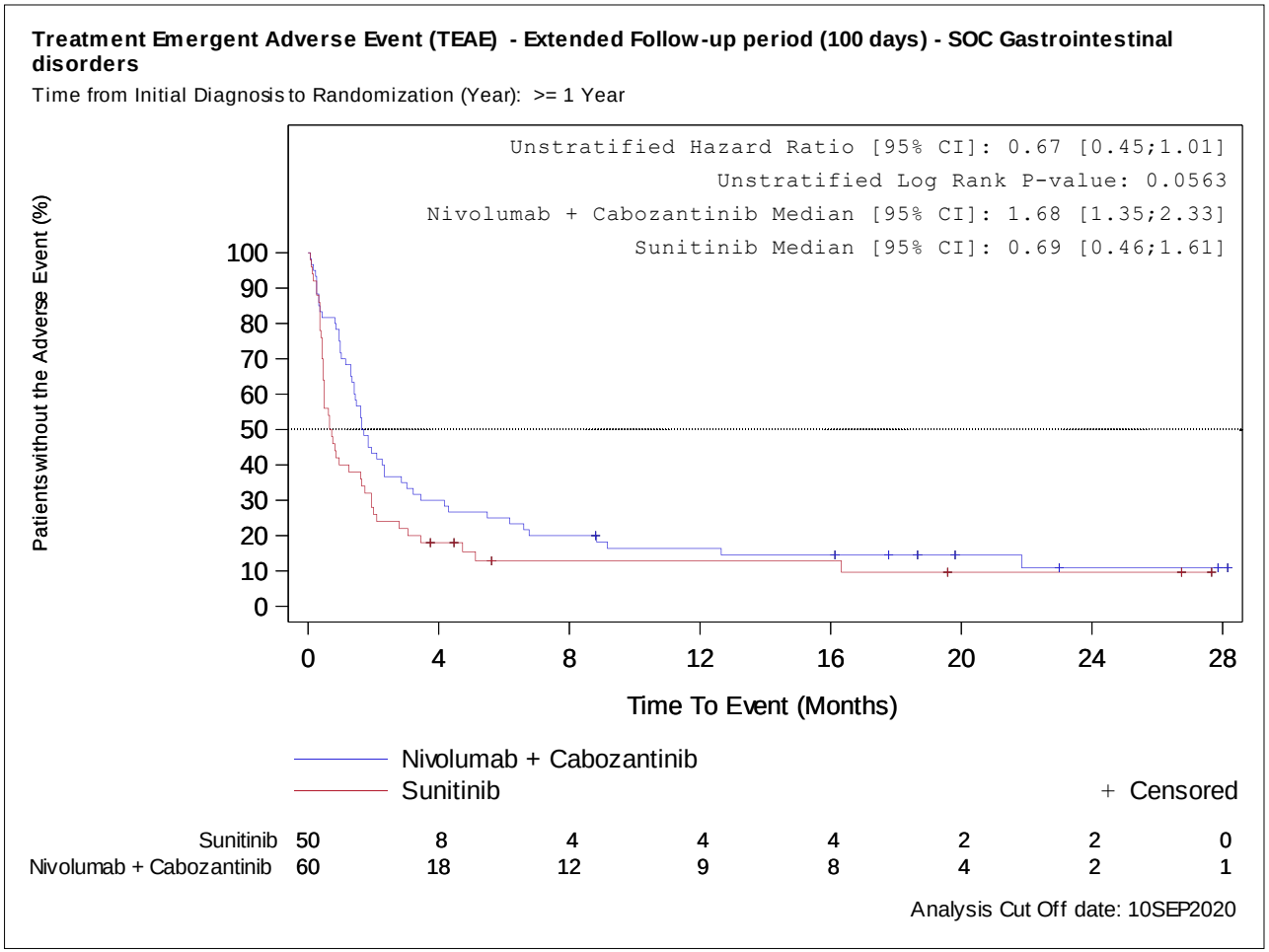
FIGURE 5.24.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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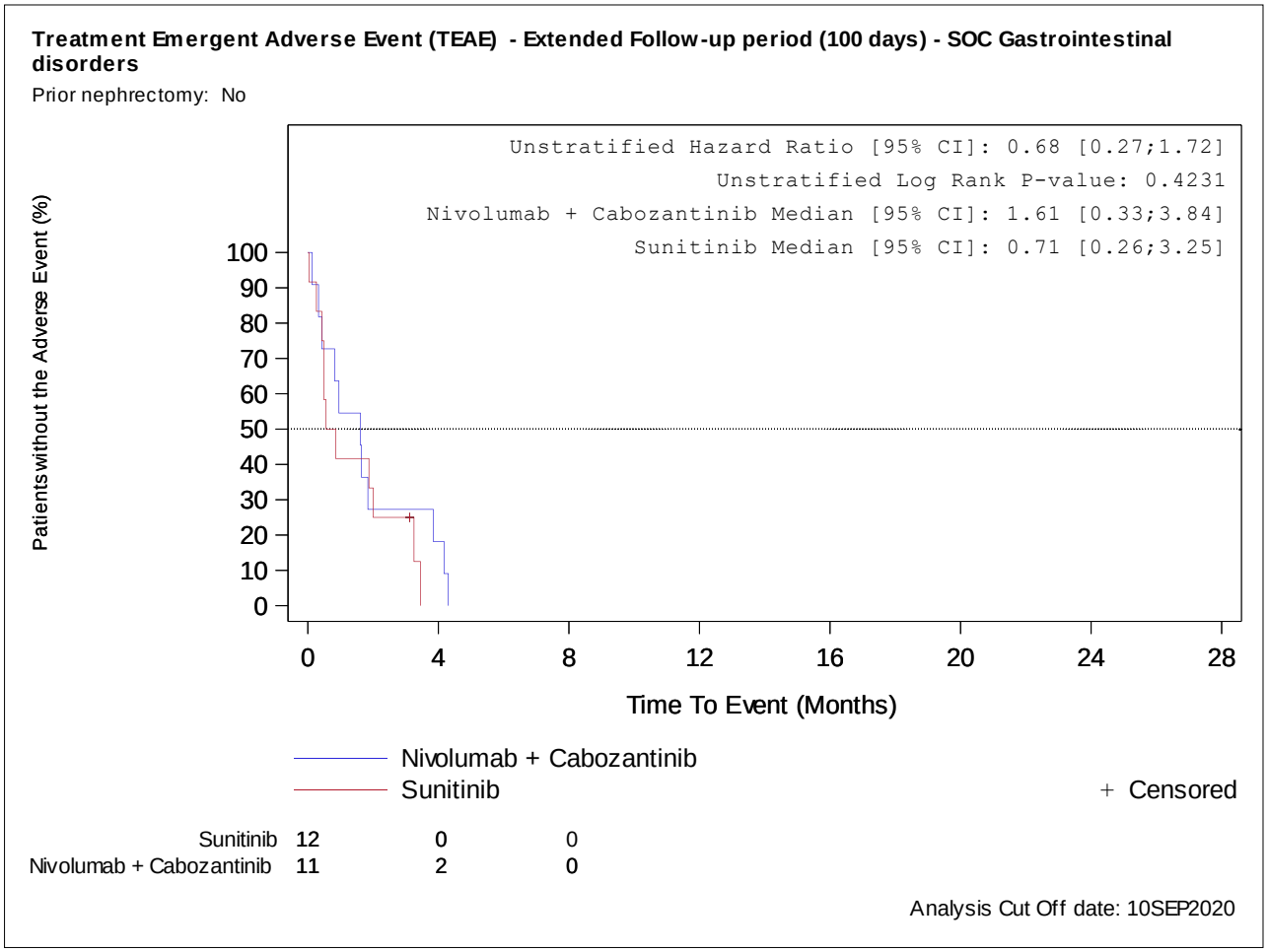
FIGURE 5.24.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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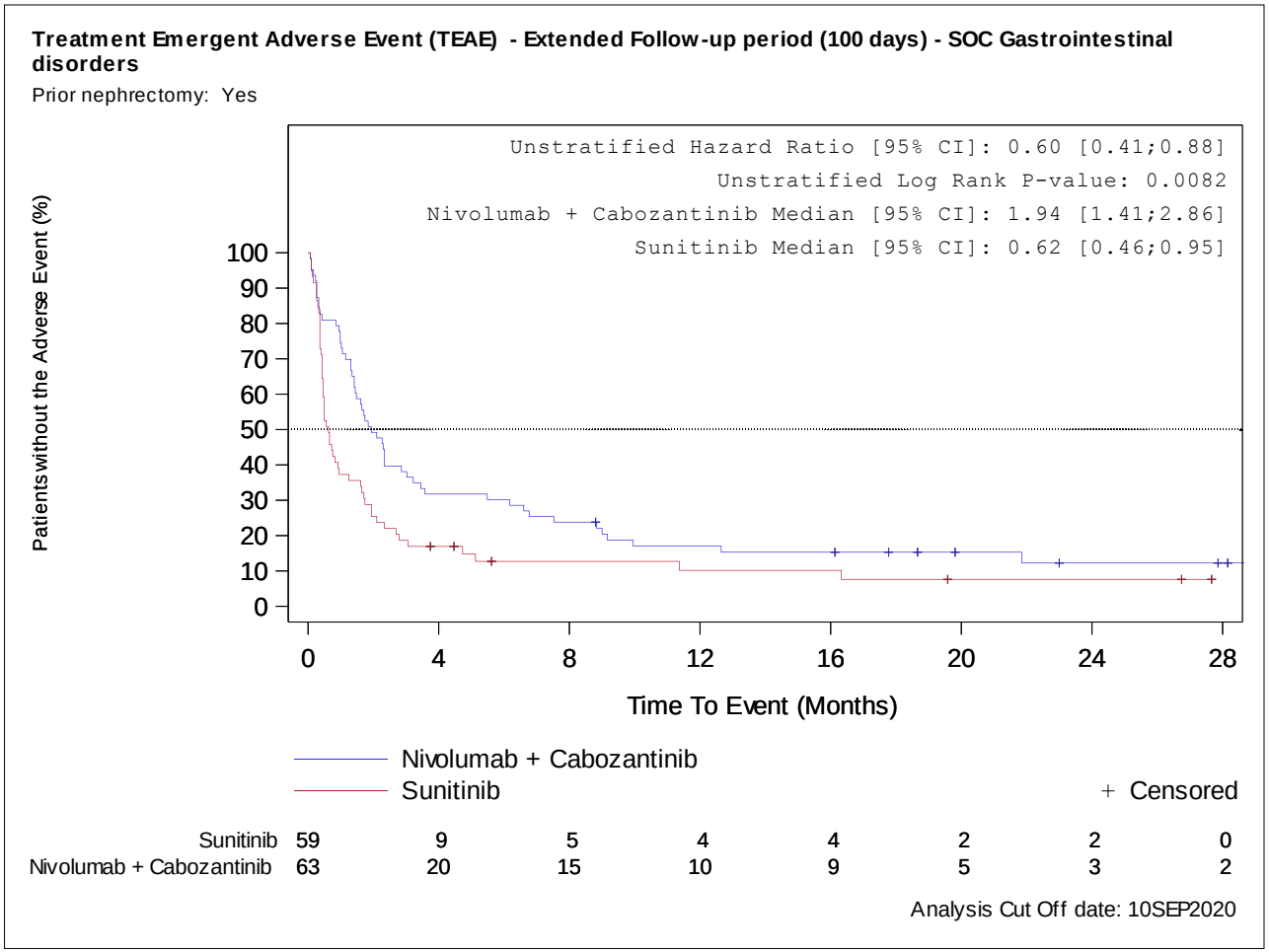
FIGURE 5.24.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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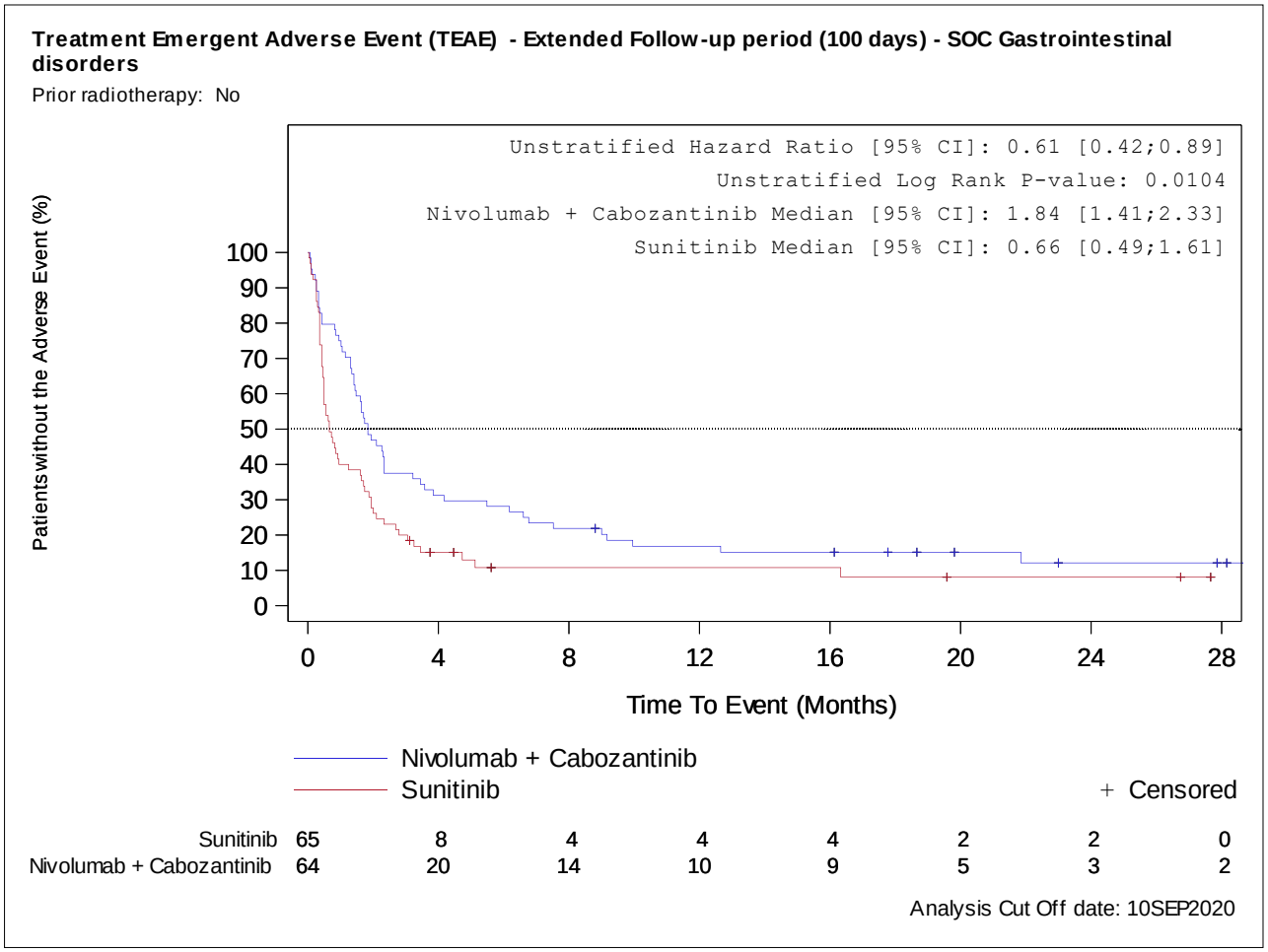
FIGURE 5.24.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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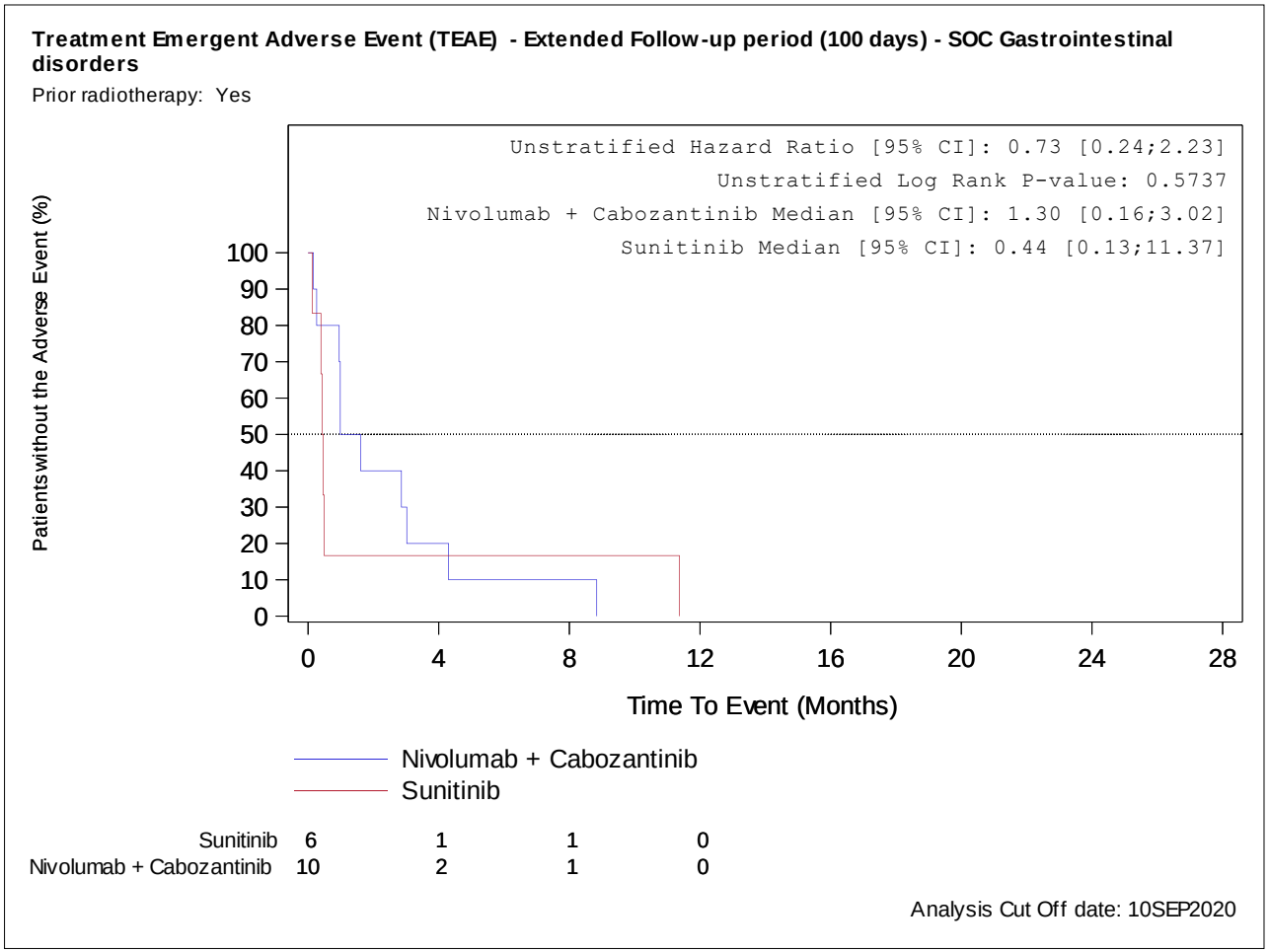
FIGURE 5.24.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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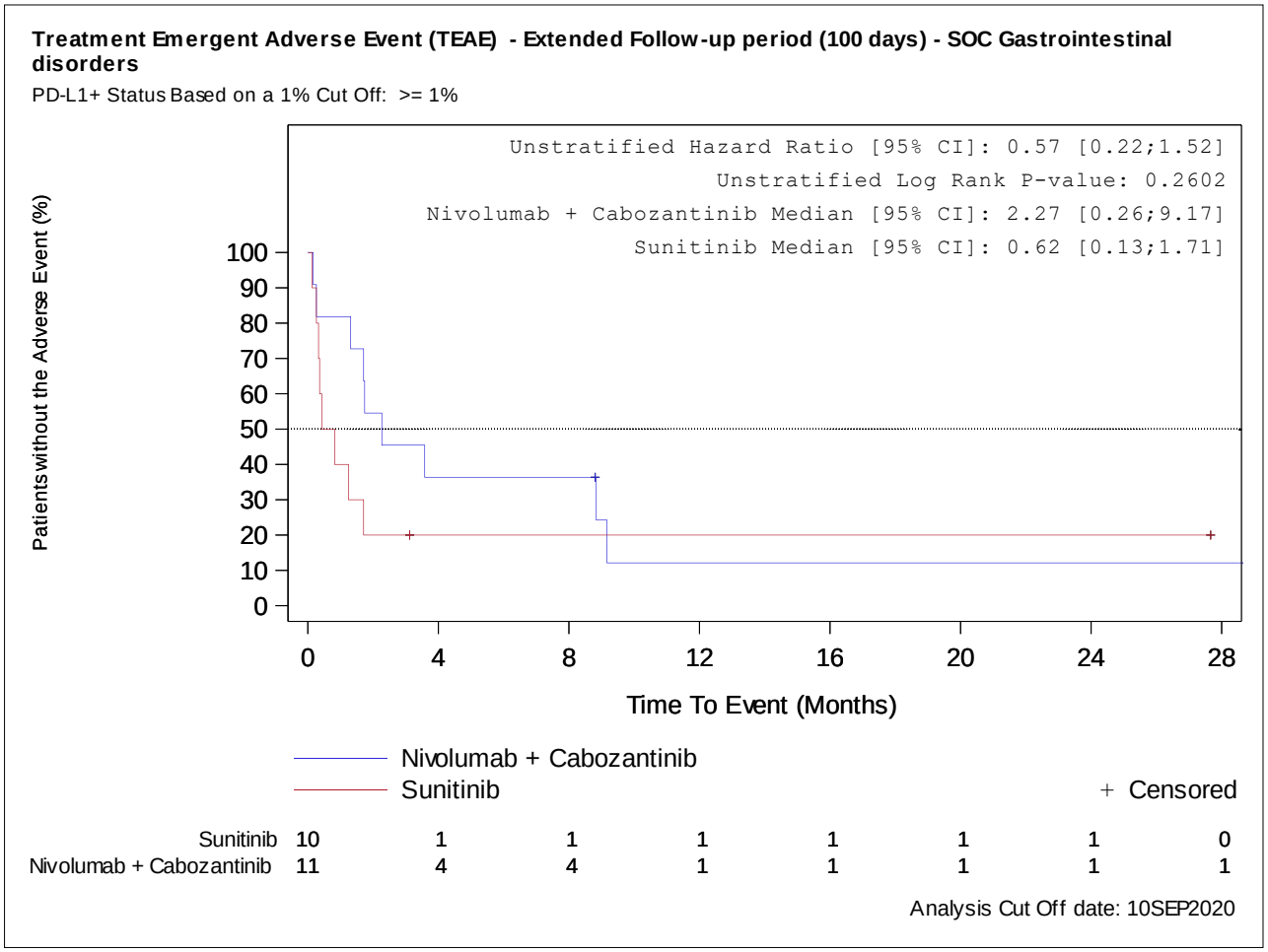
FIGURE 5.24.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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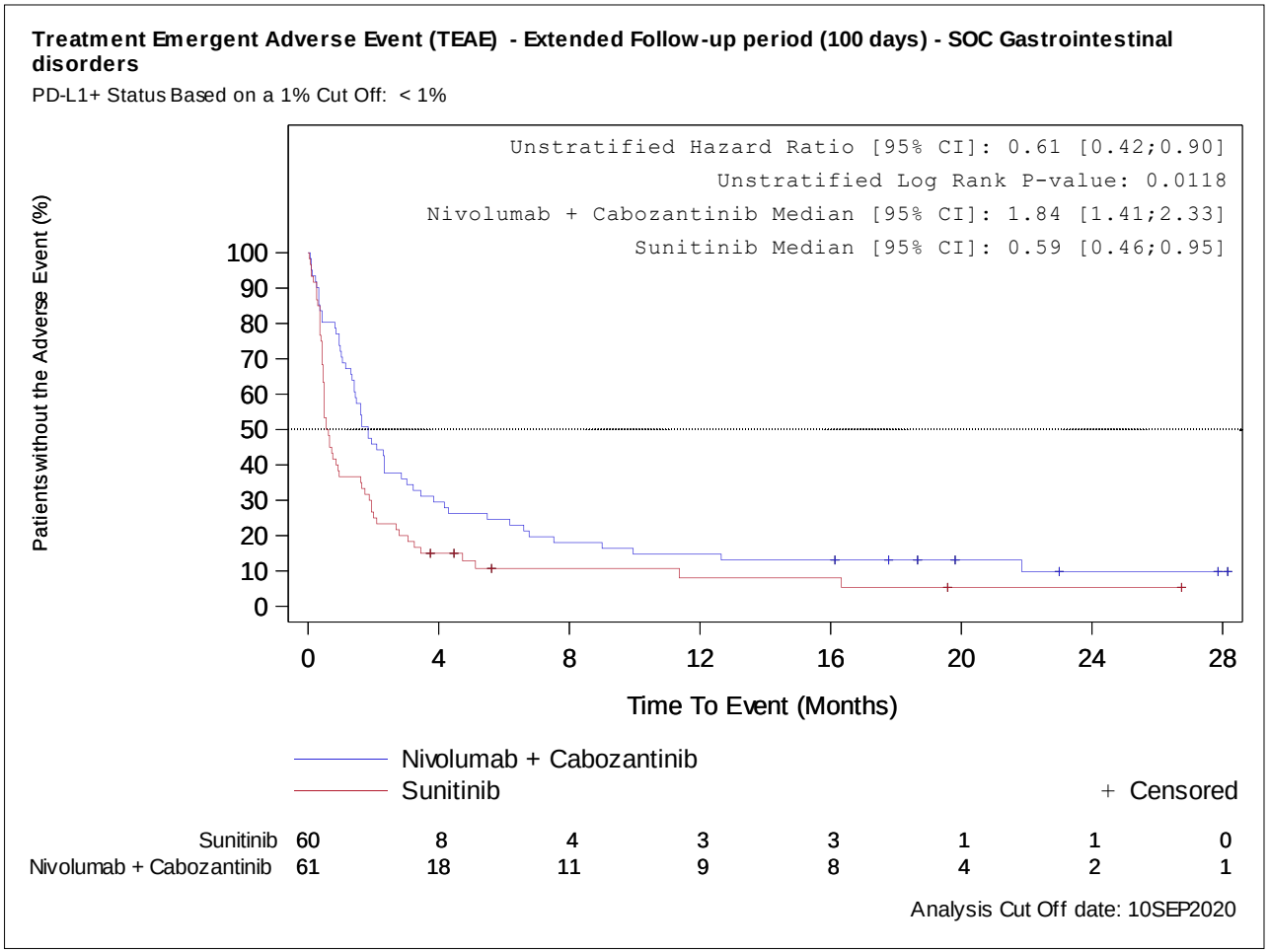
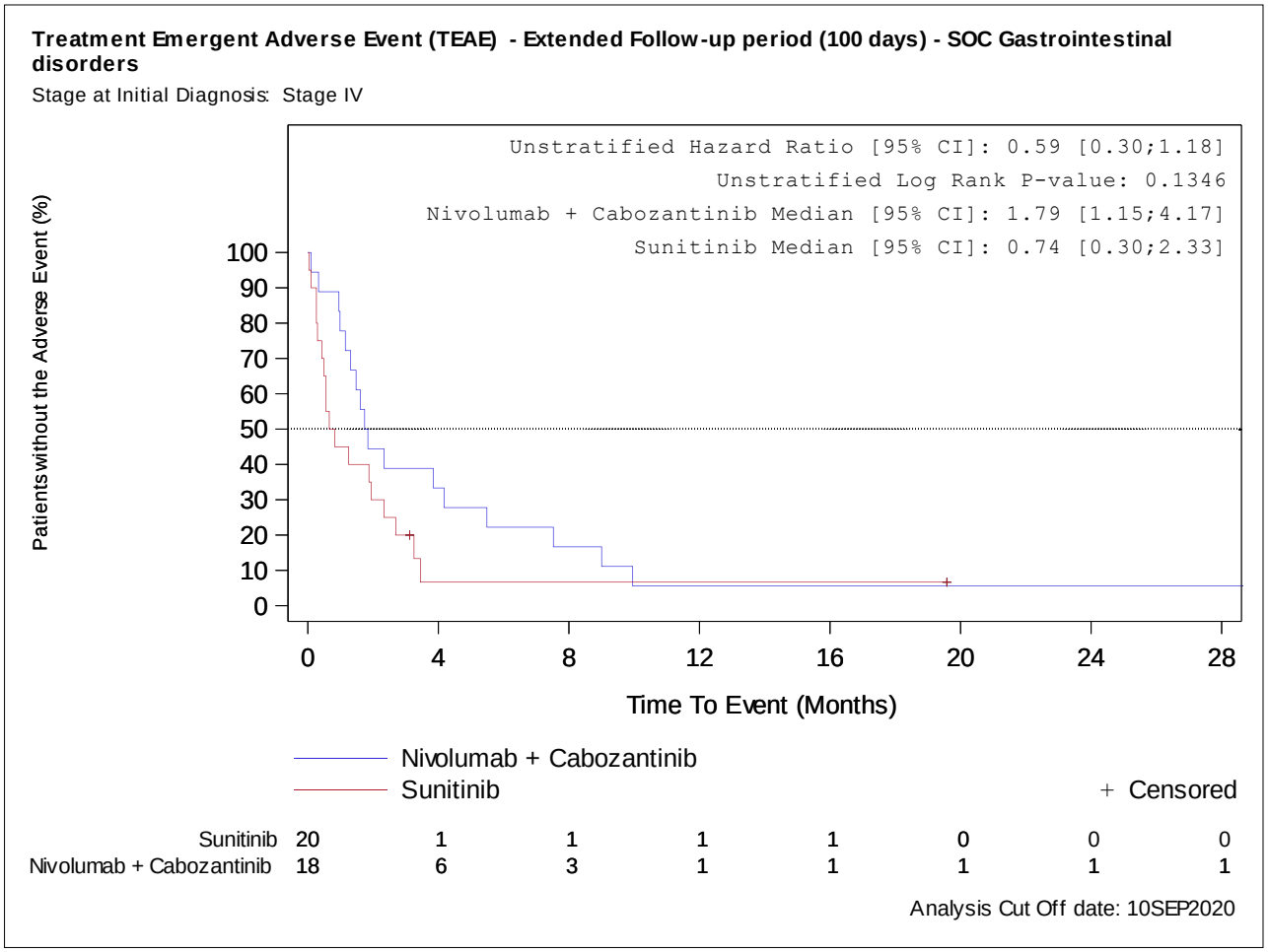
FIGURE 5.24.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



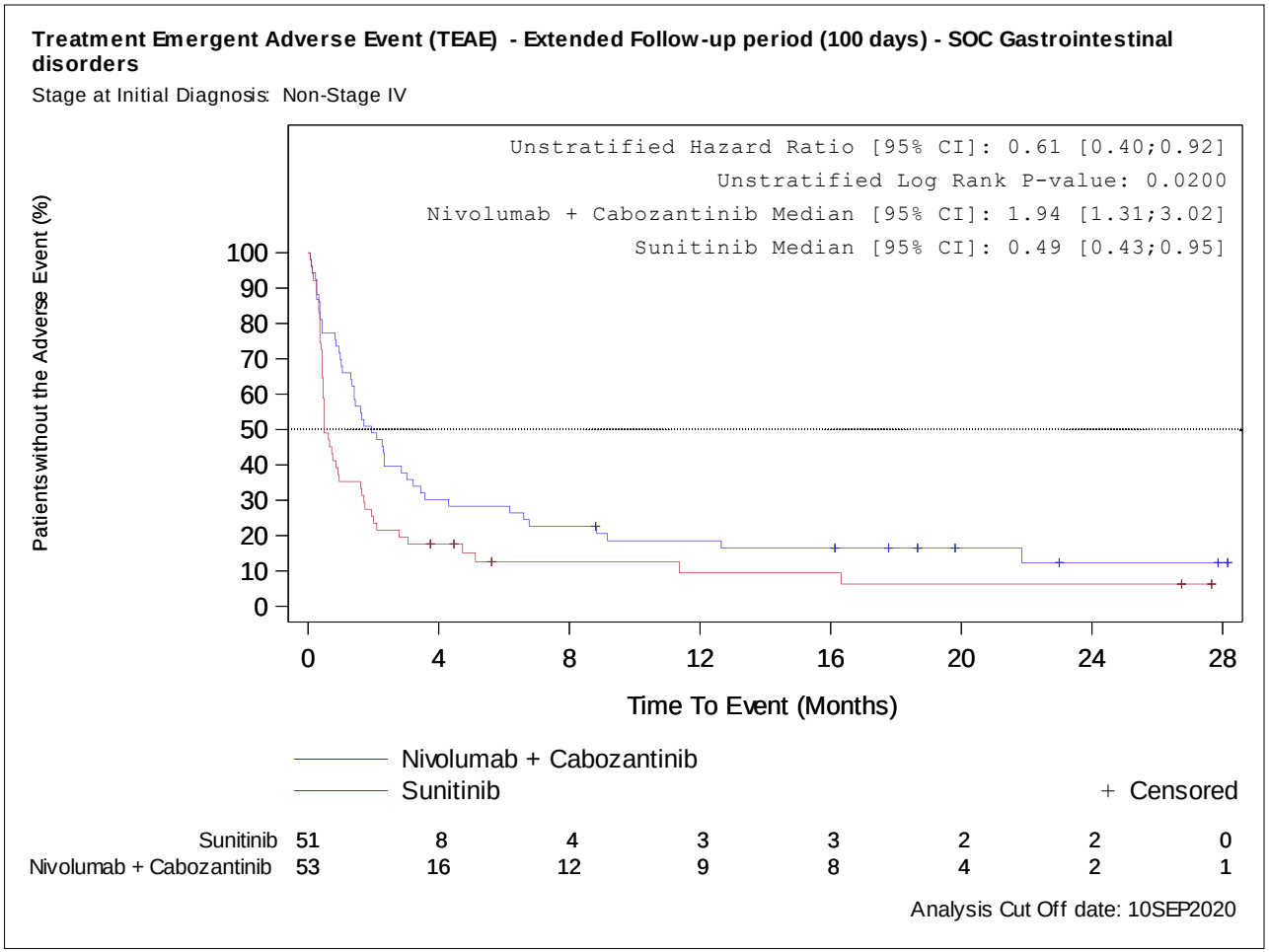

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:31:06

FIGURE 5.24.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



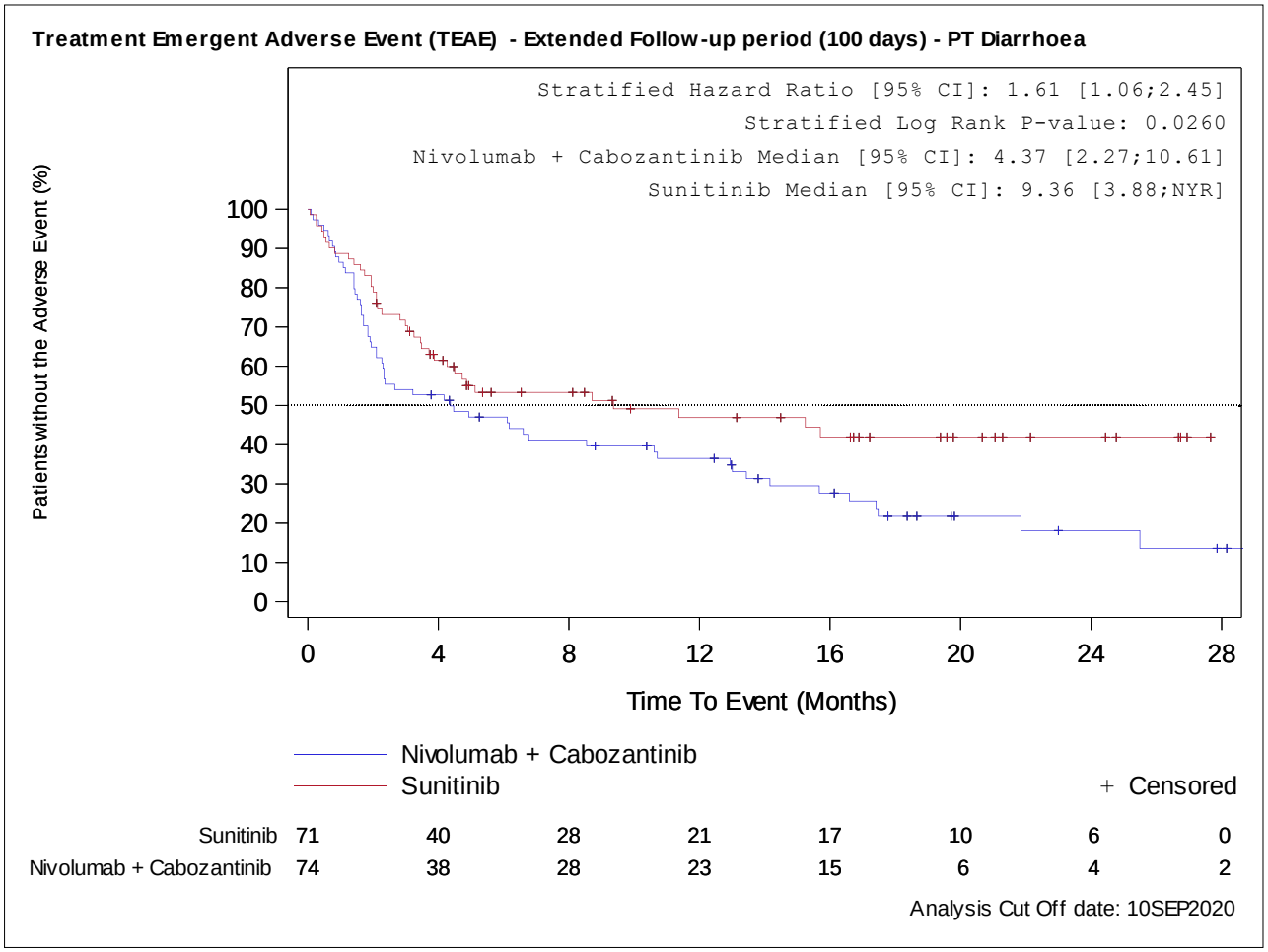

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:31:36

FIGURE 5.24.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Gastrointestinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



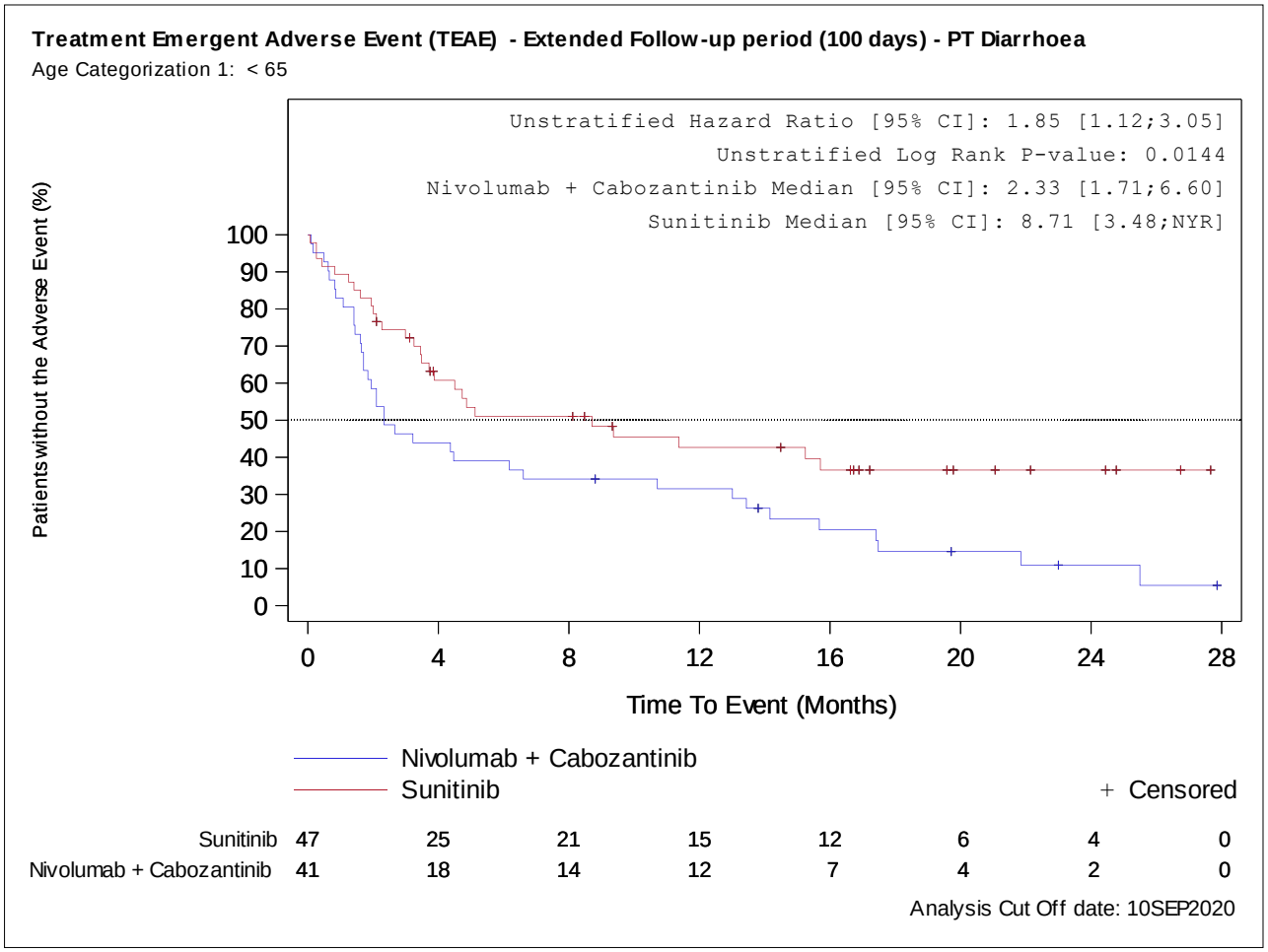

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:31:42

FIGURE 5.25.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:35:04

FIGURE 5.25.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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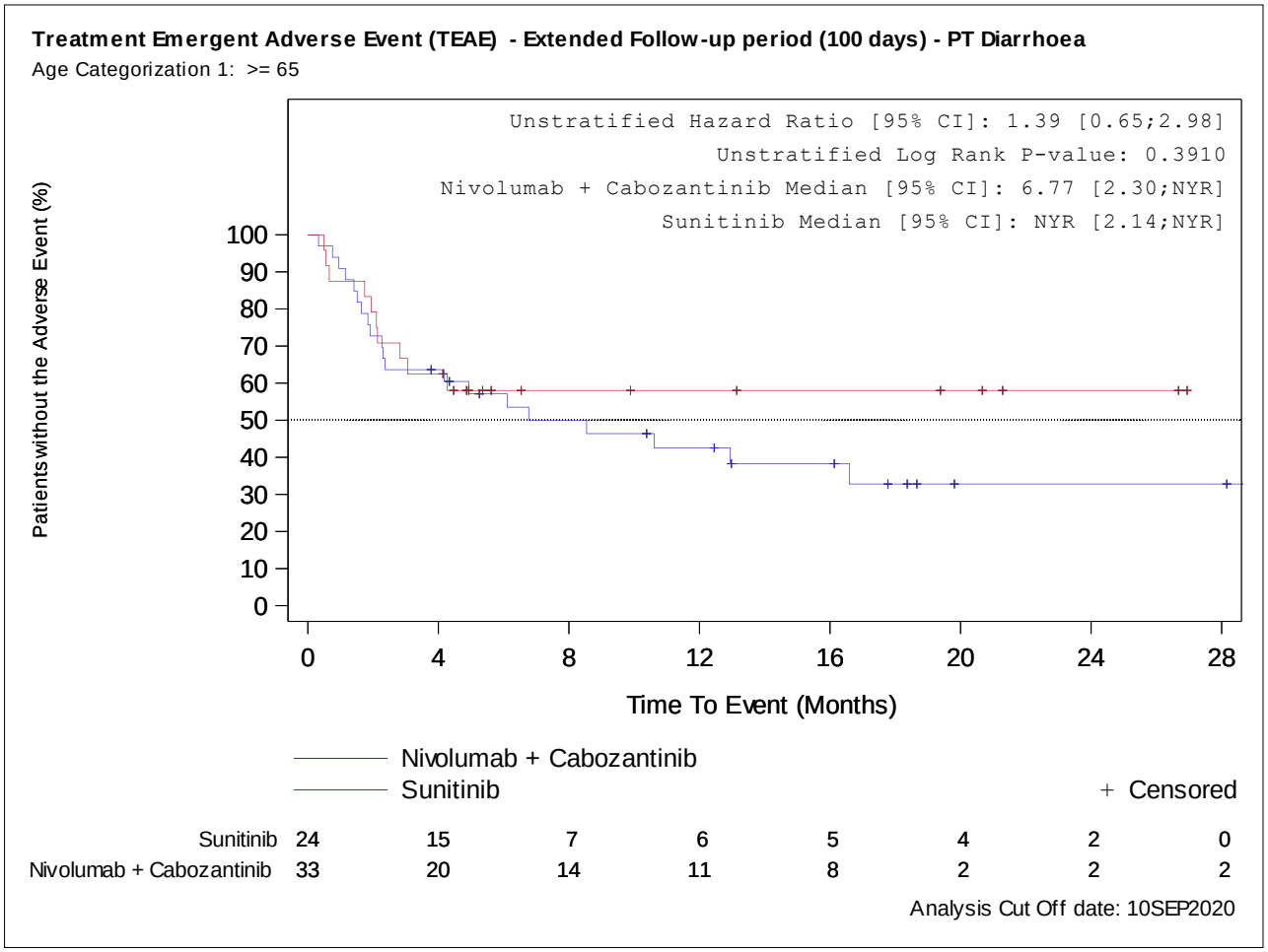
FIGURE 5.25.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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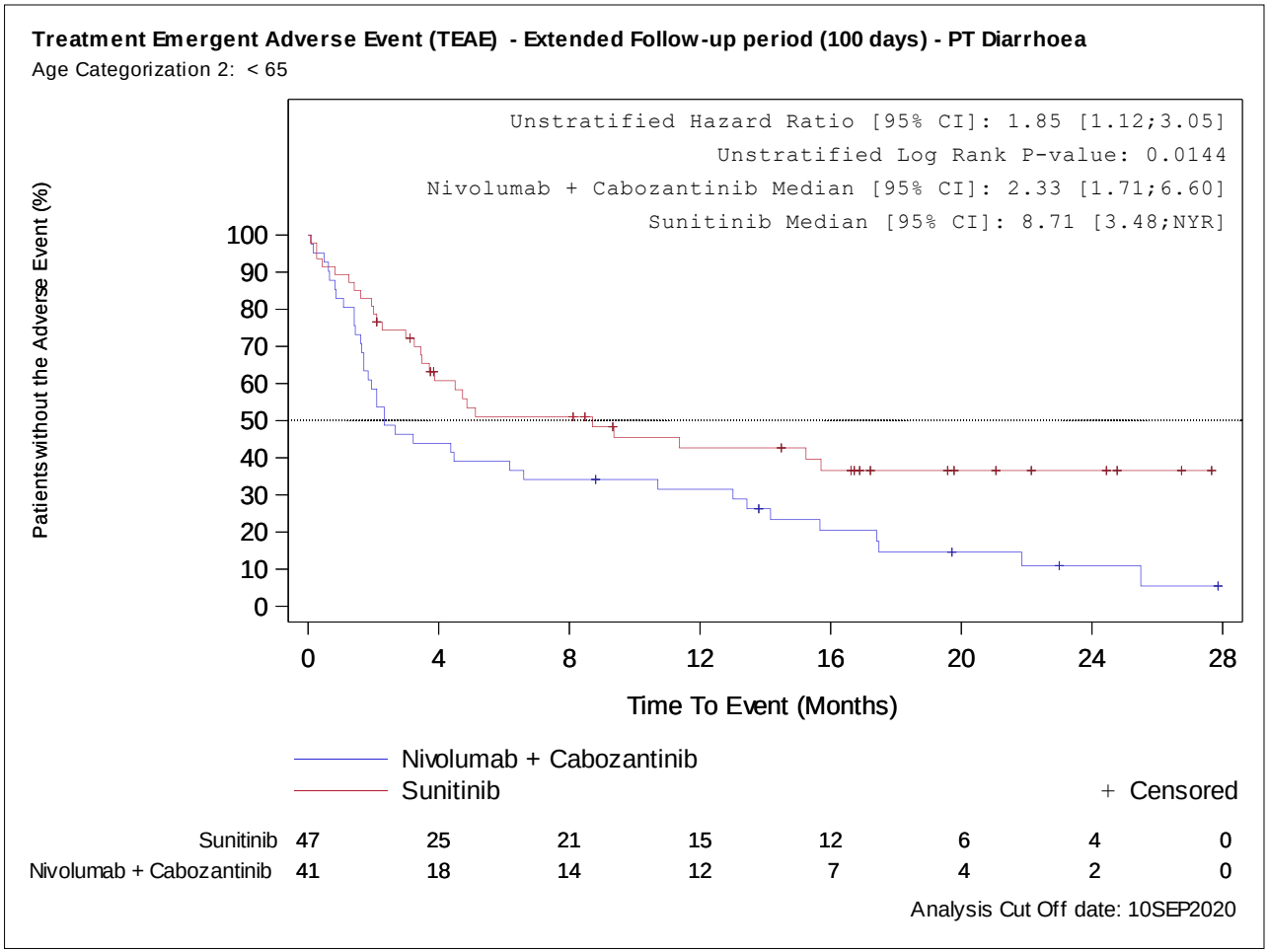
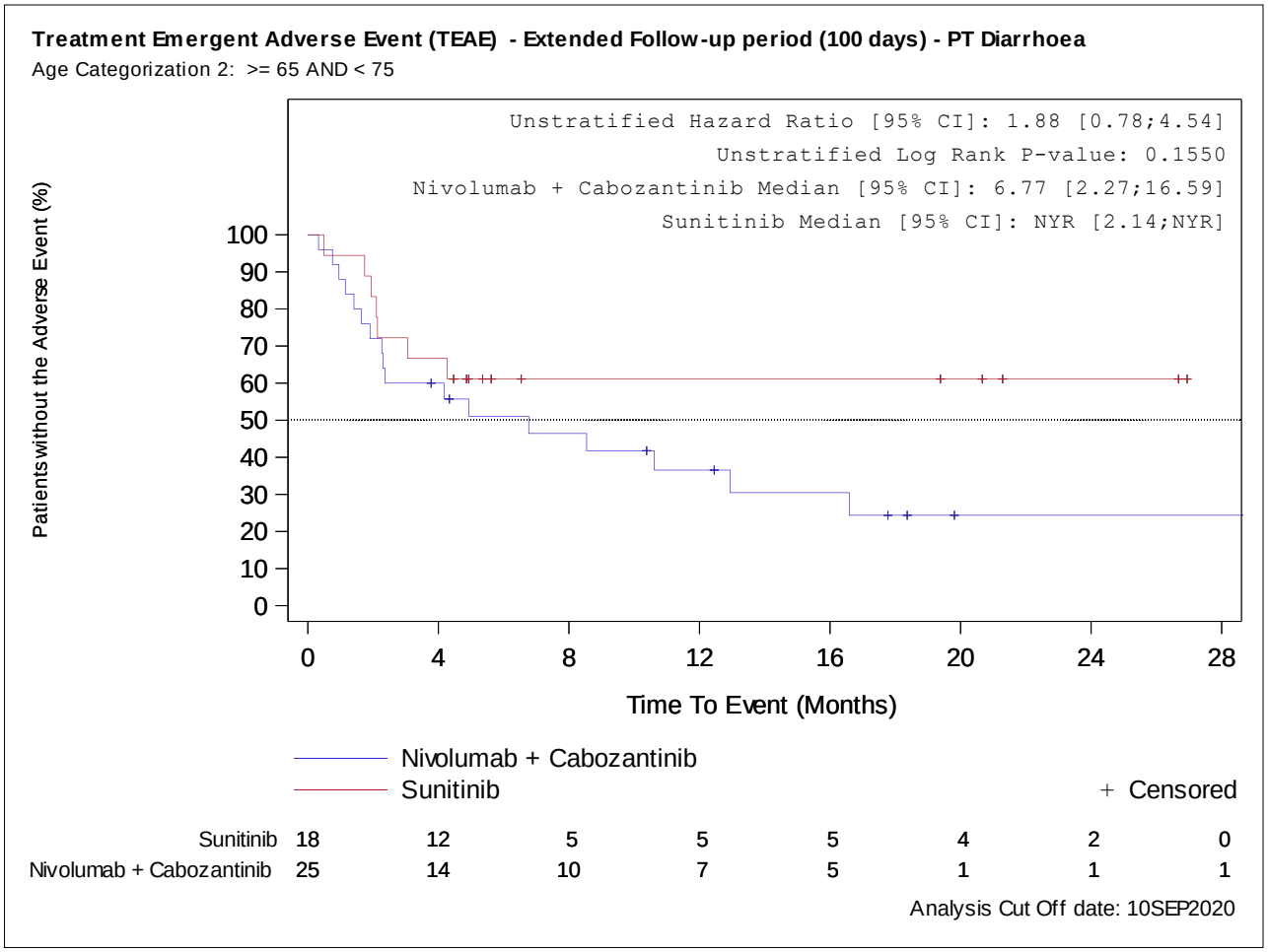
FIGURE 5.25.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



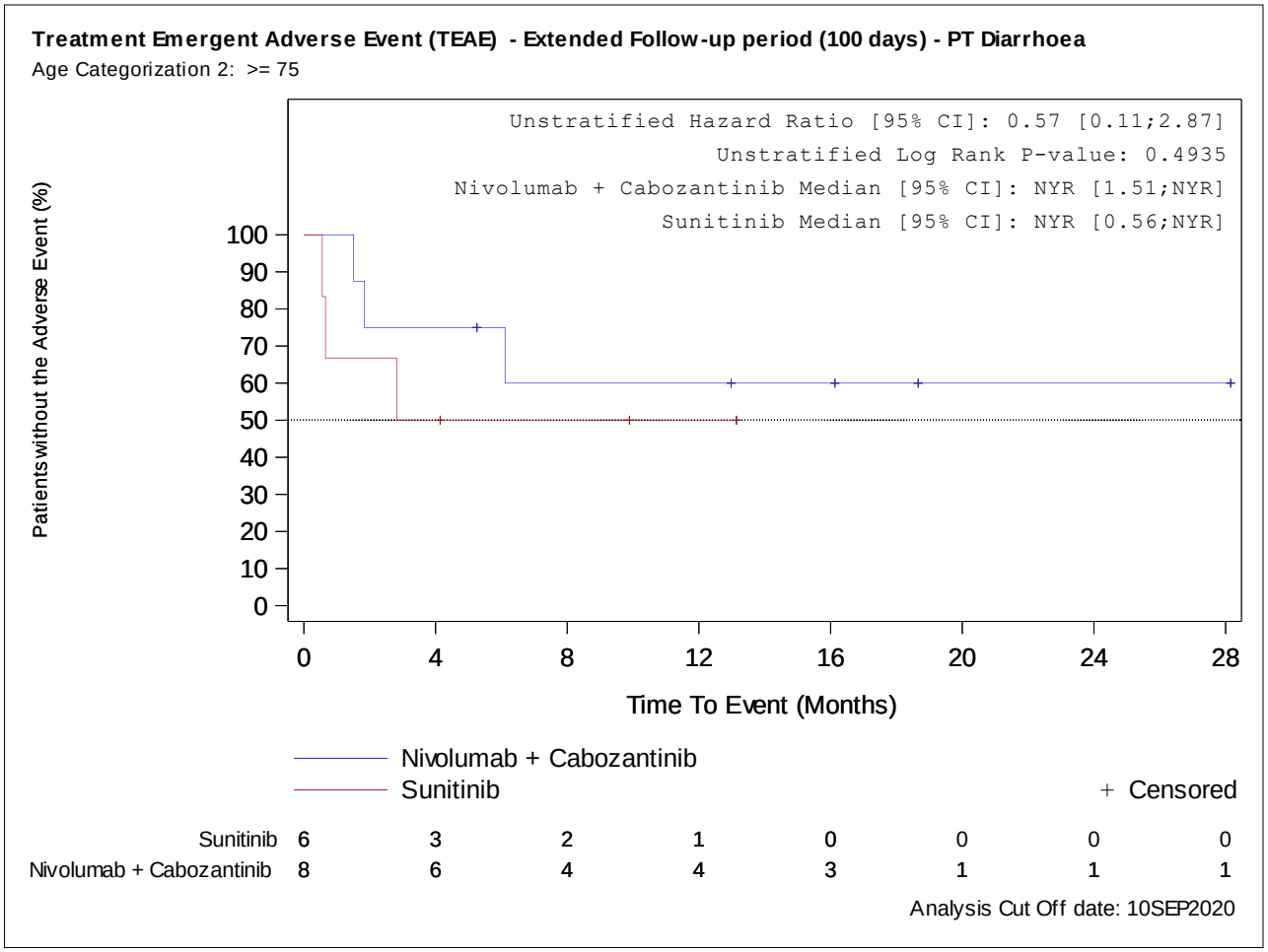

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:35:19

FIGURE 5.25.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



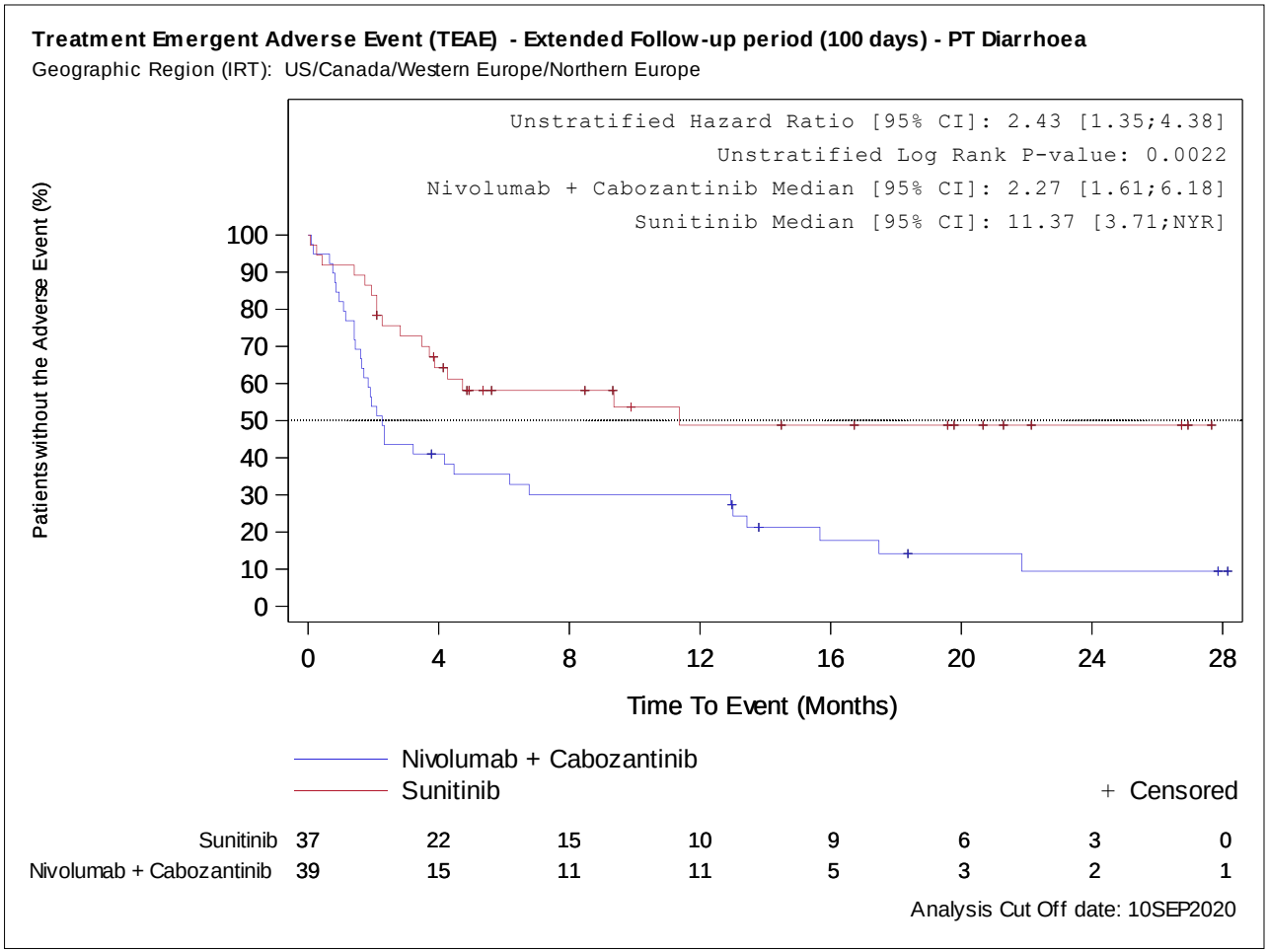

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:35:25

FIGURE 5.25.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



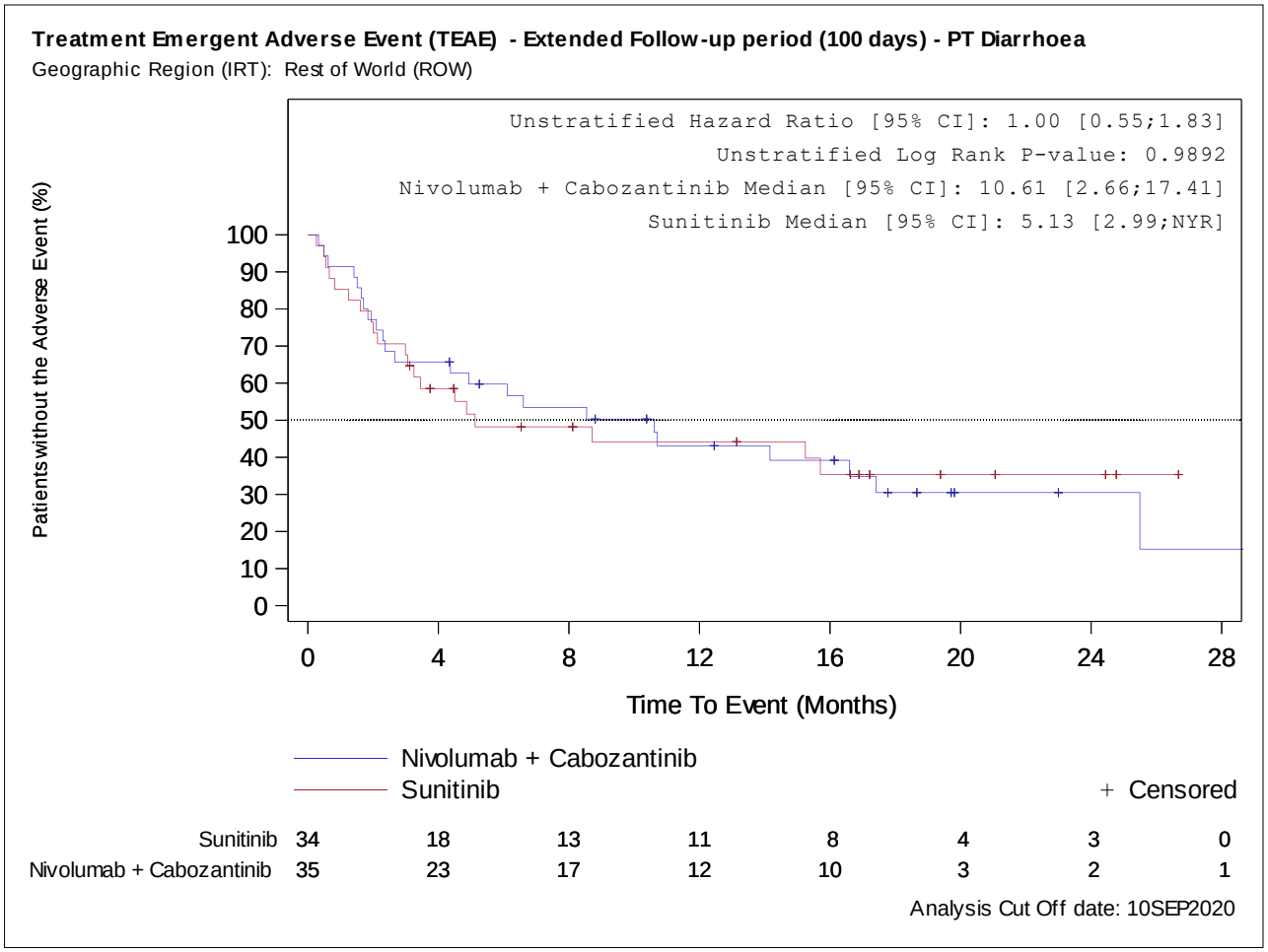

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:35:30

FIGURE 5.25.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



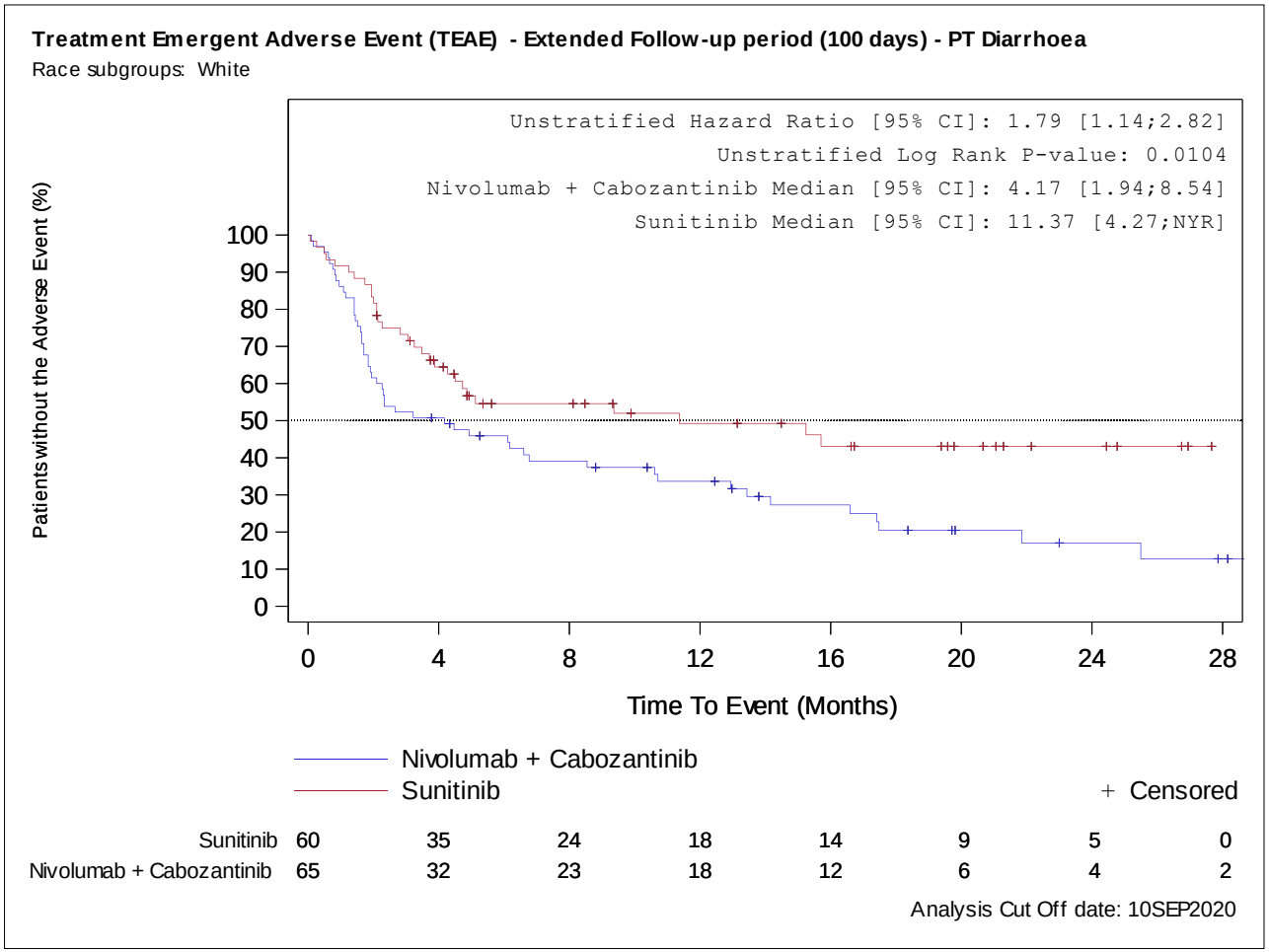

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:35:36

FIGURE 5.25.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:35:42

FIGURE 5.25.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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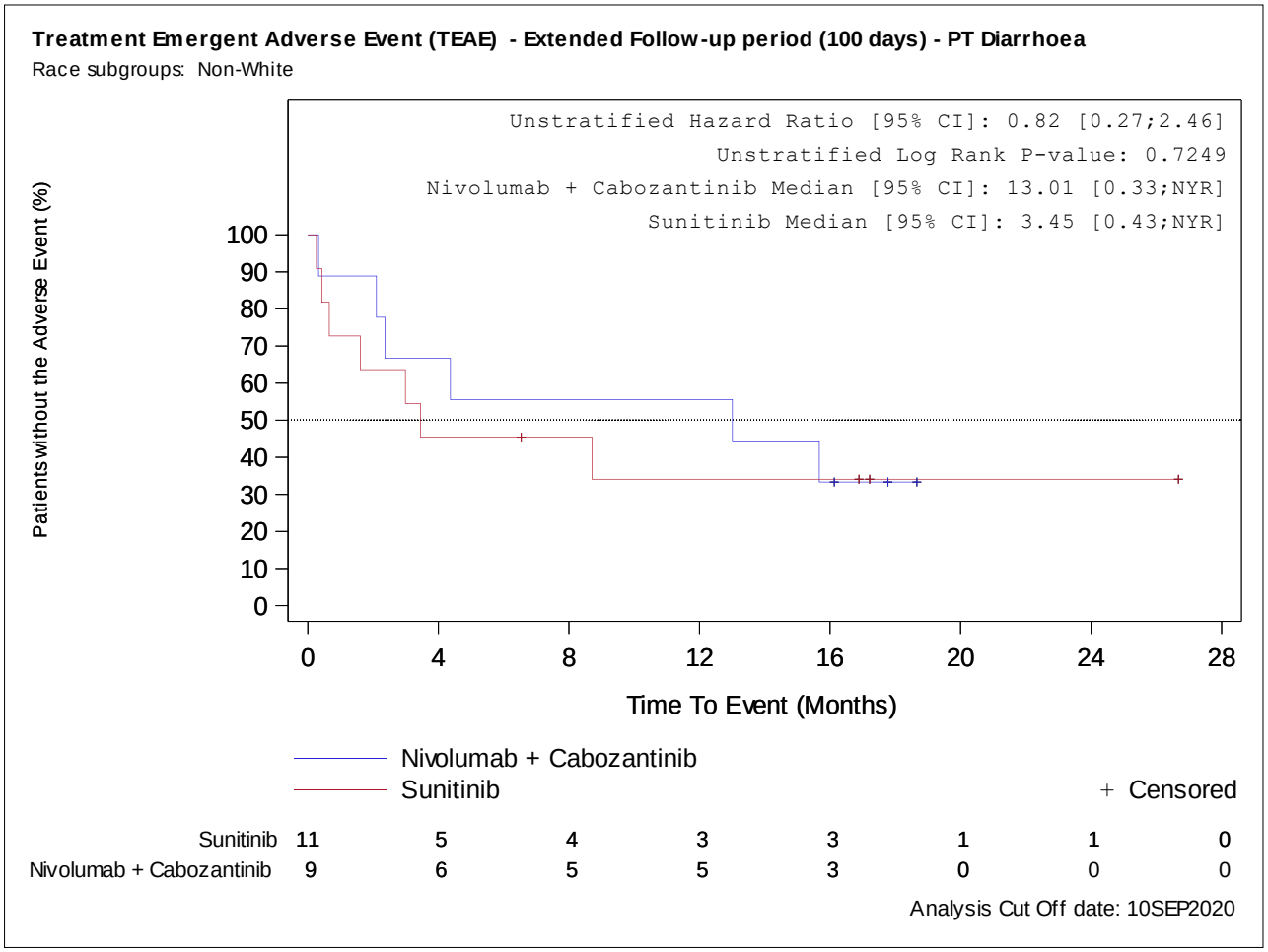
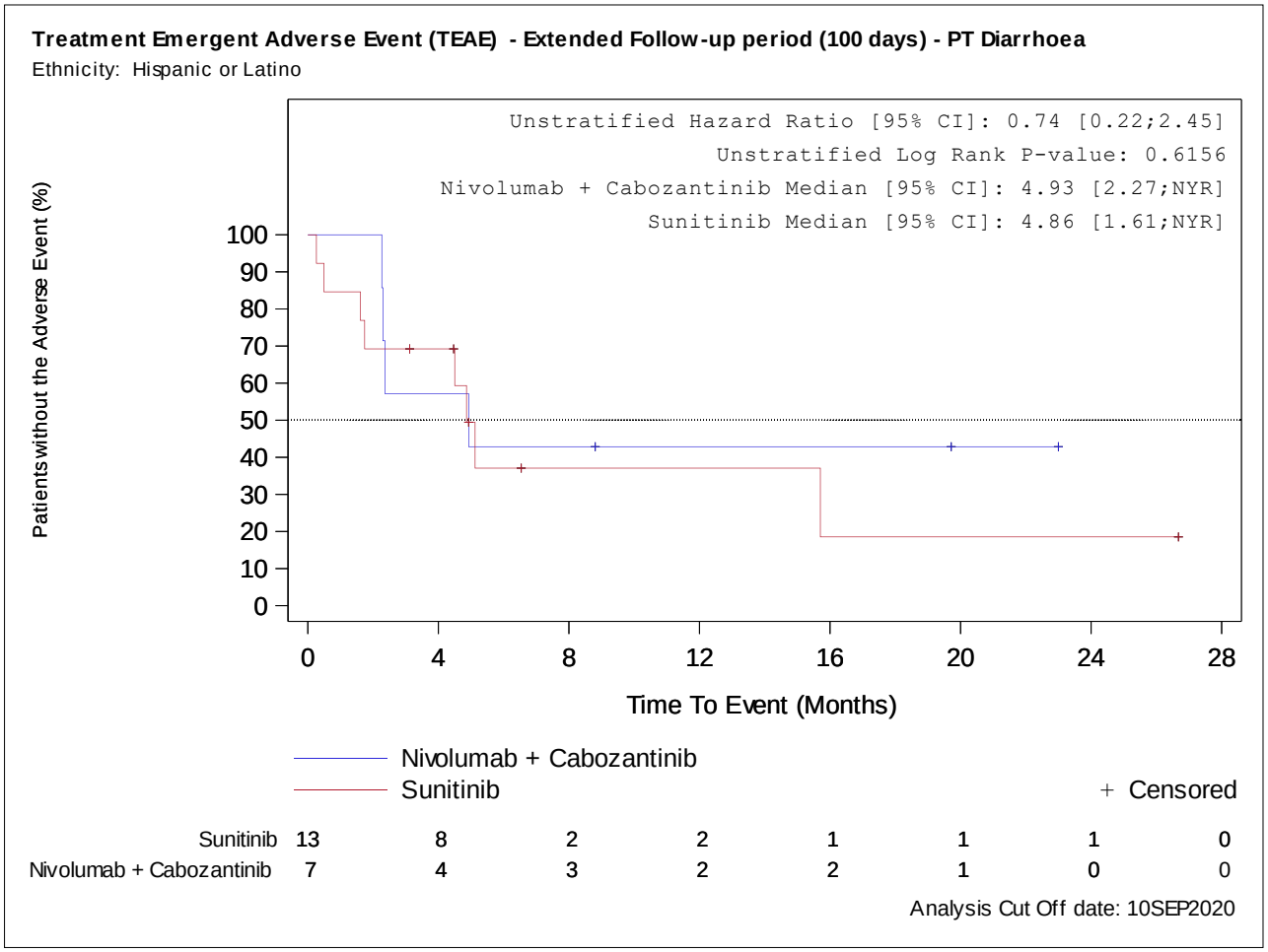
FIGURE 5.25.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:35:54

FIGURE 5.25.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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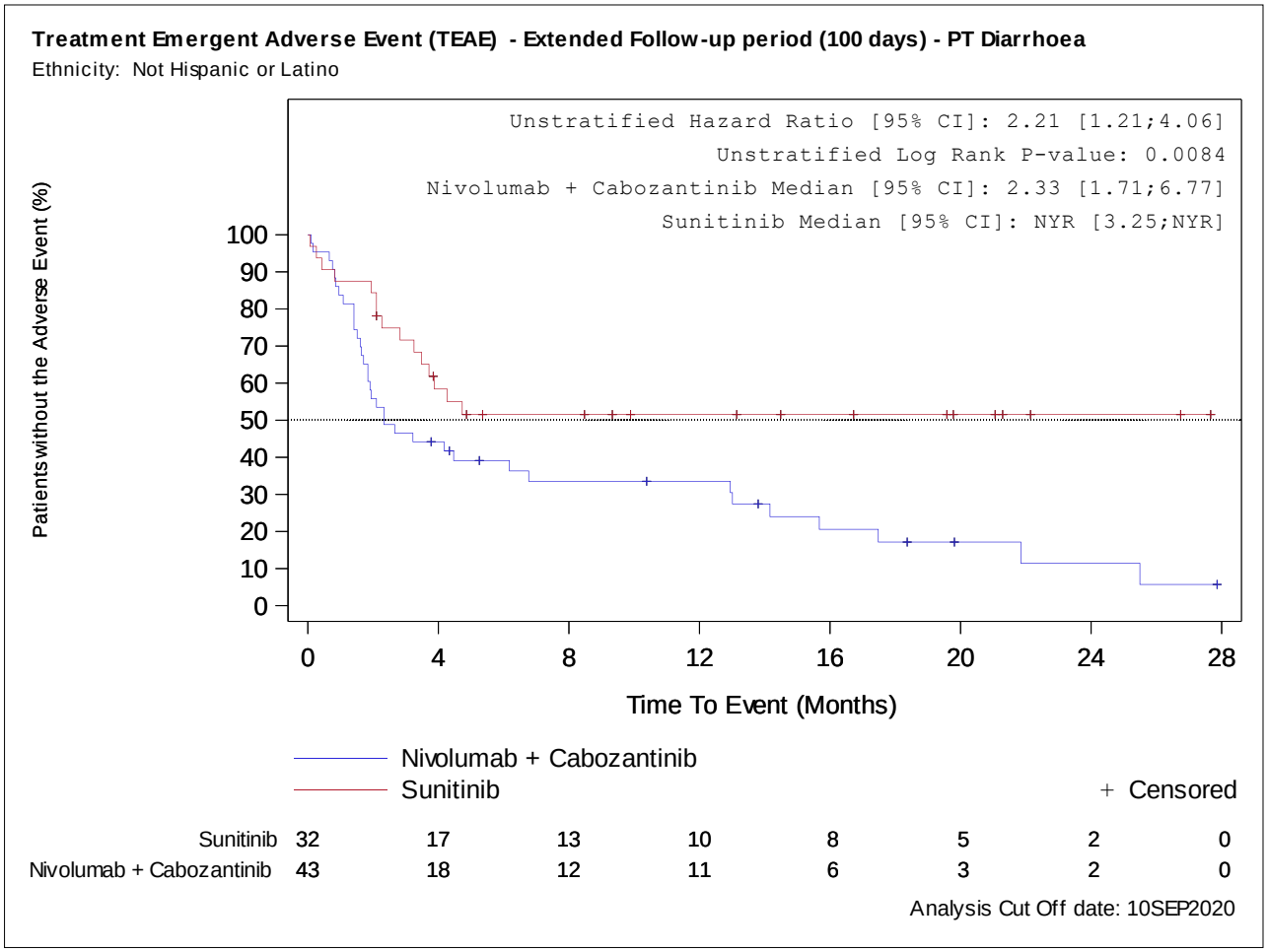
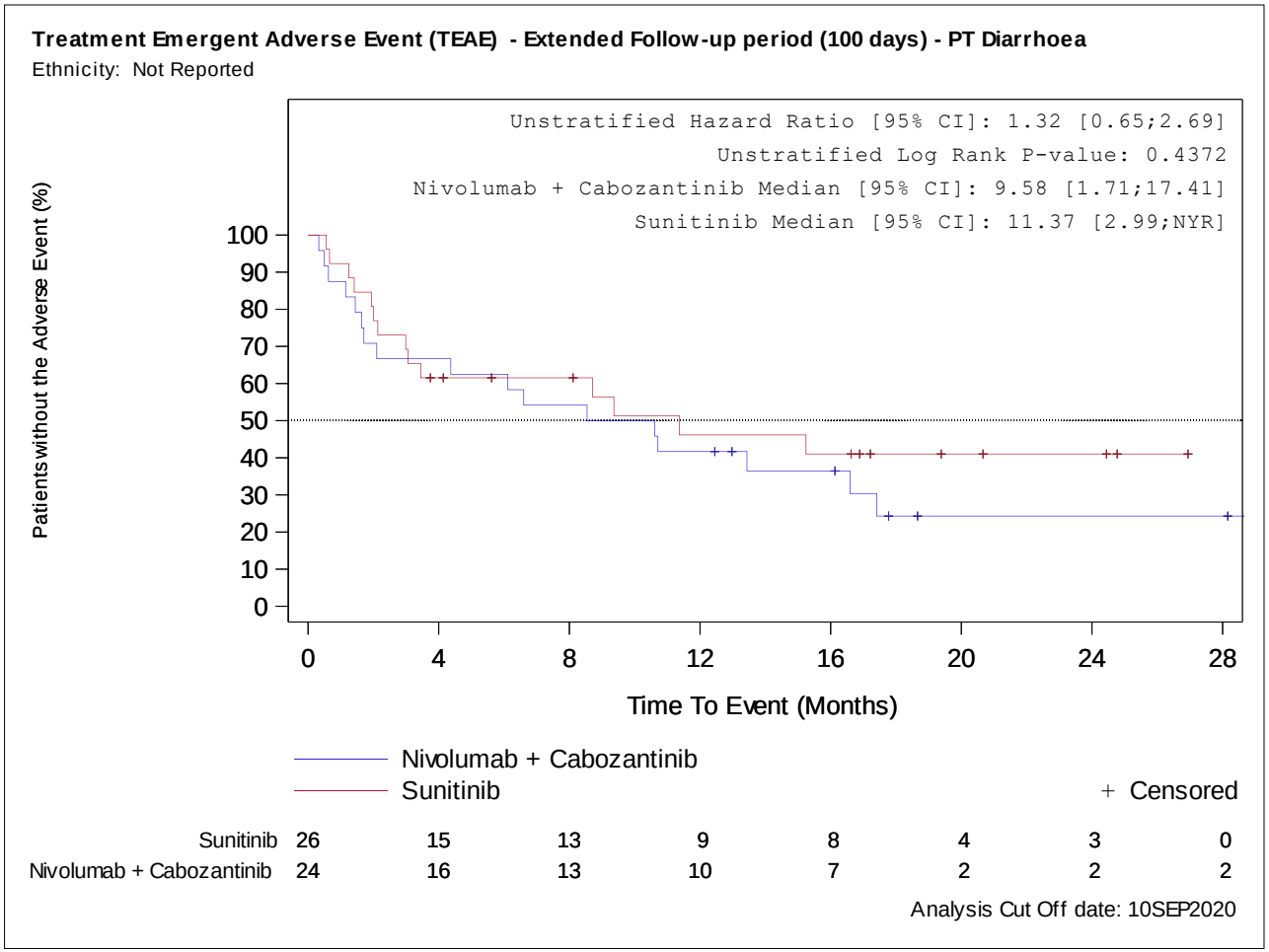
FIGURE 5.25.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:36:06

FIGURE 5.25.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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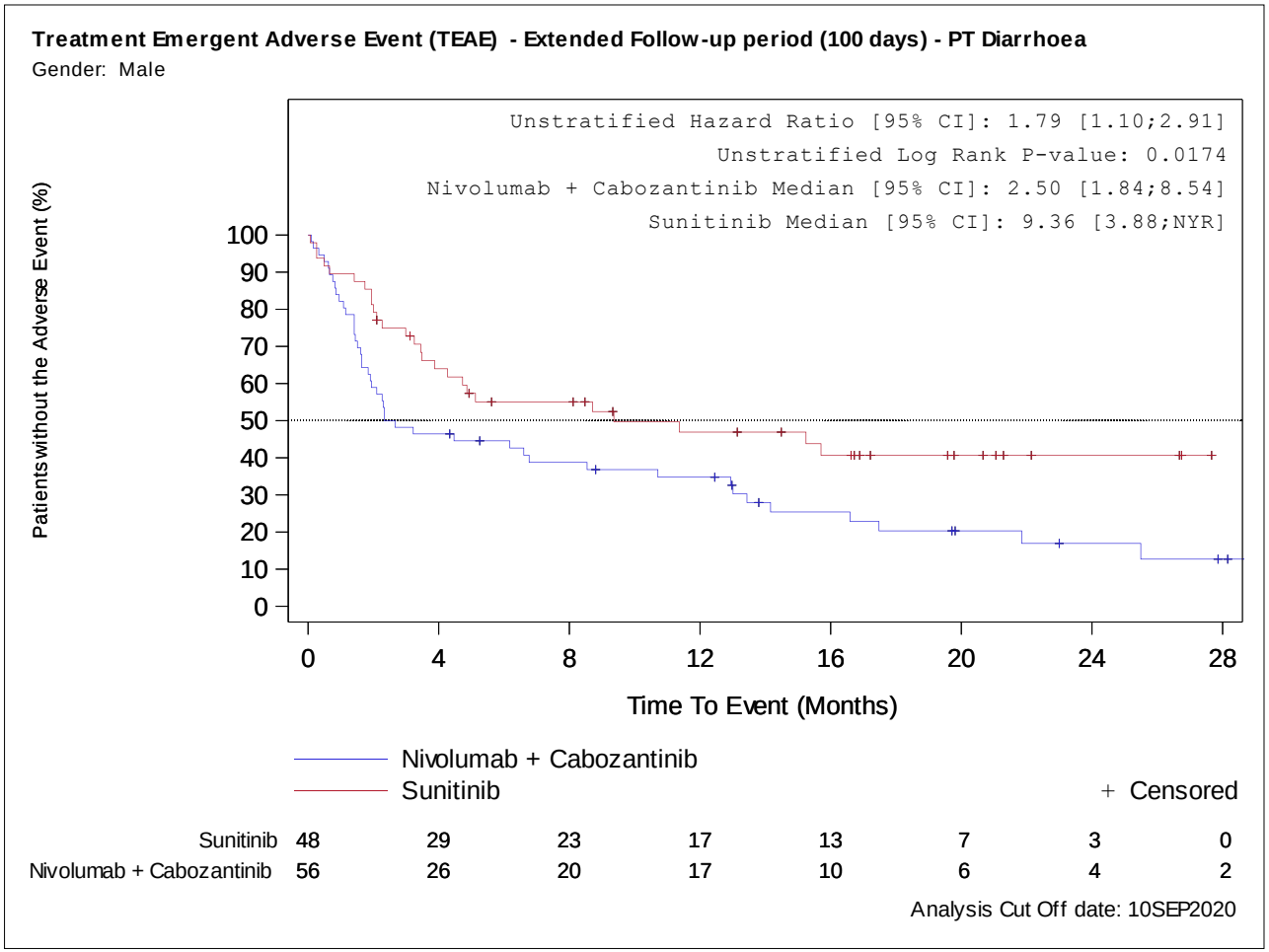
FIGURE 5.25.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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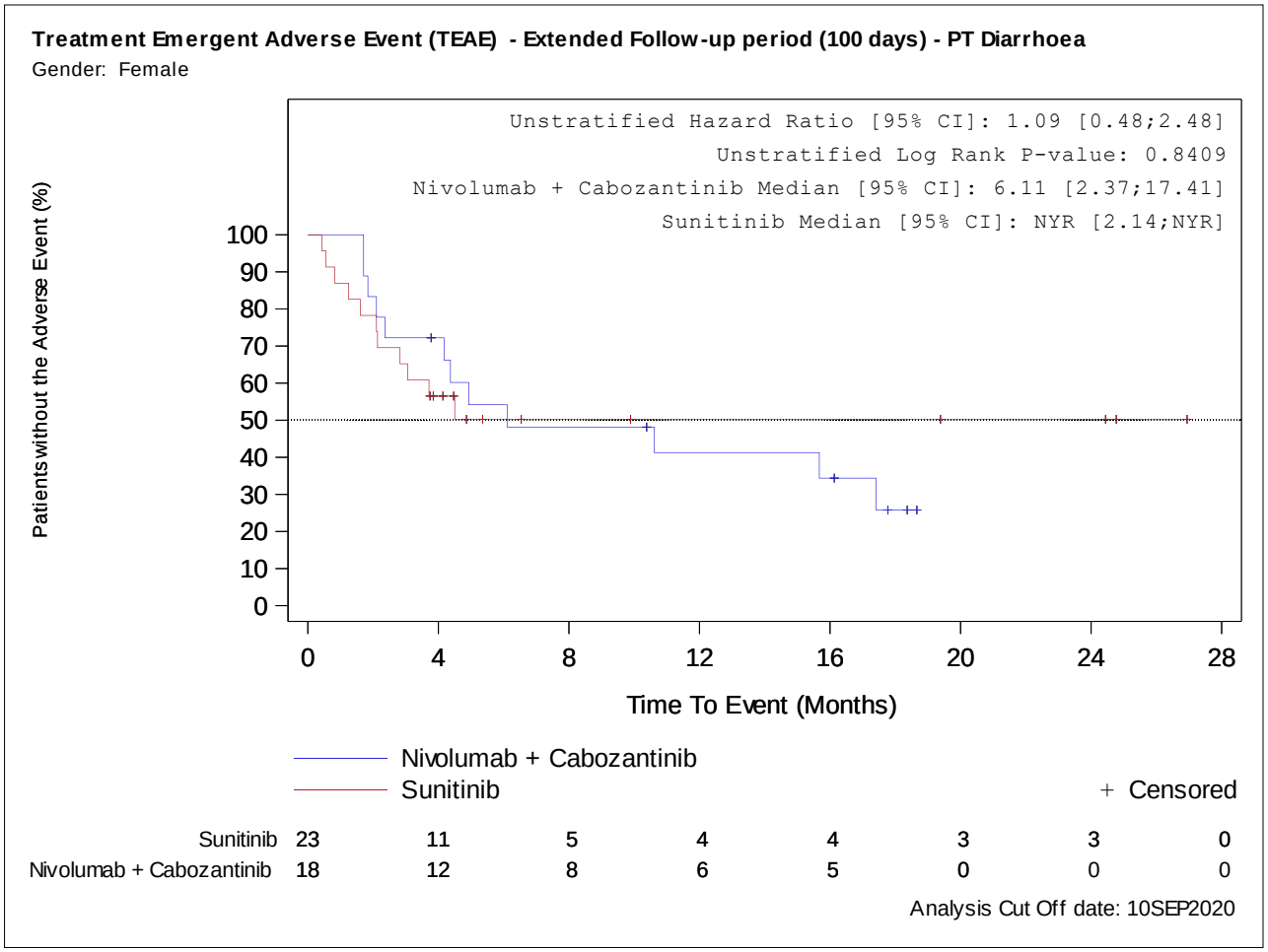
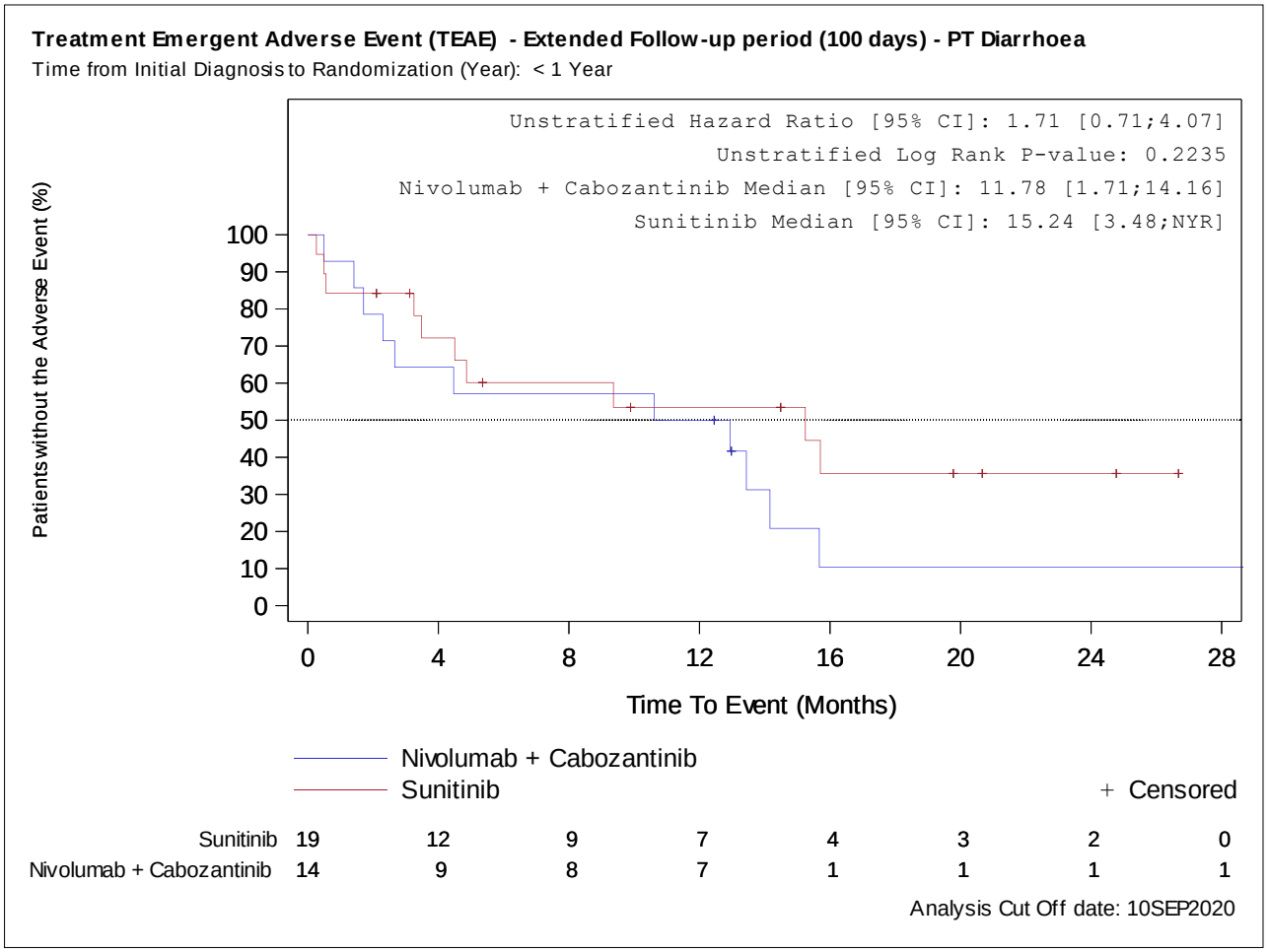
FIGURE 5.25.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:36:24

FIGURE 5.25.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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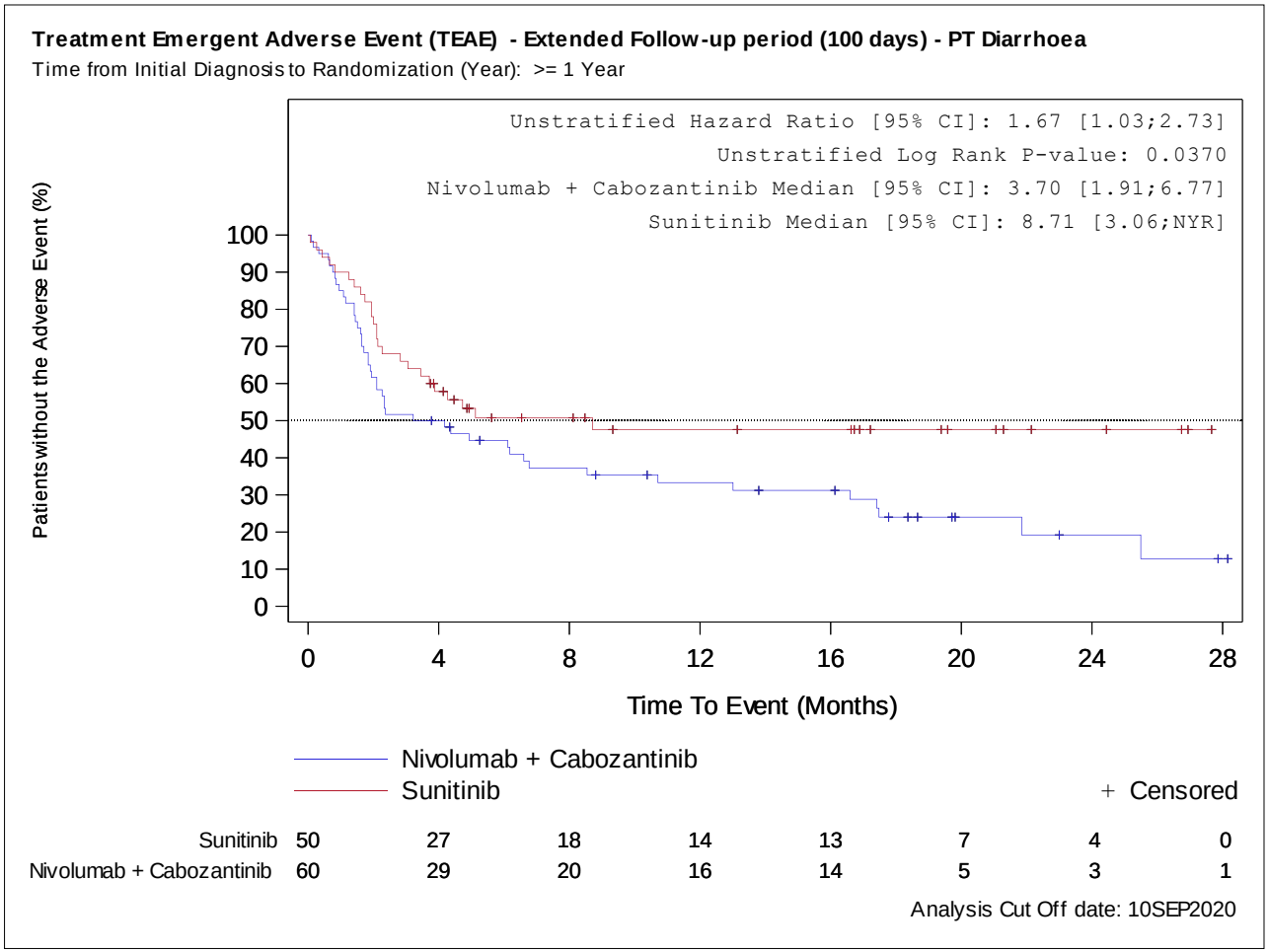
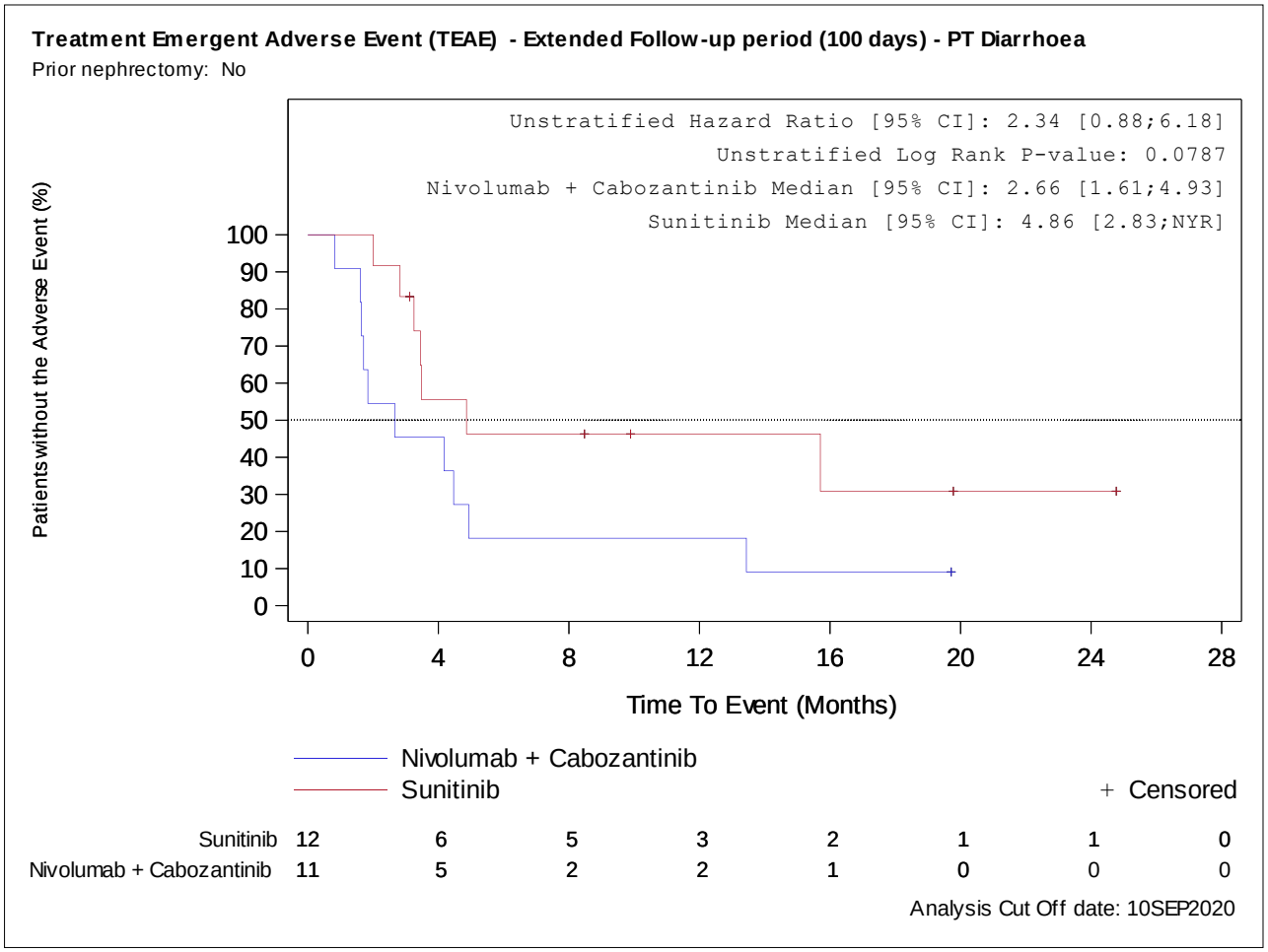
FIGURE 5.25.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:36:46

FIGURE 5.25.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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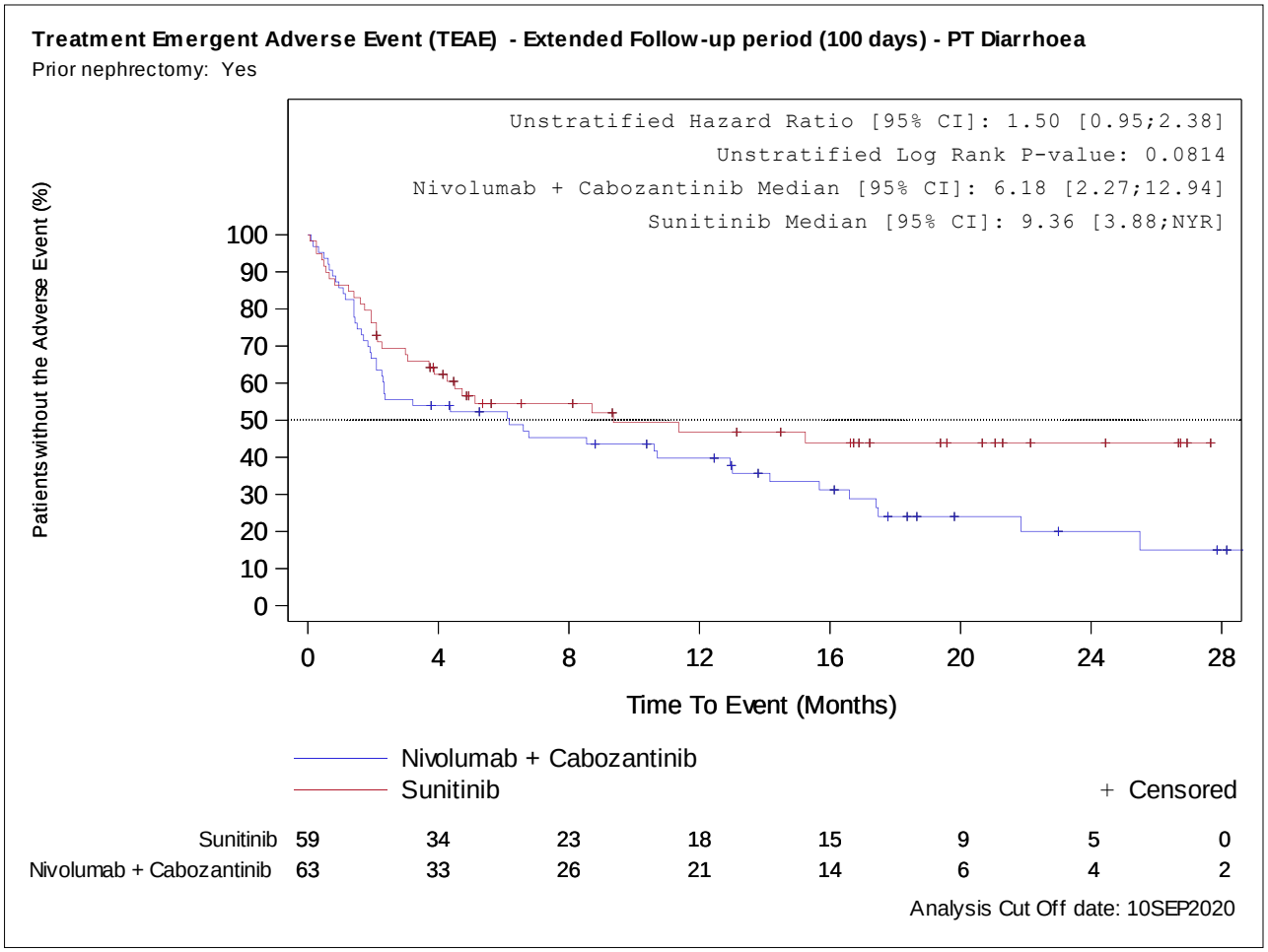
FIGURE 5.25.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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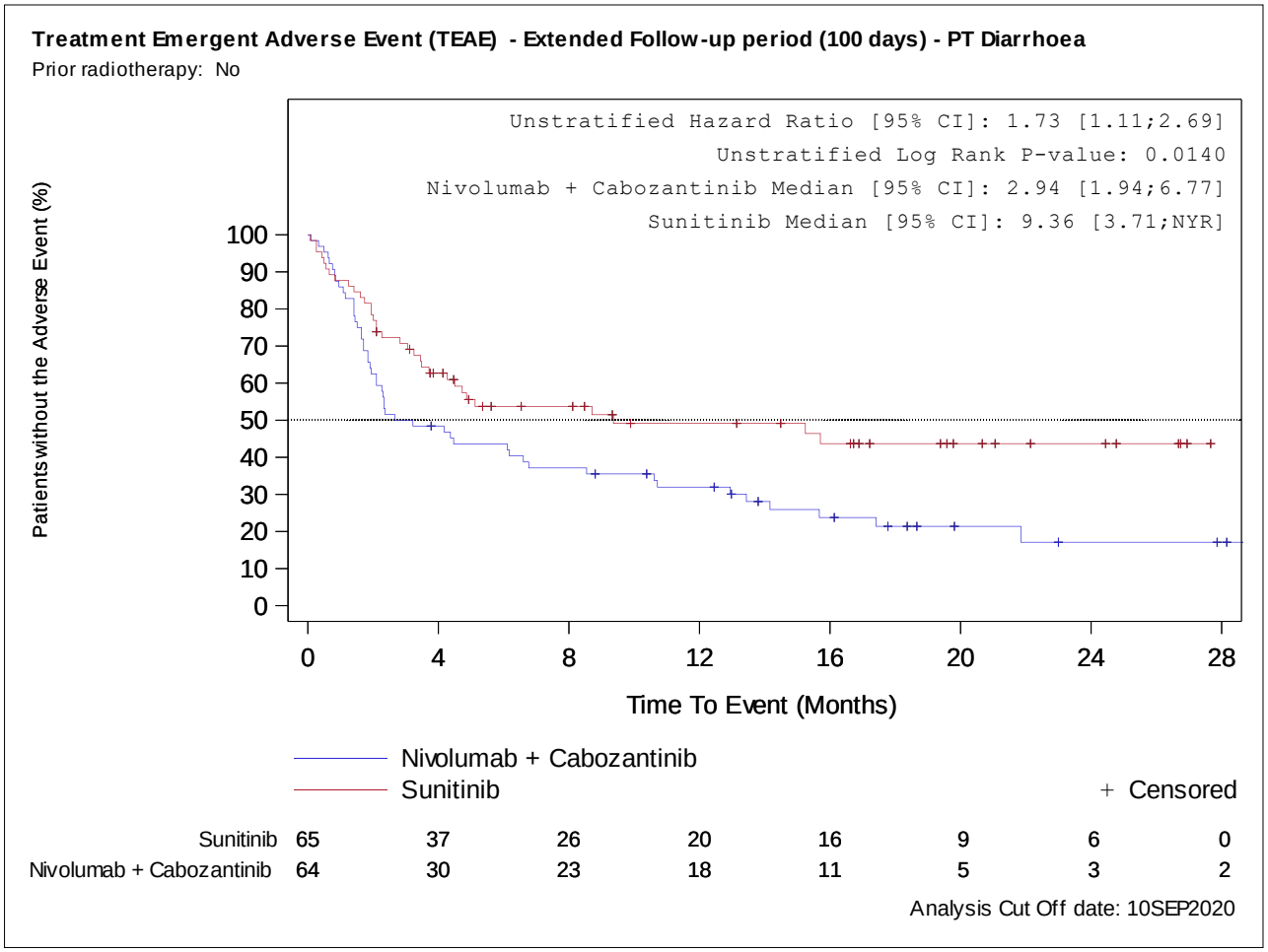
FIGURE 5.25.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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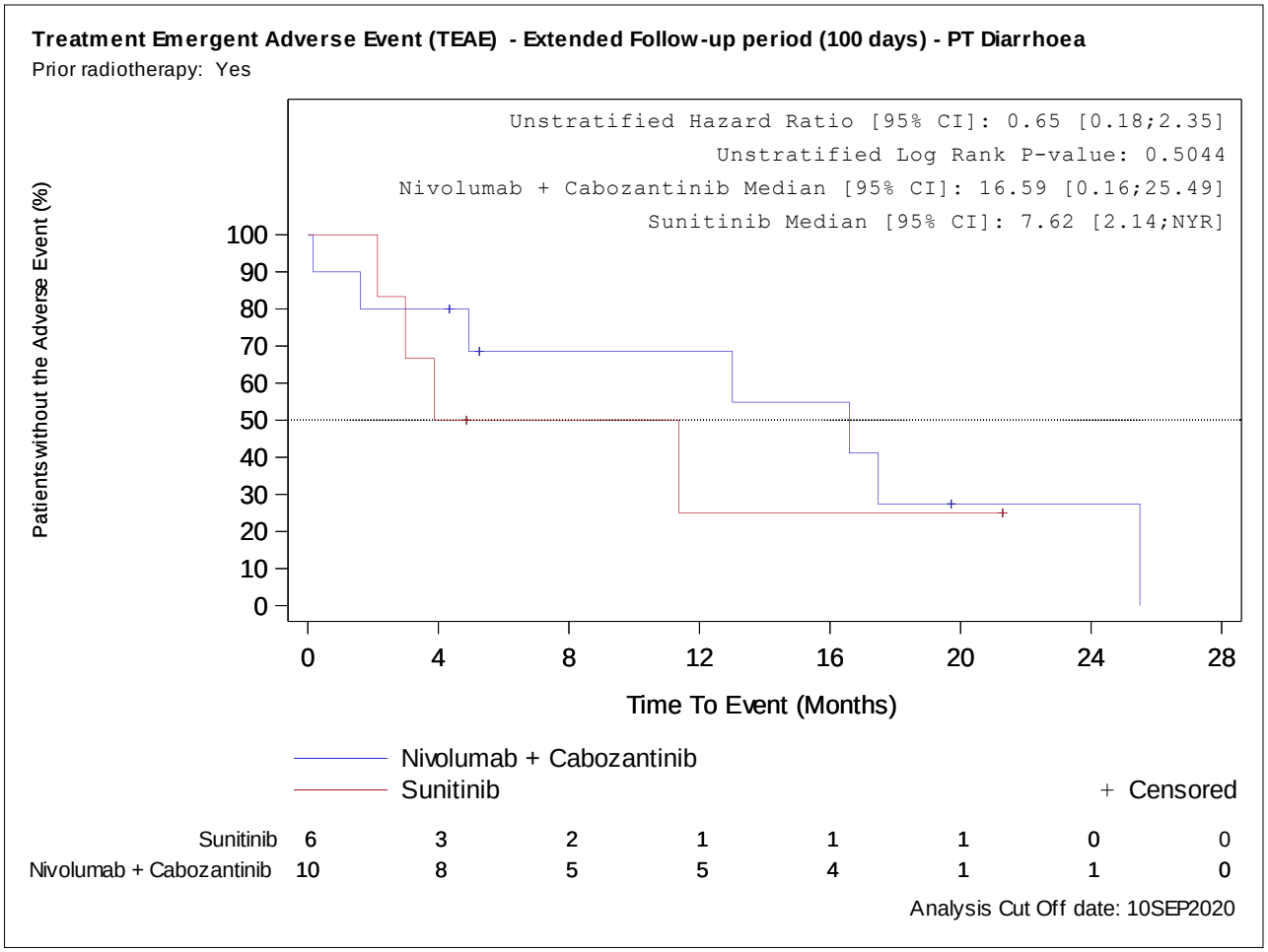
FIGURE 5.25.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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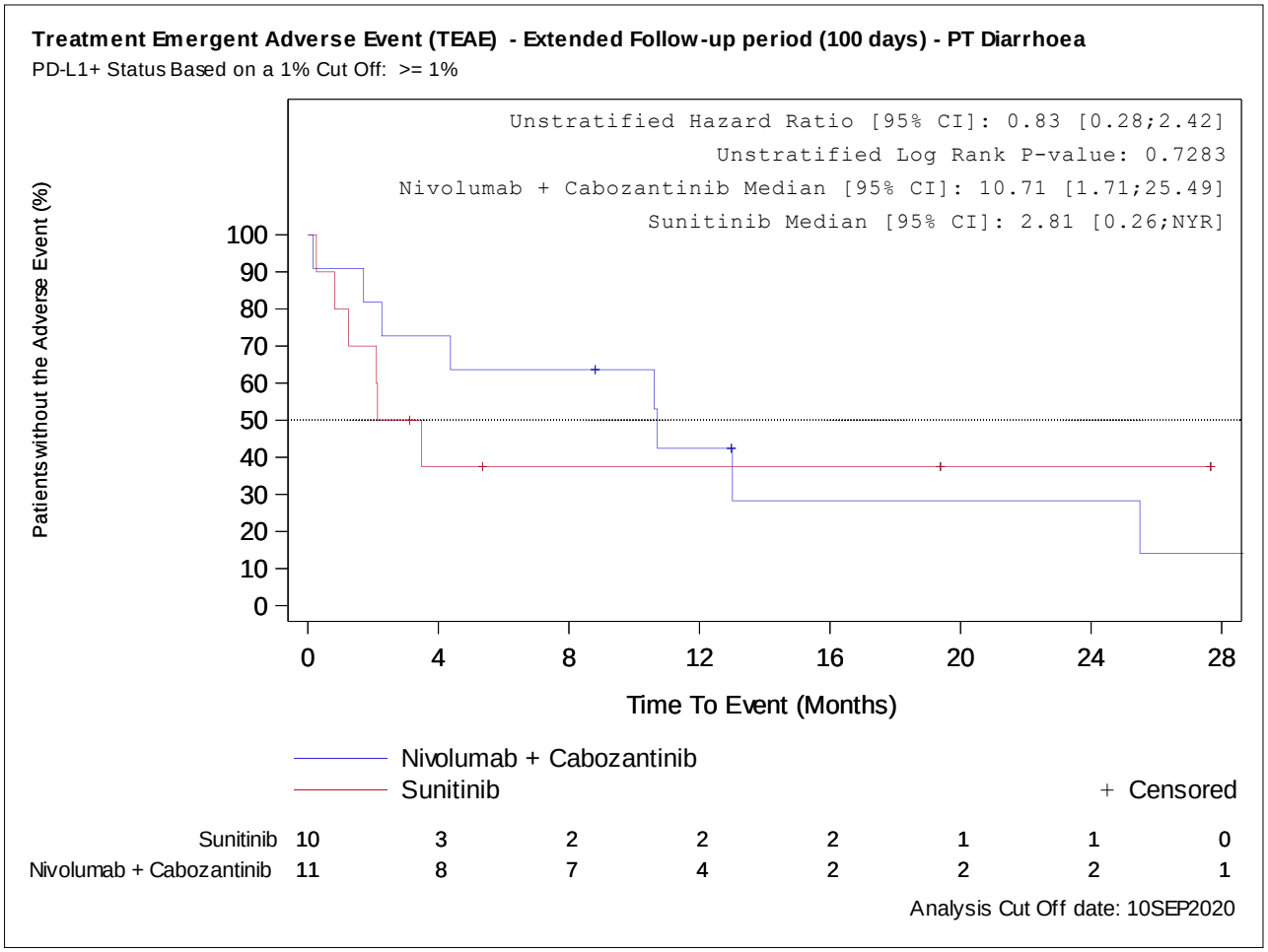
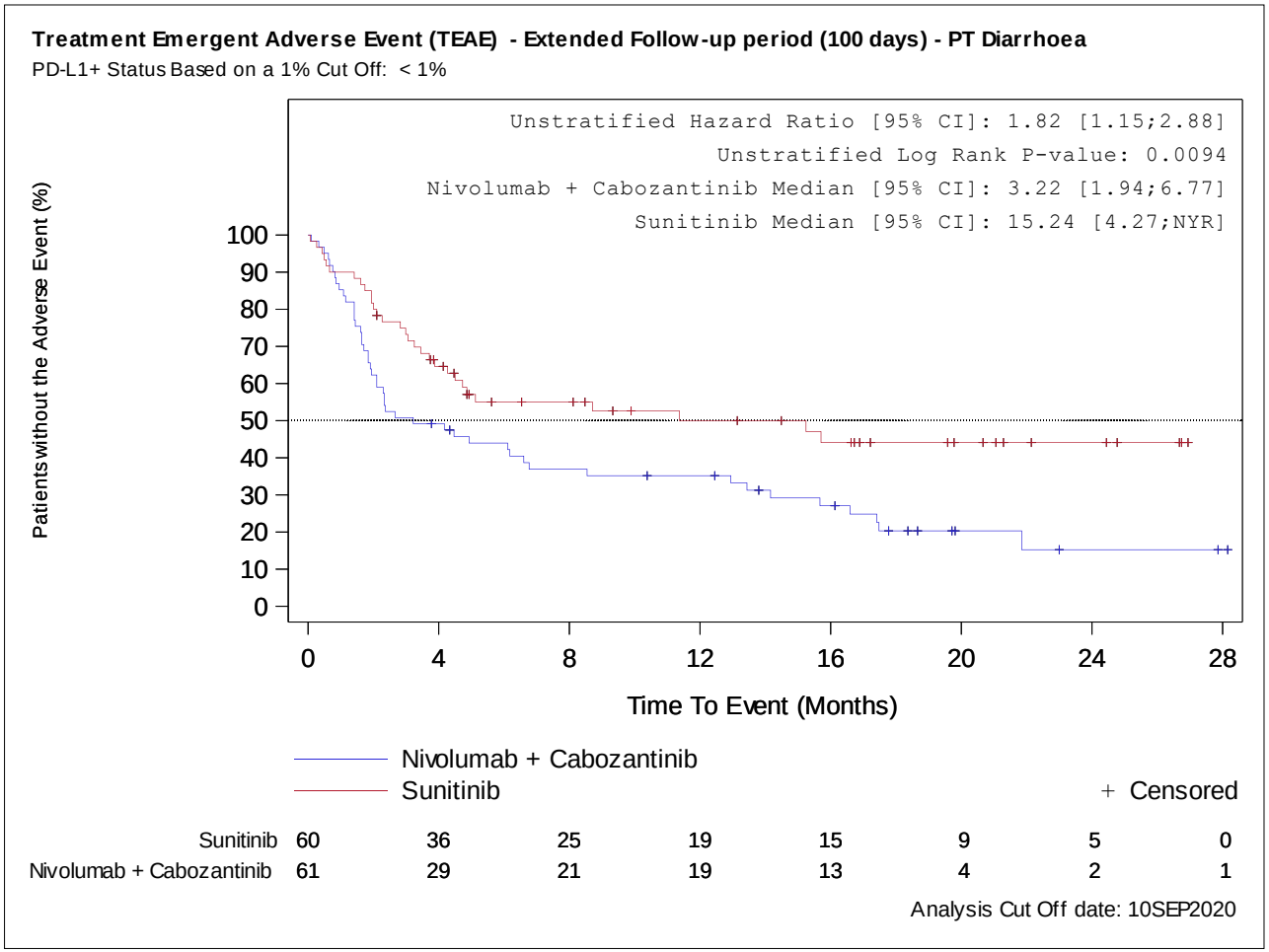
FIGURE 5.25.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:38:02

FIGURE 5.25.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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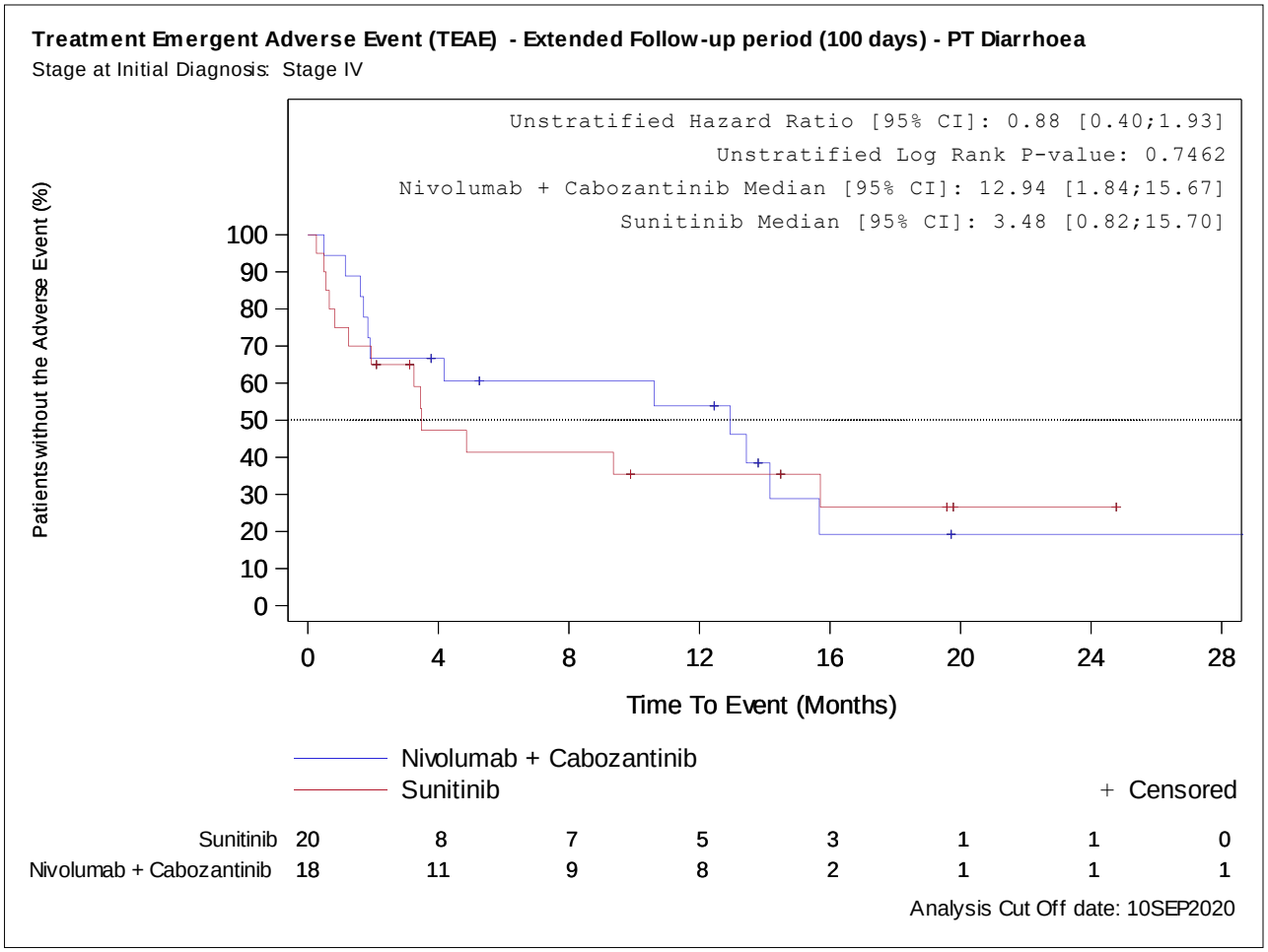
FIGURE 5.25.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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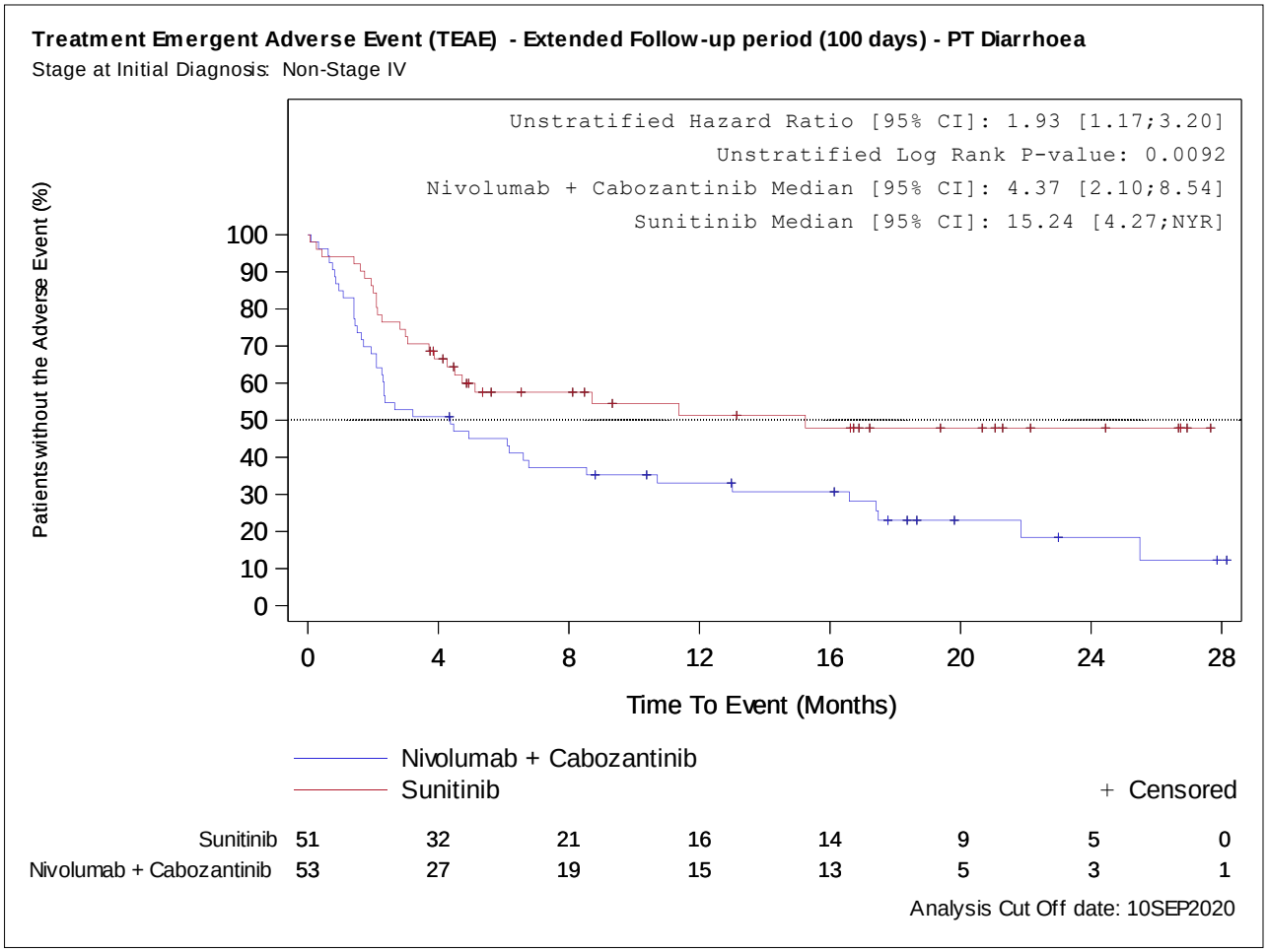
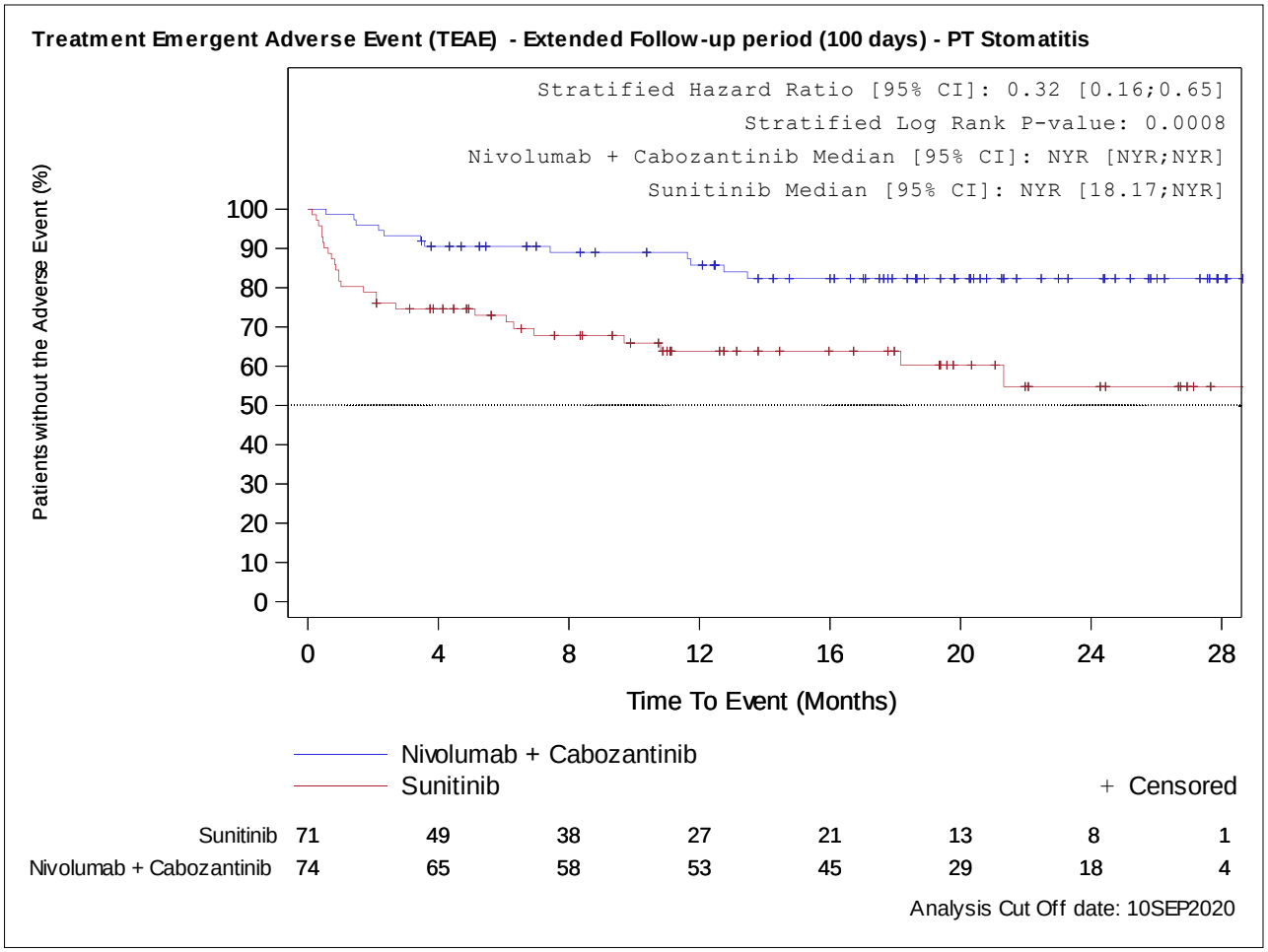
FIGURE 5.25.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Diarrhoea - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



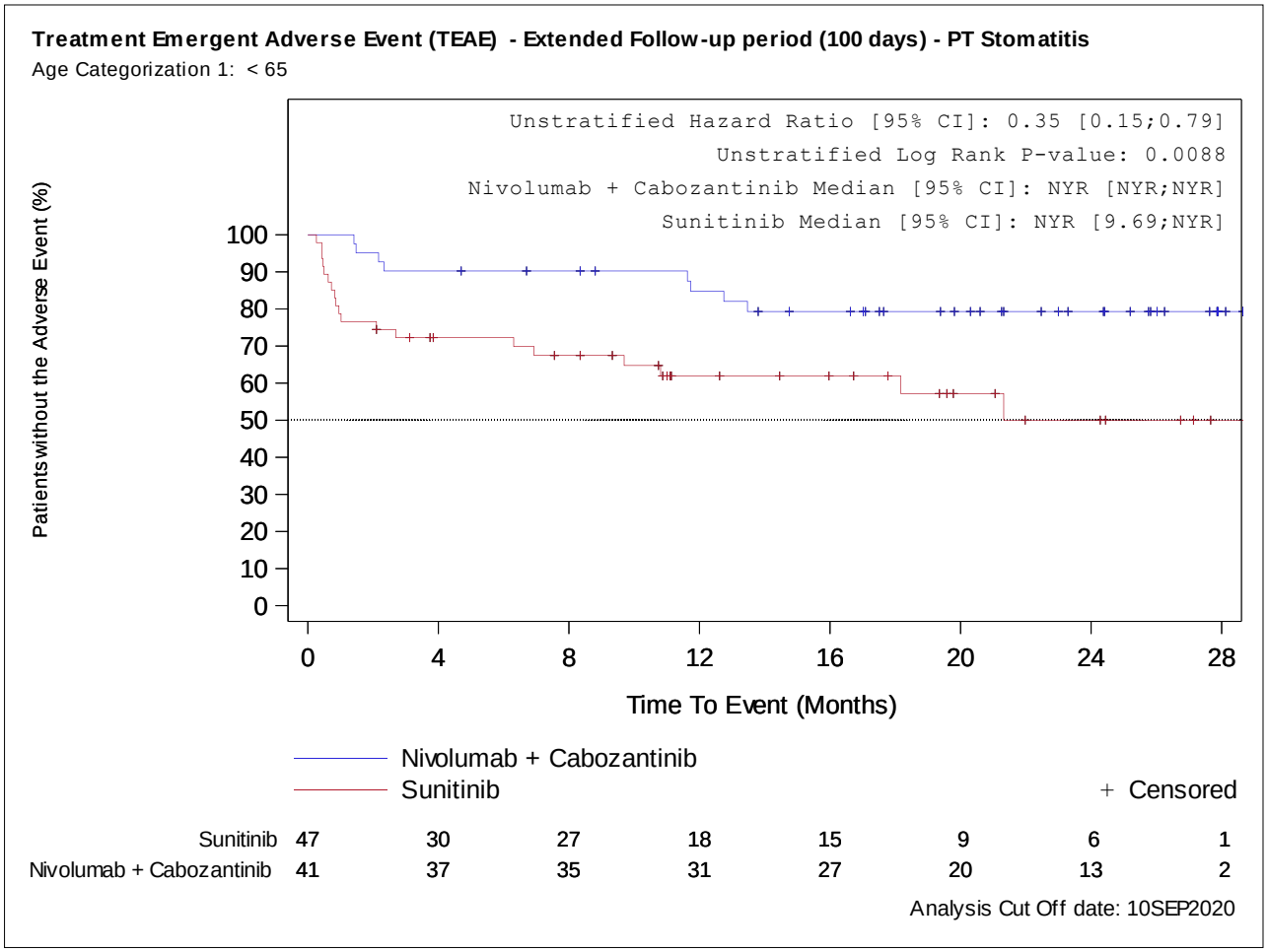

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:38:42

FIGURE 5.26.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



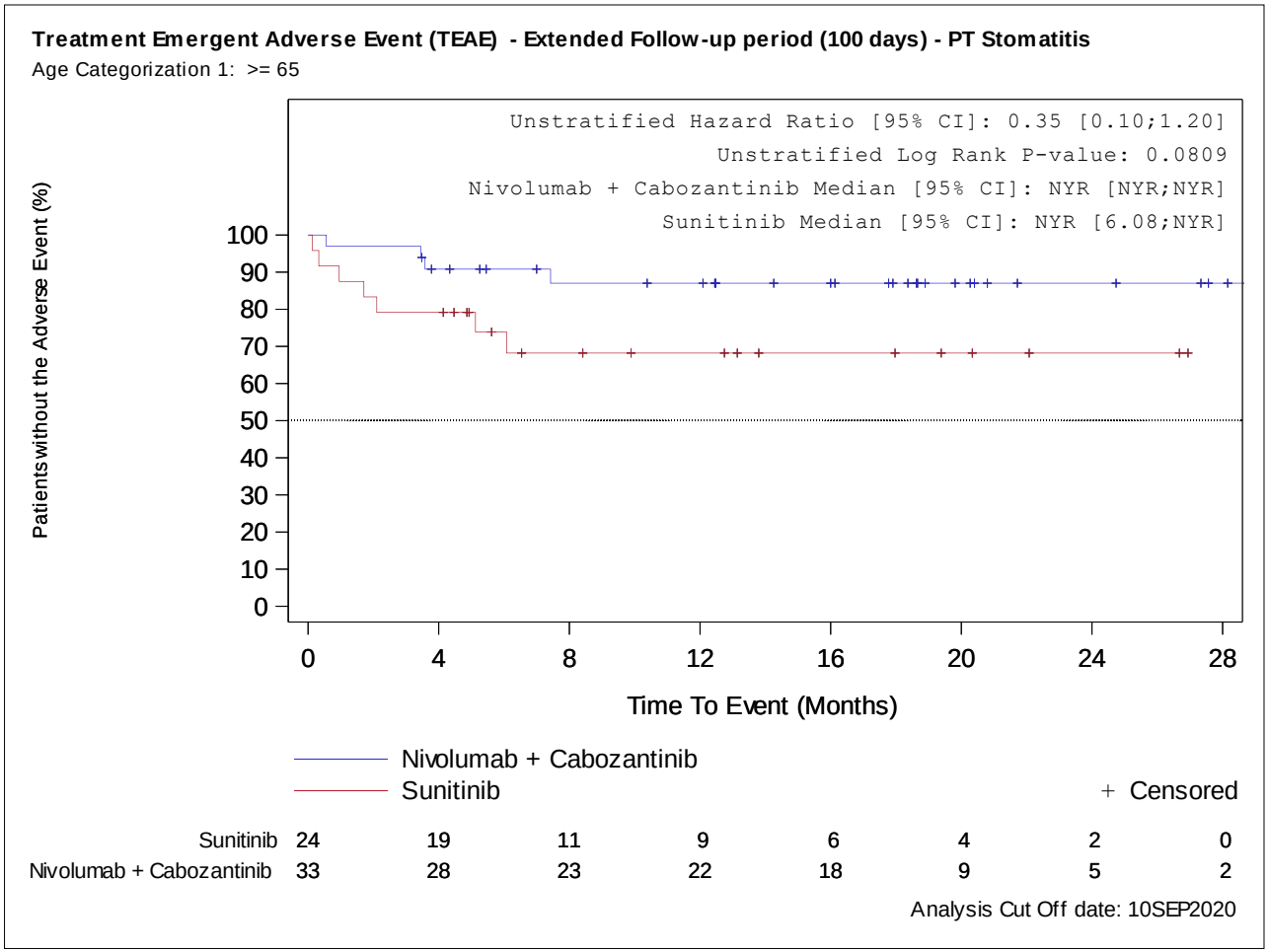

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:41:58

FIGURE 5.26.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:42:01

FIGURE 5.26.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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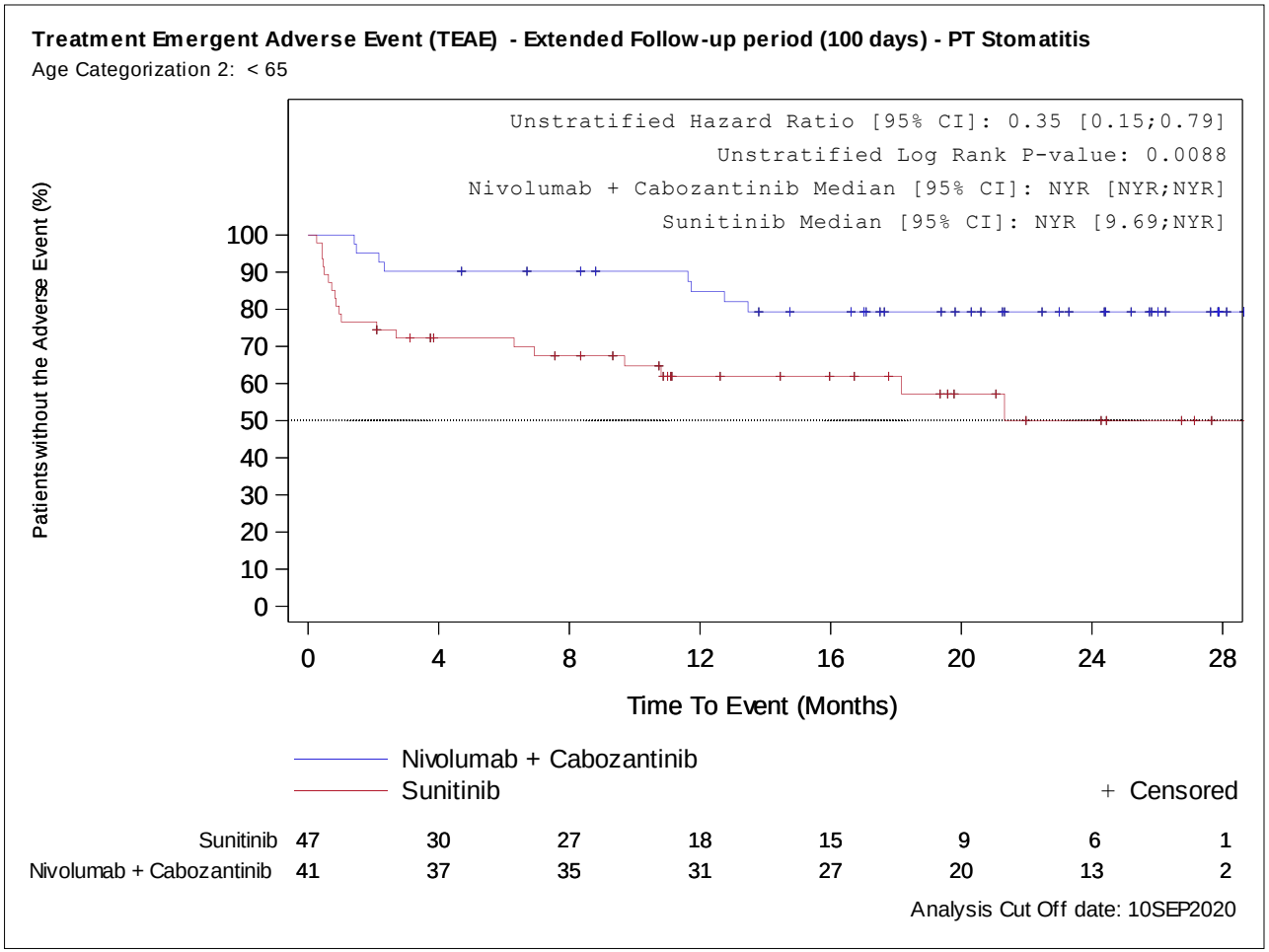
FIGURE 5.26.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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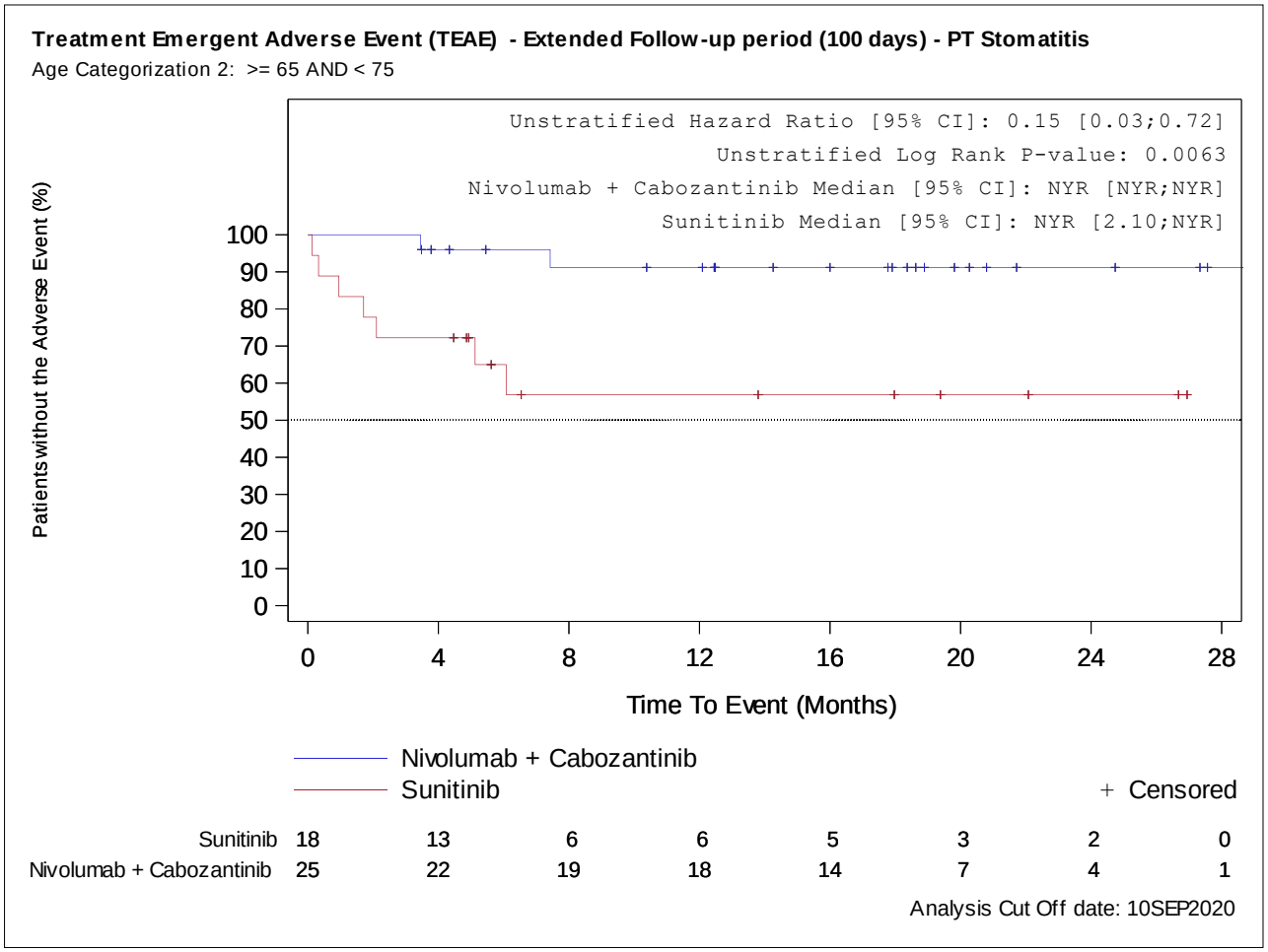
FIGURE 5.26.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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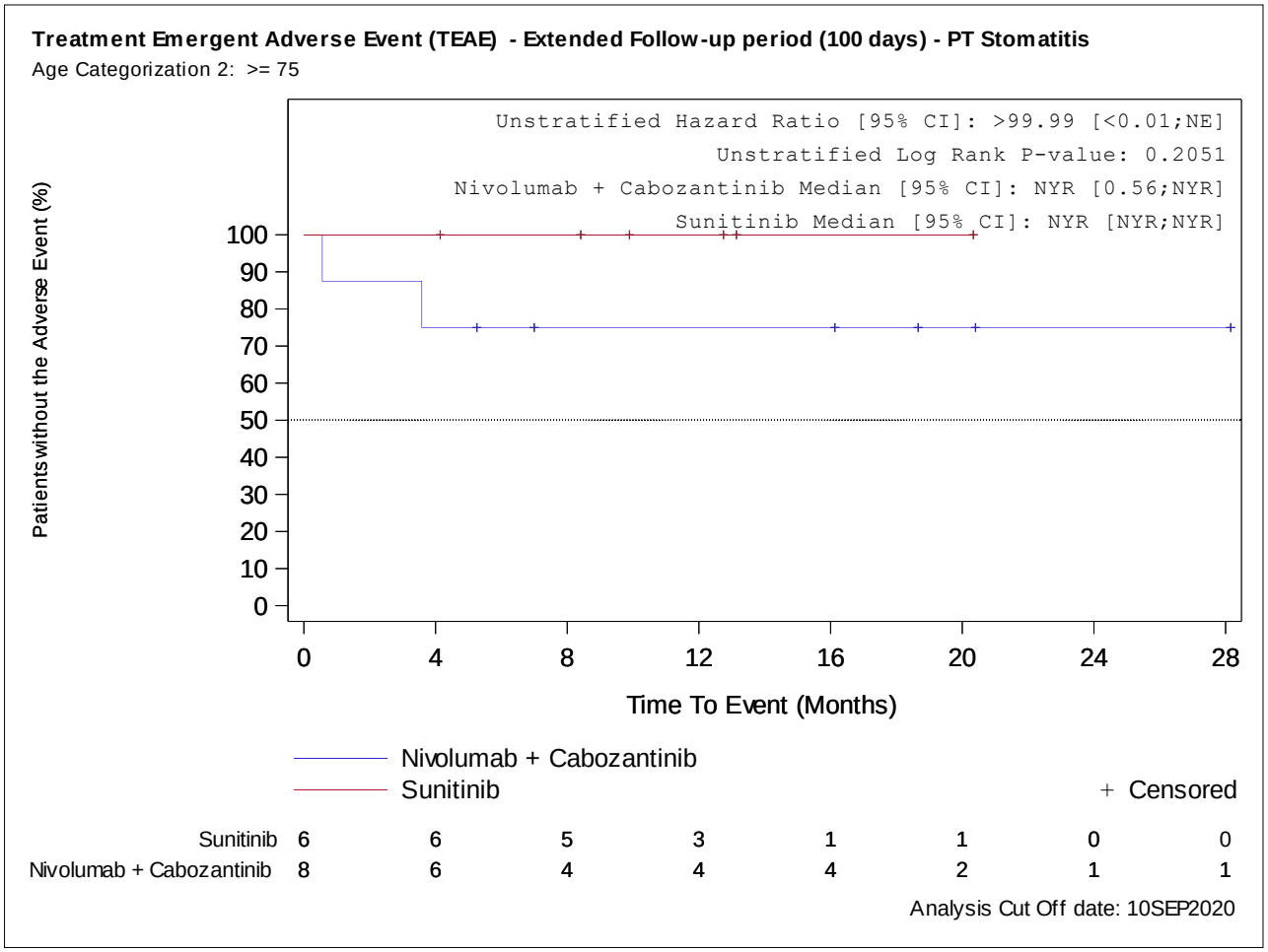
FIGURE 5.26.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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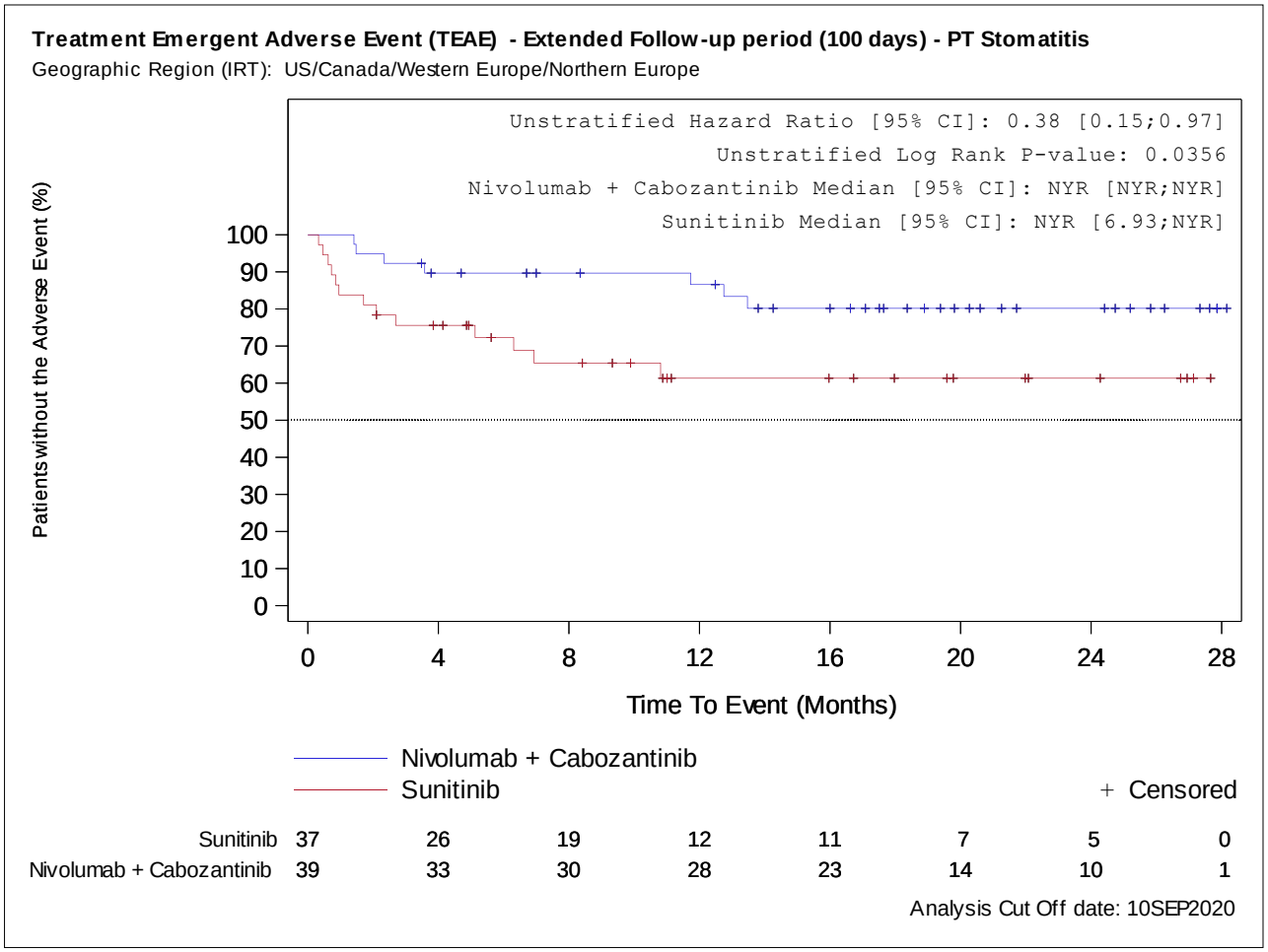
FIGURE 5.26.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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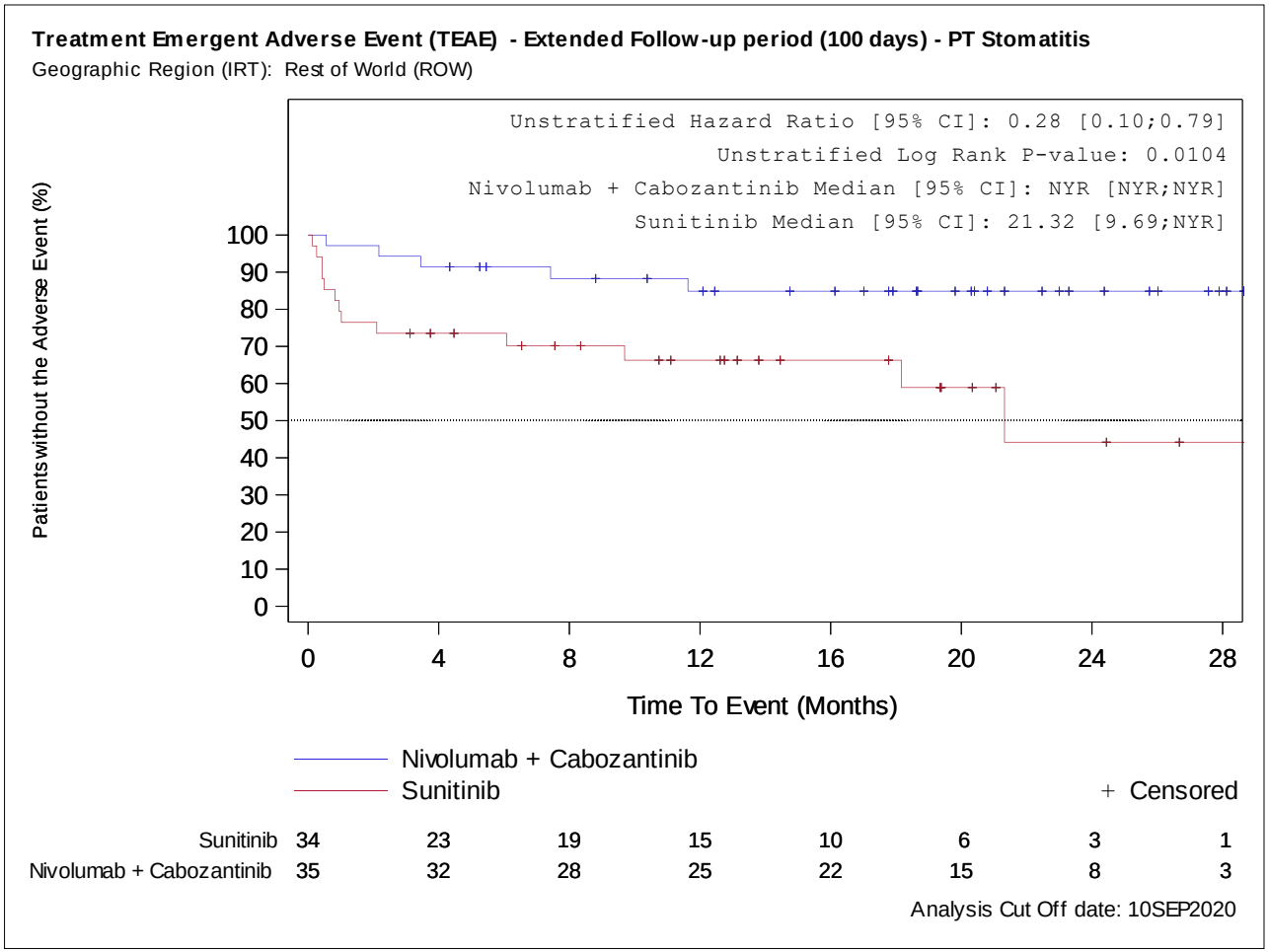
FIGURE 5.26.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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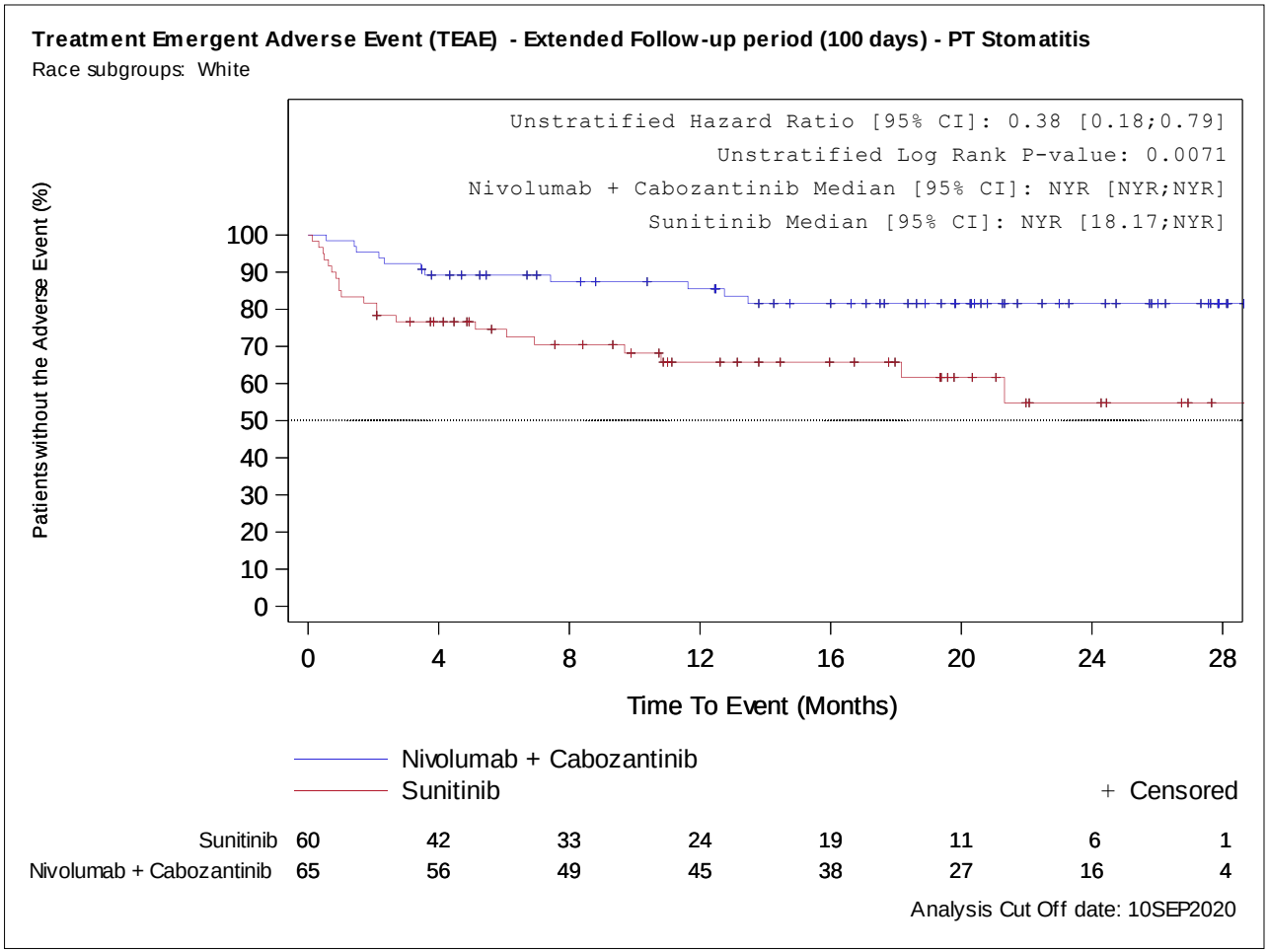
FIGURE 5.26.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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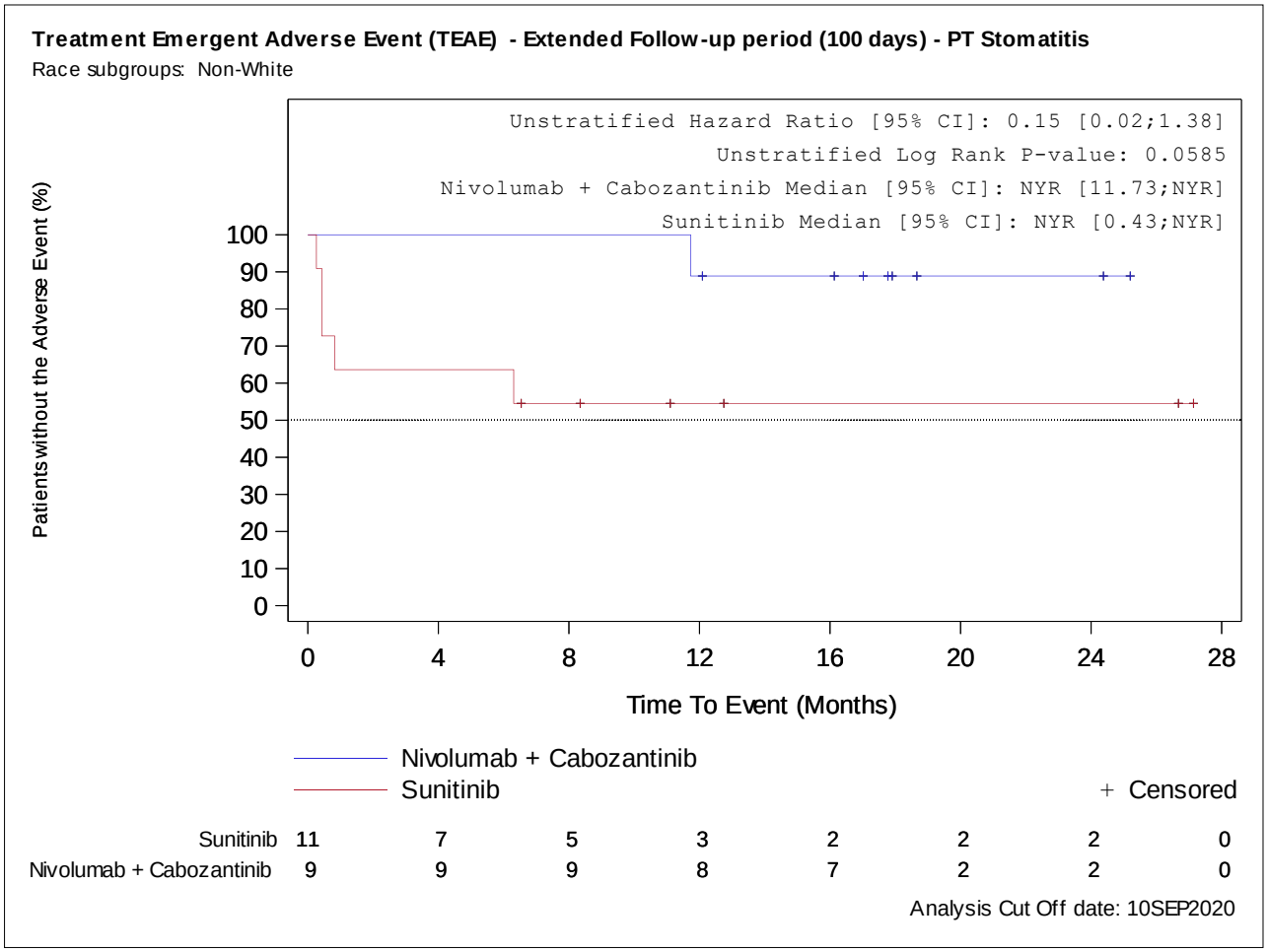
FIGURE 5.26.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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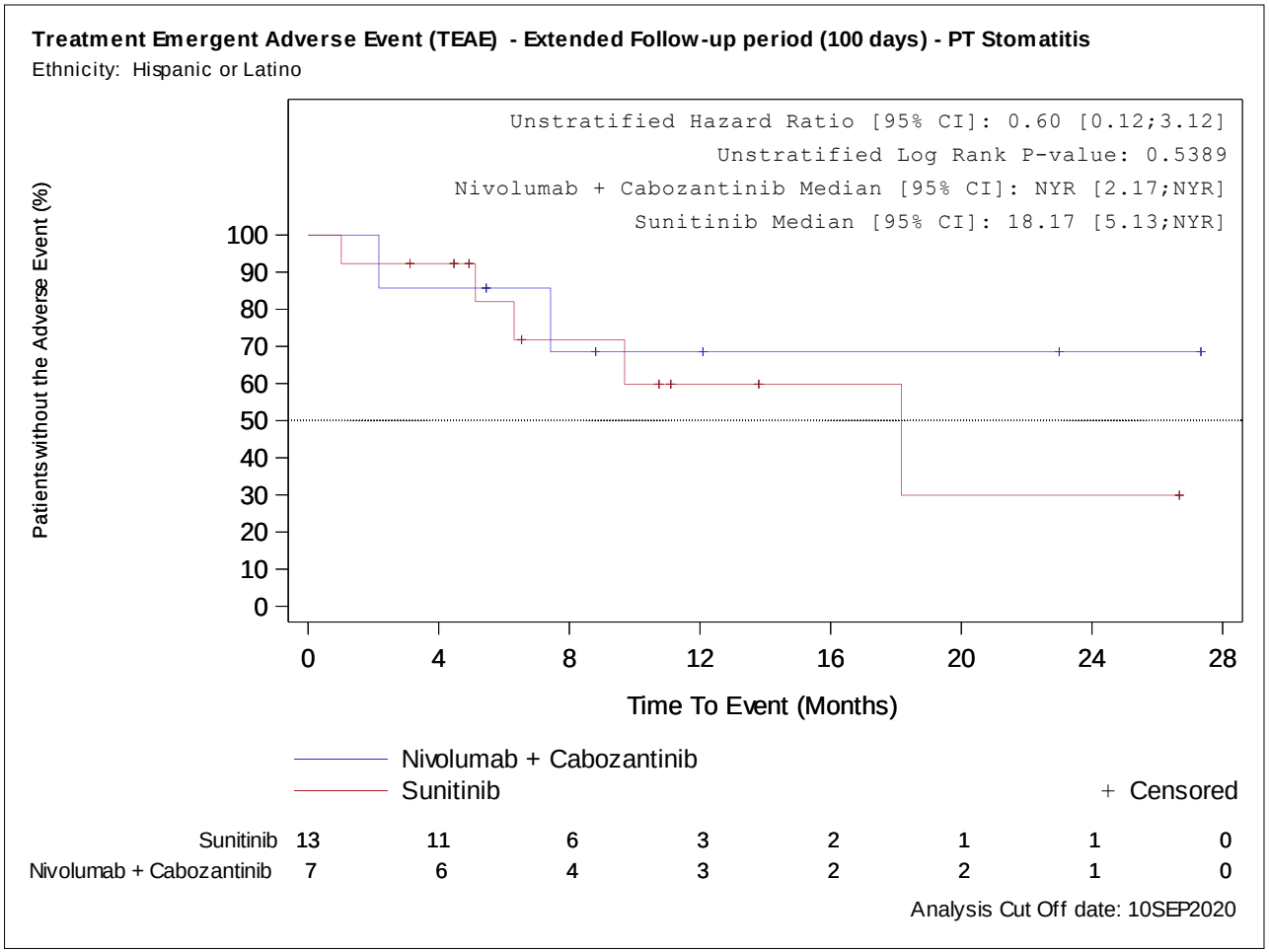
FIGURE 5.26.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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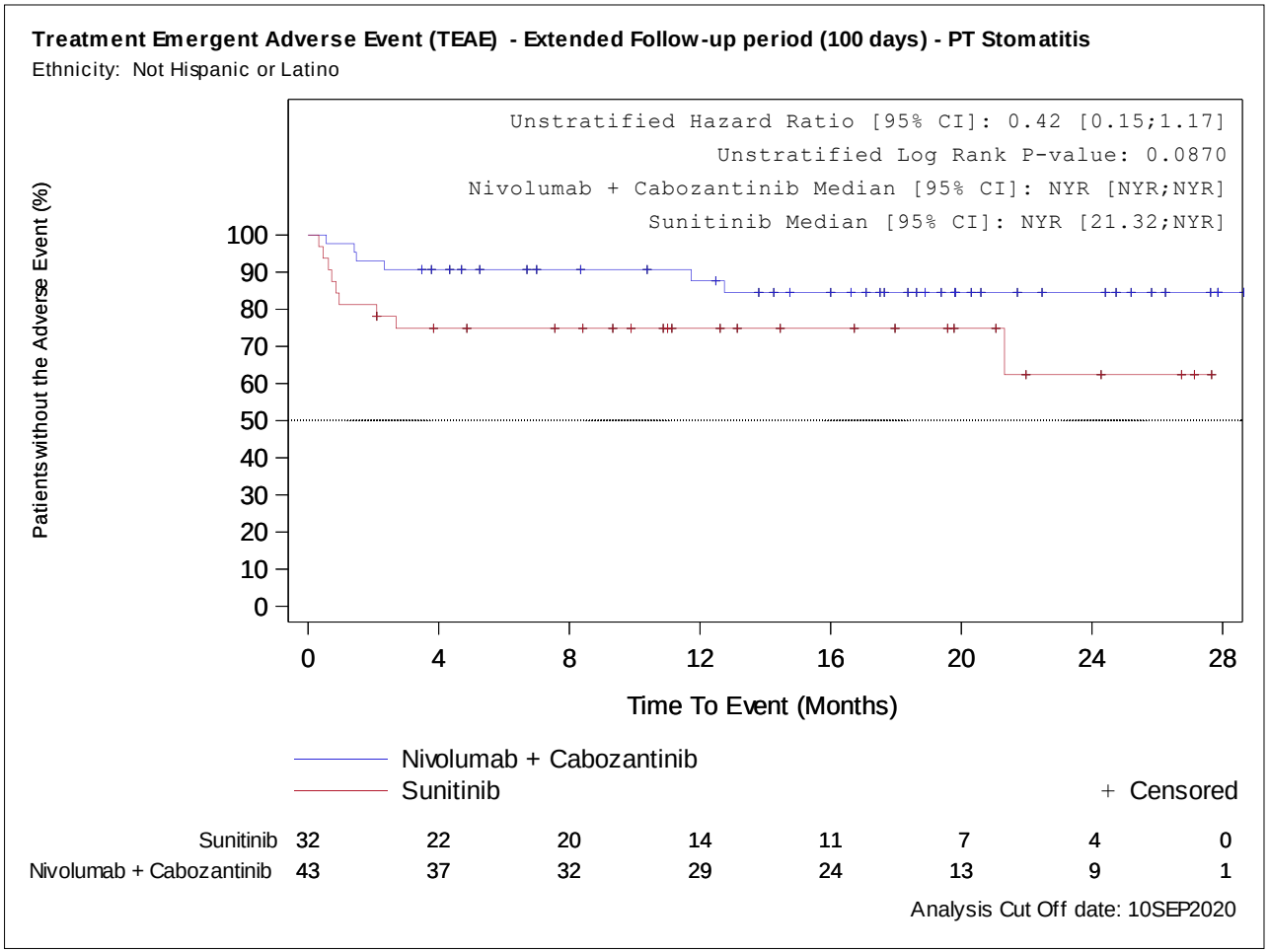
FIGURE 5.26.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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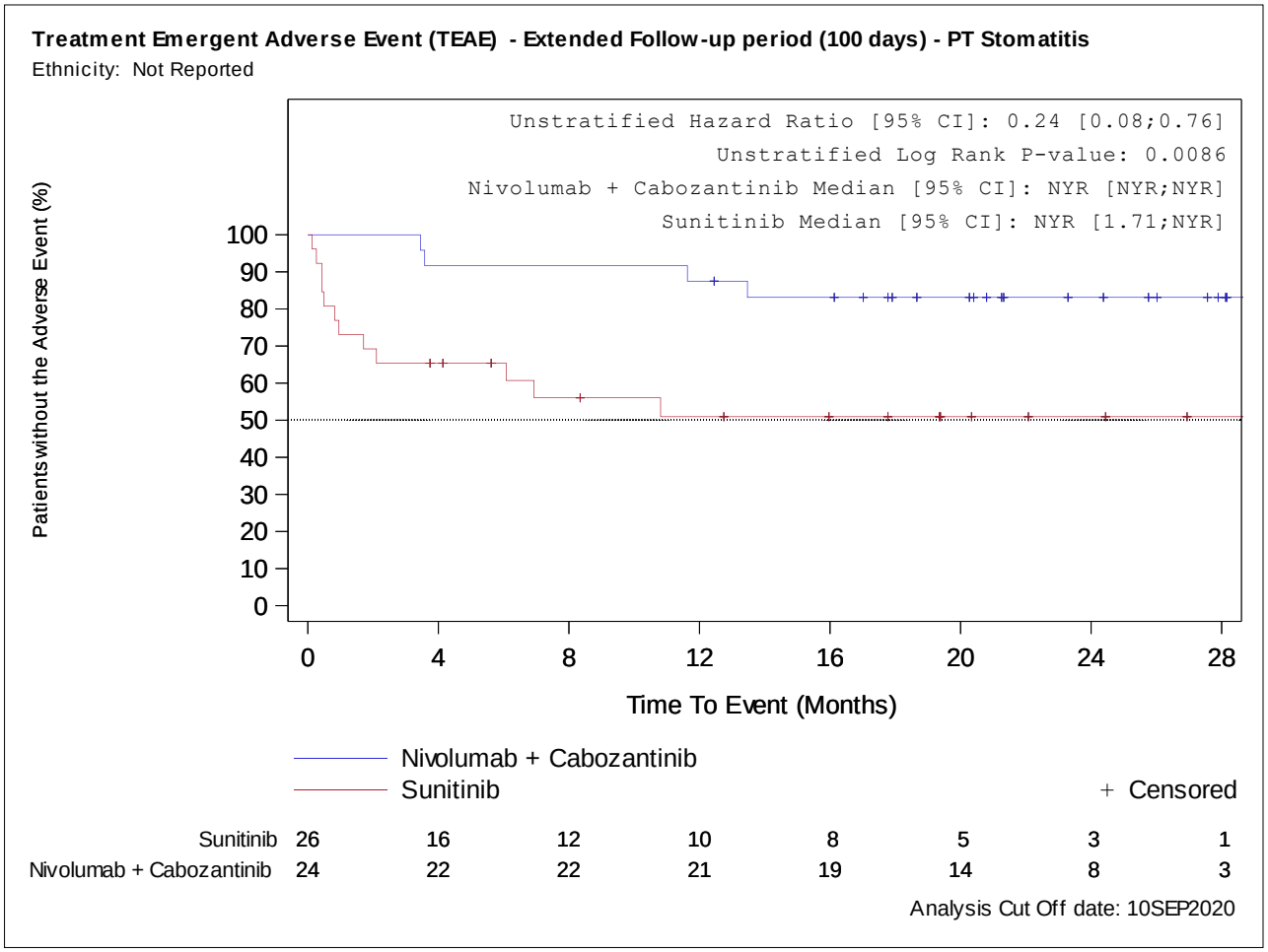
FIGURE 5.26.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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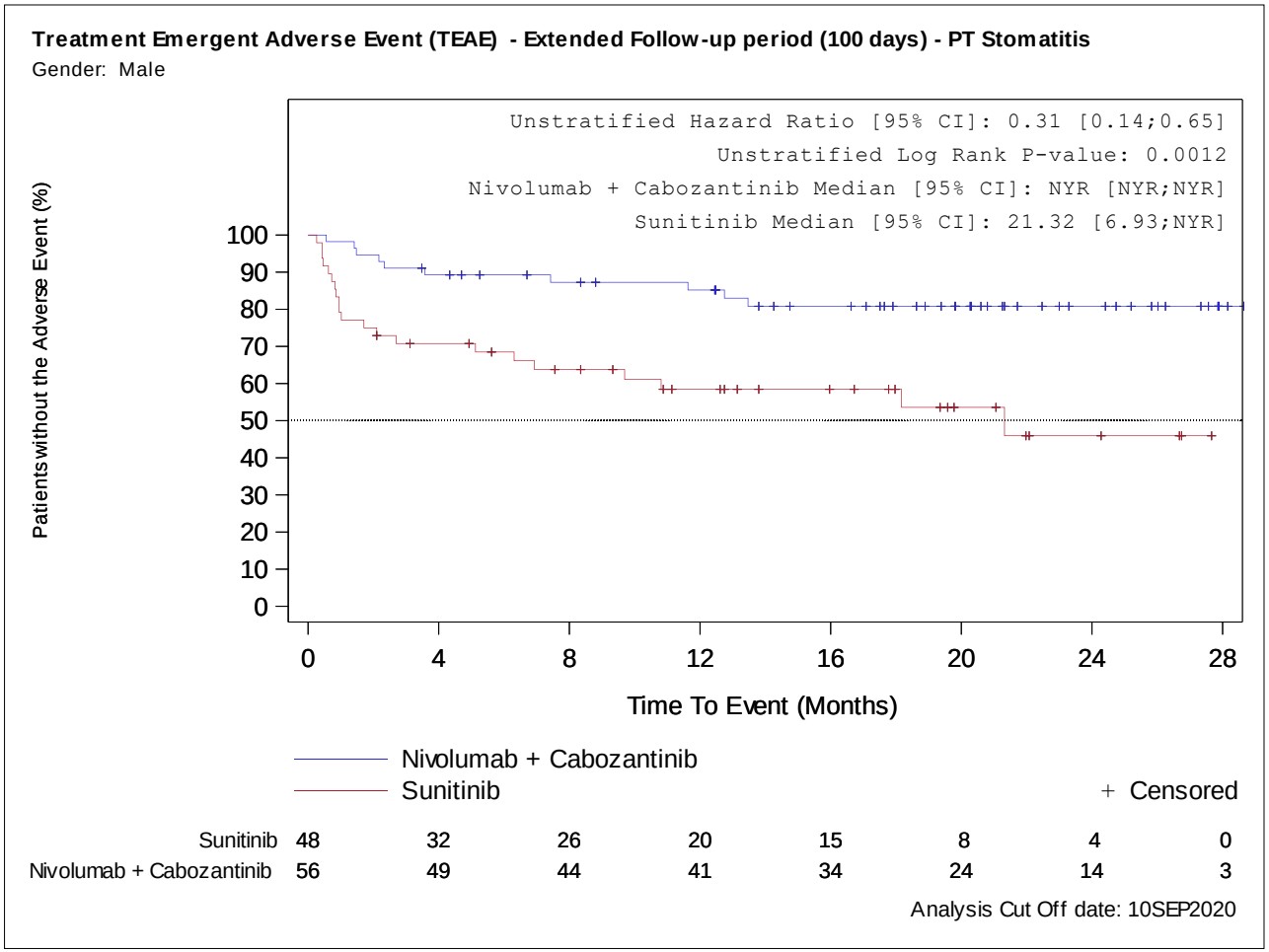
FIGURE 5.26.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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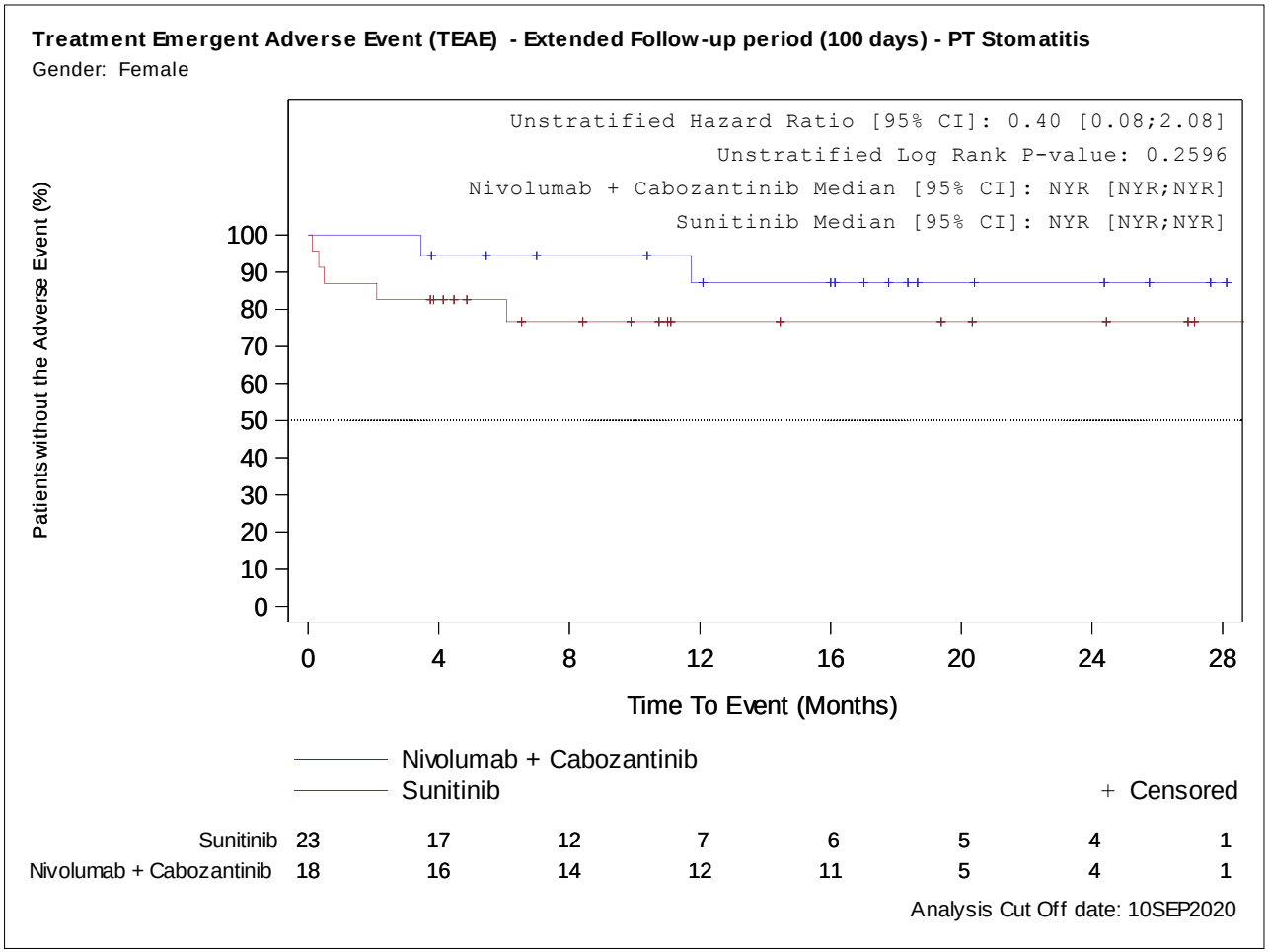
FIGURE 5.26.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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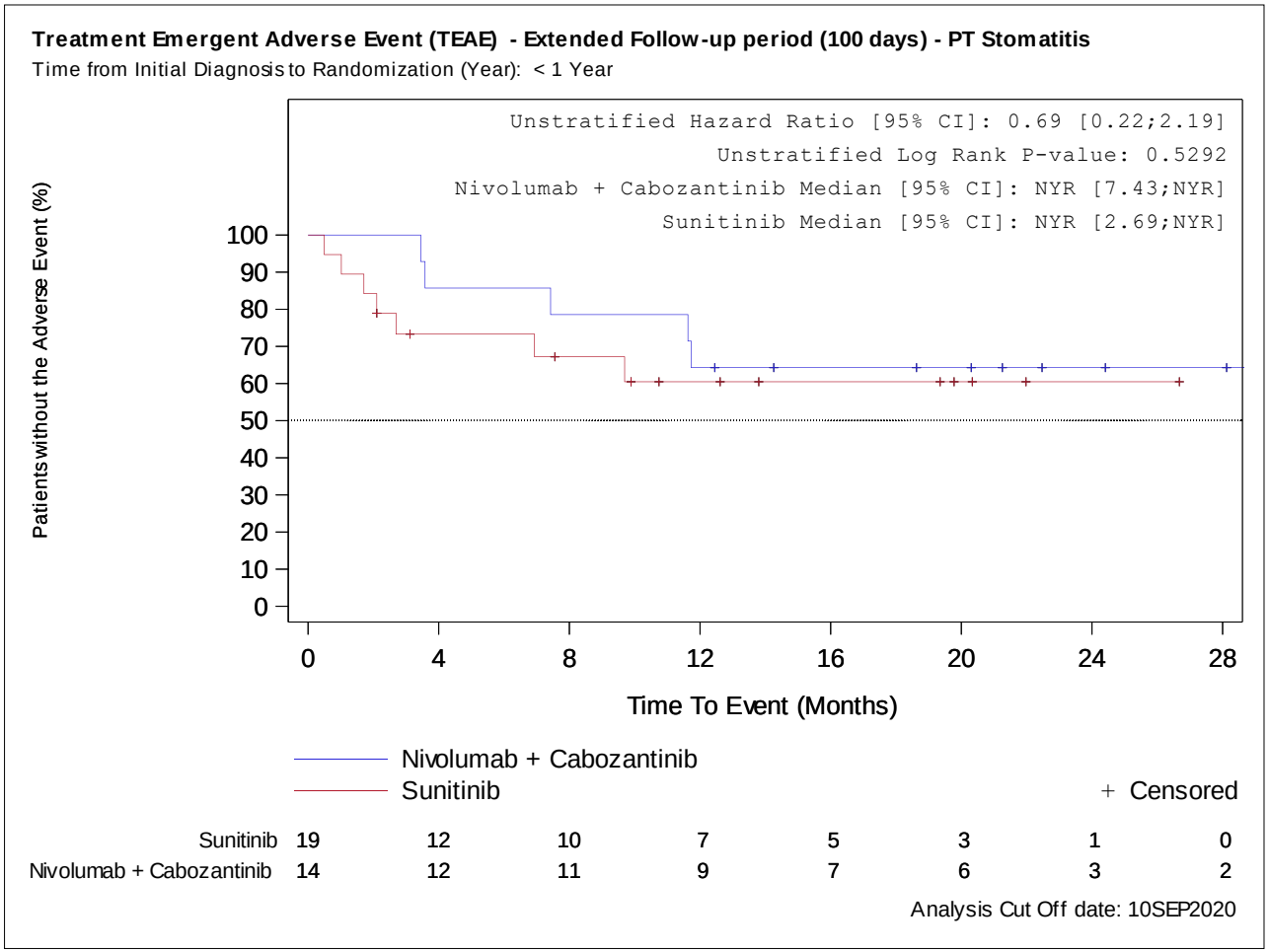
FIGURE 5.26.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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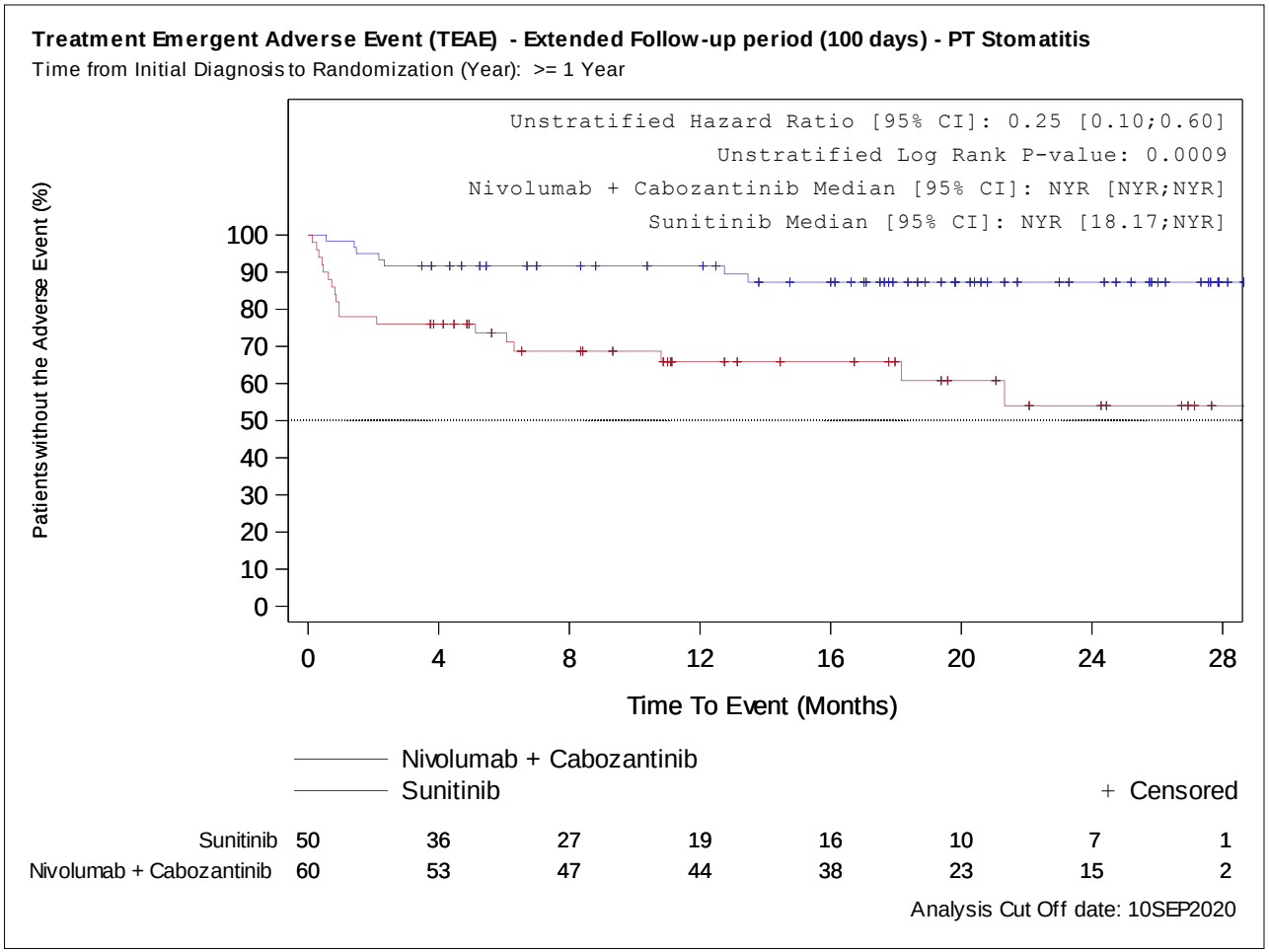
FIGURE 5.26.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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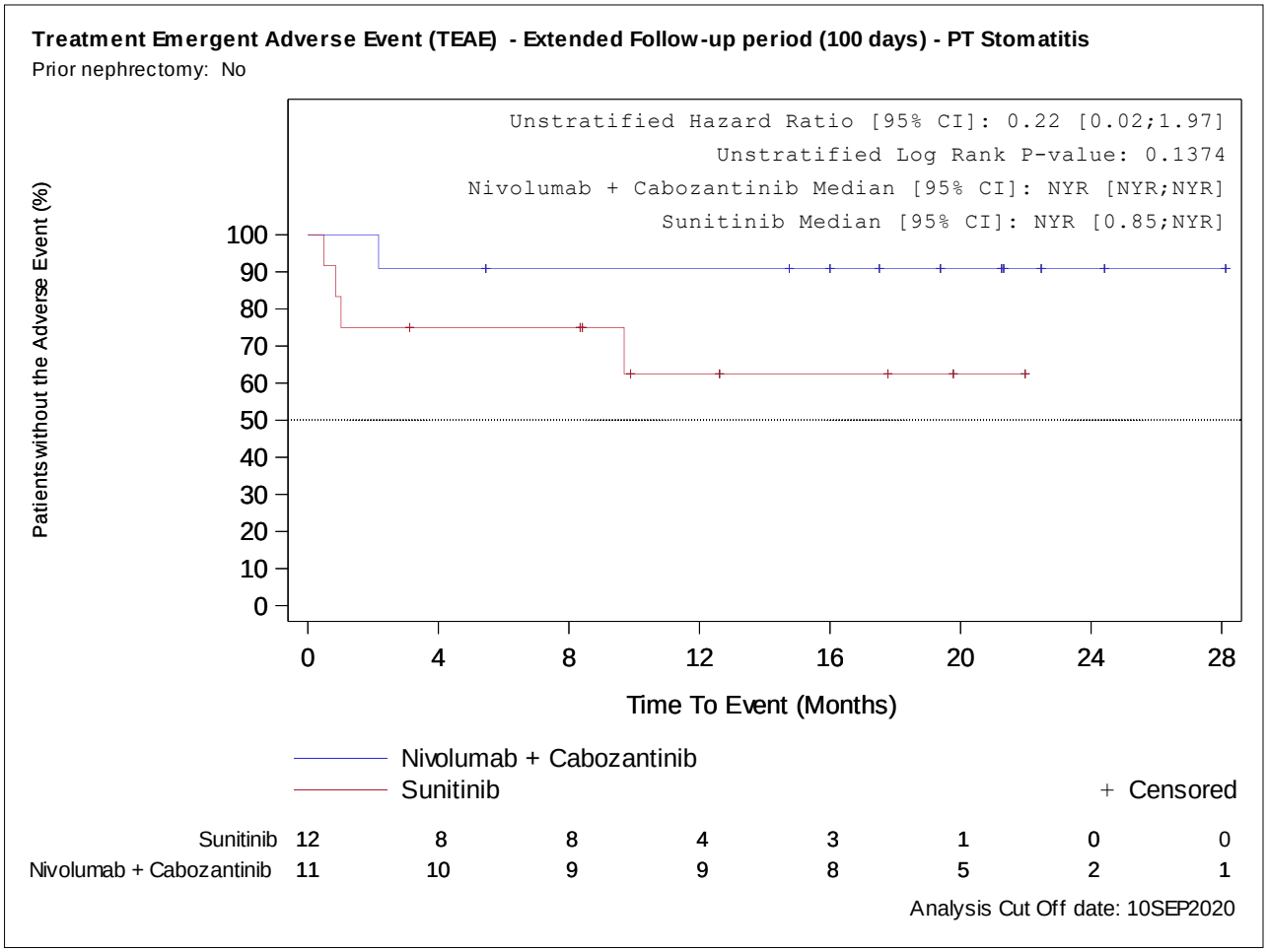
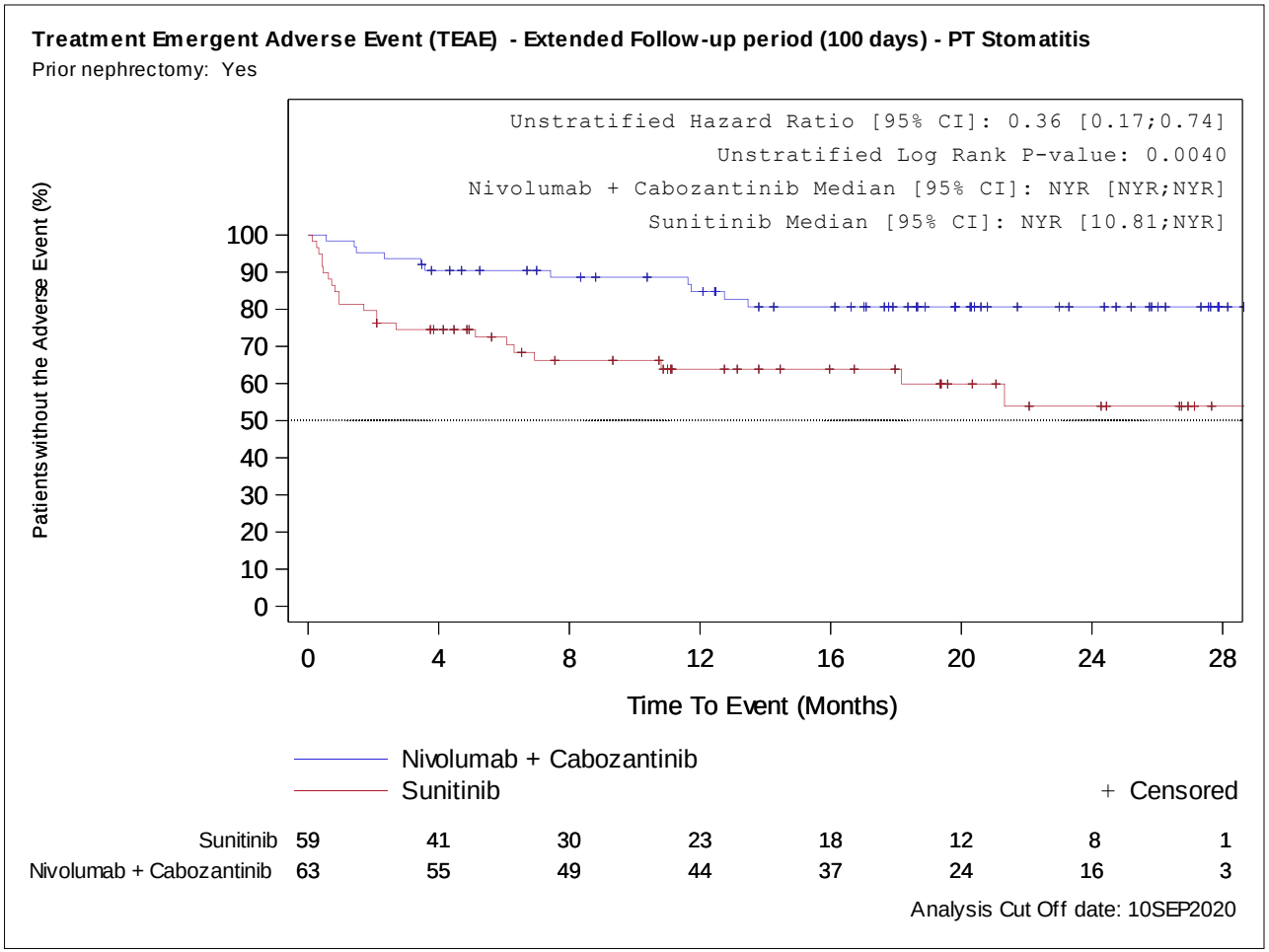
FIGURE 5.26.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:44:31

FIGURE 5.26.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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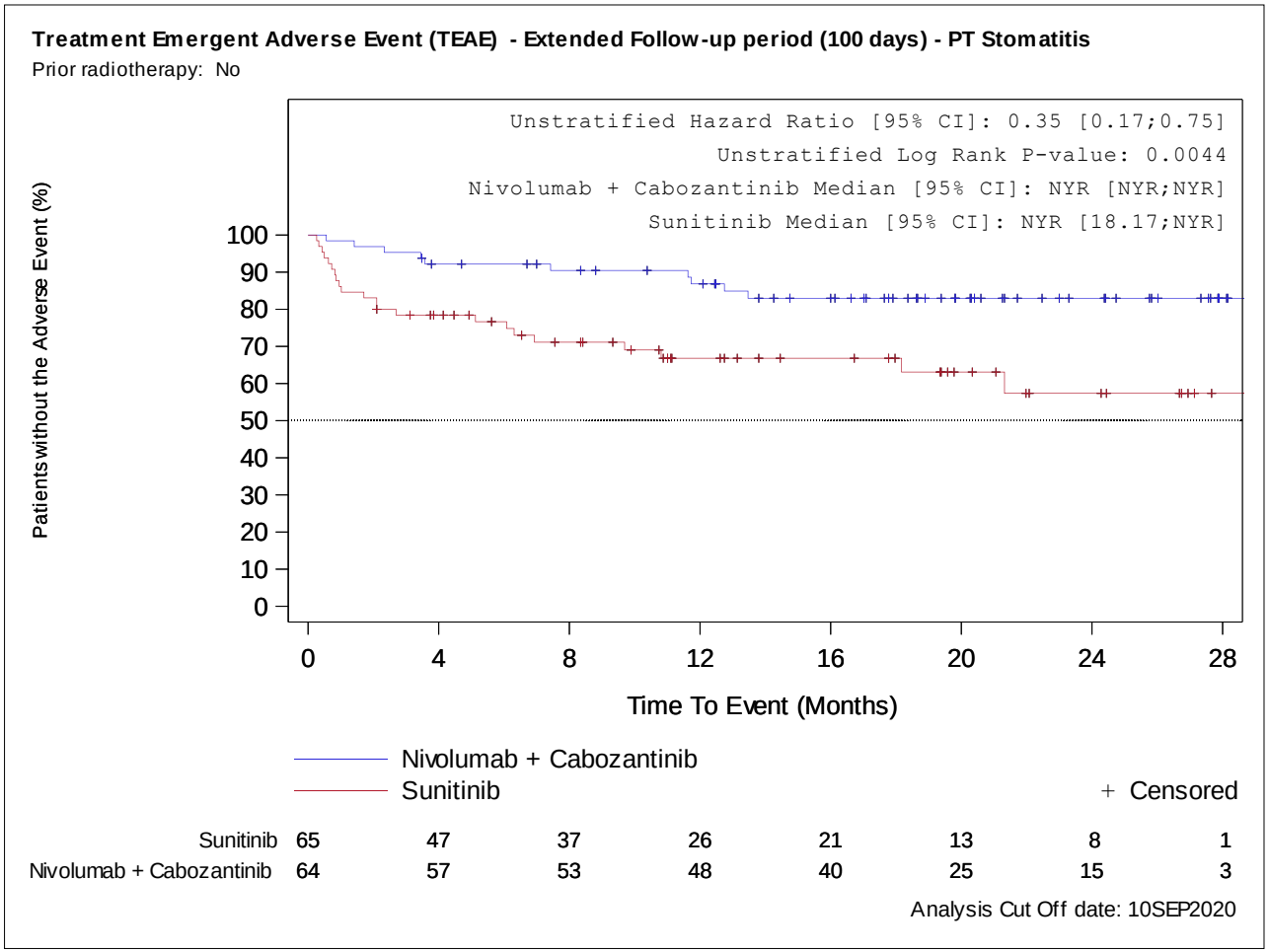
FIGURE 5.26.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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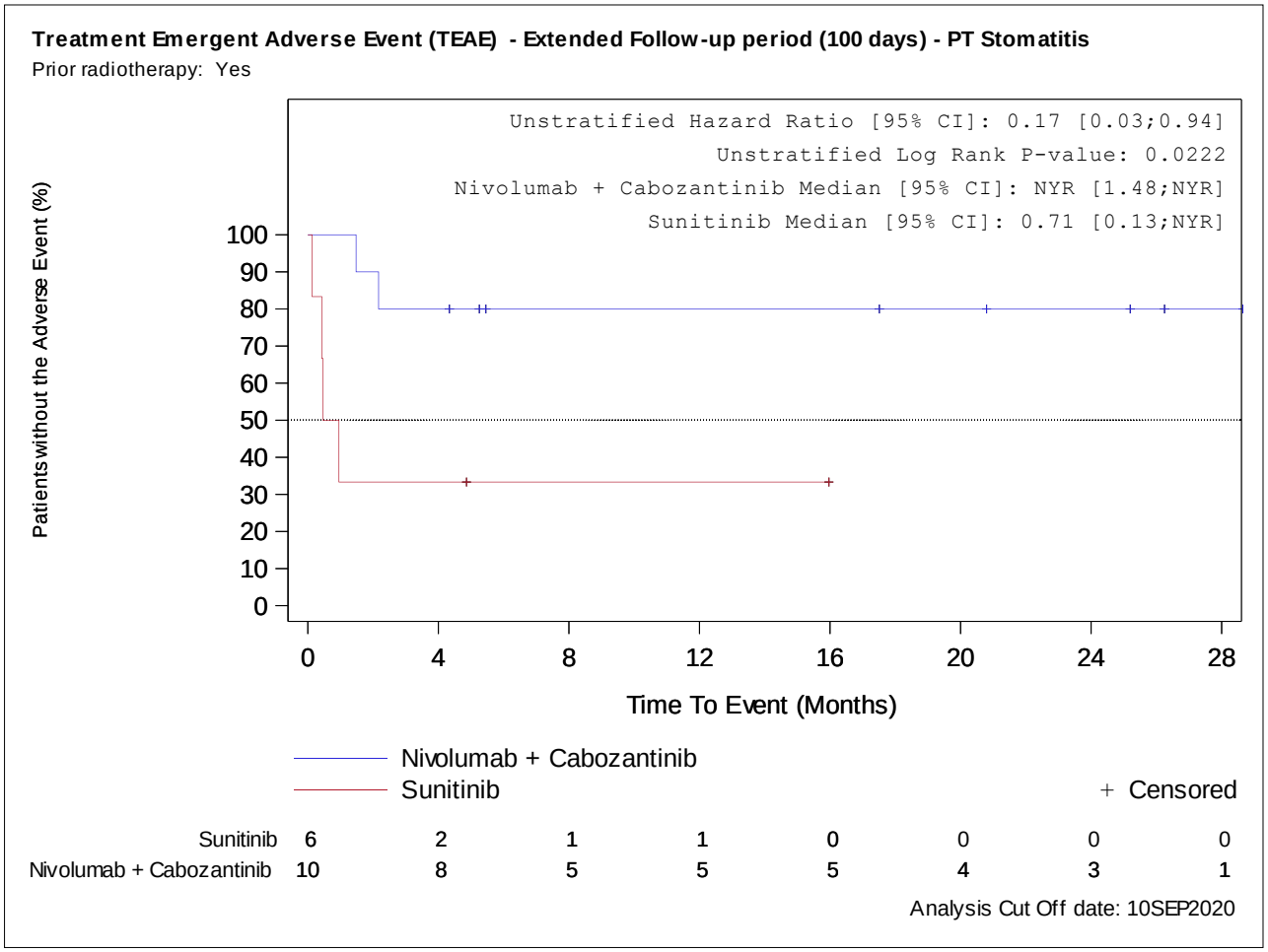
FIGURE 5.26.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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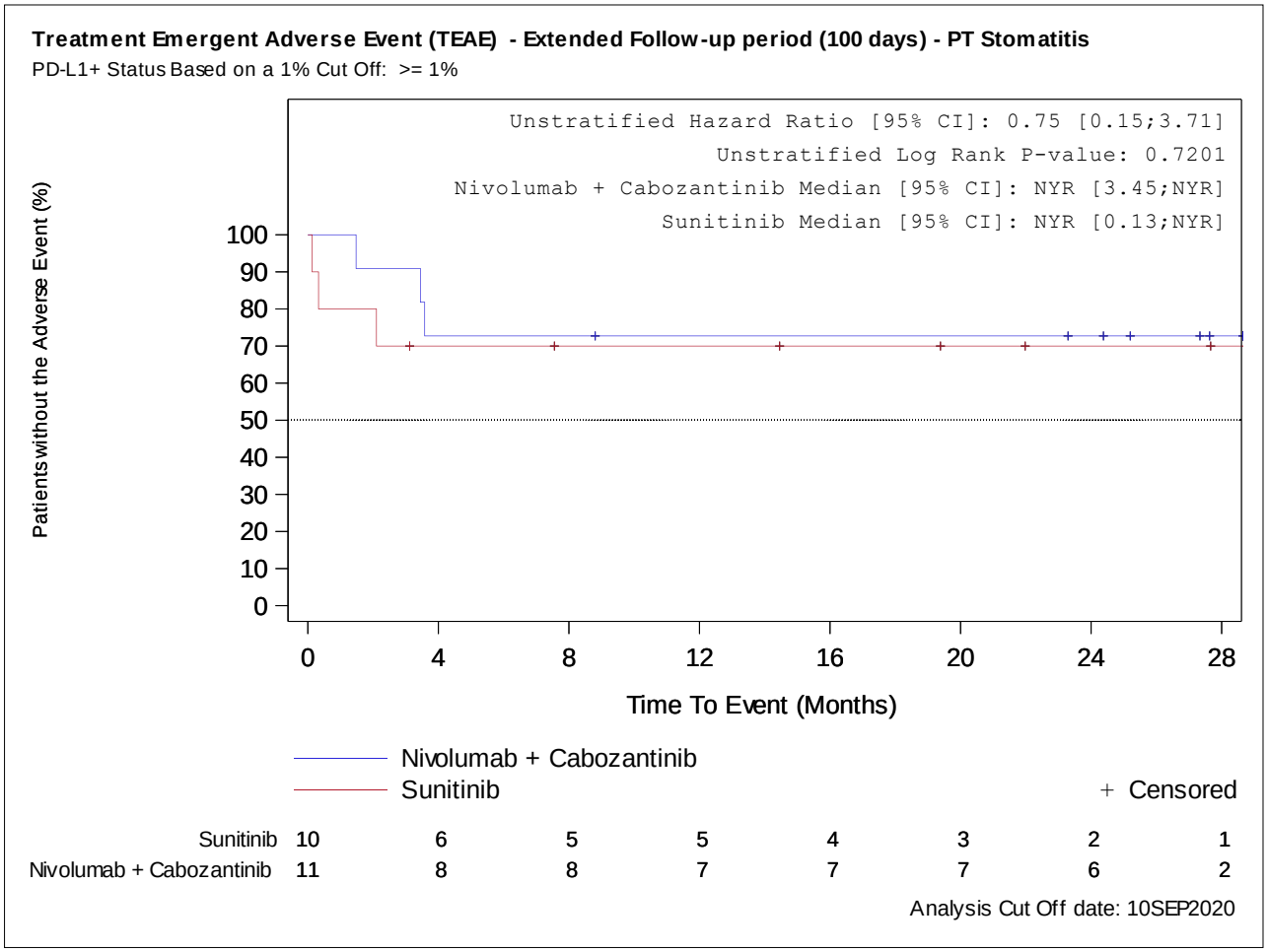
FIGURE 5.26.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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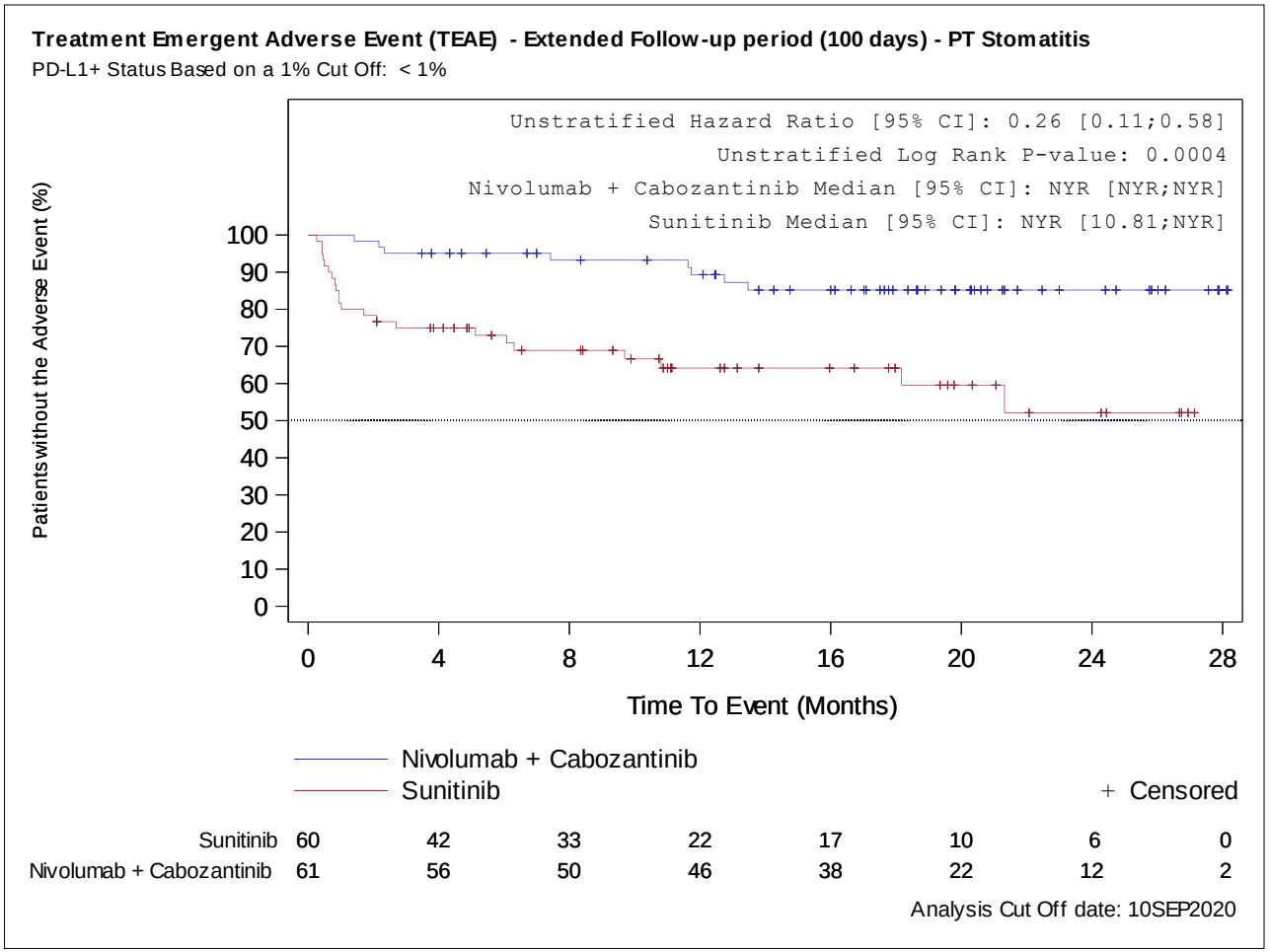
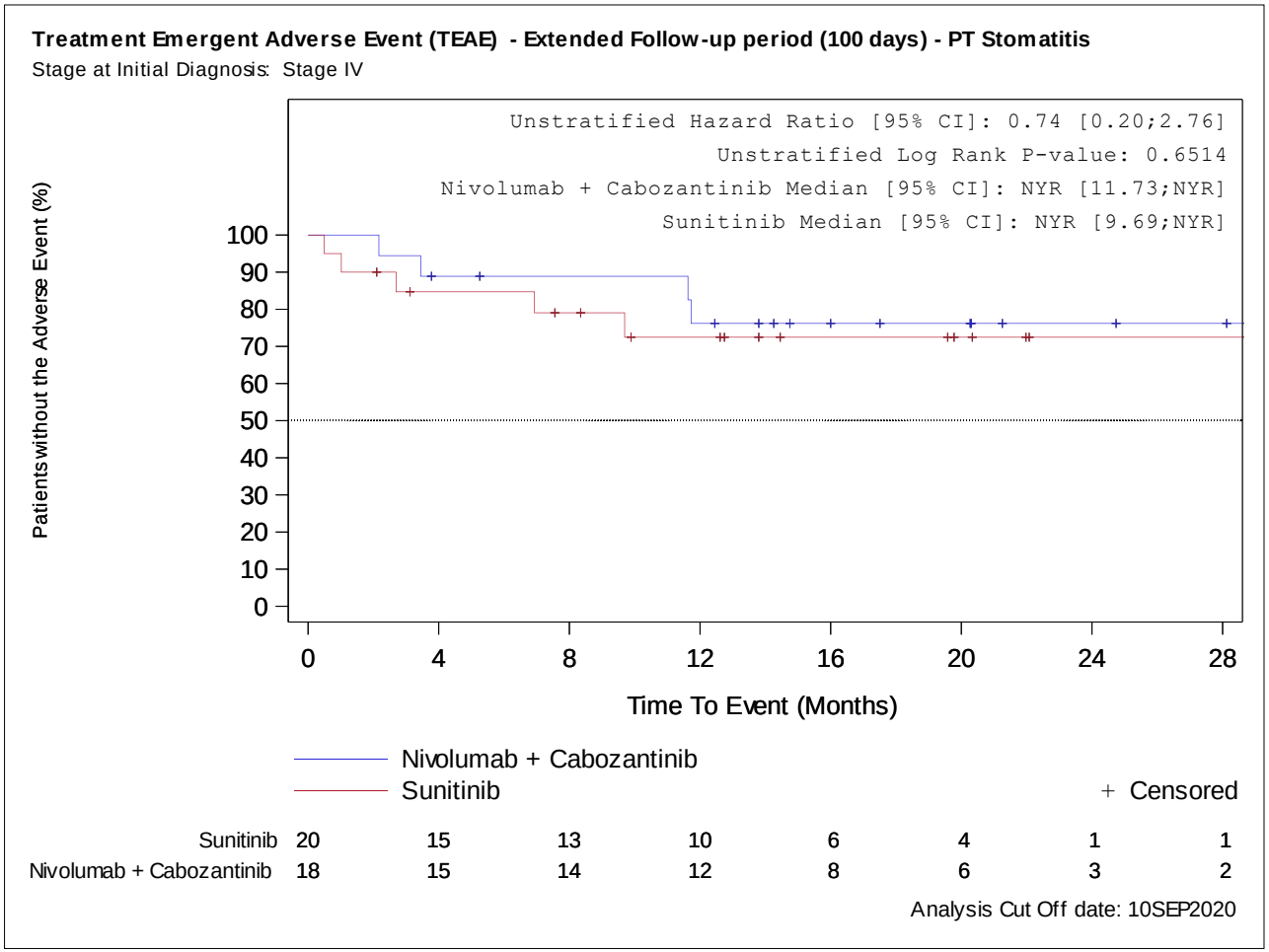
FIGURE 5.26.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:45:01

FIGURE 5.26.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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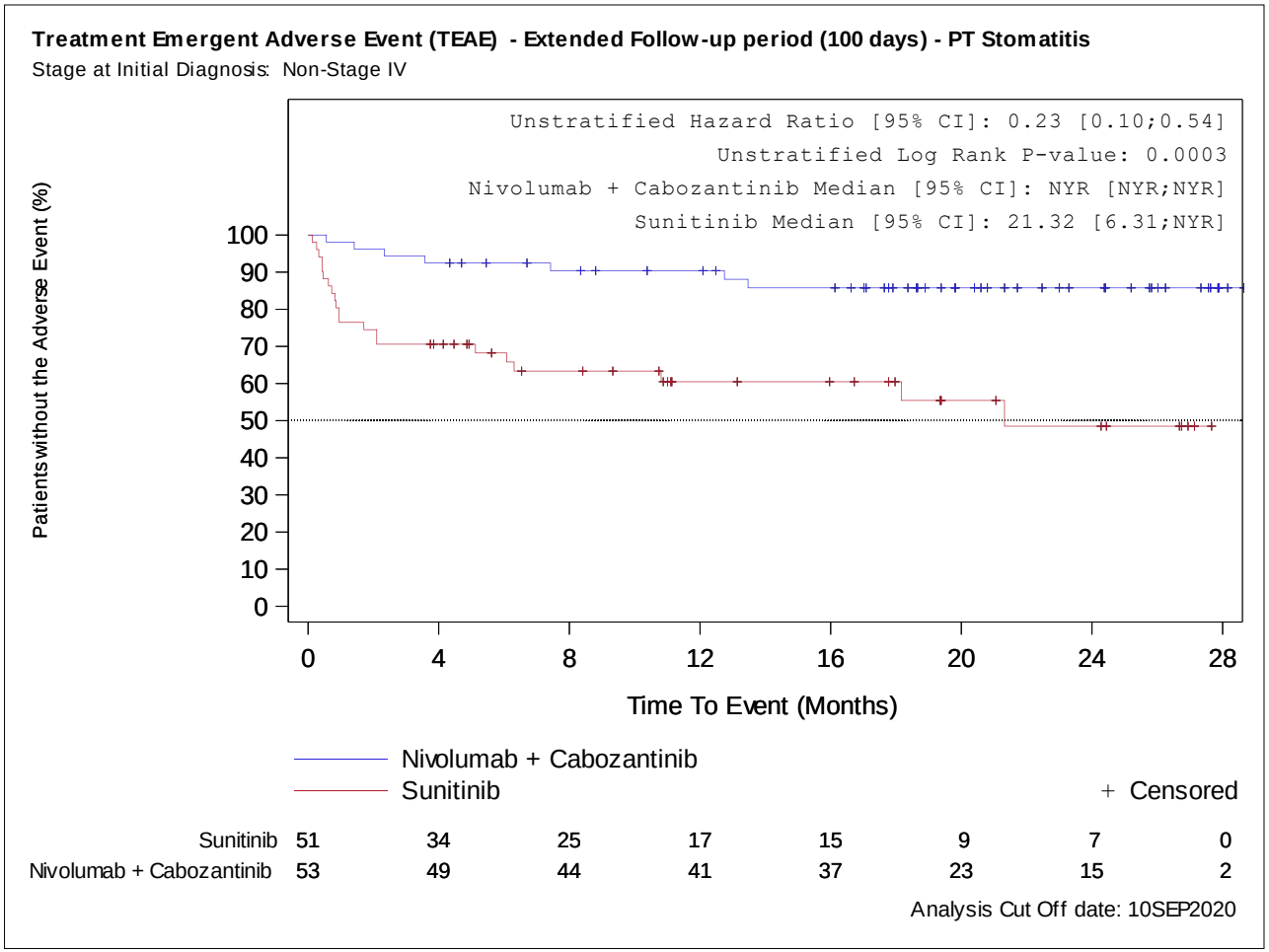
FIGURE 5.26.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Stomatitis - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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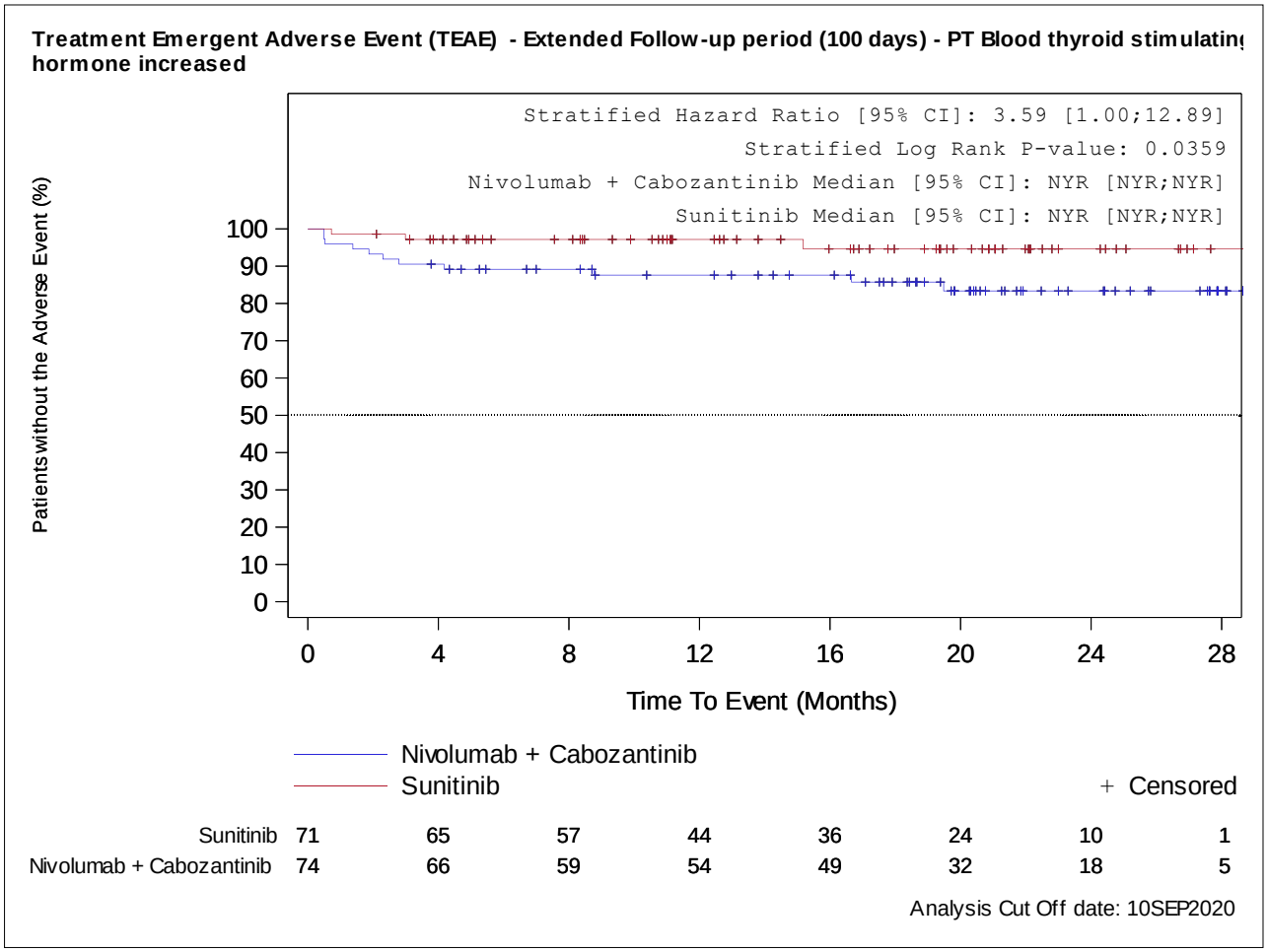
FIGURE 5.27.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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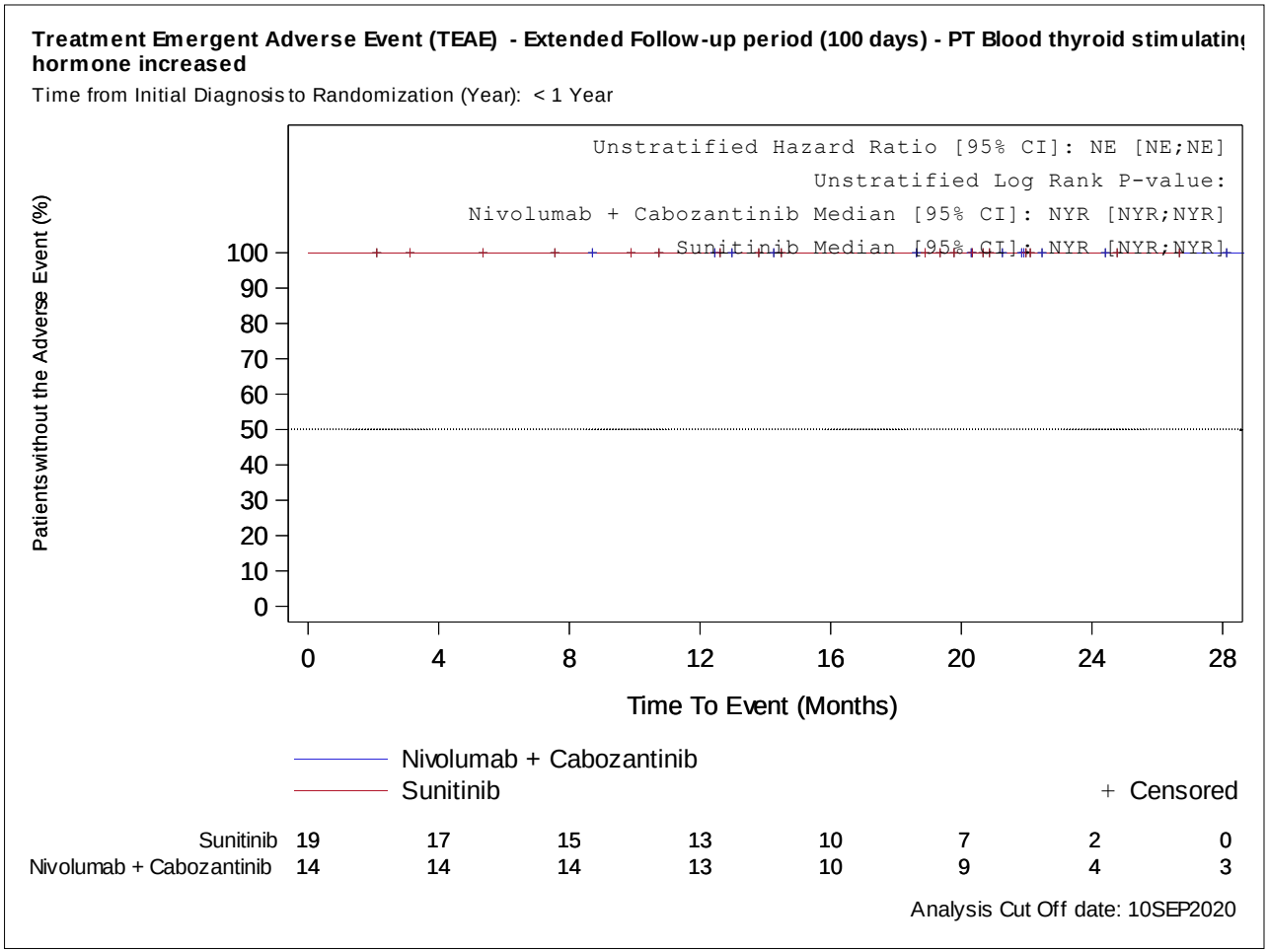
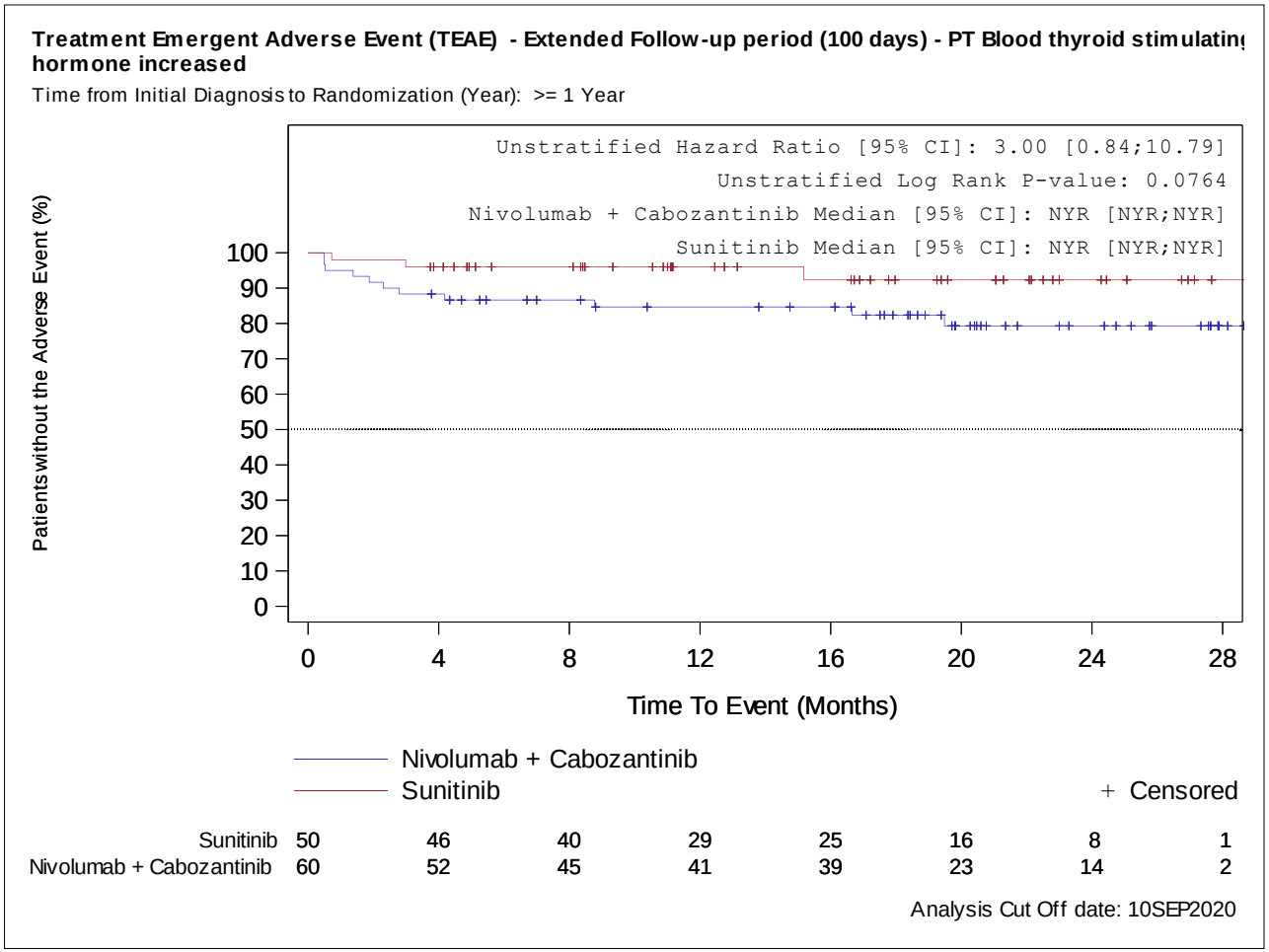
FIGURE 5.27.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:48:11

FIGURE 5.27.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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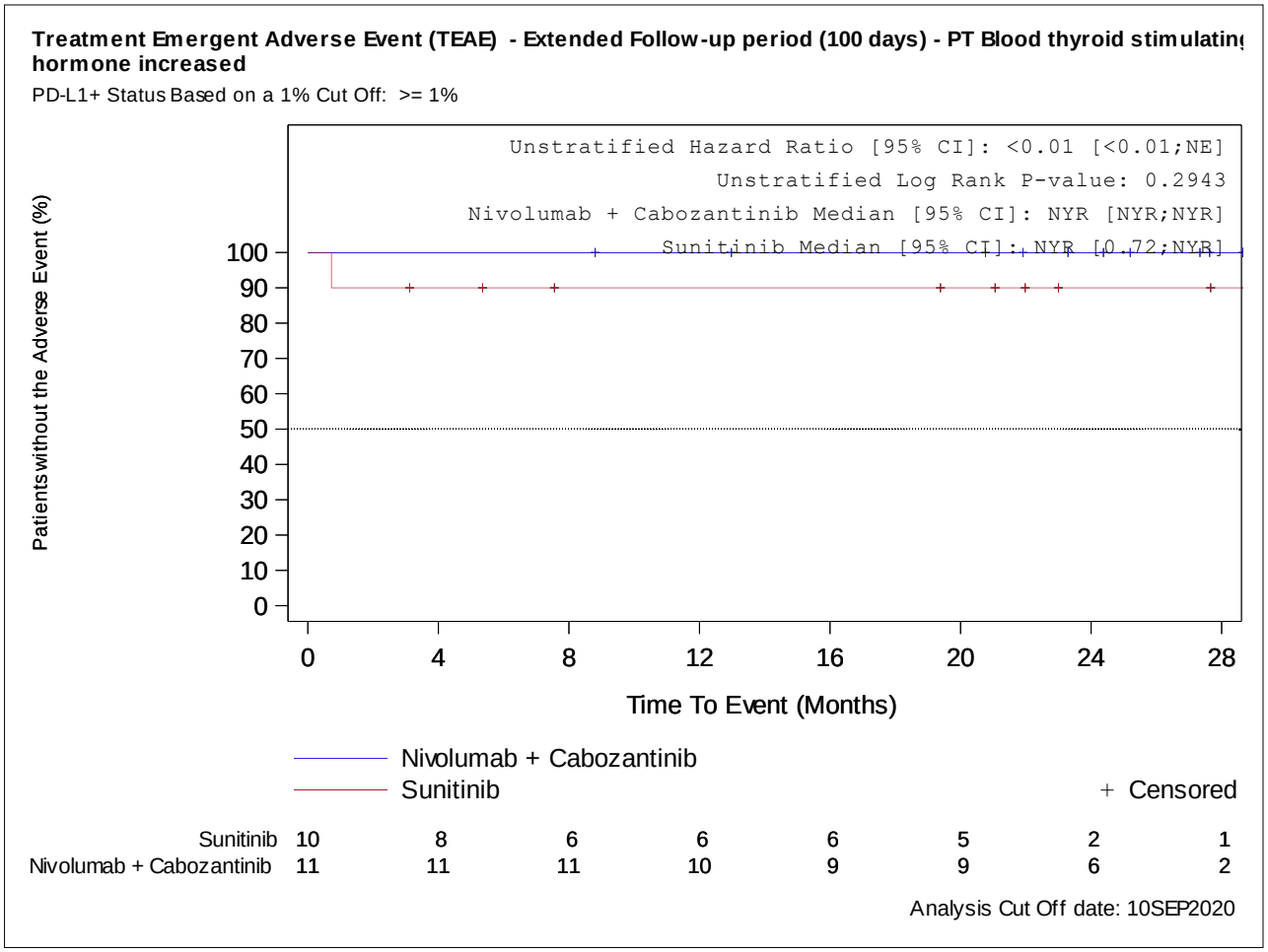
FIGURE 5.27.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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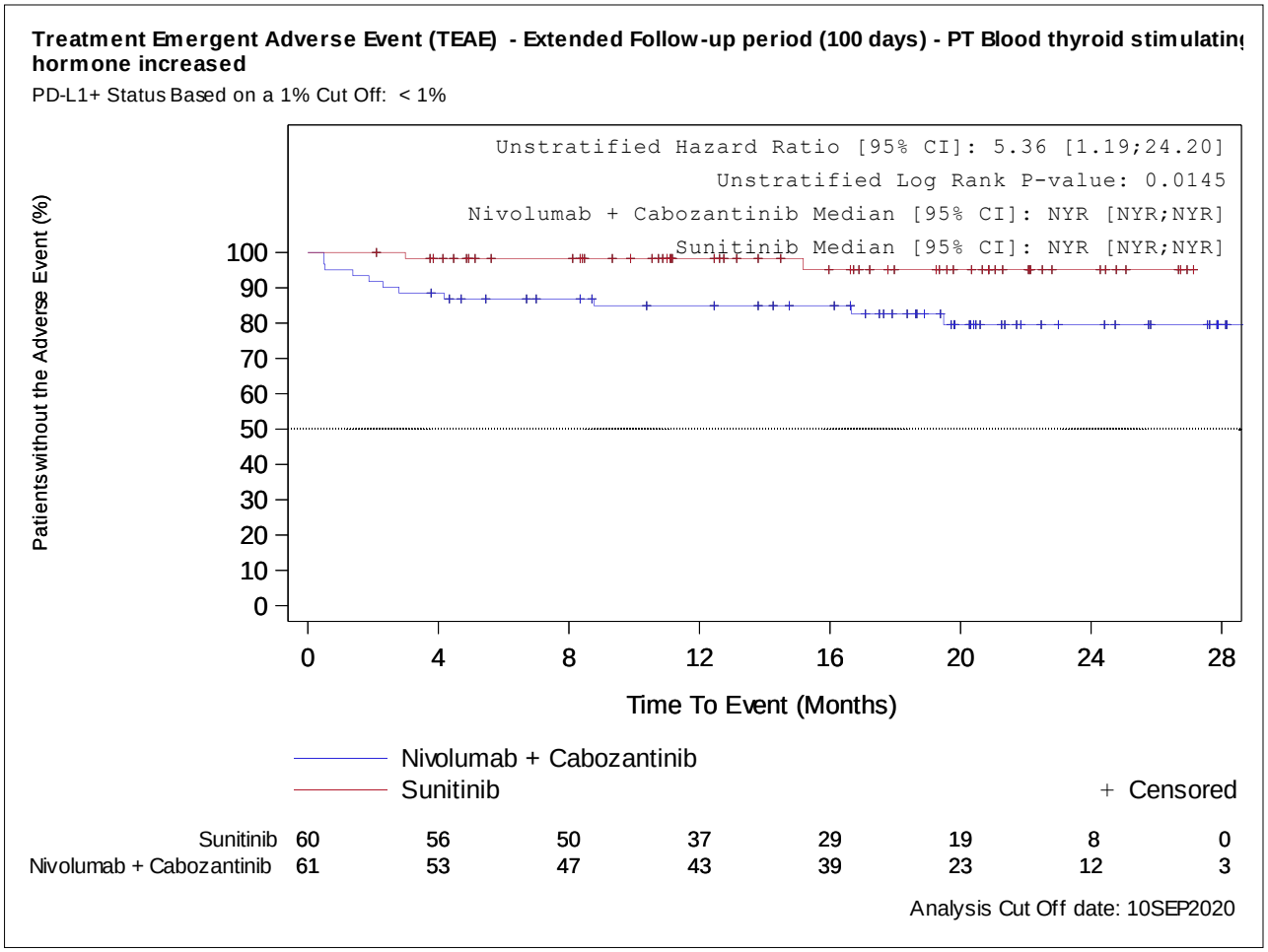
FIGURE 5.27.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Blood thyroid stimulating hormone increased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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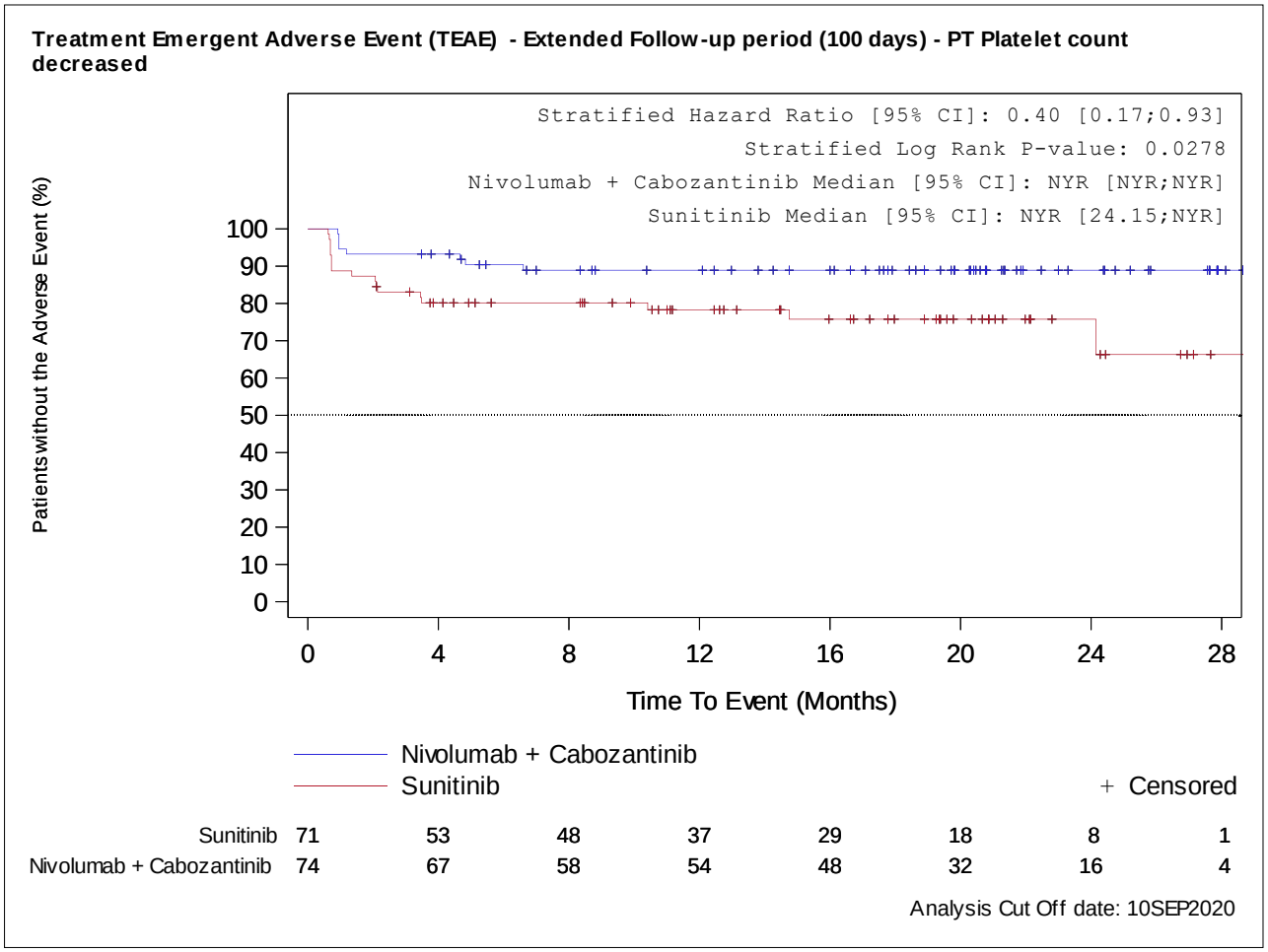
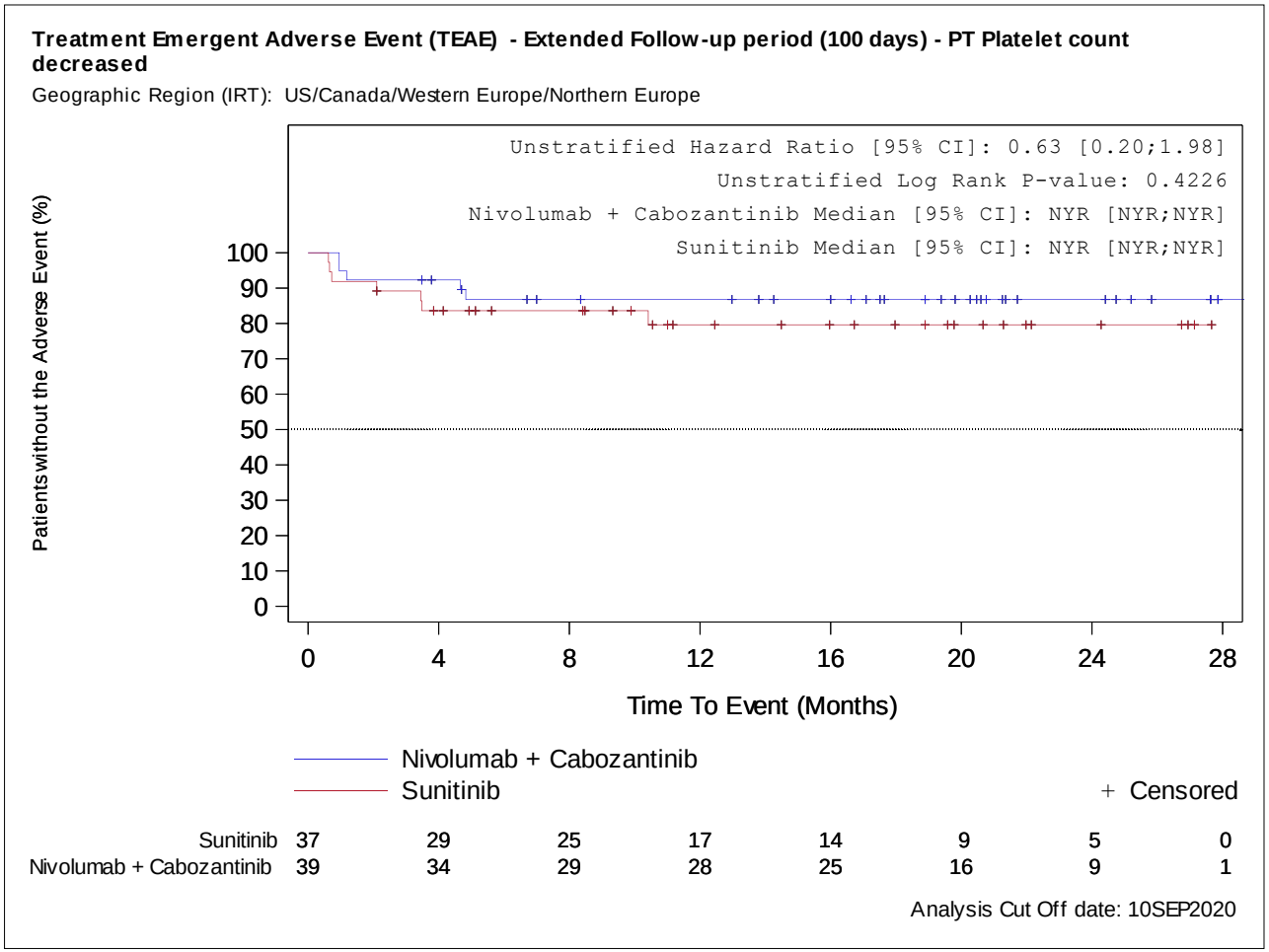
FIGURE 5.28.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:52:16

FIGURE 5.28.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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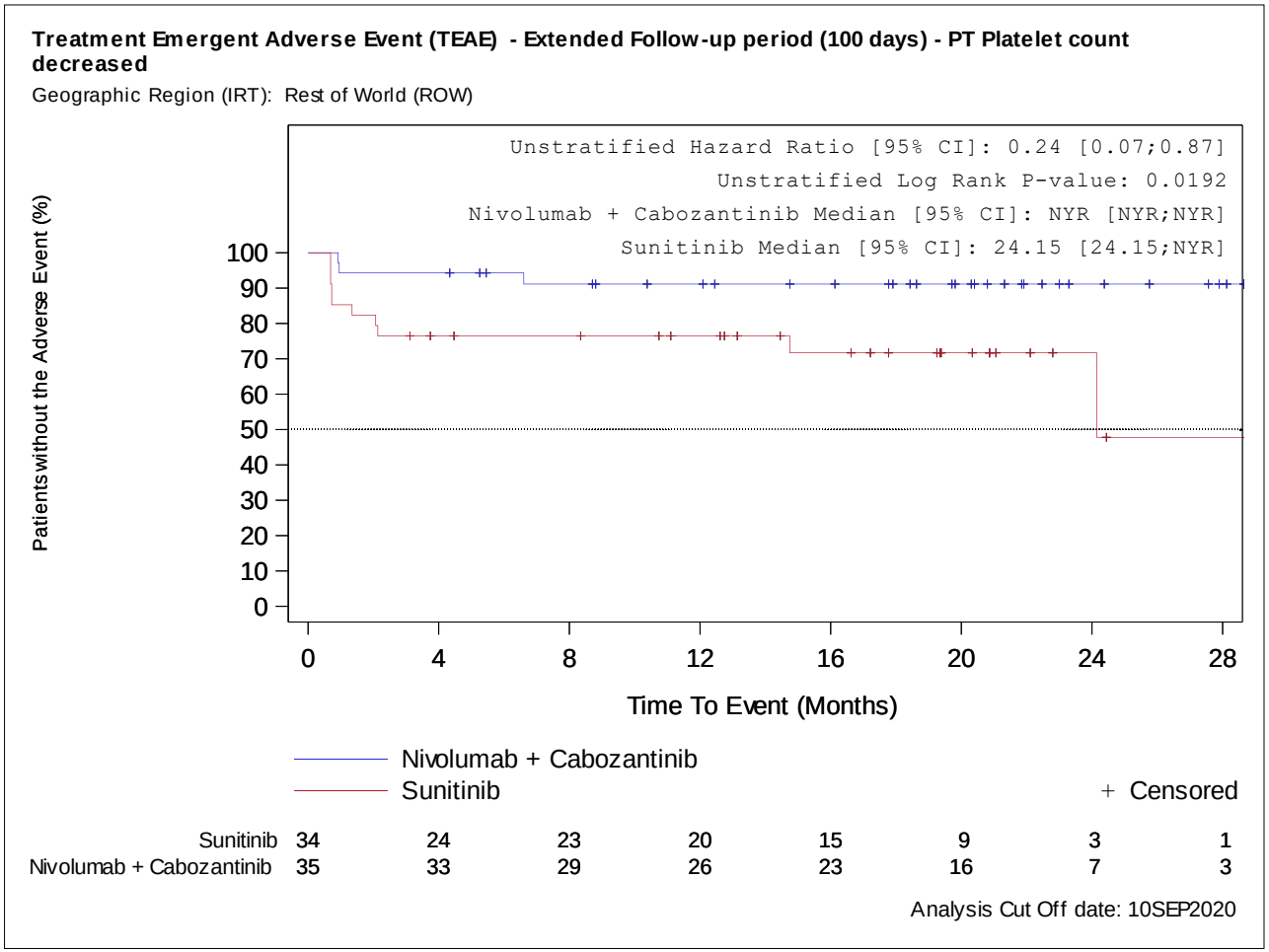
FIGURE 5.28.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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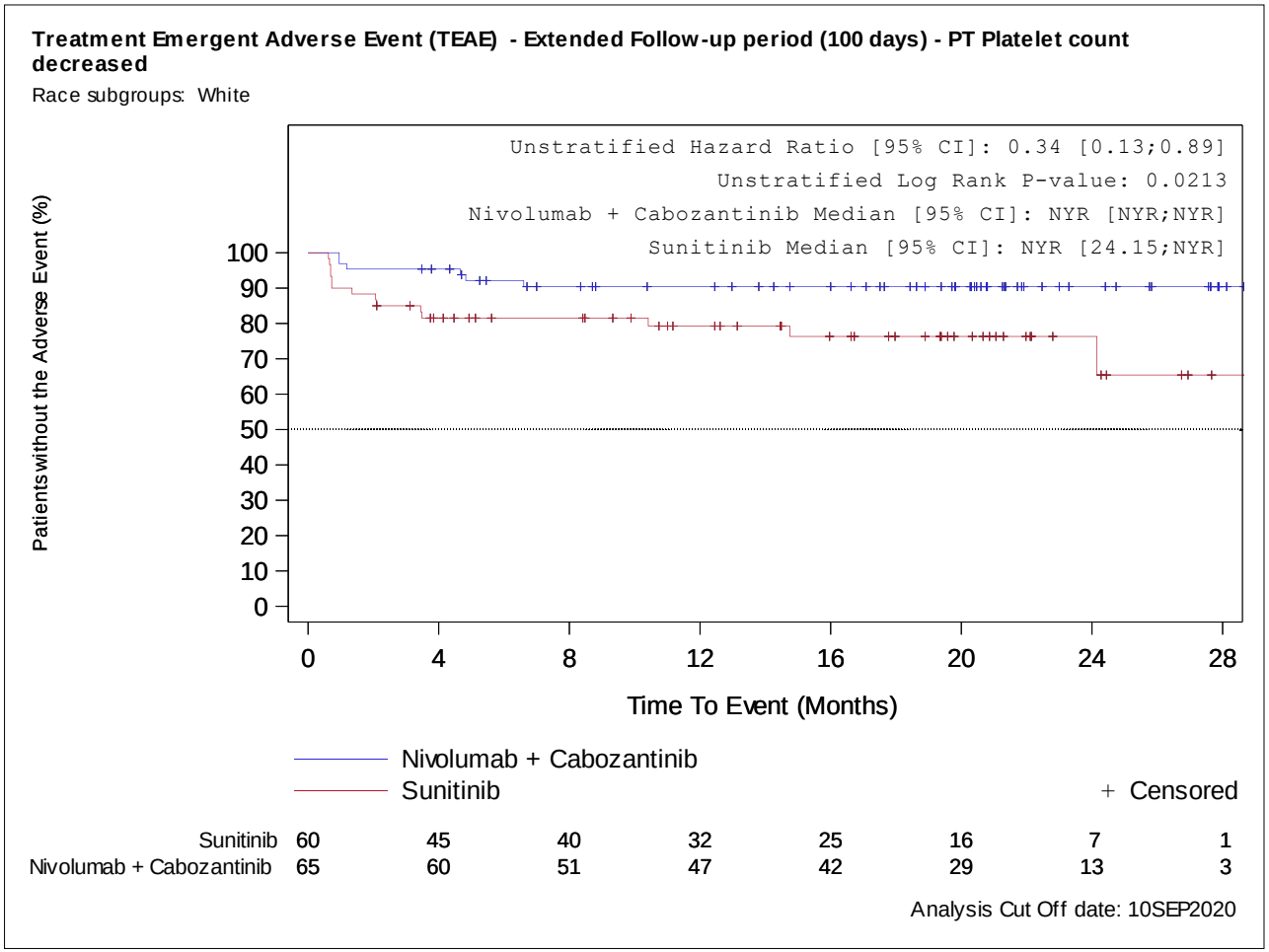
FIGURE 5.28.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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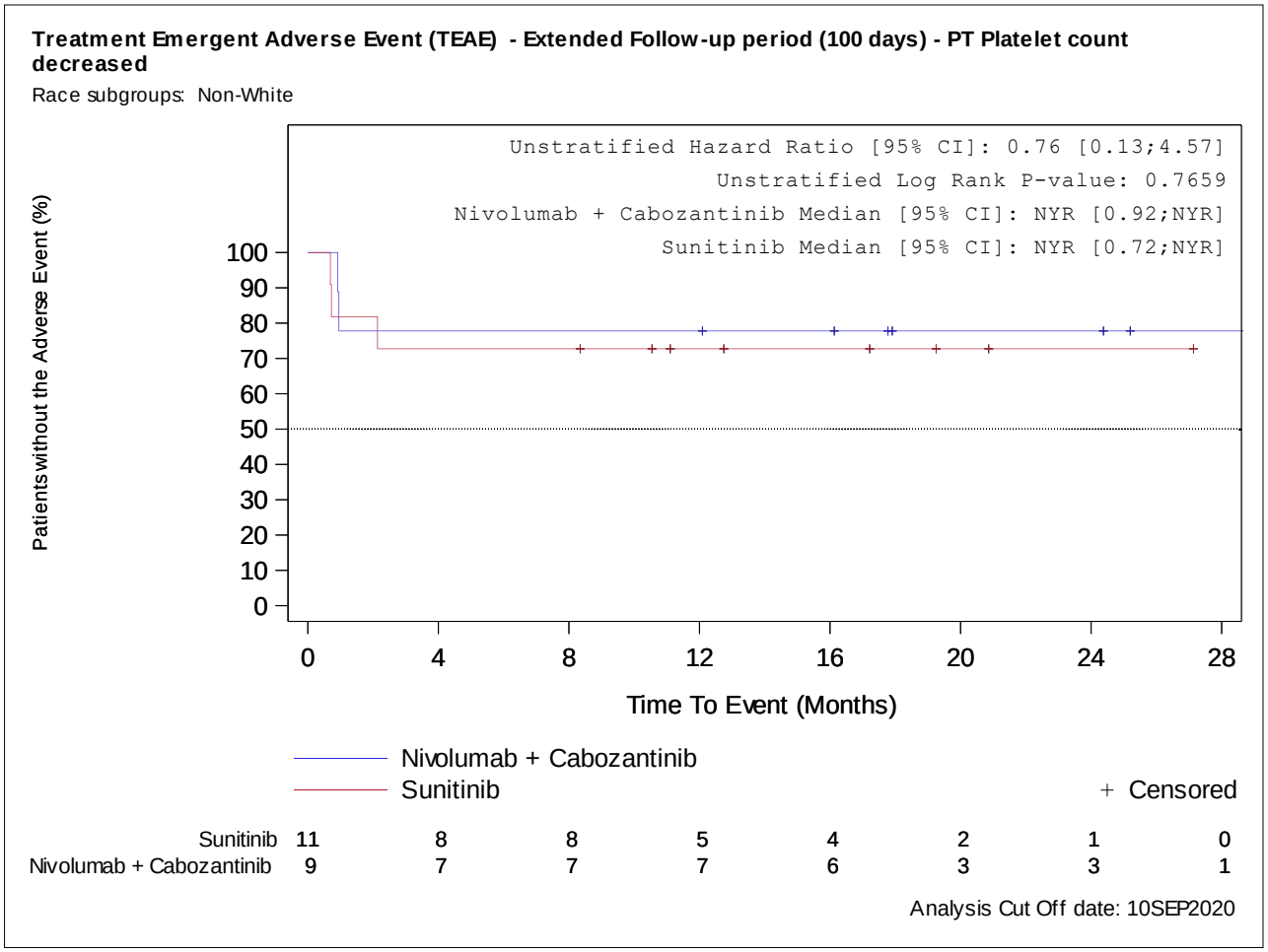
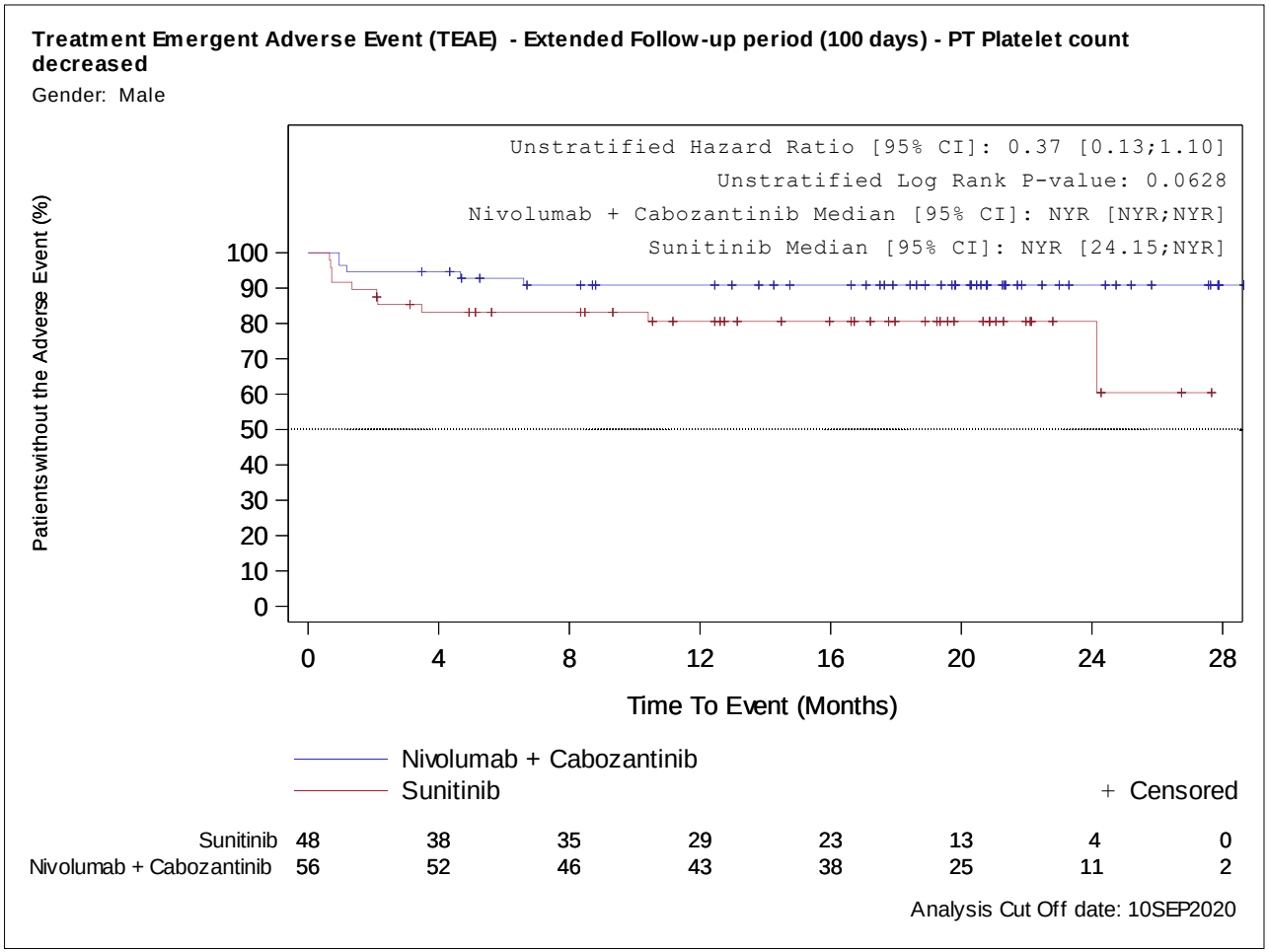
FIGURE 5.28.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



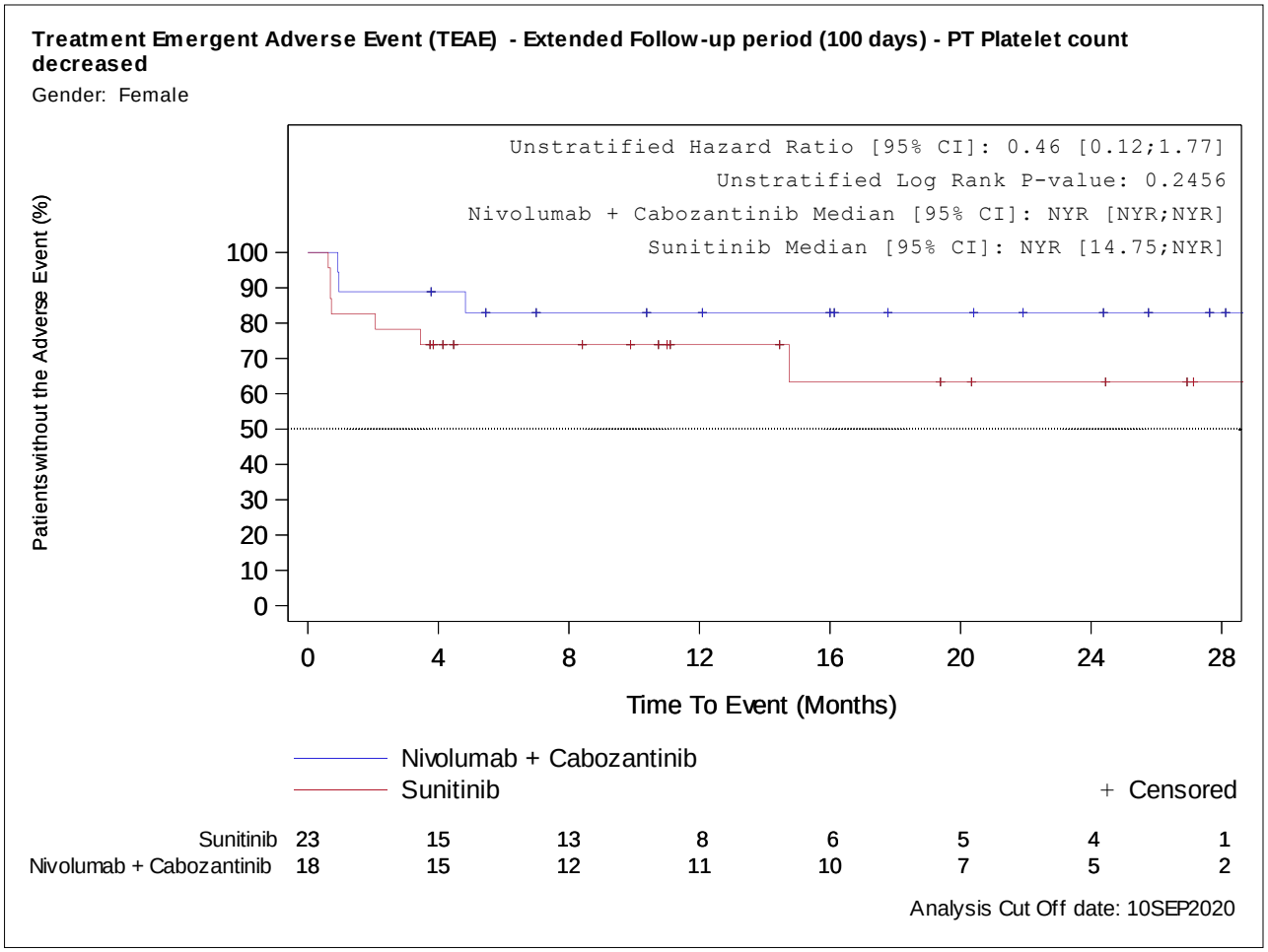

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:52:37

FIGURE 5.28.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:52:43

FIGURE 5.28.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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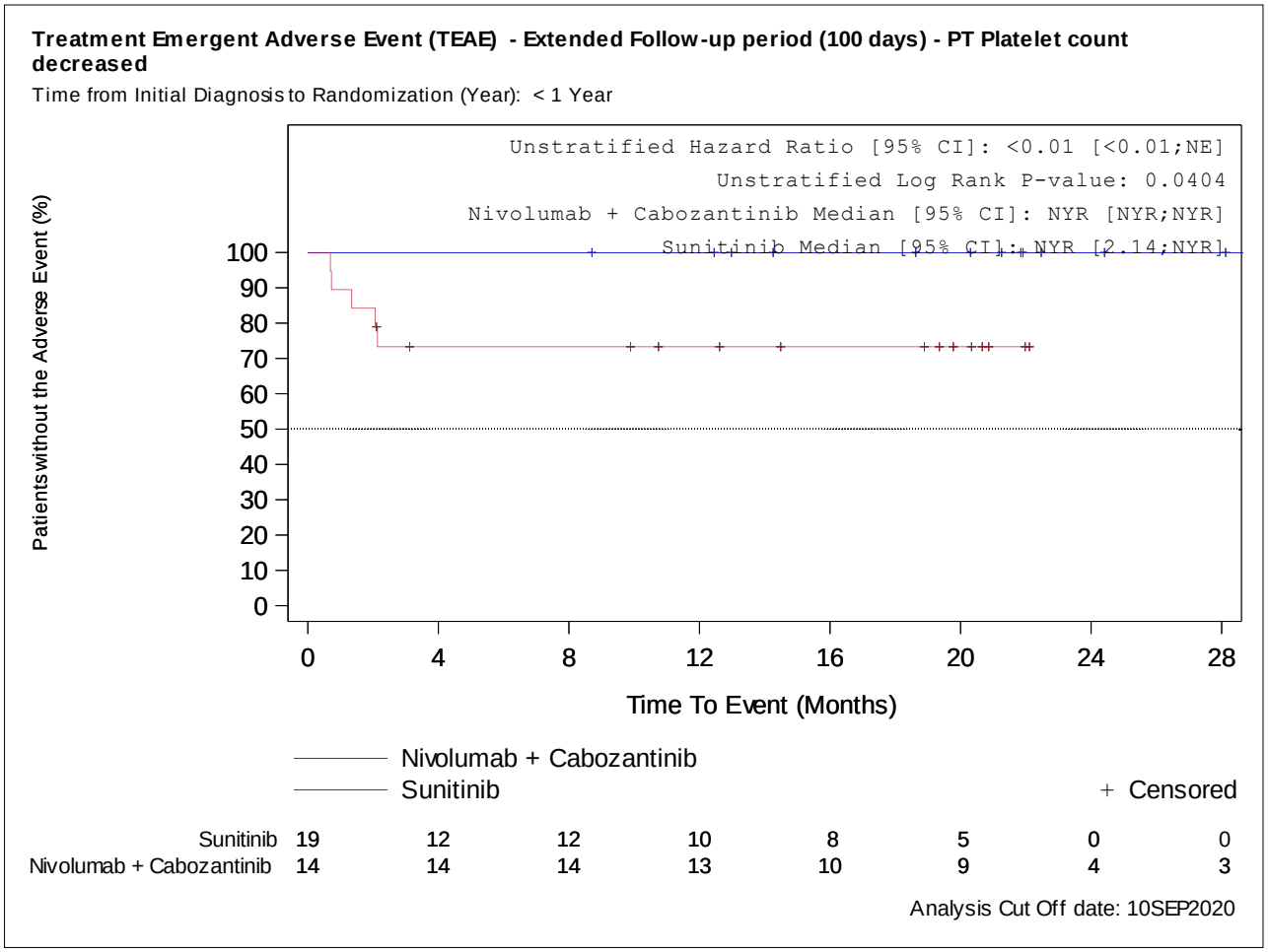
FIGURE 5.28.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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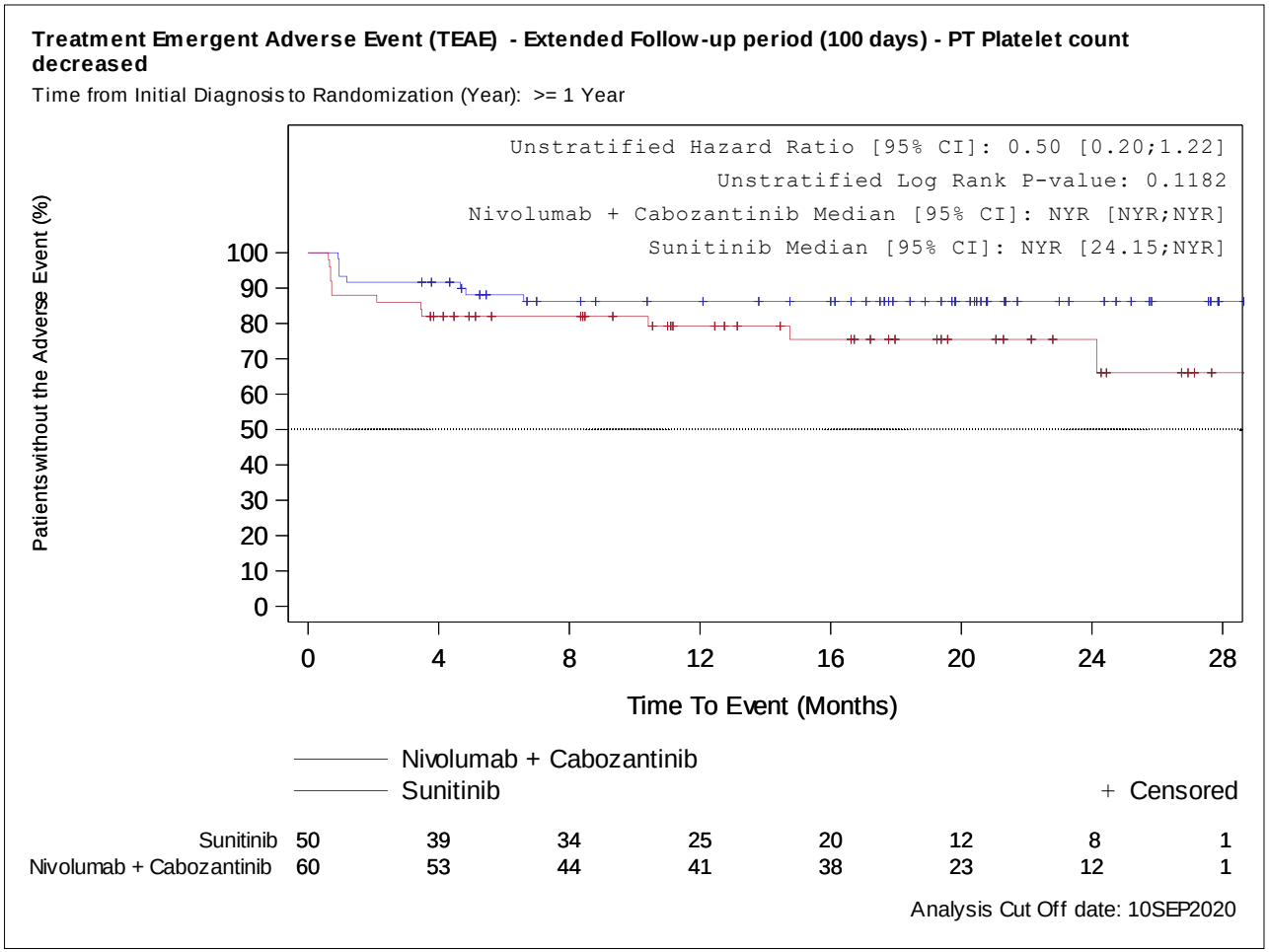
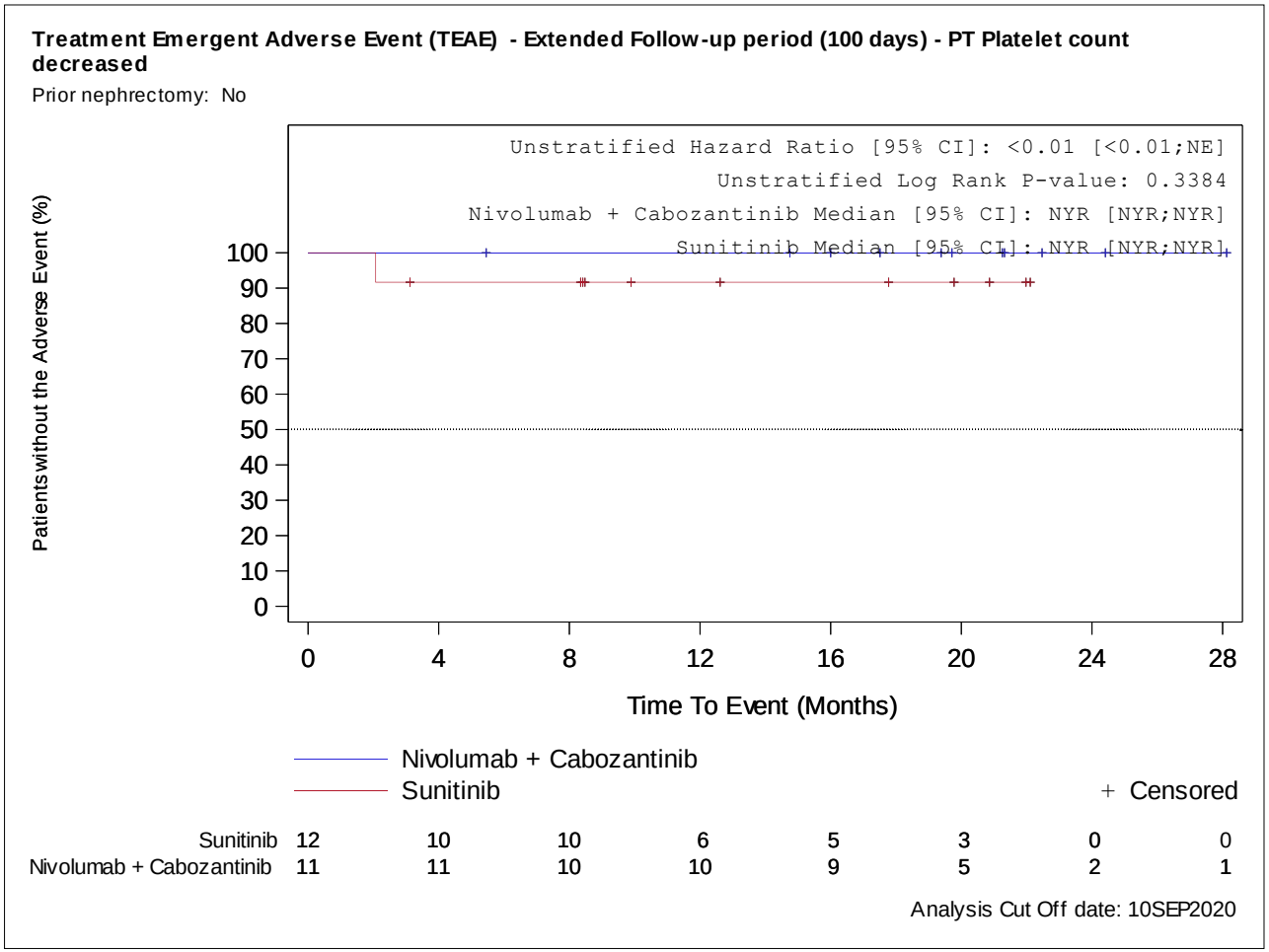
FIGURE 5.28.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



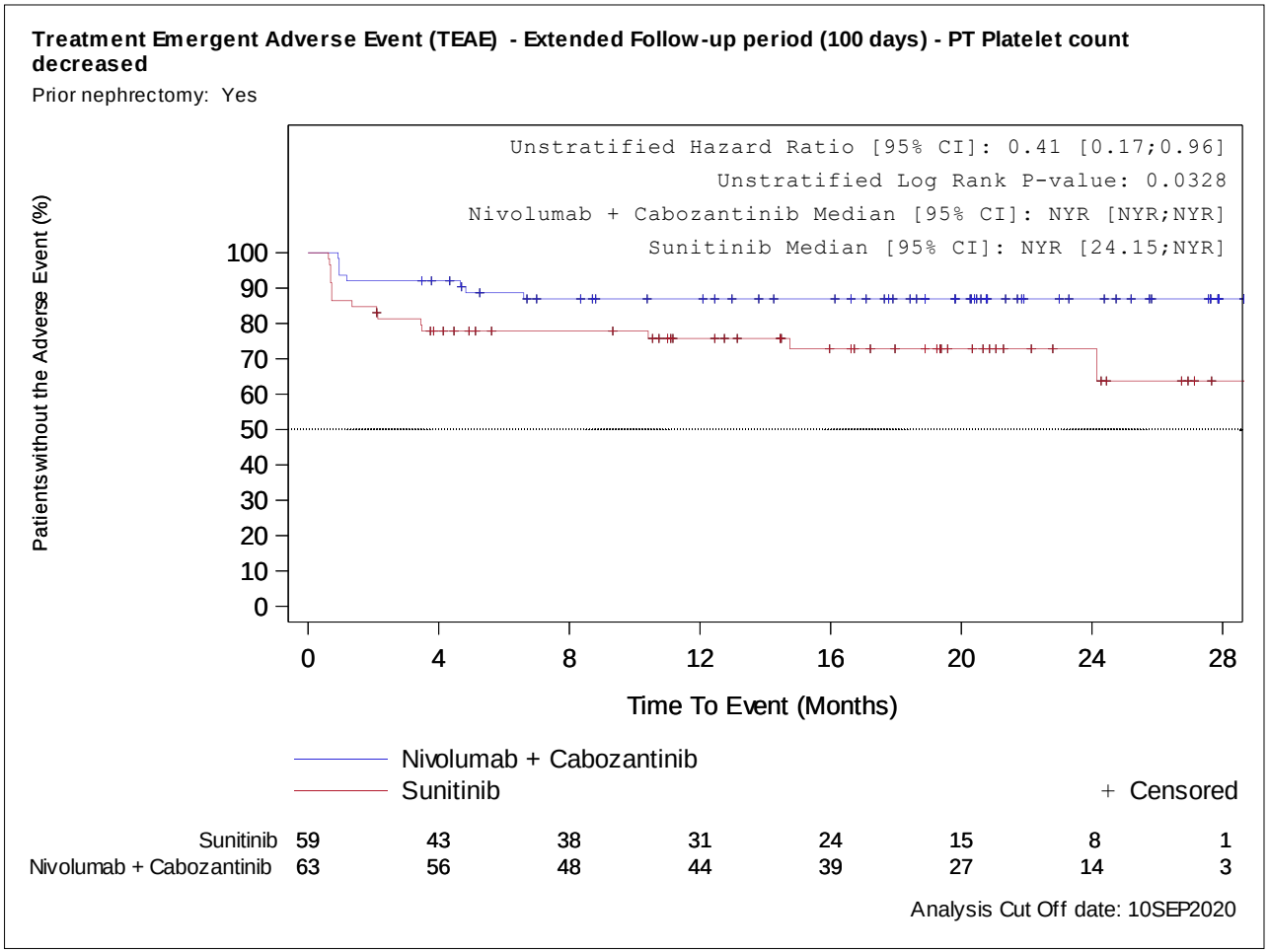

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:53:12

FIGURE 5.28.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



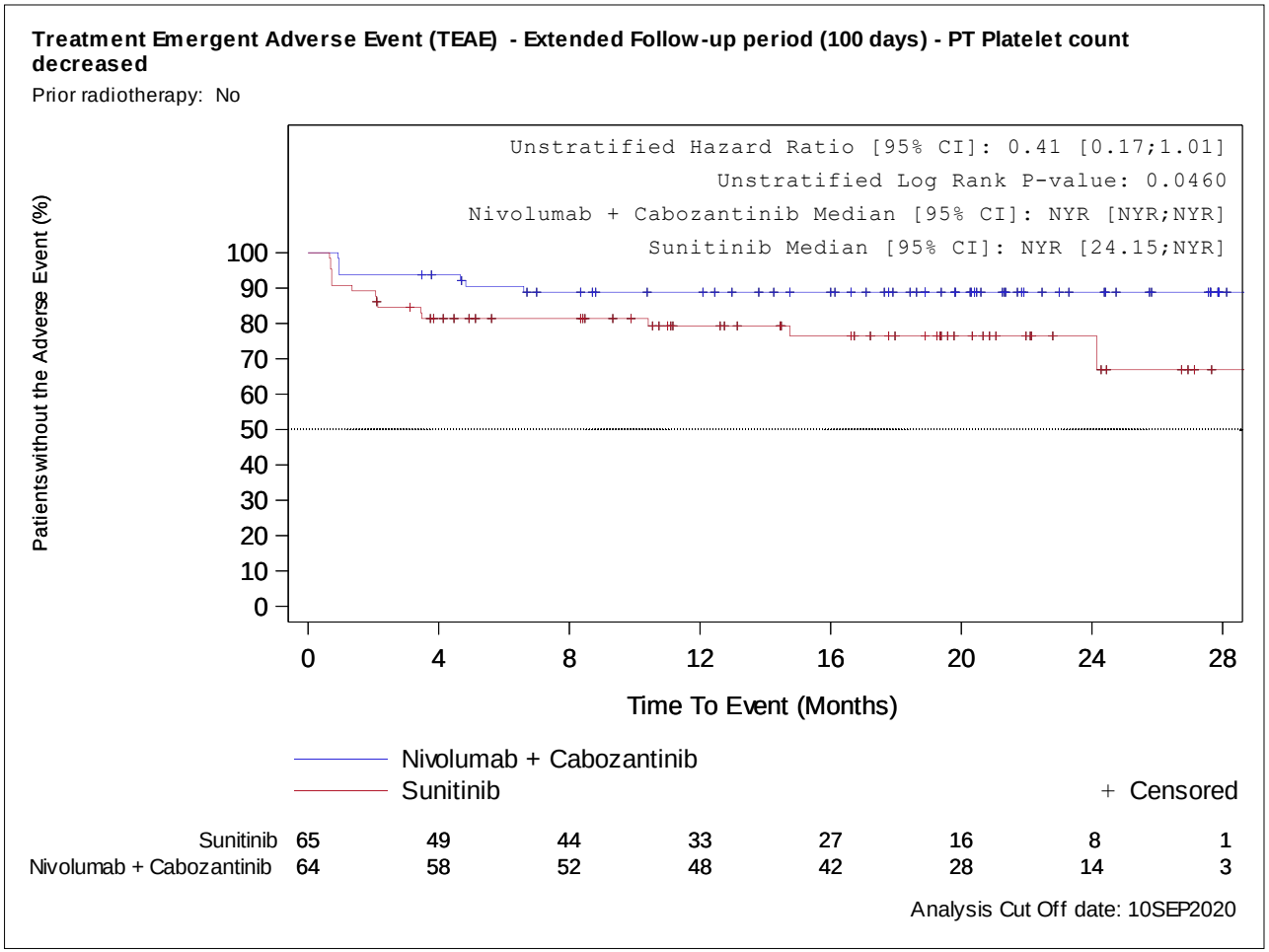

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:54:05

FIGURE 5.28.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:54:11

FIGURE 5.28.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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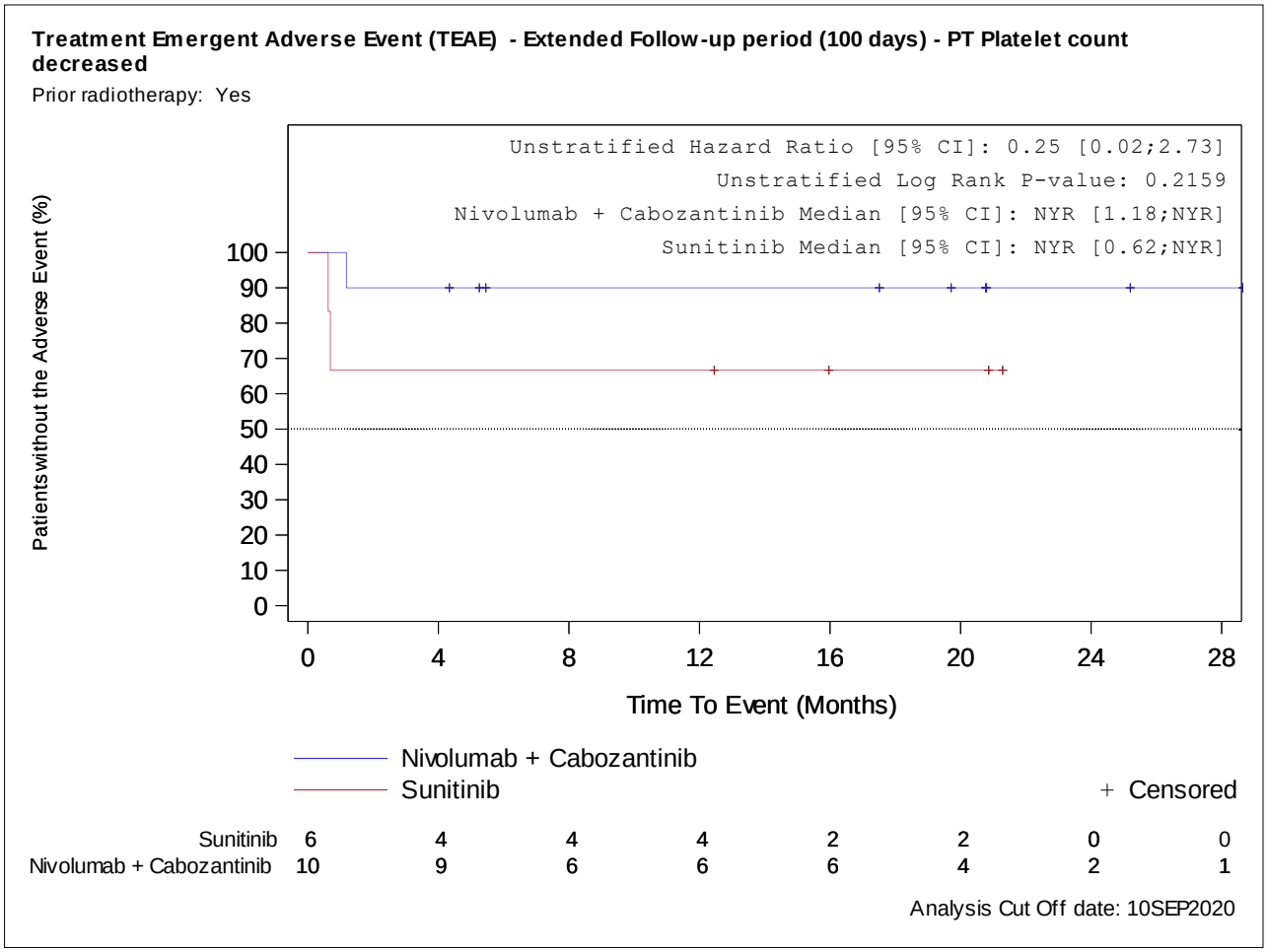
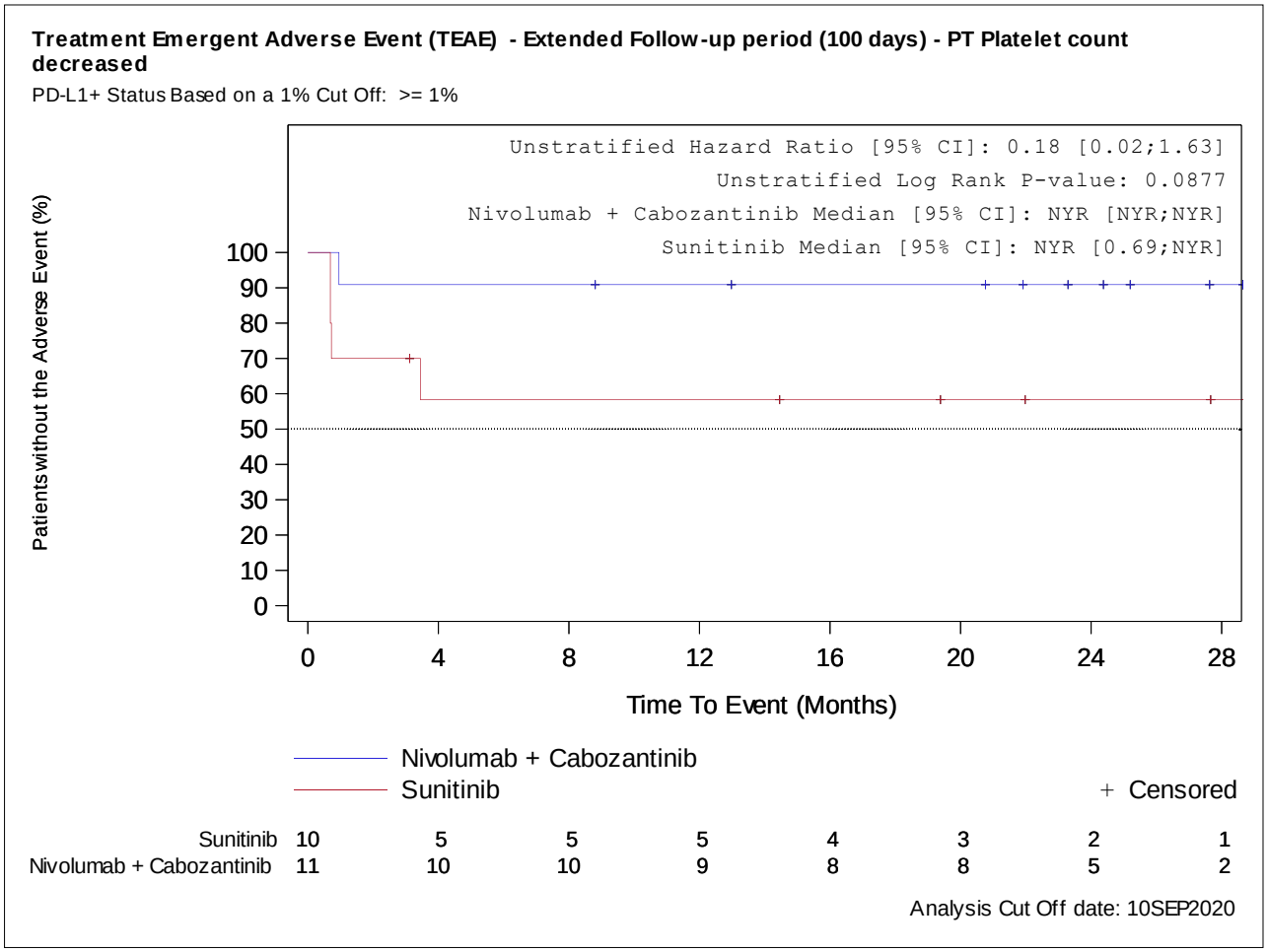
FIGURE 5.28.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



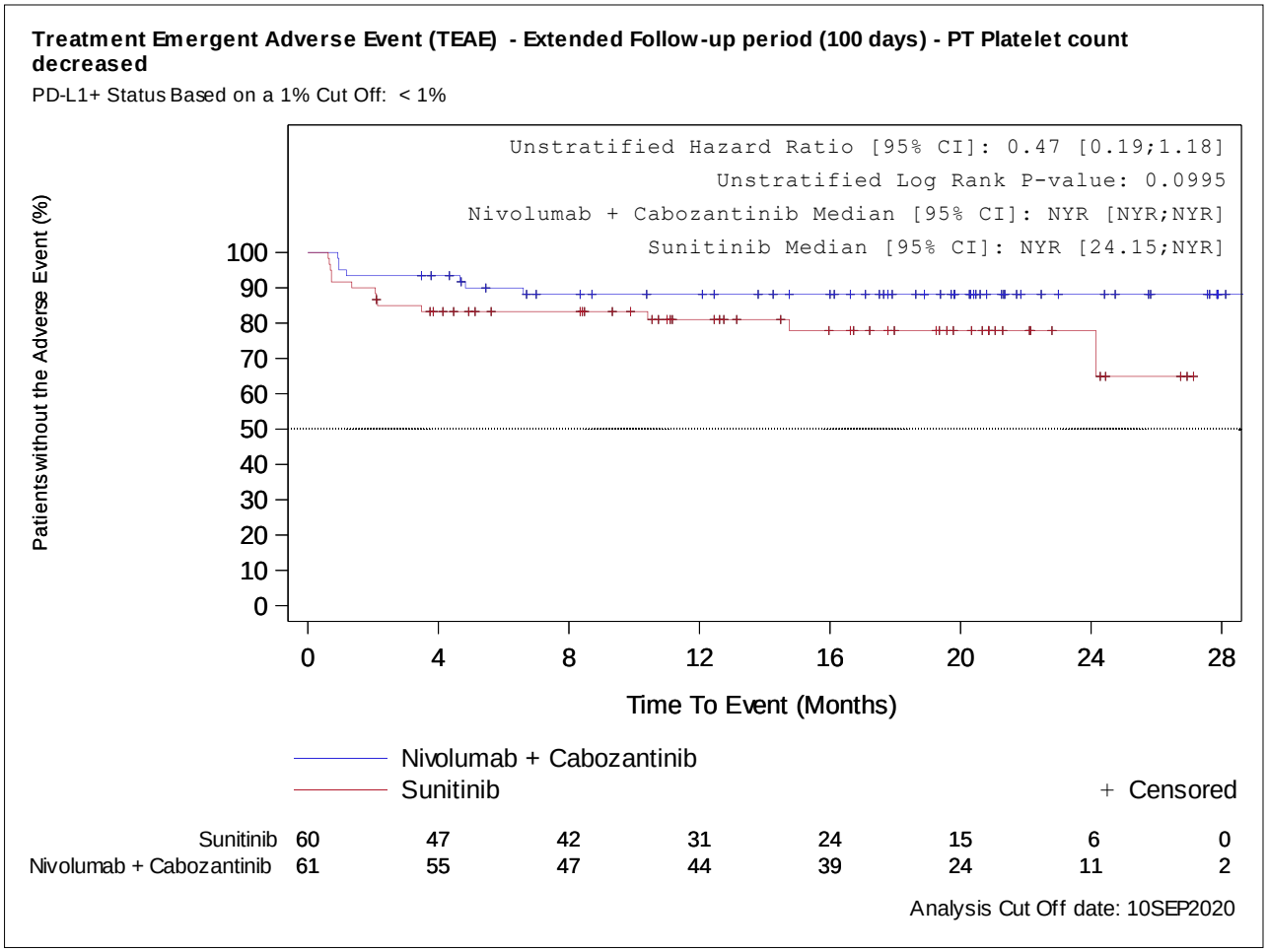

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:54:22

FIGURE 5.28.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



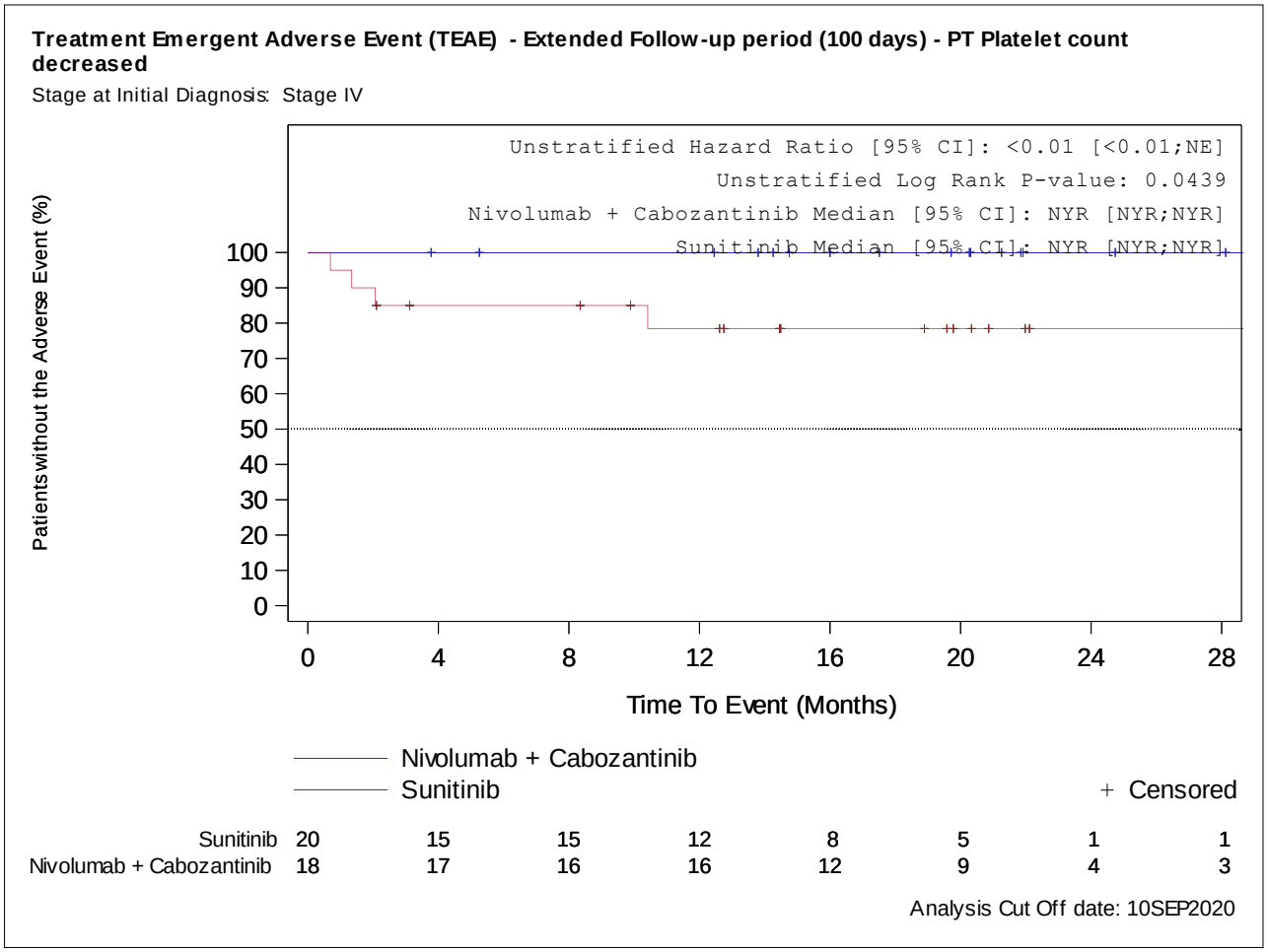

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:54:28

FIGURE 5.28.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



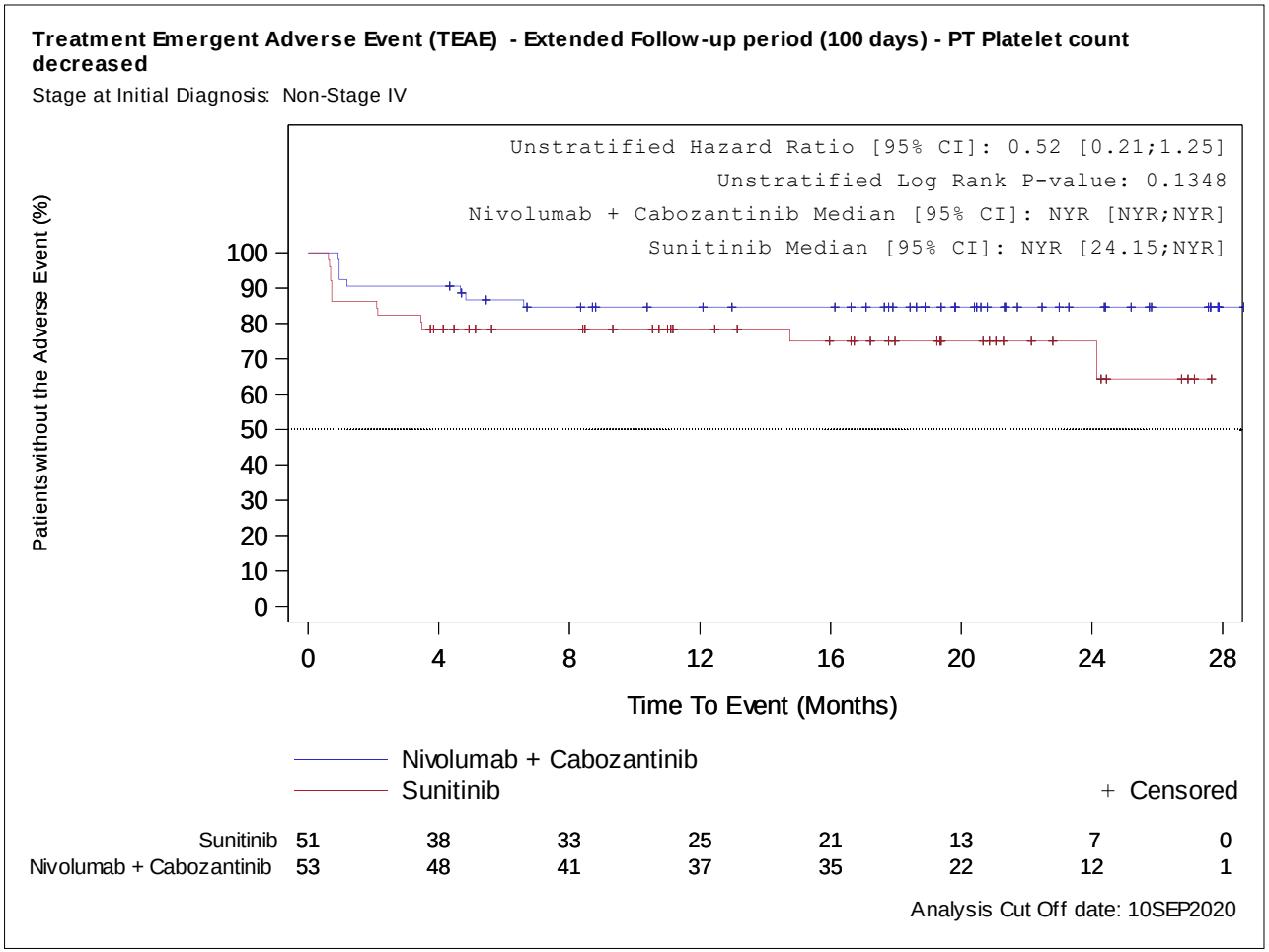

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:54:33

FIGURE 5.28.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:55:02

FIGURE 5.28.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Platelet count decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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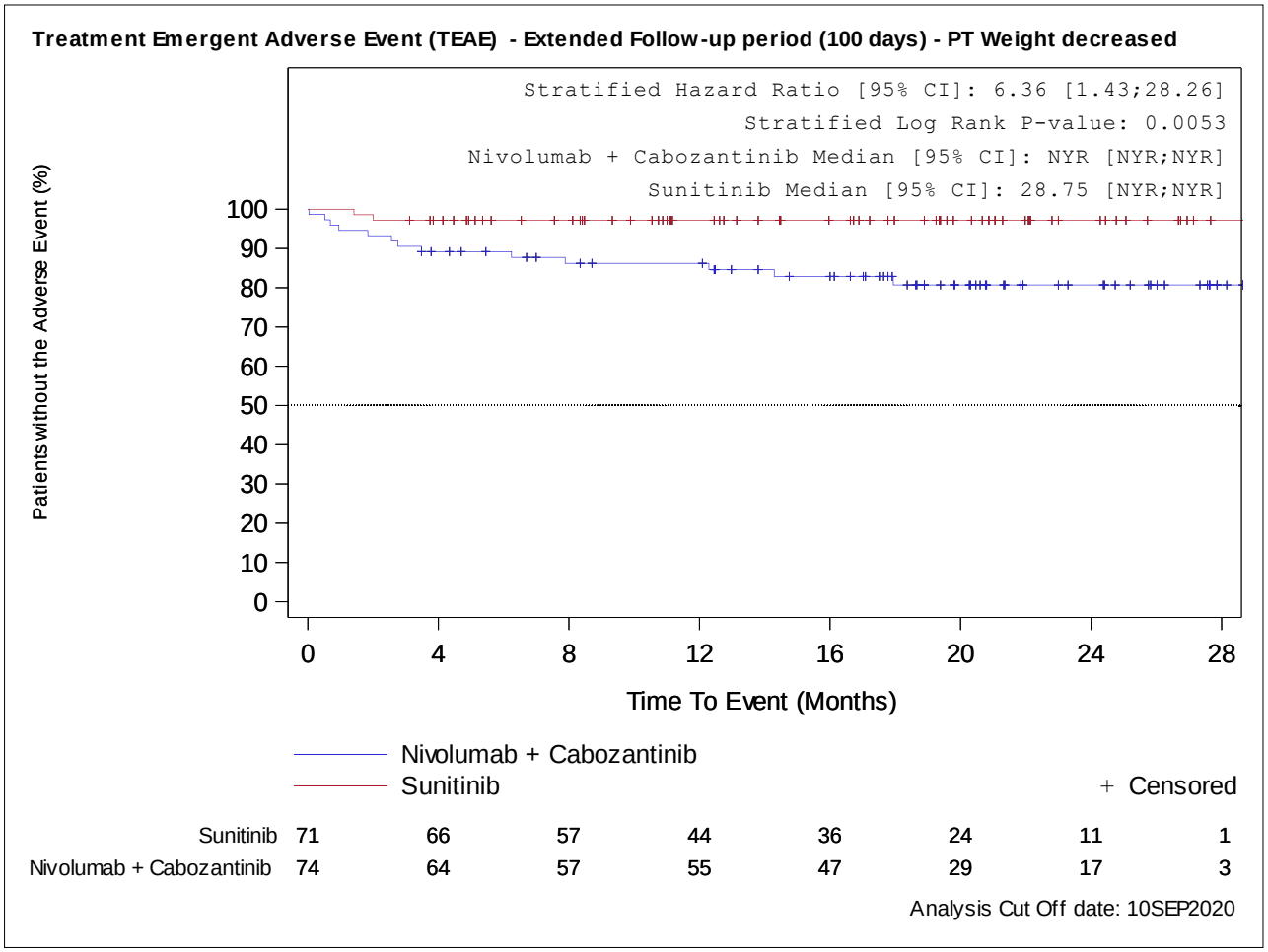
FIGURE 5.29.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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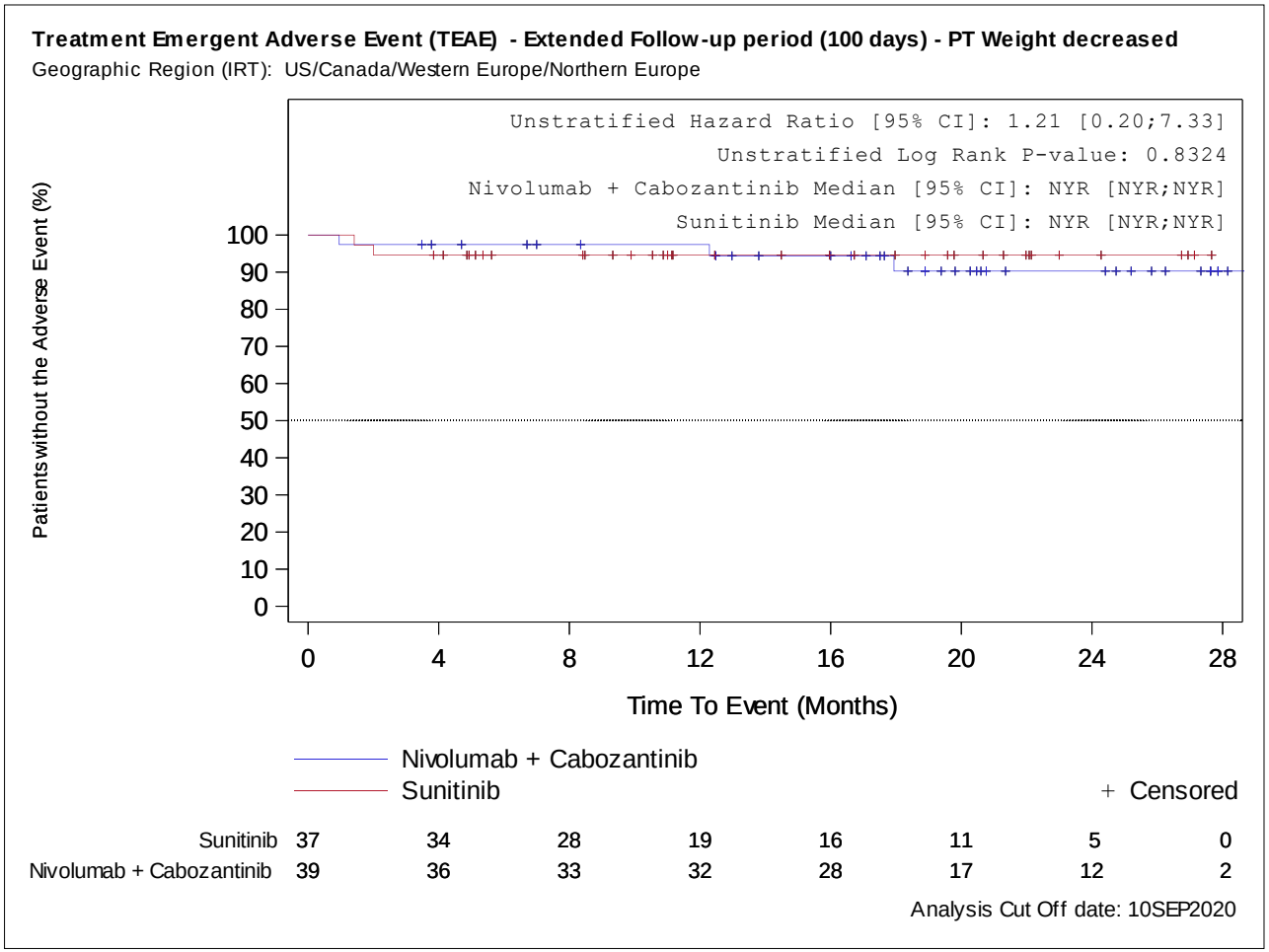
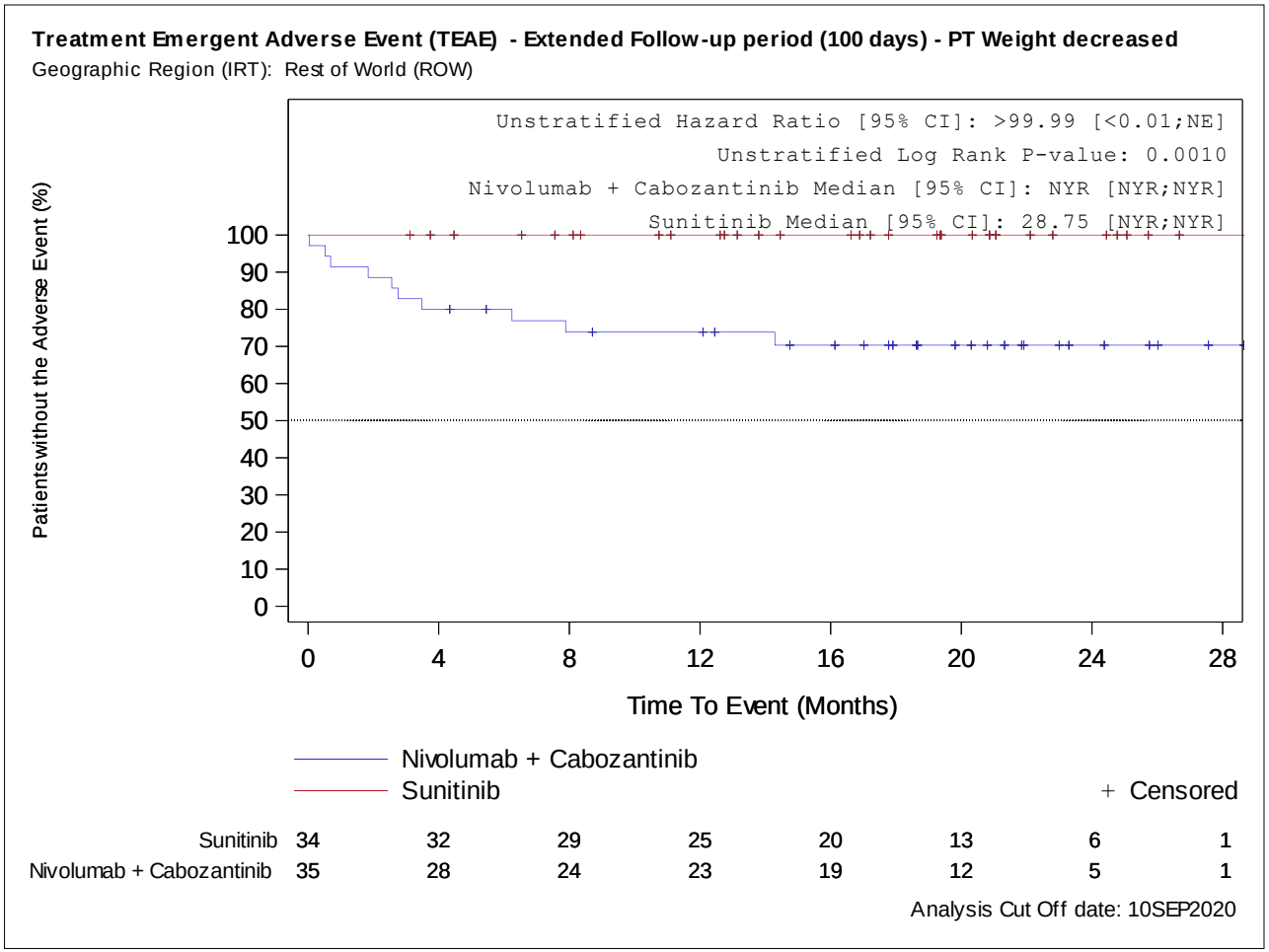
FIGURE 5.29.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:58:02

FIGURE 5.29.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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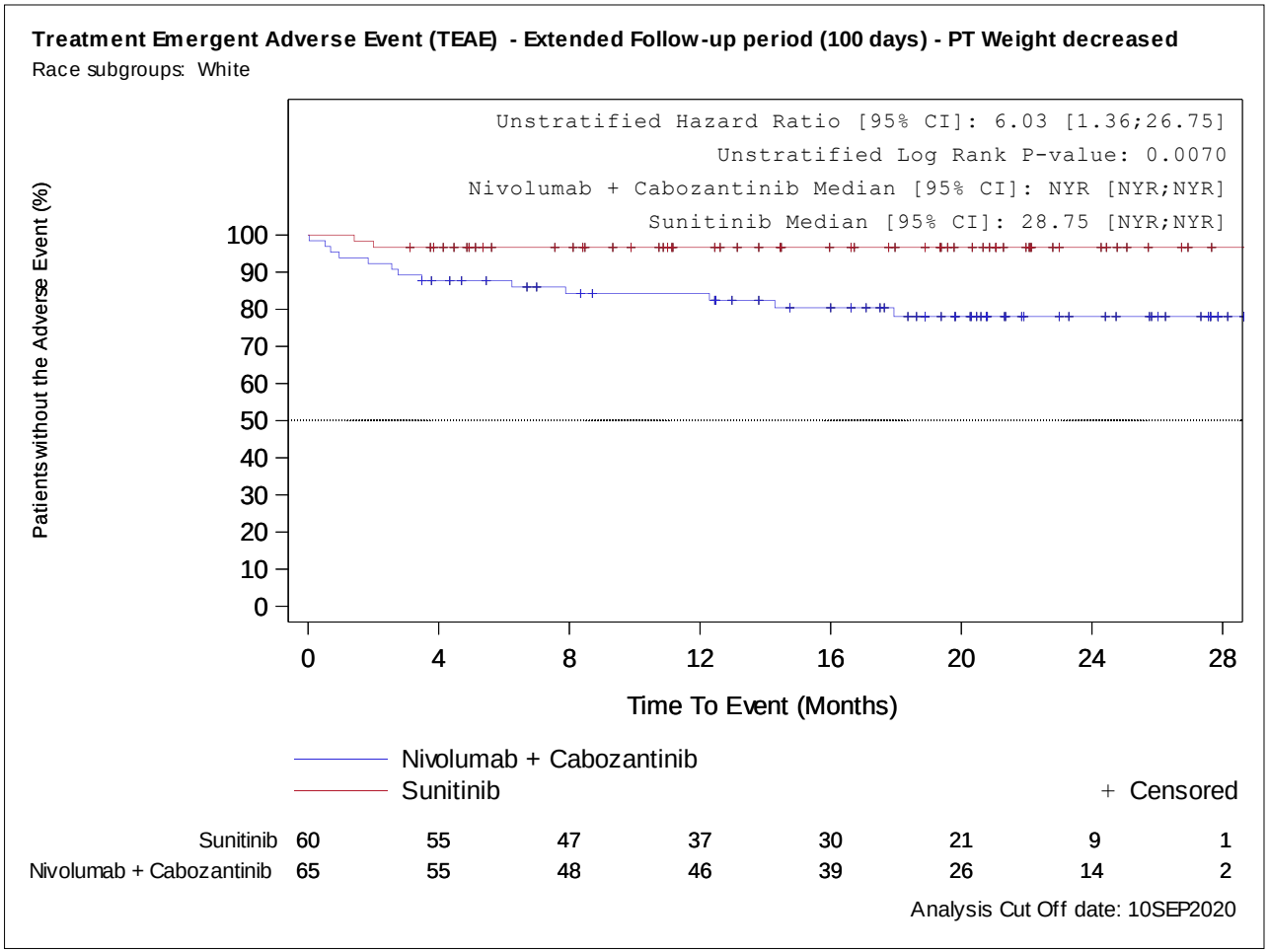
FIGURE 5.29.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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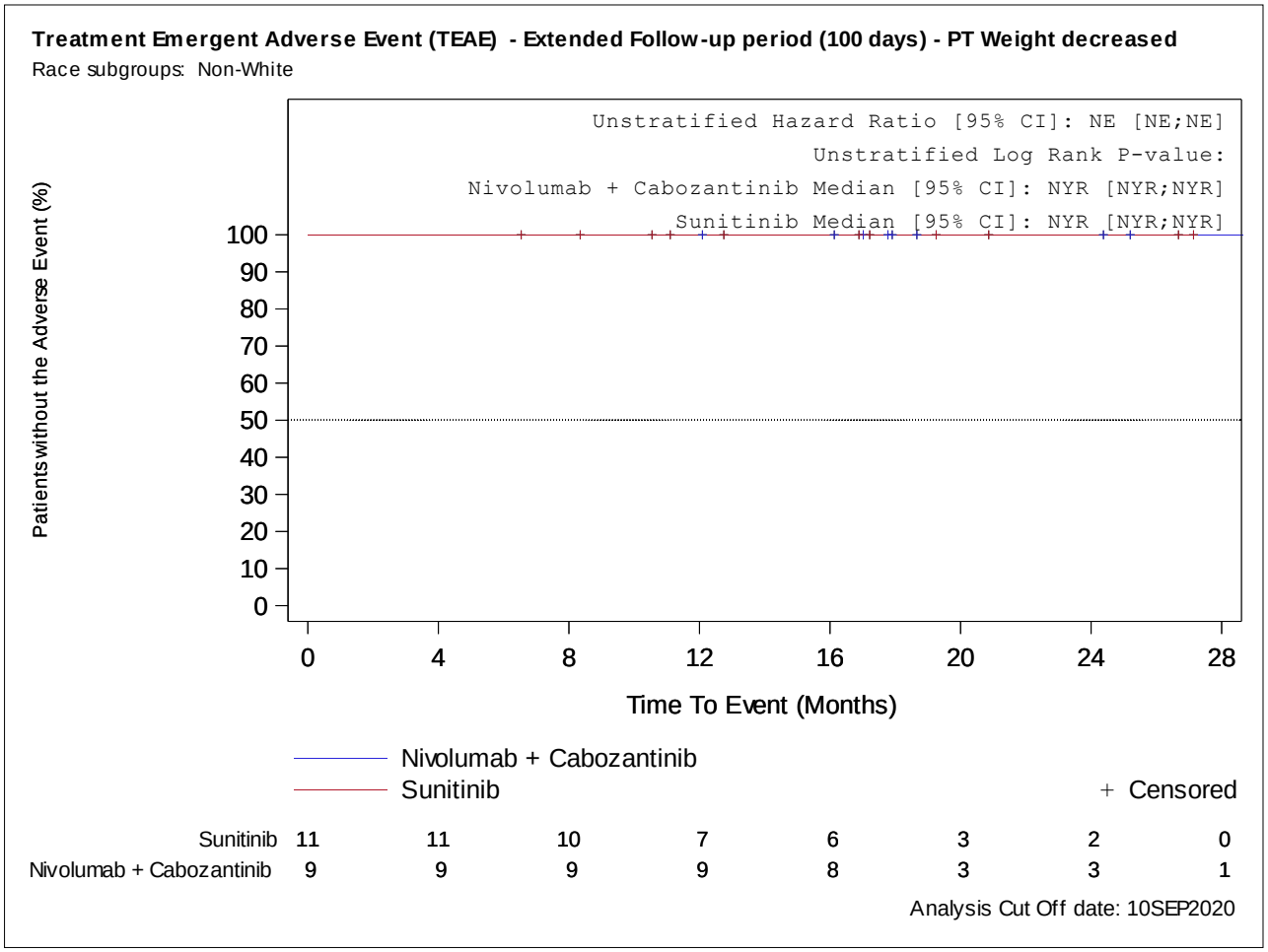
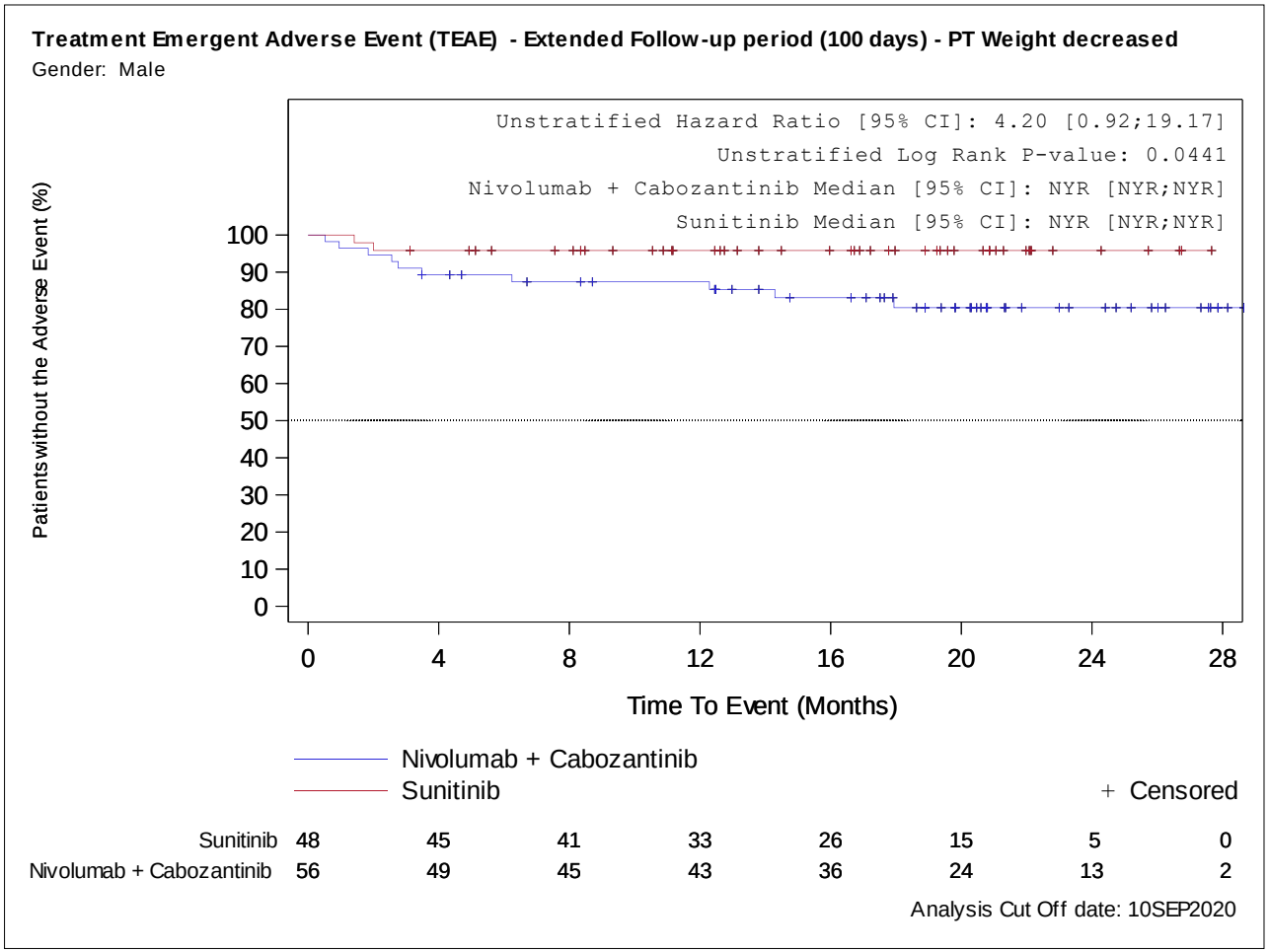
FIGURE 5.29.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



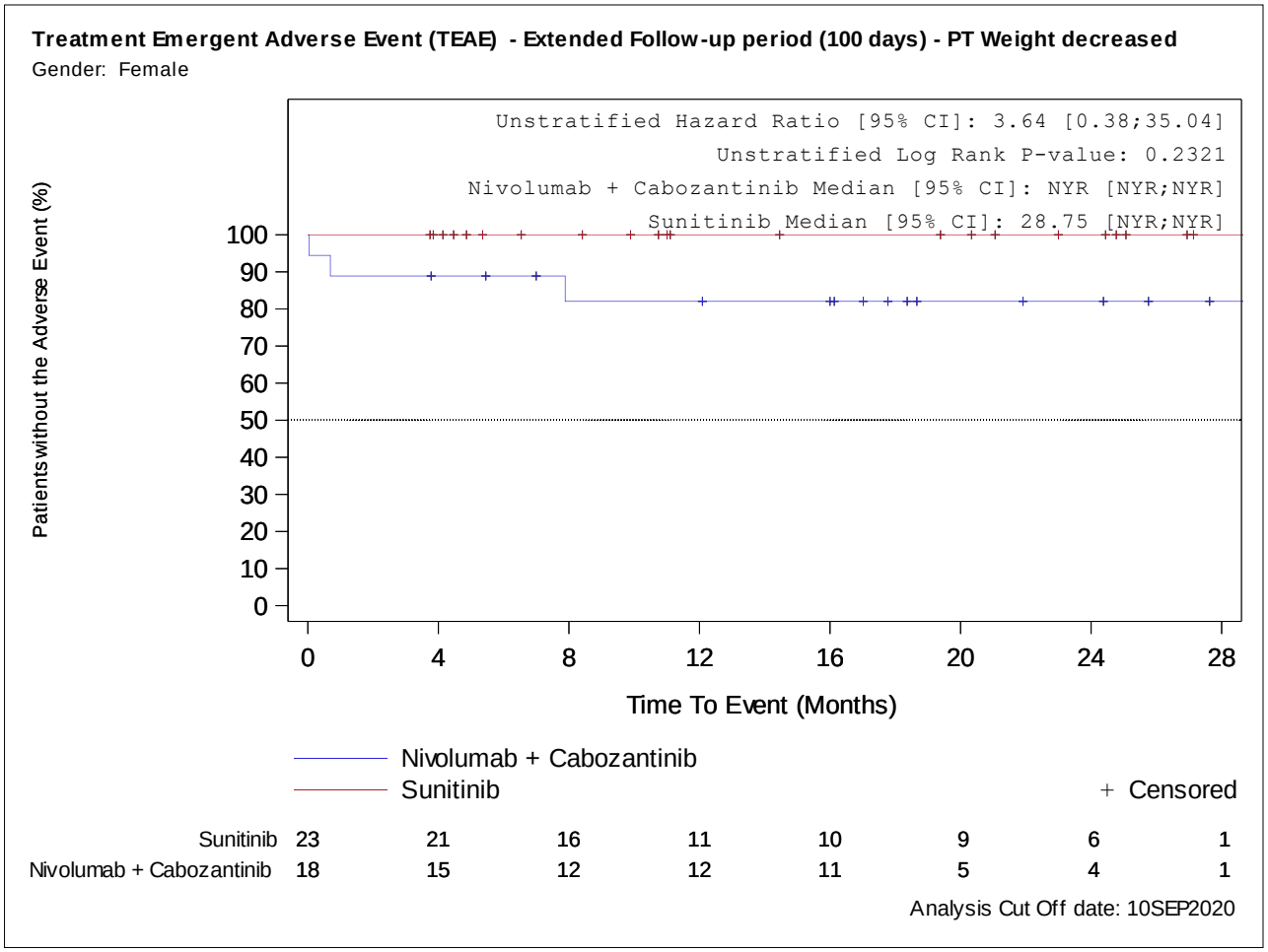

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:58:20

FIGURE 5.29.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



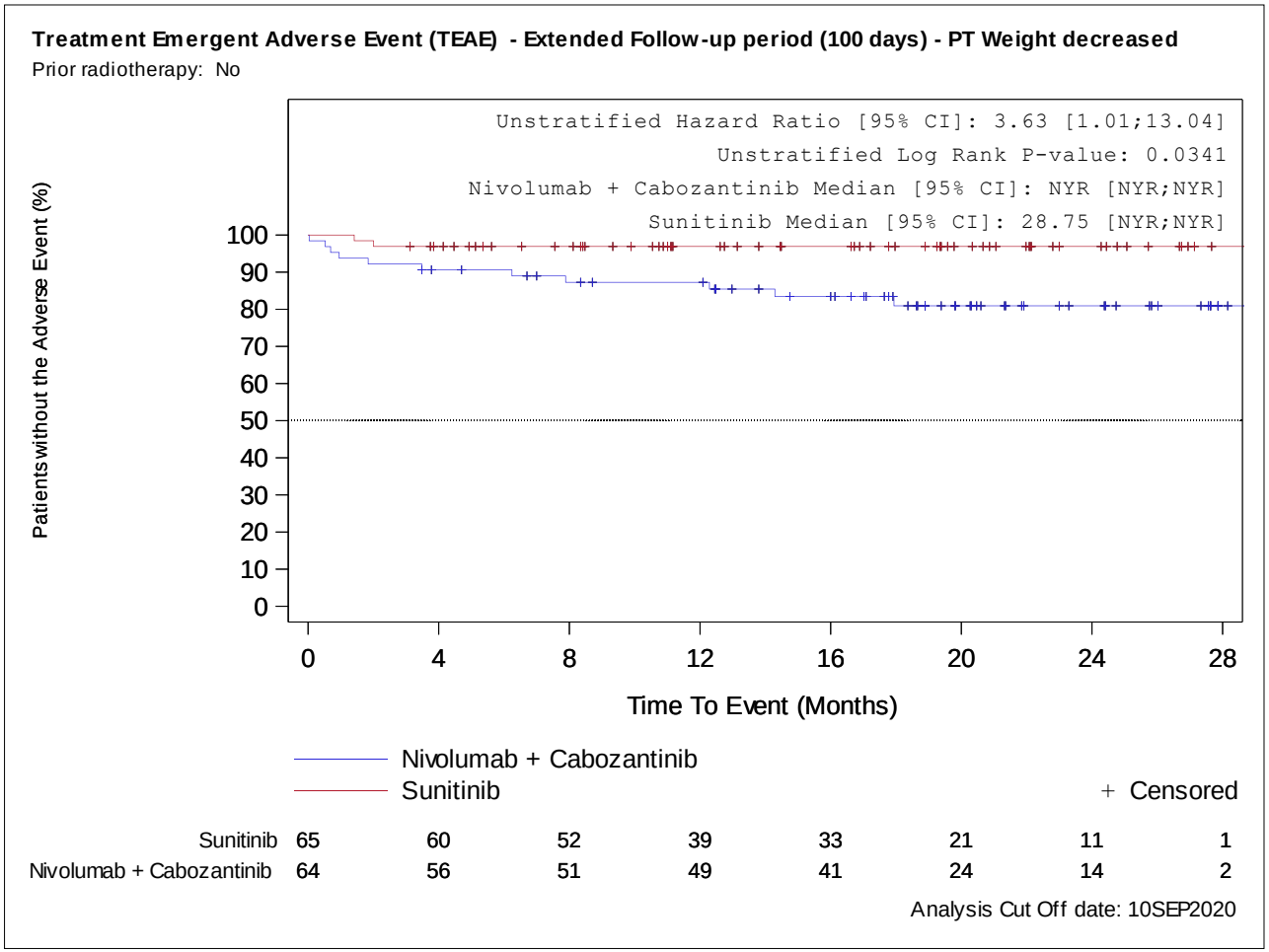

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:58:25

FIGURE 5.29.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



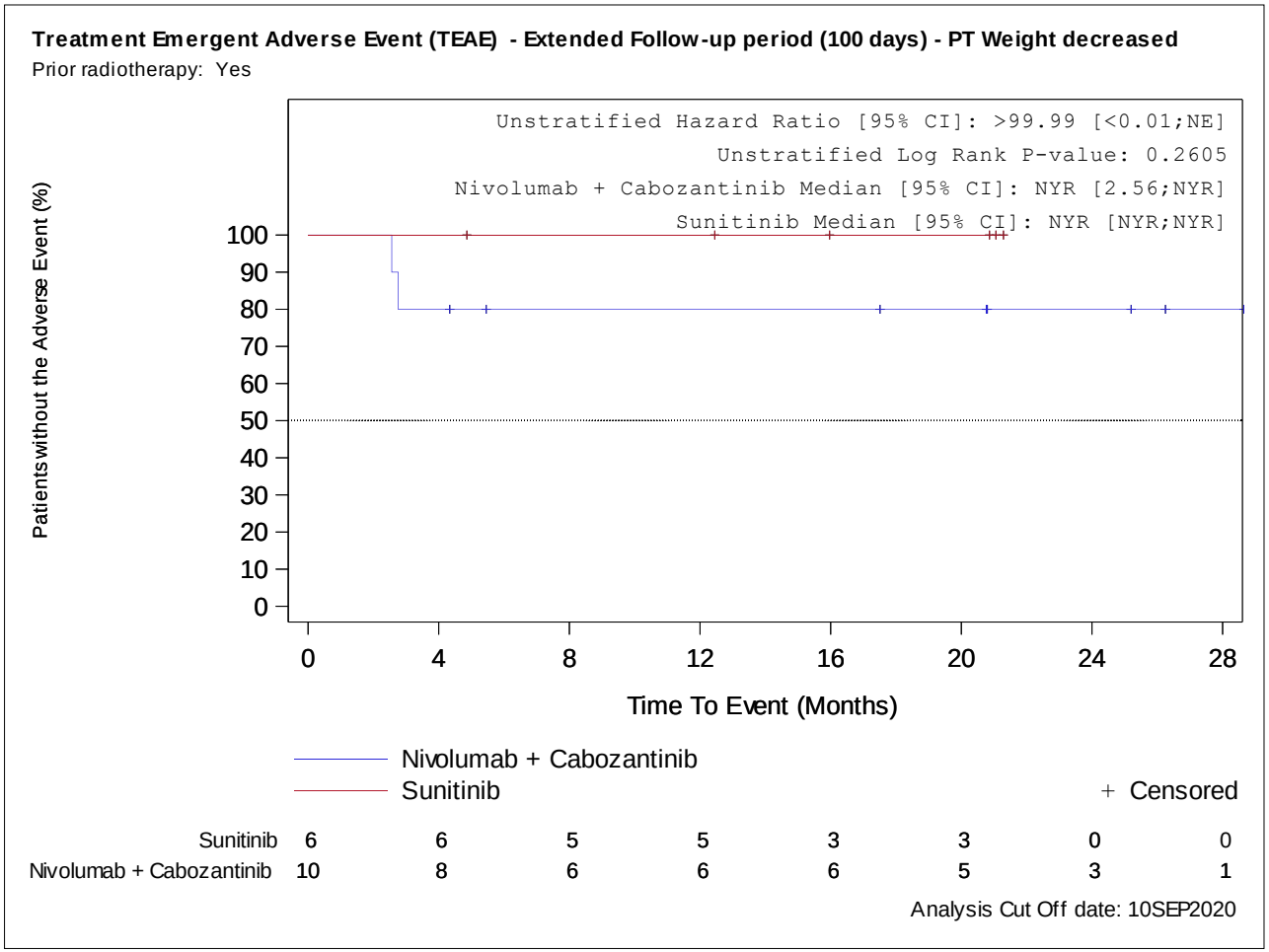

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:58:31

FIGURE 5.29.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 18:59:34

FIGURE 5.29.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Weight decreased - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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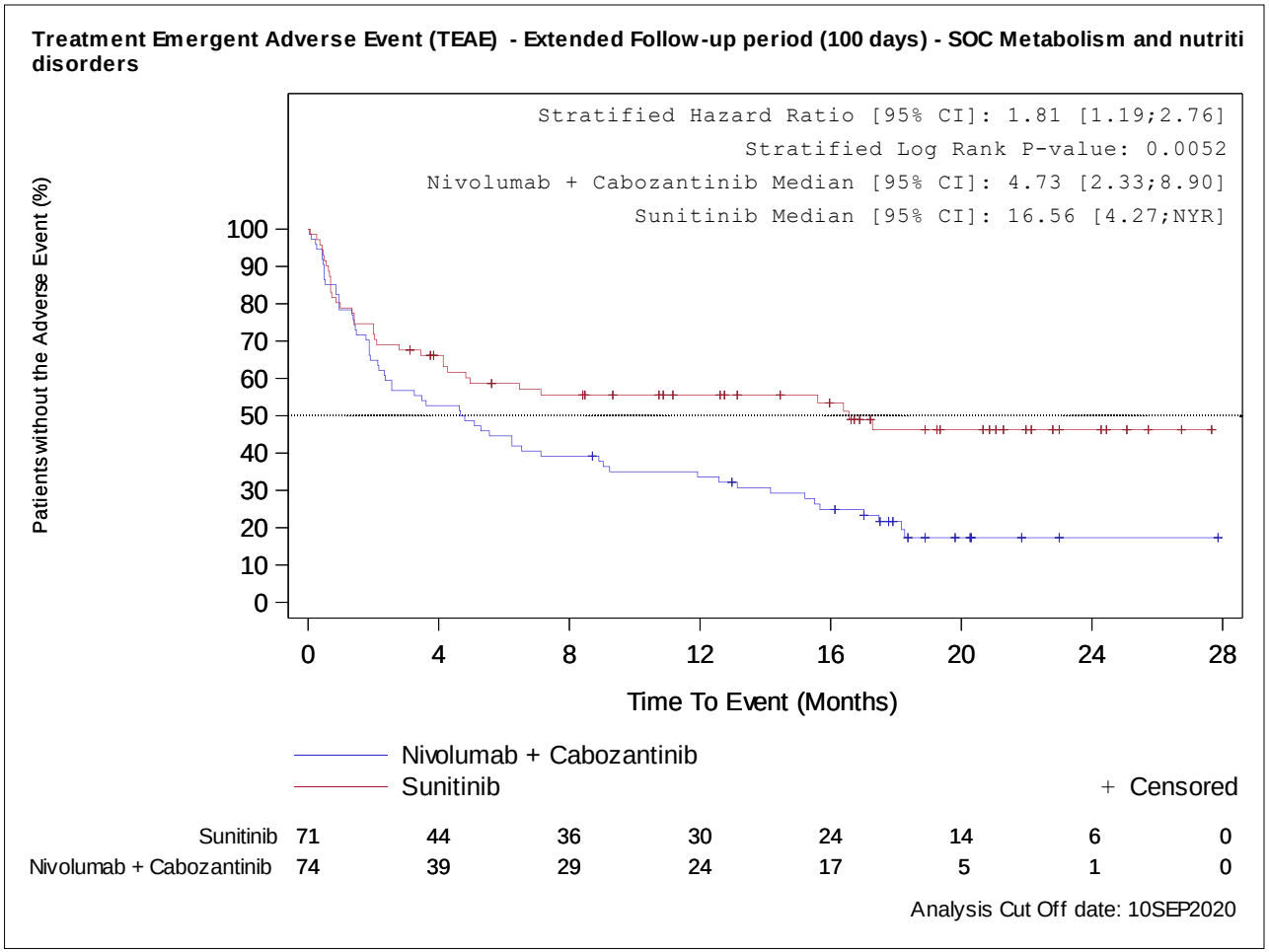
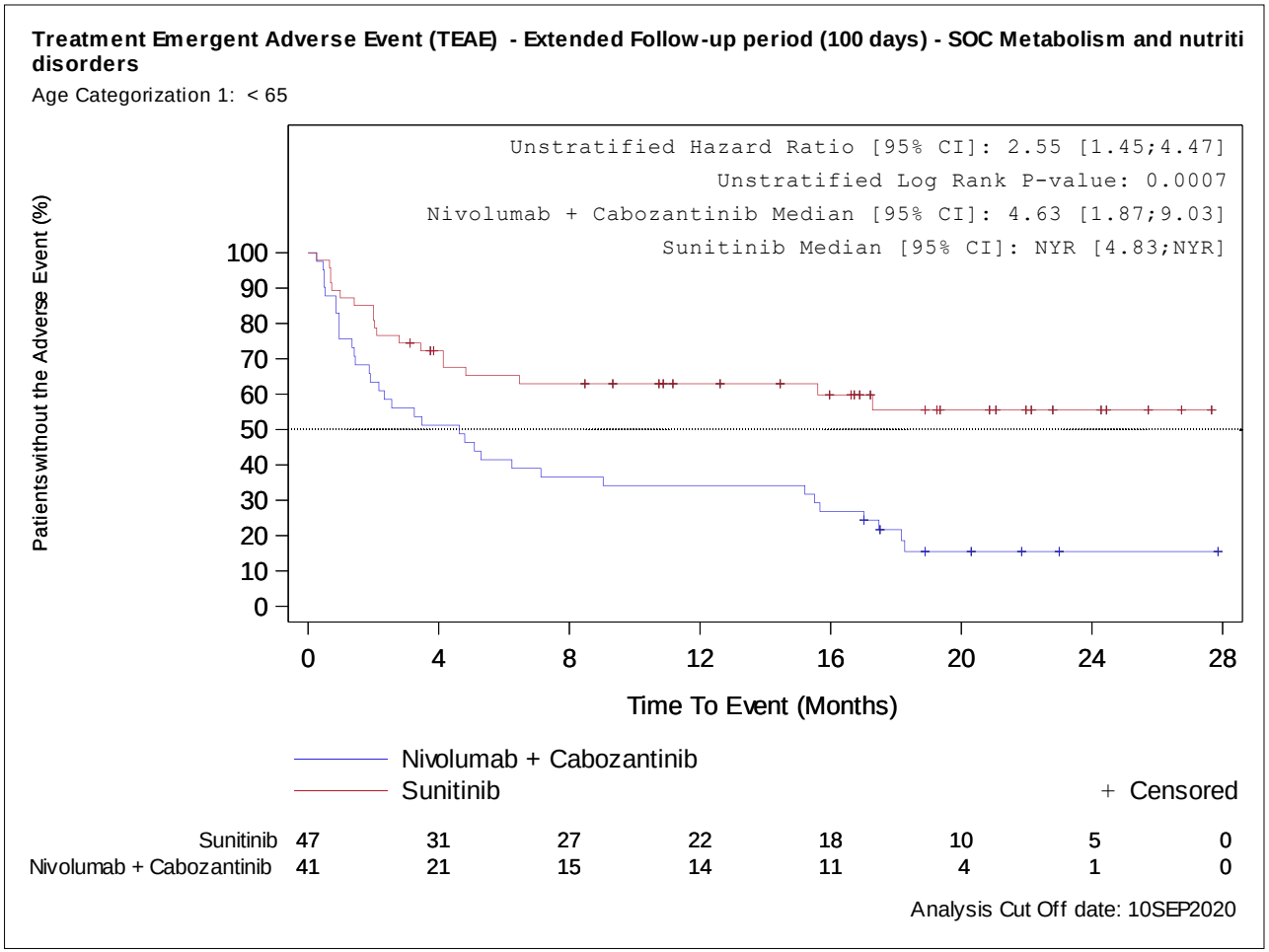
FIGURE 5.30.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



