

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Selpercatinib (Retsevm[®])

Lilly Deutschland GmbH

Modul 4B – Anhang 4-L1

Auswertungen zum Datenschnitt vom 30. März 2020 – LIBRETTO-001

*Fortgeschrittenes MTC mit RET-Mutation nach
Cabozantinib und/oder Vandetanib*

Stand: 12.03.2021

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Merkmal	Selpercatinib
	Subpopulation B – MTC (N=153)
Demographische Charakteristika und Baseline Charakteristika	
Geschlecht, n (%)	
Männer	96 (62,7)
Frauen	57 (37,3)
Ethnische Zugehörigkeit, n (%)	
Weiß	137 (89,5)
Schwarz oder Afroamerikaner	2 (1,3)
Asiaten	2 (1,3)
Amerikanische Indianer oder Ureinwohner Alaskas	1 (0,7)
Ureinwohner Hawaiis oder andere pazifische Inselbewohner	0 (0,0)
Andere	10 (6,5)
Fehlend	1 (0,7)
Geografische Region, n (%)	
Nordamerika	102 (66,7)
Europa	40 (26,1)
Rest der Welt	11 (7,2)
Altersgruppen, n (%)	
< 18 Jahre	1 (0,7)
18 bis < 45 Jahre	30 (19,6)
45 bis < 65 Jahre	69 (45,1)
65 bis < 75 Jahre	37 (24,2)
≥ 75 Jahre	16 (10,5)
Alter in Jahren	
Anzahl der Patienten	153
Mittelwert (SD)	56,6 (15,31)
Median (min–max)	58,0 (17-90)
ECOG Performance Status, n (%)	
0	42 (27,5)
1	100 (65,4)
2	11 (7,2)
Erkrankungshistorie	
Krankheitsstadium bei der Erstdiagnose, n (%)	
I	1 (0,7)
II	1 (0,7)
III	6 (3,9)
IV	142 (92,8)
Fehlend	3 (2,0)
Zeit seit der Erstdiagnose in Monaten	
Anzahl der Patienten	153
Mittelwert (SD)	103,2 (99,76)
Median (min–max)	70,9 (3-603)
Metastasierte Erkrankung bei Baseline, n (%)	
Ja	150 (98,0)

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spbc_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T002_bc_mtc.rtf

Tabelle 002: Charakterisierung der Studienpopulation – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Safety Analysis Set

Merkmal	Selpercatinib
	Subpopulation B – MTC (N=153)
Nein	3 (2,0)
Metastasen im zentralen Nervensystem (ZNS) bei Baseline ^a , n (%)	
Ja	11 (7,2)
Nein	142 (92,8)
Vorthérapien	
Vorherige systemische Therapie, n (%)	
Ja	153 (100,0)
Nein	0 (0,0)
Art der vorherigen systemischen Therapie ^b , n (%)	
Multikinase-Inhibitoren (MKI)	153 (100,0)
- Cabozantinib	84 (54,9)
- Vandetanib	121 (79,1)
- Sorafenib	9 (5,9)
- Lenvatinib	15 (9,8)
- Andere MKI	20 (13,1)
Chemotherapie	16 (10,5)
- Platinhaltige Chemotherapie	2 (1,3)
- Taxanhaltige Chemotherapie	3 (2,0)
- Andere Chemotherapien	12 (7,8)
Radiojodtherapie	0 (0,0)
PD1/PD-L1 Inhibitoren	11 (7,2)
Selektive RET Inhibitoren	2 (1,3)
Andere systemische Therapie	22 (14,4)
Anzahl der vorherigen systemischen Therapien, n (%)	
0	0 (0,0)
1-2	110 (71,9)
3 oder mehr	43 (28,1)
Anzahl der vorherigen systemischen Therapien	
Anzahl der Patienten	153
Mittelwert (SD)	2,1 (1,39)
Median (min–max)	2,0 (1-8)
Vorherige Strahlentherapie, n (%)	
Ja	83 (54,2)
Nein	70 (45,8)
Vorherige Krebsbedingte Operation, n (%)	
Ja	138 (90,2)
Nein	15 (9,8)
RET-Alterationsstatus	
Art der RET-Alteration, n (%)	
Fusion	0 (0,0)
- KIF5B	0 (0,0)
- CCDC6	0 (0,0)
- NCOA4	0 (0,0)
- Andere	0 (0,0)

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spbc_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T002_bc_mtc.rtf

Tabelle 002: Charakterisierung der Studienpopulation – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Safety Analysis Set

Merkmal	Selpercatinib
	Subpopulation B – MTC (N=153)
- Unbekannt	0 (0,0)
Mutation	153 (100,0)
- M918T	100 (65,4)
- V804 M/L	8 (5,2)
- Extrazelluläre Cystein Mutation	25 (16,3)
- Andere	20 (13,1)
Andere	0 (0,0)
Methode zur Identifizierung der vorliegenden RET-Alteration, n (%)	
Next-Generation-Sequencing (NGS) mit Tumormaterial	118 (77,1)
Next-Generation-Sequencing (NGS) mit Blut oder Plasma	5 (3,3)
PCR	22 (14,4)
FISH	0 (0,0)
Andere	8 (5,2)
Krankheitscharakteristika zu Baseline	
Messbare Erkrankung^c, n (%)	
Ja	151 (98,7)
Nein	2 (1,3)
Tumorlast in mm^d	
Anzahl der Patienten	151
Mittelwert (SD)	67,8 (43,36)
Median (min–max)	57,0 (10-191)
Vorliegen von Diarrhö bei Baseline, n (%)	
Ja	95 (62,1)
Nein	58 (37,9)
CCDC6: Coiled-Coil Domain Containing 6; CRF: Case Report Form; ECOG: Eastern Cooperative Oncology Group; FISH: Fluorescence in situ Hybridization; KIF5B: Kinesin Family Member 5B; L: Leucin; M: Methionin; max: Maximum; min: Minimum; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NCOA4: Nuclear Receptor Coactivator 4; NGS: Next-Generation-Sequencing; PCR: Polymerase-Kettenreaktion; PD1: Programmed Cell Death Protein 1; PD-L1: Programmed Cell Death Ligand 1; RET: Rearranged during Transfection; SD: Standardabweichung; T: Threonin; V: Valin; ZNS: zentrales Nervensystem. Der Prozentsatz wird basierend auf der Anzahl an Patienten in der Spaltenüberschrift als Nenner berechnet. a: Die Angaben zum Vorliegen von ZNS Metastasen bei Baseline basieren auf der Auswertung der von den Prüfarzten im CRF getätigten Eintragungen zum Erkrankungsstatus bei Baseline. b: Patienten können in mehreren Zeilen berücksichtigt sein. c: Messbare Erkrankung ist definiert als mindestens eine messbare Läsion gemäß Prüfarzt. d: Die Tumorlast ist definiert als die Summe der Durchmesser aller Zielläsionen gemäß Prüfarzt.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spbc_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T002_bc_mtc.rtf

Tabelle 002: Charakterisierung der Studienpopulation – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Merkmal	Selpercatinib
	Subpopulation B – MTC (N=143)
Demographische Charakteristika und Baseline Charakteristika	
Geschlecht, n (%)	
Männer	92 (64,3)
Frauen	51 (35,7)
Ethnische Zugehörigkeit, n (%)	
Weiß	128 (89,5)
Schwarz oder Afroamerikaner	2 (1,4)
Asiaten	2 (1,4)
Amerikanische Indianer oder Ureinwohner Alaskas	1 (0,7)
Ureinwohner Hawaiis oder andere pazifische Inselbewohner	0 (0,0)
Andere	10 (7,0)
Fehlend	0 (0,0)
Geografische Region, n (%)	
Nordamerika	96 (67,1)
Europa	36 (25,2)
Rest der Welt	11 (7,7)
Altersgruppen, n (%)	
< 18 Jahre	1 (0,7)
18 bis < 45 Jahre	27 (18,9)
45 bis < 65 Jahre	65 (45,5)
65 bis < 75 Jahre	35 (24,5)
≥ 75 Jahre	15 (10,5)
Alter in Jahren	
Anzahl der Patienten	143
Mittelwert (SD)	56,6 (15,23)
Median (min–max)	58,0 (17-90)
ECOG Performance Status, n (%)	
0	37 (25,9)
1	95 (66,4)
2	11 (7,7)
Erkrankungshistorie	
Krankheitsstadium bei der Erstdiagnose, n (%)	
I	1 (0,7)
II	1 (0,7)
III	6 (4,2)
IV	132 (92,3)
Fehlend	3 (2,1)
Zeit seit der Erstdiagnose in Monaten	
Anzahl der Patienten	143
Mittelwert (SD)	99,3 (91,57)
Median (min–max)	69,5 (3-455)
Metastasierte Erkrankung bei Baseline, n (%)	
Ja	141 (98,6)

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spbc_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T002_bc_mtc.rtf

Tabelle 002: Charakterisierung der Studienpopulation – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Merkmal	Selpercatinib
	Subpopulation B – MTC (N=143)
Nein	2 (1,4)
Metastasen im zentralen Nervensystem (ZNS) bei Baseline ^a , n (%)	
Ja	10 (7,0)
Nein	133 (93,0)
Vorthérapien	
Vorherige systemische Therapie, n (%)	
Ja	143 (100,0)
Nein	0 (0,0)
Art der vorherigen systemischen Therapie ^b , n (%)	
Multikinase-Inhibitoren (MKI)	143 (100,0)
- Cabozantinib	82 (57,3)
- Vandetanib	113 (79,0)
- Sorafenib	7 (4,9)
- Lenvatinib	15 (10,5)
- Andere MKI	18 (12,6)
Chemotherapie	16 (11,2)
- Platinhaltige Chemotherapie	2 (1,4)
- Taxanhaltige Chemotherapie	3 (2,1)
- Andere Chemotherapien	12 (8,4)
Radiojodtherapie	0 (0,0)
PD1/PD-L1 Inhibitoren	11 (7,7)
Selektive RET Inhibitoren	1 (0,7)
Andere systemische Therapie	21 (14,7)
Anzahl der vorherigen systemischen Therapien, n (%)	
0	0 (0,0)
1-2	102 (71,3)
3 oder mehr	41 (28,7)
Anzahl der vorherigen systemischen Therapien	
Anzahl der Patienten	143
Mittelwert (SD)	2,1 (1,41)
Median (min–max)	2,0 (1-8)
Vorherige Strahlentherapie, n (%)	
Ja	80 (55,9)
Nein	63 (44,1)
Vorherige Krebsbedingte Operation, n (%)	
Ja	129 (90,2)
Nein	14 (9,8)
RET-Alterationsstatus	
Art der RET-Alteration, n (%)	
Fusion	0 (0,0)
- KIF5B	0 (0,0)
- CCDC6	0 (0,0)
- NCOA4	0 (0,0)
- Andere	0 (0,0)

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spbc_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T002_bc_mtc.rtf

Tabelle 002: Charakterisierung der Studienpopulation – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Merkmal	Selpercatinib
	Subpopulation B – MTC (N=143)
- Unbekannt	0 (0,0)
Mutation	143 (100,0)
- M918T	94 (65,7)
- V804 M/L	8 (5,6)
- Extrazelluläre Cystein Mutation	23 (16,1)
- Andere	18 (12,6)
Andere	0 (0,0)
Methode zur Identifizierung der vorliegenden RET-Alteration, n (%)	
Next-Generation-Sequencing (NGS) mit Tumormaterial	111 (77,6)
Next-Generation-Sequencing (NGS) mit Blut oder Plasma	4 (2,8)
PCR	21 (14,7)
FISH	0 (0,0)
Andere	7 (4,9)
Krankheitscharakteristika zu Baseline	
Messbare Erkrankung^c, n (%)	
Ja	141 (98,6)
Nein	2 (1,4)
Tumorlast in mm^d	
Anzahl der Patienten	141
Mittelwert (SD)	68,3 (43,64)
Median (min–max)	57,0 (10-191)
Vorliegen von Diarrhö bei Baseline, n (%)	
Ja	87 (60,8)
Nein	56 (39,2)
CCDC6: Coiled-Coil Domain Containing 6; CRF: Case Report Form; ECOG: Eastern Cooperative Oncology Group; FISH: Fluorescence in situ Hybridization; KIF5B: Kinesin Family Member 5B; L: Leucin; M: Methionin; max: Maximum; min: Minimum; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NCOA4: Nuclear Receptor Coactivator 4; NGS: Next-Generation-Sequencing; PCR: Polymerase-Kettenreaktion; PD1: Programmed Cell Death Protein 1; PD-L1: Programmed Cell Death Ligand 1; RET: Rearranged during Transfection; SD: Standardabweichung; T: Threonin; V: Valin; ZNS: zentrales Nervensystem. Der Prozentsatz wird basierend auf der Anzahl an Patienten in der Spaltenüberschrift als Nenner berechnet. a: Die Angaben zum Vorliegen von ZNS Metastasen bei Baseline basieren auf der Auswertung der von den Prüfarzten im CRF getätigten Eintragungen zum Erkrankungsstatus bei Baseline. b: Patienten können in mehreren Zeilen berücksichtigt sein. c: Messbare Erkrankung ist definiert als mindestens eine messbare Läsion gemäß Prüfarzt. d: Die Tumorlast ist definiert als die Summe der Durchmesser aller Zielläsionen gemäß Prüfarzt.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spbc_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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 Protocol Number: LOXO-RET-17001
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Table 14.1.2.1
 Treatment and Study Disposition
 Safety Analysis Set
 by Subpopulation

Status	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
Subjects Who Received at Least One Dose of 160 mg BID [1] (n, %)	78 (91.8)	164 (94.8)	143 (93.5)	21 (100.0)
Starting Dose of 160 mg BID	74 (87.1)	142 (82.1)	128 (83.7)	14 (66.7)
Intra-Patient Dose Escalated to 160 mg BID	3 (3.5)	21 (12.1)	14 (9.2)	6 (28.6)
Dose Reduced to 160 mg BID	1 (1.2)	1 (0.6)	1 (0.7)	1 (4.8)
Treatment Continued Post-Progression (n, %)	19 (22.4)	37 (21.4)	31 (20.3)	6 (28.6)
Treatment Status (n, %)				
Discontinued	28 (32.9)	59 (34.1)	42 (27.5)	7 (33.3)
Continuing	57 (67.1)	114 (65.9)	111 (72.5)	14 (66.7)

Percentage is calculated using the number of patients in the column heading as the denominator.

[1] 160 mg BID is the Recommended Phase 2 Dose.

[2] Time on Study (TOS) (months) = (study exit date - first dose date + 1)/30.4375 for subjects who exited the study on or before the data cutoff date; TOS (months) = (data cutoff date - first dose date + 1)/30.4375 for subjects who were still in the treatment phase as of the data cutoff date; TOS (months) = (last visit date - first dose date + 1)/30.4375 for subjects who were in the long-term follow-up as of the data cutoff date.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spdisp.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
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Table 14.1.2.1
 Treatment and Study Disposition
 Safety Analysis Set
 by Subpopulation

Status	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
Reason Treatment Discontinued (n, %)				
Progressive Disease	20 (23.5)	32 (18.5)	23 (15.0)	4 (19.0)
Adverse Event	4 (4.7)	13 (7.5)	8 (5.2)	1 (4.8)
Intercurrent Illness Compromising Ability to fulfill Protocol Requirements	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Requirement for Alternative Treatment per Investigator	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Significant Noncompliance to Protocol	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
Withdrawal of Consent	2 (2.4)	7 (4.0)	2 (1.3)	1 (4.8)
Death	1 (1.2)	4 (2.3)	5 (3.3)	0 (0.0)
Other	1 (1.2)	3 (1.7)	3 (2.0)	0 (0.0)
Study Status (n, %)				
Discontinued	20 (23.5)	47 (27.2)	34 (22.2)	7 (33.3)
Continuing	65 (76.5)	126 (72.8)	119 (77.8)	14 (66.7)
Reason Study Discontinued (n, %)				
Death	13 (15.3)	35 (20.2)	26 (17.0)	6 (28.6)
Lost to Follow-Up	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
Withdrawal of Consent	6 (7.1)	12 (6.9)	7 (4.6)	1 (4.8)
Other	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Percentage is calculated using the number of patients in the column heading as the denominator.

[1] 160 mg BID is the Recommended Phase 2 Dose.

[2] Time on Study (TOS) (months) = (study exit date - first dose date + 1)/30.4375 for subjects who exited the study on or before the data cutoff date; TOS (months) = (data cutoff date - first dose date + 1)/30.4375 for subjects who were still in the treatment phase as of the data cutoff date; TOS (months) = (last visit date - first dose date + 1)/30.4375 for subjects who were in the long-term follow-up as of the data cutoff date.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spdisp.sas

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Table 14.1.2.1
 Treatment and Study Disposition
 Safety Analysis Set
 by Subpopulation

Status	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
Time on Study (TOS) (months) [2]				
n	85	173	153	21
Mean	11.72	13.26	13.99	14.75
Standard Deviation	6.223	7.377	7.729	8.841
Median	11.07	12.55	13.47	14.82
Minimum	0.5	0.2	0.4	0.9
Maximum	29.1	34.5	33.3	28.9

Percentage is calculated using the number of patients in the column heading as the denominator.

[1] 160 mg BID is the Recommended Phase 2 Dose.

[2] Time on Study (TOS) (months) = (study exit date - first dose date + 1)/30.4375 for subjects who exited the study on or before the data cutoff date; TOS (months) = (data cutoff date - first dose date + 1)/30.4375 for subjects who were still in the treatment phase as of the data cutoff date; TOS (months) = (last visit date - first dose date + 1)/30.4375 for subjects who were in the long-term follow-up as of the data cutoff date.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spdisp.sas

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Table 14.1.2.1
 Treatment and Study Disposition
 Efficacy Analysis Set
 by Subpopulation

Status	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
Subjects Who Received at Least One Dose of 160 mg BID [1] (n, %)	71 (91.0)	149 (94.3)	133 (93.0)	18 (100.0)
Starting Dose of 160 mg BID	67 (85.9)	127 (80.4)	118 (82.5)	11 (61.1)
Intra-Patient Dose Escalated to 160 mg BID	3 (3.8)	21 (13.3)	14 (9.8)	6 (33.3)
Dose Reduced to 160 mg BID	1 (1.3)	1 (0.6)	1 (0.7)	1 (5.6)
Treatment Continued Post-Progression (n, %)	19 (24.4)	37 (23.4)	31 (21.7)	6 (33.3)
Treatment Status (n, %)				
Discontinued	27 (34.6)	58 (36.7)	42 (29.4)	7 (38.9)
Continuing	51 (65.4)	100 (63.3)	101 (70.6)	11 (61.1)

Percentage is calculated using the number of patients in the column heading as the denominator.

[1] 160 mg BID is the Recommended Phase 2 Dose.

[2] Time on Study (TOS) (months) = (study exit date - first dose date + 1)/30.4375 for subjects who exited the study on or before the data cutoff date; TOS (months) = (data cutoff date - first dose date + 1)/30.4375 for subjects who were still in the treatment phase as of the data cutoff date; TOS (months) = (last visit date - first dose date + 1)/30.4375 for subjects who were in the long-term follow-up as of the data cutoff date.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spdisp.sas

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Table 14.1.2.1
 Treatment and Study Disposition
 Efficacy Analysis Set
 by Subpopulation

Status	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
Reason Treatment Discontinued (n, %)				
Progressive Disease	19 (24.4)	32 (20.3)	23 (16.1)	4 (22.2)
Adverse Event	4 (5.1)	12 (7.6)	8 (5.6)	1 (5.6)
Intercurrent Illness Compromising Ability to fulfill Protocol Requirements	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Requirement for Alternative Treatment per Investigator	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Significant Noncompliance to Protocol	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
Withdrawal of Consent	2 (2.6)	7 (4.4)	2 (1.4)	1 (5.6)
Death	1 (1.3)	4 (2.5)	5 (3.5)	0 (0.0)
Other	1 (1.3)	3 (1.9)	3 (2.1)	0 (0.0)
Study Status (n, %)				
Discontinued	19 (24.4)	47 (29.7)	34 (23.8)	7 (38.9)
Continuing	59 (75.6)	111 (70.3)	109 (76.2)	11 (61.1)
Reason Study Discontinued (n, %)				
Death	12 (15.4)	35 (22.2)	26 (18.2)	6 (33.3)
Lost to Follow-Up	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
Withdrawal of Consent	6 (7.7)	12 (7.6)	7 (4.9)	1 (5.6)

Percentage is calculated using the number of patients in the column heading as the denominator.

[1] 160 mg BID is the Recommended Phase 2 Dose.

[2] Time on Study (TOS) (months) = (study exit date - first dose date + 1)/30.4375 for subjects who exited the study on or before the data cutoff date; TOS (months) = (data cutoff date - first dose date + 1)/30.4375 for subjects who were still in the treatment phase as of the data cutoff date; TOS (months) = (last visit date - first dose date + 1)/30.4375 for subjects who were in the long-term follow-up as of the data cutoff date.

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Table 14.1.2.1
 Treatment and Study Disposition
 Efficacy Analysis Set
 by Subpopulation

Status	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
Time on Study (TOS) (months) [2]				
n	78	158	143	18
Mean	12.48	14.17	14.68	16.80
Standard Deviation	5.910	7.041	7.509	7.764
Median	11.68	13.72	13.80	15.13
Minimum	2.2	0.3	0.4	6.2
Maximum	29.1	34.5	33.3	28.9

Percentage is calculated using the number of patients in the column heading as the denominator.

[1] 160 mg BID is the Recommended Phase 2 Dose.

[2] Time on Study (TOS) (months) = (study exit date - first dose date + 1)/30.4375 for subjects who exited the study on or before the data cutoff date; TOS (months) = (data cutoff date - first dose date + 1)/30.4375 for subjects who were still in the treatment phase as of the data cutoff date; TOS (months) = (last visit date - first dose date + 1)/30.4375 for subjects who were in the long-term follow-up as of the data cutoff date.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spdisp.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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Table 14.1.5
 Concomitant Medications
 Safety Analysis Set
 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
Patients taking concomitant medication	85 (100.0)	173 (100.0)	153 (100.0)	21 (100.0)
THYROID HORMONES	19 (22.4)	53 (30.6)	146 (95.4)	21 (100.0)
LEVOTHYROXINE	10 (11.8)	30 (17.3)	89 (58.2)	10 (47.6)
LEVOTHYROXINE SODIUM	9 (10.6)	26 (15.0)	65 (42.5)	15 (71.4)
LIOETHYRONINE SODIUM	1 (1.2)	1 (0.6)	8 (5.2)	1 (4.8)
LIOETHYRONINE	0 (0.0)	1 (0.6)	4 (2.6)	1 (4.8)
THYROID	1 (1.2)	0 (0.0)	1 (0.7)	1 (4.8)
ANILIDES	46 (54.1)	84 (48.6)	58 (37.9)	12 (57.1)
PARACETAMOL	42 (49.4)	81 (46.8)	56 (36.6)	11 (52.4)
THOMAPYRIN N	1 (1.2)	0 (0.0)	2 (1.3)	0 (0.0)
PROPACETAMOL HYDROCHLORIDE	3 (3.5)	2 (1.2)	0 (0.0)	0 (0.0)
VICKS NYQUIL COLD AND FLU MULTI-SYMPTOM	1 (1.2)	1 (0.6)	0 (0.0)	1 (4.8)
AXOTAL	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
PA	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
NO-FLU F	0 (0.0)	0 (0.0)	1 (0.7)	1 (4.8)
SOLPADEINE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)

Percentage is calculated based on the number of patients in the column heading as the denominator.
 Patients are counted once within each preferred term.
 Reported medication terms were coded using WHO Drug Dictionary (version September 2015).
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Table 14.1.5
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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ANILIDES	46 (54.1)	84 (48.6)	58 (37.9)	12 (57.1)
ZICAM COLD & FLU	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
BENYLIN 4 FLU	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CORICIDIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DOLO MOBILAT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DOZOL	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
PROPACETAMOL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BUTALBITAL W/CAFFEINE/CODEINE/PARACETAMOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SINGLET	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NATURAL OPIUM ALKALOIDS	37 (43.5)	71 (41.0)	79 (51.6)	11 (52.4)
OXYCODONE	15 (17.6)	19 (11.0)	26 (17.0)	6 (28.6)
MORPHINE	7 (8.2)	11 (6.4)	17 (11.1)	2 (9.5)
MORPHINE SULFATE	10 (11.8)	14 (8.1)	15 (9.8)	1 (4.8)
OXYCODONE HYDROCHLORIDE	6 (7.1)	18 (10.4)	11 (7.2)	1 (4.8)
VICODIN	6 (7.1)	10 (5.8)	9 (5.9)	0 (0.0)
OXYCOCET	5 (5.9)	6 (3.5)	8 (5.2)	1 (4.8)
HYDROMORPHONE	5 (5.9)	7 (4.0)	6 (3.9)	4 (19.0)
HYDROMORPHONE HYDROCHLORIDE	3 (3.5)	6 (3.5)	7 (4.6)	1 (4.8)
PANADEINE CO	1 (1.2)	4 (2.3)	6 (3.9)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
NATURAL OPIUM ALKALOIDS	37 (43.5)	71 (41.0)	79 (51.6)	11 (52.4)
TARGIN	2 (2.4)	10 (5.8)	3 (2.0)	0 (0.0)
HYDROCODONE	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
MORPHINE HYDROCHLORIDE	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
CODEINE PHOSPHATE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
MORPHINE SULFATE PENTAHYDRATE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
CODEINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MYPRODOL	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
CODENONG	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HYDROCODONE BITARTRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MERSYNDOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NALOXONE W/OXYCODONE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
NATURAL OPIUM ALKALOIDS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DIHYDROCODEINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SOLPADEINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
H2-RECEPTOR ANTAGONISTS	37 (43.5)	67 (38.7)	46 (30.1)	8 (38.1)
FAMOTIDINE	20 (23.5)	45 (26.0)	20 (13.1)	6 (28.6)
RANITIDINE	12 (14.1)	21 (12.1)	17 (11.1)	2 (9.5)
RANITIDINE HYDROCHLORIDE	10 (11.8)	16 (9.2)	19 (12.4)	2 (9.5)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
H2-RECEPTOR ANTAGONISTS	37 (43.5)	67 (38.7)	46 (30.1)	8 (38.1)
CIMETIDINE	2 (2.4)	4 (2.3)	3 (2.0)	0 (0.0)
NIZATIDINE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
LAFUTIDINE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
PEPCIDDUAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VITAMIN D AND ANALOGUES	16 (18.8)	31 (17.9)	86 (56.2)	14 (66.7)
COLECALCIFEROL	8 (9.4)	21 (12.1)	42 (27.5)	8 (38.1)
CALCITRIOL	0 (0.0)	2 (1.2)	27 (17.6)	5 (23.8)
ERGOCALCIFEROL	2 (2.4)	3 (1.7)	14 (9.2)	1 (4.8)
VITAMIN D NOS	5 (5.9)	6 (3.5)	9 (5.9)	0 (0.0)
ALFACALCIDOL	1 (1.2)	1 (0.6)	6 (3.9)	1 (4.8)
CALCIFEDIOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
GLUCOCORTICOIDS	39 (45.9)	67 (38.7)	43 (28.1)	8 (38.1)
PREDNISONE	17 (20.0)	23 (13.3)	15 (9.8)	4 (19.0)
DEXAMETHASONE	10 (11.8)	24 (13.9)	11 (7.2)	3 (14.3)
PREDNISOLONE	8 (9.4)	12 (6.9)	2 (1.3)	0 (0.0)
METHYLPREDNISOLONE	5 (5.9)	11 (6.4)	5 (3.3)	1 (4.8)
HYDROCORTISONE	1 (1.2)	6 (3.5)	11 (7.2)	0 (0.0)

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GLUCOCORTICOIDS	39 (45.9)	67 (38.7)	43 (28.1)	8 (38.1)
METHYLPREDNISOLONE SODIUM SUCCINATE	1 (1.2)	7 (4.0)	1 (0.7)	0 (0.0)
HYDROCORTISONE SODIUM SUCCINATE	1 (1.2)	3 (1.7)	2 (1.3)	0 (0.0)
TRIAMCINOLONE ACETONIDE	0 (0.0)	0 (0.0)	2 (1.3)	1 (4.8)
BUDESONIDE	0 (0.0)	2 (1.2)	1 (0.7)	1 (4.8)
FLUTICASONE PROPIONATE	0 (0.0)	3 (1.7)	1 (0.7)	0 (0.0)
BETAMETHASONE	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
DEXAMETHASONE SODIUM PHOSPHATE	0 (0.0)	1 (0.6)	0 (0.0)	1 (4.8)
FLUTICASONE	0 (0.0)	0 (0.0)	1 (0.7)	1 (4.8)
BECLOMETASONE DIPROPIONATE	0 (0.0)	1 (0.6)	0 (0.0)	1 (4.8)
CORTISONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BECLOMETASONE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
BETAMETHASONE SODIUM PHOSPHATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DEXAMETHASONE PHOSPHATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
METHYLPREDNISOLONE ACETATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TRIAMCINOLONE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BETAMETHASONE ACETATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CORTISONE ACETATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ANTIPROPULSIVES	21 (24.7)	45 (26.0)	74 (48.4)	7 (33.3)
LOPERAMIDE HYDROCHLORIDE	17 (20.0)	25 (14.5)	38 (24.8)	2 (9.5)
LOPERAMIDE	5 (5.9)	18 (10.4)	25 (16.3)	4 (19.0)
LOMOTIL	4 (4.7)	5 (2.9)	28 (18.3)	1 (4.8)
DIACURE PLUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DIHYDROPYRIDINE DERIVATIVES	26 (30.6)	57 (32.9)	41 (26.8)	6 (28.6)
AMLODIPINE	12 (14.1)	35 (20.2)	29 (19.0)	4 (19.0)
AMLODIPINE BESILATE	14 (16.5)	13 (7.5)	9 (5.9)	2 (9.5)
NIFEDIPINE	2 (2.4)	6 (3.5)	3 (2.0)	0 (0.0)
LERCANIDIPINE	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
NICARDIPINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
AMLODIPINE CAMSILATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMLODIPINE OROTATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BENIDIPINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CILNIDIPINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FELODIPINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LERCANIDIPINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NICARDIPINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
BENZODIAZEPINE DERIVATIVES	29 (34.1)	53 (30.6)	50 (32.7)	8 (38.1)
LORAZEPAM	15 (17.6)	26 (15.0)	27 (17.6)	2 (9.5)
ALPRAZOLAM	7 (8.2)	13 (7.5)	12 (7.8)	2 (9.5)
DIAZEPAM	2 (2.4)	1 (0.6)	9 (5.9)	3 (14.3)
MIDAZOLAM	4 (4.7)	8 (4.6)	2 (1.3)	2 (9.5)
CLONAZEPAM	3 (3.5)	4 (2.3)	4 (2.6)	0 (0.0)
BROTIZOLAM	3 (3.5)	4 (2.3)	0 (0.0)	0 (0.0)
BROMAZEPAM	1 (1.2)	2 (1.2)	4 (2.6)	0 (0.0)
TEMAZEPAM	0 (0.0)	1 (0.6)	3 (2.0)	1 (4.8)
ETIZOLAM	0 (0.0)	4 (2.3)	0 (0.0)	0 (0.0)
OXAZEPAM	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
FLUNITRAZEPAM	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
ETHYL LOFLAZEPATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LOPRAZOLAM MESILATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MIDAZOLAM HYDROCHLORIDE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
NITRAZEPAM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TRIAZOLAM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CLOBAZAM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LOPRAZOLAM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
PROPIONIC ACID DERIVATIVES	24 (28.2)	44 (25.4)	41 (26.8)	7 (33.3)
IBUPROFEN	16 (18.8)	22 (12.7)	33 (21.6)	6 (28.6)
NAPROXEN	3 (3.5)	6 (3.5)	3 (2.0)	2 (9.5)
LOXOPROFEN SODIUM	4 (4.7)	9 (5.2)	0 (0.0)	0 (0.0)
NAPROXEN SODIUM	3 (3.5)	3 (1.7)	6 (3.9)	0 (0.0)
LOXOPROFEN	0 (0.0)	5 (2.9)	0 (0.0)	1 (4.8)
IBUPROFEN SODIUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
KETOPROFEN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CAROL-F	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
DEXKETOPROFEN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLURBIPROFEN AXETIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ZALTOPROFEN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CO-ADVIL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ESFLURBIPROFEN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OSMOTICALLY ACTING LAXATIVES	28 (32.9)	53 (30.6)	28 (18.3)	5 (23.8)
MACROGOL 3350	11 (12.9)	12 (6.9)	12 (7.8)	2 (9.5)
LACTULOSE	10 (11.8)	19 (11.0)	4 (2.6)	1 (4.8)
MAGNESIUM OXIDE	6 (7.1)	22 (12.7)	1 (0.7)	1 (4.8)

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OSMOTICALLY ACTING LAXATIVES	28 (32.9)	53 (30.6)	28 (18.3)	5 (23.8)
MACROGOL	5 (5.9)	9 (5.2)	6 (3.9)	2 (9.5)
MOVICOL	1 (1.2)	3 (1.7)	4 (2.6)	0 (0.0)
MAGNESIUM HYDROXIDE	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
MAGNESIUM CITRATE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
MACROGOL 4000	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LACTITOL MONOHYDRATE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
TRANSIPEG	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GOLYTELY	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SEROTONIN (5HT3) ANTAGONISTS	20 (23.5)	35 (20.2)	39 (25.5)	5 (23.8)
ONDANSETRON	18 (21.2)	32 (18.5)	38 (24.8)	5 (23.8)
ONDANSETRON HYDROCHLORIDE	2 (2.4)	0 (0.0)	2 (1.3)	0 (0.0)
GRANISETRON HYDROCHLORIDE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
GRANISETRON	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PALONOSETRON HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CONTACT LAXATIVES	22 (25.9)	44 (25.4)	23 (15.0)	7 (33.3)
SENNOSIDE A+B	19 (22.4)	31 (17.9)	18 (11.8)	4 (19.0)
BISACODYL	2 (2.4)	12 (6.9)	2 (1.3)	1 (4.8)

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Table 14.1.5
 Concomitant Medications
 Safety Analysis Set
 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
CONTACT LAXATIVES	22 (25.9)	44 (25.4)	23 (15.0)	7 (33.3)
COLOXYL WITH SENNA	1 (1.2)	3 (1.7)	2 (1.3)	2 (9.5)
SODIUM PICOSULFATE	1 (1.2)	2 (1.2)	3 (2.0)	0 (0.0)
DOCUSATE W/SENN	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
SENNOSIDE A+B CALCIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DULCODOS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SENOKOT-S	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE	19 (22.4)	41 (23.7)	29 (19.0)	3 (14.3)
SPEKTRAMOX	14 (16.5)	25 (14.5)	24 (15.7)	2 (9.5)
PIP/TAZO	7 (8.2)	18 (10.4)	7 (4.6)	2 (9.5)
UNACID	0 (0.0)	1 (0.6)	3 (2.0)	0 (0.0)
AUGMENTIN	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
PIPERACILLIN W/TAZOBACTAM	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
SULTAMICILLIN TOSILATE	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
AMINOXIDIN SULBACTAM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ELECTROLYTE SOLUTIONS	17 (20.0)	47 (27.2)	26 (17.0)	7 (33.3)
SODIUM CHLORIDE	15 (17.6)	39 (22.5)	19 (12.4)	6 (28.6)
MAGNESIUM SULFATE	4 (4.7)	11 (6.4)	9 (5.9)	2 (9.5)

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 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ELECTROLYTE SOLUTIONS	17 (20.0)	47 (27.2)	26 (17.0)	7 (33.3)
CALCIUM GLUCONATE	1 (1.2)	2 (1.2)	6 (3.9)	1 (4.8)
POTASSIUM CHLORIDE	2 (2.4)	6 (3.5)	2 (1.3)	0 (0.0)
POTASSIUM PHOSPHATE MONOBASIC	1 (1.2)	4 (2.3)	1 (0.7)	0 (0.0)
SODIUM PHOSPHATE	2 (2.4)	1 (0.6)	0 (0.0)	0 (0.0)
MULTITRACE-4	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
POTASSIUM	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
SODIUM BICARBONATE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
CALCIUM CHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ZINC SULFATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ELEMEAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SODIUM PHOSPHATE MONOBASIC (ANHYDRATE)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CALCIUM	6 (7.1)	16 (9.2)	53 (34.6)	4 (19.0)
CALCIUM CARBONATE	5 (5.9)	9 (5.2)	30 (19.6)	3 (14.3)
CALCIUM	1 (1.2)	4 (2.3)	13 (8.5)	0 (0.0)
CALCIUM CITRATE	0 (0.0)	3 (1.7)	9 (5.9)	0 (0.0)
CALCIUM LACTATE	0 (0.0)	0 (0.0)	1 (0.7)	1 (4.8)
CALCIUM ACETATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DICALCIUM MALATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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CALCIUM	6 (7.1)	16 (9.2)	53 (34.6)	4 (19.0)
CALCIUM GLUCONATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SULFONAMIDES, PLAIN	17 (20.0)	43 (24.9)	27 (17.6)	4 (19.0)
FUROSEMIDE	17 (20.0)	38 (22.0)	20 (13.1)	4 (19.0)
CHLORTALIDONE	0 (0.0)	2 (1.2)	2 (1.3)	0 (0.0)
TORASEMIDE	0 (0.0)	1 (0.6)	5 (3.3)	0 (0.0)
AZOSEMIDE	0 (0.0)	4 (2.3)	0 (0.0)	0 (0.0)
INDAPAMIDE	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
METOLAZONE	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
BUMETANIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER ANALGESICS AND ANTIPYRETICS	13 (15.3)	38 (22.0)	33 (21.6)	3 (14.3)
GABAPENTIN	10 (11.8)	17 (9.8)	20 (13.1)	3 (14.3)
PREGABALIN	2 (2.4)	22 (12.7)	8 (5.2)	0 (0.0)
CANNABIDIOL	0 (0.0)	4 (2.3)	4 (2.6)	0 (0.0)
NEFOPAM HYDROCHLORIDE	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
TOPIRAMATE	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
NEFOPAM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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FLUOROQUINOLONES	17 (20.0)	35 (20.2)	23 (15.0)	5 (23.8)
LEVOFLOXACIN	7 (8.2)	26 (15.0)	8 (5.2)	4 (19.0)
CIPROFLOXACIN	10 (11.8)	7 (4.0)	10 (6.5)	2 (9.5)
CIPROFLOXACIN HYDROCHLORIDE	1 (1.2)	5 (2.9)	2 (1.3)	0 (0.0)
OFLOXACIN	0 (0.0)	2 (1.2)	4 (2.6)	0 (0.0)
MOXIFLOXACIN	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
TOSUFLOXACIN TOSILATE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
CIPROFLOXACIN LACTATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLUOROQUINOLONES	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
MOXIFLOXACIN HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NORFLOXACIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BESIFLOXACIN HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LEVOFLOXACIN HEMIHYDRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SITAFLOXACIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MAGNESIUM	12 (14.1)	27 (15.6)	33 (21.6)	6 (28.6)
MAGNESIUM OXIDE	7 (8.2)	14 (8.1)	13 (8.5)	4 (19.0)
MAGNESIUM	2 (2.4)	8 (4.6)	19 (12.4)	2 (9.5)
MAGNESIUM AMINO ACID CHELATE	0 (0.0)	5 (2.9)	1 (0.7)	0 (0.0)

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MAGNESIUM	12 (14.1)	27 (15.6)	33 (21.6)	6 (28.6)
MAGNESIUM PIDOLATE	1 (1.2)	2 (1.2)	1 (0.7)	0 (0.0)
MAGNESIUM ASPARTATE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
MAGNESIUM SULFATE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
MAGNESIUM CITRATE	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
DYNAMAG	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MAGNESIUM GLYCINATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MAGNESIUM HYDROXIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MAGNESIUM OROTATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MAGNESIUM ASPARTATE HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MAGNESIUM HYDROGEN ASPARTATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	13 (15.3)	35 (20.2)	15 (9.8)	6 (28.6)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	4 (4.7)	10 (5.8)	10 (6.5)	5 (23.8)
BENZYLAMINE HYDROCHLORIDE	4 (4.7)	7 (4.0)	0 (0.0)	0 (0.0)
SODIUM GUALENATE HYDRATE	1 (1.2)	9 (5.2)	0 (0.0)	0 (0.0)
LIDOCAINE HYDROCHLORIDE	3 (3.5)	3 (1.7)	1 (0.7)	1 (4.8)
CALCIUM LACTATE W/GLUCOSE OXIDASE/L	2 (2.4)	5 (2.9)	0 (0.0)	0 (0.0)
MAGIC MOUTHWASH	0 (0.0)	2 (1.2)	2 (1.3)	1 (4.8)
ALUMINIUM HYDROXIDE W/DIPHENHYDRAMINE	0 (0.0)	0 (0.0)	1 (0.7)	1 (4.8)

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Table 14.1.5
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 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	13 (15.3)	35 (20.2)	15 (9.8)	6 (28.6)
SODIUM CHLORIDE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
CAPHOSOL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LIDOCAINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BIOTENE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
FIRST BLM	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
GLUCOSE OXIDASE W/LACTOFERRIN/LACTO	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
AQUORAL	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
GLYCEROL DIOLEATE W/PHOSPHOLIPIDS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GLYCO THYMOLINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BENZYDAMINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NIMESULIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SIALIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER	7 (8.2)	24 (13.9)	33 (21.6)	6 (28.6)
LEKOVIT CA	3 (3.5)	9 (5.2)	17 (11.1)	3 (14.3)
CALCIUM W/VITAMIN D NOS	1 (1.2)	4 (2.3)	3 (2.0)	1 (4.8)
SUPER CAL600-MG300	1 (1.2)	7 (4.0)	0 (0.0)	0 (0.0)
CALCIUM CITRATE W/COLECALCIFEROL	1 (1.2)	0 (0.0)	2 (1.3)	1 (4.8)
CALCIUM CARBONATE W/VITAMIN D NOS	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)

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CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER	7 (8.2)	24 (13.9)	33 (21.6)	6 (28.6)
CALCIUM D3	0 (0.0)	2 (1.2)	2 (1.3)	0 (0.0)
CALCITE D	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CALCIUM CARBONATE W/COLECALCIFEROL/MINERALS N	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OSTEOCARE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
CALCIUM CITRATE W/VITAMIN D NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CALCIUM W/MAGNESIUM/VITAMIN D NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR O	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CALCIUM W/COLECALCIFEROL/VITAMIN K NOS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
CALCIUM W/MAGNESIUM	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
DOPPELHERZ AKTIV CALCIUM+D3+BIOTIN+FOLSAEURE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
LOGICAL M	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
VIActiv	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
B-CAL-DM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CALCIDO	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CALCIUM CARBONATE W/MAGNESIUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CALCIUM MAGNESIUM ZINC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CALCIUM PLUS WITH MAGNESIUM & VITAMIN D	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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BETA BLOCKING AGENTS, SELECTIVE	12 (14.1)	23 (13.3)	35 (22.9)	5 (23.8)
METOPROLOL	4 (4.7)	6 (3.5)	5 (3.3)	1 (4.8)
METOPROLOL SUCCINATE	2 (2.4)	2 (1.2)	11 (7.2)	4 (19.0)
METOPROLOL TARTRATE	0 (0.0)	7 (4.0)	8 (5.2)	0 (0.0)
ATENOLOL	3 (3.5)	2 (1.2)	2 (1.3)	0 (0.0)
BISOPROLOL	1 (1.2)	3 (1.7)	6 (3.9)	0 (0.0)
BISOPROLOL FUMARATE	2 (2.4)	3 (1.7)	3 (2.0)	0 (0.0)
NEBIVOLOL	0 (0.0)	0 (0.0)	5 (3.3)	0 (0.0)
NEBIVOLOL HYDROCHLORIDE	1 (1.2)	2 (1.2)	1 (0.7)	0 (0.0)
HMG COA REDUCTASE INHIBITORS	16 (18.8)	31 (17.9)	18 (11.8)	4 (19.0)
ATORVASTATIN	6 (7.1)	17 (9.8)	9 (5.9)	0 (0.0)
ATORVASTATIN CALCIUM	5 (5.9)	8 (4.6)	5 (3.3)	2 (9.5)
SIMVASTATIN	2 (2.4)	3 (1.7)	1 (0.7)	0 (0.0)
ROSUVASTATIN CALCIUM	4 (4.7)	1 (0.6)	3 (2.0)	0 (0.0)
ROSUVASTATIN	1 (1.2)	1 (0.6)	2 (1.3)	1 (4.8)
PRAVASTATIN	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
PITAVASTATIN CALCIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLUVASTATIN SODIUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
HMG COA REDUCTASE INHIBITORS	16 (18.8)	31 (17.9)	18 (11.8)	4 (19.0)
PRAVASTATIN SODIUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	10 (11.8)	24 (13.9)	35 (22.9)	5 (23.8)
PLANTAGO OVATA	2 (2.4)	4 (2.3)	9 (5.9)	0 (0.0)
HERBAL PREPARATION	3 (3.5)	3 (1.7)	6 (3.9)	0 (0.0)
CURCUMA LONGA RHIZOME	1 (1.2)	4 (2.3)	4 (2.6)	1 (4.8)
PAPAYER SOMNIFERUM TINCTURE	0 (0.0)	0 (0.0)	8 (5.2)	0 (0.0)
CANNABIS SATIVA	0 (0.0)	0 (0.0)	4 (2.6)	1 (4.8)
CANNABIS SATIVA OIL	1 (1.2)	1 (0.6)	2 (1.3)	0 (0.0)
SILYBUM MARIANUM	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
ALOE VERA	1 (1.2)	0 (0.0)	1 (0.7)	1 (4.8)
LINUM USITATISSIMUM SEED OIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VACCINIUM MACROCARPON	0 (0.0)	0 (0.0)	3 (2.0)	0 (0.0)
MALUS SPP. VINEGAR EXTRACT	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
MENTHA X PIPERITA OIL	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
CINNAMOMUM VERUM	1 (1.2)	0 (0.0)	0 (0.0)	1 (4.8)
GOREISAN	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
SENNA ALEXANDRINA GLYCOSIDE EXTRACT	0 (0.0)	1 (0.6)	0 (0.0)	1 (4.8)
ALLIUM SATIVUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	10 (11.8)	24 (13.9)	35 (22.9)	5 (23.8)
CAMELLIA SINENSIS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CARICA PAPAYA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SPIRULINA SPP.	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ALOSENN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
COCOS NUCIFERA OIL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CRATAEGUS LAEVIGATA	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
FOENICULUM VULGARE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
GANODERMA LUCIDUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
GENTIANA LUTEA	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
GOSHAJINKIGAN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HARPAGOPHYTUM PROCUMBENS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
HERBAL POLLEN NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
LINUM USITATISSIMUM SEED	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
MACROCYSTIS PYRIFERA	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
OLEA EUROPAEA OIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SERENOA REPENS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
SERENOA REPENS EXTRACT	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SYZYGIUM AROMATICUM	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
TARAXACUM OFFICINALE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	10 (11.8)	24 (13.9)	35 (22.9)	5 (23.8)
VITIS VINIFERA EXTRACT	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VITIS VINIFERA SEED	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ZEA MAYS EXTRACT	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ZINGIBER OFFICINALE RHIZOME	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ARNICA MONTANA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CALENDULA OFFICINALIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HEDERA HELIX	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PLANTAGO OVATA HUSK	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PLATYCODON GRANDIFLORUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PRUNUS ARMENIACA SEED EXTRACT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VISCUM ALBUM EXTRACT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SOFTENERS, EMOLLIENTS	17 (20.0)	18 (10.4)	22 (14.4)	6 (28.6)
DOCUSATE SODIUM	15 (17.6)	14 (8.1)	17 (11.1)	4 (19.0)
DOCUSATE	3 (3.5)	5 (2.9)	5 (3.3)	1 (4.8)
SOFTENERS, EMOLLIENTS	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
DOCUSATE POTASSIUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PARAFFIN, LIQUID	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ANGIOTENSIN II ANTAGONISTS, PLAIN	17 (20.0)	31 (17.9)	21 (13.7)	3 (14.3)
LOSARTAN	3 (3.5)	11 (6.4)	4 (2.6)	1 (4.8)
LOSARTAN POTASSIUM	2 (2.4)	3 (1.7)	8 (5.2)	0 (0.0)
IRBESARTAN	3 (3.5)	1 (0.6)	5 (3.3)	0 (0.0)
VALSARTAN	2 (2.4)	0 (0.0)	4 (2.6)	1 (4.8)
CANDESARTAN CILEXETIL	3 (3.5)	5 (2.9)	1 (0.7)	0 (0.0)
CANDESARTAN	1 (1.2)	3 (1.7)	1 (0.7)	1 (4.8)
OLMESARTAN	1 (1.2)	3 (1.7)	0 (0.0)	0 (0.0)
OLMESARTAN MEDOXOMIL	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
AZILSARTAN	2 (2.4)	1 (0.6)	0 (0.0)	0 (0.0)
TELMISARTAN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FIMASARTAN POTASSIUM TRIHYDRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ACE INHIBITORS, PLAIN	10 (11.8)	24 (13.9)	21 (13.7)	2 (9.5)
LISINOPRIL	8 (9.4)	14 (8.1)	12 (7.8)	2 (9.5)
RAMIPRIL	1 (1.2)	6 (3.5)	3 (2.0)	0 (0.0)
PERINDOPRIL	0 (0.0)	1 (0.6)	4 (2.6)	0 (0.0)
ENALAPRIL	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
ENALAPRILAT	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ACE INHIBITORS, PLAIN	10 (11.8)	24 (13.9)	21 (13.7)	2 (9.5)
ENALAPRIL MALEATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TRANDOLAPRIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BENAZEPRIL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CAPTOPRIL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LISINOPRIL DIHYDRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PERINDOPRIL ARGININE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HEPARIN GROUP	17 (20.0)	32 (18.5)	18 (11.8)	4 (19.0)
ENOXAPARIN SODIUM	8 (9.4)	13 (7.5)	8 (5.2)	0 (0.0)
ENOXAPARIN	7 (8.2)	16 (9.2)	2 (1.3)	4 (19.0)
HEPARIN	2 (2.4)	5 (2.9)	5 (3.3)	0 (0.0)
TINZAPARIN SODIUM	1 (1.2)	0 (0.0)	4 (2.6)	0 (0.0)
DALTEPARIN	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
HEPARIN SODIUM	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
DALTEPARIN SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GLUCOSE W/HEPARIN	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
HEPARIN CALCIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NADROPARIN CALCIUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
AMIDES	16 (18.8)	29 (16.8)	17 (11.1)	7 (33.3)
LIDOCAINE	8 (9.4)	20 (11.6)	13 (8.5)	7 (33.3)
EMLA	3 (3.5)	3 (1.7)	0 (0.0)	0 (0.0)
BUPIVACAINE	1 (1.2)	2 (1.2)	1 (0.7)	0 (0.0)
XYLOCAINE-EPINEPHRINE	2 (2.4)	1 (0.6)	2 (1.3)	0 (0.0)
LIDOCAINE HYDROCHLORIDE	2 (2.4)	3 (1.7)	0 (0.0)	0 (0.0)
ROPIVACAINE	0 (0.0)	2 (1.2)	0 (0.0)	1 (4.8)
MARCAIN-ADRENALIN	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
BUPIVACAINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
LIDOCAINE W/SODIUM BICARBONATE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
AMIDES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LIDOCAINE W/MENTHOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OXETACAINE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
RAPYDAN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ROPIVACAINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER ANTIEMETICS	12 (14.1)	21 (12.1)	24 (15.7)	5 (23.8)
PROCHLORPERAZINE MALEATE	5 (5.9)	12 (6.9)	9 (5.9)	0 (0.0)
PROCHLORPERAZINE	5 (5.9)	4 (2.3)	5 (3.3)	3 (14.3)