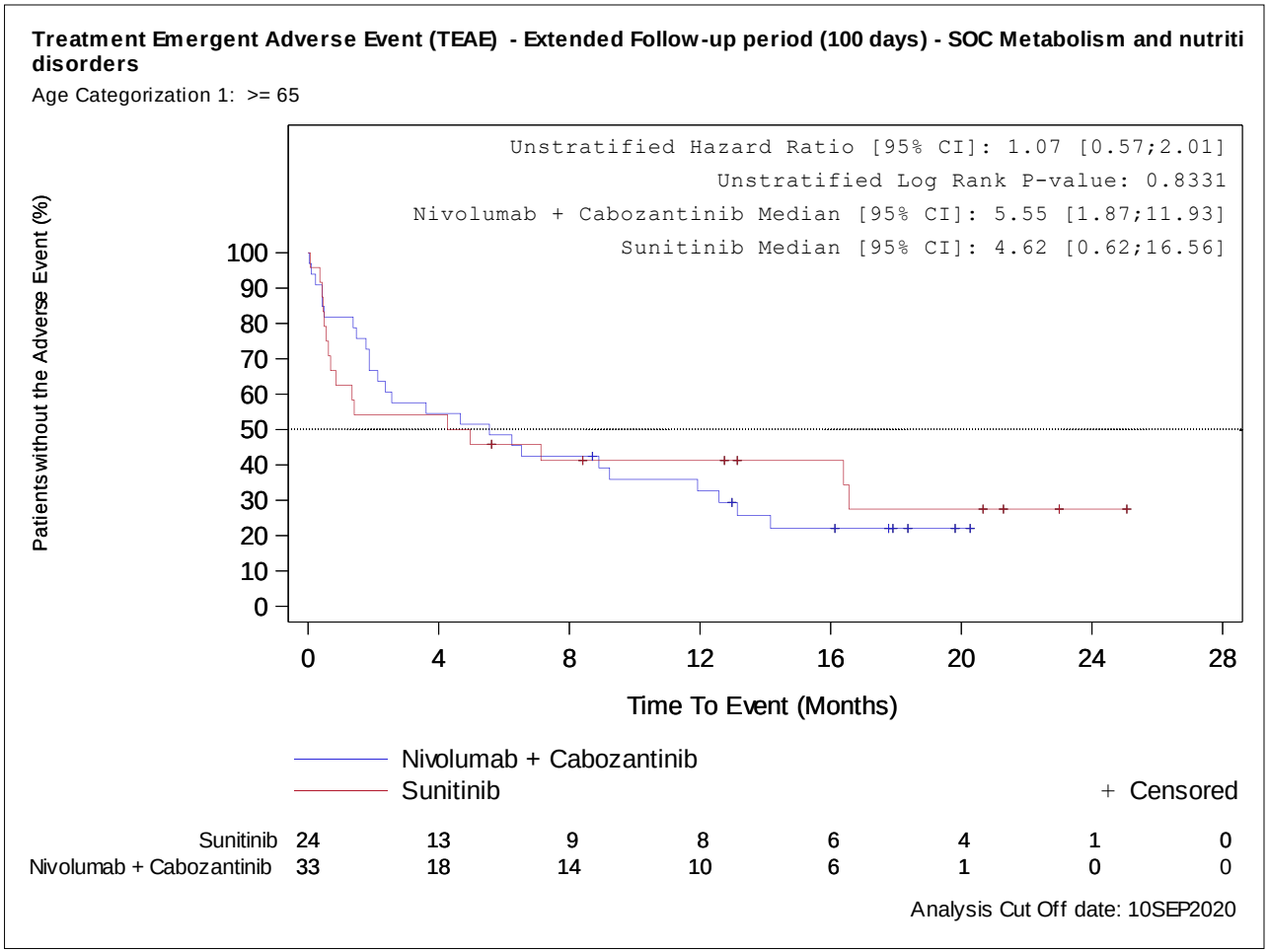

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:03:25

FIGURE 5.30.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



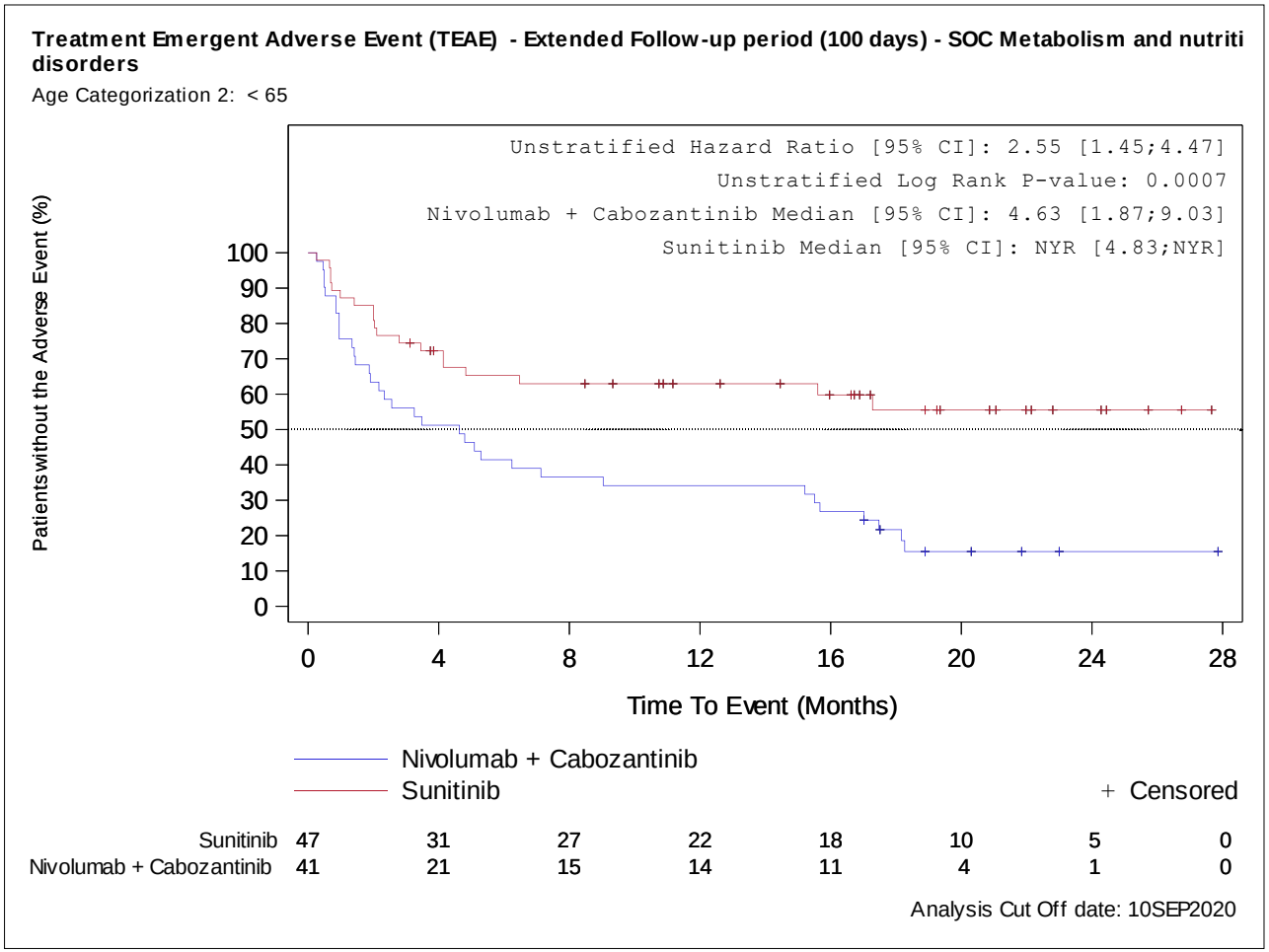

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:03:28

FIGURE 5.30.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:03:34

FIGURE 5.30.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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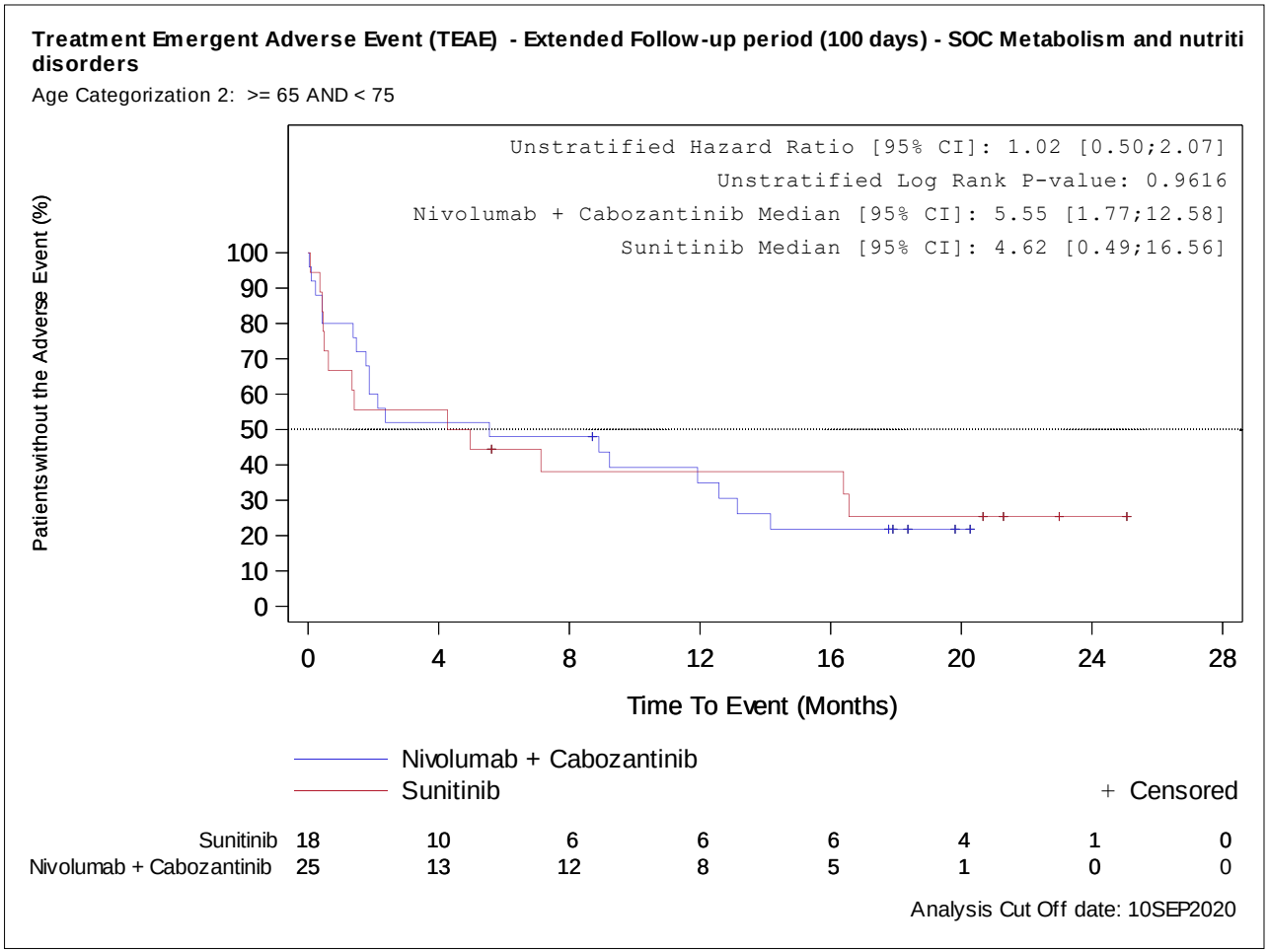
FIGURE 5.30.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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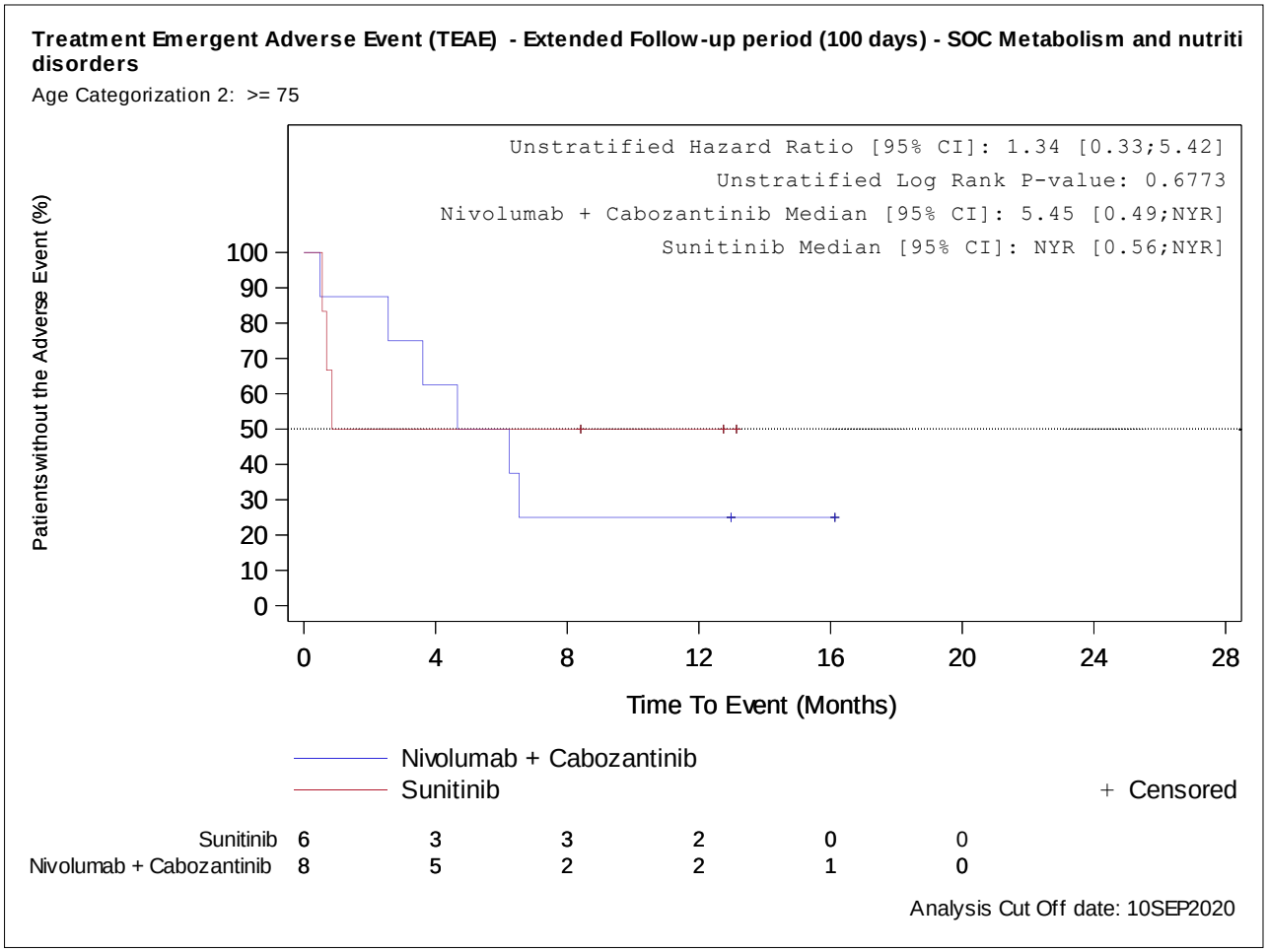
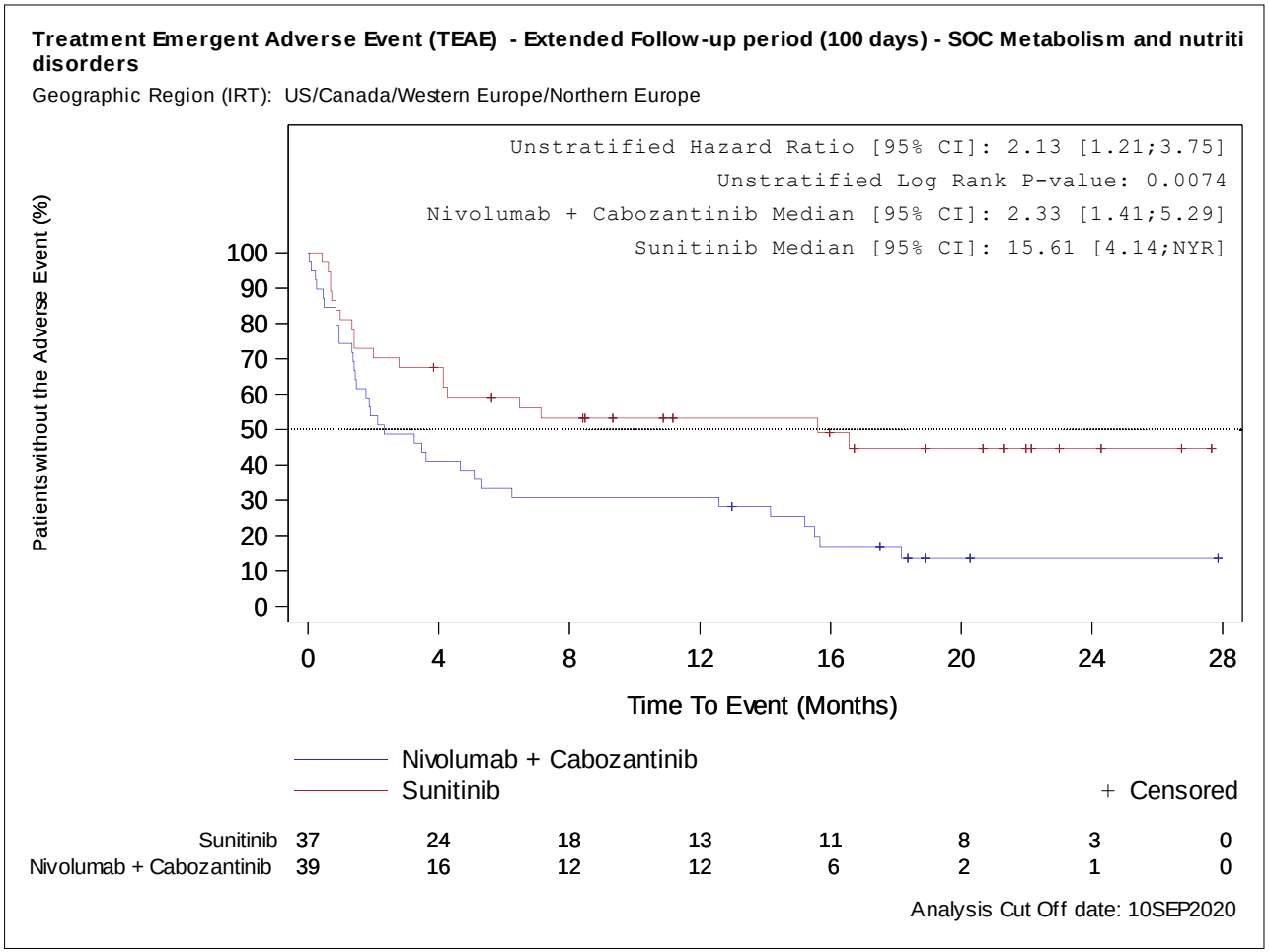
FIGURE 5.30.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



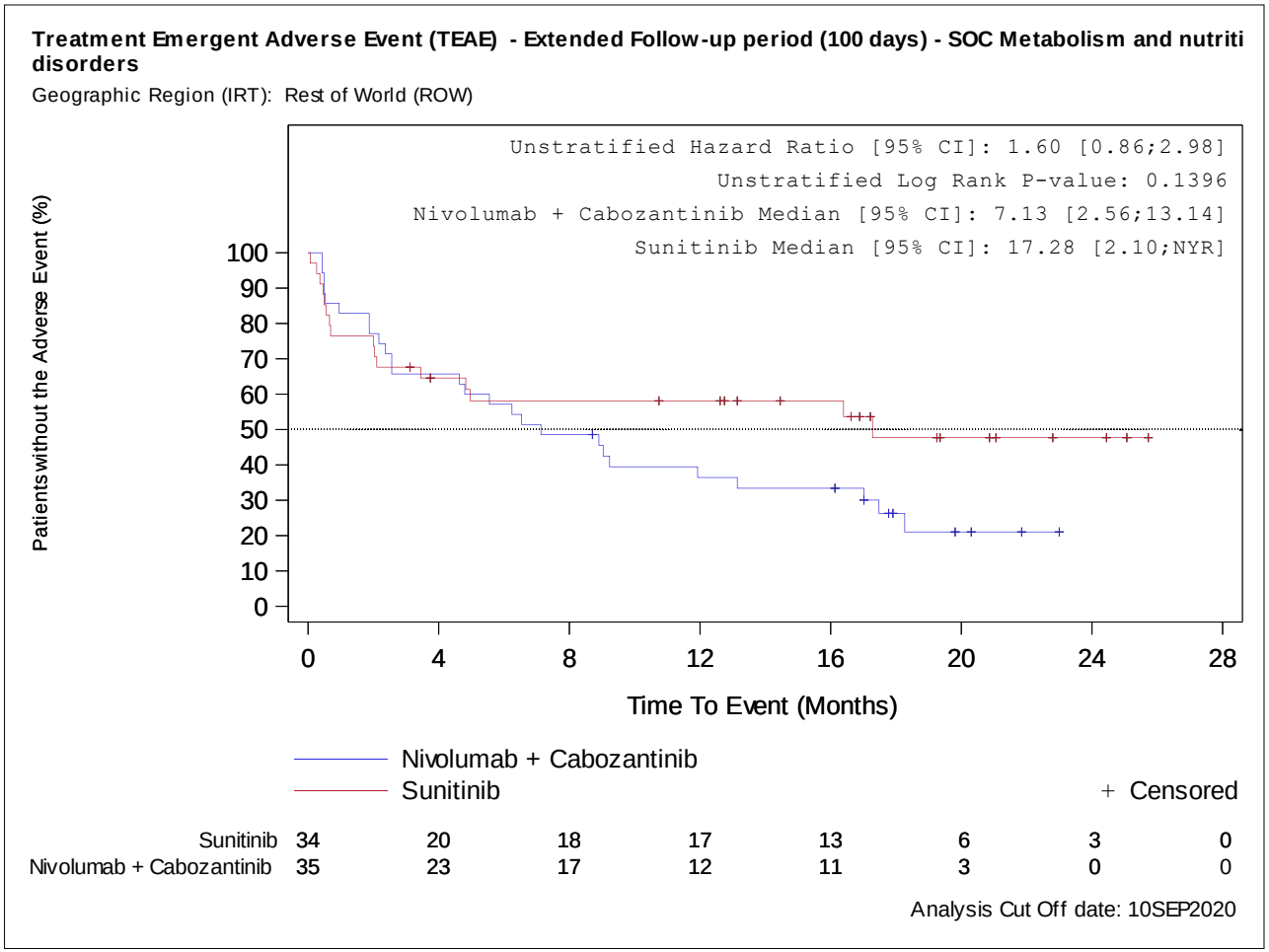

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:03:52

FIGURE 5.30.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe



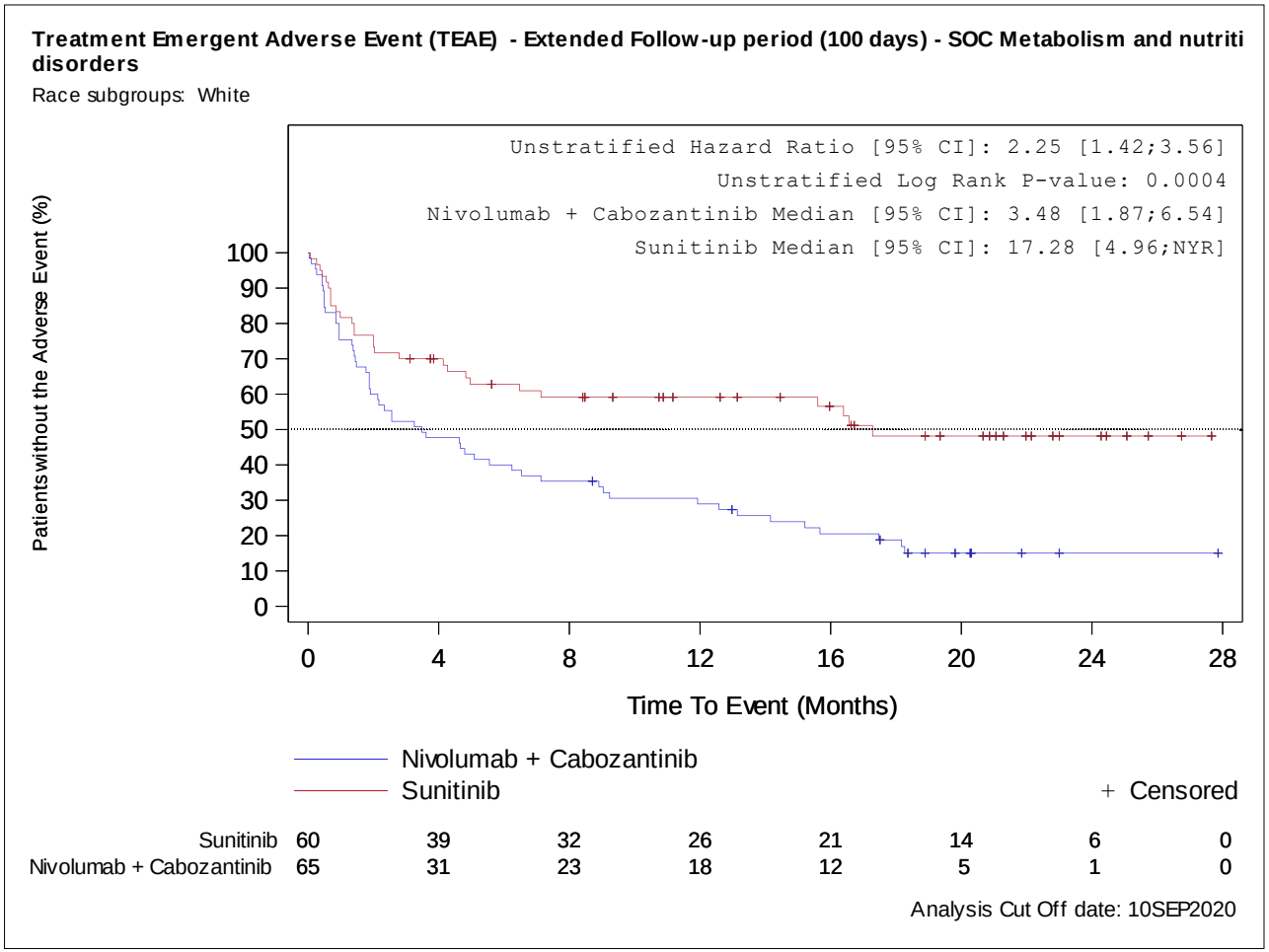

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:03:58

FIGURE 5.30.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:04:04

FIGURE 5.30.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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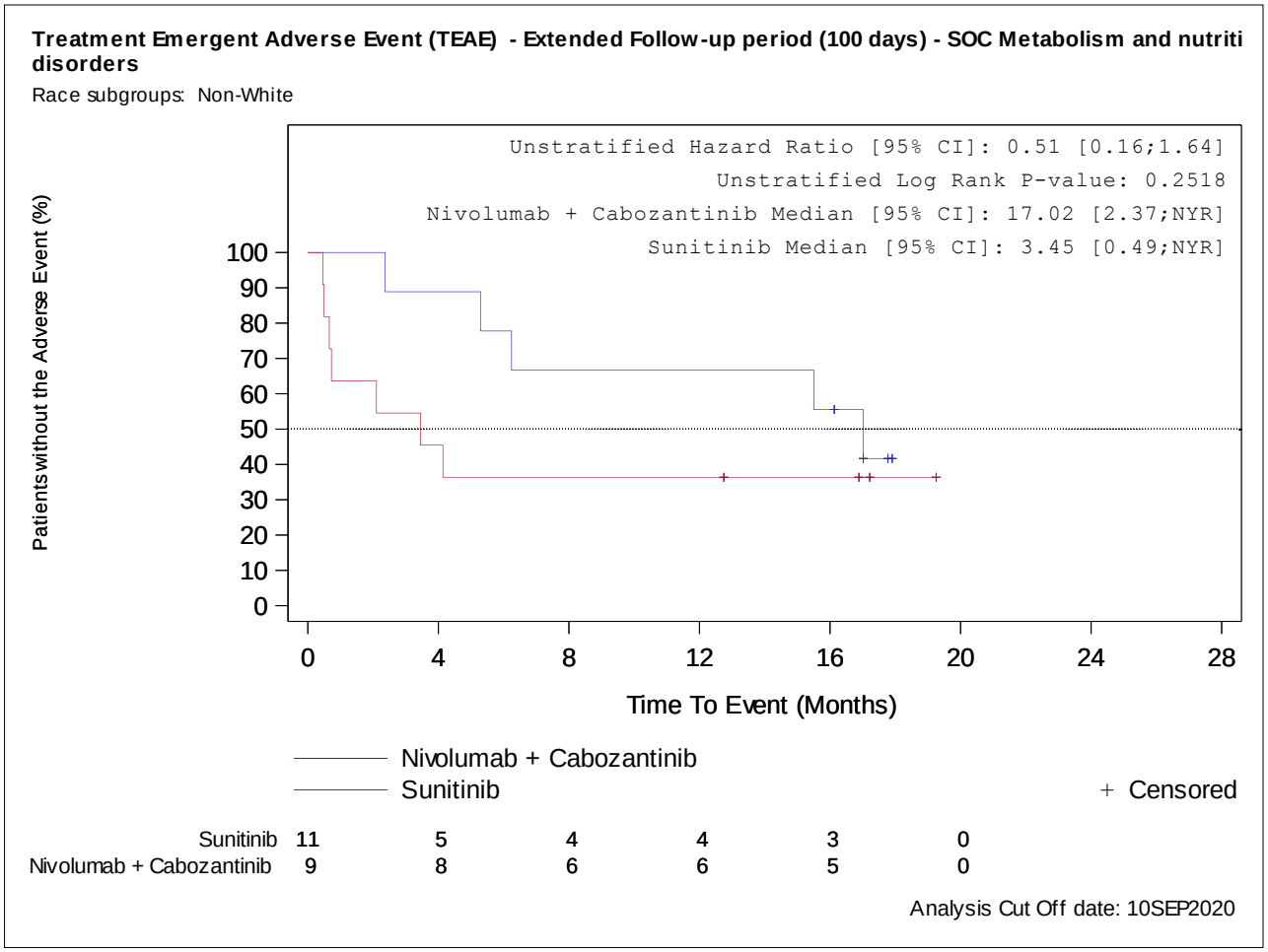
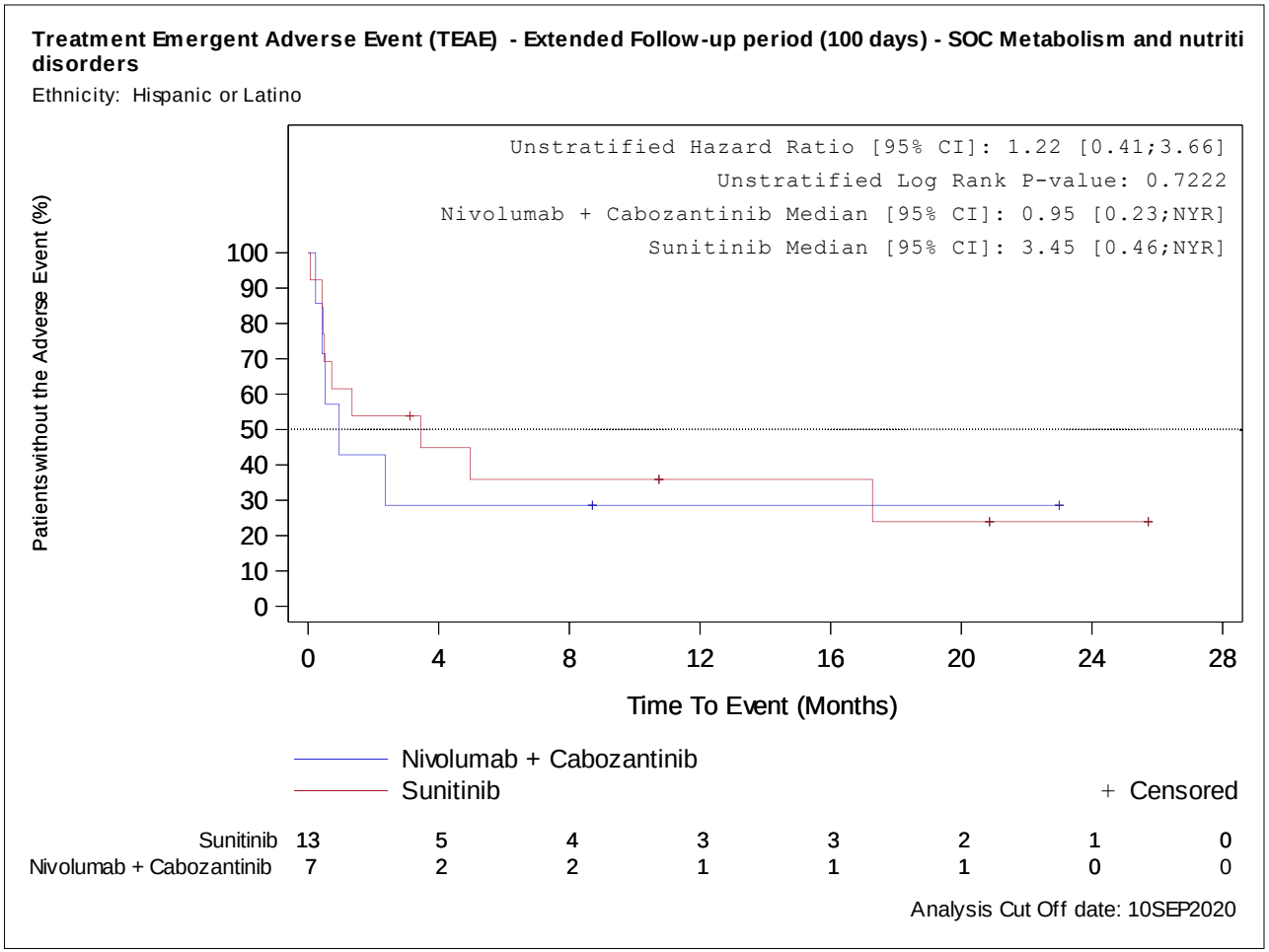
FIGURE 5.30.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:04:16

FIGURE 5.30.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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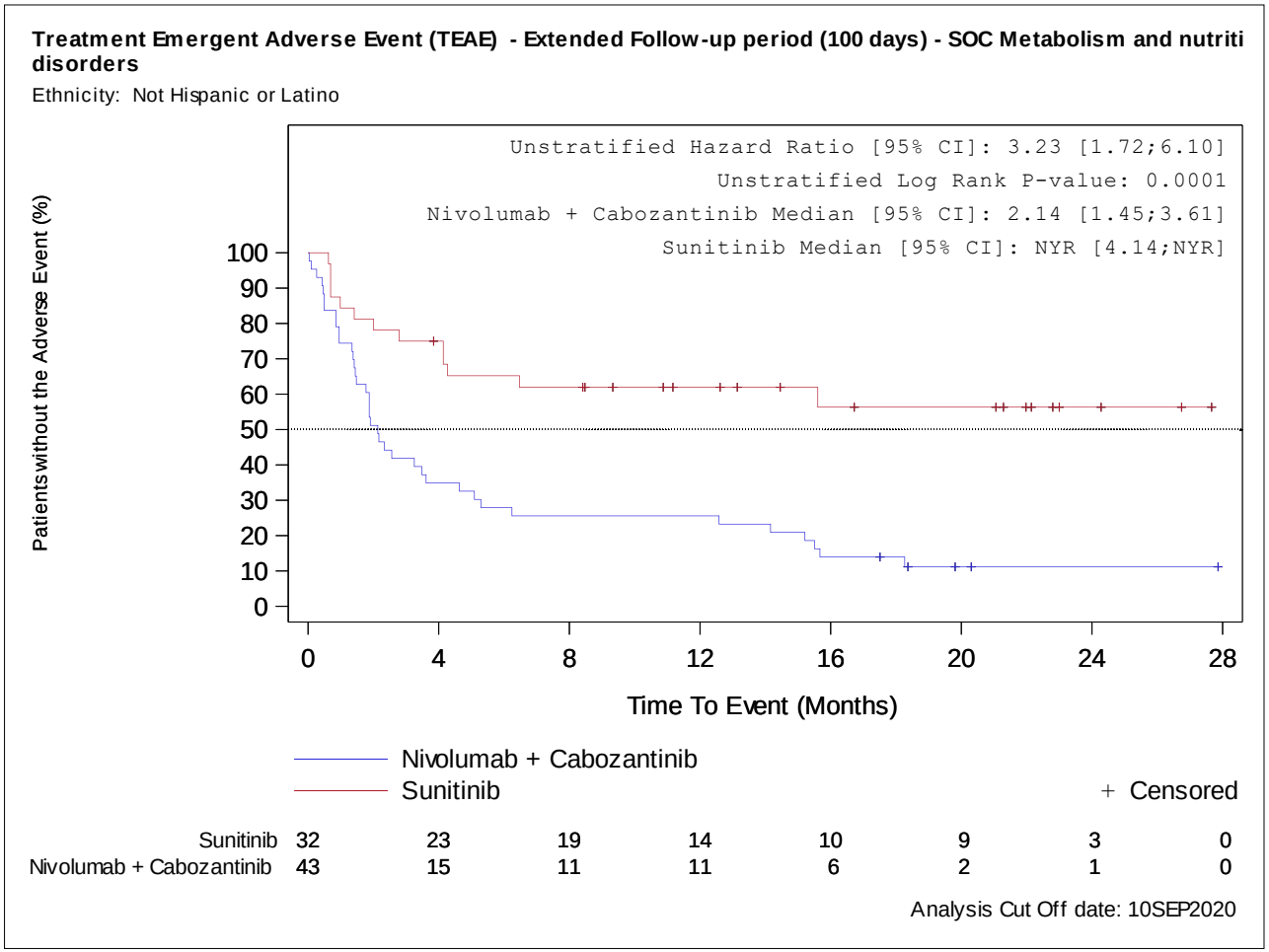
FIGURE 5.30.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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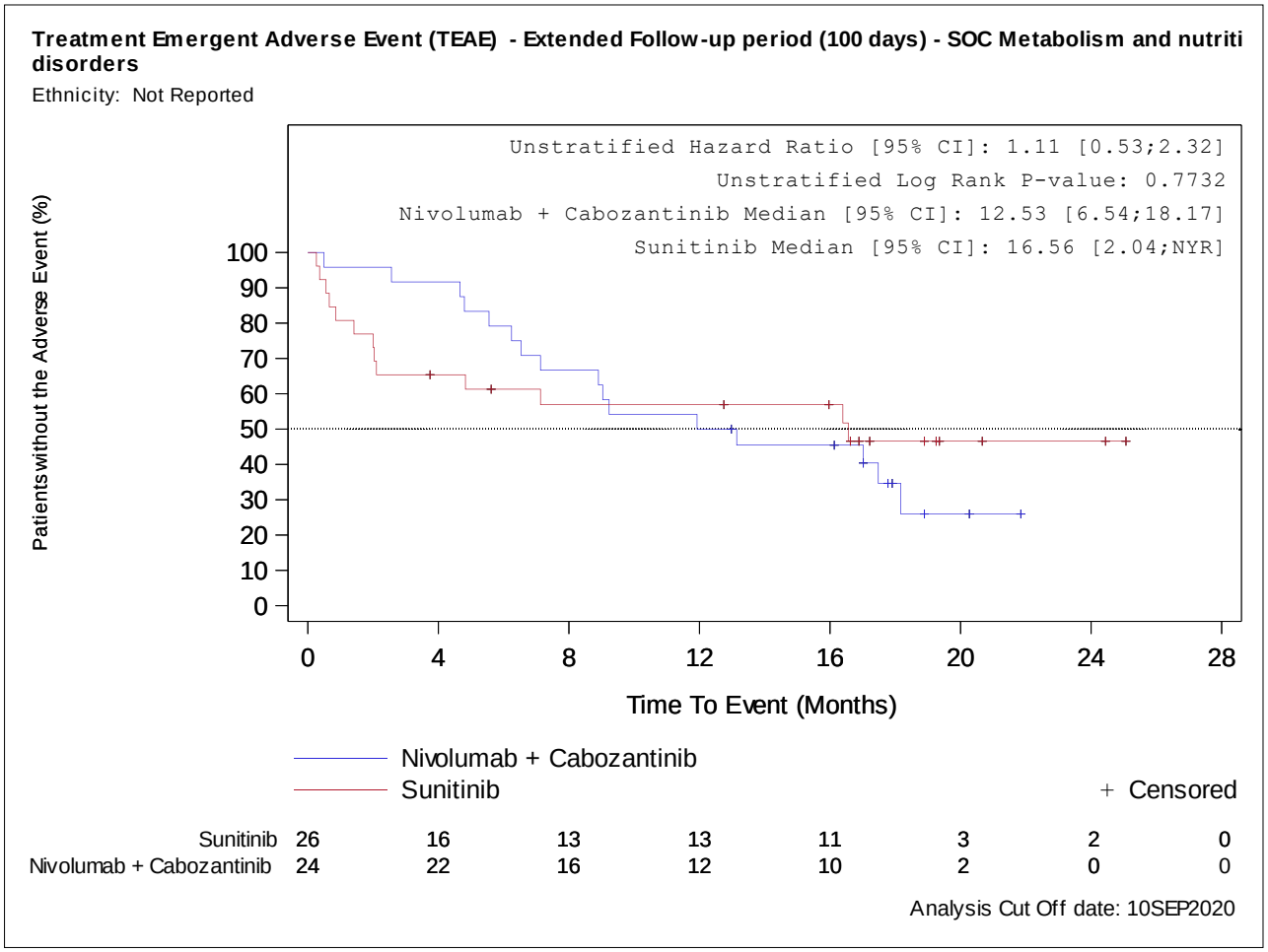
FIGURE 5.30.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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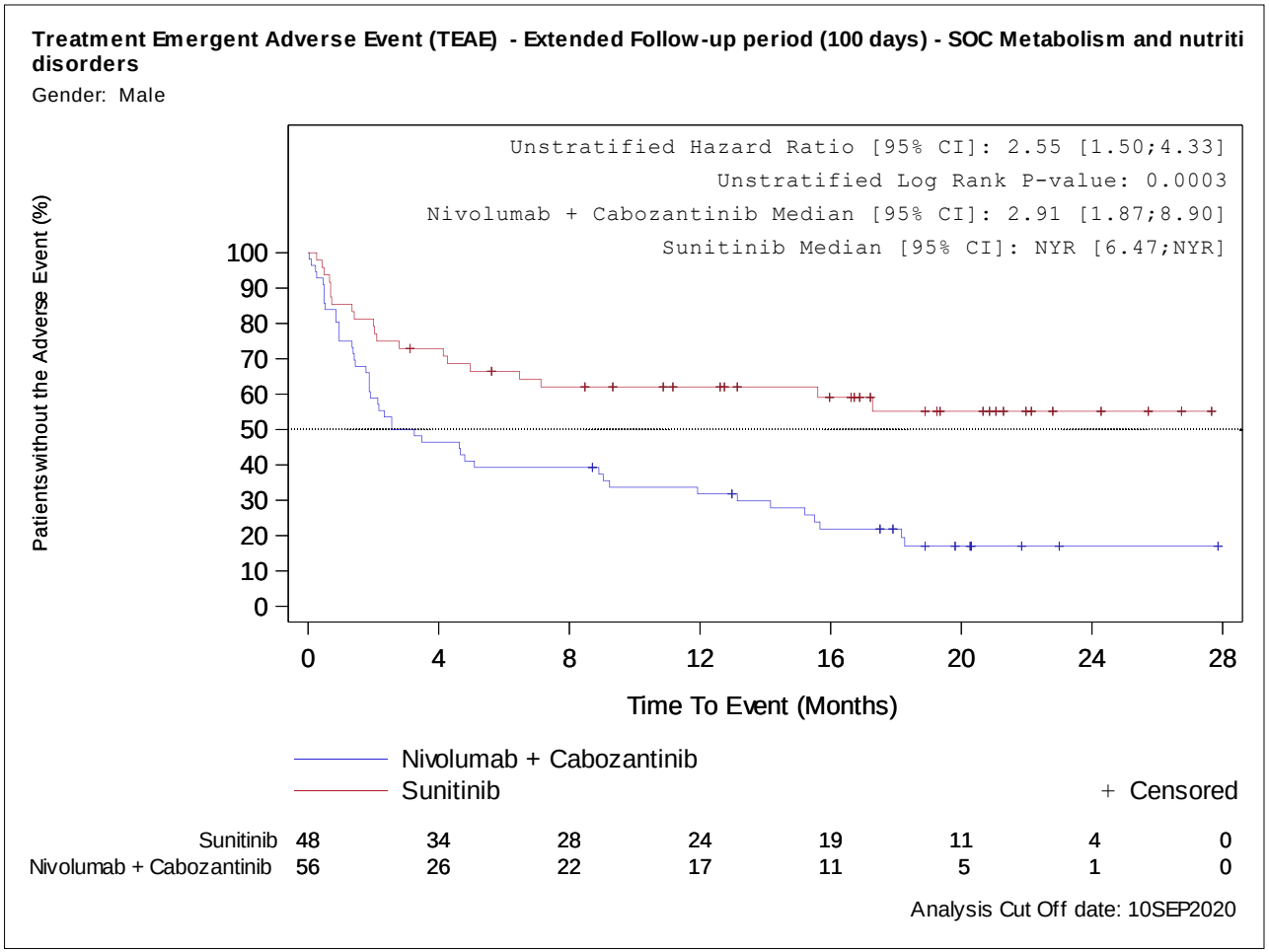
FIGURE 5.30.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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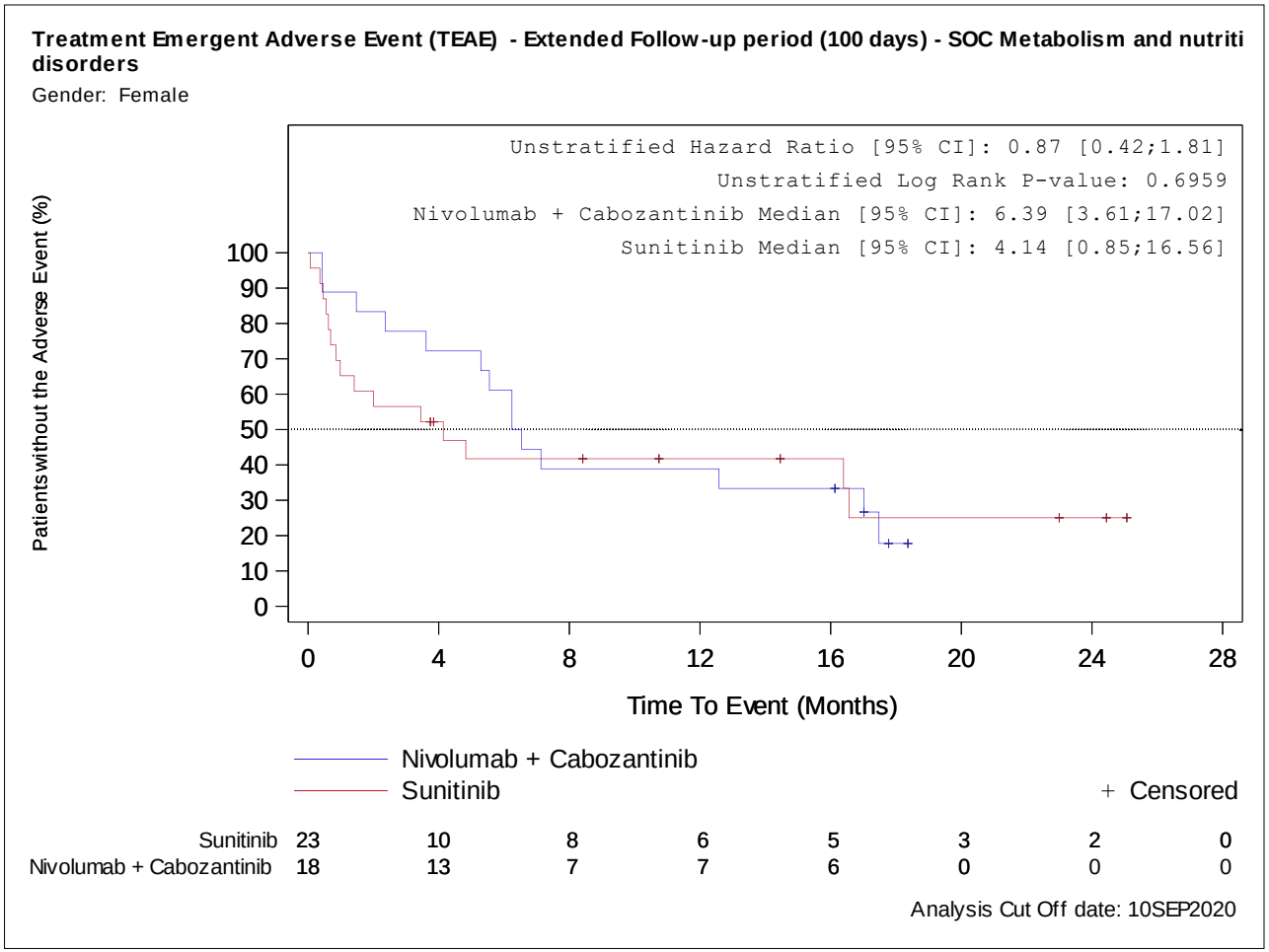
FIGURE 5.30.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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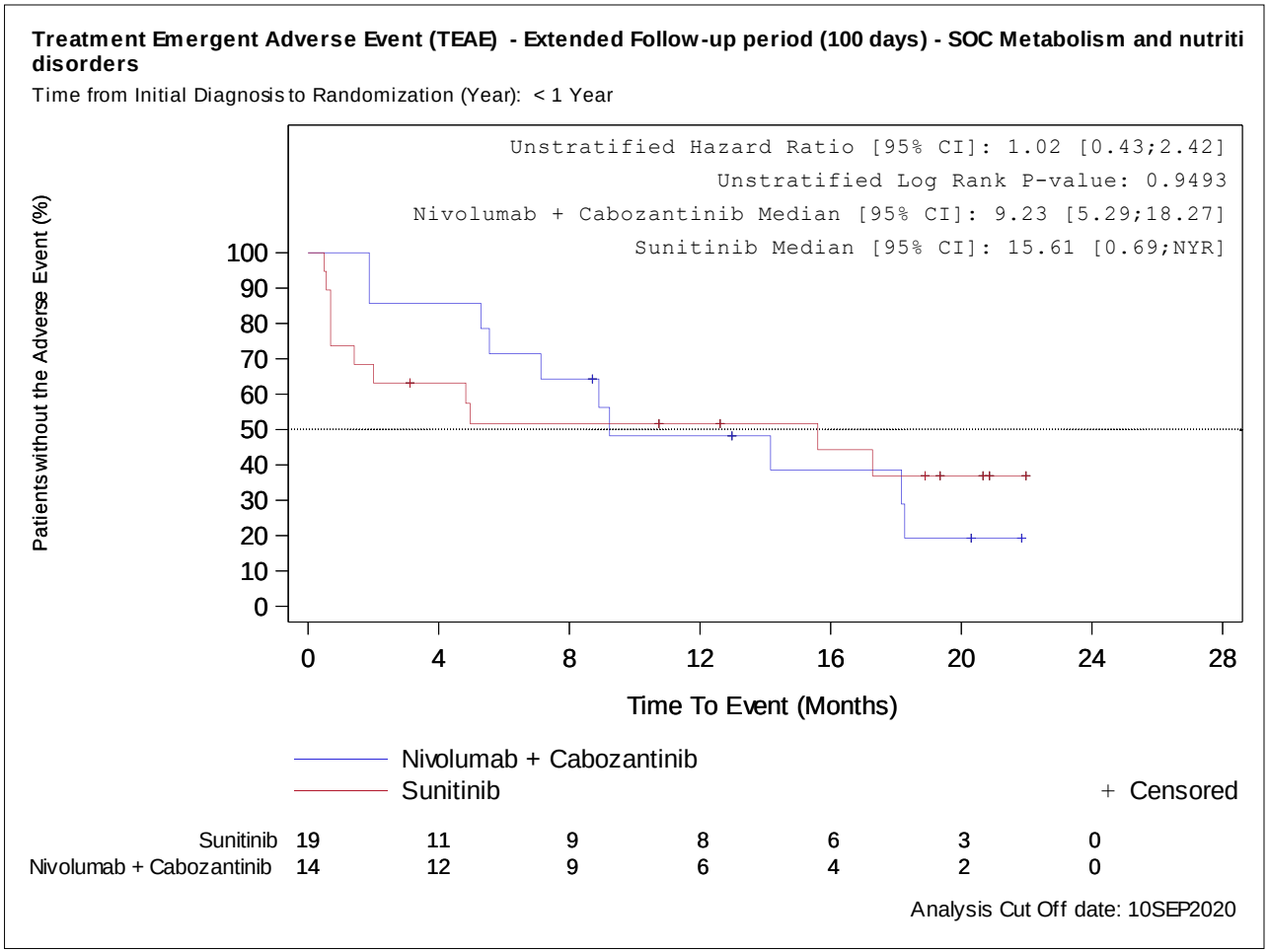
FIGURE 5.30.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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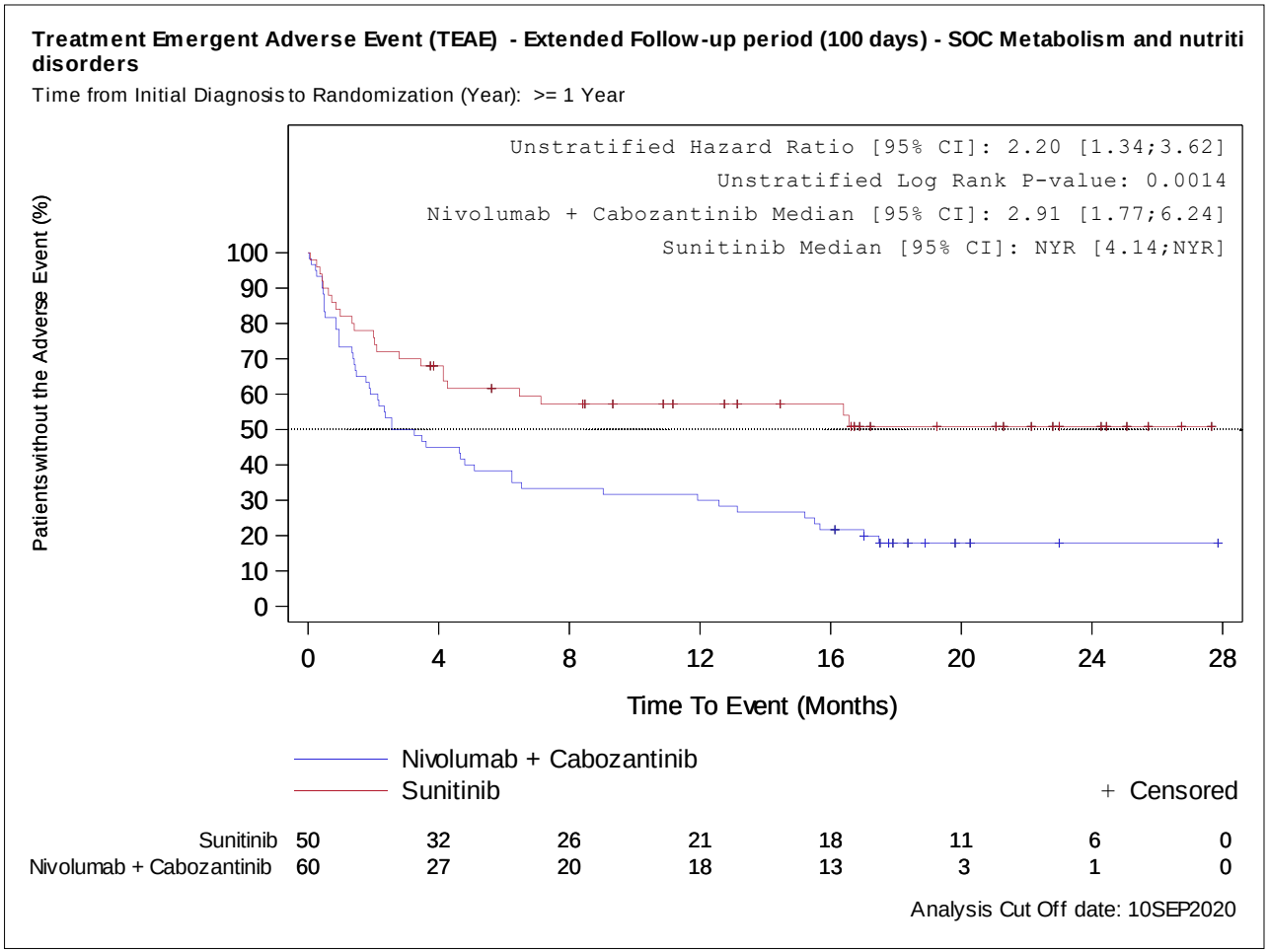
FIGURE 5.30.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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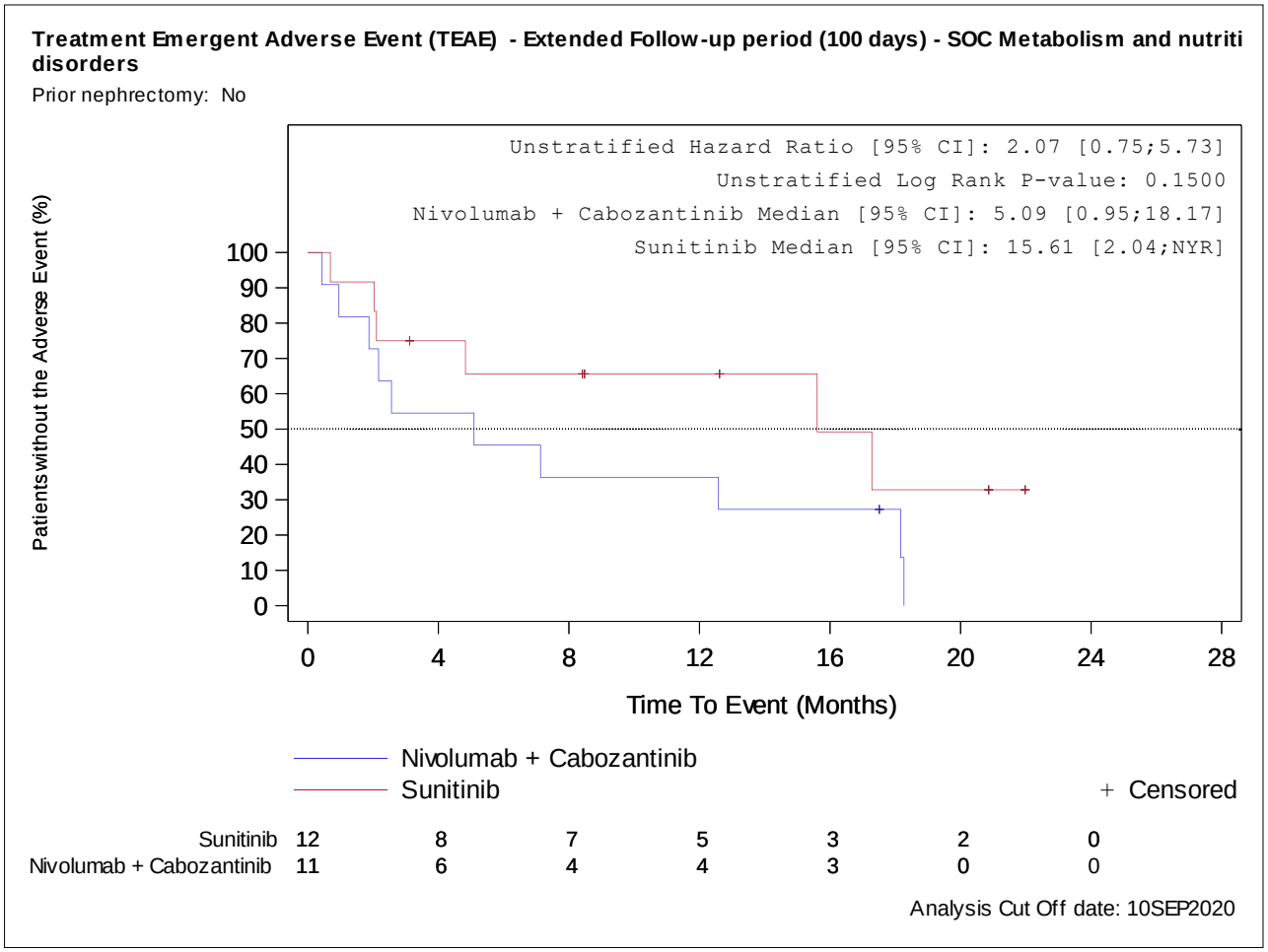
FIGURE 5.30.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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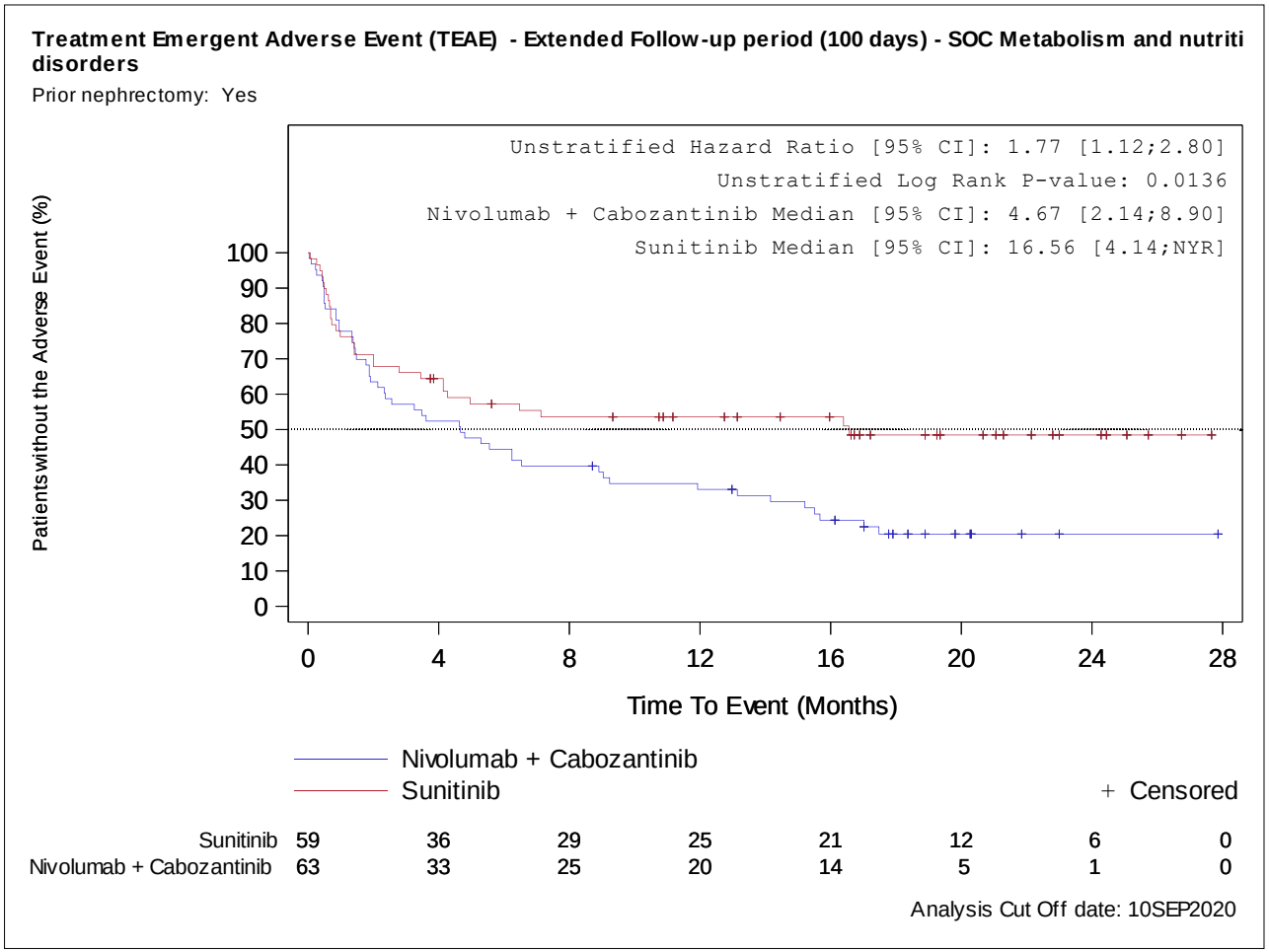
FIGURE 5.30.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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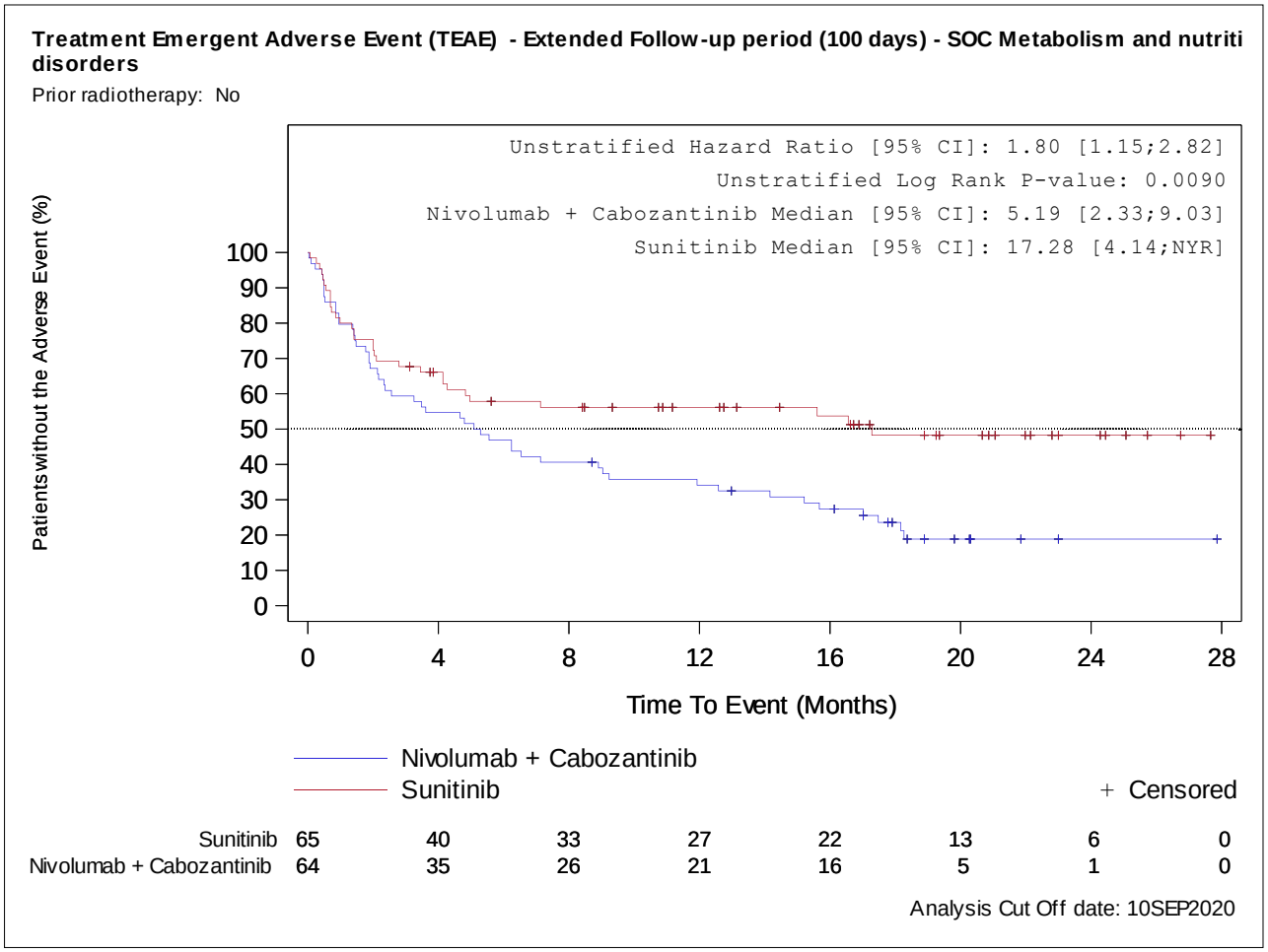
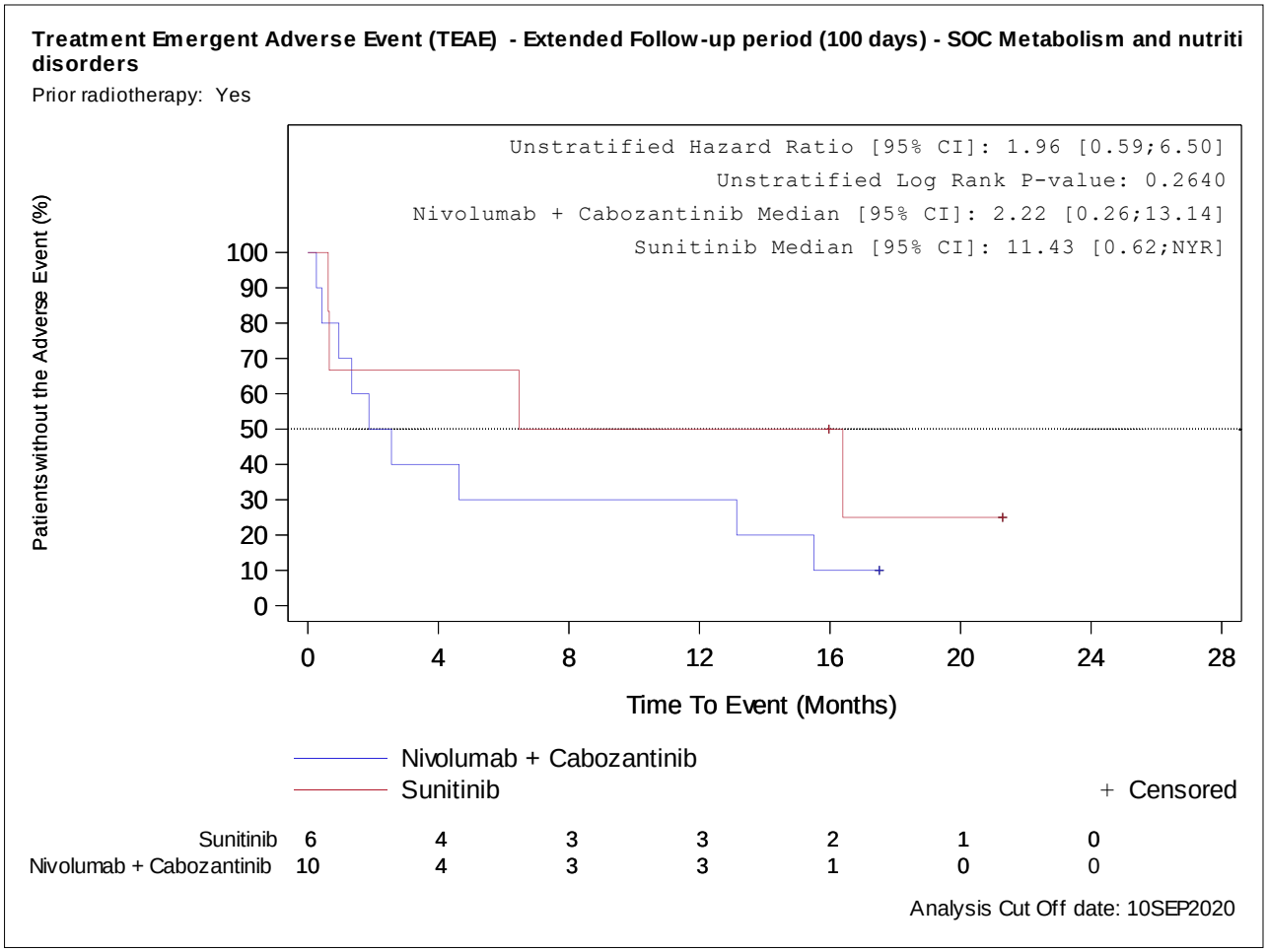
FIGURE 5.30.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



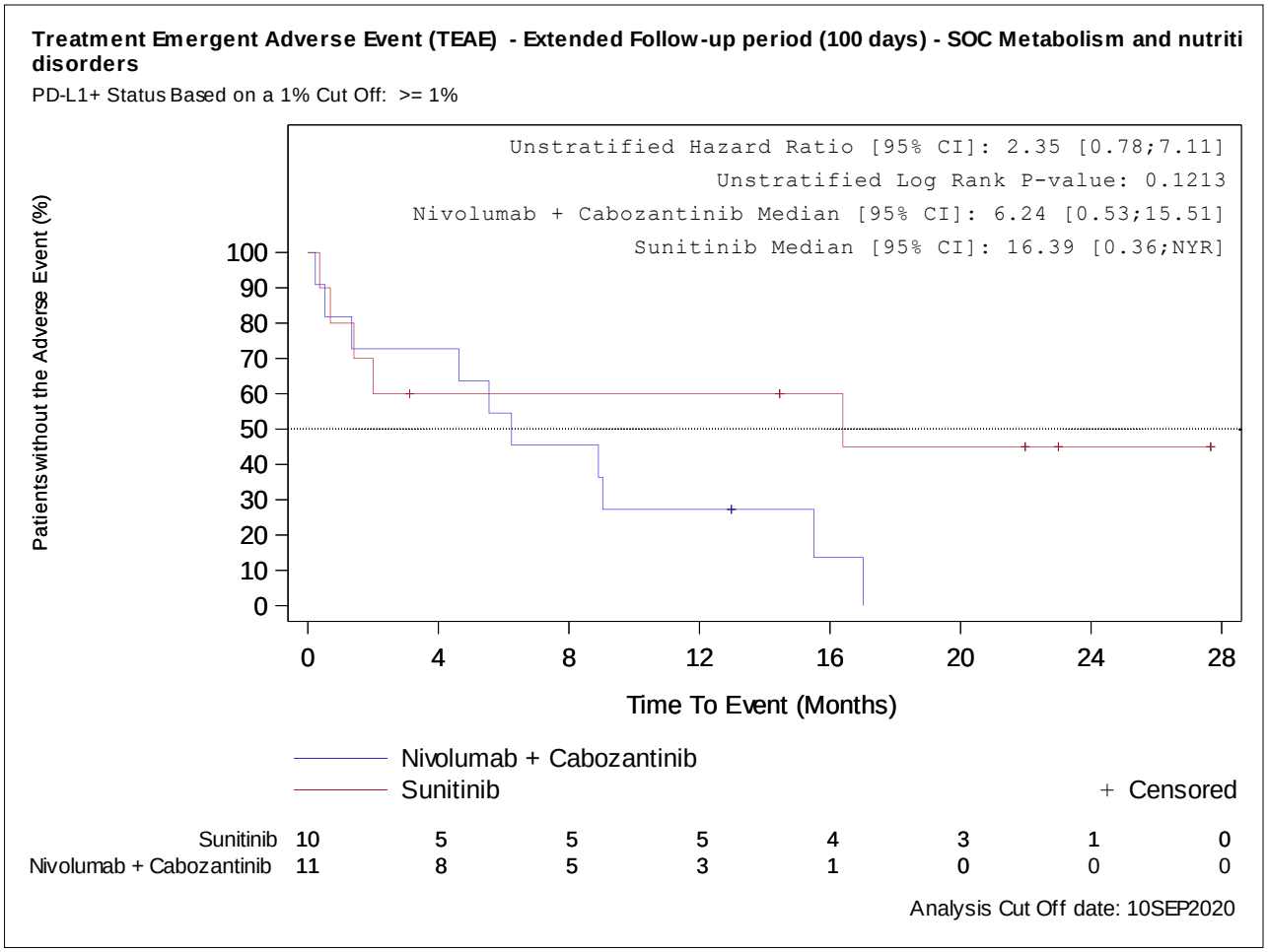

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:06:12

FIGURE 5.30.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:06:18

FIGURE 5.30.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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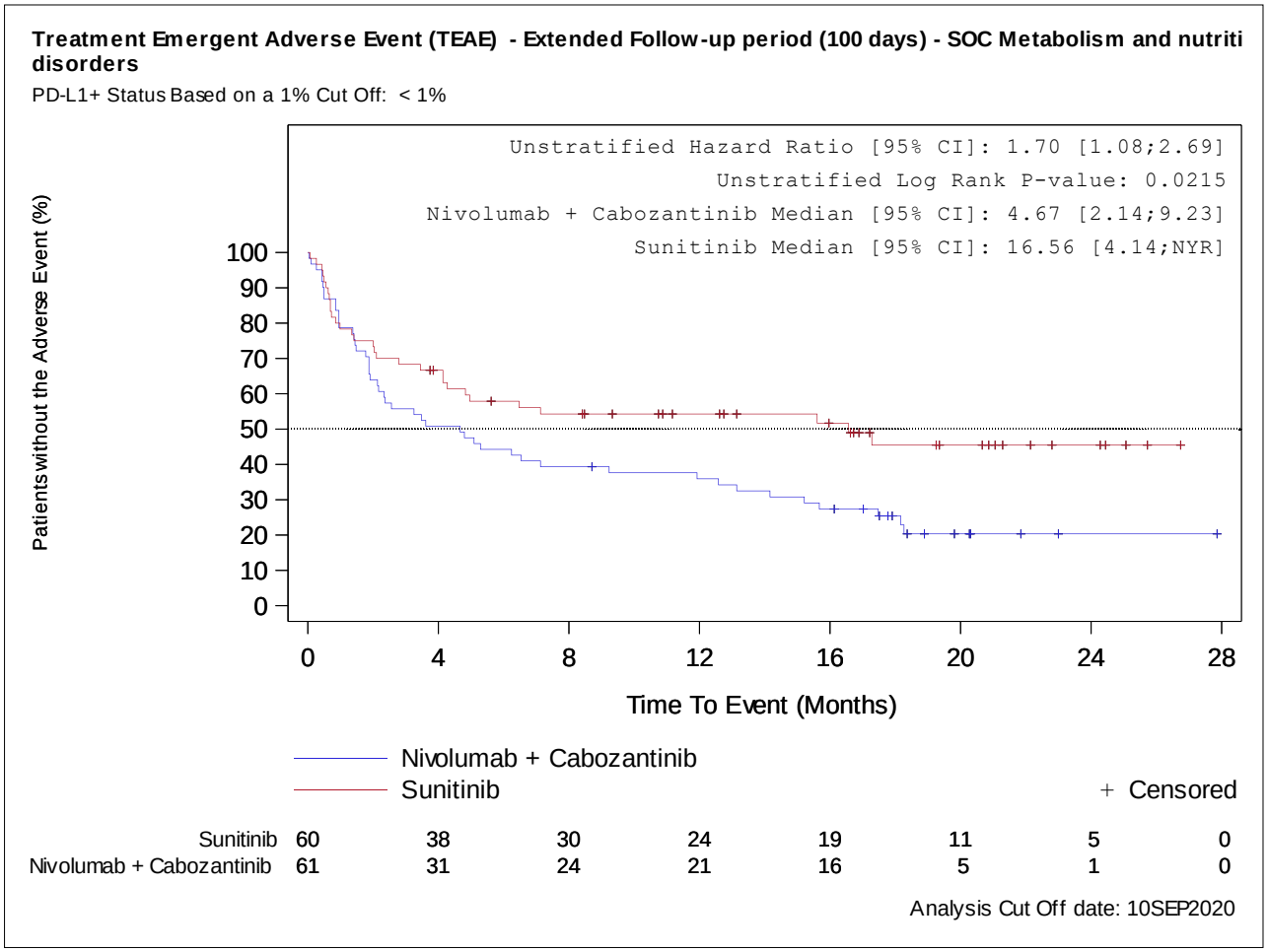
FIGURE 5.30.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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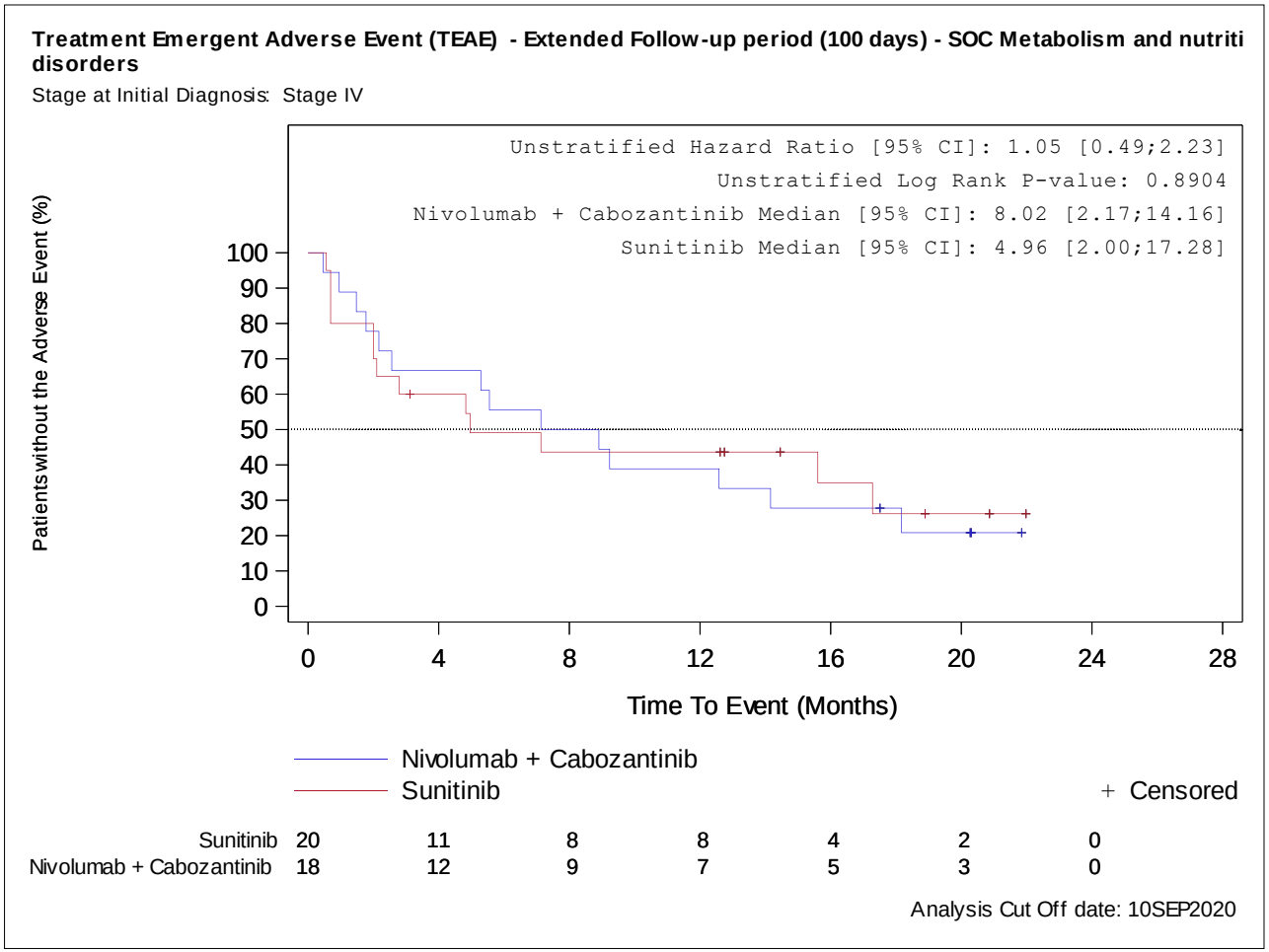
FIGURE 5.30.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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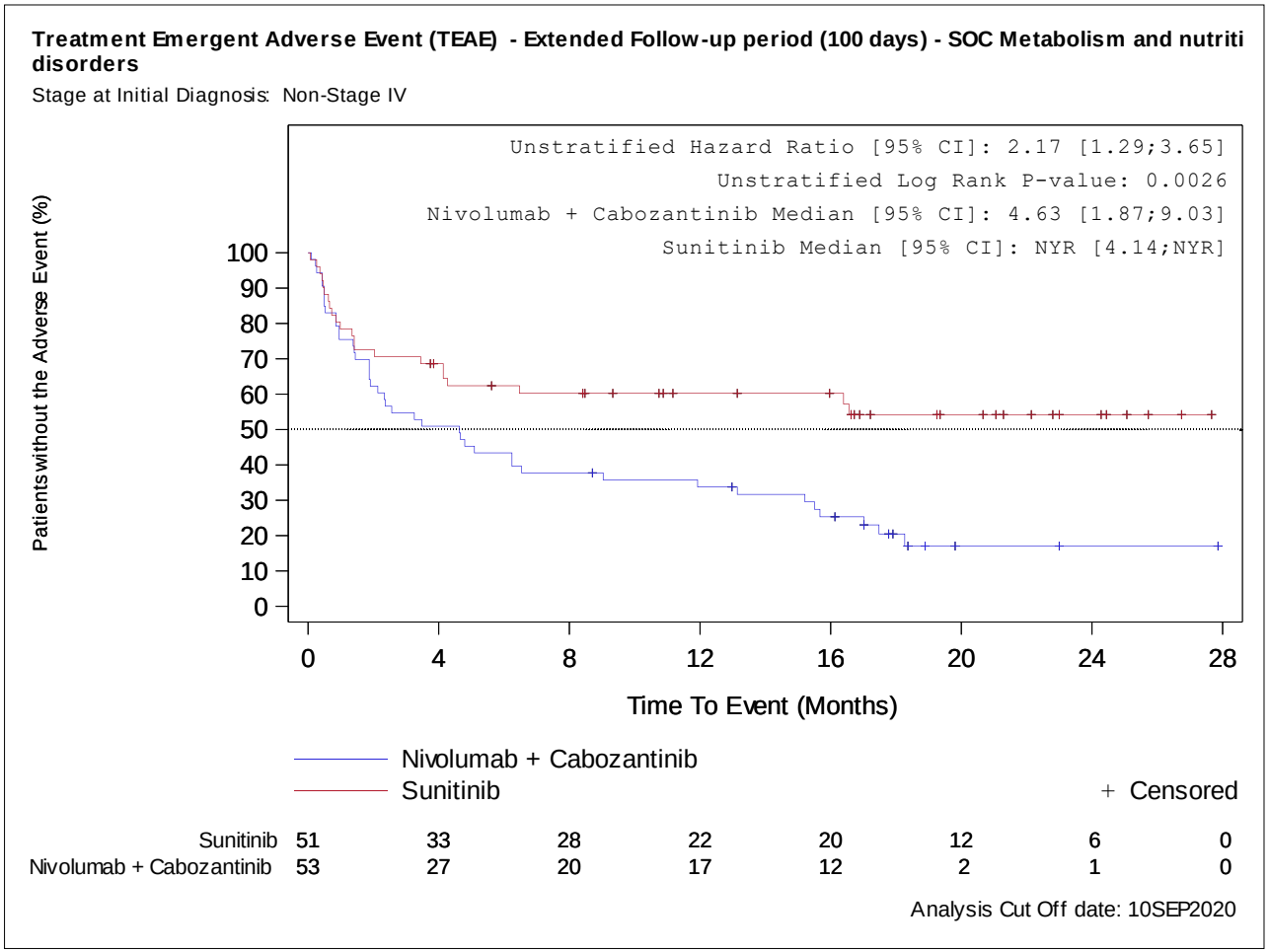
FIGURE 5.30.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - SOC Metabolism and nutrition disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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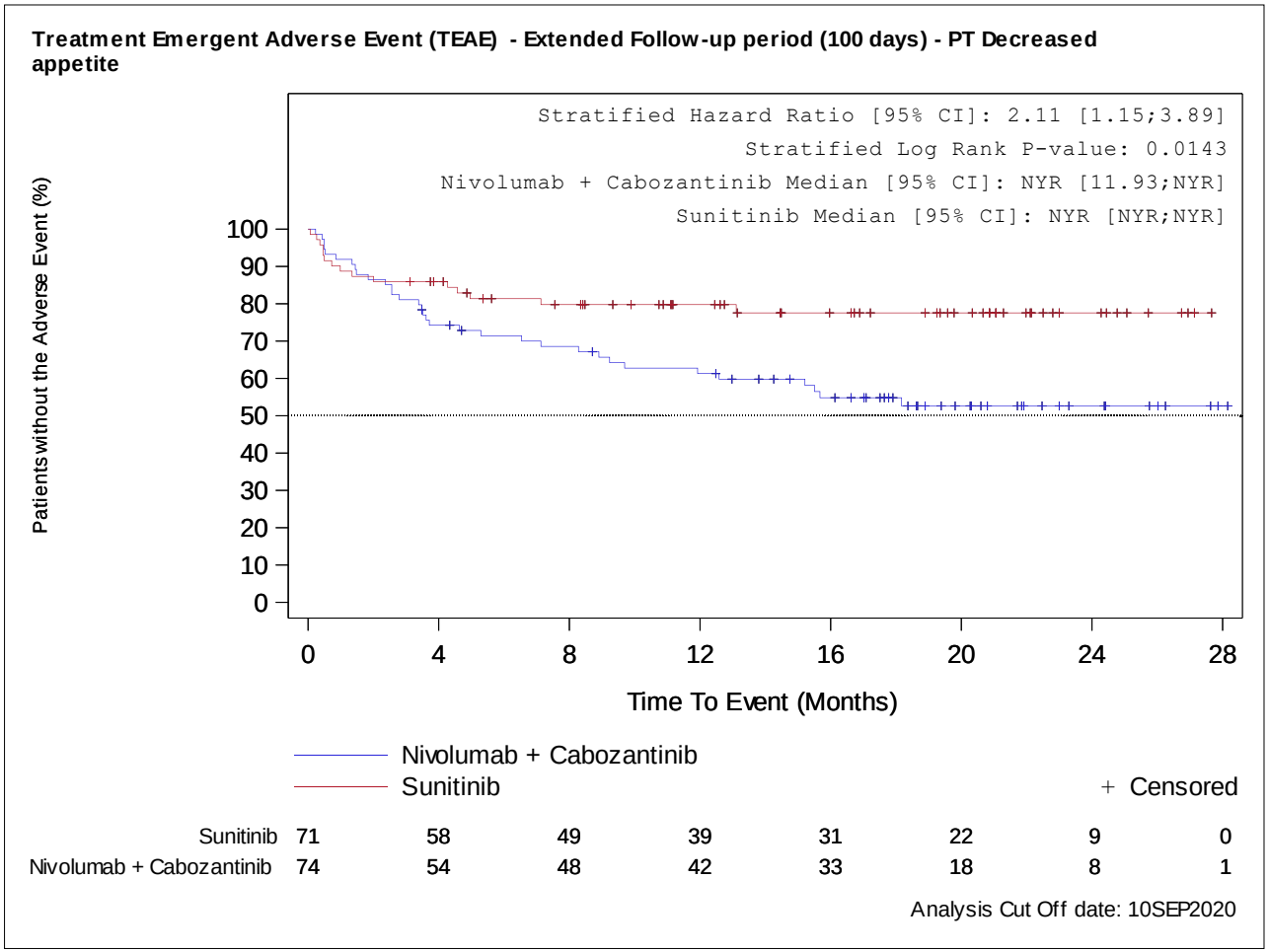
FIGURE 5.31.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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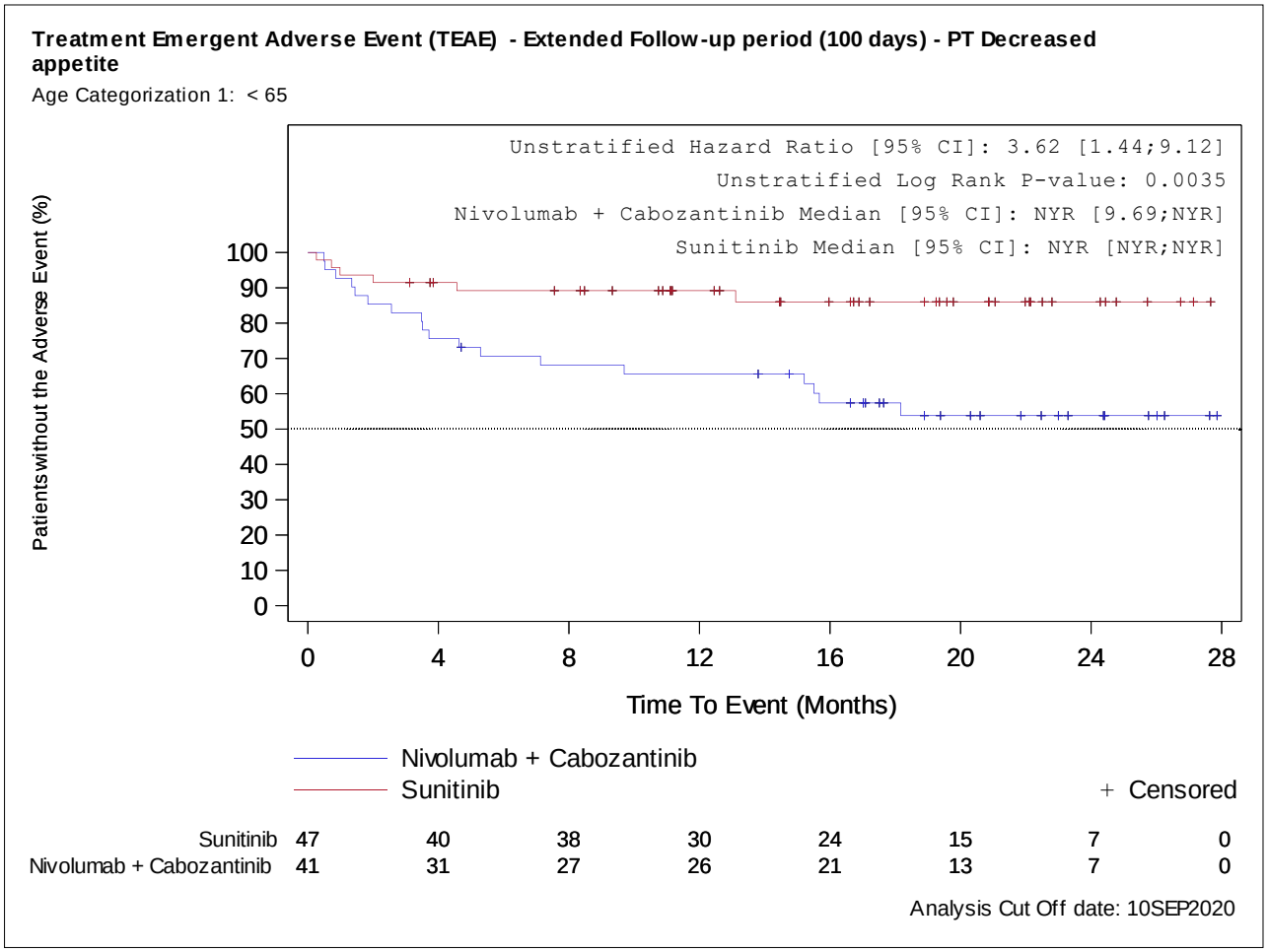
FIGURE 5.31.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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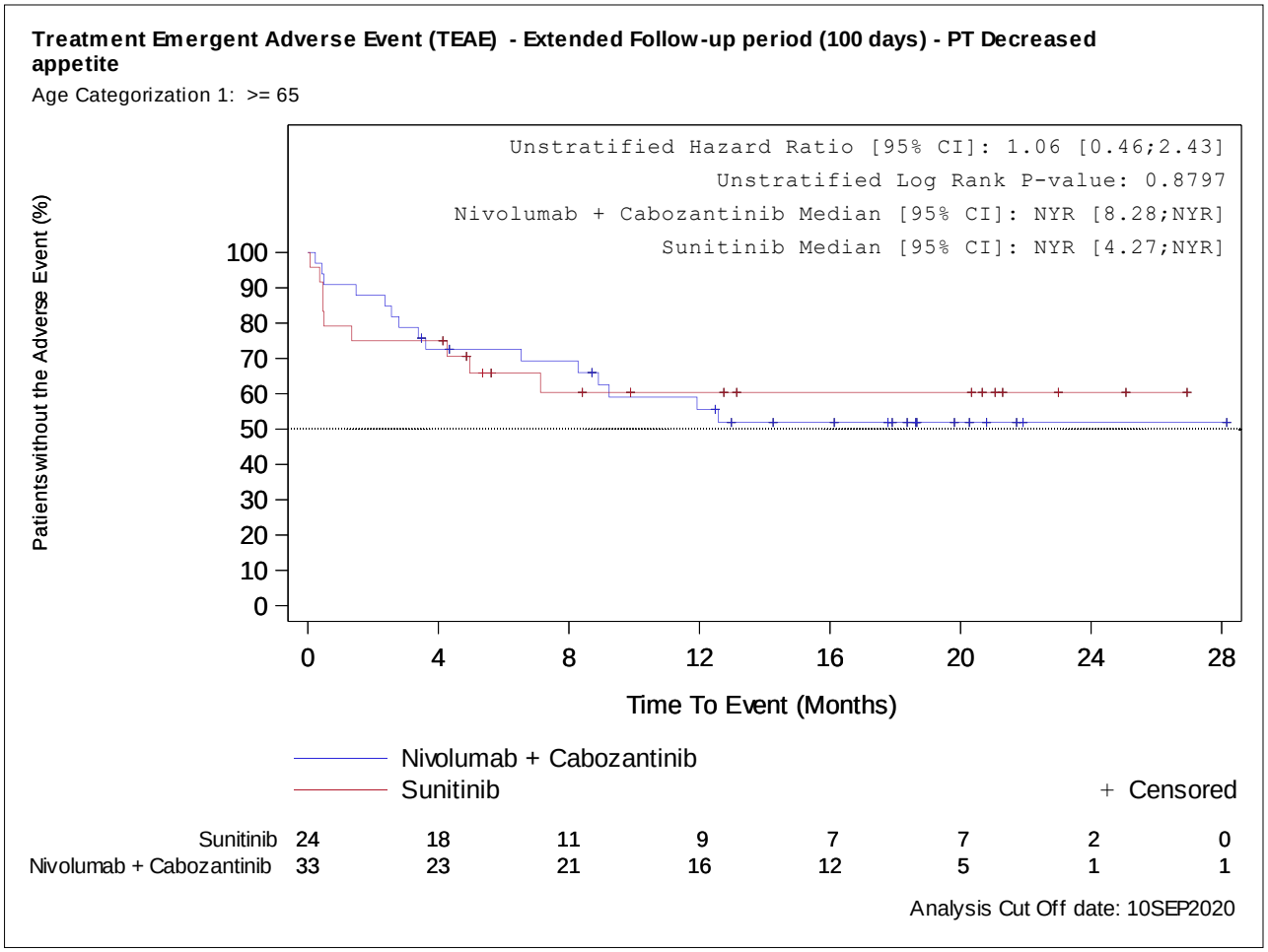
FIGURE 5.31.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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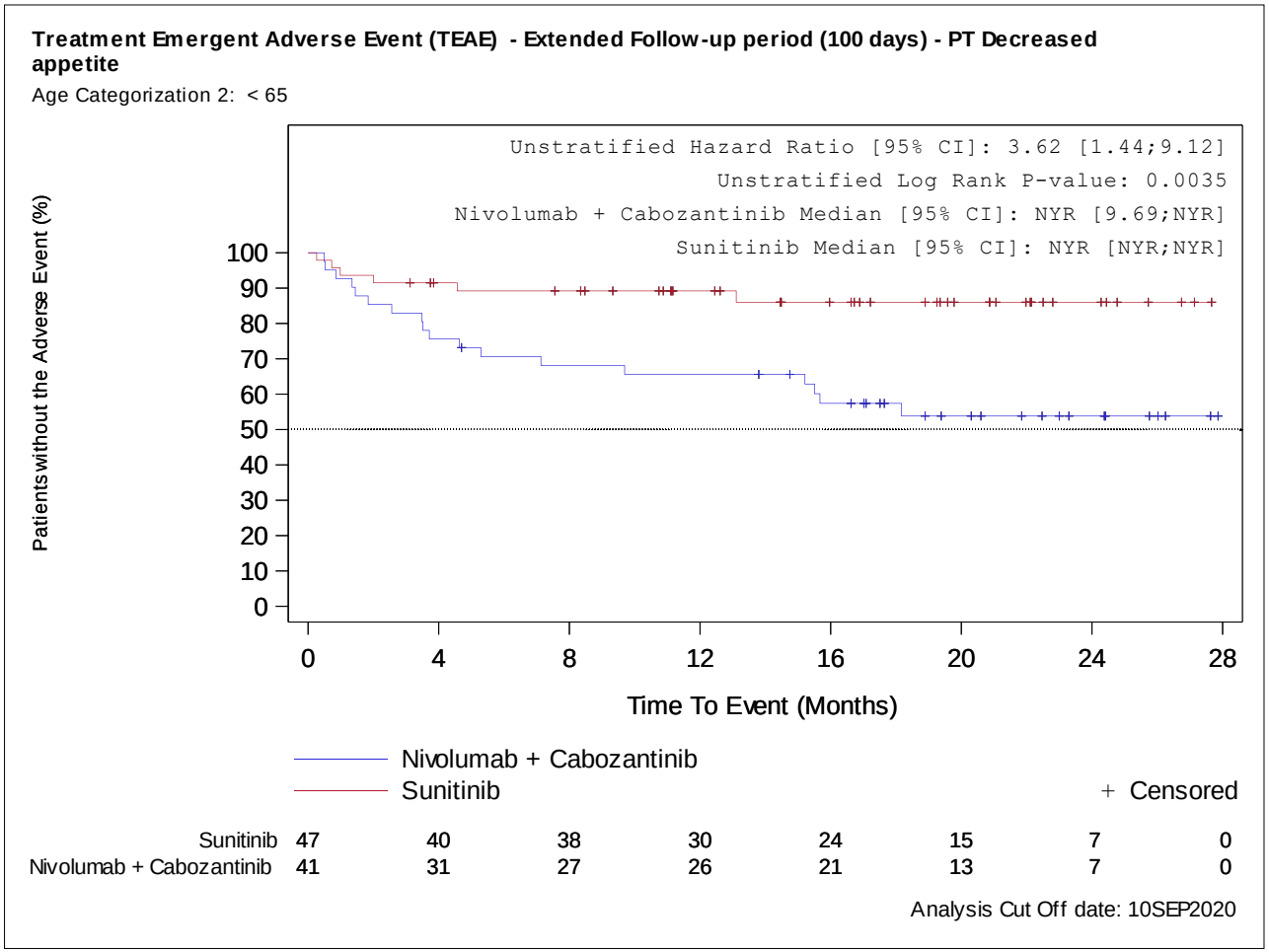
FIGURE 5.31.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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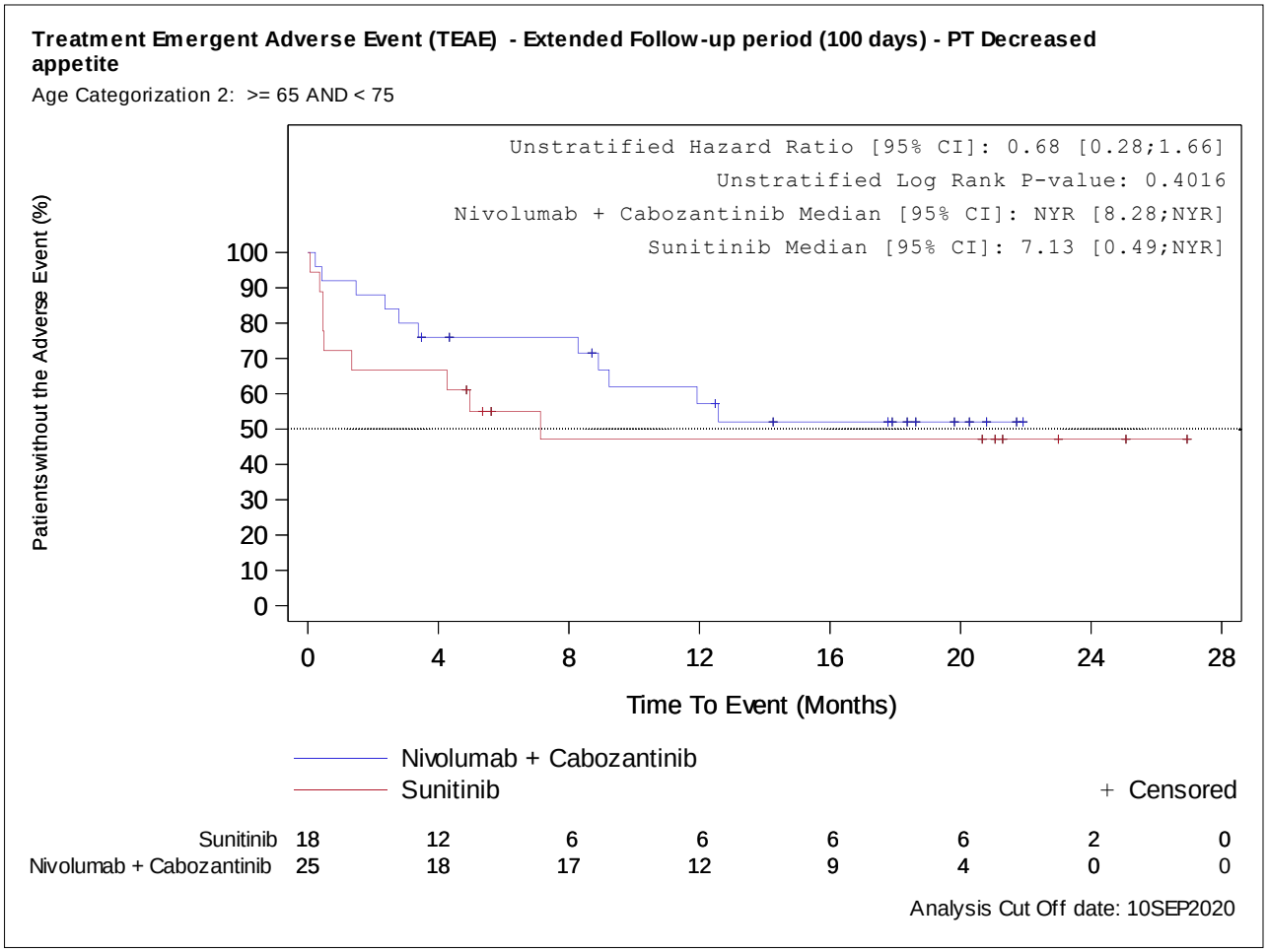
FIGURE 5.31.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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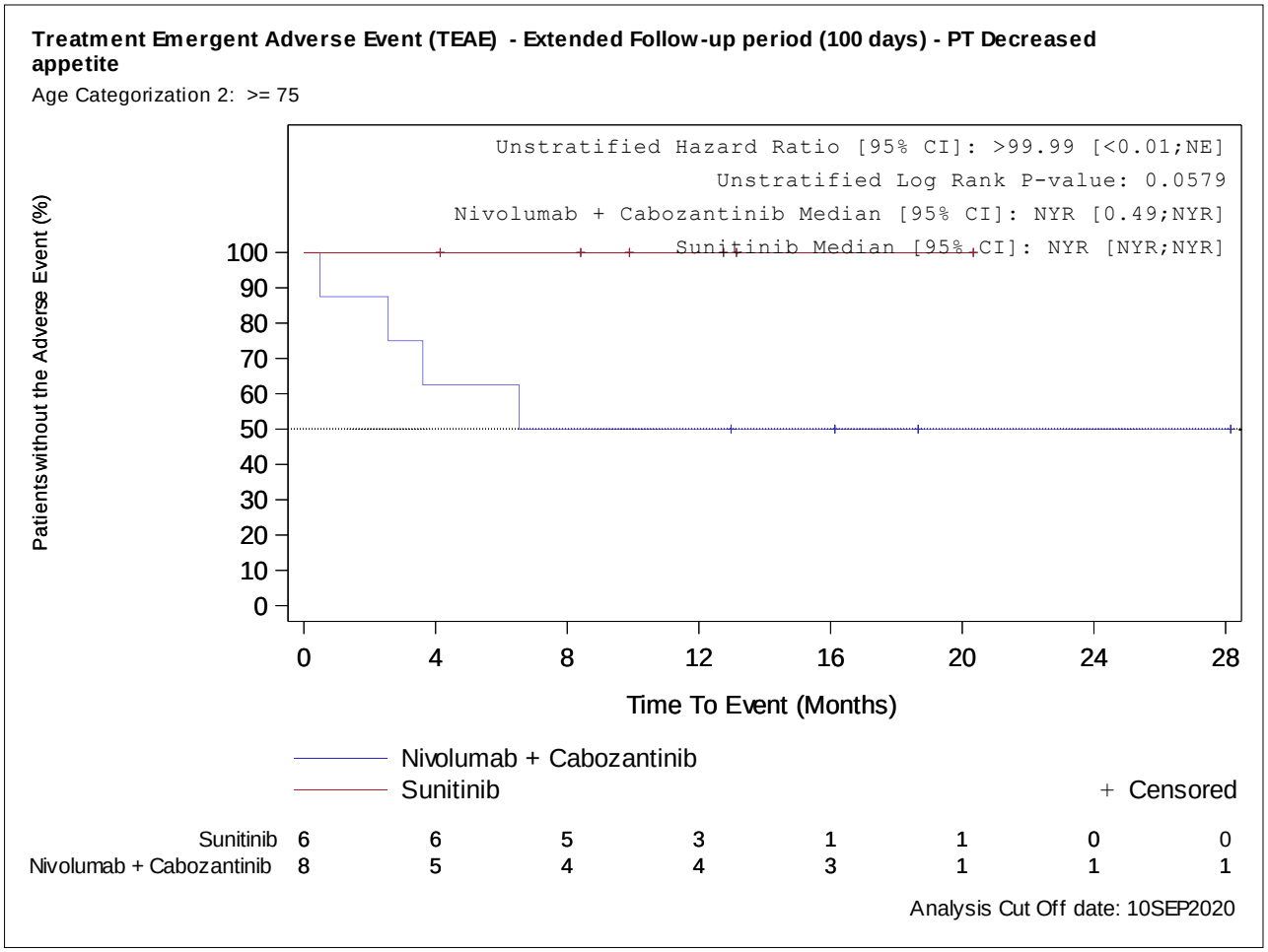
FIGURE 5.31.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
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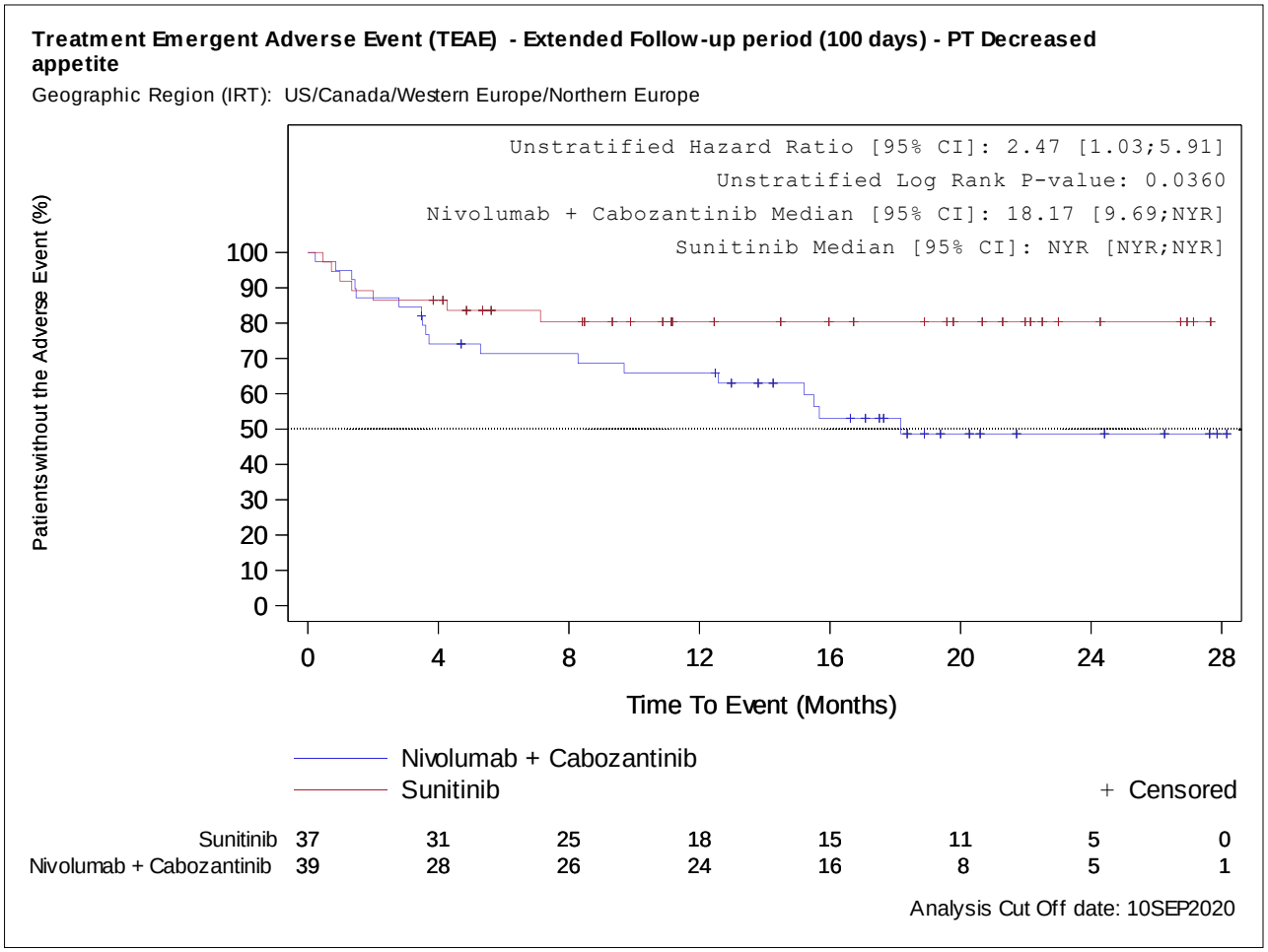
FIGURE 5.31.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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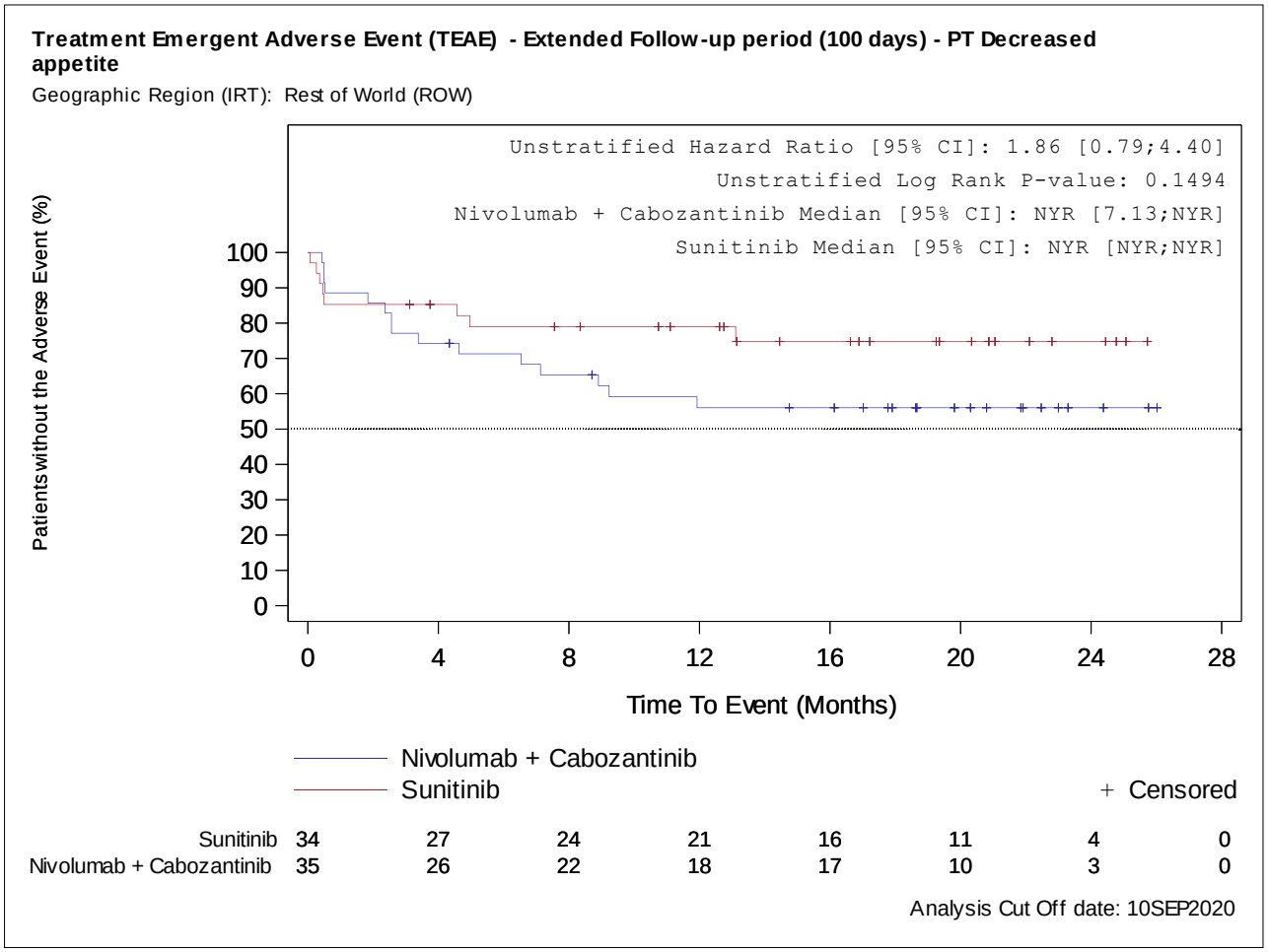
FIGURE 5.31.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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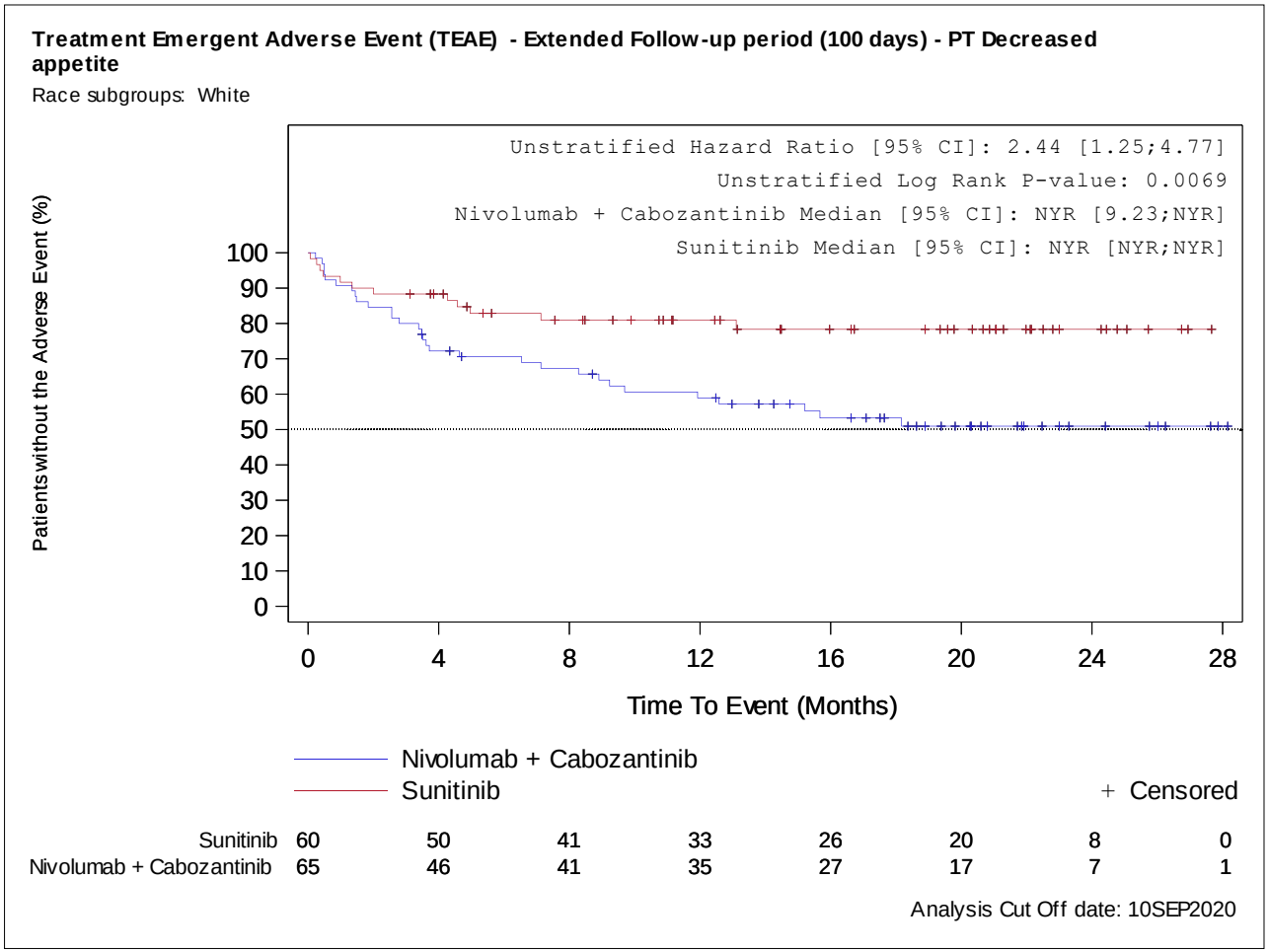
FIGURE 5.31.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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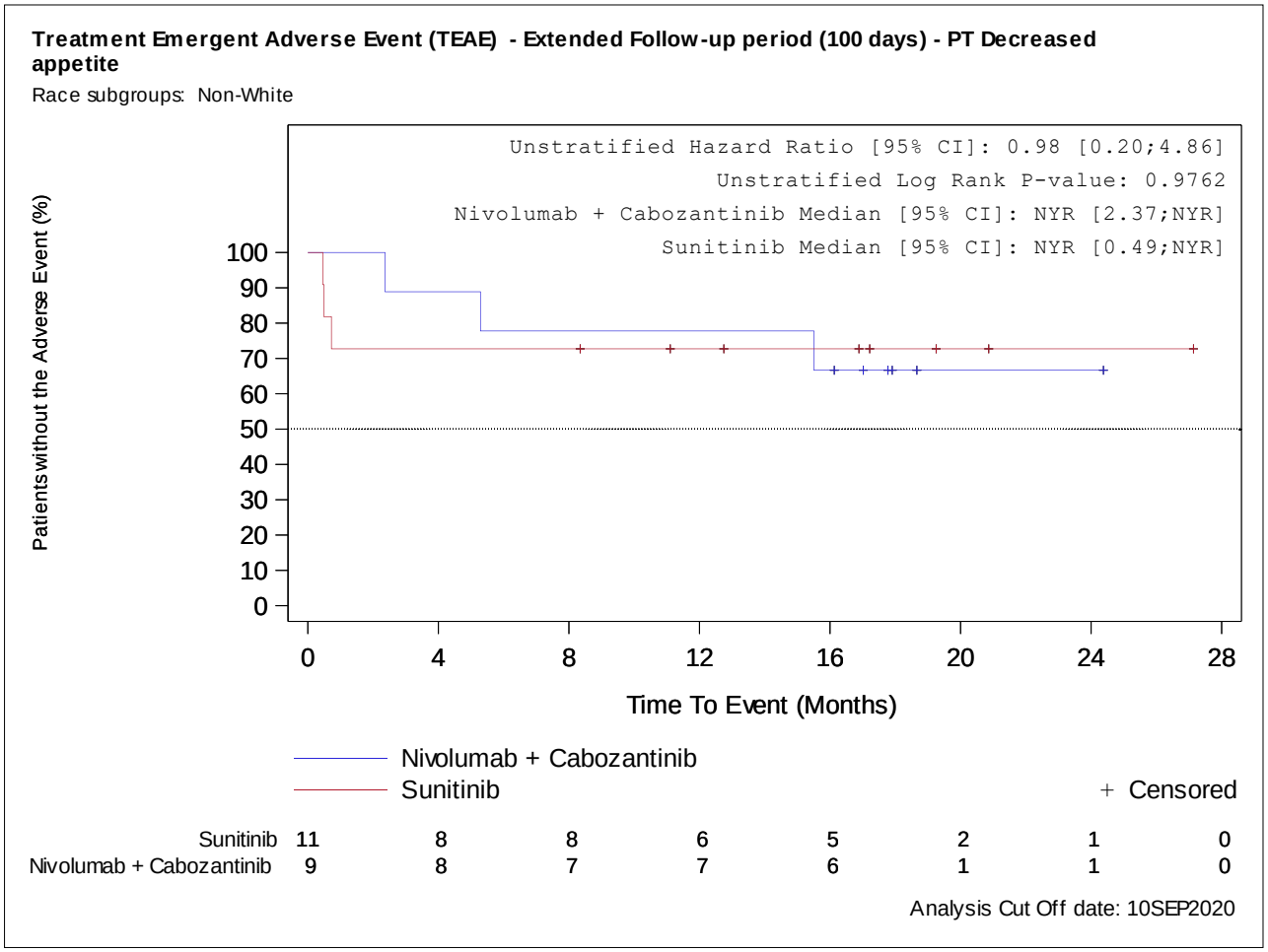
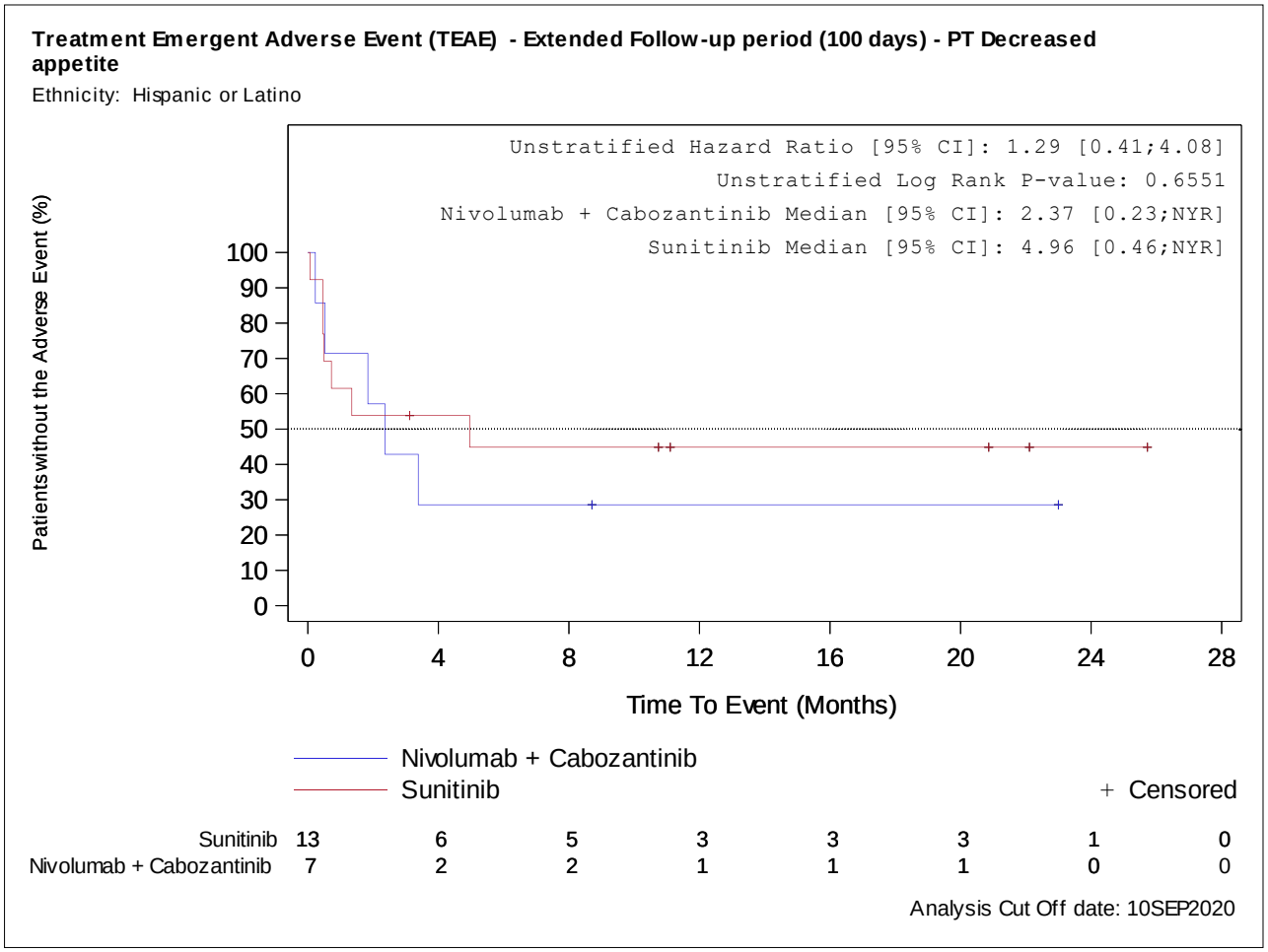
FIGURE 5.31.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:11:12

FIGURE 5.31.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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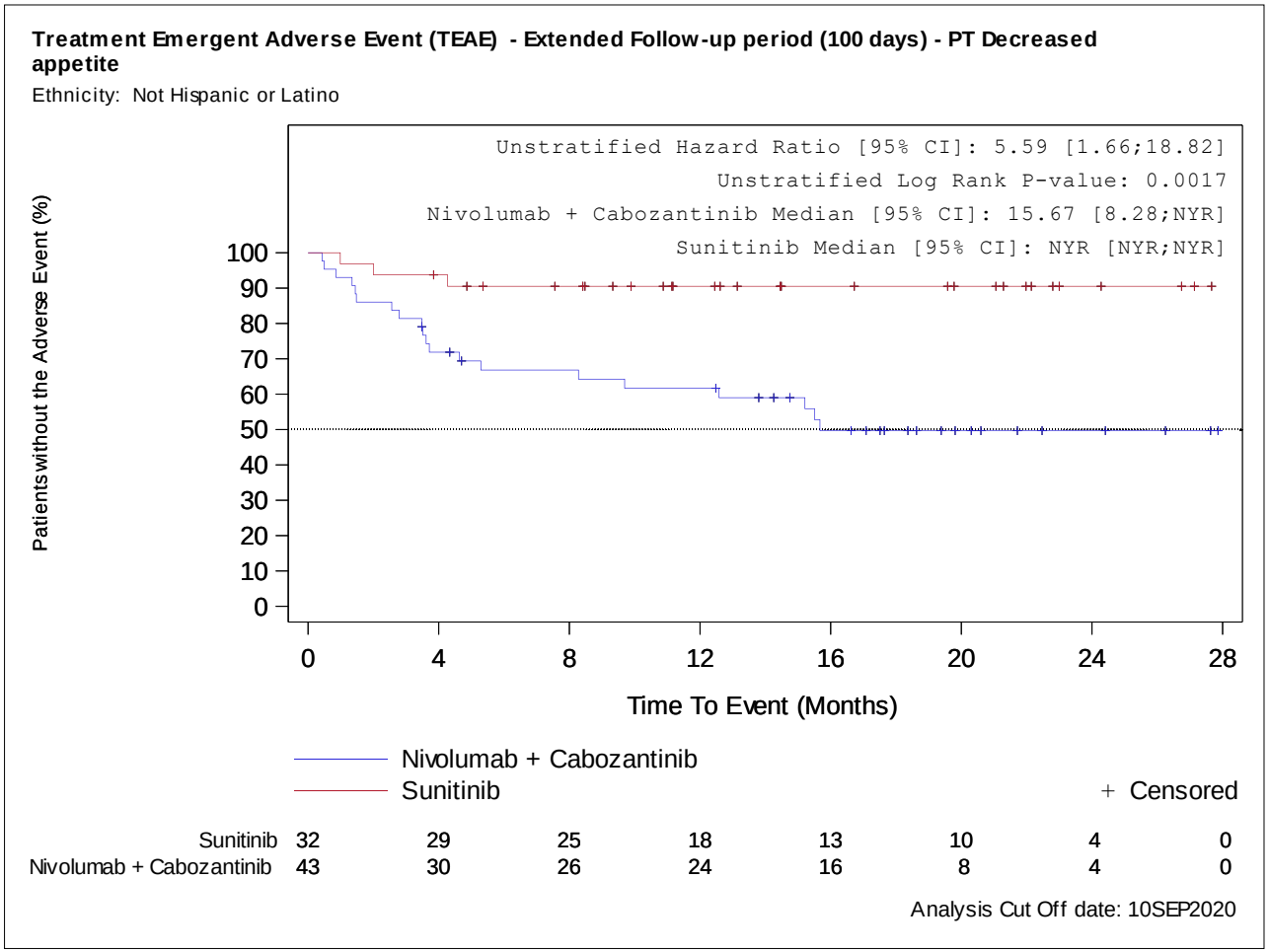
FIGURE 5.31.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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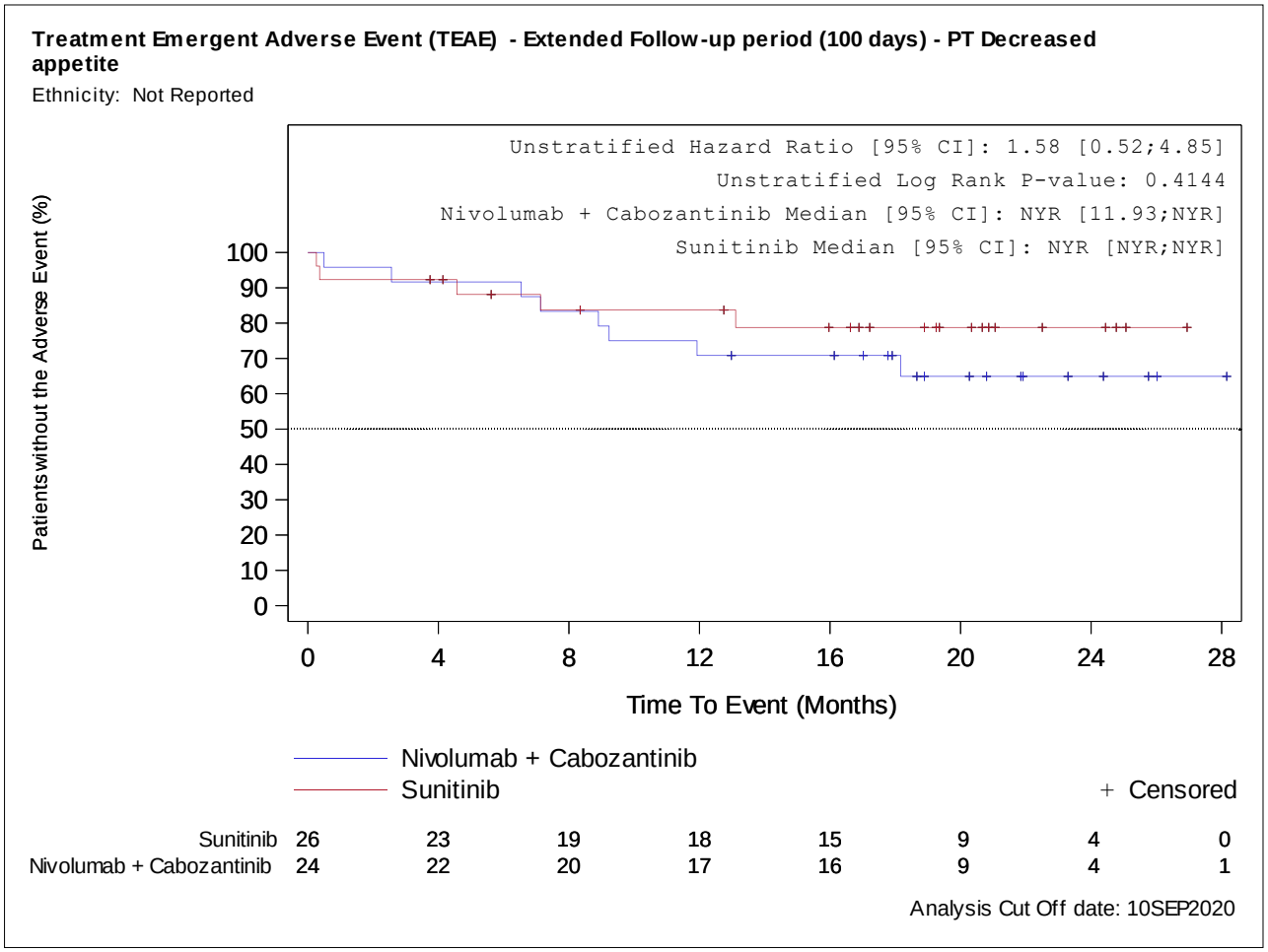
FIGURE 5.31.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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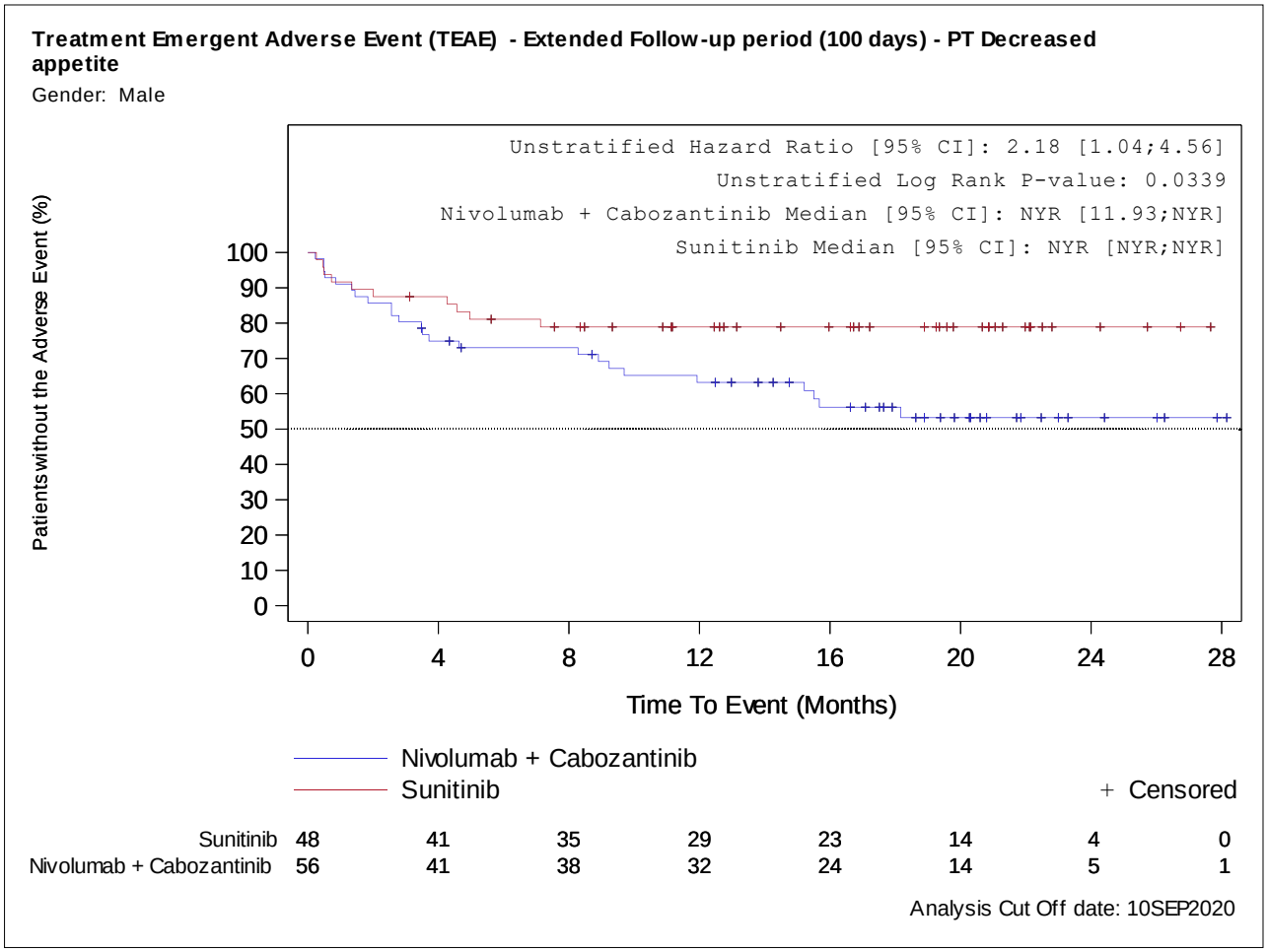
FIGURE 5.31.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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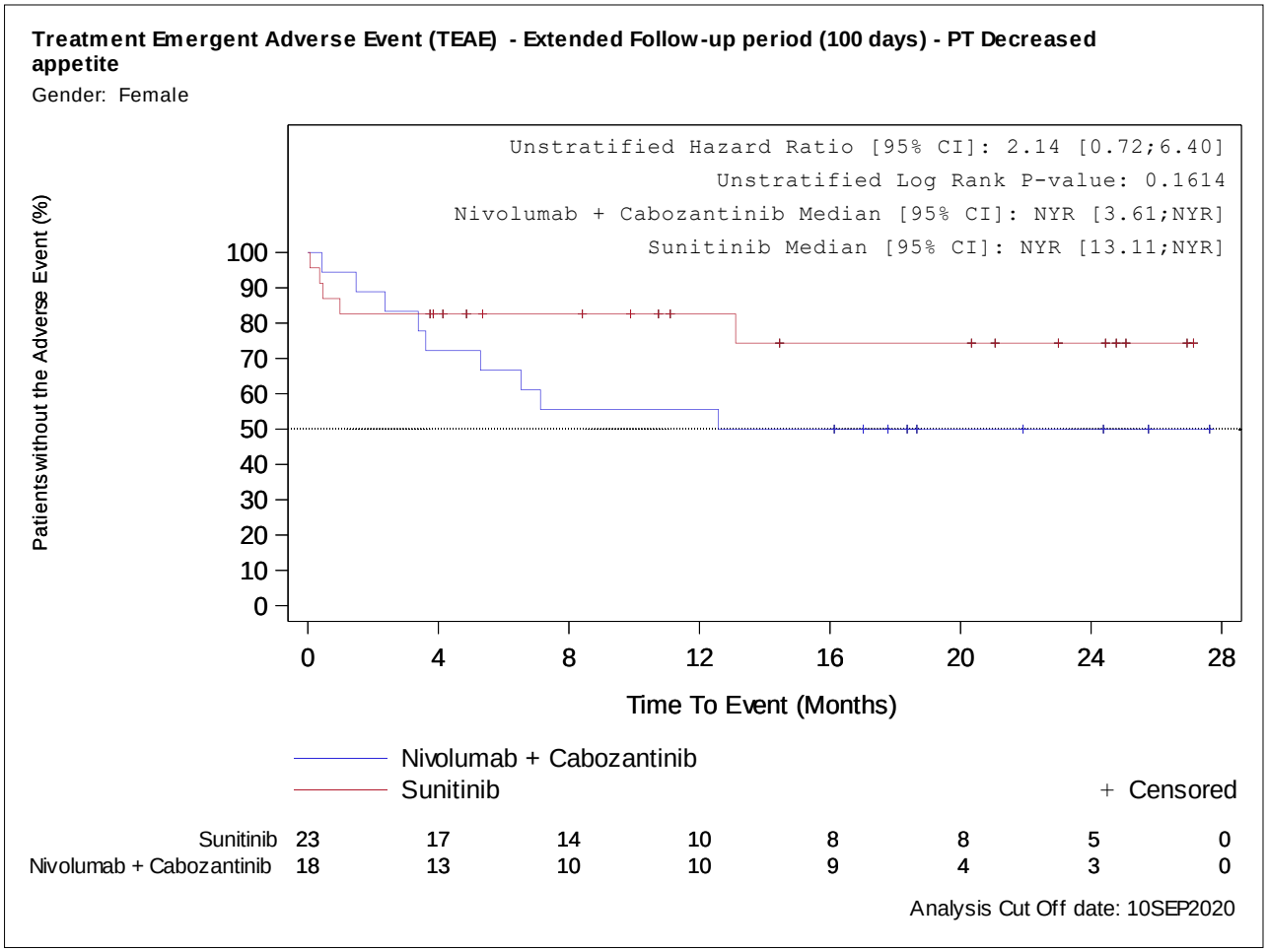
FIGURE 5.31.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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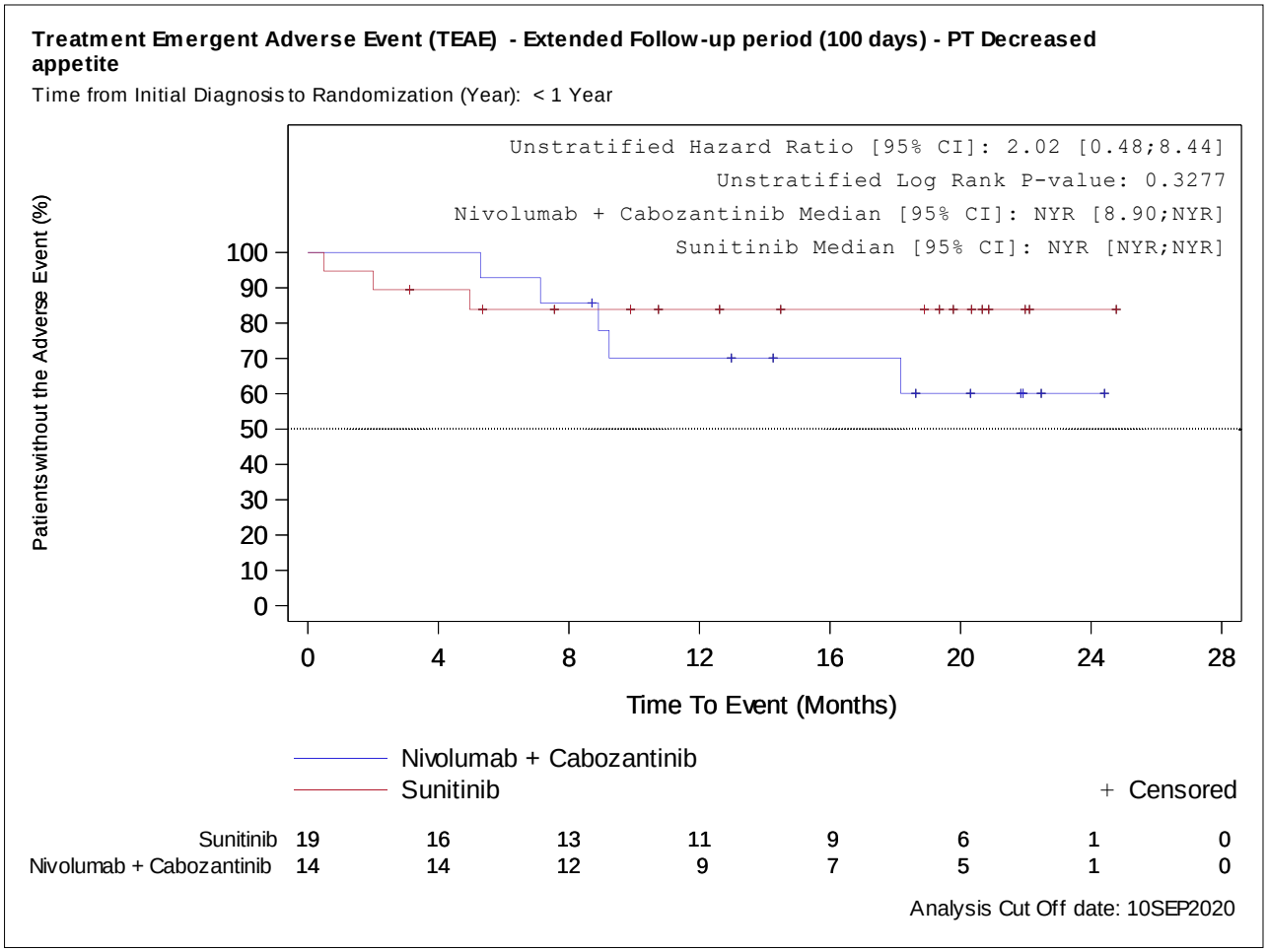
FIGURE 5.31.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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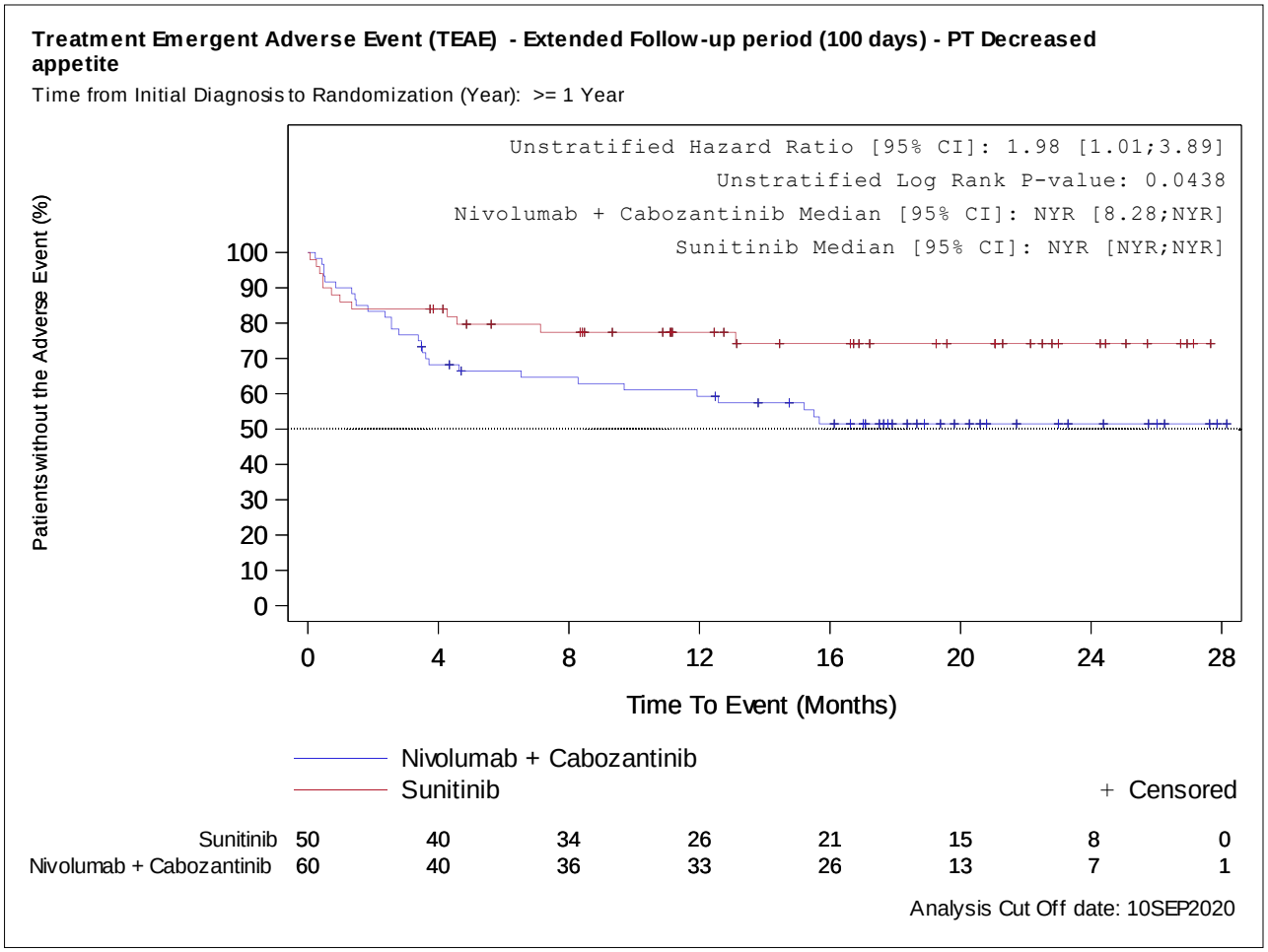
FIGURE 5.31.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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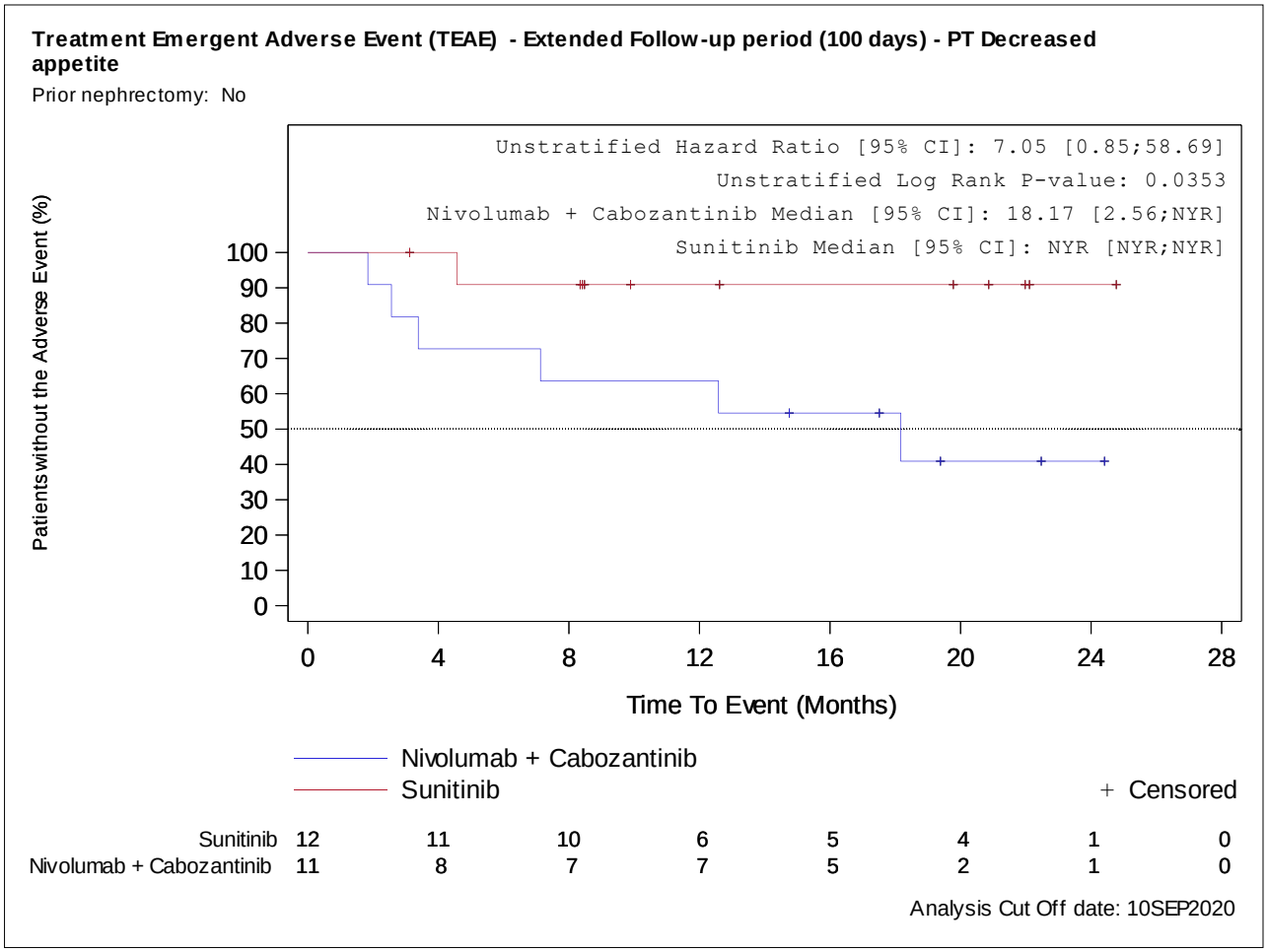
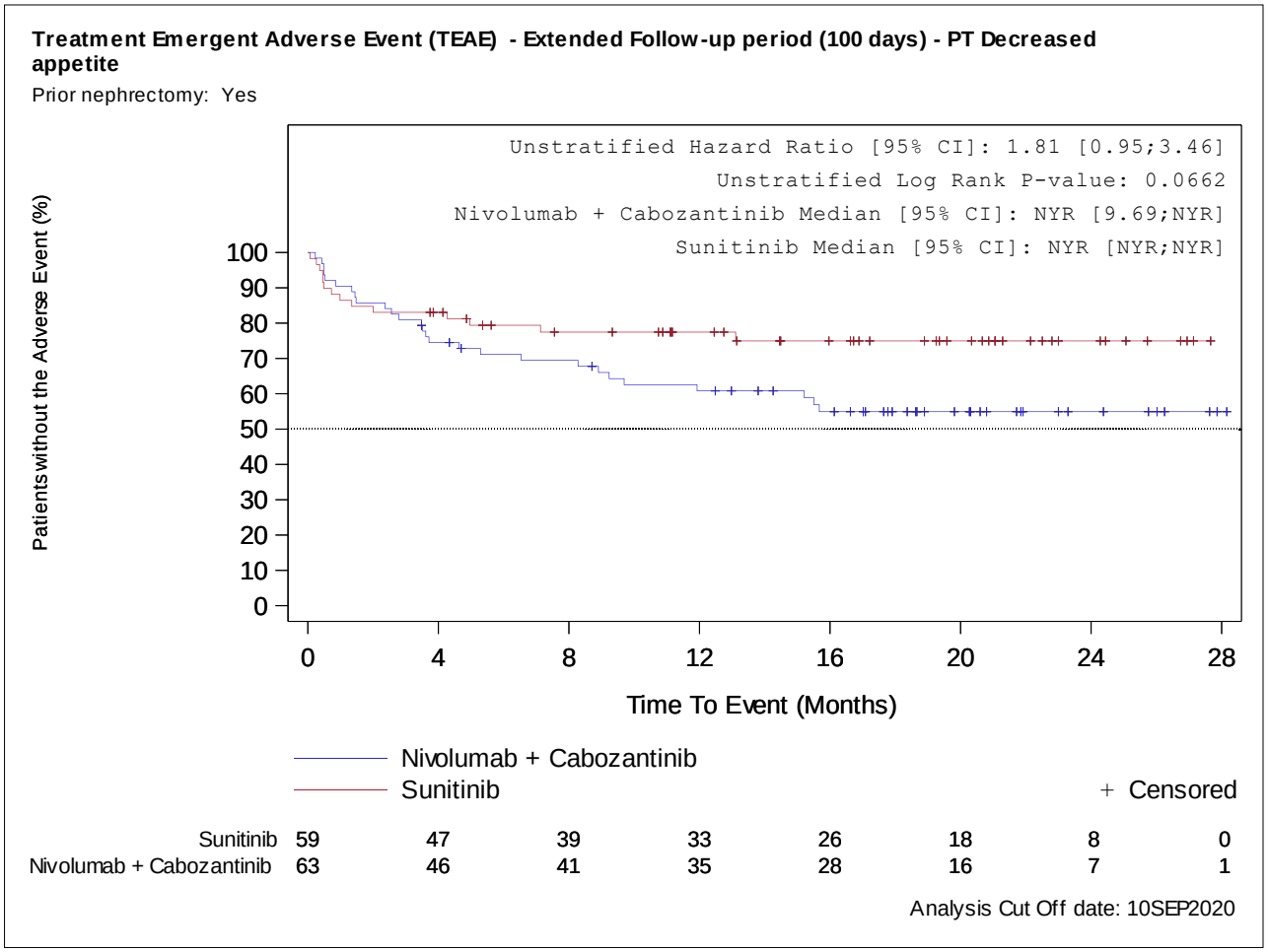
FIGURE 5.31.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



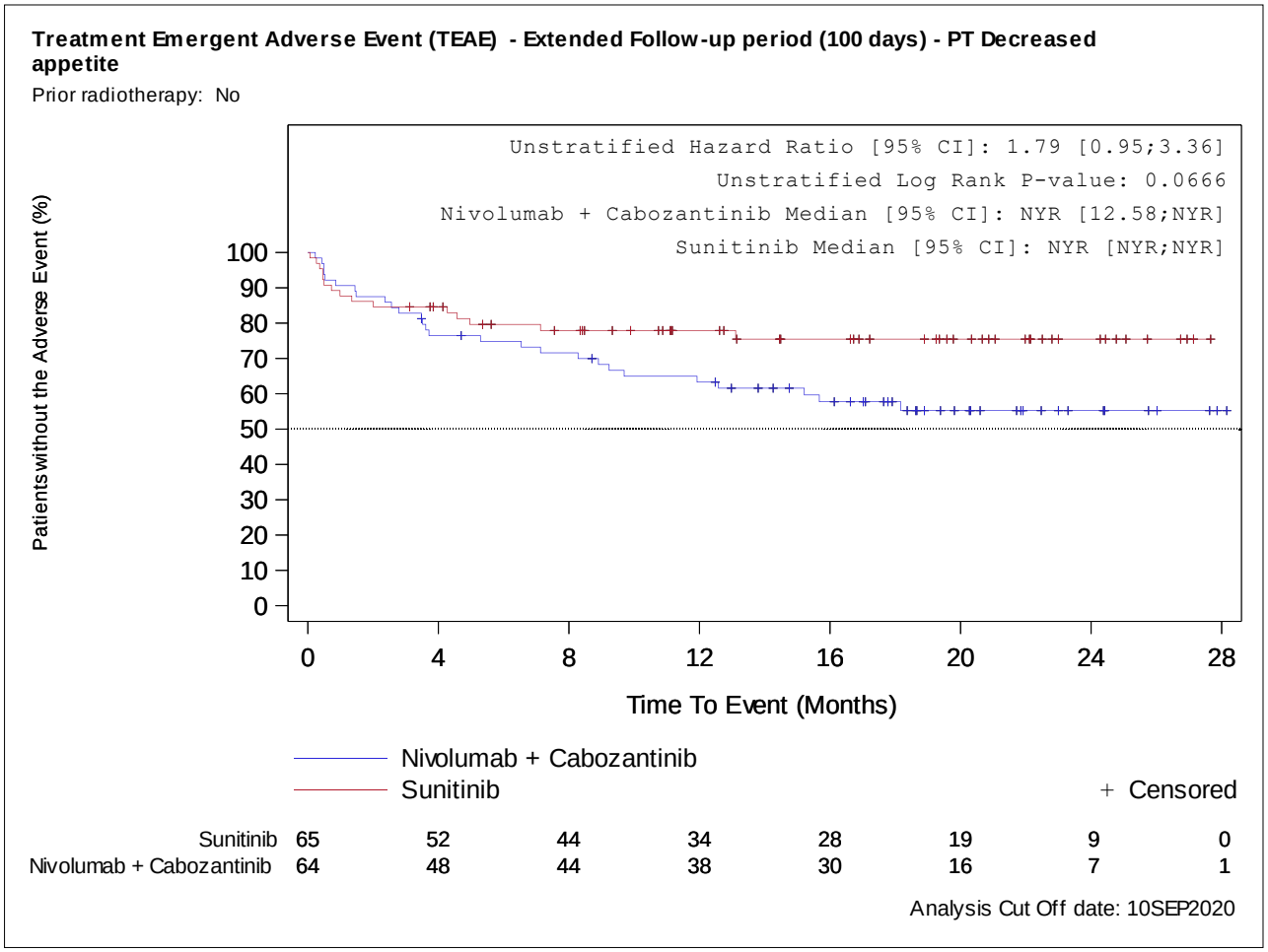

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:12:56

FIGURE 5.31.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



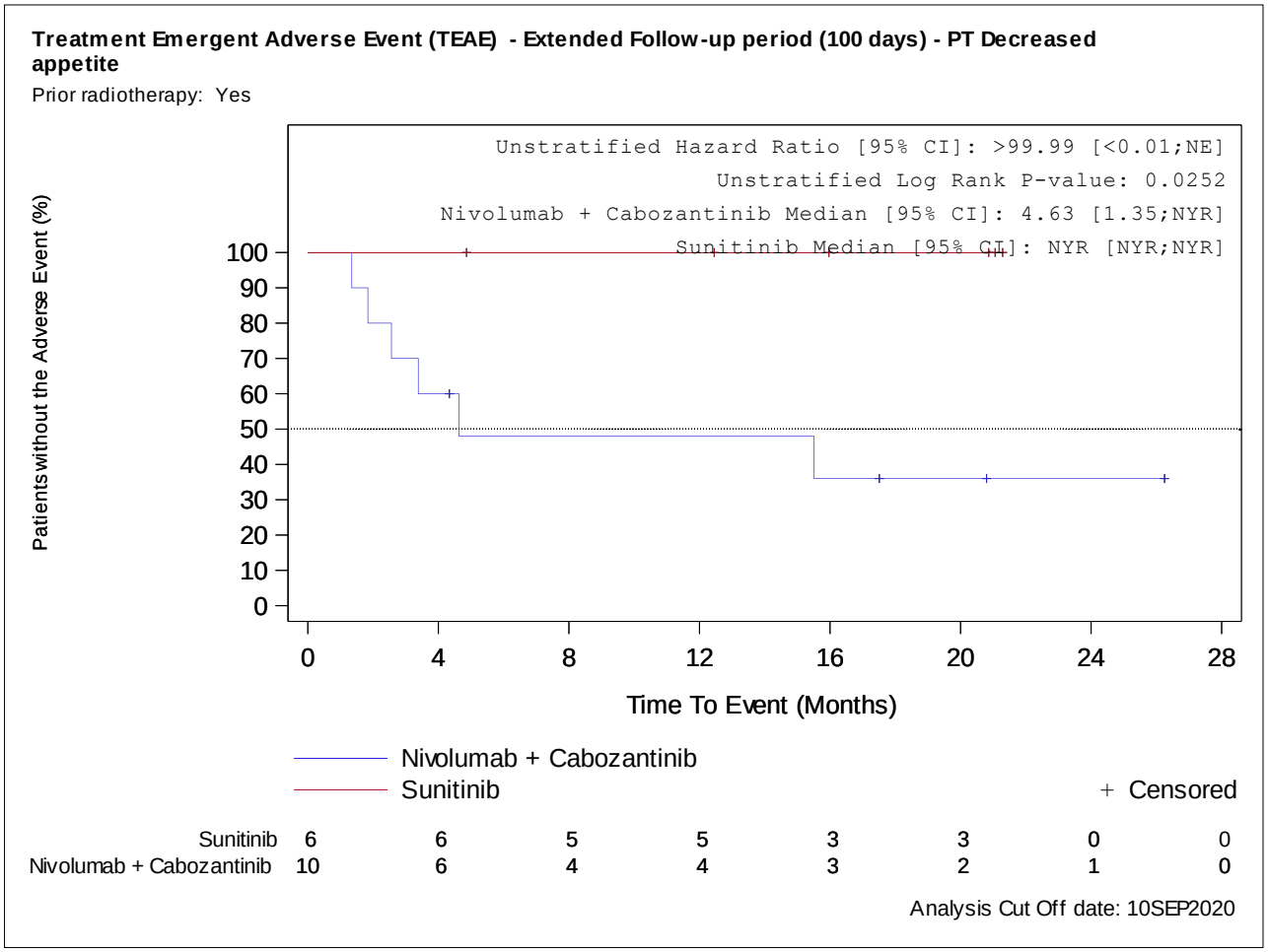

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:13:01

FIGURE 5.31.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



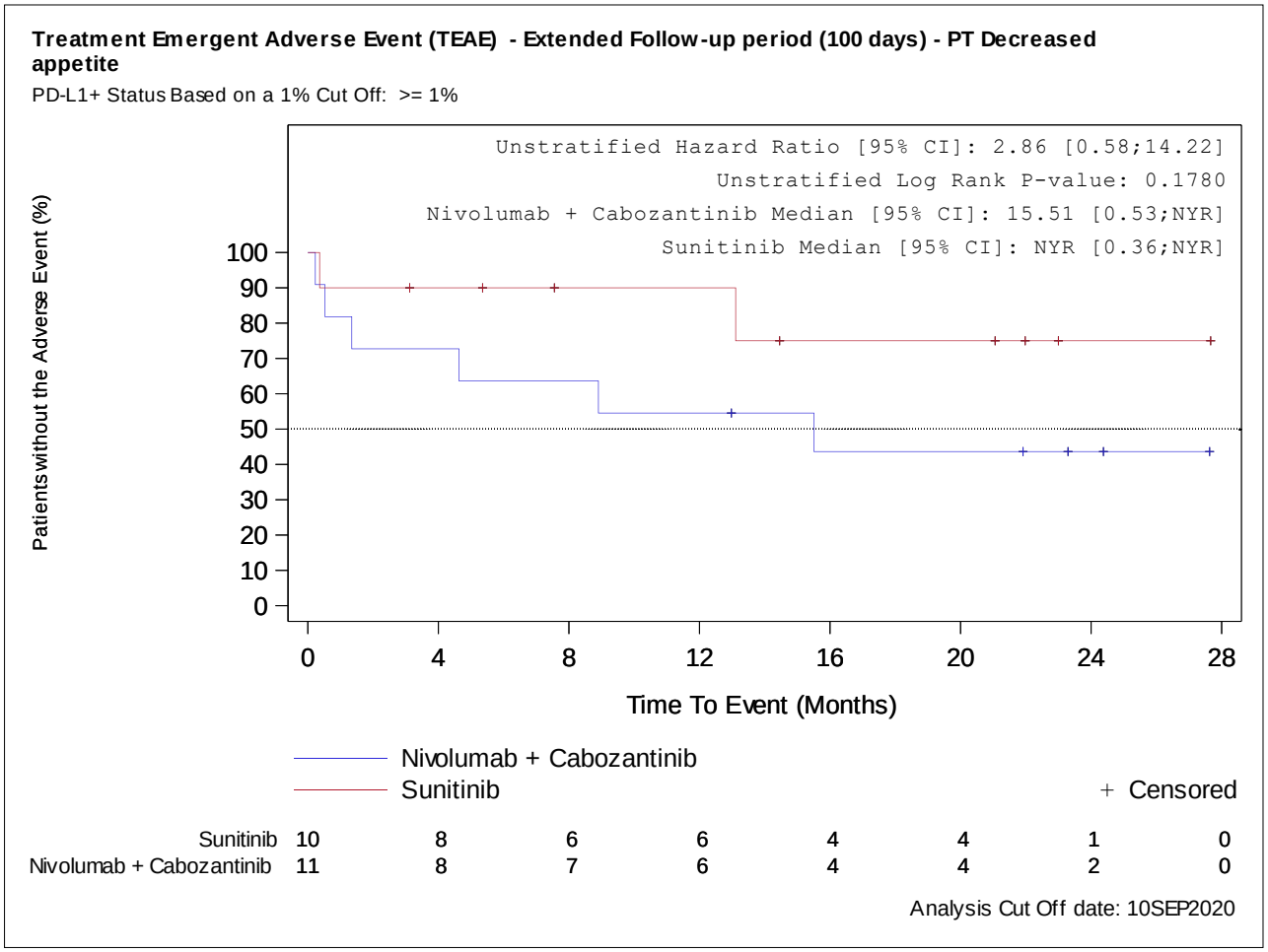

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:13:07

FIGURE 5.31.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



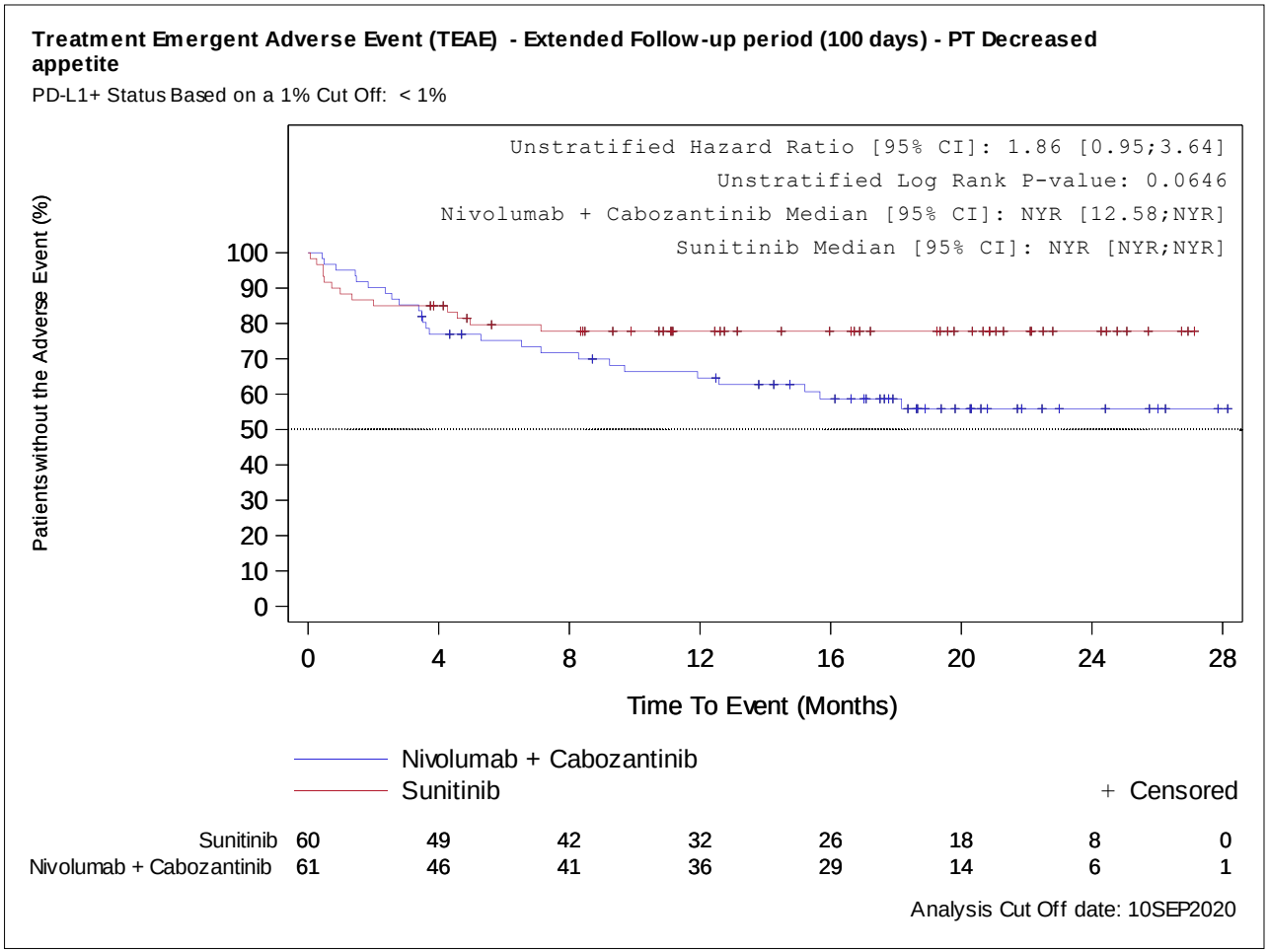

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:13:12

FIGURE 5.31.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



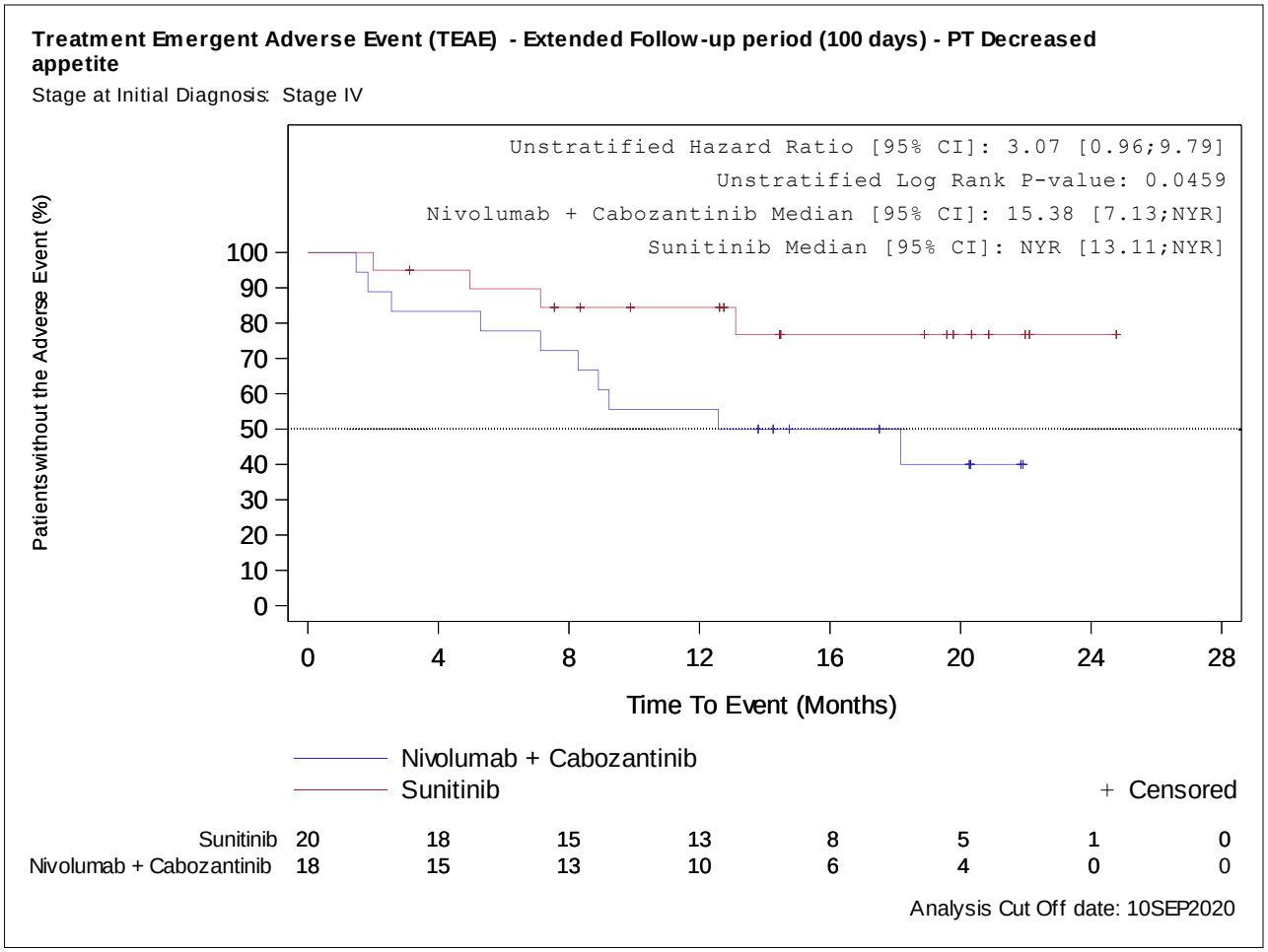

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:13:18

FIGURE 5.31.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:13:24

FIGURE 5.31.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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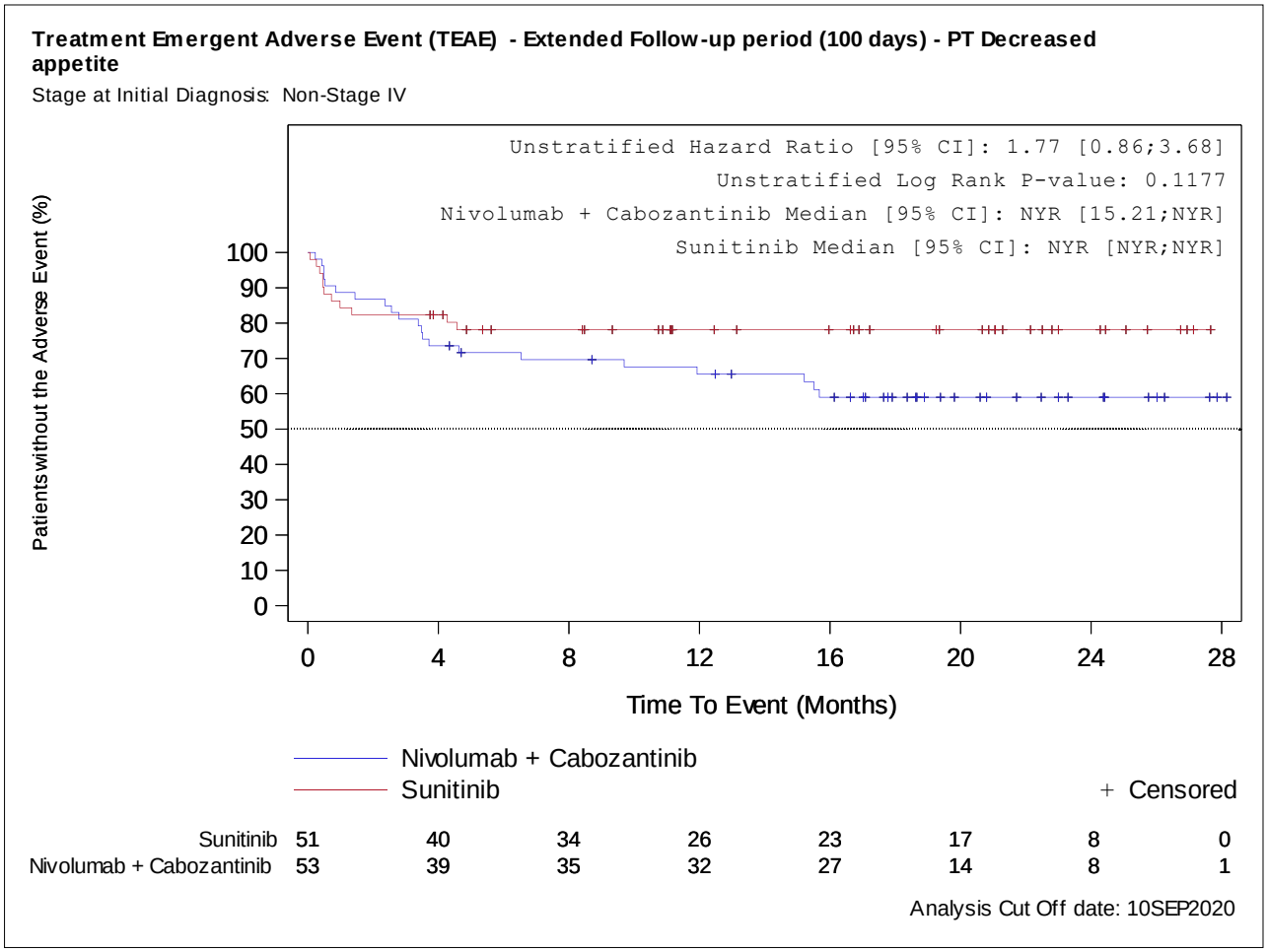
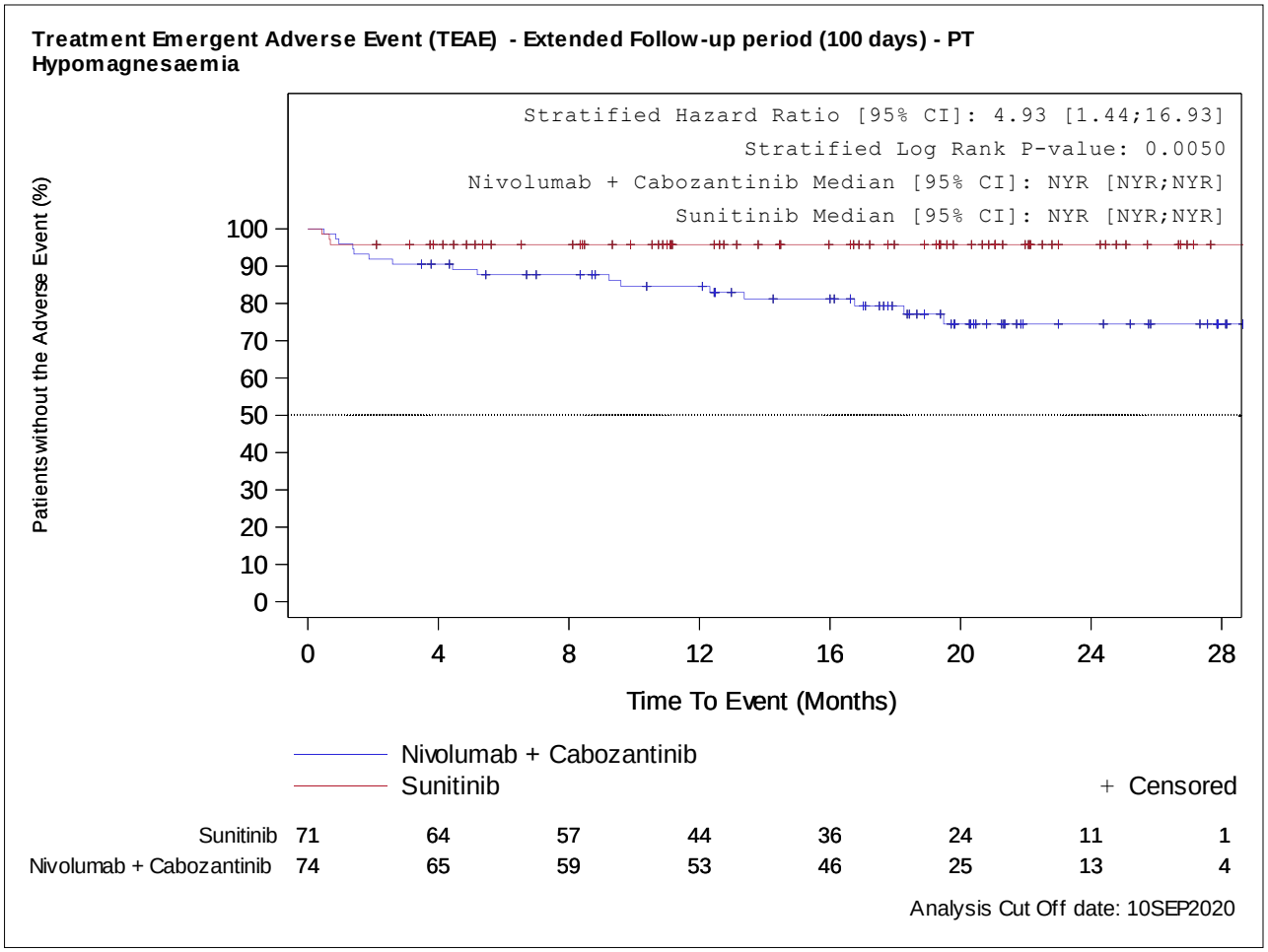
FIGURE 5.31.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Decreased appetite - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



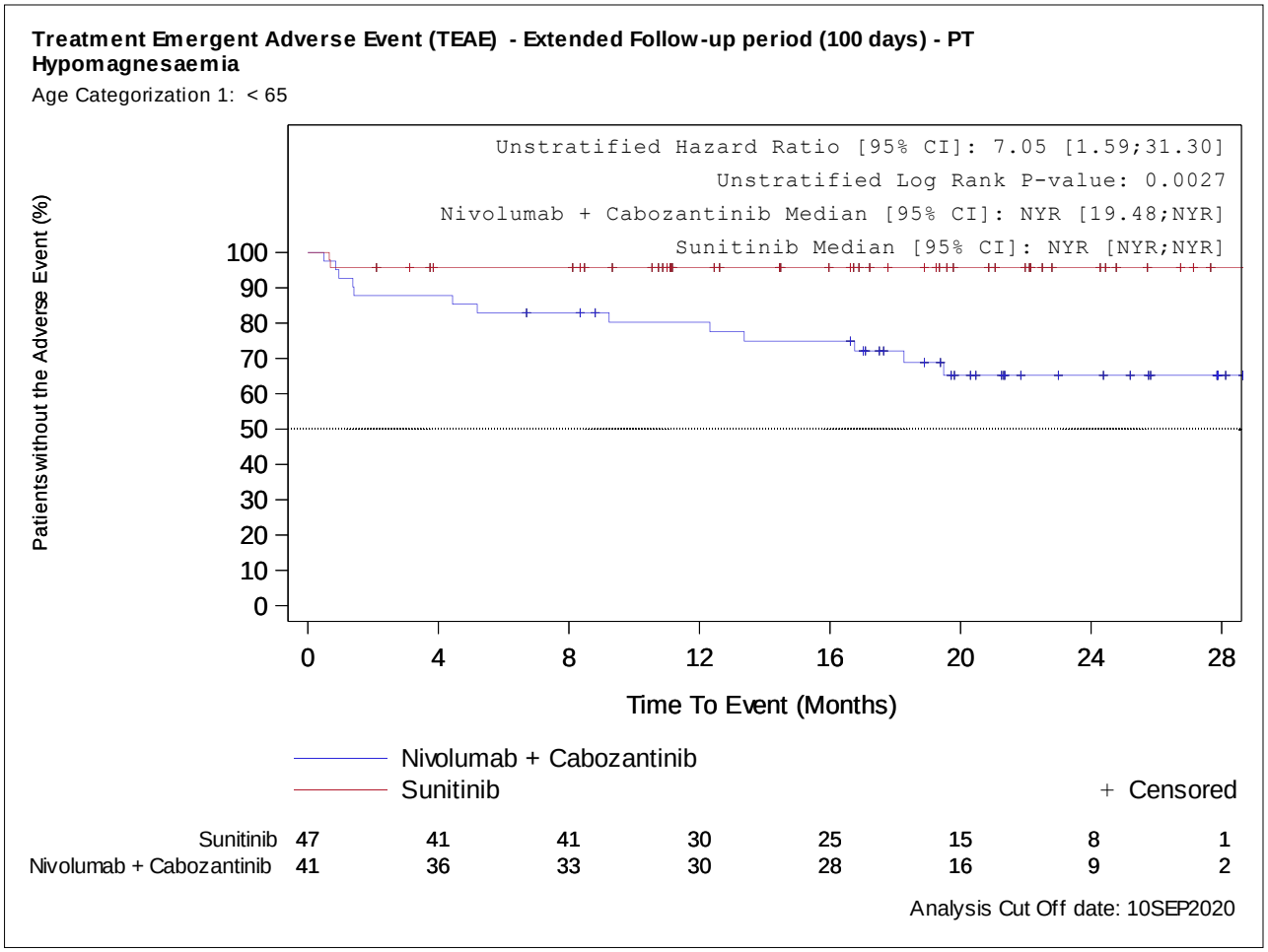

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:14:00

FIGURE 5.32.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



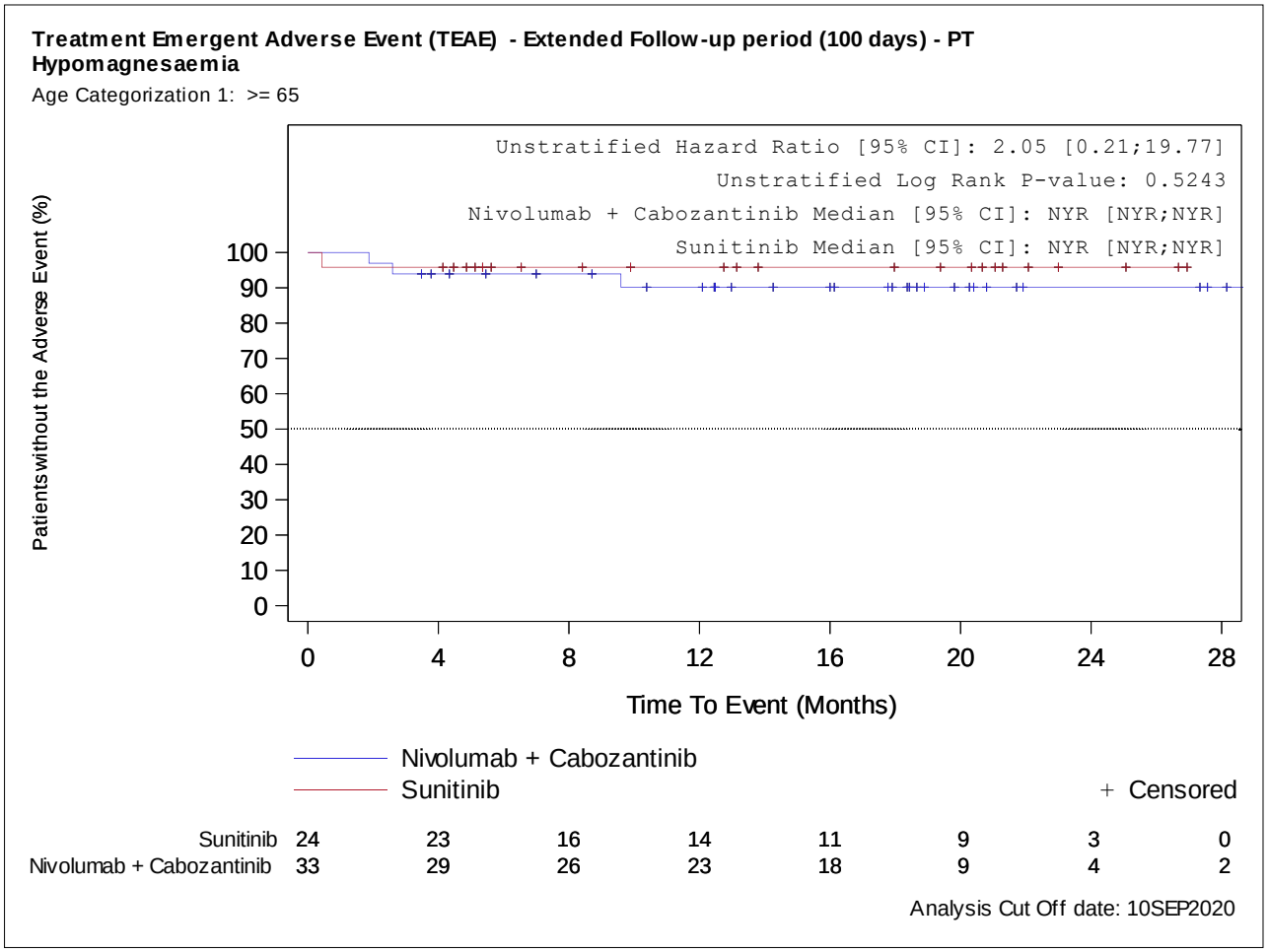

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:17:14

FIGURE 5.32.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65



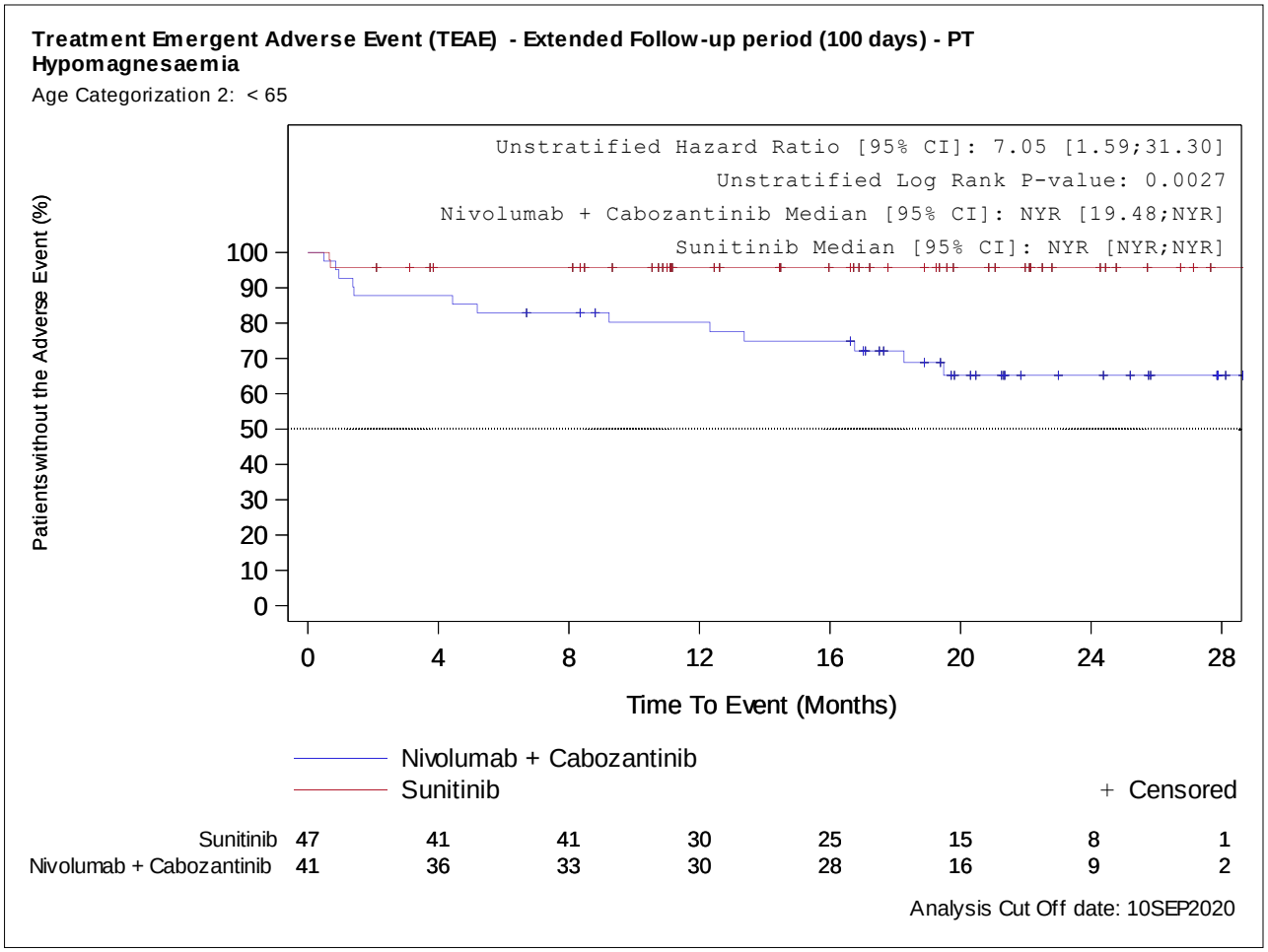

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:17:17

FIGURE 5.32.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65



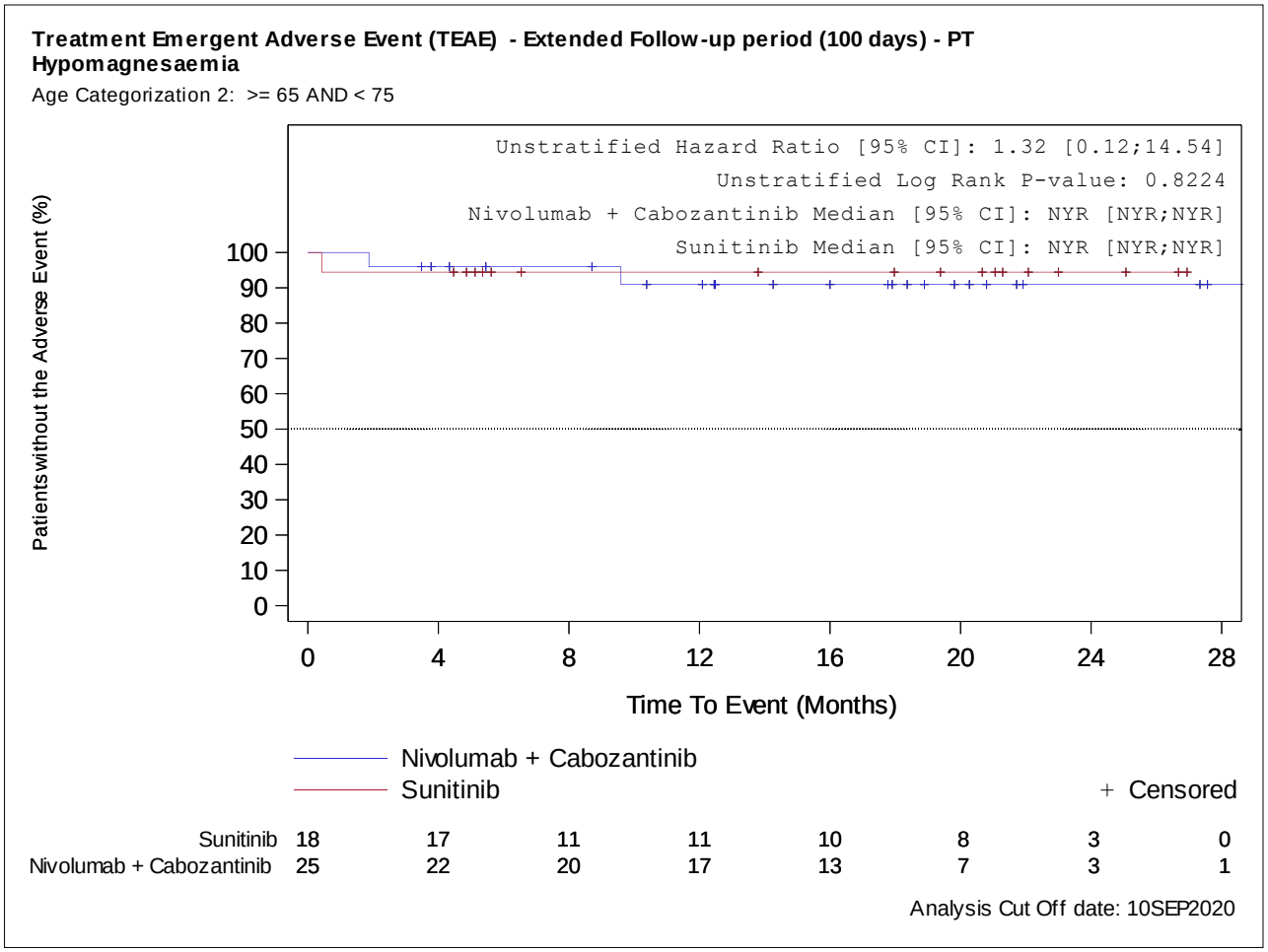

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:17:23

FIGURE 5.32.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



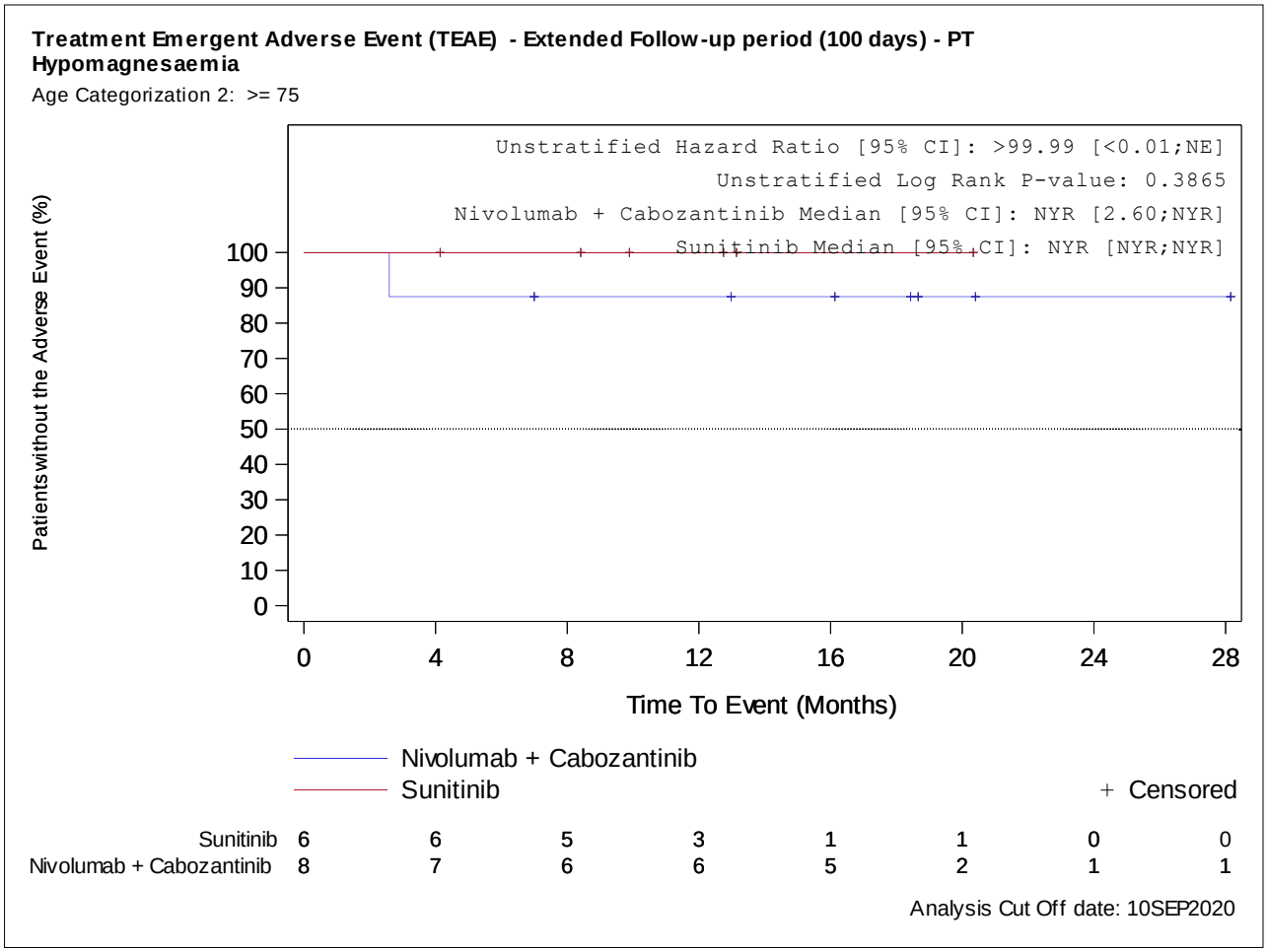

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:17:29

FIGURE 5.32.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



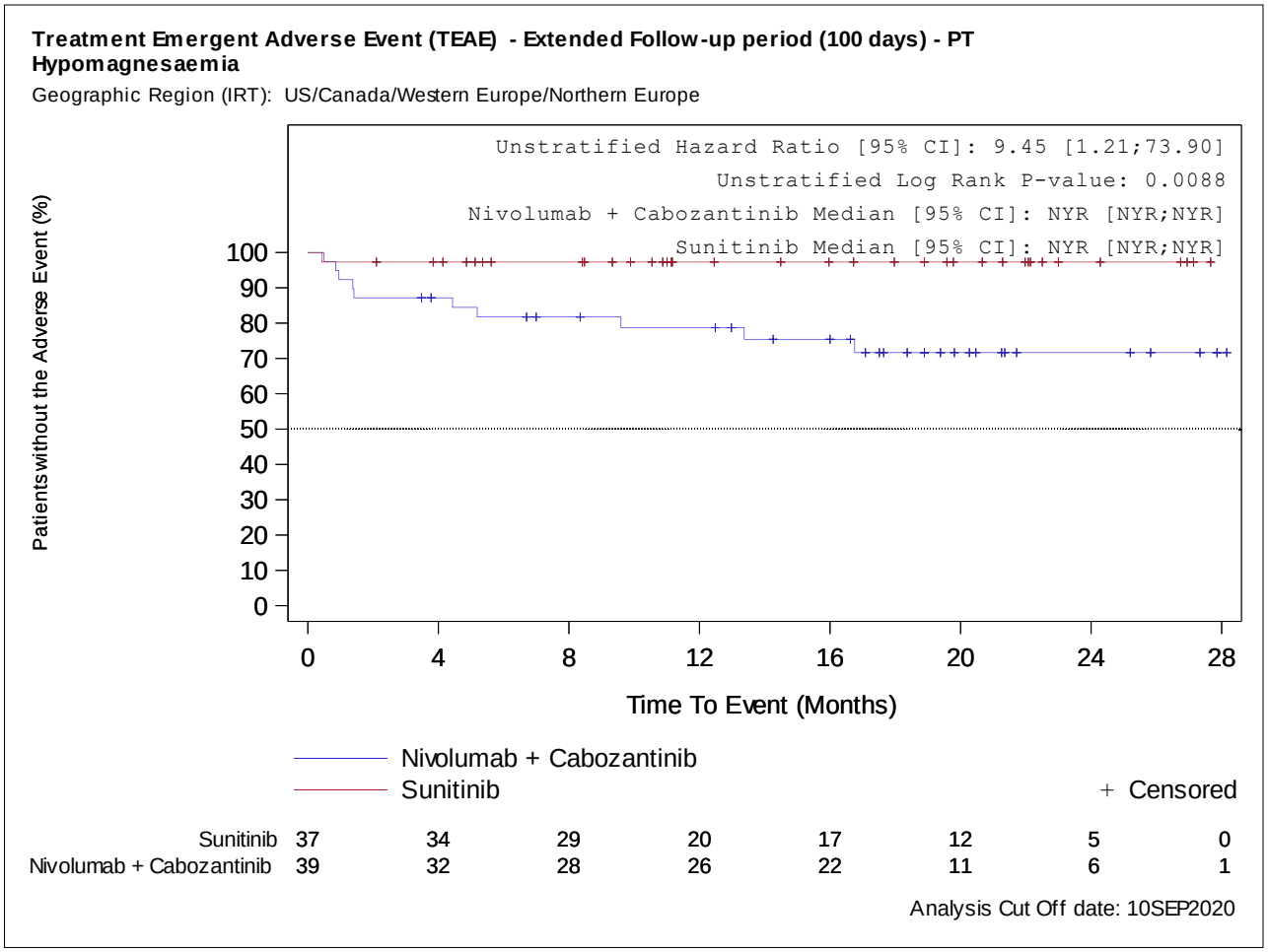

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:17:35

FIGURE 5.32.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:17:42

FIGURE 5.32.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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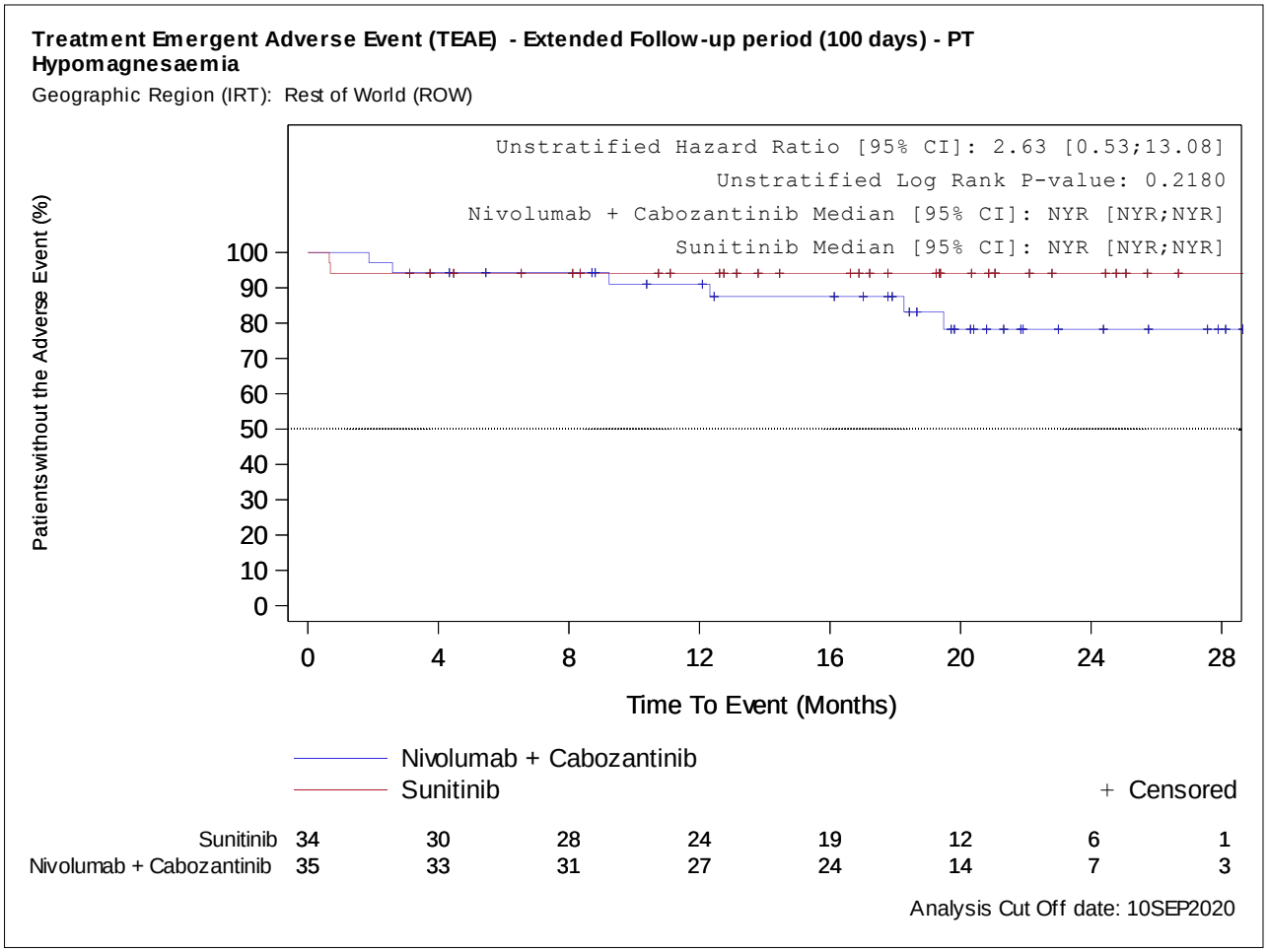
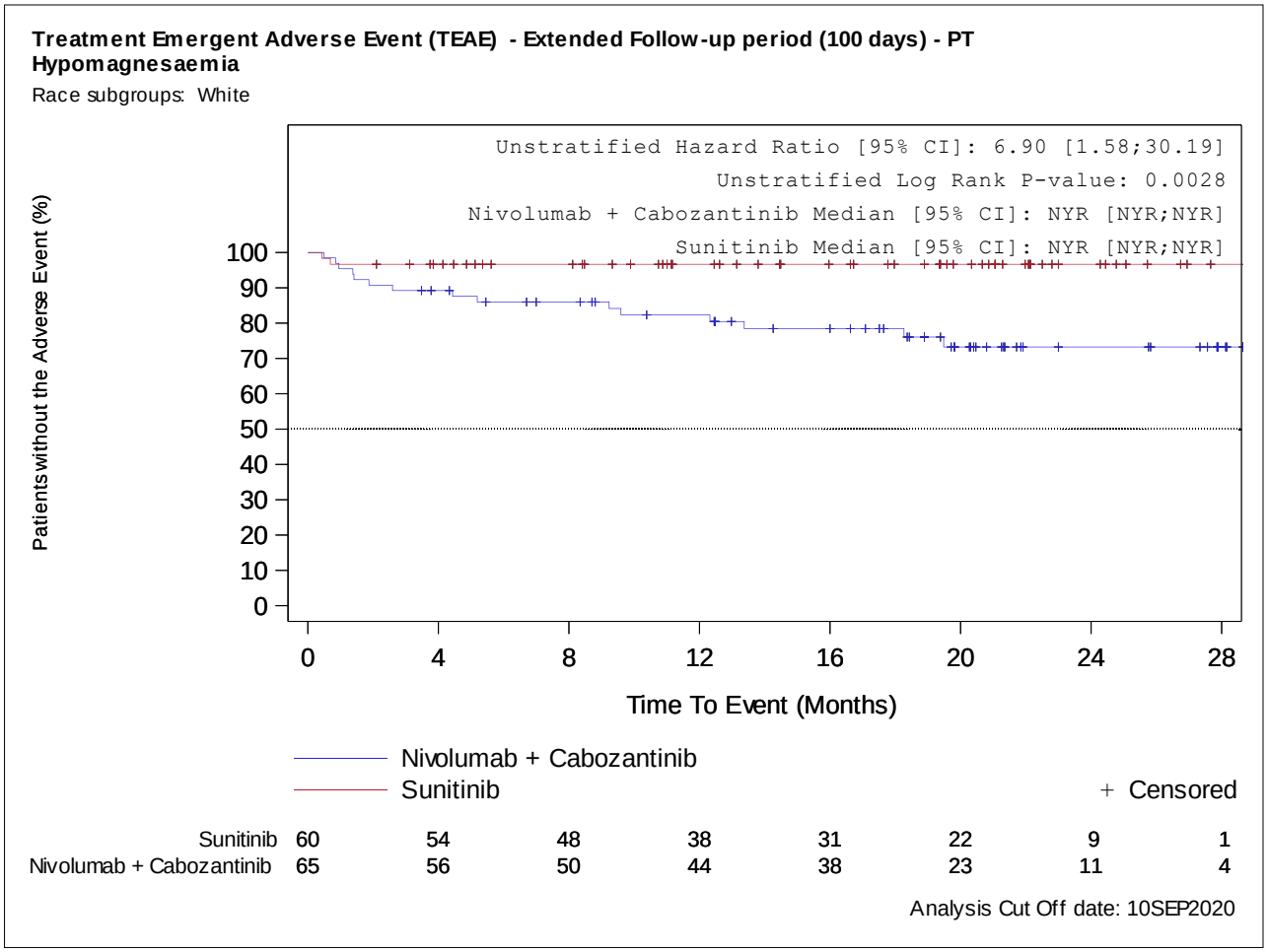
FIGURE 5.32.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



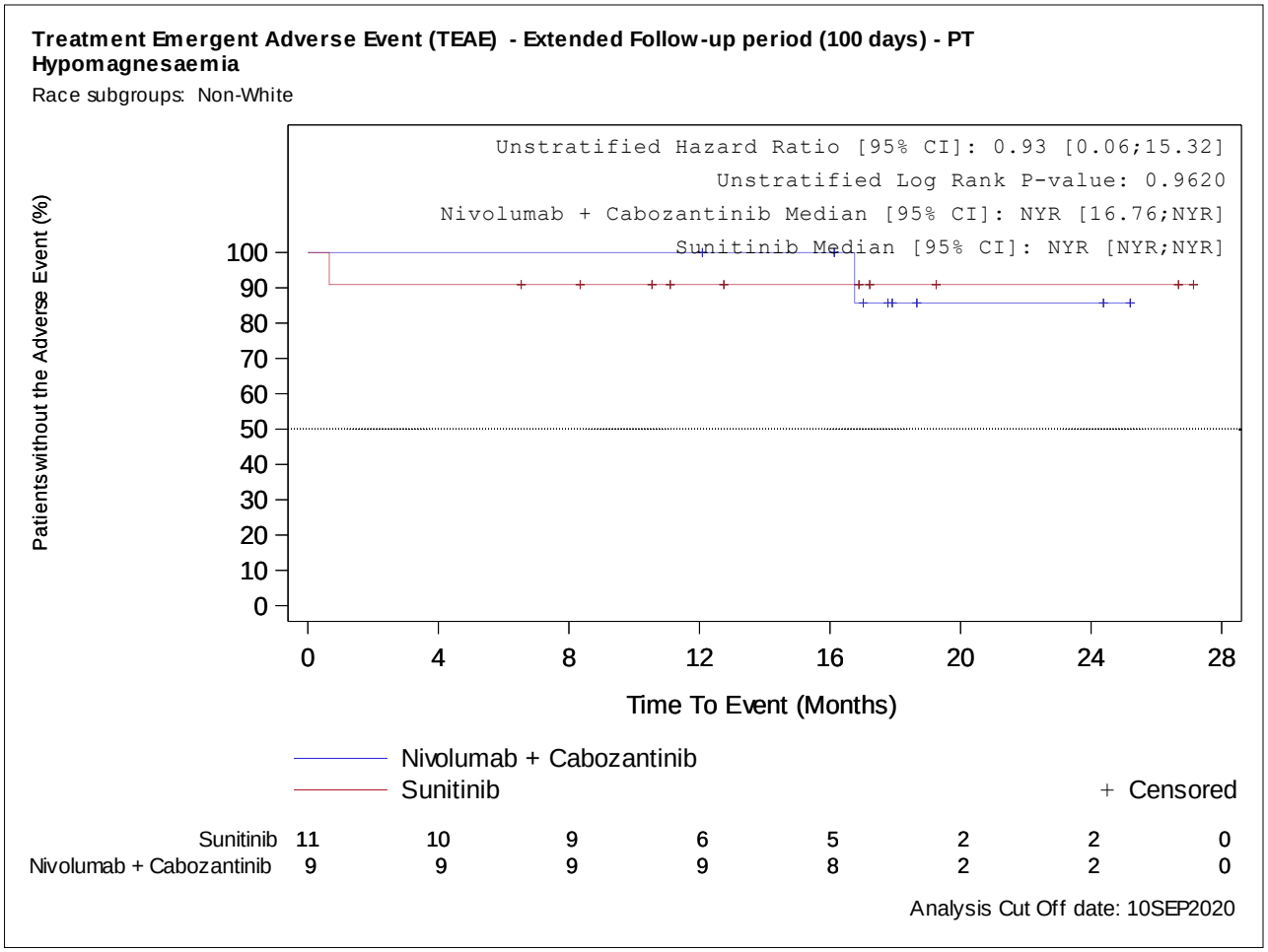

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:17:53

FIGURE 5.32.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



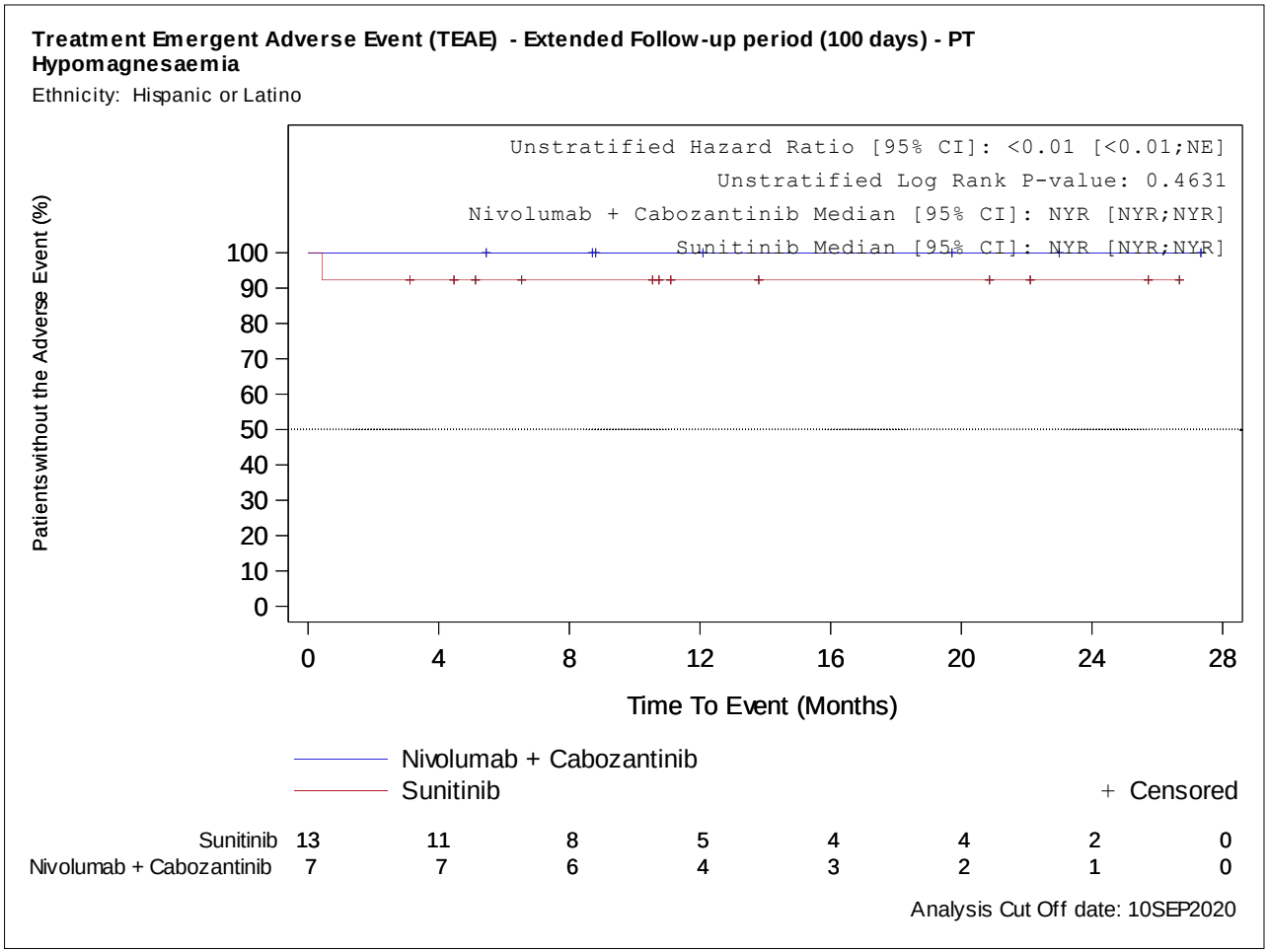

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:18:00

FIGURE 5.32.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



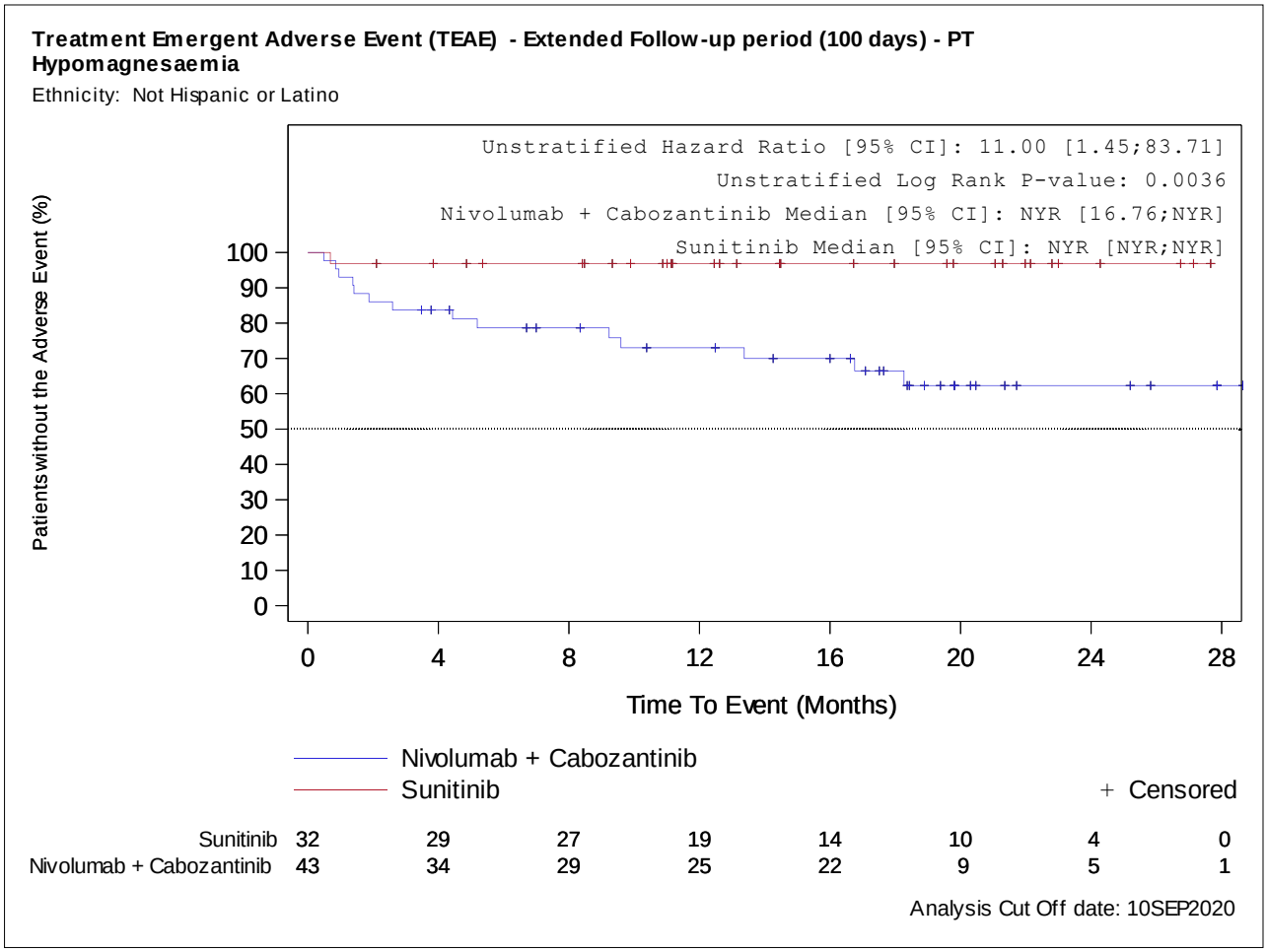

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:18:06

FIGURE 5.32.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



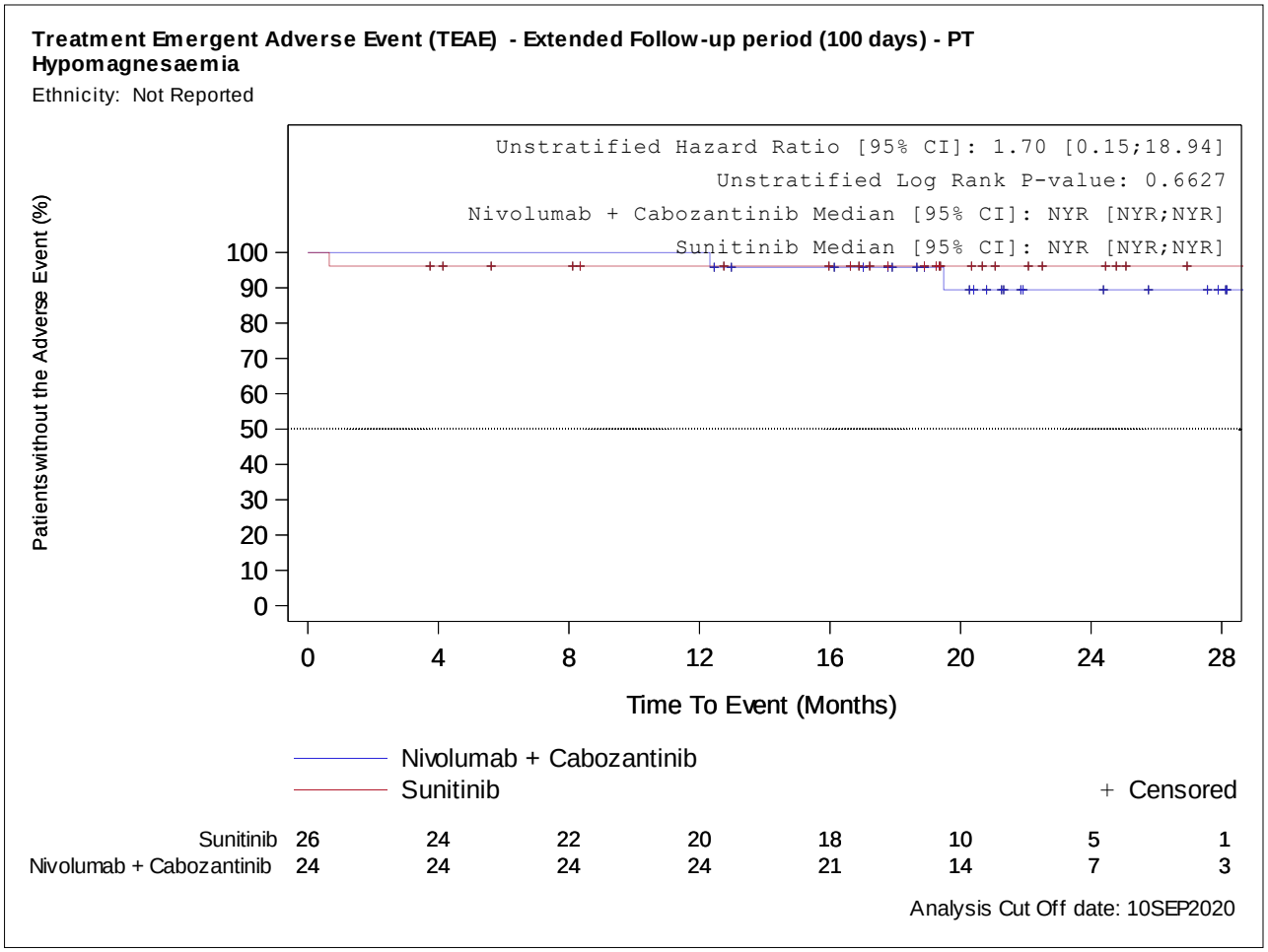

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:18:12

FIGURE 5.32.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



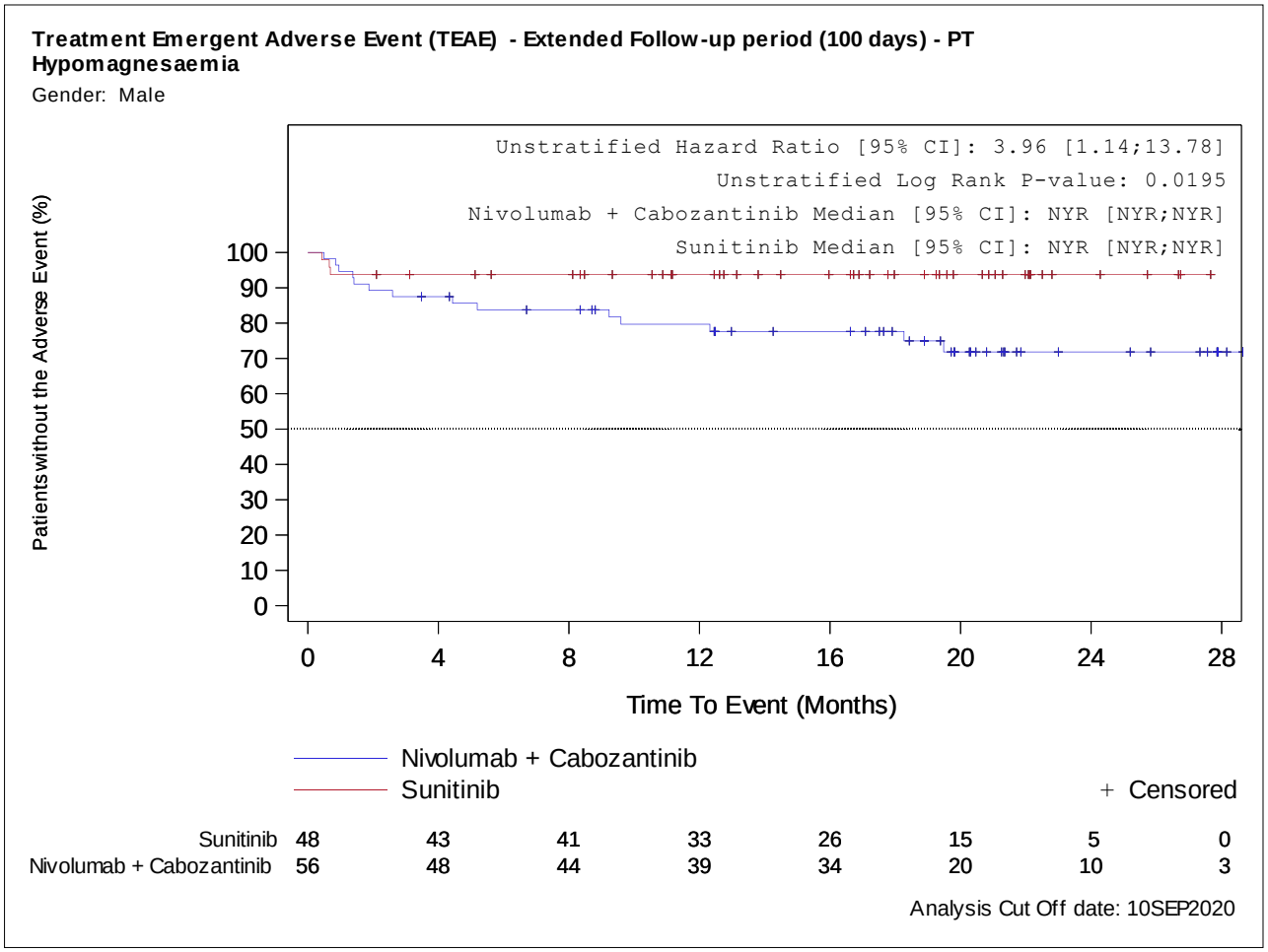

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:18:18

FIGURE 5.32.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



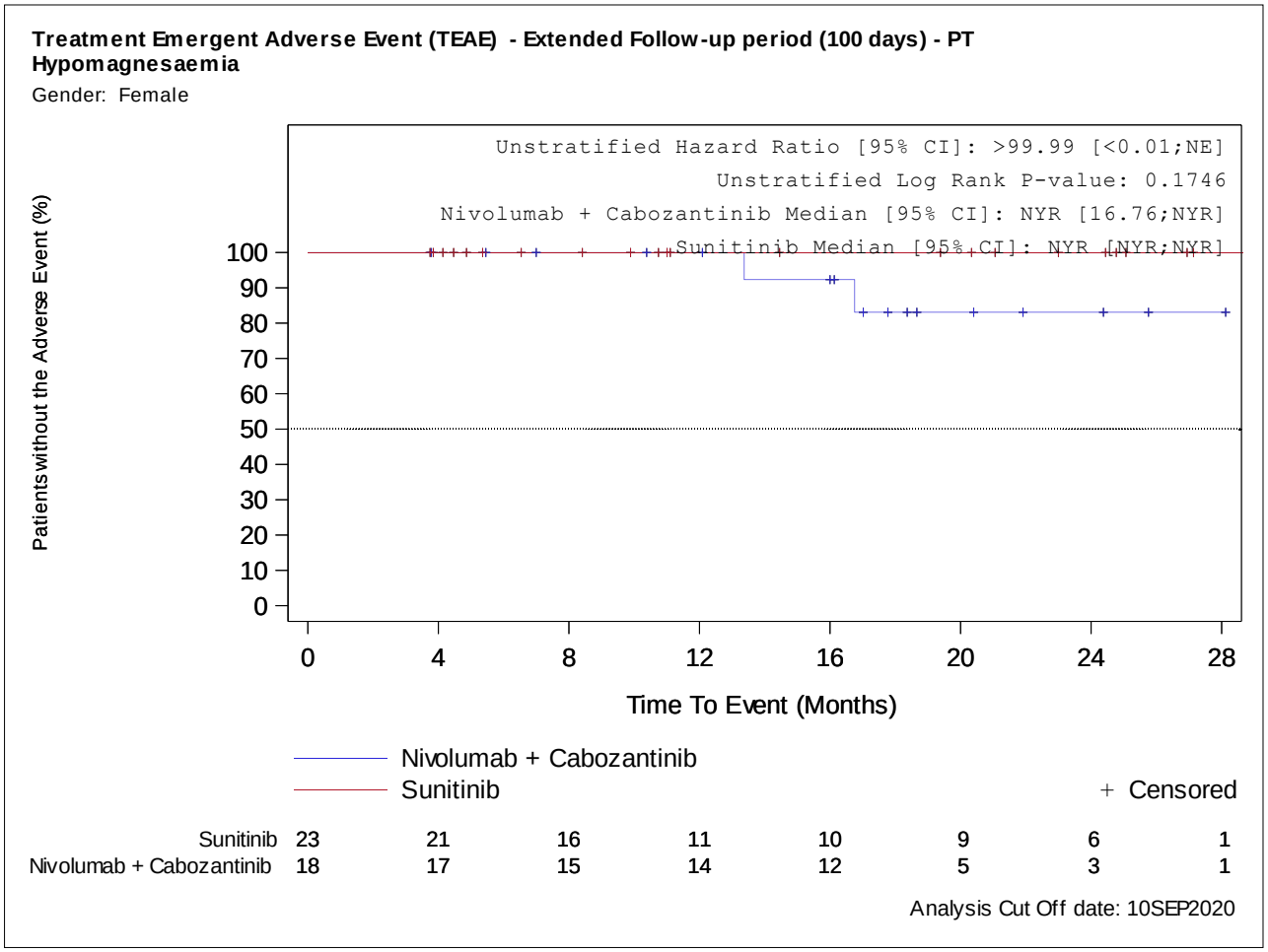

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:18:23

FIGURE 5.32.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male



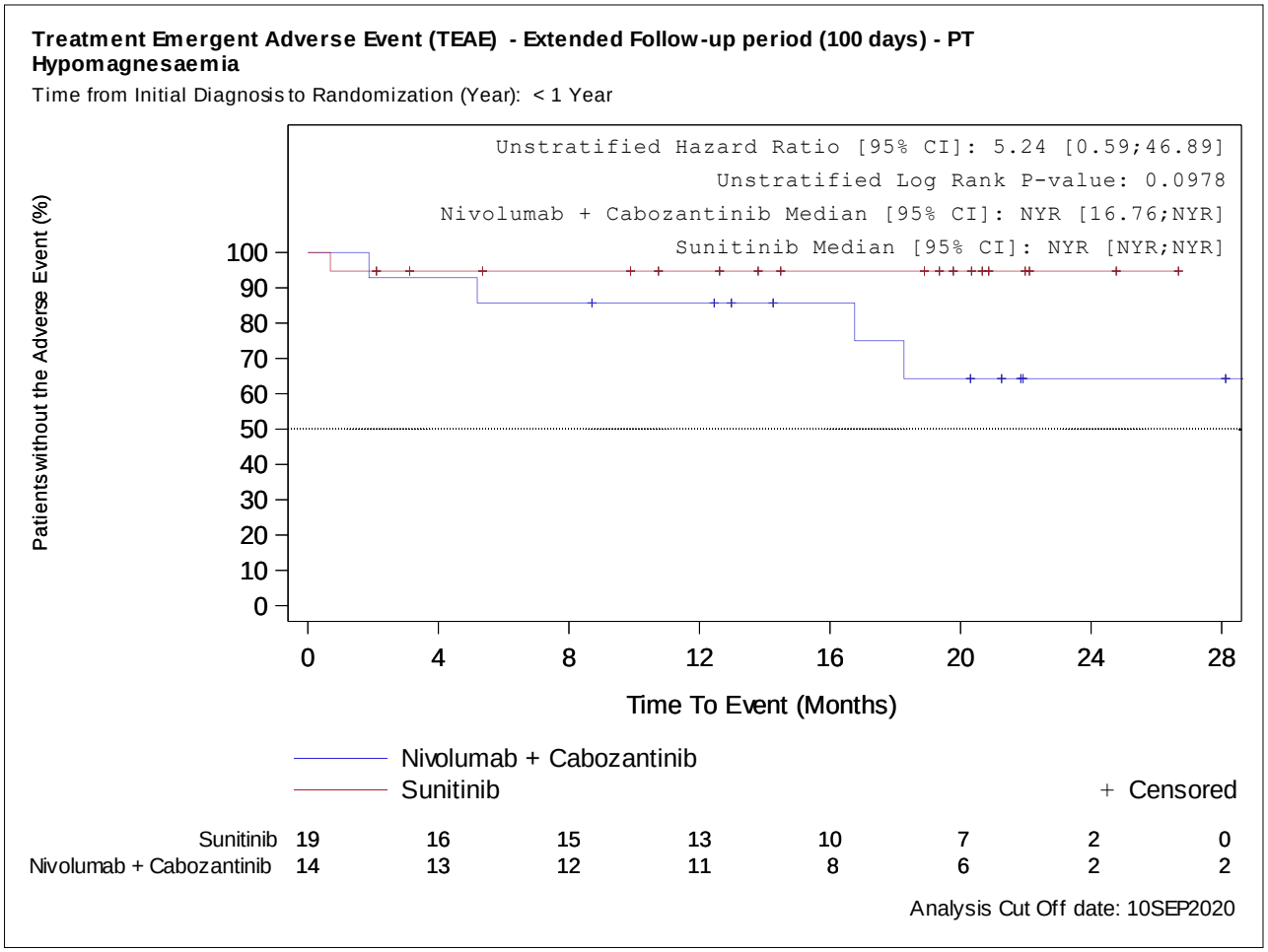

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:18:29

FIGURE 5.32.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



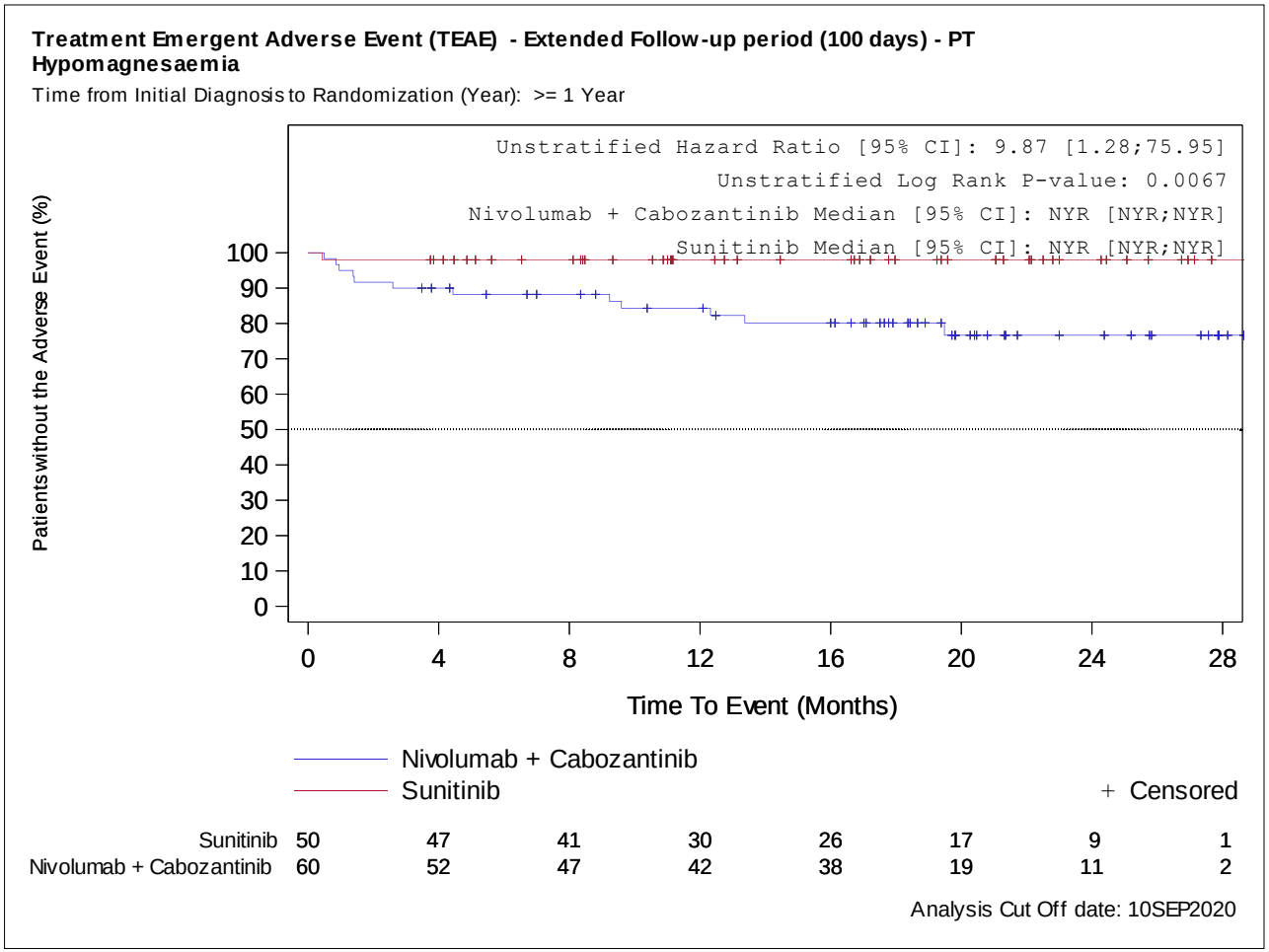

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:18:35

FIGURE 5.32.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:18:53

FIGURE 5.32.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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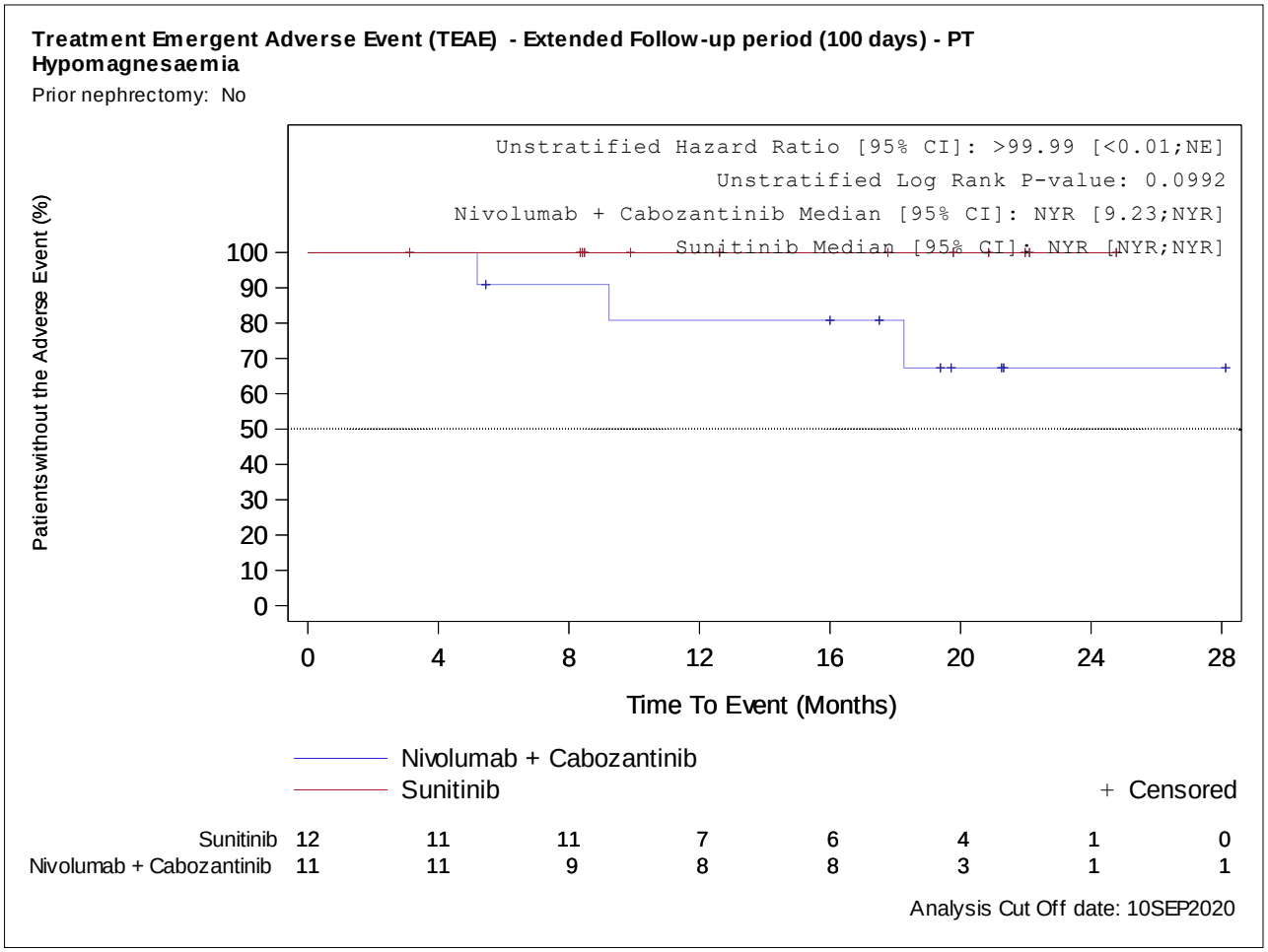
FIGURE 5.32.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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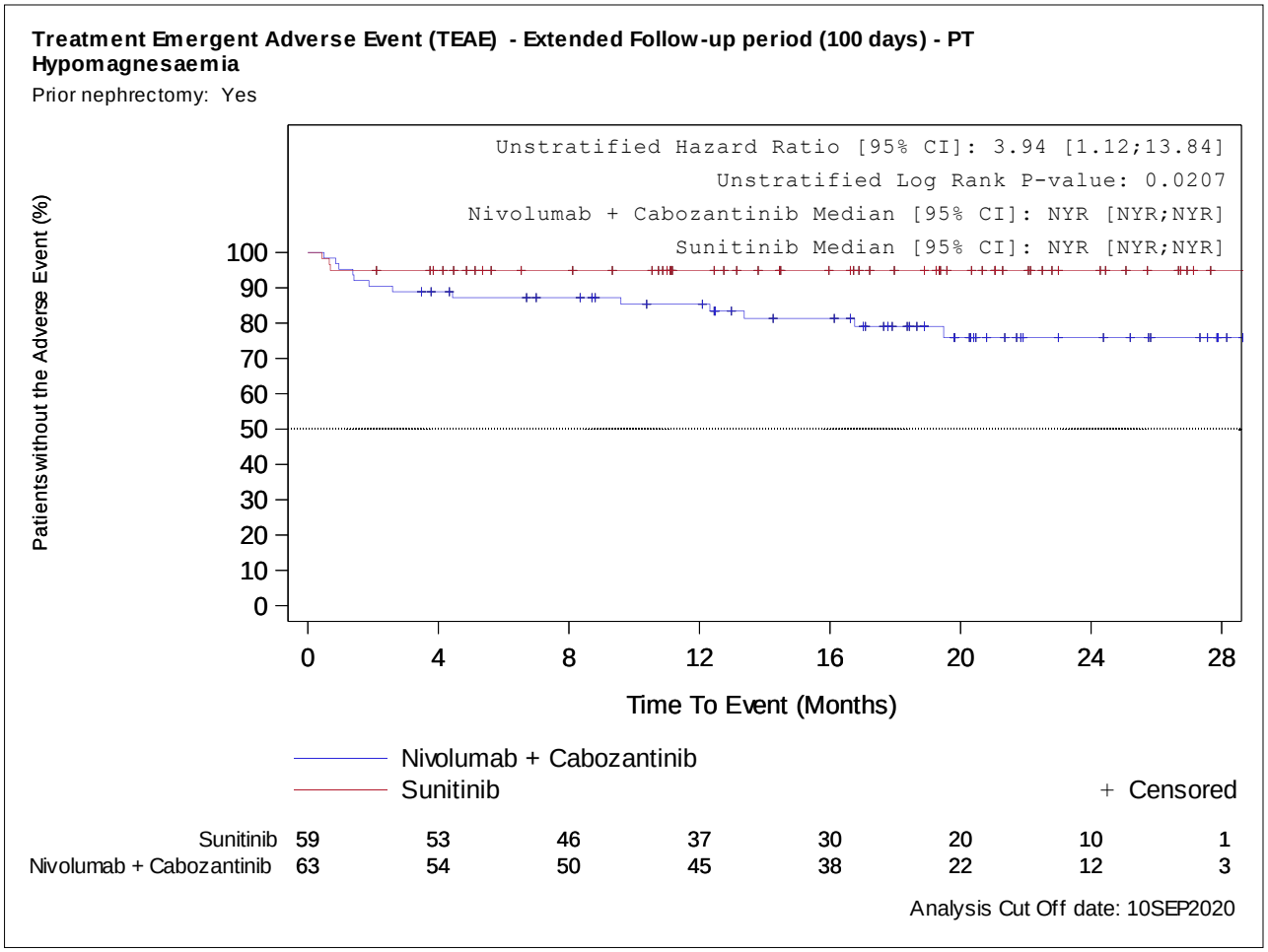
FIGURE 5.32.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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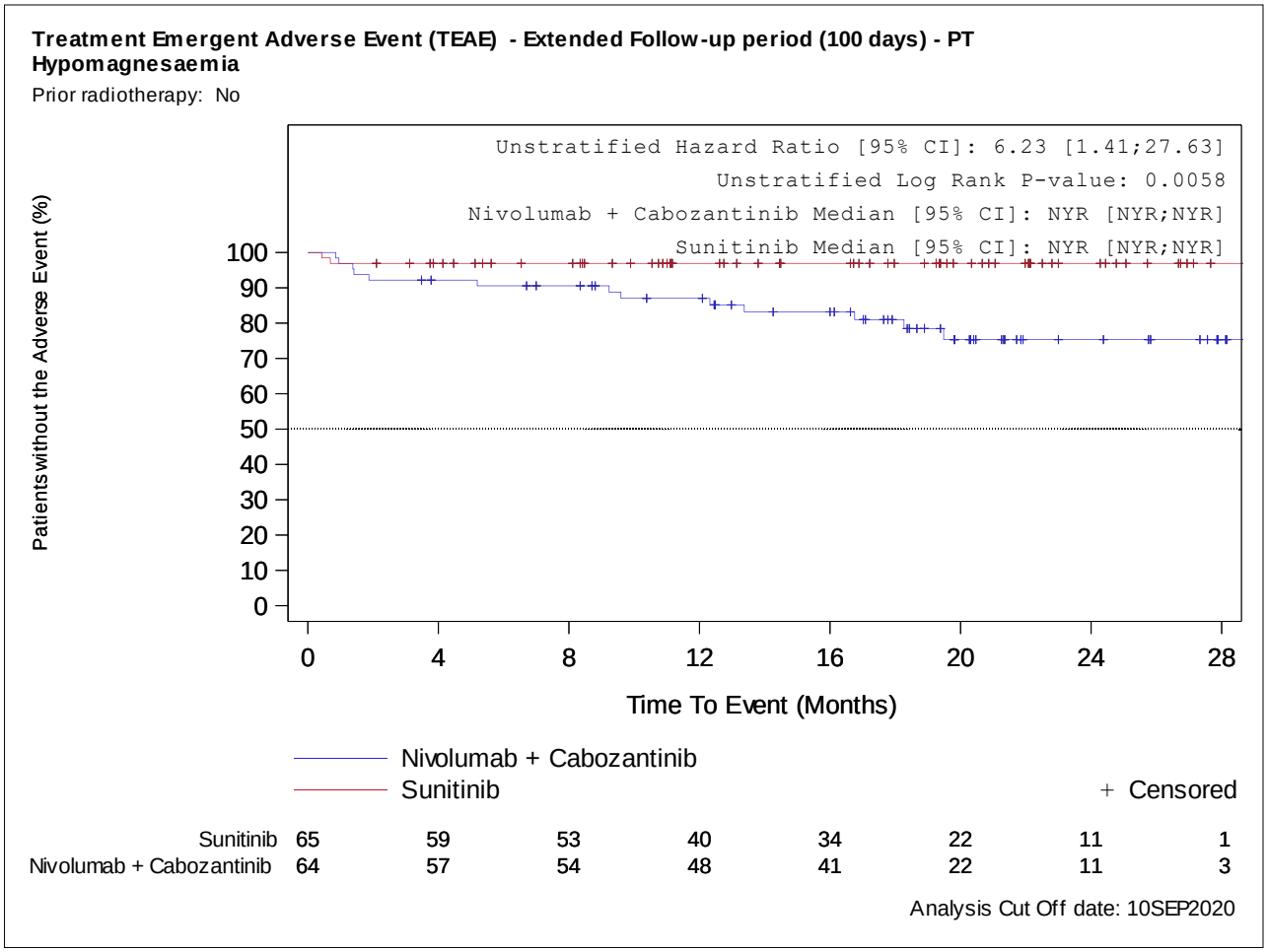
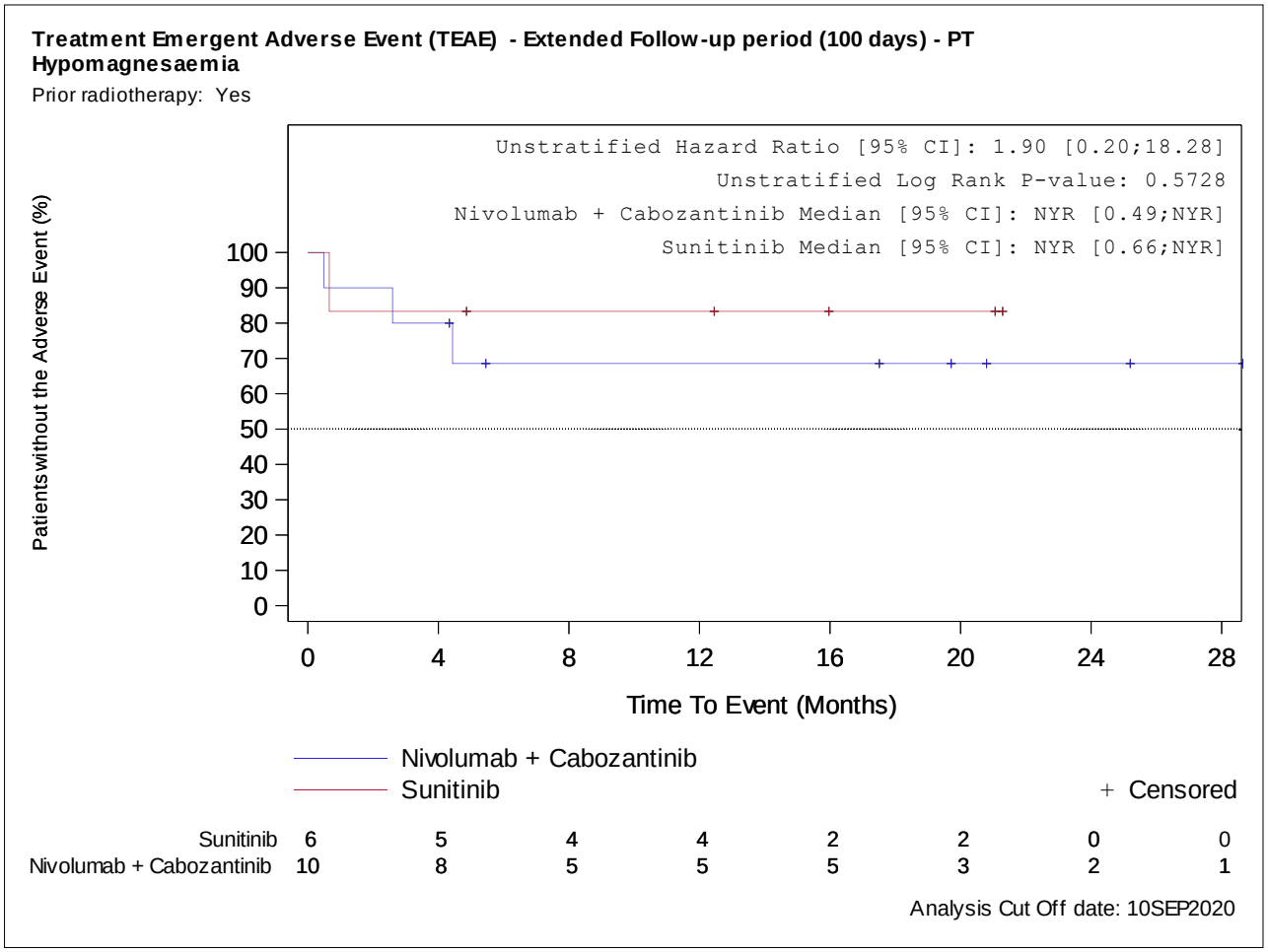
FIGURE 5.32.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:20:03

FIGURE 5.32.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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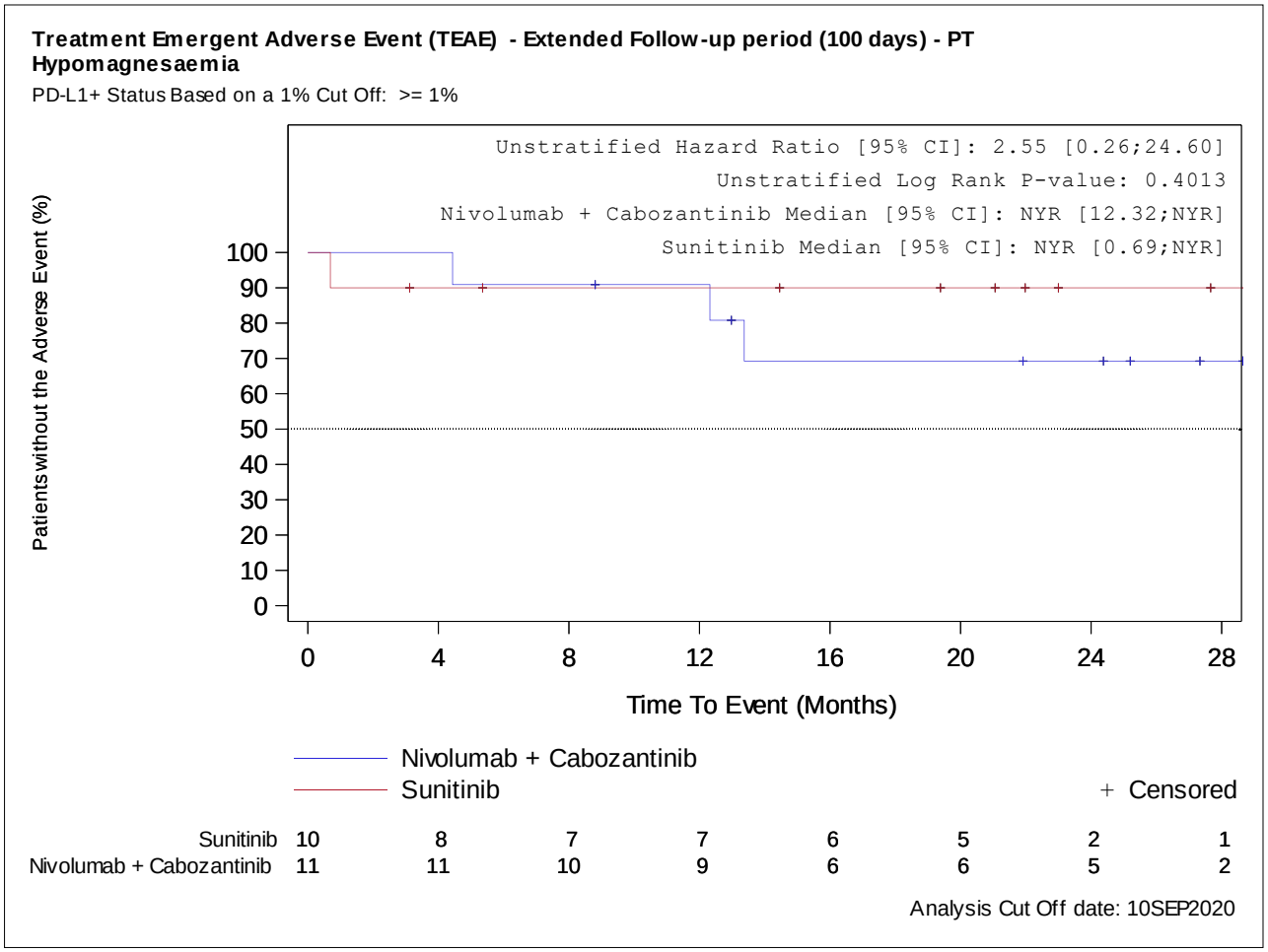
FIGURE 5.32.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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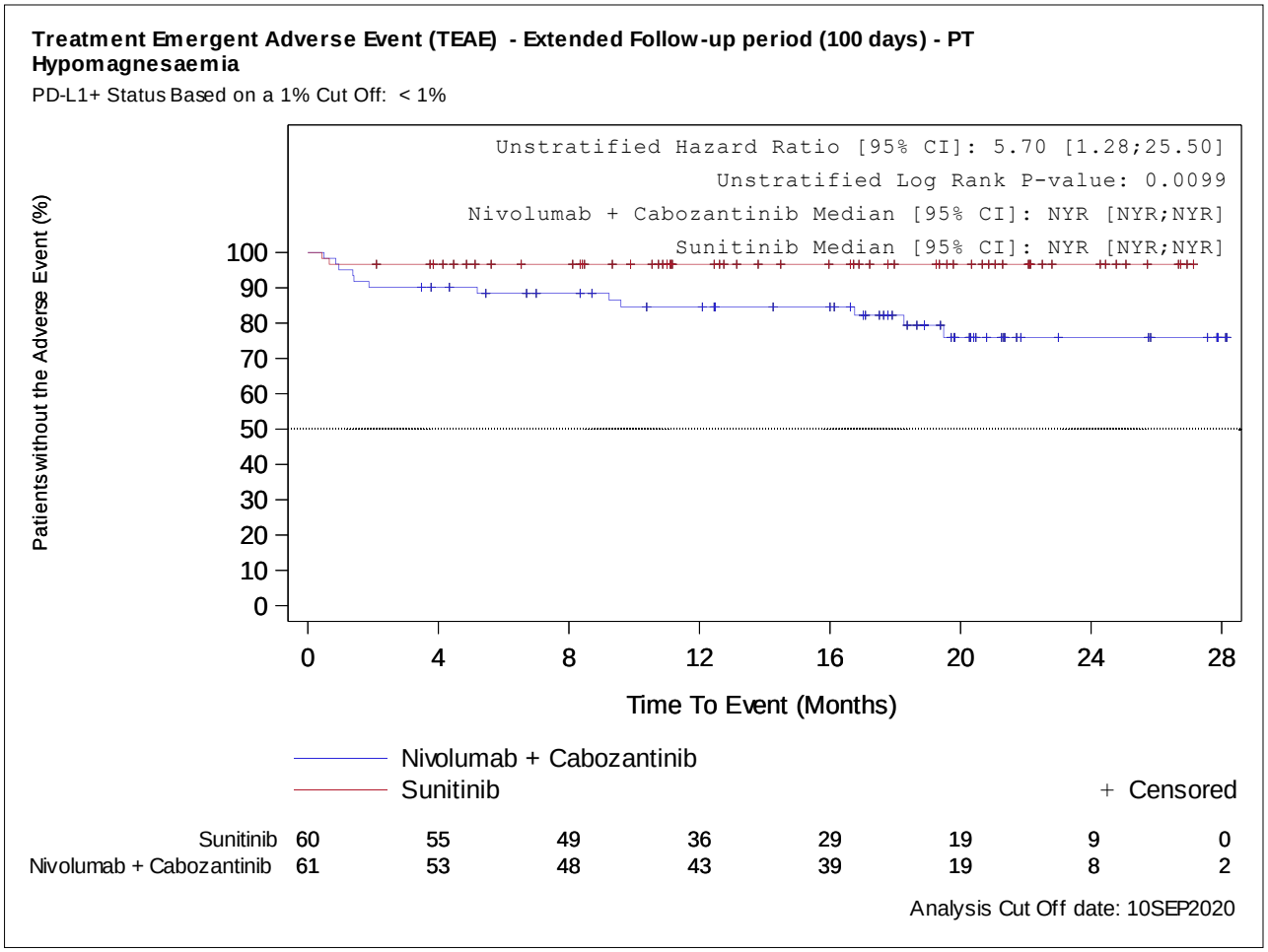
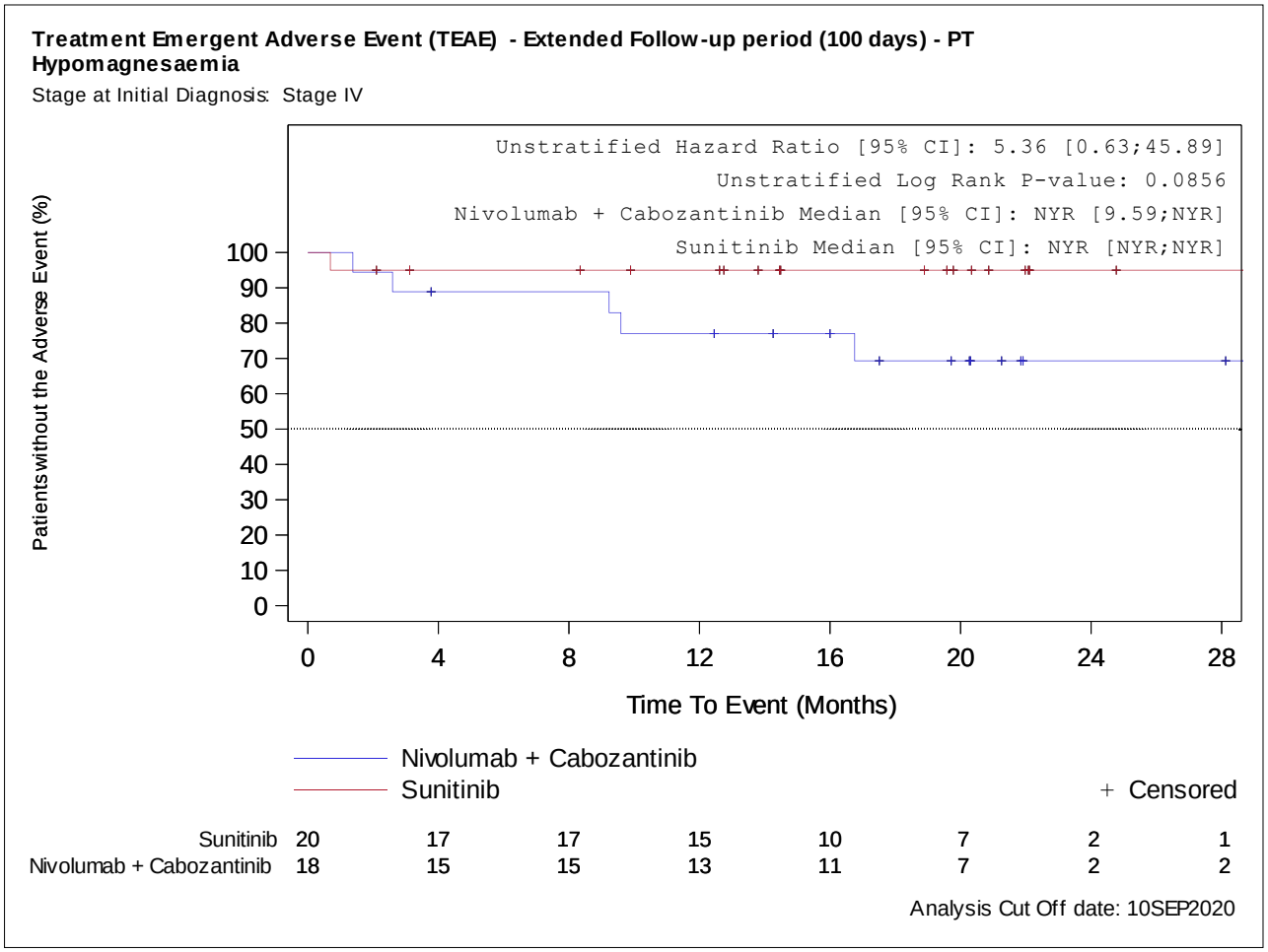
FIGURE 5.32.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



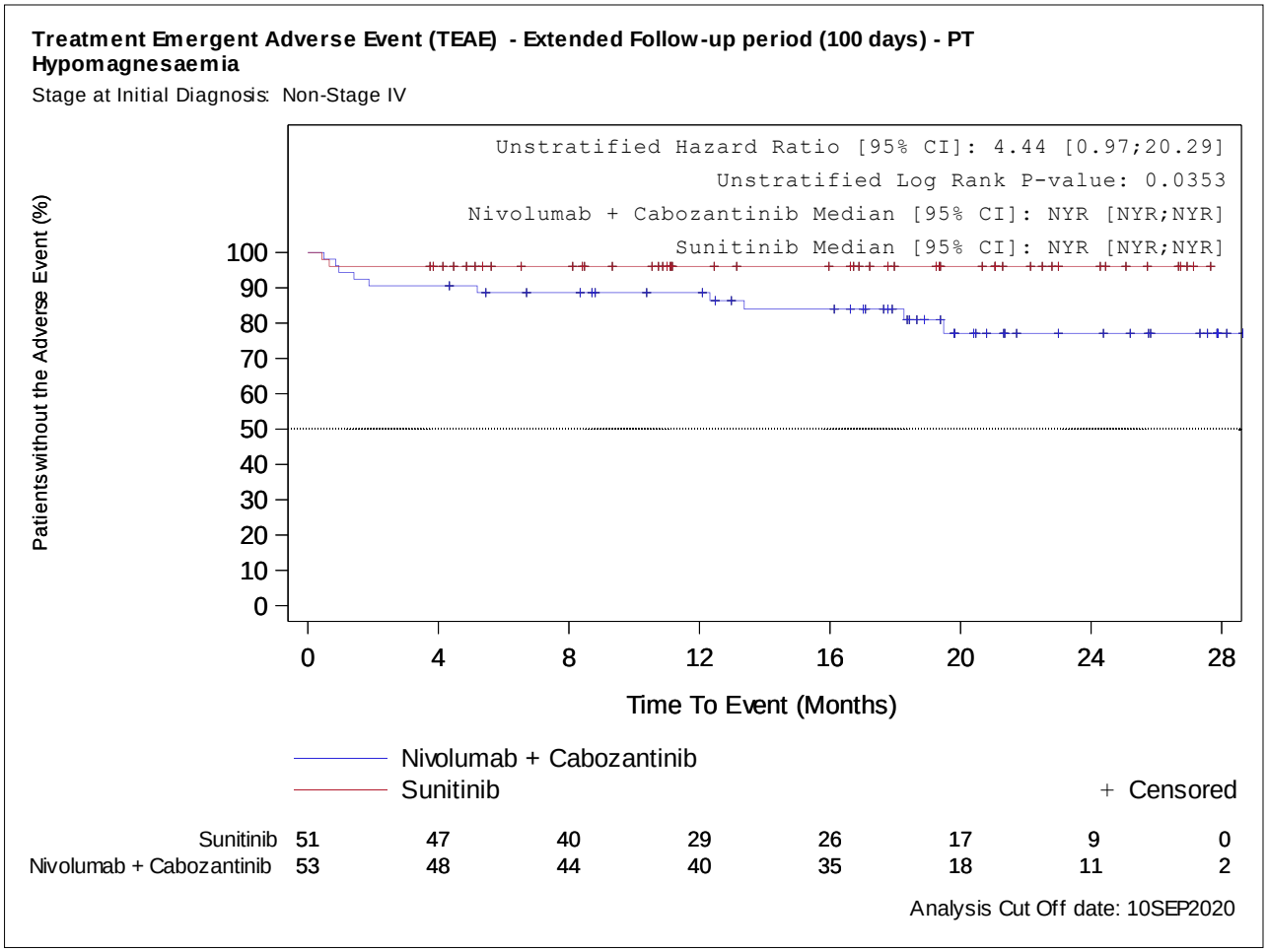

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:20:20

FIGURE 5.32.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



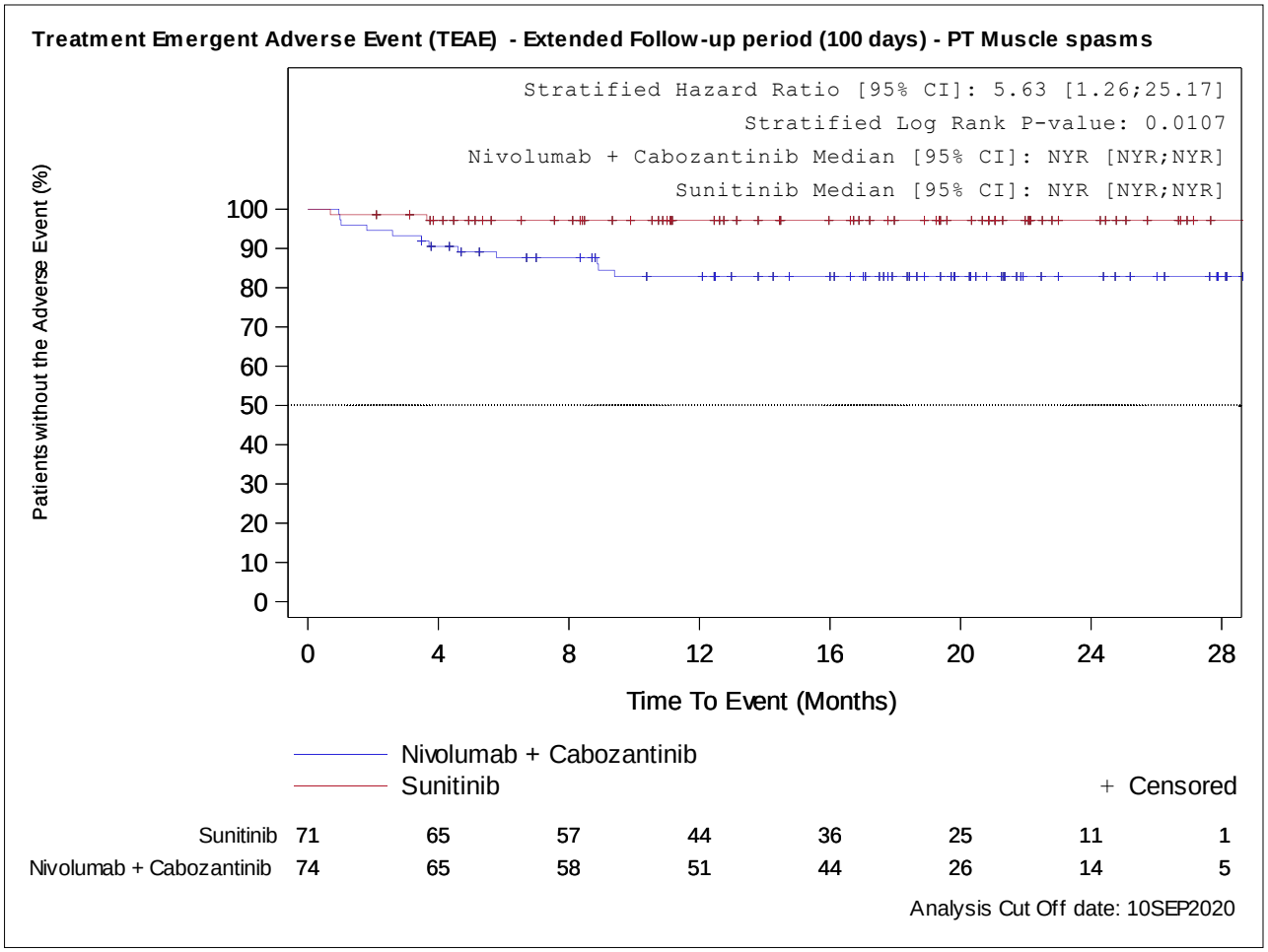

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:20:48

FIGURE 5.32.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Hypomagnesaemia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



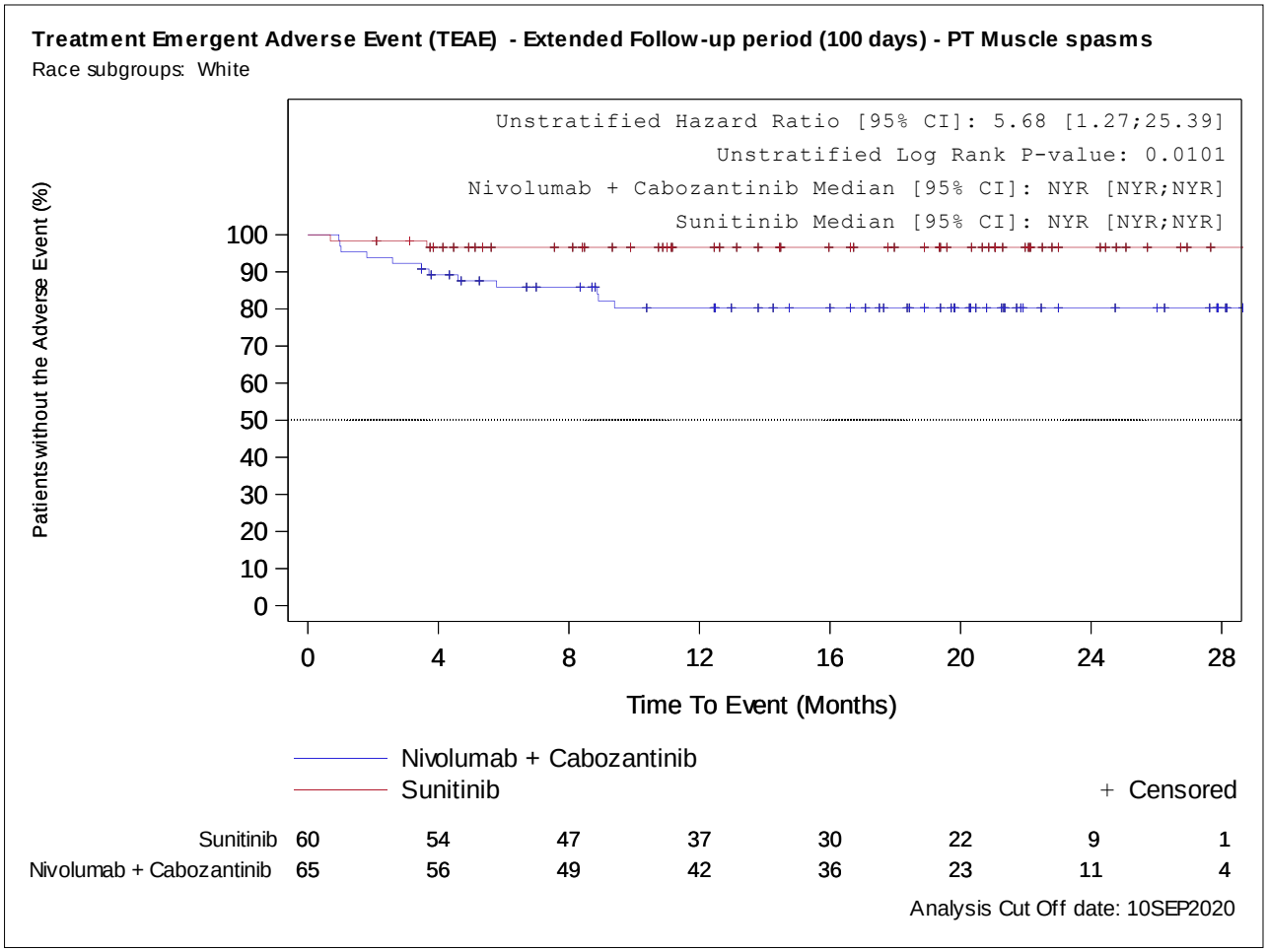

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:20:54

FIGURE 5.33.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:23:41

FIGURE 5.33.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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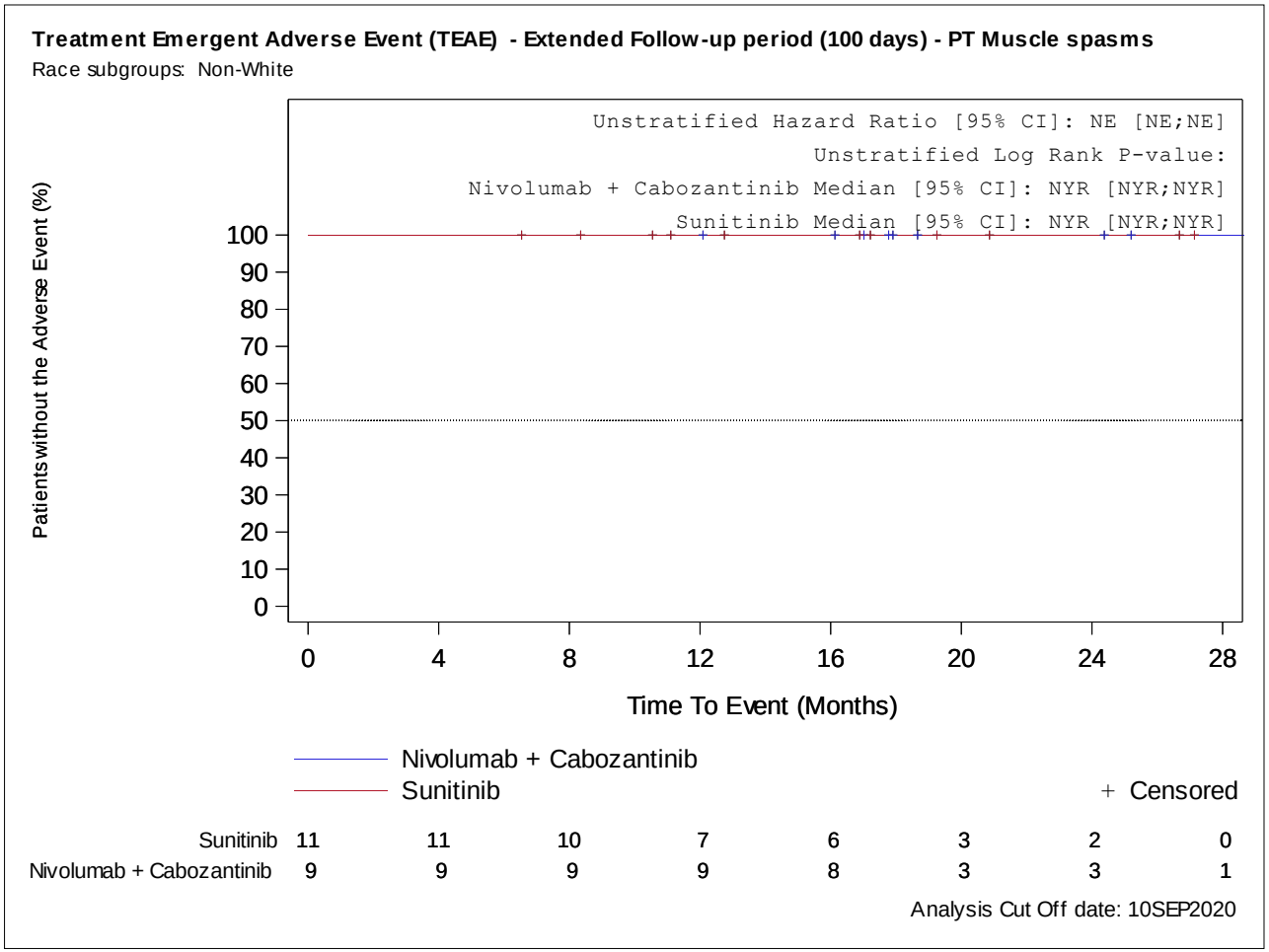
FIGURE 5.33.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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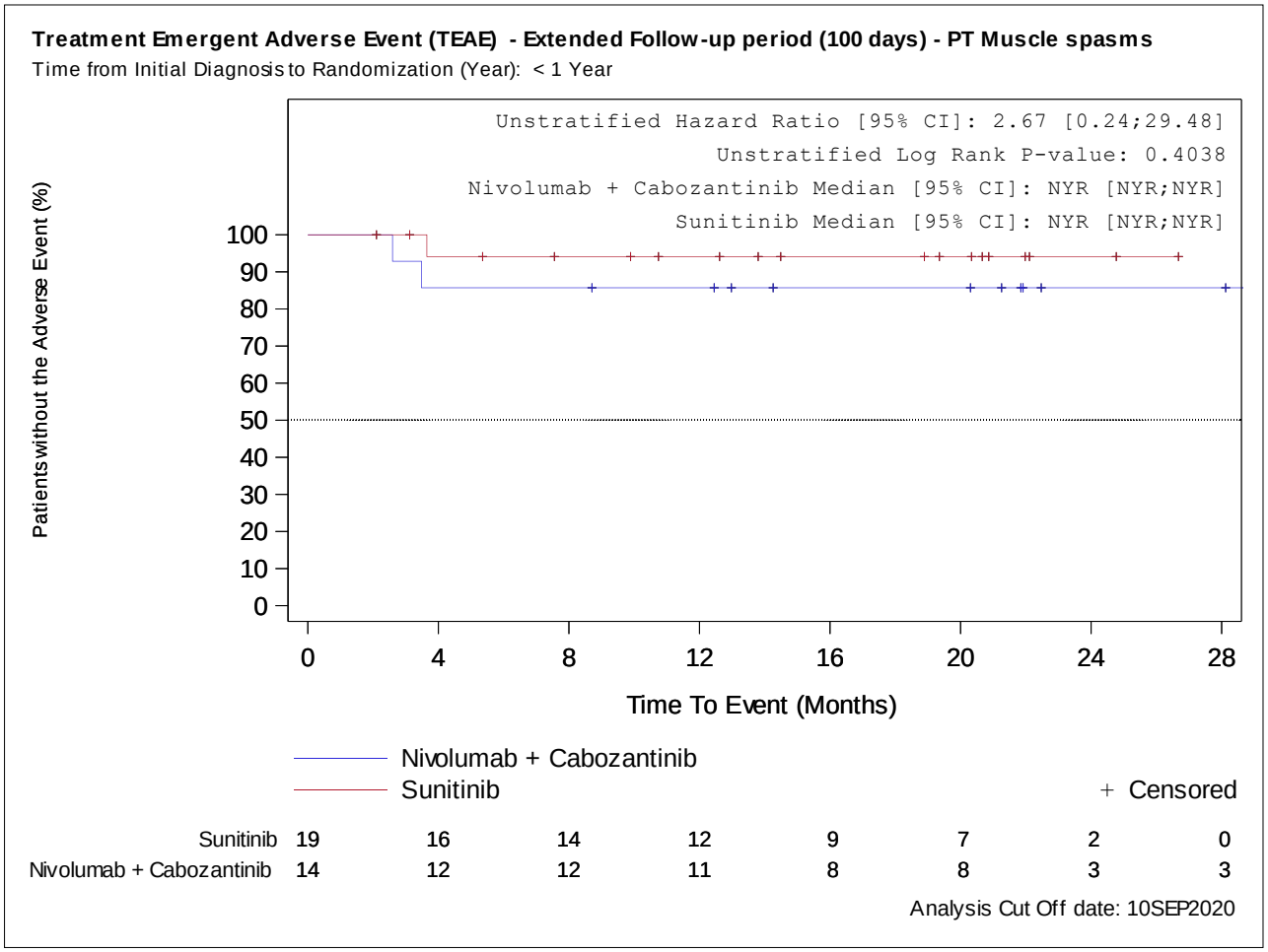
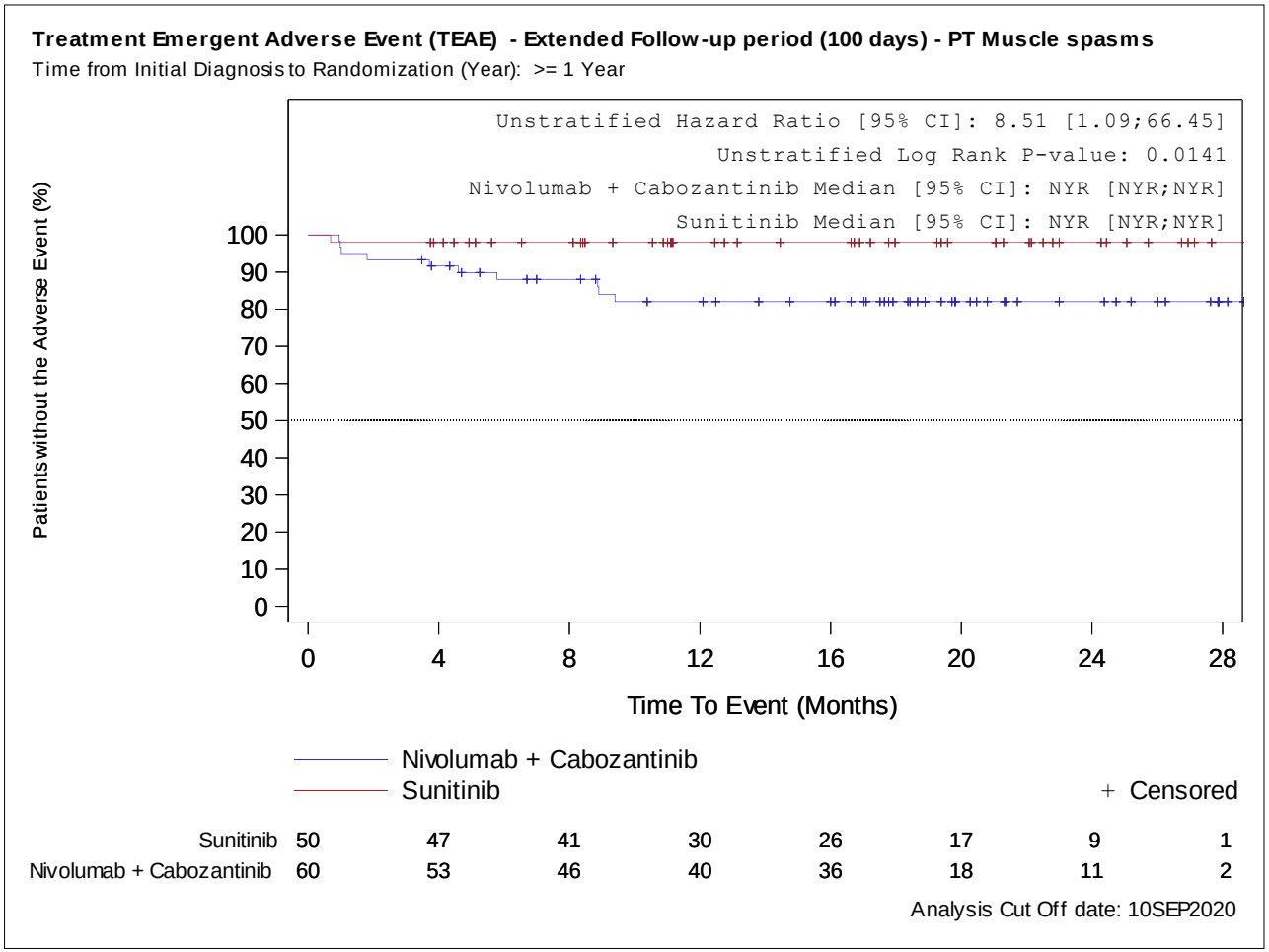
FIGURE 5.33.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



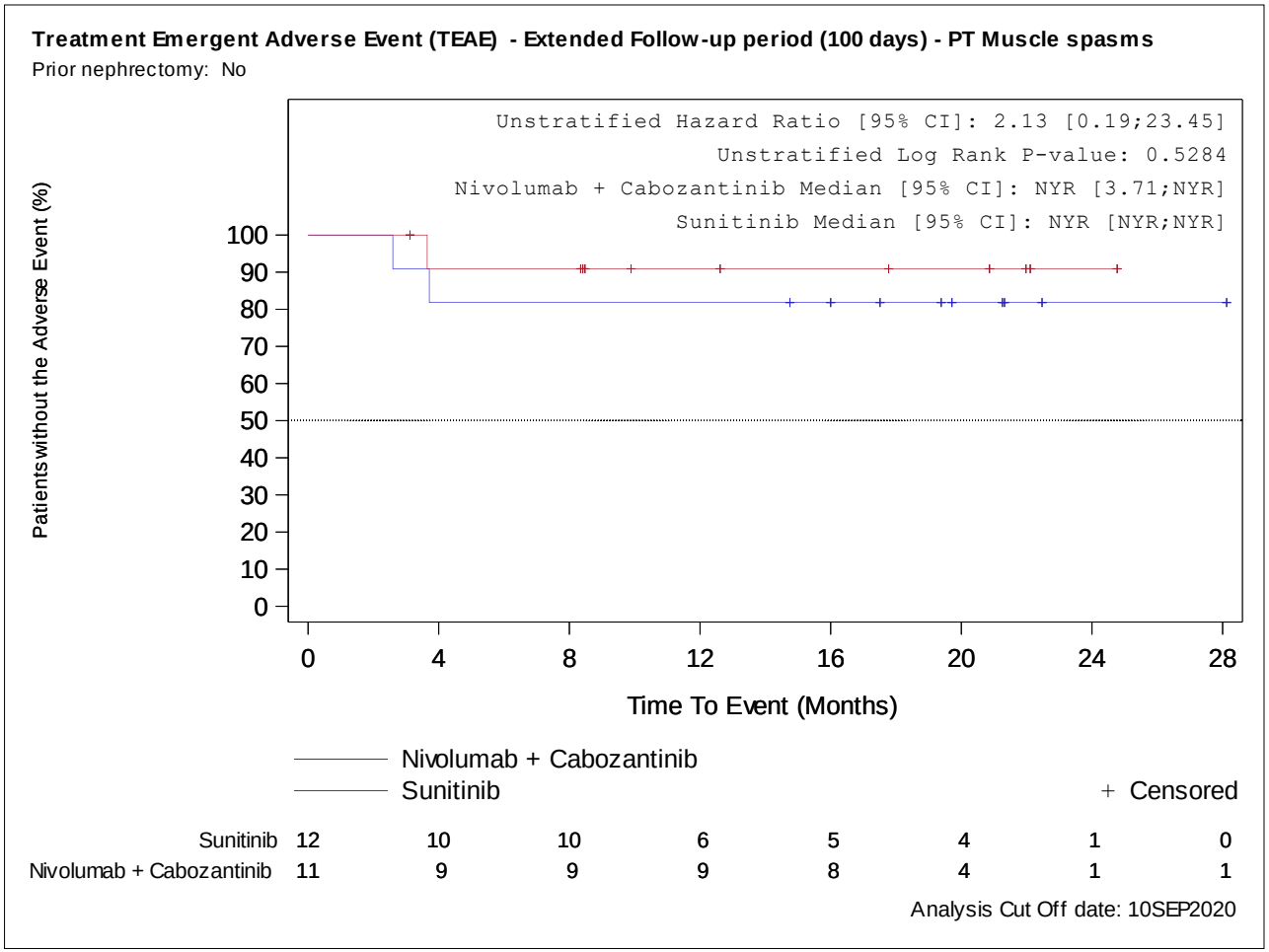

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:24:10

FIGURE 5.33.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



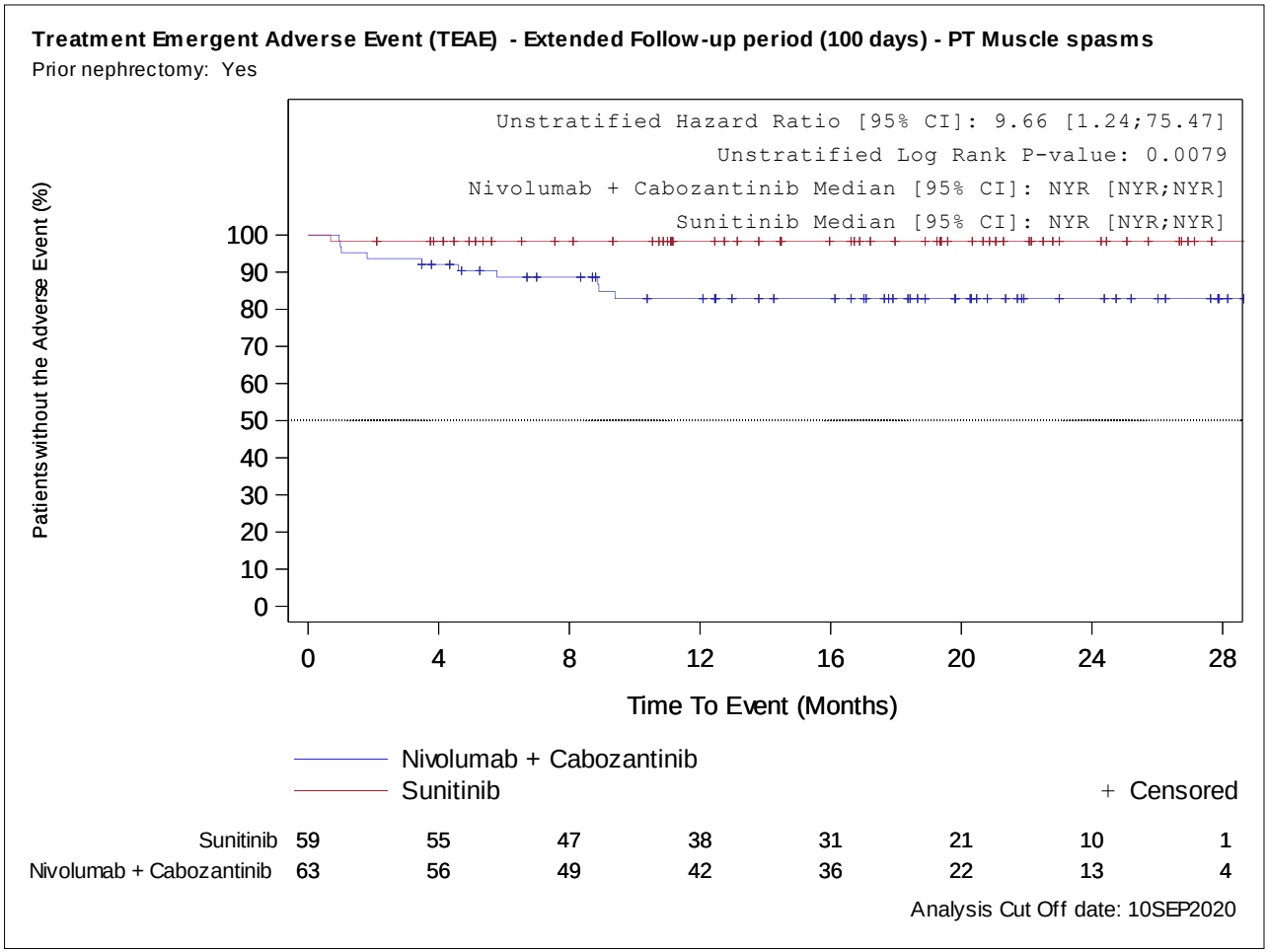

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:24:16

FIGURE 5.33.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



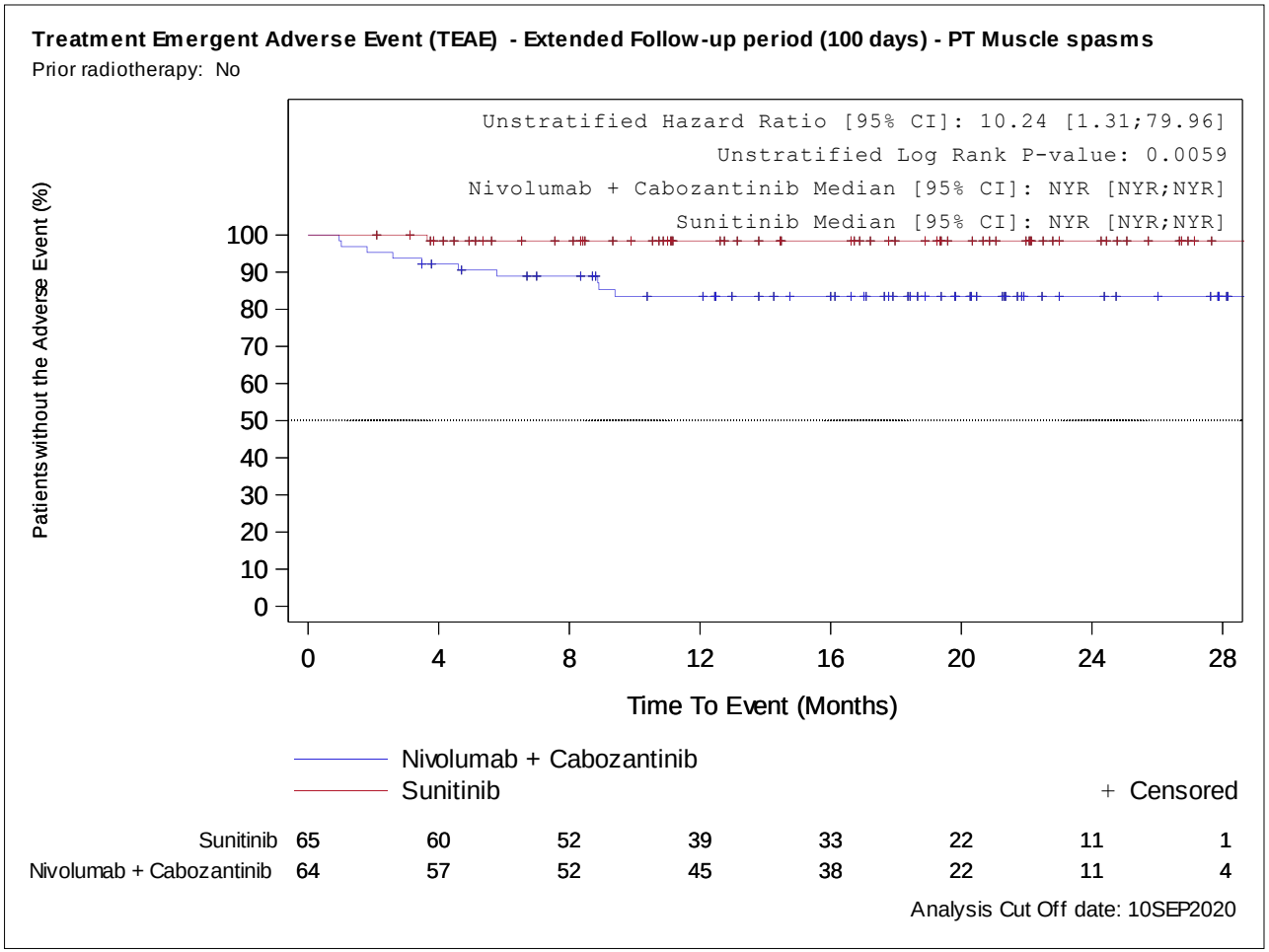

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:24:57

FIGURE 5.33.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



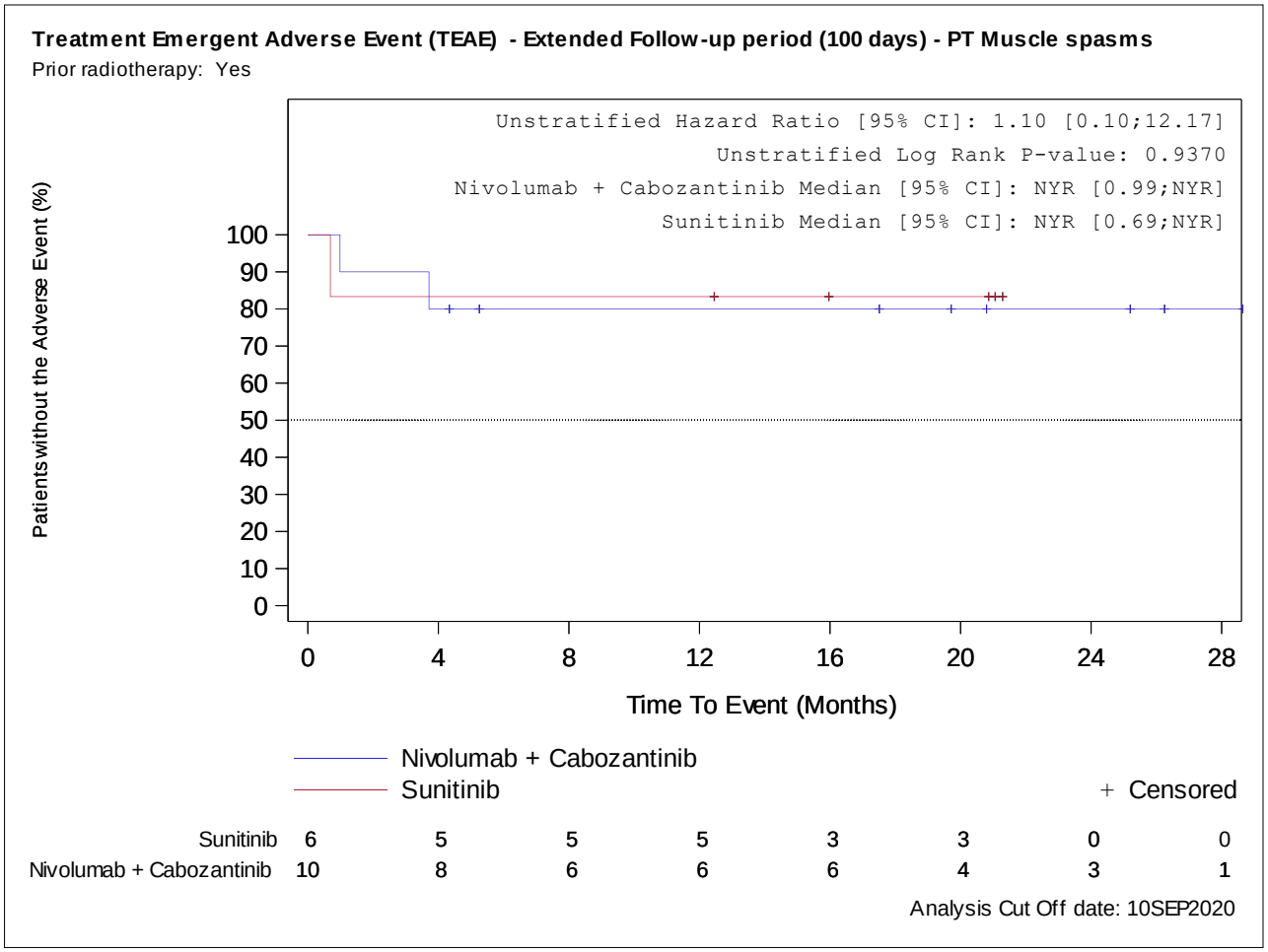

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:25:03

FIGURE 5.33.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



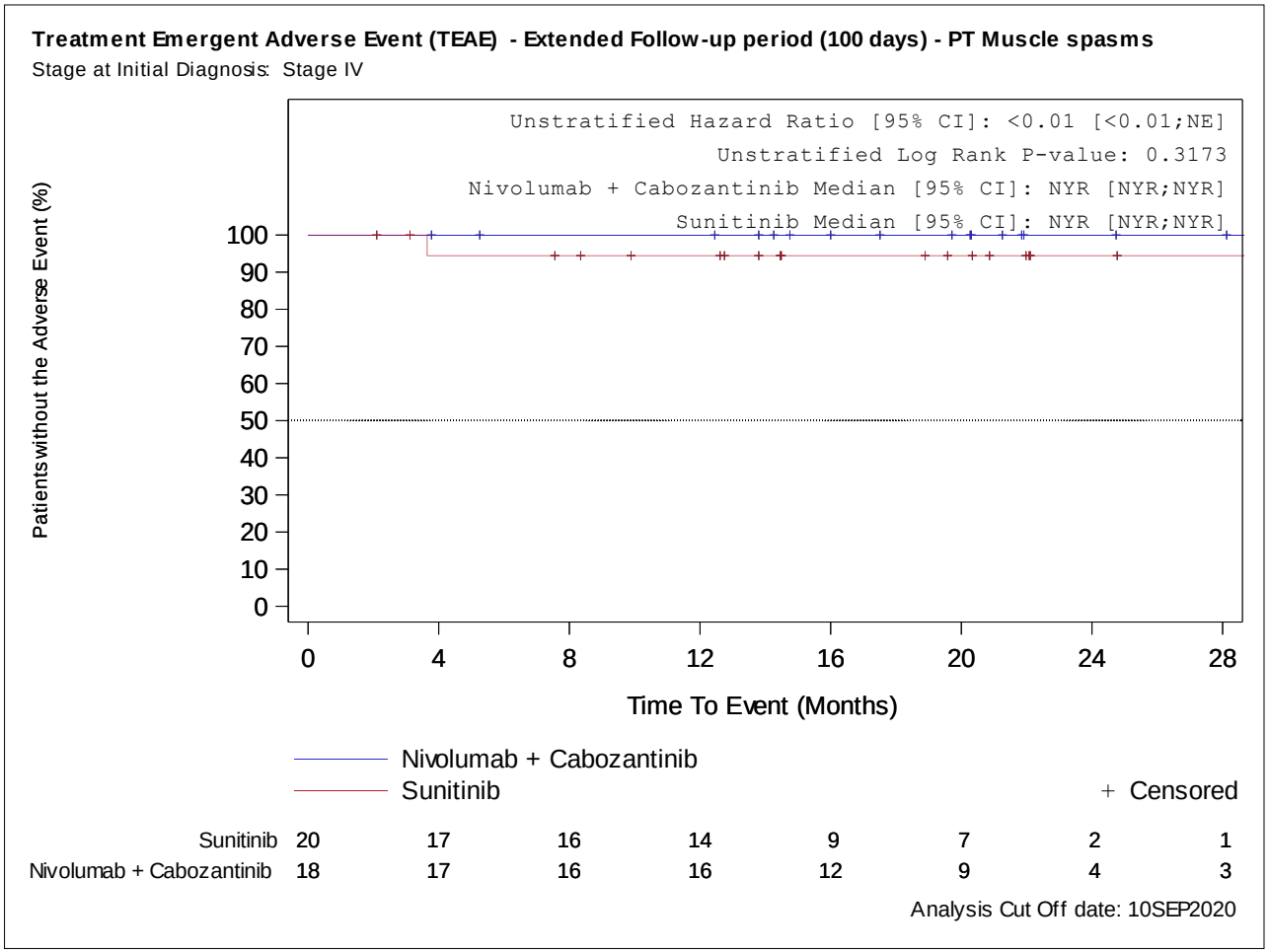

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:25:08

FIGURE 5.33.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



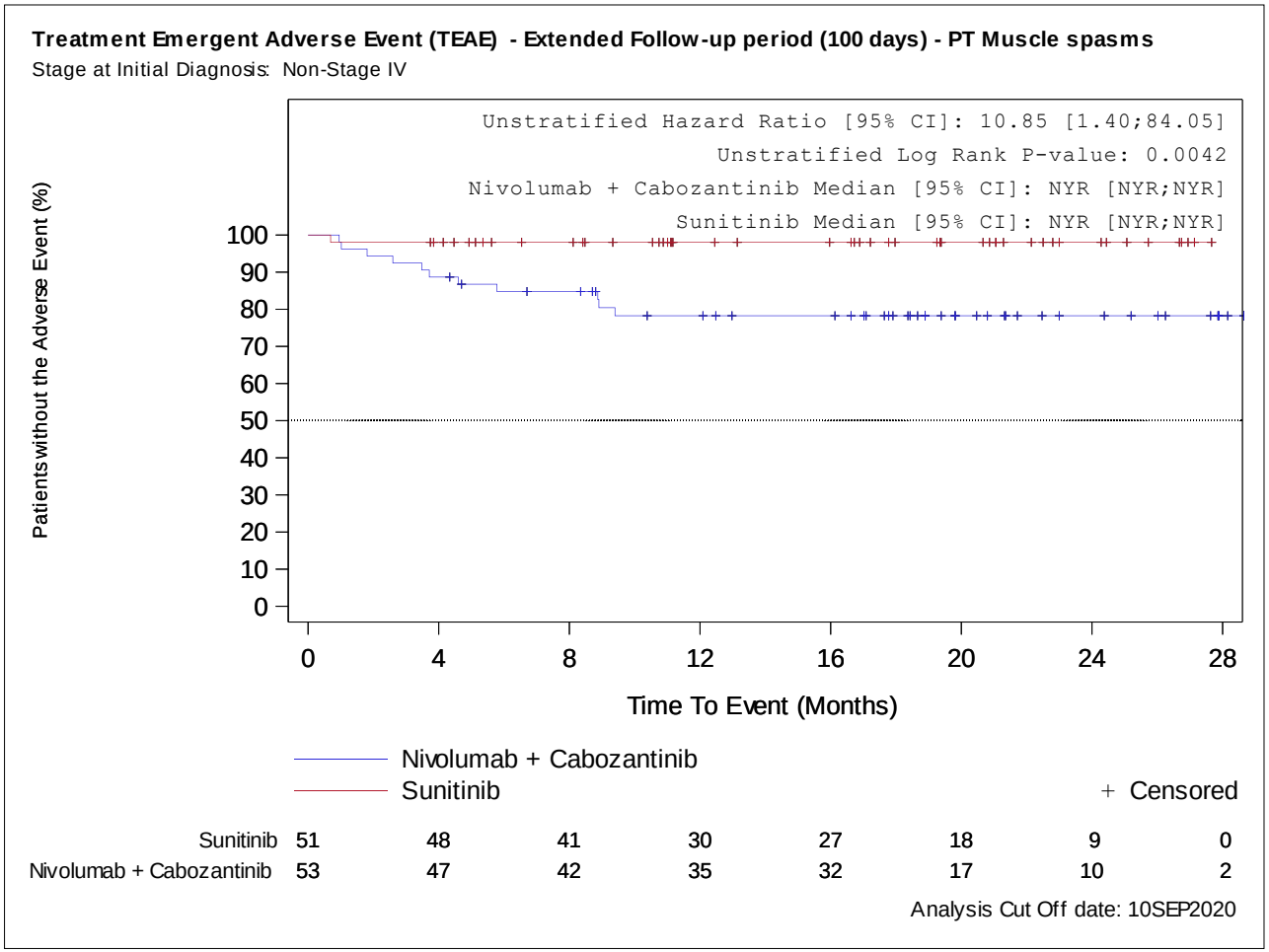

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:25:14

FIGURE 5.33.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:25:43

FIGURE 5.33.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Muscle spasms - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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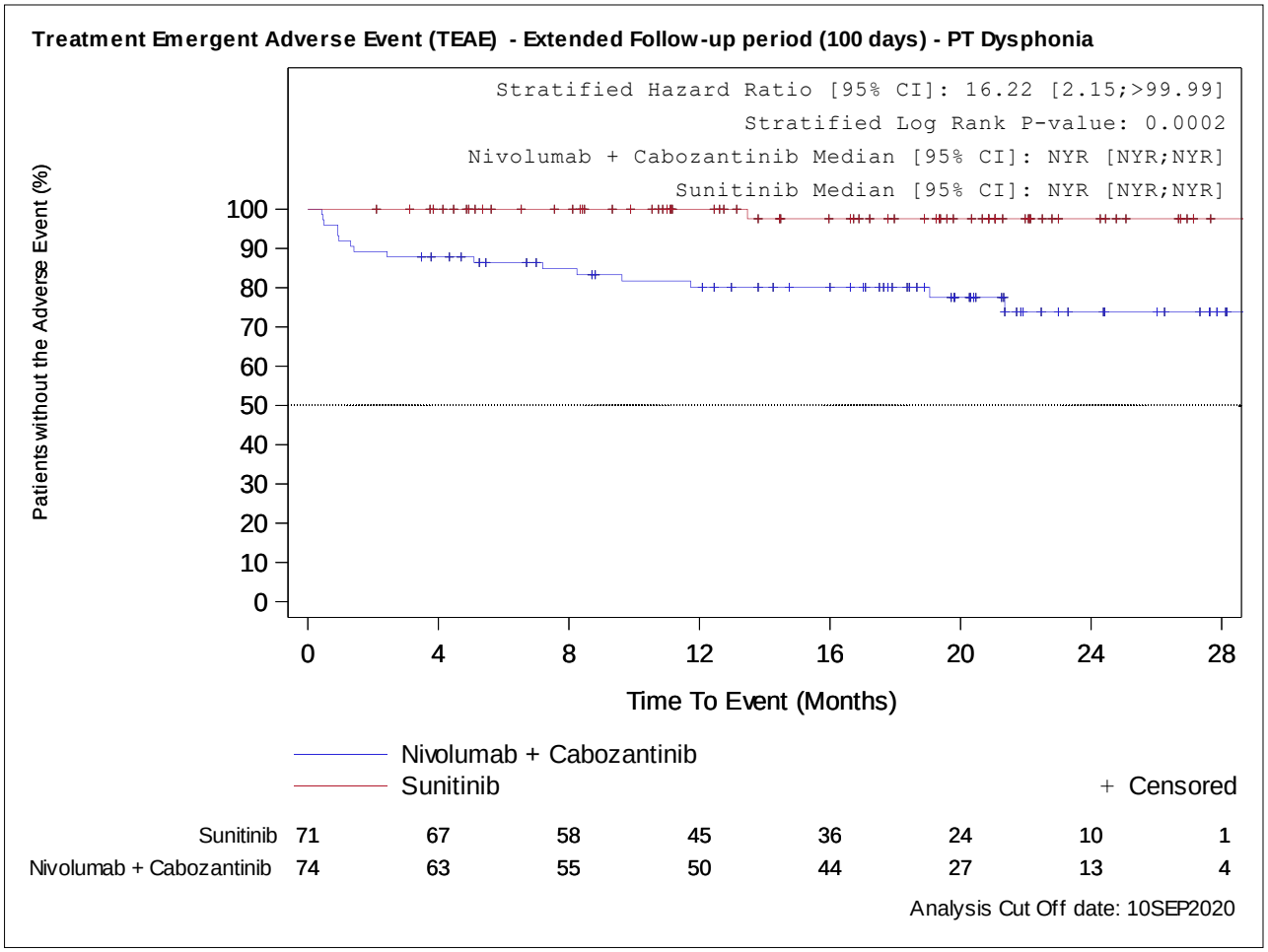
FIGURE 5.34.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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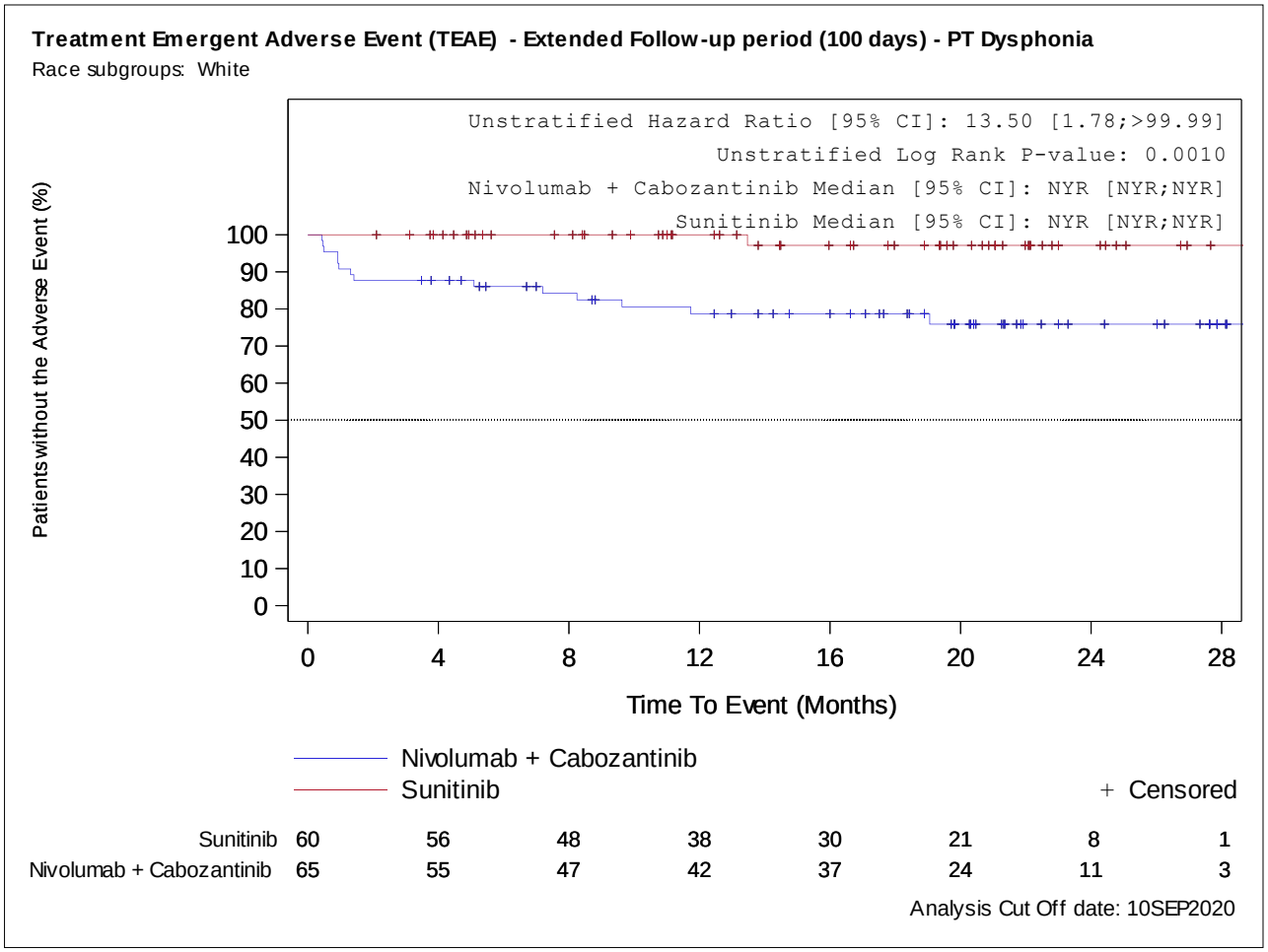
FIGURE 5.34.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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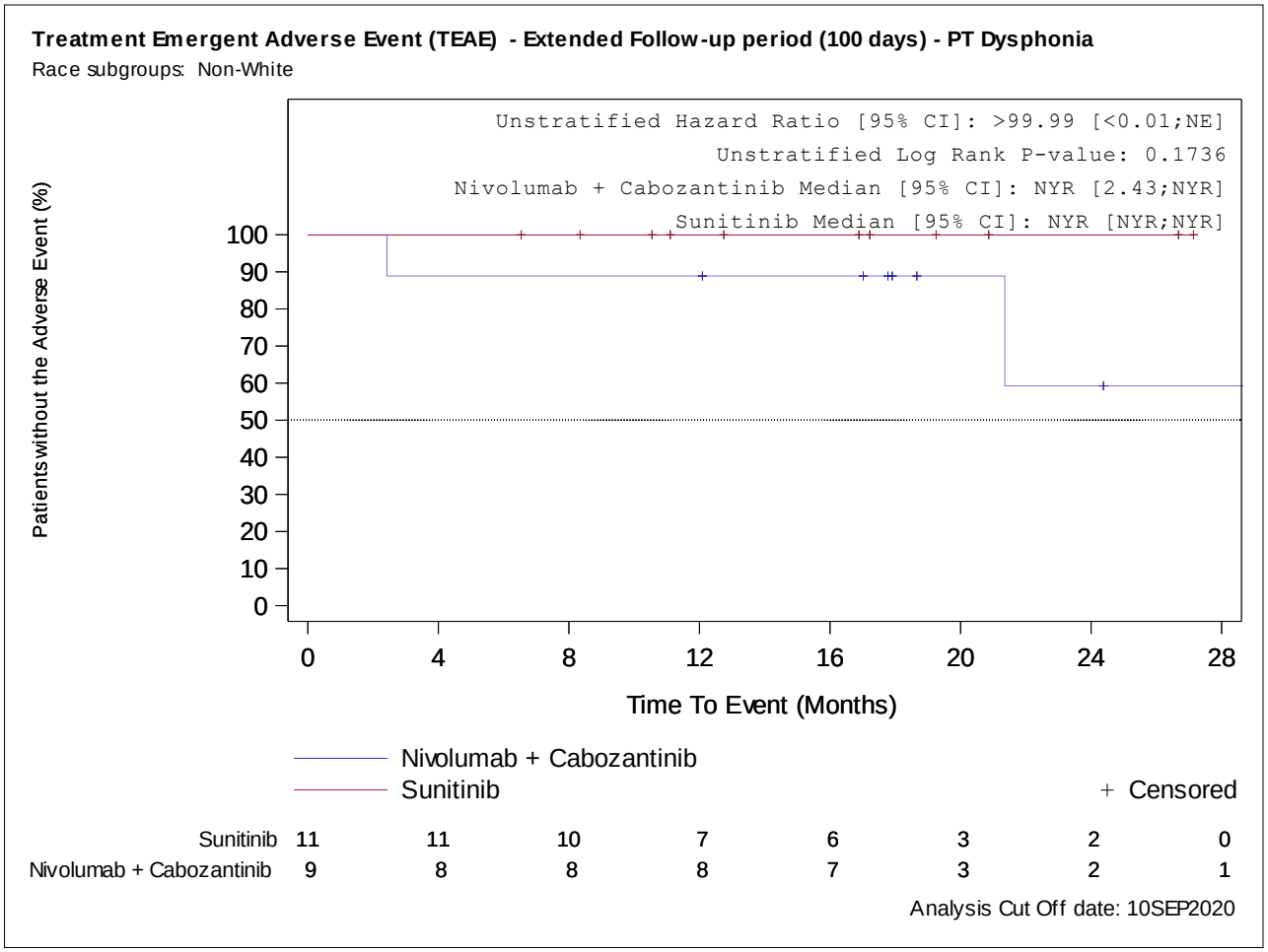
FIGURE 5.34.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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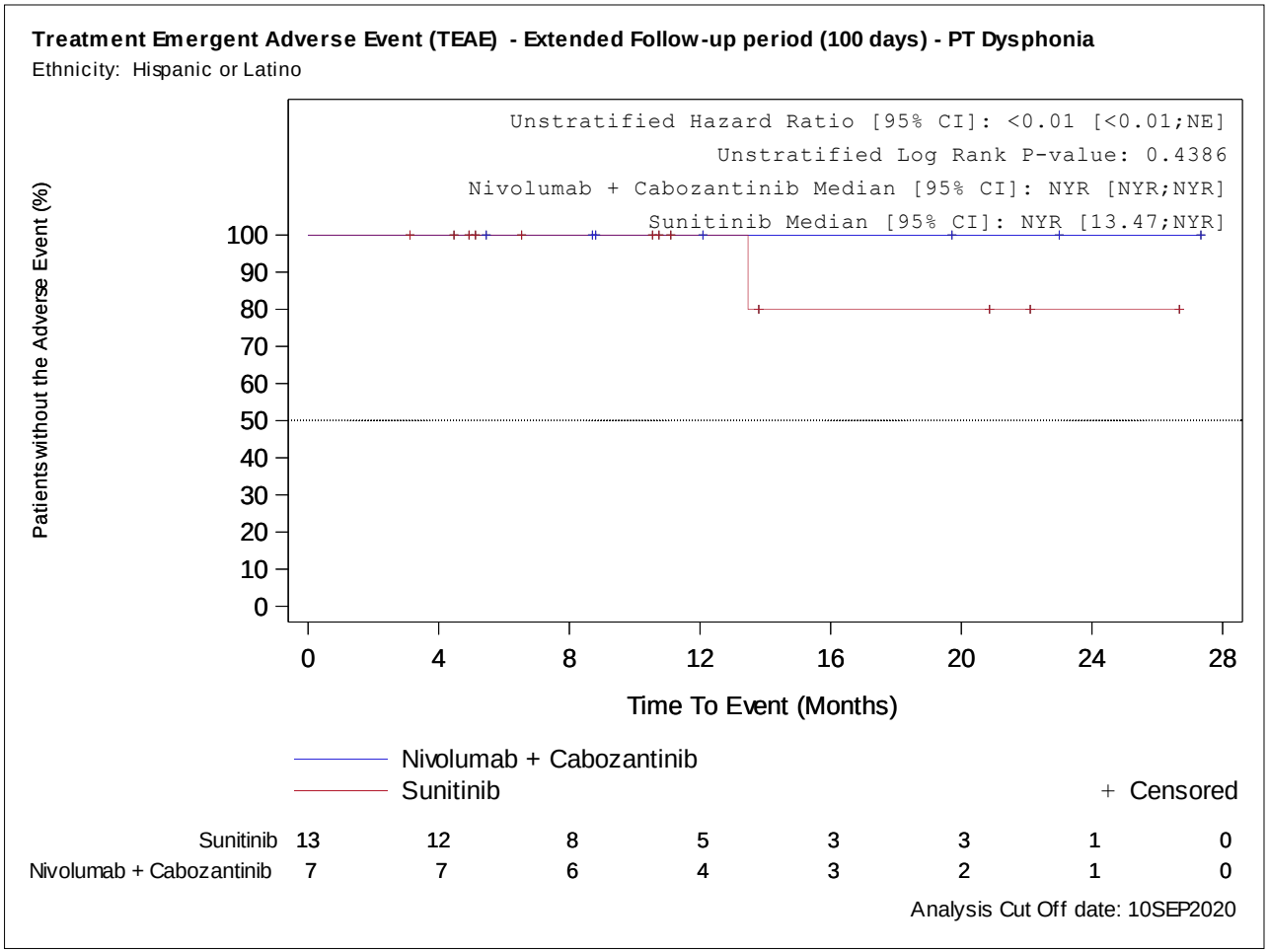
FIGURE 5.34.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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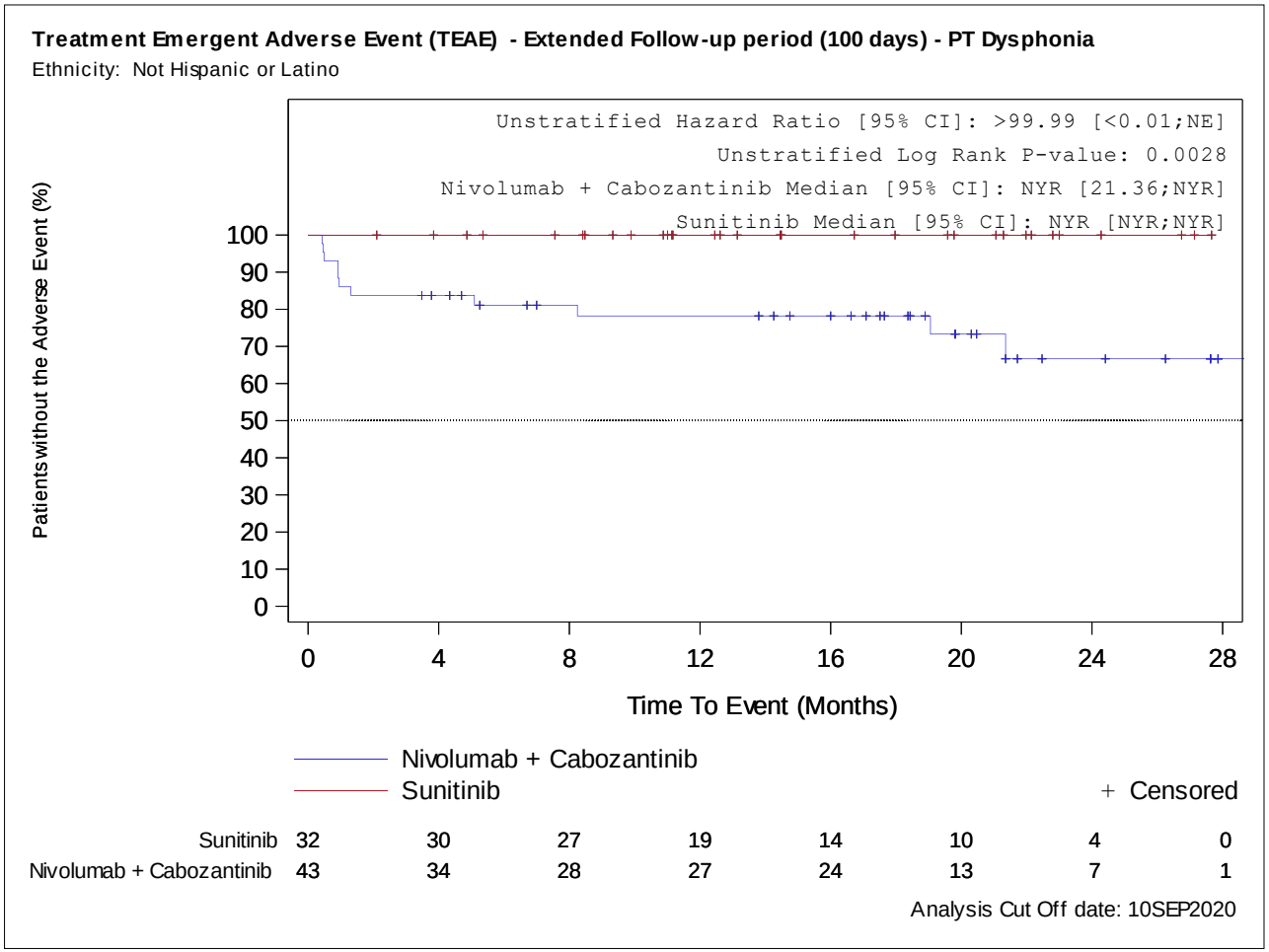
FIGURE 5.34.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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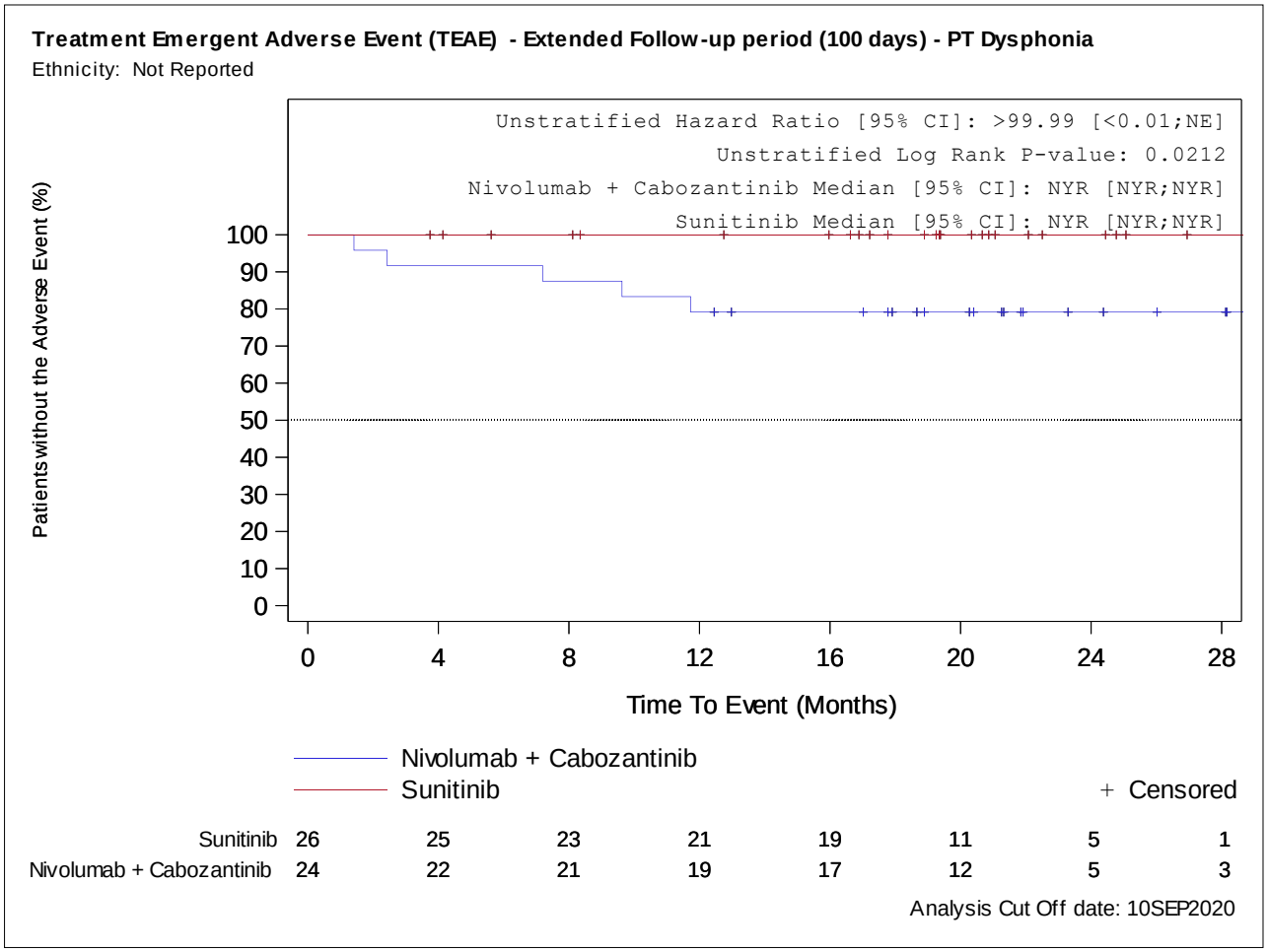
FIGURE 5.34.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
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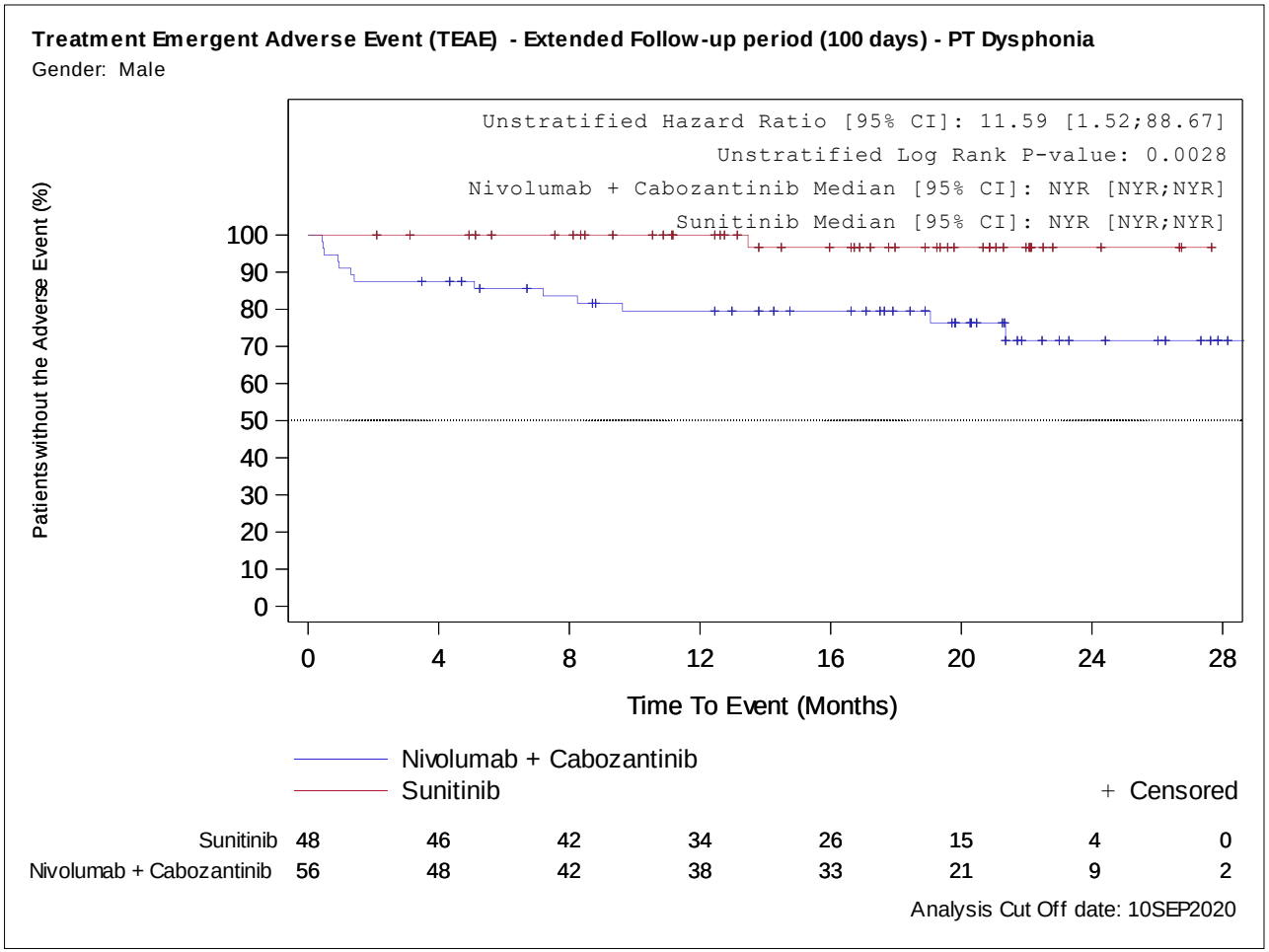
FIGURE 5.34.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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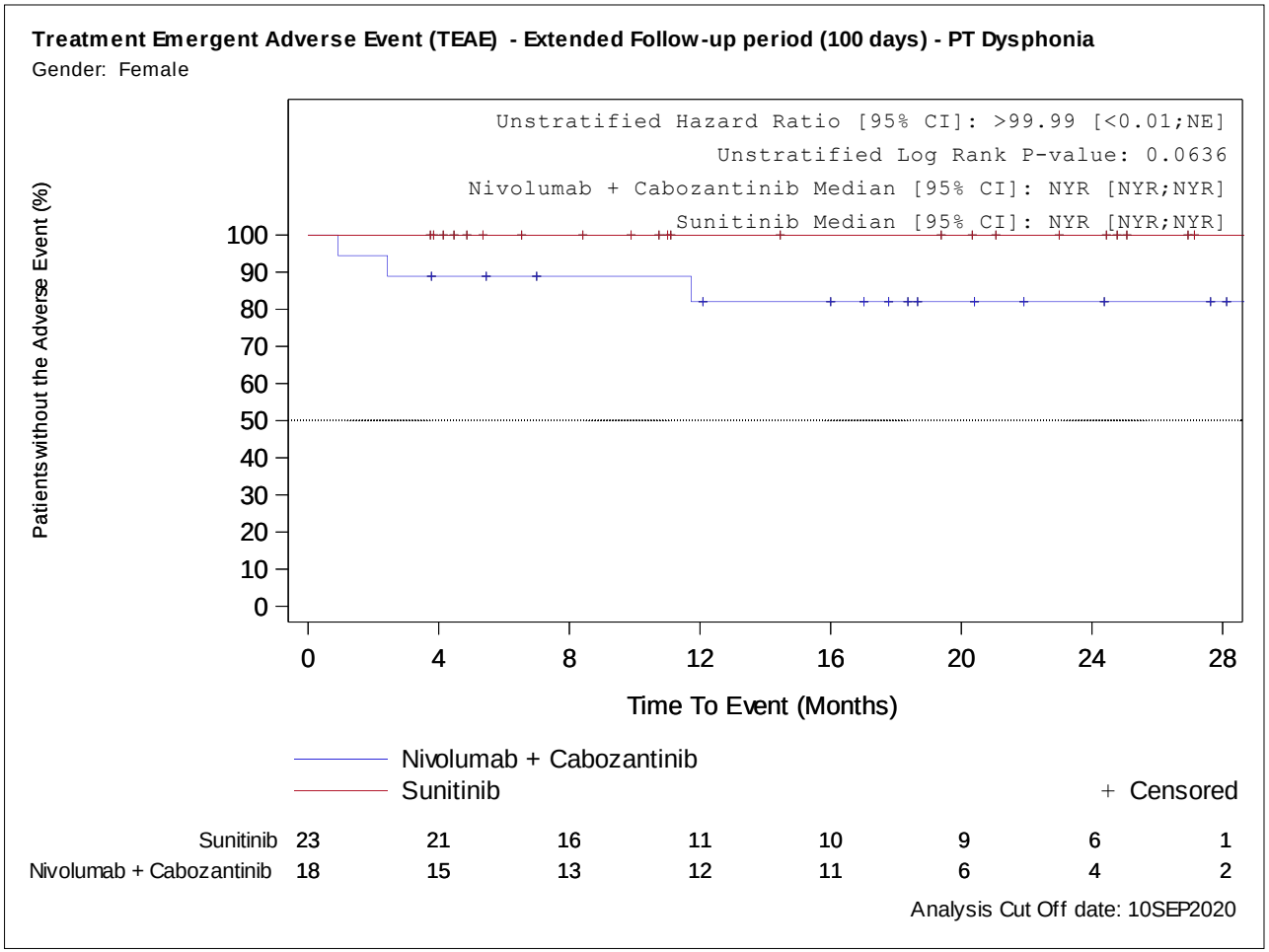
FIGURE 5.34.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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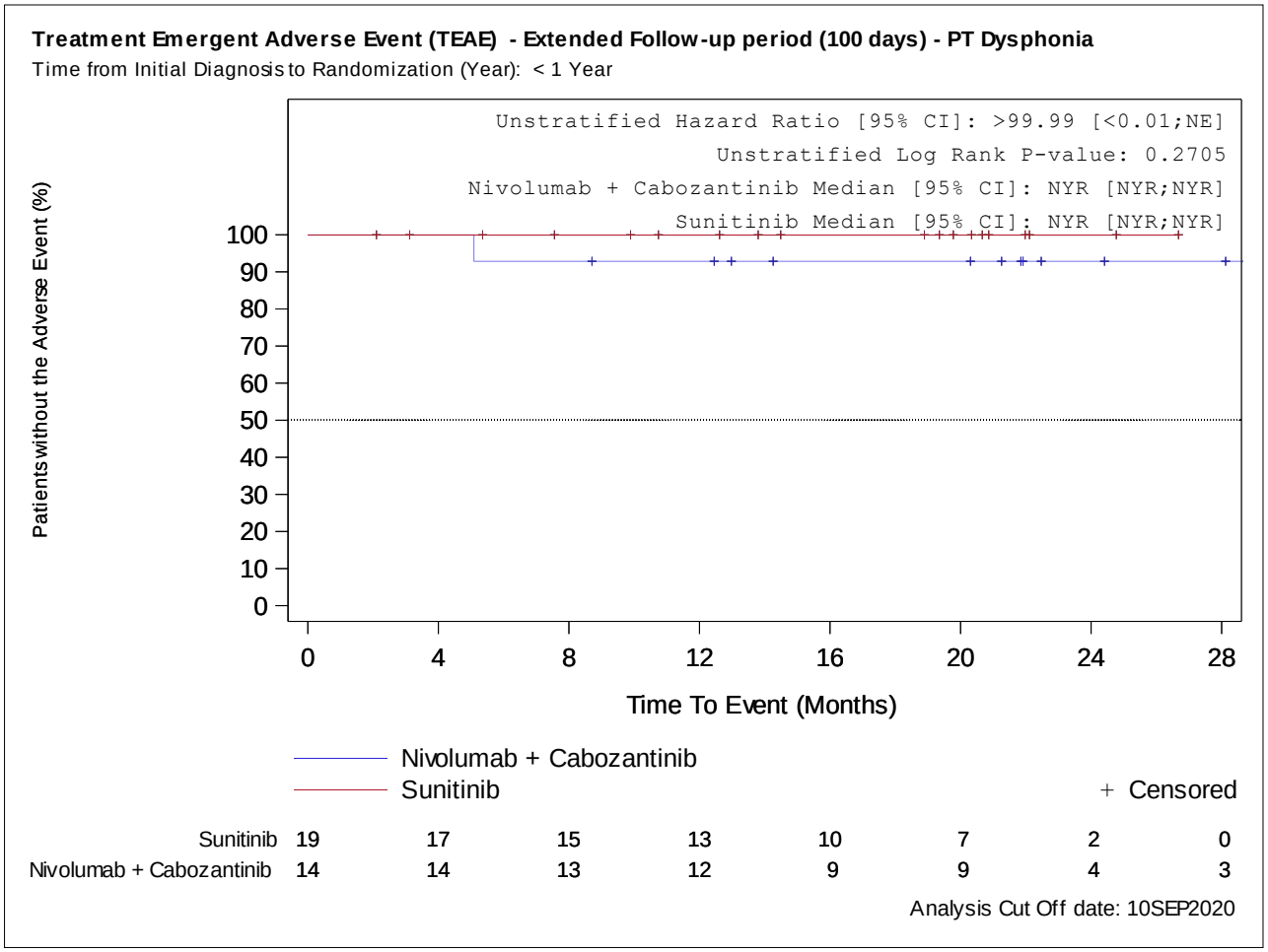
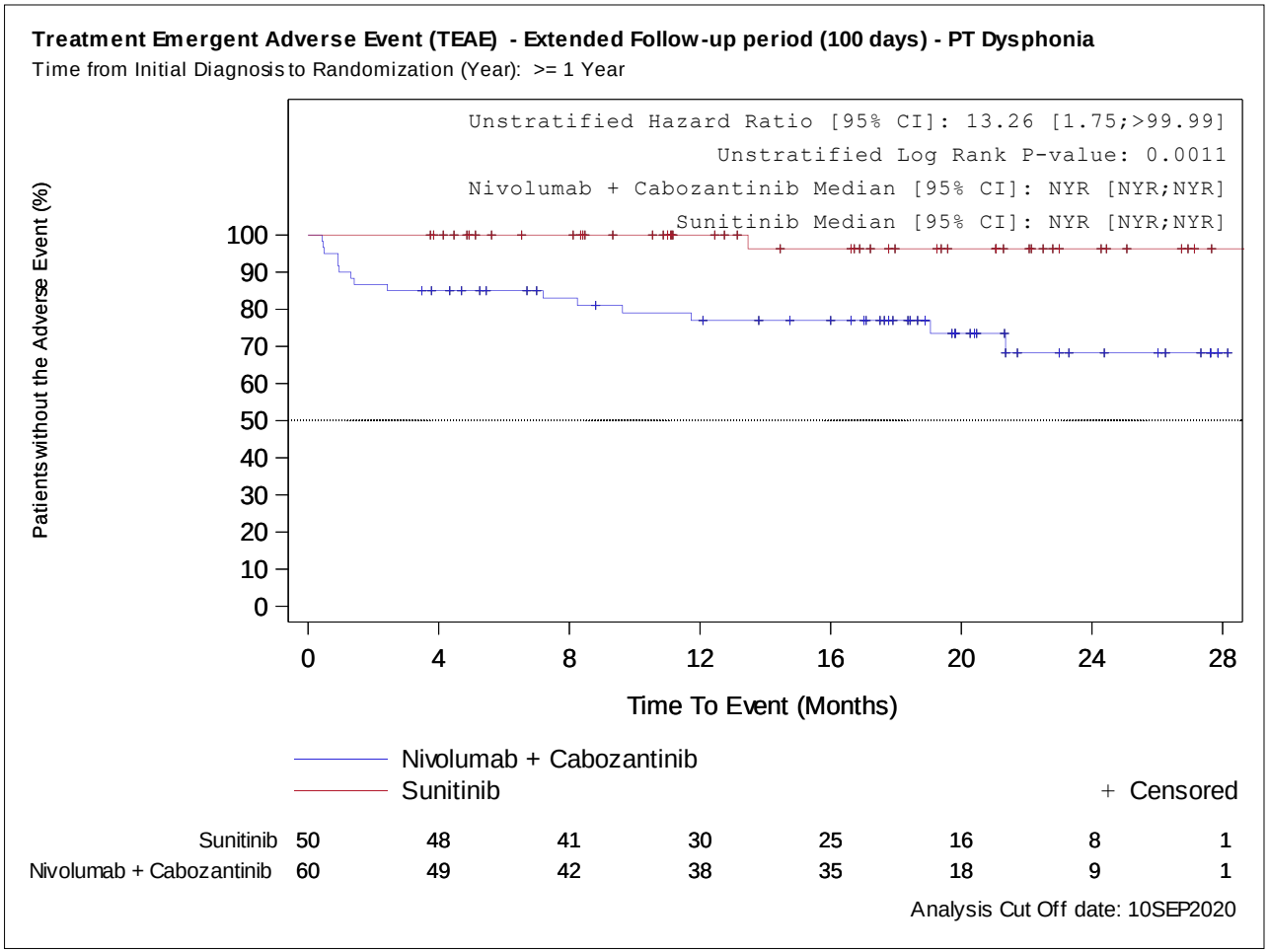
FIGURE 5.34.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