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OTHER ANTIEMETICS	12 (14.1)	21 (12.1)	24 (15.7)	5 (23.8)
DRONABINOL	1 (1.2)	1 (0.6)	6 (3.9)	1 (4.8)
PROMETHAZINE	1 (1.2)	0 (0.0)	4 (2.6)	1 (4.8)
PROCHLORPERAZINE EDISYLATE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
HYOSCINE	0 (0.0)	0 (0.0)	1 (0.7)	1 (4.8)
APREPITANT	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
OTHER ANTIEMETICS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	7 (8.2)	30 (17.3)	14 (9.2)	7 (33.3)
SALBUTAMOL	5 (5.9)	24 (13.9)	8 (5.2)	3 (14.3)
SALBUTAMOL SULFATE	1 (1.2)	5 (2.9)	6 (3.9)	1 (4.8)
LEVOSALBUTAMOL	1 (1.2)	3 (1.7)	0 (0.0)	2 (9.5)
LEVOSALBUTAMOL HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	1 (4.8)
LEVOSALBUTAMOL TARTRATE	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
PROCATEROL HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SALMETEROL	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
ARFORMOTEROL TARTRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FENOTEROL HYDROBROMIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
POTASSIUM	11 (12.9)	21 (12.1)	23 (15.0)	3 (14.3)
POTASSIUM CHLORIDE	11 (12.9)	19 (11.0)	19 (12.4)	3 (14.3)
POTASSIUM	0 (0.0)	2 (1.2)	2 (1.3)	0 (0.0)
POTASSIUM PHOSPHATE MONOBASIC	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MAGNESIUM W/POTASSIUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
POTASSIUM ASPARTATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
POTASSIUM GLUCONATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
SWISS-KAL EFF	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER ANTIDEPRESSANTS	11 (12.9)	14 (8.1)	24 (15.7)	5 (23.8)
MIRTAZAPINE	6 (7.1)	6 (3.5)	8 (5.2)	0 (0.0)
TRAZODONE	3 (3.5)	0 (0.0)	5 (3.3)	1 (4.8)
DULOXETINE	0 (0.0)	1 (0.6)	4 (2.6)	2 (9.5)
TRAZODONE HYDROCHLORIDE	2 (2.4)	1 (0.6)	2 (1.3)	0 (0.0)
BUPROPION	0 (0.0)	2 (1.2)	1 (0.7)	1 (4.8)
DULOXETINE HYDROCHLORIDE	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
BUPROPION HYDROCHLORIDE	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
VENLAFAXINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
VENLAFAXINE	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)

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OTHER ANTIDEPRESSANTS	11 (12.9)	14 (8.1)	24 (15.7)	5 (23.8)
MIANSERIN HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	1 (4.8)
VORTIOXETINE HYDROBROMIDE	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
DESVENLAFAXINE SUCCINATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OXITRIPTAN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER OPIOIDS	15 (17.6)	27 (15.6)	15 (9.8)	1 (4.8)
TRAMADOL	11 (12.9)	8 (4.6)	9 (5.9)	1 (4.8)
TRAMADOL HYDROCHLORIDE	3 (3.5)	12 (6.9)	4 (2.6)	0 (0.0)
ULTRACET	2 (2.4)	8 (4.6)	1 (0.7)	0 (0.0)
TAPENTADOL	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
TAPENTADOL HYDROCHLORIDE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
OTHER OPIOIDS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VALORON N	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MULTIVITAMINS, PLAIN	9 (10.6)	19 (11.0)	18 (11.8)	3 (14.3)
MULTIVITAMINS, PLAIN	9 (10.6)	18 (10.4)	17 (11.1)	3 (14.3)
TAB A VITE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
VITAMINS NOS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	12 (14.1)	23 (13.3)	16 (10.5)	0 (0.0)
LORATADINE	6 (7.1)	12 (6.9)	13 (8.5)	0 (0.0)
FEXOFENADINE HYDROCHLORIDE	1 (1.2)	4 (2.3)	2 (1.3)	0 (0.0)
DESLOMATADINE	1 (1.2)	2 (1.2)	1 (0.7)	0 (0.0)
HYDROXYZINE HYDROCHLORIDE	3 (3.5)	1 (0.6)	0 (0.0)	0 (0.0)
BILASTINE	3 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)
OLOPATADINE HYDROCHLORIDE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
FEXOFENADINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BEPOTASTINE BESILATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
EBASTINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
EPINASTINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HYDROXYZINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
KETOTIFEN FUMARATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROPULSIVES	13 (15.3)	26 (15.0)	15 (9.8)	1 (4.8)
METOCLOPRAMIDE	5 (5.9)	18 (10.4)	7 (4.6)	1 (4.8)
METOCLOPRAMIDE HYDROCHLORIDE	3 (3.5)	6 (3.5)	7 (4.6)	0 (0.0)
DOMPERIDONE	4 (4.7)	0 (0.0)	2 (1.3)	0 (0.0)
MOSAPRIDE CITRATE	1 (1.2)	4 (2.3)	0 (0.0)	0 (0.0)

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PROPULSIVES	13 (15.3)	26 (15.0)	15 (9.8)	1 (4.8)
ITOPRIDE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
MOSAPRIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	6 (7.1)	22 (12.7)	17 (11.1)	3 (14.3)
ACETYLSALICYLIC ACID	5 (5.9)	21 (12.1)	12 (7.8)	3 (14.3)
ACETYLSALICYLATE LYSINE	0 (0.0)	1 (0.6)	5 (3.3)	0 (0.0)
CLOPIDOGREL BISULFATE	0 (0.0)	2 (1.2)	2 (1.3)	0 (0.0)
CLOPIDOGREL	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
TICAGRELOR	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ILOPROST TROMETAMOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DIRECT FACTOR XA INHIBITORS	15 (17.6)	23 (13.3)	12 (7.8)	2 (9.5)
RIVAROXABAN	10 (11.8)	10 (5.8)	6 (3.9)	2 (9.5)
APIXABAN	5 (5.9)	8 (4.6)	6 (3.9)	0 (0.0)
EDOXABAN TOSILATE	0 (0.0)	5 (2.9)	0 (0.0)	0 (0.0)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	8 (9.4)	11 (6.4)	18 (11.8)	2 (9.5)
SERTRALINE	3 (3.5)	1 (0.6)	1 (0.7)	1 (4.8)
ESCITALOPRAM	2 (2.4)	1 (0.6)	2 (1.3)	0 (0.0)

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SELECTIVE SEROTONIN REUPTAKE INHIBITORS	8 (9.4)	11 (6.4)	18 (11.8)	2 (9.5)
SERTRALINE HYDROCHLORIDE	0 (0.0)	2 (1.2)	3 (2.0)	0 (0.0)
CITALOPRAM	0 (0.0)	0 (0.0)	5 (3.3)	0 (0.0)
ESCITALOPRAM OXALATE	0 (0.0)	1 (0.6)	3 (2.0)	0 (0.0)
PAROXETINE	1 (1.2)	3 (1.7)	1 (0.7)	1 (4.8)
CITALOPRAM HYDROBROMIDE	1 (1.2)	1 (0.6)	3 (2.0)	0 (0.0)
FLUOXETINE	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
FLUOXETINE HYDROCHLORIDE	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
PAROXETINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
BENZODIAZEPINE RELATED DRUGS	11 (12.9)	18 (10.4)	17 (11.1)	1 (4.8)
ZOLPIDEM	4 (4.7)	9 (5.2)	8 (5.2)	1 (4.8)
ZOLPIDEM TARTRATE	7 (8.2)	5 (2.9)	4 (2.6)	0 (0.0)
ZOPICLONE	3 (3.5)	4 (2.3)	4 (2.6)	0 (0.0)
ESZOPICLONE	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
ZALEPLON	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZ	11 (12.9)	24 (13.9)	10 (6.5)	2 (9.5)
DENOSUMAB	11 (12.9)	24 (13.9)	10 (6.5)	2 (9.5)

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CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	8 (9.4)	19 (11.0)	15 (9.8)	0 (0.0)
TRIAMCINOLONE ACETONIDE	3 (3.5)	4 (2.3)	5 (3.3)	0 (0.0)
TRIAMCINOLONE	3 (3.5)	4 (2.3)	6 (3.9)	0 (0.0)
ALCLOMETASONE DIPROPIONATE	0 (0.0)	5 (2.9)	0 (0.0)	0 (0.0)
DESONIDE	0 (0.0)	2 (1.2)	2 (1.3)	0 (0.0)
ALCLOMETASONE	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
CLOBETASONE BUTYRATE	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
HYDROCORTISONE BUTYRATE	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
DEXAMETHASONE DIPROPIONATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DEXAMETHASONE VALERATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLUMETASONE PIVALATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS, POTENT (GROUP III)	13 (15.3)	25 (14.5)	7 (4.6)	2 (9.5)
BETAMETHASONE VALERATE	6 (7.1)	4 (2.3)	0 (0.0)	0 (0.0)
BETAMETHASONE DIPROPIONATE	2 (2.4)	1 (0.6)	2 (1.3)	1 (4.8)
BETAMETHASONE BUTYRATE PROPIONATE	2 (2.4)	7 (4.0)	0 (0.0)	0 (0.0)
DIFLUPREDNATE	2 (2.4)	5 (2.9)	0 (0.0)	1 (4.8)
FLUOCINONIDE	1 (1.2)	3 (1.7)	2 (1.3)	0 (0.0)
MOMETASONE FUROATE	1 (1.2)	0 (0.0)	2 (1.3)	0 (0.0)

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CORTICOSTEROIDS, POTENT (GROUP III)	13 (15.3)	25 (14.5)	7 (4.6)	2 (9.5)
FLUCINOLONE ACETONIDE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
DESOXIMETASONE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
MOMETASONE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
METHYLPREDNISOLONE ACEPONATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PREDNICARBATE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
DIFLORASONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLUDROXYCORTIDE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
DIFLUCORTOLONE VALERATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
INFLUENZA VACCINES	9 (10.6)	21 (12.1)	12 (7.8)	2 (9.5)
INFLUENZA VACCINE	9 (10.6)	21 (12.1)	12 (7.8)	2 (9.5)
ALPHA-ADRENORECEPTOR ANTAGONISTS	9 (10.6)	15 (8.7)	20 (13.1)	1 (4.8)
TAMSULOSIN HYDROCHLORIDE	5 (5.9)	4 (2.3)	9 (5.9)	0 (0.0)
TAMSULOSIN	4 (4.7)	6 (3.5)	4 (2.6)	1 (4.8)
ALFUZOSIN HYDROCHLORIDE	2 (2.4)	0 (0.0)	1 (0.7)	0 (0.0)
DOXAZOSIN MESILATE	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
SILODOSIN	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
ALFUZOSIN	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)

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ALPHA-ADRENORECEPTOR ANTAGONISTS	9 (10.6)	15 (8.7)	20 (13.1)	1 (4.8)
DOXAZOSIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DUTAS-T	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
PAZOSIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
URAPIDIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TERAZOSIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PIPERAZINE DERIVATIVES	10 (11.8)	16 (9.2)	13 (8.5)	2 (9.5)
CETIRIZINE HYDROCHLORIDE	6 (7.1)	4 (2.3)	7 (4.6)	0 (0.0)
CETIRIZINE	3 (3.5)	4 (2.3)	4 (2.6)	2 (9.5)
LEVOCETIRIZINE DIHYDROCHLORIDE	0 (0.0)	6 (3.5)	1 (0.7)	0 (0.0)
MECLOZINE	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
LEVOCETIRIZINE	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
CYCLIZINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OPIUM ALKALOIDS AND DERIVATIVES	14 (16.5)	26 (15.0)	5 (3.3)	0 (0.0)
CODEINE	6 (7.1)	5 (2.9)	0 (0.0)	0 (0.0)
HYDROCODONE COMPOUND	3 (3.5)	3 (1.7)	1 (0.7)	0 (0.0)
TUSSIONEX PENNKINETIC	1 (1.2)	3 (1.7)	0 (0.0)	0 (0.0)
PROMETHAZINE W/CODEINE	3 (3.5)	2 (1.2)	0 (0.0)	0 (0.0)

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OPIUM ALKALOIDS AND DERIVATIVES	14 (16.5)	26 (15.0)	5 (3.3)	0 (0.0)
DEXTROMETHORPHAN HYDROBROMIDE	0 (0.0)	4 (2.3)	1 (0.7)	0 (0.0)
CODEINE PHOSPHATE	0 (0.0)	4 (2.3)	0 (0.0)	0 (0.0)
DEXTROMETHORPHAN	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
PHOLCODINE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
BROMPHENIRAMINE W/DEXTROMETHORPHAN/PSEUDOEPHE	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
CODIPRONT	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
DIMEMORFAN PHOSPHATE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
ACTIFED COMPOUND LINCTUS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CODENA-S	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DIMETANE DX	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HUSCODE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NOTUSS NX	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CODEINE SULFATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DEXTROMETHORPHAN W/PROMETHAZINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
THIRD-GENERATION CEPHALOSPORINS	6 (7.1)	20 (11.6)	13 (8.5)	3 (14.3)
CEFTRIAZONE	4 (4.7)	6 (3.5)	2 (1.3)	1 (4.8)
CEFTRIAZONE SODIUM	0 (0.0)	6 (3.5)	5 (3.3)	0 (0.0)
CEFDINIR	0 (0.0)	3 (1.7)	4 (2.6)	1 (4.8)

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THIRD-GENERATION CEPHALOSPORINS	6 (7.1)	20 (11.6)	13 (8.5)	3 (14.3)
CEFPODOXIME PROXETIL	2 (2.4)	3 (1.7)	0 (0.0)	1 (4.8)
CEFCAPENE PIVOXIL HYDROCHLORIDE	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
CEFIXIME	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
CEFPODOXIME	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CEFDITOREN PIVOXIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CEFOTAXIME	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CEFTAZIDIME	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
PENICILLINS WITH EXTENDED SPECTRUM	6 (7.1)	13 (7.5)	16 (10.5)	3 (14.3)
AMOXICILLIN	4 (4.7)	9 (5.2)	14 (9.2)	3 (14.3)
AMPICILLIN	1 (1.2)	1 (0.6)	2 (1.3)	0 (0.0)
AMOXICILLIN TRIHYDRATE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
PIVMECILLINAM	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
AMPICILLIN SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMOXICILLIN SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INC	9 (10.6)	14 (8.1)	13 (8.5)	2 (9.5)
BACTRIM	9 (10.6)	14 (8.1)	13 (8.5)	2 (9.5)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
TETRACYCLINES	8 (9.4)	13 (7.5)	17 (11.1)	2 (9.5)
DOXYCYCLINE	4 (4.7)	8 (4.6)	10 (6.5)	2 (9.5)
DOXYCYCLINE HYCLATE	4 (4.7)	4 (2.3)	4 (2.6)	0 (0.0)
DOXYCYCLINE MONOHYDRATE	2 (2.4)	0 (0.0)	2 (1.3)	0 (0.0)
MINOCYCLINE HYDROCHLORIDE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
MINOCYCLINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
TIGECYCLINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	4 (4.7)	14 (8.1)	17 (11.1)	2 (9.5)
CYANOCOBALAMIN	3 (3.5)	13 (7.5)	15 (9.8)	1 (4.8)
MECOBALAMIN	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
FOLGAMMA	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
HEPAGRISEVIT FORTE-N	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
VITAMIN B12 NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
FOLIC ACID AND DERIVATIVES	15 (17.6)	16 (9.2)	7 (4.6)	0 (0.0)
FOLIC ACID	15 (17.6)	16 (9.2)	7 (4.6)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ANTIDIARRHEAL MICROORGANISMS	5 (5.9)	15 (8.7)	10 (6.5)	2 (9.5)
PROBIOTICS NOS	3 (3.5)	6 (3.5)	4 (2.6)	1 (4.8)
LACTOBACILLUS ACIDOPHILUS	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
BACILLUS COAGULANS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LACTINEX	0 (0.0)	1 (0.6)	1 (0.7)	1 (4.8)
ANTIBIOTICS-RESISTANT LACTIC ACID BACTERIAE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
BACTERIA NOS	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
BIFIDOBACTERIUM LACTIS	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
BIFIDOBACTERIUM NOS	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
BIO-THREE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
LACTOBACILLUS RHAMNOSUS	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
BIFIDOBACTERIUM INFANTIS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ENTEROCOCCUS FAECALIS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LACTIBIANE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
NATURES WAY PRIMADOPHILUS ORIGINAL	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
SACCHAROMYCES BOULARDII	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
VSL#3	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIDIARRHEAL MICROORGANISMS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ENTEROCOCCUS FAECIUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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ANTIDIARRHEAL MICROORGANISMS	5 (5.9)	15 (8.7)	10 (6.5)	2 (9.5)
INNER HEALTH PLUS DAIRY FREE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
KYO-DOPHILUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS	5 (5.9)	9 (5.2)	14 (9.2)	2 (9.5)
FLUTICASONE PROPIONATE	2 (2.4)	1 (0.6)	8 (5.2)	0 (0.0)
FLUTICASONE	1 (1.2)	5 (2.9)	3 (2.0)	1 (4.8)
MOMETASONE FUROATE	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
BECLOMETASONE DIPROPIONATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
POSTERISAN F	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
BUDESONIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HYDROCORTISONE ACETATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MOMETASONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NERIPROCT	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
TRIAMCINOLONE ACETONIDE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
ULTRAPROCT	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DUONASE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FLUOCINOLONE ACETONIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FLUTICASONE FUROATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYDROCORTISONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
CORTICOSTEROIDS	5 (5.9)	9 (5.2)	14 (9.2)	2 (9.5)
PROCTOSEDYL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FIRST-GENERATION CEPHALOSPORINS	8 (9.4)	16 (9.2)	11 (7.2)	2 (9.5)
CEFALEXIN	4 (4.7)	8 (4.6)	8 (5.2)	0 (0.0)
CEFAZOLIN	3 (3.5)	7 (4.0)	3 (2.0)	0 (0.0)
CEFADROXIL	1 (1.2)	3 (1.7)	1 (0.7)	1 (4.8)
CEFAZOLIN SODIUM	1 (1.2)	2 (1.2)	1 (0.7)	0 (0.0)
CEFAZOLIN W/DEXTROSE	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
CEFALEXIN MONOHYDRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROTON PUMP INHIBITORS	7 (8.2)	22 (12.7)	8 (5.2)	1 (4.8)
PANTOPRAZOLE	4 (4.7)	8 (4.6)	3 (2.0)	1 (4.8)
PANTOPRAZOLE SODIUM SESQUIHYDRATE	0 (0.0)	7 (4.0)	3 (2.0)	0 (0.0)
OMEPRAZOLE	2 (2.4)	3 (1.7)	2 (1.3)	1 (4.8)
LANSOPRAZOLE	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
ESOMEPRAZOLE MAGNESIUM	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
DEXLANSOPRAZOLE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ESOMEPRAZOLE SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
RABEPRAZOLE SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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PROTON PUMP INHIBITORS	7 (8.2)	22 (12.7)	8 (5.2)	1 (4.8)
VONOPRAZAN FUMARATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ESOMEPRAZOLE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREA	5 (5.9)	22 (12.7)	6 (3.9)	2 (9.5)
NYSTATIN	4 (4.7)	8 (4.6)	2 (1.3)	2 (9.5)
CHLORHEXIDINE GLUCONATE	0 (0.0)	6 (3.5)	2 (1.3)	0 (0.0)
CLOTRIMAZOLE	2 (2.4)	3 (1.7)	0 (0.0)	0 (0.0)
AMPHOTERICIN B	0 (0.0)	3 (1.7)	1 (0.7)	0 (0.0)
CHLORHEXIDINE	1 (1.2)	2 (1.2)	3 (2.0)	0 (0.0)
HYDROGEN PEROXIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
THYMOL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER OPHTHALMOLOGICALS	7 (8.2)	20 (11.6)	8 (5.2)	1 (4.8)
HYALURONATE SODIUM	0 (0.0)	4 (2.3)	1 (0.7)	0 (0.0)
SYSTANE LUBRICANT	3 (3.5)	0 (0.0)	2 (1.3)	0 (0.0)
ARTIFICIAL TEARS	1 (1.2)	3 (1.7)	0 (0.0)	0 (0.0)
HYPROMELLOSE	1 (1.2)	0 (0.0)	3 (2.0)	0 (0.0)
CICLOSPORIN	0 (0.0)	4 (2.3)	0 (0.0)	0 (0.0)
TEARS PLUS	0 (0.0)	2 (1.2)	2 (1.3)	0 (0.0)