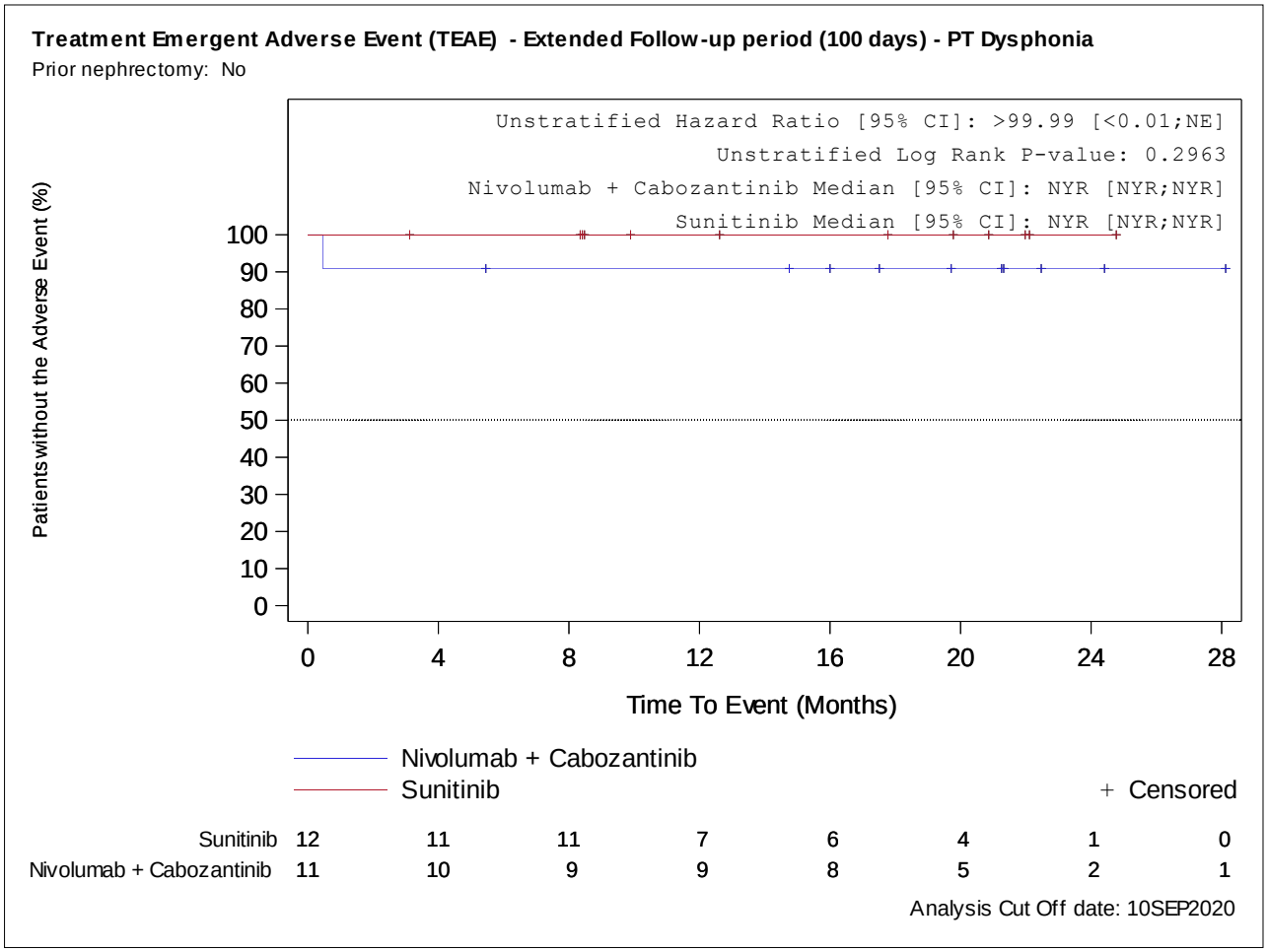

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:29:36

FIGURE 5.34.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:29:42

FIGURE 5.34.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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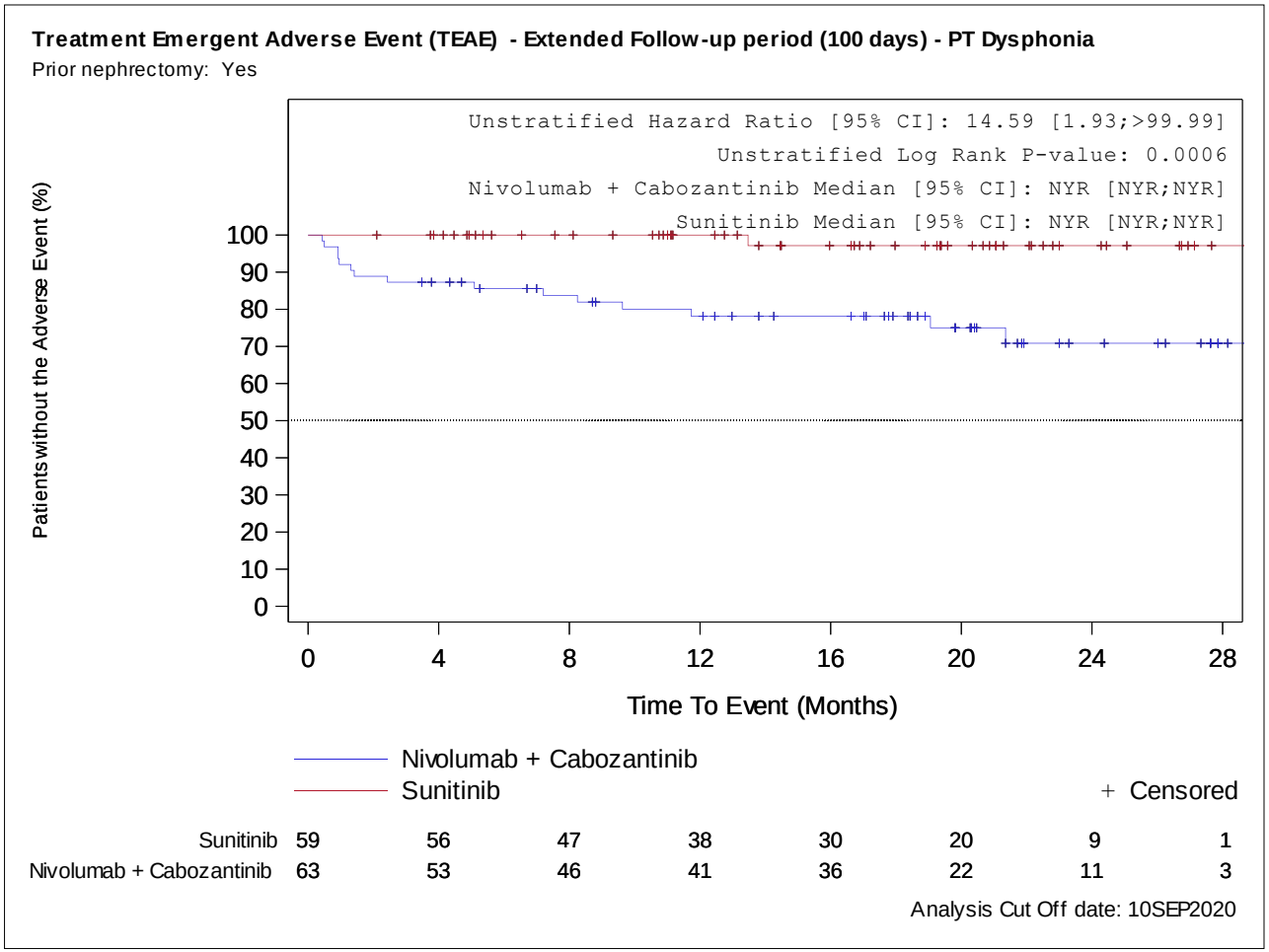
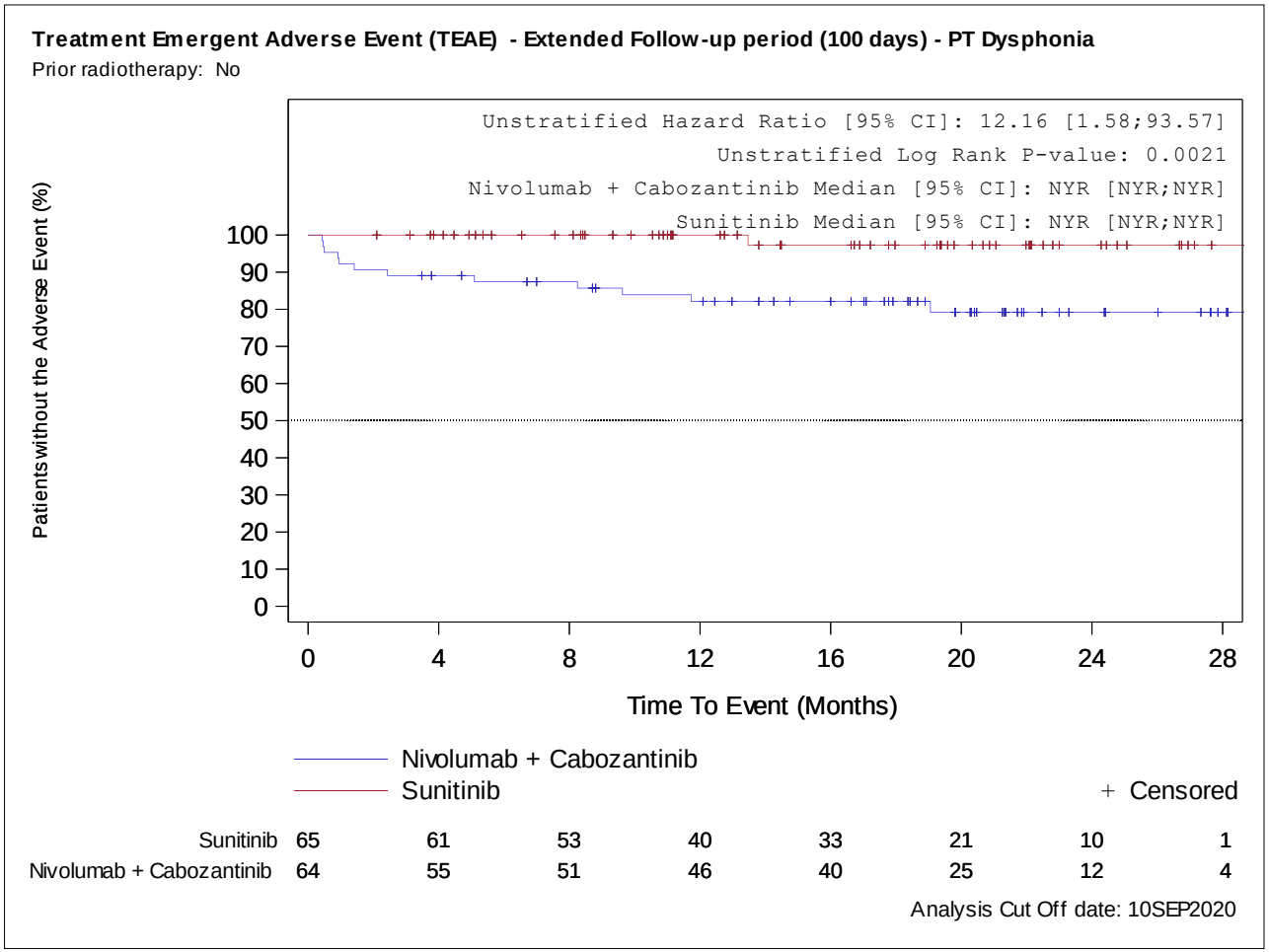
FIGURE 5.34.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:30:41

FIGURE 5.34.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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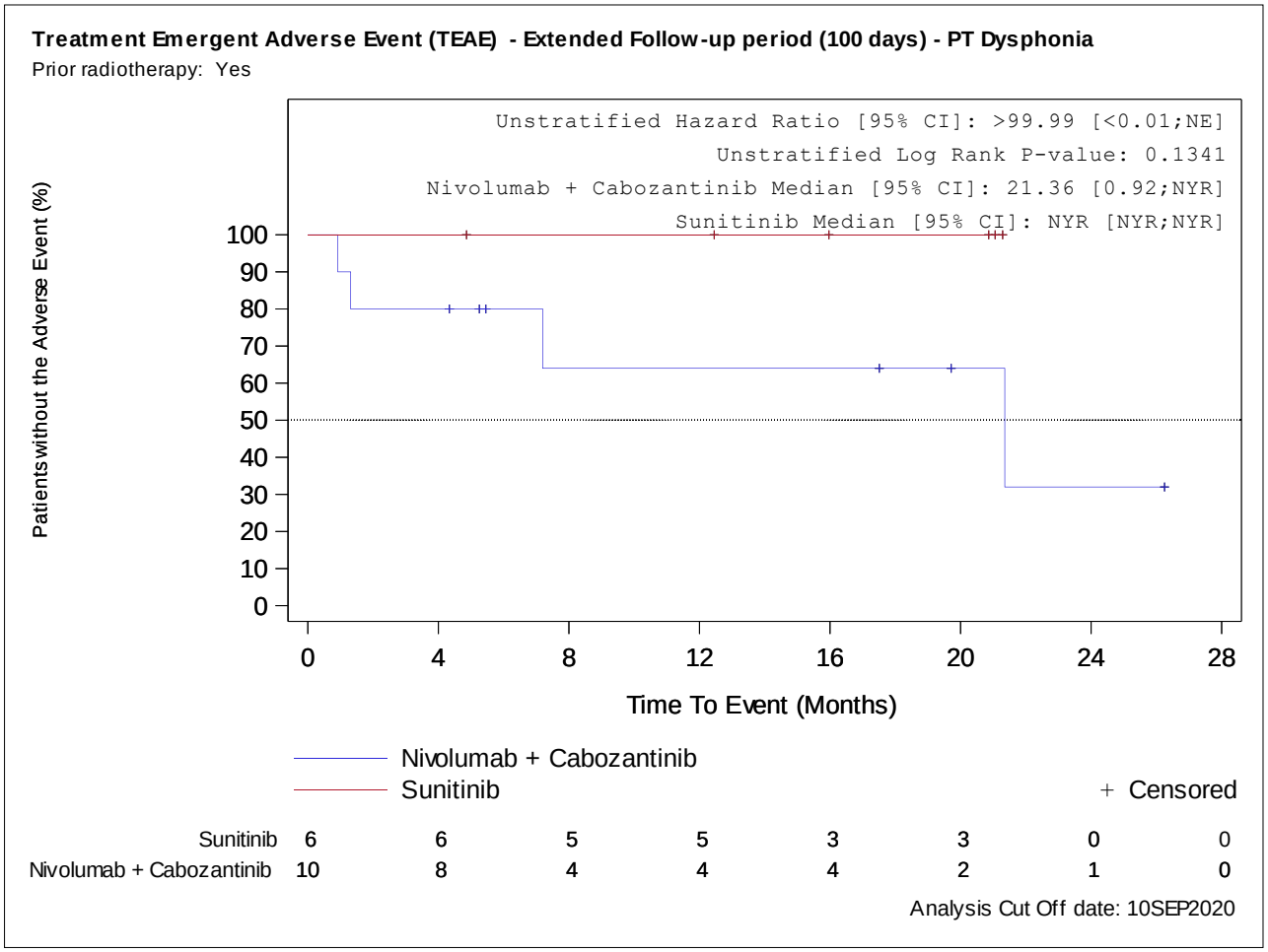
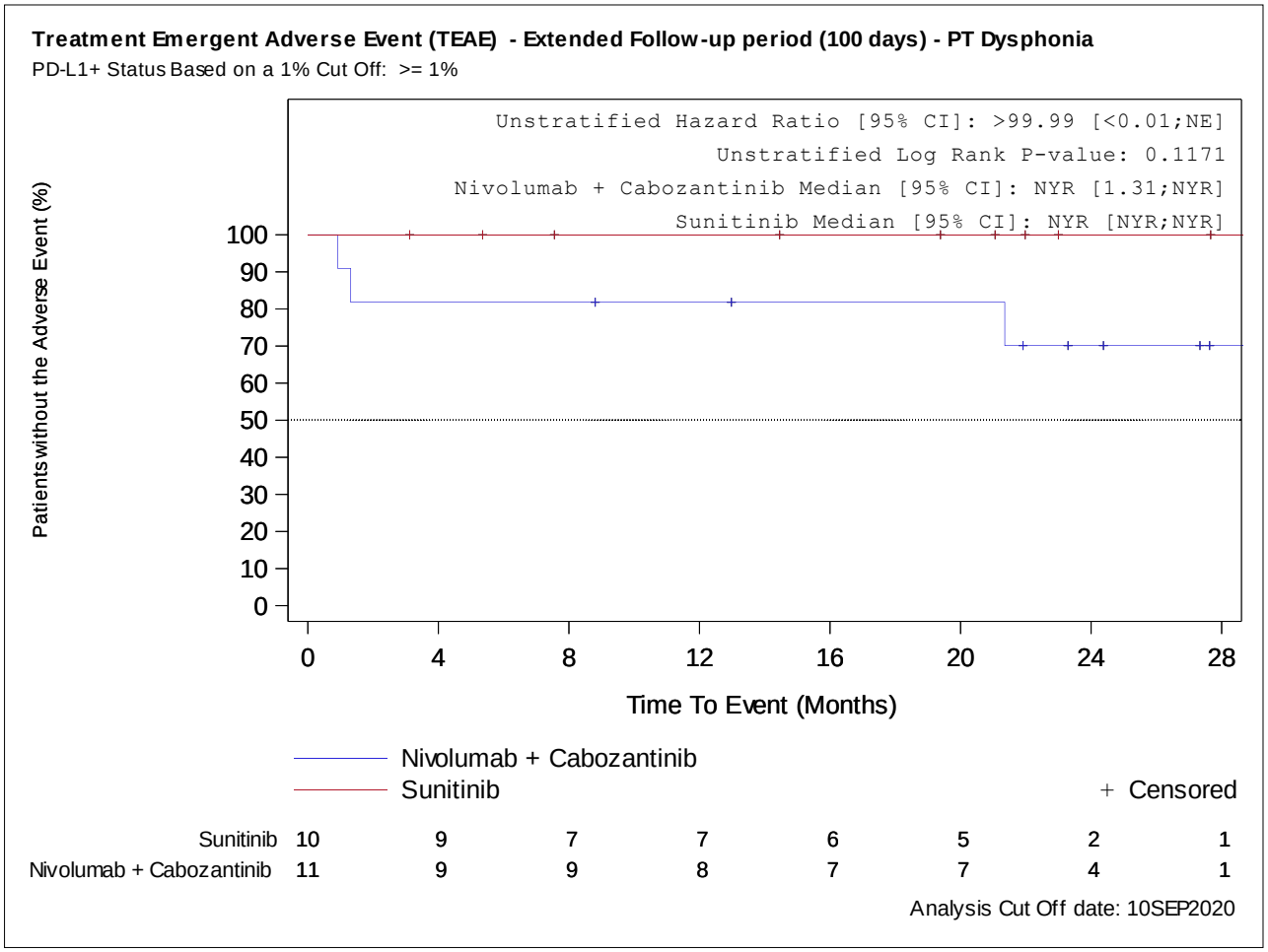
FIGURE 5.34.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



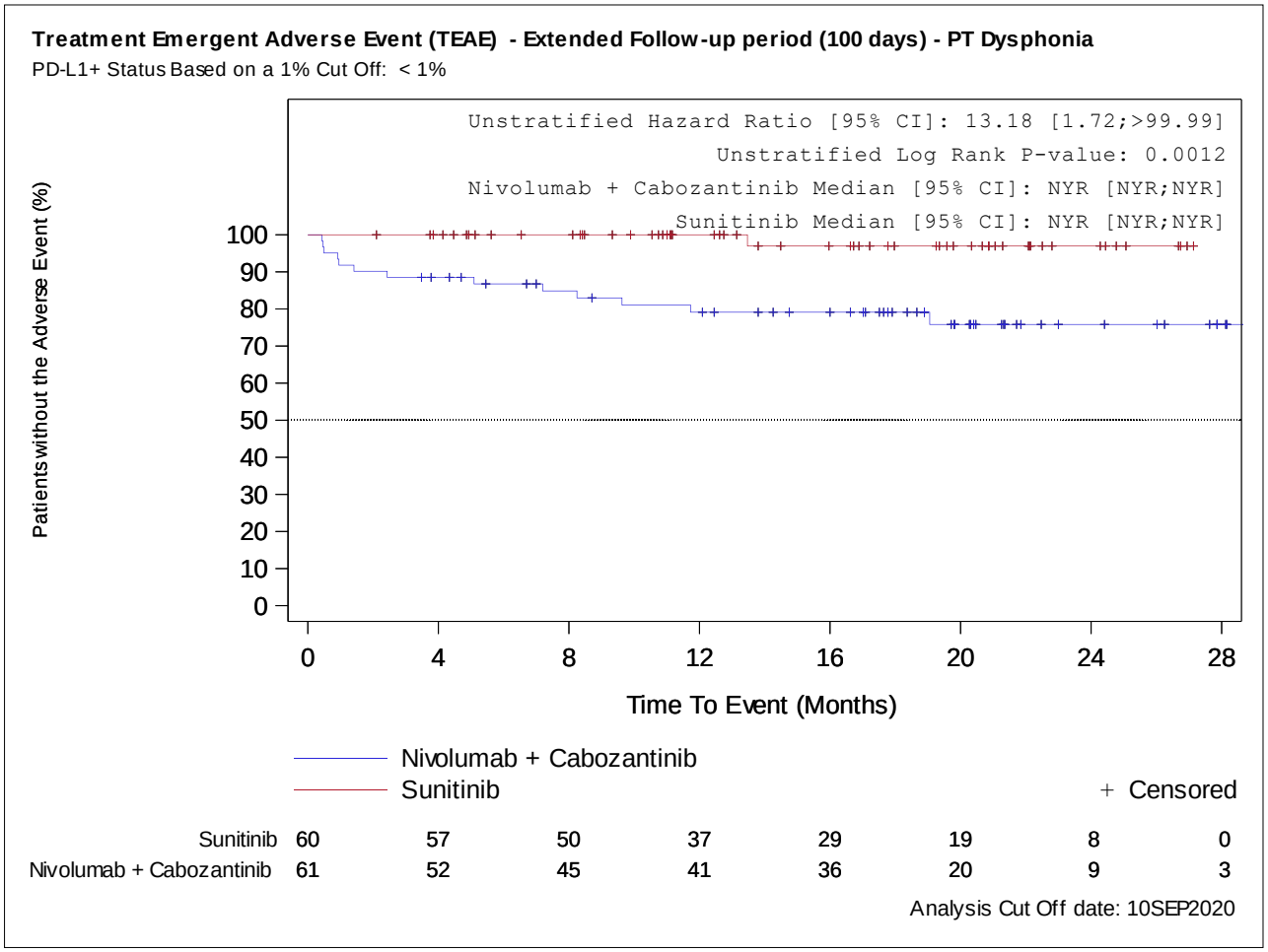

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:30:53

FIGURE 5.34.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



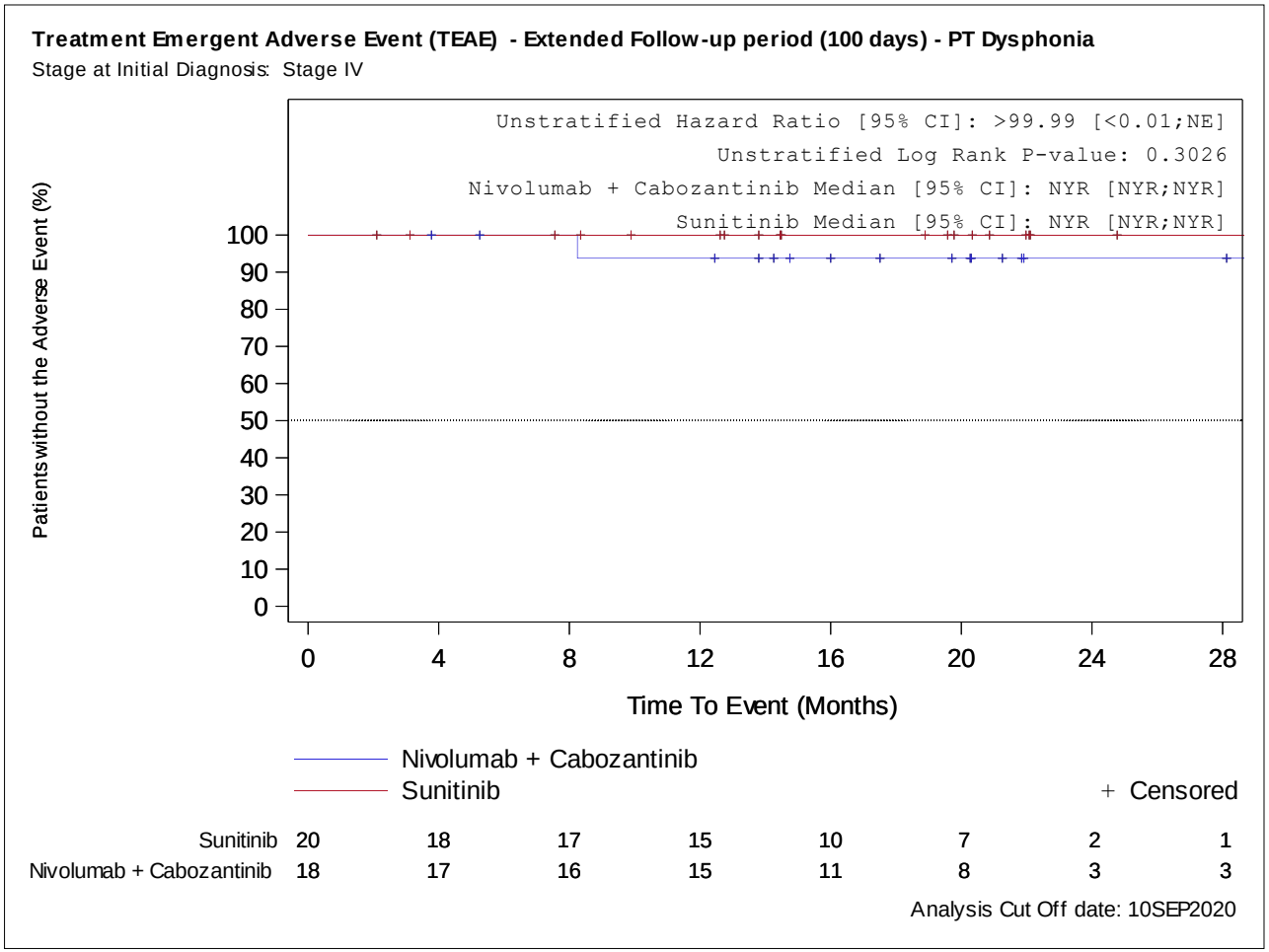

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:30:58

FIGURE 5.34.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:31:04

FIGURE 5.34.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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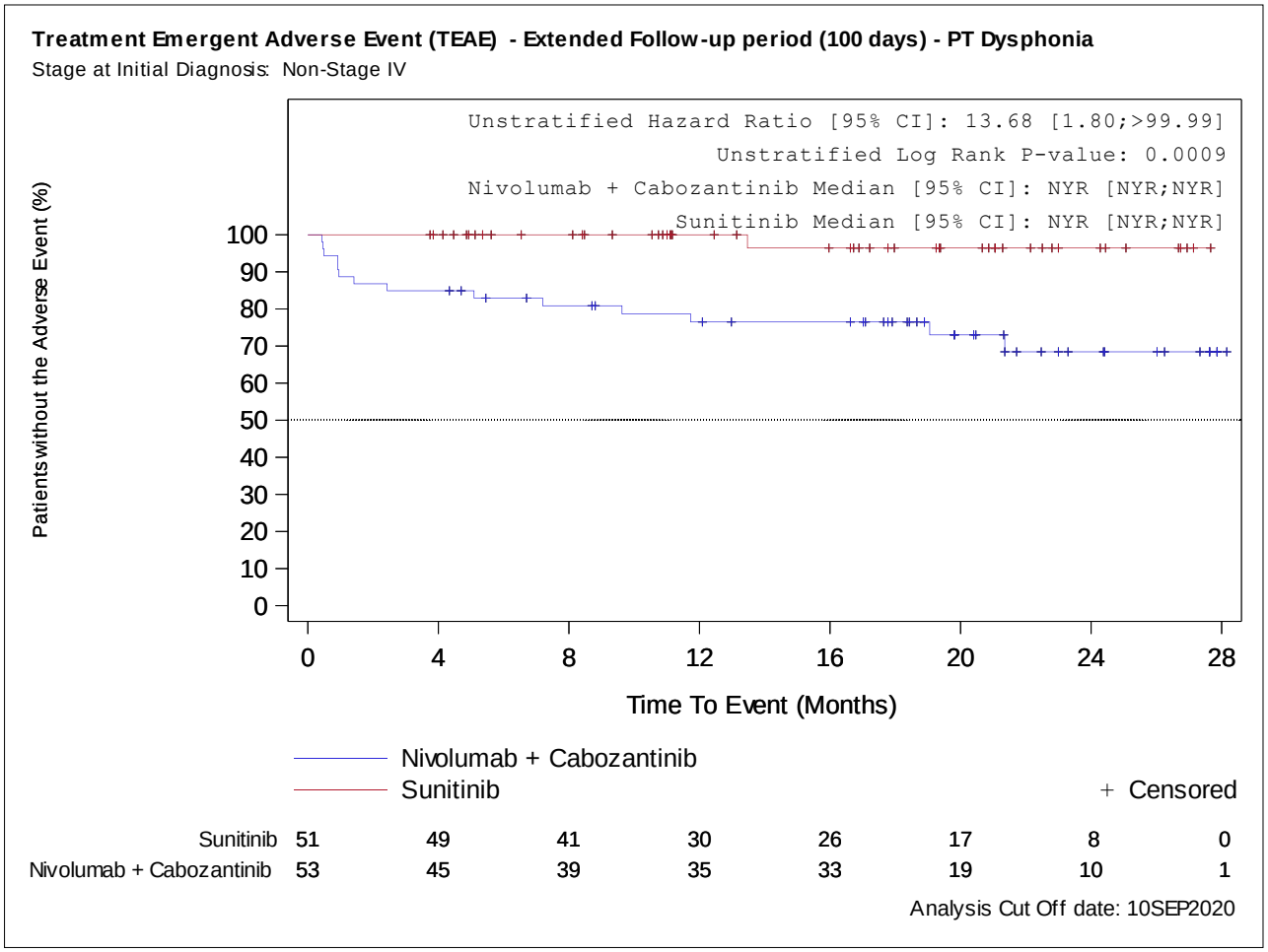
FIGURE 5.34.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Dysphonia - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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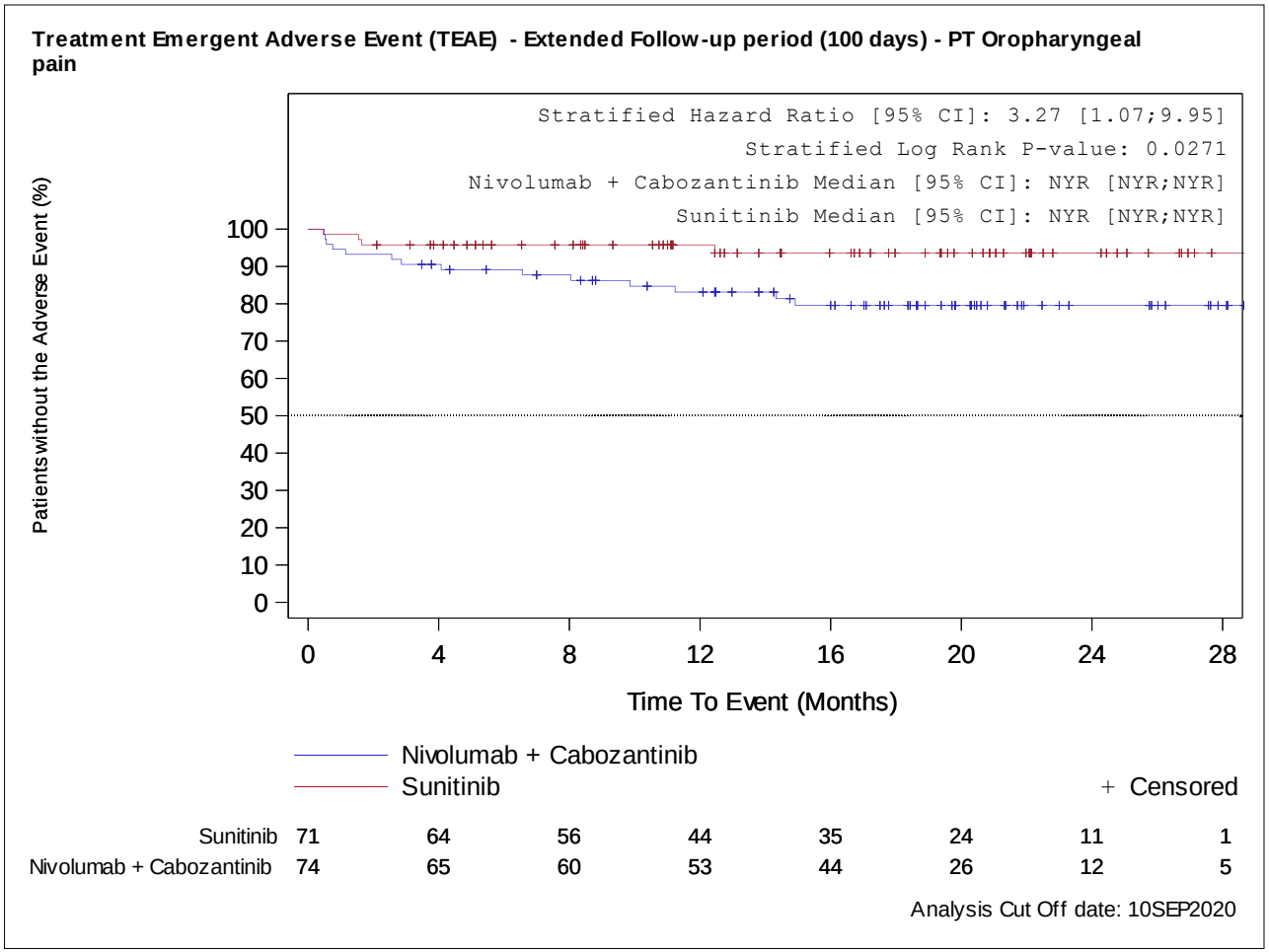
FIGURE 5.35.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
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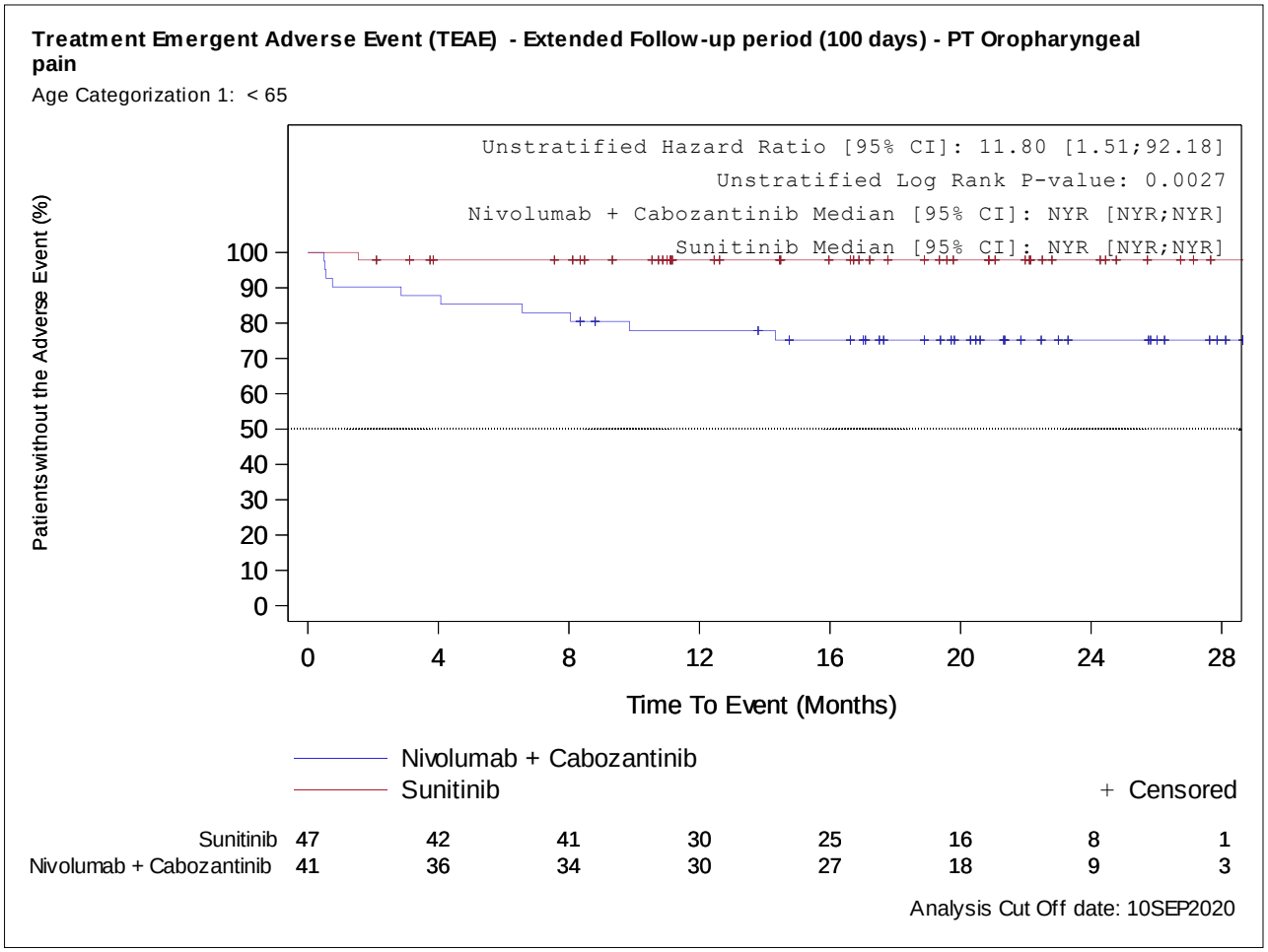
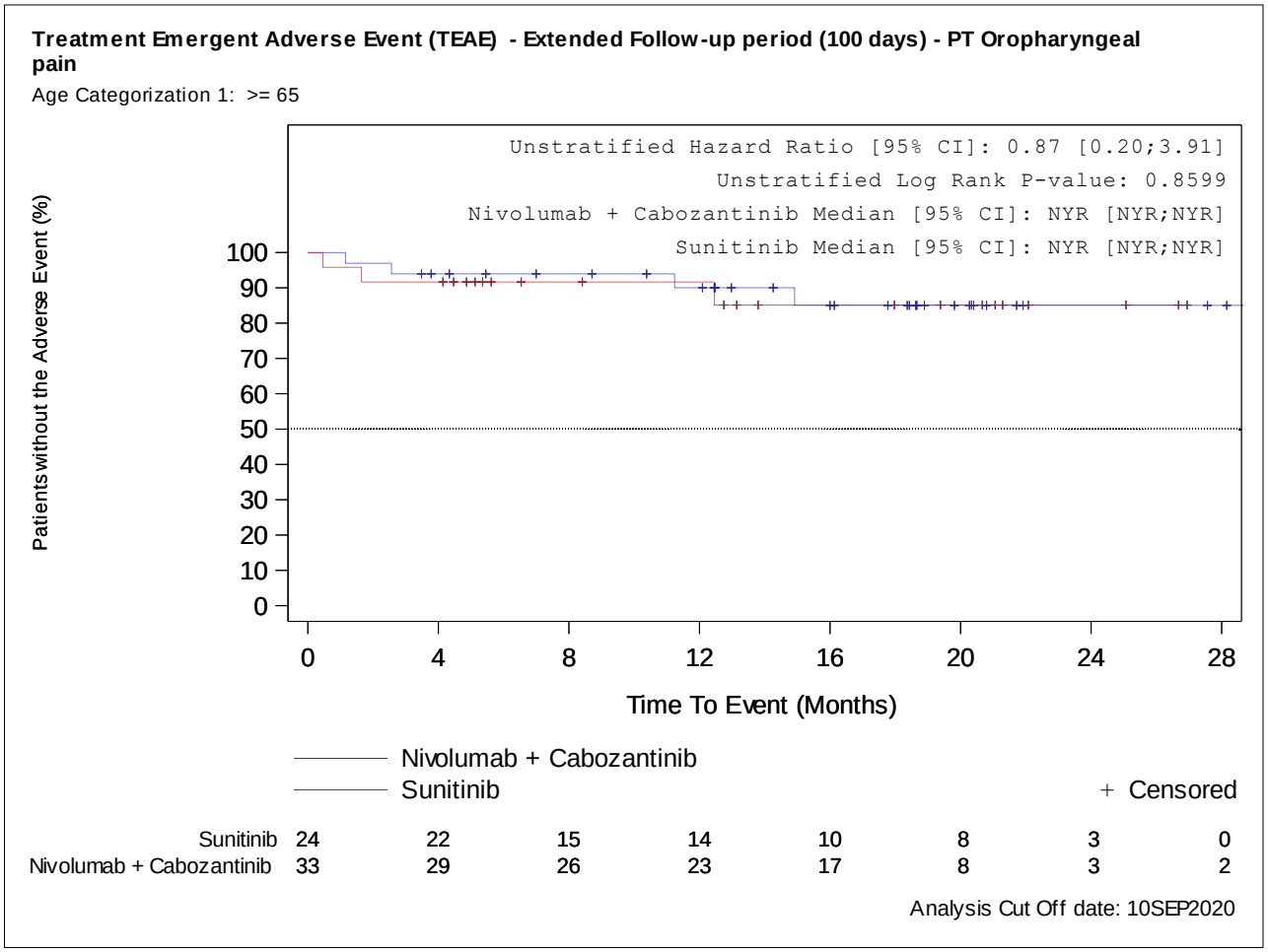
FIGURE 5.35.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:34:53

FIGURE 5.35.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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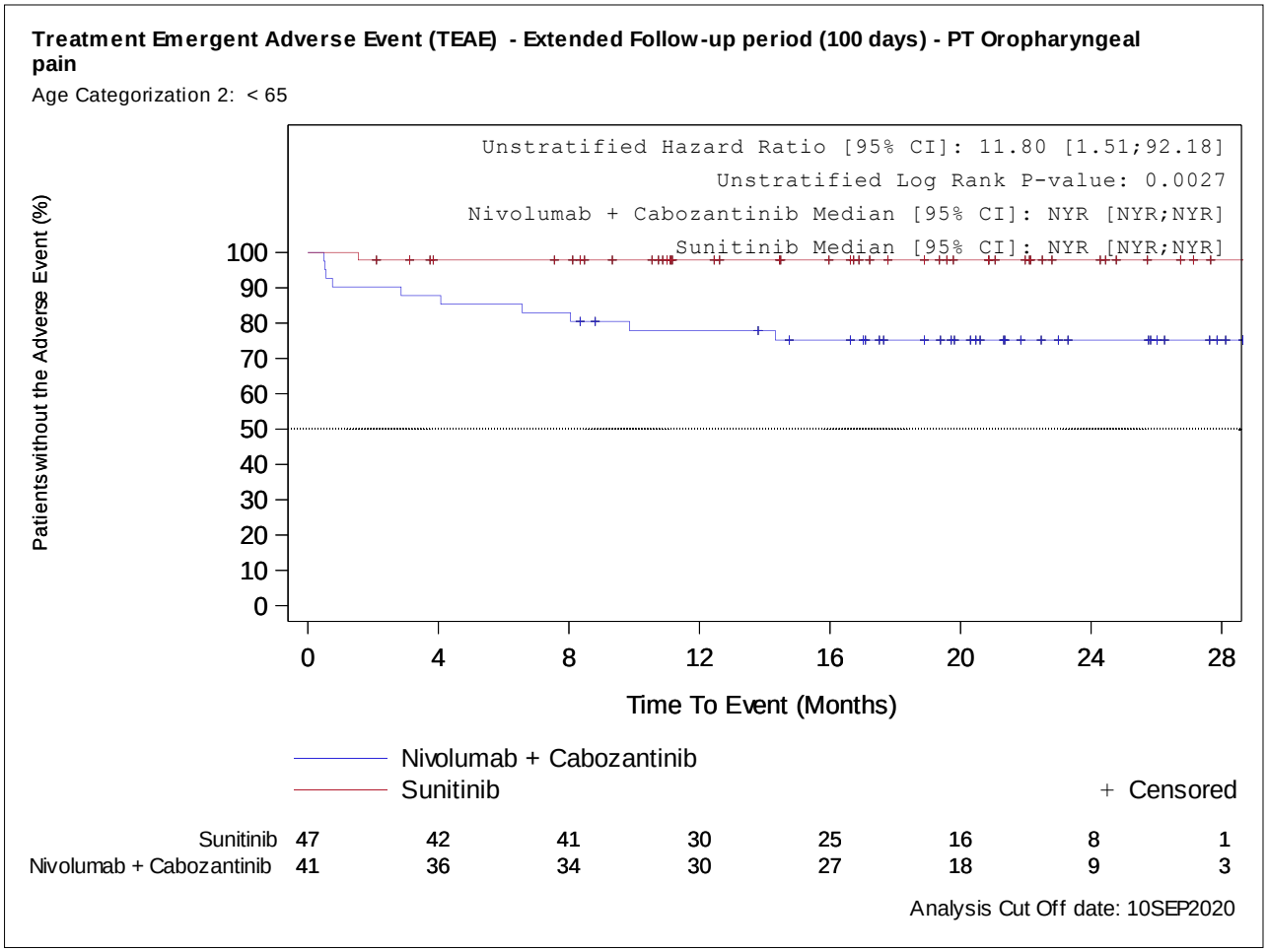
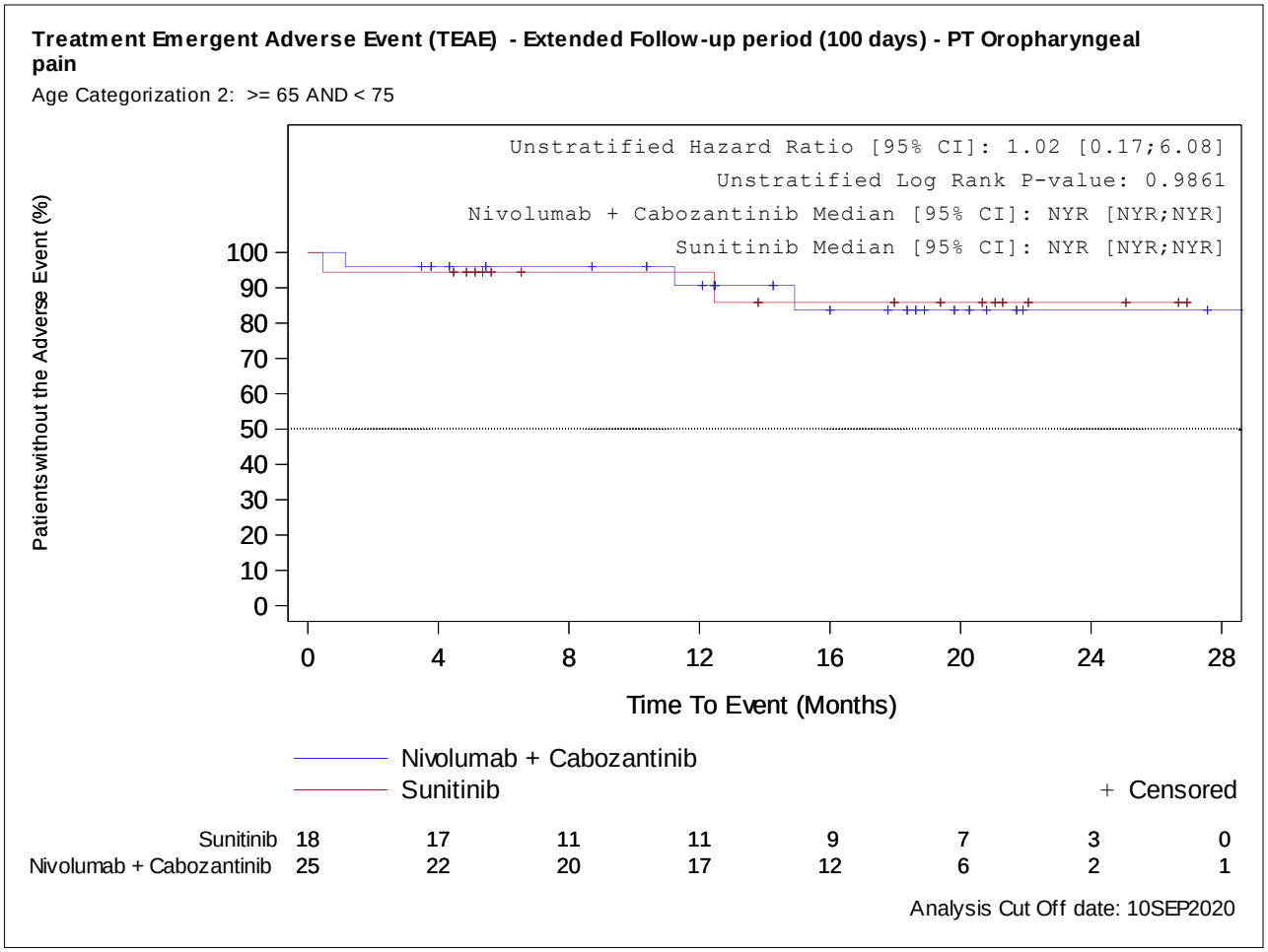
FIGURE 5.35.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65



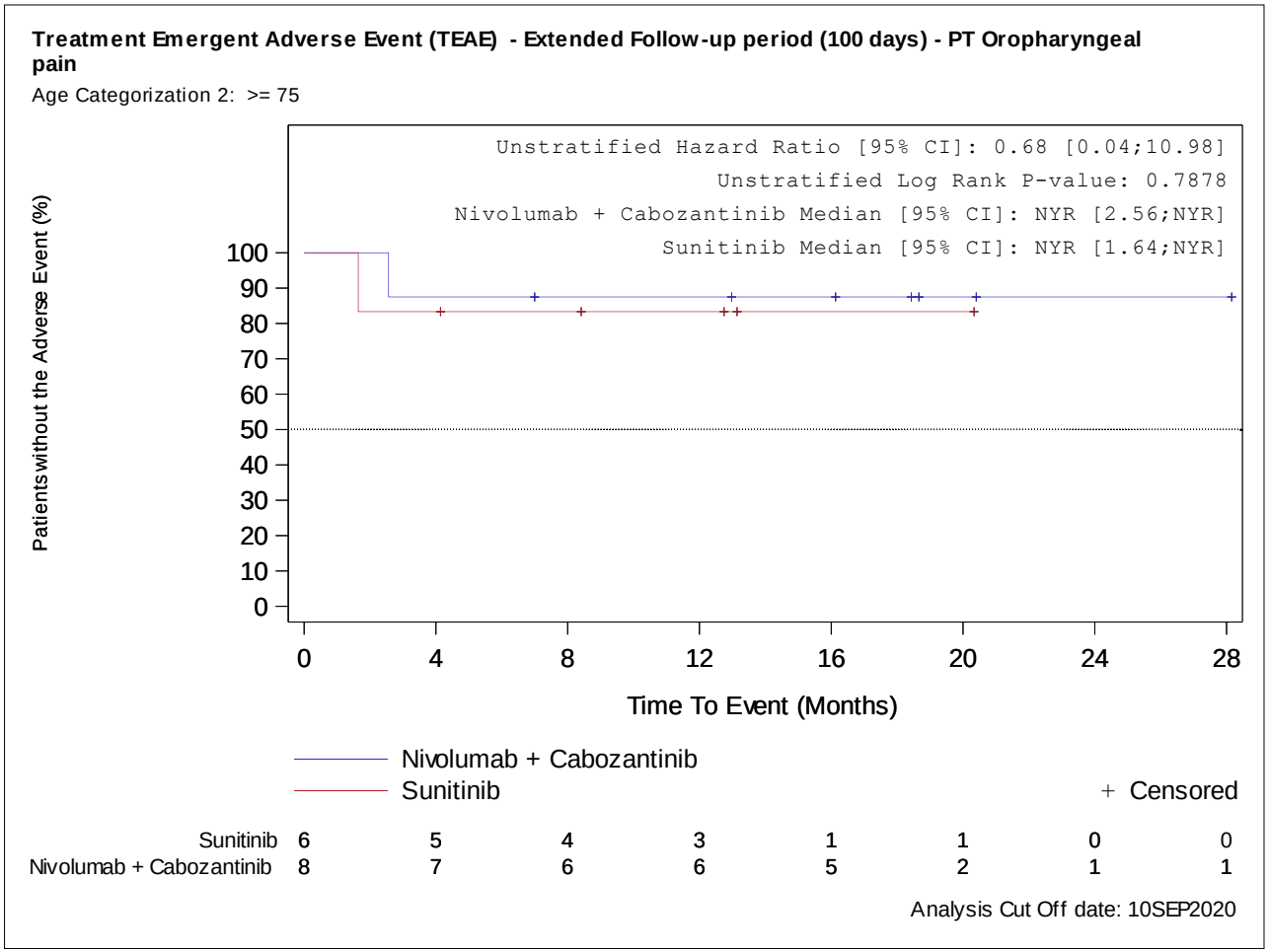

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:35:05

FIGURE 5.35.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



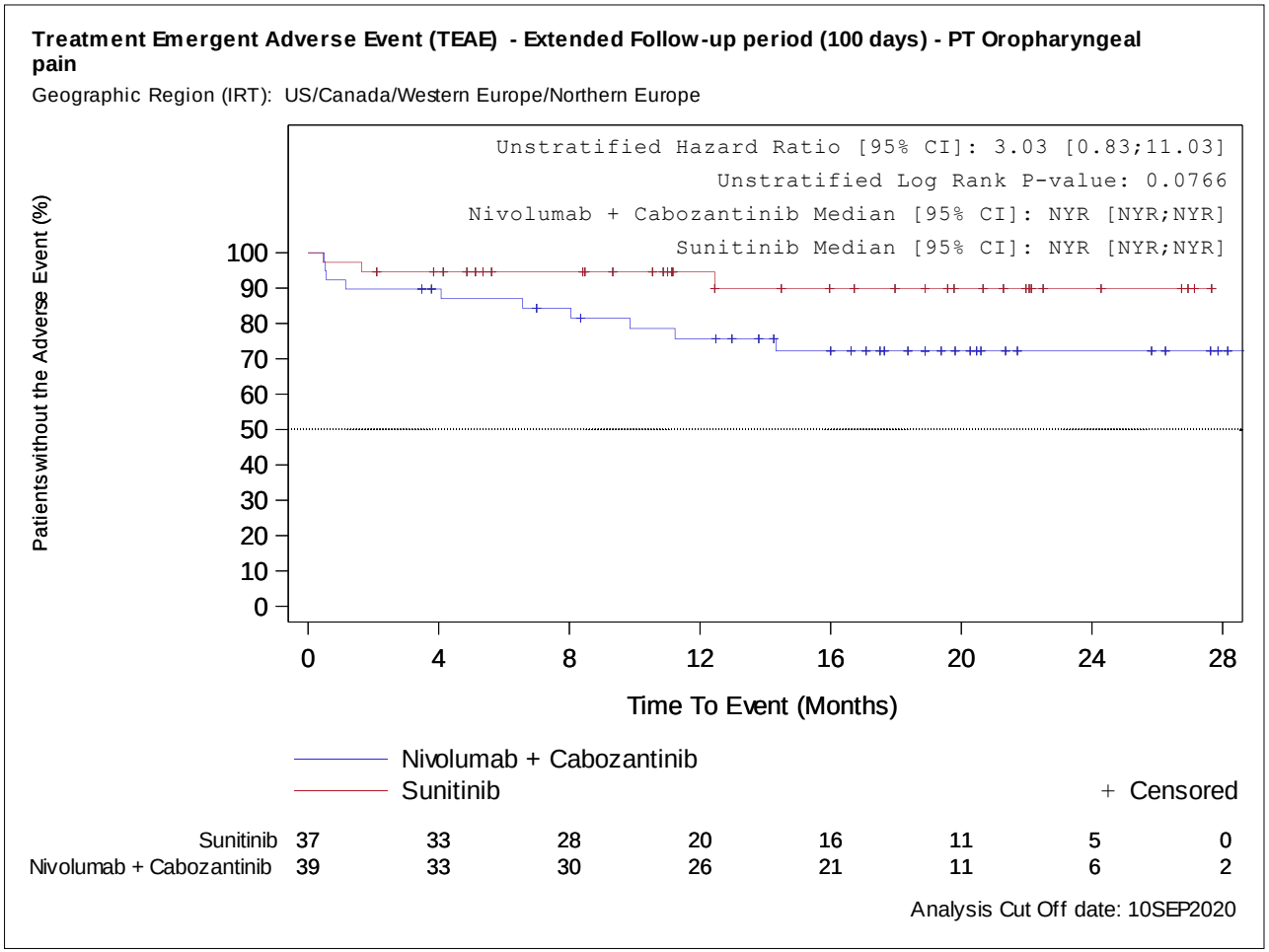

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:35:10

FIGURE 5.35.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:35:16

FIGURE 5.35.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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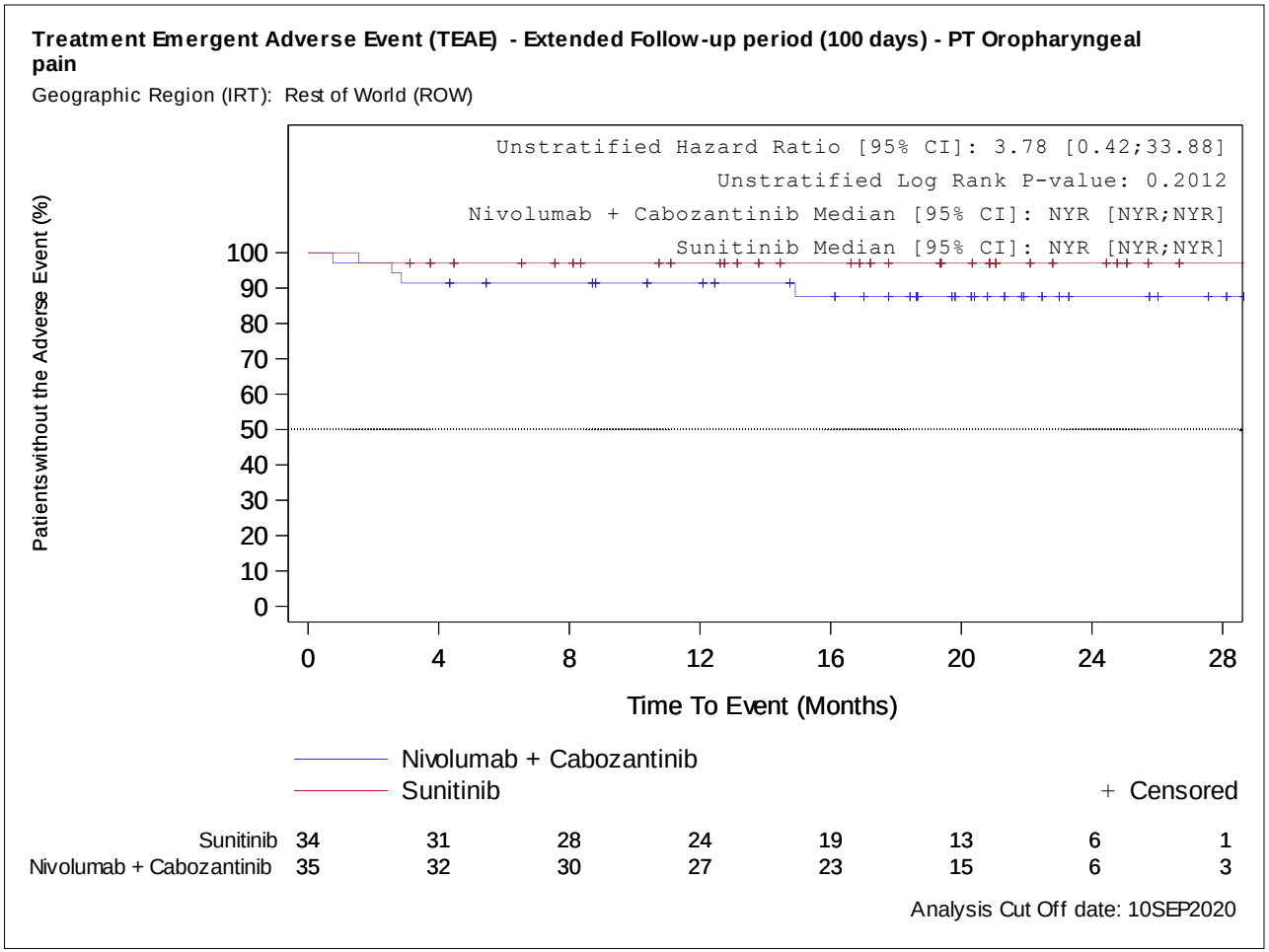
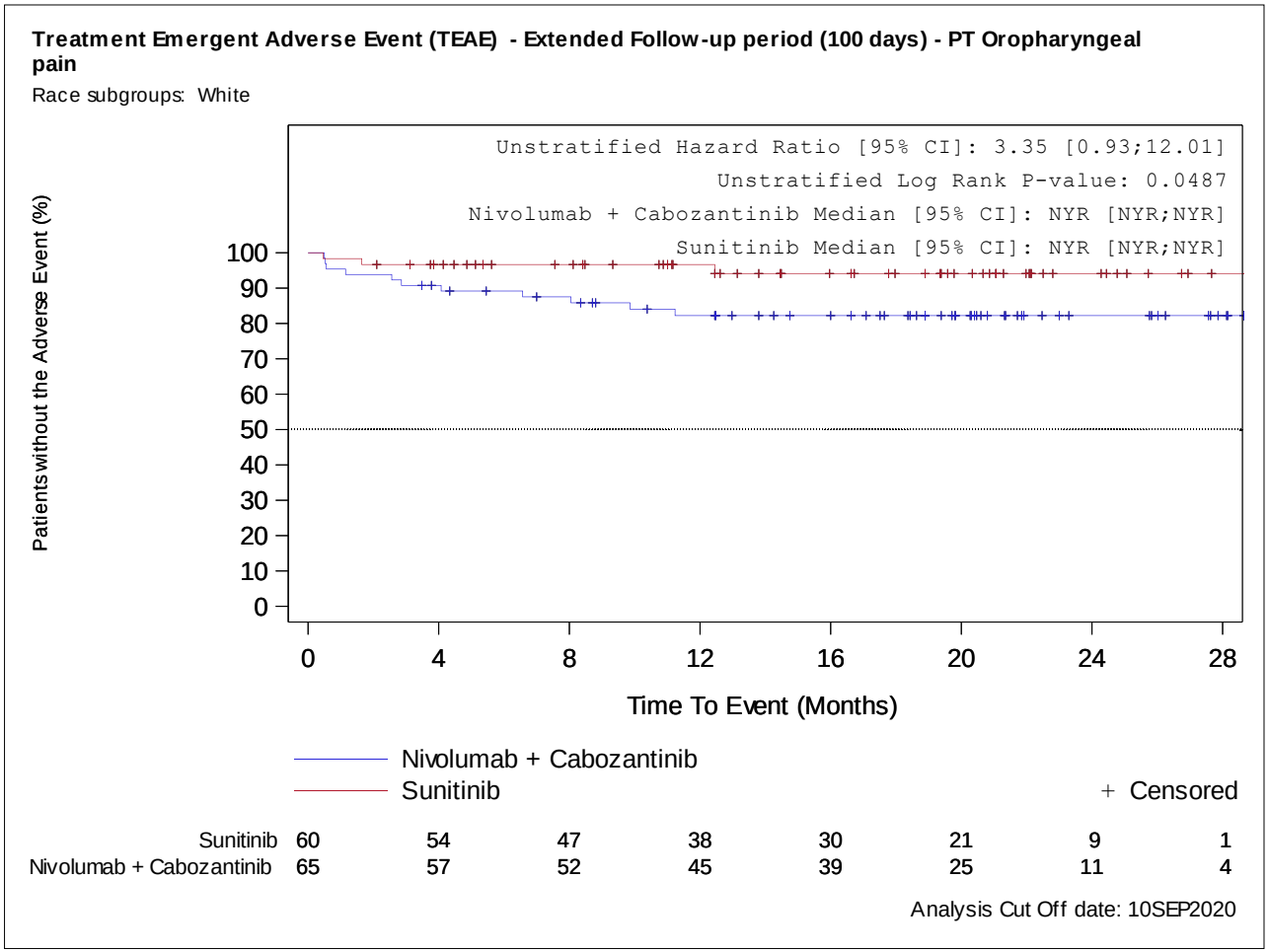
FIGURE 5.35.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)



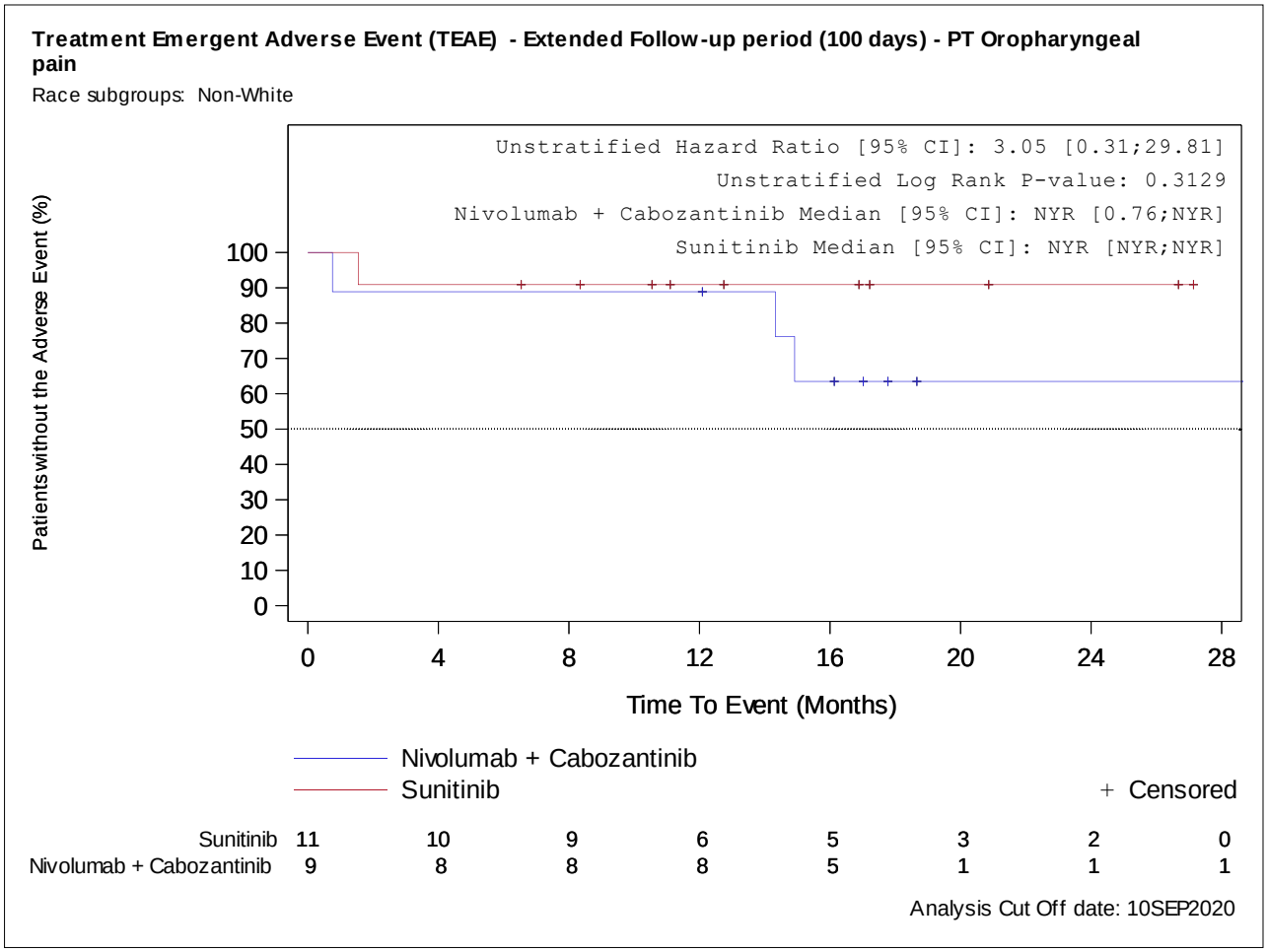

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:35:28

FIGURE 5.35.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



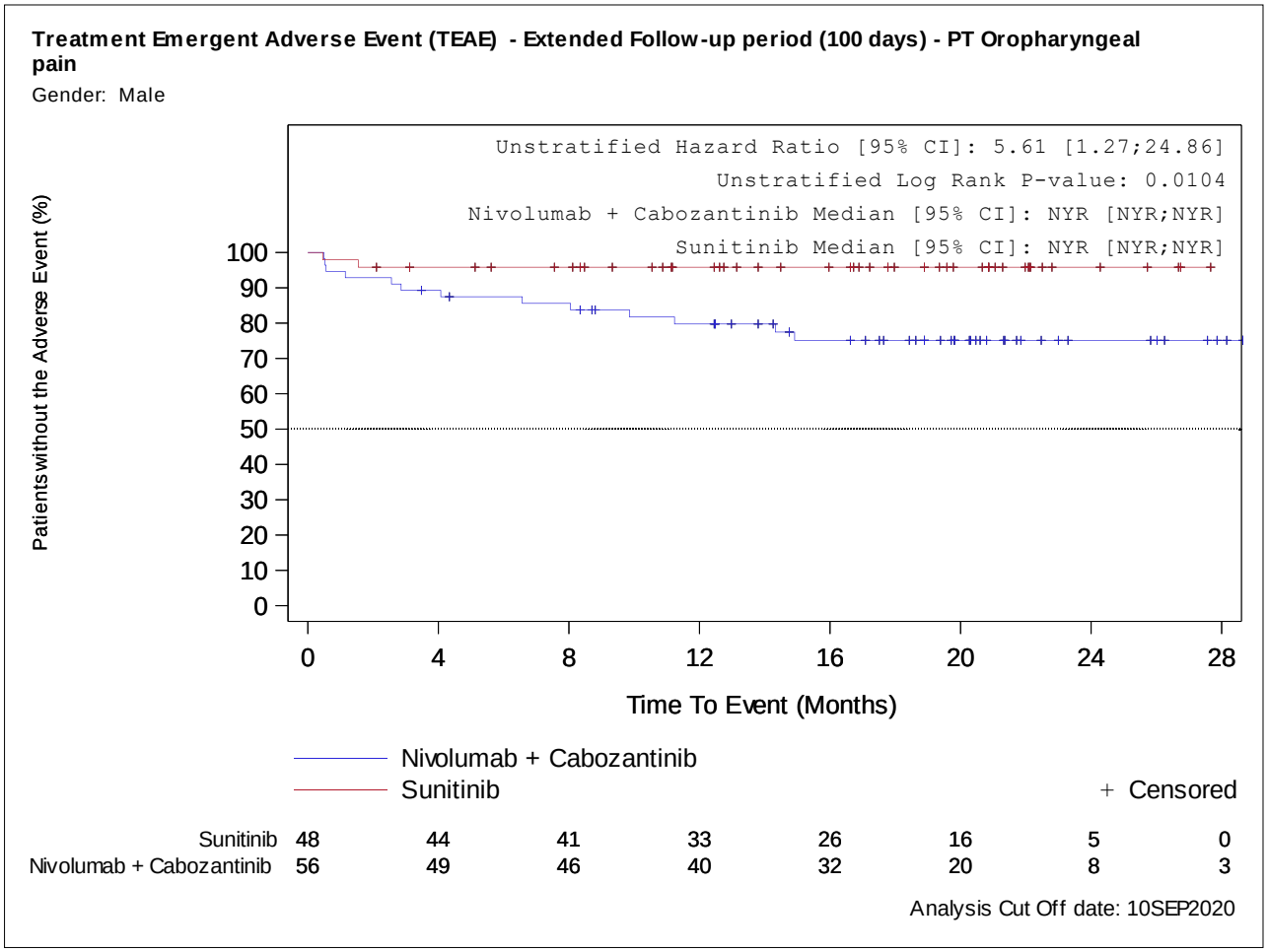

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:35:33

FIGURE 5.35.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:35:39

FIGURE 5.35.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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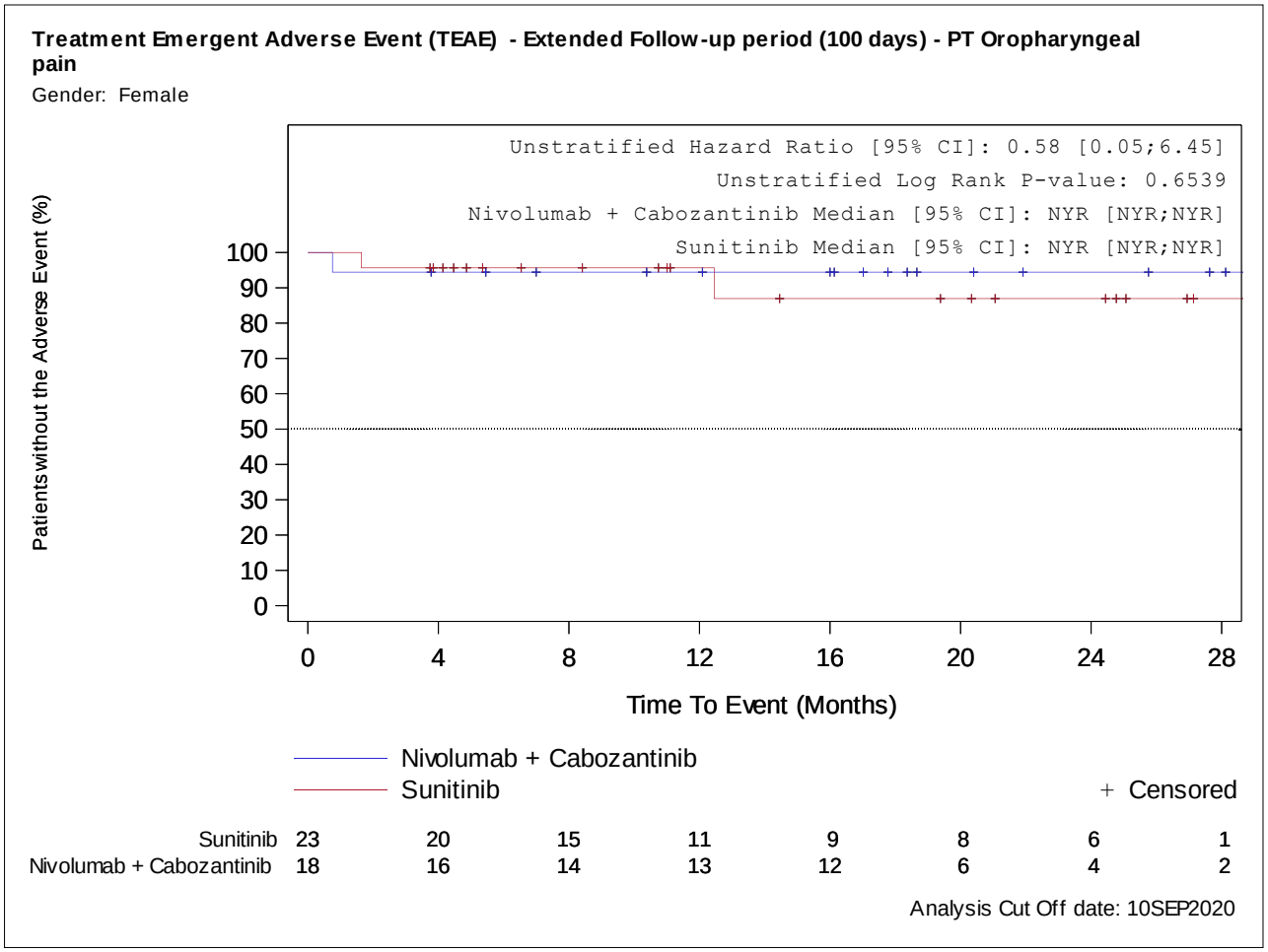
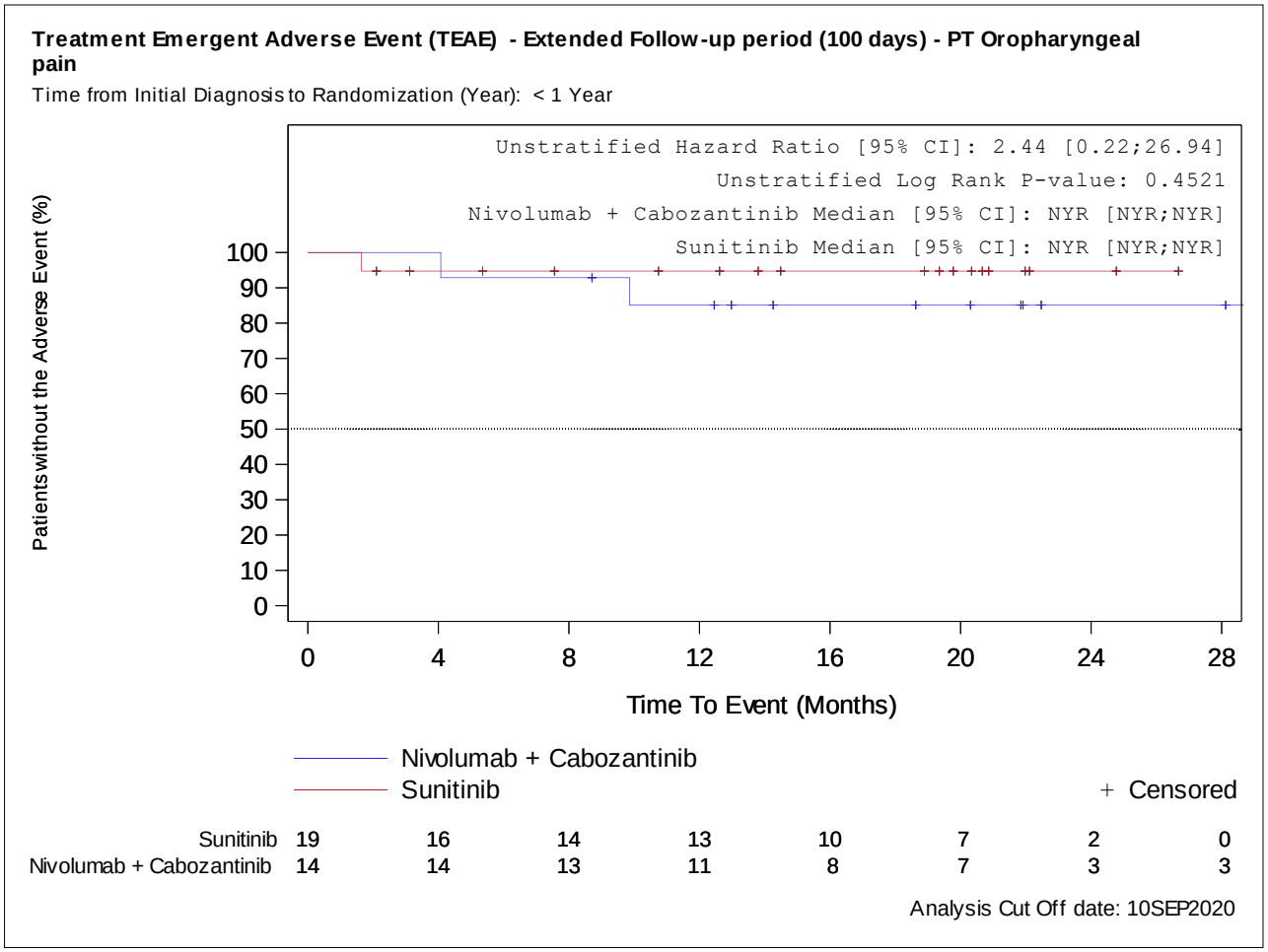
FIGURE 5.35.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female



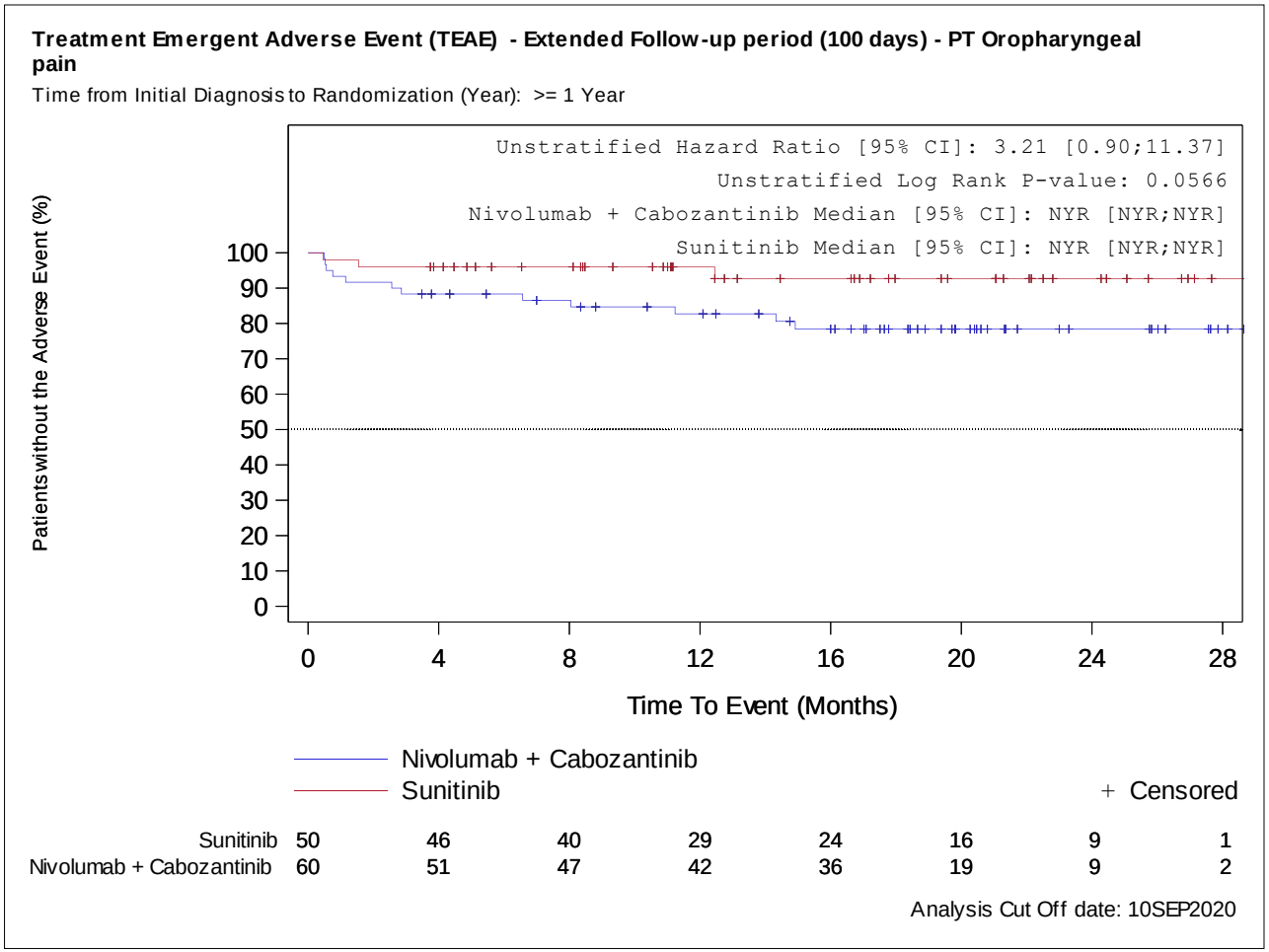

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:35:51

FIGURE 5.35.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



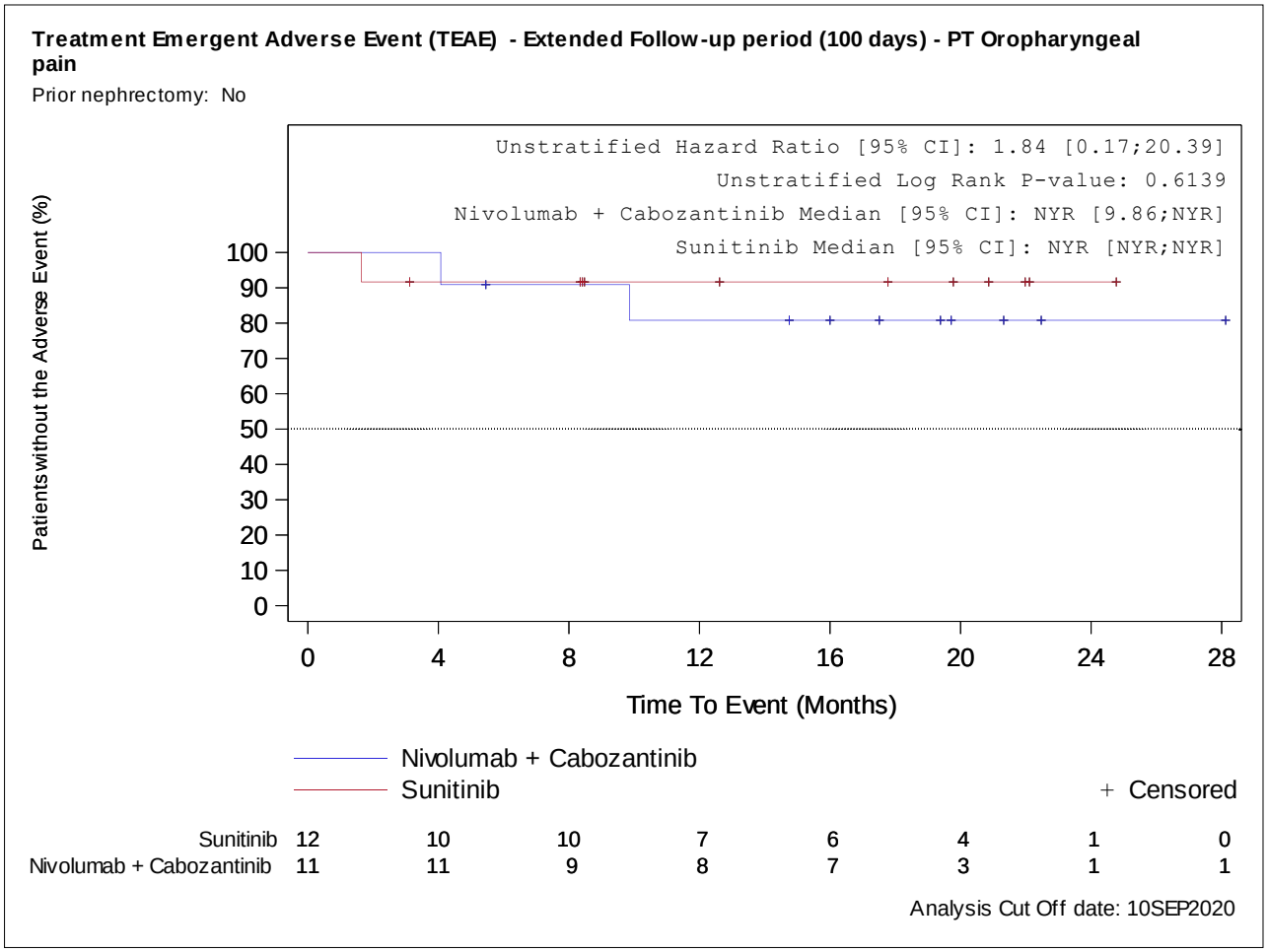

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:36:08

FIGURE 5.35.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



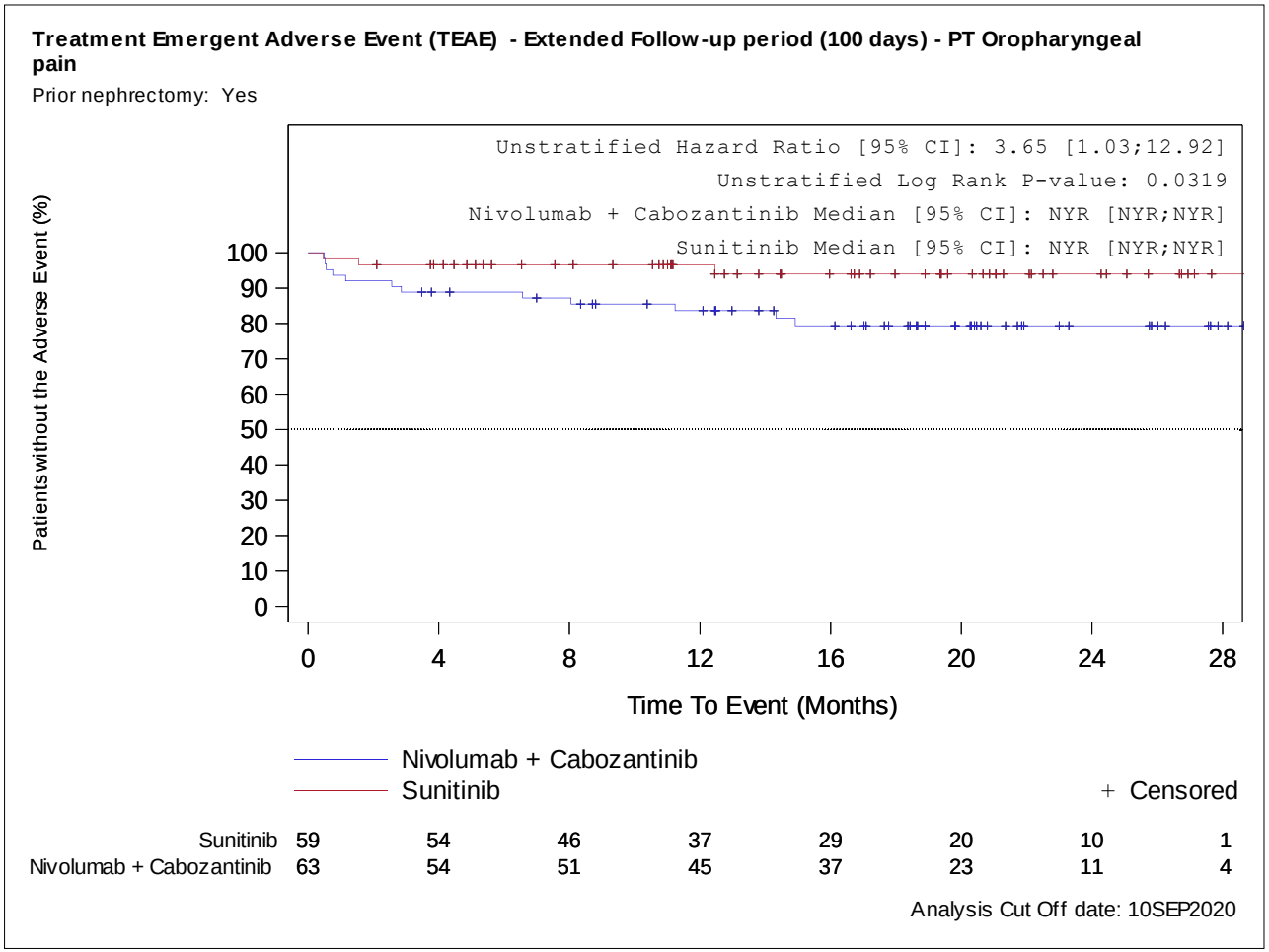

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:36:14

FIGURE 5.35.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



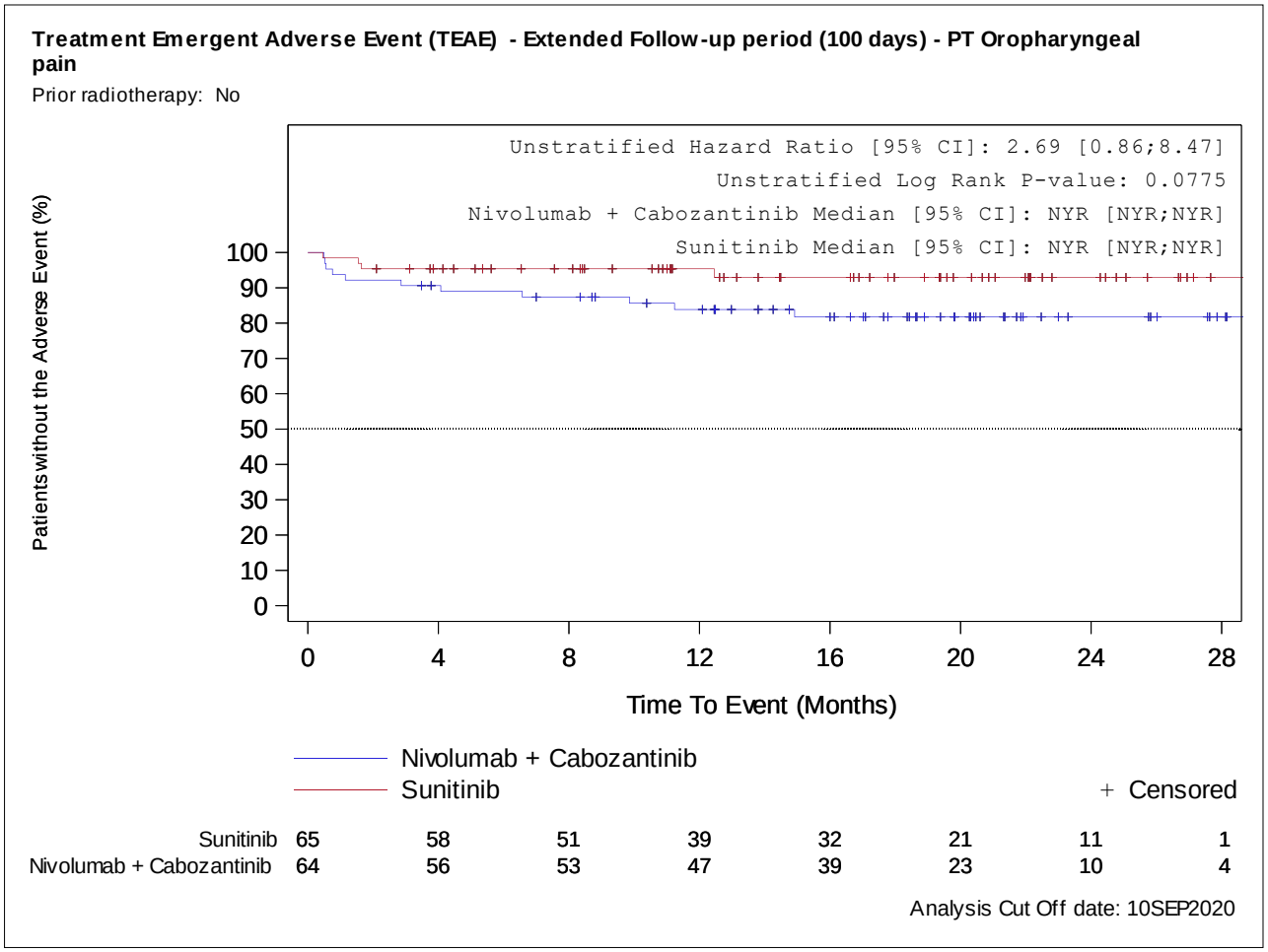

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:37:05

FIGURE 5.35.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



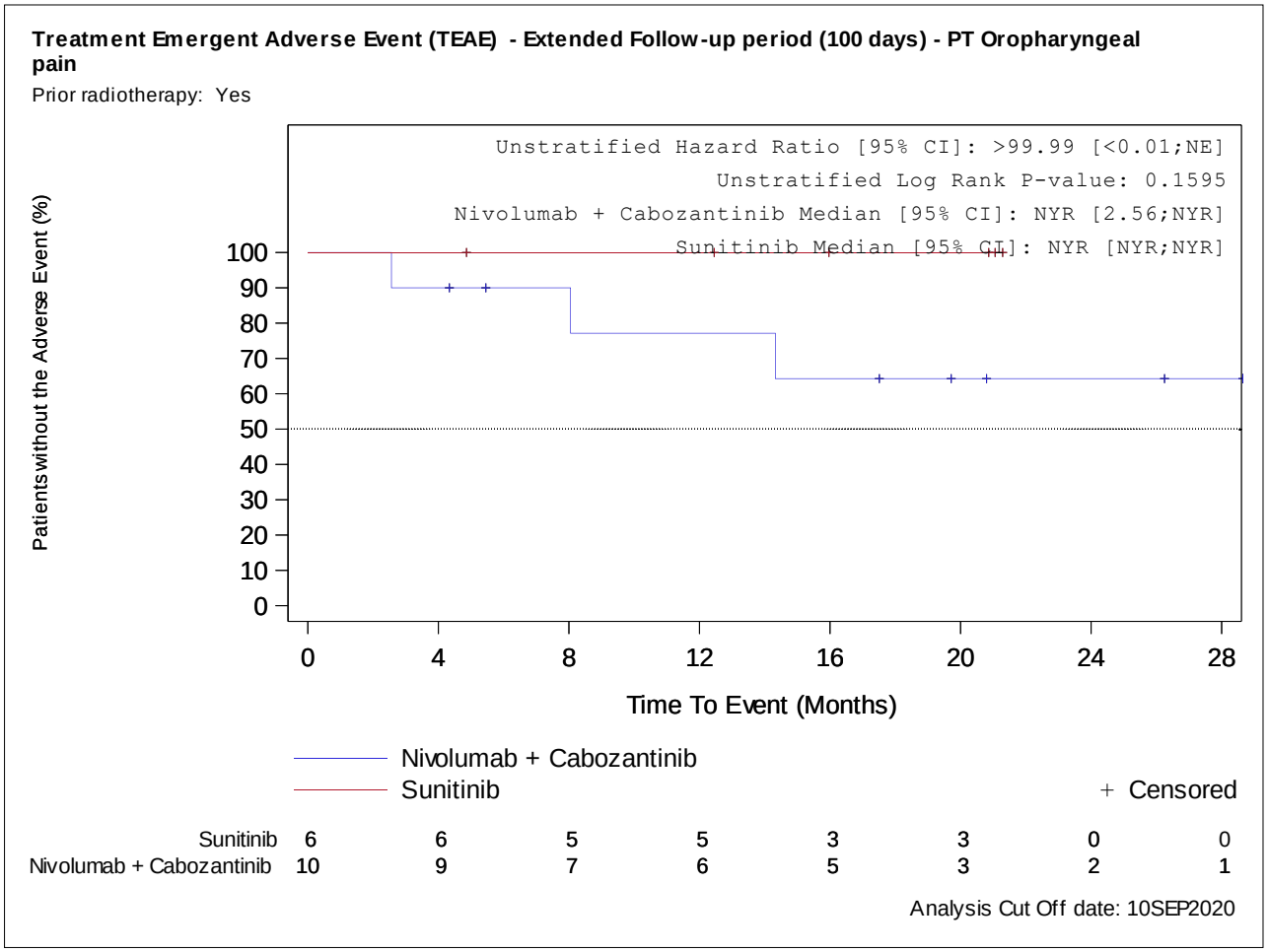

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:37:10

FIGURE 5.35.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No



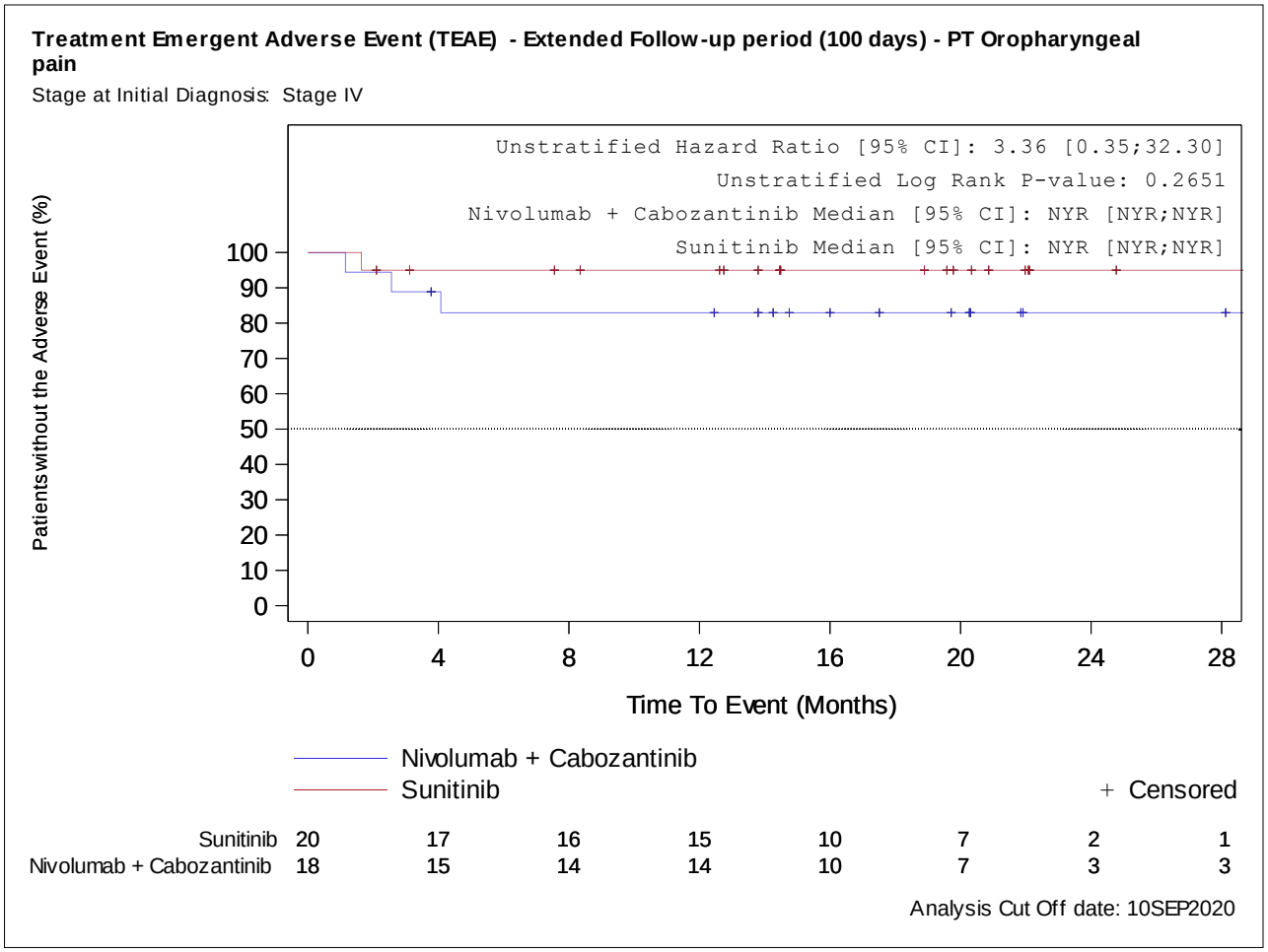

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:37:16

FIGURE 5.35.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes



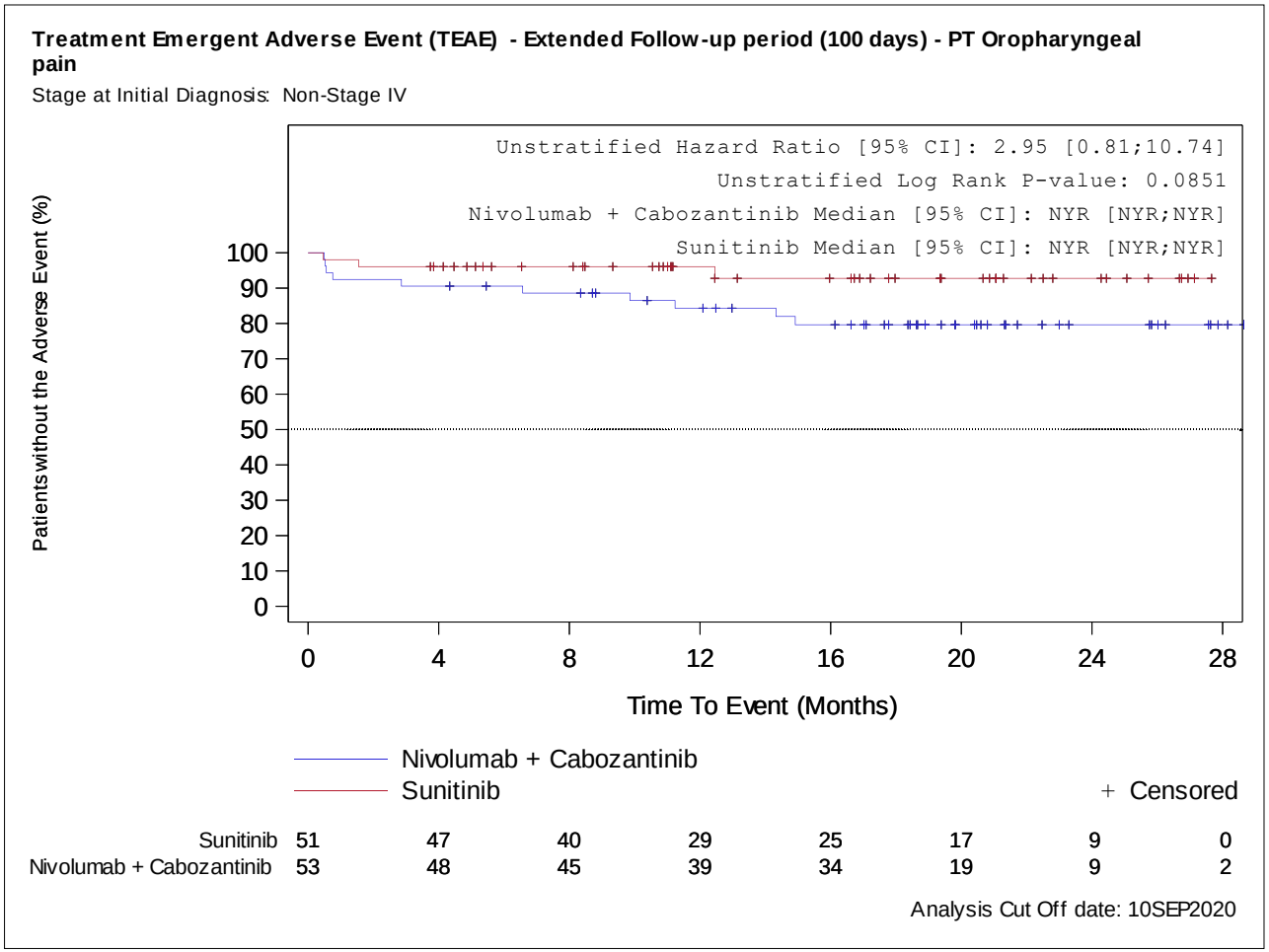

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:37:21

FIGURE 5.35.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



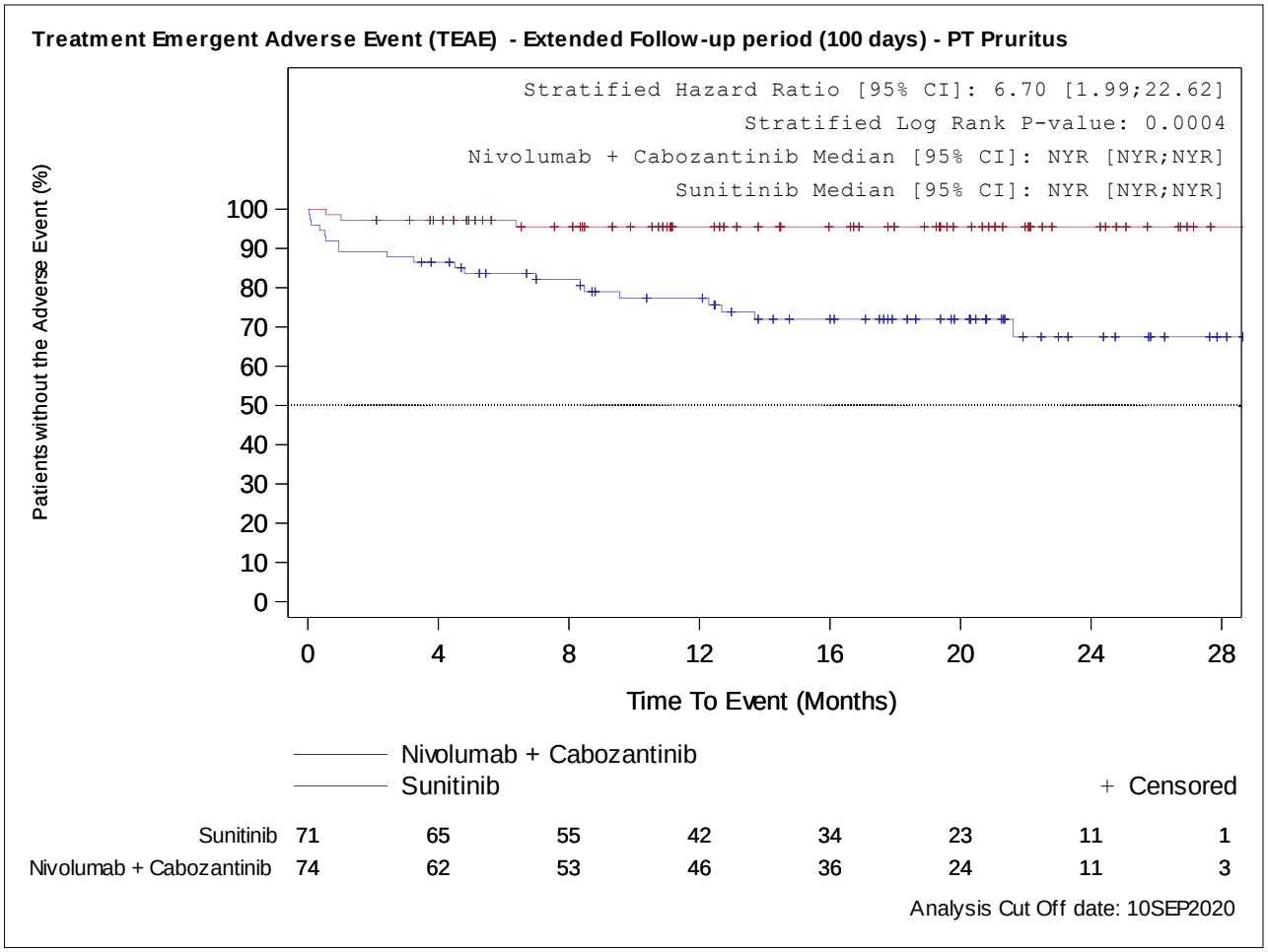

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:37:51

FIGURE 5.35.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Oropharyngeal pain - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



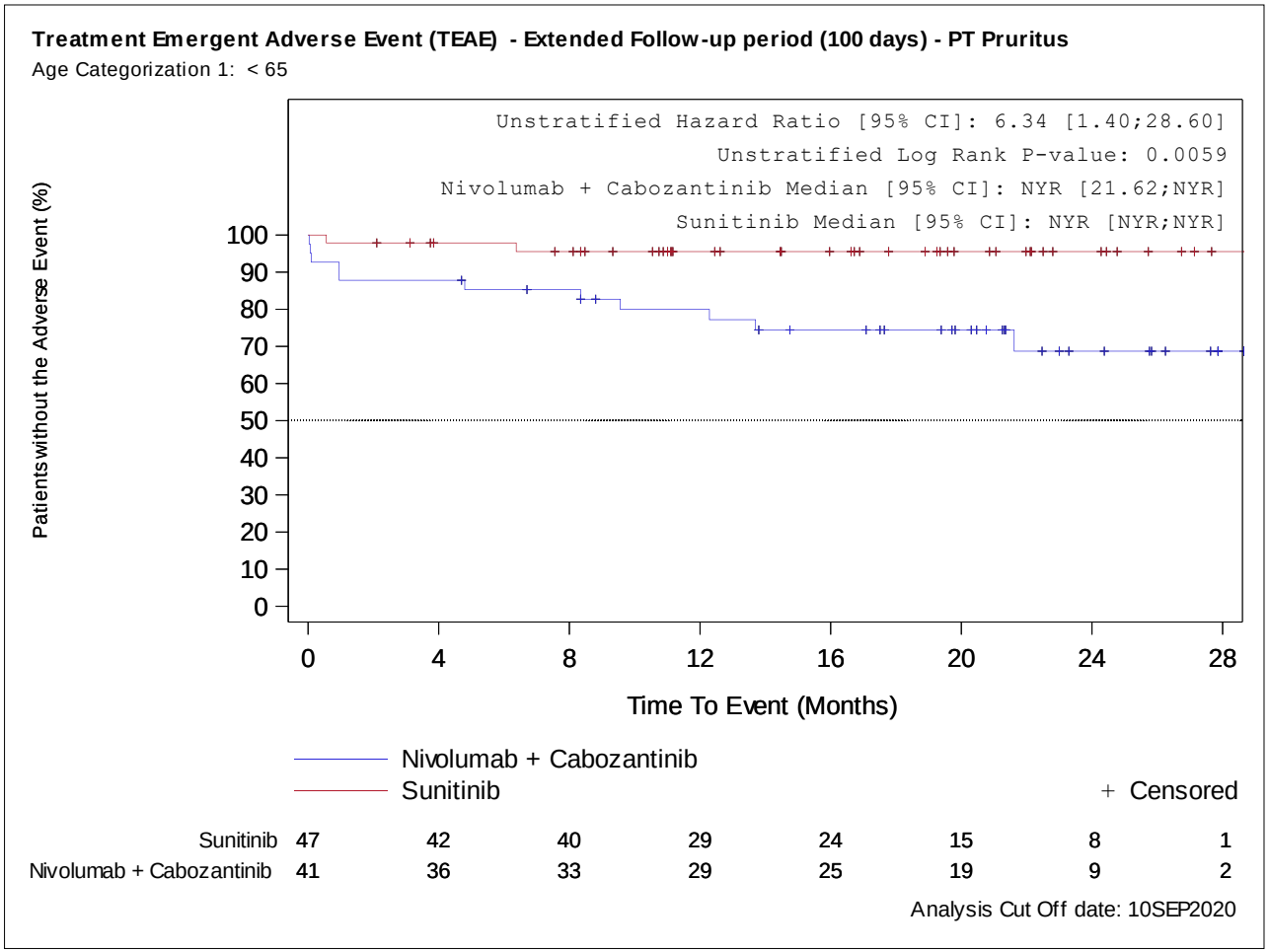

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:37:57

FIGURE 5.36.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:41:16

FIGURE 5.36.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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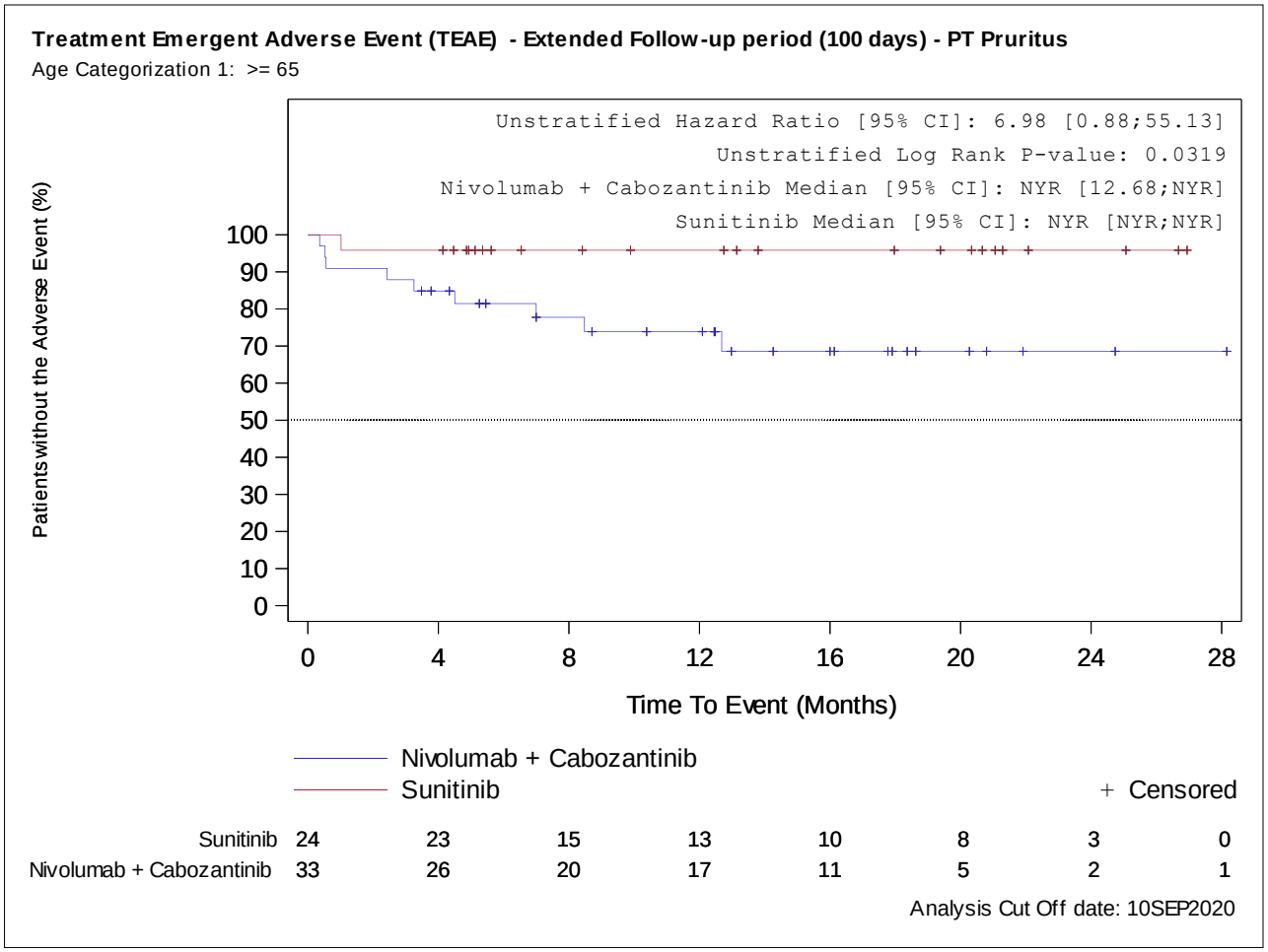
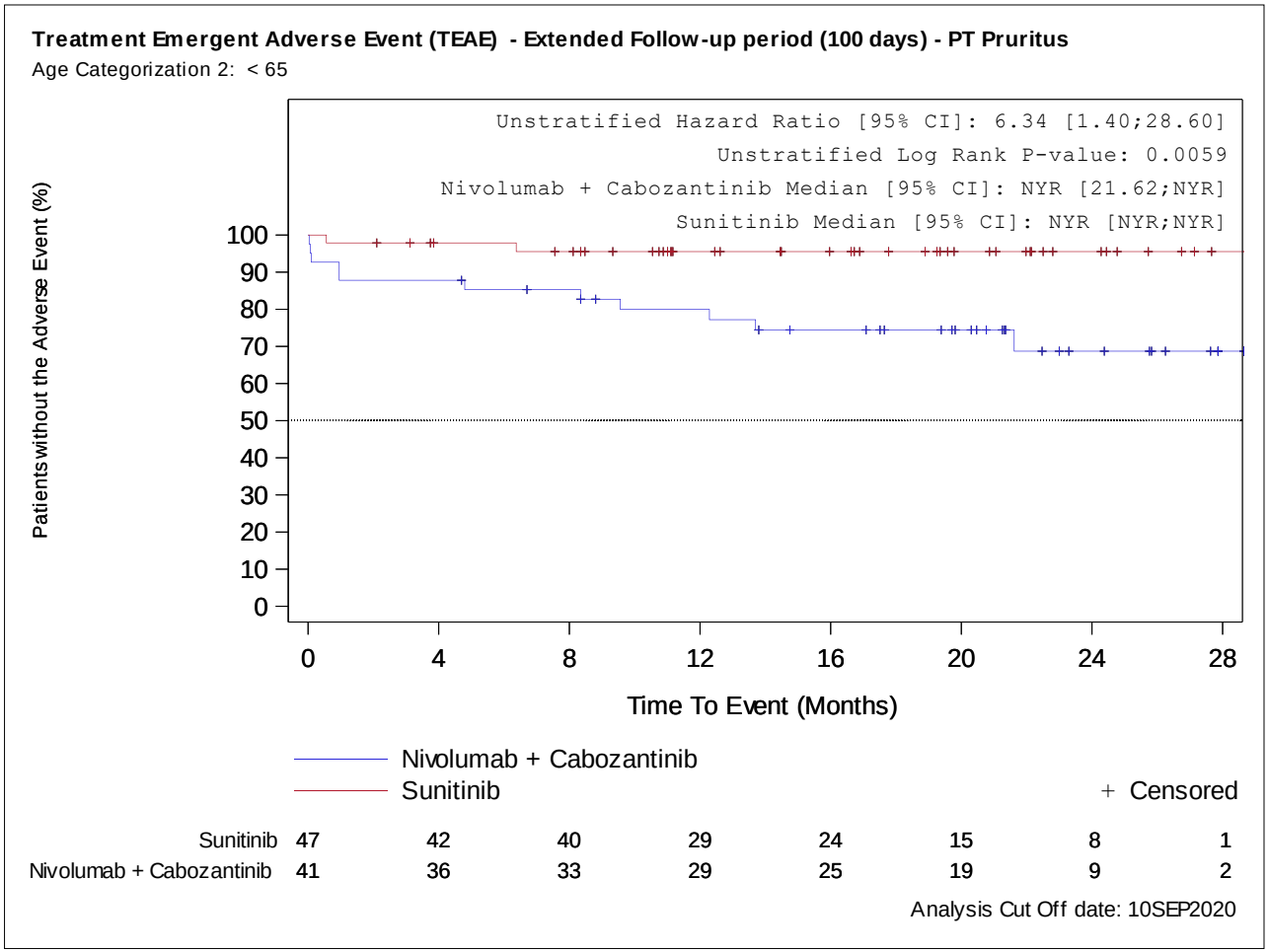
FIGURE 5.36.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:41:24

FIGURE 5.36.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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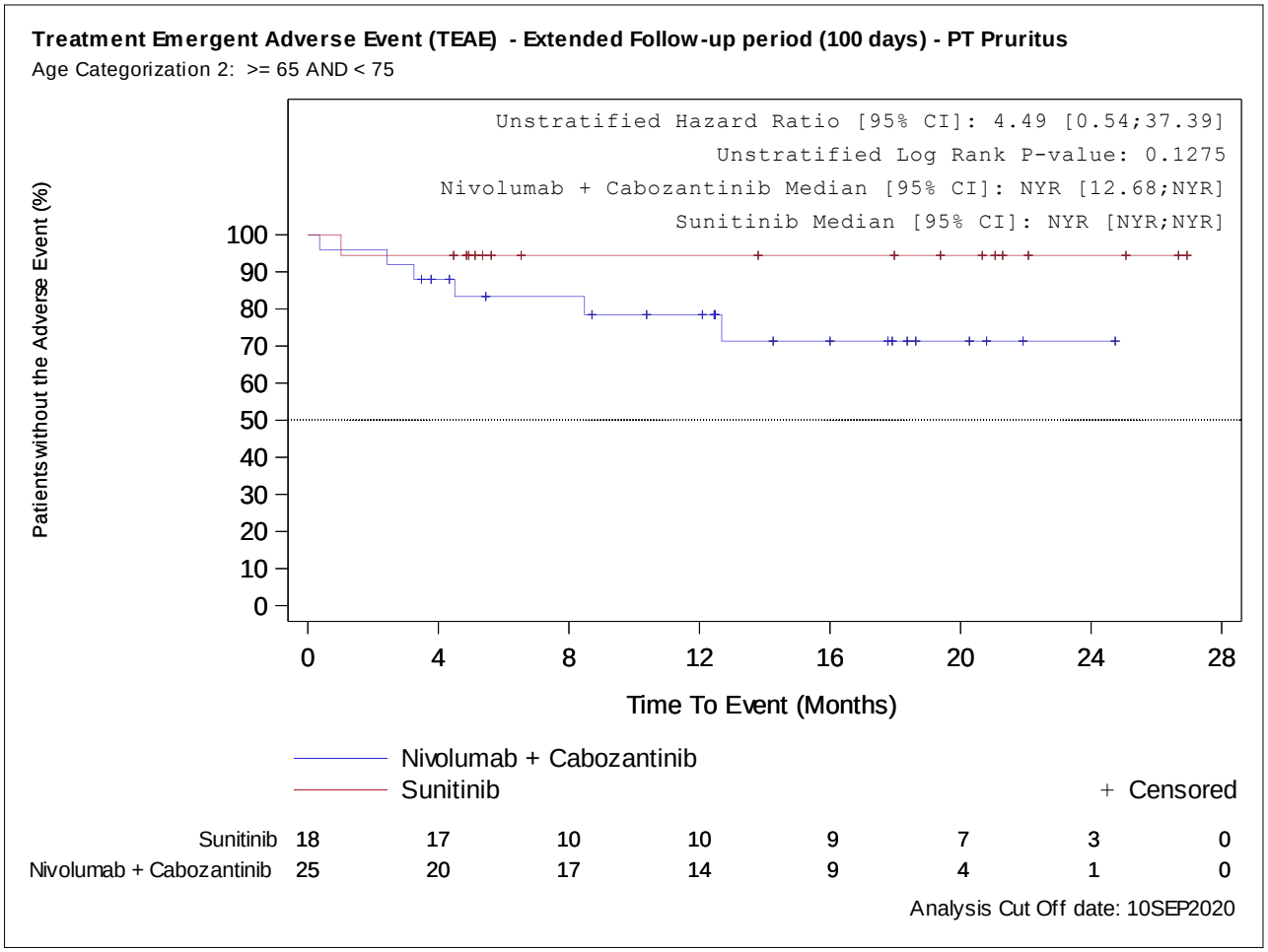
FIGURE 5.36.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75




Analysis Cut Off date: 10SEP2020
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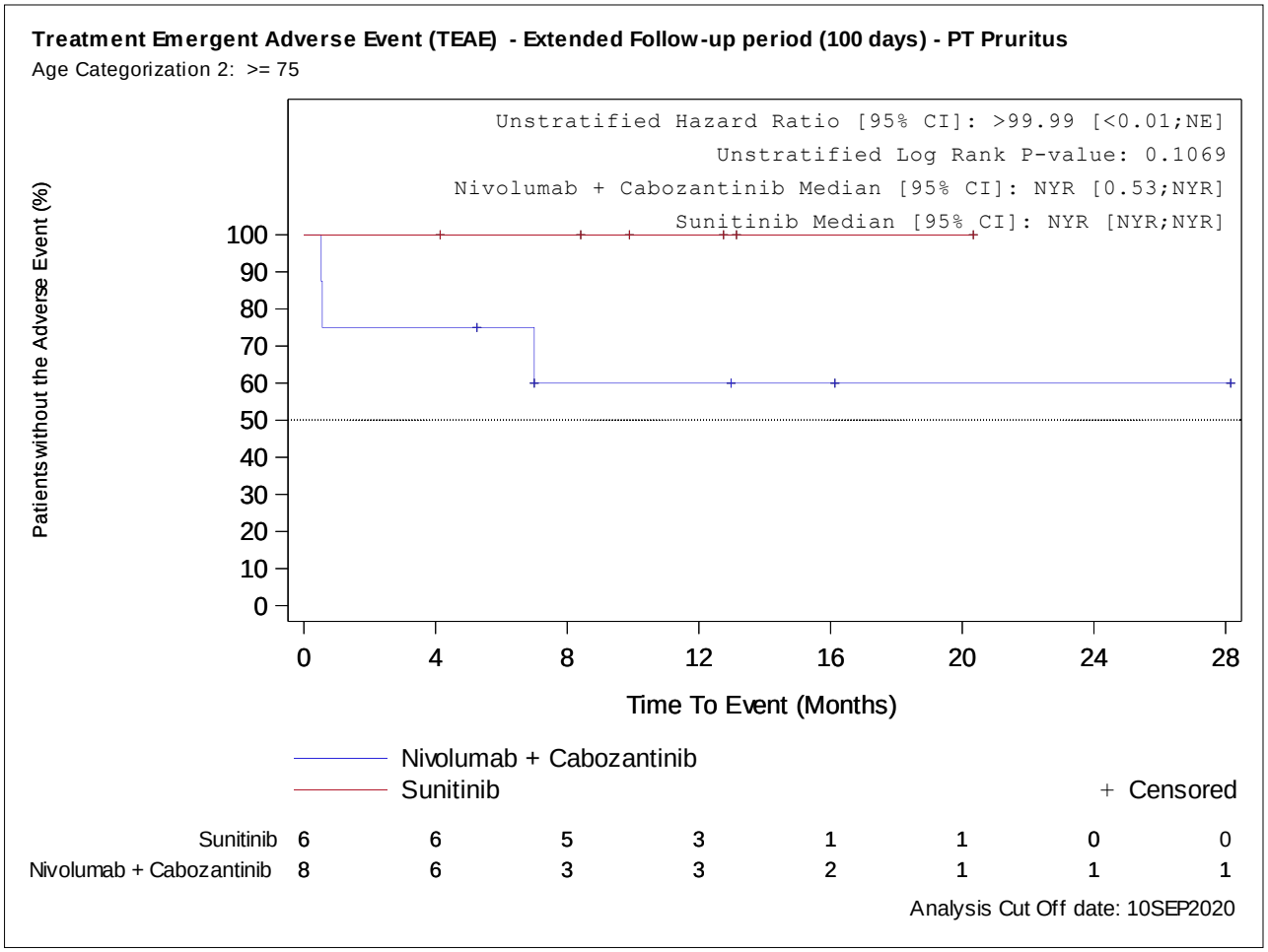
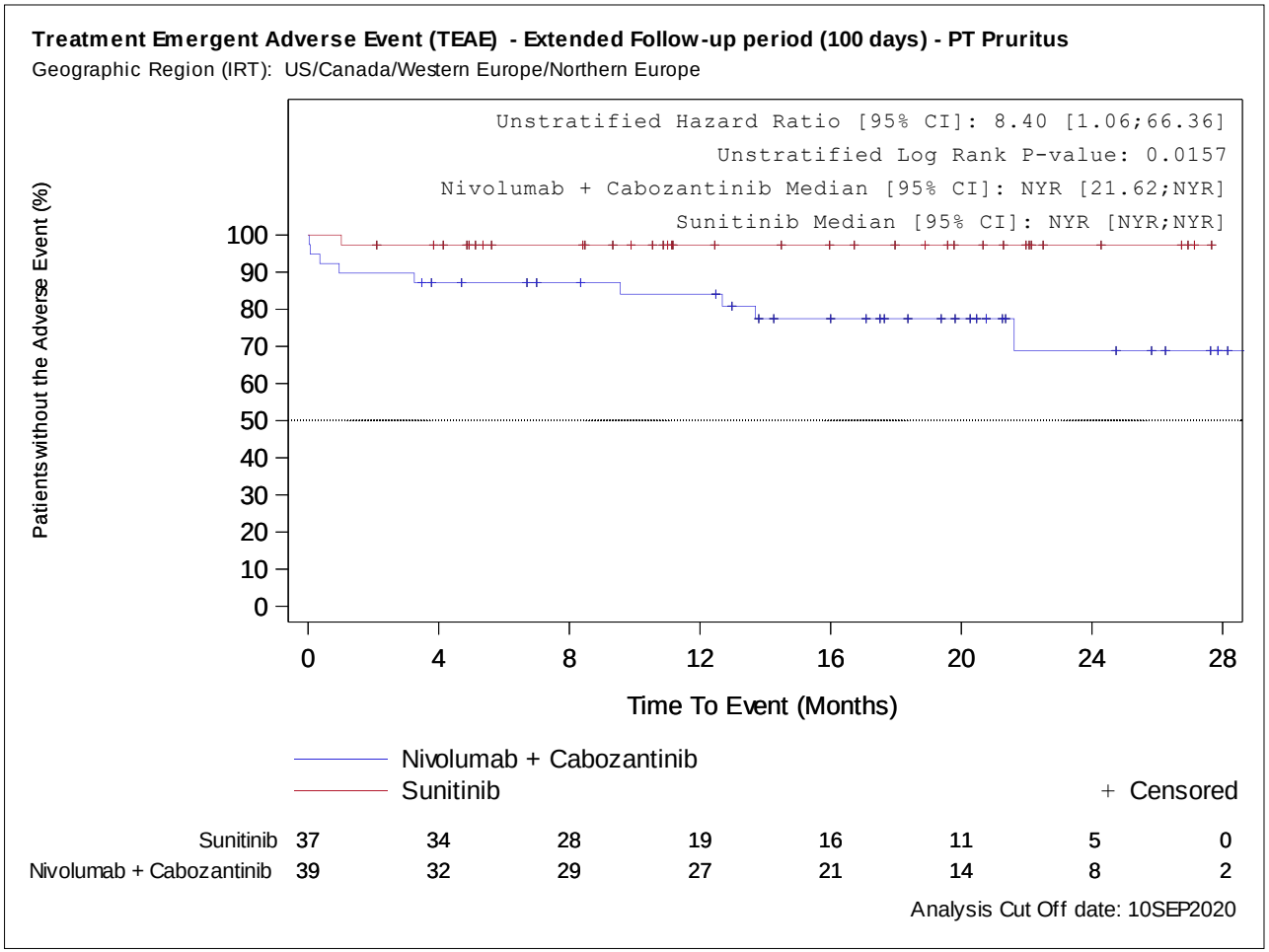
FIGURE 5.36.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75



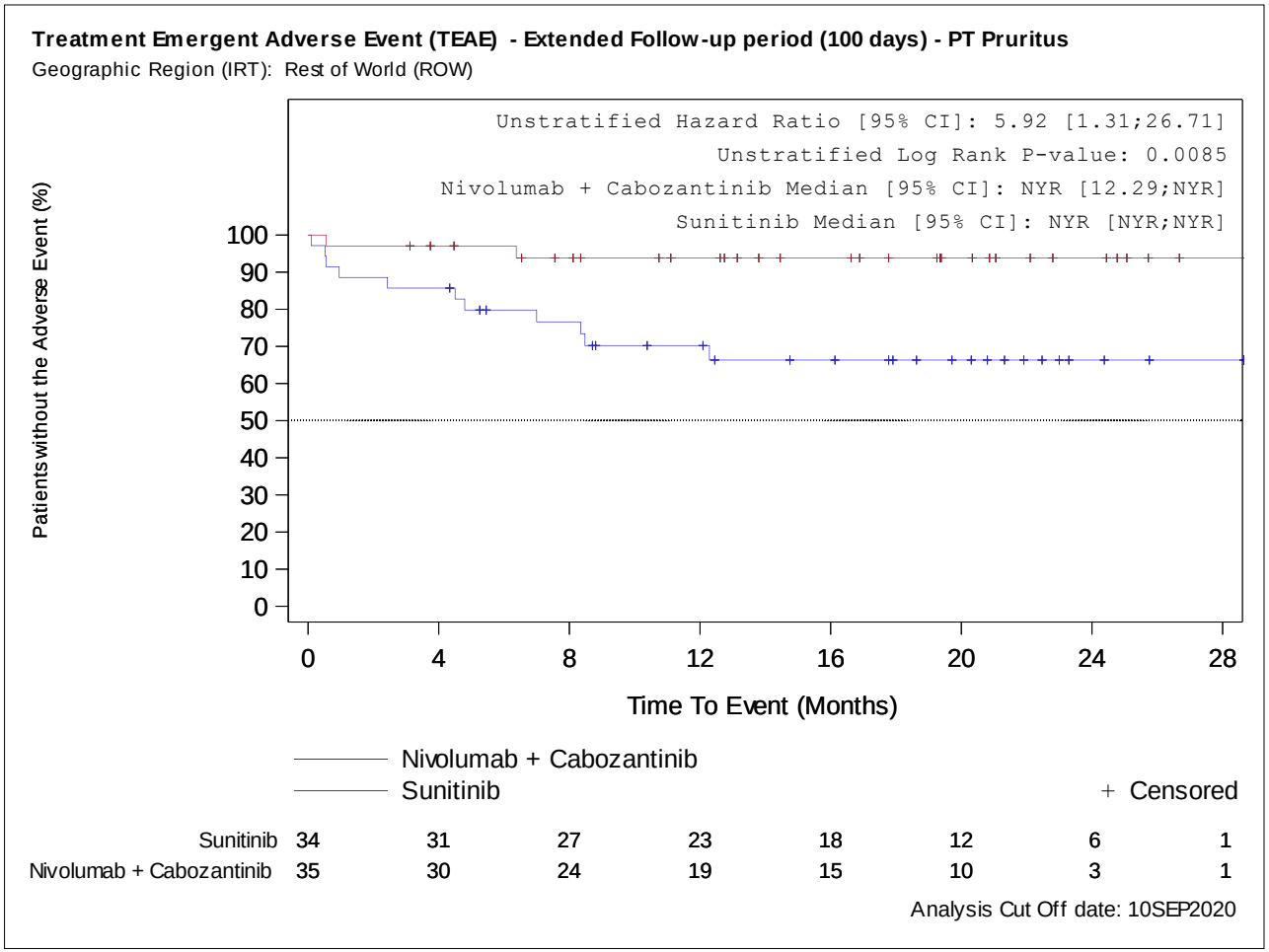

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:41:42

FIGURE 5.36.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:41:48

FIGURE 5.36.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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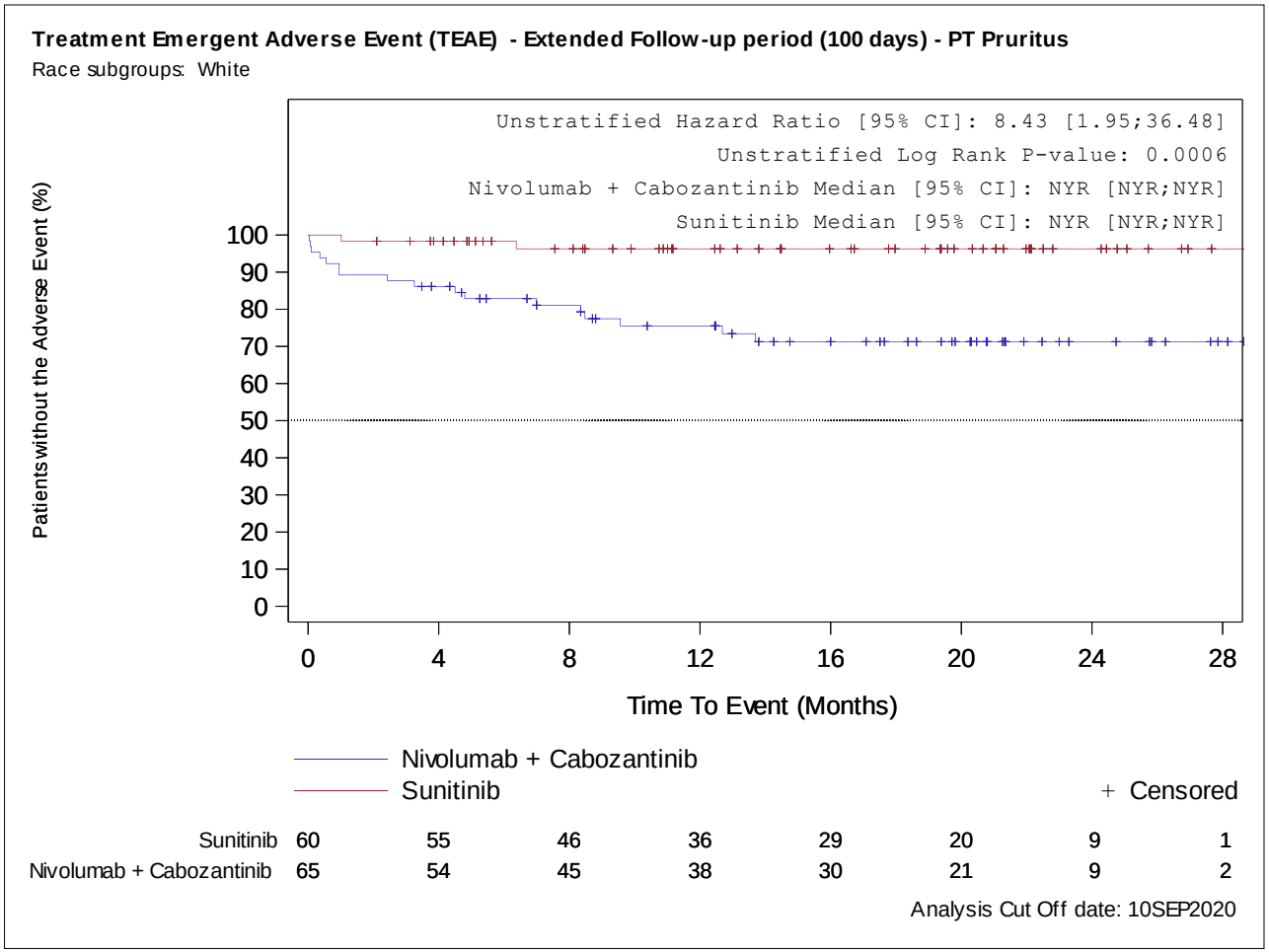
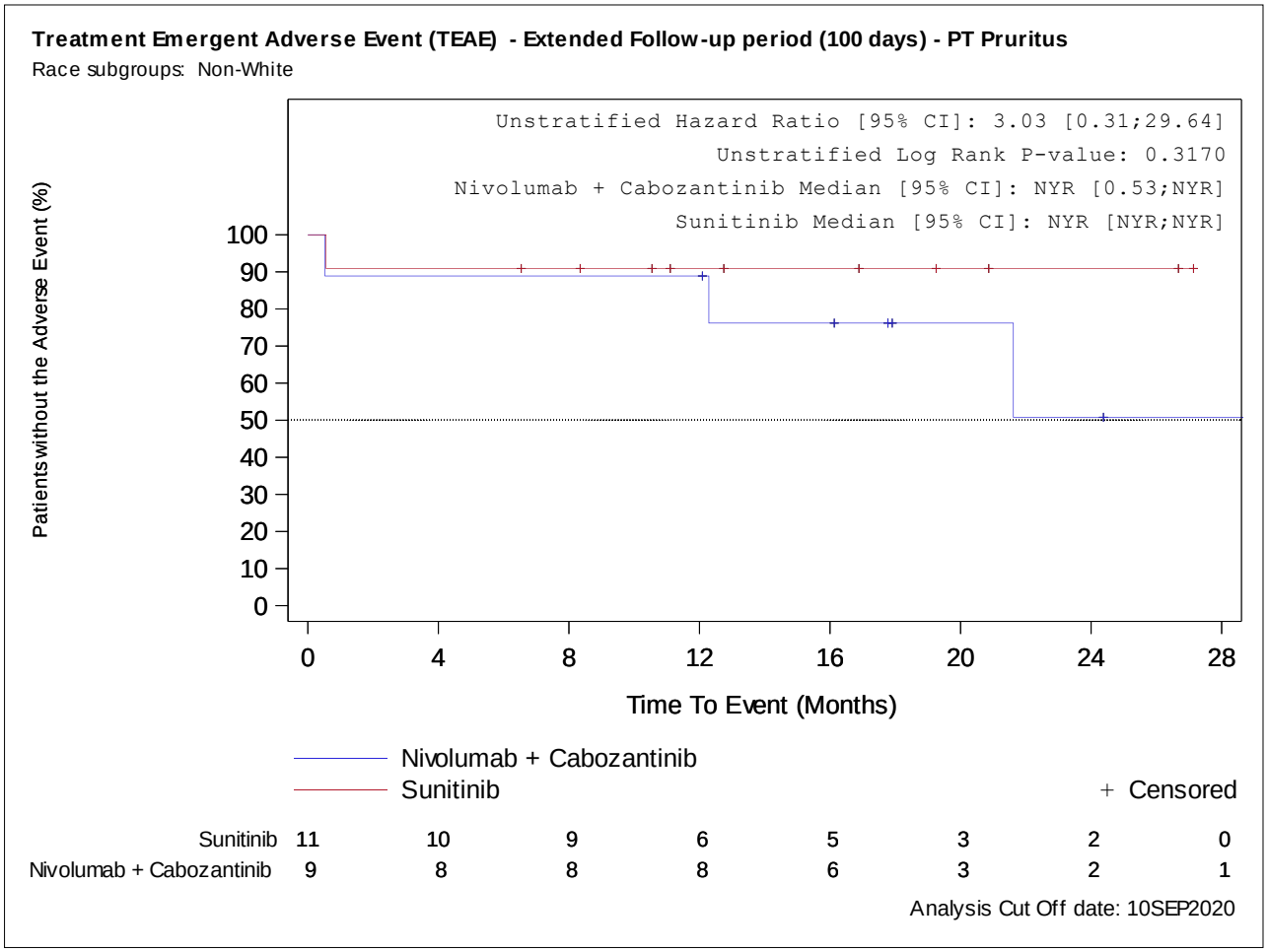
FIGURE 5.36.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



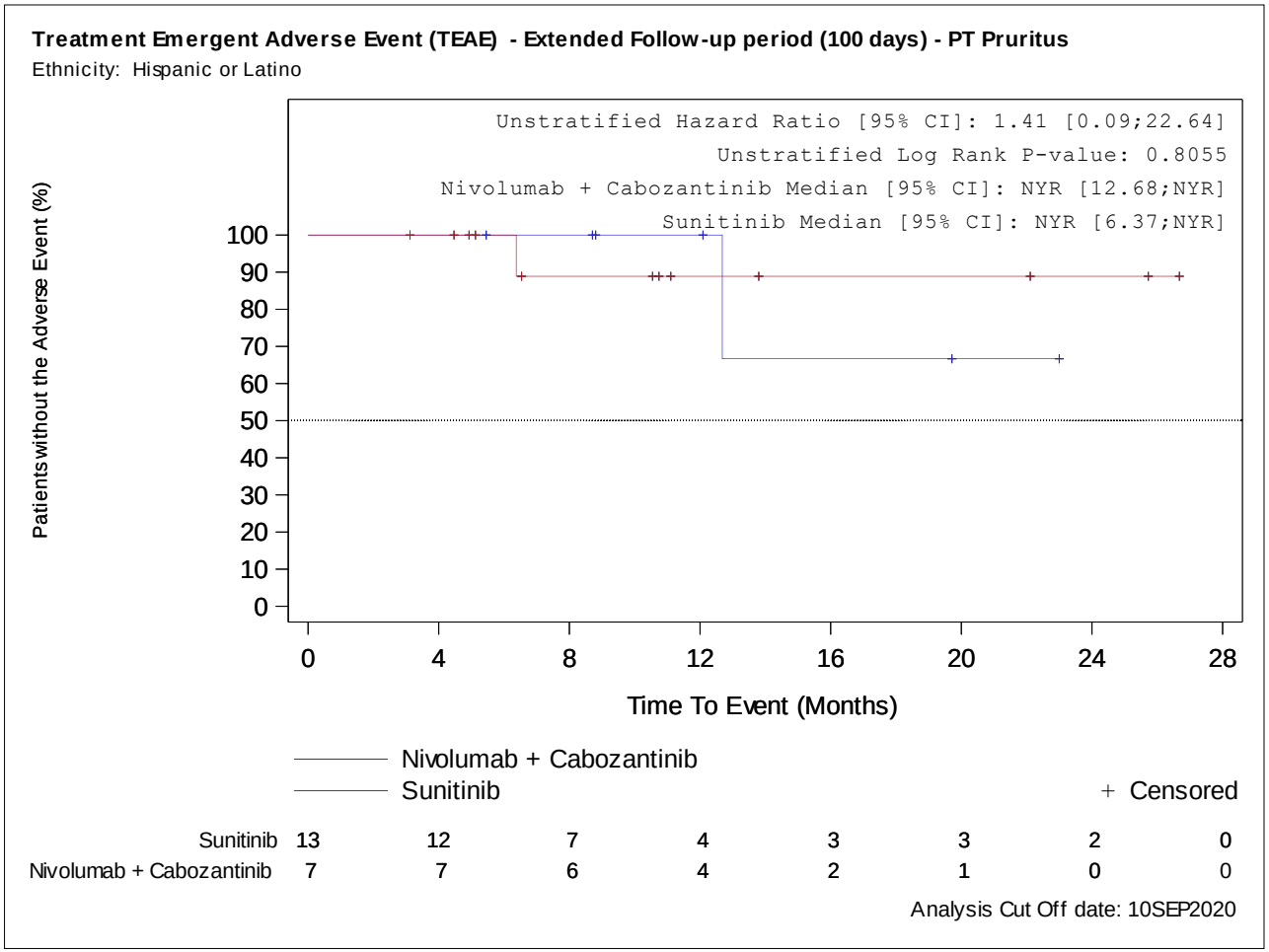

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:42:00

FIGURE 5.36.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:42:06

FIGURE 5.36.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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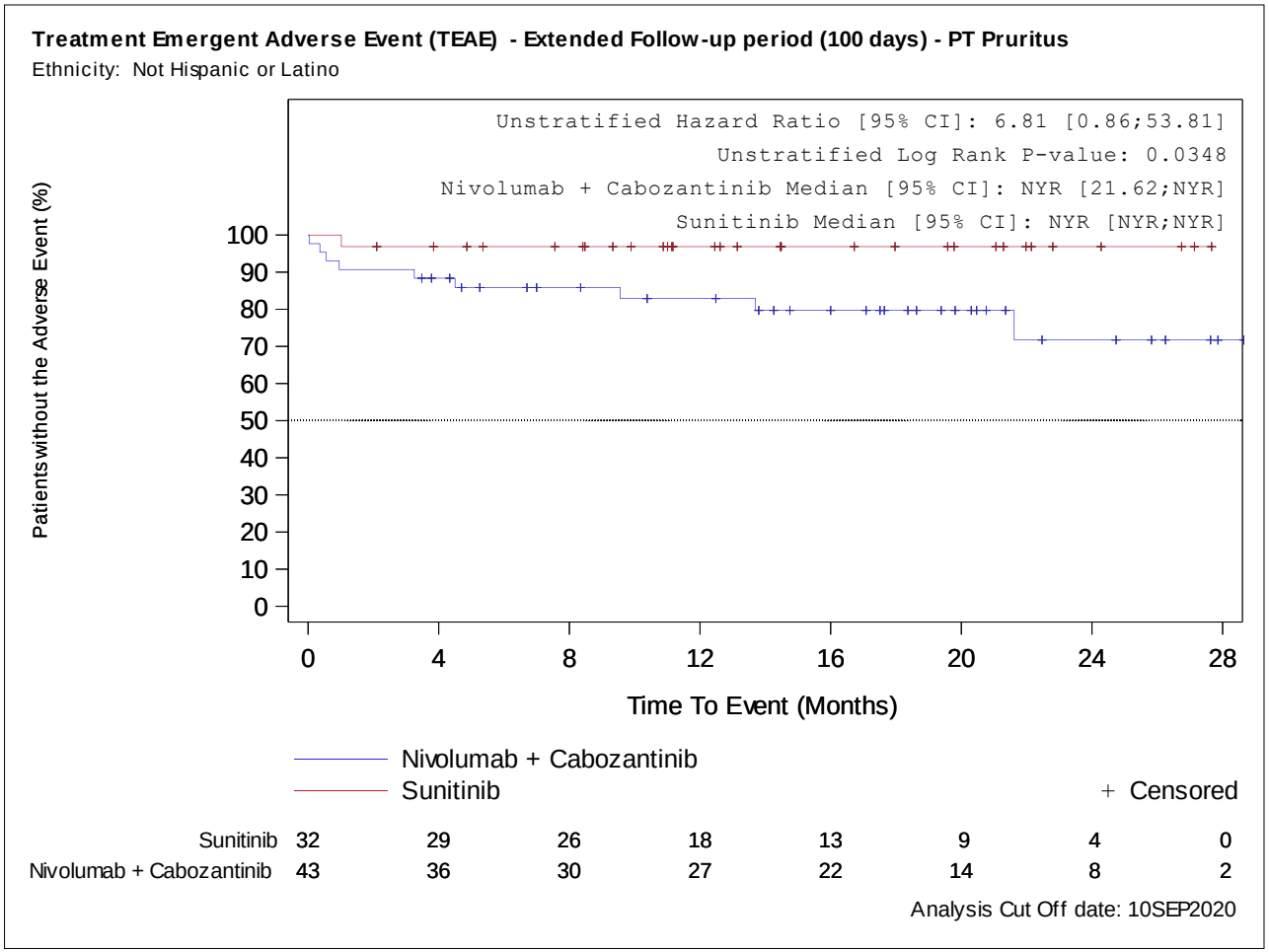
FIGURE 5.36.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino




Analysis Cut Off date: 10SEP2020
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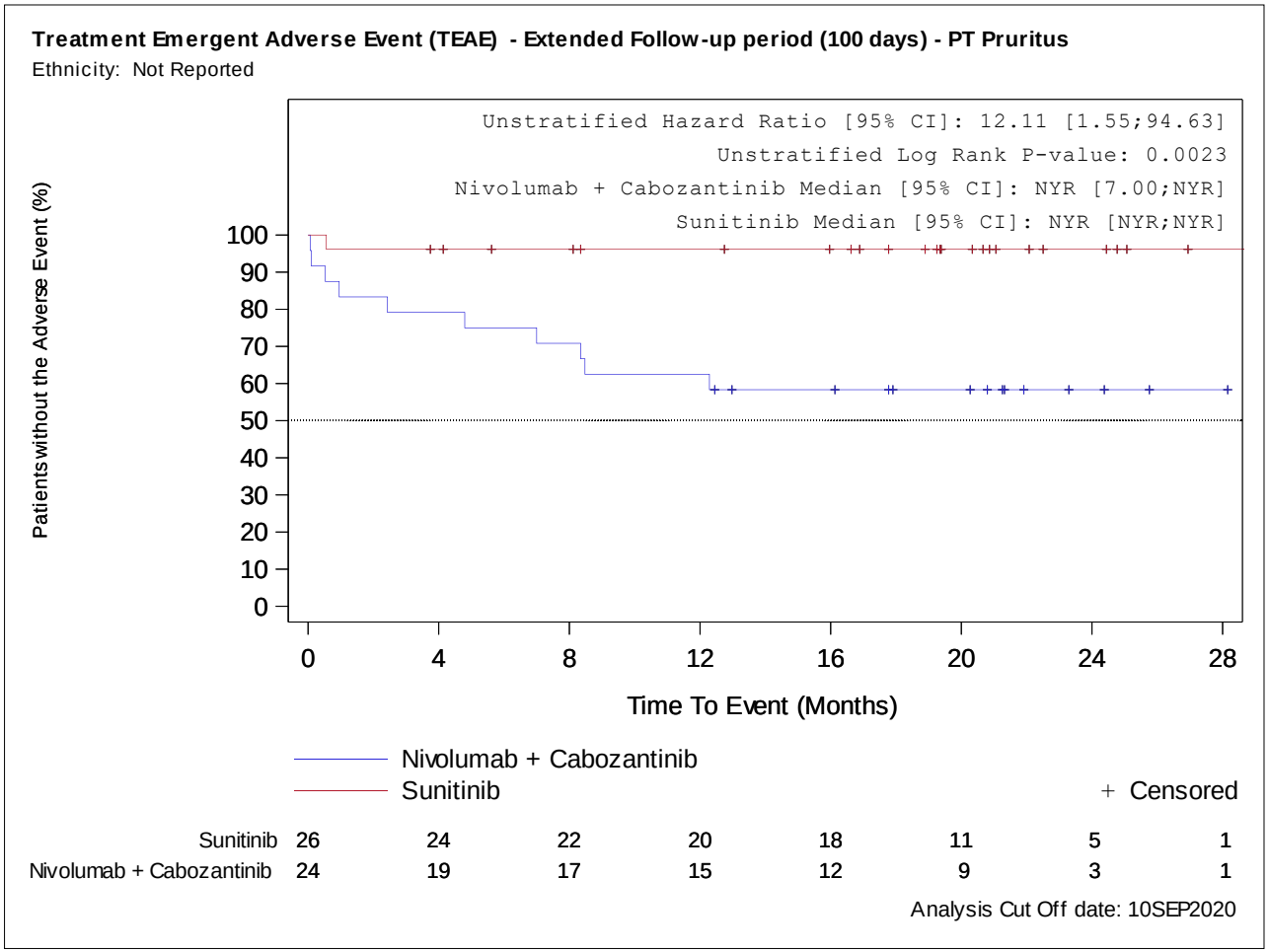
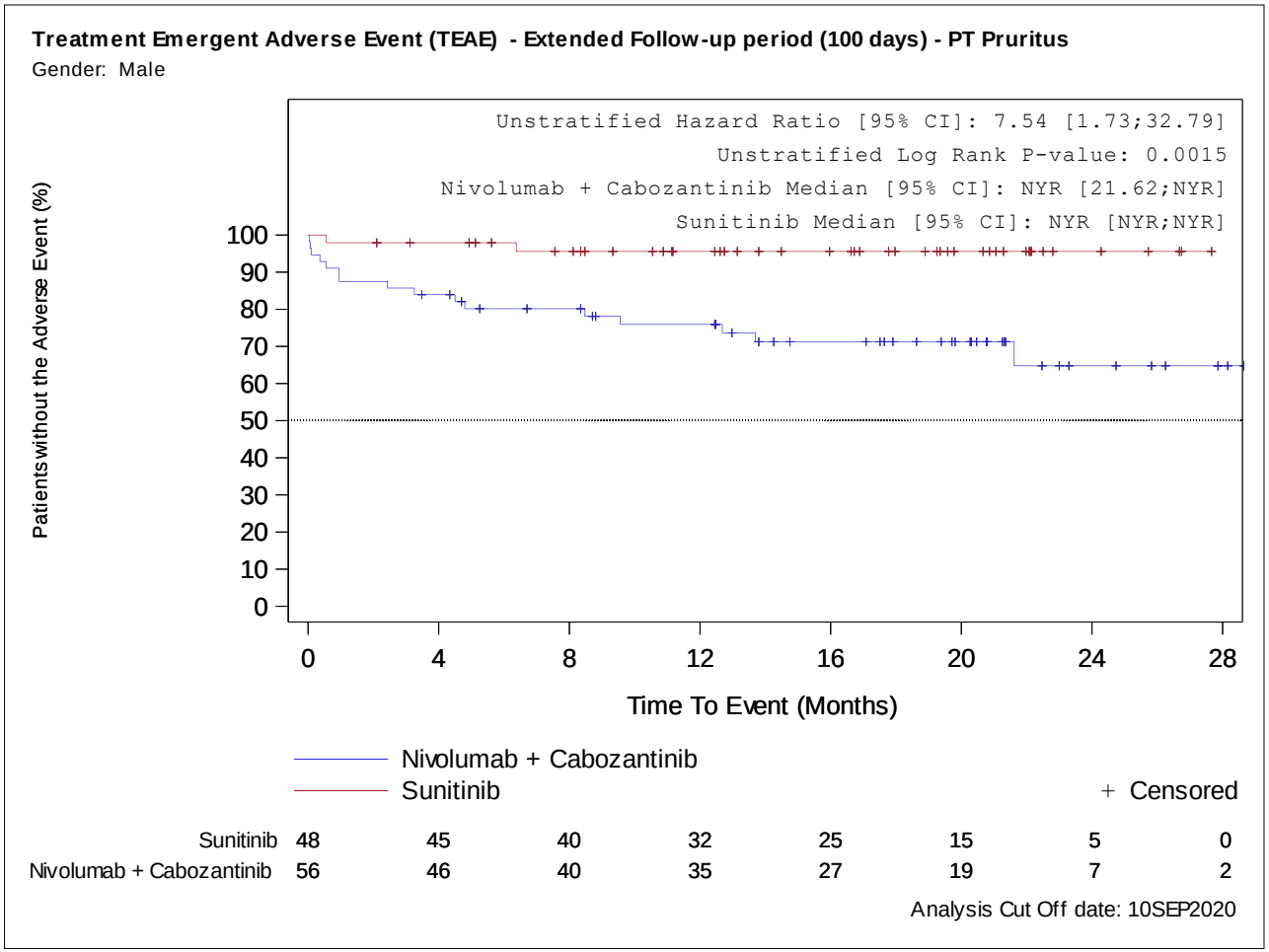
FIGURE 5.36.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:42:23

FIGURE 5.36.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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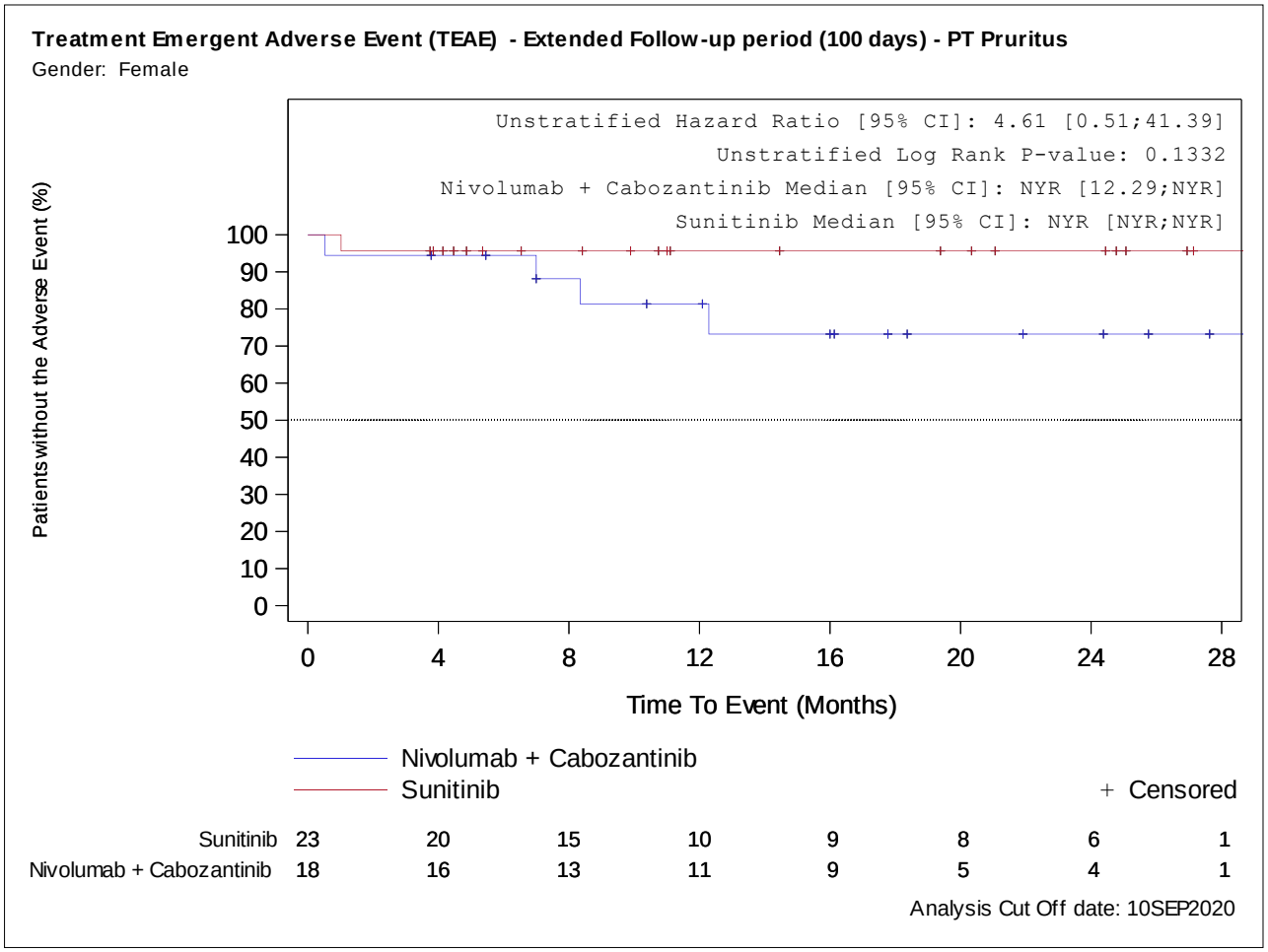
FIGURE 5.36.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
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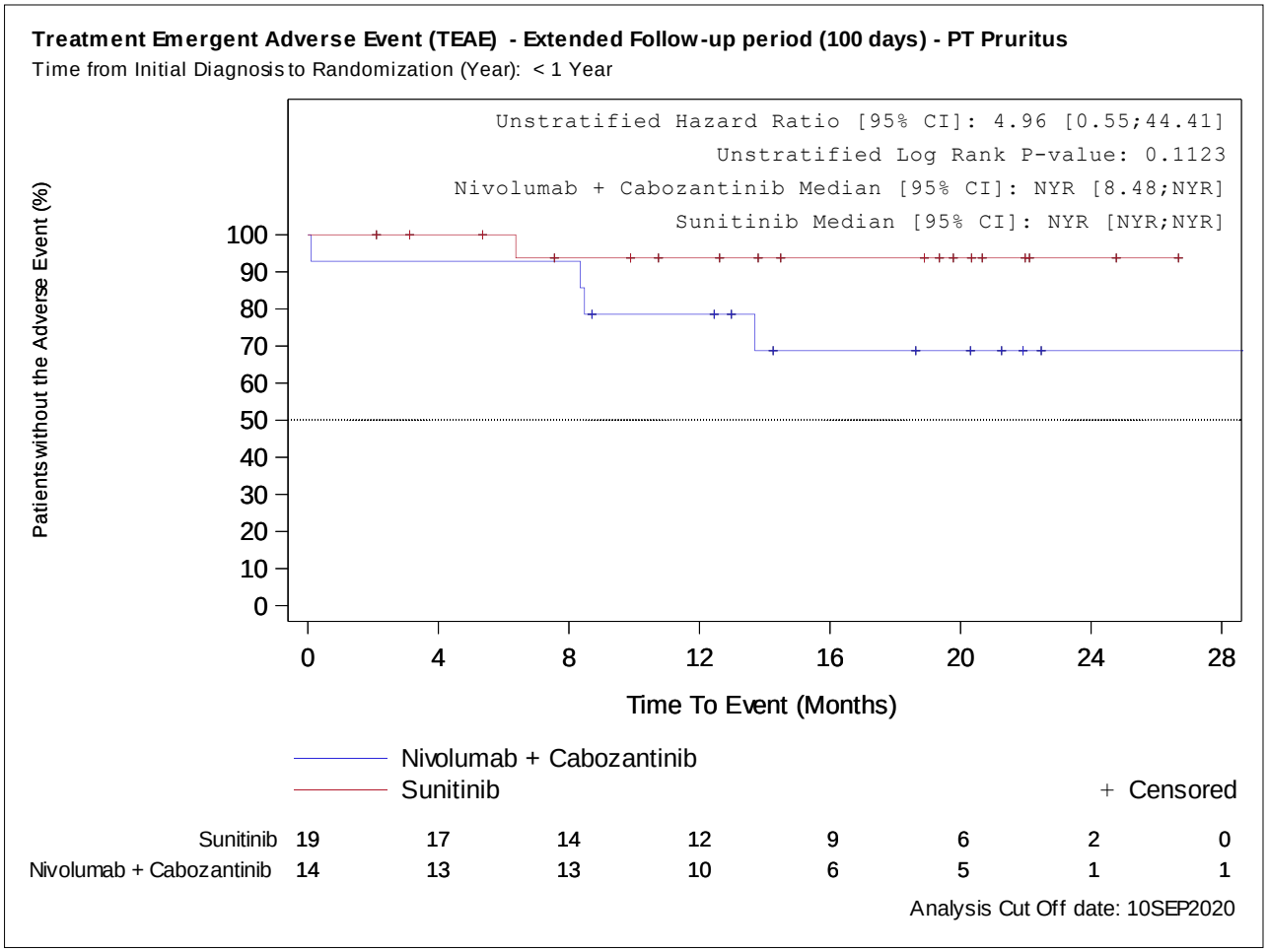
FIGURE 5.36.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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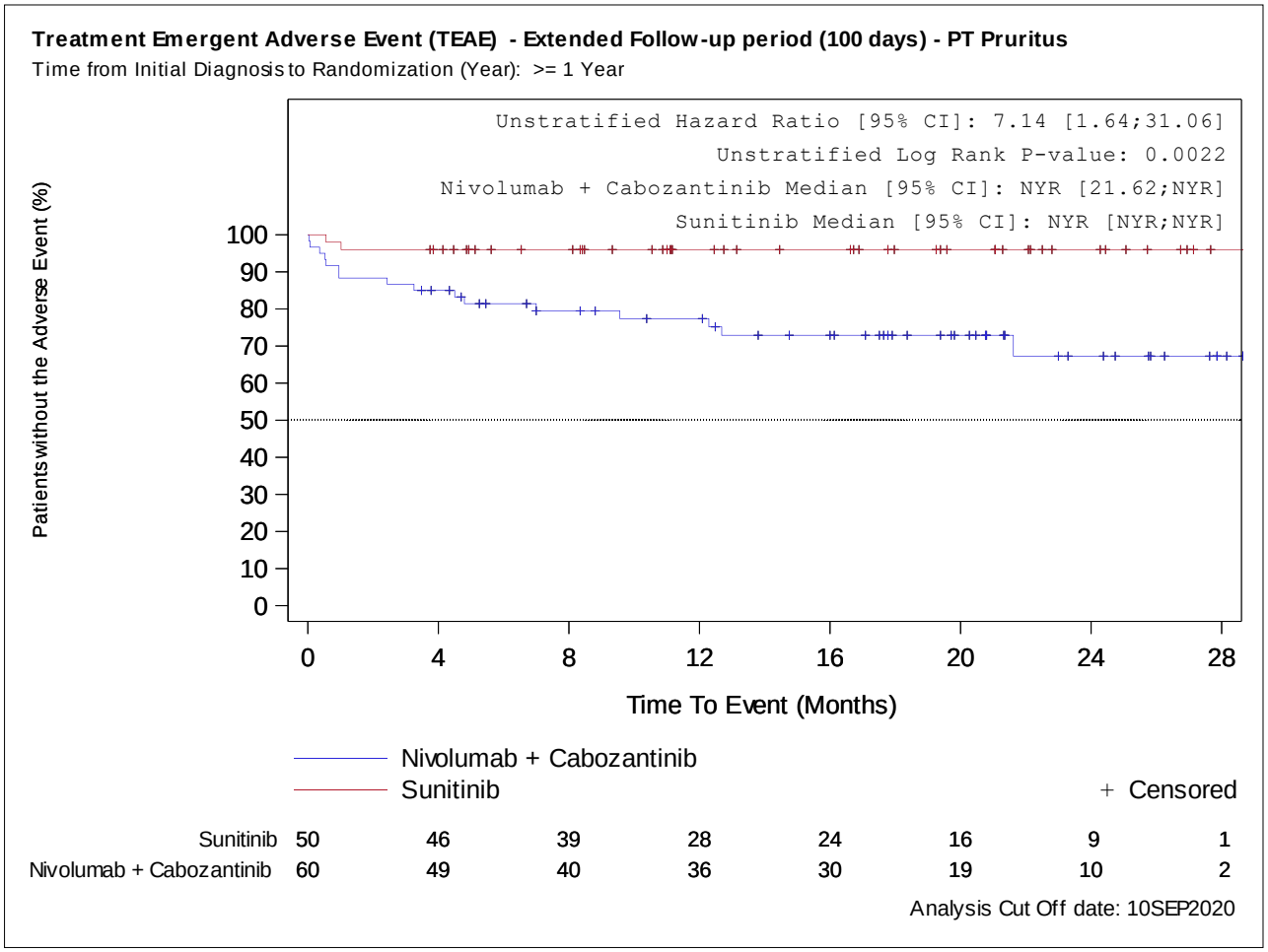
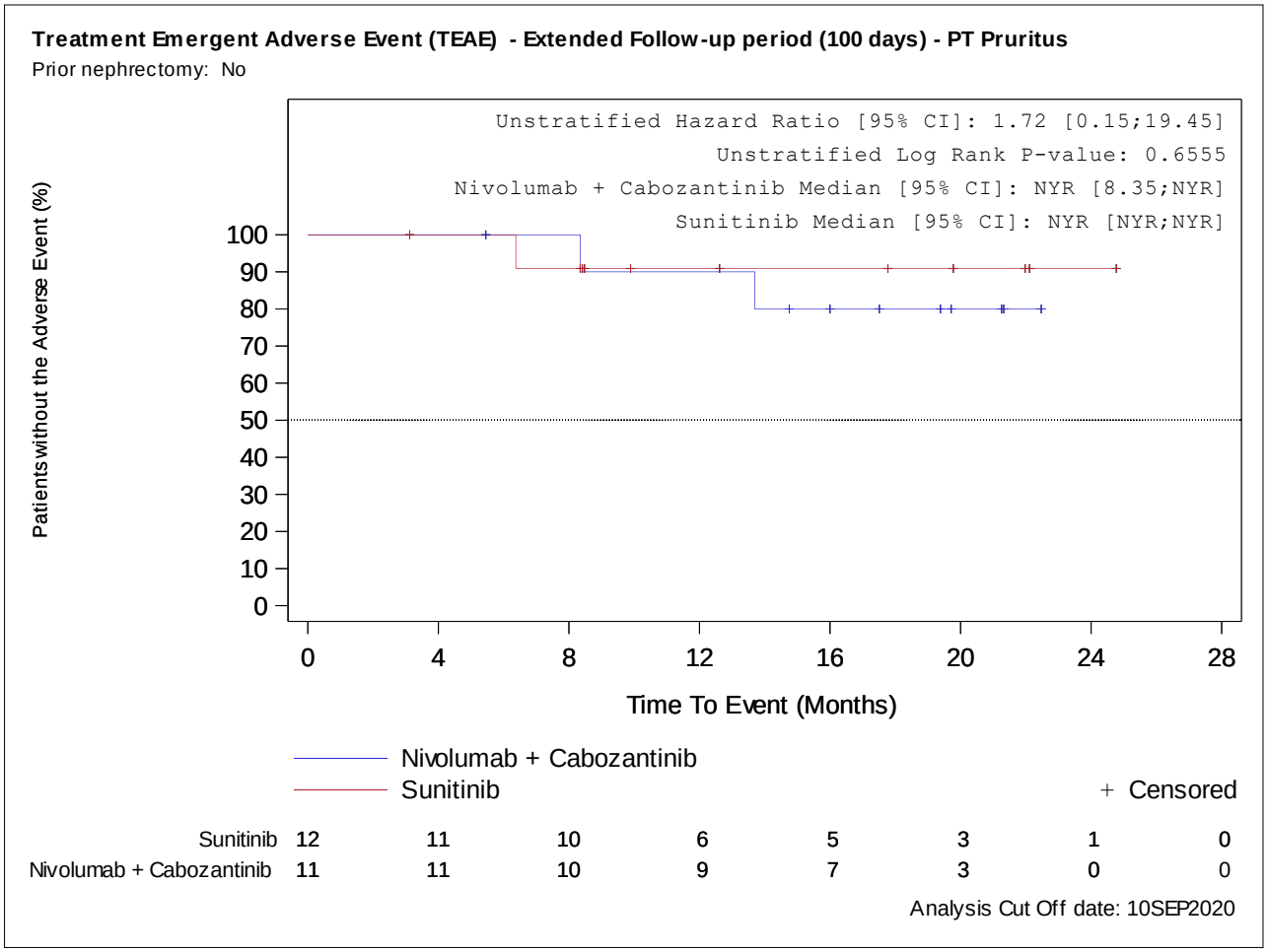
FIGURE 5.36.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:42:55

FIGURE 5.36.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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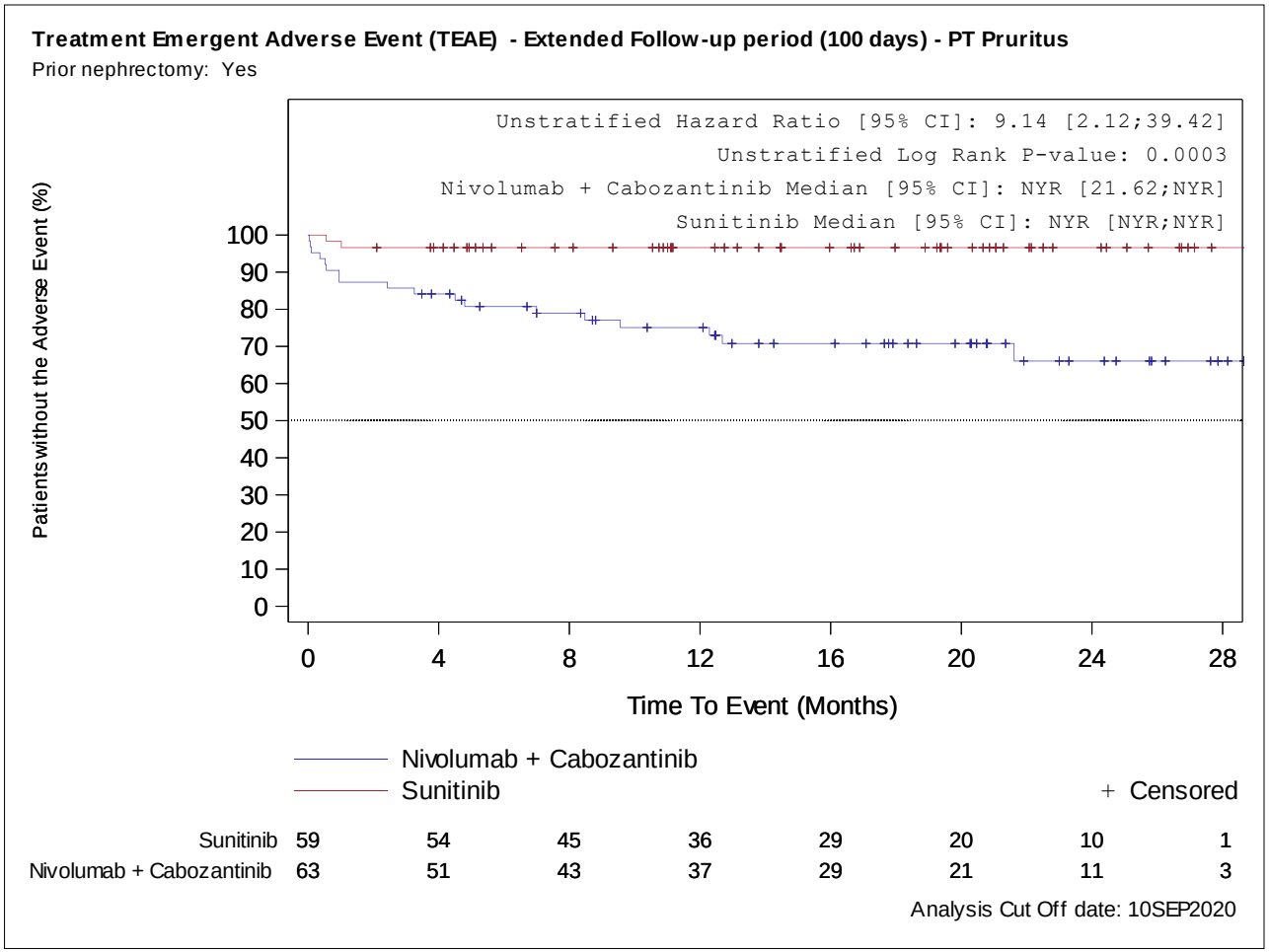
FIGURE 5.36.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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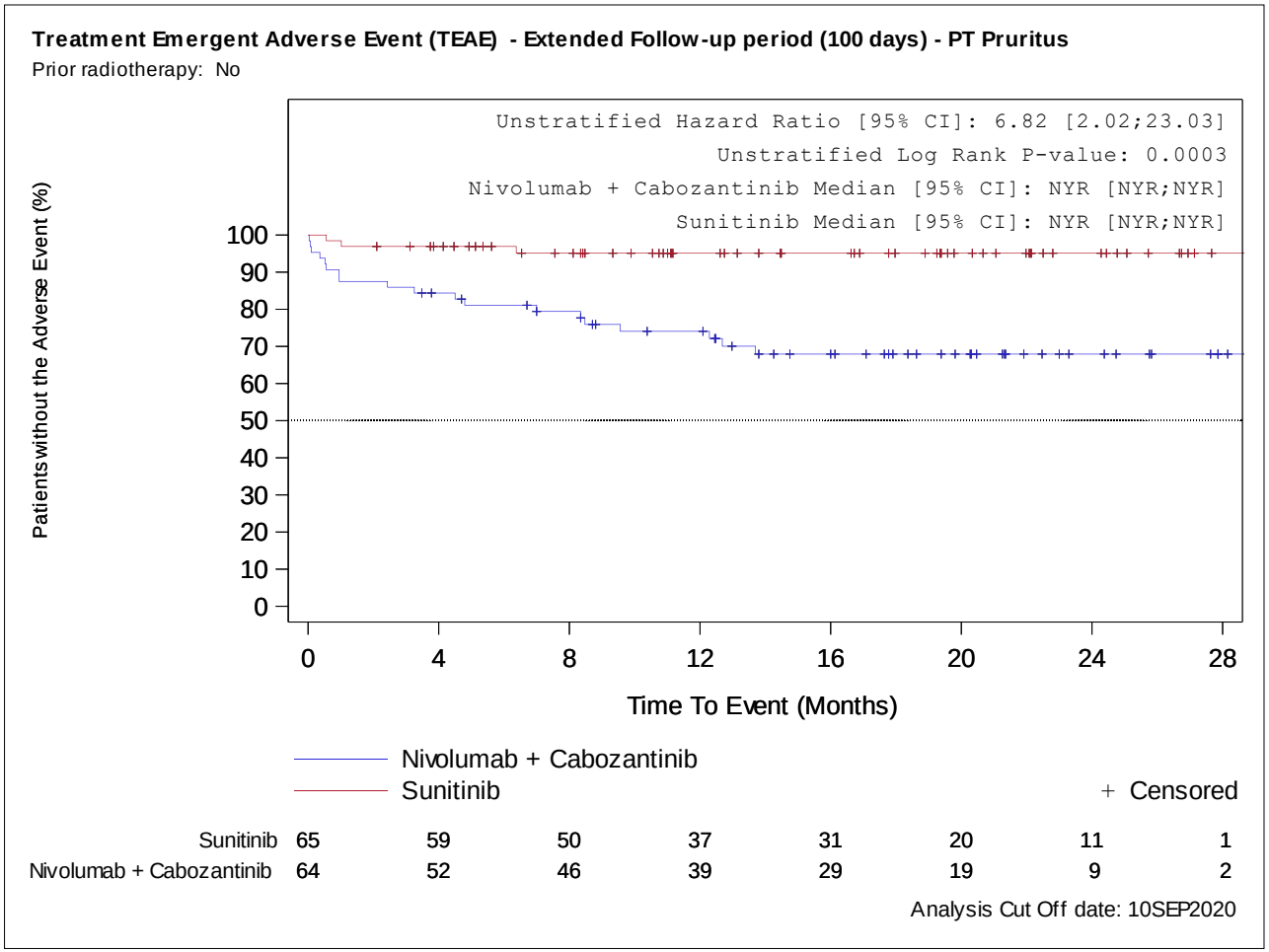
FIGURE 5.36.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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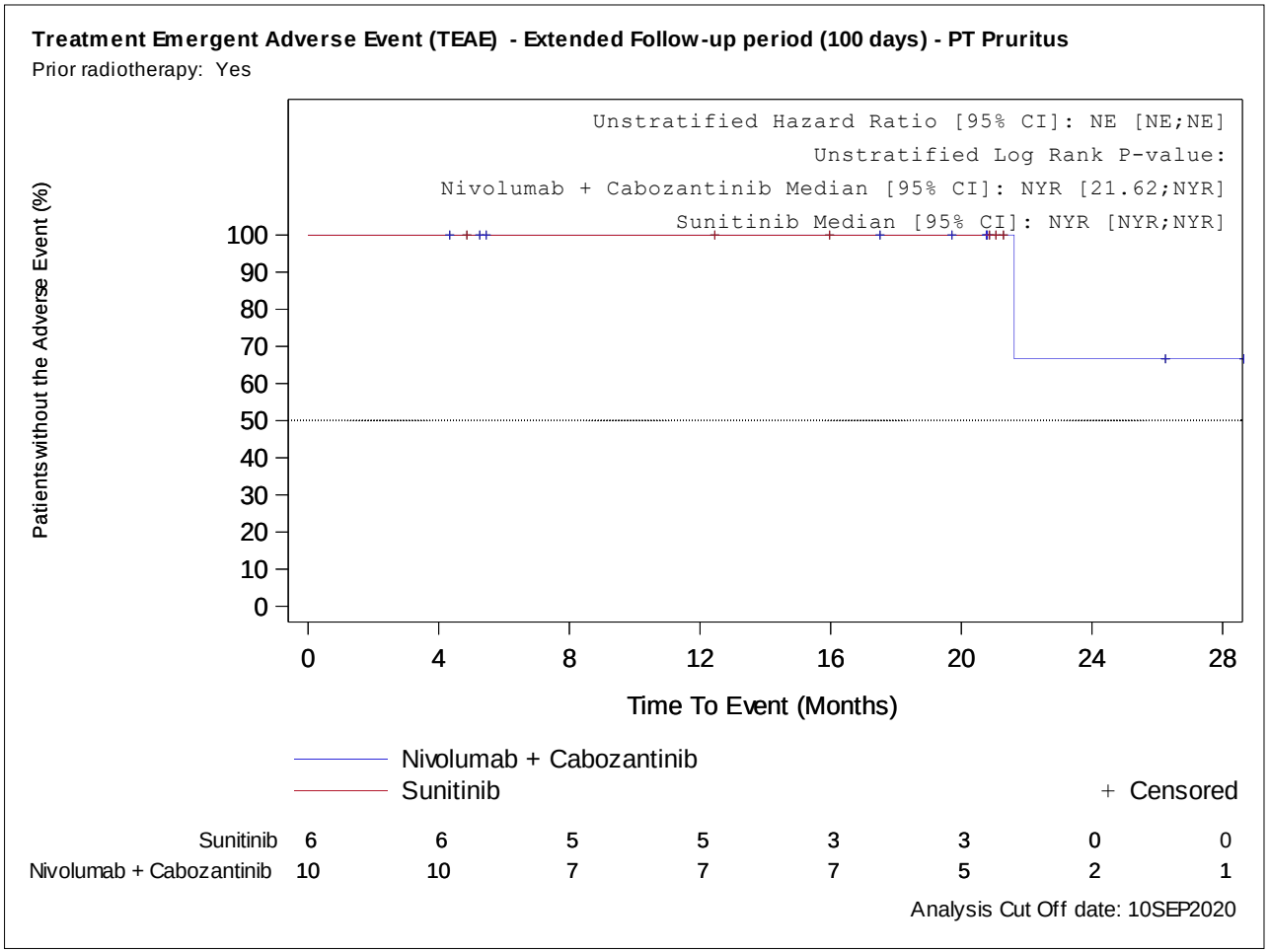
FIGURE 5.36.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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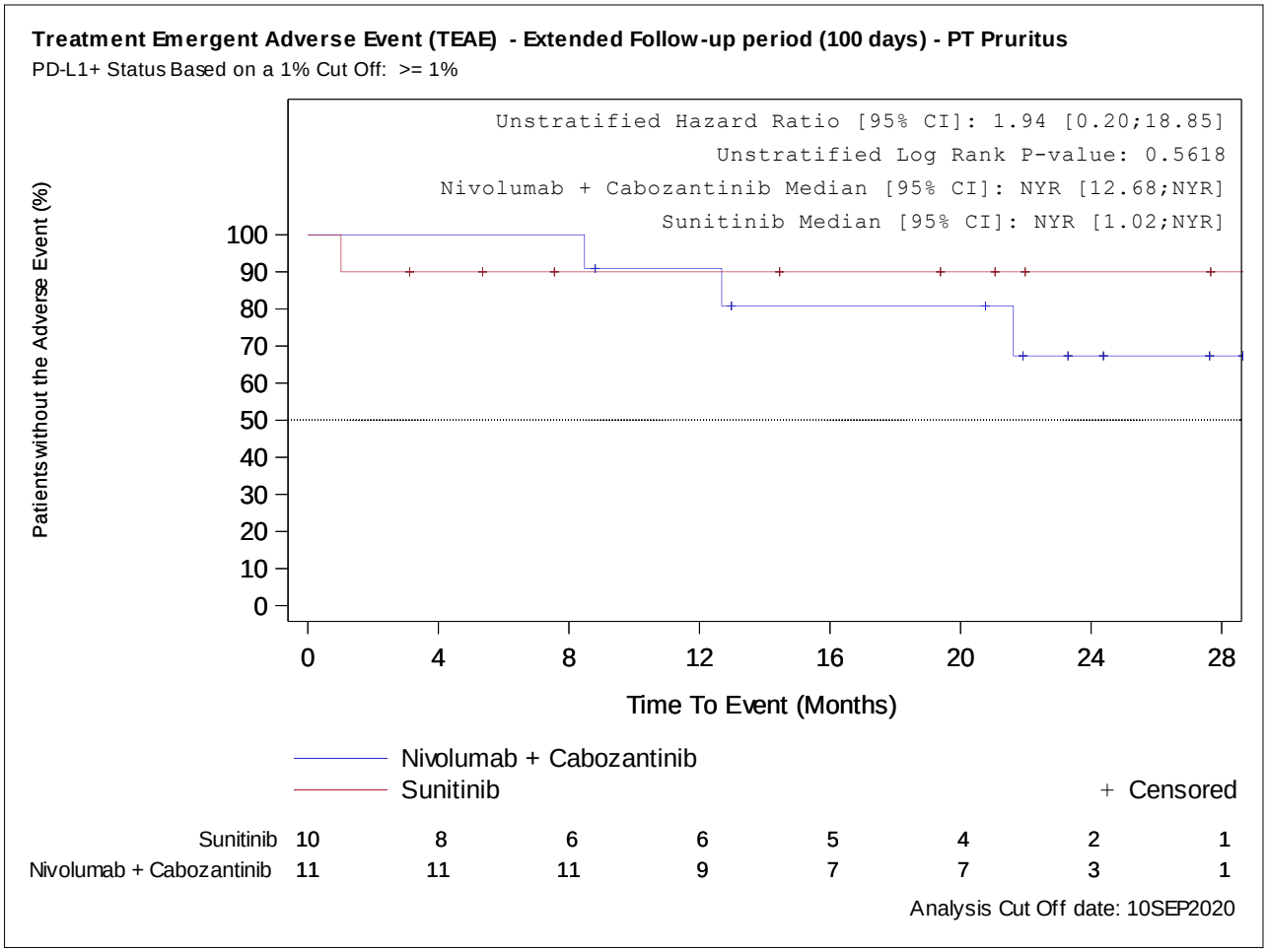
FIGURE 5.36.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%




Analysis Cut Off date: 10SEP2020
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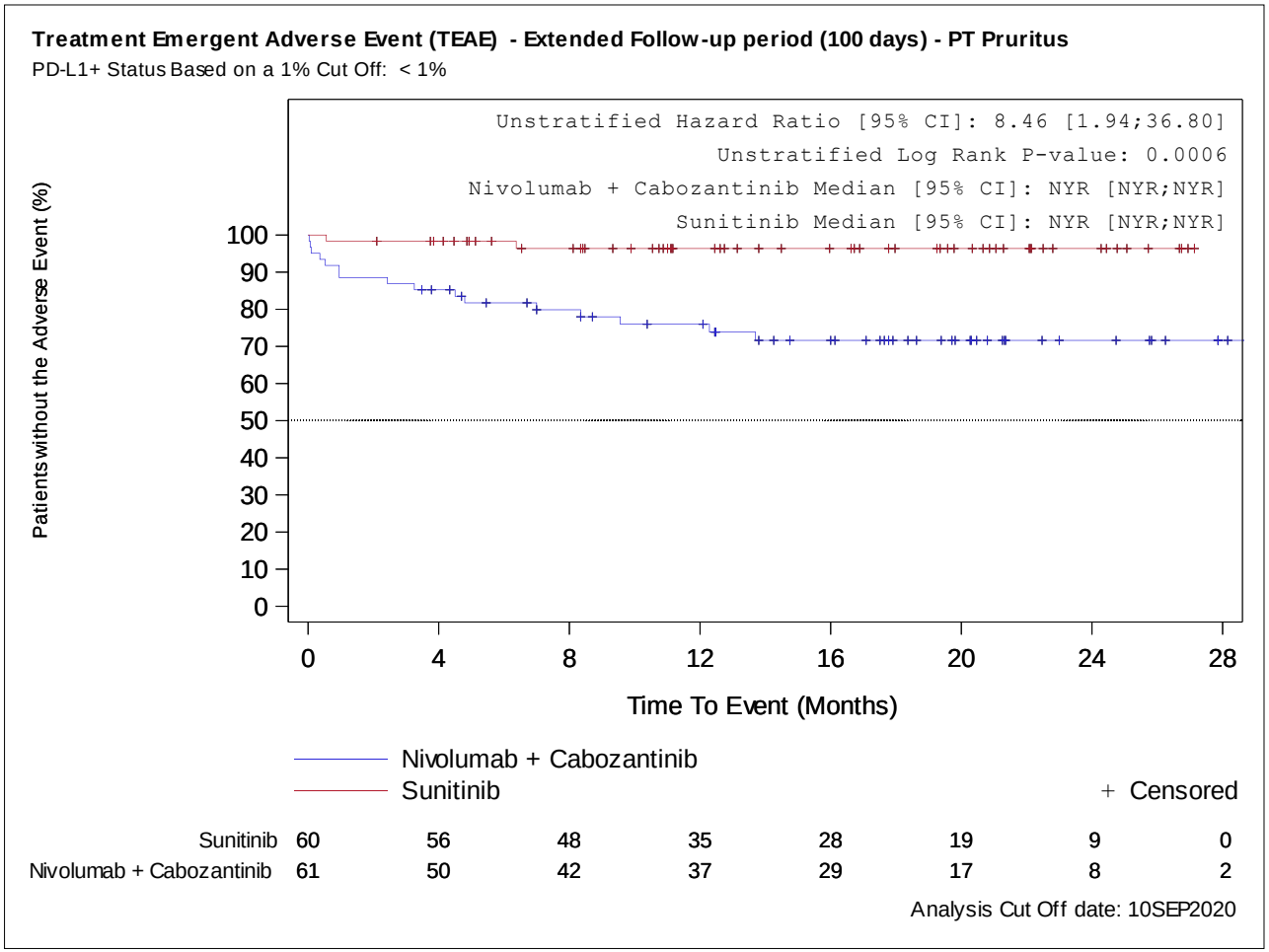
FIGURE 5.36.2.22: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%




Analysis Cut Off date: 10SEP2020
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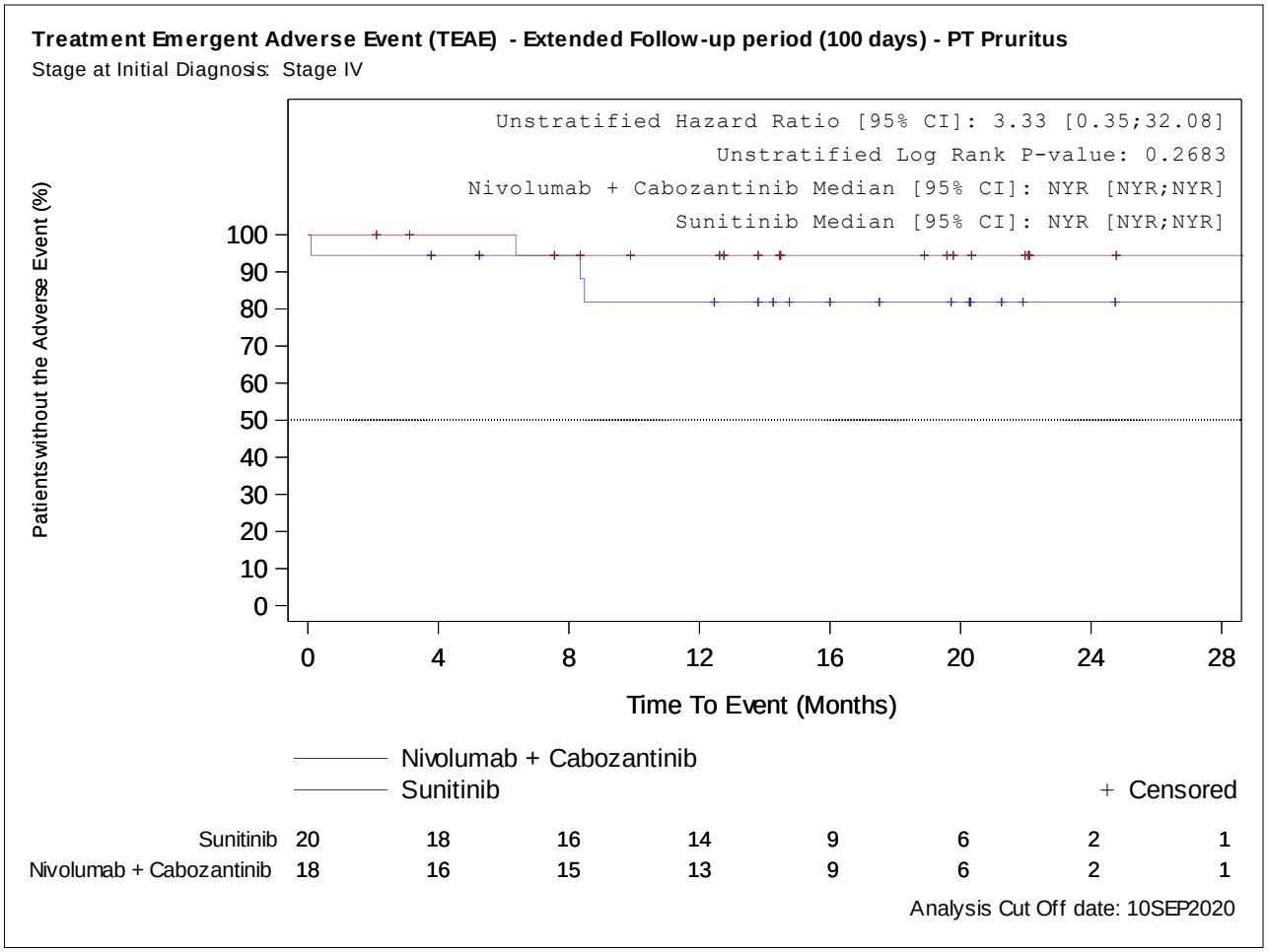
FIGURE 5.36.2.23: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV




Analysis Cut Off date: 10SEP2020
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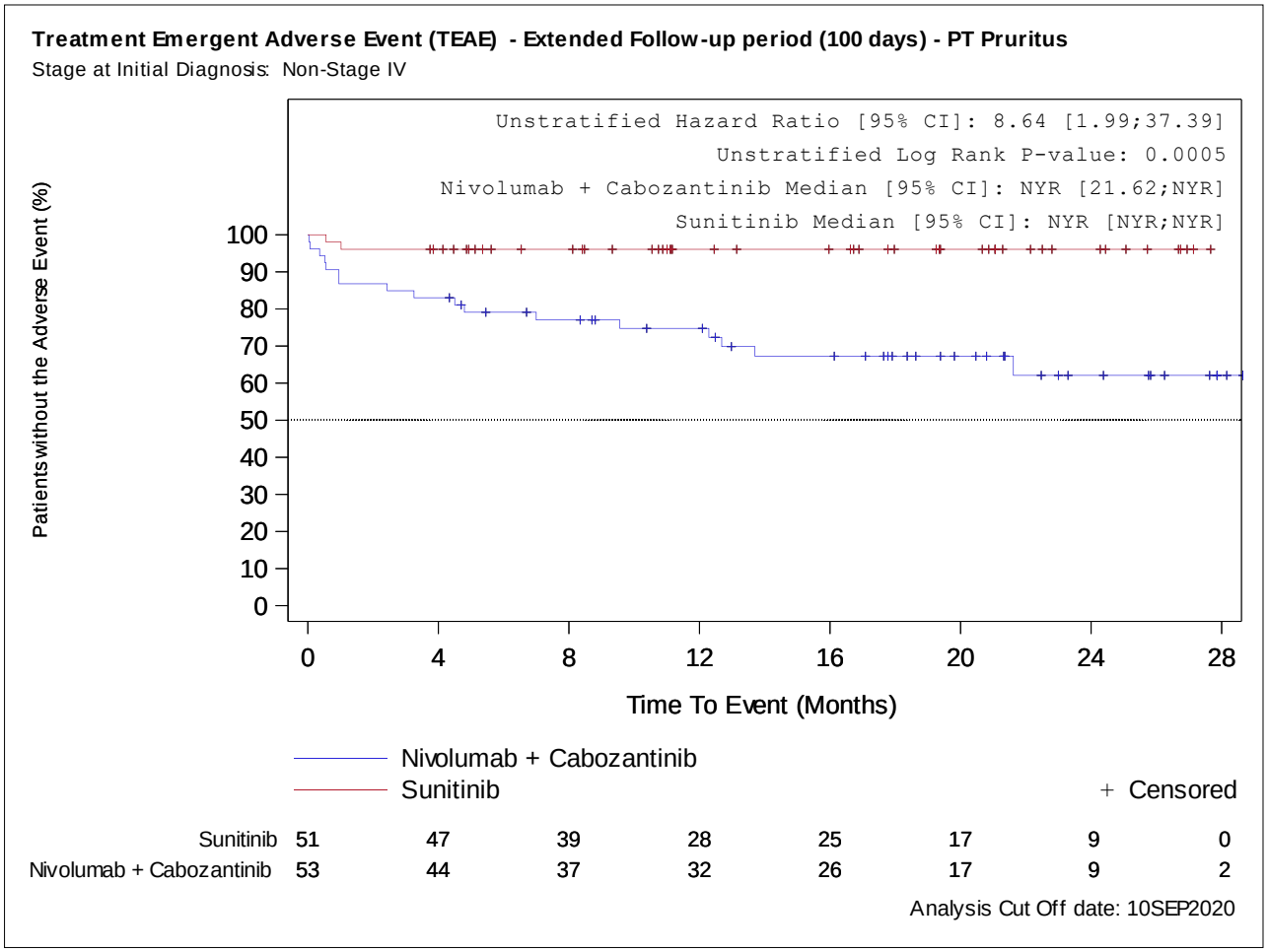
FIGURE 5.36.2.24: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Pruritus - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV




Analysis Cut Off date: 10SEP2020
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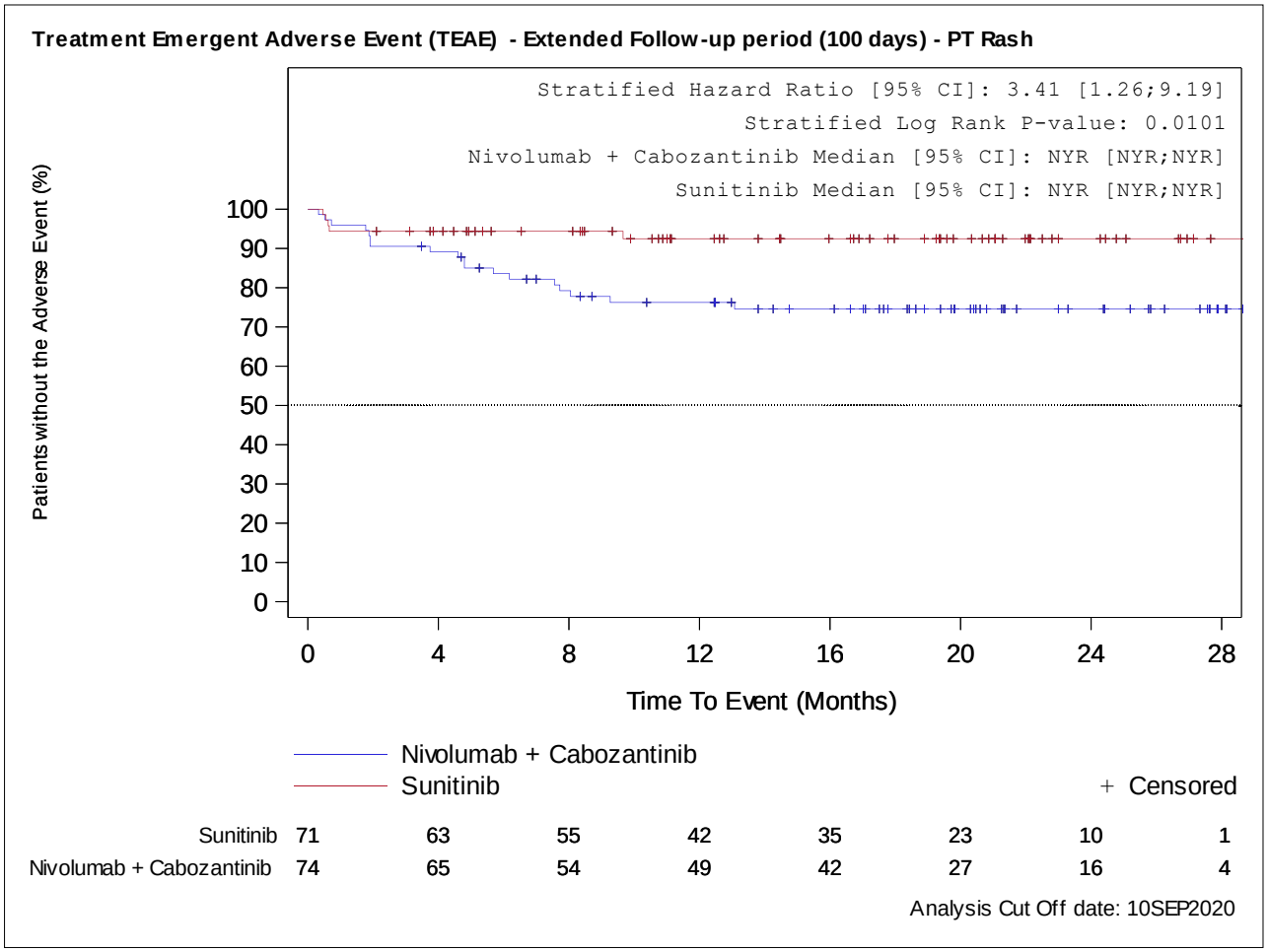
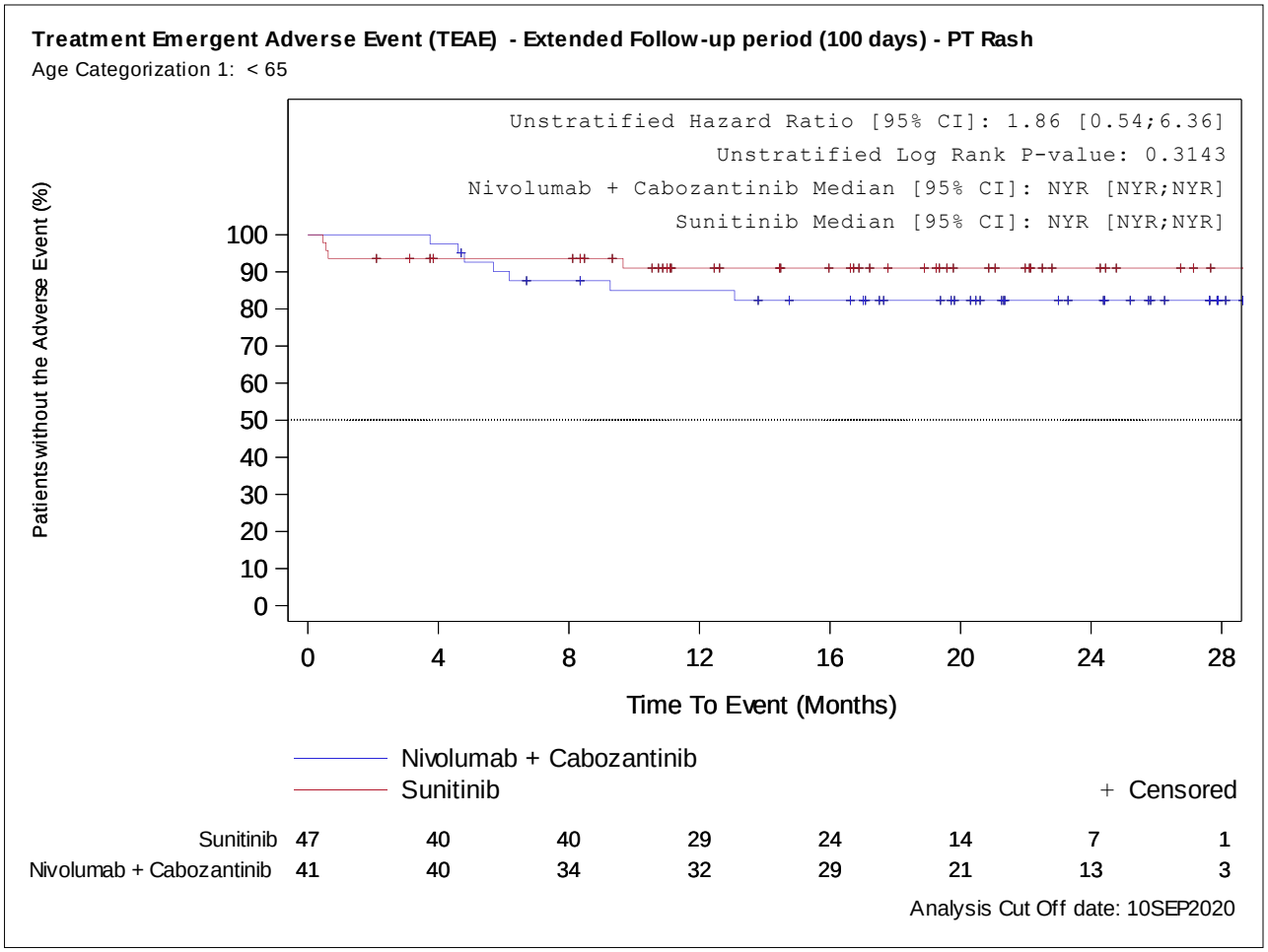
FIGURE 5.37.1: Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:48:08

FIGURE 5.37.2.1: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: < 65




Analysis Cut Off date: 10SEP2020
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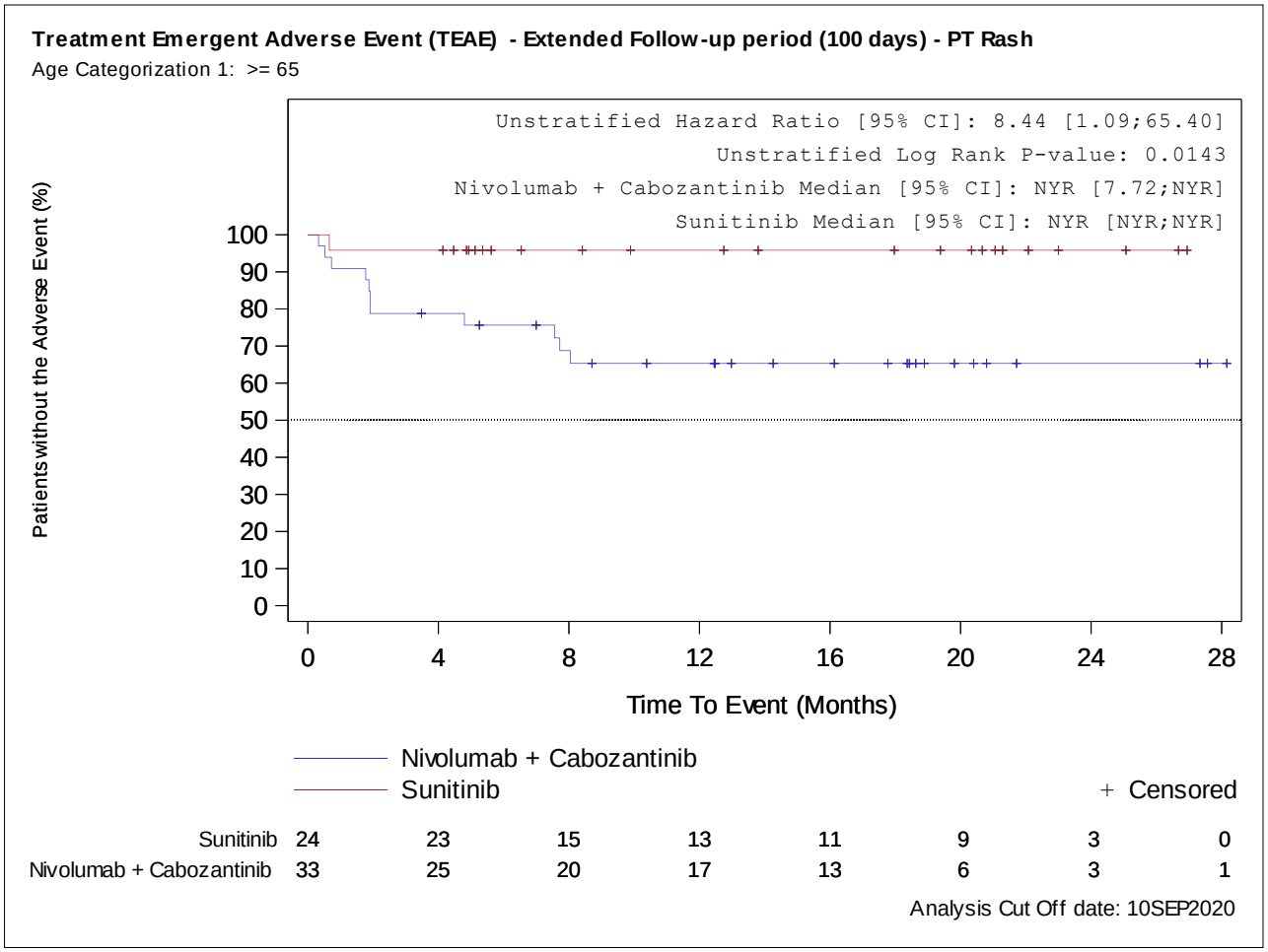
FIGURE 5.37.2.2: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1: >= 65




Analysis Cut Off date: 10SEP2020
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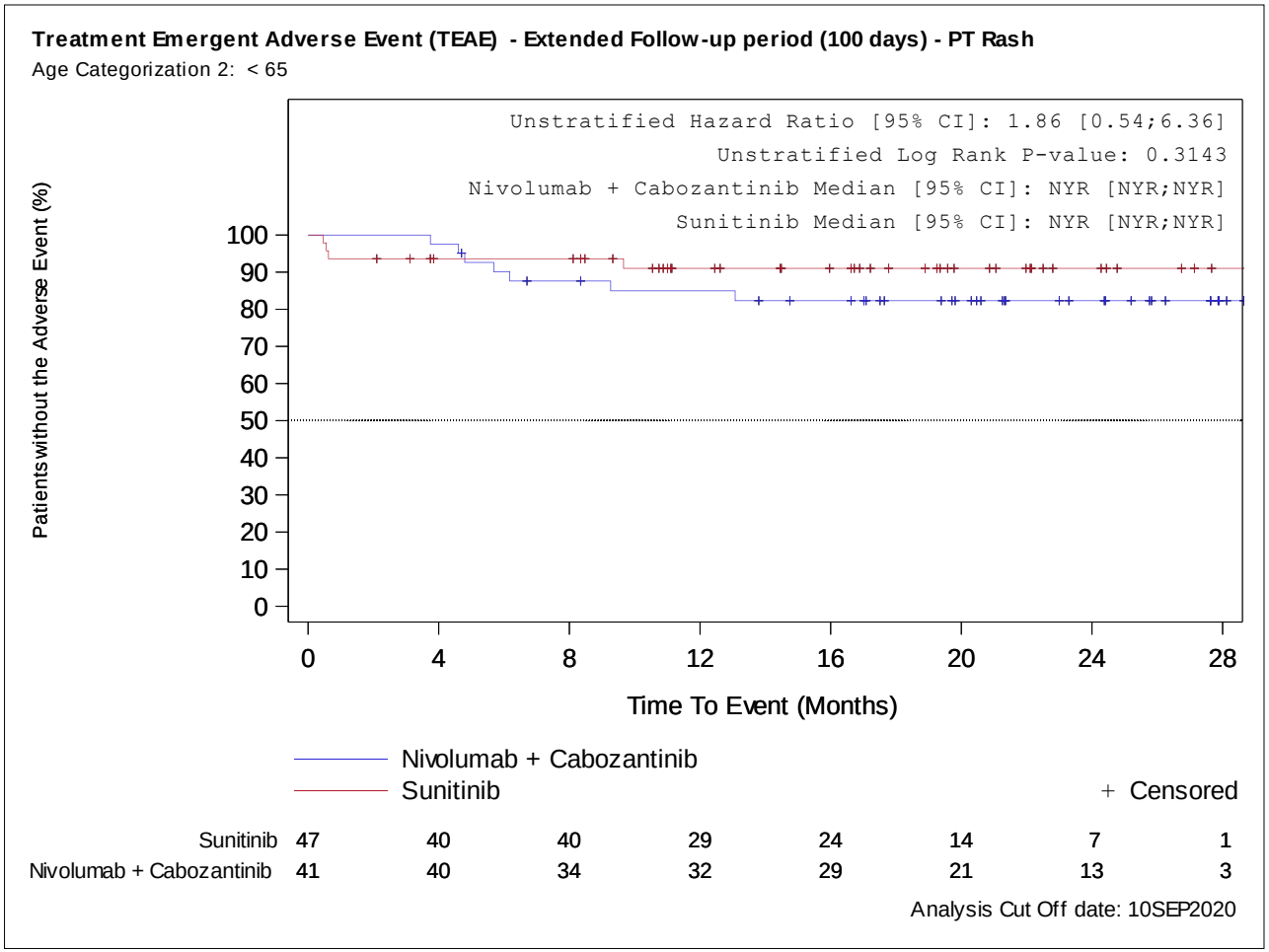
FIGURE 5.37.2.3: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: < 65




Analysis Cut Off date: 10SEP2020
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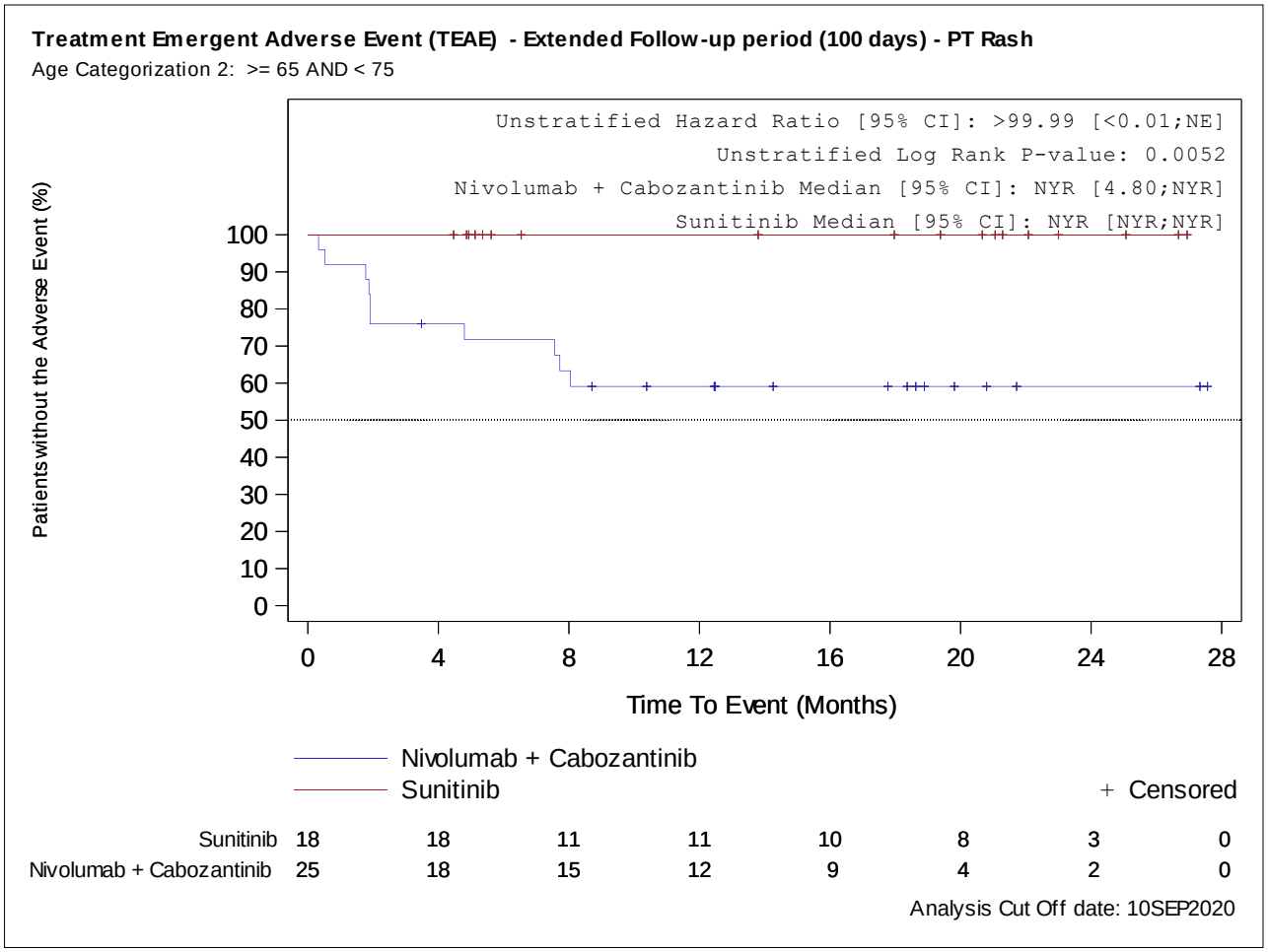
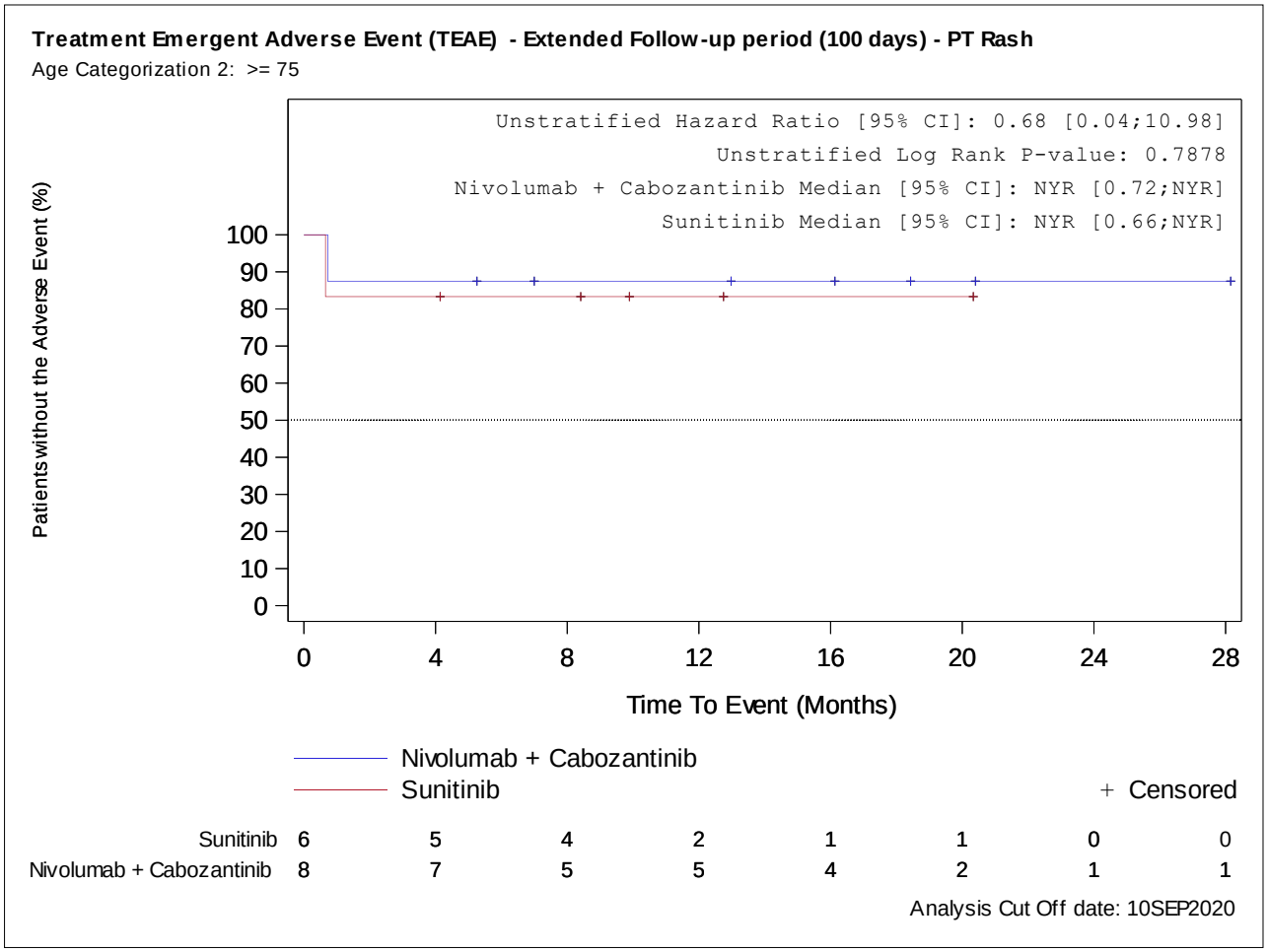
FIGURE 5.37.2.4: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 65 AND < 75



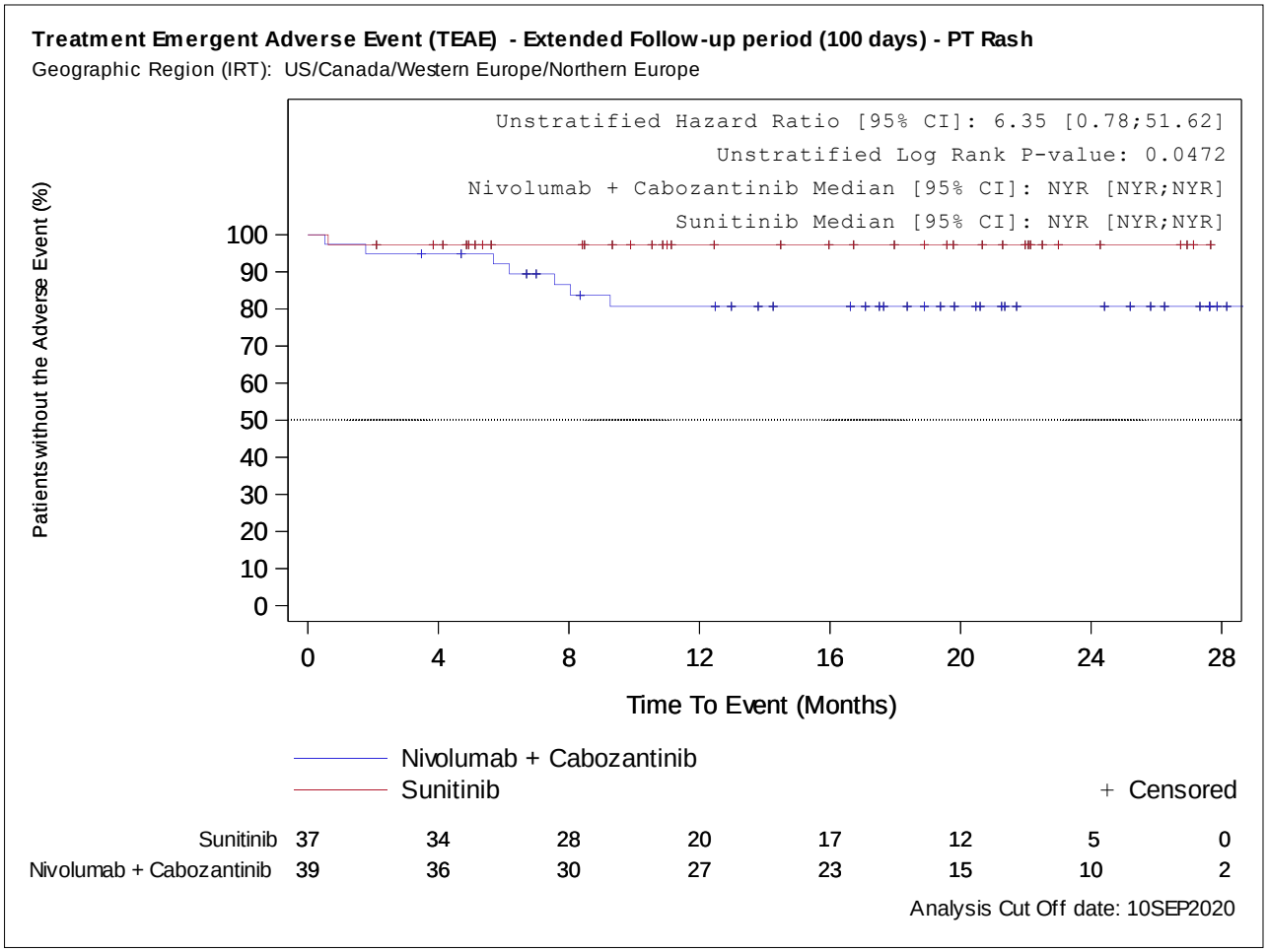

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:48:29

FIGURE 5.37.2.5: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2: >= 75




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:48:35

FIGURE 5.37.2.6: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): US/Canada/Western Europe/Northern Europe




Analysis Cut Off date: 10SEP2020
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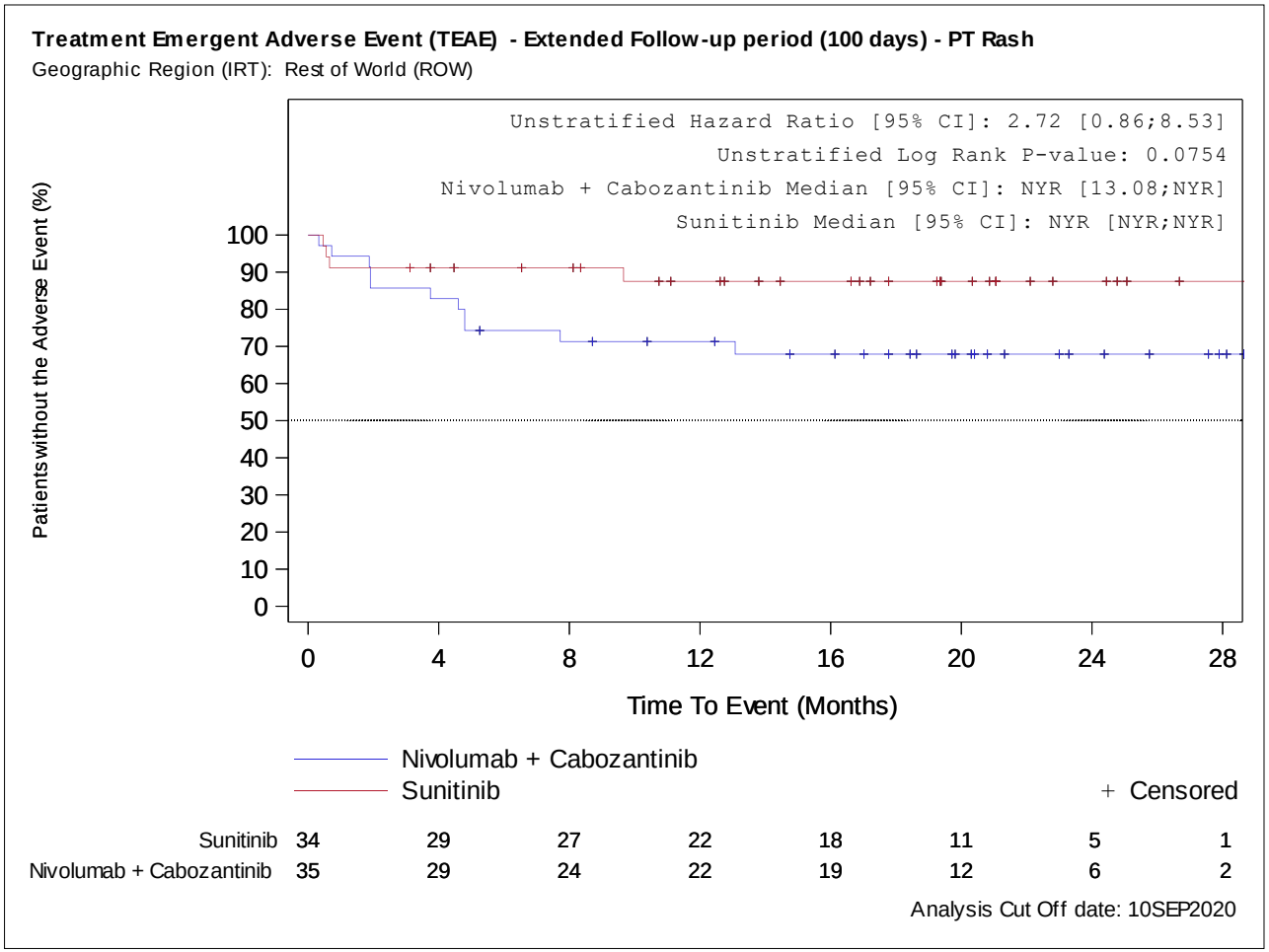
FIGURE 5.37.2.7: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT): Rest of World (ROW)




Analysis Cut Off date: 10SEP2020
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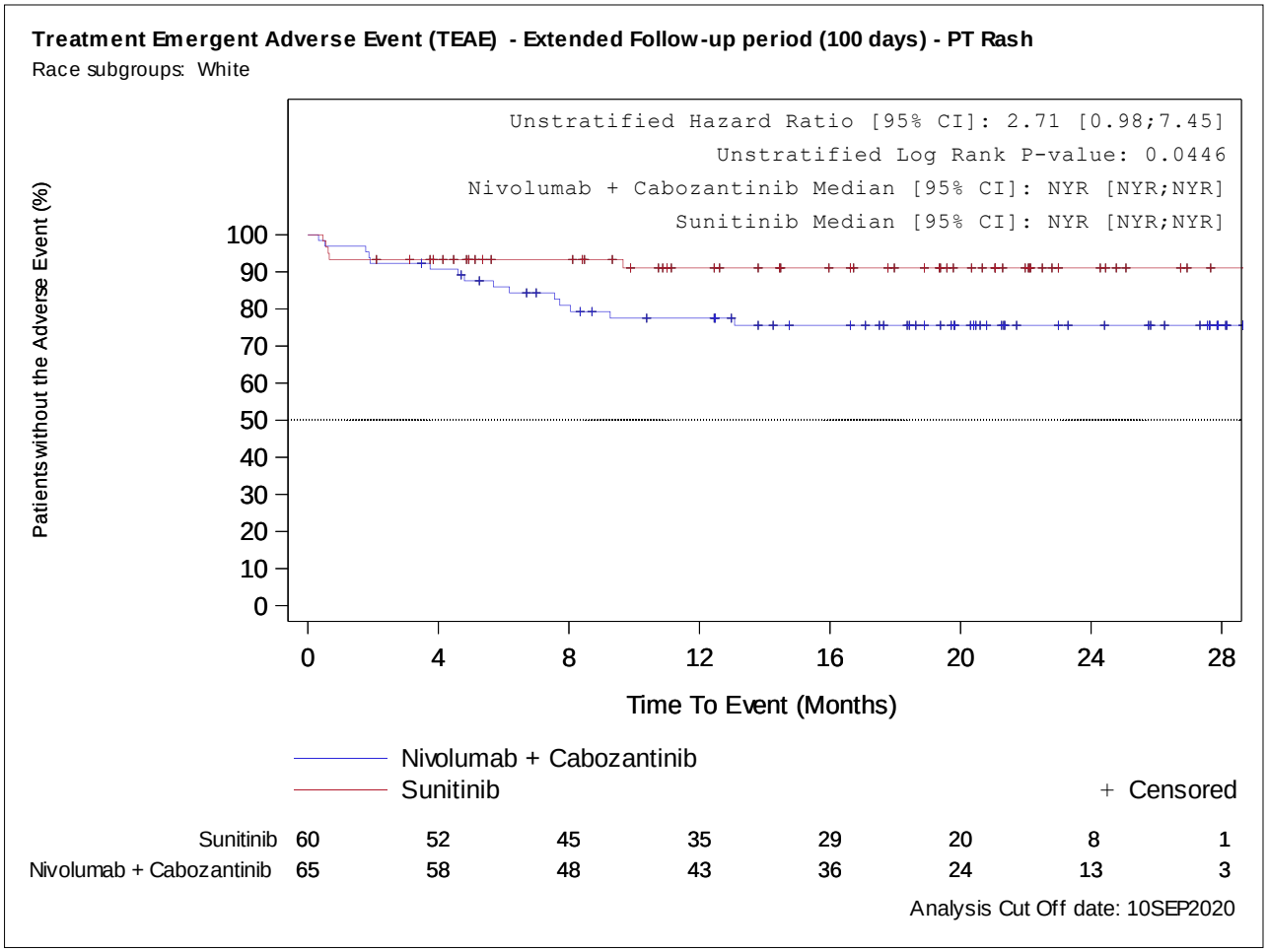
FIGURE 5.37.2.8: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White




Analysis Cut Off date: 10SEP2020
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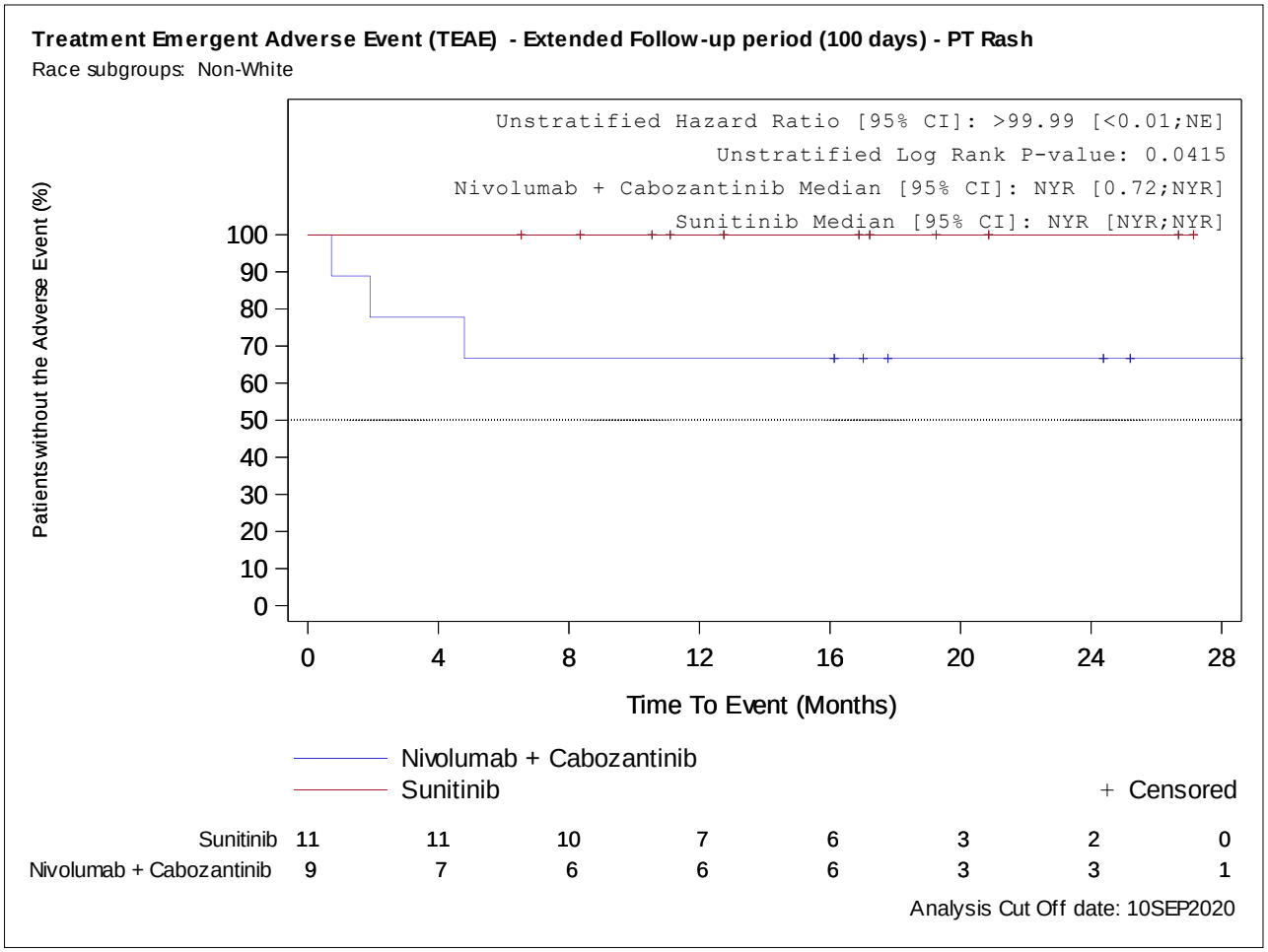
FIGURE 5.37.2.9: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White




Analysis Cut Off date: 10SEP2020
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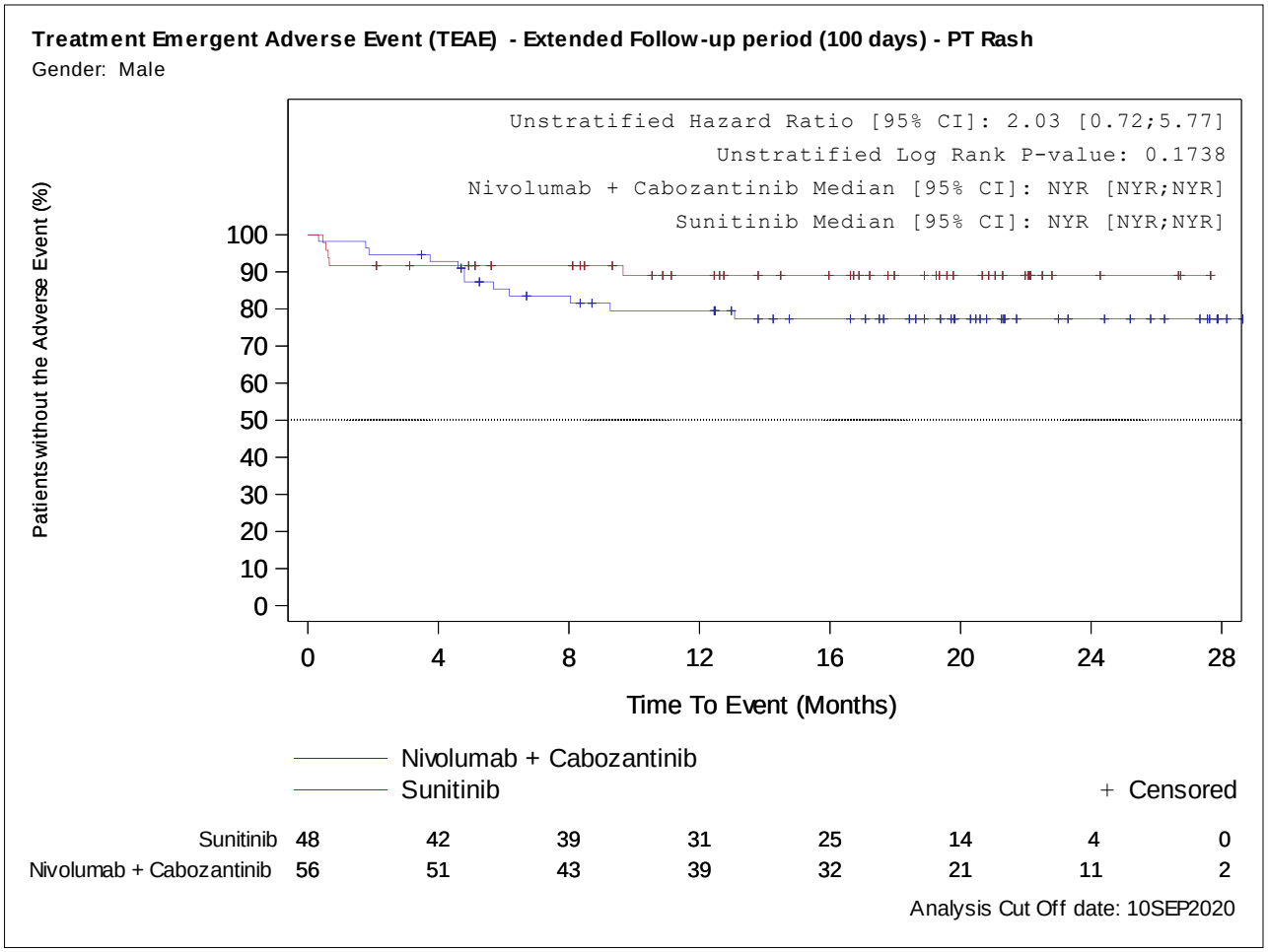
FIGURE 5.37.2.10: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Male




Analysis Cut Off date: 10SEP2020
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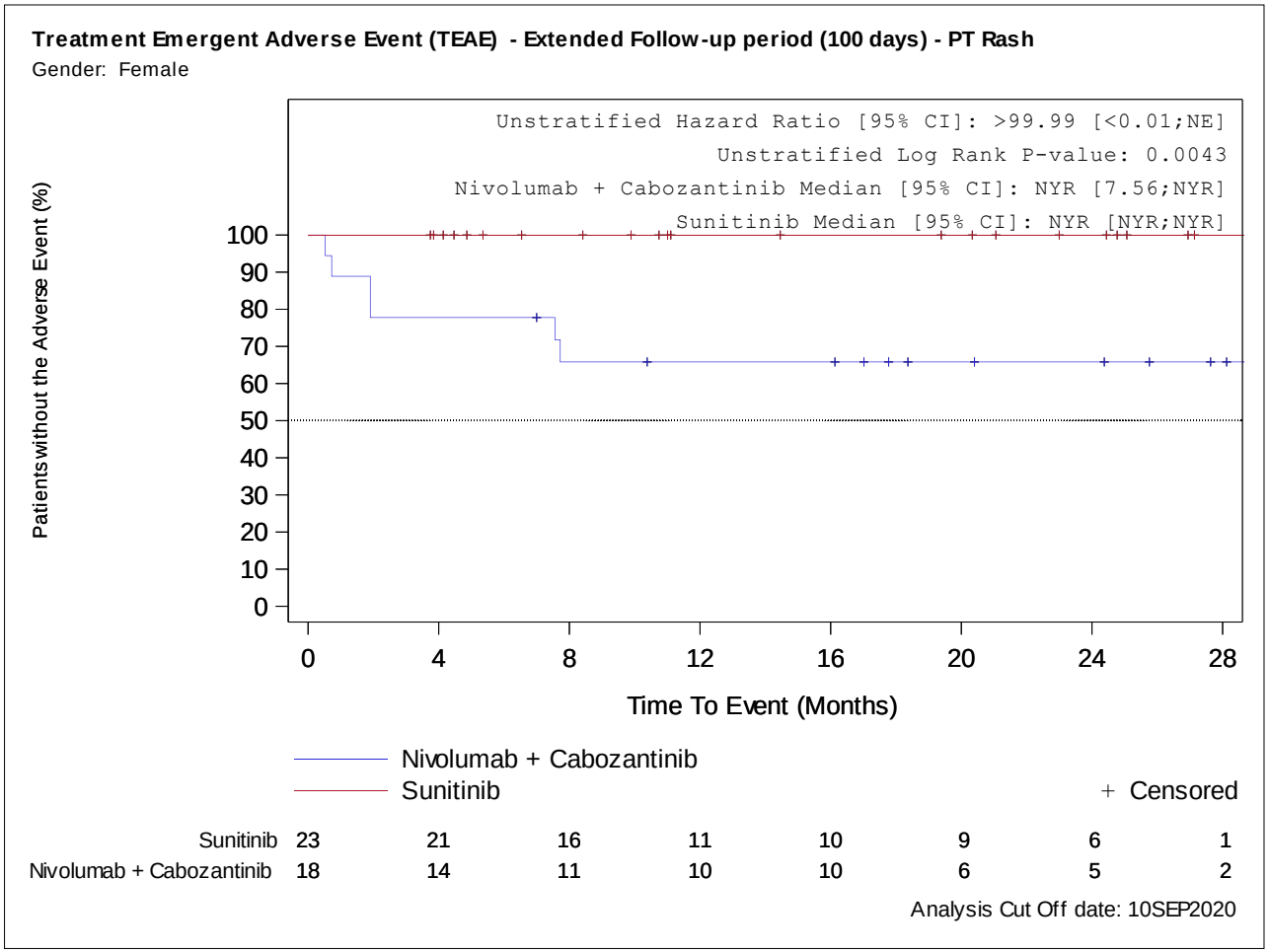
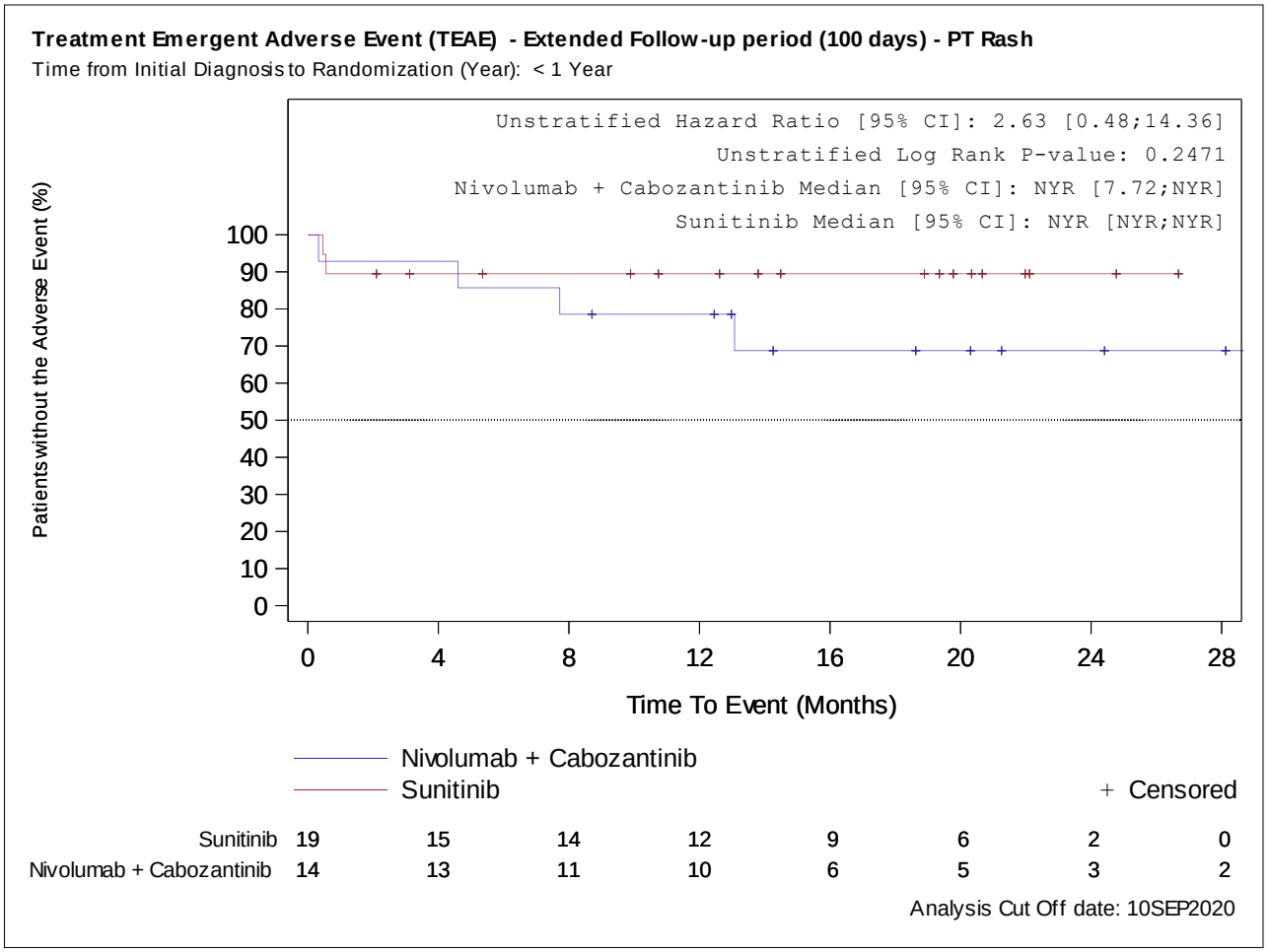
FIGURE 5.37.2.11: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender: Female




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:49:08

FIGURE 5.37.2.12: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year




Analysis Cut Off date: 10SEP2020
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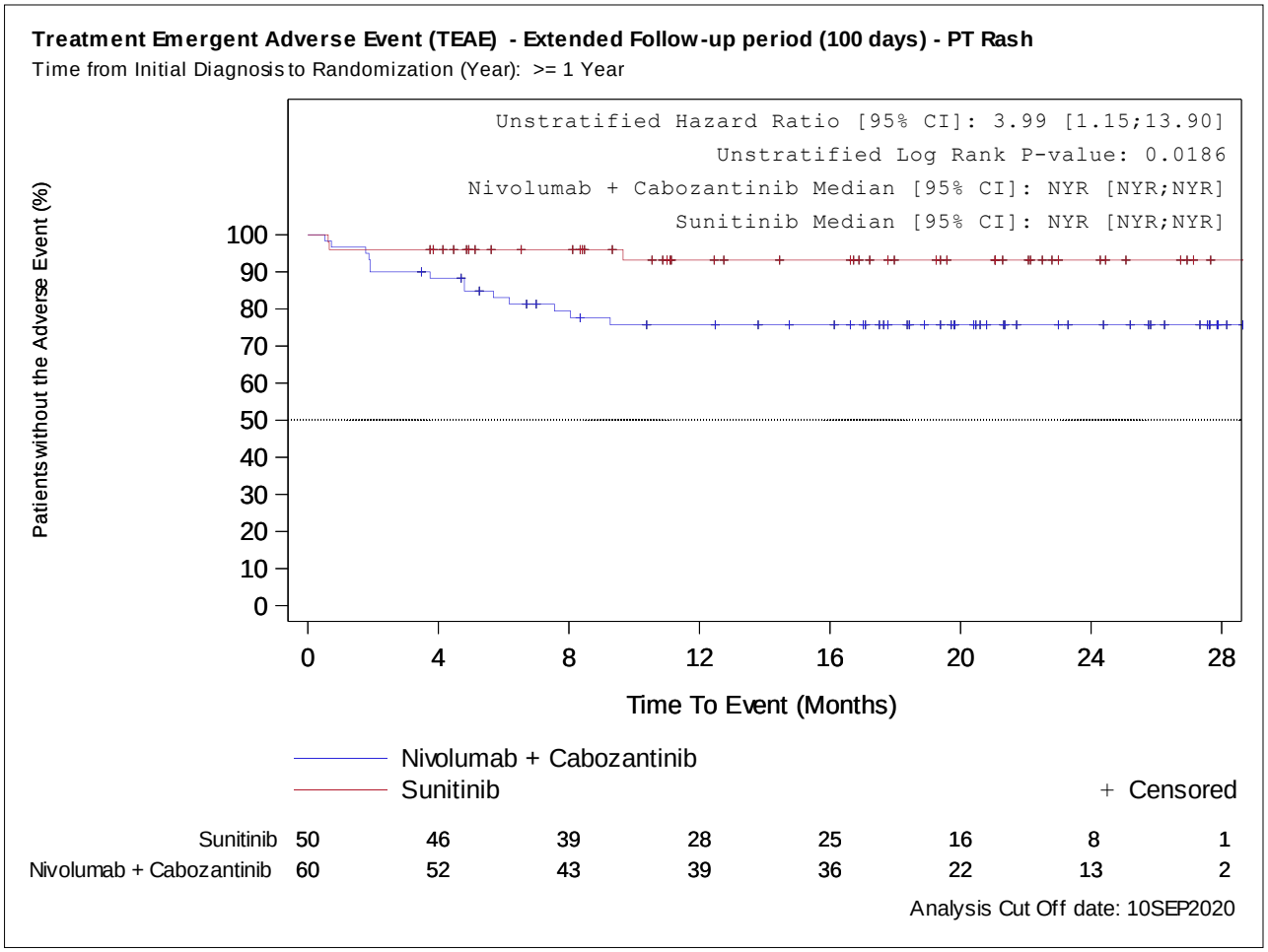
FIGURE 5.37.2.13: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year




Analysis Cut Off date: 10SEP2020
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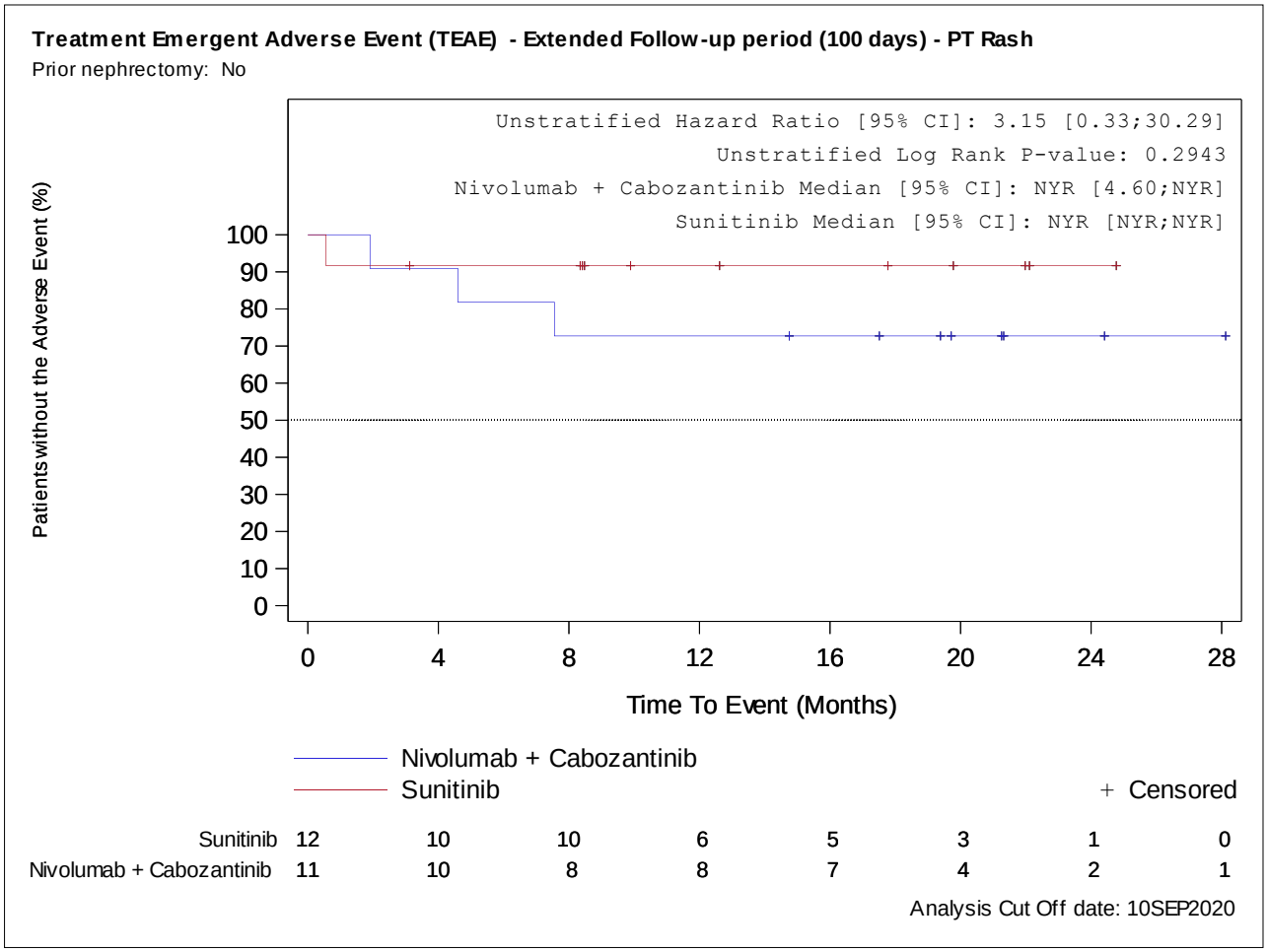
FIGURE 5.37.2.14: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No




Analysis Cut Off date: 10SEP2020
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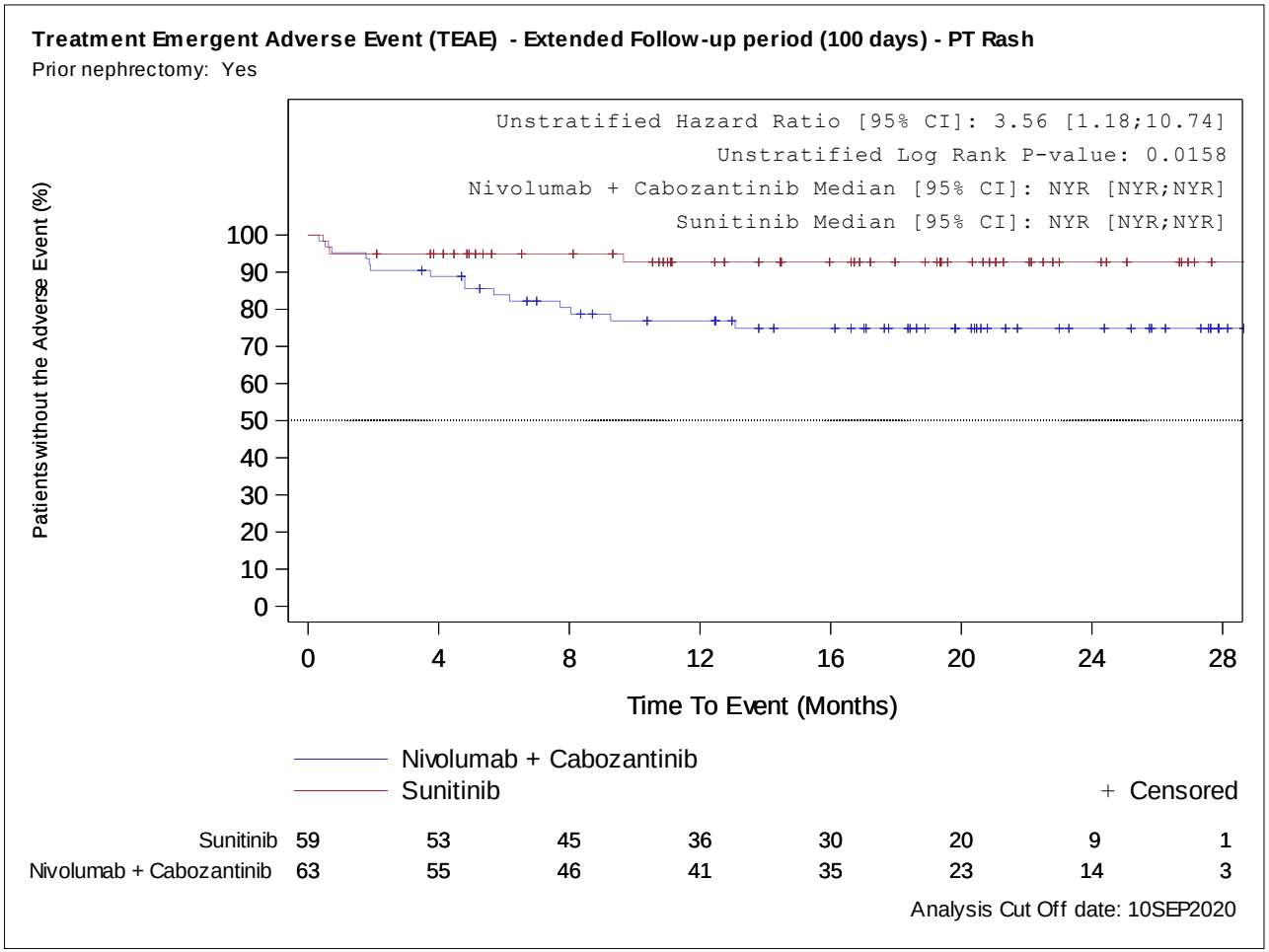
FIGURE 5.37.2.15: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes




Analysis Cut Off date: 10SEP2020
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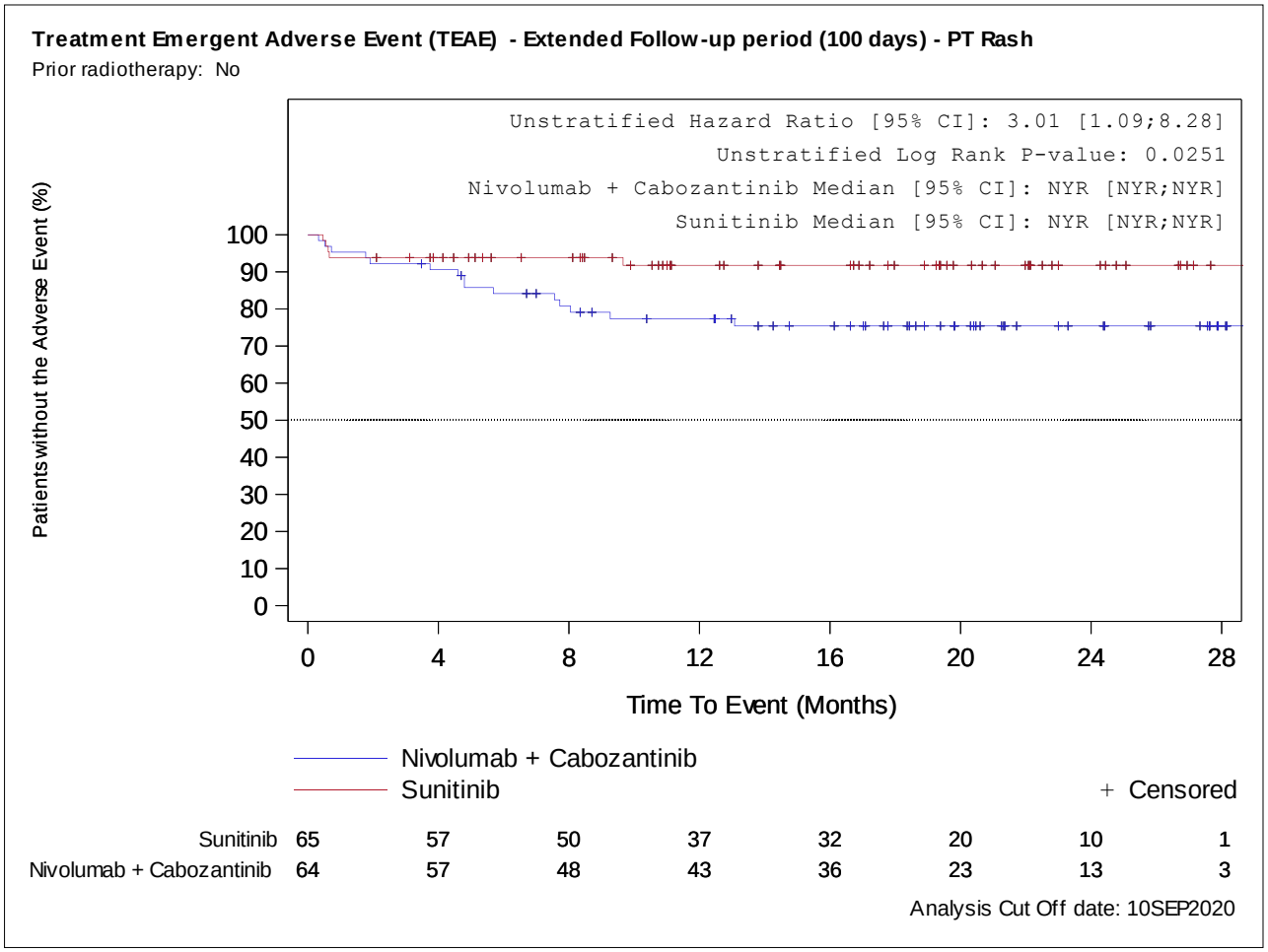
FIGURE 5.37.2.16: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
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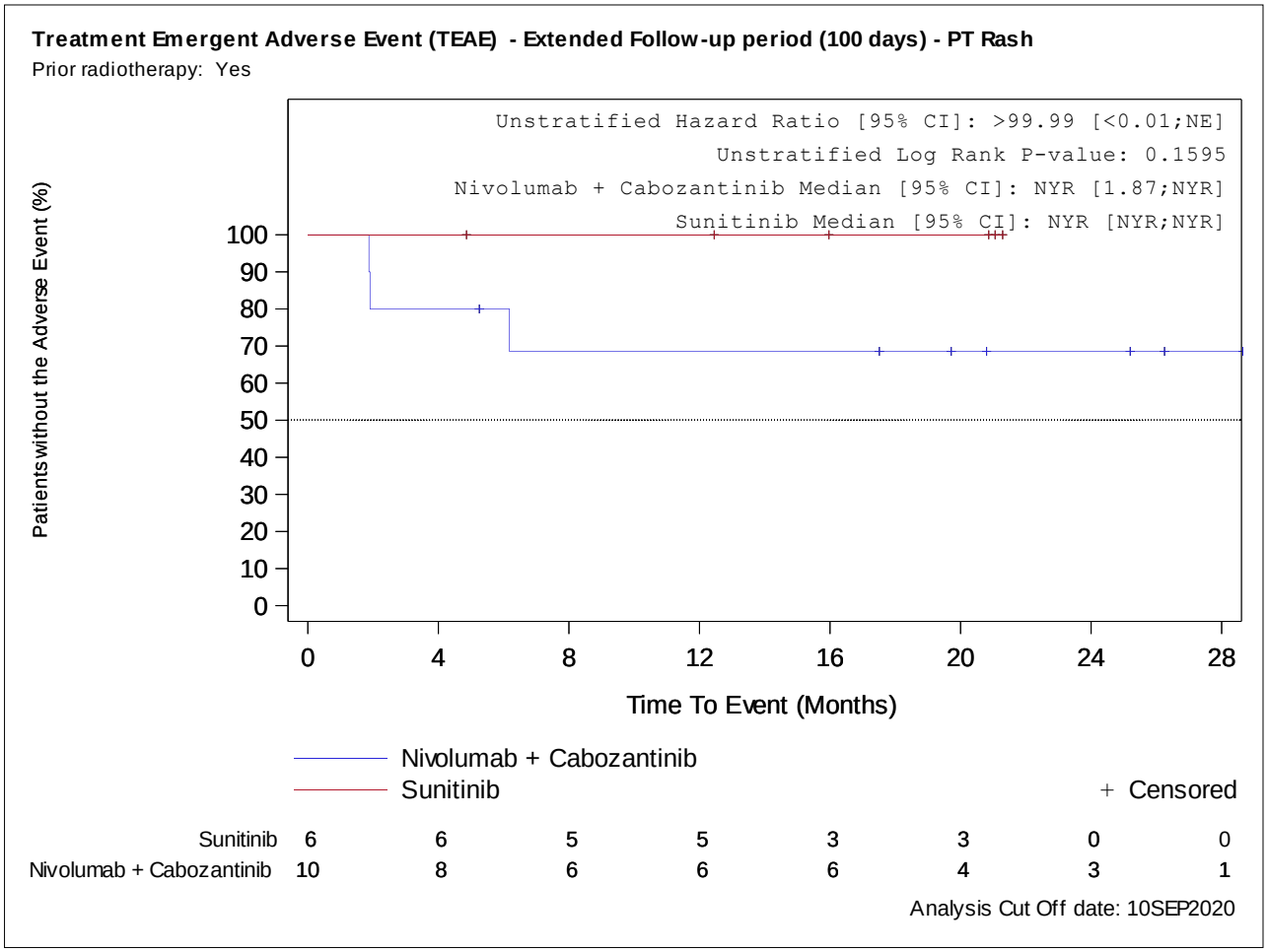
FIGURE 5.37.2.17: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
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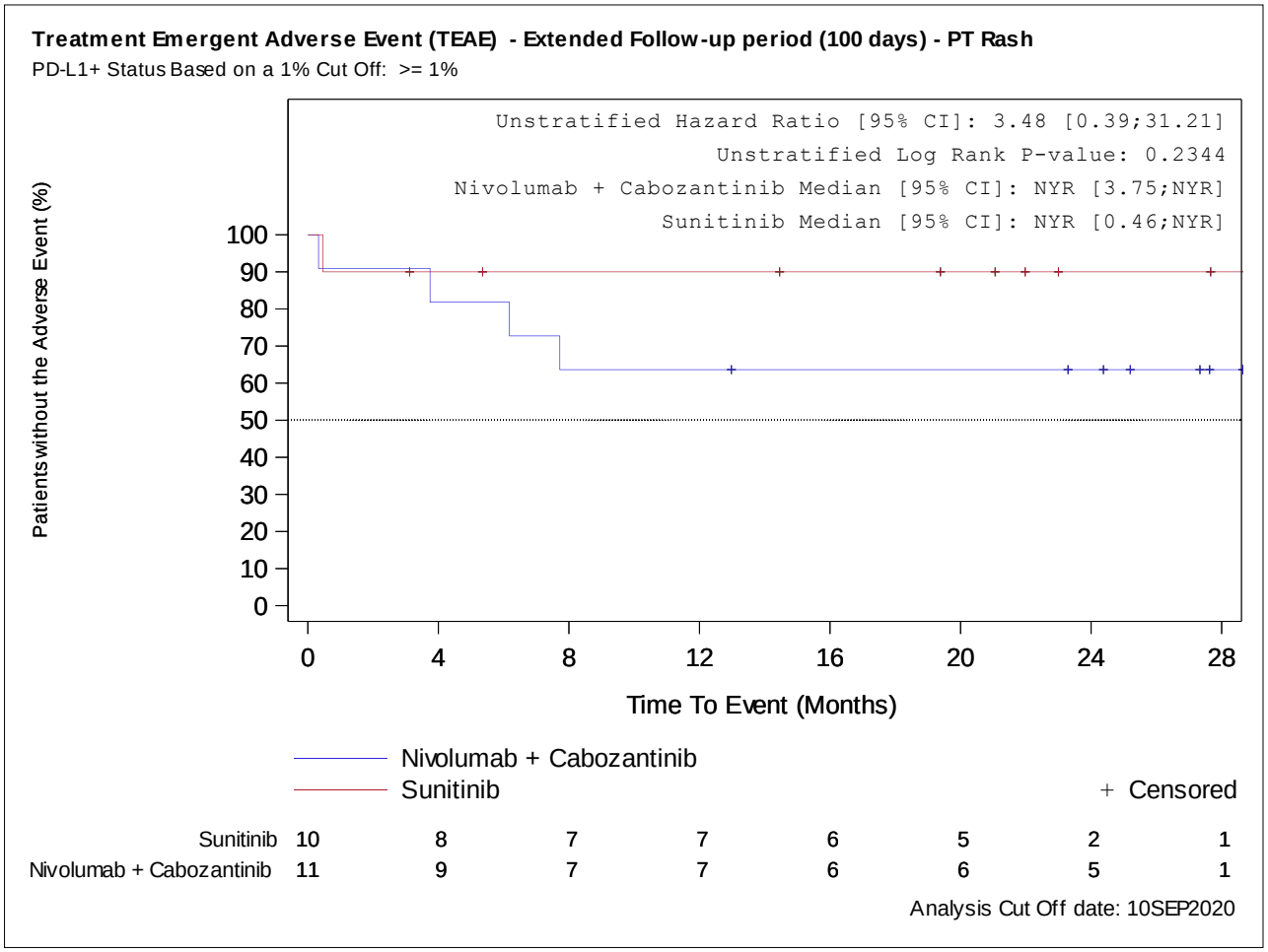
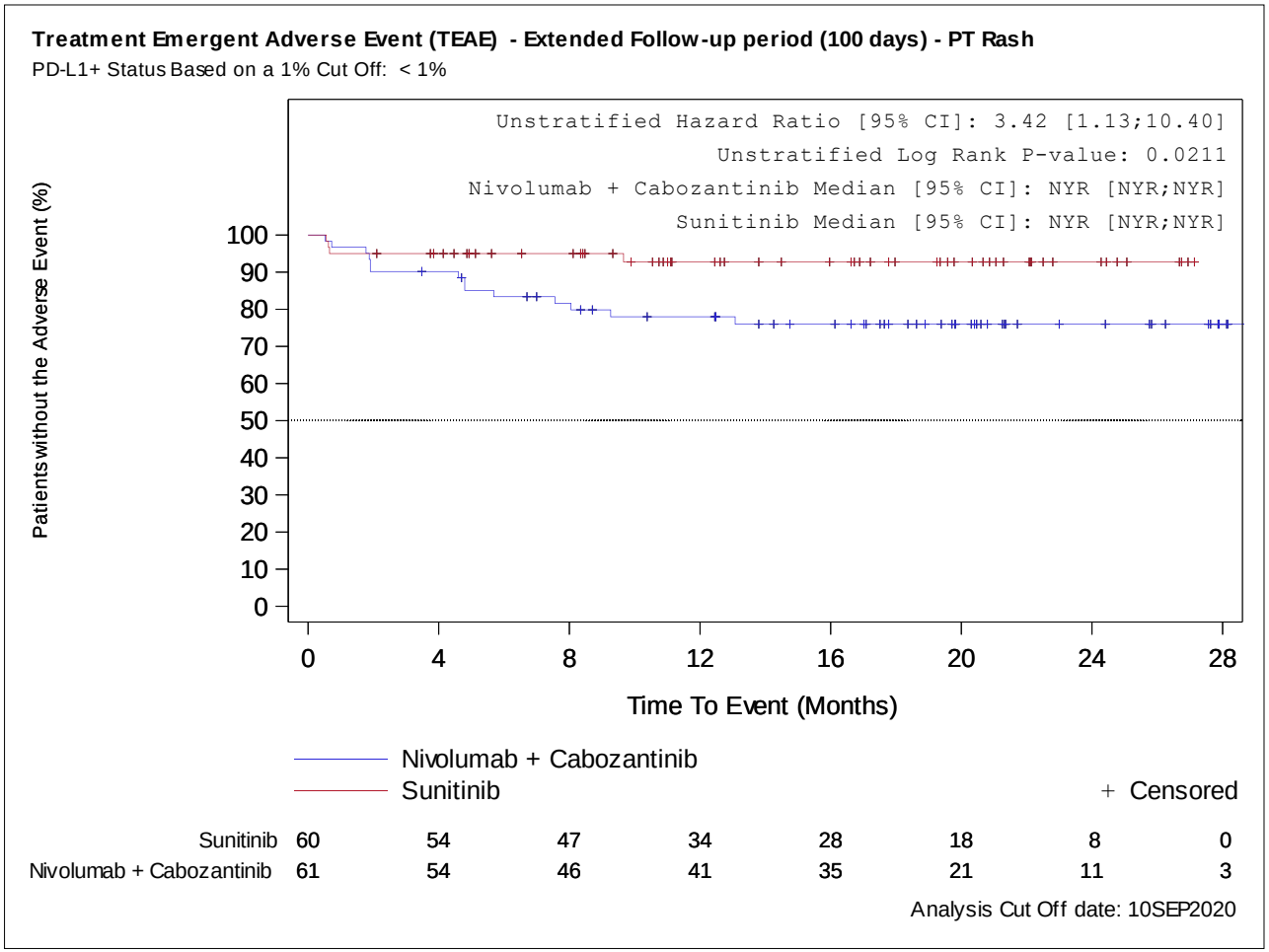
FIGURE 5.37.2.18: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: >= 1%



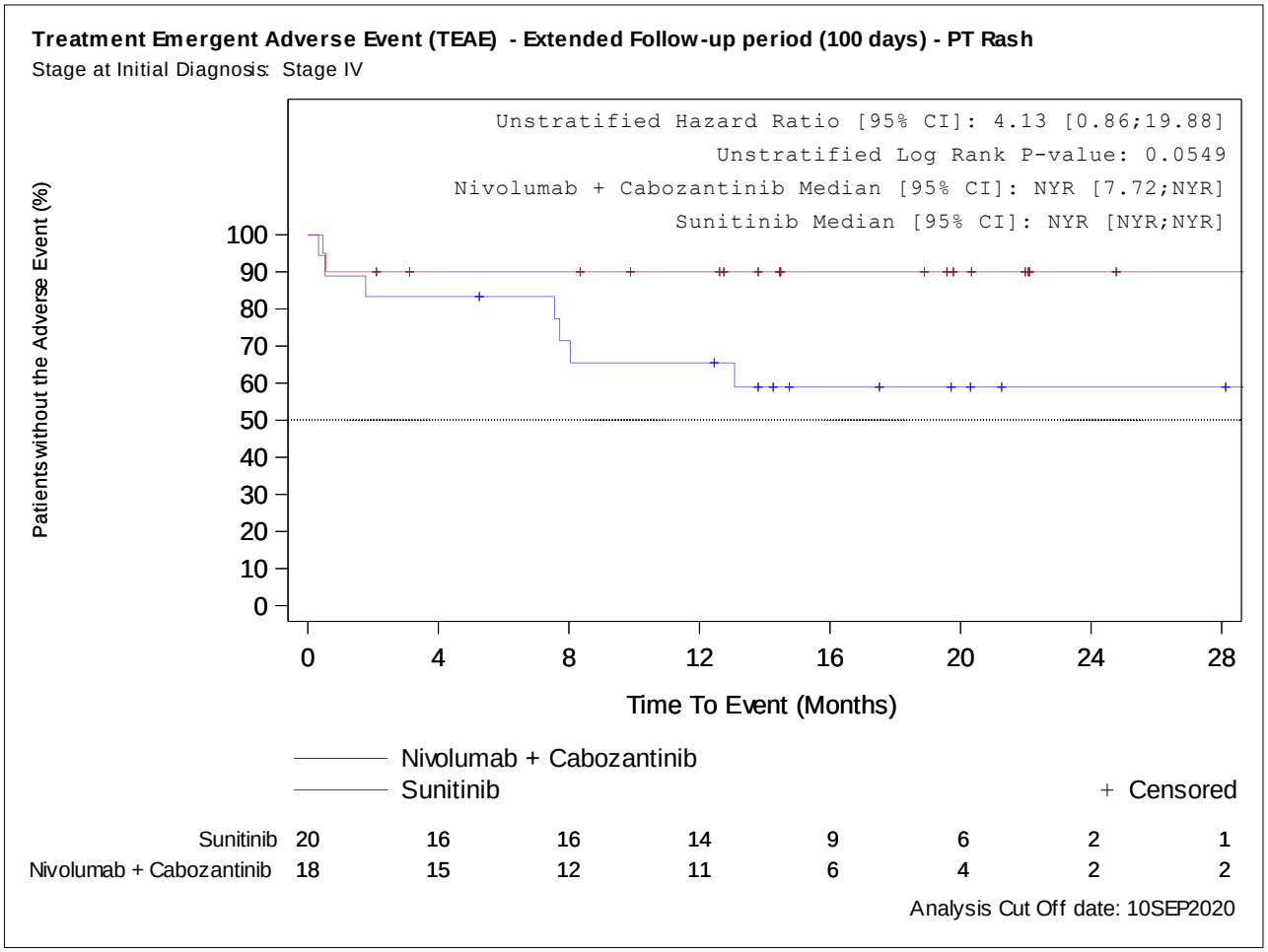

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:50:46

FIGURE 5.37.2.19: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off: < 1%



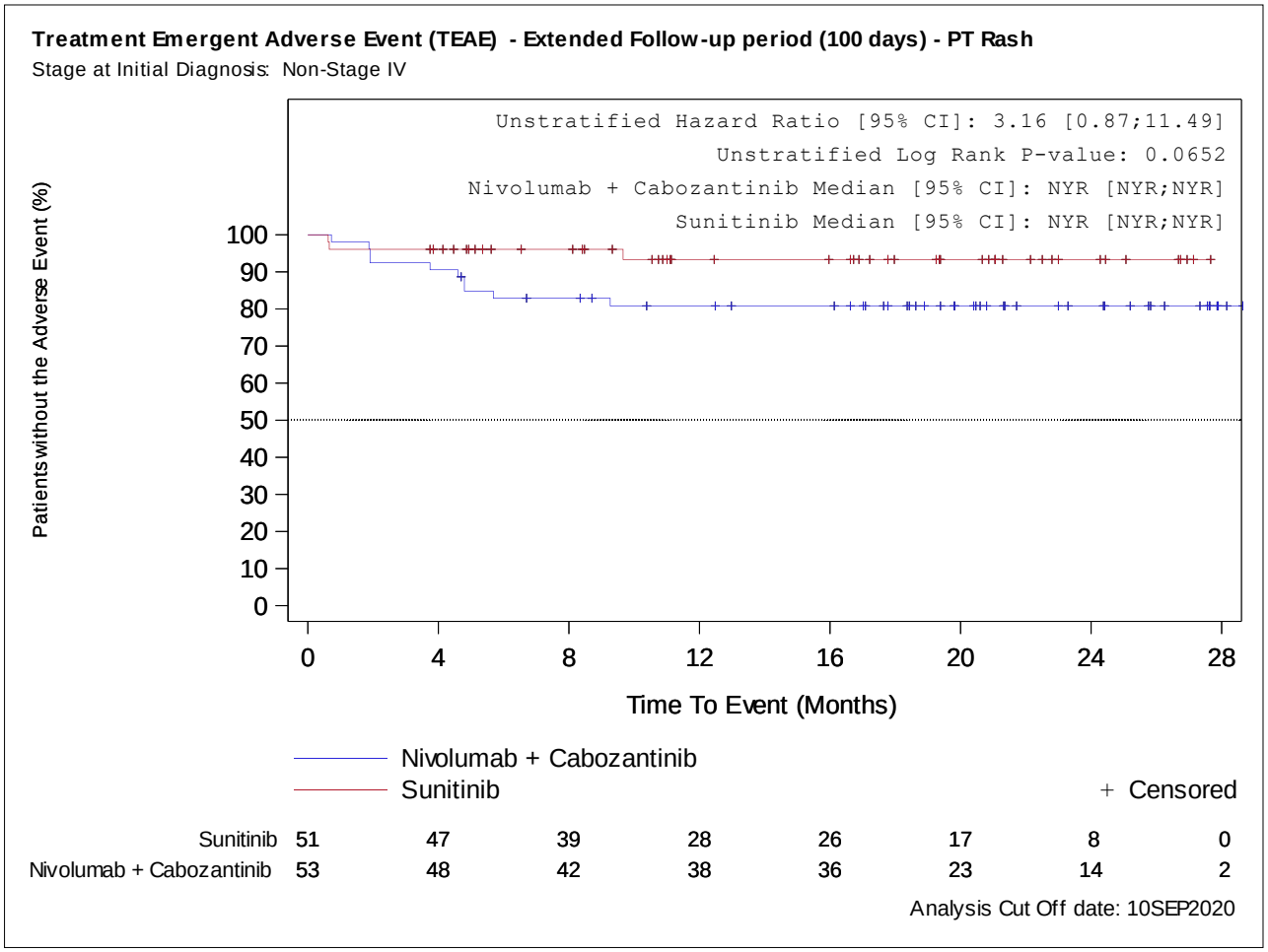

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:50:52

FIGURE 5.37.2.20: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Stage IV



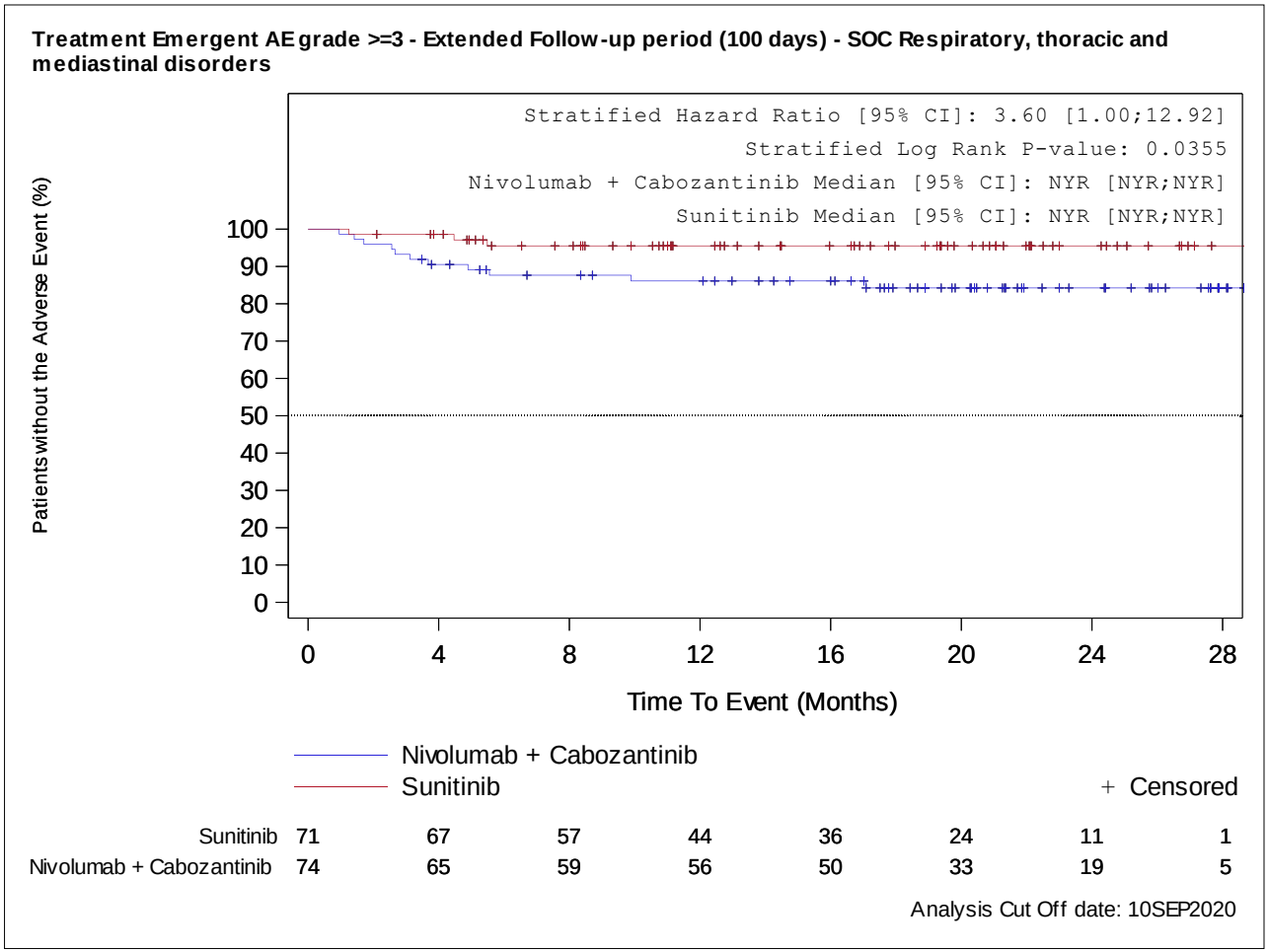

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:51:22

FIGURE 5.37.2.21: Kaplan-Meier curve - Treatment Emergent Adverse Event (TEAE) - Extended Follow-up period (100 days) - PT Rash - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis: Non-Stage IV



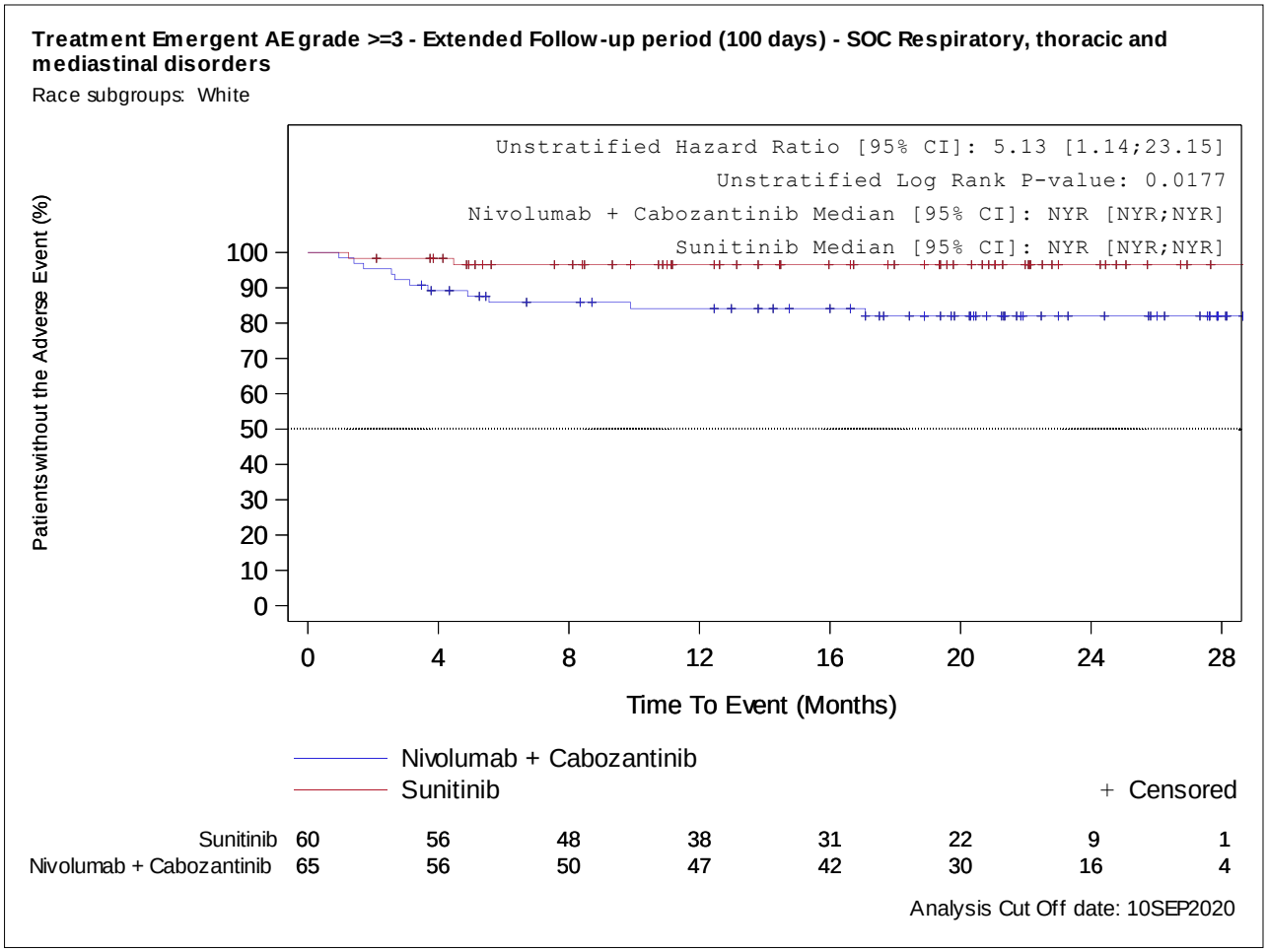

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:51:28

FIGURE 5.38.1: Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population
A: Favorable risk (IMDC prognostic risk score = 0)



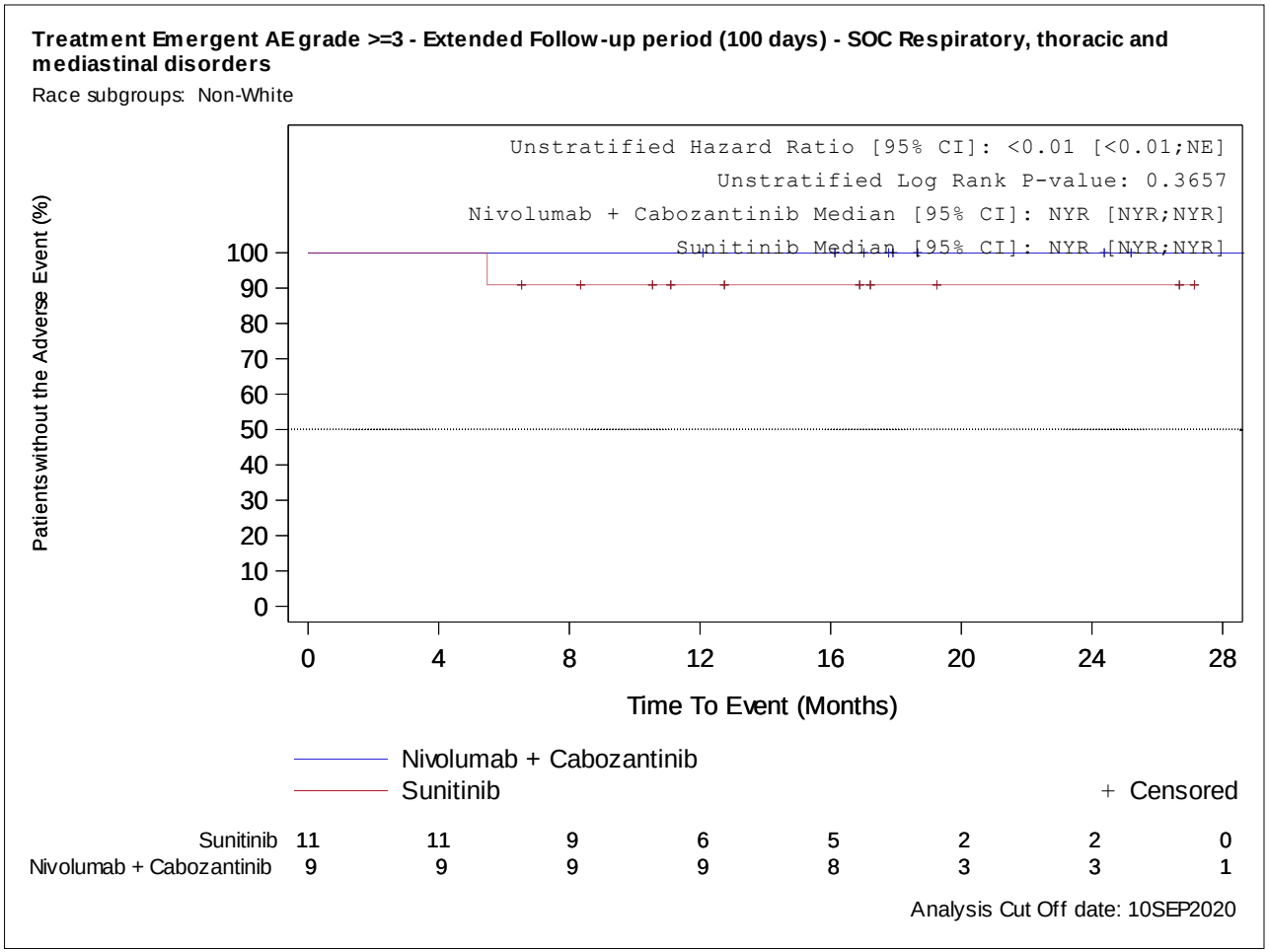

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:54:12

FIGURE 5.38.2.1: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: White



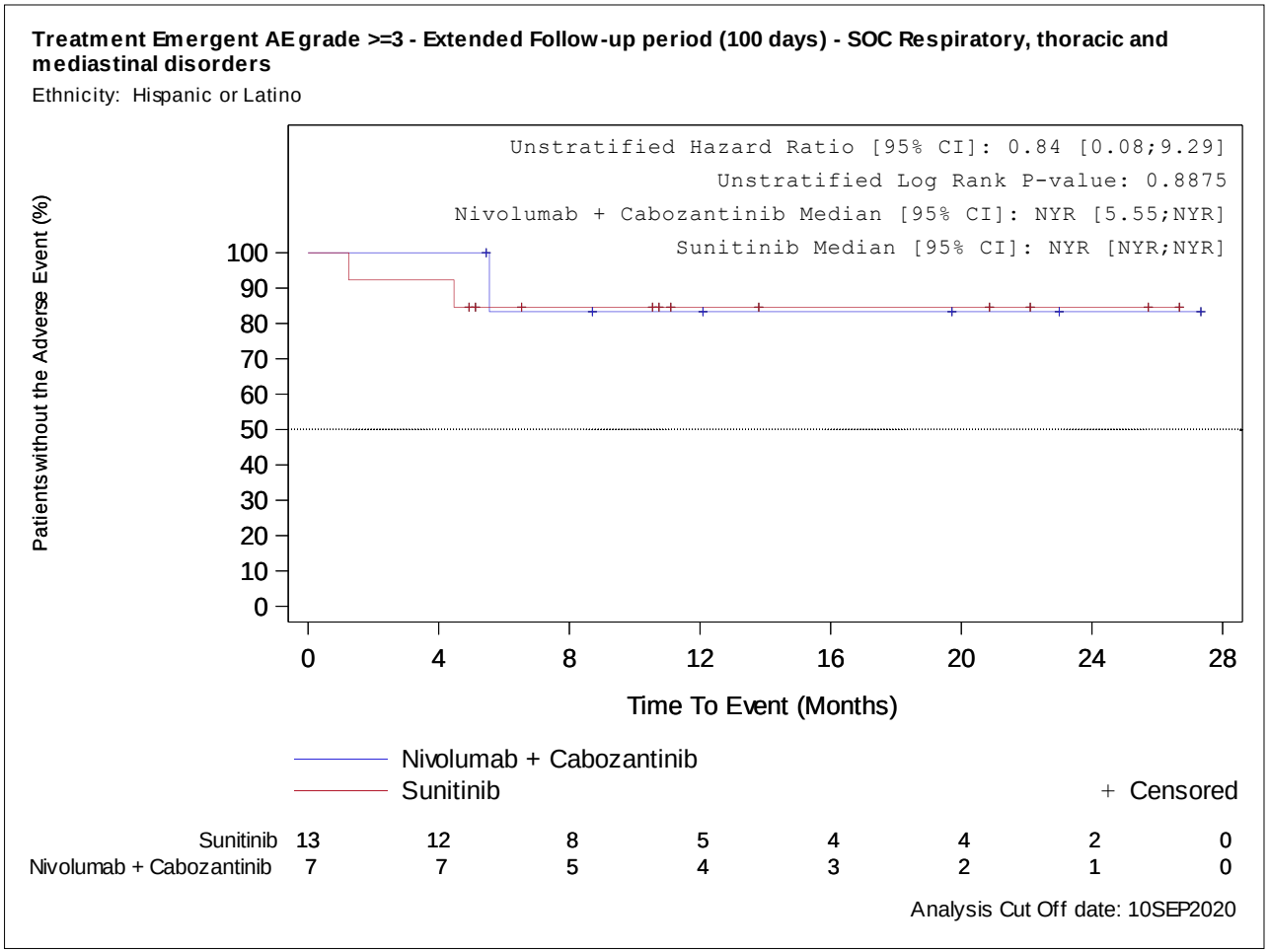

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:54:15

FIGURE 5.38.2.2: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups: Non-White



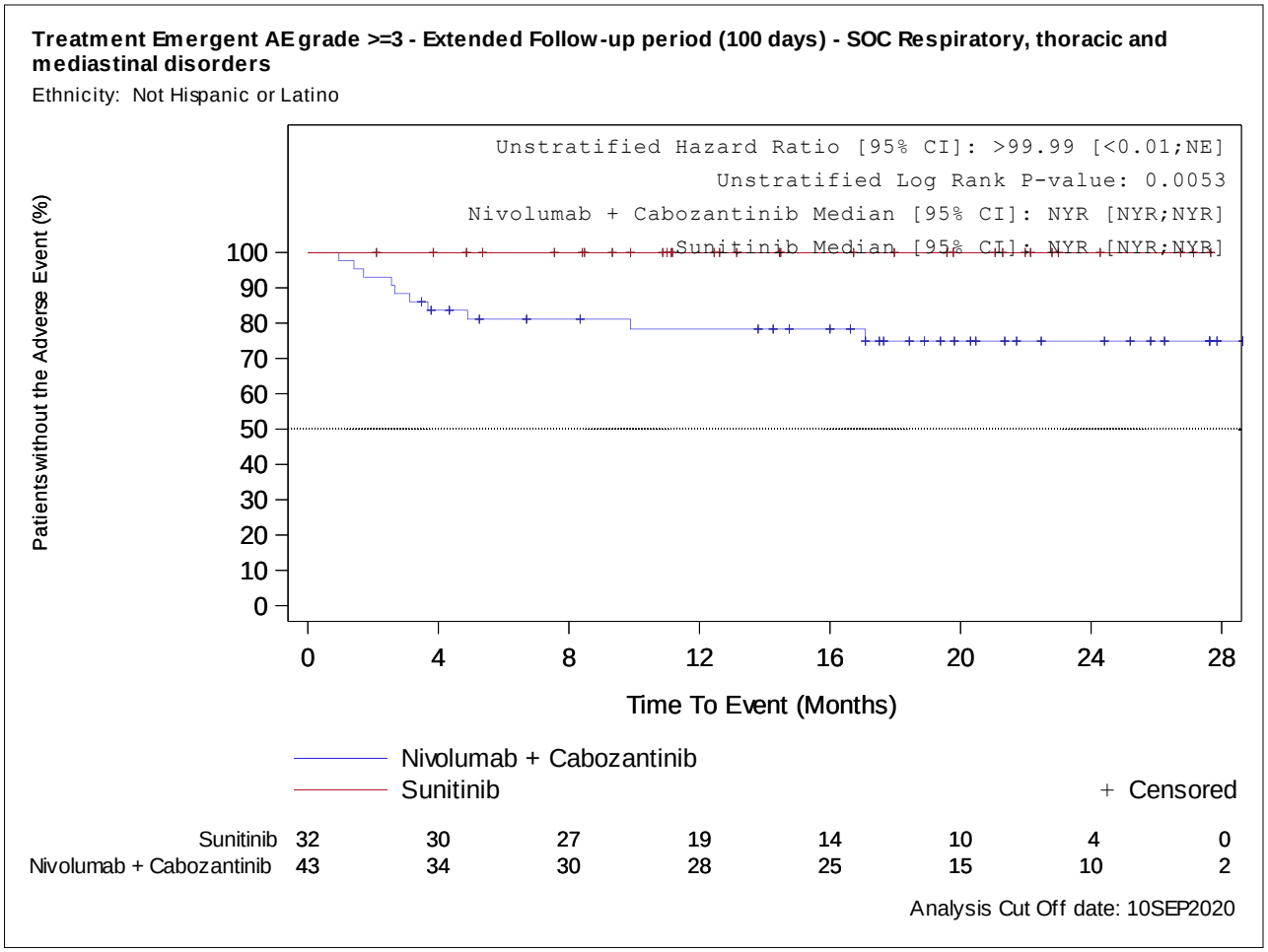

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:54:21

FIGURE 5.38.2.3: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Hispanic or Latino



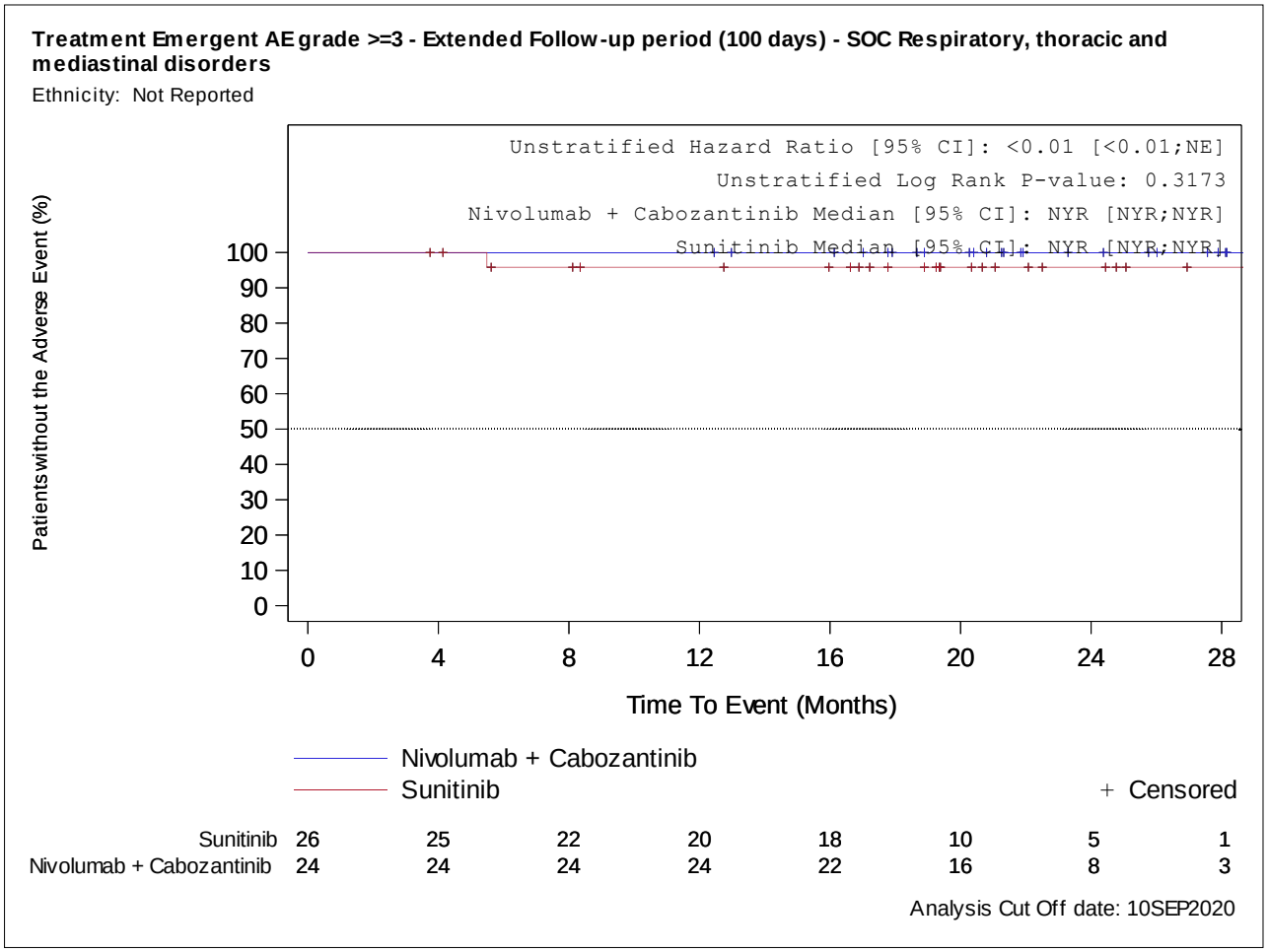

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:54:27

FIGURE 5.38.2.4: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Hispanic or Latino



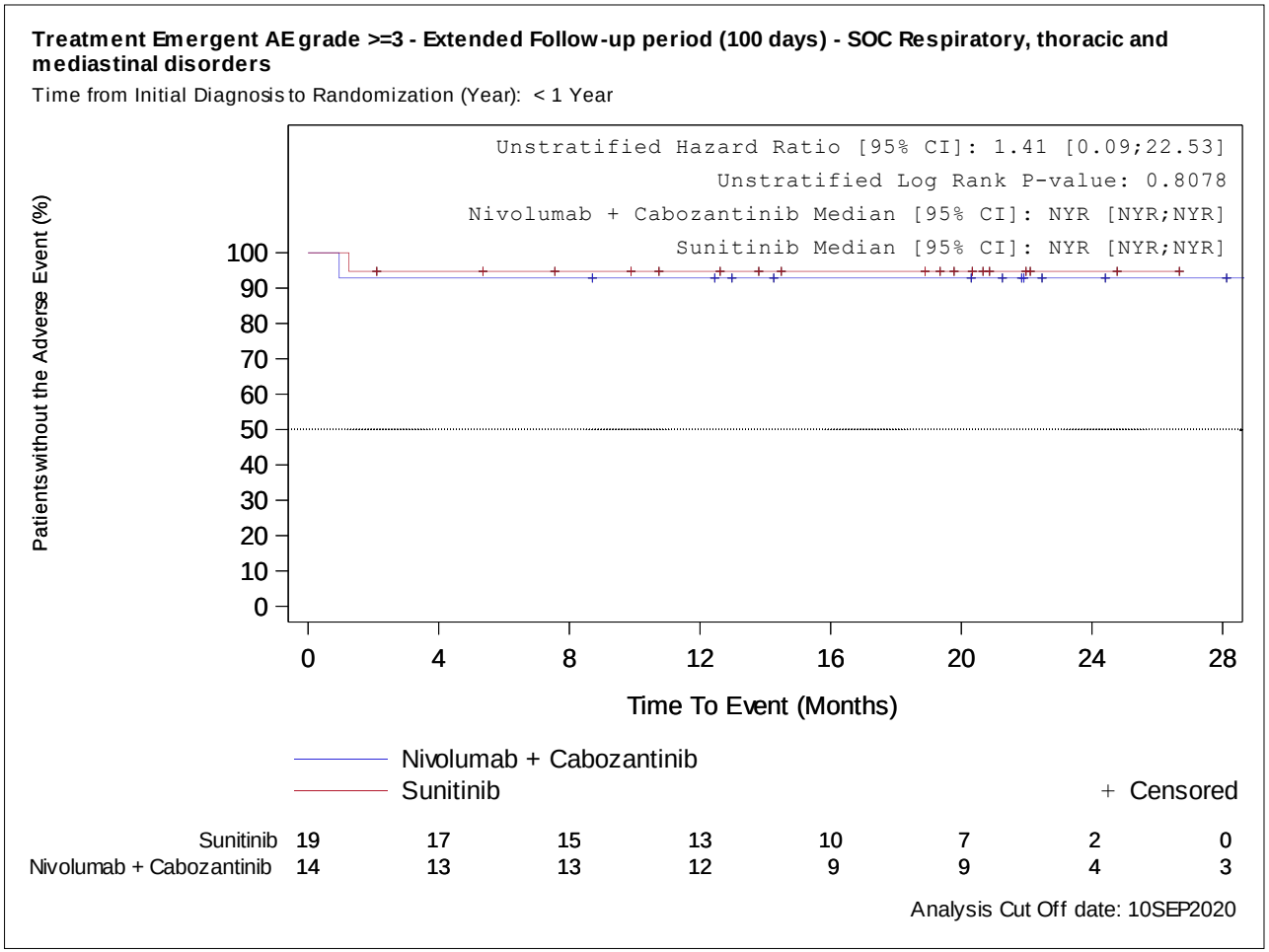

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:54:33

FIGURE 5.38.2.5: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity: Not Reported



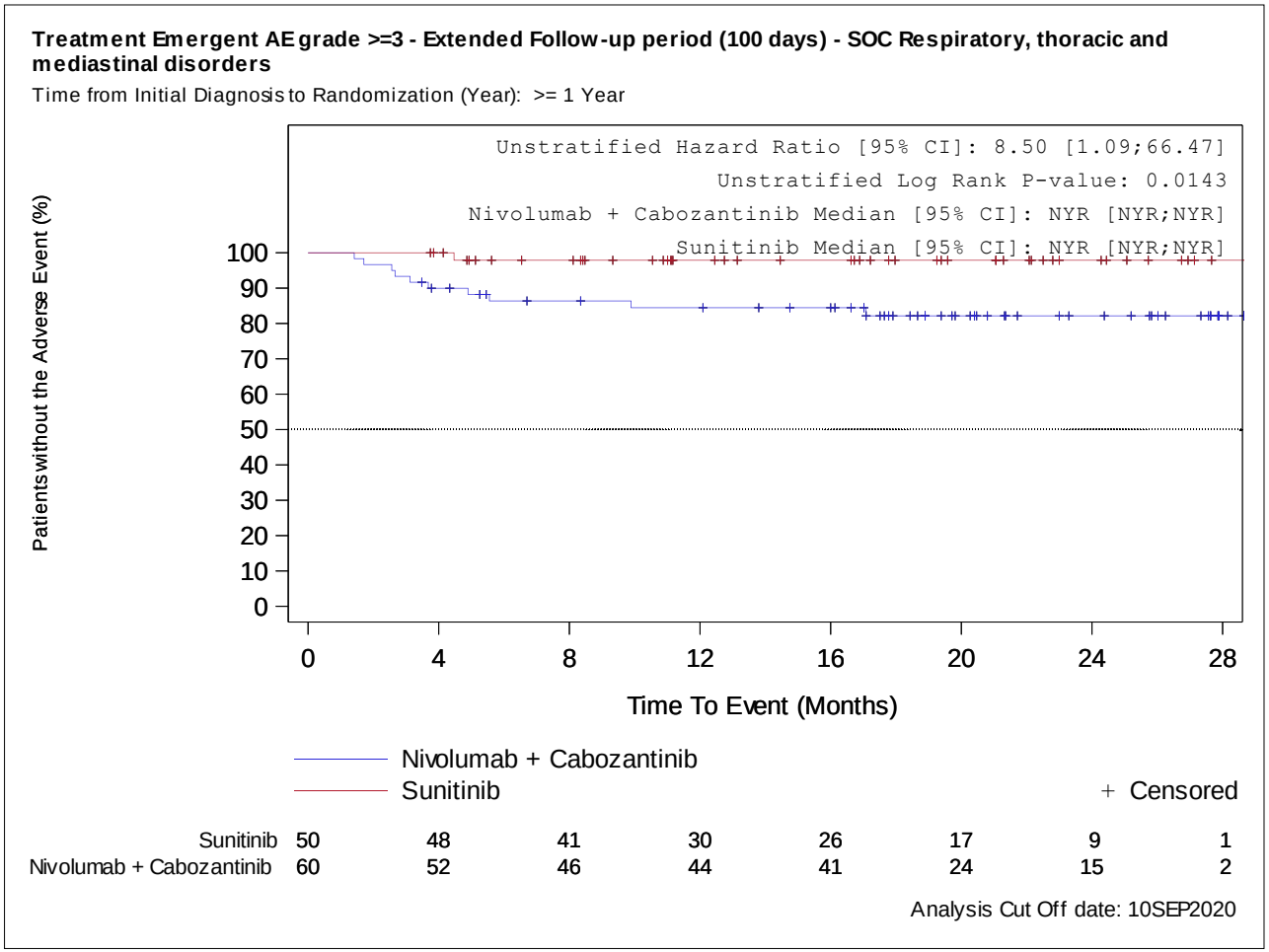

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:54:39

FIGURE 5.38.2.6: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): < 1 Year



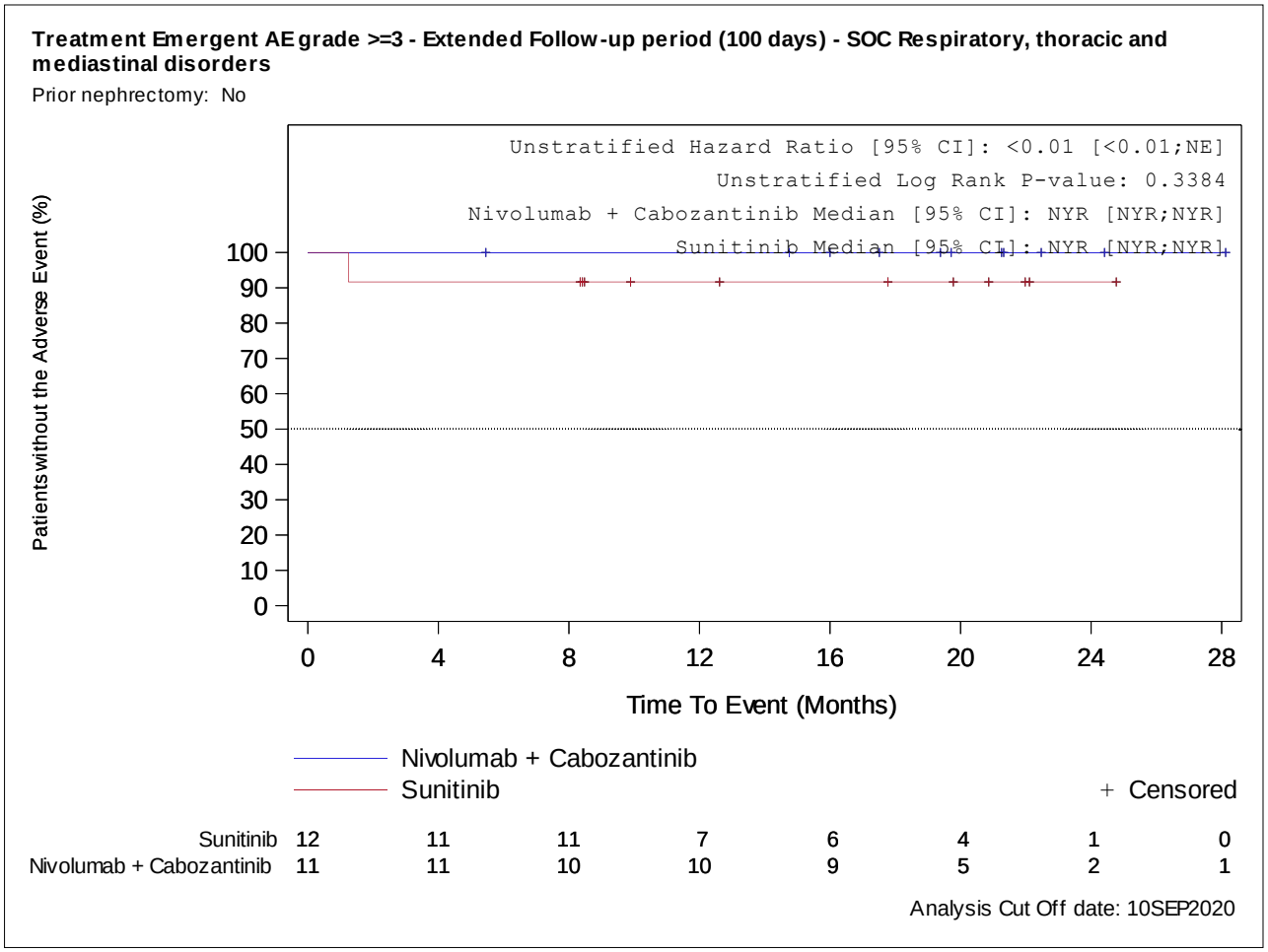

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:54:56

FIGURE 5.38.2.7: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year): >= 1 Year



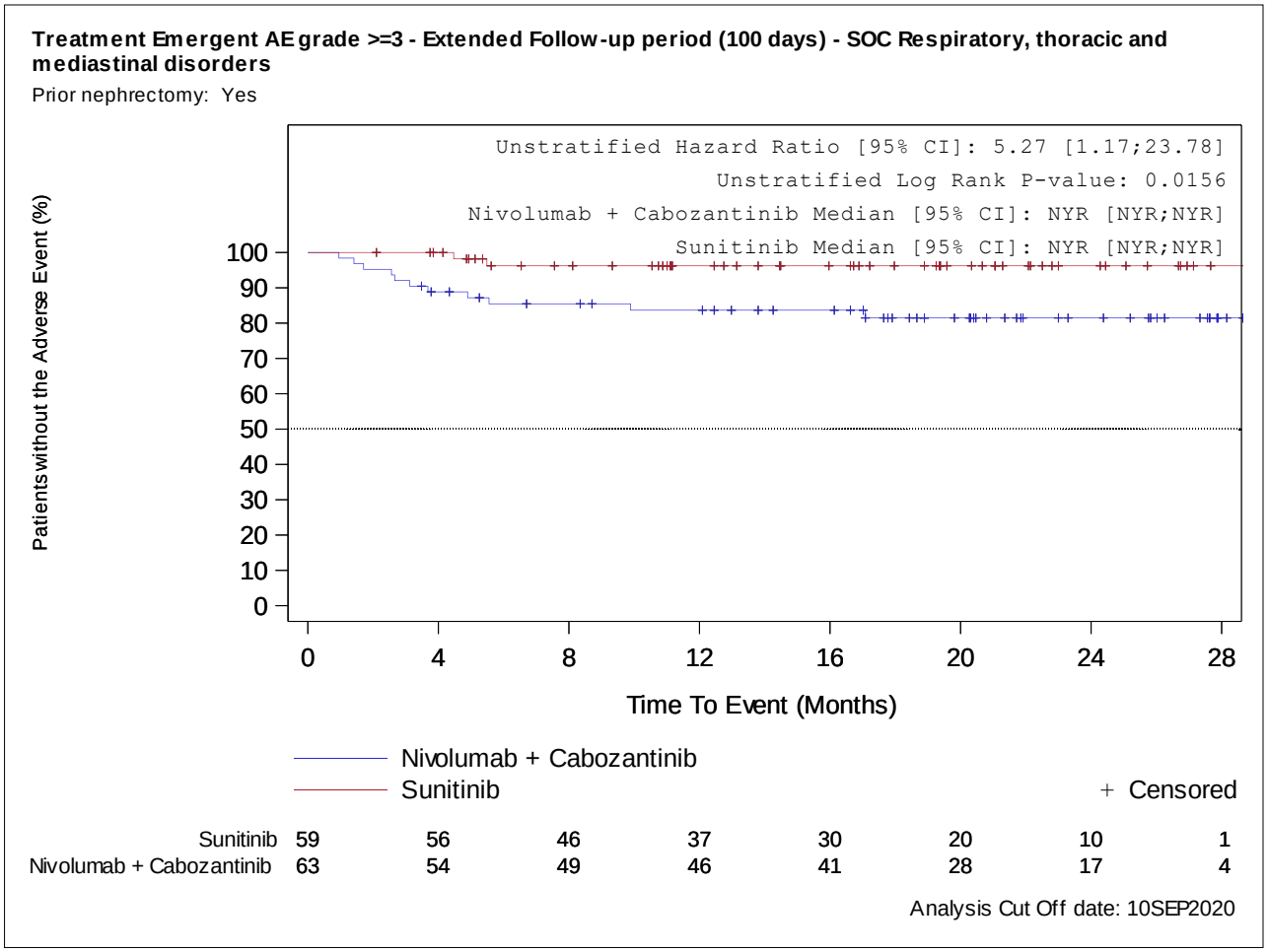

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:55:02

FIGURE 5.38.2.8: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: No



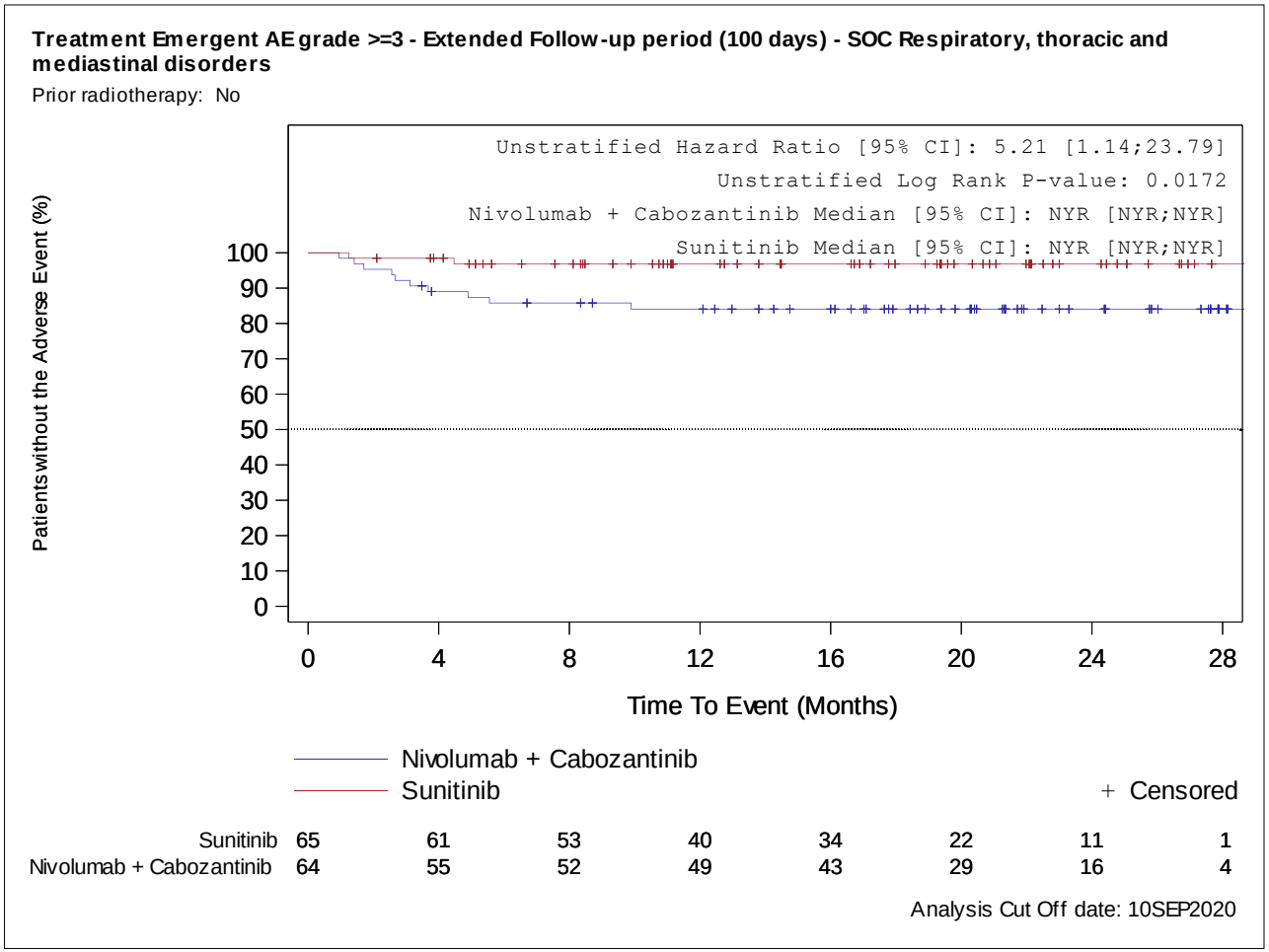

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:55:37

FIGURE 5.38.2.9: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy: Yes



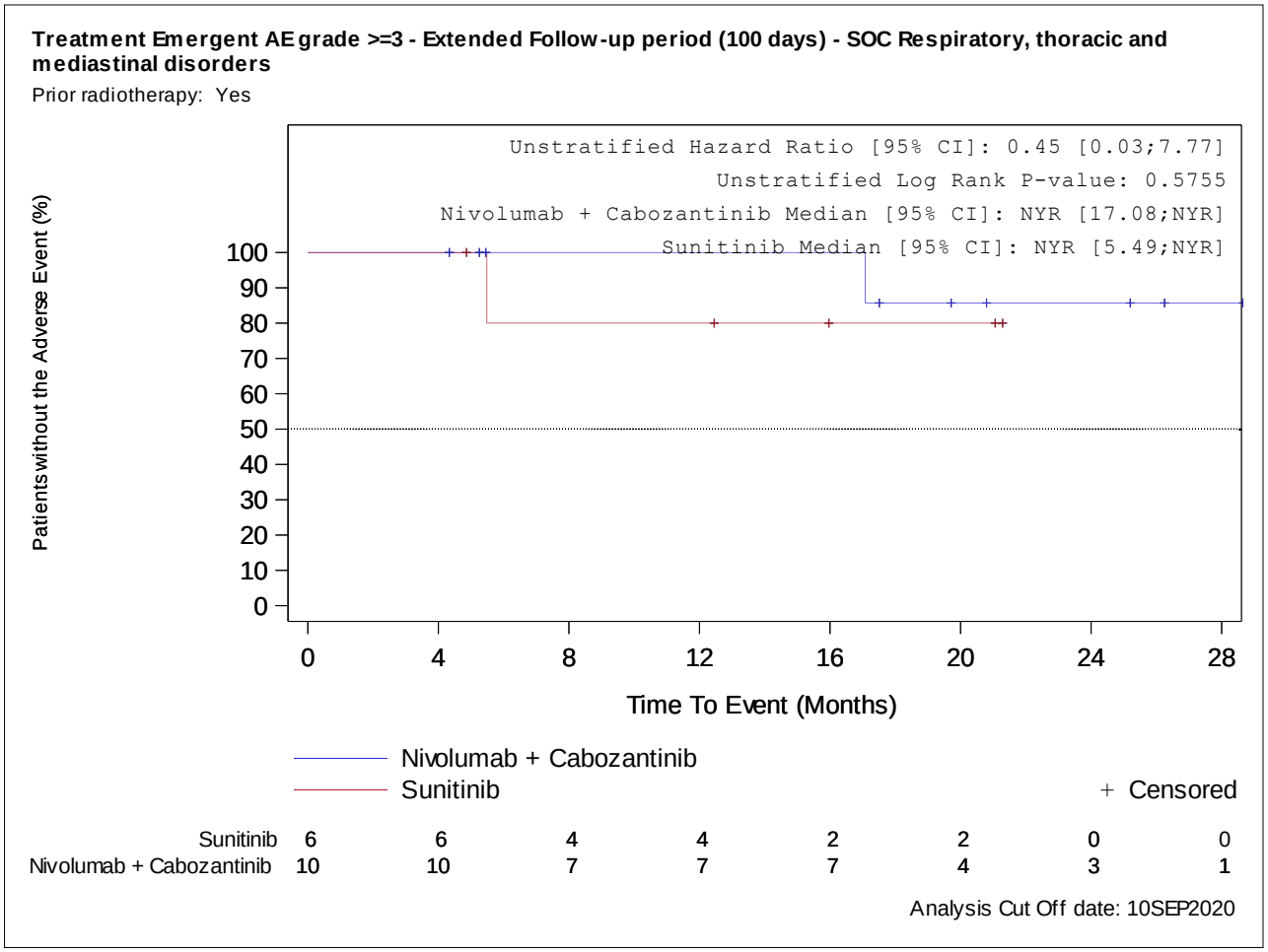

Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:55:43

FIGURE 5.38.2.10: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: No




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:55:49

FIGURE 5.38.2.11: Kaplan-Meier curve - Treatment Emergent AE grade >=3 - Extended Follow-up period (100 days) - SOC Respiratory, thoracic and mediastinal disorders - Safety Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy: Yes




Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.08 KM safety selected SOC_PT by subgroups.sas] run Thursday, April 8, 2021 at 19:55:55

TABLE 6.1: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Overall | 74 (100.0%) | 71 (100.0%) | 145 (100.0%) |
| Overall excluding Progression Events | 74 (100.0%) | 71 (100.0%) | 145 (100.0%) |
| Gastrointestinal disorders | 65 ( 87.8%) | 64 ( 90.1%) | 129 ( 89.0%) |
| Diarrhoea | 56 ( 75.7%) | 37 ( 52.1%) | 93 ( 64.1%) |
| Nausea | 25 ( 33.8%) | 28 ( 39.4%) | 53 ( 36.6%) |
| Stomatitis | 12 ( 16.2%) | 25 ( 35.2%) | 37 ( 25.5%) |
| Vomiting | 15 ( 20.3%) | 17 ( 23.9%) | 32 ( 22.1%) |
| Abdominal pain | 11 ( 14.9%) | 12 ( 16.9%) | 23 ( 15.9%) |
| Dyspepsia | 10 ( 13.5%) | 12 ( 16.9%) | 22 ( 15.2%) |
| Constipation | 8 ( 10.8%) | 11 ( 15.5%) | 19 ( 13.1%) |
| Gastrooesophageal reflux disease | 9 ( 12.2%) | 10 ( 14.1%) | 19 ( 13.1%) |
| Abdominal pain upper | 8 ( 10.8%) | 5 ( 7.0%) | 13 ( 9.0%) |
| Flatulence | 6 ( 8.1%) | 6 ( 8.5%) | 12 ( 8.3%) |
| Dry mouth | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Gingival bleeding | 6 ( 8.1%) | 0 ( 0.0%) | 6 ( 4.1%) |
| Haemorrhoids | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Mouth ulceration | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Oral pain | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Toothache | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Abdominal distension | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Gastritis | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Odynophagia | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Abdominal discomfort | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Anal fistula | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Anal inflammation | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Ascites | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Dysphagia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Epigastric discomfort | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Food poisoning | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Frequent bowel movements | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Glossodynia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Proctalgia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Abdominal pain lower | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Anal fissure | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:32

TABLE 6.1: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Aphthous ulcer | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Bowel movement irregularity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cheilitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Colitis ulcerative | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Dental caries | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Erosive oesophagitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eructation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastritis erosive | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastrointestinal disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastrointestinal toxicity | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Gingival pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Haematochezia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Haemorrhoidal haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lip oedema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Lower gastrointestinal haemorrhage | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Melaena | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Perianal erythema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Proctitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rectal haemorrhage | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Retching | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Salivary hypersecretion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Segmental diverticular colitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Small intestinal perforation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Upper gastrointestinal haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| General disorders and administration site conditions | 59 ( 79.7%) | 56 ( 78.9%) | 115 ( 79.3%) |
| Fatigue | 30 ( 40.5%) | 37 ( 52.1%) | 67 ( 46.2%) |
| Mucosal inflammation | 21 ( 28.4%) | 26 ( 36.6%) | 47 ( 32.4%) |
| Asthenia | 16 ( 21.6%) | 13 ( 18.3%) | 29 ( 20.0%) |
| Pyrexia | 13 ( 17.6%) | 6 ( 8.5%) | 19 ( 13.1%) |
| Oedema peripheral | 10 ( 13.5%) | 5 ( 7.0%) | 15 ( 10.3%) |
| Malaise | 6 ( 8.1%) | 3 ( 4.2%) | 9 ( 6.2%) |
| Chills | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Face oedema | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Influenza like illness | 4 ( 5.4%) | 1 ( 1.4%) | 5 ( 3.4%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:32

TABLE 6.1: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Pain | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Chest discomfort | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Chest pain | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Non-cardiac chest pain | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Catheter site pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gait disturbance | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hyperthermia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Mucosal dryness | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Peripheral swelling | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Swelling face | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Temperature intolerance | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin and subcutaneous tissue disorders | 61 ( 82.4%) | 50 ( 70.4%) | 111 ( 76.6%) |
| Palmar-plantar erythrodysaesthesia syndrome | 33 ( 44.6%) | 41 ( 57.7%) | 74 ( 51.0%) |
| Pruritus | 20 ( 27.0%) | 3 ( 4.2%) | 23 ( 15.9%) |
| Rash | 18 ( 24.3%) | 5 ( 7.0%) | 23 ( 15.9%) |
| Dry skin | 11 ( 14.9%) | 3 ( 4.2%) | 14 ( 9.7%) |
| Alopecia | 9 ( 12.2%) | 1 ( 1.4%) | 10 ( 6.9%) |
| Rash maculo-papular | 8 ( 10.8%) | 1 ( 1.4%) | 9 ( 6.2%) |
| Yellow skin | 0 ( 0.0%) | 8 ( 11.3%) | 8 ( 5.5%) |
| Erythema | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Dermatitis | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Acne | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Dermatitis acneiform | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Hair colour changes | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Petechiae | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Rash papular | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Skin ulcer | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Dermatitis bullous | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Eczema | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Hyperhidrosis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pemphigoid | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Skin discolouration | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Skin exfoliation | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Skin hyperpigmentation | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:32

TABLE 6.1: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Skin hypopigmentation | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Urticaria | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Angioedema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blister | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Decubitus ulcer | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eczema asteatotic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperkeratosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ingrowing nail | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Miliaria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nail discolouration | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nail disorder | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nail dystrophy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Night sweats | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pain of skin | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pemphigus | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Rash macular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rash pruritic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Scab | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin hypertrophy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin lesion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Skin reaction | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin toxicity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Umbilical haemorrhage | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Xeroderma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Investigations | 56 ( 75.7%) | 49 ( 69.0%) | 105 ( 72.4%) |
| Aspartate aminotransferase increased | 22 ( 29.7%) | 13 ( 18.3%) | 35 ( 24.1%) |
| Alanine aminotransferase increased | 22 ( 29.7%) | 11 ( 15.5%) | 33 ( 22.8%) |
| Lipase increased | 14 ( 18.9%) | 15 ( 21.1%) | 29 ( 20.0%) |
| Amylase increased | 15 ( 20.3%) | 10 ( 14.1%) | 25 ( 17.2%) |
| Platelet count decreased | 8 ( 10.8%) | 17 ( 23.9%) | 25 ( 17.2%) |
| Blood creatinine increased | 9 ( 12.2%) | 13 ( 18.3%) | 22 ( 15.2%) |
| Weight decreased | 13 ( 17.6%) | 3 ( 4.2%) | 16 ( 11.0%) |
| Blood alkaline phosphatase increased | 8 ( 10.8%) | 7 ( 9.9%) | 15 ( 10.3%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Blood thyroid stimulating hormone increased | 11 ( 14.9%) | 3 ( 4.2%) | 14 ( 9.7%) |
| Neutrophil count decreased | 5 ( 6.8%) | 9 ( 12.7%) | 14 ( 9.7%) |
| Transaminases increased | 7 ( 9.5%) | 4 ( 5.6%) | 11 ( 7.6%) |
| Blood bilirubin increased | 6 ( 8.1%) | 4 ( 5.6%) | 10 ( 6.9%) |
| Blood cholesterol increased | 5 ( 6.8%) | 5 ( 7.0%) | 10 ( 6.9%) |
| Blood lactate dehydrogenase increased | 6 ( 8.1%) | 1 ( 1.4%) | 7 ( 4.8%) |
| Blood magnesium decreased | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Blood sodium decreased | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Blood phosphorus increased | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Lymphocyte count decreased | 0 ( 0.0%) | 4 ( 5.6%) | 4 ( 2.8%) |
| Urine protein/creatinine ratio increased | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| White blood cell count decreased | 1 ( 1.4%) | 3 ( 4.2%) | 4 ( 2.8%) |
| Blood creatine phosphokinase increased | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Blood pressure increased | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hepatic enzyme increased | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Blood albumin decreased | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Blood phosphorus decreased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Blood urea increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood uric acid increased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Gamma-glutamyltransferase increased | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Haematocrit increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Aspartate aminotransferase decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood calcium decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood potassium decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood thyroid stimulating hormone decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Cortisol decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Creatinine urine increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Culture urine positive | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Glomerular filtration rate decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Liver function test abnormal | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Liver function test increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Protein urine present | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Thyroid function test abnormal | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Thyroxine free increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:32

TABLE 6.1: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Tri-iodothyronine free decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tri-iodothyronine free increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Urine osmolarity decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vitamin B12 decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Weight increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Metabolism and nutrition disorders | 59 ( 79.7%) | 35 ( 49.3%) | 94 ( 64.8%) |
| Decreased appetite | 33 ( 44.6%) | 15 ( 21.1%) | 48 ( 33.1%) |
| Hyponatraemia | 13 ( 17.6%) | 9 ( 12.7%) | 22 ( 15.2%) |
| Hypomagnesaemia | 16 ( 21.6%) | 3 ( 4.2%) | 19 ( 13.1%) |
| Hyperglycaemia | 8 ( 10.8%) | 7 ( 9.9%) | 15 ( 10.3%) |
| Hypophosphataemia | 11 ( 14.9%) | 4 ( 5.6%) | 15 ( 10.3%) |
| Hypocalcaemia | 8 ( 10.8%) | 2 ( 2.8%) | 10 ( 6.9%) |
| Hypertriglyceridaemia | 3 ( 4.1%) | 5 ( 7.0%) | 8 ( 5.5%) |
| Hypokalaemia | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Hyperkalaemia | 6 ( 8.1%) | 1 ( 1.4%) | 7 ( 4.8%) |
| Hypoalbuminaemia | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Dehydration | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Hyperuricaemia | 5 ( 6.8%) | 0 ( 0.0%) | 5 ( 3.4%) |
| Hypercholesterolaemia | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hyperlipasaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Electrolyte imbalance | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Fluid overload | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Fluid retention | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Glucose tolerance impaired | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Gout | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperamylasaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypercalcaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperchloraemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypercreatininaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypernatraemia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hypoglycaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vitamin D deficiency | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nervous system disorders | 46 ( 62.2%) | 41 ( 57.7%) | 87 ( 60.0%) |
| Dysgeusia | 22 ( 29.7%) | 23 ( 32.4%) | 45 ( 31.0%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:32

TABLE 6.1: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Headache | 14 ( 18.9%) | 9 ( 12.7%) | 23 ( 15.9%) |
| Dizziness | 13 ( 17.6%) | 5 ( 7.0%) | 18 ( 12.4%) |
| Paraesthesia | 7 ( 9.5%) | 4 ( 5.6%) | 11 ( 7.6%) |
| Sciatica | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Hypoaesthesia | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Neuropathy peripheral | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Peripheral sensory neuropathy | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Presyncope | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Taste disorder | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Tremor | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Ageusia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Disturbance in attention | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hypogeusia | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Syncope | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Aphasia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cauda equina syndrome | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Dysarthria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Haemorrhage intracranial | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Head discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ischaemic stroke | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lethargy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Migraine | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nervous system disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Neuralgia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Paraplegia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Peripheral motor neuropathy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Radicular pain | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Speech disorder | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Musculoskeletal and connective tissue disorders | 44 ( 59.5%) | 35 ( 49.3%) | 79 ( 54.5%) |
| Arthralgia | 17 ( 23.0%) | 8 ( 11.3%) | 25 ( 17.2%) |
| Back pain | 14 ( 18.9%) | 7 ( 9.9%) | 21 ( 14.5%) |
| Pain in extremity | 8 ( 10.8%) | 10 ( 14.1%) | 18 ( 12.4%) |
| Muscle spasms | 12 ( 16.2%) | 2 ( 2.8%) | 14 ( 9.7%) |
| Myalgia | 4 ( 5.4%) | 7 ( 9.9%) | 11 ( 7.6%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:32

TABLE 6.1: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Musculoskeletal pain | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Muscular weakness | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Neck pain | 5 ( 6.8%) | 1 ( 1.4%) | 6 ( 4.1%) |
| Musculoskeletal chest pain | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Bone pain | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Flank pain | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Groin pain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Myopathy | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Arthritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Bone lesion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Bursitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Intervertebral disc protrusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Joint swelling | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Metatarsalgia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Mobility decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Musculoskeletal discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Musculoskeletal stiffness | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Neck mass | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Osteonecrosis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Osteoporosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Periarthritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Plantar fasciitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Rotator cuff syndrome | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Soft tissue necrosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Spinal pain | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Synovitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tendonitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vascular disorders | 35 ( 47.3%) | 38 ( 53.5%) | 73 ( 50.3%) |
| Hypertension | 33 ( 44.6%) | 37 ( 52.1%) | 70 ( 48.3%) |
| Hot flush | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Deep vein thrombosis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Embolism | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Pallor | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood pressure fluctuation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
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TABLE 6.1: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Hypotension | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Peripheral coldness | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Phlebitis superficial | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vascular occlusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vein rupture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory, thoracic and mediastinal disorders | 42 ( 56.8%) | 26 ( 36.6%) | 68 ( 46.9%) |
| Cough | 16 ( 21.6%) | 13 ( 18.3%) | 29 ( 20.0%) |
| Oropharyngeal pain | 14 ( 18.9%) | 4 ( 5.6%) | 18 ( 12.4%) |
| Dysphonia | 16 ( 21.6%) | 1 ( 1.4%) | 17 ( 11.7%) |
| Dyspnoea | 9 ( 12.2%) | 8 ( 11.3%) | 17 ( 11.7%) |
| Epistaxis | 4 ( 5.4%) | 7 ( 9.9%) | 11 ( 7.6%) |
| Pulmonary embolism | 8 ( 10.8%) | 1 ( 1.4%) | 9 ( 6.2%) |
| Productive cough | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Rhinorrhoea | 4 ( 5.4%) | 1 ( 1.4%) | 5 ( 3.4%) |
| Dyspnoea exertional | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| Haemoptysis | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Respiratory tract congestion | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Rhinitis allergic | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hiccups | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Nasal congestion | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Nasal dryness | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pneumonitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Bronchospasm | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Catarrh | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Chronic obstructive pulmonary disease | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lung disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nasal discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pleural effusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pneumothorax | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rhinalgia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Sinus congestion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Sneezing | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Upper-airway cough syndrome | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Wheezing | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
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TABLE 6.1: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Infections and infestations | 41 ( 55.4%) | 24 ( 33.8%) | 65 ( 44.8%) |
| Urinary tract infection | 5 ( 6.8%) | 7 ( 9.9%) | 12 ( 8.3%) |
| Upper respiratory tract infection | 7 ( 9.5%) | 4 ( 5.6%) | 11 ( 7.6%) |
| Nasopharyngitis | 4 ( 5.4%) | 4 ( 5.6%) | 8 ( 5.5%) |
| Influenza | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Pneumonia | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Tooth infection | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Bronchitis | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Conjunctivitis | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Cystitis | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Lower respiratory tract infection | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Rhinitis | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Ear infection | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Gingivitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Laryngitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Lung abscess | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Otitis media | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Pharyngitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Sinusitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Skin infection | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Tinea cruris | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Tooth abscess | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Body tinea | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Candida infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cellulitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dermatophytosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Diverticulitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Epididymitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Febrile infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Furuncle | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastroenteritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Groin infection | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Infectious pleural effusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Large intestine infection | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
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TABLE 6.1: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Nail infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Oral herpes | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Paronychia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Periodontitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Peritonsillitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pseudomonas infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rash pustular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory tract infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory tract infection viral | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Sepsis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tonsillitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vulvovaginal candidiasis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vulvovaginal mycotic infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Wound infection staphylococcal | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood and lymphatic system disorders | 23 ( 31.1%) | 36 ( 50.7%) | 59 ( 40.7%) |
| Thrombocytopenia | 10 ( 13.5%) | 23 ( 32.4%) | 33 ( 22.8%) |
| Anaemia | 10 ( 13.5%) | 18 ( 25.4%) | 28 ( 19.3%) |
| Neutropenia | 6 ( 8.1%) | 15 ( 21.1%) | 21 ( 14.5%) |
| Leukopenia | 3 ( 4.1%) | 9 ( 12.7%) | 12 ( 8.3%) |
| Lymphopenia | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Eosinophilia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Increased tendency to bruise | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Leukocytosis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Lymphadenopathy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pancytopenia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Endocrine disorders | 30 ( 40.5%) | 28 ( 39.4%) | 58 ( 40.0%) |
| Hypothyroidism | 22 ( 29.7%) | 25 ( 35.2%) | 47 ( 32.4%) |
| Hyperthyroidism | 10 ( 13.5%) | 7 ( 9.9%) | 17 ( 11.7%) |
| Adrenal insufficiency | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Thyroiditis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Adrenal haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypothalamo-pituitary disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal and urinary disorders | 24 ( 32.4%) | 19 ( 26.8%) | 43 ( 29.7%) |
| Proteinuria | 9 ( 12.2%) | 9 ( 12.7%) | 18 ( 12.4%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Acute kidney injury | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Dysuria | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Haematuria | 3 ( 4.1%) | 3 ( 4.2%) | 6 ( 4.1%) |
| Renal failure | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Pollakiuria | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Urinary retention | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Leukocyturia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Azotaemia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Chromaturia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Chronic kidney disease | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Glycosuria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nephrolithiasis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nephropathy | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nocturia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal colic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal impairment | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urinary hesitation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urinary incontinence | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urinary tract pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Psychiatric disorders | 15 ( 20.3%) | 10 ( 14.1%) | 25 ( 17.2%) |
| Insomnia | 8 ( 10.8%) | 4 ( 5.6%) | 12 ( 8.3%) |
| Anxiety | 3 ( 4.1%) | 3 ( 4.2%) | 6 ( 4.1%) |
| Depression | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Delirium | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Depressed mood | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Agitation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Confusional state | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Eye disorders | 14 ( 18.9%) | 7 ( 9.9%) | 21 ( 14.5%) |
| Vision blurred | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| Diplopia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Eyelid oedema | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Lacrimation increased | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Blepharitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Conjunctivitis allergic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:32

TABLE 6.1: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Dry eye | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Erythema of eyelid | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eye pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eye pruritus | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Foreign body sensation in eyes | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Glaucoma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Periorbital swelling | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Photopsia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Uveitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Visual impairment | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vitreous detachment | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vitreous floaters | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Injury, poisoning and procedural complications | 12 ( 16.2%) | 9 ( 12.7%) | 21 ( 14.5%) |
| Contusion | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Ligament sprain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Procedural pain | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Rib fracture | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Burn oral cavity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Corneal abrasion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Fall | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hip fracture | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Lumbar vertebral fracture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Radiation pneumonitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin abrasion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Soft tissue injury | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Spinal compression fracture | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Sunburn | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tendon rupture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Thermal burn | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tooth fracture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vascular access site erythema | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hepatobiliary disorders | 9 ( 12.2%) | 10 ( 14.1%) | 19 ( 13.1%) |
| Hepatotoxicity | 4 ( 5.4%) | 5 ( 7.0%) | 9 ( 6.2%) |
| Hyperbilirubinaemia | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Hepatic function abnormal | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Hypertransaminasaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Jaundice | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Bile duct stone | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Cholecystitis acute | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cholelithiasis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ocular icterus | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Reproductive system and breast disorders | 9 ( 12.2%) | 9 ( 12.7%) | 18 ( 12.4%) |
| Testicular pain | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Balanoposthitis | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Acquired phimosis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Benign prostatic hyperplasia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Pruritus genital | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Testicular swelling | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Genital blister | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Genital burning sensation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Genital erythema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Genital rash | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Penile haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Penile pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Prostatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Scrotal dermatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Scrotal erythema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vaginal lesion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardiac disorders | 7 ( 9.5%) | 3 ( 4.2%) | 10 ( 6.9%) |
| Atrial fibrillation | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| Palpitations | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Atrioventricular block complete | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardiac failure | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Cardiac failure congestive | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardio-respiratory arrest | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Myocarditis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tachycardia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ear and labyrinth disorders | 6 ( 8.1%) | 4 ( 5.6%) | 10 ( 6.9%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Vertigo | 4 ( 5.4%) | 1 ( 1.4%) | 5 ( 3.4%) |
| Ear pain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Deafness | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Deafness unilateral | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hypoacusis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tinnitus | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 5 ( 6.8%) | 4 ( 5.6%) | 9 ( 6.2%) |
| Malignant neoplasm progression | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Metastases to central nervous system | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Basal cell carcinoma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cancer pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Metastases to spine | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin papilloma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Immune system disorders | 6 ( 8.1%) | 2 ( 2.8%) | 8 ( 5.5%) |
| Hypersensitivity | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Seasonal allergy | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Contrast media allergy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Iodine allergy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Overall | 74 (100.0%) | 70 ( 98.6%) | 144 ( 99.3%) |
| Overall excluding Progression Events | 74 (100.0%) | 70 ( 98.6%) | 144 ( 99.3%) |
| Gastrointestinal disorders | 62 ( 83.8%) | 56 ( 78.9%) | 118 ( 81.4%) |
| Diarrhoea | 49 ( 66.2%) | 31 ( 43.7%) | 80 ( 55.2%) |
| Nausea | 22 ( 29.7%) | 21 ( 29.6%) | 43 ( 29.7%) |
| Stomatitis | 9 ( 12.2%) | 22 ( 31.0%) | 31 ( 21.4%) |
| Vomiting | 13 ( 17.6%) | 13 ( 18.3%) | 26 ( 17.9%) |
| Constipation | 7 ( 9.5%) | 10 ( 14.1%) | 17 ( 11.7%) |
| Dyspepsia | 8 ( 10.8%) | 9 ( 12.7%) | 17 ( 11.7%) |
| Abdominal pain | 11 ( 14.9%) | 5 ( 7.0%) | 16 ( 11.0%) |
| Gastrooesophageal reflux disease | 7 ( 9.5%) | 6 ( 8.5%) | 13 ( 9.0%) |
| Abdominal pain upper | 8 ( 10.8%) | 4 ( 5.6%) | 12 ( 8.3%) |
| Flatulence | 5 ( 6.8%) | 6 ( 8.5%) | 11 ( 7.6%) |
| Dry mouth | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Gingival bleeding | 6 ( 8.1%) | 0 ( 0.0%) | 6 ( 4.1%) |
| Mouth ulceration | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Oral pain | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Haemorrhoids | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Toothache | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Abdominal discomfort | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Dysphagia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Gastritis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Glossodynia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Odynophagia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Proctalgia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Abdominal distension | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Abdominal pain lower | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Anal fissure | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Anal fistula | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Anal inflammation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Aphthous ulcer | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Ascites | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Bowel movement irregularity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cheilitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:34

TABLE 6.1.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Epigastric discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Erosive oesophagitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eructation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Frequent bowel movements | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastritis erosive | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastrointestinal disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gingival pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Haematochezia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Haemorrhoidal haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lip oedema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Melaena | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Perianal erythema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Rectal haemorrhage | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Salivary hypersecretion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| General disorders and administration site conditions | 55 ( 74.3%) | 52 ( 73.2%) | 107 ( 73.8%) |
| Fatigue | 27 ( 36.5%) | 33 ( 46.5%) | 60 ( 41.4%) |
| Mucosal inflammation | 20 ( 27.0%) | 21 ( 29.6%) | 41 ( 28.3%) |
| Asthenia | 14 ( 18.9%) | 11 ( 15.5%) | 25 ( 17.2%) |
| Oedema peripheral | 10 ( 13.5%) | 5 ( 7.0%) | 15 ( 10.3%) |
| Pyrexia | 9 ( 12.2%) | 5 ( 7.0%) | 14 ( 9.7%) |
| Malaise | 6 ( 8.1%) | 3 ( 4.2%) | 9 ( 6.2%) |
| Chills | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Influenza like illness | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Pain | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Chest discomfort | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Chest pain | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Face oedema | 0 ( 0.0%) | 3 ( 4.2%) | 3 ( 2.1%) |
| Non-cardiac chest pain | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Mucosal dryness | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Peripheral swelling | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Swelling face | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Temperature intolerance | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin and subcutaneous tissue disorders | 55 ( 74.3%) | 44 ( 62.0%) | 99 ( 68.3%) |
| Palmar-plantar erythrodysaesthesia syndrome | 31 ( 41.9%) | 34 ( 47.9%) | 65 ( 44.8%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Pruritus | 18 ( 24.3%) | 3 ( 4.2%) | 21 ( 14.5%) |
| Rash | 14 ( 18.9%) | 4 ( 5.6%) | 18 ( 12.4%) |
| Dry skin | 11 ( 14.9%) | 3 ( 4.2%) | 14 ( 9.7%) |
| Alopecia | 9 ( 12.2%) | 1 ( 1.4%) | 10 ( 6.9%) |
| Rash maculo-papular | 6 ( 8.1%) | 1 ( 1.4%) | 7 ( 4.8%) |
| Yellow skin | 0 ( 0.0%) | 7 ( 9.9%) | 7 ( 4.8%) |
| Erythema | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Acne | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Dermatitis | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Dermatitis acneiform | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Petechiae | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Rash papular | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hair colour changes | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Hyperhidrosis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pemphigoid | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Skin discolouration | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Skin hyperpigmentation | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Skin hypopigmentation | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Skin ulcer | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Urticaria | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blister | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Dermatitis bullous | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Eczema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hyperkeratosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ingrowing nail | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Miliaria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nail discolouration | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nail disorder | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nail dystrophy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pain of skin | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rash macular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Scab | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin exfoliation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Skin hypertrophy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin lesion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Skin reaction | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin toxicity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Umbilical haemorrhage | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Xeroderma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Investigations | 54 ( 73.0%) | 36 ( 50.7%) | 90 ( 62.1%) |
| Aspartate aminotransferase increased | 20 ( 27.0%) | 12 ( 16.9%) | 32 ( 22.1%) |
| Alanine aminotransferase increased | 20 ( 27.0%) | 7 ( 9.9%) | 27 ( 18.6%) |
| Lipase increased | 11 ( 14.9%) | 12 ( 16.9%) | 23 ( 15.9%) |
| Amylase increased | 13 ( 17.6%) | 7 ( 9.9%) | 20 ( 13.8%) |
| Platelet count decreased | 8 ( 10.8%) | 12 ( 16.9%) | 20 ( 13.8%) |
| Blood creatinine increased | 7 ( 9.5%) | 9 ( 12.7%) | 16 ( 11.0%) |
| Weight decreased | 11 ( 14.9%) | 3 ( 4.2%) | 14 ( 9.7%) |
| Blood alkaline phosphatase increased | 6 ( 8.1%) | 7 ( 9.9%) | 13 ( 9.0%) |
| Blood thyroid stimulating hormone increased | 9 ( 12.2%) | 3 ( 4.2%) | 12 ( 8.3%) |
| Blood cholesterol increased | 5 ( 6.8%) | 5 ( 7.0%) | 10 ( 6.9%) |
| Blood lactate dehydrogenase increased | 6 ( 8.1%) | 1 ( 1.4%) | 7 ( 4.8%) |
| Blood magnesium decreased | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Blood sodium decreased | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Neutrophil count decreased | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Transaminases increased | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Blood phosphorus increased | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| White blood cell count decreased | 1 ( 1.4%) | 3 ( 4.2%) | 4 ( 2.8%) |
| Blood bilirubin increased | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Blood creatine phosphokinase increased | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Blood pressure increased | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hepatic enzyme increased | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Lymphocyte count decreased | 0 ( 0.0%) | 3 ( 4.2%) | 3 ( 2.1%) |
| Urine protein/creatinine ratio increased | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Blood uric acid increased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Gamma-glutamyltransferase increased | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Haematocrit increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Aspartate aminotransferase decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:34

TABLE 6.1.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Blood albumin decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blood calcium decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood phosphorus decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blood potassium decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood thyroid stimulating hormone decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Culture urine positive | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Liver function test abnormal | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Liver function test increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Thyroid function test abnormal | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Thyroxine free increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tri-iodothyronine free decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tri-iodothyronine free increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Weight increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nervous system disorders | 44 ( 59.5%) | 40 ( 56.3%) | 84 ( 57.9%) |
| Dysgeusia | 22 ( 29.7%) | 22 ( 31.0%) | 44 ( 30.3%) |
| Headache | 14 ( 18.9%) | 7 ( 9.9%) | 21 ( 14.5%) |
| Dizziness | 13 ( 17.6%) | 5 ( 7.0%) | 18 ( 12.4%) |
| Paraesthesia | 6 ( 8.1%) | 4 ( 5.6%) | 10 ( 6.9%) |
| Sciatica | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Hypoaesthesia | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Peripheral sensory neuropathy | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Presyncope | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Taste disorder | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Tremor | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Ageusia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Disturbance in attention | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hypogeusia | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Neuropathy peripheral | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Syncope | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Head discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Migraine | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Neuralgia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Peripheral motor neuropathy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Speech disorder | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:34

TABLE 6.1.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Metabolism and nutrition disorders | 52 ( 70.3%) | 27 ( 38.0%) | 79 ( 54.5%) |
| Decreased appetite | 27 ( 36.5%) | 9 ( 12.7%) | 36 ( 24.8%) |
| Hypomagnesaemia | 13 ( 17.6%) | 3 ( 4.2%) | 16 ( 11.0%) |
| Hyperglycaemia | 7 ( 9.5%) | 7 ( 9.9%) | 14 ( 9.7%) |
| Hyponatraemia | 8 ( 10.8%) | 5 ( 7.0%) | 13 ( 9.0%) |
| Hypocalcaemia | 8 ( 10.8%) | 2 ( 2.8%) | 10 ( 6.9%) |
| Hypophosphataemia | 7 ( 9.5%) | 2 ( 2.8%) | 9 ( 6.2%) |
| Hypokalaemia | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Hypertriglyceridaemia | 3 ( 4.1%) | 3 ( 4.2%) | 6 ( 4.1%) |
| Hypoalbuminaemia | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Hyperkalaemia | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Hyperuricaemia | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Dehydration | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Hypercholesterolaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hyperlipasaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Fluid retention | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Glucose tolerance impaired | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Gout | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperamylasaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypercalcaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperchloraemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypercreatininaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypernatraemia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hypoglycaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Musculoskeletal and connective tissue disorders | 39 ( 52.7%) | 27 ( 38.0%) | 66 ( 45.5%) |
| Arthralgia | 15 ( 20.3%) | 5 ( 7.0%) | 20 ( 13.8%) |
| Back pain | 12 ( 16.2%) | 5 ( 7.0%) | 17 ( 11.7%) |
| Pain in extremity | 8 ( 10.8%) | 7 ( 9.9%) | 15 ( 10.3%) |
| Muscle spasms | 11 ( 14.9%) | 1 ( 1.4%) | 12 ( 8.3%) |
| Myalgia | 4 ( 5.4%) | 6 ( 8.5%) | 10 ( 6.9%) |
| Musculoskeletal pain | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Musculoskeletal chest pain | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Muscular weakness | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Neck pain | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:34

TABLE 6.1.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Bone pain | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Groin pain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Myopathy | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Arthritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Flank pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Metatarsalgia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Mobility decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Musculoskeletal discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Musculoskeletal stiffness | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Periarthritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rotator cuff syndrome | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Spinal pain | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Synovitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tendonitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Respiratory, thoracic and mediastinal disorders | 39 ( 52.7%) | 22 ( 31.0%) | 61 ( 42.1%) |
| Cough | 16 ( 21.6%) | 13 ( 18.3%) | 29 ( 20.0%) |
| Oropharyngeal pain | 14 ( 18.9%) | 4 ( 5.6%) | 18 ( 12.4%) |
| Dysphonia | 15 ( 20.3%) | 1 ( 1.4%) | 16 ( 11.0%) |
| Dyspnoea | 8 ( 10.8%) | 5 ( 7.0%) | 13 ( 9.0%) |
| Epistaxis | 4 ( 5.4%) | 6 ( 8.5%) | 10 ( 6.9%) |
| Rhinorrhoea | 4 ( 5.4%) | 1 ( 1.4%) | 5 ( 3.4%) |
| Dyspnoea exertional | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| Haemoptysis | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Productive cough | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Respiratory tract congestion | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hiccups | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Nasal congestion | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Nasal dryness | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Rhinitis allergic | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Bronchospasm | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Catarrh | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Chronic obstructive pulmonary disease | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nasal discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pneumonitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Rhinalgia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Sinus congestion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Sneezing | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Upper-airway cough syndrome | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Wheezing | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood and lymphatic system disorders | 22 ( 29.7%) | 28 ( 39.4%) | 50 ( 34.5%) |
| Thrombocytopenia | 10 ( 13.5%) | 16 ( 22.5%) | 26 ( 17.9%) |
| Anaemia | 9 ( 12.2%) | 16 ( 22.5%) | 25 ( 17.2%) |
| Leukopenia | 3 ( 4.1%) | 7 ( 9.9%) | 10 ( 6.9%) |
| Neutropenia | 4 ( 5.4%) | 5 ( 7.0%) | 9 ( 6.2%) |
| Lymphopenia | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Eosinophilia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Increased tendency to bruise | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lymphadenopathy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pancytopenia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Infections and infestations | 27 ( 36.5%) | 13 ( 18.3%) | 40 ( 27.6%) |
| Upper respiratory tract infection | 5 ( 6.8%) | 4 ( 5.6%) | 9 ( 6.2%) |
| Nasopharyngitis | 4 ( 5.4%) | 3 ( 4.2%) | 7 ( 4.8%) |
| Influenza | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Urinary tract infection | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Rhinitis | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Bronchitis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Ear infection | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Laryngitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pharyngitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Candida infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Conjunctivitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dermatophytosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Furuncle | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastroenteritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gingivitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Groin infection | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Lower respiratory tract infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nail infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:34

TABLE 6.1.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Otitis media | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Paronychia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rash pustular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory tract infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tinea cruris | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tonsillitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tooth abscess | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tooth infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vulvovaginal candidiasis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vulvovaginal mycotic infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Wound infection staphylococcal | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Endocrine disorders | 19 ( 25.7%) | 15 ( 21.1%) | 34 ( 23.4%) |
| Hypothyroidism | 13 ( 17.6%) | 13 ( 18.3%) | 26 ( 17.9%) |
| Hyperthyroidism | 7 ( 9.5%) | 5 ( 7.0%) | 12 ( 8.3%) |
| Thyroiditis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Adrenal insufficiency | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vascular disorders | 19 ( 25.7%) | 15 ( 21.1%) | 34 ( 23.4%) |
| Hypertension | 14 ( 18.9%) | 13 ( 18.3%) | 27 ( 18.6%) |
| Hot flush | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Pallor | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood pressure fluctuation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Deep vein thrombosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypotension | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Peripheral coldness | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vein rupture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal and urinary disorders | 21 ( 28.4%) | 11 ( 15.5%) | 32 ( 22.1%) |
| Proteinuria | 6 ( 8.1%) | 3 ( 4.2%) | 9 ( 6.2%) |
| Haematuria | 3 ( 4.1%) | 3 ( 4.2%) | 6 ( 4.1%) |
| Renal failure | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Dysuria | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Acute kidney injury | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Leukocyturia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Pollakiuria | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:34

TABLE 6.1.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Chromaturia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Glycosuria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nephrolithiasis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nephropathy | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nocturia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal impairment | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urinary hesitation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urinary incontinence | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eye disorders | 13 ( 17.6%) | 6 ( 8.5%) | 19 ( 13.1%) |
| Vision blurred | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| Diplopia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Eyelid oedema | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Lacrimation increased | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Blepharitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Conjunctivitis allergic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dry eye | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Erythema of eyelid | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eye pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eye pruritus | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Foreign body sensation in eyes | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Periorbital swelling | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Photopsia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Uveitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Visual impairment | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vitreous floaters | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Injury, poisoning and procedural complications | 12 ( 16.2%) | 7 ( 9.9%) | 19 ( 13.1%) |
| Contusion | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Ligament sprain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Rib fracture | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Burn oral cavity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Corneal abrasion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Fall | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Procedural pain | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Radiation pneumonitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Skin abrasion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Soft tissue injury | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Spinal compression fracture | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Sunburn | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tendon rupture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Thermal burn | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tooth fracture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vascular access site erythema | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Psychiatric disorders | 12 ( 16.2%) | 6 ( 8.5%) | 18 ( 12.4%) |
| Insomnia | 5 ( 6.8%) | 4 ( 5.6%) | 9 ( 6.2%) |
| Depression | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Anxiety | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Agitation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Confusional state | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Delirium | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Depressed mood | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hepatobiliary disorders | 8 ( 10.8%) | 7 ( 9.9%) | 15 ( 10.3%) |
| Hepatotoxicity | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Hyperbilirubinaemia | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Hepatic function abnormal | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Hypertransaminasaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Jaundice | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Ocular icterus | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Reproductive system and breast disorders | 7 ( 9.5%) | 8 ( 11.3%) | 15 ( 10.3%) |
| Testicular pain | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Acquired phimosis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Balanoposthitis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Pruritus genital | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Testicular swelling | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Genital blister | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Genital burning sensation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Genital erythema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Genital rash | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Penile haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Penile pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Prostatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Scrotal dermatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Scrotal erythema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vaginal lesion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ear and labyrinth disorders | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Vertigo | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Ear pain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Deafness | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hypoacusis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tinnitus | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Immune system disorders | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Hypersensitivity | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Seasonal allergy | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Cardiac disorders | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Palpitations | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Myocarditis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tachycardia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin papilloma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:34

TABLE 6.1.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Overall | 73 ( 98.6%) | 68 ( 95.8%) | 141 ( 97.2%) |
| Overall excluding Progression Events | 73 ( 98.6%) | 68 ( 95.8%) | 141 ( 97.2%) |
| Gastrointestinal disorders | 42 ( 56.8%) | 42 ( 59.2%) | 84 ( 57.9%) |
| Diarrhoea | 28 ( 37.8%) | 16 ( 22.5%) | 44 ( 30.3%) |
| Nausea | 7 ( 9.5%) | 12 ( 16.9%) | 19 ( 13.1%) |
| Stomatitis | 6 ( 8.1%) | 9 ( 12.7%) | 15 ( 10.3%) |
| Vomiting | 5 ( 6.8%) | 7 ( 9.9%) | 12 ( 8.3%) |
| Abdominal pain | 2 ( 2.7%) | 7 ( 9.9%) | 9 ( 6.2%) |
| Dyspepsia | 3 ( 4.1%) | 5 ( 7.0%) | 8 ( 5.5%) |
| Gastrooesophageal reflux disease | 3 ( 4.1%) | 5 ( 7.0%) | 8 ( 5.5%) |
| Abdominal pain upper | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Constipation | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Anal inflammation | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Ascites | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Food poisoning | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Toothache | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Abdominal distension | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Anal fistula | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cheilitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Colitis ulcerative | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Dental caries | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dry mouth | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Flatulence | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Frequent bowel movements | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastrointestinal toxicity | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Haemorrhoids | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lower gastrointestinal haemorrhage | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Odynophagia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Proctitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Retching | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Salivary hypersecretion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Investigations | 34 ( 45.9%) | 34 ( 47.9%) | 68 ( 46.9%) |
| Lipase increased | 7 ( 9.5%) | 6 ( 8.5%) | 13 ( 9.0%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Alanine aminotransferase increased | 8 ( 10.8%) | 4 ( 5.6%) | 12 ( 8.3%) |
| Amylase increased | 6 ( 8.1%) | 5 ( 7.0%) | 11 ( 7.6%) |
| Aspartate aminotransferase increased | 6 ( 8.1%) | 4 ( 5.6%) | 10 ( 6.9%) |
| Blood creatinine increased | 4 ( 5.4%) | 6 ( 8.5%) | 10 ( 6.9%) |
| Neutrophil count decreased | 2 ( 2.7%) | 7 ( 9.9%) | 9 ( 6.2%) |
| Platelet count decreased | 0 ( 0.0%) | 9 ( 12.7%) | 9 ( 6.2%) |
| Blood bilirubin increased | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Weight decreased | 6 ( 8.1%) | 0 ( 0.0%) | 6 ( 4.1%) |
| Blood alkaline phosphatase increased | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Blood thyroid stimulating hormone increased | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Lymphocyte count decreased | 0 ( 0.0%) | 3 ( 4.2%) | 3 ( 2.1%) |
| Transaminases increased | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| White blood cell count decreased | 0 ( 0.0%) | 3 ( 4.2%) | 3 ( 2.1%) |
| Blood cholesterol increased | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Blood creatine phosphokinase increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood phosphorus decreased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Blood pressure increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood urea increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood albumin decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Cortisol decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gamma-glutamyltransferase increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Glomerular filtration rate decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urine osmolarity decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urine protein/creatinine ratio increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vitamin B12 decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| General disorders and administration site conditions | 29 ( 39.2%) | 26 ( 36.6%) | 55 ( 37.9%) |
| Fatigue | 15 ( 20.3%) | 11 ( 15.5%) | 26 ( 17.9%) |
| Mucosal inflammation | 5 ( 6.8%) | 10 ( 14.1%) | 15 ( 10.3%) |
| Asthenia | 6 ( 8.1%) | 5 ( 7.0%) | 11 ( 7.6%) |
| Pyrexia | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Influenza like illness | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Oedema peripheral | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Pain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Catheter site pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Chest discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Chills | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Face oedema | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperthermia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Skin and subcutaneous tissue disorders | 26 ( 35.1%) | 26 ( 36.6%) | 52 ( 35.9%) |
| Palmar-plantar erythrodysaesthesia syndrome | 16 ( 21.6%) | 20 ( 28.2%) | 36 ( 24.8%) |
| Rash | 4 ( 5.4%) | 1 ( 1.4%) | 5 ( 3.4%) |
| Rash maculo-papular | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Alopecia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Dermatitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Erythema | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pruritus | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Angioedema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Decubitus ulcer | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dermatitis bullous | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dry skin | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eczema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Eczema asteatotic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hair colour changes | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nail dystrophy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Night sweats | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pemphigoid | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pemphigus | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Rash papular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rash pruritic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin reaction | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Yellow skin | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vascular disorders | 24 ( 32.4%) | 27 ( 38.0%) | 51 ( 35.2%) |
| Hypertension | 21 ( 28.4%) | 26 ( 36.6%) | 47 ( 32.4%) |
| Deep vein thrombosis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Embolism | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pallor | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Phlebitis superficial | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vascular occlusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Metabolism and nutrition disorders | 30 ( 40.5%) | 16 ( 22.5%) | 46 ( 31.7%) |
| Decreased appetite | 11 ( 14.9%) | 8 ( 11.3%) | 19 ( 13.1%) |
| Hypophosphataemia | 7 ( 9.5%) | 3 ( 4.2%) | 10 ( 6.9%) |
| Hypertriglyceridaemia | 2 ( 2.7%) | 4 ( 5.6%) | 6 ( 4.1%) |
| Hyperglycaemia | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Hypomagnesaemia | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| Hyperkalaemia | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hyperuricaemia | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hypokalaemia | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Hypercholesterolaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hypoalbuminaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hypocalcaemia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Hyponatraemia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Fluid overload | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperamylasaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperlipasaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vitamin D deficiency | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Endocrine disorders | 19 ( 25.7%) | 22 ( 31.0%) | 41 ( 28.3%) |
| Hypothyroidism | 12 ( 16.2%) | 19 ( 26.8%) | 31 ( 21.4%) |
| Hyperthyroidism | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Adrenal insufficiency | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Adrenal haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypothalamo-pituitary disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Infections and infestations | 21 ( 28.4%) | 13 ( 18.3%) | 34 ( 23.4%) |
| Urinary tract infection | 3 ( 4.1%) | 5 ( 7.0%) | 8 ( 5.5%) |
| Pneumonia | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Tooth infection | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Upper respiratory tract infection | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Conjunctivitis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Cystitis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Lower respiratory tract infection | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Nasopharyngitis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Sinusitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Body tinea | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Bronchitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cellulitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Diverticulitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Epididymitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gingivitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Oral herpes | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Otitis media | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Periodontitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Peritonsillitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pharyngitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory tract infection viral | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tinea cruris | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tooth abscess | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood and lymphatic system disorders | 7 ( 9.5%) | 23 ( 32.4%) | 30 ( 20.7%) |
| Neutropenia | 2 ( 2.7%) | 13 ( 18.3%) | 15 ( 10.3%) |
| Thrombocytopenia | 1 ( 1.4%) | 9 ( 12.7%) | 10 ( 6.9%) |
| Anaemia | 4 ( 5.4%) | 3 ( 4.2%) | 7 ( 4.8%) |
| Leukopenia | 0 ( 0.0%) | 5 ( 7.0%) | 5 ( 3.4%) |
| Leukocytosis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Lymphopenia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Musculoskeletal and connective tissue disorders | 15 ( 20.3%) | 15 ( 21.1%) | 30 ( 20.7%) |
| Arthralgia | 6 ( 8.1%) | 4 ( 5.6%) | 10 ( 6.9%) |
| Pain in extremity | 1 ( 1.4%) | 5 ( 7.0%) | 6 ( 4.1%) |
| Back pain | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Muscle spasms | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Myalgia | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Arthritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Bone pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Bursitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Flank pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Joint swelling | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Muscular weakness | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Musculoskeletal pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Neck mass | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Neck pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Osteoporosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Periarthritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Plantar fasciitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Soft tissue necrosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory, thoracic and mediastinal disorders | 15 ( 20.3%) | 3 ( 4.2%) | 18 ( 12.4%) |
| Dyspnoea | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Dysphonia | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Oropharyngeal pain | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pneumonitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Chronic obstructive pulmonary disease | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cough | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dyspnoea exertional | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Epistaxis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pleural effusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pneumothorax | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Productive cough | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pulmonary embolism | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory tract congestion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rhinitis allergic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rhinorrhoea | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal and urinary disorders | 9 ( 12.2%) | 8 ( 11.3%) | 17 ( 11.7%) |
| Proteinuria | 4 ( 5.4%) | 5 ( 7.0%) | 9 ( 6.2%) |
| Urinary retention | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Acute kidney injury | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Azotaemia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Dysuria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Haematuria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pollakiuria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal failure | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Renal impairment | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urinary tract pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nervous system disorders | 9 ( 12.2%) | 7 ( 9.9%) | 16 ( 11.0%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Dysgeusia | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Headache | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Neuropathy peripheral | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Sciatica | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Syncope | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Aphasia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cauda equina syndrome | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Dizziness | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dysarthria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nervous system disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Paraesthesia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Radicular pain | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hepatobiliary disorders | 6 ( 8.1%) | 6 ( 8.5%) | 12 ( 8.3%) |
| Hepatotoxicity | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Hyperbilirubinaemia | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Hepatic function abnormal | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Cholelithiasis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Psychiatric disorders | 6 ( 8.1%) | 4 ( 5.6%) | 10 ( 6.9%) |
| Anxiety | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Insomnia | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Depressed mood | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Depression | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Delirium | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Injury, poisoning and procedural complications | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Procedural pain | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Ligament sprain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lumbar vertebral fracture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Basal cell carcinoma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cancer pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Metastases to central nervous system | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Reproductive system and breast disorders | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Balanoposthitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Benign prostatic hyperplasia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Scrotal dermatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Testicular pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardiac disorders | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Atrial fibrillation | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Myocarditis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eye disorders | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Glaucoma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Uveitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Immune system disorders | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Contrast media allergy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Iodine allergy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ear and labyrinth disorders | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vertigo | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.3: CTCAE-grade 3 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Overall | 57 ( 77.0%) | 48 ( 67.6%) | 105 ( 72.4%) |
| Overall excluding Progression Events | 57 ( 77.0%) | 48 ( 67.6%) | 105 ( 72.4%) |
| Investigations | 13 ( 17.6%) | 20 ( 28.2%) | 33 ( 22.8%) |
| Lipase increased | 5 ( 6.8%) | 5 ( 7.0%) | 10 ( 6.9%) |
| Alanine aminotransferase increased | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Amylase increased | 3 ( 4.1%) | 3 ( 4.2%) | 6 ( 4.1%) |
| Neutrophil count decreased | 0 ( 0.0%) | 6 ( 8.5%) | 6 ( 4.1%) |
| Transaminases increased | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Aspartate aminotransferase increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood creatinine increased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Platelet count decreased | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Blood alkaline phosphatase increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood bilirubin increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blood creatine phosphokinase increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood magnesium decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blood pressure increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Creatinine urine increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gamma-glutamyltransferase increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Protein urine present | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| White blood cell count decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Metabolism and nutrition disorders | 20 ( 27.0%) | 12 ( 16.9%) | 32 ( 22.1%) |
| Hyponatraemia | 7 ( 9.5%) | 6 ( 8.5%) | 13 ( 9.0%) |
| Hypophosphataemia | 5 ( 6.8%) | 1 ( 1.4%) | 6 ( 4.1%) |
| Hyperglycaemia | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Hyperkalaemia | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hypertriglyceridaemia | 0 ( 0.0%) | 3 ( 4.2%) | 3 ( 2.1%) |
| Decreased appetite | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Dehydration | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hypokalaemia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Electrolyte imbalance | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperamylasaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypercholesterolaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperlipasaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypocalcaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:37

TABLE 6.1.2.3: CTCAE-grade 3 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Hypomagnesaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastrointestinal disorders | 15 ( 20.3%) | 12 ( 16.9%) | 27 ( 18.6%) |
| Diarrhoea | 8 ( 10.8%) | 4 ( 5.6%) | 12 ( 8.3%) |
| Stomatitis | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Vomiting | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Abdominal pain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Abdominal distension | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Abdominal pain upper | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Anal inflammation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Epigastric discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lower gastrointestinal haemorrhage | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Mouth ulceration | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nausea | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Segmental diverticular colitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vascular disorders | 12 ( 16.2%) | 15 ( 21.1%) | 27 ( 18.6%) |
| Hypertension | 12 ( 16.2%) | 15 ( 21.1%) | 27 ( 18.6%) |
| Embolism | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin and subcutaneous tissue disorders | 10 ( 13.5%) | 10 ( 14.1%) | 20 ( 13.8%) |
| Palmar-plantar erythrodysaesthesia syndrome | 5 ( 6.8%) | 10 ( 14.1%) | 15 ( 10.3%) |
| Rash | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Nail dystrophy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pruritus | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rash maculo-papular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rash papular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin exfoliation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin toxicity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin ulcer | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| General disorders and administration site conditions | 10 ( 13.5%) | 6 ( 8.5%) | 16 ( 11.0%) |
| Asthenia | 6 ( 8.1%) | 1 ( 1.4%) | 7 ( 4.8%) |
| Fatigue | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Mucosal inflammation | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Face oedema | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gait disturbance | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Malaise | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.3: CTCAE-grade 3 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Pyrexia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory, thoracic and mediastinal disorders | 9 ( 12.2%) | 2 ( 2.8%) | 11 ( 7.6%) |
| Pulmonary embolism | 6 ( 8.1%) | 1 ( 1.4%) | 7 ( 4.8%) |
| Chronic obstructive pulmonary disease | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dyspnoea | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Lung disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Oropharyngeal pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pneumonitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Productive cough | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Infections and infestations | 7 ( 9.5%) | 2 ( 2.8%) | 9 ( 6.2%) |
| Lung abscess | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pneumonia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Cystitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Febrile infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Infectious pleural effusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Large intestine infection | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pseudomonas infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tooth infection | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blood and lymphatic system disorders | 0 ( 0.0%) | 8 ( 11.3%) | 8 ( 5.5%) |
| Neutropenia | 0 ( 0.0%) | 4 ( 5.6%) | 4 ( 2.8%) |
| Thrombocytopenia | 0 ( 0.0%) | 4 ( 5.6%) | 4 ( 2.8%) |
| Anaemia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Leukopenia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Lymphopenia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Musculoskeletal and connective tissue disorders | 4 ( 5.4%) | 3 ( 4.2%) | 7 ( 4.8%) |
| Back pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Bone lesion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Flank pain | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Intervertebral disc protrusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Muscular weakness | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Neck pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Osteonecrosis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Renal and urinary disorders | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Proteinuria | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.3: CTCAE-grade 3 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Chronic kidney disease | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Glycosuria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal colic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal failure | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hepatobiliary disorders | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Hepatotoxicity | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Bile duct stone | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Cholecystitis acute | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hepatic function abnormal | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nervous system disorders | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Headache | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Ischaemic stroke | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lethargy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Paraplegia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardiac disorders | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Atrial fibrillation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardiac failure congestive | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Myocarditis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Malignant neoplasm progression | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Metastases to central nervous system | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Metastases to spine | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Reproductive system and breast disorders | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Benign prostatic hyperplasia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Prostatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Scrotal dermatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Endocrine disorders | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hyperthyroidism | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypothalamo-pituitary disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eye disorders | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Uveitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vitreous detachment | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Injury, poisoning and procedural complications | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Hip fracture | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:37

TABLE 6.1.2.3: CTCAE-grade 3 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Lumbar vertebral fracture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ear and labyrinth disorders | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Deafness unilateral | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:37

TABLE 6.1.2.4: CTCAE-grade 4 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Overall | 11 ( 14.9%) | 8 ( 11.3%) | 19 ( 13.1%) |
| Overall excluding Progression Events | 11 ( 14.9%) | 8 ( 11.3%) | 19 ( 13.1%) |
| Metabolism and nutrition disorders | 4 ( 5.4%) | 3 ( 4.2%) | 7 ( 4.8%) |
| Hyperlipasaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hyponatraemia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Dehydration | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hyperkalaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypertriglyceridaemia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Investigations | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Lipase increased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Neutrophil count decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blood and lymphatic system disorders | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Thrombocytopenia | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Cardiac disorders | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Atrial fibrillation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardiac failure | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nervous system disorders | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Haemorrhage intracranial | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Sciatica | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Gastrointestinal disorders | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Small intestinal perforation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| General disorders and administration site conditions | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Mucosal inflammation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hepatobiliary disorders | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hepatotoxicity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Infections and infestations | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Sepsis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Musculoskeletal and connective tissue disorders | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Spinal pain | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Renal and urinary disorders | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Acute kidney injury | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Respiratory, thoracic and mediastinal disorders | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pulmonary embolism | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vascular disorders | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.1.2.4: CTCAE-grade 4 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Hypertension | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:38

TABLE 6.1.2.5: CTCAE-grade 5 Treatment Emergent Adverse Events, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Overall | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Overall excluding Progression Events | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Cardiac disorders | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Atrioventricular block complete | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardio-respiratory arrest | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Malignant neoplasm progression | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Gastrointestinal disorders | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Upper gastrointestinal haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Overall | 74 (100.0%) | 71 (100.0%) | 145 (100.0%) |
| Overall excluding Progression Events | 74 (100.0%) | 71 (100.0%) | 145 (100.0%) |
| Gastrointestinal disorders | 65 ( 87.8%) | 64 ( 90.1%) | 129 ( 89.0%) |
| Diarrhoea | 56 ( 75.7%) | 37 ( 52.1%) | 93 ( 64.1%) |
| Nausea | 25 ( 33.8%) | 28 ( 39.4%) | 53 ( 36.6%) |
| Stomatitis | 12 ( 16.2%) | 26 ( 36.6%) | 38 ( 26.2%) |
| Vomiting | 15 ( 20.3%) | 17 ( 23.9%) | 32 ( 22.1%) |
| Abdominal pain | 11 ( 14.9%) | 12 ( 16.9%) | 23 ( 15.9%) |
| Dyspepsia | 10 ( 13.5%) | 12 ( 16.9%) | 22 ( 15.2%) |
| Constipation | 8 ( 10.8%) | 11 ( 15.5%) | 19 ( 13.1%) |
| Gastrooesophageal reflux disease | 9 ( 12.2%) | 10 ( 14.1%) | 19 ( 13.1%) |
| Abdominal pain upper | 8 ( 10.8%) | 5 ( 7.0%) | 13 ( 9.0%) |
| Flatulence | 6 ( 8.1%) | 6 ( 8.5%) | 12 ( 8.3%) |
| Dry mouth | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Gingival bleeding | 6 ( 8.1%) | 0 ( 0.0%) | 6 ( 4.1%) |
| Haemorrhoids | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Mouth ulceration | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Oral pain | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Toothache | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Abdominal distension | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Gastritis | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Odynophagia | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Abdominal discomfort | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Anal fistula | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Anal inflammation | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Ascites | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Dysphagia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Epigastric discomfort | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Food poisoning | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Frequent bowel movements | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Gastrointestinal toxicity | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Glossodynia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Proctalgia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Abdominal pain lower | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Anal fissure | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Aphthous ulcer | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Bowel movement irregularity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cheilitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Colitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Colitis ischaemic | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Colitis ulcerative | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Dental caries | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Erosive oesophagitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eructation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastritis erosive | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastrointestinal disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gingival pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Haematochezia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Haemorrhoidal haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lip oedema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Lower gastrointestinal haemorrhage | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Melaena | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Perianal erythema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Proctitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rectal haemorrhage | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Retching | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Salivary hypersecretion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Segmental diverticular colitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Small intestinal perforation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Upper gastrointestinal haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| General disorders and administration site conditions | 59 ( 79.7%) | 56 ( 78.9%) | 115 ( 79.3%) |
| Fatigue | 30 ( 40.5%) | 37 ( 52.1%) | 67 ( 46.2%) |
| Mucosal inflammation | 21 ( 28.4%) | 26 ( 36.6%) | 47 ( 32.4%) |
| Asthenia | 16 ( 21.6%) | 13 ( 18.3%) | 29 ( 20.0%) |
| Pyrexia | 13 ( 17.6%) | 6 ( 8.5%) | 19 ( 13.1%) |
| Oedema peripheral | 10 ( 13.5%) | 5 ( 7.0%) | 15 ( 10.3%) |
| Malaise | 6 ( 8.1%) | 3 ( 4.2%) | 9 ( 6.2%) |
| Chills | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Face oedema | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Influenza like illness | 4 ( 5.4%) | 1 ( 1.4%) | 5 ( 3.4%) |
| Pain | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Chest discomfort | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Chest pain | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Non-cardiac chest pain | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Catheter site pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gait disturbance | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| General physical health deterioration | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperthermia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Mucosal dryness | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Peripheral swelling | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Swelling face | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Temperature intolerance | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin and subcutaneous tissue disorders | 61 ( 82.4%) | 50 ( 70.4%) | 111 ( 76.6%) |
| Palmar-plantar erythrodysaesthesia syndrome | 33 ( 44.6%) | 41 ( 57.7%) | 74 ( 51.0%) |
| Pruritus | 20 ( 27.0%) | 3 ( 4.2%) | 23 ( 15.9%) |
| Rash | 18 ( 24.3%) | 5 ( 7.0%) | 23 ( 15.9%) |
| Dry skin | 11 ( 14.9%) | 3 ( 4.2%) | 14 ( 9.7%) |
| Alopecia | 9 ( 12.2%) | 1 ( 1.4%) | 10 ( 6.9%) |
| Rash maculo-papular | 8 ( 10.8%) | 2 ( 2.8%) | 10 ( 6.9%) |
| Yellow skin | 0 ( 0.0%) | 8 ( 11.3%) | 8 ( 5.5%) |
| Erythema | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Dermatitis | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Acne | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Dermatitis acneiform | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Hair colour changes | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Petechiae | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Rash papular | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Skin ulcer | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Dermatitis bullous | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Eczema | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Hyperhidrosis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pemphigoid | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Skin discolouration | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Skin exfoliation | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Skin hyperpigmentation | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Skin hypopigmentation | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Urticaria | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Angioedema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blister | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Decubitus ulcer | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eczema asteatotic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperkeratosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ingrowing nail | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Miliaria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nail discolouration | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nail disorder | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nail dystrophy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Night sweats | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pain of skin | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pemphigus | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Rash macular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rash pruritic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Scab | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin hypertrophy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin lesion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Skin reaction | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin toxicity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Umbilical haemorrhage | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Xeroderma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Investigations | 56 ( 75.7%) | 49 ( 69.0%) | 105 ( 72.4%) |
| Aspartate aminotransferase increased | 22 ( 29.7%) | 13 ( 18.3%) | 35 ( 24.1%) |
| Alanine aminotransferase increased | 22 ( 29.7%) | 11 ( 15.5%) | 33 ( 22.8%) |
| Lipase increased | 14 ( 18.9%) | 15 ( 21.1%) | 29 ( 20.0%) |
| Amylase increased | 15 ( 20.3%) | 10 ( 14.1%) | 25 ( 17.2%) |
| Platelet count decreased | 8 ( 10.8%) | 17 ( 23.9%) | 25 ( 17.2%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Blood creatinine increased | 9 ( 12.2%) | 13 ( 18.3%) | 22 ( 15.2%) |
| Weight decreased | 13 ( 17.6%) | 3 ( 4.2%) | 16 ( 11.0%) |
| Blood alkaline phosphatase increased | 8 ( 10.8%) | 7 ( 9.9%) | 15 ( 10.3%) |
| Blood thyroid stimulating hormone increased | 11 ( 14.9%) | 3 ( 4.2%) | 14 ( 9.7%) |
| Neutrophil count decreased | 5 ( 6.8%) | 9 ( 12.7%) | 14 ( 9.7%) |
| Transaminases increased | 7 ( 9.5%) | 4 ( 5.6%) | 11 ( 7.6%) |
| Blood bilirubin increased | 6 ( 8.1%) | 4 ( 5.6%) | 10 ( 6.9%) |
| Blood cholesterol increased | 5 ( 6.8%) | 5 ( 7.0%) | 10 ( 6.9%) |
| Blood lactate dehydrogenase increased | 6 ( 8.1%) | 1 ( 1.4%) | 7 ( 4.8%) |
| Blood magnesium decreased | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Blood sodium decreased | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Blood phosphorus increased | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Lymphocyte count decreased | 0 ( 0.0%) | 4 ( 5.6%) | 4 ( 2.8%) |
| Urine protein/creatinine ratio increased | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| White blood cell count decreased | 1 ( 1.4%) | 3 ( 4.2%) | 4 ( 2.8%) |
| Blood creatine phosphokinase increased | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Blood pressure increased | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hepatic enzyme increased | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Blood albumin decreased | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Blood phosphorus decreased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Blood urea increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood uric acid increased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Gamma-glutamyltransferase increased | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Haematocrit increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Aspartate aminotransferase decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood calcium decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood potassium decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood thyroid stimulating hormone decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Cortisol decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Creatinine urine increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Culture urine positive | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Glomerular filtration rate decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Liver function test abnormal | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Liver function test increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Protein urine present | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Thyroid function test abnormal | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Thyroxine free increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tri-iodothyronine free decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tri-iodothyronine free increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Urine osmolarity decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vitamin B12 decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Weight increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Metabolism and nutrition disorders | 59 ( 79.7%) | 35 ( 49.3%) | 94 ( 64.8%) |
| Decreased appetite | 33 ( 44.6%) | 15 ( 21.1%) | 48 ( 33.1%) |
| Hyponatraemia | 13 ( 17.6%) | 9 ( 12.7%) | 22 ( 15.2%) |
| Hypomagnesaemia | 16 ( 21.6%) | 3 ( 4.2%) | 19 ( 13.1%) |
| Hyperglycaemia | 8 ( 10.8%) | 7 ( 9.9%) | 15 ( 10.3%) |
| Hypophosphataemia | 11 ( 14.9%) | 4 ( 5.6%) | 15 ( 10.3%) |
| Hypocalcaemia | 8 ( 10.8%) | 2 ( 2.8%) | 10 ( 6.9%) |
| Hypertriglyceridaemia | 3 ( 4.1%) | 5 ( 7.0%) | 8 ( 5.5%) |
| Hypokalaemia | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Hyperkalaemia | 6 ( 8.1%) | 1 ( 1.4%) | 7 ( 4.8%) |
| Hypoalbuminaemia | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Dehydration | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Hyperuricaemia | 5 ( 6.8%) | 0 ( 0.0%) | 5 ( 3.4%) |
| Hypercholesterolaemia | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hyperlipasaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Electrolyte imbalance | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Fluid overload | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Fluid retention | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Glucose tolerance impaired | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Gout | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperamylasaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypercalcaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperchloraemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypercreatininaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypernatraemia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hypoglycaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Vitamin D deficiency | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nervous system disorders | 46 ( 62.2%) | 41 ( 57.7%) | 87 ( 60.0%) |
| Dysgeusia | 22 ( 29.7%) | 23 ( 32.4%) | 45 ( 31.0%) |
| Headache | 14 ( 18.9%) | 9 ( 12.7%) | 23 ( 15.9%) |
| Dizziness | 13 ( 17.6%) | 5 ( 7.0%) | 18 ( 12.4%) |
| Paraesthesia | 7 ( 9.5%) | 4 ( 5.6%) | 11 ( 7.6%) |
| Sciatica | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Hypoaesthesia | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Neuropathy peripheral | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Peripheral sensory neuropathy | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Presyncope | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Taste disorder | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Tremor | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Ageusia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Disturbance in attention | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hypogeusia | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Syncope | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Aphasia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cauda equina syndrome | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Dysarthria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Haemorrhage intracranial | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Head discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ischaemic stroke | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lethargy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Migraine | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nervous system disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Neuralgia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Paraplegia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Peripheral motor neuropathy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Radicular pain | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Speech disorder | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Spinal cord compression | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Musculoskeletal and connective tissue disorders | 44 ( 59.5%) | 35 ( 49.3%) | 79 ( 54.5%) |
| Arthralgia | 18 ( 24.3%) | 8 ( 11.3%) | 26 ( 17.9%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Back pain | 14 ( 18.9%) | 7 ( 9.9%) | 21 ( 14.5%) |
| Pain in extremity | 8 ( 10.8%) | 10 ( 14.1%) | 18 ( 12.4%) |
| Muscle spasms | 12 ( 16.2%) | 2 ( 2.8%) | 14 ( 9.7%) |
| Myalgia | 4 ( 5.4%) | 7 ( 9.9%) | 11 ( 7.6%) |
| Musculoskeletal pain | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Muscular weakness | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Neck pain | 5 ( 6.8%) | 1 ( 1.4%) | 6 ( 4.1%) |
| Musculoskeletal chest pain | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Bone pain | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Flank pain | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Groin pain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Myopathy | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Arthritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Bone lesion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Bursitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Intervertebral disc protrusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Joint swelling | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Metatarsalgia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Mobility decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Musculoskeletal discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Musculoskeletal stiffness | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Neck mass | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Osteonecrosis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Osteoporosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Periarthritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Plantar fasciitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Rotator cuff syndrome | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Soft tissue necrosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Spinal pain | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Synovitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tendonitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vascular disorders | 35 ( 47.3%) | 39 ( 54.9%) | 74 ( 51.0%) |
| Hypertension | 33 ( 44.6%) | 38 ( 53.5%) | 71 ( 49.0%) |
| Hot flush | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Deep vein thrombosis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Embolism | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Pallor | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood pressure fluctuation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hypotension | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Peripheral coldness | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Phlebitis superficial | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vascular occlusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vein rupture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory, thoracic and mediastinal disorders | 42 ( 56.8%) | 27 ( 38.0%) | 69 ( 47.6%) |
| Cough | 18 ( 24.3%) | 13 ( 18.3%) | 31 ( 21.4%) |
| Oropharyngeal pain | 14 ( 18.9%) | 4 ( 5.6%) | 18 ( 12.4%) |
| Dysphonia | 16 ( 21.6%) | 1 ( 1.4%) | 17 ( 11.7%) |
| Dyspnoea | 9 ( 12.2%) | 8 ( 11.3%) | 17 ( 11.7%) |
| Epistaxis | 4 ( 5.4%) | 7 ( 9.9%) | 11 ( 7.6%) |
| Pulmonary embolism | 8 ( 10.8%) | 1 ( 1.4%) | 9 ( 6.2%) |
| Productive cough | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Rhinorrhoea | 4 ( 5.4%) | 1 ( 1.4%) | 5 ( 3.4%) |
| Dyspnoea exertional | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| Rhinitis allergic | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| Haemoptysis | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Nasal congestion | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Respiratory tract congestion | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hiccups | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Nasal dryness | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pneumonitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Bronchospasm | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Catarrh | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Chronic obstructive pulmonary disease | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lung disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nasal discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pleural effusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pneumothorax | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory failure | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
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TABLE 6.2: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Rhinalgia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Sinus congestion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Sneezing | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Upper-airway cough syndrome | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Wheezing | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Infections and infestations | 42 ( 56.8%) | 25 ( 35.2%) | 67 ( 46.2%) |
| Urinary tract infection | 5 ( 6.8%) | 7 ( 9.9%) | 12 ( 8.3%) |
| Upper respiratory tract infection | 7 ( 9.5%) | 4 ( 5.6%) | 11 ( 7.6%) |
| Nasopharyngitis | 4 ( 5.4%) | 4 ( 5.6%) | 8 ( 5.5%) |
| Influenza | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Pneumonia | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Tooth infection | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Bronchitis | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Conjunctivitis | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Cystitis | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Lower respiratory tract infection | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Rhinitis | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Ear infection | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Gingivitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Laryngitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Lung abscess | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Otitis media | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Pharyngitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Sinusitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Skin infection | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Tinea cruris | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Tooth abscess | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Abdominal sepsis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Body tinea | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Candida infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cellulitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Clostridium difficile infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dermatophytosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Diverticulitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Epididymitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Febrile infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Furuncle | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastroenteritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Groin infection | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Infectious pleural effusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Large intestine infection | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nail infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Oral herpes | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Paronychia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Periodontitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Peritonsillitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pseudomonas infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rash pustular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory tract infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory tract infection viral | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Sepsis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tonsillitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vulvovaginal candidiasis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vulvovaginal mycotic infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Wound infection staphylococcal | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood and lymphatic system disorders | 23 ( 31.1%) | 37 ( 52.1%) | 60 ( 41.4%) |
| Thrombocytopenia | 10 ( 13.5%) | 23 ( 32.4%) | 33 ( 22.8%) |
| Anaemia | 10 ( 13.5%) | 19 ( 26.8%) | 29 ( 20.0%) |
| Neutropenia | 6 ( 8.1%) | 15 ( 21.1%) | 21 ( 14.5%) |
| Leukopenia | 3 ( 4.1%) | 9 ( 12.7%) | 12 ( 8.3%) |
| Lymphopenia | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Eosinophilia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Increased tendency to bruise | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Leukocytosis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Lymphadenopathy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pancytopenia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Endocrine disorders | 30 ( 40.5%) | 28 ( 39.4%) | 58 ( 40.0%) |
| Hypothyroidism | 22 ( 29.7%) | 25 ( 35.2%) | 47 ( 32.4%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
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TABLE 6.2: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Hyperthyroidism | 10 ( 13.5%) | 7 ( 9.9%) | 17 ( 11.7%) |
| Adrenal insufficiency | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Thyroiditis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Adrenal haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypothalamo-pituitary disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal and urinary disorders | 24 ( 32.4%) | 20 ( 28.2%) | 44 ( 30.3%) |
| Proteinuria | 9 ( 12.2%) | 9 ( 12.7%) | 18 ( 12.4%) |
| Haematuria | 3 ( 4.1%) | 4 ( 5.6%) | 7 ( 4.8%) |
| Acute kidney injury | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Dysuria | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Renal failure | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Pollakiuria | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Urinary retention | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Leukocyturia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Azotaemia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Chromaturia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Chronic kidney disease | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Glycosuria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nephrolithiasis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nephropathy | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nocturia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal colic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal impairment | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urinary hesitation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urinary incontinence | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urinary tract pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Psychiatric disorders | 15 ( 20.3%) | 10 ( 14.1%) | 25 ( 17.2%) |
| Insomnia | 8 ( 10.8%) | 4 ( 5.6%) | 12 ( 8.3%) |
| Anxiety | 3 ( 4.1%) | 3 ( 4.2%) | 6 ( 4.1%) |
| Depression | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Delirium | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Depressed mood | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Agitation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Confusional state | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Eye disorders | 14 ( 18.9%) | 8 ( 11.3%) | 22 ( 15.2%) |
| Vision blurred | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| Diplopia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Eyelid oedema | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Lacrimation increased | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Uveitis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Blepharitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Conjunctivitis allergic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dry eye | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Erythema of eyelid | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eye pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eye pruritus | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Foreign body sensation in eyes | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Glaucoma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Periorbital swelling | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Photopsia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Visual impairment | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vitreous detachment | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vitreous floaters | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Injury, poisoning and procedural complications | 12 ( 16.2%) | 9 ( 12.7%) | 21 ( 14.5%) |
| Contusion | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Ligament sprain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Procedural pain | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Rib fracture | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Burn oral cavity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Corneal abrasion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Fall | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hip fracture | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Lumbar vertebral fracture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Radiation pneumonitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin abrasion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Soft tissue injury | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Spinal compression fracture | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Sunburn | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Tendon rupture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Thermal burn | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tooth fracture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vascular access site erythema | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Wound complication | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hepatobiliary disorders | 9 ( 12.2%) | 10 ( 14.1%) | 19 ( 13.1%) |
| Hepatotoxicity | 4 ( 5.4%) | 5 ( 7.0%) | 9 ( 6.2%) |
| Hyperbilirubinaemia | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Hepatic function abnormal | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Hypertransaminasaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Jaundice | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Bile duct stone | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Cholecystitis acute | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cholelithiasis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hepatic failure | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ocular icterus | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Reproductive system and breast disorders | 9 ( 12.2%) | 9 ( 12.7%) | 18 ( 12.4%) |
| Testicular pain | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Balanoposthitis | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Benign prostatic hyperplasia | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Acquired phimosis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Pruritus genital | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Testicular swelling | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Genital blister | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Genital burning sensation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Genital erythema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Genital rash | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Penile haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Penile pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Prostatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Scrotal dermatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Scrotal erythema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vaginal lesion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 9 ( 12.2%) | 5 ( 7.0%) | 14 ( 9.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2: Any Treatment Emergent Adverse Event, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Malignant neoplasm progression | 4 ( 5.4%) | 3 ( 4.2%) | 7 ( 4.8%) |
| Cancer pain | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Metastases to central nervous system | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Basal cell carcinoma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Metastases to spine | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin papilloma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardiac disorders | 7 ( 9.5%) | 3 ( 4.2%) | 10 ( 6.9%) |
| Atrial fibrillation | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| Palpitations | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Atrioventricular block complete | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardiac failure | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Cardiac failure congestive | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardio-respiratory arrest | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Myocarditis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tachycardia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ear and labyrinth disorders | 6 ( 8.1%) | 4 ( 5.6%) | 10 ( 6.9%) |
| Vertigo | 4 ( 5.4%) | 1 ( 1.4%) | 5 ( 3.4%) |
| Ear pain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Deafness | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Deafness unilateral | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hypoacusis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tinnitus | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Immune system disorders | 6 ( 8.1%) | 2 ( 2.8%) | 8 ( 5.5%) |
| Hypersensitivity | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Seasonal allergy | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Contrast media allergy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Iodine allergy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Overall | 74 (100.0%) | 70 ( 98.6%) | 144 ( 99.3%) |
| Overall excluding Progression Events | 74 (100.0%) | 70 ( 98.6%) | 144 ( 99.3%) |
| Gastrointestinal disorders | 62 ( 83.8%) | 56 ( 78.9%) | 118 ( 81.4%) |
| Diarrhoea | 49 ( 66.2%) | 31 ( 43.7%) | 80 ( 55.2%) |
| Nausea | 22 ( 29.7%) | 21 ( 29.6%) | 43 ( 29.7%) |
| Stomatitis | 9 ( 12.2%) | 23 ( 32.4%) | 32 ( 22.1%) |
| Vomiting | 13 ( 17.6%) | 13 ( 18.3%) | 26 ( 17.9%) |
| Constipation | 7 ( 9.5%) | 10 ( 14.1%) | 17 ( 11.7%) |
| Dyspepsia | 8 ( 10.8%) | 9 ( 12.7%) | 17 ( 11.7%) |
| Abdominal pain | 11 ( 14.9%) | 5 ( 7.0%) | 16 ( 11.0%) |
| Gastrooesophageal reflux disease | 7 ( 9.5%) | 6 ( 8.5%) | 13 ( 9.0%) |
| Abdominal pain upper | 8 ( 10.8%) | 4 ( 5.6%) | 12 ( 8.3%) |
| Flatulence | 5 ( 6.8%) | 6 ( 8.5%) | 11 ( 7.6%) |
| Dry mouth | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Gingival bleeding | 6 ( 8.1%) | 0 ( 0.0%) | 6 ( 4.1%) |
| Mouth ulceration | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Oral pain | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Haemorrhoids | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Toothache | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Abdominal discomfort | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Dysphagia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Gastritis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Glossodynia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Odynophagia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Proctalgia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Abdominal distension | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Abdominal pain lower | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Anal fissure | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Anal fistula | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Anal inflammation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Aphthous ulcer | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Ascites | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Bowel movement irregularity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cheilitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:42

TABLE 6.2.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Epigastric discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Erosive oesophagitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eructation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Frequent bowel movements | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastritis erosive | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastrointestinal disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gingival pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Haematochezia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Haemorrhoidal haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lip oedema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Melaena | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Perianal erythema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Rectal haemorrhage | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Salivary hypersecretion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| General disorders and administration site conditions | 55 ( 74.3%) | 52 ( 73.2%) | 107 ( 73.8%) |
| Fatigue | 27 ( 36.5%) | 33 ( 46.5%) | 60 ( 41.4%) |
| Mucosal inflammation | 20 ( 27.0%) | 21 ( 29.6%) | 41 ( 28.3%) |
| Asthenia | 14 ( 18.9%) | 11 ( 15.5%) | 25 ( 17.2%) |
| Oedema peripheral | 10 ( 13.5%) | 5 ( 7.0%) | 15 ( 10.3%) |
| Pyrexia | 9 ( 12.2%) | 5 ( 7.0%) | 14 ( 9.7%) |
| Malaise | 6 ( 8.1%) | 3 ( 4.2%) | 9 ( 6.2%) |
| Chills | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Influenza like illness | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Pain | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Chest discomfort | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Chest pain | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Face oedema | 0 ( 0.0%) | 3 ( 4.2%) | 3 ( 2.1%) |
| Non-cardiac chest pain | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Mucosal dryness | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Peripheral swelling | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Swelling face | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Temperature intolerance | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin and subcutaneous tissue disorders | 55 ( 74.3%) | 44 ( 62.0%) | 99 ( 68.3%) |
| Palmar-plantar erythrodysaesthesia syndrome | 31 ( 41.9%) | 34 ( 47.9%) | 65 ( 44.8%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:42

TABLE 6.2.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Pruritus | 18 ( 24.3%) | 3 ( 4.2%) | 21 ( 14.5%) |
| Rash | 14 ( 18.9%) | 4 ( 5.6%) | 18 ( 12.4%) |
| Dry skin | 11 ( 14.9%) | 3 ( 4.2%) | 14 ( 9.7%) |
| Alopecia | 9 ( 12.2%) | 1 ( 1.4%) | 10 ( 6.9%) |
| Rash maculo-papular | 6 ( 8.1%) | 2 ( 2.8%) | 8 ( 5.5%) |
| Yellow skin | 0 ( 0.0%) | 7 ( 9.9%) | 7 ( 4.8%) |
| Erythema | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Acne | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Dermatitis | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Dermatitis acneiform | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Petechiae | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Rash papular | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hair colour changes | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Hyperhidrosis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pemphigoid | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Skin discolouration | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Skin hyperpigmentation | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Skin hypopigmentation | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Skin ulcer | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Urticaria | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blister | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Dermatitis bullous | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Eczema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hyperkeratosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ingrowing nail | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Miliaria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nail discolouration | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nail disorder | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nail dystrophy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pain of skin | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rash macular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Scab | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin exfoliation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:42

TABLE 6.2.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Skin hypertrophy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin lesion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Skin reaction | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin toxicity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Umbilical haemorrhage | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Xeroderma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Investigations | 54 ( 73.0%) | 36 ( 50.7%) | 90 ( 62.1%) |
| Aspartate aminotransferase increased | 20 ( 27.0%) | 12 ( 16.9%) | 32 ( 22.1%) |
| Alanine aminotransferase increased | 20 ( 27.0%) | 7 ( 9.9%) | 27 ( 18.6%) |
| Lipase increased | 11 ( 14.9%) | 12 ( 16.9%) | 23 ( 15.9%) |
| Amylase increased | 13 ( 17.6%) | 7 ( 9.9%) | 20 ( 13.8%) |
| Platelet count decreased | 8 ( 10.8%) | 12 ( 16.9%) | 20 ( 13.8%) |
| Blood creatinine increased | 7 ( 9.5%) | 9 ( 12.7%) | 16 ( 11.0%) |
| Weight decreased | 11 ( 14.9%) | 3 ( 4.2%) | 14 ( 9.7%) |
| Blood alkaline phosphatase increased | 6 ( 8.1%) | 7 ( 9.9%) | 13 ( 9.0%) |
| Blood thyroid stimulating hormone increased | 9 ( 12.2%) | 3 ( 4.2%) | 12 ( 8.3%) |
| Blood cholesterol increased | 5 ( 6.8%) | 5 ( 7.0%) | 10 ( 6.9%) |
| Blood lactate dehydrogenase increased | 6 ( 8.1%) | 1 ( 1.4%) | 7 ( 4.8%) |
| Blood magnesium decreased | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Blood sodium decreased | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Neutrophil count decreased | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Transaminases increased | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Blood phosphorus increased | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| White blood cell count decreased | 1 ( 1.4%) | 3 ( 4.2%) | 4 ( 2.8%) |
| Blood bilirubin increased | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Blood creatine phosphokinase increased | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Blood pressure increased | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hepatic enzyme increased | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Lymphocyte count decreased | 0 ( 0.0%) | 3 ( 4.2%) | 3 ( 2.1%) |
| Urine protein/creatinine ratio increased | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Blood uric acid increased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Gamma-glutamyltransferase increased | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Haematocrit increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Aspartate aminotransferase decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:42

TABLE 6.2.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Blood albumin decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blood calcium decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood phosphorus decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blood potassium decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood thyroid stimulating hormone decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Culture urine positive | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Liver function test abnormal | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Liver function test increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Thyroid function test abnormal | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Thyroxine free increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tri-iodothyronine free decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tri-iodothyronine free increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Weight increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nervous system disorders | 44 ( 59.5%) | 40 ( 56.3%) | 84 ( 57.9%) |
| Dysgeusia | 22 ( 29.7%) | 22 ( 31.0%) | 44 ( 30.3%) |
| Headache | 14 ( 18.9%) | 8 ( 11.3%) | 22 ( 15.2%) |
| Dizziness | 13 ( 17.6%) | 5 ( 7.0%) | 18 ( 12.4%) |
| Paraesthesia | 6 ( 8.1%) | 4 ( 5.6%) | 10 ( 6.9%) |
| Sciatica | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Hypoaesthesia | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Peripheral sensory neuropathy | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Presyncope | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Taste disorder | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Tremor | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Ageusia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Disturbance in attention | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hypogeusia | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Neuropathy peripheral | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Syncope | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Head discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Migraine | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Neuralgia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Peripheral motor neuropathy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Speech disorder | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:43

TABLE 6.2.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Metabolism and nutrition disorders | 52 ( 70.3%) | 27 ( 38.0%) | 79 ( 54.5%) |
| Decreased appetite | 27 ( 36.5%) | 9 ( 12.7%) | 36 ( 24.8%) |
| Hypomagnesaemia | 13 ( 17.6%) | 3 ( 4.2%) | 16 ( 11.0%) |
| Hyperglycaemia | 7 ( 9.5%) | 7 ( 9.9%) | 14 ( 9.7%) |
| Hyponatraemia | 8 ( 10.8%) | 5 ( 7.0%) | 13 ( 9.0%) |
| Hypocalcaemia | 8 ( 10.8%) | 2 ( 2.8%) | 10 ( 6.9%) |
| Hypophosphataemia | 7 ( 9.5%) | 2 ( 2.8%) | 9 ( 6.2%) |
| Hypokalaemia | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Hypertriglyceridaemia | 3 ( 4.1%) | 3 ( 4.2%) | 6 ( 4.1%) |
| Hypoalbuminaemia | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Hyperkalaemia | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Hyperuricaemia | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Dehydration | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Hypercholesterolaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hyperlipasaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Fluid retention | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Glucose tolerance impaired | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Gout | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperamylasaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypercalcaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperchloraemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypercreatininaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypernatraemia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hypoglycaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Musculoskeletal and connective tissue disorders | 39 ( 52.7%) | 27 ( 38.0%) | 66 ( 45.5%) |
| Arthralgia | 15 ( 20.3%) | 5 ( 7.0%) | 20 ( 13.8%) |
| Back pain | 12 ( 16.2%) | 5 ( 7.0%) | 17 ( 11.7%) |
| Pain in extremity | 8 ( 10.8%) | 7 ( 9.9%) | 15 ( 10.3%) |
| Muscle spasms | 11 ( 14.9%) | 1 ( 1.4%) | 12 ( 8.3%) |
| Myalgia | 4 ( 5.4%) | 6 ( 8.5%) | 10 ( 6.9%) |
| Musculoskeletal pain | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Musculoskeletal chest pain | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Muscular weakness | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Neck pain | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:43

TABLE 6.2.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Bone pain | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Groin pain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Myopathy | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Arthritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Flank pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Metatarsalgia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Mobility decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Musculoskeletal discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Musculoskeletal stiffness | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Periarthritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rotator cuff syndrome | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Spinal pain | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Synovitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tendonitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Respiratory, thoracic and mediastinal disorders | 39 ( 52.7%) | 22 ( 31.0%) | 61 ( 42.1%) |
| Cough | 18 ( 24.3%) | 13 ( 18.3%) | 31 ( 21.4%) |
| Oropharyngeal pain | 14 ( 18.9%) | 4 ( 5.6%) | 18 ( 12.4%) |
| Dysphonia | 15 ( 20.3%) | 1 ( 1.4%) | 16 ( 11.0%) |
| Dyspnoea | 8 ( 10.8%) | 5 ( 7.0%) | 13 ( 9.0%) |
| Epistaxis | 4 ( 5.4%) | 6 ( 8.5%) | 10 ( 6.9%) |
| Rhinorrhoea | 4 ( 5.4%) | 1 ( 1.4%) | 5 ( 3.4%) |
| Dyspnoea exertional | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| Haemoptysis | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Nasal congestion | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Productive cough | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Respiratory tract congestion | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Rhinitis allergic | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hiccups | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Nasal dryness | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Bronchospasm | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Catarrh | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Chronic obstructive pulmonary disease | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nasal discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pneumonitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:43

TABLE 6.2.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Rhinalgia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Sinus congestion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Sneezing | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Upper-airway cough syndrome | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Wheezing | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood and lymphatic system disorders | 22 ( 29.7%) | 29 ( 40.8%) | 51 ( 35.2%) |
| Anaemia | 9 ( 12.2%) | 17 ( 23.9%) | 26 ( 17.9%) |
| Thrombocytopenia | 10 ( 13.5%) | 16 ( 22.5%) | 26 ( 17.9%) |
| Leukopenia | 3 ( 4.1%) | 7 ( 9.9%) | 10 ( 6.9%) |
| Neutropenia | 4 ( 5.4%) | 5 ( 7.0%) | 9 ( 6.2%) |
| Lymphopenia | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Eosinophilia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Increased tendency to bruise | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lymphadenopathy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pancytopenia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Infections and infestations | 27 ( 36.5%) | 14 ( 19.7%) | 41 ( 28.3%) |
| Upper respiratory tract infection | 5 ( 6.8%) | 4 ( 5.6%) | 9 ( 6.2%) |
| Nasopharyngitis | 4 ( 5.4%) | 3 ( 4.2%) | 7 ( 4.8%) |
| Influenza | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Urinary tract infection | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Rhinitis | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Bronchitis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Ear infection | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Laryngitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pharyngitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Abdominal sepsis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Candida infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Conjunctivitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dermatophytosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Furuncle | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastroenteritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gingivitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Groin infection | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Lower respiratory tract infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:43

TABLE 6.2.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Nail infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Otitis media | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Paronychia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rash pustular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory tract infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tinea cruris | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tonsillitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tooth abscess | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tooth infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vulvovaginal candidiasis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vulvovaginal mycotic infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Wound infection staphylococcal | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Endocrine disorders | 19 ( 25.7%) | 15 ( 21.1%) | 34 ( 23.4%) |
| Hypothyroidism | 13 ( 17.6%) | 13 ( 18.3%) | 26 ( 17.9%) |
| Hyperthyroidism | 7 ( 9.5%) | 5 ( 7.0%) | 12 ( 8.3%) |
| Thyroiditis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Adrenal insufficiency | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vascular disorders | 19 ( 25.7%) | 15 ( 21.1%) | 34 ( 23.4%) |
| Hypertension | 14 ( 18.9%) | 13 ( 18.3%) | 27 ( 18.6%) |
| Hot flush | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Pallor | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood pressure fluctuation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Deep vein thrombosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypotension | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Peripheral coldness | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vein rupture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal and urinary disorders | 21 ( 28.4%) | 12 ( 16.9%) | 33 ( 22.8%) |
| Proteinuria | 6 ( 8.1%) | 3 ( 4.2%) | 9 ( 6.2%) |
| Haematuria | 3 ( 4.1%) | 4 ( 5.6%) | 7 ( 4.8%) |
| Renal failure | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Dysuria | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Acute kidney injury | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Leukocyturia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:43

TABLE 6.2.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Pollakiuria | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Chromaturia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Glycosuria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nephrolithiasis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nephropathy | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nocturia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal impairment | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urinary hesitation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urinary incontinence | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Injury, poisoning and procedural complications | 12 ( 16.2%) | 8 ( 11.3%) | 20 ( 13.8%) |
| Contusion | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Ligament sprain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Rib fracture | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Burn oral cavity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Corneal abrasion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Fall | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Procedural pain | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Radiation pneumonitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin abrasion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Soft tissue injury | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Spinal compression fracture | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Sunburn | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tendon rupture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Thermal burn | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tooth fracture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vascular access site erythema | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Wound complication | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Eye disorders | 13 ( 17.6%) | 6 ( 8.5%) | 19 ( 13.1%) |
| Vision blurred | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| Diplopia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Eyelid oedema | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Lacrimation increased | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Blepharitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Conjunctivitis allergic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:43

TABLE 6.2.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Dry eye | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Erythema of eyelid | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eye pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eye pruritus | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Foreign body sensation in eyes | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Periorbital swelling | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Photopsia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Uveitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Visual impairment | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vitreous floaters | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Psychiatric disorders | 12 ( 16.2%) | 6 ( 8.5%) | 18 ( 12.4%) |
| Insomnia | 5 ( 6.8%) | 4 ( 5.6%) | 9 ( 6.2%) |
| Depression | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Anxiety | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Agitation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Confusional state | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Delirium | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Depressed mood | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hepatobiliary disorders | 8 ( 10.8%) | 7 ( 9.9%) | 15 ( 10.3%) |
| Hepatotoxicity | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Hyperbilirubinaemia | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Hepatic function abnormal | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Hypertransaminasaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Jaundice | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Ocular icterus | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Reproductive system and breast disorders | 7 ( 9.5%) | 8 ( 11.3%) | 15 ( 10.3%) |
| Testicular pain | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Acquired phimosis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Balanoposthitis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Pruritus genital | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Testicular swelling | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Genital blister | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Genital burning sensation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Genital erythema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:43

TABLE 6.2.2.1: CTCAE-grade 1 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Genital rash | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Penile haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Penile pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Prostatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Scrotal dermatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Scrotal erythema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vaginal lesion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ear and labyrinth disorders | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Vertigo | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Ear pain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Deafness | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hypoacusis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tinnitus | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Immune system disorders | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Hypersensitivity | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Seasonal allergy | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Cardiac disorders | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Palpitations | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Myocarditis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tachycardia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin papilloma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:43

TABLE 6.2.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Overall | 73 ( 98.6%) | 68 ( 95.8%) | 141 ( 97.2%) |
| Overall excluding Progression Events | 73 ( 98.6%) | 68 ( 95.8%) | 141 ( 97.2%) |
| Gastrointestinal disorders | 42 ( 56.8%) | 42 ( 59.2%) | 84 ( 57.9%) |
| Diarrhoea | 28 ( 37.8%) | 16 ( 22.5%) | 44 ( 30.3%) |
| Nausea | 7 ( 9.5%) | 12 ( 16.9%) | 19 ( 13.1%) |
| Stomatitis | 6 ( 8.1%) | 9 ( 12.7%) | 15 ( 10.3%) |
| Vomiting | 5 ( 6.8%) | 7 ( 9.9%) | 12 ( 8.3%) |
| Abdominal pain | 2 ( 2.7%) | 7 ( 9.9%) | 9 ( 6.2%) |
| Dyspepsia | 3 ( 4.1%) | 5 ( 7.0%) | 8 ( 5.5%) |
| Gastrooesophageal reflux disease | 3 ( 4.1%) | 5 ( 7.0%) | 8 ( 5.5%) |
| Abdominal pain upper | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Constipation | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Anal inflammation | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Ascites | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Food poisoning | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Gastrointestinal toxicity | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Toothache | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Abdominal distension | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Anal fistula | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cheilitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Colitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Colitis ulcerative | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Dental caries | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dry mouth | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Flatulence | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Frequent bowel movements | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Haemorrhoids | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lower gastrointestinal haemorrhage | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Odynophagia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Proctitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Retching | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Salivary hypersecretion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Investigations | 34 ( 45.9%) | 34 ( 47.9%) | 68 ( 46.9%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:44

TABLE 6.2.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Lipase increased | 7 ( 9.5%) | 6 ( 8.5%) | 13 ( 9.0%) |
| Alanine aminotransferase increased | 8 ( 10.8%) | 4 ( 5.6%) | 12 ( 8.3%) |
| Amylase increased | 6 ( 8.1%) | 5 ( 7.0%) | 11 ( 7.6%) |
| Aspartate aminotransferase increased | 6 ( 8.1%) | 4 ( 5.6%) | 10 ( 6.9%) |
| Blood creatinine increased | 4 ( 5.4%) | 6 ( 8.5%) | 10 ( 6.9%) |
| Neutrophil count decreased | 2 ( 2.7%) | 7 ( 9.9%) | 9 ( 6.2%) |
| Platelet count decreased | 0 ( 0.0%) | 9 ( 12.7%) | 9 ( 6.2%) |
| Blood bilirubin increased | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Weight decreased | 6 ( 8.1%) | 0 ( 0.0%) | 6 ( 4.1%) |
| Blood alkaline phosphatase increased | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Blood thyroid stimulating hormone increased | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Lymphocyte count decreased | 0 ( 0.0%) | 3 ( 4.2%) | 3 ( 2.1%) |
| Transaminases increased | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| White blood cell count decreased | 0 ( 0.0%) | 3 ( 4.2%) | 3 ( 2.1%) |
| Blood cholesterol increased | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Blood creatine phosphokinase increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood phosphorus decreased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Blood pressure increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood urea increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood albumin decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Cortisol decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gamma-glutamyltransferase increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Glomerular filtration rate decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urine osmolarity decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urine protein/creatinine ratio increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vitamin B12 decreased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| General disorders and administration site conditions | 29 ( 39.2%) | 26 ( 36.6%) | 55 ( 37.9%) |
| Fatigue | 15 ( 20.3%) | 11 ( 15.5%) | 26 ( 17.9%) |
| Mucosal inflammation | 5 ( 6.8%) | 10 ( 14.1%) | 15 ( 10.3%) |
| Asthenia | 6 ( 8.1%) | 5 ( 7.0%) | 11 ( 7.6%) |
| Pyrexia | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Influenza like illness | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Oedema peripheral | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Pain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:44

TABLE 6.2.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Catheter site pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Chest discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Chills | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Face oedema | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperthermia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Skin and subcutaneous tissue disorders | 26 ( 35.1%) | 26 ( 36.6%) | 52 ( 35.9%) |
| Palmar-plantar erythrodysaesthesia syndrome | 16 ( 21.6%) | 20 ( 28.2%) | 36 ( 24.8%) |
| Rash | 4 ( 5.4%) | 1 ( 1.4%) | 5 ( 3.4%) |
| Rash maculo-papular | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Alopecia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Dermatitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Erythema | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pruritus | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Angioedema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Decubitus ulcer | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dermatitis bullous | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dry skin | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eczema | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Eczema asteatotic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hair colour changes | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nail dystrophy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Night sweats | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pemphigoid | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pemphigus | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Rash papular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rash pruritic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin reaction | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Yellow skin | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vascular disorders | 24 ( 32.4%) | 27 ( 38.0%) | 51 ( 35.2%) |
| Hypertension | 21 ( 28.4%) | 26 ( 36.6%) | 47 ( 32.4%) |
| Deep vein thrombosis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Embolism | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pallor | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Phlebitis superficial | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Vascular occlusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Metabolism and nutrition disorders | 30 ( 40.5%) | 16 ( 22.5%) | 46 ( 31.7%) |
| Decreased appetite | 11 ( 14.9%) | 8 ( 11.3%) | 19 ( 13.1%) |
| Hypophosphataemia | 7 ( 9.5%) | 3 ( 4.2%) | 10 ( 6.9%) |
| Hypertriglyceridaemia | 2 ( 2.7%) | 4 ( 5.6%) | 6 ( 4.1%) |
| Hyperglycaemia | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Hypomagnesaemia | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| Hyperkalaemia | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hyperuricaemia | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hypokalaemia | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Hypercholesterolaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hypoalbuminaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hypocalcaemia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Hyponatraemia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Fluid overload | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperamylasaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperlipasaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vitamin D deficiency | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Endocrine disorders | 19 ( 25.7%) | 22 ( 31.0%) | 41 ( 28.3%) |
| Hypothyroidism | 12 ( 16.2%) | 19 ( 26.8%) | 31 ( 21.4%) |
| Hyperthyroidism | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Adrenal insufficiency | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Adrenal haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypothalamo-pituitary disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Infections and infestations | 22 ( 29.7%) | 13 ( 18.3%) | 35 ( 24.1%) |
| Urinary tract infection | 3 ( 4.1%) | 5 ( 7.0%) | 8 ( 5.5%) |
| Pneumonia | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Tooth infection | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Upper respiratory tract infection | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Bronchitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Conjunctivitis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Cystitis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Lower respiratory tract infection | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Nasopharyngitis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:44

TABLE 6.2.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Sinusitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Body tinea | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cellulitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Clostridium difficile infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Diverticulitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Epididymitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gingivitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Oral herpes | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Otitis media | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Periodontitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Peritonsillitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pharyngitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory tract infection viral | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tinea cruris | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Tooth abscess | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood and lymphatic system disorders | 7 ( 9.5%) | 23 ( 32.4%) | 30 ( 20.7%) |
| Neutropenia | 2 ( 2.7%) | 13 ( 18.3%) | 15 ( 10.3%) |
| Thrombocytopenia | 1 ( 1.4%) | 9 ( 12.7%) | 10 ( 6.9%) |
| Anaemia | 4 ( 5.4%) | 3 ( 4.2%) | 7 ( 4.8%) |
| Leukopenia | 0 ( 0.0%) | 5 ( 7.0%) | 5 ( 3.4%) |
| Leukocytosis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Lymphopenia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Musculoskeletal and connective tissue disorders | 15 ( 20.3%) | 15 ( 21.1%) | 30 ( 20.7%) |
| Arthralgia | 7 ( 9.5%) | 4 ( 5.6%) | 11 ( 7.6%) |
| Pain in extremity | 1 ( 1.4%) | 5 ( 7.0%) | 6 ( 4.1%) |
| Back pain | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Muscle spasms | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Myalgia | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Arthritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Bone pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Bursitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Flank pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Joint swelling | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:44

TABLE 6.2.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Muscular weakness | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Musculoskeletal pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Neck mass | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Neck pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Osteoporosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Periarthritis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Plantar fasciitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Soft tissue necrosis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal and urinary disorders | 10 ( 13.5%) | 8 ( 11.3%) | 18 ( 12.4%) |
| Proteinuria | 4 ( 5.4%) | 5 ( 7.0%) | 9 ( 6.2%) |
| Urinary retention | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Acute kidney injury | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Renal failure | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Azotaemia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Dysuria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Haematuria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pollakiuria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal impairment | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Urinary tract pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory, thoracic and mediastinal disorders | 15 ( 20.3%) | 3 ( 4.2%) | 18 ( 12.4%) |
| Dyspnoea | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Dysphonia | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Oropharyngeal pain | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pneumonitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Chronic obstructive pulmonary disease | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cough | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dyspnoea exertional | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Epistaxis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pleural effusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pneumothorax | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Productive cough | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pulmonary embolism | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory tract congestion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rhinitis allergic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:44

TABLE 6.2.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Rhinorrhoea | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nervous system disorders | 9 ( 12.2%) | 7 ( 9.9%) | 16 ( 11.0%) |
| Dysgeusia | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Headache | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Neuropathy peripheral | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Sciatica | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Syncope | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Aphasia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cauda equina syndrome | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Dizziness | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Dysarthria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nervous system disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Paraesthesia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Radicular pain | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hepatobiliary disorders | 6 ( 8.1%) | 6 ( 8.5%) | 12 ( 8.3%) |
| Hepatotoxicity | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Hyperbilirubinaemia | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Hepatic function abnormal | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Cholelithiasis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Psychiatric disorders | 6 ( 8.1%) | 4 ( 5.6%) | 10 ( 6.9%) |
| Anxiety | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Insomnia | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Depressed mood | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Depression | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Delirium | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Injury, poisoning and procedural complications | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Procedural pain | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Ligament sprain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lumbar vertebral fracture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Reproductive system and breast disorders | 4 ( 5.4%) | 0 ( 0.0%) | 4 ( 2.8%) |
| Benign prostatic hyperplasia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Balanoposthitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Scrotal dermatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Testicular pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:45

TABLE 6.2.2.2: CTCAE-grade 2 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Eye disorders | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Uveitis | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Glaucoma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Basal cell carcinoma | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cancer pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Metastases to central nervous system | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Cardiac disorders | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Atrial fibrillation | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Myocarditis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Immune system disorders | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Contrast media allergy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Iodine allergy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ear and labyrinth disorders | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vertigo | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:45

TABLE 6.2.2.3: CTCAE-grade 3 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Overall | 57 ( 77.0%) | 48 ( 67.6%) | 105 ( 72.4%) |
| Overall excluding Progression Events | 57 ( 77.0%) | 48 ( 67.6%) | 105 ( 72.4%) |
| Investigations | 13 ( 17.6%) | 20 ( 28.2%) | 33 ( 22.8%) |
| Lipase increased | 5 ( 6.8%) | 5 ( 7.0%) | 10 ( 6.9%) |
| Alanine aminotransferase increased | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Amylase increased | 3 ( 4.1%) | 3 ( 4.2%) | 6 ( 4.1%) |
| Neutrophil count decreased | 0 ( 0.0%) | 6 ( 8.5%) | 6 ( 4.1%) |
| Transaminases increased | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Aspartate aminotransferase increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood creatinine increased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Platelet count decreased | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Blood alkaline phosphatase increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood bilirubin increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blood creatine phosphokinase increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Blood magnesium decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blood pressure increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Creatinine urine increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gamma-glutamyltransferase increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Protein urine present | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| White blood cell count decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Metabolism and nutrition disorders | 20 ( 27.0%) | 12 ( 16.9%) | 32 ( 22.1%) |
| Hyponatraemia | 7 ( 9.5%) | 6 ( 8.5%) | 13 ( 9.0%) |
| Hypophosphataemia | 5 ( 6.8%) | 1 ( 1.4%) | 6 ( 4.1%) |
| Hyperglycaemia | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Hyperkalaemia | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Hypertriglyceridaemia | 0 ( 0.0%) | 3 ( 4.2%) | 3 ( 2.1%) |
| Decreased appetite | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Dehydration | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hypokalaemia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Electrolyte imbalance | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperamylasaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypercholesterolaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hyperlipasaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypocalcaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:46

TABLE 6.2.2.3: CTCAE-grade 3 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Hypomagnesaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastrointestinal disorders | 15 ( 20.3%) | 13 ( 18.3%) | 28 ( 19.3%) |
| Diarrhoea | 8 ( 10.8%) | 4 ( 5.6%) | 12 ( 8.3%) |
| Stomatitis | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Vomiting | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Abdominal pain | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Abdominal distension | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Abdominal pain upper | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Anal inflammation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Colitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Colitis ischaemic | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Epigastric discomfort | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lower gastrointestinal haemorrhage | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Mouth ulceration | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nausea | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Segmental diverticular colitis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vascular disorders | 12 ( 16.2%) | 16 ( 22.5%) | 28 ( 19.3%) |
| Hypertension | 12 ( 16.2%) | 16 ( 22.5%) | 28 ( 19.3%) |
| Embolism | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin and subcutaneous tissue disorders | 10 ( 13.5%) | 10 ( 14.1%) | 20 ( 13.8%) |
| Palmar-plantar erythrodysaesthesia syndrome | 5 ( 6.8%) | 10 ( 14.1%) | 15 ( 10.3%) |
| Rash | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Nail dystrophy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pruritus | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rash maculo-papular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Rash papular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin exfoliation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin toxicity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin ulcer | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| General disorders and administration site conditions | 10 ( 13.5%) | 6 ( 8.5%) | 16 ( 11.0%) |
| Asthenia | 6 ( 8.1%) | 1 ( 1.4%) | 7 ( 4.8%) |
| Fatigue | 2 ( 2.7%) | 3 ( 4.2%) | 5 ( 3.4%) |
| Mucosal inflammation | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Face oedema | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:46

TABLE 6.2.2.3: CTCAE-grade 3 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Gait disturbance | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| General physical health deterioration | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Malaise | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pyrexia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory, thoracic and mediastinal disorders | 10 ( 13.5%) | 2 ( 2.8%) | 12 ( 8.3%) |
| Pulmonary embolism | 6 ( 8.1%) | 1 ( 1.4%) | 7 ( 4.8%) |
| Dyspnoea | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Chronic obstructive pulmonary disease | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lung disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Oropharyngeal pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pneumonitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Productive cough | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Infections and infestations | 7 ( 9.5%) | 2 ( 2.8%) | 9 ( 6.2%) |
| Lung abscess | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pneumonia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Cystitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Febrile infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Infectious pleural effusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Large intestine infection | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pseudomonas infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Tooth infection | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blood and lymphatic system disorders | 0 ( 0.0%) | 8 ( 11.3%) | 8 ( 5.5%) |
| Neutropenia | 0 ( 0.0%) | 4 ( 5.6%) | 4 ( 2.8%) |
| Thrombocytopenia | 0 ( 0.0%) | 4 ( 5.6%) | 4 ( 2.8%) |
| Anaemia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Leukopenia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Lymphopenia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Musculoskeletal and connective tissue disorders | 4 ( 5.4%) | 3 ( 4.2%) | 7 ( 4.8%) |
| Back pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Bone lesion | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Flank pain | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Intervertebral disc protrusion | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Muscular weakness | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Neck pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:46

TABLE 6.2.2.3: CTCAE-grade 3 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Osteonecrosis | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Renal and urinary disorders | 5 ( 6.8%) | 2 ( 2.8%) | 7 ( 4.8%) |
| Proteinuria | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Chronic kidney disease | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Glycosuria | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal colic | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal failure | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hepatobiliary disorders | 4 ( 5.4%) | 2 ( 2.8%) | 6 ( 4.1%) |
| Hepatotoxicity | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Bile duct stone | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Cholecystitis acute | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hepatic failure | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hepatic function abnormal | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nervous system disorders | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Headache | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Ischaemic stroke | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Lethargy | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Paraplegia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Spinal cord compression | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 ( 2.7%) | 2 ( 2.8%) | 4 ( 2.8%) |
| Cancer pain | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Malignant neoplasm progression | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Metastases to central nervous system | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Metastases to spine | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardiac disorders | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Atrial fibrillation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardiac failure congestive | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Myocarditis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Reproductive system and breast disorders | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Benign prostatic hyperplasia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Prostatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Scrotal dermatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Endocrine disorders | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hyperthyroidism | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:46

TABLE 6.2.2.3: CTCAE-grade 3 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Hypothalamo-pituitary disorder | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Eye disorders | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Uveitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Vitreous detachment | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Injury, poisoning and procedural complications | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Hip fracture | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Lumbar vertebral fracture | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Ear and labyrinth disorders | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Deafness unilateral | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:46

TABLE 6.2.2.4: CTCAE-grade 4 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Overall | 11 ( 14.9%) | 8 ( 11.3%) | 19 ( 13.1%) |
| Overall excluding Progression Events | 11 ( 14.9%) | 8 ( 11.3%) | 19 ( 13.1%) |
| Metabolism and nutrition disorders | 4 ( 5.4%) | 3 ( 4.2%) | 7 ( 4.8%) |
| Hyperlipasaemia | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hyponatraemia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Dehydration | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hyperkalaemia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypertriglyceridaemia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Investigations | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Lipase increased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Neutrophil count decreased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blood and lymphatic system disorders | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Thrombocytopenia | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Cardiac disorders | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Atrial fibrillation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardiac failure | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Nervous system disorders | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Haemorrhage intracranial | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Sciatica | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Respiratory, thoracic and mediastinal disorders | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Pulmonary embolism | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory failure | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Gastrointestinal disorders | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Small intestinal perforation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| General disorders and administration site conditions | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Mucosal inflammation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Hepatobiliary disorders | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hepatotoxicity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Infections and infestations | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Sepsis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Musculoskeletal and connective tissue disorders | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Spinal pain | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Malignant neoplasm progression | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.2.2.4: CTCAE-grade 4 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Renal and urinary disorders | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Acute kidney injury | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Vascular disorders | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hypertension | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:47

TABLE 6.2.2.5: CTCAE-grade 5 Treatment Emergent Adverse Events, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Overall | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Overall excluding Progression Events | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Malignant neoplasm progression | 3 ( 4.1%) | 2 ( 2.8%) | 5 ( 3.4%) |
| Cardiac disorders | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Atrioventricular block complete | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardio-respiratory arrest | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Gastrointestinal disorders | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Upper gastrointestinal haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:48

TABLE 6.3.1: Treatment Emergent Adverse Events leading to study drug discontinuation, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Overall | 24 ( 32.4%) | 12 ( 16.9%) | 36 ( 24.8%) |
| Overall excluding Progression Events | 24 ( 32.4%) | 9 ( 12.7%) | 33 ( 22.8%) |
| Investigations | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Alanine aminotransferase increased | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Transaminases increased | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Aspartate aminotransferase increased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Blood bilirubin increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Lipase increased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Amylase increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blood creatine phosphokinase increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastrointestinal disorders | 5 ( 6.8%) | 0 ( 0.0%) | 5 ( 3.4%) |
| Diarrhoea | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Small intestinal perforation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Stomatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Upper gastrointestinal haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardiac disorders | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Atrioventricular block complete | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardiac failure congestive | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardio-respiratory arrest | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Myocarditis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin and subcutaneous tissue disorders | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Palmar-plantar erythrodysaesthesia syndrome | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Rash papular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin exfoliation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| General disorders and administration site conditions | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Fatigue | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Mucosal inflammation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pyrexia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hepatobiliary disorders | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Hepatotoxicity | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Hepatic function abnormal | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Metabolism and nutrition disorders | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Hyponatraemia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Dehydration | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:50

TABLE 6.3.1: Treatment Emergent Adverse Events leading to study drug discontinuation, overall and by SOC/PT - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 ( 0.0%) | 3 ( 4.2%) | 3 ( 2.1%) |
| Metastases to central nervous system | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Malignant neoplasm progression | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Renal and urinary disorders | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Proteinuria | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Endocrine disorders | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Adrenal insufficiency | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Musculoskeletal and connective tissue disorders | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Arthralgia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Muscular weakness | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory, thoracic and mediastinal disorders | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pneumonitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood and lymphatic system disorders | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Thrombocytopenia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Eye disorders | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Uveitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Infections and infestations | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pseudomonas infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nervous system disorders | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Haemorrhage intracranial | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:50

TABLE 6.3.2: Treatment Emergent Adverse Events leading to study drug discontinuation, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Overall | 24 ( 32.4%) | 12 ( 16.9%) | 36 ( 24.8%) |
| Overall excluding Progression Events | 24 ( 32.4%) | 9 ( 12.7%) | 33 ( 22.8%) |
| Investigations | 5 ( 6.8%) | 3 ( 4.2%) | 8 ( 5.5%) |
| Alanine aminotransferase increased | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Transaminases increased | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Aspartate aminotransferase increased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Blood bilirubin increased | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Lipase increased | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Amylase increased | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Blood creatine phosphokinase increased | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Gastrointestinal disorders | 6 ( 8.1%) | 0 ( 0.0%) | 6 ( 4.1%) |
| Diarrhoea | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Gastrointestinal toxicity | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Small intestinal perforation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Stomatitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Upper gastrointestinal haemorrhage | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardiac disorders | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Atrioventricular block complete | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardiac failure congestive | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Cardio-respiratory arrest | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Myocarditis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Renal and urinary disorders | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Proteinuria | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Renal failure | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin and subcutaneous tissue disorders | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Palmar-plantar erythrodysaesthesia syndrome | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Rash papular | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Skin exfoliation | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| General disorders and administration site conditions | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Fatigue | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Mucosal inflammation | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Pyrexia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hepatobiliary disorders | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Hepatotoxicity | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
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TABLE 6.3.2: Treatment Emergent Adverse Events leading to study drug discontinuation, overall and by SOC/PT - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Hepatic failure | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Hepatic function abnormal | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Metabolism and nutrition disorders | 1 ( 1.4%) | 2 ( 2.8%) | 3 ( 2.1%) |
| Hyponatraemia | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |
| Dehydration | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 ( 0.0%) | 3 ( 4.2%) | 3 ( 2.1%) |
| Metastases to central nervous system | 0 ( 0.0%) | 2 ( 2.8%) | 2 ( 1.4%) |
| Malignant neoplasm progression | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Endocrine disorders | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Adrenal insufficiency | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Musculoskeletal and connective tissue disorders | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Arthralgia | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Muscular weakness | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Respiratory, thoracic and mediastinal disorders | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Pneumonitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Blood and lymphatic system disorders | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Thrombocytopenia | 0 ( 0.0%) | 1 ( 1.4%) | 1 ( 0.7%) |
| Eye disorders | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Uveitis | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Infections and infestations | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Pseudomonas infection | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Nervous system disorders | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Haemorrhage intracranial | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:51

TABLE 6.4.1: Adverse Event of Special Interest - 30 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Adverse Events of Special Interest - Selected adverse events | 71 ( 95.9%) | 65 ( 91.5%) | 136 ( 93.8%) |
| Endocrine Adverse Event | 35 ( 47.3%) | 29 ( 40.8%) | 64 ( 44.1%) |
| Gastrointestinal Adverse Event | 56 ( 75.7%) | 37 ( 52.1%) | 93 ( 64.1%) |
| Hepatic Adverse Event | 34 ( 45.9%) | 27 ( 38.0%) | 61 ( 42.1%) |
| Hypersensitivity/Infusion Reaction | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Pulmonary Adverse Event | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Renal Adverse Event | 16 ( 21.6%) | 14 ( 19.7%) | 30 ( 20.7%) |
| Skin Adverse Event | 55 ( 74.3%) | 46 ( 64.8%) | 101 ( 69.7%) |
| Adverse Events of Special Interest - immune mediated adverse events | 71 ( 95.9%) | 61 ( 85.9%) | 132 ( 91.0%) |
| Adrenal Insufficiency | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Diarrhea/Colitis | 56 ( 75.7%) | 37 ( 52.1%) | 93 ( 64.1%) |
| Hepatitis | 33 ( 44.6%) | 24 ( 33.8%) | 57 ( 39.3%) |
| Hyperthyroidism | 10 ( 13.5%) | 7 ( 9.9%) | 17 ( 11.7%) |
| Hypothyroidism | 22 ( 29.7%) | 25 ( 35.2%) | 47 ( 32.4%) |
| Thyroiditis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hypothyroidism/Thyroiditis | 22 ( 29.7%) | 25 ( 35.2%) | 47 ( 32.4%) |
| Nephritis And Renal Dysfunction | 15 ( 20.3%) | 14 ( 19.7%) | 29 ( 20.0%) |
| Pneumonitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Rash | 32 ( 43.2%) | 8 ( 11.3%) | 40 ( 27.6%) |
| Adverse Events of Special Interest - other adverse events of special interest | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Myocarditis Event | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Uveitis Event | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:52

TABLE 6.4.2: Adverse Event of Special Interest - 100 day follow-up period - Safety Population A: Favorable risk (IMDC prognostic risk score = 0)



| System Organ Class (SOC)<br>Preferred Term (PT) | Nivolumab + Cabozantinib<br>N=74 | Sunitinib<br>N=71 | Total Population<br>N=145 |
|---|---|---|---|
| Adverse Events of Special Interest - Selected adverse events | 71 ( 95.9%) | 65 ( 91.5%) | 136 ( 93.8%) |
| Endocrine Adverse Event | 35 ( 47.3%) | 29 ( 40.8%) | 64 ( 44.1%) |
| Gastrointestinal Adverse Event | 56 ( 75.7%) | 38 ( 53.5%) | 94 ( 64.8%) |
| Hepatic Adverse Event | 34 ( 45.9%) | 27 ( 38.0%) | 61 ( 42.1%) |
| Hypersensitivity/Infusion Reaction | 3 ( 4.1%) | 1 ( 1.4%) | 4 ( 2.8%) |
| Pulmonary Adverse Event | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Renal Adverse Event | 16 ( 21.6%) | 14 ( 19.7%) | 30 ( 20.7%) |
| Skin Adverse Event | 55 ( 74.3%) | 47 ( 66.2%) | 102 ( 70.3%) |
| Adverse Events of Special Interest - immune mediated adverse events | 71 ( 95.9%) | 61 ( 85.9%) | 132 ( 91.0%) |
| Adrenal Insufficiency | 3 ( 4.1%) | 0 ( 0.0%) | 3 ( 2.1%) |
| Diarrhea/Colitis | 56 ( 75.7%) | 38 ( 53.5%) | 94 ( 64.8%) |
| Hepatitis | 33 ( 44.6%) | 24 ( 33.8%) | 57 ( 39.3%) |
| Hyperthyroidism | 10 ( 13.5%) | 7 ( 9.9%) | 17 ( 11.7%) |
| Hypothyroidism | 22 ( 29.7%) | 25 ( 35.2%) | 47 ( 32.4%) |
| Thyroiditis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Hypothyroidism/Thyroiditis | 22 ( 29.7%) | 25 ( 35.2%) | 47 ( 32.4%) |
| Nephritis And Renal Dysfunction | 15 ( 20.3%) | 14 ( 19.7%) | 29 ( 20.0%) |
| Pneumonitis | 2 ( 2.7%) | 0 ( 0.0%) | 2 ( 1.4%) |
| Rash | 32 ( 43.2%) | 9 ( 12.7%) | 41 ( 28.3%) |
| Adverse Events of Special Interest - other adverse events of special interest | 2 ( 2.7%) | 1 ( 1.4%) | 3 ( 2.1%) |
| Myocarditis Event | 1 ( 1.4%) | 0 ( 0.0%) | 1 ( 0.7%) |
| Uveitis Event | 1 ( 1.4%) | 1 ( 1.4%) | 2 ( 1.4%) |

Note(s):
Safety Population A: Favorable risk (IMDC prognostic risk score = 0)
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.06 Safety Descriptives.sas] run Tuesday, March 23, 2021 at 14:41:53

TABLE 7.1.1: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| subtit | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| N subjects | N=71 | N=68 |
| Subjects with Baseline Value | 71 (100.0%) | 68 (100.0%) |
| Subjects with at least 1 Post-Baseline Value | 71 (100.0%) | 66 (97.1%) |
| Subjects with Baseline Value and at least 1 Post-Baseline Value | 71 (100.0%) | 66 (97.1%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:40:57

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Baseline | n= 71 (100.0%) \| 77.82 (17.62) | n= 68 (100.0%) \| 79.72 (18.21) | -0.11 [-0.44 ; 0.23] |
| Week 3 | n= 67 (94.4%) \| 80.75 (13.53) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 65 (91.5%) \| 77.98 (16.68) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 66 (93.0%) \| 76.74 (17.80) | n= 62 (91.2%) \| 77.55 (17.11) | -0.05 [-0.39 ; 0.30] |
| Week 9 | n= 59 (83.1%) \| 77.75 (16.09) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 61 (85.9%) \| 76.98 (17.50) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 59 (83.1%) \| 74.42 (22.89) | n= 53 (77.9%) \| 79.77 (13.60) | -0.28 [-0.65 ; 0.10] |
| Week 15 | n= 54 (76.1%) \| 75.65 (20.00) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 61 (85.9%) \| 78.66 (15.40) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 57 (80.3%) \| 79.26 (16.46) | n= 53 (77.9%) \| 81.06 (13.50) | -0.12 [-0.49 ; 0.26] |
| Week 21 | n= 60 (84.5%) \| 78.32 (15.81) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 56 (78.9%) \| 76.46 (17.00) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 57 (80.3%) \| 80.81 (11.88) | n= 50 (73.5%) \| 83.96 (11.36) | -0.27 [-0.65 ; 0.11] |
| Week 27 | n= 55 (77.5%) \| 81.35 (12.50) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 53 (74.6%) \| 80.79 (13.70) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \| 81.35 (11.15) | n= 43 (63.2%) \| 81.16 (14.30) | 0.01 [-0.39 ; 0.42] |
| Week 33 | n= 57 (80.3%) \| 80.74 (12.61) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 53 (74.6%) \| 80.51 (13.62) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 49 (69.0%) \| 80.67 (13.38) | n= 46 (67.6%) \| 82.11 (13.60) | -0.11 [-0.51 ; 0.30] |
| Week 39 | n= 53 (74.6%) \| 81.81 (12.57) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 51 (71.8%) \| 81.84 (13.08) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 53 (74.6%) \| 81.34 (13.64) | n= 43 (63.2%) \| 81.37 (14.32) | -0.00 [-0.41 ; 0.40] |
| Week 45 | n= 49 (69.0%) \| 79.78 (13.30) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 52 (73.2%) \| 82.25 (12.03) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 53 (74.6%) \| 81.57 (13.32) | n= 38 (55.9%) \| 81.89 (13.14) | -0.02 [-0.44 ; 0.39] |
| Week 51 | n= 51 (71.8%) \| 81.18 (12.43) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 49 (69.0%) \| 80.02 (18.17) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 47 (66.2%) \| 80.11 (18.09) | n= 37 (54.4%) \| 82.43 (13.98) | -0.14 [-0.57 ; 0.29] |
| Week 57 | n= 47 (66.2%) \| 79.91 (17.53) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 46 (64.8%) \| 79.37 (17.94) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \| 82.00 (12.97) | n= 30 (44.1%) \| 78.40 (15.14) | 0.26 [-0.20 ; 0.72] |
| Week 63 | n= 42 (59.2%) \| 80.21 (14.01) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 44 (62.0%) \| 80.16 (14.88) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \| 82.18 (13.62) | n= 30 (44.1%) \| 82.17 (12.48) | 0.00 [-0.47 ; 0.47] |
| Week 69 | n= 37 (52.1%) \| 80.35 (13.45) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 39 (54.9%) \| 82.49 (14.23) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 34 (47.9%) \| 80.94 (14.33) | n= 28 (41.2%) \| 79.11 (16.63) | 0.12 [-0.39 ; 0.62] |
| Week 75 | n= 36 (50.7%) \| 81.67 (14.90) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \| 81.41 (13.93) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \| 82.16 (16.43) | n= 25 (36.8%) \| 78.80 (16.57) | 0.20 [-0.33 ; 0.73] |
| Week 81 | n= 31 (43.7%) \| 83.26 (12.99) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \| 83.85 (12.96) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \| 86.63 (8.56) | n= 21 (30.9%) \| 81.38 (16.23) | 0.41 [-0.17 ; 1.00] |
| Week 87 | n= 24 (33.8%) \| 81.63 (14.88) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \| 82.52 (12.20) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 24 (33.8%) \| 82.38 (13.30) | n= 16 (23.5%) \| 85.00 (9.69) | -0.21 [-0.86 ; 0.43] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 21 (29.6%) \| 82.95 (14.55) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 22 (31.0%) \| 80.45 (15.00) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) \| 80.38 (16.12) | n= 11 (16.2%) \| 82.64 (11.42) | -0.15 [-0.89 ; 0.59] |
| Week 99 | n= 17 (23.9%) \| 79.00 (15.32) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) \| 80.64 (9.43) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) \| 82.47 (10.28) | n= 10 (14.7%) \| 82.20 (10.86) | 0.02 [-0.79 ; 0.84] |
| Week 105 | n= 14 (19.7%) \| 79.00 (10.78) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) \| 78.50 (10.06) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) \| 78.09 (10.30) | n= 5 ( 7.4%) \| 80.40 (9.07) | -0.22 [-1.32 ; 0.88] |
| Week 111 | n= 7 ( 9.9%) \| 78.00 (9.20) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) \| 81.38 (9.62) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 7 ( 9.9%) \| 82.86 (10.49) | n= 5 ( 7.4%) \| 82.40 (12.16) | 0.04 [-1.17 ; 1.24] |
| Week 117 | n= 7 ( 9.9%) \| 82.86 (5.58) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 ( 9.9%) \| 78.43 (9.40) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) \| 81.38 (11.20) | n= 1 ( 1.5%) \| 92.00 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 2.8%) \| 81.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) \| 89.00 (12.73) | n= 1 ( 1.5%) \| 100.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) \| 81.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.4%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.4%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.4%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.4%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.4%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) \| 78.25 (8.96) | n= 17 (25.0%) \| 78.71 (18.12) | -0.03 [-0.89 ; 0.83] |
| Week 202 | n= 2 ( 2.8%) \| 64.00 (26.87) | n= 12 (17.6%) \| 88.33 (10.26) | -1.82 [-3.55 ;-0.09] |
| Week 301 | n= 2 ( 2.8%) \| 70.00 (28.28) | n= 9 (13.2%) \| 83.22 (7.81) | -1.01 [-2.70 ; 0.68] |
| Week 302 | n= 2 ( 2.8%) \| 65.00 (21.21) | n= 6 ( 8.8%) \| 82.50 (5.24) | -1.54 [-3.51 ; 0.44] |
| Week 303 | n= 3 ( 4.2%) \| 56.67 (20.82) | n= 6 ( 8.8%) \| 82.00 (6.93) | -1.79 [-3.58 ;-0.00] |
| Week 304 | n= 1 ( 1.4%) \| 100.00 ( / ) | n= 3 ( 4.4%) \| 76.67 (11.55) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.5%) \| 75.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.5%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.5%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.5%) \| 90.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.5%) \| 85.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:40:57

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Week 3 | n= 67 (94.4%) \| 1.96 (13.11) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 65 (91.5%) \|-1.23 (15.69) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 66 (93.0%) \|-1.91 (18.22) | n= 62 (91.2%) \|-1.31 (13.90) | -0.04 [-0.38 ; 0.31] |
| Week 9 | n= 59 (83.1%) \|-1.86 (18.27) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 61 (85.9%) \|-1.56 (20.85) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 59 (83.1%) \|-3.76 (23.40) | n= 53 (77.9%) \|-2.25 (18.87) | -0.07 [-0.44 ; 0.30] |
| Week 15 | n= 54 (76.1%) \|-2.52 (23.18) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 61 (85.9%) \| 0.90 (17.41) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 57 (80.3%) \| 0.70 (16.68) | n= 53 (77.9%) \|-2.58 (10.19) | 0.23 [-0.14 ; 0.61] |
| Week 21 | n= 60 (84.5%) \| 0.08 (16.52) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 56 (78.9%) \|-0.75 (17.96) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 57 (80.3%) \| 1.33 (13.71) | n= 50 (73.5%) \| 1.32 (16.02) | 0.00 [-0.38 ; 0.38] |
| Week 27 | n= 55 (77.5%) \| 2.24 (14.06) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 53 (74.6%) \| 1.89 (14.89) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \| 3.09 (13.62) | n= 43 (63.2%) \|-2.70 (13.65) | 0.42 [ 0.01 ; 0.83] |
| Week 33 | n= 57 (80.3%) \| 0.81 (12.16) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 53 (74.6%) \| 2.02 (13.61) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 49 (69.0%) \| 2.49 (14.24) | n= 46 (67.6%) \|-1.37 (11.60) | 0.29 [-0.11 ; 0.70] |
| Week 39 | n= 53 (74.6%) \| 3.25 (13.08) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 51 (71.8%) \| 1.18 (12.19) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 53 (74.6%) \| 2.23 (14.21) | n= 43 (63.2%) \|-1.58 (13.95) | 0.27 [-0.14 ; 0.67] |
| Week 45 | n= 49 (69.0%) \| 0.63 (12.92) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 52 (73.2%) \| 3.48 (13.28) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 53 (74.6%) \| 2.96 (13.21) | n= 38 (55.9%) \|-1.05 (12.28) | 0.31 [-0.11 ; 0.73] |
| Week 51 | n= 51 (71.8%) \| 1.25 (10.52) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 49 (69.0%) \| 0.04 (18.16) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 47 (66.2%) \| 1.36 (17.66) | n= 37 (54.4%) \|-1.19 (14.35) | 0.16 [-0.28 ; 0.59] |
| Week 57 | n= 47 (66.2%) \| 0.55 (17.73) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 46 (64.8%) \| 0.30 (13.66) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \| 1.94 (12.29) | n= 30 (44.1%) \|-5.23 (14.48) | 0.54 [ 0.07 ; 1.01] |
| Week 63 | n= 42 (59.2%) \| 0.00 (9.84) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 44 (62.0%) \| 2.39 (11.49) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \| 2.30 (12.95) | n= 30 (44.1%) \|-1.40 (13.70) | 0.28 [-0.19 ; 0.75] |
| Week 69 | n= 37 (52.1%) \| 0.89 (14.20) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 39 (54.9%) \| 1.03 (11.81) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 34 (47.9%) \| 0.06 (12.35) | n= 28 (41.2%) \|-2.75 (14.15) | 0.21 [-0.30 ; 0.72] |
| Week 75 | n= 36 (50.7%) \| 0.36 (11.69) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \| 2.66 (14.85) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \| 1.29 (12.31) | n= 25 (36.8%) \|-2.56 (14.61) | 0.28 [-0.25 ; 0.82] |
| Week 81 | n= 31 (43.7%) \| 0.97 (12.14) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \| 1.45 (11.97) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \| 2.04 (10.41) | n= 21 (30.9%) \|-3.57 (13.41) | 0.47 [-0.12 ; 1.05] |
| Week 87 | n= 24 (33.8%) \|-0.13 (11.73) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \| 0.20 (10.92) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 24 (33.8%) \| 0.04 (11.56) | n= 16 (23.5%) \| 0.38 (11.14) | -0.03 [-0.67 ; 0.61] |
| Week 93 | n= 21 (29.6%) \| 1.81 (10.50) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 95 | n= 22 (31.0%) \|-2.23 (9.10) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) \|-1.95 (9.94) | n= 11 (16.2%) \|-2.27 (6.17) | 0.04 [-0.71 ; 0.78] |
| Week 99 | n= 17 (23.9%) \|-0.94 (9.42) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) \|-1.43 (8.75) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) \| 0.80 (7.49) | n= 10 (14.7%) \|-1.80 (8.42) | 0.32 [-0.50 ; 1.14] |
| Week 105 | n= 14 (19.7%) \|-2.86 (9.16) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) \| 0.50 (5.86) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) \|-1.91 (9.20) | n= 5 ( 7.4%) \|-7.60 (12.66) | 0.52 [-0.59 ; 1.63] |
| Week 111 | n= 7 ( 9.9%) \|-1.14 (5.37) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) \|-3.50 (10.11) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 7 ( 9.9%) \|-1.00 (13.06) | n= 5 ( 7.4%) \|-5.60 (18.32) | 0.28 [-0.93 ; 1.49] |
| Week 117 | n= 7 ( 9.9%) \|-4.14 (11.51) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 ( 9.9%) \|-5.86 (11.42) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) \|-2.38 (9.47) | n= 1 ( 1.5%) \|-8.00 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 2.8%) \|-13.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) \|-3.50 (16.26) | n= 1 ( 1.5%) \| 0.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.4%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.4%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.4%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.4%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.4%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) \| 2.50 (21.70) | n= 17 (25.0%) \|-7.76 (14.80) | 0.58 [-0.30 ; 1.45] |
| Week 202 | n= 2 ( 2.8%) \|-4.50 (0.71) | n= 12 (17.6%) \|-0.42 (10.81) | -0.37 [-1.93 ; 1.20] |
| Week 301 | n= 2 ( 2.8%) \| 5.00 (7.07) | n= 9 (13.2%) \| 1.89 (11.04) | 0.27 [-1.36 ; 1.89] |
| Week 302 | n= 2 ( 2.8%) \|-10.00 (14.14) | n= 6 ( 8.8%) \| 1.67 (9.03) | -1.01 [-2.85 ; 0.84] |
| Week 303 | n= 3 ( 4.2%) \|-3.33 (15.28) | n= 6 ( 8.8%) \| 14.00 (28.96) | -0.60 [-2.12 ; 0.93] |
| Week 304 | n= 1 ( 1.4%) \| 0.00 ( / ) | n= 3 ( 4.4%) \| 2.00 (15.87) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.5%) \| 67.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.5%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.5%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.5%) \| 82.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.5%) \| 77.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:40:57

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| Nr subjects used | n=71 | n=68 | | |
| Week 7 | -4.28 (2.06) [-8.35 ;-0.22] | -3.12 (2.12) [-7.32 ; 1.08] | -1.17 (2.84) [-6.79 ; 4.45] | -0.07 [-0.42 ; 0.28] |
| Week 13 | -7.90 (2.85) [-13.55 ;-2.25] | -1.84 (2.98) [-7.74 ; 4.07] | -6.07 (4.05) [-14.08 ; 1.95] | -0.28 [-0.65 ; 0.10] |
| Week 19 | -2.31 (2.00) [-6.27 ; 1.65] | -1.68 (2.09) [-5.81 ; 2.45] | -0.63 (2.78) [-6.12 ; 4.87] | -0.04 [-0.42 ; 0.33] |
| Week 25 | -0.68 (1.54) [-3.72 ; 2.37] | 1.02 (1.63) [-2.21 ; 4.24] | -1.69 (2.09) [-5.83 ; 2.44] | -0.15 [-0.53 ; 0.24] |
| Week 31 | 0.43 (1.60) [-2.74 ; 3.60] | -1.00 (1.73) [-4.42 ; 2.42] | 1.43 (2.21) [-2.95 ; 5.81] | 0.12 [-0.28 ; 0.52] |
| Week 37 | 0.39 (1.68) [-2.93 ; 3.72] | -1.05 (1.78) [-4.57 ; 2.47] | 1.44 (2.31) [-3.13 ; 6.02] | 0.12 [-0.28 ; 0.52] |
| Week 43 | 0.04 (1.73) [-3.38 ; 3.47] | -1.01 (1.90) [-4.77 ; 2.76] | 1.05 (2.45) [-3.80 ; 5.90] | 0.08 [-0.32 ; 0.49] |
| Week 49 | 0.37 (1.53) [-2.65 ; 3.39] | -0.75 (1.74) [-4.18 ; 2.68] | 1.12 (2.18) [-3.20 ; 5.43] | 0.10 [-0.32 ; 0.52] |
| Week 55 | -0.38 (2.06) [-4.46 ; 3.70] | -0.35 (2.35) [-5.00 ; 4.31] | -0.03 (3.03) [-6.03 ; 5.97] | -0.00 [-0.43 ; 0.43] |
| Week 61 | 0.18 (1.60) [-2.97 ; 3.34] | -3.56 (1.90) [-7.33 ; 0.21] | 3.75 (2.37) [-0.94 ; 8.43] | 0.34 [-0.12 ; 0.80] |
| Week 67 | 0.06 (1.72) [-3.34 ; 3.46] | -1.06 (2.04) [-5.10 ; 2.98] | 1.12 (2.56) [-3.95 ; 6.19] | 0.10 [-0.37 ; 0.56] |
| Week 73 | -1.40 (1.83) [-5.02 ; 2.22] | -2.61 (2.09) [-6.74 ; 1.52] | 1.21 (2.68) [-4.10 ; 6.52] | 0.11 [-0.39 ; 0.61] |
| Week 79 | -0.05 (1.83) [-3.68 ; 3.59] | -1.42 (2.08) [-5.55 ; 2.70] | 1.38 (2.69) [-3.94 ; 6.70] | 0.13 [-0.40 ; 0.66] |
| Week 85 | 0.99 (1.57) [-2.13 ; 4.11] | -1.85 (1.82) [-5.47 ; 1.76] | 2.84 (2.30) [-1.73 ; 7.41] | 0.34 [-0.24 ; 0.91] |
| Week 91 | 0.21 (1.55) [-2.88 ; 3.29] | -0.38 (1.90) [-4.15 ; 3.39] | 0.59 (2.35) [-4.10 ; 5.28] | 0.08 [-0.56 ; 0.71] |
| Week 97 | -0.76 (1.92) [-4.61 ; 3.09] | -1.41 (2.52) [-6.44 ; 3.63] | 0.65 (3.09) [-5.55 ; 6.84] | 0.07 [-0.66 ; 0.80] |
| Week 103 | 0.64 (1.72) [-2.86 ; 4.14] | -2.04 (2.20) [-6.49 ; 2.41] | 2.67 (2.71) [-2.84 ; 8.19] | 0.38 [-0.43 ; 1.19] |
| Overall post-baseline period estimate | -0.85 (1.03) [-2.88 ; 1.18] | -1.42 (1.16) [-3.70 ; 0.87] | 0.57 (1.35) [-2.10 ; 3.23] | 0.06 [-0.27 ; 0.40] |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit, and PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm, and uses a Heterogenous Autoregressive (ARH(1)) covariance structure.
CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Er
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:40:57

TABLE 7.1.2: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **< 65** | N=40 | N=46 |
| **>= 65** | N=31 | N=22 |
| **Subjects with Baseline Value** | | |
| **< 65** | 40 (100.0%) | 46 (100.0%) |
| **>= 65** | 31 (100.0%) | 22 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **< 65** | 40 (100.0%) | 44 (95.7%) |
| **>= 65** | 31 (100.0%) | 22 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **< 65** | 40 (100.0%) | 44 (95.7%) |
| **>= 65** | 31 (100.0%) | 22 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:40:57

TABLE 7.1.2: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Baseline | n= 40 (100.0%) \| 80.20 (14.71) | n= 46 (100.0%) \| 80.61 (17.73) | -0.02 [-0.45 ; 0.40] |
| Week 3 | n= 39 (97.5%) \| 81.95 (12.58) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 36 (90.0%) \| 82.44 (13.65) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 37 (92.5%) \| 79.76 (16.94) | n= 41 (89.1%) \| 78.10 (18.46) | 0.09 [-0.35 ; 0.54] |
| Week 9 | n= 35 (87.5%) \| 79.29 (15.86) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \| 80.26 (12.59) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 35 (87.5%) \| 79.17 (20.35) | n= 37 (80.4%) \| 79.32 (15.59) | -0.01 [-0.47 ; 0.46] |
| Week 15 | n= 34 (85.0%) \| 77.21 (19.27) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 36 (90.0%) \| 80.19 (16.19) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \| 81.50 (11.65) | n= 39 (84.8%) \| 80.44 (14.81) | 0.08 [-0.39 ; 0.55] |
| Week 21 | n= 36 (90.0%) \| 80.06 (13.17) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 35 (87.5%) \| 79.71 (12.37) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \| 81.92 (10.97) | n= 37 (80.4%) \| 83.16 (11.81) | -0.11 [-0.57 ; 0.35] |
| Week 27 | n= 33 (82.5%) \| 81.06 (12.93) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \| 82.42 (14.14) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \| 84.06 (11.03) | n= 29 (63.0%) \| 81.41 (14.49) | 0.20 [-0.30 ; 0.71] |
| Week 33 | n= 36 (90.0%) \| 82.86 (12.47) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 33 (82.5%) \| 81.79 (13.91) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \| 81.00 (14.34) | n= 32 (69.6%) \| 81.50 (14.86) | -0.03 [-0.53 ; 0.46] |
| Week 39 | n= 33 (82.5%) \| 83.85 (12.37) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \| 83.12 (13.00) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 31 (77.5%) \| 83.65 (13.01) | n= 31 (67.4%) \| 80.90 (14.77) | 0.19 [-0.31 ; 0.70] |
| Week 45 | n= 33 (82.5%) \| 82.18 (11.92) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \| 84.15 (10.63) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 34 (85.0%) \| 82.41 (12.50) | n= 27 (58.7%) \| 81.37 (14.97) | 0.08 [-0.43 ; 0.58] |
| Week 51 | n= 32 (80.0%) \| 82.16 (11.45) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 31 (77.5%) \| 81.35 (20.03) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 31 (77.5%) \| 81.00 (18.32) | n= 26 (56.5%) \| 82.85 (15.19) | -0.11 [-0.63 ; 0.42] |
| Week 57 | n= 31 (77.5%) \| 80.65 (18.66) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 28 (70.0%) \| 80.39 (18.86) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \| 82.90 (12.80) | n= 19 (41.3%) \| 77.37 (17.15) | 0.37 [-0.21 ; 0.96] |
| Week 63 | n= 30 (75.0%) \| 80.63 (13.99) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 28 (70.0%) \| 81.89 (14.10) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \| 83.31 (13.33) | n= 20 (43.5%) \| 80.90 (13.78) | 0.18 [-0.39 ; 0.74] |
| Week 69 | n= 28 (70.0%) \| 80.75 (13.45) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \| 82.07 (14.19) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \| 81.36 (14.99) | n= 18 (39.1%) \| 78.00 (19.23) | 0.20 [-0.42 ; 0.81] |
| Week 75 | n= 26 (65.0%) \| 81.58 (15.47) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \| 82.96 (13.59) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \| 82.29 (17.56) | n= 16 (34.8%) \| 76.69 (19.66) | 0.30 [-0.35 ; 0.94] |
| Week 81 | n= 24 (60.0%) \| 83.50 (13.71) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \| 83.80 (13.55) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \| 87.40 (8.48) | n= 14 (30.4%) \| 79.21 (18.98) | 0.58 [-0.13 ; 1.29] |
| Week 87 | n= 19 (47.5%) \| 82.58 (14.48) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 19 (47.5%) \| 82.74 (12.71) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (50.0%) \| 83.40 (13.75) | n= 11 (23.9%) \| 84.36 (10.41) | -0.07 [-0.82 ; 0.67] |
| Week 93 | n= 17 (42.5%) \| 83.53 (14.56) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \| 80.53 (15.70) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \| 79.82 (16.42) | n= 8 (17.4%) \| 81.75 (12.71) | -0.12 [-0.98 ; 0.74] |
| Week 99 | n= 13 (32.5%) \| 78.08 (16.41) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \| 82.17 (8.61) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \| 83.17 (10.57) | n= 7 (15.2%) \| 80.29 (11.97) | 0.25 [-0.71 ; 1.21] |
| Week 105 | n= 11 (27.5%) \| 79.45 (11.17) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \| 80.29 (9.39) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \| 79.00 (10.89) | n= 3 ( 6.5%) \| 76.00 (5.29) | 0.28 [-1.10 ; 1.65] |
| Week 111 | n= 7 (17.5%) \| 78.00 (9.20) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \| 81.57 (10.37) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \| 83.33 (11.41) | n= 3 ( 6.5%) \| 76.00 (11.53) | 0.57 [-0.95 ; 2.09] |
| Week 117 | n= 5 (12.5%) \| 83.00 (4.30) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \| 77.20 (11.17) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \| 81.17 (13.18) | n= 1 ( 2.2%) \| 92.00 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \| 98.00 ( / ) | n= 1 ( 2.2%) \| 100.00 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \| 75.25 (9.50) | n= 9 (19.6%) \| 75.67 (21.71) | -0.02 [-1.25 ; 1.21] |
| Week 202 | [No Data] | n= 7 (15.2%) \| 87.71 (10.56) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 ( 8.7%) \| 82.50 (6.45) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 1 ( 2.2%) \| 85.00 ( / ) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 2.5%) \| 40.00 ( / ) | n= 3 ( 6.5%) \| 80.00 (0.00) | [Not calculable] |
| Week 304 | [No Data] | n= 1 ( 2.2%) \| 90.00 ( / ) | [No Data for at least 1 arm] |
| **>= 65** | | | |
| N subjects in population | N=31 | N=22 | |
| Baseline | n= 31 (100.0%) \| 74.74 (20.63) | n= 22 (100.0%) \| 77.86 (19.48) | -0.15 [-0.70 ; 0.40] |
| Week 3 | n= 28 (90.3%) \| 79.07 (14.82) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 29 (93.5%) \| 72.45 (18.59) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 29 (93.5%) \| 72.90 (18.41) | n= 21 (95.5%) \| 76.48 (14.49) | -0.21 [-0.78 ; 0.36] |
| Week 9 | n= 24 (77.4%) \| 75.50 (16.50) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 26 (83.9%) \| 72.58 (22.00) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 24 (77.4%) \| 67.50 (25.00) | n= 16 (72.7%) \| 80.81 (7.52) | -0.65 [-1.31 ; 0.01] |
| Week 15 | n= 20 (64.5%) \| 73.00 (21.42) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 25 (80.6%) \| 76.44 (14.20) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 25 (80.6%) \| 76.40 (21.03) | n= 14 (63.6%) \| 82.79 (9.13) | -0.35 [-1.02 ; 0.32] |
| Week 21 | n= 24 (77.4%) \| 75.71 (19.12) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (67.7%) \| 71.05 (22.02) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 21 (67.7%) \| 78.90 (13.35) | n= 13 (59.1%) \| 86.23 (10.05) | -0.59 [-1.30 ; 0.13] |
| Week 27 | n= 22 (71.0%) \| 81.77 (12.10) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 20 (64.5%) \| 78.10 (12.84) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 21 (67.7%) \| 77.10 (10.19) | n= 14 (63.6%) \| 80.64 (14.43) | -0.29 [-0.98 ; 0.40] |
| Week 33 | n= 21 (67.7%) \| 77.10 (12.31) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 20 (64.5%) \| 78.40 (13.22) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 18 (58.1%) \| 80.11 (11.91) | n= 14 (63.6%) \| 83.50 (10.54) | -0.29 [-1.00 ; 0.42] |
| Week 39 | n= 20 (64.5%) \| 78.45 (12.48) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 17 (54.8%) \| 79.29 (13.26) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 22 (71.0%) \| 78.09 (14.15) | n= 12 (54.5%) \| 82.58 (13.65) | -0.31 [-1.03 ; 0.40] |
| Week 45 | n= 16 (51.6%) \| 74.81 (14.97) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 19 (61.3%) \| 78.95 (13.81) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 19 (61.3%) \| 80.05 (14.91) | n= 11 (50.0%) \| 83.18 (7.32) | -0.24 [-1.00 ; 0.52] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 51 | n= 19 (61.3%) \| 79.53 (14.09) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 18 (58.1%) \| 77.72 (14.69) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 16 (51.6%) \| 78.38 (18.10) | n= 11 (50.0%) \| 81.45 (11.17) | -0.19 [-0.97 ; 0.59] |
| Week 57 | n= 16 (51.6%) \| 78.50 (15.58) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 18 (58.1%) \| 77.78 (16.81) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 17 (54.8%) \| 80.35 (13.50) | n= 11 (50.0%) \| 80.18 (11.42) | 0.01 [-0.76 ; 0.79] |
| Week 63 | n= 12 (38.7%) \| 79.17 (14.60) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 16 (51.6%) \| 77.13 (16.19) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 12 (38.7%) \| 79.17 (14.52) | n= 10 (45.5%) \| 84.70 (9.53) | -0.43 [-1.29 ; 0.44] |
| Week 69 | n= 9 (29.0%) \| 79.11 (14.19) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 11 (35.5%) \| 83.55 (14.99) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 9 (29.0%) \| 79.78 (13.08) | n= 10 (45.5%) \| 81.10 (11.15) | -0.10 [-1.03 ; 0.82] |
| Week 75 | n= 10 (32.3%) \| 81.90 (14.07) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 8 (25.8%) \| 76.75 (14.81) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 7 (22.6%) \| 81.71 (12.93) | n= 9 (40.9%) \| 82.56 (8.59) | -0.07 [-1.10 ; 0.95] |
| Week 81 | n= 7 (22.6%) \| 82.43 (11.01) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 8 (25.8%) \| 84.00 (11.75) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (22.6%) \| 84.43 (9.09) | n= 7 (31.8%) \| 85.71 (8.04) | -0.14 [-1.23 ; 0.95] |
| Week 87 | n= 5 (16.1%) \| 78.00 (17.54) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 6 (19.4%) \| 81.83 (11.51) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (12.9%) \| 77.25 (10.81) | n= 5 (22.7%) \| 86.40 (8.79) | -0.84 [-2.32 ; 0.65] |
| Week 93 | n= 4 (12.9%) \| 80.50 (16.46) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (16.1%) \| 80.20 (13.97) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (12.9%) \| 82.75 (16.84) | n= 3 (13.6%) \| 85.00 (8.66) | -0.13 [-1.79 ; 1.52] |
| Week 99 | n= 4 (12.9%) \| 82.00 (12.62) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 6.5%) \| 71.50 (12.02) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 ( 9.7%) \| 79.67 (10.50) | n= 3 (13.6%) \| 86.67 (7.64) | -0.61 [-2.49 ; 1.27] |
| Week 105 | n= 3 ( 9.7%) \| 77.33 (11.24) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 3.2%) \| 66.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 6.5%) \| 74.00 (8.49) | n= 2 ( 9.1%) \| 87.00 (11.31) | -0.74 [-3.45 ; 1.96] |
| Week 113 | n= 1 ( 3.2%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 3.2%) \| 80.00 ( / ) | n= 2 ( 9.1%) \| 92.00 (4.24) | [Not calculable] |
| Week 117 | n= 2 ( 6.5%) \| 82.50 (10.61) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 ( 6.5%) \| 81.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 ( 6.5%) \| 82.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 2 ( 6.5%) \| 81.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 3.2%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.2%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 3.2%) \| 81.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 3.2%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.2%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 3.2%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 3.2%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 3.2%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 3.2%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.9%) \| 81.25 (8.54) | n= 8 (36.4%) \| 82.13 (13.64) | -0.07 [-1.33 ; 1.19] |
| Week 202 | n= 2 ( 6.5%) \| 64.00 (26.87) | n= 5 (22.7%) \| 89.20 (10.99) | -1.37 [-3.41 ; 0.67] |
| Week 301 | n= 2 ( 6.5%) \| 70.00 (28.28) | n= 5 (22.7%) \| 83.80 (9.47) | -0.76 [-2.65 ; 1.12] |
| Week 302 | n= 2 ( 6.5%) \| 65.00 (21.21) | n= 5 (22.7%) \| 82.00 (5.70) | -1.33 [-3.36 ; 0.70] |
| Week 303 | n= 2 ( 6.5%) \| 65.00 (21.21) | n= 3 (13.6%) \| 84.00 (10.39) | -0.93 [-3.24 ; 1.38] |
| Week 304 | n= 1 ( 3.2%) \| 100.00 ( / ) | n= 2 ( 9.1%) \| 70.00 (0.00) | [Not calculable] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 305 | [No Data] | n= 1 ( 4.5%) \| 75.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 4.5%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 4.5%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 4.5%) \| 90.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 4.5%) \| 85.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:40:58

TABLE 7.1.2: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Week 3 | n= 39 (97.5%) \| 1.21 (8.56) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 36 (90.0%) \| 0.61 (13.82) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 37 (92.5%) \|-1.00 (16.13) | n= 41 (89.1%) \|-1.63 (10.87) | 0.05 [-0.40 ; 0.49] |
| Week 9 | n= 35 (87.5%) \|-1.54 (18.22) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \|-0.11 (16.66) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 35 (87.5%) \|-0.77 (19.30) | n= 37 (80.4%) \|-2.14 (21.66) | 0.07 [-0.40 ; 0.53] |
| Week 15 | n= 34 (85.0%) \|-2.65 (22.61) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 36 (90.0%) \| 0.47 (18.61) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \| 1.97 (11.93) | n= 39 (84.8%) \|-3.15 (10.48) | 0.45 [-0.02 ; 0.93] |
| Week 21 | n= 36 (90.0%) \| 0.58 (12.90) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 35 (87.5%) \| 0.29 (12.04) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \| 1.78 (12.90) | n= 37 (80.4%) \| 1.16 (16.59) | 0.04 [-0.42 ; 0.50] |
| Week 27 | n= 33 (82.5%) \| 1.21 (14.27) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \| 2.24 (14.04) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \| 4.52 (12.18) | n= 29 (63.0%) \|-2.93 (12.64) | 0.59 [ 0.08 ; 1.11] |
| Week 33 | n= 36 (90.0%) \| 2.72 (12.89) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 33 (82.5%) \| 2.52 (13.30) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \| 1.16 (12.12) | n= 32 (69.6%) \|-2.25 (11.10) | 0.29 [-0.21 ; 0.79] |
| Week 39 | n= 33 (82.5%) \| 3.42 (12.35) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \| 2.59 (13.19) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 31 (77.5%) \| 3.32 (14.02) | n= 31 (67.4%) \|-2.71 (13.65) | 0.43 [-0.08 ; 0.94] |
| Week 45 | n= 33 (82.5%) \| 0.36 (10.65) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \| 3.55 (12.35) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 34 (85.0%) \| 3.15 (13.02) | n= 27 (58.7%) \|-2.22 (12.16) | 0.42 [-0.10 ; 0.93] |
| Week 51 | n= 32 (80.0%) \| 0.13 (8.23) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 31 (77.5%) \|-1.16 (20.00) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 31 (77.5%) \|-0.13 (18.52) | n= 26 (56.5%) \|-1.73 (13.30) | 0.10 [-0.43 ; 0.62] |
| Week 57 | n= 31 (77.5%) \|-1.13 (18.12) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 28 (70.0%) \|-0.64 (12.78) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \| 1.45 (10.56) | n= 19 (41.3%) \|-7.58 (14.08) | 0.74 [ 0.15 ; 1.34] |
| Week 63 | n= 30 (75.0%) \| 0.27 (10.80) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 28 (70.0%) \| 2.29 (9.87) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \| 0.97 (11.97) | n= 20 (43.5%) \|-3.70 (12.25) | 0.38 [-0.19 ; 0.95] |
| Week 69 | n= 28 (70.0%) \|-0.68 (12.30) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \| 0.79 (13.19) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \|-0.40 (13.69) | n= 18 (39.1%) \|-4.61 (13.28) | 0.31 [-0.31 ; 0.92] |
| Week 75 | n= 26 (65.0%) \| 0.08 (12.87) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \| 0.71 (12.45) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \| 1.54 (13.13) | n= 16 (34.8%) \|-5.13 (15.07) | 0.47 [-0.18 ; 1.12] |
| Week 81 | n= 24 (60.0%) \| 1.21 (12.96) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \| 1.28 (13.14) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \| 3.00 (11.10) | n= 14 (30.4%) \|-5.36 (15.26) | 0.63 [-0.08 ; 1.34] |
| Week 87 | n= 19 (47.5%) \| 0.79 (12.24) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (47.5%) \| 0.53 (11.77) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 20 (50.0%) \| 0.75 (12.12) | n= 11 (23.9%) \|-0.55 (12.44) | 0.10 [-0.65 ; 0.85] |
| Week 93 | n= 17 (42.5%) \| 2.18 (11.57) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \|-2.00 (9.71) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \|-2.12 (10.25) | n= 8 (17.4%) \|-2.50 (7.19) | 0.04 [-0.82 ; 0.90] |
| Week 99 | n= 13 (32.5%) \|-0.62 (9.91) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \|-0.58 (8.48) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \| 1.33 (6.58) | n= 7 (15.2%) \|-2.57 (9.78) | 0.47 [-0.50 ; 1.45] |
| Week 105 | n= 11 (27.5%) \|-2.64 (9.42) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \|-0.14 (6.01) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \|-1.44 (8.62) | n= 3 ( 6.5%) \|-10.67 (16.77) | 0.79 [-0.63 ; 2.21] |
| Week 111 | n= 7 (17.5%) \|-1.14 (5.37) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \|-1.86 (9.70) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \| 1.33 (12.61) | n= 3 ( 6.5%) \|-10.67 (22.94) | 0.66 [-0.87 ; 2.19] |
| Week 117 | n= 5 (12.5%) \|-1.20 (11.82) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \|-3.20 (12.72) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \| 0.83 (8.52) | n= 1 ( 2.2%) \|-8.00 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \| 8.00 ( / ) | n= 1 ( 2.2%) \| 0.00 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \| 8.00 (28.32) | n= 9 (19.6%) \|-9.89 (17.03) | 0.80 [-0.48 ; 2.08] |
| Week 202 | [No Data] | n= 7 (15.2%) \|-0.14 (10.33) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 ( 8.7%) \| 1.25 (10.31) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 1 ( 2.2%) \| 15.00 ( / ) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 2.5%) \| 10.00 ( / ) | n= 3 ( 6.5%) \| 23.67 (42.19) | [Not calculable] |
| Week 304 | [No Data] | n= 1 ( 2.2%) \| 20.00 ( / ) | [No Data for at least 1 arm] |
| **>= 65** | | | |
| N subjects in population | N=31 | N=22 | |
| Week 3 | n= 28 (90.3%) \| 3.00 (17.75) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 29 (93.5%) \|-3.52 (17.72) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 29 (93.5%) \|-3.07 (20.82) | n= 21 (95.5%) \|-0.67 (18.77) | -0.12 [-0.69 ; 0.45] |
| Week 9 | n= 24 (77.4%) \|-2.33 (18.73) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 26 (83.9%) \|-3.50 (25.66) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 24 (77.4%) \|-8.13 (28.22) | n= 16 (72.7%) \|-2.50 (10.42) | -0.24 [-0.88 ; 0.40] |
| Week 15 | n= 20 (64.5%) \|-2.30 (24.71) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 25 (80.6%) \| 1.52 (15.87) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 25 (80.6%) \|-0.92 (21.46) | n= 14 (63.6%) \|-1.00 (9.52) | 0.00 [-0.66 ; 0.67] |
| Week 21 | n= 24 (77.4%) \|-0.67 (21.11) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (67.7%) \|-2.48 (25.21) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 21 (67.7%) \| 0.57 (15.29) | n= 13 (59.1%) \| 1.77 (14.89) | -0.08 [-0.78 ; 0.62] |
| Week 27 | n= 22 (71.0%) \| 3.77 (13.93) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 20 (64.5%) \| 1.30 (16.54) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 21 (67.7%) \| 0.86 (15.67) | n= 14 (63.6%) \|-2.21 (16.06) | 0.19 [-0.50 ; 0.88] |
| Week 33 | n= 21 (67.7%) \|-2.48 (10.24) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 20 (64.5%) \| 1.20 (14.43) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 18 (58.1%) \| 4.78 (17.45) | n= 14 (63.6%) \| 0.64 (12.86) | 0.26 [-0.45 ; 0.97] |
| Week 39 | n= 20 (64.5%) \| 2.95 (14.52) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 17 (54.8%) \|-1.65 (9.63) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 22 (71.0%) \| 0.68 (14.66) | n= 12 (54.5%) \| 1.33 (14.88) | -0.04 [-0.76 ; 0.67] |
| Week 45 | n= 16 (51.6%) \| 1.19 (17.09) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 19 (61.3%) \| 3.37 (15.12) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 19 (61.3%) \| 2.63 (13.90) | n= 11 (50.0%) \| 1.82 (12.67) | 0.06 [-0.70 ; 0.81] |
| Week 51 | n= 19 (61.3%) \| 3.16 (13.60) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 18 (58.1%) \| 2.11 (14.77) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 55 | n= 16 (51.6%) \| 4.25 (16.01) | n= 11 (50.0%) \| 0.09 (17.22) | 0.24 [-0.54 ; 1.03] |
| Week 57 | n= 16 (51.6%) \| 3.81 (17.03) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 18 (58.1%) \| 1.78 (15.19) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 17 (54.8%) \| 2.82 (15.29) | n= 11 (50.0%) \|-1.18 (14.91) | 0.26 [-0.52 ; 1.03] |
| Week 63 | n= 12 (38.7%) \|-0.67 (7.25) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 16 (51.6%) \| 2.56 (14.25) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 12 (38.7%) \| 5.83 (15.26) | n= 10 (45.5%) \| 3.20 (15.89) | 0.16 [-0.70 ; 1.02] |
| Week 69 | n= 9 (29.0%) \| 5.78 (19.02) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 11 (35.5%) \| 1.64 (7.75) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 9 (29.0%) \| 1.33 (8.00) | n= 10 (45.5%) \| 0.60 (15.75) | 0.06 [-0.87 ; 0.98] |
| Week 75 | n= 10 (32.3%) \| 1.10 (8.44) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 8 (25.8%) \| 8.50 (20.38) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 7 (22.6%) \| 0.43 (9.78) | n= 9 (40.9%) \| 2.00 (13.36) | -0.12 [-1.15 ; 0.90] |
| Week 81 | n= 7 (22.6%) \| 0.14 (9.58) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 8 (25.8%) \| 2.00 (7.95) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (22.6%) \|-0.71 (8.22) | n= 7 (31.8%) \| 0.00 (8.52) | -0.08 [-1.17 ; 1.01] |
| Week 87 | n= 5 (16.1%) \|-3.60 (9.86) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 6 (19.4%) \|-0.83 (8.47) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (12.9%) \|-3.50 (8.54) | n= 5 (22.7%) \| 2.40 (8.44) | -0.62 [-2.07 ; 0.83] |
| Week 93 | n= 4 (12.9%) \| 0.25 (4.11) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (16.1%) \|-3.00 (7.48) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (12.9%) \|-1.25 (9.88) | n= 3 (13.6%) \|-1.67 (2.89) | 0.04 [-1.61 ; 1.70] |
| Week 99 | n= 4 (12.9%) \|-2.00 (8.83) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 6.5%) \|-6.50 (12.02) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 ( 9.7%) \|-1.33 (12.10) | n= 3 (13.6%) \| 0.00 (5.00) | -0.12 [-1.93 ; 1.70] |
| Week 105 | n= 3 ( 9.7%) \|-3.67 (10.02) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 3.2%) \| 5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 6.5%) \|-4.00 (15.56) | n= 2 ( 9.1%) \|-3.00 (2.83) | -0.05 [-2.51 ; 2.41] |
| Week 113 | n= 1 ( 3.2%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 3.2%) \|-15.00 ( / ) | n= 2 ( 9.1%) \| 2.00 (9.90) | [Not calculable] |
| Week 117 | n= 2 ( 6.5%) \|-11.50 (9.19) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 ( 6.5%) \|-12.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 ( 6.5%) \|-12.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 2 ( 6.5%) \|-13.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 3.2%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.2%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 3.2%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 3.2%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.2%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 3.2%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 3.2%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 3.2%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 3.2%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.9%) \|-3.00 (14.70) | n= 8 (36.4%) \|-5.38 (12.51) | 0.17 [-1.10 ; 1.43] |
| Week 202 | n= 2 ( 6.5%) \|-4.50 (0.71) | n= 5 (22.7%) \|-0.80 (12.68) | -0.27 [-2.10 ; 1.55] |
| Week 301 | n= 2 ( 6.5%) \| 5.00 (7.07) | n= 5 (22.7%) \| 2.40 (12.78) | 0.18 [-1.63 ; 2.00] |
| Week 302 | n= 2 ( 6.5%) \|-10.00 (14.14) | n= 5 (22.7%) \|-1.00 (6.96) | -0.85 [-2.76 ; 1.05] |
| Week 303 | n= 2 ( 6.5%) \|-10.00 (14.14) | n= 3 (13.6%) \| 4.33 (6.03) | -1.09 [-3.48 ; 1.29] |
| Week 304 | n= 1 ( 3.2%) \| 0.00 ( / ) | n= 2 ( 9.1%) \|-7.00 (4.24) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 4.5%) \| 67.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 4.5%) \| 62.00 ( / ) | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|---|
| Week 307 | [No Data] | n= 1 ( 4.5%) | 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 4.5%) | 82.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 4.5%) | 77.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:40:58

TABLE 7.1.2: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **< 65** | | | | |
| Nr subjects used | n=40 | n=46 | | |
| Week 7 | -2.33 (2.42) [-7.14 ; 2.49] | -2.37 (2.30) [-6.94 ; 2.20] | 0.04 (3.33) [-6.59 ; 6.67] | 0.00 [-0.44 ; 0.45] |
| Week 13 | -3.72 (3.53) [-10.74 ; 3.31] | -1.46 (3.38) [-8.18 ; 5.25] | -2.25 (4.88) [-11.97 ; 7.46] | -0.11 [-0.57 ; 0.35] |
| Week 19 | -0.48 (2.23) [-4.92 ; 3.97] | -1.88 (2.09) [-6.04 ; 2.28] | 1.41 (3.06) [-4.68 ; 7.49] | 0.11 [-0.36 ; 0.58] |
| Week 25 | 0.84 (1.93) [-3.00 ; 4.69] | 1.47 (1.86) [-2.24 ; 5.18] | -0.62 (2.68) [-5.96 ; 4.72] | -0.05 [-0.51 ; 0.41] |
| Week 31 | 2.76 (1.86) [-0.95 ; 6.46] | -0.00 (1.85) [-3.69 ; 3.69] | 2.76 (2.63) [-2.47 ; 7.99] | 0.26 [-0.24 ; 0.76] |
| Week 37 | 1.18 (1.94) [-2.68 ; 5.03] | -1.53 (1.90) [-5.30 ; 2.25] | 2.70 (2.72) [-2.69 ; 8.10] | 0.25 [-0.25 ; 0.74] |
| Week 43 | 2.21 (2.02) [-1.79 ; 6.22] | -1.88 (2.02) [-5.89 ; 2.13] | 4.09 (2.85) [-1.58 ; 9.76] | 0.36 [-0.14 ; 0.86] |
| Week 49 | 1.95 (1.88) [-1.78 ; 5.69] | -1.40 (2.00) [-5.37 ; 2.57] | 3.36 (2.75) [-2.10 ; 8.81] | 0.31 [-0.20 ; 0.82] |
| Week 55 | 1.04 (2.88) [-4.70 ; 6.78] | 0.06 (3.11) [-6.14 ; 6.26] | 0.97 (4.24) [-7.48 ; 9.43] | 0.06 [-0.46 ; 0.58] |
| Week 61 | 1.50 (2.06) [-2.62 ; 5.61] | -4.38 (2.42) [-9.20 ; 0.44] | 5.88 (3.18) [-0.46 ; 12.23] | 0.52 [-0.06 ; 1.10] |
| Week 67 | 1.10 (2.19) [-3.28 ; 5.48] | -2.94 (2.63) [-8.19 ; 2.30] | 4.04 (3.43) [-2.80 ; 10.88] | 0.33 [-0.24 ; 0.89] |
| Week 73 | -0.62 (2.34) [-5.29 ; 4.05] | -3.63 (2.79) [-9.18 ; 1.93] | 3.01 (3.64) [-4.25 ; 10.26] | 0.25 [-0.36 ; 0.86] |
| Week 79 | 0.55 (2.28) [-3.98 ; 5.08] | -2.96 (2.76) [-8.46 ; 2.53] | 3.51 (3.58) [-3.61 ; 10.64] | 0.31 [-0.33 ; 0.95] |
| Week 85 | 1.49 (1.96) [-2.42 ; 5.40] | -3.97 (2.39) [-8.74 ; 0.80] | 5.46 (3.09) [-0.71 ; 11.63] | 0.60 [-0.10 ; 1.30] |
| Week 91 | 0.74 (1.98) [-3.25 ; 4.72] | -2.19 (2.58) [-7.37 ; 2.99] | 2.92 (3.25) [-3.61 ; 9.46] | 0.33 [-0.42 ; 1.07] |
| Overall post-baseline period estimate | 0.55 (1.31) [-2.05 ; 3.15] | -1.94 (1.37) [-4.66 ; 0.78] | 2.49 (1.90) [-1.28 ; 6.25] | 0.28 [-0.15 ; 0.71] |
| **>= 65** | | | | |
| Nr subjects used | n=31 | n=22 | | |
| Week 7 | -4.57 (3.04) [-10.69 ; 1.54] | -1.59 (3.58) [-8.79 ; 5.61] | -2.98 (4.70) [-12.42 ; 6.46] | -0.18 [-0.74 ; 0.38] |
| Week 13 | -11.19 (4.23) [-19.73 ;-2.65] | 0.83 (5.18) [-9.62 ; 11.29] | -12.03 (6.69) [-25.53 ; 1.48] | -0.57 [-1.21 ; 0.08] |
| Week 19 | -1.96 (3.17) [-8.35 ; 4.43] | 2.38 (4.12) [-5.91 ; 10.67] | -4.34 (5.20) [-14.81 ; 6.13] | -0.27 [-0.93 ; 0.39] |
| Week 25 | -0.05 (2.11) [-4.32 ; 4.23] | 4.08 (2.67) [-1.32 ; 9.48] | -4.12 (3.42) [-11.02 ; 2.77] | -0.42 [-1.12 ; 0.28] |
| Week 31 | -0.44 (2.31) [-5.11 ; 4.23] | 0.39 (2.88) [-5.41 ; 6.20] | -0.83 (3.70) [-8.29 ; 6.63] | -0.08 [-0.75 ; 0.60] |
| Week 37 | 2.39 (2.37) [-2.42 ; 7.20] | 3.23 (2.84) [-2.55 ; 9.01] | -0.84 (3.70) [-8.37 ; 6.69] | -0.08 [-0.78 ; 0.62] |
| Week 43 | -0.22 (2.73) [-5.78 ; 5.34] | 4.20 (3.63) [-3.19 ; 11.59] | -4.42 (4.55) [-13.67 ; 4.83] | -0.34 [-1.05 ; 0.37] |
| Week 49 | 1.14 (1.95) [-2.81 ; 5.09] | 3.60 (2.59) [-1.64 ; 8.83] | -2.45 (3.24) [-9.02 ; 4.11] | -0.28 [-1.03 ; 0.47] |
| Week 55 | 1.21 (2.43) [-3.70 ; 6.12] | 1.84 (3.06) [-4.34 ; 8.02] | -0.63 (3.92) [-8.53 ; 7.28] | -0.06 [-0.83 ; 0.71] |
| Week 61 | 1.21 (2.05) [-2.92 ; 5.34] | 0.53 (2.58) [-4.68 ; 5.75] | 0.68 (3.30) [-5.98 ; 7.34] | 0.08 [-0.68 ; 0.84] |
| Week 67 | 1.66 (2.38) [-3.22 ; 6.54] | 5.00 (2.70) [-0.55 ; 10.55] | -3.34 (3.61) [-10.75 ; 4.06] | -0.38 [-1.23 ; 0.46] |
| Overall post-baseline period estimate | -0.98 (1.35) [-3.68 ; 1.72] | 2.23 (1.70) [-1.17 ; 5.62] | -3.21 (2.18) [-7.56 ; 1.14] | -0.41 [-0.96 ; 0.14] |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.7878 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:40:58

TABLE 7.1.3: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **< 65** | N=40 | N=46 |
| **>= 65 AND < 75** | N=23 | N=17 |
| **>= 75** | N=8 | N=5 |
| **Subjects with Baseline Value** | | |
| **< 65** | 40 (100.0%) | 46 (100.0%) |
| **>= 65 AND < 75** | 23 (100.0%) | 17 (100.0%) |
| **>= 75** | 8 (100.0%) | 5 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **< 65** | 40 (100.0%) | 44 (95.7%) |
| **>= 65 AND < 75** | 23 (100.0%) | 17 (100.0%) |
| **>= 75** | 8 (100.0%) | 5 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **< 65** | 40 (100.0%) | 44 (95.7%) |
| **>= 65 AND < 75** | 23 (100.0%) | 17 (100.0%) |
| **>= 75** | 8 (100.0%) | 5 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:40:58

TABLE 7.1.3: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Baseline | n= 40 (100.0%) \| 80.20 (14.71) | n= 46 (100.0%) \| 80.61 (17.73) | -0.02 [-0.45 ; 0.40] |
| Week 3 | n= 39 (97.5%) \| 81.95 (12.58) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 36 (90.0%) \| 82.44 (13.65) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 37 (92.5%) \| 79.76 (16.94) | n= 41 (89.1%) \| 78.10 (18.46) | 0.09 [-0.35 ; 0.54] |
| Week 9 | n= 35 (87.5%) \| 79.29 (15.86) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \| 80.26 (12.59) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 35 (87.5%) \| 79.17 (20.35) | n= 37 (80.4%) \| 79.32 (15.59) | -0.01 [-0.47 ; 0.46] |
| Week 15 | n= 34 (85.0%) \| 77.21 (19.27) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 36 (90.0%) \| 80.19 (16.19) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \| 81.50 (11.65) | n= 39 (84.8%) \| 80.44 (14.81) | 0.08 [-0.39 ; 0.55] |
| Week 21 | n= 36 (90.0%) \| 80.06 (13.17) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 35 (87.5%) \| 79.71 (12.37) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \| 81.92 (10.97) | n= 37 (80.4%) \| 83.16 (11.81) | -0.11 [-0.57 ; 0.35] |
| Week 27 | n= 33 (82.5%) \| 81.06 (12.93) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \| 82.42 (14.14) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \| 84.06 (11.03) | n= 29 (63.0%) \| 81.41 (14.49) | 0.20 [-0.30 ; 0.71] |
| Week 33 | n= 36 (90.0%) \| 82.86 (12.47) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 33 (82.5%) \| 81.79 (13.91) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \| 81.00 (14.34) | n= 32 (69.6%) \| 81.50 (14.86) | -0.03 [-0.53 ; 0.46] |
| Week 39 | n= 33 (82.5%) \| 83.85 (12.37) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \| 83.12 (13.00) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 31 (77.5%) \| 83.65 (13.01) | n= 31 (67.4%) \| 80.90 (14.77) | 0.19 [-0.31 ; 0.70] |
| Week 45 | n= 33 (82.5%) \| 82.18 (11.92) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \| 84.15 (10.63) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 34 (85.0%) \| 82.41 (12.50) | n= 27 (58.7%) \| 81.37 (14.97) | 0.08 [-0.43 ; 0.58] |
| Week 51 | n= 32 (80.0%) \| 82.16 (11.45) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 31 (77.5%) \| 81.35 (20.03) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 31 (77.5%) \| 81.00 (18.32) | n= 26 (56.5%) \| 82.85 (15.19) | -0.11 [-0.63 ; 0.42] |
| Week 57 | n= 31 (77.5%) \| 80.65 (18.66) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 28 (70.0%) \| 80.39 (18.86) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \| 82.90 (12.80) | n= 19 (41.3%) \| 77.37 (17.15) | 0.37 [-0.21 ; 0.96] |
| Week 63 | n= 30 (75.0%) \| 80.63 (13.99) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 28 (70.0%) \| 81.89 (14.10) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \| 83.31 (13.33) | n= 20 (43.5%) \| 80.90 (13.78) | 0.18 [-0.39 ; 0.74] |
| Week 69 | n= 28 (70.0%) \| 80.75 (13.45) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \| 82.07 (14.19) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \| 81.36 (14.99) | n= 18 (39.1%) \| 78.00 (19.23) | 0.20 [-0.42 ; 0.81] |
| Week 75 | n= 26 (65.0%) \| 81.58 (15.47) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \| 82.96 (13.59) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \| 82.29 (17.56) | n= 16 (34.8%) \| 76.69 (19.66) | 0.30 [-0.35 ; 0.94] |
| Week 81 | n= 24 (60.0%) \| 83.50 (13.71) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \| 83.80 (13.55) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \| 87.40 (8.48) | n= 14 (30.4%) \| 79.21 (18.98) | 0.58 [-0.13 ; 1.29] |
| Week 87 | n= 19 (47.5%) \| 82.58 (14.48) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 19 (47.5%) \| 82.74 (12.71) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (50.0%) \| 83.40 (13.75) | n= 11 (23.9%) \| 84.36 (10.41) | -0.07 [-0.82 ; 0.67] |
| Week 93 | n= 17 (42.5%) \| 83.53 (14.56) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \| 80.53 (15.70) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \| 79.82 (16.42) | n= 8 (17.4%) \| 81.75 (12.71) | -0.12 [-0.98 ; 0.74] |
| Week 99 | n= 13 (32.5%) \| 78.08 (16.41) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \| 82.17 (8.61) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \| 83.17 (10.57) | n= 7 (15.2%) \| 80.29 (11.97) | 0.25 [-0.71 ; 1.21] |
| Week 105 | n= 11 (27.5%) \| 79.45 (11.17) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \| 80.29 (9.39) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \| 79.00 (10.89) | n= 3 ( 6.5%) \| 76.00 (5.29) | 0.28 [-1.10 ; 1.65] |
| Week 111 | n= 7 (17.5%) \| 78.00 (9.20) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \| 81.57 (10.37) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \| 83.33 (11.41) | n= 3 ( 6.5%) \| 76.00 (11.53) | 0.57 [-0.95 ; 2.09] |
| Week 117 | n= 5 (12.5%) \| 83.00 (4.30) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \| 77.20 (11.17) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \| 81.17 (13.18) | n= 1 ( 2.2%) \| 92.00 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \| 98.00 ( / ) | n= 1 ( 2.2%) \| 100.00 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \| 75.25 (9.50) | n= 9 (19.6%) \| 75.67 (21.71) | -0.02 [-1.25 ; 1.21] |
| Week 202 | [No Data] | n= 7 (15.2%) \| 87.71 (10.56) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 ( 8.7%) \| 82.50 (6.45) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 1 ( 2.2%) \| 85.00 ( / ) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 2.5%) \| 40.00 ( / ) | n= 3 ( 6.5%) \| 80.00 (0.00) | [Not calculable] |
| Week 304 | [No Data] | n= 1 ( 2.2%) \| 90.00 ( / ) | [No Data for at least 1 arm] |
| **>= 65 AND < 75** | | | |
| N subjects in population | N=23 | N=17 | |
| Baseline | n= 23 (100.0%) \| 75.35 (22.40) | n= 17 (100.0%) \| 73.53 (20.07) | 0.08 [-0.55 ; 0.72] |
| Week 3 | n= 20 (87.0%) \| 78.75 (14.18) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 22 (95.7%) \| 73.50 (17.42) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 22 (95.7%) \| 72.18 (19.56) | n= 17 (100.0%) \| 73.29 (13.91) | -0.06 [-0.70 ; 0.58] |
| Week 9 | n= 18 (78.3%) \| 76.11 (17.98) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 19 (82.6%) \| 70.89 (24.57) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 19 (82.6%) \| 69.58 (23.13) | n= 12 (70.6%) \| 79.00 (6.19) | -0.49 [-1.24 ; 0.25] |
| Week 15 | n= 14 (60.9%) \| 70.57 (24.29) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 18 (78.3%) \| 76.28 (15.61) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 19 (82.6%) \| 74.89 (22.74) | n= 10 (58.8%) \| 80.40 (9.23) | -0.28 [-1.06 ; 0.51] |
| Week 21 | n= 18 (78.3%) \| 74.78 (21.17) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (65.2%) \| 67.07 (23.66) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 15 (65.2%) \| 78.60 (13.38) | n= 8 (47.1%) \| 82.75 (9.97) | -0.32 [-1.21 ; 0.56] |
| Week 27 | n= 16 (69.6%) \| 82.63 (12.12) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 15 (65.2%) \| 78.80 (13.46) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 15 (65.2%) \| 76.33 (10.03) | n= 11 (64.7%) \| 76.36 (13.06) | -0.00 [-0.80 ; 0.79] |
| Week 33 | n= 15 (65.2%) \| 76.13 (12.73) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 14 (60.9%) \| 77.86 (14.09) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 13 (56.5%) \| 80.08 (12.30) | n= 11 (64.7%) \| 81.18 (9.71) | -0.10 [-0.92 ; 0.73] |
| Week 39 | n= 15 (65.2%) \| 79.13 (13.09) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 12 (52.2%) \| 80.33 (13.61) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 16 (69.6%) \| 77.13 (14.92) | n= 11 (64.7%) \| 81.91 (14.11) | -0.32 [-1.10 ; 0.47] |
| Week 45 | n= 11 (47.8%) \| 73.64 (16.64) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 13 (56.5%) \| 78.15 (14.71) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 13 (56.5%) \| 79.69 (16.32) | n= 10 (58.8%) \| 82.50 (7.34) | -0.20 [-1.05 ; 0.64] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 51 | n= 13 (56.5%) \| 79.46 (15.22) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (56.5%) \| 77.38 (15.94) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 11 (47.8%) \| 77.36 (19.98) | n= 10 (58.8%) \| 80.60 (11.38) | -0.19 [-1.07 ; 0.69] |
| Week 57 | n= 12 (52.2%) \| 79.17 (17.01) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 13 (56.5%) \| 76.38 (18.09) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 12 (52.2%) \| 79.92 (14.11) | n= 10 (58.8%) \| 79.20 (11.54) | 0.05 [-0.81 ; 0.91] |
| Week 63 | n= 9 (39.1%) \| 77.78 (16.62) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (47.8%) \| 75.09 (17.56) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (34.8%) \| 77.50 (14.02) | n= 9 (52.9%) \| 84.11 (9.92) | -0.52 [-1.52 ; 0.48] |
| Week 69 | n= 7 (30.4%) \| 80.29 (13.65) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 8 (34.8%) \| 83.63 (14.04) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 6 (26.1%) \| 79.83 (12.07) | n= 10 (58.8%) \| 81.10 (11.15) | -0.10 [-1.15 ; 0.94] |
| Week 75 | n= 8 (34.8%) \| 83.75 (12.90) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (21.7%) \| 73.20 (11.88) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (21.7%) \| 76.40 (10.71) | n= 8 (47.1%) \| 81.63 (8.68) | -0.51 [-1.70 ; 0.67] |
| Week 81 | n= 5 (21.7%) \| 79.00 (11.40) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (26.1%) \| 81.17 (12.34) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (21.7%) \| 82.20 (10.11) | n= 6 (35.3%) \| 85.00 (8.56) | -0.28 [-1.54 ; 0.98] |
| Week 87 | n= 3 (13.0%) \| 68.33 (16.07) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 4 (17.4%) \| 77.00 (11.22) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (17.4%) \| 77.25 (10.81) | n= 5 (29.4%) \| 86.40 (8.79) | -0.84 [-2.32 ; 0.65] |
| Week 93 | n= 3 (13.0%) \| 75.00 (15.00) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (17.4%) \| 76.25 (12.50) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (13.0%) \| 78.33 (17.56) | n= 3 (17.6%) \| 85.00 (8.66) | -0.39 [-2.22 ; 1.45] |
| Week 99 | n= 3 (13.0%) \| 78.33 (12.58) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 8.7%) \| 71.50 (12.02) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (13.0%) \| 79.67 (10.50) | n= 3 (17.6%) \| 86.67 (7.64) | -0.61 [-2.49 ; 1.27] |
| Week 105 | n= 3 (13.0%) \| 77.33 (11.24) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 4.3%) \| 66.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 8.7%) \| 74.00 (8.49) | n= 2 (11.8%) \| 87.00 (11.31) | -0.74 [-3.45 ; 1.96] |
| Week 113 | n= 1 ( 4.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 4.3%) \| 80.00 ( / ) | n= 2 (11.8%) \| 92.00 (4.24) | [Not calculable] |
| Week 117 | n= 1 ( 4.3%) \| 90.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 4.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 4.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 4.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 4.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 4.3%) \| 81.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 4.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 4.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 4.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 4.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (13.0%) \| 80.00 (10.00) | n= 4 (23.5%) \| 73.00 (12.49) | 0.51 [-1.18 ; 2.20] |
| Week 202 | n= 1 ( 4.3%) \| 83.00 ( / ) | n= 2 (11.8%) \| 80.00 (14.14) | [Not calculable] |
| Week 301 | n= 1 ( 4.3%) \| 90.00 ( / ) | n= 3 (17.6%) \| 78.33 (7.64) | [Not calculable] |
| Week 302 | n= 1 ( 4.3%) \| 80.00 ( / ) | n= 3 (17.6%) \| 80.00 (5.00) | [Not calculable] |
| Week 303 | n= 1 ( 4.3%) \| 80.00 ( / ) | n= 2 (11.8%) \| 81.00 (12.73) | [Not calculable] |
| Week 304 | n= 1 ( 4.3%) \| 100.00 ( / ) | n= 2 (11.8%) \| 70.00 (0.00) | [Not calculable] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 305 | [No Data] | n= 1 ( 5.9%) \| 75.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 5.9%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 5.9%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 5.9%) \| 90.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 5.9%) \| 85.00 ( / ) | [No Data for at least 1 arm] |
| **>= 75** | | | |
| N subjects in population | N=8 | N=5 | |
| Baseline | n= 8 (100.0%) \| 73.00 (15.54) | n= 5 (100.0%) \| 92.60 (5.59) | -1.42 [-2.74 ;-0.10] |
| Week 3 | n= 8 (100.0%) \| 79.88 (17.33) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 7 (87.5%) \| 69.14 (23.11) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (87.5%) \| 75.14 (15.30) | n= 4 (80.0%) \| 90.00 (8.16) | -1.02 [-2.40 ; 0.37] |
| Week 9 | n= 6 (75.0%) \| 73.67 (12.16) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 7 (87.5%) \| 77.14 (13.09) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 5 (62.5%) \| 59.60 (32.99) | n= 4 (80.0%) \| 86.25 (9.46) | -0.92 [-2.42 ; 0.58] |
| Week 15 | n= 6 (75.0%) \| 78.67 (12.42) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 7 (87.5%) \| 76.86 (10.76) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 6 (75.0%) \| 81.17 (14.97) | n= 4 (80.0%) \| 88.75 (6.29) | -0.55 [-1.92 ; 0.82] |
| Week 21 | n= 6 (75.0%) \| 78.50 (12.10) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (75.0%) \| 81.00 (14.32) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (75.0%) \| 79.67 (14.50) | n= 5 (100.0%) \| 91.80 (8.14) | -0.92 [-2.25 ; 0.41] |
| Week 27 | n= 6 (75.0%) \| 79.50 (12.90) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 5 (62.5%) \| 76.00 (11.90) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 6 (75.0%) \| 79.00 (11.30) | n= 3 (60.0%) \| 96.33 (5.51) | -1.54 [-3.26 ; 0.17] |
| Week 33 | n= 6 (75.0%) \| 79.50 (11.95) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 6 (75.0%) \| 79.67 (12.04) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 5 (62.5%) \| 80.20 (12.19) | n= 3 (60.0%) \| 92.00 (10.58) | -0.88 [-2.52 ; 0.77] |
| Week 39 | n= 5 (62.5%) \| 76.40 (11.55) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 5 (62.5%) \| 76.80 (13.52) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 6 (75.0%) \| 80.67 (12.74) | n= 1 (20.0%) \| 90.00 ( / ) | [Not calculable] |
| Week 45 | n= 5 (62.5%) \| 77.40 (11.65) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (75.0%) \| 80.67 (12.74) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (75.0%) \| 80.83 (12.64) | n= 1 (20.0%) \| 90.00 ( / ) | [Not calculable] |
| Week 51 | n= 6 (75.0%) \| 79.67 (12.60) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 5 (62.5%) \| 78.60 (12.40) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 5 (62.5%) \| 80.60 (14.89) | n= 1 (20.0%) \| 90.00 ( / ) | [Not calculable] |
| Week 57 | n= 4 (50.0%) \| 76.50 (12.07) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 5 (62.5%) \| 81.40 (14.01) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 5 (62.5%) \| 81.40 (13.41) | n= 1 (20.0%) \| 90.00 ( / ) | [Not calculable] |
| Week 63 | n= 3 (37.5%) \| 83.33 (5.77) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 5 (62.5%) \| 81.60 (13.24) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 4 (50.0%) \| 82.50 (17.08) | n= 1 (20.0%) \| 90.00 ( / ) | [Not calculable] |
| Week 69 | n= 2 (25.0%) \| 75.00 (21.21) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 3 (37.5%) \| 83.33 (20.82) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (37.5%) \| 79.67 (17.90) | [No Data] | [No Data for at least 1 arm] |
| Week 75 | n= 2 (25.0%) \| 74.50 (21.92) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (37.5%) \| 82.67 (20.03) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 2 (25.0%) \| 95.00 (7.07) | n= 1 (20.0%) \| 90.00 ( / ) | [Not calculable] |
| Week 81 | n= 2 (25.0%) \| 91.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (25.0%) \| 92.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (25.0%) \| 90.00 (0.00) | n= 1 (20.0%) \| 90.00 ( / ) | [Not calculable] |
| Week 87 | n= 2 (25.0%) \| 92.50 (3.54) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 2 (25.0%) \| 91.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 93 | n= 1 (12.5%) \| 97.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 1 (12.5%) \| 96.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 1 (12.5%) \| 96.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 1 (12.5%) \| 93.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (12.5%) \| 75.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (12.5%) \| 83.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 (12.5%) \| 84.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 (12.5%) \| 82.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (12.5%) \| 85.00 ( / ) | n= 4 (80.0%) \| 91.25 (7.50) | [Not calculable] |
| Week 202 | n= 1 (12.5%) \| 45.00 ( / ) | n= 3 (60.0%) \| 95.33 (0.58) | [Not calculable] |
| Week 301 | n= 1 (12.5%) \| 50.00 ( / ) | n= 2 (40.0%) \| 92.00 (4.24) | [Not calculable] |
| Week 302 | n= 1 (12.5%) \| 50.00 ( / ) | n= 2 (40.0%) \| 85.00 (7.07) | [Not calculable] |
| Week 303 | n= 1 (12.5%) \| 50.00 ( / ) | n= 1 (20.0%) \| 90.00 ( / ) | [Not calculable] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:40:59

TABLE 7.1.3: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Week 3 | n= 39 (97.5%) \| 1.21 (8.56) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 36 (90.0%) \| 0.61 (13.82) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 37 (92.5%) \|-1.00 (16.13) | n= 41 (89.1%) \|-1.63 (10.87) | 0.05 [-0.40 ; 0.49] |
| Week 9 | n= 35 (87.5%) \|-1.54 (18.22) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \|-0.11 (16.66) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 35 (87.5%) \|-0.77 (19.30) | n= 37 (80.4%) \|-2.14 (21.66) | 0.07 [-0.40 ; 0.53] |
| Week 15 | n= 34 (85.0%) \|-2.65 (22.61) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 36 (90.0%) \| 0.47 (18.61) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \| 1.97 (11.93) | n= 39 (84.8%) \|-3.15 (10.48) | 0.45 [-0.02 ; 0.93] |
| Week 21 | n= 36 (90.0%) \| 0.58 (12.90) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 35 (87.5%) \| 0.29 (12.04) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \| 1.78 (12.90) | n= 37 (80.4%) \| 1.16 (16.59) | 0.04 [-0.42 ; 0.50] |
| Week 27 | n= 33 (82.5%) \| 1.21 (14.27) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \| 2.24 (14.04) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \| 4.52 (12.18) | n= 29 (63.0%) \|-2.93 (12.64) | 0.59 [ 0.08 ; 1.11] |
| Week 33 | n= 36 (90.0%) \| 2.72 (12.89) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 33 (82.5%) \| 2.52 (13.30) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \| 1.16 (12.12) | n= 32 (69.6%) \|-2.25 (11.10) | 0.29 [-0.21 ; 0.79] |
| Week 39 | n= 33 (82.5%) \| 3.42 (12.35) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \| 2.59 (13.19) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 31 (77.5%) \| 3.32 (14.02) | n= 31 (67.4%) \|-2.71 (13.65) | 0.43 [-0.08 ; 0.94] |
| Week 45 | n= 33 (82.5%) \| 0.36 (10.65) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \| 3.55 (12.35) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 34 (85.0%) \| 3.15 (13.02) | n= 27 (58.7%) \|-2.22 (12.16) | 0.42 [-0.10 ; 0.93] |
| Week 51 | n= 32 (80.0%) \| 0.13 (8.23) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 31 (77.5%) \|-1.16 (20.00) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 31 (77.5%) \|-0.13 (18.52) | n= 26 (56.5%) \|-1.73 (13.30) | 0.10 [-0.43 ; 0.62] |
| Week 57 | n= 31 (77.5%) \|-1.13 (18.12) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 28 (70.0%) \|-0.64 (12.78) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \| 1.45 (10.56) | n= 19 (41.3%) \|-7.58 (14.08) | 0.74 [ 0.15 ; 1.34] |
| Week 63 | n= 30 (75.0%) \| 0.27 (10.80) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 28 (70.0%) \| 2.29 (9.87) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \| 0.97 (11.97) | n= 20 (43.5%) \|-3.70 (12.25) | 0.38 [-0.19 ; 0.95] |
| Week 69 | n= 28 (70.0%) \|-0.68 (12.30) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \| 0.79 (13.19) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \|-0.40 (13.69) | n= 18 (39.1%) \|-4.61 (13.28) | 0.31 [-0.31 ; 0.92] |
| Week 75 | n= 26 (65.0%) \| 0.08 (12.87) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \| 0.71 (12.45) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \| 1.54 (13.13) | n= 16 (34.8%) \|-5.13 (15.07) | 0.47 [-0.18 ; 1.12] |
| Week 81 | n= 24 (60.0%) \| 1.21 (12.96) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \| 1.28 (13.14) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \| 3.00 (11.10) | n= 14 (30.4%) \|-5.36 (15.26) | 0.63 [-0.08 ; 1.34] |
| Week 87 | n= 19 (47.5%) \| 0.79 (12.24) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (47.5%) \| 0.53 (11.77) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 20 (50.0%) \| 0.75 (12.12) | n= 11 (23.9%) \|-0.55 (12.44) | 0.10 [-0.65 ; 0.85] |
| Week 93 | n= 17 (42.5%) \| 2.18 (11.57) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \|-2.00 (9.71) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \|-2.12 (10.25) | n= 8 (17.4%) \|-2.50 (7.19) | 0.04 [-0.82 ; 0.90] |
| Week 99 | n= 13 (32.5%) \|-0.62 (9.91) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \|-0.58 (8.48) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \| 1.33 (6.58) | n= 7 (15.2%) \|-2.57 (9.78) | 0.47 [-0.50 ; 1.45] |
| Week 105 | n= 11 (27.5%) \|-2.64 (9.42) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \|-0.14 (6.01) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \|-1.44 (8.62) | n= 3 ( 6.5%) \|-10.67 (16.77) | 0.79 [-0.63 ; 2.21] |
| Week 111 | n= 7 (17.5%) \|-1.14 (5.37) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \|-1.86 (9.70) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \| 1.33 (12.61) | n= 3 ( 6.5%) \|-10.67 (22.94) | 0.66 [-0.87 ; 2.19] |
| Week 117 | n= 5 (12.5%) \|-1.20 (11.82) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \|-3.20 (12.72) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \| 0.83 (8.52) | n= 1 ( 2.2%) \|-8.00 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \| 8.00 ( / ) | n= 1 ( 2.2%) \| 0.00 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \| 8.00 (28.32) | n= 9 (19.6%) \|-9.89 (17.03) | 0.80 [-0.48 ; 2.08] |
| Week 202 | [No Data] | n= 7 (15.2%) \|-0.14 (10.33) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 ( 8.7%) \| 1.25 (10.31) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 1 ( 2.2%) \| 15.00 ( / ) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 2.5%) \| 10.00 ( / ) | n= 3 ( 6.5%) \| 23.67 (42.19) | [Not calculable] |
| Week 304 | [No Data] | n= 1 ( 2.2%) \| 20.00 ( / ) | [No Data for at least 1 arm] |
| **>= 65 AND < 75** | | | |
| N subjects in population | N=23 | N=17 | |
| Week 3 | n= 20 (87.0%) \| 1.45 (18.65) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 22 (95.7%) \|-3.73 (19.88) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 22 (95.7%) \|-5.05 (22.60) | n= 17 (100.0%) \|-0.24 (20.77) | -0.22 [-0.86 ; 0.43] |
| Week 9 | n= 18 (78.3%) \|-2.33 (21.38) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 19 (82.6%) \|-5.11 (28.93) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 19 (82.6%) \|-6.42 (27.78) | n= 12 (70.6%) \|-1.42 (11.42) | -0.21 [-0.95 ; 0.52] |
| Week 15 | n= 14 (60.9%) \|-3.86 (29.17) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 18 (78.3%) \| 1.89 (18.39) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 19 (82.6%) \|-2.42 (23.99) | n= 10 (58.8%) \|-0.10 (9.56) | -0.11 [-0.89 ; 0.67] |
| Week 21 | n= 18 (78.3%) \|-1.28 (24.15) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (65.2%) \|-4.93 (29.09) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 15 (65.2%) \|-0.13 (16.88) | n= 8 (47.1%) \| 3.38 (17.32) | -0.20 [-1.08 ; 0.68] |
| Week 27 | n= 16 (69.6%) \| 4.38 (15.76) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 15 (65.2%) \| 1.13 (18.71) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 15 (65.2%) \| 0.53 (18.12) | n= 11 (64.7%) \|-4.09 (16.85) | 0.25 [-0.54 ; 1.05] |
| Week 33 | n= 15 (65.2%) \|-4.33 (10.75) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 14 (60.9%) \| 0.71 (16.67) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 13 (56.5%) \| 5.31 (20.30) | n= 11 (64.7%) \| 0.73 (13.89) | 0.25 [-0.57 ; 1.07] |
| Week 39 | n= 15 (65.2%) \| 3.20 (16.38) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 12 (52.2%) \|-2.33 (10.44) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 16 (69.6%) \|-0.31 (16.79) | n= 11 (64.7%) \| 1.45 (15.60) | -0.10 [-0.89 ; 0.68] |
| Week 45 | n= 11 (47.8%) \| 0.27 (20.28) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 13 (56.5%) \| 3.38 (18.00) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 13 (56.5%) \| 2.23 (16.51) | n= 10 (58.8%) \| 2.00 (13.34) | 0.01 [-0.83 ; 0.86] |
| Week 51 | n= 13 (56.5%) \| 3.54 (16.03) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (56.5%) \| 2.00 (16.93) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 55 | n= 11 (47.8%) \| 4.18 (18.93) | n= 10 (58.8%) \| 0.10 (18.15) | 0.21 [-0.67 ; 1.09] |
| Week 57 | n= 12 (52.2%) \| 3.58 (19.50) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 13 (56.5%) \| 0.46 (17.65) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 12 (52.2%) \| 1.83 (18.13) | n= 10 (58.8%) \|-1.30 (15.71) | 0.18 [-0.68 ; 1.04] |
| Week 63 | n= 9 (39.1%) \|-2.22 (7.38) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (47.8%) \| 1.27 (16.93) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (34.8%) \| 5.38 (18.86) | n= 9 (52.9%) \| 3.56 (16.81) | 0.10 [-0.89 ; 1.08] |
| Week 69 | n= 7 (30.4%) \| 4.57 (21.79) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 8 (34.8%) \|-1.13 (7.28) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 6 (26.1%) \|-0.67 (8.19) | n= 10 (58.8%) \| 0.60 (15.75) | -0.09 [-1.14 ; 0.96] |
| Week 75 | n= 8 (34.8%) \|-1.00 (8.14) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (21.7%) \| 8.60 (26.88) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (21.7%) \|-2.80 (9.83) | n= 8 (47.1%) \| 2.25 (14.26) | -0.37 [-1.54 ; 0.81] |
| Week 81 | n= 5 (21.7%) \|-1.60 (10.45) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (26.1%) \| 0.67 (8.57) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (21.7%) \|-2.40 (8.23) | n= 6 (35.3%) \| 0.00 (9.34) | -0.25 [-1.51 ; 1.01] |
| Week 87 | n= 3 (13.0%) \|-10.00 (5.00) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 4 (17.4%) \|-3.75 (8.30) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (17.4%) \|-3.50 (8.54) | n= 5 (29.4%) \| 2.40 (8.44) | -0.62 [-2.07 ; 0.83] |
| Week 93 | n= 3 (13.0%) \|-1.00 (4.00) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (17.4%) \|-4.50 (7.72) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (13.0%) \|-2.67 (11.59) | n= 3 (17.6%) \|-1.67 (2.89) | -0.09 [-1.91 ; 1.72] |
| Week 99 | n= 3 (13.0%) \|-2.67 (10.69) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 8.7%) \|-6.50 (12.02) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (13.0%) \|-1.33 (12.10) | n= 3 (17.6%) \| 0.00 (5.00) | -0.12 [-1.93 ; 1.70] |
| Week 105 | n= 3 (13.0%) \|-3.67 (10.02) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 4.3%) \| 5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 8.7%) \|-4.00 (15.56) | n= 2 (11.8%) \|-3.00 (2.83) | -0.05 [-2.51 ; 2.41] |
| Week 113 | n= 1 ( 4.3%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 4.3%) \|-15.00 ( / ) | n= 2 (11.8%) \| 2.00 (9.90) | [Not calculable] |
| Week 117 | n= 1 ( 4.3%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 4.3%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 4.3%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 4.3%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.3%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 4.3%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 4.3%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 4.3%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.3%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 4.3%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 4.3%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 4.3%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.3%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (13.0%) \|-9.00 (10.39) | n= 4 (23.5%) \|-8.75 (15.56) | -0.02 [-1.67 ; 1.64] |
| Week 202 | n= 1 ( 4.3%) \|-4.00 ( / ) | n= 2 (11.8%) \|-5.00 (21.21) | [Not calculable] |
| Week 301 | n= 1 ( 4.3%) \| 10.00 ( / ) | n= 3 (17.6%) \| 7.00 (15.72) | [Not calculable] |
| Week 302 | n= 1 ( 4.3%) \| 0.00 ( / ) | n= 3 (17.6%) \| 1.00 (1.00) | [Not calculable] |
| Week 303 | n= 1 ( 4.3%) \| 0.00 ( / ) | n= 2 (11.8%) \| 4.00 (8.49) | [Not calculable] |
| Week 304 | n= 1 ( 4.3%) \| 0.00 ( / ) | n= 2 (11.8%) \|-7.00 (4.24) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 5.9%) \| 67.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 5.9%) \| 62.00 ( / ) | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 307 | [No Data] | n= 1 ( 5.9%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 5.9%) \| 82.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 5.9%) \| 77.00 ( / ) | [No Data for at least 1 arm] |
| **>= 75** | | | |
| N subjects in population | N=8 | N=5 | |
| Week 3 | n= 8 (100.0%) \| 6.88 (15.72) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 7 (87.5%) \|-2.86 (8.95) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (87.5%) \| 3.14 (13.27) | n= 4 (80.0%) \|-2.50 (6.45) | 0.45 [-0.86 ; 1.76] |
| Week 9 | n= 6 (75.0%) \|-2.33 (7.66) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 7 (87.5%) \| 0.86 (14.23) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 5 (62.5%) \|-14.60 (32.26) | n= 4 (80.0%) \|-5.75 (6.75) | -0.32 [-1.74 ; 1.10] |
| Week 15 | n= 6 (75.0%) \| 1.33 (9.20) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 7 (87.5%) \| 0.57 (6.88) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 6 (75.0%) \| 3.83 (10.21) | n= 4 (80.0%) \|-3.25 (10.44) | 0.62 [-0.76 ; 2.00] |
| Week 21 | n= 6 (75.0%) \| 1.17 (7.91) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (75.0%) \| 3.67 (10.52) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (75.0%) \| 2.33 (11.50) | n= 5 (100.0%) \|-0.80 (11.26) | 0.25 [-1.01 ; 1.51] |
| Week 27 | n= 6 (75.0%) \| 2.17 (8.16) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 5 (62.5%) \| 1.80 (8.61) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 6 (75.0%) \| 1.67 (7.84) | n= 3 (60.0%) \| 4.67 (12.86) | -0.28 [-1.77 ; 1.22] |
| Week 33 | n= 6 (75.0%) \| 2.17 (7.73) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 6 (75.0%) \| 2.33 (8.14) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 5 (62.5%) \| 3.40 (7.40) | n= 3 (60.0%) \| 0.33 (10.50) | 0.31 [-1.25 ; 1.88] |
| Week 39 | n= 5 (62.5%) \| 2.20 (7.85) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 5 (62.5%) \| 0.00 (8.15) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 6 (75.0%) \| 3.33 (6.74) | n= 1 (20.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 45 | n= 5 (62.5%) \| 3.20 (7.73) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (75.0%) \| 3.33 (6.74) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (75.0%) \| 3.50 (6.32) | n= 1 (20.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 51 | n= 6 (75.0%) \| 2.33 (6.89) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 5 (62.5%) \| 2.40 (8.20) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 5 (62.5%) \| 4.40 (8.08) | n= 1 (20.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 57 | n= 4 (50.0%) \| 4.50 (7.51) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 5 (62.5%) \| 5.20 (5.07) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 5 (62.5%) \| 5.20 (4.60) | n= 1 (20.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 63 | n= 3 (37.5%) \| 4.00 (5.29) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 5 (62.5%) \| 5.40 (5.46) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 4 (50.0%) \| 6.75 (4.72) | n= 1 (20.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 69 | n= 2 (25.0%) \| 10.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 3 (37.5%) \| 9.00 (1.73) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (37.5%) \| 5.33 (7.23) | [No Data] | [No Data for at least 1 arm] |
| Week 75 | n= 2 (25.0%) \| 9.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (37.5%) \| 8.33 (2.89) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 2 (25.0%) \| 8.50 (2.12) | n= 1 (20.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 81 | n= 2 (25.0%) \| 4.50 (7.78) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (25.0%) \| 6.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (25.0%) \| 3.50 (9.19) | n= 1 (20.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 87 | n= 2 (25.0%) \| 6.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (25.0%) \| 5.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 93 | n= 1 (12.5%) \| 4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 1 (12.5%) \| 3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 97 | n= 1 (12.5%) \| 3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 1 (12.5%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (12.5%) \|-18.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (12.5%) \|-10.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 (12.5%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 (12.5%) \|-11.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (12.5%) \| 15.00 ( / ) | n= 4 (80.0%) \|-2.00 (9.63) | [Not calculable] |
| Week 202 | n= 1 (12.5%) \|-5.00 ( / ) | n= 3 (60.0%) \| 2.00 (8.19) | [Not calculable] |
| Week 301 | n= 1 (12.5%) \| 0.00 ( / ) | n= 2 (40.0%) \|-4.50 (0.71) | [Not calculable] |
| Week 302 | n= 1 (12.5%) \|-20.00 ( / ) | n= 2 (40.0%) \|-4.00 (12.73) | [Not calculable] |
| Week 303 | n= 1 (12.5%) \|-20.00 ( / ) | n= 1 (20.0%) \| 5.00 ( / ) | [Not calculable] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:40:59

TABLE 7.1.3: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **< 65** | | | | |
| Nr subjects used | n=40 | n=46 | | |
| Week 7 | -2.33 (2.42) [-7.14 ; 2.49] | -2.37 (2.30) [-6.94 ; 2.20] | 0.04 (3.33) [-6.59 ; 6.67] | 0.00 [-0.44 ; 0.45] |
| Week 13 | -3.72 (3.53) [-10.74 ; 3.31] | -1.46 (3.38) [-8.18 ; 5.25] | -2.25 (4.88) [-11.97 ; 7.46] | -0.11 [-0.57 ; 0.35] |
| Week 19 | -0.48 (2.23) [-4.92 ; 3.97] | -1.88 (2.09) [-6.04 ; 2.28] | 1.41 (3.06) [-4.68 ; 7.49] | 0.11 [-0.36 ; 0.58] |
| Week 25 | 0.84 (1.93) [-3.00 ; 4.69] | 1.47 (1.86) [-2.24 ; 5.18] | -0.62 (2.68) [-5.96 ; 4.72] | -0.05 [-0.51 ; 0.41] |
| Week 31 | 2.76 (1.86) [-0.95 ; 6.46] | -0.00 (1.85) [-3.69 ; 3.69] | 2.76 (2.63) [-2.47 ; 7.99] | 0.26 [-0.24 ; 0.76] |
| Week 37 | 1.18 (1.94) [-2.68 ; 5.03] | -1.53 (1.90) [-5.30 ; 2.25] | 2.70 (2.72) [-2.69 ; 8.10] | 0.25 [-0.25 ; 0.74] |
| Week 43 | 2.21 (2.02) [-1.79 ; 6.22] | -1.88 (2.02) [-5.89 ; 2.13] | 4.09 (2.85) [-1.58 ; 9.76] | 0.36 [-0.14 ; 0.86] |
| Week 49 | 1.95 (1.88) [-1.78 ; 5.69] | -1.40 (2.00) [-5.37 ; 2.57] | 3.36 (2.75) [-2.10 ; 8.81] | 0.31 [-0.20 ; 0.82] |
| Week 55 | 1.04 (2.88) [-4.70 ; 6.78] | 0.06 (3.11) [-6.14 ; 6.26] | 0.97 (4.24) [-7.48 ; 9.43] | 0.06 [-0.46 ; 0.58] |
| Week 61 | 1.50 (2.06) [-2.62 ; 5.61] | -4.38 (2.42) [-9.20 ; 0.44] | 5.88 (3.18) [-0.46 ; 12.23] | 0.52 [-0.06 ; 1.10] |
| Week 67 | 1.10 (2.19) [-3.28 ; 5.48] | -2.94 (2.63) [-8.19 ; 2.30] | 4.04 (3.43) [-2.80 ; 10.88] | 0.33 [-0.24 ; 0.89] |
| Week 73 | -0.62 (2.34) [-5.29 ; 4.05] | -3.63 (2.79) [-9.18 ; 1.93] | 3.01 (3.64) [-4.25 ; 10.26] | 0.25 [-0.36 ; 0.86] |
| Week 79 | 0.55 (2.28) [-3.98 ; 5.08] | -2.96 (2.76) [-8.46 ; 2.53] | 3.51 (3.58) [-3.61 ; 10.64] | 0.31 [-0.33 ; 0.95] |
| Week 85 | 1.49 (1.96) [-2.42 ; 5.40] | -3.97 (2.39) [-8.74 ; 0.80] | 5.46 (3.09) [-0.71 ; 11.63] | 0.60 [-0.10 ; 1.30] |
| Week 91 | 0.74 (1.98) [-3.25 ; 4.72] | -2.19 (2.58) [-7.37 ; 2.99] | 2.92 (3.25) [-3.61 ; 9.46] | 0.33 [-0.42 ; 1.07] |
| Overall post-baseline period estimate | 0.55 (1.31) [-2.05 ; 3.15] | -1.94 (1.37) [-4.66 ; 0.78] | 2.49 (1.90) [-1.28 ; 6.25] | 0.28 [-0.15 ; 0.71] |
| **>= 65 AND < 75** | | | | |
| Nr subjects used | n=23 | n=17 | | |
| Week 7 | -5.34 (3.64) [-12.72 ; 2.05] | -2.92 (4.18) [-11.39 ; 5.55] | -2.42 (5.54) [-13.65 ; 8.82] | -0.14 [-0.77 ; 0.50] |
| Week 13 | -8.52 (4.20) [-17.08 ; 0.04] | 0.44 (5.24) [-10.22 ; 11.10] | -8.96 (6.72) [-22.62 ; 4.71] | -0.48 [-1.21 ; 0.26] |
| Week 19 | -2.65 (3.88) [-10.56 ; 5.26] | 2.20 (5.23) [-8.43 ; 12.84] | -4.85 (6.52) [-18.11 ; 8.41] | -0.28 [-1.05 ; 0.49] |
| Week 31 | 0.04 (2.93) [-5.99 ; 6.06] | -2.26 (3.56) [-9.59 ; 5.06] | 2.30 (4.61) [-7.19 ; 11.79] | 0.19 [-0.59 ; 0.97] |
| Week 37 | 3.46 (2.89) [-2.51 ; 9.43] | 2.54 (3.32) [-4.33 ; 9.41] | 0.92 (4.40) [-8.18 ; 10.03] | 0.08 [-0.72 ; 0.89] |
| Week 43 | -0.72 (3.44) [-7.81 ; 6.37] | 3.26 (4.17) [-5.35 ; 11.87] | -3.98 (5.41) [-15.14 ; 7.18] | -0.28 [-1.05 ; 0.49] |
| Week 49 | 1.06 (2.54) [-4.16 ; 6.28] | 3.43 (2.97) [-2.65 ; 9.52] | -2.38 (3.91) [-10.39 ; 5.64] | -0.25 [-1.08 ; 0.58] |
| Week 55 | 0.94 (3.24) [-5.67 ; 7.55] | 1.68 (3.55) [-5.57 ; 8.92] | -0.73 (4.81) [-10.55 ; 9.08] | -0.06 [-0.92 ; 0.79] |
| Week 61 | 0.71 (2.74) [-4.91 ; 6.34] | 0.41 (3.04) [-5.84 ; 6.66] | 0.30 (4.09) [-8.11 ; 8.71] | 0.03 [-0.81 ; 0.87] |
| Overall post-baseline period estimate | -1.22 (1.74) [-4.73 ; 2.28] | 0.98 (2.13) [-3.33 ; 5.28] | -2.20 (2.75) [-7.76 ; 3.36] | -0.25 [-0.88 ; 0.38] |
| **>= 75** | | | | |
| Nr subjects used | n=8 | n=5 | | |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.6207 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:40:59

TABLE 7.1.4: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **US/Canada/Western Europe/Northern Europe** | N=38 | N=34 |
| **Rest of World (ROW)** | N=33 | N=34 |
| **Subjects with Baseline Value** | | |
| **US/Canada/Western Europe/Northern Europe** | 38 (100.0%) | 34 (100.0%) |
| **Rest of World (ROW)** | 33 (100.0%) | 34 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **US/Canada/Western Europe/Northern Europe** | 38 (100.0%) | 33 (97.1%) |
| **Rest of World (ROW)** | 33 (100.0%) | 33 (97.1%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **US/Canada/Western Europe/Northern Europe** | 38 (100.0%) | 33 (97.1%) |
| **Rest of World (ROW)** | 33 (100.0%) | 33 (97.1%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:40:59

TABLE 7.1.4: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **US/Canada/Western Europe/Northern Europe** | | | |
| N subjects in population | N=38 | N=34 | |
| Baseline | n= 38 (100.0%) \| 77.26 (19.93) | n= 34 (100.0%) \| 76.09 (21.19) | 0.06 [-0.41 ; 0.52] |
| Week 3 | n= 36 (94.7%) \| 79.39 (14.87) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 35 (92.1%) \| 79.83 (14.85) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 35 (92.1%) \| 78.37 (17.90) | n= 30 (88.2%) \| 74.63 (18.16) | 0.20 [-0.29 ; 0.70] |
| Week 9 | n= 30 (78.9%) \| 79.37 (14.92) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 32 (84.2%) \| 75.63 (17.71) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 31 (81.6%) \| 73.84 (24.46) | n= 24 (70.6%) \| 78.58 (12.93) | -0.23 [-0.77 ; 0.31] |
| Week 15 | n= 27 (71.1%) \| 75.70 (18.57) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 32 (84.2%) \| 78.50 (15.27) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 30 (78.9%) \| 77.20 (19.25) | n= 25 (73.5%) \| 77.16 (14.66) | 0.00 [-0.53 ; 0.54] |
| Week 21 | n= 30 (78.9%) \| 79.03 (17.64) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 28 (73.7%) \| 77.00 (13.32) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 29 (76.3%) \| 79.97 (11.87) | n= 25 (73.5%) \| 81.36 (11.76) | -0.12 [-0.66 ; 0.42] |
| Week 27 | n= 27 (71.1%) \| 80.93 (11.77) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 27 (71.1%) \| 77.74 (13.98) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 25 (65.8%) \| 80.16 (10.63) | n= 20 (58.8%) \| 78.65 (16.85) | 0.11 [-0.49 ; 0.70] |
| Week 33 | n= 30 (78.9%) \| 78.87 (13.05) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 27 (71.1%) \| 78.48 (15.89) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 25 (65.8%) \| 77.52 (14.31) | n= 22 (64.7%) \| 80.73 (11.80) | -0.24 [-0.82 ; 0.34] |
| Week 39 | n= 28 (73.7%) \| 79.11 (13.23) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 28 (73.7%) \| 80.57 (13.78) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 29 (76.3%) \| 79.21 (13.96) | n= 21 (61.8%) \| 82.14 (14.08) | -0.21 [-0.77 ; 0.36] |
| Week 45 | n= 25 (65.8%) \| 78.64 (12.75) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 27 (71.1%) \| 80.41 (12.55) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 29 (76.3%) \| 79.31 (14.33) | n= 18 (52.9%) \| 80.44 (14.20) | -0.08 [-0.67 ; 0.52] |
| Week 51 | n= 27 (71.1%) \| 80.30 (13.56) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 26 (68.4%) \| 76.19 (22.53) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 26 (68.4%) \| 76.42 (21.91) | n= 16 (47.1%) \| 80.31 (15.88) | -0.19 [-0.82 ; 0.44] |
| Week 57 | n= 26 (68.4%) \| 75.50 (20.94) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 24 (63.2%) \| 74.58 (21.57) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 24 (63.2%) \| 80.29 (14.78) | n= 12 (35.3%) \| 76.83 (18.05) | 0.21 [-0.49 ; 0.92] |
| Week 63 | n= 21 (55.3%) \| 75.90 (16.17) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (57.9%) \| 76.64 (17.92) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 23 (60.5%) \| 80.87 (15.69) | n= 12 (35.3%) \| 82.08 (10.79) | -0.08 [-0.79 ; 0.62] |
| Week 69 | n= 19 (50.0%) \| 77.37 (14.31) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 21 (55.3%) \| 80.71 (15.85) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (42.1%) \| 75.88 (16.02) | n= 14 (41.2%) \| 77.79 (19.01) | -0.11 [-0.84 ; 0.62] |
| Week 75 | n= 17 (44.7%) \| 76.88 (18.00) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (42.1%) \| 78.13 (16.06) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 15 (39.5%) \| 77.60 (21.17) | n= 11 (32.4%) \| 76.36 (19.16) | 0.06 [-0.73 ; 0.85] |
| Week 81 | n= 16 (42.1%) \| 80.25 (15.60) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 16 (42.1%) \| 80.69 (15.20) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (28.9%) \| 85.09 (10.13) | n= 10 (29.4%) \| 80.20 (20.38) | 0.30 [-0.59 ; 1.18] |
| Week 87 | n= 10 (26.3%) \| 79.40 (18.48) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 11 (28.9%) \| 79.36 (15.42) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 12 (31.6%) \| 79.25 (16.08) | n= 7 (20.6%) \| 85.71 (11.03) | -0.43 [-1.40 ; 0.54] |
| Week 93 | n= 11 (28.9%) \| 78.45 (17.45) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (28.9%) \| 74.91 (18.17) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (31.6%) \| 76.75 (19.60) | n= 5 (14.7%) \| 82.80 (12.91) | -0.32 [-1.40 ; 0.77] |
| Week 99 | n= 9 (23.7%) \| 74.00 (18.23) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (15.8%) \| 77.83 (10.50) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (21.1%) \| 82.50 (12.68) | n= 5 (14.7%) \| 83.40 (13.48) | -0.06 [-1.23 ; 1.10] |
| Week 105 | n= 8 (21.1%) \| 80.13 (13.35) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (10.5%) \| 78.50 (12.66) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (18.4%) \| 75.86 (12.09) | n= 2 ( 5.9%) \| 78.50 (0.71) | -0.21 [-1.90 ; 1.48] |
| Week 111 | n= 4 (10.5%) \| 76.50 (10.60) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (10.5%) \| 80.00 (11.80) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 (10.5%) \| 83.75 (13.38) | n= 3 ( 8.8%) \| 84.67 (4.51) | -0.07 [-1.73 ; 1.58] |
| Week 117 | n= 4 (10.5%) \| 81.50 (5.07) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 (10.5%) \| 76.50 (12.50) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (13.2%) \| 83.60 (14.17) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.6%) \| 82.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.6%) \| 98.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (10.5%) \| 81.25 (2.50) | n= 8 (23.5%) \| 74.63 (24.37) | 0.30 [-0.97 ; 1.57] |
| Week 202 | [No Data] | n= 5 (14.7%) \| 89.80 (12.56) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 (11.8%) \| 79.75 (8.77) | [No Data for at least 1 arm] |
| Week 302 | n= 1 ( 2.6%) \| 50.00 ( / ) | n= 3 ( 8.8%) \| 80.00 (5.00) | [Not calculable] |
| Week 303 | n= 2 ( 5.3%) \| 45.00 (7.07) | n= 2 ( 5.9%) \| 76.00 (5.66) | -2.77 [-7.64 ; 2.11] |
| Week 304 | n= 1 ( 2.6%) \| 100.00 ( / ) | n= 1 ( 2.9%) \| 70.00 ( / ) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 2.9%) \| 75.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 2.9%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 2.9%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 2.9%) \| 90.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 2.9%) \| 85.00 ( / ) | [No Data for at least 1 arm] |
| **Rest of World (ROW)** | | | |
| N subjects in population | N=33 | N=34 | |
| Baseline | n= 33 (100.0%) \| 78.45 (14.79) | n= 34 (100.0%) \| 83.35 (14.05) | -0.34 [-0.82 ; 0.15] |
| Week 3 | n= 31 (93.9%) \| 82.32 (11.83) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 30 (90.9%) \| 75.83 (18.61) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 31 (93.9%) \| 74.90 (17.79) | n= 32 (94.1%) \| 80.28 (15.86) | -0.32 [-0.82 ; 0.19] |
| Week 9 | n= 29 (87.9%) \| 76.07 (17.32) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 29 (87.9%) \| 78.48 (17.44) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 28 (84.8%) \| 75.07 (21.45) | n= 29 (85.3%) \| 80.76 (14.29) | -0.31 [-0.84 ; 0.22] |
| Week 15 | n= 27 (81.8%) \| 75.59 (21.68) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 29 (87.9%) \| 78.83 (15.80) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 27 (81.8%) \| 81.56 (12.66) | n= 28 (82.4%) \| 84.54 (11.55) | -0.24 [-0.78 ; 0.29] |
| Week 21 | n= 30 (90.9%) \| 77.60 (14.03) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 28 (84.8%) \| 75.93 (20.26) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 28 (84.8%) \| 81.68 (12.03) | n= 25 (73.5%) \| 86.56 (10.53) | -0.42 [-0.97 ; 0.13] |
| Week 27 | n= 28 (84.8%) \| 81.75 (13.36) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 26 (78.8%) \| 83.96 (12.92) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 29 (87.9%) \| 82.38 (11.67) | n= 23 (67.6%) \| 83.35 (11.61) | -0.08 [-0.63 ; 0.47] |
| Week 33 | n= 27 (81.8%) \| 82.81 (12.01) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 26 (78.8%) \| 82.62 (10.71) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 24 (72.7%) \| 83.96 (11.73) | n= 24 (70.6%) \| 83.38 (15.21) | 0.04 [-0.53 ; 0.61] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 39 | n= 25 (75.8%) \| 84.84 (11.29) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 23 (69.7%) \| 83.39 (12.29) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 24 (72.7%) \| 83.92 (13.07) | n= 22 (64.7%) \| 80.64 (14.85) | 0.23 [-0.36 ; 0.82] |
| Week 45 | n= 24 (72.7%) \| 80.96 (14.02) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 25 (75.8%) \| 84.24 (11.35) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 24 (72.7%) \| 84.29 (11.70) | n= 20 (58.8%) \| 83.20 (12.34) | 0.09 [-0.51 ; 0.69] |
| Week 51 | n= 24 (72.7%) \| 82.17 (11.22) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 23 (69.7%) \| 84.35 (10.33) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 21 (63.6%) \| 84.67 (10.63) | n= 21 (61.8%) \| 84.05 (12.50) | 0.05 [-0.56 ; 0.66] |
| Week 57 | n= 21 (63.6%) \| 85.38 (10.10) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 22 (66.7%) \| 84.59 (11.20) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 24 (72.7%) \| 83.71 (10.91) | n= 18 (52.9%) \| 79.44 (13.32) | 0.35 [-0.27 ; 0.97] |
| Week 63 | n= 21 (63.6%) \| 84.52 (10.08) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (66.7%) \| 83.68 (10.31) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 21 (63.6%) \| 83.62 (11.13) | n= 18 (52.9%) \| 82.22 (13.80) | 0.11 [-0.53 ; 0.75] |
| Week 69 | n= 18 (54.5%) \| 83.50 (12.07) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 18 (54.5%) \| 84.56 (12.21) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 18 (54.5%) \| 85.44 (11.26) | n= 14 (41.2%) \| 80.43 (14.47) | 0.38 [-0.33 ; 1.10] |
| Week 75 | n= 19 (57.6%) \| 85.95 (10.14) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (48.5%) \| 84.69 (10.95) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 16 (48.5%) \| 86.44 (9.01) | n= 14 (41.2%) \| 80.71 (14.67) | 0.46 [-0.27 ; 1.20] |
| Week 81 | n= 15 (45.5%) \| 86.47 (8.91) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (51.5%) \| 86.82 (9.98) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 16 (48.5%) \| 87.69 (7.46) | n= 11 (32.4%) \| 82.45 (12.26) | 0.52 [-0.27 ; 1.32] |
| Week 87 | n= 14 (42.4%) \| 83.21 (12.19) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 14 (42.4%) \| 85.00 (8.77) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 12 (36.4%) \| 85.50 (9.48) | n= 9 (26.5%) \| 84.44 (9.17) | 0.11 [-0.78 ; 1.00] |
| Week 93 | n= 10 (30.3%) \| 87.90 (8.95) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (33.3%) \| 86.00 (8.65) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 9 (27.3%) \| 85.22 (8.67) | n= 6 (17.6%) \| 82.50 (11.29) | 0.26 [-0.81 ; 1.34] |
| Week 99 | n= 8 (24.2%) \| 84.63 (9.40) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 8 (24.2%) \| 82.75 (8.63) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 7 (21.2%) \| 82.43 (7.68) | n= 5 (14.7%) \| 81.00 (8.94) | 0.16 [-1.05 ; 1.37] |
| Week 105 | n= 6 (18.2%) \| 77.50 (6.92) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (12.1%) \| 78.50 (8.70) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (12.1%) \| 82.00 (5.42) | n= 3 ( 8.8%) \| 81.67 (12.58) | 0.03 [-1.62 ; 1.68] |
| Week 111 | n= 3 ( 9.1%) \| 80.00 (8.66) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (12.1%) \| 82.75 (8.46) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 ( 9.1%) \| 81.67 (7.64) | n= 2 ( 5.9%) \| 79.00 (22.63) | 0.13 [-1.98 ; 2.25] |
| Week 117 | n= 3 ( 9.1%) \| 84.67 (6.81) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 ( 9.1%) \| 81.00 (3.61) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 ( 9.1%) \| 77.67 (2.08) | n= 1 ( 2.9%) \| 92.00 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 3.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 3.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.0%) \| 80.00 ( / ) | n= 1 ( 2.9%) \| 100.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 3.0%) \| 81.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 3.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 3.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 3.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 3.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 141 | n= 1 ( 3.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.1%) \| 75.25 (12.53) | n= 9 (26.5%) \| 82.33 (10.26) | -0.60 [-1.86 ; 0.65] |
| Week 202 | n= 2 ( 6.1%) \| 64.00 (26.87) | n= 7 (20.6%) \| 87.29 (9.21) | -1.56 [-3.46 ; 0.34] |
| Week 301 | n= 2 ( 6.1%) \| 70.00 (28.28) | n= 5 (14.7%) \| 86.00 (6.52) | -0.97 [-2.90 ; 0.96] |
| Week 302 | n= 1 ( 3.0%) \| 80.00 ( / ) | n= 3 ( 8.8%) \| 85.00 (5.00) | [Not calculable] |
| Week 303 | n= 1 ( 3.0%) \| 80.00 ( / ) | n= 4 (11.8%) \| 85.00 (5.77) | [Not calculable] |
| Week 304 | [No Data] | n= 2 ( 5.9%) \| 80.00 (14.14) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:00

TABLE 7.1.4: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **US/Canada/Western Europe/Northern Europe** | | | |
| N subjects in population | N=38 | N=34 | |
| Week 3 | n= 36 (94.7%) \| 1.42 (14.35) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 35 (92.1%) \| 1.69 (16.63) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 35 (92.1%) \| 0.11 (18.33) | n= 30 (88.2%) \| 0.63 (16.59) | -0.03 [-0.52 ; 0.46] |
| Week 9 | n= 30 (78.9%) \| 1.80 (18.58) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 32 (84.2%) \|-0.59 (22.25) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 31 (81.6%) \|-2.48 (25.71) | n= 24 (70.6%) \| 0.96 (22.04) | -0.14 [-0.68 ; 0.40] |
| Week 15 | n= 27 (71.1%) \| 1.93 (25.10) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 32 (84.2%) \| 2.91 (18.10) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 30 (78.9%) \| 2.07 (19.96) | n= 25 (73.5%) \|-4.00 (10.44) | 0.37 [-0.17 ; 0.91] |
| Week 21 | n= 30 (78.9%) \| 2.73 (20.29) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 28 (73.7%) \| 3.00 (16.41) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 29 (76.3%) \| 3.55 (16.02) | n= 25 (73.5%) \| 3.24 (18.37) | 0.02 [-0.52 ; 0.56] |
| Week 27 | n= 27 (71.1%) \| 4.74 (15.40) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 27 (71.1%) \| 2.56 (17.54) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 25 (65.8%) \| 6.08 (15.50) | n= 20 (58.8%) \|-2.40 (14.89) | 0.55 [-0.06 ; 1.15] |
| Week 33 | n= 30 (78.9%) \| 0.97 (12.31) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 27 (71.1%) \| 4.11 (15.98) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 25 (65.8%) \| 4.04 (17.08) | n= 22 (64.7%) \| 0.68 (10.85) | 0.23 [-0.35 ; 0.81] |
| Week 39 | n= 28 (73.7%) \| 4.07 (15.10) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 28 (73.7%) \| 1.93 (13.71) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 29 (76.3%) \| 3.38 (17.31) | n= 21 (61.8%) \| 2.95 (12.36) | 0.03 [-0.54 ; 0.59] |
| Week 45 | n= 25 (65.8%) \| 1.48 (14.53) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 27 (71.1%) \| 5.15 (15.92) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 29 (76.3%) \| 5.03 (15.90) | n= 18 (52.9%) \| 1.11 (12.23) | 0.26 [-0.33 ; 0.86] |
| Week 51 | n= 27 (71.1%) \| 3.48 (12.23) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 26 (68.4%) \|-1.08 (24.18) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 26 (68.4%) \| 1.00 (22.63) | n= 16 (47.1%) \| 0.94 (16.19) | 0.00 [-0.63 ; 0.63] |
| Week 57 | n= 26 (68.4%) \| 0.19 (23.43) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 24 (63.2%) \|-0.21 (17.80) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 24 (63.2%) \| 3.58 (15.52) | n= 12 (35.3%) \|-2.75 (16.92) | 0.39 [-0.32 ; 1.10] |
| Week 63 | n= 21 (55.3%) \| 0.14 (11.90) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (57.9%) \| 3.86 (14.41) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 23 (60.5%) \| 3.65 (16.15) | n= 12 (35.3%) \| 2.67 (11.24) | 0.07 [-0.64 ; 0.77] |
| Week 69 | n= 19 (50.0%) \| 2.79 (17.48) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 21 (55.3%) \| 1.00 (13.38) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (42.1%) \|-2.75 (15.32) | n= 14 (41.2%) \|-2.79 (15.54) | 0.00 [-0.73 ; 0.73] |
| Week 75 | n= 17 (44.7%) \|-1.65 (14.03) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (42.1%) \| 3.31 (18.81) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 15 (39.5%) \| 1.27 (15.65) | n= 11 (32.4%) \|-0.91 (17.89) | 0.13 [-0.67 ; 0.92] |
| Week 81 | n= 16 (42.1%) \| 0.38 (15.12) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 16 (42.1%) \| 0.88 (14.62) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (28.9%) \| 3.09 (14.35) | n= 10 (29.4%) \|-1.80 (15.38) | 0.32 [-0.57 ; 1.20] |
| Week 87 | n= 10 (26.3%) \| 1.50 (16.64) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 11 (28.9%) \| 1.55 (15.02) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 12 (31.6%) \| 2.25 (15.09) | n= 7 (20.6%) \| 5.71 (7.41) | -0.26 [-1.22 ; 0.71] |
| Week 93 | n= 11 (28.9%) \| 3.27 (14.00) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (28.9%) \|-3.91 (11.54) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (31.6%) \|-3.00 (11.72) | n= 5 (14.7%) \| 2.80 (4.09) | -0.54 [-1.63 ; 0.56] |
| Week 99 | n= 9 (23.7%) \|-1.22 (10.24) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (15.8%) \| 0.00 (11.08) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (21.1%) \| 3.38 (7.48) | n= 5 (14.7%) \| 3.40 (4.67) | -0.00 [-1.17 ; 1.16] |
| Week 105 | n= 8 (21.1%) \|-0.25 (10.78) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (10.5%) \| 4.50 (4.20) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (18.4%) \|-0.86 (10.40) | n= 2 ( 5.9%) \|-1.50 (0.71) | 0.06 [-1.63 ; 1.74] |
| Week 111 | n= 4 (10.5%) \| 0.00 (7.12) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (10.5%) \|-4.00 (11.89) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 (10.5%) \|-0.25 (15.33) | n= 3 ( 8.8%) \| 4.67 (4.51) | -0.34 [-2.01 ; 1.33] |
| Week 117 | n= 4 (10.5%) \|-8.00 (13.95) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 (10.5%) \|-8.25 (12.87) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (13.2%) \|-0.20 (10.47) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.6%) \|-11.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.6%) \| 8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (10.5%) \| 10.25 (29.50) | n= 8 (23.5%) \|-12.25 (14.65) | 1.02 [-0.32 ; 2.37] |
| Week 202 | [No Data] | n= 5 (14.7%) \|-0.20 (3.19) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 (11.8%) \| 1.75 (15.76) | [No Data for at least 1 arm] |
| Week 302 | n= 1 ( 2.6%) \|-20.00 ( / ) | n= 3 ( 8.8%) \|-3.33 (8.39) | [Not calculable] |
| Week 303 | n= 2 ( 5.3%) \|-5.00 (21.21) | n= 2 ( 5.9%) \| 34.50 (51.62) | -0.57 [-3.18 ; 2.04] |
| Week 304 | n= 1 ( 2.6%) \| 0.00 ( / ) | n= 1 ( 2.9%) \|-4.00 ( / ) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 2.9%) \| 67.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 2.9%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 2.9%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 2.9%) \| 82.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 2.9%) \| 77.00 ( / ) | [No Data for at least 1 arm] |
| **Rest of World (ROW)** | | | |
| N subjects in population | N=33 | N=34 | |
| Week 3 | n= 31 (93.9%) \| 2.58 (11.70) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 30 (90.9%) \|-4.63 (14.02) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 31 (93.9%) \|-4.19 (18.12) | n= 32 (94.1%) \|-3.13 (10.75) | -0.07 [-0.57 ; 0.43] |
| Week 9 | n= 29 (87.9%) \|-5.66 (17.45) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 29 (87.9%) \|-2.62 (19.52) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 28 (84.8%) \|-5.18 (20.92) | n= 29 (85.3%) \|-4.90 (15.69) | -0.02 [-0.54 ; 0.51] |
| Week 15 | n= 27 (81.8%) \|-6.96 (20.60) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 29 (87.9%) \|-1.31 (16.64) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 27 (81.8%) \|-0.81 (12.27) | n= 28 (82.4%) \|-1.32 (9.97) | 0.04 [-0.49 ; 0.58] |
| Week 21 | n= 30 (90.9%) \|-2.57 (11.36) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 28 (84.8%) \|-4.50 (18.94) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 28 (84.8%) \|-0.96 (10.62) | n= 25 (73.5%) \|-0.60 (13.37) | -0.03 [-0.57 ; 0.51] |
| Week 27 | n= 28 (84.8%) \|-0.18 (12.44) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 26 (78.8%) \| 1.19 (11.83) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 29 (87.9%) \| 0.52 (11.41) | n= 23 (67.6%) \|-2.96 (12.82) | 0.28 [-0.27 ; 0.84] |
| Week 33 | n= 27 (81.8%) \| 0.63 (12.21) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 26 (78.8%) \|-0.15 (10.49) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 24 (72.7%) \| 0.88 (10.66) | n= 24 (70.6%) \|-3.25 (12.17) | 0.35 [-0.22 ; 0.93] |
| Week 39 | n= 25 (75.8%) \| 2.32 (10.61) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 23 (69.7%) \| 0.26 (10.27) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 43 | n= 24 (72.7%) \| 0.83 (9.40) | n= 22 (64.7%) \|-5.91 (14.26) | 0.55 [-0.04 ; 1.15] |
| Week 45 | n= 24 (72.7%) \|-0.25 (11.26) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 25 (75.8%) \| 1.68 (9.68) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 24 (72.7%) \| 0.46 (8.65) | n= 20 (58.8%) \|-3.00 (12.30) | 0.32 [-0.28 ; 0.93] |
| Week 51 | n= 24 (72.7%) \|-1.25 (7.71) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 23 (69.7%) \| 1.30 (7.21) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 21 (63.6%) \| 1.81 (8.76) | n= 21 (61.8%) \|-2.81 (12.96) | 0.41 [-0.21 ; 1.03] |
| Week 57 | n= 21 (63.6%) \| 1.00 (6.05) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 22 (66.7%) \| 0.86 (7.22) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 24 (72.7%) \| 0.29 (7.90) | n= 18 (52.9%) \|-6.89 (12.85) | 0.68 [ 0.05 ; 1.32] |
| Week 63 | n= 21 (63.6%) \|-0.14 (7.53) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (66.7%) \| 0.91 (7.62) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 21 (63.6%) \| 0.81 (8.32) | n= 18 (52.9%) \|-4.11 (14.79) | 0.41 [-0.23 ; 1.05] |
| Week 69 | n= 18 (54.5%) \|-1.11 (9.78) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 18 (54.5%) \| 1.06 (10.07) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 18 (54.5%) \| 2.56 (8.65) | n= 14 (41.2%) \|-2.71 (13.21) | 0.47 [-0.25 ; 1.19] |
| Week 75 | n= 19 (57.6%) \| 2.16 (9.15) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (48.5%) \| 2.00 (10.05) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 16 (48.5%) \| 1.31 (8.63) | n= 14 (41.2%) \|-3.86 (12.01) | 0.49 [-0.25 ; 1.23] |
| Week 81 | n= 15 (45.5%) \| 1.60 (8.37) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (51.5%) \| 2.00 (9.25) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 16 (48.5%) \| 1.31 (7.02) | n= 11 (32.4%) \|-5.18 (11.87) | 0.68 [-0.13 ; 1.48] |
| Week 87 | n= 14 (42.4%) \|-1.29 (6.93) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 14 (42.4%) \|-0.86 (6.63) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 12 (36.4%) \|-2.17 (6.39) | n= 9 (26.5%) \|-3.78 (12.13) | 0.17 [-0.72 ; 1.05] |
| Week 93 | n= 10 (30.3%) \| 0.20 (4.66) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (33.3%) \|-0.55 (5.87) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 9 (27.3%) \|-0.56 (7.35) | n= 6 (17.6%) \|-6.50 (3.94) | 0.89 [-0.23 ; 2.02] |
| Week 99 | n= 8 (24.2%) \|-0.63 (9.09) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 8 (24.2%) \|-2.50 (7.17) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 7 (21.2%) \|-2.14 (6.84) | n= 5 (14.7%) \|-7.00 (8.37) | 0.60 [-0.64 ; 1.83] |
| Week 105 | n= 6 (18.2%) \|-6.33 (5.47) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (12.1%) \|-3.50 (4.43) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (12.1%) \|-3.75 (7.68) | n= 3 ( 8.8%) \|-11.67 (16.07) | 0.57 [-1.13 ; 2.26] |
| Week 111 | n= 3 ( 9.1%) \|-2.67 (2.08) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (12.1%) \|-3.00 (9.83) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 ( 9.1%) \|-2.00 (12.53) | n= 2 ( 5.9%) \|-21.00 (22.63) | 0.83 [-1.44 ; 3.11] |
| Week 117 | n= 3 ( 9.1%) \| 1.00 (6.00) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 ( 9.1%) \|-2.67 (10.79) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 ( 9.1%) \|-6.00 (7.94) | n= 1 ( 2.9%) \|-8.00 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 3.0%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 3.0%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.0%) \|-15.00 ( / ) | n= 1 ( 2.9%) \| 0.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 3.0%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 3.0%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.0%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 3.0%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 3.0%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 3.0%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 3.0%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.1%) \|-5.25 (8.26) | n= 9 (26.5%) \|-3.78 (14.57) | -0.10 [-1.34 ; 1.13] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 202 | n= 2 ( 6.1%) \|-4.50 (0.71) | n= 7 (20.6%) \|-0.57 (14.40) | -0.26 [-1.95 ; 1.43] |
| Week 301 | n= 2 ( 6.1%) \| 5.00 (7.07) | n= 5 (14.7%) \| 2.00 (7.58) | 0.34 [-1.49 ; 2.16] |
| Week 302 | n= 1 ( 3.0%) \| 0.00 ( / ) | n= 3 ( 8.8%) \| 6.67 (7.64) | [Not calculable] |
| Week 303 | n= 1 ( 3.0%) \| 0.00 ( / ) | n= 4 (11.8%) \| 3.75 (9.46) | [Not calculable] |
| Week 304 | [No Data] | n= 2 ( 5.9%) \| 5.00 (21.21) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:00

TABLE 7.1.4: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **US/Canada/Western Europe/Northern Europe** | | | | |
| Nr subjects used | n=38 | n=34 | | |
| Week 7 | -0.06 (2.69) [-5.44 ; 5.31] | -1.49 (2.90) [-7.28 ; 4.31] | 1.43 (3.96) [-6.48 ; 9.33] | 0.09 [-0.40 ; 0.58] |
| Week 13 | -4.55 (3.70) [-11.95 ; 2.84] | 3.89 (4.10) [-4.29 ; 12.08] | -8.45 (5.53) [-19.48 ; 2.58] | -0.41 [-0.95 ; 0.13] |
| Week 19 | 0.38 (2.80) [-5.21 ; 5.98] | 0.74 (3.08) [-5.40 ; 6.89] | -0.36 (4.16) [-8.67 ; 7.95] | -0.02 [-0.55 ; 0.51] |
| Week 25 | 2.50 (1.93) [-1.36 ; 6.37] | 3.69 (2.10) [-0.51 ; 7.89] | -1.19 (2.86) [-6.90 ; 4.52] | -0.11 [-0.65 ; 0.42] |
| Week 31 | 3.35 (2.22) [-1.09 ; 7.78] | 0.64 (2.45) [-4.26 ; 5.53] | 2.71 (3.31) [-3.90 ; 9.32] | 0.24 [-0.35 ; 0.83] |
| Week 37 | 2.69 (2.01) [-1.32 ; 6.70] | 2.93 (2.21) [-1.48 ; 7.35] | -0.24 (2.99) [-6.21 ; 5.72] | -0.02 [-0.60 ; 0.55] |
| Week 43 | 2.26 (1.99) [-1.71 ; 6.22] | 3.90 (2.32) [-0.72 ; 8.52] | -1.64 (3.06) [-7.73 ; 4.45] | -0.15 [-0.71 ; 0.41] |
| Week 49 | 3.09 (1.94) [-0.78 ; 6.96] | 2.40 (2.38) [-2.34 ; 7.13] | 0.69 (3.07) [-5.43 ; 6.82] | 0.07 [-0.52 ; 0.65] |
| Week 55 | 0.90 (3.21) [-5.51 ; 7.32] | 2.28 (4.04) [-5.78 ; 10.34] | -1.38 (5.16) [-11.68 ; 8.92] | -0.08 [-0.71 ; 0.54] |
| Week 61 | 2.39 (2.26) [-2.13 ; 6.92] | -0.74 (3.02) [-6.78 ; 5.29] | 3.13 (3.77) [-4.41 ; 10.68] | 0.28 [-0.41 ; 0.98] |
| Week 67 | 2.16 (2.49) [-2.85 ; 7.17] | 2.07 (3.30) [-4.57 ; 8.72] | 0.08 (4.14) [-8.24 ; 8.41] | 0.01 [-0.69 ; 0.70] |
| Week 73 | -1.78 (3.04) [-7.88 ; 4.32] | -0.60 (3.55) [-7.75 ; 6.54] | -1.18 (4.68) [-10.57 ; 8.22] | -0.09 [-0.81 ; 0.63] |
| Week 79 | 0.84 (3.54) [-6.29 ; 7.98] | 2.74 (4.20) [-5.73 ; 11.21] | -1.89 (5.49) [-12.97 ; 9.18] | -0.13 [-0.91 ; 0.65] |
| Week 85 | 3.14 (3.28) [-3.56 ; 9.85] | 1.67 (3.59) [-5.68 ; 9.02] | 1.48 (4.86) [-8.46 ; 11.42] | 0.13 [-0.73 ; 0.99] |
| Overall post-baseline period estimate | 1.24 (1.42) [-1.58 ; 4.05] | 1.72 (1.66) [-1.58 ; 5.02] | -0.49 (2.19) [-4.82 ; 3.85] | -0.05 [-0.52 ; 0.41] |
| **Rest of World (ROW)** | | | | |
| Nr subjects used | n=33 | n=34 | | |
| Week 7 | -6.65 (2.84) [-12.33 ;-0.97] | -3.30 (2.79) [-8.88 ; 2.28] | -3.35 (3.98) [-11.31 ; 4.60] | -0.21 [-0.70 ; 0.29] |
| Week 13 | -9.31 (4.08) [-17.48 ;-1.13] | -5.29 (4.02) [-13.35 ; 2.77] | -4.01 (5.73) [-15.49 ; 7.47] | -0.18 [-0.70 ; 0.34] |
| Week 19 | -2.83 (2.37) [-7.59 ; 1.92] | -1.90 (2.33) [-6.57 ; 2.78] | -0.93 (3.33) [-7.61 ; 5.74] | -0.07 [-0.60 ; 0.45] |
| Week 25 | -1.88 (2.00) [-5.88 ; 2.12] | 0.15 (2.04) [-3.93 ; 4.23] | -2.03 (2.87) [-7.76 ; 3.69] | -0.19 [-0.73 ; 0.35] |
| Week 31 | -0.63 (1.94) [-4.51 ; 3.24] | -1.02 (2.05) [-5.11 ; 3.07] | 0.38 (2.83) [-5.27 ; 6.04] | 0.04 [-0.51 ; 0.58] |
| Week 37 | -0.02 (2.34) [-4.71 ; 4.66] | -3.20 (2.37) [-7.94 ; 1.55] | 3.17 (3.34) [-3.51 ; 9.86] | 0.27 [-0.30 ; 0.84] |
| Week 43 | -0.19 (2.59) [-5.39 ; 5.00] | -3.98 (2.70) [-9.39 ; 1.43] | 3.79 (3.75) [-3.73 ; 11.30] | 0.29 [-0.29 ; 0.88] |
| Week 49 | -0.55 (1.91) [-4.38 ; 3.28] | -2.19 (2.07) [-6.32 ; 1.95] | 1.64 (2.82) [-4.01 ; 7.29] | 0.17 [-0.42 ; 0.77] |
| Week 55 | 0.84 (1.92) [-2.99 ; 4.68] | -1.47 (2.01) [-5.50 ; 2.55] | 2.32 (2.78) [-3.25 ; 7.89] | 0.25 [-0.36 ; 0.86] |
| Week 61 | -0.02 (1.91) [-3.86 ; 3.81] | -4.48 (2.14) [-8.77 ;-0.20] | 4.46 (2.88) [-1.30 ; 10.22] | 0.47 [-0.15 ; 1.09] |
| Week 67 | -0.07 (2.05) [-4.18 ; 4.04] | -2.13 (2.26) [-6.65 ; 2.40] | 2.06 (3.06) [-4.06 ; 8.18] | 0.21 [-0.42 ; 0.84] |
| Week 73 | 0.76 (1.79) [-2.82 ; 4.35] | -2.71 (2.00) [-6.72 ; 1.29] | 3.48 (2.69) [-1.90 ; 8.86] | 0.45 [-0.26 ; 1.16] |
| Week 79 | 1.02 (1.63) [-2.25 ; 4.29] | -3.43 (1.77) [-6.97 ; 0.11] | 4.45 (2.41) [-0.36 ; 9.27] | 0.66 [-0.08 ; 1.40] |
| Week 85 | 1.61 (1.64) [-1.71 ; 4.93] | -3.38 (1.90) [-7.22 ; 0.45] | 5.00 (2.51) [-0.07 ; 10.06] | 0.75 [-0.05 ; 1.55] |
| Overall post-baseline period estimate | -1.28 (1.23) [-3.74 ; 1.18] | -2.74 (1.27) [-5.27 ;-0.21] | 1.46 (1.78) [-2.09 ; 5.00] | 0.20 [-0.28 ; 0.68] |
| **MMRM subgroups interaction p-value** | | | 0.9410 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.

TABLE 7.1.5: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **White** | N=62 | N=58 |
| **Non-White** | N=9 | N=10 |
| **Subjects with Baseline Value** | | |
| **White** | 62 (100.0%) | 58 (100.0%) |
| **Non-White** | 9 (100.0%) | 10 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **White** | 62 (100.0%) | 56 (96.6%) |
| **Non-White** | 9 (100.0%) | 10 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **White** | 62 (100.0%) | 56 (96.6%) |
| **Non-White** | 9 (100.0%) | 10 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:00

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **White** | | | |
| N subjects in population | N=62 | N=58 | |
| Baseline | n= 62 (100.0%) \| 77.90 (17.86) | n= 58 (100.0%) \| 78.12 (18.41) | -0.01 [-0.37 ; 0.35] |
| Week 3 | n= 58 (93.5%) \| 80.66 (13.51) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 57 (91.9%) \| 78.84 (15.13) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 59 (95.2%) \| 76.00 (18.18) | n= 53 (91.4%) \| 75.81 (16.27) | 0.01 [-0.36 ; 0.38] |
| Week 9 | n= 50 (80.6%) \| 78.98 (15.32) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 52 (83.9%) \| 78.63 (17.26) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 51 (82.3%) \| 76.73 (21.91) | n= 43 (74.1%) \| 79.00 (12.21) | -0.12 [-0.53 ; 0.28] |
| Week 15 | n= 47 (75.8%) \| 77.36 (17.53) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 52 (83.9%) \| 80.52 (12.32) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 49 (79.0%) \| 79.84 (16.50) | n= 44 (75.9%) \| 79.20 (13.07) | 0.04 [-0.37 ; 0.45] |
| Week 21 | n= 51 (82.3%) \| 79.02 (15.86) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 47 (75.8%) \| 76.55 (17.33) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 48 (77.4%) \| 81.69 (10.92) | n= 42 (72.4%) \| 82.69 (11.34) | -0.09 [-0.51 ; 0.33] |
| Week 27 | n= 46 (74.2%) \| 83.20 (9.92) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 45 (72.6%) \| 82.27 (11.02) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (72.6%) \| 82.13 (10.64) | n= 36 (62.1%) \| 80.25 (13.78) | 0.15 [-0.29 ; 0.60] |
| Week 33 | n= 49 (79.0%) \| 81.90 (12.12) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 45 (72.6%) \| 81.62 (13.11) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 43 (69.4%) \| 81.84 (12.87) | n= 39 (67.2%) \| 81.31 (10.55) | 0.04 [-0.39 ; 0.48] |
| Week 39 | n= 45 (72.6%) \| 83.02 (11.58) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 43 (69.4%) \| 82.88 (12.14) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 46 (74.2%) \| 82.09 (13.05) | n= 37 (63.8%) \| 81.05 (13.55) | 0.08 [-0.36 ; 0.51] |
| Week 45 | n= 42 (67.7%) \| 81.07 (12.89) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 44 (71.0%) \| 82.75 (11.82) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 45 (72.6%) \| 82.71 (12.24) | n= 34 (58.6%) \| 81.56 (12.93) | 0.09 [-0.36 ; 0.54] |
| Week 51 | n= 43 (69.4%) \| 82.16 (11.46) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 42 (67.7%) \| 79.93 (18.90) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 40 (64.5%) \| 81.48 (18.37) | n= 31 (53.4%) \| 81.23 (13.70) | 0.01 [-0.46 ; 0.49] |
| Week 57 | n= 40 (64.5%) \| 80.60 (17.35) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 39 (62.9%) \| 80.00 (18.09) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 40 (64.5%) \| 83.43 (11.69) | n= 24 (41.4%) \| 77.29 (13.07) | 0.50 [-0.02 ; 1.01] |
| Week 63 | n= 36 (58.1%) \| 80.69 (12.97) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (58.1%) \| 81.39 (13.45) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (61.3%) \| 82.74 (13.34) | n= 25 (43.1%) \| 81.68 (11.00) | 0.08 [-0.43 ; 0.59] |
| Week 69 | n= 31 (50.0%) \| 81.97 (11.81) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 34 (54.8%) \| 84.29 (11.60) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 29 (46.8%) \| 83.72 (10.81) | n= 24 (41.4%) \| 77.92 (15.41) | 0.44 [-0.12 ; 0.99] |
| Week 75 | n= 32 (51.6%) \| 83.19 (13.16) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 29 (46.8%) \| 83.79 (11.85) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 28 (45.2%) \| 83.57 (15.73) | n= 21 (36.2%) \| 77.38 (15.09) | 0.39 [-0.18 ; 0.97] |
| Week 81 | n= 28 (45.2%) \| 84.68 (11.26) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 31 (50.0%) \| 85.29 (11.47) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (40.3%) \| 86.64 (8.27) | n= 18 (31.0%) \| 78.56 (15.80) | 0.66 [ 0.03 ; 1.29] |
| Week 87 | n= 22 (35.5%) \| 83.09 (13.98) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 23 (37.1%) \| 83.70 (11.55) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 21 (33.9%) \| 83.62 (11.78) | n= 13 (22.4%) \| 81.92 (7.83) | 0.16 [-0.54 ; 0.86] |
| Week 93 | n= 19 (30.6%) \| 84.79 (13.21) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 20 (32.3%) \| 82.10 (13.80) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.0%) \| 81.22 (13.25) | n= 9 (15.5%) \| 79.33 (9.70) | 0.15 [-0.67 ; 0.97] |
| Week 99 | n= 15 (24.2%) \| 80.60 (13.02) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.0%) \| 80.69 (9.81) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.0%) \| 81.38 (9.94) | n= 8 (13.8%) \| 78.38 (8.14) | 0.31 [-0.60 ; 1.22] |
| Week 105 | n= 13 (21.0%) \| 79.69 (10.89) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.3%) \| 79.71 (10.21) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.1%) \| 76.10 (8.33) | n= 4 ( 6.9%) \| 76.75 (4.57) | -0.08 [-1.29 ; 1.13] |
| Week 111 | n= 7 (11.3%) \| 78.00 (9.20) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (12.9%) \| 81.38 (9.62) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 ( 9.7%) \| 80.33 (8.87) | n= 4 ( 6.9%) \| 79.25 (11.44) | 0.10 [-1.25 ; 1.44] |
| Week 117 | n= 7 (11.3%) \| 82.86 (5.58) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 (11.3%) \| 78.43 (9.40) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.3%) \| 79.00 (9.68) | n= 1 ( 1.7%) \| 92.00 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.2%) \| 81.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.6%) \| 80.00 ( / ) | n= 1 ( 1.7%) \| 100.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) \| 81.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 7 (11.3%) \| 79.43 (8.98) | n= 12 (20.7%) \| 73.58 (18.98) | 0.35 [-0.62 ; 1.31] |
| Week 202 | n= 2 ( 3.2%) \| 64.00 (26.87) | n= 8 (13.8%) \| 85.63 (11.43) | -1.37 [-3.16 ; 0.43] |
| Week 301 | n= 1 ( 1.6%) \| 50.00 ( / ) | n= 7 (12.1%) \| 81.29 (7.30) | [Not calculable] |
| Week 302 | n= 1 ( 1.6%) \| 50.00 ( / ) | n= 5 ( 8.6%) \| 82.00 (5.70) | [Not calculable] |
| Week 303 | n= 2 ( 3.2%) \| 45.00 (7.07) | n= 5 ( 8.6%) \| 82.40 (7.67) | -4.17 [-7.56 ;-0.78] |
| Week 304 | n= 1 ( 1.6%) \| 100.00 ( / ) | n= 2 ( 3.4%) \| 70.00 (0.00) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.7%) \| 75.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.7%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.7%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.7%) \| 90.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.7%) \| 85.00 ( / ) | [No Data for at least 1 arm] |
| **Non-White** | | | |
| N subjects in population | N=9 | N=10 | |
| Baseline | n= 9 (100.0%) \| 77.22 (16.79) | n= 10 (100.0%) \| 89.00 (14.49) | -0.72 [-1.68 ; 0.24] |
| Week 3 | n= 9 (100.0%) \| 81.33 (14.47) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (88.9%) \| 71.88 (25.75) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (77.8%) \| 83.00 (13.60) | n= 9 (90.0%) \| 87.78 (19.37) | -0.26 [-1.29 ; 0.76] |
| Week 9 | n= 9 (100.0%) \| 70.89 (19.45) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (100.0%) \| 67.44 (16.66) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 8 (88.9%) \| 59.75 (25.05) | n= 10 (100.0%) \| 83.10 (18.93) | -1.02 [-2.04 ; 0.00] |
| Week 15 | n= 7 (77.8%) \| 64.14 (31.62) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (100.0%) \| 67.89 (25.62) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 8 (88.9%) \| 75.75 (16.92) | n= 9 (90.0%) \| 90.11 (12.45) | -0.93 [-1.97 ; 0.11] |
| Week 21 | n= 9 (100.0%) \| 74.33 (15.87) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 9 (100.0%) \| 76.00 (16.07) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 25 | n= 9 (100.0%) \| 76.11 (16.03) | n= 8 (80.0%) \| 90.63 (9.43) | -1.03 [-2.08 ; 0.02] |
| Week 27 | n= 9 (100.0%) \| 71.89 (19.51) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 8 (88.9%) \| 72.50 (23.24) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 9 (100.0%) \| 77.44 (13.45) | n= 7 (70.0%) \| 85.86 (17.13) | -0.53 [-1.57 ; 0.52] |
| Week 33 | n= 8 (88.9%) \| 73.63 (14.09) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (88.9%) \| 74.25 (15.69) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 6 (66.7%) \| 72.33 (15.21) | n= 7 (70.0%) \| 86.57 (25.61) | -0.62 [-1.79 ; 0.55] |
| Week 39 | n= 8 (88.9%) \| 75.00 (16.39) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 8 (88.9%) \| 76.25 (17.16) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 7 (77.8%) \| 76.43 (17.43) | n= 6 (60.0%) \| 83.33 (19.92) | -0.35 [-1.49 ; 0.80] |
| Week 45 | n= 7 (77.8%) \| 72.00 (14.06) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 8 (88.9%) \| 79.50 (13.59) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 8 (88.9%) \| 75.13 (17.89) | n= 4 (40.0%) \| 84.75 (16.74) | -0.51 [-1.79 ; 0.77] |
| Week 51 | n= 8 (88.9%) \| 75.88 (16.65) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 7 (77.8%) \| 80.57 (14.12) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (77.8%) \| 72.29 (15.20) | n= 6 (60.0%) \| 88.67 (14.99) | -1.01 [-2.23 ; 0.21] |
| Week 57 | n= 7 (77.8%) \| 76.00 (19.46) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (77.8%) \| 75.86 (18.01) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (88.9%) \| 74.88 (17.27) | n= 6 (60.0%) \| 82.83 (22.70) | -0.38 [-1.49 ; 0.73] |
| Week 63 | n= 6 (66.7%) \| 77.33 (20.49) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (88.9%) \| 74.63 (20.33) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (66.7%) \| 78.67 (16.18) | n= 5 (50.0%) \| 84.60 (19.89) | -0.30 [-1.56 ; 0.96] |
| Week 69 | n= 6 (66.7%) \| 72.00 (19.13) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 5 (55.6%) \| 70.20 (24.44) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 5 (55.6%) \| 64.80 (22.24) | n= 4 (40.0%) \| 86.25 (24.28) | -0.82 [-2.31 ; 0.66] |
| Week 75 | n= 4 (44.4%) \| 69.50 (24.03) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (33.3%) \| 58.33 (12.58) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 3 (33.3%) \| 69.00 (20.52) | n= 4 (40.0%) \| 86.25 (24.28) | -0.64 [-2.35 ; 1.07] |
| Week 81 | n= 3 (33.3%) \| 70.00 (22.91) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (22.2%) \| 61.50 (19.09) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (22.2%) \| 86.50 (16.26) | n= 3 (30.0%) \| 98.33 (2.89) | -0.89 [-3.18 ; 1.41] |
| Week 87 | n= 2 (22.2%) \| 65.50 (20.51) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (22.2%) \| 69.00 (15.56) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (33.3%) \| 73.67 (22.72) | n= 3 (30.0%) \| 98.33 (2.89) | -1.22 [-3.28 ; 0.84] |
| Week 93 | n= 2 (22.2%) \| 65.50 (20.51) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (22.2%) \| 64.00 (22.63) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (33.3%) \| 75.33 (32.58) | n= 2 (20.0%) \| 97.50 (3.54) | -0.60 [-2.80 ; 1.59] |
| Week 99 | n= 2 (22.2%) \| 67.00 (32.53) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (11.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (22.2%) \| 89.50 (13.44) | n= 2 (20.0%) \| 97.50 (3.54) | -0.47 [-3.02 ; 2.09] |
| Week 105 | n= 1 (11.1%) \| 70.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (11.1%) \| 70.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 (11.1%) \| 98.00 ( / ) | n= 1 (10.0%) \| 95.00 ( / ) | [Not calculable] |
| Week 115 | n= 1 (11.1%) \| 98.00 ( / ) | n= 1 (10.0%) \| 95.00 ( / ) | [Not calculable] |
| Week 121 | n= 1 (11.1%) \| 98.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 (11.1%) \| 98.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (11.1%) \| 70.00 ( / ) | n= 5 (50.0%) \| 91.00 (7.42) | [Not calculable] |
| Week 202 | [No Data] | n= 4 (40.0%) \| 93.75 (4.79) | [No Data for at least 1 arm] |
| Week 301 | n= 1 (11.1%) \| 90.00 ( / ) | n= 2 (20.0%) \| 90.00 (7.07) | [Not calculable] |
| Week 302 | n= 1 (11.1%) \| 80.00 ( / ) | n= 1 (10.0%) \| 85.00 ( / ) | [Not calculable] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 303 | n= 1 (11.1%) \| 80.00 ( / ) | n= 1 (10.0%) \| 80.00 ( / ) | [Not calculable] |
| Week 304 | [No Data] | n= 1 (10.0%) \| 90.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:01

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **White** | | | |
| N subjects in population | N=62 | N=58 | |
| Week 3 | n= 58 (93.5%) \| 1.79 (12.87) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 57 (91.9%) \|-0.53 (16.08) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 59 (95.2%) \|-2.41 (18.62) | n= 53 (91.4%) \|-1.34 (14.28) | -0.06 [-0.44 ; 0.31] |
| Week 9 | n= 50 (80.6%) \|-0.86 (18.81) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 52 (83.9%) \| 0.06 (21.28) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 51 (82.3%) \|-1.57 (23.39) | n= 43 (74.1%) \|-1.40 (18.93) | -0.01 [-0.42 ; 0.40] |
| Week 15 | n= 47 (75.8%) \|-0.53 (21.77) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 52 (83.9%) \| 2.87 (16.17) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 49 (79.0%) \| 1.20 (17.53) | n= 44 (75.9%) \|-3.14 (10.50) | 0.29 [-0.12 ; 0.71] |
| Week 21 | n= 51 (82.3%) \| 0.80 (17.31) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 47 (75.8%) \|-0.45 (19.30) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 48 (77.4%) \| 2.00 (14.37) | n= 42 (72.4%) \| 1.93 (17.09) | 0.00 [-0.41 ; 0.42] |
| Week 27 | n= 46 (74.2%) \| 3.93 (13.46) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 45 (72.6%) \| 3.22 (14.82) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (72.6%) \| 3.89 (14.43) | n= 36 (62.1%) \|-1.86 (14.50) | 0.39 [-0.05 ; 0.84] |
| Week 33 | n= 49 (79.0%) \| 1.57 (12.53) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 45 (72.6%) \| 3.07 (14.06) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 43 (69.4%) \| 3.33 (14.63) | n= 39 (67.2%) \|-0.49 (11.28) | 0.29 [-0.15 ; 0.73] |
| Week 39 | n= 45 (72.6%) \| 4.27 (13.53) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 43 (69.4%) \| 1.74 (12.83) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 46 (74.2%) \| 2.78 (14.90) | n= 37 (63.8%) \|-0.49 (13.86) | 0.22 [-0.21 ; 0.66] |
| Week 45 | n= 42 (67.7%) \| 1.24 (13.41) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 44 (71.0%) \| 3.86 (13.55) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 45 (72.6%) \| 4.02 (13.53) | n= 34 (58.6%) \|-0.85 (12.82) | 0.36 [-0.09 ; 0.82] |
| Week 51 | n= 43 (69.4%) \| 1.91 (10.58) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 42 (67.7%) \| 0.07 (19.43) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 40 (64.5%) \| 2.33 (18.74) | n= 31 (53.4%) \|-0.84 (15.33) | 0.18 [-0.29 ; 0.65] |
| Week 57 | n= 40 (64.5%) \| 0.98 (18.88) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 39 (62.9%) \| 0.72 (14.49) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 40 (64.5%) \| 2.98 (12.73) | n= 24 (41.4%) \|-4.33 (13.96) | 0.55 [ 0.03 ; 1.07] |
| Week 63 | n= 36 (58.1%) \| 0.72 (9.96) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (58.1%) \| 3.69 (11.21) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (61.3%) \| 2.87 (13.29) | n= 25 (43.1%) \|-0.60 (14.46) | 0.25 [-0.26 ; 0.76] |
| Week 69 | n= 31 (50.0%) \| 1.97 (14.88) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 34 (54.8%) \| 2.03 (11.51) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 29 (46.8%) \| 2.00 (10.14) | n= 24 (41.4%) \|-3.00 (15.00) | 0.39 [-0.16 ; 0.94] |
| Week 75 | n= 32 (51.6%) \| 0.78 (11.86) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 29 (46.8%) \| 3.45 (14.99) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 28 (45.2%) \| 2.25 (12.49) | n= 21 (36.2%) \|-2.81 (15.65) | 0.36 [-0.22 ; 0.93] |
| Week 81 | n= 28 (45.2%) \| 1.79 (12.34) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 31 (50.0%) \| 2.10 (12.05) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (40.3%) \| 2.08 (10.67) | n= 18 (31.0%) \|-4.44 (14.11) | 0.52 [-0.10 ; 1.15] |
| Week 87 | n= 22 (35.5%) \| 0.27 (12.11) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 23 (37.1%) \| 0.30 (11.40) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 21 (33.9%) \| 0.48 (11.94) | n= 13 (22.4%) \| 0.08 (12.04) | 0.03 [-0.67 ; 0.73] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 19 (30.6%) \| 2.47 (10.74) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 20 (32.3%) \|-1.85 (9.28) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.0%) \|-2.06 (8.85) | n= 9 (15.5%) \|-2.22 (6.78) | 0.02 [-0.80 ; 0.83] |
| Week 99 | n= 15 (24.2%) \|-0.67 (8.75) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.0%) \|-1.54 (9.10) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.0%) \| 0.23 (7.72) | n= 8 (13.8%) \|-1.63 (9.44) | 0.21 [-0.69 ; 1.12] |
| Week 105 | n= 13 (21.0%) \|-2.31 (9.29) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.3%) \| 2.00 (4.36) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.1%) \|-2.90 (9.06) | n= 4 ( 6.9%) \|-8.25 (14.52) | 0.47 [-0.75 ; 1.69] |
| Week 111 | n= 7 (11.3%) \|-1.14 (5.37) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (12.9%) \|-3.50 (10.11) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 ( 9.7%) \|-2.50 (13.63) | n= 4 ( 6.9%) \|-5.75 (21.16) | 0.17 [-1.17 ; 1.52] |
| Week 117 | n= 7 (11.3%) \|-4.14 (11.51) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 (11.3%) \|-5.86 (11.42) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.3%) \|-3.86 (9.17) | n= 1 ( 1.7%) \|-8.00 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.2%) \|-13.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.6%) \|-15.00 ( / ) | n= 1 ( 1.7%) \| 0.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 7 (11.3%) \| 5.00 (22.16) | n= 12 (20.7%) \|-12.25 (13.82) | 0.96 [-0.06 ; 1.97] |
| Week 202 | n= 2 ( 3.2%) \|-4.50 (0.71) | n= 8 (13.8%) \|-3.75 (9.63) | -0.08 [-1.72 ; 1.57] |
| Week 301 | n= 1 ( 1.6%) \| 0.00 ( / ) | n= 7 (12.1%) \| 1.00 (11.18) | [Not calculable] |
| Week 302 | n= 1 ( 1.6%) \|-20.00 ( / ) | n= 5 ( 8.6%) \|-1.00 (6.96) | [Not calculable] |
| Week 303 | n= 2 ( 3.2%) \|-5.00 (21.21) | n= 5 ( 8.6%) \| 14.80 (32.31) | -0.55 [-2.40 ; 1.30] |
| Week 304 | n= 1 ( 1.6%) \| 0.00 ( / ) | n= 2 ( 3.4%) \|-7.00 (4.24) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.7%) \| 67.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.7%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.7%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.7%) \| 82.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.7%) \| 77.00 ( / ) | [No Data for at least 1 arm] |
| **Non-White** | | | |
| N subjects in population | N=9 | N=10 | |
| Week 3 | n= 9 (100.0%) \| 3.00 (15.35) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (88.9%) \|-6.25 (12.15) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (77.8%) \| 2.29 (14.90) | n= 9 (90.0%) \|-1.11 (12.12) | 0.24 [-0.79 ; 1.27] |
| Week 9 | n= 9 (100.0%) \|-7.44 (14.54) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (100.0%) \|-10.89 (16.07) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 8 (88.9%) \|-17.75 (19.25) | n= 10 (100.0%) \|-5.90 (19.13) | -0.59 [-1.57 ; 0.39] |
| Week 15 | n= 7 (77.8%) \|-15.86 (29.55) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (100.0%) \|-10.44 (20.88) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 8 (88.9%) \|-2.38 (10.34) | n= 9 (90.0%) \| 0.11 (8.52) | -0.25 [-1.24 ; 0.74] |
| Week 21 | n= 9 (100.0%) \|-4.00 (10.82) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 9 (100.0%) \|-2.33 (8.56) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 9 (100.0%) \|-2.22 (9.24) | n= 8 (80.0%) \|-1.88 (8.43) | -0.04 [-1.02 ; 0.95] |
| Week 27 | n= 9 (100.0%) \|-6.44 (14.66) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 29 | n= 8 (88.9%) \|-5.63 (13.74) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 9 (100.0%) \|-0.89 (7.85) | n= 7 (70.0%) \|-7.00 (7.28) | 0.76 [-0.30 ; 1.82] |
| Week 33 | n= 8 (88.9%) \|-3.88 (8.74) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (88.9%) \|-3.88 (9.36) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 6 (66.7%) \|-3.50 (10.01) | n= 7 (70.0%) \|-6.29 (13.03) | 0.22 [-0.92 ; 1.36] |
| Week 39 | n= 8 (88.9%) \|-2.50 (8.70) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 8 (88.9%) \|-1.88 (7.75) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 7 (77.8%) \|-1.43 (8.20) | n= 6 (60.0%) \|-8.33 (13.66) | 0.58 [-0.58 ; 1.75] |
| Week 45 | n= 7 (77.8%) \|-3.00 (9.45) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 8 (88.9%) \| 1.38 (12.27) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 8 (88.9%) \|-3.00 (9.89) | n= 4 (40.0%) \|-2.75 (6.85) | -0.03 [-1.28 ; 1.23] |
| Week 51 | n= 8 (88.9%) \|-2.25 (10.15) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 7 (77.8%) \|-0.14 (7.67) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (77.8%) \|-4.14 (8.13) | n= 6 (60.0%) \|-3.00 (8.25) | -0.13 [-1.27 ; 1.01] |
| Week 57 | n= 7 (77.8%) \|-1.86 (9.26) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (77.8%) \|-2.00 (7.90) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (88.9%) \|-3.25 (8.68) | n= 6 (60.0%) \|-8.83 (17.30) | 0.40 [-0.71 ; 1.52] |
| Week 63 | n= 6 (66.7%) \|-4.33 (8.59) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (88.9%) \|-3.50 (11.59) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (66.7%) \|-1.33 (10.86) | n= 5 (50.0%) \|-5.40 (8.99) | 0.37 [-0.90 ; 1.63] |
| Week 69 | n= 6 (66.7%) \|-4.67 (8.98) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 5 (55.6%) \|-5.80 (12.85) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 5 (55.6%) \|-11.20 (18.75) | n= 4 (40.0%) \|-1.25 (8.54) | -0.58 [-2.03 ; 0.87] |
| Week 75 | n= 4 (44.4%) \|-3.00 (11.22) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (33.3%) \|-5.00 (13.23) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 3 (33.3%) \|-7.67 (5.86) | n= 4 (40.0%) \|-1.25 (8.54) | -0.71 [-2.44 ; 1.01] |
| Week 81 | n= 3 (33.3%) \|-6.67 (7.64) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (22.2%) \|-8.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (22.2%) \| 1.50 (9.19) | n= 3 (30.0%) \| 1.67 (7.64) | -0.01 [-2.13 ; 2.10] |
| Week 87 | n= 2 (22.2%) \|-4.50 (6.36) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (22.2%) \|-1.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (33.3%) \|-3.00 (9.64) | n= 3 (30.0%) \| 1.67 (7.64) | -0.43 [-2.28 ; 1.42] |
| Week 93 | n= 2 (22.2%) \|-4.50 (6.36) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (22.2%) \|-6.00 (8.49) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (33.3%) \|-1.33 (17.93) | n= 2 (20.0%) \|-2.50 (3.54) | 0.06 [-2.06 ; 2.17] |
| Week 99 | n= 2 (22.2%) \|-3.00 (18.38) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (11.1%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (22.2%) \| 4.50 (6.36) | n= 2 (20.0%) \|-2.50 (3.54) | 0.78 [-1.95 ; 3.51] |
| Week 105 | n= 1 (11.1%) \|-10.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (11.1%) \|-10.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 (11.1%) \| 8.00 ( / ) | n= 1 (10.0%) \|-5.00 ( / ) | [Not calculable] |
| Week 115 | n= 1 (11.1%) \| 8.00 ( / ) | n= 1 (10.0%) \|-5.00 ( / ) | [Not calculable] |
| Week 121 | n= 1 (11.1%) \| 8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 (11.1%) \| 8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (11.1%) \|-15.00 ( / ) | n= 5 (50.0%) \| 3.00 (12.04) | [Not calculable] |
| Week 202 | [No Data] | n= 4 (40.0%) \| 6.25 (11.09) | [No Data for at least 1 arm] |
| Week 301 | n= 1 (11.1%) \| 10.00 ( / ) | n= 2 (20.0%) \| 5.00 (14.14) | [Not calculable] |
| Week 302 | n= 1 (11.1%) \| 0.00 ( / ) | n= 1 (10.0%) \| 15.00 ( / ) | [Not calculable] |
| Week 303 | n= 1 (11.1%) \| 0.00 ( / ) | n= 1 (10.0%) \| 10.00 ( / ) | [Not calculable] |
| Week 304 | [No Data] | n= 1 (10.0%) \| 20.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:01

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **White** | | | | |
| Nr subjects used | n=62 | n=58 | | |
| Week 7 | -3.63 (2.14) [-7.87 ; 0.60] | -3.14 (2.25) [-7.60 ; 1.31] | -0.49 (3.10) [-6.63 ; 5.65] | -0.03 [-0.40 ; 0.34] |
| Week 13 | -5.21 (2.93) [-11.02 ; 0.59] | -0.35 (3.13) [-6.55 ; 5.85] | -4.86 (4.28) [-13.35 ; 3.63] | -0.23 [-0.64 ; 0.17] |
| Week 19 | -0.57 (2.13) [-4.79 ; 3.65] | -1.59 (2.25) [-6.05 ; 2.87] | 1.02 (3.09) [-5.11 ; 7.16] | 0.07 [-0.34 ; 0.48] |
| Week 25 | 0.94 (1.58) [-2.19 ; 4.07] | 1.81 (1.67) [-1.51 ; 5.13] | -0.87 (2.30) [-5.43 ; 3.69] | -0.08 [-0.49 ; 0.34] |
| Week 31 | 1.92 (1.69) [-1.43 ; 5.28] | 0.08 (1.83) [-3.55 ; 3.71] | 1.84 (2.49) [-3.10 ; 6.79] | 0.16 [-0.28 ; 0.60] |
| Week 37 | 2.37 (1.62) [-0.84 ; 5.59] | 0.15 (1.73) [-3.27 ; 3.58] | 2.22 (2.37) [-2.48 ; 6.92] | 0.21 [-0.23 ; 0.64] |
| Week 43 | 2.07 (1.81) [-1.52 ; 5.66] | 0.45 (2.00) [-3.51 ; 4.41] | 1.61 (2.70) [-3.74 ; 6.96] | 0.13 [-0.30 ; 0.56] |
| Week 49 | 2.34 (1.56) [-0.76 ; 5.44] | 0.31 (1.78) [-3.22 ; 3.84] | 2.03 (2.37) [-2.67 ; 6.73] | 0.19 [-0.25 ; 0.64] |
| Week 55 | 1.18 (2.24) [-3.26 ; 5.62] | 0.41 (2.57) [-4.70 ; 5.51] | 0.77 (3.41) [-5.99 ; 7.54] | 0.05 [-0.42 ; 0.52] |
| Week 61 | 2.34 (1.45) [-0.53 ; 5.21] | -2.37 (1.77) [-5.89 ; 1.14] | 4.71 (2.29) [ 0.17 ; 9.25] | 0.52 [ 0.00 ; 1.03] |
| Week 67 | 2.22 (1.65) [-1.05 ; 5.49] | -0.42 (2.00) [-4.39 ; 3.55] | 2.64 (2.59) [-2.50 ; 7.78] | 0.26 [-0.25 ; 0.77] |
| Week 73 | 2.28 (1.54) [-0.78 ; 5.34] | -2.12 (1.78) [-5.64 ; 1.40] | 4.40 (2.35) [-0.26 ; 9.06] | 0.51 [-0.04 ; 1.06] |
| Week 79 | 2.09 (1.80) [-1.49 ; 5.66] | -0.49 (2.09) [-4.64 ; 3.65] | 2.58 (2.76) [-2.90 ; 8.05] | 0.27 [-0.30 ; 0.83] |
| Week 85 | 2.58 (1.57) [-0.56 ; 5.71] | -1.56 (1.85) [-5.25 ; 2.14] | 4.13 (2.43) [-0.70 ; 8.97] | 0.52 [-0.10 ; 1.13] |
| Week 91 | 1.78 (1.68) [-1.58 ; 5.15] | -0.27 (2.08) [-4.44 ; 3.89] | 2.05 (2.66) [-3.30 ; 7.41] | 0.26 [-0.43 ; 0.96] |
| Overall post-baseline period estimate | 0.98 (0.99) [-0.98 ; 2.94] | -0.61 (1.10) [-2.79 ; 1.57] | 1.59 (1.48) [-1.35 ; 4.52] | 0.20 [-0.17 ; 0.56] |
| **Non-White** | | | | |
| Nr subjects used | n=9 | n=10 | | |
| **MMRM subgroups interaction p-value** | | | | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:01

TABLE 7.1.6: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **Hispanic or Latino** | | |
| | N=7 | N=12 |
| **Not Hispanic or Latino** | | |
| | N=42 | N=31 |
| **Not Reported** | | |
| | N=22 | N=25 |
| **Subjects with Baseline Value** | | |
| **Hispanic or Latino** | | |
| | 7 (100.0%) | 12 (100.0%) |
| **Not Hispanic or Latino** | | |
| | 42 (100.0%) | 31 (100.0%) |
| **Not Reported** | | |
| | 22 (100.0%) | 25 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **Hispanic or Latino** | | |
| | 7 (100.0%) | 12 (100.0%) |
| **Not Hispanic or Latino** | | |
| | 42 (100.0%) | 30 (96.8%) |
| **Not Reported** | | |
| | 22 (100.0%) | 24 (96.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **Hispanic or Latino** | | |
| | 7 (100.0%) | 12 (100.0%) |
| **Not Hispanic or Latino** | | |
| | 42 (100.0%) | 30 (96.8%) |
| **Not Reported** | | |
| | 22 (100.0%) | 24 (96.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:01

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Hispanic or Latino** | | | |
| N subjects in population | N=7 | N=12 | |
| Baseline | n= 7 (100.0%) \| 81.00 (6.35) | n= 12 (100.0%) \| 73.08 (28.01) | 0.33 [-0.63 ; 1.30] |
| Week 3 | n= 7 (100.0%) \| 78.00 (6.93) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 6 (85.7%) \| 79.17 (6.65) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (100.0%) \| 76.14 (12.94) | n= 11 (91.7%) \| 77.18 (19.43) | -0.06 [-1.03 ; 0.92] |
| Week 9 | n= 5 (71.4%) \| 68.00 (17.89) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 6 (85.7%) \| 78.33 (14.72) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 6 (85.7%) \| 76.83 (18.66) | n= 7 (58.3%) \| 85.43 (6.16) | -0.60 [-1.77 ; 0.57] |
| Week 15 | n= 5 (71.4%) \| 74.00 (19.49) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 7 (100.0%) \| 80.00 (7.64) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 5 (71.4%) \| 82.00 (8.37) | n= 6 (50.0%) \| 87.50 (9.87) | -0.54 [-1.82 ; 0.74] |
| Week 21 | n= 7 (100.0%) \| 76.57 (15.19) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (85.7%) \| 75.83 (14.29) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 4 (57.1%) \| 88.75 (8.54) | n= 7 (58.3%) \| 89.14 (9.14) | -0.04 [-1.34 ; 1.26] |
| Week 27 | n= 4 (57.1%) \| 84.50 (6.40) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 4 (57.1%) \| 85.00 (12.91) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 4 (57.1%) \| 85.00 (12.91) | n= 5 (41.7%) \| 88.00 (8.37) | -0.25 [-1.67 ; 1.16] |
| Week 33 | n= 5 (71.4%) \| 81.80 (13.27) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 3 (42.9%) \| 90.00 (10.00) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 2 (28.6%) \| 95.00 (7.07) | n= 5 (41.7%) \| 86.60 (7.77) | 0.93 [-0.99 ; 2.85] |
| Week 39 | n= 4 (57.1%) \| 90.25 (8.18) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 3 (42.9%) \| 91.67 (7.64) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 3 (42.9%) \| 93.33 (5.77) | n= 5 (41.7%) \| 80.20 (9.09) | 1.40 [-0.37 ; 3.18] |
| Week 45 | n= 2 (28.6%) \| 95.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 2 (28.6%) \| 95.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 3 (42.9%) \| 90.00 (0.00) | n= 4 (33.3%) \| 85.00 (10.80) | 0.50 [-1.19 ; 2.19] |
| Week 51 | n= 3 (42.9%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 2 (28.6%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 3 (42.9%) \| 91.67 (2.89) | n= 4 (33.3%) \| 85.00 (10.80) | 0.66 [-1.06 ; 2.37] |
| Week 57 | n= 3 (42.9%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 3 (42.9%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 3 (42.9%) \| 90.00 (0.00) | n= 4 (33.3%) \| 83.75 (12.50) | 0.54 [-1.15 ; 2.24] |
| Week 63 | n= 3 (42.9%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 3 (42.9%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 3 (42.9%) \| 90.00 (0.00) | n= 4 (33.3%) \| 81.75 (12.61) | 0.71 [-1.01 ; 2.44] |
| Week 69 | n= 3 (42.9%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 3 (42.9%) \| 88.67 (2.31) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (42.9%) \| 89.00 (1.73) | n= 3 (25.0%) \| 87.33 (8.62) | 0.21 [-1.61 ; 2.04] |
| Week 75 | n= 3 (42.9%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 2 (28.6%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 2 (28.6%) \| 90.00 (0.00) | n= 4 (33.3%) \| 86.50 (11.21) | 0.29 [-1.65 ; 2.23] |
| Week 81 | n= 3 (42.9%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 3 (42.9%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 3 (42.9%) \| 89.33 (1.15) | n= 3 (25.0%) \| 92.33 (2.52) | -1.23 [-3.29 ; 0.84] |
| Week 87 | n= 2 (28.6%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (28.6%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 2 (28.6%) \| 90.00 (0.00) | n= 3 (25.0%) \| 90.00 (5.00) | 0.00 [-2.11 ; 2.11] |
| Week 93 | n= 2 (28.6%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (28.6%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 2 (28.6%) \| 92.50 (3.54) | n= 3 (25.0%) \| 91.67 (5.77) | 0.12 [-2.00 ; 2.23] |
| Week 99 | n= 2 (28.6%) \| 90.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (14.3%) \| 90.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 1 (14.3%) \| 90.00 ( / ) | n= 2 (16.7%) \| 87.50 (10.61) | [Not calculable] |
| Week 105 | n= 1 (14.3%) \| 87.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | [No Data] | n= 2 (16.7%) \| 82.50 (17.68) | [No Data for at least 1 arm] |
| Week 115 | [No Data] | n= 1 ( 8.3%) \| 95.00 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 1 (14.3%) \| 61.00 ( / ) | n= 3 (25.0%) \| 80.00 (10.00) | [Not calculable] |
| Week 202 | [No Data] | n= 2 (16.7%) \| 85.00 (7.07) | [No Data for at least 1 arm] |
| Week 301 | n= 1 (14.3%) \| 90.00 ( / ) | n= 3 (25.0%) \| 85.00 (5.00) | [Not calculable] |
| Week 302 | n= 1 (14.3%) \| 80.00 ( / ) | n= 1 ( 8.3%) \| 80.00 ( / ) | [Not calculable] |
| Week 303 | n= 1 (14.3%) \| 80.00 ( / ) | n= 2 (16.7%) \| 85.00 (7.07) | [Not calculable] |
| Week 304 | [No Data] | n= 1 ( 8.3%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 305 | [No Data] | n= 1 ( 8.3%) \| 75.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 8.3%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 8.3%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 8.3%) \| 90.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 8.3%) \| 85.00 ( / ) | [No Data for at least 1 arm] |
| **Not Hispanic or Latino** | | | |
| N subjects in population | N=42 | N=31 | |
| Baseline | n= 42 (100.0%) \| 77.38 (17.42) | n= 31 (100.0%) \| 77.48 (17.34) | -0.01 [-0.47 ; 0.46] |
| Week 3 | n= 39 (92.9%) \| 78.72 (15.54) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 40 (95.2%) \| 76.88 (17.64) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 39 (92.9%) \| 77.15 (16.76) | n= 28 (90.3%) \| 76.04 (18.21) | 0.06 [-0.43 ; 0.55] |
| Week 9 | n= 34 (81.0%) \| 78.62 (16.62) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 36 (85.7%) \| 75.42 (19.69) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 34 (81.0%) \| 75.24 (24.40) | n= 23 (74.2%) \| 79.13 (13.03) | -0.19 [-0.72 ; 0.35] |
| Week 15 | n= 29 (69.0%) \| 76.59 (19.28) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 32 (76.2%) \| 79.28 (15.52) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 31 (73.8%) \| 77.48 (18.87) | n= 25 (80.6%) \| 76.04 (15.89) | 0.08 [-0.45 ; 0.61] |
| Week 21 | n= 32 (76.2%) \| 77.69 (17.51) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 29 (69.0%) \| 73.59 (19.74) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 32 (76.2%) \| 80.69 (11.11) | n= 24 (77.4%) \| 82.38 (12.33) | -0.14 [-0.68 ; 0.39] |
| Week 27 | n= 30 (71.4%) \| 82.13 (10.86) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 30 (71.4%) \| 80.60 (14.58) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 28 (66.7%) \| 81.32 (10.23) | n= 19 (61.3%) \| 80.21 (15.06) | 0.09 [-0.50 ; 0.68] |
| Week 33 | n= 32 (76.2%) \| 79.59 (13.14) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 29 (69.0%) \| 80.31 (14.22) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 26 (61.9%) \| 79.42 (13.56) | n= 21 (67.7%) \| 81.05 (12.31) | -0.12 [-0.70 ; 0.46] |
| Week 39 | n= 31 (73.8%) \| 80.65 (12.25) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 31 (73.8%) \| 81.42 (13.17) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 30 (71.4%) \| 80.27 (13.30) | n= 18 (58.1%) \| 81.50 (14.86) | -0.09 [-0.68 ; 0.50] |
| Week 45 | n= 29 (69.0%) \| 80.52 (11.55) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 30 (71.4%) \| 81.60 (11.43) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 30 (71.4%) \| 80.10 (13.75) | n= 15 (48.4%) \| 78.73 (15.42) | 0.09 [-0.53 ; 0.72] |
| Week 51 | n= 27 (64.3%) \| 80.59 (12.44) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 28 (66.7%) \| 78.00 (21.61) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 26 (61.9%) \| 77.04 (21.02) | n= 15 (48.4%) \| 83.53 (16.35) | -0.33 [-0.97 ; 0.32] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 57 | n= 27 (64.3%) \| 76.89 (20.59) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 25 (59.5%) \| 75.64 (20.76) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 25 (59.5%) \| 82.00 (13.13) | n= 11 (35.5%) \| 78.18 (17.79) | 0.25 [-0.47 ; 0.98] |
| Week 63 | n= 24 (57.1%) \| 77.42 (15.21) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 23 (54.8%) \| 78.52 (16.38) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 22 (52.4%) \| 82.64 (11.10) | n= 11 (35.5%) \| 82.73 (10.57) | -0.01 [-0.74 ; 0.73] |
| Week 69 | n= 20 (47.6%) \| 80.50 (13.57) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 21 (50.0%) \| 81.71 (15.68) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 15 (35.7%) \| 77.00 (16.10) | n= 12 (38.7%) \| 76.83 (19.84) | 0.01 [-0.76 ; 0.78] |
| Week 75 | n= 18 (42.9%) \| 79.61 (16.44) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 17 (40.5%) \| 80.12 (14.84) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 15 (35.7%) \| 80.87 (16.20) | n= 10 (32.3%) \| 75.50 (19.97) | 0.29 [-0.53 ; 1.11] |
| Week 81 | n= 17 (40.5%) \| 80.35 (15.22) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (40.5%) \| 81.82 (15.49) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 13 (31.0%) \| 85.46 (9.85) | n= 9 (29.0%) \| 79.33 (21.89) | 0.37 [-0.51 ; 1.25] |
| Week 87 | n= 11 (26.2%) \| 79.27 (17.54) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 12 (28.6%) \| 78.83 (14.60) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 13 (31.0%) \| 80.38 (15.99) | n= 7 (22.6%) \| 85.71 (11.03) | -0.35 [-1.30 ; 0.60] |
| Week 93 | n= 11 (26.2%) \| 78.27 (17.33) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (26.2%) \| 74.36 (17.83) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (28.6%) \| 75.58 (18.89) | n= 5 (16.1%) \| 80.80 (14.17) | -0.28 [-1.36 ; 0.80] |
| Week 99 | n= 8 (19.0%) \| 71.63 (17.94) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 7 (16.7%) \| 79.14 (10.19) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (19.0%) \| 81.88 (12.38) | n= 4 (12.9%) \| 83.00 (15.53) | -0.08 [-1.34 ; 1.18] |
| Week 105 | n= 8 (19.0%) \| 78.50 (13.18) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 5 (11.9%) \| 78.80 (10.99) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (19.0%) \| 76.38 (11.29) | n= 1 ( 3.2%) \| 78.00 ( / ) | [Not calculable] |
| Week 111 | n= 5 (11.9%) \| 76.20 (9.20) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 (11.9%) \| 81.80 (10.99) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 5 (11.9%) \| 85.00 (11.92) | n= 2 ( 6.5%) \| 82.50 (3.54) | 0.20 [-1.62 ; 2.01] |
| Week 117 | n= 4 ( 9.5%) \| 84.50 (3.11) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 9.5%) \| 77.00 (12.88) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (11.9%) \| 82.20 (14.46) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.4%) \| 98.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (14.3%) \| 82.50 (4.18) | n= 9 (29.0%) \| 77.22 (23.73) | 0.26 [-0.81 ; 1.34] |
| Week 202 | n= 2 ( 4.8%) \| 64.00 (26.87) | n= 5 (16.1%) \| 89.20 (12.07) | -1.31 [-3.34 ; 0.71] |
| Week 301 | n= 1 ( 2.4%) \| 50.00 ( / ) | n= 2 ( 6.5%) \| 82.00 (9.90) | [Not calculable] |
| Week 302 | n= 1 ( 2.4%) \| 50.00 ( / ) | n= 3 ( 9.7%) \| 85.00 (5.00) | [Not calculable] |
| Week 303 | n= 2 ( 4.8%) \| 45.00 (7.07) | n= 2 ( 6.5%) \| 85.00 (7.07) | -3.23 [-8.73 ; 2.27] |
| Week 304 | n= 1 ( 2.4%) \| 100.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| **Not Reported** | | | |
| N subjects in population | N=22 | N=25 | |
| Baseline | n= 22 (100.0%) \| 77.64 (20.65) | n= 25 (100.0%) \| 85.68 (11.19) | -0.49 [-1.07 ; 0.10] |
| Week 3 | n= 21 (95.5%) \| 85.43 (9.86) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 19 (86.4%) \| 79.95 (17.18) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 20 (90.9%) \| 76.15 (21.63) | n= 23 (92.0%) \| 79.57 (15.05) | -0.18 [-0.79 ; 0.43] |
| Week 9 | n= 20 (90.9%) \| 78.70 (14.72) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 19 (86.4%) \| 79.53 (13.93) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 19 (86.4%) \| 72.21 (22.19) | n= 23 (92.0%) \| 78.70 (15.67) | -0.34 [-0.96 ; 0.28] |
| Week 15 | n= 20 (90.9%) \| 74.70 (22.01) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 22 (100.0%) \| 77.32 (17.38) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 19 | n= 21 (95.5%) \| 81.24 (14.15) | n= 22 (88.0%) \| 85.00 (9.03) | -0.31 [-0.92 ; 0.30] |
| Week 21 | n= 21 (95.5%) \| 79.86 (13.75) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (95.5%) \| 80.62 (12.95) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 21 (95.5%) \| 79.48 (13.34) | n= 19 (76.0%) \| 84.05 (10.74) | -0.37 [-1.00 ; 0.27] |
| Week 27 | n= 21 (95.5%) \| 79.62 (15.44) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 19 (86.4%) \| 80.21 (12.96) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 22 (100.0%) \| 80.73 (12.35) | n= 19 (76.0%) \| 80.32 (14.84) | 0.03 [-0.59 ; 0.65] |
| Week 33 | n= 20 (90.9%) \| 82.30 (12.04) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 21 (95.5%) \| 79.43 (13.22) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 21 (95.5%) \| 80.86 (13.21) | n= 20 (80.0%) \| 82.10 (16.11) | -0.08 [-0.70 ; 0.54] |
| Week 39 | n= 18 (81.8%) \| 81.94 (13.69) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 17 (77.3%) \| 80.88 (13.52) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 20 (90.9%) \| 81.15 (14.53) | n= 20 (80.0%) \| 81.55 (15.43) | -0.03 [-0.65 ; 0.60] |
| Week 45 | n= 18 (81.8%) \| 76.89 (15.48) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 20 (90.9%) \| 81.95 (12.97) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 20 (90.9%) \| 82.50 (13.47) | n= 19 (76.0%) \| 83.74 (11.68) | -0.10 [-0.73 ; 0.54] |
| Week 51 | n= 21 (95.5%) \| 80.67 (13.13) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 19 (86.4%) \| 81.95 (12.61) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 18 (81.8%) \| 82.61 (13.78) | n= 18 (72.0%) \| 80.94 (12.96) | 0.12 [-0.54 ; 0.78] |
| Week 57 | n= 17 (77.3%) \| 82.94 (12.27) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 18 (81.8%) \| 82.78 (13.81) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 20 (90.9%) \| 80.80 (13.66) | n= 15 (60.0%) \| 77.13 (14.34) | 0.26 [-0.43 ; 0.94] |
| Week 63 | n= 15 (68.2%) \| 82.73 (12.41) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 18 (81.8%) \| 80.61 (13.86) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 19 (86.4%) \| 80.42 (16.91) | n= 15 (60.0%) \| 81.87 (14.44) | -0.09 [-0.78 ; 0.60] |
| Week 69 | n= 14 (63.6%) \| 78.07 (14.31) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 15 (68.2%) \| 82.33 (13.74) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (72.7%) \| 83.13 (13.26) | n= 13 (52.0%) \| 79.31 (15.07) | 0.26 [-0.48 ; 1.01] |
| Week 75 | n= 15 (68.2%) \| 82.47 (14.35) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 13 (59.1%) \| 81.77 (13.88) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 14 (63.6%) \| 82.43 (18.12) | n= 11 (44.0%) \| 79.00 (15.08) | 0.20 [-0.61 ; 1.00] |
| Week 81 | n= 11 (50.0%) \| 85.91 (9.97) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 13 (59.1%) \| 85.08 (10.53) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (50.0%) \| 87.27 (8.33) | n= 9 (36.0%) \| 79.78 (11.19) | 0.74 [-0.20 ; 1.68] |
| Week 87 | n= 11 (50.0%) \| 82.45 (13.43) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 11 (50.0%) \| 85.18 (9.35) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 9 (40.9%) \| 83.56 (10.11) | n= 6 (24.0%) \| 81.67 (9.83) | 0.18 [-0.90 ; 1.25] |
| Week 93 | n= 8 (36.4%) \| 87.63 (10.11) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 9 (40.9%) \| 85.78 (9.36) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (31.8%) \| 85.14 (9.39) | n= 3 (12.0%) \| 76.67 (5.77) | 0.89 [-0.62 ; 2.40] |
| Week 99 | n= 7 (31.8%) \| 84.29 (10.24) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (27.3%) \| 80.83 (9.26) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 6 (27.3%) \| 82.00 (8.32) | n= 4 (16.0%) \| 78.75 (6.29) | 0.39 [-0.97 ; 1.74] |
| Week 105 | n= 5 (22.7%) \| 78.20 (7.50) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 3 (13.6%) \| 78.00 (10.58) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (13.6%) \| 82.67 (6.43) | n= 2 ( 8.0%) \| 79.50 (0.71) | 0.44 [-1.72 ; 2.60] |
| Week 111 | n= 2 ( 9.1%) \| 82.50 (10.61) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (13.6%) \| 80.67 (9.02) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 2 ( 9.1%) \| 77.50 (3.54) | n= 2 ( 8.0%) \| 76.00 (18.38) | 0.06 [-2.40 ; 2.53] |
| Week 117 | n= 3 (13.6%) \| 80.67 (8.14) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 (13.6%) \| 80.33 (2.52) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 121 | n= 3 (13.6%) \| 80.00 (4.00) | n= 1 ( 4.0%) \| 92.00 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 9.1%) \| 81.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.5%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 4.5%) \| 80.00 ( / ) | n= 1 ( 4.0%) \| 100.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 4.5%) \| 81.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 4.5%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.5%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 4.5%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 4.5%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 4.5%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.5%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 4.5%) \| 70.00 ( / ) | n= 5 (20.0%) \| 80.60 (11.22) | [Not calculable] |
| Week 202 | [No Data] | n= 5 (20.0%) \| 88.80 (11.17) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 (16.0%) \| 82.50 (10.41) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 2 ( 8.0%) \| 80.00 (7.07) | [No Data for at least 1 arm] |
| Week 303 | [No Data] | n= 2 ( 8.0%) \| 76.00 (5.66) | [No Data for at least 1 arm] |
| Week 304 | [No Data] | n= 2 ( 8.0%) \| 80.00 (14.14) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:02

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Hispanic or Latino** | | | |
| N subjects in population | N=7 | N=12 | |
| Week 3 | n= 7 (100.0%) \| 1.29 (9.21) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 6 (85.7%) \| 1.33 (15.06) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (100.0%) \|-0.57 (15.35) | n= 11 (91.7%) \| 5.64 (23.83) | -0.28 [-1.26 ; 0.70] |
| Week 9 | n= 5 (71.4%) \|-12.00 (13.04) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 6 (85.7%) \| 0.50 (19.01) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 6 (85.7%) \|-1.00 (22.65) | n= 7 (58.3%) \|-2.29 (5.38) | 0.08 [-1.06 ; 1.22] |
| Week 15 | n= 5 (71.4%) \|-6.00 (13.42) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 7 (100.0%) \| 3.29 (10.44) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 5 (71.4%) \|-1.40 (4.98) | n= 6 (50.0%) \|-4.83 (5.31) | 0.61 [-0.68 ; 1.89] |
| Week 21 | n= 7 (100.0%) \|-0.14 (9.08) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (85.7%) \| 0.83 (12.81) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 4 (57.1%) \| 6.25 (9.46) | n= 7 (58.3%) \|-1.43 (7.16) | 0.88 [-0.49 ; 2.24] |
| Week 27 | n= 4 (57.1%) \| 2.00 (5.42) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 4 (57.1%) \| 2.50 (12.58) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 4 (57.1%) \| 2.50 (12.58) | n= 5 (41.7%) \| 0.00 (7.07) | 0.23 [-1.19 ; 1.64] |
| Week 33 | n= 5 (71.4%) \|-1.60 (12.82) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 3 (42.9%) \| 6.67 (11.55) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 2 (28.6%) \| 10.00 (14.14) | n= 5 (41.7%) \|-4.20 (10.33) | 1.07 [-0.89 ; 3.02] |
| Week 39 | n= 4 (57.1%) \| 6.00 (9.52) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 3 (42.9%) \| 6.00 (12.17) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 3 (42.9%) \| 7.67 (10.79) | n= 5 (41.7%) \|-10.60 (8.73) | 1.68 [-0.18 ; 3.54] |
| Week 45 | n= 2 (28.6%) \| 10.00 (14.14) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 2 (28.6%) \| 10.00 (14.14) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 3 (42.9%) \| 4.33 (5.13) | n= 4 (33.3%) \|-8.50 (2.38) | 2.90 [ 0.31 ; 5.48] |
| Week 51 | n= 3 (42.9%) \| 4.33 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 2 (28.6%) \| 5.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 3 (42.9%) \| 6.00 (5.29) | n= 4 (33.3%) \|-8.50 (2.38) | 3.20 [ 0.45 ; 5.94] |
| Week 57 | n= 3 (42.9%) \| 4.33 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 3 (42.9%) \| 4.33 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 3 (42.9%) \| 4.33 (5.13) | n= 4 (33.3%) \|-9.75 (8.18) | 1.67 [-0.34 ; 3.68] |
| Week 63 | n= 3 (42.9%) \| 4.33 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 3 (42.9%) \| 4.33 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 3 (42.9%) \| 4.33 (5.13) | n= 4 (33.3%) \|-11.75 (12.28) | 1.35 [-0.55 ; 3.24] |
| Week 69 | n= 3 (42.9%) \| 4.33 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 3 (42.9%) \| 3.00 (6.08) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (42.9%) \| 3.33 (5.77) | n= 3 (25.0%) \|-4.00 (1.73) | 1.38 [-0.75 ; 3.50] |
| Week 75 | n= 3 (42.9%) \| 4.33 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 2 (28.6%) \| 5.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 2 (28.6%) \| 5.00 (7.07) | n= 4 (33.3%) \|-7.00 (2.94) | 2.20 [-0.41 ; 4.81] |
| Week 81 | n= 3 (42.9%) \| 4.33 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 3 (42.9%) \| 4.33 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 3 (42.9%) \| 3.67 (5.51) | n= 3 (25.0%) \|-5.67 (2.08) | 1.79 [-0.52 ; 4.11] |
| Week 87 | n= 2 (28.6%) \| 5.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (28.6%) \| 1.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 2 (28.6%) \| 1.50 (2.12) | n= 3 (25.0%) \|-8.00 (2.65) | 2.78 [-0.73 ; 6.29] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 2 (28.6%) \| 1.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (28.6%) \| 1.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 2 (28.6%) \| 4.00 (5.66) | n= 3 (25.0%) \|-6.33 (2.31) | 1.99 [-0.92 ; 4.91] |
| Week 99 | n= 2 (28.6%) \| 1.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (14.3%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 1 (14.3%) \| 3.00 ( / ) | n= 2 (16.7%) \|-12.50 (10.61) | [Not calculable] |
| Week 105 | n= 1 (14.3%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | [No Data] | n= 2 (16.7%) \|-17.50 (17.68) | [No Data for at least 1 arm] |
| Week 115 | [No Data] | n= 1 ( 8.3%) \|-5.00 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 1 (14.3%) \|-9.00 ( / ) | n= 3 (25.0%) \|-3.33 (11.55) | [Not calculable] |
| Week 202 | [No Data] | n= 2 (16.7%) \| 0.00 (14.14) | [No Data for at least 1 arm] |
| Week 301 | n= 1 (14.3%) \| 10.00 ( / ) | n= 3 (25.0%) \| 8.33 (14.43) | [Not calculable] |
| Week 302 | n= 1 (14.3%) \| 0.00 ( / ) | n= 1 ( 8.3%) \| 0.00 ( / ) | [Not calculable] |
| Week 303 | n= 1 (14.3%) \| 0.00 ( / ) | n= 2 (16.7%) \| 0.00 (14.14) | [Not calculable] |
| Week 304 | [No Data] | n= 1 ( 8.3%) \|-10.00 ( / ) | [No Data for at least 1 arm] |
| Week 305 | [No Data] | n= 1 ( 8.3%) \| 67.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 8.3%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 8.3%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 8.3%) \| 82.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 8.3%) \| 77.00 ( / ) | [No Data for at least 1 arm] |
| **Not Hispanic or Latino** | | | |
| N subjects in population | N=42 | N=31 | |
| Week 3 | n= 39 (92.9%) \|-0.79 (8.28) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 40 (95.2%) \|-2.23 (16.07) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 39 (92.9%) \|-2.67 (18.19) | n= 28 (90.3%) \|-0.21 (8.56) | -0.16 [-0.65 ; 0.33] |
| Week 9 | n= 34 (81.0%) \|-1.24 (17.70) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 36 (85.7%) \|-2.86 (21.99) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 34 (81.0%) \|-4.26 (25.40) | n= 23 (74.2%) \| 3.26 (21.94) | -0.31 [-0.85 ; 0.23] |
| Week 15 | n= 29 (69.0%) \|-1.10 (23.10) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 32 (76.2%) \| 1.38 (16.73) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 31 (73.8%) \|-0.84 (18.27) | n= 25 (80.6%) \|-3.60 (11.46) | 0.17 [-0.36 ; 0.71] |
| Week 21 | n= 32 (76.2%) \|-1.47 (18.35) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 29 (69.0%) \|-3.41 (20.77) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 32 (76.2%) \| 1.09 (13.23) | n= 24 (77.4%) \| 6.33 (17.91) | -0.34 [-0.87 ; 0.20] |
| Week 27 | n= 30 (71.4%) \| 2.53 (12.70) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 30 (71.4%) \| 1.13 (15.66) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 28 (66.7%) \| 3.36 (13.63) | n= 19 (61.3%) \| 1.11 (12.22) | 0.17 [-0.42 ; 0.76] |
| Week 33 | n= 32 (76.2%) \| 0.91 (13.19) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 29 (69.0%) \| 2.07 (13.96) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 26 (61.9%) \| 1.42 (12.58) | n= 21 (67.7%) \| 2.81 (11.20) | -0.11 [-0.70 ; 0.47] |
| Week 39 | n= 31 (73.8%) \| 2.48 (12.34) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 31 (73.8%) \| 2.77 (13.63) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 30 (71.4%) \| 1.67 (14.53) | n= 18 (58.1%) \| 5.39 (12.95) | -0.26 [-0.85 ; 0.33] |
| Week 45 | n= 29 (69.0%) \|-0.10 (9.99) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 30 (71.4%) \| 3.33 (12.24) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 30 (71.4%) \| 2.50 (13.32) | n= 15 (48.4%) \| 3.07 (13.57) | -0.04 [-0.67 ; 0.59] |
| Week 51 | n= 27 (64.3%) \|-0.07 (5.90) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 28 (66.7%) \|-3.54 (20.30) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 26 (61.9%) \|-2.23 (19.60) | n= 15 (48.4%) \| 5.53 (14.71) | -0.42 [-1.07 ; 0.23] |
| Week 57 | n= 27 (64.3%) \|-3.41 (18.63) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 25 (59.5%) \|-3.64 (12.81) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 61 | n= 25 (59.5%) \| 0.88 (11.76) | n= 11 (35.5%) \| 0.45 (15.08) | 0.03 [-0.69 ; 0.75] |
| Week 63 | n= 24 (57.1%) \|-0.83 (11.28) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 23 (54.8%) \| 0.78 (10.84) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 22 (52.4%) \| 1.50 (12.57) | n= 11 (35.5%) \| 6.82 (9.02) | -0.45 [-1.19 ; 0.29] |
| Week 69 | n= 20 (47.6%) \| 0.10 (13.46) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 21 (50.0%) \| 0.62 (13.75) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 15 (35.7%) \|-2.13 (16.55) | n= 12 (38.7%) \|-0.67 (16.42) | -0.09 [-0.86 ; 0.69] |
| Week 75 | n= 18 (42.9%) \|-1.33 (14.24) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 17 (40.5%) \| 0.06 (14.03) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 15 (35.7%) \| 2.13 (14.24) | n= 10 (32.3%) \| 0.50 (18.38) | 0.10 [-0.72 ; 0.92] |
| Week 81 | n= 17 (40.5%) \| 0.24 (14.83) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (40.5%) \| 1.76 (14.96) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 13 (31.0%) \| 3.77 (13.34) | n= 9 (29.0%) \|-0.67 (16.71) | 0.29 [-0.59 ; 1.16] |
| Week 87 | n= 11 (26.2%) \| 1.45 (15.86) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 12 (28.6%) \| 2.50 (14.48) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 13 (31.0%) \| 2.92 (14.56) | n= 7 (22.6%) \| 7.14 (7.08) | -0.32 [-1.27 ; 0.63] |
| Week 93 | n= 11 (26.2%) \| 4.00 (14.11) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (26.2%) \|-3.55 (11.84) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (28.6%) \|-3.33 (11.53) | n= 5 (16.1%) \| 0.80 (7.12) | -0.37 [-1.46 ; 0.71] |
| Week 99 | n= 8 (19.0%) \|-0.50 (11.60) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 7 (16.7%) \| 1.00 (10.46) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (19.0%) \| 3.63 (7.50) | n= 4 (12.9%) \| 3.00 (5.29) | 0.08 [-1.18 ; 1.34] |
| Week 105 | n= 8 (19.0%) \|-1.00 (10.97) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 5 (11.9%) \| 3.60 (4.16) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (19.0%) \|-0.75 (9.63) | n= 1 ( 3.2%) \|-2.00 ( / ) | [Not calculable] |
| Week 111 | n= 5 (11.9%) \|-1.00 (6.56) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 (11.9%) \|-1.40 (11.82) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 5 (11.9%) \| 1.80 (14.04) | n= 2 ( 6.5%) \| 2.50 (3.54) | -0.05 [-1.86 ; 1.76] |
| Week 117 | n= 4 ( 9.5%) \|-1.75 (13.57) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 9.5%) \|-4.50 (14.29) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (11.9%) \| 1.00 (9.51) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.4%) \| 8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (14.3%) \| 7.33 (23.31) | n= 9 (29.0%) \|-10.11 (15.42) | 0.87 [-0.25 ; 2.00] |
| Week 202 | n= 2 ( 4.8%) \|-4.50 (0.71) | n= 5 (16.1%) \| 1.20 (5.89) | -0.91 [-2.83 ; 1.01] |
| Week 301 | n= 1 ( 2.4%) \| 0.00 ( / ) | n= 2 ( 6.5%) \|-7.00 (4.24) | [Not calculable] |
| Week 302 | n= 1 ( 2.4%) \|-20.00 ( / ) | n= 3 ( 9.7%) \|-2.00 (9.64) | [Not calculable] |
| Week 303 | n= 2 ( 4.8%) \|-5.00 (21.21) | n= 2 ( 6.5%) \| 38.00 (46.67) | -0.68 [-3.34 ; 1.99] |
| Week 304 | n= 1 ( 2.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| **Not Reported** | | | |
| N subjects in population | N=22 | N=25 | |
| Week 3 | n= 21 (95.5%) \| 7.29 (19.14) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 19 (86.4%) \| 0.05 (15.70) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 20 (90.9%) \|-0.90 (19.92) | n= 23 (92.0%) \|-5.96 (11.81) | 0.31 [-0.30 ; 0.92] |
| Week 9 | n= 20 (90.9%) \|-0.40 (20.22) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 19 (86.4%) \| 0.26 (20.00) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 19 (86.4%) \|-3.74 (20.87) | n= 23 (92.0%) \|-7.74 (17.00) | 0.21 [-0.41 ; 0.82] |
| Week 15 | n= 20 (90.9%) \|-3.70 (25.82) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 22 (100.0%) \|-0.55 (20.42) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 21 (95.5%) \| 3.48 (16.15) | n= 22 (88.0%) \|-0.82 (9.71) | 0.32 [-0.29 ; 0.93] |
| Week 21 | n= 21 (95.5%) \| 2.52 (15.75) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (95.5%) \| 2.48 (14.84) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 25 | n= 21 (95.5%) \| 0.76 (15.37) | n= 19 (76.0%) \|-4.00 (14.32) | 0.31 [-0.32 ; 0.95] |
| Week 27 | n= 21 (95.5%) \| 1.86 (17.18) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 19 (86.4%) \| 2.95 (14.72) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 22 (100.0%) \| 2.86 (14.36) | n= 19 (76.0%) \|-7.21 (15.35) | 0.67 [ 0.03 ; 1.31] |
| Week 33 | n= 20 (90.9%) \| 1.25 (10.74) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 21 (95.5%) \| 1.29 (13.84) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 21 (95.5%) \| 3.10 (16.47) | n= 20 (80.0%) \|-5.05 (11.33) | 0.56 [-0.07 ; 1.19] |
| Week 39 | n= 18 (81.8%) \| 3.94 (15.33) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 17 (77.3%) \|-2.59 (8.54) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 20 (90.9%) \| 2.25 (14.61) | n= 20 (80.0%) \|-5.60 (13.39) | 0.55 [-0.09 ; 1.19] |
| Week 45 | n= 18 (81.8%) \| 0.78 (16.85) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 20 (90.9%) \| 3.05 (15.15) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 20 (90.9%) \| 3.45 (14.26) | n= 19 (76.0%) \|-2.74 (11.67) | 0.46 [-0.18 ; 1.11] |
| Week 51 | n= 21 (95.5%) \| 2.52 (14.95) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 19 (86.4%) \| 4.79 (14.57) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 18 (81.8%) \| 5.78 (15.20) | n= 18 (72.0%) \|-5.17 (13.70) | 0.74 [ 0.05 ; 1.43] |
| Week 57 | n= 17 (77.3%) \| 6.18 (16.55) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 18 (81.8%) \| 5.11 (14.45) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 20 (90.9%) \| 2.90 (13.90) | n= 15 (60.0%) \|-8.20 (14.72) | 0.76 [ 0.06 ; 1.46] |
| Week 63 | n= 15 (68.2%) \| 0.47 (8.08) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 18 (81.8%) \| 4.11 (13.09) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 19 (86.4%) \| 2.89 (14.54) | n= 15 (60.0%) \|-4.67 (14.25) | 0.51 [-0.19 ; 1.21] |
| Week 69 | n= 14 (63.6%) \| 1.29 (16.92) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 15 (68.2%) \| 1.20 (10.12) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (72.7%) \| 1.50 (8.12) | n= 13 (52.0%) \|-4.38 (13.98) | 0.51 [-0.24 ; 1.27] |
| Week 75 | n= 15 (68.2%) \| 1.60 (9.12) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 13 (59.1%) \| 5.69 (16.81) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 14 (63.6%) \|-0.14 (11.07) | n= 11 (44.0%) \|-3.73 (13.68) | 0.28 [-0.53 ; 1.09] |
| Week 81 | n= 11 (50.0%) \| 1.18 (8.98) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 13 (59.1%) \| 0.38 (8.73) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (50.0%) \|-0.45 (7.13) | n= 9 (36.0%) \|-5.78 (12.36) | 0.52 [-0.40 ; 1.44] |
| Week 87 | n= 11 (50.0%) \|-2.64 (6.68) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 11 (50.0%) \|-2.55 (6.33) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 9 (40.9%) \|-4.44 (5.34) | n= 6 (24.0%) \|-3.33 (13.66) | -0.11 [-1.18 ; 0.96] |
| Week 93 | n= 8 (36.4%) \|-1.13 (3.56) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 9 (40.9%) \|-1.44 (5.92) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (31.8%) \|-1.29 (7.99) | n= 3 (12.0%) \|-3.33 (5.77) | 0.25 [-1.20 ; 1.69] |
| Week 99 | n= 7 (31.8%) \|-2.14 (8.65) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (27.3%) \|-4.50 (6.92) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 6 (27.3%) \|-3.33 (6.65) | n= 4 (16.0%) \|-1.25 (6.29) | -0.29 [-1.64 ; 1.06] |
| Week 105 | n= 5 (22.7%) \|-6.40 (6.11) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 3 (13.6%) \|-4.67 (4.62) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (13.6%) \|-5.00 (8.89) | n= 2 ( 8.0%) \|-0.50 (0.71) | -0.45 [-2.61 ; 1.71] |
| Week 111 | n= 2 ( 9.1%) \|-1.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (13.6%) \|-7.00 (7.00) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 2 ( 9.1%) \|-8.00 (9.90) | n= 2 ( 8.0%) \|-14.00 (32.53) | 0.14 [-2.33 ; 2.61] |
| Week 117 | n= 3 (13.6%) \|-7.33 (9.71) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 (13.6%) \|-7.67 (8.74) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (13.6%) \|-8.00 (7.55) | n= 1 ( 4.0%) \|-8.00 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 9.1%) \|-13.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.5%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 127 | n= 1 ( 4.5%) \|-15.00 ( / ) | n= 1 ( 4.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 4.5%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 4.5%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.5%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 4.5%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 4.5%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 4.5%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.5%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 4.5%) \|-15.00 ( / ) | n= 5 (20.0%) \|-6.20 (17.41) | [Not calculable] |
| Week 202 | [No Data] | n= 5 (20.0%) \|-2.20 (15.14) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 (16.0%) \| 1.50 (9.26) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 2 ( 8.0%) \| 8.00 (9.90) | [No Data for at least 1 arm] |
| Week 303 | [No Data] | n= 2 ( 8.0%) \| 4.00 (8.49) | [No Data for at least 1 arm] |
| Week 304 | [No Data] | n= 2 ( 8.0%) \| 8.00 (16.97) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:02

TABLE 7.1.6: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **Hispanic or Latino** | | | | |
| Nr subjects used | n=7 | n=12 | | |
| **Not Hispanic or Latino** | | | | |
| Nr subjects used | n=42 | n=31 | | |
| Week 7 | -2.39 (2.52) [-7.42 ; 2.64] | -1.52 (2.98) [-7.47 ; 4.43] | -0.87 (3.90) [-8.66 ; 6.92] | -0.05 [-0.54 ; 0.43] |
| Week 13 | -6.90 (3.90) [-14.70 ; 0.90] | 3.70 (4.66) [-5.60 ; 13.00] | -10.60 (6.08) [-22.74 ; 1.54] | -0.46 [-1.00 ; 0.07] |
| Week 19 | -1.95 (2.77) [-7.48 ; 3.59] | -0.93 (3.15) [-7.23 ; 5.36] | -1.01 (4.20) [-9.40 ; 7.37] | -0.06 [-0.59 ; 0.46] |
| Week 25 | 0.85 (1.85) [-2.85 ; 4.54] | 4.88 (2.13) [ 0.63 ; 9.13] | -4.03 (2.82) [-9.67 ; 1.61] | -0.38 [-0.91 ; 0.15] |
| Week 31 | 2.14 (1.86) [-1.57 ; 5.86] | 2.80 (2.20) [-1.60 ; 7.19] | -0.65 (2.88) [-6.41 ; 5.11] | -0.07 [-0.65 ; 0.52] |
| Week 37 | 1.96 (1.81) [-1.65 ; 5.58] | 3.06 (2.08) [-1.09 ; 7.21] | -1.09 (2.76) [-6.60 ; 4.41] | -0.11 [-0.69 ; 0.46] |
| Week 43 | 1.98 (1.99) [-2.00 ; 5.95] | 4.34 (2.50) [-0.65 ; 9.32] | -2.36 (3.20) [-8.74 ; 4.02] | -0.21 [-0.80 ; 0.37] |
| Week 49 | 1.70 (2.01) [-2.31 ; 5.71] | 1.93 (2.72) [-3.50 ; 7.35] | -0.23 (3.38) [-6.97 ; 6.52] | -0.02 [-0.64 ; 0.60] |
| Week 55 | -0.45 (3.15) [-6.76 ; 5.86] | 4.58 (4.23) [-3.88 ; 13.03] | -5.03 (5.27) [-15.58 ; 5.52] | -0.30 [-0.94 ; 0.33] |
| Week 61 | 1.68 (2.09) [-2.51 ; 5.88] | 0.53 (3.02) [-5.51 ; 6.58] | 1.15 (3.67) [-6.21 ; 8.51] | 0.11 [-0.60 ; 0.82] |
| Week 67 | 1.98 (2.13) [-2.31 ; 6.27] | 3.65 (2.97) [-2.35 ; 9.66] | -1.67 (3.66) [-9.05 ; 5.71] | -0.16 [-0.89 ; 0.56] |
| Week 73 | -2.26 (3.26) [-8.83 ; 4.32] | -0.53 (4.00) [-8.62 ; 7.55] | -1.72 (5.16) [-12.15 ; 8.70] | -0.13 [-0.89 ; 0.63] |
| Week 79 | 2.26 (3.46) [-4.79 ; 9.31] | 0.85 (4.33) [-7.98 ; 9.67] | 1.41 (5.55) [-9.89 ; 12.72] | 0.10 [-0.70 ; 0.90] |
| Overall post-baseline period estimate | 0.05 (1.33) [-2.59 ; 2.68] | 2.10 (1.66) [-1.20 ; 5.41] | -2.05 (2.13) [-6.29 ; 2.18] | -0.23 [-0.70 ; 0.24] |
| **Not Reported** | | | | |
| Nr subjects used | n=22 | n=25 | | |
| Week 7 | -4.43 (3.54) [-11.54 ; 2.68] | -4.02 (3.32) [-10.69 ; 2.65] | -0.40 (4.86) [-10.18 ; 9.37] | -0.02 [-0.62 ; 0.57] |
| Week 13 | -6.73 (4.23) [-15.23 ; 1.78] | -5.52 (3.97) [-13.51 ; 2.47] | -1.20 (5.82) [-12.89 ; 10.48] | -0.06 [-0.67 ; 0.54] |
| Week 19 | 0.29 (2.38) [-4.50 ; 5.08] | 0.21 (2.31) [-4.45 ; 4.86] | 0.09 (3.34) [-6.63 ; 6.81] | 0.01 [-0.59 ; 0.61] |
| Week 25 | -1.08 (2.24) [-5.58 ; 3.41] | -1.08 (2.27) [-5.63 ; 3.47] | -0.00 (3.21) [-6.45 ; 6.44] | -0.00 [-0.62 ; 0.62] |
| Week 31 | 0.65 (2.54) [-4.45 ; 5.75] | -3.52 (2.62) [-8.78 ; 1.74] | 4.17 (3.67) [-3.20 ; 11.54] | 0.35 [-0.27 ; 0.97] |
| Week 37 | 0.36 (2.90) [-5.47 ; 6.19] | -3.14 (2.95) [-9.08 ; 2.80] | 3.50 (4.16) [-4.86 ; 11.86] | 0.26 [-0.36 ; 0.87] |
| Week 43 | -0.70 (2.81) [-6.36 ; 4.96] | -2.44 (2.86) [-8.20 ; 3.32] | 1.74 (4.04) [-6.38 ; 9.85] | 0.13 [-0.49 ; 0.75] |
| Week 49 | 1.09 (2.01) [-2.93 ; 5.12] | -0.48 (2.07) [-4.64 ; 3.67] | 1.58 (2.91) [-4.26 ; 7.41] | 0.17 [-0.46 ; 0.80] |
| Week 55 | 2.31 (2.18) [-2.07 ; 6.69] | -2.21 (2.23) [-6.68 ; 2.27] | 4.52 (3.15) [-1.79 ; 10.83] | 0.47 [-0.19 ; 1.13] |
| Week 61 | 0.38 (2.30) [-4.25 ; 5.00] | -4.66 (2.51) [-9.70 ; 0.38] | 5.03 (3.43) [-1.85 ; 11.92] | 0.49 [-0.19 ; 1.17] |
| Week 67 | -0.12 (2.56) [-5.27 ; 5.03] | -0.79 (2.81) [-6.43 ; 4.85] | 0.67 (3.82) [-7.01 ; 8.34] | 0.06 [-0.62 ; 0.74] |
| Week 73 | 0.40 (2.26) [-4.15 ; 4.95] | -2.50 (2.47) [-7.47 ; 2.47] | 2.90 (3.36) [-3.86 ; 9.66] | 0.31 [-0.42 ; 1.05] |
| Week 79 | -0.82 (2.98) [-6.87 ; 5.23] | -2.20 (3.30) [-8.90 ; 4.50] | 1.38 (4.45) [-7.66 ; 10.42] | 0.12 [-0.67 ; 0.91] |
| Overall post-baseline period estimate | -0.65 (1.54) [-3.73 ; 2.44] | -2.49 (1.56) [-5.60 ; 0.63] | 1.84 (2.22) [-2.60 ; 6.29] | 0.24 [-0.34 ; 0.82] |
| **MMRM subgroups interaction p-value** | | | 0.6565 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020

TABLE 7.1.7: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **Male** | | |
| | N=54 | N=47 |
| **Female** | | |
| | N=17 | N=21 |
| **Subjects with Baseline Value** | | |
| **Male** | | |
| | 54 (100.0%) | 47 (100.0%) |
| **Female** | | |
| | 17 (100.0%) | 21 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **Male** | | |
| | 54 (100.0%) | 47 (100.0%) |
| **Female** | | |
| | 17 (100.0%) | 19 (90.5%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **Male** | | |
| | 54 (100.0%) | 47 (100.0%) |
| **Female** | | |
| | 17 (100.0%) | 19 (90.5%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:02

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Male** | | | |
| N subjects in population | N=54 | N=47 | |
| Baseline | n= 54 (100.0%) \| 78.41 (18.93) | n= 47 (100.0%) \| 78.00 (20.08) | 0.02 [-0.37 ; 0.41] |
| Week 3 | n= 50 (92.6%) \| 81.60 (12.94) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 49 (90.7%) \| 80.61 (14.46) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 51 (94.4%) \| 76.76 (18.97) | n= 45 (95.7%) \| 78.13 (17.84) | -0.07 [-0.48 ; 0.33] |
| Week 9 | n= 46 (85.2%) \| 79.22 (16.43) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 46 (85.2%) \| 81.07 (14.53) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 46 (85.2%) \| 77.07 (21.65) | n= 37 (78.7%) \| 79.16 (14.53) | -0.11 [-0.55 ; 0.33] |
| Week 15 | n= 42 (77.8%) \| 80.07 (14.23) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 47 (87.0%) \| 81.17 (13.34) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 45 (83.3%) \| 81.76 (12.54) | n= 39 (83.0%) \| 80.13 (13.91) | 0.12 [-0.31 ; 0.55] |
| Week 21 | n= 47 (87.0%) \| 80.94 (12.70) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 41 (75.9%) \| 77.68 (16.90) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 43 (79.6%) \| 82.37 (10.86) | n= 35 (74.5%) \| 83.83 (12.01) | -0.13 [-0.58 ; 0.32] |
| Week 27 | n= 43 (79.6%) \| 83.07 (11.19) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 41 (75.9%) \| 81.29 (14.15) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 42 (77.8%) \| 82.67 (11.05) | n= 30 (63.8%) \| 81.60 (15.45) | 0.08 [-0.39 ; 0.55] |
| Week 33 | n= 45 (83.3%) \| 82.44 (11.87) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 42 (77.8%) \| 81.86 (13.29) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 41 (75.9%) \| 82.56 (12.97) | n= 35 (74.5%) \| 82.91 (13.94) | -0.03 [-0.48 ; 0.43] |
| Week 39 | n= 43 (79.6%) \| 83.23 (12.18) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 40 (74.1%) \| 82.98 (13.57) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 43 (79.6%) \| 82.44 (13.82) | n= 31 (66.0%) \| 82.55 (14.02) | -0.01 [-0.47 ; 0.46] |
| Week 45 | n= 39 (72.2%) \| 80.44 (13.78) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 42 (77.8%) \| 83.79 (11.56) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 42 (77.8%) \| 83.38 (12.59) | n= 28 (59.6%) \| 82.61 (13.80) | 0.06 [-0.42 ; 0.54] |
| Week 51 | n= 40 (74.1%) \| 83.05 (11.28) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 37 (68.5%) \| 81.11 (19.65) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 38 (70.4%) \| 81.79 (18.33) | n= 26 (55.3%) \| 83.23 (14.55) | -0.08 [-0.59 ; 0.42] |
| Week 57 | n= 39 (72.2%) \| 80.85 (17.91) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (68.5%) \| 80.76 (18.14) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (72.2%) \| 82.97 (13.27) | n= 20 (42.6%) \| 77.60 (17.57) | 0.36 [-0.19 ; 0.90] |
| Week 63 | n= 34 (63.0%) \| 80.85 (14.10) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 34 (63.0%) \| 81.41 (15.24) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 35 (64.8%) \| 83.26 (13.90) | n= 21 (44.7%) \| 83.33 (12.95) | -0.01 [-0.55 ; 0.54] |
| Week 69 | n= 29 (53.7%) \| 81.76 (13.81) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 32 (59.3%) \| 83.97 (14.35) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 27 (50.0%) \| 83.30 (13.77) | n= 19 (40.4%) \| 80.26 (18.24) | 0.19 [-0.41 ; 0.78] |
| Week 75 | n= 30 (55.6%) \| 82.53 (15.63) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (50.0%) \| 82.67 (14.19) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (48.1%) \| 82.46 (17.62) | n= 17 (36.2%) \| 77.88 (18.39) | 0.25 [-0.37 ; 0.87] |
| Week 81 | n= 26 (48.1%) \| 83.62 (13.80) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (51.9%) \| 84.89 (13.39) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 21 (38.9%) \| 87.67 (8.32) | n= 14 (29.8%) \| 82.14 (18.07) | 0.41 [-0.28 ; 1.11] |
| Week 87 | n= 19 (35.2%) \| 81.47 (16.45) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 20 (37.0%) \| 83.30 (13.15) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 19 (35.2%) \| 83.21 (13.96) | n= 11 (23.4%) \| 86.36 (9.29) | -0.25 [-1.00 ; 0.51] |
| Week 93 | n= 18 (33.3%) \| 84.11 (15.41) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 18 (33.3%) \| 81.17 (16.53) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (31.5%) \| 79.29 (17.14) | n= 7 (14.9%) \| 82.71 (11.76) | -0.21 [-1.11 ; 0.69] |
| Week 99 | n= 15 (27.8%) \| 78.73 (16.00) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (20.4%) \| 81.55 (10.35) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (22.2%) \| 82.08 (10.04) | n= 5 (10.6%) \| 81.40 (11.99) | 0.06 [-1.02 ; 1.14] |
| Week 105 | n= 11 (20.4%) \| 80.00 (11.87) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (11.1%) \| 80.67 (10.84) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.8%) \| 75.38 (9.27) | n= 3 ( 6.4%) \| 81.00 (12.77) | -0.51 [-1.93 ; 0.91] |
| Week 111 | n= 6 (11.1%) \| 78.50 (9.97) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (11.1%) \| 82.83 (10.46) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 7.4%) \| 81.75 (10.90) | n= 3 ( 6.4%) \| 86.67 (7.64) | -0.43 [-2.10 ; 1.25] |
| Week 117 | n= 5 ( 9.3%) \| 84.60 (5.68) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 9.3%) \| 78.20 (11.48) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (11.1%) \| 79.50 (10.50) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 2 ( 3.7%) \| 81.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.9%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.9%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 1.9%) \| 81.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.9%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.9%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.9%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.9%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.9%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.9%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (11.1%) \| 78.50 (9.46) | n= 10 (21.3%) \| 76.30 (20.86) | 0.12 [-0.93 ; 1.17] |
| Week 202 | n= 2 ( 3.7%) \| 64.00 (26.87) | n= 7 (14.9%) \| 89.29 (9.69) | -1.66 [-3.58 ; 0.26] |
| Week 301 | n= 1 ( 1.9%) \| 50.00 ( / ) | n= 7 (14.9%) \| 81.43 (8.02) | [Not calculable] |
| Week 302 | [No Data] | n= 4 ( 8.5%) \| 82.50 (6.45) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 1.9%) \| 40.00 ( / ) | n= 5 (10.6%) \| 82.40 (7.67) | [Not calculable] |
| Week 304 | n= 1 ( 1.9%) \| 100.00 ( / ) | n= 3 ( 6.4%) \| 76.67 (11.55) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 2.1%) \| 75.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 2.1%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 2.1%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 2.1%) \| 90.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 2.1%) \| 85.00 ( / ) | [No Data for at least 1 arm] |
| **Female** | | | |
| N subjects in population | N=17 | N=21 | |
| Baseline | n= 17 (100.0%) \| 75.94 (12.90) | n= 21 (100.0%) \| 83.57 (12.69) | -0.58 [-1.25 ; 0.08] |
| Week 3 | n= 17 (100.0%) \| 78.24 (15.27) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 16 (94.1%) \| 69.94 (20.64) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 15 (88.2%) \| 76.67 (13.59) | n= 17 (81.0%) \| 76.00 (15.42) | 0.04 [-0.66 ; 0.75] |
| Week 9 | n= 13 (76.5%) \| 72.54 (14.22) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (88.2%) \| 64.47 (20.26) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 13 (76.5%) \| 65.08 (25.57) | n= 16 (76.2%) \| 81.19 (11.48) | -0.82 [-1.60 ;-0.04] |
| Week 15 | n= 12 (70.6%) \| 60.17 (28.92) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (82.4%) \| 70.21 (19.09) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 12 (70.6%) \| 69.92 (25.11) | n= 14 (66.7%) \| 83.64 (12.39) | -0.69 [-1.50 ; 0.12] |
| Week 21 | n= 13 (76.5%) \| 68.85 (22.08) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (88.2%) \| 73.13 (17.38) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 25 | n= 14 (82.4%) \| 76.00 (13.92) | n= 15 (71.4%) \| 84.27 (10.05) | -0.67 [-1.43 ; 0.10] |
| Week 27 | n= 12 (70.6%) \| 75.17 (15.33) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 12 (70.6%) \| 79.08 (12.49) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 12 (70.6%) \| 76.75 (10.70) | n= 13 (61.9%) \| 80.15 (11.74) | -0.29 [-1.10 ; 0.51] |
| Week 33 | n= 12 (70.6%) \| 74.33 (13.79) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 11 (64.7%) \| 75.36 (14.31) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (47.1%) \| 71.00 (11.72) | n= 11 (52.4%) \| 79.55 (12.74) | -0.66 [-1.63 ; 0.30] |
| Week 39 | n= 10 (58.8%) \| 75.70 (13.04) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 11 (64.7%) \| 77.73 (10.65) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 10 (58.8%) \| 76.60 (12.40) | n= 12 (57.1%) \| 78.33 (15.28) | -0.12 [-0.98 ; 0.74] |
| Week 45 | n= 10 (58.8%) \| 77.20 (11.49) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 10 (58.8%) \| 75.80 (12.41) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 11 (64.7%) \| 74.64 (14.34) | n= 10 (47.6%) \| 79.90 (11.51) | -0.39 [-1.27 ; 0.50] |
| Week 51 | n= 11 (64.7%) \| 74.36 (14.53) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 12 (70.6%) \| 76.67 (12.71) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 9 (52.9%) \| 73.00 (16.07) | n= 11 (52.4%) \| 80.55 (12.97) | -0.50 [-1.42 ; 0.42] |
| Week 57 | n= 8 (47.1%) \| 75.38 (15.81) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 9 (52.9%) \| 73.67 (16.89) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 9 (52.9%) \| 77.78 (11.26) | n= 10 (47.6%) \| 80.00 (9.13) | -0.21 [-1.14 ; 0.72] |
| Week 63 | n= 8 (47.1%) \| 77.50 (14.18) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (58.8%) \| 75.90 (13.46) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 9 (52.9%) \| 78.00 (12.32) | n= 9 (42.9%) \| 79.44 (11.58) | -0.12 [-1.07 ; 0.84] |
| Week 69 | n= 8 (47.1%) \| 75.25 (11.40) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (41.2%) \| 75.71 (12.41) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (41.2%) \| 71.86 (13.68) | n= 9 (42.9%) \| 76.67 (13.23) | -0.34 [-1.37 ; 0.69] |
| Week 75 | n= 6 (35.3%) \| 77.33 (10.50) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (29.4%) \| 74.60 (11.22) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (29.4%) \| 80.60 (8.88) | n= 8 (38.1%) \| 80.75 (12.71) | -0.01 [-1.18 ; 1.16] |
| Week 81 | n= 5 (29.4%) \| 81.40 (8.35) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (29.4%) \| 78.00 (9.08) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 6 (35.3%) \| 83.00 (9.17) | n= 7 (33.3%) \| 79.86 (12.92) | 0.26 [-0.89 ; 1.40] |
| Week 87 | n= 5 (29.4%) \| 82.20 (7.36) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 5 (29.4%) \| 79.40 (7.54) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 5 (29.4%) \| 79.20 (11.12) | n= 5 (23.8%) \| 82.00 (10.95) | -0.23 [-1.55 ; 1.09] |
| Week 93 | n= 3 (17.6%) \| 76.00 (3.61) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (23.5%) \| 77.25 (3.20) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (23.5%) \| 85.00 (11.37) | n= 4 (19.0%) \| 82.50 (12.58) | 0.18 [-1.33 ; 1.69] |
| Week 99 | n= 2 (11.8%) \| 81.00 (12.73) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (17.6%) \| 77.33 (4.62) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (17.6%) \| 84.00 (13.45) | n= 5 (23.8%) \| 83.00 (10.95) | 0.07 [-1.48 ; 1.63] |
| Week 105 | n= 3 (17.6%) \| 75.33 (5.03) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.8%) \| 72.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (17.6%) \| 85.33 (11.02) | n= 2 ( 9.5%) \| 79.50 (0.71) | 0.47 [-1.69 ; 2.64] |
| Week 111 | n= 1 ( 5.9%) \| 75.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.8%) \| 77.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (17.6%) \| 84.33 (12.10) | n= 2 ( 9.5%) \| 76.00 (18.38) | 0.42 [-1.74 ; 2.57] |
| Week 117 | n= 2 (11.8%) \| 78.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (11.8%) \| 79.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (11.8%) \| 87.00 (15.56) | n= 1 ( 4.8%) \| 92.00 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 5.9%) \| 98.00 ( / ) | n= 1 ( 4.8%) \| 100.00 ( / ) | [Not calculable] |
| Week 201 | n= 2 (11.8%) \| 77.50 (10.61) | n= 7 (33.3%) \| 82.14 (14.10) | -0.30 [-2.00 ; 1.39] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 202 | [No Data] | n= 5 (23.8%) \| 87.00 (12.04) | [No Data for at least 1 arm] |
| Week 301 | n= 1 ( 5.9%) \| 90.00 ( / ) | n= 2 ( 9.5%) \| 89.50 (0.71) | [Not calculable] |
| Week 302 | n= 2 (11.8%) \| 65.00 (21.21) | n= 2 ( 9.5%) \| 82.50 (3.54) | -0.66 [-3.31 ; 2.00] |
| Week 303 | n= 2 (11.8%) \| 65.00 (21.21) | n= 1 ( 4.8%) \| 80.00 ( / ) | [Not calculable] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:03

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Male** | | | |
| N subjects in population | N=54 | N=47 | |
| Week 3 | n= 50 (92.6%) \| 1.24 (13.11) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 49 (90.7%) \|-0.37 (15.71) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 51 (94.4%) \|-3.04 (19.16) | n= 45 (95.7%) \| 0.44 (14.99) | -0.20 [-0.60 ; 0.20] |
| Week 9 | n= 46 (85.2%) \|-0.61 (19.31) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 46 (85.2%) \| 0.85 (19.22) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 46 (85.2%) \|-2.43 (21.98) | n= 37 (78.7%) \|-2.16 (20.05) | -0.01 [-0.45 ; 0.42] |
| Week 15 | n= 42 (77.8%) \| 0.90 (19.93) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 47 (87.0%) \| 1.98 (16.81) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 45 (83.3%) \| 2.27 (13.90) | n= 39 (83.0%) \|-3.85 (10.52) | 0.49 [ 0.05 ; 0.92] |
| Week 21 | n= 47 (87.0%) \| 1.94 (14.35) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 41 (75.9%) \|-0.20 (19.43) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 43 (79.6%) \| 2.16 (14.40) | n= 35 (74.5%) \| 1.86 (17.53) | 0.02 [-0.43 ; 0.47] |
| Week 27 | n= 43 (79.6%) \| 4.00 (13.33) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 41 (75.9%) \| 2.49 (15.61) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 42 (77.8%) \| 4.21 (14.76) | n= 30 (63.8%) \|-2.77 (14.70) | 0.47 [-0.01 ; 0.95] |
| Week 33 | n= 45 (83.3%) \| 1.78 (12.80) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 42 (77.8%) \| 3.07 (14.12) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 41 (75.9%) \| 3.29 (14.69) | n= 35 (74.5%) \|-1.51 (11.06) | 0.36 [-0.10 ; 0.82] |
| Week 39 | n= 43 (79.6%) \| 3.84 (13.86) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 40 (74.1%) \| 1.40 (12.81) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 43 (79.6%) \| 2.40 (15.37) | n= 31 (66.0%) \|-0.74 (13.58) | 0.21 [-0.25 ; 0.68] |
| Week 45 | n= 39 (72.2%) \| 1.03 (13.86) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 42 (77.8%) \| 4.14 (14.20) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 42 (77.8%) \| 3.98 (14.02) | n= 28 (59.6%) \|-0.14 (11.37) | 0.31 [-0.17 ; 0.80] |
| Week 51 | n= 40 (74.1%) \| 1.93 (10.84) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 37 (68.5%) \| 0.35 (20.40) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 38 (70.4%) \| 1.79 (19.12) | n= 26 (55.3%) \| 0.19 (14.43) | 0.09 [-0.41 ; 0.59] |
| Week 57 | n= 39 (72.2%) \| 0.36 (19.23) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (68.5%) \| 0.59 (14.77) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (72.2%) \| 2.41 (13.07) | n= 20 (42.6%) \|-5.60 (16.78) | 0.55 [-0.00 ; 1.10] |
| Week 63 | n= 34 (63.0%) \|-0.12 (10.56) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 34 (63.0%) \| 2.85 (12.48) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 35 (64.8%) \| 3.29 (13.29) | n= 21 (44.7%) \|-0.57 (12.53) | 0.29 [-0.26 ; 0.84] |
| Week 69 | n= 29 (53.7%) \| 2.31 (14.84) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 32 (59.3%) \| 2.06 (11.73) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 27 (50.0%) \| 2.04 (10.12) | n= 19 (40.4%) \|-0.63 (13.92) | 0.22 [-0.37 ; 0.82] |
| Week 75 | n= 30 (55.6%) \| 0.50 (12.13) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (50.0%) \| 3.63 (15.19) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (48.1%) \| 1.65 (13.15) | n= 17 (36.2%) \|-2.06 (15.22) | 0.26 [-0.36 ; 0.88] |
| Week 81 | n= 26 (48.1%) \| 1.88 (12.36) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (51.9%) \| 2.64 (11.89) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 21 (38.9%) \| 3.00 (10.37) | n= 14 (29.8%) \|-1.71 (13.93) | 0.39 [-0.31 ; 1.08] |
| Week 87 | n= 19 (35.2%) \| 0.11 (12.78) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 20 (37.0%) \| 1.20 (11.12) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 19 (35.2%) \| 1.63 (11.60) | n= 11 (23.4%) \| 3.27 (9.20) | -0.15 [-0.90 ; 0.61] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 18 (33.3%) \| 2.56 (11.17) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 18 (33.3%) \|-1.22 (9.05) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (31.5%) \|-2.06 (9.36) | n= 7 (14.9%) \|-2.14 (7.13) | 0.01 [-0.89 ; 0.91] |
| Week 99 | n= 15 (27.8%) \|-1.47 (9.58) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (20.4%) \| 0.36 (7.79) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (22.2%) \| 0.50 (7.99) | n= 5 (10.6%) \|-2.60 (11.30) | 0.33 [-0.76 ; 1.41] |
| Week 105 | n= 11 (20.4%) \|-0.91 (8.34) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (11.1%) \| 2.67 (4.37) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.8%) \|-1.38 (7.60) | n= 3 ( 6.4%) \|-12.33 (15.37) | 1.02 [-0.47 ; 2.50] |
| Week 111 | n= 6 (11.1%) \|-1.17 (5.88) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (11.1%) \|-1.00 (9.67) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 7.4%) \| 1.50 (13.63) | n= 3 ( 6.4%) \| 0.00 (5.00) | 0.11 [-1.54 ; 1.77] |
| Week 117 | n= 5 ( 9.3%) \|-2.00 (11.11) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 9.3%) \|-4.60 (11.33) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (11.1%) \|-4.50 (9.87) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 2 ( 3.7%) \|-13.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.9%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.9%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 1.9%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.9%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.9%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.9%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.9%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.9%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.9%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (11.1%) \| 3.33 (23.79) | n= 10 (21.3%) \|-7.60 (17.17) | 0.52 [-0.54 ; 1.59] |
| Week 202 | n= 2 ( 3.7%) \|-4.50 (0.71) | n= 7 (14.9%) \| 2.14 (10.45) | -0.61 [-2.33 ; 1.11] |
| Week 301 | n= 1 ( 1.9%) \| 0.00 ( / ) | n= 7 (14.9%) \| 3.00 (12.44) | [Not calculable] |
| Week 302 | [No Data] | n= 4 ( 8.5%) \| 5.25 (6.85) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 1.9%) \| 10.00 ( / ) | n= 5 (10.6%) \| 18.80 (29.59) | [Not calculable] |
| Week 304 | n= 1 ( 1.9%) \| 0.00 ( / ) | n= 3 ( 6.4%) \| 2.00 (15.87) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 2.1%) \| 67.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 2.1%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 2.1%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 2.1%) \| 82.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 2.1%) \| 77.00 ( / ) | [No Data for at least 1 arm] |
| **Female** | | | |
| N subjects in population | N=17 | N=21 | |
| Week 3 | n= 17 (100.0%) \| 4.06 (13.26) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 16 (94.1%) \|-3.88 (15.84) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 15 (88.2%) \| 1.93 (14.47) | n= 17 (81.0%) \|-5.94 (9.33) | 0.64 [-0.08 ; 1.36] |
| Week 9 | n= 13 (76.5%) \|-6.31 (13.68) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (88.2%) \|-8.93 (24.46) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 13 (76.5%) \|-8.46 (28.34) | n= 16 (76.2%) \|-2.44 (16.41) | -0.26 [-1.01 ; 0.49] |
| Week 15 | n= 12 (70.6%) \|-14.50 (30.11) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (82.4%) \|-2.71 (19.50) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 12 (70.6%) \|-5.17 (24.42) | n= 14 (66.7%) \| 0.93 (8.57) | -0.33 [-1.13 ; 0.46] |
| Week 21 | n= 13 (76.5%) \|-6.62 (22.14) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (88.2%) \|-2.27 (13.61) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 14 (82.4%) \|-1.21 (11.42) | n= 15 (71.4%) \| 0.07 (12.20) | -0.11 [-0.85 ; 0.64] |
| Week 27 | n= 12 (70.6%) \|-4.08 (15.38) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 29 | n= 12 (70.6%) \|-0.17 (12.47) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 12 (70.6%) \|-0.83 (7.73) | n= 13 (61.9%) \|-2.54 (11.42) | 0.17 [-0.63 ; 0.97] |
| Week 33 | n= 12 (70.6%) \|-2.83 (8.84) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 11 (64.7%) \|-2.00 (11.11) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (47.1%) \|-1.63 (11.62) | n= 11 (52.4%) \|-0.91 (13.75) | -0.05 [-0.99 ; 0.88] |
| Week 39 | n= 10 (58.8%) \| 0.70 (9.13) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 11 (64.7%) \| 0.36 (10.10) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 10 (58.8%) \| 1.50 (7.96) | n= 12 (57.1%) \|-3.75 (15.24) | 0.40 [-0.46 ; 1.27] |
| Week 45 | n= 10 (58.8%) \|-0.90 (8.74) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 10 (58.8%) \| 0.70 (8.38) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 11 (64.7%) \|-0.91 (8.97) | n= 10 (47.6%) \|-3.60 (14.90) | 0.21 [-0.67 ; 1.09] |
| Week 51 | n= 11 (64.7%) \|-1.18 (9.34) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 12 (70.6%) \|-0.92 (8.75) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 9 (52.9%) \|-0.44 (9.85) | n= 11 (52.4%) \|-4.45 (14.29) | 0.31 [-0.60 ; 1.22] |
| Week 57 | n= 8 (47.1%) \| 1.50 (7.50) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 9 (52.9%) \|-0.89 (8.12) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 9 (52.9%) \|-0.11 (8.40) | n= 10 (47.6%) \|-4.50 (8.96) | 0.48 [-0.46 ; 1.42] |
| Week 63 | n= 8 (47.1%) \| 0.50 (6.41) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (58.8%) \| 0.80 (7.48) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 9 (52.9%) \|-1.56 (11.42) | n= 9 (42.9%) \|-3.33 (16.77) | 0.12 [-0.83 ; 1.07] |
| Week 69 | n= 8 (47.1%) \|-4.25 (10.86) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (41.2%) \|-3.71 (11.86) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (41.2%) \|-7.57 (17.58) | n= 9 (42.9%) \|-7.22 (14.39) | -0.02 [-1.04 ; 1.00] |
| Week 75 | n= 6 (35.3%) \|-0.33 (10.13) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (29.4%) \|-2.60 (12.99) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (29.4%) \|-0.60 (7.13) | n= 8 (38.1%) \|-3.63 (14.17) | 0.23 [-0.94 ; 1.40] |
| Week 81 | n= 5 (29.4%) \|-3.80 (10.83) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (29.4%) \|-5.20 (11.30) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 6 (35.3%) \|-1.33 (10.76) | n= 7 (33.3%) \|-7.29 (12.45) | 0.47 [-0.68 ; 1.63] |
| Week 87 | n= 5 (29.4%) \|-1.00 (7.42) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 5 (29.4%) \|-3.80 (10.16) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 5 (29.4%) \|-6.00 (10.22) | n= 5 (23.8%) \|-6.00 (13.42) | 0.00 [-1.32 ; 1.32] |
| Week 93 | n= 3 (17.6%) \|-2.67 (2.52) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (23.5%) \|-6.75 (9.07) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (23.5%) \|-1.50 (13.80) | n= 4 (19.0%) \|-2.50 (5.00) | 0.08 [-1.42 ; 1.59] |
| Week 99 | n= 2 (11.8%) \| 3.00 (9.90) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (17.6%) \|-8.00 (10.58) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (17.6%) \| 2.00 (6.24) | n= 5 (23.8%) \|-1.00 (5.48) | 0.45 [-1.12 ; 2.03] |
| Week 105 | n= 3 (17.6%) \|-10.00 (10.00) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.8%) \|-6.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (17.6%) \|-3.33 (14.74) | n= 2 ( 9.5%) \|-0.50 (0.71) | -0.17 [-2.29 ; 1.95] |
| Week 111 | n= 1 ( 5.9%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.8%) \|-11.00 (9.90) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (17.6%) \|-4.33 (14.29) | n= 2 ( 9.5%) \|-14.00 (32.53) | 0.32 [-1.82 ; 2.45] |
| Week 117 | n= 2 (11.8%) \|-9.50 (14.85) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (11.8%) \|-9.00 (15.56) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (11.8%) \| 4.00 (5.66) | n= 1 ( 4.8%) \|-8.00 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 5.9%) \| 8.00 ( / ) | n= 1 ( 4.8%) \| 0.00 ( / ) | [Not calculable] |
| Week 201 | n= 2 (11.8%) \| 0.00 (21.21) | n= 7 (33.3%) \|-8.00 (11.90) | 0.52 [-1.19 ; 2.23] |
| Week 202 | [No Data] | n= 5 (23.8%) \|-4.00 (11.40) | [No Data for at least 1 arm] |
| Week 301 | n= 1 ( 5.9%) \| 10.00 ( / ) | n= 2 ( 9.5%) \|-2.00 (2.83) | [Not calculable] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 302 | n= 2 (11.8%) \|-10.00 (14.14) | n= 2 ( 9.5%) \|-5.50 (10.61) | -0.21 [-2.68 ; 2.27] |
| Week 303 | n= 2 (11.8%) \|-10.00 (14.14) | n= 1 ( 4.8%) \|-10.00 ( / ) | [Not calculable] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:03

TABLE 7.1.7: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **Male** | | | | |
| Nr subjects used | n=54 | n=47 | | |
| Week 7 | -4.34 (2.41) [-9.12 ; 0.43] | -1.13 (2.57) [-6.23 ; 3.96] | -3.21 (3.52) [-10.19 ; 3.76] | -0.19 [-0.59 ; 0.22] |
| Week 13 | -5.42 (3.26) [-11.89 ; 1.05] | -0.80 (3.54) [-7.84 ; 6.23] | -4.62 (4.81) [-14.17 ; 4.94] | -0.21 [-0.64 ; 0.22] |
| Week 19 | 0.87 (1.83) [-2.77 ; 4.51] | -1.41 (1.97) [-5.33 ; 2.51] | 2.28 (2.69) [-3.07 ; 7.63] | 0.18 [-0.25 ; 0.61] |
| Week 25 | 0.74 (1.72) [-2.68 ; 4.17] | 2.38 (1.88) [-1.35 ; 6.12] | -1.64 (2.55) [-6.71 ; 3.43] | -0.14 [-0.59 ; 0.30] |
| Week 31 | 2.39 (1.84) [-1.28 ; 6.05] | 0.09 (2.07) [-4.03 ; 4.21] | 2.30 (2.77) [-3.21 ; 7.81] | 0.19 [-0.28 ; 0.66] |
| Week 37 | 2.69 (1.77) [-0.84 ; 6.21] | 0.69 (1.95) [-3.19 ; 4.56] | 2.00 (2.64) [-3.24 ; 7.24] | 0.17 [-0.28 ; 0.62] |
| Week 43 | 1.95 (1.87) [-1.76 ; 5.66] | 0.95 (2.15) [-3.32 ; 5.22] | 1.00 (2.85) [-4.66 ; 6.66] | 0.08 [-0.38 ; 0.54] |
| Week 49 | 2.47 (1.59) [-0.69 ; 5.64] | 0.42 (1.90) [-3.36 ; 4.19] | 2.06 (2.48) [-2.87 ; 6.98] | 0.20 [-0.28 ; 0.68] |
| Week 55 | 1.14 (2.42) [-3.67 ; 5.96] | 1.48 (2.93) [-4.34 ; 7.30] | -0.34 (3.80) [-7.90 ; 7.22] | -0.02 [-0.52 ; 0.48] |
| Week 61 | 2.01 (1.79) [-1.54 ; 5.56] | -3.50 (2.31) [-8.09 ; 1.08] | 5.51 (2.92) [-0.29 ; 11.31] | 0.50 [-0.05 ; 1.05] |
| Week 67 | 1.88 (1.70) [-1.50 ; 5.26] | -0.53 (2.16) [-4.83 ; 3.77] | 2.41 (2.75) [-3.06 ; 7.89] | 0.24 [-0.30 ; 0.78] |
| Week 73 | 1.91 (1.63) [-1.33 ; 5.15] | -0.70 (2.01) [-4.70 ; 3.30] | 2.61 (2.59) [-2.54 ; 7.76] | 0.30 [-0.29 ; 0.89] |
| Week 79 | 1.68 (1.92) [-2.15 ; 5.50] | -0.36 (2.40) [-5.12 ; 4.40] | 2.03 (3.07) [-4.07 ; 8.14] | 0.20 [-0.41 ; 0.82] |
| Week 85 | 2.01 (1.72) [-1.43 ; 5.45] | -0.19 (2.15) [-4.49 ; 4.10] | 2.20 (2.75) [-3.30 ; 7.70] | 0.27 [-0.41 ; 0.95] |
| Week 91 | 1.55 (1.77) [-2.02 ; 5.13] | 1.65 (2.30) [-2.99 ; 6.30] | -0.10 (2.91) [-5.96 ; 5.76] | -0.01 [-0.76 ; 0.73] |
| Overall post-baseline period estimate | 0.90 (1.11) [-1.29 ; 3.10] | -0.06 (1.27) [-2.59 ; 2.46] | 0.97 (1.69) [-2.38 ; 4.31] | 0.11 [-0.28 ; 0.51] |
| **Female** | | | | |
| Nr subjects used | n=17 | n=21 | | |
| Week 7 | 0.29 (3.09) [-6.01 ; 6.59] | -5.04 (2.88) [-10.92 ; 0.84] | 5.33 (4.26) [-3.35 ; 14.02] | 0.44 [-0.27 ; 1.14] |
| Week 13 | -12.28 (5.53) [-23.53 ;-1.04] | -1.14 (5.11) [-11.54 ; 9.26] | -11.14 (7.55) [-26.51 ; 4.22] | -0.54 [-1.28 ; 0.21] |
| Week 19 | -8.97 (4.89) [-18.94 ; 1.01] | -0.02 (4.60) [-9.42 ; 9.37] | -8.94 (6.73) [-22.69 ; 4.80] | -0.51 [-1.29 ; 0.28] |
| Week 25 | -1.74 (2.57) [-6.97 ; 3.48] | 1.02 (2.49) [-4.03 ; 6.06] | -2.76 (3.62) [-10.10 ; 4.59] | -0.28 [-1.01 ; 0.45] |
| Week 31 | -2.08 (2.36) [-6.90 ; 2.74] | -0.61 (2.28) [-5.26 ; 4.04] | -1.47 (3.32) [-8.23 ; 5.30] | -0.17 [-0.96 ; 0.61] |
| Week 43 | -2.16 (3.45) [-9.25 ; 4.93] | -2.91 (3.23) [-9.55 ; 3.73] | 0.75 (4.76) [-9.02 ; 10.53] | 0.07 [-0.77 ; 0.90] |
| Week 49 | -2.94 (3.43) [-10.05 ; 4.17] | -0.83 (3.50) [-8.07 ; 6.42] | -2.11 (4.94) [-12.32 ; 8.09] | -0.18 [-1.04 ; 0.68] |
| Overall post-baseline period estimate | -4.27 (2.31) [-8.93 ; 0.40] | -1.36 (2.21) [-5.82 ; 3.10] | -2.91 (3.24) [-9.46 ; 3.65] | -0.30 [-0.96 ; 0.36] |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.2824 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:03

TABLE 7.1.8: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **< 1 Year** | N=14 | N=18 |
| **>= 1 Year** | N=57 | N=48 |
| **Not Reported** | [No Data] | N=2 |
| **Subjects with Baseline Value** | | |
| **< 1 Year** | 14 (100.0%) | 18 (100.0%) |
| **>= 1 Year** | 57 (100.0%) | 48 (100.0%) |
| **Not Reported** | [No Data] | 2 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **< 1 Year** | 14 (100.0%) | 18 (100.0%) |
| **>= 1 Year** | 57 (100.0%) | 46 (95.8%) |
| **Not Reported** | [No Data] | 2 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **< 1 Year** | 14 (100.0%) | 18 (100.0%) |
| **>= 1 Year** | 57 (100.0%) | 46 (95.8%) |
| **Not Reported** | [No Data] | 2 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:04

TABLE 7.1.8: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 1 Year** | | | |
| N subjects in population | N=14 | N=18 | |
| Baseline | n= 14 (100.0%) \| 81.64 (11.18) | n= 18 (100.0%) \| 82.72 (15.32) | -0.08 [-0.79 ; 0.63] |
| Week 3 | n= 13 (92.9%) \| 81.85 (10.04) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 13 (92.9%) \| 78.85 (12.75) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 14 (100.0%) \| 73.86 (25.09) | n= 18 (100.0%) \| 81.11 (12.55) | -0.37 [-1.09 ; 0.34] |
| Week 9 | n= 12 (85.7%) \| 84.33 (14.09) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 13 (92.9%) \| 81.38 (14.68) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 14 (100.0%) \| 76.07 (23.43) | n= 13 (72.2%) \| 84.92 (6.74) | -0.49 [-1.27 ; 0.29] |
| Week 15 | n= 14 (100.0%) \| 81.79 (14.53) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (100.0%) \| 82.07 (11.87) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 14 (100.0%) \| 80.93 (12.56) | n= 14 (77.8%) \| 84.21 (10.21) | -0.28 [-1.04 ; 0.48] |
| Week 21 | n= 14 (100.0%) \| 83.43 (11.73) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 11 (78.6%) \| 76.45 (26.41) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 13 (92.9%) \| 80.77 (11.30) | n= 14 (77.8%) \| 85.71 (11.01) | -0.43 [-1.21 ; 0.35] |
| Week 27 | n= 13 (92.9%) \| 85.54 (10.32) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 13 (92.9%) \| 81.31 (12.49) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 14 (100.0%) \| 82.79 (11.60) | n= 11 (61.1%) \| 86.36 (15.83) | -0.25 [-1.06 ; 0.55] |
| Week 33 | n= 14 (100.0%) \| 82.64 (12.14) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (92.9%) \| 82.31 (12.35) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 12 (85.7%) \| 80.75 (13.14) | n= 12 (66.7%) \| 85.58 (8.92) | -0.42 [-1.24 ; 0.41] |
| Week 39 | n= 11 (78.6%) \| 87.09 (11.25) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 11 (78.6%) \| 83.18 (13.69) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 12 (85.7%) \| 82.33 (14.75) | n= 12 (66.7%) \| 84.58 (9.37) | -0.18 [-0.99 ; 0.64] |
| Week 45 | n= 11 (78.6%) \| 80.36 (17.04) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 11 (78.6%) \| 83.64 (12.71) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 12 (85.7%) \| 82.50 (13.14) | n= 11 (61.1%) \| 84.91 (10.91) | -0.19 [-1.03 ; 0.65] |
| Week 51 | n= 11 (78.6%) \| 83.82 (9.85) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 11 (78.6%) \| 84.55 (11.77) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 8 (57.1%) \| 83.88 (13.83) | n= 10 (55.6%) \| 84.70 (11.92) | -0.06 [-1.02 ; 0.90] |
| Week 57 | n= 9 (64.3%) \| 84.22 (13.04) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 11 (78.6%) \| 83.09 (13.10) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 11 (78.6%) \| 82.45 (13.71) | n= 8 (44.4%) \| 85.00 (15.48) | -0.17 [-1.11 ; 0.77] |
| Week 63 | n= 10 (71.4%) \| 84.00 (12.94) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (71.4%) \| 84.60 (12.58) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 10 (71.4%) \| 83.00 (17.09) | n= 9 (50.0%) \| 87.11 (9.83) | -0.28 [-1.21 ; 0.65] |
| Week 69 | n= 9 (64.3%) \| 83.33 (11.42) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 9 (64.3%) \| 84.22 (11.54) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 9 (64.3%) \| 79.78 (17.09) | n= 7 (38.9%) \| 87.57 (11.47) | -0.49 [-1.53 ; 0.55] |
| Week 75 | n= 8 (57.1%) \| 82.88 (16.08) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (42.9%) \| 88.17 (9.79) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (64.3%) \| 80.33 (20.41) | n= 6 (33.3%) \| 85.50 (11.11) | -0.28 [-1.36 ; 0.80] |
| Week 81 | n= 7 (50.0%) \| 87.14 (10.01) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (50.0%) \| 86.71 (12.11) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (57.1%) \| 87.00 (9.30) | n= 6 (33.3%) \| 89.00 (8.25) | -0.21 [-1.32 ; 0.89] |
| Week 87 | n= 6 (42.9%) \| 86.17 (10.42) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 7 (50.0%) \| 82.71 (10.16) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 7 (50.0%) \| 87.29 (10.92) | n= 3 (16.7%) \| 86.67 (7.64) | 0.05 [-1.38 ; 1.49] |
| Week 93 | n= 5 (35.7%) \| 87.00 (12.10) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 6 (42.9%) \| 86.50 (11.54) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 5 (35.7%) \| 88.00 (11.47) | n= 2 (11.1%) \| 90.00 (7.07) | -0.16 [-1.97 ; 1.66] |
| Week 99 | n= 3 (21.4%) \| 81.33 (10.07) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (21.4%) \| 81.00 (9.54) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (28.6%) \| 86.00 (11.69) | n= 2 (11.1%) \| 87.50 (10.61) | -0.10 [-2.03 ; 1.82] |
| Week 105 | n= 3 (21.4%) \| 85.33 (12.86) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (14.3%) \| 83.50 (13.44) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (21.4%) \| 85.33 (11.02) | n= 2 (11.1%) \| 87.50 (10.61) | -0.14 [-2.26 ; 1.97] |
| Week 111 | n= 1 ( 7.1%) \| 75.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (14.3%) \| 76.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (21.4%) \| 84.33 (12.10) | n= 1 ( 5.6%) \| 95.00 ( / ) | [Not calculable] |
| Week 117 | n= 2 (14.3%) \| 83.50 (9.19) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (14.3%) \| 79.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (21.4%) \| 84.67 (11.72) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 7.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 7.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (14.3%) \| 89.00 (12.73) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 7.1%) \| 81.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 7.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 7.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 7.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 7.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 7.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 7.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 7.1%) \| 90.00 ( / ) | n= 4 (22.2%) \| 85.00 (14.72) | [Not calculable] |
| Week 202 | n= 1 ( 7.1%) \| 83.00 ( / ) | n= 3 (16.7%) \| 81.67 (12.58) | [Not calculable] |
| Week 301 | [No Data] | n= 2 (11.1%) \| 85.00 (7.07) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 1 ( 5.6%) \| 80.00 ( / ) | [No Data for at least 1 arm] |
| Week 303 | [No Data] | n= 2 (11.1%) \| 85.00 (7.07) | [No Data for at least 1 arm] |
| Week 304 | [No Data] | n= 1 ( 5.6%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| **>= 1 Year** | | | |
| N subjects in population | N=57 | N=48 | |
| Baseline | n= 57 (100.0%) \| 76.88 (18.82) | n= 48 (100.0%) \| 78.06 (19.35) | -0.06 [-0.45 ; 0.32] |
| Week 3 | n= 54 (94.7%) \| 80.48 (14.31) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 52 (91.2%) \| 77.77 (17.62) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 52 (91.2%) \| 77.52 (15.50) | n= 43 (89.6%) \| 75.58 (18.50) | 0.11 [-0.29 ; 0.52] |
| Week 9 | n= 47 (82.5%) \| 76.06 (16.28) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 48 (84.2%) \| 75.79 (18.14) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 45 (78.9%) \| 73.91 (22.97) | n= 38 (79.2%) \| 77.21 (14.68) | -0.17 [-0.60 ; 0.27] |
| Week 15 | n= 40 (70.2%) \| 73.50 (21.32) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 47 (82.5%) \| 77.64 (16.27) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 43 (75.4%) \| 78.72 (17.65) | n= 37 (77.1%) \| 78.89 (14.11) | -0.01 [-0.45 ; 0.43] |
| Week 21 | n= 46 (80.7%) \| 76.76 (16.66) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 45 (78.9%) \| 76.47 (14.23) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 44 (77.2%) \| 80.82 (12.17) | n= 34 (70.8%) \| 82.41 (11.30) | -0.13 [-0.58 ; 0.32] |
| Week 27 | n= 42 (73.7%) \| 80.05 (12.93) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 40 (70.2%) \| 80.63 (14.22) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 40 (70.2%) \| 80.85 (11.10) | n= 31 (64.6%) \| 78.74 (13.28) | 0.17 [-0.30 ; 0.65] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 33 | n= 43 (75.4%) \| 80.12 (12.84) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 40 (70.2%) \| 79.93 (14.11) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 37 (64.9%) \| 80.65 (13.63) | n= 32 (66.7%) \| 79.78 (14.58) | 0.06 [-0.42 ; 0.54] |
| Week 39 | n= 42 (73.7%) \| 80.43 (12.66) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 40 (70.2%) \| 81.48 (13.06) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 41 (71.9%) \| 81.05 (13.48) | n= 29 (60.4%) \| 78.83 (15.49) | 0.15 [-0.33 ; 0.63] |
| Week 45 | n= 38 (66.7%) \| 79.61 (12.28) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 41 (71.9%) \| 81.88 (11.97) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 41 (71.9%) \| 81.29 (13.52) | n= 25 (52.1%) \| 79.40 (13.71) | 0.14 [-0.36 ; 0.64] |
| Week 51 | n= 40 (70.2%) \| 80.45 (13.06) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 38 (66.7%) \| 78.71 (19.57) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (68.4%) \| 79.33 (18.90) | n= 26 (54.2%) \| 80.88 (14.61) | -0.09 [-0.59 ; 0.41] |
| Week 57 | n= 38 (66.7%) \| 78.89 (18.43) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 35 (61.4%) \| 78.20 (19.23) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 37 (64.9%) \| 81.86 (12.93) | n= 21 (43.8%) \| 74.86 (13.95) | 0.52 [-0.03 ; 1.07] |
| Week 63 | n= 32 (56.1%) \| 79.03 (14.31) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 34 (59.6%) \| 78.85 (15.42) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 34 (59.6%) \| 81.94 (12.72) | n= 20 (41.7%) \| 79.05 (12.60) | 0.22 [-0.33 ; 0.78] |
| Week 69 | n= 28 (49.1%) \| 79.39 (14.10) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 30 (52.6%) \| 81.97 (15.08) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (43.9%) \| 81.36 (13.58) | n= 20 (41.7%) \| 75.10 (16.89) | 0.41 [-0.19 ; 1.01] |
| Week 75 | n= 28 (49.1%) \| 81.32 (14.84) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (45.6%) \| 79.85 (14.42) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 22 (38.6%) \| 82.91 (14.99) | n= 18 (37.5%) \| 75.39 (17.22) | 0.46 [-0.18 ; 1.10] |
| Week 81 | n= 24 (42.1%) \| 82.13 (13.71) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 26 (45.6%) \| 83.08 (13.30) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (33.3%) \| 86.47 (8.49) | n= 14 (29.2%) \| 76.79 (17.41) | 0.73 [ 0.00 ; 1.45] |
| Week 87 | n= 18 (31.6%) \| 80.11 (16.05) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 18 (31.6%) \| 82.44 (13.18) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 17 (29.8%) \| 80.35 (13.95) | n= 12 (25.0%) \| 83.33 (9.65) | -0.23 [-0.99 ; 0.52] |
| Week 93 | n= 16 (28.1%) \| 81.69 (15.36) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 16 (28.1%) \| 78.19 (15.83) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 16 (28.1%) \| 78.00 (16.91) | n= 9 (18.8%) \| 81.00 (11.84) | -0.19 [-1.02 ; 0.65] |
| Week 99 | n= 14 (24.6%) \| 78.50 (16.49) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (19.3%) \| 80.55 (9.86) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (19.3%) \| 81.18 (10.01) | n= 8 (16.7%) \| 80.88 (11.21) | 0.03 [-0.91 ; 0.96] |
| Week 105 | n= 11 (19.3%) \| 77.27 (10.13) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.5%) \| 76.83 (9.60) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.0%) \| 75.38 (9.27) | n= 3 ( 6.3%) \| 75.67 (4.93) | -0.03 [-1.43 ; 1.37] |
| Week 111 | n= 6 (10.5%) \| 78.50 (9.97) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (10.5%) \| 83.17 (10.38) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 7.0%) \| 81.75 (10.90) | n= 4 ( 8.3%) \| 79.25 (11.44) | 0.19 [-1.31 ; 1.70] |
| Week 117 | n= 5 ( 8.8%) \| 82.60 (5.03) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 8.8%) \| 78.20 (11.48) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 ( 8.8%) \| 79.40 (11.74) | n= 1 ( 2.1%) \| 92.00 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.8%) \| 82.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | [No Data] | n= 1 ( 2.1%) \| 100.00 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 7 (12.3%) \| 76.57 (8.20) | n= 13 (27.1%) \| 76.77 (19.14) | -0.01 [-0.95 ; 0.93] |
| Week 202 | n= 1 ( 1.8%) \| 45.00 ( / ) | n= 8 (16.7%) \| 89.50 (9.13) | [Not calculable] |
| Week 301 | n= 2 ( 3.5%) \| 70.00 (28.28) | n= 7 (14.6%) \| 82.71 (8.46) | -0.85 [-2.60 ; 0.90] |
| Week 302 | n= 2 ( 3.5%) \| 65.00 (21.21) | n= 5 (10.4%) \| 83.00 (5.70) | -1.41 [-3.46 ; 0.65] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 303 | n= 3 ( 5.3%) \| 56.67 (20.82) | n= 4 ( 8.3%) \| 80.50 (7.37) | -1.40 [-3.31 ; 0.51] |
| Week 304 | n= 1 ( 1.8%) \| 100.00 ( / ) | n= 2 ( 4.2%) \| 80.00 (14.14) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 2.1%) \| 75.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 2.1%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 2.1%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 2.1%) \| 90.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 2.1%) \| 85.00 ( / ) | [No Data for at least 1 arm] |
| **Not Reported** | | | |
| N subjects in population | [No Data] | N=2 | |
| Nr subjects used | [No Data] | n= 2 (100.0%) \| 92.50 (3.54) | |
| Week 7 | [No Data] | n= 1 (50.0%) \| 98.00 ( / ) | [No Data for at least 1 arm] |
| Week 13 | [No Data] | n= 2 (100.0%) \| 95.00 (7.07) | [No Data for at least 1 arm] |
| Week 19 | [No Data] | n= 2 (100.0%) \| 99.00 (1.41) | [No Data for at least 1 arm] |
| Week 25 | [No Data] | n= 2 (100.0%) \| 98.00 (2.83) | [No Data for at least 1 arm] |
| Week 31 | [No Data] | n= 1 (50.0%) \| 99.00 ( / ) | [No Data for at least 1 arm] |
| Week 37 | [No Data] | n= 2 (100.0%) \| 98.50 (2.12) | [No Data for at least 1 arm] |
| Week 43 | [No Data] | n= 2 (100.0%) \| 99.00 (1.41) | [No Data for at least 1 arm] |
| Week 49 | [No Data] | n= 2 (100.0%) \| 96.50 (2.12) | [No Data for at least 1 arm] |
| Week 55 | [No Data] | n= 1 (50.0%) \| 100.00 ( / ) | [No Data for at least 1 arm] |
| Week 61 | [No Data] | n= 1 (50.0%) \| 100.00 ( / ) | [No Data for at least 1 arm] |
| Week 67 | [No Data] | n= 1 (50.0%) \| 100.00 ( / ) | [No Data for at least 1 arm] |
| Week 73 | [No Data] | n= 1 (50.0%) \| 100.00 ( / ) | [No Data for at least 1 arm] |
| Week 79 | [No Data] | n= 1 (50.0%) \| 100.00 ( / ) | [No Data for at least 1 arm] |
| Week 85 | [No Data] | n= 1 (50.0%) \| 100.00 ( / ) | [No Data for at least 1 arm] |
| Week 91 | [No Data] | n= 1 (50.0%) \| 100.00 ( / ) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 1 (50.0%) \| 99.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:05