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OTHER OPHTHALMOLOGICALS	7 (8.2)	20 (11.6)	8 (5.2)	1 (4.8)
CYANOCOBALAMIN	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
DIQUAFOSOL TETRASODIUM	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
OTHER OPHTHALMOLOGICALS	0 (0.0)	1 (0.6)	0 (0.0)	1 (4.8)
CARMELLOSE SODIUM	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
CARBOMER	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
MYTEAR	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
PIRENOXINE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
HYALURONIC ACID	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MUCOFADIN	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
VISINE ADVANCED RELIEF	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
XANTOXYL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CARMELLOSE SODIUM W/GLYCEROL/HYALURONATE SODI	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
RETINOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SOOTHE XP	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TEARS NATURAL II	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TEARS NATURALE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TREHALOSE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
AMINOALKYL ETHERS	6 (7.1)	13 (7.5)	11 (7.2)	4 (19.0)
DIPHENHYDRAMINE HYDROCHLORIDE	5 (5.9)	9 (5.2)	9 (5.9)	3 (14.3)
DIPHENHYDRAMINE	1 (1.2)	5 (2.9)	2 (1.3)	1 (4.8)
DIMENHYDRINATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEA	6 (7.1)	20 (11.6)	9 (5.9)	3 (14.3)
SUCRALFATE	2 (2.4)	6 (3.5)	7 (4.6)	2 (9.5)
REBAMIPIDE	4 (4.7)	9 (5.2)	0 (0.0)	1 (4.8)
PEPTAC	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
SODIUM ALGINATE	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
ECABET MONOSODIUM	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOP	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
POLAPREZINC	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ALGITAB	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MACROLIDES	8 (9.4)	11 (6.4)	12 (7.8)	3 (14.3)
AZITHROMYCIN	8 (9.4)	10 (5.8)	12 (7.8)	3 (14.3)
ROXITHROMYCIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
CORTICOSTEROIDS, WEAK (GROUP I)	13 (15.3)	11 (6.4)	8 (5.2)	2 (9.5)
HYDROCORTISONE	13 (15.3)	9 (5.2)	6 (3.9)	2 (9.5)
HYDROCORTISONE ACETATE	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
PREDNISOLONE VALEROACETATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PHENYLPIPERIDINE DERIVATIVES	8 (9.4)	18 (10.4)	6 (3.9)	2 (9.5)
FENTANYL	7 (8.2)	17 (9.8)	5 (3.3)	2 (9.5)
FENTANYL CITRATE	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
PETHIDINE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
PETHIDINE HYDROCHLORIDE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER EMOLLIENTS AND PROTECTIVES	9 (10.6)	20 (11.6)	5 (3.3)	1 (4.8)
HEPARINOID	6 (7.1)	16 (9.2)	0 (0.0)	1 (4.8)
DEXERYL	0 (0.0)	1 (0.6)	5 (3.3)	0 (0.0)
PARAFFIN SOFT	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CETAPHIL	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
AMMONIUM LACTATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CAMPBOR W/MENTHOL	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
TOCOPHEROL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
MUCOLYTICS	8 (9.4)	20 (11.6)	3 (2.0)	1 (4.8)
ACETYLCYSTEINE	4 (4.7)	9 (5.2)	1 (0.7)	1 (4.8)
SODIUM CHLORIDE	1 (1.2)	2 (1.2)	2 (1.3)	0 (0.0)
AMBROXOL	2 (2.4)	3 (1.7)	0 (0.0)	0 (0.0)
ERDOSTEINE	2 (2.4)	2 (1.2)	0 (0.0)	0 (0.0)
BROMHEXINE HYDROCHLORIDE	1 (1.2)	3 (1.7)	0 (0.0)	0 (0.0)
CARBOCISTEINE	0 (0.0)	4 (2.3)	0 (0.0)	0 (0.0)
AMBROXOL HYDROCHLORIDE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
AMBROXOL ACEFYLLINATE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
BROMHEXINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DORNASE ALFA	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ASCORBIC ACID (VITAMIN C), PLAIN	6 (7.1)	10 (5.8)	11 (7.2)	4 (19.0)
ASCORBIC ACID	6 (7.1)	10 (5.8)	10 (6.5)	3 (14.3)
CALCIUM ASCORBATE	0 (0.0)	0 (0.0)	1 (0.7)	1 (4.8)
BIGUANIDES	5 (5.9)	12 (6.9)	10 (6.5)	2 (9.5)
METFORMIN	2 (2.4)	8 (4.6)	5 (3.3)	2 (9.5)
METFORMIN HYDROCHLORIDE	3 (3.5)	4 (2.3)	5 (3.3)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
PREPARATIONS INHIBITING URIC ACID PRODUCTION	3 (3.5)	13 (7.5)	11 (7.2)	1 (4.8)
ALLOPURINOL	1 (1.2)	9 (5.2)	10 (6.5)	1 (4.8)
FEBUXOSTAT	2 (2.4)	4 (2.3)	1 (0.7)	0 (0.0)
DRUGS USED IN ERECTILE DYSFUNCTION	2 (2.4)	8 (4.6)	12 (7.8)	0 (0.0)
SILDENAFIL CITRATE	0 (0.0)	5 (2.9)	6 (3.9)	0 (0.0)
TADALAFIL	1 (1.2)	2 (1.2)	3 (2.0)	0 (0.0)
SILDENAFIL	1 (1.2)	2 (1.2)	4 (2.6)	0 (0.0)
TRIMIX	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VARDENAFIL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER COUGH SUPPRESSANTS	8 (9.4)	12 (6.9)	7 (4.6)	1 (4.8)
BENZONATATE	8 (9.4)	8 (4.6)	7 (4.6)	1 (4.8)
LEVODROPROPIZINE	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
BENPROPERINE PHOSPHATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER COUGH SUPPRESSANTS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
CALCIUM COMPOUNDS	3 (3.5)	7 (4.0)	12 (7.8)	0 (0.0)
CALCIUM CARBONATE	3 (3.5)	7 (4.0)	12 (7.8)	0 (0.0)
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORD	7 (8.2)	10 (5.8)	10 (6.5)	2 (9.5)
SIMETICONE	7 (8.2)	9 (5.2)	8 (5.2)	2 (9.5)
DIMETICONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SPASFON	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PHLOROGLUCINOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
EXPECTORANTS	5 (5.9)	12 (6.9)	10 (6.5)	1 (4.8)
GUAIFENESIN	4 (4.7)	11 (6.4)	10 (6.5)	1 (4.8)
AMMONIUM BICARBONATE W/CEPHAELIS SP	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
OPHAN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
RESPIRE-SR-120	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MELATONIN RECEPTOR AGONISTS	5 (5.9)	5 (2.9)	14 (9.2)	2 (9.5)
MELATONIN	4 (4.7)	5 (2.9)	14 (9.2)	2 (9.5)
RAMELTEON	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	5 (5.9)	15 (8.7)	7 (4.6)	4 (19.0)
NORMOSOL	3 (3.5)	7 (4.0)	0 (0.0)	1 (4.8)
RINGER-LACTATE	2 (2.4)	3 (1.7)	3 (2.0)	2 (9.5)
DEXTROSE AND SODIUM CHLORIDE INJECTION	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
OSMOTAN	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
LACTEC	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
EL-4	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
POTACOL R	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DEXTROSE W/POTASSIUM CHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
HAEMOFILTRATIONSLOESUNG HF 24	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
JONOSTERIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
RINGOLACT D	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BISPHOSPHONATES	3 (3.5)	8 (4.6)	10 (6.5)	3 (14.3)
ZOLEDRONIC ACID	2 (2.4)	3 (1.7)	8 (5.2)	2 (9.5)
ALENDRONATE SODIUM	1 (1.2)	3 (1.7)	0 (0.0)	0 (0.0)
PAMIDRONATE DISODIUM	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
RISEDRONATE SODIUM	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
IBANDRONATE SODIUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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BISPHOSPHONATES	3 (3.5)	8 (4.6)	10 (6.5)	3 (14.3)
RISEDRONIC ACID	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	7 (8.2)	13 (7.5)	8 (5.2)	2 (9.5)
KETOROLAC	3 (3.5)	4 (2.3)	3 (2.0)	1 (4.8)
KETOROLAC TROMETHAMINE	2 (2.4)	2 (1.2)	4 (2.6)	0 (0.0)
DICLOFENAC	2 (2.4)	2 (1.2)	2 (1.3)	0 (0.0)
DICLOFENAC SODIUM	1 (1.2)	2 (1.2)	0 (0.0)	1 (4.8)
ACECLOFENAC	0 (0.0)	4 (2.3)	0 (0.0)	0 (0.0)
INDOMETACIN	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
ETODOLAC	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
SULINDAC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
THIAZIDES, PLAIN	4 (4.7)	9 (5.2)	9 (5.9)	1 (4.8)
HYDROCHLOROTHIAZIDE	4 (4.7)	7 (4.0)	9 (5.9)	1 (4.8)
TRICHLORMETHIAZIDE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS FOR LOCAL ORAL TREATMENT	8 (9.4)	14 (8.1)	2 (1.3)	2 (9.5)
DEXAMETHASONE	4 (4.7)	9 (5.2)	2 (1.3)	1 (4.8)
TRIAMCINOLONE ACETONIDE	3 (3.5)	4 (2.3)	0 (0.0)	1 (4.8)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
CORTICOSTEROIDS FOR LOCAL ORAL TREATMENT	8 (9.4)	14 (8.1)	2 (1.3)	2 (9.5)
ORAL AID	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
TRIAMCINOLONE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
PREDNISOLONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GLYCOPEPTIDE ANTIBACTERIALS	4 (4.7)	12 (6.9)	10 (6.5)	2 (9.5)
VANCOMYCIN	3 (3.5)	9 (5.2)	8 (5.2)	2 (9.5)
VANCOMYCIN HYDROCHLORIDE	1 (1.2)	3 (1.7)	1 (0.7)	1 (4.8)
DALBAVANCIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
NITROFURAN DERIVATIVES	5 (5.9)	8 (4.6)	10 (6.5)	3 (14.3)
NITROFURANTOIN	5 (5.9)	8 (4.6)	10 (6.5)	3 (14.3)
CORTICOSTEROIDS, VERY POTENT (GROUP IV)	5 (5.9)	10 (5.8)	9 (5.9)	0 (0.0)
CLOBETASOL PROPIONATE	3 (3.5)	7 (4.0)	4 (2.6)	0 (0.0)
CLOBETASOL	2 (2.4)	3 (1.7)	5 (3.3)	0 (0.0)
OTHER ANTIEPILEPTICS	8 (9.4)	11 (6.4)	4 (2.6)	2 (9.5)
LEVETIRACETAM	5 (5.9)	7 (4.0)	2 (1.3)	2 (9.5)
LACOSAMIDE	1 (1.2)	3 (1.7)	0 (0.0)	1 (4.8)

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OTHER ANTIEPILEPTICS	8 (9.4)	11 (6.4)	4 (2.6)	2 (9.5)
LAMOTRIGINE	1 (1.2)	1 (0.6)	2 (1.3)	0 (0.0)
GABAPENTIN	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
PREGABALIN	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
TOPIRAMATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER CENTRALLY ACTING AGENTS	5 (5.9)	9 (5.2)	8 (5.2)	1 (4.8)
CYCLOBENZAPRINE	1 (1.2)	2 (1.2)	4 (2.6)	0 (0.0)
CYCLOBENZAPRINE HYDROCHLORIDE	2 (2.4)	2 (1.2)	3 (2.0)	0 (0.0)
BACLOFEN	1 (1.2)	0 (0.0)	2 (1.3)	1 (4.8)
TIZANIDINE	0 (0.0)	2 (1.2)	0 (0.0)	1 (4.8)
EPERISONE HYDROCHLORIDE	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
EPERISONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANTIINFLAMMATORY PREPARATIONS, NON-STERIODS FOR TO	6 (7.1)	15 (8.7)	4 (2.6)	0 (0.0)
LOXOPROFEN SODIUM	2 (2.4)	7 (4.0)	0 (0.0)	0 (0.0)
DICLOFENAC SODIUM	1 (1.2)	2 (1.2)	2 (1.3)	0 (0.0)
KETOPROFEN	1 (1.2)	4 (2.3)	1 (0.7)	0 (0.0)
DICLOFENAC	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
INDOMETACIN	2 (2.4)	1 (0.6)	0 (0.0)	0 (0.0)

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ANTIINFLAMMATORY PREPARATIONS, NON-STERIODS FOR TO	6 (7.1)	15 (8.7)	4 (2.6)	0 (0.0)
PIROXICAM	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
DEKETOPIROFEN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DICLOFENAC EPOLAMINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ETOFENAMATE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
IBUPROFEN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES	4 (4.7)	10 (5.8)	8 (5.2)	3 (14.3)
OLANZAPINE	2 (2.4)	9 (5.2)	8 (5.2)	3 (14.3)
QUETIAPINE	2 (2.4)	1 (0.6)	0 (0.0)	0 (0.0)
QUETIAPINE FUMARATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER LIPID MODIFYING AGENTS	4 (4.7)	11 (6.4)	5 (3.3)	0 (0.0)
FISH OIL	0 (0.0)	5 (2.9)	1 (0.7)	0 (0.0)
OMEGA-3 FATTY ACIDS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
WILD SALMON	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
EZETIMIBE	2 (2.4)	0 (0.0)	1 (0.7)	0 (0.0)
OMEGA-3 FATTY ACIDS W/TOCOPHEROL	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
DOCOSAHEXAENOIC ACID	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
EPACAPS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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OTHER LIPID MODIFYING AGENTS	4 (4.7)	11 (6.4)	5 (3.3)	0 (0.0)
COLECALCIFEROL W/DOCOSAHEXAENOIC AC	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
EICOSAPENTAENOIC ACID	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER ANTIBIOTICS FOR TOPICAL USE	3 (3.5)	11 (6.4)	8 (5.2)	1 (4.8)
MUPIROCIN	0 (0.0)	7 (4.0)	5 (3.3)	1 (4.8)
BACITRACIN	1 (1.2)	2 (1.2)	1 (0.7)	0 (0.0)
NEOTRACIN	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
FUSIDATE SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FUSIDIC ACID	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GENTAMICIN SULFATE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
NEOSPORIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CHLORAMPHENICOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTICHOLINERGICS	4 (4.7)	14 (8.1)	2 (1.3)	3 (14.3)
IPRATROPIUM BROMIDE	2 (2.4)	7 (4.0)	1 (0.7)	2 (9.5)
IPRATROPIUM	1 (1.2)	4 (2.3)	0 (0.0)	3 (14.3)
TIOTROPIUM BROMIDE	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
MYDRIN P	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
ATROPINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ANTICHOLINERGICS	4 (4.7)	14 (8.1)	2 (1.3)	3 (14.3)
UMECLIDINIUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
TIOTROPIUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TIOTROPIUM BROMIDE MONOHYDRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BILE ACID PREPARATIONS	7 (8.2)	17 (9.8)	0 (0.0)	1 (4.8)
URSODEOXYCHOLIC ACID	7 (8.2)	17 (9.8)	0 (0.0)	1 (4.8)
SOFT PARAFFIN AND FAT PRODUCTS	7 (8.2)	11 (6.4)	1 (0.7)	1 (4.8)
WHITE SOFT PARAFFIN	4 (4.7)	5 (2.9)	0 (0.0)	0 (0.0)
SOFT PARAFFIN AND FAT PRODUCTS	3 (3.5)	3 (1.7)	0 (0.0)	0 (0.0)
EUCERIN	0 (0.0)	2 (1.2)	0 (0.0)	1 (4.8)
AQUAPHOR	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
AQUEOUS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LIPIKAR	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AKWA TEARS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DIPROBASE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PARAFFIN, LIQUID	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
PETROLATUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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COXIBS	5 (5.9)	12 (6.9)	3 (2.0)	1 (4.8)
CELECOXIB	2 (2.4)	6 (3.5)	3 (2.0)	1 (4.8)
ETORICOXIB	3 (3.5)	6 (3.5)	0 (0.0)	0 (0.0)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR	1 (1.2)	12 (6.9)	5 (3.3)	2 (9.5)
BUDESONIDE W/FORMOTEROL FUMARATE	1 (1.2)	10 (5.8)	1 (0.7)	0 (0.0)
SERETIDE	1 (1.2)	1 (0.6)	1 (0.7)	1 (4.8)
BREO ELLIPTA	0 (0.0)	3 (1.7)	1 (0.7)	0 (0.0)
BUDESONIDE W/FORMOTEROL	0 (0.0)	1 (0.6)	0 (0.0)	1 (4.8)
FLUTICASONE FUROATE W/VILANTEROL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DULERA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLUTICASONE W/SALMETEROL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OPIOID ANESTHETICS	8 (9.4)	10 (5.8)	4 (2.6)	1 (4.8)
FENTANYL	6 (7.1)	10 (5.8)	2 (1.3)	1 (4.8)
FENTANYL CITRATE	2 (2.4)	0 (0.0)	1 (0.7)	0 (0.0)
BUPIVACAINE W/FENTANYL	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
APPETITE STIMULANTS	4 (4.7)	14 (8.1)	5 (3.3)	0 (0.0)
MEGESTROL ACETATE	2 (2.4)	7 (4.0)	5 (3.3)	0 (0.0)
MEGESTROL	2 (2.4)	7 (4.0)	0 (0.0)	0 (0.0)
CARNITINE HYDROCHLORIDE W/CYANOCOPA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CYPROHEPTADINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
IMIDAZOLE DERIVATIVES	3 (3.5)	8 (4.6)	8 (5.2)	0 (0.0)
METRONIDAZOLE	3 (3.5)	7 (4.0)	5 (3.3)	0 (0.0)
ECONAZOLE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ORNIDAZOLE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
TINIDAZOLE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
TIOCONAZOLE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MICONAZOLE NITRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRI	5 (5.9)	6 (3.5)	6 (3.9)	0 (0.0)
VALACICLOVIR HYDROCHLORIDE	3 (3.5)	3 (1.7)	1 (0.7)	0 (0.0)
ACICLOVIR	1 (1.2)	0 (0.0)	3 (2.0)	0 (0.0)
VALACICLOVIR	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
FAMCICLOVIR	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)

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MULTIVITAMINS WITH MINERALS	4 (4.7)	5 (2.9)	7 (4.6)	0 (0.0)
MULTIVITAMINS WITH MINERALS	2 (2.4)	1 (0.6)	2 (1.3)	0 (0.0)
MINERALS NOS W/VITAMINS NOS	1 (1.2)	2 (1.2)	1 (0.7)	0 (0.0)
CENTRUM SILVER	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
ALVITYL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
AQUADEKS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CENTRUM SILVER ADULTS 50+	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
FOLIC ACID W/IRON/MINERALS NOS/VITAMINS NOS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
ASCORBIC ACID W/CHROMIUM/COPPER/CYANOCOBALAMI	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FOLIC ACID W/MINERALS NOS/VITAMINS NOS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DRUGS FOR TREATMENT OF HYPERKALEMIA AND HYPERPHOSP	1 (1.2)	7 (4.0)	9 (5.9)	0 (0.0)
SODIUM POLYSTYRENE SULFONATE	1 (1.2)	4 (2.3)	2 (1.3)	0 (0.0)
SEVELAMER HYDROCHLORIDE	1 (1.2)	2 (1.2)	2 (1.3)	0 (0.0)
SEVELAMER	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
CALCIUM POLYSTYRENE SULFONATE	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
SEVELAMER CARBONATE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
LANTHANUM CARBONATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ALDOSTERONE ANTAGONISTS	2 (2.4)	9 (5.2)	6 (3.9)	2 (9.5)
SPIRONOLACTONE	2 (2.4)	8 (4.6)	6 (3.9)	2 (9.5)
EPLERENONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
POTASSIUM CANRENOATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
IRON BIVALENT, ORAL PREPARATIONS	1 (1.2)	6 (3.5)	7 (4.6)	3 (14.3)
FERROUS SULFATE	1 (1.2)	5 (2.9)	7 (4.6)	1 (4.8)
FERROUS SODIUM CITRATE	0 (0.0)	1 (0.6)	0 (0.0)	1 (4.8)
FERROUS SULFATE EXSICCATED	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
FERROUS BISGLYCINATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OPIUM DERIVATIVES AND EXPECTORANTS	5 (5.9)	7 (4.0)	5 (3.3)	1 (4.8)
CHERACOL	3 (3.5)	3 (1.7)	3 (2.0)	0 (0.0)
TUSSIN DM	1 (1.2)	2 (1.2)	1 (0.7)	1 (4.8)
DEX-CO	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
KODEL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MEIJI SEKIDOME	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NEO CODION	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OPIUM DERIVATIVES AND EXPECTORANTS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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OPIUM DERIVATIVES AND EXPECTORANTS	5 (5.9)	7 (4.0)	5 (3.3)	1 (4.8)
RESYL PLUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER PLAIN VITAMIN PREPARATIONS	2 (2.4)	7 (4.0)	3 (2.0)	3 (14.3)
BIOTIN	1 (1.2)	3 (1.7)	0 (0.0)	2 (9.5)
TOCOPHEROL	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
PYRIDOXINE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
NICOTINAMIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CALCIUM PANTOTHENATE	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
OTHER PLAIN VITAMIN PREPARATIONS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PYRIDOXINE HYDROCHLORIDE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
TOCOPHERYL ACETATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DL-ALPHA TOCOPHERYL ACETATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
RIBOFLAVIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIBIOTICS	3 (3.5)	7 (4.0)	6 (3.9)	1 (4.8)
VANCOMYCIN	1 (1.2)	2 (1.2)	2 (1.3)	0 (0.0)
CHLORAMPHENICOL	1 (1.2)	1 (0.6)	2 (1.3)	0 (0.0)
NYSTATIN	2 (2.4)	1 (0.6)	0 (0.0)	0 (0.0)
POLYTRIM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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ANTIBIOTICS	3 (3.5)	7 (4.0)	6 (3.9)	1 (4.8)
TOBRAMYCIN	1 (1.2)	0 (0.0)	0 (0.0)	1 (4.8)
ERYTHROMYCIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMPHOTERICIN B	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BACITRACIN	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
CEFMENOXIME HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
RIFAXIMIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AZITHROMYCIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
POLYMYXIN B	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CENTRALLY ACTING SYMPATHOMIMETICS	2 (2.4)	6 (3.5)	5 (3.3)	2 (9.5)
METHYLPHENIDATE HYDROCHLORIDE	1 (1.2)	1 (0.6)	3 (2.0)	0 (0.0)
METHYLPHENIDATE	1 (1.2)	4 (2.3)	0 (0.0)	1 (4.8)
OBETROL	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
AMFETAMINE	0 (0.0)	1 (0.6)	0 (0.0)	1 (4.8)
MODAFINIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ATOMOXETINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DUROPHET	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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ALPHA AND BETA BLOCKING AGENTS	2 (2.4)	7 (4.0)	5 (3.3)	0 (0.0)
CARVEDILOL	1 (1.2)	5 (2.9)	4 (2.6)	0 (0.0)
LABETALOL	1 (1.2)	1 (0.6)	2 (1.3)	0 (0.0)
LABETALOL HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ADRENERGIC AND DOPAMINERGIC AGENTS	4 (4.7)	7 (4.0)	7 (4.6)	1 (4.8)
EPINEPHRINE	2 (2.4)	2 (1.2)	3 (2.0)	0 (0.0)
NOREPINEPHRINE	1 (1.2)	3 (1.7)	0 (0.0)	0 (0.0)
PHENYLEPHRINE	1 (1.2)	1 (0.6)	1 (0.7)	1 (4.8)
MIDODRINE	1 (1.2)	0 (0.0)	2 (1.3)	0 (0.0)
EPHEDRINE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
EPHEDRINE SULFATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
NOREPINEPHRINE BITARTRATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PHENYLEPHRINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CARIES PROPHYLACTIC AGENTS	0 (0.0)	8 (4.6)	3 (2.0)	3 (14.3)
XYLITOL	0 (0.0)	5 (2.9)	0 (0.0)	2 (9.5)
SODIUM FLUORIDE	0 (0.0)	2 (1.2)	3 (2.0)	1 (4.8)
SALIVET	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
CARIES PROPHYLACTIC AGENTS	0 (0.0)	8 (4.6)	3 (2.0)	3 (14.3)
SENSODYNE PROTECCION TOTAL	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
LEUKOTRIENE RECEPTOR ANTAGONISTS	0 (0.0)	8 (4.6)	7 (4.6)	2 (9.5)
MONTELUKAST	0 (0.0)	4 (2.3)	3 (2.0)	2 (9.5)
MONTELUKAST SODIUM	0 (0.0)	3 (1.7)	4 (2.6)	0 (0.0)
PRANLUKAST	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PYRAZOLONES	3 (3.5)	8 (4.6)	5 (3.3)	0 (0.0)
METAMIZOLE SODIUM	2 (2.4)	5 (2.9)	4 (2.6)	0 (0.0)
METAMIZOLE	1 (1.2)	2 (1.2)	1 (0.7)	0 (0.0)
METAMIZOLE SODIUM MONOHYDRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANTIDOTES	6 (7.1)	11 (6.4)	0 (0.0)	1 (4.8)
GLYCYRON	0 (0.0)	6 (3.5)	0 (0.0)	1 (4.8)
NALOXONE HYDROCHLORIDE	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
ACETYLCYSTEINE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
FLUMAZENIL	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
GLUTATHIONE	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
NALOXONE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)

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ANTIDOTES	6 (7.1)	11 (6.4)	0 (0.0)	1 (4.8)
SUGAMMADEX	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER NASAL PREPARATIONS	1 (1.2)	9 (5.2)	3 (2.0)	3 (14.3)
SODIUM CHLORIDE	1 (1.2)	5 (2.9)	3 (2.0)	1 (4.8)
MUPIROCIN	0 (0.0)	3 (1.7)	0 (0.0)	1 (4.8)
IPRATROPIUM BROMIDE	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
FLO POST OPERATIVE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NISITA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER NASAL PREPARATIONS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER CARDIAC PREPARATIONS	2 (2.4)	7 (4.0)	5 (3.3)	0 (0.0)
UBIDECARENONE	2 (2.4)	7 (4.0)	4 (2.6)	0 (0.0)
OTHER CARDIAC PREPARATIONS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ADENOSINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
UBIQUINOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
IMIDAZOLE AND TRIAZOLE DERIVATIVES	2 (2.4)	3 (1.7)	8 (5.2)	0 (0.0)
KETOCONAZOLE	2 (2.4)	1 (0.6)	3 (2.0)	0 (0.0)
CLOTRIMAZOLE	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)

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IMIDAZOLE AND TRIAZOLE DERIVATIVES	2 (2.4)	3 (1.7)	8 (5.2)	0 (0.0)
MICONAZOLE	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
ECONAZOLE NITRATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DAKTOZIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
LANOCONAZOLE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LOTRISONE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CANESTEN-HC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ECONAZOLE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER RESPIRATORY SYSTEM PRODUCTS	2 (2.4)	6 (3.5)	5 (3.3)	2 (9.5)
OXYGEN	2 (2.4)	6 (3.5)	5 (3.3)	2 (9.5)
SOLUTIONS FOR PARENTERAL NUTRITION	1 (1.2)	13 (7.5)	0 (0.0)	2 (9.5)
GLUCOSE	0 (0.0)	5 (2.9)	0 (0.0)	2 (9.5)
AMINO ACIDS NOS W/GLUCOSE/LIPIDS NOS	1 (1.2)	4 (2.3)	0 (0.0)	0 (0.0)
AMINO ACIDS NOS W/ELECTROLYTES NOS/GLUCOSE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
CLINIMIX N14G30E	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
FREAMINE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
TRIFLUID	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
AMINIC	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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SOLUTIONS FOR PARENTERAL NUTRITION	1 (1.2)	13 (7.5)	0 (0.0)	2 (9.5)
MG TNA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMINO ACIDS NOS W/ELECTROLYTES NOS/GLUCOSE/VI	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SOLUTIONS FOR PARENTERAL NUTRITION	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ADRENERGICS IN COMBINATION WITH ANTICHOLINERGICS	0 (0.0)	11 (6.4)	4 (2.6)	0 (0.0)
COMBIVENT	0 (0.0)	7 (4.0)	3 (2.0)	0 (0.0)
OLODATEROL HYDROCHLORIDE W/TIOTROPIUM BROMIDE	0 (0.0)	3 (1.7)	1 (0.7)	0 (0.0)
UMECLIDINIUM BROMIDE W/VILANTEROL TRIFENATATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANGIOTENSIN II ANTAGONISTS AND DIURETICS	1 (1.2)	3 (1.7)	2 (1.3)	2 (9.5)
HYZAAR	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
KARVEA HCT	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
PRITORPLUS	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
BENICAR HCT	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
BLOPRESS PLUS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CO-DIOVAN	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
HYDROCHLOROTHIAZIDE W/OLMESARTAN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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CORTICOSTEROIDS, PLAIN	3 (3.5)	8 (4.6)	3 (2.0)	0 (0.0)
PREDNISOLONE ACETATE	1 (1.2)	3 (1.7)	0 (0.0)	0 (0.0)
FLUOROMETHOLONE	0 (0.0)	3 (1.7)	1 (0.7)	0 (0.0)
LOTEPREDNOL ETABONATE	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
PREDNISOLONE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DEXAMETHASONE SODIUM PHOSPHATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DIFLUPREDNATE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
LOTEPREDNOL	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
TRIAMCINOLONE ACETONIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DEXAMETHASONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYDROCORTISONE SODIUM PHOSPHATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FOURTH-GENERATION CEPHALOSPORINS	2 (2.4)	4 (2.3)	8 (5.2)	2 (9.5)
CEFEPIME	2 (2.4)	2 (1.2)	5 (3.3)	2 (9.5)
CEFEPIME HYDROCHLORIDE	0 (0.0)	2 (1.2)	3 (2.0)	0 (0.0)
TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS	4 (4.7)	2 (1.2)	6 (3.9)	1 (4.8)
FINASTERIDE	3 (3.5)	2 (1.2)	4 (2.6)	1 (4.8)
DUTASTERIDE	1 (1.2)	1 (0.6)	2 (1.3)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ZINC	5 (5.9)	2 (1.2)	5 (3.3)	3 (14.3)
ZINC	1 (1.2)	1 (0.6)	4 (2.6)	1 (4.8)
ZINC SULFATE	3 (3.5)	1 (0.6)	1 (0.7)	2 (9.5)
ZINC GLUCONATE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
EMOLLIENTS AND PROTECTIVES	1 (1.2)	6 (3.5)	4 (2.6)	0 (0.0)
EMOLLIENTS AND PROTECTIVES	1 (1.2)	5 (2.9)	4 (2.6)	0 (0.0)
TOPIALYSE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ENZYME PREPARATIONS	3 (3.5)	5 (2.9)	3 (2.0)	0 (0.0)
PANCRELIPASE	1 (1.2)	0 (0.0)	2 (1.3)	0 (0.0)
TILACTASE	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
PANCREATIN	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
BESZYME	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BIODIASTASE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
METEOZYM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ENZYMES NOS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NORTASE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	1 (1.2)	6 (3.5)	3 (2.0)	1 (4.8)
INSULIN ASPART	0 (0.0)	3 (1.7)	3 (2.0)	1 (4.8)
INSULIN LISPRO	0 (0.0)	4 (2.3)	0 (0.0)	0 (0.0)
INSULIN	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER MINERAL PRODUCTS	1 (1.2)	5 (2.9)	5 (3.3)	0 (0.0)
K-PHOS NEUTRAL	1 (1.2)	2 (1.2)	3 (2.0)	0 (0.0)
POTASSIUM PHOSPHATE MONOBASIC W/SOD	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
PHOSPHONEUROL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MINERALS NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
NEUTRA-PHOS-K	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
COPPER	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
STOMATOLOGICAL PREPARATIONS	1 (1.2)	8 (4.6)	4 (2.6)	0 (0.0)
SODIUM BICARBONATE	1 (1.2)	7 (4.0)	3 (2.0)	0 (0.0)
GELCLAIR	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GLANDOMED	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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VITAMIN B-COMPLEX, PLAIN	4 (4.7)	2 (1.2)	4 (2.6)	1 (4.8)
VITAMIN B COMPLEX	4 (4.7)	2 (1.2)	4 (2.6)	1 (4.8)
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, N	0 (0.0)	7 (4.0)	3 (2.0)	1 (4.8)
GLUCOSAMINE	0 (0.0)	2 (1.2)	2 (1.3)	0 (0.0)
CURCUMIN	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
CHONDROITIN W/GLUCOSAMINE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
BIOGLAN JOINT MOBILITY	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HYDROXYCHLOROQUINE	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
MOVE FREE JOINT STRENGTHENER	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
RABBIT VACCINIA EXTRACT	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GLUCOSAMINE SULFATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYDROXYCHLOROQUINE SULFATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NABUMETONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER INTESTINAL ADSORBENTS	1 (1.2)	9 (5.2)	4 (2.6)	0 (0.0)
DIOSMECTITE	1 (1.2)	8 (4.6)	4 (2.6)	0 (0.0)
EUPATILIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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SECOND-GENERATION CEPHALOSPORINS	1 (1.2)	8 (4.6)	2 (1.3)	1 (4.8)
CEFUROXIME	1 (1.2)	2 (1.2)	1 (0.7)	1 (4.8)
CEFUROXIME AXETIL	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
CEFACLOX	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
CEFOTETAN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLOMOXEF SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ALL OTHER NON-THERAPEUTIC PRODUCTS	1 (1.2)	6 (3.5)	5 (3.3)	1 (4.8)
ALL OTHER NON-THERAPEUTIC PRODUCTS	1 (1.2)	6 (3.5)	5 (3.3)	1 (4.8)
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS	1 (1.2)	7 (4.0)	3 (2.0)	1 (4.8)
AMITRIPTYLINE HYDROCHLORIDE	0 (0.0)	4 (2.3)	2 (1.3)	0 (0.0)
AMITRIPTYLINE	1 (1.2)	1 (0.6)	1 (0.7)	1 (4.8)
DOXEPIN HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
IMIPRAMINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NORTRIPTYLINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
PROSTAGLANDIN ANALOGUES	3 (3.5)	3 (1.7)	4 (2.6)	1 (4.8)
LATANOPROST	3 (3.5)	3 (1.7)	3 (2.0)	0 (0.0)
BIMATOPROST	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
TRAVOPROST	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ANTIINFECTIVES FOR TREATMENT OF ACNE	1 (1.2)	3 (1.7)	6 (3.9)	0 (0.0)
CLINDAMYCIN	0 (0.0)	1 (0.6)	5 (3.3)	0 (0.0)
CLINDAMYCIN PHOSPHATE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
NADIFLOXACIN	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
BENZACLIN TOPICAL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	0 (0.0)	3 (1.7)	6 (3.9)	0 (0.0)
OXYBUTYNIN	0 (0.0)	0 (0.0)	3 (2.0)	0 (0.0)
MIRABEGRON	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OXYBUTYNIN HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
SOLIFENACIN	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
FESOTERODINE FUMARATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PROPIVERINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SOLIFENACIN SUCCINATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	0 (0.0)	3 (1.7)	6 (3.9)	0 (0.0)
TOLTERODINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TOLTERODINE L-TARTRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS	4 (4.7)	9 (5.2)	0 (0.0)	0 (0.0)
ALBUMIN HUMAN	2 (2.4)	7 (4.0)	0 (0.0)	0 (0.0)
CALCIUM CHLORIDE W/GLUCONATE SODIUM/MAGNESIUM	2 (2.4)	4 (2.3)	0 (0.0)	0 (0.0)
ANTACIDS WITH SODIUM BICARBONATE	3 (3.5)	7 (4.0)	2 (1.3)	0 (0.0)
SODIUM BICARBONATE	2 (2.4)	4 (2.3)	0 (0.0)	0 (0.0)
GAVISCON	0 (0.0)	2 (1.2)	2 (1.3)	0 (0.0)
MIST. MAG. TRISIL. CO.	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
CARMINATIVE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GASTRON	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER BLOOD PRODUCTS	3 (3.5)	6 (3.5)	0 (0.0)	1 (4.8)
RED BLOOD CELLS, CONCENTRATED	2 (2.4)	1 (0.6)	0 (0.0)	0 (0.0)
PLATELETS, CONCENTRATED	1 (1.2)	2 (1.2)	0 (0.0)	1 (4.8)
PLATELETS	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
PLASMA	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)

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OTHER BLOOD PRODUCTS	3 (3.5)	6 (3.5)	0 (0.0)	1 (4.8)
RED BLOOD CELLS	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
RED BLOOD CELLS, LEUCOCYTE DEPLETED	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
TRIAZOLE DERIVATIVES	3 (3.5)	5 (2.9)	2 (1.3)	1 (4.8)
FLUCONAZOLE	3 (3.5)	5 (2.9)	2 (1.3)	1 (4.8)
CARBAMIDE PRODUCTS	0 (0.0)	4 (2.3)	6 (3.9)	0 (0.0)
UREA	0 (0.0)	3 (1.7)	6 (3.9)	0 (0.0)
OPTIDERM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TOPICREM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	0 (0.0)	4 (2.3)	5 (3.3)	1 (4.8)
INSULIN GLARGINE	0 (0.0)	4 (2.3)	3 (2.0)	1 (4.8)
INSULIN DEGLUDEC	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
INSULIN DETEMIR	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OTHER HYPNOTICS AND SEDATIVES	1 (1.2)	2 (1.2)	4 (2.6)	1 (4.8)
DIPHENHYDRAMINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	1 (0.7)	1 (4.8)
DIPHENHYDRAMINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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OTHER HYPNOTICS AND SEDATIVES	1 (1.2)	2 (1.2)	4 (2.6)	1 (4.8)
DOXYLAMINE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
DOXYLAMINE SUCCINATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DEXMEDETOMIDINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
SUVOREXANT	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SALICYLIC ACID AND DERIVATIVES	0 (0.0)	5 (2.9)	2 (1.3)	0 (0.0)
ACETYLSALICYLIC ACID	0 (0.0)	2 (1.2)	2 (1.3)	0 (0.0)
ACETYLSALICYLATE LYSINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ALKA-SELTZER	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BUFFERIN A	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SODIUM	3 (3.5)	2 (1.2)	1 (0.7)	3 (14.3)
SODIUM CHLORIDE	3 (3.5)	2 (1.2)	1 (0.7)	3 (14.3)
ANTISEPTICS	2 (2.4)	7 (4.0)	0 (0.0)	0 (0.0)
DEQUALINIUM CHLORIDE	0 (0.0)	4 (2.3)	0 (0.0)	0 (0.0)
POVIDONE-IODINE	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
BENZETHONIUM CHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
IODINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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ANTISEPTICS	2 (2.4)	7 (4.0)	0 (0.0)	0 (0.0)
PHENOL	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
SODIUM GUALENATE HYDRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DIFFLAM MOUTH	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
STREPSILS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
STREPSILS SORE THROAT & BLOCKED NOSE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER UROLOGICALS	2 (2.4)	3 (1.7)	3 (2.0)	1 (4.8)
PHENAZOPYRIDINE HYDROCHLORIDE	0 (0.0)	3 (1.7)	1 (0.7)	1 (4.8)
PHENAZOPYRIDINE	2 (2.4)	0 (0.0)	1 (0.7)	0 (0.0)
METHENAMINE W/SALICYLATE SODIUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MIST. POT. CIT.	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
URAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SELECTIVE SEROTONIN (5HT1) AGONISTS	1 (1.2)	1 (0.6)	4 (2.6)	2 (9.5)
SUMATRIPTAN	0 (0.0)	0 (0.0)	1 (0.7)	2 (9.5)
ELETRIPTAN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ELETRIPTAN HYDROBROMIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
NARATRIPTAN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
RIZATRIPTAN	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)

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SELECTIVE SEROTONIN (5HT1) AGONISTS	1 (1.2)	1 (0.6)	4 (2.6)	2 (9.5)
RIZATRIPTAN BENZOATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ZOLMITRIPTAN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
NARATRIPTAN HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SUMATRIPTAN SUCCINATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SUBSTITUTED ALKYLAMINES	2 (2.4)	7 (4.0)	0 (0.0)	1 (4.8)
CHLORPHENAMINE MALEATE	2 (2.4)	3 (1.7)	0 (0.0)	0 (0.0)
CHLORPHENAMINE	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
DEXCHLORPHENIRAMINE MALEATE	0 (0.0)	2 (1.2)	0 (0.0)	1 (4.8)
MINERALOCORTICOIDS	0 (0.0)	0 (0.0)	8 (5.2)	0 (0.0)
FLUDROCORTISONE	0 (0.0)	0 (0.0)	5 (3.3)	0 (0.0)
FLUDROCORTISONE ACETATE	0 (0.0)	0 (0.0)	3 (2.0)	0 (0.0)
DIPHENYLPROPYLAMINE DERIVATIVES	1 (1.2)	2 (1.2)	4 (2.6)	2 (9.5)
METHADONE	1 (1.2)	2 (1.2)	3 (2.0)	2 (9.5)
METHADONE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
NEURAMINIDASE INHIBITORS	4 (4.7)	4 (2.3)	0 (0.0)	0 (0.0)
OSELTAMIVIR PHOSPHATE	4 (4.7)	3 (1.7)	0 (0.0)	0 (0.0)
PERAMIVIR	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OSELTAMIVIR	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTACIDS WITH ANTIFLATULENTS	1 (1.2)	1 (0.6)	3 (2.0)	1 (4.8)
SIMECO	1 (1.2)	1 (0.6)	2 (1.3)	1 (4.8)
MAALOX MAX	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BELLADONNA ALKALOIDS, SEMISYNTHETIC, QUATERNARY AM	3 (3.5)	3 (1.7)	3 (2.0)	0 (0.0)
HYOSCINE BUTYLBROMIDE	1 (1.2)	2 (1.2)	3 (2.0)	0 (0.0)
HYOSCINE METHOBROMIDE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
CIMETROPIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
METHYLSCOPOLAMINE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	2 (2.4)	3 (1.7)	3 (2.0)	1 (4.8)
SITAGLIPTIN PHOSPHATE	1 (1.2)	2 (1.2)	2 (1.3)	0 (0.0)
LINAGLIPTIN	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
SITAGLIPTIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	2 (2.4)	3 (1.7)	3 (2.0)	1 (4.8)
SAXAGLIPTIN	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
SITAGLIPTIN PHOSPHATE MONOHYDRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VILDAGLIPTIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER DRUGS FOR CONSTIPATION	0 (0.0)	6 (3.5)	3 (2.0)	1 (4.8)
LINACLOTIDE	0 (0.0)	1 (0.6)	3 (2.0)	1 (4.8)
GLYCEROL	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
PRUCALOPRIDE SUCCINATE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
LUBIPROSTONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM A	1 (1.2)	4 (2.3)	3 (2.0)	0 (0.0)
ALUDROX	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
GAVISCON	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MAGALDRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NOVALUCOL NOVUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANTACIDA FNA	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
MOXYDAR	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
BETA BLOCKING AGENTS, NON-SELECTIVE	2 (2.4)	2 (1.2)	4 (2.6)	0 (0.0)
PROPRANOLOL	1 (1.2)	2 (1.2)	1 (0.7)	0 (0.0)
SOTALOL	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
NADOLOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PROPRANOLOL HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CORTICOSTEROIDS ACTING LOCALLY	0 (0.0)	4 (2.3)	3 (2.0)	1 (4.8)
BUDESONIDE	0 (0.0)	4 (2.3)	3 (2.0)	1 (4.8)
PREDNISOLONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYDRAZINOPHTHALAZINE DERIVATIVES	1 (1.2)	3 (1.7)	4 (2.6)	0 (0.0)
HYDRALAZINE	1 (1.2)	2 (1.2)	3 (2.0)	0 (0.0)
HYDRALAZINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	0 (0.0)	2 (1.2)	1 (0.7)	1 (4.8)
ESTRADIOL	0 (0.0)	1 (0.6)	1 (0.7)	1 (4.8)
ESTROGENS CONJUGATED	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ESTRIOL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	3 (3.5)	5 (2.9)	0 (0.0)	0 (0.0)
CLOSTRIDIUM BUTYRICUM	2 (2.4)	3 (1.7)	0 (0.0)	0 (0.0)
ARTISIAL	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
RESVERATROL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OXICAMS	0 (0.0)	1 (0.6)	3 (2.0)	0 (0.0)
MELOXICAM	0 (0.0)	1 (0.6)	3 (2.0)	0 (0.0)
PIROXICAM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PNEUMOCOCCAL VACCINES	2 (2.4)	4 (2.3)	2 (1.3)	0 (0.0)
PNEUMOCOCCAL VACCINE	2 (2.4)	4 (2.3)	2 (1.3)	0 (0.0)
SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY A	0 (0.0)	4 (2.3)	3 (2.0)	0 (0.0)
DICYCLOVERINE HYDROCHLORIDE	0 (0.0)	3 (1.7)	2 (1.3)	0 (0.0)
DICYCLOVERINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TRIMEBUTINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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LINCOSAMIDES	1 (1.2)	4 (2.3)	3 (2.0)	0 (0.0)
CLINDAMYCIN	1 (1.2)	3 (1.7)	2 (1.3)	0 (0.0)
CLINDAMYCIN HYDROCHLORIDE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
OTHER ANTIALLERGICS	2 (2.4)	3 (1.7)	2 (1.3)	0 (0.0)
EPINASTINE HYDROCHLORIDE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
LEVOCABASTINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OLOPATADINE HYDROCHLORIDE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
AZELASTINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ISOSPAGLUMIC ACID SODIUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OLOPATADINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AZELASTINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LEVOCABASTINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER COMBINATIONS OF NUTRIENTS	1 (1.2)	3 (1.7)	5 (3.3)	0 (0.0)
OTHER COMBINATIONS OF NUTRIENTS	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
BETA GLUCAN	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
CARBOHYDRATES NOS W/FATS NOS/FIBRE,	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CARBOHYDRATES NOS W/PROTEINS NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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OTHER COMBINATIONS OF NUTRIENTS	1 (1.2)	3 (1.7)	5 (3.3)	0 (0.0)
FATS NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MINERALS NOS W/PROTEINS NOS/VITAMINS NOS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
THERMOTABS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS	1 (1.2)	1 (0.6)	4 (2.6)	1 (4.8)
MARVELON	0 (0.0)	0 (0.0)	1 (0.7)	1 (4.8)
OVIDON	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
NORLESTRIN FE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
EUGYNON	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LAFAMME	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ZUMESTON	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
NORMENSAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VITAMIN K ANTAGONISTS	2 (2.4)	2 (1.2)	4 (2.6)	0 (0.0)
WARFARIN	1 (1.2)	0 (0.0)	2 (1.3)	0 (0.0)
WARFARIN SODIUM	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
FLUINDIONE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONT	2 (2.4)	2 (1.2)	2 (1.3)	2 (9.5)
IOHEXOL	2 (2.4)	1 (0.6)	2 (1.3)	2 (9.5)
IOPAMIDOL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LIVER THERAPY	4 (4.7)	4 (2.3)	0 (0.0)	0 (0.0)
GODEX	2 (2.4)	3 (1.7)	0 (0.0)	0 (0.0)
MINOFIT	2 (2.4)	1 (0.6)	0 (0.0)	0 (0.0)
GLICYRRHIZIC ACID, AMMONIUM SALT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTIDIARRHEALS	0 (0.0)	5 (2.9)	3 (2.0)	0 (0.0)
RACECADOTRIL	0 (0.0)	4 (2.3)	3 (2.0)	0 (0.0)
ALBUMIN TANNATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER PARASYMPATHOMIMETICS	1 (1.2)	5 (2.9)	1 (0.7)	0 (0.0)
PILOCARPINE HYDROCHLORIDE	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
PILOCARPINE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
CHOLINE ALFOSCERATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER PARASYMPATHOMIMETICS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
SYMPATHOMIMETICS	0 (0.0)	3 (1.7)	2 (1.3)	0 (0.0)
NARINE	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
PSEUDOEPHEDRINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CIRRUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PHENYLEPHRINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ALLEGRA-D	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LORATADINE W/PSEUDOEPHEDRINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PHENYLEPHRINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PSEUDOEPHEDRINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VITAMINS, OTHER COMBINATIONS	1 (1.2)	1 (0.6)	3 (2.0)	1 (4.8)
VITAMINS, OTHER COMBINATIONS	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
OCUVITE	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
ALANERV	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
ASCORBIC ACID W/BIOTIN/CALCIUM PANT	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OCUVITE ADULT 50+	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
COMPLIDERMOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
EAGLE TRESOS B PLUSE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HERBAL NOS W/LECITHIN/MINERALS NOS/UBIDEACAREN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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AMINO ACIDS	4 (4.7)	4 (2.3)	0 (0.0)	0 (0.0)
TRANEXAMIC ACID	4 (4.7)	4 (2.3)	0 (0.0)	0 (0.0)
AMINOSALICYLIC ACID AND SIMILAR AGENTS	0 (0.0)	2 (1.2)	4 (2.6)	1 (4.8)
MESALAZINE	0 (0.0)	2 (1.2)	3 (2.0)	0 (0.0)
SULFASALAZINE	0 (0.0)	0 (0.0)	1 (0.7)	1 (4.8)
ANESTHETICS, LOCAL	2 (2.4)	5 (2.9)	0 (0.0)	0 (0.0)
LIDOCAINE	0 (0.0)	4 (2.3)	0 (0.0)	0 (0.0)
LARYTON	2 (2.4)	1 (0.6)	0 (0.0)	0 (0.0)
LIDOCAINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FAT/CARBOHYDRATES/PROTEINS/MINERALS/VITAMINS, COMB	0 (0.0)	4 (2.3)	2 (1.3)	1 (4.8)
ASCORBIC ACID W/BIOTIN/CALCIUM/CARB	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
CARBOHYDRATES NOS W/FATTY ACIDS NOS/MINERALS	0 (0.0)	1 (0.6)	0 (0.0)	1 (4.8)
CARBOHYDRATES NOS W/ELECTROLYTES NOS/FATTY AC	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CARBOHYDRATES NOS W/FATS NOS/MINERA	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
COLOSTRUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
FAT/CARBOHYDRATES/PROTEINS/MINERALS/VITAMINS,	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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FAT/CARBOHYDRATES/PROTEINS/MINERALS/VITAMINS, COMB	0 (0.0)	4 (2.3)	2 (1.3)	1 (4.8)
FATS NOS W/PROTEINS NOS/VITAMINS NOS	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
ASCORBIC ACID W/BIOTIN/CALCIUM CASEINATE/CALC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
IMIDAZOLINE RECEPTOR AGONISTS	1 (1.2)	0 (0.0)	4 (2.6)	0 (0.0)
CLONIDINE	0 (0.0)	0 (0.0)	3 (2.0)	0 (0.0)
CLONIDINE HYDROCHLORIDE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
MOXONIDINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OTHER GENERAL ANESTHETICS	1 (1.2)	3 (1.7)	2 (1.3)	1 (4.8)
PROPOFOL	0 (0.0)	3 (1.7)	2 (1.3)	1 (4.8)
ETOMIDATE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
KETAMINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BENZOTHAZEPINE DERIVATIVES	1 (1.2)	3 (1.7)	1 (0.7)	1 (4.8)
DILTIAZEM	0 (0.0)	2 (1.2)	1 (0.7)	1 (4.8)
DILTIAZEM HYDROCHLORIDE	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)