TABLE 7.1.8: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 1 Year** | | | |
| N subjects in population | N=14 | N=18 | |
| Week 3 | n= 13 (92.9%) \|-0.92 (10.04) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 13 (92.9%) \|-5.23 (10.84) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 14 (100.0%) \|-8.14 (19.77) | n= 18 (100.0%) \|-1.61 (10.83) | -0.41 [-1.13 ; 0.30] |
| Week 9 | n= 12 (85.7%) \|-0.42 (16.54) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 13 (92.9%) \|-2.69 (17.19) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 14 (100.0%) \|-5.93 (17.31) | n= 13 (72.2%) \|-2.69 (9.56) | -0.22 [-0.99 ; 0.55] |
| Week 15 | n= 14 (100.0%) \|-0.21 (16.97) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (100.0%) \| 0.07 (14.20) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 14 (100.0%) \|-1.07 (12.19) | n= 14 (77.8%) \|-2.50 (6.45) | 0.14 [-0.61 ; 0.90] |
| Week 21 | n= 14 (100.0%) \| 1.43 (11.50) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 11 (78.6%) \|-7.73 (26.54) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 13 (92.9%) \|-1.38 (10.51) | n= 14 (77.8%) \|-1.36 (8.27) | -0.00 [-0.77 ; 0.77] |
| Week 27 | n= 13 (92.9%) \| 3.38 (12.51) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 13 (92.9%) \|-1.46 (13.67) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 14 (100.0%) \| 0.79 (12.70) | n= 11 (61.1%) \|-1.36 (15.98) | 0.15 [-0.66 ; 0.95] |
| Week 33 | n= 14 (100.0%) \| 0.64 (14.32) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (92.9%) \|-0.46 (9.16) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 12 (85.7%) \|-0.75 (12.25) | n= 12 (66.7%) \|-1.83 (5.31) | 0.11 [-0.71 ; 0.93] |
| Week 39 | n= 11 (78.6%) \| 1.91 (13.03) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 11 (78.6%) \|-1.64 (10.73) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 12 (85.7%) \|-2.08 (10.22) | n= 12 (66.7%) \|-1.58 (9.01) | -0.05 [-0.87 ; 0.77] |
| Week 45 | n= 11 (78.6%) \|-3.09 (11.30) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 11 (78.6%) \|-1.18 (7.40) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 12 (85.7%) \|-0.50 (8.42) | n= 11 (61.1%) \|-1.82 (7.39) | 0.16 [-0.68 ; 1.00] |
| Week 51 | n= 11 (78.6%) \| 0.55 (7.13) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 11 (78.6%) \| 1.55 (10.64) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 8 (57.1%) \| 3.75 (12.46) | n= 10 (55.6%) \|-4.20 (11.37) | 0.64 [-0.35 ; 1.62] |
| Week 57 | n= 9 (64.3%) \|-0.56 (9.71) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 11 (78.6%) \| 0.09 (10.70) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 11 (78.6%) \|-0.55 (9.66) | n= 8 (44.4%) \|-5.50 (12.49) | 0.43 [-0.51 ; 1.38] |
| Week 63 | n= 10 (71.4%) \| 0.70 (7.83) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (71.4%) \| 1.30 (7.69) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 10 (71.4%) \|-0.30 (9.27) | n= 9 (50.0%) \|-1.67 (8.32) | 0.15 [-0.78 ; 1.08] |
| Week 69 | n= 9 (64.3%) \| 0.44 (11.36) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 9 (64.3%) \| 1.33 (12.29) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 9 (64.3%) \|-3.11 (17.49) | n= 7 (38.9%) \|-3.00 (8.68) | -0.01 [-1.03 ; 1.01] |
| Week 75 | n= 8 (57.1%) \| 0.88 (11.33) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (42.9%) \| 1.33 (13.06) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (64.3%) \|-2.56 (11.48) | n= 6 (33.3%) \|-5.17 (7.68) | 0.24 [-0.83 ; 1.32] |
| Week 81 | n= 7 (50.0%) \|-0.14 (7.90) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (50.0%) \| 0.86 (12.98) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (57.1%) \| 0.63 (7.52) | n= 6 (33.3%) \|-3.33 (4.37) | 0.58 [-0.55 ; 1.71] |
| Week 87 | n= 6 (42.9%) \|-2.33 (7.03) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 7 (50.0%) \|-3.14 (6.62) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 7 (50.0%) \|-1.43 (7.72) | n= 3 (16.7%) \|-4.67 (4.51) | 0.41 [-1.04 ; 1.87] |
| Week 93 | n= 5 (35.7%) \|-0.20 (4.76) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 6 (42.9%) \|-2.00 (7.59) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 5 (35.7%) \|-0.20 (9.52) | n= 2 (11.1%) \|-7.00 (2.83) | 0.66 [-1.20 ; 2.53] |
| Week 99 | n= 3 (21.4%) \|-5.67 (8.62) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (21.4%) \|-6.00 (8.19) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (28.6%) \|-1.75 (10.11) | n= 2 (11.1%) \|-2.50 (3.54) | 0.07 [-1.86 ; 1.99] |
| Week 105 | n= 3 (21.4%) \|-1.67 (12.58) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (14.3%) \| 0.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (21.4%) \|-1.67 (11.93) | n= 2 (11.1%) \|-2.50 (3.54) | 0.06 [-2.05 ; 2.17] |
| Week 111 | n= 1 ( 7.1%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (14.3%) \|-9.50 (7.78) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (21.4%) \|-2.67 (11.59) | n= 1 ( 5.6%) \|-5.00 ( / ) | [Not calculable] |
| Week 117 | n= 2 (14.3%) \|-2.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (14.3%) \|-6.50 (12.02) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (21.4%) \|-2.33 (11.68) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 7.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 7.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (14.3%) \|-3.50 (16.26) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 7.1%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 7.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 7.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 7.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 7.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 7.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 7.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 7.1%) \| 3.00 ( / ) | n= 4 (22.2%) \|-3.75 (4.79) | [Not calculable] |
| Week 202 | n= 1 ( 7.1%) \|-4.00 ( / ) | n= 3 (16.7%) \|-5.00 (5.00) | [Not calculable] |
| Week 301 | [No Data] | n= 2 (11.1%) \| 0.00 (0.00) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 1 ( 5.6%) \| 0.00 ( / ) | [No Data for at least 1 arm] |
| Week 303 | [No Data] | n= 2 (11.1%) \| 0.00 (14.14) | [No Data for at least 1 arm] |
| Week 304 | [No Data] | n= 1 ( 5.6%) \|-10.00 ( / ) | [No Data for at least 1 arm] |
| **>= 1 Year** | | | |
| N subjects in population | N=57 | N=48 | |
| Week 3 | n= 54 (94.7%) \| 2.65 (13.73) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 52 (91.2%) \|-0.23 (16.62) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 52 (91.2%) \|-0.23 (17.61) | n= 43 (89.6%) \|-1.40 (15.20) | 0.07 [-0.34 ; 0.48] |
| Week 9 | n= 47 (82.5%) \|-2.23 (18.83) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 48 (84.2%) \|-1.25 (21.88) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 45 (78.9%) \|-3.09 (25.12) | n= 38 (79.2%) \|-2.34 (21.60) | -0.03 [-0.47 ; 0.40] |
| Week 15 | n= 40 (70.2%) \|-3.33 (25.13) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 47 (82.5%) \| 1.15 (18.38) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 43 (75.4%) \| 1.28 (17.99) | n= 37 (77.1%) \|-3.11 (11.37) | 0.28 [-0.16 ; 0.73] |
| Week 21 | n= 46 (80.7%) \|-0.33 (17.86) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 45 (78.9%) \| 0.96 (15.10) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 44 (77.2%) \| 2.14 (14.53) | n= 34 (70.8%) \| 2.18 (18.65) | -0.00 [-0.45 ; 0.45] |
| Week 27 | n= 42 (73.7%) \| 1.88 (14.63) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 40 (70.2%) \| 2.98 (15.26) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 40 (70.2%) \| 3.90 (13.99) | n= 31 (64.6%) \|-3.39 (13.16) | 0.53 [ 0.05 ; 1.01] |
| Week 33 | n= 43 (75.4%) \| 0.86 (11.56) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 40 (70.2%) \| 2.83 (14.78) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 37 | n= 37 (64.9%) \| 3.54 (14.83) | n= 32 (66.7%) \|-1.66 (13.44) | 0.36 [-0.12 ; 0.84] |
| Week 39 | n= 42 (73.7%) \| 3.60 (13.22) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 40 (70.2%) \| 1.95 (12.57) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 41 (71.9%) \| 3.49 (15.06) | n= 29 (60.4%) \|-2.14 (15.94) | 0.36 [-0.12 ; 0.84] |
| Week 45 | n= 38 (66.7%) \| 1.71 (13.30) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 41 (71.9%) \| 4.73 (14.27) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 41 (71.9%) \| 3.98 (14.24) | n= 25 (52.1%) \|-1.12 (14.39) | 0.35 [-0.15 ; 0.86] |
| Week 51 | n= 40 (70.2%) \| 1.45 (11.35) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 38 (66.7%) \|-0.39 (19.91) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (68.4%) \| 0.87 (18.64) | n= 26 (54.2%) \|-0.46 (15.52) | 0.08 [-0.42 ; 0.58] |
| Week 57 | n= 38 (66.7%) \| 0.82 (19.24) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 35 (61.4%) \| 0.37 (14.60) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 37 (64.9%) \| 2.68 (13.00) | n= 21 (43.8%) \|-5.86 (15.40) | 0.61 [ 0.05 ; 1.16] |
| Week 63 | n= 32 (56.1%) \|-0.22 (10.49) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 34 (59.6%) \| 2.71 (12.46) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 34 (59.6%) \| 3.06 (13.87) | n= 20 (41.7%) \|-1.85 (15.81) | 0.33 [-0.23 ; 0.89] |
| Week 69 | n= 28 (49.1%) \| 1.04 (15.19) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 30 (52.6%) \| 0.93 (11.88) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (43.9%) \| 1.20 (10.12) | n= 20 (41.7%) \|-3.30 (15.87) | 0.34 [-0.26 ; 0.94] |
| Week 75 | n= 28 (49.1%) \| 0.21 (11.99) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (45.6%) \| 2.96 (15.45) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 22 (38.6%) \| 2.86 (12.55) | n= 18 (37.5%) \|-2.39 (16.51) | 0.36 [-0.28 ; 0.99] |
| Week 81 | n= 24 (42.1%) \| 1.29 (13.25) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 26 (45.6%) \| 1.62 (11.96) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (33.3%) \| 2.63 (11.55) | n= 14 (29.2%) \|-4.64 (15.94) | 0.52 [-0.19 ; 1.24] |
| Week 87 | n= 18 (31.6%) \| 0.61 (13.01) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 18 (31.6%) \| 1.50 (12.10) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 17 (29.8%) \| 0.65 (12.97) | n= 12 (25.0%) \| 0.83 (12.25) | -0.01 [-0.77 ; 0.74] |
| Week 93 | n= 16 (28.1%) \| 2.44 (11.80) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 16 (28.1%) \|-2.31 (9.83) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 16 (28.1%) \|-2.50 (10.30) | n= 9 (18.8%) \|-1.22 (6.30) | -0.14 [-0.97 ; 0.70] |
| Week 99 | n= 14 (24.6%) \| 0.07 (9.56) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (19.3%) \|-0.18 (8.84) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (19.3%) \| 1.73 (6.66) | n= 8 (16.7%) \|-1.63 (9.44) | 0.40 [-0.54 ; 1.35] |
| Week 105 | n= 11 (19.3%) \|-3.18 (8.76) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.5%) \| 0.50 (6.75) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.0%) \|-2.00 (8.96) | n= 3 ( 6.3%) \|-11.00 (16.46) | 0.74 [-0.70 ; 2.19] |
| Week 111 | n= 6 (10.5%) \|-1.17 (5.88) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (10.5%) \|-1.50 (10.58) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 7.0%) \| 0.25 (15.71) | n= 4 ( 8.3%) \|-5.75 (21.16) | 0.28 [-1.23 ; 1.79] |
| Week 117 | n= 5 ( 8.8%) \|-5.00 (13.82) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 8.8%) \|-5.60 (12.62) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 ( 8.8%) \|-2.40 (9.42) | n= 1 ( 2.1%) \|-8.00 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.8%) \|-11.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | [No Data] | n= 1 ( 2.1%) \| 0.00 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 7 (12.3%) \| 2.43 (23.44) | n= 13 (27.1%) \|-9.00 (16.71) | 0.57 [-0.39 ; 1.53] |
| Week 202 | n= 1 ( 1.8%) \|-5.00 ( / ) | n= 8 (16.7%) \| 0.75 (12.77) | [Not calculable] |
| Week 301 | n= 2 ( 3.5%) \| 5.00 (7.07) | n= 7 (14.6%) \| 2.43 (12.69) | 0.19 [-1.50 ; 1.88] |
| Week 302 | n= 2 ( 3.5%) \|-10.00 (14.14) | n= 5 (10.4%) \| 2.00 (10.05) | -0.92 [-2.84 ; 1.00] |
| Week 303 | n= 3 ( 5.3%) \|-3.33 (15.28) | n= 4 ( 8.3%) \| 21.00 (33.69) | -0.74 [-2.47 ; 0.99] |
| Week 304 | n= 1 ( 1.8%) \| 0.00 ( / ) | n= 2 ( 4.2%) \| 8.00 (16.97) | [Not calculable] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 305 | [No Data] | n= 1 ( 2.1%) \| 67.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 2.1%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 2.1%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 2.1%) \| 82.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 2.1%) \| 77.00 ( / ) | [No Data for at least 1 arm] |
| **Not Reported** | | | |
| N subjects in population | [No Data] | N=2 | |
| Week 7 | [No Data] | n= 1 (50.0%) \| 8.00 ( / ) | [No Data for at least 1 arm] |
| Week 13 | [No Data] | n= 2 (100.0%) \| 2.50 (10.61) | [No Data for at least 1 arm] |
| Week 19 | [No Data] | n= 2 (100.0%) \| 6.50 (4.95) | [No Data for at least 1 arm] |
| Week 25 | [No Data] | n= 2 (100.0%) \| 5.50 (6.36) | [No Data for at least 1 arm] |
| Week 31 | [No Data] | n= 1 (50.0%) \| 4.00 ( / ) | [No Data for at least 1 arm] |
| Week 37 | [No Data] | n= 2 (100.0%) \| 6.00 (5.66) | [No Data for at least 1 arm] |
| Week 43 | [No Data] | n= 2 (100.0%) \| 6.50 (4.95) | [No Data for at least 1 arm] |
| Week 49 | [No Data] | n= 2 (100.0%) \| 4.00 (1.41) | [No Data for at least 1 arm] |
| Week 55 | [No Data] | n= 1 (50.0%) \| 10.00 ( / ) | [No Data for at least 1 arm] |
| Week 61 | [No Data] | n= 1 (50.0%) \| 10.00 ( / ) | [No Data for at least 1 arm] |
| Week 67 | [No Data] | n= 1 (50.0%) \| 10.00 ( / ) | [No Data for at least 1 arm] |
| Week 73 | [No Data] | n= 1 (50.0%) \| 10.00 ( / ) | [No Data for at least 1 arm] |
| Week 79 | [No Data] | n= 1 (50.0%) \| 10.00 ( / ) | [No Data for at least 1 arm] |
| Week 85 | [No Data] | n= 1 (50.0%) \| 10.00 ( / ) | [No Data for at least 1 arm] |
| Week 91 | [No Data] | n= 1 (50.0%) \| 10.00 ( / ) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 1 (50.0%) \| 4.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:05

TABLE 7.1.8: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **< 1 Year** | | | | |
| Nr subjects used | n=14 | n=18 | | |
| Week 7 | -8.68 (3.74) [-16.25 ;-1.11] | -1.98 (3.29) [-8.66 ; 4.69] | -6.70 (4.97) [-16.78 ; 3.38] | -0.47 [-1.18 ; 0.24] |
| Week 13 | -6.47 (3.82) [-14.25 ; 1.32] | -0.62 (3.72) [-8.20 ; 6.95] | -5.84 (5.33) [-16.70 ; 5.02] | -0.41 [-1.17 ; 0.36] |
| Week 19 | -1.61 (2.81) [-7.40 ; 4.18] | -1.37 (2.72) [-6.96 ; 4.21] | -0.24 (3.92) [-8.30 ; 7.83] | -0.02 [-0.76 ; 0.72] |
| Week 25 | -2.40 (2.37) [-7.25 ; 2.45] | -0.84 (2.26) [-5.46 ; 3.79] | -1.56 (3.30) [-8.29 ; 5.16] | -0.18 [-0.93 ; 0.58] |
| Week 31 | 0.25 (3.43) [-6.77 ; 7.27] | -0.36 (3.62) [-7.75 ; 7.03] | 0.61 (5.00) [-9.60 ; 10.82] | 0.05 [-0.74 ; 0.84] |
| Week 37 | -0.74 (2.71) [-6.33 ; 4.86] | -0.32 (2.71) [-5.90 ; 5.26] | -0.42 (3.85) [-8.35 ; 7.51] | -0.04 [-0.84 ; 0.76] |
| Week 43 | -1.67 (2.76) [-7.36 ; 4.01] | -1.11 (2.78) [-6.83 ; 4.60] | -0.56 (3.93) [-8.64 ; 7.52] | -0.06 [-0.86 ; 0.74] |
| Week 49 | -1.71 (2.21) [-6.28 ; 2.86] | -1.61 (2.31) [-6.37 ; 3.14] | -0.09 (3.21) [-6.71 ; 6.53] | -0.01 [-0.83 ; 0.81] |
| Overall post-baseline period estimate | -2.88 (1.80) [-6.54 ; 0.78] | -1.03 (1.71) [-4.49 ; 2.43] | -1.85 (2.49) [-6.91 ; 3.21] | -0.26 [-0.96 ; 0.44] |
| **>= 1 Year** | | | | |
| Nr subjects used | n=57 | n=48 | | |
| Week 7 | -1.53 (2.25) [-6.00 ; 2.94] | -2.56 (2.49) [-7.50 ; 2.38] | 1.03 (3.35) [-5.63 ; 7.69] | 0.06 [-0.34 ; 0.47] |
| Week 13 | -7.52 (3.61) [-14.69 ;-0.35] | -1.38 (3.98) [-9.29 ; 6.53] | -6.14 (5.37) [-16.81 ; 4.53] | -0.25 [-0.68 ; 0.18] |
| Week 19 | -1.33 (2.41) [-6.12 ; 3.46] | -1.24 (2.65) [-6.51 ; 4.03] | -0.09 (3.58) [-7.21 ; 7.03] | -0.01 [-0.45 ; 0.43] |
| Week 25 | 1.25 (1.70) [-2.13 ; 4.64] | 2.47 (1.91) [-1.32 ; 6.26] | -1.22 (2.56) [-6.30 ; 3.86] | -0.11 [-0.56 ; 0.34] |
| Week 31 | 1.93 (1.56) [-1.17 ; 5.04] | -0.75 (1.76) [-4.25 ; 2.74] | 2.69 (2.36) [-1.99 ; 7.36] | 0.27 [-0.20 ; 0.74] |
| Week 37 | 2.04 (1.89) [-1.72 ; 5.80] | -0.84 (2.11) [-5.03 ; 3.34] | 2.89 (2.84) [-2.75 ; 8.52] | 0.24 [-0.23 ; 0.72] |
| Week 43 | 1.90 (2.01) [-2.09 ; 5.88] | -0.38 (2.35) [-5.05 ; 4.28] | 2.28 (3.09) [-3.86 ; 8.42] | 0.18 [-0.30 ; 0.65] |
| Week 49 | 2.40 (1.74) [-1.05 ; 5.85] | 0.28 (2.14) [-3.96 ; 4.52] | 2.12 (2.76) [-3.35 ; 7.60] | 0.19 [-0.31 ; 0.69] |
| Week 55 | 0.49 (2.44) [-4.35 ; 5.33] | 1.67 (2.99) [-4.28 ; 7.61] | -1.18 (3.86) [-8.85 ; 6.50] | -0.08 [-0.57 ; 0.42] |
| Week 61 | 2.07 (1.69) [-1.29 ; 5.42] | -3.39 (2.15) [-7.67 ; 0.89] | 5.46 (2.74) [ 0.02 ; 10.90] | 0.53 [-0.01 ; 1.08] |
| Week 67 | 2.10 (1.84) [-1.56 ; 5.75] | -0.70 (2.34) [-5.36 ; 3.96] | 2.80 (2.98) [-3.13 ; 8.72] | 0.26 [-0.30 ; 0.81] |
| Week 73 | 1.24 (1.70) [-2.14 ; 4.62] | -3.18 (2.03) [-7.22 ; 0.85] | 4.42 (2.65) [-0.84 ; 9.69] | 0.50 [-0.10 ; 1.09] |
| Week 79 | 2.69 (1.90) [-1.09 ; 6.47] | -1.05 (2.22) [-5.46 ; 3.36] | 3.74 (2.92) [-2.06 ; 9.55] | 0.40 [-0.23 ; 1.03] |
| Week 85 | 3.03 (1.82) [-0.59 ; 6.66] | -2.00 (2.16) [-6.32 ; 2.31] | 5.03 (2.82) [-0.60 ; 10.67] | 0.61 [-0.09 ; 1.32] |
| Week 91 | 1.64 (1.96) [-2.31 ; 5.59] | 0.08 (2.37) [-4.68 ; 4.84] | 1.56 (3.07) [-4.63 ; 7.75] | 0.19 [-0.55 ; 0.93] |
| Overall post-baseline period estimate | 0.83 (1.15) [-1.45 ; 3.10] | -0.87 (1.34) [-3.51 ; 1.78] | 1.69 (1.76) [-1.80 ; 5.18] | 0.19 [-0.20 ; 0.58] |
| **Not Reported** | | | | |
| Nr subjects used | [No Data] | n=2 | | |
| **MMRM subgroups interaction p-value** | | | 0.9011 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:05

TABLE 7.1.9: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **No** | | |
| | N=11 | N=12 |
| **Yes** | | |
| | N=60 | N=56 |
| **Subjects with Baseline Value** | | |
| **No** | | |
| | 11 (100.0%) | 12 (100.0%) |
| **Yes** | | |
| | 60 (100.0%) | 56 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **No** | | |
| | 11 (100.0%) | 12 (100.0%) |
| **Yes** | | |
| | 60 (100.0%) | 54 (96.4%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **No** | | |
| | 11 (100.0%) | 12 (100.0%) |
| **Yes** | | |
| | 60 (100.0%) | 54 (96.4%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:11

TABLE 7.1.9: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=11 | N=12 | |
| Baseline | n= 11 (100.0%) \| 80.00 (12.34) | n= 12 (100.0%) \| 82.25 (17.85) | -0.14 [-0.98 ; 0.70] |
| Week 3 | n= 11 (100.0%) \| 81.55 (8.50) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 10 (90.9%) \| 82.30 (10.63) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 11 (100.0%) \| 75.45 (24.13) | n= 11 (91.7%) \| 83.00 (14.83) | -0.36 [-1.23 ; 0.50] |
| Week 9 | n= 8 (72.7%) \| 80.00 (9.06) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 10 (90.9%) \| 73.40 (25.14) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 11 (100.0%) \| 67.73 (31.85) | n= 9 (75.0%) \| 84.56 (10.51) | -0.65 [-1.58 ; 0.28] |
| Week 15 | n= 9 (81.8%) \| 73.00 (25.97) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (81.8%) \| 81.33 (9.99) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 8 (72.7%) \| 74.00 (28.45) | n= 10 (83.3%) \| 81.60 (8.57) | -0.36 [-1.33 ; 0.60] |
| Week 21 | n= 11 (100.0%) \| 70.82 (25.42) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \| 80.40 (10.19) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 10 (90.9%) \| 84.70 (10.72) | n= 8 (66.7%) \| 85.00 (14.84) | -0.02 [-0.98 ; 0.94] |
| Week 27 | n= 10 (90.9%) \| 83.30 (9.19) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 9 (81.8%) \| 84.78 (12.06) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 10 (90.9%) \| 84.70 (11.94) | n= 6 (50.0%) \| 86.67 (10.33) | -0.16 [-1.21 ; 0.89] |
| Week 33 | n= 10 (90.9%) \| 84.90 (12.06) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (72.7%) \| 82.13 (16.21) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \| 81.50 (19.48) | n= 6 (50.0%) \| 88.33 (6.83) | -0.41 [-1.53 ; 0.70] |
| Week 39 | n= 8 (72.7%) \| 88.50 (11.75) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 9 (81.8%) \| 87.22 (12.32) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 8 (72.7%) \| 86.75 (14.29) | n= 6 (50.0%) \| 86.67 (9.83) | 0.01 [-1.10 ; 1.11] |
| Week 45 | n= 9 (81.8%) \| 87.22 (9.80) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 9 (81.8%) \| 87.33 (10.85) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 10 (90.9%) \| 85.00 (10.32) | n= 6 (50.0%) \| 86.67 (10.80) | -0.15 [-1.20 ; 0.90] |
| Week 51 | n= 9 (81.8%) \| 84.00 (9.51) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 9 (81.8%) \| 84.67 (10.01) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 8 (72.7%) \| 83.50 (9.94) | n= 6 (50.0%) \| 87.00 (11.14) | -0.31 [-1.42 ; 0.80] |
| Week 57 | n= 8 (72.7%) \| 83.50 (11.63) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 8 (72.7%) \| 84.50 (12.44) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (72.7%) \| 83.00 (12.90) | n= 4 (33.3%) \| 83.75 (12.50) | -0.05 [-1.31 ; 1.21] |
| Week 63 | n= 8 (72.7%) \| 82.00 (13.94) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (72.7%) \| 83.50 (13.15) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \| 78.25 (19.34) | n= 5 (41.7%) \| 86.40 (10.11) | -0.46 [-1.64 ; 0.73] |
| Week 69 | n= 8 (72.7%) \| 79.88 (15.22) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (63.6%) \| 84.43 (12.22) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (63.6%) \| 84.29 (13.97) | n= 4 (33.3%) \| 86.75 (10.05) | -0.18 [-1.48 ; 1.12] |
| Week 75 | n= 7 (63.6%) \| 81.29 (15.69) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (45.5%) \| 88.00 (8.63) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (54.5%) \| 79.33 (25.41) | n= 2 (16.7%) \| 80.00 (14.14) | -0.02 [-1.76 ; 1.71] |
| Week 81 | n= 5 (45.5%) \| 89.00 (9.72) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (45.5%) \| 87.80 (12.91) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (45.5%) \| 88.80 (7.92) | n= 3 (25.0%) \| 90.00 (10.00) | -0.12 [-1.68 ; 1.44] |
| Week 87 | n= 5 (45.5%) \| 89.00 (7.48) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 4 (36.4%) \| 87.00 (11.46) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (36.4%) \| 89.00 (10.80) | n= 2 (16.7%) \| 82.50 (3.54) | 0.55 [-1.43 ; 2.52] |
| Week 93 | n= 4 (36.4%) \| 89.25 (11.03) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (27.3%) \| 88.00 (12.29) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (27.3%) \| 87.33 (13.43) | n= 1 ( 8.3%) \| 85.00 ( / ) | [Not calculable] |
| Week 99 | n= 2 (18.2%) \| 82.00 (14.14) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 (18.2%) \| 81.50 (13.44) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (18.2%) \| 82.50 (13.44) | n= 1 ( 8.3%) \| 80.00 ( / ) | [Not calculable] |
| Week 105 | n= 2 (18.2%) \| 88.00 (16.97) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \| 83.50 (13.44) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 ( 9.1%) \| 78.00 ( / ) | n= 1 ( 8.3%) \| 80.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 9.1%) \| 75.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 ( 9.1%) \| 72.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 9.1%) \| 75.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 ( 9.1%) \| 77.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 9.1%) \| 78.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 9.1%) \| 76.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | [No Data] | n= 6 (50.0%) \| 85.17 (11.67) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 4 (33.3%) \| 86.25 (11.09) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 2 (16.7%) \| 87.00 (2.83) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 2 (16.7%) \| 82.50 (3.54) | [No Data for at least 1 arm] |
| Week 303 | [No Data] | n= 1 ( 8.3%) \| 80.00 ( / ) | [No Data for at least 1 arm] |
| Week 304 | [No Data] | n= 1 ( 8.3%) \| 90.00 ( / ) | [No Data for at least 1 arm] |
| **Yes** | | | |
| N subjects in population | N=60 | N=56 | |
| Baseline | n= 60 (100.0%) \| 77.42 (18.48) | n= 56 (100.0%) \| 79.18 (18.40) | -0.09 [-0.46 ; 0.27] |
| Week 3 | n= 56 (93.3%) \| 80.59 (14.37) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 55 (91.7%) \| 77.20 (17.52) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 55 (91.7%) \| 77.00 (16.52) | n= 51 (91.1%) \| 76.37 (17.47) | 0.04 [-0.35 ; 0.42] |
| Week 9 | n= 51 (85.0%) \| 77.39 (16.97) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 51 (85.0%) \| 77.69 (15.83) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 48 (80.0%) \| 75.96 (20.45) | n= 44 (78.6%) \| 78.80 (14.05) | -0.16 [-0.57 ; 0.25] |
| Week 15 | n= 45 (75.0%) \| 76.18 (18.90) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 52 (86.7%) \| 78.19 (16.18) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 49 (81.7%) \| 80.12 (13.89) | n= 43 (76.8%) \| 80.93 (14.49) | -0.06 [-0.47 ; 0.36] |
| Week 21 | n= 49 (81.7%) \| 80.00 (12.53) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 46 (76.7%) \| 75.61 (18.11) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 47 (78.3%) \| 79.98 (12.05) | n= 42 (75.0%) \| 83.76 (10.78) | -0.33 [-0.75 ; 0.09] |
| Week 27 | n= 45 (75.0%) \| 80.91 (13.16) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 44 (73.3%) \| 79.98 (14.00) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 44 (73.3%) \| 80.59 (10.96) | n= 37 (66.1%) \| 80.27 (14.76) | 0.02 [-0.42 ; 0.46] |
| Week 33 | n= 47 (78.3%) \| 79.85 (12.68) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 45 (75.0%) \| 80.22 (13.31) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 41 (68.3%) \| 80.51 (12.17) | n= 40 (71.4%) \| 81.18 (14.17) | -0.05 [-0.49 ; 0.39] |
| Week 39 | n= 45 (75.0%) \| 80.62 (12.46) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 42 (70.0%) \| 80.69 (13.09) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 45 (75.0%) \| 80.38 (13.46) | n= 37 (66.1%) \| 80.51 (14.85) | -0.01 [-0.45 ; 0.43] |
| Week 45 | n= 40 (66.7%) \| 78.10 (13.50) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 43 (71.7%) \| 81.19 (12.10) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 43 (71.7%) \| 80.77 (13.91) | n= 32 (57.1%) \| 81.00 (13.50) | -0.02 [-0.48 ; 0.44] |
| Week 51 | n= 42 (70.0%) \| 80.57 (12.98) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 53 | n= 40 (66.7%) \| 78.98 (19.49) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (65.0%) \| 79.41 (19.37) | n= 31 (55.4%) \| 81.55 (14.45) | -0.12 [-0.60 ; 0.35] |
| Week 57 | n= 39 (65.0%) \| 79.18 (18.54) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 38 (63.3%) \| 78.29 (18.85) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 40 (66.7%) \| 81.80 (13.14) | n= 26 (46.4%) \| 77.58 (15.56) | 0.30 [-0.20 ; 0.80] |
| Week 63 | n= 34 (56.7%) \| 79.79 (14.20) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (60.0%) \| 79.42 (15.31) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (60.0%) \| 83.06 (12.20) | n= 25 (44.6%) \| 81.32 (12.92) | 0.14 [-0.38 ; 0.65] |
| Week 69 | n= 29 (48.3%) \| 80.48 (13.22) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 32 (53.3%) \| 82.06 (14.78) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 27 (45.0%) \| 80.07 (14.55) | n= 24 (42.9%) \| 77.83 (17.31) | 0.14 [-0.42 ; 0.69] |
| Week 75 | n= 29 (48.3%) \| 81.76 (14.99) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (45.0%) \| 80.19 (14.49) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 25 (41.7%) \| 82.84 (14.15) | n= 23 (41.1%) \| 78.70 (17.04) | 0.26 [-0.31 ; 0.84] |
| Week 81 | n= 26 (43.3%) \| 82.15 (13.39) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (46.7%) \| 83.14 (13.07) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 22 (36.7%) \| 86.14 (8.80) | n= 18 (32.1%) \| 79.94 (16.82) | 0.47 [-0.17 ; 1.11] |
| Week 87 | n= 19 (31.7%) \| 79.68 (15.85) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 21 (35.0%) \| 81.67 (12.42) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (33.3%) \| 81.05 (13.59) | n= 14 (25.0%) \| 85.36 (10.31) | -0.34 [-1.04 ; 0.36] |
| Week 93 | n= 17 (28.3%) \| 81.47 (15.15) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.7%) \| 79.26 (15.32) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (30.0%) \| 79.22 (16.57) | n= 10 (17.9%) \| 82.40 (12.01) | -0.20 [-0.99 ; 0.59] |
| Week 99 | n= 15 (25.0%) \| 78.60 (15.89) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (20.0%) \| 80.50 (9.41) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.7%) \| 82.46 (10.41) | n= 9 (16.1%) \| 82.44 (11.49) | 0.00 [-0.87 ; 0.87] |
| Week 105 | n= 12 (20.0%) \| 77.50 (9.69) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.0%) \| 76.83 (9.60) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.7%) \| 78.10 (10.86) | n= 4 ( 7.1%) \| 80.50 (10.47) | -0.21 [-1.42 ; 1.00] |
| Week 111 | n= 6 (10.0%) \| 78.50 (9.97) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.7%) \| 82.71 (9.55) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (10.0%) \| 84.17 (10.85) | n= 5 ( 8.9%) \| 82.40 (12.16) | 0.14 [-1.11 ; 1.40] |
| Week 117 | n= 6 (10.0%) \| 83.83 (5.42) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 (10.0%) \| 78.50 (10.29) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.7%) \| 82.14 (11.87) | n= 1 ( 1.8%) \| 92.00 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.3%) \| 81.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.7%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) \| 89.00 (12.73) | n= 1 ( 1.8%) \| 100.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.7%) \| 81.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.7%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.7%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.7%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.7%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.7%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.7%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (13.3%) \| 78.25 (8.96) | n= 11 (19.6%) \| 75.18 (20.45) | 0.18 [-0.76 ; 1.11] |
| Week 202 | n= 2 ( 3.3%) \| 64.00 (26.87) | n= 8 (14.3%) \| 89.38 (10.45) | -1.68 [-3.54 ; 0.18] |
| Week 301 | n= 2 ( 3.3%) \| 70.00 (28.28) | n= 7 (12.5%) \| 82.14 (8.59) | -0.81 [-2.55 ; 0.93] |
| Week 302 | n= 2 ( 3.3%) \| 65.00 (21.21) | n= 4 ( 7.1%) \| 82.50 (6.45) | -1.17 [-3.31 ; 0.97] |
| Week 303 | n= 3 ( 5.0%) \| 56.67 (20.82) | n= 5 ( 8.9%) \| 82.40 (7.67) | -1.65 [-3.50 ; 0.20] |
| Week 304 | n= 1 ( 1.7%) \| 100.00 ( / ) | n= 2 ( 3.6%) \| 70.00 (0.00) | [Not calculable] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 305 | [No Data] | n= 1 ( 1.8%) \| 75.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.8%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.8%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.8%) \| 90.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.8%) \| 85.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:11

TABLE 7.1.9: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=11 | N=12 | |
| Week 3 | n= 11 (100.0%) \| 4.18 (10.19) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 10 (90.9%) \| 2.70 (10.81) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 11 (100.0%) \|-1.91 (19.51) | n= 11 (91.7%) \| 1.27 (10.01) | -0.20 [-1.06 ; 0.66] |
| Week 9 | n= 8 (72.7%) \|-3.75 (6.98) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 10 (90.9%) \|-6.20 (27.19) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 11 (100.0%) \|-9.64 (27.67) | n= 9 (75.0%) \|-2.89 (12.55) | -0.29 [-1.20 ; 0.62] |
| Week 15 | n= 9 (81.8%) \|-8.22 (25.39) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (81.8%) \| 3.44 (9.58) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 8 (72.7%) \|-6.13 (27.30) | n= 10 (83.3%) \|-4.60 (11.03) | -0.07 [-1.03 ; 0.88] |
| Week 21 | n= 11 (100.0%) \|-6.55 (23.39) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \| 4.30 (7.78) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 10 (90.9%) \| 4.60 (7.81) | n= 8 (66.7%) \|-4.63 (15.88) | 0.73 [-0.26 ; 1.72] |
| Week 27 | n= 10 (90.9%) \| 3.20 (8.89) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 9 (81.8%) \| 3.56 (9.68) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 10 (90.9%) \| 4.60 (10.12) | n= 6 (50.0%) \|-0.83 (15.63) | 0.42 [-0.64 ; 1.47] |
| Week 33 | n= 10 (90.9%) \| 4.80 (12.49) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (72.7%) \| 3.25 (11.61) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \| 0.13 (11.78) | n= 6 (50.0%) \|-2.33 (5.89) | 0.24 [-0.87 ; 1.34] |
| Week 39 | n= 8 (72.7%) \| 4.75 (8.48) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 9 (81.8%) \| 4.33 (9.94) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 8 (72.7%) \| 2.25 (8.63) | n= 6 (50.0%) \|-1.50 (10.93) | 0.36 [-0.75 ; 1.48] |
| Week 45 | n= 9 (81.8%) \| 4.33 (9.17) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 9 (81.8%) \| 4.44 (9.00) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 10 (90.9%) \| 4.90 (9.00) | n= 6 (50.0%) \|-1.50 (9.14) | 0.67 [-0.41 ; 1.75] |
| Week 51 | n= 9 (81.8%) \| 2.78 (6.36) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 9 (81.8%) \| 3.44 (7.20) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 8 (72.7%) \| 2.13 (7.51) | n= 6 (50.0%) \|-1.17 (9.02) | 0.38 [-0.74 ; 1.49] |
| Week 57 | n= 8 (72.7%) \| 2.13 (7.06) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 8 (72.7%) \| 3.13 (6.64) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (72.7%) \| 1.63 (4.66) | n= 4 (33.3%) \|-4.75 (5.50) | 1.19 [-0.18 ; 2.57] |
| Week 63 | n= 8 (72.7%) \| 0.63 (6.39) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (72.7%) \| 2.13 (4.02) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \|-3.13 (7.43) | n= 5 (41.7%) \| 0.60 (7.13) | -0.47 [-1.66 ; 0.71] |
| Week 69 | n= 8 (72.7%) \|-1.50 (10.34) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (63.6%) \| 1.43 (8.87) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (63.6%) \| 1.29 (5.50) | n= 4 (33.3%) \|-1.75 (2.36) | 0.59 [-0.74 ; 1.92] |
| Week 75 | n= 7 (63.6%) \|-1.71 (7.45) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (45.5%) \| 0.80 (5.81) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (54.5%) \|-2.50 (12.21) | n= 2 (16.7%) \|-7.00 (4.24) | 0.35 [-1.40 ; 2.10] |
| Week 81 | n= 5 (45.5%) \| 1.80 (6.30) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (45.5%) \| 0.60 (8.44) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (45.5%) \| 1.60 (5.50) | n= 3 (25.0%) \|-1.33 (2.31) | 0.54 [-1.05 ; 2.13] |
| Week 87 | n= 5 (45.5%) \| 1.80 (6.65) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 4 (36.4%) \|-2.00 (4.08) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 4 (36.4%) \| 0.00 (4.97) | n= 2 (16.7%) \|-4.50 (6.36) | 0.67 [-1.32 ; 2.67] |
| Week 93 | n= 4 (36.4%) \| 0.25 (5.38) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (27.3%) \| 2.67 (4.51) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (27.3%) \| 2.00 (5.57) | n= 1 ( 8.3%) \|-9.00 ( / ) | [Not calculable] |
| Week 99 | n= 2 (18.2%) \|-1.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 (18.2%) \|-1.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (18.2%) \|-0.50 (3.54) | n= 1 ( 8.3%) \| 0.00 ( / ) | [Not calculable] |
| Week 105 | n= 2 (18.2%) \| 5.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \| 0.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 ( 9.1%) \| 2.00 ( / ) | n= 1 ( 8.3%) \| 0.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 9.1%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 ( 9.1%) \|-4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 9.1%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 ( 9.1%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 9.1%) \| 2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 9.1%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | [No Data] | n= 6 (50.0%) \|-4.50 (14.99) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 4 (33.3%) \| 1.25 (13.15) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 2 (16.7%) \| 5.50 (13.44) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 2 (16.7%) \| 1.00 (19.80) | [No Data for at least 1 arm] |
| Week 303 | [No Data] | n= 1 ( 8.3%) \| 10.00 ( / ) | [No Data for at least 1 arm] |
| Week 304 | [No Data] | n= 1 ( 8.3%) \| 20.00 ( / ) | [No Data for at least 1 arm] |
| **Yes** | | | |
| N subjects in population | N=60 | N=56 | |
| Week 3 | n= 56 (93.3%) \| 1.52 (13.64) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 55 (91.7%) \|-1.95 (16.39) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 55 (91.7%) \|-1.91 (18.14) | n= 51 (91.1%) \|-1.86 (14.62) | -0.00 [-0.39 ; 0.38] |
| Week 9 | n= 51 (85.0%) \|-1.57 (19.49) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 51 (85.0%) \|-0.65 (19.58) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 48 (80.0%) \|-2.42 (22.42) | n= 44 (78.6%) \|-2.11 (20.03) | -0.01 [-0.43 ; 0.40] |
| Week 15 | n= 45 (75.0%) \|-1.38 (22.85) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 52 (86.7%) \| 0.46 (18.46) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 49 (81.7%) \| 1.82 (14.39) | n= 43 (76.8%) \|-2.12 (10.06) | 0.31 [-0.10 ; 0.72] |
| Week 21 | n= 49 (81.7%) \| 1.57 (14.46) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 46 (76.7%) \|-1.85 (19.37) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 47 (78.3%) \| 0.64 (14.63) | n= 42 (75.0%) \| 2.45 (15.98) | -0.12 [-0.54 ; 0.30] |
| Week 27 | n= 45 (75.0%) \| 2.02 (15.04) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 44 (73.3%) \| 1.55 (15.80) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 44 (73.3%) \| 2.75 (14.37) | n= 37 (66.1%) \|-3.00 (13.53) | 0.41 [-0.04 ; 0.85] |
| Week 33 | n= 47 (78.3%) \|-0.04 (12.05) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 45 (75.0%) \| 1.80 (14.04) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 41 (68.3%) \| 2.95 (14.76) | n= 40 (71.4%) \|-1.23 (12.27) | 0.30 [-0.14 ; 0.75] |
| Week 39 | n= 45 (75.0%) \| 2.98 (13.79) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 42 (70.0%) \| 0.50 (12.62) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 45 (75.0%) \| 2.22 (15.06) | n= 37 (66.1%) \|-1.59 (14.50) | 0.26 [-0.18 ; 0.69] |
| Week 45 | n= 40 (66.7%) \|-0.20 (13.58) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 43 (71.7%) \| 3.28 (14.09) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 43 (71.7%) \| 2.51 (14.06) | n= 32 (57.1%) \|-0.97 (12.90) | 0.25 [-0.21 ; 0.72] |
| Week 51 | n= 42 (70.0%) \| 0.93 (11.25) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 40 (66.7%) \|-0.73 (19.80) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (65.0%) \| 1.21 (19.15) | n= 31 (55.4%) \|-1.19 (15.28) | 0.14 [-0.34 ; 0.61] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 57 | n= 39 (65.0%) \| 0.23 (19.26) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 38 (63.3%) \|-0.29 (14.71) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 40 (66.7%) \| 2.00 (13.35) | n= 26 (46.4%) \|-5.31 (15.47) | 0.51 [ 0.00 ; 1.01] |
| Week 63 | n= 34 (56.7%) \|-0.15 (10.56) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (60.0%) \| 2.44 (12.60) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (60.0%) \| 3.50 (13.67) | n= 25 (44.6%) \|-1.80 (14.74) | 0.37 [-0.15 ; 0.89] |
| Week 69 | n= 29 (48.3%) \| 1.55 (15.19) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 32 (53.3%) \| 0.94 (12.48) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 27 (45.0%) \|-0.26 (13.64) | n= 24 (42.9%) \|-2.92 (15.30) | 0.18 [-0.38 ; 0.74] |
| Week 75 | n= 29 (48.3%) \| 0.86 (12.56) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (45.0%) \| 3.00 (16.03) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 25 (41.7%) \| 2.20 (12.41) | n= 23 (41.1%) \|-2.17 (15.17) | 0.31 [-0.26 ; 0.89] |
| Week 81 | n= 26 (43.3%) \| 0.81 (13.05) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (46.7%) \| 1.61 (12.62) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 22 (36.7%) \| 2.14 (11.33) | n= 18 (32.1%) \|-3.94 (14.49) | 0.46 [-0.18 ; 1.10] |
| Week 87 | n= 19 (31.7%) \|-0.63 (12.83) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 21 (35.0%) \| 0.62 (11.81) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (33.3%) \| 0.05 (12.56) | n= 14 (25.0%) \| 1.07 (11.66) | -0.08 [-0.78 ; 0.61] |
| Week 93 | n= 17 (28.3%) \| 2.18 (11.47) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.7%) \|-3.00 (9.47) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (30.0%) \|-2.61 (10.46) | n= 10 (17.9%) \|-1.60 (6.06) | -0.11 [-0.89 ; 0.68] |
| Week 99 | n= 15 (25.0%) \|-0.93 (10.00) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (20.0%) \|-1.42 (9.45) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.7%) \| 1.00 (8.01) | n= 9 (16.1%) \|-2.00 (8.90) | 0.34 [-0.53 ; 1.22] |
| Week 105 | n= 12 (20.0%) \|-4.17 (9.02) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.0%) \| 0.50 (6.75) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.7%) \|-2.30 (9.60) | n= 4 ( 7.1%) \|-9.50 (13.77) | 0.62 [-0.61 ; 1.86] |
| Week 111 | n= 6 (10.0%) \|-1.17 (5.88) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.7%) \|-3.43 (10.92) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (10.0%) \|-1.00 (14.31) | n= 5 ( 8.9%) \|-5.60 (18.32) | 0.26 [-1.00 ; 1.52] |
| Week 117 | n= 6 (10.0%) \|-5.00 (12.36) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 (10.0%) \|-7.17 (11.92) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.7%) \|-2.71 (10.18) | n= 1 ( 1.8%) \|-8.00 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.3%) \|-13.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.7%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) \|-3.50 (16.26) | n= 1 ( 1.8%) \| 0.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.7%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.7%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.7%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.7%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.7%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.7%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.7%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (13.3%) \| 2.50 (21.70) | n= 11 (19.6%) \|-9.55 (15.10) | 0.64 [-0.33 ; 1.60] |
| Week 202 | n= 2 ( 3.3%) \|-4.50 (0.71) | n= 8 (14.3%) \|-1.25 (10.35) | -0.30 [-1.96 ; 1.35] |
| Week 301 | n= 2 ( 3.3%) \| 5.00 (7.07) | n= 7 (12.5%) \| 0.86 (11.26) | 0.34 [-1.35 ; 2.04] |
| Week 302 | n= 2 ( 3.3%) \|-10.00 (14.14) | n= 4 ( 7.1%) \| 2.00 (2.16) | -1.31 [-3.50 ; 0.88] |
| Week 303 | n= 3 ( 5.0%) \|-3.33 (15.28) | n= 5 ( 8.9%) \| 14.80 (32.31) | -0.57 [-2.16 ; 1.03] |
| Week 304 | n= 1 ( 1.7%) \| 0.00 ( / ) | n= 2 ( 3.6%) \|-7.00 (4.24) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.8%) \| 67.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.8%) \| 62.00 ( / ) | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|---|
| Week 307 | [No Data] | n= 1 ( 1.8%) | 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.8%) | 82.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.8%) | 77.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:12

TABLE 7.1.9: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **No** | | | | |
| Nr subjects used | n=11 | n=12 | | |
| Week 7 | -2.40 (4.67) [-12.17 ; 7.38] | 1.76 (4.67) [-8.02 ; 11.54] | -4.15 (6.64) [-18.04 ; 9.74] | -0.26 [-1.10 ; 0.58] |
| Overall post-baseline period estimate | -2.40 (4.67) [-12.17 ; 7.38] | 1.76 (4.67) [-8.02 ; 11.54] | -4.15 (6.64) [-18.04 ; 9.74] | -0.25 [-1.07 ; 0.57] |
| **Yes** | | | | |
| Nr subjects used | n=60 | n=56 | | |
| Week 7 | -3.34 (2.15) [-7.60 ; 0.92] | -2.89 (2.24) [-7.34 ; 1.56] | -0.45 (3.11) [-6.61 ; 5.71] | -0.03 [-0.41 ; 0.35] |
| Week 13 | -6.04 (3.01) [-12.02 ;-0.06] | -1.13 (3.16) [-7.41 ; 5.14] | -4.91 (4.37) [-13.57 ; 3.76] | -0.23 [-0.64 ; 0.18] |
| Week 19 | -0.61 (1.78) [-4.15 ; 2.92] | -0.46 (1.89) [-4.21 ; 3.28] | -0.15 (2.60) [-5.30 ; 5.00] | -0.01 [-0.42 ; 0.40] |
| Week 25 | -0.67 (1.47) [-3.59 ; 2.24] | 2.62 (1.56) [-0.46 ; 5.70] | -3.29 (2.14) [-7.54 ; 0.95] | -0.32 [-0.74 ; 0.10] |
| Week 31 | 0.69 (1.67) [-2.62 ; 4.00] | -0.26 (1.78) [-3.79 ; 3.28] | 0.94 (2.45) [-3.90 ; 5.79] | 0.09 [-0.35 ; 0.52] |
| Week 37 | 1.25 (1.77) [-2.27 ; 4.76] | -0.47 (1.85) [-4.15 ; 3.20] | 1.72 (2.57) [-3.37 ; 6.81] | 0.15 [-0.29 ; 0.58] |
| Week 43 | 0.07 (1.91) [-3.71 ; 3.86] | -0.16 (2.08) [-4.28 ; 3.95] | 0.24 (2.82) [-5.36 ; 5.83] | 0.02 [-0.42 ; 0.45] |
| Week 49 | 0.53 (1.70) [-2.84 ; 3.89] | 0.07 (1.91) [-3.72 ; 3.86] | 0.45 (2.56) [-4.62 ; 5.53] | 0.04 [-0.42 ; 0.50] |
| Week 55 | -0.20 (2.39) [-4.95 ; 4.55] | 0.54 (2.72) [-4.84 ; 5.93] | -0.74 (3.62) [-7.93 ; 6.44] | -0.05 [-0.52 ; 0.42] |
| Week 61 | 0.75 (1.76) [-2.74 ; 4.24] | -3.05 (2.10) [-7.22 ; 1.13] | 3.79 (2.74) [-1.65 ; 9.23] | 0.34 [-0.16 ; 0.84] |
| Week 67 | 1.82 (1.79) [-1.74 ; 5.37] | -0.58 (2.13) [-4.80 ; 3.65] | 2.39 (2.78) [-3.13 ; 7.92] | 0.22 [-0.29 ; 0.73] |
| Week 73 | -1.17 (2.03) [-5.20 ; 2.85] | -2.36 (2.27) [-6.87 ; 2.14] | 1.19 (3.04) [-4.86 ; 7.23] | 0.11 [-0.44 ; 0.66] |
| Week 79 | 1.62 (1.88) [-2.12 ; 5.35] | -0.79 (2.06) [-4.87 ; 3.29] | 2.40 (2.79) [-3.13 ; 7.93] | 0.25 [-0.32 ; 0.81] |
| Week 85 | 2.10 (1.72) [-1.32 ; 5.51] | -1.16 (1.93) [-4.99 ; 2.68] | 3.26 (2.58) [-1.88 ; 8.39] | 0.39 [-0.24 ; 1.02] |
| Week 91 | 0.84 (1.74) [-2.64 ; 4.31] | 0.90 (2.04) [-3.18 ; 4.98] | -0.07 (2.68) [-5.42 ; 5.29] | -0.01 [-0.69 ; 0.67] |
| Week 97 | -0.31 (2.24) [-4.85 ; 4.23] | -0.29 (2.85) [-6.04 ; 5.47] | -0.03 (3.62) [-7.36 ; 7.30] | -0.00 [-0.78 ; 0.77] |
| Overall post-baseline period estimate | -0.17 (1.04) [-2.22 ; 1.88] | -0.59 (1.15) [-2.86 ; 1.68] | 0.42 (1.55) [-2.64 ; 3.49] | 0.05 [-0.32 ; 0.42] |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.5225 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:12

TABLE 7.1.10: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **No** | N=61 | N=62 |
| **Yes** | N=10 | N=6 |
| **Subjects with Baseline Value** | | |
| **No** | 61 (100.0%) | 62 (100.0%) |
| **Yes** | 10 (100.0%) | 6 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **No** | 61 (100.0%) | 60 (96.8%) |
| **Yes** | 10 (100.0%) | 6 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **No** | 61 (100.0%) | 60 (96.8%) |
| **Yes** | 10 (100.0%) | 6 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:12

TABLE 7.1.10: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=61 | N=62 | |
| Baseline | n= 61 (100.0%) \| 79.48 (16.86) | n= 62 (100.0%) \| 79.00 (18.86) | 0.03 [-0.33 ; 0.38] |
| Week 3 | n= 58 (95.1%) \| 82.41 (12.34) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 57 (93.4%) \| 79.84 (15.58) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 57 (93.4%) \| 78.37 (16.65) | n= 57 (91.9%) \| 76.84 (17.37) | 0.09 [-0.28 ; 0.46] |
| Week 9 | n= 51 (83.6%) \| 79.27 (15.57) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 53 (86.9%) \| 78.19 (16.98) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 52 (85.2%) \| 74.46 (23.06) | n= 49 (79.0%) \| 79.14 (13.76) | -0.24 [-0.64 ; 0.15] |
| Week 15 | n= 49 (80.3%) \| 75.84 (20.72) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 53 (86.9%) \| 79.49 (15.12) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 51 (83.6%) \| 79.65 (17.01) | n= 48 (77.4%) \| 80.67 (13.59) | -0.07 [-0.46 ; 0.33] |
| Week 21 | n= 52 (85.2%) \| 79.06 (16.43) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 49 (80.3%) \| 77.33 (17.60) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 51 (83.6%) \| 80.86 (11.64) | n= 47 (75.8%) \| 83.34 (11.32) | -0.21 [-0.61 ; 0.19] |
| Week 27 | n= 49 (80.3%) \| 81.88 (12.31) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 47 (77.0%) \| 81.60 (11.25) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 48 (78.7%) \| 81.15 (10.83) | n= 39 (62.9%) \| 81.10 (14.49) | 0.00 [-0.42 ; 0.43] |
| Week 33 | n= 50 (82.0%) \| 81.42 (11.88) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 48 (78.7%) \| 81.65 (12.29) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 42 (68.9%) \| 81.57 (12.76) | n= 41 (66.1%) \| 81.83 (13.68) | -0.02 [-0.45 ; 0.41] |
| Week 39 | n= 46 (75.4%) \| 82.65 (11.93) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 45 (73.8%) \| 82.53 (11.71) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 46 (75.4%) \| 81.91 (13.06) | n= 38 (61.3%) \| 80.29 (14.21) | 0.12 [-0.31 ; 0.55] |
| Week 45 | n= 42 (68.9%) \| 80.07 (13.15) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 46 (75.4%) \| 81.85 (12.30) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 47 (77.0%) \| 82.21 (13.12) | n= 34 (54.8%) \| 81.44 (13.32) | 0.06 [-0.39 ; 0.50] |
| Week 51 | n= 44 (72.1%) \| 81.93 (12.53) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 43 (70.5%) \| 82.47 (12.88) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 40 (65.6%) \| 82.58 (14.41) | n= 34 (54.8%) \| 82.06 (14.04) | 0.04 [-0.42 ; 0.50] |
| Week 57 | n= 40 (65.6%) \| 82.78 (12.93) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 39 (63.9%) \| 80.46 (18.40) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 42 (68.9%) \| 82.76 (12.51) | n= 27 (43.5%) \| 77.30 (15.20) | 0.40 [-0.09 ; 0.89] |
| Week 63 | n= 35 (57.4%) \| 81.71 (13.16) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 37 (60.7%) \| 81.14 (13.75) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (62.3%) \| 82.76 (14.12) | n= 27 (43.5%) \| 81.67 (12.38) | 0.08 [-0.42 ; 0.58] |
| Week 69 | n= 32 (52.5%) \| 80.75 (12.73) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 32 (52.5%) \| 84.25 (12.55) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 28 (45.9%) \| 82.50 (13.11) | n= 25 (40.3%) \| 77.80 (16.92) | 0.31 [-0.24 ; 0.86] |
| Week 75 | n= 30 (49.2%) \| 84.40 (12.01) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (42.6%) \| 83.92 (11.46) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (42.6%) \| 84.96 (14.80) | n= 24 (38.7%) \| 77.92 (16.31) | 0.45 [-0.12 ; 1.01] |
| Week 81 | n= 26 (42.6%) \| 85.92 (9.31) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 27 (44.3%) \| 86.74 (9.58) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (41.0%) \| 86.52 (8.88) | n= 19 (30.6%) \| 79.58 (16.01) | 0.55 [-0.07 ; 1.16] |
| Week 87 | n= 19 (31.1%) \| 86.58 (8.37) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 22 (36.1%) \| 84.77 (9.32) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 21 (34.4%) \| 85.05 (9.94) | n= 14 (22.6%) \| 83.07 (8.71) | 0.20 [-0.48 ; 0.89] |
| Week 93 | n= 18 (29.5%) \| 86.11 (11.14) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.1%) \| 84.05 (10.38) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.5%) \| 84.56 (10.94) | n= 11 (17.7%) \| 82.64 (11.42) | 0.17 [-0.60 ; 0.93] |
| Week 99 | n= 14 (23.0%) \| 82.79 (10.26) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.3%) \| 80.15 (9.63) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.3%) \| 84.00 (8.84) | n= 10 (16.1%) \| 82.20 (10.86) | 0.18 [-0.67 ; 1.02] |
| Week 105 | n= 12 (19.7%) \| 80.83 (10.25) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.5%) \| 78.29 (10.84) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (14.8%) \| 79.67 (9.85) | n= 5 ( 8.1%) \| 80.40 (9.07) | -0.07 [-1.21 ; 1.07] |
| Week 111 | n= 6 ( 9.8%) \| 78.50 (9.97) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.5%) \| 80.29 (9.84) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 ( 9.8%) \| 81.67 (10.97) | n= 5 ( 8.1%) \| 82.40 (12.16) | -0.06 [-1.31 ; 1.19] |
| Week 117 | n= 6 ( 9.8%) \| 82.17 (5.78) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 ( 9.8%) \| 77.33 (9.79) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.5%) \| 82.00 (11.94) | n= 1 ( 1.6%) \| 92.00 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.3%) \| 81.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) \| 89.00 (12.73) | n= 1 ( 1.6%) \| 100.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) \| 81.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 ( 9.8%) \| 77.67 (10.52) | n= 15 (24.2%) \| 80.53 (18.47) | -0.16 [-1.14 ; 0.81] |
| Week 202 | n= 1 ( 1.6%) \| 83.00 ( / ) | n= 9 (14.5%) \| 89.56 (9.25) | [Not calculable] |
| Week 301 | n= 1 ( 1.6%) \| 90.00 ( / ) | n= 8 (12.9%) \| 84.25 (7.67) | [Not calculable] |
| Week 302 | n= 2 ( 3.3%) \| 65.00 (21.21) | n= 5 ( 8.1%) \| 82.00 (5.70) | -1.33 [-3.36 ; 0.70] |
| Week 303 | n= 3 ( 4.9%) \| 56.67 (20.82) | n= 6 ( 9.7%) \| 82.00 (6.93) | -1.79 [-3.58 ;-0.00] |
| Week 304 | n= 1 ( 1.6%) \| 100.00 ( / ) | n= 3 ( 4.8%) \| 76.67 (11.55) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.6%) \| 75.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.6%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.6%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.6%) \| 90.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.6%) \| 85.00 ( / ) | [No Data for at least 1 arm] |
| **Yes** | | | |
| N subjects in population | N=10 | N=6 | |
| Baseline | n= 10 (100.0%) \| 67.70 (19.64) | n= 6 (100.0%) \| 87.17 (5.49) | -1.14 [-2.28 ;-0.01] |
| Week 3 | n= 9 (90.0%) \| 70.00 (16.59) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (80.0%) \| 64.75 (19.35) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 9 (90.0%) \| 66.44 (22.22) | n= 5 (83.3%) \| 85.60 (12.42) | -0.92 [-2.12 ; 0.28] |
| Week 9 | n= 8 (80.0%) \| 68.00 (16.97) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 8 (80.0%) \| 69.00 (19.95) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 7 (70.0%) \| 74.14 (23.36) | n= 4 (66.7%) \| 87.50 (9.57) | -0.61 [-1.94 ; 0.71] |
| Week 15 | n= 5 (50.0%) \| 73.80 (11.82) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 8 (80.0%) \| 73.13 (17.10) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 6 (60.0%) \| 76.00 (11.40) | n= 5 (83.3%) \| 84.80 (13.46) | -0.65 [-1.94 ; 0.64] |
| Week 21 | n= 8 (80.0%) \| 73.50 (10.57) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 23 | n= 7 (70.0%) \| 70.43 (11.01) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (60.0%) \| 80.33 (14.94) | n= 3 (50.0%) \| 93.67 (7.77) | -0.89 [-2.46 ; 0.68] |
| Week 27 | n= 6 (60.0%) \| 77.00 (14.35) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 6 (60.0%) \| 74.50 (27.12) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 6 (60.0%) \| 83.00 (14.56) | n= 4 (66.7%) \| 81.75 (14.29) | 0.08 [-1.27 ; 1.42] |
| Week 33 | n= 7 (70.0%) \| 75.86 (17.32) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 5 (50.0%) \| 69.60 (21.76) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 7 (70.0%) \| 75.29 (16.70) | n= 5 (83.3%) \| 84.40 (14.29) | -0.53 [-1.76 ; 0.70] |
| Week 39 | n= 7 (70.0%) \| 76.29 (16.14) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 6 (60.0%) \| 76.67 (21.64) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 7 (70.0%) \| 77.57 (17.73) | n= 5 (83.3%) \| 89.60 (13.81) | -0.68 [-1.93 ; 0.56] |
| Week 45 | n= 7 (70.0%) \| 78.00 (15.11) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (60.0%) \| 85.33 (10.03) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (60.0%) \| 76.50 (15.10) | n= 4 (66.7%) \| 85.75 (12.47) | -0.59 [-1.97 ; 0.79] |
| Week 51 | n= 7 (70.0%) \| 76.43 (11.43) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 6 (60.0%) \| 62.50 (36.83) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (70.0%) \| 66.00 (29.77) | n= 3 (50.0%) \| 86.67 (15.28) | -0.69 [-2.18 ; 0.79] |
| Week 57 | n= 7 (70.0%) \| 63.57 (30.06) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (70.0%) \| 73.29 (14.80) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 6 (60.0%) \| 76.67 (16.07) | n= 3 (50.0%) \| 88.33 (12.58) | -0.68 [-2.22 ; 0.85] |
| Week 63 | n= 7 (70.0%) \| 72.71 (16.75) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (70.0%) \| 75.00 (20.41) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (60.0%) \| 78.50 (10.09) | n= 3 (50.0%) \| 86.67 (15.28) | -0.61 [-2.14 ; 0.91] |
| Week 69 | n= 5 (50.0%) \| 77.80 (19.04) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (70.0%) \| 74.43 (19.40) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 6 (60.0%) \| 73.67 (18.73) | n= 3 (50.0%) \| 90.00 (10.00) | -0.87 [-2.43 ; 0.69] |
| Week 75 | n= 6 (60.0%) \| 68.00 (21.17) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (60.0%) \| 70.50 (19.22) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (50.0%) \| 67.60 (18.41) | n= 1 (16.7%) \| 100.00 ( / ) | [Not calculable] |
| Week 81 | n= 5 (50.0%) \| 69.40 (20.90) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (60.0%) \| 70.83 (18.68) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (20.0%) \| 88.00 (2.83) | n= 2 (33.3%) \| 98.50 (2.12) | -2.40 [-6.80 ; 2.00] |
| Week 87 | n= 5 (50.0%) \| 62.80 (19.94) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 3 (30.0%) \| 66.00 (20.22) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (30.0%) \| 63.67 (21.13) | n= 2 (33.3%) \| 98.50 (2.12) | -1.46 [-4.04 ; 1.11] |
| Week 93 | n= 3 (30.0%) \| 64.00 (20.81) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (30.0%) \| 57.67 (22.14) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (30.0%) \| 55.33 (21.94) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 3 (30.0%) \| 61.33 (25.01) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (10.0%) \| 87.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (20.0%) \| 72.50 (17.68) | [No Data] | [No Data for at least 1 arm] |
| Week 105 | n= 2 (20.0%) \| 68.00 (8.49) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (10.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 (20.0%) \| 71.00 (12.73) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 (10.0%) \| 75.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 (10.0%) \| 89.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 (10.0%) \| 90.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (10.0%) \| 87.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (10.0%) \| 85.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 (10.0%) \| 77.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (20.0%) \| 80.00 (0.00) | n= 2 (33.3%) \| 65.00 (7.07) | 1.71 [-1.87 ; 5.30] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 202 | n= 1 (10.0%) \| 45.00 ( / ) | n= 3 (50.0%) \| 84.67 (14.50) | [Not calculable] |
| Week 301 | n= 1 (10.0%) \| 50.00 ( / ) | n= 1 (16.7%) \| 75.00 ( / ) | [Not calculable] |
| Week 302 | [No Data] | n= 1 (16.7%) \| 85.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:12

TABLE 7.1.10: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=61 | N=62 | |
| Week 3 | n= 58 (95.1%) \| 2.24 (13.12) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 57 (93.4%) \|-0.67 (15.41) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 57 (93.4%) \|-1.32 (17.84) | n= 57 (91.9%) \|-1.42 (14.30) | 0.01 [-0.36 ; 0.38] |
| Week 9 | n= 51 (83.6%) \|-0.88 (18.66) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 53 (86.9%) \|-0.91 (20.78) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 52 (85.2%) \|-4.46 (23.94) | n= 49 (79.0%) \|-2.33 (19.52) | -0.10 [-0.49 ; 0.30] |
| Week 15 | n= 49 (80.3%) \|-1.96 (23.86) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 53 (86.9%) \| 0.92 (18.16) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 51 (83.6%) \| 0.45 (17.51) | n= 48 (77.4%) \|-2.52 (10.33) | 0.20 [-0.19 ; 0.60] |
| Week 21 | n= 52 (85.2%) \|-0.08 (17.66) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 49 (80.3%) \|-0.94 (18.85) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 51 (83.6%) \| 1.24 (14.20) | n= 47 (75.8%) \| 1.17 (16.48) | 0.00 [-0.39 ; 0.40] |
| Week 27 | n= 49 (80.3%) \| 2.45 (14.66) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 47 (77.0%) \| 1.98 (14.59) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 48 (78.7%) \| 2.67 (14.21) | n= 39 (62.9%) \|-2.38 (13.95) | 0.36 [-0.07 ; 0.78] |
| Week 33 | n= 50 (82.0%) \| 0.88 (12.25) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 48 (78.7%) \| 2.27 (13.58) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 42 (68.9%) \| 2.95 (14.54) | n= 41 (66.1%) \|-1.10 (11.71) | 0.30 [-0.13 ; 0.74] |
| Week 39 | n= 46 (75.4%) \| 3.63 (13.42) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 45 (73.8%) \| 1.53 (11.93) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 46 (75.4%) \| 2.26 (14.48) | n= 38 (61.3%) \|-2.00 (13.94) | 0.30 [-0.14 ; 0.73] |
| Week 45 | n= 42 (68.9%) \| 0.33 (13.29) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 46 (75.4%) \| 2.78 (12.85) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 47 (77.0%) \| 3.55 (13.73) | n= 34 (54.8%) \|-0.82 (12.69) | 0.33 [-0.12 ; 0.77] |
| Week 51 | n= 44 (72.1%) \| 1.32 (11.05) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 43 (70.5%) \| 2.23 (12.69) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 40 (65.6%) \| 3.28 (13.43) | n= 34 (54.8%) \|-1.29 (14.37) | 0.33 [-0.14 ; 0.79] |
| Week 57 | n= 40 (65.6%) \| 2.75 (13.29) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 39 (63.9%) \| 0.77 (14.30) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 42 (68.9%) \| 2.19 (12.56) | n= 27 (43.5%) \|-6.00 (14.55) | 0.61 [ 0.11 ; 1.10] |
| Week 63 | n= 35 (57.4%) \| 0.57 (9.38) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 37 (60.7%) \| 2.95 (11.35) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (62.3%) \| 2.61 (13.58) | n= 27 (43.5%) \|-1.56 (13.63) | 0.30 [-0.20 ; 0.80] |
| Week 69 | n= 32 (52.5%) \| 1.34 (14.64) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 32 (52.5%) \| 1.50 (11.80) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 28 (45.9%) \| 0.00 (12.85) | n= 25 (40.3%) \|-3.48 (14.46) | 0.25 [-0.29 ; 0.80] |
| Week 75 | n= 30 (49.2%) \| 1.50 (10.67) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (42.6%) \| 3.88 (15.10) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (42.6%) \| 2.35 (12.05) | n= 24 (38.7%) \|-3.08 (14.69) | 0.40 [-0.17 ; 0.97] |
| Week 81 | n= 26 (42.6%) \| 1.27 (11.94) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 27 (44.3%) \| 2.30 (11.74) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (41.0%) \| 1.56 (10.67) | n= 19 (30.6%) \|-5.37 (12.76) | 0.59 [-0.03 ; 1.20] |
| Week 87 | n= 19 (31.1%) \| 1.74 (11.04) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 22 (36.1%) \| 0.77 (10.70) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 21 (34.4%) \| 0.95 (11.27) | n= 14 (22.6%) \|-1.50 (10.54) | 0.22 [-0.47 ; 0.91] |
| Week 93 | n= 18 (29.5%) \| 3.11 (9.90) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.1%) \|-0.63 (7.08) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.5%) \| 0.17 (7.99) | n= 11 (17.7%) \|-2.27 (6.17) | 0.32 [-0.45 ; 1.09] |
| Week 99 | n= 14 (23.0%) \| 0.71 (7.18) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.3%) \|-2.08 (8.75) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.3%) \| 1.31 (7.35) | n= 10 (16.1%) \|-1.80 (8.42) | 0.38 [-0.47 ; 1.23] |
| Week 105 | n= 12 (19.7%) \|-2.17 (9.76) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.5%) \| 0.57 (6.32) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (14.8%) \|-1.44 (10.03) | n= 5 ( 8.1%) \|-7.60 (12.66) | 0.53 [-0.63 ; 1.68] |
| Week 111 | n= 6 ( 9.8%) \|-0.50 (5.58) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.5%) \|-5.29 (9.46) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 ( 9.8%) \|-2.83 (13.29) | n= 5 ( 8.1%) \|-5.60 (18.32) | 0.16 [-1.09 ; 1.42] |
| Week 117 | n= 6 ( 9.8%) \|-6.00 (11.40) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 ( 9.8%) \|-7.67 (11.36) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.5%) \|-2.29 (10.23) | n= 1 ( 1.6%) \|-8.00 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.3%) \|-13.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) \|-3.50 (16.26) | n= 1 ( 1.6%) \| 0.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 ( 9.8%) \| 4.83 (25.00) | n= 15 (24.2%) \|-5.93 (14.81) | 0.57 [-0.42 ; 1.56] |
| Week 202 | n= 1 ( 1.6%) \|-4.00 ( / ) | n= 9 (14.5%) \| 1.22 (10.35) | [Not calculable] |
| Week 301 | n= 1 ( 1.6%) \| 10.00 ( / ) | n= 8 (12.9%) \| 3.38 (10.80) | [Not calculable] |
| Week 302 | n= 2 ( 3.3%) \|-10.00 (14.14) | n= 5 ( 8.1%) \| 1.60 (10.09) | -0.89 [-2.80 ; 1.02] |
| Week 303 | n= 3 ( 4.9%) \|-3.33 (15.28) | n= 6 ( 9.7%) \| 14.00 (28.96) | -0.60 [-2.12 ; 0.93] |
| Week 304 | n= 1 ( 1.6%) \| 0.00 ( / ) | n= 3 ( 4.8%) \| 2.00 (15.87) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.6%) \| 67.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.6%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.6%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.6%) \| 82.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.6%) \| 77.00 ( / ) | [No Data for at least 1 arm] |
| **Yes** | | | |
| N subjects in population | N=10 | N=6 | |
| Week 3 | n= 9 (90.0%) \| 0.11 (13.66) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (80.0%) \|-5.25 (18.13) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 9 (90.0%) \|-5.67 (21.26) | n= 5 (83.3%) \| 0.00 (8.92) | -0.29 [-1.44 ; 0.85] |
| Week 9 | n= 8 (80.0%) \|-8.13 (15.03) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 8 (80.0%) \|-5.88 (22.20) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 7 (70.0%) \| 1.43 (19.59) | n= 4 (66.7%) \|-1.25 (8.54) | 0.15 [-1.15 ; 1.44] |
| Week 15 | n= 5 (50.0%) \|-8.00 (15.67) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 8 (80.0%) \| 0.75 (12.08) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 6 (60.0%) \| 2.83 (6.62) | n= 5 (83.3%) \|-3.20 (9.73) | 0.68 [-0.62 ; 1.97] |
| Week 21 | n= 8 (80.0%) \| 1.13 (5.08) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 7 (70.0%) \| 0.57 (10.55) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (60.0%) \| 2.17 (9.37) | n= 3 (50.0%) \| 3.67 (5.51) | -0.16 [-1.65 ; 1.33] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 27 | n= 6 (60.0%) \| 0.50 (8.29) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 6 (60.0%) \| 1.17 (18.61) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 6 (60.0%) \| 6.50 (7.23) | n= 4 (66.7%) \|-5.75 (11.44) | 1.22 [-0.26 ; 2.71] |
| Week 33 | n= 7 (70.0%) \| 0.29 (12.42) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 5 (50.0%) \|-0.40 (15.27) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 7 (70.0%) \|-0.29 (12.97) | n= 5 (83.3%) \|-3.60 (11.61) | 0.25 [-0.96 ; 1.46] |
| Week 39 | n= 7 (70.0%) \| 0.71 (11.09) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 6 (60.0%) \|-1.50 (14.94) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 7 (70.0%) \| 2.00 (13.34) | n= 5 (83.3%) \| 1.60 (15.18) | 0.03 [-1.18 ; 1.23] |
| Week 45 | n= 7 (70.0%) \| 2.43 (11.16) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (60.0%) \| 8.83 (16.53) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (60.0%) \|-1.67 (7.17) | n= 4 (66.7%) \|-3.00 (9.09) | 0.15 [-1.20 ; 1.50] |
| Week 51 | n= 7 (70.0%) \| 0.86 (6.94) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 6 (60.0%) \|-15.67 (38.44) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (70.0%) \|-9.57 (32.47) | n= 3 (50.0%) \| 0.00 (17.32) | -0.29 [-1.74 ; 1.15] |
| Week 57 | n= 7 (70.0%) \|-12.00 (32.35) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (70.0%) \|-2.29 (9.69) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 6 (60.0%) \| 0.17 (11.07) | n= 3 (50.0%) \| 1.67 (14.43) | -0.11 [-1.60 ; 1.38] |
| Week 63 | n= 7 (70.0%) \|-2.86 (12.31) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (70.0%) \|-0.57 (12.67) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (60.0%) \| 0.33 (8.52) | n= 3 (50.0%) \| 0.00 (17.32) | 0.03 [-1.46 ; 1.51] |
| Week 69 | n= 5 (50.0%) \|-2.00 (11.96) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (70.0%) \|-1.14 (12.55) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 6 (60.0%) \| 0.33 (10.71) | n= 3 (50.0%) \| 3.33 (11.55) | -0.24 [-1.74 ; 1.25] |
| Week 75 | n= 6 (60.0%) \|-5.33 (15.83) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (60.0%) \|-2.67 (13.62) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (50.0%) \|-4.20 (13.57) | n= 1 (16.7%) \| 10.00 ( / ) | [Not calculable] |
| Week 81 | n= 5 (50.0%) \|-0.60 (14.55) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (60.0%) \|-2.33 (13.40) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (20.0%) \| 8.00 (2.83) | n= 2 (33.3%) \| 13.50 (4.95) | -0.78 [-3.51 ; 1.95] |
| Week 87 | n= 5 (50.0%) \|-7.20 (12.76) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 3 (30.0%) \|-4.00 (14.11) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (30.0%) \|-6.33 (14.01) | n= 2 (33.3%) \| 13.50 (4.95) | -1.22 [-3.67 ; 1.22] |
| Week 93 | n= 3 (30.0%) \|-6.00 (12.77) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (30.0%) \|-12.33 (15.50) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (30.0%) \|-14.67 (12.70) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 3 (30.0%) \|-8.67 (16.29) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (10.0%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (20.0%) \|-2.50 (10.61) | [No Data] | [No Data for at least 1 arm] |
| Week 105 | n= 2 (20.0%) \|-7.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (10.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 (20.0%) \|-4.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 (10.0%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 (10.0%) \| 9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 (10.0%) \| 10.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (10.0%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (10.0%) \| 5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 (10.0%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (20.0%) \|-4.50 (6.36) | n= 2 (33.3%) \|-21.50 (2.12) | 2.05 [-1.92 ; 6.02] |
| Week 202 | n= 1 (10.0%) \|-5.00 ( / ) | n= 3 (50.0%) \|-5.33 (12.86) | [Not calculable] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 301 | n= 1 (10.0%) \| 0.00 ( / ) | n= 1 (16.7%) \|-10.00 ( / ) | [Not calculable] |
| Week 302 | [No Data] | n= 1 (16.7%) \| 2.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:12

TABLE 7.1.10: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **No** | | | | |
| Nr subjects used | n=61 | n=62 | | |
| Week 7 | -2.32 (2.11) [-6.49 ; 1.85] | -2.94 (2.11) [-7.13 ; 1.24] | 0.62 (2.98) [-5.28 ; 6.52] | 0.04 [-0.33 ; 0.41] |
| Week 13 | -6.74 (3.06) [-12.81 ;-0.67] | -1.59 (3.12) [-7.77 ; 4.59] | -5.15 (4.37) [-13.80 ; 3.51] | -0.23 [-0.62 ; 0.16] |
| Week 19 | -1.66 (2.13) [-5.87 ; 2.55] | -1.09 (2.18) [-5.40 ; 3.22] | -0.57 (3.04) [-6.60 ; 5.46] | -0.04 [-0.43 ; 0.36] |
| Week 25 | 0.01 (1.53) [-3.02 ; 3.03] | 1.77 (1.58) [-1.35 ; 4.89] | -1.76 (2.20) [-6.11 ; 2.59] | -0.16 [-0.56 ; 0.24] |
| Week 31 | 0.97 (1.61) [-2.22 ; 4.16] | -0.30 (1.71) [-3.70 ; 3.09] | 1.27 (2.35) [-3.39 ; 5.93] | 0.12 [-0.31 ; 0.54] |
| Week 37 | 1.75 (1.68) [-1.58 ; 5.08] | -0.25 (1.75) [-3.71 ; 3.22] | 2.00 (2.43) [-2.81 ; 6.80] | 0.18 [-0.25 ; 0.61] |
| Week 43 | 0.90 (1.68) [-2.44 ; 4.23] | -0.93 (1.83) [-4.56 ; 2.70] | 1.83 (2.49) [-3.11 ; 6.76] | 0.16 [-0.27 ; 0.59] |
| Week 49 | 1.57 (1.40) [-1.21 ; 4.34] | 0.03 (1.59) [-3.12 ; 3.19] | 1.53 (2.12) [-2.67 ; 5.74] | 0.16 [-0.28 ; 0.60] |
| Week 55 | 2.36 (1.50) [-0.61 ; 5.33] | -0.04 (1.68) [-3.36 ; 3.28] | 2.40 (2.25) [-2.06 ; 6.86] | 0.25 [-0.21 ; 0.71] |
| Week 61 | 1.27 (1.50) [-1.70 ; 4.23] | -3.43 (1.78) [-6.94 ; 0.09] | 4.69 (2.32) [ 0.09 ; 9.30] | 0.49 [-0.00 ; 0.98] |
| Week 67 | 1.32 (1.78) [-2.22 ; 4.86] | -0.42 (2.09) [-4.56 ; 3.72] | 1.74 (2.74) [-3.71 ; 7.19] | 0.16 [-0.34 ; 0.65] |
| Week 73 | -0.55 (1.99) [-4.50 ; 3.40] | -2.64 (2.19) [-6.99 ; 1.71] | 2.09 (2.96) [-3.78 ; 7.96] | 0.19 [-0.35 ; 0.73] |
| Week 79 | 1.60 (1.96) [-2.30 ; 5.50] | -1.68 (2.11) [-5.87 ; 2.51] | 3.28 (2.88) [-2.44 ; 9.00] | 0.32 [-0.24 ; 0.88] |
| Week 85 | 2.52 (1.59) [-0.64 ; 5.68] | -2.46 (1.78) [-6.01 ; 1.08] | 4.98 (2.38) [ 0.24 ; 9.72] | 0.62 [ 0.01 ; 1.23] |
| Week 91 | 1.97 (1.52) [-1.07 ; 5.01] | -1.05 (1.79) [-4.64 ; 2.54] | 3.02 (2.35) [-1.67 ; 7.72] | 0.43 [-0.25 ; 1.11] |
| Week 97 | 2.29 (1.68) [-1.10 ; 5.68] | -1.60 (2.06) [-5.76 ; 2.55] | 3.89 (2.66) [-1.46 ; 9.25] | 0.54 [-0.23 ; 1.30] |
| Week 103 | 2.37 (1.74) [-1.18 ; 5.93] | -1.96 (2.03) [-6.10 ; 2.19] | 4.33 (2.67) [-1.13 ; 9.79] | 0.66 [-0.19 ; 1.51] |
| Overall post-baseline period estimate | 0.57 (0.93) [-1.26 ; 2.39] | -1.21 (1.00) [-3.19 ; 0.77] | 1.78 (1.37) [-0.92 ; 4.47] | 0.24 [-0.12 ; 0.59] |
| **Yes** | | | | |
| Nr subjects used | n=10 | n=6 | | |
| **MMRM subgroups interaction p-value** | | | | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:12

TABLE 7.1.11: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **>= 1%** | N=11 | N=9 |
| **< 1%** | N=58 | N=58 |
| **Not Reported** | N=2 | N=1 |
| **Subjects with Baseline Value** | | |
| **>= 1%** | 11 (100.0%) | 9 (100.0%) |
| **< 1%** | 58 (100.0%) | 58 (100.0%) |
| **Not Reported** | 2 (100.0%) | 1 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **>= 1%** | 11 (100.0%) | 9 (100.0%) |
| **< 1%** | 58 (100.0%) | 56 (96.6%) |
| **Not Reported** | 2 (100.0%) | 1 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **>= 1%** | 11 (100.0%) | 9 (100.0%) |
| **< 1%** | 58 (100.0%) | 56 (96.6%) |
| **Not Reported** | 2 (100.0%) | 1 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:12

TABLE 7.1.11: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **>= 1%** | | | |
| N subjects in population | N=11 | N=9 | |
| Baseline | n= 11 (100.0%) \| 81.64 (13.00) | n= 9 (100.0%) \| 80.00 (19.84) | 0.10 [-0.81 ; 1.00] |
| Week 3 | n= 11 (100.0%) \| 78.00 (13.79) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 9 (81.8%) \| 77.00 (14.31) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 10 (90.9%) \| 78.70 (11.94) | n= 9 (100.0%) \| 78.00 (15.96) | 0.05 [-0.88 ; 0.97] |
| Week 9 | n= 10 (90.9%) \| 74.70 (14.92) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (81.8%) \| 76.67 (13.51) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 9 (81.8%) \| 78.11 (21.17) | n= 7 (77.8%) \| 80.29 (16.55) | -0.11 [-1.13 ; 0.92] |
| Week 15 | n= 8 (72.7%) \| 65.25 (29.13) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 10 (90.9%) \| 77.90 (15.37) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 9 (81.8%) \| 79.11 (12.62) | n= 7 (77.8%) \| 86.57 (11.28) | -0.58 [-1.63 ; 0.46] |
| Week 21 | n= 9 (81.8%) \| 75.33 (14.65) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \| 73.90 (14.30) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 9 (81.8%) \| 77.67 (10.21) | n= 6 (66.7%) \| 86.67 (12.52) | -0.76 [-1.87 ; 0.35] |
| Week 27 | n= 8 (72.7%) \| 80.00 (13.61) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 8 (72.7%) \| 75.25 (21.31) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 8 (72.7%) \| 82.25 (8.83) | n= 6 (66.7%) \| 79.17 (11.14) | 0.29 [-0.82 ; 1.40] |
| Week 33 | n= 10 (90.9%) \| 80.20 (10.26) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (72.7%) \| 78.00 (13.53) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \| 78.63 (9.62) | n= 6 (66.7%) \| 85.83 (12.81) | -0.61 [-1.74 ; 0.52] |
| Week 39 | n= 9 (81.8%) \| 78.89 (11.26) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 10 (90.9%) \| 79.30 (11.40) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 9 (81.8%) \| 80.22 (12.74) | n= 7 (77.8%) \| 78.57 (17.73) | 0.10 [-0.92 ; 1.13] |
| Week 45 | n= 7 (63.6%) \| 77.86 (11.47) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 7 (63.6%) \| 82.86 (9.39) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 9 (81.8%) \| 79.22 (13.48) | n= 7 (77.8%) \| 85.71 (12.67) | -0.47 [-1.50 ; 0.57] |
| Week 51 | n= 9 (81.8%) \| 78.00 (11.74) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 7 (63.6%) \| 73.29 (29.52) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (63.6%) \| 71.29 (32.46) | n= 7 (77.8%) \| 84.00 (13.05) | -0.48 [-1.59 ; 0.63] |
| Week 57 | n= 6 (54.5%) \| 68.17 (34.98) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 8 (72.7%) \| 78.88 (14.11) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (72.7%) \| 79.63 (15.15) | n= 6 (66.7%) \| 80.00 (10.49) | -0.03 [-1.13 ; 1.08] |
| Week 63 | n= 7 (63.6%) \| 77.29 (16.49) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (63.6%) \| 78.57 (19.73) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \| 84.63 (6.14) | n= 6 (66.7%) \| 81.67 (12.11) | 0.30 [-0.80 ; 1.41] |
| Week 69 | n= 8 (72.7%) \| 76.63 (14.44) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 8 (72.7%) \| 74.75 (16.74) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 8 (72.7%) \| 77.63 (15.32) | n= 6 (66.7%) \| 79.17 (14.29) | -0.10 [-1.20 ; 1.01] |
| Week 75 | n= 8 (72.7%) \| 78.75 (15.56) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (54.5%) \| 73.83 (15.24) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (54.5%) \| 75.50 (15.67) | n= 4 (44.4%) \| 83.00 (9.27) | -0.50 [-1.87 ; 0.87] |
| Week 81 | n= 6 (54.5%) \| 76.67 (16.63) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 9 (81.8%) \| 79.33 (13.12) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (63.6%) \| 83.29 (6.40) | n= 3 (33.3%) \| 85.67 (15.04) | -0.23 [-1.67 ; 1.21] |
| Week 87 | n= 6 (54.5%) \| 75.67 (13.09) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 8 (72.7%) \| 80.88 (11.06) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 8 (72.7%) \| 78.50 (12.78) | n= 2 (22.2%) \| 81.50 (16.26) | -0.20 [-1.85 ; 1.45] |
| Week 93 | n= 6 (54.5%) \| 79.50 (15.48) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 8 (72.7%) \| 78.63 (13.69) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (63.6%) \| 79.43 (19.39) | n= 1 (11.1%) \| 89.00 ( / ) | [Not calculable] |
| Week 99 | n= 6 (54.5%) \| 81.50 (19.01) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 5 (45.5%) \| 84.00 (5.87) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 5 (45.5%) \| 85.80 (6.18) | n= 1 (11.1%) \| 90.00 ( / ) | [Not calculable] |
| Week 105 | n= 5 (45.5%) \| 78.20 (6.50) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \| 75.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (27.3%) \| 80.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 ( 9.1%) \| 75.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (27.3%) \| 83.67 (4.73) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (27.3%) \| 83.33 (5.77) | n= 2 (22.2%) \| 74.00 (15.56) | 0.67 [-1.55 ; 2.89] |
| Week 117 | n= 3 (27.3%) \| 85.67 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 (27.3%) \| 81.67 (2.89) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (18.2%) \| 78.50 (2.12) | n= 1 (11.1%) \| 92.00 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 9.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 9.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 9.1%) \| 80.00 ( / ) | n= 1 (11.1%) \| 100.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 9.1%) \| 81.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 9.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 9.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 9.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 9.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 9.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 9.1%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (27.3%) \| 73.67 (10.97) | n= 3 (33.3%) \| 81.67 (16.07) | -0.47 [-2.32 ; 1.39] |
| Week 202 | [No Data] | n= 1 (11.1%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| **< 1%** | | | |
| N subjects in population | N=58 | N=58 | |
| Baseline | n= 58 (100.0%) \| 77.57 (18.30) | n= 58 (100.0%) \| 79.50 (18.24) | -0.10 [-0.47 ; 0.26] |
| Week 3 | n= 54 (93.1%) \| 81.94 (13.08) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 54 (93.1%) \| 78.76 (16.84) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 54 (93.1%) \| 76.91 (18.71) | n= 52 (89.7%) \| 77.23 (17.53) | -0.02 [-0.40 ; 0.36] |
| Week 9 | n= 49 (84.5%) \| 78.37 (16.40) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 51 (87.9%) \| 76.82 (18.32) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 49 (84.5%) \| 75.10 (21.53) | n= 45 (77.6%) \| 79.47 (13.37) | -0.24 [-0.65 ; 0.17] |
| Week 15 | n= 45 (77.6%) \| 77.40 (17.98) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 50 (86.2%) \| 78.78 (15.71) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 47 (81.0%) \| 79.28 (17.39) | n= 45 (77.6%) \| 80.29 (13.86) | -0.06 [-0.47 ; 0.35] |
| Week 21 | n= 50 (86.2%) \| 78.82 (16.25) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 45 (77.6%) \| 76.93 (17.81) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 47 (81.0%) \| 81.38 (12.30) | n= 43 (74.1%) \| 83.67 (11.42) | -0.19 [-0.61 ; 0.23] |
| Week 27 | n= 46 (79.3%) \| 81.57 (12.58) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 44 (75.9%) \| 81.77 (12.10) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (77.6%) \| 81.20 (11.71) | n= 37 (63.8%) \| 81.49 (14.85) | -0.02 [-0.46 ; 0.42] |
| Week 33 | n= 46 (79.3%) \| 80.83 (13.30) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 44 (75.9%) \| 80.93 (13.90) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 40 (69.0%) \| 81.05 (14.23) | n= 39 (67.2%) \| 81.59 (13.96) | -0.04 [-0.48 ; 0.41] |
| Week 39 | n= 43 (74.1%) \| 82.42 (13.01) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 41 | n= 40 (69.0%) \| 82.43 (13.68) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 43 (74.1%) \| 81.53 (14.11) | n= 35 (60.3%) \| 81.97 (14.00) | -0.03 [-0.48 ; 0.42] |
| Week 45 | n= 41 (70.7%) \| 80.02 (13.84) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 44 (75.9%) \| 82.14 (12.62) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 43 (74.1%) \| 82.05 (13.55) | n= 30 (51.7%) \| 81.07 (13.52) | 0.07 [-0.40 ; 0.54] |
| Week 51 | n= 41 (70.7%) \| 81.93 (12.75) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 41 (70.7%) \| 81.17 (16.01) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (67.2%) \| 81.72 (14.59) | n= 29 (50.0%) \| 82.14 (14.62) | -0.03 [-0.51 ; 0.46] |
| Week 57 | n= 40 (69.0%) \| 81.68 (13.46) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (63.8%) \| 79.32 (19.05) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (67.2%) \| 82.49 (12.82) | n= 24 (41.4%) \| 78.00 (16.26) | 0.31 [-0.20 ; 0.83] |
| Week 63 | n= 34 (58.6%) \| 80.82 (13.86) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (62.1%) \| 80.47 (14.31) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (62.1%) \| 81.64 (14.79) | n= 24 (41.4%) \| 82.29 (12.83) | -0.05 [-0.57 ; 0.47] |
| Week 69 | n= 29 (50.0%) \| 81.38 (13.25) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (53.4%) \| 84.48 (13.08) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 26 (44.8%) \| 81.96 (14.17) | n= 22 (37.9%) \| 79.09 (17.52) | 0.18 [-0.40 ; 0.75] |
| Week 75 | n= 28 (48.3%) \| 82.50 (14.89) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (44.8%) \| 83.15 (13.31) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 25 (43.1%) \| 83.76 (16.50) | n= 21 (36.2%) \| 78.00 (17.67) | 0.33 [-0.26 ; 0.92] |
| Week 81 | n= 25 (43.1%) \| 84.84 (11.82) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 24 (41.4%) \| 85.54 (12.76) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (34.5%) \| 87.80 (9.05) | n= 18 (31.0%) \| 80.67 (16.72) | 0.53 [-0.13 ; 1.18] |
| Week 87 | n= 18 (31.0%) \| 83.61 (15.24) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 17 (29.3%) \| 83.29 (12.95) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 16 (27.6%) \| 84.31 (13.52) | n= 14 (24.1%) \| 85.50 (9.26) | -0.10 [-0.83 ; 0.63] |
| Week 93 | n= 15 (25.9%) \| 84.33 (14.48) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 14 (24.1%) \| 81.50 (16.10) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 14 (24.1%) \| 80.86 (15.01) | n= 10 (17.2%) \| 82.00 (11.83) | -0.08 [-0.91 ; 0.75] |
| Week 99 | n= 11 (19.0%) \| 77.64 (13.75) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 9 (15.5%) \| 78.78 (10.78) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 10 (17.2%) \| 80.80 (11.75) | n= 9 (15.5%) \| 81.33 (11.15) | -0.04 [-0.97 ; 0.88] |
| Week 105 | n= 9 (15.5%) \| 79.44 (12.92) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.3%) \| 79.67 (11.18) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (13.8%) \| 77.38 (12.22) | n= 5 ( 8.6%) \| 80.40 (9.07) | -0.25 [-1.42 ; 0.92] |
| Week 111 | n= 6 (10.3%) \| 78.50 (9.97) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 ( 8.6%) \| 80.00 (12.02) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 6.9%) \| 82.50 (14.06) | n= 3 ( 5.2%) \| 88.00 (7.55) | -0.39 [-2.06 ; 1.29] |
| Week 117 | n= 4 ( 6.9%) \| 80.75 (5.56) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 6.9%) \| 76.00 (12.36) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (10.3%) \| 82.33 (13.05) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 1.7%) \| 82.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.7%) \| 98.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 ( 8.6%) \| 81.00 (7.42) | n= 14 (24.1%) \| 78.07 (19.02) | 0.16 [-0.89 ; 1.22] |
| Week 202 | n= 1 ( 1.7%) \| 83.00 ( / ) | n= 11 (19.0%) \| 90.00 (8.90) | [Not calculable] |
| Week 301 | n= 1 ( 1.7%) \| 90.00 ( / ) | n= 9 (15.5%) \| 83.22 (7.81) | [Not calculable] |
| Week 302 | n= 2 ( 3.4%) \| 65.00 (21.21) | n= 6 (10.3%) \| 82.50 (5.24) | -1.54 [-3.51 ; 0.44] |
| Week 303 | n= 3 ( 5.2%) \| 56.67 (20.82) | n= 6 (10.3%) \| 82.00 (6.93) | -1.79 [-3.58 ;-0.00] |
| Week 304 | n= 1 ( 1.7%) \| 100.00 ( / ) | n= 3 ( 5.2%) \| 76.67 (11.55) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.7%) \| 75.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.7%) \| 70.00 ( / ) | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 307 | [No Data] | n= 1 ( 1.7%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.7%) \| 90.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.7%) \| 85.00 ( / ) | [No Data for at least 1 arm] |
| **Not Reported** | | | |
| N subjects in population | N=2 | N=1 | |
| Baseline | n= 2 (100.0%) \| 64.00 (19.80) | n= 1 (100.0%) \| 90.00 ( / ) | . [ . ; .] |
| Week 3 | n= 2 (100.0%) \| 63.50 (19.09) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (100.0%) \| 61.50 (23.33) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 2 (100.0%) \| 62.50 (17.68) | n= 1 (100.0%) \| 90.00 ( / ) | [Not calculable] |
| Week 11 | n= 1 (50.0%) \| 88.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (50.0%) \| 8.00 ( / ) | n= 1 (100.0%) \| 90.00 ( / ) | [Not calculable] |
| Week 15 | n= 1 (50.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 1 (50.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (50.0%) \| 80.00 ( / ) | n= 1 (100.0%) \| 77.00 ( / ) | [Not calculable] |
| Week 21 | n= 1 (50.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (50.0%) \| 81.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (50.0%) \| 82.00 ( / ) | n= 1 (100.0%) \| 80.00 ( / ) | [Not calculable] |
| Week 27 | n= 1 (50.0%) \| 82.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 1 (50.0%) \| 82.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (50.0%) \| 81.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (50.0%) \| 82.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 1 (50.0%) \| 82.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (50.0%) \| 82.00 ( / ) | n= 1 (100.0%) \| 80.00 ( / ) | [Not calculable] |
| Week 39 | n= 1 (50.0%) \| 82.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (50.0%) \| 84.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (50.0%) \| 83.00 ( / ) | n= 1 (100.0%) \| 80.00 ( / ) | [Not calculable] |
| Week 45 | n= 1 (50.0%) \| 83.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (50.0%) \| 83.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (50.0%) \| 82.00 ( / ) | n= 1 (100.0%) \| 80.00 ( / ) | [Not calculable] |
| Week 51 | n= 1 (50.0%) \| 79.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (50.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (50.0%) \| 79.00 ( / ) | n= 1 (100.0%) \| 80.00 ( / ) | [Not calculable] |
| Week 57 | n= 1 (50.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (50.0%) \| 85.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (50.0%) \| 82.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (50.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (50.0%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 202 | n= 1 (50.0%) \| 45.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 301 | n= 1 (50.0%) \| 50.00 ( / ) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:13

TABLE 7.1.11: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **>= 1%** | | | |
| N subjects in population | N=11 | N=9 | |
| Week 3 | n= 11 (100.0%) \|-5.00 (9.96) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 9 (81.8%) \|-6.78 (7.68) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 10 (90.9%) \|-6.60 (8.15) | n= 9 (100.0%) \|-2.00 (12.64) | -0.42 [-1.36 ; 0.52] |
| Week 9 | n= 10 (90.9%) \|-7.90 (8.94) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (81.8%) \|-5.89 (8.24) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 9 (81.8%) \|-4.44 (13.70) | n= 7 (77.8%) \|-6.14 (21.62) | 0.09 [-0.93 ; 1.11] |
| Week 15 | n= 8 (72.7%) \|-18.00 (26.50) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 10 (90.9%) \|-3.40 (10.53) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 9 (81.8%) \|-3.44 (8.53) | n= 7 (77.8%) \| 3.00 (11.24) | -0.62 [-1.67 ; 0.43] |
| Week 21 | n= 9 (81.8%) \|-5.11 (8.49) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \|-8.70 (7.70) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 9 (81.8%) \|-6.33 (7.47) | n= 6 (66.7%) \| 0.83 (16.86) | -0.56 [-1.66 ; 0.53] |
| Week 27 | n= 8 (72.7%) \|-4.50 (9.52) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 8 (72.7%) \|-8.13 (14.64) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 8 (72.7%) \| 0.25 (7.01) | n= 6 (66.7%) \|-6.67 (15.06) | 0.58 [-0.54 ; 1.71] |
| Week 33 | n= 10 (90.9%) \|-4.10 (7.13) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (72.7%) \|-5.38 (10.45) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \|-3.38 (6.72) | n= 6 (66.7%) \| 1.67 (13.29) | -0.47 [-1.59 ; 0.65] |
| Week 39 | n= 9 (81.8%) \|-3.67 (6.87) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 10 (90.9%) \|-5.00 (8.04) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 9 (81.8%) \|-2.33 (9.91) | n= 7 (77.8%) \|-7.86 (15.24) | 0.42 [-0.62 ; 1.45] |
| Week 45 | n= 7 (63.6%) \|-2.29 (7.50) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 7 (63.6%) \| 0.57 (14.05) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 9 (81.8%) \|-3.33 (6.73) | n= 7 (77.8%) \|-0.71 (17.43) | -0.20 [-1.22 ; 0.83] |
| Week 51 | n= 9 (81.8%) \|-4.56 (7.92) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 7 (63.6%) \|-14.29 (30.79) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (63.6%) \|-9.43 (32.86) | n= 7 (77.8%) \|-2.43 (17.16) | -0.25 [-1.35 ; 0.85] |
| Week 57 | n= 6 (54.5%) \|-15.17 (33.70) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 8 (72.7%) \|-3.63 (6.70) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (72.7%) \|-2.88 (8.71) | n= 6 (66.7%) \|-5.83 (11.14) | 0.28 [-0.83 ; 1.39] |
| Week 63 | n= 7 (63.6%) \|-4.29 (9.48) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (63.6%) \|-3.00 (10.89) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \|-2.88 (8.41) | n= 6 (66.7%) \|-4.17 (18.00) | 0.09 [-1.01 ; 1.19] |
| Week 69 | n= 8 (72.7%) \|-7.25 (10.57) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 8 (72.7%) \|-9.13 (11.24) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 8 (72.7%) \|-6.25 (9.97) | n= 6 (66.7%) \|-6.67 (16.63) | 0.03 [-1.07 ; 1.13] |
| Week 75 | n= 8 (72.7%) \|-5.13 (9.98) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (54.5%) \|-10.17 (9.75) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (54.5%) \|-6.67 (7.99) | n= 4 (44.4%) \| 1.75 (19.64) | -0.56 [-1.93 ; 0.82] |
| Week 81 | n= 6 (54.5%) \|-7.00 (11.75) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 9 (81.8%) \|-5.11 (9.55) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (63.6%) \|-4.00 (10.00) | n= 3 (33.3%) \|-7.67 (19.66) | 0.25 [-1.19 ; 1.70] |
| Week 87 | n= 6 (54.5%) \|-6.83 (5.56) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 8 (72.7%) \|-3.00 (9.35) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 8 (72.7%) \|-5.38 (9.64) | n= 2 (22.2%) \|-8.50 (30.41) | 0.20 [-1.45 ; 1.85] |
| Week 93 | n= 6 (54.5%) \| 0.17 (6.24) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 8 (72.7%) \|-5.25 (9.32) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (63.6%) \|-5.00 (13.63) | n= 1 (11.1%) \| 9.00 ( / ) | [Not calculable] |
| Week 99 | n= 6 (54.5%) \|-0.33 (12.04) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 5 (45.5%) \|-4.80 (11.99) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 5 (45.5%) \|-0.40 (8.41) | n= 1 (11.1%) \| 10.00 ( / ) | [Not calculable] |
| Week 105 | n= 5 (45.5%) \|-10.20 (7.76) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \|-5.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (27.3%) \|-11.67 (10.41) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 ( 9.1%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (27.3%) \|-8.00 (14.80) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (27.3%) \|-8.33 (16.07) | n= 2 (22.2%) \|-16.00 (29.70) | 0.26 [-1.87 ; 2.39] |
| Week 117 | n= 3 (27.3%) \|-6.00 (13.53) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 (27.3%) \|-10.00 (13.23) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (18.2%) \|-9.00 (8.49) | n= 1 (11.1%) \|-8.00 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 9.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 9.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 9.1%) \|-15.00 ( / ) | n= 1 (11.1%) \| 0.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 9.1%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 9.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 9.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 9.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 9.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 9.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 9.1%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (27.3%) \|-6.00 (5.20) | n= 3 (33.3%) \|-8.33 (10.41) | 0.23 [-1.60 ; 2.05] |
| Week 202 | [No Data] | n= 1 (11.1%) \|-20.00 ( / ) | [No Data for at least 1 arm] |
| **< 1%** | | | |
| N subjects in population | N=58 | N=58 | |
| Week 3 | n= 54 (93.1%) \| 3.46 (13.52) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 54 (93.1%) \|-0.26 (16.79) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 54 (93.1%) \|-1.06 (19.77) | n= 52 (89.7%) \|-1.21 (14.35) | 0.01 [-0.37 ; 0.39] |
| Week 9 | n= 49 (84.5%) \|-0.63 (19.47) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 51 (87.9%) \|-1.02 (22.46) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 49 (84.5%) \|-2.29 (23.16) | n= 45 (77.6%) \|-1.69 (18.82) | -0.03 [-0.43 ; 0.38] |
| Week 15 | n= 45 (77.6%) \| 0.13 (22.00) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 50 (86.2%) \| 1.74 (18.60) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 47 (81.0%) \| 1.47 (17.95) | n= 45 (77.6%) \|-3.22 (9.88) | 0.32 [-0.09 ; 0.73] |
| Week 21 | n= 50 (86.2%) \| 0.98 (17.63) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 45 (77.6%) \| 0.93 (19.33) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 47 (81.0%) \| 2.74 (14.33) | n= 43 (74.1%) \| 1.65 (16.20) | 0.07 [-0.34 ; 0.49] |
| Week 27 | n= 46 (79.3%) \| 3.37 (14.62) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 44 (75.9%) \| 3.66 (14.53) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (77.6%) \| 3.60 (14.62) | n= 37 (63.8%) \|-2.05 (13.53) | 0.40 [-0.05 ; 0.84] |
| Week 33 | n= 46 (79.3%) \| 1.80 (12.93) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 44 (75.9%) \| 3.32 (13.94) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 40 (69.0%) \| 3.63 (15.27) | n= 39 (67.2%) \|-1.62 (11.51) | 0.38 [-0.06 ; 0.83] |
| Week 39 | n= 43 (74.1%) \| 4.67 (13.80) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 40 (69.0%) \| 2.60 (12.77) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 43 (74.1%) \| 3.12 (15.03) | n= 35 (60.3%) \|-0.09 (13.67) | 0.22 [-0.23 ; 0.67] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 45 | n= 41 (70.7%) \| 1.02 (13.78) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 44 (75.9%) \| 3.91 (13.42) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 43 (74.1%) \| 4.26 (14.04) | n= 30 (51.7%) \|-0.83 (11.25) | 0.39 [-0.09 ; 0.86] |
| Week 51 | n= 41 (70.7%) \| 2.54 (10.80) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 41 (70.7%) \| 2.44 (14.55) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (67.2%) \| 3.31 (13.48) | n= 29 (50.0%) \|-0.59 (14.08) | 0.28 [-0.21 ; 0.77] |
| Week 57 | n= 40 (69.0%) \| 2.88 (13.48) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (63.8%) \| 0.97 (14.81) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (67.2%) \| 2.87 (12.93) | n= 24 (41.4%) \|-5.08 (15.40) | 0.56 [ 0.04 ; 1.09] |
| Week 63 | n= 34 (58.6%) \| 0.82 (9.96) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (62.1%) \| 3.44 (11.61) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (62.1%) \| 3.44 (13.58) | n= 24 (41.4%) \|-0.71 (12.79) | 0.31 [-0.21 ; 0.83] |
| Week 69 | n= 29 (50.0%) \| 3.14 (14.40) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (53.4%) \| 3.65 (10.62) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 26 (44.8%) \| 2.00 (12.52) | n= 22 (37.9%) \|-1.68 (13.64) | 0.28 [-0.30 ; 0.85] |
| Week 75 | n= 28 (48.3%) \| 1.93 (11.83) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (44.8%) \| 5.62 (14.35) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 25 (43.1%) \| 3.20 (12.51) | n= 21 (36.2%) \|-3.38 (13.93) | 0.49 [-0.10 ; 1.09] |
| Week 81 | n= 25 (43.1%) \| 2.88 (11.66) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 24 (41.4%) \| 3.92 (12.03) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (34.5%) \| 4.15 (9.93) | n= 18 (31.0%) \|-2.89 (12.76) | 0.61 [-0.05 ; 1.27] |
| Week 87 | n= 18 (31.0%) \| 2.11 (12.48) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 17 (29.3%) \| 1.71 (11.54) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 16 (27.6%) \| 2.75 (11.74) | n= 14 (24.1%) \| 1.64 (7.63) | 0.11 [-0.62 ; 0.84] |
| Week 93 | n= 15 (25.9%) \| 2.47 (11.92) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 14 (24.1%) \|-0.50 (8.84) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 14 (24.1%) \|-0.43 (7.66) | n= 10 (17.2%) \|-3.40 (5.17) | 0.42 [-0.41 ; 1.26] |
| Week 99 | n= 11 (19.0%) \|-1.27 (8.31) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 9 (15.5%) \| 0.44 (6.44) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 10 (17.2%) \| 1.40 (7.40) | n= 9 (15.5%) \|-3.11 (7.77) | 0.57 [-0.38 ; 1.52] |
| Week 105 | n= 9 (15.5%) \| 1.22 (7.33) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.3%) \| 2.33 (4.68) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (13.8%) \| 1.75 (5.82) | n= 5 ( 8.6%) \|-7.60 (12.66) | 0.97 [-0.27 ; 2.21] |
| Week 111 | n= 6 (10.3%) \|-0.50 (5.58) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 ( 8.6%) \|-0.80 (6.72) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 6.9%) \| 4.50 (8.66) | n= 3 ( 5.2%) \| 1.33 (7.09) | 0.33 [-1.34 ; 2.00] |
| Week 117 | n= 4 ( 6.9%) \|-2.75 (11.70) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 6.9%) \|-2.75 (10.69) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (10.3%) \|-0.17 (9.37) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 1.7%) \|-11.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.7%) \| 8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 ( 8.6%) \| 7.60 (26.90) | n= 14 (24.1%) \|-7.64 (15.90) | 0.76 [-0.32 ; 1.85] |
| Week 202 | n= 1 ( 1.7%) \|-4.00 ( / ) | n= 11 (19.0%) \| 1.36 (9.31) | [Not calculable] |
| Week 301 | n= 1 ( 1.7%) \| 10.00 ( / ) | n= 9 (15.5%) \| 1.89 (11.04) | [Not calculable] |
| Week 302 | n= 2 ( 3.4%) \|-10.00 (14.14) | n= 6 (10.3%) \| 1.67 (9.03) | -1.01 [-2.85 ; 0.84] |
| Week 303 | n= 3 ( 5.2%) \|-3.33 (15.28) | n= 6 (10.3%) \| 14.00 (28.96) | -0.60 [-2.12 ; 0.93] |
| Week 304 | n= 1 ( 1.7%) \| 0.00 ( / ) | n= 3 ( 5.2%) \| 2.00 (15.87) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.7%) \| 67.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.7%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.7%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.7%) \| 82.00 ( / ) | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 309 | [No Data] | n= 1 ( 1.7%) \| 77.00 ( / ) | [No Data for at least 1 arm] |
| **Not Reported** | | | |
| N subjects in population | N=2 | N=1 | |
| Week 3 | n= 2 (100.0%) \|-0.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (100.0%) \|-2.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 2 (100.0%) \|-1.50 (2.12) | n= 1 (100.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 11 | n= 1 (50.0%) \| 10.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (50.0%) \|-70.00 ( / ) | n= 1 (100.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 15 | n= 1 (50.0%) \| 2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 1 (50.0%) \| 2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (50.0%) \| 2.00 ( / ) | n= 1 (100.0%) \|-13.00 ( / ) | [Not calculable] |
| Week 21 | n= 1 (50.0%) \| 2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (50.0%) \| 3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (50.0%) \| 4.00 ( / ) | n= 1 (100.0%) \|-10.00 ( / ) | [Not calculable] |
| Week 27 | n= 1 (50.0%) \| 4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 1 (50.0%) \| 4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (50.0%) \| 3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (50.0%) \| 4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 1 (50.0%) \| 4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (50.0%) \| 4.00 ( / ) | n= 1 (100.0%) \|-10.00 ( / ) | [Not calculable] |
| Week 39 | n= 1 (50.0%) \| 4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (50.0%) \| 6.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (50.0%) \| 5.00 ( / ) | n= 1 (100.0%) \|-10.00 ( / ) | [Not calculable] |
| Week 45 | n= 1 (50.0%) \| 5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (50.0%) \| 5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (50.0%) \| 4.00 ( / ) | n= 1 (100.0%) \|-10.00 ( / ) | [Not calculable] |
| Week 51 | n= 1 (50.0%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (50.0%) \| 2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (50.0%) \| 1.00 ( / ) | n= 1 (100.0%) \|-10.00 ( / ) | [Not calculable] |
| Week 57 | n= 1 (50.0%) \| 2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (50.0%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (50.0%) \| 4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (50.0%) \| 2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (50.0%) \| 2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 202 | n= 1 (50.0%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 301 | n= 1 (50.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:13

TABLE 7.1.11: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **>= 1%** | | | | |
| Nr subjects used | n=11 | n=9 | | |
| **< 1%** | | | | |
| Nr subjects used | n=58 | n=58 | | |
| Week 7 | -2.46 (2.36) [-7.14 ; 2.23] | -2.12 (2.40) [-6.88 ; 2.63] | -0.33 (3.37) [-7.01 ; 6.34] | -0.02 [-0.40 ; 0.36] |
| Week 13 | -5.26 (3.02) [-11.25 ; 0.74] | -0.25 (3.11) [-6.42 ; 5.92] | -5.01 (4.34) [-13.61 ; 3.59] | -0.24 [-0.64 ; 0.17] |
| Week 19 | -0.66 (2.25) [-5.13 ; 3.81] | -0.46 (2.31) [-5.05 ; 4.12] | -0.20 (3.23) [-6.60 ; 6.20] | -0.01 [-0.42 ; 0.40] |
| Week 25 | 1.36 (1.69) [-1.99 ; 4.71] | 2.50 (1.75) [-0.96 ; 5.97] | -1.14 (2.43) [-5.97 ; 3.68] | -0.10 [-0.51 ; 0.32] |
| Week 31 | 1.70 (1.79) [-1.85 ; 5.25] | 0.75 (1.90) [-3.02 ; 4.52] | 0.95 (2.61) [-4.23 ; 6.13] | 0.08 [-0.36 ; 0.51] |
| Week 37 | 2.39 (1.82) [-1.22 ; 6.00] | 0.26 (1.90) [-3.51 ; 4.02] | 2.13 (2.63) [-3.09 ; 7.36] | 0.18 [-0.26 ; 0.62] |
| Week 43 | 1.79 (1.76) [-1.70 ; 5.28] | 1.31 (1.92) [-2.50 ; 5.12] | 0.48 (2.61) [-4.69 ; 5.66] | 0.04 [-0.40 ; 0.49] |
| Week 49 | 2.41 (1.41) [-0.39 ; 5.20] | 0.04 (1.62) [-3.17 ; 3.24] | 2.37 (2.15) [-1.89 ; 6.63] | 0.26 [-0.21 ; 0.73] |
| Week 55 | 2.65 (1.55) [-0.41 ; 5.71] | 0.91 (1.79) [-2.64 ; 4.45] | 1.75 (2.37) [-2.95 ; 6.44] | 0.18 [-0.30 ; 0.66] |
| Week 61 | 1.80 (1.62) [-1.42 ; 5.01] | -2.21 (1.96) [-6.10 ; 1.68] | 4.01 (2.55) [-1.05 ; 9.06] | 0.40 [-0.12 ; 0.91] |
| Week 67 | 1.58 (1.89) [-2.17 ; 5.33] | 0.45 (2.26) [-4.04 ; 4.94] | 1.12 (2.95) [-4.73 ; 6.98] | 0.10 [-0.42 ; 0.62] |
| Week 73 | 0.52 (2.08) [-3.61 ; 4.66] | -0.76 (2.35) [-5.44 ; 3.93] | 1.28 (3.14) [-4.97 ; 7.53] | 0.12 [-0.45 ; 0.68] |
| Week 79 | 2.21 (2.09) [-1.95 ; 6.37] | -1.21 (2.32) [-5.83 ; 3.41] | 3.42 (3.13) [-2.80 ; 9.64] | 0.32 [-0.27 ; 0.90] |
| Week 85 | 3.11 (1.82) [-0.52 ; 6.73] | -0.77 (1.97) [-4.71 ; 3.17] | 3.88 (2.68) [-1.47 ; 9.23] | 0.46 [-0.19 ; 1.11] |
| Week 91 | 2.91 (1.66) [-0.42 ; 6.25] | 0.95 (1.80) [-2.66 ; 4.57] | 1.96 (2.45) [-2.95 ; 6.87] | 0.28 [-0.44 ; 1.01] |
| Week 97 | 1.17 (1.94) [-2.76 ; 5.10] | -0.16 (2.21) [-4.65 ; 4.33] | 1.33 (2.94) [-4.64 ; 7.29] | 0.18 [-0.63 ; 0.99] |
| Overall post-baseline period estimate | 1.08 (1.05) [-1.00 ; 3.16] | -0.05 (1.14) [-2.31 ; 2.21] | 1.12 (1.56) [-1.95 ; 4.20] | 0.14 [-0.23 ; 0.50] |
| **Not Reported** | | | | |
| Nr subjects used | n=2 | n=1 | | |
| **MMRM subgroups interaction p-value** | | | | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:13

TABLE 7.1.12: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **Stage IV** | N=18 | N=20 |
| **Non-Stage IV** | N=50 | N=48 |
| **Not Reported** | N=3 | [No Data] |
| **Subjects with Baseline Value** | | |
| **Stage IV** | 18 (100.0%) | 20 (100.0%) |
| **Non-Stage IV** | 50 (100.0%) | 48 (100.0%) |
| **Not Reported** | 3 (100.0%) | [No Data] |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **Stage IV** | 18 (100.0%) | 20 (100.0%) |
| **Non-Stage IV** | 50 (100.0%) | 46 (95.8%) |
| **Not Reported** | 3 (100.0%) | [No Data] |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **Stage IV** | 18 (100.0%) | 20 (100.0%) |
| **Non-Stage IV** | 50 (100.0%) | 46 (95.8%) |
| **Not Reported** | 3 (100.0%) | [No Data] |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:16

TABLE 7.1.12: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Stage IV** | | | |
| N subjects in population | N=18 | N=20 | |
| Baseline | n= 18 (100.0%) \| 69.39 (22.74) | n= 20 (100.0%) \| 81.70 (15.20) | -0.63 [-1.29 ; 0.03] |
| Week 3 | n= 16 (88.9%) \| 74.94 (14.40) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 17 (94.4%) \| 76.12 (14.82) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 17 (94.4%) \| 74.47 (22.49) | n= 20 (100.0%) \| 81.75 (11.84) | -0.41 [-1.07 ; 0.26] |
| Week 9 | n= 14 (77.8%) \| 82.07 (14.82) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (83.3%) \| 77.73 (23.39) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 17 (94.4%) \| 68.00 (28.52) | n= 14 (70.0%) \| 84.64 (12.95) | -0.71 [-1.45 ; 0.03] |
| Week 15 | n= 15 (83.3%) \| 76.33 (22.89) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (77.8%) \| 80.57 (15.56) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 14 (77.8%) \| 71.14 (23.22) | n= 15 (75.0%) \| 82.60 (9.69) | -0.63 [-1.39 ; 0.13] |
| Week 21 | n= 16 (88.9%) \| 73.63 (22.43) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 12 (66.7%) \| 76.83 (11.83) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 14 (77.8%) \| 80.93 (12.06) | n= 14 (70.0%) \| 85.29 (11.56) | -0.36 [-1.12 ; 0.40] |
| Week 27 | n= 15 (83.3%) \| 81.27 (11.81) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 14 (77.8%) \| 80.43 (13.77) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 16 (88.9%) \| 81.88 (13.14) | n= 11 (55.0%) \| 86.36 (9.24) | -0.37 [-1.16 ; 0.42] |
| Week 33 | n= 15 (83.3%) \| 82.47 (13.31) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (72.2%) \| 80.00 (15.43) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 13 (72.2%) \| 78.92 (13.07) | n= 13 (65.0%) \| 84.69 (10.48) | -0.47 [-1.27 ; 0.32] |
| Week 39 | n= 14 (77.8%) \| 83.00 (14.14) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 13 (72.2%) \| 82.15 (14.20) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 14 (77.8%) \| 78.57 (15.70) | n= 13 (65.0%) \| 82.69 (10.30) | -0.30 [-1.07 ; 0.48] |
| Week 45 | n= 13 (72.2%) \| 78.08 (18.06) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 14 (77.8%) \| 79.86 (14.79) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 15 (83.3%) \| 79.47 (13.85) | n= 12 (60.0%) \| 81.50 (11.97) | -0.15 [-0.93 ; 0.62] |
| Week 51 | n= 12 (66.7%) \| 79.42 (12.58) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (72.2%) \| 80.00 (13.77) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 10 (55.6%) \| 78.90 (15.43) | n= 11 (55.0%) \| 83.64 (10.51) | -0.35 [-1.23 ; 0.54] |
| Week 57 | n= 10 (55.6%) \| 79.60 (14.70) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 12 (66.7%) \| 79.42 (14.91) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 12 (66.7%) \| 79.25 (14.35) | n= 7 (35.0%) \| 83.57 (9.45) | -0.32 [-1.29 ; 0.64] |
| Week 63 | n= 10 (55.6%) \| 81.20 (13.84) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (61.1%) \| 79.36 (17.30) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 11 (61.1%) \| 78.55 (18.92) | n= 8 (40.0%) \| 83.38 (10.34) | -0.29 [-1.23 ; 0.65] |
| Week 69 | n= 11 (61.1%) \| 79.27 (13.03) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 10 (55.6%) \| 81.70 (13.23) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 10 (55.6%) \| 77.80 (16.51) | n= 7 (35.0%) \| 82.43 (9.95) | -0.31 [-1.31 ; 0.70] |
| Week 75 | n= 9 (50.0%) \| 78.89 (15.46) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 7 (38.9%) \| 80.43 (14.89) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (50.0%) \| 76.44 (20.24) | n= 6 (30.0%) \| 80.00 (8.37) | -0.20 [-1.27 ; 0.87] |
| Week 81 | n= 7 (38.9%) \| 82.43 (11.89) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (38.9%) \| 82.14 (12.98) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (44.4%) \| 83.75 (10.96) | n= 6 (30.0%) \| 85.00 (10.49) | -0.11 [-1.21 ; 0.99] |
| Week 87 | n= 5 (27.8%) \| 84.00 (10.27) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 6 (33.3%) \| 76.50 (11.15) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 6 (33.3%) \| 81.17 (13.67) | n= 4 (20.0%) \| 78.75 (6.29) | 0.19 [-1.16 ; 1.54] |
| Week 93 | n= 4 (22.2%) \| 76.50 (15.80) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (27.8%) \| 77.80 (14.46) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (22.2%) \| 77.50 (15.95) | n= 1 ( 5.0%) \| 85.00 ( / ) | [Not calculable] |
| Week 99 | n= 3 (16.7%) \| 72.33 (7.51) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (16.7%) \| 71.67 (8.50) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (22.2%) \| 80.25 (13.30) | n= 1 ( 5.0%) \| 80.00 ( / ) | [Not calculable] |
| Week 105 | n= 3 (16.7%) \| 73.67 (7.77) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.1%) \| 70.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (22.2%) \| 81.00 (12.49) | n= 1 ( 5.0%) \| 80.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 5.6%) \| 75.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.1%) \| 76.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (16.7%) \| 84.33 (12.10) | n= 1 ( 5.0%) \| 63.00 ( / ) | [Not calculable] |
| Week 117 | n= 2 (11.1%) \| 83.50 (9.19) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (11.1%) \| 79.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (16.7%) \| 84.67 (11.72) | n= 1 ( 5.0%) \| 92.00 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 5.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 5.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (11.1%) \| 89.00 (12.73) | n= 1 ( 5.0%) \| 100.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 5.6%) \| 81.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 5.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 5.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 5.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 5.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 5.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 5.6%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 5.6%) \| 80.00 ( / ) | n= 6 (30.0%) \| 87.50 (12.14) | [Not calculable] |
| Week 202 | n= 1 ( 5.6%) \| 45.00 ( / ) | n= 4 (20.0%) \| 87.50 (11.90) | [Not calculable] |
| Week 301 | n= 1 ( 5.6%) \| 50.00 ( / ) | n= 3 (15.0%) \| 86.67 (7.64) | [Not calculable] |
| Week 302 | [No Data] | n= 2 (10.0%) \| 82.50 (3.54) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 5.6%) \| 40.00 ( / ) | n= 2 (10.0%) \| 85.00 (7.07) | [Not calculable] |
| Week 304 | [No Data] | n= 2 (10.0%) \| 80.00 (14.14) | [No Data for at least 1 arm] |
| **Non-Stage IV** | | | |
| N subjects in population | N=50 | N=48 | |
| Baseline | n= 50 (100.0%) \| 80.34 (14.75) | n= 48 (100.0%) \| 78.90 (19.42) | 0.08 [-0.31 ; 0.48] |
| Week 3 | n= 48 (96.0%) \| 83.02 (12.78) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 46 (92.0%) \| 78.59 (17.64) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 46 (92.0%) \| 77.43 (16.21) | n= 42 (87.5%) \| 75.55 (18.92) | 0.11 [-0.31 ; 0.53] |
| Week 9 | n= 43 (86.0%) \| 76.47 (16.45) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 44 (88.0%) \| 77.16 (15.56) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 41 (82.0%) \| 76.71 (20.14) | n= 39 (81.3%) \| 78.03 (13.57) | -0.08 [-0.52 ; 0.37] |
| Week 15 | n= 38 (76.0%) \| 75.92 (19.05) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 45 (90.0%) \| 78.00 (15.67) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 42 (84.0%) \| 81.71 (12.96) | n= 38 (79.2%) \| 80.45 (14.81) | 0.09 [-0.35 ; 0.53] |
| Week 21 | n= 43 (86.0%) \| 79.91 (12.64) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 43 (86.0%) \| 76.28 (18.47) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 42 (84.0%) \| 80.67 (12.08) | n= 36 (75.0%) \| 83.44 (11.40) | -0.23 [-0.68 ; 0.22] |
| Week 27 | n= 39 (78.0%) \| 81.41 (13.06) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 39 (78.0%) \| 80.92 (13.86) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 37 (74.0%) \| 80.89 (10.42) | n= 32 (66.7%) \| 79.38 (15.38) | 0.12 [-0.36 ; 0.59] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 33 | n= 41 (82.0%) \| 80.07 (12.61) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 40 (80.0%) \| 80.68 (13.20) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 35 (70.0%) \| 81.34 (13.81) | n= 33 (68.8%) \| 81.09 (14.67) | 0.02 [-0.46 ; 0.50] |
| Week 39 | n= 38 (76.0%) \| 81.42 (12.29) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 37 (74.0%) \| 81.78 (13.05) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 38 (76.0%) \| 82.55 (13.00) | n= 30 (62.5%) \| 80.80 (15.88) | 0.12 [-0.36 ; 0.60] |
| Week 45 | n= 35 (70.0%) \| 80.54 (11.50) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 37 (74.0%) \| 83.49 (10.86) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 37 (74.0%) \| 82.46 (13.38) | n= 26 (54.2%) \| 82.08 (13.88) | 0.03 [-0.48 ; 0.53] |
| Week 51 | n= 38 (76.0%) \| 81.76 (12.66) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 35 (70.0%) \| 82.06 (15.71) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 36 (72.0%) \| 82.44 (14.64) | n= 26 (54.2%) \| 81.92 (15.37) | 0.03 [-0.47 ; 0.54] |
| Week 57 | n= 36 (72.0%) \| 82.03 (13.85) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 33 (66.0%) \| 79.48 (19.38) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 35 (70.0%) \| 83.09 (12.70) | n= 23 (47.9%) \| 76.83 (16.34) | 0.43 [-0.10 ; 0.97] |
| Week 63 | n= 31 (62.0%) \| 80.06 (14.47) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 32 (64.0%) \| 80.28 (14.48) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (64.0%) \| 83.50 (11.63) | n= 22 (45.8%) \| 81.73 (13.37) | 0.14 [-0.41 ; 0.69] |
| Week 69 | n= 25 (50.0%) \| 80.92 (14.13) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (56.0%) \| 82.89 (15.03) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 24 (48.0%) \| 82.25 (13.49) | n= 21 (43.8%) \| 78.00 (18.40) | 0.26 [-0.33 ; 0.86] |
| Week 75 | n= 27 (54.0%) \| 82.59 (14.89) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (48.0%) \| 81.75 (14.25) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 21 (42.0%) \| 84.71 (14.80) | n= 19 (39.6%) \| 78.42 (18.60) | 0.37 [-0.26 ; 1.00] |
| Week 81 | n= 24 (48.0%) \| 83.50 (13.52) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (50.0%) \| 84.48 (13.41) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (38.0%) \| 87.84 (7.34) | n= 15 (31.3%) \| 79.93 (18.14) | 0.58 [-0.12 ; 1.29] |
| Week 87 | n= 19 (38.0%) \| 81.00 (16.04) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (38.0%) \| 84.42 (12.17) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 18 (36.0%) \| 82.78 (13.55) | n= 12 (25.0%) \| 87.08 (9.91) | -0.34 [-1.09 ; 0.41] |
| Week 93 | n= 17 (34.0%) \| 84.47 (14.31) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (34.0%) \| 81.24 (15.50) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (34.0%) \| 81.06 (16.57) | n= 10 (20.8%) \| 82.40 (12.01) | -0.09 [-0.88 ; 0.71] |
| Week 99 | n= 14 (28.0%) \| 80.43 (16.36) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (22.0%) \| 83.09 (8.38) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (22.0%) \| 83.27 (9.60) | n= 9 (18.8%) \| 82.44 (11.49) | 0.08 [-0.83 ; 0.98] |
| Week 105 | n= 11 (22.0%) \| 80.45 (11.32) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (12.0%) \| 81.33 (9.83) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (14.0%) \| 76.43 (9.48) | n= 4 ( 8.3%) \| 80.50 (10.47) | -0.38 [-1.69 ; 0.93] |
| Week 111 | n= 6 (12.0%) \| 78.50 (9.97) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (12.0%) \| 83.17 (10.38) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 8.0%) \| 81.75 (10.90) | n= 4 ( 8.3%) \| 87.25 (6.34) | -0.54 [-2.08 ; 1.00] |
| Week 117 | n= 5 (10.0%) \| 82.60 (5.03) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (10.0%) \| 78.20 (11.48) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (10.0%) \| 79.40 (11.74) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.0%) \| 82.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 (10.0%) \| 76.20 (11.05) | n= 11 (22.9%) \| 73.91 (19.49) | 0.12 [-0.97 ; 1.22] |
| Week 202 | n= 1 ( 2.0%) \| 83.00 ( / ) | n= 8 (16.7%) \| 88.75 (10.21) | [Not calculable] |
| Week 301 | n= 1 ( 2.0%) \| 90.00 ( / ) | n= 6 (12.5%) \| 81.50 (7.97) | [Not calculable] |
| Week 302 | n= 1 ( 2.0%) \| 80.00 ( / ) | n= 4 ( 8.3%) \| 82.50 (6.45) | [Not calculable] |
| Week 303 | n= 1 ( 2.0%) \| 80.00 ( / ) | n= 4 ( 8.3%) \| 80.50 (7.37) | [Not calculable] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 304 | n= 1 ( 2.0%) \| 100.00 ( / ) | n= 1 ( 2.1%) \| 70.00 ( / ) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 2.1%) \| 75.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 2.1%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 2.1%) \| 70.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 2.1%) \| 90.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 2.1%) \| 85.00 ( / ) | [No Data for at least 1 arm] |
| **Not Reported** | | | |
| N subjects in population | N=3 | [No Data] | |
| Baseline | n= 3 (100.0%) \| 86.33 (15.18) | [No Data] | |
| Week 3 | n= 3 (100.0%) \| 75.33 (14.50) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (66.7%) \| 80.00 (14.14) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 3 (100.0%) \| 79.00 (16.52) | [No Data] | [No Data for at least 1 arm] |
| Week 9 | n= 2 (66.7%) \| 75.00 (21.21) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 2 (66.7%) \| 67.50 (10.61) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (33.3%) \| 90.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 15 | n= 1 (33.3%) \| 55.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 2 (66.7%) \| 80.00 (14.14) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (33.3%) \| 90.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 21 | n= 1 (33.3%) \| 85.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (33.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (33.3%) \| 85.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 27 | n= 1 (33.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (33.3%) \| 90.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (33.3%) \| 82.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (33.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 39 | n= 1 (33.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (33.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (33.3%) \| 74.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 45 | n= 1 (33.3%) \| 75.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (33.3%) \| 70.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (33.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 51 | n= 1 (33.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (33.3%) \| 9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (33.3%) \| 8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 57 | n= 1 (33.3%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (33.3%) \| 75.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (33.3%) \| 77.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (33.3%) \| 75.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (33.3%) \| 85.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 1 (33.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 69 | n= 1 (33.3%) \| 78.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 1 (33.3%) \| 79.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 1 (33.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 1 (33.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 1 (33.3%) \| 80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (66.7%) \| 82.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 302 | n= 1 (33.3%) \| 50.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 303 | n= 1 (33.3%) \| 50.00 ( / ) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:17

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Stage IV** | | | |
| N subjects in population | N=18 | N=20 | |
| Week 3 | n= 16 (88.9%) \| 5.38 (19.87) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 17 (94.4%) \| 6.06 (22.40) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 17 (94.4%) \| 4.71 (25.17) | n= 20 (100.0%) \| 0.05 (11.10) | 0.24 [-0.42 ; 0.90] |
| Week 9 | n= 14 (77.8%) \| 10.29 (25.85) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (83.3%) \| 5.67 (33.44) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 17 (94.4%) \|-2.35 (32.87) | n= 14 (70.0%) \|-1.71 (16.85) | -0.02 [-0.74 ; 0.70] |
| Week 15 | n= 15 (83.3%) \| 5.27 (32.80) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (77.8%) \| 10.14 (25.26) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 14 (77.8%) \| 1.43 (28.68) | n= 15 (75.0%) \|-1.33 (8.49) | 0.13 [-0.61 ; 0.87] |
| Week 21 | n= 16 (88.9%) \| 2.63 (27.08) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 12 (66.7%) \| 8.17 (19.79) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 14 (77.8%) \| 9.86 (19.95) | n= 14 (70.0%) \|-1.43 (10.65) | 0.69 [-0.09 ; 1.46] |
| Week 27 | n= 15 (83.3%) \| 10.87 (17.19) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 14 (77.8%) \| 9.43 (20.14) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 16 (88.9%) \| 10.88 (18.60) | n= 11 (55.0%) \| 0.00 (12.04) | 0.65 [-0.16 ; 1.45] |
| Week 33 | n= 15 (83.3%) \| 7.20 (16.11) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (72.2%) \| 11.23 (18.64) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 13 (72.2%) \| 10.00 (22.85) | n= 13 (65.0%) \|-1.00 (6.03) | 0.64 [-0.17 ; 1.44] |
| Week 39 | n= 14 (77.8%) \| 11.21 (19.03) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 13 (72.2%) \| 5.69 (15.84) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 14 (77.8%) \| 6.36 (21.62) | n= 13 (65.0%) \|-1.85 (12.60) | 0.45 [-0.33 ; 1.22] |
| Week 45 | n= 13 (72.2%) \| 4.54 (19.35) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 14 (77.8%) \| 8.36 (19.60) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 15 (83.3%) \| 8.53 (20.03) | n= 12 (60.0%) \|-3.42 (11.49) | 0.69 [-0.11 ; 1.49] |
| Week 51 | n= 12 (66.7%) \| 5.75 (16.55) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (72.2%) \| 5.85 (17.34) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 10 (55.6%) \| 9.00 (19.13) | n= 11 (55.0%) \|-3.09 (11.84) | 0.74 [-0.17 ; 1.65] |
| Week 57 | n= 10 (55.6%) \| 6.20 (21.57) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 12 (66.7%) \| 5.75 (17.81) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 12 (66.7%) \| 5.58 (17.36) | n= 7 (35.0%) \|-5.57 (7.79) | 0.72 [-0.27 ; 1.71] |
| Week 63 | n= 10 (55.6%) \| 1.50 (6.84) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (61.1%) \| 6.27 (15.60) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 11 (61.1%) \| 5.45 (17.36) | n= 8 (40.0%) \|-3.38 (12.03) | 0.55 [-0.41 ; 1.50] |
| Week 69 | n= 11 (61.1%) \| 6.18 (18.37) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 10 (55.6%) \| 2.00 (11.94) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 10 (55.6%) \|-1.90 (16.99) | n= 7 (35.0%) \|-4.57 (11.60) | 0.17 [-0.83 ; 1.17] |
| Week 75 | n= 9 (50.0%) \| 0.33 (11.66) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 7 (38.9%) \| 10.57 (22.40) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (50.0%) \|-2.11 (11.96) | n= 6 (30.0%) \|-6.50 (9.87) | 0.37 [-0.71 ; 1.45] |
| Week 81 | n= 7 (38.9%) \| 0.71 (8.69) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (38.9%) \| 1.86 (13.46) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (44.4%) \| 2.25 (8.45) | n= 6 (30.0%) \|-5.67 (12.03) | 0.73 [-0.41 ; 1.88] |
| Week 87 | n= 5 (27.8%) \|-2.20 (9.04) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 6 (33.3%) \|-3.83 (6.97) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 6 (33.3%) \|-2.50 (7.79) | n= 4 (20.0%) \|-9.75 (14.15) | 0.62 [-0.77 ; 2.00] |
| Week 93 | n= 4 (22.2%) \|-2.75 (1.71) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (27.8%) \|-4.60 (6.11) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (22.2%) \|-3.00 (9.49) | n= 1 ( 5.0%) \|-9.00 ( / ) | [Not calculable] |
| Week 99 | n= 3 (16.7%) \|-5.00 (9.54) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (16.7%) \|-5.67 (8.62) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (22.2%) \|-0.25 (11.24) | n= 1 ( 5.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 105 | n= 3 (16.7%) \|-3.67 (10.02) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.1%) \| 1.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (22.2%) \| 0.50 (10.66) | n= 1 ( 5.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 5.6%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.1%) \|-9.50 (7.78) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (16.7%) \|-2.67 (11.59) | n= 1 ( 5.0%) \|-37.00 ( / ) | [Not calculable] |
| Week 117 | n= 2 (11.1%) \|-2.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (11.1%) \|-6.50 (12.02) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (16.7%) \|-2.33 (11.68) | n= 1 ( 5.0%) \|-8.00 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 5.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 5.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (11.1%) \|-3.50 (16.26) | n= 1 ( 5.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 5.6%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 5.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 5.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 5.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 5.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 5.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 5.6%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 5.6%) \| 50.00 ( / ) | n= 6 (30.0%) \| 0.00 (10.49) | [Not calculable] |
| Week 202 | n= 1 ( 5.6%) \|-5.00 ( / ) | n= 4 (20.0%) \| 2.50 (11.90) | [Not calculable] |
| Week 301 | n= 1 ( 5.6%) \| 0.00 ( / ) | n= 3 (15.0%) \| 3.33 (10.41) | [Not calculable] |
| Week 302 | [No Data] | n= 2 (10.0%) \| 7.50 (10.61) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 5.6%) \| 10.00 ( / ) | n= 2 (10.0%) \| 10.00 (0.00) | [Not calculable] |
| Week 304 | [No Data] | n= 2 (10.0%) \| 5.00 (21.21) | [No Data for at least 1 arm] |
| **Non-Stage IV** | | | |
| N subjects in population | N=50 | N=48 | |
| Week 3 | n= 48 (96.0%) \| 1.63 (10.01) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 46 (92.0%) \|-3.76 (11.97) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 46 (92.0%) \|-4.00 (15.13) | n= 42 (87.5%) \|-1.95 (15.13) | -0.13 [-0.56 ; 0.29] |
| Week 9 | n= 43 (86.0%) \|-5.70 (13.71) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 44 (88.0%) \|-3.55 (14.66) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 41 (82.0%) \|-4.46 (18.96) | n= 39 (81.3%) \|-2.44 (19.75) | -0.10 [-0.55 ; 0.34] |
| Week 15 | n= 38 (76.0%) \|-4.76 (17.49) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 45 (90.0%) \|-1.96 (13.75) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 42 (84.0%) \| 0.45 (10.91) | n= 38 (79.2%) \|-3.08 (10.85) | 0.32 [-0.12 ; 0.77] |
| Week 21 | n= 43 (86.0%) \|-0.77 (10.85) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 43 (86.0%) \|-3.05 (17.03) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 42 (84.0%) \|-1.38 (9.87) | n= 36 (75.0%) \| 2.39 (17.69) | -0.27 [-0.72 ; 0.18] |
| Week 27 | n= 39 (78.0%) \|-0.79 (11.40) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 39 (78.0%) \|-0.82 (11.66) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 37 (74.0%) \|-0.22 (9.52) | n= 32 (66.7%) \|-3.63 (14.23) | 0.28 [-0.20 ; 0.76] |
| Week 33 | n= 41 (82.0%) \|-1.34 (9.72) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 40 (80.0%) \|-0.98 (10.13) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 37 | n= 35 (70.0%) \| 0.03 (8.39) | n= 33 (68.8%) \|-1.52 (13.25) | 0.14 [-0.34 ; 0.62] |
| Week 39 | n= 38 (76.0%) \| 0.63 (8.84) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 37 (74.0%) \|-0.14 (10.52) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 38 (76.0%) \| 1.16 (10.20) | n= 30 (62.5%) \|-1.47 (14.70) | 0.21 [-0.27 ; 0.69] |
| Week 45 | n= 35 (70.0%) \|-0.40 (9.51) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 37 (74.0%) \| 2.24 (9.29) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 37 (74.0%) \| 1.03 (8.68) | n= 26 (54.2%) \| 0.04 (12.69) | 0.09 [-0.41 ; 0.60] |
| Week 51 | n= 38 (76.0%) \| 0.11 (7.58) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 35 (70.0%) \| 0.17 (12.58) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 36 (72.0%) \| 1.53 (10.25) | n= 26 (54.2%) \|-0.38 (15.44) | 0.15 [-0.36 ; 0.66] |
| Week 57 | n= 36 (72.0%) \| 1.28 (9.45) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 33 (66.0%) \|-1.24 (11.55) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 35 (70.0%) \| 1.09 (10.02) | n= 23 (47.9%) \|-5.13 (16.11) | 0.48 [-0.06 ; 1.02] |
| Week 63 | n= 31 (62.0%) \|-0.03 (10.54) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 32 (64.0%) \| 1.25 (9.83) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (64.0%) \| 1.56 (11.28) | n= 22 (45.8%) \|-0.68 (14.45) | 0.17 [-0.37 ; 0.72] |
| Week 69 | n= 25 (50.0%) \|-0.96 (11.82) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (56.0%) \| 1.07 (12.00) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 24 (48.0%) \| 0.88 (10.17) | n= 21 (43.8%) \|-2.14 (15.11) | 0.23 [-0.36 ; 0.83] |
| Week 75 | n= 27 (54.0%) \| 0.37 (11.93) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (48.0%) \| 0.83 (11.74) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 21 (42.0%) \| 3.24 (12.48) | n= 19 (39.6%) \|-1.32 (15.84) | 0.31 [-0.32 ; 0.95] |
| Week 81 | n= 24 (48.0%) \| 1.04 (13.14) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (50.0%) \| 1.76 (11.88) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (38.0%) \| 1.95 (11.35) | n= 15 (31.3%) \|-2.73 (14.24) | 0.36 [-0.33 ; 1.05] |
| Week 87 | n= 19 (38.0%) \| 0.42 (12.49) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (38.0%) \| 1.47 (11.76) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 18 (36.0%) \| 0.89 (12.64) | n= 12 (25.0%) \| 3.75 (8.06) | -0.25 [-1.00 ; 0.49] |
| Week 93 | n= 17 (34.0%) \| 2.88 (11.44) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (34.0%) \|-1.53 (9.85) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (34.0%) \|-1.71 (10.31) | n= 10 (20.8%) \|-1.60 (6.06) | -0.01 [-0.81 ; 0.78] |
| Week 99 | n= 14 (28.0%) \|-0.07 (9.51) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (22.0%) \|-0.27 (8.82) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (22.0%) \| 1.18 (6.34) | n= 9 (18.8%) \|-2.00 (8.90) | 0.40 [-0.51 ; 1.32] |
| Week 105 | n= 11 (22.0%) \|-2.64 (9.42) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (12.0%) \| 0.17 (6.52) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (14.0%) \|-3.29 (8.85) | n= 4 ( 8.3%) \|-9.50 (13.77) | 0.53 [-0.79 ; 1.85] |
| Week 111 | n= 6 (12.0%) \|-1.17 (5.88) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (12.0%) \|-1.50 (10.58) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 8.0%) \| 0.25 (15.71) | n= 4 ( 8.3%) \| 2.25 (6.08) | -0.15 [-1.65 ; 1.36] |
| Week 117 | n= 5 (10.0%) \|-5.00 (13.82) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (10.0%) \|-5.60 (12.62) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (10.0%) \|-2.40 (9.42) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.0%) \|-11.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 (10.0%) \|-7.20 (8.38) | n= 11 (22.9%) \|-12.00 (15.47) | 0.33 [-0.77 ; 1.43] |
| Week 202 | n= 1 ( 2.0%) \|-4.00 ( / ) | n= 8 (16.7%) \|-1.88 (10.75) | [Not calculable] |
| Week 301 | n= 1 ( 2.0%) \| 10.00 ( / ) | n= 6 (12.5%) \| 1.17 (12.24) | [Not calculable] |
| Week 302 | n= 1 ( 2.0%) \| 0.00 ( / ) | n= 4 ( 8.3%) \|-1.25 (8.02) | [Not calculable] |
| Week 303 | n= 1 ( 2.0%) \| 0.00 ( / ) | n= 4 ( 8.3%) \| 16.00 (37.18) | [Not calculable] |
| Week 304 | n= 1 ( 2.0%) \| 0.00 ( / ) | n= 1 ( 2.1%) \|-4.00 ( / ) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 2.1%) \| 67.00 ( / ) | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 306 | [No Data] | n= 1 ( 2.1%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 2.1%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 2.1%) \| 82.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 2.1%) \| 77.00 ( / ) | [No Data for at least 1 arm] |
| **Not Reported** | | | |
| N subjects in population | N=3 | [No Data] | |
| Week 3 | n= 3 (100.0%) \|-11.00 (2.65) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (66.7%) \|-5.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 3 (100.0%) \|-7.33 (7.37) | [No Data] | [No Data for at least 1 arm] |
| Week 9 | n= 2 (66.7%) \|-4.50 (7.78) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 2 (66.7%) \|-12.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (33.3%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 15 | n= 1 (33.3%) \|-34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 2 (66.7%) \| 0.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (33.3%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 21 | n= 1 (33.3%) \|-4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (33.3%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (33.3%) \|-4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 27 | n= 1 (33.3%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (33.3%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (33.3%) \|-7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (33.3%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 39 | n= 1 (33.3%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (33.3%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (33.3%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 45 | n= 1 (33.3%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (33.3%) \|-19.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (33.3%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 51 | n= 1 (33.3%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (33.3%) \|-80.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (33.3%) \|-81.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 57 | n= 1 (33.3%) \|-82.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (33.3%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (33.3%) \|-12.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (33.3%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (33.3%) \|-4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 1 (33.3%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 69 | n= 1 (33.3%) \|-11.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 1 (33.3%) \|-10.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 1 (33.3%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 1 (33.3%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 1 (33.3%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (66.7%) \| 3.00 (16.97) | [No Data] | [No Data for at least 1 arm] |
| Week 302 | n= 1 (33.3%) \|-20.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 303 | n= 1 (33.3%) \|-20.00 ( / ) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020

[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:17

TABLE 7.1.12: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **Stage IV** | | | | |
| Nr subjects used | n=18 | n=20 | | |
| Week 7 | 0.00 (3.80) [-7.67 ; 7.68] | 2.59 (3.52) [-4.53 ; 9.71] | -2.59 (5.22) [-13.12 ; 7.95] | -0.16 [-0.81 ; 0.49] |
| Week 13 | -7.70 (5.55) [-18.95 ; 3.55] | 3.40 (5.61) [-7.95 ; 14.75] | -11.10 (7.92) [-27.12 ; 4.92] | -0.49 [-1.21 ; 0.23] |
| Week 19 | -3.63 (4.88) [-13.58 ; 6.32] | 0.61 (4.70) [-8.96 ; 10.19] | -4.24 (6.81) [-18.12 ; 9.63] | -0.23 [-0.96 ; 0.50] |
| Week 25 | 4.38 (2.76) [-1.26 ; 10.01] | 4.07 (2.73) [-1.48 ; 9.62] | 0.31 (3.96) [-7.74 ; 8.36] | 0.03 [-0.71 ; 0.77] |
| Week 31 | 6.77 (2.46) [ 1.78 ; 11.77] | 6.66 (2.66) [ 1.27 ; 12.05] | 0.12 (3.71) [-7.39 ; 7.62] | 0.01 [-0.76 ; 0.78] |
| Week 37 | 6.06 (2.91) [ 0.12 ; 11.99] | 3.43 (2.95) [-2.58 ; 9.43] | 2.63 (4.22) [-5.94 ; 11.20] | 0.24 [-0.53 ; 1.01] |
| Week 43 | 3.50 (3.03) [-2.64 ; 9.64] | 3.57 (3.16) [-2.83 ; 9.98] | -0.07 (4.44) [-9.07 ; 8.93] | -0.01 [-0.76 ; 0.75] |
| Week 49 | 3.33 (2.62) [-1.97 ; 8.62] | 1.27 (2.88) [-4.54 ; 7.09] | 2.05 (3.96) [-5.95 ; 10.06] | 0.20 [-0.56 ; 0.96] |
| Week 55 | 6.43 (2.98) [ 0.33 ; 12.53] | 2.03 (3.02) [-4.15 ; 8.21] | 4.40 (4.31) [-4.41 ; 13.22] | 0.43 [-0.43 ; 1.30] |
| Overall post-baseline period estimate | 2.13 (2.26) [-2.45 ; 6.70] | 3.07 (2.22) [-1.42 ; 7.56] | -0.94 (3.26) [-7.52 ; 5.63] | -0.09 [-0.73 ; 0.54] |
| **Non-Stage IV** | | | | |
| Nr subjects used | n=50 | n=48 | | |
| Week 7 | -4.91 (2.51) [-9.90 ; 0.08] | -3.53 (2.62) [-8.75 ; 1.69] | -1.38 (3.63) [-8.59 ; 5.84] | -0.08 [-0.50 ; 0.34] |
| Week 13 | -7.21 (3.61) [-14.41 ;-0.01] | -1.89 (3.76) [-9.38 ; 5.60] | -5.32 (5.21) [-15.70 ; 5.06] | -0.23 [-0.67 ; 0.21] |
| Week 19 | -0.86 (2.04) [-4.92 ; 3.20] | -0.98 (2.15) [-5.26 ; 3.30] | 0.12 (2.97) [-5.78 ; 6.02] | 0.01 [-0.43 ; 0.45] |
| Week 25 | -1.44 (1.80) [-5.03 ; 2.14] | 1.78 (1.93) [-2.05 ; 5.61] | -3.22 (2.64) [-8.47 ; 2.03] | -0.27 [-0.72 ; 0.17] |
| Week 31 | -1.17 (1.94) [-5.02 ; 2.68] | -1.83 (2.07) [-5.96 ; 2.29] | 0.66 (2.84) [-4.98 ; 6.30] | 0.06 [-0.42 ; 0.53] |
| Week 37 | -0.61 (2.00) [-4.59 ; 3.37] | -0.91 (2.13) [-5.15 ; 3.33] | 0.29 (2.92) [-5.52 ; 6.11] | 0.02 [-0.45 ; 0.50] |
| Week 43 | -0.04 (2.08) [-4.17 ; 4.08] | -0.87 (2.30) [-5.45 ; 3.71] | 0.82 (3.10) [-5.34 ; 6.99] | 0.06 [-0.41 ; 0.54] |
| Week 49 | 0.46 (1.58) [-2.67 ; 3.60] | 0.41 (1.82) [-3.20 ; 4.02] | 0.05 (2.41) [-4.73 ; 4.83] | 0.01 [-0.50 ; 0.51] |
| Week 55 | 0.52 (1.69) [-2.83 ; 3.87] | 0.50 (1.97) [-3.41 ; 4.40] | 0.03 (2.59) [-5.12 ; 5.17] | 0.00 [-0.50 ; 0.51] |
| Week 61 | -0.19 (1.73) [-3.62 ; 3.24] | -3.46 (2.08) [-7.59 ; 0.66] | 3.27 (2.70) [-2.10 ; 8.63] | 0.32 [-0.21 ; 0.85] |
| Week 67 | 0.35 (1.81) [-3.25 ; 3.95] | -0.56 (2.18) [-4.89 ; 3.76] | 0.91 (2.83) [-4.71 ; 6.54] | 0.09 [-0.46 ; 0.63] |
| Week 73 | -0.43 (1.75) [-3.91 ; 3.04] | -2.57 (2.00) [-6.53 ; 1.40] | 2.13 (2.66) [-3.14 ; 7.41] | 0.24 [-0.35 ; 0.82] |
| Week 79 | 1.52 (1.93) [-2.30 ; 5.35] | -0.60 (2.15) [-4.86 ; 3.66] | 2.13 (2.88) [-3.60 ; 7.85] | 0.23 [-0.39 ; 0.85] |
| Week 85 | 1.30 (1.80) [-2.29 ; 4.89] | -0.77 (2.06) [-4.88 ; 3.34] | 2.07 (2.74) [-3.39 ; 7.53] | 0.26 [-0.42 ; 0.94] |
| Week 91 | 1.09 (1.79) [-2.49 ; 4.66] | 1.64 (2.14) [-2.64 ; 5.91] | -0.55 (2.78) [-6.12 ; 5.03] | -0.07 [-0.80 ; 0.66] |
| Week 97 | 0.28 (2.27) [-4.32 ; 4.88] | 0.27 (2.84) [-5.47 ; 6.01] | 0.01 (3.63) [-7.35 ; 7.37] | 0.00 [-0.78 ; 0.78] |
| Overall post-baseline period estimate | -0.71 (1.15) [-2.99 ; 1.57] | -0.84 (1.28) [-3.36 ; 1.69] | 0.13 (1.72) [-3.28 ; 3.53] | 0.02 [-0.39 ; 0.42] |
| **Not Reported** | | | | |
| Nr subjects used | n=3 | [No Data] | | |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.1792 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020

[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:18

TABLE 7.2.1: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| subtit | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| N subjects | N=71 | N=68 |
| Subjects with Baseline Value | 71 (100.0%) | 68 (100.0%) |
| Subjects with at least 1 Post-Baseline Value | 71 (100.0%) | 66 (97.1%) |
| Subjects with Baseline Value and at least 1 Post-Baseline Value | 71 (100.0%) | 66 (97.1%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:41

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Baseline | n= 71 (100.0%) \| 0.83 (0.20) | n= 68 (100.0%) \| 0.79 (0.29) | 0.18 [-0.15 ; 0.52] |
| Week 3 | n= 66 (93.0%) \| 0.83 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 64 (90.1%) \| 0.80 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 64 (90.1%) \| 0.79 (0.21) | n= 62 (91.2%) \| 0.79 (0.24) | 0.03 [-0.32 ; 0.38] |
| Week 9 | n= 59 (83.1%) \| 0.80 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 61 (85.9%) \| 0.79 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 59 (83.1%) \| 0.81 (0.21) | n= 52 (76.5%) \| 0.76 (0.23) | 0.24 [-0.14 ; 0.62] |
| Week 15 | n= 54 (76.1%) \| 0.78 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 61 (85.9%) \| 0.79 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 57 (80.3%) \| 0.81 (0.20) | n= 51 (75.0%) \| 0.82 (0.19) | -0.04 [-0.42 ; 0.34] |
| Week 21 | n= 60 (84.5%) \| 0.81 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 55 (77.5%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 58 (81.7%) \| 0.83 (0.21) | n= 50 (73.5%) \| 0.81 (0.17) | 0.08 [-0.30 ; 0.46] |
| Week 27 | n= 55 (77.5%) \| 0.84 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 53 (74.6%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \| 0.82 (0.21) | n= 43 (63.2%) \| 0.80 (0.21) | 0.11 [-0.29 ; 0.51] |
| Week 33 | n= 57 (80.3%) \| 0.82 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 53 (74.6%) \| 0.83 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 49 (69.0%) \| 0.85 (0.19) | n= 44 (64.7%) \| 0.81 (0.17) | 0.18 [-0.23 ; 0.59] |
| Week 39 | n= 53 (74.6%) \| 0.83 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 51 (71.8%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 53 (74.6%) \| 0.83 (0.18) | n= 41 (60.3%) \| 0.81 (0.18) | 0.12 [-0.29 ; 0.53] |
| Week 45 | n= 49 (69.0%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 52 (73.2%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 53 (74.6%) \| 0.86 (0.17) | n= 37 (54.4%) \| 0.77 (0.25) | 0.42 [-0.00 ; 0.85] |
| Week 51 | n= 51 (71.8%) \| 0.83 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 48 (67.6%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 47 (66.2%) \| 0.84 (0.17) | n= 38 (55.9%) \| 0.83 (0.18) | 0.06 [-0.37 ; 0.49] |
| Week 57 | n= 47 (66.2%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 44 (62.0%) \| 0.81 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \| 0.84 (0.18) | n= 30 (44.1%) \| 0.77 (0.27) | 0.32 [-0.15 ; 0.78] |
| Week 63 | n= 42 (59.2%) \| 0.83 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 44 (62.0%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \| 0.84 (0.19) | n= 30 (44.1%) \| 0.80 (0.18) | 0.22 [-0.25 ; 0.68] |
| Week 69 | n= 36 (50.7%) \| 0.82 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 39 (54.9%) \| 0.83 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 34 (47.9%) \| 0.82 (0.18) | n= 27 (39.7%) \| 0.75 (0.20) | 0.35 [-0.17 ; 0.86] |
| Week 75 | n= 36 (50.7%) \| 0.85 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \| 0.84 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \| 0.86 (0.17) | n= 24 (35.3%) \| 0.79 (0.21) | 0.37 [-0.17 ; 0.92] |
| Week 81 | n= 31 (43.7%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \| 0.84 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \| 0.87 (0.17) | n= 20 (29.4%) \| 0.77 (0.20) | 0.57 [-0.03 ; 1.16] |
| Week 87 | n= 24 (33.8%) \| 0.79 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \| 0.82 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 24 (33.8%) \| 0.79 (0.23) | n= 17 (25.0%) \| 0.83 (0.14) | -0.19 [-0.82 ; 0.44] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 20 (28.2%) \| 0.81 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 22 (31.0%) \| 0.79 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) \| 0.78 (0.24) | n= 10 (14.7%) \| 0.82 (0.18) | -0.16 [-0.93 ; 0.60] |
| Week 99 | n= 17 (23.9%) \| 0.76 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) \| 0.81 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) \| 0.81 (0.14) | n= 9 (13.2%) \| 0.84 (0.18) | -0.20 [-1.05 ; 0.64] |
| Week 105 | n= 14 (19.7%) \| 0.74 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) \| 0.81 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) \| 0.67 (0.24) | n= 4 ( 5.9%) \| 0.95 (0.10) | -1.19 [-2.47 ; 0.09] |
| Week 111 | n= 7 ( 9.9%) \| 0.58 (0.53) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) \| 0.80 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 ( 8.5%) \| 0.80 (0.22) | n= 5 ( 7.4%) \| 0.83 (0.16) | -0.11 [-1.37 ; 1.14] |
| Week 117 | n= 6 ( 8.5%) \| 0.72 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 ( 8.5%) \| 0.70 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) \| 0.78 (0.17) | n= 1 ( 1.5%) \| 0.62 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.4%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) \| 0.90 (0.14) | n= 1 ( 1.5%) \| 0.62 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.4%) \| 0.82 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) \| 0.86 (0.13) | n= 17 (25.0%) \| 0.73 (0.25) | 0.56 [-0.32 ; 1.43] |
| Week 202 | n= 2 ( 2.8%) \| 0.44 (0.35) | n= 12 (17.6%) \| 0.82 (0.19) | -1.70 [-3.41 ; 0.01] |
| Week 301 | n= 2 ( 2.8%) \| 0.76 (0.34) | n= 9 (13.2%) \| 0.82 (0.16) | -0.28 [-1.90 ; 1.34] |
| Week 302 | n= 2 ( 2.8%) \| 0.69 (0.05) | n= 6 ( 8.8%) \| 0.72 (0.07) | -0.44 [-2.20 ; 1.32] |
| Week 303 | n= 3 ( 4.2%) \| 0.76 (0.21) | n= 6 ( 8.8%) \| 0.67 (0.29) | 0.29 [-1.21 ; 1.78] |
| Week 304 | n= 1 ( 1.4%) \| 1.00 ( / ) | n= 3 ( 4.4%) \| 0.58 (0.29) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.5%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.5%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.5%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.5%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.5%) \| 1.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:42

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Week 3 | n= 66 (93.0%) \|-0.00 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 64 (90.1%) \|-0.04 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 64 (90.1%) \|-0.05 (0.21) | n= 62 (91.2%) \| 0.01 (0.20) | -0.28 [-0.63 ; 0.07] |
| Week 9 | n= 59 (83.1%) \|-0.04 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 61 (85.9%) \|-0.05 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 59 (83.1%) \|-0.03 (0.19) | n= 52 (76.5%) \|-0.07 (0.25) | 0.21 [-0.16 ; 0.59] |
| Week 15 | n= 54 (76.1%) \|-0.07 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 61 (85.9%) \|-0.04 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 57 (80.3%) \|-0.02 (0.18) | n= 51 (75.0%) \|-0.01 (0.20) | -0.04 [-0.42 ; 0.34] |
| Week 21 | n= 60 (84.5%) \|-0.03 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 55 (77.5%) \|-0.02 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 58 (81.7%) \|-0.02 (0.18) | n= 50 (73.5%) \|-0.06 (0.14) | 0.23 [-0.15 ; 0.61] |
| Week 27 | n= 55 (77.5%) \|-0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 53 (74.6%) \|-0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \|-0.03 (0.19) | n= 43 (63.2%) \|-0.08 (0.19) | 0.27 [-0.14 ; 0.67] |
| Week 33 | n= 57 (80.3%) \|-0.02 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 53 (74.6%) \|-0.02 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 49 (69.0%) \|-0.00 (0.17) | n= 44 (64.7%) \|-0.07 (0.15) | 0.40 [-0.01 ; 0.81] |
| Week 39 | n= 53 (74.6%) \|-0.01 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 51 (71.8%) \|-0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 53 (74.6%) \|-0.01 (0.19) | n= 41 (60.3%) \|-0.06 (0.19) | 0.26 [-0.15 ; 0.67] |
| Week 45 | n= 49 (69.0%) \| 0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 52 (73.2%) \|-0.00 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 53 (74.6%) \| 0.02 (0.17) | n= 37 (54.4%) \|-0.08 (0.23) | 0.51 [ 0.08 ; 0.94] |
| Week 51 | n= 51 (71.8%) \|-0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 48 (67.6%) \|-0.00 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 47 (66.2%) \| 0.00 (0.21) | n= 38 (55.9%) \|-0.03 (0.18) | 0.15 [-0.28 ; 0.58] |
| Week 57 | n= 47 (66.2%) \|-0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 44 (62.0%) \|-0.03 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \|-0.01 (0.22) | n= 30 (44.1%) \|-0.10 (0.24) | 0.39 [-0.07 ; 0.86] |
| Week 63 | n= 42 (59.2%) \|-0.01 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 44 (62.0%) \| 0.01 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \|-0.01 (0.21) | n= 30 (44.1%) \|-0.06 (0.17) | 0.25 [-0.22 ; 0.71] |
| Week 69 | n= 36 (50.7%) \|-0.01 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 39 (54.9%) \| 0.00 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 34 (47.9%) \| 0.00 (0.22) | n= 27 (39.7%) \|-0.10 (0.20) | 0.47 [-0.04 ; 0.99] |
| Week 75 | n= 36 (50.7%) \| 0.03 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \| 0.03 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \| 0.06 (0.21) | n= 24 (35.3%) \|-0.06 (0.19) | 0.57 [ 0.02 ; 1.12] |
| Week 81 | n= 31 (43.7%) \| 0.02 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \| 0.03 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \| 0.02 (0.17) | n= 20 (29.4%) \|-0.11 (0.22) | 0.66 [ 0.06 ; 1.26] |
| Week 87 | n= 24 (33.8%) \|-0.05 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \| 0.00 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 24 (33.8%) \|-0.04 (0.20) | n= 17 (25.0%) \|-0.06 (0.23) | 0.09 [-0.53 ; 0.72] |
| Week 93 | n= 20 (28.2%) \|-0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 95 | n= 22 (31.0%) \|-0.05 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) \|-0.06 (0.19) | n= 10 (14.7%) \|-0.10 (0.21) | 0.20 [-0.57 ; 0.97] |
| Week 99 | n= 17 (23.9%) \|-0.07 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) \|-0.08 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) \|-0.07 (0.14) | n= 9 (13.2%) \|-0.10 (0.19) | 0.19 [-0.65 ; 1.04] |
| Week 105 | n= 14 (19.7%) \|-0.12 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) \|-0.10 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) \|-0.15 (0.28) | n= 4 ( 5.9%) \| 0.00 (0.00) | -0.58 [-1.79 ; 0.63] |
| Week 111 | n= 7 ( 9.9%) \|-0.29 (0.44) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) \|-0.07 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 ( 8.5%) \|-0.03 (0.26) | n= 5 ( 7.4%) \|-0.13 (0.18) | 0.40 [-0.87 ; 1.66] |
| Week 117 | n= 6 ( 8.5%) \|-0.19 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 ( 8.5%) \|-0.16 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) \|-0.11 (0.16) | n= 1 ( 1.5%) \|-0.38 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.4%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) \| 0.05 (0.14) | n= 1 ( 1.5%) \|-0.38 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.4%) \|-0.03 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) \| 0.03 (0.23) | n= 17 (25.0%) \|-0.12 (0.25) | 0.58 [-0.30 ; 1.45] |
| Week 202 | n= 2 ( 2.8%) \|-0.41 (0.14) | n= 12 (17.6%) \|-0.07 (0.19) | -1.68 [-3.38 ; 0.03] |
| Week 301 | n= 2 ( 2.8%) \|-0.01 (0.23) | n= 9 (13.2%) \| 0.08 (0.16) | -0.49 [-2.12 ; 1.15] |
| Week 302 | n= 2 ( 2.8%) \|-0.04 (0.11) | n= 6 ( 8.8%) \|-0.13 (0.16) | 0.50 [-1.27 ; 2.26] |
| Week 303 | n= 3 ( 4.2%) \|-0.01 (0.19) | n= 6 ( 8.8%) \|-0.18 (0.28) | 0.57 [-0.95 ; 2.09] |
| Week 304 | n= 1 ( 1.4%) \| 0.15 ( / ) | n= 3 ( 4.4%) \|-0.20 (0.22) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.5%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.5%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.5%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.5%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.5%) \| 0.59 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:42

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| Nr subjects used | n=71 | n=68 | | |
| Week 7 | -0.08 (0.02) [-0.13 ;-0.03] | -0.04 (0.03) [-0.09 ; 0.01] | -0.03 (0.03) [-0.10 ; 0.03] | -0.17 [-0.52 ; 0.18] |
| Week 13 | -0.06 (0.03) [-0.11 ;-0.00] | -0.11 (0.03) [-0.17 ;-0.05] | 0.05 (0.04) [-0.03 ; 0.13] | 0.24 [-0.14 ; 0.61] |
| Week 19 | -0.05 (0.02) [-0.10 ;-0.00] | -0.05 (0.02) [-0.10 ; 0.00] | -0.00 (0.03) [-0.06 ; 0.06] | -0.01 [-0.38 ; 0.37] |
| Week 25 | -0.04 (0.02) [-0.08 ; 0.01] | -0.07 (0.02) [-0.11 ;-0.02] | 0.03 (0.03) [-0.03 ; 0.09] | 0.17 [-0.20 ; 0.55] |
| Week 31 | -0.05 (0.03) [-0.10 ;-0.00] | -0.08 (0.03) [-0.13 ;-0.02] | 0.03 (0.04) [-0.04 ; 0.10] | 0.15 [-0.25 ; 0.55] |
| Week 37 | -0.02 (0.02) [-0.06 ; 0.03] | -0.07 (0.02) [-0.12 ;-0.02] | 0.05 (0.03) [-0.01 ; 0.12] | 0.34 [-0.07 ; 0.75] |
| Week 43 | -0.03 (0.02) [-0.08 ; 0.02] | -0.07 (0.03) [-0.12 ;-0.01] | 0.04 (0.03) [-0.03 ; 0.11] | 0.20 [-0.21 ; 0.61] |
| Week 49 | -0.01 (0.03) [-0.06 ; 0.04] | -0.09 (0.03) [-0.15 ;-0.03] | 0.08 (0.04) [ 0.00 ; 0.16] | 0.42 [-0.00 ; 0.85] |
| Week 55 | -0.02 (0.03) [-0.07 ; 0.03] | -0.03 (0.03) [-0.09 ; 0.02] | 0.01 (0.04) [-0.06 ; 0.08] | 0.06 [-0.37 ; 0.49] |
| Week 61 | -0.04 (0.03) [-0.10 ; 0.01] | -0.08 (0.04) [-0.15 ;-0.01] | 0.03 (0.04) [-0.05 ; 0.12] | 0.17 [-0.28 ; 0.63] |
| Week 67 | -0.03 (0.03) [-0.08 ; 0.02] | -0.07 (0.03) [-0.13 ;-0.01] | 0.04 (0.04) [-0.04 ; 0.11] | 0.22 [-0.25 ; 0.68] |
| Week 73 | -0.03 (0.03) [-0.08 ; 0.02] | -0.10 (0.03) [-0.15 ;-0.04] | 0.07 (0.04) [-0.01 ; 0.14] | 0.46 [-0.06 ; 0.97] |
| Week 79 | 0.00 (0.02) [-0.05 ; 0.05] | -0.06 (0.03) [-0.12 ;-0.01] | 0.07 (0.04) [-0.01 ; 0.14] | 0.48 [-0.06 ; 1.02] |
| Week 85 | -0.00 (0.02) [-0.05 ; 0.05] | -0.11 (0.03) [-0.16 ;-0.05] | 0.11 (0.04) [ 0.03 ; 0.18] | 0.80 [ 0.20 ; 1.40] |
| Week 91 | -0.03 (0.03) [-0.10 ; 0.03] | -0.08 (0.04) [-0.15 ;-0.01] | 0.05 (0.05) [-0.05 ; 0.14] | 0.30 [-0.32 ; 0.93] |
| Week 97 | -0.05 (0.03) [-0.12 ; 0.02] | -0.07 (0.05) [-0.17 ; 0.02] | 0.02 (0.06) [-0.09 ; 0.14] | 0.14 [-0.62 ; 0.89] |
| Overall post-baseline period estimate | -0.03 (0.01) [-0.06 ;-0.01] | -0.07 (0.02) [-0.10 ;-0.04] | 0.04 (0.02) [ 0.00 ; 0.07] | 0.33 [-0.01 ; 0.66] |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit, and PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm, and uses a Heterogenous Autoregressive (ARH(1)) covariance structure.
CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Er
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:42

TABLE 7.2.2: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **< 65** | | |
| | N=40 | N=46 |
| **>= 65** | | |
| | N=31 | N=22 |
| **Subjects with Baseline Value** | | |
| **< 65** | | |
| | 40 (100.0%) | 46 (100.0%) |
| **>= 65** | | |
| | 31 (100.0%) | 22 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **< 65** | | |
| | 40 (100.0%) | 44 (95.7%) |
| **>= 65** | | |
| | 31 (100.0%) | 22 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **< 65** | | |
| | 40 (100.0%) | 44 (95.7%) |
| **>= 65** | | |
| | 31 (100.0%) | 22 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:42

TABLE 7.2.2: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Baseline | n= 40 (100.0%) \| 0.85 (0.22) | n= 46 (100.0%) \| 0.79 (0.29) | 0.22 [-0.21 ; 0.64] |
| Week 3 | n= 38 (95.0%) \| 0.87 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 35 (87.5%) \| 0.86 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 37 (92.5%) \| 0.85 (0.18) | n= 41 (89.1%) \| 0.80 (0.23) | 0.21 [-0.24 ; 0.66] |
| Week 9 | n= 35 (87.5%) \| 0.83 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 35 (87.5%) \| 0.86 (0.20) | n= 37 (80.4%) \| 0.74 (0.25) | 0.51 [ 0.04 ; 0.99] |
| Week 15 | n= 34 (85.0%) \| 0.78 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 36 (90.0%) \| 0.83 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \| 0.81 (0.23) | n= 38 (82.6%) \| 0.82 (0.20) | -0.06 [-0.53 ; 0.41] |
| Week 21 | n= 36 (90.0%) \| 0.81 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 34 (85.0%) \| 0.84 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \| 0.85 (0.22) | n= 37 (80.4%) \| 0.80 (0.18) | 0.23 [-0.23 ; 0.70] |
| Week 27 | n= 33 (82.5%) \| 0.84 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \| 0.83 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \| 0.84 (0.24) | n= 29 (63.0%) \| 0.79 (0.22) | 0.18 [-0.32 ; 0.69] |
| Week 33 | n= 36 (90.0%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 33 (82.5%) \| 0.86 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \| 0.85 (0.21) | n= 30 (65.2%) \| 0.82 (0.17) | 0.12 [-0.38 ; 0.63] |
| Week 39 | n= 33 (82.5%) \| 0.85 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 31 (77.5%) \| 0.86 (0.17) | n= 29 (63.0%) \| 0.80 (0.19) | 0.32 [-0.20 ; 0.83] |
| Week 45 | n= 33 (82.5%) \| 0.89 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \| 0.89 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 34 (85.0%) \| 0.89 (0.15) | n= 27 (58.7%) \| 0.81 (0.19) | 0.46 [-0.06 ; 0.98] |
| Week 51 | n= 32 (80.0%) \| 0.84 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 30 (75.0%) \| 0.87 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 31 (77.5%) \| 0.86 (0.15) | n= 27 (58.7%) \| 0.83 (0.20) | 0.14 [-0.38 ; 0.66] |
| Week 57 | n= 31 (77.5%) \| 0.85 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 26 (65.0%) \| 0.86 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \| 0.87 (0.17) | n= 19 (41.3%) \| 0.80 (0.20) | 0.36 [-0.22 ; 0.94] |
| Week 63 | n= 30 (75.0%) \| 0.84 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 28 (70.0%) \| 0.87 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \| 0.85 (0.20) | n= 20 (43.5%) \| 0.82 (0.13) | 0.16 [-0.41 ; 0.72] |
| Week 69 | n= 27 (67.5%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \| 0.85 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \| 0.83 (0.17) | n= 17 (37.0%) \| 0.74 (0.21) | 0.45 [-0.18 ; 1.08] |
| Week 75 | n= 26 (65.0%) \| 0.86 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \| 0.86 (0.17) | n= 15 (32.6%) \| 0.77 (0.23) | 0.44 [-0.22 ; 1.10] |
| Week 81 | n= 24 (60.0%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \| 0.85 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \| 0.88 (0.16) | n= 13 (28.3%) \| 0.72 (0.20) | 0.90 [ 0.15 ; 1.64] |
| Week 87 | n= 19 (47.5%) \| 0.83 (0.19) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 19 (47.5%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (50.0%) \| 0.81 (0.24) | n= 12 (26.1%) \| 0.82 (0.14) | -0.04 [-0.76 ; 0.69] |
| Week 93 | n= 16 (40.0%) \| 0.84 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \| 0.80 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \| 0.79 (0.25) | n= 7 (15.2%) \| 0.84 (0.17) | -0.20 [-1.10 ; 0.70] |
| Week 99 | n= 13 (32.5%) \| 0.76 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \| 0.83 (0.14) | n= 6 (13.0%) \| 0.84 (0.13) | -0.07 [-1.08 ; 0.94] |
| Week 105 | n= 11 (27.5%) \| 0.76 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \| 0.82 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \| 0.66 (0.27) | n= 2 ( 4.3%) \| 0.90 (0.14) | -0.86 [-2.53 ; 0.81] |
| Week 111 | n= 7 (17.5%) \| 0.58 (0.53) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \| 0.80 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \| 0.80 (0.22) | n= 3 ( 6.5%) \| 0.71 (0.07) | 0.42 [-1.09 ; 1.92] |
| Week 117 | n= 5 (12.5%) \| 0.72 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \| 0.68 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \| 0.77 (0.20) | n= 1 ( 2.2%) \| 0.62 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \| 1.00 ( / ) | n= 1 ( 2.2%) \| 0.62 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \| 0.88 (0.14) | n= 9 (19.6%) \| 0.65 (0.27) | 0.91 [-0.38 ; 2.20] |
| Week 202 | [No Data] | n= 7 (15.2%) \| 0.74 (0.19) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 ( 8.7%) \| 0.84 (0.11) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 1 ( 2.2%) \| 0.81 ( / ) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 2.5%) \| 0.62 ( / ) | n= 3 ( 6.5%) \| 0.58 (0.37) | [Not calculable] |
| Week 304 | [No Data] | n= 1 ( 2.2%) \| 0.80 ( / ) | [No Data for at least 1 arm] |
| **>= 65** | | | |
| N subjects in population | N=31 | N=22 | |
| Baseline | n= 31 (100.0%) \| 0.81 (0.17) | n= 22 (100.0%) \| 0.78 (0.28) | 0.14 [-0.41 ; 0.70] |
| Week 3 | n= 28 (90.3%) \| 0.78 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 29 (93.5%) \| 0.72 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 27 (87.1%) \| 0.72 (0.22) | n= 21 (95.5%) \| 0.75 (0.26) | -0.14 [-0.71 ; 0.44] |
| Week 9 | n= 24 (77.4%) \| 0.76 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 26 (83.9%) \| 0.73 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 24 (77.4%) \| 0.73 (0.20) | n= 15 (68.2%) \| 0.79 (0.15) | -0.30 [-0.96 ; 0.36] |
| Week 15 | n= 20 (64.5%) \| 0.79 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 25 (80.6%) \| 0.74 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 25 (80.6%) \| 0.82 (0.17) | n= 13 (59.1%) \| 0.82 (0.16) | -0.01 [-0.69 ; 0.67] |
| Week 21 | n= 24 (77.4%) \| 0.80 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (67.7%) \| 0.79 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 22 (71.0%) \| 0.80 (0.20) | n= 13 (59.1%) \| 0.85 (0.12) | -0.28 [-0.98 ; 0.42] |
| Week 27 | n= 22 (71.0%) \| 0.83 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 20 (64.5%) \| 0.81 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 21 (67.7%) \| 0.80 (0.16) | n= 14 (63.6%) \| 0.81 (0.22) | -0.05 [-0.74 ; 0.63] |
| Week 33 | n= 21 (67.7%) \| 0.74 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 20 (64.5%) \| 0.78 (0.33) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 18 (58.1%) \| 0.85 (0.17) | n= 14 (63.6%) \| 0.80 (0.16) | 0.30 [-0.42 ; 1.01] |
| Week 39 | n= 20 (64.5%) \| 0.80 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 17 (54.8%) \| 0.82 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 22 (71.0%) \| 0.79 (0.19) | n= 12 (54.5%) \| 0.83 (0.14) | -0.22 [-0.94 ; 0.49] |
| Week 45 | n= 16 (51.6%) \| 0.80 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 19 (61.3%) \| 0.81 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 19 (61.3%) \| 0.81 (0.19) | n= 10 (45.5%) \| 0.67 (0.38) | 0.52 [-0.27 ; 1.31] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 51 | n= 19 (61.3%) \| 0.80 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 18 (58.1%) \| 0.82 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 16 (51.6%) \| 0.81 (0.20) | n= 11 (50.0%) \| 0.83 (0.15) | -0.07 [-0.86 ; 0.71] |
| Week 57 | n= 16 (51.6%) \| 0.82 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 18 (58.1%) \| 0.74 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 17 (54.8%) \| 0.80 (0.20) | n= 11 (50.0%) \| 0.72 (0.37) | 0.26 [-0.52 ; 1.03] |
| Week 63 | n= 12 (38.7%) \| 0.80 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 16 (51.6%) \| 0.79 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 12 (38.7%) \| 0.81 (0.17) | n= 10 (45.5%) \| 0.76 (0.26) | 0.26 [-0.60 ; 1.12] |
| Week 69 | n= 9 (29.0%) \| 0.77 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 11 (35.5%) \| 0.77 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 9 (29.0%) \| 0.80 (0.21) | n= 10 (45.5%) \| 0.77 (0.19) | 0.11 [-0.82 ; 1.03] |
| Week 75 | n= 10 (32.3%) \| 0.82 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 8 (25.8%) \| 0.86 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 7 (22.6%) \| 0.89 (0.19) | n= 9 (40.9%) \| 0.83 (0.16) | 0.29 [-0.74 ; 1.32] |
| Week 81 | n= 7 (22.6%) \| 0.86 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 8 (25.8%) \| 0.81 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (22.6%) \| 0.85 (0.19) | n= 7 (31.8%) \| 0.86 (0.16) | -0.08 [-1.18 ; 1.01] |
| Week 87 | n= 5 (16.1%) \| 0.63 (0.49) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 6 (19.4%) \| 0.79 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (12.9%) \| 0.72 (0.19) | n= 5 (22.7%) \| 0.87 (0.14) | -0.79 [-2.27 ; 0.68] |
| Week 93 | n= 4 (12.9%) \| 0.69 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (16.1%) \| 0.76 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (12.9%) \| 0.77 (0.18) | n= 3 (13.6%) \| 0.79 (0.25) | -0.08 [-1.73 ; 1.58] |
| Week 99 | n= 4 (12.9%) \| 0.74 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 6.5%) \| 0.74 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 ( 9.7%) \| 0.72 (0.13) | n= 3 (13.6%) \| 0.84 (0.28) | -0.44 [-2.28 ; 1.41] |
| Week 105 | n= 3 ( 9.7%) \| 0.67 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 3.2%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 6.5%) \| 0.74 (0.07) | n= 2 ( 9.1%) \| 1.00 (0.00) | -2.79 [-7.70 ; 2.12] |
| Week 113 | n= 1 ( 3.2%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | [No Data] | n= 2 ( 9.1%) \| 1.00 (0.00) | [No Data for at least 1 arm] |
| Week 117 | n= 1 ( 3.2%) \| 0.73 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 3.2%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 ( 6.5%) \| 0.80 (0.06) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 3.2%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 3.2%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.2%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 3.2%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.2%) \| 0.82 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 3.2%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.9%) \| 0.83 (0.13) | n= 8 (36.4%) \| 0.83 (0.19) | 0.02 [-1.24 ; 1.28] |
| Week 202 | n= 2 ( 6.5%) \| 0.44 (0.35) | n= 5 (22.7%) \| 0.94 (0.13) | -2.15 [-4.49 ; 0.19] |
| Week 301 | n= 2 ( 6.5%) \| 0.76 (0.34) | n= 5 (22.7%) \| 0.80 (0.21) | -0.15 [-1.96 ; 1.67] |
| Week 302 | n= 2 ( 6.5%) \| 0.69 (0.05) | n= 5 (22.7%) \| 0.70 (0.05) | -0.22 [-2.04 ; 1.60] |
| Week 303 | n= 2 ( 6.5%) \| 0.83 (0.24) | n= 3 (13.6%) \| 0.77 (0.20) | 0.20 [-1.93 ; 2.32] |
| Week 304 | n= 1 ( 3.2%) \| 1.00 ( / ) | n= 2 ( 9.1%) \| 0.47 (0.31) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 4.5%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 4.5%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 4.5%) \| 1.00 ( / ) | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 308 | [No Data] | n= 1 ( 4.5%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 4.5%) \| 1.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:42

TABLE 7.2.2: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Week 3 | n= 38 (95.0%) \| 0.00 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 35 (87.5%) \|-0.02 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 37 (92.5%) \|-0.02 (0.19) | n= 41 (89.1%) \| 0.03 (0.19) | -0.25 [-0.70 ; 0.20] |
| Week 9 | n= 35 (87.5%) \|-0.03 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \|-0.04 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 35 (87.5%) \|-0.00 (0.19) | n= 37 (80.4%) \|-0.07 (0.29) | 0.30 [-0.17 ; 0.76] |
| Week 15 | n= 34 (85.0%) \|-0.09 (0.31) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 36 (90.0%) \|-0.02 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \|-0.03 (0.19) | n= 38 (82.6%) \| 0.00 (0.21) | -0.18 [-0.65 ; 0.30] |
| Week 21 | n= 36 (90.0%) \|-0.03 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 34 (85.0%) \|-0.02 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \|-0.01 (0.18) | n= 37 (80.4%) \|-0.06 (0.16) | 0.34 [-0.13 ; 0.81] |
| Week 27 | n= 33 (82.5%) \|-0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \|-0.03 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \|-0.02 (0.21) | n= 29 (63.0%) \|-0.07 (0.20) | 0.25 [-0.26 ; 0.75] |
| Week 33 | n= 36 (90.0%) \| 0.01 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 33 (82.5%) \| 0.01 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \|-0.01 (0.20) | n= 30 (65.2%) \|-0.06 (0.17) | 0.27 [-0.24 ; 0.77] |
| Week 39 | n= 33 (82.5%) \|-0.02 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \| 0.00 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 31 (77.5%) \| 0.00 (0.22) | n= 29 (63.0%) \|-0.07 (0.21) | 0.35 [-0.17 ; 0.86] |
| Week 45 | n= 33 (82.5%) \| 0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \| 0.02 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 34 (85.0%) \| 0.03 (0.20) | n= 27 (58.7%) \|-0.04 (0.17) | 0.42 [-0.10 ; 0.93] |
| Week 51 | n= 32 (80.0%) \|-0.02 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 30 (75.0%) \| 0.00 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 31 (77.5%) \| 0.00 (0.21) | n= 27 (58.7%) \|-0.02 (0.20) | 0.11 [-0.41 ; 0.63] |
| Week 57 | n= 31 (77.5%) \|-0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 26 (65.0%) \| 0.02 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \| 0.01 (0.24) | n= 19 (41.3%) \|-0.07 (0.18) | 0.35 [-0.23 ; 0.93] |
| Week 63 | n= 30 (75.0%) \|-0.01 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 28 (70.0%) \| 0.04 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \|-0.02 (0.23) | n= 20 (43.5%) \|-0.04 (0.15) | 0.11 [-0.46 ; 0.67] |
| Week 69 | n= 27 (67.5%) \|-0.01 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \| 0.02 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \|-0.00 (0.24) | n= 17 (37.0%) \|-0.10 (0.21) | 0.45 [-0.18 ; 1.08] |
| Week 75 | n= 26 (65.0%) \| 0.03 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \| 0.02 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \| 0.05 (0.22) | n= 15 (32.6%) \|-0.07 (0.24) | 0.51 [-0.15 ; 1.18] |
| Week 81 | n= 24 (60.0%) \| 0.01 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \| 0.02 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \| 0.01 (0.17) | n= 13 (28.3%) \|-0.13 (0.23) | 0.66 [-0.06 ; 1.39] |
| Week 87 | n= 19 (47.5%) \|-0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (47.5%) \| 0.00 (0.21) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 20 (50.0%) \|-0.05 (0.21) | n= 12 (26.1%) \|-0.06 (0.25) | 0.05 [-0.68 ; 0.78] |
| Week 93 | n= 16 (40.0%) \|-0.00 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \|-0.05 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \|-0.06 (0.21) | n= 7 (15.2%) \|-0.05 (0.19) | -0.05 [-0.94 ; 0.85] |
| Week 99 | n= 13 (32.5%) \|-0.06 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \|-0.08 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \|-0.08 (0.16) | n= 6 (13.0%) \|-0.07 (0.15) | -0.03 [-1.04 ; 0.98] |
| Week 105 | n= 11 (27.5%) \|-0.13 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \|-0.09 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \|-0.16 (0.32) | n= 2 ( 4.3%) \| 0.00 (0.00) | -0.50 [-2.14 ; 1.13] |
| Week 111 | n= 7 (17.5%) \|-0.29 (0.44) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \|-0.08 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \|-0.03 (0.26) | n= 3 ( 6.5%) \|-0.22 (0.19) | 0.68 [-0.86 ; 2.21] |
| Week 117 | n= 5 (12.5%) \|-0.18 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \|-0.16 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \|-0.10 (0.18) | n= 1 ( 2.2%) \|-0.38 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \| 0.15 ( / ) | n= 1 ( 2.2%) \|-0.38 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \| 0.12 (0.27) | n= 9 (19.6%) \|-0.17 (0.28) | 0.96 [-0.33 ; 2.26] |
| Week 202 | [No Data] | n= 7 (15.2%) \|-0.13 (0.16) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 ( 8.7%) \| 0.03 (0.08) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 1 ( 2.2%) \| 0.02 ( / ) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 2.5%) \|-0.23 ( / ) | n= 3 ( 6.5%) \|-0.29 (0.31) | [Not calculable] |
| Week 304 | [No Data] | n= 1 ( 2.2%) \| 0.00 ( / ) | [No Data for at least 1 arm] |
| **>= 65** | | | |
| N subjects in population | N=31 | N=22 | |
| Week 3 | n= 28 (90.3%) \|-0.01 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 29 (93.5%) \|-0.07 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 27 (87.1%) \|-0.09 (0.23) | n= 21 (95.5%) \|-0.03 (0.22) | -0.26 [-0.84 ; 0.31] |
| Week 9 | n= 24 (77.4%) \|-0.05 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 26 (83.9%) \|-0.07 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 24 (77.4%) \|-0.07 (0.18) | n= 15 (68.2%) \|-0.07 (0.10) | 0.05 [-0.60 ; 0.70] |
| Week 15 | n= 20 (64.5%) \|-0.03 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 25 (80.6%) \|-0.08 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 25 (80.6%) \|-0.00 (0.16) | n= 13 (59.1%) \|-0.06 (0.16) | 0.34 [-0.35 ; 1.02] |
| Week 21 | n= 24 (77.4%) \|-0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (67.7%) \|-0.04 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 22 (71.0%) \|-0.04 (0.18) | n= 13 (59.1%) \|-0.04 (0.09) | -0.02 [-0.72 ; 0.67] |
| Week 27 | n= 22 (71.0%) \|-0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 20 (64.5%) \|-0.00 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 21 (67.7%) \|-0.03 (0.15) | n= 14 (63.6%) \|-0.08 (0.15) | 0.32 [-0.37 ; 1.02] |
| Week 33 | n= 21 (67.7%) \|-0.07 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 20 (64.5%) \|-0.05 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 18 (58.1%) \| 0.01 (0.13) | n= 14 (63.6%) \|-0.09 (0.11) | 0.80 [ 0.06 ; 1.54] |
| Week 39 | n= 20 (64.5%) \|-0.01 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 17 (54.8%) \|-0.03 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 22 (71.0%) \|-0.04 (0.13) | n= 12 (54.5%) \|-0.04 (0.14) | 0.03 [-0.68 ; 0.75] |
| Week 45 | n= 16 (51.6%) \|-0.03 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 19 (61.3%) \|-0.03 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 19 (61.3%) \|-0.01 (0.12) | n= 10 (45.5%) \|-0.19 (0.32) | 0.84 [ 0.03 ; 1.65] |
| Week 51 | n= 19 (61.3%) \|-0.02 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 18 (58.1%) \|-0.01 (0.16) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 55 | n= 16 (51.6%) \|-0.00 (0.21) | n= 11 (50.0%) \|-0.05 (0.12) | 0.24 [-0.54 ; 1.03] |
| Week 57 | n= 16 (51.6%) \|-0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 18 (58.1%) \|-0.09 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 17 (54.8%) \|-0.04 (0.18) | n= 11 (50.0%) \|-0.15 (0.32) | 0.44 [-0.34 ; 1.22] |
| Week 63 | n= 12 (38.7%) \|-0.02 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 16 (51.6%) \|-0.03 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 12 (38.7%) \| 0.00 (0.17) | n= 10 (45.5%) \|-0.11 (0.21) | 0.55 [-0.33 ; 1.43] |
| Week 69 | n= 9 (29.0%) \| 0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 11 (35.5%) \|-0.03 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 9 (29.0%) \| 0.02 (0.18) | n= 10 (45.5%) \|-0.09 (0.20) | 0.52 [-0.42 ; 1.46] |
| Week 75 | n= 10 (32.3%) \| 0.04 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 8 (25.8%) \| 0.08 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 7 (22.6%) \| 0.08 (0.20) | n= 9 (40.9%) \|-0.05 (0.09) | 0.82 [-0.25 ; 1.89] |
| Week 81 | n= 7 (22.6%) \| 0.07 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 8 (25.8%) \| 0.03 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (22.6%) \| 0.07 (0.16) | n= 7 (31.8%) \|-0.07 (0.20) | 0.69 [-0.44 ; 1.82] |
| Week 87 | n= 5 (16.1%) \|-0.17 (0.44) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 6 (19.4%) \| 0.00 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (12.9%) \|-0.02 (0.13) | n= 5 (22.7%) \|-0.07 (0.18) | 0.28 [-1.14 ; 1.70] |
| Week 93 | n= 4 (12.9%) \|-0.10 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (16.1%) \|-0.04 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (12.9%) \|-0.05 (0.07) | n= 3 (13.6%) \|-0.21 (0.25) | 0.80 [-0.94 ; 2.55] |
| Week 99 | n= 4 (12.9%) \|-0.08 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 6.5%) \|-0.11 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 ( 9.7%) \|-0.04 (0.07) | n= 3 (13.6%) \|-0.16 (0.28) | 0.47 [-1.38 ; 2.32] |
| Week 105 | n= 3 ( 9.7%) \|-0.09 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 3.2%) \|-0.16 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 6.5%) \|-0.11 (0.08) | n= 2 ( 9.1%) \| 0.00 (0.00) | -1.13 [-4.12 ; 1.87] |
| Week 113 | n= 1 ( 3.2%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | [No Data] | n= 2 ( 9.1%) \| 0.00 (0.00) | [No Data for at least 1 arm] |
| Week 117 | n= 1 ( 3.2%) \|-0.27 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 3.2%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 ( 6.5%) \|-0.12 (0.05) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 3.2%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 3.2%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.2%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 3.2%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.2%) \|-0.03 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 3.2%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.9%) \|-0.07 (0.16) | n= 8 (36.4%) \|-0.07 (0.21) | -0.02 [-1.28 ; 1.24] |
| Week 202 | n= 2 ( 6.5%) \|-0.41 (0.14) | n= 5 (22.7%) \| 0.00 (0.21) | -1.73 [-3.89 ; 0.44] |
| Week 301 | n= 2 ( 6.5%) \|-0.01 (0.23) | n= 5 (22.7%) \| 0.12 (0.20) | -0.52 [-2.37 ; 1.33] |
| Week 302 | n= 2 ( 6.5%) \|-0.04 (0.11) | n= 5 (22.7%) \|-0.16 (0.16) | 0.66 [-1.21 ; 2.52] |
| Week 303 | n= 2 ( 6.5%) \| 0.09 (0.08) | n= 3 (13.6%) \|-0.08 (0.27) | 0.54 [-1.64 ; 2.72] |
| Week 304 | n= 1 ( 3.2%) \| 0.15 ( / ) | n= 2 ( 9.1%) \|-0.30 (0.20) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 4.5%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 4.5%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 4.5%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 4.5%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 4.5%) \| 0.59 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:43

TABLE 7.2.2: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **< 65** | | | | |
| Nr subjects used | n=40 | n=46 | | |
| Week 7 | -0.01 (0.03) [-0.07 ; 0.04] | -0.01 (0.03) [-0.06 ; 0.05] | -0.01 (0.04) [-0.08 ; 0.07] | -0.05 [-0.49 ; 0.40] |
| Week 13 | -0.01 (0.04) [-0.09 ; 0.07] | -0.10 (0.04) [-0.18 ;-0.02] | 0.09 (0.06) [-0.02 ; 0.20] | 0.37 [-0.10 ; 0.84] |
| Week 19 | -0.05 (0.03) [-0.11 ; 0.02] | -0.02 (0.03) [-0.08 ; 0.04] | -0.03 (0.04) [-0.11 ; 0.06] | -0.14 [-0.61 ; 0.33] |
| Week 25 | -0.01 (0.03) [-0.06 ; 0.04] | -0.05 (0.03) [-0.10 ;-0.00] | 0.05 (0.04) [-0.03 ; 0.12] | 0.28 [-0.18 ; 0.74] |
| Week 31 | -0.03 (0.03) [-0.10 ; 0.03] | -0.06 (0.03) [-0.13 ; 0.01] | 0.03 (0.05) [-0.06 ; 0.12] | 0.15 [-0.35 ; 0.65] |
| Week 37 | 0.00 (0.03) [-0.06 ; 0.06] | -0.05 (0.03) [-0.10 ; 0.01] | 0.05 (0.04) [-0.04 ; 0.13] | 0.28 [-0.22 ; 0.79] |
| Week 43 | 0.01 (0.03) [-0.05 ; 0.07] | -0.06 (0.03) [-0.12 ; 0.01] | 0.07 (0.04) [-0.02 ; 0.16] | 0.39 [-0.12 ; 0.91] |
| Week 49 | 0.03 (0.02) [-0.02 ; 0.08] | -0.04 (0.03) [-0.09 ; 0.01] | 0.07 (0.04) [-0.00 ; 0.14] | 0.48 [-0.03 ; 1.00] |
| Week 55 | 0.00 (0.03) [-0.05 ; 0.06] | -0.01 (0.03) [-0.07 ; 0.05] | 0.01 (0.04) [-0.07 ; 0.09] | 0.09 [-0.42 ; 0.61] |
| Week 61 | -0.00 (0.03) [-0.06 ; 0.05] | -0.02 (0.04) [-0.09 ; 0.05] | 0.02 (0.05) [-0.07 ; 0.11] | 0.11 [-0.46 ; 0.69] |
| Week 67 | -0.01 (0.03) [-0.07 ; 0.05] | -0.04 (0.04) [-0.11 ; 0.04] | 0.03 (0.05) [-0.07 ; 0.13] | 0.17 [-0.39 ; 0.73] |
| Week 73 | -0.01 (0.03) [-0.07 ; 0.05] | -0.08 (0.04) [-0.16 ;-0.01] | 0.08 (0.05) [-0.02 ; 0.17] | 0.50 [-0.12 ; 1.13] |
| Week 79 | 0.02 (0.03) [-0.05 ; 0.08] | -0.05 (0.04) [-0.13 ; 0.03] | 0.07 (0.05) [-0.03 ; 0.16] | 0.44 [-0.22 ; 1.09] |
| Week 85 | 0.00 (0.03) [-0.05 ; 0.06] | -0.11 (0.04) [-0.18 ;-0.03] | 0.11 (0.05) [ 0.02 ; 0.21] | 0.83 [ 0.10 ; 1.56] |
| Week 91 | -0.03 (0.04) [-0.11 ; 0.05] | -0.07 (0.05) [-0.18 ; 0.03] | 0.04 (0.07) [-0.09 ; 0.18] | 0.24 [-0.48 ; 0.96] |
| Overall post-baseline period estimate | -0.01 (0.02) [-0.04 ; 0.03] | -0.05 (0.02) [-0.09 ;-0.02] | 0.04 (0.02) [-0.00 ; 0.09] | 0.41 [-0.02 ; 0.84] |
| **>= 65** | | | | |
| Nr subjects used | n=31 | n=22 | | |
| Week 7 | -0.12 (0.04) [-0.20 ;-0.03] | -0.05 (0.05) [-0.14 ; 0.04] | -0.06 (0.06) [-0.19 ; 0.06] | -0.30 [-0.88 ; 0.27] |
| Week 13 | -0.08 (0.03) [-0.14 ;-0.01] | -0.06 (0.04) [-0.14 ; 0.01] | -0.01 (0.05) [-0.11 ; 0.09] | -0.08 [-0.73 ; 0.56] |
| Week 19 | -0.01 (0.03) [-0.06 ; 0.05] | -0.05 (0.04) [-0.13 ; 0.03] | 0.04 (0.05) [-0.05 ; 0.14] | 0.30 [-0.38 ; 0.97] |
| Week 25 | -0.03 (0.03) [-0.10 ; 0.03] | -0.04 (0.04) [-0.12 ; 0.05] | 0.00 (0.05) [-0.11 ; 0.11] | 0.01 [-0.67 ; 0.70] |
| Week 31 | -0.03 (0.03) [-0.10 ; 0.04] | -0.06 (0.04) [-0.14 ; 0.02] | 0.03 (0.05) [-0.07 ; 0.14] | 0.20 [-0.48 ; 0.88] |
| Week 37 | 0.01 (0.03) [-0.05 ; 0.06] | -0.07 (0.03) [-0.14 ;-0.01] | 0.08 (0.04) [-0.01 ; 0.17] | 0.67 [-0.05 ; 1.39] |
| Week 43 | -0.04 (0.03) [-0.10 ; 0.02] | -0.03 (0.04) [-0.11 ; 0.05] | -0.01 (0.05) [-0.11 ; 0.09] | -0.08 [-0.78 ; 0.63] |
| Week 49 | -0.02 (0.05) [-0.13 ; 0.09] | -0.16 (0.07) [-0.31 ;-0.02] | 0.14 (0.09) [-0.04 ; 0.32] | 0.61 [-0.17 ; 1.40] |
| Week 55 | -0.01 (0.04) [-0.09 ; 0.07] | -0.03 (0.05) [-0.13 ; 0.07] | 0.02 (0.06) [-0.11 ; 0.15] | 0.13 [-0.64 ; 0.89] |
| Week 61 | -0.05 (0.05) [-0.16 ; 0.06] | -0.14 (0.07) [-0.27 ; 0.00] | 0.08 (0.09) [-0.09 ; 0.26] | 0.36 [-0.41 ; 1.12] |
| Week 67 | -0.02 (0.04) [-0.11 ; 0.07] | -0.09 (0.05) [-0.19 ; 0.01] | 0.07 (0.07) [-0.07 ; 0.21] | 0.43 [-0.42 ; 1.28] |
| Overall post-baseline period estimate | -0.04 (0.02) [-0.07 ;-0.00] | -0.07 (0.02) [-0.12 ;-0.03] | 0.04 (0.03) [-0.02 ; 0.09] | 0.34 [-0.21 ; 0.89] |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.1149 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:43

TABLE 7.2.3: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **< 65** | N=40 | N=46 |
| **>= 65 AND < 75** | N=23 | N=17 |
| **>= 75** | N=8 | N=5 |
| **Subjects with Baseline Value** | | |
| **< 65** | 40 (100.0%) | 46 (100.0%) |
| **>= 65 AND < 75** | 23 (100.0%) | 17 (100.0%) |
| **>= 75** | 8 (100.0%) | 5 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **< 65** | 40 (100.0%) | 44 (95.7%) |
| **>= 65 AND < 75** | 23 (100.0%) | 17 (100.0%) |
| **>= 75** | 8 (100.0%) | 5 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **< 65** | 40 (100.0%) | 44 (95.7%) |
| **>= 65 AND < 75** | 23 (100.0%) | 17 (100.0%) |
| **>= 75** | 8 (100.0%) | 5 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:43

TABLE 7.2.3: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Baseline | n= 40 (100.0%) \| 0.85 (0.22) | n= 46 (100.0%) \| 0.79 (0.29) | 0.22 [-0.21 ; 0.64] |
| Week 3 | n= 38 (95.0%) \| 0.87 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 35 (87.5%) \| 0.86 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 37 (92.5%) \| 0.85 (0.18) | n= 41 (89.1%) \| 0.80 (0.23) | 0.21 [-0.24 ; 0.66] |
| Week 9 | n= 35 (87.5%) \| 0.83 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 35 (87.5%) \| 0.86 (0.20) | n= 37 (80.4%) \| 0.74 (0.25) | 0.51 [ 0.04 ; 0.99] |
| Week 15 | n= 34 (85.0%) \| 0.78 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 36 (90.0%) \| 0.83 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \| 0.81 (0.23) | n= 38 (82.6%) \| 0.82 (0.20) | -0.06 [-0.53 ; 0.41] |
| Week 21 | n= 36 (90.0%) \| 0.81 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 34 (85.0%) \| 0.84 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \| 0.85 (0.22) | n= 37 (80.4%) \| 0.80 (0.18) | 0.23 [-0.23 ; 0.70] |
| Week 27 | n= 33 (82.5%) \| 0.84 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \| 0.83 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \| 0.84 (0.24) | n= 29 (63.0%) \| 0.79 (0.22) | 0.18 [-0.32 ; 0.69] |
| Week 33 | n= 36 (90.0%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 33 (82.5%) \| 0.86 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \| 0.85 (0.21) | n= 30 (65.2%) \| 0.82 (0.17) | 0.12 [-0.38 ; 0.63] |
| Week 39 | n= 33 (82.5%) \| 0.85 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 31 (77.5%) \| 0.86 (0.17) | n= 29 (63.0%) \| 0.80 (0.19) | 0.32 [-0.20 ; 0.83] |
| Week 45 | n= 33 (82.5%) \| 0.89 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \| 0.89 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 34 (85.0%) \| 0.89 (0.15) | n= 27 (58.7%) \| 0.81 (0.19) | 0.46 [-0.06 ; 0.98] |
| Week 51 | n= 32 (80.0%) \| 0.84 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 30 (75.0%) \| 0.87 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 31 (77.5%) \| 0.86 (0.15) | n= 27 (58.7%) \| 0.83 (0.20) | 0.14 [-0.38 ; 0.66] |
| Week 57 | n= 31 (77.5%) \| 0.85 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 26 (65.0%) \| 0.86 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \| 0.87 (0.17) | n= 19 (41.3%) \| 0.80 (0.20) | 0.36 [-0.22 ; 0.94] |
| Week 63 | n= 30 (75.0%) \| 0.84 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 28 (70.0%) \| 0.87 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \| 0.85 (0.20) | n= 20 (43.5%) \| 0.82 (0.13) | 0.16 [-0.41 ; 0.72] |
| Week 69 | n= 27 (67.5%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \| 0.85 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \| 0.83 (0.17) | n= 17 (37.0%) \| 0.74 (0.21) | 0.45 [-0.18 ; 1.08] |
| Week 75 | n= 26 (65.0%) \| 0.86 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \| 0.86 (0.17) | n= 15 (32.6%) \| 0.77 (0.23) | 0.44 [-0.22 ; 1.10] |
| Week 81 | n= 24 (60.0%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \| 0.85 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \| 0.88 (0.16) | n= 13 (28.3%) \| 0.72 (0.20) | 0.90 [ 0.15 ; 1.64] |
| Week 87 | n= 19 (47.5%) \| 0.83 (0.19) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 19 (47.5%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (50.0%) \| 0.81 (0.24) | n= 12 (26.1%) \| 0.82 (0.14) | -0.04 [-0.76 ; 0.69] |
| Week 93 | n= 16 (40.0%) \| 0.84 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \| 0.80 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \| 0.79 (0.25) | n= 7 (15.2%) \| 0.84 (0.17) | -0.20 [-1.10 ; 0.70] |
| Week 99 | n= 13 (32.5%) \| 0.76 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \| 0.83 (0.14) | n= 6 (13.0%) \| 0.84 (0.13) | -0.07 [-1.08 ; 0.94] |
| Week 105 | n= 11 (27.5%) \| 0.76 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \| 0.82 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \| 0.66 (0.27) | n= 2 ( 4.3%) \| 0.90 (0.14) | -0.86 [-2.53 ; 0.81] |
| Week 111 | n= 7 (17.5%) \| 0.58 (0.53) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \| 0.80 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \| 0.80 (0.22) | n= 3 ( 6.5%) \| 0.71 (0.07) | 0.42 [-1.09 ; 1.92] |
| Week 117 | n= 5 (12.5%) \| 0.72 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \| 0.68 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \| 0.77 (0.20) | n= 1 ( 2.2%) \| 0.62 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \| 1.00 ( / ) | n= 1 ( 2.2%) \| 0.62 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \| 0.88 (0.14) | n= 9 (19.6%) \| 0.65 (0.27) | 0.91 [-0.38 ; 2.20] |
| Week 202 | [No Data] | n= 7 (15.2%) \| 0.74 (0.19) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 ( 8.7%) \| 0.84 (0.11) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 1 ( 2.2%) \| 0.81 ( / ) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 2.5%) \| 0.62 ( / ) | n= 3 ( 6.5%) \| 0.58 (0.37) | [Not calculable] |
| Week 304 | [No Data] | n= 1 ( 2.2%) \| 0.80 ( / ) | [No Data for at least 1 arm] |
| **>= 65 AND < 75** | | | |
| N subjects in population | N=23 | N=17 | |
| Baseline | n= 23 (100.0%) \| 0.82 (0.17) | n= 17 (100.0%) \| 0.73 (0.29) | 0.37 [-0.27 ; 1.01] |
| Week 3 | n= 20 (87.0%) \| 0.78 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 22 (95.7%) \| 0.75 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 21 (91.3%) \| 0.72 (0.24) | n= 17 (100.0%) \| 0.71 (0.28) | 0.03 [-0.61 ; 0.68] |
| Week 9 | n= 18 (78.3%) \| 0.76 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 19 (82.6%) \| 0.75 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 19 (82.6%) \| 0.74 (0.22) | n= 12 (70.6%) \| 0.78 (0.16) | -0.17 [-0.91 ; 0.57] |
| Week 15 | n= 14 (60.9%) \| 0.81 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 18 (78.3%) \| 0.74 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 19 (82.6%) \| 0.82 (0.16) | n= 10 (58.8%) \| 0.80 (0.18) | 0.10 [-0.68 ; 0.88] |
| Week 21 | n= 18 (78.3%) \| 0.79 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (65.2%) \| 0.78 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 16 (69.6%) \| 0.80 (0.22) | n= 8 (47.1%) \| 0.81 (0.12) | -0.06 [-0.93 ; 0.80] |
| Week 27 | n= 16 (69.6%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 15 (65.2%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 15 (65.2%) \| 0.79 (0.16) | n= 11 (64.7%) \| 0.76 (0.22) | 0.17 [-0.63 ; 0.96] |
| Week 33 | n= 15 (65.2%) \| 0.70 (0.31) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 14 (60.9%) \| 0.76 (0.38) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 13 (56.5%) \| 0.85 (0.17) | n= 11 (64.7%) \| 0.77 (0.16) | 0.48 [-0.35 ; 1.31] |
| Week 39 | n= 15 (65.2%) \| 0.80 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 12 (52.2%) \| 0.81 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 16 (69.6%) \| 0.77 (0.18) | n= 11 (64.7%) \| 0.83 (0.15) | -0.32 [-1.11 ; 0.47] |
| Week 45 | n= 11 (47.8%) \| 0.80 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 13 (56.5%) \| 0.80 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 13 (56.5%) \| 0.79 (0.20) | n= 9 (52.9%) \| 0.65 (0.40) | 0.45 [-0.43 ; 1.34] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 51 | n= 13 (56.5%) \| 0.81 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (56.5%) \| 0.83 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 11 (47.8%) \| 0.83 (0.18) | n= 10 (58.8%) \| 0.81 (0.14) | 0.15 [-0.73 ; 1.03] |
| Week 57 | n= 12 (52.2%) \| 0.83 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 13 (56.5%) \| 0.76 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 12 (52.2%) \| 0.79 (0.18) | n= 10 (58.8%) \| 0.72 (0.39) | 0.26 [-0.61 ; 1.12] |
| Week 63 | n= 9 (39.1%) \| 0.78 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (47.8%) \| 0.78 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (34.8%) \| 0.80 (0.15) | n= 9 (52.9%) \| 0.73 (0.26) | 0.31 [-0.68 ; 1.30] |
| Week 69 | n= 7 (30.4%) \| 0.78 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 8 (34.8%) \| 0.75 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 6 (26.1%) \| 0.80 (0.22) | n= 10 (58.8%) \| 0.77 (0.19) | 0.12 [-0.93 ; 1.17] |
| Week 75 | n= 8 (34.8%) \| 0.83 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (21.7%) \| 0.87 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (21.7%) \| 0.84 (0.22) | n= 8 (47.1%) \| 0.81 (0.16) | 0.15 [-1.01 ; 1.32] |
| Week 81 | n= 5 (21.7%) \| 0.80 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (26.1%) \| 0.79 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (21.7%) \| 0.79 (0.20) | n= 6 (35.3%) \| 0.88 (0.17) | -0.43 [-1.70 ; 0.84] |
| Week 87 | n= 3 (13.0%) \| 0.38 (0.49) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 4 (17.4%) \| 0.68 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (17.4%) \| 0.72 (0.19) | n= 5 (29.4%) \| 0.87 (0.14) | -0.79 [-2.27 ; 0.68] |
| Week 93 | n= 3 (13.0%) \| 0.63 (0.05) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (17.4%) \| 0.73 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (13.0%) \| 0.69 (0.10) | n= 3 (17.6%) \| 0.79 (0.25) | -0.41 [-2.25 ; 1.44] |
| Week 99 | n= 3 (13.0%) \| 0.66 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 8.7%) \| 0.74 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (13.0%) \| 0.72 (0.13) | n= 3 (17.6%) \| 0.84 (0.28) | -0.44 [-2.28 ; 1.41] |
| Week 105 | n= 3 (13.0%) \| 0.67 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 4.3%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 8.7%) \| 0.74 (0.07) | n= 2 (11.8%) \| 1.00 (0.00) | -2.79 [-7.70 ; 2.12] |
| Week 113 | n= 1 ( 4.3%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | [No Data] | n= 2 (11.8%) \| 1.00 (0.00) | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 4.3%) \| 0.76 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.3%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 4.3%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 4.3%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.3%) \| 0.82 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.3%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (13.0%) \| 0.87 (0.14) | n= 4 (23.5%) \| 0.74 (0.23) | 0.57 [-1.13 ; 2.27] |
| Week 202 | n= 1 ( 4.3%) \| 0.69 ( / ) | n= 2 (11.8%) \| 0.86 (0.21) | [Not calculable] |
| Week 301 | n= 1 ( 4.3%) \| 1.00 ( / ) | n= 3 (17.6%) \| 0.67 (0.14) | [Not calculable] |
| Week 302 | n= 1 ( 4.3%) \| 0.73 ( / ) | n= 3 (17.6%) \| 0.71 (0.02) | [Not calculable] |
| Week 303 | n= 1 ( 4.3%) \| 1.00 ( / ) | n= 2 (11.8%) \| 0.84 (0.22) | [Not calculable] |
| Week 304 | n= 1 ( 4.3%) \| 1.00 ( / ) | n= 2 (11.8%) \| 0.47 (0.31) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 5.9%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 5.9%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 5.9%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 5.9%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 5.9%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| **>= 75** | | | |
| N subjects in population | N=8 | N=5 | |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Baseline | n= 8 (100.0%) \| 0.80 (0.18) | n= 5 (100.0%) \| 0.96 (0.09) | -0.96 [-2.20 ; 0.28] |
| Week 3 | n= 8 (100.0%) \| 0.80 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 7 (87.5%) \| 0.65 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 6 (75.0%) \| 0.70 (0.16) | n= 4 (80.0%) \| 0.90 (0.11) | -1.32 [-2.82 ; 0.19] |
| Week 9 | n= 6 (75.0%) \| 0.76 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 7 (87.5%) \| 0.68 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 5 (62.5%) \| 0.69 (0.13) | n= 3 (60.0%) \| 0.83 (0.15) | -0.94 [-2.60 ; 0.71] |
| Week 15 | n= 6 (75.0%) \| 0.75 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 7 (87.5%) \| 0.75 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 6 (75.0%) \| 0.82 (0.21) | n= 3 (60.0%) \| 0.88 (0.11) | -0.31 [-1.81 ; 1.19] |
| Week 21 | n= 6 (75.0%) \| 0.82 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (75.0%) \| 0.81 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (75.0%) \| 0.80 (0.17) | n= 5 (100.0%) \| 0.91 (0.08) | -0.74 [-2.04 ; 0.57] |
| Week 27 | n= 6 (75.0%) \| 0.83 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 5 (62.5%) \| 0.76 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 6 (75.0%) \| 0.83 (0.15) | n= 3 (60.0%) \| 1.00 (0.00) | -1.25 [-2.89 ; 0.39] |
| Week 33 | n= 6 (75.0%) \| 0.85 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 6 (75.0%) \| 0.80 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 5 (62.5%) \| 0.83 (0.19) | n= 3 (60.0%) \| 0.90 (0.09) | -0.36 [-1.93 ; 1.21] |
| Week 39 | n= 5 (62.5%) \| 0.78 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 5 (62.5%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 6 (75.0%) \| 0.84 (0.20) | n= 1 (20.0%) \| 0.85 ( / ) | [Not calculable] |
| Week 45 | n= 5 (62.5%) \| 0.82 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (75.0%) \| 0.83 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (75.0%) \| 0.85 (0.18) | n= 1 (20.0%) \| 0.80 ( / ) | [Not calculable] |
| Week 51 | n= 6 (75.0%) \| 0.78 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 5 (62.5%) \| 0.80 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 5 (62.5%) \| 0.77 (0.24) | n= 1 (20.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 57 | n= 4 (50.0%) \| 0.78 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 5 (62.5%) \| 0.68 (0.43) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 5 (62.5%) \| 0.81 (0.27) | n= 1 (20.0%) \| 0.80 ( / ) | [Not calculable] |
| Week 63 | n= 3 (37.5%) \| 0.86 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 5 (62.5%) \| 0.81 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 4 (50.0%) \| 0.84 (0.23) | n= 1 (20.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 69 | n= 2 (25.0%) \| 0.76 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 3 (37.5%) \| 0.81 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (37.5%) \| 0.79 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 75 | n= 2 (25.0%) \| 0.76 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (37.5%) \| 0.84 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 2 (25.0%) \| 1.00 (0.00) | n= 1 (20.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 81 | n= 2 (25.0%) \| 1.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (25.0%) \| 0.85 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (25.0%) \| 1.00 (0.00) | n= 1 (20.0%) \| 0.80 ( / ) | [Not calculable] |
| Week 87 | n= 2 (25.0%) \| 1.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (25.0%) \| 1.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 93 | n= 1 (12.5%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 1 (12.5%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 1 (12.5%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 1 (12.5%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (12.5%) \| 0.73 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (12.5%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 121 | n= 1 (12.5%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 (12.5%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (12.5%) \| 0.73 ( / ) | n= 4 (80.0%) \| 0.92 (0.09) | [Not calculable] |
| Week 202 | n= 1 (12.5%) \| 0.19 ( / ) | n= 3 (60.0%) \| 1.00 (0.00) | [Not calculable] |
| Week 301 | n= 1 (12.5%) \| 0.52 ( / ) | n= 2 (40.0%) \| 1.00 (0.00) | [Not calculable] |
| Week 302 | n= 1 (12.5%) \| 0.66 ( / ) | n= 2 (40.0%) \| 0.69 (0.10) | [Not calculable] |
| Week 303 | n= 1 (12.5%) \| 0.66 ( / ) | n= 1 (20.0%) \| 0.62 ( / ) | [Not calculable] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:43

TABLE 7.2.3: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Week 3 | n= 38 (95.0%) \| 0.00 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 35 (87.5%) \|-0.02 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 37 (92.5%) \|-0.02 (0.19) | n= 41 (89.1%) \| 0.03 (0.19) | -0.25 [-0.70 ; 0.20] |
| Week 9 | n= 35 (87.5%) \|-0.03 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \|-0.04 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 35 (87.5%) \|-0.00 (0.19) | n= 37 (80.4%) \|-0.07 (0.29) | 0.30 [-0.17 ; 0.76] |
| Week 15 | n= 34 (85.0%) \|-0.09 (0.31) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 36 (90.0%) \|-0.02 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \|-0.03 (0.19) | n= 38 (82.6%) \| 0.00 (0.21) | -0.18 [-0.65 ; 0.30] |
| Week 21 | n= 36 (90.0%) \|-0.03 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 34 (85.0%) \|-0.02 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \|-0.01 (0.18) | n= 37 (80.4%) \|-0.06 (0.16) | 0.34 [-0.13 ; 0.81] |
| Week 27 | n= 33 (82.5%) \|-0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \|-0.03 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \|-0.02 (0.21) | n= 29 (63.0%) \|-0.07 (0.20) | 0.25 [-0.26 ; 0.75] |
| Week 33 | n= 36 (90.0%) \| 0.01 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 33 (82.5%) \| 0.01 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \|-0.01 (0.20) | n= 30 (65.2%) \|-0.06 (0.17) | 0.27 [-0.24 ; 0.77] |
| Week 39 | n= 33 (82.5%) \|-0.02 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \| 0.00 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 31 (77.5%) \| 0.00 (0.22) | n= 29 (63.0%) \|-0.07 (0.21) | 0.35 [-0.17 ; 0.86] |
| Week 45 | n= 33 (82.5%) \| 0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \| 0.02 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 34 (85.0%) \| 0.03 (0.20) | n= 27 (58.7%) \|-0.04 (0.17) | 0.42 [-0.10 ; 0.93] |
| Week 51 | n= 32 (80.0%) \|-0.02 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 30 (75.0%) \| 0.00 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 31 (77.5%) \| 0.00 (0.21) | n= 27 (58.7%) \|-0.02 (0.20) | 0.11 [-0.41 ; 0.63] |
| Week 57 | n= 31 (77.5%) \|-0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 26 (65.0%) \| 0.02 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \| 0.01 (0.24) | n= 19 (41.3%) \|-0.07 (0.18) | 0.35 [-0.23 ; 0.93] |
| Week 63 | n= 30 (75.0%) \|-0.01 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 28 (70.0%) \| 0.04 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \|-0.02 (0.23) | n= 20 (43.5%) \|-0.04 (0.15) | 0.11 [-0.46 ; 0.67] |
| Week 69 | n= 27 (67.5%) \|-0.01 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \| 0.02 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \|-0.00 (0.24) | n= 17 (37.0%) \|-0.10 (0.21) | 0.45 [-0.18 ; 1.08] |
| Week 75 | n= 26 (65.0%) \| 0.03 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \| 0.02 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \| 0.05 (0.22) | n= 15 (32.6%) \|-0.07 (0.24) | 0.51 [-0.15 ; 1.18] |
| Week 81 | n= 24 (60.0%) \| 0.01 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \| 0.02 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \| 0.01 (0.17) | n= 13 (28.3%) \|-0.13 (0.23) | 0.66 [-0.06 ; 1.39] |
| Week 87 | n= 19 (47.5%) \|-0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (47.5%) \| 0.00 (0.21) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 20 (50.0%) \|-0.05 (0.21) | n= 12 (26.1%) \|-0.06 (0.25) | 0.05 [-0.68 ; 0.78] |
| Week 93 | n= 16 (40.0%) \|-0.00 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \|-0.05 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \|-0.06 (0.21) | n= 7 (15.2%) \|-0.05 (0.19) | -0.05 [-0.94 ; 0.85] |
| Week 99 | n= 13 (32.5%) \|-0.06 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \|-0.08 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \|-0.08 (0.16) | n= 6 (13.0%) \|-0.07 (0.15) | -0.03 [-1.04 ; 0.98] |
| Week 105 | n= 11 (27.5%) \|-0.13 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \|-0.09 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \|-0.16 (0.32) | n= 2 ( 4.3%) \| 0.00 (0.00) | -0.50 [-2.14 ; 1.13] |
| Week 111 | n= 7 (17.5%) \|-0.29 (0.44) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \|-0.08 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \|-0.03 (0.26) | n= 3 ( 6.5%) \|-0.22 (0.19) | 0.68 [-0.86 ; 2.21] |
| Week 117 | n= 5 (12.5%) \|-0.18 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \|-0.16 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \|-0.10 (0.18) | n= 1 ( 2.2%) \|-0.38 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \| 0.15 ( / ) | n= 1 ( 2.2%) \|-0.38 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \| 0.12 (0.27) | n= 9 (19.6%) \|-0.17 (0.28) | 0.96 [-0.33 ; 2.26] |
| Week 202 | [No Data] | n= 7 (15.2%) \|-0.13 (0.16) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 ( 8.7%) \| 0.03 (0.08) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 1 ( 2.2%) \| 0.02 ( / ) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 2.5%) \|-0.23 ( / ) | n= 3 ( 6.5%) \|-0.29 (0.31) | [Not calculable] |
| Week 304 | [No Data] | n= 1 ( 2.2%) \| 0.00 ( / ) | [No Data for at least 1 arm] |
| **>= 65 AND < 75** | | | |
| N subjects in population | N=23 | N=17 | |
| Week 3 | n= 20 (87.0%) \|-0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 22 (95.7%) \|-0.05 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 21 (91.3%) \|-0.09 (0.25) | n= 17 (100.0%) \|-0.02 (0.23) | -0.30 [-0.96 ; 0.35] |
| Week 9 | n= 18 (78.3%) \|-0.06 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 19 (82.6%) \|-0.04 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 19 (82.6%) \|-0.05 (0.18) | n= 12 (70.6%) \|-0.07 (0.09) | 0.13 [-0.60 ; 0.87] |
| Week 15 | n= 14 (60.9%) \| 0.01 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 18 (78.3%) \|-0.08 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 19 (82.6%) \| 0.01 (0.15) | n= 10 (58.8%) \|-0.06 (0.17) | 0.41 [-0.37 ; 1.20] |
| Week 21 | n= 18 (78.3%) \|-0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (65.2%) \|-0.03 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 16 (69.6%) \|-0.04 (0.18) | n= 8 (47.1%) \|-0.03 (0.10) | -0.03 [-0.89 ; 0.84] |
| Week 27 | n= 16 (69.6%) \|-0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 15 (65.2%) \| 0.02 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 15 (65.2%) \|-0.03 (0.15) | n= 11 (64.7%) \|-0.10 (0.17) | 0.44 [-0.37 ; 1.24] |
| Week 33 | n= 15 (65.2%) \|-0.10 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 14 (60.9%) \|-0.06 (0.31) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 13 (56.5%) \| 0.01 (0.13) | n= 11 (64.7%) \|-0.09 (0.12) | 0.78 [-0.07 ; 1.63] |
| Week 39 | n= 15 (65.2%) \| 0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 12 (52.2%) \|-0.03 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 16 (69.6%) \|-0.05 (0.13) | n= 11 (64.7%) \|-0.03 (0.15) | -0.11 [-0.89 ; 0.68] |
| Week 45 | n= 11 (47.8%) \|-0.04 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 13 (56.5%) \|-0.04 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 13 (56.5%) \|-0.02 (0.11) | n= 9 (52.9%) \|-0.19 (0.34) | 0.74 [-0.16 ; 1.64] |
| Week 51 | n= 13 (56.5%) \| 0.00 (0.10) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (56.5%) \| 0.01 (0.13) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 55 | n= 11 (47.8%) \| 0.04 (0.17) | n= 10 (58.8%) \|-0.05 (0.12) | 0.59 [-0.31 ; 1.49] |
| Week 57 | n= 12 (52.2%) \| 0.01 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 13 (56.5%) \|-0.05 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 12 (52.2%) \|-0.03 (0.15) | n= 10 (58.8%) \|-0.15 (0.34) | 0.43 [-0.44 ; 1.30] |
| Week 63 | n= 9 (39.1%) \|-0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (47.8%) \|-0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (34.8%) \|-0.00 (0.17) | n= 9 (52.9%) \|-0.12 (0.22) | 0.54 [-0.46 ; 1.55] |
| Week 69 | n= 7 (30.4%) \|-0.00 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 8 (34.8%) \|-0.06 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 6 (26.1%) \| 0.02 (0.19) | n= 10 (58.8%) \|-0.09 (0.20) | 0.51 [-0.56 ; 1.57] |
| Week 75 | n= 8 (34.8%) \| 0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (21.7%) \| 0.08 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (21.7%) \| 0.06 (0.22) | n= 8 (47.1%) \|-0.05 (0.10) | 0.69 [-0.52 ; 1.89] |
| Week 81 | n= 5 (21.7%) \| 0.05 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (26.1%) \| 0.05 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (21.7%) \| 0.04 (0.15) | n= 6 (35.3%) \|-0.04 (0.21) | 0.39 [-0.87 ; 1.66] |
| Week 87 | n= 3 (13.0%) \|-0.37 (0.45) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 4 (17.4%) \|-0.07 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (17.4%) \|-0.02 (0.13) | n= 5 (29.4%) \|-0.07 (0.18) | 0.28 [-1.14 ; 1.70] |
| Week 93 | n= 3 (13.0%) \|-0.08 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (17.4%) \|-0.01 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (13.0%) \|-0.07 (0.08) | n= 3 (17.6%) \|-0.21 (0.25) | 0.62 [-1.26 ; 2.49] |
| Week 99 | n= 3 (13.0%) \|-0.11 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 8.7%) \|-0.11 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (13.0%) \|-0.04 (0.07) | n= 3 (17.6%) \|-0.16 (0.28) | 0.47 [-1.38 ; 2.32] |
| Week 105 | n= 3 (13.0%) \|-0.09 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 4.3%) \|-0.16 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 8.7%) \|-0.11 (0.08) | n= 2 (11.8%) \| 0.00 (0.00) | -1.13 [-4.12 ; 1.87] |
| Week 113 | n= 1 ( 4.3%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | [No Data] | n= 2 (11.8%) \| 0.00 (0.00) | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 4.3%) \|-0.09 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.3%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 4.3%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 4.3%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.3%) \|-0.03 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.3%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (13.0%) \|-0.13 (0.14) | n= 4 (23.5%) \|-0.11 (0.30) | -0.08 [-1.73 ; 1.58] |
| Week 202 | n= 1 ( 4.3%) \|-0.31 ( / ) | n= 2 (11.8%) \| 0.01 (0.42) | [Not calculable] |
| Week 301 | n= 1 ( 4.3%) \| 0.15 ( / ) | n= 3 (17.6%) \| 0.13 (0.26) | [Not calculable] |
| Week 302 | n= 1 ( 4.3%) \|-0.12 ( / ) | n= 3 (17.6%) \|-0.13 (0.14) | [Not calculable] |
| Week 303 | n= 1 ( 4.3%) \| 0.15 ( / ) | n= 2 (11.8%) \| 0.08 (0.11) | [Not calculable] |
| Week 304 | n= 1 ( 4.3%) \| 0.15 ( / ) | n= 2 (11.8%) \|-0.30 (0.20) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 5.9%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 5.9%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 5.9%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 5.9%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 5.9%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| **>= 75** | | | |
| N subjects in population | N=8 | N=5 | |
| Week 3 | n= 8 (100.0%) \|-0.00 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 7 (87.5%) \|-0.13 (0.23) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 7 | n= 6 (75.0%) \|-0.09 (0.12) | n= 4 (80.0%) \|-0.10 (0.11) | 0.07 [-1.28 ; 1.41] |
| Week 9 | n= 6 (75.0%) \|-0.03 (0.06) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 7 (87.5%) \|-0.14 (0.33) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 5 (62.5%) \|-0.13 (0.20) | n= 3 (60.0%) \|-0.10 (0.15) | -0.17 [-1.73 ; 1.39] |
| Week 15 | n= 6 (75.0%) \|-0.11 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 7 (87.5%) \|-0.07 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 6 (75.0%) \|-0.04 (0.19) | n= 3 (60.0%) \|-0.05 (0.14) | 0.07 [-1.42 ; 1.55] |
| Week 21 | n= 6 (75.0%) \|-0.03 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (75.0%) \|-0.05 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (75.0%) \|-0.06 (0.20) | n= 5 (100.0%) \|-0.05 (0.10) | -0.04 [-1.29 ; 1.22] |
| Week 27 | n= 6 (75.0%) \|-0.03 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 5 (62.5%) \|-0.07 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 6 (75.0%) \|-0.03 (0.16) | n= 3 (60.0%) \| 0.00 (0.00) | -0.18 [-1.67 ; 1.31] |
| Week 33 | n= 6 (75.0%) \|-0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 6 (75.0%) \|-0.05 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 5 (62.5%) \| 0.01 (0.16) | n= 3 (60.0%) \|-0.10 (0.09) | 0.67 [-0.94 ; 2.28] |
| Week 39 | n= 5 (62.5%) \|-0.05 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 5 (62.5%) \|-0.05 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 6 (75.0%) \|-0.01 (0.15) | n= 1 (20.0%) \|-0.15 ( / ) | [Not calculable] |
| Week 45 | n= 5 (62.5%) \|-0.00 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (75.0%) \|-0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (75.0%) \|-0.01 (0.16) | n= 1 (20.0%) \|-0.20 ( / ) | [Not calculable] |
| Week 51 | n= 6 (75.0%) \|-0.07 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 5 (62.5%) \|-0.06 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 5 (62.5%) \|-0.10 (0.28) | n= 1 (20.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 57 | n= 4 (50.0%) \|-0.05 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 5 (62.5%) \|-0.18 (0.49) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 5 (62.5%) \|-0.06 (0.27) | n= 1 (20.0%) \|-0.20 ( / ) | [Not calculable] |
| Week 63 | n= 3 (37.5%) \|-0.05 (0.35) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 5 (62.5%) \|-0.05 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 4 (50.0%) \| 0.01 (0.19) | n= 1 (20.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 69 | n= 2 (25.0%) \| 0.10 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 3 (37.5%) \| 0.04 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (37.5%) \| 0.02 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 75 | n= 2 (25.0%) \| 0.10 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (37.5%) \| 0.07 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 2 (25.0%) \| 0.14 (0.19) | n= 1 (20.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 81 | n= 2 (25.0%) \| 0.14 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (25.0%) \|-0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (25.0%) \| 0.14 (0.19) | n= 1 (20.0%) \|-0.20 ( / ) | [Not calculable] |
| Week 87 | n= 2 (25.0%) \| 0.14 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (25.0%) \| 0.14 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 93 | n= 1 (12.5%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 1 (12.5%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 1 (12.5%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 1 (12.5%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (12.5%) \|-0.27 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (12.5%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 (12.5%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 (12.5%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (12.5%) \| 0.11 ( / ) | n= 4 (80.0%) \|-0.02 (0.09) | [Not calculable] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 202 | n= 1 (12.5%) \|-0.50 ( / ) | n= 3 (60.0%) \| 0.00 (0.00) | [Not calculable] |
| Week 301 | n= 1 (12.5%) \|-0.17 ( / ) | n= 2 (40.0%) \| 0.10 (0.14) | [Not calculable] |
| Week 302 | n= 1 (12.5%) \| 0.04 ( / ) | n= 2 (40.0%) \|-0.21 (0.24) | [Not calculable] |
| Week 303 | n= 1 (12.5%) \| 0.04 ( / ) | n= 1 (20.0%) \|-0.38 ( / ) | [Not calculable] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:44

TABLE 7.2.3: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **< 65** | | | | |
| Nr subjects used | n=40 | n=46 | | |
| Week 7 | -0.01 (0.03) [-0.07 ; 0.04] | -0.01 (0.03) [-0.06 ; 0.05] | -0.01 (0.04) [-0.08 ; 0.07] | -0.05 [-0.49 ; 0.40] |
| Week 13 | -0.01 (0.04) [-0.09 ; 0.07] | -0.10 (0.04) [-0.18 ;-0.02] | 0.09 (0.06) [-0.02 ; 0.20] | 0.37 [-0.10 ; 0.84] |
| Week 19 | -0.05 (0.03) [-0.11 ; 0.02] | -0.02 (0.03) [-0.08 ; 0.04] | -0.03 (0.04) [-0.11 ; 0.06] | -0.14 [-0.61 ; 0.33] |
| Week 25 | -0.01 (0.03) [-0.06 ; 0.04] | -0.05 (0.03) [-0.10 ;-0.00] | 0.05 (0.04) [-0.03 ; 0.12] | 0.28 [-0.18 ; 0.74] |
| Week 31 | -0.03 (0.03) [-0.10 ; 0.03] | -0.06 (0.03) [-0.13 ; 0.01] | 0.03 (0.05) [-0.06 ; 0.12] | 0.15 [-0.35 ; 0.65] |
| Week 37 | 0.00 (0.03) [-0.06 ; 0.06] | -0.05 (0.03) [-0.10 ; 0.01] | 0.05 (0.04) [-0.04 ; 0.13] | 0.28 [-0.22 ; 0.79] |
| Week 43 | 0.01 (0.03) [-0.05 ; 0.07] | -0.06 (0.03) [-0.12 ; 0.01] | 0.07 (0.04) [-0.02 ; 0.16] | 0.39 [-0.12 ; 0.91] |
| Week 49 | 0.03 (0.02) [-0.02 ; 0.08] | -0.04 (0.03) [-0.09 ; 0.01] | 0.07 (0.04) [-0.00 ; 0.14] | 0.48 [-0.03 ; 1.00] |
| Week 55 | 0.00 (0.03) [-0.05 ; 0.06] | -0.01 (0.03) [-0.07 ; 0.05] | 0.01 (0.04) [-0.07 ; 0.09] | 0.09 [-0.42 ; 0.61] |
| Week 61 | -0.00 (0.03) [-0.06 ; 0.05] | -0.02 (0.04) [-0.09 ; 0.05] | 0.02 (0.05) [-0.07 ; 0.11] | 0.11 [-0.46 ; 0.69] |
| Week 67 | -0.01 (0.03) [-0.07 ; 0.05] | -0.04 (0.04) [-0.11 ; 0.04] | 0.03 (0.05) [-0.07 ; 0.13] | 0.17 [-0.39 ; 0.73] |
| Week 73 | -0.01 (0.03) [-0.07 ; 0.05] | -0.08 (0.04) [-0.16 ;-0.01] | 0.08 (0.05) [-0.02 ; 0.17] | 0.50 [-0.12 ; 1.13] |
| Week 79 | 0.02 (0.03) [-0.05 ; 0.08] | -0.05 (0.04) [-0.13 ; 0.03] | 0.07 (0.05) [-0.03 ; 0.16] | 0.44 [-0.22 ; 1.09] |
| Week 85 | 0.00 (0.03) [-0.05 ; 0.06] | -0.11 (0.04) [-0.18 ;-0.03] | 0.11 (0.05) [ 0.02 ; 0.21] | 0.83 [ 0.10 ; 1.56] |
| Week 91 | -0.03 (0.04) [-0.11 ; 0.05] | -0.07 (0.05) [-0.18 ; 0.03] | 0.04 (0.07) [-0.09 ; 0.18] | 0.24 [-0.48 ; 0.96] |
| Overall post-baseline period estimate | -0.01 (0.02) [-0.04 ; 0.03] | -0.05 (0.02) [-0.09 ;-0.02] | 0.04 (0.02) [-0.00 ; 0.09] | 0.41 [-0.02 ; 0.84] |
| **>= 65 AND < 75** | | | | |
| Nr subjects used | n=23 | n=17 | | |
| Week 7 | -0.11 (0.05) [-0.21 ;-0.01] | -0.05 (0.06) [-0.16 ; 0.07] | -0.07 (0.08) [-0.22 ; 0.09] | -0.28 [-0.92 ; 0.36] |
| Week 13 | -0.06 (0.03) [-0.13 ; 0.01] | -0.06 (0.04) [-0.15 ; 0.03] | 0.00 (0.05) [-0.11 ; 0.11] | 0.01 [-0.71 ; 0.73] |
| Week 19 | 0.01 (0.03) [-0.06 ; 0.08] | -0.05 (0.05) [-0.14 ; 0.04] | 0.06 (0.06) [-0.06 ; 0.17] | 0.37 [-0.40 ; 1.14] |
| Week 31 | -0.02 (0.04) [-0.10 ; 0.07] | -0.09 (0.05) [-0.19 ; 0.01] | 0.07 (0.06) [-0.06 ; 0.20] | 0.45 [-0.34 ; 1.24] |
| Week 37 | 0.01 (0.03) [-0.05 ; 0.08] | -0.08 (0.04) [-0.16 ;-0.00] | 0.09 (0.05) [-0.01 ; 0.20] | 0.75 [-0.09 ; 1.59] |
| Week 43 | -0.05 (0.03) [-0.11 ; 0.02] | -0.02 (0.04) [-0.10 ; 0.06] | -0.03 (0.05) [-0.13 ; 0.07] | -0.22 [-0.99 ; 0.55] |
| Week 55 | 0.03 (0.04) [-0.05 ; 0.11] | -0.03 (0.04) [-0.12 ; 0.05] | 0.07 (0.06) [-0.05 ; 0.18] | 0.49 [-0.38 ; 1.36] |
| Week 61 | -0.05 (0.08) [-0.21 ; 0.10] | -0.13 (0.08) [-0.30 ; 0.05] | 0.07 (0.11) [-0.16 ; 0.31] | 0.27 [-0.57 ; 1.12] |
| Overall post-baseline period estimate | -0.03 (0.02) [-0.07 ; 0.01] | -0.06 (0.02) [-0.11 ;-0.01] | 0.03 (0.03) [-0.03 ; 0.10] | 0.32 [-0.31 ; 0.96] |
| **>= 75** | | | | |
| Nr subjects used | n=8 | n=5 | | |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.1690 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:44

TABLE 7.2.4: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **US/Canada/Western Europe/Northern Europe** | N=38 | N=34 |
| **Rest of World (ROW)** | N=33 | N=34 |
| **Subjects with Baseline Value** | | |
| **US/Canada/Western Europe/Northern Europe** | 38 (100.0%) | 34 (100.0%) |
| **Rest of World (ROW)** | 33 (100.0%) | 34 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **US/Canada/Western Europe/Northern Europe** | 38 (100.0%) | 33 (97.1%) |
| **Rest of World (ROW)** | 33 (100.0%) | 33 (97.1%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **US/Canada/Western Europe/Northern Europe** | 38 (100.0%) | 33 (97.1%) |
| **Rest of World (ROW)** | 33 (100.0%) | 33 (97.1%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:44

TABLE 7.2.4: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **US/Canada/Western Europe/Northern Europe** | | | |
| N subjects in population | N=38 | N=34 | |
| Baseline | n= 38 (100.0%) \| 0.81 (0.21) | n= 34 (100.0%) \| 0.77 (0.31) | 0.17 [-0.29 ; 0.64] |
| Week 3 | n= 35 (92.1%) \| 0.82 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 34 (89.5%) \| 0.81 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 34 (89.5%) \| 0.83 (0.15) | n= 31 (91.2%) \| 0.83 (0.16) | 0.04 [-0.45 ; 0.53] |
| Week 9 | n= 30 (78.9%) \| 0.79 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 32 (84.2%) \| 0.78 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 31 (81.6%) \| 0.80 (0.25) | n= 24 (70.6%) \| 0.82 (0.19) | -0.11 [-0.65 ; 0.42] |
| Week 15 | n= 27 (71.1%) \| 0.79 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 32 (84.2%) \| 0.79 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 30 (78.9%) \| 0.79 (0.23) | n= 25 (73.5%) \| 0.82 (0.24) | -0.11 [-0.65 ; 0.43] |
| Week 21 | n= 30 (78.9%) \| 0.79 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 27 (71.1%) \| 0.78 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 30 (78.9%) \| 0.78 (0.25) | n= 25 (73.5%) \| 0.80 (0.18) | -0.08 [-0.62 ; 0.45] |
| Week 27 | n= 27 (71.1%) \| 0.80 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 27 (71.1%) \| 0.76 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 25 (65.8%) \| 0.76 (0.25) | n= 20 (58.8%) \| 0.74 (0.28) | 0.05 [-0.55 ; 0.64] |
| Week 33 | n= 30 (78.9%) \| 0.80 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 27 (71.1%) \| 0.80 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 25 (65.8%) \| 0.80 (0.22) | n= 22 (64.7%) \| 0.79 (0.19) | 0.03 [-0.55 ; 0.61] |
| Week 39 | n= 28 (73.7%) \| 0.77 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 28 (73.7%) \| 0.80 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 29 (76.3%) \| 0.79 (0.19) | n= 20 (58.8%) \| 0.83 (0.21) | -0.23 [-0.81 ; 0.35] |
| Week 45 | n= 25 (65.8%) \| 0.82 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 27 (71.1%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 29 (76.3%) \| 0.81 (0.18) | n= 17 (50.0%) \| 0.78 (0.21) | 0.16 [-0.45 ; 0.76] |
| Week 51 | n= 27 (71.1%) \| 0.78 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 26 (68.4%) \| 0.82 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 26 (68.4%) \| 0.82 (0.17) | n= 17 (50.0%) \| 0.84 (0.21) | -0.08 [-0.70 ; 0.54] |
| Week 57 | n= 26 (68.4%) \| 0.79 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 22 (57.9%) \| 0.78 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 24 (63.2%) \| 0.83 (0.19) | n= 13 (38.2%) \| 0.80 (0.22) | 0.15 [-0.54 ; 0.83] |
| Week 63 | n= 21 (55.3%) \| 0.76 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (57.9%) \| 0.79 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 23 (60.5%) \| 0.81 (0.22) | n= 13 (38.2%) \| 0.82 (0.10) | -0.03 [-0.72 ; 0.66] |
| Week 69 | n= 18 (47.4%) \| 0.78 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 21 (55.3%) \| 0.80 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (42.1%) \| 0.74 (0.18) | n= 14 (41.2%) \| 0.76 (0.23) | -0.08 [-0.81 ; 0.65] |
| Week 75 | n= 17 (44.7%) \| 0.79 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (42.1%) \| 0.77 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 15 (39.5%) \| 0.81 (0.19) | n= 11 (32.4%) \| 0.78 (0.27) | 0.13 [-0.67 ; 0.92] |
| Week 81 | n= 16 (42.1%) \| 0.76 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 16 (42.1%) \| 0.76 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (28.9%) \| 0.80 (0.20) | n= 10 (29.4%) \| 0.78 (0.24) | 0.10 [-0.78 ; 0.98] |
| Week 87 | n= 10 (26.3%) \| 0.76 (0.20) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 11 (28.9%) \| 0.76 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 12 (31.6%) \| 0.69 (0.25) | n= 8 (23.5%) \| 0.83 (0.14) | -0.65 [-1.60 ; 0.29] |
| Week 93 | n= 11 (28.9%) \| 0.74 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (28.9%) \| 0.69 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (31.6%) \| 0.68 (0.25) | n= 5 (14.7%) \| 0.80 (0.15) | -0.49 [-1.58 ; 0.60] |
| Week 99 | n= 9 (23.7%) \| 0.65 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (15.8%) \| 0.69 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (21.1%) \| 0.79 (0.15) | n= 5 (14.7%) \| 0.90 (0.13) | -0.72 [-1.93 ; 0.48] |
| Week 105 | n= 8 (21.1%) \| 0.65 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (10.5%) \| 0.76 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (18.4%) \| 0.69 (0.17) | n= 2 ( 5.9%) \| 0.90 (0.14) | -1.17 [-2.97 ; 0.64] |
| Week 111 | n= 4 (10.5%) \| 0.39 (0.66) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (10.5%) \| 0.73 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 (10.5%) \| 0.78 (0.25) | n= 3 ( 8.8%) \| 0.82 (0.17) | -0.13 [-1.78 ; 1.53] |
| Week 117 | n= 4 (10.5%) \| 0.66 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 (10.5%) \| 0.63 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (13.2%) \| 0.76 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.6%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.6%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (10.5%) \| 0.93 (0.14) | n= 8 (23.5%) \| 0.61 (0.24) | 1.35 [-0.05 ; 2.75] |
| Week 202 | [No Data] | n= 5 (14.7%) \| 0.77 (0.26) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 (11.8%) \| 0.74 (0.20) | [No Data for at least 1 arm] |
| Week 302 | n= 1 ( 2.6%) \| 0.66 ( / ) | n= 3 ( 8.8%) \| 0.72 (0.04) | [Not calculable] |
| Week 303 | n= 2 ( 5.3%) \| 0.64 (0.03) | n= 2 ( 5.9%) \| 0.77 (0.11) | -0.91 [-3.74 ; 1.91] |
| Week 304 | n= 1 ( 2.6%) \| 1.00 ( / ) | n= 1 ( 2.9%) \| 0.26 ( / ) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 2.9%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 2.9%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 2.9%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 2.9%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 2.9%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| **Rest of World (ROW)** | | | |
| N subjects in population | N=33 | N=34 | |
| Baseline | n= 33 (100.0%) \| 0.86 (0.19) | n= 34 (100.0%) \| 0.81 (0.27) | 0.21 [-0.27 ; 0.69] |
| Week 3 | n= 31 (93.9%) \| 0.84 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 30 (90.9%) \| 0.78 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 30 (90.9%) \| 0.75 (0.26) | n= 31 (91.2%) \| 0.75 (0.30) | 0.01 [-0.50 ; 0.52] |
| Week 9 | n= 29 (87.9%) \| 0.82 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 29 (87.9%) \| 0.80 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 28 (84.8%) \| 0.82 (0.16) | n= 28 (82.4%) \| 0.70 (0.24) | 0.59 [ 0.05 ; 1.13] |
| Week 15 | n= 27 (81.8%) \| 0.78 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 29 (87.9%) \| 0.80 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 27 (81.8%) \| 0.84 (0.16) | n= 26 (76.5%) \| 0.82 (0.14) | 0.08 [-0.47 ; 0.62] |
| Week 21 | n= 30 (90.9%) \| 0.83 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 28 (84.8%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 28 (84.8%) \| 0.88 (0.15) | n= 25 (73.5%) \| 0.83 (0.15) | 0.35 [-0.20 ; 0.90] |
| Week 27 | n= 28 (84.8%) \| 0.88 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 26 (78.8%) \| 0.89 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 29 (87.9%) \| 0.88 (0.15) | n= 23 (67.6%) \| 0.85 (0.13) | 0.23 [-0.33 ; 0.78] |
| Week 33 | n= 27 (81.8%) \| 0.84 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 26 (78.8%) \| 0.85 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 24 (72.7%) \| 0.90 (0.15) | n= 22 (64.7%) \| 0.84 (0.14) | 0.41 [-0.18 ; 1.00] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 39 | n= 25 (75.8%) \| 0.90 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 23 (69.7%) \| 0.90 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 24 (72.7%) \| 0.88 (0.15) | n= 21 (61.8%) \| 0.79 (0.15) | 0.63 [ 0.02 ; 1.24] |
| Week 45 | n= 24 (72.7%) \| 0.90 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 25 (75.8%) \| 0.89 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 24 (72.7%) \| 0.92 (0.14) | n= 20 (58.8%) \| 0.76 (0.29) | 0.70 [ 0.08 ; 1.32] |
| Week 51 | n= 24 (72.7%) \| 0.88 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 22 (66.7%) \| 0.88 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 21 (63.6%) \| 0.87 (0.16) | n= 21 (61.8%) \| 0.82 (0.16) | 0.25 [-0.36 ; 0.87] |
| Week 57 | n= 21 (63.6%) \| 0.90 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 22 (66.7%) \| 0.85 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 24 (72.7%) \| 0.85 (0.19) | n= 17 (50.0%) \| 0.75 (0.31) | 0.42 [-0.22 ; 1.05] |
| Week 63 | n= 21 (63.6%) \| 0.90 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (66.7%) \| 0.90 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 21 (63.6%) \| 0.87 (0.16) | n= 17 (50.0%) \| 0.79 (0.23) | 0.43 [-0.22 ; 1.09] |
| Week 69 | n= 18 (54.5%) \| 0.87 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 18 (54.5%) \| 0.85 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 18 (54.5%) \| 0.89 (0.16) | n= 13 (38.2%) \| 0.75 (0.17) | 0.86 [ 0.10 ; 1.62] |
| Week 75 | n= 19 (57.6%) \| 0.90 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (48.5%) \| 0.91 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 16 (48.5%) \| 0.92 (0.13) | n= 13 (38.2%) \| 0.81 (0.15) | 0.77 [ 0.00 ; 1.55] |
| Week 81 | n= 15 (45.5%) \| 0.93 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (51.5%) \| 0.92 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 16 (48.5%) \| 0.93 (0.12) | n= 10 (29.4%) \| 0.77 (0.15) | 1.16 [ 0.29 ; 2.03] |
| Week 87 | n= 14 (42.4%) \| 0.81 (0.32) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 14 (42.4%) \| 0.87 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 12 (36.4%) \| 0.90 (0.15) | n= 9 (26.5%) \| 0.83 (0.15) | 0.44 [-0.46 ; 1.34] |
| Week 93 | n= 9 (27.3%) \| 0.89 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (33.3%) \| 0.90 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 9 (27.3%) \| 0.92 (0.12) | n= 5 (14.7%) \| 0.84 (0.23) | 0.45 [-0.71 ; 1.60] |
| Week 99 | n= 8 (24.2%) \| 0.89 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 8 (24.2%) \| 0.90 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 7 (21.2%) \| 0.82 (0.13) | n= 4 (11.8%) \| 0.76 (0.20) | 0.38 [-0.93 ; 1.68] |
| Week 105 | n= 6 (18.2%) \| 0.87 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (12.1%) \| 0.85 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (12.1%) \| 0.65 (0.38) | n= 2 ( 5.9%) \| 1.00 (0.00) | -0.86 [-2.90 ; 1.19] |
| Week 111 | n= 3 ( 9.1%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (12.1%) \| 0.87 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 2 ( 6.1%) \| 0.84 (0.22) | n= 2 ( 5.9%) \| 0.85 (0.22) | -0.00 [-2.46 ; 2.46] |
| Week 117 | n= 2 ( 6.1%) \| 0.84 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 ( 6.1%) \| 0.84 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 ( 9.1%) \| 0.82 (0.16) | n= 1 ( 2.9%) \| 0.62 ( / ) | [Not calculable] |
| Week 125 | n= 1 ( 3.0%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.0%) \| 0.80 ( / ) | n= 1 ( 2.9%) \| 0.62 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 3.0%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.0%) \| 0.82 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 3.0%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.1%) \| 0.79 (0.08) | n= 9 (26.5%) \| 0.84 (0.20) | -0.30 [-1.54 ; 0.94] |
| Week 202 | n= 2 ( 6.1%) \| 0.44 (0.35) | n= 7 (20.6%) \| 0.86 (0.13) | -2.05 [-4.09 ;-0.02] |
| Week 301 | n= 2 ( 6.1%) \| 0.76 (0.34) | n= 5 (14.7%) \| 0.88 (0.11) | -0.55 [-2.40 ; 1.30] |
| Week 302 | n= 1 ( 3.0%) \| 0.73 ( / ) | n= 3 ( 8.8%) \| 0.72 (0.10) | [Not calculable] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 303 | n= 1 ( 3.0%) \| 1.00 ( / ) | n= 4 (11.8%) \| 0.63 (0.35) | [Not calculable] |
| Week 304 | [No Data] | n= 2 ( 5.9%) \| 0.74 (0.07) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:44

TABLE 7.2.4: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **US/Canada/Western Europe/Northern Europe** | | | |
| N subjects in population | N=38 | N=34 | |
| Week 3 | n= 35 (92.1%) \| 0.00 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 34 (89.5%) \|-0.01 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 34 (89.5%) \|-0.01 (0.11) | n= 31 (91.2%) \| 0.08 (0.23) | -0.48 [-0.98 ; 0.02] |
| Week 9 | n= 30 (78.9%) \|-0.03 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 32 (84.2%) \|-0.03 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 31 (81.6%) \|-0.01 (0.15) | n= 24 (70.6%) \| 0.02 (0.24) | -0.16 [-0.70 ; 0.38] |
| Week 15 | n= 27 (71.1%) \|-0.04 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 32 (84.2%) \|-0.02 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 30 (78.9%) \|-0.00 (0.15) | n= 25 (73.5%) \| 0.02 (0.22) | -0.11 [-0.65 ; 0.42] |
| Week 21 | n= 30 (78.9%) \|-0.02 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 27 (71.1%) \|-0.03 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 30 (78.9%) \|-0.04 (0.15) | n= 25 (73.5%) \|-0.05 (0.14) | 0.12 [-0.42 ; 0.65] |
| Week 27 | n= 27 (71.1%) \|-0.01 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 27 (71.1%) \|-0.05 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 25 (65.8%) \|-0.05 (0.19) | n= 20 (58.8%) \|-0.10 (0.22) | 0.22 [-0.38 ; 0.81] |
| Week 33 | n= 30 (78.9%) \|-0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 27 (71.1%) \|-0.01 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 25 (65.8%) \|-0.02 (0.14) | n= 22 (64.7%) \|-0.08 (0.16) | 0.42 [-0.17 ; 1.00] |
| Week 39 | n= 28 (73.7%) \|-0.03 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 28 (73.7%) \|-0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 29 (76.3%) \|-0.02 (0.18) | n= 20 (58.8%) \|-0.02 (0.19) | -0.01 [-0.59 ; 0.56] |
| Week 45 | n= 25 (65.8%) \| 0.00 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 27 (71.1%) \| 0.00 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 29 (76.3%) \| 0.01 (0.18) | n= 17 (50.0%) \|-0.05 (0.18) | 0.31 [-0.29 ; 0.92] |
| Week 51 | n= 27 (71.1%) \|-0.03 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 26 (68.4%) \|-0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 26 (68.4%) \| 0.01 (0.19) | n= 17 (50.0%) \| 0.01 (0.18) | 0.01 [-0.61 ; 0.63] |
| Week 57 | n= 26 (68.4%) \|-0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 22 (57.9%) \|-0.02 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 24 (63.2%) \| 0.02 (0.18) | n= 13 (38.2%) \|-0.03 (0.18) | 0.29 [-0.39 ; 0.98] |
| Week 63 | n= 21 (55.3%) \|-0.02 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (57.9%) \| 0.01 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 23 (60.5%) \|-0.02 (0.20) | n= 13 (38.2%) \|-0.00 (0.11) | -0.07 [-0.76 ; 0.62] |
| Week 69 | n= 18 (47.4%) \|-0.01 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 21 (55.3%) \| 0.01 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (42.1%) \|-0.02 (0.22) | n= 14 (41.2%) \|-0.08 (0.20) | 0.27 [-0.46 ; 1.01] |
| Week 75 | n= 17 (44.7%) \| 0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (42.1%) \| 0.00 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 15 (39.5%) \| 0.06 (0.18) | n= 11 (32.4%) \|-0.06 (0.20) | 0.60 [-0.21 ; 1.41] |
| Week 81 | n= 16 (42.1%) \|-0.01 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 16 (42.1%) \|-0.01 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (28.9%) \|-0.02 (0.16) | n= 10 (29.4%) \|-0.07 (0.21) | 0.29 [-0.60 ; 1.17] |
| Week 87 | n= 10 (26.3%) \| 0.00 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 11 (28.9%) \| 0.01 (0.23) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 12 (31.6%) \|-0.05 (0.26) | n= 8 (23.5%) \|-0.06 (0.17) | 0.07 [-0.85 ; 0.99] |
| Week 93 | n= 11 (28.9%) \|-0.01 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (28.9%) \|-0.06 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (31.6%) \|-0.07 (0.25) | n= 5 (14.7%) \|-0.09 (0.24) | 0.06 [-1.02 ; 1.14] |
| Week 99 | n= 9 (23.7%) \|-0.07 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (15.8%) \|-0.13 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (21.1%) \|-0.03 (0.16) | n= 5 (14.7%) \| 0.01 (0.03) | -0.29 [-1.47 ; 0.88] |
| Week 105 | n= 8 (21.1%) \|-0.16 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (10.5%) \|-0.11 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (18.4%) \|-0.10 (0.19) | n= 2 ( 5.9%) \| 0.00 (0.00) | -0.51 [-2.22 ; 1.20] |
| Week 111 | n= 4 (10.5%) \|-0.47 (0.54) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (10.5%) \|-0.13 (0.32) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 (10.5%) \|-0.04 (0.34) | n= 3 ( 8.8%) \|-0.11 (0.20) | 0.22 [-1.44 ; 1.88] |
| Week 117 | n= 4 (10.5%) \|-0.28 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 (10.5%) \|-0.22 (0.10) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (13.2%) \|-0.14 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.6%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.6%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (10.5%) \| 0.14 (0.13) | n= 8 (23.5%) \|-0.19 (0.20) | 1.67 [ 0.20 ; 3.15] |
| Week 202 | [No Data] | n= 5 (14.7%) \|-0.13 (0.17) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 (11.8%) \| 0.15 (0.21) | [No Data for at least 1 arm] |
| Week 302 | n= 1 ( 2.6%) \| 0.04 ( / ) | n= 3 ( 8.8%) \|-0.10 (0.15) | [Not calculable] |
| Week 303 | n= 2 ( 5.3%) \|-0.10 (0.19) | n= 2 ( 5.9%) \|-0.08 (0.11) | -0.08 [-2.54 ; 2.39] |
| Week 304 | n= 1 ( 2.6%) \| 0.15 ( / ) | n= 1 ( 2.9%) \|-0.43 ( / ) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 2.9%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 2.9%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 2.9%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 2.9%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 2.9%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| **Rest of World (ROW)** | | | |
| N subjects in population | N=33 | N=34 | |
| Week 3 | n= 31 (93.9%) \|-0.01 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 30 (90.9%) \|-0.08 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 30 (90.9%) \|-0.10 (0.27) | n= 31 (91.2%) \|-0.06 (0.13) | -0.16 [-0.66 ; 0.35] |
| Week 9 | n= 29 (87.9%) \|-0.04 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 29 (87.9%) \|-0.07 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 28 (84.8%) \|-0.04 (0.22) | n= 28 (82.4%) \|-0.15 (0.24) | 0.47 [-0.06 ; 1.01] |
| Week 15 | n= 27 (81.8%) \|-0.09 (0.35) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 29 (87.9%) \|-0.07 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 27 (81.8%) \|-0.04 (0.21) | n= 26 (76.5%) \|-0.04 (0.18) | 0.02 [-0.53 ; 0.56] |
| Week 21 | n= 30 (90.9%) \|-0.03 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 28 (84.8%) \|-0.02 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 28 (84.8%) \|-0.00 (0.21) | n= 25 (73.5%) \|-0.06 (0.15) | 0.32 [-0.23 ; 0.86] |
| Week 27 | n= 28 (84.8%) \|-0.01 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 26 (78.8%) \| 0.01 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 29 (87.9%) \|-0.00 (0.18) | n= 23 (67.6%) \|-0.06 (0.15) | 0.32 [-0.24 ; 0.88] |
| Week 33 | n= 27 (81.8%) \|-0.04 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 26 (78.8%) \|-0.02 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 24 (72.7%) \| 0.01 (0.20) | n= 22 (64.7%) \|-0.06 (0.16) | 0.38 [-0.21 ; 0.97] |
| Week 39 | n= 25 (75.8%) \| 0.01 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 23 (69.7%) \| 0.00 (0.21) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 43 | n= 24 (72.7%) \|-0.01 (0.20) | n= 21 (61.8%) \|-0.11 (0.18) | 0.51 [-0.09 ; 1.11] |
| Week 45 | n= 24 (72.7%) \| 0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 25 (75.8%) \|-0.01 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 24 (72.7%) \| 0.03 (0.17) | n= 20 (58.8%) \|-0.12 (0.26) | 0.65 [ 0.03 ; 1.26] |
| Week 51 | n= 24 (72.7%) \|-0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 22 (66.7%) \| 0.01 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 21 (63.6%) \|-0.01 (0.24) | n= 21 (61.8%) \|-0.06 (0.17) | 0.22 [-0.40 ; 0.83] |
| Week 57 | n= 21 (63.6%) \|-0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 22 (66.7%) \|-0.03 (0.31) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 24 (72.7%) \|-0.04 (0.26) | n= 17 (50.0%) \|-0.15 (0.27) | 0.42 [-0.22 ; 1.05] |
| Week 63 | n= 21 (63.6%) \| 0.00 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (66.7%) \| 0.02 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 21 (63.6%) \|-0.01 (0.23) | n= 17 (50.0%) \|-0.11 (0.20) | 0.44 [-0.22 ; 1.09] |
| Week 69 | n= 18 (54.5%) \|-0.00 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 18 (54.5%) \|-0.00 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 18 (54.5%) \| 0.02 (0.23) | n= 13 (38.2%) \|-0.12 (0.21) | 0.63 [-0.11 ; 1.38] |
| Week 75 | n= 19 (57.6%) \| 0.04 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (48.5%) \| 0.06 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 16 (48.5%) \| 0.06 (0.24) | n= 13 (38.2%) \|-0.06 (0.20) | 0.51 [-0.24 ; 1.27] |
| Week 81 | n= 15 (45.5%) \| 0.06 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (51.5%) \| 0.06 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 16 (48.5%) \| 0.05 (0.17) | n= 10 (29.4%) \|-0.14 (0.24) | 0.93 [ 0.08 ; 1.78] |
| Week 87 | n= 14 (42.4%) \|-0.10 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 14 (42.4%) \|-0.00 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 12 (36.4%) \|-0.04 (0.11) | n= 9 (26.5%) \|-0.06 (0.28) | 0.12 [-0.77 ; 1.00] |
| Week 93 | n= 9 (27.3%) \|-0.04 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (33.3%) \|-0.04 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 9 (27.3%) \|-0.03 (0.07) | n= 5 (14.7%) \|-0.10 (0.21) | 0.50 [-0.66 ; 1.65] |
| Week 99 | n= 8 (24.2%) \|-0.06 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 8 (24.2%) \|-0.05 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 7 (21.2%) \|-0.12 (0.12) | n= 4 (11.8%) \|-0.25 (0.20) | 0.77 [-0.58 ; 2.12] |
| Week 105 | n= 6 (18.2%) \|-0.06 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (12.1%) \|-0.08 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (12.1%) \|-0.24 (0.42) | n= 2 ( 5.9%) \| 0.00 (0.00) | -0.53 [-2.49 ; 1.44] |
| Week 111 | n= 3 ( 9.1%) \|-0.06 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (12.1%) \|-0.02 (0.03) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 2 ( 6.1%) \|-0.02 (0.03) | n= 2 ( 5.9%) \|-0.15 (0.22) | 0.50 [-2.07 ; 3.08] |
| Week 117 | n= 2 ( 6.1%) \|-0.02 (0.03) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 ( 6.1%) \|-0.02 (0.03) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 ( 9.1%) \|-0.04 (0.04) | n= 1 ( 2.9%) \|-0.38 ( / ) | [Not calculable] |
| Week 125 | n= 1 ( 3.0%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.0%) \|-0.05 ( / ) | n= 1 ( 2.9%) \|-0.38 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 3.0%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.0%) \|-0.03 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 3.0%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.1%) \|-0.09 (0.27) | n= 9 (26.5%) \|-0.06 (0.28) | -0.11 [-1.34 ; 1.12] |
| Week 202 | n= 2 ( 6.1%) \|-0.41 (0.14) | n= 7 (20.6%) \|-0.04 (0.20) | -1.69 [-3.62 ; 0.24] |
| Week 301 | n= 2 ( 6.1%) \|-0.01 (0.23) | n= 5 (14.7%) \| 0.02 (0.08) | -0.21 [-2.03 ; 1.60] |
| Week 302 | n= 1 ( 3.0%) \|-0.12 ( / ) | n= 3 ( 8.8%) \|-0.16 (0.20) | [Not calculable] |
| Week 303 | n= 1 ( 3.0%) \| 0.15 ( / ) | n= 4 (11.8%) \|-0.23 (0.35) | [Not calculable] |
| Week 304 | [No Data] | n= 2 ( 5.9%) \|-0.08 (0.11) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:45

TABLE 7.2.4: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **US/Canada/Western Europe/Northern Europe** | | | | |
| Nr subjects used | n=38 | n=34 | | |
| Week 7 | -0.01 (0.02) [-0.05 ; 0.03] | 0.05 (0.02) [ 0.00 ; 0.10] | -0.06 (0.03) [-0.12 ; 0.00] | -0.46 [-0.95 ; 0.04] |
| Week 13 | -0.03 (0.03) [-0.09 ; 0.04] | 0.01 (0.04) [-0.06 ; 0.08] | -0.03 (0.05) [-0.13 ; 0.06] | -0.18 [-0.71 ; 0.36] |
| Week 19 | -0.01 (0.03) [-0.07 ; 0.05] | 0.01 (0.03) [-0.05 ; 0.08] | -0.03 (0.05) [-0.12 ; 0.07] | -0.15 [-0.69 ; 0.38] |
| Week 25 | -0.04 (0.03) [-0.10 ; 0.02] | -0.03 (0.03) [-0.10 ; 0.03] | -0.00 (0.04) [-0.09 ; 0.08] | -0.03 [-0.56 ; 0.50] |
| Week 31 | -0.07 (0.04) [-0.15 ; 0.02] | -0.06 (0.05) [-0.15 ; 0.04] | -0.01 (0.06) [-0.14 ; 0.12] | -0.05 [-0.63 ; 0.54] |
| Week 37 | -0.00 (0.03) [-0.07 ; 0.06] | -0.05 (0.03) [-0.12 ; 0.02] | 0.04 (0.05) [-0.05 ; 0.13] | 0.28 [-0.30 ; 0.86] |
| Week 43 | -0.02 (0.03) [-0.08 ; 0.04] | 0.00 (0.04) [-0.07 ; 0.07] | -0.02 (0.05) [-0.12 ; 0.07] | -0.13 [-0.70 ; 0.44] |
| Week 49 | -0.00 (0.03) [-0.05 ; 0.05] | -0.03 (0.03) [-0.10 ; 0.03] | 0.03 (0.04) [-0.05 ; 0.12] | 0.23 [-0.37 ; 0.83] |
| Week 55 | 0.01 (0.03) [-0.05 ; 0.06] | 0.03 (0.03) [-0.04 ; 0.10] | -0.02 (0.04) [-0.11 ; 0.07] | -0.14 [-0.75 ; 0.48] |
| Week 61 | -0.01 (0.03) [-0.07 ; 0.05] | 0.00 (0.04) [-0.08 ; 0.08] | -0.01 (0.05) [-0.11 ; 0.09] | -0.06 [-0.74 ; 0.61] |
| Week 67 | -0.02 (0.04) [-0.09 ; 0.06] | -0.02 (0.05) [-0.11 ; 0.08] | -0.00 (0.06) [-0.12 ; 0.12] | -0.00 [-0.68 ; 0.68] |
| Week 73 | -0.05 (0.04) [-0.12 ; 0.03] | -0.05 (0.04) [-0.14 ; 0.04] | 0.00 (0.06) [-0.11 ; 0.12] | 0.01 [-0.70 ; 0.73] |
| Week 79 | -0.00 (0.04) [-0.08 ; 0.07] | -0.02 (0.05) [-0.11 ; 0.07] | 0.02 (0.06) [-0.10 ; 0.14] | 0.11 [-0.67 ; 0.89] |
| Week 85 | -0.02 (0.04) [-0.10 ; 0.07] | -0.05 (0.05) [-0.14 ; 0.05] | 0.03 (0.06) [-0.10 ; 0.16] | 0.20 [-0.66 ; 1.05] |
| Overall post-baseline period estimate | -0.02 (0.02) [-0.05 ; 0.02] | -0.01 (0.02) [-0.05 ; 0.03] | -0.00 (0.03) [-0.06 ; 0.05] | -0.04 [-0.50 ; 0.43] |
| **Rest of World (ROW)** | | | | |
| Nr subjects used | n=33 | n=34 | | |
| Week 7 | -0.12 (0.04) [-0.21 ;-0.03] | -0.11 (0.04) [-0.20 ;-0.02] | -0.01 (0.06) [-0.13 ; 0.11] | -0.04 [-0.54 ; 0.46] |
| Week 13 | -0.06 (0.04) [-0.14 ; 0.03] | -0.18 (0.04) [-0.27 ;-0.10] | 0.13 (0.06) [ 0.01 ; 0.24] | 0.56 [ 0.03 ; 1.10] |
| Week 19 | -0.05 (0.03) [-0.11 ; 0.01] | -0.07 (0.03) [-0.13 ;-0.01] | 0.02 (0.04) [-0.06 ; 0.11] | 0.13 [-0.40 ; 0.67] |
| Week 25 | 0.00 (0.03) [-0.05 ; 0.06] | -0.06 (0.03) [-0.12 ;-0.00] | 0.06 (0.04) [-0.02 ; 0.14] | 0.41 [-0.13 ; 0.96] |
| Week 31 | -0.00 (0.02) [-0.05 ; 0.05] | -0.05 (0.03) [-0.10 ; 0.00] | 0.05 (0.04) [-0.02 ; 0.12] | 0.38 [-0.17 ; 0.94] |
| Week 37 | 0.01 (0.03) [-0.05 ; 0.06] | -0.05 (0.03) [-0.11 ; 0.01] | 0.06 (0.04) [-0.02 ; 0.14] | 0.44 [-0.15 ; 1.03] |
| Week 43 | -0.00 (0.03) [-0.07 ; 0.06] | -0.09 (0.03) [-0.16 ;-0.03] | 0.09 (0.05) [-0.00 ; 0.18] | 0.58 [-0.02 ; 1.18] |
| Week 49 | 0.02 (0.05) [-0.07 ; 0.11] | -0.11 (0.05) [-0.21 ;-0.01] | 0.13 (0.07) [-0.01 ; 0.26] | 0.56 [-0.04 ; 1.17] |
| Week 55 | -0.02 (0.04) [-0.09 ; 0.06] | -0.05 (0.04) [-0.13 ; 0.02] | 0.04 (0.05) [-0.07 ; 0.14] | 0.22 [-0.39 ; 0.82] |
| Week 61 | -0.03 (0.05) [-0.12 ; 0.06] | -0.11 (0.05) [-0.22 ;-0.00] | 0.08 (0.07) [-0.06 ; 0.22] | 0.34 [-0.29 ; 0.97] |
| Week 67 | -0.01 (0.03) [-0.08 ; 0.05] | -0.09 (0.04) [-0.16 ;-0.01] | 0.07 (0.05) [-0.03 ; 0.17] | 0.46 [-0.18 ; 1.11] |
| Week 73 | 0.02 (0.03) [-0.04 ; 0.08] | -0.11 (0.03) [-0.18 ;-0.04] | 0.13 (0.05) [ 0.03 ; 0.22] | 0.96 [ 0.20 ; 1.72] |
| Week 79 | 0.04 (0.03) [-0.02 ; 0.10] | -0.07 (0.03) [-0.14 ;-0.01] | 0.11 (0.04) [ 0.02 ; 0.20] | 0.94 [ 0.16 ; 1.71] |
| Week 85 | 0.05 (0.03) [-0.01 ; 0.11] | -0.13 (0.03) [-0.20 ;-0.06] | 0.18 (0.04) [ 0.09 ; 0.27] | 1.60 [ 0.68 ; 2.52] |
| Overall post-baseline period estimate | -0.01 (0.02) [-0.04 ; 0.02] | -0.09 (0.02) [-0.12 ;-0.06] | 0.08 (0.02) [ 0.04 ; 0.13] | 0.85 [ 0.35 ; 1.36] |
| **MMRM subgroups interaction p-value** | | | 0.2439 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.

TABLE 7.2.5: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **White** | N=62 | N=58 |
| **Non-White** | N=9 | N=10 |
| **Subjects with Baseline Value** | | |
| **White** | 62 (100.0%) | 58 (100.0%) |
| **Non-White** | 9 (100.0%) | 10 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **White** | 62 (100.0%) | 56 (96.6%) |
| **Non-White** | 9 (100.0%) | 10 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **White** | 62 (100.0%) | 56 (96.6%) |
| **Non-White** | 9 (100.0%) | 10 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:45

TABLE 7.2.5: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **White** | | | |
| N subjects in population | N=62 | N=58 | |
| Baseline | n= 62 (100.0%) \| 0.84 (0.18) | n= 58 (100.0%) \| 0.77 (0.30) | 0.29 [-0.07 ; 0.65] |
| Week 3 | n= 57 (91.9%) \| 0.83 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 56 (90.3%) \| 0.81 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 57 (91.9%) \| 0.79 (0.21) | n= 53 (91.4%) \| 0.77 (0.25) | 0.09 [-0.28 ; 0.47] |
| Week 9 | n= 50 (80.6%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 52 (83.9%) \| 0.81 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 51 (82.3%) \| 0.83 (0.17) | n= 42 (72.4%) \| 0.76 (0.22) | 0.34 [-0.07 ; 0.75] |
| Week 15 | n= 47 (75.8%) \| 0.79 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 52 (83.9%) \| 0.81 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 49 (79.0%) \| 0.83 (0.15) | n= 42 (72.4%) \| 0.80 (0.20) | 0.15 [-0.27 ; 0.56] |
| Week 21 | n= 51 (82.3%) \| 0.81 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 46 (74.2%) \| 0.83 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 49 (79.0%) \| 0.84 (0.18) | n= 42 (72.4%) \| 0.80 (0.17) | 0.21 [-0.21 ; 0.62] |
| Week 27 | n= 46 (74.2%) \| 0.86 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 45 (72.6%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (72.6%) \| 0.82 (0.18) | n= 36 (62.1%) \| 0.79 (0.21) | 0.17 [-0.27 ; 0.61] |
| Week 33 | n= 49 (79.0%) \| 0.82 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 45 (72.6%) \| 0.82 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 43 (69.4%) \| 0.87 (0.16) | n= 37 (63.8%) \| 0.81 (0.17) | 0.34 [-0.11 ; 0.78] |
| Week 39 | n= 45 (72.6%) \| 0.83 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 43 (69.4%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 46 (74.2%) \| 0.83 (0.17) | n= 35 (60.3%) \| 0.80 (0.19) | 0.14 [-0.31 ; 0.58] |
| Week 45 | n= 42 (67.7%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 44 (71.0%) \| 0.86 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 45 (72.6%) \| 0.86 (0.16) | n= 33 (56.9%) \| 0.75 (0.26) | 0.50 [ 0.04 ; 0.96] |
| Week 51 | n= 43 (69.4%) \| 0.82 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 42 (67.7%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 40 (64.5%) \| 0.85 (0.16) | n= 32 (55.2%) \| 0.82 (0.18) | 0.18 [-0.29 ; 0.65] |
| Week 57 | n= 40 (64.5%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (59.7%) \| 0.81 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 40 (64.5%) \| 0.84 (0.18) | n= 24 (41.4%) \| 0.75 (0.29) | 0.43 [-0.09 ; 0.94] |
| Week 63 | n= 36 (58.1%) \| 0.82 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (58.1%) \| 0.83 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (61.3%) \| 0.84 (0.19) | n= 24 (41.4%) \| 0.79 (0.19) | 0.28 [-0.24 ; 0.79] |
| Week 69 | n= 30 (48.4%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 34 (54.8%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 29 (46.8%) \| 0.84 (0.17) | n= 23 (39.7%) \| 0.75 (0.21) | 0.48 [-0.08 ; 1.04] |
| Week 75 | n= 32 (51.6%) \| 0.86 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 29 (46.8%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 28 (45.2%) \| 0.87 (0.16) | n= 20 (34.5%) \| 0.78 (0.21) | 0.45 [-0.13 ; 1.04] |
| Week 81 | n= 28 (45.2%) \| 0.85 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 31 (50.0%) \| 0.85 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (40.3%) \| 0.86 (0.17) | n= 17 (29.3%) \| 0.75 (0.19) | 0.60 [-0.03 ; 1.24] |
| Week 87 | n= 22 (35.5%) \| 0.79 (0.28) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 23 (37.1%) \| 0.83 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 21 (33.9%) \| 0.79 (0.23) | n= 14 (24.1%) \| 0.83 (0.13) | -0.23 [-0.92 ; 0.46] |
| Week 93 | n= 18 (29.0%) \| 0.81 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 20 (32.3%) \| 0.80 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.0%) \| 0.78 (0.24) | n= 8 (13.8%) \| 0.83 (0.18) | -0.23 [-1.09 ; 0.62] |
| Week 99 | n= 15 (24.2%) \| 0.76 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.0%) \| 0.79 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.0%) \| 0.79 (0.14) | n= 7 (12.1%) \| 0.79 (0.17) | -0.00 [-0.94 ; 0.94] |
| Week 105 | n= 13 (21.0%) \| 0.72 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.3%) \| 0.78 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.1%) \| 0.64 (0.23) | n= 3 ( 5.2%) \| 0.93 (0.12) | -1.27 [-2.73 ; 0.18] |
| Week 111 | n= 7 (11.3%) \| 0.58 (0.53) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (12.9%) \| 0.80 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 5 ( 8.1%) \| 0.77 (0.22) | n= 4 ( 6.9%) \| 0.79 (0.15) | -0.09 [-1.50 ; 1.32] |
| Week 117 | n= 6 ( 9.7%) \| 0.72 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 ( 9.7%) \| 0.70 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.3%) \| 0.75 (0.16) | n= 1 ( 1.7%) \| 0.62 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.6%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.6%) \| 0.80 ( / ) | n= 1 ( 1.7%) \| 0.62 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) \| 0.82 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 7 (11.3%) \| 0.88 (0.13) | n= 12 (20.7%) \| 0.68 (0.25) | 0.85 [-0.15 ; 1.86] |
| Week 202 | n= 2 ( 3.2%) \| 0.44 (0.35) | n= 8 (13.8%) \| 0.80 (0.21) | -1.37 [-3.16 ; 0.42] |
| Week 301 | n= 1 ( 1.6%) \| 0.52 ( / ) | n= 7 (12.1%) \| 0.79 (0.17) | [Not calculable] |
| Week 302 | n= 1 ( 1.6%) \| 0.66 ( / ) | n= 5 ( 8.6%) \| 0.70 (0.05) | [Not calculable] |
| Week 303 | n= 2 ( 3.2%) \| 0.64 (0.03) | n= 5 ( 8.6%) \| 0.78 (0.15) | -0.87 [-2.77 ; 1.04] |
| Week 304 | n= 1 ( 1.6%) \| 1.00 ( / ) | n= 2 ( 3.4%) \| 0.47 (0.31) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.7%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.7%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.7%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.7%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.7%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| **Non-White** | | | |
| N subjects in population | N=9 | N=10 | |
| Baseline | n= 9 (100.0%) \| 0.81 (0.34) | n= 10 (100.0%) \| 0.91 (0.14) | -0.40 [-1.34 ; 0.53] |
| Week 3 | n= 9 (100.0%) \| 0.84 (0.31) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (88.9%) \| 0.71 (0.33) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (77.8%) \| 0.82 (0.18) | n= 9 (90.0%) \| 0.89 (0.14) | -0.41 [-1.44 ; 0.62] |
| Week 9 | n= 9 (100.0%) \| 0.72 (0.33) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (100.0%) \| 0.63 (0.38) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 8 (88.9%) \| 0.68 (0.37) | n= 10 (100.0%) \| 0.73 (0.26) | -0.16 [-1.12 ; 0.80] |
| Week 15 | n= 7 (77.8%) \| 0.72 (0.38) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (100.0%) \| 0.72 (0.32) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 8 (88.9%) \| 0.72 (0.38) | n= 9 (90.0%) \| 0.91 (0.11) | -0.66 [-1.67 ; 0.35] |
| Week 21 | n= 9 (100.0%) \| 0.78 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 9 (100.0%) \| 0.77 (0.35) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 9 (100.0%) \| 0.79 (0.36) | n= 8 (80.0%) \| 0.88 (0.15) | -0.33 [-1.32 ; 0.66] |
| Week 27 | n= 9 (100.0%) \| 0.75 (0.32) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 8 (88.9%) \| 0.72 (0.34) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 31 | n= 9 (100.0%) \| 0.81 (0.34) | n= 7 (70.0%) \| 0.84 (0.25) | -0.08 [-1.10 ; 0.94] |
| Week 33 | n= 8 (88.9%) \| 0.79 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (88.9%) \| 0.83 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 6 (66.7%) \| 0.71 (0.34) | n= 7 (70.0%) \| 0.84 (0.17) | -0.45 [-1.60 ; 0.71] |
| Week 39 | n= 8 (88.9%) \| 0.81 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 8 (88.9%) \| 0.88 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 7 (77.8%) \| 0.86 (0.24) | n= 6 (60.0%) \| 0.86 (0.12) | 0.02 [-1.12 ; 1.16] |
| Week 45 | n= 7 (77.8%) \| 0.88 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 8 (88.9%) \| 0.85 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 8 (88.9%) \| 0.85 (0.21) | n= 4 (40.0%) \| 0.90 (0.21) | -0.20 [-1.46 ; 1.06] |
| Week 51 | n= 8 (88.9%) \| 0.84 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 6 (66.7%) \| 0.89 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (77.8%) \| 0.80 (0.22) | n= 6 (60.0%) \| 0.90 (0.17) | -0.46 [-1.61 ; 0.70] |
| Week 57 | n= 7 (77.8%) \| 0.86 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (77.8%) \| 0.81 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (88.9%) \| 0.83 (0.21) | n= 6 (60.0%) \| 0.87 (0.17) | -0.20 [-1.30 ; 0.91] |
| Week 63 | n= 6 (66.7%) \| 0.89 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (88.9%) \| 0.88 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (66.7%) \| 0.85 (0.19) | n= 6 (60.0%) \| 0.86 (0.17) | -0.03 [-1.22 ; 1.15] |
| Week 69 | n= 6 (66.7%) \| 0.77 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 5 (55.6%) \| 0.77 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 5 (55.6%) \| 0.72 (0.25) | n= 4 (40.0%) \| 0.80 (0.17) | -0.29 [-1.71 ; 1.13] |
| Week 75 | n= 4 (44.4%) \| 0.76 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (33.3%) \| 0.64 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 3 (33.3%) \| 0.84 (0.28) | n= 4 (40.0%) \| 0.85 (0.20) | -0.04 [-1.70 ; 1.61] |
| Week 81 | n= 3 (33.3%) \| 0.80 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (22.2%) \| 0.76 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (22.2%) \| 1.00 (0.00) | n= 3 (30.0%) \| 0.86 (0.24) | 0.51 [-1.66 ; 2.69] |
| Week 87 | n= 2 (22.2%) \| 0.76 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (22.2%) \| 0.76 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (33.3%) \| 0.84 (0.28) | n= 3 (30.0%) \| 0.82 (0.21) | 0.05 [-1.76 ; 1.86] |
| Week 93 | n= 2 (22.2%) \| 0.76 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (22.2%) \| 0.76 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (33.3%) \| 0.84 (0.28) | n= 2 (20.0%) \| 0.79 (0.29) | 0.12 [-2.00 ; 2.23] |
| Week 99 | n= 2 (22.2%) \| 0.76 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (11.1%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (22.2%) \| 0.90 (0.14) | n= 2 (20.0%) \| 1.00 (0.00) | -0.57 [-3.18 ; 2.04] |
| Week 105 | n= 1 (11.1%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (11.1%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 (11.1%) \| 1.00 ( / ) | n= 1 (10.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 115 | n= 1 (11.1%) \| 1.00 ( / ) | n= 1 (10.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 121 | n= 1 (11.1%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 (11.1%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (11.1%) \| 0.73 ( / ) | n= 5 (50.0%) \| 0.86 (0.20) | [Not calculable] |
| Week 202 | [No Data] | n= 4 (40.0%) \| 0.87 (0.15) | [No Data for at least 1 arm] |
| Week 301 | n= 1 (11.1%) \| 1.00 ( / ) | n= 2 (20.0%) \| 0.90 (0.14) | [Not calculable] |
| Week 302 | n= 1 (11.1%) \| 0.73 ( / ) | n= 1 (10.0%) \| 0.81 ( / ) | [Not calculable] |
| Week 303 | n= 1 (11.1%) \| 1.00 ( / ) | n= 1 (10.0%) \| 0.16 ( / ) | [Not calculable] |
| Week 304 | [No Data] | n= 1 (10.0%) \| 0.80 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:46

TABLE 7.2.5: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **White** | | | |
| N subjects in population | N=62 | N=58 | |
| Week 3 | n= 57 (91.9%) \|-0.01 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 56 (90.3%) \|-0.04 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 57 (91.9%) \|-0.05 (0.21) | n= 53 (91.4%) \| 0.01 (0.22) | -0.27 [-0.65 ; 0.11] |
| Week 9 | n= 50 (80.6%) \|-0.03 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 52 (83.9%) \|-0.03 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 51 (82.3%) \|-0.01 (0.19) | n= 42 (72.4%) \|-0.05 (0.24) | 0.17 [-0.25 ; 0.58] |
| Week 15 | n= 47 (75.8%) \|-0.05 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 52 (83.9%) \|-0.03 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 49 (79.0%) \|-0.01 (0.18) | n= 42 (72.4%) \|-0.01 (0.22) | -0.01 [-0.42 ; 0.40] |
| Week 21 | n= 51 (82.3%) \|-0.03 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 46 (74.2%) \|-0.02 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 49 (79.0%) \|-0.02 (0.19) | n= 42 (72.4%) \|-0.06 (0.15) | 0.21 [-0.21 ; 0.62] |
| Week 27 | n= 46 (74.2%) \| 0.00 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 45 (72.6%) \|-0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (72.6%) \|-0.03 (0.20) | n= 36 (62.1%) \|-0.06 (0.17) | 0.16 [-0.28 ; 0.60] |
| Week 33 | n= 49 (79.0%) \|-0.02 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 45 (72.6%) \|-0.02 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 43 (69.4%) \| 0.01 (0.18) | n= 37 (63.8%) \|-0.06 (0.15) | 0.40 [-0.05 ; 0.84] |
| Week 39 | n= 45 (72.6%) \|-0.02 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 43 (69.4%) \|-0.02 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 46 (74.2%) \|-0.03 (0.19) | n= 35 (60.3%) \|-0.06 (0.20) | 0.17 [-0.28 ; 0.61] |
| Week 45 | n= 42 (67.7%) \|-0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 44 (71.0%) \|-0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 45 (72.6%) \| 0.01 (0.17) | n= 33 (56.9%) \|-0.09 (0.24) | 0.52 [ 0.06 ; 0.98] |
| Week 51 | n= 43 (69.4%) \|-0.03 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 42 (67.7%) \| 0.00 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 40 (64.5%) \| 0.00 (0.21) | n= 32 (55.2%) \|-0.03 (0.19) | 0.14 [-0.33 ; 0.61] |
| Week 57 | n= 40 (64.5%) \|-0.03 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (59.7%) \|-0.03 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 40 (64.5%) \|-0.01 (0.22) | n= 24 (41.4%) \|-0.11 (0.26) | 0.38 [-0.13 ; 0.89] |
| Week 63 | n= 36 (58.1%) \|-0.02 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (58.1%) \| 0.00 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (61.3%) \|-0.01 (0.22) | n= 24 (41.4%) \|-0.06 (0.19) | 0.24 [-0.28 ; 0.75] |
| Week 69 | n= 30 (48.4%) \|-0.01 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 34 (54.8%) \|-0.00 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 29 (46.8%) \| 0.00 (0.22) | n= 23 (39.7%) \|-0.09 (0.22) | 0.43 [-0.13 ; 0.99] |
| Week 75 | n= 32 (51.6%) \| 0.02 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 29 (46.8%) \| 0.03 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 28 (45.2%) \| 0.04 (0.21) | n= 20 (34.5%) \|-0.06 (0.21) | 0.48 [-0.11 ; 1.07] |
| Week 81 | n= 28 (45.2%) \| 0.01 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 31 (50.0%) \| 0.01 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (40.3%) \| 0.02 (0.17) | n= 17 (29.3%) \|-0.12 (0.24) | 0.68 [ 0.04 ; 1.32] |
| Week 87 | n= 22 (35.5%) \|-0.08 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 23 (37.1%) \|-0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 21 (33.9%) \|-0.08 (0.17) | n= 14 (24.1%) \|-0.06 (0.22) | -0.07 [-0.75 ; 0.62] |
| Week 93 | n= 18 (29.0%) \|-0.05 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 20 (32.3%) \|-0.07 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.0%) \|-0.10 (0.15) | n= 8 (13.8%) \|-0.07 (0.20) | -0.16 [-1.01 ; 0.69] |
| Week 99 | n= 15 (24.2%) \|-0.10 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.0%) \|-0.09 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.0%) \|-0.08 (0.14) | n= 7 (12.1%) \|-0.13 (0.20) | 0.32 [-0.63 ; 1.27] |
| Week 105 | n= 13 (21.0%) \|-0.13 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.3%) \|-0.11 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.1%) \|-0.18 (0.28) | n= 3 ( 5.2%) \| 0.00 (0.00) | -0.67 [-2.05 ; 0.71] |
| Week 111 | n= 7 (11.3%) \|-0.29 (0.44) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (12.9%) \|-0.07 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 5 ( 8.1%) \|-0.07 (0.28) | n= 4 ( 6.9%) \|-0.16 (0.19) | 0.35 [-1.07 ; 1.77] |
| Week 117 | n= 6 ( 9.7%) \|-0.19 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 ( 9.7%) \|-0.16 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.3%) \|-0.14 (0.13) | n= 1 ( 1.7%) \|-0.38 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.6%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.6%) \|-0.05 ( / ) | n= 1 ( 1.7%) \|-0.38 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) \|-0.03 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 7 (11.3%) \| 0.07 (0.21) | n= 12 (20.7%) \|-0.15 (0.22) | 0.96 [-0.06 ; 1.97] |
| Week 202 | n= 2 ( 3.2%) \|-0.41 (0.14) | n= 8 (13.8%) \|-0.11 (0.15) | -1.75 [-3.62 ; 0.13] |
| Week 301 | n= 1 ( 1.6%) \|-0.17 ( / ) | n= 7 (12.1%) \| 0.10 (0.17) | [Not calculable] |
| Week 302 | n= 1 ( 1.6%) \| 0.04 ( / ) | n= 5 ( 8.6%) \|-0.16 (0.16) | [Not calculable] |
| Week 303 | n= 2 ( 3.2%) \|-0.10 (0.19) | n= 5 ( 8.6%) \|-0.09 (0.20) | -0.03 [-1.84 ; 1.79] |
| Week 304 | n= 1 ( 1.6%) \| 0.15 ( / ) | n= 2 ( 3.4%) \|-0.30 (0.20) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.7%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.7%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.7%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.7%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.7%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| **Non-White** | | | |
| N subjects in population | N=9 | N=10 | |
| Week 3 | n= 9 (100.0%) \| 0.02 (0.10) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (88.9%) \|-0.08 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (77.8%) \|-0.08 (0.17) | n= 9 (90.0%) \|-0.02 (0.09) | -0.47 [-1.50 ; 0.57] |
| Week 9 | n= 9 (100.0%) \|-0.10 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (100.0%) \|-0.19 (0.30) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 8 (88.9%) \|-0.12 (0.17) | n= 10 (100.0%) \|-0.18 (0.26) | 0.27 [-0.69 ; 1.24] |
| Week 15 | n= 7 (77.8%) \|-0.18 (0.42) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (100.0%) \|-0.10 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 8 (88.9%) \|-0.08 (0.19) | n= 9 (90.0%) \|-0.03 (0.11) | -0.30 [-1.29 ; 0.69] |
| Week 21 | n= 9 (100.0%) \|-0.03 (0.10) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 9 (100.0%) \|-0.05 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 9 (100.0%) \|-0.03 (0.14) | n= 8 (80.0%) \|-0.07 (0.09) | 0.35 [-0.64 ; 1.34] |
| Week 27 | n= 9 (100.0%) \|-0.07 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 8 (88.9%) \|-0.08 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 9 (100.0%) \|-0.01 (0.11) | n= 7 (70.0%) \|-0.16 (0.25) | 0.80 [-0.27 ; 1.86] |
| Week 33 | n= 8 (88.9%) \|-0.00 (0.21) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 35 | n= 8 (88.9%) \| 0.01 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 6 (66.7%) \|-0.07 (0.10) | n= 7 (70.0%) \|-0.11 (0.17) | 0.30 [-0.85 ; 1.45] |
| Week 39 | n= 8 (88.9%) \| 0.01 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 8 (88.9%) \| 0.06 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 7 (77.8%) \| 0.07 (0.17) | n= 6 (60.0%) \|-0.08 (0.13) | 0.95 [-0.26 ; 2.17] |
| Week 45 | n= 7 (77.8%) \| 0.09 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 8 (88.9%) \| 0.04 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 8 (88.9%) \| 0.04 (0.20) | n= 4 (40.0%) \|-0.02 (0.03) | 0.29 [-0.97 ; 1.56] |
| Week 51 | n= 8 (88.9%) \| 0.03 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 6 (66.7%) \|-0.02 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (77.8%) \|-0.01 (0.21) | n= 6 (60.0%) \|-0.04 (0.08) | 0.20 [-0.94 ; 1.34] |
| Week 57 | n= 7 (77.8%) \| 0.07 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (77.8%) \| 0.02 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (88.9%) \| 0.01 (0.20) | n= 6 (60.0%) \|-0.07 (0.10) | 0.48 [-0.64 ; 1.60] |
| Week 63 | n= 6 (66.7%) \| 0.06 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (88.9%) \| 0.06 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (66.7%) \|-0.05 (0.14) | n= 6 (60.0%) \|-0.08 (0.11) | 0.23 [-0.96 ; 1.42] |
| Week 69 | n= 6 (66.7%) \| 0.01 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 5 (55.6%) \| 0.07 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 5 (55.6%) \| 0.02 (0.25) | n= 4 (40.0%) \|-0.12 (0.11) | 0.60 [-0.85 ; 2.05] |
| Week 75 | n= 4 (44.4%) \| 0.09 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (33.3%) \| 0.08 (0.30) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 3 (33.3%) \| 0.19 (0.22) | n= 4 (40.0%) \|-0.06 (0.09) | 1.41 [-0.50 ; 3.33] |
| Week 81 | n= 3 (33.3%) \| 0.15 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (22.2%) \| 0.21 (0.30) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (22.2%) \| 0.08 (0.11) | n= 3 (30.0%) \|-0.02 (0.04) | 1.03 [-1.32 ; 3.38] |
| Week 87 | n= 2 (22.2%) \| 0.21 (0.30) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (22.2%) \| 0.21 (0.30) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (33.3%) \| 0.19 (0.22) | n= 3 (30.0%) \|-0.06 (0.32) | 0.74 [-1.17 ; 2.65] |
| Week 93 | n= 2 (22.2%) \| 0.21 (0.30) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (22.2%) \| 0.21 (0.30) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (33.3%) \| 0.19 (0.22) | n= 2 (20.0%) \|-0.21 (0.29) | 1.19 [-1.24 ; 3.62] |
| Week 99 | n= 2 (22.2%) \| 0.21 (0.30) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (11.1%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (22.2%) \|-0.03 (0.25) | n= 2 (20.0%) \| 0.00 (0.00) | -0.08 [-2.55 ; 2.38] |
| Week 105 | n= 1 (11.1%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (11.1%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 (11.1%) \| 0.15 ( / ) | n= 1 (10.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 115 | n= 1 (11.1%) \| 0.15 ( / ) | n= 1 (10.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 121 | n= 1 (11.1%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 (11.1%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (11.1%) \|-0.27 ( / ) | n= 5 (50.0%) \|-0.04 (0.31) | [Not calculable] |
| Week 202 | [No Data] | n= 4 (40.0%) \| 0.00 (0.25) | [No Data for at least 1 arm] |
| Week 301 | n= 1 (11.1%) \| 0.15 ( / ) | n= 2 (20.0%) \| 0.00 (0.00) | [Not calculable] |
| Week 302 | n= 1 (11.1%) \|-0.12 ( / ) | n= 1 (10.0%) \| 0.02 ( / ) | [Not calculable] |
| Week 303 | n= 1 (11.1%) \| 0.15 ( / ) | n= 1 (10.0%) \|-0.64 ( / ) | [Not calculable] |
| Week 304 | [No Data] | n= 1 (10.0%) \| 0.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:46

TABLE 7.2.5: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **White** | | | | |
| Nr subjects used | n=62 | n=58 | | |
| Week 7 | -0.05 (0.03) [-0.11 ;-0.00] | -0.03 (0.03) [-0.09 ; 0.02] | -0.02 (0.04) [-0.10 ; 0.05] | -0.11 [-0.48 ; 0.27] |
| Week 13 | -0.03 (0.03) [-0.08 ; 0.03] | -0.08 (0.03) [-0.13 ;-0.02] | 0.05 (0.04) [-0.03 ; 0.13] | 0.26 [-0.15 ; 0.67] |
| Week 19 | -0.02 (0.02) [-0.06 ; 0.03] | -0.04 (0.02) [-0.09 ; 0.01] | 0.02 (0.03) [-0.05 ; 0.09] | 0.13 [-0.29 ; 0.54] |
| Week 25 | -0.01 (0.02) [-0.06 ; 0.03] | -0.05 (0.02) [-0.10 ;-0.00] | 0.04 (0.03) [-0.03 ; 0.10] | 0.24 [-0.18 ; 0.65] |
| Week 31 | -0.04 (0.03) [-0.09 ; 0.01] | -0.05 (0.03) [-0.10 ; 0.00] | 0.01 (0.04) [-0.06 ; 0.09] | 0.09 [-0.35 ; 0.52] |
| Week 37 | 0.01 (0.02) [-0.03 ; 0.06] | -0.05 (0.02) [-0.09 ; 0.00] | 0.06 (0.03) [-0.00 ; 0.13] | 0.42 [-0.03 ; 0.86] |
| Week 43 | -0.02 (0.03) [-0.07 ; 0.03] | -0.05 (0.03) [-0.10 ; 0.01] | 0.03 (0.04) [-0.05 ; 0.10] | 0.15 [-0.29 ; 0.59] |
| Week 49 | 0.01 (0.03) [-0.05 ; 0.07] | -0.08 (0.03) [-0.15 ;-0.01] | 0.09 (0.05) [-0.00 ; 0.18] | 0.43 [-0.02 ; 0.89] |
| Week 55 | -0.00 (0.03) [-0.06 ; 0.05] | -0.02 (0.03) [-0.08 ; 0.05] | 0.01 (0.04) [-0.07 ; 0.09] | 0.08 [-0.39 ; 0.54] |
| Week 61 | -0.03 (0.03) [-0.10 ; 0.04] | -0.06 (0.04) [-0.14 ; 0.02] | 0.03 (0.05) [-0.07 ; 0.14] | 0.15 [-0.36 ; 0.65] |
| Week 67 | -0.01 (0.03) [-0.07 ; 0.04] | -0.05 (0.03) [-0.12 ; 0.02] | 0.04 (0.04) [-0.05 ; 0.13] | 0.23 [-0.29 ; 0.74] |
| Week 73 | -0.01 (0.03) [-0.06 ; 0.05] | -0.08 (0.03) [-0.14 ;-0.02] | 0.07 (0.04) [-0.00 ; 0.15] | 0.51 [-0.04 ; 1.07] |
| Week 79 | 0.01 (0.03) [-0.04 ; 0.06] | -0.05 (0.03) [-0.11 ; 0.01] | 0.06 (0.04) [-0.02 ; 0.14] | 0.44 [-0.15 ; 1.02] |
| Week 85 | 0.01 (0.03) [-0.05 ; 0.06] | -0.10 (0.03) [-0.16 ;-0.04] | 0.11 (0.04) [ 0.03 ; 0.18] | 0.81 [ 0.17 ; 1.46] |
| Week 91 | -0.03 (0.03) [-0.10 ; 0.03] | -0.06 (0.04) [-0.14 ; 0.02] | 0.03 (0.05) [-0.08 ; 0.13] | 0.17 [-0.51 ; 0.84] |
| Overall post-baseline period estimate | -0.01 (0.01) [-0.04 ; 0.01] | -0.06 (0.02) [-0.09 ;-0.03] | 0.04 (0.02) [ 0.00 ; 0.08] | 0.38 [ 0.01 ; 0.74] |
| **Non-White** | | | | |
| Nr subjects used | n=9 | n=10 | | |
| **MMRM subgroups interaction p-value** | | | | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:46

TABLE 7.2.6: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **Hispanic or Latino** | N=7 | N=12 |
| **Not Hispanic or Latino** | N=42 | N=31 |
| **Not Reported** | N=22 | N=25 |
| **Subjects with Baseline Value** | | |
| **Hispanic or Latino** | 7 (100.0%) | 12 (100.0%) |
| **Not Hispanic or Latino** | 42 (100.0%) | 31 (100.0%) |
| **Not Reported** | 22 (100.0%) | 25 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **Hispanic or Latino** | 7 (100.0%) | 12 (100.0%) |
| **Not Hispanic or Latino** | 42 (100.0%) | 30 (96.8%) |
| **Not Reported** | 22 (100.0%) | 24 (96.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **Hispanic or Latino** | 7 (100.0%) | 12 (100.0%) |
| **Not Hispanic or Latino** | 42 (100.0%) | 30 (96.8%) |
| **Not Reported** | 22 (100.0%) | 24 (96.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:46

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Hispanic or Latino** | | | |
| N subjects in population | N=7 | N=12 | |
| Baseline | n= 7 (100.0%) \| 0.76 (0.20) | n= 12 (100.0%) \| 0.64 (0.39) | 0.34 [-0.63 ; 1.30] |
| Week 3 | n= 7 (100.0%) \| 0.69 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 6 (85.7%) \| 0.81 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (100.0%) \| 0.71 (0.32) | n= 11 (91.7%) \| 0.59 (0.37) | 0.34 [-0.64 ; 1.33] |
| Week 9 | n= 5 (71.4%) \| 0.63 (0.44) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 6 (85.7%) \| 0.75 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 6 (85.7%) \| 0.69 (0.13) | n= 7 (58.3%) \| 0.74 (0.13) | -0.37 [-1.52 ; 0.78] |
| Week 15 | n= 5 (71.4%) \| 0.84 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 7 (100.0%) \| 0.70 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 5 (71.4%) \| 0.85 (0.16) | n= 6 (50.0%) \| 0.84 (0.13) | 0.08 [-1.17 ; 1.33] |
| Week 21 | n= 7 (100.0%) \| 0.61 (0.37) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (85.7%) \| 0.80 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 4 (57.1%) \| 0.92 (0.15) | n= 7 (58.3%) \| 0.86 (0.14) | 0.41 [-0.90 ; 1.72] |
| Week 27 | n= 4 (57.1%) \| 0.85 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 4 (57.1%) \| 0.89 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 4 (57.1%) \| 0.83 (0.20) | n= 5 (41.7%) \| 0.84 (0.10) | -0.09 [-1.50 ; 1.32] |
| Week 33 | n= 5 (71.4%) \| 0.62 (0.54) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 3 (42.9%) \| 0.52 (0.83) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 2 (28.6%) \| 1.00 (0.00) | n= 4 (33.3%) \| 0.82 (0.13) | 1.25 [-0.92 ; 3.42] |
| Week 39 | n= 4 (57.1%) \| 0.83 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 3 (42.9%) \| 0.81 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 3 (42.9%) \| 0.86 (0.24) | n= 5 (41.7%) \| 0.80 (0.18) | 0.27 [-1.30 ; 1.83] |
| Week 45 | n= 2 (28.6%) \| 1.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 2 (28.6%) \| 1.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 3 (42.9%) \| 0.86 (0.24) | n= 4 (33.3%) \| 0.82 (0.12) | 0.20 [-1.46 ; 1.86] |
| Week 51 | n= 3 (42.9%) \| 0.86 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 2 (28.6%) \| 1.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 3 (42.9%) \| 1.00 (0.00) | n= 4 (33.3%) \| 0.76 (0.20) | 1.31 [-0.57 ; 3.20] |
| Week 57 | n= 3 (42.9%) \| 0.86 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 3 (42.9%) \| 0.86 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 3 (42.9%) \| 0.86 (0.24) | n= 4 (33.3%) \| 0.89 (0.15) | -0.14 [-1.80 ; 1.52] |
| Week 63 | n= 3 (42.9%) \| 0.86 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 3 (42.9%) \| 0.86 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 3 (42.9%) \| 0.90 (0.17) | n= 4 (33.3%) \| 0.84 (0.19) | 0.31 [-1.36 ; 1.98] |
| Week 69 | n= 3 (42.9%) \| 0.86 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 3 (42.9%) \| 0.86 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (42.9%) \| 0.86 (0.24) | n= 3 (25.0%) \| 0.87 (0.22) | -0.04 [-1.85 ; 1.78] |
| Week 75 | n= 3 (42.9%) \| 0.86 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 2 (28.6%) \| 1.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 2 (28.6%) \| 1.00 (0.00) | n= 4 (33.3%) \| 0.82 (0.12) | 1.35 [-0.86 ; 3.56] |
| Week 81 | n= 3 (42.9%) \| 0.90 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 3 (42.9%) \| 0.86 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 3 (42.9%) \| 0.86 (0.24) | n= 3 (25.0%) \| 0.85 (0.13) | 0.04 [-1.77 ; 1.86] |
| Week 87 | n= 2 (28.6%) \| 1.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (28.6%) \| 0.79 (0.29) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 2 (28.6%) \| 0.79 (0.29) | n= 3 (25.0%) \| 0.88 (0.11) | -0.34 [-2.48 ; 1.80] |
| Week 93 | n= 2 (28.6%) \| 0.79 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (28.6%) \| 0.79 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 2 (28.6%) \| 0.79 (0.29) | n= 3 (25.0%) \| 1.00 (0.00) | -0.89 [-3.19 ; 1.40] |
| Week 99 | n= 2 (28.6%) \| 0.79 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (14.3%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 1 (14.3%) \| 0.59 ( / ) | n= 2 (16.7%) \| 0.84 (0.22) | [Not calculable] |
| Week 105 | n= 1 (14.3%) \| 0.59 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | [No Data] | n= 1 ( 8.3%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 115 | [No Data] | n= 1 ( 8.3%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 1 (14.3%) \| 0.81 ( / ) | n= 3 (25.0%) \| 0.83 (0.16) | [Not calculable] |
| Week 202 | [No Data] | n= 2 (16.7%) \| 0.90 (0.14) | [No Data for at least 1 arm] |
| Week 301 | n= 1 (14.3%) \| 1.00 ( / ) | n= 3 (25.0%) \| 0.70 (0.16) | [Not calculable] |
| Week 302 | n= 1 (14.3%) \| 0.73 ( / ) | n= 1 ( 8.3%) \| 0.73 ( / ) | [Not calculable] |
| Week 303 | n= 1 (14.3%) \| 1.00 ( / ) | n= 2 (16.7%) \| 0.86 (0.19) | [Not calculable] |
| Week 304 | [No Data] | n= 1 ( 8.3%) \| 0.69 ( / ) | [No Data for at least 1 arm] |
| Week 305 | [No Data] | n= 1 ( 8.3%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 8.3%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 8.3%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 8.3%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 8.3%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| **Not Hispanic or Latino** | | | |
| N subjects in population | N=42 | N=31 | |
| Baseline | n= 42 (100.0%) \| 0.83 (0.22) | n= 31 (100.0%) \| 0.78 (0.29) | 0.17 [-0.30 ; 0.64] |
| Week 3 | n= 39 (92.9%) \| 0.84 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 39 (92.9%) \| 0.79 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 38 (90.5%) \| 0.82 (0.21) | n= 29 (93.5%) \| 0.81 (0.14) | 0.05 [-0.44 ; 0.53] |
| Week 9 | n= 34 (81.0%) \| 0.81 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 36 (85.7%) \| 0.80 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 34 (81.0%) \| 0.84 (0.24) | n= 23 (74.2%) \| 0.78 (0.18) | 0.25 [-0.29 ; 0.78] |
| Week 15 | n= 29 (69.0%) \| 0.80 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 32 (76.2%) \| 0.81 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 31 (73.8%) \| 0.80 (0.22) | n= 25 (80.6%) \| 0.80 (0.23) | 0.03 [-0.50 ; 0.56] |
| Week 21 | n= 32 (76.2%) \| 0.82 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 28 (66.7%) \| 0.79 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 33 (78.6%) \| 0.81 (0.25) | n= 24 (77.4%) \| 0.78 (0.18) | 0.12 [-0.41 ; 0.65] |
| Week 27 | n= 30 (71.4%) \| 0.83 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 30 (71.4%) \| 0.81 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 28 (66.7%) \| 0.77 (0.24) | n= 19 (61.3%) \| 0.74 (0.25) | 0.13 [-0.46 ; 0.72] |
| Week 33 | n= 32 (76.2%) \| 0.83 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 29 (69.0%) \| 0.83 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 26 (61.9%) \| 0.83 (0.22) | n= 21 (67.7%) \| 0.78 (0.18) | 0.27 [-0.31 ; 0.86] |
| Week 39 | n= 31 (73.8%) \| 0.81 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 31 (73.8%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 30 (71.4%) \| 0.83 (0.19) | n= 17 (54.8%) \| 0.78 (0.21) | 0.25 [-0.35 ; 0.85] |
| Week 45 | n= 29 (69.0%) \| 0.86 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 30 (71.4%) \| 0.85 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 30 (71.4%) \| 0.84 (0.18) | n= 15 (48.4%) \| 0.74 (0.21) | 0.54 [-0.10 ; 1.18] |
| Week 51 | n= 27 (64.3%) \| 0.82 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 28 (66.7%) \| 0.85 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 26 (61.9%) \| 0.82 (0.19) | n= 15 (48.4%) \| 0.81 (0.22) | 0.05 [-0.59 ; 0.69] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 57 | n= 27 (64.3%) \| 0.82 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 24 (57.1%) \| 0.79 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 25 (59.5%) \| 0.86 (0.18) | n= 11 (35.5%) \| 0.75 (0.22) | 0.55 [-0.18 ; 1.28] |
| Week 63 | n= 24 (57.1%) \| 0.79 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 23 (54.8%) \| 0.82 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 22 (52.4%) \| 0.83 (0.22) | n= 12 (38.7%) \| 0.81 (0.10) | 0.08 [-0.64 ; 0.79] |
| Week 69 | n= 19 (45.2%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 21 (50.0%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 15 (35.7%) \| 0.78 (0.20) | n= 12 (38.7%) \| 0.72 (0.22) | 0.28 [-0.50 ; 1.06] |
| Week 75 | n= 18 (42.9%) \| 0.85 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 17 (40.5%) \| 0.81 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 15 (35.7%) \| 0.84 (0.19) | n= 10 (32.3%) \| 0.78 (0.28) | 0.25 [-0.57 ; 1.07] |
| Week 81 | n= 17 (40.5%) \| 0.80 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (40.5%) \| 0.81 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 13 (31.0%) \| 0.84 (0.18) | n= 9 (29.0%) \| 0.75 (0.24) | 0.45 [-0.43 ; 1.34] |
| Week 87 | n= 11 (26.2%) \| 0.78 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 12 (28.6%) \| 0.79 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 13 (31.0%) \| 0.74 (0.26) | n= 7 (22.6%) \| 0.83 (0.15) | -0.36 [-1.31 ; 0.59] |
| Week 93 | n= 11 (26.2%) \| 0.79 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (26.2%) \| 0.74 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (28.6%) \| 0.72 (0.27) | n= 5 (16.1%) \| 0.77 (0.16) | -0.21 [-1.29 ; 0.87] |
| Week 99 | n= 8 (19.0%) \| 0.65 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 7 (16.7%) \| 0.73 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (19.0%) \| 0.84 (0.14) | n= 4 (12.9%) \| 0.88 (0.14) | -0.24 [-1.51 ; 1.02] |
| Week 105 | n= 8 (19.0%) \| 0.70 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 5 (11.9%) \| 0.81 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (19.0%) \| 0.72 (0.19) | n= 1 ( 3.2%) \| 0.80 ( / ) | [Not calculable] |
| Week 111 | n= 5 (11.9%) \| 0.51 (0.63) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 (11.9%) \| 0.79 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 5 (11.9%) \| 0.83 (0.24) | n= 2 ( 6.5%) \| 0.73 (0.10) | 0.39 [-1.44 ; 2.22] |
| Week 117 | n= 4 ( 9.5%) \| 0.73 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 9.5%) \| 0.67 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (11.9%) \| 0.79 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.4%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (14.3%) \| 0.89 (0.13) | n= 9 (29.0%) \| 0.71 (0.28) | 0.72 [-0.39 ; 1.83] |
| Week 202 | n= 2 ( 4.8%) \| 0.44 (0.35) | n= 5 (16.1%) \| 0.77 (0.26) | -0.98 [-2.91 ; 0.95] |
| Week 301 | n= 1 ( 2.4%) \| 0.52 ( / ) | n= 2 ( 6.5%) \| 0.88 (0.17) | [Not calculable] |
| Week 302 | n= 1 ( 2.4%) \| 0.66 ( / ) | n= 3 ( 9.7%) \| 0.70 (0.07) | [Not calculable] |
| Week 303 | n= 2 ( 4.8%) \| 0.64 (0.03) | n= 2 ( 6.5%) \| 0.73 (0.16) | -0.48 [-3.04 ; 2.09] |
| Week 304 | n= 1 ( 2.4%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| **Not Reported** | | | |
| N subjects in population | N=22 | N=25 | |
| Baseline | n= 22 (100.0%) \| 0.88 (0.16) | n= 25 (100.0%) \| 0.87 (0.20) | 0.04 [-0.54 ; 0.62] |
| Week 3 | n= 20 (90.9%) \| 0.87 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 19 (86.4%) \| 0.81 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 19 (86.4%) \| 0.77 (0.15) | n= 22 (88.0%) \| 0.86 (0.23) | -0.40 [-1.03 ; 0.23] |
| Week 9 | n= 20 (90.9%) \| 0.84 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 19 (86.4%) \| 0.78 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 19 (86.4%) \| 0.79 (0.16) | n= 22 (88.0%) \| 0.73 (0.29) | 0.25 [-0.37 ; 0.87] |
| Week 15 | n= 20 (90.9%) \| 0.74 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 22 (100.0%) \| 0.81 (0.18) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 19 | n= 21 (95.5%) \| 0.82 (0.18) | n= 20 (80.0%) \| 0.85 (0.16) | -0.17 [-0.79 ; 0.46] |
| Week 21 | n= 21 (95.5%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (95.5%) \| 0.87 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 21 (95.5%) \| 0.84 (0.16) | n= 19 (76.0%) \| 0.83 (0.15) | 0.04 [-0.59 ; 0.66] |
| Week 27 | n= 21 (95.5%) \| 0.85 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 19 (86.4%) \| 0.83 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 22 (100.0%) \| 0.89 (0.15) | n= 19 (76.0%) \| 0.85 (0.18) | 0.23 [-0.40 ; 0.85] |
| Week 33 | n= 20 (90.9%) \| 0.85 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 21 (95.5%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 21 (95.5%) \| 0.85 (0.16) | n= 19 (76.0%) \| 0.85 (0.16) | -0.03 [-0.66 ; 0.60] |
| Week 39 | n= 18 (81.8%) \| 0.86 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 17 (77.3%) \| 0.86 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 20 (90.9%) \| 0.83 (0.15) | n= 19 (76.0%) \| 0.84 (0.15) | -0.08 [-0.72 ; 0.55] |
| Week 45 | n= 18 (81.8%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 20 (90.9%) \| 0.87 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 20 (90.9%) \| 0.88 (0.16) | n= 18 (72.0%) \| 0.78 (0.31) | 0.40 [-0.25 ; 1.05] |
| Week 51 | n= 21 (95.5%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 18 (81.8%) \| 0.84 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 18 (81.8%) \| 0.85 (0.14) | n= 19 (76.0%) \| 0.86 (0.14) | -0.08 [-0.74 ; 0.57] |
| Week 57 | n= 17 (77.3%) \| 0.87 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 17 (77.3%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 20 (90.9%) \| 0.82 (0.18) | n= 15 (60.0%) \| 0.75 (0.33) | 0.24 [-0.44 ; 0.92] |
| Week 63 | n= 15 (68.2%) \| 0.88 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 18 (81.8%) \| 0.86 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 19 (86.4%) \| 0.85 (0.15) | n= 14 (56.0%) \| 0.78 (0.24) | 0.34 [-0.37 ; 1.04] |
| Week 69 | n= 14 (63.6%) \| 0.81 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 15 (68.2%) \| 0.81 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (72.7%) \| 0.85 (0.16) | n= 12 (48.0%) \| 0.76 (0.17) | 0.55 [-0.23 ; 1.32] |
| Week 75 | n= 15 (68.2%) \| 0.85 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 13 (59.1%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 14 (63.6%) \| 0.87 (0.15) | n= 10 (40.0%) \| 0.79 (0.15) | 0.47 [-0.37 ; 1.31] |
| Week 81 | n= 11 (50.0%) \| 0.89 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 13 (59.1%) \| 0.88 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (50.0%) \| 0.91 (0.13) | n= 8 (32.0%) \| 0.77 (0.18) | 0.92 [-0.07 ; 1.91] |
| Week 87 | n= 11 (50.0%) \| 0.76 (0.35) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 11 (50.0%) \| 0.87 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 9 (40.9%) \| 0.87 (0.16) | n= 7 (28.0%) \| 0.81 (0.16) | 0.33 [-0.70 ; 1.35] |
| Week 93 | n= 7 (31.8%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 9 (40.9%) \| 0.86 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (31.8%) \| 0.90 (0.13) | n= 2 ( 8.0%) \| 0.68 (0.23) | 1.26 [-0.56 ; 3.09] |
| Week 99 | n= 7 (31.8%) \| 0.87 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (27.3%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 6 (27.3%) \| 0.79 (0.12) | n= 3 (12.0%) \| 0.78 (0.24) | 0.08 [-1.41 ; 1.56] |
| Week 105 | n= 5 (22.7%) \| 0.84 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 3 (13.6%) \| 0.80 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (13.6%) \| 0.54 (0.36) | n= 2 ( 8.0%) \| 1.00 (0.00) | -1.14 [-3.55 ; 1.26] |
| Week 111 | n= 2 ( 9.1%) \| 0.77 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (13.6%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 4.5%) \| 0.69 ( / ) | n= 2 ( 8.0%) \| 0.85 (0.22) | [Not calculable] |
| Week 117 | n= 2 ( 9.1%) \| 0.71 (0.03) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 ( 9.1%) \| 0.77 (0.11) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 121 | n= 3 (13.6%) \| 0.77 (0.08) | n= 1 ( 4.0%) \| 0.62 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 4.5%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.5%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 4.5%) \| 0.80 ( / ) | n= 1 ( 4.0%) \| 0.62 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 4.5%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.5%) \| 0.82 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.5%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 4.5%) \| 0.73 ( / ) | n= 5 (20.0%) \| 0.72 (0.25) | [Not calculable] |
| Week 202 | [No Data] | n= 5 (20.0%) \| 0.85 (0.14) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 (16.0%) \| 0.87 (0.15) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 2 ( 8.0%) \| 0.75 (0.09) | [No Data for at least 1 arm] |
| Week 303 | [No Data] | n= 2 ( 8.0%) \| 0.42 (0.38) | [No Data for at least 1 arm] |
| Week 304 | [No Data] | n= 2 ( 8.0%) \| 0.53 (0.38) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:47

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Hispanic or Latino** | | | |
| N subjects in population | N=7 | N=12 | |
| Week 3 | n= 7 (100.0%) \|-0.08 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 6 (85.7%) \| 0.01 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (100.0%) \|-0.05 (0.21) | n= 11 (91.7%) \|-0.02 (0.27) | -0.10 [-1.07 ; 0.88] |
| Week 9 | n= 5 (71.4%) \|-0.17 (0.35) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 6 (85.7%) \|-0.05 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 6 (85.7%) \|-0.11 (0.15) | n= 7 (58.3%) \|-0.13 (0.09) | 0.17 [-0.97 ; 1.32] |
| Week 15 | n= 5 (71.4%) \| 0.04 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 7 (100.0%) \|-0.06 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 5 (71.4%) \| 0.04 (0.22) | n= 6 (50.0%) \|-0.09 (0.09) | 0.76 [-0.54 ; 2.07] |
| Week 21 | n= 7 (100.0%) \|-0.15 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (85.7%) \| 0.01 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 4 (57.1%) \| 0.06 (0.07) | n= 7 (58.3%) \|-0.06 (0.15) | 0.85 [-0.51 ; 2.21] |
| Week 27 | n= 4 (57.1%) \|-0.02 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 4 (57.1%) \| 0.03 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 4 (57.1%) \|-0.04 (0.13) | n= 5 (41.7%) \|-0.04 (0.11) | 0.04 [-1.37 ; 1.45] |
| Week 33 | n= 5 (71.4%) \|-0.19 (0.43) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 3 (42.9%) \|-0.35 (0.61) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 2 (28.6%) \| 0.00 (0.00) | n= 4 (33.3%) \|-0.09 (0.15) | 0.52 [-1.45 ; 2.49] |
| Week 39 | n= 4 (57.1%) \|-0.03 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 3 (42.9%) \|-0.05 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 3 (42.9%) \| 0.00 (0.00) | n= 5 (41.7%) \|-0.13 (0.20) | 0.68 [-0.93 ; 2.29] |
| Week 45 | n= 2 (28.6%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 2 (28.6%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 3 (42.9%) \| 0.00 (0.00) | n= 4 (33.3%) \|-0.13 (0.11) | 1.24 [-0.62 ; 3.09] |
| Week 51 | n= 3 (42.9%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 2 (28.6%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 3 (42.9%) \| 0.14 (0.24) | n= 4 (33.3%) \|-0.19 (0.17) | 1.36 [-0.54 ; 3.25] |
| Week 57 | n= 3 (42.9%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 3 (42.9%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 3 (42.9%) \| 0.00 (0.00) | n= 4 (33.3%) \|-0.06 (0.06) | 0.94 [-0.84 ; 2.71] |
| Week 63 | n= 3 (42.9%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 3 (42.9%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 3 (42.9%) \| 0.04 (0.07) | n= 4 (33.3%) \|-0.11 (0.15) | 1.05 [-0.75 ; 2.86] |
| Week 69 | n= 3 (42.9%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 3 (42.9%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (42.9%) \| 0.00 (0.00) | n= 3 (25.0%) \|-0.06 (0.10) | 0.65 [-1.23 ; 2.54] |
| Week 75 | n= 3 (42.9%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 2 (28.6%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 2 (28.6%) \| 0.00 (0.00) | n= 4 (33.3%) \|-0.13 (0.11) | 1.05 [-1.05 ; 3.15] |
| Week 81 | n= 3 (42.9%) \| 0.04 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 3 (42.9%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 3 (42.9%) \| 0.00 (0.00) | n= 3 (25.0%) \|-0.15 (0.13) | 1.29 [-0.80 ; 3.38] |
| Week 87 | n= 2 (28.6%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (28.6%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 2 (28.6%) \| 0.00 (0.00) | n= 3 (25.0%) \|-0.12 (0.11) | 1.00 [-1.34 ; 3.34] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 2 (28.6%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (28.6%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 2 (28.6%) \| 0.00 (0.00) | n= 3 (25.0%) \| 0.00 (0.00) | [Not calculable] |
| Week 99 | n= 2 (28.6%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (14.3%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 1 (14.3%) \| 0.00 ( / ) | n= 2 (16.7%) \|-0.16 (0.22) | [Not calculable] |
| Week 105 | n= 1 (14.3%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | [No Data] | n= 1 ( 8.3%) \| 0.00 ( / ) | [No Data for at least 1 arm] |
| Week 115 | [No Data] | n= 1 ( 8.3%) \| 0.00 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 1 (14.3%) \| 0.30 ( / ) | n= 3 (25.0%) \| 0.00 (0.31) | [Not calculable] |
| Week 202 | [No Data] | n= 2 (16.7%) \| 0.16 (0.22) | [No Data for at least 1 arm] |
| Week 301 | n= 1 (14.3%) \| 0.15 ( / ) | n= 3 (25.0%) \| 0.13 (0.26) | [Not calculable] |
| Week 302 | n= 1 (14.3%) \|-0.12 ( / ) | n= 1 ( 8.3%) \|-0.12 ( / ) | [Not calculable] |
| Week 303 | n= 1 (14.3%) \| 0.15 ( / ) | n= 2 (16.7%) \| 0.04 (0.16) | [Not calculable] |
| Week 304 | [No Data] | n= 1 ( 8.3%) \|-0.16 ( / ) | [No Data for at least 1 arm] |
| Week 305 | [No Data] | n= 1 ( 8.3%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 8.3%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 8.3%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 8.3%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 8.3%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| **Not Hispanic or Latino** | | | |
| N subjects in population | N=42 | N=31 | |
| Week 3 | n= 39 (92.9%) \| 0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 39 (92.9%) \|-0.03 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 38 (90.5%) \|-0.03 (0.24) | n= 29 (93.5%) \| 0.03 (0.22) | -0.28 [-0.77 ; 0.20] |
| Week 9 | n= 34 (81.0%) \|-0.01 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 36 (85.7%) \|-0.02 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 34 (81.0%) \| 0.00 (0.21) | n= 23 (74.2%) \| 0.01 (0.26) | -0.01 [-0.54 ; 0.52] |
| Week 15 | n= 29 (69.0%) \|-0.04 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 32 (76.2%) \|-0.02 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 31 (73.8%) \|-0.01 (0.18) | n= 25 (80.6%) \| 0.02 (0.23) | -0.16 [-0.69 ; 0.37] |
| Week 21 | n= 32 (76.2%) \|-0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 28 (66.7%) \|-0.05 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 33 (78.6%) \|-0.02 (0.21) | n= 24 (77.4%) \|-0.05 (0.15) | 0.13 [-0.40 ; 0.66] |
| Week 27 | n= 30 (71.4%) \| 0.00 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 30 (71.4%) \|-0.02 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 28 (66.7%) \|-0.06 (0.23) | n= 19 (61.3%) \|-0.08 (0.21) | 0.08 [-0.51 ; 0.67] |
| Week 33 | n= 32 (76.2%) \| 0.01 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 29 (69.0%) \| 0.01 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 26 (61.9%) \| 0.00 (0.19) | n= 21 (67.7%) \|-0.07 (0.17) | 0.38 [-0.21 ; 0.96] |
| Week 39 | n= 31 (73.8%) \|-0.01 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 31 (73.8%) \| 0.01 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 30 (71.4%) \| 0.01 (0.23) | n= 17 (54.8%) \|-0.02 (0.22) | 0.13 [-0.48 ; 0.73] |
| Week 45 | n= 29 (69.0%) \| 0.03 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 30 (71.4%) \| 0.01 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 30 (71.4%) \| 0.02 (0.20) | n= 15 (48.4%) \|-0.03 (0.20) | 0.27 [-0.36 ; 0.90] |
| Week 51 | n= 27 (64.3%) \|-0.01 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 28 (66.7%) \| 0.00 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 26 (61.9%) \|-0.01 (0.24) | n= 15 (48.4%) \| 0.03 (0.20) | -0.18 [-0.82 ; 0.47] |
| Week 57 | n= 27 (64.3%) \|-0.03 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 24 (57.1%) \|-0.03 (0.32) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 61 | n= 25 (59.5%) \| 0.02 (0.25) | n= 11 (35.5%) \|-0.02 (0.21) | 0.16 [-0.56 ; 0.88] |
| Week 63 | n= 24 (57.1%) \|-0.03 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 23 (54.8%) \| 0.02 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 22 (52.4%) \|-0.03 (0.25) | n= 12 (38.7%) \| 0.04 (0.14) | -0.29 [-1.01 ; 0.42] |
| Week 69 | n= 19 (45.2%) \| 0.02 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 21 (50.0%) \| 0.03 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 15 (35.7%) \| 0.00 (0.29) | n= 12 (38.7%) \|-0.06 (0.24) | 0.23 [-0.54 ; 1.01] |
| Week 75 | n= 18 (42.9%) \| 0.05 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 17 (40.5%) \| 0.05 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 15 (35.7%) \| 0.11 (0.26) | n= 10 (32.3%) \| 0.00 (0.26) | 0.40 [-0.43 ; 1.22] |
| Week 81 | n= 17 (40.5%) \| 0.03 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (40.5%) \| 0.05 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 13 (31.0%) \| 0.04 (0.22) | n= 9 (29.0%) \|-0.04 (0.26) | 0.33 [-0.55 ; 1.21] |
| Week 87 | n= 11 (26.2%) \| 0.00 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 12 (28.6%) \| 0.04 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 13 (31.0%) \|-0.04 (0.25) | n= 7 (22.6%) \| 0.04 (0.26) | -0.30 [-1.25 ; 0.64] |
| Week 93 | n= 11 (26.2%) \| 0.01 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (26.2%) \|-0.04 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (28.6%) \|-0.07 (0.25) | n= 5 (16.1%) \|-0.07 (0.23) | -0.03 [-1.11 ; 1.05] |
| Week 99 | n= 8 (19.0%) \|-0.08 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 7 (16.7%) \|-0.11 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (19.0%) \|-0.03 (0.16) | n= 4 (12.9%) \| 0.02 (0.03) | -0.30 [-1.57 ; 0.97] |
| Week 105 | n= 8 (19.0%) \|-0.16 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 5 (11.9%) \|-0.09 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (19.0%) \|-0.09 (0.18) | n= 1 ( 3.2%) \| 0.00 ( / ) | [Not calculable] |
| Week 111 | n= 5 (11.9%) \|-0.37 (0.51) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 (11.9%) \|-0.10 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 5 (11.9%) \|-0.03 (0.30) | n= 2 ( 6.5%) \|-0.17 (0.24) | 0.42 [-1.41 ; 2.25] |
| Week 117 | n= 4 ( 9.5%) \|-0.21 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 9.5%) \|-0.19 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (11.9%) \|-0.11 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.4%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (14.3%) \| 0.03 (0.21) | n= 9 (29.0%) \|-0.13 (0.22) | 0.69 [-0.42 ; 1.79] |
| Week 202 | n= 2 ( 4.8%) \|-0.41 (0.14) | n= 5 (16.1%) \|-0.13 (0.17) | -1.40 [-3.45 ; 0.65] |
| Week 301 | n= 1 ( 2.4%) \|-0.17 ( / ) | n= 2 ( 6.5%) \| 0.08 (0.17) | [Not calculable] |
| Week 302 | n= 1 ( 2.4%) \| 0.04 ( / ) | n= 3 ( 9.7%) \|-0.23 (0.18) | [Not calculable] |
| Week 303 | n= 2 ( 4.8%) \|-0.10 (0.19) | n= 2 ( 6.5%) \|-0.27 (0.16) | 0.56 [-2.04 ; 3.16] |
| Week 304 | n= 1 ( 2.4%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| **Not Reported** | | | |
| N subjects in population | N=22 | N=25 | |
| Week 3 | n= 20 (90.9%) \|-0.01 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 19 (86.4%) \|-0.08 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 19 (86.4%) \|-0.09 (0.13) | n= 22 (88.0%) \|-0.01 (0.12) | -0.58 [-1.22 ; 0.05] |
| Week 9 | n= 20 (90.9%) \|-0.05 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 19 (86.4%) \|-0.11 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 19 (86.4%) \|-0.06 (0.14) | n= 22 (88.0%) \|-0.14 (0.26) | 0.39 [-0.24 ; 1.01] |
| Week 15 | n= 20 (90.9%) \|-0.13 (0.33) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 22 (100.0%) \|-0.06 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 21 (95.5%) \|-0.04 (0.17) | n= 20 (80.0%) \|-0.03 (0.19) | -0.08 [-0.70 ; 0.54] |
| Week 21 | n= 21 (95.5%) \|-0.01 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (95.5%) \| 0.01 (0.10) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 25 | n= 21 (95.5%) \|-0.04 (0.14) | n= 19 (76.0%) \|-0.07 (0.13) | 0.26 [-0.37 ; 0.89] |
| Week 27 | n= 21 (95.5%) \|-0.03 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 19 (86.4%) \|-0.02 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 22 (100.0%) \| 0.02 (0.12) | n= 19 (76.0%) \|-0.08 (0.18) | 0.67 [ 0.03 ; 1.31] |
| Week 33 | n= 20 (90.9%) \|-0.02 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 21 (95.5%) \|-0.00 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 21 (95.5%) \|-0.01 (0.16) | n= 19 (76.0%) \|-0.07 (0.15) | 0.37 [-0.27 ; 1.00] |
| Week 39 | n= 18 (81.8%) \|-0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 17 (77.3%) \|-0.04 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 20 (90.9%) \|-0.05 (0.13) | n= 19 (76.0%) \|-0.09 (0.16) | 0.23 [-0.40 ; 0.87] |
| Week 45 | n= 18 (81.8%) \|-0.03 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 20 (90.9%) \|-0.02 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 20 (90.9%) \| 0.01 (0.15) | n= 18 (72.0%) \|-0.12 (0.26) | 0.60 [-0.06 ; 1.27] |
| Week 51 | n= 21 (95.5%) \|-0.03 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 18 (81.8%) \|-0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 18 (81.8%) \|-0.01 (0.15) | n= 19 (76.0%) \|-0.04 (0.14) | 0.24 [-0.41 ; 0.90] |
| Week 57 | n= 17 (77.3%) \| 0.01 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 17 (77.3%) \|-0.03 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 20 (90.9%) \|-0.05 (0.19) | n= 15 (60.0%) \|-0.17 (0.27) | 0.52 [-0.17 ; 1.21] |
| Week 63 | n= 15 (68.2%) \| 0.02 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 18 (81.8%) \| 0.01 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 19 (86.4%) \|-0.01 (0.19) | n= 14 (56.0%) \|-0.14 (0.17) | 0.69 [-0.04 ; 1.41] |
| Week 69 | n= 14 (63.6%) \|-0.04 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 15 (68.2%) \|-0.03 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (72.7%) \| 0.00 (0.17) | n= 12 (48.0%) \|-0.15 (0.18) | 0.84 [ 0.04 ; 1.63] |
| Week 75 | n= 15 (68.2%) \| 0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 13 (59.1%) \| 0.01 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 14 (63.6%) \| 0.01 (0.16) | n= 10 (40.0%) \|-0.09 (0.12) | 0.69 [-0.16 ; 1.55] |
| Week 81 | n= 11 (50.0%) \| 0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 13 (59.1%) \| 0.00 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (50.0%) \| 0.00 (0.12) | n= 8 (32.0%) \|-0.17 (0.19) | 1.06 [ 0.06 ; 2.07] |
| Week 87 | n= 11 (50.0%) \|-0.12 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 11 (50.0%) \|-0.04 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 9 (40.9%) \|-0.05 (0.13) | n= 7 (28.0%) \|-0.14 (0.23) | 0.48 [-0.56 ; 1.51] |
| Week 93 | n= 7 (31.8%) \|-0.08 (0.10) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 9 (40.9%) \|-0.06 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (31.8%) \|-0.04 (0.07) | n= 2 ( 8.0%) \|-0.32 (0.23) | 2.18 [ 0.10 ; 4.26] |
| Week 99 | n= 7 (31.8%) \|-0.07 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (27.3%) \|-0.07 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 6 (27.3%) \|-0.14 (0.11) | n= 3 (12.0%) \|-0.22 (0.24) | 0.47 [-1.04 ; 1.98] |
| Week 105 | n= 5 (22.7%) \|-0.07 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 3 (13.6%) \|-0.10 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (13.6%) \|-0.32 (0.48) | n= 2 ( 8.0%) \| 0.00 (0.00) | -0.60 [-2.79 ; 1.60] |
| Week 111 | n= 2 ( 9.1%) \|-0.09 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (13.6%) \|-0.03 (0.03) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 4.5%) \|-0.04 ( / ) | n= 2 ( 8.0%) \|-0.15 (0.22) | [Not calculable] |
| Week 117 | n= 2 ( 9.1%) \|-0.16 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 ( 9.1%) \|-0.09 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (13.6%) \|-0.09 (0.06) | n= 1 ( 4.0%) \|-0.38 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 4.5%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.5%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 127 | n= 1 ( 4.5%) \|-0.05 ( / ) | n= 1 ( 4.0%) \|-0.38 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 4.5%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.5%) \|-0.03 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.5%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 4.5%) \|-0.27 ( / ) | n= 5 (20.0%) \|-0.17 (0.29) | [Not calculable] |
| Week 202 | [No Data] | n= 5 (20.0%) \|-0.11 (0.15) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 4 (16.0%) \| 0.04 (0.08) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 2 ( 8.0%) \| 0.01 (0.01) | [No Data for at least 1 arm] |
| Week 303 | [No Data] | n= 2 ( 8.0%) \|-0.32 (0.45) | [No Data for at least 1 arm] |
| Week 304 | [No Data] | n= 2 ( 8.0%) \|-0.22 (0.31) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:47

TABLE 7.2.6: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **Hispanic or Latino** | | | | |
| Nr subjects used | n=7 | n=12 | | |
| **Not Hispanic or Latino** | | | | |
| Nr subjects used | n=42 | n=31 | | |
| Week 7 | -0.03 (0.03) [-0.10 ; 0.03] | 0.01 (0.04) [-0.06 ; 0.09] | -0.05 (0.05) [-0.15 ; 0.06] | -0.23 [-0.71 ; 0.26] |
| Week 13 | 0.00 (0.03) [-0.07 ; 0.07] | -0.02 (0.04) [-0.10 ; 0.06] | 0.02 (0.05) [-0.09 ; 0.13] | 0.11 [-0.42 ; 0.64] |
| Week 19 | -0.01 (0.03) [-0.08 ; 0.05] | 0.00 (0.04) [-0.07 ; 0.07] | -0.02 (0.05) [-0.11 ; 0.08] | -0.09 [-0.62 ; 0.44] |
| Week 25 | -0.02 (0.03) [-0.08 ; 0.04] | -0.04 (0.04) [-0.11 ; 0.04] | 0.02 (0.05) [-0.08 ; 0.12] | 0.09 [-0.43 ; 0.62] |
| Week 31 | -0.07 (0.04) [-0.14 ; 0.01] | -0.06 (0.04) [-0.15 ; 0.03] | -0.00 (0.06) [-0.12 ; 0.11] | -0.02 [-0.60 ; 0.56] |
| Week 37 | 0.02 (0.03) [-0.04 ; 0.09] | -0.05 (0.04) [-0.12 ; 0.03] | 0.07 (0.05) [-0.02 ; 0.17] | 0.43 [-0.15 ; 1.01] |
| Week 43 | 0.01 (0.03) [-0.05 ; 0.07] | -0.02 (0.04) [-0.10 ; 0.06] | 0.03 (0.05) [-0.07 ; 0.13] | 0.17 [-0.43 ; 0.77] |
| Week 49 | 0.02 (0.03) [-0.03 ; 0.07] | -0.04 (0.03) [-0.11 ; 0.03] | 0.06 (0.04) [-0.02 ; 0.15] | 0.46 [-0.17 ; 1.09] |
| Week 55 | 0.00 (0.03) [-0.05 ; 0.06] | 0.03 (0.04) [-0.05 ; 0.10] | -0.02 (0.05) [-0.12 ; 0.07] | -0.17 [-0.81 ; 0.46] |
| Week 61 | 0.01 (0.03) [-0.05 ; 0.07] | -0.01 (0.04) [-0.10 ; 0.07] | 0.02 (0.05) [-0.08 ; 0.12] | 0.15 [-0.56 ; 0.86] |
| Week 67 | -0.02 (0.04) [-0.10 ; 0.05] | -0.00 (0.05) [-0.11 ; 0.10] | -0.02 (0.06) [-0.15 ; 0.11] | -0.11 [-0.81 ; 0.60] |
| Week 73 | -0.03 (0.04) [-0.11 ; 0.06] | -0.05 (0.05) [-0.16 ; 0.05] | 0.03 (0.07) [-0.11 ; 0.16] | 0.16 [-0.60 ; 0.92] |
| Week 79 | 0.04 (0.05) [-0.05 ; 0.13] | 0.02 (0.06) [-0.10 ; 0.14] | 0.02 (0.07) [-0.13 ; 0.17] | 0.11 [-0.69 ; 0.92] |
| Overall post-baseline period estimate | -0.01 (0.02) [-0.04 ; 0.03] | -0.02 (0.02) [-0.07 ; 0.03] | 0.01 (0.03) [-0.05 ; 0.07] | 0.09 [-0.37 ; 0.56] |
| **Not Reported** | | | | |
| Nr subjects used | n=22 | n=25 | | |
| Week 7 | -0.10 (0.03) [-0.16 ;-0.04] | -0.02 (0.03) [-0.07 ; 0.04] | -0.08 (0.04) [-0.16 ; 0.00] | -0.61 [-1.24 ; 0.02] |
| Week 13 | -0.05 (0.05) [-0.15 ; 0.05] | -0.14 (0.05) [-0.24 ;-0.05] | 0.09 (0.07) [-0.04 ; 0.23] | 0.42 [-0.20 ; 1.04] |
| Week 19 | -0.05 (0.04) [-0.13 ; 0.02] | -0.04 (0.04) [-0.11 ; 0.03] | -0.01 (0.05) [-0.11 ; 0.09] | -0.08 [-0.69 ; 0.54] |
| Week 25 | -0.03 (0.03) [-0.09 ; 0.02] | -0.06 (0.03) [-0.12 ;-0.00] | 0.03 (0.04) [-0.05 ; 0.11] | 0.22 [-0.40 ; 0.84] |
| Week 31 | 0.01 (0.03) [-0.05 ; 0.07] | -0.06 (0.03) [-0.12 ; 0.01] | 0.07 (0.04) [-0.02 ; 0.16] | 0.49 [-0.14 ; 1.11] |
| Week 37 | -0.02 (0.03) [-0.08 ; 0.04] | -0.05 (0.03) [-0.11 ; 0.01] | 0.03 (0.04) [-0.06 ; 0.12] | 0.23 [-0.39 ; 0.86] |
| Week 43 | -0.04 (0.03) [-0.11 ; 0.02] | -0.07 (0.03) [-0.13 ; 0.00] | 0.02 (0.05) [-0.07 ; 0.12] | 0.16 [-0.47 ; 0.79] |
| Week 49 | 0.00 (0.05) [-0.10 ; 0.11] | -0.11 (0.05) [-0.21 ; 0.00] | 0.11 (0.07) [-0.04 ; 0.26] | 0.47 [-0.17 ; 1.12] |
| Week 55 | -0.02 (0.03) [-0.08 ; 0.04] | -0.03 (0.03) [-0.09 ; 0.03] | 0.01 (0.04) [-0.08 ; 0.10] | 0.08 [-0.57 ; 0.72] |
| Week 61 | -0.06 (0.05) [-0.16 ; 0.04] | -0.12 (0.06) [-0.24 ;-0.01] | 0.07 (0.07) [-0.08 ; 0.21] | 0.30 [-0.38 ; 0.97] |
| Week 67 | -0.02 (0.03) [-0.09 ; 0.05] | -0.10 (0.04) [-0.18 ;-0.02] | 0.08 (0.05) [-0.03 ; 0.19] | 0.53 [-0.18 ; 1.23] |
| Week 73 | -0.01 (0.03) [-0.07 ; 0.06] | -0.11 (0.04) [-0.19 ;-0.04] | 0.10 (0.05) [ 0.00 ; 0.20] | 0.77 [-0.01 ; 1.55] |
| Week 79 | -0.00 (0.03) [-0.06 ; 0.06] | -0.09 (0.04) [-0.16 ;-0.02] | 0.09 (0.05) [-0.01 ; 0.18] | 0.75 [-0.09 ; 1.60] |
| Overall post-baseline period estimate | -0.03 (0.02) [-0.06 ; 0.00] | -0.08 (0.02) [-0.11 ;-0.04] | 0.05 (0.02) [ 0.00 ; 0.09] | 0.60 [ 0.01 ; 1.19] |
| **MMRM subgroups interaction p-value** | | | 0.6931 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020

TABLE 7.2.7: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender Subgroups Analysis


| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **Male** | | |
| | N=54 | N=47 |
| **Female** | | |
| | N=17 | N=21 |
| **Subjects with Baseline Value** | | |
| **Male** | | |
| | 54 (100.0%) | 47 (100.0%) |
| **Female** | | |
| | 17 (100.0%) | 21 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **Male** | | |
| | 54 (100.0%) | 47 (100.0%) |
| **Female** | | |
| | 17 (100.0%) | 19 (90.5%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **Male** | | |
| | 54 (100.0%) | 47 (100.0%) |
| **Female** | | |
| | 17 (100.0%) | 19 (90.5%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:47

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Male** | | | |
| N subjects in population | N=54 | N=47 | |
| Baseline | n= 54 (100.0%) \| 0.85 (0.21) | n= 47 (100.0%) \| 0.76 (0.31) | 0.36 [-0.03 ; 0.76] |
| Week 3 | n= 49 (90.7%) \| 0.84 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 48 (88.9%) \| 0.82 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 51 (94.4%) \| 0.81 (0.22) | n= 45 (95.7%) \| 0.79 (0.24) | 0.08 [-0.32 ; 0.48] |
| Week 9 | n= 46 (85.2%) \| 0.81 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 46 (85.2%) \| 0.83 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 46 (85.2%) \| 0.84 (0.19) | n= 37 (78.7%) \| 0.76 (0.24) | 0.38 [-0.06 ; 0.82] |
| Week 15 | n= 42 (77.8%) \| 0.80 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 47 (87.0%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 45 (83.3%) \| 0.82 (0.20) | n= 39 (83.0%) \| 0.83 (0.21) | -0.02 [-0.45 ; 0.41] |
| Week 21 | n= 47 (87.0%) \| 0.82 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 40 (74.1%) \| 0.84 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 44 (81.5%) \| 0.85 (0.20) | n= 35 (74.5%) \| 0.81 (0.17) | 0.19 [-0.26 ; 0.63] |
| Week 27 | n= 43 (79.6%) \| 0.85 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 41 (75.9%) \| 0.84 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 42 (77.8%) \| 0.82 (0.22) | n= 30 (63.8%) \| 0.81 (0.23) | 0.05 [-0.42 ; 0.53] |
| Week 33 | n= 45 (83.3%) \| 0.83 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 42 (77.8%) \| 0.83 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 41 (75.9%) \| 0.86 (0.19) | n= 34 (72.3%) \| 0.81 (0.17) | 0.25 [-0.20 ; 0.71] |
| Week 39 | n= 43 (79.6%) \| 0.84 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 40 (74.1%) \| 0.86 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 43 (79.6%) \| 0.84 (0.17) | n= 30 (63.8%) \| 0.81 (0.19) | 0.13 [-0.34 ; 0.60] |
| Week 45 | n= 39 (72.2%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 42 (77.8%) \| 0.86 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 42 (77.8%) \| 0.88 (0.16) | n= 28 (59.6%) \| 0.80 (0.19) | 0.41 [-0.08 ; 0.89] |
| Week 51 | n= 40 (74.1%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 37 (68.5%) \| 0.87 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 38 (70.4%) \| 0.86 (0.16) | n= 27 (57.4%) \| 0.83 (0.20) | 0.15 [-0.35 ; 0.64] |
| Week 57 | n= 39 (72.2%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 35 (64.8%) \| 0.83 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (72.2%) \| 0.85 (0.19) | n= 21 (44.7%) \| 0.82 (0.20) | 0.14 [-0.40 ; 0.67] |
| Week 63 | n= 34 (63.0%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 34 (63.0%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 35 (64.8%) \| 0.85 (0.19) | n= 21 (44.7%) \| 0.83 (0.14) | 0.11 [-0.44 ; 0.66] |
| Week 69 | n= 28 (51.9%) \| 0.85 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 32 (59.3%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 27 (50.0%) \| 0.85 (0.16) | n= 19 (40.4%) \| 0.77 (0.22) | 0.42 [-0.18 ; 1.02] |
| Week 75 | n= 30 (55.6%) \| 0.87 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (50.0%) \| 0.87 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (48.1%) \| 0.86 (0.17) | n= 17 (36.2%) \| 0.78 (0.22) | 0.42 [-0.21 ; 1.04] |
| Week 81 | n= 26 (48.1%) \| 0.85 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (51.9%) \| 0.86 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 21 (38.9%) \| 0.89 (0.15) | n= 14 (29.8%) \| 0.76 (0.21) | 0.71 [ 0.00 ; 1.42] |
| Week 87 | n= 19 (35.2%) \| 0.80 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 20 (37.0%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 19 (35.2%) \| 0.80 (0.24) | n= 12 (25.5%) \| 0.90 (0.10) | -0.46 [-1.21 ; 0.28] |
| Week 93 | n= 17 (31.5%) \| 0.81 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 18 (33.3%) \| 0.81 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (31.5%) \| 0.78 (0.24) | n= 7 (14.9%) \| 0.90 (0.14) | -0.50 [-1.42 ; 0.41] |
| Week 99 | n= 15 (27.8%) \| 0.75 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (20.4%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (22.2%) \| 0.80 (0.14) | n= 5 (10.6%) \| 0.84 (0.15) | -0.28 [-1.36 ; 0.80] |
| Week 105 | n= 11 (20.4%) \| 0.74 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (11.1%) \| 0.79 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.8%) \| 0.65 (0.25) | n= 2 ( 4.3%) \| 0.90 (0.14) | -0.92 [-2.64 ; 0.79] |
| Week 111 | n= 6 (11.1%) \| 0.57 (0.58) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (11.1%) \| 0.87 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 ( 5.6%) \| 0.87 (0.22) | n= 3 ( 6.4%) \| 0.82 (0.17) | 0.23 [-1.60 ; 2.05] |
| Week 117 | n= 4 ( 7.4%) \| 0.79 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 7.4%) \| 0.76 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (11.1%) \| 0.76 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 1.9%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.9%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.9%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 1.9%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.9%) \| 0.82 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.9%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (11.1%) \| 0.90 (0.12) | n= 10 (21.3%) \| 0.71 (0.30) | 0.74 [-0.35 ; 1.82] |
| Week 202 | n= 2 ( 3.7%) \| 0.44 (0.35) | n= 7 (14.9%) \| 0.81 (0.23) | -1.32 [-3.16 ; 0.52] |
| Week 301 | n= 1 ( 1.9%) \| 0.52 ( / ) | n= 7 (14.9%) \| 0.79 (0.17) | [Not calculable] |
| Week 302 | [No Data] | n= 4 ( 8.5%) \| 0.71 (0.08) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 1.9%) \| 0.62 ( / ) | n= 5 (10.6%) \| 0.66 (0.32) | [Not calculable] |
| Week 304 | n= 1 ( 1.9%) \| 1.00 ( / ) | n= 3 ( 6.4%) \| 0.58 (0.29) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 2.1%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 2.1%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 2.1%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 2.1%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 2.1%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| **Female** | | | |
| N subjects in population | N=17 | N=21 | |
| Baseline | n= 17 (100.0%) \| 0.78 (0.16) | n= 21 (100.0%) \| 0.86 (0.22) | -0.41 [-1.07 ; 0.24] |
| Week 3 | n= 17 (100.0%) \| 0.80 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 16 (94.1%) \| 0.71 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 13 (76.5%) \| 0.74 (0.16) | n= 17 (81.0%) \| 0.78 (0.26) | -0.18 [-0.91 ; 0.56] |
| Week 9 | n= 13 (76.5%) \| 0.76 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (88.2%) \| 0.66 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 13 (76.5%) \| 0.70 (0.24) | n= 15 (71.4%) \| 0.75 (0.21) | -0.22 [-0.98 ; 0.54] |
| Week 15 | n= 12 (70.6%) \| 0.72 (0.30) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (82.4%) \| 0.71 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 12 (70.6%) \| 0.78 (0.21) | n= 12 (57.1%) \| 0.80 (0.13) | -0.13 [-0.95 ; 0.69] |
| Week 21 | n= 13 (76.5%) \| 0.78 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (88.2%) \| 0.77 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 14 (82.4%) \| 0.76 (0.24) | n= 15 (71.4%) \| 0.81 (0.15) | -0.24 [-0.98 ; 0.51] |
| Week 27 | n= 12 (70.6%) \| 0.80 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 12 (70.6%) \| 0.76 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 12 (70.6%) \| 0.82 (0.18) | n= 13 (61.9%) \| 0.77 (0.18) | 0.25 [-0.56 ; 1.05] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 33 | n= 12 (70.6%) \| 0.77 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 11 (64.7%) \| 0.81 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (47.1%) \| 0.78 (0.19) | n= 10 (47.6%) \| 0.82 (0.17) | -0.21 [-1.17 ; 0.75] |
| Week 39 | n= 10 (58.8%) \| 0.78 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 11 (64.7%) \| 0.81 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 10 (58.8%) \| 0.80 (0.22) | n= 11 (52.4%) \| 0.80 (0.17) | 0.00 [-0.87 ; 0.88] |
| Week 45 | n= 10 (58.8%) \| 0.86 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 10 (58.8%) \| 0.84 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 11 (64.7%) \| 0.79 (0.20) | n= 9 (42.9%) \| 0.66 (0.38) | 0.43 [-0.49 ; 1.34] |
| Week 51 | n= 11 (64.7%) \| 0.80 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 11 (64.7%) \| 0.78 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 9 (52.9%) \| 0.78 (0.19) | n= 11 (52.4%) \| 0.83 (0.14) | -0.30 [-1.21 ; 0.61] |
| Week 57 | n= 8 (47.1%) \| 0.83 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 9 (52.9%) \| 0.77 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 9 (52.9%) \| 0.82 (0.19) | n= 9 (42.9%) \| 0.66 (0.39) | 0.52 [-0.45 ; 1.49] |
| Week 63 | n= 8 (47.1%) \| 0.84 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (58.8%) \| 0.83 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 9 (52.9%) \| 0.81 (0.20) | n= 9 (42.9%) \| 0.73 (0.26) | 0.32 [-0.64 ; 1.28] |
| Week 69 | n= 8 (47.1%) \| 0.75 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (41.2%) \| 0.74 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (41.2%) \| 0.70 (0.21) | n= 8 (38.1%) \| 0.71 (0.16) | -0.05 [-1.11 ; 1.00] |
| Week 75 | n= 6 (35.3%) \| 0.72 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (29.4%) \| 0.72 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (29.4%) \| 0.86 (0.19) | n= 7 (33.3%) \| 0.82 (0.17) | 0.22 [-0.99 ; 1.43] |
| Week 81 | n= 5 (29.4%) \| 0.82 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (29.4%) \| 0.74 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 6 (35.3%) \| 0.81 (0.22) | n= 6 (28.6%) \| 0.78 (0.19) | 0.13 [-1.06 ; 1.31] |
| Week 87 | n= 5 (29.4%) \| 0.74 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 5 (29.4%) \| 0.74 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 5 (29.4%) \| 0.77 (0.22) | n= 5 (23.8%) \| 0.68 (0.11) | 0.43 [-0.90 ; 1.77] |
| Week 93 | n= 3 (17.6%) \| 0.77 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (23.5%) \| 0.72 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (23.5%) \| 0.80 (0.24) | n= 3 (14.3%) \| 0.65 (0.17) | 0.59 [-1.11 ; 2.29] |
| Week 99 | n= 2 (11.8%) \| 0.84 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (17.6%) \| 0.74 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (17.6%) \| 0.83 (0.16) | n= 4 (19.0%) \| 0.83 (0.23) | -0.02 [-1.67 ; 1.64] |
| Week 105 | n= 3 (17.6%) \| 0.74 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.8%) \| 0.84 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (17.6%) \| 0.74 (0.25) | n= 2 ( 9.5%) \| 1.00 (0.00) | -0.96 [-3.29 ; 1.36] |
| Week 111 | n= 1 ( 5.9%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.8%) \| 0.60 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (17.6%) \| 0.74 (0.25) | n= 2 ( 9.5%) \| 0.85 (0.22) | -0.34 [-2.48 ; 1.80] |
| Week 117 | n= 2 (11.8%) \| 0.60 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (11.8%) \| 0.60 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (11.8%) \| 0.84 (0.22) | n= 1 ( 4.8%) \| 0.62 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 5.9%) \| 1.00 ( / ) | n= 1 ( 4.8%) \| 0.62 ( / ) | [Not calculable] |
| Week 201 | n= 2 (11.8%) \| 0.73 (0.00) | n= 7 (33.3%) \| 0.77 (0.16) | -0.28 [-1.97 ; 1.41] |
| Week 202 | [No Data] | n= 5 (23.8%) \| 0.84 (0.15) | [No Data for at least 1 arm] |
| Week 301 | n= 1 ( 5.9%) \| 1.00 ( / ) | n= 2 ( 9.5%) \| 0.90 (0.14) | [Not calculable] |
| Week 302 | n= 2 (11.8%) \| 0.69 (0.05) | n= 2 ( 9.5%) \| 0.74 (0.02) | -0.77 [-3.49 ; 1.95] |
| Week 303 | n= 2 (11.8%) \| 0.83 (0.24) | n= 1 ( 4.8%) \| 0.73 ( / ) | [Not calculable] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:48