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CORTICOSTEROIDS, POTENT, COMBINATIONS WITH ANTIBIO	1 (1.2)	6 (3.5)	0 (0.0)	0 (0.0)
VALISONE-G	0 (0.0)	5 (2.9)	0 (0.0)	0 (0.0)
FUCICORT	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
TRIDERM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ENEMAS	1 (1.2)	3 (1.7)	2 (1.3)	1 (4.8)
FLEET	0 (0.0)	1 (0.6)	1 (0.7)	1 (4.8)
ENEMAS	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
GLYCEROL	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
MICROKLIST	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTIFUNGALS FOR TOPICAL USE	0 (0.0)	4 (2.3)	2 (1.3)	0 (0.0)
CICLOPIROX	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
TERBINAFINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CICLOPIROX OLAMINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LULICONAZOLE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TERBINAFINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Table 14.1.5
 Concomitant Medications
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 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
OTHER DERMATOLOGICALS	0 (0.0)	5 (2.9)	1 (0.7)	0 (0.0)
GUAIAZULENE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
FINASTERIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MINOXIDIL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
POLYURETHANE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
RETINOL W/VITAMIN D NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
TRI-LUMA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLIS	0 (0.0)	2 (1.2)	3 (2.0)	1 (4.8)
COLCHICINE	0 (0.0)	2 (1.2)	3 (2.0)	1 (4.8)
SULFONYLUREAS	2 (2.4)	1 (0.6)	2 (1.3)	1 (4.8)
GLIMEPIRIDE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
GLIPIZIDE	0 (0.0)	0 (0.0)	1 (0.7)	1 (4.8)
GLICLAZIDE	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
ACE INHIBITORS AND DIURETICS	2 (2.4)	2 (1.2)	3 (2.0)	0 (0.0)
ZESTORETIC	1 (1.2)	1 (0.6)	2 (1.3)	0 (0.0)
PRETERAX ARGININE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ACE INHIBITORS AND DIURETICS	2 (2.4)	2 (1.2)	3 (2.0)	0 (0.0)
INDAPAMIDE W/PERINDOPRIL	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS	0 (0.0)	2 (1.2)	2 (1.3)	0 (0.0)
AZELASTINE	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
AZELASTINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CARBAPENEMS	1 (1.2)	3 (1.7)	2 (1.3)	0 (0.0)
MEROPENEM	1 (1.2)	2 (1.2)	1 (0.7)	0 (0.0)
ERTAPENEM	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
MEROPENEM TRIHYDRATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
COUGH AND COLD PREPARATIONS	2 (2.4)	2 (1.2)	2 (1.3)	0 (0.0)
COUGH AND COLD PREPARATIONS	2 (2.4)	1 (0.6)	1 (0.7)	0 (0.0)
GLYCEROL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ZINC	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
IRON, PARENTERAL PREPARATIONS	1 (1.2)	2 (1.2)	2 (1.3)	0 (0.0)
FERRIC CARBOXYMALTOSE	1 (1.2)	1 (0.6)	2 (1.3)	0 (0.0)
FERRIC SODIUM GLUCONATE COMPLEX	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
IRON, PARENTERAL PREPARATIONS	1 (1.2)	2 (1.2)	2 (1.3)	0 (0.0)
IRON	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ORGANIC NITRATES	0 (0.0)	3 (1.7)	1 (0.7)	0 (0.0)
GLYCERYL TRINITRATE	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
ISOSORBIDE DINITRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ISOSORBIDE MONONITRATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OTHER ANTIBACTERIALS	2 (2.4)	1 (0.6)	2 (1.3)	0 (0.0)
FOSFOMYCIN	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
LINEZOLID	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BACITRACIN	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
BETA BLOCKING AGENTS	0 (0.0)	2 (1.2)	2 (1.3)	0 (0.0)
TIMOLOL MALEATE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
COSOPT	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
GANFORT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CARTEOLOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
COMBIGAN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION	1 (1.2)	3 (1.7)	1 (0.7)	1 (4.8)
BETNESOL-N	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
FRAMOPTIC-D	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NETILDEX	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OTOSPORIN	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
TOBRADEX	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
CIPRODAC-DM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFL	1 (1.2)	5 (2.9)	0 (0.0)	0 (0.0)
TEPRENONE	1 (1.2)	5 (2.9)	0 (0.0)	0 (0.0)
GENERAL NUTRIENTS	1 (1.2)	2 (1.2)	1 (0.7)	1 (4.8)
NUTRIENTS NOS	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
GENERAL NUTRIENTS	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
WHEY PROTEIN	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
3-OXOANDROSTEN (4) DERIVATIVES	1 (1.2)	1 (0.6)	4 (2.6)	0 (0.0)
TESTOSTERONE	1 (1.2)	1 (0.6)	3 (2.0)	0 (0.0)
TESTOSTERONE CIPIONATE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)

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3-OXOANDROSTEN (4) DERIVATIVES	1 (1.2)	1 (0.6)	4 (2.6)	0 (0.0)
TESTOSTERONE ENANTHATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
AGENTS FOR DERMATITIS, EXCLUDING CORTICOSTEROIDS	1 (1.2)	2 (1.2)	2 (1.3)	0 (0.0)
TACROLIMUS	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
PIMECROLIMUS	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
ANTI-HISTAMINES FOR TOPICAL USE	2 (2.4)	1 (0.6)	1 (0.7)	1 (4.8)
DIPHENHYDRAMINE HYDROCHLORIDE	2 (2.4)	0 (0.0)	1 (0.7)	1 (4.8)
DIPHENHYDRAMINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DIPHENHYDRAMINE W/ZINC ACETATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DOXEPIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DOXEPIN HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTI-VERTIGO PREPARATIONS	1 (1.2)	4 (2.3)	0 (0.0)	0 (0.0)
BETAHISTINE MESILATE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
CINNARIZINE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
DIMENHYDRINATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ACETYLLLEUCINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
DIGITALIS GLYCOSIDES	0 (0.0)	5 (2.9)	0 (0.0)	0 (0.0)
DIGOXIN	0 (0.0)	5 (2.9)	0 (0.0)	0 (0.0)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	3 (3.5)	1 (0.6)	1 (0.7)	0 (0.0)
THIOCTIC ACID	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
ZINC ACETATE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
PHOSPHORUS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
NATURES WAY RESTORE DAILY PROBIOTIC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VITAMIN B1, PLAIN	2 (2.4)	2 (1.2)	1 (0.7)	0 (0.0)
THIAMINE	2 (2.4)	2 (1.2)	1 (0.7)	0 (0.0)
VITAMINS	1 (1.2)	5 (2.9)	0 (0.0)	0 (0.0)
VITAMINS NOS	1 (1.2)	5 (2.9)	0 (0.0)	0 (0.0)
ANGIOTENSIN II ANTAGONISTS AND CALCIUM CHANNEL BLO	0 (0.0)	2 (1.2)	3 (2.0)	0 (0.0)
DIOVAN AMLO	0 (0.0)	0 (0.0)	3 (2.0)	0 (0.0)
AMLODIPINE W/VALSARTAN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AZOR	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ANTIINFLAMMATORY AGENTS, NON-STERIODS	0 (0.0)	4 (2.3)	1 (0.7)	0 (0.0)
BROMFENAC SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
KETOROLAC	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
KETOROLAC TROMETHAMINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NEPAFENAC	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PRANOPROFEN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DICLOFENAC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CARBAMIC ACID ESTERS	0 (0.0)	2 (1.2)	2 (1.3)	0 (0.0)
CARISOPRODOL	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
METHOCARBAMOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
HEPARINS OR HEPARINOIDS FOR TOPICAL USE	0 (0.0)	5 (2.9)	0 (0.0)	0 (0.0)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	0 (0.0)	5 (2.9)	0 (0.0)	0 (0.0)
OTHER CICATRIZANTS	0 (0.0)	2 (1.2)	3 (2.0)	0 (0.0)
DEXPANTHENOL	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
OTHER CICATRIZANTS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BUCLADESINE SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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OTHER CICATRIZANTS	0 (0.0)	2 (1.2)	3 (2.0)	0 (0.0)
PURILON	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PROTEIN SUPPLEMENTS	1 (1.2)	2 (1.2)	2 (1.3)	0 (0.0)
PROTEINS NOS	1 (1.2)	2 (1.2)	2 (1.3)	0 (0.0)
ZINC PRODUCTS	0 (0.0)	2 (1.2)	1 (0.7)	1 (4.8)
ZINC OXIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ZINC PRODUCTS	0 (0.0)	1 (0.6)	0 (0.0)	1 (4.8)
GOLD BOND	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SUDOCREM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
AYRTONS ANTISEPTIC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANALGESICS	0 (0.0)	2 (1.2)	2 (1.3)	0 (0.0)
DULOXETINE	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
DULOXETINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANALGESICS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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BILE ACID SEQUESTRANTS	1 (1.2)	0 (0.0)	2 (1.3)	0 (0.0)
COLESTYRAMINE	1 (1.2)	0 (0.0)	2 (1.3)	0 (0.0)
COLESTIPOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
COLESEVELAM HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BULK-FORMING LAXATIVES	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
POLYCARBOPHIL CALCIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FIBRE, DIETARY	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BULK-FORMING LAXATIVES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
METHYLCELLULOSE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ENZYMES	3 (3.5)	0 (0.0)	2 (1.3)	0 (0.0)
ALTEPLASE	2 (2.4)	0 (0.0)	2 (1.3)	0 (0.0)
BROEN-C	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
FATTY ACID DERIVATIVES	2 (2.4)	2 (1.2)	1 (0.7)	0 (0.0)
VALPROATE SODIUM	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
GAMMA-AMINOBUTYRIC ACID	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
VALPROATE SEMISODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ORIPAVINE DERIVATIVES	1 (1.2)	1 (0.6)	2 (1.3)	0 (0.0)
BUPRENORPHINE	1 (1.2)	1 (0.6)	2 (1.3)	0 (0.0)
OTHER ANTIPSORIATICS FOR TOPICAL USE	1 (1.2)	1 (0.6)	2 (1.3)	0 (0.0)
CALCIPOTRIOL	1 (1.2)	0 (0.0)	2 (1.3)	0 (0.0)
CRISABOROLE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
XAMIEL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OTHER ANTIPSYCHOTICS	1 (1.2)	0 (0.0)	3 (2.0)	0 (0.0)
ARIPIRAZOLE	1 (1.2)	0 (0.0)	2 (1.3)	0 (0.0)
RISPERIDONE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OTHER BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	0 (0.0)	3 (1.7)	1 (0.7)	0 (0.0)
EMPAGLIFLOZIN	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
CANAGLIFLOZIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
REPAGLINIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LIRAGLUTIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
PERIPHERAL OPIOID RECEPTOR ANTAGONISTS	1 (1.2)	1 (0.6)	0 (0.0)	1 (4.8)
NALOXEGOL OXALATE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
METHYLNALTREXONE	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
NALDEMEDINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
METHYLNALTREXONE BROMIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NALOXEGOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SULFONAMIDES	0 (0.0)	1 (0.6)	3 (2.0)	0 (0.0)
SULFADIAZINE SILVER	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
SULFACETAMIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
SYMPATHOMIMETICS IN GLAUCOMA THERAPY	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
BRIMONIDINE	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
BRIMONIDINE TARTRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SIMBRINZA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SYMPATHOMIMETICS, PLAIN	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
OXYMETAZOLINE HYDROCHLORIDE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
OXYMETAZOLINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS	0 (0.0)	1 (0.6)	3 (2.0)	0 (0.0)
COVERAM	0 (0.0)	0 (0.0)	3 (2.0)	0 (0.0)
COROVAL B	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMLODIPINE W/BENAZEPRIL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIARRHYTHMICS, CLASS III	2 (2.4)	0 (0.0)	2 (1.3)	0 (0.0)
AMIODARONE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
AMIODARONE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DRONEDARONE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
DRONEDARONE HYDROCHLORIDE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
RISTFOR	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
ALOGLIPTIN BENZOATE W/PIOGLITAZONE HYDROCHLOR	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
METFORMIN HYDROCHLORIDE W/SITAGLIPTIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
METFORMIN W/SAXAGLIPTIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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I.V. SOLUTIONS	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
I.V. SOLUTIONS	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
PHYSIO 140	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS	1 (1.2)	3 (1.7)	0 (0.0)	0 (0.0)
ENTECAVIR	1 (1.2)	3 (1.7)	0 (0.0)	0 (0.0)
TENOFVIR ALAFENAMIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOA	2 (2.4)	2 (1.2)	0 (0.0)	0 (0.0)
ATOVAQUONE	2 (2.4)	2 (1.2)	0 (0.0)	0 (0.0)
OTHER COLD PREPARATIONS	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
MENTHOL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER COLD PREPARATIONS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
CEDOVIX	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ESSENTIAL OILS NOS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HALL'S MENTHO-LYPTUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PHENOTHIAZINE DERIVATIVES	0 (0.0)	4 (2.3)	0 (0.0)	0 (0.0)
PROMETHAZINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MEQUITAZINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OXOMEMAZINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PROMETHAZINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PROGESTOGENS AND ESTROGENS, SEQUENTIAL PREPARATION	1 (1.2)	1 (0.6)	2 (1.3)	0 (0.0)
CILEST	1 (1.2)	0 (0.0)	2 (1.3)	0 (0.0)
ANOVLAR	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ALL OTHER THERAPEUTIC PRODUCTS	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
ALL OTHER THERAPEUTIC PRODUCTS	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
AMINO ACIDS, INCL. COMBINATIONS WITH POLYPEPTIDES	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
LYSINE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
AMINO ACIDS NOS W/ELECTROLYTES NOS/GLUCOSE/TH	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ARGININE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ANTIBACTERIALS FOR SYSTEMIC USE	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
ANTIBIOTICS	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
BISMUTH PREPARATIONS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
BISMUTH SUBSALICYLATE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	0 (0.0)	4 (2.3)	0 (0.0)	0 (0.0)
CARBOHYDRATES NOS W/POTASSIUM CHLORIDE/SODIUM	0 (0.0)	4 (2.3)	0 (0.0)	0 (0.0)
SOLACET F	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS FOR SYSTEMIC USE, COMBINATIONS	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS FOR SYSTEMIC USE, COMBINATION	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
STELAMIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SOLOMET C. BUPIVACAINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FIBRATES	1 (1.2)	1 (0.6)	2 (1.3)	0 (0.0)
FENOFIBRATE	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
GEMFIBROZIL	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
INTRAUTERINE CONTRACEPTIVES	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
LEVONORGESTREL	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
OTHER CHEMOTHERAPEUTICS	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
METRONIDAZOLE	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
SYMPATHOMIMETICS USED AS DECONGESTANTS	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
NAPHAZOLINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
NAPHCON-A	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
ADVANCED EYE RELIEF REDNESS INSTANT RELIEF	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VISINE ALLERGY	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TETRACYCLINE AND DERIVATIVES	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
TETRACYCLINE HYDROCHLORIDE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
OXYTETRACYCLINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VITAMINS WITH MINERALS	2 (2.4)	1 (0.6)	0 (0.0)	0 (0.0)
ARONAMIN C PLUS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BORON W/CALCIUM/COPPER/MAGNESIUM/MANGANESE/PY	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)

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VITAMINS WITH MINERALS	2 (2.4)	1 (0.6)	0 (0.0)	0 (0.0)
MACULA SUPPORT	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
CHROMIC CHLORIDE W/MAGNESIUM AMINO ACID CHELA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VITAMINS WITH MINERALS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CARBONIC ANHYDRASE INHIBITORS	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
DORZOLAMIDE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ACETAZOLAMIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DORZOLAMIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
COLONY STIMULATING FACTORS	1 (1.2)	1 (0.6)	0 (0.0)	1 (4.8)
FILGRASTIM	1 (1.2)	1 (0.6)	0 (0.0)	1 (4.8)
PEGFILGRASTIM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DRUGS USED IN NICOTINE DEPENDENCE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
NICOTINE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
BUPROPION	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
VARENICLINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VARENICLINE TARTRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
DIAZIDE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
MODURETIC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OPHTHALMOLOGICALS	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
OPHTHALMOLOGICALS	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
PREPARATIONS WITH SALICYLIC ACID DERIVATIVES	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
DUYUNGSON	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
MEDIPLASTER	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
METHYL SALICYLATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TROLAMINE SALICYLATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
RETINOIDS FOR TOPICAL USE IN ACNE	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
TRETINOIN	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR V	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
LYO-DIAMIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VITAMEDIN INTRAVENOUS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR V VITAMINES-B-LABAZ NEUROBION	0 (0.0) 0 (0.0) 0 (0.0)	2 (1.2) 0 (0.0) 0 (0.0)	1 (0.7) 1 (0.7) 0 (0.0)	0 (0.0) 0 (0.0) 0 (0.0)
ANTICHOLINESTERASES AM BENONIUM CHLORIDE DONEPEZIL HYDROCHLORIDE NEOSTIGMINE	0 (0.0) 0 (0.0) 0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6) 0 (0.0) 0 (0.0)	1 (0.7) 0 (0.0) 1 (0.7) 0 (0.0)	1 (4.8) 0 (0.0) 0 (0.0) 1 (4.8)
ASCORBIC ACID (VITAMIN C), COMBINATIONS ASCORBIC ACID (VITAMIN C), COMBINATIONS CINAL PROANTHENOLS 100 SCHIFF VITAMIN C WITH ROSE HIPS	1 (1.2) 0 (0.0) 1 (1.2) 0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0) 0 (0.0) 0 (0.0) 0 (0.0)	1 (0.7) 1 (0.7) 0 (0.0) 0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0) 0 (0.0) 0 (0.0) 0 (0.0)
AZASPIRODECANEDIONE DERIVATIVES BUSPIRONE HYDROCHLORIDE BUSPIRONE	0 (0.0) 0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6) 0 (0.0)	0 (0.0) 0 (0.0) 0 (0.0)	1 (4.8) 0 (0.0) 1 (4.8)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
DOPA AND DOPA DERIVATIVES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SINEMET	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DOPAMINE AGONISTS	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
ROPINIROLE	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
PRAMIPEXOLE DIHYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HMG COA REDUCTASE INHIBITORS IN COMBINATION WITH O	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
INEGY	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
ROSUVAST EZ	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
IODINE PRODUCTS	1 (1.2)	1 (0.6)	0 (0.0)	1 (4.8)
POVIDONE-IODINE	1 (1.2)	1 (0.6)	0 (0.0)	1 (4.8)
NICOTINIC ACID AND DERIVATIVES	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
NICOTINIC ACID	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TOCOPHERYL NICOTINATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
OTHER ANTI-DEMENTIA DRUGS	2 (2.4)	1 (0.6)	0 (0.0)	0 (0.0)
MEMANTINE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
MEMANTINE HYDROCHLORIDE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS	0 (0.0)	1 (0.6)	1 (0.7)	1 (4.8)
BOTULINUM TOXIN TYPE A	0 (0.0)	1 (0.6)	1 (0.7)	1 (4.8)
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEAS	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
OMALIZUMAB	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
ZILEUTON	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PEROXIDES	0 (0.0)	0 (0.0)	3 (2.0)	0 (0.0)
BENZOYL PEROXIDE	0 (0.0)	0 (0.0)	3 (2.0)	0 (0.0)
PHENYLALKYLAMINE DERIVATIVES	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
VERAPAMIL	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
VERAPAMIL HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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PROSTAGLANDINS	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
MISOPROSTOL	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
ALPROSTADIL ALFADEX	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PYRIMIDINE ANALOGUES	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
FLUOROURACIL	0 (0.0)	1 (0.6)	2 (1.3)	0 (0.0)
SOLUTIONS PRODUCING OSMOTIC DIURESIS	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
MANNITOL	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
ISOSORBIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
STREPTOGRAMINS	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
PRISTINAMYCIN	0 (0.0)	2 (1.2)	1 (0.7)	0 (0.0)
VARICELLA ZOSTER VACCINES	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
VARICELLA ZOSTER VACCINE	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)