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Male** | | | |
| N subjects in population | N=54 | N=47 | |
| Week 3 | n= 49 (90.7%) \|-0.01 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 48 (88.9%) \|-0.04 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 51 (94.4%) \|-0.05 (0.22) | n= 45 (95.7%) \| 0.04 (0.22) | -0.38 [-0.79 ; 0.02] |
| Week 9 | n= 46 (85.2%) \|-0.03 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 46 (85.2%) \|-0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 46 (85.2%) \|-0.01 (0.18) | n= 37 (78.7%) \|-0.05 (0.26) | 0.19 [-0.25 ; 0.63] |
| Week 15 | n= 42 (77.8%) \|-0.06 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 47 (87.0%) \|-0.02 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 45 (83.3%) \|-0.02 (0.18) | n= 39 (83.0%) \| 0.02 (0.21) | -0.18 [-0.61 ; 0.25] |
| Week 21 | n= 47 (87.0%) \|-0.02 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 40 (74.1%) \|-0.02 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 44 (81.5%) \|-0.01 (0.18) | n= 35 (74.5%) \|-0.04 (0.15) | 0.20 [-0.25 ; 0.65] |
| Week 27 | n= 43 (79.6%) \|-0.00 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 41 (75.9%) \|-0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 42 (77.8%) \|-0.03 (0.20) | n= 30 (63.8%) \|-0.05 (0.17) | 0.10 [-0.38 ; 0.57] |
| Week 33 | n= 45 (83.3%) \|-0.02 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 42 (77.8%) \|-0.02 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 41 (75.9%) \|-0.00 (0.18) | n= 34 (72.3%) \|-0.06 (0.16) | 0.34 [-0.12 ; 0.80] |
| Week 39 | n= 43 (79.6%) \|-0.01 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 40 (74.1%) \|-0.01 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 43 (79.6%) \|-0.02 (0.20) | n= 30 (63.8%) \|-0.04 (0.19) | 0.10 [-0.37 ; 0.56] |
| Week 45 | n= 39 (72.2%) \|-0.00 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 42 (77.8%) \|-0.01 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 42 (77.8%) \| 0.03 (0.18) | n= 28 (59.6%) \|-0.04 (0.16) | 0.39 [-0.10 ; 0.87] |
| Week 51 | n= 40 (74.1%) \|-0.02 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 37 (68.5%) \|-0.00 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 38 (70.4%) \| 0.01 (0.22) | n= 27 (57.4%) \|-0.01 (0.18) | 0.11 [-0.39 ; 0.61] |
| Week 57 | n= 39 (72.2%) \|-0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 35 (64.8%) \|-0.02 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (72.2%) \|-0.01 (0.23) | n= 21 (44.7%) \|-0.03 (0.16) | 0.09 [-0.45 ; 0.62] |
| Week 63 | n= 34 (63.0%) \|-0.01 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 34 (63.0%) \| 0.02 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 35 (64.8%) \|-0.02 (0.23) | n= 21 (44.7%) \|-0.01 (0.14) | -0.05 [-0.60 ; 0.49] |
| Week 69 | n= 28 (51.9%) \| 0.01 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 32 (59.3%) \| 0.01 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 27 (50.0%) \| 0.02 (0.23) | n= 19 (40.4%) \|-0.05 (0.20) | 0.33 [-0.27 ; 0.92] |
| Week 75 | n= 30 (55.6%) \| 0.04 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (50.0%) \| 0.04 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (48.1%) \| 0.06 (0.22) | n= 17 (36.2%) \|-0.05 (0.21) | 0.46 [-0.17 ; 1.08] |
| Week 81 | n= 26 (48.1%) \| 0.02 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (51.9%) \| 0.04 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 21 (38.9%) \| 0.02 (0.17) | n= 14 (29.8%) \|-0.06 (0.22) | 0.42 [-0.27 ; 1.12] |
| Week 87 | n= 19 (35.2%) \|-0.06 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 20 (37.0%) \| 0.01 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 19 (35.2%) \|-0.04 (0.21) | n= 12 (25.5%) \| 0.05 (0.17) | -0.43 [-1.17 ; 0.32] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 17 (31.5%) \|-0.02 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 18 (33.3%) \|-0.04 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (31.5%) \|-0.06 (0.20) | n= 7 (14.9%) \| 0.01 (0.11) | -0.39 [-1.30 ; 0.51] |
| Week 99 | n= 15 (27.8%) \|-0.07 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (20.4%) \|-0.08 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (22.2%) \|-0.08 (0.14) | n= 5 (10.6%) \|-0.05 (0.15) | -0.20 [-1.28 ; 0.88] |
| Week 105 | n= 11 (20.4%) \|-0.13 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (11.1%) \|-0.12 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.8%) \|-0.19 (0.31) | n= 2 ( 4.3%) \| 0.00 (0.00) | -0.60 [-2.27 ; 1.08] |
| Week 111 | n= 6 (11.1%) \|-0.34 (0.47) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (11.1%) \|-0.05 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 ( 5.6%) \|-0.01 (0.36) | n= 3 ( 6.4%) \|-0.11 (0.20) | 0.28 [-1.55 ; 2.11] |
| Week 117 | n= 4 ( 7.4%) \|-0.21 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 7.4%) \|-0.16 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (11.1%) \|-0.16 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 1.9%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.9%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.9%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 1.9%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.9%) \|-0.03 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.9%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (11.1%) \| 0.06 (0.23) | n= 10 (21.3%) \|-0.09 (0.25) | 0.61 [-0.46 ; 1.68] |
| Week 202 | n= 2 ( 3.7%) \|-0.41 (0.14) | n= 7 (14.9%) \|-0.09 (0.15) | -1.95 [-3.96 ; 0.05] |
| Week 301 | n= 1 ( 1.9%) \|-0.17 ( / ) | n= 7 (14.9%) \| 0.07 (0.17) | [Not calculable] |
| Week 302 | [No Data] | n= 4 ( 8.5%) \|-0.12 (0.18) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 1.9%) \|-0.23 ( / ) | n= 5 (10.6%) \|-0.20 (0.31) | [Not calculable] |
| Week 304 | n= 1 ( 1.9%) \| 0.15 ( / ) | n= 3 ( 6.4%) \|-0.20 (0.22) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 2.1%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 2.1%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 2.1%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 2.1%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 2.1%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| **Female** | | | |
| N subjects in population | N=17 | N=21 | |
| Week 3 | n= 17 (100.0%) \| 0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 16 (94.1%) \|-0.05 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 13 (76.5%) \|-0.06 (0.14) | n= 17 (81.0%) \|-0.07 (0.10) | 0.11 [-0.63 ; 0.84] |
| Week 9 | n= 13 (76.5%) \|-0.06 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (88.2%) \|-0.13 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 13 (76.5%) \|-0.09 (0.20) | n= 15 (71.4%) \|-0.13 (0.23) | 0.19 [-0.57 ; 0.95] |
| Week 15 | n= 12 (70.6%) \|-0.08 (0.35) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (82.4%) \|-0.10 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 12 (70.6%) \|-0.02 (0.18) | n= 12 (57.1%) \|-0.10 (0.16) | 0.45 [-0.37 ; 1.28] |
| Week 21 | n= 13 (76.5%) \|-0.04 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (88.2%) \|-0.03 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 14 (82.4%) \|-0.05 (0.18) | n= 15 (71.4%) \|-0.09 (0.12) | 0.24 [-0.50 ; 0.99] |
| Week 27 | n= 12 (70.6%) \|-0.04 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 12 (70.6%) \|-0.05 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 12 (70.6%) \|-0.01 (0.11) | n= 13 (61.9%) \|-0.14 (0.22) | 0.72 [-0.11 ; 1.55] |
| Week 33 | n= 12 (70.6%) \|-0.02 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 11 (64.7%) \|-0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 37 | n= 8 (47.1%) \|-0.02 (0.14) | n= 10 (47.6%) \|-0.10 (0.14) | 0.59 [-0.39 ; 1.57] |
| Week 39 | n= 10 (58.8%) \|-0.02 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 11 (64.7%) \|-0.01 (0.10) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 10 (58.8%) \| 0.01 (0.12) | n= 11 (52.4%) \|-0.13 (0.17) | 0.94 [ 0.01 ; 1.86] |
| Week 45 | n= 10 (58.8%) \| 0.03 (0.10) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 10 (58.8%) \| 0.02 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 11 (64.7%) \|-0.01 (0.14) | n= 9 (42.9%) \|-0.21 (0.34) | 0.77 [-0.17 ; 1.71] |
| Week 51 | n= 11 (64.7%) \|-0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 11 (64.7%) \|-0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 9 (52.9%) \|-0.04 (0.15) | n= 11 (52.4%) \|-0.07 (0.16) | 0.16 [-0.74 ; 1.07] |
| Week 57 | n= 8 (47.1%) \| 0.01 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 9 (52.9%) \|-0.03 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 9 (52.9%) \|-0.02 (0.15) | n= 9 (42.9%) \|-0.27 (0.31) | 1.00 [-0.02 ; 2.01] |
| Week 63 | n= 8 (47.1%) \| 0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (58.8%) \| 0.01 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 9 (52.9%) \|-0.01 (0.15) | n= 9 (42.9%) \|-0.20 (0.18) | 1.12 [ 0.09 ; 2.15] |
| Week 69 | n= 8 (47.1%) \|-0.05 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (41.2%) \|-0.03 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (41.2%) \|-0.06 (0.18) | n= 8 (38.1%) \|-0.21 (0.17) | 0.78 [-0.31 ; 1.88] |
| Week 75 | n= 6 (35.3%) \|-0.03 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (29.4%) \|-0.04 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (29.4%) \| 0.06 (0.14) | n= 7 (33.3%) \|-0.09 (0.14) | 1.03 [-0.26 ; 2.32] |
| Week 81 | n= 5 (29.4%) \| 0.00 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (29.4%) \|-0.04 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 6 (35.3%) \| 0.02 (0.18) | n= 6 (28.6%) \|-0.22 (0.19) | 1.16 [-0.14 ; 2.46] |
| Week 87 | n= 5 (29.4%) \|-0.04 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 5 (29.4%) \|-0.04 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 5 (29.4%) \|-0.04 (0.15) | n= 5 (23.8%) \|-0.32 (0.11) | 1.90 [ 0.26 ; 3.54] |
| Week 93 | n= 3 (17.6%) \|-0.04 (0.03) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (23.5%) \|-0.08 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (23.5%) \|-0.04 (0.17) | n= 3 (14.3%) \|-0.35 (0.17) | 1.52 [-0.43 ; 3.48] |
| Week 99 | n= 2 (11.8%) \|-0.02 (0.03) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (17.6%) \|-0.10 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (17.6%) \|-0.03 (0.18) | n= 4 (19.0%) \|-0.17 (0.23) | 0.55 [-1.14 ; 2.25] |
| Week 105 | n= 3 (17.6%) \|-0.10 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.8%) \|-0.02 (0.03) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (17.6%) \|-0.05 (0.21) | n= 2 ( 9.5%) \| 0.00 (0.00) | -0.21 [-2.33 ; 1.91] |
| Week 111 | n= 1 ( 5.9%) \|-0.04 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.8%) \|-0.15 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (17.6%) \|-0.05 (0.21) | n= 2 ( 9.5%) \|-0.15 (0.22) | 0.36 [-1.78 ; 2.51] |
| Week 117 | n= 2 (11.8%) \|-0.15 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (11.8%) \|-0.15 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (11.8%) \| 0.06 (0.13) | n= 1 ( 4.8%) \|-0.38 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 5.9%) \| 0.15 ( / ) | n= 1 ( 4.8%) \|-0.38 ( / ) | [Not calculable] |
| Week 201 | n= 2 (11.8%) \|-0.08 (0.27) | n= 7 (33.3%) \|-0.15 (0.26) | 0.24 [-1.45 ; 1.93] |
| Week 202 | [No Data] | n= 5 (23.8%) \|-0.06 (0.25) | [No Data for at least 1 arm] |
| Week 301 | n= 1 ( 5.9%) \| 0.15 ( / ) | n= 2 ( 9.5%) \| 0.10 (0.14) | [Not calculable] |
| Week 302 | n= 2 (11.8%) \|-0.04 (0.11) | n= 2 ( 9.5%) \|-0.16 (0.17) | 0.45 [-2.10 ; 3.00] |
| Week 303 | n= 2 (11.8%) \| 0.09 (0.08) | n= 1 ( 4.8%) \|-0.07 ( / ) | [Not calculable] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:48

TABLE 7.2.7: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **Male** | | | | |
| Nr subjects used | n=54 | n=47 | | |
| Week 7 | -0.04 (0.03) [-0.10 ; 0.01] | -0.01 (0.03) [-0.07 ; 0.06] | -0.04 (0.04) [-0.13 ; 0.05] | -0.18 [-0.58 ; 0.22] |
| Week 13 | -0.02 (0.03) [-0.08 ; 0.04] | -0.07 (0.03) [-0.14 ;-0.00] | 0.05 (0.05) [-0.04 ; 0.15] | 0.25 [-0.18 ; 0.69] |
| Week 19 | -0.02 (0.03) [-0.07 ; 0.03] | 0.00 (0.03) [-0.05 ; 0.05] | -0.02 (0.04) [-0.10 ; 0.05] | -0.14 [-0.57 ; 0.29] |
| Week 25 | -0.00 (0.02) [-0.05 ; 0.04] | -0.04 (0.02) [-0.09 ; 0.01] | 0.03 (0.03) [-0.03 ; 0.10] | 0.22 [-0.22 ; 0.67] |
| Week 31 | -0.03 (0.03) [-0.09 ; 0.02] | -0.04 (0.03) [-0.10 ; 0.03] | 0.00 (0.04) [-0.08 ; 0.09] | 0.03 [-0.44 ; 0.49] |
| Week 37 | 0.01 (0.02) [-0.04 ; 0.06] | -0.05 (0.03) [-0.10 ; 0.01] | 0.06 (0.04) [-0.01 ; 0.13] | 0.38 [-0.08 ; 0.83] |
| Week 43 | -0.01 (0.03) [-0.06 ; 0.04] | -0.03 (0.03) [-0.09 ; 0.02] | 0.03 (0.04) [-0.05 ; 0.10] | 0.15 [-0.31 ; 0.62] |
| Week 49 | 0.02 (0.02) [-0.02 ; 0.07] | -0.04 (0.03) [-0.09 ; 0.01] | 0.06 (0.03) [-0.00 ; 0.13] | 0.45 [-0.03 ; 0.93] |
| Week 55 | 0.01 (0.03) [-0.04 ; 0.06] | -0.00 (0.03) [-0.06 ; 0.06] | 0.01 (0.04) [-0.07 ; 0.09] | 0.07 [-0.42 ; 0.57] |
| Week 61 | -0.02 (0.03) [-0.07 ; 0.04] | 0.00 (0.03) [-0.07 ; 0.07] | -0.02 (0.04) [-0.10 ; 0.07] | -0.10 [-0.64 ; 0.43] |
| Week 67 | -0.01 (0.03) [-0.06 ; 0.04] | -0.01 (0.04) [-0.08 ; 0.06] | 0.00 (0.04) [-0.09 ; 0.09] | 0.02 [-0.53 ; 0.56] |
| Week 73 | 0.01 (0.03) [-0.04 ; 0.06] | -0.05 (0.03) [-0.11 ; 0.01] | 0.06 (0.04) [-0.02 ; 0.14] | 0.43 [-0.17 ; 1.02] |
| Week 79 | 0.02 (0.03) [-0.03 ; 0.08] | -0.03 (0.03) [-0.09 ; 0.04] | 0.05 (0.04) [-0.03 ; 0.14] | 0.37 [-0.25 ; 0.98] |
| Week 85 | 0.02 (0.03) [-0.03 ; 0.07] | -0.06 (0.03) [-0.12 ; 0.01] | 0.08 (0.04) [-0.01 ; 0.16] | 0.63 [-0.06 ; 1.32] |
| Week 91 | -0.02 (0.03) [-0.09 ; 0.05] | 0.02 (0.04) [-0.07 ; 0.10] | -0.04 (0.05) [-0.15 ; 0.07] | -0.24 [-0.97 ; 0.49] |
| Overall post-baseline period estimate | -0.01 (0.01) [-0.03 ; 0.02] | -0.03 (0.02) [-0.06 ; 0.01] | 0.02 (0.02) [-0.02 ; 0.06] | 0.20 [-0.19 ; 0.59] |
| **Female** | | | | |
| Nr subjects used | n=17 | n=21 | | |
| Week 7 | -0.08 (0.03) [-0.14 ;-0.01] | -0.07 (0.03) [-0.13 ;-0.02] | -0.00 (0.04) [-0.09 ; 0.08] | -0.01 [-0.74 ; 0.71] |
| Week 13 | -0.08 (0.06) [-0.20 ; 0.03] | -0.14 (0.05) [-0.25 ;-0.04] | 0.06 (0.08) [-0.10 ; 0.21] | 0.28 [-0.46 ; 1.03] |
| Week 19 | -0.03 (0.05) [-0.13 ; 0.07] | -0.12 (0.05) [-0.21 ;-0.02] | 0.09 (0.07) [-0.05 ; 0.22] | 0.50 [-0.31 ; 1.32] |
| Week 25 | -0.05 (0.04) [-0.14 ; 0.03] | -0.09 (0.04) [-0.17 ;-0.00] | 0.03 (0.06) [-0.09 ; 0.15] | 0.20 [-0.53 ; 0.93] |
| Week 31 | -0.02 (0.05) [-0.12 ; 0.08] | -0.13 (0.05) [-0.23 ;-0.03] | 0.11 (0.07) [-0.03 ; 0.25] | 0.61 [-0.20 ; 1.42] |
| Week 43 | -0.01 (0.05) [-0.10 ; 0.09] | -0.11 (0.04) [-0.20 ;-0.02] | 0.11 (0.06) [-0.03 ; 0.24] | 0.70 [-0.19 ; 1.59] |
| Overall post-baseline period estimate | -0.05 (0.03) [-0.10 ; 0.01] | -0.11 (0.02) [-0.16 ;-0.06] | 0.06 (0.04) [-0.01 ; 0.14] | 0.60 [-0.07 ; 1.27] |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.7988 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:48

TABLE 7.2.8: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **< 1 Year** | | |
| | N=14 | N=18 |
| **>= 1 Year** | | |
| | N=57 | N=48 |
| **Not Reported** | | |
| | [No Data] | N=2 |
| **Subjects with Baseline Value** | | |
| **< 1 Year** | | |
| | 14 (100.0%) | 18 (100.0%) |
| **>= 1 Year** | | |
| | 57 (100.0%) | 48 (100.0%) |
| **Not Reported** | | |
| | [No Data] | 2 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **< 1 Year** | | |
| | 14 (100.0%) | 18 (100.0%) |
| **>= 1 Year** | | |
| | 57 (100.0%) | 46 (95.8%) |
| **Not Reported** | | |
| | [No Data] | 2 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **< 1 Year** | | |
| | 14 (100.0%) | 18 (100.0%) |
| **>= 1 Year** | | |
| | 57 (100.0%) | 46 (95.8%) |
| **Not Reported** | | |
| | [No Data] | 2 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:49

TABLE 7.2.8: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 1 Year** | | | |
| N subjects in population | N=14 | N=18 | |
| Baseline | n= 14 (100.0%) \| 0.80 (0.21) | n= 18 (100.0%) \| 0.80 (0.28) | 0.00 [-0.71 ; 0.71] |
| Week 3 | n= 12 (85.7%) \| 0.84 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 12 (85.7%) \| 0.81 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 14 (100.0%) \| 0.73 (0.27) | n= 17 (94.4%) \| 0.78 (0.28) | -0.18 [-0.90 ; 0.54] |
| Week 9 | n= 12 (85.7%) \| 0.79 (0.32) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 13 (92.9%) \| 0.83 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 14 (100.0%) \| 0.81 (0.17) | n= 12 (66.7%) \| 0.81 (0.13) | 0.01 [-0.77 ; 0.80] |
| Week 15 | n= 14 (100.0%) \| 0.78 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (100.0%) \| 0.76 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 14 (100.0%) \| 0.76 (0.15) | n= 13 (72.2%) \| 0.83 (0.13) | -0.44 [-1.22 ; 0.34] |
| Week 21 | n= 14 (100.0%) \| 0.82 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 11 (78.6%) \| 0.85 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 13 (92.9%) \| 0.83 (0.17) | n= 14 (77.8%) \| 0.85 (0.13) | -0.14 [-0.91 ; 0.63] |
| Week 27 | n= 13 (92.9%) \| 0.82 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 13 (92.9%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 14 (100.0%) \| 0.82 (0.17) | n= 11 (61.1%) \| 0.80 (0.20) | 0.11 [-0.70 ; 0.92] |
| Week 33 | n= 14 (100.0%) \| 0.77 (0.35) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (92.9%) \| 0.79 (0.39) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 12 (85.7%) \| 0.84 (0.18) | n= 11 (61.1%) \| 0.86 (0.14) | -0.11 [-0.94 ; 0.73] |
| Week 39 | n= 11 (78.6%) \| 0.86 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 11 (78.6%) \| 0.87 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 12 (85.7%) \| 0.82 (0.17) | n= 12 (66.7%) \| 0.82 (0.18) | 0.03 [-0.79 ; 0.85] |
| Week 45 | n= 11 (78.6%) \| 0.80 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 11 (78.6%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 12 (85.7%) \| 0.87 (0.17) | n= 11 (61.1%) \| 0.82 (0.13) | 0.32 [-0.52 ; 1.17] |
| Week 51 | n= 11 (78.6%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 11 (78.6%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 8 (57.1%) \| 0.79 (0.15) | n= 10 (55.6%) \| 0.81 (0.16) | -0.11 [-1.07 ; 0.84] |
| Week 57 | n= 9 (64.3%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 10 (71.4%) \| 0.81 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 11 (78.6%) \| 0.82 (0.16) | n= 8 (44.4%) \| 0.82 (0.12) | 0.02 [-0.91 ; 0.96] |
| Week 63 | n= 10 (71.4%) \| 0.88 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (71.4%) \| 0.88 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 10 (71.4%) \| 0.86 (0.16) | n= 9 (50.0%) \| 0.83 (0.14) | 0.17 [-0.76 ; 1.09] |
| Week 69 | n= 9 (64.3%) \| 0.82 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 9 (64.3%) \| 0.76 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 9 (64.3%) \| 0.81 (0.16) | n= 7 (38.9%) \| 0.82 (0.15) | -0.05 [-1.08 ; 0.97] |
| Week 75 | n= 8 (57.1%) \| 0.82 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (42.9%) \| 0.90 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (64.3%) \| 0.85 (0.18) | n= 6 (33.3%) \| 0.82 (0.14) | 0.15 [-0.92 ; 1.23] |
| Week 81 | n= 7 (50.0%) \| 0.86 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (50.0%) \| 0.87 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (57.1%) \| 0.87 (0.15) | n= 6 (33.3%) \| 0.79 (0.13) | 0.53 [-0.60 ; 1.65] |
| Week 87 | n= 6 (42.9%) \| 0.79 (0.19) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 7 (50.0%) \| 0.77 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 7 (50.0%) \| 0.86 (0.17) | n= 3 (16.7%) \| 0.79 (0.21) | 0.33 [-1.11 ; 1.78] |
| Week 93 | n= 5 (35.7%) \| 0.81 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 6 (42.9%) \| 0.85 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 5 (35.7%) \| 0.90 (0.15) | n= 2 (11.1%) \| 1.00 (0.00) | -0.66 [-2.53 ; 1.20] |
| Week 99 | n= 3 (21.4%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (21.4%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (28.6%) \| 0.85 (0.17) | n= 2 (11.1%) \| 0.91 (0.13) | -0.27 [-2.20 ; 1.67] |
| Week 105 | n= 3 (21.4%) \| 0.80 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (14.3%) \| 0.84 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (21.4%) \| 0.83 (0.16) | n= 2 (11.1%) \| 1.00 (0.00) | -0.97 [-3.29 ; 1.36] |
| Week 111 | n= 1 ( 7.1%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (14.3%) \| 0.74 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 2 (14.3%) \| 0.84 (0.22) | n= 1 ( 5.6%) \| 1.00 ( / ) | [Not calculable] |
| Week 117 | n= 1 ( 7.1%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 7.1%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (21.4%) \| 0.82 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 7.1%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (14.3%) \| 0.90 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 7.1%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 7.1%) \| 0.82 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 7.1%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 7.1%) \| 0.88 ( / ) | n= 4 (22.2%) \| 0.83 (0.13) | [Not calculable] |
| Week 202 | n= 1 ( 7.1%) \| 0.69 ( / ) | n= 3 (16.7%) \| 0.72 (0.32) | [Not calculable] |
| Week 301 | [No Data] | n= 2 (11.1%) \| 0.80 (0.00) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 1 ( 5.6%) \| 0.73 ( / ) | [No Data for at least 1 arm] |
| Week 303 | [No Data] | n= 2 (11.1%) \| 0.86 (0.19) | [No Data for at least 1 arm] |
| Week 304 | [No Data] | n= 1 ( 5.6%) \| 0.69 ( / ) | [No Data for at least 1 arm] |
| **>= 1 Year** | | | |
| N subjects in population | N=57 | N=48 | |
| Baseline | n= 57 (100.0%) \| 0.84 (0.20) | n= 48 (100.0%) \| 0.79 (0.30) | 0.24 [-0.15 ; 0.62] |
| Week 3 | n= 54 (94.7%) \| 0.83 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 52 (91.2%) \| 0.79 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 50 (87.7%) \| 0.81 (0.19) | n= 44 (91.7%) \| 0.79 (0.23) | 0.11 [-0.30 ; 0.52] |
| Week 9 | n= 47 (82.5%) \| 0.81 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 48 (84.2%) \| 0.77 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 45 (78.9%) \| 0.81 (0.23) | n= 38 (79.2%) \| 0.74 (0.25) | 0.30 [-0.14 ; 0.73] |
| Week 15 | n= 40 (70.2%) \| 0.78 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 47 (82.5%) \| 0.80 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 43 (75.4%) \| 0.83 (0.21) | n= 36 (75.0%) \| 0.82 (0.21) | 0.07 [-0.38 ; 0.51] |
| Week 21 | n= 46 (80.7%) \| 0.81 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 44 (77.2%) \| 0.81 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 45 (78.9%) \| 0.83 (0.22) | n= 34 (70.8%) \| 0.80 (0.18) | 0.12 [-0.33 ; 0.57] |
| Week 27 | n= 42 (73.7%) \| 0.85 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 40 (70.2%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 40 (70.2%) \| 0.82 (0.22) | n= 31 (64.6%) \| 0.79 (0.22) | 0.14 [-0.34 ; 0.61] |
| Week 33 | n= 43 (75.4%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 40 (70.2%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 37 (64.9%) \| 0.85 (0.20) | n= 31 (64.6%) \| 0.80 (0.18) | 0.24 [-0.24 ; 0.72] |
| Week 39 | n= 42 (73.7%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 40 (70.2%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 43 | n= 41 (71.9%) \| 0.83 (0.18) | n= 27 (56.3%) \| 0.80 (0.18) | 0.17 [-0.32 ; 0.66] |
| Week 45 | n= 38 (66.7%) \| 0.88 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 41 (71.9%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 41 (71.9%) \| 0.86 (0.17) | n= 24 (50.0%) \| 0.75 (0.30) | 0.48 [-0.03 ; 1.00] |
| Week 51 | n= 40 (70.2%) \| 0.83 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 37 (64.9%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (68.4%) \| 0.85 (0.17) | n= 27 (56.3%) \| 0.85 (0.19) | 0.02 [-0.47 ; 0.52] |
| Week 57 | n= 38 (66.7%) \| 0.84 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 34 (59.6%) \| 0.82 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 37 (64.9%) \| 0.85 (0.19) | n= 21 (43.8%) \| 0.76 (0.32) | 0.35 [-0.20 ; 0.89] |
| Week 63 | n= 32 (56.1%) \| 0.81 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 34 (59.6%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 34 (59.6%) \| 0.84 (0.20) | n= 20 (41.7%) \| 0.80 (0.20) | 0.19 [-0.36 ; 0.75] |
| Week 69 | n= 27 (47.4%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 30 (52.6%) \| 0.85 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (43.9%) \| 0.82 (0.19) | n= 19 (39.6%) \| 0.74 (0.22) | 0.42 [-0.19 ; 1.03] |
| Week 75 | n= 28 (49.1%) \| 0.86 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (45.6%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 22 (38.6%) \| 0.87 (0.17) | n= 17 (35.4%) \| 0.80 (0.23) | 0.37 [-0.28 ; 1.02] |
| Week 81 | n= 24 (42.1%) \| 0.84 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 26 (45.6%) \| 0.84 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (33.3%) \| 0.88 (0.18) | n= 13 (27.1%) \| 0.77 (0.23) | 0.50 [-0.23 ; 1.22] |
| Week 87 | n= 18 (31.6%) \| 0.79 (0.30) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 18 (31.6%) \| 0.84 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 17 (29.8%) \| 0.77 (0.25) | n= 13 (27.1%) \| 0.84 (0.14) | -0.33 [-1.07 ; 0.41] |
| Week 93 | n= 15 (26.3%) \| 0.81 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 16 (28.1%) \| 0.77 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 16 (28.1%) \| 0.75 (0.25) | n= 8 (16.7%) \| 0.78 (0.18) | -0.12 [-0.98 ; 0.75] |
| Week 99 | n= 14 (24.6%) \| 0.74 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (19.3%) \| 0.80 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (19.3%) \| 0.79 (0.13) | n= 7 (14.6%) \| 0.82 (0.19) | -0.18 [-1.16 ; 0.80] |
| Week 105 | n= 11 (19.3%) \| 0.72 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.5%) \| 0.79 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.0%) \| 0.61 (0.25) | n= 2 ( 4.2%) \| 0.90 (0.14) | -1.07 [-2.80 ; 0.67] |
| Week 111 | n= 6 (10.5%) \| 0.57 (0.58) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (10.5%) \| 0.82 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 7.0%) \| 0.78 (0.25) | n= 4 ( 8.3%) \| 0.79 (0.15) | -0.01 [-1.51 ; 1.50] |
| Week 117 | n= 5 ( 8.8%) \| 0.73 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 8.8%) \| 0.71 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 ( 8.8%) \| 0.76 (0.19) | n= 1 ( 2.1%) \| 0.62 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.8%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | [No Data] | n= 1 ( 2.1%) \| 0.62 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 7 (12.3%) \| 0.86 (0.14) | n= 13 (27.1%) \| 0.70 (0.27) | 0.62 [-0.34 ; 1.59] |
| Week 202 | n= 1 ( 1.8%) \| 0.19 ( / ) | n= 8 (16.7%) \| 0.84 (0.14) | [Not calculable] |
| Week 301 | n= 2 ( 3.5%) \| 0.76 (0.34) | n= 7 (14.6%) \| 0.82 (0.19) | -0.27 [-1.96 ; 1.42] |
| Week 302 | n= 2 ( 3.5%) \| 0.69 (0.05) | n= 5 (10.4%) \| 0.72 (0.07) | -0.38 [-2.21 ; 1.45] |
| Week 303 | n= 3 ( 5.3%) \| 0.76 (0.21) | n= 4 ( 8.3%) \| 0.58 (0.30) | 0.57 [-1.13 ; 2.27] |
| Week 304 | n= 1 ( 1.8%) \| 1.00 ( / ) | n= 2 ( 4.2%) \| 0.53 (0.38) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 2.1%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 2.1%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 2.1%) \| 1.00 ( / ) | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 308 | [No Data] | n= 1 ( 2.1%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 2.1%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| **Not Reported** | | | |
| N subjects in population | [No Data] | N=2 | |
| Nr subjects used | [No Data] | n= 2 (100.0%) \| 0.83 (0.24) | |
| Week 7 | [No Data] | n= 1 (50.0%) \| 0.78 ( / ) | [No Data for at least 1 arm] |
| Week 13 | [No Data] | n= 2 (100.0%) \| 0.79 (0.29) | [No Data for at least 1 arm] |
| Week 19 | [No Data] | n= 2 (100.0%) \| 0.90 (0.14) | [No Data for at least 1 arm] |
| Week 25 | [No Data] | n= 2 (100.0%) \| 0.72 (0.19) | [No Data for at least 1 arm] |
| Week 31 | [No Data] | n= 1 (50.0%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 37 | [No Data] | n= 2 (100.0%) \| 0.74 (0.07) | [No Data for at least 1 arm] |
| Week 43 | [No Data] | n= 2 (100.0%) \| 0.86 (0.19) | [No Data for at least 1 arm] |
| Week 49 | [No Data] | n= 2 (100.0%) \| 0.79 (0.29) | [No Data for at least 1 arm] |
| Week 55 | [No Data] | n= 1 (50.0%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 61 | [No Data] | n= 1 (50.0%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 67 | [No Data] | n= 1 (50.0%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 73 | [No Data] | n= 1 (50.0%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 79 | [No Data] | n= 1 (50.0%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 85 | [No Data] | n= 1 (50.0%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 91 | [No Data] | n= 1 (50.0%) \| 0.88 ( / ) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 1 (50.0%) \| 1.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:50

TABLE 7.2.8: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 1 Year** | | | |
| N subjects in population | N=14 | N=18 | |
| Week 3 | n= 12 (85.7%) \| 0.05 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 12 (85.7%) \| 0.01 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 14 (100.0%) \|-0.05 (0.38) | n= 17 (94.4%) \|-0.02 (0.19) | -0.13 [-0.85 ; 0.59] |
| Week 9 | n= 12 (85.7%) \|-0.02 (0.33) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 13 (92.9%) \| 0.03 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 14 (100.0%) \| 0.02 (0.25) | n= 12 (66.7%) \|-0.08 (0.12) | 0.48 [-0.32 ; 1.27] |
| Week 15 | n= 14 (100.0%) \|-0.01 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (100.0%) \|-0.02 (0.30) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 14 (100.0%) \|-0.02 (0.23) | n= 13 (72.2%) \|-0.04 (0.13) | 0.10 [-0.67 ; 0.86] |
| Week 21 | n= 14 (100.0%) \| 0.03 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 11 (78.6%) \| 0.03 (0.10) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 13 (92.9%) \| 0.03 (0.25) | n= 14 (77.8%) \|-0.03 (0.14) | 0.31 [-0.46 ; 1.09] |
| Week 27 | n= 13 (92.9%) \| 0.02 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 13 (92.9%) \| 0.06 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 14 (100.0%) \| 0.04 (0.23) | n= 11 (61.1%) \|-0.06 (0.18) | 0.43 [-0.39 ; 1.24] |
| Week 33 | n= 14 (100.0%) \|-0.01 (0.35) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (92.9%) \| 0.02 (0.39) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 12 (85.7%) \| 0.05 (0.26) | n= 11 (61.1%) \|-0.03 (0.09) | 0.38 [-0.46 ; 1.23] |
| Week 39 | n= 11 (78.6%) \| 0.04 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 11 (78.6%) \| 0.04 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 12 (85.7%) \| 0.01 (0.26) | n= 12 (66.7%) \|-0.06 (0.21) | 0.26 [-0.56 ; 1.08] |
| Week 45 | n= 11 (78.6%) \|-0.01 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 11 (78.6%) \| 0.02 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 12 (85.7%) \| 0.09 (0.22) | n= 11 (61.1%) \|-0.06 (0.09) | 0.83 [-0.04 ; 1.71] |
| Week 51 | n= 11 (78.6%) \| 0.04 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 11 (78.6%) \| 0.06 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 8 (57.1%) \| 0.05 (0.32) | n= 10 (55.6%) \|-0.06 (0.16) | 0.44 [-0.53 ; 1.41] |
| Week 57 | n= 9 (64.3%) \| 0.01 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 10 (71.4%) \| 0.01 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 11 (78.6%) \| 0.04 (0.27) | n= 8 (44.4%) \|-0.07 (0.12) | 0.49 [-0.46 ; 1.44] |
| Week 63 | n= 10 (71.4%) \| 0.10 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (71.4%) \| 0.10 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 10 (71.4%) \| 0.08 (0.32) | n= 9 (50.0%) \|-0.03 (0.09) | 0.43 [-0.50 ; 1.37] |
| Week 69 | n= 9 (64.3%) \| 0.05 (0.31) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 9 (64.3%) \|-0.00 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 9 (64.3%) \| 0.05 (0.31) | n= 7 (38.9%) \|-0.06 (0.10) | 0.40 [-0.63 ; 1.44] |
| Week 75 | n= 8 (57.1%) \| 0.07 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (42.9%) \| 0.12 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (64.3%) \| 0.09 (0.28) | n= 6 (33.3%) \|-0.06 (0.08) | 0.65 [-0.45 ; 1.75] |
| Week 81 | n= 7 (50.0%) \| 0.06 (0.32) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (50.0%) \| 0.09 (0.31) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (57.1%) \| 0.09 (0.20) | n= 6 (33.3%) \|-0.14 (0.16) | 1.16 [-0.04 ; 2.36] |
| Week 87 | n= 6 (42.9%) \|-0.07 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 7 (50.0%) \|-0.00 (0.22) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 7 (50.0%) \| 0.01 (0.15) | n= 3 (16.7%) \|-0.21 (0.21) | 1.14 [-0.42 ; 2.69] |
| Week 93 | n= 5 (35.7%) \|-0.05 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 6 (42.9%) \|-0.01 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 5 (35.7%) \| 0.04 (0.09) | n= 2 (11.1%) \| 0.00 (0.00) | 0.37 [-1.46 ; 2.20] |
| Week 99 | n= 3 (21.4%) \| 0.01 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (21.4%) \| 0.01 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (28.6%) \| 0.03 (0.13) | n= 2 (11.1%) \|-0.09 (0.13) | 0.74 [-1.27 ; 2.75] |
| Week 105 | n= 3 (21.4%) \|-0.01 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (14.3%) \| 0.04 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (21.4%) \| 0.02 (0.11) | n= 2 (11.1%) \| 0.00 (0.00) | 0.17 [-1.95 ; 2.29] |
| Week 111 | n= 1 ( 7.1%) \|-0.04 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (14.3%) \|-0.04 (0.01) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 2 (14.3%) \| 0.06 (0.13) | n= 1 ( 5.6%) \| 0.00 ( / ) | [Not calculable] |
| Week 117 | n= 1 ( 7.1%) \|-0.04 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 7.1%) \|-0.04 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (21.4%) \| 0.01 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 7.1%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (14.3%) \| 0.05 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 7.1%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 7.1%) \|-0.03 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 7.1%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 7.1%) \|-0.12 ( / ) | n= 4 (22.2%) \|-0.03 (0.13) | [Not calculable] |
| Week 202 | n= 1 ( 7.1%) \|-0.31 ( / ) | n= 3 (16.7%) \|-0.11 (0.19) | [Not calculable] |
| Week 301 | [No Data] | n= 2 (11.1%) \|-0.03 (0.04) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 1 ( 5.6%) \|-0.12 ( / ) | [No Data for at least 1 arm] |
| Week 303 | [No Data] | n= 2 (11.1%) \| 0.04 (0.16) | [No Data for at least 1 arm] |
| Week 304 | [No Data] | n= 1 ( 5.6%) \|-0.16 ( / ) | [No Data for at least 1 arm] |
| **>= 1 Year** | | | |
| N subjects in population | N=57 | N=48 | |
| Week 3 | n= 54 (94.7%) \|-0.02 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 52 (91.2%) \|-0.06 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 50 (87.7%) \|-0.05 (0.13) | n= 44 (91.7%) \| 0.01 (0.21) | -0.36 [-0.77 ; 0.05] |
| Week 9 | n= 47 (82.5%) \|-0.04 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 48 (84.2%) \|-0.07 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 45 (78.9%) \|-0.04 (0.16) | n= 38 (79.2%) \|-0.07 (0.29) | 0.14 [-0.29 ; 0.58] |
| Week 15 | n= 40 (70.2%) \|-0.09 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 47 (82.5%) \|-0.05 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 43 (75.4%) \|-0.02 (0.16) | n= 36 (75.0%) \|-0.01 (0.22) | -0.06 [-0.51 ; 0.38] |
| Week 21 | n= 46 (80.7%) \|-0.05 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 44 (77.2%) \|-0.04 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 45 (78.9%) \|-0.04 (0.15) | n= 34 (70.8%) \|-0.07 (0.15) | 0.19 [-0.25 ; 0.64] |
| Week 27 | n= 42 (73.7%) \|-0.02 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 40 (70.2%) \|-0.04 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 40 (70.2%) \|-0.05 (0.16) | n= 31 (64.6%) \|-0.09 (0.19) | 0.21 [-0.26 ; 0.68] |
| Week 33 | n= 43 (75.4%) \|-0.02 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 40 (70.2%) \|-0.03 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 37 (64.9%) \|-0.02 (0.13) | n= 31 (64.6%) \|-0.08 (0.17) | 0.41 [-0.08 ; 0.89] |
| Week 39 | n= 42 (73.7%) \|-0.03 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 40 (70.2%) \|-0.02 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 41 (71.9%) \|-0.02 (0.17) | n= 27 (56.3%) \|-0.07 (0.19) | 0.30 [-0.19 ; 0.80] |
| Week 45 | n= 38 (66.7%) \| 0.01 (0.17) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 47 | n= 41 (71.9%) \|-0.01 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 41 (71.9%) \|-0.00 (0.15) | n= 24 (50.0%) \|-0.10 (0.27) | 0.46 [-0.05 ; 0.98] |
| Week 51 | n= 40 (70.2%) \|-0.04 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 37 (64.9%) \|-0.02 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (68.4%) \|-0.01 (0.18) | n= 27 (56.3%) \|-0.02 (0.19) | 0.03 [-0.46 ; 0.53] |
| Week 57 | n= 38 (66.7%) \|-0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 34 (59.6%) \|-0.04 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 37 (64.9%) \|-0.03 (0.20) | n= 21 (43.8%) \|-0.11 (0.28) | 0.37 [-0.17 ; 0.91] |
| Week 63 | n= 32 (56.1%) \|-0.04 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 34 (59.6%) \|-0.01 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 34 (59.6%) \|-0.04 (0.17) | n= 20 (41.7%) \|-0.08 (0.20) | 0.20 [-0.36 ; 0.76] |
| Week 69 | n= 27 (47.4%) \|-0.03 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 30 (52.6%) \| 0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (43.9%) \|-0.01 (0.19) | n= 19 (39.6%) \|-0.11 (0.23) | 0.49 [-0.12 ; 1.10] |
| Week 75 | n= 28 (49.1%) \| 0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (45.6%) \| 0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 22 (38.6%) \| 0.04 (0.18) | n= 17 (35.4%) \|-0.06 (0.23) | 0.49 [-0.16 ; 1.14] |
| Week 81 | n= 24 (42.1%) \| 0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 26 (45.6%) \| 0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (33.3%) \|-0.01 (0.15) | n= 13 (27.1%) \|-0.09 (0.25) | 0.43 [-0.29 ; 1.16] |
| Week 87 | n= 18 (31.6%) \|-0.05 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 18 (31.6%) \| 0.00 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 17 (29.8%) \|-0.06 (0.21) | n= 13 (27.1%) \|-0.05 (0.23) | -0.05 [-0.78 ; 0.69] |
| Week 93 | n= 15 (26.3%) \|-0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 16 (28.1%) \|-0.06 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 16 (28.1%) \|-0.08 (0.20) | n= 8 (16.7%) \|-0.12 (0.23) | 0.16 [-0.71 ; 1.03] |
| Week 99 | n= 14 (24.6%) \|-0.08 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (19.3%) \|-0.11 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (19.3%) \|-0.10 (0.14) | n= 7 (14.6%) \|-0.10 (0.21) | -0.00 [-0.98 ; 0.97] |
| Week 105 | n= 11 (19.3%) \|-0.15 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.5%) \|-0.14 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.0%) \|-0.22 (0.31) | n= 2 ( 4.2%) \| 0.00 (0.00) | -0.69 [-2.37 ; 1.00] |
| Week 111 | n= 6 (10.5%) \|-0.34 (0.47) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (10.5%) \|-0.08 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 7.0%) \|-0.07 (0.32) | n= 4 ( 8.3%) \|-0.16 (0.19) | 0.29 [-1.22 ; 1.81] |
| Week 117 | n= 5 ( 8.8%) \|-0.22 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 8.8%) \|-0.18 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 ( 8.8%) \|-0.18 (0.14) | n= 1 ( 2.1%) \|-0.38 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.8%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | [No Data] | n= 1 ( 2.1%) \|-0.38 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 7 (12.3%) \| 0.05 (0.24) | n= 13 (27.1%) \|-0.15 (0.27) | 0.71 [-0.26 ; 1.68] |
| Week 202 | n= 1 ( 1.8%) \|-0.50 ( / ) | n= 8 (16.7%) \|-0.07 (0.21) | [Not calculable] |
| Week 301 | n= 2 ( 3.5%) \|-0.01 (0.23) | n= 7 (14.6%) \| 0.11 (0.17) | -0.59 [-2.31 ; 1.13] |
| Week 302 | n= 2 ( 3.5%) \|-0.04 (0.11) | n= 5 (10.4%) \|-0.13 (0.18) | 0.45 [-1.39 ; 2.29] |
| Week 303 | n= 3 ( 5.3%) \|-0.01 (0.19) | n= 4 ( 8.3%) \|-0.29 (0.28) | 0.95 [-0.83 ; 2.72] |
| Week 304 | n= 1 ( 1.8%) \| 0.15 ( / ) | n= 2 ( 4.2%) \|-0.22 (0.31) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 2.1%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 2.1%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 2.1%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 2.1%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 2.1%) \| 0.59 ( / ) | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Not Reported** | | | |
| N subjects in population | [No Data] | N=2 | |
| Week 7 | [No Data] | n= 1 (50.0%) \| 0.12 ( / ) | [No Data for at least 1 arm] |
| Week 13 | [No Data] | n= 2 (100.0%) \|-0.03 (0.05) | [No Data for at least 1 arm] |
| Week 19 | [No Data] | n= 2 (100.0%) \| 0.07 (0.10) | [No Data for at least 1 arm] |
| Week 25 | [No Data] | n= 2 (100.0%) \|-0.11 (0.06) | [No Data for at least 1 arm] |
| Week 31 | [No Data] | n= 1 (50.0%) \| 0.00 ( / ) | [No Data for at least 1 arm] |
| Week 37 | [No Data] | n= 2 (100.0%) \|-0.08 (0.17) | [No Data for at least 1 arm] |
| Week 43 | [No Data] | n= 2 (100.0%) \| 0.04 (0.05) | [No Data for at least 1 arm] |
| Week 49 | [No Data] | n= 2 (100.0%) \|-0.03 (0.05) | [No Data for at least 1 arm] |
| Week 55 | [No Data] | n= 1 (50.0%) \|-0.07 ( / ) | [No Data for at least 1 arm] |
| Week 61 | [No Data] | n= 1 (50.0%) \|-0.07 ( / ) | [No Data for at least 1 arm] |
| Week 67 | [No Data] | n= 1 (50.0%) \|-0.07 ( / ) | [No Data for at least 1 arm] |
| Week 73 | [No Data] | n= 1 (50.0%) \|-0.07 ( / ) | [No Data for at least 1 arm] |
| Week 79 | [No Data] | n= 1 (50.0%) \|-0.07 ( / ) | [No Data for at least 1 arm] |
| Week 85 | [No Data] | n= 1 (50.0%) \|-0.07 ( / ) | [No Data for at least 1 arm] |
| Week 91 | [No Data] | n= 1 (50.0%) \| 0.23 ( / ) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 1 (50.0%) \| 0.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:50

TABLE 7.2.8: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **< 1 Year** | | | | |
| Nr subjects used | n=14 | n=18 | | |
| Week 7 | -0.08 (0.07) [-0.22 ; 0.06] | -0.04 (0.06) [-0.16 ; 0.09] | -0.04 (0.09) [-0.23 ; 0.15] | -0.16 [-0.87 ; 0.55] |
| Week 13 | -0.00 (0.04) [-0.08 ; 0.08] | -0.06 (0.04) [-0.13 ; 0.02] | 0.05 (0.05) [-0.06 ; 0.16] | 0.37 [-0.41 ; 1.15] |
| Week 19 | -0.05 (0.04) [-0.12 ; 0.03] | -0.02 (0.03) [-0.10 ; 0.05] | -0.02 (0.05) [-0.12 ; 0.08] | -0.16 [-0.92 ; 0.60] |
| Week 25 | 0.00 (0.04) [-0.08 ; 0.08] | 0.00 (0.04) [-0.08 ; 0.08] | -0.00 (0.06) [-0.12 ; 0.11] | -0.01 [-0.77 ; 0.74] |
| Week 31 | 0.01 (0.05) [-0.08 ; 0.11] | -0.04 (0.05) [-0.14 ; 0.06] | 0.05 (0.07) [-0.08 ; 0.19] | 0.30 [-0.49 ; 1.10] |
| Week 37 | 0.04 (0.04) [-0.05 ; 0.13] | 0.01 (0.05) [-0.09 ; 0.10] | 0.03 (0.06) [-0.10 ; 0.16] | 0.19 [-0.63 ; 1.01] |
| Week 43 | 0.02 (0.06) [-0.10 ; 0.13] | -0.03 (0.06) [-0.14 ; 0.09] | 0.04 (0.08) [-0.12 ; 0.20] | 0.21 [-0.59 ; 1.01] |
| Week 49 | 0.05 (0.04) [-0.03 ; 0.14] | -0.02 (0.04) [-0.11 ; 0.07] | 0.07 (0.06) [-0.05 ; 0.19] | 0.48 [-0.35 ; 1.31] |
| Overall post-baseline period estimate | -0.00 (0.03) [-0.06 ; 0.06] | -0.02 (0.03) [-0.08 ; 0.03] | 0.02 (0.04) [-0.06 ; 0.10] | 0.20 [-0.50 ; 0.90] |
| **>= 1 Year** | | | | |
| Nr subjects used | n=57 | n=48 | | |
| Week 7 | -0.05 (0.02) [-0.10 ;-0.01] | -0.02 (0.02) [-0.07 ; 0.03] | -0.03 (0.03) [-0.10 ; 0.03] | -0.22 [-0.63 ; 0.19] |
| Week 13 | -0.06 (0.03) [-0.12 ; 0.01] | -0.10 (0.04) [-0.17 ;-0.02] | 0.04 (0.05) [-0.06 ; 0.14] | 0.17 [-0.27 ; 0.60] |
| Week 19 | -0.03 (0.03) [-0.08 ; 0.02] | -0.03 (0.03) [-0.09 ; 0.03] | 0.00 (0.04) [-0.08 ; 0.08] | 0.00 [-0.44 ; 0.45] |
| Week 25 | -0.03 (0.02) [-0.08 ; 0.02] | -0.06 (0.03) [-0.11 ;-0.01] | 0.03 (0.04) [-0.04 ; 0.10] | 0.18 [-0.26 ; 0.63] |
| Week 31 | -0.05 (0.03) [-0.11 ; 0.00] | -0.07 (0.03) [-0.13 ;-0.01] | 0.02 (0.04) [-0.07 ; 0.10] | 0.10 [-0.37 ; 0.57] |
| Week 37 | -0.01 (0.02) [-0.06 ; 0.03] | -0.07 (0.03) [-0.12 ;-0.02] | 0.06 (0.04) [-0.01 ; 0.13] | 0.39 [-0.10 ; 0.87] |
| Week 43 | -0.02 (0.02) [-0.07 ; 0.03] | -0.06 (0.03) [-0.12 ;-0.00] | 0.04 (0.04) [-0.04 ; 0.12] | 0.24 [-0.25 ; 0.72] |
| Week 49 | -0.01 (0.03) [-0.07 ; 0.05] | -0.10 (0.04) [-0.17 ;-0.02] | 0.09 (0.05) [-0.01 ; 0.19] | 0.46 [-0.05 ; 0.97] |
| Week 55 | -0.01 (0.03) [-0.06 ; 0.04] | -0.01 (0.03) [-0.07 ; 0.05] | -0.00 (0.04) [-0.08 ; 0.08] | -0.00 [-0.49 ; 0.49] |
| Week 61 | -0.04 (0.03) [-0.11 ; 0.03] | -0.08 (0.04) [-0.17 ; 0.01] | 0.04 (0.06) [-0.07 ; 0.15] | 0.20 [-0.34 ; 0.73] |
| Week 67 | -0.03 (0.03) [-0.09 ; 0.02] | -0.07 (0.04) [-0.14 ; 0.00] | 0.04 (0.05) [-0.05 ; 0.13] | 0.23 [-0.32 ; 0.79] |
| Week 73 | -0.01 (0.03) [-0.07 ; 0.04] | -0.11 (0.03) [-0.17 ;-0.04] | 0.09 (0.04) [ 0.00 ; 0.18] | 0.63 [ 0.02 ; 1.25] |
| Week 79 | 0.01 (0.03) [-0.05 ; 0.07] | -0.04 (0.03) [-0.11 ; 0.02] | 0.05 (0.04) [-0.04 ; 0.14] | 0.37 [-0.27 ; 1.01] |
| Week 85 | -0.00 (0.03) [-0.06 ; 0.06] | -0.08 (0.04) [-0.16 ;-0.01] | 0.08 (0.05) [-0.02 ; 0.18] | 0.59 [-0.13 ; 1.32] |
| Week 91 | -0.04 (0.04) [-0.12 ; 0.04] | -0.07 (0.05) [-0.17 ; 0.03] | 0.03 (0.06) [-0.10 ; 0.16] | 0.18 [-0.55 ; 0.90] |
| Overall post-baseline period estimate | -0.03 (0.01) [-0.05 ; 0.00] | -0.06 (0.02) [-0.10 ;-0.03] | 0.04 (0.02) [-0.00 ; 0.08] | 0.36 [-0.03 ; 0.75] |
| **Not Reported** | | | | |
| Nr subjects used | [No Data] | n=2 | | |
| **MMRM subgroups interaction p-value** | | | 0.8535 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:50

TABLE 7.2.9: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **No** | N=11 | N=12 |
| **Yes** | N=60 | N=56 |
| **Subjects with Baseline Value** | | |
| **No** | 11 (100.0%) | 12 (100.0%) |
| **Yes** | 60 (100.0%) | 56 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **No** | 11 (100.0%) | 12 (100.0%) |
| **Yes** | 60 (100.0%) | 54 (96.4%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **No** | 11 (100.0%) | 12 (100.0%) |
| **Yes** | 60 (100.0%) | 54 (96.4%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:55

TABLE 7.2.9: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=11 | N=12 | |
| Baseline | n= 11 (100.0%) \| 0.85 (0.15) | n= 12 (100.0%) \| 0.71 (0.44) | 0.40 [-0.45 ; 1.24] |
| Week 3 | n= 10 (90.9%) \| 0.79 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 9 (81.8%) \| 0.86 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 10 (90.9%) \| 0.85 (0.15) | n= 11 (91.7%) \| 0.71 (0.29) | 0.58 [-0.32 ; 1.48] |
| Week 9 | n= 8 (72.7%) \| 0.87 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 10 (90.9%) \| 0.79 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 11 (100.0%) \| 0.80 (0.24) | n= 9 (75.0%) \| 0.74 (0.09) | 0.27 [-0.64 ; 1.18] |
| Week 15 | n= 9 (81.8%) \| 0.80 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (81.8%) \| 0.77 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 8 (72.7%) \| 0.81 (0.17) | n= 10 (83.3%) \| 0.75 (0.13) | 0.36 [-0.60 ; 1.33] |
| Week 21 | n= 11 (100.0%) \| 0.78 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \| 0.82 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 10 (90.9%) \| 0.83 (0.27) | n= 8 (66.7%) \| 0.83 (0.12) | -0.02 [-0.97 ; 0.94] |
| Week 27 | n= 10 (90.9%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 9 (81.8%) \| 0.85 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 10 (90.9%) \| 0.86 (0.16) | n= 6 (50.0%) \| 0.82 (0.11) | 0.26 [-0.79 ; 1.31] |
| Week 33 | n= 10 (90.9%) \| 0.88 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (72.7%) \| 0.86 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \| 0.90 (0.16) | n= 5 (41.7%) \| 0.88 (0.12) | 0.09 [-1.08 ; 1.26] |
| Week 39 | n= 8 (72.7%) \| 0.90 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 9 (81.8%) \| 0.90 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 8 (72.7%) \| 0.85 (0.16) | n= 6 (50.0%) \| 0.74 (0.18) | 0.64 [-0.49 ; 1.77] |
| Week 45 | n= 9 (81.8%) \| 0.90 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 9 (81.8%) \| 0.89 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 10 (90.9%) \| 0.91 (0.15) | n= 6 (50.0%) \| 0.79 (0.11) | 0.79 [-0.30 ; 1.88] |
| Week 51 | n= 9 (81.8%) \| 0.88 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 9 (81.8%) \| 0.88 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 8 (72.7%) \| 0.85 (0.14) | n= 6 (50.0%) \| 0.75 (0.15) | 0.62 [-0.51 ; 1.76] |
| Week 57 | n= 8 (72.7%) \| 0.85 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (63.6%) \| 0.91 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (72.7%) \| 0.90 (0.14) | n= 4 (33.3%) \| 0.79 (0.14) | 0.76 [-0.54 ; 2.07] |
| Week 63 | n= 8 (72.7%) \| 0.87 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (72.7%) \| 0.92 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \| 0.86 (0.15) | n= 5 (41.7%) \| 0.80 (0.13) | 0.44 [-0.74 ; 1.62] |
| Week 69 | n= 8 (72.7%) \| 0.84 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (63.6%) \| 0.90 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (63.6%) \| 0.88 (0.13) | n= 4 (33.3%) \| 0.79 (0.16) | 0.55 [-0.78 ; 1.87] |
| Week 75 | n= 7 (63.6%) \| 0.91 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (45.5%) \| 0.94 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (54.5%) \| 0.88 (0.18) | n= 2 (16.7%) \| 0.76 (0.05) | 0.65 [-1.13 ; 2.43] |
| Week 81 | n= 5 (45.5%) \| 0.94 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (45.5%) \| 0.94 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (45.5%) \| 0.94 (0.14) | n= 3 (25.0%) \| 0.70 (0.09) | 1.64 [-0.21 ; 3.50] |
| Week 87 | n= 5 (45.5%) \| 0.94 (0.14) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 4 (36.4%) \| 0.92 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (36.4%) \| 0.92 (0.16) | n= 2 (16.7%) \| 0.69 (0.15) | 1.20 [-0.95 ; 3.35] |
| Week 93 | n= 4 (36.4%) \| 0.92 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (27.3%) \| 0.90 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (27.3%) \| 0.90 (0.18) | n= 1 ( 8.3%) \| 1.00 ( / ) | [Not calculable] |
| Week 99 | n= 2 (18.2%) \| 0.84 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 (18.2%) \| 0.84 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (18.2%) \| 0.84 (0.22) | n= 1 ( 8.3%) \| 0.82 ( / ) | [Not calculable] |
| Week 105 | n= 2 (18.2%) \| 0.84 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \| 0.84 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 ( 9.1%) \| 0.69 ( / ) | n= 1 ( 8.3%) \| 1.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 9.1%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 ( 9.1%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 9.1%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 ( 9.1%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 9.1%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 9.1%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | [No Data] | n= 6 (50.0%) \| 0.78 (0.16) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 4 (33.3%) \| 0.72 (0.27) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 2 (16.7%) \| 0.90 (0.14) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 2 (16.7%) \| 0.79 (0.04) | [No Data for at least 1 arm] |
| Week 303 | [No Data] | n= 1 ( 8.3%) \| 0.16 ( / ) | [No Data for at least 1 arm] |
| Week 304 | [No Data] | n= 1 ( 8.3%) \| 0.80 ( / ) | [No Data for at least 1 arm] |
| **Yes** | | | |
| N subjects in population | N=60 | N=56 | |
| Baseline | n= 60 (100.0%) \| 0.83 (0.21) | n= 56 (100.0%) \| 0.81 (0.25) | 0.11 [-0.25 ; 0.48] |
| Week 3 | n= 56 (93.3%) \| 0.84 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 55 (91.7%) \| 0.79 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 54 (90.0%) \| 0.78 (0.22) | n= 51 (91.1%) \| 0.80 (0.23) | -0.09 [-0.47 ; 0.30] |
| Week 9 | n= 51 (85.0%) \| 0.79 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 51 (85.0%) \| 0.78 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 48 (80.0%) \| 0.81 (0.21) | n= 43 (76.8%) \| 0.76 (0.25) | 0.23 [-0.18 ; 0.65] |
| Week 15 | n= 45 (75.0%) \| 0.78 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 52 (86.7%) \| 0.80 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 49 (81.7%) \| 0.81 (0.21) | n= 41 (73.2%) \| 0.84 (0.20) | -0.12 [-0.54 ; 0.30] |
| Week 21 | n= 49 (81.7%) \| 0.82 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 45 (75.0%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 48 (80.0%) \| 0.83 (0.20) | n= 42 (75.0%) \| 0.81 (0.17) | 0.10 [-0.31 ; 0.52] |
| Week 27 | n= 45 (75.0%) \| 0.84 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 44 (73.3%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 44 (73.3%) \| 0.81 (0.22) | n= 37 (66.1%) \| 0.80 (0.23) | 0.08 [-0.36 ; 0.52] |
| Week 33 | n= 47 (78.3%) \| 0.81 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 45 (75.0%) \| 0.82 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 41 (68.3%) \| 0.84 (0.20) | n= 39 (69.6%) \| 0.81 (0.17) | 0.17 [-0.27 ; 0.61] |
| Week 39 | n= 45 (75.0%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 42 (70.0%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 45 (75.0%) \| 0.83 (0.18) | n= 35 (62.5%) \| 0.82 (0.18) | 0.03 [-0.42 ; 0.47] |
| Week 45 | n= 40 (66.7%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 43 (71.7%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 43 (71.7%) \| 0.85 (0.17) | n= 31 (55.4%) \| 0.77 (0.27) | 0.37 [-0.10 ; 0.83] |
| Week 51 | n= 42 (70.0%) \| 0.82 (0.19) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 53 | n= 39 (65.0%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (65.0%) \| 0.84 (0.18) | n= 32 (57.1%) \| 0.84 (0.18) | -0.03 [-0.50 ; 0.45] |
| Week 57 | n= 39 (65.0%) \| 0.84 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (61.7%) \| 0.80 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 40 (66.7%) \| 0.83 (0.19) | n= 26 (46.4%) \| 0.77 (0.29) | 0.26 [-0.24 ; 0.76] |
| Week 63 | n= 34 (56.7%) \| 0.82 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (60.0%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (60.0%) \| 0.84 (0.20) | n= 25 (44.6%) \| 0.80 (0.19) | 0.17 [-0.34 ; 0.69] |
| Week 69 | n= 28 (46.7%) \| 0.82 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 32 (53.3%) \| 0.81 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 27 (45.0%) \| 0.81 (0.19) | n= 23 (41.1%) \| 0.75 (0.21) | 0.29 [-0.27 ; 0.86] |
| Week 75 | n= 29 (48.3%) \| 0.83 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (45.0%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 25 (41.7%) \| 0.86 (0.17) | n= 22 (39.3%) \| 0.80 (0.22) | 0.32 [-0.26 ; 0.90] |
| Week 81 | n= 26 (43.3%) \| 0.82 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (46.7%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 22 (36.7%) \| 0.86 (0.17) | n= 17 (30.4%) \| 0.78 (0.21) | 0.40 [-0.25 ; 1.05] |
| Week 87 | n= 19 (31.7%) \| 0.75 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 21 (35.0%) \| 0.80 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (33.3%) \| 0.77 (0.24) | n= 15 (26.8%) \| 0.85 (0.13) | -0.40 [-1.09 ; 0.28] |
| Week 93 | n= 16 (26.7%) \| 0.78 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.7%) \| 0.78 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (30.0%) \| 0.77 (0.24) | n= 9 (16.1%) \| 0.80 (0.18) | -0.15 [-0.97 ; 0.66] |
| Week 99 | n= 15 (25.0%) \| 0.75 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (20.0%) \| 0.80 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.7%) \| 0.80 (0.13) | n= 8 (14.3%) \| 0.84 (0.19) | -0.25 [-1.16 ; 0.65] |
| Week 105 | n= 12 (20.0%) \| 0.72 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.0%) \| 0.79 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.7%) \| 0.67 (0.26) | n= 3 ( 5.4%) \| 0.93 (0.12) | -1.02 [-2.44 ; 0.39] |
| Week 111 | n= 6 (10.0%) \| 0.57 (0.58) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.7%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 5 ( 8.3%) \| 0.83 (0.24) | n= 5 ( 8.9%) \| 0.83 (0.16) | -0.01 [-1.32 ; 1.31] |
| Week 117 | n= 5 ( 8.3%) \| 0.73 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 8.3%) \| 0.71 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.7%) \| 0.79 (0.18) | n= 1 ( 1.8%) \| 0.62 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.7%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.7%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) \| 0.90 (0.14) | n= 1 ( 1.8%) \| 0.62 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.7%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.7%) \| 0.82 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.7%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (13.3%) \| 0.86 (0.13) | n= 11 (19.6%) \| 0.71 (0.28) | 0.62 [-0.34 ; 1.58] |
| Week 202 | n= 2 ( 3.3%) \| 0.44 (0.35) | n= 8 (14.3%) \| 0.87 (0.14) | -2.17 [-4.16 ;-0.18] |
| Week 301 | n= 2 ( 3.3%) \| 0.76 (0.34) | n= 7 (12.5%) \| 0.79 (0.17) | -0.16 [-1.84 ; 1.53] |
| Week 302 | n= 2 ( 3.3%) \| 0.69 (0.05) | n= 4 ( 7.1%) \| 0.69 (0.05) | 0.00 [-1.92 ; 1.93] |
| Week 303 | n= 3 ( 5.0%) \| 0.76 (0.21) | n= 5 ( 8.9%) \| 0.78 (0.15) | -0.09 [-1.64 ; 1.47] |
| Week 304 | n= 1 ( 1.7%) \| 1.00 ( / ) | n= 2 ( 3.6%) \| 0.47 (0.31) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.8%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.8%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.8%) \| 1.00 ( / ) | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 308 | [No Data] | n= 1 ( 1.8%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.8%) \| 1.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:55

TABLE 7.2.9: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=11 | N=12 | |
| Week 3 | n= 10 (90.9%) \|-0.08 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 9 (81.8%) \|-0.02 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 10 (90.9%) \|-0.01 (0.09) | n= 11 (91.7%) \| 0.01 (0.30) | -0.09 [-0.97 ; 0.79] |
| Week 9 | n= 8 (72.7%) \|-0.03 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 10 (90.9%) \|-0.08 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 11 (100.0%) \|-0.05 (0.16) | n= 9 (75.0%) \|-0.02 (0.35) | -0.12 [-1.03 ; 0.78] |
| Week 15 | n= 9 (81.8%) \|-0.06 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (81.8%) \|-0.10 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 8 (72.7%) \|-0.03 (0.09) | n= 10 (83.3%) \|-0.00 (0.34) | -0.10 [-1.06 ; 0.86] |
| Week 21 | n= 11 (100.0%) \|-0.06 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \|-0.01 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 10 (90.9%) \|-0.03 (0.17) | n= 8 (66.7%) \|-0.06 (0.18) | 0.15 [-0.81 ; 1.11] |
| Week 27 | n= 10 (90.9%) \|-0.02 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 9 (81.8%) \|-0.00 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 10 (90.9%) \| 0.01 (0.08) | n= 6 (50.0%) \|-0.06 (0.17) | 0.50 [-0.56 ; 1.57] |
| Week 33 | n= 10 (90.9%) \| 0.03 (0.10) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (72.7%) \| 0.00 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \| 0.02 (0.14) | n= 5 (41.7%) \|-0.03 (0.06) | 0.42 [-0.76 ; 1.60] |
| Week 39 | n= 8 (72.7%) \|-0.01 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 9 (81.8%) \| 0.02 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 8 (72.7%) \|-0.04 (0.10) | n= 6 (50.0%) \|-0.14 (0.27) | 0.52 [-0.60 ; 1.65] |
| Week 45 | n= 9 (81.8%) \| 0.02 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 9 (81.8%) \| 0.01 (0.04) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 10 (90.9%) \| 0.05 (0.15) | n= 6 (50.0%) \|-0.09 (0.10) | 1.03 [-0.09 ; 2.15] |
| Week 51 | n= 9 (81.8%) \| 0.02 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 9 (81.8%) \| 0.03 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 8 (72.7%) \|-0.03 (0.14) | n= 6 (50.0%) \|-0.13 (0.17) | 0.56 [-0.56 ; 1.69] |
| Week 57 | n= 8 (72.7%) \|-0.03 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (63.6%) \|-0.01 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (72.7%) \| 0.02 (0.10) | n= 4 (33.3%) \|-0.11 (0.12) | 1.20 [-0.17 ; 2.58] |
| Week 63 | n= 8 (72.7%) \|-0.01 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (72.7%) \| 0.04 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \|-0.02 (0.22) | n= 5 (41.7%) \|-0.06 (0.12) | 0.22 [-0.95 ; 1.39] |
| Week 69 | n= 8 (72.7%) \|-0.04 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (63.6%) \| 0.02 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (63.6%) \|-0.01 (0.14) | n= 4 (33.3%) \|-0.10 (0.10) | 0.67 [-0.67 ; 2.00] |
| Week 75 | n= 7 (63.6%) \| 0.03 (0.06) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (45.5%) \| 0.02 (0.06) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (54.5%) \| 0.02 (0.05) | n= 2 (16.7%) \|-0.14 (0.10) | 2.18 [-0.01 ; 4.38] |
| Week 81 | n= 5 (45.5%) \| 0.02 (0.06) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (45.5%) \| 0.02 (0.06) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (45.5%) \| 0.02 (0.06) | n= 3 (25.0%) \|-0.23 (0.14) | 2.29 [ 0.20 ; 4.38] |
| Week 87 | n= 5 (45.5%) \| 0.02 (0.06) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 4 (36.4%) \| 0.02 (0.07) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 4 (36.4%) \| 0.02 (0.07) | n= 2 (16.7%) \|-0.31 (0.15) | 2.80 [-0.15 ; 5.76] |
| Week 93 | n= 4 (36.4%) \| 0.02 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (27.3%) \| 0.03 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (27.3%) \| 0.03 (0.08) | n= 1 ( 8.3%) \| 0.00 ( / ) | [Not calculable] |
| Week 99 | n= 2 (18.2%) \| 0.04 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 (18.2%) \| 0.04 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (18.2%) \| 0.04 (0.11) | n= 1 ( 8.3%) \|-0.19 ( / ) | [Not calculable] |
| Week 105 | n= 2 (18.2%) \| 0.04 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \| 0.04 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 ( 9.1%) \|-0.04 ( / ) | n= 1 ( 8.3%) \| 0.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 9.1%) \|-0.04 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 ( 9.1%) \|-0.04 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 9.1%) \|-0.04 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 ( 9.1%) \|-0.04 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 9.1%) \|-0.04 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 9.1%) \|-0.04 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | [No Data] | n= 6 (50.0%) \|-0.08 (0.23) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 4 (33.3%) \|-0.15 (0.17) | [No Data for at least 1 arm] |
| Week 301 | [No Data] | n= 2 (16.7%) \| 0.10 (0.14) | [No Data for at least 1 arm] |
| Week 302 | [No Data] | n= 2 (16.7%) \|-0.01 (0.04) | [No Data for at least 1 arm] |
| Week 303 | [No Data] | n= 1 ( 8.3%) \|-0.64 ( / ) | [No Data for at least 1 arm] |
| Week 304 | [No Data] | n= 1 ( 8.3%) \| 0.00 ( / ) | [No Data for at least 1 arm] |
| **Yes** | | | |
| N subjects in population | N=60 | N=56 | |
| Week 3 | n= 56 (93.3%) \| 0.01 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 55 (91.7%) \|-0.05 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 54 (90.0%) \|-0.06 (0.22) | n= 51 (91.1%) \| 0.01 (0.18) | -0.32 [-0.70 ; 0.07] |
| Week 9 | n= 51 (85.0%) \|-0.04 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 51 (85.0%) \|-0.05 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 48 (80.0%) \|-0.02 (0.19) | n= 43 (76.8%) \|-0.09 (0.23) | 0.30 [-0.11 ; 0.72] |
| Week 15 | n= 45 (75.0%) \|-0.07 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 52 (86.7%) \|-0.03 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 49 (81.7%) \|-0.02 (0.19) | n= 41 (73.2%) \|-0.01 (0.16) | -0.02 [-0.44 ; 0.40] |
| Week 21 | n= 49 (81.7%) \|-0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 45 (75.0%) \|-0.03 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 48 (80.0%) \|-0.02 (0.18) | n= 42 (75.0%) \|-0.06 (0.14) | 0.24 [-0.18 ; 0.66] |
| Week 27 | n= 45 (75.0%) \|-0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 44 (73.3%) \|-0.02 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 44 (73.3%) \|-0.03 (0.20) | n= 37 (66.1%) \|-0.08 (0.19) | 0.23 [-0.21 ; 0.67] |
| Week 33 | n= 47 (78.3%) \|-0.03 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 45 (75.0%) \|-0.02 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 41 (68.3%) \|-0.01 (0.18) | n= 39 (69.6%) \|-0.07 (0.16) | 0.38 [-0.06 ; 0.83] |
| Week 39 | n= 45 (75.0%) \|-0.02 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 42 (70.0%) \|-0.02 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 45 (75.0%) \|-0.01 (0.20) | n= 35 (62.5%) \|-0.05 (0.18) | 0.21 [-0.24 ; 0.65] |
| Week 45 | n= 40 (66.7%) \| 0.00 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 43 (71.7%) \|-0.00 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 43 (71.7%) \| 0.01 (0.18) | n= 31 (55.4%) \|-0.08 (0.24) | 0.44 [-0.03 ; 0.91] |
| Week 51 | n= 42 (70.0%) \|-0.03 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 39 (65.0%) \|-0.01 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (65.0%) \| 0.01 (0.22) | n= 32 (57.1%) \|-0.01 (0.17) | 0.09 [-0.38 ; 0.56] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 57 | n= 39 (65.0%) \|-0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (61.7%) \|-0.03 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 40 (66.7%) \|-0.02 (0.24) | n= 26 (46.4%) \|-0.10 (0.25) | 0.33 [-0.17 ; 0.83] |
| Week 63 | n= 34 (56.7%) \|-0.01 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (60.0%) \| 0.01 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (60.0%) \|-0.01 (0.22) | n= 25 (44.6%) \|-0.06 (0.18) | 0.24 [-0.27 ; 0.76] |
| Week 69 | n= 28 (46.7%) \| 0.01 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 32 (53.3%) \| 0.00 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 27 (45.0%) \| 0.01 (0.24) | n= 23 (41.1%) \|-0.10 (0.22) | 0.45 [-0.12 ; 1.02] |
| Week 75 | n= 29 (48.3%) \| 0.03 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (45.0%) \| 0.03 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 25 (41.7%) \| 0.07 (0.23) | n= 22 (39.3%) \|-0.05 (0.20) | 0.54 [-0.05 ; 1.13] |
| Week 81 | n= 26 (43.3%) \| 0.02 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (46.7%) \| 0.03 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 22 (36.7%) \| 0.02 (0.18) | n= 17 (30.4%) \|-0.08 (0.23) | 0.52 [-0.13 ; 1.17] |
| Week 87 | n= 19 (31.7%) \|-0.07 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 21 (35.0%) \|-0.00 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (33.3%) \|-0.05 (0.21) | n= 15 (26.8%) \|-0.03 (0.22) | -0.11 [-0.79 ; 0.57] |
| Week 93 | n= 16 (26.7%) \|-0.03 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.7%) \|-0.06 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (30.0%) \|-0.07 (0.20) | n= 9 (16.1%) \|-0.11 (0.22) | 0.18 [-0.64 ; 0.99] |
| Week 99 | n= 15 (25.0%) \|-0.08 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (20.0%) \|-0.11 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.7%) \|-0.09 (0.14) | n= 8 (14.3%) \|-0.09 (0.20) | 0.03 [-0.87 ; 0.93] |
| Week 105 | n= 12 (20.0%) \|-0.15 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.0%) \|-0.14 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.7%) \|-0.16 (0.30) | n= 3 ( 5.4%) \| 0.00 (0.00) | -0.57 [-1.94 ; 0.80] |
| Week 111 | n= 6 (10.0%) \|-0.34 (0.47) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.7%) \|-0.08 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 5 ( 8.3%) \|-0.03 (0.30) | n= 5 ( 8.9%) \|-0.13 (0.18) | 0.37 [-0.96 ; 1.70] |
| Week 117 | n= 5 ( 8.3%) \|-0.22 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 8.3%) \|-0.18 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.7%) \|-0.12 (0.17) | n= 1 ( 1.8%) \|-0.38 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.7%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.7%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) \| 0.05 (0.14) | n= 1 ( 1.8%) \|-0.38 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.7%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.7%) \|-0.03 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.7%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (13.3%) \| 0.03 (0.23) | n= 11 (19.6%) \|-0.14 (0.26) | 0.63 [-0.33 ; 1.59] |
| Week 202 | n= 2 ( 3.3%) \|-0.41 (0.14) | n= 8 (14.3%) \|-0.04 (0.19) | -1.77 [-3.65 ; 0.11] |
| Week 301 | n= 2 ( 3.3%) \|-0.01 (0.23) | n= 7 (12.5%) \| 0.07 (0.17) | -0.40 [-2.10 ; 1.30] |
| Week 302 | n= 2 ( 3.3%) \|-0.04 (0.11) | n= 4 ( 7.1%) \|-0.19 (0.17) | 0.77 [-1.25 ; 2.80] |
| Week 303 | n= 3 ( 5.0%) \|-0.01 (0.19) | n= 5 ( 8.9%) \|-0.09 (0.20) | 0.34 [-1.23 ; 1.91] |
| Week 304 | n= 1 ( 1.7%) \| 0.15 ( / ) | n= 2 ( 3.6%) \|-0.30 (0.20) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.8%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.8%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.8%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.8%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.8%) \| 0.59 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:55

TABLE 7.2.9: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **No** | | | | |
| Nr subjects used | n=11 | n=12 | | |
| Week 7 | 0.03 (0.05) [-0.08 ; 0.13] | -0.03 (0.05) [-0.13 ; 0.07] | 0.06 (0.07) [-0.09 ; 0.21] | 0.35 [-0.52 ; 1.21] |
| Overall post-baseline period estimate | 0.03 (0.05) [-0.08 ; 0.13] | -0.03 (0.05) [-0.13 ; 0.07] | 0.06 (0.07) [-0.09 ; 0.21] | 0.33 [-0.49 ; 1.16] |
| **Yes** | | | | |
| Nr subjects used | n=60 | n=56 | | |
| Week 7 | -0.06 (0.03) [-0.12 ;-0.01] | -0.02 (0.03) [-0.07 ; 0.04] | -0.05 (0.04) [-0.12 ; 0.03] | -0.24 [-0.63 ; 0.14] |
| Week 13 | -0.04 (0.03) [-0.10 ; 0.03] | -0.09 (0.03) [-0.15 ;-0.02] | 0.05 (0.05) [-0.04 ; 0.14] | 0.23 [-0.18 ; 0.65] |
| Week 19 | -0.03 (0.02) [-0.08 ; 0.02] | -0.02 (0.03) [-0.07 ; 0.03] | -0.02 (0.04) [-0.09 ; 0.06] | -0.09 [-0.50 ; 0.33] |
| Week 25 | -0.02 (0.02) [-0.06 ; 0.03] | -0.05 (0.02) [-0.10 ;-0.01] | 0.04 (0.03) [-0.03 ; 0.10] | 0.24 [-0.18 ; 0.66] |
| Week 31 | -0.04 (0.03) [-0.10 ; 0.01] | -0.06 (0.03) [-0.12 ;-0.00] | 0.02 (0.04) [-0.06 ; 0.10] | 0.11 [-0.32 ; 0.55] |
| Week 37 | -0.00 (0.02) [-0.05 ; 0.04] | -0.06 (0.02) [-0.11 ;-0.01] | 0.06 (0.03) [-0.01 ; 0.13] | 0.38 [-0.06 ; 0.83] |
| Week 43 | -0.02 (0.02) [-0.07 ; 0.03] | -0.04 (0.03) [-0.09 ; 0.02] | 0.02 (0.04) [-0.05 ; 0.09] | 0.12 [-0.32 ; 0.56] |
| Week 49 | -0.00 (0.03) [-0.06 ; 0.06] | -0.07 (0.03) [-0.14 ;-0.01] | 0.07 (0.04) [-0.02 ; 0.16] | 0.37 [-0.09 ; 0.84] |
| Week 55 | -0.00 (0.03) [-0.05 ; 0.05] | 0.00 (0.03) [-0.06 ; 0.06] | -0.00 (0.04) [-0.08 ; 0.07] | -0.01 [-0.48 ; 0.46] |
| Week 61 | -0.04 (0.03) [-0.10 ; 0.02] | -0.06 (0.04) [-0.14 ; 0.01] | 0.02 (0.05) [-0.08 ; 0.12] | 0.11 [-0.38 ; 0.61] |
| Week 67 | -0.02 (0.03) [-0.07 ; 0.04] | -0.05 (0.03) [-0.12 ; 0.01] | 0.04 (0.04) [-0.05 ; 0.12] | 0.21 [-0.30 ; 0.72] |
| Week 73 | -0.01 (0.03) [-0.07 ; 0.04] | -0.08 (0.03) [-0.15 ;-0.02] | 0.07 (0.04) [-0.02 ; 0.15] | 0.45 [-0.12 ; 1.01] |
| Week 79 | 0.02 (0.03) [-0.04 ; 0.07] | -0.04 (0.03) [-0.10 ; 0.03] | 0.05 (0.04) [-0.03 ; 0.14] | 0.37 [-0.21 ; 0.95] |
| Week 85 | 0.01 (0.03) [-0.05 ; 0.07] | -0.07 (0.03) [-0.14 ;-0.01] | 0.08 (0.04) [-0.01 ; 0.17] | 0.59 [-0.06 ; 1.23] |
| Week 91 | -0.03 (0.04) [-0.11 ; 0.04] | -0.04 (0.04) [-0.13 ; 0.05] | 0.01 (0.06) [-0.11 ; 0.12] | 0.04 [-0.63 ; 0.71] |
| Overall post-baseline period estimate | -0.02 (0.01) [-0.05 ; 0.01] | -0.05 (0.02) [-0.08 ;-0.02] | 0.03 (0.02) [-0.01 ; 0.07] | 0.28 [-0.09 ; 0.65] |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.2638 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:55

TABLE 7.2.10: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **No** | | |
| | N=61 | N=62 |
| **Yes** | | |
| | N=10 | N=6 |
| **Subjects with Baseline Value** | | |
| **No** | | |
| | 61 (100.0%) | 62 (100.0%) |
| **Yes** | | |
| | 10 (100.0%) | 6 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **No** | | |
| | 61 (100.0%) | 60 (96.8%) |
| **Yes** | | |
| | 10 (100.0%) | 6 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **No** | | |
| | 61 (100.0%) | 60 (96.8%) |
| **Yes** | | |
| | 10 (100.0%) | 6 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:55

TABLE 7.2.10: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=61 | N=62 | |
| Baseline | n= 61 (100.0%) \| 0.86 (0.17) | n= 62 (100.0%) \| 0.78 (0.30) | 0.30 [-0.06 ; 0.65] |
| Week 3 | n= 57 (93.4%) \| 0.86 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 56 (91.8%) \| 0.82 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 55 (90.2%) \| 0.80 (0.22) | n= 57 (91.9%) \| 0.79 (0.25) | 0.04 [-0.33 ; 0.41] |
| Week 9 | n= 51 (83.6%) \| 0.82 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 53 (86.9%) \| 0.80 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 52 (85.2%) \| 0.82 (0.18) | n= 48 (77.4%) \| 0.75 (0.23) | 0.30 [-0.10 ; 0.70] |
| Week 15 | n= 49 (80.3%) \| 0.79 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 53 (86.9%) \| 0.81 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 51 (83.6%) \| 0.83 (0.16) | n= 46 (74.2%) \| 0.83 (0.19) | -0.01 [-0.41 ; 0.39] |
| Week 21 | n= 52 (85.2%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 49 (80.3%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 52 (85.2%) \| 0.84 (0.18) | n= 47 (75.8%) \| 0.82 (0.17) | 0.13 [-0.26 ; 0.53] |
| Week 27 | n= 49 (80.3%) \| 0.84 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 47 (77.0%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 48 (78.7%) \| 0.83 (0.18) | n= 39 (62.9%) \| 0.80 (0.22) | 0.13 [-0.29 ; 0.56] |
| Week 33 | n= 50 (82.0%) \| 0.81 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 48 (78.7%) \| 0.82 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 42 (68.9%) \| 0.86 (0.16) | n= 39 (62.9%) \| 0.82 (0.17) | 0.18 [-0.26 ; 0.62] |
| Week 39 | n= 46 (75.4%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 45 (73.8%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 46 (75.4%) \| 0.83 (0.18) | n= 37 (59.7%) \| 0.81 (0.19) | 0.15 [-0.29 ; 0.58] |
| Week 45 | n= 42 (68.9%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 46 (75.4%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 47 (77.0%) \| 0.86 (0.17) | n= 33 (53.2%) \| 0.78 (0.26) | 0.40 [-0.05 ; 0.85] |
| Week 51 | n= 44 (72.1%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 42 (68.9%) \| 0.85 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 40 (65.6%) \| 0.84 (0.17) | n= 35 (56.5%) \| 0.84 (0.18) | -0.01 [-0.46 ; 0.45] |
| Week 57 | n= 40 (65.6%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (60.7%) \| 0.81 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 42 (68.9%) \| 0.83 (0.18) | n= 27 (43.5%) \| 0.77 (0.29) | 0.26 [-0.23 ; 0.75] |
| Week 63 | n= 35 (57.4%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 37 (60.7%) \| 0.83 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (62.3%) \| 0.84 (0.15) | n= 27 (43.5%) \| 0.81 (0.19) | 0.21 [-0.28 ; 0.71] |
| Week 69 | n= 31 (50.8%) \| 0.81 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 32 (52.5%) \| 0.82 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 28 (45.9%) \| 0.81 (0.18) | n= 24 (38.7%) \| 0.76 (0.21) | 0.23 [-0.32 ; 0.79] |
| Week 75 | n= 30 (49.2%) \| 0.84 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (42.6%) \| 0.85 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (42.6%) \| 0.88 (0.16) | n= 23 (37.1%) \| 0.80 (0.21) | 0.39 [-0.18 ; 0.96] |
| Week 81 | n= 26 (42.6%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 27 (44.3%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (41.0%) \| 0.86 (0.17) | n= 18 (29.0%) \| 0.78 (0.20) | 0.47 [-0.15 ; 1.09] |
| Week 87 | n= 19 (31.1%) \| 0.84 (0.18) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 22 (36.1%) \| 0.83 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 21 (34.4%) \| 0.83 (0.18) | n= 15 (24.2%) \| 0.83 (0.15) | 0.00 [-0.67 ; 0.67] |
| Week 93 | n= 17 (27.9%) \| 0.82 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.1%) \| 0.80 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.5%) \| 0.82 (0.18) | n= 10 (16.1%) \| 0.82 (0.18) | 0.00 [-0.78 ; 0.79] |
| Week 99 | n= 14 (23.0%) \| 0.80 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.3%) \| 0.79 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.3%) \| 0.80 (0.13) | n= 9 (14.5%) \| 0.84 (0.18) | -0.24 [-1.12 ; 0.63] |
| Week 105 | n= 12 (19.7%) \| 0.77 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.5%) \| 0.78 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (14.8%) \| 0.63 (0.24) | n= 4 ( 6.5%) \| 0.95 (0.10) | -1.40 [-2.77 ;-0.03] |
| Week 111 | n= 6 ( 9.8%) \| 0.51 (0.55) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.5%) \| 0.77 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 5 ( 8.2%) \| 0.77 (0.22) | n= 5 ( 8.1%) \| 0.83 (0.16) | -0.29 [-1.62 ; 1.03] |
| Week 117 | n= 5 ( 8.2%) \| 0.67 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 8.2%) \| 0.65 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.5%) \| 0.75 (0.16) | n= 1 ( 1.6%) \| 0.62 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.6%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) \| 0.90 (0.14) | n= 1 ( 1.6%) \| 0.62 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) \| 0.82 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 ( 9.8%) \| 0.86 (0.12) | n= 15 (24.2%) \| 0.74 (0.26) | 0.50 [-0.48 ; 1.49] |
| Week 202 | n= 1 ( 1.6%) \| 0.69 ( / ) | n= 9 (14.5%) \| 0.82 (0.21) | [Not calculable] |
| Week 301 | n= 1 ( 1.6%) \| 1.00 ( / ) | n= 8 (12.9%) \| 0.82 (0.17) | [Not calculable] |
| Week 302 | n= 2 ( 3.3%) \| 0.69 (0.05) | n= 5 ( 8.1%) \| 0.72 (0.07) | -0.38 [-2.21 ; 1.45] |
| Week 303 | n= 3 ( 4.9%) \| 0.76 (0.21) | n= 6 ( 9.7%) \| 0.67 (0.29) | 0.29 [-1.21 ; 1.78] |
| Week 304 | n= 1 ( 1.6%) \| 1.00 ( / ) | n= 3 ( 4.8%) \| 0.58 (0.29) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.6%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.6%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.6%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.6%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.6%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| **Yes** | | | |
| N subjects in population | N=10 | N=6 | |
| Baseline | n= 10 (100.0%) \| 0.71 (0.30) | n= 6 (100.0%) \| 0.86 (0.16) | -0.56 [-1.62 ; 0.51] |
| Week 3 | n= 9 (90.0%) \| 0.67 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (80.0%) \| 0.66 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 9 (90.0%) \| 0.76 (0.17) | n= 5 (83.3%) \| 0.76 (0.18) | 0.03 [-1.11 ; 1.17] |
| Week 9 | n= 8 (80.0%) \| 0.70 (0.33) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 8 (80.0%) \| 0.69 (0.33) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 7 (70.0%) \| 0.76 (0.38) | n= 4 (66.7%) \| 0.79 (0.24) | -0.09 [-1.38 ; 1.21] |
| Week 15 | n= 5 (50.0%) \| 0.69 (0.32) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 8 (80.0%) \| 0.70 (0.41) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 6 (60.0%) \| 0.70 (0.40) | n= 5 (83.3%) \| 0.76 (0.18) | -0.17 [-1.42 ; 1.09] |
| Week 21 | n= 8 (80.0%) \| 0.67 (0.41) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (60.0%) \| 0.73 (0.38) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (60.0%) \| 0.73 (0.42) | n= 3 (50.0%) \| 0.74 (0.14) | -0.04 [-1.53 ; 1.44] |
| Week 27 | n= 6 (60.0%) \| 0.83 (0.41) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 6 (60.0%) \| 0.78 (0.41) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 31 | n= 6 (60.0%) \| 0.80 (0.41) | n= 4 (66.7%) \| 0.80 (0.21) | 0.00 [-1.34 ; 1.35] |
| Week 33 | n= 7 (70.0%) \| 0.84 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 5 (50.0%) \| 0.84 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 7 (70.0%) \| 0.80 (0.34) | n= 5 (83.3%) \| 0.74 (0.10) | 0.21 [-1.00 ; 1.42] |
| Week 39 | n= 7 (70.0%) \| 0.78 (0.35) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 6 (60.0%) \| 0.86 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 7 (70.0%) \| 0.82 (0.20) | n= 4 (66.7%) \| 0.85 (0.11) | -0.14 [-1.44 ; 1.15] |
| Week 45 | n= 7 (70.0%) \| 0.87 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (60.0%) \| 0.86 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (60.0%) \| 0.82 (0.21) | n= 4 (66.7%) \| 0.70 (0.21) | 0.53 [-0.84 ; 1.90] |
| Week 51 | n= 7 (70.0%) \| 0.77 (0.32) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 6 (60.0%) \| 0.89 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (70.0%) \| 0.83 (0.20) | n= 3 (50.0%) \| 0.66 (0.07) | 0.86 [-0.64 ; 2.37] |
| Week 57 | n= 7 (70.0%) \| 0.87 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (70.0%) \| 0.86 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 6 (60.0%) \| 0.89 (0.19) | n= 3 (50.0%) \| 0.74 (0.13) | 0.77 [-0.77 ; 2.32] |
| Week 63 | n= 7 (70.0%) \| 0.73 (0.30) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (70.0%) \| 0.89 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (60.0%) \| 0.82 (0.37) | n= 3 (50.0%) \| 0.74 (0.13) | 0.24 [-1.26 ; 1.73] |
| Week 69 | n= 5 (50.0%) \| 0.90 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (70.0%) \| 0.86 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 6 (60.0%) \| 0.87 (0.21) | n= 3 (50.0%) \| 0.66 (0.13) | 0.95 [-0.63 ; 2.52] |
| Week 75 | n= 6 (60.0%) \| 0.87 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (60.0%) \| 0.82 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (50.0%) \| 0.80 (0.21) | n= 1 (16.7%) \| 0.59 ( / ) | [Not calculable] |
| Week 81 | n= 5 (50.0%) \| 0.83 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (60.0%) \| 0.84 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (20.0%) \| 1.00 (0.00) | n= 2 (33.3%) \| 0.72 (0.19) | 1.22 [-1.86 ; 4.31] |
| Week 87 | n= 5 (50.0%) \| 0.61 (0.48) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 3 (30.0%) \| 0.74 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (30.0%) \| 0.56 (0.42) | n= 2 (33.3%) \| 0.87 (0.02) | -0.65 [-2.86 ; 1.56] |
| Week 93 | n= 3 (30.0%) \| 0.74 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (30.0%) \| 0.74 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (30.0%) \| 0.56 (0.42) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 3 (30.0%) \| 0.56 (0.42) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (10.0%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (20.0%) \| 0.85 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 105 | n= 2 (20.0%) \| 0.60 (0.57) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (10.0%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 (20.0%) \| 0.86 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 (10.0%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 (10.0%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 (10.0%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (10.0%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (10.0%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 (10.0%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (20.0%) \| 0.86 (0.19) | n= 2 (33.3%) \| 0.72 (0.18) | 0.44 [-2.11 ; 2.98] |
| Week 202 | n= 1 (10.0%) \| 0.19 ( / ) | n= 3 (50.0%) \| 0.84 (0.15) | [Not calculable] |
| Week 301 | n= 1 (10.0%) \| 0.52 ( / ) | n= 1 (16.7%) \| 0.76 ( / ) | [Not calculable] |
| Week 302 | [No Data] | n= 1 (16.7%) \| 0.73 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:55

TABLE 7.2.10: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=61 | N=62 | |
| Week 3 | n= 57 (93.4%) \| 0.01 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 56 (91.8%) \|-0.04 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 55 (90.2%) \|-0.05 (0.22) | n= 57 (91.9%) \| 0.01 (0.20) | -0.32 [-0.70 ; 0.05] |
| Week 9 | n= 51 (83.6%) \|-0.04 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 53 (86.9%) \|-0.05 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 52 (85.2%) \|-0.03 (0.19) | n= 48 (77.4%) \|-0.08 (0.26) | 0.20 [-0.20 ; 0.59] |
| Week 15 | n= 49 (80.3%) \|-0.05 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 53 (86.9%) \|-0.04 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 51 (83.6%) \|-0.02 (0.18) | n= 46 (74.2%) \|-0.00 (0.20) | -0.09 [-0.49 ; 0.31] |
| Week 21 | n= 52 (85.2%) \|-0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 49 (80.3%) \|-0.03 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 52 (85.2%) \|-0.02 (0.19) | n= 47 (75.8%) \|-0.06 (0.15) | 0.20 [-0.19 ; 0.60] |
| Week 27 | n= 49 (80.3%) \|-0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 47 (77.0%) \|-0.03 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 48 (78.7%) \|-0.03 (0.19) | n= 39 (62.9%) \|-0.08 (0.19) | 0.21 [-0.22 ; 0.64] |
| Week 33 | n= 50 (82.0%) \|-0.04 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 48 (78.7%) \|-0.04 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 42 (68.9%) \|-0.01 (0.18) | n= 39 (62.9%) \|-0.07 (0.16) | 0.30 [-0.14 ; 0.74] |
| Week 39 | n= 46 (75.4%) \|-0.02 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 45 (73.8%) \|-0.03 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 46 (75.4%) \|-0.03 (0.19) | n= 37 (59.7%) \|-0.07 (0.19) | 0.21 [-0.22 ; 0.65] |
| Week 45 | n= 42 (68.9%) \|-0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 46 (75.4%) \|-0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 47 (77.0%) \| 0.01 (0.17) | n= 33 (53.2%) \|-0.08 (0.23) | 0.42 [-0.03 ; 0.87] |
| Week 51 | n= 44 (72.1%) \|-0.03 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 42 (68.9%) \|-0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 40 (65.6%) \|-0.02 (0.21) | n= 35 (56.5%) \|-0.02 (0.18) | 0.02 [-0.43 ; 0.48] |
| Week 57 | n= 40 (65.6%) \|-0.04 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (60.7%) \|-0.05 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 42 (68.9%) \|-0.03 (0.22) | n= 27 (43.5%) \|-0.11 (0.25) | 0.32 [-0.17 ; 0.81] |
| Week 63 | n= 35 (57.4%) \|-0.01 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 37 (60.7%) \|-0.01 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (62.3%) \|-0.01 (0.21) | n= 27 (43.5%) \|-0.07 (0.18) | 0.26 [-0.24 ; 0.76] |
| Week 69 | n= 31 (50.8%) \|-0.03 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 32 (52.5%) \|-0.02 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 28 (45.9%) \|-0.02 (0.22) | n= 24 (38.7%) \|-0.09 (0.20) | 0.33 [-0.22 ; 0.89] |
| Week 75 | n= 30 (49.2%) \| 0.01 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (42.6%) \| 0.01 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (42.6%) \| 0.03 (0.21) | n= 23 (37.1%) \|-0.06 (0.20) | 0.45 [-0.13 ; 1.02] |
| Week 81 | n= 26 (42.6%) \|-0.00 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 27 (44.3%) \|-0.00 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (41.0%) \| 0.02 (0.17) | n= 18 (29.0%) \|-0.12 (0.22) | 0.73 [ 0.10 ; 1.37] |
| Week 87 | n= 19 (31.1%) \|-0.05 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 22 (36.1%) \|-0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 21 (34.4%) \|-0.05 (0.16) | n= 15 (24.2%) \|-0.09 (0.22) | 0.25 [-0.42 ; 0.93] |
| Week 93 | n= 17 (27.9%) \|-0.06 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.1%) \|-0.08 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.5%) \|-0.06 (0.14) | n= 10 (16.1%) \|-0.10 (0.21) | 0.19 [-0.59 ; 0.98] |
| Week 99 | n= 14 (23.0%) \|-0.08 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.3%) \|-0.09 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.3%) \|-0.09 (0.15) | n= 9 (14.5%) \|-0.10 (0.19) | 0.09 [-0.78 ; 0.97] |
| Week 105 | n= 12 (19.7%) \|-0.10 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.5%) \|-0.11 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (14.8%) \|-0.20 (0.30) | n= 4 ( 6.5%) \| 0.00 (0.00) | -0.73 [-2.00 ; 0.54] |
| Week 111 | n= 6 ( 9.8%) \|-0.34 (0.46) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.5%) \|-0.08 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 5 ( 8.2%) \|-0.04 (0.30) | n= 5 ( 8.1%) \|-0.13 (0.18) | 0.35 [-0.98 ; 1.68] |
| Week 117 | n= 5 ( 8.2%) \|-0.23 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 8.2%) \|-0.19 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.5%) \|-0.12 (0.16) | n= 1 ( 1.6%) \|-0.38 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.6%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) \| 0.05 (0.14) | n= 1 ( 1.6%) \|-0.38 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) \|-0.03 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 ( 9.8%) \| 0.03 (0.20) | n= 15 (24.2%) \|-0.10 (0.25) | 0.50 [-0.48 ; 1.49] |
| Week 202 | n= 1 ( 1.6%) \|-0.31 ( / ) | n= 9 (14.5%) \|-0.07 (0.20) | [Not calculable] |
| Week 301 | n= 1 ( 1.6%) \| 0.15 ( / ) | n= 8 (12.9%) \| 0.09 (0.16) | [Not calculable] |
| Week 302 | n= 2 ( 3.3%) \|-0.04 (0.11) | n= 5 ( 8.1%) \|-0.10 (0.16) | 0.33 [-1.50 ; 2.15] |
| Week 303 | n= 3 ( 4.9%) \|-0.01 (0.19) | n= 6 ( 9.7%) \|-0.18 (0.28) | 0.57 [-0.95 ; 2.09] |
| Week 304 | n= 1 ( 1.6%) \| 0.15 ( / ) | n= 3 ( 4.8%) \|-0.20 (0.22) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.6%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.6%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.6%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.6%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.6%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| **Yes** | | | |
| N subjects in population | N=10 | N=6 | |
| Week 3 | n= 9 (90.0%) \|-0.06 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (80.0%) \|-0.06 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 9 (90.0%) \|-0.03 (0.07) | n= 5 (83.3%) \|-0.08 (0.17) | 0.39 [-0.76 ; 1.54] |
| Week 9 | n= 8 (80.0%) \|-0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 8 (80.0%) \|-0.04 (0.10) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 7 (70.0%) \| 0.01 (0.17) | n= 4 (66.7%) \|-0.05 (0.06) | 0.36 [-0.94 ; 1.67] |
| Week 15 | n= 5 (50.0%) \|-0.17 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 8 (80.0%) \|-0.03 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 6 (60.0%) \| 0.01 (0.11) | n= 5 (83.3%) \|-0.07 (0.18) | 0.56 [-0.72 ; 1.84] |
| Week 21 | n= 8 (80.0%) \|-0.06 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (60.0%) \| 0.02 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (60.0%) \|-0.01 (0.09) | n= 3 (50.0%) \|-0.07 (0.08) | 0.68 [-0.85 ; 2.22] |
| Week 27 | n= 6 (60.0%) \| 0.08 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 6 (60.0%) \| 0.04 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 6 (60.0%) \| 0.05 (0.13) | n= 4 (66.7%) \|-0.08 (0.10) | 0.96 [-0.47 ; 2.39] |
| Week 33 | n= 7 (70.0%) \| 0.11 (0.16) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 35 | n= 5 (50.0%) \| 0.15 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 7 (70.0%) \| 0.07 (0.10) | n= 5 (83.3%) \|-0.10 (0.11) | 1.41 [ 0.05 ; 2.77] |
| Week 39 | n= 7 (70.0%) \| 0.05 (0.30) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 6 (60.0%) \| 0.12 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 7 (70.0%) \| 0.09 (0.16) | n= 4 (66.7%) \| 0.01 (0.14) | 0.50 [-0.82 ; 1.82] |
| Week 45 | n= 7 (70.0%) \| 0.13 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (60.0%) \| 0.11 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (60.0%) \| 0.09 (0.17) | n= 4 (66.7%) \|-0.14 (0.14) | 1.33 [-0.18 ; 2.84] |
| Week 51 | n= 7 (70.0%) \| 0.04 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 6 (60.0%) \| 0.05 (0.06) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (70.0%) \| 0.10 (0.16) | n= 3 (50.0%) \|-0.13 (0.14) | 1.30 [-0.28 ; 2.89] |
| Week 57 | n= 7 (70.0%) \| 0.13 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (70.0%) \| 0.12 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 6 (60.0%) \| 0.14 (0.19) | n= 3 (50.0%) \|-0.05 (0.15) | 0.99 [-0.60 ; 2.57] |
| Week 63 | n= 7 (70.0%) \|-0.01 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (70.0%) \| 0.16 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (60.0%) \|-0.02 (0.28) | n= 3 (50.0%) \|-0.05 (0.15) | 0.12 [-1.37 ; 1.61] |
| Week 69 | n= 5 (50.0%) \| 0.15 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (70.0%) \| 0.13 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 6 (60.0%) \| 0.13 (0.18) | n= 3 (50.0%) \|-0.13 (0.26) | 1.09 [-0.52 ; 2.70] |
| Week 75 | n= 6 (60.0%) \| 0.13 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (60.0%) \| 0.14 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (50.0%) \| 0.18 (0.17) | n= 1 (16.7%) \|-0.07 ( / ) | [Not calculable] |
| Week 81 | n= 5 (50.0%) \| 0.14 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (60.0%) \| 0.16 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (20.0%) \| 0.00 (0.00) | n= 2 (33.3%) \| 0.04 (0.15) | -0.19 [-2.67 ; 2.28] |
| Week 87 | n= 5 (50.0%) \|-0.08 (0.49) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 3 (30.0%) \| 0.17 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (30.0%) \|-0.01 (0.44) | n= 2 (33.3%) \| 0.18 (0.06) | -0.39 [-2.54 ; 1.76] |
| Week 93 | n= 3 (30.0%) \| 0.17 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (30.0%) \| 0.17 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (30.0%) \|-0.01 (0.44) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 3 (30.0%) \|-0.01 (0.44) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (10.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (20.0%) \| 0.04 (0.05) | [No Data] | [No Data for at least 1 arm] |
| Week 105 | n= 2 (20.0%) \|-0.21 (0.30) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (10.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 (20.0%) \| 0.05 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 (10.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 (10.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 (10.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (10.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (10.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 (10.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (20.0%) \| 0.02 (0.41) | n= 2 (33.3%) \|-0.28 (0.18) | 0.54 [-2.05 ; 3.13] |
| Week 202 | n= 1 (10.0%) \|-0.50 ( / ) | n= 3 (50.0%) \|-0.10 (0.17) | [Not calculable] |
| Week 301 | n= 1 (10.0%) \|-0.17 ( / ) | n= 1 (16.7%) \|-0.04 ( / ) | [Not calculable] |
| Week 302 | [No Data] | n= 1 (16.7%) \|-0.27 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:56

TABLE 7.2.10: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **No** | | | | |
| Nr subjects used | n=61 | n=62 | | |
| Week 7 | -0.06 (0.03) [-0.11 ;-0.01] | -0.03 (0.03) [-0.08 ; 0.02] | -0.03 (0.04) [-0.11 ; 0.04] | -0.16 [-0.53 ; 0.21] |
| Week 13 | -0.04 (0.03) [-0.10 ; 0.02] | -0.10 (0.03) [-0.16 ;-0.04] | 0.06 (0.04) [-0.03 ; 0.14] | 0.27 [-0.13 ; 0.66] |
| Week 19 | -0.03 (0.02) [-0.08 ; 0.01] | -0.03 (0.02) [-0.08 ; 0.02] | -0.00 (0.03) [-0.07 ; 0.06] | -0.02 [-0.42 ; 0.38] |
| Week 25 | -0.02 (0.02) [-0.07 ; 0.02] | -0.04 (0.02) [-0.09 ; 0.00] | 0.02 (0.03) [-0.04 ; 0.09] | 0.15 [-0.25 ; 0.54] |
| Week 31 | -0.04 (0.03) [-0.09 ; 0.01] | -0.06 (0.03) [-0.12 ;-0.01] | 0.02 (0.04) [-0.05 ; 0.10] | 0.13 [-0.29 ; 0.55] |
| Week 37 | -0.00 (0.02) [-0.05 ; 0.04] | -0.05 (0.02) [-0.10 ;-0.00] | 0.05 (0.03) [-0.02 ; 0.11] | 0.31 [-0.13 ; 0.75] |
| Week 43 | -0.03 (0.03) [-0.08 ; 0.02] | -0.06 (0.03) [-0.12 ;-0.00] | 0.03 (0.04) [-0.04 ; 0.11] | 0.20 [-0.23 ; 0.64] |
| Week 49 | -0.00 (0.03) [-0.06 ; 0.05] | -0.07 (0.03) [-0.13 ;-0.00] | 0.07 (0.04) [-0.02 ; 0.15] | 0.34 [-0.11 ; 0.79] |
| Week 55 | -0.02 (0.03) [-0.07 ; 0.03] | -0.01 (0.03) [-0.07 ; 0.05] | -0.01 (0.04) [-0.08 ; 0.07] | -0.03 [-0.49 ; 0.42] |
| Week 61 | -0.04 (0.03) [-0.10 ; 0.02] | -0.07 (0.04) [-0.14 ; 0.01] | 0.03 (0.05) [-0.07 ; 0.12] | 0.14 [-0.34 ; 0.63] |
| Week 67 | -0.02 (0.02) [-0.07 ; 0.03] | -0.06 (0.03) [-0.11 ; 0.00] | 0.04 (0.04) [-0.04 ; 0.11] | 0.24 [-0.26 ; 0.73] |
| Week 73 | -0.04 (0.03) [-0.09 ; 0.02] | -0.08 (0.03) [-0.13 ;-0.02] | 0.04 (0.04) [-0.04 ; 0.12] | 0.27 [-0.28 ; 0.81] |
| Week 79 | -0.00 (0.03) [-0.05 ; 0.05] | -0.05 (0.03) [-0.10 ; 0.01] | 0.05 (0.04) [-0.03 ; 0.12] | 0.32 [-0.24 ; 0.89] |
| Week 85 | 0.00 (0.03) [-0.05 ; 0.06] | -0.09 (0.03) [-0.15 ;-0.03] | 0.10 (0.04) [ 0.02 ; 0.18] | 0.75 [ 0.12 ; 1.38] |
| Week 91 | -0.02 (0.03) [-0.08 ; 0.04] | -0.08 (0.03) [-0.15 ;-0.01] | 0.06 (0.05) [-0.03 ; 0.15] | 0.47 [-0.20 ; 1.14] |
| Week 97 | -0.04 (0.03) [-0.10 ; 0.03] | -0.07 (0.04) [-0.16 ; 0.02] | 0.03 (0.05) [-0.08 ; 0.14] | 0.23 [-0.55 ; 1.00] |
| Overall post-baseline period estimate | -0.02 (0.01) [-0.05 ; 0.00] | -0.06 (0.01) [-0.09 ;-0.03] | 0.03 (0.02) [-0.00 ; 0.07] | 0.33 [-0.03 ; 0.69] |
| **Yes** | | | | |
| Nr subjects used | n=10 | n=6 | | |
| **MMRM subgroups interaction p-value** | | | | . |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:56

TABLE 7.2.11: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **>= 1%** | N=11 | N=9 |
| **< 1%** | N=58 | N=58 |
| **Not Reported** | N=2 | N=1 |
| **Subjects with Baseline Value** | | |
| **>= 1%** | 11 (100.0%) | 9 (100.0%) |
| **< 1%** | 58 (100.0%) | 58 (100.0%) |
| **Not Reported** | 2 (100.0%) | 1 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **>= 1%** | 11 (100.0%) | 9 (100.0%) |
| **< 1%** | 58 (100.0%) | 56 (96.6%) |
| **Not Reported** | 2 (100.0%) | 1 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **>= 1%** | 11 (100.0%) | 9 (100.0%) |
| **< 1%** | 58 (100.0%) | 56 (96.6%) |
| **Not Reported** | 2 (100.0%) | 1 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:56

TABLE 7.2.11: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **>= 1%** | | | |
| N subjects in population | N=11 | N=9 | |
| Baseline | n= 11 (100.0%) \| 0.73 (0.30) | n= 9 (100.0%) \| 0.76 (0.32) | -0.09 [-1.00 ; 0.81] |
| Week 3 | n= 11 (100.0%) \| 0.73 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 9 (81.8%) \| 0.70 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 10 (90.9%) \| 0.68 (0.27) | n= 9 (100.0%) \| 0.73 (0.32) | -0.16 [-1.09 ; 0.77] |
| Week 9 | n= 10 (90.9%) \| 0.69 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (81.8%) \| 0.71 (0.32) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 9 (81.8%) \| 0.75 (0.37) | n= 7 (77.8%) \| 0.73 (0.29) | 0.07 [-0.95 ; 1.10] |
| Week 15 | n= 8 (72.7%) \| 0.70 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 10 (90.9%) \| 0.72 (0.35) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 9 (81.8%) \| 0.73 (0.35) | n= 7 (77.8%) \| 0.78 (0.10) | -0.18 [-1.21 ; 0.84] |
| Week 21 | n= 9 (81.8%) \| 0.65 (0.37) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \| 0.75 (0.31) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 9 (81.8%) \| 0.74 (0.35) | n= 6 (66.7%) \| 0.78 (0.06) | -0.11 [-1.18 ; 0.97] |
| Week 27 | n= 8 (72.7%) \| 0.75 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 8 (72.7%) \| 0.71 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 8 (72.7%) \| 0.74 (0.34) | n= 6 (66.7%) \| 0.77 (0.08) | -0.12 [-1.23 ; 0.98] |
| Week 33 | n= 10 (90.9%) \| 0.77 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (72.7%) \| 0.83 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \| 0.75 (0.31) | n= 6 (66.7%) \| 0.74 (0.09) | 0.02 [-1.08 ; 1.13] |
| Week 39 | n= 9 (81.8%) \| 0.80 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 10 (90.9%) \| 0.77 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 9 (81.8%) \| 0.78 (0.19) | n= 7 (77.8%) \| 0.75 (0.12) | 0.17 [-0.85 ; 1.19] |
| Week 45 | n= 7 (63.6%) \| 0.81 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 7 (63.6%) \| 0.83 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 9 (81.8%) \| 0.77 (0.19) | n= 7 (77.8%) \| 0.60 (0.41) | 0.51 [-0.53 ; 1.55] |
| Week 51 | n= 9 (81.8%) \| 0.76 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 7 (63.6%) \| 0.84 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (63.6%) \| 0.84 (0.18) | n= 7 (77.8%) \| 0.80 (0.14) | 0.20 [-0.90 ; 1.29] |
| Week 57 | n= 6 (54.5%) \| 0.82 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 8 (72.7%) \| 0.76 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (72.7%) \| 0.81 (0.21) | n= 6 (66.7%) \| 0.59 (0.45) | 0.64 [-0.49 ; 1.78] |
| Week 63 | n= 7 (63.6%) \| 0.77 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (63.6%) \| 0.82 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \| 0.83 (0.16) | n= 6 (66.7%) \| 0.66 (0.29) | 0.70 [-0.44 ; 1.84] |
| Week 69 | n= 8 (72.7%) \| 0.75 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 8 (72.7%) \| 0.68 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 8 (72.7%) \| 0.78 (0.24) | n= 6 (66.7%) \| 0.66 (0.07) | 0.62 [-0.51 ; 1.75] |
| Week 75 | n= 8 (72.7%) \| 0.76 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (54.5%) \| 0.79 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (54.5%) \| 0.82 (0.21) | n= 4 (44.4%) \| 0.75 (0.17) | 0.34 [-1.02 ; 1.69] |
| Week 81 | n= 6 (54.5%) \| 0.74 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 9 (81.8%) \| 0.79 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (63.6%) \| 0.82 (0.22) | n= 3 (33.3%) \| 0.69 (0.04) | 0.61 [-0.86 ; 2.08] |
| Week 87 | n= 6 (54.5%) \| 0.72 (0.24) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 8 (72.7%) \| 0.74 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 8 (72.7%) \| 0.78 (0.24) | n= 2 (22.2%) \| 0.79 (0.09) | -0.03 [-1.68 ; 1.62] |
| Week 93 | n= 6 (54.5%) \| 0.79 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 8 (72.7%) \| 0.78 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (63.6%) \| 0.77 (0.23) | n= 1 (11.1%) \| 0.85 ( / ) | [Not calculable] |
| Week 99 | n= 6 (54.5%) \| 0.82 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 5 (45.5%) \| 0.86 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 5 (45.5%) \| 0.82 (0.18) | n= 1 (11.1%) \| 1.00 ( / ) | [Not calculable] |
| Week 105 | n= 5 (45.5%) \| 0.77 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \| 1.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (27.3%) \| 0.77 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 ( 9.1%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (27.3%) \| 0.77 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 2 (18.2%) \| 0.76 (0.34) | n= 2 (22.2%) \| 0.67 (0.02) | 0.20 [-2.28 ; 2.68] |
| Week 117 | n= 2 (18.2%) \| 0.76 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (18.2%) \| 0.76 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (18.2%) \| 0.88 (0.17) | n= 1 (11.1%) \| 0.62 ( / ) | [Not calculable] |
| Week 125 | n= 1 ( 9.1%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 9.1%) \| 0.80 ( / ) | n= 1 (11.1%) \| 0.62 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 9.1%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 9.1%) \| 0.82 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 9.1%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (27.3%) \| 0.85 (0.14) | n= 3 (33.3%) \| 0.76 (0.21) | 0.38 [-1.46 ; 2.22] |
| Week 202 | [No Data] | n= 1 (11.1%) \| 0.71 ( / ) | [No Data for at least 1 arm] |

**< 1%**

| N subjects in population | N=58 | N=58 | |
|---|---|---|---|
| Baseline | n= 58 (100.0%) \| 0.85 (0.17) | n= 58 (100.0%) \| 0.79 (0.29) | 0.26 [-0.11 ; 0.62] |
| Week 3 | n= 53 (91.4%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 53 (91.4%) \| 0.83 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 52 (89.7%) \| 0.82 (0.19) | n= 52 (89.7%) \| 0.79 (0.23) | 0.14 [-0.25 ; 0.52] |
| Week 9 | n= 49 (84.5%) \| 0.82 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 51 (87.9%) \| 0.80 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 49 (84.5%) \| 0.82 (0.17) | n= 44 (75.9%) \| 0.76 (0.22) | 0.34 [-0.07 ; 0.75] |
| Week 15 | n= 45 (77.6%) \| 0.80 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 50 (86.2%) \| 0.81 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 47 (81.0%) \| 0.83 (0.16) | n= 43 (74.1%) \| 0.83 (0.21) | 0.03 [-0.39 ; 0.44] |
| Week 21 | n= 50 (86.2%) \| 0.84 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 44 (75.9%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 48 (82.8%) \| 0.85 (0.18) | n= 43 (74.1%) \| 0.81 (0.18) | 0.18 [-0.23 ; 0.60] |
| Week 27 | n= 46 (79.3%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 44 (75.9%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (77.6%) \| 0.84 (0.18) | n= 37 (63.8%) \| 0.80 (0.23) | 0.18 [-0.26 ; 0.61] |
| Week 33 | n= 46 (79.3%) \| 0.83 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 44 (75.9%) \| 0.82 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 40 (69.0%) \| 0.87 (0.16) | n= 37 (63.8%) \| 0.82 (0.17) | 0.26 [-0.19 ; 0.71] |
| Week 39 | n= 43 (74.1%) \| 0.84 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 40 (69.0%) \| 0.86 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 43 (74.1%) \| 0.84 (0.18) | n= 33 (56.9%) \| 0.82 (0.19) | 0.13 [-0.33 ; 0.59] |
| Week 45 | n= 41 (70.7%) \| 0.87 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 44 (75.9%) \| 0.87 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 43 (74.1%) \| 0.88 (0.16) | n= 29 (50.0%) \| 0.81 (0.19) | 0.38 [-0.10 ; 0.85] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 51 | n= 41 (70.7%) \| 0.85 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 40 (69.0%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (67.2%) \| 0.85 (0.16) | n= 30 (51.7%) \| 0.83 (0.19) | 0.11 [-0.37 ; 0.59] |
| Week 57 | n= 40 (69.0%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 35 (60.3%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (67.2%) \| 0.86 (0.17) | n= 24 (41.4%) \| 0.82 (0.20) | 0.21 [-0.31 ; 0.72] |
| Week 63 | n= 34 (58.6%) \| 0.84 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (62.1%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (62.1%) \| 0.85 (0.20) | n= 24 (41.4%) \| 0.84 (0.13) | 0.05 [-0.47 ; 0.57] |
| Week 69 | n= 28 (48.3%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (53.4%) \| 0.86 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 26 (44.8%) \| 0.83 (0.16) | n= 21 (36.2%) \| 0.78 (0.22) | 0.27 [-0.32 ; 0.85] |
| Week 75 | n= 28 (48.3%) \| 0.87 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (44.8%) \| 0.86 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 25 (43.1%) \| 0.87 (0.16) | n= 20 (34.5%) \| 0.80 (0.22) | 0.38 [-0.22 ; 0.98] |
| Week 81 | n= 25 (43.1%) \| 0.86 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 24 (41.4%) \| 0.86 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (34.5%) \| 0.89 (0.14) | n= 17 (29.3%) \| 0.78 (0.21) | 0.59 [-0.08 ; 1.26] |
| Week 87 | n= 18 (31.0%) \| 0.81 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 17 (29.3%) \| 0.86 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 16 (27.6%) \| 0.80 (0.23) | n= 15 (25.9%) \| 0.84 (0.15) | -0.18 [-0.90 ; 0.54] |
| Week 93 | n= 14 (24.1%) \| 0.81 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 14 (24.1%) \| 0.80 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 14 (24.1%) \| 0.79 (0.25) | n= 9 (15.5%) \| 0.82 (0.19) | -0.12 [-0.98 ; 0.74] |
| Week 99 | n= 11 (19.0%) \| 0.73 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 9 (15.5%) \| 0.78 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 10 (17.2%) \| 0.80 (0.12) | n= 8 (13.8%) \| 0.82 (0.18) | -0.13 [-1.09 ; 0.83] |
| Week 105 | n= 9 (15.5%) \| 0.73 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.3%) \| 0.74 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (13.8%) \| 0.64 (0.25) | n= 4 ( 6.9%) \| 0.95 (0.10) | -1.34 [-2.74 ; 0.06] |
| Week 111 | n= 6 (10.3%) \| 0.51 (0.55) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 ( 8.6%) \| 0.82 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 6.9%) \| 0.83 (0.20) | n= 3 ( 5.2%) \| 0.93 (0.12) | -0.51 [-2.20 ; 1.18] |
| Week 117 | n= 4 ( 6.9%) \| 0.71 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 6.9%) \| 0.68 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (10.3%) \| 0.74 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 1.7%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.7%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 ( 8.6%) \| 0.87 (0.14) | n= 14 (24.1%) \| 0.73 (0.26) | 0.56 [-0.51 ; 1.63] |
| Week 202 | n= 1 ( 1.7%) \| 0.69 ( / ) | n= 11 (19.0%) \| 0.83 (0.20) | [Not calculable] |
| Week 301 | n= 1 ( 1.7%) \| 1.00 ( / ) | n= 9 (15.5%) \| 0.82 (0.16) | [Not calculable] |
| Week 302 | n= 2 ( 3.4%) \| 0.69 (0.05) | n= 6 (10.3%) \| 0.72 (0.07) | -0.44 [-2.20 ; 1.32] |
| Week 303 | n= 3 ( 5.2%) \| 0.76 (0.21) | n= 6 (10.3%) \| 0.67 (0.29) | 0.29 [-1.21 ; 1.78] |
| Week 304 | n= 1 ( 1.7%) \| 1.00 ( / ) | n= 3 ( 5.2%) \| 0.58 (0.29) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.7%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.7%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.7%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.7%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.7%) \| 1.00 ( / ) | [No Data for at least 1 arm] |

**Not Reported**

| | | |
|---|---|---|
| N subjects in population | N=2 | N=1 |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Baseline | n= 2 (100.0%) \| 0.85 (0.22) | n= 1 (100.0%) \| 0.85 ( / ) | . [ . ; .] |
| Week 3 | n= 2 (100.0%) \| 0.58 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (100.0%) \| 0.45 (0.10) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 2 (100.0%) \| 0.64 (0.07) | n= 1 (100.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 11 | n= 1 (50.0%) \| 0.88 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (50.0%) \| 0.64 ( / ) | n= 1 (100.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 15 | n= 1 (50.0%) \| 0.59 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 1 (50.0%) \| 0.59 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (50.0%) \| 0.69 ( / ) | n= 1 (100.0%) \| 0.85 ( / ) | [Not calculable] |
| Week 21 | n= 1 (50.0%) \| 0.71 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (50.0%) \| 0.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (50.0%) \| 0.71 ( / ) | n= 1 (100.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 27 | n= 1 (50.0%) \| 0.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 1 (50.0%) \| 0.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (50.0%) \| 0.71 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (50.0%) \| 0.88 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 1 (50.0%) \| 0.82 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (50.0%) \| 0.88 ( / ) | n= 1 (100.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 39 | n= 1 (50.0%) \| 0.68 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (50.0%) \| 0.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (50.0%) \| 0.85 ( / ) | n= 1 (100.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 45 | n= 1 (50.0%) \| 0.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (50.0%) \| 0.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (50.0%) \| 0.82 ( / ) | n= 1 (100.0%) \| 0.73 ( / ) | [Not calculable] |
| Week 51 | n= 1 (50.0%) \| 0.64 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (50.0%) \| 0.62 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (50.0%) \| 0.52 ( / ) | n= 1 (100.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 57 | n= 1 (50.0%) \| 0.59 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (50.0%) \|-0.02 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (50.0%) \| 0.52 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (50.0%) \| 0.59 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (50.0%) \| 0.52 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 202 | n= 1 (50.0%) \| 0.19 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 301 | n= 1 (50.0%) \| 0.52 ( / ) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:56

TABLE 7.2.11: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **>= 1%** | | | |
| N subjects in population | N=11 | N=9 | |
| Week 3 | n= 11 (100.0%) \| 0.00 (0.06) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 9 (81.8%) \|-0.06 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 10 (90.9%) \|-0.11 (0.17) | n= 9 (100.0%) \|-0.03 (0.07) | -0.57 [-1.52 ; 0.37] |
| Week 9 | n= 10 (90.9%) \|-0.05 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (81.8%) \|-0.03 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 9 (81.8%) \| 0.01 (0.15) | n= 7 (77.8%) \|-0.13 (0.31) | 0.57 [-0.48 ; 1.61] |
| Week 15 | n= 8 (72.7%) \|-0.12 (0.39) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 10 (90.9%) \|-0.00 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 9 (81.8%) \|-0.02 (0.25) | n= 7 (77.8%) \|-0.06 (0.12) | 0.18 [-0.84 ; 1.21] |
| Week 21 | n= 9 (81.8%) \|-0.04 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \| 0.01 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 9 (81.8%) \|-0.02 (0.11) | n= 6 (66.7%) \|-0.06 (0.12) | 0.32 [-0.76 ; 1.40] |
| Week 27 | n= 8 (72.7%) \|-0.02 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 8 (72.7%) \|-0.07 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 8 (72.7%) \|-0.03 (0.08) | n= 6 (66.7%) \|-0.09 (0.13) | 0.56 [-0.56 ; 1.69] |
| Week 33 | n= 10 (90.9%) \| 0.02 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (72.7%) \| 0.06 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \|-0.02 (0.12) | n= 6 (66.7%) \|-0.09 (0.06) | 0.74 [-0.41 ; 1.88] |
| Week 39 | n= 9 (81.8%) \| 0.05 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 10 (90.9%) \| 0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 9 (81.8%) \| 0.04 (0.16) | n= 7 (77.8%) \|-0.11 (0.14) | 0.89 [-0.18 ; 1.97] |
| Week 45 | n= 7 (63.6%) \| 0.06 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 7 (63.6%) \| 0.05 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 9 (81.8%) \| 0.02 (0.20) | n= 7 (77.8%) \|-0.26 (0.35) | 0.97 [-0.12 ; 2.05] |
| Week 51 | n= 9 (81.8%) \| 0.02 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 7 (63.6%) \|-0.02 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (63.6%) \| 0.11 (0.23) | n= 7 (77.8%) \|-0.06 (0.16) | 0.81 [-0.33 ; 1.95] |
| Week 57 | n= 6 (54.5%) \| 0.12 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 8 (72.7%) \| 0.02 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (72.7%) \| 0.08 (0.21) | n= 6 (66.7%) \|-0.28 (0.37) | 1.15 [-0.05 ; 2.35] |
| Week 63 | n= 7 (63.6%) \| 0.07 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (63.6%) \| 0.12 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \| 0.00 (0.14) | n= 6 (66.7%) \|-0.20 (0.21) | 1.12 [-0.07 ; 2.31] |
| Week 69 | n= 8 (72.7%) \| 0.04 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 8 (72.7%) \|-0.03 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 8 (72.7%) \| 0.03 (0.20) | n= 6 (66.7%) \|-0.21 (0.17) | 1.19 [-0.01 ; 2.40] |
| Week 75 | n= 8 (72.7%) \| 0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (54.5%) \| 0.05 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (54.5%) \| 0.11 (0.18) | n= 4 (44.4%) \|-0.09 (0.15) | 1.08 [-0.38 ; 2.53] |
| Week 81 | n= 6 (54.5%) \| 0.03 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 9 (81.8%) \| 0.05 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (63.6%) \|-0.02 (0.12) | n= 3 (33.3%) \|-0.24 (0.12) | 1.62 [-0.04 ; 3.28] |
| Week 87 | n= 6 (54.5%) \|-0.01 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 8 (72.7%) \|-0.01 (0.20) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 8 (72.7%) \| 0.03 (0.20) | n= 2 (22.2%) \|-0.21 (0.09) | 1.18 [-0.58 ; 2.93] |
| Week 93 | n= 6 (54.5%) \| 0.06 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 8 (72.7%) \| 0.04 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (63.6%) \| 0.02 (0.21) | n= 1 (11.1%) \|-0.15 ( / ) | [Not calculable] |
| Week 99 | n= 6 (54.5%) \| 0.06 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 5 (45.5%) \|-0.06 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 5 (45.5%) \|-0.07 (0.09) | n= 1 (11.1%) \| 0.00 ( / ) | [Not calculable] |
| Week 105 | n= 5 (45.5%) \|-0.08 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (27.3%) \|-0.11 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 ( 9.1%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (27.3%) \|-0.11 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 2 (18.2%) \|-0.13 (0.19) | n= 2 (22.2%) \|-0.33 (0.02) | 0.84 [-1.93 ; 3.61] |
| Week 117 | n= 2 (18.2%) \|-0.13 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (18.2%) \|-0.13 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (18.2%) \|-0.04 (0.06) | n= 1 (11.1%) \|-0.38 ( / ) | [Not calculable] |
| Week 125 | n= 1 ( 9.1%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 9.1%) \|-0.05 ( / ) | n= 1 (11.1%) \|-0.38 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 9.1%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 9.1%) \|-0.03 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 9.1%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (27.3%) \| 0.11 (0.33) | n= 3 (33.3%) \|-0.12 (0.28) | 0.60 [-1.28 ; 2.48] |
| Week 202 | [No Data] | n= 1 (11.1%) \|-0.29 ( / ) | [No Data for at least 1 arm] |
| **< 1%** | | | |
| N subjects in population | N=58 | N=58 | |
| Week 3 | n= 53 (91.4%) \| 0.01 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 53 (91.4%) \|-0.03 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 52 (89.7%) \|-0.03 (0.21) | n= 52 (89.7%) \| 0.01 (0.22) | -0.20 [-0.59 ; 0.18] |
| Week 9 | n= 49 (84.5%) \|-0.03 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 51 (87.9%) \|-0.05 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 49 (84.5%) \|-0.03 (0.19) | n= 44 (75.9%) \|-0.07 (0.24) | 0.20 [-0.21 ; 0.61] |
| Week 15 | n= 45 (77.6%) \|-0.05 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 50 (86.2%) \|-0.04 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 47 (81.0%) \|-0.01 (0.16) | n= 43 (74.1%) \|-0.00 (0.21) | -0.05 [-0.46 ; 0.37] |
| Week 21 | n= 50 (86.2%) \|-0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 44 (75.9%) \|-0.03 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 48 (82.8%) \|-0.01 (0.19) | n= 43 (74.1%) \|-0.06 (0.15) | 0.28 [-0.14 ; 0.70] |
| Week 27 | n= 46 (79.3%) \|-0.00 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 44 (75.9%) \|-0.00 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (77.6%) \|-0.02 (0.20) | n= 37 (63.8%) \|-0.07 (0.19) | 0.27 [-0.16 ; 0.71] |
| Week 33 | n= 46 (79.3%) \|-0.03 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 44 (75.9%) \|-0.03 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 40 (69.0%) \| 0.00 (0.19) | n= 37 (63.8%) \|-0.07 (0.16) | 0.42 [-0.03 ; 0.87] |
| Week 39 | n= 43 (74.1%) \|-0.02 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 40 (69.0%) \|-0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 43 (74.1%) \|-0.02 (0.20) | n= 33 (56.9%) \|-0.06 (0.20) | 0.20 [-0.26 ; 0.66] |
| Week 45 | n= 41 (70.7%) \| 0.00 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 44 (75.9%) \|-0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 43 (74.1%) \| 0.02 (0.17) | n= 29 (50.0%) \|-0.04 (0.17) | 0.36 [-0.12 ; 0.84] |
| Week 51 | n= 41 (70.7%) \|-0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 40 (69.0%) \| 0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 55 | n= 39 (67.2%) \|-0.01 (0.19) | n= 30 (51.7%) \|-0.03 (0.18) | 0.11 [-0.37 ; 0.59] |
| Week 57 | n= 40 (69.0%) \|-0.03 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 35 (60.3%) \|-0.01 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (67.2%) \|-0.02 (0.21) | n= 24 (41.4%) \|-0.06 (0.18) | 0.20 [-0.31 ; 0.72] |
| Week 63 | n= 34 (58.6%) \|-0.02 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (62.1%) \| 0.01 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (62.1%) \|-0.02 (0.23) | n= 24 (41.4%) \|-0.03 (0.15) | 0.05 [-0.47 ; 0.57] |
| Week 69 | n= 28 (48.3%) \|-0.02 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (53.4%) \| 0.01 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 26 (44.8%) \|-0.00 (0.23) | n= 21 (36.2%) \|-0.07 (0.20) | 0.28 [-0.30 ; 0.86] |
| Week 75 | n= 28 (48.3%) \| 0.04 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (44.8%) \| 0.03 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 25 (43.1%) \| 0.04 (0.22) | n= 20 (34.5%) \|-0.05 (0.20) | 0.46 [-0.15 ; 1.06] |
| Week 81 | n= 25 (43.1%) \| 0.02 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 24 (41.4%) \| 0.02 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (34.5%) \| 0.04 (0.18) | n= 17 (29.3%) \|-0.08 (0.23) | 0.58 [-0.09 ; 1.25] |
| Week 87 | n= 18 (31.0%) \|-0.07 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 17 (29.3%) \| 0.00 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 16 (27.6%) \|-0.08 (0.19) | n= 15 (25.9%) \|-0.04 (0.24) | -0.16 [-0.88 ; 0.55] |
| Week 93 | n= 14 (24.1%) \|-0.06 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 14 (24.1%) \|-0.09 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 14 (24.1%) \|-0.09 (0.18) | n= 9 (15.5%) \|-0.09 (0.22) | -0.01 [-0.86 ; 0.85] |
| Week 99 | n= 11 (19.0%) \|-0.13 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 9 (15.5%) \|-0.10 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 10 (17.2%) \|-0.07 (0.17) | n= 8 (13.8%) \|-0.11 (0.20) | 0.23 [-0.73 ; 1.19] |
| Week 105 | n= 9 (15.5%) \|-0.14 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.3%) \|-0.13 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (13.8%) \|-0.17 (0.33) | n= 4 ( 6.9%) \| 0.00 (0.00) | -0.57 [-1.86 ; 0.71] |
| Week 111 | n= 6 (10.3%) \|-0.34 (0.46) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 ( 8.6%) \|-0.06 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 6.9%) \| 0.02 (0.31) | n= 3 ( 5.2%) \| 0.00 (0.00) | 0.07 [-1.58 ; 1.72] |
| Week 117 | n= 4 ( 6.9%) \|-0.22 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 6.9%) \|-0.17 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (10.3%) \|-0.13 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 1.7%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.7%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 ( 8.6%) \|-0.03 (0.17) | n= 14 (24.1%) \|-0.12 (0.25) | 0.38 [-0.68 ; 1.43] |
| Week 202 | n= 1 ( 1.7%) \|-0.31 ( / ) | n= 11 (19.0%) \|-0.05 (0.18) | [Not calculable] |
| Week 301 | n= 1 ( 1.7%) \| 0.15 ( / ) | n= 9 (15.5%) \| 0.08 (0.16) | [Not calculable] |
| Week 302 | n= 2 ( 3.4%) \|-0.04 (0.11) | n= 6 (10.3%) \|-0.13 (0.16) | 0.50 [-1.27 ; 2.26] |
| Week 303 | n= 3 ( 5.2%) \|-0.01 (0.19) | n= 6 (10.3%) \|-0.18 (0.28) | 0.57 [-0.95 ; 2.09] |
| Week 304 | n= 1 ( 1.7%) \| 0.15 ( / ) | n= 3 ( 5.2%) \|-0.20 (0.22) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 1.7%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 1.7%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 1.7%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 1.7%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 1.7%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| **Not Reported** | | | |
| N subjects in population | N=2 | N=1 | |
| Week 3 | n= 2 (100.0%) \|-0.27 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (100.0%) \|-0.40 (0.32) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 7 | n= 2 (100.0%) \|-0.21 (0.15) | n= 1 (100.0%) \| 0.15 ( / ) | [Not calculable] |
| Week 11 | n= 1 (50.0%) \|-0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (50.0%) \|-0.36 ( / ) | n= 1 (100.0%) \| 0.15 ( / ) | [Not calculable] |
| Week 15 | n= 1 (50.0%) \|-0.41 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 1 (50.0%) \|-0.41 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (50.0%) \|-0.31 ( / ) | n= 1 (100.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 21 | n= 1 (50.0%) \|-0.29 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (50.0%) \|-0.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (50.0%) \|-0.29 ( / ) | n= 1 (100.0%) \| 0.15 ( / ) | [Not calculable] |
| Week 27 | n= 1 (50.0%) \|-0.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 1 (50.0%) \|-0.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (50.0%) \|-0.29 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (50.0%) \|-0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 1 (50.0%) \|-0.19 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (50.0%) \|-0.12 ( / ) | n= 1 (100.0%) \| 0.15 ( / ) | [Not calculable] |
| Week 39 | n= 1 (50.0%) \|-0.32 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (50.0%) \|-0.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (50.0%) \|-0.15 ( / ) | n= 1 (100.0%) \| 0.15 ( / ) | [Not calculable] |
| Week 45 | n= 1 (50.0%) \|-0.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (50.0%) \|-0.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (50.0%) \|-0.19 ( / ) | n= 1 (100.0%) \|-0.12 ( / ) | [Not calculable] |
| Week 51 | n= 1 (50.0%) \|-0.36 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (50.0%) \|-0.38 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (50.0%) \|-0.48 ( / ) | n= 1 (100.0%) \| 0.15 ( / ) | [Not calculable] |
| Week 57 | n= 1 (50.0%) \|-0.41 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (50.0%) \|-1.02 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (50.0%) \|-0.48 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (50.0%) \|-0.41 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (50.0%) \|-0.48 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 202 | n= 1 (50.0%) \|-0.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 301 | n= 1 (50.0%) \|-0.17 ( / ) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:57

TABLE 7.2.11: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **>= 1%** | | | | |
| Nr subjects used | n=11 | n=9 | | |
| **< 1%** | | | | |
| Nr subjects used | n=58 | n=58 | | |
| Week 7 | -0.04 (0.03) [-0.09 ; 0.01] | -0.03 (0.03) [-0.08 ; 0.03] | -0.01 (0.04) [-0.09 ; 0.06] | -0.07 [-0.45 ; 0.32] |
| Week 13 | -0.03 (0.03) [-0.09 ; 0.02] | -0.09 (0.03) [-0.15 ;-0.03] | 0.06 (0.04) [-0.03 ; 0.14] | 0.28 [-0.13 ; 0.69] |
| Week 19 | -0.02 (0.02) [-0.07 ; 0.03] | -0.02 (0.02) [-0.07 ; 0.03] | -0.00 (0.03) [-0.07 ; 0.07] | -0.00 [-0.41 ; 0.41] |
| Week 25 | -0.01 (0.02) [-0.06 ; 0.03] | -0.05 (0.02) [-0.10 ;-0.00] | 0.04 (0.03) [-0.03 ; 0.10] | 0.22 [-0.19 ; 0.63] |
| Week 31 | -0.03 (0.03) [-0.08 ; 0.03] | -0.06 (0.03) [-0.12 ;-0.00] | 0.04 (0.04) [-0.05 ; 0.12] | 0.19 [-0.24 ; 0.63] |
| Week 37 | 0.01 (0.02) [-0.04 ; 0.06] | -0.05 (0.02) [-0.10 ;-0.00] | 0.06 (0.03) [-0.00 ; 0.13] | 0.42 [-0.03 ; 0.87] |
| Week 43 | -0.01 (0.02) [-0.06 ; 0.04] | -0.05 (0.03) [-0.10 ; 0.01] | 0.03 (0.04) [-0.04 ; 0.11] | 0.20 [-0.25 ; 0.66] |
| Week 49 | 0.02 (0.02) [-0.02 ; 0.06] | -0.03 (0.02) [-0.08 ; 0.01] | 0.05 (0.03) [-0.01 ; 0.11] | 0.38 [-0.10 ; 0.85] |
| Week 55 | -0.01 (0.02) [-0.05 ; 0.03] | -0.02 (0.03) [-0.07 ; 0.03] | 0.01 (0.03) [-0.06 ; 0.08] | 0.06 [-0.42 ; 0.53] |
| Week 61 | -0.02 (0.03) [-0.07 ; 0.03] | -0.02 (0.03) [-0.09 ; 0.04] | 0.00 (0.04) [-0.08 ; 0.08] | 0.00 [-0.51 ; 0.51] |
| Week 67 | -0.02 (0.03) [-0.07 ; 0.03] | -0.03 (0.03) [-0.09 ; 0.04] | 0.01 (0.04) [-0.08 ; 0.09] | 0.05 [-0.46 ; 0.57] |
| Week 73 | -0.01 (0.03) [-0.07 ; 0.04] | -0.05 (0.03) [-0.12 ; 0.01] | 0.04 (0.04) [-0.04 ; 0.12] | 0.27 [-0.30 ; 0.85] |
| Week 79 | 0.02 (0.03) [-0.03 ; 0.08] | -0.04 (0.03) [-0.10 ; 0.02] | 0.06 (0.04) [-0.02 ; 0.14] | 0.41 [-0.18 ; 1.01] |
| Week 85 | 0.02 (0.03) [-0.04 ; 0.08] | -0.07 (0.03) [-0.13 ;-0.00] | 0.08 (0.04) [-0.00 ; 0.17] | 0.63 [-0.03 ; 1.30] |
| Week 91 | -0.03 (0.04) [-0.12 ; 0.06] | -0.05 (0.05) [-0.15 ; 0.04] | 0.03 (0.06) [-0.10 ; 0.15] | 0.15 [-0.56 ; 0.85] |
| Overall post-baseline period estimate | -0.01 (0.01) [-0.04 ; 0.01] | -0.04 (0.01) [-0.07 ;-0.02] | 0.03 (0.02) [-0.01 ; 0.07] | 0.31 [-0.06 ; 0.68] |
| **Not Reported** | | | | |
| Nr subjects used | n=2 | n=1 | | |
| **MMRM subgroups interaction p-value** | | | | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:42:57

TABLE 7.2.12: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **Stage IV** | N=18 | N=20 |
| **Non-Stage IV** | N=50 | N=48 |
| **Not Reported** | N=3 | [No Data] |
| **Subjects with Baseline Value** | | |
| **Stage IV** | 18 (100.0%) | 20 (100.0%) |
| **Non-Stage IV** | 50 (100.0%) | 48 (100.0%) |
| **Not Reported** | 3 (100.0%) | [No Data] |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **Stage IV** | 18 (100.0%) | 20 (100.0%) |
| **Non-Stage IV** | 50 (100.0%) | 46 (95.8%) |
| **Not Reported** | 3 (100.0%) | [No Data] |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **Stage IV** | 18 (100.0%) | 20 (100.0%) |
| **Non-Stage IV** | 50 (100.0%) | 46 (95.8%) |
| **Not Reported** | 3 (100.0%) | [No Data] |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:43:00

TABLE 7.2.12: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Stage IV** | | | |
| N subjects in population | N=18 | N=20 | |
| Baseline | n= 18 (100.0%) \| 0.78 (0.21) | n= 20 (100.0%) \| 0.82 (0.27) | -0.16 [-0.81 ; 0.48] |
| Week 3 | n= 15 (83.3%) \| 0.78 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 17 (94.4%) \| 0.79 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 16 (88.9%) \| 0.80 (0.17) | n= 20 (100.0%) \| 0.80 (0.26) | -0.02 [-0.69 ; 0.64] |
| Week 9 | n= 14 (77.8%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (83.3%) \| 0.80 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 17 (94.4%) \| 0.74 (0.21) | n= 13 (65.0%) \| 0.78 (0.22) | -0.16 [-0.90 ; 0.57] |
| Week 15 | n= 15 (83.3%) \| 0.77 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (77.8%) \| 0.79 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 14 (77.8%) \| 0.75 (0.16) | n= 14 (70.0%) \| 0.82 (0.11) | -0.47 [-1.23 ; 0.30] |
| Week 21 | n= 16 (88.9%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 12 (66.7%) \| 0.80 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 15 (83.3%) \| 0.81 (0.23) | n= 14 (70.0%) \| 0.84 (0.12) | -0.14 [-0.88 ; 0.60] |
| Week 27 | n= 15 (83.3%) \| 0.79 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 14 (77.8%) \| 0.80 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 16 (88.9%) \| 0.82 (0.18) | n= 11 (55.0%) \| 0.86 (0.13) | -0.21 [-1.00 ; 0.57] |
| Week 33 | n= 15 (83.3%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (72.2%) \| 0.83 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 13 (72.2%) \| 0.83 (0.18) | n= 12 (60.0%) \| 0.88 (0.11) | -0.33 [-1.13 ; 0.48] |
| Week 39 | n= 14 (77.8%) \| 0.82 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 13 (72.2%) \| 0.84 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 14 (77.8%) \| 0.77 (0.17) | n= 13 (65.0%) \| 0.83 (0.18) | -0.37 [-1.14 ; 0.41] |
| Week 45 | n= 13 (72.2%) \| 0.78 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 14 (77.8%) \| 0.81 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 15 (83.3%) \| 0.84 (0.17) | n= 12 (60.0%) \| 0.80 (0.13) | 0.23 [-0.55 ; 1.00] |
| Week 51 | n= 12 (66.7%) \| 0.80 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (72.2%) \| 0.82 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 10 (55.6%) \| 0.80 (0.15) | n= 11 (55.0%) \| 0.81 (0.16) | -0.09 [-0.97 ; 0.78] |
| Week 57 | n= 10 (55.6%) \| 0.82 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 11 (61.1%) \| 0.78 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 12 (66.7%) \| 0.79 (0.19) | n= 7 (35.0%) \| 0.81 (0.13) | -0.12 [-1.08 ; 0.84] |
| Week 63 | n= 10 (55.6%) \| 0.85 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (61.1%) \| 0.83 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 11 (61.1%) \| 0.86 (0.17) | n= 8 (40.0%) \| 0.82 (0.12) | 0.21 [-0.73 ; 1.15] |
| Week 69 | n= 11 (61.1%) \| 0.81 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 10 (55.6%) \| 0.76 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 10 (55.6%) \| 0.80 (0.18) | n= 7 (35.0%) \| 0.82 (0.14) | -0.09 [-1.09 ; 0.90] |
| Week 75 | n= 9 (50.0%) \| 0.80 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 7 (38.9%) \| 0.82 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (50.0%) \| 0.80 (0.19) | n= 6 (30.0%) \| 0.85 (0.13) | -0.25 [-1.32 ; 0.83] |
| Week 81 | n= 7 (38.9%) \| 0.80 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (38.9%) \| 0.80 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (44.4%) \| 0.83 (0.15) | n= 6 (30.0%) \| 0.77 (0.13) | 0.40 [-0.71 ; 1.52] |
| Week 87 | n= 5 (27.8%) \| 0.75 (0.18) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 6 (33.3%) \| 0.70 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 6 (33.3%) \| 0.79 (0.17) | n= 4 (20.0%) \| 0.78 (0.17) | 0.05 [-1.29 ; 1.40] |
| Week 93 | n= 4 (22.2%) \| 0.68 (0.04) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (27.8%) \| 0.75 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (22.2%) \| 0.79 (0.15) | n= 1 ( 5.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 99 | n= 3 (16.7%) \| 0.69 (0.10) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (16.7%) \| 0.73 (0.06) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (22.2%) \| 0.82 (0.14) | n= 1 ( 5.0%) \| 0.82 ( / ) | [Not calculable] |
| Week 105 | n= 3 (16.7%) \| 0.70 (0.02) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.1%) \| 0.69 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (22.2%) \| 0.79 (0.15) | n= 1 ( 5.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 5.6%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.1%) \| 0.74 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 2 (11.1%) \| 0.84 (0.22) | n= 1 ( 5.0%) \| 0.69 ( / ) | [Not calculable] |
| Week 117 | n= 1 ( 5.6%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 5.6%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (16.7%) \| 0.82 (0.16) | n= 1 ( 5.0%) \| 0.62 ( / ) | [Not calculable] |
| Week 125 | n= 1 ( 5.6%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (11.1%) \| 0.90 (0.14) | n= 1 ( 5.0%) \| 0.62 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 5.6%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 5.6%) \| 0.82 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 5.6%) \| 0.80 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 5.6%) \| 1.00 ( / ) | n= 6 (30.0%) \| 0.89 (0.13) | [Not calculable] |
| Week 202 | n= 1 ( 5.6%) \| 0.19 ( / ) | n= 4 (20.0%) \| 0.79 (0.30) | [Not calculable] |
| Week 301 | n= 1 ( 5.6%) \| 0.52 ( / ) | n= 3 (15.0%) \| 0.86 (0.12) | [Not calculable] |
| Week 302 | [No Data] | n= 2 (10.0%) \| 0.77 (0.06) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 5.6%) \| 0.62 ( / ) | n= 2 (10.0%) \| 0.58 (0.60) | [Not calculable] |
| Week 304 | [No Data] | n= 2 (10.0%) \| 0.74 (0.07) | [No Data for at least 1 arm] |
| **Non-Stage IV** | | | |
| N subjects in population | N=50 | N=48 | |
| Baseline | n= 50 (100.0%) \| 0.86 (0.20) | n= 48 (100.0%) \| 0.77 (0.29) | 0.33 [-0.07 ; 0.73] |
| Week 3 | n= 48 (96.0%) \| 0.85 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 45 (90.0%) \| 0.80 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 45 (90.0%) \| 0.80 (0.23) | n= 42 (87.5%) \| 0.78 (0.24) | 0.09 [-0.34 ; 0.51] |
| Week 9 | n= 43 (86.0%) \| 0.79 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 44 (88.0%) \| 0.78 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 41 (82.0%) \| 0.83 (0.21) | n= 39 (81.3%) \| 0.75 (0.23) | 0.37 [-0.07 ; 0.82] |
| Week 15 | n= 38 (76.0%) \| 0.79 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 45 (90.0%) \| 0.79 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 42 (84.0%) \| 0.83 (0.21) | n= 37 (77.1%) \| 0.82 (0.22) | 0.05 [-0.39 ; 0.49] |
| Week 21 | n= 43 (86.0%) \| 0.80 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 42 (84.0%) \| 0.83 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 42 (84.0%) \| 0.84 (0.21) | n= 36 (75.0%) \| 0.80 (0.18) | 0.16 [-0.29 ; 0.61] |
| Week 27 | n= 39 (78.0%) \| 0.85 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 39 (78.0%) \| 0.83 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 37 (74.0%) \| 0.82 (0.23) | n= 32 (66.7%) \| 0.78 (0.24) | 0.18 [-0.29 ; 0.66] |
| Week 33 | n= 41 (82.0%) \| 0.81 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 40 (80.0%) \| 0.82 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 35 (70.0%) \| 0.86 (0.20) | n= 32 (66.7%) \| 0.79 (0.18) | 0.34 [-0.15 ; 0.82] |
| Week 39 | n= 38 (76.0%) \| 0.83 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 37 (74.0%) \| 0.85 (0.16) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | | Sunitinib | | Hedge G difference [95% CI] |
|---|---|---|---|---|---|
| Week 43 | n= 38 (76.0%) | 0.86 (0.18) | n= 28 (58.3%) | 0.80 (0.18) | 0.30 [-0.19 ; 0.80] |
| Week 45 | n= 35 (70.0%) | 0.89 (0.15) | | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 37 (74.0%) | 0.88 (0.16) | | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 37 (74.0%) | 0.87 (0.17) | n= 25 (52.1%) | 0.75 (0.30) | 0.49 [-0.03 ; 1.01] |
| Week 51 | n= 38 (76.0%) | 0.84 (0.20) | | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 34 (68.0%) | 0.86 (0.16) | | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 36 (72.0%) | 0.85 (0.18) | n= 27 (56.3%) | 0.84 (0.19) | 0.09 [-0.41 ; 0.60] |
| Week 57 | n= 36 (72.0%) | 0.85 (0.18) | | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 32 (64.0%) | 0.83 (0.22) | | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 35 (70.0%) | 0.85 (0.18) | n= 23 (47.9%) | 0.76 (0.30) | 0.40 [-0.14 ; 0.93] |
| Week 63 | n= 31 (62.0%) | 0.82 (0.21) | | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 32 (64.0%) | 0.84 (0.17) | | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (64.0%) | 0.84 (0.20) | n= 22 (45.8%) | 0.79 (0.20) | 0.21 [-0.34 ; 0.76] |
| Week 69 | n= 24 (48.0%) | 0.82 (0.18) | | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (56.0%) | 0.85 (0.16) | | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 24 (48.0%) | 0.83 (0.18) | n= 20 (41.7%) | 0.73 (0.22) | 0.48 [-0.13 ; 1.09] |
| Week 75 | n= 27 (54.0%) | 0.87 (0.19) | | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (48.0%) | 0.85 (0.19) | | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 21 (42.0%) | 0.89 (0.16) | n= 18 (37.5%) | 0.77 (0.23) | 0.59 [-0.06 ; 1.24] |
| Week 81 | n= 24 (48.0%) | 0.85 (0.18) | | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (50.0%) | 0.85 (0.17) | | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (38.0%) | 0.89 (0.17) | n= 14 (29.2%) | 0.77 (0.23) | 0.61 [-0.11 ; 1.32] |
| Week 87 | n= 19 (38.0%) | 0.80 (0.30) | | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (38.0%) | 0.86 (0.18) | | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 18 (36.0%) | 0.80 (0.25) | n= 13 (27.1%) | 0.85 (0.13) | -0.24 [-0.97 ; 0.48] |
| Week 93 | n= 16 (32.0%) | 0.84 (0.19) | | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (34.0%) | 0.80 (0.20) | | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (34.0%) | 0.78 (0.26) | n= 9 (18.8%) | 0.80 (0.18) | -0.08 [-0.90 ; 0.74] |
| Week 99 | n= 14 (28.0%) | 0.77 (0.26) | | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (22.0%) | 0.83 (0.21) | | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (22.0%) | 0.80 (0.14) | n= 8 (16.7%) | 0.84 (0.19) | -0.23 [-1.17 ; 0.71] |
| Week 105 | n= 11 (22.0%) | 0.75 (0.26) | | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (12.0%) | 0.85 (0.17) | | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (14.0%) | 0.60 (0.27) | n= 3 ( 6.3%) | 0.93 (0.12) | -1.23 [-2.81 ; 0.34] |
| Week 111 | n= 6 (12.0%) | 0.57 (0.58) | | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (12.0%) | 0.82 (0.21) | | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 8.0%) | 0.78 (0.25) | n= 4 ( 8.3%) | 0.86 (0.17) | -0.32 [-1.84 ; 1.20] |
| Week 117 | n= 5 (10.0%) | 0.73 (0.18) | | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (10.0%) | 0.71 (0.21) | | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (10.0%) | 0.76 (0.19) | | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.0%) | 0.85 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 (10.0%) | 0.83 (0.12) | n= 11 (22.9%) | 0.65 (0.26) | 0.75 [-0.38 ; 1.88] |
| Week 202 | n= 1 ( 2.0%) | 0.69 ( / ) | n= 8 (16.7%) | 0.84 (0.14) | [Not calculable] |
| Week 301 | n= 1 ( 2.0%) | 1.00 ( / ) | n= 6 (12.5%) | 0.79 (0.19) | [Not calculable] |
| Week 302 | n= 1 ( 2.0%) | 0.73 ( / ) | n= 4 ( 8.3%) | 0.70 (0.06) | [Not calculable] |
| Week 303 | n= 1 ( 2.0%) | 1.00 ( / ) | n= 4 ( 8.3%) | 0.72 (0.10) | [Not calculable] |
| Week 304 | n= 1 ( 2.0%) | 1.00 ( / ) | n= 1 ( 2.1%) | 0.26 ( / ) | [Not calculable] |
| Week 305 | | [No Data] | n= 1 ( 2.1%) | 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 306 | | [No Data] | n= 1 ( 2.1%) | 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 307 | | [No Data] | n= 1 ( 2.1%) | 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 308 | | [No Data] | n= 1 ( 2.1%) | 1.00 ( / ) | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 309 | [No Data] | n= 1 ( 2.1%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| **Not Reported** | | | |
| N subjects in population | N=3 | [No Data] | |
| Baseline | n= 3 (100.0%) \| 0.77 (0.20) | [No Data] | |
| Week 3 | n= 3 (100.0%) \| 0.74 (0.10) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (66.7%) \| 0.83 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 3 (100.0%) \| 0.70 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 9 | n= 2 (66.7%) \| 0.71 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 2 (66.7%) \| 0.72 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (33.3%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 15 | n= 1 (33.3%) \| 0.69 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 2 (66.7%) \| 0.85 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 21 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 27 | n= 1 (33.3%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (33.3%) \| 0.88 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 39 | n= 1 (33.3%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 45 | n= 1 (33.3%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 51 | n= 1 (33.3%) \| 0.88 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 57 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (33.3%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (33.3%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (33.3%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 1 (33.3%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 69 | n= 1 (33.3%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 1 (33.3%) \| 0.81 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 1 (33.3%) \| 0.85 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (66.7%) \| 0.86 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 302 | n= 1 (33.3%) \| 0.66 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 303 | n= 1 (33.3%) \| 0.66 ( / ) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:43:01

TABLE 7.2.12: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Stage IV** | | | |
| N subjects in population | N=18 | N=20 | |
| Week 3 | n= 15 (83.3%) \| 0.02 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 17 (94.4%) \| 0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 16 (88.9%) \| 0.01 (0.24) | n= 20 (100.0%) \|-0.02 (0.18) | 0.14 [-0.53 ; 0.80] |
| Week 9 | n= 14 (77.8%) \| 0.04 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (83.3%) \|-0.01 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 17 (94.4%) \|-0.03 (0.26) | n= 13 (65.0%) \|-0.14 (0.24) | 0.42 [-0.32 ; 1.17] |
| Week 15 | n= 15 (83.3%) \|-0.01 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (77.8%) \|-0.00 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 14 (77.8%) \|-0.02 (0.23) | n= 14 (70.0%) \|-0.07 (0.11) | 0.31 [-0.45 ; 1.07] |
| Week 21 | n= 16 (88.9%) \| 0.04 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 12 (66.7%) \|-0.00 (0.12) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 15 (83.3%) \| 0.02 (0.27) | n= 14 (70.0%) \|-0.07 (0.14) | 0.38 [-0.36 ; 1.13] |
| Week 27 | n= 15 (83.3%) \|-0.00 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 14 (77.8%) \| 0.03 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 16 (88.9%) \| 0.03 (0.23) | n= 11 (55.0%) \|-0.05 (0.14) | 0.42 [-0.37 ; 1.21] |
| Week 33 | n= 15 (83.3%) \| 0.04 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (72.2%) \| 0.06 (0.24) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 13 (72.2%) \| 0.04 (0.26) | n= 12 (60.0%) \|-0.04 (0.09) | 0.36 [-0.45 ; 1.17] |
| Week 39 | n= 14 (77.8%) \| 0.01 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 13 (72.2%) \| 0.03 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 14 (77.8%) \|-0.03 (0.25) | n= 13 (65.0%) \|-0.07 (0.21) | 0.15 [-0.62 ; 0.92] |
| Week 45 | n= 13 (72.2%) \|-0.02 (0.22) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 14 (77.8%) \| 0.00 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 15 (83.3%) \| 0.07 (0.20) | n= 12 (60.0%) \|-0.10 (0.10) | 0.96 [ 0.14 ; 1.78] |
| Week 51 | n= 12 (66.7%) \| 0.03 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (72.2%) \| 0.06 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 10 (55.6%) \| 0.04 (0.28) | n= 11 (55.0%) \|-0.08 (0.18) | 0.50 [-0.39 ; 1.40] |
| Week 57 | n= 10 (55.6%) \|-0.01 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 11 (61.1%) \|-0.01 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 12 (66.7%) \| 0.02 (0.27) | n= 7 (35.0%) \|-0.13 (0.11) | 0.63 [-0.35 ; 1.62] |
| Week 63 | n= 10 (55.6%) \| 0.07 (0.29) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (61.1%) \| 0.05 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 11 (61.1%) \| 0.08 (0.28) | n= 8 (40.0%) \|-0.07 (0.11) | 0.62 [-0.34 ; 1.58] |
| Week 69 | n= 11 (61.1%) \| 0.04 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 10 (55.6%) \|-0.02 (0.32) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 10 (55.6%) \| 0.02 (0.30) | n= 7 (35.0%) \|-0.10 (0.11) | 0.48 [-0.54 ; 1.49] |
| Week 75 | n= 9 (50.0%) \| 0.02 (0.30) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 7 (38.9%) \| 0.05 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (50.0%) \| 0.05 (0.30) | n= 6 (30.0%) \|-0.09 (0.14) | 0.52 [-0.57 ; 1.62] |
| Week 81 | n= 7 (38.9%) \| 0.01 (0.34) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (38.9%) \| 0.03 (0.35) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (44.4%) \| 0.05 (0.22) | n= 6 (30.0%) \|-0.19 (0.13) | 1.24 [ 0.03 ; 2.45] |
| Week 87 | n= 5 (27.8%) \|-0.11 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 6 (33.3%) \|-0.03 (0.23) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 6 (33.3%) \|-0.04 (0.17) | n= 4 (20.0%) \|-0.22 (0.17) | 0.97 [-0.46 ; 2.41] |
| Week 93 | n= 4 (22.2%) \|-0.13 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (27.8%) \|-0.07 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (22.2%) \|-0.02 (0.13) | n= 1 ( 5.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 99 | n= 3 (16.7%) \|-0.12 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (16.7%) \|-0.08 (0.07) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (22.2%) \|-0.00 (0.11) | n= 1 ( 5.0%) \|-0.19 ( / ) | [Not calculable] |
| Week 105 | n= 3 (16.7%) \|-0.11 (0.06) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.1%) \|-0.10 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (22.2%) \|-0.02 (0.13) | n= 1 ( 5.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 5.6%) \|-0.04 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.1%) \|-0.04 (0.01) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 2 (11.1%) \| 0.06 (0.13) | n= 1 ( 5.0%) \|-0.31 ( / ) | [Not calculable] |
| Week 117 | n= 1 ( 5.6%) \|-0.04 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 5.6%) \|-0.04 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (16.7%) \| 0.01 (0.13) | n= 1 ( 5.0%) \|-0.38 ( / ) | [Not calculable] |
| Week 125 | n= 1 ( 5.6%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (11.1%) \| 0.05 (0.14) | n= 1 ( 5.0%) \|-0.38 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 5.6%) \| 0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 5.6%) \|-0.03 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 5.6%) \|-0.05 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 5.6%) \| 0.15 ( / ) | n= 6 (30.0%) \| 0.02 (0.14) | [Not calculable] |
| Week 202 | n= 1 ( 5.6%) \|-0.50 ( / ) | n= 4 (20.0%) \|-0.08 (0.16) | [Not calculable] |
| Week 301 | n= 1 ( 5.6%) \|-0.17 ( / ) | n= 3 (15.0%) \|-0.02 (0.03) | [Not calculable] |
| Week 302 | [No Data] | n= 2 (10.0%) \|-0.05 (0.10) | [No Data for at least 1 arm] |
| Week 303 | n= 1 ( 5.6%) \|-0.23 ( / ) | n= 2 (10.0%) \|-0.24 (0.56) | [Not calculable] |
| Week 304 | [No Data] | n= 2 (10.0%) \|-0.08 (0.11) | [No Data for at least 1 arm] |
| **Non-Stage IV** | | | |
| N subjects in population | N=50 | N=48 | |
| Week 3 | n= 48 (96.0%) \|-0.01 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 45 (90.0%) \|-0.07 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 45 (90.0%) \|-0.07 (0.20) | n= 42 (87.5%) \| 0.02 (0.21) | -0.44 [-0.87 ;-0.01] |
| Week 9 | n= 43 (86.0%) \|-0.07 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 44 (88.0%) \|-0.07 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 41 (82.0%) \|-0.03 (0.14) | n= 39 (81.3%) \|-0.05 (0.25) | 0.09 [-0.35 ; 0.53] |
| Week 15 | n= 38 (76.0%) \|-0.09 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 45 (90.0%) \|-0.06 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 42 (84.0%) \|-0.02 (0.16) | n= 37 (77.1%) \| 0.01 (0.22) | -0.18 [-0.63 ; 0.27] |
| Week 21 | n= 43 (86.0%) \|-0.06 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 42 (84.0%) \|-0.03 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 42 (84.0%) \|-0.04 (0.14) | n= 36 (75.0%) \|-0.05 (0.14) | 0.11 [-0.33 ; 0.56] |
| Week 27 | n= 39 (78.0%) \|-0.02 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 39 (78.0%) \|-0.03 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 37 (74.0%) \|-0.06 (0.16) | n= 32 (66.7%) \|-0.08 (0.20) | 0.16 [-0.32 ; 0.64] |
| Week 33 | n= 41 (82.0%) \|-0.05 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 40 (80.0%) \|-0.04 (0.23) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 35 (70.0%) \|-0.02 (0.13) | n= 32 (66.7%) \|-0.08 (0.17) | 0.39 [-0.10 ; 0.88] |
| Week 39 | n= 38 (76.0%) \|-0.03 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 37 (74.0%) \|-0.03 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 38 (76.0%) \|-0.01 (0.17) | n= 28 (58.3%) \|-0.06 (0.19) | 0.29 [-0.20 ; 0.79] |
| Week 45 | n= 35 (70.0%) \| 0.01 (0.17) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 47 | n= 37 (74.0%) \|-0.01 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 37 (74.0%) \|-0.01 (0.16) | n= 25 (52.1%) \|-0.08 (0.27) | 0.34 [-0.17 ; 0.86] |
| Week 51 | n= 38 (76.0%) \|-0.04 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 34 (68.0%) \|-0.03 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 36 (72.0%) \|-0.01 (0.19) | n= 27 (56.3%) \|-0.01 (0.17) | -0.03 [-0.54 ; 0.47] |
| Week 57 | n= 36 (72.0%) \|-0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 32 (64.0%) \|-0.04 (0.25) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 35 (70.0%) \|-0.03 (0.20) | n= 23 (47.9%) \|-0.09 (0.27) | 0.27 [-0.26 ; 0.80] |
| Week 63 | n= 31 (62.0%) \|-0.04 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 32 (64.0%) \|-0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (64.0%) \|-0.05 (0.18) | n= 22 (45.8%) \|-0.06 (0.19) | 0.05 [-0.50 ; 0.60] |
| Week 69 | n= 24 (48.0%) \|-0.04 (0.20) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (56.0%) \| 0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 24 (48.0%) \|-0.00 (0.19) | n= 20 (41.7%) \|-0.10 (0.23) | 0.45 [-0.16 ; 1.05] |
| Week 75 | n= 27 (54.0%) \| 0.03 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (48.0%) \| 0.02 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 21 (42.0%) \| 0.06 (0.17) | n= 18 (37.5%) \|-0.05 (0.21) | 0.55 [-0.10 ; 1.20] |
| Week 81 | n= 24 (48.0%) \| 0.02 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (50.0%) \| 0.02 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (38.0%) \| 0.01 (0.14) | n= 14 (29.2%) \|-0.07 (0.24) | 0.39 [-0.32 ; 1.10] |
| Week 87 | n= 19 (38.0%) \|-0.04 (0.28) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (38.0%) \| 0.01 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 18 (36.0%) \|-0.04 (0.21) | n= 13 (27.1%) \|-0.01 (0.23) | -0.13 [-0.86 ; 0.59] |
| Week 93 | n= 16 (32.0%) \| 0.01 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (34.0%) \|-0.04 (0.18) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (34.0%) \|-0.06 (0.20) | n= 9 (18.8%) \|-0.11 (0.22) | 0.20 [-0.62 ; 1.03] |
| Week 99 | n= 14 (28.0%) \|-0.05 (0.21) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (22.0%) \|-0.09 (0.16) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (22.0%) \|-0.09 (0.15) | n= 8 (16.7%) \|-0.09 (0.20) | -0.01 [-0.95 ; 0.92] |
| Week 105 | n= 11 (22.0%) \|-0.12 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (12.0%) \|-0.10 (0.19) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (14.0%) \|-0.23 (0.33) | n= 3 ( 6.3%) \| 0.00 (0.00) | -0.72 [-2.20 ; 0.77] |
| Week 111 | n= 6 (12.0%) \|-0.34 (0.47) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (12.0%) \|-0.08 (0.26) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 8.0%) \|-0.07 (0.32) | n= 4 ( 8.3%) \|-0.09 (0.17) | 0.04 [-1.47 ; 1.54] |
| Week 117 | n= 5 (10.0%) \|-0.22 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (10.0%) \|-0.18 (0.13) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (10.0%) \|-0.18 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.0%) \|-0.15 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 (10.0%) \|-0.07 (0.24) | n= 11 (22.9%) \|-0.19 (0.27) | 0.44 [-0.67 ; 1.54] |
| Week 202 | n= 1 ( 2.0%) \|-0.31 ( / ) | n= 8 (16.7%) \|-0.07 (0.21) | [Not calculable] |
| Week 301 | n= 1 ( 2.0%) \| 0.15 ( / ) | n= 6 (12.5%) \| 0.12 (0.18) | [Not calculable] |
| Week 302 | n= 1 ( 2.0%) \|-0.12 ( / ) | n= 4 ( 8.3%) \|-0.17 (0.18) | [Not calculable] |
| Week 303 | n= 1 ( 2.0%) \| 0.15 ( / ) | n= 4 ( 8.3%) \|-0.15 (0.16) | [Not calculable] |
| Week 304 | n= 1 ( 2.0%) \| 0.15 ( / ) | n= 1 ( 2.1%) \|-0.43 ( / ) | [Not calculable] |
| Week 305 | [No Data] | n= 1 ( 2.1%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 306 | [No Data] | n= 1 ( 2.1%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 307 | [No Data] | n= 1 ( 2.1%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 308 | [No Data] | n= 1 ( 2.1%) \| 0.59 ( / ) | [No Data for at least 1 arm] |
| Week 309 | [No Data] | n= 1 ( 2.1%) \| 0.59 ( / ) | [No Data for at least 1 arm] |

**Not Reported**

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| N subjects in population | N=3 | [No Data] | |
| Week 3 | n= 3 (100.0%) \|-0.03 (0.11) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (66.7%) \| 0.02 (0.03) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 3 (100.0%) \|-0.07 (0.15) | [No Data] | [No Data for at least 1 arm] |
| Week 9 | n= 2 (66.7%) \| 0.05 (0.08) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 2 (66.7%) \| 0.06 (0.09) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (33.3%) \| 0.31 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 15 | n= 1 (33.3%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 2 (66.7%) \| 0.19 (0.17) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 21 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 27 | n= 1 (33.3%) \| 0.31 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (33.3%) \| 0.19 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 39 | n= 1 (33.3%) \| 0.16 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 45 | n= 1 (33.3%) \| 0.16 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 51 | n= 1 (33.3%) \| 0.19 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 57 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (33.3%) \| 0.16 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (33.3%) \| 0.31 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (33.3%) \| 0.31 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 1 (33.3%) \| 0.16 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 69 | n= 1 (33.3%) \| 0.31 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 1 (33.3%) \| 0.12 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 1 (33.3%) \| 0.16 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (66.7%) \| 0.21 (0.14) | [No Data] | [No Data for at least 1 arm] |
| Week 302 | n= 1 (33.3%) \| 0.04 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 303 | n= 1 (33.3%) \| 0.04 ( / ) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:43:01

TABLE 7.2.12: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **Stage IV** | | | | |
| Nr subjects used | n=18 | n=20 | | |
| Week 7 | -0.04 (0.05) [-0.13 ; 0.05] | -0.03 (0.04) [-0.11 ; 0.06] | -0.01 (0.06) [-0.14 ; 0.12] | -0.05 [-0.71 ; 0.60] |
| Week 13 | -0.07 (0.05) [-0.17 ; 0.04] | -0.10 (0.05) [-0.21 ; 0.01] | 0.03 (0.07) [-0.12 ; 0.18] | 0.16 [-0.57 ; 0.88] |
| Week 19 | -0.05 (0.03) [-0.12 ; 0.02] | -0.07 (0.03) [-0.14 ; 0.00] | 0.02 (0.05) [-0.08 ; 0.12] | 0.14 [-0.60 ; 0.89] |
| Week 25 | -0.02 (0.05) [-0.12 ; 0.07] | -0.01 (0.05) [-0.11 ; 0.08] | -0.01 (0.07) [-0.14 ; 0.12] | -0.06 [-0.79 ; 0.67] |
| Week 31 | 0.01 (0.04) [-0.07 ; 0.08] | -0.01 (0.04) [-0.10 ; 0.07] | 0.02 (0.06) [-0.09 ; 0.14] | 0.14 [-0.63 ; 0.91] |
| Week 37 | 0.02 (0.04) [-0.07 ; 0.11] | 0.00 (0.04) [-0.09 ; 0.10] | 0.01 (0.06) [-0.11 ; 0.14] | 0.08 [-0.71 ; 0.86] |
| Week 43 | -0.03 (0.05) [-0.13 ; 0.08] | -0.03 (0.05) [-0.14 ; 0.08] | 0.00 (0.07) [-0.15 ; 0.16] | 0.01 [-0.74 ; 0.77] |
| Week 49 | 0.03 (0.04) [-0.05 ; 0.10] | -0.05 (0.04) [-0.14 ; 0.03] | 0.08 (0.06) [-0.03 ; 0.19] | 0.54 [-0.23 ; 1.32] |
| Week 55 | 0.01 (0.05) [-0.10 ; 0.12] | -0.03 (0.05) [-0.14 ; 0.08] | 0.04 (0.08) [-0.12 ; 0.20] | 0.22 [-0.64 ; 1.08] |
| Overall post-baseline period estimate | -0.02 (0.03) [-0.07 ; 0.04] | -0.04 (0.03) [-0.09 ; 0.01] | 0.02 (0.04) [-0.05 ; 0.10] | 0.18 [-0.46 ; 0.82] |
| **Non-Stage IV** | | | | |
| Nr subjects used | n=50 | n=48 | | |
| Week 7 | -0.07 (0.03) [-0.12 ;-0.01] | -0.02 (0.03) [-0.08 ; 0.04] | -0.05 (0.04) [-0.13 ; 0.03] | -0.25 [-0.67 ; 0.17] |
| Week 13 | -0.03 (0.03) [-0.10 ; 0.03] | -0.08 (0.03) [-0.14 ;-0.01] | 0.05 (0.05) [-0.04 ; 0.14] | 0.22 [-0.22 ; 0.66] |
| Week 19 | -0.03 (0.03) [-0.08 ; 0.02] | -0.01 (0.03) [-0.06 ; 0.05] | -0.02 (0.04) [-0.10 ; 0.06] | -0.12 [-0.57 ; 0.32] |
| Week 25 | -0.02 (0.02) [-0.07 ; 0.02] | -0.05 (0.02) [-0.10 ;-0.01] | 0.03 (0.03) [-0.03 ; 0.10] | 0.21 [-0.24 ; 0.66] |
| Week 31 | -0.05 (0.03) [-0.11 ; 0.00] | -0.07 (0.03) [-0.14 ;-0.01] | 0.02 (0.04) [-0.07 ; 0.11] | 0.10 [-0.37 ; 0.58] |
| Week 37 | -0.01 (0.02) [-0.06 ; 0.04] | -0.07 (0.03) [-0.12 ;-0.02] | 0.06 (0.03) [-0.00 ; 0.13] | 0.45 [-0.04 ; 0.93] |
| Week 43 | -0.01 (0.02) [-0.06 ; 0.04] | -0.05 (0.03) [-0.11 ; 0.00] | 0.04 (0.04) [-0.03 ; 0.12] | 0.29 [-0.20 ; 0.78] |
| Week 49 | -0.00 (0.03) [-0.07 ; 0.06] | -0.08 (0.04) [-0.16 ;-0.00] | 0.08 (0.05) [-0.02 ; 0.18] | 0.39 [-0.12 ; 0.91] |
| Week 55 | -0.01 (0.03) [-0.07 ; 0.04] | -0.01 (0.03) [-0.07 ; 0.05] | -0.01 (0.04) [-0.09 ; 0.07] | -0.04 [-0.54 ; 0.45] |
| Week 61 | -0.04 (0.03) [-0.11 ; 0.03] | -0.07 (0.04) [-0.16 ; 0.01] | 0.03 (0.05) [-0.08 ; 0.14] | 0.16 [-0.37 ; 0.68] |
| Week 67 | -0.04 (0.03) [-0.10 ; 0.02] | -0.07 (0.04) [-0.14 ;-0.00] | 0.03 (0.05) [-0.06 ; 0.12] | 0.19 [-0.35 ; 0.73] |
| Week 73 | -0.01 (0.03) [-0.06 ; 0.05] | -0.10 (0.03) [-0.16 ;-0.03] | 0.09 (0.04) [ 0.00 ; 0.18] | 0.62 [ 0.02 ; 1.23] |
| Week 79 | 0.02 (0.03) [-0.03 ; 0.08] | -0.05 (0.03) [-0.11 ; 0.02] | 0.07 (0.04) [-0.01 ; 0.16] | 0.54 [-0.10 ; 1.18] |
| Week 85 | 0.01 (0.03) [-0.05 ; 0.07] | -0.08 (0.04) [-0.15 ;-0.00] | 0.09 (0.05) [-0.01 ; 0.19] | 0.61 [-0.10 ; 1.31] |
| Week 91 | -0.02 (0.04) [-0.11 ; 0.06] | -0.04 (0.05) [-0.14 ; 0.06] | 0.02 (0.06) [-0.11 ; 0.14] | 0.09 [-0.63 ; 0.80] |
| Overall post-baseline period estimate | -0.02 (0.01) [-0.05 ; 0.01] | -0.06 (0.02) [-0.09 ;-0.03] | 0.04 (0.02) [-0.01 ; 0.08] | 0.34 [-0.06 ; 0.75] |
| **Not Reported** | | | | |
| Nr subjects used | n=3 | [No Data] | | |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.7462 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:43:01

TABLE 7.3.1: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| subtit | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| N subjects | N=71 | N=68 |
| Subjects with Baseline Value | 69 (97.2%) | 67 (98.5%) |
| Subjects with at least 1 Post-Baseline Value | 71 (100.0%) | 66 (97.1%) |
| Subjects with Baseline Value and at least 1 Post-Baseline Value | 69 (97.2%) | 65 (95.6%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:26

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Baseline | n= 69 (97.2%) \| 62.04 (8.11) | n= 67 (98.5%) \| 61.28 (8.65) | 0.09 [-0.25 ; 0.43] |
| Week 3 | n= 67 (94.4%) \| 62.39 (7.79) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 63 (88.7%) \| 60.30 (9.54) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 64 (90.1%) \| 58.24 (9.23) | n= 64 (94.1%) \| 59.20 (8.96) | -0.11 [-0.45 ; 0.24] |
| Week 9 | n= 61 (85.9%) \| 59.39 (10.09) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 61 (85.9%) \| 58.30 (9.63) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 60 (84.5%) \| 59.13 (9.48) | n= 55 (80.9%) \| 58.87 (8.43) | 0.03 [-0.34 ; 0.40] |
| Week 15 | n= 54 (76.1%) \| 59.89 (9.47) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 63 (88.7%) \| 59.44 (9.53) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 57 (80.3%) \| 60.43 (7.96) | n= 54 (79.4%) \| 58.98 (8.38) | 0.18 [-0.20 ; 0.55] |
| Week 21 | n= 59 (83.1%) \| 59.64 (9.08) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 56 (78.9%) \| 59.01 (8.79) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 58 (81.7%) \| 60.83 (8.34) | n= 49 (72.1%) \| 60.90 (9.09) | -0.01 [-0.39 ; 0.37] |
| Week 27 | n= 56 (78.9%) \| 61.65 (8.88) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 52 (73.2%) \| 60.81 (8.76) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \| 60.50 (9.15) | n= 42 (61.8%) \| 60.63 (8.78) | -0.01 [-0.42 ; 0.39] |
| Week 33 | n= 56 (78.9%) \| 60.20 (9.20) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 54 (76.1%) \| 60.12 (10.02) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 48 (67.6%) \| 60.71 (9.32) | n= 47 (69.1%) \| 60.89 (7.35) | -0.02 [-0.43 ; 0.38] |
| Week 39 | n= 52 (73.2%) \| 61.67 (8.30) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 52 (73.2%) \| 61.05 (8.59) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 52 (73.2%) \| 60.79 (9.20) | n= 42 (61.8%) \| 59.80 (8.59) | 0.11 [-0.30 ; 0.52] |
| Week 45 | n= 48 (67.6%) \| 59.49 (9.95) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 51 (71.8%) \| 60.99 (9.32) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 52 (73.2%) \| 60.80 (9.51) | n= 36 (52.9%) \| 59.94 (8.08) | 0.10 [-0.33 ; 0.52] |
| Week 51 | n= 51 (71.8%) \| 59.44 (10.05) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 52 (73.2%) \| 60.44 (9.31) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 46 (64.8%) \| 60.47 (9.71) | n= 38 (55.9%) \| 59.09 (7.94) | 0.15 [-0.28 ; 0.59] |
| Week 57 | n= 48 (67.6%) \| 60.66 (9.35) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 46 (64.8%) \| 60.83 (9.56) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \| 61.24 (8.96) | n= 31 (45.6%) \| 58.61 (8.57) | 0.30 [-0.16 ; 0.75] |
| Week 63 | n= 42 (59.2%) \| 59.99 (9.88) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 43 (60.6%) \| 59.62 (10.65) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \| 61.49 (8.80) | n= 30 (44.1%) \| 59.50 (7.12) | 0.24 [-0.23 ; 0.71] |
| Week 69 | n= 38 (53.5%) \| 58.94 (11.56) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 38 (53.5%) \| 60.59 (10.29) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 35 (49.3%) \| 61.83 (9.91) | n= 28 (41.2%) \| 56.53 (7.87) | 0.58 [ 0.07 ; 1.09] |
| Week 75 | n= 35 (49.3%) \| 62.36 (8.25) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \| 60.77 (8.25) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \| 60.72 (11.96) | n= 25 (36.8%) \| 59.16 (6.65) | 0.15 [-0.38 ; 0.69] |
| Week 81 | n= 29 (40.8%) \| 61.69 (8.71) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \| 60.89 (9.68) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \| 62.52 (8.24) | n= 21 (30.9%) \| 60.24 (8.04) | 0.28 [-0.30 ; 0.85] |
| Week 87 | n= 24 (33.8%) \| 58.96 (10.10) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \| 59.76 (8.76) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 24 (33.8%) \| 59.29 (10.07) | n= 18 (26.5%) \| 61.28 (9.18) | -0.20 [-0.82 ; 0.42] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 23 (32.4%) \| 60.02 (9.46) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 22 (31.0%) \| 59.02 (9.61) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) \| 58.82 (9.68) | n= 11 (16.2%) \| 62.22 (7.46) | -0.37 [-1.11 ; 0.38] |
| Week 99 | n= 17 (23.9%) \| 58.18 (11.05) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) \| 60.00 (8.58) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) \| 59.33 (8.48) | n= 10 (14.7%) \| 59.60 (7.63) | -0.03 [-0.85 ; 0.78] |
| Week 105 | n= 13 (18.3%) \| 57.92 (7.64) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) \| 58.25 (8.08) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) \| 55.13 (8.49) | n= 5 ( 7.4%) \| 57.40 (11.52) | -0.23 [-1.32 ; 0.87] |
| Week 111 | n= 7 ( 9.9%) \| 54.57 (4.96) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) \| 56.81 (7.50) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 7 ( 9.9%) \| 58.71 (7.48) | n= 5 ( 7.4%) \| 61.20 (8.26) | -0.29 [-1.51 ; 0.92] |
| Week 117 | n= 7 ( 9.9%) \| 59.43 (5.32) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 ( 9.9%) \| 56.14 (10.11) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) \| 57.69 (8.70) | n= 1 ( 1.5%) \| 45.39 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 2.8%) \| 56.89 (5.81) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) \| 50.67 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) \| 65.00 (5.66) | n= 1 ( 1.5%) \| 43.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) \| 51.72 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.4%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.4%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.4%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.4%) \| 65.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.4%) \| 50.29 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) \| 46.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) \| 60.38 (9.13) | n= 16 (23.5%) \| 56.38 (11.05) | 0.37 [-0.51 ; 1.24] |
| Week 202 | n= 2 ( 2.8%) \| 48.00 (14.14) | n= 11 (16.2%) \| 64.18 (7.55) | -1.80 [-3.55 ;-0.04] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:26

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Week 3 | n= 66 (93.0%) \| 0.10 (5.68) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 61 (85.9%) \|-1.73 (7.64) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 62 (87.3%) \|-3.52 (8.19) | n= 63 (92.6%) \|-2.10 (8.20) | -0.17 [-0.52 ; 0.18] |
| Week 9 | n= 60 (84.5%) \|-3.69 (8.38) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 60 (84.5%) \|-4.07 (8.90) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 59 (83.1%) \|-3.50 (8.21) | n= 55 (80.9%) \|-4.50 (8.58) | 0.12 [-0.25 ; 0.49] |
| Week 15 | n= 54 (76.1%) \|-2.75 (8.94) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 62 (87.3%) \|-3.35 (8.12) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 56 (78.9%) \|-2.91 (7.43) | n= 53 (77.9%) \|-3.81 (8.25) | 0.11 [-0.26 ; 0.49] |
| Week 21 | n= 59 (83.1%) \|-3.13 (8.11) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 56 (78.9%) \|-3.37 (7.43) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 57 (80.3%) \|-2.27 (8.48) | n= 48 (70.6%) \|-2.99 (9.59) | 0.08 [-0.31 ; 0.47] |
| Week 27 | n= 55 (77.5%) \|-2.09 (8.65) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 52 (73.2%) \|-2.45 (8.02) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \|-2.84 (8.59) | n= 42 (61.8%) \|-2.51 (8.57) | -0.04 [-0.44 ; 0.37] |
| Week 33 | n= 56 (78.9%) \|-2.87 (7.91) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 53 (74.6%) \|-3.10 (8.32) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 48 (67.6%) \|-2.08 (7.64) | n= 46 (67.6%) \|-2.35 (6.77) | 0.04 [-0.37 ; 0.44] |
| Week 39 | n= 51 (71.8%) \|-1.92 (7.81) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 52 (73.2%) \|-3.01 (8.31) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 51 (71.8%) \|-2.77 (8.80) | n= 41 (60.3%) \|-3.89 (7.38) | 0.14 [-0.28 ; 0.55] |
| Week 45 | n= 48 (67.6%) \|-3.66 (9.38) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 51 (71.8%) \|-2.97 (8.38) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 52 (73.2%) \|-2.47 (7.98) | n= 35 (51.5%) \|-3.47 (7.24) | 0.13 [-0.30 ; 0.56] |
| Week 51 | n= 51 (71.8%) \|-3.49 (8.72) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 52 (73.2%) \|-2.81 (8.62) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 46 (64.8%) \|-2.88 (8.58) | n= 37 (54.4%) \|-4.09 (7.08) | 0.15 [-0.29 ; 0.59] |
| Week 57 | n= 48 (67.6%) \|-2.69 (8.87) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 46 (64.8%) \|-2.09 (9.06) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \|-2.35 (8.27) | n= 30 (44.1%) \|-4.33 (6.71) | 0.25 [-0.21 ; 0.72] |
| Week 63 | n= 42 (59.2%) \|-2.80 (8.69) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 43 (60.6%) \|-2.63 (9.53) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \|-1.58 (8.77) | n= 29 (42.6%) \|-3.34 (7.66) | 0.21 [-0.26 ; 0.68] |
| Week 69 | n= 38 (53.5%) \|-4.44 (11.27) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 38 (53.5%) \|-2.54 (10.34) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 35 (49.3%) \|-1.06 (10.57) | n= 28 (41.2%) \|-5.61 (8.53) | 0.46 [-0.04 ; 0.97] |
| Week 75 | n= 35 (49.3%) \|-0.90 (8.00) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \|-1.11 (8.90) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \|-1.67 (10.95) | n= 24 (35.3%) \|-2.25 (7.07) | 0.06 [-0.48 ; 0.60] |
| Week 81 | n= 29 (40.8%) \|-1.17 (6.98) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \|-1.45 (10.01) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \|-0.75 (8.24) | n= 20 (29.4%) \|-2.70 (8.69) | 0.23 [-0.36 ; 0.81] |
| Week 87 | n= 24 (33.8%) \|-3.04 (9.13) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \|-2.20 (7.85) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 24 (33.8%) \|-4.00 (8.03) | n= 17 (25.0%) \|-2.93 (12.64) | -0.10 [-0.73 ; 0.53] |
| Week 93 | n= 23 (32.4%) \|-2.86 (7.97) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 95 | n= 22 (31.0%) \|-3.30 (8.45) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) \|-3.61 (8.84) | n= 10 (14.7%) \|-2.06 (6.70) | -0.18 [-0.95 ; 0.58] |
| Week 99 | n= 17 (23.9%) \|-3.30 (9.50) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) \|-3.78 (7.46) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) \|-3.74 (7.02) | n= 9 (13.2%) \|-4.78 (7.10) | 0.14 [-0.70 ; 0.99] |
| Week 105 | n= 13 (18.3%) \|-4.39 (6.35) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) \|-5.86 (8.05) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) \|-6.23 (7.74) | n= 4 ( 5.9%) \|-8.25 (9.00) | 0.24 [-0.95 ; 1.43] |
| Week 111 | n= 7 ( 9.9%) \|-7.84 (6.83) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) \|-5.80 (8.21) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 7 ( 9.9%) \|-4.13 (7.08) | n= 5 ( 7.4%) \|-6.80 (7.76) | 0.34 [-0.88 ; 1.55] |
| Week 117 | n= 7 ( 9.9%) \|-2.41 (6.78) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 ( 9.9%) \|-4.41 (9.63) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) \|-4.42 (9.27) | n= 1 ( 1.5%) \|-23.61 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 2.8%) \| 0.39 (6.52) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) \|-6.33 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) \| 0.50 (4.95) | n= 1 ( 1.5%) \|-26.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) \|-5.28 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.4%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.4%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.4%) \| 8.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.4%) \|-6.71 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) \|-10.06 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) \|-3.09 (5.17) | n= 16 (23.5%) \|-4.38 (11.07) | 0.13 [-0.74 ; 1.00] |
| Week 202 | n= 2 ( 2.8%) \|-12.50 (9.19) | n= 11 (16.2%) \| 0.82 (10.18) | -1.23 [-2.89 ; 0.43] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:26

TABLE 7.3.1: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| Nr subjects used | n=69 | n=67 | | |
| Week 7 | -5.84 (1.19) [-8.20 ;-3.48] | -4.27 (1.22) [-6.68 ;-1.86] | -1.57 (1.60) [-4.73 ; 1.59] | -0.16 [-0.51 ; 0.19] |
| Week 13 | -5.10 (1.20) [-7.47 ;-2.72] | -6.10 (1.25) [-8.57 ;-3.63] | 1.01 (1.63) [-2.21 ; 4.23] | 0.11 [-0.26 ; 0.48] |
| Week 19 | -4.42 (1.00) [-6.39 ;-2.44] | -5.89 (1.05) [-7.96 ;-3.83] | 1.48 (1.32) [-1.13 ; 4.08] | 0.19 [-0.18 ; 0.57] |
| Week 25 | -3.71 (1.10) [-5.87 ;-1.54] | -4.39 (1.17) [-6.69 ;-2.09] | 0.68 (1.49) [-2.26 ; 3.63] | 0.08 [-0.30 ; 0.47] |
| Week 31 | -4.36 (1.07) [-6.48 ;-2.25] | -3.90 (1.16) [-6.18 ;-1.62] | -0.46 (1.46) [-3.35 ; 2.43] | -0.06 [-0.46 ; 0.34] |
| Week 37 | -3.83 (0.99) [-5.79 ;-1.88] | -4.22 (1.05) [-6.29 ;-2.15] | 0.39 (1.32) [-2.22 ; 2.99] | 0.05 [-0.35 ; 0.46] |
| Week 43 | -4.27 (1.09) [-6.42 ;-2.13] | -4.72 (1.19) [-7.07 ;-2.37] | 0.45 (1.51) [-2.53 ; 3.43] | 0.06 [-0.35 ; 0.47] |
| Week 49 | -4.20 (0.98) [-6.14 ;-2.26] | -4.14 (1.12) [-6.34 ;-1.93] | -0.07 (1.38) [-2.79 ; 2.66] | -0.01 [-0.44 ; 0.42] |
| Week 55 | -4.28 (1.11) [-6.48 ;-2.08] | -4.67 (1.26) [-7.15 ;-2.19] | 0.39 (1.58) [-2.74 ; 3.52] | 0.05 [-0.38 ; 0.48] |
| Week 61 | -3.92 (1.04) [-5.98 ;-1.86] | -4.70 (1.24) [-7.14 ;-2.26] | 0.78 (1.52) [-2.23 ; 3.79] | 0.11 [-0.35 ; 0.57] |
| Week 67 | -3.53 (1.13) [-5.78 ;-1.29] | -4.29 (1.35) [-6.97 ;-1.60] | 0.75 (1.68) [-2.58 ; 4.09] | 0.10 [-0.37 ; 0.57] |
| Week 73 | -4.18 (1.40) [-6.96 ;-1.40] | -6.43 (1.62) [-9.64 ;-3.22] | 2.25 (2.08) [-1.87 ; 6.37] | 0.26 [-0.24 ; 0.76] |
| Week 79 | -3.70 (1.37) [-6.42 ;-0.99] | -4.10 (1.58) [-7.24 ;-0.96] | 0.40 (2.03) [-3.63 ; 4.42] | 0.05 [-0.48 ; 0.58] |
| Week 85 | -4.10 (1.23) [-6.55 ;-1.66] | -4.19 (1.43) [-7.03 ;-1.35] | 0.09 (1.82) [-3.53 ; 3.70] | 0.01 [-0.56 ; 0.59] |
| Week 91 | -4.30 (1.46) [-7.20 ;-1.40] | -3.87 (1.72) [-7.29 ;-0.46] | -0.42 (2.20) [-4.81 ; 3.96] | -0.06 [-0.68 ; 0.56] |
| Week 97 | -4.59 (1.46) [-7.52 ;-1.66] | -3.58 (1.95) [-7.49 ; 0.34] | -1.01 (2.39) [-5.82 ; 3.79] | -0.15 [-0.91 ; 0.60] |
| Overall post-baseline period estimate | -4.27 (0.72) [-5.68 ;-2.86] | -4.59 (0.80) [-6.17 ;-3.01] | 0.32 (0.92) [-1.49 ; 2.14] | 0.05 [-0.29 ; 0.39] |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit, and PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm, and uses a Heterogenous Autoregressive (ARH(1)) covariance structure.
CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Er
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:26

TABLE 7.3.2: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **< 65** | | |
| | N=40 | N=46 |
| **>= 65** | | |
| | N=31 | N=22 |
| **Subjects with Baseline Value** | | |
| **< 65** | | |
| | 39 (97.5%) | 45 (97.8%) |
| **>= 65** | | |
| | 30 (96.8%) | 22 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **< 65** | | |
| | 40 (100.0%) | 44 (95.7%) |
| **>= 65** | | |
| | 31 (100.0%) | 22 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **< 65** | | |
| | 39 (97.5%) | 43 (93.5%) |
| **>= 65** | | |
| | 30 (96.8%) | 22 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:26

TABLE 7.3.2: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Baseline | n= 39 (97.5%) \| 63.18 (7.47) | n= 45 (97.8%) \| 61.97 (7.98) | 0.15 [-0.28 ; 0.59] |
| Week 3 | n= 38 (95.0%) \| 63.47 (7.06) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 35 (87.5%) \| 62.74 (8.51) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 37 (92.5%) \| 59.93 (9.18) | n= 43 (93.5%) \| 60.50 (9.06) | -0.06 [-0.50 ; 0.38] |
| Week 9 | n= 36 (90.0%) \| 60.52 (8.56) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \| 59.37 (9.48) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 36 (90.0%) \| 61.36 (8.65) | n= 38 (82.6%) \| 58.36 (9.09) | 0.33 [-0.13 ; 0.80] |
| Week 15 | n= 34 (85.0%) \| 61.50 (9.62) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 37 (92.5%) \| 61.14 (7.68) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \| 62.02 (7.23) | n= 40 (87.0%) \| 59.67 (8.34) | 0.30 [-0.17 ; 0.77] |
| Week 21 | n= 36 (90.0%) \| 60.67 (7.58) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 35 (87.5%) \| 60.44 (8.35) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \| 61.58 (8.10) | n= 37 (80.4%) \| 60.51 (9.31) | 0.12 [-0.34 ; 0.58] |
| Week 27 | n= 34 (85.0%) \| 60.97 (9.77) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \| 61.88 (8.80) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \| 61.88 (10.10) | n= 29 (63.0%) \| 60.89 (8.25) | 0.11 [-0.40 ; 0.61] |
| Week 33 | n= 36 (90.0%) \| 61.25 (9.62) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 34 (85.0%) \| 60.32 (10.57) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \| 60.68 (10.32) | n= 33 (71.7%) \| 60.94 (7.10) | -0.03 [-0.52 ; 0.46] |
| Week 39 | n= 33 (82.5%) \| 62.21 (8.90) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \| 61.67 (8.78) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 30 (75.0%) \| 62.10 (9.61) | n= 31 (67.4%) \| 60.26 (8.93) | 0.20 [-0.31 ; 0.70] |
| Week 45 | n= 32 (80.0%) \| 60.20 (10.40) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \| 61.35 (9.75) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 33 (82.5%) \| 60.99 (10.09) | n= 25 (54.3%) \| 61.15 (7.20) | -0.02 [-0.54 ; 0.51] |
| Week 51 | n= 32 (80.0%) \| 59.85 (10.58) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 34 (85.0%) \| 60.76 (9.57) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 30 (75.0%) \| 60.09 (10.27) | n= 27 (58.7%) \| 59.43 (8.58) | 0.07 [-0.46 ; 0.59] |
| Week 57 | n= 32 (80.0%) \| 60.19 (9.95) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 28 (70.0%) \| 61.51 (9.86) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \| 61.53 (9.54) | n= 20 (43.5%) \| 58.45 (8.79) | 0.33 [-0.24 ; 0.90] |
| Week 63 | n= 30 (75.0%) \| 59.88 (10.24) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 27 (67.5%) \| 59.32 (11.71) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \| 61.24 (9.44) | n= 20 (43.5%) \| 59.65 (7.82) | 0.18 [-0.39 ; 0.74] |
| Week 69 | n= 29 (72.5%) \| 58.13 (12.41) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \| 59.54 (10.99) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \| 61.68 (11.05) | n= 18 (39.1%) \| 57.04 (7.99) | 0.46 [-0.16 ; 1.08] |
| Week 75 | n= 25 (62.5%) \| 62.44 (8.44) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \| 60.69 (9.17) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \| 60.72 (13.07) | n= 17 (37.0%) \| 58.18 (6.89) | 0.23 [-0.40 ; 0.86] |
| Week 81 | n= 23 (57.5%) \| 61.48 (9.05) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \| 61.00 (10.57) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \| 63.10 (8.70) | n= 14 (30.4%) \| 59.50 (8.86) | 0.40 [-0.30 ; 1.10] |
| Week 87 | n= 19 (47.5%) \| 59.47 (9.55) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 19 (47.5%) \| 60.00 (9.61) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (50.0%) \| 60.00 (10.73) | n= 12 (26.1%) \| 61.17 (9.95) | -0.11 [-0.84 ; 0.62] |
| Week 93 | n= 19 (47.5%) \| 60.58 (9.58) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \| 59.20 (10.27) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \| 58.47 (10.21) | n= 8 (17.4%) \| 62.55 (7.57) | -0.42 [-1.28 ; 0.45] |
| Week 99 | n= 13 (32.5%) \| 57.77 (12.24) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \| 61.00 (8.74) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \| 60.63 (8.45) | n= 7 (15.2%) \| 59.86 (7.49) | 0.09 [-0.87 ; 1.05] |
| Week 105 | n= 11 (27.5%) \| 58.55 (7.67) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \| 59.14 (8.30) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \| 56.44 (8.71) | n= 3 ( 6.5%) \| 53.67 (14.57) | 0.25 [-1.12 ; 1.63] |
| Week 111 | n= 7 (17.5%) \| 54.57 (4.96) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \| 58.14 (7.01) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \| 59.83 (7.52) | n= 3 ( 6.5%) \| 58.00 (8.54) | 0.21 [-1.28 ; 1.70] |
| Week 117 | n= 5 (12.5%) \| 60.60 (5.50) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \| 57.60 (8.82) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \| 57.83 (8.68) | n= 1 ( 2.2%) \| 45.39 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \| 69.00 ( / ) | n= 1 ( 2.2%) \| 43.00 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \| 60.50 (11.56) | n= 9 (19.6%) \| 53.33 (9.71) | 0.65 [-0.61 ; 1.91] |
| Week 202 | [No Data] | n= 7 (15.2%) \| 62.14 (8.15) | [No Data for at least 1 arm] |
| **>= 65** | | | |
| N subjects in population | N=31 | N=22 | |
| Baseline | n= 30 (96.8%) \| 60.55 (8.78) | n= 22 (100.0%) \| 59.86 (9.92) | 0.07 [-0.48 ; 0.63] |
| Week 3 | n= 29 (93.5%) \| 60.96 (8.57) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 28 (90.3%) \| 57.24 (10.00) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 27 (87.1%) \| 55.92 (8.96) | n= 21 (95.5%) \| 56.55 (8.32) | -0.07 [-0.65 ; 0.50] |
| Week 9 | n= 25 (80.6%) \| 57.77 (11.96) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 26 (83.9%) \| 56.86 (9.82) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 24 (77.4%) \| 55.77 (9.86) | n= 17 (77.3%) \| 60.00 (6.84) | -0.47 [-1.11 ; 0.16] |
| Week 15 | n= 20 (64.5%) \| 57.14 (8.77) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 26 (83.9%) \| 57.01 (11.40) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 25 (80.6%) \| 58.40 (8.54) | n= 14 (63.6%) \| 57.02 (8.47) | 0.16 [-0.50 ; 0.82] |
| Week 21 | n= 23 (74.2%) \| 58.04 (11.03) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (67.7%) \| 56.62 (9.19) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 22 (71.0%) \| 59.59 (8.77) | n= 12 (54.5%) \| 62.08 (8.64) | -0.28 [-1.00 ; 0.44] |
| Week 27 | n= 22 (71.0%) \| 62.70 (7.38) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 19 (61.3%) \| 58.95 (8.59) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 21 (67.7%) \| 58.33 (7.11) | n= 13 (59.1%) \| 60.08 (10.21) | -0.20 [-0.91 ; 0.50] |
| Week 33 | n= 20 (64.5%) \| 58.30 (8.28) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 20 (64.5%) \| 59.80 (9.25) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 17 (54.8%) \| 60.76 (7.46) | n= 14 (63.6%) \| 60.79 (8.20) | -0.00 [-0.72 ; 0.72] |
| Week 39 | n= 19 (61.3%) \| 60.74 (7.28) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 18 (58.1%) \| 59.89 (8.34) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 22 (71.0%) \| 59.00 (8.51) | n= 11 (50.0%) \| 58.51 (7.80) | 0.06 [-0.68 ; 0.79] |
| Week 45 | n= 16 (51.6%) \| 58.06 (9.12) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 18 (58.1%) \| 60.33 (8.71) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 19 (61.3%) \| 60.47 (8.66) | n= 11 (50.0%) \| 57.17 (9.57) | 0.36 [-0.40 ; 1.12] |
| Week 51 | n= 19 (61.3%) \| 58.76 (9.31) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 18 (58.1%) \| 59.85 (9.06) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 16 (51.6%) \| 61.20 (8.83) | n= 11 (50.0%) \| 58.27 (6.42) | 0.36 [-0.43 ; 1.15] |
| Week 57 | n= 16 (51.6%) \| 61.59 (8.24) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 59 | n= 18 (58.1%) \| 59.78 (9.25) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 17 (54.8%) \| 60.72 (8.04) | n= 11 (50.0%) \| 58.91 (8.55) | 0.21 [-0.56 ; 0.99] |
| Week 63 | n= 12 (38.7%) \| 60.28 (9.36) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 16 (51.6%) \| 60.13 (8.91) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 12 (38.7%) \| 62.17 (7.15) | n= 10 (45.5%) \| 59.20 (5.83) | 0.43 [-0.44 ; 1.30] |
| Week 69 | n= 9 (29.0%) \| 61.56 (8.31) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 10 (32.3%) \| 63.53 (7.76) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 10 (32.3%) \| 62.20 (6.71) | n= 10 (45.5%) \| 55.61 (7.99) | 0.86 [-0.09 ; 1.80] |
| Week 75 | n= 10 (32.3%) \| 62.14 (8.18) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 8 (25.8%) \| 60.99 (5.03) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 7 (22.6%) \| 60.71 (7.74) | n= 8 (36.4%) \| 61.25 (5.97) | -0.07 [-1.13 ; 0.98] |
| Week 81 | n= 6 (19.4%) \| 62.50 (7.97) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 8 (25.8%) \| 60.54 (6.72) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (22.6%) \| 60.86 (7.08) | n= 7 (31.8%) \| 61.71 (6.42) | -0.12 [-1.21 ; 0.97] |
| Week 87 | n= 5 (16.1%) \| 57.00 (13.06) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 6 (19.4%) \| 59.01 (5.90) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (12.9%) \| 55.75 (5.32) | n= 6 (27.3%) \| 61.50 (8.29) | -0.71 [-2.10 ; 0.68] |
| Week 93 | n= 4 (12.9%) \| 57.35 (9.73) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (16.1%) \| 58.40 (7.89) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (12.9%) \| 60.32 (8.04) | n= 3 (13.6%) \| 61.33 (8.74) | -0.10 [-1.76 ; 1.55] |
| Week 99 | n= 4 (12.9%) \| 59.50 (7.00) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 6.5%) \| 54.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 ( 9.7%) \| 54.15 (7.78) | n= 3 (13.6%) \| 59.00 (9.64) | -0.44 [-2.29 ; 1.40] |
| Week 105 | n= 2 ( 6.5%) \| 54.50 (9.19) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 3.2%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 6.5%) \| 49.19 (5.38) | n= 2 ( 9.1%) \| 63.00 (1.41) | -2.00 [-5.92 ; 1.91] |
| Week 113 | n= 1 ( 3.2%) \| 47.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 3.2%) \| 52.00 ( / ) | n= 2 ( 9.1%) \| 66.00 (7.07) | [Not calculable] |
| Week 117 | n= 2 ( 6.5%) \| 56.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 ( 6.5%) \| 52.50 (16.26) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 ( 6.5%) \| 57.28 (12.34) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 2 ( 6.5%) \| 56.89 (5.81) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 3.2%) \| 50.67 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.2%) \| 61.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 3.2%) \| 51.72 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 3.2%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.2%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 3.2%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 3.2%) \| 65.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 3.2%) \| 50.29 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 3.2%) \| 46.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.9%) \| 60.25 (7.80) | n= 7 (31.8%) \| 60.29 (12.16) | -0.00 [-1.30 ; 1.29] |
| Week 202 | n= 2 ( 6.5%) \| 48.00 (14.14) | n= 4 (18.2%) \| 67.75 (5.50) | -1.85 [-4.28 ; 0.58] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:26

TABLE 7.3.2: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Week 3 | n= 37 (92.5%) \|-0.32 (5.64) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 34 (85.0%) \|-1.03 (6.94) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 36 (90.0%) \|-2.80 (7.75) | n= 42 (91.3%) \|-1.67 (7.78) | -0.14 [-0.59 ; 0.30] |
| Week 9 | n= 36 (90.0%) \|-3.23 (8.60) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \|-4.28 (9.99) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 36 (90.0%) \|-2.38 (8.56) | n= 38 (82.6%) \|-5.23 (9.07) | 0.32 [-0.14 ; 0.78] |
| Week 15 | n= 34 (85.0%) \|-1.85 (9.48) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 37 (92.5%) \|-2.18 (7.51) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \|-2.32 (7.34) | n= 39 (84.8%) \|-3.44 (8.04) | 0.14 [-0.33 ; 0.61] |
| Week 21 | n= 36 (90.0%) \|-2.42 (6.93) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 35 (87.5%) \|-2.64 (6.53) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \|-2.00 (8.26) | n= 36 (78.3%) \|-3.46 (9.75) | 0.16 [-0.31 ; 0.63] |
| Week 27 | n= 34 (85.0%) \|-3.08 (9.08) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \|-1.85 (8.03) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \|-2.09 (9.05) | n= 29 (63.0%) \|-2.91 (8.00) | 0.09 [-0.41 ; 0.60] |
| Week 33 | n= 36 (90.0%) \|-2.33 (8.27) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 34 (85.0%) \|-3.12 (8.98) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \|-2.90 (8.56) | n= 32 (69.6%) \|-2.94 (6.47) | 0.01 [-0.49 ; 0.50] |
| Week 39 | n= 33 (82.5%) \|-1.94 (8.29) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \|-2.27 (8.19) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 30 (75.0%) \|-2.00 (8.85) | n= 30 (65.2%) \|-3.74 (7.76) | 0.21 [-0.31 ; 0.72] |
| Week 45 | n= 32 (80.0%) \|-3.18 (9.69) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \|-2.83 (8.72) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 33 (82.5%) \|-2.64 (8.35) | n= 24 (52.2%) \|-2.88 (6.75) | 0.03 [-0.50 ; 0.56] |
| Week 51 | n= 32 (80.0%) \|-3.79 (9.28) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 34 (85.0%) \|-2.83 (8.93) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 30 (75.0%) \|-3.55 (8.41) | n= 26 (56.5%) \|-4.29 (7.20) | 0.09 [-0.44 ; 0.62] |
| Week 57 | n= 32 (80.0%) \|-3.32 (9.61) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 28 (70.0%) \|-1.64 (9.34) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \|-2.16 (8.73) | n= 19 (41.3%) \|-5.11 (7.62) | 0.35 [-0.23 ; 0.93] |
| Week 63 | n= 30 (75.0%) \|-3.20 (9.25) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 27 (67.5%) \|-3.36 (10.30) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \|-2.64 (8.96) | n= 19 (41.3%) \|-3.79 (8.57) | 0.13 [-0.45 ; 0.70] |
| Week 69 | n= 29 (72.5%) \|-5.91 (12.19) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \|-3.85 (11.02) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \|-1.72 (12.04) | n= 18 (39.1%) \|-5.30 (9.24) | 0.32 [-0.30 ; 0.94] |
| Week 75 | n= 25 (62.5%) \|-1.00 (8.53) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \|-2.26 (8.33) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \|-2.19 (11.74) | n= 16 (34.8%) \|-2.63 (7.91) | 0.04 [-0.60 ; 0.68] |
| Week 81 | n= 23 (57.5%) \|-2.34 (7.02) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \|-2.08 (10.09) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \|-1.15 (8.07) | n= 13 (28.3%) \|-3.23 (9.71) | 0.23 [-0.48 ; 0.94] |
| Week 87 | n= 19 (47.5%) \|-3.89 (7.21) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (47.5%) \|-3.10 (7.58) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 20 (50.0%) \|-3.85 (8.31) | n= 11 (23.9%) \|-3.36 (14.74) | -0.04 [-0.79 ; 0.70] |
| Week 93 | n= 19 (47.5%) \|-2.84 (7.18) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \|-3.91 (7.94) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \|-4.76 (8.22) | n= 7 (15.2%) \| 0.06 (6.55) | -0.60 [-1.51 ; 0.32] |
| Week 99 | n= 13 (32.5%) \|-4.45 (9.57) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \|-3.41 (7.47) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \|-3.20 (7.27) | n= 6 (13.0%) \|-2.50 (6.89) | -0.09 [-1.10 ; 0.92] |
| Week 105 | n= 11 (27.5%) \|-4.44 (6.59) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \|-5.13 (8.40) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \|-5.21 (8.26) | n= 2 ( 4.3%) \|-8.00 (15.56) | 0.27 [-1.35 ; 1.89] |
| Week 111 | n= 7 (17.5%) \|-7.84 (6.83) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \|-5.27 (8.72) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \|-3.98 (7.75) | n= 3 ( 6.5%) \|-7.67 (10.26) | 0.38 [-1.12 ; 1.88] |
| Week 117 | n= 5 (12.5%) \|-3.38 (7.54) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \|-4.58 (8.18) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \|-6.15 (8.47) | n= 1 ( 2.2%) \|-23.61 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \|-3.00 ( / ) | n= 1 ( 2.2%) \|-26.00 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \|-1.18 (5.09) | n= 9 (19.6%) \|-7.89 (10.37) | 0.68 [-0.59 ; 1.94] |
| Week 202 | [No Data] | n= 7 (15.2%) \|-2.29 (10.42) | [No Data for at least 1 arm] |
| **>= 65** | | | |
| N subjects in population | N=31 | N=22 | |
| Week 3 | n= 29 (93.5%) \| 0.64 (5.79) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 27 (87.1%) \|-2.62 (8.49) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 26 (83.9%) \|-4.52 (8.81) | n= 21 (95.5%) \|-2.97 (9.11) | -0.17 [-0.75 ; 0.41] |
| Week 9 | n= 24 (77.4%) \|-4.38 (8.15) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 25 (80.6%) \|-3.76 (7.28) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 23 (74.2%) \|-5.26 (7.48) | n= 17 (77.3%) \|-2.88 (7.38) | -0.31 [-0.95 ; 0.33] |
| Week 15 | n= 20 (64.5%) \|-4.28 (7.93) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 25 (80.6%) \|-5.08 (8.82) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 24 (77.4%) \|-3.69 (7.64) | n= 14 (63.6%) \|-4.84 (9.04) | 0.14 [-0.53 ; 0.81] |
| Week 21 | n= 23 (74.2%) \|-4.24 (9.75) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (67.7%) \|-4.58 (8.75) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 21 (67.7%) \|-2.73 (9.03) | n= 12 (54.5%) \|-1.60 (9.35) | -0.12 [-0.84 ; 0.60] |
| Week 27 | n= 21 (67.7%) \|-0.48 (7.84) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 19 (61.3%) \|-3.49 (8.12) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 21 (67.7%) \|-4.02 (7.87) | n= 13 (59.1%) \|-1.62 (10.02) | -0.27 [-0.97 ; 0.44] |
| Week 33 | n= 20 (64.5%) \|-3.85 (7.31) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 19 (61.3%) \|-3.06 (7.23) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 17 (54.8%) \|-0.59 (5.52) | n= 14 (63.6%) \|-1.00 (7.48) | 0.06 [-0.66 ; 0.78] |
| Week 39 | n= 18 (58.1%) \|-1.90 (7.08) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 18 (58.1%) \|-4.40 (8.59) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 21 (67.7%) \|-3.87 (8.83) | n= 11 (50.0%) \|-4.31 (6.53) | 0.05 [-0.69 ; 0.79] |
| Week 45 | n= 16 (51.6%) \|-4.63 (8.96) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 18 (58.1%) \|-3.23 (7.96) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 19 (61.3%) \|-2.17 (7.50) | n= 11 (50.0%) \|-4.74 (8.41) | 0.32 [-0.44 ; 1.08] |
| Week 51 | n= 19 (61.3%) \|-2.99 (7.90) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 18 (58.1%) \|-2.77 (8.25) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 16 (51.6%) \|-1.63 (9.05) | n= 11 (50.0%) \|-3.64 (7.12) | 0.23 [-0.55 ; 1.02] |
| Week 57 | n= 16 (51.6%) \|-1.42 (7.30) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 18 (58.1%) \|-2.79 (8.82) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 17 (54.8%) \|-2.70 (7.60) | n= 11 (50.0%) \|-3.00 (4.78) | 0.04 [-0.73 ; 0.82] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 63 | n= 12 (38.7%) \|-1.81 (7.36) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 16 (51.6%) \|-1.39 (8.23) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 12 (38.7%) \| 1.23 (7.91) | n= 10 (45.5%) \|-2.50 (5.87) | 0.51 [-0.37 ; 1.38] |
| Week 69 | n= 9 (29.0%) \| 0.31 (5.90) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 10 (32.3%) \| 1.13 (7.38) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 10 (32.3%) \| 0.58 (5.63) | n= 10 (45.5%) \|-6.19 (7.52) | 0.98 [ 0.02 ; 1.93] |
| Week 75 | n= 10 (32.3%) \|-0.67 (6.89) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 8 (25.8%) \| 2.36 (10.22) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 7 (22.6%) \| 0.12 (8.19) | n= 8 (36.4%) \|-1.51 (5.42) | 0.22 [-0.83 ; 1.28] |
| Week 81 | n= 6 (19.4%) \| 3.31 (5.04) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 8 (25.8%) \| 0.52 (10.17) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (22.6%) \| 0.40 (9.27) | n= 7 (31.8%) \|-1.71 (7.02) | 0.24 [-0.85 ; 1.34] |
| Week 87 | n= 5 (16.1%) \| 0.20 (15.14) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 6 (19.4%) \| 0.65 (8.73) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (12.9%) \|-4.79 (7.47) | n= 6 (27.3%) \|-2.15 (8.69) | -0.29 [-1.64 ; 1.06] |
| Week 93 | n= 4 (12.9%) \|-2.94 (12.51) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (16.1%) \|-1.23 (10.79) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (12.9%) \| 1.28 (11.00) | n= 3 (13.6%) \|-7.00 (4.58) | 0.77 [-0.96 ; 2.51] |
| Week 99 | n= 4 (12.9%) \| 0.46 (9.53) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 6.5%) \|-6.00 (9.90) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 ( 9.7%) \|-5.91 (6.75) | n= 3 (13.6%) \|-9.33 (6.03) | 0.43 [-1.42 ; 2.27] |
| Week 105 | n= 2 ( 6.5%) \|-4.08 (6.95) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 3.2%) \|-11.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 6.5%) \|-10.81 (1.14) | n= 2 ( 9.1%) \|-8.50 (0.71) | -1.39 [-4.63 ; 1.85] |
| Week 113 | n= 1 ( 3.2%) \|-9.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 3.2%) \|-5.00 ( / ) | n= 2 ( 9.1%) \|-5.50 (4.95) | [Not calculable] |
| Week 117 | n= 2 ( 6.5%) \| 0.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 ( 6.5%) \|-4.00 (16.97) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 ( 6.5%) \| 0.78 (13.04) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 2 ( 6.5%) \| 0.39 (6.52) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 3.2%) \|-6.33 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.2%) \| 4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 3.2%) \|-5.28 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 3.2%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.2%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 3.2%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 3.2%) \| 8.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 3.2%) \|-6.71 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 3.2%) \|-10.06 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.9%) \|-5.00 (5.16) | n= 7 (31.8%) \| 0.14 (10.98) | -0.50 [-1.82 ; 0.82] |
| Week 202 | n= 2 ( 6.5%) \|-12.50 (9.19) | n= 4 (18.2%) \| 6.25 (8.14) | -1.78 [-4.18 ; 0.61] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:27

TABLE 7.3.2: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **< 65** | | | | |
| Nr subjects used | n=39 | n=45 | | |
| Week 7 | -3.36 (1.43) [-6.20 ;-0.53] | -2.02 (1.35) [-4.70 ; 0.66] | -1.35 (1.96) [-5.25 ; 2.55] | -0.15 [-0.60 ; 0.29] |
| Week 13 | -2.71 (1.52) [-5.72 ; 0.30] | -5.41 (1.46) [-8.30 ;-2.51] | 2.70 (2.10) [-1.48 ; 6.87] | 0.30 [-0.16 ; 0.75] |
| Week 19 | -2.23 (1.19) [-4.59 ; 0.13] | -4.11 (1.13) [-6.34 ;-1.87] | 1.88 (1.64) [-1.37 ; 5.13] | 0.27 [-0.20 ; 0.74] |
| Week 25 | -1.83 (1.35) [-4.51 ; 0.85] | -3.60 (1.32) [-6.22 ;-0.99] | 1.78 (1.89) [-1.97 ; 5.52] | 0.22 [-0.24 ; 0.68] |
| Week 31 | -2.09 (1.30) [-4.68 ; 0.49] | -2.58 (1.30) [-5.17 ; 0.01] | 0.48 (1.84) [-3.17 ; 4.14] | 0.07 [-0.43 ; 0.56] |
| Week 37 | -2.48 (1.20) [-4.87 ;-0.09] | -3.43 (1.19) [-5.79 ;-1.07] | 0.95 (1.69) [-2.41 ; 4.30] | 0.14 [-0.36 ; 0.63] |
| Week 43 | -2.00 (1.30) [-4.58 ; 0.59] | -3.80 (1.32) [-6.41 ;-1.19] | 1.80 (1.85) [-1.87 ; 5.47] | 0.25 [-0.26 ; 0.76] |
| Week 49 | -2.77 (1.16) [-5.07 ;-0.47] | -2.42 (1.26) [-4.91 ; 0.07] | -0.35 (1.71) [-3.74 ; 3.04] | -0.05 [-0.58 ; 0.47] |
| Week 55 | -2.86 (1.36) [-5.57 ;-0.15] | -3.58 (1.48) [-6.52 ;-0.64] | 0.72 (2.01) [-3.28 ; 4.72] | 0.09 [-0.43 ; 0.62] |
| Week 61 | -1.89 (1.31) [-4.49 ; 0.71] | -3.72 (1.54) [-6.78 ;-0.67] | 1.83 (2.02) [-2.17 ; 5.84] | 0.26 [-0.32 ; 0.83] |
| Week 67 | -2.55 (1.41) [-5.35 ; 0.25] | -3.65 (1.71) [-7.05 ;-0.24] | 1.10 (2.22) [-3.31 ; 5.51] | 0.14 [-0.43 ; 0.71] |
| Week 73 | -3.21 (1.87) [-6.95 ; 0.52] | -4.40 (2.26) [-8.90 ; 0.09] | 1.19 (2.93) [-4.66 ; 7.03] | 0.12 [-0.48 ; 0.73] |
| Week 79 | -3.07 (1.75) [-6.57 ; 0.43] | -3.45 (2.15) [-7.75 ; 0.84] | 0.38 (2.78) [-5.16 ; 5.92] | 0.04 [-0.59 ; 0.68] |
| Week 85 | -3.59 (1.63) [-6.85 ;-0.34] | -3.05 (2.02) [-7.10 ; 0.99] | -0.54 (2.59) [-5.73 ; 4.65] | -0.07 [-0.77 ; 0.63] |
| Week 91 | -3.74 (2.04) [-7.85 ; 0.37] | -3.24 (2.65) [-8.58 ; 2.09] | -0.50 (3.34) [-7.23 ; 6.23] | -0.05 [-0.79 ; 0.68] |
| Overall post-baseline period estimate | -2.69 (0.88) [-4.43 ;-0.95] | -3.50 (0.95) [-5.38 ;-1.61] | 0.80 (1.29) [-1.76 ; 3.37] | 0.14 [-0.30 ; 0.57] |
| **>= 65** | | | | |
| Nr subjects used | n=30 | n=22 | | |
| Week 7 | -5.57 (1.70) [-8.99 ;-2.15] | -4.03 (1.93) [-7.91 ;-0.15] | -1.54 (2.56) [-6.70 ; 3.62] | -0.17 [-0.75 ; 0.40] |
| Week 13 | -4.91 (1.57) [-8.08 ;-1.74] | -2.39 (1.85) [-6.12 ; 1.33] | -2.52 (2.42) [-7.40 ; 2.36] | -0.33 [-0.96 ; 0.31] |
| Week 19 | -3.79 (1.43) [-6.66 ;-0.92] | -4.83 (1.80) [-8.45 ;-1.22] | 1.04 (2.30) [-3.58 ; 5.65] | 0.15 [-0.51 ; 0.81] |
| Week 25 | -2.66 (1.56) [-5.79 ; 0.47] | -0.54 (1.98) [-4.51 ; 3.43] | -2.13 (2.52) [-7.18 ; 2.93] | -0.29 [-1.01 ; 0.42] |
| Week 31 | -3.98 (1.48) [-6.97 ;-1.00] | -1.79 (1.86) [-5.52 ; 1.95] | -2.20 (2.38) [-6.98 ; 2.58] | -0.32 [-1.01 ; 0.38] |
| Week 37 | -1.74 (1.38) [-4.53 ; 1.05] | -1.09 (1.63) [-4.39 ; 2.21] | -0.65 (2.14) [-4.98 ; 3.67] | -0.11 [-0.82 ; 0.60] |
| Week 43 | -3.78 (1.60) [-7.02 ;-0.55] | -1.97 (2.11) [-6.23 ; 2.28] | -1.81 (2.64) [-7.15 ; 3.53] | -0.24 [-0.98 ; 0.49] |
| Week 49 | -2.53 (1.50) [-5.56 ; 0.50] | -3.47 (1.97) [-7.44 ; 0.51] | 0.94 (2.48) [-4.06 ; 5.94] | 0.14 [-0.60 ; 0.88] |
| Week 55 | -2.25 (1.49) [-5.26 ; 0.77] | -2.85 (1.88) [-6.66 ; 0.96] | 0.60 (2.40) [-4.25 ; 5.46] | 0.10 [-0.67 ; 0.86] |
| Week 61 | -3.07 (1.48) [-6.07 ;-0.06] | -2.49 (1.87) [-6.29 ; 1.31] | -0.58 (2.39) [-5.42 ; 4.26] | -0.09 [-0.85 ; 0.67] |
| Week 67 | -0.01 (1.57) [-3.23 ; 3.21] | -1.50 (1.81) [-5.21 ; 2.20] | 1.49 (2.40) [-3.41 ; 6.40] | 0.26 [-0.59 ; 1.10] |
| Week 73 | -0.81 (1.70) [-4.32 ; 2.71] | -6.01 (1.79) [-9.71 ;-2.32] | 5.20 (2.47) [ 0.10 ; 10.30] | 0.90 [-0.03 ; 1.83] |
| Overall post-baseline period estimate | -2.93 (0.83) [-4.58 ;-1.27] | -2.75 (1.02) [-4.79 ;-0.70] | -0.18 (1.32) [-2.81 ; 2.45] | -0.04 [-0.59 ; 0.51] |
| **MMRM subgroups interaction p-value** | | | 0.1016 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020

TABLE 7.3.3: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **< 65** | N=40 | N=46 |
| **>= 65 AND < 75** | N=23 | N=17 |
| **>= 75** | N=8 | N=5 |
| **Subjects with Baseline Value** | | |
| **< 65** | 39 (97.5%) | 45 (97.8%) |
| **>= 65 AND < 75** | 22 (95.7%) | 17 (100.0%) |
| **>= 75** | 8 (100.0%) | 5 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **< 65** | 40 (100.0%) | 44 (95.7%) |
| **>= 65 AND < 75** | 23 (100.0%) | 17 (100.0%) |
| **>= 75** | 8 (100.0%) | 5 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **< 65** | 39 (97.5%) | 43 (93.5%) |
| **>= 65 AND < 75** | 22 (95.7%) | 17 (100.0%) |
| **>= 75** | 8 (100.0%) | 5 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:27

TABLE 7.3.3: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Baseline | n= 39 (97.5%) \| 63.18 (7.47) | n= 45 (97.8%) \| 61.97 (7.98) | 0.15 [-0.28 ; 0.59] |
| Week 3 | n= 38 (95.0%) \| 63.47 (7.06) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 35 (87.5%) \| 62.74 (8.51) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 37 (92.5%) \| 59.93 (9.18) | n= 43 (93.5%) \| 60.50 (9.06) | -0.06 [-0.50 ; 0.38] |
| Week 9 | n= 36 (90.0%) \| 60.52 (8.56) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \| 59.37 (9.48) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 36 (90.0%) \| 61.36 (8.65) | n= 38 (82.6%) \| 58.36 (9.09) | 0.33 [-0.13 ; 0.80] |
| Week 15 | n= 34 (85.0%) \| 61.50 (9.62) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 37 (92.5%) \| 61.14 (7.68) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \| 62.02 (7.23) | n= 40 (87.0%) \| 59.67 (8.34) | 0.30 [-0.17 ; 0.77] |
| Week 21 | n= 36 (90.0%) \| 60.67 (7.58) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 35 (87.5%) \| 60.44 (8.35) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \| 61.58 (8.10) | n= 37 (80.4%) \| 60.51 (9.31) | 0.12 [-0.34 ; 0.58] |
| Week 27 | n= 34 (85.0%) \| 60.97 (9.77) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \| 61.88 (8.80) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \| 61.88 (10.10) | n= 29 (63.0%) \| 60.89 (8.25) | 0.11 [-0.40 ; 0.61] |
| Week 33 | n= 36 (90.0%) \| 61.25 (9.62) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 34 (85.0%) \| 60.32 (10.57) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \| 60.68 (10.32) | n= 33 (71.7%) \| 60.94 (7.10) | -0.03 [-0.52 ; 0.46] |
| Week 39 | n= 33 (82.5%) \| 62.21 (8.90) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \| 61.67 (8.78) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 30 (75.0%) \| 62.10 (9.61) | n= 31 (67.4%) \| 60.26 (8.93) | 0.20 [-0.31 ; 0.70] |
| Week 45 | n= 32 (80.0%) \| 60.20 (10.40) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \| 61.35 (9.75) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 33 (82.5%) \| 60.99 (10.09) | n= 25 (54.3%) \| 61.15 (7.20) | -0.02 [-0.54 ; 0.51] |
| Week 51 | n= 32 (80.0%) \| 59.85 (10.58) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 34 (85.0%) \| 60.76 (9.57) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 30 (75.0%) \| 60.09 (10.27) | n= 27 (58.7%) \| 59.43 (8.58) | 0.07 [-0.46 ; 0.59] |
| Week 57 | n= 32 (80.0%) \| 60.19 (9.95) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 28 (70.0%) \| 61.51 (9.86) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \| 61.53 (9.54) | n= 20 (43.5%) \| 58.45 (8.79) | 0.33 [-0.24 ; 0.90] |
| Week 63 | n= 30 (75.0%) \| 59.88 (10.24) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 27 (67.5%) \| 59.32 (11.71) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \| 61.24 (9.44) | n= 20 (43.5%) \| 59.65 (7.82) | 0.18 [-0.39 ; 0.74] |
| Week 69 | n= 29 (72.5%) \| 58.13 (12.41) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \| 59.54 (10.99) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \| 61.68 (11.05) | n= 18 (39.1%) \| 57.04 (7.99) | 0.46 [-0.16 ; 1.08] |
| Week 75 | n= 25 (62.5%) \| 62.44 (8.44) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \| 60.69 (9.17) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \| 60.72 (13.07) | n= 17 (37.0%) \| 58.18 (6.89) | 0.23 [-0.40 ; 0.86] |
| Week 81 | n= 23 (57.5%) \| 61.48 (9.05) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \| 61.00 (10.57) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \| 63.10 (8.70) | n= 14 (30.4%) \| 59.50 (8.86) | 0.40 [-0.30 ; 1.10] |
| Week 87 | n= 19 (47.5%) \| 59.47 (9.55) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 19 (47.5%) \| 60.00 (9.61) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (50.0%) \| 60.00 (10.73) | n= 12 (26.1%) \| 61.17 (9.95) | -0.11 [-0.84 ; 0.62] |
| Week 93 | n= 19 (47.5%) \| 60.58 (9.58) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \| 59.20 (10.27) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \| 58.47 (10.21) | n= 8 (17.4%) \| 62.55 (7.57) | -0.42 [-1.28 ; 0.45] |
| Week 99 | n= 13 (32.5%) \| 57.77 (12.24) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \| 61.00 (8.74) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \| 60.63 (8.45) | n= 7 (15.2%) \| 59.86 (7.49) | 0.09 [-0.87 ; 1.05] |
| Week 105 | n= 11 (27.5%) \| 58.55 (7.67) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \| 59.14 (8.30) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \| 56.44 (8.71) | n= 3 ( 6.5%) \| 53.67 (14.57) | 0.25 [-1.12 ; 1.63] |
| Week 111 | n= 7 (17.5%) \| 54.57 (4.96) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \| 58.14 (7.01) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \| 59.83 (7.52) | n= 3 ( 6.5%) \| 58.00 (8.54) | 0.21 [-1.28 ; 1.70] |
| Week 117 | n= 5 (12.5%) \| 60.60 (5.50) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \| 57.60 (8.82) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \| 57.83 (8.68) | n= 1 ( 2.2%) \| 45.39 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \| 69.00 ( / ) | n= 1 ( 2.2%) \| 43.00 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \| 60.50 (11.56) | n= 9 (19.6%) \| 53.33 (9.71) | 0.65 [-0.61 ; 1.91] |
| Week 202 | [No Data] | n= 7 (15.2%) \| 62.14 (8.15) | [No Data for at least 1 arm] |
| **>= 65 AND < 75** | | | |
| N subjects in population | N=23 | N=17 | |
| Baseline | n= 22 (95.7%) \| 60.70 (9.44) | n= 17 (100.0%) \| 58.71 (10.01) | 0.20 [-0.44 ; 0.84] |
| Week 3 | n= 21 (91.3%) \| 61.93 (8.25) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 21 (91.3%) \| 57.81 (11.30) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 20 (87.0%) \| 57.30 (9.86) | n= 17 (100.0%) \| 55.80 (8.37) | 0.16 [-0.50 ; 0.82] |
| Week 9 | n= 19 (82.6%) \| 59.10 (10.70) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 19 (82.6%) \| 57.74 (10.04) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 19 (82.6%) \| 56.26 (9.66) | n= 12 (70.6%) \| 58.75 (6.54) | -0.28 [-1.02 ; 0.46] |
| Week 15 | n= 14 (60.9%) \| 57.64 (9.02) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 19 (82.6%) \| 57.97 (11.99) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 19 (82.6%) \| 58.79 (9.50) | n= 10 (58.8%) \| 54.38 (8.28) | 0.47 [-0.32 ; 1.26] |
| Week 21 | n= 17 (73.9%) \| 57.75 (12.80) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (65.2%) \| 56.07 (10.78) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 16 (69.6%) \| 59.31 (10.04) | n= 7 (41.2%) \| 57.71 (7.80) | 0.16 [-0.75 ; 1.07] |
| Week 27 | n= 16 (69.6%) \| 63.81 (8.02) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 14 (60.9%) \| 59.21 (9.89) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 15 (65.2%) \| 57.67 (8.10) | n= 11 (64.7%) \| 57.64 (9.01) | 0.00 [-0.79 ; 0.80] |
| Week 33 | n= 14 (60.9%) \| 57.36 (9.42) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 14 (60.9%) \| 60.14 (10.68) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 12 (52.2%) \| 62.08 (8.17) | n= 11 (64.7%) \| 59.27 (8.00) | 0.33 [-0.51 ; 1.18] |
| Week 39 | n= 14 (60.9%) \| 62.00 (7.50) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 13 (56.5%) \| 59.62 (9.07) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 16 (69.6%) \| 58.56 (9.70) | n= 10 (58.8%) \| 58.16 (8.13) | 0.04 [-0.76 ; 0.85] |
| Week 45 | n= 11 (47.8%) \| 57.73 (10.74) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 12 (52.2%) \| 61.00 (10.36) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 13 (56.5%) \| 60.15 (9.95) | n= 10 (58.8%) \| 56.87 (10.03) | 0.32 [-0.53 ; 1.17] |
| Week 51 | n= 13 (56.5%) \| 58.71 (10.80) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (56.5%) \| 59.94 (10.23) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 11 (47.8%) \| 60.91 (9.97) | n= 10 (58.8%) \| 57.50 (6.20) | 0.39 [-0.50 ; 1.28] |
| Week 57 | n= 12 (52.2%) \| 61.70 (9.07) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 59 | n= 13 (56.5%) \| 59.77 (10.35) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 12 (52.2%) \| 60.44 (8.53) | n= 10 (58.8%) \| 58.80 (9.00) | 0.18 [-0.68 ; 1.04] |
| Week 63 | n= 9 (39.1%) \| 59.56 (9.74) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (47.8%) \| 60.18 (8.89) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (34.8%) \| 61.00 (8.32) | n= 9 (52.9%) \| 59.00 (6.14) | 0.26 [-0.73 ; 1.25] |
| Week 69 | n= 7 (30.4%) \| 62.00 (9.52) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (30.4%) \| 63.29 (9.38) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (30.4%) \| 62.57 (8.06) | n= 10 (58.8%) \| 55.61 (7.99) | 0.82 [-0.22 ; 1.87] |
| Week 75 | n= 8 (34.8%) \| 61.88 (9.17) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (21.7%) \| 58.80 (4.82) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (26.1%) \| 60.17 (8.33) | n= 7 (41.2%) \| 61.14 (6.44) | -0.12 [-1.26 ; 1.02] |
| Week 81 | n= 4 (17.4%) \| 62.75 (9.74) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (26.1%) \| 59.33 (7.47) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (21.7%) \| 59.20 (7.66) | n= 6 (35.3%) \| 61.83 (7.03) | -0.33 [-1.59 ; 0.93] |
| Week 87 | n= 3 (13.0%) \| 50.33 (13.05) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 4 (17.4%) \| 57.25 (5.68) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (17.4%) \| 55.75 (5.32) | n= 6 (35.3%) \| 61.50 (8.29) | -0.71 [-2.10 ; 0.68] |
| Week 93 | n= 3 (13.0%) \| 54.13 (8.94) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (17.4%) \| 56.25 (7.23) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (13.0%) \| 57.76 (7.59) | n= 3 (17.6%) \| 61.33 (8.74) | -0.35 [-2.18 ; 1.49] |
| Week 99 | n= 3 (13.0%) \| 57.00 (6.00) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 8.7%) \| 54.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (13.0%) \| 54.15 (7.78) | n= 3 (17.6%) \| 59.00 (9.64) | -0.44 [-2.29 ; 1.40] |
| Week 105 | n= 2 ( 8.7%) \| 54.50 (9.19) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 4.3%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 8.7%) \| 49.19 (5.38) | n= 2 (11.8%) \| 63.00 (1.41) | -2.00 [-5.92 ; 1.91] |
| Week 113 | n= 1 ( 4.3%) \| 47.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 4.3%) \| 52.00 ( / ) | n= 2 (11.8%) \| 66.00 (7.07) | [Not calculable] |
| Week 117 | n= 1 ( 4.3%) \| 53.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 4.3%) \| 41.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 4.3%) \| 48.56 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 4.3%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.3%) \| 50.67 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 4.3%) \| 61.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 4.3%) \| 51.72 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 4.3%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.3%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 4.3%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 4.3%) \| 65.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 4.3%) \| 50.29 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.3%) \| 46.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (13.0%) \| 63.67 (4.62) | n= 4 (23.5%) \| 56.25 (15.65) | 0.50 [-1.19 ; 2.19] |
| Week 202 | n= 1 ( 4.3%) \| 58.00 ( / ) | n= 2 (11.8%) \| 65.00 (0.00) | [Not calculable] |
| **>= 75** | | | |
| N subjects in population | N=8 | N=5 | |
| Baseline | n= 8 (100.0%) \| 60.13 (7.20) | n= 5 (100.0%) \| 63.80 (9.52) | -0.42 [-1.60 ; 0.76] |
| Week 3 | n= 8 (100.0%) \| 58.42 (9.43) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 7 (87.5%) \| 55.52 (4.45) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (87.5%) \| 51.99 (3.94) | n= 4 (80.0%) \| 59.75 (8.42) | -1.22 [-2.64 ; 0.21] |
| Week 9 | n= 6 (75.0%) \| 53.57 (15.69) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 7 (87.5%) \| 54.49 (9.50) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 13 | n= 5 (62.5%) \| 53.91 (11.55) | n= 5 (100.0%) \| 63.00 (7.31) | -0.85 [-2.24 ; 0.54] |
| Week 15 | n= 6 (75.0%) \| 55.95 (8.86) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 7 (87.5%) \| 54.41 (9.96) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 6 (75.0%) \| 57.17 (4.75) | n= 4 (80.0%) \| 63.61 (4.88) | -1.21 [-2.70 ; 0.27] |
| Week 21 | n= 6 (75.0%) \| 58.86 (3.14) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (75.0%) \| 58.00 (3.10) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (75.0%) \| 60.33 (4.41) | n= 5 (100.0%) \| 68.20 (5.81) | -1.42 [-2.84 ; 0.01] |
| Week 27 | n= 6 (75.0%) \| 59.73 (4.60) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 5 (62.5%) \| 58.20 (3.70) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 6 (75.0%) \| 60.00 (3.69) | n= 2 (40.0%) \| 73.50 (3.54) | -3.20 [-5.82 ;-0.59] |
| Week 33 | n= 6 (75.0%) \| 60.50 (4.64) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 6 (75.0%) \| 59.00 (5.22) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 5 (62.5%) \| 57.60 (4.62) | n= 3 (60.0%) \| 66.33 (7.64) | -1.31 [-3.06 ; 0.44] |
| Week 39 | n= 5 (62.5%) \| 57.20 (5.85) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 5 (62.5%) \| 60.60 (6.91) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 6 (75.0%) \| 60.16 (4.40) | n= 1 (20.0%) \| 62.00 ( / ) | [Not calculable] |
| Week 45 | n= 5 (62.5%) \| 58.80 (4.76) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (75.0%) \| 58.99 (4.32) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (75.0%) \| 61.17 (5.64) | n= 1 (20.0%) \| 60.17 ( / ) | [Not calculable] |
| Week 51 | n= 6 (75.0%) \| 58.86 (5.67) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 5 (62.5%) \| 59.60 (5.90) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 5 (62.5%) \| 61.84 (6.53) | n= 1 (20.0%) \| 66.00 ( / ) | [Not calculable] |
| Week 57 | n= 4 (50.0%) \| 61.25 (6.13) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 5 (62.5%) \| 59.80 (6.53) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 5 (62.5%) \| 61.40 (7.60) | n= 1 (20.0%) \| 60.00 ( / ) | [Not calculable] |
| Week 63 | n= 3 (37.5%) \| 62.46 (9.65) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 5 (62.5%) \| 60.00 (10.00) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 4 (50.0%) \| 64.50 (3.87) | n= 1 (20.0%) \| 61.00 ( / ) | [Not calculable] |
| Week 69 | n= 2 (25.0%) \| 60.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 3 (37.5%) \| 64.11 (2.59) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (37.5%) \| 61.33 (2.52) | [No Data] | [No Data for at least 1 arm] |
| Week 75 | n= 2 (25.0%) \| 63.22 (3.14) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (37.5%) \| 64.65 (3.20) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 1 (12.5%) \| 64.00 ( / ) | n= 1 (20.0%) \| 62.00 ( / ) | [Not calculable] |
| Week 81 | n= 2 (25.0%) \| 62.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (25.0%) \| 64.17 (1.18) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (25.0%) \| 65.00 (4.24) | n= 1 (20.0%) \| 61.00 ( / ) | [Not calculable] |
| Week 87 | n= 2 (25.0%) \| 67.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (25.0%) \| 62.53 (6.32) | [No Data] | [No Data for at least 1 arm] |
| Week 93 | n= 1 (12.5%) \| 67.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 1 (12.5%) \| 67.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 1 (12.5%) \| 68.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 1 (12.5%) \| 67.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (12.5%) \| 60.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (12.5%) \| 64.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 (12.5%) \| 66.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 (12.5%) \| 61.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (12.5%) \| 50.00 ( / ) | n= 3 (60.0%) \| 65.67 (0.58) | [Not calculable] |
| Week 202 | n= 1 (12.5%) \| 38.00 ( / ) | n= 2 (40.0%) \| 70.50 (7.78) | [Not calculable] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:27

TABLE 7.3.3: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Week 3 | n= 37 (92.5%) \|-0.32 (5.64) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 34 (85.0%) \|-1.03 (6.94) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 36 (90.0%) \|-2.80 (7.75) | n= 42 (91.3%) \|-1.67 (7.78) | -0.14 [-0.59 ; 0.30] |
| Week 9 | n= 36 (90.0%) \|-3.23 (8.60) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \|-4.28 (9.99) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 36 (90.0%) \|-2.38 (8.56) | n= 38 (82.6%) \|-5.23 (9.07) | 0.32 [-0.14 ; 0.78] |
| Week 15 | n= 34 (85.0%) \|-1.85 (9.48) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 37 (92.5%) \|-2.18 (7.51) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \|-2.32 (7.34) | n= 39 (84.8%) \|-3.44 (8.04) | 0.14 [-0.33 ; 0.61] |
| Week 21 | n= 36 (90.0%) \|-2.42 (6.93) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 35 (87.5%) \|-2.64 (6.53) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \|-2.00 (8.26) | n= 36 (78.3%) \|-3.46 (9.75) | 0.16 [-0.31 ; 0.63] |
| Week 27 | n= 34 (85.0%) \|-3.08 (9.08) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \|-1.85 (8.03) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \|-2.09 (9.05) | n= 29 (63.0%) \|-2.91 (8.00) | 0.09 [-0.41 ; 0.60] |
| Week 33 | n= 36 (90.0%) \|-2.33 (8.27) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 34 (85.0%) \|-3.12 (8.98) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \|-2.90 (8.56) | n= 32 (69.6%) \|-2.94 (6.47) | 0.01 [-0.49 ; 0.50] |
| Week 39 | n= 33 (82.5%) \|-1.94 (8.29) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \|-2.27 (8.19) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 30 (75.0%) \|-2.00 (8.85) | n= 30 (65.2%) \|-3.74 (7.76) | 0.21 [-0.31 ; 0.72] |
| Week 45 | n= 32 (80.0%) \|-3.18 (9.69) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \|-2.83 (8.72) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 33 (82.5%) \|-2.64 (8.35) | n= 24 (52.2%) \|-2.88 (6.75) | 0.03 [-0.50 ; 0.56] |
| Week 51 | n= 32 (80.0%) \|-3.79 (9.28) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 34 (85.0%) \|-2.83 (8.93) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 30 (75.0%) \|-3.55 (8.41) | n= 26 (56.5%) \|-4.29 (7.20) | 0.09 [-0.44 ; 0.62] |
| Week 57 | n= 32 (80.0%) \|-3.32 (9.61) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 28 (70.0%) \|-1.64 (9.34) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \|-2.16 (8.73) | n= 19 (41.3%) \|-5.11 (7.62) | 0.35 [-0.23 ; 0.93] |
| Week 63 | n= 30 (75.0%) \|-3.20 (9.25) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 27 (67.5%) \|-3.36 (10.30) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \|-2.64 (8.96) | n= 19 (41.3%) \|-3.79 (8.57) | 0.13 [-0.45 ; 0.70] |
| Week 69 | n= 29 (72.5%) \|-5.91 (12.19) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \|-3.85 (11.02) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \|-1.72 (12.04) | n= 18 (39.1%) \|-5.30 (9.24) | 0.32 [-0.30 ; 0.94] |
| Week 75 | n= 25 (62.5%) \|-1.00 (8.53) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \|-2.26 (8.33) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \|-2.19 (11.74) | n= 16 (34.8%) \|-2.63 (7.91) | 0.04 [-0.60 ; 0.68] |
| Week 81 | n= 23 (57.5%) \|-2.34 (7.02) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \|-2.08 (10.09) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \|-1.15 (8.07) | n= 13 (28.3%) \|-3.23 (9.71) | 0.23 [-0.48 ; 0.94] |
| Week 87 | n= 19 (47.5%) \|-3.89 (7.21) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (47.5%) \|-3.10 (7.58) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 20 (50.0%) \|-3.85 (8.31) | n= 11 (23.9%) \|-3.36 (14.74) | -0.04 [-0.79 ; 0.70] |
| Week 93 | n= 19 (47.5%) \|-2.84 (7.18) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \|-3.91 (7.94) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \|-4.76 (8.22) | n= 7 (15.2%) \| 0.06 (6.55) | -0.60 [-1.51 ; 0.32] |
| Week 99 | n= 13 (32.5%) \|-4.45 (9.57) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \|-3.41 (7.47) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \|-3.20 (7.27) | n= 6 (13.0%) \|-2.50 (6.89) | -0.09 [-1.10 ; 0.92] |
| Week 105 | n= 11 (27.5%) \|-4.44 (6.59) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \|-5.13 (8.40) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \|-5.21 (8.26) | n= 2 ( 4.3%) \|-8.00 (15.56) | 0.27 [-1.35 ; 1.89] |
| Week 111 | n= 7 (17.5%) \|-7.84 (6.83) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \|-5.27 (8.72) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \|-3.98 (7.75) | n= 3 ( 6.5%) \|-7.67 (10.26) | 0.38 [-1.12 ; 1.88] |
| Week 117 | n= 5 (12.5%) \|-3.38 (7.54) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \|-4.58 (8.18) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \|-6.15 (8.47) | n= 1 ( 2.2%) \|-23.61 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \|-3.00 ( / ) | n= 1 ( 2.2%) \|-26.00 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \|-1.18 (5.09) | n= 9 (19.6%) \|-7.89 (10.37) | 0.68 [-0.59 ; 1.94] |
| Week 202 | [No Data] | n= 7 (15.2%) \|-2.29 (10.42) | [No Data for at least 1 arm] |
| **>= 65 AND < 75** | | | |
| N subjects in population | N=23 | N=17 | |
| Week 3 | n= 21 (91.3%) \| 1.53 (6.26) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 20 (87.0%) \|-2.73 (9.39) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 19 (82.6%) \|-4.03 (10.08) | n= 17 (100.0%) \|-2.91 (7.32) | -0.12 [-0.79 ; 0.54] |
| Week 9 | n= 18 (78.3%) \|-3.47 (6.88) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 18 (78.3%) \|-2.86 (7.11) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 18 (78.3%) \|-4.42 (7.74) | n= 12 (70.6%) \|-3.75 (5.94) | -0.09 [-0.83 ; 0.65] |
| Week 15 | n= 14 (60.9%) \|-3.88 (8.56) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 18 (78.3%) \|-4.66 (9.16) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 18 (78.3%) \|-3.58 (8.33) | n= 10 (58.8%) \|-7.62 (7.68) | 0.48 [-0.32 ; 1.28] |
| Week 21 | n= 17 (73.9%) \|-4.92 (10.55) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (65.2%) \|-5.15 (8.12) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 15 (65.2%) \|-3.49 (9.00) | n= 7 (41.2%) \|-5.89 (4.51) | 0.29 [-0.63 ; 1.21] |
| Week 27 | n= 15 (65.2%) \|-0.09 (6.98) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 14 (60.9%) \|-3.31 (9.05) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 15 (65.2%) \|-5.16 (6.92) | n= 11 (64.7%) \|-4.73 (6.33) | -0.06 [-0.86 ; 0.73] |
| Week 33 | n= 14 (60.9%) \|-5.21 (6.83) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (56.5%) \|-3.47 (7.69) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 12 (52.2%) \|-0.59 (5.91) | n= 11 (64.7%) \|-3.09 (4.33) | 0.46 [-0.39 ; 1.31] |
| Week 39 | n= 13 (56.5%) \|-0.71 (7.31) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 13 (56.5%) \|-5.17 (8.77) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 15 (65.2%) \|-5.02 (8.98) | n= 10 (58.8%) \|-4.64 (6.78) | -0.04 [-0.86 ; 0.77] |
| Week 45 | n= 11 (47.8%) \|-5.19 (9.82) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 12 (52.2%) \|-3.75 (8.36) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 13 (56.5%) \|-3.17 (7.40) | n= 10 (58.8%) \|-4.93 (8.84) | 0.21 [-0.63 ; 1.06] |
| Week 51 | n= 13 (56.5%) \|-3.30 (8.00) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (56.5%) \|-3.14 (8.60) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 11 (47.8%) \|-2.57 (8.75) | n= 10 (58.8%) \|-4.30 (7.14) | 0.21 [-0.67 ; 1.09] |
| Week 57 | n= 12 (52.2%) \|-1.40 (7.62) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 13 (56.5%) \|-3.25 (8.74) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 12 (52.2%) \|-3.83 (6.94) | n= 10 (58.8%) \|-3.00 (5.04) | -0.13 [-0.99 ; 0.73] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 63 | n= 9 (39.1%) \|-2.35 (6.55) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (47.8%) \|-1.38 (7.13) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (34.8%) \| 0.47 (7.79) | n= 9 (52.9%) \|-2.56 (6.22) | 0.41 [-0.58 ; 1.40] |
| Week 69 | n= 7 (30.4%) \|-0.32 (6.14) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (30.4%) \|-1.43 (6.29) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (30.4%) \|-1.02 (4.48) | n= 10 (58.8%) \|-6.19 (7.52) | 0.76 [-0.28 ; 1.79] |
| Week 75 | n= 8 (34.8%) \|-2.27 (5.43) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (21.7%) \|-0.81 (10.64) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (26.1%) \|-1.86 (6.90) | n= 7 (41.2%) \|-1.59 (5.85) | -0.04 [-1.18 ; 1.10] |
| Week 81 | n= 4 (17.4%) \| 0.96 (4.19) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (26.1%) \|-2.69 (9.73) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (21.7%) \|-3.83 (7.06) | n= 6 (35.3%) \|-1.67 (7.69) | -0.27 [-1.53 ; 0.99] |
| Week 87 | n= 3 (13.0%) \|-8.33 (13.61) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 4 (17.4%) \|-3.29 (7.80) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (17.4%) \|-4.79 (7.47) | n= 6 (35.3%) \|-2.15 (8.69) | -0.29 [-1.64 ; 1.06] |
| Week 93 | n= 3 (13.0%) \|-7.59 (10.24) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (17.4%) \|-4.29 (9.64) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (13.0%) \|-2.30 (10.24) | n= 3 (17.6%) \|-7.00 (4.58) | 0.47 [-1.38 ; 2.33] |
| Week 99 | n= 3 (13.0%) \|-3.06 (7.87) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 8.7%) \|-6.00 (9.90) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (13.0%) \|-5.91 (6.75) | n= 3 (17.6%) \|-9.33 (6.03) | 0.43 [-1.42 ; 2.27] |
| Week 105 | n= 2 ( 8.7%) \|-4.08 (6.95) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 4.3%) \|-11.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 8.7%) \|-10.81 (1.14) | n= 2 (11.8%) \|-8.50 (0.71) | -1.39 [-4.63 ; 1.85] |
| Week 113 | n= 1 ( 4.3%) \|-9.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 4.3%) \|-5.00 ( / ) | n= 2 (11.8%) \|-5.50 (4.95) | [Not calculable] |
| Week 117 | n= 1 ( 4.3%) \|-4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 4.3%) \|-16.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 4.3%) \|-8.44 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 4.3%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.3%) \|-6.33 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 4.3%) \| 4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 4.3%) \|-5.28 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 4.3%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.3%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 4.3%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 4.3%) \| 8.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 4.3%) \|-6.71 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.3%) \|-10.06 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (13.0%) \|-4.33 (6.11) | n= 4 (23.5%) \|-3.25 (10.78) | -0.10 [-1.75 ; 1.56] |
| Week 202 | n= 1 ( 4.3%) \|-6.00 ( / ) | n= 2 (11.8%) \| 0.00 (1.41) | [Not calculable] |
| **>= 75** | | | |
| N subjects in population | N=8 | N=5 | |
| Week 3 | n= 8 (100.0%) \|-1.71 (3.65) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 7 (87.5%) \|-2.33 (5.73) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (87.5%) \|-5.87 (3.98) | n= 4 (80.0%) \|-3.25 (16.36) | -0.24 [-1.54 ; 1.06] |
| Week 9 | n= 6 (75.0%) \|-7.10 (11.53) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 7 (87.5%) \|-6.08 (7.75) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 5 (62.5%) \|-8.29 (6.22) | n= 5 (100.0%) \|-0.80 (10.64) | -0.78 [-2.15 ; 0.60] |
| Week 15 | n= 6 (75.0%) \|-5.21 (6.85) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 7 (87.5%) \|-6.16 (8.46) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 19 | n= 6 (75.0%) \|-4.00 (5.73) | n= 4 (80.0%) \| 2.11 (9.33) | -0.76 [-2.16 ; 0.64] |
| Week 21 | n= 6 (75.0%) \|-2.31 (7.49) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (75.0%) \|-3.17 (10.87) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (75.0%) \|-0.83 (9.68) | n= 5 (100.0%) \| 4.40 (11.52) | -0.45 [-1.73 ; 0.82] |
| Week 27 | n= 6 (75.0%) \|-1.44 (10.40) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 5 (62.5%) \|-4.00 (5.52) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 6 (75.0%) \|-1.17 (9.99) | n= 2 (40.0%) \| 15.50 (10.61) | -1.44 [-3.38 ; 0.51] |
| Week 33 | n= 6 (75.0%) \|-0.67 (8.04) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 6 (75.0%) \|-2.17 (6.71) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 5 (62.5%) \|-0.60 (5.08) | n= 3 (60.0%) \| 6.67 (12.58) | -0.76 [-2.38 ; 0.87] |
| Week 39 | n= 5 (62.5%) \|-5.00 (6.04) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 5 (62.5%) \|-2.40 (8.73) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 6 (75.0%) \|-1.01 (8.50) | n= 1 (20.0%) \|-1.00 ( / ) | [Not calculable] |
| Week 45 | n= 5 (62.5%) \|-3.40 (7.57) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (75.0%) \|-2.18 (7.74) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (75.0%) \| 0.00 (7.95) | n= 1 (20.0%) \|-2.83 ( / ) | [Not calculable] |
| Week 51 | n= 6 (75.0%) \|-2.30 (8.40) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 5 (62.5%) \|-1.80 (8.11) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 5 (62.5%) \| 0.44 (10.38) | n= 1 (20.0%) \| 3.00 ( / ) | [Not calculable] |
| Week 57 | n= 4 (50.0%) \|-1.50 (7.33) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 5 (62.5%) \|-1.60 (9.96) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 5 (62.5%) \| 0.00 (9.27) | n= 1 (20.0%) \|-3.00 ( / ) | [Not calculable] |
| Week 63 | n= 3 (37.5%) \|-0.20 (11.01) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 5 (62.5%) \|-1.40 (11.26) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 4 (50.0%) \| 2.75 (9.11) | n= 1 (20.0%) \|-2.00 ( / ) | [Not calculable] |
| Week 69 | n= 2 (25.0%) \| 2.50 (6.36) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 3 (37.5%) \| 7.11 (7.03) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (37.5%) \| 4.33 (7.23) | [No Data] | [No Data for at least 1 arm] |
| Week 75 | n= 2 (25.0%) \| 5.72 (10.92) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (37.5%) \| 7.65 (8.48) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 1 (12.5%) \| 12.00 ( / ) | n= 1 (20.0%) \|-1.00 ( / ) | [Not calculable] |
| Week 81 | n= 2 (25.0%) \| 8.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (25.0%) \| 10.17 (1.65) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (25.0%) \| 11.00 (1.41) | n= 1 (20.0%) \|-2.00 ( / ) | [Not calculable] |
| Week 87 | n= 2 (25.0%) \| 13.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (25.0%) \| 8.53 (3.50) | [No Data] | [No Data for at least 1 arm] |
| Week 93 | n= 1 (12.5%) \| 11.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 1 (12.5%) \| 11.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 1 (12.5%) \| 12.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 1 (12.5%) \| 11.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (12.5%) \| 4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (12.5%) \| 8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 (12.5%) \| 10.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 (12.5%) \| 5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (12.5%) \|-7.00 ( / ) | n= 3 (60.0%) \| 4.67 (11.55) | [Not calculable] |
| Week 202 | n= 1 (12.5%) \|-19.00 ( / ) | n= 2 (40.0%) \| 12.50 (6.36) | [Not calculable] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.

TABLE 7.3.3: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **< 65** | | | | |
| Nr subjects used | n=39 | n=45 | | |
| Week 7 | -3.36 (1.43) [-6.20 ;-0.53] | -2.02 (1.35) [-4.70 ; 0.66] | -1.35 (1.96) [-5.25 ; 2.55] | -0.15 [-0.60 ; 0.29] |
| Week 13 | -2.71 (1.52) [-5.72 ; 0.30] | -5.41 (1.46) [-8.30 ;-2.51] | 2.70 (2.10) [-1.48 ; 6.87] | 0.30 [-0.16 ; 0.75] |
| Week 19 | -2.23 (1.19) [-4.59 ; 0.13] | -4.11 (1.13) [-6.34 ;-1.87] | 1.88 (1.64) [-1.37 ; 5.13] | 0.27 [-0.20 ; 0.74] |
| Week 25 | -1.83 (1.35) [-4.51 ; 0.85] | -3.60 (1.32) [-6.22 ;-0.99] | 1.78 (1.89) [-1.97 ; 5.52] | 0.22 [-0.24 ; 0.68] |
| Week 31 | -2.09 (1.30) [-4.68 ; 0.49] | -2.58 (1.30) [-5.17 ; 0.01] | 0.48 (1.84) [-3.17 ; 4.14] | 0.07 [-0.43 ; 0.56] |
| Week 37 | -2.48 (1.20) [-4.87 ;-0.09] | -3.43 (1.19) [-5.79 ;-1.07] | 0.95 (1.69) [-2.41 ; 4.30] | 0.14 [-0.36 ; 0.63] |
| Week 43 | -2.00 (1.30) [-4.58 ; 0.59] | -3.80 (1.32) [-6.41 ;-1.19] | 1.80 (1.85) [-1.87 ; 5.47] | 0.25 [-0.26 ; 0.76] |
| Week 49 | -2.77 (1.16) [-5.07 ;-0.47] | -2.42 (1.26) [-4.91 ; 0.07] | -0.35 (1.71) [-3.74 ; 3.04] | -0.05 [-0.58 ; 0.47] |
| Week 55 | -2.86 (1.36) [-5.57 ;-0.15] | -3.58 (1.48) [-6.52 ;-0.64] | 0.72 (2.01) [-3.28 ; 4.72] | 0.09 [-0.43 ; 0.62] |
| Week 61 | -1.89 (1.31) [-4.49 ; 0.71] | -3.72 (1.54) [-6.78 ;-0.67] | 1.83 (2.02) [-2.17 ; 5.84] | 0.26 [-0.32 ; 0.83] |
| Week 67 | -2.55 (1.41) [-5.35 ; 0.25] | -3.65 (1.71) [-7.05 ;-0.24] | 1.10 (2.22) [-3.31 ; 5.51] | 0.14 [-0.43 ; 0.71] |
| Week 73 | -3.21 (1.87) [-6.95 ; 0.52] | -4.40 (2.26) [-8.90 ; 0.09] | 1.19 (2.93) [-4.66 ; 7.03] | 0.12 [-0.48 ; 0.73] |
| Week 79 | -3.07 (1.75) [-6.57 ; 0.43] | -3.45 (2.15) [-7.75 ; 0.84] | 0.38 (2.78) [-5.16 ; 5.92] | 0.04 [-0.59 ; 0.68] |
| Week 85 | -3.59 (1.63) [-6.85 ;-0.34] | -3.05 (2.02) [-7.10 ; 0.99] | -0.54 (2.59) [-5.73 ; 4.65] | -0.07 [-0.77 ; 0.63] |
| Week 91 | -3.74 (2.04) [-7.85 ; 0.37] | -3.24 (2.65) [-8.58 ; 2.09] | -0.50 (3.34) [-7.23 ; 6.23] | -0.05 [-0.79 ; 0.68] |
| Overall post-baseline period estimate | -2.69 (0.88) [-4.43 ;-0.95] | -3.50 (0.95) [-5.38 ;-1.61] | 0.80 (1.29) [-1.76 ; 3.37] | 0.14 [-0.30 ; 0.57] |
| **>= 65 AND < 75** | | | | |
| Nr subjects used | n=22 | n=17 | | |
| Week 7 | -4.85 (2.02) [-8.96 ;-0.74] | -3.86 (2.21) [-8.35 ; 0.63] | -0.99 (2.98) [-7.05 ; 5.07] | -0.11 [-0.76 ; 0.55] |
| Week 13 | -4.14 (1.60) [-7.39 ;-0.88] | -3.26 (1.93) [-7.19 ; 0.67] | -0.87 (2.50) [-5.97 ; 4.22] | -0.13 [-0.86 ; 0.61] |
| Week 19 | -3.63 (1.67) [-7.01 ;-0.25] | -6.97 (2.17) [-11.37 ;-2.58] | 3.35 (2.73) [-2.20 ; 8.89] | 0.46 [-0.32 ; 1.25] |
| Week 31 | -4.75 (1.57) [-7.94 ;-1.55] | -4.59 (1.90) [-8.47 ;-0.71] | -0.16 (2.46) [-5.18 ; 4.87] | -0.02 [-0.80 ; 0.75] |
| Week 37 | -1.06 (1.51) [-4.16 ; 2.04] | -2.99 (1.69) [-6.49 ; 0.51] | 1.92 (2.27) [-2.75 ; 6.60] | 0.34 [-0.48 ; 1.17] |
| Week 43 | -4.87 (1.95) [-8.86 ;-0.88] | -3.90 (2.35) [-8.71 ; 0.91] | -0.97 (3.06) [-7.22 ; 5.28] | -0.12 [-0.93 ; 0.68] |
| Week 49 | -3.53 (1.87) [-7.34 ; 0.28] | -4.67 (2.17) [-9.09 ;-0.25] | 1.14 (2.86) [-4.70 ; 6.97] | 0.16 [-0.66 ; 0.99] |
| Week 55 | -2.92 (1.80) [-6.60 ; 0.77] | -4.20 (1.99) [-8.27 ;-0.13] | 1.28 (2.68) [-4.21 ; 6.77] | 0.20 [-0.66 ; 1.06] |
| Week 61 | -4.05 (1.67) [-7.48 ;-0.62] | -2.98 (1.85) [-6.80 ; 0.83] | -1.07 (2.49) [-6.20 ; 4.07] | -0.18 [-1.02 ; 0.66] |
| Overall post-baseline period estimate | -3.76 (0.98) [-5.73 ;-1.78] | -4.16 (1.17) [-6.53 ;-1.79] | 0.40 (1.53) [-2.68 ; 3.49] | 0.08 [-0.55 ; 0.72] |
| **>= 75** | | | | |
| Nr subjects used | n=8 | n=5 | | |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.0852 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:28

TABLE 7.3.4: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **US/Canada/Western Europe/Northern Europe** | N=38 | N=34 |
| **Rest of World (ROW)** | N=33 | N=34 |
| **Subjects with Baseline Value** | | |
| **US/Canada/Western Europe/Northern Europe** | 36 (94.7%) | 34 (100.0%) |
| **Rest of World (ROW)** | 33 (100.0%) | 33 (97.1%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **US/Canada/Western Europe/Northern Europe** | 38 (100.0%) | 33 (97.1%) |
| **Rest of World (ROW)** | 33 (100.0%) | 33 (97.1%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **US/Canada/Western Europe/Northern Europe** | 36 (94.7%) | 33 (97.1%) |
| **Rest of World (ROW)** | 33 (100.0%) | 32 (94.1%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:28

TABLE 7.3.4: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **US/Canada/Western Europe/Northern Europe** | | | |
| N subjects in population | N=38 | N=34 | |
| Baseline | n= 36 (94.7%) \| 62.23 (8.17) | n= 34 (100.0%) \| 61.58 (7.42) | 0.08 [-0.39 ; 0.55] |
| Week 3 | n= 36 (94.7%) \| 61.63 (7.55) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 34 (89.5%) \| 59.65 (8.76) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 34 (89.5%) \| 57.62 (8.57) | n= 31 (91.2%) \| 59.65 (6.55) | -0.26 [-0.75 ; 0.23] |
| Week 9 | n= 31 (81.6%) \| 58.70 (9.48) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 32 (84.2%) \| 56.53 (9.01) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 30 (78.9%) \| 58.87 (8.61) | n= 26 (76.5%) \| 60.54 (8.44) | -0.19 [-0.72 ; 0.34] |
| Week 15 | n= 27 (71.1%) \| 59.41 (8.71) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 33 (86.8%) \| 58.22 (8.36) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 30 (78.9%) \| 59.19 (6.89) | n= 26 (76.5%) \| 59.79 (7.83) | -0.08 [-0.61 ; 0.45] |
| Week 21 | n= 29 (76.3%) \| 59.03 (7.23) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 27 (71.1%) \| 57.98 (8.09) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 31 (81.6%) \| 59.32 (7.48) | n= 24 (70.6%) \| 60.63 (7.85) | -0.17 [-0.71 ; 0.37] |
| Week 27 | n= 28 (73.7%) \| 59.86 (8.39) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 26 (68.4%) \| 58.85 (7.83) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 25 (65.8%) \| 59.56 (8.56) | n= 20 (58.8%) \| 60.18 (9.70) | -0.07 [-0.66 ; 0.53] |
| Week 33 | n= 29 (76.3%) \| 59.01 (8.41) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 28 (73.7%) \| 58.67 (9.33) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 24 (63.2%) \| 59.05 (8.71) | n= 23 (67.6%) \| 60.86 (6.77) | -0.23 [-0.81 ; 0.35] |
| Week 39 | n= 27 (71.1%) \| 59.63 (9.17) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 28 (73.7%) \| 58.42 (8.89) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 28 (73.7%) \| 58.93 (9.07) | n= 20 (58.8%) \| 61.42 (8.38) | -0.28 [-0.86 ; 0.30] |
| Week 45 | n= 23 (60.5%) \| 57.19 (10.83) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 26 (68.4%) \| 58.69 (9.75) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 28 (73.7%) \| 58.42 (10.48) | n= 17 (50.0%) \| 61.94 (7.21) | -0.37 [-0.98 ; 0.25] |
| Week 51 | n= 27 (71.1%) \| 57.72 (10.48) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 28 (73.7%) \| 58.25 (9.61) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 26 (68.4%) \| 58.68 (10.16) | n= 17 (50.0%) \| 59.88 (7.71) | -0.13 [-0.75 ; 0.49] |
| Week 57 | n= 26 (68.4%) \| 57.56 (9.97) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 24 (63.2%) \| 58.89 (9.80) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 24 (63.2%) \| 59.57 (9.59) | n= 13 (38.2%) \| 59.38 (9.00) | 0.02 [-0.66 ; 0.70] |
| Week 63 | n= 21 (55.3%) \| 56.82 (10.73) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 21 (55.3%) \| 56.07 (12.01) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 23 (60.5%) \| 59.39 (9.65) | n= 13 (38.2%) \| 60.77 (7.26) | -0.15 [-0.84 ; 0.54] |
| Week 69 | n= 20 (52.6%) \| 56.54 (11.82) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 20 (52.6%) \| 57.41 (11.37) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (42.1%) \| 58.62 (12.05) | n= 14 (41.2%) \| 58.08 (9.28) | 0.05 [-0.68 ; 0.78] |
| Week 75 | n= 16 (42.1%) \| 60.06 (8.40) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (42.1%) \| 58.98 (9.71) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 15 (39.5%) \| 56.68 (14.43) | n= 11 (32.4%) \| 59.27 (6.39) | -0.21 [-1.01 ; 0.58] |
| Week 81 | n= 15 (39.5%) \| 60.47 (9.85) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 16 (42.1%) \| 58.00 (11.02) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (28.9%) \| 61.73 (8.88) | n= 10 (29.4%) \| 59.90 (9.34) | 0.19 [-0.69 ; 1.07] |
| Week 87 | n= 10 (26.3%) \| 57.30 (11.55) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 11 (28.9%) \| 58.45 (10.57) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 12 (31.6%) \| 56.66 (11.71) | n= 9 (26.5%) \| 60.67 (7.92) | -0.37 [-1.27 ; 0.52] |
| Week 93 | n= 12 (31.6%) \| 57.78 (10.50) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (28.9%) \| 56.04 (10.87) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (31.6%) \| 56.36 (11.00) | n= 5 (14.7%) \| 60.20 (9.55) | -0.34 [-1.43 ; 0.74] |
| Week 99 | n= 9 (23.7%) \| 55.44 (12.89) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (15.8%) \| 57.83 (9.64) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (21.1%) \| 59.31 (8.36) | n= 5 (14.7%) \| 61.00 (8.15) | -0.19 [-1.36 ; 0.98] |
| Week 105 | n= 7 (18.4%) \| 59.14 (8.91) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (10.5%) \| 58.25 (11.03) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (18.4%) \| 55.71 (9.21) | n= 2 ( 5.9%) \| 65.50 (4.95) | -1.00 [-2.77 ; 0.78] |
| Week 111 | n= 4 (10.5%) \| 54.00 (6.63) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (10.5%) \| 56.25 (6.40) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 (10.5%) \| 58.50 (8.19) | n= 3 ( 8.8%) \| 61.67 (5.03) | -0.38 [-2.05 ; 1.30] |
| Week 117 | n= 4 (10.5%) \| 59.75 (2.36) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 (10.5%) \| 57.50 (9.26) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (13.2%) \| 58.40 (9.84) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.6%) \| 61.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.6%) \| 69.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (10.5%) \| 63.00 (11.17) | n= 7 (20.6%) \| 52.71 (13.84) | 0.72 [-0.62 ; 2.07] |
| Week 202 | [No Data] | n= 4 (11.8%) \| 63.00 (9.42) | [No Data for at least 1 arm] |
| **Rest of World (ROW)** | | | |
| N subjects in population | N=33 | N=34 | |
| Baseline | n= 33 (100.0%) \| 61.83 (8.17) | n= 33 (97.1%) \| 60.96 (9.87) | 0.09 [-0.39 ; 0.58] |
| Week 3 | n= 31 (93.9%) \| 63.27 (8.09) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 29 (87.9%) \| 61.06 (10.48) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 30 (90.9%) \| 58.94 (10.03) | n= 33 (97.1%) \| 58.79 (10.84) | 0.01 [-0.48 ; 0.51] |
| Week 9 | n= 30 (90.9%) \| 60.11 (10.79) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 29 (87.9%) \| 60.26 (10.06) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 30 (90.9%) \| 59.38 (10.42) | n= 29 (85.3%) \| 57.37 (8.27) | 0.21 [-0.31 ; 0.73] |
| Week 15 | n= 27 (81.8%) \| 60.36 (10.32) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 30 (90.9%) \| 60.78 (10.65) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 27 (81.8%) \| 61.81 (8.94) | n= 28 (82.4%) \| 58.22 (8.93) | 0.40 [-0.14 ; 0.93] |
| Week 21 | n= 30 (90.9%) \| 60.23 (10.67) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 29 (87.9%) \| 59.97 (9.45) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 27 (81.8%) \| 62.56 (9.07) | n= 25 (73.5%) \| 61.16 (10.29) | 0.14 [-0.41 ; 0.69] |
| Week 27 | n= 28 (84.8%) \| 63.45 (9.13) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 26 (78.8%) \| 62.77 (9.34) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 29 (87.9%) \| 61.31 (9.70) | n= 22 (64.7%) \| 61.05 (8.06) | 0.03 [-0.53 ; 0.59] |
| Week 33 | n= 27 (81.8%) \| 61.48 (9.97) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 26 (78.8%) \| 61.69 (10.67) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 24 (72.7%) \| 62.38 (9.80) | n= 24 (70.6%) \| 60.92 (8.02) | 0.16 [-0.41 ; 0.73] |
| Week 39 | n= 25 (75.8%) \| 63.88 (6.75) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 24 (72.7%) \| 64.13 (7.26) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 24 (72.7%) \| 62.96 (9.07) | n= 22 (64.7%) \| 58.32 (8.71) | 0.51 [-0.08 ; 1.11] |
| Week 45 | n= 25 (75.8%) \| 61.60 (8.76) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 25 (75.8%) \| 63.38 (8.38) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 24 (72.7%) \| 63.58 (7.52) | n= 19 (55.9%) \| 58.14 (8.56) | 0.67 [ 0.04 ; 1.29] |
| Week 51 | n= 24 (72.7%) \| 61.38 (9.37) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 24 (72.7%) \| 63.01 (8.44) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 20 (60.6%) \| 62.81 (8.79) | n= 21 (61.8%) \| 58.46 (8.26) | 0.50 [-0.13 ; 1.13] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 57 | n= 22 (66.7%) \| 64.32 (7.17) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 22 (66.7%) \| 62.95 (9.04) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 24 (72.7%) \| 62.91 (8.13) | n= 18 (52.9%) \| 58.06 (8.46) | 0.58 [-0.06 ; 1.21] |
| Week 63 | n= 21 (63.6%) \| 63.16 (8.00) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (66.7%) \| 63.00 (8.05) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 21 (63.6%) \| 63.80 (7.32) | n= 17 (50.0%) \| 58.53 (7.07) | 0.72 [ 0.05 ; 1.38] |
| Week 69 | n= 18 (54.5%) \| 61.61 (10.97) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 18 (54.5%) \| 64.13 (7.81) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 19 (57.6%) \| 64.53 (6.90) | n= 14 (41.2%) \| 54.98 (6.12) | 1.42 [ 0.63 ; 2.20] |
| Week 75 | n= 19 (57.6%) \| 64.29 (7.81) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (48.5%) \| 62.56 (6.29) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 16 (48.5%) \| 64.50 (7.75) | n= 14 (41.2%) \| 59.07 (7.09) | 0.71 [-0.04 ; 1.46] |
| Week 81 | n= 14 (42.4%) \| 63.00 (7.45) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (51.5%) \| 63.61 (7.57) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 16 (48.5%) \| 63.06 (8.02) | n= 11 (32.4%) \| 60.55 (7.10) | 0.32 [-0.47 ; 1.11] |
| Week 87 | n= 14 (42.4%) \| 60.14 (9.20) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 14 (42.4%) \| 60.79 (7.29) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 12 (36.4%) \| 61.92 (7.73) | n= 9 (26.5%) \| 61.89 (10.75) | 0.00 [-0.88 ; 0.89] |
| Week 93 | n= 11 (33.3%) \| 62.45 (7.94) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (33.3%) \| 62.00 (7.50) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 9 (27.3%) \| 62.11 (6.81) | n= 6 (17.6%) \| 63.90 (5.57) | -0.26 [-1.34 ; 0.81] |
| Week 99 | n= 8 (24.2%) \| 61.25 (8.29) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 8 (24.2%) \| 61.63 (7.95) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 7 (21.2%) \| 59.35 (9.29) | n= 5 (14.7%) \| 58.20 (7.73) | 0.12 [-1.08 ; 1.33] |
| Week 105 | n= 6 (18.2%) \| 56.50 (6.35) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (12.1%) \| 58.25 (5.56) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (12.1%) \| 54.10 (8.27) | n= 3 ( 8.8%) \| 52.00 (12.00) | 0.18 [-1.48 ; 1.84] |
| Week 111 | n= 3 ( 9.1%) \| 55.33 (2.52) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (12.1%) \| 57.38 (9.46) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 ( 9.1%) \| 59.00 (8.19) | n= 2 ( 5.9%) \| 60.50 (14.85) | -0.10 [-2.22 ; 2.01] |
| Week 117 | n= 3 ( 9.1%) \| 59.00 (8.72) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 ( 9.1%) \| 54.33 (13.01) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 ( 9.1%) \| 56.52 (8.23) | n= 1 ( 2.9%) \| 45.39 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 3.0%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 3.0%) \| 50.67 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.0%) \| 61.00 ( / ) | n= 1 ( 2.9%) \| 43.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 3.0%) \| 51.72 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 3.0%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.0%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 3.0%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 3.0%) \| 65.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 3.0%) \| 50.29 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 3.0%) \| 46.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.1%) \| 57.75 (7.18) | n= 9 (26.5%) \| 59.22 (8.03) | -0.18 [-1.41 ; 1.06] |
| Week 202 | n= 2 ( 6.1%) \| 48.00 (14.14) | n= 7 (20.6%) \| 64.86 (7.01) | -1.78 [-3.74 ; 0.17] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020

TABLE 7.3.4: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **US/Canada/Western Europe/Northern Europe** | | | |
| N subjects in population | N=38 | N=34 | |
| Week 3 | n= 35 (92.1%) \|-0.84 (6.24) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 32 (84.2%) \|-2.44 (5.35) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 32 (84.2%) \|-4.79 (6.11) | n= 31 (91.2%) \|-1.86 (6.66) | -0.45 [-0.96 ; 0.05] |
| Week 9 | n= 30 (78.9%) \|-4.98 (7.17) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 31 (81.6%) \|-5.72 (8.86) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 29 (76.3%) \|-4.24 (6.43) | n= 26 (76.5%) \|-3.57 (7.44) | -0.10 [-0.63 ; 0.44] |
| Week 15 | n= 27 (71.1%) \|-3.00 (8.12) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 32 (84.2%) \|-4.68 (6.53) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 29 (76.3%) \|-4.02 (6.90) | n= 26 (76.5%) \|-3.29 (5.97) | -0.11 [-0.65 ; 0.42] |
| Week 21 | n= 29 (76.3%) \|-4.14 (6.05) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 27 (71.1%) \|-4.24 (6.42) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 30 (78.9%) \|-3.33 (7.06) | n= 24 (70.6%) \|-2.91 (5.69) | -0.06 [-0.61 ; 0.48] |
| Week 27 | n= 27 (71.1%) \|-4.37 (7.05) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 26 (68.4%) \|-4.27 (6.81) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 25 (65.8%) \|-3.76 (7.87) | n= 20 (58.8%) \|-2.48 (7.70) | -0.16 [-0.76 ; 0.43] |
| Week 33 | n= 29 (76.3%) \|-4.06 (7.39) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 27 (71.1%) \|-4.34 (7.61) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 24 (63.2%) \|-2.62 (7.38) | n= 23 (67.6%) \|-2.23 (5.45) | -0.06 [-0.64 ; 0.52] |
| Week 39 | n= 26 (68.4%) \|-3.54 (7.36) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 28 (73.7%) \|-4.94 (7.90) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 27 (71.1%) \|-4.01 (8.27) | n= 20 (58.8%) \|-2.04 (6.80) | -0.25 [-0.84 ; 0.33] |
| Week 45 | n= 23 (60.5%) \|-5.34 (9.33) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 26 (68.4%) \|-5.07 (7.40) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 28 (73.7%) \|-4.02 (8.36) | n= 17 (50.0%) \|-0.72 (6.34) | -0.42 [-1.04 ; 0.19] |
| Week 51 | n= 27 (71.1%) \|-4.00 (8.75) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 28 (73.7%) \|-4.12 (8.72) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 26 (68.4%) \|-3.19 (8.76) | n= 17 (50.0%) \|-2.42 (6.55) | -0.09 [-0.71 ; 0.52] |
| Week 57 | n= 26 (68.4%) \|-4.92 (9.11) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 24 (63.2%) \|-2.88 (8.94) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 24 (63.2%) \|-3.32 (8.74) | n= 13 (38.2%) \|-3.71 (5.63) | 0.05 [-0.64 ; 0.73] |
| Week 63 | n= 21 (55.3%) \|-4.86 (8.54) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 21 (55.3%) \|-4.23 (10.49) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 23 (60.5%) \|-3.11 (8.69) | n= 13 (38.2%) \|-1.71 (6.69) | -0.17 [-0.86 ; 0.52] |
| Week 69 | n= 20 (52.6%) \|-6.48 (10.94) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 20 (52.6%) \|-5.59 (11.06) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (42.1%) \|-3.63 (12.94) | n= 14 (41.2%) \|-4.36 (7.72) | 0.07 [-0.66 ; 0.80] |
| Week 75 | n= 16 (42.1%) \|-3.00 (6.70) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (42.1%) \|-2.02 (9.90) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 15 (39.5%) \|-5.46 (11.99) | n= 11 (32.4%) \|-3.21 (6.83) | -0.21 [-1.01 ; 0.58] |
| Week 81 | n= 15 (39.5%) \|-1.74 (7.88) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 16 (42.1%) \|-3.75 (10.00) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (28.9%) \|-1.56 (7.62) | n= 10 (29.4%) \|-2.90 (7.31) | 0.17 [-0.71 ; 1.05] |
| Week 87 | n= 10 (26.3%) \|-3.59 (10.08) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 11 (28.9%) \|-2.91 (9.43) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 12 (31.6%) \|-5.68 (8.51) | n= 9 (26.5%) \|-3.54 (8.14) | -0.25 [-1.13 ; 0.64] |
| Week 93 | n= 12 (31.6%) \|-3.22 (8.83) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (28.9%) \|-4.96 (9.21) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (31.6%) \|-5.56 (9.34) | n= 5 (14.7%) \|-5.20 (5.81) | -0.04 [-1.12 ; 1.04] |
| Week 99 | n= 9 (23.7%) \|-4.56 (10.76) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (15.8%) \|-6.81 (5.86) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (21.1%) \|-4.57 (6.40) | n= 5 (14.7%) \|-4.40 (6.54) | -0.02 [-1.19 ; 1.14] |
| Week 105 | n= 7 (18.4%) \|-3.87 (6.37) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (10.5%) \|-8.22 (7.01) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (18.4%) \|-6.56 (6.83) | n= 2 ( 5.9%) \|-2.50 (7.78) | -0.52 [-2.23 ; 1.19] |
| Week 111 | n= 4 (10.5%) \|-9.72 (1.47) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (10.5%) \|-9.22 (3.26) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 (10.5%) \|-8.47 (2.96) | n= 3 ( 8.8%) \|-4.33 (5.03) | -0.89 [-2.65 ; 0.87] |
| Week 117 | n= 4 (10.5%) \|-5.47 (6.53) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 (10.5%) \|-5.47 (9.45) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (13.2%) \|-6.58 (10.02) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.6%) \| 5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.6%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (10.5%) \|-1.93 (5.46) | n= 7 (20.6%) \|-9.00 (8.83) | 0.82 [-0.53 ; 2.18] |
| Week 202 | [No Data] | n= 4 (11.8%) \|-4.50 (10.75) | [No Data for at least 1 arm] |
| **Rest of World (ROW)** | | | |
| N subjects in population | N=33 | N=34 | |
| Week 3 | n= 31 (93.9%) \| 1.16 (4.86) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 29 (87.9%) \|-0.95 (9.59) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 30 (90.9%) \|-2.17 (9.87) | n= 32 (94.1%) \|-2.34 (9.56) | 0.02 [-0.48 ; 0.52] |
| Week 9 | n= 30 (90.9%) \|-2.40 (9.37) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 29 (87.9%) \|-2.30 (8.75) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 30 (90.9%) \|-2.79 (9.69) | n= 29 (85.3%) \|-5.34 (9.54) | 0.26 [-0.25 ; 0.78] |
| Week 15 | n= 27 (81.8%) \|-2.50 (9.84) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 30 (90.9%) \|-1.93 (9.44) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 27 (81.8%) \|-1.71 (7.92) | n= 27 (79.4%) \|-4.31 (10.06) | 0.28 [-0.26 ; 0.82] |
| Week 21 | n= 30 (90.9%) \|-2.15 (9.71) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 29 (87.9%) \|-2.56 (8.28) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 27 (81.8%) \|-1.08 (9.83) | n= 24 (70.6%) \|-3.08 (12.47) | 0.18 [-0.38 ; 0.73] |
| Week 27 | n= 28 (84.8%) \| 0.11 (9.56) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 26 (78.8%) \|-0.63 (8.84) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 29 (87.9%) \|-2.04 (9.22) | n= 22 (64.7%) \|-2.54 (9.48) | 0.05 [-0.51 ; 0.61] |
| Week 33 | n= 27 (81.8%) \|-1.59 (8.38) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 26 (78.8%) \|-1.81 (8.97) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 24 (72.7%) \|-1.54 (8.02) | n= 23 (67.6%) \|-2.46 (8.00) | 0.11 [-0.47 ; 0.69] |
| Week 39 | n= 25 (75.8%) \|-0.24 (8.06) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 24 (72.7%) \|-0.75 (8.36) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 24 (72.7%) \|-1.38 (9.35) | n= 21 (61.8%) \|-5.65 (7.63) | 0.49 [-0.11 ; 1.09] |
| Week 45 | n= 25 (75.8%) \|-2.12 (9.35) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 25 (75.8%) \|-0.78 (8.92) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 24 (72.7%) \|-0.67 (7.26) | n= 18 (52.9%) \|-6.06 (7.23) | 0.73 [ 0.09 ; 1.37] |
| Week 51 | n= 24 (72.7%) \|-2.91 (8.84) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 24 (72.7%) \|-1.28 (8.43) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 20 (60.6%) \|-2.49 (8.56) | n= 20 (58.8%) \|-5.51 (7.37) | 0.37 [-0.26 ; 1.00] |
| Week 57 | n= 22 (66.7%) \|-0.05 (7.98) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 22 (66.7%) \|-1.23 (9.31) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 61 | n= 24 (72.7%) \|-1.38 (7.84) | n= 17 (50.0%) \|-4.81 (7.57) | 0.44 [-0.20 ; 1.07] |
| Week 63 | n= 21 (63.6%) \|-0.74 (8.54) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (66.7%) \|-1.09 (8.47) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 21 (63.6%) \| 0.08 (8.77) | n= 16 (47.1%) \|-4.67 (8.34) | 0.54 [-0.13 ; 1.21] |
| Week 69 | n= 18 (54.5%) \|-2.17 (11.51) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 18 (54.5%) \| 0.85 (8.54) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 19 (57.6%) \| 1.11 (7.80) | n= 14 (41.2%) \|-6.87 (9.38) | 0.91 [ 0.18 ; 1.65] |
| Week 75 | n= 19 (57.6%) \| 0.87 (8.74) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (48.5%) \|-0.19 (7.99) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 16 (48.5%) \| 1.88 (8.83) | n= 13 (38.2%) \|-1.44 (7.44) | 0.39 [-0.36 ; 1.14] |
| Week 81 | n= 14 (42.4%) \|-0.57 (6.10) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (51.5%) \| 0.73 (9.82) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 16 (48.5%) \|-0.19 (8.85) | n= 10 (29.4%) \|-2.50 (10.30) | 0.24 [-0.57 ; 1.05] |
| Week 87 | n= 14 (42.4%) \|-2.64 (8.77) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 14 (42.4%) \|-1.64 (6.68) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 12 (36.4%) \|-2.33 (7.50) | n= 8 (23.5%) \|-2.25 (16.99) | -0.01 [-0.93 ; 0.91] |
| Week 93 | n= 11 (33.3%) \|-2.45 (7.33) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (33.3%) \|-1.64 (7.70) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 9 (27.3%) \|-1.00 (7.87) | n= 5 (14.7%) \| 1.08 (6.53) | -0.26 [-1.40 ; 0.88] |
| Week 99 | n= 8 (24.2%) \|-1.88 (8.36) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 8 (24.2%) \|-1.50 (8.05) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 7 (21.2%) \|-2.79 (8.08) | n= 4 (11.8%) \|-5.25 (8.77) | 0.27 [-1.03 ; 1.57] |
| Week 105 | n= 6 (18.2%) \|-5.00 (6.87) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (12.1%) \|-3.50 (9.33) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (12.1%) \|-5.65 (10.26) | n= 2 ( 5.9%) \|-14.00 (7.07) | 0.70 [-1.31 ; 2.70] |
| Week 111 | n= 3 ( 9.1%) \|-5.33 (10.97) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (12.1%) \|-2.38 (10.73) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 ( 9.1%) \| 1.67 (7.02) | n= 2 ( 5.9%) \|-10.50 (12.02) | 0.98 [-1.35 ; 3.32] |
| Week 117 | n= 3 ( 9.1%) \| 1.67 (5.51) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 ( 9.1%) \|-3.00 (11.79) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 ( 9.1%) \|-0.81 (8.29) | n= 1 ( 2.9%) \|-23.61 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 3.0%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 3.0%) \|-6.33 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.0%) \| 4.00 ( / ) | n= 1 ( 2.9%) \|-26.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 3.0%) \|-5.28 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 3.0%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 3.0%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 3.0%) \| 8.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 3.0%) \|-6.71 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 3.0%) \|-10.06 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.1%) \|-4.25 (5.38) | n= 9 (26.5%) \|-0.78 (11.74) | -0.31 [-1.55 ; 0.93] |
| Week 202 | n= 2 ( 6.1%) \|-12.50 (9.19) | n= 7 (20.6%) \| 3.86 (9.23) | -1.58 [-3.48 ; 0.32] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:28

TABLE 7.3.4: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **US/Canada/Western Europe/Northern Europe** | | | | |
| Nr subjects used | n=36 | n=34 | | |
| Week 7 | -5.02 (1.16) [-7.35 ;-2.70] | -2.12 (1.20) [-4.52 ; 0.28] | -2.90 (1.67) [-6.24 ; 0.44] | -0.43 [-0.93 ; 0.07] |
| Week 13 | -4.12 (1.30) [-6.72 ;-1.53] | -2.87 (1.37) [-5.61 ;-0.13] | -1.25 (1.89) [-5.03 ; 2.52] | -0.18 [-0.71 ; 0.35] |
| Week 19 | -4.45 (1.07) [-6.59 ;-2.32] | -3.43 (1.14) [-5.70 ;-1.16] | -1.02 (1.56) [-4.14 ; 2.09] | -0.17 [-0.70 ; 0.36] |
| Week 25 | -3.24 (1.06) [-5.35 ;-1.13] | -2.72 (1.15) [-5.02 ;-0.42] | -0.52 (1.57) [-3.64 ; 2.60] | -0.09 [-0.63 ; 0.45] |
| Week 31 | -3.81 (1.38) [-6.57 ;-1.06] | -2.50 (1.51) [-5.51 ; 0.52] | -1.32 (2.05) [-5.40 ; 2.77] | -0.19 [-0.78 ; 0.40] |
| Week 37 | -2.97 (1.14) [-5.24 ;-0.70] | -2.68 (1.22) [-5.12 ;-0.24] | -0.29 (1.67) [-3.62 ; 3.04] | -0.05 [-0.62 ; 0.52] |
| Week 43 | -4.53 (1.22) [-6.97 ;-2.09] | -2.08 (1.40) [-4.87 ; 0.71] | -2.45 (1.86) [-6.16 ; 1.26] | -0.38 [-0.97 ; 0.20] |
| Week 49 | -4.22 (1.18) [-6.57 ;-1.86] | -0.71 (1.44) [-3.57 ; 2.15] | -3.51 (1.86) [-7.22 ; 0.20] | -0.56 [-1.18 ; 0.05] |
| Week 55 | -3.66 (1.27) [-6.18 ;-1.13] | -1.96 (1.56) [-5.07 ; 1.15] | -1.69 (2.01) [-5.70 ; 2.31] | -0.26 [-0.87 ; 0.36] |
| Week 61 | -3.65 (1.30) [-6.25 ;-1.05] | -2.75 (1.69) [-6.13 ; 0.63] | -0.90 (2.13) [-5.16 ; 3.36] | -0.14 [-0.82 ; 0.54] |
| Week 67 | -4.00 (1.52) [-7.05 ;-0.96] | -2.17 (1.97) [-6.12 ; 1.78] | -1.84 (2.48) [-6.82 ; 3.15] | -0.25 [-0.93 ; 0.43] |
| Week 73 | -6.15 (2.50) [-11.19 ;-1.12] | -3.97 (2.93) [-9.88 ; 1.94] | -2.18 (3.85) [-9.95 ; 5.58] | -0.20 [-0.92 ; 0.52] |
| Week 79 | -6.12 (2.38) [-10.94 ;-1.30] | -3.02 (2.84) [-8.79 ; 2.74] | -3.09 (3.70) [-10.61 ; 4.42] | -0.32 [-1.11 ; 0.46] |
| Week 85 | -3.96 (2.12) [-8.34 ; 0.41] | -2.85 (2.35) [-7.70 ; 2.01] | -1.12 (3.17) [-7.65 ; 5.42] | -0.15 [-1.01 ; 0.71] |
| Overall post-baseline period estimate | -4.28 (0.83) [-5.92 ;-2.64] | -2.56 (0.97) [-4.49 ;-0.63] | -1.72 (1.28) [-4.25 ; 0.81] | -0.32 [-0.80 ; 0.15] |
| **Rest of World (ROW)** | | | | |
| Nr subjects used | n=33 | n=33 | | |
| Week 7 | -3.81 (1.95) [-7.71 ; 0.08] | -3.49 (1.94) [-7.37 ; 0.39] | -0.32 (2.74) [-5.80 ; 5.16] | -0.03 [-0.53 ; 0.47] |
| Week 13 | -3.10 (1.83) [-6.75 ; 0.55] | -6.19 (1.86) [-9.91 ;-2.48] | 3.09 (2.60) [-2.11 ; 8.28] | 0.30 [-0.21 ; 0.82] |
| Week 19 | -1.38 (1.49) [-4.35 ; 1.59] | -5.22 (1.51) [-8.23 ;-2.21] | 3.85 (2.12) [-0.37 ; 8.06] | 0.49 [-0.06 ; 1.03] |
| Week 25 | -1.21 (1.74) [-4.68 ; 2.25] | -3.01 (1.80) [-6.59 ; 0.58] | 1.79 (2.50) [-3.19 ; 6.77] | 0.20 [-0.35 ; 0.75] |
| Week 31 | -1.93 (1.42) [-4.76 ; 0.90] | -2.20 (1.52) [-5.23 ; 0.83] | 0.27 (2.08) [-3.88 ; 4.41] | 0.04 [-0.52 ; 0.59] |
| Week 37 | -1.58 (1.47) [-4.51 ; 1.35] | -2.58 (1.52) [-5.61 ; 0.45] | 1.00 (2.11) [-3.21 ; 5.22] | 0.14 [-0.44 ; 0.71] |
| Week 43 | -0.85 (1.59) [-4.04 ; 2.33] | -4.25 (1.69) [-7.63 ;-0.88] | 3.40 (2.32) [-1.24 ; 8.04] | 0.43 [-0.16 ; 1.02] |
| Week 49 | -1.04 (1.37) [-3.77 ; 1.69] | -4.50 (1.51) [-7.53 ;-1.48] | 3.46 (2.04) [-0.61 ; 7.54] | 0.52 [-0.11 ; 1.14] |
| Week 55 | -1.89 (1.64) [-5.17 ; 1.40] | -4.41 (1.75) [-7.90 ;-0.91] | 2.52 (2.39) [-2.28 ; 7.32] | 0.33 [-0.30 ; 0.95] |
| Week 61 | -1.12 (1.48) [-4.08 ; 1.85] | -3.81 (1.69) [-7.19 ;-0.44] | 2.70 (2.24) [-1.79 ; 7.18] | 0.37 [-0.26 ; 1.00] |
| Week 67 | 0.10 (1.39) [-2.68 ; 2.88] | -3.61 (1.58) [-6.78 ;-0.45] | 3.72 (2.11) [-0.49 ; 7.93] | 0.57 [-0.09 ; 1.24] |
| Week 73 | 0.57 (1.27) [-1.98 ; 3.11] | -6.44 (1.46) [-9.35 ;-3.52] | 7.00 (1.94) [ 3.13 ; 10.88] | 1.24 [ 0.48 ; 2.00] |
| Week 79 | 1.23 (1.41) [-1.60 ; 4.06] | -2.29 (1.58) [-5.45 ; 0.88] | 3.52 (2.12) [-0.73 ; 7.76] | 0.60 [-0.15 ; 1.35] |
| Week 85 | -0.77 (1.57) [-3.95 ; 2.42] | -2.52 (1.88) [-6.32 ; 1.27] | 1.76 (2.45) [-3.20 ; 6.71] | 0.28 [-0.52 ; 1.07] |
| Overall post-baseline period estimate | -1.20 (0.91) [-3.01 ; 0.61] | -3.90 (0.97) [-5.82 ;-1.97] | 2.70 (1.33) [ 0.06 ; 5.34] | 0.50 [ 0.00 ; 0.99] |
| **MMRM subgroups interaction p-value** | | | 0.7377 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.

TABLE 7.3.5: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **White** | | |
| | N=62 | N=58 |
| **Non-White** | | |
| | N=9 | N=10 |
| **Subjects with Baseline Value** | | |
| **White** | | |
| | 60 (96.8%) | 57 (98.3%) |
| **Non-White** | | |
| | 9 (100.0%) | 10 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **White** | | |
| | 62 (100.0%) | 56 (96.6%) |
| **Non-White** | | |
| | 9 (100.0%) | 10 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **White** | | |
| | 60 (96.8%) | 55 (94.8%) |
| **Non-White** | | |
| | 9 (100.0%) | 10 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:28

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **White** | | | |
| N subjects in population | N=62 | N=58 | |
| Baseline | n= 60 (96.8%) \| 61.37 (8.05) | n= 57 (98.3%) \| 60.76 (8.55) | 0.07 [-0.29 ; 0.44] |
| Week 3 | n= 58 (93.5%) \| 61.64 (7.21) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 55 (88.7%) \| 59.81 (9.13) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 57 (91.9%) \| 57.32 (8.82) | n= 54 (93.1%) \| 58.17 (8.70) | -0.10 [-0.47 ; 0.28] |
| Week 9 | n= 52 (83.9%) \| 58.82 (9.82) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 52 (83.9%) \| 58.10 (9.19) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 52 (83.9%) \| 59.53 (9.15) | n= 45 (77.6%) \| 58.00 (8.75) | 0.17 [-0.23 ; 0.57] |
| Week 15 | n= 47 (75.8%) \| 59.40 (9.50) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 54 (87.1%) \| 59.32 (9.49) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 50 (80.6%) \| 60.17 (7.59) | n= 45 (77.6%) \| 57.95 (8.28) | 0.28 [-0.13 ; 0.68] |
| Week 21 | n= 50 (80.6%) \| 59.22 (8.95) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 47 (75.8%) \| 58.61 (8.46) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 49 (79.0%) \| 60.57 (8.27) | n= 41 (70.7%) \| 59.49 (8.97) | 0.13 [-0.29 ; 0.54] |
| Week 27 | n= 47 (75.8%) \| 61.86 (8.38) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 44 (71.0%) \| 60.71 (8.33) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (72.6%) \| 60.62 (9.17) | n= 35 (60.3%) \| 59.19 (8.44) | 0.16 [-0.29 ; 0.61] |
| Week 33 | n= 48 (77.4%) \| 60.15 (9.23) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 46 (74.2%) \| 59.67 (9.92) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 42 (67.7%) \| 60.57 (8.82) | n= 40 (69.0%) \| 59.95 (6.78) | 0.08 [-0.36 ; 0.51] |
| Week 39 | n= 44 (71.0%) \| 61.70 (8.04) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 44 (71.0%) \| 60.72 (8.12) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 46 (74.2%) \| 59.96 (9.05) | n= 36 (62.1%) \| 59.38 (8.69) | 0.06 [-0.37 ; 0.50] |
| Week 45 | n= 41 (66.1%) \| 59.40 (9.85) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 43 (69.4%) \| 60.66 (8.97) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 44 (71.0%) \| 60.56 (9.06) | n= 32 (55.2%) \| 59.83 (8.30) | 0.08 [-0.38 ; 0.54] |
| Week 51 | n= 43 (69.4%) \| 59.22 (9.48) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 44 (71.0%) \| 60.39 (8.79) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (62.9%) \| 60.84 (8.73) | n= 32 (55.2%) \| 58.05 (7.45) | 0.34 [-0.14 ; 0.81] |
| Week 57 | n= 41 (66.1%) \| 60.38 (8.52) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 39 (62.9%) \| 60.77 (9.18) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 40 (64.5%) \| 60.99 (8.37) | n= 25 (43.1%) \| 56.80 (7.79) | 0.51 [-0.00 ; 1.02] |
| Week 63 | n= 36 (58.1%) \| 59.99 (9.12) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 35 (56.5%) \| 60.04 (8.73) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (61.3%) \| 61.07 (9.00) | n= 24 (41.4%) \| 58.63 (7.09) | 0.29 [-0.23 ; 0.81] |
| Week 69 | n= 32 (51.6%) \| 60.68 (8.73) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 33 (53.2%) \| 61.50 (9.22) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 30 (48.4%) \| 63.56 (6.54) | n= 24 (41.4%) \| 55.82 (7.88) | 1.06 [ 0.49 ; 1.64] |
| Week 75 | n= 32 (51.6%) \| 62.23 (8.14) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 29 (46.8%) \| 61.71 (7.58) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 28 (45.2%) \| 61.65 (11.49) | n= 21 (36.2%) \| 58.14 (6.10) | 0.36 [-0.22 ; 0.94] |
| Week 81 | n= 26 (41.9%) \| 62.73 (7.55) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 31 (50.0%) \| 61.85 (8.88) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (40.3%) \| 62.64 (8.16) | n= 18 (31.0%) \| 58.56 (7.38) | 0.51 [-0.11 ; 1.13] |
| Week 87 | n= 22 (35.5%) \| 60.18 (9.08) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 23 (37.1%) \| 61.05 (7.28) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 21 (33.9%) \| 60.14 (8.80) | n= 15 (25.9%) \| 60.20 (9.70) | -0.01 [-0.68 ; 0.67] |
| Week 93 | n= 21 (33.9%) \| 61.26 (8.47) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 20 (32.3%) \| 60.42 (8.16) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.0%) \| 59.90 (8.16) | n= 9 (15.5%) \| 60.60 (7.27) | -0.09 [-0.90 ; 0.73] |
| Week 99 | n= 15 (24.2%) \| 60.13 (8.87) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.0%) \| 60.31 (8.84) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.0%) \| 59.23 (9.12) | n= 8 (13.8%) \| 57.00 (6.02) | 0.26 [-0.64 ; 1.17] |
| Week 105 | n= 12 (19.4%) \| 58.00 (7.98) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.3%) \| 58.29 (8.73) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.1%) \| 53.34 (6.41) | n= 4 ( 6.9%) \| 55.75 (12.61) | -0.27 [-1.48 ; 0.94] |
| Week 111 | n= 7 (11.3%) \| 54.57 (4.96) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (12.9%) \| 56.81 (7.50) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 ( 9.7%) \| 57.50 (7.40) | n= 4 ( 6.9%) \| 58.75 (7.14) | -0.15 [-1.50 ; 1.19] |
| Week 117 | n= 7 (11.3%) \| 59.43 (5.32) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 (11.3%) \| 56.14 (10.11) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.3%) \| 56.51 (8.67) | n= 1 ( 1.7%) \| 45.39 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.2%) \| 56.89 (5.81) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) \| 50.67 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.6%) \| 61.00 ( / ) | n= 1 ( 1.7%) \| 43.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) \| 51.72 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.6%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.6%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.6%) \| 65.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.6%) \| 50.29 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) \| 46.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 7 (11.3%) \| 60.29 (9.86) | n= 11 (19.0%) \| 53.82 (11.52) | 0.56 [-0.43 ; 1.56] |
| Week 202 | n= 2 ( 3.2%) \| 48.00 (14.14) | n= 7 (12.1%) \| 64.57 (7.14) | -1.73 [-3.68 ; 0.21] |
| **Non-White** | | | |
| N subjects in population | N=9 | N=10 | |
| Baseline | n= 9 (100.0%) \| 66.44 (7.54) | n= 10 (100.0%) \| 64.20 (9.09) | 0.26 [-0.67 ; 1.19] |
| Week 3 | n= 9 (100.0%) \| 67.22 (9.97) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (88.9%) \| 63.63 (12.18) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (77.8%) \| 65.71 (9.76) | n= 10 (100.0%) \| 64.80 (8.63) | 0.10 [-0.90 ; 1.09] |
| Week 9 | n= 9 (100.0%) \| 62.67 (11.55) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (100.0%) \| 59.44 (12.44) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 8 (88.9%) \| 56.50 (11.82) | n= 10 (100.0%) \| 62.80 (5.53) | -0.68 [-1.67 ; 0.31] |
| Week 15 | n= 7 (77.8%) \| 63.14 (9.26) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (100.0%) \| 60.11 (10.33) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 7 (77.8%) \| 62.29 (10.81) | n= 9 (90.0%) \| 64.11 (7.24) | -0.19 [-1.22 ; 0.83] |
| Week 21 | n= 9 (100.0%) \| 62.00 (10.01) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 9 (100.0%) \| 61.11 (10.67) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 9 (100.0%) \| 62.22 (9.09) | n= 8 (80.0%) \| 68.13 (5.91) | -0.72 [-1.74 ; 0.30] |
| Week 27 | n= 9 (100.0%) \| 60.56 (11.68) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 8 (88.9%) \| 61.38 (11.48) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 9 (100.0%) \| 59.89 (9.56) | n= 7 (70.0%) \| 67.86 (7.06) | -0.88 [-1.95 ; 0.20] |
| Week 33 | n= 8 (88.9%) \| 60.50 (9.59) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (88.9%) \| 62.75 (10.82) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 6 (66.7%) \| 61.67 (13.32) | n= 7 (70.0%) \| 66.29 (8.73) | -0.39 [-1.54 ; 0.76] |
| Week 39 | n= 8 (88.9%) \| 61.50 (10.24) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 8 (88.9%) \| 62.88 (11.32) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 43 | n= 6 (66.7%) \| 67.17 (8.52) | n= 6 (60.0%) \| 62.33 (8.19) | 0.53 [-0.68 ; 1.75] |
| Week 45 | n= 7 (77.8%) \| 60.00 (11.33) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 8 (88.9%) \| 62.75 (11.54) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 8 (88.9%) \| 62.13 (12.31) | n= 4 (40.0%) \| 60.75 (6.90) | 0.12 [-1.14 ; 1.38] |
| Week 51 | n= 8 (88.9%) \| 60.63 (13.42) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 8 (88.9%) \| 60.75 (12.53) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (77.8%) \| 58.43 (14.79) | n= 6 (60.0%) \| 64.67 (8.87) | -0.47 [-1.62 ; 0.69] |
| Week 57 | n= 7 (77.8%) \| 62.29 (14.04) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (77.8%) \| 61.17 (12.33) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (88.9%) \| 62.50 (12.07) | n= 6 (60.0%) \| 66.17 (7.99) | -0.32 [-1.43 ; 0.78] |
| Week 63 | n= 6 (66.7%) \| 60.00 (14.79) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (88.9%) \| 57.75 (17.46) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (66.7%) \| 64.17 (7.52) | n= 6 (60.0%) \| 63.00 (6.63) | 0.15 [-1.04 ; 1.34] |
| Week 69 | n= 6 (66.7%) \| 49.67 (19.86) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 5 (55.6%) \| 54.60 (15.77) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 5 (55.6%) \| 51.40 (19.11) | n= 4 (40.0%) \| 60.75 (7.32) | -0.55 [-1.99 ; 0.90] |
| Week 75 | n= 3 (33.3%) \| 63.67 (11.24) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (33.3%) \| 51.67 (10.69) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 3 (33.3%) \| 52.00 (15.39) | n= 4 (40.0%) \| 64.50 (7.77) | -0.92 [-2.69 ; 0.85] |
| Week 81 | n= 3 (33.3%) \| 52.67 (14.64) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (22.2%) \| 46.00 (12.73) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (22.2%) \| 61.00 (12.73) | n= 3 (30.0%) \| 70.33 (2.08) | -0.90 [-3.20 ; 1.40] |
| Week 87 | n= 2 (22.2%) \| 45.50 (14.85) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (22.2%) \| 45.00 (14.14) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (33.3%) \| 53.33 (18.15) | n= 3 (30.0%) \| 66.67 (2.52) | -0.82 [-2.75 ; 1.11] |
| Week 93 | n= 2 (22.2%) \| 47.00 (12.73) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (22.2%) \| 45.00 (15.56) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (33.3%) \| 52.33 (17.21) | n= 2 (20.0%) \| 69.50 (2.12) | -0.88 [-3.18 ; 1.41] |
| Week 99 | n= 2 (22.2%) \| 43.50 (19.09) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (11.1%) \| 56.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (22.2%) \| 60.00 (2.83) | n= 2 (20.0%) \| 70.00 (0.00) | -2.86 [-7.85 ; 2.14] |
| Week 105 | n= 1 (11.1%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (11.1%) \| 58.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 (11.1%) \| 73.00 ( / ) | n= 1 (10.0%) \| 64.00 ( / ) | [Not calculable] |
| Week 115 | n= 1 (11.1%) \| 66.00 ( / ) | n= 1 (10.0%) \| 71.00 ( / ) | [Not calculable] |
| Week 121 | n= 1 (11.1%) \| 66.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 (11.1%) \| 69.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (11.1%) \| 61.00 ( / ) | n= 5 (50.0%) \| 62.00 (8.28) | [Not calculable] |
| Week 202 | [No Data] | n= 4 (40.0%) \| 63.50 (9.33) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:29

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **White** | | | |
| N subjects in population | N=62 | N=58 | |
| Week 3 | n= 57 (91.9%) \|-0.01 (5.83) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 53 (85.5%) \|-1.75 (7.84) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 55 (88.7%) \|-3.82 (8.44) | n= 53 (91.4%) \|-2.61 (8.11) | -0.15 [-0.52 ; 0.23] |
| Week 9 | n= 51 (82.3%) \|-3.68 (8.84) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 51 (82.3%) \|-3.55 (9.04) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 51 (82.3%) \|-2.60 (8.24) | n= 45 (77.6%) \|-5.19 (8.42) | 0.31 [-0.10 ; 0.71] |
| Week 15 | n= 47 (75.8%) \|-2.52 (9.14) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 53 (85.5%) \|-2.85 (8.31) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 49 (79.0%) \|-2.47 (7.43) | n= 44 (75.9%) \|-4.57 (8.23) | 0.27 [-0.14 ; 0.68] |
| Week 21 | n= 50 (80.6%) \|-2.89 (8.11) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 47 (75.8%) \|-2.99 (7.24) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 48 (77.4%) \|-1.90 (8.64) | n= 40 (69.0%) \|-3.97 (10.11) | 0.22 [-0.20 ; 0.64] |
| Week 27 | n= 46 (74.2%) \|-1.34 (8.28) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 44 (71.0%) \|-1.96 (8.07) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (72.6%) \|-2.10 (8.69) | n= 35 (60.3%) \|-3.21 (9.00) | 0.12 [-0.32 ; 0.57] |
| Week 33 | n= 48 (77.4%) \|-2.47 (8.14) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 45 (72.6%) \|-2.78 (8.62) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 42 (67.7%) \|-1.83 (7.75) | n= 39 (67.2%) \|-2.49 (6.81) | 0.09 [-0.35 ; 0.53] |
| Week 39 | n= 43 (69.4%) \|-1.49 (8.02) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 44 (71.0%) \|-2.69 (8.65) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 45 (72.6%) \|-2.74 (9.09) | n= 35 (60.3%) \|-3.61 (7.57) | 0.10 [-0.34 ; 0.55] |
| Week 45 | n= 41 (66.1%) \|-3.12 (9.81) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 43 (69.4%) \|-2.62 (8.73) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 44 (71.0%) \|-1.92 (7.91) | n= 31 (53.4%) \|-3.40 (7.20) | 0.19 [-0.27 ; 0.66] |
| Week 51 | n= 43 (69.4%) \|-2.84 (8.66) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 44 (71.0%) \|-2.07 (8.63) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (62.9%) \|-1.86 (7.94) | n= 31 (53.4%) \|-4.27 (7.05) | 0.32 [-0.16 ; 0.79] |
| Week 57 | n= 41 (66.1%) \|-2.17 (8.96) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 39 (62.9%) \|-1.27 (9.21) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 40 (64.5%) \|-1.80 (8.54) | n= 24 (41.4%) \|-5.00 (7.02) | 0.39 [-0.12 ; 0.91] |
| Week 63 | n= 36 (58.1%) \|-1.99 (8.70) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 35 (56.5%) \|-0.97 (8.37) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (61.3%) \|-1.05 (9.19) | n= 23 (39.7%) \|-2.96 (8.32) | 0.21 [-0.31 ; 0.74] |
| Week 69 | n= 32 (51.6%) \|-2.30 (8.93) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 33 (53.2%) \|-1.28 (9.50) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 30 (48.4%) \| 1.10 (7.45) | n= 24 (41.4%) \|-5.68 (8.78) | 0.83 [ 0.26 ; 1.39] |
| Week 75 | n= 32 (51.6%) \|-0.68 (8.14) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 29 (46.8%) \|-0.29 (8.81) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 28 (45.2%) \|-0.60 (10.86) | n= 20 (34.5%) \|-2.41 (7.50) | 0.18 [-0.40 ; 0.77] |
| Week 81 | n= 26 (41.9%) \|-0.04 (6.25) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 31 (50.0%) \|-0.67 (9.79) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (40.3%) \|-0.21 (8.19) | n= 17 (29.3%) \|-3.29 (8.97) | 0.36 [-0.27 ; 0.98] |
| Week 87 | n= 22 (35.5%) \|-2.04 (8.75) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 23 (37.1%) \|-1.13 (7.10) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 21 (33.9%) \|-3.10 (7.68) | n= 14 (24.1%) \|-2.92 (13.58) | -0.02 [-0.70 ; 0.67] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 21 (33.9%) \|-1.94 (7.65) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 20 (32.3%) \|-2.18 (7.83) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.0%) \|-2.32 (8.45) | n= 8 (13.8%) \|-1.58 (7.43) | -0.09 [-0.94 ; 0.76] |
| Week 99 | n= 15 (24.2%) \|-1.60 (8.24) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.0%) \|-3.38 (7.60) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.0%) \|-3.01 (7.26) | n= 7 (12.1%) \|-5.14 (8.15) | 0.27 [-0.68 ; 1.22] |
| Week 105 | n= 12 (19.4%) \|-4.09 (6.53) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.3%) \|-5.70 (8.68) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.1%) \|-6.95 (7.75) | n= 3 ( 5.2%) \|-8.00 (11.00) | 0.12 [-1.23 ; 1.46] |
| Week 111 | n= 7 (11.3%) \|-7.84 (6.83) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (12.9%) \|-5.80 (8.21) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 ( 9.7%) \|-3.81 (7.71) | n= 4 ( 6.9%) \|-8.00 (8.41) | 0.47 [-0.89 ; 1.84] |
| Week 117 | n= 7 (11.3%) \|-2.41 (6.78) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 (11.3%) \|-4.41 (9.63) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.3%) \|-4.19 (9.99) | n= 1 ( 1.7%) \|-23.61 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.2%) \| 0.39 (6.52) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) \|-6.33 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.6%) \| 4.00 ( / ) | n= 1 ( 1.7%) \|-26.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) \|-5.28 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.6%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.6%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.6%) \| 8.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.6%) \|-6.71 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) \|-10.06 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 7 (11.3%) \|-1.96 (4.39) | n= 11 (19.0%) \|-6.45 (12.27) | 0.43 [-0.56 ; 1.41] |
| Week 202 | n= 2 ( 3.2%) \|-12.50 (9.19) | n= 7 (12.1%) \| 1.29 (9.18) | -1.33 [-3.18 ; 0.51] |
| **Non-White** | | | |
| N subjects in population | N=9 | N=10 | |
| Week 3 | n= 9 (100.0%) \| 0.78 (4.87) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (88.9%) \|-1.63 (6.59) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (77.8%) \|-1.14 (5.73) | n= 10 (100.0%) \| 0.60 (8.55) | -0.22 [-1.22 ; 0.78] |
| Week 9 | n= 9 (100.0%) \|-3.78 (5.40) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (100.0%) \|-7.00 (7.89) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 8 (88.9%) \|-9.25 (5.55) | n= 10 (100.0%) \|-1.40 (9.06) | -0.97 [-1.99 ; 0.05] |
| Week 15 | n= 7 (77.8%) \|-4.29 (7.89) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (100.0%) \|-6.33 (6.52) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 7 (77.8%) \|-6.00 (7.23) | n= 9 (90.0%) \|-0.11 (7.70) | -0.74 [-1.80 ; 0.32] |
| Week 21 | n= 9 (100.0%) \|-4.44 (8.47) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 9 (100.0%) \|-5.33 (8.51) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 9 (100.0%) \|-4.22 (7.71) | n= 8 (80.0%) \| 1.88 (3.91) | -0.93 [-1.97 ; 0.11] |
| Week 27 | n= 9 (100.0%) \|-5.89 (9.97) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 8 (88.9%) \|-5.13 (7.68) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 9 (100.0%) \|-6.56 (7.37) | n= 7 (70.0%) \| 1.00 (5.03) | -1.10 [-2.21 ; 0.00] |
| Week 33 | n= 8 (88.9%) \|-5.25 (6.27) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (88.9%) \|-4.88 (6.58) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 6 (66.7%) \|-3.83 (7.22) | n= 7 (70.0%) \|-1.57 (7.02) | -0.30 [-1.44 ; 0.85] |
| Week 39 | n= 8 (88.9%) \|-4.25 (6.54) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 8 (88.9%) \|-4.75 (6.27) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 6 (66.7%) \|-3.00 (6.96) | n= 6 (60.0%) \|-5.50 (6.50) | 0.34 [-0.85 ; 1.54] |
| Week 45 | n= 7 (77.8%) \|-6.86 (5.81) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 47 | n= 8 (88.9%) \|-4.88 (6.29) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 8 (88.9%) \|-5.50 (8.16) | n= 4 (40.0%) \|-4.00 (8.68) | -0.17 [-1.43 ; 1.10] |
| Week 51 | n= 8 (88.9%) \|-7.00 (8.77) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 8 (88.9%) \|-6.88 (7.83) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (77.8%) \|-8.57 (10.44) | n= 6 (60.0%) \|-3.17 (7.83) | -0.54 [-1.70 ; 0.62] |
| Week 57 | n= 7 (77.8%) \|-5.71 (8.32) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (77.8%) \|-6.69 (7.02) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (88.9%) \|-5.13 (6.49) | n= 6 (60.0%) \|-1.67 (4.84) | -0.55 [-1.68 ; 0.57] |
| Week 63 | n= 6 (66.7%) \|-7.67 (7.50) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (88.9%) \|-9.88 (11.42) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (66.7%) \|-5.00 (4.52) | n= 6 (60.0%) \|-4.83 (4.49) | -0.03 [-1.22 ; 1.15] |
| Week 69 | n= 6 (66.7%) \|-15.83 (16.17) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 5 (55.6%) \|-10.80 (12.97) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 5 (55.6%) \|-14.00 (17.44) | n= 4 (40.0%) \|-5.25 (7.93) | -0.55 [-1.99 ; 0.89] |
| Week 75 | n= 3 (33.3%) \|-3.33 (7.09) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (33.3%) \|-9.00 (6.24) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 3 (33.3%) \|-11.67 (6.43) | n= 4 (40.0%) \|-1.50 (5.07) | -1.52 [-3.47 ; 0.44] |
| Week 81 | n= 3 (33.3%) \|-11.00 (5.57) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (22.2%) \|-13.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (22.2%) \|-7.50 (7.78) | n= 3 (30.0%) \| 0.67 (7.37) | -0.79 [-3.05 ; 1.47] |
| Week 87 | n= 2 (22.2%) \|-14.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (22.2%) \|-14.50 (6.36) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (33.3%) \|-10.33 (9.07) | n= 3 (30.0%) \|-3.00 (8.89) | -0.65 [-2.54 ; 1.23] |
| Week 93 | n= 2 (22.2%) \|-12.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (22.2%) \|-14.50 (7.78) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (33.3%) \|-11.33 (8.39) | n= 2 (20.0%) \|-4.00 (2.83) | -0.76 [-3.00 ; 1.49] |
| Week 99 | n= 2 (22.2%) \|-16.00 (11.31) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (11.1%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (22.2%) \|-8.50 (2.12) | n= 2 (20.0%) \|-3.50 (0.71) | -1.81 [-5.50 ; 1.88] |
| Week 105 | n= 1 (11.1%) \|-8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (11.1%) \|-7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 (11.1%) \| 1.00 ( / ) | n= 1 (10.0%) \|-9.00 ( / ) | [Not calculable] |
| Week 115 | n= 1 (11.1%) \|-6.00 ( / ) | n= 1 (10.0%) \|-2.00 ( / ) | [Not calculable] |
| Week 121 | n= 1 (11.1%) \|-6.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 (11.1%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (11.1%) \|-11.00 ( / ) | n= 5 (50.0%) \| 0.20 (6.72) | [Not calculable] |
| Week 202 | [No Data] | n= 4 (40.0%) \| 0.00 (13.24) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:29

TABLE 7.3.5: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **White** | | | | |
| Nr subjects used | n=60 | n=57 | | |
| Week 7 | -4.61 (1.21) [-7.02 ;-2.20] | -3.26 (1.26) [-5.75 ;-0.77] | -1.35 (1.74) [-4.81 ; 2.11] | -0.15 [-0.53 ; 0.23] |
| Week 13 | -2.99 (1.24) [-5.46 ;-0.52] | -5.03 (1.31) [-7.63 ;-2.43] | 2.04 (1.81) [-1.54 ; 5.62] | 0.23 [-0.17 ; 0.63] |
| Week 19 | -2.41 (0.99) [-4.37 ;-0.44] | -4.90 (1.05) [-6.98 ;-2.83] | 2.50 (1.44) [-0.36 ; 5.35] | 0.36 [-0.05 ; 0.77] |
| Week 25 | -1.99 (1.14) [-4.24 ; 0.26] | -3.80 (1.22) [-6.21 ;-1.39] | 1.81 (1.67) [-1.49 ; 5.11] | 0.23 [-0.19 ; 0.65] |
| Week 31 | -2.25 (1.09) [-4.42 ;-0.09] | -3.10 (1.19) [-5.45 ;-0.75] | 0.84 (1.61) [-2.35 ; 4.04] | 0.12 [-0.33 ; 0.56] |
| Week 37 | -2.00 (0.97) [-3.92 ;-0.07] | -3.01 (1.04) [-5.06 ;-0.96] | 1.02 (1.42) [-1.79 ; 3.83] | 0.16 [-0.28 ; 0.59] |
| Week 43 | -2.69 (1.12) [-4.91 ;-0.48] | -3.09 (1.24) [-5.55 ;-0.64] | 0.40 (1.67) [-2.91 ; 3.71] | 0.05 [-0.39 ; 0.50] |
| Week 49 | -2.49 (1.03) [-4.54 ;-0.45] | -2.65 (1.19) [-5.01 ;-0.30] | 0.16 (1.57) [-2.96 ; 3.28] | 0.02 [-0.44 ; 0.48] |
| Week 55 | -1.91 (1.07) [-4.02 ; 0.20] | -3.49 (1.22) [-5.91 ;-1.06] | 1.57 (1.62) [-1.64 ; 4.79] | 0.23 [-0.24 ; 0.70] |
| Week 61 | -2.23 (1.07) [-4.36 ;-0.11] | -3.82 (1.31) [-6.42 ;-1.22] | 1.59 (1.69) [-1.77 ; 4.95] | 0.24 [-0.27 ; 0.74] |
| Week 67 | -1.64 (1.14) [-3.89 ; 0.62] | -2.52 (1.41) [-5.31 ; 0.27] | 0.88 (1.81) [-2.71 ; 4.47] | 0.13 [-0.39 ; 0.64] |
| Week 73 | -0.58 (1.04) [-2.64 ; 1.48] | -5.40 (1.22) [-7.82 ;-2.98] | 4.82 (1.60) [ 1.64 ; 7.99] | 0.82 [ 0.26 ; 1.38] |
| Week 79 | -1.86 (1.32) [-4.49 ; 0.77] | -3.07 (1.57) [-6.18 ; 0.05] | 1.20 (2.05) [-2.88 ; 5.28] | 0.17 [-0.41 ; 0.74] |
| Week 85 | -2.29 (1.24) [-4.75 ; 0.18] | -3.55 (1.47) [-6.48 ;-0.61] | 1.26 (1.92) [-2.57 ; 5.09] | 0.20 [-0.42 ; 0.82] |
| Week 91 | -2.67 (1.67) [-6.01 ; 0.67] | -2.49 (2.01) [-6.52 ; 1.54] | -0.18 (2.61) [-5.41 ; 5.05] | -0.02 [-0.70 ; 0.65] |
| Overall post-baseline period estimate | -2.31 (0.67) [-3.63 ;-0.98] | -3.55 (0.75) [-5.04 ;-2.05] | 1.24 (1.01) [-0.76 ; 3.23] | 0.23 [-0.14 ; 0.60] |
| **Non-White** | | | | |
| Nr subjects used | n=9 | n=10 | | |
| **MMRM subgroups interaction p-value** | | | | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:29

TABLE 7.3.6: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **Hispanic or Latino** | N=7 | N=12 |
| **Not Hispanic or Latino** | N=42 | N=31 |
| **Not Reported** | N=22 | N=25 |
| **Subjects with Baseline Value** | | |
| **Hispanic or Latino** | 7 (100.0%) | 11 (91.7%) |
| **Not Hispanic or Latino** | 40 (95.2%) | 31 (100.0%) |
| **Not Reported** | 22 (100.0%) | 25 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **Hispanic or Latino** | 7 (100.0%) | 12 (100.0%) |
| **Not Hispanic or Latino** | 42 (100.0%) | 30 (96.8%) |
| **Not Reported** | 22 (100.0%) | 24 (96.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **Hispanic or Latino** | 7 (100.0%) | 11 (91.7%) |
| **Not Hispanic or Latino** | 40 (95.2%) | 30 (96.8%) |
| **Not Reported** | 22 (100.0%) | 24 (96.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:29

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Hispanic or Latino** | | | |
| N subjects in population | N=7 | N=12 | |
| Baseline | n= 7 (100.0%) \| 57.74 (8.29) | n= 11 (91.7%) \| 57.82 (12.97) | -0.01 [-0.98 ; 0.97] |
| Week 3 | n= 7 (100.0%) \| 60.02 (6.73) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 6 (85.7%) \| 61.50 (4.55) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (100.0%) \| 60.14 (6.77) | n= 12 (100.0%) \| 56.08 (11.42) | 0.39 [-0.58 ; 1.35] |
| Week 9 | n= 6 (85.7%) \| 55.50 (10.09) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 6 (85.7%) \| 59.00 (8.00) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 7 (100.0%) \| 55.14 (8.71) | n= 7 (58.3%) \| 58.68 (6.22) | -0.44 [-1.54 ; 0.67] |
| Week 15 | n= 5 (71.4%) \| 57.00 (9.41) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 6 (85.7%) \| 53.57 (13.72) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 5 (71.4%) \| 58.60 (9.40) | n= 7 (58.3%) \| 58.14 (5.98) | 0.06 [-1.15 ; 1.26] |
| Week 21 | n= 6 (85.7%) \| 53.30 (17.10) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (85.7%) \| 56.33 (11.84) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 4 (57.1%) \| 64.50 (7.14) | n= 7 (58.3%) \| 61.57 (6.32) | 0.41 [-0.91 ; 1.72] |
| Week 27 | n= 4 (57.1%) \| 65.50 (7.05) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 4 (57.1%) \| 62.25 (9.00) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 4 (57.1%) \| 59.75 (11.59) | n= 5 (41.7%) \| 60.80 (4.76) | -0.11 [-1.52 ; 1.30] |
| Week 33 | n= 4 (57.1%) \| 58.50 (16.30) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 3 (42.9%) \| 59.33 (17.62) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 2 (28.6%) \| 69.00 (0.00) | n= 5 (41.7%) \| 60.67 (9.94) | 0.79 [-1.10 ; 2.68] |
| Week 39 | n= 4 (57.1%) \| 66.25 (3.77) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 3 (42.9%) \| 66.00 (5.29) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 3 (42.9%) \| 66.33 (3.79) | n= 5 (41.7%) \| 58.92 (5.80) | 1.24 [-0.49 ; 2.96] |
| Week 45 | n= 2 (28.6%) \| 69.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 2 (28.6%) \| 68.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 3 (42.9%) \| 67.00 (4.36) | n= 4 (33.3%) \| 58.00 (1.63) | 2.50 [ 0.12 ; 4.88] |
| Week 51 | n= 3 (42.9%) \| 66.09 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 2 (28.6%) \| 69.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 3 (42.9%) \| 68.33 (2.08) | n= 4 (33.3%) \| 54.00 (7.79) | 1.95 [-0.18 ; 4.08] |
| Week 57 | n= 3 (42.9%) \| 67.33 (3.79) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 3 (42.9%) \| 67.33 (3.79) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 3 (42.9%) \| 65.09 (3.49) | n= 4 (33.3%) \| 59.25 (6.13) | 0.94 [-0.84 ; 2.71] |
| Week 63 | n= 3 (42.9%) \| 66.67 (4.93) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 3 (42.9%) \| 67.00 (3.46) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 3 (42.9%) \| 67.00 (4.36) | n= 4 (33.3%) \| 56.25 (4.35) | 2.08 [-0.11 ; 4.26] |
| Week 69 | n= 3 (42.9%) \| 66.67 (3.21) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 2 (28.6%) \| 69.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (42.9%) \| 67.00 (3.61) | n= 3 (25.0%) \| 54.67 (5.13) | 2.22 [-0.32 ; 4.77] |
| Week 75 | n= 3 (42.9%) \| 66.67 (4.16) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 2 (28.6%) \| 69.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 3 (42.9%) \| 66.67 (4.93) | n= 4 (33.3%) \| 62.75 (9.84) | 0.40 [-1.28 ; 2.08] |
| Week 81 | n= 3 (42.9%) \| 67.67 (2.31) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 3 (42.9%) \| 66.67 (4.04) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 3 (42.9%) \| 66.33 (5.51) | n= 3 (25.0%) \| 66.00 (2.65) | 0.06 [-1.75 ; 1.88] |
| Week 87 | n= 2 (28.6%) \| 69.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (28.6%) \| 66.00 (4.24) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 2 (28.6%) \| 64.50 (6.36) | n= 3 (25.0%) \| 66.00 (1.00) | -0.29 [-2.42 ; 1.84] |
| Week 93 | n= 2 (28.6%) \| 66.69 (3.26) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (28.6%) \| 65.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 2 (28.6%) \| 64.14 (2.63) | n= 3 (25.0%) \| 67.33 (3.21) | -0.77 [-3.02 ; 1.48] |
| Week 99 | n= 2 (28.6%) \| 66.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (14.3%) \| 69.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 1 (14.3%) \| 62.00 ( / ) | n= 2 (16.7%) \| 60.50 (13.44) | [Not calculable] |
| Week 105 | n= 1 (14.3%) \| 61.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | [No Data] | n= 2 (16.7%) \| 52.00 (16.97) | [No Data for at least 1 arm] |
| Week 115 | [No Data] | n= 1 ( 8.3%) \| 71.00 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 1 (14.3%) \| 47.00 ( / ) | n= 3 (25.0%) \| 57.33 (8.50) | [Not calculable] |
| Week 202 | [No Data] | n= 2 (16.7%) \| 67.50 (3.54) | [No Data for at least 1 arm] |
| **Not Hispanic or Latino** | | | |
| N subjects in population | N=42 | N=31 | |
| Baseline | n= 40 (95.2%) \| 62.51 (8.22) | n= 31 (100.0%) \| 61.25 (7.42) | 0.16 [-0.32 ; 0.63] |
| Week 3 | n= 40 (95.2%) \| 62.09 (7.68) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 38 (90.5%) \| 59.37 (10.71) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 37 (88.1%) \| 57.66 (9.97) | n= 29 (93.5%) \| 60.65 (7.23) | -0.33 [-0.83 ; 0.16] |
| Week 9 | n= 35 (83.3%) \| 59.16 (9.92) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 36 (85.7%) \| 57.08 (9.86) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 33 (78.6%) \| 60.22 (9.14) | n= 25 (80.6%) \| 59.08 (8.98) | 0.12 [-0.40 ; 0.65] |
| Week 15 | n= 29 (69.0%) \| 60.24 (9.71) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 35 (83.3%) \| 59.09 (9.16) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 31 (73.8%) \| 60.11 (7.85) | n= 26 (83.9%) \| 58.97 (7.42) | 0.15 [-0.38 ; 0.67] |
| Week 21 | n= 32 (76.2%) \| 59.77 (8.04) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 29 (69.0%) \| 57.64 (8.36) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 34 (81.0%) \| 60.12 (8.46) | n= 24 (77.4%) \| 61.21 (7.49) | -0.13 [-0.66 ; 0.39] |
| Week 27 | n= 30 (71.4%) \| 61.40 (8.87) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 29 (69.0%) \| 60.03 (9.06) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 28 (66.7%) \| 60.29 (9.25) | n= 19 (61.3%) \| 60.77 (8.49) | -0.05 [-0.64 ; 0.54] |
| Week 33 | n= 32 (76.2%) \| 59.53 (8.68) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 30 (71.4%) \| 59.87 (9.53) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 25 (59.5%) \| 60.12 (9.25) | n= 22 (71.0%) \| 61.04 (6.37) | -0.11 [-0.69 ; 0.47] |
| Week 39 | n= 30 (71.4%) \| 60.83 (9.29) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 32 (76.2%) \| 59.86 (9.00) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 29 (69.0%) \| 60.27 (9.73) | n= 17 (54.8%) \| 60.32 (9.38) | -0.01 [-0.61 ; 0.60] |
| Week 45 | n= 27 (64.3%) \| 59.16 (10.70) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 30 (71.4%) \| 60.30 (9.72) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 29 (69.0%) \| 59.21 (10.55) | n= 13 (41.9%) \| 60.90 (7.49) | -0.17 [-0.83 ; 0.49] |
| Week 51 | n= 27 (64.3%) \| 58.18 (10.72) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 30 (71.4%) \| 59.17 (10.17) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 25 (59.5%) \| 58.80 (10.39) | n= 15 (48.4%) \| 59.47 (8.36) | -0.07 [-0.72 ; 0.58] |
| Week 57 | n= 28 (66.7%) \| 58.41 (10.32) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 25 (59.5%) \| 59.21 (10.54) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 26 (61.9%) \| 60.09 (10.05) | n= 11 (35.5%) \| 57.36 (9.29) | 0.27 [-0.45 ; 0.99] |
| Week 63 | n= 24 (57.1%) \| 58.54 (11.09) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (52.4%) \| 57.05 (12.92) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 22 (52.4%) \| 59.86 (10.06) | n= 12 (38.7%) \| 60.83 (8.11) | -0.10 [-0.81 ; 0.61] |
| Week 69 | n= 20 (47.6%) \| 58.55 (12.76) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 21 (50.0%) \| 59.86 (11.58) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (38.1%) \| 60.83 (12.73) | n= 12 (38.7%) \| 57.76 (10.17) | 0.25 [-0.51 ; 1.02] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 75 | n= 17 (40.5%) \| 62.71 (8.64) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 17 (40.5%) \| 59.09 (9.59) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 15 (35.7%) \| 61.07 (12.31) | n= 10 (32.3%) \| 59.30 (7.35) | 0.16 [-0.66 ; 0.98] |
| Week 81 | n= 15 (35.7%) \| 61.20 (10.53) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (40.5%) \| 59.00 (11.31) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 13 (31.0%) \| 62.62 (8.40) | n= 9 (29.0%) \| 59.78 (9.76) | 0.30 [-0.57 ; 1.18] |
| Week 87 | n= 11 (26.2%) \| 57.27 (10.66) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 12 (28.6%) \| 58.00 (10.20) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 13 (31.0%) \| 58.30 (12.16) | n= 8 (25.8%) \| 62.63 (10.01) | -0.36 [-1.27 ; 0.55] |
| Week 93 | n= 12 (28.6%) \| 57.92 (10.60) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (26.2%) \| 56.59 (11.36) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (28.6%) \| 56.50 (11.07) | n= 5 (16.1%) \| 61.00 (9.59) | -0.40 [-1.49 ; 0.69] |
| Week 99 | n= 8 (19.0%) \| 54.50 (13.45) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 7 (16.7%) \| 59.14 (9.46) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (19.0%) \| 59.69 (8.56) | n= 4 (12.9%) \| 62.50 (8.58) | -0.30 [-1.57 ; 0.96] |
| Week 105 | n= 7 (16.7%) \| 60.00 (9.40) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 5 (11.9%) \| 59.80 (10.16) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (19.0%) \| 56.88 (9.14) | n= 1 ( 3.2%) \| 69.00 ( / ) | [Not calculable] |
| Week 111 | n= 5 (11.9%) \| 54.80 (6.02) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 (11.9%) \| 59.00 (8.28) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 5 (11.9%) \| 60.40 (8.26) | n= 2 ( 6.5%) \| 62.00 (7.07) | -0.17 [-1.98 ; 1.65] |
| Week 117 | n= 4 ( 9.5%) \| 62.00 (5.23) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 9.5%) \| 58.25 (10.05) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (11.9%) \| 58.20 (9.65) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.4%) \| 69.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (14.3%) \| 62.50 (8.69) | n= 8 (25.8%) \| 57.88 (10.64) | 0.44 [-0.68 ; 1.55] |
| Week 202 | n= 2 ( 4.8%) \| 48.00 (14.14) | n= 4 (12.9%) \| 60.50 (5.80) | -1.15 [-3.29 ; 0.98] |
| **Not Reported** | | | |
| N subjects in population | N=22 | N=25 | |
| Baseline | n= 22 (100.0%) \| 62.55 (7.81) | n= 25 (100.0%) \| 62.83 (7.66) | -0.04 [-0.61 ; 0.54] |
| Week 3 | n= 20 (90.9%) \| 63.82 (8.42) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 19 (86.4%) \| 61.77 (8.19) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 20 (90.9%) \| 58.63 (8.81) | n= 23 (92.0%) \| 59.01 (9.48) | -0.04 [-0.65 ; 0.57] |
| Week 9 | n= 20 (90.9%) \| 60.96 (10.53) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 19 (86.4%) \| 60.39 (9.70) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 20 (90.9%) \| 58.73 (10.32) | n= 23 (92.0%) \| 58.70 (8.70) | 0.00 [-0.60 ; 0.61] |
| Week 15 | n= 20 (90.9%) \| 60.09 (9.51) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 22 (100.0%) \| 61.59 (8.52) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 21 (95.5%) \| 61.34 (8.09) | n= 21 (84.0%) \| 59.27 (10.30) | 0.22 [-0.39 ; 0.83] |
| Week 21 | n= 21 (95.5%) \| 61.25 (7.15) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (95.5%) \| 61.67 (8.21) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 20 (90.9%) \| 61.30 (8.51) | n= 18 (72.0%) \| 60.22 (11.93) | 0.10 [-0.54 ; 0.75] |
| Week 27 | n= 22 (100.0%) \| 61.29 (9.35) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 19 (86.4%) \| 61.69 (8.59) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 22 (100.0%) \| 60.91 (9.03) | n= 18 (72.0%) \| 60.44 (10.21) | 0.05 [-0.58 ; 0.68] |
| Week 33 | n= 20 (90.9%) \| 61.61 (8.74) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 21 (95.5%) \| 60.61 (10.13) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 21 (95.5%) \| 60.62 (9.71) | n= 20 (80.0%) \| 60.79 (8.07) | -0.02 [-0.64 ; 0.60] |
| Week 39 | n= 18 (81.8%) \| 62.06 (7.12) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 17 (77.3%) \| 62.41 (8.09) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 20 (90.9%) \| 60.71 (9.00) | n= 20 (80.0%) \| 59.58 (8.81) | 0.12 [-0.50 ; 0.75] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 45 | n= 19 (86.4%) \| 58.95 (9.09) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 19 (86.4%) \| 61.29 (9.05) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 20 (90.9%) \| 62.18 (8.04) | n= 19 (76.0%) \| 59.68 (9.35) | 0.28 [-0.36 ; 0.92] |
| Week 51 | n= 21 (95.5%) \| 60.11 (9.62) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 20 (90.9%) \| 61.46 (7.92) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 18 (81.8%) \| 61.49 (8.96) | n= 19 (76.0%) \| 59.87 (7.67) | 0.19 [-0.46 ; 0.85] |
| Week 57 | n= 17 (77.3%) \| 63.18 (7.17) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 18 (81.8%) \| 62.01 (8.40) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 19 (86.4%) \| 62.20 (7.90) | n= 16 (64.0%) \| 59.31 (8.94) | 0.34 [-0.34 ; 1.02] |
| Week 63 | n= 15 (68.2%) \| 60.98 (8.14) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 18 (81.8%) \| 61.53 (7.10) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 19 (86.4%) \| 62.51 (7.46) | n= 14 (56.0%) \| 59.29 (6.93) | 0.43 [-0.27 ; 1.14] |
| Week 69 | n= 15 (68.2%) \| 57.92 (10.80) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 15 (68.2%) \| 60.50 (8.80) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (72.7%) \| 61.85 (7.23) | n= 13 (52.0%) \| 55.82 (6.10) | 0.87 [ 0.09 ; 1.65] |
| Week 75 | n= 15 (68.2%) \| 61.10 (8.45) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 13 (59.1%) \| 61.69 (6.08) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 13 (59.1%) \| 58.94 (12.81) | n= 11 (44.0%) \| 57.73 (4.58) | 0.12 [-0.70 ; 0.94] |
| Week 81 | n= 11 (50.0%) \| 60.73 (6.65) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 13 (59.1%) \| 62.03 (7.85) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (50.0%) \| 61.36 (8.94) | n= 9 (36.0%) \| 58.78 (7.03) | 0.30 [-0.61 ; 1.21] |
| Week 87 | n= 11 (50.0%) \| 58.73 (9.78) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 11 (50.0%) \| 60.55 (7.46) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 9 (40.9%) \| 59.56 (7.49) | n= 7 (28.0%) \| 57.71 (9.66) | 0.21 [-0.82 ; 1.23] |
| Week 93 | n= 9 (40.9%) \| 61.33 (8.40) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 9 (40.9%) \| 60.56 (7.54) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (31.8%) \| 61.29 (7.67) | n= 3 (12.0%) \| 59.13 (5.20) | 0.27 [-1.17 ; 1.72] |
| Week 99 | n= 7 (31.8%) \| 60.14 (8.30) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (27.3%) \| 59.50 (8.14) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 6 (27.3%) \| 58.41 (9.80) | n= 4 (16.0%) \| 56.25 (3.77) | 0.24 [-1.11 ; 1.59] |
| Week 105 | n= 5 (22.7%) \| 54.40 (4.16) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 3 (13.6%) \| 55.67 (2.52) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (13.6%) \| 50.46 (4.83) | n= 2 ( 8.0%) \| 57.00 (7.07) | -0.84 [-3.11 ; 1.44] |
| Week 111 | n= 2 ( 9.1%) \| 54.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (13.6%) \| 53.17 (5.30) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 2 ( 9.1%) \| 54.50 (3.54) | n= 2 ( 8.0%) \| 55.50 (7.78) | -0.09 [-2.56 ; 2.37] |
| Week 117 | n= 3 (13.6%) \| 56.00 (3.61) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 (13.6%) \| 53.33 (11.59) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (13.6%) \| 56.85 (8.75) | n= 1 ( 4.0%) \| 45.39 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 9.1%) \| 56.89 (5.81) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.5%) \| 50.67 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 4.5%) \| 61.00 ( / ) | n= 1 ( 4.0%) \| 43.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 4.5%) \| 51.72 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 4.5%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.5%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 4.5%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 4.5%) \| 65.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 4.5%) \| 50.29 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.5%) \| 46.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 4.5%) \| 61.00 ( / ) | n= 5 (20.0%) \| 53.40 (14.40) | [Not calculable] |
| Week 202 | [No Data] | n= 5 (20.0%) \| 65.80 (9.58) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:29

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Hispanic or Latino** | | | |
| N subjects in population | N=7 | N=12 | |
| Week 3 | n= 7 (100.0%) \| 2.29 (2.87) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 6 (85.7%) \| 1.64 (2.69) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (100.0%) \| 2.40 (4.25) | n= 11 (91.7%) \|-2.55 (10.16) | 0.56 [-0.44 ; 1.55] |
| Week 9 | n= 6 (85.7%) \|-1.83 (9.02) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 6 (85.7%) \|-0.86 (3.62) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 7 (100.0%) \|-2.60 (10.12) | n= 7 (58.3%) \|-6.32 (8.82) | 0.37 [-0.73 ; 1.47] |
| Week 15 | n= 5 (71.4%) \|-0.80 (10.38) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 6 (85.7%) \|-3.77 (13.36) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 5 (71.4%) \|-2.23 (3.29) | n= 6 (50.0%) \|-8.83 (7.22) | 1.04 [-0.31 ; 2.39] |
| Week 21 | n= 6 (85.7%) \|-4.03 (14.46) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (85.7%) \|-1.00 (9.65) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 4 (57.1%) \| 3.50 (4.20) | n= 6 (50.0%) \|-4.00 (5.62) | 1.32 [-0.19 ; 2.83] |
| Week 27 | n= 4 (57.1%) \| 4.50 (5.00) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 4 (57.1%) \| 1.25 (2.87) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 4 (57.1%) \|-1.25 (4.50) | n= 5 (41.7%) \|-4.80 (7.46) | 0.50 [-0.94 ; 1.93] |
| Week 33 | n= 4 (57.1%) \|-2.50 (9.98) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 3 (42.9%) \|-3.00 (9.17) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 2 (28.6%) \| 1.50 (3.54) | n= 4 (33.3%) \|-4.42 (5.44) | 0.94 [-1.13 ; 3.01] |
| Week 39 | n= 4 (57.1%) \| 3.21 (3.10) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 3 (42.9%) \| 0.94 (3.63) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 3 (42.9%) \| 1.28 (3.04) | n= 4 (33.3%) \|-7.60 (7.93) | 1.16 [-0.67 ; 3.00] |
| Week 45 | n= 2 (28.6%) \| 1.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 2 (28.6%) \| 1.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 3 (42.9%) \| 1.94 (3.00) | n= 3 (25.0%) \|-10.00 (6.24) | 1.95 [-0.44 ; 4.34] |
| Week 51 | n= 3 (42.9%) \| 1.04 (3.62) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 2 (28.6%) \| 2.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 3 (42.9%) \| 3.28 (3.73) | n= 3 (25.0%) \|-15.00 (10.58) | 1.84 [-0.50 ; 4.18] |
| Week 57 | n= 3 (42.9%) \| 2.28 (3.04) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 3 (42.9%) \| 2.28 (3.04) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 3 (42.9%) \| 0.04 (1.80) | n= 3 (25.0%) \|-6.67 (3.79) | 1.81 [-0.51 ; 4.13] |
| Week 63 | n= 3 (42.9%) \| 1.61 (3.07) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 3 (42.9%) \| 1.94 (2.62) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 3 (42.9%) \| 1.94 (2.00) | n= 3 (25.0%) \|-10.00 (6.08) | 2.11 [-0.37 ; 4.59] |
| Week 69 | n= 3 (42.9%) \| 1.61 (3.18) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 2 (28.6%) \| 1.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (42.9%) \| 1.94 (3.58) | n= 3 (25.0%) \|-12.67 (7.51) | 1.99 [-0.43 ; 4.40] |
| Week 75 | n= 3 (42.9%) \| 1.61 (3.51) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 2 (28.6%) \| 1.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 3 (42.9%) \| 1.61 (3.07) | n= 3 (25.0%) \|-1.67 (8.33) | 0.42 [-1.43 ; 2.26] |
| Week 81 | n= 3 (42.9%) \| 2.61 (3.15) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 3 (42.9%) \| 1.61 (2.51) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 3 (42.9%) \| 1.28 (3.25) | n= 2 (16.7%) \|-0.50 (6.36) | 0.29 [-1.85 ; 2.42] |
| Week 87 | n= 2 (28.6%) \| 2.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (28.6%) \| 0.92 (2.71) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 2 (28.6%) \|-0.58 (0.59) | n= 2 (16.7%) \|-1.50 (6.36) | 0.12 [-2.35 ; 2.58] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 2 (28.6%) \| 1.61 (3.69) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (28.6%) \| 0.42 (2.00) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 2 (28.6%) \|-0.94 (4.32) | n= 2 (16.7%) \| 0.00 (2.83) | -0.15 [-2.62 ; 2.32] |
| Week 99 | n= 2 (28.6%) \| 0.92 (2.71) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (14.3%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 1 (14.3%) \| 1.83 ( / ) | n= 1 ( 8.3%) \|-3.00 ( / ) | [Not calculable] |
| Week 105 | n= 1 (14.3%) \| 0.83 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | [No Data] | n= 1 ( 8.3%) \|-9.00 ( / ) | [No Data for at least 1 arm] |
| Week 115 | [No Data] | n= 1 ( 8.3%) \|-2.00 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 1 (14.3%) \| 2.00 ( / ) | n= 3 (25.0%) \|-4.33 (5.69) | [Not calculable] |
| Week 202 | [No Data] | n= 2 (16.7%) \| 2.50 (2.12) | [No Data for at least 1 arm] |
| **Not Hispanic or Latino** | | | |
| N subjects in population | N=42 | N=31 | |
| Week 3 | n= 39 (92.9%) \|-0.63 (5.76) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 36 (85.7%) \|-2.92 (9.05) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 35 (83.3%) \|-4.99 (9.65) | n= 29 (93.5%) \|-0.72 (8.11) | -0.47 [-0.97 ; 0.03] |
| Week 9 | n= 34 (81.0%) \|-4.73 (8.64) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (83.3%) \|-5.52 (9.59) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 32 (76.2%) \|-3.60 (8.22) | n= 25 (80.6%) \|-3.87 (9.03) | 0.03 [-0.50 ; 0.56] |
| Week 15 | n= 29 (69.0%) \|-3.42 (9.68) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 34 (81.0%) \|-4.83 (7.66) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 30 (71.4%) \|-4.33 (8.19) | n= 26 (83.9%) \|-2.76 (7.68) | -0.19 [-0.72 ; 0.34] |
| Week 21 | n= 32 (76.2%) \|-4.27 (7.88) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 29 (69.0%) \|-5.16 (6.64) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 33 (78.6%) \|-3.40 (8.86) | n= 24 (77.4%) \|-1.11 (8.13) | -0.26 [-0.80 ; 0.27] |
| Week 27 | n= 29 (69.0%) \|-3.63 (8.05) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 29 (69.0%) \|-4.04 (8.75) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 28 (66.7%) \|-4.01 (9.20) | n= 19 (61.3%) \|-0.03 (9.40) | -0.42 [-1.02 ; 0.17] |
| Week 33 | n= 32 (76.2%) \|-3.97 (8.39) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 29 (69.0%) \|-4.10 (8.75) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 25 (59.5%) \|-3.04 (8.23) | n= 22 (71.0%) \|-0.70 (7.35) | -0.29 [-0.88 ; 0.29] |
| Week 39 | n= 29 (69.0%) \|-3.00 (8.60) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 32 (76.2%) \|-3.63 (8.86) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 28 (66.7%) \|-3.86 (9.15) | n= 17 (54.8%) \|-1.69 (7.13) | -0.25 [-0.86 ; 0.36] |
| Week 45 | n= 27 (64.3%) \|-4.10 (9.60) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 30 (71.4%) \|-3.70 (8.16) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 29 (69.0%) \|-4.34 (7.97) | n= 13 (41.9%) \|-0.58 (5.71) | -0.50 [-1.17 ; 0.17] |
| Week 51 | n= 27 (64.3%) \|-4.98 (8.28) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 30 (71.4%) \|-4.34 (8.98) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 25 (59.5%) \|-4.89 (7.19) | n= 15 (48.4%) \|-1.35 (6.19) | -0.51 [-1.17 ; 0.15] |
| Week 57 | n= 28 (66.7%) \|-5.13 (9.44) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 25 (59.5%) \|-4.04 (9.17) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 26 (61.9%) \|-4.03 (9.04) | n= 11 (35.5%) \|-3.38 (5.71) | -0.08 [-0.79 ; 0.64] |
| Week 63 | n= 24 (57.1%) \|-3.88 (9.43) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (52.4%) \|-5.01 (11.04) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 22 (52.4%) \|-3.92 (9.30) | n= 12 (38.7%) \| 0.48 (7.67) | -0.49 [-1.21 ; 0.23] |
| Week 69 | n= 20 (47.6%) \|-6.01 (12.03) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 21 (50.0%) \|-4.09 (11.56) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (38.1%) \|-2.85 (13.91) | n= 12 (38.7%) \|-2.43 (8.85) | -0.03 [-0.80 ; 0.73] |
| Week 75 | n= 17 (40.5%) \|-1.29 (8.43) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 17 (40.5%) \|-3.84 (8.65) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 79 | n= 15 (35.7%) \|-1.86 (10.70) | n= 10 (32.3%) \|-1.63 (7.84) | -0.02 [-0.84 ; 0.79] |
| Week 81 | n= 15 (35.7%) \|-3.06 (6.42) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (40.5%) \|-3.93 (10.72) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 13 (31.0%) \|-1.54 (7.71) | n= 9 (29.0%) \|-1.33 (8.03) | -0.03 [-0.90 ; 0.85] |
| Week 87 | n= 11 (26.2%) \|-4.81 (7.92) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 12 (28.6%) \|-3.66 (7.96) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 13 (31.0%) \|-4.61 (8.84) | n= 8 (25.8%) \| 2.64 (11.96) | -0.69 [-1.62 ; 0.24] |
| Week 93 | n= 12 (28.6%) \|-4.24 (7.61) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (26.2%) \|-5.68 (8.23) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (28.6%) \|-6.57 (7.89) | n= 5 (16.1%) \|-2.20 (5.93) | -0.56 [-1.66 ; 0.54] |
| Week 99 | n= 8 (19.0%) \|-6.86 (9.32) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 7 (16.7%) \|-5.84 (5.94) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (19.0%) \|-5.05 (5.98) | n= 4 (12.9%) \|-1.75 (3.20) | -0.57 [-1.86 ; 0.71] |
| Week 105 | n= 7 (16.7%) \|-3.98 (6.27) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 5 (11.9%) \|-6.78 (6.88) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (19.0%) \|-5.99 (6.53) | n= 1 ( 3.2%) \| 3.00 ( / ) | [Not calculable] |
| Week 111 | n= 5 (11.9%) \|-9.58 (1.31) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 (11.9%) \|-6.78 (6.15) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 5 (11.9%) \|-6.58 (4.95) | n= 2 ( 6.5%) \|-2.00 (4.24) | -0.80 [-2.69 ; 1.09] |
| Week 117 | n= 4 ( 9.5%) \|-5.97 (5.56) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 9.5%) \|-7.47 (5.78) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (11.9%) \|-8.98 (5.45) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.4%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (14.3%) \|-2.62 (4.41) | n= 8 (25.8%) \|-2.88 (11.59) | 0.03 [-1.08 ; 1.13] |
| Week 202 | n= 2 ( 4.8%) \|-12.50 (9.19) | n= 4 (12.9%) \|-2.00 (14.74) | -0.62 [-2.61 ; 1.37] |
| **Not Reported** | | | |
| N subjects in population | N=22 | N=25 | |
| Week 3 | n= 20 (90.9%) \| 0.76 (6.19) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 19 (86.4%) \|-0.55 (4.99) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 20 (90.9%) \|-3.02 (5.07) | n= 23 (92.0%) \|-3.64 (7.32) | 0.09 [-0.51 ; 0.70] |
| Week 9 | n= 20 (90.9%) \|-2.49 (7.88) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 19 (86.4%) \|-2.40 (8.47) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 20 (90.9%) \|-3.68 (7.94) | n= 23 (92.0%) \|-4.64 (8.32) | 0.12 [-0.49 ; 0.72] |
| Week 15 | n= 20 (90.9%) \|-2.26 (7.76) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 22 (100.0%) \|-0.96 (6.88) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 21 (95.5%) \|-1.04 (6.77) | n= 21 (84.0%) \|-3.67 (9.01) | 0.32 [-0.29 ; 0.94] |
| Week 21 | n= 21 (95.5%) \|-1.13 (6.00) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (95.5%) \|-1.57 (7.54) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 20 (90.9%) \|-1.55 (8.20) | n= 18 (72.0%) \|-5.17 (12.06) | 0.35 [-0.30 ; 1.00] |
| Week 27 | n= 22 (100.0%) \|-1.25 (9.49) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 19 (86.4%) \|-0.79 (7.21) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 22 (100.0%) \|-1.64 (8.41) | n= 18 (72.0%) \|-4.49 (7.62) | 0.35 [-0.29 ; 0.98] |
| Week 33 | n= 20 (90.9%) \|-1.19 (6.75) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 21 (95.5%) \|-1.73 (7.82) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 21 (95.5%) \|-1.28 (7.22) | n= 20 (80.0%) \|-3.75 (6.18) | 0.36 [-0.27 ; 0.98] |
| Week 39 | n= 18 (81.8%) \|-1.34 (6.90) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 17 (77.3%) \|-2.53 (7.90) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 20 (90.9%) \|-1.85 (8.88) | n= 20 (80.0%) \|-5.01 (7.30) | 0.38 [-0.25 ; 1.02] |
| Week 45 | n= 19 (86.4%) \|-3.58 (9.63) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 19 (86.4%) \|-2.24 (9.15) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 20 (90.9%) \|-0.42 (7.97) | n= 19 (76.0%) \|-4.41 (7.67) | 0.50 [-0.15 ; 1.15] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 51 | n= 21 (95.5%) \|-2.22 (9.59) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 20 (90.9%) \|-1.00 (8.12) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 18 (81.8%) \|-1.12 (10.23) | n= 19 (76.0%) \|-4.54 (5.64) | 0.41 [-0.25 ; 1.07] |
| Week 57 | n= 17 (77.3%) \| 0.47 (7.35) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 18 (81.8%) \|-0.11 (9.18) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 19 (86.4%) \|-0.43 (7.48) | n= 16 (64.0%) \|-4.55 (7.85) | 0.53 [-0.16 ; 1.21] |
| Week 63 | n= 15 (68.2%) \|-1.95 (8.15) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 18 (81.8%) \|-0.47 (7.54) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 19 (86.4%) \| 0.56 (8.30) | n= 14 (56.0%) \|-5.20 (6.59) | 0.74 [ 0.01 ; 1.46] |
| Week 69 | n= 15 (68.2%) \|-3.55 (11.22) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 15 (68.2%) \|-0.90 (9.00) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (72.7%) \| 0.16 (7.17) | n= 13 (52.0%) \|-6.93 (7.62) | 0.94 [ 0.15 ; 1.72] |
| Week 75 | n= 15 (68.2%) \|-0.97 (8.42) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 13 (59.1%) \| 2.07 (8.95) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 13 (59.1%) \|-2.21 (12.72) | n= 11 (44.0%) \|-2.98 (6.69) | 0.07 [-0.75 ; 0.89] |
| Week 81 | n= 11 (50.0%) \| 0.36 (8.02) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 13 (59.1%) \| 1.10 (9.74) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (50.0%) \|-0.36 (10.05) | n= 9 (36.0%) \|-4.56 (10.14) | 0.40 [-0.52 ; 1.31] |
| Week 87 | n= 11 (50.0%) \|-2.18 (10.86) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 11 (50.0%) \|-1.18 (8.48) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 9 (40.9%) \|-3.89 (8.02) | n= 7 (28.0%) \|-9.71 (12.51) | 0.54 [-0.50 ; 1.58] |
| Week 93 | n= 9 (40.9%) \|-2.00 (9.21) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 9 (40.9%) \|-1.22 (9.30) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (31.8%) \| 0.71 (10.08) | n= 3 (12.0%) \|-3.20 (11.01) | 0.34 [-1.11 ; 1.79] |
| Week 99 | n= 7 (31.8%) \|-0.43 (10.29) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (27.3%) \|-1.83 (9.50) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 6 (27.3%) \|-2.93 (8.84) | n= 4 (16.0%) \|-8.25 (9.74) | 0.52 [-0.85 ; 1.89] |
| Week 105 | n= 5 (22.7%) \|-6.00 (7.18) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 3 (13.6%) \|-4.33 (11.24) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (13.6%) \|-6.87 (12.21) | n= 2 ( 8.0%) \|-13.50 (7.78) | 0.44 [-1.72 ; 2.60] |
| Week 111 | n= 2 ( 9.1%) \|-3.50 (14.85) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (13.6%) \|-4.17 (12.39) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 2 ( 9.1%) \| 2.00 (9.90) | n= 2 ( 8.0%) \|-14.00 (7.07) | 1.06 [-1.88 ; 4.01] |
| Week 117 | n= 3 (13.6%) \| 2.33 (5.69) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 (13.6%) \|-0.33 (13.58) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (13.6%) \| 3.19 (10.12) | n= 1 ( 4.0%) \|-23.61 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 9.1%) \| 0.39 (6.52) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.5%) \|-6.33 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 4.5%) \| 4.00 ( / ) | n= 1 ( 4.0%) \|-26.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 4.5%) \|-5.28 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 4.5%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.5%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 4.5%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 4.5%) \| 8.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 4.5%) \|-6.71 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.5%) \|-10.06 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 4.5%) \|-11.00 ( / ) | n= 5 (20.0%) \|-6.80 (14.01) | [Not calculable] |
| Week 202 | [No Data] | n= 5 (20.0%) \| 2.40 (9.07) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:30

TABLE 7.3.6: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **Hispanic or Latino** | | | | |
| Nr subjects used | n=7 | n=11 | | |
| **Not Hispanic or Latino** | | | | |
| Nr subjects used | n=40 | n=31 | | |
| Week 7 | -5.66 (1.62) [-8.89 ;-2.43] | -1.29 (1.83) [-4.94 ; 2.37] | -4.38 (2.44) [-9.25 ; 0.50] | -0.45 [-0.94 ; 0.05] |
| Week 13 | -3.30 (1.46) [-6.20 ;-0.40] | -3.87 (1.67) [-7.19 ;-0.55] | 0.57 (2.21) [-3.84 ; 4.98] | 0.07 [-0.46 ; 0.59] |
| Week 19 | -4.10 (1.17) [-6.42 ;-1.78] | -3.41 (1.31) [-6.01 ;-0.81] | -0.69 (1.75) [-4.18 ; 2.80] | -0.10 [-0.63 ; 0.42] |
| Week 25 | -3.20 (1.19) [-5.57 ;-0.82] | -1.81 (1.37) [-4.53 ; 0.92] | -1.39 (1.82) [-5.01 ; 2.23] | -0.20 [-0.73 ; 0.33] |
| Week 31 | -3.91 (1.33) [-6.56 ;-1.27] | -1.19 (1.55) [-4.28 ; 1.90] | -2.72 (2.05) [-6.80 ; 1.35] | -0.39 [-0.97 ; 0.20] |
| Week 37 | -2.78 (1.21) [-5.19 ;-0.37] | -1.95 (1.37) [-4.68 ; 0.77] | -0.83 (1.83) [-4.47 ; 2.81] | -0.13 [-0.70 ; 0.44] |
| Week 43 | -3.75 (1.42) [-6.58 ;-0.93] | -2.10 (1.74) [-5.56 ; 1.36] | -1.65 (2.24) [-6.12 ; 2.82] | -0.22 [-0.82 ; 0.38] |
| Week 49 | -4.24 (1.17) [-6.57 ;-1.90] | -1.00 (1.57) [-4.13 ; 2.13] | -3.24 (1.97) [-7.15 ; 0.68] | -0.52 [-1.18 ; 0.15] |
| Week 55 | -3.70 (1.26) [-6.21 ;-1.19] | -1.77 (1.66) [-5.08 ; 1.53] | -1.93 (2.08) [-6.09 ; 2.23] | -0.30 [-0.94 ; 0.35] |
| Week 61 | -3.39 (1.40) [-6.19 ;-0.58] | -3.07 (2.00) [-7.07 ; 0.92] | -0.31 (2.45) [-5.20 ; 4.58] | -0.04 [-0.75 ; 0.66] |
| Week 67 | -4.20 (1.67) [-7.56 ;-0.84] | -1.26 (2.31) [-5.89 ; 3.37] | -2.94 (2.86) [-8.67 ; 2.79] | -0.36 [-1.07 ; 0.35] |
| Week 73 | -5.56 (2.60) [-10.81 ;-0.31] | -2.78 (3.32) [-9.49 ; 3.92] | -2.78 (4.22) [-11.29 ; 5.74] | -0.25 [-1.00 ; 0.50] |
| Week 79 | -2.60 (2.11) [-6.89 ; 1.69] | -2.66 (2.68) [-8.10 ; 2.79] | 0.05 (3.41) [-6.88 ; 6.99] | 0.01 [-0.79 ; 0.81] |
| Overall post-baseline period estimate | -3.88 (0.91) [-5.68 ;-2.07] | -2.17 (1.14) [-4.42 ; 0.09] | -1.71 (1.46) [-4.60 ; 1.18] | -0.28 [-0.76 ; 0.19] |
| **Not Reported** | | | | |
| Nr subjects used | n=22 | n=25 | | |
| Week 7 | -3.84 (1.66) [-7.20 ;-0.49] | -3.51 (1.57) [-6.68 ;-0.35] | -0.33 (2.29) [-4.94 ; 4.28] | -0.04 [-0.64 ; 0.56] |
| Week 13 | -3.32 (1.96) [-7.26 ; 0.62] | -4.50 (1.87) [-8.26 ;-0.75] | 1.18 (2.71) [-4.26 ; 6.63] | 0.13 [-0.47 ; 0.73] |
| Week 19 | -1.36 (1.63) [-4.62 ; 1.90] | -3.90 (1.59) [-7.10 ;-0.71] | 2.54 (2.28) [-2.02 ; 7.10] | 0.34 [-0.27 ; 0.95] |
| Week 25 | -2.12 (2.01) [-6.15 ; 1.91] | -3.69 (2.03) [-7.76 ; 0.37] | 1.57 (2.86) [-4.15 ; 7.30] | 0.17 [-0.46 ; 0.81] |
| Week 31 | -1.80 (1.61) [-5.03 ; 1.43] | -2.86 (1.67) [-6.20 ; 0.48] | 1.07 (2.32) [-3.58 ; 5.71] | 0.14 [-0.48 ; 0.77] |
| Week 37 | -2.03 (1.51) [-5.06 ; 0.99] | -3.57 (1.54) [-6.65 ;-0.49] | 1.54 (2.15) [-2.78 ; 5.85] | 0.22 [-0.40 ; 0.83] |
| Week 43 | -1.96 (1.58) [-5.12 ; 1.19] | -3.89 (1.60) [-7.10 ;-0.68] | 1.93 (2.25) [-2.58 ; 6.43] | 0.27 [-0.36 ; 0.89] |
| Week 49 | -1.34 (1.56) [-4.46 ; 1.79] | -3.43 (1.61) [-6.66 ;-0.21] | 2.10 (2.24) [-2.40 ; 6.59] | 0.29 [-0.34 ; 0.93] |
| Week 55 | -2.53 (1.68) [-5.91 ; 0.85] | -3.17 (1.70) [-6.59 ; 0.25] | 0.64 (2.40) [-4.17 ; 5.46] | 0.09 [-0.56 ; 0.73] |
| Week 61 | -1.48 (1.53) [-4.56 ; 1.59] | -3.64 (1.63) [-6.91 ;-0.36] | 2.15 (2.24) [-2.34 ; 6.65] | 0.32 [-0.35 ; 0.99] |
| Week 67 | -0.01 (1.43) [-2.88 ; 2.87] | -3.43 (1.58) [-6.61 ;-0.25] | 3.42 (2.14) [-0.87 ; 7.71] | 0.55 [-0.16 ; 1.25] |
| Week 73 | -0.74 (1.38) [-3.51 ; 2.04] | -6.21 (1.50) [-9.23 ;-3.19] | 5.47 (2.04) [ 1.37 ; 9.58] | 0.97 [ 0.19 ; 1.75] |
| Week 79 | -2.57 (2.39) [-7.44 ; 2.30] | -3.63 (2.59) [-8.90 ; 1.64] | 1.06 (3.53) [-6.12 ; 8.25] | 0.12 [-0.68 ; 0.92] |
| Overall post-baseline period estimate | -1.93 (1.02) [-3.97 ; 0.11] | -3.80 (1.03) [-5.87 ;-1.74] | 1.87 (1.45) [-1.03 ; 4.78] | 0.37 [-0.21 ; 0.96] |
| **MMRM subgroups interaction p-value** | | | 0.8520 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020

TABLE 7.3.7: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **Male** | | |
| | N=54 | N=47 |
| **Female** | | |
| | N=17 | N=21 |
| **Subjects with Baseline Value** | | |
| **Male** | | |
| | 52 (96.3%) | 46 (97.9%) |
| **Female** | | |
| | 17 (100.0%) | 21 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **Male** | | |
| | 54 (100.0%) | 47 (100.0%) |
| **Female** | | |
| | 17 (100.0%) | 19 (90.5%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **Male** | | |
| | 52 (96.3%) | 46 (97.9%) |
| **Female** | | |
| | 17 (100.0%) | 19 (90.5%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:30

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Male** | | | |
| N subjects in population | N=54 | N=47 | |
| Baseline | n= 52 (96.3%) \| 62.62 (7.76) | n= 46 (97.9%) \| 61.00 (8.23) | 0.20 [-0.20 ; 0.60] |
| Week 3 | n= 51 (94.4%) \| 62.83 (7.09) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 47 (87.0%) \| 61.53 (8.36) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 50 (92.6%) \| 58.59 (9.14) | n= 46 (97.9%) \| 59.96 (8.45) | -0.15 [-0.56 ; 0.25] |
| Week 9 | n= 47 (87.0%) \| 60.12 (9.17) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 46 (85.2%) \| 59.48 (9.32) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 47 (87.0%) \| 60.83 (8.64) | n= 38 (80.9%) \| 59.55 (8.77) | 0.15 [-0.28 ; 0.58] |
| Week 15 | n= 42 (77.8%) \| 60.91 (9.48) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 48 (88.9%) \| 61.30 (8.30) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 45 (83.3%) \| 61.41 (7.59) | n= 41 (87.2%) \| 59.78 (8.23) | 0.20 [-0.22 ; 0.63] |
| Week 21 | n= 46 (85.2%) \| 60.70 (7.81) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 41 (75.9%) \| 60.33 (8.29) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 45 (83.3%) \| 61.78 (8.14) | n= 35 (74.5%) \| 60.86 (9.61) | 0.10 [-0.34 ; 0.55] |
| Week 27 | n= 43 (79.6%) \| 62.63 (9.04) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 40 (74.1%) \| 61.50 (9.16) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 42 (77.8%) \| 61.21 (9.19) | n= 30 (63.8%) \| 61.32 (9.45) | -0.01 [-0.48 ; 0.46] |
| Week 33 | n= 44 (81.5%) \| 61.50 (9.11) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 43 (79.6%) \| 60.64 (9.80) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 40 (74.1%) \| 61.73 (8.44) | n= 36 (76.6%) \| 61.88 (7.30) | -0.02 [-0.47 ; 0.43] |
| Week 39 | n= 42 (77.8%) \| 62.26 (8.75) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 41 (75.9%) \| 61.46 (8.83) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 42 (77.8%) \| 61.23 (9.24) | n= 30 (63.8%) \| 60.67 (8.26) | 0.06 [-0.41 ; 0.53] |
| Week 45 | n= 38 (70.4%) \| 59.48 (10.45) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 41 (75.9%) \| 61.38 (9.28) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 41 (75.9%) \| 61.63 (9.26) | n= 26 (55.3%) \| 61.42 (6.60) | 0.02 [-0.47 ; 0.52] |
| Week 51 | n= 40 (74.1%) \| 60.01 (10.15) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 40 (74.1%) \| 61.60 (9.29) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 37 (68.5%) \| 61.26 (9.37) | n= 27 (57.4%) \| 59.22 (7.68) | 0.23 [-0.27 ; 0.73] |
| Week 57 | n= 40 (74.1%) \| 60.60 (9.56) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (68.5%) \| 61.90 (9.24) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (72.2%) \| 61.27 (9.38) | n= 21 (44.7%) \| 59.43 (8.26) | 0.20 [-0.33 ; 0.74] |
| Week 63 | n= 34 (63.0%) \| 60.45 (10.28) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 33 (61.1%) \| 60.05 (11.64) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 35 (64.8%) \| 62.11 (9.38) | n= 21 (44.7%) \| 60.24 (7.07) | 0.21 [-0.33 ; 0.76] |
| Week 69 | n= 30 (55.6%) \| 60.89 (11.22) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (57.4%) \| 61.97 (10.50) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 28 (51.9%) \| 63.82 (8.92) | n= 19 (40.4%) \| 57.84 (6.97) | 0.72 [ 0.11 ; 1.32] |
| Week 75 | n= 29 (53.7%) \| 63.66 (8.09) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (50.0%) \| 61.36 (8.59) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (48.1%) \| 61.28 (12.76) | n= 18 (38.3%) \| 59.72 (7.24) | 0.14 [-0.47 ; 0.75] |
| Week 81 | n= 24 (44.4%) \| 62.46 (9.23) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (51.9%) \| 61.96 (9.92) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 21 (38.9%) \| 64.19 (7.69) | n= 14 (29.8%) \| 61.07 (8.40) | 0.38 [-0.31 ; 1.07] |
| Week 87 | n= 19 (35.2%) \| 59.95 (10.83) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 20 (37.0%) \| 61.25 (9.14) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 19 (35.2%) \| 60.05 (10.58) | n= 12 (25.5%) \| 65.33 (6.89) | -0.55 [-1.30 ; 0.20] |
| Week 93 | n= 19 (35.2%) \| 61.34 (9.82) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 18 (33.3%) \| 60.30 (10.16) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (31.5%) \| 58.78 (10.62) | n= 7 (14.9%) \| 62.71 (8.56) | -0.38 [-1.28 ; 0.53] |
| Week 99 | n= 15 (27.8%) \| 58.40 (11.79) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (20.4%) \| 60.73 (9.58) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (22.2%) \| 59.66 (9.38) | n= 5 (10.6%) \| 60.20 (9.04) | -0.05 [-1.13 ; 1.02] |
| Week 105 | n= 10 (18.5%) \| 58.50 (8.70) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (11.1%) \| 58.67 (9.50) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.8%) \| 52.67 (7.07) | n= 3 ( 6.4%) \| 57.67 (15.50) | -0.48 [-1.89 ; 0.94] |
| Week 111 | n= 6 (11.1%) \| 54.50 (5.43) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (11.1%) \| 56.08 (8.71) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 7.4%) \| 57.25 (9.50) | n= 3 ( 6.4%) \| 65.00 (7.21) | -0.75 [-2.49 ; 0.98] |
| Week 117 | n= 5 ( 9.3%) \| 60.60 (5.94) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 9.3%) \| 55.80 (12.28) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (11.1%) \| 56.59 (9.49) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 2 ( 3.7%) \| 56.89 (5.81) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.9%) \| 50.67 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.9%) \| 61.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 1.9%) \| 51.72 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.9%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.9%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.9%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.9%) \| 65.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.9%) \| 50.29 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.9%) \| 46.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (11.1%) \| 62.00 (9.59) | n= 10 (21.3%) \| 52.60 (11.48) | 0.82 [-0.27 ; 1.91] |
| Week 202 | n= 2 ( 3.7%) \| 48.00 (14.14) | n= 7 (14.9%) \| 64.43 (8.66) | -1.52 [-3.40 ; 0.37] |
| **Female** | | | |
| N subjects in population | N=17 | N=21 | |
| Baseline | n= 17 (100.0%) \| 60.25 (9.12) | n= 21 (100.0%) \| 61.89 (9.68) | -0.17 [-0.82 ; 0.48] |
| Week 3 | n= 16 (94.1%) \| 60.99 (9.84) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 16 (94.1%) \| 56.67 (11.94) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 14 (82.4%) \| 56.99 (9.82) | n= 18 (85.7%) \| 57.27 (10.14) | -0.03 [-0.74 ; 0.68] |
| Week 9 | n= 14 (82.4%) \| 56.96 (12.79) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (88.2%) \| 54.70 (9.97) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 13 (76.5%) \| 52.97 (10.19) | n= 17 (81.0%) \| 57.35 (7.63) | -0.48 [-1.23 ; 0.26] |
| Week 15 | n= 12 (70.6%) \| 56.31 (8.93) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 15 (88.2%) \| 53.49 (10.99) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 12 (70.6%) \| 56.75 (8.58) | n= 13 (61.9%) \| 56.46 (8.64) | 0.03 [-0.77 ; 0.83] |
| Week 21 | n= 13 (76.5%) \| 55.90 (12.28) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (88.2%) \| 55.40 (9.41) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 13 (76.5%) \| 57.54 (8.50) | n= 14 (66.7%) \| 61.00 (7.97) | -0.41 [-1.19 ; 0.37] |
| Week 27 | n= 13 (76.5%) \| 58.41 (7.77) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 12 (70.6%) \| 58.50 (7.09) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 12 (70.6%) \| 58.00 (8.90) | n= 12 (57.1%) \| 58.92 (6.89) | -0.11 [-0.93 ; 0.71] |
| Week 33 | n= 12 (70.6%) \| 55.42 (8.17) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 11 (64.7%) \| 58.09 (11.08) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (47.1%) \| 55.63 (12.30) | n= 11 (52.4%) \| 57.68 (6.88) | -0.21 [-1.15 ; 0.73] |
| Week 39 | n= 10 (58.8%) \| 59.20 (5.73) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 11 (64.7%) \| 59.55 (7.84) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 43 | n= 10 (58.8%) \| 58.91 (9.27) | n= 12 (57.1%) \| 57.63 (9.38) | 0.13 [-0.73 ; 0.99] |
| Week 45 | n= 10 (58.8%) \| 59.50 (8.28) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 10 (58.8%) \| 59.39 (9.81) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 11 (64.7%) \| 57.73 (10.25) | n= 10 (47.6%) \| 56.07 (10.47) | 0.15 [-0.73 ; 1.03] |
| Week 51 | n= 11 (64.7%) \| 57.38 (9.83) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 12 (70.6%) \| 56.58 (8.65) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 9 (52.9%) \| 57.25 (10.97) | n= 11 (52.4%) \| 58.78 (8.94) | -0.15 [-1.05 ; 0.76] |
| Week 57 | n= 8 (47.1%) \| 60.93 (8.80) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 9 (52.9%) \| 56.44 (10.15) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 9 (52.9%) \| 61.11 (7.32) | n= 10 (47.6%) \| 56.90 (9.39) | 0.47 [-0.47 ; 1.41] |
| Week 63 | n= 8 (47.1%) \| 58.05 (8.25) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (58.8%) \| 58.20 (6.63) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 9 (52.9%) \| 59.11 (5.90) | n= 9 (42.9%) \| 57.78 (7.34) | 0.19 [-0.76 ; 1.14] |
| Week 69 | n= 8 (47.1%) \| 51.63 (10.36) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (41.2%) \| 54.48 (6.97) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (41.2%) \| 53.86 (10.27) | n= 9 (42.9%) \| 53.75 (9.33) | 0.01 [-1.01 ; 1.03] |
| Week 75 | n= 6 (35.3%) \| 56.07 (6.20) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (29.4%) \| 57.59 (5.75) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (29.4%) \| 57.80 (6.50) | n= 7 (33.3%) \| 57.71 (4.99) | 0.01 [-1.19 ; 1.22] |
| Week 81 | n= 5 (29.4%) \| 58.00 (4.64) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (29.4%) \| 54.87 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 6 (35.3%) \| 56.67 (7.97) | n= 7 (33.3%) \| 58.57 (7.59) | -0.23 [-1.37 ; 0.92] |
| Week 87 | n= 5 (29.4%) \| 55.20 (6.02) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 5 (29.4%) \| 53.81 (2.80) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 5 (29.4%) \| 56.40 (8.08) | n= 6 (28.6%) \| 53.17 (7.99) | 0.37 [-0.90 ; 1.63] |
| Week 93 | n= 4 (23.5%) \| 53.75 (3.86) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (23.5%) \| 53.25 (2.75) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (23.5%) \| 59.00 (4.76) | n= 4 (19.0%) \| 61.35 (6.14) | -0.37 [-1.89 ; 1.15] |
| Week 99 | n= 2 (11.8%) \| 56.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (17.6%) \| 57.33 (2.31) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (17.6%) \| 58.00 (4.00) | n= 5 (23.8%) \| 59.00 (6.96) | -0.14 [-1.70 ; 1.41] |
| Week 105 | n= 3 (17.6%) \| 56.00 (1.73) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.8%) \| 57.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (17.6%) \| 61.67 (9.87) | n= 2 ( 9.5%) \| 57.00 (7.07) | 0.38 [-1.77 ; 2.52] |
| Week 111 | n= 1 ( 5.9%) \| 55.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.8%) \| 59.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (17.6%) \| 60.67 (4.73) | n= 2 ( 9.5%) \| 55.50 (7.78) | 0.63 [-1.57 ; 2.84] |
| Week 117 | n= 2 (11.8%) \| 56.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (11.8%) \| 57.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (11.8%) \| 61.00 (7.07) | n= 1 ( 4.8%) \| 45.39 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 5.9%) \| 69.00 ( / ) | n= 1 ( 4.8%) \| 43.00 ( / ) | [Not calculable] |
| Week 201 | n= 2 (11.8%) \| 55.50 (7.78) | n= 6 (28.6%) \| 62.67 (7.28) | -0.85 [-2.66 ; 0.97] |
| Week 202 | [No Data] | n= 4 (19.0%) \| 63.75 (6.29) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:30

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Male** | | | |
| N subjects in population | N=54 | N=47 | |
| Week 3 | n= 50 (92.6%) \| 0.14 (5.86) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 45 (83.3%) \|-1.43 (6.72) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 48 (88.9%) \|-3.58 (8.52) | n= 45 (95.7%) \|-0.99 (7.77) | -0.31 [-0.73 ; 0.10] |
| Week 9 | n= 46 (85.2%) \|-2.90 (8.38) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 45 (83.3%) \|-3.29 (9.45) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 46 (85.2%) \|-2.46 (8.18) | n= 38 (80.9%) \|-3.29 (8.26) | 0.10 [-0.33 ; 0.53] |
| Week 15 | n= 42 (77.8%) \|-2.19 (9.20) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 47 (87.0%) \|-2.00 (7.55) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 44 (81.5%) \|-2.40 (7.22) | n= 40 (85.1%) \|-2.76 (8.58) | 0.04 [-0.39 ; 0.48] |
| Week 21 | n= 46 (85.2%) \|-2.17 (6.82) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 41 (75.9%) \|-2.33 (6.86) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 44 (81.5%) \|-1.59 (8.61) | n= 34 (72.3%) \|-2.44 (10.28) | 0.09 [-0.36 ; 0.54] |
| Week 27 | n= 42 (77.8%) \|-1.26 (8.51) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 40 (74.1%) \|-1.85 (8.26) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 42 (77.8%) \|-2.21 (8.90) | n= 30 (63.8%) \|-1.76 (9.09) | -0.05 [-0.52 ; 0.42] |
| Week 33 | n= 44 (81.5%) \|-2.06 (8.09) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 42 (77.8%) \|-2.72 (8.58) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 40 (74.1%) \|-1.72 (7.74) | n= 35 (74.5%) \|-1.11 (6.48) | -0.08 [-0.54 ; 0.37] |
| Week 39 | n= 41 (75.9%) \|-1.66 (8.18) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 41 (75.9%) \|-2.77 (8.53) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 41 (75.9%) \|-2.72 (9.32) | n= 29 (61.7%) \|-2.70 (7.34) | -0.00 [-0.48 ; 0.48] |
| Week 45 | n= 38 (70.4%) \|-3.52 (9.93) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 41 (75.9%) \|-2.99 (8.78) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 41 (75.9%) \|-1.91 (8.09) | n= 25 (53.2%) \|-1.89 (6.87) | -0.00 [-0.50 ; 0.50] |
| Week 51 | n= 40 (74.1%) \|-3.10 (8.92) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 40 (74.1%) \|-1.88 (8.98) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 37 (68.5%) \|-2.59 (8.07) | n= 26 (55.3%) \|-3.44 (7.38) | 0.11 [-0.40 ; 0.61] |
| Week 57 | n= 40 (74.1%) \|-2.99 (9.17) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (68.5%) \|-1.25 (9.22) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (72.2%) \|-2.23 (8.65) | n= 20 (42.6%) \|-3.07 (5.69) | 0.11 [-0.44 ; 0.65] |
| Week 63 | n= 34 (63.0%) \|-2.74 (8.94) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 33 (61.1%) \|-2.15 (10.15) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 35 (64.8%) \|-0.94 (8.89) | n= 20 (42.6%) \|-1.72 (7.48) | 0.09 [-0.46 ; 0.65] |
| Week 69 | n= 30 (55.6%) \|-2.95 (10.04) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (57.4%) \|-1.64 (9.62) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 28 (51.9%) \| 0.46 (8.16) | n= 19 (40.4%) \|-3.49 (8.31) | 0.47 [-0.12 ; 1.07] |
| Week 75 | n= 29 (53.7%) \|-0.45 (7.23) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (50.0%) \|-1.12 (8.60) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (48.1%) \|-1.61 (11.25) | n= 17 (36.2%) \|-0.73 (6.65) | -0.09 [-0.71 ; 0.53] |
| Week 81 | n= 24 (44.4%) \|-0.92 (6.74) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (51.9%) \|-1.07 (9.79) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 21 (38.9%) \| 0.18 (7.60) | n= 13 (27.7%) \| 0.00 (7.38) | 0.02 [-0.68 ; 0.73] |
| Week 87 | n= 19 (35.2%) \|-2.99 (8.76) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 20 (37.0%) \|-1.60 (7.60) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 19 (35.2%) \|-3.48 (8.04) | n= 11 (23.4%) \| 2.91 (10.38) | -0.69 [-1.47 ; 0.08] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 19 (35.2%) \|-2.14 (7.66) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 18 (33.3%) \|-2.53 (8.34) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (31.5%) \|-3.63 (9.29) | n= 6 (12.8%) \|-0.83 (5.15) | -0.32 [-1.27 ; 0.64] |
| Week 99 | n= 15 (27.8%) \|-3.74 (9.61) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (20.4%) \|-4.26 (7.43) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (22.2%) \|-3.76 (7.04) | n= 4 ( 8.5%) \|-1.50 (3.00) | -0.33 [-1.51 ; 0.84] |
| Week 105 | n= 10 (18.5%) \|-4.71 (6.22) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (11.1%) \|-7.98 (6.82) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.8%) \|-8.56 (6.81) | n= 2 ( 4.3%) \|-3.00 (8.49) | -0.71 [-2.40 ; 0.97] |
| Week 111 | n= 6 (11.1%) \|-10.31 (2.15) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (11.1%) \|-8.56 (5.92) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 7.4%) \|-6.47 (5.77) | n= 3 ( 6.4%) \|-2.00 (3.00) | -0.78 [-2.51 ; 0.96] |
| Week 117 | n= 5 ( 9.3%) \|-3.38 (6.35) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 9.3%) \|-6.38 (10.05) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (11.1%) \|-6.22 (9.22) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 2 ( 3.7%) \| 0.39 (6.52) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.9%) \|-6.33 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.9%) \| 4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 1.9%) \|-5.28 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.9%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.9%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.9%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.9%) \| 8.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.9%) \|-6.71 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.9%) \|-10.06 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (11.1%) \|-1.12 (4.14) | n= 10 (21.3%) \|-6.40 (13.53) | 0.45 [-0.61 ; 1.51] |
| Week 202 | n= 2 ( 3.7%) \|-12.50 (9.19) | n= 7 (14.9%) \| 3.43 (9.85) | -1.45 [-3.32 ; 0.42] |
| **Female** | | | |
| N subjects in population | N=17 | N=21 | |
| Week 3 | n= 16 (94.1%) \|-0.03 (5.29) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 16 (94.1%) \|-2.60 (9.98) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 14 (82.4%) \|-3.31 (7.19) | n= 18 (85.7%) \|-4.88 (8.79) | 0.19 [-0.52 ; 0.90] |
| Week 9 | n= 14 (82.4%) \|-6.28 (8.10) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (88.2%) \|-6.39 (6.75) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 13 (76.5%) \|-7.21 (7.48) | n= 17 (81.0%) \|-7.22 (8.92) | 0.00 [-0.73 ; 0.73] |
| Week 15 | n= 12 (70.6%) \|-4.71 (8.02) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 15 (88.2%) \|-7.60 (8.64) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 12 (70.6%) \|-4.77 (8.24) | n= 13 (61.9%) \|-7.06 (6.37) | 0.30 [-0.50 ; 1.11] |
| Week 21 | n= 13 (76.5%) \|-6.51 (11.31) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (88.2%) \|-6.22 (8.39) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 13 (76.5%) \|-4.56 (7.90) | n= 14 (66.7%) \|-4.35 (7.85) | -0.03 [-0.80 ; 0.74] |
| Week 27 | n= 13 (76.5%) \|-4.76 (8.87) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 12 (70.6%) \|-4.44 (7.15) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 12 (70.6%) \|-5.02 (7.33) | n= 12 (57.1%) \|-4.39 (7.11) | -0.08 [-0.90 ; 0.73] |
| Week 33 | n= 12 (70.6%) \|-5.83 (6.67) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 11 (64.7%) \|-4.55 (7.45) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (47.1%) \|-3.88 (7.32) | n= 11 (52.4%) \|-6.29 (6.43) | 0.34 [-0.61 ; 1.28] |
| Week 39 | n= 10 (58.8%) \|-3.00 (6.36) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 11 (64.7%) \|-3.91 (7.74) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 10 (58.8%) \|-2.99 (6.69) | n= 12 (57.1%) \|-6.76 (6.94) | 0.53 [-0.34 ; 1.41] |
| Week 45 | n= 10 (58.8%) \|-4.20 (7.35) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 47 | n= 10 (58.8%) \|-2.91 (6.89) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 11 (64.7%) \|-4.55 (7.53) | n= 10 (47.6%) \|-7.40 (6.94) | 0.38 [-0.51 ; 1.26] |
| Week 51 | n= 11 (64.7%) \|-4.89 (8.22) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 12 (70.6%) \|-5.92 (6.71) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 9 (52.9%) \|-4.09 (10.92) | n= 11 (52.4%) \|-5.65 (6.36) | 0.17 [-0.73 ; 1.08] |
| Week 57 | n= 8 (47.1%) \|-1.19 (7.51) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 9 (52.9%) \|-5.56 (7.88) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 9 (52.9%) \|-2.89 (6.81) | n= 10 (47.6%) \|-6.87 (8.13) | 0.50 [-0.44 ; 1.45] |
| Week 63 | n= 8 (47.1%) \|-3.08 (8.04) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (58.8%) \|-4.20 (7.32) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 9 (52.9%) \|-4.11 (8.31) | n= 9 (42.9%) \|-6.96 (7.14) | 0.35 [-0.61 ; 1.31] |
| Week 69 | n= 8 (47.1%) \|-10.00 (14.48) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (41.2%) \|-6.52 (13.19) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (41.2%) \|-7.14 (16.74) | n= 9 (42.9%) \|-10.10 (7.54) | 0.23 [-0.80 ; 1.25] |
| Week 75 | n= 6 (35.3%) \|-3.09 (11.64) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (29.4%) \|-1.01 (11.54) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (29.4%) \|-2.00 (10.42) | n= 7 (33.3%) \|-5.97 (7.15) | 0.43 [-0.79 ; 1.65] |
| Week 81 | n= 5 (29.4%) \|-2.40 (8.76) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (29.4%) \|-3.53 (12.20) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 6 (35.3%) \|-4.00 (10.30) | n= 7 (33.3%) \|-7.71 (9.23) | 0.36 [-0.79 ; 1.50] |
| Week 87 | n= 5 (29.4%) \|-3.20 (11.58) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 5 (29.4%) \|-4.59 (9.31) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 5 (29.4%) \|-6.00 (8.54) | n= 6 (28.6%) \|-13.65 (9.11) | 0.79 [-0.52 ; 2.10] |
| Week 93 | n= 4 (23.5%) \|-6.25 (9.74) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (23.5%) \|-6.75 (9.32) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (23.5%) \|-3.50 (7.77) | n= 4 (19.0%) \|-3.90 (9.10) | 0.04 [-1.46 ; 1.55] |
| Week 99 | n= 2 (11.8%) \| 0.00 (11.31) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (17.6%) \|-2.00 (8.89) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (17.6%) \|-3.67 (8.50) | n= 5 (23.8%) \|-7.40 (8.65) | 0.38 [-1.19 ; 1.95] |
| Week 105 | n= 3 (17.6%) \|-3.33 (8.08) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.8%) \| 0.50 (10.61) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (17.6%) \| 0.00 (7.55) | n= 2 ( 9.5%) \|-13.50 (7.78) | 1.29 [-1.19 ; 3.77] |
| Week 111 | n= 1 ( 5.9%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.8%) \| 2.50 (10.61) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (17.6%) \|-1.00 (8.66) | n= 2 ( 9.5%) \|-14.00 (7.07) | 1.16 [-1.25 ; 3.57] |
| Week 117 | n= 2 (11.8%) \| 0.00 (9.90) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (11.8%) \| 0.50 (9.19) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (11.8%) \| 1.00 (9.90) | n= 1 ( 4.8%) \|-23.61 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 5.9%) \|-3.00 ( / ) | n= 1 ( 4.8%) \|-26.00 ( / ) | [Not calculable] |
| Week 201 | n= 2 (11.8%) \|-9.00 (2.83) | n= 6 (28.6%) \|-1.00 (4.00) | -1.82 [-3.88 ; 0.25] |
| Week 202 | [No Data] | n= 4 (19.0%) \|-3.75 (10.37) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:30

TABLE 7.3.7: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **Male** | | | | |
| Nr subjects used | n=52 | n=46 | | |
| Week 7 | -4.37 (1.27) [-6.90 ;-1.84] | -1.73 (1.35) [-4.41 ; 0.94] | -2.64 (1.85) [-6.31 ; 1.04] | -0.29 [-0.70 ; 0.12] |
| Week 13 | -2.47 (1.23) [-4.91 ;-0.04] | -3.78 (1.33) [-6.41 ;-1.15] | 1.31 (1.81) [-2.27 ; 4.89] | 0.16 [-0.27 ; 0.59] |
| Week 19 | -2.12 (1.06) [-4.21 ;-0.02] | -3.39 (1.13) [-5.64 ;-1.14] | 1.27 (1.55) [-1.80 ; 4.34] | 0.18 [-0.25 ; 0.61] |
| Week 25 | -1.27 (1.23) [-3.70 ; 1.16] | -2.59 (1.35) [-5.27 ; 0.09] | 1.32 (1.83) [-2.30 ; 4.94] | 0.16 [-0.29 ; 0.61] |
| Week 31 | -2.09 (1.23) [-4.52 ; 0.34] | -2.04 (1.38) [-4.77 ; 0.70] | -0.05 (1.85) [-3.71 ; 3.61] | -0.01 [-0.48 ; 0.46] |
| Week 37 | -1.40 (1.03) [-3.44 ; 0.65] | -1.50 (1.13) [-3.75 ; 0.75] | 0.10 (1.53) [-2.94 ; 3.14] | 0.01 [-0.44 ; 0.47] |
| Week 43 | -2.60 (1.22) [-5.03 ;-0.18] | -2.32 (1.41) [-5.11 ; 0.48] | -0.29 (1.87) [-3.99 ; 3.42] | -0.04 [-0.51 ; 0.44] |
| Week 49 | -2.13 (1.02) [-4.14 ;-0.11] | -1.55 (1.23) [-3.99 ; 0.89] | -0.58 (1.60) [-3.74 ; 2.59] | -0.09 [-0.59 ; 0.41] |
| Week 55 | -2.15 (1.14) [-4.41 ; 0.11] | -2.86 (1.37) [-5.59 ;-0.13] | 0.71 (1.79) [-2.83 ; 4.25] | 0.10 [-0.40 ; 0.60] |
| Week 61 | -2.10 (1.11) [-4.29 ; 0.10] | -2.23 (1.43) [-5.07 ; 0.60] | 0.14 (1.81) [-3.45 ; 3.73] | 0.02 [-0.52 ; 0.56] |
| Week 67 | -1.85 (1.24) [-4.31 ; 0.62] | -2.02 (1.60) [-5.21 ; 1.16] | 0.17 (2.03) [-3.86 ; 4.20] | 0.02 [-0.53 ; 0.57] |
| Week 73 | -1.17 (1.19) [-3.54 ; 1.19] | -3.52 (1.50) [-6.51 ;-0.53] | 2.35 (1.92) [-1.46 ; 6.16] | 0.36 [-0.23 ; 0.95] |
| Week 79 | -2.21 (1.48) [-5.15 ; 0.73] | -0.74 (1.87) [-4.45 ; 2.98] | -1.48 (2.38) [-6.22 ; 3.27] | -0.19 [-0.80 ; 0.42] |
| Week 85 | -2.67 (1.41) [-5.50 ; 0.17] | -1.55 (1.80) [-5.16 ; 2.06] | -1.12 (2.29) [-5.71 ; 3.47] | -0.17 [-0.86 ; 0.52] |
| Week 91 | -3.26 (1.72) [-6.73 ; 0.22] | 0.56 (2.24) [-3.96 ; 5.08] | -3.81 (2.83) [-9.52 ; 1.89] | -0.50 [-1.25 ; 0.26] |
| Overall post-baseline period estimate | -2.26 (0.74) [-3.72 ;-0.79] | -2.08 (0.87) [-3.81 ;-0.36] | -0.17 (1.15) [-2.44 ; 2.09] | -0.03 [-0.43 ; 0.37] |
| **Female** | | | | |
| Nr subjects used | n=17 | n=21 | | |
| Week 7 | -3.97 (2.29) [-8.65 ; 0.71] | -5.00 (2.05) [-9.19 ;-0.81] | 1.03 (3.07) [-5.24 ; 7.30] | 0.12 [-0.58 ; 0.82] |
| Week 13 | -7.23 (2.48) [-12.32 ;-2.15] | -6.41 (2.24) [-11.01 ;-1.81] | -0.82 (3.34) [-7.68 ; 6.03] | -0.09 [-0.81 ; 0.63] |
| Week 19 | -5.34 (1.88) [-9.19 ;-1.49] | -6.90 (1.80) [-10.58 ;-3.22] | 1.56 (2.61) [-3.78 ; 6.89] | 0.23 [-0.56 ; 1.02] |
| Week 25 | -5.09 (1.83) [-8.81 ;-1.37] | -3.71 (1.75) [-7.27 ;-0.15] | -1.38 (2.54) [-6.54 ; 3.78] | -0.20 [-0.96 ; 0.55] |
| Week 31 | -5.34 (1.60) [-8.58 ;-2.10] | -3.28 (1.56) [-6.44 ;-0.11] | -2.06 (2.24) [-6.60 ; 2.48] | -0.36 [-1.17 ; 0.44] |
| Week 43 | -2.81 (1.70) [-6.27 ; 0.64] | -5.86 (1.59) [-9.10 ;-2.62] | 3.04 (2.33) [-1.70 ; 7.79] | 0.54 [-0.32 ; 1.40] |
| Week 49 | -4.72 (2.03) [-8.90 ;-0.54] | -5.76 (2.07) [-10.02 ;-1.50] | 1.04 (2.90) [-4.93 ; 7.02] | 0.15 [-0.71 ; 1.01] |
| Overall post-baseline period estimate | -4.93 (1.23) [-7.42 ;-2.44] | -5.27 (1.17) [-7.63 ;-2.92] | 0.34 (1.71) [-3.10 ; 3.79] | 0.07 [-0.59 ; 0.72] |
| **MMRM subgroups interaction p-value** | | | 0.5396 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:30

TABLE 7.3.8: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **< 1 Year** | N=14 | N=18 |
| **>= 1 Year** | N=57 | N=48 |
| **Not Reported** | [No Data] | N=2 |
| **Subjects with Baseline Value** | | |
| **< 1 Year** | 14 (100.0%) | 18 (100.0%) |
| **>= 1 Year** | 55 (96.5%) | 47 (97.9%) |
| **Not Reported** | [No Data] | 2 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **< 1 Year** | 14 (100.0%) | 18 (100.0%) |
| **>= 1 Year** | 57 (100.0%) | 46 (95.8%) |
| **Not Reported** | [No Data] | 2 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **< 1 Year** | 14 (100.0%) | 18 (100.0%) |
| **>= 1 Year** | 55 (96.5%) | 45 (93.8%) |
| **Not Reported** | [No Data] | 2 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:32

TABLE 7.3.8: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 1 Year** | | | |
| N subjects in population | N=14 | N=18 | |
| Baseline | n= 14 (100.0%) \| 62.14 (8.20) | n= 18 (100.0%) \| 63.17 (9.00) | -0.12 [-0.83 ; 0.59] |
| Week 3 | n= 12 (85.7%) \| 64.17 (6.74) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 12 (85.7%) \| 61.42 (6.93) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 13 (92.9%) \| 61.44 (7.15) | n= 18 (100.0%) \| 59.28 (8.88) | 0.26 [-0.47 ; 0.99] |
| Week 9 | n= 12 (85.7%) \| 62.33 (10.48) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 13 (92.9%) \| 61.00 (10.12) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 14 (100.0%) \| 60.71 (9.69) | n= 14 (77.8%) \| 60.34 (6.89) | 0.04 [-0.71 ; 0.80] |
| Week 15 | n= 14 (100.0%) \| 61.29 (9.88) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (100.0%) \| 59.80 (8.90) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 14 (100.0%) \| 59.59 (9.07) | n= 15 (83.3%) \| 58.01 (5.92) | 0.20 [-0.54 ; 0.95] |
| Week 21 | n= 14 (100.0%) \| 60.21 (8.75) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 12 (85.7%) \| 59.75 (8.29) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 13 (92.9%) \| 60.24 (10.16) | n= 15 (83.3%) \| 61.13 (8.04) | -0.10 [-0.85 ; 0.66] |
| Week 27 | n= 13 (92.9%) \| 62.85 (7.72) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 13 (92.9%) \| 60.16 (9.62) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 14 (100.0%) \| 59.64 (10.54) | n= 11 (61.1%) \| 59.79 (9.24) | -0.01 [-0.82 ; 0.79] |
| Week 33 | n= 14 (100.0%) \| 58.87 (11.63) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (92.9%) \| 58.82 (12.18) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 11 (78.6%) \| 60.01 (11.70) | n= 13 (72.2%) \| 60.88 (6.47) | -0.09 [-0.91 ; 0.73] |
| Week 39 | n= 11 (78.6%) \| 63.91 (8.07) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 12 (85.7%) \| 61.42 (8.16) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 12 (85.7%) \| 60.58 (10.18) | n= 12 (66.7%) \| 59.67 (6.97) | 0.10 [-0.72 ; 0.92] |
| Week 45 | n= 11 (78.6%) \| 58.85 (9.11) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 11 (78.6%) \| 61.09 (8.77) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 12 (85.7%) \| 60.80 (6.47) | n= 11 (61.1%) \| 60.17 (4.57) | 0.11 [-0.73 ; 0.95] |
| Week 51 | n= 11 (78.6%) \| 59.73 (9.25) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 11 (78.6%) \| 60.54 (7.62) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (50.0%) \| 60.66 (8.27) | n= 10 (55.6%) \| 56.70 (6.63) | 0.51 [-0.50 ; 1.53] |
| Week 57 | n= 10 (71.4%) \| 61.70 (6.70) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 11 (78.6%) \| 61.46 (8.88) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 10 (71.4%) \| 61.80 (8.18) | n= 8 (44.4%) \| 58.38 (5.34) | 0.46 [-0.51 ; 1.43] |
| Week 63 | n= 10 (71.4%) \| 62.33 (8.94) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (71.4%) \| 61.65 (8.49) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 10 (71.4%) \| 63.50 (7.66) | n= 9 (50.0%) \| 57.00 (4.58) | 0.97 [-0.01 ; 1.95] |
| Week 69 | n= 9 (64.3%) \| 60.43 (10.04) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 9 (64.3%) \| 58.80 (12.59) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 9 (64.3%) \| 58.85 (13.47) | n= 7 (38.9%) \| 53.57 (3.64) | 0.48 [-0.56 ; 1.51] |
| Week 75 | n= 8 (57.1%) \| 61.13 (10.95) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (42.9%) \| 63.00 (8.07) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (64.3%) \| 59.80 (15.90) | n= 7 (38.9%) \| 61.00 (7.51) | -0.09 [-1.11 ; 0.94] |
| Week 81 | n= 6 (42.9%) \| 64.50 (6.16) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (50.0%) \| 64.00 (9.31) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (57.1%) \| 63.00 (8.70) | n= 6 (33.3%) \| 59.83 (6.68) | 0.37 [-0.74 ; 1.49] |
| Week 87 | n= 6 (42.9%) \| 60.83 (8.89) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 7 (50.0%) \| 59.86 (8.17) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 7 (50.0%) \| 62.71 (8.71) | n= 3 (16.7%) \| 58.33 (14.15) | 0.38 [-1.07 ; 1.83] |
| Week 93 | n= 5 (35.7%) \| 61.80 (10.01) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 6 (42.9%) \| 62.50 (8.83) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 5 (35.7%) \| 65.00 (6.63) | n= 2 (11.1%) \| 68.00 (4.24) | -0.41 [-2.24 ; 1.43] |
| Week 99 | n= 3 (21.4%) \| 62.33 (10.12) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (21.4%) \| 62.67 (9.87) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (28.6%) \| 59.11 (11.78) | n= 2 (11.1%) \| 63.50 (9.19) | -0.31 [-2.25 ; 1.63] |
| Week 105 | n= 3 (21.4%) \| 59.00 (14.18) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (14.3%) \| 64.50 (12.02) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (21.4%) \| 57.80 (14.02) | n= 2 (11.1%) \| 58.00 (8.49) | -0.01 [-2.12 ; 2.10] |
| Week 111 | n= 1 ( 7.1%) \| 55.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (14.3%) \| 52.75 (7.42) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (21.4%) \| 58.33 (7.09) | n= 1 ( 5.6%) \| 71.00 ( / ) | [Not calculable] |
| Week 117 | n= 2 (14.3%) \| 54.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (14.3%) \| 48.00 (9.90) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (21.4%) \| 56.85 (8.75) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 7.1%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 7.1%) \| 50.67 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (14.3%) \| 65.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 7.1%) \| 51.72 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 7.1%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 7.1%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 7.1%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 7.1%) \| 65.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 7.1%) \| 50.29 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 7.1%) \| 46.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 7.1%) \| 61.00 ( / ) | n= 3 (16.7%) \| 58.00 (2.65) | [Not calculable] |
| Week 202 | n= 1 ( 7.1%) \| 58.00 ( / ) | n= 2 (11.1%) \| 63.00 (9.90) | [Not calculable] |
| **>= 1 Year** | | | |
| N subjects in population | N=57 | N=48 | |
| Baseline | n= 55 (96.5%) \| 62.01 (8.17) | n= 47 (97.9%) \| 60.39 (8.61) | 0.19 [-0.20 ; 0.58] |
| Week 3 | n= 55 (96.5%) \| 62.00 (8.00) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 51 (89.5%) \| 60.03 (10.09) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 51 (89.5%) \| 57.42 (9.58) | n= 45 (93.8%) \| 59.04 (9.14) | -0.17 [-0.58 ; 0.23] |
| Week 9 | n= 49 (86.0%) \| 58.67 (9.96) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 48 (84.2%) \| 57.57 (9.47) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 46 (80.7%) \| 58.64 (9.48) | n= 39 (81.3%) \| 58.08 (8.91) | 0.06 [-0.37 ; 0.49] |
| Week 15 | n= 40 (70.2%) \| 59.39 (9.41) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 49 (86.0%) \| 59.33 (9.79) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 43 (75.4%) \| 60.71 (7.67) | n= 37 (77.1%) \| 58.91 (9.20) | 0.21 [-0.23 ; 0.65] |
| Week 21 | n= 45 (78.9%) \| 59.46 (9.27) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 44 (77.2%) \| 58.81 (9.01) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 45 (78.9%) \| 61.00 (7.87) | n= 32 (66.7%) \| 60.19 (9.58) | 0.09 [-0.36 ; 0.55] |
| Week 27 | n= 43 (75.4%) \| 61.29 (9.25) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 39 (68.4%) \| 61.03 (8.58) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 40 (70.2%) \| 60.80 (8.74) | n= 30 (62.5%) \| 60.53 (8.61) | 0.03 [-0.45 ; 0.51] |
| Week 33 | n= 42 (73.7%) \| 60.64 (8.35) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 41 (71.9%) \| 60.54 (9.37) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 37 (64.9%) \| 60.92 (8.67) | n= 32 (66.7%) \| 60.36 (7.59) | 0.07 [-0.41 ; 0.54] |
| Week 39 | n= 41 (71.9%) \| 61.07 (8.36) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 41 | n= 40 (70.2%) \| 60.94 (8.82) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 40 (70.2%) \| 60.85 (9.03) | n= 28 (58.3%) \| 59.27 (9.13) | 0.17 [-0.31 ; 0.66] |
| Week 45 | n= 37 (64.9%) \| 59.68 (10.30) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 40 (70.2%) \| 60.96 (9.57) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 40 (70.2%) \| 60.80 (10.32) | n= 23 (47.9%) \| 59.04 (9.02) | 0.18 [-0.34 ; 0.69] |
| Week 51 | n= 40 (70.2%) \| 59.36 (10.36) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 41 (71.9%) \| 60.42 (9.80) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (68.4%) \| 60.44 (10.04) | n= 27 (56.3%) \| 59.87 (8.45) | 0.06 [-0.43 ; 0.55] |
| Week 57 | n= 38 (66.7%) \| 60.38 (9.99) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 35 (61.4%) \| 60.63 (9.88) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 38 (66.7%) \| 61.10 (9.25) | n= 22 (45.8%) \| 58.23 (9.49) | 0.30 [-0.23 ; 0.84] |
| Week 63 | n= 32 (56.1%) \| 59.26 (10.18) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 33 (57.9%) \| 59.00 (11.26) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 34 (59.6%) \| 60.90 (9.13) | n= 20 (41.7%) \| 60.55 (8.02) | 0.04 [-0.52 ; 0.60] |
| Week 69 | n= 29 (50.9%) \| 58.48 (12.12) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 29 (50.9%) \| 61.15 (9.66) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 26 (45.6%) \| 62.86 (8.43) | n= 20 (41.7%) \| 57.34 (8.88) | 0.63 [ 0.02 ; 1.23] |
| Week 75 | n= 27 (47.4%) \| 62.72 (7.49) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (45.6%) \| 60.25 (8.36) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 22 (38.6%) \| 61.09 (10.37) | n= 17 (35.4%) \| 58.12 (6.41) | 0.33 [-0.32 ; 0.97] |
| Week 81 | n= 23 (40.4%) \| 60.96 (9.24) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 26 (45.6%) \| 60.05 (9.78) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (33.3%) \| 62.32 (8.27) | n= 14 (29.2%) \| 59.64 (8.54) | 0.31 [-0.39 ; 1.02] |
| Week 87 | n= 18 (31.6%) \| 58.33 (10.64) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 18 (31.6%) \| 59.73 (9.20) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 17 (29.8%) \| 57.88 (10.49) | n= 14 (29.2%) \| 61.36 (8.54) | -0.35 [-1.08 ; 0.37] |
| Week 93 | n= 18 (31.6%) \| 59.52 (9.54) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 16 (28.1%) \| 57.72 (9.83) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 16 (28.1%) \| 56.89 (9.82) | n= 9 (18.8%) \| 60.93 (7.56) | -0.43 [-1.27 ; 0.41] |
| Week 99 | n= 14 (24.6%) \| 57.29 (11.39) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (19.3%) \| 59.27 (8.57) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (19.3%) \| 59.41 (7.68) | n= 8 (16.7%) \| 58.63 (7.58) | 0.10 [-0.84 ; 1.04] |
| Week 105 | n= 10 (17.5%) \| 57.60 (5.72) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.5%) \| 56.17 (6.46) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.0%) \| 54.13 (6.53) | n= 3 ( 6.3%) \| 57.00 (15.13) | -0.29 [-1.69 ; 1.12] |
| Week 111 | n= 6 (10.5%) \| 54.50 (5.43) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (10.5%) \| 58.17 (7.68) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 7.0%) \| 59.00 (8.83) | n= 4 ( 8.3%) \| 58.75 (7.14) | 0.03 [-1.48 ; 1.53] |
| Week 117 | n= 5 ( 8.8%) \| 61.60 (4.62) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 8.8%) \| 59.40 (9.07) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 ( 8.8%) \| 58.20 (9.65) | n= 1 ( 2.1%) \| 45.39 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.8%) \| 61.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | [No Data] | n= 1 ( 2.1%) \| 43.00 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 7 (12.3%) \| 60.29 (9.86) | n= 13 (27.1%) \| 56.00 (12.27) | 0.36 [-0.59 ; 1.31] |
| Week 202 | n= 1 ( 1.8%) \| 38.00 ( / ) | n= 8 (16.7%) \| 63.13 (7.00) | [Not calculable] |
| **Not Reported** | | | |
| N subjects in population | [No Data] | N=2 | |
| Nr subjects used | [No Data] | n= 2 (100.0%) \| 65.00 (4.24) | |
| Week 7 | [No Data] | n= 1 (50.0%) \| 65.00 ( / ) | [No Data for at least 1 arm] |
| Week 13 | [No Data] | n= 2 (100.0%) \| 64.00 (9.90) | [No Data for at least 1 arm] |
| Week 19 | [No Data] | n= 2 (100.0%) \| 67.50 (4.95) | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 25 | [No Data] | n= 2 (100.0%) \| 70.50 (3.54) | [No Data for at least 1 arm] |
| Week 31 | [No Data] | n= 1 (50.0%) \| 73.00 ( / ) | [No Data for at least 1 arm] |
| Week 37 | [No Data] | n= 2 (100.0%) \| 69.50 (6.36) | [No Data for at least 1 arm] |
| Week 43 | [No Data] | n= 2 (100.0%) \| 68.00 (9.90) | [No Data for at least 1 arm] |
| Week 49 | [No Data] | n= 2 (100.0%) \| 69.00 (9.90) | [No Data for at least 1 arm] |
| Week 55 | [No Data] | n= 1 (50.0%) \| 62.00 ( / ) | [No Data for at least 1 arm] |
| Week 61 | [No Data] | n= 1 (50.0%) \| 69.00 ( / ) | [No Data for at least 1 arm] |
| Week 67 | [No Data] | n= 1 (50.0%) \| 61.00 ( / ) | [No Data for at least 1 arm] |
| Week 73 | [No Data] | n= 1 (50.0%) \| 61.00 ( / ) | [No Data for at least 1 arm] |
| Week 79 | [No Data] | n= 1 (50.0%) \| 64.00 ( / ) | [No Data for at least 1 arm] |
| Week 85 | [No Data] | n= 1 (50.0%) \| 71.00 ( / ) | [No Data for at least 1 arm] |
| Week 91 | [No Data] | n= 1 (50.0%) \| 69.00 ( / ) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 1 (50.0%) \| 75.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:32

TABLE 7.3.8: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 1 Year** | | | |
| N subjects in population | N=14 | N=18 | |
| Week 3 | n= 12 (85.7%) \| 1.25 (6.21) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 12 (85.7%) \|-0.83 (9.71) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 13 (92.9%) \|-0.56 (8.71) | n= 18 (100.0%) \|-3.89 (7.96) | 0.39 [-0.34 ; 1.12] |
| Week 9 | n= 12 (85.7%) \|-1.25 (9.62) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 13 (92.9%) \|-1.38 (10.05) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 14 (100.0%) \|-1.43 (9.57) | n= 14 (77.8%) \|-6.30 (8.12) | 0.53 [-0.24 ; 1.30] |
| Week 15 | n= 14 (100.0%) \|-0.85 (10.31) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (100.0%) \|-2.35 (9.99) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 14 (100.0%) \|-2.56 (10.25) | n= 15 (83.3%) \|-7.13 (6.62) | 0.52 [-0.24 ; 1.27] |
| Week 21 | n= 14 (100.0%) \|-1.93 (9.75) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 12 (85.7%) \|-2.33 (6.83) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 13 (92.9%) \|-1.92 (11.35) | n= 15 (83.3%) \|-5.00 (7.68) | 0.31 [-0.45 ; 1.07] |
| Week 27 | n= 13 (92.9%) \| 0.85 (8.58) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 13 (92.9%) \|-1.61 (11.65) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 14 (100.0%) \|-2.50 (10.29) | n= 11 (61.1%) \|-6.30 (7.54) | 0.40 [-0.41 ; 1.21] |
| Week 33 | n= 14 (100.0%) \|-3.27 (9.66) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (92.9%) \|-2.94 (10.36) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 11 (78.6%) \|-1.08 (10.19) | n= 13 (72.2%) \|-4.73 (5.81) | 0.43 [-0.40 ; 1.27] |
| Week 39 | n= 11 (78.6%) \|-0.73 (10.72) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 12 (85.7%) \|-1.83 (11.37) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 12 (85.7%) \|-2.67 (12.24) | n= 12 (66.7%) \|-5.25 (9.18) | 0.23 [-0.59 ; 1.05] |
| Week 45 | n= 11 (78.6%) \|-3.42 (11.41) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 11 (78.6%) \|-2.27 (10.67) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 12 (85.7%) \|-1.78 (7.84) | n= 11 (61.1%) \|-4.47 (7.79) | 0.33 [-0.51 ; 1.17] |
| Week 51 | n= 11 (78.6%) \|-1.81 (9.05) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 11 (78.6%) \|-2.28 (11.23) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (50.0%) \|-3.20 (9.27) | n= 10 (55.6%) \|-7.70 (10.00) | 0.44 [-0.57 ; 1.45] |
| Week 57 | n= 10 (71.4%) \|-1.20 (11.54) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 11 (78.6%) \|-1.35 (11.20) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 10 (71.4%) \|-1.40 (10.78) | n= 8 (44.4%) \|-6.50 (6.37) | 0.53 [-0.44 ; 1.51] |
| Week 63 | n= 10 (71.4%) \| 0.63 (10.14) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (71.4%) \|-0.05 (10.42) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 10 (71.4%) \| 1.80 (9.81) | n= 9 (50.0%) \|-7.22 (8.17) | 0.95 [-0.03 ; 1.93] |
| Week 69 | n= 9 (64.3%) \|-1.02 (12.81) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 9 (64.3%) \|-2.65 (15.39) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 9 (64.3%) \|-2.60 (17.25) | n= 7 (38.9%) \|-11.57 (7.83) | 0.61 [-0.44 ; 1.65] |
| Week 75 | n= 8 (57.1%) \| 1.00 (11.71) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (42.9%) \| 3.00 (7.62) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (64.3%) \|-1.64 (16.14) | n= 7 (38.9%) \|-3.00 (7.00) | 0.10 [-0.92 ; 1.12] |
| Week 81 | n= 6 (42.9%) \| 1.00 (4.69) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (50.0%) \| 3.71 (11.69) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (57.1%) \| 1.25 (8.60) | n= 6 (33.3%) \|-5.50 (8.31) | 0.75 [-0.40 ; 1.89] |
| Week 87 | n= 6 (42.9%) \|-1.00 (7.56) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 7 (50.0%) \|-0.43 (5.91) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 7 (50.0%) \|-0.57 (6.95) | n= 3 (16.7%) \|-10.67 (16.50) | 0.89 [-0.62 ; 2.40] |
| Week 93 | n= 5 (35.7%) \|-1.00 (8.63) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 6 (42.9%) \| 0.67 (7.84) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 5 (35.7%) \| 2.80 (5.26) | n= 2 (11.1%) \| 0.00 (2.83) | 0.48 [-1.36 ; 2.33] |
| Week 99 | n= 3 (21.4%) \| 3.67 (4.04) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (21.4%) \| 4.00 (3.61) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (28.6%) \|-2.89 (8.62) | n= 2 (11.1%) \|-8.50 (7.78) | 0.53 [-1.44 ; 2.50] |
| Week 105 | n= 3 (21.4%) \| 0.33 (8.14) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (14.3%) \| 5.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (21.4%) \|-1.20 (9.50) | n= 2 (11.1%) \|-14.00 (7.07) | 1.06 [-1.31 ; 3.43] |
| Week 111 | n= 1 ( 7.1%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (14.3%) \| 0.25 (13.79) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (21.4%) \|-0.67 (8.39) | n= 1 ( 5.6%) \|-2.00 ( / ) | [Not calculable] |
| Week 117 | n= 2 (14.3%) \| 1.50 (7.78) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (14.3%) \|-4.50 (16.26) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (21.4%) \|-2.15 (8.87) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 7.1%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 7.1%) \|-6.33 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (14.3%) \| 0.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 7.1%) \|-5.28 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 7.1%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 7.1%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 7.1%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 7.1%) \| 8.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 7.1%) \|-6.71 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 7.1%) \|-10.06 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 7.1%) \|-3.00 ( / ) | n= 3 (16.7%) \|-6.00 (7.94) | [Not calculable] |
| Week 202 | n= 1 ( 7.1%) \|-6.00 ( / ) | n= 2 (11.1%) \| 0.50 (4.95) | [Not calculable] |
| **>= 1 Year** | | | |
| N subjects in population | N=57 | N=48 | |
| Week 3 | n= 54 (94.7%) \|-0.16 (5.59) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 49 (86.0%) \|-1.95 (7.14) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 49 (86.0%) \|-4.31 (7.95) | n= 44 (91.7%) \|-1.49 (8.33) | -0.34 [-0.76 ; 0.07] |
| Week 9 | n= 48 (84.2%) \|-4.30 (8.03) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 47 (82.5%) \|-4.81 (8.53) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 45 (78.9%) \|-4.15 (7.75) | n= 39 (81.3%) \|-4.04 (8.90) | -0.01 [-0.44 ; 0.42] |
| Week 15 | n= 40 (70.2%) \|-3.41 (8.45) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 48 (84.2%) \|-3.65 (7.59) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 42 (73.7%) \|-3.03 (6.38) | n= 36 (75.0%) \|-2.78 (8.69) | -0.03 [-0.48 ; 0.42] |
| Week 21 | n= 45 (78.9%) \|-3.50 (7.62) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 44 (77.2%) \|-3.65 (7.63) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 44 (77.2%) \|-2.37 (7.59) | n= 31 (64.6%) \|-2.57 (10.47) | 0.02 [-0.44 ; 0.48] |
| Week 27 | n= 42 (73.7%) \|-3.00 (8.56) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 39 (68.4%) \|-2.73 (6.57) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 40 (70.2%) \|-2.96 (8.05) | n= 30 (62.5%) \|-1.37 (8.69) | -0.19 [-0.67 ; 0.29] |
| Week 33 | n= 42 (73.7%) \|-2.74 (7.37) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 40 (70.2%) \|-3.15 (7.70) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 37 (64.9%) \|-2.38 (6.85) | n= 31 (64.6%) \|-1.79 (7.02) | -0.08 [-0.56 ; 0.40] |
| Week 39 | n= 40 (70.2%) \|-2.25 (6.95) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 40 (70.2%) \|-3.36 (7.30) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 39 (68.4%) \|-2.80 (7.66) | n= 27 (56.3%) \|-3.80 (6.50) | 0.14 [-0.36 ; 0.63] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 45 | n= 37 (64.9%) \|-3.74 (8.87) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 40 (70.2%) \|-3.16 (7.79) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 40 (70.2%) \|-2.68 (8.11) | n= 22 (45.8%) \|-3.64 (6.97) | 0.12 [-0.40 ; 0.65] |
| Week 51 | n= 40 (70.2%) \|-3.95 (8.69) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 41 (71.9%) \|-2.95 (7.94) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (68.4%) \|-2.83 (8.58) | n= 26 (54.2%) \|-2.86 (5.36) | 0.00 [-0.50 ; 0.50] |
| Week 57 | n= 38 (66.7%) \|-3.08 (8.18) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 35 (61.4%) \|-2.32 (8.45) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 38 (66.7%) \|-2.60 (7.64) | n= 21 (43.8%) \|-4.05 (6.53) | 0.20 [-0.34 ; 0.73] |
| Week 63 | n= 32 (56.1%) \|-3.88 (8.06) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 33 (57.9%) \|-3.41 (9.27) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 34 (59.6%) \|-2.58 (8.34) | n= 19 (39.6%) \|-1.63 (7.12) | -0.12 [-0.68 ; 0.45] |
| Week 69 | n= 29 (50.9%) \|-5.50 (10.77) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 29 (50.9%) \|-2.50 (8.58) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 26 (45.6%) \|-0.53 (7.46) | n= 20 (41.7%) \|-3.76 (8.14) | 0.41 [-0.19 ; 1.00] |
| Week 75 | n= 27 (47.4%) \|-1.47 (6.73) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (45.6%) \|-2.05 (9.04) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 22 (38.6%) \|-1.68 (8.49) | n= 16 (33.3%) \|-2.19 (7.46) | 0.06 [-0.59 ; 0.71] |
| Week 81 | n= 23 (40.4%) \|-1.74 (7.44) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 26 (45.6%) \|-2.84 (9.28) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (33.3%) \|-1.59 (8.18) | n= 13 (27.1%) \|-2.31 (8.68) | 0.08 [-0.63 ; 0.80] |
| Week 87 | n= 18 (31.6%) \|-3.72 (9.70) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 18 (31.6%) \|-2.89 (8.54) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 17 (29.8%) \|-5.42 (8.20) | n= 13 (27.1%) \|-1.91 (11.97) | -0.34 [-1.08 ; 0.40] |
| Week 93 | n= 18 (31.6%) \|-3.37 (7.96) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 16 (28.1%) \|-4.79 (8.42) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 16 (28.1%) \|-5.61 (8.88) | n= 8 (16.7%) \|-2.58 (7.42) | -0.35 [-1.22 ; 0.53] |
| Week 99 | n= 14 (24.6%) \|-4.79 (9.75) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (19.3%) \|-5.90 (6.82) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (19.3%) \|-4.05 (6.80) | n= 7 (14.6%) \|-3.71 (7.16) | -0.05 [-1.02 ; 0.93] |
| Week 105 | n= 10 (17.5%) \|-5.81 (5.41) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.5%) \|-9.48 (4.91) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.0%) \|-8.11 (6.70) | n= 2 ( 4.2%) \|-2.50 (7.78) | -0.74 [-2.43 ; 0.95] |
| Week 111 | n= 6 (10.5%) \|-10.31 (2.15) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (10.5%) \|-7.81 (6.06) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 7.0%) \|-6.72 (5.70) | n= 4 ( 8.3%) \|-8.00 (8.41) | 0.15 [-1.35 ; 1.66] |
| Week 117 | n= 5 ( 8.8%) \|-3.98 (6.57) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 8.8%) \|-4.38 (8.54) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 ( 8.8%) \|-5.78 (10.23) | n= 1 ( 2.1%) \|-23.61 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.8%) \| 5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | [No Data] | n= 1 ( 2.1%) \|-26.00 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 7 (12.3%) \|-3.10 (5.58) | n= 13 (27.1%) \|-4.00 (11.91) | 0.08 [-0.86 ; 1.03] |
| Week 202 | n= 1 ( 1.8%) \|-19.00 ( / ) | n= 8 (16.7%) \| 0.13 (11.76) | [Not calculable] |
| **Not Reported** | | | |
| N subjects in population | [No Data] | N=2 | |
| Week 7 | [No Data] | n= 1 (50.0%) \| 3.00 ( / ) | [No Data for at least 1 arm] |
| Week 13 | [No Data] | n= 2 (100.0%) \|-1.00 (5.66) | [No Data for at least 1 arm] |
| Week 19 | [No Data] | n= 2 (100.0%) \| 2.50 (0.71) | [No Data for at least 1 arm] |
| Week 25 | [No Data] | n= 2 (100.0%) \| 5.50 (0.71) | [No Data for at least 1 arm] |
| Week 31 | [No Data] | n= 1 (50.0%) \| 5.00 ( / ) | [No Data for at least 1 arm] |
| Week 37 | [No Data] | n= 2 (100.0%) \| 4.50 (2.12) | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 43 | [No Data] | n= 2 (100.0%) \| 3.00 (5.66) | [No Data for at least 1 arm] |
| Week 49 | [No Data] | n= 2 (100.0%) \| 4.00 (5.66) | [No Data for at least 1 arm] |
| Week 55 | [No Data] | n= 1 (50.0%) \| 0.00 ( / ) | [No Data for at least 1 arm] |
| Week 61 | [No Data] | n= 1 (50.0%) \| 7.00 ( / ) | [No Data for at least 1 arm] |
| Week 67 | [No Data] | n= 1 (50.0%) \|-1.00 ( / ) | [No Data for at least 1 arm] |
| Week 73 | [No Data] | n= 1 (50.0%) \|-1.00 ( / ) | [No Data for at least 1 arm] |
| Week 79 | [No Data] | n= 1 (50.0%) \| 2.00 ( / ) | [No Data for at least 1 arm] |
| Week 85 | [No Data] | n= 1 (50.0%) \| 9.00 ( / ) | [No Data for at least 1 arm] |
| Week 91 | [No Data] | n= 1 (50.0%) \| 7.00 ( / ) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 1 (50.0%) \| 7.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:32

TABLE 7.3.8: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **< 1 Year** | | | | |
| Nr subjects used | n=14 | n=18 | | |
| Week 7 | -2.33 (2.15) [-6.72 ; 2.06] | -4.24 (1.86) [-8.03 ;-0.45] | 1.91 (2.84) [-3.88 ; 7.70] | 0.24 [-0.48 ; 0.95] |
| Week 13 | -2.40 (2.18) [-6.85 ; 2.05] | -5.39 (2.03) [-9.51 ;-1.27] | 2.99 (2.98) [-3.07 ; 9.06] | 0.37 [-0.38 ; 1.12] |
| Week 19 | -3.52 (1.82) [-7.21 ; 0.16] | -6.61 (1.69) [-10.03 ;-3.19] | 3.08 (2.49) [-1.96 ; 8.12] | 0.45 [-0.29 ; 1.19] |
| Week 25 | -3.55 (2.24) [-8.10 ; 1.00] | -4.13 (2.09) [-8.36 ; 0.11] | 0.58 (3.07) [-5.65 ; 6.81] | 0.07 [-0.67 ; 0.81] |
| Week 31 | -3.47 (2.29) [-8.15 ; 1.21] | -4.89 (2.33) [-9.63 ;-0.15] | 1.42 (3.28) [-5.25 ; 8.10] | 0.17 [-0.62 ; 0.96] |
| Week 37 | -3.94 (2.47) [-9.00 ; 1.12] | -3.64 (2.37) [-8.49 ; 1.21] | -0.30 (3.43) [-7.33 ; 6.72] | -0.04 [-0.84 ; 0.77] |
| Week 43 | -3.14 (2.55) [-8.35 ; 2.07] | -4.58 (2.55) [-9.79 ; 0.63] | 1.44 (3.62) [-5.94 ; 8.83] | 0.16 [-0.64 ; 0.96] |
| Week 49 | -3.48 (1.59) [-6.74 ;-0.21] | -3.64 (1.64) [-7.00 ;-0.28] | 0.17 (2.29) [-4.53 ; 4.87] | 0.03 [-0.79 ; 0.85] |
| Overall post-baseline period estimate | -3.23 (1.52) [-6.32 ;-0.13] | -4.64 (1.43) [-7.54 ;-1.75] | 1.41 (2.09) [-2.84 ; 5.67] | 0.23 [-0.47 ; 0.93] |
| **>= 1 Year** | | | | |
| Nr subjects used | n=55 | n=47 | | |
| Week 7 | -4.95 (1.36) [-7.64 ;-2.25] | -2.31 (1.48) [-5.25 ; 0.63] | -2.64 (2.00) [-6.62 ; 1.34] | -0.27 [-0.68 ; 0.14] |
| Week 13 | -4.01 (1.39) [-6.77 ;-1.25] | -4.24 (1.53) [-7.29 ;-1.20] | 0.24 (2.07) [-3.87 ; 4.34] | 0.02 [-0.40 ; 0.45] |
| Week 19 | -2.82 (1.11) [-5.02 ;-0.62] | -3.62 (1.23) [-6.06 ;-1.17] | 0.80 (1.66) [-2.49 ; 4.08] | 0.11 [-0.34 ; 0.55] |
| Week 25 | -1.94 (1.21) [-4.33 ; 0.45] | -2.68 (1.38) [-5.41 ; 0.05] | 0.74 (1.83) [-2.89 ; 4.36] | 0.09 [-0.37 ; 0.55] |
| Week 31 | -2.81 (1.13) [-5.05 ;-0.58] | -1.57 (1.28) [-4.11 ; 0.97] | -1.24 (1.71) [-4.63 ; 2.14] | -0.17 [-0.65 ; 0.30] |
| Week 37 | -2.06 (0.99) [-4.01 ;-0.11] | -2.54 (1.11) [-4.74 ;-0.35] | 0.48 (1.48) [-2.46 ; 3.42] | 0.08 [-0.40 ; 0.56] |
| Week 43 | -2.82 (1.07) [-4.94 ;-0.71] | -2.85 (1.25) [-5.33 ;-0.36] | 0.02 (1.65) [-3.24 ; 3.29] | 0.00 [-0.49 ; 0.49] |
| Week 49 | -2.57 (1.08) [-4.71 ;-0.42] | -2.59 (1.35) [-5.27 ; 0.08] | 0.03 (1.73) [-3.40 ; 3.45] | 0.00 [-0.52 ; 0.52] |
| Week 55 | -2.65 (1.08) [-4.79 ;-0.50] | -2.27 (1.33) [-4.91 ; 0.37] | -0.38 (1.72) [-3.78 ; 3.03] | -0.05 [-0.55 ; 0.44] |
| Week 61 | -2.34 (1.05) [-4.42 ;-0.26] | -3.44 (1.35) [-6.11 ;-0.77] | 1.10 (1.71) [-2.29 ; 4.49] | 0.17 [-0.36 ; 0.70] |
| Week 67 | -2.75 (1.12) [-4.98 ;-0.52] | -1.46 (1.46) [-4.35 ; 1.43] | -1.29 (1.84) [-4.95 ; 2.36] | -0.20 [-0.76 ; 0.37] |
| Week 73 | -1.56 (1.10) [-3.74 ; 0.63] | -3.92 (1.35) [-6.59 ;-1.24] | 2.36 (1.74) [-1.09 ; 5.81] | 0.40 [-0.19 ; 0.99] |
| Week 79 | -1.90 (1.13) [-4.14 ; 0.35] | -2.87 (1.37) [-5.60 ;-0.14] | 0.97 (1.78) [-2.56 ; 4.51] | 0.18 [-0.47 ; 0.82] |
| Week 85 | -3.12 (1.37) [-5.86 ;-0.38] | -2.40 (1.66) [-5.72 ; 0.93] | -0.72 (2.16) [-5.03 ; 3.59] | -0.12 [-0.82 ; 0.59] |
| Week 91 | -3.55 (1.79) [-7.15 ; 0.05] | -1.04 (2.11) [-5.28 ; 3.20] | -2.51 (2.77) [-8.07 ; 3.06] | -0.33 [-1.05 ; 0.40] |
| Overall post-baseline period estimate | -2.79 (0.70) [-4.18 ;-1.40] | -2.65 (0.83) [-4.29 ;-1.01] | -0.14 (1.09) [-2.28 ; 2.01] | -0.03 [-0.42 ; 0.37] |
| **Not Reported** | | | | |
| Nr subjects used | [No Data] | n=2 | | |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.8876 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:33

TABLE 7.3.9: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **No** | N=11 | N=12 |
| **Yes** | N=60 | N=56 |
| **Subjects with Baseline Value** | | |
| **No** | 11 (100.0%) | 12 (100.0%) |
| **Yes** | 58 (96.7%) | 55 (98.2%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **No** | 11 (100.0%) | 12 (100.0%) |
| **Yes** | 60 (100.0%) | 54 (96.4%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **No** | 11 (100.0%) | 12 (100.0%) |
| **Yes** | 58 (96.7%) | 53 (94.6%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:37

TABLE 7.3.9: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=11 | N=12 | |
| Baseline | n= 11 (100.0%) \| 61.85 (7.07) | n= 12 (100.0%) \| 63.42 (9.89) | -0.17 [-1.01 ; 0.66] |
| Week 3 | n= 10 (90.9%) \| 63.75 (7.49) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 10 (90.9%) \| 62.60 (7.46) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 10 (90.9%) \| 61.18 (8.12) | n= 11 (91.7%) \| 57.00 (9.26) | 0.46 [-0.43 ; 1.35] |
| Week 9 | n= 9 (81.8%) \| 62.52 (6.89) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 10 (90.9%) \| 59.50 (8.02) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 11 (100.0%) \| 60.64 (8.69) | n= 10 (83.3%) \| 56.58 (7.38) | 0.48 [-0.41 ; 1.37] |
| Week 15 | n= 9 (81.8%) \| 60.46 (10.32) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 10 (90.9%) \| 58.66 (13.31) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 9 (81.8%) \| 62.25 (9.51) | n= 10 (83.3%) \| 56.10 (8.70) | 0.65 [-0.31 ; 1.60] |
| Week 21 | n= 11 (100.0%) \| 57.71 (13.88) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \| 58.90 (11.89) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 10 (90.9%) \| 62.21 (10.00) | n= 9 (75.0%) \| 56.33 (13.44) | 0.48 [-0.46 ; 1.42] |
| Week 27 | n= 10 (90.9%) \| 62.90 (9.09) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 9 (81.8%) \| 63.56 (8.69) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 10 (90.9%) \| 63.10 (10.43) | n= 6 (50.0%) \| 60.28 (6.91) | 0.29 [-0.77 ; 1.34] |
| Week 33 | n= 10 (90.9%) \| 61.82 (11.27) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (72.7%) \| 60.34 (13.64) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \| 61.14 (14.02) | n= 7 (58.3%) \| 57.74 (4.66) | 0.30 [-0.76 ; 1.36] |
| Week 39 | n= 8 (72.7%) \| 65.00 (9.20) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 9 (81.8%) \| 63.67 (9.30) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 8 (72.7%) \| 62.50 (10.47) | n= 6 (50.0%) \| 57.57 (4.91) | 0.54 [-0.59 ; 1.66] |
| Week 45 | n= 9 (81.8%) \| 61.82 (9.17) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 9 (81.8%) \| 63.22 (8.38) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 10 (90.9%) \| 63.56 (7.97) | n= 6 (50.0%) \| 58.67 (3.98) | 0.68 [-0.40 ; 1.76] |
| Week 51 | n= 9 (81.8%) \| 62.45 (9.06) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 9 (81.8%) \| 61.99 (9.04) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 8 (72.7%) \| 61.95 (9.57) | n= 6 (50.0%) \| 56.83 (7.78) | 0.54 [-0.58 ; 1.66] |
| Week 57 | n= 8 (72.7%) \| 61.25 (8.56) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 8 (72.7%) \| 64.26 (9.34) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 7 (63.6%) \| 66.29 (5.99) | n= 4 (33.3%) \| 57.00 (5.16) | 1.48 [ 0.00 ; 2.96] |
| Week 63 | n= 8 (72.7%) \| 62.29 (10.71) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (72.7%) \| 62.44 (9.76) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \| 62.13 (9.33) | n= 5 (41.7%) \| 56.80 (5.17) | 0.61 [-0.58 ; 1.81] |
| Week 69 | n= 8 (72.7%) \| 61.35 (9.25) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (63.6%) \| 62.74 (11.73) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (63.6%) \| 64.09 (8.29) | n= 4 (33.3%) \| 53.25 (4.65) | 1.36 [-0.09 ; 2.81] |
| Week 75 | n= 7 (63.6%) \| 63.43 (9.16) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (45.5%) \| 65.40 (8.35) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (54.5%) \| 59.54 (19.08) | n= 3 (25.0%) \| 59.67 (7.23) | -0.01 [-1.49 ; 1.48] |
| Week 81 | n= 5 (45.5%) \| 66.60 (6.58) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (45.5%) \| 66.60 (6.91) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (45.5%) \| 65.20 (7.92) | n= 3 (25.0%) \| 58.67 (7.64) | 0.73 [-0.89 ; 2.34] |
| Week 87 | n= 5 (45.5%) \| 65.80 (8.64) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 4 (36.4%) \| 64.75 (9.03) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (36.4%) \| 65.50 (7.85) | n= 2 (16.7%) \| 54.00 (16.97) | 0.85 [-1.19 ; 2.89] |
| Week 93 | n= 4 (36.4%) \| 66.75 (7.89) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (27.3%) \| 66.00 (9.85) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (27.3%) \| 65.67 (9.07) | n= 1 ( 8.3%) \| 65.00 ( / ) | [Not calculable] |
| Week 99 | n= 2 (18.2%) \| 65.00 (12.73) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 (18.2%) \| 65.00 (12.73) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (18.2%) \| 64.00 (14.14) | n= 1 ( 8.3%) \| 57.00 ( / ) | [Not calculable] |
| Week 105 | n= 2 (18.2%) \| 64.50 (14.85) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \| 64.50 (12.02) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 ( 9.1%) \| 55.00 ( / ) | n= 1 ( 8.3%) \| 52.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 9.1%) \| 55.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 ( 9.1%) \| 58.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 9.1%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 ( 9.1%) \| 55.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 9.1%) \| 55.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 9.1%) \| 56.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | [No Data] | n= 5 (41.7%) \| 56.20 (7.66) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 3 (25.0%) \| 56.33 (1.53) | [No Data for at least 1 arm] |
| **Yes** | | | |
| N subjects in population | N=60 | N=56 | |
| Baseline | n= 58 (96.7%) \| 62.07 (8.35) | n= 55 (98.2%) \| 60.81 (8.38) | 0.15 [-0.22 ; 0.52] |
| Week 3 | n= 57 (95.0%) \| 62.15 (7.88) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 53 (88.3%) \| 59.86 (9.88) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 54 (90.0%) \| 57.69 (9.39) | n= 53 (94.6%) \| 59.66 (8.91) | -0.21 [-0.60 ; 0.17] |
| Week 9 | n= 52 (86.7%) \| 58.85 (10.50) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 51 (85.0%) \| 58.07 (9.96) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 49 (81.7%) \| 58.79 (9.71) | n= 45 (80.4%) \| 59.38 (8.64) | -0.06 [-0.47 ; 0.34] |
| Week 15 | n= 45 (75.0%) \| 59.77 (9.42) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 53 (88.3%) \| 59.58 (8.80) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 48 (80.0%) \| 60.09 (7.71) | n= 44 (78.6%) \| 59.64 (8.26) | 0.06 [-0.35 ; 0.47] |
| Week 21 | n= 48 (80.0%) \| 60.08 (7.73) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 46 (76.7%) \| 59.03 (8.14) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 48 (80.0%) \| 60.54 (8.05) | n= 40 (71.4%) \| 61.93 (7.66) | -0.17 [-0.60 ; 0.25] |
| Week 27 | n= 46 (76.7%) \| 61.38 (8.91) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 43 (71.7%) \| 60.23 (8.76) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 44 (73.3%) \| 59.91 (8.85) | n= 36 (64.3%) \| 60.69 (9.14) | -0.09 [-0.53 ; 0.36] |
| Week 33 | n= 46 (76.7%) \| 59.85 (8.79) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 46 (76.7%) \| 60.09 (9.44) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 40 (66.7%) \| 60.63 (8.33) | n= 40 (71.4%) \| 61.45 (7.64) | -0.10 [-0.54 ; 0.34] |
| Week 39 | n= 44 (73.3%) \| 61.07 (8.09) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 43 (71.7%) \| 60.50 (8.45) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 44 (73.3%) \| 60.48 (9.05) | n= 36 (64.3%) \| 60.17 (9.06) | 0.03 [-0.41 ; 0.48] |
| Week 45 | n= 39 (65.0%) \| 58.95 (10.16) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 42 (70.0%) \| 60.51 (9.53) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 42 (70.0%) \| 60.15 (9.81) | n= 30 (53.6%) \| 60.19 (8.69) | -0.00 [-0.48 ; 0.47] |
| Week 51 | n= 42 (70.0%) \| 58.80 (10.23) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 43 (71.7%) \| 60.12 (9.44) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 38 (63.3%) \| 60.16 (9.83) | n= 32 (57.1%) \| 59.52 (8.02) | 0.07 [-0.40 ; 0.54] |
| Week 57 | n= 40 (66.7%) \| 60.54 (9.60) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 38 (63.3%) \| 60.11 (9.57) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 61 | n= 41 (68.3%) \| 60.38 (9.15) | n= 27 (48.2%) \| 58.85 (9.01) | 0.17 [-0.32 ; 0.66] |
| Week 63 | n= 34 (56.7%) \| 59.45 (9.77) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 35 (58.3%) \| 58.97 (10.87) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (60.0%) \| 61.35 (8.81) | n= 25 (44.6%) \| 60.04 (7.41) | 0.16 [-0.36 ; 0.67] |
| Week 69 | n= 30 (50.0%) \| 58.30 (12.16) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (51.7%) \| 60.11 (10.09) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 28 (46.7%) \| 61.26 (10.33) | n= 24 (42.9%) \| 57.07 (8.23) | 0.44 [-0.12 ; 0.99] |
| Week 75 | n= 28 (46.7%) \| 62.09 (8.16) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (45.0%) \| 59.91 (8.10) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 25 (41.7%) \| 61.00 (10.12) | n= 22 (39.3%) \| 59.09 (6.75) | 0.22 [-0.37 ; 0.80] |
| Week 81 | n= 24 (40.0%) \| 60.67 (8.86) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (46.7%) \| 59.87 (9.84) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 22 (36.7%) \| 61.91 (8.37) | n= 18 (32.1%) \| 60.50 (8.28) | 0.17 [-0.47 ; 0.80] |
| Week 87 | n= 19 (31.7%) \| 57.16 (9.87) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 21 (35.0%) \| 58.81 (8.59) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (33.3%) \| 58.05 (10.16) | n= 16 (28.6%) \| 62.19 (8.27) | -0.43 [-1.11 ; 0.24] |
| Week 93 | n= 19 (31.7%) \| 58.60 (9.32) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.7%) \| 57.92 (9.36) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (30.0%) \| 57.68 (9.53) | n= 10 (17.9%) \| 61.94 (7.81) | -0.46 [-1.26 ; 0.34] |
| Week 99 | n= 15 (25.0%) \| 57.27 (10.98) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (20.0%) \| 59.17 (8.18) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.7%) \| 58.61 (7.94) | n= 9 (16.1%) \| 59.89 (8.04) | -0.15 [-1.03 ; 0.72] |
| Week 105 | n= 11 (18.3%) \| 56.73 (6.15) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.0%) \| 56.17 (6.46) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.7%) \| 55.14 (8.95) | n= 4 ( 7.1%) \| 58.75 (12.84) | -0.34 [-1.55 ; 0.88] |
| Week 111 | n= 6 (10.0%) \| 54.50 (5.43) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.7%) \| 56.64 (8.09) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (10.0%) \| 59.00 (8.15) | n= 5 ( 8.9%) \| 61.20 (8.26) | -0.25 [-1.50 ; 1.01] |
| Week 117 | n= 6 (10.0%) \| 60.17 (5.42) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 (10.0%) \| 56.33 (11.06) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.7%) \| 57.94 (9.36) | n= 1 ( 1.8%) \| 45.39 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.3%) \| 56.89 (5.81) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.7%) \| 50.67 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) \| 65.00 (5.66) | n= 1 ( 1.8%) \| 43.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.7%) \| 51.72 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.7%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.7%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.7%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.7%) \| 65.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.7%) \| 50.29 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.7%) \| 46.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (13.3%) \| 60.38 (9.13) | n= 11 (19.6%) \| 56.45 (12.64) | 0.33 [-0.61 ; 1.27] |
| Week 202 | n= 2 ( 3.3%) \| 48.00 (14.14) | n= 8 (14.3%) \| 67.13 (6.66) | -2.16 [-4.15 ;-0.17] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:37

TABLE 7.3.9: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=11 | N=12 | |
| Week 3 | n= 10 (90.9%) \| 0.51 (5.48) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 10 (90.9%) \| 0.47 (8.60) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 10 (90.9%) \|-0.76 (8.48) | n= 11 (91.7%) \|-6.09 (8.61) | 0.60 [-0.30 ; 1.50] |
| Week 9 | n= 9 (81.8%) \|-1.18 (7.66) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 10 (90.9%) \|-2.63 (8.07) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 11 (100.0%) \|-1.21 (5.87) | n= 10 (83.3%) \|-9.52 (10.54) | 0.95 [ 0.02 ; 1.88] |
| Week 15 | n= 9 (81.8%) \|-2.80 (8.31) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 10 (90.9%) \|-3.78 (9.61) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 9 (81.8%) \|-1.01 (6.40) | n= 10 (83.3%) \|-8.60 (11.58) | 0.76 [-0.20 ; 1.73] |
| Week 21 | n= 11 (100.0%) \|-4.14 (10.73) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \|-2.33 (7.45) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 10 (90.9%) \|-0.33 (6.61) | n= 9 (75.0%) \|-11.22 (13.81) | 0.98 [-0.01 ; 1.96] |
| Week 27 | n= 10 (90.9%) \| 0.37 (5.81) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 9 (81.8%) \| 0.30 (5.59) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 10 (90.9%) \| 0.57 (6.44) | n= 6 (50.0%) \|-7.22 (9.52) | 0.96 [-0.15 ; 2.07] |
| Week 33 | n= 10 (90.9%) \|-0.72 (6.94) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (72.7%) \|-1.70 (8.47) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \|-2.40 (8.04) | n= 7 (58.3%) \|-9.12 (6.24) | 0.87 [-0.24 ; 1.98] |
| Week 39 | n= 8 (72.7%) \| 0.21 (7.78) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 9 (81.8%) \| 0.74 (8.40) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 8 (72.7%) \|-1.29 (7.02) | n= 6 (50.0%) \|-8.09 (8.98) | 0.81 [-0.34 ; 1.96] |
| Week 45 | n= 9 (81.8%) \|-1.10 (7.88) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 9 (81.8%) \| 0.30 (5.02) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 10 (90.9%) \| 1.03 (6.09) | n= 6 (50.0%) \|-7.00 (7.62) | 1.14 [ 0.00 ; 2.27] |
| Week 51 | n= 9 (81.8%) \|-0.81 (6.86) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 9 (81.8%) \|-1.27 (6.13) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 8 (72.7%) \|-1.59 (7.51) | n= 6 (50.0%) \|-8.83 (10.40) | 0.77 [-0.38 ; 1.91] |
| Week 57 | n= 8 (72.7%) \|-2.29 (7.60) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 8 (72.7%) \| 0.72 (7.08) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 7 (63.6%) \| 2.10 (2.86) | n= 4 (33.3%) \|-10.00 (7.35) | 2.28 [ 0.58 ; 3.98] |
| Week 63 | n= 8 (72.7%) \|-1.25 (8.03) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (72.7%) \|-1.10 (6.79) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \|-1.42 (7.79) | n= 5 (41.7%) \|-8.60 (9.37) | 0.80 [-0.42 ; 2.01] |
| Week 69 | n= 8 (72.7%) \|-2.19 (6.40) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (63.6%) \|-0.83 (7.89) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (63.6%) \| 0.52 (5.99) | n= 4 (33.3%) \|-13.75 (7.27) | 2.02 [ 0.40 ; 3.65] |
| Week 75 | n= 7 (63.6%) \|-0.14 (6.82) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (45.5%) \| 1.80 (4.82) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (54.5%) \|-3.30 (16.09) | n= 3 (25.0%) \|-6.00 (9.54) | 0.17 [-1.32 ; 1.65] |
| Week 81 | n= 5 (45.5%) \| 3.00 (3.32) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (45.5%) \| 3.00 (3.39) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (45.5%) \| 1.60 (4.04) | n= 3 (25.0%) \|-8.67 (11.68) | 1.19 [-0.53 ; 2.91] |
| Week 87 | n= 5 (45.5%) \| 2.20 (3.11) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 4 (36.4%) \| 1.50 (3.11) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 4 (36.4%) \| 2.25 (5.12) | n= 2 (16.7%) \|-13.00 (22.63) | 1.00 [-1.08 ; 3.09] |
| Week 93 | n= 4 (36.4%) \| 3.50 (3.32) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (27.3%) \| 5.33 (2.08) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (27.3%) \| 5.00 (2.65) | n= 1 ( 8.3%) \| 2.00 ( / ) | [Not calculable] |
| Week 99 | n= 2 (18.2%) \| 5.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 (18.2%) \| 5.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (18.2%) \| 4.50 (2.12) | n= 1 ( 8.3%) \|-14.00 ( / ) | [Not calculable] |
| Week 105 | n= 2 (18.2%) \| 5.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \| 5.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 ( 9.1%) \| 7.00 ( / ) | n= 1 ( 8.3%) \|-19.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 9.1%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 ( 9.1%) \| 10.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 9.1%) \| 9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 ( 9.1%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 9.1%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 9.1%) \| 8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | [No Data] | n= 5 (41.7%) \|-7.00 (12.59) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 3 (25.0%) \|-1.67 (11.06) | [No Data for at least 1 arm] |
| **Yes** | | | |
| N subjects in population | N=60 | N=56 | |
| Week 3 | n= 56 (93.3%) \| 0.02 (5.76) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 51 (85.0%) \|-2.17 (7.45) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 52 (86.7%) \|-4.05 (8.10) | n= 52 (92.9%) \|-1.26 (7.94) | -0.35 [-0.73 ; 0.04] |
| Week 9 | n= 51 (85.0%) \|-4.13 (8.49) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 50 (83.3%) \|-4.35 (9.11) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 48 (80.0%) \|-4.03 (8.62) | n= 45 (80.4%) \|-3.39 (7.79) | -0.08 [-0.49 ; 0.33] |
| Week 15 | n= 45 (75.0%) \|-2.74 (9.15) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 52 (86.7%) \|-3.27 (7.91) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 47 (78.3%) \|-3.27 (7.62) | n= 43 (76.8%) \|-2.70 (6.99) | -0.08 [-0.49 ; 0.34] |
| Week 21 | n= 48 (80.0%) \|-2.89 (7.52) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 46 (76.7%) \|-3.60 (7.48) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 47 (78.3%) \|-2.68 (8.83) | n= 39 (69.6%) \|-1.10 (7.34) | -0.19 [-0.62 ; 0.24] |
| Week 27 | n= 45 (75.0%) \|-2.63 (9.12) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 43 (71.7%) \|-3.02 (8.38) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 44 (73.3%) \|-3.61 (8.88) | n= 36 (64.3%) \|-1.72 (8.29) | -0.22 [-0.66 ; 0.23] |
| Week 33 | n= 46 (76.7%) \|-3.34 (8.10) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 45 (75.0%) \|-3.35 (8.37) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 40 (66.7%) \|-2.02 (7.66) | n= 39 (69.6%) \|-1.13 (6.18) | -0.13 [-0.57 ; 0.32] |
| Week 39 | n= 43 (71.7%) \|-2.32 (7.85) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 43 (71.7%) \|-3.79 (8.17) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 43 (71.7%) \|-3.04 (9.14) | n= 35 (62.5%) \|-3.17 (6.96) | 0.01 [-0.43 ; 0.46] |
| Week 45 | n= 39 (65.0%) \|-4.26 (9.69) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 42 (70.0%) \|-3.67 (8.83) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 42 (70.0%) \|-3.30 (8.21) | n= 29 (51.8%) \|-2.74 (7.07) | -0.07 [-0.55 ; 0.40] |
| Week 51 | n= 42 (70.0%) \|-4.06 (9.04) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 43 (71.7%) \|-3.13 (9.08) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 38 (63.3%) \|-3.16 (8.86) | n= 31 (55.4%) \|-3.18 (6.06) | 0.00 [-0.48 ; 0.48] |
| Week 57 | n= 40 (66.7%) \|-2.77 (9.19) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 38 (63.3%) \|-2.68 (9.39) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 41 (68.3%) \|-3.11 (8.67) | n= 26 (46.4%) \|-3.46 (6.31) | 0.04 [-0.45 ; 0.54] |
| Week 63 | n= 34 (56.7%) \|-3.17 (8.91) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 65 | n= 35 (58.3%) \|-2.97 (10.10) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (60.0%) \|-1.62 (9.08) | n= 24 (42.9%) \|-2.25 (6.99) | 0.07 [-0.45 ; 0.60] |
| Week 69 | n= 30 (50.0%) \|-5.04 (12.27) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (51.7%) \|-2.92 (10.89) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 28 (46.7%) \|-1.45 (11.49) | n= 24 (42.9%) \|-4.26 (8.07) | 0.27 [-0.28 ; 0.83] |
| Week 75 | n= 28 (46.7%) \|-1.09 (8.37) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (45.0%) \|-1.64 (9.43) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 25 (41.7%) \|-1.28 (9.76) | n= 21 (37.5%) \|-1.72 (6.78) | 0.05 [-0.54 ; 0.64] |
| Week 81 | n= 24 (40.0%) \|-2.04 (7.26) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (46.7%) \|-2.24 (10.62) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 22 (36.7%) \|-1.28 (8.91) | n= 17 (30.4%) \|-1.65 (8.05) | 0.04 [-0.60 ; 0.68] |
| Week 87 | n= 19 (31.7%) \|-4.42 (9.74) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 21 (35.0%) \|-2.90 (8.32) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (33.3%) \|-5.26 (8.00) | n= 15 (26.8%) \|-1.59 (11.38) | -0.37 [-1.06 ; 0.31] |
| Week 93 | n= 19 (31.7%) \|-4.19 (8.06) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.7%) \|-4.66 (8.28) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (30.0%) \|-5.04 (8.71) | n= 9 (16.1%) \|-2.51 (6.94) | -0.30 [-1.12 ; 0.52] |
| Week 99 | n= 15 (25.0%) \|-4.47 (9.48) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (20.0%) \|-5.32 (6.80) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.7%) \|-5.01 (6.64) | n= 8 (14.3%) \|-3.63 (6.63) | -0.20 [-1.11 ; 0.71] |
| Week 105 | n= 11 (18.3%) \|-6.10 (5.23) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.0%) \|-9.48 (4.91) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.7%) \|-7.55 (6.72) | n= 3 ( 5.4%) \|-4.67 (6.66) | -0.40 [-1.76 ; 0.96] |
| Week 111 | n= 6 (10.0%) \|-10.31 (2.15) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.7%) \|-8.06 (5.57) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (10.0%) \|-6.31 (4.47) | n= 5 ( 8.9%) \|-6.80 (7.76) | 0.07 [-1.18 ; 1.32] |
| Week 117 | n= 6 (10.0%) \|-3.98 (5.87) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 (10.0%) \|-6.31 (8.99) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.7%) \|-6.19 (8.42) | n= 1 ( 1.8%) \|-23.61 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.3%) \| 0.39 (6.52) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.7%) \|-6.33 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) \| 0.50 (4.95) | n= 1 ( 1.8%) \|-26.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.7%) \|-5.28 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.7%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.7%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.7%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.7%) \| 8.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.7%) \|-6.71 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.7%) \|-10.06 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (13.3%) \|-3.09 (5.17) | n= 11 (19.6%) \|-3.18 (10.74) | 0.01 [-0.93 ; 0.95] |
| Week 202 | n= 2 ( 3.3%) \|-12.50 (9.19) | n= 8 (14.3%) \| 1.75 (10.46) | -1.25 [-3.02 ; 0.52] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:37

TABLE 7.3.9: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **No** | | | | |
| Nr subjects used | n=11 | n=12 | | |
| Week 7 | -1.55 (2.37) [-6.51 ; 3.42] | -6.00 (2.25) [-10.71 ;-1.29] | 4.45 (3.27) [-2.39 ; 11.30] | 0.57 [-0.31 ; 1.45] |
| Week 13 | -1.84 (2.30) [-6.66 ; 2.97] | -8.46 (2.41) [-13.49 ;-3.43] | 6.62 (3.36) [-0.39 ; 13.62] | 0.83 [-0.07 ; 1.73] |
| Overall post-baseline period estimate | -1.69 (1.93) [-5.74 ; 2.35] | -7.23 (1.89) [-11.17 ;-3.28] | 5.54 (2.72) [-0.14 ; 11.21] | 0.82 [-0.04 ; 1.68] |
| **Yes** | | | | |
| Nr subjects used | n=58 | n=55 | | |
| Week 7 | -4.81 (1.22) [-7.24 ;-2.39] | -1.89 (1.26) [-4.38 ; 0.60] | -2.92 (1.75) [-6.39 ; 0.55] | -0.32 [-0.71 ; 0.06] |
| Week 13 | -3.90 (1.26) [-6.39 ;-1.41] | -3.51 (1.32) [-6.11 ;-0.90] | -0.39 (1.82) [-3.99 ; 3.21] | -0.04 [-0.45 ; 0.36] |
| Week 19 | -3.34 (0.98) [-5.29 ;-1.40] | -3.31 (1.04) [-5.37 ;-1.26] | -0.03 (1.43) [-2.86 ; 2.80] | -0.00 [-0.42 ; 0.41] |
| Week 25 | -2.47 (0.99) [-4.43 ;-0.51] | -1.13 (1.06) [-3.24 ; 0.97] | -1.33 (1.45) [-4.21 ; 1.54] | -0.20 [-0.62 ; 0.23] |
| Week 31 | -3.52 (1.08) [-5.65 ;-1.38] | -1.71 (1.16) [-4.01 ; 0.59] | -1.80 (1.59) [-4.94 ; 1.34] | -0.25 [-0.69 ; 0.19] |
| Week 37 | -2.34 (0.96) [-4.23 ;-0.44] | -1.66 (1.00) [-3.65 ; 0.32] | -0.68 (1.39) [-3.42 ; 2.07] | -0.11 [-0.55 ; 0.33] |
| Week 43 | -3.40 (1.12) [-5.62 ;-1.18] | -2.44 (1.22) [-4.86 ;-0.02] | -0.96 (1.66) [-4.25 ; 2.32] | -0.13 [-0.58 ; 0.32] |
| Week 49 | -3.53 (1.03) [-5.57 ;-1.50] | -1.96 (1.18) [-4.29 ; 0.37] | -1.57 (1.56) [-4.67 ; 1.52] | -0.24 [-0.71 ; 0.24] |
| Week 55 | -3.07 (1.06) [-5.18 ;-0.97] | -2.34 (1.21) [-4.73 ; 0.04] | -0.73 (1.61) [-3.91 ; 2.45] | -0.11 [-0.58 ; 0.37] |
| Week 61 | -3.25 (1.06) [-5.35 ;-1.16] | -2.73 (1.27) [-5.25 ;-0.21] | -0.53 (1.65) [-3.80 ; 2.75] | -0.08 [-0.57 ; 0.41] |
| Week 67 | -2.21 (1.15) [-4.49 ; 0.07] | -1.93 (1.39) [-4.69 ; 0.82] | -0.28 (1.80) [-3.86 ; 3.29] | -0.04 [-0.56 ; 0.48] |
| Week 73 | -3.25 (1.55) [-6.33 ;-0.17] | -4.05 (1.77) [-7.56 ;-0.54] | 0.80 (2.35) [-3.87 ; 5.47] | 0.09 [-0.45 ; 0.64] |
| Week 79 | -1.73 (1.27) [-4.26 ; 0.81] | -2.06 (1.44) [-4.92 ; 0.80] | 0.33 (1.92) [-3.49 ; 4.15] | 0.05 [-0.53 ; 0.63] |
| Week 85 | -2.83 (1.36) [-5.54 ;-0.13] | -2.05 (1.54) [-5.13 ; 1.02] | -0.78 (2.05) [-4.88 ; 3.32] | -0.12 [-0.75 ; 0.51] |
| Week 91 | -3.66 (1.64) [-6.95 ;-0.36] | -1.19 (1.88) [-4.98 ; 2.59] | -2.46 (2.50) [-7.48 ; 2.55] | -0.33 [-1.00 ; 0.35] |
| Overall post-baseline period estimate | -3.16 (0.66) [-4.46 ;-1.85] | -2.27 (0.74) [-3.72 ;-0.81] | -0.89 (0.99) [-2.85 ; 1.07] | -0.17 [-0.54 ; 0.20] |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.2774 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:37

TABLE 7.3.10: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **No** | N=61 | N=62 |
| **Yes** | N=10 | N=6 |
| **Subjects with Baseline Value** | | |
| **No** | 59 (96.7%) | 61 (98.4%) |
| **Yes** | 10 (100.0%) | 6 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **No** | 61 (100.0%) | 60 (96.8%) |
| **Yes** | 10 (100.0%) | 6 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **No** | 59 (96.7%) | 59 (95.2%) |
| **Yes** | 10 (100.0%) | 6 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:37

TABLE 7.3.10: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=61 | N=62 | |
| Baseline | n= 59 (96.7%) \| 62.72 (8.02) | n= 61 (98.4%) \| 61.09 (8.91) | 0.19 [-0.17 ; 0.55] |
| Week 3 | n= 57 (93.4%) \| 63.35 (7.51) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 55 (90.2%) \| 61.12 (9.28) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 55 (90.2%) \| 58.54 (9.25) | n= 59 (95.2%) \| 58.81 (9.06) | -0.03 [-0.40 ; 0.34] |
| Week 9 | n= 52 (85.2%) \| 60.44 (10.20) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 53 (86.9%) \| 59.25 (9.17) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 53 (86.9%) \| 59.80 (9.32) | n= 50 (80.6%) \| 58.24 (8.43) | 0.18 [-0.21 ; 0.56] |
| Week 15 | n= 49 (80.3%) \| 60.67 (8.78) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 55 (90.2%) \| 60.22 (8.87) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 51 (83.6%) \| 60.62 (7.92) | n= 50 (80.6%) \| 58.56 (8.49) | 0.25 [-0.14 ; 0.64] |
| Week 21 | n= 51 (83.6%) \| 60.84 (7.36) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 49 (80.3%) \| 60.20 (7.87) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 52 (85.2%) \| 60.92 (8.37) | n= 47 (75.8%) \| 60.49 (9.04) | 0.05 [-0.35 ; 0.45] |
| Week 27 | n= 50 (82.0%) \| 61.89 (8.30) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 46 (75.4%) \| 60.98 (8.49) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 48 (78.7%) \| 60.75 (8.74) | n= 39 (62.9%) \| 60.09 (8.81) | 0.07 [-0.35 ; 0.50] |
| Week 33 | n= 49 (80.3%) \| 60.66 (8.75) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 48 (78.7%) \| 60.74 (9.81) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 41 (67.2%) \| 61.39 (8.88) | n= 42 (67.7%) \| 60.29 (7.34) | 0.13 [-0.30 ; 0.57] |
| Week 39 | n= 45 (73.8%) \| 62.33 (7.55) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 46 (75.4%) \| 61.54 (7.88) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 46 (75.4%) \| 60.78 (8.91) | n= 38 (61.3%) \| 59.17 (8.62) | 0.18 [-0.25 ; 0.61] |
| Week 45 | n= 41 (67.2%) \| 60.30 (8.52) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 45 (73.8%) \| 61.37 (8.40) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 46 (75.4%) \| 61.54 (8.62) | n= 32 (51.6%) \| 59.21 (8.01) | 0.28 [-0.18 ; 0.73] |
| Week 51 | n= 44 (72.1%) \| 60.13 (9.49) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 45 (73.8%) \| 60.78 (8.86) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (63.9%) \| 60.92 (9.47) | n= 35 (56.5%) \| 58.87 (8.23) | 0.23 [-0.23 ; 0.69] |
| Week 57 | n= 41 (67.2%) \| 61.60 (8.02) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 39 (63.9%) \| 61.26 (9.30) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 41 (67.2%) \| 62.19 (8.06) | n= 28 (45.2%) \| 57.96 (8.63) | 0.50 [ 0.01 ; 0.99] |
| Week 63 | n= 35 (57.4%) \| 60.82 (8.79) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (59.0%) \| 60.60 (8.52) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (62.3%) \| 61.91 (8.64) | n= 27 (43.5%) \| 58.96 (7.27) | 0.36 [-0.14 ; 0.86] |
| Week 69 | n= 33 (54.1%) \| 59.66 (10.21) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (50.8%) \| 61.56 (9.31) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 29 (47.5%) \| 62.52 (9.13) | n= 25 (40.3%) \| 55.95 (8.14) | 0.74 [ 0.19 ; 1.30] |
| Week 75 | n= 30 (49.2%) \| 62.28 (8.38) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (42.6%) \| 62.00 (6.86) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (42.6%) \| 62.59 (10.99) | n= 24 (38.7%) \| 58.96 (6.71) | 0.39 [-0.18 ; 0.95] |
| Week 81 | n= 24 (39.3%) \| 63.13 (7.01) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 27 (44.3%) \| 62.57 (7.90) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (41.0%) \| 62.04 (8.37) | n= 19 (30.6%) \| 59.21 (7.74) | 0.34 [-0.27 ; 0.95] |
| Week 87 | n= 19 (31.1%) \| 60.84 (7.62) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 22 (36.1%) \| 60.96 (7.13) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 21 (34.4%) \| 60.52 (8.27) | n= 16 (25.8%) \| 60.19 (9.17) | 0.04 [-0.62 ; 0.70] |
| Week 93 | n= 20 (32.8%) \| 61.37 (8.13) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.1%) \| 60.44 (7.97) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.5%) \| 60.46 (7.76) | n= 11 (17.7%) \| 62.22 (7.46) | -0.22 [-0.99 ; 0.54] |
| Week 99 | n= 14 (23.0%) \| 60.21 (8.51) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.3%) \| 59.46 (8.68) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.3%) \| 59.53 (8.69) | n= 10 (16.1%) \| 59.60 (7.63) | -0.01 [-0.85 ; 0.84] |
| Week 105 | n= 11 (18.0%) \| 57.91 (7.34) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.5%) \| 57.14 (8.05) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (14.8%) \| 54.38 (8.72) | n= 5 ( 8.1%) \| 57.40 (11.52) | -0.29 [-1.43 ; 0.85] |
| Week 111 | n= 6 ( 9.8%) \| 54.00 (5.18) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.5%) \| 54.93 (5.70) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 ( 9.8%) \| 57.17 (6.85) | n= 5 ( 8.1%) \| 61.20 (8.26) | -0.49 [-1.77 ; 0.78] |
| Week 117 | n= 6 ( 9.8%) \| 57.83 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 ( 9.8%) \| 54.33 (9.75) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.5%) \| 56.65 (8.84) | n= 1 ( 1.6%) \| 45.39 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.3%) \| 56.89 (5.81) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) \| 50.67 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) \| 65.00 (5.66) | n= 1 ( 1.6%) \| 43.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) \| 51.72 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.6%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.6%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.6%) \| 65.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.6%) \| 50.29 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) \| 46.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 ( 9.8%) \| 60.50 (10.73) | n= 14 (22.6%) \| 55.43 (11.51) | 0.43 [-0.56 ; 1.42] |
| Week 202 | n= 1 ( 1.6%) \| 58.00 ( / ) | n= 8 (12.9%) \| 62.50 (7.80) | [Not calculable] |
| **Yes** | | | |
| N subjects in population | N=10 | N=6 | |
| Baseline | n= 10 (100.0%) \| 58.00 (7.87) | n= 6 (100.0%) \| 63.17 (5.38) | -0.69 [-1.77 ; 0.39] |
| Week 3 | n= 10 (100.0%) \| 56.90 (7.39) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (80.0%) \| 54.63 (9.91) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 9 (90.0%) \| 56.40 (9.45) | n= 5 (83.3%) \| 63.80 (6.72) | -0.80 [-1.99 ; 0.38] |
| Week 9 | n= 9 (90.0%) \| 53.30 (7.15) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 8 (80.0%) \| 52.00 (10.85) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 7 (70.0%) \| 54.00 (9.85) | n= 5 (83.3%) \| 65.20 (5.81) | -1.22 [-2.55 ; 0.11] |
| Week 15 | n= 5 (50.0%) \| 52.20 (13.54) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 8 (80.0%) \| 54.05 (12.64) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 6 (60.0%) \| 58.83 (8.91) | n= 4 (66.7%) \| 64.25 (4.79) | -0.64 [-2.03 ; 0.74] |
| Week 21 | n= 8 (80.0%) \| 52.00 (14.81) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 7 (70.0%) \| 50.64 (10.94) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (60.0%) \| 60.00 (8.79) | n= 2 (33.3%) \| 70.50 (3.54) | -1.12 [-2.99 ; 0.75] |
| Week 27 | n= 6 (60.0%) \| 59.67 (13.63) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 6 (60.0%) \| 59.50 (11.47) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 6 (60.0%) \| 58.50 (12.76) | n= 3 (50.0%) \| 67.67 (5.03) | -0.73 [-2.27 ; 0.81] |
| Week 33 | n= 7 (70.0%) \| 57.00 (12.25) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 6 (60.0%) \| 55.17 (11.23) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 7 (70.0%) \| 56.71 (11.53) | n= 5 (83.3%) \| 66.00 (5.79) | -0.89 [-2.16 ; 0.38] |
| Week 39 | n= 7 (70.0%) \| 57.43 (11.98) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 41 | n= 6 (60.0%) \| 57.28 (13.22) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 6 (60.0%) \| 60.83 (12.25) | n= 4 (66.7%) \| 65.75 (6.29) | -0.43 [-1.79 ; 0.94] |
| Week 45 | n= 7 (70.0%) \| 54.71 (16.15) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (60.0%) \| 58.17 (15.41) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (60.0%) \| 55.17 (14.52) | n= 4 (66.7%) \| 65.75 (6.85) | -0.78 [-2.19 ; 0.62] |
| Week 51 | n= 7 (70.0%) \| 55.14 (13.04) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 7 (70.0%) \| 58.32 (12.47) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (70.0%) \| 58.00 (11.42) | n= 3 (50.0%) \| 61.67 (2.52) | -0.33 [-1.78 ; 1.12] |
| Week 57 | n= 7 (70.0%) \| 55.14 (14.65) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (70.0%) \| 58.45 (11.39) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 7 (70.0%) \| 55.71 (12.41) | n= 3 (50.0%) \| 64.67 (5.86) | -0.73 [-2.21 ; 0.76] |
| Week 63 | n= 7 (70.0%) \| 55.86 (14.33) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (70.0%) \| 54.57 (18.30) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (60.0%) \| 58.83 (10.23) | n= 3 (50.0%) \| 64.33 (2.89) | -0.56 [-2.08 ; 0.96] |
| Week 69 | n= 5 (50.0%) \| 54.20 (19.25) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (70.0%) \| 56.29 (13.90) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 6 (60.0%) \| 58.50 (13.61) | n= 3 (50.0%) \| 61.33 (1.53) | -0.22 [-1.71 ; 1.27] |
| Week 75 | n= 5 (50.0%) \| 62.80 (8.29) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (60.0%) \| 55.44 (12.03) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (50.0%) \| 51.00 (13.29) | n= 1 (16.7%) \| 64.00 ( / ) | [Not calculable] |
| Week 81 | n= 5 (50.0%) \| 54.80 (13.31) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (60.0%) \| 53.33 (13.84) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (20.0%) \| 68.50 (2.12) | n= 2 (33.3%) \| 70.00 (1.41) | -0.48 [-3.04 ; 2.09] |
| Week 87 | n= 5 (50.0%) \| 51.80 (15.64) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 3 (30.0%) \| 51.00 (16.00) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (30.0%) \| 50.65 (18.78) | n= 2 (33.3%) \| 70.00 (1.41) | -0.92 [-3.22 ; 1.39] |
| Week 93 | n= 3 (30.0%) \| 51.00 (14.73) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (30.0%) \| 50.00 (16.00) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (30.0%) \| 49.00 (16.00) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 3 (30.0%) \| 48.67 (18.50) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (10.0%) \| 67.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (20.0%) \| 58.00 (9.90) | [No Data] | [No Data for at least 1 arm] |
| Week 105 | n= 2 (20.0%) \| 58.00 (12.73) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (10.0%) \| 66.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 (20.0%) \| 58.50 (9.19) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 (10.0%) \| 58.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 (10.0%) \| 70.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 (10.0%) \| 68.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (10.0%) \| 69.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (10.0%) \| 67.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 (10.0%) \| 65.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (20.0%) \| 60.00 (2.83) | n= 2 (33.3%) \| 63.00 (2.83) | -0.61 [-3.23 ; 2.02] |
| Week 202 | n= 1 (10.0%) \| 38.00 ( / ) | n= 3 (50.0%) \| 68.67 (5.51) | [Not calculable] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:38

TABLE 7.3.10: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=61 | N=62 | |
| Week 3 | n= 56 (91.8%) \| 0.31 (5.95) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 53 (86.9%) \|-1.58 (8.04) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 53 (86.9%) \|-3.77 (8.56) | n= 58 (93.5%) \|-2.42 (8.46) | -0.16 [-0.53 ; 0.22] |
| Week 9 | n= 51 (83.6%) \|-3.49 (8.86) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 52 (85.2%) \|-3.73 (8.92) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 52 (85.2%) \|-2.98 (8.15) | n= 50 (80.6%) \|-5.01 (8.79) | 0.24 [-0.15 ; 0.63] |
| Week 15 | n= 49 (80.3%) \|-2.01 (8.20) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 54 (88.5%) \|-3.02 (8.01) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 50 (82.0%) \|-2.96 (7.65) | n= 49 (79.0%) \|-4.12 (8.43) | 0.14 [-0.25 ; 0.54] |
| Week 21 | n= 51 (83.6%) \|-2.42 (7.43) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 49 (80.3%) \|-2.74 (7.19) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 51 (83.6%) \|-2.44 (8.76) | n= 46 (74.2%) \|-3.36 (9.63) | 0.10 [-0.30 ; 0.50] |
| Week 27 | n= 49 (80.3%) \|-2.00 (8.56) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 46 (75.4%) \|-2.74 (8.25) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 48 (78.7%) \|-2.69 (8.58) | n= 39 (62.9%) \|-2.98 (8.70) | 0.03 [-0.39 ; 0.46] |
| Week 33 | n= 49 (80.3%) \|-2.81 (7.67) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 47 (77.0%) \|-3.01 (8.24) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 41 (67.2%) \|-1.83 (7.48) | n= 41 (66.1%) \|-2.80 (6.98) | 0.13 [-0.30 ; 0.57] |
| Week 39 | n= 44 (72.1%) \|-1.78 (7.68) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 46 (75.4%) \|-2.94 (8.20) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 45 (73.8%) \|-3.07 (8.74) | n= 37 (59.7%) \|-4.26 (7.53) | 0.14 [-0.30 ; 0.58] |
| Week 45 | n= 41 (67.2%) \|-3.34 (8.60) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 45 (73.8%) \|-2.79 (7.74) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 46 (75.4%) \|-2.05 (7.44) | n= 31 (50.0%) \|-4.20 (7.19) | 0.29 [-0.17 ; 0.75] |
| Week 51 | n= 44 (72.1%) \|-3.23 (8.47) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 45 (73.8%) \|-2.94 (8.49) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (63.9%) \|-2.99 (8.80) | n= 34 (54.8%) \|-4.42 (7.29) | 0.17 [-0.29 ; 0.64] |
| Week 57 | n= 41 (67.2%) \|-2.27 (8.10) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 39 (63.9%) \|-2.14 (9.10) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 41 (67.2%) \|-1.97 (8.19) | n= 27 (43.5%) \|-5.11 (6.54) | 0.41 [-0.09 ; 0.90] |
| Week 63 | n= 35 (57.4%) \|-2.48 (8.16) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (59.0%) \|-2.03 (8.29) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (62.3%) \|-1.44 (8.71) | n= 26 (41.9%) \|-4.00 (7.71) | 0.30 [-0.20 ; 0.81] |
| Week 69 | n= 33 (54.1%) \|-3.69 (10.80) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (50.8%) \|-2.21 (10.13) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 29 (47.5%) \|-1.04 (10.80) | n= 25 (40.3%) \|-6.21 (8.82) | 0.51 [-0.04 ; 1.06] |
| Week 75 | n= 30 (49.2%) \|-1.39 (8.53) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (42.6%) \|-0.54 (8.94) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (42.6%) \|-0.76 (10.73) | n= 23 (37.1%) \|-2.44 (7.17) | 0.18 [-0.39 ; 0.75] |
| Week 81 | n= 24 (39.3%) \|-0.75 (6.77) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 27 (44.3%) \|-0.51 (9.47) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (41.0%) \|-1.01 (8.49) | n= 18 (29.0%) \|-4.11 (7.95) | 0.37 [-0.25 ; 0.99] |
| Week 87 | n= 19 (31.1%) \|-2.20 (8.44) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 22 (36.1%) \|-1.82 (7.40) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 21 (34.4%) \|-3.81 (7.57) | n= 15 (24.2%) \|-4.66 (12.42) | 0.08 [-0.59 ; 0.76] |
| Week 93 | n= 20 (32.8%) \|-2.53 (7.95) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.1%) \|-2.87 (8.08) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.5%) \|-3.04 (8.47) | n= 10 (16.1%) \|-2.06 (6.70) | -0.12 [-0.91 ; 0.67] |
| Week 99 | n= 14 (23.0%) \|-2.43 (8.63) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.3%) \|-4.07 (7.68) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.3%) \|-4.47 (7.19) | n= 9 (14.5%) \|-4.78 (7.10) | 0.04 [-0.83 ; 0.91] |
| Week 105 | n= 11 (18.0%) \|-5.37 (6.42) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.5%) \|-6.56 (8.43) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (14.8%) \|-7.94 (7.31) | n= 4 ( 6.5%) \|-8.25 (9.00) | 0.04 [-1.19 ; 1.27] |
| Week 111 | n= 6 ( 9.8%) \|-7.65 (7.46) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.5%) \|-7.06 (7.99) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 ( 9.8%) \|-4.98 (7.35) | n= 5 ( 8.1%) \|-6.80 (7.76) | 0.22 [-1.04 ; 1.48] |
| Week 117 | n= 6 ( 9.8%) \|-3.15 (7.11) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 ( 9.8%) \|-5.15 (10.33) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.5%) \|-4.76 (9.95) | n= 1 ( 1.6%) \|-23.61 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.3%) \| 0.39 (6.52) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) \|-6.33 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) \| 0.50 (4.95) | n= 1 ( 1.6%) \|-26.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) \|-5.28 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.6%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.6%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.6%) \| 8.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.6%) \|-6.71 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) \|-10.06 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 ( 9.8%) \|-2.29 (5.85) | n= 14 (22.6%) \|-5.29 (11.53) | 0.28 [-0.71 ; 1.27] |
| Week 202 | n= 1 ( 1.6%) \|-6.00 ( / ) | n= 8 (12.9%) \| 0.75 (11.83) | [Not calculable] |
| **Yes** | | | |
| N subjects in population | N=10 | N=6 | |
| Week 3 | n= 10 (100.0%) \|-1.10 (3.84) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (80.0%) \|-2.75 (4.20) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 9 (90.0%) \|-2.04 (5.59) | n= 5 (83.3%) \| 1.60 (1.67) | -0.73 [-1.91 ; 0.45] |
| Week 9 | n= 9 (90.0%) \|-4.81 (4.96) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 8 (80.0%) \|-6.25 (9.04) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 7 (70.0%) \|-7.43 (8.20) | n= 5 (83.3%) \| 0.60 (3.51) | -1.10 [-2.41 ; 0.20] |
| Week 15 | n= 5 (50.0%) \|-10.00 (13.38) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 8 (80.0%) \|-5.58 (9.08) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 6 (60.0%) \|-2.50 (5.89) | n= 4 (66.7%) \| 0.00 (4.69) | -0.41 [-1.77 ; 0.95] |
| Week 21 | n= 8 (80.0%) \|-7.63 (11.17) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 7 (70.0%) \|-7.79 (8.11) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (60.0%) \|-0.83 (6.01) | n= 2 (33.3%) \| 5.50 (0.71) | -1.00 [-2.84 ; 0.84] |
| Week 27 | n= 6 (60.0%) \|-2.83 (10.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 6 (60.0%) \|-0.17 (6.15) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 6 (60.0%) \|-4.00 (9.34) | n= 3 (50.0%) \| 3.67 (2.31) | -0.85 [-2.41 ; 0.71] |
| Week 33 | n= 7 (70.0%) \|-3.29 (10.14) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 6 (60.0%) \|-3.83 (9.75) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 7 (70.0%) \|-3.57 (9.00) | n= 5 (83.3%) \| 1.40 (3.05) | -0.63 [-1.87 ; 0.60] |
| Week 39 | n= 7 (70.0%) \|-2.86 (9.23) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 6 (60.0%) \|-3.56 (9.95) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 6 (60.0%) \|-0.50 (9.75) | n= 4 (66.7%) \|-0.50 (5.26) | 0.00 [-1.34 ; 1.34] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 45 | n= 7 (70.0%) \|-5.57 (13.83) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (60.0%) \|-4.33 (13.17) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (60.0%) \|-5.67 (11.69) | n= 4 (66.7%) \| 2.25 (5.32) | -0.73 [-2.13 ; 0.67] |
| Week 51 | n= 7 (70.0%) \|-5.14 (10.78) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 7 (70.0%) \|-1.97 (10.12) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (70.0%) \|-2.29 (7.87) | n= 3 (50.0%) \|-0.33 (1.53) | -0.26 [-1.70 ; 1.19] |
| Week 57 | n= 7 (70.0%) \|-5.14 (13.06) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (70.0%) \|-1.83 (9.53) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 7 (70.0%) \|-4.57 (9.03) | n= 3 (50.0%) \| 2.67 (3.79) | -0.81 [-2.31 ; 0.68] |
| Week 63 | n= 7 (70.0%) \|-4.43 (11.62) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (70.0%) \|-5.71 (14.89) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (60.0%) \|-2.50 (9.99) | n= 3 (50.0%) \| 2.33 (4.93) | -0.49 [-2.00 ; 1.03] |
| Week 69 | n= 5 (50.0%) \|-9.40 (14.36) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (70.0%) \|-4.00 (11.96) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 6 (60.0%) \|-1.17 (10.34) | n= 3 (50.0%) \|-0.67 (2.52) | -0.05 [-1.54 ; 1.44] |
| Week 75 | n= 5 (50.0%) \| 2.00 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (60.0%) \|-3.56 (9.08) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (50.0%) \|-6.40 (12.10) | n= 1 (16.7%) \| 2.00 ( / ) | [Not calculable] |
| Week 81 | n= 5 (50.0%) \|-3.20 (8.41) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (60.0%) \|-5.67 (12.23) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (20.0%) \| 2.50 (3.54) | n= 2 (33.3%) \| 10.00 (1.41) | -1.59 [-5.04 ; 1.86] |
| Week 87 | n= 5 (50.0%) \|-6.20 (11.99) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 3 (30.0%) \|-5.00 (12.29) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (30.0%) \|-5.35 (12.85) | n= 2 (33.3%) \| 10.00 (4.24) | -1.04 [-3.39 ; 1.32] |
| Week 93 | n= 3 (30.0%) \|-5.00 (9.54) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (30.0%) \|-6.00 (12.29) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (30.0%) \|-7.00 (12.29) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 3 (30.0%) \|-7.33 (14.47) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (10.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (20.0%) \| 1.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 105 | n= 2 (20.0%) \| 1.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (10.0%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 (20.0%) \| 1.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 (10.0%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 (10.0%) \| 3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 (10.0%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (10.0%) \| 2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (10.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 (10.0%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (20.0%) \|-5.50 (0.71) | n= 2 (33.3%) \| 2.00 (4.24) | -1.41 [-4.67 ; 1.85] |
| Week 202 | n= 1 (10.0%) \|-19.00 ( / ) | n= 3 (50.0%) \| 1.00 (5.29) | [Not calculable] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:38

TABLE 7.3.10: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **No** | | | | |
| Nr subjects used | n=59 | n=61 | | |
| Week 7 | -4.42 (1.21) [-6.81 ;-2.03] | -3.31 (1.19) [-5.66 ;-0.96] | -1.11 (1.69) [-4.45 ; 2.24] | -0.12 [-0.50 ; 0.25] |
| Week 13 | -3.03 (1.18) [-5.37 ;-0.68] | -5.15 (1.20) [-7.53 ;-2.78] | 2.13 (1.69) [-1.21 ; 5.46] | 0.25 [-0.14 ; 0.64] |
| Week 19 | -2.84 (0.99) [-4.79 ;-0.89] | -4.82 (1.00) [-6.81 ;-2.83] | 1.98 (1.41) [-0.80 ; 4.77] | 0.28 [-0.12 ; 0.68] |
| Week 25 | -2.46 (1.10) [-4.65 ;-0.28] | -3.46 (1.15) [-5.72 ;-1.19] | 1.00 (1.59) [-2.15 ; 4.14] | 0.13 [-0.27 ; 0.52] |
| Week 31 | -2.85 (1.05) [-4.93 ;-0.77] | -2.98 (1.12) [-5.20 ;-0.77] | 0.13 (1.54) [-2.91 ; 3.17] | 0.02 [-0.40 ; 0.44] |
| Week 37 | -2.11 (1.00) [-4.08 ;-0.14] | -3.21 (1.03) [-5.26 ;-1.16] | 1.10 (1.43) [-1.74 ; 3.94] | 0.17 [-0.27 ; 0.60] |
| Week 43 | -2.85 (1.09) [-5.00 ;-0.70] | -3.66 (1.19) [-6.01 ;-1.31] | 0.81 (1.61) [-2.38 ; 3.99] | 0.11 [-0.32 ; 0.55] |
| Week 49 | -2.41 (0.94) [-4.28 ;-0.55] | -3.27 (1.09) [-5.42 ;-1.11] | 0.85 (1.44) [-2.00 ; 3.70] | 0.13 [-0.32 ; 0.59] |
| Week 55 | -2.97 (1.12) [-5.20 ;-0.75] | -3.70 (1.26) [-6.19 ;-1.21] | 0.73 (1.69) [-2.61 ; 4.07] | 0.10 [-0.36 ; 0.56] |
| Week 61 | -2.09 (1.04) [-4.15 ;-0.04] | -4.05 (1.23) [-6.49 ;-1.61] | 1.96 (1.61) [-1.23 ; 5.15] | 0.30 [-0.19 ; 0.78] |
| Week 67 | -1.70 (1.16) [-3.99 ; 0.60] | -3.53 (1.37) [-6.26 ;-0.81] | 1.83 (1.80) [-1.73 ; 5.40] | 0.26 [-0.24 ; 0.76] |
| Week 73 | -2.61 (1.54) [-5.66 ; 0.44] | -5.55 (1.73) [-8.98 ;-2.12] | 2.94 (2.31) [-1.65 ; 7.54] | 0.34 [-0.20 ; 0.88] |
| Week 79 | -1.84 (1.50) [-4.82 ; 1.14] | -3.36 (1.64) [-6.63 ;-0.10] | 1.52 (2.22) [-2.90 ; 5.94] | 0.19 [-0.37 ; 0.76] |
| Week 85 | -2.50 (1.27) [-5.04 ; 0.03] | -4.05 (1.44) [-6.92 ;-1.17] | 1.54 (1.92) [-2.29 ; 5.37] | 0.24 [-0.37 ; 0.85] |
| Week 91 | -2.74 (1.53) [-5.80 ; 0.33] | -3.73 (1.77) [-7.27 ;-0.19] | 0.99 (2.34) [-3.69 ; 5.68] | 0.14 [-0.52 ; 0.80] |
| Week 97 | -2.89 (1.46) [-5.85 ; 0.07] | -2.89 (1.84) [-6.62 ; 0.84] | -0.00 (2.35) [-4.76 ; 4.76] | -0.00 [-0.77 ; 0.77] |
| Overall post-baseline period estimate | -2.64 (0.65) [-3.93 ;-1.36] | -3.80 (0.72) [-5.21 ;-2.38] | 1.15 (0.97) [-0.76 ; 3.06] | 0.22 [-0.14 ; 0.58] |
| **Yes** | | | | |
| Nr subjects used | n=10 | n=6 | | |
| **MMRM subgroups interaction p-value** | | | | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:38

TABLE 7.3.11: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **>= 1%** | N=11 | N=9 |
| **< 1%** | N=58 | N=58 |
| **Not Reported** | N=2 | N=1 |
| **Subjects with Baseline Value** | | |
| **>= 1%** | 11 (100.0%) | 9 (100.0%) |
| **< 1%** | 56 (96.6%) | 57 (98.3%) |
| **Not Reported** | 2 (100.0%) | 1 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **>= 1%** | 11 (100.0%) | 9 (100.0%) |
| **< 1%** | 58 (100.0%) | 56 (96.6%) |
| **Not Reported** | 2 (100.0%) | 1 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **>= 1%** | 11 (100.0%) | 9 (100.0%) |
| **< 1%** | 56 (96.6%) | 55 (94.8%) |
| **Not Reported** | 2 (100.0%) | 1 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:38

TABLE 7.3.11: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **>= 1%** | | | |
| N subjects in population | N=11 | N=9 | |
| Baseline | n= 11 (100.0%) \| 60.47 (6.50) | n= 9 (100.0%) \| 60.30 (9.67) | 0.02 [-0.88 ; 0.93] |
| Week 3 | n= 11 (100.0%) \| 59.92 (7.50) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 9 (81.8%) \| 59.22 (7.98) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 10 (90.9%) \| 58.53 (4.97) | n= 9 (100.0%) \| 55.85 (12.89) | 0.27 [-0.66 ; 1.20] |
| Week 9 | n= 10 (90.9%) \| 56.58 (8.08) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (81.8%) \| 55.67 (12.50) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 10 (90.9%) \| 56.20 (11.05) | n= 7 (77.8%) \| 57.57 (10.58) | -0.12 [-1.12 ; 0.88] |
| Week 15 | n= 8 (72.7%) \| 56.50 (12.41) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (81.8%) \| 58.11 (8.04) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 8 (72.7%) \| 58.63 (9.26) | n= 6 (66.7%) \| 53.97 (10.87) | 0.44 [-0.68 ; 1.55] |
| Week 21 | n= 8 (72.7%) \| 54.38 (7.17) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \| 57.20 (9.37) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 8 (72.7%) \| 58.38 (8.58) | n= 5 (55.6%) \| 59.00 (5.92) | -0.08 [-1.24 ; 1.09] |
| Week 27 | n= 9 (81.8%) \| 57.56 (12.32) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 8 (72.7%) \| 58.13 (10.91) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 8 (72.7%) \| 57.50 (11.33) | n= 6 (66.7%) \| 56.83 (7.19) | 0.06 [-1.04 ; 1.17] |
| Week 33 | n= 9 (81.8%) \| 55.56 (11.05) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 9 (81.8%) \| 57.00 (10.72) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \| 55.75 (10.91) | n= 6 (66.7%) \| 58.14 (8.05) | -0.23 [-1.33 ; 0.88] |
| Week 39 | n= 9 (81.8%) \| 56.67 (10.20) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 10 (90.9%) \| 55.30 (9.09) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 8 (72.7%) \| 59.63 (10.16) | n= 7 (77.8%) \| 55.71 (9.11) | 0.38 [-0.68 ; 1.44] |
| Week 45 | n= 8 (72.7%) \| 53.50 (13.13) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 7 (63.6%) \| 56.00 (14.19) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 9 (81.8%) \| 54.89 (11.34) | n= 7 (77.8%) \| 55.67 (12.35) | -0.06 [-1.08 ; 0.96] |
| Week 51 | n= 9 (81.8%) \| 52.03 (12.84) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 8 (72.7%) \| 56.25 (12.46) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (63.6%) \| 57.43 (14.73) | n= 7 (77.8%) \| 58.00 (8.29) | -0.04 [-1.14 ; 1.05] |
| Week 57 | n= 6 (54.5%) \| 57.00 (17.24) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 8 (72.7%) \| 56.15 (11.73) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (72.7%) \| 56.41 (12.59) | n= 6 (66.7%) \| 54.17 (9.95) | 0.18 [-0.92 ; 1.29] |
| Week 63 | n= 7 (63.6%) \| 54.29 (13.09) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (63.6%) \| 52.57 (17.05) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \| 59.25 (11.02) | n= 6 (66.7%) \| 55.33 (6.44) | 0.39 [-0.72 ; 1.50] |
| Week 69 | n= 8 (72.7%) \| 49.63 (15.95) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (63.6%) \| 52.57 (11.77) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 8 (72.7%) \| 57.75 (11.77) | n= 6 (66.7%) \| 51.96 (7.82) | 0.53 [-0.60 ; 1.65] |
| Week 75 | n= 7 (63.6%) \| 58.57 (8.62) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (54.5%) \| 53.00 (9.55) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 7 (63.6%) \| 54.71 (12.83) | n= 4 (44.4%) \| 56.50 (3.42) | -0.15 [-1.45 ; 1.15] |
| Week 81 | n= 6 (54.5%) \| 56.33 (10.71) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 9 (81.8%) \| 56.33 (13.72) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (63.6%) \| 59.71 (9.32) | n= 3 (33.3%) \| 54.67 (4.04) | 0.55 [-0.92 ; 2.01] |
| Week 87 | n= 6 (54.5%) \| 53.67 (11.06) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 8 (72.7%) \| 57.38 (12.09) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 8 (72.7%) \| 57.00 (12.66) | n= 3 (33.3%) \| 51.67 (4.62) | 0.43 [-0.99 ; 1.84] |
| Week 93 | n= 7 (63.6%) \| 57.34 (11.95) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 8 (72.7%) \| 57.25 (12.36) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (63.6%) \| 58.75 (12.89) | n= 1 (11.1%) \| 58.00 ( / ) | [Not calculable] |
| Week 99 | n= 6 (54.5%) \| 58.33 (15.59) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 5 (45.5%) \| 63.40 (8.17) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 5 (45.5%) \| 61.49 (10.74) | n= 1 (11.1%) \| 59.00 ( / ) | [Not calculable] |
| Week 105 | n= 5 (45.5%) \| 58.00 (6.93) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \| 62.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (27.3%) \| 55.80 (9.86) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 ( 9.1%) \| 58.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (27.3%) \| 59.17 (11.27) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (27.3%) \| 59.67 (8.02) | n= 2 (22.2%) \| 53.50 (4.95) | 0.63 [-1.58 ; 2.83] |
| Week 117 | n= 3 (27.3%) \| 60.00 (8.19) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 (27.3%) \| 55.67 (13.32) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (18.2%) \| 56.78 (11.63) | n= 1 (11.1%) \| 45.39 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 9.1%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 9.1%) \| 50.67 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 9.1%) \| 61.00 ( / ) | n= 1 (11.1%) \| 43.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 9.1%) \| 51.72 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 9.1%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 9.1%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 9.1%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 9.1%) \| 65.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 9.1%) \| 50.29 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 9.1%) \| 46.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (27.3%) \| 55.67 (7.77) | n= 3 (33.3%) \| 60.67 (4.51) | -0.63 [-2.51 ; 1.25] |
| Week 202 | [No Data] | n= 1 (11.1%) \| 65.00 ( / ) | [No Data for at least 1 arm] |
| **< 1%** | | | |
| N subjects in population | N=58 | N=58 | |
| Baseline | n= 56 (96.6%) \| 62.47 (8.51) | n= 57 (98.3%) \| 61.35 (8.62) | 0.13 [-0.24 ; 0.50] |
| Week 3 | n= 54 (93.1%) \| 63.05 (7.89) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 52 (89.7%) \| 60.72 (9.93) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 52 (89.7%) \| 58.46 (9.92) | n= 54 (93.1%) \| 59.60 (8.17) | -0.12 [-0.51 ; 0.26] |
| Week 9 | n= 51 (87.9%) \| 59.94 (10.41) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 51 (87.9%) \| 58.87 (9.17) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 49 (84.5%) \| 59.83 (9.21) | n= 47 (81.0%) \| 58.93 (8.23) | 0.10 [-0.30 ; 0.50] |
| Week 15 | n= 45 (77.6%) \| 60.60 (8.97) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 53 (91.4%) \| 59.86 (9.79) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 48 (82.8%) \| 60.89 (7.80) | n= 47 (81.0%) \| 59.49 (7.98) | 0.18 [-0.23 ; 0.58] |
| Week 21 | n= 50 (86.2%) \| 60.54 (9.21) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 45 (77.6%) \| 59.46 (8.81) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 49 (84.5%) \| 61.29 (8.40) | n= 43 (74.1%) \| 61.07 (9.51) | 0.02 [-0.39 ; 0.44] |
| Week 27 | n= 46 (79.3%) \| 62.58 (8.02) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 43 (74.1%) \| 61.40 (8.44) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (77.6%) \| 61.13 (8.82) | n= 36 (62.1%) \| 61.27 (8.95) | -0.02 [-0.46 ; 0.43] |
| Week 33 | n= 46 (79.3%) \| 61.18 (8.73) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 44 (75.9%) \| 60.93 (9.92) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 39 (67.2%) \| 61.85 (8.86) | n= 40 (69.0%) \| 61.25 (7.35) | 0.07 [-0.37 ; 0.52] |
| Week 39 | n= 42 (72.4%) \| 62.95 (7.51) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 41 | n= 41 (70.7%) \| 62.60 (7.99) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 43 (74.1%) \| 61.17 (9.17) | n= 34 (58.6%) \| 60.63 (8.51) | 0.06 [-0.39 ; 0.51] |
| Week 45 | n= 39 (67.2%) \| 60.78 (9.02) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 43 (74.1%) \| 61.90 (8.32) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 42 (72.4%) \| 62.16 (8.80) | n= 28 (48.3%) \| 60.89 (6.68) | 0.16 [-0.33 ; 0.64] |
| Week 51 | n= 41 (70.7%) \| 61.20 (8.77) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 43 (74.1%) \| 61.42 (8.57) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 38 (65.5%) \| 61.29 (8.63) | n= 30 (51.7%) \| 59.35 (8.12) | 0.23 [-0.26 ; 0.71] |
| Week 57 | n= 41 (70.7%) \| 61.35 (7.87) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (63.8%) \| 62.11 (8.85) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (67.2%) \| 62.52 (7.75) | n= 25 (43.1%) \| 59.68 (8.06) | 0.36 [-0.15 ; 0.87] |
| Week 63 | n= 34 (58.6%) \| 61.40 (8.91) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 35 (60.3%) \| 61.47 (8.23) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (62.1%) \| 61.99 (8.34) | n= 24 (41.4%) \| 60.54 (7.02) | 0.18 [-0.34 ; 0.70] |
| Week 69 | n= 30 (51.7%) \| 61.43 (8.88) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (53.4%) \| 62.40 (9.20) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 27 (46.6%) \| 63.03 (9.19) | n= 22 (37.9%) \| 57.77 (7.58) | 0.61 [ 0.03 ; 1.19] |
| Week 75 | n= 28 (48.3%) \| 63.30 (8.03) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (44.8%) \| 62.56 (6.96) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (41.4%) \| 62.47 (11.38) | n= 21 (36.2%) \| 59.67 (7.05) | 0.29 [-0.31 ; 0.88] |
| Week 81 | n= 23 (39.7%) \| 63.09 (7.79) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 24 (41.4%) \| 62.60 (7.33) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (34.5%) \| 63.50 (7.84) | n= 18 (31.0%) \| 61.17 (8.23) | 0.28 [-0.36 ; 0.93] |
| Week 87 | n= 18 (31.0%) \| 60.72 (9.43) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 17 (29.3%) \| 60.89 (6.84) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 16 (27.6%) \| 60.43 (8.74) | n= 15 (25.9%) \| 63.20 (8.69) | -0.31 [-1.03 ; 0.41] |
| Week 93 | n= 16 (27.6%) \| 61.19 (8.33) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 14 (24.1%) \| 60.03 (7.99) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 14 (24.1%) \| 58.86 (8.21) | n= 10 (17.2%) \| 62.64 (7.73) | -0.46 [-1.30 ; 0.38] |
| Week 99 | n= 11 (19.0%) \| 58.09 (8.60) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 9 (15.5%) \| 58.11 (8.65) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 10 (17.2%) \| 58.25 (7.53) | n= 9 (15.5%) \| 59.67 (8.09) | -0.17 [-1.10 ; 0.75] |
| Week 105 | n= 8 (13.8%) \| 57.88 (8.53) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.3%) \| 57.00 (8.81) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (13.8%) \| 54.88 (8.66) | n= 5 ( 8.6%) \| 57.40 (11.52) | -0.24 [-1.41 ; 0.93] |
| Week 111 | n= 6 (10.3%) \| 54.00 (5.18) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 ( 8.6%) \| 55.40 (5.32) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 6.9%) \| 58.00 (8.21) | n= 3 ( 5.2%) \| 66.33 (5.03) | -0.99 [-2.77 ; 0.80] |
| Week 117 | n= 4 ( 6.9%) \| 59.00 (3.37) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 6.9%) \| 56.50 (9.26) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (10.3%) \| 58.00 (8.85) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 1.7%) \| 61.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.7%) \| 69.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 ( 8.6%) \| 63.20 (9.44) | n= 13 (22.4%) \| 55.38 (11.98) | 0.65 [-0.43 ; 1.74] |
| Week 202 | n= 1 ( 1.7%) \| 58.00 ( / ) | n= 10 (17.2%) \| 64.10 (7.95) | [Not calculable] |
| **Not Reported** | | | |
| N subjects in population | N=2 | N=1 | |
| Baseline | n= 2 (100.0%) \| 58.50 (2.12) | n= 1 (100.0%) \| 66.00 ( / ) | . [ . ; .] |
| Week 3 | n= 2 (100.0%) \| 58.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (100.0%) \| 54.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 2 (100.0%) \| 51.00 (4.24) | n= 1 (100.0%) \| 68.00 ( / ) | [Not calculable] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 11 | n= 1 (50.0%) \| 53.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (50.0%) \| 54.00 ( / ) | n= 1 (100.0%) \| 65.00 ( / ) | [Not calculable] |
| Week 15 | n= 1 (50.0%) \| 55.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 1 (50.0%) \| 49.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (50.0%) \| 53.00 ( / ) | n= 1 (100.0%) \| 65.00 ( / ) | [Not calculable] |
| Week 21 | n= 1 (50.0%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (50.0%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (50.0%) \| 58.00 ( / ) | n= 1 (100.0%) \| 63.00 ( / ) | [Not calculable] |
| Week 27 | n= 1 (50.0%) \| 56.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 1 (50.0%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (50.0%) \| 56.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (50.0%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 1 (50.0%) \| 53.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (50.0%) \| 56.00 ( / ) | n= 1 (100.0%) \| 63.00 ( / ) | [Not calculable] |
| Week 39 | n= 1 (50.0%) \| 53.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (50.0%) \| 55.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (50.0%) \| 53.83 ( / ) | n= 1 (100.0%) \| 60.00 ( / ) | [Not calculable] |
| Week 45 | n= 1 (50.0%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (50.0%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (50.0%) \| 57.00 ( / ) | n= 1 (100.0%) \| 63.00 ( / ) | [Not calculable] |
| Week 51 | n= 1 (50.0%) \| 54.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (50.0%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (50.0%) \| 51.00 ( / ) | n= 1 (100.0%) \| 59.00 ( / ) | [Not calculable] |
| Week 57 | n= 1 (50.0%) \| 54.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (50.0%) \| 51.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (50.0%) \| 50.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (50.0%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (50.0%) \| 44.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 202 | n= 1 (50.0%) \| 38.00 ( / ) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:39

TABLE 7.3.11: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **>= 1%** | | | |
| N subjects in population | N=11 | N=9 | |
| Week 3 | n= 11 (100.0%) \|-0.55 (5.07) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 9 (81.8%) \|-2.57 (5.83) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 10 (90.9%) \|-2.59 (4.57) | n= 9 (100.0%) \|-4.45 (7.11) | 0.30 [-0.63 ; 1.23] |
| Week 9 | n= 10 (90.9%) \|-3.92 (10.27) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (81.8%) \|-6.02 (11.35) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 10 (90.9%) \|-3.82 (12.02) | n= 7 (77.8%) \|-5.81 (11.22) | 0.16 [-0.84 ; 1.16] |
| Week 15 | n= 8 (72.7%) \|-4.25 (13.65) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (81.8%) \|-1.89 (9.77) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 8 (72.7%) \|-4.02 (9.59) | n= 6 (66.7%) \|-7.14 (6.73) | 0.34 [-0.77 ; 1.45] |
| Week 21 | n= 8 (72.7%) \|-4.88 (7.18) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \|-3.30 (9.63) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 8 (72.7%) \|-3.88 (8.17) | n= 5 (55.6%) \|-5.98 (4.98) | 0.27 [-0.90 ; 1.45] |
| Week 27 | n= 9 (81.8%) \|-4.67 (11.18) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 8 (72.7%) \|-3.88 (9.46) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 8 (72.7%) \|-4.38 (9.59) | n= 6 (66.7%) \|-5.28 (6.64) | 0.10 [-1.00 ; 1.20] |
| Week 33 | n= 9 (81.8%) \|-6.67 (10.09) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 9 (81.8%) \|-5.22 (9.98) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \|-6.13 (9.40) | n= 6 (66.7%) \|-4.31 (2.86) | -0.23 [-1.34 ; 0.88] |
| Week 39 | n= 9 (81.8%) \|-5.02 (9.09) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 10 (90.9%) \|-6.72 (8.11) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 8 (72.7%) \|-3.02 (9.61) | n= 7 (77.8%) \|-7.67 (6.29) | 0.53 [-0.54 ; 1.60] |
| Week 45 | n= 8 (72.7%) \|-8.38 (12.20) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 7 (63.6%) \|-5.86 (13.01) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 9 (81.8%) \|-6.80 (10.70) | n= 7 (77.8%) \|-7.71 (7.82) | 0.09 [-0.93 ; 1.11] |
| Week 51 | n= 9 (81.8%) \|-9.65 (11.43) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 8 (72.7%) \|-6.25 (10.90) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (63.6%) \|-5.17 (13.15) | n= 7 (77.8%) \|-5.38 (5.37) | 0.02 [-1.07 ; 1.11] |
| Week 57 | n= 6 (54.5%) \|-4.36 (15.51) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 8 (72.7%) \|-5.75 (10.42) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (72.7%) \|-5.49 (10.14) | n= 6 (66.7%) \|-7.94 (7.36) | 0.25 [-0.85 ; 1.36] |
| Week 63 | n= 7 (63.6%) \|-7.02 (12.04) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (63.6%) \|-8.74 (14.95) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \|-4.02 (12.05) | n= 6 (66.7%) \|-6.78 (6.15) | 0.26 [-0.85 ; 1.36] |
| Week 69 | n= 8 (72.7%) \|-12.15 (15.32) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (63.6%) \|-9.43 (10.52) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 8 (72.7%) \|-4.27 (8.71) | n= 6 (66.7%) \|-10.15 (6.58) | 0.70 [-0.44 ; 1.84] |
| Week 75 | n= 7 (63.6%) \|-4.60 (7.97) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (54.5%) \|-9.00 (7.27) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 7 (63.6%) \|-6.45 (11.50) | n= 4 (44.4%) \|-6.44 (9.97) | -0.00 [-1.30 ; 1.30] |
| Week 81 | n= 6 (54.5%) \|-5.03 (8.54) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 9 (81.8%) \|-5.91 (12.93) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (63.6%) \|-3.45 (9.21) | n= 3 (33.3%) \|-11.67 (7.02) | 0.85 [-0.65 ; 2.35] |
| Week 87 | n= 6 (54.5%) \|-8.00 (9.21) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 8 (72.7%) \|-4.65 (9.88) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 8 (72.7%) \|-5.02 (10.05) | n= 3 (33.3%) \|-10.30 (8.42) | 0.50 [-0.92 ; 1.92] |
| Week 93 | n= 7 (63.6%) \|-5.40 (9.09) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 8 (72.7%) \|-4.77 (10.23) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (63.6%) \|-3.27 (10.09) | n= 1 (11.1%) \|-4.00 ( / ) | [Not calculable] |
| Week 99 | n= 6 (54.5%) \|-3.19 (11.72) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 5 (45.5%) \|-0.60 (7.16) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 5 (45.5%) \|-1.54 (8.00) | n= 1 (11.1%) \|-3.00 ( / ) | [Not calculable] |
| Week 105 | n= 5 (45.5%) \|-4.83 (4.82) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \|-4.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (27.3%) \|-7.20 (4.85) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 ( 9.1%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (27.3%) \|-3.83 (6.33) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (27.3%) \|-3.33 (3.79) | n= 2 (22.2%) \|-12.00 (9.90) | 0.97 [-1.36 ; 3.30] |
| Week 117 | n= 3 (27.3%) \|-3.00 (4.58) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 (27.3%) \|-7.33 (8.08) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (18.2%) \|-5.22 (4.56) | n= 1 (11.1%) \|-23.61 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 9.1%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 9.1%) \|-6.33 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 9.1%) \| 4.00 ( / ) | n= 1 (11.1%) \|-26.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 9.1%) \|-5.28 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 9.1%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 9.1%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 9.1%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 9.1%) \| 8.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 9.1%) \|-6.71 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 9.1%) \|-10.06 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (27.3%) \|-3.00 (4.36) | n= 3 (33.3%) \|-3.33 (7.77) | 0.04 [-1.77 ; 1.86] |
| Week 202 | [No Data] | n= 1 (11.1%) \|-1.00 ( / ) | [No Data for at least 1 arm] |
| **< 1%** | | | |
| N subjects in population | N=58 | N=58 | |
| Week 3 | n= 53 (91.4%) \| 0.26 (5.90) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 50 (86.2%) \|-1.47 (8.07) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 50 (86.2%) \|-3.55 (8.83) | n= 53 (91.4%) \|-1.78 (8.42) | -0.20 [-0.59 ; 0.19] |
| Week 9 | n= 50 (86.2%) \|-3.65 (8.07) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 50 (86.2%) \|-3.66 (8.56) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 48 (82.8%) \|-3.39 (7.44) | n= 47 (81.0%) \|-4.38 (8.34) | 0.13 [-0.28 ; 0.53] |
| Week 15 | n= 45 (77.6%) \|-2.43 (8.12) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 52 (89.7%) \|-3.46 (7.90) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 47 (81.0%) \|-2.63 (7.17) | n= 46 (79.3%) \|-3.44 (8.47) | 0.10 [-0.31 ; 0.51] |
| Week 21 | n= 50 (86.2%) \|-2.85 (8.37) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 45 (77.6%) \|-3.39 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 48 (82.8%) \|-2.00 (8.68) | n= 42 (72.4%) \|-2.64 (10.09) | 0.07 [-0.35 ; 0.48] |
| Week 27 | n= 45 (77.6%) \|-1.53 (8.20) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 43 (74.1%) \|-2.17 (7.92) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (77.6%) \|-2.54 (8.58) | n= 36 (62.1%) \|-2.05 (8.84) | -0.06 [-0.50 ; 0.38] |
| Week 33 | n= 46 (79.3%) \|-2.13 (7.41) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 43 (74.1%) \|-2.56 (8.07) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 39 (67.2%) \|-1.20 (7.18) | n= 39 (67.2%) \|-2.03 (7.25) | 0.11 [-0.33 ; 0.56] |
| Week 39 | n= 41 (70.7%) \|-1.12 (7.50) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 41 (70.7%) \|-2.06 (8.29) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 42 (72.4%) \|-2.64 (8.86) | n= 33 (56.9%) \|-3.02 (7.52) | 0.05 [-0.41 ; 0.50] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 45 | n= 39 (67.2%) \|-2.72 (8.71) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 43 (74.1%) \|-2.50 (7.61) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 42 (72.4%) \|-1.53 (7.20) | n= 27 (46.6%) \|-2.38 (6.95) | 0.12 [-0.37 ; 0.61] |
| Week 51 | n= 41 (70.7%) \|-2.07 (7.63) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 43 (74.1%) \|-2.05 (8.18) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 38 (65.5%) \|-2.30 (7.70) | n= 29 (50.0%) \|-3.68 (7.58) | 0.18 [-0.31 ; 0.67] |
| Week 57 | n= 41 (70.7%) \|-2.36 (7.85) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (63.8%) \|-1.11 (8.73) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (67.2%) \|-1.51 (7.83) | n= 24 (41.4%) \|-3.43 (6.38) | 0.26 [-0.26 ; 0.77] |
| Week 63 | n= 34 (58.6%) \|-1.78 (7.86) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 35 (60.3%) \|-1.02 (7.55) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (62.1%) \|-1.04 (7.99) | n= 23 (39.7%) \|-2.45 (7.87) | 0.17 [-0.35 ; 0.70] |
| Week 69 | n= 30 (51.7%) \|-2.38 (9.20) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (53.4%) \|-0.98 (9.80) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 27 (46.6%) \|-0.11 (11.03) | n= 22 (37.9%) \|-4.38 (8.70) | 0.42 [-0.16 ; 0.99] |
| Week 75 | n= 28 (48.3%) \| 0.02 (7.88) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (44.8%) \| 0.72 (8.32) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (41.4%) \|-0.28 (10.63) | n= 20 (34.5%) \|-1.42 (6.35) | 0.12 [-0.48 ; 0.73] |
| Week 81 | n= 23 (39.7%) \|-0.17 (6.34) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 24 (41.4%) \| 0.23 (8.40) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (34.5%) \| 0.20 (7.91) | n= 17 (29.3%) \|-1.12 (8.12) | 0.16 [-0.50 ; 0.82] |
| Week 87 | n= 18 (31.0%) \|-1.38 (8.74) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 17 (29.3%) \|-1.05 (6.73) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 16 (27.6%) \|-3.50 (7.13) | n= 14 (24.1%) \|-1.36 (13.06) | -0.20 [-0.93 ; 0.53] |
| Week 93 | n= 16 (27.6%) \|-1.74 (7.47) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 14 (24.1%) \|-2.46 (7.55) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 14 (24.1%) \|-3.78 (8.55) | n= 9 (15.5%) \|-1.85 (7.07) | -0.23 [-1.09 ; 0.63] |
| Week 99 | n= 11 (19.0%) \|-3.35 (8.71) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 9 (15.5%) \|-5.54 (7.41) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 10 (17.2%) \|-4.84 (6.65) | n= 8 (13.8%) \|-5.00 (7.56) | 0.02 [-0.94 ; 0.98] |
| Week 105 | n= 8 (13.8%) \|-4.11 (7.45) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.3%) \|-6.48 (9.23) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (13.8%) \|-5.86 (8.84) | n= 4 ( 6.9%) \|-8.25 (9.00) | 0.25 [-1.02 ; 1.51] |
| Week 111 | n= 6 (10.3%) \|-7.65 (7.46) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 ( 8.6%) \|-6.98 (9.65) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 6.9%) \|-4.72 (9.47) | n= 3 ( 5.2%) \|-3.33 (5.13) | -0.15 [-1.80 ; 1.51] |
| Week 117 | n= 4 ( 6.9%) \|-1.97 (8.79) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 6.9%) \|-2.22 (11.27) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (10.3%) \|-4.15 (10.76) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 1.7%) \| 5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.7%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 ( 8.6%) \|-3.14 (6.10) | n= 13 (22.4%) \|-4.62 (11.95) | 0.13 [-0.93 ; 1.19] |
| Week 202 | n= 1 ( 1.7%) \|-6.00 ( / ) | n= 10 (17.2%) \| 1.00 (10.71) | [Not calculable] |
| **Not Reported** | | | |
| N subjects in population | N=2 | N=1 | |
| Week 3 | n= 2 (100.0%) \|-0.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (100.0%) \|-4.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 2 (100.0%) \|-7.50 (6.36) | n= 1 (100.0%) \| 2.00 ( / ) | [Not calculable] |
| Week 11 | n= 1 (50.0%) \|-7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (50.0%) \|-6.00 ( / ) | n= 1 (100.0%) \|-1.00 ( / ) | [Not calculable] |
| Week 15 | n= 1 (50.0%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 17 | n= 1 (50.0%) \|-11.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (50.0%) \|-7.00 ( / ) | n= 1 (100.0%) \|-1.00 ( / ) | [Not calculable] |
| Week 21 | n= 1 (50.0%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (50.0%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (50.0%) \|-2.00 ( / ) | n= 1 (100.0%) \|-3.00 ( / ) | [Not calculable] |
| Week 27 | n= 1 (50.0%) \|-4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 1 (50.0%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (50.0%) \|-4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (50.0%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 1 (50.0%) \|-7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (50.0%) \|-4.00 ( / ) | n= 1 (100.0%) \|-3.00 ( / ) | [Not calculable] |
| Week 39 | n= 1 (50.0%) \|-7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (50.0%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (50.0%) \|-6.17 ( / ) | n= 1 (100.0%) \|-6.00 ( / ) | [Not calculable] |
| Week 45 | n= 1 (50.0%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (50.0%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (50.0%) \|-3.00 ( / ) | n= 1 (100.0%) \|-3.00 ( / ) | [Not calculable] |
| Week 51 | n= 1 (50.0%) \|-6.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (50.0%) \|-8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (50.0%) \|-9.00 ( / ) | n= 1 (100.0%) \|-7.00 ( / ) | [Not calculable] |
| Week 57 | n= 1 (50.0%) \|-6.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (50.0%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (50.0%) \|-10.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (50.0%) \|-8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (50.0%) \|-16.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 202 | n= 1 (50.0%) \|-19.00 ( / ) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:39

TABLE 7.3.11: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **>= 1%** | | | | |
| Nr subjects used | n=11 | n=9 | | |
| **< 1%** | | | | |
| Nr subjects used | n=56 | n=57 | | |
| Week 7 | -4.30 (1.25) [-6.77 ;-1.84] | -2.43 (1.24) [-4.88 ; 0.02] | -1.87 (1.75) [-5.34 ; 1.60] | -0.21 [-0.60 ; 0.18] |
| Week 13 | -3.28 (1.16) [-5.57 ;-0.99] | -4.30 (1.17) [-6.62 ;-1.97] | 1.02 (1.65) [-2.24 ; 4.28] | 0.13 [-0.28 ; 0.53] |
| Week 19 | -2.60 (0.96) [-4.49 ;-0.70] | -3.80 (0.98) [-5.74 ;-1.87] | 1.20 (1.37) [-1.50 ; 3.91] | 0.18 [-0.23 ; 0.59] |
| Week 25 | -2.07 (1.13) [-4.31 ; 0.17] | -2.33 (1.18) [-4.67 ; 0.01] | 0.26 (1.64) [-2.98 ; 3.50] | 0.03 [-0.38 ; 0.45] |
| Week 31 | -2.67 (1.09) [-4.82 ;-0.52] | -1.91 (1.17) [-4.22 ; 0.39] | -0.75 (1.59) [-3.91 ; 2.40] | -0.10 [-0.54 ; 0.33] |
| Week 37 | -1.62 (1.00) [-3.60 ; 0.36] | -2.10 (1.04) [-4.16 ;-0.04] | 0.48 (1.44) [-2.38 ; 3.34] | 0.07 [-0.37 ; 0.52] |
| Week 43 | -2.39 (1.10) [-4.57 ;-0.21] | -2.33 (1.22) [-4.74 ; 0.08] | -0.06 (1.64) [-3.31 ; 3.19] | -0.01 [-0.46 ; 0.45] |
| Week 49 | -1.76 (0.87) [-3.48 ;-0.04] | -1.72 (1.02) [-3.75 ; 0.30] | -0.04 (1.34) [-2.69 ; 2.62] | -0.01 [-0.49 ; 0.48] |
| Week 55 | -2.22 (1.02) [-4.25 ;-0.19] | -2.87 (1.19) [-5.23 ;-0.51] | 0.65 (1.57) [-2.46 ; 3.77] | 0.10 [-0.38 ; 0.59] |
| Week 61 | -1.46 (0.96) [-3.35 ; 0.44] | -2.40 (1.17) [-4.72 ;-0.08] | 0.94 (1.51) [-2.06 ; 3.94] | 0.16 [-0.35 ; 0.67] |
| Week 67 | -1.26 (1.10) [-3.44 ; 0.92] | -2.15 (1.34) [-4.82 ; 0.52] | 0.89 (1.73) [-2.55 ; 4.34] | 0.13 [-0.39 ; 0.66] |
| Week 73 | -1.99 (1.60) [-5.17 ; 1.19] | -3.84 (1.84) [-7.51 ;-0.18] | 1.85 (2.43) [-2.99 ; 6.70] | 0.22 [-0.35 ; 0.78] |
| Week 79 | -1.42 (1.60) [-4.62 ; 1.78] | -1.94 (1.79) [-5.52 ; 1.65] | 0.51 (2.41) [-4.29 ; 5.32] | 0.06 [-0.53 ; 0.66] |
| Week 85 | -1.70 (1.42) [-4.55 ; 1.15] | -1.64 (1.57) [-4.78 ; 1.49] | -0.06 (2.12) [-4.30 ; 4.18] | -0.01 [-0.66 ; 0.64] |
| Week 91 | -2.36 (1.98) [-6.35 ; 1.64] | -1.47 (2.14) [-5.80 ; 2.86] | -0.89 (2.91) [-6.78 ; 5.00] | -0.11 [-0.83 ; 0.61] |
| Overall post-baseline period estimate | -2.21 (0.65) [-3.50 ;-0.92] | -2.48 (0.72) [-3.91 ;-1.06] | 0.28 (0.97) [-1.65 ; 2.20] | 0.05 [-0.32 ; 0.43] |
| **Not Reported** | | | | |
| Nr subjects used | n=2 | n=1 | | |
| **MMRM subgroups interaction p-value** | | | | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:39

TABLE 7.3.12: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **Stage IV** | N=18 | N=20 |
| **Non-Stage IV** | N=50 | N=48 |
| **Not Reported** | N=3 | [No Data] |
| **Subjects with Baseline Value** | | |
| **Stage IV** | 18 (100.0%) | 20 (100.0%) |
| **Non-Stage IV** | 48 (96.0%) | 47 (97.9%) |
| **Not Reported** | 3 (100.0%) | [No Data] |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **Stage IV** | 18 (100.0%) | 20 (100.0%) |
| **Non-Stage IV** | 50 (100.0%) | 46 (95.8%) |
| **Not Reported** | 3 (100.0%) | [No Data] |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **Stage IV** | 18 (100.0%) | 20 (100.0%) |
| **Non-Stage IV** | 48 (96.0%) | 45 (93.8%) |
| **Not Reported** | 3 (100.0%) | [No Data] |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:42

TABLE 7.3.12: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Stage IV** | | | |
| N subjects in population | N=18 | N=20 | |
| Baseline | n= 18 (100.0%) \| 60.65 (9.05) | n= 20 (100.0%) \| 62.85 (9.22) | -0.24 [-0.88 ; 0.41] |
| Week 3 | n= 16 (88.9%) \| 62.72 (6.57) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 17 (94.4%) \| 61.53 (8.22) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 16 (88.9%) \| 60.84 (8.09) | n= 20 (100.0%) \| 58.60 (8.91) | 0.26 [-0.41 ; 0.93] |
| Week 9 | n= 14 (77.8%) \| 63.79 (7.43) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (83.3%) \| 61.60 (8.27) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 17 (94.4%) \| 58.41 (9.49) | n= 15 (75.0%) \| 60.05 (8.30) | -0.18 [-0.89 ; 0.53] |
| Week 15 | n= 15 (83.3%) \| 60.54 (9.11) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 15 (83.3%) \| 59.48 (7.23) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 15 (83.3%) \| 60.01 (8.04) | n= 16 (80.0%) \| 59.94 (6.16) | 0.01 [-0.71 ; 0.73] |
| Week 21 | n= 16 (88.9%) \| 61.25 (7.33) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 12 (66.7%) \| 60.50 (7.10) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 15 (83.3%) \| 62.07 (8.70) | n= 15 (75.0%) \| 62.20 (7.40) | -0.02 [-0.74 ; 0.71] |
| Week 27 | n= 16 (88.9%) \| 62.44 (7.44) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 14 (77.8%) \| 61.58 (7.54) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 16 (88.9%) \| 61.19 (8.98) | n= 11 (55.0%) \| 62.88 (7.76) | -0.19 [-0.98 ; 0.59] |
| Week 33 | n= 15 (83.3%) \| 61.54 (9.40) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (72.2%) \| 60.44 (10.61) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 12 (66.7%) \| 61.68 (10.81) | n= 14 (70.0%) \| 61.25 (6.20) | 0.05 [-0.74 ; 0.83] |
| Week 39 | n= 13 (72.2%) \| 64.54 (7.04) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 14 (77.8%) \| 61.50 (8.24) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 14 (77.8%) \| 59.64 (10.38) | n= 13 (65.0%) \| 61.39 (7.30) | -0.19 [-0.96 ; 0.58] |
| Week 45 | n= 13 (72.2%) \| 58.54 (10.02) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 13 (72.2%) \| 61.92 (8.96) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 15 (83.3%) \| 61.51 (7.04) | n= 12 (60.0%) \| 61.65 (5.40) | -0.02 [-0.80 ; 0.75] |
| Week 51 | n= 12 (66.7%) \| 58.85 (9.20) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (72.2%) \| 59.61 (7.22) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 9 (50.0%) \| 59.62 (7.60) | n= 11 (55.0%) \| 59.27 (7.35) | 0.05 [-0.86 ; 0.95] |
| Week 57 | n= 11 (61.1%) \| 61.27 (6.71) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 12 (66.7%) \| 60.59 (7.78) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 11 (61.1%) \| 60.18 (7.47) | n= 7 (35.0%) \| 58.00 (6.48) | 0.29 [-0.69 ; 1.27] |
| Week 63 | n= 10 (55.6%) \| 61.73 (8.61) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (61.1%) \| 60.41 (8.25) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 11 (61.1%) \| 62.55 (7.37) | n= 8 (40.0%) \| 57.50 (5.10) | 0.74 [-0.23 ; 1.71] |
| Week 69 | n= 11 (61.1%) \| 59.26 (8.85) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 10 (55.6%) \| 58.52 (11.64) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 10 (55.6%) \| 58.36 (12.37) | n= 7 (35.0%) \| 56.24 (6.92) | 0.19 [-0.81 ; 1.19] |
| Week 75 | n= 9 (50.0%) \| 60.56 (10.09) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 7 (38.9%) \| 62.29 (6.99) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (50.0%) \| 58.14 (15.34) | n= 7 (35.0%) \| 60.14 (5.87) | -0.16 [-1.18 ; 0.87] |
| Week 81 | n= 5 (27.8%) \| 63.60 (5.77) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (38.9%) \| 62.14 (8.99) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (44.4%) \| 62.25 (8.46) | n= 6 (30.0%) \| 58.83 (7.08) | 0.40 [-0.71 ; 1.52] |
| Week 87 | n= 5 (27.8%) \| 60.00 (8.69) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 6 (33.3%) \| 56.00 (5.22) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 6 (33.3%) \| 58.67 (7.58) | n= 4 (20.0%) \| 56.00 (12.46) | 0.25 [-1.10 ; 1.60] |
| Week 93 | n= 4 (22.2%) \| 54.75 (7.63) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (27.8%) \| 56.40 (6.80) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (22.2%) \| 58.25 (7.41) | n= 1 ( 5.0%) \| 65.00 ( / ) | [Not calculable] |
| Week 99 | n= 3 (16.7%) \| 54.67 (3.21) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (16.7%) \| 54.67 (4.16) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (22.2%) \| 54.11 (6.35) | n= 1 ( 5.0%) \| 57.00 ( / ) | [Not calculable] |
| Week 105 | n= 2 (11.1%) \| 51.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.1%) \| 54.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (22.2%) \| 56.60 (11.69) | n= 1 ( 5.0%) \| 52.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 5.6%) \| 55.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.1%) \| 52.75 (7.42) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (16.7%) \| 58.33 (7.09) | n= 1 ( 5.0%) \| 50.00 ( / ) | [Not calculable] |
| Week 117 | n= 2 (11.1%) \| 54.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (11.1%) \| 48.00 (9.90) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (16.7%) \| 56.85 (8.75) | n= 1 ( 5.0%) \| 45.39 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 5.6%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 5.6%) \| 50.67 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (11.1%) \| 65.00 (5.66) | n= 1 ( 5.0%) \| 43.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 5.6%) \| 51.72 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 5.6%) \| 52.78 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 5.6%) \| 57.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 5.6%) \| 52.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 5.6%) \| 65.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 5.6%) \| 50.29 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 5.6%) \| 46.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 5.6%) \| 75.00 ( / ) | n= 5 (25.0%) \| 59.80 (3.96) | [Not calculable] |
| Week 202 | n= 1 ( 5.6%) \| 38.00 ( / ) | n= 3 (15.0%) \| 63.33 (11.02) | [Not calculable] |
| **Non-Stage IV** | | | |
| N subjects in population | N=50 | N=48 | |
| Baseline | n= 48 (96.0%) \| 62.39 (7.85) | n= 47 (97.9%) \| 60.61 (8.41) | 0.22 [-0.19 ; 0.62] |
| Week 3 | n= 48 (96.0%) \| 62.36 (8.25) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 44 (88.0%) \| 59.42 (9.99) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 45 (90.0%) \| 57.25 (9.69) | n= 44 (91.7%) \| 59.48 (9.07) | -0.23 [-0.65 ; 0.18] |
| Week 9 | n= 45 (90.0%) \| 58.62 (10.23) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 44 (88.0%) \| 57.92 (9.52) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 42 (84.0%) \| 59.73 (9.46) | n= 40 (83.3%) \| 58.43 (8.54) | 0.14 [-0.29 ; 0.58] |
| Week 15 | n= 38 (76.0%) \| 60.31 (8.87) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 46 (92.0%) \| 59.96 (9.98) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 41 (82.0%) \| 60.84 (7.95) | n= 38 (79.2%) \| 58.57 (9.20) | 0.26 [-0.18 ; 0.71] |
| Week 21 | n= 42 (84.0%) \| 59.23 (9.70) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 43 (86.0%) \| 58.85 (9.19) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 42 (84.0%) \| 60.50 (8.34) | n= 34 (70.8%) \| 60.32 (9.79) | 0.02 [-0.44 ; 0.47] |
| Week 27 | n= 39 (78.0%) \| 61.70 (9.29) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 38 (76.0%) \| 60.53 (9.24) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 37 (74.0%) \| 60.62 (9.09) | n= 31 (64.6%) \| 59.84 (9.10) | 0.09 [-0.40 ; 0.57] |
| Week 33 | n= 40 (80.0%) \| 60.18 (8.80) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 40 (80.0%) \| 60.43 (9.74) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 35 (70.0%) \| 60.83 (8.64) | n= 33 (68.8%) \| 60.74 (7.88) | 0.01 [-0.47 ; 0.49] |
| Week 39 | n= 38 (76.0%) \| 61.13 (8.26) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 41 | n= 37 (74.0%) \| 61.32 (8.53) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 37 (74.0%) \| 61.67 (8.48) | n= 29 (60.4%) \| 59.09 (9.14) | 0.29 [-0.20 ; 0.78] |
| Week 45 | n= 34 (68.0%) \| 60.72 (8.73) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 37 (74.0%) \| 61.34 (8.72) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 36 (72.0%) \| 61.14 (9.83) | n= 24 (50.0%) \| 59.08 (9.11) | 0.21 [-0.31 ; 0.74] |
| Week 51 | n= 38 (76.0%) \| 60.19 (9.90) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 38 (76.0%) \| 61.08 (9.85) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 36 (72.0%) \| 60.87 (10.32) | n= 27 (56.3%) \| 59.02 (8.31) | 0.19 [-0.31 ; 0.70] |
| Week 57 | n= 36 (72.0%) \| 61.15 (9.32) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 33 (66.0%) \| 61.34 (10.07) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 36 (72.0%) \| 62.02 (9.13) | n= 24 (50.0%) \| 58.79 (9.20) | 0.35 [-0.18 ; 0.87] |
| Week 63 | n= 31 (62.0%) \| 60.01 (9.97) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 31 (62.0%) \| 59.68 (11.49) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (64.0%) \| 61.74 (8.79) | n= 22 (45.8%) \| 60.23 (7.70) | 0.18 [-0.37 ; 0.73] |
| Week 69 | n= 26 (52.0%) \| 59.38 (12.54) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 27 (54.0%) \| 62.12 (9.14) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (50.0%) \| 63.21 (8.64) | n= 21 (43.8%) \| 56.62 (8.32) | 0.76 [ 0.15 ; 1.37] |
| Week 75 | n= 26 (52.0%) \| 62.98 (7.64) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (48.0%) \| 60.86 (8.44) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 21 (42.0%) \| 62.62 (9.98) | n= 18 (37.5%) \| 58.78 (7.05) | 0.43 [-0.22 ; 1.07] |
| Week 81 | n= 24 (48.0%) \| 61.29 (9.26) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (50.0%) \| 61.41 (9.16) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (38.0%) \| 62.63 (8.37) | n= 15 (31.3%) \| 60.80 (8.55) | 0.21 [-0.48 ; 0.90] |
| Week 87 | n= 19 (38.0%) \| 58.68 (10.64) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (38.0%) \| 60.95 (9.41) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 18 (36.0%) \| 59.50 (10.95) | n= 14 (29.2%) \| 62.79 (7.96) | -0.33 [-1.04 ; 0.39] |
| Week 93 | n= 19 (38.0%) \| 61.13 (9.60) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (34.0%) \| 59.79 (10.34) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (34.0%) \| 58.96 (10.33) | n= 10 (20.8%) \| 61.94 (7.81) | -0.30 [-1.10 ; 0.50] |
| Week 99 | n= 14 (28.0%) \| 58.93 (12.05) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (22.0%) \| 61.45 (9.02) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (22.0%) \| 61.23 (8.59) | n= 9 (18.8%) \| 59.89 (8.04) | 0.15 [-0.75 ; 1.06] |
| Week 105 | n= 11 (22.0%) \| 59.18 (7.55) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (12.0%) \| 59.67 (8.96) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (14.0%) \| 54.29 (7.04) | n= 4 ( 8.3%) \| 58.75 (12.84) | -0.44 [-1.75 ; 0.88] |
| Week 111 | n= 6 (12.0%) \| 54.50 (5.43) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (12.0%) \| 58.17 (7.68) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 8.0%) \| 59.00 (8.83) | n= 4 ( 8.3%) \| 64.00 (6.22) | -0.57 [-2.11 ; 0.98] |
| Week 117 | n= 5 (10.0%) \| 61.60 (4.62) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (10.0%) \| 59.40 (9.07) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (10.0%) \| 58.20 (9.65) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.0%) \| 61.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 (10.0%) \| 60.00 (8.00) | n= 11 (22.9%) \| 54.82 (12.98) | 0.42 [-0.69 ; 1.52] |
| Week 202 | n= 1 ( 2.0%) \| 58.00 ( / ) | n= 8 (16.7%) \| 64.50 (6.80) | [Not calculable] |
| **Not Reported** | | | |
| N subjects in population | N=3 | [No Data] | |
| Baseline | n= 3 (100.0%) \| 64.67 (8.02) | [No Data] | |
| Week 3 | n= 3 (100.0%) \| 61.00 (8.54) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (66.7%) \| 69.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 3 (100.0%) \| 59.09 (7.06) | [No Data] | [No Data for at least 1 arm] |
| Week 9 | n= 2 (66.7%) \| 45.92 (11.20) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 11 | n= 2 (66.7%) \| 42.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (33.3%) \| 46.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 15 | n= 1 (33.3%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 2 (66.7%) \| 47.00 (9.90) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (33.3%) \| 50.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 21 | n= 1 (33.3%) \| 51.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (33.3%) \| 48.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (33.3%) \| 56.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 27 | n= 1 (33.3%) \| 47.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (33.3%) \| 45.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (33.3%) \| 41.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 1 (33.3%) \| 44.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (33.3%) \| 45.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 39 | n= 1 (33.3%) \| 45.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (33.3%) \| 45.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (33.3%) \| 44.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 45 | n= 1 (33.3%) \| 30.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (33.3%) \| 36.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (33.3%) \| 38.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 51 | n= 1 (33.3%) \| 38.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (33.3%) \| 47.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (33.3%) \| 54.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 57 | n= 1 (33.3%) \| 36.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (33.3%) \| 47.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (33.3%) \| 45.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (33.3%) \| 42.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (33.3%) \| 49.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 1 (33.3%) \| 42.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 69 | n= 1 (33.3%) \| 44.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 1 (33.3%) \| 40.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 1 (33.3%) \| 48.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 1 (33.3%) \| 44.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 1 (33.3%) \| 39.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (66.7%) \| 54.00 (5.66) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:43

TABLE 7.3.12: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Stage IV** | | | |
| N subjects in population | N=18 | N=20 | |
| Week 3 | n= 16 (88.9%) \| 1.67 (7.71) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 17 (94.4%) \| 0.78 (7.87) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 16 (88.9%) \|-0.90 (8.48) | n= 20 (100.0%) \|-4.25 (8.56) | 0.38 [-0.29 ; 1.06] |
| Week 9 | n= 14 (77.8%) \| 0.59 (7.95) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (83.3%) \|-0.59 (9.84) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 17 (94.4%) \|-2.46 (9.22) | n= 15 (75.0%) \|-6.55 (11.20) | 0.39 [-0.32 ; 1.10] |
| Week 15 | n= 15 (83.3%) \|-1.84 (10.01) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 15 (83.3%) \|-2.91 (9.56) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 15 (83.3%) \|-2.37 (9.79) | n= 16 (80.0%) \|-4.31 (8.47) | 0.21 [-0.51 ; 0.92] |
| Week 21 | n= 16 (88.9%) \|-0.74 (8.37) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 12 (66.7%) \|-2.06 (5.74) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 15 (83.3%) \| 0.08 (10.14) | n= 15 (75.0%) \|-4.47 (9.04) | 0.46 [-0.28 ; 1.20] |
| Week 27 | n= 16 (88.9%) \| 0.45 (9.08) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 14 (77.8%) \|-0.48 (9.91) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 16 (88.9%) \|-0.80 (9.62) | n= 11 (55.0%) \|-3.30 (9.59) | 0.25 [-0.53 ; 1.04] |
| Week 33 | n= 15 (83.3%) \|-1.37 (9.40) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (72.2%) \|-0.77 (10.48) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 12 (66.7%) \| 0.94 (9.54) | n= 14 (70.0%) \|-4.61 (5.68) | 0.70 [-0.11 ; 1.51] |
| Week 39 | n= 13 (72.2%) \| 1.32 (10.03) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 14 (77.8%) \|-1.69 (11.55) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 14 (77.8%) \|-2.98 (11.74) | n= 13 (65.0%) \|-3.92 (9.09) | 0.09 [-0.68 ; 0.86] |
| Week 45 | n= 13 (72.2%) \|-2.08 (11.68) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 13 (72.2%) \|-1.36 (10.52) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 15 (83.3%) \|-0.15 (8.68) | n= 12 (60.0%) \|-3.43 (7.03) | 0.40 [-0.38 ; 1.18] |
| Week 51 | n= 12 (66.7%) \|-1.49 (10.41) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (72.2%) \|-1.78 (11.16) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 9 (50.0%) \|-2.27 (10.27) | n= 11 (55.0%) \|-5.64 (9.18) | 0.33 [-0.58 ; 1.24] |
| Week 57 | n= 11 (61.1%) \|-0.10 (11.54) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 12 (66.7%) \|-0.83 (10.96) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 11 (61.1%) \|-1.46 (10.70) | n= 7 (35.0%) \|-8.29 (8.83) | 0.65 [-0.36 ; 1.65] |
| Week 63 | n= 10 (55.6%) \| 0.23 (10.20) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (61.1%) \| 0.13 (10.20) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 11 (61.1%) \| 2.27 (9.40) | n= 8 (40.0%) \|-6.63 (10.31) | 0.87 [-0.11 ; 1.85] |
| Week 69 | n= 11 (61.1%) \|-1.02 (11.73) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 10 (55.6%) \|-2.98 (14.66) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 10 (55.6%) \|-3.14 (16.37) | n= 7 (35.0%) \|-8.76 (11.67) | 0.36 [-0.64 ; 1.37] |
| Week 75 | n= 9 (50.0%) \| 0.22 (11.36) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 7 (38.9%) \| 4.85 (9.32) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (50.0%) \|-2.64 (16.27) | n= 7 (35.0%) \|-3.71 (9.71) | 0.07 [-0.95 ; 1.10] |
| Week 81 | n= 5 (27.8%) \| 1.20 (5.40) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (38.9%) \| 2.71 (12.38) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (44.4%) \| 1.25 (8.99) | n= 6 (30.0%) \|-7.50 (10.29) | 0.86 [-0.30 ; 2.01] |
| Week 87 | n= 5 (27.8%) \|-0.40 (8.71) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 6 (33.3%) \|-2.50 (7.01) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 6 (33.3%) \|-3.33 (7.50) | n= 4 (20.0%) \|-10.75 (16.30) | 0.58 [-0.80 ; 1.95] |
| Week 93 | n= 4 (22.2%) \|-6.00 (10.17) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (27.8%) \|-3.60 (9.61) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (22.2%) \|-1.75 (10.14) | n= 1 ( 5.0%) \| 2.00 ( / ) | [Not calculable] |
| Week 99 | n= 3 (16.7%) \|-1.33 (10.07) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (16.7%) \|-1.33 (10.69) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (22.2%) \|-5.89 (7.95) | n= 1 ( 5.0%) \|-14.00 ( / ) | [Not calculable] |
| Week 105 | n= 2 (11.1%) \|-1.50 (10.61) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.1%) \|-1.50 (13.44) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (22.2%) \|-3.40 (8.92) | n= 1 ( 5.0%) \|-19.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 5.6%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.1%) \| 0.25 (13.79) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (16.7%) \|-0.67 (8.39) | n= 1 ( 5.0%) \|-19.00 ( / ) | [Not calculable] |
| Week 117 | n= 2 (11.1%) \| 1.50 (7.78) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (11.1%) \|-4.50 (16.26) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (16.7%) \|-2.15 (8.87) | n= 1 ( 5.0%) \|-23.61 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 5.6%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 5.6%) \|-6.33 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (11.1%) \| 0.50 (4.95) | n= 1 ( 5.0%) \|-26.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 5.6%) \|-5.28 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 5.6%) \|-4.22 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 5.6%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 5.6%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 5.6%) \| 8.94 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 5.6%) \|-6.71 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 5.6%) \|-10.06 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 5.6%) \| 4.28 ( / ) | n= 5 (25.0%) \|-1.80 (9.26) | [Not calculable] |
| Week 202 | n= 1 ( 5.6%) \|-19.00 ( / ) | n= 3 (15.0%) \| 5.00 (7.00) | [Not calculable] |
| **Non-Stage IV** | | | |
| N subjects in population | N=50 | N=48 | |
| Week 3 | n= 47 (94.0%) \|-0.20 (4.94) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 42 (84.0%) \|-3.02 (7.40) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 43 (86.0%) \|-4.35 (8.21) | n= 43 (89.6%) \|-1.10 (7.92) | -0.40 [-0.83 ; 0.03] |
| Week 9 | n= 44 (88.0%) \|-4.56 (8.00) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 43 (86.0%) \|-4.61 (7.99) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 41 (82.0%) \|-3.59 (7.62) | n= 40 (83.3%) \|-3.74 (7.40) | 0.02 [-0.42 ; 0.46] |
| Week 15 | n= 38 (76.0%) \|-2.39 (7.48) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 45 (90.0%) \|-3.05 (7.55) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 40 (80.0%) \|-2.83 (6.35) | n= 37 (77.1%) \|-3.60 (8.26) | 0.10 [-0.35 ; 0.55] |
| Week 21 | n= 42 (84.0%) \|-3.80 (7.90) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 43 (86.0%) \|-3.44 (7.70) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 41 (82.0%) \|-2.99 (7.83) | n= 33 (68.8%) \|-2.32 (9.89) | -0.07 [-0.54 ; 0.39] |
| Week 27 | n= 38 (76.0%) \|-2.76 (8.15) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 38 (76.0%) \|-3.17 (7.23) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 37 (74.0%) \|-3.28 (7.79) | n= 31 (64.6%) \|-2.23 (8.33) | -0.13 [-0.61 ; 0.35] |
| Week 33 | n= 40 (80.0%) \|-2.93 (6.73) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 39 (78.0%) \|-3.44 (7.12) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 35 (70.0%) \|-2.63 (6.27) | n= 32 (66.7%) \|-1.36 (7.05) | -0.19 [-0.67 ; 0.29] |
| Week 39 | n= 37 (74.0%) \|-2.61 (6.24) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 37 (74.0%) \|-3.07 (6.47) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 36 (72.0%) \|-2.21 (7.12) | n= 28 (58.3%) \|-3.88 (6.62) | 0.24 [-0.26 ; 0.74] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 45 | n= 34 (68.0%) \|-3.38 (6.84) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 37 (74.0%) \|-2.86 (6.51) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 36 (72.0%) \|-2.79 (6.66) | n= 23 (47.9%) \|-3.49 (7.50) | 0.10 [-0.43 ; 0.63] |
| Week 51 | n= 38 (76.0%) \|-3.53 (7.45) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 38 (76.0%) \|-2.79 (7.50) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 36 (72.0%) \|-2.84 (8.31) | n= 26 (54.2%) \|-3.44 (6.08) | 0.08 [-0.43 ; 0.59] |
| Week 57 | n= 36 (72.0%) \|-2.78 (6.87) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 33 (66.0%) \|-2.10 (8.15) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 36 (72.0%) \|-2.16 (7.14) | n= 23 (47.9%) \|-3.13 (5.62) | 0.15 [-0.38 ; 0.67] |
| Week 63 | n= 31 (62.0%) \|-3.16 (7.51) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 31 (62.0%) \|-3.21 (9.17) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (64.0%) \|-2.27 (7.68) | n= 21 (43.8%) \|-2.10 (6.24) | -0.02 [-0.58 ; 0.53] |
| Week 69 | n= 26 (52.0%) \|-5.28 (10.84) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 27 (54.0%) \|-1.58 (7.68) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (50.0%) \|-0.23 (7.44) | n= 21 (43.8%) \|-4.57 (7.26) | 0.58 [-0.02 ; 1.18] |
| Week 75 | n= 26 (52.0%) \|-1.29 (6.72) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (48.0%) \|-2.22 (7.90) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 21 (42.0%) \|-0.38 (7.43) | n= 17 (35.4%) \|-1.65 (5.93) | 0.18 [-0.47 ; 0.83] |
| Week 81 | n= 24 (48.0%) \|-1.67 (7.26) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (50.0%) \|-1.67 (8.19) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (38.0%) \|-1.59 (8.01) | n= 14 (29.2%) \|-0.64 (7.39) | -0.12 [-0.82 ; 0.58] |
| Week 87 | n= 19 (38.0%) \|-3.73 (9.34) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (38.0%) \|-2.11 (8.28) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 18 (36.0%) \|-4.23 (8.39) | n= 13 (27.1%) \|-0.53 (10.95) | -0.38 [-1.11 ; 0.35] |
| Week 93 | n= 19 (38.0%) \|-2.19 (7.60) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (34.0%) \|-3.21 (8.41) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (34.0%) \|-4.05 (8.79) | n= 9 (18.8%) \|-2.51 (6.94) | -0.18 [-1.01 ; 0.64] |
| Week 99 | n= 14 (28.0%) \|-3.72 (9.72) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (22.0%) \|-4.44 (6.86) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (22.0%) \|-2.96 (6.89) | n= 8 (16.7%) \|-3.63 (6.63) | 0.09 [-0.84 ; 1.03] |
| Week 105 | n= 11 (22.0%) \|-4.91 (5.93) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (12.0%) \|-7.31 (6.66) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (14.0%) \|-7.84 (7.18) | n= 3 ( 6.3%) \|-4.67 (6.66) | -0.41 [-1.86 ; 1.05] |
| Week 111 | n= 6 (12.0%) \|-10.31 (2.15) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (12.0%) \|-7.81 (6.06) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 8.0%) \|-6.72 (5.70) | n= 4 ( 8.3%) \|-3.75 (4.27) | -0.51 [-2.05 ; 1.02] |
| Week 117 | n= 5 (10.0%) \|-3.98 (6.57) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (10.0%) \|-4.38 (8.54) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (10.0%) \|-5.78 (10.23) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.0%) \| 5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 (10.0%) \|-3.20 (5.22) | n= 11 (22.9%) \|-5.55 (12.03) | 0.21 [-0.89 ; 1.31] |
| Week 202 | n= 1 ( 2.0%) \|-6.00 ( / ) | n= 8 (16.7%) \|-0.75 (11.12) | [Not calculable] |
| **Not Reported** | | | |
| N subjects in population | N=3 | [No Data] | |
| Week 3 | n= 3 (100.0%) \|-3.67 (0.58) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (66.7%) \| 4.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 3 (100.0%) \|-5.57 (3.66) | [No Data] | [No Data for at least 1 arm] |
| Week 9 | n= 2 (66.7%) \|-14.58 (6.25) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 2 (66.7%) \|-18.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (33.3%) \|-18.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 15 | n= 1 (33.3%) \|-30.00 ( / ) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 17 | n= 2 (66.7%) \|-13.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (33.3%) \|-14.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 21 | n= 1 (33.3%) \|-13.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (33.3%) \|-16.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (33.3%) \|-8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 27 | n= 1 (33.3%) \|-17.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (33.3%) \|-19.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (33.3%) \|-23.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 1 (33.3%) \|-20.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (33.3%) \|-19.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 39 | n= 1 (33.3%) \|-19.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (33.3%) \|-19.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (33.3%) \|-20.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 45 | n= 1 (33.3%) \|-34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (33.3%) \|-28.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (33.3%) \|-26.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 51 | n= 1 (33.3%) \|-26.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (33.3%) \|-17.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (33.3%) \|-10.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 57 | n= 1 (33.3%) \|-28.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (33.3%) \|-17.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (33.3%) \|-19.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (33.3%) \|-22.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (33.3%) \|-15.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 1 (33.3%) \|-22.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 69 | n= 1 (33.3%) \|-20.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 1 (33.3%) \|-24.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 1 (33.3%) \|-16.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 1 (33.3%) \|-20.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 1 (33.3%) \|-25.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (66.7%) \|-6.50 (0.71) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:43

TABLE 7.3.12: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **Stage IV** | | | | |
| Nr subjects used | n=18 | n=20 | | |
| Week 7 | -2.44 (2.06) [-6.63 ; 1.74] | -4.61 (1.89) [-8.45 ;-0.77] | 2.16 (2.79) [-3.50 ; 7.83] | 0.25 [-0.41 ; 0.91] |
| Week 13 | -4.22 (2.26) [-8.81 ; 0.37] | -5.45 (2.21) [-9.93 ;-0.97] | 1.23 (3.16) [-5.17 ; 7.63] | 0.13 [-0.56 ; 0.83] |
| Week 19 | -3.15 (1.71) [-6.61 ; 0.31] | -4.61 (1.63) [-7.90 ;-1.32] | 1.46 (2.36) [-3.32 ; 6.24] | 0.22 [-0.49 ; 0.92] |
| Week 25 | -1.80 (1.90) [-5.65 ; 2.05] | -2.31 (1.84) [-6.03 ; 1.42] | 0.51 (2.66) [-4.87 ; 5.88] | 0.07 [-0.65 ; 0.78] |
| Week 31 | -1.95 (1.83) [-5.66 ; 1.76] | -1.24 (1.92) [-5.12 ; 2.64] | -0.71 (2.67) [-6.10 ; 4.68] | -0.10 [-0.87 ; 0.67] |
| Week 37 | -1.27 (2.06) [-5.44 ; 2.90] | -3.88 (2.01) [-7.96 ; 0.20] | 2.61 (2.89) [-3.25 ; 8.47] | 0.34 [-0.43 ; 1.12] |
| Week 43 | -2.70 (2.30) [-7.36 ; 1.95] | -1.83 (2.37) [-6.63 ; 2.97] | -0.87 (3.32) [-7.59 ; 5.84] | -0.10 [-0.85 ; 0.66] |
| Week 49 | -2.05 (1.54) [-5.17 ; 1.07] | -1.69 (1.66) [-5.07 ; 1.69] | -0.36 (2.28) [-4.99 ; 4.28] | -0.06 [-0.82 ; 0.70] |
| Overall post-baseline period estimate | -2.45 (1.43) [-5.35 ; 0.45] | -3.20 (1.39) [-6.00 ;-0.40] | 0.75 (2.01) [-3.30 ; 4.81] | 0.12 [-0.52 ; 0.76] |
| **Non-Stage IV** | | | | |
| Nr subjects used | n=48 | n=47 | | |
| Week 7 | -5.26 (1.39) [-8.02 ;-2.50] | -1.57 (1.42) [-4.40 ; 1.25] | -3.69 (1.98) [-7.63 ; 0.26] | -0.40 [-0.82 ; 0.03] |
| Week 13 | -3.16 (1.30) [-5.74 ;-0.57] | -3.92 (1.35) [-6.60 ;-1.24] | 0.77 (1.87) [-2.95 ; 4.49] | 0.09 [-0.35 ; 0.53] |
| Week 19 | -2.78 (1.12) [-4.99 ;-0.56] | -3.93 (1.18) [-6.28 ;-1.59] | 1.15 (1.63) [-2.07 ; 4.38] | 0.16 [-0.29 ; 0.61] |
| Week 25 | -2.48 (1.26) [-4.98 ; 0.02] | -2.81 (1.37) [-5.53 ;-0.10] | 0.34 (1.86) [-3.36 ; 4.03] | 0.04 [-0.42 ; 0.50] |
| Week 31 | -3.04 (1.19) [-5.40 ;-0.69] | -2.38 (1.28) [-4.92 ; 0.17] | -0.67 (1.75) [-4.13 ; 2.80] | -0.09 [-0.57 ; 0.39] |
| Week 37 | -2.59 (1.01) [-4.59 ;-0.58] | -1.82 (1.09) [-3.98 ; 0.33] | -0.76 (1.48) [-3.71 ; 2.18] | -0.12 [-0.60 ; 0.36] |
| Week 43 | -2.59 (1.07) [-4.71 ;-0.47] | -3.46 (1.19) [-5.82 ;-1.09] | 0.87 (1.60) [-2.31 ; 4.05] | 0.14 [-0.36 ; 0.63] |
| Week 49 | -2.64 (1.02) [-4.66 ;-0.62] | -2.90 (1.20) [-5.29 ;-0.52] | 0.27 (1.58) [-2.86 ; 3.39] | 0.04 [-0.48 ; 0.57] |
| Week 55 | -3.20 (1.12) [-5.41 ;-0.98] | -2.85 (1.31) [-5.46 ;-0.24] | -0.34 (1.73) [-3.77 ; 3.08] | -0.05 [-0.56 ; 0.45] |
| Week 61 | -2.17 (1.03) [-4.21 ;-0.13] | -2.90 (1.26) [-5.40 ;-0.41] | 0.73 (1.63) [-2.50 ; 3.96] | 0.12 [-0.41 ; 0.64] |
| Week 67 | -2.75 (1.14) [-5.01 ;-0.49] | -2.27 (1.40) [-5.04 ; 0.51] | -0.49 (1.80) [-4.07 ; 3.09] | -0.07 [-0.63 ; 0.48] |
| Week 73 | -1.23 (1.12) [-3.46 ; 1.00] | -4.64 (1.30) [-7.23 ;-2.06] | 3.41 (1.72) [-0.00 ; 6.83] | 0.58 [-0.01 ; 1.18] |
| Week 79 | -1.14 (1.14) [-3.41 ; 1.13] | -2.10 (1.31) [-4.72 ; 0.51] | 0.96 (1.74) [-2.50 ; 4.43] | 0.18 [-0.46 ; 0.82] |
| Week 85 | -2.96 (1.38) [-5.72 ;-0.20] | -1.77 (1.60) [-4.98 ; 1.43] | -1.19 (2.12) [-5.42 ; 3.05] | -0.19 [-0.89 ; 0.50] |
| Week 91 | -2.70 (1.77) [-6.27 ; 0.87] | -0.71 (2.07) [-4.88 ; 3.47] | -1.99 (2.73) [-7.48 ; 3.50] | -0.26 [-0.98 ; 0.46] |
| Overall post-baseline period estimate | -2.71 (0.67) [-4.04 ;-1.39] | -2.67 (0.76) [-4.17 ;-1.17] | -0.04 (1.01) [-2.04 ; 1.96] | -0.01 [-0.42 ; 0.40] |
| **Not Reported** | | | | |
| Nr subjects used | n=3 | [No Data] | | |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.4813 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:43

TABLE 7.4.1: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| subtit | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| N subjects | N=71 | N=68 |
| Subjects with Baseline Value | 69 (97.2%) | 67 (98.5%) |
| Subjects with at least 1 Post-Baseline Value | 71 (100.0%) | 66 (97.1%) |
| Subjects with Baseline Value and at least 1 Post-Baseline Value | 69 (97.2%) | 65 (95.6%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:47

TABLE 7.4.1: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Baseline | n= 69 (97.2%) \| 31.65 (4.41) | n= 67 (98.5%) \| 31.47 (4.23) | 0.04 [-0.30 ; 0.38] |
| Week 3 | n= 67 (94.4%) \| 31.53 (3.97) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 63 (88.7%) \| 31.13 (4.70) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 64 (90.1%) \| 30.71 (4.24) | n= 64 (94.1%) \| 30.29 (4.02) | 0.10 [-0.25 ; 0.45] |
| Week 9 | n= 61 (85.9%) \| 30.99 (4.26) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 61 (85.9%) \| 30.84 (3.96) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 60 (84.5%) \| 31.38 (3.90) | n= 55 (80.9%) \| 30.75 (3.67) | 0.17 [-0.20 ; 0.54] |
| Week 15 | n= 54 (76.1%) \| 31.27 (3.73) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 63 (88.7%) \| 31.39 (4.21) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 57 (80.3%) \| 32.04 (3.08) | n= 54 (79.4%) \| 31.14 (3.40) | 0.27 [-0.10 ; 0.65] |
| Week 21 | n= 59 (83.1%) \| 31.80 (4.08) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 56 (78.9%) \| 31.00 (3.94) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 58 (81.7%) \| 31.94 (3.66) | n= 49 (72.1%) \| 31.51 (3.10) | 0.12 [-0.26 ; 0.51] |
| Week 27 | n= 56 (78.9%) \| 32.61 (3.88) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 52 (73.2%) \| 32.10 (3.62) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \| 32.09 (4.19) | n= 42 (61.8%) \| 31.40 (3.78) | 0.17 [-0.24 ; 0.58] |
| Week 33 | n= 56 (78.9%) \| 31.81 (4.41) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 54 (76.1%) \| 31.50 (5.01) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 48 (67.6%) \| 32.09 (4.78) | n= 47 (69.1%) \| 31.33 (3.15) | 0.19 [-0.22 ; 0.59] |
| Week 39 | n= 52 (73.2%) \| 32.37 (3.85) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 52 (73.2%) \| 32.12 (4.10) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 52 (73.2%) \| 31.97 (4.02) | n= 42 (61.8%) \| 31.07 (4.06) | 0.22 [-0.19 ; 0.63] |
| Week 45 | n= 48 (67.6%) \| 31.38 (4.37) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 51 (71.8%) \| 31.98 (4.12) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 52 (73.2%) \| 32.04 (4.37) | n= 36 (52.9%) \| 31.30 (3.94) | 0.18 [-0.25 ; 0.60] |
| Week 51 | n= 51 (71.8%) \| 31.63 (4.27) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 52 (73.2%) \| 32.02 (4.09) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 46 (64.8%) \| 31.79 (4.47) | n= 38 (55.9%) \| 30.96 (3.43) | 0.21 [-0.23 ; 0.64] |
| Week 57 | n= 48 (67.6%) \| 31.64 (4.35) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 46 (64.8%) \| 31.59 (4.47) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \| 32.22 (4.14) | n= 31 (45.6%) \| 30.87 (3.58) | 0.34 [-0.12 ; 0.80] |
| Week 63 | n= 42 (59.2%) \| 31.51 (4.82) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 43 (60.6%) \| 31.05 (5.28) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \| 32.02 (4.23) | n= 30 (44.1%) \| 30.90 (3.69) | 0.28 [-0.19 ; 0.75] |
| Week 69 | n= 38 (53.5%) \| 31.16 (5.04) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 38 (53.5%) \| 31.94 (4.53) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 35 (49.3%) \| 32.23 (4.04) | n= 28 (41.2%) \| 30.15 (3.68) | 0.53 [ 0.02 ; 1.04] |
| Week 75 | n= 35 (49.3%) \| 32.26 (3.76) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \| 32.13 (3.88) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \| 31.40 (5.93) | n= 25 (36.8%) \| 31.20 (3.15) | 0.04 [-0.49 ; 0.57] |
| Week 81 | n= 29 (40.8%) \| 31.90 (4.25) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \| 32.21 (4.08) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \| 32.30 (3.85) | n= 21 (30.9%) \| 31.62 (3.22) | 0.19 [-0.39 ; 0.76] |
| Week 87 | n= 24 (33.8%) \| 31.04 (4.70) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \| 31.56 (4.14) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 24 (33.8%) \| 30.80 (4.77) | n= 18 (26.5%) \| 32.06 (3.59) | -0.29 [-0.91 ; 0.34] |
| Week 93 | n= 23 (32.4%) \| 31.39 (4.03) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 22 (31.0%) \| 31.17 (4.56) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) \| 30.92 (4.46) | n= 11 (16.2%) \| 32.27 (3.55) | -0.32 [-1.06 ; 0.43] |
| Week 99 | n= 17 (23.9%) \| 30.76 (4.99) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) \| 31.43 (3.69) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) \| 31.60 (3.42) | n= 10 (14.7%) \| 32.30 (2.58) | -0.22 [-1.04 ; 0.60] |
| Week 105 | n= 13 (18.3%) \| 30.85 (3.91) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) \| 31.75 (3.24) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) \| 29.08 (3.79) | n= 5 ( 7.4%) \| 31.40 (5.22) | -0.52 [-1.63 ; 0.59] |
| Week 111 | n= 7 ( 9.9%) \| 30.29 (3.90) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) \| 31.44 (3.70) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 7 ( 9.9%) \| 31.00 (4.16) | n= 5 ( 7.4%) \| 32.60 (2.19) | -0.42 [-1.64 ; 0.80] |
| Week 117 | n= 7 ( 9.9%) \| 32.71 (2.98) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 ( 9.9%) \| 29.29 (4.46) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) \| 31.16 (4.50) | n= 1 ( 1.5%) \| 30.38 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 2.8%) \| 31.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) \| 32.00 (1.41) | n= 1 ( 1.5%) \| 24.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) \| 29.25 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.4%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.4%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.4%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.4%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.4%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) \| 31.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) \| 31.50 (4.41) | n= 16 (23.5%) \| 30.38 (4.54) | 0.24 [-0.63 ; 1.11] |
| Week 202 | n= 2 ( 2.8%) \| 25.00 (7.07) | n= 11 (16.2%) \| 32.36 (2.34) | -2.22 [-4.06 ;-0.38] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:47

TABLE 7.4.1: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Week 3 | n= 66 (93.0%) \|-0.18 (2.26) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 61 (85.9%) \|-0.66 (3.04) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 62 (87.3%) \|-0.83 (3.67) | n= 63 (92.6%) \|-1.12 (3.38) | 0.08 [-0.27 ; 0.43] |
| Week 9 | n= 60 (84.5%) \|-1.10 (3.89) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 60 (84.5%) \|-1.09 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 59 (83.1%) \|-0.59 (3.57) | n= 55 (80.9%) \|-1.40 (3.20) | 0.24 [-0.13 ; 0.61] |
| Week 15 | n= 54 (76.1%) \|-0.74 (4.01) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 62 (87.3%) \|-0.56 (3.60) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 56 (78.9%) \|-0.51 (3.20) | n= 53 (77.9%) \|-0.94 (3.59) | 0.13 [-0.25 ; 0.50] |
| Week 21 | n= 59 (83.1%) \|-0.21 (3.59) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 56 (78.9%) \|-0.91 (3.03) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 57 (80.3%) \|-0.20 (3.57) | n= 48 (70.6%) \|-0.87 (3.56) | 0.19 [-0.20 ; 0.57] |
| Week 27 | n= 55 (77.5%) \| 0.14 (3.60) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 52 (73.2%) \| 0.01 (3.65) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \|-0.29 (3.67) | n= 42 (61.8%) \|-0.92 (2.46) | 0.20 [-0.21 ; 0.60] |
| Week 33 | n= 56 (78.9%) \|-0.49 (3.41) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 53 (74.6%) \|-0.61 (3.62) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 48 (67.6%) \|-0.02 (3.54) | n= 46 (67.6%) \|-0.74 (3.14) | 0.21 [-0.20 ; 0.62] |
| Week 39 | n= 51 (71.8%) \|-0.07 (3.31) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 52 (73.2%) \|-0.56 (3.52) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 51 (71.8%) \|-0.45 (3.96) | n= 41 (60.3%) \|-0.88 (2.93) | 0.12 [-0.30 ; 0.53] |
| Week 45 | n= 48 (67.6%) \|-0.88 (4.28) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 51 (71.8%) \|-0.71 (3.27) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 52 (73.2%) \|-0.32 (3.70) | n= 35 (51.5%) \|-0.94 (3.25) | 0.17 [-0.26 ; 0.61] |
| Week 51 | n= 51 (71.8%) \|-0.53 (3.52) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 52 (73.2%) \|-0.18 (3.26) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 46 (64.8%) \|-0.49 (3.38) | n= 37 (54.4%) \|-0.88 (2.89) | 0.12 [-0.31 ; 0.56] |
| Week 57 | n= 48 (67.6%) \|-0.40 (3.73) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 46 (64.8%) \|-0.47 (3.99) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \|-0.11 (3.57) | n= 30 (44.1%) \|-0.59 (3.03) | 0.14 [-0.32 ; 0.60] |
| Week 63 | n= 42 (59.2%) \|-0.19 (3.84) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 43 (60.6%) \|-0.59 (4.68) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \|-0.04 (3.85) | n= 29 (42.6%) \|-0.58 (2.79) | 0.15 [-0.32 ; 0.63] |
| Week 69 | n= 38 (53.5%) \|-0.91 (5.07) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 38 (53.5%) \|-0.16 (4.45) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 35 (49.3%) \| 0.22 (4.27) | n= 28 (41.2%) \|-1.09 (2.85) | 0.35 [-0.16 ; 0.85] |
| Week 75 | n= 35 (49.3%) \| 0.22 (4.29) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \| 0.77 (4.39) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \| 0.07 (5.48) | n= 24 (35.3%) \| 0.20 (2.81) | -0.03 [-0.57 ; 0.51] |
| Week 81 | n= 29 (40.8%) \| 0.19 (3.61) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \| 0.59 (4.23) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \| 0.36 (4.18) | n= 20 (29.4%) \|-0.35 (2.76) | 0.19 [-0.40 ; 0.78] |
| Week 87 | n= 24 (33.8%) \|-0.42 (4.27) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \| 0.18 (3.98) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 24 (33.8%) \|-1.05 (3.29) | n= 17 (25.0%) \|-0.39 (4.24) | -0.17 [-0.80 ; 0.46] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 23 (32.4%) \|-0.45 (3.17) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 22 (31.0%) \|-0.62 (3.50) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) \|-0.71 (3.39) | n= 10 (14.7%) \|-0.60 (2.88) | -0.03 [-0.80 ; 0.73] |
| Week 99 | n= 17 (23.9%) \|-0.38 (3.84) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) \|-0.36 (3.13) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) \| 0.18 (3.21) | n= 9 (13.2%) \| 0.11 (2.76) | 0.02 [-0.82 ; 0.86] |
| Week 105 | n= 13 (18.3%) \| 0.05 (3.37) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) \| 0.38 (3.96) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) \|-1.56 (4.02) | n= 4 ( 5.9%) \|-0.75 (3.59) | -0.19 [-1.38 ; 1.00] |
| Week 111 | n= 7 ( 9.9%) \|-0.71 (4.35) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) \|-0.44 (4.03) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 7 ( 9.9%) \|-0.57 (4.65) | n= 5 ( 7.4%) \|-1.00 (1.58) | 0.11 [-1.10 ; 1.31] |
| Week 117 | n= 7 ( 9.9%) \| 0.57 (3.05) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 ( 9.9%) \|-2.29 (4.89) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) \|-1.22 (4.42) | n= 1 ( 1.5%) \|-1.63 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 2.8%) \|-2.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) \|-1.50 (0.71) | n= 1 ( 1.5%) \|-8.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) \|-2.75 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.4%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.4%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.4%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) \|-0.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) \|-0.50 (3.16) | n= 16 (23.5%) \|-1.56 (4.91) | 0.23 [-0.64 ; 1.10] |
| Week 202 | n= 2 ( 2.8%) \|-5.50 (4.95) | n= 11 (16.2%) \|-0.18 (3.40) | -1.39 [-3.07 ; 0.30] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:48

TABLE 7.4.1: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| Nr subjects used | n=69 | n=67 | | |
| Week 7 | -1.76 (0.45) [-2.66 ;-0.87] | -2.11 (0.46) [-3.02 ;-1.21] | 0.35 (0.61) [-0.86 ; 1.56] | 0.10 [-0.25 ; 0.45] |
| Week 13 | -1.42 (0.45) [-2.32 ;-0.53] | -2.12 (0.47) [-3.04 ;-1.19] | 0.69 (0.62) [-0.53 ; 1.91] | 0.20 [-0.17 ; 0.57] |
| Week 19 | -1.09 (0.39) [-1.87 ;-0.32] | -1.80 (0.41) [-2.61 ;-0.99] | 0.71 (0.53) [-0.33 ; 1.75] | 0.24 [-0.14 ; 0.62] |
| Week 25 | -0.87 (0.41) [-1.67 ;-0.07] | -1.55 (0.43) [-2.40 ;-0.69] | 0.68 (0.56) [-0.42 ; 1.78] | 0.22 [-0.16 ; 0.61] |
| Week 31 | -0.97 (0.44) [-1.84 ;-0.11] | -1.39 (0.48) [-2.34 ;-0.45] | 0.42 (0.61) [-0.80 ; 1.64] | 0.13 [-0.27 ; 0.53] |
| Week 37 | -0.77 (0.46) [-1.67 ; 0.13] | -1.59 (0.48) [-2.54 ;-0.64] | 0.82 (0.63) [-0.43 ; 2.06] | 0.25 [-0.15 ; 0.66] |
| Week 43 | -0.96 (0.46) [-1.87 ;-0.04] | -1.56 (0.51) [-2.57 ;-0.56] | 0.61 (0.66) [-0.69 ; 1.91] | 0.18 [-0.23 ; 0.60] |
| Week 49 | -0.98 (0.45) [-1.87 ;-0.09] | -1.35 (0.52) [-2.39 ;-0.31] | 0.37 (0.66) [-0.95 ; 1.68] | 0.11 [-0.31 ; 0.54] |
| Week 55 | -1.02 (0.45) [-1.91 ;-0.13] | -1.50 (0.51) [-2.50 ;-0.49] | 0.47 (0.65) [-0.82 ; 1.77] | 0.15 [-0.28 ; 0.59] |
| Week 61 | -0.92 (0.41) [-1.74 ;-0.11] | -1.32 (0.50) [-2.31 ;-0.34] | 0.40 (0.62) [-0.82 ; 1.62] | 0.14 [-0.32 ; 0.60] |
| Week 67 | -0.90 (0.44) [-1.77 ;-0.04] | -1.35 (0.53) [-2.39 ;-0.30] | 0.44 (0.66) [-0.86 ; 1.75] | 0.15 [-0.32 ; 0.62] |
| Week 73 | -0.85 (0.50) [-1.84 ; 0.13] | -1.88 (0.57) [-3.02 ;-0.75] | 1.03 (0.74) [-0.44 ; 2.49] | 0.34 [-0.16 ; 0.84] |
| Week 79 | -1.04 (0.66) [-2.36 ; 0.28] | -1.09 (0.76) [-2.61 ; 0.42] | 0.05 (0.99) [-1.93 ; 2.03] | 0.01 [-0.52 ; 0.55] |
| Week 85 | -0.98 (0.49) [-1.95 ;-0.00] | -1.21 (0.57) [-2.34 ;-0.07] | 0.23 (0.73) [-1.23 ; 1.68] | 0.09 [-0.49 ; 0.67] |
| Week 91 | -1.08 (0.59) [-2.25 ; 0.09] | -1.00 (0.69) [-2.39 ; 0.38] | -0.07 (0.89) [-1.86 ; 1.71] | -0.03 [-0.65 ; 0.60] |
| Week 97 | -1.11 (0.61) [-2.34 ; 0.13] | -1.33 (0.84) [-3.02 ; 0.37] | 0.22 (1.02) [-1.85 ; 2.30] | 0.08 [-0.67 ; 0.83] |
| Overall post-baseline period estimate | -1.05 (0.25) [-1.53 ;-0.56] | -1.51 (0.28) [-2.06 ;-0.96] | 0.46 (0.32) [-0.17 ; 1.10] | 0.21 [-0.13 ; 0.55] |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit, and PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm, and uses a Heterogenous Autoregressive (ARH(1)) covariance structure.
CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Er
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:48

TABLE 7.4.2: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **< 65** | | |
| | N=40 | N=46 |
| **>= 65** | | |
| | N=31 | N=22 |
| **Subjects with Baseline Value** | | |
| **< 65** | | |
| | 39 (97.5%) | 45 (97.8%) |
| **>= 65** | | |
| | 30 (96.8%) | 22 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **< 65** | | |
| | 40 (100.0%) | 44 (95.7%) |
| **>= 65** | | |
| | 31 (100.0%) | 22 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **< 65** | | |
| | 39 (97.5%) | 43 (93.5%) |
| **>= 65** | | |
| | 30 (96.8%) | 22 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:48

TABLE 7.4.2: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Baseline | n= 39 (97.5%) \| 32.03 (4.48) | n= 45 (97.8%) \| 31.62 (3.75) | 0.10 [-0.33 ; 0.53] |
| Week 3 | n= 38 (95.0%) \| 31.87 (3.93) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 35 (87.5%) \| 31.94 (3.99) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 37 (92.5%) \| 31.06 (4.22) | n= 43 (93.5%) \| 30.33 (4.04) | 0.18 [-0.27 ; 0.62] |
| Week 9 | n= 36 (90.0%) \| 31.43 (3.64) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \| 31.00 (3.98) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 36 (90.0%) \| 31.87 (3.74) | n= 38 (82.6%) \| 30.34 (3.59) | 0.41 [-0.05 ; 0.88] |
| Week 15 | n= 34 (85.0%) \| 31.25 (4.14) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 37 (92.5%) \| 31.77 (3.68) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \| 32.19 (3.37) | n= 40 (87.0%) \| 31.37 (2.98) | 0.26 [-0.21 ; 0.73] |
| Week 21 | n= 36 (90.0%) \| 31.81 (3.76) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 35 (87.5%) \| 30.94 (4.21) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \| 31.70 (3.76) | n= 37 (80.4%) \| 31.30 (2.86) | 0.12 [-0.34 ; 0.58] |
| Week 27 | n= 34 (85.0%) \| 31.88 (4.53) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \| 31.94 (4.03) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \| 31.97 (4.92) | n= 29 (63.0%) \| 31.59 (3.06) | 0.09 [-0.41 ; 0.59] |
| Week 33 | n= 36 (90.0%) \| 31.62 (4.94) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 34 (85.0%) \| 31.03 (5.62) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \| 31.62 (5.32) | n= 33 (71.7%) \| 30.97 (2.91) | 0.15 [-0.34 ; 0.65] |
| Week 39 | n= 33 (82.5%) \| 32.27 (4.31) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \| 31.97 (4.49) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 30 (75.0%) \| 32.03 (4.26) | n= 31 (67.4%) \| 31.09 (3.55) | 0.24 [-0.27 ; 0.74] |
| Week 45 | n= 32 (80.0%) \| 31.10 (4.70) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \| 31.56 (4.40) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 33 (82.5%) \| 31.79 (4.80) | n= 25 (54.3%) \| 31.70 (2.23) | 0.02 [-0.50 ; 0.55] |
| Week 51 | n= 32 (80.0%) \| 31.52 (4.66) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 34 (85.0%) \| 31.92 (4.28) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 30 (75.0%) \| 31.55 (4.75) | n= 27 (58.7%) \| 30.90 (3.33) | 0.16 [-0.37 ; 0.68] |
| Week 57 | n= 32 (80.0%) \| 31.23 (4.78) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 28 (70.0%) \| 31.52 (4.37) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \| 31.88 (4.82) | n= 20 (43.5%) \| 30.55 (3.09) | 0.31 [-0.26 ; 0.88] |
| Week 63 | n= 30 (75.0%) \| 31.41 (5.04) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 27 (67.5%) \| 30.94 (5.98) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \| 31.81 (4.73) | n= 20 (43.5%) \| 30.75 (3.11) | 0.25 [-0.32 ; 0.82] |
| Week 69 | n= 29 (72.5%) \| 30.84 (5.51) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \| 31.49 (4.85) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \| 32.12 (4.53) | n= 18 (39.1%) \| 30.12 (2.84) | 0.50 [-0.12 ; 1.12] |
| Week 75 | n= 25 (62.5%) \| 32.08 (4.02) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \| 31.92 (4.25) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \| 31.29 (6.64) | n= 17 (37.0%) \| 30.53 (3.26) | 0.13 [-0.49 ; 0.76] |
| Week 81 | n= 23 (57.5%) \| 31.78 (4.43) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \| 31.96 (4.22) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \| 32.45 (3.73) | n= 14 (30.4%) \| 31.07 (2.97) | 0.39 [-0.31 ; 1.09] |
| Week 87 | n= 19 (47.5%) \| 31.26 (4.52) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 19 (47.5%) \| 31.74 (4.31) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (50.0%) \| 30.96 (5.10) | n= 12 (26.1%) \| 31.92 (2.97) | -0.21 [-0.94 ; 0.52] |
| Week 93 | n= 19 (47.5%) \| 31.58 (4.10) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \| 30.99 (4.84) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \| 30.94 (4.74) | n= 8 (17.4%) \| 31.88 (3.94) | -0.20 [-1.06 ; 0.66] |
| Week 99 | n= 13 (32.5%) \| 30.62 (5.47) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \| 31.58 (3.94) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \| 32.00 (3.57) | n= 7 (15.2%) \| 32.00 (2.58) | 0.00 [-0.96 ; 0.96] |
| Week 105 | n= 11 (27.5%) \| 31.27 (3.98) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \| 32.00 (3.42) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \| 29.33 (4.06) | n= 3 ( 6.5%) \| 28.67 (5.13) | 0.14 [-1.23 ; 1.52] |
| Week 111 | n= 7 (17.5%) \| 30.29 (3.90) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \| 31.43 (3.99) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \| 30.50 (4.32) | n= 3 ( 6.5%) \| 31.33 (1.15) | -0.20 [-1.69 ; 1.29] |
| Week 117 | n= 5 (12.5%) \| 32.40 (3.58) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \| 29.40 (4.16) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \| 30.67 (4.76) | n= 1 ( 2.2%) \| 30.38 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \| 33.00 ( / ) | n= 1 ( 2.2%) \| 24.00 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \| 30.75 (6.08) | n= 9 (19.6%) \| 29.78 (3.83) | 0.20 [-1.03 ; 1.43] |
| Week 202 | [No Data] | n= 7 (15.2%) \| 31.86 (2.41) | [No Data for at least 1 arm] |
| **>= 65** | | | |
| N subjects in population | N=31 | N=22 | |
| Baseline | n= 30 (96.8%) \| 31.16 (4.34) | n= 22 (100.0%) \| 31.17 (5.17) | -0.00 [-0.56 ; 0.55] |
| Week 3 | n= 29 (93.5%) \| 31.08 (4.04) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 28 (90.3%) \| 30.13 (5.37) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 27 (87.1%) \| 30.24 (4.29) | n= 21 (95.5%) \| 30.21 (4.06) | 0.01 [-0.57 ; 0.58] |
| Week 9 | n= 25 (80.6%) \| 30.36 (5.03) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 26 (83.9%) \| 30.63 (4.01) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 24 (77.4%) \| 30.66 (4.09) | n= 17 (77.3%) \| 31.65 (3.79) | -0.24 [-0.88 ; 0.39] |
| Week 15 | n= 20 (64.5%) \| 31.31 (3.02) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 26 (83.9%) \| 30.85 (4.89) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 25 (80.6%) \| 31.84 (2.73) | n= 14 (63.6%) \| 30.50 (4.45) | 0.38 [-0.29 ; 1.05] |
| Week 21 | n= 23 (74.2%) \| 31.79 (4.63) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (67.7%) \| 31.10 (3.55) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 22 (71.0%) \| 32.32 (3.55) | n= 12 (54.5%) \| 32.17 (3.83) | 0.04 [-0.67 ; 0.75] |
| Week 27 | n= 22 (71.0%) \| 33.73 (2.25) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 19 (61.3%) \| 32.37 (2.85) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 21 (67.7%) \| 32.29 (2.80) | n= 13 (59.1%) \| 31.00 (5.16) | 0.33 [-0.38 ; 1.03] |
| Week 33 | n= 20 (64.5%) \| 32.15 (3.31) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 20 (64.5%) \| 32.30 (3.77) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 17 (54.8%) \| 32.94 (3.56) | n= 14 (63.6%) \| 32.19 (3.62) | 0.20 [-0.52 ; 0.93] |
| Week 39 | n= 19 (61.3%) \| 32.53 (2.97) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 18 (58.1%) \| 32.39 (3.35) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 22 (71.0%) \| 31.89 (3.75) | n= 11 (50.0%) \| 30.99 (5.47) | 0.20 [-0.54 ; 0.94] |
| Week 45 | n= 16 (51.6%) \| 31.94 (3.71) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 18 (58.1%) \| 32.76 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 19 (61.3%) \| 32.47 (3.56) | n= 11 (50.0%) \| 30.39 (6.41) | 0.43 [-0.34 ; 1.19] |
| Week 51 | n= 19 (61.3%) \| 31.81 (3.64) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 18 (58.1%) \| 32.22 (3.81) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 16 (51.6%) \| 32.24 (3.98) | n= 11 (50.0%) \| 31.09 (3.83) | 0.28 [-0.50 ; 1.07] |
| Week 57 | n= 16 (51.6%) \| 32.44 (3.33) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 59 | n= 18 (58.1%) \| 31.71 (4.74) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 17 (54.8%) \| 32.85 (2.51) | n= 11 (50.0%) \| 31.45 (4.44) | 0.40 [-0.38 ; 1.18] |
| Week 63 | n= 12 (38.7%) \| 31.75 (4.39) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 16 (51.6%) \| 31.25 (3.97) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 12 (38.7%) \| 32.58 (2.54) | n= 10 (45.5%) \| 31.20 (4.83) | 0.36 [-0.51 ; 1.22] |
| Week 69 | n= 9 (29.0%) \| 32.22 (3.07) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 10 (32.3%) \| 33.20 (3.36) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 10 (32.3%) \| 32.50 (2.64) | n= 10 (45.5%) \| 30.20 (5.03) | 0.55 [-0.37 ; 1.47] |
| Week 75 | n= 10 (32.3%) \| 32.70 (3.16) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 8 (25.8%) \| 32.75 (2.60) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 7 (22.6%) \| 31.80 (2.59) | n= 8 (36.4%) \| 32.63 (2.50) | -0.30 [-1.36 ; 0.75] |
| Week 81 | n= 6 (19.4%) \| 32.33 (3.83) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 8 (25.8%) \| 33.00 (3.78) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (22.6%) \| 31.86 (4.45) | n= 7 (31.8%) \| 32.71 (3.64) | -0.20 [-1.29 ; 0.90] |
| Week 87 | n= 5 (16.1%) \| 30.20 (5.85) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 6 (19.4%) \| 30.98 (3.87) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (12.9%) \| 30.00 (2.94) | n= 6 (27.3%) \| 32.33 (4.93) | -0.49 [-1.86 ; 0.88] |
| Week 93 | n= 4 (12.9%) \| 30.50 (4.12) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (16.1%) \| 31.80 (3.83) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (12.9%) \| 30.84 (3.57) | n= 3 (13.6%) \| 33.33 (2.52) | -0.66 [-2.37 ; 1.06] |
| Week 99 | n= 4 (12.9%) \| 31.25 (3.59) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 6.5%) \| 30.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 ( 9.7%) \| 30.00 (2.65) | n= 3 (13.6%) \| 33.00 (3.00) | -0.85 [-2.79 ; 1.09] |
| Week 105 | n= 2 ( 6.5%) \| 28.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 3.2%) \| 30.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 6.5%) \| 27.94 (2.92) | n= 2 ( 9.1%) \| 35.50 (0.71) | -2.04 [-5.99 ; 1.92] |
| Week 113 | n= 1 ( 3.2%) \| 31.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 3.2%) \| 34.00 ( / ) | n= 2 ( 9.1%) \| 34.50 (2.12) | [Not calculable] |
| Week 117 | n= 2 ( 6.5%) \| 33.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 ( 6.5%) \| 29.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 ( 6.5%) \| 32.63 (4.77) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 2 ( 6.5%) \| 31.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 3.2%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.2%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 3.2%) \| 29.25 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 3.2%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.2%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 3.2%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 3.2%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 3.2%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 3.2%) \| 31.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.9%) \| 32.25 (2.63) | n= 7 (31.8%) \| 31.14 (5.55) | 0.21 [-1.09 ; 1.51] |
| Week 202 | n= 2 ( 6.5%) \| 25.00 (7.07) | n= 4 (18.2%) \| 33.25 (2.22) | -1.64 [-3.97 ; 0.69] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:48

TABLE 7.4.2: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Week 3 | n= 37 (92.5%) \|-0.38 (2.34) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 34 (85.0%) \|-0.41 (2.50) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 36 (90.0%) \|-0.66 (3.63) | n= 42 (91.3%) \|-1.29 (3.45) | 0.18 [-0.27 ; 0.62] |
| Week 9 | n= 36 (90.0%) \|-0.88 (4.19) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \|-1.37 (3.76) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 36 (90.0%) \|-0.47 (3.53) | n= 38 (82.6%) \|-1.82 (3.62) | 0.37 [-0.09 ; 0.84] |
| Week 15 | n= 34 (85.0%) \|-0.84 (4.27) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 37 (92.5%) \|-0.31 (3.47) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \|-0.59 (2.88) | n= 39 (84.8%) \|-0.75 (3.94) | 0.05 [-0.43 ; 0.52] |
| Week 21 | n= 36 (90.0%) \|-0.08 (3.19) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 35 (87.5%) \|-0.94 (3.18) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \|-0.44 (3.17) | n= 36 (78.3%) \|-1.17 (3.94) | 0.20 [-0.26 ; 0.67] |
| Week 27 | n= 34 (85.0%) \|-0.41 (3.34) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \|-0.15 (3.52) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \|-0.39 (3.47) | n= 29 (63.0%) \|-1.00 (2.62) | 0.19 [-0.31 ; 0.70] |
| Week 33 | n= 36 (90.0%) \|-0.52 (3.64) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 34 (85.0%) \|-0.94 (3.82) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \|-0.48 (3.41) | n= 32 (69.6%) \|-1.22 (3.46) | 0.21 [-0.29 ; 0.71] |
| Week 39 | n= 33 (82.5%) \|-0.30 (3.33) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \|-0.26 (3.73) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 30 (75.0%) \|-0.33 (3.59) | n= 30 (65.2%) \|-1.07 (3.00) | 0.22 [-0.29 ; 0.73] |
| Week 45 | n= 32 (80.0%) \|-0.99 (3.85) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \|-0.96 (3.18) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 33 (82.5%) \|-0.54 (3.81) | n= 24 (52.2%) \|-0.98 (2.38) | 0.13 [-0.40 ; 0.66] |
| Week 51 | n= 32 (80.0%) \|-0.64 (3.66) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 34 (85.0%) \|-0.14 (3.18) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 30 (75.0%) \|-0.71 (3.27) | n= 26 (56.5%) \|-1.18 (2.97) | 0.15 [-0.38 ; 0.68] |
| Week 57 | n= 32 (80.0%) \|-0.83 (4.00) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 28 (70.0%) \|-0.41 (3.61) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \|-0.22 (3.70) | n= 19 (41.3%) \|-1.05 (3.27) | 0.23 [-0.35 ; 0.81] |
| Week 63 | n= 30 (75.0%) \|-0.36 (3.81) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 27 (67.5%) \|-0.62 (4.71) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \|-0.34 (3.85) | n= 19 (41.3%) \|-1.11 (3.02) | 0.21 [-0.36 ; 0.78] |
| Week 69 | n= 29 (72.5%) \|-1.51 (5.03) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \|-0.37 (4.31) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \| 0.20 (4.35) | n= 18 (39.1%) \|-1.22 (3.24) | 0.35 [-0.26 ; 0.97] |
| Week 75 | n= 25 (62.5%) \| 0.16 (4.08) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \| 0.38 (4.11) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \|-0.17 (5.69) | n= 16 (34.8%) \|-0.13 (3.14) | -0.01 [-0.65 ; 0.63] |
| Week 81 | n= 23 (57.5%) \|-0.13 (3.24) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \| 0.28 (3.74) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \| 0.35 (3.38) | n= 13 (28.3%) \|-0.46 (3.36) | 0.24 [-0.48 ; 0.95] |
| Week 87 | n= 19 (47.5%) \|-0.26 (2.84) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (47.5%) \| 0.32 (3.20) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 20 (50.0%) \|-0.84 (3.20) | n= 11 (23.9%) \|-0.55 (5.28) | -0.07 [-0.82 ; 0.68] |
| Week 93 | n= 19 (47.5%) \|-0.05 (2.95) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \|-0.54 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \|-0.53 (3.62) | n= 7 (15.2%) \|-0.57 (3.51) | 0.01 [-0.89 ; 0.91] |
| Week 99 | n= 13 (32.5%) \|-0.15 (4.18) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \|-0.17 (3.30) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \| 0.58 (3.23) | n= 6 (13.0%) \| 0.67 (3.27) | -0.02 [-1.03 ; 0.99] |
| Week 105 | n= 11 (27.5%) \| 0.55 (3.11) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \| 0.71 (4.15) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \|-1.00 (4.15) | n= 2 ( 4.3%) \|-2.00 (5.66) | 0.21 [-1.41 ; 1.83] |
| Week 111 | n= 7 (17.5%) \|-0.71 (4.35) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \|-0.43 (4.35) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \|-1.00 (4.94) | n= 3 ( 6.5%) \|-1.33 (2.08) | 0.07 [-1.42 ; 1.56] |
| Week 117 | n= 5 (12.5%) \| 0.80 (3.42) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \|-1.40 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \|-1.33 (5.09) | n= 1 ( 2.2%) \|-1.63 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \|-2.00 ( / ) | n= 1 ( 2.2%) \|-8.00 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \|-0.50 (1.73) | n= 9 (19.6%) \|-1.44 (5.55) | 0.18 [-1.05 ; 1.42] |
| Week 202 | [No Data] | n= 7 (15.2%) \|-0.57 (4.24) | [No Data for at least 1 arm] |
| **>= 65** | | | |
| N subjects in population | N=31 | N=22 | |
| Week 3 | n= 29 (93.5%) \| 0.08 (2.16) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 27 (87.1%) \|-0.98 (3.63) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 26 (83.9%) \|-1.06 (3.78) | n= 21 (95.5%) \|-0.78 (3.28) | -0.08 [-0.66 ; 0.50] |
| Week 9 | n= 24 (77.4%) \|-1.44 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 25 (80.6%) \|-0.70 (3.00) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 23 (74.2%) \|-0.79 (3.70) | n= 17 (77.3%) \|-0.46 (1.71) | -0.11 [-0.74 ; 0.53] |
| Week 15 | n= 20 (64.5%) \|-0.57 (3.62) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 25 (80.6%) \|-0.93 (3.82) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 24 (77.4%) \|-0.41 (3.66) | n= 14 (63.6%) \|-1.48 (2.43) | 0.32 [-0.35 ; 0.99] |
| Week 21 | n= 23 (74.2%) \|-0.41 (4.22) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (67.7%) \|-0.86 (2.85) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 21 (67.7%) \| 0.21 (4.23) | n= 12 (54.5%) \| 0.03 (1.90) | 0.05 [-0.67 ; 0.77] |
| Week 27 | n= 21 (67.7%) \| 1.02 (3.90) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 19 (61.3%) \| 0.29 (3.95) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 21 (67.7%) \|-0.12 (4.05) | n= 13 (59.1%) \|-0.75 (2.14) | 0.18 [-0.53 ; 0.88] |
| Week 33 | n= 20 (64.5%) \|-0.45 (3.05) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 19 (61.3%) \|-0.02 (3.24) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 17 (54.8%) \| 0.80 (3.75) | n= 14 (63.6%) \| 0.35 (1.95) | 0.14 [-0.58 ; 0.86] |
| Week 39 | n= 18 (58.1%) \| 0.34 (3.31) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 18 (58.1%) \|-1.13 (3.12) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 21 (67.7%) \|-0.63 (4.53) | n= 11 (50.0%) \|-0.35 (2.79) | -0.07 [-0.81 ; 0.67] |
| Week 45 | n= 16 (51.6%) \|-0.65 (5.18) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 18 (58.1%) \|-0.24 (3.47) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 19 (61.3%) \| 0.06 (3.57) | n= 11 (50.0%) \|-0.86 (4.79) | 0.22 [-0.53 ; 0.98] |
| Week 51 | n= 19 (61.3%) \|-0.34 (3.38) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 18 (58.1%) \|-0.25 (3.49) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 16 (51.6%) \|-0.06 (3.65) | n= 11 (50.0%) \|-0.16 (2.66) | 0.03 [-0.75 ; 0.81] |
| Week 57 | n= 16 (51.6%) \| 0.45 (3.06) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 18 (58.1%) \|-0.56 (4.63) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 17 (54.8%) \| 0.09 (3.43) | n= 11 (50.0%) \| 0.20 (2.50) | -0.04 [-0.81 ; 0.74] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 63 | n= 12 (38.7%) \| 0.22 (4.05) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 16 (51.6%) \|-0.55 (4.79) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 12 (38.7%) \| 0.77 (3.91) | n= 10 (45.5%) \| 0.43 (2.08) | 0.10 [-0.76 ; 0.96] |
| Week 69 | n= 9 (29.0%) \| 1.02 (4.99) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 10 (32.3%) \| 0.40 (5.02) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 10 (32.3%) \| 0.26 (4.28) | n= 10 (45.5%) \|-0.88 (2.11) | 0.32 [-0.58 ; 1.23] |
| Week 75 | n= 10 (32.3%) \| 0.36 (5.01) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 8 (25.8%) \| 1.95 (5.28) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 7 (22.6%) \| 0.89 (5.02) | n= 8 (36.4%) \| 0.86 (2.01) | 0.01 [-1.04 ; 1.06] |
| Week 81 | n= 6 (19.4%) \| 1.44 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 8 (25.8%) \| 1.58 (5.71) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (22.6%) \| 0.38 (6.28) | n= 7 (31.8%) \|-0.14 (1.21) | 0.11 [-0.98 ; 1.20] |
| Week 87 | n= 5 (16.1%) \|-1.00 (8.25) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 6 (19.4%) \|-0.25 (6.25) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (12.9%) \|-2.09 (4.03) | n= 6 (27.3%) \|-0.10 (1.29) | -0.67 [-2.06 ; 0.71] |
| Week 93 | n= 4 (12.9%) \|-2.34 (3.97) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (16.1%) \|-0.88 (4.09) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (12.9%) \|-1.50 (2.38) | n= 3 (13.6%) \|-0.67 (0.58) | -0.37 [-2.05 ; 1.30] |
| Week 99 | n= 4 (12.9%) \|-1.09 (2.82) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 6.5%) \|-1.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 ( 9.7%) \|-1.46 (3.08) | n= 3 (13.6%) \|-1.00 (1.00) | -0.16 [-1.98 ; 1.66] |
| Week 105 | n= 2 ( 6.5%) \|-2.69 (4.68) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 3.2%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 6.5%) \|-4.06 (2.92) | n= 2 ( 9.1%) \| 0.50 (0.71) | -1.23 [-4.32 ; 1.86] |
| Week 113 | n= 1 ( 3.2%) \|-0.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 3.2%) \| 2.00 ( / ) | n= 2 ( 9.1%) \|-0.50 (0.71) | [Not calculable] |
| Week 117 | n= 2 ( 6.5%) \| 0.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 ( 6.5%) \|-4.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 ( 6.5%) \|-0.88 (2.65) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 2 ( 6.5%) \|-2.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 3.2%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.2%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 3.2%) \|-2.75 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 3.2%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.2%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 3.2%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 3.2%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 3.2%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 3.2%) \|-0.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.9%) \|-0.50 (4.51) | n= 7 (31.8%) \|-1.71 (4.39) | 0.25 [-1.05 ; 1.55] |
| Week 202 | n= 2 ( 6.5%) \|-5.50 (4.95) | n= 4 (18.2%) \| 0.50 (1.29) | -1.77 [-4.16 ; 0.62] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:49

TABLE 7.4.2: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 1 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **< 65** | | | | |
| Nr subjects used | n=39 | n=45 | | |
| Week 7 | -0.74 (0.53) [-1.79 ; 0.32] | -1.46 (0.50) [-2.46 ;-0.47] | 0.73 (0.73) [-0.73 ; 2.18] | 0.22 [-0.22 ; 0.67] |
| Week 13 | -0.65 (0.54) [-1.73 ; 0.43] | -1.84 (0.52) [-2.88 ;-0.80] | 1.19 (0.76) [-0.31 ; 2.69] | 0.36 [-0.10 ; 0.82] |
| Week 19 | -0.37 (0.49) [-1.35 ; 0.60] | -0.97 (0.46) [-1.89 ;-0.06] | 0.60 (0.67) [-0.74 ; 1.93] | 0.21 [-0.26 ; 0.68] |
| Week 25 | -0.37 (0.49) [-1.35 ; 0.60] | -1.10 (0.48) [-2.06 ;-0.14] | 0.73 (0.69) [-0.64 ; 2.09] | 0.25 [-0.22 ; 0.71] |
| Week 31 | -0.35 (0.53) [-1.41 ; 0.70] | -0.63 (0.54) [-1.70 ; 0.44] | 0.27 (0.76) [-1.23 ; 1.78] | 0.09 [-0.41 ; 0.59] |
| Week 37 | -0.45 (0.60) [-1.64 ; 0.75] | -1.41 (0.59) [-2.60 ;-0.23] | 0.97 (0.84) [-0.71 ; 2.65] | 0.29 [-0.21 ; 0.78] |
| Week 43 | -0.14 (0.56) [-1.25 ; 0.97] | -1.06 (0.57) [-2.19 ; 0.06] | 0.92 (0.79) [-0.66 ; 2.50] | 0.30 [-0.21 ; 0.80] |
| Week 49 | -0.43 (0.55) [-1.53 ; 0.67] | -0.48 (0.61) [-1.71 ; 0.74] | 0.05 (0.82) [-1.59 ; 1.69] | 0.02 [-0.51 ; 0.54] |
| Week 55 | -0.40 (0.57) [-1.54 ; 0.74] | -1.00 (0.62) [-2.24 ; 0.25] | 0.60 (0.85) [-1.08 ; 2.29] | 0.19 [-0.34 ; 0.72] |
| Week 61 | -0.40 (0.55) [-1.51 ; 0.70] | -0.91 (0.67) [-2.25 ; 0.42] | 0.51 (0.87) [-1.22 ; 2.24] | 0.17 [-0.41 ; 0.74] |
| Week 67 | -0.52 (0.57) [-1.65 ; 0.62] | -1.08 (0.71) [-2.50 ; 0.34] | 0.56 (0.91) [-1.26 ; 2.38] | 0.17 [-0.40 ; 0.74] |
| Week 73 | -0.38 (0.67) [-1.72 ; 0.96] | -1.26 (0.81) [-2.88 ; 0.37] | 0.88 (1.05) [-1.23 ; 2.99] | 0.25 [-0.36 ; 0.86] |
| Week 79 | -0.78 (0.88) [-2.53 ; 0.98] | -0.74 (1.08) [-2.91 ; 1.42] | -0.03 (1.39) [-2.82 ; 2.75] | -0.01 [-0.64 ; 0.62] |
| Week 85 | -0.50 (0.57) [-1.65 ; 0.64] | -0.70 (0.71) [-2.13 ; 0.73] | 0.20 (0.91) [-1.64 ; 2.03] | 0.07 [-0.62 ; 0.77] |
| Week 91 | -0.78 (0.76) [-2.32 ; 0.75] | -0.76 (1.00) [-2.77 ; 1.26] | -0.03 (1.25) [-2.56 ; 2.50] | -0.01 [-0.74 ; 0.73] |
| Overall post-baseline period estimate | -0.48 (0.30) [-1.08 ; 0.11] | -1.03 (0.33) [-1.69 ;-0.36] | 0.54 (0.45) [-0.35 ; 1.44] | 0.26 [-0.17 ; 0.70] |
| **>= 65** | | | | |
| Nr subjects used | n=30 | n=22 | | |
| Week 7 | -1.47 (0.70) [-2.89 ;-0.05] | -1.13 (0.79) [-2.73 ; 0.48] | -0.35 (1.06) [-2.48 ; 1.79] | -0.09 [-0.67 ; 0.48] |
| Week 13 | -0.79 (0.70) [-2.20 ; 0.63] | -0.32 (0.82) [-1.98 ; 1.35] | -0.47 (1.08) [-2.65 ; 1.71] | -0.14 [-0.76 ; 0.49] |
| Week 19 | -0.36 (0.59) [-1.55 ; 0.84] | -1.36 (0.75) [-2.87 ; 0.16] | 1.00 (0.96) [-0.93 ; 2.93] | 0.34 [-0.32 ; 1.01] |
| Week 25 | 0.22 (0.65) [-1.09 ; 1.52] | 0.11 (0.83) [-1.56 ; 1.78] | 0.11 (1.05) [-2.01 ; 2.23] | 0.04 [-0.67 ; 0.75] |
| Week 31 | -0.12 (0.68) [-1.50 ; 1.25] | -0.68 (0.85) [-2.40 ; 1.05] | 0.55 (1.09) [-1.65 ; 2.76] | 0.17 [-0.52 ; 0.87] |
| Week 37 | 0.69 (0.58) [-0.48 ; 1.86] | 0.34 (0.68) [-1.03 ; 1.70] | 0.35 (0.89) [-1.44 ; 2.15] | 0.14 [-0.57 ; 0.85] |
| Week 43 | -0.40 (0.73) [-1.88 ; 1.07] | -0.34 (0.97) [-2.29 ; 1.61] | -0.07 (1.21) [-2.51 ; 2.38] | -0.02 [-0.75 ; 0.71] |
| Week 49 | -0.11 (0.79) [-1.71 ; 1.49] | -0.99 (1.04) [-3.09 ; 1.12] | 0.88 (1.31) [-1.77 ; 3.52] | 0.25 [-0.50 ; 0.99] |
| Week 55 | -0.15 (0.61) [-1.39 ; 1.09] | -0.34 (0.77) [-1.90 ; 1.21] | 0.19 (0.98) [-1.80 ; 2.19] | 0.08 [-0.69 ; 0.84] |
| Week 61 | 0.08 (0.57) [-1.08 ; 1.24] | -0.00 (0.72) [-1.46 ; 1.46] | 0.08 (0.92) [-1.78 ; 1.95] | 0.03 [-0.72 ; 0.79] |
| Week 67 | 0.45 (0.65) [-0.87 ; 1.77] | 0.20 (0.74) [-1.31 ; 1.70] | 0.25 (0.99) [-1.75 ; 2.26] | 0.11 [-0.73 ; 0.95] |
| Week 73 | 0.07 (0.82) [-1.62 ; 1.76] | -1.01 (0.85) [-2.77 ; 0.74] | 1.08 (1.18) [-1.36 ; 3.51] | 0.39 [-0.50 ; 1.28] |
| Overall post-baseline period estimate | -0.16 (0.33) [-0.82 ; 0.51] | -0.46 (0.41) [-1.28 ; 0.37] | 0.30 (0.53) [-0.76 ; 1.36] | 0.16 [-0.39 ; 0.71] |
| **MMRM subgroups interaction p-value** | | | 0.4214 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020

TABLE 7.4.3: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **< 65** | N=40 | N=46 |
| **>= 65 AND < 75** | N=23 | N=17 |
| **>= 75** | N=8 | N=5 |
| **Subjects with Baseline Value** | | |
| **< 65** | 39 (97.5%) | 45 (97.8%) |
| **>= 65 AND < 75** | 22 (95.7%) | 17 (100.0%) |
| **>= 75** | 8 (100.0%) | 5 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **< 65** | 40 (100.0%) | 44 (95.7%) |
| **>= 65 AND < 75** | 23 (100.0%) | 17 (100.0%) |
| **>= 75** | 8 (100.0%) | 5 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **< 65** | 39 (97.5%) | 43 (93.5%) |
| **>= 65 AND < 75** | 22 (95.7%) | 17 (100.0%) |
| **>= 75** | 8 (100.0%) | 5 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:49

TABLE 7.4.3: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Baseline | n= 39 (97.5%) \| 32.03 (4.48) | n= 45 (97.8%) \| 31.62 (3.75) | 0.10 [-0.33 ; 0.53] |
| Week 3 | n= 38 (95.0%) \| 31.87 (3.93) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 35 (87.5%) \| 31.94 (3.99) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 37 (92.5%) \| 31.06 (4.22) | n= 43 (93.5%) \| 30.33 (4.04) | 0.18 [-0.27 ; 0.62] |
| Week 9 | n= 36 (90.0%) \| 31.43 (3.64) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \| 31.00 (3.98) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 36 (90.0%) \| 31.87 (3.74) | n= 38 (82.6%) \| 30.34 (3.59) | 0.41 [-0.05 ; 0.88] |
| Week 15 | n= 34 (85.0%) \| 31.25 (4.14) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 37 (92.5%) \| 31.77 (3.68) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \| 32.19 (3.37) | n= 40 (87.0%) \| 31.37 (2.98) | 0.26 [-0.21 ; 0.73] |
| Week 21 | n= 36 (90.0%) \| 31.81 (3.76) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 35 (87.5%) \| 30.94 (4.21) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \| 31.70 (3.76) | n= 37 (80.4%) \| 31.30 (2.86) | 0.12 [-0.34 ; 0.58] |
| Week 27 | n= 34 (85.0%) \| 31.88 (4.53) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \| 31.94 (4.03) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \| 31.97 (4.92) | n= 29 (63.0%) \| 31.59 (3.06) | 0.09 [-0.41 ; 0.59] |
| Week 33 | n= 36 (90.0%) \| 31.62 (4.94) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 34 (85.0%) \| 31.03 (5.62) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \| 31.62 (5.32) | n= 33 (71.7%) \| 30.97 (2.91) | 0.15 [-0.34 ; 0.65] |
| Week 39 | n= 33 (82.5%) \| 32.27 (4.31) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \| 31.97 (4.49) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 30 (75.0%) \| 32.03 (4.26) | n= 31 (67.4%) \| 31.09 (3.55) | 0.24 [-0.27 ; 0.74] |
| Week 45 | n= 32 (80.0%) \| 31.10 (4.70) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \| 31.56 (4.40) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 33 (82.5%) \| 31.79 (4.80) | n= 25 (54.3%) \| 31.70 (2.23) | 0.02 [-0.50 ; 0.55] |
| Week 51 | n= 32 (80.0%) \| 31.52 (4.66) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 34 (85.0%) \| 31.92 (4.28) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 30 (75.0%) \| 31.55 (4.75) | n= 27 (58.7%) \| 30.90 (3.33) | 0.16 [-0.37 ; 0.68] |
| Week 57 | n= 32 (80.0%) \| 31.23 (4.78) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 28 (70.0%) \| 31.52 (4.37) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \| 31.88 (4.82) | n= 20 (43.5%) \| 30.55 (3.09) | 0.31 [-0.26 ; 0.88] |
| Week 63 | n= 30 (75.0%) \| 31.41 (5.04) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 27 (67.5%) \| 30.94 (5.98) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \| 31.81 (4.73) | n= 20 (43.5%) \| 30.75 (3.11) | 0.25 [-0.32 ; 0.82] |
| Week 69 | n= 29 (72.5%) \| 30.84 (5.51) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \| 31.49 (4.85) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \| 32.12 (4.53) | n= 18 (39.1%) \| 30.12 (2.84) | 0.50 [-0.12 ; 1.12] |
| Week 75 | n= 25 (62.5%) \| 32.08 (4.02) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \| 31.92 (4.25) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \| 31.29 (6.64) | n= 17 (37.0%) \| 30.53 (3.26) | 0.13 [-0.49 ; 0.76] |
| Week 81 | n= 23 (57.5%) \| 31.78 (4.43) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \| 31.96 (4.22) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \| 32.45 (3.73) | n= 14 (30.4%) \| 31.07 (2.97) | 0.39 [-0.31 ; 1.09] |
| Week 87 | n= 19 (47.5%) \| 31.26 (4.52) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 19 (47.5%) \| 31.74 (4.31) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (50.0%) \| 30.96 (5.10) | n= 12 (26.1%) \| 31.92 (2.97) | -0.21 [-0.94 ; 0.52] |
| Week 93 | n= 19 (47.5%) \| 31.58 (4.10) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \| 30.99 (4.84) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \| 30.94 (4.74) | n= 8 (17.4%) \| 31.88 (3.94) | -0.20 [-1.06 ; 0.66] |
| Week 99 | n= 13 (32.5%) \| 30.62 (5.47) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \| 31.58 (3.94) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \| 32.00 (3.57) | n= 7 (15.2%) \| 32.00 (2.58) | 0.00 [-0.96 ; 0.96] |
| Week 105 | n= 11 (27.5%) \| 31.27 (3.98) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \| 32.00 (3.42) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \| 29.33 (4.06) | n= 3 ( 6.5%) \| 28.67 (5.13) | 0.14 [-1.23 ; 1.52] |
| Week 111 | n= 7 (17.5%) \| 30.29 (3.90) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \| 31.43 (3.99) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \| 30.50 (4.32) | n= 3 ( 6.5%) \| 31.33 (1.15) | -0.20 [-1.69 ; 1.29] |
| Week 117 | n= 5 (12.5%) \| 32.40 (3.58) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \| 29.40 (4.16) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \| 30.67 (4.76) | n= 1 ( 2.2%) \| 30.38 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \| 33.00 ( / ) | n= 1 ( 2.2%) \| 24.00 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \| 30.75 (6.08) | n= 9 (19.6%) \| 29.78 (3.83) | 0.20 [-1.03 ; 1.43] |
| Week 202 | [No Data] | n= 7 (15.2%) \| 31.86 (2.41) | [No Data for at least 1 arm] |
| **>= 65 AND < 75** | | | |
| N subjects in population | N=23 | N=17 | |
| Baseline | n= 22 (95.7%) \| 31.04 (4.42) | n= 17 (100.0%) \| 30.28 (5.54) | 0.15 [-0.49 ; 0.79] |
| Week 3 | n= 21 (91.3%) \| 30.72 (4.30) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 21 (91.3%) \| 30.05 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 20 (87.0%) \| 30.17 (4.57) | n= 17 (100.0%) \| 29.79 (4.25) | 0.08 [-0.57 ; 0.74] |
| Week 9 | n= 19 (82.6%) \| 30.95 (4.21) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 19 (82.6%) \| 30.95 (3.60) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 19 (82.6%) \| 30.84 (3.61) | n= 12 (70.6%) \| 30.75 (4.07) | 0.02 [-0.71 ; 0.76] |
| Week 15 | n= 14 (60.9%) \| 30.93 (3.29) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 19 (82.6%) \| 31.01 (5.00) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 19 (82.6%) \| 31.79 (2.94) | n= 10 (58.8%) \| 29.53 (4.96) | 0.59 [-0.21 ; 1.38] |
| Week 21 | n= 17 (73.9%) \| 31.30 (5.10) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (65.2%) \| 30.67 (3.94) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 16 (69.6%) \| 32.13 (4.06) | n= 7 (41.2%) \| 30.43 (4.20) | 0.40 [-0.52 ; 1.32] |
| Week 27 | n= 16 (69.6%) \| 34.00 (2.22) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 14 (60.9%) \| 32.14 (3.23) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 15 (65.2%) \| 31.87 (2.97) | n= 11 (64.7%) \| 30.18 (5.21) | 0.40 [-0.40 ; 1.20] |
| Week 33 | n= 14 (60.9%) \| 31.50 (3.63) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 14 (60.9%) \| 31.86 (4.22) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 12 (52.2%) \| 33.00 (3.95) | n= 11 (64.7%) \| 31.78 (4.02) | 0.29 [-0.55 ; 1.14] |
| Week 39 | n= 14 (60.9%) \| 32.43 (3.18) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 13 (56.5%) \| 32.23 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 16 (69.6%) \| 31.19 (4.07) | n= 10 (58.8%) \| 30.59 (5.59) | 0.12 [-0.68 ; 0.93] |
| Week 45 | n= 11 (47.8%) \| 31.91 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 12 (52.2%) \| 32.75 (3.93) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 13 (56.5%) \| 31.92 (4.03) | n= 10 (58.8%) \| 30.16 (6.71) | 0.32 [-0.53 ; 1.17] |
| Week 51 | n= 13 (56.5%) \| 31.57 (4.10) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (56.5%) \| 31.85 (4.22) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 11 (47.8%) \| 31.81 (4.43) | n= 10 (58.8%) \| 30.70 (3.80) | 0.26 [-0.63 ; 1.14] |
| Week 57 | n= 12 (52.2%) \| 32.17 (3.69) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 59 | n= 13 (56.5%) \| 31.15 (5.24) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 12 (52.2%) \| 32.53 (2.62) | n= 10 (58.8%) \| 31.20 (4.59) | 0.35 [-0.51 ; 1.22] |
| Week 63 | n= 9 (39.1%) \| 31.00 (4.80) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (47.8%) \| 30.55 (3.91) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (34.8%) \| 31.88 (2.53) | n= 9 (52.9%) \| 30.78 (4.92) | 0.26 [-0.73 ; 1.25] |
| Week 69 | n= 7 (30.4%) \| 32.29 (3.35) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (30.4%) \| 32.57 (3.69) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (30.4%) \| 32.14 (2.61) | n= 10 (58.8%) \| 30.20 (5.03) | 0.44 [-0.57 ; 1.45] |
| Week 75 | n= 8 (34.8%) \| 32.38 (3.34) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (21.7%) \| 31.60 (2.19) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (26.1%) \| 31.44 (2.63) | n= 7 (41.2%) \| 32.43 (2.64) | -0.35 [-1.50 ; 0.80] |
| Week 81 | n= 4 (17.4%) \| 31.25 (4.27) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (26.1%) \| 32.00 (3.90) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (21.7%) \| 30.40 (4.51) | n= 6 (35.3%) \| 32.67 (3.98) | -0.49 [-1.77 ; 0.78] |
| Week 87 | n= 3 (13.0%) \| 26.33 (3.51) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 4 (17.4%) \| 28.75 (2.22) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (17.4%) \| 30.00 (2.94) | n= 6 (35.3%) \| 32.33 (4.93) | -0.49 [-1.86 ; 0.88] |
| Week 93 | n= 3 (13.0%) \| 28.67 (2.31) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (17.4%) \| 30.75 (3.50) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (13.0%) \| 29.13 (1.19) | n= 3 (17.6%) \| 33.33 (2.52) | -1.71 [-3.98 ; 0.56] |
| Week 99 | n= 3 (13.0%) \| 29.67 (2.08) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 8.7%) \| 30.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (13.0%) \| 30.00 (2.65) | n= 3 (17.6%) \| 33.00 (3.00) | -0.85 [-2.79 ; 1.09] |
| Week 105 | n= 2 ( 8.7%) \| 28.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 4.3%) \| 30.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 8.7%) \| 27.94 (2.92) | n= 2 (11.8%) \| 35.50 (0.71) | -2.04 [-5.99 ; 1.92] |
| Week 113 | n= 1 ( 4.3%) \| 31.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 4.3%) \| 34.00 ( / ) | n= 2 (11.8%) \| 34.50 (2.12) | [Not calculable] |
| Week 117 | n= 1 ( 4.3%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 4.3%) \| 24.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 4.3%) \| 29.25 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 4.3%) \| 27.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.3%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 4.3%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 4.3%) \| 29.25 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 4.3%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.3%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 4.3%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 4.3%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 4.3%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.3%) \| 31.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (13.0%) \| 32.33 (3.21) | n= 4 (23.5%) \| 29.00 (6.68) | 0.50 [-1.18 ; 2.19] |
| Week 202 | n= 1 ( 4.3%) \| 30.00 ( / ) | n= 2 (11.8%) \| 33.00 (1.41) | [Not calculable] |
| **>= 75** | | | |
| N subjects in population | N=8 | N=5 | |
| Baseline | n= 8 (100.0%) \| 31.50 (4.38) | n= 5 (100.0%) \| 34.20 (1.64) | -0.69 [-1.90 ; 0.51] |
| Week 3 | n= 8 (100.0%) \| 32.00 (3.30) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 7 (87.5%) \| 30.36 (4.78) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (87.5%) \| 30.43 (3.69) | n= 4 (80.0%) \| 32.00 (2.94) | -0.42 [-1.73 ; 0.90] |
| Week 9 | n= 6 (75.0%) \| 28.50 (7.23) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 7 (87.5%) \| 29.79 (5.20) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 13 | n= 5 (62.5%) \| 29.96 (6.08) | n= 5 (100.0%) \| 33.80 (1.92) | -0.77 [-2.14 ; 0.61] |
| Week 15 | n= 6 (75.0%) \| 32.21 (2.25) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 7 (87.5%) \| 30.43 (4.93) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 6 (75.0%) \| 32.00 (2.19) | n= 4 (80.0%) \| 32.94 (0.79) | -0.47 [-1.84 ; 0.89] |
| Week 21 | n= 6 (75.0%) \| 33.17 (2.79) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (75.0%) \| 32.17 (2.23) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (75.0%) \| 32.83 (1.72) | n= 5 (100.0%) \| 34.60 (1.14) | -1.08 [-2.44 ; 0.27] |
| Week 27 | n= 6 (75.0%) \| 33.00 (2.37) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 5 (62.5%) \| 33.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 6 (75.0%) \| 33.33 (2.16) | n= 2 (40.0%) \| 35.50 (0.71) | -0.95 [-2.78 ; 0.89] |
| Week 33 | n= 6 (75.0%) \| 33.67 (1.86) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 6 (75.0%) \| 33.33 (2.42) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 5 (62.5%) \| 32.80 (2.77) | n= 3 (60.0%) \| 33.67 (0.58) | -0.33 [-1.90 ; 1.24] |
| Week 39 | n= 5 (62.5%) \| 32.80 (2.59) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 5 (62.5%) \| 32.80 (3.11) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 6 (75.0%) \| 33.77 (1.87) | n= 1 (20.0%) \| 35.00 ( / ) | [Not calculable] |
| Week 45 | n= 5 (62.5%) \| 32.00 (4.69) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (75.0%) \| 32.77 (2.93) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (75.0%) \| 33.67 (2.07) | n= 1 (20.0%) \| 32.63 ( / ) | [Not calculable] |
| Week 51 | n= 6 (75.0%) \| 32.33 (2.58) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 5 (62.5%) \| 33.20 (2.59) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 5 (62.5%) \| 33.20 (2.95) | n= 1 (20.0%) \| 35.00 ( / ) | [Not calculable] |
| Week 57 | n= 4 (50.0%) \| 33.25 (2.06) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 5 (62.5%) \| 33.15 (3.10) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 5 (62.5%) \| 33.60 (2.30) | n= 1 (20.0%) \| 34.00 ( / ) | [Not calculable] |
| Week 63 | n= 3 (37.5%) \| 34.00 (2.00) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 5 (62.5%) \| 32.80 (4.09) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 4 (50.0%) \| 34.00 (2.16) | n= 1 (20.0%) \| 35.00 ( / ) | [Not calculable] |
| Week 69 | n= 2 (25.0%) \| 32.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 3 (37.5%) \| 34.67 (2.31) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (37.5%) \| 33.33 (3.06) | [No Data] | [No Data for at least 1 arm] |
| Week 75 | n= 2 (25.0%) \| 34.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (37.5%) \| 34.67 (2.31) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 1 (12.5%) \| 34.00 ( / ) | n= 1 (20.0%) \| 34.00 ( / ) | [Not calculable] |
| Week 81 | n= 2 (25.0%) \| 34.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (25.0%) \| 36.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (25.0%) \| 35.50 (0.71) | n= 1 (20.0%) \| 33.00 ( / ) | [Not calculable] |
| Week 87 | n= 2 (25.0%) \| 36.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (25.0%) \| 35.44 (0.80) | [No Data] | [No Data for at least 1 arm] |
| Week 93 | n= 1 (12.5%) \| 36.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 1 (12.5%) \| 36.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 1 (12.5%) \| 36.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 1 (12.5%) \| 36.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (12.5%) \| 33.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (12.5%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 (12.5%) \| 36.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 (12.5%) \| 35.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (12.5%) \| 32.00 ( / ) | n= 3 (60.0%) \| 34.00 (2.00) | [Not calculable] |
| Week 202 | n= 1 (12.5%) \| 20.00 ( / ) | n= 2 (40.0%) \| 33.50 (3.54) | [Not calculable] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:49

TABLE 7.4.3: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 65** | | | |
| N subjects in population | N=40 | N=46 | |
| Week 3 | n= 37 (92.5%) \|-0.38 (2.34) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 34 (85.0%) \|-0.41 (2.50) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 36 (90.0%) \|-0.66 (3.63) | n= 42 (91.3%) \|-1.29 (3.45) | 0.18 [-0.27 ; 0.62] |
| Week 9 | n= 36 (90.0%) \|-0.88 (4.19) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (87.5%) \|-1.37 (3.76) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 36 (90.0%) \|-0.47 (3.53) | n= 38 (82.6%) \|-1.82 (3.62) | 0.37 [-0.09 ; 0.84] |
| Week 15 | n= 34 (85.0%) \|-0.84 (4.27) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 37 (92.5%) \|-0.31 (3.47) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 32 (80.0%) \|-0.59 (2.88) | n= 39 (84.8%) \|-0.75 (3.94) | 0.05 [-0.43 ; 0.52] |
| Week 21 | n= 36 (90.0%) \|-0.08 (3.19) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 35 (87.5%) \|-0.94 (3.18) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 36 (90.0%) \|-0.44 (3.17) | n= 36 (78.3%) \|-1.17 (3.94) | 0.20 [-0.26 ; 0.67] |
| Week 27 | n= 34 (85.0%) \|-0.41 (3.34) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 33 (82.5%) \|-0.15 (3.52) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 33 (82.5%) \|-0.39 (3.47) | n= 29 (63.0%) \|-1.00 (2.62) | 0.19 [-0.31 ; 0.70] |
| Week 33 | n= 36 (90.0%) \|-0.52 (3.64) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 34 (85.0%) \|-0.94 (3.82) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 31 (77.5%) \|-0.48 (3.41) | n= 32 (69.6%) \|-1.22 (3.46) | 0.21 [-0.29 ; 0.71] |
| Week 39 | n= 33 (82.5%) \|-0.30 (3.33) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 34 (85.0%) \|-0.26 (3.73) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 30 (75.0%) \|-0.33 (3.59) | n= 30 (65.2%) \|-1.07 (3.00) | 0.22 [-0.29 ; 0.73] |
| Week 45 | n= 32 (80.0%) \|-0.99 (3.85) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 33 (82.5%) \|-0.96 (3.18) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 33 (82.5%) \|-0.54 (3.81) | n= 24 (52.2%) \|-0.98 (2.38) | 0.13 [-0.40 ; 0.66] |
| Week 51 | n= 32 (80.0%) \|-0.64 (3.66) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 34 (85.0%) \|-0.14 (3.18) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 30 (75.0%) \|-0.71 (3.27) | n= 26 (56.5%) \|-1.18 (2.97) | 0.15 [-0.38 ; 0.68] |
| Week 57 | n= 32 (80.0%) \|-0.83 (4.00) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 28 (70.0%) \|-0.41 (3.61) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 31 (77.5%) \|-0.22 (3.70) | n= 19 (41.3%) \|-1.05 (3.27) | 0.23 [-0.35 ; 0.81] |
| Week 63 | n= 30 (75.0%) \|-0.36 (3.81) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 27 (67.5%) \|-0.62 (4.71) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (80.0%) \|-0.34 (3.85) | n= 19 (41.3%) \|-1.11 (3.02) | 0.21 [-0.36 ; 0.78] |
| Week 69 | n= 29 (72.5%) \|-1.51 (5.03) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 28 (70.0%) \|-0.37 (4.31) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (62.5%) \| 0.20 (4.35) | n= 18 (39.1%) \|-1.22 (3.24) | 0.35 [-0.26 ; 0.97] |
| Week 75 | n= 25 (62.5%) \| 0.16 (4.08) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (60.0%) \| 0.38 (4.11) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (60.0%) \|-0.17 (5.69) | n= 16 (34.8%) \|-0.13 (3.14) | -0.01 [-0.65 ; 0.63] |
| Week 81 | n= 23 (57.5%) \|-0.13 (3.24) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (62.5%) \| 0.28 (3.74) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (50.0%) \| 0.35 (3.38) | n= 13 (28.3%) \|-0.46 (3.36) | 0.24 [-0.48 ; 0.95] |
| Week 87 | n= 19 (47.5%) \|-0.26 (2.84) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (47.5%) \| 0.32 (3.20) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 20 (50.0%) \|-0.84 (3.20) | n= 11 (23.9%) \|-0.55 (5.28) | -0.07 [-0.82 ; 0.68] |
| Week 93 | n= 19 (47.5%) \|-0.05 (2.95) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (42.5%) \|-0.54 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (42.5%) \|-0.53 (3.62) | n= 7 (15.2%) \|-0.57 (3.51) | 0.01 [-0.89 ; 0.91] |
| Week 99 | n= 13 (32.5%) \|-0.15 (4.18) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (30.0%) \|-0.17 (3.30) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (30.0%) \| 0.58 (3.23) | n= 6 (13.0%) \| 0.67 (3.27) | -0.02 [-1.03 ; 0.99] |
| Week 105 | n= 11 (27.5%) \| 0.55 (3.11) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (17.5%) \| 0.71 (4.15) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (22.5%) \|-1.00 (4.15) | n= 2 ( 4.3%) \|-2.00 (5.66) | 0.21 [-1.41 ; 1.83] |
| Week 111 | n= 7 (17.5%) \|-0.71 (4.35) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (17.5%) \|-0.43 (4.35) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (15.0%) \|-1.00 (4.94) | n= 3 ( 6.5%) \|-1.33 (2.08) | 0.07 [-1.42 ; 1.56] |
| Week 117 | n= 5 (12.5%) \| 0.80 (3.42) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (12.5%) \|-1.40 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (15.0%) \|-1.33 (5.09) | n= 1 ( 2.2%) \|-1.63 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 2.5%) \|-2.00 ( / ) | n= 1 ( 2.2%) \|-8.00 ( / ) | [Not calculable] |
| Week 201 | n= 4 (10.0%) \|-0.50 (1.73) | n= 9 (19.6%) \|-1.44 (5.55) | 0.18 [-1.05 ; 1.42] |
| Week 202 | [No Data] | n= 7 (15.2%) \|-0.57 (4.24) | [No Data for at least 1 arm] |
| **>= 65 AND < 75** | | | |
| N subjects in population | N=23 | N=17 | |
| Week 3 | n= 21 (91.3%) \|-0.08 (2.24) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 20 (87.0%) \|-1.15 (4.13) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 19 (82.6%) \|-1.29 (4.27) | n= 17 (100.0%) \|-0.49 (3.29) | -0.20 [-0.87 ; 0.46] |
| Week 9 | n= 18 (78.3%) \|-0.92 (3.52) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 18 (78.3%) \|-0.16 (3.20) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 18 (78.3%) \|-0.38 (3.96) | n= 12 (70.6%) \|-0.48 (1.84) | 0.03 [-0.71 ; 0.77] |
| Week 15 | n= 14 (60.9%) \|-0.61 (3.80) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 18 (78.3%) \|-0.74 (3.87) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 18 (78.3%) \|-0.33 (3.22) | n= 10 (58.8%) \|-1.65 (2.77) | 0.42 [-0.38 ; 1.21] |
| Week 21 | n= 17 (73.9%) \|-0.73 (3.60) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (65.2%) \|-1.01 (2.20) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 15 (65.2%) \| 0.23 (4.27) | n= 7 (41.2%) \|-0.23 (1.88) | 0.12 [-0.80 ; 1.04] |
| Week 27 | n= 15 (65.2%) \| 1.30 (2.94) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 14 (60.9%) \| 0.10 (3.59) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 15 (65.2%) \|-0.44 (3.16) | n= 11 (64.7%) \|-1.16 (1.97) | 0.26 [-0.54 ; 1.05] |
| Week 33 | n= 14 (60.9%) \|-1.07 (1.90) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (56.5%) \|-0.34 (2.41) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 12 (52.2%) \| 0.80 (3.04) | n= 11 (64.7%) \| 0.44 (2.08) | 0.13 [-0.71 ; 0.97] |
| Week 39 | n= 13 (56.5%) \| 0.25 (2.72) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 13 (56.5%) \|-0.95 (3.53) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 15 (65.2%) \|-1.32 (4.23) | n= 10 (58.8%) \|-0.59 (2.82) | -0.19 [-1.01 ; 0.63] |
| Week 45 | n= 11 (47.8%) \|-0.86 (4.25) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 12 (52.2%) \|-0.42 (2.64) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 13 (56.5%) \|-0.37 (3.16) | n= 10 (58.8%) \|-0.91 (5.05) | 0.13 [-0.72 ; 0.97] |
| Week 51 | n= 13 (56.5%) \|-0.34 (3.20) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (56.5%) \|-0.49 (3.10) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 11 (47.8%) \|-0.27 (3.25) | n= 10 (58.8%) \|-0.38 (2.70) | 0.03 [-0.84 ; 0.91] |
| Week 57 | n= 12 (52.2%) \| 0.27 (2.01) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 13 (56.5%) \|-0.91 (4.26) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 12 (52.2%) \|-0.20 (3.16) | n= 10 (58.8%) \| 0.13 (2.62) | -0.11 [-0.97 ; 0.75] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 63 | n= 9 (39.1%) \|-0.60 (3.04) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (47.8%) \|-0.80 (3.75) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (34.8%) \| 0.40 (2.83) | n= 9 (52.9%) \| 0.25 (2.12) | 0.06 [-0.93 ; 1.04] |
| Week 69 | n= 7 (30.4%) \| 0.60 (3.67) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (30.4%) \|-0.86 (3.39) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (30.4%) \|-0.48 (2.52) | n= 10 (58.8%) \|-0.88 (2.11) | 0.16 [-0.84 ; 1.16] |
| Week 75 | n= 8 (34.8%) \|-0.67 (3.18) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (21.7%) \| 1.11 (4.03) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (26.1%) \|-0.63 (3.31) | n= 7 (41.2%) \| 0.84 (2.17) | -0.50 [-1.65 ; 0.66] |
| Week 81 | n= 4 (17.4%) \|-0.34 (4.18) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (26.1%) \|-0.06 (4.55) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (21.7%) \|-1.88 (4.96) | n= 6 (35.3%) \|-0.17 (1.33) | -0.45 [-1.72 ; 0.82] |
| Week 87 | n= 3 (13.0%) \|-6.00 (3.46) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 4 (17.4%) \|-3.34 (3.25) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (17.4%) \|-2.09 (4.03) | n= 6 (35.3%) \|-0.10 (1.29) | -0.67 [-2.06 ; 0.71] |
| Week 93 | n= 3 (13.0%) \|-3.46 (4.02) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (17.4%) \|-1.34 (4.56) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (13.0%) \|-2.33 (2.08) | n= 3 (17.6%) \|-0.67 (0.58) | -0.87 [-2.82 ; 1.07] |
| Week 99 | n= 3 (13.0%) \|-1.79 (3.00) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 ( 8.7%) \|-1.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (13.0%) \|-1.46 (3.08) | n= 3 (17.6%) \|-1.00 (1.00) | -0.16 [-1.98 ; 1.66] |
| Week 105 | n= 2 ( 8.7%) \|-2.69 (4.68) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 ( 4.3%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 ( 8.7%) \|-4.06 (2.92) | n= 2 (11.8%) \| 0.50 (0.71) | -1.23 [-4.32 ; 1.86] |
| Week 113 | n= 1 ( 4.3%) \|-0.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 4.3%) \| 2.00 ( / ) | n= 2 (11.8%) \|-0.50 (0.71) | [Not calculable] |
| Week 117 | n= 1 ( 4.3%) \| 2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 4.3%) \|-8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 4.3%) \|-2.75 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 4.3%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.3%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 4.3%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 4.3%) \|-2.75 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 4.3%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.3%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 4.3%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 4.3%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 4.3%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.3%) \|-0.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (13.0%) \|-2.33 (3.21) | n= 4 (23.5%) \|-2.75 (5.91) | 0.07 [-1.58 ; 1.72] |
| Week 202 | n= 1 ( 4.3%) \|-2.00 ( / ) | n= 2 (11.8%) \| 1.50 (0.71) | [Not calculable] |
| **>= 75** | | | |
| N subjects in population | N=8 | N=5 | |
| Week 3 | n= 8 (100.0%) \| 0.50 (2.00) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 7 (87.5%) \|-0.50 (1.66) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (87.5%) \|-0.43 (2.07) | n= 4 (80.0%) \|-2.00 (3.37) | 0.56 [-0.77 ; 1.88] |
| Week 9 | n= 6 (75.0%) \|-3.00 (2.97) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 7 (87.5%) \|-2.07 (1.97) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 5 (62.5%) \|-2.24 (2.32) | n= 5 (100.0%) \|-0.40 (1.52) | -0.85 [-2.24 ; 0.54] |
| Week 15 | n= 6 (75.0%) \|-0.46 (3.47) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 7 (87.5%) \|-1.43 (3.95) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 19 | n= 6 (75.0%) \|-0.67 (5.13) | n= 4 (80.0%) \|-1.06 (1.49) | 0.09 [-1.26 ; 1.43] |
| Week 21 | n= 6 (75.0%) \| 0.50 (5.96) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (75.0%) \|-0.50 (4.32) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (75.0%) \| 0.17 (4.54) | n= 5 (100.0%) \| 0.40 (2.07) | -0.06 [-1.31 ; 1.19] |
| Week 27 | n= 6 (75.0%) \| 0.33 (5.99) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 5 (62.5%) \| 0.80 (5.26) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 6 (75.0%) \| 0.67 (6.06) | n= 2 (40.0%) \| 1.50 (2.12) | -0.13 [-1.87 ; 1.61] |
| Week 33 | n= 6 (75.0%) \| 1.00 (4.73) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 6 (75.0%) \| 0.67 (4.80) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 5 (62.5%) \| 0.80 (5.54) | n= 3 (60.0%) \| 0.00 (1.73) | 0.15 [-1.41 ; 1.71] |
| Week 39 | n= 5 (62.5%) \| 0.60 (4.93) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 5 (62.5%) \|-1.60 (1.95) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 6 (75.0%) \| 1.10 (5.19) | n= 1 (20.0%) \| 2.00 ( / ) | [Not calculable] |
| Week 45 | n= 5 (62.5%) \|-0.20 (7.43) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (75.0%) \| 0.10 (5.03) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (75.0%) \| 1.00 (4.52) | n= 1 (20.0%) \|-0.38 ( / ) | [Not calculable] |
| Week 51 | n= 6 (75.0%) \|-0.33 (4.08) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 5 (62.5%) \| 0.40 (4.72) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 5 (62.5%) \| 0.40 (4.83) | n= 1 (20.0%) \| 2.00 ( / ) | [Not calculable] |
| Week 57 | n= 4 (50.0%) \| 1.00 (5.60) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 5 (62.5%) \| 0.35 (5.93) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 5 (62.5%) \| 0.80 (4.32) | n= 1 (20.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 63 | n= 3 (37.5%) \| 2.67 (6.43) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 5 (62.5%) \| 0.00 (7.11) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 4 (50.0%) \| 1.50 (6.03) | n= 1 (20.0%) \| 2.00 ( / ) | [Not calculable] |
| Week 69 | n= 2 (25.0%) \| 2.50 (10.61) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 3 (37.5%) \| 3.33 (7.77) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (37.5%) \| 2.00 (7.55) | [No Data] | [No Data for at least 1 arm] |
| Week 75 | n= 2 (25.0%) \| 4.50 (10.61) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (37.5%) \| 3.33 (7.77) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 1 (12.5%) \| 10.00 ( / ) | n= 1 (20.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 81 | n= 2 (25.0%) \| 5.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (25.0%) \| 6.50 (7.78) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (25.0%) \| 6.00 (7.07) | n= 1 (20.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 87 | n= 2 (25.0%) \| 6.50 (7.78) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (25.0%) \| 5.94 (6.98) | [No Data] | [No Data for at least 1 arm] |
| Week 93 | n= 1 (12.5%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 1 (12.5%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 1 (12.5%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 1 (12.5%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (12.5%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (12.5%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 (12.5%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 (12.5%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (12.5%) \| 5.00 ( / ) | n= 3 (60.0%) \|-0.33 (0.58) | [Not calculable] |
| Week 202 | n= 1 (12.5%) \|-9.00 ( / ) | n= 2 (40.0%) \|-0.50 (0.71) | [Not calculable] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.

TABLE 7.4.3: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Age Categorization 2 Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **< 65** | | | | |
| Nr subjects used | n=39 | n=45 | | |
| Week 7 | -0.74 (0.53) [-1.79 ; 0.32] | -1.46 (0.50) [-2.46 ;-0.47] | 0.73 (0.73) [-0.73 ; 2.18] | 0.22 [-0.22 ; 0.67] |
| Week 13 | -0.65 (0.54) [-1.73 ; 0.43] | -1.84 (0.52) [-2.88 ;-0.80] | 1.19 (0.76) [-0.31 ; 2.69] | 0.36 [-0.10 ; 0.82] |
| Week 19 | -0.37 (0.49) [-1.35 ; 0.60] | -0.97 (0.46) [-1.89 ;-0.06] | 0.60 (0.67) [-0.74 ; 1.93] | 0.21 [-0.26 ; 0.68] |
| Week 25 | -0.37 (0.49) [-1.35 ; 0.60] | -1.10 (0.48) [-2.06 ;-0.14] | 0.73 (0.69) [-0.64 ; 2.09] | 0.25 [-0.22 ; 0.71] |
| Week 31 | -0.35 (0.53) [-1.41 ; 0.70] | -0.63 (0.54) [-1.70 ; 0.44] | 0.27 (0.76) [-1.23 ; 1.78] | 0.09 [-0.41 ; 0.59] |
| Week 37 | -0.45 (0.60) [-1.64 ; 0.75] | -1.41 (0.59) [-2.60 ;-0.23] | 0.97 (0.84) [-0.71 ; 2.65] | 0.29 [-0.21 ; 0.78] |
| Week 43 | -0.14 (0.56) [-1.25 ; 0.97] | -1.06 (0.57) [-2.19 ; 0.06] | 0.92 (0.79) [-0.66 ; 2.50] | 0.30 [-0.21 ; 0.80] |
| Week 49 | -0.43 (0.55) [-1.53 ; 0.67] | -0.48 (0.61) [-1.71 ; 0.74] | 0.05 (0.82) [-1.59 ; 1.69] | 0.02 [-0.51 ; 0.54] |
| Week 55 | -0.40 (0.57) [-1.54 ; 0.74] | -1.00 (0.62) [-2.24 ; 0.25] | 0.60 (0.85) [-1.08 ; 2.29] | 0.19 [-0.34 ; 0.72] |
| Week 61 | -0.40 (0.55) [-1.51 ; 0.70] | -0.91 (0.67) [-2.25 ; 0.42] | 0.51 (0.87) [-1.22 ; 2.24] | 0.17 [-0.41 ; 0.74] |
| Week 67 | -0.52 (0.57) [-1.65 ; 0.62] | -1.08 (0.71) [-2.50 ; 0.34] | 0.56 (0.91) [-1.26 ; 2.38] | 0.17 [-0.40 ; 0.74] |
| Week 73 | -0.38 (0.67) [-1.72 ; 0.96] | -1.26 (0.81) [-2.88 ; 0.37] | 0.88 (1.05) [-1.23 ; 2.99] | 0.25 [-0.36 ; 0.86] |
| Week 79 | -0.78 (0.88) [-2.53 ; 0.98] | -0.74 (1.08) [-2.91 ; 1.42] | -0.03 (1.39) [-2.82 ; 2.75] | -0.01 [-0.64 ; 0.62] |
| Week 85 | -0.50 (0.57) [-1.65 ; 0.64] | -0.70 (0.71) [-2.13 ; 0.73] | 0.20 (0.91) [-1.64 ; 2.03] | 0.07 [-0.62 ; 0.77] |
| Week 91 | -0.78 (0.76) [-2.32 ; 0.75] | -0.76 (1.00) [-2.77 ; 1.26] | -0.03 (1.25) [-2.56 ; 2.50] | -0.01 [-0.74 ; 0.73] |
| Overall post-baseline period estimate | -0.48 (0.30) [-1.08 ; 0.11] | -1.03 (0.33) [-1.69 ;-0.36] | 0.54 (0.45) [-0.35 ; 1.44] | 0.26 [-0.17 ; 0.70] |
| **>= 65 AND < 75** | | | | |
| Nr subjects used | n=22 | n=17 | | |
| Week 7 | -1.68 (0.83) [-3.37 ; 0.02] | -0.90 (0.90) [-2.73 ; 0.93] | -0.78 (1.22) [-3.27 ; 1.71] | -0.21 [-0.86 ; 0.45] |
| Week 13 | -0.34 (0.70) [-1.77 ; 1.08] | -0.52 (0.85) [-2.26 ; 1.21] | 0.18 (1.10) [-2.07 ; 2.42] | 0.06 [-0.67 ; 0.79] |
| Week 19 | -0.23 (0.65) [-1.56 ; 1.11] | -1.63 (0.86) [-3.39 ; 0.13] | 1.40 (1.08) [-0.80 ; 3.61] | 0.49 [-0.29 ; 1.28] |
| Week 31 | -0.20 (0.74) [-1.72 ; 1.32] | -1.19 (0.89) [-3.03 ; 0.64] | 0.99 (1.16) [-1.39 ; 3.38] | 0.33 [-0.45 ; 1.12] |
| Week 37 | 0.84 (0.68) [-0.55 ; 2.23] | 0.39 (0.74) [-1.15 ; 1.92] | 0.45 (1.01) [-1.62 ; 2.52] | 0.18 [-0.64 ; 1.00] |
| Week 43 | -1.06 (0.85) [-2.80 ; 0.68] | -0.49 (1.03) [-2.59 ; 1.61] | -0.57 (1.34) [-3.30 ; 2.16] | -0.17 [-0.97 ; 0.63] |
| Week 49 | -0.58 (1.00) [-2.62 ; 1.46] | -0.94 (1.15) [-3.30 ; 1.41] | 0.36 (1.53) [-2.75 ; 3.48] | 0.10 [-0.73 ; 0.92] |
| Week 55 | -0.26 (0.72) [-1.74 ; 1.22] | -0.49 (0.78) [-2.10 ; 1.12] | 0.23 (1.07) [-1.96 ; 2.42] | 0.09 [-0.77 ; 0.95] |
| Week 61 | -0.21 (0.76) [-1.78 ; 1.36] | -0.01 (0.84) [-1.75 ; 1.73] | -0.20 (1.13) [-2.55 ; 2.14] | -0.07 [-0.91 ; 0.77] |
| Overall post-baseline period estimate | -0.41 (0.40) [-1.21 ; 0.38] | -0.64 (0.47) [-1.59 ; 0.31] | 0.23 (0.62) [-1.01 ; 1.47] | 0.12 [-0.51 ; 0.75] |
| **>= 75** | | | | |
| Nr subjects used | n=8 | n=5 | | |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.2115 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:50

TABLE 7.4.4: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **US/Canada/Western Europe/Northern Europe** | | |
| | N=38 | N=34 |
| **Rest of World (ROW)** | | |
| | N=33 | N=34 |
| **Subjects with Baseline Value** | | |
| **US/Canada/Western Europe/Northern Europe** | | |
| | 36 (94.7%) | 34 (100.0%) |
| **Rest of World (ROW)** | | |
| | 33 (100.0%) | 33 (97.1%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **US/Canada/Western Europe/Northern Europe** | | |
| | 38 (100.0%) | 33 (97.1%) |
| **Rest of World (ROW)** | | |
| | 33 (100.0%) | 33 (97.1%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **US/Canada/Western Europe/Northern Europe** | | |
| | 36 (94.7%) | 33 (97.1%) |
| **Rest of World (ROW)** | | |
| | 33 (100.0%) | 32 (94.1%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:50

TABLE 7.4.4: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **US/Canada/Western Europe/Northern Europe** | | | |
| N subjects in population | N=38 | N=34 | |
| Baseline | n= 36 (94.7%) \| 31.66 (4.37) | n= 34 (100.0%) \| 31.67 (3.54) | -0.00 [-0.47 ; 0.47] |
| Week 3 | n= 36 (94.7%) \| 31.28 (3.87) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 34 (89.5%) \| 31.24 (4.31) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 34 (89.5%) \| 30.40 (4.31) | n= 31 (91.2%) \| 30.66 (2.84) | -0.07 [-0.56 ; 0.42] |
| Week 9 | n= 31 (81.6%) \| 30.92 (4.22) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 32 (84.2%) \| 30.34 (4.05) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 30 (78.9%) \| 31.24 (3.64) | n= 26 (76.5%) \| 31.46 (3.15) | -0.06 [-0.59 ; 0.47] |
| Week 15 | n= 27 (71.1%) \| 30.87 (3.94) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 33 (86.8%) \| 30.77 (4.26) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 30 (78.9%) \| 31.67 (3.16) | n= 26 (76.5%) \| 31.26 (3.03) | 0.13 [-0.40 ; 0.66] |
| Week 21 | n= 29 (76.3%) \| 31.69 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 27 (71.1%) \| 30.22 (3.89) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 31 (81.6%) \| 30.98 (3.73) | n= 24 (70.6%) \| 31.13 (2.91) | -0.04 [-0.58 ; 0.49] |
| Week 27 | n= 28 (73.7%) \| 31.71 (3.83) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 26 (68.4%) \| 31.04 (3.83) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 25 (65.8%) \| 31.52 (4.06) | n= 20 (58.8%) \| 31.20 (4.35) | 0.08 [-0.52 ; 0.67] |
| Week 33 | n= 29 (76.3%) \| 30.88 (4.40) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 28 (73.7%) \| 30.25 (4.93) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 24 (63.2%) \| 30.97 (4.98) | n= 23 (67.6%) \| 30.77 (3.45) | 0.05 [-0.53 ; 0.62] |
| Week 39 | n= 27 (71.1%) \| 30.89 (4.58) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 28 (73.7%) \| 30.71 (4.63) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 28 (73.7%) \| 31.25 (4.29) | n= 20 (58.8%) \| 31.64 (4.17) | -0.09 [-0.67 ; 0.49] |
| Week 45 | n= 23 (60.5%) \| 30.14 (4.97) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 26 (68.4%) \| 30.88 (4.78) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 28 (73.7%) \| 30.76 (5.10) | n= 17 (50.0%) \| 31.71 (3.39) | -0.21 [-0.82 ; 0.41] |
| Week 51 | n= 27 (71.1%) \| 30.81 (5.02) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 28 (73.7%) \| 31.01 (4.83) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 26 (68.4%) \| 30.99 (5.27) | n= 17 (50.0%) \| 31.00 (3.12) | -0.00 [-0.62 ; 0.62] |
| Week 57 | n= 26 (68.4%) \| 30.06 (5.05) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 24 (63.2%) \| 30.48 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 24 (63.2%) \| 31.07 (5.07) | n= 13 (38.2%) \| 31.08 (3.59) | -0.00 [-0.69 ; 0.68] |
| Week 63 | n= 21 (55.3%) \| 29.54 (5.62) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 21 (55.3%) \| 29.39 (6.43) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 23 (60.5%) \| 30.96 (5.25) | n= 13 (38.2%) \| 30.77 (4.19) | 0.04 [-0.65 ; 0.73] |
| Week 69 | n= 20 (52.6%) \| 30.36 (5.56) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 20 (52.6%) \| 30.64 (5.22) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (42.1%) \| 31.00 (5.15) | n= 14 (41.2%) \| 29.93 (4.51) | 0.21 [-0.52 ; 0.95] |
| Week 75 | n= 16 (42.1%) \| 31.19 (4.68) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (42.1%) \| 30.63 (4.62) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 15 (39.5%) \| 29.13 (7.53) | n= 11 (32.4%) \| 31.55 (3.50) | -0.38 [-1.18 ; 0.42] |
| Week 81 | n= 15 (39.5%) \| 30.80 (5.10) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 16 (42.1%) \| 30.56 (4.62) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (28.9%) \| 31.27 (4.29) | n= 10 (29.4%) \| 31.20 (4.10) | 0.02 [-0.86 ; 0.89] |
| Week 87 | n= 10 (26.3%) \| 29.30 (5.14) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 11 (28.9%) \| 30.18 (4.79) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 12 (31.6%) \| 28.77 (5.39) | n= 9 (26.5%) \| 31.56 (4.10) | -0.55 [-1.45 ; 0.36] |
| Week 93 | n= 12 (31.6%) \| 29.75 (4.33) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (28.9%) \| 29.34 (5.28) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (31.6%) \| 29.45 (5.00) | n= 5 (14.7%) \| 31.40 (4.83) | -0.37 [-1.46 ; 0.71] |
| Week 99 | n= 9 (23.7%) \| 28.89 (5.73) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (15.8%) \| 29.50 (4.28) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (21.1%) \| 31.38 (3.46) | n= 5 (14.7%) \| 32.60 (2.19) | -0.37 [-1.55 ; 0.81] |
| Week 105 | n= 7 (18.4%) \| 30.57 (4.28) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (10.5%) \| 30.50 (3.70) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (18.4%) \| 28.57 (4.24) | n= 2 ( 5.9%) \| 34.00 (1.41) | -1.22 [-3.04 ; 0.60] |
| Week 111 | n= 4 (10.5%) \| 29.75 (5.19) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (10.5%) \| 30.25 (4.65) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 (10.5%) \| 29.50 (4.80) | n= 3 ( 8.8%) \| 32.33 (0.58) | -0.64 [-2.35 ; 1.07] |
| Week 117 | n= 4 (10.5%) \| 32.75 (2.50) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 (10.5%) \| 29.50 (4.80) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (13.2%) \| 31.60 (5.68) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.6%) \| 35.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.6%) \| 33.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (10.5%) \| 34.00 (2.31) | n= 7 (20.6%) \| 28.71 (6.24) | 0.92 [-0.45 ; 2.29] |
| Week 202 | [No Data] | n= 4 (11.8%) \| 32.50 (2.38) | [No Data for at least 1 arm] |
| **Rest of World (ROW)** | | | |
| N subjects in population | N=33 | N=34 | |
| Baseline | n= 33 (100.0%) \| 31.64 (4.52) | n= 33 (97.1%) \| 31.28 (4.90) | 0.08 [-0.41 ; 0.56] |
| Week 3 | n= 31 (93.9%) \| 31.81 (4.12) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 29 (87.9%) \| 31.02 (5.20) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 30 (90.9%) \| 31.07 (4.20) | n= 33 (97.1%) \| 29.94 (4.89) | 0.24 [-0.26 ; 0.74] |
| Week 9 | n= 30 (90.9%) \| 31.07 (4.37) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 29 (87.9%) \| 31.40 (3.85) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 30 (90.9%) \| 31.53 (4.19) | n= 29 (85.3%) \| 30.10 (4.02) | 0.34 [-0.18 ; 0.86] |
| Week 15 | n= 27 (81.8%) \| 31.68 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 30 (90.9%) \| 32.07 (4.11) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 27 (81.8%) \| 32.44 (3.00) | n= 28 (82.4%) \| 31.04 (3.75) | 0.41 [-0.13 ; 0.95] |
| Week 21 | n= 30 (90.9%) \| 31.90 (4.66) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 29 (87.9%) \| 31.72 (3.92) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 27 (81.8%) \| 33.04 (3.31) | n= 25 (73.5%) \| 31.88 (3.30) | 0.34 [-0.21 ; 0.90] |
| Week 27 | n= 28 (84.8%) \| 33.50 (3.80) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 26 (78.8%) \| 33.15 (3.12) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 29 (87.9%) \| 32.59 (4.31) | n= 22 (64.7%) \| 31.59 (3.28) | 0.25 [-0.31 ; 0.81] |
| Week 33 | n= 27 (81.8%) \| 32.81 (4.27) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 26 (78.8%) \| 32.85 (4.84) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 24 (72.7%) \| 33.21 (4.38) | n= 24 (70.6%) \| 31.88 (2.80) | 0.36 [-0.22 ; 0.93] |
| Week 39 | n= 25 (75.8%) \| 33.96 (1.90) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 24 (72.7%) \| 33.75 (2.64) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 24 (72.7%) \| 32.82 (3.57) | n= 22 (64.7%) \| 30.54 (3.99) | 0.59 [-0.01 ; 1.19] |
| Week 45 | n= 25 (75.8%) \| 32.52 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 25 (75.8%) \| 33.12 (2.99) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 24 (72.7%) \| 33.54 (2.70) | n= 19 (55.9%) \| 30.93 (4.43) | 0.72 [ 0.09 ; 1.35] |
| Week 51 | n= 24 (72.7%) \| 32.54 (3.09) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 24 (72.7%) \| 33.21 (2.64) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 20 (60.6%) \| 32.84 (2.93) | n= 21 (61.8%) \| 30.92 (3.74) | 0.56 [-0.07 ; 1.19] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 57 | n= 22 (66.7%) \| 33.50 (2.30) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 22 (66.7%) \| 32.81 (3.33) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 24 (72.7%) \| 33.38 (2.57) | n= 18 (52.9%) \| 30.72 (3.66) | 0.85 [ 0.20 ; 1.49] |
| Week 63 | n= 21 (63.6%) \| 33.48 (2.79) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (66.7%) \| 32.64 (3.30) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 21 (63.6%) \| 33.19 (2.32) | n= 17 (50.0%) \| 31.00 (3.39) | 0.75 [ 0.08 ; 1.43] |
| Week 69 | n= 18 (54.5%) \| 32.06 (4.36) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 18 (54.5%) \| 33.39 (3.16) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 19 (57.6%) \| 33.26 (2.51) | n= 14 (41.2%) \| 30.37 (2.75) | 1.08 [ 0.33 ; 1.83] |
| Week 75 | n= 19 (57.6%) \| 33.16 (2.57) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (48.5%) \| 33.63 (2.25) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 16 (48.5%) \| 33.54 (2.74) | n= 14 (41.2%) \| 30.93 (2.95) | 0.90 [ 0.13 ; 1.66] |
| Week 81 | n= 14 (42.4%) \| 33.07 (2.84) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (51.5%) \| 33.76 (2.84) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 16 (48.5%) \| 33.00 (3.48) | n= 11 (32.4%) \| 32.00 (2.28) | 0.32 [-0.47 ; 1.10] |
| Week 87 | n= 14 (42.4%) \| 32.29 (4.10) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 14 (42.4%) \| 32.63 (3.34) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 12 (36.4%) \| 32.83 (3.07) | n= 9 (26.5%) \| 32.56 (3.17) | 0.09 [-0.80 ; 0.97] |
| Week 93 | n= 11 (33.3%) \| 33.18 (2.89) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (33.3%) \| 33.00 (2.90) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 9 (27.3%) \| 32.89 (2.76) | n= 6 (17.6%) \| 33.00 (2.28) | -0.04 [-1.11 ; 1.03] |
| Week 99 | n= 8 (24.2%) \| 32.88 (3.14) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 8 (24.2%) \| 32.88 (2.59) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 7 (21.2%) \| 31.86 (3.63) | n= 5 (14.7%) \| 32.00 (3.16) | -0.04 [-1.24 ; 1.17] |
| Week 105 | n= 6 (18.2%) \| 31.17 (3.82) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (12.1%) \| 33.00 (2.58) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (12.1%) \| 29.97 (3.22) | n= 3 ( 8.8%) \| 29.67 (6.51) | 0.05 [-1.60 ; 1.71] |
| Week 111 | n= 3 ( 9.1%) \| 31.00 (2.00) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (12.1%) \| 32.63 (2.56) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 ( 9.1%) \| 33.00 (2.65) | n= 2 ( 5.9%) \| 33.00 (4.24) | 0.00 [-2.11 ; 2.11] |
| Week 117 | n= 3 ( 9.1%) \| 32.67 (4.16) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 ( 9.1%) \| 29.00 (5.00) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 ( 9.1%) \| 30.42 (2.24) | n= 1 ( 2.9%) \| 30.38 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 3.0%) \| 27.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 3.0%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.0%) \| 31.00 ( / ) | n= 1 ( 2.9%) \| 24.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 3.0%) \| 29.25 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 3.0%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.0%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 3.0%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 3.0%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 3.0%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 3.0%) \| 31.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.1%) \| 29.00 (4.83) | n= 9 (26.5%) \| 31.67 (2.29) | -0.78 [-2.05 ; 0.50] |
| Week 202 | n= 2 ( 6.1%) \| 25.00 (7.07) | n= 7 (20.6%) \| 32.29 (2.50) | -1.83 [-3.80 ; 0.14] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020

TABLE 7.4.4: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **US/Canada/Western Europe/Northern Europe** | | | |
| N subjects in population | N=38 | N=34 | |
| Week 3 | n= 35 (92.1%) \|-0.33 (2.52) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 32 (84.2%) \|-0.49 (2.08) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 32 (84.2%) \|-1.32 (2.88) | n= 31 (91.2%) \|-0.78 (3.09) | -0.18 [-0.68 ; 0.32] |
| Week 9 | n= 30 (78.9%) \|-1.30 (3.34) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 31 (81.6%) \|-1.54 (3.64) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 29 (76.3%) \|-0.92 (2.95) | n= 26 (76.5%) \|-0.49 (3.05) | -0.14 [-0.68 ; 0.39] |
| Week 15 | n= 27 (71.1%) \|-1.00 (3.93) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 32 (84.2%) \|-1.19 (2.99) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 29 (76.3%) \|-0.89 (2.99) | n= 26 (76.5%) \|-0.50 (2.94) | -0.13 [-0.66 ; 0.40] |
| Week 21 | n= 29 (76.3%) \|-0.50 (3.26) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 27 (71.1%) \|-1.48 (3.20) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 30 (78.9%) \|-0.77 (3.33) | n= 24 (70.6%) \|-0.48 (2.77) | -0.09 [-0.63 ; 0.45] |
| Week 27 | n= 27 (71.1%) \|-0.65 (2.81) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 26 (68.4%) \|-0.70 (3.50) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 25 (65.8%) \|-0.62 (3.56) | n= 20 (58.8%) \|-0.58 (2.57) | -0.01 [-0.61 ; 0.58] |
| Week 33 | n= 29 (76.3%) \|-1.13 (3.18) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 27 (71.1%) \|-1.39 (3.41) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 24 (63.2%) \|-0.34 (3.38) | n= 23 (67.6%) \|-0.65 (3.74) | 0.09 [-0.49 ; 0.66] |
| Week 39 | n= 26 (68.4%) \|-0.84 (3.28) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 28 (73.7%) \|-1.33 (3.15) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 27 (71.1%) \|-0.73 (3.28) | n= 20 (58.8%) \| 0.16 (3.05) | -0.28 [-0.86 ; 0.31] |
| Week 45 | n= 23 (60.5%) \|-1.49 (4.15) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 26 (68.4%) \|-1.58 (2.87) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 28 (73.7%) \|-1.13 (3.55) | n= 17 (50.0%) \| 0.08 (2.50) | -0.37 [-0.99 ; 0.24] |
| Week 51 | n= 27 (71.1%) \|-0.66 (3.23) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 28 (73.7%) \|-0.58 (3.33) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 26 (68.4%) \|-0.35 (3.27) | n= 17 (50.0%) \|-0.21 (3.12) | -0.04 [-0.66 ; 0.58] |
| Week 57 | n= 26 (68.4%) \|-1.28 (3.69) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 24 (63.2%) \|-0.76 (3.46) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 24 (63.2%) \|-0.67 (3.49) | n= 13 (38.2%) \| 0.11 (2.92) | -0.23 [-0.92 ; 0.46] |
| Week 63 | n= 21 (55.3%) \|-1.29 (3.48) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 21 (55.3%) \|-1.12 (4.68) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 23 (60.5%) \|-0.51 (3.61) | n= 13 (38.2%) \|-0.05 (2.46) | -0.14 [-0.83 ; 0.55] |
| Week 69 | n= 20 (52.6%) \|-1.28 (4.75) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 20 (52.6%) \|-1.26 (4.19) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (42.1%) \|-0.46 (4.40) | n= 14 (41.2%) \|-0.97 (3.13) | 0.13 [-0.60 ; 0.86] |
| Week 75 | n= 16 (42.1%) \|-0.34 (3.56) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (42.1%) \|-0.09 (3.88) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 15 (39.5%) \|-1.63 (6.19) | n= 11 (32.4%) \| 0.55 (2.84) | -0.42 [-1.22 ; 0.39] |
| Week 81 | n= 15 (39.5%) \|-0.43 (3.20) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 16 (42.1%) \|-0.52 (3.32) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (28.9%) \|-0.31 (2.51) | n= 10 (29.4%) \|-0.30 (2.41) | -0.00 [-0.88 ; 0.88] |
| Week 87 | n= 10 (26.3%) \|-1.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 11 (28.9%) \|-0.31 (2.78) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 12 (31.6%) \|-1.68 (3.25) | n= 9 (26.5%) \|-0.40 (2.29) | -0.42 [-1.32 ; 0.47] |
| Week 93 | n= 12 (31.6%) \|-0.70 (2.49) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (28.9%) \|-1.15 (3.53) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (31.6%) \|-1.42 (3.26) | n= 5 (14.7%) \|-0.60 (2.30) | -0.26 [-1.34 ; 0.83] |
| Week 99 | n= 9 (23.7%) \|-1.15 (4.34) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (15.8%) \|-1.50 (3.21) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (21.1%) \| 0.33 (2.92) | n= 5 (14.7%) \| 0.60 (2.41) | -0.09 [-1.26 ; 1.08] |
| Week 105 | n= 7 (18.4%) \| 0.23 (2.80) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (10.5%) \|-0.75 (2.75) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (18.4%) \|-1.71 (3.25) | n= 2 ( 5.9%) \| 1.50 (0.71) | -0.95 [-2.71 ; 0.82] |
| Week 111 | n= 4 (10.5%) \|-1.25 (3.30) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (10.5%) \|-2.25 (2.99) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 (10.5%) \|-3.25 (2.63) | n= 3 ( 8.8%) \|-1.00 (2.00) | -0.79 [-2.53 ; 0.95] |
| Week 117 | n= 4 (10.5%) \|-1.00 (2.16) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 (10.5%) \|-3.25 (2.63) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (13.2%) \|-2.20 (3.83) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.6%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.6%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (10.5%) \| 1.25 (2.50) | n= 7 (20.6%) \|-3.71 (4.46) | 1.16 [-0.25 ; 2.57] |
| Week 202 | [No Data] | n= 4 (11.8%) \|-1.25 (2.50) | [No Data for at least 1 arm] |
| **Rest of World (ROW)** | | | |
| N subjects in population | N=33 | N=34 | |
| Week 3 | n= 31 (93.9%) \|-0.00 (1.94) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 29 (87.9%) \|-0.85 (3.86) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 30 (90.9%) \|-0.30 (4.34) | n= 32 (94.1%) \|-1.44 (3.65) | 0.28 [-0.22 ; 0.79] |
| Week 9 | n= 30 (90.9%) \|-0.90 (4.43) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 29 (87.9%) \|-0.61 (3.23) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 30 (90.9%) \|-0.28 (4.11) | n= 29 (85.3%) \|-2.21 (3.16) | 0.52 [-0.00 ; 1.04] |
| Week 15 | n= 27 (81.8%) \|-0.48 (4.13) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 30 (90.9%) \| 0.10 (4.09) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 27 (81.8%) \|-0.12 (3.43) | n= 27 (79.4%) \|-1.37 (4.14) | 0.33 [-0.22 ; 0.87] |
| Week 21 | n= 30 (90.9%) \| 0.07 (3.93) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 29 (87.9%) \|-0.38 (2.82) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 27 (81.8%) \| 0.44 (3.78) | n= 24 (70.6%) \|-1.25 (4.23) | 0.42 [-0.15 ; 0.98] |
| Week 27 | n= 28 (84.8%) \| 0.89 (4.13) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 26 (78.8%) \| 0.73 (3.72) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 29 (87.9%) \|-0.00 (3.81) | n= 22 (64.7%) \|-1.23 (2.36) | 0.37 [-0.19 ; 0.93] |
| Week 33 | n= 27 (81.8%) \| 0.19 (3.58) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 26 (78.8%) \| 0.19 (3.71) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 24 (72.7%) \| 0.29 (3.75) | n= 23 (67.6%) \|-0.83 (2.50) | 0.35 [-0.24 ; 0.93] |
| Week 39 | n= 25 (75.8%) \| 0.72 (3.21) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 24 (72.7%) \| 0.33 (3.78) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 24 (72.7%) \|-0.14 (4.67) | n= 21 (61.8%) \|-1.87 (2.49) | 0.45 [-0.15 ; 1.04] |
| Week 45 | n= 25 (75.8%) \|-0.32 (4.41) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 25 (75.8%) \| 0.20 (3.46) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 24 (72.7%) \| 0.63 (3.73) | n= 18 (52.9%) \|-1.91 (3.64) | 0.67 [ 0.04 ; 1.31] |
| Week 51 | n= 24 (72.7%) \|-0.38 (3.90) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 24 (72.7%) \| 0.29 (3.18) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 20 (60.6%) \|-0.66 (3.60) | n= 20 (58.8%) \|-1.44 (2.62) | 0.24 [-0.39 ; 0.87] |
| Week 57 | n= 22 (66.7%) \| 0.64 (3.58) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 22 (66.7%) \|-0.15 (4.55) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 61 | n= 24 (72.7%) \| 0.46 (3.64) | n= 17 (50.0%) \|-1.13 (3.09) | 0.45 [-0.18 ; 1.09] |
| Week 63 | n= 21 (63.6%) \| 0.90 (3.95) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (66.7%) \|-0.09 (4.74) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 21 (63.6%) \| 0.48 (4.13) | n= 16 (47.1%) \|-1.01 (3.04) | 0.39 [-0.27 ; 1.06] |
| Week 69 | n= 18 (54.5%) \|-0.50 (5.51) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 18 (54.5%) \| 1.06 (4.53) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 19 (57.6%) \| 0.79 (4.18) | n= 14 (41.2%) \|-1.21 (2.66) | 0.54 [-0.17 ; 1.25] |
| Week 75 | n= 19 (57.6%) \| 0.68 (4.87) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 16 (48.5%) \| 1.63 (4.81) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 16 (48.5%) \| 1.66 (4.33) | n= 13 (38.2%) \|-0.09 (2.86) | 0.45 [-0.30 ; 1.21] |
| Week 81 | n= 14 (42.4%) \| 0.86 (4.02) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (51.5%) \| 1.65 (4.81) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 16 (48.5%) \| 0.81 (5.05) | n= 10 (29.4%) \|-0.40 (3.20) | 0.26 [-0.55 ; 1.07] |
| Week 87 | n= 14 (42.4%) \| 0.00 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 14 (42.4%) \| 0.56 (4.79) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 12 (36.4%) \|-0.42 (3.34) | n= 8 (23.5%) \|-0.38 (5.93) | -0.01 [-0.93 ; 0.91] |
| Week 93 | n= 11 (33.3%) \|-0.18 (3.89) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (33.3%) \|-0.09 (3.56) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 9 (27.3%) \| 0.22 (3.53) | n= 5 (14.7%) \|-0.60 (3.65) | 0.22 [-0.93 ; 1.36] |
| Week 99 | n= 8 (24.2%) \| 0.50 (3.25) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 8 (24.2%) \| 0.50 (2.98) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 7 (21.2%) \| 0.00 (3.74) | n= 4 (11.8%) \|-0.50 (3.42) | 0.13 [-1.17 ; 1.42] |
| Week 105 | n= 6 (18.2%) \|-0.17 (4.22) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 4 (12.1%) \| 1.50 (5.07) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (12.1%) \|-1.28 (5.71) | n= 2 ( 5.9%) \|-3.00 (4.24) | 0.26 [-1.68 ; 2.19] |
| Week 111 | n= 3 ( 9.1%) \| 0.00 (6.24) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 4 (12.1%) \| 1.38 (4.50) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 ( 9.1%) \| 3.00 (4.58) | n= 2 ( 5.9%) \|-1.00 (1.41) | 0.76 [-1.49 ; 3.01] |
| Week 117 | n= 3 ( 9.1%) \| 2.67 (3.06) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 ( 9.1%) \|-1.00 (7.55) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 ( 9.1%) \| 0.42 (5.70) | n= 1 ( 2.9%) \|-1.63 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 3.0%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 3.0%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 3.0%) \|-1.00 ( / ) | n= 1 ( 2.9%) \|-8.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 3.0%) \|-2.75 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 3.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 3.0%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 3.0%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 3.0%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 3.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 3.0%) \|-0.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 4 (12.1%) \|-2.25 (2.99) | n= 9 (26.5%) \| 0.11 (4.81) | -0.50 [-1.75 ; 0.75] |
| Week 202 | n= 2 ( 6.1%) \|-5.50 (4.95) | n= 7 (20.6%) \| 0.43 (3.87) | -1.30 [-3.14 ; 0.53] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:51

TABLE 7.4.4: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Geographic Region (IRT) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **US/Canada/Western Europe/Northern Europe** | | | | |
| Nr subjects used | n=36 | n=34 | | |
| Week 7 | -1.40 (0.47) [-2.35 ;-0.45] | -0.83 (0.49) [-1.80 ; 0.14] | -0.57 (0.68) [-1.92 ; 0.79] | -0.21 [-0.70 ; 0.29] |
| Week 13 | -0.91 (0.48) [-1.86 ; 0.04] | -0.31 (0.50) [-1.32 ; 0.69] | -0.60 (0.69) [-1.98 ; 0.79] | -0.23 [-0.76 ; 0.30] |
| Week 19 | -0.89 (0.46) [-1.80 ; 0.02] | -0.52 (0.49) [-1.49 ; 0.45] | -0.38 (0.67) [-1.71 ; 0.95] | -0.15 [-0.68 ; 0.38] |
| Week 25 | -0.77 (0.49) [-1.74 ; 0.20] | -0.67 (0.53) [-1.74 ; 0.40] | -0.10 (0.72) [-1.54 ; 1.34] | -0.04 [-0.57 ; 0.50] |
| Week 31 | -0.64 (0.62) [-1.89 ; 0.61] | -0.43 (0.69) [-1.80 ; 0.95] | -0.22 (0.93) [-2.08 ; 1.64] | -0.07 [-0.66 ; 0.52] |
| Week 37 | -0.65 (0.68) [-2.01 ; 0.71] | -0.91 (0.72) [-2.36 ; 0.54] | 0.26 (0.99) [-1.73 ; 2.24] | 0.07 [-0.50 ; 0.65] |
| Week 43 | -0.68 (0.55) [-1.78 ; 0.41] | 0.11 (0.63) [-1.15 ; 1.36] | -0.79 (0.83) [-2.46 ; 0.88] | -0.27 [-0.86 ; 0.31] |
| Week 49 | -0.99 (0.56) [-2.10 ; 0.12] | 0.43 (0.69) [-0.94 ; 1.80] | -1.42 (0.88) [-3.18 ; 0.34] | -0.48 [-1.09 ; 0.13] |
| Week 55 | -0.57 (0.53) [-1.63 ; 0.49] | -0.23 (0.66) [-1.54 ; 1.08] | -0.34 (0.84) [-2.02 ; 1.35] | -0.12 [-0.73 ; 0.49] |
| Week 61 | -1.09 (0.56) [-2.21 ; 0.04] | -0.20 (0.74) [-1.69 ; 1.28] | -0.88 (0.93) [-2.75 ; 0.98] | -0.32 [-1.00 ; 0.36] |
| Week 67 | -0.93 (0.64) [-2.21 ; 0.35] | -0.43 (0.83) [-2.11 ; 1.24] | -0.49 (1.05) [-2.60 ; 1.62] | -0.16 [-0.84 ; 0.52] |
| Week 73 | -1.11 (0.92) [-2.98 ; 0.76] | -1.26 (1.06) [-3.41 ; 0.89] | 0.15 (1.41) [-2.69 ; 3.00] | 0.04 [-0.68 ; 0.76] |
| Week 79 | -1.98 (1.27) [-4.58 ; 0.62] | -0.09 (1.51) [-3.17 ; 2.99] | -1.89 (1.98) [-5.92 ; 2.15] | -0.37 [-1.15 ; 0.42] |
| Week 85 | -0.91 (0.77) [-2.52 ; 0.69] | -0.57 (0.84) [-2.32 ; 1.18] | -0.35 (1.14) [-2.72 ; 2.03] | -0.13 [-0.98 ; 0.73] |
| Overall post-baseline period estimate | -0.97 (0.32) [-1.60 ;-0.33] | -0.42 (0.38) [-1.17 ; 0.32] | -0.54 (0.49) [-1.52 ; 0.44] | -0.26 [-0.74 ; 0.21] |
| **Rest of World (ROW)** | | | | |
| Nr subjects used | n=33 | n=33 | | |
| Week 7 | -0.85 (0.73) [-2.31 ; 0.61] | -2.07 (0.72) [-3.51 ;-0.63] | 1.22 (1.02) [-0.83 ; 3.26] | 0.30 [-0.20 ; 0.80] |
| Week 13 | -0.60 (0.72) [-2.03 ; 0.83] | -2.49 (0.73) [-3.94 ;-1.03] | 1.89 (1.02) [-0.15 ; 3.93] | 0.48 [-0.04 ; 0.99] |
| Week 19 | 0.07 (0.59) [-1.09 ; 1.24] | -1.61 (0.59) [-2.79 ;-0.43] | 1.69 (0.83) [ 0.03 ; 3.35] | 0.54 [-0.00 ; 1.09] |
| Week 25 | 0.46 (0.59) [-0.72 ; 1.63] | -0.91 (0.61) [-2.14 ; 0.32] | 1.37 (0.85) [-0.33 ; 3.07] | 0.44 [-0.11 ; 1.00] |
| Week 31 | 0.13 (0.56) [-1.00 ; 1.25] | -0.84 (0.61) [-2.06 ; 0.38] | 0.97 (0.83) [-0.70 ; 2.63] | 0.32 [-0.24 ; 0.88] |
| Week 37 | 0.54 (0.57) [-0.61 ; 1.68] | -0.71 (0.59) [-1.89 ; 0.48] | 1.24 (0.83) [-0.41 ; 2.89] | 0.43 [-0.15 ; 1.01] |
| Week 43 | 0.25 (0.67) [-1.10 ; 1.59] | -1.71 (0.72) [-3.15 ;-0.28] | 1.96 (0.98) [-0.01 ; 3.93] | 0.58 [-0.02 ; 1.18] |
| Week 49 | 0.52 (0.70) [-0.89 ; 1.93] | -1.62 (0.79) [-3.20 ;-0.03] | 2.14 (1.06) [ 0.02 ; 4.26] | 0.62 [-0.01 ; 1.24] |
| Week 55 | -0.03 (0.67) [-1.37 ; 1.31] | -1.31 (0.70) [-2.72 ; 0.10] | 1.28 (0.97) [-0.66 ; 3.23] | 0.41 [-0.22 ; 1.04] |
| Week 61 | 0.69 (0.55) [-0.42 ; 1.79] | -1.04 (0.63) [-2.32 ; 0.23] | 1.73 (0.84) [ 0.05 ; 3.41] | 0.64 [-0.00 ; 1.28] |
| Week 67 | 0.59 (0.52) [-0.45 ; 1.64] | -0.92 (0.60) [-2.12 ; 0.28] | 1.51 (0.79) [-0.08 ; 3.11] | 0.62 [-0.05 ; 1.29] |
| Week 73 | 0.69 (0.48) [-0.27 ; 1.64] | -1.28 (0.55) [-2.38 ;-0.18] | 1.97 (0.73) [ 0.51 ; 3.42] | 0.93 [ 0.20 ; 1.66] |
| Week 79 | 1.12 (0.51) [ 0.10 ; 2.13] | -0.69 (0.57) [-1.82 ; 0.45] | 1.80 (0.76) [ 0.28 ; 3.33] | 0.86 [ 0.09 ; 1.63] |
| Week 85 | 0.51 (0.63) [-0.78 ; 1.79] | -0.34 (0.77) [-1.91 ; 1.22] | 0.85 (1.00) [-1.17 ; 2.87] | 0.33 [-0.47 ; 1.13] |
| Overall post-baseline period estimate | 0.29 (0.30) [-0.31 ; 0.89] | -1.25 (0.33) [-1.90 ;-0.61] | 1.54 (0.45) [ 0.66 ; 2.43] | 0.85 [ 0.34 ; 1.36] |
| **MMRM subgroups interaction p-value** | | | 0.4377 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.