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VASOPRESSIN AND ANALOGUES	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
VASOPRESSIN	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
DESMOPRESSIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VITAMIN K	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
PHYTOMENADIONE	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
VITAMIN K NOS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
XANTHINES	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)
AMINOPHYLLINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DIPROPHYLLINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
THEOPHYLLINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ACTH	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
TETRACOSACTIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TETRACOSACTIDE ACETATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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ANTIVIRALS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ACICLOVIR	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GANCICLOVIR	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TRIFLURIDINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BELLADONNA ALKALOIDS, TERTIARY AMINES	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
HYOSCYAMINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
HYOSCYAMINE SULFATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BETA-LACTAMASE SENSITIVE PENICILLINS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PHENOXYMETHYLPENICILLIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PHENOXYMETHYLPENICILLIN POTASSIUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BIOFLAVONOIDS	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
QUERCETIN	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
CAPIVEN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
CALCITONIN PREPARATIONS	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
CALCITONIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ELCATONIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MONOBACTAMS	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
AZTREONAM	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
HYALURONATE SODIUM	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
HYALURONIC ACID	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HYLAN G-F 20	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER NUTRIENTS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
OTHER NUTRIENTS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
LINOLEIC ACID	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER PSYCHOSTIMULANTS AND NOOTROPICS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
GINKGO BILOBA W/VINPOCETINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OXIRACETAM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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OTHER PSYCHOSTIMULANTS AND NOOTROPICS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
OTHER PSYCHOSTIMULANTS AND NOOTROPICS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
THROAT PREPARATIONS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
THROAT PREPARATIONS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
ANTACIDS	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
ANTACIDS	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
ANTIINFECTIVES	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
CIPROFLOXACIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OFLOXACIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BARIUM SULFATE CONTAINING X-RAY CONTRAST MEDIA	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
BARIUM SULFATE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
BETA BLOCKING AGENTS, SELECTIVE, AND THIAZIDES	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
BISELECT	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NEBICARD-H	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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BETA-LACTAMASE RESISTANT PENICILLINS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
DICLOXACILLIN SODIUM MONOHYDRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLUCLOXACILLIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BLOOD AND RELATED PRODUCTS	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
BLOOD AND RELATED PRODUCTS	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
CARBOHYDRATES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GLUCOSE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DEXTRIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CARBOXAMIDE DERIVATIVES	1 (1.2)	0 (0.0)	0 (0.0)	1 (4.8)
CARBAMAZEPINE	1 (1.2)	0 (0.0)	0 (0.0)	1 (4.8)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)
CORTICOSTEROID NOS	1 (1.2)	0 (0.0)	1 (0.7)	0 (0.0)

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DIPHENYLMETHANE DERIVATIVES	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
HYDROXYZINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
HYDROXYZINE EMBONATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ETHERS, CHEMICALLY CLOSE TO ANTIHISTAMINES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NORGESIC	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ORPHENADRINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
IRON PREPARATIONS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
IRON	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LIVER THERAPY, LIPOTROPICS	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
NEUPHAGEN	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
LOCAL ANESTHETICS	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
PROXYMETACAINE	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
LIDOCAINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TETRACAINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
MAGNESIUM COMPOUNDS	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
MAGNESIUM CARBONATE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
MAGNESIUM HYDROXIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MINERAL SUPPLEMENTS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
MINERAL SUPPLEMENTS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
POTASSIUM W/SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MULTIVITAMINS, OTHER COMBINATIONS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MULTIVITAMINS, OTHER COMBINATIONS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER AMINOGLYCOSIDES	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
GENTAMICIN	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
OTHER ANTITHROMBOTIC AGENTS	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
FONDAPARINUX	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
FONDAPARINUX SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
OTHER QUATERNARY AMMONIUM COMPOUNDS	0 (0.0)	1 (0.6)	0 (0.0)	1 (4.8)
ROCURONIUM	0 (0.0)	1 (0.6)	0 (0.0)	1 (4.8)
PARAMAGNETIC CONTRAST MEDIA	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
GADOBUTROL	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
MEGLUMINE GADOTERATE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
PARATHYROID HORMONES AND ANALOGUES	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
PARATHYROID HORMONE	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
TERIPARATIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
U-PASTA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PURINE DERIVATIVES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PENTOXIFYLLINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
SALT SOLUTIONS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
SODIUM CHLORIDE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
SELECTIVE ESTROGEN RECEPTOR MODULATORS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BAZEDOXIFENE ACETATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
RALOXIFENE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SELENIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SELENIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SYNTHETIC ANTICHOLINERGICS, QUATERNARY AMMONIUM CO	1 (1.2)	0 (0.0)	0 (0.0)	1 (4.8)
GLYCOPYRRONIUM	1 (1.2)	0 (0.0)	0 (0.0)	1 (4.8)
VITAMIN A, PLAIN	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
RETINOL	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
AMINO ACIDS AND DERIVATIVES	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BETAINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
LEVOCARNITINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ANGIOTENSIN II ANTAGONISTS, OTHER COMBINATIONS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TRIBENZOR	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANGIOTENSIN II ANTAGONISTS, OTHER COMBINATION	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIARRHYTHMICS, CLASS IC	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
FLECAINIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
FLECAINIDE ACETATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIFUNGALS FOR SYSTEMIC USE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TERBINAFINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
EMTRICITABINE W/TENOFOVIR	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, C	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BETA-LACTAMASE INHIBITORS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CLAVULANATE POTASSIUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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BIGUANIDES AND AMIDINES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CHLORHEXIDINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CHLORHEXIDINE GLUCONATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
COMBINATIONS OF VITAMINS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
COMBINATIONS OF VITAMINS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VITAMEDIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VITAMINS NOS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS FOR SYSTEMIC USE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CORTICOSTEROID NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DIRECT THROMBIN INHIBITORS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DABIGATRAN ETEXILATE MESILATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DIURETICS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ACETAZOLAMIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
HEPATITIS VACCINES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HEPATITIS A VACCINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HYPNOTICS AND SEDATIVES	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
HYPNOTICS AND SEDATIVES	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
PROMETHAZINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
IRON IN OTHER COMBINATIONS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
ASCORBIC ACID W/FOLIC ACID/IRON/VIT	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
IRON PLUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ORAL REHYDRATION SALT FORMULATIONS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ORAL REHYDRATION SALT FORMULATIONS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ELECTROLYTES NOS W/GLUCOSE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTIANEMIC PREPARATIONS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
LIVALAVIN	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
EPOETIN ALFA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
OTHER ANTISEPTICS AND DISINFECTANTS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ETHANOL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HYPOCHLOROUS ACID	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTIVIRALS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
LYSOZYME CHLORIDE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
OXAZOL, THIAZINE, AND TRIAZINE DERIVATIVES	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
METAXALONE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PHENOTHIAZINES WITH ALIPHATIC SIDE-CHAIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CHLORPROMAZINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CYAMEMAZINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SENSITIZERS USED IN PHOTODYNAMIC/RADIATION THERAPY	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMINOLEVULINIC ACID	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
SOMATOSTATIN AND ANALOGUES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LANREOTIDE ACETATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OCTREOTIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OCTREOTIDE ACETATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TETANUS VACCINES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DITEMER	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TONICS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CITRULLINE MALATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ARMAFORCE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ACE INHIBITORS, COMBINATIONS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ACE INHIBITORS, COMBINATIONS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ADRENERGICS, INHALANTS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ADRENERGICS, INHALANTS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSU	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ALUMINIUM COMPOUNDS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
ALUMINIUM SILICATE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
ANESTHETICS FOR TOPICAL USE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
PRAMOCAINE HYDROCHLORIDE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
ANTACIDS, OTHER COMBINATIONS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ANTACIDS, OTHER COMBINATIONS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ANTHRACYCLINES AND RELATED SUBSTANCES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
EPIRUBICIN HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANTIARRHYTHMICS, CLASS IB	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LIDOCAINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SHARK CARTILAGE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANTINEOVASCULARISATION AGENTS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
AFLIBERCEPT	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
ANTISPASMODICS, PSYCHOLEPTICS AND ANALGESICS IN CO	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SPASMALGIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BENZAMIDES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMISULPRIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BETA-LACTAM ANTIBACTERIALS, PENICILLINS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PENICILLIN NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BUTYROPHENONE DERIVATIVES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HALOPERIDOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
CALCINEURIN INHIBITORS CICLOSPORIN	0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
CALCIUM CHANNEL BLOCKERS AND DIURETICS AMLODAC D	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	1 (0.7) 1 (0.7)	0 (0.0) 0 (0.0)
CAPSAICIN AND SIMILAR AGENTS CAPZASIN QUICK RELIEF	1 (1.2) 1 (1.2)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
CHARCOAL PREPARATIONS CHARCOAL, ACTIVATED	0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
COMBINATIONS OF ADRENERGICS COMBINATIONS OF ADRENERGICS	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	1 (0.7) 1 (0.7)	0 (0.0) 0 (0.0)
CORTICOSTEROIDS, WEAK, COMBINATIONS WITH ANTIBIOTI CHLOMY-P	0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)

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CORTICOSTEROIDS, WEAK, COMBINATIONS WITH ANTISEPTI VIOFORM+HYDROCORTISONE	0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
DRUGS FOR BILE THERAPY AND LIPOTROPICS IN COMBINAT DRUGS FOR BILE THERAPY AND LIPOTROPICS IN COM	1 (1.2) 1 (1.2)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
DRUGS USED IN ALCOHOL DEPENDENCE NALTREXONE	1 (1.2) 1 (1.2)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
ECTOPARASITICIDES, INCL. SCABICIDES SODIUM CHLORIDE	1 (1.2) 1 (1.2)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
EMERGENCY CONTRACEPTIVES LEVONORGESTREL	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	1 (0.7) 1 (0.7)	0 (0.0) 0 (0.0)
GLYCOGENOLYTIC HORMONES GLUCAGON	0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
HMG COA REDUCTASE INHIBITORS, OTHER COMBINATIONS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
HMG COA REDUCTASE INHIBITORS, OTHER COMBINATI	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ORAL CONTRACEPTIVE NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
HYDANTOIN DERIVATIVES	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
FOSPHENYTOIN	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
PHENYTOIN	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
IMMUNOGLOBULINS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
IMMUNOGLOBULINS NOS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
INDOLE DERIVATIVES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LURASIDONE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
INSULIN HUMAN INJECTION, ISOPHANE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
IRON IN COMBINATION WITH FOLIC ACID HIERROQUICK	1 (1.2) 1 (1.2)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
LITHIUM LITHIUM CARBONATE	0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
LOCAL HEMOSTATICS EPINEPHRINE	0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
MEDICATED DRESSINGS WITH ANTIINFECTIVES POVIDONE-IODINE	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	1 (0.7) 1 (0.7)	0 (0.0) 0 (0.0)
METHYLDOPA METHYLDOPA	0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
MORPHINAN DERIVATIVES NALBUPHINE	1 (1.2) 1 (1.2)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
OTHER AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL PREPARATION H TUCKS	0 (0.0) 0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0) 0 (0.0)
OTHER ANTI-PARATHYROID AGENTS CINACALCET	0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
OTHER ANTINEOPLASTIC AGENTS MODIFIED CITRUSPECTIN	1 (1.2) 1 (1.2)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
OTHER ANTIPRURITICS CALAMINE OTHER ANTIPRURITICS	0 (0.0) 0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0) 0 (0.0)
OTHER DRUGS FOR BILE THERAPY ANETHOLE TRITHIONE	0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTRO	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER LOCAL ANESTHETICS	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
CAPSAICIN	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
OTHER PERIPHERAL VASODILATORS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PHENOXYBENZAMINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER SPECIFIC ANTIRHEUMATIC AGENTS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
METHOTREXATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OTHER SYSTEMIC HEMOSTATICS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
CARBAZOCHROME SODIUM SULFONATE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER THROAT PREPARATIONS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AZ	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
OTHER TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MENTHOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PERTUSSIS VACCINES	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
VACCIN IPAD D.T.C.	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
PHENOL AND DERIVATIVES	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
HEXACHLOROPHENE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PHENOTHIAZINES WITH PIPERAZINE STRUCTURE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
PROCHLORPERAZINE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
PROTEOLYTIC ENZYMES	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
COLLAGENASE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PYRETHRINES, INCL. SYNTHETIC COMPOUNDS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
MARIE ROSE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
QUININE AND DERIVATIVES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HEXAQUINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SELECTIVE IMMUNOSUPPRESSANTS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
APREMILAST	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
THIAMAZOLE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SYNTHETIC ANTISPASMODICS, AMIDES WITH TERTIARY AMI	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TIROPRAMIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
THIAZIDES AND POTASSIUM IN COMBINATION	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SALURES-K	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
THIAZOLIDINEDIONES	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PIOGLITAZONE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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TRIMETHOPRIM AND DERIVATIVES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TRIMETHOPRIM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TYPHOID VACCINES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TYPHOID VACCINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VITAMIN A AND D IN COMBINATION	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
COD-LIVER OIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VITAMIN B-COMPLEX WITH VITAMIN C	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
ASCORBIC ACID W/VITAMIN B NOS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
WART AND ANTI-CORN PREPARATIONS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SALICYLIC ACID	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANESTHETICS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANESTHETICS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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ANTI-GONADOTROPIN-RELEASING HORMONES CETRORELIX	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
ANTIARRHYTHMICS, CLASS I AND III ATROPINE	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
ANTIBIOTICS FOR TOPICAL USE ANTIBIOTICS FOR TOPICAL USE	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ANTI-PRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
ANTISEPTICS AND DISINFECTANTS ANTISEPTICS AND DISINFECTANTS	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
BARBITURATES AND DERIVATIVES PRIMIDONE	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)

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BETA BLOCKING AGENTS, SELECTIVE, AND OTHER DIURETI TENORETIC	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
BISPHOSPHONATES, COMBINATIONS FOSAVANCE	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
CENTRALLY ACTING ANTIPOBESITY PRODUCTS LORCASERIN	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
CORTICOSTEROIDS, MODERATELY POTENT, COMBINATIONS W MYCOLOG	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
DETOXIFYING AGENTS FOR ANTINEOPLASTIC TREATMENT RASBURICASE	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
DRUGS FOR CONSTIPATION DRUGS FOR CONSTIPATION	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
ESTROGENS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ESTROGEN NOS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
GENITO URINARY SYSTEM AND SEX HORMONES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ARGININE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
INTRAVAGINAL CONTRACEPTIVES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NUVARING	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MENINGOCOCCAL VACCINES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MENINGOCOCCAL VACCINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTIINFECTIVES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HEXAMIDINE ISETIONATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTIMIGRAINE PREPARATIONS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTIMIGRAINE PREPARATIONS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Table 14.1.5
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 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
OTHER ANXIOLYTICS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PREGABALIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER INTESTINAL ANTIINFECTIVES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NIFUROXAZIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PARASYMPATHOMIMETICS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PILOCARPINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PREGNEN (4) DERIVATIVES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROGESTERONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROGESTOGENS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MEDROXYPROGESTERONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROLACTINE INHIBITORS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CABERGOLINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
PROTECTIVES AGAINST UV-RADIATION FOR TOPICAL USE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROTECTIVES AGAINST UV-RADIATION FOR TOPICAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TUBERCULOSIS DIAGNOSTICS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TUBERCULIN PPD	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ULTRASOUND CONTRAST MEDIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SULFUR HEXAFLUORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Table 14.1.5
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 Efficacy Analysis Set
 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
Patients taking concomitant medication	78 (100.0)	158 (100.0)	143 (100.0)	18 (100.0)
THYROID HORMONES	18 (23.1)	49 (31.0)	136 (95.1)	18 (100.0)
LEVOTHYROXINE	10 (12.8)	28 (17.7)	84 (58.7)	9 (50.0)
LEVOTHYROXINE SODIUM	8 (10.3)	24 (15.2)	60 (42.0)	13 (72.2)
LIOTHYRONINE SODIUM	1 (1.3)	1 (0.6)	8 (5.6)	1 (5.6)
LIOTHYRONINE	0 (0.0)	1 (0.6)	2 (1.4)	1 (5.6)
THYROID	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
ANILIDES	42 (53.8)	81 (51.3)	53 (37.1)	10 (55.6)
PARACETAMOL	38 (48.7)	78 (49.4)	51 (35.7)	9 (50.0)
PROPACETAMOL HYDROCHLORIDE	3 (3.8)	2 (1.3)	0 (0.0)	0 (0.0)
THOMAPYRIN N	1 (1.3)	0 (0.0)	2 (1.4)	0 (0.0)
VICKS NYQUIL COLD AND FLU MULTI-SYMPTOM	1 (1.3)	1 (0.6)	0 (0.0)	1 (5.6)
AXOTAL	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
NO-FLU F	0 (0.0)	0 (0.0)	1 (0.7)	1 (5.6)
PA	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
SOLPADEINE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)

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Table 14.1.5
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 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
ANILIDES	42 (53.8)	81 (51.3)	53 (37.1)	10 (55.6)
ZICAM COLD & FLU	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
BENYLIN 4 FLU	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CORICIDIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DOLO MOBILAT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DOZOL	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
PROPACETAMOL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SINGLET	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NATURAL OPIUM ALKALOIDS	34 (43.6)	66 (41.8)	75 (52.4)	10 (55.6)
OXYCODONE	15 (19.2)	18 (11.4)	25 (17.5)	6 (33.3)
MORPHINE	6 (7.7)	11 (7.0)	17 (11.9)	2 (11.1)
MORPHINE SULFATE	10 (12.8)	14 (8.9)	14 (9.8)	1 (5.6)
OXYCODONE HYDROCHLORIDE	5 (6.4)	17 (10.8)	11 (7.7)	0 (0.0)
VICODIN	5 (6.4)	10 (6.3)	9 (6.3)	0 (0.0)
HYDROMORPHONE	5 (6.4)	7 (4.4)	5 (3.5)	4 (22.2)
OXYCOCET	5 (6.4)	5 (3.2)	7 (4.9)	1 (5.6)
HYDROMORPHONE HYDROCHLORIDE	3 (3.8)	5 (3.2)	6 (4.2)	1 (5.6)
PANADEINE CO	1 (1.3)	4 (2.5)	6 (4.2)	0 (0.0)
TARGIN	2 (2.6)	10 (6.3)	3 (2.1)	0 (0.0)

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Table 14.1.5
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 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
NATURAL OPIUM ALKALOIDS	34 (43.6)	66 (41.8)	75 (52.4)	10 (55.6)
HYDROCODONE	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
MORPHINE HYDROCHLORIDE	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
CODEINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MYPRODOL	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
MORPHINE SULFATE PENTAHYDRATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CODENONG	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HYDROCODONE BITARTRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MERSYNDOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NALOXONE W/OXYCODONE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
NATURAL OPIUM ALKALOIDS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CODEINE PHOSPHATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DIHYDROCODEINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
H2-RECEPTOR ANTAGONISTS	35 (44.9)	61 (38.6)	44 (30.8)	7 (38.9)
FAMOTIDINE	18 (23.1)	40 (25.3)	20 (14.0)	5 (27.8)
RANITIDINE	12 (15.4)	20 (12.7)	17 (11.9)	2 (11.1)
RANITIDINE HYDROCHLORIDE	10 (12.8)	16 (10.1)	19 (13.3)	2 (11.1)
CIMETIDINE	2 (2.6)	3 (1.9)	1 (0.7)	0 (0.0)
NIZATIDINE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
H2-RECEPTOR ANTAGONISTS	35 (44.9)	61 (38.6)	44 (30.8)	7 (38.9)
LAFUTIDINE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
PEPCIDDUAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
GLUCOCORTICOIDS	36 (46.2)	63 (39.9)	43 (30.1)	6 (33.3)
PREDNISONE	16 (20.5)	23 (14.6)	15 (10.5)	4 (22.2)
DEXAMETHASONE	10 (12.8)	24 (15.2)	11 (7.7)	2 (11.1)
METHYLPREDNISOLONE	5 (6.4)	10 (6.3)	5 (3.5)	1 (5.6)
PREDNISOLONE	6 (7.7)	10 (6.3)	2 (1.4)	0 (0.0)
HYDROCORTISONE	1 (1.3)	6 (3.8)	11 (7.7)	0 (0.0)
METHYLPREDNISOLONE SODIUM SUCCINATE	1 (1.3)	7 (4.4)	1 (0.7)	0 (0.0)
HYDROCORTISONE SODIUM SUCCINATE	1 (1.3)	3 (1.9)	2 (1.4)	0 (0.0)
TRIAMCINOLONE ACETONIDE	0 (0.0)	0 (0.0)	2 (1.4)	1 (5.6)
BUDESONIDE	0 (0.0)	2 (1.3)	1 (0.7)	1 (5.6)
FLUTICASONE PROPIONATE	0 (0.0)	3 (1.9)	1 (0.7)	0 (0.0)
BETAMETHASONE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
FLUTICASONE	0 (0.0)	0 (0.0)	1 (0.7)	1 (5.6)
BECLOMETASONE DIPROPIONATE	0 (0.0)	1 (0.6)	0 (0.0)	1 (5.6)
DEXAMETHASONE SODIUM PHOSPHATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BECLOMETASONE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)

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Table 14.1.5
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 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
GLUCOCORTICOIDS	36 (46.2)	63 (39.9)	43 (30.1)	6 (33.3)
BETAMETHASONE SODIUM PHOSPHATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CORTISONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DEXAMETHASONE PHOSPHATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
METHYLPREDNISOLONE ACETATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TRIAMCINOLONE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BETAMETHASONE ACETATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CORTISONE ACETATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VITAMIN D AND ANALOGUES	15 (19.2)	30 (19.0)	81 (56.6)	12 (66.7)
COLECALCIFEROL	8 (10.3)	20 (12.7)	39 (27.3)	7 (38.9)
CALCITRIOL	0 (0.0)	2 (1.3)	27 (18.9)	5 (27.8)
ERGOCALCIFEROL	2 (2.6)	3 (1.9)	14 (9.8)	1 (5.6)
VITAMIN D NOS	4 (5.1)	6 (3.8)	8 (5.6)	0 (0.0)
ALFACALCIDOL	1 (1.3)	1 (0.6)	4 (2.8)	0 (0.0)
CALCIFEDIOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BENZODIAZEPINE DERIVATIVES	28 (35.9)	52 (32.9)	48 (33.6)	8 (44.4)
LORAZEPAM	15 (19.2)	26 (16.5)	26 (18.2)	2 (11.1)
ALPRAZOLAM	7 (9.0)	13 (8.2)	12 (8.4)	2 (11.1)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
BENZODIAZEPINE DERIVATIVES	28 (35.9)	52 (32.9)	48 (33.6)	8 (44.4)
DIAZEPAM	2 (2.6)	1 (0.6)	9 (6.3)	3 (16.7)
MIDAZOLAM	4 (5.1)	8 (5.1)	2 (1.4)	2 (11.1)
CLONAZEPAM	3 (3.8)	4 (2.5)	4 (2.8)	0 (0.0)
TEMAZEPAM	0 (0.0)	1 (0.6)	3 (2.1)	1 (5.6)
BROMAZEPAM	1 (1.3)	2 (1.3)	3 (2.1)	0 (0.0)
BROTIZOLAM	2 (2.6)	3 (1.9)	0 (0.0)	0 (0.0)
ETIZOLAM	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)
OXAZEPAM	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
FLUNITRAZEPAM	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
ETHYL LOFLAZEPATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LOPRAZOLAM MESILATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MIDAZOLAM HYDROCHLORIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
NITRAZEPAM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TRIAZOLAM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CLOBAZAM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LOPRAZOLAM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
ANTIPROPULSIVES	20 (25.6)	41 (25.9)	68 (47.6)	7 (38.9)
LOPERAMIDE HYDROCHLORIDE	16 (20.5)	22 (13.9)	36 (25.2)	2 (11.1)
LOPERAMIDE	5 (6.4)	17 (10.8)	22 (15.4)	4 (22.2)
LOMOTIL	4 (5.1)	5 (3.2)	27 (18.9)	1 (5.6)
DIACURE PLUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DIHYDROPYRIDINE DERIVATIVES	24 (30.8)	52 (32.9)	40 (28.0)	4 (22.2)
AMLODIPINE	12 (15.4)	32 (20.3)	28 (19.6)	3 (16.7)
AMLODIPINE BESILATE	12 (15.4)	12 (7.6)	9 (6.3)	1 (5.6)
NIFEDIPINE	2 (2.6)	5 (3.2)	3 (2.1)	0 (0.0)
LERCANIDIPINE	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
NICARDIPINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
AMLODIPINE CAMSILATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMLODIPINE OROTATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BENIDIPINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CILNIDIPINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FELODIPINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LERCANIDIPINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NICARDIPINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROPIONIC ACID DERIVATIVES	22 (28.2)	40 (25.3)	40 (28.0)	6 (33.3)
IBUPROFEN	16 (20.5)	22 (13.9)	32 (22.4)	6 (33.3)
NAPROXEN	3 (3.8)	6 (3.8)	3 (2.1)	1 (5.6)
NAPROXEN SODIUM	3 (3.8)	3 (1.9)	6 (4.2)	0 (0.0)
LOXOPROFEN SODIUM	2 (2.6)	6 (3.8)	0 (0.0)	0 (0.0)
LOXOPROFEN	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)
IBUPROFEN SODIUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
KETOPROFEN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CAROL-F	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
DEXKETOPROFEN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLURBIPROFEN AXETIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ZALTOPROFEN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CO-ADVIL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OSMOTICALLY ACTING LAXATIVES	25 (32.1)	46 (29.1)	27 (18.9)	4 (22.2)
MACROGOL 3350	11 (14.1)	11 (7.0)	11 (7.7)	2 (11.1)
LACTULOSE	9 (11.5)	19 (12.0)	4 (2.8)	1 (5.6)
MACROGOL	5 (6.4)	9 (5.7)	6 (4.2)	2 (11.1)
MAGNESIUM OXIDE	4 (5.1)	16 (10.1)	1 (0.7)	0 (0.0)