TABLE 7.4.5: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **White** | | |
| | N=62 | N=58 |
| **Non-White** | | |
| | N=9 | N=10 |
| **Subjects with Baseline Value** | | |
| **White** | | |
| | 60 (96.8%) | 57 (98.3%) |
| **Non-White** | | |
| | 9 (100.0%) | 10 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **White** | | |
| | 62 (100.0%) | 56 (96.6%) |
| **Non-White** | | |
| | 9 (100.0%) | 10 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **White** | | |
| | 60 (96.8%) | 55 (94.8%) |
| **Non-White** | | |
| | 9 (100.0%) | 10 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:51

TABLE 7.4.5: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **White** | | | |
| N subjects in population | N=62 | N=58 | |
| Baseline | n= 60 (96.8%) \| 31.33 (4.49) | n= 57 (98.3%) \| 31.26 (4.25) | 0.02 [-0.35 ; 0.38] |
| Week 3 | n= 58 (93.5%) \| 31.21 (3.71) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 55 (88.7%) \| 30.92 (4.75) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 57 (91.9%) \| 30.29 (4.27) | n= 54 (93.1%) \| 29.91 (3.96) | 0.09 [-0.28 ; 0.46] |
| Week 9 | n= 52 (83.9%) \| 30.80 (4.34) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 52 (83.9%) \| 30.80 (3.89) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 52 (83.9%) \| 31.37 (3.92) | n= 45 (77.6%) \| 30.51 (3.67) | 0.22 [-0.18 ; 0.63] |
| Week 15 | n= 47 (75.8%) \| 30.99 (3.82) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 54 (87.1%) \| 31.33 (4.41) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 50 (80.6%) \| 31.94 (3.12) | n= 45 (77.6%) \| 30.71 (3.38) | 0.38 [-0.03 ; 0.79] |
| Week 21 | n= 50 (80.6%) \| 31.80 (4.07) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 47 (75.8%) \| 30.85 (3.84) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 49 (79.0%) \| 31.80 (3.67) | n= 41 (70.7%) \| 30.95 (2.99) | 0.25 [-0.17 ; 0.67] |
| Week 27 | n= 47 (75.8%) \| 32.74 (3.86) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 44 (71.0%) \| 32.12 (3.57) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (72.6%) \| 32.09 (4.32) | n= 35 (60.3%) \| 30.91 (3.78) | 0.28 [-0.16 ; 0.73] |
| Week 33 | n= 48 (77.4%) \| 31.65 (4.50) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 46 (74.2%) \| 31.17 (5.12) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 42 (67.7%) \| 31.96 (4.87) | n= 40 (69.0%) \| 31.27 (3.16) | 0.17 [-0.27 ; 0.60] |
| Week 39 | n= 44 (71.0%) \| 32.25 (3.87) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 44 (71.0%) \| 31.93 (4.11) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 46 (74.2%) \| 31.64 (4.11) | n= 36 (62.1%) \| 31.05 (3.94) | 0.15 [-0.29 ; 0.59] |
| Week 45 | n= 41 (66.1%) \| 31.42 (4.23) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 43 (69.4%) \| 31.84 (4.10) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 44 (71.0%) \| 31.98 (4.40) | n= 32 (55.2%) \| 31.09 (4.03) | 0.21 [-0.25 ; 0.67] |
| Week 51 | n= 43 (69.4%) \| 31.60 (4.29) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 44 (71.0%) \| 32.01 (3.98) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (62.9%) \| 31.94 (4.34) | n= 32 (55.2%) \| 30.51 (3.45) | 0.35 [-0.12 ; 0.83] |
| Week 57 | n= 41 (66.1%) \| 31.62 (4.22) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 39 (62.9%) \| 31.67 (4.55) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 40 (64.5%) \| 32.19 (3.98) | n= 25 (43.1%) \| 30.12 (3.32) | 0.55 [ 0.03 ; 1.06] |
| Week 63 | n= 36 (58.1%) \| 31.48 (4.69) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 35 (56.5%) \| 31.46 (4.18) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (61.3%) \| 31.79 (4.46) | n= 24 (41.4%) \| 30.38 (3.67) | 0.33 [-0.18 ; 0.85] |
| Week 69 | n= 32 (51.6%) \| 31.98 (3.85) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 33 (53.2%) \| 32.33 (4.15) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 30 (48.4%) \| 32.93 (2.89) | n= 24 (41.4%) \| 29.67 (3.62) | 0.99 [ 0.42 ; 1.57] |
| Week 75 | n= 32 (51.6%) \| 32.16 (3.88) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 29 (46.8%) \| 32.34 (3.76) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 28 (45.2%) \| 31.66 (5.90) | n= 21 (36.2%) \| 30.71 (3.05) | 0.19 [-0.38 ; 0.76] |
| Week 81 | n= 26 (41.9%) \| 32.23 (3.91) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 31 (50.0%) \| 32.45 (3.93) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (40.3%) \| 32.28 (3.98) | n= 18 (31.0%) \| 31.06 (3.11) | 0.33 [-0.29 ; 0.95] |
| Week 87 | n= 22 (35.5%) \| 31.32 (4.45) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 23 (37.1%) \| 31.86 (3.60) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 21 (33.9%) \| 30.87 (4.57) | n= 15 (25.9%) \| 31.67 (3.77) | -0.18 [-0.86 ; 0.49] |
| Week 93 | n= 21 (33.9%) \| 31.62 (3.84) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 20 (32.3%) \| 31.59 (3.97) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.0%) \| 31.08 (3.97) | n= 9 (15.5%) \| 31.56 (3.54) | -0.12 [-0.94 ; 0.70] |
| Week 99 | n= 15 (24.2%) \| 31.27 (3.83) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.0%) \| 31.23 (3.77) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.0%) \| 31.38 (3.43) | n= 8 (13.8%) \| 31.50 (2.20) | -0.04 [-0.94 ; 0.87] |
| Week 105 | n= 12 (19.4%) \| 30.42 (3.75) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.3%) \| 31.14 (2.97) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.1%) \| 28.39 (3.18) | n= 4 ( 6.9%) \| 30.25 (5.25) | -0.46 [-1.68 ; 0.76] |
| Week 111 | n= 7 (11.3%) \| 30.29 (3.90) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (12.9%) \| 31.44 (3.70) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 ( 9.7%) \| 30.50 (4.32) | n= 4 ( 6.9%) \| 31.75 (1.26) | -0.32 [-1.68 ; 1.03] |
| Week 117 | n= 7 (11.3%) \| 32.71 (2.98) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 (11.3%) \| 29.29 (4.46) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.3%) \| 30.75 (4.70) | n= 1 ( 1.7%) \| 30.38 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.2%) \| 31.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.6%) \| 31.00 ( / ) | n= 1 ( 1.7%) \| 24.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) \| 29.25 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.6%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.6%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.6%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.6%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) \| 31.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 7 (11.3%) \| 31.71 (4.72) | n= 11 (19.0%) \| 29.18 (4.64) | 0.52 [-0.48 ; 1.51] |
| Week 202 | n= 2 ( 3.2%) \| 25.00 (7.07) | n= 7 (12.1%) \| 32.43 (2.37) | -1.91 [-3.90 ; 0.08] |
| **Non-White** | | | |
| N subjects in population | N=9 | N=10 | |
| Baseline | n= 9 (100.0%) \| 33.78 (3.23) | n= 10 (100.0%) \| 32.70 (4.14) | 0.28 [-0.66 ; 1.21] |
| Week 3 | n= 9 (100.0%) \| 33.56 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (88.9%) \| 32.63 (4.34) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (77.8%) \| 34.14 (1.68) | n= 10 (100.0%) \| 32.30 (3.92) | 0.54 [-0.47 ; 1.56] |
| Week 9 | n= 9 (100.0%) \| 32.11 (3.79) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (100.0%) \| 31.11 (4.62) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 8 (88.9%) \| 31.50 (4.00) | n= 10 (100.0%) \| 31.80 (3.65) | -0.08 [-1.03 ; 0.88] |
| Week 15 | n= 7 (77.8%) \| 33.14 (2.61) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (100.0%) \| 31.78 (2.86) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 7 (77.8%) \| 32.71 (2.93) | n= 9 (90.0%) \| 33.33 (2.65) | -0.21 [-1.24 ; 0.81] |
| Week 21 | n= 9 (100.0%) \| 31.78 (4.35) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 9 (100.0%) \| 31.78 (4.58) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 9 (100.0%) \| 32.67 (3.74) | n= 8 (80.0%) \| 34.38 (1.92) | -0.53 [-1.54 ; 0.47] |
| Week 27 | n= 9 (100.0%) \| 31.89 (4.14) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 8 (88.9%) \| 32.00 (4.14) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 9 (100.0%) \| 32.11 (3.72) | n= 7 (70.0%) \| 33.86 (2.85) | -0.49 [-1.53 ; 0.55] |
| Week 33 | n= 8 (88.9%) \| 32.75 (3.92) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (88.9%) \| 33.38 (4.10) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 6 (66.7%) \| 33.00 (4.34) | n= 7 (70.0%) \| 31.71 (3.30) | 0.31 [-0.83 ; 1.46] |
| Week 39 | n= 8 (88.9%) \| 33.00 (3.89) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 41 | n= 8 (88.9%) \| 33.13 (4.16) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 6 (66.7%) \| 34.50 (1.87) | n= 6 (60.0%) \| 31.17 (5.15) | 0.79 [-0.45 ; 2.03] |
| Week 45 | n= 7 (77.8%) \| 31.14 (5.52) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 8 (88.9%) \| 32.75 (4.43) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 8 (88.9%) \| 32.38 (4.44) | n= 4 (40.0%) \| 33.00 (2.94) | -0.14 [-1.40 ; 1.12] |
| Week 51 | n= 8 (88.9%) \| 31.75 (4.43) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 8 (88.9%) \| 32.13 (4.97) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (77.8%) \| 31.00 (5.42) | n= 6 (60.0%) \| 33.33 (2.25) | -0.51 [-1.67 ; 0.65] |
| Week 57 | n= 7 (77.8%) \| 31.71 (5.47) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (77.8%) \| 31.14 (4.30) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (88.9%) \| 32.38 (5.21) | n= 6 (60.0%) \| 34.00 (3.03) | -0.34 [-1.45 ; 0.77] |
| Week 63 | n= 6 (66.7%) \| 31.67 (6.02) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (88.9%) \| 29.25 (8.81) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (66.7%) \| 33.50 (1.87) | n= 6 (60.0%) \| 33.00 (3.22) | 0.18 [-1.02 ; 1.37] |
| Week 69 | n= 6 (66.7%) \| 26.83 (8.30) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 5 (55.6%) \| 29.40 (6.54) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 5 (55.6%) \| 28.00 (7.25) | n= 4 (40.0%) \| 33.00 (2.94) | -0.77 [-2.24 ; 0.71] |
| Week 75 | n= 3 (33.3%) \| 33.33 (2.31) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (33.3%) \| 30.00 (5.29) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 3 (33.3%) \| 29.00 (7.00) | n= 4 (40.0%) \| 33.75 (2.63) | -0.82 [-2.57 ; 0.93] |
| Week 81 | n= 3 (33.3%) \| 29.00 (6.93) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (22.2%) \| 28.50 (6.36) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (22.2%) \| 32.50 (2.12) | n= 3 (30.0%) \| 35.00 (1.00) | -1.24 [-3.69 ; 1.22] |
| Week 87 | n= 2 (22.2%) \| 28.00 (8.49) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (22.2%) \| 28.00 (9.90) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (33.3%) \| 30.33 (7.23) | n= 3 (30.0%) \| 34.00 (1.73) | -0.56 [-2.43 ; 1.31] |
| Week 93 | n= 2 (22.2%) \| 29.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (22.2%) \| 27.00 (9.90) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (33.3%) \| 30.00 (7.94) | n= 2 (20.0%) \| 35.50 (0.71) | -0.62 [-2.82 ; 1.59] |
| Week 99 | n= 2 (22.2%) \| 27.00 (12.73) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (11.1%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (22.2%) \| 33.00 (4.24) | n= 2 (20.0%) \| 35.50 (0.71) | -0.47 [-3.03 ; 2.09] |
| Week 105 | n= 1 (11.1%) \| 36.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (11.1%) \| 36.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 (11.1%) \| 36.00 ( / ) | n= 1 (10.0%) \| 36.00 ( / ) | [Not calculable] |
| Week 115 | n= 1 (11.1%) \| 34.00 ( / ) | n= 1 (10.0%) \| 36.00 ( / ) | [Not calculable] |
| Week 121 | n= 1 (11.1%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 (11.1%) \| 33.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (11.1%) \| 30.00 ( / ) | n= 5 (50.0%) \| 33.00 (3.32) | [Not calculable] |
| Week 202 | [No Data] | n= 4 (40.0%) \| 32.25 (2.63) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:51

TABLE 7.4.5: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **White** | | | |
| N subjects in population | N=62 | N=58 | |
| Week 3 | n= 57 (91.9%) \|-0.17 (2.26) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 53 (85.5%) \|-0.63 (3.22) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 55 (88.7%) \|-0.88 (3.87) | n= 53 (91.4%) \|-1.25 (3.42) | 0.10 [-0.28 ; 0.48] |
| Week 9 | n= 51 (82.3%) \|-1.00 (4.15) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 51 (82.3%) \|-0.81 (3.52) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 51 (82.3%) \|-0.37 (3.74) | n= 45 (77.6%) \|-1.51 (3.02) | 0.33 [-0.08 ; 0.73] |
| Week 15 | n= 47 (75.8%) \|-0.63 (4.18) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 53 (85.5%) \|-0.32 (3.78) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 49 (79.0%) \|-0.30 (3.29) | n= 44 (75.9%) \|-1.20 (3.47) | 0.27 [-0.15 ; 0.68] |
| Week 21 | n= 50 (80.6%) \| 0.11 (3.66) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 47 (75.8%) \|-0.70 (3.00) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 48 (77.4%) \|-0.03 (3.75) | n= 40 (69.0%) \|-1.07 (3.83) | 0.27 [-0.15 ; 0.70] |
| Week 27 | n= 46 (74.2%) \| 0.53 (3.62) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 44 (71.0%) \| 0.31 (3.83) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (72.6%) \|-0.01 (3.82) | n= 35 (60.3%) \|-0.96 (2.64) | 0.28 [-0.17 ; 0.73] |
| Week 33 | n= 48 (77.4%) \|-0.45 (3.62) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 45 (72.6%) \|-0.61 (3.88) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 42 (67.7%) \| 0.04 (3.73) | n= 39 (67.2%) \|-0.44 (3.15) | 0.14 [-0.30 ; 0.58] |
| Week 39 | n= 43 (69.4%) \| 0.00 (3.53) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 44 (71.0%) \|-0.51 (3.75) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 45 (72.6%) \|-0.43 (4.18) | n= 35 (60.3%) \|-0.57 (2.82) | 0.04 [-0.41 ; 0.48] |
| Week 45 | n= 41 (66.1%) \|-0.59 (4.30) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 43 (69.4%) \|-0.60 (3.41) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 44 (71.0%) \|-0.08 (3.90) | n= 31 (53.4%) \|-1.00 (3.44) | 0.24 [-0.22 ; 0.71] |
| Week 51 | n= 43 (69.4%) \|-0.20 (3.64) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 44 (71.0%) \| 0.13 (3.37) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (62.9%) \|-0.06 (3.33) | n= 31 (53.4%) \|-0.95 (3.10) | 0.27 [-0.21 ; 0.75] |
| Week 57 | n= 41 (66.1%) \|-0.06 (3.81) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 39 (62.9%) \|-0.07 (4.12) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 40 (64.5%) \| 0.20 (3.74) | n= 24 (41.4%) \|-0.78 (3.28) | 0.27 [-0.24 ; 0.78] |
| Week 63 | n= 36 (58.1%) \| 0.08 (3.96) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 35 (56.5%) \| 0.36 (3.84) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (61.3%) \| 0.19 (4.05) | n= 23 (39.7%) \|-0.51 (3.08) | 0.19 [-0.34 ; 0.71] |
| Week 69 | n= 32 (51.6%) \| 0.14 (4.37) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 33 (53.2%) \| 0.36 (4.23) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 30 (48.4%) \| 1.09 (3.43) | n= 24 (41.4%) \|-1.23 (3.06) | 0.70 [ 0.14 ; 1.26] |
| Week 75 | n= 32 (51.6%) \| 0.36 (4.45) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 29 (46.8%) \| 0.99 (4.53) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 28 (45.2%) \| 0.33 (5.66) | n= 20 (34.5%) \| 0.14 (3.08) | 0.04 [-0.54 ; 0.62] |
| Week 81 | n= 26 (41.9%) \| 0.49 (3.64) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 31 (50.0%) \| 0.70 (4.34) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (40.3%) \| 0.51 (4.31) | n= 17 (29.3%) \|-0.53 (2.94) | 0.27 [-0.36 ; 0.89] |
| Week 87 | n= 22 (35.5%) \|-0.32 (4.39) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 23 (37.1%) \| 0.33 (3.99) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 21 (33.9%) \|-1.05 (3.43) | n= 14 (24.1%) \|-0.40 (4.67) | -0.16 [-0.85 ; 0.53] |
| Week 93 | n= 21 (33.9%) \|-0.45 (3.29) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 20 (32.3%) \|-0.43 (3.44) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.0%) \|-0.61 (3.40) | n= 8 (13.8%) \|-0.75 (3.24) | 0.04 [-0.81 ; 0.89] |
| Week 99 | n= 15 (24.2%) \|-0.09 (3.44) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.0%) \|-0.46 (3.23) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.0%) \| 0.36 (3.01) | n= 7 (12.1%) \| 0.14 (3.18) | 0.07 [-0.88 ; 1.01] |
| Week 105 | n= 12 (19.4%) \|-0.20 (3.40) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.3%) \| 0.00 (4.12) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.1%) \|-1.81 (4.15) | n= 3 ( 5.2%) \|-1.00 (4.36) | -0.18 [-1.53 ; 1.17] |
| Week 111 | n= 7 (11.3%) \|-0.71 (4.35) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (12.9%) \|-0.44 (4.03) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 ( 9.7%) \|-0.50 (5.09) | n= 4 ( 6.9%) \|-1.25 (1.71) | 0.16 [-1.18 ; 1.51] |
| Week 117 | n= 7 (11.3%) \| 0.57 (3.05) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 (11.3%) \|-2.29 (4.89) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.3%) \|-1.25 (4.77) | n= 1 ( 1.7%) \|-1.63 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.2%) \|-2.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.6%) \|-1.00 ( / ) | n= 1 ( 1.7%) \|-8.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) \|-2.75 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.6%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.6%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.6%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.6%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) \|-0.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 7 (11.3%) \| 0.29 (2.43) | n= 11 (19.0%) \|-2.82 (4.17) | 0.82 [-0.20 ; 1.84] |
| Week 202 | n= 2 ( 3.2%) \|-5.50 (4.95) | n= 7 (12.1%) \|-1.00 (2.58) | -1.32 [-3.16 ; 0.52] |
| **Non-White** | | | |
| N subjects in population | N=9 | N=10 | |
| Week 3 | n= 9 (100.0%) \|-0.22 (2.39) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (88.9%) \|-0.88 (1.36) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (77.8%) \|-0.43 (1.27) | n= 10 (100.0%) \|-0.40 (3.20) | -0.01 [-1.01 ; 0.99] |
| Week 9 | n= 9 (100.0%) \|-1.67 (1.87) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (100.0%) \|-2.67 (2.69) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 8 (88.9%) \|-2.00 (1.69) | n= 10 (100.0%) \|-0.90 (4.07) | -0.32 [-1.29 ; 0.64] |
| Week 15 | n= 7 (77.8%) \|-1.43 (2.64) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (100.0%) \|-2.00 (1.73) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 7 (77.8%) \|-2.00 (2.16) | n= 9 (90.0%) \| 0.33 (4.15) | -0.64 [-1.69 ; 0.41] |
| Week 21 | n= 9 (100.0%) \|-2.00 (2.69) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 9 (100.0%) \|-2.00 (3.16) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 9 (100.0%) \|-1.11 (2.37) | n= 8 (80.0%) \| 0.13 (1.46) | -0.59 [-1.59 ; 0.42] |
| Week 27 | n= 9 (100.0%) \|-1.89 (2.89) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 8 (88.9%) \|-1.63 (1.77) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 9 (100.0%) \|-1.67 (2.60) | n= 7 (70.0%) \|-0.71 (1.25) | -0.42 [-1.46 ; 0.61] |
| Week 33 | n= 8 (88.9%) \|-0.75 (1.83) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (88.9%) \|-0.63 (1.51) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 6 (66.7%) \|-0.50 (1.97) | n= 7 (70.0%) \|-2.43 (2.70) | 0.75 [-0.44 ; 1.93] |
| Week 39 | n= 8 (88.9%) \|-0.50 (1.69) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 8 (88.9%) \|-0.88 (2.03) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 6 (66.7%) \|-0.67 (1.75) | n= 6 (60.0%) \|-2.67 (3.20) | 0.72 [-0.52 ; 1.95] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 45 | n= 7 (77.8%) \|-2.57 (4.08) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 8 (88.9%) \|-1.25 (2.49) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 8 (88.9%) \|-1.63 (2.00) | n= 4 (40.0%) \|-0.50 (1.29) | -0.57 [-1.86 ; 0.71] |
| Week 51 | n= 8 (88.9%) \|-2.25 (2.25) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 8 (88.9%) \|-1.88 (1.89) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (77.8%) \|-2.86 (2.79) | n= 6 (60.0%) \|-0.50 (1.38) | -0.97 [-2.18 ; 0.24] |
| Week 57 | n= 7 (77.8%) \|-2.43 (2.57) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (77.8%) \|-2.71 (2.21) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (88.9%) \|-1.63 (2.20) | n= 6 (60.0%) \| 0.17 (1.72) | -0.83 [-1.99 ; 0.32] |
| Week 63 | n= 6 (66.7%) \|-1.83 (2.71) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (88.9%) \|-4.75 (5.97) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (66.7%) \|-1.50 (1.87) | n= 6 (60.0%) \|-0.83 (1.33) | -0.38 [-1.58 ; 0.82] |
| Week 69 | n= 6 (66.7%) \|-6.50 (5.24) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 5 (55.6%) \|-3.60 (4.77) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 5 (55.6%) \|-5.00 (5.43) | n= 4 (40.0%) \|-0.25 (0.50) | -1.03 [-2.55 ; 0.50] |
| Week 75 | n= 3 (33.3%) \|-1.33 (1.53) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 3 (33.3%) \|-1.33 (2.08) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 3 (33.3%) \|-2.33 (3.06) | n= 4 (40.0%) \| 0.50 (0.58) | -1.20 [-3.05 ; 0.65] |
| Week 81 | n= 3 (33.3%) \|-2.33 (2.52) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 2 (22.2%) \|-1.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (22.2%) \|-1.50 (0.71) | n= 3 (30.0%) \| 0.67 (1.15) | -1.53 [-4.15 ; 1.08] |
| Week 87 | n= 2 (22.2%) \|-1.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (22.2%) \|-1.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (33.3%) \|-1.00 (2.65) | n= 3 (30.0%) \|-0.33 (1.53) | -0.25 [-2.07 ; 1.58] |
| Week 93 | n= 2 (22.2%) \|-0.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (22.2%) \|-2.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (33.3%) \|-1.33 (4.04) | n= 2 (20.0%) \| 0.00 (0.00) | -0.29 [-2.43 ; 1.84] |
| Week 99 | n= 2 (22.2%) \|-2.50 (7.78) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (11.1%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (22.2%) \|-1.00 (5.66) | n= 2 (20.0%) \| 0.00 (0.00) | -0.14 [-2.61 ; 2.33] |
| Week 105 | n= 1 (11.1%) \| 3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (11.1%) \| 3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 (11.1%) \| 1.00 ( / ) | n= 1 (10.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 115 | n= 1 (11.1%) \|-1.00 ( / ) | n= 1 (10.0%) \| 0.00 ( / ) | [Not calculable] |
| Week 121 | n= 1 (11.1%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 (11.1%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 (11.1%) \|-6.00 ( / ) | n= 5 (50.0%) \| 1.20 (5.76) | [Not calculable] |
| Week 202 | [No Data] | n= 4 (40.0%) \| 1.25 (4.57) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:51

TABLE 7.4.5: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Race subgroups Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **White** | | | | |
| Nr subjects used | n=60 | n=57 | | |
| Week 7 | -1.16 (0.47) [-2.09 ;-0.22] | -1.47 (0.49) [-2.44 ;-0.51] | 0.32 (0.68) [-1.02 ; 1.66] | 0.09 [-0.29 ; 0.47] |
| Week 13 | -0.55 (0.48) [-1.51 ; 0.40] | -1.36 (0.51) [-2.37 ;-0.35] | 0.81 (0.70) [-0.58 ; 2.20] | 0.23 [-0.17 ; 0.64] |
| Week 19 | -0.14 (0.41) [-0.94 ; 0.66] | -1.26 (0.43) [-2.11 ;-0.41] | 1.12 (0.59) [-0.05 ; 2.29] | 0.39 [-0.02 ; 0.80] |
| Week 25 | -0.02 (0.44) [-0.89 ; 0.85] | -1.10 (0.47) [-2.04 ;-0.17] | 1.08 (0.65) [-0.19 ; 2.36] | 0.36 [-0.07 ; 0.78] |
| Week 31 | -0.02 (0.48) [-0.96 ; 0.93] | -0.77 (0.52) [-1.80 ; 0.27] | 0.75 (0.71) [-0.65 ; 2.15] | 0.24 [-0.21 ; 0.68] |
| Week 37 | 0.04 (0.49) [-0.92 ; 1.01] | -0.61 (0.52) [-1.63 ; 0.41] | 0.65 (0.71) [-0.75 ; 2.06] | 0.20 [-0.23 ; 0.64] |
| Week 43 | -0.24 (0.47) [-1.17 ; 0.69] | -0.56 (0.52) [-1.59 ; 0.48] | 0.32 (0.70) [-1.07 ; 1.71] | 0.10 [-0.34 ; 0.54] |
| Week 49 | -0.14 (0.51) [-1.15 ; 0.87] | -0.67 (0.59) [-1.85 ; 0.50] | 0.53 (0.78) [-1.02 ; 2.08] | 0.16 [-0.30 ; 0.62] |
| Week 55 | 0.09 (0.45) [-0.80 ; 0.99] | -0.89 (0.52) [-1.92 ; 0.14] | 0.98 (0.69) [-0.39 ; 2.35] | 0.34 [-0.13 ; 0.82] |
| Week 61 | -0.08 (0.44) [-0.96 ; 0.80] | -0.85 (0.55) [-1.95 ; 0.24] | 0.77 (0.71) [-0.63 ; 2.18] | 0.28 [-0.23 ; 0.78] |
| Week 67 | 0.01 (0.48) [-0.96 ; 0.97] | -0.61 (0.61) [-1.81 ; 0.60] | 0.61 (0.78) [-0.93 ; 2.16] | 0.20 [-0.31 ; 0.72] |
| Week 73 | 0.63 (0.44) [-0.25 ; 1.51] | -1.43 (0.52) [-2.46 ;-0.40] | 2.06 (0.68) [ 0.71 ; 3.42] | 0.82 [ 0.26 ; 1.38] |
| Week 79 | -0.25 (0.72) [-1.69 ; 1.18] | -0.62 (0.85) [-2.32 ; 1.07] | 0.37 (1.11) [-1.85 ; 2.60] | 0.10 [-0.48 ; 0.67] |
| Week 85 | -0.20 (0.57) [-1.34 ; 0.93] | -0.80 (0.68) [-2.16 ; 0.56] | 0.60 (0.88) [-1.17 ; 2.36] | 0.21 [-0.41 ; 0.82] |
| Week 91 | -0.50 (0.69) [-1.89 ; 0.89] | -0.46 (0.83) [-2.14 ; 1.23] | -0.04 (1.08) [-2.22 ; 2.14] | -0.01 [-0.69 ; 0.66] |
| Overall post-baseline period estimate | -0.17 (0.25) [-0.66 ; 0.32] | -0.90 (0.28) [-1.46 ;-0.34] | 0.73 (0.38) [-0.02 ; 1.48] | 0.36 [-0.01 ; 0.73] |
| **Non-White** | | | | |
| Nr subjects used | n=9 | n=10 | | |
| **MMRM subgroups interaction p-value** | | | | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:51

TABLE 7.4.6: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **Hispanic or Latino** | N=7 | N=12 |
| **Not Hispanic or Latino** | N=42 | N=31 |
| **Not Reported** | N=22 | N=25 |
| **Subjects with Baseline Value** | | |
| **Hispanic or Latino** | 7 (100.0%) | 11 (91.7%) |
| **Not Hispanic or Latino** | 40 (95.2%) | 31 (100.0%) |
| **Not Reported** | 22 (100.0%) | 25 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **Hispanic or Latino** | 7 (100.0%) | 12 (100.0%) |
| **Not Hispanic or Latino** | 42 (100.0%) | 30 (96.8%) |
| **Not Reported** | 22 (100.0%) | 24 (96.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **Hispanic or Latino** | 7 (100.0%) | 11 (91.7%) |
| **Not Hispanic or Latino** | 40 (95.2%) | 30 (96.8%) |
| **Not Reported** | 22 (100.0%) | 24 (96.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:51

TABLE 7.4.6: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Hispanic or Latino** | | | |
| N subjects in population | N=7 | N=12 | |
| Baseline | n= 7 (100.0%) \| 29.20 (5.25) | n= 11 (91.7%) \| 30.27 (6.87) | -0.16 [-1.14 ; 0.82] |
| Week 3 | n= 7 (100.0%) \| 29.77 (5.44) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 6 (85.7%) \| 31.33 (3.33) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (100.0%) \| 31.86 (2.04) | n= 12 (100.0%) \| 28.75 (5.96) | 0.60 [-0.38 ; 1.58] |
| Week 9 | n= 6 (85.7%) \| 29.17 (4.71) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 6 (85.7%) \| 31.50 (2.43) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 7 (100.0%) \| 30.00 (3.27) | n= 7 (58.3%) \| 32.29 (3.50) | -0.63 [-1.75 ; 0.49] |
| Week 15 | n= 5 (71.4%) \| 30.60 (4.93) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 6 (85.7%) \| 29.03 (6.68) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 5 (71.4%) \| 32.20 (2.86) | n= 7 (58.3%) \| 31.57 (3.21) | 0.19 [-1.02 ; 1.40] |
| Week 21 | n= 6 (85.7%) \| 28.67 (7.66) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (85.7%) \| 29.83 (4.83) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 4 (57.1%) \| 35.00 (1.41) | n= 7 (58.3%) \| 32.43 (1.90) | 1.34 [-0.11 ; 2.79] |
| Week 27 | n= 4 (57.1%) \| 35.00 (2.00) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 4 (57.1%) \| 33.75 (2.87) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 4 (57.1%) \| 32.75 (3.59) | n= 5 (41.7%) \| 32.80 (2.59) | -0.01 [-1.42 ; 1.40] |
| Week 33 | n= 4 (57.1%) \| 32.00 (6.16) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 3 (42.9%) \| 32.00 (6.93) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 2 (28.6%) \| 35.50 (0.71) | n= 5 (41.7%) \| 32.60 (2.97) | 0.91 [-1.00 ; 2.83] |
| Week 39 | n= 4 (57.1%) \| 34.25 (2.36) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 3 (42.9%) \| 33.33 (3.79) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 3 (42.9%) \| 33.67 (2.31) | n= 5 (41.7%) \| 31.78 (3.54) | 0.52 [-1.07 ; 2.10] |
| Week 45 | n= 2 (28.6%) \| 35.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 2 (28.6%) \| 35.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 3 (42.9%) \| 34.00 (3.46) | n= 4 (33.3%) \| 32.50 (2.38) | 0.44 [-1.24 ; 2.12] |
| Week 51 | n= 3 (42.9%) \| 33.46 (2.67) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 2 (28.6%) \| 36.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 3 (42.9%) \| 35.33 (1.15) | n= 4 (33.3%) \| 29.50 (5.57) | 1.12 [-0.70 ; 2.95] |
| Week 57 | n= 3 (42.9%) \| 34.33 (2.89) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 3 (42.9%) \| 34.33 (2.89) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 3 (42.9%) \| 34.13 (3.25) | n= 4 (33.3%) \| 30.75 (3.86) | 0.78 [-0.96 ; 2.52] |
| Week 63 | n= 3 (42.9%) \| 34.00 (3.46) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 3 (42.9%) \| 34.33 (2.08) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 3 (42.9%) \| 34.00 (2.65) | n= 4 (33.3%) \| 30.50 (3.70) | 0.89 [-0.87 ; 2.65] |
| Week 69 | n= 3 (42.9%) \| 34.33 (2.08) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 2 (28.6%) \| 35.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (42.9%) \| 34.33 (2.08) | n= 3 (25.0%) \| 32.33 (4.73) | 0.44 [-1.41 ; 2.29] |
| Week 75 | n= 3 (42.9%) \| 34.00 (2.65) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 2 (28.6%) \| 35.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 3 (42.9%) \| 34.33 (2.89) | n= 4 (33.3%) \| 31.75 (4.35) | 0.57 [-1.13 ; 2.27] |
| Week 81 | n= 3 (42.9%) \| 34.67 (1.53) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 3 (42.9%) \| 34.00 (2.65) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 3 (42.9%) \| 33.67 (4.04) | n= 3 (25.0%) \| 33.67 (2.52) | 0.00 [-1.81 ; 1.81] |
| Week 87 | n= 2 (28.6%) \| 36.00 (0.00) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 2 (28.6%) \| 33.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 2 (28.6%) \| 33.00 (4.24) | n= 3 (25.0%) \| 34.67 (1.15) | -0.46 [-2.63 ; 1.70] |
| Week 93 | n= 2 (28.6%) \| 33.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (28.6%) \| 34.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 2 (28.6%) \| 33.19 (3.98) | n= 3 (25.0%) \| 34.00 (1.73) | -0.22 [-2.34 ; 1.91] |
| Week 99 | n= 2 (28.6%) \| 34.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (14.3%) \| 36.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 1 (14.3%) \| 31.00 ( / ) | n= 2 (16.7%) \| 32.00 (5.66) | [Not calculable] |
| Week 105 | n= 1 (14.3%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | [No Data] | n= 2 (16.7%) \| 29.50 (9.19) | [No Data for at least 1 arm] |
| Week 115 | [No Data] | n= 1 ( 8.3%) \| 36.00 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 1 (14.3%) \| 22.00 ( / ) | n= 3 (25.0%) \| 30.67 (2.52) | [Not calculable] |
| Week 202 | [No Data] | n= 2 (16.7%) \| 33.00 (1.41) | [No Data for at least 1 arm] |
| **Not Hispanic or Latino** | | | |
| N subjects in population | N=42 | N=31 | |
| Baseline | n= 40 (95.2%) \| 31.65 (4.33) | n= 31 (100.0%) \| 31.54 (3.68) | 0.03 [-0.44 ; 0.50] |
| Week 3 | n= 40 (95.2%) \| 31.02 (4.03) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 38 (90.5%) \| 30.47 (5.26) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 37 (88.1%) \| 30.01 (4.79) | n= 29 (93.5%) \| 30.81 (3.13) | -0.19 [-0.68 ; 0.30] |
| Week 9 | n= 35 (83.3%) \| 30.67 (4.22) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 36 (85.7%) \| 30.44 (4.12) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 33 (78.6%) \| 31.70 (3.56) | n= 25 (80.6%) \| 31.08 (3.53) | 0.17 [-0.35 ; 0.70] |
| Week 15 | n= 29 (69.0%) \| 30.93 (3.98) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 35 (83.3%) \| 31.00 (4.35) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 31 (73.8%) \| 31.79 (3.18) | n= 26 (83.9%) \| 30.91 (2.98) | 0.28 [-0.25 ; 0.81] |
| Week 21 | n= 32 (76.2%) \| 31.75 (3.47) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 29 (69.0%) \| 30.24 (3.83) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 34 (81.0%) \| 31.29 (3.84) | n= 24 (77.4%) \| 31.38 (2.46) | -0.02 [-0.55 ; 0.50] |
| Week 27 | n= 30 (71.4%) \| 32.47 (3.87) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 29 (69.0%) \| 31.62 (4.14) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 28 (66.7%) \| 31.75 (4.22) | n= 19 (61.3%) \| 31.26 (3.84) | 0.12 [-0.47 ; 0.71] |
| Week 33 | n= 32 (76.2%) \| 31.19 (4.32) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 30 (71.4%) \| 30.87 (4.79) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 25 (59.5%) \| 31.44 (4.92) | n= 22 (71.0%) \| 30.66 (3.28) | 0.18 [-0.40 ; 0.76] |
| Week 39 | n= 30 (71.4%) \| 31.50 (4.54) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 32 (76.2%) \| 31.50 (4.49) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 29 (69.0%) \| 31.64 (4.32) | n= 17 (54.8%) \| 30.88 (4.60) | 0.17 [-0.44 ; 0.78] |
| Week 45 | n= 27 (64.3%) \| 30.90 (4.83) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 30 (71.4%) \| 31.23 (4.52) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 29 (69.0%) \| 31.31 (5.22) | n= 13 (41.9%) \| 30.77 (3.35) | 0.11 [-0.55 ; 0.77] |
| Week 51 | n= 27 (64.3%) \| 31.07 (5.05) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 30 (71.4%) \| 31.27 (4.74) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 25 (59.5%) \| 31.12 (5.09) | n= 15 (48.4%) \| 30.33 (3.46) | 0.17 [-0.48 ; 0.82] |
| Week 57 | n= 28 (66.7%) \| 30.61 (5.07) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 25 (59.5%) \| 30.68 (5.15) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 26 (61.9%) \| 31.32 (4.97) | n= 11 (35.5%) \| 30.00 (3.41) | 0.28 [-0.44 ; 1.00] |
| Week 63 | n= 24 (57.1%) \| 30.46 (5.62) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (52.4%) \| 29.91 (6.47) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 22 (52.4%) \| 31.05 (5.29) | n= 12 (38.7%) \| 30.67 (4.40) | 0.07 [-0.64 ; 0.79] |
| Week 69 | n= 20 (47.6%) \| 30.95 (5.80) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 21 (50.0%) \| 31.43 (5.12) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | | Sunitinib | | Hedge G difference [95% CI] |
|---|---|---|---|---|---|
| Week 73 | n= 16 (38.1%) | 31.63 (5.16) | n= 12 (38.7%) | 29.50 (4.52) | 0.42 [-0.35 ; 1.19] |
| Week 75 | n= 17 (40.5%) | 32.12 (4.39) | | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 17 (40.5%) | 30.82 (4.59) | | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 15 (35.7%) | 31.27 (5.01) | n= 10 (32.3%) | 31.20 (3.43) | 0.01 [-0.80 ; 0.83] |
| Week 81 | n= 15 (35.7%) | 30.80 (5.09) | | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (40.5%) | 31.06 (4.71) | | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 13 (31.0%) | 32.08 (4.03) | n= 9 (29.0%) | 31.11 (3.59) | 0.24 [-0.63 ; 1.11] |
| Week 87 | n= 11 (26.2%) | 29.45 (4.78) | | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 12 (28.6%) | 30.58 (4.64) | | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 13 (31.0%) | 29.71 (5.76) | n= 8 (25.8%) | 31.63 (4.41) | -0.35 [-1.26 ; 0.56] |
| Week 93 | n= 12 (28.6%) | 29.92 (4.29) | | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (26.2%) | 29.52 (5.41) | | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (28.6%) | 29.58 (5.00) | n= 5 (16.1%) | 30.80 (4.76) | -0.23 [-1.31 ; 0.85] |
| Week 99 | n= 8 (19.0%) | 28.25 (5.68) | | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 7 (16.7%) | 30.14 (4.26) | | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (19.0%) | 31.63 (3.50) | n= 4 (12.9%) | 32.50 (2.52) | -0.25 [-1.51 ; 1.02] |
| Week 105 | n= 7 (16.7%) | 31.00 (4.47) | | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 5 (11.9%) | 31.20 (3.56) | | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (19.0%) | 29.13 (4.22) | n= 1 ( 3.2%) | 33.00 ( / ) | [Not calculable] |
| Week 111 | n= 5 (11.9%) | 30.00 (4.53) | | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 (11.9%) | 31.40 (4.77) | | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 5 (11.9%) | 30.60 (4.83) | n= 2 ( 6.5%) | 32.00 (0.00) | -0.27 [-2.09 ; 1.55] |
| Week 117 | n= 4 ( 9.5%) | 33.50 (3.00) | | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 9.5%) | 29.50 (4.80) | | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (11.9%) | 31.00 (5.24) | | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.4%) | 33.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (14.3%) | 33.33 (2.16) | n= 8 (25.8%) | 30.75 (4.27) | 0.68 [-0.45 ; 1.82] |
| Week 202 | n= 2 ( 4.8%) | 25.00 (7.07) | n= 4 (12.9%) | 31.25 (0.50) | -1.40 [-3.63 ; 0.82] |
| **Not Reported** | | | | | |
| N subjects in population | | N=22 | | N=25 | |
| Baseline | n= 22 (100.0%) | 32.43 (4.20) | n= 25 (100.0%) | 31.93 (3.45) | 0.13 [-0.45 ; 0.71] |
| Week 3 | n= 20 (90.9%) | 33.15 (2.74) | | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 19 (86.4%) | 32.39 (3.70) | | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 20 (90.9%) | 31.62 (3.51) | n= 23 (92.0%) | 30.43 (3.79) | 0.32 [-0.29 ; 0.93] |
| Week 9 | n= 20 (90.9%) | 32.10 (4.12) | | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 19 (86.4%) | 31.39 (4.12) | | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 20 (90.9%) | 31.34 (4.64) | n= 23 (92.0%) | 29.91 (3.80) | 0.33 [-0.28 ; 0.94] |
| Week 15 | n= 20 (90.9%) | 31.94 (3.11) | | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 22 (100.0%) | 32.66 (2.72) | | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 21 (95.5%) | 32.36 (3.10) | n= 21 (84.0%) | 31.29 (4.02) | 0.29 [-0.32 ; 0.91] |
| Week 21 | n= 21 (95.5%) | 32.76 (3.32) | | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (95.5%) | 32.38 (3.61) | | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 20 (90.9%) | 32.41 (3.37) | n= 18 (72.0%) | 31.33 (4.16) | 0.28 [-0.37 ; 0.93] |
| Week 27 | n= 22 (100.0%) | 32.36 (4.14) | | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 19 (86.4%) | 32.48 (2.82) | | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 22 (100.0%) | 32.41 (4.39) | n= 18 (72.0%) | 31.17 (4.08) | 0.29 [-0.35 ; 0.92] |
| Week 33 | n= 20 (90.9%) | 32.77 (4.25) | | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 21 (95.5%) | 32.33 (5.22) | | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 21 (95.5%) | 32.54 (4.76) | n= 20 (80.0%) | 31.75 (3.02) | 0.19 [-0.43 ; 0.81] |
| Week 39 | n= 18 (81.8%) | 33.39 (2.23) | | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 17 (77.3%) | 33.06 (3.29) | | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 43 | n= 20 (90.9%) \| 32.20 (3.82) | n= 20 (80.0%) \| 31.05 (3.87) | 0.29 [-0.34 ; 0.92] |
| Week 45 | n= 19 (86.4%) \| 31.63 (3.71) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 19 (86.4%) \| 32.84 (3.39) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 20 (90.9%) \| 32.81 (2.76) | n= 19 (76.0%) \| 31.41 (4.61) | 0.36 [-0.28 ; 1.00] |
| Week 51 | n= 21 (95.5%) \| 32.08 (3.27) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 20 (90.9%) \| 32.76 (2.73) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 18 (81.8%) \| 32.14 (3.61) | n= 19 (76.0%) \| 31.76 (2.87) | 0.11 [-0.54 ; 0.77] |
| Week 57 | n= 17 (77.3%) \| 32.85 (2.56) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 18 (81.8%) \| 32.40 (3.36) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 19 (86.4%) \| 33.16 (2.57) | n= 16 (64.0%) \| 31.50 (3.72) | 0.51 [-0.17 ; 1.20] |
| Week 63 | n= 15 (68.2%) \| 32.69 (3.10) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 18 (81.8%) \| 31.90 (3.50) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 19 (86.4%) \| 32.84 (2.61) | n= 14 (56.0%) \| 31.21 (3.26) | 0.55 [-0.17 ; 1.26] |
| Week 69 | n= 15 (68.2%) \| 30.82 (4.29) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 15 (68.2%) \| 32.18 (3.80) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (72.7%) \| 32.44 (2.92) | n= 13 (52.0%) \| 30.24 (2.51) | 0.78 [ 0.00 ; 1.55] |
| Week 75 | n= 15 (68.2%) \| 32.07 (3.26) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 13 (59.1%) \| 33.31 (2.25) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 13 (59.1%) \| 30.88 (7.41) | n= 11 (44.0%) \| 31.00 (2.72) | -0.02 [-0.84 ; 0.80] |
| Week 81 | n= 11 (50.0%) \| 32.64 (3.04) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 13 (59.1%) \| 33.31 (3.12) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (50.0%) \| 32.18 (3.89) | n= 9 (36.0%) \| 31.44 (3.09) | 0.20 [-0.71 ; 1.11] |
| Week 87 | n= 11 (50.0%) \| 31.73 (4.45) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 11 (50.0%) \| 32.26 (3.71) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 9 (40.9%) \| 31.89 (2.98) | n= 7 (28.0%) \| 31.43 (3.05) | 0.14 [-0.88 ; 1.17] |
| Week 93 | n= 9 (40.9%) \| 33.00 (3.20) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 9 (40.9%) \| 32.56 (3.00) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (31.8%) \| 32.57 (3.05) | n= 3 (12.0%) \| 33.00 (2.00) | -0.14 [-1.58 ; 1.30] |
| Week 99 | n= 7 (31.8%) \| 32.71 (3.35) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (27.3%) \| 32.17 (2.56) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 6 (27.3%) \| 31.67 (3.93) | n= 4 (16.0%) \| 32.25 (1.71) | -0.16 [-1.51 ; 1.19] |
| Week 105 | n= 5 (22.7%) \| 30.60 (3.97) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 3 (13.6%) \| 32.67 (3.06) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (13.6%) \| 28.96 (3.06) | n= 2 ( 8.0%) \| 32.50 (3.54) | -0.80 [-3.06 ; 1.46] |
| Week 111 | n= 2 ( 9.1%) \| 31.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (13.6%) \| 31.50 (1.50) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 2 ( 9.1%) \| 32.00 (2.83) | n= 2 ( 8.0%) \| 31.50 (2.12) | 0.11 [-2.35 ; 2.58] |
| Week 117 | n= 3 (13.6%) \| 31.67 (3.21) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 (13.6%) \| 29.00 (5.00) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (13.6%) \| 31.42 (3.97) | n= 1 ( 4.0%) \| 30.38 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 9.1%) \| 31.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.5%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 4.5%) \| 31.00 ( / ) | n= 1 ( 4.0%) \| 24.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 4.5%) \| 29.25 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 4.5%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.5%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 4.5%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 4.5%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 4.5%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.5%) \| 31.50 ( / ) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 201 | n= 1 ( 4.5%) \| 30.00 ( / ) | n= 5 (20.0%) \| 29.60 (6.43) | [Not calculable] |
| Week 202 | [No Data] | n= 5 (20.0%) \| 33.00 (3.32) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:52

TABLE 7.4.6: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Hispanic or Latino** | | | |
| N subjects in population | N=7 | N=12 | |
| Week 3 | n= 7 (100.0%) \| 0.57 (0.98) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 6 (85.7%) \| 0.77 (2.04) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 7 (100.0%) \| 2.66 (3.76) | n= 11 (91.7%) \|-1.82 (3.92) | 1.10 [ 0.05 ; 2.16] |
| Week 9 | n= 6 (85.7%) \| 0.17 (5.98) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 6 (85.7%) \| 0.94 (2.69) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 7 (100.0%) \| 0.80 (5.91) | n= 7 (58.3%) \|-1.29 (2.43) | 0.43 [-0.67 ; 1.54] |
| Week 15 | n= 5 (71.4%) \| 0.60 (6.19) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 6 (85.7%) \| 0.03 (5.91) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 5 (71.4%) \| 0.33 (2.01) | n= 6 (50.0%) \|-3.17 (2.48) | 1.40 [-0.02 ; 2.82] |
| Week 21 | n= 6 (85.7%) \|-0.33 (4.50) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 6 (85.7%) \| 0.83 (2.48) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 4 (57.1%) \| 2.75 (2.22) | n= 6 (50.0%) \|-1.67 (2.16) | 1.83 [ 0.19 ; 3.47] |
| Week 27 | n= 4 (57.1%) \| 2.75 (1.89) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 4 (57.1%) \| 1.50 (1.29) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 4 (57.1%) \| 0.50 (1.00) | n= 5 (41.7%) \|-1.20 (1.10) | 1.43 [-0.19 ; 3.05] |
| Week 33 | n= 4 (57.1%) \|-0.25 (3.40) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 3 (42.9%) \|-0.33 (3.51) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 2 (28.6%) \| 1.00 (1.41) | n= 4 (33.3%) \|-0.50 (0.58) | 1.39 [-0.84 ; 3.61] |
| Week 39 | n= 4 (57.1%) \| 1.41 (1.35) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 3 (42.9%) \| 0.21 (2.42) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 3 (42.9%) \| 0.54 (1.50) | n= 4 (33.3%) \|-1.28 (2.18) | 0.79 [-0.95 ; 2.53] |
| Week 45 | n= 2 (28.6%) \| 1.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 2 (28.6%) \| 0.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 3 (42.9%) \| 0.88 (1.85) | n= 3 (25.0%) \|-1.00 (2.65) | 0.66 [-1.23 ; 2.55] |
| Week 51 | n= 3 (42.9%) \| 0.33 (1.53) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 2 (28.6%) \| 1.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 3 (42.9%) \| 2.21 (1.94) | n= 3 (25.0%) \|-4.33 (4.16) | 1.61 [-0.61 ; 3.84] |
| Week 57 | n= 3 (42.9%) \| 1.21 (1.58) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 3 (42.9%) \| 1.21 (1.58) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 3 (42.9%) \| 1.00 (1.73) | n= 3 (25.0%) \|-2.00 (2.00) | 1.28 [-0.80 ; 3.37] |
| Week 63 | n= 3 (42.9%) \| 0.88 (1.85) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 3 (42.9%) \| 1.21 (1.06) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 3 (42.9%) \| 0.88 (1.02) | n= 3 (25.0%) \|-2.67 (3.06) | 1.24 [-0.83 ; 3.31] |
| Week 69 | n= 3 (42.9%) \| 1.21 (2.03) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 2 (28.6%) \| 1.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 3 (42.9%) \| 1.21 (2.03) | n= 3 (25.0%) \|-1.67 (2.08) | 1.12 [-0.90 ; 3.14] |
| Week 75 | n= 3 (42.9%) \| 0.88 (2.01) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 2 (28.6%) \| 1.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 3 (42.9%) \| 1.21 (1.58) | n= 3 (25.0%) \|-1.00 (1.73) | 1.06 [-0.94 ; 3.07] |
| Week 81 | n= 3 (42.9%) \| 1.54 (1.37) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 3 (42.9%) \| 0.88 (1.02) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 3 (42.9%) \| 0.54 (2.24) | n= 2 (16.7%) \|-0.50 (0.71) | 0.40 [-1.75 ; 2.56] |
| Week 87 | n= 2 (28.6%) \| 1.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 2 (28.6%) \| 0.31 (0.44) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 2 (28.6%) \|-0.19 (0.27) | n= 2 (16.7%) \|-0.50 (0.71) | 0.33 [-2.18 ; 2.85] |
| Week 93 | n= 2 (28.6%) \|-0.19 (0.27) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 2 (28.6%) \| 0.81 (1.15) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 2 (28.6%) \| 0.00 (0.00) | n= 2 (16.7%) \|-1.00 (1.41) | 0.57 [-2.04 ; 3.18] |
| Week 99 | n= 2 (28.6%) \| 0.81 (1.15) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (14.3%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 1 (14.3%) \| 0.63 ( / ) | n= 1 ( 8.3%) \| 0.00 ( / ) | [Not calculable] |
| Week 105 | n= 1 (14.3%) \| 0.63 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | [No Data] | n= 1 ( 8.3%) \| 0.00 ( / ) | [No Data for at least 1 arm] |
| Week 115 | [No Data] | n= 1 ( 8.3%) \| 0.00 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 1 (14.3%) \| 1.00 ( / ) | n= 3 (25.0%) \|-1.33 (5.13) | [Not calculable] |
| Week 202 | [No Data] | n= 2 (16.7%) \| 1.00 (1.41) | [No Data for at least 1 arm] |
| **Not Hispanic or Latino** | | | |
| N subjects in population | N=42 | N=31 | |
| Week 3 | n= 39 (92.9%) \|-0.60 (2.38) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 36 (85.7%) \|-1.20 (3.47) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 35 (83.3%) \|-1.71 (3.89) | n= 29 (93.5%) \|-0.56 (3.04) | -0.32 [-0.82 ; 0.18] |
| Week 9 | n= 34 (81.0%) \|-1.37 (4.04) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 35 (83.3%) \|-1.40 (3.86) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 32 (76.2%) \|-0.78 (3.29) | n= 25 (80.6%) \|-0.71 (3.09) | -0.02 [-0.55 ; 0.51] |
| Week 15 | n= 29 (69.0%) \|-1.21 (4.15) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 34 (81.0%) \|-1.18 (3.51) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 30 (71.4%) \|-1.05 (3.21) | n= 26 (83.9%) \|-0.58 (3.05) | -0.15 [-0.68 ; 0.38] |
| Week 21 | n= 32 (76.2%) \|-0.63 (3.47) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 29 (69.0%) \|-1.63 (3.17) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 33 (78.6%) \|-0.67 (3.64) | n= 24 (77.4%) \|-0.23 (3.11) | -0.13 [-0.66 ; 0.41] |
| Week 27 | n= 29 (69.0%) \|-0.07 (3.47) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 29 (69.0%) \|-0.52 (4.00) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 28 (66.7%) \|-0.61 (3.72) | n= 19 (61.3%) \|-0.19 (2.33) | -0.13 [-0.72 ; 0.46] |
| Week 33 | n= 32 (76.2%) \|-0.91 (3.72) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 29 (69.0%) \|-1.14 (3.74) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 25 (59.5%) \|-0.36 (3.55) | n= 22 (71.0%) \|-0.55 (3.60) | 0.05 [-0.53 ; 0.63] |
| Week 39 | n= 29 (69.0%) \|-0.66 (3.51) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 32 (76.2%) \|-0.59 (3.66) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 28 (66.7%) \|-0.69 (3.67) | n= 17 (54.8%) \|-0.04 (2.91) | -0.19 [-0.80 ; 0.42] |
| Week 45 | n= 27 (64.3%) \|-1.18 (4.08) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 30 (71.4%) \|-1.17 (3.21) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 29 (69.0%) \|-1.00 (3.83) | n= 13 (41.9%) \|-0.74 (2.20) | -0.07 [-0.74 ; 0.59] |
| Week 51 | n= 27 (64.3%) \|-0.89 (3.43) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 30 (71.4%) \|-0.73 (3.32) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 25 (59.5%) \|-0.96 (2.91) | n= 15 (48.4%) \|-0.38 (2.95) | -0.20 [-0.85 ; 0.45] |
| Week 57 | n= 28 (66.7%) \|-1.36 (3.91) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 25 (59.5%) \|-1.12 (3.75) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 26 (61.9%) \|-0.84 (3.70) | n= 11 (35.5%) \|-0.06 (3.33) | -0.21 [-0.93 ; 0.50] |
| Week 63 | n= 24 (57.1%) \|-0.88 (3.99) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 22 (52.4%) \|-1.27 (5.04) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 22 (52.4%) \|-0.86 (4.20) | n= 12 (38.7%) \| 0.28 (2.83) | -0.30 [-1.01 ; 0.42] |
| Week 69 | n= 20 (47.6%) \|-1.40 (5.26) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 21 (50.0%) \|-0.57 (4.69) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (38.1%) \|-0.06 (5.08) | n= 12 (38.7%) \|-0.55 (3.59) | 0.11 [-0.66 ; 0.87] |
| Week 75 | n= 17 (40.5%) \| 0.18 (4.13) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 77 | n= 17 (40.5%) \|-0.35 (4.17) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 15 (35.7%) \| 0.33 (3.99) | n= 10 (32.3%) \| 0.80 (3.29) | -0.12 [-0.94 ; 0.70] |
| Week 81 | n= 15 (35.7%) \|-0.87 (3.07) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 17 (40.5%) \|-0.12 (3.95) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 13 (31.0%) \| 0.38 (3.62) | n= 9 (29.0%) \| 0.22 (3.38) | 0.04 [-0.83 ; 0.91] |
| Week 87 | n= 11 (26.2%) \|-1.36 (2.66) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 12 (28.6%) \| 0.00 (3.64) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 13 (31.0%) \|-1.52 (3.16) | n= 8 (25.8%) \| 1.42 (4.81) | -0.73 [-1.67 ; 0.20] |
| Week 93 | n= 12 (28.6%) \|-1.00 (2.45) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 11 (26.2%) \|-1.48 (3.41) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 12 (28.6%) \|-1.75 (3.19) | n= 5 (16.1%) \|-1.40 (3.05) | -0.11 [-1.18 ; 0.97] |
| Week 99 | n= 8 (19.0%) \|-1.88 (4.39) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 7 (16.7%) \|-1.57 (2.94) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 8 (19.0%) \|-0.13 (3.14) | n= 4 (12.9%) \| 1.00 (2.58) | -0.35 [-1.62 ; 0.92] |
| Week 105 | n= 7 (16.7%) \|-0.14 (2.91) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 5 (11.9%) \|-1.00 (2.45) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (19.0%) \|-1.88 (3.04) | n= 1 ( 3.2%) \| 2.00 ( / ) | [Not calculable] |
| Week 111 | n= 5 (11.9%) \|-2.00 (3.32) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 (11.9%) \|-1.80 (2.77) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 5 (11.9%) \|-2.80 (2.49) | n= 2 ( 6.5%) \|-1.00 (2.83) | -0.59 [-2.45 ; 1.26] |
| Week 117 | n= 4 ( 9.5%) \|-0.50 (2.08) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 9.5%) \|-3.50 (2.38) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (11.9%) \|-3.00 (3.39) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 2.4%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (14.3%) \| 0.17 (2.64) | n= 8 (25.8%) \|-1.50 (3.51) | 0.49 [-0.63 ; 1.61] |
| Week 202 | n= 2 ( 4.8%) \|-5.50 (4.95) | n= 4 (12.9%) \|-2.00 (1.41) | -1.01 [-3.10 ; 1.07] |
| **Not Reported** | | | |
| N subjects in population | N=22 | N=25 | |
| Week 3 | n= 20 (90.9%) \| 0.38 (2.20) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 19 (86.4%) \|-0.10 (2.15) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 20 (90.9%) \|-0.50 (2.34) | n= 23 (92.0%) \|-1.48 (3.55) | 0.32 [-0.29 ; 0.93] |
| Week 9 | n= 20 (90.9%) \|-1.02 (2.95) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 19 (86.4%) \|-1.15 (2.70) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 20 (90.9%) \|-0.78 (3.07) | n= 23 (92.0%) \|-2.18 (3.45) | 0.42 [-0.19 ; 1.03] |
| Week 15 | n= 20 (90.9%) \|-0.38 (3.23) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 22 (100.0%) \| 0.23 (2.91) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 21 (95.5%) \| 0.06 (3.39) | n= 21 (84.0%) \|-0.76 (4.33) | 0.21 [-0.41 ; 0.82] |
| Week 21 | n= 21 (95.5%) \| 0.46 (3.60) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 21 (95.5%) \|-0.43 (2.80) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 20 (90.9%) \|-0.01 (3.50) | n= 18 (72.0%) \|-1.44 (4.41) | 0.36 [-0.29 ; 1.01] |
| Week 27 | n= 22 (100.0%) \|-0.06 (3.92) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 19 (86.4%) \| 0.51 (3.37) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 22 (100.0%) \|-0.02 (3.97) | n= 18 (72.0%) \|-1.62 (2.72) | 0.45 [-0.19 ; 1.09] |
| Week 33 | n= 20 (90.9%) \| 0.12 (2.94) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 21 (95.5%) \| 0.07 (3.51) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 21 (95.5%) \| 0.28 (3.74) | n= 20 (80.0%) \|-1.01 (2.99) | 0.37 [-0.25 ; 1.00] |
| Week 39 | n= 18 (81.8%) \| 0.53 (3.17) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 17 (77.3%) \|-0.65 (3.57) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 20 (90.9%) \|-0.27 (4.65) | n= 20 (80.0%) \|-1.51 (3.02) | 0.31 [-0.32 ; 0.94] |
| Week 45 | n= 19 (86.4%) \|-0.65 (4.82) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 19 (86.4%) \|-0.11 (3.46) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 49 | n= 20 (90.9%) \| 0.49 (3.64) | n= 19 (76.0%) \|-1.07 (3.99) | 0.40 [-0.24 ; 1.04] |
| Week 51 | n= 21 (95.5%) \|-0.18 (3.88) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 20 (90.9%) \| 0.49 (3.19) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 18 (81.8%) \|-0.27 (4.03) | n= 19 (76.0%) \|-0.72 (2.39) | 0.13 [-0.52 ; 0.79] |
| Week 57 | n= 17 (77.3%) \| 0.89 (3.30) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 18 (81.8%) \| 0.16 (4.52) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 19 (86.4%) \| 0.71 (3.52) | n= 16 (64.0%) \|-0.70 (3.04) | 0.42 [-0.27 ; 1.10] |
| Week 63 | n= 15 (68.2%) \| 0.69 (3.82) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 18 (81.8%) \|-0.07 (4.60) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 19 (86.4%) \| 0.77 (3.62) | n= 14 (56.0%) \|-0.87 (2.61) | 0.49 [-0.22 ; 1.20] |
| Week 69 | n= 15 (68.2%) \|-0.68 (5.34) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 15 (68.2%) \| 0.25 (4.45) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 16 (72.7%) \| 0.31 (3.82) | n= 13 (52.0%) \|-1.46 (2.29) | 0.53 [-0.23 ; 1.29] |
| Week 75 | n= 15 (68.2%) \| 0.13 (4.96) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 13 (59.1%) \| 2.20 (4.69) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 13 (59.1%) \|-0.50 (7.44) | n= 11 (44.0%) \|-0.01 (2.63) | -0.08 [-0.90 ; 0.74] |
| Week 81 | n= 11 (50.0%) \| 1.27 (4.41) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 13 (59.1%) \| 1.46 (5.03) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 11 (50.0%) \| 0.27 (5.35) | n= 9 (36.0%) \|-0.89 (2.42) | 0.26 [-0.65 ; 1.17] |
| Week 87 | n= 11 (50.0%) \| 0.18 (5.69) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 11 (50.0%) \| 0.35 (4.84) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 9 (40.9%) \|-0.56 (3.91) | n= 7 (28.0%) \|-2.43 (3.41) | 0.48 [-0.56 ; 1.52] |
| Week 93 | n= 9 (40.9%) \| 0.22 (4.29) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 9 (40.9%) \| 0.11 (3.92) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (31.8%) \| 0.86 (3.80) | n= 3 (12.0%) \| 1.00 (3.46) | -0.03 [-1.47 ; 1.40] |
| Week 99 | n= 7 (31.8%) \| 1.00 (3.32) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 6 (27.3%) \| 1.00 (3.29) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 6 (27.3%) \| 0.50 (3.83) | n= 4 (16.0%) \|-0.75 (3.40) | 0.31 [-1.05 ; 1.66] |
| Week 105 | n= 5 (22.7%) \| 0.20 (4.60) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 3 (13.6%) \| 2.67 (5.51) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (13.6%) \|-0.71 (6.86) | n= 2 ( 8.0%) \|-2.50 (4.95) | 0.21 [-1.92 ; 2.33] |
| Week 111 | n= 2 ( 9.1%) \| 2.50 (6.36) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (13.6%) \| 1.83 (5.39) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 2 ( 9.1%) \| 5.00 (4.24) | n= 2 ( 8.0%) \|-1.50 (0.71) | 1.22 [-1.86 ; 4.30] |
| Week 117 | n= 3 (13.6%) \| 2.00 (4.00) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 (13.6%) \|-0.67 (7.51) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (13.6%) \| 1.75 (4.92) | n= 1 ( 4.0%) \|-1.63 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 9.1%) \|-2.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 4.5%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 4.5%) \|-1.00 ( / ) | n= 1 ( 4.0%) \|-8.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 4.5%) \|-2.75 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 4.5%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 4.5%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 4.5%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 4.5%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 4.5%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 4.5%) \|-0.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 4.5%) \|-6.00 ( / ) | n= 5 (20.0%) \|-1.80 (7.46) | [Not calculable] |
| Week 202 | [No Data] | n= 5 (20.0%) \| 0.80 (4.66) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:52

TABLE 7.4.6: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Ethnicity Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **Hispanic or Latino** | | | | |
| Nr subjects used | n=7 | n=11 | | |
| **Not Hispanic or Latino** | | | | |
| Nr subjects used | n=40 | n=31 | | |
| Week 7 | -1.89 (0.60) [-3.10 ;-0.69] | -0.69 (0.67) [-2.03 ; 0.66] | -1.21 (0.90) [-3.01 ; 0.59] | -0.33 [-0.83 ; 0.16] |
| Week 13 | -0.66 (0.51) [-1.68 ; 0.37] | -0.58 (0.58) [-1.74 ; 0.59] | -0.08 (0.78) [-1.63 ; 1.47] | -0.03 [-0.55 ; 0.50] |
| Week 19 | -0.89 (0.45) [-1.79 ; 0.01] | -0.70 (0.50) [-1.70 ; 0.30] | -0.19 (0.67) [-1.53 ; 1.15] | -0.07 [-0.60 ; 0.45] |
| Week 25 | -0.64 (0.49) [-1.62 ; 0.34] | -0.52 (0.56) [-1.64 ; 0.61] | -0.12 (0.75) [-1.61 ; 1.37] | -0.04 [-0.57 ; 0.48] |
| Week 31 | -0.61 (0.57) [-1.75 ; 0.53] | -0.10 (0.67) [-1.45 ; 1.24] | -0.51 (0.88) [-2.28 ; 1.25] | -0.17 [-0.75 ; 0.42] |
| Week 37 | -0.43 (0.64) [-1.70 ; 0.84] | -0.93 (0.71) [-2.35 ; 0.49] | 0.50 (0.95) [-1.41 ; 2.41] | 0.15 [-0.42 ; 0.73] |
| Week 43 | -0.46 (0.58) [-1.62 ; 0.70] | -0.27 (0.72) [-1.72 ; 1.17] | -0.19 (0.93) [-2.04 ; 1.67] | -0.06 [-0.66 ; 0.54] |
| Week 49 | -0.74 (0.57) [-1.88 ; 0.39] | -0.35 (0.79) [-1.92 ; 1.22] | -0.39 (0.97) [-2.33 ; 1.55] | -0.13 [-0.78 ; 0.53] |
| Week 55 | -0.55 (0.51) [-1.57 ; 0.47] | -0.63 (0.67) [-1.97 ; 0.72] | 0.08 (0.85) [-1.62 ; 1.77] | 0.03 [-0.61 ; 0.67] |
| Week 61 | -0.94 (0.57) [-2.08 ; 0.21] | -0.54 (0.83) [-2.21 ; 1.12] | -0.39 (1.01) [-2.42 ; 1.63] | -0.13 [-0.84 ; 0.57] |
| Week 67 | -1.10 (0.71) [-2.52 ; 0.31] | -0.37 (0.97) [-2.32 ; 1.59] | -0.74 (1.20) [-3.16 ; 1.68] | -0.22 [-0.92 ; 0.49] |
| Week 73 | -0.92 (0.93) [-2.79 ; 0.96] | -1.11 (1.16) [-3.45 ; 1.23] | 0.19 (1.49) [-2.81 ; 3.20] | 0.05 [-0.70 ; 0.80] |
| Week 79 | -0.15 (0.82) [-1.83 ; 1.53] | 0.06 (1.03) [-2.05 ; 2.17] | -0.21 (1.32) [-2.90 ; 2.49] | -0.06 [-0.86 ; 0.74] |
| Overall post-baseline period estimate | -0.77 (0.32) [-1.40 ;-0.13] | -0.52 (0.40) [-1.31 ; 0.28] | -0.25 (0.51) [-1.27 ; 0.77] | -0.12 [-0.59 ; 0.36] |
| **Not Reported** | | | | |
| Nr subjects used | n=22 | n=25 | | |
| Week 7 | -0.48 (0.65) [-1.80 ; 0.83] | -1.59 (0.61) [-2.82 ;-0.35] | 1.10 (0.89) [-0.70 ; 2.90] | 0.37 [-0.24 ; 0.97] |
| Week 13 | -0.64 (0.78) [-2.20 ; 0.93] | -2.22 (0.74) [-3.70 ;-0.73] | 1.58 (1.07) [-0.58 ; 3.74] | 0.44 [-0.17 ; 1.05] |
| Week 19 | 0.09 (0.68) [-1.27 ; 1.46] | -0.92 (0.67) [-2.27 ; 0.43] | 1.01 (0.96) [-0.91 ; 2.93] | 0.32 [-0.29 ; 0.93] |
| Week 25 | -0.10 (0.70) [-1.51 ; 1.31] | -1.01 (0.72) [-2.46 ; 0.43] | 0.91 (1.01) [-1.11 ; 2.93] | 0.29 [-0.35 ; 0.93] |
| Week 31 | 0.06 (0.69) [-1.33 ; 1.46] | -1.17 (0.74) [-2.64 ; 0.31] | 1.23 (1.01) [-0.79 ; 3.26] | 0.38 [-0.25 ; 1.01] |
| Week 37 | 0.25 (0.70) [-1.15 ; 1.66] | -0.86 (0.72) [-2.30 ; 0.57] | 1.11 (1.00) [-0.89 ; 3.12] | 0.34 [-0.28 ; 0.96] |
| Week 43 | -0.12 (0.74) [-1.62 ; 1.37] | -1.30 (0.75) [-2.81 ; 0.22] | 1.17 (1.06) [-0.95 ; 3.30] | 0.34 [-0.28 ; 0.97] |
| Week 49 | 0.16 (0.76) [-1.36 ; 1.69] | -0.95 (0.78) [-2.52 ; 0.62] | 1.11 (1.09) [-1.08 ; 3.30] | 0.32 [-0.31 ; 0.95] |
| Week 55 | -0.43 (0.65) [-1.74 ; 0.87] | -0.50 (0.65) [-1.80 ; 0.81] | 0.06 (0.91) [-1.78 ; 1.90] | 0.02 [-0.62 ; 0.67] |
| Week 61 | 0.48 (0.59) [-0.72 ; 1.67] | -0.61 (0.64) [-1.89 ; 0.67] | 1.09 (0.87) [-0.66 ; 2.84] | 0.41 [-0.26 ; 1.09] |
| Week 67 | 0.62 (0.50) [-0.38 ; 1.63] | -0.67 (0.56) [-1.81 ; 0.46] | 1.29 (0.75) [-0.22 ; 2.81] | 0.59 [-0.12 ; 1.29] |
| Week 73 | 0.17 (0.53) [-0.90 ; 1.25] | -1.42 (0.58) [-2.60 ;-0.24] | 1.59 (0.79) [-0.00 ; 3.19] | 0.73 [-0.03 ; 1.49] |
| Week 79 | -1.06 (1.39) [-3.91 ; 1.80] | -0.73 (1.51) [-3.83 ; 2.36] | -0.33 (2.06) [-4.54 ; 3.88] | -0.06 [-0.87 ; 0.74] |
| Overall post-baseline period estimate | -0.08 (0.36) [-0.79 ; 0.63] | -1.07 (0.37) [-1.80 ;-0.35] | 1.00 (0.51) [-0.02 ; 2.01] | 0.56 [-0.03 ; 1.16] |
| **MMRM subgroups interaction p-value** | | | 0.7379 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.

TABLE 7.4.7: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **Male** | | |
| | N=54 | N=47 |
| **Female** | | |
| | N=17 | N=21 |
| **Subjects with Baseline Value** | | |
| **Male** | | |
| | 52 (96.3%) | 46 (97.9%) |
| **Female** | | |
| | 17 (100.0%) | 21 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **Male** | | |
| | 54 (100.0%) | 47 (100.0%) |
| **Female** | | |
| | 17 (100.0%) | 19 (90.5%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **Male** | | |
| | 52 (96.3%) | 46 (97.9%) |
| **Female** | | |
| | 17 (100.0%) | 19 (90.5%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:52

TABLE 7.4.7: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Male** | | | |
| N subjects in population | N=54 | N=47 | |
| Baseline | n= 52 (96.3%) \| 32.11 (4.12) | n= 46 (97.9%) \| 31.41 (3.92) | 0.17 [-0.23 ; 0.57] |
| Week 3 | n= 51 (94.4%) \| 31.65 (3.75) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 47 (87.0%) \| 31.98 (3.79) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 50 (92.6%) \| 31.13 (3.88) | n= 46 (97.9%) \| 30.50 (3.70) | 0.17 [-0.24 ; 0.57] |
| Week 9 | n= 47 (87.0%) \| 31.37 (3.80) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 46 (85.2%) \| 31.54 (3.51) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 47 (87.0%) \| 32.07 (3.10) | n= 38 (80.9%) \| 30.76 (3.66) | 0.38 [-0.05 ; 0.82] |
| Week 15 | n= 42 (77.8%) \| 31.54 (3.81) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 48 (88.9%) \| 32.28 (3.35) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 45 (83.3%) \| 32.45 (2.90) | n= 41 (87.2%) \| 31.30 (3.04) | 0.38 [-0.05 ; 0.81] |
| Week 21 | n= 46 (85.2%) \| 32.35 (3.35) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 41 (75.9%) \| 31.61 (3.52) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 45 (83.3%) \| 32.32 (3.26) | n= 35 (74.5%) \| 31.20 (3.13) | 0.34 [-0.10 ; 0.79] |
| Week 27 | n= 43 (79.6%) \| 32.93 (3.84) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 40 (74.1%) \| 32.30 (3.81) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 42 (77.8%) \| 32.33 (4.01) | n= 30 (63.8%) \| 31.70 (3.86) | 0.16 [-0.31 ; 0.63] |
| Week 33 | n= 44 (81.5%) \| 32.17 (4.05) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 43 (79.6%) \| 31.76 (4.35) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 40 (74.1%) \| 32.56 (4.06) | n= 36 (76.6%) \| 31.56 (2.95) | 0.28 [-0.18 ; 0.73] |
| Week 39 | n= 42 (77.8%) \| 32.36 (4.00) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 41 (75.9%) \| 32.32 (4.19) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 42 (77.8%) \| 32.16 (3.84) | n= 30 (63.8%) \| 31.26 (3.64) | 0.24 [-0.24 ; 0.71] |
| Week 45 | n= 38 (70.4%) \| 31.35 (4.48) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 41 (75.9%) \| 32.20 (3.88) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 41 (75.9%) \| 32.30 (4.31) | n= 26 (55.3%) \| 32.08 (2.45) | 0.06 [-0.44 ; 0.55] |
| Week 51 | n= 40 (74.1%) \| 31.85 (4.37) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 40 (74.1%) \| 32.46 (3.92) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 37 (68.5%) \| 32.18 (4.32) | n= 27 (57.4%) \| 30.93 (3.43) | 0.31 [-0.19 ; 0.81] |
| Week 57 | n= 40 (74.1%) \| 31.76 (4.37) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (68.5%) \| 32.26 (3.93) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (72.2%) \| 32.20 (4.43) | n= 21 (44.7%) \| 30.95 (3.17) | 0.30 [-0.23 ; 0.84] |
| Week 63 | n= 34 (63.0%) \| 31.77 (4.81) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 33 (61.1%) \| 31.34 (5.57) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 35 (64.8%) \| 32.23 (4.43) | n= 21 (44.7%) \| 31.05 (3.07) | 0.29 [-0.26 ; 0.84] |
| Week 69 | n= 30 (55.6%) \| 31.94 (4.98) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (57.4%) \| 32.51 (4.40) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 28 (51.9%) \| 32.93 (3.83) | n= 19 (40.4%) \| 30.58 (3.15) | 0.65 [ 0.04 ; 1.25] |
| Week 75 | n= 29 (53.7%) \| 32.69 (3.61) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (50.0%) \| 32.19 (3.97) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (48.1%) \| 31.48 (6.36) | n= 18 (38.3%) \| 31.17 (3.17) | 0.06 [-0.55 ; 0.67] |
| Week 81 | n= 24 (44.4%) \| 32.08 (4.49) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (51.9%) \| 32.61 (3.94) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 21 (38.9%) \| 33.00 (3.52) | n= 14 (29.8%) \| 31.57 (3.67) | 0.39 [-0.30 ; 1.08] |
| Week 87 | n= 19 (35.2%) \| 31.26 (4.85) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 20 (37.0%) \| 31.90 (4.12) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 19 (35.2%) \| 31.07 (4.94) | n= 12 (25.5%) \| 33.50 (2.50) | -0.57 [-1.32 ; 0.18] |
| Week 93 | n= 19 (35.2%) \| 31.84 (4.06) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 18 (33.3%) \| 31.71 (4.62) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (31.5%) \| 30.79 (4.68) | n= 7 (14.9%) \| 31.57 (4.20) | -0.17 [-1.07 ; 0.73] |
| Week 99 | n= 15 (27.8%) \| 30.53 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (20.4%) \| 31.55 (4.03) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (22.2%) \| 31.67 (3.42) | n= 5 (10.6%) \| 31.80 (3.27) | -0.04 [-1.11 ; 1.04] |
| Week 105 | n= 10 (18.5%) \| 30.90 (3.96) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (11.1%) \| 31.33 (3.20) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.8%) \| 28.36 (3.60) | n= 3 ( 6.4%) \| 30.67 (6.81) | -0.47 [-1.89 ; 0.95] |
| Week 111 | n= 6 (11.1%) \| 30.50 (4.23) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (11.1%) \| 31.92 (4.25) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 7.4%) \| 31.00 (5.48) | n= 3 ( 6.4%) \| 33.33 (2.31) | -0.44 [-2.12 ; 1.24] |
| Week 117 | n= 5 ( 9.3%) \| 34.20 (1.79) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 9.3%) \| 29.40 (5.46) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (11.1%) \| 31.04 (5.08) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 2 ( 3.7%) \| 31.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.9%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.9%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 1.9%) \| 29.25 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.9%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.9%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.9%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.9%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.9%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.9%) \| 31.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (11.1%) \| 31.67 (5.16) | n= 10 (21.3%) \| 29.10 (5.07) | 0.48 [-0.59 ; 1.54] |
| Week 202 | n= 2 ( 3.7%) \| 25.00 (7.07) | n= 7 (14.9%) \| 32.14 (2.79) | -1.71 [-3.64 ; 0.23] |
| **Female** | | | |
| N subjects in population | N=17 | N=21 | |
| Baseline | n= 17 (100.0%) \| 30.24 (5.08) | n= 21 (100.0%) \| 31.61 (4.95) | -0.27 [-0.92 ; 0.38] |
| Week 3 | n= 16 (94.1%) \| 31.11 (4.71) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 16 (94.1%) \| 28.66 (6.21) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 14 (82.4%) \| 29.21 (5.21) | n= 18 (85.7%) \| 29.74 (4.80) | -0.10 [-0.81 ; 0.61] |
| Week 9 | n= 14 (82.4%) \| 29.71 (5.51) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (88.2%) \| 28.70 (4.59) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 13 (76.5%) \| 28.91 (5.40) | n= 17 (81.0%) \| 30.71 (3.79) | -0.38 [-1.13 ; 0.36] |
| Week 15 | n= 12 (70.6%) \| 30.35 (3.46) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 15 (88.2%) \| 28.55 (5.42) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 12 (70.6%) \| 30.50 (3.40) | n= 13 (61.9%) \| 30.65 (4.44) | -0.04 [-0.84 ; 0.77] |
| Week 21 | n= 13 (76.5%) \| 29.86 (5.74) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (88.2%) \| 29.33 (4.64) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 13 (76.5%) \| 30.62 (4.72) | n= 14 (66.7%) \| 32.29 (3.00) | -0.41 [-1.19 ; 0.36] |
| Week 27 | n= 13 (76.5%) \| 31.54 (3.97) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 12 (70.6%) \| 31.42 (2.91) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 12 (70.6%) \| 31.25 (4.88) | n= 12 (57.1%) \| 30.67 (3.63) | 0.13 [-0.69 ; 0.95] |
| Week 33 | n= 12 (70.6%) \| 30.50 (5.52) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 11 (64.7%) \| 30.45 (7.23) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (47.1%) \| 29.75 (7.34) | n= 11 (52.4%) \| 30.60 (3.79) | -0.15 [-1.08 ; 0.79] |
| Week 39 | n= 10 (58.8%) \| 32.40 (3.31) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 41 | n= 11 (64.7%) \| 31.36 (3.85) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 10 (58.8%) \| 31.20 (4.85) | n= 12 (57.1%) \| 30.58 (5.12) | 0.12 [-0.74 ; 0.98] |
| Week 45 | n= 10 (58.8%) \| 31.50 (4.14) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 10 (58.8%) \| 31.06 (5.12) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 11 (64.7%) \| 31.09 (4.64) | n= 10 (47.6%) \| 29.28 (6.11) | 0.32 [-0.56 ; 1.21] |
| Week 51 | n= 11 (64.7%) \| 30.82 (3.97) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 12 (70.6%) \| 30.58 (4.48) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 9 (52.9%) \| 30.22 (4.99) | n= 11 (52.4%) \| 31.03 (3.60) | -0.18 [-1.09 ; 0.72] |
| Week 57 | n= 8 (47.1%) \| 31.00 (4.50) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 9 (52.9%) \| 28.86 (5.71) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 9 (52.9%) \| 32.33 (2.78) | n= 10 (47.6%) \| 30.70 (4.50) | 0.41 [-0.52 ; 1.35] |
| Week 63 | n= 8 (47.1%) \| 30.38 (5.01) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (58.8%) \| 30.10 (4.25) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 9 (52.9%) \| 31.22 (3.46) | n= 9 (42.9%) \| 30.56 (5.05) | 0.15 [-0.81 ; 1.10] |
| Week 69 | n= 8 (47.1%) \| 28.25 (4.37) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (41.2%) \| 29.43 (4.54) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (41.2%) \| 29.43 (3.91) | n= 9 (42.9%) \| 29.24 (4.68) | 0.04 [-0.98 ; 1.06] |
| Week 75 | n= 6 (35.3%) \| 30.17 (4.12) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (29.4%) \| 31.80 (3.77) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (29.4%) \| 31.00 (3.32) | n= 7 (33.3%) \| 31.29 (3.35) | -0.08 [-1.28 ; 1.13] |
| Week 81 | n= 5 (29.4%) \| 31.00 (3.08) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (29.4%) \| 30.00 (4.64) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 6 (35.3%) \| 29.83 (4.26) | n= 7 (33.3%) \| 31.71 (2.29) | -0.52 [-1.69 ; 0.64] |
| Week 87 | n= 5 (29.4%) \| 30.20 (4.49) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 5 (29.4%) \| 30.18 (4.40) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 5 (29.4%) \| 29.80 (4.38) | n= 6 (28.6%) \| 29.17 (3.87) | 0.14 [-1.11 ; 1.40] |
| Week 93 | n= 4 (23.5%) \| 29.25 (3.59) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (23.5%) \| 28.75 (3.86) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (23.5%) \| 31.50 (3.87) | n= 4 (19.0%) \| 33.50 (1.91) | -0.57 [-2.11 ; 0.98] |
| Week 99 | n= 2 (11.8%) \| 32.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (17.6%) \| 31.00 (2.65) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (17.6%) \| 31.33 (4.16) | n= 5 (23.8%) \| 32.80 (1.92) | -0.44 [-2.02 ; 1.13] |
| Week 105 | n= 3 (17.6%) \| 30.67 (4.62) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.8%) \| 33.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (17.6%) \| 31.00 (4.36) | n= 2 ( 9.5%) \| 32.50 (3.54) | -0.27 [-2.40 ; 1.86] |
| Week 111 | n= 1 ( 5.9%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.8%) \| 30.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (17.6%) \| 31.00 (2.65) | n= 2 ( 9.5%) \| 31.50 (2.12) | -0.15 [-2.26 ; 1.97] |
| Week 117 | n= 2 (11.8%) \| 29.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (11.8%) \| 29.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (11.8%) \| 31.50 (3.54) | n= 1 ( 4.8%) \| 30.38 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 5.9%) \| 33.00 ( / ) | n= 1 ( 4.8%) \| 24.00 ( / ) | [Not calculable] |
| Week 201 | n= 2 (11.8%) \| 31.00 (1.41) | n= 6 (28.6%) \| 32.50 (2.66) | -0.52 [-2.29 ; 1.24] |
| Week 202 | [No Data] | n= 4 (19.0%) \| 32.75 (1.50) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:53

TABLE 7.4.7: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Male** | | | |
| N subjects in population | N=54 | N=47 | |
| Week 3 | n= 50 (92.6%) \|-0.35 (2.22) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 45 (83.3%) \|-0.46 (2.64) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 48 (88.9%) \|-0.84 (3.73) | n= 45 (95.7%) \|-0.89 (3.47) | 0.01 [-0.39 ; 0.42] |
| Week 9 | n= 46 (85.2%) \|-0.82 (3.94) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 45 (83.3%) \|-0.82 (3.44) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 46 (85.2%) \|-0.32 (3.41) | n= 38 (80.9%) \|-1.21 (3.54) | 0.26 [-0.18 ; 0.69] |
| Week 15 | n= 42 (77.8%) \|-0.76 (4.09) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 47 (87.0%) \|-0.08 (3.28) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 44 (81.5%) \|-0.49 (2.82) | n= 40 (85.1%) \|-0.64 (3.70) | 0.04 [-0.39 ; 0.48] |
| Week 21 | n= 46 (85.2%) \| 0.16 (2.97) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 41 (75.9%) \|-0.68 (2.78) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 44 (81.5%) \|-0.09 (3.47) | n= 34 (72.3%) \|-0.94 (3.73) | 0.23 [-0.22 ; 0.69] |
| Week 27 | n= 42 (77.8%) \| 0.30 (3.14) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 40 (74.1%) \| 0.09 (3.40) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 42 (77.8%) \|-0.15 (3.39) | n= 30 (63.8%) \|-0.70 (2.44) | 0.18 [-0.29 ; 0.65] |
| Week 33 | n= 44 (81.5%) \|-0.42 (3.17) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 42 (77.8%) \|-0.54 (3.33) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 40 (74.1%) \| 0.10 (3.18) | n= 35 (74.5%) \|-0.54 (2.93) | 0.21 [-0.25 ; 0.66] |
| Week 39 | n= 41 (75.9%) \|-0.14 (3.29) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 41 (75.9%) \|-0.47 (3.47) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 41 (75.9%) \|-0.54 (3.83) | n= 29 (61.7%) \|-0.66 (3.00) | 0.03 [-0.44 ; 0.51] |
| Week 45 | n= 38 (70.4%) \|-0.87 (3.97) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 41 (75.9%) \|-0.80 (3.14) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 41 (75.9%) \|-0.26 (3.58) | n= 25 (53.2%) \|-0.40 (2.60) | 0.04 [-0.46 ; 0.54] |
| Week 51 | n= 40 (74.1%) \|-0.45 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 40 (74.1%) \| 0.07 (3.13) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 37 (68.5%) \|-0.41 (2.95) | n= 26 (55.3%) \|-0.88 (3.22) | 0.15 [-0.35 ; 0.66] |
| Week 57 | n= 40 (74.1%) \|-0.51 (3.53) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (68.5%) \|-0.06 (3.37) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (72.2%) \|-0.16 (3.42) | n= 20 (42.6%) \|-0.40 (2.98) | 0.07 [-0.47 ; 0.62] |
| Week 63 | n= 34 (63.0%) \|-0.24 (3.48) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 33 (61.1%) \|-0.38 (4.31) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 35 (64.8%) \| 0.06 (3.36) | n= 20 (42.6%) \|-0.25 (2.84) | 0.10 [-0.46 ; 0.65] |
| Week 69 | n= 30 (55.6%) \|-0.39 (4.38) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (57.4%) \| 0.06 (3.46) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 28 (51.9%) \| 0.56 (3.11) | n= 19 (40.4%) \|-0.53 (3.08) | 0.34 [-0.25 ; 0.94] |
| Week 75 | n= 29 (53.7%) \| 0.19 (3.32) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (50.0%) \| 0.39 (3.68) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (48.1%) \|-0.19 (5.32) | n= 17 (36.2%) \| 0.59 (2.79) | -0.17 [-0.79 ; 0.45] |
| Week 81 | n= 24 (44.4%) \|-0.18 (2.88) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (51.9%) \| 0.49 (3.13) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 21 (38.9%) \| 0.46 (2.95) | n= 13 (27.7%) \| 0.23 (2.83) | 0.08 [-0.63 ; 0.78] |
| Week 87 | n= 19 (35.2%) \|-0.89 (2.87) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 20 (37.0%) \|-0.12 (3.02) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 19 (35.2%) \|-1.01 (2.69) | n= 11 (23.4%) \| 1.00 (4.17) | -0.59 [-1.36 ; 0.18] |
| Week 93 | n= 19 (35.2%) \|-0.39 (2.09) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 18 (33.3%) \|-0.48 (2.73) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (31.5%) \|-1.18 (2.79) | n= 6 (12.8%) \|-1.50 (2.74) | 0.11 [-0.84 ; 1.06] |
| Week 99 | n= 15 (27.8%) \|-1.09 (3.41) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (20.4%) \|-1.09 (2.55) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 12 (22.2%) \|-0.11 (2.60) | n= 4 ( 8.5%) \| 1.00 (2.58) | -0.41 [-1.59 ; 0.77] |
| Week 105 | n= 10 (18.5%) \|-0.54 (2.97) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (11.1%) \|-1.33 (2.34) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.8%) \|-2.77 (3.12) | n= 2 ( 4.3%) \| 1.00 (1.41) | -1.15 [-2.90 ; 0.60] |
| Week 111 | n= 6 (11.1%) \|-2.00 (2.97) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (11.1%) \|-1.75 (2.52) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 7.4%) \|-2.25 (3.77) | n= 3 ( 6.4%) \|-0.67 (2.08) | -0.42 [-2.09 ; 1.26] |
| Week 117 | n= 5 ( 9.3%) \|-0.20 (2.28) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 9.3%) \|-4.20 (3.11) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (11.1%) \|-2.63 (3.38) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 2 ( 3.7%) \|-2.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.9%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.9%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 1.9%) \|-2.75 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.9%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.9%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.9%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.9%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.9%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.9%) \|-0.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 (11.1%) \|-0.50 (1.38) | n= 10 (21.3%) \|-1.80 (5.81) | 0.26 [-0.79 ; 1.31] |
| Week 202 | n= 2 ( 3.7%) \|-5.50 (4.95) | n= 7 (14.9%) \|-0.14 (3.98) | -1.15 [-2.96 ; 0.65] |
| **Female** | | | |
| N subjects in population | N=17 | N=21 | |
| Week 3 | n= 16 (94.1%) \| 0.35 (2.35) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 16 (94.1%) \|-1.23 (4.00) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 14 (82.4%) \|-0.79 (3.56) | n= 18 (85.7%) \|-1.69 (3.15) | 0.26 [-0.45 ; 0.97] |
| Week 9 | n= 14 (82.4%) \|-2.01 (3.72) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (88.2%) \|-1.91 (3.48) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 13 (76.5%) \|-1.56 (4.08) | n= 17 (81.0%) \|-1.81 (2.28) | 0.08 [-0.66 ; 0.81] |
| Week 15 | n= 12 (70.6%) \|-0.66 (3.87) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 15 (88.2%) \|-2.06 (4.23) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 12 (70.6%) \|-0.59 (4.49) | n= 13 (61.9%) \|-1.87 (3.22) | 0.32 [-0.49 ; 1.13] |
| Week 21 | n= 13 (76.5%) \|-1.54 (5.19) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 15 (88.2%) \|-1.54 (3.68) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 13 (76.5%) \|-0.55 (4.02) | n= 14 (66.7%) \|-0.69 (3.22) | 0.04 [-0.73 ; 0.81] |
| Week 27 | n= 13 (76.5%) \|-0.39 (4.91) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 12 (70.6%) \|-0.26 (4.54) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 12 (70.6%) \|-0.76 (4.69) | n= 12 (57.1%) \|-1.48 (2.53) | 0.18 [-0.64 ; 1.00] |
| Week 33 | n= 12 (70.6%) \|-0.75 (4.35) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 11 (64.7%) \|-0.91 (4.72) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (47.1%) \|-0.63 (5.24) | n= 11 (52.4%) \|-1.38 (3.83) | 0.16 [-0.78 ; 1.10] |
| Week 39 | n= 10 (58.8%) \| 0.20 (3.52) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 11 (64.7%) \|-0.91 (3.88) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 10 (58.8%) \|-0.10 (4.68) | n= 12 (57.1%) \|-1.40 (2.81) | 0.33 [-0.53 ; 1.20] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 45 | n= 10 (58.8%) \|-0.90 (5.57) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 10 (58.8%) \|-0.34 (3.93) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 11 (64.7%) \|-0.55 (4.32) | n= 10 (47.6%) \|-2.30 (4.37) | 0.39 [-0.50 ; 1.27] |
| Week 51 | n= 11 (64.7%) \|-0.82 (3.95) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 12 (70.6%) \|-1.00 (3.67) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 9 (52.9%) \|-0.78 (4.99) | n= 11 (52.4%) \|-0.85 (2.03) | 0.02 [-0.88 ; 0.92] |
| Week 57 | n= 8 (47.1%) \| 0.13 (4.82) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 9 (52.9%) \|-2.14 (5.88) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 9 (52.9%) \| 0.11 (4.40) | n= 10 (47.6%) \|-0.98 (3.26) | 0.27 [-0.66 ; 1.20] |
| Week 63 | n= 8 (47.1%) \| 0.00 (5.40) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (58.8%) \|-1.30 (5.96) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 9 (52.9%) \|-0.44 (5.61) | n= 9 (42.9%) \|-1.31 (2.68) | 0.19 [-0.77 ; 1.14] |
| Week 69 | n= 8 (47.1%) \|-2.88 (7.12) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (41.2%) \|-1.14 (7.80) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (41.2%) \|-1.14 (7.54) | n= 9 (42.9%) \|-2.29 (1.93) | 0.21 [-0.81 ; 1.24] |
| Week 75 | n= 6 (35.3%) \| 0.33 (7.97) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (29.4%) \| 2.80 (7.43) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (29.4%) \| 1.40 (6.80) | n= 7 (33.3%) \|-0.73 (2.84) | 0.41 [-0.81 ; 1.63] |
| Week 81 | n= 5 (29.4%) \| 2.00 (6.20) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (29.4%) \| 1.20 (8.76) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 6 (35.3%) \| 0.00 (7.46) | n= 7 (33.3%) \|-1.43 (2.44) | 0.25 [-0.90 ; 1.39] |
| Week 87 | n= 5 (29.4%) \| 1.40 (7.92) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 5 (29.4%) \| 1.38 (7.05) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 5 (29.4%) \|-1.20 (5.45) | n= 6 (28.6%) \|-2.94 (3.27) | 0.36 [-0.90 ; 1.63] |
| Week 93 | n= 4 (23.5%) \|-0.75 (6.90) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 4 (23.5%) \|-1.25 (6.55) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (23.5%) \| 1.25 (5.38) | n= 4 (19.0%) \| 0.75 (2.87) | 0.10 [-1.40 ; 1.61] |
| Week 99 | n= 2 (11.8%) \| 5.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (17.6%) \| 2.33 (4.16) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 3 (17.6%) \| 1.33 (5.69) | n= 5 (23.8%) \|-0.60 (2.97) | 0.41 [-1.16 ; 1.99] |
| Week 105 | n= 3 (17.6%) \| 2.00 (4.58) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.8%) \| 5.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (17.6%) \| 1.67 (5.03) | n= 2 ( 9.5%) \|-2.50 (4.95) | 0.61 [-1.59 ; 2.80] |
| Week 111 | n= 1 ( 5.9%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.8%) \| 3.50 (6.36) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (17.6%) \| 1.67 (5.51) | n= 2 ( 9.5%) \|-1.50 (0.71) | 0.51 [-1.66 ; 2.68] |
| Week 117 | n= 2 (11.8%) \| 2.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (11.8%) \| 2.50 (6.36) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (11.8%) \| 3.00 (5.66) | n= 1 ( 4.8%) \|-1.63 ( / ) | [Not calculable] |
| Week 127 | n= 1 ( 5.9%) \|-2.00 ( / ) | n= 1 ( 4.8%) \|-8.00 ( / ) | [Not calculable] |
| Week 201 | n= 2 (11.8%) \|-0.50 (7.78) | n= 6 (28.6%) \|-1.17 (3.37) | 0.13 [-1.61 ; 1.87] |
| Week 202 | [No Data] | n= 4 (19.0%) \|-0.25 (2.63) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:53

TABLE 7.4.7: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Gender Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **Male** | | | | |
| Nr subjects used | n=52 | n=46 | | |
| Week 7 | -0.93 (0.46) [-1.84 ;-0.02] | -1.19 (0.48) [-2.14 ;-0.23] | 0.26 (0.66) [-1.06 ; 1.57] | 0.08 [-0.33 ; 0.49] |
| Week 13 | -0.31 (0.45) [-1.19 ; 0.58] | -1.36 (0.48) [-2.32 ;-0.39] | 1.05 (0.66) [-0.26 ; 2.36] | 0.35 [-0.09 ; 0.78] |
| Week 19 | -0.21 (0.40) [-1.00 ; 0.57] | -0.88 (0.42) [-1.72 ;-0.04] | 0.67 (0.58) [-0.48 ; 1.81] | 0.25 [-0.18 ; 0.68] |
| Week 25 | 0.07 (0.44) [-0.81 ; 0.95] | -1.00 (0.49) [-1.98 ;-0.02] | 1.07 (0.66) [-0.25 ; 2.39] | 0.36 [-0.09 ; 0.81] |
| Week 31 | -0.00 (0.48) [-0.96 ; 0.95] | -0.51 (0.55) [-1.60 ; 0.58] | 0.51 (0.73) [-0.94 ; 1.96] | 0.16 [-0.31 ; 0.63] |
| Week 37 | 0.21 (0.46) [-0.70 ; 1.13] | -0.63 (0.51) [-1.63 ; 0.38] | 0.84 (0.69) [-0.52 ; 2.20] | 0.28 [-0.17 ; 0.74] |
| Week 43 | -0.30 (0.49) [-1.27 ; 0.68] | -0.70 (0.57) [-1.84 ; 0.43] | 0.41 (0.75) [-1.09 ; 1.91] | 0.13 [-0.35 ; 0.61] |
| Week 49 | -0.22 (0.46) [-1.15 ; 0.70] | -0.18 (0.57) [-1.32 ; 0.96] | -0.05 (0.74) [-1.51 ; 1.42] | -0.02 [-0.51 ; 0.48] |
| Week 55 | -0.08 (0.46) [-1.00 ; 0.84] | -0.89 (0.57) [-2.01 ; 0.23] | 0.81 (0.73) [-0.65 ; 2.27] | 0.28 [-0.22 ; 0.78] |
| Week 61 | -0.23 (0.44) [-1.11 ; 0.66] | -0.54 (0.59) [-1.71 ; 0.63] | 0.32 (0.74) [-1.15 ; 1.78] | 0.12 [-0.42 ; 0.66] |
| Week 67 | -0.22 (0.48) [-1.18 ; 0.73] | -0.53 (0.63) [-1.78 ; 0.72] | 0.31 (0.79) [-1.27 ; 1.88] | 0.11 [-0.44 ; 0.66] |
| Week 73 | 0.12 (0.50) [-0.88 ; 1.11] | -0.85 (0.63) [-2.10 ; 0.41] | 0.96 (0.80) [-0.64 ; 2.57] | 0.35 [-0.23 ; 0.94] |
| Week 79 | -0.52 (0.77) [-2.06 ; 1.01] | 0.06 (0.97) [-1.87 ; 1.99] | -0.58 (1.23) [-3.05 ; 1.88] | -0.14 [-0.76 ; 0.47] |
| Week 85 | -0.30 (0.55) [-1.42 ; 0.81] | -0.32 (0.71) [-1.74 ; 1.10] | 0.01 (0.90) [-1.79 ; 1.82] | 0.00 [-0.69 ; 0.70] |
| Week 91 | -0.71 (0.68) [-2.10 ; 0.68] | 0.40 (0.89) [-1.41 ; 2.22] | -1.11 (1.12) [-3.40 ; 1.17] | -0.36 [-1.11 ; 0.38] |
| Overall post-baseline period estimate | -0.24 (0.25) [-0.74 ; 0.25] | -0.61 (0.30) [-1.20 ;-0.01] | 0.36 (0.39) [-0.41 ; 1.14] | 0.19 [-0.21 ; 0.59] |
| **Female** | | | | |
| Nr subjects used | n=17 | n=21 | | |
| Week 7 | -1.29 (0.95) [-3.24 ; 0.66] | -1.74 (0.84) [-3.47 ;-0.01] | 0.45 (1.27) [-2.15 ; 3.06] | 0.12 [-0.58 ; 0.82] |
| Week 13 | -2.04 (1.01) [-4.13 ; 0.04] | -1.42 (0.90) [-3.29 ; 0.44] | -0.62 (1.36) [-3.42 ; 2.19] | -0.16 [-0.89 ; 0.56] |
| Week 19 | -0.85 (0.97) [-2.85 ; 1.14] | -1.61 (0.93) [-3.52 ; 0.30] | 0.76 (1.35) [-2.01 ; 3.52] | 0.22 [-0.57 ; 1.01] |
| Week 25 | -0.82 (0.80) [-2.45 ; 0.80] | -0.32 (0.77) [-1.89 ; 1.24] | -0.50 (1.11) [-2.76 ; 1.76] | -0.17 [-0.92 ; 0.59] |
| Week 31 | -1.06 (0.86) [-2.80 ; 0.69] | -1.13 (0.84) [-2.85 ; 0.59] | 0.07 (1.20) [-2.38 ; 2.52] | 0.02 [-0.78 ; 0.82] |
| Week 43 | -0.00 (0.96) [-1.96 ; 1.96] | -1.29 (0.89) [-3.11 ; 0.54] | 1.29 (1.31) [-1.39 ; 3.97] | 0.40 [-0.45 ; 1.25] |
| Week 49 | -0.54 (1.17) [-2.95 ; 1.88] | -1.87 (1.20) [-4.34 ; 0.61] | 1.33 (1.67) [-2.13 ; 4.79] | 0.33 [-0.53 ; 1.20] |
| Overall post-baseline period estimate | -0.94 (0.55) [-2.05 ; 0.16] | -1.34 (0.52) [-2.39 ;-0.29] | 0.40 (0.76) [-1.13 ; 1.93] | 0.17 [-0.48 ; 0.83] |
| **MMRM subgroups interaction p-value** | | | 0.6536 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:53

TABLE 7.4.8: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **< 1 Year** | N=14 | N=18 |
| **>= 1 Year** | N=57 | N=48 |
| **Not Reported** | [No Data] | N=2 |
| **Subjects with Baseline Value** | | |
| **< 1 Year** | 14 (100.0%) | 18 (100.0%) |
| **>= 1 Year** | 55 (96.5%) | 47 (97.9%) |
| **Not Reported** | [No Data] | 2 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **< 1 Year** | 14 (100.0%) | 18 (100.0%) |
| **>= 1 Year** | 57 (100.0%) | 46 (95.8%) |
| **Not Reported** | [No Data] | 2 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **< 1 Year** | 14 (100.0%) | 18 (100.0%) |
| **>= 1 Year** | 55 (96.5%) | 45 (93.8%) |
| **Not Reported** | [No Data] | 2 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:54

TABLE 7.4.8: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 1 Year** | | | |
| N subjects in population | N=14 | N=18 | |
| Baseline | n= 14 (100.0%) \| 31.86 (4.22) | n= 18 (100.0%) \| 31.50 (4.36) | 0.08 [-0.63 ; 0.79] |
| Week 3 | n= 12 (85.7%) \| 32.08 (2.07) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 12 (85.7%) \| 32.00 (2.92) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 13 (92.9%) \| 31.77 (3.56) | n= 18 (100.0%) \| 30.06 (4.54) | 0.40 [-0.33 ; 1.13] |
| Week 9 | n= 12 (85.7%) \| 31.92 (4.19) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 13 (92.9%) \| 31.46 (3.93) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 14 (100.0%) \| 32.00 (4.08) | n= 14 (77.8%) \| 31.64 (3.46) | 0.09 [-0.66 ; 0.85] |
| Week 15 | n= 14 (100.0%) \| 31.68 (3.38) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (100.0%) \| 31.89 (3.34) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 14 (100.0%) \| 31.76 (3.32) | n= 15 (83.3%) \| 31.48 (2.78) | 0.09 [-0.65 ; 0.83] |
| Week 21 | n= 14 (100.0%) \| 31.64 (4.13) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 12 (85.7%) \| 30.75 (3.98) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 13 (92.9%) \| 31.33 (3.93) | n= 15 (83.3%) \| 31.20 (3.17) | 0.03 [-0.72 ; 0.79] |
| Week 27 | n= 13 (92.9%) \| 32.31 (4.09) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 13 (92.9%) \| 31.24 (3.51) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 14 (100.0%) \| 31.00 (4.85) | n= 11 (61.1%) \| 31.27 (4.61) | -0.06 [-0.86 ; 0.75] |
| Week 33 | n= 14 (100.0%) \| 31.24 (5.23) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (92.9%) \| 30.68 (6.18) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 11 (78.6%) \| 31.39 (6.13) | n= 13 (72.2%) \| 30.85 (3.36) | 0.11 [-0.71 ; 0.93] |
| Week 39 | n= 11 (78.6%) \| 33.09 (2.43) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 12 (85.7%) \| 31.83 (3.38) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 12 (85.7%) \| 31.42 (4.40) | n= 12 (66.7%) \| 32.15 (3.05) | -0.19 [-1.01 ; 0.63] |
| Week 45 | n= 11 (78.6%) \| 30.66 (3.06) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 11 (78.6%) \| 31.91 (3.21) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 12 (85.7%) \| 31.93 (2.68) | n= 11 (61.1%) \| 32.24 (2.14) | -0.12 [-0.96 ; 0.71] |
| Week 51 | n= 11 (78.6%) \| 31.60 (3.43) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 11 (78.6%) \| 31.84 (2.90) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (50.0%) \| 31.38 (4.27) | n= 10 (55.6%) \| 30.60 (4.27) | 0.17 [-0.83 ; 1.17] |
| Week 57 | n= 10 (71.4%) \| 31.95 (2.59) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 11 (78.6%) \| 31.59 (3.61) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 10 (71.4%) \| 32.20 (2.86) | n= 8 (44.4%) \| 31.25 (2.55) | 0.33 [-0.63 ; 1.30] |
| Week 63 | n= 10 (71.4%) \| 31.93 (3.60) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (71.4%) \| 31.63 (3.35) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 10 (71.4%) \| 32.30 (2.95) | n= 9 (50.0%) \| 30.78 (3.31) | 0.47 [-0.47 ; 1.41] |
| Week 69 | n= 9 (64.3%) \| 31.14 (3.94) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 9 (64.3%) \| 30.31 (5.08) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 9 (64.3%) \| 30.78 (4.97) | n= 7 (38.9%) \| 29.86 (4.14) | 0.19 [-0.84 ; 1.21] |
| Week 75 | n= 8 (57.1%) \| 31.50 (4.41) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (42.9%) \| 33.00 (3.03) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (64.3%) \| 29.76 (8.87) | n= 7 (38.9%) \| 30.86 (4.34) | -0.14 [-1.17 ; 0.88] |
| Week 81 | n= 6 (42.9%) \| 32.17 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (50.0%) \| 32.71 (3.95) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (57.1%) \| 31.88 (4.19) | n= 6 (33.3%) \| 30.83 (4.45) | 0.23 [-0.88 ; 1.33] |
| Week 87 | n= 6 (42.9%) \| 31.50 (4.09) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 7 (50.0%) \| 31.14 (4.02) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 7 (50.0%) \| 32.29 (3.82) | n= 3 (16.7%) \| 32.33 (4.73) | -0.01 [-1.45 ; 1.43] |
| Week 93 | n= 5 (35.7%) \| 32.00 (4.00) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 6 (42.9%) \| 32.67 (3.83) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 5 (35.7%) \| 32.60 (3.05) | n= 2 (11.1%) \| 34.50 (2.12) | -0.55 [-2.40 ; 1.30] |
| Week 99 | n= 3 (21.4%) \| 31.33 (4.04) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (21.4%) \| 32.33 (3.51) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (28.6%) \| 30.25 (4.03) | n= 2 (11.1%) \| 34.00 (2.83) | -0.80 [-2.82 ; 1.23] |
| Week 105 | n= 3 (21.4%) \| 30.00 (5.29) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (14.3%) \| 32.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (21.4%) \| 30.29 (5.18) | n= 2 (11.1%) \| 33.00 (4.24) | -0.40 [-2.55 ; 1.75] |
| Week 111 | n= 1 ( 7.1%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (14.3%) \| 30.75 (1.06) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (21.4%) \| 32.67 (2.31) | n= 1 ( 5.6%) \| 36.00 ( / ) | [Not calculable] |
| Week 117 | n= 2 (14.3%) \| 31.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (14.3%) \| 26.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (21.4%) \| 30.75 (2.82) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 7.1%) \| 27.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 7.1%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (14.3%) \| 32.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 7.1%) \| 29.25 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 7.1%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 7.1%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 7.1%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 7.1%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 7.1%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 7.1%) \| 31.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 7.1%) \| 31.00 ( / ) | n= 3 (16.7%) \| 28.33 (5.51) | [Not calculable] |
| Week 202 | n= 1 ( 7.1%) \| 30.00 ( / ) | n= 2 (11.1%) \| 33.00 (1.41) | [Not calculable] |
| **>= 1 Year** | | | |
| N subjects in population | N=57 | N=48 | |
| Baseline | n= 55 (96.5%) \| 31.60 (4.49) | n= 47 (97.9%) \| 31.40 (4.31) | 0.04 [-0.35 ; 0.44] |
| Week 3 | n= 55 (96.5%) \| 31.40 (4.28) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 51 (89.5%) \| 30.93 (5.03) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 51 (89.5%) \| 30.44 (4.38) | n= 45 (93.8%) \| 30.32 (3.86) | 0.03 [-0.37 ; 0.43] |
| Week 9 | n= 49 (86.0%) \| 30.77 (4.29) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 48 (84.2%) \| 30.68 (4.00) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 46 (80.7%) \| 31.20 (3.87) | n= 39 (81.3%) \| 30.36 (3.78) | 0.22 [-0.21 ; 0.65] |
| Week 15 | n= 40 (70.2%) \| 31.13 (3.88) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 49 (86.0%) \| 31.25 (4.44) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 43 (75.4%) \| 32.13 (3.04) | n= 37 (77.1%) \| 30.91 (3.70) | 0.36 [-0.09 ; 0.81] |
| Week 21 | n= 45 (78.9%) \| 31.85 (4.11) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 44 (77.2%) \| 31.07 (3.97) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 45 (78.9%) \| 32.11 (3.61) | n= 32 (66.7%) \| 31.50 (3.14) | 0.18 [-0.28 ; 0.63] |
| Week 27 | n= 43 (75.4%) \| 32.70 (3.86) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 39 (68.4%) \| 32.38 (3.65) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 40 (70.2%) \| 32.48 (3.94) | n= 30 (62.5%) \| 31.30 (3.49) | 0.31 [-0.17 ; 0.79] |
| Week 33 | n= 42 (73.7%) \| 32.00 (4.15) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 41 (71.9%) \| 31.76 (4.65) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 37 (64.9%) \| 32.30 (4.38) | n= 32 (66.7%) \| 31.39 (3.13) | 0.23 [-0.25 ; 0.71] |
| Week 39 | n= 41 (71.9%) \| 32.17 (4.15) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 41 | n= 40 (70.2%) \| 32.20 (4.33) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 40 (70.2%) \| 32.14 (3.94) | n= 28 (58.3%) \| 30.46 (4.41) | 0.40 [-0.09 ; 0.89] |
| Week 45 | n= 37 (64.9%) \| 31.59 (4.70) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 40 (70.2%) \| 32.00 (4.37) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 40 (70.2%) \| 32.08 (4.78) | n= 23 (47.9%) \| 30.70 (4.55) | 0.29 [-0.23 ; 0.81] |
| Week 51 | n= 40 (70.2%) \| 31.63 (4.51) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 41 (71.9%) \| 32.07 (4.38) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (68.4%) \| 31.87 (4.55) | n= 27 (56.3%) \| 31.13 (3.21) | 0.18 [-0.31 ; 0.68] |
| Week 57 | n= 38 (66.7%) \| 31.55 (4.73) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 35 (61.4%) \| 31.59 (4.76) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 38 (66.7%) \| 32.23 (4.45) | n= 22 (45.8%) \| 30.55 (3.89) | 0.39 [-0.14 ; 0.92] |
| Week 63 | n= 32 (56.1%) \| 31.38 (5.18) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 33 (57.9%) \| 30.88 (5.76) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 34 (59.6%) \| 31.94 (4.57) | n= 20 (41.7%) \| 31.00 (4.01) | 0.21 [-0.35 ; 0.77] |
| Week 69 | n= 29 (50.9%) \| 31.17 (5.39) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 29 (50.9%) \| 32.45 (4.31) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 26 (45.6%) \| 32.73 (3.65) | n= 20 (41.7%) \| 30.21 (3.70) | 0.68 [ 0.07 ; 1.28] |
| Week 75 | n= 27 (47.4%) \| 32.48 (3.61) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (45.6%) \| 31.92 (4.08) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 22 (38.6%) \| 32.07 (4.33) | n= 17 (35.4%) \| 31.29 (2.78) | 0.20 [-0.44 ; 0.85] |
| Week 81 | n= 23 (40.4%) \| 31.83 (4.49) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 26 (45.6%) \| 32.08 (4.18) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (33.3%) \| 32.47 (3.81) | n= 14 (29.2%) \| 31.79 (2.75) | 0.20 [-0.51 ; 0.90] |
| Week 87 | n= 18 (31.6%) \| 30.89 (4.99) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 18 (31.6%) \| 31.72 (4.29) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 17 (29.8%) \| 30.19 (5.08) | n= 14 (29.2%) \| 31.93 (3.65) | -0.38 [-1.10 ; 0.35] |
| Week 93 | n= 18 (31.6%) \| 31.22 (4.14) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 16 (28.1%) \| 30.61 (4.79) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 16 (28.1%) \| 30.40 (4.77) | n= 9 (18.8%) \| 31.78 (3.70) | -0.30 [-1.14 ; 0.54] |
| Week 99 | n= 14 (24.6%) \| 30.64 (5.30) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (19.3%) \| 31.18 (3.87) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (19.3%) \| 32.09 (3.24) | n= 8 (16.7%) \| 31.88 (2.53) | 0.07 [-0.87 ; 1.01] |
| Week 105 | n= 10 (17.5%) \| 31.10 (3.73) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.5%) \| 31.50 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.0%) \| 28.63 (3.46) | n= 3 ( 6.3%) \| 30.33 (6.43) | -0.36 [-1.77 ; 1.05] |
| Week 111 | n= 6 (10.5%) \| 30.50 (4.23) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (10.5%) \| 31.67 (4.32) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 7.0%) \| 29.75 (5.12) | n= 4 ( 8.3%) \| 31.75 (1.26) | -0.47 [-2.00 ; 1.07] |
| Week 117 | n= 5 ( 8.8%) \| 33.40 (2.61) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 8.8%) \| 30.40 (4.62) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 ( 8.8%) \| 31.40 (5.59) | n= 1 ( 2.1%) \| 30.38 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.8%) \| 35.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | [No Data] | n= 1 ( 2.1%) \| 24.00 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 7 (12.3%) \| 31.57 (4.76) | n= 13 (27.1%) \| 30.85 (4.41) | 0.15 [-0.79 ; 1.10] |
| Week 202 | n= 1 ( 1.8%) \| 20.00 ( / ) | n= 8 (16.7%) \| 31.75 (2.25) | [Not calculable] |
| **Not Reported** | | | |
| N subjects in population | [No Data] | N=2 | |
| Nr subjects used | [No Data] | n= 2 (100.0%) \| 33.00 (1.41) | |
| Week 7 | [No Data] | n= 1 (50.0%) \| 33.00 ( / ) | [No Data for at least 1 arm] |
| Week 13 | [No Data] | n= 2 (100.0%) \| 32.00 (2.83) | [No Data for at least 1 arm] |
| Week 19 | [No Data] | n= 2 (100.0%) \| 33.00 (0.00) | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 25 | [No Data] | n= 2 (100.0%) \| 34.00 (1.41) | [No Data for at least 1 arm] |
| Week 31 | [No Data] | n= 1 (50.0%) \| 36.00 ( / ) | [No Data for at least 1 arm] |
| Week 37 | [No Data] | n= 2 (100.0%) \| 33.50 (2.12) | [No Data for at least 1 arm] |
| Week 43 | [No Data] | n= 2 (100.0%) \| 33.00 (4.24) | [No Data for at least 1 arm] |
| Week 49 | [No Data] | n= 2 (100.0%) \| 33.00 (4.24) | [No Data for at least 1 arm] |
| Week 55 | [No Data] | n= 1 (50.0%) \| 30.00 ( / ) | [No Data for at least 1 arm] |
| Week 61 | [No Data] | n= 1 (50.0%) \| 35.00 ( / ) | [No Data for at least 1 arm] |
| Week 67 | [No Data] | n= 1 (50.0%) \| 30.00 ( / ) | [No Data for at least 1 arm] |
| Week 73 | [No Data] | n= 1 (50.0%) \| 31.00 ( / ) | [No Data for at least 1 arm] |
| Week 79 | [No Data] | n= 1 (50.0%) \| 32.00 ( / ) | [No Data for at least 1 arm] |
| Week 85 | [No Data] | n= 1 (50.0%) \| 34.00 ( / ) | [No Data for at least 1 arm] |
| Week 91 | [No Data] | n= 1 (50.0%) \| 33.00 ( / ) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 1 (50.0%) \| 36.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:54

TABLE 7.4.8: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **< 1 Year** | | | |
| N subjects in population | N=14 | N=18 | |
| Week 3 | n= 12 (85.7%) \|-0.25 (2.49) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 12 (85.7%) \|-0.08 (3.82) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 13 (92.9%) \|-0.08 (3.90) | n= 18 (100.0%) \|-1.44 (3.50) | 0.36 [-0.37 ; 1.09] |
| Week 9 | n= 12 (85.7%) \|-1.00 (4.43) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 13 (92.9%) \|-0.62 (4.03) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 14 (100.0%) \| 0.14 (3.72) | n= 14 (77.8%) \|-1.14 (2.88) | 0.38 [-0.39 ; 1.14] |
| Week 15 | n= 14 (100.0%) \|-0.18 (3.85) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 14 (100.0%) \| 0.04 (3.94) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 14 (100.0%) \|-0.10 (3.72) | n= 15 (83.3%) \|-0.99 (2.90) | 0.26 [-0.48 ; 1.01] |
| Week 21 | n= 14 (100.0%) \|-0.21 (4.19) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 12 (85.7%) \|-1.25 (3.02) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 13 (92.9%) \|-0.37 (4.43) | n= 15 (83.3%) \|-1.67 (3.18) | 0.33 [-0.43 ; 1.09] |
| Week 27 | n= 13 (92.9%) \| 0.46 (4.07) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 13 (92.9%) \|-0.30 (4.42) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 14 (100.0%) \|-0.86 (4.26) | n= 11 (61.1%) \|-1.27 (2.76) | 0.11 [-0.70 ; 0.92] |
| Week 33 | n= 14 (100.0%) \|-0.62 (3.71) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (92.9%) \|-0.86 (4.25) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 11 (78.6%) \|-0.16 (4.54) | n= 13 (72.2%) \|-1.77 (3.68) | 0.38 [-0.45 ; 1.21] |
| Week 39 | n= 11 (78.6%) \|-0.27 (3.95) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 12 (85.7%) \|-0.58 (5.35) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 12 (85.7%) \|-1.00 (5.72) | n= 12 (66.7%) \|-0.19 (2.85) | -0.17 [-0.99 ; 0.65] |
| Week 45 | n= 11 (78.6%) \|-1.43 (4.75) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 11 (78.6%) \|-0.36 (3.50) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 12 (85.7%) \| 0.10 (4.22) | n= 11 (61.1%) \| 0.06 (3.15) | 0.01 [-0.83 ; 0.85] |
| Week 51 | n= 11 (78.6%) \| 0.15 (4.93) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 11 (78.6%) \| 0.02 (3.85) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (50.0%) \|-0.77 (4.10) | n= 10 (55.6%) \|-1.50 (4.03) | 0.17 [-0.83 ; 1.17] |
| Week 57 | n= 10 (71.4%) \| 0.35 (4.85) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 11 (78.6%) \|-0.23 (5.07) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 10 (71.4%) \| 0.10 (5.02) | n= 8 (44.4%) \|-0.63 (2.97) | 0.16 [-0.80 ; 1.12] |
| Week 63 | n= 10 (71.4%) \| 0.53 (4.85) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 10 (71.4%) \| 0.23 (4.73) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 10 (71.4%) \| 0.90 (4.84) | n= 9 (50.0%) \|-1.33 (3.28) | 0.51 [-0.43 ; 1.45] |
| Week 69 | n= 9 (64.3%) \|-0.19 (5.59) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 9 (64.3%) \|-1.03 (6.42) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 9 (64.3%) \|-0.56 (6.60) | n= 7 (38.9%) \|-1.86 (3.24) | 0.23 [-0.80 ; 1.25] |
| Week 75 | n= 8 (57.1%) \| 0.63 (6.05) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (42.9%) \| 2.33 (6.06) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (64.3%) \|-1.57 (8.87) | n= 7 (38.9%) \|-0.43 (3.21) | -0.15 [-1.18 ; 0.87] |
| Week 81 | n= 6 (42.9%) \| 0.00 (4.69) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (50.0%) \| 1.57 (6.27) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (57.1%) \| 0.25 (5.73) | n= 6 (33.3%) \|-1.83 (2.48) | 0.42 [-0.70 ; 1.53] |
| Week 87 | n= 6 (42.9%) \|-0.50 (4.76) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 7 (50.0%) \| 0.00 (5.48) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 7 (50.0%) \|-0.14 (4.45) | n= 3 (16.7%) \|-3.33 (4.93) | 0.63 [-0.84 ; 2.10] |
| Week 93 | n= 5 (35.7%) \| 0.00 (5.96) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 6 (42.9%) \| 0.67 (4.97) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 5 (35.7%) \| 1.20 (4.44) | n= 2 (11.1%) \|-1.00 (1.41) | 0.46 [-1.38 ; 2.30] |
| Week 99 | n= 3 (21.4%) \| 2.33 (5.03) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (21.4%) \| 3.33 (3.51) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (28.6%) \|-0.25 (5.62) | n= 2 (11.1%) \|-2.00 (2.83) | 0.28 [-1.66 ; 2.21] |
| Week 105 | n= 3 (21.4%) \| 1.00 (6.24) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (14.3%) \| 5.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (21.4%) \| 0.63 (6.57) | n= 2 (11.1%) \|-3.00 (4.24) | 0.45 [-1.71 ; 2.61] |
| Week 111 | n= 1 ( 7.1%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (14.3%) \| 3.75 (6.01) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (21.4%) \| 3.00 (4.58) | n= 1 ( 5.6%) \| 0.00 ( / ) | [Not calculable] |
| Week 117 | n= 2 (14.3%) \| 4.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (14.3%) \|-0.50 (10.61) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (21.4%) \| 1.08 (5.20) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 7.1%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 7.1%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (14.3%) \|-1.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 129 | n= 1 ( 7.1%) \|-2.75 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 7.1%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 7.1%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 7.1%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 7.1%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 7.1%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 7.1%) \|-0.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 7.1%) \|-1.00 ( / ) | n= 3 (16.7%) \|-1.67 (5.69) | [Not calculable] |
| Week 202 | n= 1 ( 7.1%) \|-2.00 ( / ) | n= 2 (11.1%) \|-1.00 (1.41) | [Not calculable] |
| **>= 1 Year** | | | |
| N subjects in population | N=57 | N=48 | |
| Week 3 | n= 54 (94.7%) \|-0.16 (2.23) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 49 (86.0%) \|-0.80 (2.84) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 49 (86.0%) \|-1.03 (3.62) | n= 44 (91.7%) \|-1.03 (3.38) | 0.00 [-0.41 ; 0.41] |
| Week 9 | n= 48 (84.2%) \|-1.13 (3.80) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 47 (82.5%) \|-1.22 (3.31) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 45 (78.9%) \|-0.82 (3.53) | n= 39 (81.3%) \|-1.51 (3.41) | 0.20 [-0.24 ; 0.63] |
| Week 15 | n= 40 (70.2%) \|-0.93 (4.09) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 48 (84.2%) \|-0.74 (3.51) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 42 (73.7%) \|-0.65 (3.05) | n= 36 (75.0%) \|-0.98 (3.96) | 0.09 [-0.36 ; 0.54] |
| Week 21 | n= 45 (78.9%) \|-0.21 (3.44) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 44 (77.2%) \|-0.82 (3.07) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 44 (77.2%) \|-0.15 (3.34) | n= 31 (64.6%) \|-0.60 (3.81) | 0.13 [-0.34 ; 0.59] |
| Week 27 | n= 42 (73.7%) \| 0.03 (3.49) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 39 (68.4%) \| 0.11 (3.41) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 40 (70.2%) \|-0.09 (3.49) | n= 30 (62.5%) \|-0.89 (2.36) | 0.26 [-0.22 ; 0.74] |
| Week 33 | n= 42 (73.7%) \|-0.45 (3.36) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 40 (70.2%) \|-0.54 (3.44) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 37 (64.9%) \| 0.02 (3.27) | n= 31 (64.6%) \|-0.39 (2.95) | 0.13 [-0.35 ; 0.61] |
| Week 39 | n= 40 (70.2%) \|-0.02 (3.16) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 40 (70.2%) \|-0.56 (2.86) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 39 (68.4%) \|-0.29 (3.33) | n= 27 (56.3%) \|-1.25 (3.01) | 0.30 [-0.20 ; 0.79] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 45 | n= 37 (64.9%) \|-0.71 (4.19) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 40 (70.2%) \|-0.80 (3.24) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 40 (70.2%) \|-0.45 (3.58) | n= 22 (45.8%) \|-1.53 (3.33) | 0.31 [-0.22 ; 0.83] |
| Week 51 | n= 40 (70.2%) \|-0.71 (3.09) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 41 (71.9%) \|-0.23 (3.13) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (68.4%) \|-0.43 (3.30) | n= 26 (54.2%) \|-0.59 (2.42) | 0.05 [-0.45 ; 0.55] |
| Week 57 | n= 38 (66.7%) \|-0.60 (3.42) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 35 (61.4%) \|-0.54 (3.67) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 38 (66.7%) \|-0.16 (3.17) | n= 21 (43.8%) \|-0.75 (3.09) | 0.18 [-0.35 ; 0.72] |
| Week 63 | n= 32 (56.1%) \|-0.42 (3.53) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 33 (57.9%) \|-0.84 (4.71) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 34 (59.6%) \|-0.32 (3.55) | n= 19 (39.6%) \|-0.14 (2.60) | -0.05 [-0.62 ; 0.51] |
| Week 69 | n= 29 (50.9%) \|-1.13 (4.98) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 29 (50.9%) \| 0.10 (3.75) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 26 (45.6%) \| 0.49 (3.25) | n= 20 (41.7%) \|-0.83 (2.82) | 0.42 [-0.17 ; 1.02] |
| Week 75 | n= 27 (47.4%) \| 0.10 (3.76) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (45.6%) \| 0.41 (3.98) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 22 (38.6%) \| 0.74 (3.37) | n= 16 (33.3%) \| 0.49 (2.77) | 0.08 [-0.58 ; 0.73] |
| Week 81 | n= 23 (40.4%) \| 0.24 (3.40) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 26 (45.6%) \| 0.33 (3.63) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (33.3%) \| 0.40 (3.53) | n= 13 (27.1%) \| 0.15 (2.76) | 0.07 [-0.64 ; 0.79] |
| Week 87 | n= 18 (31.6%) \|-0.39 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 18 (31.6%) \| 0.25 (3.43) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 17 (29.8%) \|-1.42 (2.76) | n= 13 (27.1%) \| 0.18 (4.15) | -0.45 [-1.20 ; 0.29] |
| Week 93 | n= 18 (31.6%) \|-0.58 (2.14) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 16 (28.1%) \|-1.10 (2.84) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 16 (28.1%) \|-1.31 (2.91) | n= 8 (16.7%) \|-0.50 (3.21) | -0.26 [-1.13 ; 0.61] |
| Week 99 | n= 14 (24.6%) \|-0.96 (3.50) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (19.3%) \|-1.36 (2.25) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (19.3%) \| 0.33 (2.20) | n= 7 (14.6%) \| 0.71 (2.63) | -0.15 [-1.13 ; 0.82] |
| Week 105 | n= 10 (17.5%) \|-0.24 (2.47) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.5%) \|-1.17 (2.64) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (14.0%) \|-2.38 (2.83) | n= 2 ( 4.2%) \| 1.50 (0.71) | -1.32 [-3.10 ; 0.46] |
| Week 111 | n= 6 (10.5%) \|-2.00 (2.97) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (10.5%) \|-1.83 (2.48) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 7.0%) \|-3.25 (2.63) | n= 4 ( 8.3%) \|-1.25 (1.71) | -0.78 [-2.36 ; 0.79] |
| Week 117 | n= 5 ( 8.8%) \|-0.80 (1.92) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 ( 8.8%) \|-3.00 (2.35) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 ( 8.8%) \|-2.60 (3.78) | n= 1 ( 2.1%) \|-1.63 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 1.8%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | [No Data] | n= 1 ( 2.1%) \|-8.00 ( / ) | [No Data for at least 1 arm] |
| Week 201 | n= 7 (12.3%) \|-0.43 (3.41) | n= 13 (27.1%) \|-1.54 (4.98) | 0.24 [-0.71 ; 1.18] |
| Week 202 | n= 1 ( 1.8%) \|-9.00 ( / ) | n= 8 (16.7%) \|-0.25 (3.92) | [Not calculable] |
| **Not Reported** | | | |
| N subjects in population | [No Data] | N=2 | |
| Week 7 | [No Data] | n= 1 (50.0%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 13 | [No Data] | n= 2 (100.0%) \|-1.00 (1.41) | [No Data for at least 1 arm] |
| Week 19 | [No Data] | n= 2 (100.0%) \| 0.00 (1.41) | [No Data for at least 1 arm] |
| Week 25 | [No Data] | n= 2 (100.0%) \| 1.00 (0.00) | [No Data for at least 1 arm] |
| Week 31 | [No Data] | n= 1 (50.0%) \| 2.00 ( / ) | [No Data for at least 1 arm] |
| Week 37 | [No Data] | n= 2 (100.0%) \| 0.50 (0.71) | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 43 | [No Data] | n= 2 (100.0%) \| 0.00 (2.83) | [No Data for at least 1 arm] |
| Week 49 | [No Data] | n= 2 (100.0%) \| 0.00 (2.83) | [No Data for at least 1 arm] |
| Week 55 | [No Data] | n= 1 (50.0%) \|-2.00 ( / ) | [No Data for at least 1 arm] |
| Week 61 | [No Data] | n= 1 (50.0%) \| 3.00 ( / ) | [No Data for at least 1 arm] |
| Week 67 | [No Data] | n= 1 (50.0%) \|-2.00 ( / ) | [No Data for at least 1 arm] |
| Week 73 | [No Data] | n= 1 (50.0%) \|-1.00 ( / ) | [No Data for at least 1 arm] |
| Week 79 | [No Data] | n= 1 (50.0%) \| 0.00 ( / ) | [No Data for at least 1 arm] |
| Week 85 | [No Data] | n= 1 (50.0%) \| 2.00 ( / ) | [No Data for at least 1 arm] |
| Week 91 | [No Data] | n= 1 (50.0%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 1 (50.0%) \| 2.00 ( / ) | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:55

TABLE 7.4.8: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Time from Initial Diagnosis to Randomization (Year) Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **< 1 Year** | | | | |
| Nr subjects used | n=14 | n=18 | | |
| Week 7 | -0.35 (0.94) [-2.27 ; 1.57] | -1.82 (0.81) [-3.47 ;-0.16] | 1.46 (1.24) [-1.07 ; 4.00] | 0.42 [-0.31 ; 1.14] |
| Week 13 | -0.02 (0.84) [-1.74 ; 1.70] | -1.04 (0.80) [-2.67 ; 0.58] | 1.02 (1.16) [-1.34 ; 3.39] | 0.33 [-0.42 ; 1.07] |
| Week 19 | -0.26 (0.66) [-1.60 ; 1.08] | -0.90 (0.62) [-2.16 ; 0.37] | 0.64 (0.91) [-1.21 ; 2.48] | 0.25 [-0.48 ; 0.99] |
| Week 25 | -0.85 (0.85) [-2.59 ; 0.89] | -1.43 (0.80) [-3.06 ; 0.19] | 0.58 (1.17) [-1.79 ; 2.96] | 0.18 [-0.56 ; 0.93] |
| Week 31 | -1.02 (1.07) [-3.21 ; 1.18] | -0.96 (1.12) [-3.25 ; 1.33] | -0.06 (1.55) [-3.23 ; 3.11] | -0.02 [-0.80 ; 0.77] |
| Week 37 | -0.84 (1.29) [-3.50 ; 1.82] | -1.52 (1.23) [-4.06 ; 1.02] | 0.68 (1.79) [-3.01 ; 4.36] | 0.15 [-0.66 ; 0.95] |
| Week 43 | -0.80 (1.05) [-2.94 ; 1.35] | -0.05 (1.05) [-2.21 ; 2.10] | -0.74 (1.48) [-3.79 ; 2.30] | -0.20 [-1.00 ; 0.60] |
| Week 49 | -0.43 (0.69) [-1.86 ; 1.00] | 0.17 (0.72) [-1.31 ; 1.65] | -0.60 (0.99) [-2.65 ; 1.46] | -0.24 [-1.06 ; 0.58] |
| Overall post-baseline period estimate | -0.57 (0.58) [-1.75 ; 0.61] | -0.94 (0.55) [-2.07 ; 0.18] | 0.37 (0.80) [-1.26 ; 2.00] | 0.16 [-0.54 ; 0.86] |
| **>= 1 Year** | | | | |
| Nr subjects used | n=55 | n=47 | | |
| Week 7 | -1.23 (0.49) [-2.21 ;-0.26] | -1.26 (0.53) [-2.31 ;-0.21] | 0.03 (0.72) [-1.41 ; 1.46] | 0.01 [-0.40 ; 0.41] |
| Week 13 | -0.93 (0.52) [-1.97 ; 0.11] | -1.47 (0.57) [-2.61 ;-0.33] | 0.54 (0.77) [-1.00 ; 2.08] | 0.15 [-0.28 ; 0.58] |
| Week 19 | -0.46 (0.47) [-1.40 ; 0.48] | -1.12 (0.52) [-2.15 ;-0.09] | 0.66 (0.70) [-0.73 ; 2.06] | 0.21 [-0.23 ; 0.66] |
| Week 25 | 0.01 (0.45) [-0.88 ; 0.90] | -0.53 (0.51) [-1.55 ; 0.49] | 0.54 (0.68) [-0.81 ; 1.89] | 0.18 [-0.28 ; 0.64] |
| Week 31 | -0.04 (0.44) [-0.92 ; 0.84] | -0.58 (0.50) [-1.58 ; 0.42] | 0.53 (0.67) [-0.80 ; 1.87] | 0.19 [-0.28 ; 0.66] |
| Week 37 | 0.12 (0.44) [-0.75 ; 0.98] | -0.60 (0.49) [-1.57 ; 0.37] | 0.72 (0.65) [-0.58 ; 2.02] | 0.26 [-0.21 ; 0.74] |
| Week 43 | -0.13 (0.46) [-1.05 ; 0.79] | -1.23 (0.55) [-2.31 ;-0.14] | 1.10 (0.72) [-0.32 ; 2.52] | 0.38 [-0.12 ; 0.87] |
| Week 49 | -0.25 (0.54) [-1.31 ; 0.82] | -1.02 (0.69) [-2.39 ; 0.34] | 0.78 (0.87) [-0.95 ; 2.51] | 0.23 [-0.29 ; 0.75] |
| Week 55 | -0.33 (0.43) [-1.17 ; 0.52] | -0.60 (0.53) [-1.65 ; 0.44] | 0.28 (0.68) [-1.07 ; 1.62] | 0.10 [-0.39 ; 0.60] |
| Week 61 | -0.25 (0.45) [-1.15 ; 0.66] | -0.89 (0.59) [-2.07 ; 0.29] | 0.65 (0.75) [-0.84 ; 2.13] | 0.23 [-0.31 ; 0.76] |
| Week 67 | -0.49 (0.48) [-1.46 ; 0.47] | -0.27 (0.64) [-1.53 ; 1.00] | -0.23 (0.80) [-1.82 ; 1.36] | -0.08 [-0.64 ; 0.48] |
| Week 73 | 0.11 (0.47) [-0.82 ; 1.04] | -1.09 (0.56) [-2.22 ; 0.03] | 1.20 (0.73) [-0.26 ; 2.66] | 0.48 [-0.11 ; 1.08] |
| Week 79 | 0.21 (0.50) [-0.79 ; 1.21] | -0.10 (0.60) [-1.31 ; 1.10] | 0.31 (0.78) [-1.25 ; 1.88] | 0.13 [-0.51 ; 0.77] |
| Week 85 | -0.21 (0.52) [-1.26 ; 0.83] | -0.16 (0.63) [-1.43 ; 1.10] | -0.05 (0.82) [-1.69 ; 1.59] | -0.02 [-0.73 ; 0.68] |
| Week 91 | -0.69 (0.70) [-2.11 ; 0.73] | 0.19 (0.82) [-1.47 ; 1.85] | -0.88 (1.08) [-3.07 ; 1.30] | -0.29 [-1.02 ; 0.43] |
| Overall post-baseline period estimate | -0.30 (0.24) [-0.79 ; 0.18] | -0.72 (0.29) [-1.29 ;-0.14] | 0.41 (0.38) [-0.34 ; 1.16] | 0.22 [-0.18 ; 0.61] |
| **Not Reported** | | | | |
| Nr subjects used | [No Data] | n=2 | | |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.7403 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:47:55

TABLE 7.4.9: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **No** | N=11 | N=12 |
| **Yes** | N=60 | N=56 |
| **Subjects with Baseline Value** | | |
| **No** | 11 (100.0%) | 12 (100.0%) |
| **Yes** | 58 (96.7%) | 55 (98.2%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **No** | 11 (100.0%) | 12 (100.0%) |
| **Yes** | 60 (100.0%) | 54 (96.4%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **No** | 11 (100.0%) | 12 (100.0%) |
| **Yes** | 58 (96.7%) | 53 (94.6%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:00

TABLE 7.4.9: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=11 | N=12 | |
| Baseline | n= 11 (100.0%) \| 31.45 (4.61) | n= 12 (100.0%) \| 32.25 (4.92) | -0.16 [-1.00 ; 0.68] |
| Week 3 | n= 10 (90.9%) \| 30.98 (3.14) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 10 (90.9%) \| 32.20 (3.97) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 10 (90.9%) \| 31.10 (3.81) | n= 11 (91.7%) \| 28.82 (5.12) | 0.48 [-0.41 ; 1.37] |
| Week 9 | n= 9 (81.8%) \| 31.72 (2.64) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 10 (90.9%) \| 30.80 (3.97) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 11 (100.0%) \| 31.18 (4.29) | n= 10 (83.3%) \| 30.40 (3.06) | 0.20 [-0.68 ; 1.08] |
| Week 15 | n= 9 (81.8%) \| 31.17 (4.60) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 10 (90.9%) \| 30.37 (6.12) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 9 (81.8%) \| 32.74 (3.90) | n= 10 (83.3%) \| 30.50 (3.63) | 0.57 [-0.38 ; 1.51] |
| Week 21 | n= 11 (100.0%) \| 30.73 (6.40) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \| 30.50 (4.84) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 10 (90.9%) \| 32.13 (4.29) | n= 9 (75.0%) \| 29.78 (3.87) | 0.55 [-0.40 ; 1.49] |
| Week 27 | n= 10 (90.9%) \| 32.90 (4.51) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 9 (81.8%) \| 33.01 (3.41) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 10 (90.9%) \| 32.70 (5.33) | n= 6 (50.0%) \| 31.17 (2.32) | 0.32 [-0.73 ; 1.38] |
| Week 33 | n= 10 (90.9%) \| 32.34 (5.72) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (72.7%) \| 30.98 (7.65) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \| 31.53 (7.14) | n= 7 (58.3%) \| 30.43 (3.69) | 0.18 [-0.88 ; 1.23] |
| Week 39 | n= 8 (72.7%) \| 34.25 (2.25) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 9 (81.8%) \| 33.56 (2.96) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 8 (72.7%) \| 32.63 (3.93) | n= 6 (50.0%) \| 31.81 (2.53) | 0.22 [-0.88 ; 1.33] |
| Week 45 | n= 9 (81.8%) \| 32.25 (3.35) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 9 (81.8%) \| 32.22 (3.90) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 10 (90.9%) \| 33.41 (2.98) | n= 6 (50.0%) \| 31.83 (2.04) | 0.56 [-0.51 ; 1.63] |
| Week 51 | n= 9 (81.8%) \| 33.40 (2.89) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 9 (81.8%) \| 32.92 (3.59) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 8 (72.7%) \| 32.33 (4.44) | n= 6 (50.0%) \| 30.50 (4.93) | 0.37 [-0.74 ; 1.48] |
| Week 57 | n= 8 (72.7%) \| 32.69 (3.17) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 8 (72.7%) \| 33.06 (3.63) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 7 (63.6%) \| 34.43 (3.05) | n= 4 (33.3%) \| 30.00 (1.15) | 1.57 [ 0.07 ; 3.07] |
| Week 63 | n= 8 (72.7%) \| 32.66 (3.73) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (72.7%) \| 32.91 (3.61) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \| 32.50 (3.30) | n= 5 (41.7%) \| 29.60 (2.61) | 0.88 [-0.35 ; 2.11] |
| Week 69 | n= 8 (72.7%) \| 32.16 (3.84) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (63.6%) \| 32.96 (4.90) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (63.6%) \| 33.14 (3.93) | n= 4 (33.3%) \| 29.00 (4.40) | 0.93 [-0.45 ; 2.30] |
| Week 75 | n= 7 (63.6%) \| 32.71 (4.11) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (45.5%) \| 34.00 (2.74) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (54.5%) \| 29.81 (11.19) | n= 3 (25.0%) \| 29.00 (5.57) | 0.07 [-1.41 ; 1.56] |
| Week 81 | n= 5 (45.5%) \| 34.00 (2.35) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (45.5%) \| 34.40 (2.51) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (45.5%) \| 33.40 (3.21) | n= 3 (25.0%) \| 30.00 (4.58) | 0.79 [-0.83 ; 2.42] |
| Week 87 | n= 5 (45.5%) \| 34.00 (3.46) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 4 (36.4%) \| 33.00 (4.08) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 4 (36.4%) \| 33.50 (3.70) | n= 2 (16.7%) \| 30.50 (4.95) | 0.59 [-1.39 ; 2.57] |
| Week 93 | n= 4 (36.4%) \| 34.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (27.3%) \| 33.67 (4.04) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (27.3%) \| 33.67 (3.21) | n= 1 ( 8.3%) \| 33.00 ( / ) | [Not calculable] |
| Week 99 | n= 2 (18.2%) \| 32.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 (18.2%) \| 32.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (18.2%) \| 32.00 (5.66) | n= 1 ( 8.3%) \| 32.00 ( / ) | [Not calculable] |
| Week 105 | n= 2 (18.2%) \| 32.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \| 32.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 ( 9.1%) \| 29.00 ( / ) | n= 1 ( 8.3%) \| 30.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 9.1%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 ( 9.1%) \| 30.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 9.1%) \| 30.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 ( 9.1%) \| 28.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 9.1%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 9.1%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | [No Data] | n= 5 (41.7%) \| 29.60 (4.62) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 3 (25.0%) \| 30.33 (1.53) | [No Data for at least 1 arm] |
| **Yes** | | | |
| N subjects in population | N=60 | N=56 | |
| Baseline | n= 58 (96.7%) \| 31.69 (4.41) | n= 55 (98.2%) \| 31.30 (4.10) | 0.09 [-0.28 ; 0.46] |
| Week 3 | n= 57 (95.0%) \| 31.62 (4.11) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 53 (88.3%) \| 30.93 (4.84) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 54 (90.0%) \| 30.64 (4.34) | n= 53 (94.6%) \| 30.59 (3.74) | 0.01 [-0.37 ; 0.39] |
| Week 9 | n= 52 (86.7%) \| 30.87 (4.49) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 51 (85.0%) \| 30.85 (4.00) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 49 (81.7%) \| 31.43 (3.85) | n= 45 (80.4%) \| 30.82 (3.82) | 0.16 [-0.25 ; 0.56] |
| Week 15 | n= 45 (75.0%) \| 31.29 (3.60) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 53 (88.3%) \| 31.58 (3.79) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 48 (80.0%) \| 31.91 (2.94) | n= 44 (78.6%) \| 31.29 (3.37) | 0.19 [-0.22 ; 0.61] |
| Week 21 | n= 48 (80.0%) \| 32.04 (3.39) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 46 (76.7%) \| 31.11 (3.77) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 48 (80.0%) \| 31.90 (3.57) | n= 40 (71.4%) \| 31.90 (2.82) | -0.00 [-0.42 ; 0.42] |
| Week 27 | n= 46 (76.7%) \| 32.54 (3.79) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 43 (71.7%) \| 31.91 (3.67) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 44 (73.3%) \| 31.95 (3.95) | n= 36 (64.3%) \| 31.44 (4.00) | 0.13 [-0.32 ; 0.57] |
| Week 33 | n= 46 (76.7%) \| 31.70 (4.14) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 46 (76.7%) \| 31.59 (4.52) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 40 (66.7%) \| 32.20 (4.27) | n= 40 (71.4%) \| 31.49 (3.07) | 0.19 [-0.25 ; 0.63] |
| Week 39 | n= 44 (73.3%) \| 32.02 (3.99) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 43 (71.7%) \| 31.81 (4.27) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 44 (73.3%) \| 31.86 (4.06) | n= 36 (64.3%) \| 30.94 (4.28) | 0.22 [-0.23 ; 0.66] |
| Week 45 | n= 39 (65.0%) \| 31.18 (4.59) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 42 (70.0%) \| 31.93 (4.21) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 42 (70.0%) \| 31.71 (4.60) | n= 30 (53.6%) \| 31.19 (4.23) | 0.12 [-0.36 ; 0.59] |
| Week 51 | n= 42 (70.0%) \| 31.25 (4.45) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 43 (71.7%) \| 31.84 (4.20) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 38 (63.3%) \| 31.68 (4.52) | n= 32 (57.1%) \| 31.04 (3.17) | 0.16 [-0.32 ; 0.63] |
| Week 57 | n= 40 (66.7%) \| 31.43 (4.56) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 38 (63.3%) \| 31.28 (4.61) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 61 | n= 41 (68.3%) \| 31.84 (4.22) | n= 27 (48.2%) \| 31.00 (3.80) | 0.21 [-0.28 ; 0.70] |
| Week 63 | n= 34 (56.7%) \| 31.24 (5.05) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 35 (58.3%) \| 30.63 (5.54) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (60.0%) \| 31.92 (4.44) | n= 25 (44.6%) \| 31.16 (3.86) | 0.18 [-0.34 ; 0.69] |
| Week 69 | n= 30 (50.0%) \| 30.90 (5.33) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (51.7%) \| 31.71 (4.50) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 28 (46.7%) \| 32.00 (4.11) | n= 24 (42.9%) \| 30.34 (3.62) | 0.42 [-0.14 ; 0.98] |
| Week 75 | n= 28 (46.7%) \| 32.14 (3.74) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (45.0%) \| 31.78 (4.00) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 25 (41.7%) \| 31.79 (4.14) | n= 22 (39.3%) \| 31.50 (2.76) | 0.08 [-0.50 ; 0.66] |
| Week 81 | n= 24 (40.0%) \| 31.46 (4.46) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (46.7%) \| 31.82 (4.22) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 22 (36.7%) \| 32.05 (4.01) | n= 18 (32.1%) \| 31.89 (3.03) | 0.04 [-0.59 ; 0.67] |
| Week 87 | n= 19 (31.7%) \| 30.26 (4.75) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 21 (35.0%) \| 31.28 (4.19) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (33.3%) \| 30.26 (4.85) | n= 16 (28.6%) \| 32.25 (3.55) | -0.45 [-1.12 ; 0.23] |
| Week 93 | n= 19 (31.7%) \| 30.84 (4.09) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.7%) \| 30.78 (4.61) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (30.0%) \| 30.47 (4.54) | n= 10 (17.9%) \| 32.20 (3.74) | -0.39 [-1.19 ; 0.40] |
| Week 99 | n= 15 (25.0%) \| 30.53 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (20.0%) \| 31.25 (3.70) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.7%) \| 31.54 (3.31) | n= 9 (16.1%) \| 32.33 (2.74) | -0.25 [-1.12 ; 0.63] |
| Week 105 | n= 11 (18.3%) \| 30.64 (3.85) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.0%) \| 31.50 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.7%) \| 29.09 (4.00) | n= 4 ( 7.1%) \| 31.75 (5.97) | -0.55 [-1.77 ; 0.68] |
| Week 111 | n= 6 (10.0%) \| 30.50 (4.23) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.7%) \| 31.64 (3.94) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (10.0%) \| 31.17 (4.54) | n= 5 ( 8.9%) \| 32.60 (2.19) | -0.36 [-1.62 ; 0.91] |
| Week 117 | n= 6 (10.0%) \| 33.50 (2.35) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 (10.0%) \| 29.33 (4.89) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.7%) \| 31.46 (4.77) | n= 1 ( 1.8%) \| 30.38 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.3%) \| 31.00 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.7%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) \| 32.00 (1.41) | n= 1 ( 1.8%) \| 24.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.7%) \| 29.25 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.7%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.7%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.7%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.7%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.7%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.7%) \| 31.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (13.3%) \| 31.50 (4.41) | n= 11 (19.6%) \| 30.73 (4.69) | 0.16 [-0.78 ; 1.10] |
| Week 202 | n= 2 ( 3.3%) \| 25.00 (7.07) | n= 8 (14.3%) \| 33.13 (2.17) | -2.28 [-4.30 ;-0.26] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:01

TABLE 7.4.9: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=11 | N=12 | |
| Week 3 | n= 10 (90.9%) \|-1.42 (2.05) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 10 (90.9%) \| 0.50 (1.35) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 10 (90.9%) \|-0.10 (3.18) | n= 11 (91.7%) \|-3.18 (4.24) | 0.78 [-0.13 ; 1.70] |
| Week 9 | n= 9 (81.8%) \|-1.06 (2.24) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 10 (90.9%) \|-0.90 (3.81) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 11 (100.0%) \|-0.27 (3.41) | n= 10 (83.3%) \|-2.70 (5.12) | 0.54 [-0.35 ; 1.44] |
| Week 15 | n= 9 (81.8%) \|-1.17 (4.23) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 10 (90.9%) \|-1.13 (3.72) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 9 (81.8%) \| 0.40 (2.59) | n= 10 (83.3%) \|-2.50 (6.04) | 0.58 [-0.36 ; 1.53] |
| Week 21 | n= 11 (100.0%) \|-0.73 (3.52) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \|-0.60 (1.84) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 10 (90.9%) \|-0.08 (2.19) | n= 9 (75.0%) \|-4.33 (4.80) | 1.11 [ 0.11 ; 2.11] |
| Week 27 | n= 10 (90.9%) \| 0.70 (2.11) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 9 (81.8%) \| 0.68 (2.39) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 10 (90.9%) \| 0.50 (2.27) | n= 6 (50.0%) \|-2.50 (2.95) | 1.12 [-0.01 ; 2.25] |
| Week 33 | n= 10 (90.9%) \| 0.14 (2.94) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 8 (72.7%) \|-0.64 (3.94) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \|-0.59 (3.34) | n= 7 (58.3%) \|-3.43 (3.60) | 0.77 [-0.32 ; 1.87] |
| Week 39 | n= 8 (72.7%) \| 0.38 (2.88) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 9 (81.8%) \| 1.00 (3.28) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 8 (72.7%) \|-0.13 (2.47) | n= 6 (50.0%) \|-1.69 (2.39) | 0.60 [-0.53 ; 1.73] |
| Week 45 | n= 9 (81.8%) \|-0.31 (2.79) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 9 (81.8%) \|-0.33 (1.73) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 10 (90.9%) \| 1.21 (2.54) | n= 6 (50.0%) \|-1.67 (2.50) | 1.08 [-0.05 ; 2.20] |
| Week 51 | n= 9 (81.8%) \| 1.07 (2.71) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 9 (81.8%) \| 0.58 (2.55) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 8 (72.7%) \| 0.20 (3.73) | n= 6 (50.0%) \|-3.00 (3.63) | 0.81 [-0.34 ; 1.96] |
| Week 57 | n= 8 (72.7%) \| 0.56 (3.33) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 8 (72.7%) \| 0.94 (2.93) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 7 (63.6%) \| 1.86 (2.48) | n= 4 (33.3%) \|-3.00 (1.83) | 1.95 [ 0.35 ; 3.55] |
| Week 63 | n= 8 (72.7%) \| 0.54 (3.19) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 8 (72.7%) \| 0.78 (2.96) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \| 0.38 (4.03) | n= 5 (41.7%) \|-3.60 (2.07) | 1.07 [-0.18 ; 2.33] |
| Week 69 | n= 8 (72.7%) \| 0.03 (3.51) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (63.6%) \| 1.25 (2.95) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 7 (63.6%) \| 1.43 (2.76) | n= 4 (33.3%) \|-4.00 (2.16) | 1.93 [ 0.33 ; 3.52] |
| Week 75 | n= 7 (63.6%) \| 1.00 (4.12) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 5 (45.5%) \| 2.40 (4.67) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 6 (54.5%) \|-1.35 (9.90) | n= 3 (25.0%) \|-3.00 (3.00) | 0.17 [-1.32 ; 1.66] |
| Week 81 | n= 5 (45.5%) \| 2.40 (3.36) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 5 (45.5%) \| 2.80 (3.11) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 5 (45.5%) \| 1.80 (3.03) | n= 3 (25.0%) \|-3.67 (2.31) | 1.69 [-0.18 ; 3.56] |
| Week 87 | n= 5 (45.5%) \| 2.40 (2.61) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 4 (36.4%) \| 1.75 (2.75) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 4 (36.4%) \| 2.25 (2.87) | n= 2 (16.7%) \|-5.00 (5.66) | 1.54 [-0.75 ; 3.83] |
| Week 93 | n= 4 (36.4%) \| 2.75 (3.86) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (27.3%) \| 3.67 (3.06) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (27.3%) \| 3.67 (4.04) | n= 1 ( 8.3%) \|-2.00 ( / ) | [Not calculable] |
| Week 99 | n= 2 (18.2%) \| 5.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 2 (18.2%) \| 5.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (18.2%) \| 4.50 (2.12) | n= 1 ( 8.3%) \|-4.00 ( / ) | [Not calculable] |
| Week 105 | n= 2 (18.2%) \| 4.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \| 5.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 1 ( 9.1%) \| 7.00 ( / ) | n= 1 ( 8.3%) \|-6.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 9.1%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 ( 9.1%) \| 8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 ( 9.1%) \| 8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 ( 9.1%) \| 6.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 ( 9.1%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 ( 9.1%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | [No Data] | n= 5 (41.7%) \|-1.20 (6.61) | [No Data for at least 1 arm] |
| Week 202 | [No Data] | n= 3 (25.0%) \|-0.33 (6.66) | [No Data for at least 1 arm] |
| **Yes** | | | |
| N subjects in population | N=60 | N=56 | |
| Week 3 | n= 56 (93.3%) \| 0.04 (2.23) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 51 (85.0%) \|-0.89 (3.23) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 52 (86.7%) \|-0.97 (3.76) | n= 52 (92.9%) \|-0.68 (3.04) | -0.08 [-0.47 ; 0.30] |
| Week 9 | n= 51 (85.0%) \|-1.11 (4.13) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 50 (83.3%) \|-1.13 (3.41) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 48 (80.0%) \|-0.66 (3.64) | n= 45 (80.4%) \|-1.11 (2.59) | 0.14 [-0.27 ; 0.55] |
| Week 15 | n= 45 (75.0%) \|-0.65 (4.00) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 52 (86.7%) \|-0.45 (3.60) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 47 (78.3%) \|-0.69 (3.30) | n= 43 (76.8%) \|-0.58 (2.73) | -0.04 [-0.45 ; 0.38] |
| Week 21 | n= 48 (80.0%) \|-0.09 (3.64) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 46 (76.7%) \|-0.98 (3.25) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 47 (78.3%) \|-0.22 (3.82) | n= 39 (69.6%) \|-0.07 (2.71) | -0.05 [-0.47 ; 0.38] |
| Week 27 | n= 45 (75.0%) \| 0.01 (3.86) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 43 (71.7%) \|-0.13 (3.87) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 44 (73.3%) \|-0.47 (3.92) | n= 36 (64.3%) \|-0.66 (2.31) | 0.06 [-0.39 ; 0.50] |
| Week 33 | n= 46 (76.7%) \|-0.63 (3.52) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 45 (75.0%) \|-0.61 (3.60) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 40 (66.7%) \| 0.09 (3.61) | n= 39 (69.6%) \|-0.26 (2.85) | 0.11 [-0.34 ; 0.55] |
| Week 39 | n= 43 (71.7%) \|-0.16 (3.40) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 43 (71.7%) \|-0.89 (3.52) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 43 (71.7%) \|-0.52 (4.20) | n= 35 (62.5%) \|-0.74 (3.02) | 0.06 [-0.39 ; 0.51] |
| Week 45 | n= 39 (65.0%) \|-1.01 (4.58) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 42 (70.0%) \|-0.79 (3.52) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 42 (70.0%) \|-0.69 (3.86) | n= 29 (51.8%) \|-0.79 (3.41) | 0.03 [-0.45 ; 0.51] |
| Week 51 | n= 42 (70.0%) \|-0.87 (3.61) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 43 (71.7%) \|-0.34 (3.39) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 38 (63.3%) \|-0.63 (3.34) | n= 31 (55.4%) \|-0.46 (2.59) | -0.05 [-0.53 ; 0.42] |
| Week 57 | n= 40 (66.7%) \|-0.60 (3.81) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 38 (63.3%) \|-0.76 (4.15) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 41 (68.3%) \|-0.44 (3.65) | n= 26 (46.4%) \|-0.22 (3.03) | -0.06 [-0.56 ; 0.43] |
| Week 63 | n= 34 (56.7%) \|-0.36 (4.00) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 65 | n= 35 (58.3%) \|-0.91 (4.97) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (60.0%) \|-0.13 (3.86) | n= 24 (42.9%) \| 0.05 (2.52) | -0.05 [-0.57 ; 0.47] |
| Week 69 | n= 30 (50.0%) \|-1.16 (5.43) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (51.7%) \|-0.48 (4.70) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 28 (46.7%) \|-0.08 (4.56) | n= 24 (42.9%) \|-0.61 (2.69) | 0.14 [-0.42 ; 0.69] |
| Week 75 | n= 28 (46.7%) \| 0.02 (4.38) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 27 (45.0%) \| 0.47 (4.36) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 25 (41.7%) \| 0.41 (4.07) | n= 21 (37.5%) \| 0.66 (2.53) | -0.07 [-0.66 ; 0.52] |
| Week 81 | n= 24 (40.0%) \|-0.27 (3.55) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 28 (46.7%) \| 0.20 (4.33) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 22 (36.7%) \| 0.03 (4.39) | n= 17 (30.4%) \| 0.24 (2.44) | -0.06 [-0.70 ; 0.59] |
| Week 87 | n= 19 (31.7%) \|-1.16 (4.36) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 21 (35.0%) \|-0.12 (4.16) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 20 (33.3%) \|-1.71 (3.01) | n= 15 (26.8%) \| 0.23 (3.85) | -0.56 [-1.25 ; 0.14] |
| Week 93 | n= 19 (31.7%) \|-1.13 (2.66) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.7%) \|-1.30 (3.12) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (30.0%) \|-1.44 (2.77) | n= 9 (16.1%) \|-0.44 (3.00) | -0.34 [-1.16 ; 0.48] |
| Week 99 | n= 15 (25.0%) \|-1.09 (3.41) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 12 (20.0%) \|-1.25 (2.18) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.7%) \|-0.49 (2.83) | n= 8 (14.3%) \| 0.63 (2.45) | -0.40 [-1.31 ; 0.51] |
| Week 105 | n= 11 (18.3%) \|-0.76 (2.92) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.0%) \|-1.17 (2.64) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 10 (16.7%) \|-2.41 (3.01) | n= 3 ( 5.4%) \| 1.00 (1.00) | -1.15 [-2.59 ; 0.28] |
| Week 111 | n= 6 (10.0%) \|-2.00 (2.97) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.7%) \|-1.64 (2.32) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 (10.0%) \|-2.00 (2.97) | n= 5 ( 8.9%) \|-1.00 (1.58) | -0.37 [-1.64 ; 0.89] |
| Week 117 | n= 6 (10.0%) \|-0.33 (2.07) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 (10.0%) \|-3.83 (2.93) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.7%) \|-2.39 (3.15) | n= 1 ( 1.8%) \|-1.63 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.3%) \|-2.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.7%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) \|-1.50 (0.71) | n= 1 ( 1.8%) \|-8.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.7%) \|-2.75 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.7%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.7%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.7%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.7%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.7%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.7%) \|-0.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (13.3%) \|-0.50 (3.16) | n= 11 (19.6%) \|-1.73 (4.31) | 0.30 [-0.64 ; 1.24] |
| Week 202 | n= 2 ( 3.3%) \|-5.50 (4.95) | n= 8 (14.3%) \|-0.13 (1.96) | -1.92 [-3.84 ; 0.00] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:01

TABLE 7.4.9: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior nephrectomy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **No** | | | | |
| Nr subjects used | n=11 | n=12 | | |
| Week 7 | -0.48 (1.05) [-2.67 ; 1.71] | -3.07 (1.00) [-5.16 ;-0.99] | 2.59 (1.45) [-0.44 ; 5.62] | 0.75 [-0.14 ; 1.64] |
| Week 13 | -0.46 (1.11) [-2.82 ; 1.89] | -2.42 (1.15) [-4.83 ;-0.02] | 1.96 (1.60) [-1.41 ; 5.33] | 0.51 [-0.36 ; 1.39] |
| Overall post-baseline period estimate | -0.47 (0.95) [-2.47 ; 1.53] | -2.75 (0.93) [-4.69 ;-0.80] | 2.27 (1.33) [-0.53 ; 5.07] | 0.69 [-0.16 ; 1.53] |
| **Yes** | | | | |
| Nr subjects used | n=58 | n=55 | | |
| Week 7 | -1.12 (0.47) [-2.05 ;-0.19] | -0.92 (0.48) [-1.87 ; 0.03] | -0.20 (0.67) [-1.52 ; 1.13] | -0.06 [-0.44 ; 0.33] |
| Week 13 | -0.72 (0.49) [-1.69 ; 0.24] | -1.06 (0.51) [-2.06 ;-0.05] | 0.33 (0.70) [-1.06 ; 1.73] | 0.10 [-0.31 ; 0.51] |
| Week 19 | -0.60 (0.40) [-1.39 ; 0.20] | -0.73 (0.42) [-1.57 ; 0.11] | 0.13 (0.58) [-1.03 ; 1.28] | 0.05 [-0.37 ; 0.46] |
| Week 25 | -0.17 (0.40) [-0.97 ; 0.62] | -0.13 (0.43) [-0.98 ; 0.73] | -0.05 (0.59) [-1.21 ; 1.11] | -0.02 [-0.44 ; 0.41] |
| Week 31 | -0.45 (0.46) [-1.37 ; 0.48] | -0.46 (0.50) [-1.45 ; 0.54] | 0.01 (0.68) [-1.35 ; 1.37] | 0.00 [-0.44 ; 0.44] |
| Week 37 | 0.02 (0.44) [-0.85 ; 0.89] | -0.47 (0.46) [-1.37 ; 0.43] | 0.49 (0.63) [-0.76 ; 1.74] | 0.17 [-0.27 ; 0.61] |
| Week 43 | -0.42 (0.49) [-1.40 ; 0.56] | -0.77 (0.54) [-1.85 ; 0.30] | 0.35 (0.73) [-1.10 ; 1.81] | 0.11 [-0.34 ; 0.56] |
| Week 49 | -0.66 (0.52) [-1.69 ; 0.36] | -0.51 (0.60) [-1.70 ; 0.67] | -0.15 (0.79) [-1.72 ; 1.42] | -0.05 [-0.52 ; 0.43] |
| Week 55 | -0.47 (0.42) [-1.31 ; 0.37] | -0.47 (0.48) [-1.42 ; 0.49] | -0.00 (0.64) [-1.27 ; 1.27] | -0.00 [-0.48 ; 0.47] |
| Week 61 | -0.61 (0.45) [-1.50 ; 0.27] | -0.42 (0.54) [-1.50 ; 0.66] | -0.19 (0.70) [-1.59 ; 1.21] | -0.07 [-0.56 ; 0.43] |
| Week 67 | -0.37 (0.47) [-1.30 ; 0.56] | -0.18 (0.57) [-1.31 ; 0.96] | -0.20 (0.74) [-1.67 ; 1.27] | -0.07 [-0.59 ; 0.45] |
| Week 73 | -0.53 (0.56) [-1.64 ; 0.59] | -0.84 (0.63) [-2.09 ; 0.42] | 0.31 (0.84) [-1.36 ; 1.99] | 0.10 [-0.44 ; 0.65] |
| Week 79 | 0.01 (0.49) [-0.97 ; 0.99] | 0.12 (0.55) [-0.98 ; 1.21] | -0.11 (0.74) [-1.57 ; 1.36] | -0.04 [-0.62 ; 0.54] |
| Week 85 | -0.49 (0.55) [-1.58 ; 0.60] | -0.10 (0.62) [-1.34 ; 1.14] | -0.39 (0.82) [-2.04 ; 1.26] | -0.15 [-0.78 ; 0.48] |
| Week 91 | -0.86 (0.65) [-2.16 ; 0.44] | 0.18 (0.74) [-1.32 ; 1.67] | -1.04 (0.98) [-3.02 ; 0.94] | -0.35 [-1.03 ; 0.32] |
| Overall post-baseline period estimate | -0.50 (0.24) [-0.96 ;-0.03] | -0.45 (0.26) [-0.97 ; 0.07] | -0.05 (0.36) [-0.75 ; 0.66] | -0.02 [-0.40 ; 0.35] |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.3916 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:01

TABLE 7.4.10: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **No** | N=61 | N=62 |
| **Yes** | N=10 | N=6 |
| **Subjects with Baseline Value** | | |
| **No** | 59 (96.7%) | 61 (98.4%) |
| **Yes** | 10 (100.0%) | 6 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **No** | 61 (100.0%) | 60 (96.8%) |
| **Yes** | 10 (100.0%) | 6 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **No** | 59 (96.7%) | 59 (95.2%) |
| **Yes** | 10 (100.0%) | 6 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:01

TABLE 7.4.10: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=61 | N=62 | |
| Baseline | n= 59 (96.7%) \| 32.02 (4.32) | n= 61 (98.4%) \| 31.32 (4.41) | 0.16 [-0.20 ; 0.52] |
| Week 3 | n= 57 (93.4%) \| 32.14 (3.49) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 55 (90.2%) \| 31.63 (4.47) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 55 (90.2%) \| 30.85 (4.43) | n= 59 (95.2%) \| 30.06 (4.08) | 0.19 [-0.18 ; 0.56] |
| Week 9 | n= 52 (85.2%) \| 31.51 (4.18) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 53 (86.9%) \| 31.20 (3.75) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 53 (86.9%) \| 31.64 (3.87) | n= 50 (80.6%) \| 30.56 (3.77) | 0.28 [-0.11 ; 0.67] |
| Week 15 | n= 49 (80.3%) \| 31.65 (3.19) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 55 (90.2%) \| 31.81 (3.69) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 51 (83.6%) \| 32.20 (2.87) | n= 50 (80.6%) \| 31.12 (3.50) | 0.34 [-0.06 ; 0.73] |
| Week 21 | n= 51 (83.6%) \| 32.38 (3.16) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 49 (80.3%) \| 31.45 (3.70) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 52 (85.2%) \| 32.06 (3.58) | n= 47 (75.8%) \| 31.40 (3.12) | 0.19 [-0.20 ; 0.59] |
| Week 27 | n= 50 (82.0%) \| 32.66 (3.72) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 46 (75.4%) \| 32.13 (3.41) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 48 (78.7%) \| 32.15 (4.17) | n= 39 (62.9%) \| 31.23 (3.84) | 0.23 [-0.20 ; 0.65] |
| Week 33 | n= 49 (80.3%) \| 32.05 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 48 (78.7%) \| 31.79 (4.98) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 41 (67.2%) \| 32.42 (4.75) | n= 42 (67.7%) \| 31.01 (3.15) | 0.35 [-0.09 ; 0.78] |
| Week 39 | n= 45 (73.8%) \| 32.71 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 46 (75.4%) \| 32.41 (3.76) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 46 (75.4%) \| 32.06 (3.89) | n= 38 (61.3%) \| 30.94 (4.19) | 0.27 [-0.16 ; 0.71] |
| Week 45 | n= 41 (67.2%) \| 31.81 (3.73) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 45 (73.8%) \| 32.11 (3.90) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 46 (75.4%) \| 32.39 (4.05) | n= 32 (51.6%) \| 31.12 (4.07) | 0.31 [-0.15 ; 0.77] |
| Week 51 | n= 44 (72.1%) \| 31.91 (4.03) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 45 (73.8%) \| 32.18 (3.82) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (63.9%) \| 31.99 (4.38) | n= 35 (56.5%) \| 30.98 (3.57) | 0.25 [-0.21 ; 0.71] |
| Week 57 | n= 41 (67.2%) \| 31.99 (3.89) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 39 (63.9%) \| 31.70 (4.44) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 41 (67.2%) \| 32.58 (3.60) | n= 28 (45.2%) \| 30.54 (3.60) | 0.56 [ 0.07 ; 1.05] |
| Week 63 | n= 35 (57.4%) \| 31.78 (4.51) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (59.0%) \| 31.45 (4.11) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (62.3%) \| 32.05 (4.36) | n= 27 (43.5%) \| 30.70 (3.79) | 0.32 [-0.18 ; 0.82] |
| Week 69 | n= 33 (54.1%) \| 31.46 (4.11) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (50.8%) \| 32.25 (4.14) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 29 (47.5%) \| 32.48 (3.43) | n= 25 (40.3%) \| 29.97 (3.85) | 0.68 [ 0.13 ; 1.24] |
| Week 75 | n= 30 (49.2%) \| 32.13 (3.76) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (42.6%) \| 32.73 (3.32) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (42.6%) \| 31.92 (5.93) | n= 24 (38.7%) \| 31.17 (3.21) | 0.15 [-0.41 ; 0.71] |
| Week 81 | n= 24 (39.3%) \| 32.54 (3.60) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 27 (44.3%) \| 32.74 (3.75) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (41.0%) \| 32.08 (3.91) | n= 19 (30.6%) \| 31.32 (3.23) | 0.21 [-0.40 ; 0.81] |
| Week 87 | n= 19 (31.1%) \| 31.84 (4.06) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | | Sunitinib | | Hedge G difference [95% CI] |
|---|---|---|---|---|---|
| Week 89 | n= 22 (36.1%) | 32.18 (3.48) | | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 21 (34.4%) | 31.48 (3.86) | n= 16 (25.8%) | 31.81 (3.73) | -0.09 [-0.75 ; 0.57] |
| Week 93 | n= 20 (32.8%) | 31.95 (3.62) | | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.1%) | 31.88 (3.85) | | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.5%) | 31.63 (3.92) | n= 11 (17.7%) | 32.27 (3.55) | -0.16 [-0.93 ; 0.60] |
| Week 99 | n= 14 (23.0%) | 31.71 (3.91) | | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.3%) | 31.23 (3.77) | | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.3%) | 31.85 (3.41) | n= 10 (16.1%) | 32.30 (2.58) | -0.14 [-0.99 ; 0.70] |
| Week 105 | n= 11 (18.0%) | 30.91 (3.99) | | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.5%) | 31.43 (3.36) | | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (14.8%) | 28.99 (3.85) | n= 5 ( 8.1%) | 31.40 (5.22) | -0.52 [-1.68 ; 0.64] |
| Week 111 | n= 6 ( 9.8%) | 30.17 (4.26) | | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.5%) | 30.79 (3.46) | | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 ( 9.8%) | 30.33 (4.13) | n= 5 ( 8.1%) | 32.60 (2.19) | -0.61 [-1.89 ; 0.68] |
| Week 117 | n= 6 ( 9.8%) | 32.17 (2.86) | | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 ( 9.8%) | 28.50 (4.32) | | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.5%) | 30.89 (4.80) | n= 1 ( 1.6%) | 30.38 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.3%) | 31.00 (5.66) | | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) | 29.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) | 32.00 (1.41) | n= 1 ( 1.6%) | 24.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) | 29.25 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.6%) | 32.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) | 29.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.6%) | 31.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.6%) | 31.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.6%) | 32.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) | 31.50 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 ( 9.8%) | 31.17 (5.15) | n= 14 (22.6%) | 30.14 (4.83) | 0.20 [-0.78 ; 1.18] |
| Week 202 | n= 1 ( 1.6%) | 30.00 ( / ) | n= 8 (12.9%) | 31.88 (2.23) | [Not calculable] |
| **Yes** | | | | | |
| N subjects in population | | N=10 | | N=6 | |
| Baseline | n= 10 (100.0%) | 29.50 (4.55) | n= 6 (100.0%) | 33.00 (0.89) | -0.90 [-2.00 ; 0.20] |
| Week 3 | n= 10 (100.0%) | 28.00 (4.85) | | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (80.0%) | 27.75 (5.18) | | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 9 (90.0%) | 29.85 (2.84) | n= 5 (83.3%) | 33.00 (1.58) | -1.18 [-2.42 ; 0.05] |
| Week 9 | n= 9 (90.0%) | 28.00 (3.57) | | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 8 (80.0%) | 28.50 (4.75) | | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 7 (70.0%) | 29.43 (3.78) | n= 5 (83.3%) | 32.60 (1.67) | -0.94 [-2.22 ; 0.34] |
| Week 15 | n= 5 (50.0%) | 27.60 (6.66) | | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 8 (80.0%) | 28.53 (6.40) | | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 6 (60.0%) | 30.67 (4.68) | n= 4 (66.7%) | 31.50 (1.91) | -0.19 [-1.54 ; 1.15] |
| Week 21 | n= 8 (80.0%) | 28.13 (6.96) | | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 7 (70.0%) | 27.86 (4.45) | | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (60.0%) | 30.83 (4.49) | n= 2 (33.3%) | 34.00 (1.41) | -0.67 [-2.45 ; 1.12] |
| Week 27 | n= 6 (60.0%) | 32.17 (5.46) | | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 6 (60.0%) | 31.83 (5.38) | | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 6 (60.0%) | 31.67 (4.80) | n= 3 (50.0%) | 33.67 (2.08) | -0.42 [-1.93 ; 1.08] |
| Week 33 | n= 7 (70.0%) | 30.14 (5.52) | | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 6 (60.0%) | 29.17 (5.15) | | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 7 (70.0%) | 30.14 (4.78) | n= 5 (83.3%) | 34.00 (1.58) | -0.93 [-2.21 ; 0.35] |
| Week 39 | n= 7 (70.0%) | 30.14 (5.64) | | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 41 | n= 6 (60.0%) \| 29.83 (6.08) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 6 (60.0%) \| 31.33 (5.24) | n= 4 (66.7%) \| 32.25 (2.63) | -0.19 [-1.53 ; 1.16] |
| Week 45 | n= 7 (70.0%) \| 28.86 (6.96) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (60.0%) \| 31.00 (5.87) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (60.0%) \| 29.33 (6.06) | n= 4 (66.7%) \| 32.75 (2.50) | -0.61 [-2.00 ; 0.77] |
| Week 51 | n= 7 (70.0%) \| 29.86 (5.58) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 7 (70.0%) \| 31.00 (5.83) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (70.0%) \| 30.69 (5.15) | n= 3 (50.0%) \| 30.67 (1.15) | 0.01 [-1.43 ; 1.44] |
| Week 57 | n= 7 (70.0%) \| 29.57 (6.48) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (70.0%) \| 31.00 (4.97) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 7 (70.0%) \| 30.14 (6.49) | n= 3 (50.0%) \| 34.00 (1.00) | -0.62 [-2.09 ; 0.85] |
| Week 63 | n= 7 (70.0%) \| 30.14 (6.36) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (70.0%) \| 29.00 (9.50) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (60.0%) \| 31.83 (3.66) | n= 3 (50.0%) \| 32.67 (2.31) | -0.22 [-1.71 ; 1.27] |
| Week 69 | n= 5 (50.0%) \| 29.20 (9.68) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (70.0%) \| 30.57 (6.19) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 6 (60.0%) \| 31.00 (6.57) | n= 3 (50.0%) \| 31.67 (0.58) | -0.11 [-1.59 ; 1.38] |
| Week 75 | n= 5 (50.0%) \| 33.00 (4.12) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (60.0%) \| 29.50 (5.32) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (50.0%) \| 28.73 (5.83) | n= 1 (16.7%) \| 32.00 ( / ) | [Not calculable] |
| Week 81 | n= 5 (50.0%) \| 28.80 (6.14) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (60.0%) \| 29.83 (5.04) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (20.0%) \| 35.00 (1.41) | n= 2 (33.3%) \| 34.50 (0.71) | 0.26 [-2.23 ; 2.74] |
| Week 87 | n= 5 (50.0%) \| 28.00 (6.20) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 3 (30.0%) \| 27.00 (6.56) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (30.0%) \| 26.08 (8.63) | n= 2 (33.3%) \| 34.00 (1.41) | -0.81 [-3.08 ; 1.45] |
| Week 93 | n= 3 (30.0%) \| 27.67 (5.51) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (30.0%) \| 26.67 (7.02) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (30.0%) \| 26.67 (6.03) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 3 (30.0%) \| 26.33 (8.02) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (10.0%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (20.0%) \| 30.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 105 | n= 2 (20.0%) \| 30.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (10.0%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 (20.0%) \| 29.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 (10.0%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 (10.0%) \| 36.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 (10.0%) \| 35.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (10.0%) \| 36.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (10.0%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 (10.0%) \| 33.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (20.0%) \| 32.50 (0.71) | n= 2 (33.3%) \| 32.00 (0.00) | 0.57 [-2.04 ; 3.18] |
| Week 202 | n= 1 (10.0%) \| 20.00 ( / ) | n= 3 (50.0%) \| 33.67 (2.52) | [Not calculable] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:02

TABLE 7.4.10: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **No** | | | |
| N subjects in population | N=61 | N=62 | |
| Week 3 | n= 56 (91.8%) \| 0.06 (2.24) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 53 (86.9%) \|-0.57 (3.16) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 53 (86.9%) \|-0.96 (3.79) | n= 58 (93.5%) \|-1.23 (3.46) | 0.07 [-0.30 ; 0.45] |
| Week 9 | n= 51 (83.6%) \|-1.02 (4.01) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 52 (85.2%) \|-1.12 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 52 (85.2%) \|-0.46 (3.48) | n= 50 (80.6%) \|-1.52 (3.31) | 0.31 [-0.08 ; 0.70] |
| Week 15 | n= 49 (80.3%) \|-0.36 (3.64) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 54 (88.5%) \|-0.41 (3.64) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 50 (82.0%) \|-0.44 (3.30) | n= 49 (79.0%) \|-0.92 (3.72) | 0.14 [-0.26 ; 0.53] |
| Week 21 | n= 51 (83.6%) \| 0.07 (3.56) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 49 (80.3%) \|-0.82 (3.07) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 51 (83.6%) \|-0.20 (3.71) | n= 46 (74.2%) \|-0.95 (3.62) | 0.20 [-0.20 ; 0.60] |
| Week 27 | n= 49 (80.3%) \| 0.15 (3.69) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 46 (75.4%) \|-0.12 (3.78) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 48 (78.7%) \|-0.26 (3.82) | n= 39 (62.9%) \|-1.02 (2.50) | 0.23 [-0.20 ; 0.65] |
| Week 33 | n= 49 (80.3%) \|-0.44 (3.35) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 47 (77.0%) \|-0.54 (3.60) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 41 (67.2%) \| 0.12 (3.67) | n= 41 (66.1%) \|-0.98 (3.23) | 0.31 [-0.12 ; 0.75] |
| Week 39 | n= 44 (72.1%) \| 0.05 (3.18) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 46 (75.4%) \|-0.49 (3.52) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 45 (73.8%) \|-0.45 (4.08) | n= 37 (59.7%) \|-0.92 (3.04) | 0.13 [-0.31 ; 0.57] |
| Week 45 | n= 41 (67.2%) \|-0.66 (4.16) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 45 (73.8%) \|-0.64 (3.16) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 46 (75.4%) \|-0.14 (3.58) | n= 31 (50.0%) \|-1.03 (3.41) | 0.25 [-0.21 ; 0.71] |
| Week 51 | n= 44 (72.1%) \|-0.43 (3.55) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 45 (73.8%) \|-0.20 (3.29) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 39 (63.9%) \|-0.52 (3.53) | n= 34 (54.8%) \|-0.78 (2.98) | 0.08 [-0.39 ; 0.54] |
| Week 57 | n= 41 (67.2%) \|-0.23 (3.59) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 39 (63.9%) \|-0.55 (4.08) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 41 (67.2%) \| 0.02 (3.59) | n= 27 (43.5%) \|-0.81 (3.10) | 0.24 [-0.25 ; 0.73] |
| Week 63 | n= 35 (57.4%) \|-0.06 (3.84) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 36 (59.0%) \|-0.32 (4.12) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 38 (62.3%) \|-0.05 (3.97) | n= 26 (41.9%) \|-0.64 (2.90) | 0.16 [-0.34 ; 0.67] |
| Week 69 | n= 33 (54.1%) \|-0.56 (4.90) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (50.8%) \|-0.10 (4.61) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 29 (47.5%) \| 0.23 (4.38) | n= 25 (40.3%) \|-1.11 (3.02) | 0.34 [-0.20 ; 0.89] |
| Week 75 | n= 30 (49.2%) \| 0.05 (4.57) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (42.6%) \| 1.14 (4.45) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 26 (42.6%) \| 0.17 (5.81) | n= 23 (37.1%) \| 0.21 (2.87) | -0.01 [-0.57 ; 0.56] |
| Week 81 | n= 24 (39.3%) \| 0.48 (3.77) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 27 (44.3%) \| 0.84 (4.44) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 25 (41.0%) \| 0.35 (4.29) | n= 18 (29.0%) \|-0.61 (2.79) | 0.25 [-0.36 ; 0.87] |
| Week 87 | n= 19 (31.1%) \| 0.00 (4.23) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 22 (36.1%) \| 0.43 (4.05) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 21 (34.4%) \|-0.83 (3.40) | n= 15 (24.2%) \|-0.64 (4.47) | -0.05 [-0.72 ; 0.62] |
| Week 93 | n= 20 (32.8%) \|-0.37 (3.36) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 19 (31.1%) \|-0.40 (3.49) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 18 (29.5%) \|-0.50 (3.42) | n= 10 (16.1%) \|-0.60 (2.88) | 0.03 [-0.76 ; 0.82] |
| Week 99 | n= 14 (23.0%) \| 0.04 (3.53) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 13 (21.3%) \|-0.23 (3.22) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 13 (21.3%) \| 0.20 (3.24) | n= 9 (14.5%) \| 0.11 (2.76) | 0.03 [-0.84 ; 0.90] |
| Week 105 | n= 11 (18.0%) \|-0.03 (3.51) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 7 (11.5%) \| 0.71 (4.15) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 9 (14.8%) \|-1.79 (4.28) | n= 4 ( 6.5%) \|-0.75 (3.59) | -0.24 [-1.47 ; 1.00] |
| Week 111 | n= 6 ( 9.8%) \| 0.00 (4.29) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 7 (11.5%) \|-0.50 (4.35) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 6 ( 9.8%) \|-0.50 (5.09) | n= 5 ( 8.1%) \|-1.00 (1.58) | 0.12 [-1.14 ; 1.37] |
| Week 117 | n= 6 ( 9.8%) \| 0.67 (3.33) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 6 ( 9.8%) \|-2.33 (5.35) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 7 (11.5%) \|-0.96 (4.71) | n= 1 ( 1.6%) \|-1.63 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 3.3%) \|-2.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.6%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 3.3%) \|-1.50 (0.71) | n= 1 ( 1.6%) \|-8.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.6%) \|-2.75 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.6%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.6%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.6%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.6%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.6%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.6%) \|-0.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 6 ( 9.8%) \|-0.17 (3.54) | n= 14 (22.6%) \|-1.57 (5.27) | 0.28 [-0.71 ; 1.26] |
| Week 202 | n= 1 ( 1.6%) \|-2.00 ( / ) | n= 8 (12.9%) \|-0.50 (3.93) | [Not calculable] |
| **Yes** | | | |
| N subjects in population | N=10 | N=6 | |
| Week 3 | n= 10 (100.0%) \|-1.50 (1.96) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 8 (80.0%) \|-1.25 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 9 (90.0%) \|-0.04 (2.90) | n= 5 (83.3%) \| 0.20 (2.05) | -0.09 [-1.22 ; 1.05] |
| Week 9 | n= 9 (90.0%) \|-1.56 (3.32) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 8 (80.0%) \|-0.88 (3.72) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 7 (70.0%) \|-1.57 (4.35) | n= 5 (83.3%) \|-0.20 (1.48) | -0.36 [-1.58 ; 0.85] |
| Week 15 | n= 5 (50.0%) \|-4.40 (5.90) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 8 (80.0%) \|-1.60 (3.32) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 6 (60.0%) \|-1.17 (2.40) | n= 4 (66.7%) \|-1.25 (1.71) | 0.03 [-1.31 ; 1.38] |
| Week 21 | n= 8 (80.0%) \|-2.00 (3.55) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 7 (70.0%) \|-1.57 (2.88) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 6 (60.0%) \|-0.17 (2.32) | n= 2 (33.3%) \| 1.00 (0.00) | -0.48 [-2.24 ; 1.28] |
| Week 27 | n= 6 (60.0%) \| 0.00 (2.97) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 6 (60.0%) \| 1.00 (2.45) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 6 (60.0%) \|-0.50 (2.43) | n= 3 (50.0%) \| 0.33 (1.53) | -0.34 [-1.83 ; 1.16] |
| Week 33 | n= 7 (70.0%) \|-0.86 (4.14) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 6 (60.0%) \|-1.17 (4.07) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 7 (70.0%) \|-0.86 (2.79) | n= 5 (83.3%) \| 1.20 (1.30) | -0.82 [-2.08 ; 0.44] |
| Week 39 | n= 7 (70.0%) \|-0.86 (4.22) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 6 (60.0%) \|-1.17 (3.87) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 6 (60.0%) \|-0.50 (3.27) | n= 4 (66.7%) \|-0.50 (1.73) | 0.00 [-1.34 ; 1.34] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 45 | n= 7 (70.0%) \|-2.14 (5.11) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 6 (60.0%) \|-1.17 (4.36) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 6 (60.0%) \|-1.67 (4.68) | n= 4 (66.7%) \|-0.25 (1.71) | -0.33 [-1.69 ; 1.02] |
| Week 51 | n= 7 (70.0%) \|-1.14 (3.58) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 7 (70.0%) \| 0.00 (3.27) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (70.0%) \|-0.31 (2.56) | n= 3 (50.0%) \|-2.00 (1.00) | 0.67 [-0.81 ; 2.15] |
| Week 57 | n= 7 (70.0%) \|-1.43 (4.65) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 7 (70.0%) \| 0.00 (3.65) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 7 (70.0%) \|-0.86 (3.63) | n= 3 (50.0%) \| 1.33 (1.53) | -0.61 [-2.08 ; 0.86] |
| Week 63 | n= 7 (70.0%) \|-0.86 (4.06) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (70.0%) \|-2.00 (7.21) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 6 (60.0%) \| 0.00 (3.35) | n= 3 (50.0%) \| 0.00 (1.73) | 0.00 [-1.49 ; 1.49] |
| Week 69 | n= 5 (50.0%) \|-3.20 (6.18) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (70.0%) \|-0.43 (3.99) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 6 (60.0%) \| 0.17 (4.07) | n= 3 (50.0%) \|-1.00 (0.00) | 0.30 [-1.19 ; 1.80] |
| Week 75 | n= 5 (50.0%) \| 1.20 (1.92) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (60.0%) \|-0.83 (4.07) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 5 (50.0%) \|-0.48 (3.73) | n= 1 (16.7%) \| 0.00 ( / ) | [Not calculable] |
| Week 81 | n= 5 (50.0%) \|-1.20 (2.59) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 6 (60.0%) \|-0.50 (3.21) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 2 (20.0%) \| 0.50 (3.54) | n= 2 (33.3%) \| 2.00 (0.00) | -0.34 [-2.86 ; 2.17] |
| Week 87 | n= 5 (50.0%) \|-2.00 (4.53) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 3 (30.0%) \|-1.67 (3.51) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 3 (30.0%) \|-2.58 (2.24) | n= 2 (33.3%) \| 1.50 (0.71) | -1.58 [-4.23 ; 1.06] |
| Week 93 | n= 3 (30.0%) \|-1.00 (1.73) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 3 (30.0%) \|-2.00 (4.00) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 3 (30.0%) \|-2.00 (3.61) | [No Data] | [No Data for at least 1 arm] |
| Week 99 | n= 3 (30.0%) \|-2.33 (5.51) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 1 (10.0%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 2 (20.0%) \| 0.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 105 | n= 2 (20.0%) \| 0.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 1 (10.0%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 2 (20.0%) \|-0.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 (10.0%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 1 (10.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 1 (10.0%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 117 | n= 1 (10.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 1 (10.0%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 1 (10.0%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (20.0%) \|-1.50 (2.12) | n= 2 (33.3%) \|-1.50 (0.71) | 0.00 [-2.46 ; 2.46] |
| Week 202 | n= 1 (10.0%) \|-9.00 ( / ) | n= 3 (50.0%) \| 0.67 (1.53) | [Not calculable] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:02

TABLE 7.4.10: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Prior radiotherapy Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **No** | | | | |
| Nr subjects used | n=59 | n=61 | | |
| Week 7 | -1.09 (0.48) [-2.03 ;-0.15] | -1.58 (0.46) [-2.50 ;-0.66] | 0.49 (0.66) [-0.82 ; 1.81] | 0.14 [-0.23 ; 0.51] |
| Week 13 | -0.54 (0.46) [-1.45 ; 0.37] | -1.52 (0.47) [-2.45 ;-0.60] | 0.98 (0.66) [-0.32 ; 2.28] | 0.29 [-0.10 ; 0.68] |
| Week 19 | -0.30 (0.40) [-1.09 ; 0.50] | -1.06 (0.41) [-1.87 ;-0.25] | 0.77 (0.57) [-0.37 ; 1.90] | 0.27 [-0.13 ; 0.66] |
| Week 25 | -0.19 (0.42) [-1.03 ; 0.65] | -0.89 (0.44) [-1.76 ;-0.01] | 0.70 (0.61) [-0.51 ; 1.91] | 0.23 [-0.17 ; 0.63] |
| Week 31 | -0.27 (0.46) [-1.18 ; 0.64] | -0.79 (0.49) [-1.77 ; 0.18] | 0.52 (0.67) [-0.81 ; 1.85] | 0.17 [-0.26 ; 0.59] |
| Week 37 | 0.07 (0.49) [-0.90 ; 1.05] | -1.13 (0.51) [-2.13 ;-0.12] | 1.20 (0.71) [-0.20 ; 2.60] | 0.37 [-0.06 ; 0.81] |
| Week 43 | -0.20 (0.49) [-1.17 ; 0.77] | -0.95 (0.53) [-2.01 ; 0.11] | 0.75 (0.72) [-0.68 ; 2.19] | 0.23 [-0.21 ; 0.67] |
| Week 49 | -0.11 (0.48) [-1.07 ; 0.84] | -0.72 (0.57) [-1.84 ; 0.40] | 0.60 (0.74) [-0.87 ; 2.08] | 0.18 [-0.27 ; 0.64] |
| Week 55 | -0.35 (0.46) [-1.27 ; 0.57] | -0.78 (0.52) [-1.80 ; 0.25] | 0.43 (0.70) [-0.95 ; 1.81] | 0.14 [-0.32 ; 0.60] |
| Week 61 | -0.12 (0.42) [-0.95 ; 0.71] | -0.94 (0.50) [-1.93 ; 0.06] | 0.82 (0.65) [-0.47 ; 2.12] | 0.31 [-0.18 ; 0.80] |
| Week 67 | -0.14 (0.48) [-1.09 ; 0.81] | -0.79 (0.57) [-1.92 ; 0.34] | 0.65 (0.74) [-0.82 ; 2.13] | 0.22 [-0.28 ; 0.72] |
| Week 73 | -0.20 (0.57) [-1.33 ; 0.93] | -1.30 (0.63) [-2.56 ;-0.05] | 1.10 (0.85) [-0.59 ; 2.79] | 0.35 [-0.19 ; 0.89] |
| Week 79 | -0.44 (0.76) [-1.95 ; 1.08] | -0.57 (0.83) [-2.22 ; 1.07] | 0.14 (1.12) [-2.10 ; 2.37] | 0.03 [-0.53 ; 0.60] |
| Week 85 | -0.38 (0.56) [-1.49 ; 0.73] | -0.86 (0.64) [-2.13 ; 0.41] | 0.48 (0.85) [-1.21 ; 2.17] | 0.17 [-0.43 ; 0.78] |
| Week 91 | -0.35 (0.62) [-1.59 ; 0.89] | -0.56 (0.72) [-2.00 ; 0.88] | 0.21 (0.95) [-1.69 ; 2.11] | 0.07 [-0.59 ; 0.73] |
| Week 97 | -0.45 (0.66) [-1.80 ; 0.89] | -0.75 (0.85) [-2.48 ; 0.98] | 0.29 (1.08) [-1.90 ; 2.49] | 0.10 [-0.67 ; 0.88] |
| Overall post-baseline period estimate | -0.32 (0.24) [-0.80 ; 0.17] | -0.95 (0.27) [-1.48 ;-0.42] | 0.63 (0.36) [-0.08 ; 1.35] | 0.32 [-0.04 ; 0.68] |
| **Yes** | | | | |
| Nr subjects used | n=10 | n=6 | | |
| **MMRM subgroups interaction p-value** | | | | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:02

TABLE 7.4.11: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **>= 1%** | N=11 | N=9 |
| **< 1%** | N=58 | N=58 |
| **Not Reported** | N=2 | N=1 |
| **Subjects with Baseline Value** | | |
| **>= 1%** | 11 (100.0%) | 9 (100.0%) |
| **< 1%** | 56 (96.6%) | 57 (98.3%) |
| **Not Reported** | 2 (100.0%) | 1 (100.0%) |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **>= 1%** | 11 (100.0%) | 9 (100.0%) |
| **< 1%** | 58 (100.0%) | 56 (96.6%) |
| **Not Reported** | 2 (100.0%) | 1 (100.0%) |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **>= 1%** | 11 (100.0%) | 9 (100.0%) |
| **< 1%** | 56 (96.6%) | 55 (94.8%) |
| **Not Reported** | 2 (100.0%) | 1 (100.0%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:02

TABLE 7.4.11: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **>= 1%** | | | |
| N subjects in population | N=11 | N=9 | |
| Baseline | n= 11 (100.0%) \| 31.13 (4.27) | n= 9 (100.0%) \| 29.64 (4.50) | 0.33 [-0.59 ; 1.24] |
| Week 3 | n= 11 (100.0%) \| 30.76 (5.38) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 9 (81.8%) \| 31.00 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 10 (90.9%) \| 31.45 (2.63) | n= 9 (100.0%) \| 28.38 (6.47) | 0.61 [-0.34 ; 1.56] |
| Week 9 | n= 10 (90.9%) \| 29.90 (3.84) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (81.8%) \| 30.22 (4.18) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 10 (90.9%) \| 30.00 (3.80) | n= 7 (77.8%) \| 29.14 (4.71) | 0.19 [-0.81 ; 1.19] |
| Week 15 | n= 8 (72.7%) \| 30.00 (4.75) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (81.8%) \| 31.00 (2.69) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 8 (72.7%) \| 31.38 (2.83) | n= 6 (66.7%) \| 27.88 (5.12) | 0.83 [-0.32 ; 1.98] |
| Week 21 | n= 8 (72.7%) \| 29.25 (4.17) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \| 30.00 (4.94) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 8 (72.7%) \| 30.88 (3.87) | n= 5 (55.6%) \| 29.00 (1.87) | 0.53 [-0.66 ; 1.72] |
| Week 27 | n= 9 (81.8%) \| 31.11 (4.37) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 8 (72.7%) \| 30.75 (4.65) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 8 (72.7%) \| 31.25 (4.03) | n= 6 (66.7%) \| 29.00 (4.05) | 0.52 [-0.60 ; 1.64] |
| Week 33 | n= 9 (81.8%) \| 29.89 (4.94) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 9 (81.8%) \| 30.11 (4.86) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \| 31.00 (4.31) | n= 6 (66.7%) \| 29.60 (3.99) | 0.31 [-0.80 ; 1.42] |
| Week 39 | n= 9 (81.8%) \| 30.44 (4.42) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 10 (90.9%) \| 29.50 (4.38) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 8 (72.7%) \| 31.88 (4.02) | n= 7 (77.8%) \| 28.14 (5.15) | 0.77 [-0.33 ; 1.86] |
| Week 45 | n= 8 (72.7%) \| 29.38 (5.53) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 7 (63.6%) \| 30.57 (5.06) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 9 (81.8%) \| 29.22 (3.99) | n= 7 (77.8%) \| 27.66 (6.75) | 0.28 [-0.75 ; 1.30] |
| Week 51 | n= 9 (81.8%) \| 28.82 (4.16) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 8 (72.7%) \| 30.25 (5.01) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (63.6%) \| 30.57 (5.13) | n= 7 (77.8%) \| 29.71 (4.03) | 0.17 [-0.92 ; 1.27] |
| Week 57 | n= 6 (54.5%) \| 29.50 (6.41) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 8 (72.7%) \| 29.50 (4.04) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (72.7%) \| 30.55 (5.63) | n= 6 (66.7%) \| 27.83 (3.97) | 0.51 [-0.61 ; 1.63] |
| Week 63 | n= 7 (63.6%) \| 29.57 (5.91) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (63.6%) \| 27.71 (8.77) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \| 31.00 (4.04) | n= 6 (66.7%) \| 27.50 (4.76) | 0.75 [-0.39 ; 1.90] |
| Week 69 | n= 8 (72.7%) \| 26.75 (7.05) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (63.6%) \| 28.14 (5.21) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 8 (72.7%) \| 30.00 (5.07) | n= 6 (66.7%) \| 26.52 (4.65) | 0.66 [-0.47 ; 1.80] |
| Week 75 | n= 7 (63.6%) \| 30.29 (3.59) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (54.5%) \| 28.67 (4.89) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 7 (63.6%) \| 29.43 (4.58) | n= 4 (44.4%) \| 28.50 (4.20) | 0.19 [-1.11 ; 1.49] |
| Week 81 | n= 6 (54.5%) \| 28.83 (5.27) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 9 (81.8%) \| 30.11 (4.86) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (63.6%) \| 30.14 (4.06) | n= 3 (33.3%) \| 28.33 (3.51) | 0.42 [-1.04 ; 1.87] |
| Week 87 | n= 6 (54.5%) \| 28.67 (4.55) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 8 (72.7%) \| 29.63 (5.26) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 8 (72.7%) \| 30.13 (4.97) | n= 3 (33.3%) \| 27.67 (4.51) | 0.46 [-0.96 ; 1.88] |
| Week 93 | n= 7 (63.6%) \| 30.00 (4.43) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 8 (72.7%) \| 30.25 (5.60) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (63.6%) \| 30.20 (5.18) | n= 1 (11.1%) \| 32.00 ( / ) | [Not calculable] |
| Week 99 | n= 6 (54.5%) \| 30.83 (6.82) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 5 (45.5%) \| 33.20 (2.28) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 5 (45.5%) \| 32.60 (3.78) | n= 1 (11.1%) \| 33.00 ( / ) | [Not calculable] |
| Week 105 | n= 5 (45.5%) \| 31.00 (4.12) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \| 35.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (27.3%) \| 28.96 (3.66) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 ( 9.1%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (27.3%) \| 32.50 (3.12) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (27.3%) \| 32.67 (3.21) | n= 2 (22.2%) \| 31.00 (1.41) | 0.44 [-1.72 ; 2.60] |
| Week 117 | n= 3 (27.3%) \| 33.33 (3.06) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 (27.3%) \| 29.00 (5.00) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (18.2%) \| 31.13 (2.65) | n= 1 (11.1%) \| 30.38 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 9.1%) \| 27.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 9.1%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 9.1%) \| 31.00 ( / ) | n= 1 (11.1%) \| 24.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 9.1%) \| 29.25 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 9.1%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 9.1%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 9.1%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 9.1%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 9.1%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 9.1%) \| 31.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (27.3%) \| 29.00 (6.08) | n= 3 (33.3%) \| 28.67 (5.77) | 0.04 [-1.77 ; 1.86] |
| Week 202 | [No Data] | n= 1 (11.1%) \| 34.00 ( / ) | [No Data for at least 1 arm] |
| **< 1%** | | | |
| N subjects in population | N=58 | N=58 | |
| Baseline | n= 56 (96.6%) \| 31.76 (4.52) | n= 57 (98.3%) \| 31.75 (4.20) | 0.00 [-0.37 ; 0.37] |
| Week 3 | n= 54 (93.1%) \| 31.74 (3.70) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 52 (89.7%) \| 31.22 (4.93) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 52 (89.7%) \| 30.58 (4.55) | n= 54 (93.1%) \| 30.61 (3.48) | -0.01 [-0.39 ; 0.37] |
| Week 9 | n= 51 (87.9%) \| 31.21 (4.34) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 51 (87.9%) \| 30.95 (4.00) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 49 (84.5%) \| 31.65 (3.93) | n= 47 (81.0%) \| 31.00 (3.53) | 0.17 [-0.23 ; 0.58] |
| Week 15 | n= 45 (77.6%) \| 31.48 (3.59) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 53 (91.4%) \| 31.47 (4.47) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 48 (82.8%) \| 32.15 (3.17) | n= 47 (81.0%) \| 31.52 (2.97) | 0.20 [-0.20 ; 0.61] |
| Week 21 | n= 50 (86.2%) \| 32.16 (3.99) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 45 (77.6%) \| 31.16 (3.74) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 49 (84.5%) \| 32.07 (3.67) | n= 43 (74.1%) \| 31.84 (3.12) | 0.07 [-0.35 ; 0.48] |
| Week 27 | n= 46 (79.3%) \| 32.87 (3.80) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 43 (74.1%) \| 32.31 (3.44) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (77.6%) \| 32.20 (4.29) | n= 36 (62.1%) \| 31.81 (3.64) | 0.10 [-0.34 ; 0.54] |
| Week 33 | n= 46 (79.3%) \| 32.14 (4.29) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 44 (75.9%) \| 31.77 (5.11) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 39 (67.2%) \| 32.26 (4.94) | n= 40 (69.0%) \| 31.70 (2.93) | 0.14 [-0.31 ; 0.58] |
| Week 39 | n= 42 (72.4%) \| 32.74 (3.68) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 41 | n= 41 (70.7%) \| 32.73 (3.87) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 43 (74.1%) \| 31.98 (4.11) | n= 34 (58.6%) \| 31.70 (3.67) | 0.07 [-0.38 ; 0.52] |
| Week 45 | n= 39 (67.2%) \| 31.72 (4.11) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 43 (74.1%) \| 32.16 (4.01) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 42 (72.4%) \| 32.60 (4.29) | n= 28 (48.3%) \| 32.22 (2.38) | 0.10 [-0.38 ; 0.58] |
| Week 51 | n= 41 (70.7%) \| 32.23 (4.14) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 43 (74.1%) \| 32.38 (3.92) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 38 (65.5%) \| 32.09 (4.41) | n= 30 (51.7%) \| 31.28 (3.34) | 0.20 [-0.28 ; 0.69] |
| Week 57 | n= 41 (70.7%) \| 31.91 (4.04) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (63.8%) \| 32.06 (4.54) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (67.2%) \| 32.60 (3.82) | n= 25 (43.1%) \| 31.60 (3.14) | 0.28 [-0.23 ; 0.78] |
| Week 63 | n= 34 (58.6%) \| 31.89 (4.64) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 35 (60.3%) \| 31.75 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (62.1%) \| 32.25 (4.29) | n= 24 (41.4%) \| 31.75 (2.91) | 0.13 [-0.39 ; 0.65] |
| Week 69 | n= 30 (51.7%) \| 32.34 (3.68) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (53.4%) \| 32.80 (3.97) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 27 (46.6%) \| 32.89 (3.53) | n= 22 (37.9%) \| 31.14 (2.73) | 0.54 [-0.04 ; 1.12] |
| Week 75 | n= 28 (48.3%) \| 32.75 (3.70) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (44.8%) \| 32.92 (3.22) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (41.4%) \| 31.98 (6.24) | n= 21 (36.2%) \| 31.71 (2.74) | 0.05 [-0.54 ; 0.64] |
| Week 81 | n= 23 (39.7%) \| 32.70 (3.67) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 24 (41.4%) \| 33.00 (3.55) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (34.5%) \| 33.05 (3.58) | n= 18 (31.0%) \| 32.17 (2.92) | 0.26 [-0.38 ; 0.91] |
| Week 87 | n= 18 (31.0%) \| 31.83 (4.60) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 17 (29.3%) \| 32.46 (3.29) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 16 (27.6%) \| 31.14 (4.79) | n= 15 (25.9%) \| 32.93 (2.79) | -0.44 [-1.17 ; 0.28] |
| Week 93 | n= 16 (27.6%) \| 32.00 (3.83) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 14 (24.1%) \| 31.70 (3.98) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 14 (24.1%) \| 31.29 (4.21) | n= 10 (17.2%) \| 32.30 (3.74) | -0.24 [-1.08 ; 0.59] |
| Week 99 | n= 11 (19.0%) \| 30.73 (4.08) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 9 (15.5%) \| 30.44 (4.07) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 10 (17.2%) \| 31.10 (3.31) | n= 9 (15.5%) \| 32.22 (2.73) | -0.35 [-1.28 ; 0.58] |
| Week 105 | n= 8 (13.8%) \| 30.75 (4.06) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.3%) \| 30.67 (2.94) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (13.8%) \| 29.13 (4.09) | n= 5 ( 8.6%) \| 31.40 (5.22) | -0.47 [-1.65 ; 0.72] |
| Week 111 | n= 6 (10.3%) \| 30.17 (4.26) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 ( 8.6%) \| 30.80 (4.21) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 6.9%) \| 29.75 (4.79) | n= 3 ( 5.2%) \| 33.67 (2.08) | -0.84 [-2.59 ; 0.91] |
| Week 117 | n= 4 ( 6.9%) \| 32.25 (3.30) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 6.9%) \| 29.50 (4.80) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (10.3%) \| 31.17 (5.19) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 1.7%) \| 35.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.7%) \| 33.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 ( 8.6%) \| 33.00 (2.83) | n= 13 (22.4%) \| 30.77 (4.40) | 0.52 [-0.56 ; 1.60] |
| Week 202 | n= 1 ( 1.7%) \| 30.00 ( / ) | n= 10 (17.2%) \| 32.20 (2.39) | [Not calculable] |
| **Not Reported** | | | |
| N subjects in population | N=2 | N=1 | |
| Baseline | n= 2 (100.0%) \| 31.50 (3.54) | n= 1 (100.0%) \| 32.00 ( / ) | . [ . ; .] |
| Week 3 | n= 2 (100.0%) \| 30.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (100.0%) \| 29.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 2 (100.0%) \| 30.50 (2.12) | n= 1 (100.0%) \| 30.00 ( / ) | [Not calculable] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 11 | n= 1 (50.0%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (50.0%) \| 32.00 ( / ) | n= 1 (100.0%) \| 30.00 ( / ) | [Not calculable] |
| Week 15 | n= 1 (50.0%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 1 (50.0%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (50.0%) \| 32.00 ( / ) | n= 1 (100.0%) \| 33.00 ( / ) | [Not calculable] |
| Week 21 | n= 1 (50.0%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (50.0%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (50.0%) \| 34.00 ( / ) | n= 1 (100.0%) \| 30.00 ( / ) | [Not calculable] |
| Week 27 | n= 1 (50.0%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 1 (50.0%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (50.0%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (50.0%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 1 (50.0%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (50.0%) \| 34.00 ( / ) | n= 1 (100.0%) \| 27.00 ( / ) | [Not calculable] |
| Week 39 | n= 1 (50.0%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (50.0%) \| 33.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (50.0%) \| 32.63 ( / ) | n= 1 (100.0%) \| 30.00 ( / ) | [Not calculable] |
| Week 45 | n= 1 (50.0%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (50.0%) \| 34.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (50.0%) \| 34.00 ( / ) | n= 1 (100.0%) \| 31.00 ( / ) | [Not calculable] |
| Week 51 | n= 1 (50.0%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (50.0%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (50.0%) \| 29.00 ( / ) | n= 1 (100.0%) \| 30.00 ( / ) | [Not calculable] |
| Week 57 | n= 1 (50.0%) \| 33.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (50.0%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (50.0%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (50.0%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (50.0%) \| 30.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 202 | n= 1 (50.0%) \| 20.00 ( / ) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:02

TABLE 7.4.11: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **>= 1%** | | | |
| N subjects in population | N=11 | N=9 | |
| Week 3 | n= 11 (100.0%) \|-0.36 (2.46) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 9 (81.8%) \|-1.15 (1.71) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 10 (90.9%) \|-0.19 (3.83) | n= 9 (100.0%) \|-1.26 (2.65) | 0.31 [-0.62 ; 1.24] |
| Week 9 | n= 10 (90.9%) \|-1.30 (5.44) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 9 (81.8%) \|-2.04 (2.69) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 10 (90.9%) \|-1.14 (4.79) | n= 7 (77.8%) \|-1.68 (3.12) | 0.12 [-0.88 ; 1.12] |
| Week 15 | n= 8 (72.7%) \|-1.88 (5.77) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 9 (81.8%) \|-0.22 (4.27) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 8 (72.7%) \|-1.67 (2.91) | n= 6 (66.7%) \|-2.08 (3.75) | 0.12 [-0.99 ; 1.22] |
| Week 21 | n= 8 (72.7%) \|-1.50 (3.12) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 10 (90.9%) \|-1.20 (4.08) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 8 (72.7%) \|-1.25 (1.98) | n= 5 (55.6%) \|-1.93 (3.21) | 0.25 [-0.92 ; 1.42] |
| Week 27 | n= 9 (81.8%) \|-1.22 (2.49) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 8 (72.7%) \|-1.63 (2.62) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 8 (72.7%) \|-1.25 (2.19) | n= 6 (66.7%) \|-1.29 (2.38) | 0.02 [-1.08 ; 1.12] |
| Week 33 | n= 9 (81.8%) \|-2.44 (3.47) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 9 (81.8%) \|-2.22 (3.31) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 8 (72.7%) \|-1.50 (3.30) | n= 6 (66.7%) \|-1.02 (0.90) | -0.17 [-1.28 ; 0.93] |
| Week 39 | n= 9 (81.8%) \|-1.82 (3.27) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 10 (90.9%) \|-2.64 (3.49) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 8 (72.7%) \|-1.17 (3.61) | n= 7 (77.8%) \|-2.68 (2.01) | 0.48 [-0.59 ; 1.54] |
| Week 45 | n= 8 (72.7%) \|-3.13 (4.32) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 7 (63.6%) \|-1.71 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 9 (81.8%) \|-3.04 (3.08) | n= 7 (77.8%) \|-3.16 (4.70) | 0.03 [-0.99 ; 1.05] |
| Week 51 | n= 9 (81.8%) \|-3.44 (3.09) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 8 (72.7%) \|-2.13 (2.47) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 7 (63.6%) \|-1.77 (3.73) | n= 7 (77.8%) \|-1.11 (1.31) | -0.22 [-1.32 ; 0.87] |
| Week 57 | n= 6 (54.5%) \|-2.40 (4.40) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 8 (72.7%) \|-2.80 (3.40) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 8 (72.7%) \|-1.75 (3.58) | n= 6 (66.7%) \|-2.46 (3.74) | 0.18 [-0.92 ; 1.29] |
| Week 63 | n= 7 (63.6%) \|-2.34 (4.20) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 7 (63.6%) \|-4.20 (6.38) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 8 (72.7%) \|-1.92 (3.56) | n= 6 (66.7%) \|-2.79 (2.04) | 0.27 [-0.84 ; 1.38] |
| Week 69 | n= 8 (72.7%) \|-5.05 (5.62) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 7 (63.6%) \|-3.86 (3.18) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 8 (72.7%) \|-2.17 (2.77) | n= 6 (66.7%) \|-3.77 (1.88) | 0.61 [-0.52 ; 1.74] |
| Week 75 | n= 7 (63.6%) \|-2.77 (3.08) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 6 (54.5%) \|-3.00 (3.16) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 7 (63.6%) \|-2.34 (3.03) | n= 4 (44.4%) \|-2.78 (4.22) | 0.12 [-1.18 ; 1.41] |
| Week 81 | n= 6 (54.5%) \|-2.56 (3.39) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 9 (81.8%) \|-2.04 (3.87) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 7 (63.6%) \|-2.91 (3.45) | n= 3 (33.3%) \|-4.00 (1.00) | 0.32 [-1.12 ; 1.77] |
| Week 87 | n= 6 (54.5%) \|-3.33 (2.94) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 8 (72.7%) \|-2.55 (3.37) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 8 (72.7%) \|-2.05 (3.27) | n= 3 (33.3%) \|-2.54 (1.73) | 0.15 [-1.25 ; 1.55] |
| Week 93 | n= 7 (63.6%) \|-2.20 (3.04) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 8 (72.7%) \|-1.92 (3.93) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 7 (63.6%) \|-1.71 (2.81) | n= 1 (11.1%) \|-3.00 ( / ) | [Not calculable] |
| Week 99 | n= 6 (54.5%) \|-1.23 (4.01) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 5 (45.5%) \|-0.20 (1.30) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 5 (45.5%) \|-0.68 (3.24) | n= 1 (11.1%) \|-2.00 ( / ) | [Not calculable] |
| Week 105 | n= 5 (45.5%) \|-1.48 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (18.2%) \| 0.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 3 (27.3%) \|-4.04 (1.80) | [No Data] | [No Data for at least 1 arm] |
| Week 111 | n= 1 ( 9.1%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 3 (27.3%) \|-0.50 (0.50) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (27.3%) \|-0.33 (2.08) | n= 2 (22.2%) \|-2.50 (0.71) | 0.90 [-1.40 ; 3.20] |
| Week 117 | n= 3 (27.3%) \| 0.33 (1.53) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 3 (27.3%) \|-4.00 (3.46) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 2 (18.2%) \|-2.88 (0.18) | n= 1 (11.1%) \|-1.63 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 9.1%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 9.1%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 9.1%) \|-1.00 ( / ) | n= 1 (11.1%) \|-8.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 9.1%) \|-2.75 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 9.1%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 9.1%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 9.1%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 9.1%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 9.1%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 9.1%) \|-0.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 3 (27.3%) \|-0.67 (2.08) | n= 3 (33.3%) \|-2.00 (5.57) | 0.25 [-1.57 ; 2.08] |
| Week 202 | [No Data] | n= 1 (11.1%) \| 1.00 ( / ) | [No Data for at least 1 arm] |
| **< 1%** | | | |
| N subjects in population | N=58 | N=58 | |
| Week 3 | n= 53 (91.4%) \|-0.09 (2.26) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 50 (86.2%) \|-0.52 (3.26) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 50 (86.2%) \|-0.95 (3.73) | n= 53 (91.4%) \|-1.08 (3.53) | 0.03 [-0.35 ; 0.42] |
| Week 9 | n= 50 (86.2%) \|-1.06 (3.58) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 50 (86.2%) \|-0.88 (3.59) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 48 (82.8%) \|-0.45 (3.35) | n= 47 (81.0%) \|-1.34 (3.27) | 0.27 [-0.14 ; 0.67] |
| Week 15 | n= 45 (77.6%) \|-0.51 (3.70) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 52 (89.7%) \|-0.57 (3.53) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 47 (81.0%) \|-0.29 (3.26) | n= 46 (79.3%) \|-0.84 (3.62) | 0.16 [-0.25 ; 0.57] |
| Week 21 | n= 50 (86.2%) \|-0.01 (3.69) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 45 (77.6%) \|-0.87 (2.84) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 48 (82.8%) \|-0.03 (3.79) | n= 42 (72.4%) \|-0.71 (3.65) | 0.18 [-0.23 ; 0.60] |
| Week 27 | n= 45 (77.6%) \| 0.41 (3.78) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 43 (74.1%) \| 0.32 (3.80) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 45 (77.6%) \|-0.12 (3.91) | n= 36 (62.1%) \|-0.86 (2.50) | 0.22 [-0.22 ; 0.66] |
| Week 33 | n= 46 (79.3%) \|-0.12 (3.35) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 43 (74.1%) \|-0.25 (3.66) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 39 (67.2%) \| 0.28 (3.60) | n= 39 (67.2%) \|-0.59 (3.33) | 0.25 [-0.20 ; 0.70] |
| Week 39 | n= 41 (70.7%) \| 0.31 (3.27) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 41 (70.7%) \|-0.05 (3.43) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 42 (72.4%) \|-0.30 (4.10) | n= 33 (56.9%) \|-0.46 (3.01) | 0.04 [-0.41 ; 0.50] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 45 | n= 39 (67.2%) \|-0.44 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 43 (74.1%) \|-0.56 (3.29) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 42 (72.4%) \| 0.26 (3.64) | n= 27 (46.6%) \|-0.37 (2.66) | 0.19 [-0.30 ; 0.67] |
| Week 51 | n= 41 (70.7%) \| 0.15 (3.34) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 43 (74.1%) \| 0.25 (3.28) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 38 (65.5%) \|-0.13 (3.26) | n= 29 (50.0%) \|-0.78 (3.20) | 0.20 [-0.29 ; 0.69] |
| Week 57 | n= 41 (70.7%) \|-0.10 (3.63) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 37 (63.8%) \| 0.10 (3.99) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 39 (67.2%) \| 0.30 (3.53) | n= 24 (41.4%) \|-0.13 (2.72) | 0.13 [-0.38 ; 0.64] |
| Week 63 | n= 34 (58.6%) \| 0.30 (3.71) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 35 (60.3%) \| 0.22 (4.03) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 36 (62.1%) \| 0.38 (3.84) | n= 23 (39.7%) \| 0.00 (2.70) | 0.11 [-0.42 ; 0.64] |
| Week 69 | n= 30 (51.7%) \| 0.19 (4.38) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 31 (53.4%) \| 0.67 (4.30) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 27 (46.6%) \| 0.93 (4.41) | n= 22 (37.9%) \|-0.36 (2.65) | 0.34 [-0.23 ; 0.91] |
| Week 75 | n= 28 (48.3%) \| 0.96 (4.26) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 26 (44.8%) \| 1.64 (4.21) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 24 (41.4%) \| 0.77 (5.88) | n= 20 (34.5%) \| 0.80 (2.12) | -0.01 [-0.61 ; 0.59] |
| Week 81 | n= 23 (39.7%) \| 0.91 (3.37) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 24 (41.4%) \| 1.58 (4.00) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 20 (34.5%) \| 1.50 (3.85) | n= 17 (29.3%) \| 0.29 (2.44) | 0.36 [-0.30 ; 1.02] |
| Week 87 | n= 18 (31.0%) \| 0.56 (4.26) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 17 (29.3%) \| 1.46 (3.66) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 16 (27.6%) \|-0.55 (3.29) | n= 14 (24.1%) \| 0.07 (4.51) | -0.15 [-0.88 ; 0.58] |
| Week 93 | n= 16 (27.6%) \| 0.31 (3.00) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 14 (24.1%) \| 0.13 (3.14) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 14 (24.1%) \|-0.21 (3.64) | n= 9 (15.5%) \|-0.33 (2.92) | 0.03 [-0.82 ; 0.89] |
| Week 99 | n= 11 (19.0%) \| 0.09 (3.86) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 9 (15.5%) \|-0.44 (3.88) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 10 (17.2%) \| 0.60 (3.27) | n= 8 (13.8%) \| 0.38 (2.83) | 0.07 [-0.89 ; 1.03] |
| Week 105 | n= 8 (13.8%) \| 1.00 (3.16) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (10.3%) \| 0.33 (4.41) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 8 (13.8%) \|-0.63 (4.31) | n= 4 ( 6.9%) \|-0.75 (3.59) | 0.03 [-1.23 ; 1.29] |
| Week 111 | n= 6 (10.3%) \| 0.00 (4.29) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 5 ( 8.6%) \|-0.40 (5.32) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 6.9%) \|-0.75 (6.34) | n= 3 ( 5.2%) \| 0.00 (1.00) | -0.13 [-1.78 ; 1.53] |
| Week 117 | n= 4 ( 6.9%) \| 0.75 (4.11) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 4 ( 6.9%) \|-1.00 (5.89) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 6 (10.3%) \|-0.67 (5.09) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 1.7%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 1 ( 1.7%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 ( 8.6%) \|-0.40 (3.91) | n= 13 (22.4%) \|-1.46 (4.99) | 0.21 [-0.85 ; 1.28] |
| Week 202 | n= 1 ( 1.7%) \|-2.00 ( / ) | n= 10 (17.2%) \|-0.30 (3.56) | [Not calculable] |
| **Not Reported** | | | |
| N subjects in population | N=2 | N=1 | |
| Week 3 | n= 2 (100.0%) \|-1.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (100.0%) \|-2.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 2 (100.0%) \|-1.00 (1.41) | n= 1 (100.0%) \|-2.00 ( / ) | [Not calculable] |
| Week 11 | n= 1 (50.0%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (50.0%) \|-2.00 ( / ) | n= 1 (100.0%) \|-2.00 ( / ) | [Not calculable] |
| Week 15 | n= 1 (50.0%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 17 | n= 1 (50.0%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (50.0%) \|-2.00 ( / ) | n= 1 (100.0%) \| 1.00 ( / ) | [Not calculable] |
| Week 21 | n= 1 (50.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (50.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (50.0%) \| 0.00 ( / ) | n= 1 (100.0%) \|-2.00 ( / ) | [Not calculable] |
| Week 27 | n= 1 (50.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 1 (50.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (50.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (50.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 1 (50.0%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (50.0%) \| 0.00 ( / ) | n= 1 (100.0%) \|-5.00 ( / ) | [Not calculable] |
| Week 39 | n= 1 (50.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (50.0%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (50.0%) \|-1.38 ( / ) | n= 1 (100.0%) \|-2.00 ( / ) | [Not calculable] |
| Week 45 | n= 1 (50.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (50.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (50.0%) \| 0.00 ( / ) | n= 1 (100.0%) \|-1.00 ( / ) | [Not calculable] |
| Week 51 | n= 1 (50.0%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (50.0%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (50.0%) \|-5.00 ( / ) | n= 1 (100.0%) \|-2.00 ( / ) | [Not calculable] |
| Week 57 | n= 1 (50.0%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (50.0%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (50.0%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (50.0%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (50.0%) \|-4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 202 | n= 1 (50.0%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:02

TABLE 7.4.11: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - PD-L1+ Status Based on a 1% Cut Off Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **>= 1%** | | | | |
| Nr subjects used | n=11 | n=9 | | |
| **< 1%** | | | | |
| Nr subjects used | n=56 | n=57 | | |
| Week 7 | -1.22 (0.48) [-2.17 ;-0.27] | -1.25 (0.47) [-2.18 ;-0.31] | 0.03 (0.67) [-1.31 ; 1.36] | 0.01 [-0.38 ; 0.39] |
| Week 13 | -0.53 (0.48) [-1.48 ; 0.41] | -1.18 (0.48) [-2.14 ;-0.22] | 0.65 (0.68) [-0.70 ; 2.00] | 0.20 [-0.21 ; 0.60] |
| Week 19 | -0.21 (0.39) [-0.99 ; 0.57] | -0.76 (0.40) [-1.55 ; 0.04] | 0.54 (0.56) [-0.57 ; 1.66] | 0.20 [-0.21 ; 0.61] |
| Week 25 | -0.07 (0.43) [-0.91 ; 0.78] | -0.49 (0.45) [-1.39 ; 0.40] | 0.43 (0.62) [-0.80 ; 1.66] | 0.14 [-0.27 ; 0.56] |
| Week 31 | -0.18 (0.46) [-1.10 ; 0.74] | -0.39 (0.50) [-1.39 ; 0.61] | 0.21 (0.68) [-1.14 ; 1.57] | 0.07 [-0.37 ; 0.51] |
| Week 37 | 0.11 (0.49) [-0.87 ; 1.09] | -0.54 (0.51) [-1.56 ; 0.48] | 0.65 (0.71) [-0.76 ; 2.07] | 0.21 [-0.24 ; 0.65] |
| Week 43 | -0.11 (0.47) [-1.05 ; 0.83] | -0.37 (0.53) [-1.42 ; 0.68] | 0.26 (0.71) [-1.14 ; 1.67] | 0.09 [-0.37 ; 0.54] |
| Week 49 | 0.24 (0.41) [-0.58 ; 1.06] | 0.02 (0.49) [-0.96 ; 1.00] | 0.22 (0.64) [-1.06 ; 1.49] | 0.08 [-0.40 ; 0.57] |
| Week 55 | -0.04 (0.43) [-0.89 ; 0.82] | -0.64 (0.50) [-1.64 ; 0.35] | 0.60 (0.66) [-0.71 ; 1.92] | 0.22 [-0.26 ; 0.71] |
| Week 61 | 0.15 (0.39) [-0.62 ; 0.91] | -0.12 (0.48) [-1.07 ; 0.83] | 0.26 (0.62) [-0.96 ; 1.49] | 0.11 [-0.40 ; 0.62] |
| Week 67 | 0.19 (0.45) [-0.69 ; 1.08] | -0.06 (0.55) [-1.16 ; 1.03] | 0.26 (0.71) [-1.15 ; 1.67] | 0.10 [-0.43 ; 0.62] |
| Week 73 | 0.25 (0.56) [-0.86 ; 1.37] | -0.47 (0.64) [-1.74 ; 0.80] | 0.72 (0.85) [-0.97 ; 2.41] | 0.24 [-0.32 ; 0.81] |
| Week 79 | -0.05 (0.81) [-1.67 ; 1.57] | 0.16 (0.90) [-1.64 ; 1.95] | -0.21 (1.21) [-2.63 ; 2.21] | -0.05 [-0.64 ; 0.54] |
| Week 85 | 0.47 (0.55) [-0.63 ; 1.57] | 0.05 (0.60) [-1.15 ; 1.24] | 0.42 (0.81) [-1.20 ; 2.05] | 0.17 [-0.48 ; 0.82] |
| Week 91 | -0.19 (0.77) [-1.75 ; 1.38] | 0.10 (0.83) [-1.59 ; 1.79] | -0.29 (1.14) [-2.59 ; 2.02] | -0.09 [-0.81 ; 0.63] |
| Overall post-baseline period estimate | -0.08 (0.24) [-0.55 ; 0.39] | -0.40 (0.27) [-0.92 ; 0.13] | 0.32 (0.36) [-0.39 ; 1.02] | 0.17 [-0.20 ; 0.54] |
| **Not Reported** | | | | |
| Nr subjects used | n=2 | n=1 | | |
| **MMRM subgroups interaction p-value** | | | | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:02

TABLE 7.4.12: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis Subgroups Analysis



| | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| **N subjects** | | |
| **Stage IV** | N=18 | N=20 |
| **Non-Stage IV** | N=50 | N=48 |
| **Not Reported** | N=3 | [No Data] |
| **Subjects with Baseline Value** | | |
| **Stage IV** | 18 (100.0%) | 20 (100.0%) |
| **Non-Stage IV** | 48 (96.0%) | 47 (97.9%) |
| **Not Reported** | 3 (100.0%) | [No Data] |
| **Subjects with at least 1 Post-Baseline Value** | | |
| **Stage IV** | 18 (100.0%) | 20 (100.0%) |
| **Non-Stage IV** | 50 (100.0%) | 46 (95.8%) |
| **Not Reported** | 3 (100.0%) | [No Data] |
| **Subjects with Baseline Value and at least 1 Post-Baseline Value** | | |
| **Stage IV** | 18 (100.0%) | 20 (100.0%) |
| **Non-Stage IV** | 48 (96.0%) | 45 (93.8%) |
| **Not Reported** | 3 (100.0%) | [No Data] |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:06

TABLE 7.4.12: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Stage IV** | | | |
| N subjects in population | N=18 | N=20 | |
| Baseline | n= 18 (100.0%) \| 31.36 (4.60) | n= 20 (100.0%) \| 31.70 (4.44) | -0.07 [-0.72 ; 0.57] |
| Week 3 | n= 16 (88.9%) \| 31.18 (2.80) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 17 (94.4%) \| 31.29 (3.90) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 16 (88.9%) \| 31.08 (3.25) | n= 20 (100.0%) \| 30.05 (4.37) | 0.26 [-0.41 ; 0.93] |
| Week 9 | n= 14 (77.8%) \| 32.79 (2.64) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (83.3%) \| 31.73 (3.79) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 17 (94.4%) \| 30.65 (4.55) | n= 15 (75.0%) \| 32.07 (3.37) | -0.34 [-1.05 ; 0.37] |
| Week 15 | n= 15 (83.3%) \| 31.50 (3.72) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 15 (83.3%) \| 32.10 (3.25) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 15 (83.3%) \| 31.98 (3.16) | n= 16 (80.0%) \| 31.88 (2.47) | 0.03 [-0.68 ; 0.75] |
| Week 21 | n= 16 (88.9%) \| 32.31 (3.63) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 12 (66.7%) \| 31.25 (3.91) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 15 (83.3%) \| 32.22 (3.57) | n= 15 (75.0%) \| 31.47 (2.50) | 0.24 [-0.49 ; 0.97] |
| Week 27 | n= 16 (88.9%) \| 32.63 (3.91) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 14 (77.8%) \| 32.44 (2.99) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 16 (88.9%) \| 32.06 (4.43) | n= 11 (55.0%) \| 32.55 (3.11) | -0.12 [-0.90 ; 0.66] |
| Week 33 | n= 15 (83.3%) \| 32.29 (4.79) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (72.2%) \| 31.14 (5.82) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 12 (66.7%) \| 32.19 (5.97) | n= 14 (70.0%) \| 31.29 (3.36) | 0.18 [-0.60 ; 0.97] |
| Week 39 | n= 13 (72.2%) \| 33.69 (1.89) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 14 (77.8%) \| 32.36 (3.05) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 14 (77.8%) \| 31.43 (4.27) | n= 13 (65.0%) \| 32.06 (3.05) | -0.16 [-0.93 ; 0.61] |
| Week 45 | n= 13 (72.2%) \| 31.15 (3.26) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 13 (72.2%) \| 32.31 (3.25) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 15 (83.3%) \| 32.68 (2.84) | n= 12 (60.0%) \| 31.89 (2.53) | 0.28 [-0.49 ; 1.06] |
| Week 51 | n= 12 (66.7%) \| 31.64 (3.46) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (72.2%) \| 31.94 (2.73) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 9 (50.0%) \| 31.51 (3.97) | n= 11 (55.0%) \| 31.27 (4.03) | 0.06 [-0.85 ; 0.96] |
| Week 57 | n= 11 (61.1%) \| 32.05 (3.05) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 12 (66.7%) \| 31.71 (3.52) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 11 (61.1%) \| 32.45 (2.91) | n= 7 (35.0%) \| 31.00 (3.11) | 0.46 [-0.53 ; 1.45] |
| Week 63 | n= 10 (55.6%) \| 32.33 (3.80) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (61.1%) \| 31.57 (3.43) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 11 (61.1%) \| 32.45 (3.05) | n= 8 (40.0%) \| 30.13 (3.00) | 0.74 [-0.23 ; 1.71] |
| Week 69 | n= 11 (61.1%) \| 31.66 (3.89) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 10 (55.6%) \| 30.68 (4.98) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 10 (55.6%) \| 31.00 (4.81) | n= 7 (35.0%) \| 30.30 (4.18) | 0.14 [-0.85 ; 1.14] |
| Week 75 | n= 9 (50.0%) \| 31.89 (4.34) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 7 (38.9%) \| 32.86 (2.79) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (50.0%) \| 29.43 (8.70) | n= 7 (35.0%) \| 30.43 (4.69) | -0.13 [-1.15 ; 0.89] |
| Week 81 | n= 5 (27.8%) \| 31.80 (3.83) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (38.9%) \| 32.14 (3.67) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (44.4%) \| 32.00 (4.31) | n= 6 (30.0%) \| 31.17 (4.07) | 0.19 [-0.92 ; 1.29] |
| Week 87 | n= 5 (27.8%) \| 31.00 (4.36) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 89 | n= 6 (33.3%) \| 29.67 (3.27) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 6 (33.3%) \| 31.00 (3.41) | n= 4 (20.0%) \| 31.25 (4.43) | -0.06 [-1.40 ; 1.29] |
| Week 93 | n= 4 (22.2%) \| 30.00 (3.27) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (27.8%) \| 30.60 (3.29) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (22.2%) \| 30.00 (2.16) | n= 1 ( 5.0%) \| 33.00 ( / ) | [Not calculable] |
| Week 99 | n= 3 (16.7%) \| 28.67 (0.58) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (16.7%) \| 30.00 (1.73) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (22.2%) \| 29.25 (2.22) | n= 1 ( 5.0%) \| 32.00 ( / ) | [Not calculable] |
| Week 105 | n= 2 (11.1%) \| 27.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.1%) \| 30.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (22.2%) \| 30.22 (4.24) | n= 1 ( 5.0%) \| 30.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 5.6%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.1%) \| 30.75 (1.06) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (16.7%) \| 32.67 (2.31) | n= 1 ( 5.0%) \| 30.00 ( / ) | [Not calculable] |
| Week 117 | n= 2 (11.1%) \| 31.00 (4.24) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (11.1%) \| 26.50 (3.54) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (16.7%) \| 30.75 (2.82) | n= 1 ( 5.0%) \| 30.38 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 5.6%) \| 27.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 5.6%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (11.1%) \| 32.00 (1.41) | n= 1 ( 5.0%) \| 24.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 5.6%) \| 29.25 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 5.6%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 5.6%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 5.6%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 5.6%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 5.6%) \| 32.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 5.6%) \| 31.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 5.6%) \| 36.00 ( / ) | n= 5 (25.0%) \| 30.60 (5.18) | [Not calculable] |
| Week 202 | n= 1 ( 5.6%) \| 20.00 ( / ) | n= 3 (15.0%) \| 32.67 (3.06) | [Not calculable] |
| **Non-Stage IV** | | | |
| N subjects in population | N=50 | N=48 | |
| Baseline | n= 48 (96.0%) \| 31.78 (4.44) | n= 47 (97.9%) \| 31.38 (4.19) | 0.09 [-0.31 ; 0.50] |
| Week 3 | n= 48 (96.0%) \| 31.61 (4.39) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 44 (88.0%) \| 31.01 (5.06) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 45 (90.0%) \| 30.66 (4.61) | n= 44 (91.7%) \| 30.39 (3.89) | 0.06 [-0.36 ; 0.48] |
| Week 9 | n= 45 (90.0%) \| 30.79 (4.30) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 44 (88.0%) \| 30.83 (3.87) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 42 (84.0%) \| 31.79 (3.59) | n= 40 (83.3%) \| 30.25 (3.69) | 0.42 [-0.02 ; 0.86] |
| Week 15 | n= 38 (76.0%) \| 31.48 (3.35) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 46 (92.0%) \| 31.46 (4.23) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 41 (82.0%) \| 32.18 (3.03) | n= 38 (79.2%) \| 30.83 (3.70) | 0.40 [-0.05 ; 0.85] |
| Week 21 | n= 42 (84.0%) \| 31.67 (4.29) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 43 (86.0%) \| 31.05 (3.96) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 42 (84.0%) \| 31.86 (3.77) | n= 34 (70.8%) \| 31.53 (3.37) | 0.09 [-0.37 ; 0.55] |
| Week 27 | n= 39 (78.0%) \| 32.72 (3.90) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 38 (76.0%) \| 31.97 (3.85) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 37 (74.0%) \| 32.24 (4.12) | n= 31 (64.6%) \| 31.00 (3.96) | 0.30 [-0.18 ; 0.79] |
| Week 33 | n= 40 (80.0%) \| 31.85 (4.13) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 40 (80.0%) \| 31.80 (4.71) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 35 (70.0%) \| 32.23 (4.35) | n= 33 (68.8%) \| 31.35 (3.11) | 0.23 [-0.25 ; 0.71] |
| Week 39 | n= 38 (76.0%) \| 32.16 (4.02) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 41 | n= 37 (74.0%) \| 32.24 (4.31) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 37 (74.0%) \| 32.37 (3.82) | n= 29 (60.4%) \| 30.62 (4.42) | 0.42 [-0.07 ; 0.92] |
| Week 45 | n= 34 (68.0%) \| 31.83 (4.30) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 37 (74.0%) \| 32.11 (4.22) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 36 (72.0%) \| 32.06 (4.63) | n= 24 (50.0%) \| 31.01 (4.50) | 0.23 [-0.30 ; 0.75] |
| Week 51 | n= 38 (76.0%) \| 31.83 (4.41) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 38 (76.0%) \| 32.16 (4.49) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 36 (72.0%) \| 31.88 (4.69) | n= 27 (56.3%) \| 30.83 (3.23) | 0.25 [-0.25 ; 0.76] |
| Week 57 | n= 36 (72.0%) \| 31.78 (4.48) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 33 (66.0%) \| 31.69 (4.81) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 36 (72.0%) \| 32.32 (4.42) | n= 24 (50.0%) \| 30.83 (3.76) | 0.35 [-0.17 ; 0.88] |
| Week 63 | n= 31 (62.0%) \| 31.45 (5.07) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 31 (62.0%) \| 31.00 (5.87) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (64.0%) \| 32.03 (4.58) | n= 22 (45.8%) \| 31.18 (3.94) | 0.19 [-0.36 ; 0.74] |
| Week 69 | n= 26 (52.0%) \| 31.19 (5.46) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 27 (54.0%) \| 32.67 (4.20) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (50.0%) \| 32.72 (3.69) | n= 21 (43.8%) \| 30.10 (3.60) | 0.71 [ 0.10 ; 1.31] |
| Week 75 | n= 26 (52.0%) \| 32.38 (3.62) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (48.0%) \| 32.25 (3.90) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 21 (42.0%) \| 32.41 (4.38) | n= 18 (37.5%) \| 31.50 (2.43) | 0.25 [-0.39 ; 0.89] |
| Week 81 | n= 24 (48.0%) \| 31.92 (4.41) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (50.0%) \| 32.48 (4.14) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (38.0%) \| 32.42 (3.76) | n= 15 (31.3%) \| 31.80 (2.96) | 0.18 [-0.51 ; 0.86] |
| Week 87 | n= 19 (38.0%) \| 31.05 (4.90) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (38.0%) \| 32.15 (4.28) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 18 (36.0%) \| 30.74 (5.23) | n= 14 (29.2%) \| 32.29 (3.47) | -0.33 [-1.05 ; 0.38] |
| Week 93 | n= 19 (38.0%) \| 31.68 (4.19) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (34.0%) \| 31.34 (4.94) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (34.0%) \| 31.14 (4.87) | n= 10 (20.8%) \| 32.20 (3.74) | -0.23 [-1.03 ; 0.57] |
| Week 99 | n= 14 (28.0%) \| 31.21 (5.42) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (22.0%) \| 31.82 (4.05) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (22.0%) \| 32.45 (3.45) | n= 9 (18.8%) \| 32.33 (2.74) | 0.04 [-0.87 ; 0.94] |
| Week 105 | n= 11 (22.0%) \| 31.55 (3.83) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (12.0%) \| 32.33 (3.61) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (14.0%) \| 28.43 (3.69) | n= 4 ( 8.3%) \| 31.75 (5.97) | -0.66 [-2.00 ; 0.67] |
| Week 111 | n= 6 (12.0%) \| 30.50 (4.23) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (12.0%) \| 31.67 (4.32) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 8.0%) \| 29.75 (5.12) | n= 4 ( 8.3%) \| 33.25 (1.89) | -0.79 [-2.37 ; 0.79] |
| Week 117 | n= 5 (10.0%) \| 33.40 (2.61) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (10.0%) \| 30.40 (4.62) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (10.0%) \| 31.40 (5.59) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.0%) \| 35.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 (10.0%) \| 30.40 (5.22) | n= 11 (22.9%) \| 30.27 (4.50) | 0.03 [-1.07 ; 1.12] |
| Week 202 | n= 1 ( 2.0%) \| 30.00 ( / ) | n= 8 (16.7%) \| 32.25 (2.25) | [Not calculable] |
| **Not Reported** | | | |
| N subjects in population | N=3 | [No Data] | |
| Baseline | n= 3 (100.0%) \| 31.33 (4.04) | [No Data] | |
| Week 3 | n= 3 (100.0%) \| 32.00 (2.65) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (66.7%) \| 32.50 (4.95) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 3 (100.0%) \| 29.50 (3.91) | [No Data] | [No Data for at least 1 arm] |
| Week 9 | n= 2 (66.7%) \| 23.00 (2.83) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 11 | n= 2 (66.7%) \| 24.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (33.3%) \| 27.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 15 | n= 1 (33.3%) \| 20.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 2 (66.7%) \| 24.50 (6.36) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (33.3%) \| 27.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 21 | n= 1 (33.3%) \| 29.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (33.3%) \| 26.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (33.3%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 27 | n= 1 (33.3%) \| 28.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (33.3%) \| 27.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (33.3%) \| 23.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 1 (33.3%) \| 24.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (33.3%) \| 26.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 39 | n= 1 (33.3%) \| 23.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (33.3%) \| 24.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (33.3%) \| 25.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 45 | n= 1 (33.3%) \| 19.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (33.3%) \| 23.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (33.3%) \| 22.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 51 | n= 1 (33.3%) \| 24.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (33.3%) \| 28.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (33.3%) \| 31.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 57 | n= 1 (33.3%) \| 22.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (33.3%) \| 27.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (33.3%) \| 26.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (33.3%) \| 25.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (33.3%) \| 27.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 1 (33.3%) \| 27.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 69 | n= 1 (33.3%) \| 25.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 1 (33.3%) \| 25.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 1 (33.3%) \| 24.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 1 (33.3%) \| 28.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 1 (33.3%) \| 26.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (66.7%) \| 32.00 (0.00) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:06

TABLE 7.4.12: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| **Stage IV** | | | |
| N subjects in population | N=18 | N=20 | |
| Week 3 | n= 16 (88.9%) \|-0.48 (2.86) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 17 (94.4%) \|-0.20 (3.48) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 16 (88.9%) \|-0.57 (3.71) | n= 20 (100.0%) \|-1.65 (3.41) | 0.30 [-0.37 ; 0.97] |
| Week 9 | n= 14 (77.8%) \|-0.10 (3.77) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 15 (83.3%) \|-0.43 (4.35) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 17 (94.4%) \|-0.85 (4.21) | n= 15 (75.0%) \|-1.00 (3.93) | 0.04 [-0.67 ; 0.74] |
| Week 15 | n= 15 (83.3%) \|-0.53 (4.69) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 15 (83.3%) \| 0.07 (4.29) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 15 (83.3%) \|-0.05 (3.86) | n= 16 (80.0%) \|-0.74 (4.06) | 0.17 [-0.55 ; 0.89] |
| Week 21 | n= 16 (88.9%) \| 0.35 (4.13) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 12 (66.7%) \|-1.25 (2.80) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 15 (83.3%) \| 0.39 (4.39) | n= 15 (75.0%) \|-1.93 (3.13) | 0.59 [-0.15 ; 1.34] |
| Week 27 | n= 16 (88.9%) \| 0.66 (3.86) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 14 (77.8%) \| 0.69 (3.94) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 16 (88.9%) \| 0.10 (4.42) | n= 11 (55.0%) \|-0.91 (2.66) | 0.26 [-0.53 ; 1.04] |
| Week 33 | n= 15 (83.3%) \|-0.18 (3.92) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 13 (72.2%) \|-0.12 (4.66) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 12 (66.7%) \| 0.90 (4.90) | n= 14 (70.0%) \|-2.29 (3.02) | 0.77 [-0.04 ; 1.59] |
| Week 39 | n= 13 (72.2%) \| 0.74 (4.05) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 14 (77.8%) \|-0.36 (4.96) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 14 (77.8%) \|-0.82 (5.40) | n= 13 (65.0%) \|-1.02 (2.53) | 0.05 [-0.72 ; 0.82] |
| Week 45 | n= 13 (72.2%) \|-0.42 (4.71) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 13 (72.2%) \|-0.31 (3.40) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 15 (83.3%) \| 0.98 (4.38) | n= 12 (60.0%) \|-1.11 (2.01) | 0.57 [-0.22 ; 1.36] |
| Week 51 | n= 12 (66.7%) \| 0.60 (5.05) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 13 (72.2%) \| 0.52 (3.98) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 9 (50.0%) \| 0.24 (4.11) | n= 11 (55.0%) \|-1.73 (3.10) | 0.53 [-0.39 ; 1.45] |
| Week 57 | n= 11 (61.1%) \| 1.10 (4.68) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 12 (66.7%) \| 0.51 (5.18) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 11 (61.1%) \| 1.05 (5.02) | n= 7 (35.0%) \|-2.29 (2.43) | 0.75 [-0.26 ; 1.76] |
| Week 63 | n= 10 (55.6%) \| 0.93 (4.74) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 11 (61.1%) \| 0.80 (4.46) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 11 (61.1%) \| 1.69 (4.33) | n= 8 (40.0%) \|-2.50 (2.98) | 1.04 [ 0.04 ; 2.05] |
| Week 69 | n= 11 (61.1%) \| 0.89 (4.89) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 10 (55.6%) \|-0.73 (6.11) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 10 (55.6%) \|-0.40 (6.24) | n= 7 (35.0%) \|-2.55 (2.93) | 0.39 [-0.61 ; 1.40] |
| Week 75 | n= 9 (50.0%) \| 0.89 (5.62) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 7 (38.9%) \| 3.51 (5.36) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 9 (50.0%) \|-1.57 (8.87) | n= 7 (35.0%) \|-2.00 (3.00) | 0.06 [-0.96 ; 1.08] |
| Week 81 | n= 5 (27.8%) \| 0.20 (5.22) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 7 (38.9%) \| 1.43 (6.24) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 8 (44.4%) \| 0.75 (5.70) | n= 6 (30.0%) \|-2.50 (2.43) | 0.66 [-0.48 ; 1.79] |
| Week 87 | n= 5 (27.8%) \|-0.40 (5.32) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 6 (33.3%) \|-0.67 (5.85) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 6 (33.3%) \|-0.83 (4.62) | n= 4 (20.0%) \|-3.50 (4.04) | 0.55 [-0.83 ; 1.92] |
| Week 93 | n= 4 (22.2%) \|-1.00 (6.63) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 5 (27.8%) \|-0.60 (5.55) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 4 (22.2%) \|-0.25 (5.56) | n= 1 ( 5.0%) \|-2.00 ( / ) | [Not calculable] |
| Week 99 | n= 3 (16.7%) \| 0.00 (6.08) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 3 (16.7%) \| 1.33 (5.13) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 4 (22.2%) \|-1.00 (5.23) | n= 1 ( 5.0%) \|-4.00 ( / ) | [Not calculable] |
| Week 105 | n= 2 (11.1%) \| 0.00 (8.49) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 2 (11.1%) \| 3.00 (7.07) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 4 (22.2%) \|-0.03 (5.52) | n= 1 ( 5.0%) \|-6.00 ( / ) | [Not calculable] |
| Week 111 | n= 1 ( 5.6%) \| 7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 2 (11.1%) \| 3.75 (6.01) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 3 (16.7%) \| 3.00 (4.58) | n= 1 ( 5.0%) \|-2.00 ( / ) | [Not calculable] |
| Week 117 | n= 2 (11.1%) \| 4.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 2 (11.1%) \|-0.50 (10.61) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 3 (16.7%) \| 1.08 (5.20) | n= 1 ( 5.0%) \|-1.63 ( / ) | [Not calculable] |
| Week 123 | n= 1 ( 5.6%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 5.6%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 (11.1%) \|-1.50 (0.71) | n= 1 ( 5.0%) \|-8.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 5.6%) \|-2.75 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 5.6%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 5.6%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 5.6%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 5.6%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 5.6%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 5.6%) \|-0.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 1 ( 5.6%) \| 0.00 ( / ) | n= 5 (25.0%) \| 0.80 (6.14) | [Not calculable] |
| Week 202 | n= 1 ( 5.6%) \|-9.00 ( / ) | n= 3 (15.0%) \| 1.67 (4.73) | [Not calculable] |
| **Non-Stage IV** | | | |
| N subjects in population | N=50 | N=48 | |
| Week 3 | n= 47 (94.0%) \|-0.13 (2.01) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 42 (84.0%) \|-0.95 (2.89) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 43 (86.0%) \|-0.85 (3.80) | n= 43 (89.6%) \|-0.87 (3.37) | 0.00 [-0.42 ; 0.43] |
| Week 9 | n= 44 (88.0%) \|-1.17 (3.85) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 43 (86.0%) \|-1.14 (3.08) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 41 (82.0%) \|-0.38 (3.29) | n= 40 (83.3%) \|-1.54 (2.92) | 0.37 [-0.07 ; 0.81] |
| Week 15 | n= 38 (76.0%) \|-0.52 (3.34) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 45 (90.0%) \|-0.58 (3.30) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 40 (80.0%) \|-0.58 (2.92) | n= 37 (77.1%) \|-1.03 (3.43) | 0.14 [-0.31 ; 0.59] |
| Week 21 | n= 42 (84.0%) \|-0.36 (3.42) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 43 (86.0%) \|-0.70 (3.05) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 41 (82.0%) \|-0.39 (3.30) | n= 33 (68.8%) \|-0.38 (3.68) | -0.00 [-0.46 ; 0.46] |
| Week 27 | n= 38 (76.0%) \| 0.02 (3.50) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 38 (76.0%) \|-0.24 (3.56) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 37 (74.0%) \|-0.33 (3.32) | n= 31 (64.6%) \|-0.93 (2.43) | 0.20 [-0.28 ; 0.68] |
| Week 33 | n= 40 (80.0%) \|-0.40 (3.00) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 39 (78.0%) \|-0.59 (3.08) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 35 (70.0%) \|-0.17 (2.86) | n= 32 (66.7%) \|-0.07 (3.00) | -0.04 [-0.52 ; 0.45] |
| Week 39 | n= 37 (74.0%) \|-0.12 (2.69) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 37 (74.0%) \|-0.44 (2.68) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 36 (72.0%) \|-0.13 (3.20) | n= 28 (58.3%) \|-0.81 (3.14) | 0.21 [-0.29 ; 0.71] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 45 | n= 34 (68.0%) \|-0.70 (3.67) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 37 (74.0%) \|-0.62 (3.00) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 36 (72.0%) \|-0.59 (2.97) | n= 23 (47.9%) \|-0.85 (3.78) | 0.08 [-0.45 ; 0.61] |
| Week 51 | n= 38 (76.0%) \|-0.68 (2.69) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 38 (76.0%) \|-0.32 (2.99) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 36 (72.0%) \|-0.65 (3.26) | n= 26 (54.2%) \|-0.51 (2.77) | -0.04 [-0.55 ; 0.46] |
| Week 57 | n= 36 (72.0%) \|-0.59 (3.00) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 33 (66.0%) \|-0.69 (3.48) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 36 (72.0%) \|-0.30 (2.91) | n= 23 (47.9%) \|-0.08 (3.05) | -0.07 [-0.60 ; 0.45] |
| Week 63 | n= 31 (62.0%) \|-0.33 (3.38) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 31 (62.0%) \|-0.95 (4.75) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 32 (64.0%) \|-0.48 (3.53) | n= 21 (43.8%) \| 0.15 (2.40) | -0.20 [-0.76 ; 0.36] |
| Week 69 | n= 26 (52.0%) \|-1.44 (5.03) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 27 (54.0%) \| 0.30 (3.62) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 25 (50.0%) \| 0.47 (3.31) | n= 21 (43.8%) \|-0.61 (2.72) | 0.34 [-0.25 ; 0.94] |
| Week 75 | n= 26 (52.0%) \|-0.01 (3.83) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 24 (48.0%) \| 0.33 (3.56) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 21 (42.0%) \| 0.96 (3.28) | n= 17 (35.4%) \| 1.11 (2.23) | -0.05 [-0.70 ; 0.60] |
| Week 81 | n= 24 (48.0%) \| 0.19 (3.34) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 25 (50.0%) \| 0.63 (3.49) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 19 (38.0%) \| 0.19 (3.53) | n= 14 (29.2%) \| 0.57 (2.41) | -0.12 [-0.82 ; 0.58] |
| Week 87 | n= 19 (38.0%) \|-0.42 (4.13) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 19 (38.0%) \| 0.45 (3.37) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 18 (36.0%) \|-1.12 (2.89) | n= 13 (27.1%) \| 0.57 (3.96) | -0.49 [-1.22 ; 0.25] |
| Week 93 | n= 19 (38.0%) \|-0.34 (2.21) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 17 (34.0%) \|-0.63 (2.90) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 17 (34.0%) \|-0.82 (2.92) | n= 9 (18.8%) \|-0.44 (3.00) | -0.12 [-0.95 ; 0.70] |
| Week 99 | n= 14 (28.0%) \|-0.46 (3.53) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 11 (22.0%) \|-0.82 (2.52) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 11 (22.0%) \| 0.60 (2.33) | n= 8 (16.7%) \| 0.63 (2.45) | -0.01 [-0.95 ; 0.93] |
| Week 105 | n= 11 (22.0%) \| 0.06 (2.54) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 6 (12.0%) \|-0.50 (2.88) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 7 (14.0%) \|-2.43 (3.05) | n= 3 ( 6.3%) \| 1.00 (1.00) | -1.15 [-2.71 ; 0.40] |
| Week 111 | n= 6 (12.0%) \|-2.00 (2.97) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 6 (12.0%) \|-1.83 (2.48) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 4 ( 8.0%) \|-3.25 (2.63) | n= 4 ( 8.3%) \|-0.75 (1.71) | -0.98 [-2.60 ; 0.64] |
| Week 117 | n= 5 (10.0%) \|-0.80 (1.92) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 5 (10.0%) \|-3.00 (2.35) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 5 (10.0%) \|-2.60 (3.78) | [No Data] | [No Data for at least 1 arm] |
| Week 123 | n= 1 ( 2.0%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 5 (10.0%) \|-1.80 (2.77) | n= 11 (22.9%) \|-2.64 (4.13) | 0.21 [-0.89 ; 1.31] |
| Week 202 | n= 1 ( 2.0%) \|-2.00 ( / ) | n= 8 (16.7%) \|-0.88 (2.85) | [Not calculable] |
| **Not Reported** | | | |
| N subjects in population | N=3 | [No Data] | |
| Week 3 | n= 3 (100.0%) \| 0.67 (3.06) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 2 (66.7%) \| 1.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 3 (100.0%) \|-1.83 (1.26) | [No Data] | [No Data for at least 1 arm] |
| Week 9 | n= 2 (66.7%) \|-6.50 (0.71) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 2 (66.7%) \|-5.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 1 (33.3%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 15 | n= 1 (33.3%) \|-12.00 ( / ) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 17 | n= 2 (66.7%) \|-5.00 (2.83) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 1 (33.3%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 21 | n= 1 (33.3%) \|-3.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 1 (33.3%) \|-6.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 1 (33.3%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 27 | n= 1 (33.3%) \|-4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 1 (33.3%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 33 | n= 1 (33.3%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 1 (33.3%) \|-8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 1 (33.3%) \|-6.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 39 | n= 1 (33.3%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 1 (33.3%) \|-8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 1 (33.3%) \|-7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 45 | n= 1 (33.3%) \|-13.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 1 (33.3%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 1 (33.3%) \|-10.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 51 | n= 1 (33.3%) \|-8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 1 (33.3%) \|-4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 1 (33.3%) \|-1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 57 | n= 1 (33.3%) \|-10.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 1 (33.3%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 1 (33.3%) \|-6.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 63 | n= 1 (33.3%) \|-7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 1 (33.3%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 1 (33.3%) \|-5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 69 | n= 1 (33.3%) \|-7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 1 (33.3%) \|-7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 1 (33.3%) \|-8.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 1 (33.3%) \|-4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 1 (33.3%) \|-6.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 2 (66.7%) \| 2.50 (3.54) | [No Data] | [No Data for at least 1 arm] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:06

TABLE 7.4.12: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Stage at Initial Diagnosis Subgroups Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| **Stage IV** | | | | |
| Nr subjects used | n=18 | n=20 | | |
| Week 7 | -1.24 (0.79) [-2.84 ; 0.36] | -2.03 (0.72) [-3.49 ;-0.57] | 0.79 (1.06) [-1.37 ; 2.94] | 0.24 [-0.42 ; 0.90] |
| Week 13 | -1.38 (0.89) [-3.19 ; 0.43] | -0.85 (0.89) [-2.65 ; 0.96] | -0.53 (1.26) [-3.08 ; 2.02] | -0.15 [-0.84 ; 0.55] |
| Week 19 | -0.40 (0.70) [-1.83 ; 1.03] | -0.94 (0.67) [-2.31 ; 0.42] | 0.55 (0.97) [-1.43 ; 2.52] | 0.20 [-0.51 ; 0.90] |
| Week 25 | -0.30 (0.78) [-1.89 ; 1.29] | -1.12 (0.77) [-2.67 ; 0.44] | 0.82 (1.10) [-1.41 ; 3.05] | 0.27 [-0.45 ; 0.99] |
| Week 31 | -0.24 (0.83) [-1.93 ; 1.45] | -0.02 (0.90) [-1.85 ; 1.82] | -0.23 (1.23) [-2.72 ; 2.27] | -0.07 [-0.84 ; 0.70] |
| Week 37 | 0.06 (1.16) [-2.30 ; 2.42] | -1.88 (1.12) [-4.18 ; 0.42] | 1.94 (1.61) [-1.36 ; 5.23] | 0.46 [-0.33 ; 1.24] |
| Week 43 | -0.65 (0.93) [-2.54 ; 1.23] | -0.39 (0.96) [-2.36 ; 1.57] | -0.26 (1.34) [-2.99 ; 2.46] | -0.07 [-0.83 ; 0.68] |
| Week 49 | 0.25 (0.65) [-1.06 ; 1.57] | -0.54 (0.71) [-1.99 ; 0.92] | 0.79 (0.96) [-1.18 ; 2.76] | 0.31 [-0.46 ; 1.07] |
| Overall post-baseline period estimate | -0.49 (0.55) [-1.61 ; 0.63] | -0.97 (0.54) [-2.07 ; 0.13] | 0.48 (0.78) [-1.09 ; 2.06] | 0.20 [-0.44 ; 0.84] |
| **Non-Stage IV** | | | | |
| Nr subjects used | n=48 | n=47 | | |
| Week 7 | -0.99 (0.54) [-2.06 ; 0.09] | -1.05 (0.55) [-2.14 ; 0.03] | 0.07 (0.77) [-1.46 ; 1.59] | 0.02 [-0.40 ; 0.44] |
| Week 13 | -0.39 (0.50) [-1.38 ; 0.61] | -1.56 (0.52) [-2.59 ;-0.54] | 1.18 (0.72) [-0.25 ; 2.60] | 0.36 [-0.08 ; 0.80] |
| Week 19 | -0.33 (0.46) [-1.24 ; 0.58] | -1.07 (0.48) [-2.02 ;-0.11] | 0.73 (0.66) [-0.58 ; 2.05] | 0.25 [-0.20 ; 0.70] |
| Week 25 | -0.17 (0.46) [-1.09 ; 0.75] | -0.58 (0.51) [-1.59 ; 0.42] | 0.41 (0.69) [-0.95 ; 1.77] | 0.14 [-0.32 ; 0.60] |
| Week 31 | -0.23 (0.48) [-1.19 ; 0.74] | -0.75 (0.53) [-1.79 ; 0.30] | 0.52 (0.71) [-0.90 ; 1.94] | 0.17 [-0.30 ; 0.65] |
| Week 37 | -0.06 (0.44) [-0.93 ; 0.82] | -0.32 (0.47) [-1.25 ; 0.62] | 0.26 (0.64) [-1.02 ; 1.54] | 0.10 [-0.38 ; 0.58] |
| Week 43 | -0.00 (0.48) [-0.95 ; 0.95] | -0.93 (0.54) [-2.00 ; 0.13] | 0.93 (0.72) [-0.49 ; 2.36] | 0.32 [-0.17 ; 0.82] |
| Week 49 | -0.32 (0.53) [-1.37 ; 0.73] | -0.59 (0.63) [-1.85 ; 0.67] | 0.27 (0.82) [-1.36 ; 1.91] | 0.09 [-0.44 ; 0.61] |
| Week 55 | -0.57 (0.45) [-1.45 ; 0.32] | -0.60 (0.53) [-1.65 ; 0.46] | 0.03 (0.69) [-1.35 ; 1.41] | 0.01 [-0.49 ; 0.52] |
| Week 61 | -0.35 (0.45) [-1.25 ; 0.55] | -0.32 (0.56) [-1.44 ; 0.79] | -0.02 (0.72) [-1.46 ; 1.41] | -0.01 [-0.53 ; 0.51] |
| Week 67 | -0.61 (0.50) [-1.60 ; 0.38] | -0.14 (0.61) [-1.36 ; 1.09] | -0.47 (0.79) [-2.05 ; 1.10] | -0.17 [-0.72 ; 0.39] |
| Week 73 | 0.18 (0.47) [-0.75 ; 1.12] | -0.96 (0.54) [-2.03 ; 0.11] | 1.14 (0.71) [-0.28 ; 2.57] | 0.47 [-0.12 ; 1.06] |
| Week 79 | 0.42 (0.47) [-0.51 ; 1.36] | 0.43 (0.53) [-0.64 ; 1.50] | -0.01 (0.71) [-1.43 ; 1.42] | -0.00 [-0.64 ; 0.64] |
| Week 85 | -0.31 (0.52) [-1.34 ; 0.73] | 0.09 (0.60) [-1.12 ; 1.29] | -0.39 (0.79) [-1.98 ; 1.19] | -0.17 [-0.86 ; 0.52] |
| Week 91 | -0.43 (0.69) [-1.82 ; 0.96] | 0.38 (0.81) [-1.25 ; 2.01] | -0.81 (1.06) [-2.96 ; 1.33] | -0.27 [-0.99 ; 0.44] |
| Overall post-baseline period estimate | -0.28 (0.24) [-0.75 ; 0.19] | -0.53 (0.27) [-1.07 ; 0.00] | 0.26 (0.36) [-0.46 ; 0.97] | 0.15 [-0.26 ; 0.55] |
| **Not Reported** | | | | |
| Nr subjects used | n=3 | [No Data] | | |
| **MMRM subgroups interaction p-value** | | | | |
| | | | 0.2285 | |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm.CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Error.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:07

TABLE 7.5.1: PRO Analysis: FKSI-19: Disease Related Symptoms Physical Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| subtit | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| N subjects | N=71 | N=68 |
| Subjects with Baseline Value | 69 (97.2%) | 67 (98.5%) |
| Subjects with at least 1 Post-Baseline Value | 71 (100.0%) | 66 (97.1%) |
| Subjects with Baseline Value and at least 1 Post-Baseline Value | 69 (97.2%) | 65 (95.6%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:49:27

TABLE 7.5.1: PRO Analysis: FKSI-19: Disease Related Symptoms Physical Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Baseline | n= 69 (97.2%) \| 40.28 (5.55) | n= 67 (98.5%) \| 39.97 (5.48) | 0.06 [-0.28 ; 0.39] |
| Week 3 | n= 66 (93.0%) \| 40.32 (5.21) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 62 (87.3%) \| 39.47 (6.16) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 64 (90.1%) \| 38.29 (5.68) | n= 64 (94.1%) \| 38.28 (5.98) | 0.00 [-0.35 ; 0.35] |
| Week 9 | n= 60 (84.5%) \| 39.34 (5.64) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 61 (85.9%) \| 38.88 (5.60) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 60 (84.5%) \| 39.32 (5.76) | n= 55 (80.9%) \| 38.64 (5.05) | 0.13 [-0.24 ; 0.49] |
| Week 15 | n= 54 (76.1%) \| 39.50 (5.37) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 63 (88.7%) \| 39.53 (6.10) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 57 (80.3%) \| 40.25 (4.52) | n= 54 (79.4%) \| 39.24 (4.83) | 0.21 [-0.16 ; 0.59] |
| Week 21 | n= 59 (83.1%) \| 39.81 (5.59) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 56 (78.9%) \| 39.05 (5.48) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 58 (81.7%) \| 40.26 (5.24) | n= 49 (72.1%) \| 40.27 (4.89) | -0.00 [-0.38 ; 0.38] |
| Week 27 | n= 56 (78.9%) \| 41.12 (5.25) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 52 (73.2%) \| 40.52 (5.21) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \| 40.11 (5.77) | n= 42 (61.8%) \| 39.83 (5.31) | 0.05 [-0.36 ; 0.45] |
| Week 33 | n= 56 (78.9%) \| 39.93 (5.72) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 54 (76.1%) \| 39.68 (6.49) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 48 (67.6%) \| 40.48 (6.10) | n= 47 (69.1%) \| 39.82 (4.36) | 0.12 [-0.28 ; 0.53] |
| Week 39 | n= 52 (73.2%) \| 40.75 (5.09) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 52 (73.2%) \| 40.50 (5.50) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 52 (73.2%) \| 40.00 (5.68) | n= 42 (61.8%) \| 39.17 (5.17) | 0.15 [-0.26 ; 0.56] |
| Week 45 | n= 48 (67.6%) \| 39.40 (5.79) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 51 (71.8%) \| 40.30 (5.75) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 52 (73.2%) \| 40.23 (5.57) | n= 36 (52.9%) \| 39.67 (5.34) | 0.10 [-0.33 ; 0.53] |
| Week 51 | n= 51 (71.8%) \| 39.58 (5.88) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 52 (73.2%) \| 39.96 (5.65) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 46 (64.8%) \| 39.82 (5.99) | n= 38 (55.9%) \| 39.08 (4.50) | 0.14 [-0.30 ; 0.57] |
| Week 57 | n= 48 (67.6%) \| 40.07 (5.93) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 46 (64.8%) \| 39.97 (6.04) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \| 40.53 (5.58) | n= 31 (45.6%) \| 38.48 (5.04) | 0.38 [-0.08 ; 0.84] |
| Week 63 | n= 42 (59.2%) \| 39.73 (6.34) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 43 (60.6%) \| 39.35 (6.79) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \| 40.43 (5.58) | n= 30 (44.1%) \| 39.00 (4.38) | 0.28 [-0.19 ; 0.75] |
| Week 69 | n= 38 (53.5%) \| 39.26 (7.24) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 38 (53.5%) \| 40.27 (6.32) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 35 (49.3%) \| 40.93 (5.80) | n= 28 (41.2%) \| 37.46 (4.74) | 0.64 [ 0.13 ; 1.15] |
| Week 75 | n= 35 (49.3%) \| 41.14 (5.04) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \| 40.80 (5.36) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \| 39.91 (8.08) | n= 25 (36.8%) \| 38.72 (3.89) | 0.18 [-0.35 ; 0.71] |
| Week 81 | n= 29 (40.8%) \| 40.48 (5.74) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \| 40.35 (5.72) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \| 41.00 (5.45) | n= 21 (30.9%) \| 39.62 (5.08) | 0.26 [-0.32 ; 0.84] |
| Week 87 | n= 24 (33.8%) \| 39.04 (6.31) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \| 39.62 (5.57) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | | Sunitinib | | Hedge G difference [95% CI] |
|---|---|---|---|---|---|
| Week 91 | n= 24 (33.8%) | 38.84 (6.73) | n= 18 (26.5%) | 40.00 (5.28) | -0.18 [-0.80 ; 0.43] |
| Week 93 | n= 23 (32.4%) | 39.43 (5.98) | | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 22 (31.0%) | 38.98 (6.28) | | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) | 38.95 (6.14) | n= 11 (16.2%) | 41.25 (5.08) | -0.39 [-1.13 ; 0.36] |
| Week 99 | n= 17 (23.9%) | 38.35 (6.89) | | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) | 39.93 (5.17) | | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) | 39.78 (4.63) | n= 10 (14.7%) | 40.50 (4.09) | -0.16 [-0.97 ; 0.66] |
| Week 105 | n= 13 (18.3%) | 38.62 (4.52) | | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) | 39.63 (4.53) | | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) | 36.96 (5.23) | n= 5 ( 7.4%) | 38.60 (7.02) | -0.27 [-1.37 ; 0.83] |
| Week 111 | n= 7 ( 9.9%) | 37.57 (3.64) | | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) | 39.00 (4.57) | | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 7 ( 9.9%) | 39.57 (5.41) | n= 5 ( 7.4%) | 40.80 (3.70) | -0.24 [-1.45 ; 0.97] |
| Week 117 | n= 7 ( 9.9%) | 40.71 (2.69) | | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 ( 9.9%) | 37.29 (6.37) | | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) | 38.73 (5.44) | n= 1 ( 1.5%) | 33.82 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 2.8%) | 38.00 (2.83) | | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) | 38.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) | 41.00 (4.24) | n= 1 ( 1.5%) | 29.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) | 37.09 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.4%) | 40.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.4%) | 34.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.4%) | 37.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.4%) | 42.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.4%) | 36.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) | 36.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) | 40.25 (5.23) | n= 16 (23.5%) | 37.44 (6.20) | 0.46 [-0.42 ; 1.34] |
| Week 202 | n= 2 ( 2.8%) | 32.00 (8.49) | n= 11 (16.2%) | 41.55 (3.93) | -1.96 [-3.74 ;-0.17] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:49:28

TABLE 7.5.1: PRO Analysis: FKSI-19: Disease Related Symptoms Physical Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Week 3 | n= 65 (91.5%) \|-0.16 (3.39) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 60 (84.5%) \|-0.99 (4.57) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 62 (87.3%) \|-1.79 (5.29) | n= 63 (92.6%) \|-1.60 (4.95) | -0.04 [-0.39 ; 0.31] |
| Week 9 | n= 59 (83.1%) \|-1.69 (5.06) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 60 (84.5%) \|-1.51 (5.08) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 59 (83.1%) \|-1.22 (5.25) | n= 55 (80.9%) \|-2.45 (4.96) | 0.24 [-0.13 ; 0.61] |
| Week 15 | n= 54 (76.1%) \|-1.08 (5.11) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 62 (87.3%) \|-1.12 (5.28) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 56 (78.9%) \|-0.79 (4.65) | n= 53 (77.9%) \|-1.47 (5.14) | 0.14 [-0.24 ; 0.51] |
| Week 21 | n= 59 (83.1%) \|-0.86 (5.15) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 56 (78.9%) \|-1.39 (4.51) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 57 (80.3%) \|-0.71 (4.83) | n= 48 (70.6%) \|-0.93 (5.56) | 0.04 [-0.34 ; 0.43] |
| Week 27 | n= 55 (77.5%) \|-0.46 (5.10) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 52 (73.2%) \|-0.49 (5.15) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \|-1.10 (5.11) | n= 42 (61.8%) \|-0.95 (4.58) | -0.03 [-0.44 ; 0.37] |
| Week 33 | n= 56 (78.9%) \|-1.10 (4.80) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 53 (74.6%) \|-1.47 (5.20) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 48 (67.6%) \|-0.47 (4.91) | n= 46 (67.6%) \|-1.00 (4.29) | 0.11 [-0.29 ; 0.52] |
| Week 39 | n= 51 (71.8%) \|-0.44 (4.61) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 52 (73.2%) \|-1.02 (5.22) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 51 (71.8%) \|-1.18 (5.78) | n= 41 (60.3%) \|-1.89 (4.27) | 0.14 [-0.28 ; 0.55] |
| Week 45 | n= 48 (67.6%) \|-1.61 (6.04) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 51 (71.8%) \|-1.23 (5.30) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 52 (73.2%) \|-0.90 (4.82) | n= 35 (51.5%) \|-1.50 (4.77) | 0.12 [-0.31 ; 0.56] |
| Week 51 | n= 51 (71.8%) \|-1.28 (5.41) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 52 (73.2%) \|-1.11 (5.18) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 46 (64.8%) \|-1.43 (5.25) | n= 37 (54.4%) \|-1.67 (4.34) | 0.05 [-0.39 ; 0.48] |
| Week 57 | n= 48 (67.6%) \|-0.86 (5.55) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 46 (64.8%) \|-0.87 (5.88) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \|-0.73 (5.15) | n= 30 (44.1%) \|-1.92 (4.57) | 0.24 [-0.22 ; 0.70] |
| Week 63 | n= 42 (59.2%) \|-0.72 (5.74) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 43 (60.6%) \|-1.04 (6.39) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \|-0.53 (5.61) | n= 29 (42.6%) \|-1.47 (4.53) | 0.18 [-0.29 ; 0.65] |
| Week 69 | n= 38 (53.5%) \|-1.99 (7.29) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 38 (53.5%) \|-0.86 (6.53) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 35 (49.3%) \| 0.04 (6.30) | n= 28 (41.2%) \|-2.53 (5.01) | 0.44 [-0.07 ; 0.95] |
| Week 75 | n= 35 (49.3%) \| 0.14 (5.67) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \| 0.60 (5.98) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \|-0.15 (7.76) | n= 24 (35.3%) \|-0.88 (4.55) | 0.11 [-0.43 ; 0.65] |
| Week 81 | n= 29 (40.8%) \| 0.24 (5.09) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \| 0.11 (6.23) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \| 0.34 (5.44) | n= 20 (29.4%) \|-1.00 (5.42) | 0.24 [-0.34 ; 0.83] |
| Week 87 | n= 24 (33.8%) \|-0.83 (6.13) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \|-0.29 (5.32) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 24 (33.8%) \|-1.78 (5.45) | n= 17 (25.0%) \|-1.45 (8.06) | -0.05 [-0.68 ; 0.58] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 23 (32.4%) \|-1.13 (5.25) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 22 (31.0%) \|-1.29 (5.95) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) \|-1.28 (5.53) | n= 10 (14.7%) \|-0.43 (5.00) | -0.15 [-0.92 ; 0.61] |
| Week 99 | n= 17 (23.9%) \|-1.35 (6.13) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) \|-1.29 (5.04) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) \|-0.55 (4.39) | n= 9 (13.2%) \|-0.56 (4.48) | 0.00 [-0.84 ; 0.85] |
| Week 105 | n= 13 (18.3%) \|-0.84 (4.38) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) \|-1.88 (5.89) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) \|-2.77 (5.48) | n= 4 ( 5.9%) \|-3.25 (5.38) | 0.08 [-1.10 ; 1.27] |
| Week 111 | n= 7 ( 9.9%) \|-2.86 (5.61) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) \|-1.75 (5.85) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 7 ( 9.9%) \|-1.00 (6.56) | n= 5 ( 7.4%) \|-3.00 (3.94) | 0.33 [-0.89 ; 1.54] |
| Week 117 | n= 7 ( 9.9%) \| 0.29 (4.75) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 ( 9.9%) \|-2.43 (6.63) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) \|-1.90 (6.38) | n= 1 ( 1.5%) \|-10.18 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 2.8%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) \| 2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) \| 0.00 (2.83) | n= 1 ( 1.5%) \|-15.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) \| 1.09 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.4%) \| 4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.4%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.4%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.4%) \| 6.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) \|-0.75 (4.33) | n= 16 (23.5%) \|-2.38 (5.75) | 0.29 [-0.58 ; 1.17] |
| Week 202 | n= 2 ( 2.8%) \|-5.00 (9.90) | n= 11 (16.2%) \| 0.36 (5.55) | -0.82 [-2.43 ; 0.79] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:49:28

TABLE 7.5.1: PRO Analysis: FKSI-19: Disease Related Symptoms Physical Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| Nr subjects used | n=69 | n=67 | | |
| Week 7 | -3.26 (0.70) [-4.65 ;-1.88] | -3.07 (0.71) [-4.48 ;-1.67] | -0.19 (0.95) [-2.07 ; 1.68] | -0.03 [-0.39 ; 0.32] |
| Week 13 | -2.40 (0.69) [-3.78 ;-1.03] | -3.64 (0.72) [-5.06 ;-2.21] | 1.23 (0.95) [-0.65 ; 3.11] | 0.23 [-0.14 ; 0.60] |
| Week 19 | -1.86 (0.57) [-2.99 ;-0.72] | -2.98 (0.60) [-4.16 ;-1.80] | 1.12 (0.77) [-0.39 ; 2.64] | 0.26 [-0.12 ; 0.63] |
| Week 25 | -1.60 (0.61) [-2.80 ;-0.39] | -2.09 (0.65) [-3.37 ;-0.80] | 0.49 (0.83) [-1.16 ; 2.14] | 0.11 [-0.28 ; 0.49] |
| Week 31 | -2.13 (0.65) [-3.42 ;-0.85] | -2.06 (0.71) [-3.46 ;-0.66] | -0.07 (0.91) [-1.88 ; 1.73] | -0.02 [-0.42 ; 0.39] |
| Week 37 | -1.59 (0.63) [-2.84 ;-0.35] | -2.33 (0.66) [-3.64 ;-1.02] | 0.74 (0.86) [-0.96 ; 2.44] | 0.17 [-0.24 ; 0.57] |
| Week 43 | -2.12 (0.66) [-3.43 ;-0.81] | -2.50 (0.73) [-3.95 ;-1.06] | 0.38 (0.94) [-1.47 ; 2.23] | 0.08 [-0.33 ; 0.49] |
| Week 49 | -1.96 (0.60) [-3.14 ;-0.77] | -1.97 (0.69) [-3.34 ;-0.59] | 0.01 (0.87) [-1.71 ; 1.73] | 0.00 [-0.43 ; 0.43] |
| Week 55 | -2.13 (0.66) [-3.43 ;-0.83] | -2.32 (0.74) [-3.79 ;-0.85] | 0.19 (0.94) [-1.68 ; 2.06] | 0.04 [-0.39 ; 0.47] |
| Week 61 | -1.81 (0.61) [-3.01 ;-0.61] | -2.51 (0.73) [-3.96 ;-1.07] | 0.70 (0.90) [-1.09 ; 2.50] | 0.17 [-0.29 ; 0.63] |
| Week 67 | -1.79 (0.64) [-3.06 ;-0.51] | -2.27 (0.77) [-3.81 ;-0.74] | 0.49 (0.96) [-1.43 ; 2.40] | 0.11 [-0.35 ; 0.58] |
| Week 73 | -1.75 (0.77) [-3.28 ;-0.21] | -3.55 (0.89) [-5.32 ;-1.78] | 1.80 (1.15) [-0.47 ; 4.08] | 0.38 [-0.12 ; 0.89] |
| Week 79 | -1.79 (0.94) [-3.66 ; 0.08] | -2.46 (1.08) [-4.61 ;-0.31] | 0.67 (1.41) [-2.13 ; 3.47] | 0.13 [-0.41 ; 0.66] |
| Week 85 | -1.85 (0.78) [-3.40 ;-0.30] | -2.25 (0.90) [-4.05 ;-0.45] | 0.40 (1.16) [-1.92 ; 2.73] | 0.10 [-0.48 ; 0.68] |
| Week 91 | -1.99 (0.96) [-3.91 ;-0.08] | -2.29 (1.13) [-4.55 ;-0.03] | 0.30 (1.46) [-2.63 ; 3.22] | 0.06 [-0.56 ; 0.68] |
| Week 97 | -1.86 (0.94) [-3.76 ; 0.03] | -1.52 (1.28) [-4.11 ; 1.07] | -0.34 (1.57) [-3.51 ; 2.83] | -0.08 [-0.83 ; 0.67] |
| Overall post-baseline period estimate | -1.99 (0.38) [-2.75 ;-1.24] | -2.49 (0.43) [-3.34 ;-1.64] | 0.49 (0.49) [-0.48 ; 1.47] | 0.15 [-0.19 ; 0.49] |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit, and PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm, and uses a Heterogenous Autoregressive (ARH(1)) covariance structure.
CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Er
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:49:28

TABLE 7.6.1: PRO Analysis: FKSI-19: Disease Related Symptoms Physical Score and Emotional Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| subtit | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| N subjects | N=71 | N=68 |
| Subjects with Baseline Value | 69 (97.2%) | 67 (98.5%) |
| Subjects with at least 1 Post-Baseline Value | 71 (100.0%) | 66 (97.1%) |
| Subjects with Baseline Value and at least 1 Post-Baseline Value | 69 (97.2%) | 65 (95.6%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:51:10

TABLE 7.6.1: PRO Analysis: FKSI-19: Disease Related Symptoms Physical Score and Emotional Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Baseline | n= 69 (97.2%) \| 42.52 (6.04) | n= 67 (98.5%) \| 42.23 (6.12) | 0.05 [-0.29 ; 0.38] |
| Week 3 | n= 66 (93.0%) \| 43.16 (5.47) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 62 (87.3%) \| 42.32 (6.31) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 64 (90.1%) \| 40.96 (6.16) | n= 64 (94.1%) \| 40.88 (6.64) | 0.01 [-0.33 ; 0.36] |
| Week 9 | n= 60 (84.5%) \| 42.28 (6.06) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 61 (85.9%) \| 41.69 (6.01) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 60 (84.5%) \| 42.00 (6.17) | n= 55 (80.9%) \| 41.25 (5.70) | 0.12 [-0.24 ; 0.49] |
| Week 15 | n= 54 (76.1%) \| 42.34 (5.75) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 63 (88.7%) \| 42.31 (6.44) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 57 (80.3%) \| 43.06 (4.82) | n= 54 (79.4%) \| 41.83 (5.55) | 0.24 [-0.14 ; 0.61] |
| Week 21 | n= 59 (83.1%) \| 42.58 (5.92) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 56 (78.9%) \| 41.77 (5.61) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 58 (81.7%) \| 43.16 (5.61) | n= 49 (72.1%) \| 42.82 (5.58) | 0.06 [-0.32 ; 0.44] |
| Week 27 | n= 56 (78.9%) \| 44.00 (5.60) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 52 (73.2%) \| 43.42 (5.54) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \| 42.91 (6.06) | n= 42 (61.8%) \| 42.52 (5.94) | 0.06 [-0.34 ; 0.47] |
| Week 33 | n= 56 (78.9%) \| 42.77 (6.15) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 54 (76.1%) \| 42.57 (6.99) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 48 (67.6%) \| 43.25 (6.44) | n= 47 (69.1%) \| 42.60 (4.85) | 0.11 [-0.29 ; 0.52] |
| Week 39 | n= 52 (73.2%) \| 43.69 (5.37) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 52 (73.2%) \| 43.46 (5.77) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 52 (73.2%) \| 42.96 (5.88) | n= 42 (61.8%) \| 42.01 (5.70) | 0.16 [-0.25 ; 0.57] |
| Week 45 | n= 48 (67.6%) \| 42.25 (6.11) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 51 (71.8%) \| 43.09 (6.17) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 52 (73.2%) \| 43.05 (6.07) | n= 36 (52.9%) \| 42.30 (6.09) | 0.12 [-0.31 ; 0.55] |
| Week 51 | n= 51 (71.8%) \| 42.39 (6.28) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 52 (73.2%) \| 42.76 (6.00) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 46 (64.8%) \| 42.68 (6.29) | n= 38 (55.9%) \| 41.63 (5.27) | 0.18 [-0.25 ; 0.61] |
| Week 57 | n= 48 (67.6%) \| 42.90 (6.22) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 46 (64.8%) \| 42.86 (6.36) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \| 43.45 (5.78) | n= 31 (45.6%) \| 41.26 (5.77) | 0.38 [-0.08 ; 0.83] |
| Week 63 | n= 42 (59.2%) \| 42.56 (6.64) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 43 (60.6%) \| 42.11 (7.21) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \| 43.36 (5.75) | n= 30 (44.1%) \| 41.80 (5.01) | 0.28 [-0.19 ; 0.75] |
| Week 69 | n= 38 (53.5%) \| 41.89 (7.55) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 38 (53.5%) \| 42.92 (6.68) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 35 (49.3%) \| 43.72 (6.18) | n= 28 (41.2%) \| 40.03 (5.52) | 0.62 [ 0.11 ; 1.13] |
| Week 75 | n= 35 (49.3%) \| 43.94 (5.55) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \| 43.30 (5.66) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \| 42.59 (8.61) | n= 25 (36.8%) \| 41.40 (4.62) | 0.16 [-0.37 ; 0.70] |
| Week 81 | n= 29 (40.8%) \| 43.31 (5.97) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \| 43.05 (6.19) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \| 43.70 (5.87) | n= 21 (30.9%) \| 42.71 (5.45) | 0.17 [-0.41 ; 0.75] |
| Week 87 | n= 24 (33.8%) \| 41.58 (6.76) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \| 42.30 (5.78) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | | Sunitinib | | Hedge G difference [95% CI] |
|---|---|---|---|---|---|
| Week 91 | n= 24 (33.8%) | 41.30 (7.08) | n= 18 (26.5%) | 42.78 (5.96) | -0.22 [-0.84 ; 0.40] |
| Week 93 | n= 23 (32.4%) | 42.13 (6.28) | | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 22 (31.0%) | 41.48 (6.45) | | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) | 41.48 (6.62) | n= 11 (16.2%) | 43.67 (6.01) | -0.33 [-1.08 ; 0.41] |
| Week 99 | n= 17 (23.9%) | 40.94 (7.27) | | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) | 42.43 (5.50) | | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) | 42.37 (5.22) | n= 10 (14.7%) | 42.60 (5.27) | -0.04 [-0.86 ; 0.77] |
| Week 105 | n= 13 (18.3%) | 41.00 (4.97) | | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) | 41.88 (4.97) | | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) | 39.04 (6.03) | n= 5 ( 7.4%) | 41.40 (8.11) | -0.33 [-1.43 ; 0.77] |
| Week 111 | n= 7 ( 9.9%) | 39.43 (3.69) | | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) | 40.84 (5.60) | | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 7 ( 9.9%) | 41.86 (5.76) | n= 5 ( 7.4%) | 44.00 (4.00) | -0.39 [-1.60 ; 0.83] |
| Week 117 | n= 7 ( 9.9%) | 42.86 (3.08) | | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 ( 9.9%) | 39.43 (6.88) | | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) | 40.96 (6.30) | n= 1 ( 1.5%) | 37.92 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 2.8%) | 39.42 (3.65) | | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) | 41.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) | 43.50 (6.36) | n= 1 ( 1.5%) | 33.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) | 37.92 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.4%) | 43.33 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.4%) | 36.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.4%) | 40.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.4%) | 43.73 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.4%) | 37.00 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) | 36.83 ( / ) | | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) | 43.00 (5.21) | n= 16 (23.5%) | 39.56 (7.09) | 0.51 [-0.37 ; 1.39] |
| Week 202 | n= 2 ( 2.8%) | 34.00 (9.90) | n= 11 (16.2%) | 44.55 (4.61) | -1.85 [-3.61 ;-0.08] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:51:10

TABLE 7.6.1: PRO Analysis: FKSI-19: Disease Related Symptoms Physical Score and Emotional Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Week 3 | n= 65 (91.5%) \| 0.44 (3.61) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 60 (84.5%) \|-0.44 (4.74) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 62 (87.3%) \|-1.32 (5.67) | n= 63 (92.6%) \|-1.16 (5.26) | -0.03 [-0.38 ; 0.32] |
| Week 9 | n= 59 (83.1%) \|-1.08 (5.37) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 60 (84.5%) \|-1.05 (5.23) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 59 (83.1%) \|-0.86 (5.68) | n= 55 (80.9%) \|-2.01 (5.39) | 0.21 [-0.16 ; 0.58] |
| Week 15 | n= 54 (76.1%) \|-0.43 (5.62) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 62 (87.3%) \|-0.58 (5.64) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 56 (78.9%) \|-0.36 (5.09) | n= 53 (77.9%) \|-1.05 (5.66) | 0.13 [-0.25 ; 0.51] |
| Week 21 | n= 59 (83.1%) \|-0.40 (5.68) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 56 (78.9%) \|-0.86 (4.90) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 57 (80.3%) \|-0.10 (5.42) | n= 48 (70.6%) \|-0.58 (5.81) | 0.08 [-0.30 ; 0.47] |
| Week 27 | n= 55 (77.5%) \| 0.12 (5.47) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 52 (73.2%) \| 0.10 (5.57) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \|-0.60 (5.67) | n= 42 (61.8%) \|-0.41 (4.72) | -0.04 [-0.44 ; 0.37] |
| Week 33 | n= 56 (78.9%) \|-0.48 (5.28) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 53 (74.6%) \|-0.88 (5.60) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 48 (67.6%) \| 0.07 (5.19) | n= 46 (67.6%) \|-0.37 (4.39) | 0.09 [-0.32 ; 0.50] |
| Week 39 | n= 51 (71.8%) \| 0.22 (5.05) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 52 (73.2%) \|-0.42 (5.55) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 51 (71.8%) \|-0.62 (6.05) | n= 41 (60.3%) \|-1.15 (4.39) | 0.10 [-0.32 ; 0.51] |
| Week 45 | n= 48 (67.6%) \|-1.03 (6.22) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 51 (71.8%) \|-0.77 (5.55) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 52 (73.2%) \|-0.33 (5.04) | n= 35 (51.5%) \|-0.90 (4.85) | 0.11 [-0.32 ; 0.55] |
| Week 51 | n= 51 (71.8%) \|-0.72 (5.72) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 52 (73.2%) \|-0.54 (5.36) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 46 (64.8%) \|-0.83 (5.40) | n= 37 (54.4%) \|-1.21 (4.63) | 0.07 [-0.36 ; 0.51] |
| Week 57 | n= 48 (67.6%) \|-0.30 (5.87) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 46 (64.8%) \|-0.22 (6.07) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \|-0.17 (5.44) | n= 30 (44.1%) \|-1.18 (4.74) | 0.19 [-0.27 ; 0.65] |
| Week 63 | n= 42 (59.2%) \|-0.06 (5.85) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 43 (60.6%) \|-0.46 (6.70) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \| 0.17 (5.67) | n= 29 (42.6%) \|-0.67 (4.82) | 0.15 [-0.32 ; 0.63] |
| Week 69 | n= 38 (53.5%) \|-1.57 (7.39) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 38 (53.5%) \|-0.42 (6.58) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 35 (49.3%) \| 0.63 (6.61) | n= 28 (41.2%) \|-1.88 (5.23) | 0.41 [-0.10 ; 0.92] |
| Week 75 | n= 35 (49.3%) \| 0.65 (6.08) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \| 0.78 (6.21) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \| 0.26 (8.16) | n= 24 (35.3%) \| 0.01 (4.99) | 0.04 [-0.50 ; 0.57] |
| Week 81 | n= 29 (40.8%) \| 0.62 (5.30) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \| 0.50 (6.71) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \| 0.70 (5.61) | n= 20 (29.4%) \| 0.00 (5.40) | 0.13 [-0.46 ; 0.71] |
| Week 87 | n= 24 (33.8%) \|-0.46 (6.67) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \| 0.18 (5.85) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 24 (33.8%) \|-1.62 (5.71) | n= 17 (25.0%) \|-0.98 (8.63) | -0.09 [-0.72 ; 0.54] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 23 (32.4%) \|-0.87 (5.45) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 22 (31.0%) \|-1.11 (6.16) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) \|-1.09 (6.08) | n= 10 (14.7%) \|-0.36 (4.95) | -0.12 [-0.89 ; 0.64] |
| Week 99 | n= 17 (23.9%) \|-1.18 (6.54) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) \|-1.07 (5.41) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) \|-0.23 (4.62) | n= 9 (13.2%) \|-0.67 (4.50) | 0.09 [-0.75 ; 0.94] |
| Week 105 | n= 13 (18.3%) \|-0.69 (4.55) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) \|-2.00 (6.39) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) \|-2.69 (5.99) | n= 4 ( 5.9%) \|-2.50 (4.20) | -0.03 [-1.22 ; 1.16] |
| Week 111 | n= 7 ( 9.9%) \|-3.29 (5.71) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) \|-1.66 (6.29) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 7 ( 9.9%) \|-0.57 (6.75) | n= 5 ( 7.4%) \|-2.80 (3.56) | 0.36 [-0.85 ; 1.58] |
| Week 117 | n= 7 ( 9.9%) \| 0.43 (5.03) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 ( 9.9%) \|-2.29 (6.29) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) \|-1.67 (6.59) | n= 1 ( 1.5%) \|-8.08 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 2.8%) \|-0.08 (1.30) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) \| 5.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) \| 1.50 (2.12) | n= 1 ( 1.5%) \|-13.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) \| 1.92 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.4%) \| 7.33 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.4%) \| 4.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.4%) \| 7.73 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.4%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) \| 0.83 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) \| 0.38 (4.47) | n= 16 (23.5%) \|-2.38 (6.40) | 0.45 [-0.42 ; 1.33] |
| Week 202 | n= 2 ( 2.8%) \|-6.00 (9.90) | n= 11 (16.2%) \| 1.00 (5.90) | -1.02 [-2.66 ; 0.61] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:51:10

TABLE 7.6.1: PRO Analysis: FKSI-19: Disease Related Symptoms Physical Score and Emotional Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| Nr subjects used | n=69 | n=67 | | |
| Week 7 | -2.85 (0.75) [-4.33 ;-1.36] | -2.61 (0.76) [-4.11 ;-1.10] | -0.24 (1.01) [-2.24 ; 1.76] | -0.04 [-0.39 ; 0.31] |
| Week 13 | -1.93 (0.75) [-3.41 ;-0.46] | -3.24 (0.78) [-4.78 ;-1.71] | 1.31 (1.02) [-0.71 ; 3.33] | 0.23 [-0.14 ; 0.60] |
| Week 19 | -1.33 (0.63) [-2.56 ;-0.09] | -2.57 (0.65) [-3.86 ;-1.29] | 1.25 (0.83) [-0.40 ; 2.89] | 0.26 [-0.12 ; 0.64] |
| Week 25 | -0.97 (0.67) [-2.30 ; 0.36] | -1.79 (0.72) [-3.21 ;-0.37] | 0.82 (0.92) [-1.00 ; 2.64] | 0.16 [-0.22 ; 0.55] |
| Week 31 | -1.59 (0.70) [-2.98 ;-0.20] | -1.52 (0.77) [-3.03 ;-0.00] | -0.08 (0.98) [-2.02 ; 1.86] | -0.01 [-0.42 ; 0.39] |
| Week 37 | -0.99 (0.67) [-2.30 ; 0.33] | -1.75 (0.70) [-3.14 ;-0.36] | 0.76 (0.90) [-1.03 ; 2.56] | 0.16 [-0.24 ; 0.57] |
| Week 43 | -1.44 (0.70) [-2.82 ;-0.07] | -1.86 (0.77) [-3.37 ;-0.34] | 0.42 (0.98) [-1.52 ; 2.36] | 0.08 [-0.33 ; 0.49] |
| Week 49 | -1.37 (0.65) [-2.65 ;-0.09] | -1.43 (0.75) [-2.91 ; 0.05] | 0.06 (0.93) [-1.79 ; 1.90] | 0.01 [-0.42 ; 0.44] |
| Week 55 | -1.46 (0.71) [-2.86 ;-0.06] | -1.88 (0.80) [-3.47 ;-0.30] | 0.42 (1.02) [-1.60 ; 2.44] | 0.09 [-0.35 ; 0.52] |
| Week 61 | -1.16 (0.65) [-2.44 ; 0.12] | -1.83 (0.77) [-3.37 ;-0.30] | 0.67 (0.96) [-1.23 ; 2.57] | 0.15 [-0.31 ; 0.61] |
| Week 67 | -1.08 (0.67) [-2.40 ; 0.23] | -1.69 (0.80) [-3.28 ;-0.11] | 0.61 (0.99) [-1.36 ; 2.58] | 0.14 [-0.33 ; 0.61] |
| Week 73 | -1.14 (0.80) [-2.74 ; 0.45] | -2.94 (0.92) [-4.77 ;-1.11] | 1.79 (1.18) [-0.56 ; 4.15] | 0.37 [-0.13 ; 0.87] |
| Week 79 | -1.29 (0.97) [-3.22 ; 0.63] | -1.63 (1.11) [-3.84 ; 0.59] | 0.34 (1.45) [-2.54 ; 3.21] | 0.06 [-0.47 ; 0.59] |
| Week 85 | -1.49 (0.80) [-3.08 ; 0.09] | -1.20 (0.93) [-3.04 ; 0.65] | -0.30 (1.19) [-2.67 ; 2.07] | -0.07 [-0.65 ; 0.51] |
| Week 91 | -1.78 (1.03) [-3.84 ; 0.29] | -1.84 (1.22) [-4.27 ; 0.60] | 0.06 (1.57) [-3.09 ; 3.20] | 0.01 [-0.61 ; 0.63] |
| Week 97 | -1.62 (1.03) [-3.70 ; 0.46] | -1.14 (1.40) [-3.97 ; 1.68] | -0.48 (1.72) [-3.95 ; 2.99] | -0.10 [-0.85 ; 0.65] |
| Overall post-baseline period estimate | -1.47 (0.42) [-2.29 ;-0.65] | -1.93 (0.47) [-2.86 ;-1.01] | 0.46 (0.54) [-0.60 ; 1.53] | 0.13 [-0.21 ; 0.47] |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit, and PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm, and uses a Heterogenous Autoregressive (ARH(1)) covariance structure.
CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Er
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:51:10

TABLE 7.7.1: PRO Analysis: FKSI-19: Treatment Side Effects Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| subtit | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| N subjects | N=71 | N=68 |
| Subjects with Baseline Value | 69 (97.2%) | 67 (98.5%) |
| Subjects with at least 1 Post-Baseline Value | 71 (100.0%) | 66 (97.1%) |
| Subjects with Baseline Value and at least 1 Post-Baseline Value | 69 (97.2%) | 65 (95.6%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:52:51

TABLE 7.7.1: PRO Analysis: FKSI-19: Treatment Side Effects Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Baseline | n= 69 (97.2%) \| 11.38 (1.22) | n= 67 (98.5%) \| 11.36 (1.12) | 0.02 [-0.32 ; 0.36] |
| Week 3 | n= 66 (93.0%) \| 11.26 (1.10) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 63 (88.7%) \| 10.63 (1.55) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 63 (88.7%) \| 10.04 (1.91) | n= 64 (94.1%) \| 10.31 (1.51) | -0.16 [-0.51 ; 0.19] |
| Week 9 | n= 60 (84.5%) \| 10.06 (1.90) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 60 (84.5%) \| 9.78 (2.27) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 59 (83.1%) \| 9.92 (1.98) | n= 55 (80.9%) \| 10.02 (1.65) | -0.06 [-0.42 ; 0.31] |
| Week 15 | n= 53 (74.6%) \| 10.10 (1.92) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 63 (88.7%) \| 9.92 (1.79) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 57 (80.3%) \| 10.00 (2.03) | n= 54 (79.4%) \| 9.46 (1.93) | 0.27 [-0.11 ; 0.64] |
| Week 21 | n= 59 (83.1%) \| 9.85 (1.92) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 56 (78.9%) \| 10.13 (1.82) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 58 (81.7%) \| 10.03 (1.72) | n= 49 (72.1%) \| 9.82 (2.04) | 0.12 [-0.27 ; 0.50] |
| Week 27 | n= 56 (78.9%) \| 9.99 (2.01) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 52 (73.2%) \| 9.88 (1.84) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \| 10.13 (1.76) | n= 42 (61.8%) \| 9.79 (2.14) | 0.18 [-0.23 ; 0.58] |
| Week 33 | n= 56 (78.9%) \| 10.07 (1.64) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 54 (76.1%) \| 10.04 (1.74) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 48 (67.6%) \| 10.23 (1.72) | n= 47 (69.1%) \| 10.14 (1.99) | 0.05 [-0.36 ; 0.45] |
| Week 39 | n= 52 (73.2%) \| 10.44 (1.59) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 52 (73.2%) \| 10.04 (1.56) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 52 (73.2%) \| 10.12 (1.60) | n= 42 (61.8%) \| 9.90 (2.06) | 0.11 [-0.29 ; 0.52] |
| Week 45 | n= 48 (67.6%) \| 9.94 (2.09) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 51 (71.8%) \| 10.18 (1.58) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 52 (73.2%) \| 10.06 (1.69) | n= 36 (52.9%) \| 9.89 (1.97) | 0.09 [-0.33 ; 0.52] |
| Week 51 | n= 51 (71.8%) \| 9.78 (1.96) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 52 (73.2%) \| 10.12 (1.73) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 46 (64.8%) \| 9.97 (1.84) | n= 38 (55.9%) \| 9.82 (2.05) | 0.08 [-0.35 ; 0.51] |
| Week 57 | n= 48 (67.6%) \| 9.96 (1.80) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 46 (64.8%) \| 10.37 (1.62) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \| 10.27 (1.67) | n= 31 (45.6%) \| 9.94 (1.71) | 0.20 [-0.26 ; 0.65] |
| Week 63 | n= 42 (59.2%) \| 10.10 (1.69) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 43 (60.6%) \| 9.99 (1.90) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \| 10.24 (1.96) | n= 30 (44.1%) \| 10.00 (1.55) | 0.13 [-0.34 ; 0.60] |
| Week 69 | n= 38 (53.5%) \| 9.84 (2.21) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 38 (53.5%) \| 10.00 (2.22) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 35 (49.3%) \| 10.23 (2.38) | n= 28 (41.2%) \| 9.80 (1.79) | 0.20 [-0.31 ; 0.70] |
| Week 75 | n= 35 (49.3%) \| 10.29 (1.87) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \| 10.25 (1.83) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \| 10.32 (1.85) | n= 25 (36.8%) \| 10.00 (1.58) | 0.18 [-0.35 ; 0.72] |
| Week 81 | n= 29 (40.8%) \| 10.52 (1.35) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \| 10.33 (1.78) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \| 10.63 (1.57) | n= 21 (30.9%) \| 10.19 (1.66) | 0.27 [-0.31 ; 0.85] |
| Week 87 | n= 24 (33.8%) \| 10.13 (1.75) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \| 10.32 (1.52) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 24 (33.8%) \| 10.17 (1.40) | n= 18 (26.5%) \| 10.28 (1.99) | -0.06 [-0.68 ; 0.55] |
| Week 93 | n= 23 (32.4%) \| 10.26 (1.42) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 22 (31.0%) \| 10.14 (1.42) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) \| 9.71 (1.45) | n= 11 (16.2%) \| 10.36 (1.21) | -0.46 [-1.21 ; 0.29] |
| Week 99 | n= 17 (23.9%) \| 10.29 (1.45) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) \| 10.21 (1.19) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) \| 10.03 (1.67) | n= 10 (14.7%) \| 9.70 (2.00) | 0.18 [-0.64 ; 1.00] |
| Week 105 | n= 13 (18.3%) \| 10.15 (1.63) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) \| 9.63 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) \| 9.45 (1.37) | n= 5 ( 7.4%) \| 9.20 (3.83) | 0.10 [-0.99 ; 1.20] |
| Week 111 | n= 7 ( 9.9%) \| 9.29 (1.50) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) \| 10.13 (0.99) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 7 ( 9.9%) \| 9.71 (1.70) | n= 5 ( 7.4%) \| 10.00 (3.08) | -0.11 [-1.32 ; 1.09] |
| Week 117 | n= 7 ( 9.9%) \| 10.00 (1.63) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 ( 9.9%) \| 10.14 (1.95) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) \| 9.63 (2.07) | n= 1 ( 1.5%) \| 6.00 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 2.8%) \| 12.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) \| 7.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) \| 10.50 (2.12) | n= 1 ( 1.5%) \| 6.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) \| 12.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.4%) \| 10.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.4%) \| 12.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.4%) \| 12.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.4%) \| 12.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.4%) \| 12.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) \| 12.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) \| 11.38 (1.06) | n= 16 (23.5%) \| 9.94 (1.77) | 0.88 [-0.03 ; 1.79] |
| Week 202 | n= 2 ( 2.8%) \| 9.00 (1.41) | n= 11 (16.2%) \| 10.82 (2.44) | -0.71 [-2.32 ; 0.89] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:52:51

TABLE 7.7.1: PRO Analysis: FKSI-19: Treatment Side Effects Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Week 3 | n= 65 (91.5%) \|-0.19 (1.34) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 61 (85.9%) \|-0.90 (1.72) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 61 (85.9%) \|-1.39 (1.93) | n= 63 (92.6%) \|-1.03 (1.78) | -0.19 [-0.55 ; 0.16] |
| Week 9 | n= 59 (83.1%) \|-1.49 (2.05) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 59 (83.1%) \|-1.88 (2.31) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 58 (81.7%) \|-1.51 (2.04) | n= 55 (80.9%) \|-1.45 (1.92) | -0.03 [-0.40 ; 0.34] |
| Week 15 | n= 53 (74.6%) \|-1.39 (2.07) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 62 (87.3%) \|-1.59 (1.91) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 56 (78.9%) \|-1.58 (1.88) | n= 53 (77.9%) \|-1.92 (2.04) | 0.17 [-0.20 ; 0.55] |
| Week 21 | n= 59 (83.1%) \|-1.64 (2.00) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 56 (78.9%) \|-1.35 (1.87) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 57 (80.3%) \|-1.49 (1.70) | n= 48 (70.6%) \|-1.60 (2.48) | 0.05 [-0.33 ; 0.44] |
| Week 27 | n= 55 (77.5%) \|-1.62 (2.09) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 52 (73.2%) \|-1.72 (1.95) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \|-1.49 (1.78) | n= 42 (61.8%) \|-1.74 (2.36) | 0.12 [-0.29 ; 0.53] |
| Week 33 | n= 56 (78.9%) \|-1.46 (1.70) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 53 (74.6%) \|-1.58 (1.80) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 48 (67.6%) \|-1.28 (1.70) | n= 46 (67.6%) \|-1.18 (1.92) | -0.05 [-0.46 ; 0.35] |
| Week 39 | n= 51 (71.8%) \|-1.19 (1.66) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 52 (73.2%) \|-1.56 (1.60) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 51 (71.8%) \|-1.50 (1.63) | n= 41 (60.3%) \|-1.44 (2.18) | -0.03 [-0.45 ; 0.38] |
| Week 45 | n= 48 (67.6%) \|-1.59 (2.09) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 51 (71.8%) \|-1.44 (1.72) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 52 (73.2%) \|-1.52 (1.70) | n= 35 (51.5%) \|-1.43 (2.15) | -0.05 [-0.48 ; 0.38] |
| Week 51 | n= 51 (71.8%) \|-1.75 (2.07) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 52 (73.2%) \|-1.43 (1.90) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 46 (64.8%) \|-1.57 (1.90) | n= 37 (54.4%) \|-1.59 (2.02) | 0.01 [-0.42 ; 0.45] |
| Week 57 | n= 48 (67.6%) \|-1.55 (1.91) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 46 (64.8%) \|-1.18 (1.65) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \|-1.26 (1.63) | n= 30 (44.1%) \|-1.60 (1.90) | 0.19 [-0.27 ; 0.65] |
| Week 63 | n= 42 (59.2%) \|-1.46 (1.72) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 43 (60.6%) \|-1.58 (1.92) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \|-1.32 (1.96) | n= 29 (42.6%) \|-1.38 (1.52) | 0.03 [-0.44 ; 0.51] |
| Week 69 | n= 38 (53.5%) \|-1.82 (2.20) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 38 (53.5%) \|-1.49 (2.14) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 35 (49.3%) \|-1.30 (2.46) | n= 28 (41.2%) \|-1.63 (1.91) | 0.14 [-0.36 ; 0.65] |
| Week 75 | n= 35 (49.3%) \|-1.16 (1.79) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \|-1.30 (1.60) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \|-1.15 (1.60) | n= 24 (35.3%) \|-1.33 (1.76) | 0.11 [-0.43 ; 0.65] |
| Week 81 | n= 29 (40.8%) \|-1.12 (1.03) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \|-1.17 (1.62) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \|-1.00 (1.54) | n= 20 (29.4%) \|-1.45 (1.88) | 0.26 [-0.33 ; 0.85] |
| Week 87 | n= 24 (33.8%) \|-1.44 (1.62) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \|-1.24 (1.51) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 24 (33.8%) \|-1.38 (1.58) | n= 17 (25.0%) \|-1.35 (2.18) | -0.01 [-0.64 ; 0.62] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 23 (32.4%) \|-1.26 (1.32) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 22 (31.0%) \|-1.36 (1.53) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) \|-1.76 (1.61) | n= 10 (14.7%) \|-1.40 (1.07) | -0.24 [-1.01 ; 0.53] |
| Week 99 | n= 17 (23.9%) \|-1.12 (1.36) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) \|-1.29 (1.33) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) \|-1.43 (1.61) | n= 9 (13.2%) \|-1.44 (1.33) | 0.01 [-0.84 ; 0.85] |
| Week 105 | n= 13 (18.3%) \|-1.38 (1.39) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) \|-2.00 (1.41) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) \|-1.82 (1.60) | n= 4 ( 5.9%) \|-1.25 (1.89) | -0.32 [-1.51 ; 0.87] |
| Week 111 | n= 7 ( 9.9%) \|-2.00 (1.53) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) \|-1.25 (1.16) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 7 ( 9.9%) \|-1.57 (1.81) | n= 5 ( 7.4%) \|-1.60 (3.05) | 0.01 [-1.19 ; 1.22] |
| Week 117 | n= 7 ( 9.9%) \|-1.57 (1.51) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 ( 9.9%) \|-1.14 (1.21) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) \|-1.75 (1.75) | n= 1 ( 1.5%) \|-6.00 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 2.8%) \| 0.00 (0.00) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) \|-4.50 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) \|-1.50 (2.12) | n= 1 ( 1.5%) \|-6.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.4%) \|-2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 133 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) \| 0.75 (1.28) | n= 16 (23.5%) \|-1.75 (2.11) | 1.28 [ 0.33 ; 2.23] |
| Week 202 | n= 2 ( 2.8%) \|-2.00 (0.00) | n= 11 (16.2%) \|-0.73 (2.65) | -0.47 [-2.06 ; 1.12] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:52:51

TABLE 7.7.1: PRO Analysis: FKSI-19: Treatment Side Effects Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| Nr subjects used | n=69 | n=67 | | |
| Week 7 | -1.74 (0.24) [-2.22 ;-1.26] | -1.38 (0.25) [-1.86 ;-0.90] | -0.36 (0.33) [-1.00 ; 0.28] | -0.19 [-0.54 ; 0.17] |
| Week 13 | -1.79 (0.26) [-2.30 ;-1.28] | -1.77 (0.27) [-2.30 ;-1.24] | -0.02 (0.35) [-0.71 ; 0.68] | -0.01 [-0.38 ; 0.36] |
| Week 19 | -1.81 (0.24) [-2.29 ;-1.33] | -2.26 (0.25) [-2.76 ;-1.76] | 0.45 (0.33) [-0.21 ; 1.11] | 0.24 [-0.13 ; 0.62] |
| Week 25 | -1.75 (0.26) [-2.25 ;-1.24] | -1.91 (0.27) [-2.45 ;-1.37] | 0.16 (0.36) [-0.54 ; 0.87] | 0.09 [-0.30 ; 0.47] |
| Week 31 | -1.76 (0.27) [-2.29 ;-1.24] | -1.79 (0.29) [-2.37 ;-1.22] | 0.03 (0.38) [-0.72 ; 0.78] | 0.02 [-0.39 ; 0.42] |
| Week 37 | -1.54 (0.24) [-2.02 ;-1.06] | -1.67 (0.26) [-2.18 ;-1.17] | 0.13 (0.33) [-0.53 ; 0.79] | 0.08 [-0.33 ; 0.48] |
| Week 43 | -1.79 (0.25) [-2.28 ;-1.30] | -1.84 (0.27) [-2.38 ;-1.31] | 0.05 (0.35) [-0.64 ; 0.75] | 0.03 [-0.38 ; 0.44] |
| Week 49 | -1.78 (0.24) [-2.26 ;-1.29] | -1.70 (0.29) [-2.26 ;-1.14] | -0.08 (0.36) [-0.79 ; 0.63] | -0.05 [-0.47 ; 0.38] |
| Week 55 | -1.95 (0.30) [-2.54 ;-1.37] | -1.87 (0.34) [-2.54 ;-1.21] | -0.08 (0.43) [-0.94 ; 0.78] | -0.04 [-0.47 ; 0.39] |
| Week 61 | -1.59 (0.25) [-2.09 ;-1.10] | -1.81 (0.30) [-2.41 ;-1.22] | 0.22 (0.38) [-0.53 ; 0.97] | 0.13 [-0.33 ; 0.59] |
| Week 67 | -1.53 (0.25) [-2.02 ;-1.04] | -1.68 (0.30) [-2.27 ;-1.09] | 0.15 (0.37) [-0.60 ; 0.89] | 0.09 [-0.38 ; 0.56] |
| Week 73 | -1.78 (0.36) [-2.49 ;-1.07] | -1.80 (0.41) [-2.61 ;-0.98] | 0.02 (0.54) [-1.05 ; 1.08] | 0.01 [-0.49 ; 0.51] |
| Week 79 | -1.45 (0.27) [-1.98 ;-0.92] | -1.66 (0.31) [-2.27 ;-1.05] | 0.21 (0.39) [-0.57 ; 1.00] | 0.14 [-0.39 ; 0.67] |
| Week 85 | -1.43 (0.28) [-1.99 ;-0.88] | -1.83 (0.32) [-2.48 ;-1.19] | 0.40 (0.42) [-0.43 ; 1.23] | 0.27 [-0.31 ; 0.85] |
| Week 91 | -1.40 (0.29) [-1.99 ;-0.82] | -1.69 (0.35) [-2.38 ;-1.00] | 0.29 (0.45) [-0.60 ; 1.18] | 0.20 [-0.43 ; 0.82] |
| Week 97 | -1.89 (0.30) [-2.50 ;-1.29] | -1.78 (0.41) [-2.62 ;-0.95] | -0.11 (0.50) [-1.12 ; 0.91] | -0.08 [-0.83 ; 0.67] |
| Overall post-baseline period estimate | -1.69 (0.14) [-1.96 ;-1.41] | -1.78 (0.16) [-2.09 ;-1.47] | 0.09 (0.18) [-0.27 ; 0.45] | 0.07 [-0.26 ; 0.41] |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit, and PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm, and uses a Heterogenous Autoregressive (ARH(1)) covariance structure.
CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Er
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:52:51

TABLE 7.8.1: PRO Analysis: FKSI-19: Functional Well Being Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| subtit | Nivolumab + Cabozantinib | Sunitinib |
|---|---|---|
| N subjects | N=71 | N=68 |
| Subjects with Baseline Value | 69 (97.2%) | 67 (98.5%) |
| Subjects with at least 1 Post-Baseline Value | 71 (100.0%) | 66 (97.1%) |
| Subjects with Baseline Value and at least 1 Post-Baseline Value | 69 (97.2%) | 65 (95.6%) |

Notes:
PRO: Patient-Reported Outcomes.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:54:34

TABLE 7.8.1: PRO Analysis: FKSI-19: Functional Well Being Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Actual Values and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Baseline | n= 69 (97.2%) \| 8.23 (2.96) | n= 67 (98.5%) \| 7.78 (3.65) | 0.14 [-0.20 ; 0.47] |
| Week 3 | n= 67 (94.4%) \| 8.21 (3.15) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 63 (88.7%) \| 7.51 (3.74) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 64 (90.1%) \| 7.31 (3.24) | n= 64 (94.1%) \| 8.01 (2.92) | -0.22 [-0.57 ; 0.12] |
| Week 9 | n= 61 (85.9%) \| 7.48 (3.01) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 61 (85.9%) \| 6.89 (3.21) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 60 (84.5%) \| 7.28 (3.18) | n= 55 (80.9%) \| 7.55 (2.99) | -0.08 [-0.45 ; 0.28] |
| Week 15 | n= 54 (76.1%) \| 7.51 (3.29) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 63 (88.7%) \| 7.21 (3.39) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 57 (80.3%) \| 7.37 (3.14) | n= 54 (79.4%) \| 7.70 (2.98) | -0.11 [-0.48 ; 0.27] |
| Week 21 | n= 59 (83.1%) \| 7.24 (2.98) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 56 (78.9%) \| 7.11 (3.14) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 58 (81.7%) \| 7.64 (2.96) | n= 49 (72.1%) \| 8.27 (2.90) | -0.21 [-0.60 ; 0.17] |
| Week 27 | n= 56 (78.9%) \| 7.64 (3.00) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 52 (73.2%) \| 7.50 (2.97) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \| 7.46 (2.99) | n= 42 (61.8%) \| 8.33 (2.76) | -0.30 [-0.71 ; 0.11] |
| Week 33 | n= 56 (78.9%) \| 7.36 (3.14) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 54 (76.1%) \| 7.52 (3.07) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 48 (67.6%) \| 7.23 (3.22) | n= 47 (69.1%) \| 8.09 (3.20) | -0.26 [-0.67 ; 0.14] |
| Week 39 | n= 52 (73.2%) \| 7.54 (2.89) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 52 (73.2%) \| 7.55 (3.17) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 52 (73.2%) \| 7.71 (3.00) | n= 42 (61.8%) \| 7.86 (3.03) | -0.05 [-0.46 ; 0.36] |
| Week 45 | n= 48 (67.6%) \| 7.29 (3.25) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 51 (71.8%) \| 7.72 (3.26) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 52 (73.2%) \| 7.69 (2.87) | n= 36 (52.9%) \| 7.74 (2.88) | -0.02 [-0.44 ; 0.41] |
| Week 51 | n= 51 (71.8%) \| 7.27 (2.99) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 52 (73.2%) \| 7.58 (2.86) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 46 (64.8%) \| 7.79 (2.89) | n= 38 (55.9%) \| 7.66 (2.80) | 0.05 [-0.39 ; 0.48] |
| Week 57 | n= 48 (67.6%) \| 7.83 (2.86) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 46 (64.8%) \| 7.62 (2.97) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \| 7.50 (3.25) | n= 31 (45.6%) \| 7.42 (2.50) | 0.03 [-0.43 ; 0.48] |
| Week 63 | n= 42 (59.2%) \| 7.33 (3.03) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 43 (60.6%) \| 7.51 (2.84) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \| 7.89 (2.61) | n= 30 (44.1%) \| 7.70 (2.31) | 0.07 [-0.39 ; 0.54] |
| Week 69 | n= 38 (53.5%) \| 7.21 (3.02) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 38 (53.5%) \| 7.68 (2.94) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 35 (49.3%) \| 7.89 (2.87) | n= 28 (41.2%) \| 6.71 (2.71) | 0.41 [-0.09 ; 0.92] |
| Week 75 | n= 35 (49.3%) \| 8.14 (2.61) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \| 7.25 (2.85) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \| 7.81 (3.02) | n= 25 (36.8%) \| 7.76 (2.39) | 0.02 [-0.51 ; 0.55] |
| Week 81 | n= 29 (40.8%) \| 7.86 (2.76) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \| 7.52 (2.81) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \| 8.19 (2.53) | n= 21 (30.9%) \| 7.33 (2.63) | 0.33 [-0.25 ; 0.91] |
| Week 87 | n= 24 (33.8%) \| 7.25 (2.95) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \| 7.16 (3.17) | [No Data] | [No Data for at least 1 arm] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 91 | n= 24 (33.8%) \| 7.83 (2.84) | n= 18 (26.5%) \| 8.22 (2.37) | -0.14 [-0.76 ; 0.48] |
| Week 93 | n= 23 (32.4%) \| 7.65 (2.90) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 22 (31.0%) \| 7.41 (2.65) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) \| 7.62 (3.01) | n= 11 (16.2%) \| 8.18 (1.60) | -0.21 [-0.95 ; 0.53] |
| Week 99 | n= 17 (23.9%) \| 6.94 (3.17) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) \| 7.36 (2.73) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) \| 6.93 (3.31) | n= 10 (14.7%) \| 7.30 (2.00) | -0.12 [-0.94 ; 0.69] |
| Week 105 | n= 13 (18.3%) \| 6.77 (2.65) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) \| 6.75 (3.24) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) \| 6.64 (2.84) | n= 5 ( 7.4%) \| 6.80 (2.17) | -0.06 [-1.15 ; 1.04] |
| Week 111 | n= 7 ( 9.9%) \| 5.86 (2.48) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) \| 5.88 (3.09) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 7 ( 9.9%) \| 7.14 (3.53) | n= 5 ( 7.4%) \| 7.20 (1.79) | -0.02 [-1.22 ; 1.19] |
| Week 117 | n= 7 ( 9.9%) \| 6.57 (2.82) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 ( 9.9%) \| 6.57 (3.10) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) \| 7.13 (2.80) | n= 1 ( 1.5%) \| 2.00 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 2.8%) \| 5.50 (2.12) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) \| 2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) \| 11.00 (1.41) | n= 1 ( 1.5%) \| 4.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) \| 2.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.4%) \| 10.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) \| 0.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) \| 6.00 (3.63) | n= 16 (23.5%) \| 6.88 (3.96) | -0.22 [-1.09 ; 0.65] |
| Week 202 | n= 2 ( 2.8%) \| 5.00 (2.83) | n= 11 (16.2%) \| 8.82 (2.96) | -1.20 [-2.86 ; 0.45] |

Notes:
Treatment arms reported values are actual values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:54:34

TABLE 7.8.1: PRO Analysis: FKSI-19: Functional Well Being Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| **Change from Baseline and Standardized Differences (Hedge's G) - mean (SD)** | | | |
| N subjects in population | N=71 | N=68 | |
| Week 3 | n= 66 (93.0%) \|-0.08 (2.84) | [No Data] | [No Data for at least 1 arm] |
| Week 5 | n= 61 (85.9%) \|-0.39 (3.06) | [No Data] | [No Data for at least 1 arm] |
| Week 7 | n= 62 (87.3%) \|-0.73 (2.62) | n= 63 (92.6%) \| 0.07 (3.50) | -0.26 [-0.61 ; 0.10] |
| Week 9 | n= 60 (84.5%) \|-0.88 (3.24) | [No Data] | [No Data for at least 1 arm] |
| Week 11 | n= 60 (84.5%) \|-1.08 (3.63) | [No Data] | [No Data for at least 1 arm] |
| Week 13 | n= 59 (83.1%) \|-1.07 (2.90) | n= 55 (80.9%) \|-1.11 (3.90) | 0.01 [-0.36 ; 0.38] |
| Week 15 | n= 54 (76.1%) \|-0.86 (3.45) | [No Data] | [No Data for at least 1 arm] |
| Week 17 | n= 62 (87.3%) \|-1.19 (3.17) | [No Data] | [No Data for at least 1 arm] |
| Week 19 | n= 56 (78.9%) \|-0.98 (2.72) | n= 53 (77.9%) \|-0.83 (3.83) | -0.05 [-0.42 ; 0.33] |
| Week 21 | n= 59 (83.1%) \|-1.08 (2.82) | [No Data] | [No Data for at least 1 arm] |
| Week 23 | n= 56 (78.9%) \|-1.18 (3.06) | [No Data] | [No Data for at least 1 arm] |
| Week 25 | n= 57 (80.3%) \|-0.68 (3.33) | n= 48 (70.6%) \|-0.83 (3.91) | 0.04 [-0.34 ; 0.43] |
| Week 27 | n= 55 (77.5%) \|-0.62 (3.23) | [No Data] | [No Data for at least 1 arm] |
| Week 29 | n= 52 (73.2%) \|-0.85 (2.78) | [No Data] | [No Data for at least 1 arm] |
| Week 31 | n= 54 (76.1%) \|-0.76 (3.30) | n= 42 (61.8%) \|-0.36 (4.37) | -0.10 [-0.51 ; 0.30] |
| Week 33 | n= 56 (78.9%) \|-0.95 (3.08) | [No Data] | [No Data for at least 1 arm] |
| Week 35 | n= 53 (74.6%) \|-0.66 (3.25) | [No Data] | [No Data for at least 1 arm] |
| Week 37 | n= 48 (67.6%) \|-0.90 (2.95) | n= 46 (67.6%) \|-0.87 (4.07) | -0.01 [-0.41 ; 0.40] |
| Week 39 | n= 51 (71.8%) \|-0.98 (2.85) | [No Data] | [No Data for at least 1 arm] |
| Week 41 | n= 52 (73.2%) \|-1.03 (3.53) | [No Data] | [No Data for at least 1 arm] |
| Week 43 | n= 51 (71.8%) \|-0.67 (2.91) | n= 41 (60.3%) \|-1.34 (3.95) | 0.20 [-0.22 ; 0.61] |
| Week 45 | n= 48 (67.6%) \|-1.08 (3.09) | [No Data] | [No Data for at least 1 arm] |
| Week 47 | n= 51 (71.8%) \|-0.77 (3.00) | [No Data] | [No Data for at least 1 arm] |
| Week 49 | n= 52 (73.2%) \|-0.63 (3.26) | n= 35 (51.5%) \|-1.16 (4.10) | 0.14 [-0.29 ; 0.57] |
| Week 51 | n= 51 (71.8%) \|-1.04 (3.19) | [No Data] | [No Data for at least 1 arm] |
| Week 53 | n= 52 (73.2%) \|-0.87 (3.04) | [No Data] | [No Data for at least 1 arm] |
| Week 55 | n= 46 (64.8%) \|-0.55 (3.13) | n= 37 (54.4%) \|-1.30 (3.70) | 0.22 [-0.22 ; 0.65] |
| Week 57 | n= 48 (67.6%) \|-0.83 (2.86) | [No Data] | [No Data for at least 1 arm] |
| Week 59 | n= 46 (64.8%) \|-0.71 (3.19) | [No Data] | [No Data for at least 1 arm] |
| Week 61 | n= 48 (67.6%) \|-0.98 (3.36) | n= 30 (44.1%) \|-1.57 (3.13) | 0.18 [-0.28 ; 0.64] |
| Week 63 | n= 42 (59.2%) \|-1.31 (2.80) | [No Data] | [No Data for at least 1 arm] |
| Week 65 | n= 43 (60.6%) \|-0.63 (3.01) | [No Data] | [No Data for at least 1 arm] |
| Week 67 | n= 44 (62.0%) \|-0.48 (2.95) | n= 29 (42.6%) \|-1.31 (4.06) | 0.24 [-0.23 ; 0.71] |
| Week 69 | n= 38 (53.5%) \|-1.08 (3.10) | [No Data] | [No Data for at least 1 arm] |
| Week 71 | n= 38 (53.5%) \|-0.63 (3.22) | [No Data] | [No Data for at least 1 arm] |
| Week 73 | n= 35 (49.3%) \|-0.40 (3.15) | n= 28 (41.2%) \|-2.11 (4.20) | 0.46 [-0.05 ; 0.97] |
| Week 75 | n= 35 (49.3%) \|-0.40 (2.49) | [No Data] | [No Data for at least 1 arm] |
| Week 77 | n= 32 (45.1%) \|-0.59 (3.75) | [No Data] | [No Data for at least 1 arm] |
| Week 79 | n= 31 (43.7%) \|-0.81 (2.83) | n= 24 (35.3%) \|-0.96 (3.21) | 0.05 [-0.49 ; 0.59] |
| Week 81 | n= 29 (40.8%) \|-0.69 (2.85) | [No Data] | [No Data for at least 1 arm] |
| Week 83 | n= 33 (46.5%) \|-0.79 (3.30) | [No Data] | [No Data for at least 1 arm] |
| Week 85 | n= 27 (38.0%) \|-0.44 (2.69) | n= 20 (29.4%) \|-1.25 (3.80) | 0.25 [-0.34 ; 0.83] |
| Week 87 | n= 24 (33.8%) \|-1.17 (2.93) | [No Data] | [No Data for at least 1 arm] |
| Week 89 | n= 25 (35.2%) \|-1.12 (2.85) | [No Data] | [No Data for at least 1 arm] |
| Week 91 | n= 24 (33.8%) \|-1.00 (2.19) | n= 17 (25.0%) \|-0.59 (4.00) | -0.13 [-0.76 ; 0.50] |

| Study Visit | Nivolumab + Cabozantinib | Sunitinib | Hedge G difference [95% CI] |
|---|---|---|---|
| Week 93 | n= 23 (32.4%) \|-0.70 (2.74) | [No Data] | [No Data for at least 1 arm] |
| Week 95 | n= 22 (31.0%) \|-0.82 (2.50) | [No Data] | [No Data for at least 1 arm] |
| Week 97 | n= 21 (29.6%) \|-0.76 (2.98) | n= 10 (14.7%) \|-0.30 (4.16) | -0.13 [-0.90 ; 0.63] |
| Week 99 | n= 17 (23.9%) \|-1.00 (3.32) | [No Data] | [No Data for at least 1 arm] |
| Week 101 | n= 14 (19.7%) \|-1.43 (2.41) | [No Data] | [No Data for at least 1 arm] |
| Week 103 | n= 15 (21.1%) \|-2.07 (2.79) | n= 9 (13.2%) \|-2.67 (2.45) | 0.22 [-0.63 ; 1.06] |
| Week 105 | n= 13 (18.3%) \|-2.31 (2.39) | [No Data] | [No Data for at least 1 arm] |
| Week 107 | n= 8 (11.3%) \|-1.88 (2.59) | [No Data] | [No Data for at least 1 arm] |
| Week 109 | n= 11 (15.5%) \|-1.73 (2.24) | n= 4 ( 5.9%) \|-4.50 (3.42) | 1.02 [-0.23 ; 2.27] |
| Week 111 | n= 7 ( 9.9%) \|-2.57 (2.82) | [No Data] | [No Data for at least 1 arm] |
| Week 113 | n= 8 (11.3%) \|-2.88 (3.31) | [No Data] | [No Data for at least 1 arm] |
| Week 115 | n= 7 ( 9.9%) \|-2.00 (3.32) | n= 5 ( 7.4%) \|-2.40 (2.51) | 0.12 [-1.08 ; 1.33] |
| Week 117 | n= 7 ( 9.9%) \|-1.29 (4.39) | [No Data] | [No Data for at least 1 arm] |
| Week 119 | n= 7 ( 9.9%) \|-1.00 (4.51) | [No Data] | [No Data for at least 1 arm] |
| Week 121 | n= 8 (11.3%) \|-1.00 (4.11) | n= 1 ( 1.5%) \|-9.00 ( / ) | [Not calculable] |
| Week 123 | n= 2 ( 2.8%) \| 0.50 (7.78) | [No Data] | [No Data for at least 1 arm] |
| Week 125 | n= 1 ( 1.4%) \|-7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 127 | n= 2 ( 2.8%) \| 0.50 (0.71) | n= 1 ( 1.5%) \|-7.00 ( / ) | [Not calculable] |
| Week 129 | n= 1 ( 1.4%) \|-7.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 131 | n= 1 ( 1.4%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 135 | n= 1 ( 1.4%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 137 | n= 1 ( 1.4%) \| 1.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 139 | n= 1 ( 1.4%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 141 | n= 1 ( 1.4%) \|-9.00 ( / ) | [No Data] | [No Data for at least 1 arm] |
| Week 201 | n= 8 (11.3%) \|-4.13 (3.64) | n= 16 (23.5%) \|-0.25 (4.65) | -0.86 [-1.76 ; 0.05] |
| Week 202 | n= 2 ( 2.8%) \|-4.50 (0.71) | n= 11 (16.2%) \| 0.55 (4.37) | -1.13 [-2.77 ; 0.52] |

Notes:
Treatment arms reported values are change from baseline values.
Differences between treatment arms are standardized differences using Hedge's G method.
CI: Confidence Interval; PRO: Patient-Reported Outcomes; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:54:34

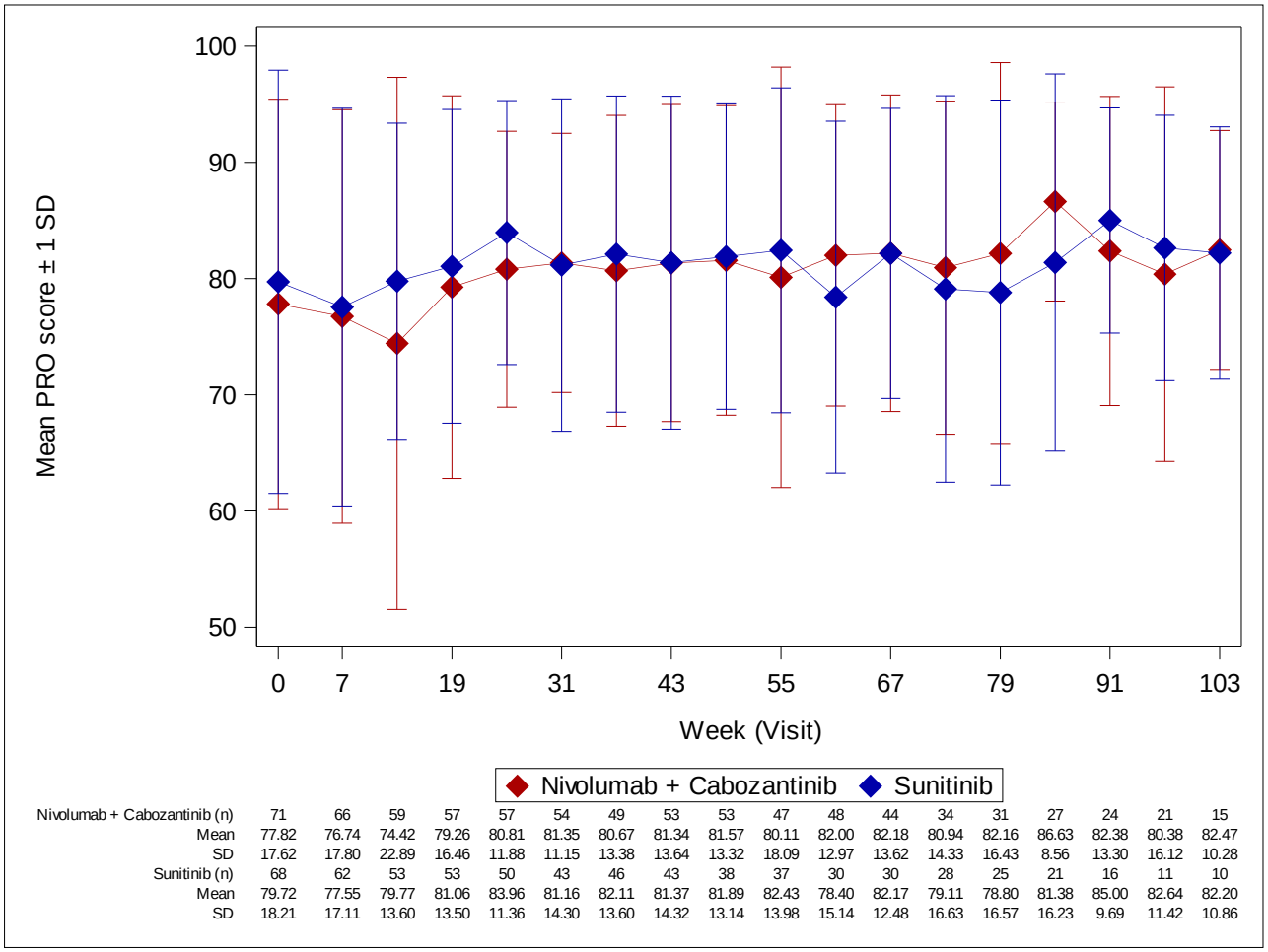
TABLE 7.8.1: PRO Analysis: FKSI-19: Functional Well Being Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Total Population Analysis



| Study Visit | Nivolumab + Cabozantinib | Sunitinib | LS-means difference (Nivolumab + Cabozantinib vs Sunitinib) | Hedge G of LS-means difference [95% CI] |
|---|---|---|---|---|
| **Change from Baseline MMRM LS-means and difference - mean (SE) [95% CI]** | | | | |
| Nr subjects used | n=69 | n=67 | | |
| Week 7 | -1.14 (0.40) [-1.93 ;-0.35] | -0.43 (0.41) [-1.23 ; 0.37] | -0.71 (0.53) [-1.76 ; 0.34] | -0.22 [-0.57 ; 0.13] |
| Week 13 | -1.33 (0.44) [-2.19 ;-0.46] | -1.18 (0.46) [-2.09 ;-0.28] | -0.14 (0.60) [-1.32 ; 1.04] | -0.04 [-0.41 ; 0.33] |
| Week 19 | -1.29 (0.40) [-2.07 ;-0.50] | -1.04 (0.41) [-1.85 ;-0.22] | -0.25 (0.54) [-1.31 ; 0.80] | -0.08 [-0.46 ; 0.29] |
| Week 25 | -1.00 (0.37) [-1.72 ;-0.27] | -0.63 (0.39) [-1.40 ; 0.15] | -0.37 (0.49) [-1.35 ; 0.60] | -0.14 [-0.52 ; 0.25] |
| Week 31 | -1.01 (0.36) [-1.72 ;-0.31] | -0.45 (0.38) [-1.20 ; 0.31] | -0.57 (0.48) [-1.52 ; 0.38] | -0.22 [-0.62 ; 0.18] |
| Week 37 | -1.29 (0.41) [-2.10 ;-0.49] | -0.68 (0.43) [-1.54 ; 0.17] | -0.61 (0.56) [-1.71 ; 0.49] | -0.21 [-0.62 ; 0.20] |
| Week 43 | -0.96 (0.38) [-1.72 ;-0.21] | -0.87 (0.42) [-1.70 ;-0.05] | -0.09 (0.53) [-1.14 ; 0.95] | -0.03 [-0.44 ; 0.38] |
| Week 49 | -0.99 (0.35) [-1.69 ;-0.29] | -0.85 (0.40) [-1.65 ;-0.05] | -0.14 (0.50) [-1.12 ; 0.85] | -0.05 [-0.48 ; 0.37] |
| Week 55 | -0.81 (0.38) [-1.56 ;-0.06] | -0.83 (0.43) [-1.67 ; 0.02] | 0.02 (0.54) [-1.04 ; 1.08] | 0.01 [-0.42 ; 0.44] |
| Week 61 | -1.09 (0.41) [-1.90 ;-0.27] | -0.93 (0.49) [-1.90 ; 0.05] | -0.16 (0.61) [-1.38 ; 1.06] | -0.06 [-0.51 ; 0.40] |
| Week 67 | -0.79 (0.40) [-1.57 ;-0.00] | -0.86 (0.47) [-1.80 ; 0.08] | 0.07 (0.59) [-1.10 ; 1.24] | 0.03 [-0.44 ; 0.50] |
| Week 73 | -1.00 (0.46) [-1.91 ;-0.08] | -1.68 (0.53) [-2.74 ;-0.62] | 0.68 (0.68) [-0.67 ; 2.03] | 0.24 [-0.26 ; 0.74] |
| Week 79 | -0.82 (0.43) [-1.68 ; 0.03] | -0.80 (0.50) [-1.79 ; 0.18] | -0.02 (0.63) [-1.28 ; 1.23] | -0.01 [-0.54 ; 0.52] |
| Week 85 | -0.85 (0.43) [-1.70 ;-0.00] | -1.10 (0.49) [-2.08 ;-0.11] | 0.25 (0.63) [-1.00 ; 1.50] | 0.11 [-0.47 ; 0.69] |
| Week 91 | -0.90 (0.45) [-1.79 ; 0.00] | -0.26 (0.53) [-1.32 ; 0.80] | -0.63 (0.68) [-1.98 ; 0.72] | -0.28 [-0.91 ; 0.34] |
| Week 97 | -0.92 (0.49) [-1.91 ; 0.07] | -0.51 (0.66) [-1.83 ; 0.81] | -0.41 (0.81) [-2.03 ; 1.21] | -0.18 [-0.94 ; 0.57] |
| Overall post-baseline period estimate | -1.01 (0.25) [-1.50 ;-0.52] | -0.82 (0.28) [-1.37 ;-0.27] | -0.19 (0.32) [-0.82 ; 0.44] | -0.09 [-0.43 ; 0.25] |

Notes:
Treatment arms values and treatment arm differenes are LS-means values for change from baseline values, from a MMRM model with the baseline PRO value, treatment arm, visit (week), the interaction between treatment and visit, and PD-L1 tumor expression (>= 1% versus < 1% or indeterminate) and region (US/Canada/W Europe/N Europe, ROW) as entered in the IRT, as fixed effects,and subject as random effect.
The MMRM model used all available PRO data from scheduled visits up to week 103, only using visits with data for both treatment arms and at least 10 subjects with data in each arm, and uses a Heterogenous Autoregressive (ARH(1)) covariance structure.
CI: Confidence Interval; LS: Least-Squares; MMRM: Mixed Model Repeated Measures; PRO: Patient-Reported Outcomes; SE: Standard Er
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:54:34

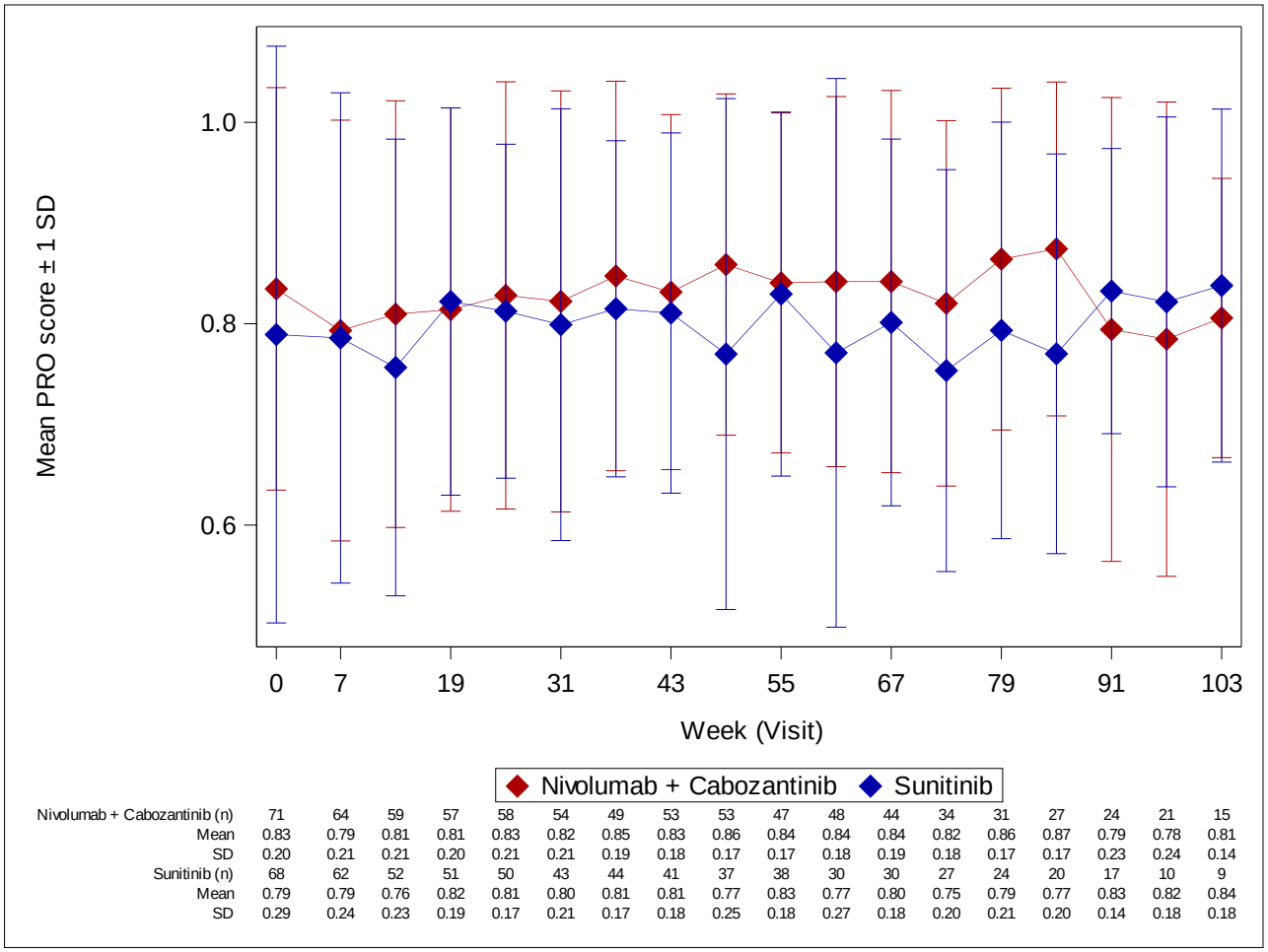
FIGURE 7.1: PRO Analysis: EQ-5D: Health Status - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Plot of actual values (mean ± 1 SD)




| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nivolumab + Cabozantinib (n) | 71 | 66 | 59 | 57 | 57 | 54 | 49 | 53 | 53 | 47 | 48 | 44 | 34 | 31 | 27 | 24 | 21 | 15 |
| Mean | 77.82 | 76.74 | 74.42 | 79.26 | 80.81 | 81.35 | 80.67 | 81.34 | 81.57 | 80.11 | 82.00 | 82.18 | 80.94 | 82.16 | 86.63 | 82.38 | 80.38 | 82.47 |
| SD | 17.62 | 17.80 | 22.89 | 16.46 | 11.88 | 11.15 | 13.38 | 13.64 | 13.32 | 18.09 | 12.97 | 13.62 | 14.33 | 16.43 | 8.56 | 13.30 | 16.12 | 10.28 |
| Sunitinib (n) | 68 | 62 | 53 | 53 | 50 | 43 | 46 | 43 | 38 | 37 | 30 | 30 | 28 | 25 | 21 | 16 | 11 | 10 |
| Mean | 79.72 | 77.55 | 79.77 | 81.06 | 83.96 | 81.16 | 82.11 | 81.37 | 81.89 | 82.43 | 78.40 | 82.17 | 79.11 | 78.80 | 81.38 | 85.00 | 82.64 | 82.20 |
| SD | 18.21 | 17.11 | 13.60 | 13.50 | 11.36 | 14.30 | 13.60 | 14.32 | 13.14 | 13.98 | 15.14 | 12.48 | 16.63 | 16.57 | 16.23 | 9.69 | 11.42 | 10.86 |

Notes:
PRO: Patient-Reported Outcome; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:41:21

FIGURE 7.2: PRO Analysis: EQ-5D: Utility Index UK - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Plot of actual values (mean ± 1 SD)

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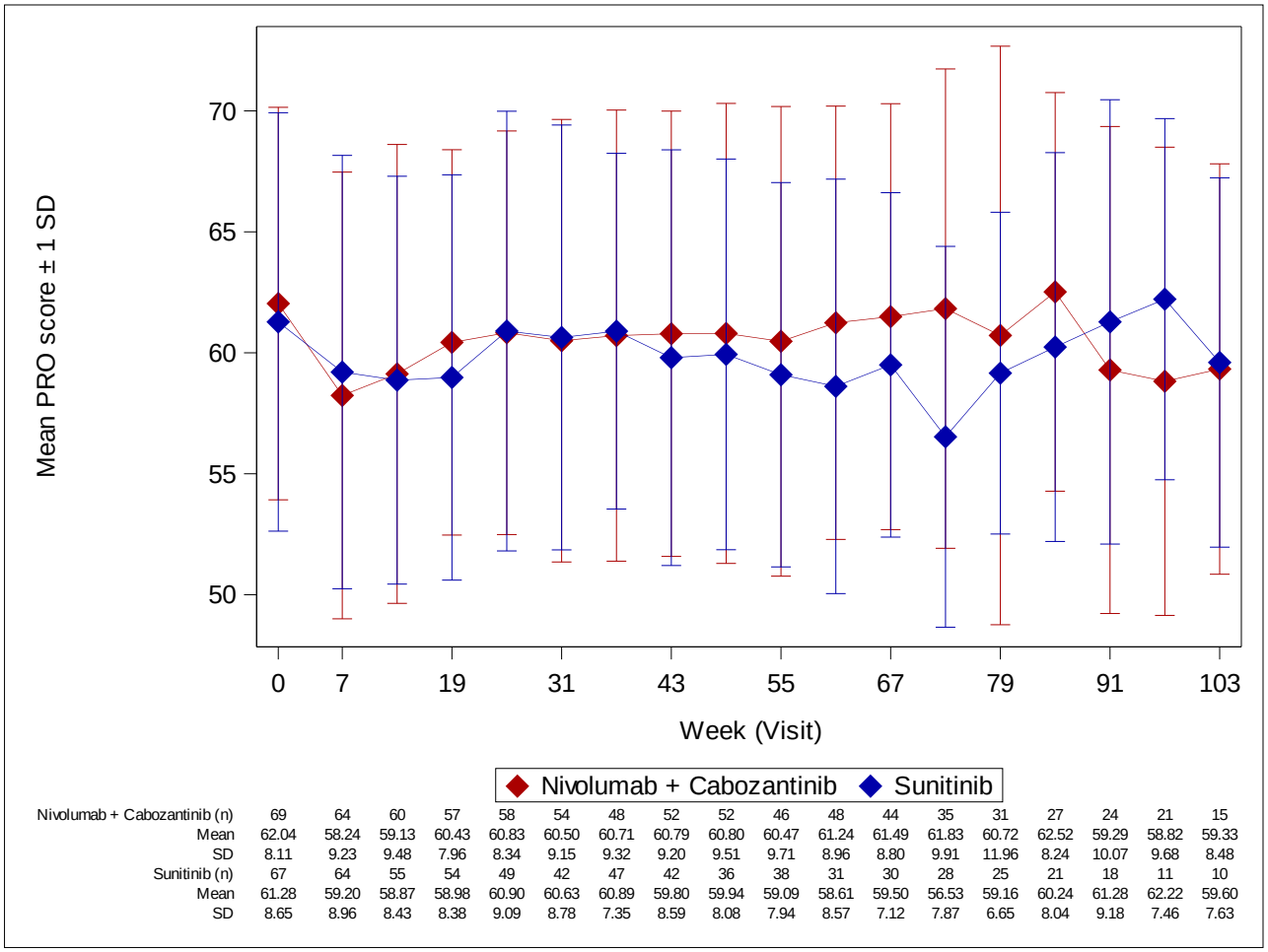
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nivolumab + Cabozantinib (n) | 71 | 64 | 59 | 57 | 58 | 54 | 49 | 53 | 53 | 47 | 48 | 44 | 34 | 31 | 27 | 24 | 21 | 15 |
| Mean | 0.83 | 0.79 | 0.81 | 0.81 | 0.83 | 0.82 | 0.85 | 0.83 | 0.86 | 0.84 | 0.84 | 0.84 | 0.82 | 0.86 | 0.87 | 0.79 | 0.78 | 0.81 |
| SD | 0.20 | 0.21 | 0.21 | 0.20 | 0.21 | 0.21 | 0.19 | 0.18 | 0.17 | 0.17 | 0.18 | 0.19 | 0.18 | 0.17 | 0.17 | 0.23 | 0.24 | 0.14 |
| Sunitinib (n) | 68 | 62 | 52 | 51 | 50 | 43 | 44 | 41 | 37 | 38 | 30 | 30 | 27 | 24 | 20 | 17 | 10 | 9 |
| Mean | 0.79 | 0.79 | 0.76 | 0.82 | 0.81 | 0.80 | 0.81 | 0.81 | 0.77 | 0.83 | 0.77 | 0.80 | 0.75 | 0.79 | 0.77 | 0.83 | 0.82 | 0.84 |
| SD | 0.29 | 0.24 | 0.23 | 0.19 | 0.17 | 0.21 | 0.17 | 0.18 | 0.25 | 0.18 | 0.27 | 0.18 | 0.20 | 0.21 | 0.20 | 0.14 | 0.18 | 0.18 |

Notes:
PRO: Patient-Reported Outcome; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:43:04

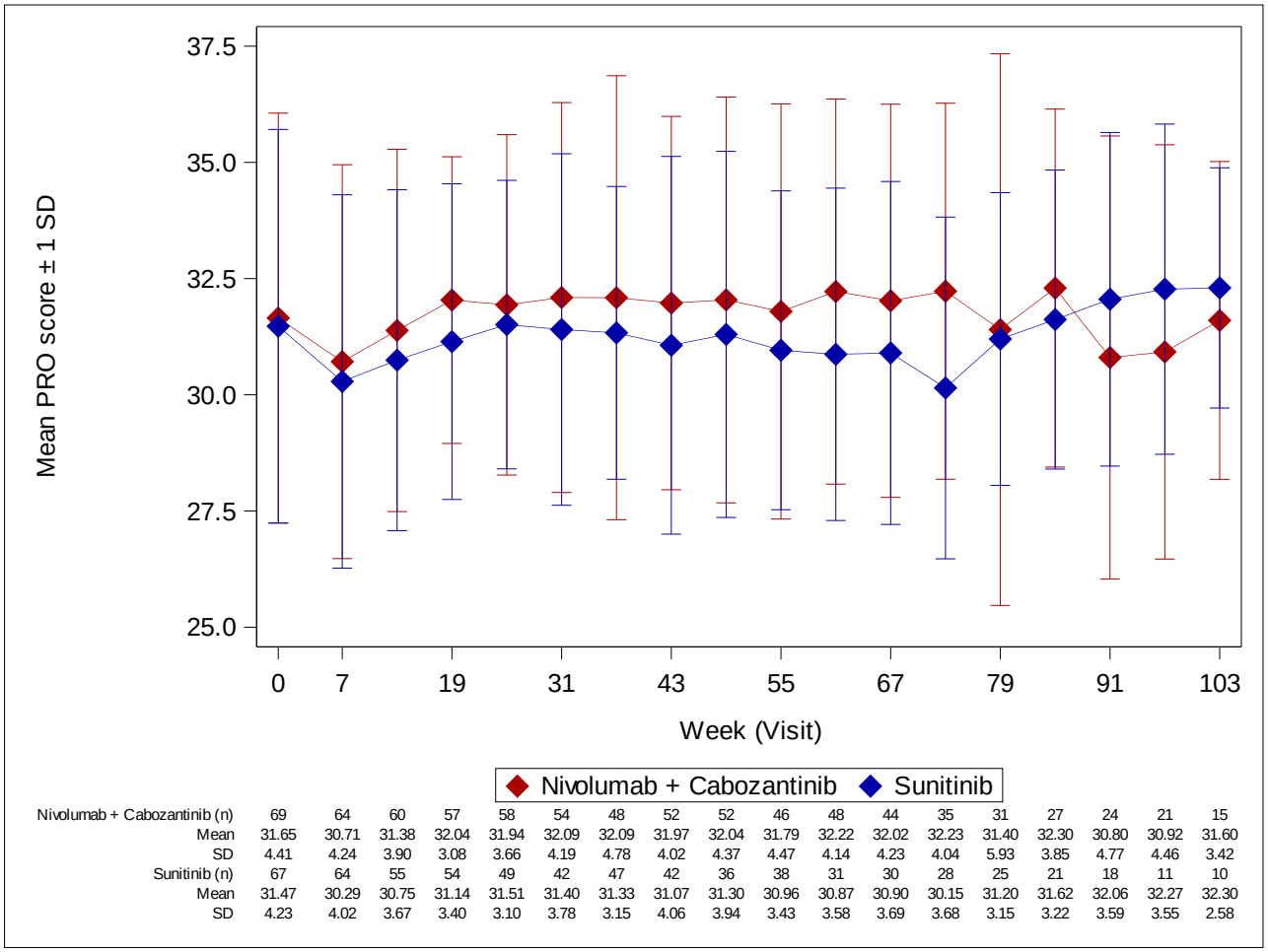
FIGURE 7.3: PRO Analysis: FKSI-19: Total Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Plot of actual values (mean ± 1 SD)




| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nivolumab + Cabozantinib (n) | 69 | 64 | 60 | 57 | 58 | 54 | 48 | 52 | 52 | 46 | 48 | 44 | 35 | 31 | 27 | 24 | 21 | 15 |
| Mean | 62.04 | 58.24 | 59.13 | 60.43 | 60.83 | 60.50 | 60.71 | 60.79 | 60.80 | 60.47 | 61.24 | 61.49 | 61.83 | 60.72 | 62.52 | 59.29 | 58.82 | 59.33 |
| SD | 8.11 | 9.23 | 9.48 | 7.96 | 8.34 | 9.15 | 9.32 | 9.20 | 9.51 | 9.71 | 8.96 | 8.80 | 9.91 | 11.96 | 8.24 | 10.07 | 9.68 | 8.48 |
| Sunitinib (n) | 67 | 64 | 55 | 54 | 49 | 42 | 47 | 42 | 36 | 38 | 31 | 30 | 28 | 25 | 21 | 18 | 11 | 10 |
| Mean | 61.28 | 59.20 | 58.87 | 58.98 | 60.90 | 60.63 | 60.89 | 59.80 | 59.94 | 59.09 | 58.61 | 59.50 | 56.53 | 59.16 | 60.24 | 61.28 | 62.22 | 59.60 |
| SD | 8.65 | 8.96 | 8.43 | 8.38 | 9.09 | 8.78 | 7.35 | 8.59 | 8.08 | 7.94 | 8.57 | 7.12 | 7.87 | 6.65 | 8.04 | 9.18 | 7.46 | 7.63 |

Notes:
PRO: Patient-Reported Outcome; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:44:46

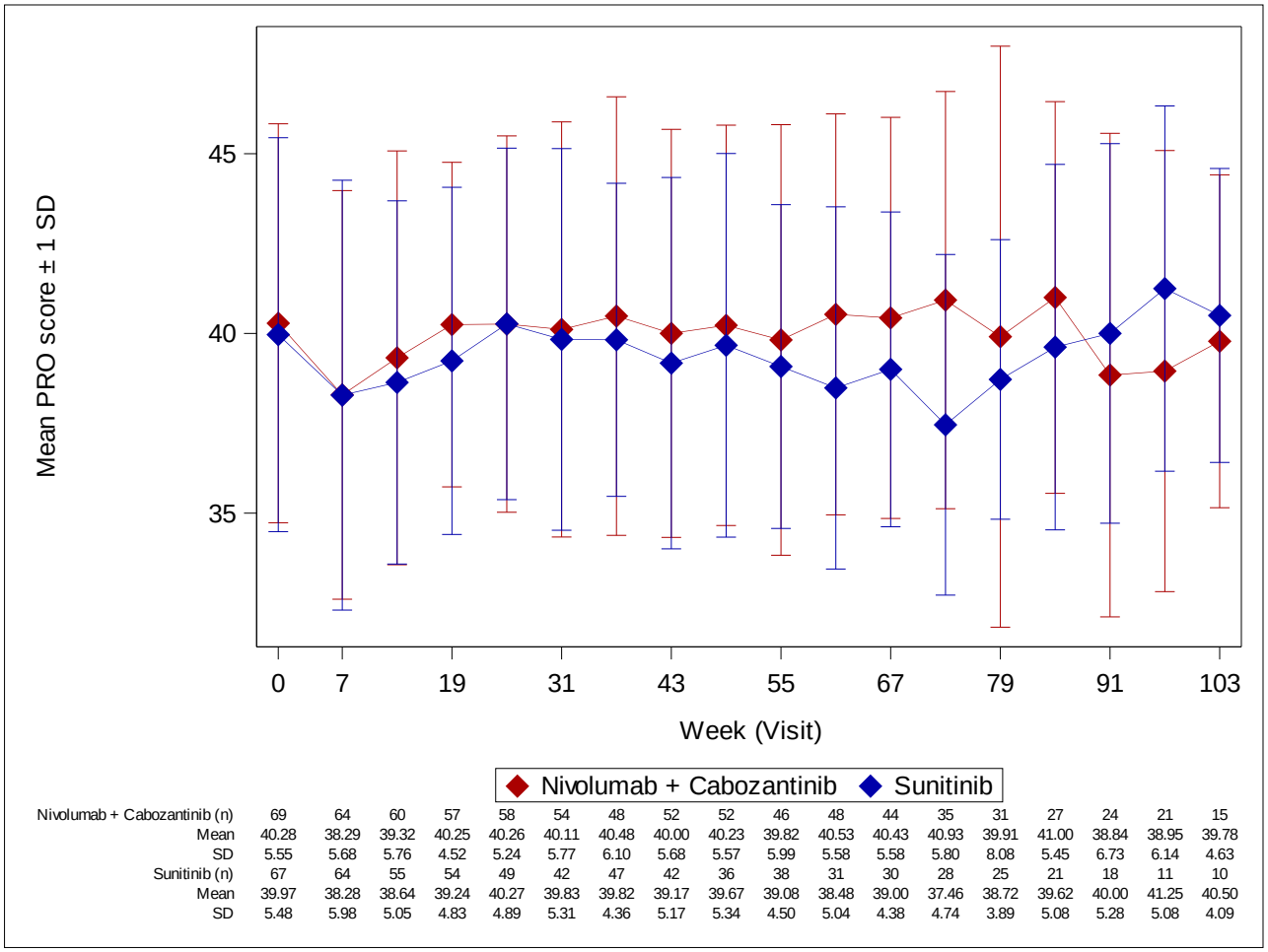
FIGURE 7.4: PRO Analysis: FKSI-19: Kidney Symptom Disease-related Symptom Subscale (FKSI-DRS) - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Plot of actual values (mean ± 1 SD)




| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nivolumab + Cabozantinib (n) | 69 | 64 | 60 | 57 | 58 | 54 | 48 | 52 | 52 | 46 | 48 | 44 | 35 | 31 | 27 | 24 | 21 | 15 |
| Mean | 31.65 | 30.71 | 31.38 | 32.04 | 31.94 | 32.09 | 32.09 | 31.97 | 32.04 | 31.79 | 32.22 | 32.02 | 32.23 | 31.40 | 32.30 | 30.80 | 30.92 | 31.60 |
| SD | 4.41 | 4.24 | 3.90 | 3.08 | 3.66 | 4.19 | 4.78 | 4.02 | 4.37 | 4.47 | 4.14 | 4.23 | 4.04 | 5.93 | 3.85 | 4.77 | 4.46 | 3.42 |
| Sunitinib (n) | 67 | 64 | 55 | 54 | 49 | 42 | 47 | 42 | 36 | 38 | 31 | 30 | 28 | 25 | 21 | 18 | 11 | 10 |
| Mean | 31.47 | 30.29 | 30.75 | 31.14 | 31.51 | 31.40 | 31.33 | 31.07 | 31.30 | 30.96 | 30.87 | 30.90 | 30.15 | 31.20 | 31.62 | 32.06 | 32.27 | 32.30 |
| SD | 4.23 | 4.02 | 3.67 | 3.40 | 3.10 | 3.78 | 3.15 | 4.06 | 3.94 | 3.43 | 3.58 | 3.69 | 3.68 | 3.15 | 3.22 | 3.59 | 3.55 | 2.58 |

Notes:
PRO: Patient-Reported Outcome; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:48:09

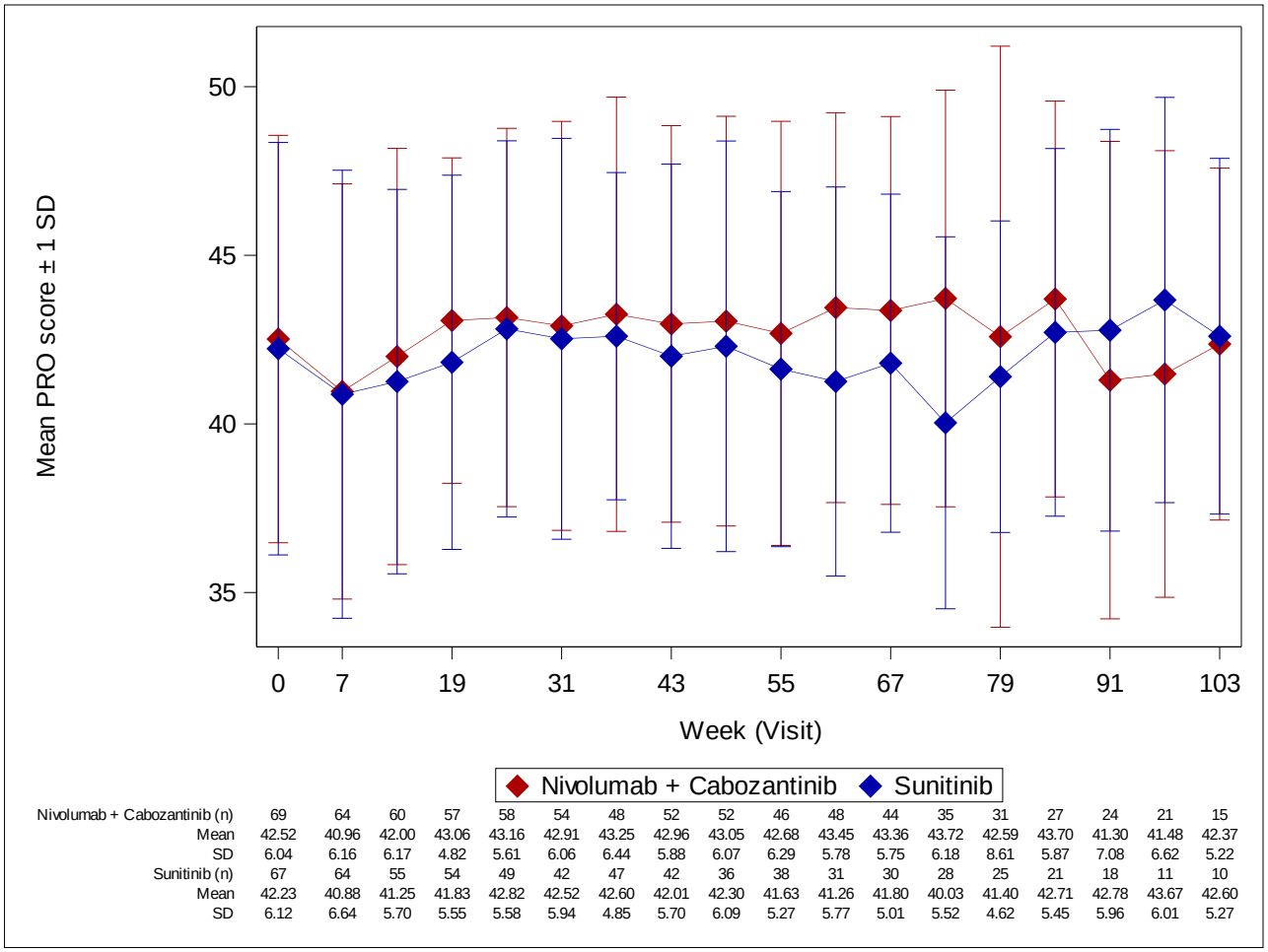
FIGURE 7.5: PRO Analysis: FKSI-19: Disease Related Symptoms Physical Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Plot of actual values (mean ± 1 SD)




| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nivolumab + Cabozantinib (n) | 69 | 64 | 60 | 57 | 58 | 54 | 48 | 52 | 52 | 46 | 48 | 44 | 35 | 31 | 27 | 24 | 21 | 15 |
| Mean | 40.28 | 38.29 | 39.32 | 40.25 | 40.26 | 40.11 | 40.48 | 40.00 | 40.23 | 39.82 | 40.53 | 40.43 | 40.93 | 39.91 | 41.00 | 38.84 | 38.95 | 39.78 |
| SD | 5.55 | 5.68 | 5.76 | 4.52 | 5.24 | 5.77 | 6.10 | 5.68 | 5.57 | 5.99 | 5.58 | 5.58 | 5.80 | 8.08 | 5.45 | 6.73 | 6.14 | 4.63 |
| Sunitinib (n) | 67 | 64 | 55 | 54 | 49 | 42 | 47 | 42 | 36 | 38 | 31 | 30 | 28 | 25 | 21 | 18 | 11 | 10 |
| Mean | 39.97 | 38.28 | 38.64 | 39.24 | 40.27 | 39.83 | 39.82 | 39.17 | 39.67 | 39.08 | 38.48 | 39.00 | 37.46 | 38.72 | 39.62 | 40.00 | 41.25 | 40.50 |
| SD | 5.48 | 5.98 | 5.05 | 4.83 | 4.89 | 5.31 | 4.36 | 5.17 | 5.34 | 4.50 | 5.04 | 4.38 | 4.74 | 3.89 | 5.08 | 5.28 | 5.08 | 4.09 |

Notes:
PRO: Patient-Reported Outcome; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:49:49

FIGURE 7.6: PRO Analysis: FKSI-19: Disease Related Symptoms Physical Score and Emotional Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Plot of actual values (mean ± 1 SD)

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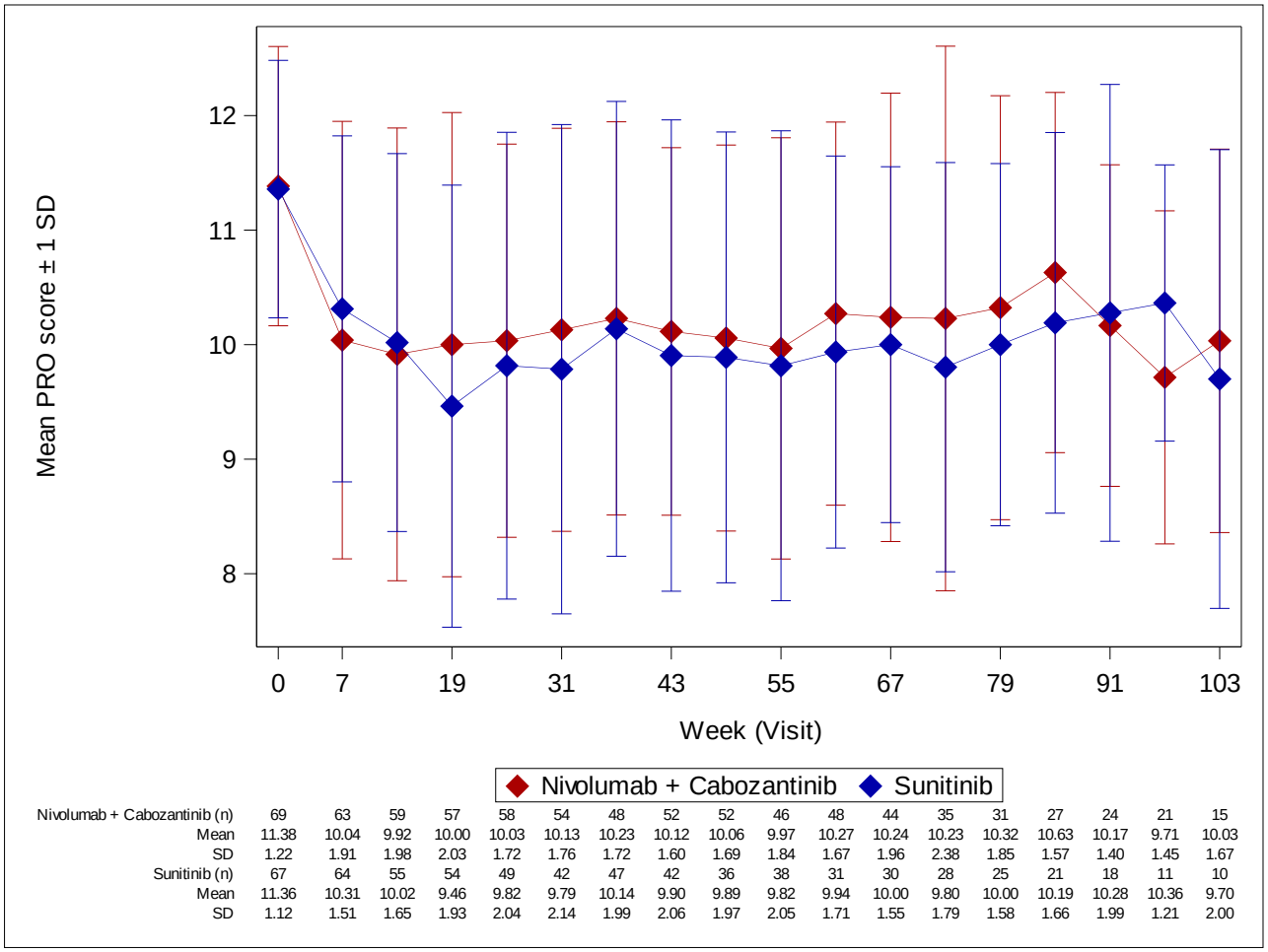
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nivolumab + Cabozantinib (n) | 69 | 64 | 60 | 57 | 58 | 54 | 48 | 52 | 52 | 46 | 48 | 44 | 35 | 31 | 27 | 24 | 21 | 15 |
| Mean | 42.52 | 40.96 | 42.00 | 43.06 | 43.16 | 42.91 | 43.25 | 42.96 | 43.05 | 42.68 | 43.45 | 43.36 | 43.72 | 42.59 | 43.70 | 41.30 | 41.48 | 42.37 |
| SD | 6.04 | 6.16 | 6.17 | 4.82 | 5.61 | 6.06 | 6.44 | 5.88 | 6.07 | 6.29 | 5.78 | 5.75 | 6.18 | 8.61 | 5.87 | 7.08 | 6.62 | 5.22 |
| Sunitinib (n) | 67 | 64 | 55 | 54 | 49 | 42 | 47 | 42 | 36 | 38 | 31 | 30 | 28 | 25 | 21 | 18 | 11 | 10 |
| Mean | 42.23 | 40.88 | 41.25 | 41.83 | 42.82 | 42.52 | 42.60 | 42.01 | 42.30 | 41.63 | 41.26 | 41.80 | 40.03 | 41.40 | 42.71 | 42.78 | 43.67 | 42.60 |
| SD | 6.12 | 6.64 | 5.70 | 5.55 | 5.58 | 5.94 | 4.85 | 5.70 | 6.09 | 5.27 | 5.77 | 5.01 | 5.52 | 4.62 | 5.45 | 5.96 | 6.01 | 5.27 |

Notes:
PRO: Patient-Reported Outcome; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:51:32

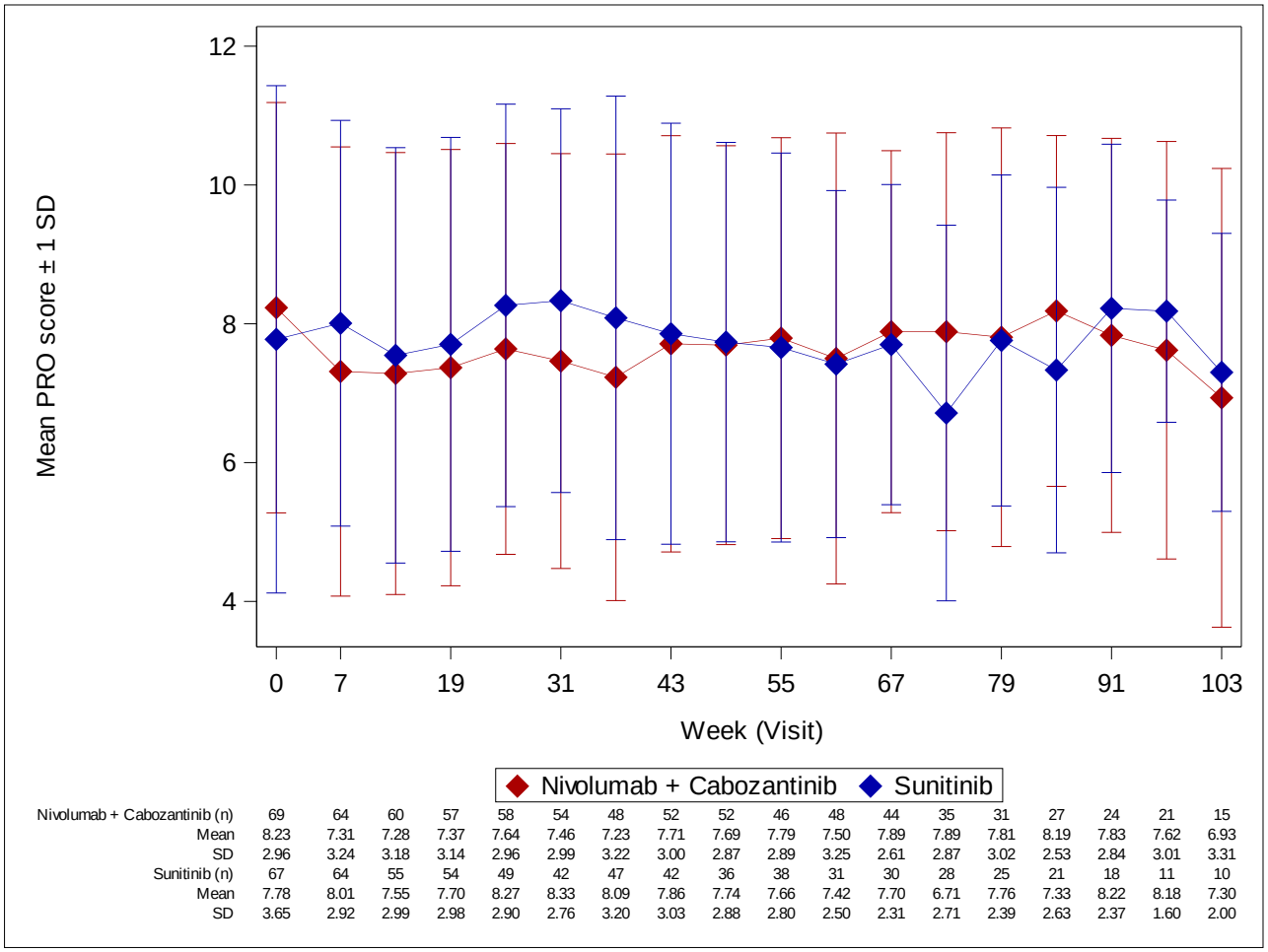
FIGURE 7.7: PRO Analysis: FKSI-19: Treatment Side Effects Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Plot of actual values (mean ± 1 SD)




| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nivolumab + Cabozantinib (n) | 69 | 63 | 59 | 57 | 58 | 54 | 48 | 52 | 52 | 46 | 48 | 44 | 35 | 31 | 27 | 24 | 21 | 15 |
| Mean | 11.38 | 10.04 | 9.92 | 10.00 | 10.03 | 10.13 | 10.23 | 10.12 | 10.06 | 9.97 | 10.27 | 10.24 | 10.23 | 10.32 | 10.63 | 10.17 | 9.71 | 10.03 |
| SD | 1.22 | 1.91 | 1.98 | 2.03 | 1.72 | 1.76 | 1.72 | 1.60 | 1.69 | 1.84 | 1.67 | 1.96 | 2.38 | 1.85 | 1.57 | 1.40 | 1.45 | 1.67 |
| Sunitinib (n) | 67 | 64 | 55 | 54 | 49 | 42 | 47 | 42 | 36 | 38 | 31 | 30 | 28 | 25 | 21 | 18 | 11 | 10 |
| Mean | 11.36 | 10.31 | 10.02 | 9.46 | 9.82 | 9.79 | 10.14 | 9.90 | 9.89 | 9.82 | 9.94 | 10.00 | 9.80 | 10.00 | 10.19 | 10.28 | 10.36 | 9.70 |
| SD | 1.12 | 1.51 | 1.65 | 1.93 | 2.04 | 2.14 | 1.99 | 2.06 | 1.97 | 2.05 | 1.71 | 1.55 | 1.79 | 1.58 | 1.66 | 1.99 | 1.21 | 2.00 |

Notes:
PRO: Patient-Reported Outcome; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
[[root]\02 Programs\02.07 PRO mmrm.sas] run Tuesday, March 23, 2021 at 17:53:12

FIGURE 7.8: PRO Analysis: FKSI-19: Functional Well Being Score - Intent-to-treat Population A: Favorable risk (IMDC prognostic risk score = 0) - Plot of actual values (mean ± 1 SD)




| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nivolumab + Cabozantinib (n) | 69 | 64 | 60 | 57 | 58 | 54 | 48 | 52 | 52 | 46 | 48 | 44 | 35 | 31 | 27 | 24 | 21 | 15 |
| Mean | 8.23 | 7.31 | 7.28 | 7.37 | 7.64 | 7.46 | 7.23 | 7.71 | 7.69 | 7.79 | 7.50 | 7.89 | 7.89 | 7.81 | 8.19 | 7.83 | 7.62 | 6.93 |
| SD | 2.96 | 3.24 | 3.18 | 3.14 | 2.96 | 2.99 | 3.22 | 3.00 | 2.87 | 2.89 | 3.25 | 2.61 | 2.87 | 3.02 | 2.53 | 2.84 | 3.01 | 3.31 |
| Sunitinib (n) | 67 | 64 | 55 | 54 | 49 | 42 | 47 | 42 | 36 | 38 | 31 | 30 | 28 | 25 | 21 | 18 | 11 | 10 |
| Mean | 7.78 | 8.01 | 7.55 | 7.70 | 8.27 | 8.33 | 8.09 | 7.86 | 7.74 | 7.66 | 7.42 | 7.70 | 6.71 | 7.76 | 7.33 | 8.22 | 8.18 | 7.30 |
| SD | 3.65 | 2.92 | 2.99 | 2.98 | 2.90 | 2.76 | 3.20 | 3.03 | 2.88 | 2.80 | 2.50 | 2.31 | 2.71 | 2.39 | 2.63 | 2.37 | 1.60 | 2.00 |

Notes:
PRO: Patient-Reported Outcome; SD: Standard Deviation.
Analysis Cut Off date: 10SEP2020
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