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OSMOTICALLY ACTING LAXATIVES	25 (32.1)	46 (29.1)	27 (18.9)	4 (22.2)
MOVICOL	1 (1.3)	3 (1.9)	4 (2.8)	0 (0.0)
MAGNESIUM HYDROXIDE	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
MAGNESIUM CITRATE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
MACROGOL 4000	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TRANSIPEG	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SEROTONIN (5HT3) ANTAGONISTS	20 (25.6)	35 (22.2)	38 (26.6)	5 (27.8)
ONDANSETRON	18 (23.1)	32 (20.3)	37 (25.9)	5 (27.8)
ONDANSETRON HYDROCHLORIDE	2 (2.6)	0 (0.0)	2 (1.4)	0 (0.0)
GRANISETRON HYDROCHLORIDE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
GRANISETRON	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PALONOSETRON HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CONTACT LAXATIVES	22 (28.2)	40 (25.3)	21 (14.7)	6 (33.3)
SENNOSIDE A+B	19 (24.4)	27 (17.1)	16 (11.2)	4 (22.2)
BISACODYL	2 (2.6)	10 (6.3)	2 (1.4)	0 (0.0)
COLOXYL WITH SENNA	1 (1.3)	3 (1.9)	2 (1.4)	2 (11.1)
SODIUM PICOSULFATE	1 (1.3)	2 (1.3)	3 (2.1)	0 (0.0)
DOCUSATE W/SENN	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)

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CONTACT LAXATIVES	22 (28.2)	40 (25.3)	21 (14.7)	6 (33.3)
SENNOSIDE A+B CALCIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DULCODOS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SENOKOT-S	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE	18 (23.1)	38 (24.1)	29 (20.3)	3 (16.7)
SPEKTRAMOX	13 (16.7)	24 (15.2)	24 (16.8)	2 (11.1)
PIP/TAZO	7 (9.0)	16 (10.1)	7 (4.9)	2 (11.1)
UNACID	0 (0.0)	1 (0.6)	3 (2.1)	0 (0.0)
AUGMENTIN	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
PIPERACILLIN W/TAZOBACTAM	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
SULTAMICILLIN TOSILATE	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
AMINOXIDIN SULBACTAM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ELECTROLYTE SOLUTIONS	17 (21.8)	45 (28.5)	24 (16.8)	7 (38.9)
SODIUM CHLORIDE	15 (19.2)	37 (23.4)	18 (12.6)	6 (33.3)
MAGNESIUM SULFATE	4 (5.1)	10 (6.3)	8 (5.6)	2 (11.1)
CALCIUM GLUCONATE	1 (1.3)	2 (1.3)	5 (3.5)	1 (5.6)
POTASSIUM CHLORIDE	2 (2.6)	6 (3.8)	2 (1.4)	0 (0.0)
POTASSIUM PHOSPHATE MONOBASIC	1 (1.3)	4 (2.5)	1 (0.7)	0 (0.0)

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ELECTROLYTE SOLUTIONS	17 (21.8)	45 (28.5)	24 (16.8)	7 (38.9)
SODIUM PHOSPHATE	2 (2.6)	1 (0.6)	0 (0.0)	0 (0.0)
MULTITRACE-4	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
POTASSIUM	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
SODIUM BICARBONATE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
CALCIUM CHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ZINC SULFATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ELEMAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SODIUM PHOSPHATE MONOBASIC (ANHYDRATE)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANALGESICS AND ANTIPYRETICS	12 (15.4)	37 (23.4)	33 (23.1)	3 (16.7)
GABAPENTIN	9 (11.5)	17 (10.8)	20 (14.0)	3 (16.7)
PREGABALIN	2 (2.6)	21 (13.3)	8 (5.6)	0 (0.0)
CANNABIDIOL	0 (0.0)	4 (2.5)	4 (2.8)	0 (0.0)
NEFOPAM HYDROCHLORIDE	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
TOPIRAMATE	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
NEFOPAM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
CALCIUM	5 (6.4)	14 (8.9)	51 (35.7)	3 (16.7)
CALCIUM CARBONATE	5 (6.4)	7 (4.4)	29 (20.3)	3 (16.7)
CALCIUM	0 (0.0)	4 (2.5)	13 (9.1)	0 (0.0)
CALCIUM CITRATE	0 (0.0)	3 (1.9)	8 (5.6)	0 (0.0)
CALCIUM ACETATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CALCIUM LACTATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DICALCIUM MALATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CALCIUM GLUCONATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SULFONAMIDES, PLAIN	16 (20.5)	39 (24.7)	26 (18.2)	2 (11.1)
FUROSEMIDE	16 (20.5)	34 (21.5)	20 (14.0)	2 (11.1)
CHLORTALIDONE	0 (0.0)	2 (1.3)	2 (1.4)	0 (0.0)
TORASEMIDE	0 (0.0)	1 (0.6)	4 (2.8)	0 (0.0)
AZOSEMIDE	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)
INDAPAMIDE	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
METOLAZONE	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
BUMETANIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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FLUOROQUINOLONES	16 (20.5)	32 (20.3)	23 (16.1)	5 (27.8)
LEVOFLOXACIN	6 (7.7)	23 (14.6)	8 (5.6)	4 (22.2)
CIPROFLOXACIN	10 (12.8)	7 (4.4)	10 (7.0)	2 (11.1)
CIPROFLOXACIN HYDROCHLORIDE	1 (1.3)	5 (3.2)	2 (1.4)	0 (0.0)
OFLOXACIN	0 (0.0)	2 (1.3)	4 (2.8)	0 (0.0)
MOXIFLOXACIN	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
TOSUFLOXACIN TOSILATE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
CIPROFLOXACIN LACTATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLUOROQUINOLONES	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
MOXIFLOXACIN HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NORFLOXACIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BESIFLOXACIN HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LEVOFLOXACIN HEMIHYDRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SITAFLOXACIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MAGNESIUM	12 (15.4)	27 (17.1)	30 (21.0)	6 (33.3)
MAGNESIUM OXIDE	7 (9.0)	14 (8.9)	13 (9.1)	4 (22.2)
MAGNESIUM	2 (2.6)	8 (5.1)	16 (11.2)	2 (11.1)
MAGNESIUM AMINO ACID CHELATE	0 (0.0)	5 (3.2)	1 (0.7)	0 (0.0)

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MAGNESIUM	12 (15.4)	27 (17.1)	30 (21.0)	6 (33.3)
MAGNESIUM PIDOLATE	1 (1.3)	2 (1.3)	1 (0.7)	0 (0.0)
MAGNESIUM ASPARTATE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
MAGNESIUM SULFATE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
MAGNESIUM CITRATE	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
DYNAMAG	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MAGNESIUM GLYCINATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MAGNESIUM HYDROXIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MAGNESIUM OROTATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MAGNESIUM ASPARTATE HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MAGNESIUM HYDROGEN ASPARTATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	13 (16.7)	33 (20.9)	13 (9.1)	6 (33.3)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	4 (5.1)	10 (6.3)	8 (5.6)	5 (27.8)
BENZYDAMINE HYDROCHLORIDE	4 (5.1)	7 (4.4)	0 (0.0)	0 (0.0)
LIDOCAINE HYDROCHLORIDE	3 (3.8)	3 (1.9)	1 (0.7)	1 (5.6)
SODIUM GUALENATE HYDRATE	1 (1.3)	7 (4.4)	0 (0.0)	0 (0.0)
CALCIUM LACTATE W/GLUCOSE OXIDASE/L	2 (2.6)	5 (3.2)	0 (0.0)	0 (0.0)
MAGIC MOUTHWASH	0 (0.0)	2 (1.3)	2 (1.4)	1 (5.6)
ALUMINIUM HYDROXIDE W/DIPHENHYDRAMINE	0 (0.0)	0 (0.0)	1 (0.7)	1 (5.6)

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 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	13 (16.7)	33 (20.9)	13 (9.1)	6 (33.3)
SODIUM CHLORIDE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
CAPHOSOL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BIOTENE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
FIRST BLM	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
LIDOCAINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AQUORAL	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
GLUCOSE OXIDASE W/LACTOFERRIN/LACTO	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
GLYCEROL DIOLEATE W/PHOSPHOLIPIDS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GLYCO THYMOLINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BENZYDAMINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SIALIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HMG COA REDUCTASE INHIBITORS	16 (20.5)	29 (18.4)	18 (12.6)	3 (16.7)
ATORVASTATIN	6 (7.7)	15 (9.5)	9 (6.3)	0 (0.0)
ATORVASTATIN CALCIUM	5 (6.4)	8 (5.1)	5 (3.5)	1 (5.6)
SIMVASTATIN	2 (2.6)	3 (1.9)	1 (0.7)	0 (0.0)
ROSUVASTATIN CALCIUM	4 (5.1)	1 (0.6)	3 (2.1)	0 (0.0)
ROSUVASTATIN	1 (1.3)	1 (0.6)	2 (1.4)	1 (5.6)
PRAVASTATIN	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
HMG COA REDUCTASE INHIBITORS	16 (20.5)	29 (18.4)	18 (12.6)	3 (16.7)
PITAVASTATIN CALCIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLUVASTATIN SODIUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PRAVASTATIN SODIUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SOFTENERS, EMOLLIENTS	17 (21.8)	18 (11.4)	22 (15.4)	6 (33.3)
DOCUSATE SODIUM	15 (19.2)	14 (8.9)	17 (11.9)	4 (22.2)
DOCUSATE	3 (3.8)	5 (3.2)	5 (3.5)	1 (5.6)
SOFTENERS, EMOLLIENTS	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
DOCUSATE POTASSIUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PARAFFIN, LIQUID	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BETA BLOCKING AGENTS, SELECTIVE	12 (15.4)	21 (13.3)	33 (23.1)	5 (27.8)
METOPROLOL SUCCINATE	2 (2.6)	2 (1.3)	11 (7.7)	4 (22.2)
METOPROLOL	4 (5.1)	6 (3.8)	5 (3.5)	1 (5.6)
METOPROLOL TARTRATE	0 (0.0)	7 (4.4)	8 (5.6)	0 (0.0)
ATENOLOL	3 (3.8)	1 (0.6)	2 (1.4)	0 (0.0)
BISOPROLOL	1 (1.3)	3 (1.9)	5 (3.5)	0 (0.0)
BISOPROLOL FUMARATE	2 (2.6)	3 (1.9)	3 (2.1)	0 (0.0)
NEBIVOLOL	0 (0.0)	0 (0.0)	4 (2.8)	0 (0.0)

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BETA BLOCKING AGENTS, SELECTIVE	12 (15.4)	21 (13.3)	33 (23.1)	5 (27.8)
NEBIVOLOL HYDROCHLORIDE	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER	7 (9.0)	21 (13.3)	32 (22.4)	5 (27.8)
LEKOVIT CA	3 (3.8)	9 (5.7)	16 (11.2)	2 (11.1)
CALCIUM W/VITAMIN D NOS	1 (1.3)	3 (1.9)	3 (2.1)	1 (5.6)
SUPER CAL600-MG300	1 (1.3)	5 (3.2)	0 (0.0)	0 (0.0)
CALCIUM CITRATE W/COLECALCIFEROL	1 (1.3)	0 (0.0)	2 (1.4)	1 (5.6)
CALCIUM CARBONATE W/VITAMIN D NOS	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
CALCIUM D3	0 (0.0)	2 (1.3)	2 (1.4)	0 (0.0)
CALCITE D	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OSTEOCARE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
CALCIUM CARBONATE W/COLECALCIFEROL/MINERALS N	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CALCIUM CITRATE W/VITAMIN D NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CALCIUM W/MAGNESIUM/VITAMIN D NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR O	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CALCIUM W/COLECALCIFEROL/VITAMIN K NOS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
CALCIUM W/MAGNESIUM	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
DOPPELHERZ AKTIV CALCIUM+D3+BIOTIN+FOLSAEURE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
LOGICAL M	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER	7 (9.0)	21 (13.3)	32 (22.4)	5 (27.8)
VIActiv	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
B-CAL-DM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CALCIDO	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CALCIUM CARBONATE W/MAGNESIUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CALCIUM MAGNESIUM ZINC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CALCIUM PLUS WITH MAGNESIUM & VITAMIN D	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	9 (11.5)	23 (14.6)	32 (22.4)	5 (27.8)
PLANTAGO OVATA	1 (1.3)	4 (2.5)	9 (6.3)	0 (0.0)
HERBAL PREPARATION	3 (3.8)	3 (1.9)	6 (4.2)	0 (0.0)
CURCUMA LONGA RHIZOME	1 (1.3)	4 (2.5)	2 (1.4)	1 (5.6)
PAPAVER SOMNIFERUM TINCTURE	0 (0.0)	0 (0.0)	7 (4.9)	0 (0.0)
CANNABIS SATIVA	0 (0.0)	0 (0.0)	4 (2.8)	1 (5.6)
CANNABIS SATIVA OIL	1 (1.3)	1 (0.6)	2 (1.4)	0 (0.0)
SILYBUM MARIANUM	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
ALOE VERA	1 (1.3)	0 (0.0)	1 (0.7)	1 (5.6)
LINUM USITATISSIMUM SEED OIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VACCINIUM MACROCARPON	0 (0.0)	0 (0.0)	3 (2.1)	0 (0.0)
MALUS SPP. VINEGAR EXTRACT	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	9 (11.5)	23 (14.6)	32 (22.4)	5 (27.8)
MENTHA X PIPERITA OIL	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
CINNAMOMUM VERUM	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.6)
SENNA ALEXANDRINA GLYCOSIDE EXTRACT	0 (0.0)	1 (0.6)	0 (0.0)	1 (5.6)
CARICA PAPAYA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SPIRULINA SPP.	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ALOSENN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
COCOS NUCIFERA OIL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CRATAEGUS LAEVIGATA	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
FOENICULUM VULGARE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
GENTIANA LUTEA	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
GOREISAN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GOSHAJINKIGAN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HARPAGOPHYTUM PROCUMBENS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
HERBAL POLLEN NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
LINUM USITATISSIMUM SEED	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
MACROCYSTIS PYRIFERA	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
OLEA EUROPAEA OIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SERENOA REPENS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
SERENOA REPENS EXTRACT	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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 by Subpopulation

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UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	9 (11.5)	23 (14.6)	32 (22.4)	5 (27.8)
SYZYGIUM AROMATICUM	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
TARAXACUM OFFICINALE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
VITIS VINIFERA EXTRACT	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VITIS VINIFERA SEED	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ZEA MAYS EXTRACT	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ZINGIBER OFFICINALE RHIZOME	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ALLIUM SATIVUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ARNICA MONTANA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CAMELLIA SINENSIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HEDERA HELIX	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PLANTAGO OVATA HUSK	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PLATYCODON GRANDIFLORUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PRUNUS ARMENIACA SEED EXTRACT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VISCUM ALBUM EXTRACT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HEPARIN GROUP	17 (21.8)	32 (20.3)	18 (12.6)	4 (22.2)
ENOXAPARIN SODIUM	8 (10.3)	13 (8.2)	8 (5.6)	0 (0.0)
ENOXAPARIN	7 (9.0)	16 (10.1)	2 (1.4)	4 (22.2)
HEPARIN	2 (2.6)	5 (3.2)	5 (3.5)	0 (0.0)

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HEPARIN GROUP	17 (21.8)	32 (20.3)	18 (12.6)	4 (22.2)
TINZAPARIN SODIUM	1 (1.3)	0 (0.0)	4 (2.8)	0 (0.0)
DALTEPARIN	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
HEPARIN SODIUM	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
DALTEPARIN SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GLUCOSE W/HEPARIN	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
HEPARIN CALCIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ACE INHIBITORS, PLAIN	10 (12.8)	23 (14.6)	21 (14.7)	2 (11.1)
LISINOPRIL	8 (10.3)	14 (8.9)	12 (8.4)	2 (11.1)
RAMIPRIL	1 (1.3)	6 (3.8)	3 (2.1)	0 (0.0)
PERINDOPRIL	0 (0.0)	0 (0.0)	4 (2.8)	0 (0.0)
ENALAPRIL	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
ENALAPRILAT	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
ENALAPRIL MALEATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TRANDOLAPRIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BENAZEPRIL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CAPTOPRIL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LISINOPRIL DIHYDRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PERINDOPRIL ARGININE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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ANGIOTENSIN II ANTAGONISTS, PLAIN	16 (20.5)	28 (17.7)	20 (14.0)	1 (5.6)
LOSARTAN	3 (3.8)	10 (6.3)	4 (2.8)	1 (5.6)
LOSARTAN POTASSIUM	2 (2.6)	3 (1.9)	8 (5.6)	0 (0.0)
IRBESARTAN	3 (3.8)	1 (0.6)	5 (3.5)	0 (0.0)
CANDESARTAN CILEXETIL	3 (3.8)	5 (3.2)	1 (0.7)	0 (0.0)
VALSARTAN	2 (2.6)	0 (0.0)	4 (2.8)	0 (0.0)
CANDESARTAN	1 (1.3)	3 (1.9)	0 (0.0)	0 (0.0)
OLMESARTAN	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
OLMESARTAN MEDOXOMIL	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
TELMISARTAN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AZILSARTAN	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
FIMASARTAN POTASSIUM TRIHYDRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMIDES	15 (19.2)	29 (18.4)	17 (11.9)	7 (38.9)
LIDOCAINE	8 (10.3)	20 (12.7)	13 (9.1)	7 (38.9)
EMLA	3 (3.8)	3 (1.9)	0 (0.0)	0 (0.0)
BUPIVACAINE	1 (1.3)	2 (1.3)	1 (0.7)	0 (0.0)
XYLOCAINE-EPINEPHRINE	2 (2.6)	1 (0.6)	2 (1.4)	0 (0.0)
LIDOCAINE HYDROCHLORIDE	1 (1.3)	3 (1.9)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
AMIDES	15 (19.2)	29 (18.4)	17 (11.9)	7 (38.9)
ROPIVACAINE	0 (0.0)	2 (1.3)	0 (0.0)	1 (5.6)
MARCAIN-ADRENALIN	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
BUPIVACAINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
LIDOCAINE W/SODIUM BICARBONATE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
AMIDES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LIDOCAINE W/MENTHOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OXETACAINE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
RAPYDAN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ROPIVACAINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER ANTIEMETICS	11 (14.1)	21 (13.3)	23 (16.1)	4 (22.2)
PROCHLORPERAZINE MALEATE	4 (5.1)	12 (7.6)	8 (5.6)	0 (0.0)
PROCHLORPERAZINE	5 (6.4)	4 (2.5)	5 (3.5)	2 (11.1)
DRONABINOL	1 (1.3)	1 (0.6)	6 (4.2)	1 (5.6)
PROMETHAZINE	1 (1.3)	0 (0.0)	4 (2.8)	1 (5.6)
PROCHLORPERAZINE EDISYLATE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
HYOSCINE	0 (0.0)	0 (0.0)	1 (0.7)	1 (5.6)
APREPITANT	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
OTHER ANTIEMETICS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	6 (7.7)	30 (19.0)	14 (9.8)	6 (33.3)
SALBUTAMOL	4 (5.1)	24 (15.2)	8 (5.6)	2 (11.1)
SALBUTAMOL SULFATE	1 (1.3)	5 (3.2)	6 (4.2)	1 (5.6)
LEVOSALBUTAMOL	1 (1.3)	3 (1.9)	0 (0.0)	2 (11.1)
LEVOSALBUTAMOL HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	1 (5.6)
LEVOSALBUTAMOL TARTRATE	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
PROCATEROL HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SALMETEROL	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
ARFORMOTEROL TARTRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FENOTEROL HYDROBROMIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER OPIOIDS	15 (19.2)	26 (16.5)	14 (9.8)	1 (5.6)
TRAMADOL	11 (14.1)	8 (5.1)	9 (6.3)	1 (5.6)
TRAMADOL HYDROCHLORIDE	3 (3.8)	11 (7.0)	4 (2.8)	0 (0.0)
ULTRACET	2 (2.6)	8 (5.1)	1 (0.7)	0 (0.0)
TAPENTADOL	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
TAPENTADOL HYDROCHLORIDE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
OTHER OPIOIDS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
POTASSIUM	10 (12.8)	20 (12.7)	21 (14.7)	3 (16.7)
POTASSIUM CHLORIDE	10 (12.8)	18 (11.4)	19 (13.3)	3 (16.7)
POTASSIUM	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
MAGNESIUM W/POTASSIUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
POTASSIUM ASPARTATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
POTASSIUM PHOSPHATE MONOBASIC	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SWISS-KAL EFF	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MULTIVITAMINS, PLAIN	9 (11.5)	19 (12.0)	17 (11.9)	3 (16.7)
MULTIVITAMINS, PLAIN	9 (11.5)	18 (11.4)	16 (11.2)	3 (16.7)
TAB A VITE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
VITAMINS NOS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER ANTIDEPRESSANTS	10 (12.8)	14 (8.9)	22 (15.4)	3 (16.7)
MIRTAZAPINE	6 (7.7)	6 (3.8)	6 (4.2)	0 (0.0)
DULOXETINE	0 (0.0)	1 (0.6)	4 (2.8)	2 (11.1)
TRAZODONE	2 (2.6)	0 (0.0)	5 (3.5)	0 (0.0)
TRAZODONE HYDROCHLORIDE	2 (2.6)	1 (0.6)	2 (1.4)	0 (0.0)
BUPROPION	0 (0.0)	2 (1.3)	1 (0.7)	1 (5.6)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER ANTIDEPRESSANTS	10 (12.8)	14 (8.9)	22 (15.4)	3 (16.7)
DULOXETINE HYDROCHLORIDE	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
BUPROPION HYDROCHLORIDE	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
VENLAFAXINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
VENLAFAXINE	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
VORTIOXETINE HYDROBROMIDE	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
MIANSERIN HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DESVENLAFAXINE SUCCINATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OXITRIPTAN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROPULSIVES	12 (15.4)	25 (15.8)	15 (10.5)	1 (5.6)
METOCLOPRAMIDE	5 (6.4)	17 (10.8)	7 (4.9)	1 (5.6)
METOCLOPRAMIDE HYDROCHLORIDE	3 (3.8)	6 (3.8)	7 (4.9)	0 (0.0)
DOMPERIDONE	3 (3.8)	0 (0.0)	2 (1.4)	0 (0.0)
MOSAPRIDE CITRATE	1 (1.3)	4 (2.5)	0 (0.0)	0 (0.0)
ITOPRIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
MOSAPRIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	11 (14.1)	20 (12.7)	16 (11.2)	0 (0.0)
LORATADINE	5 (6.4)	12 (7.6)	13 (9.1)	0 (0.0)
FEXOFENADINE HYDROCHLORIDE	1 (1.3)	3 (1.9)	2 (1.4)	0 (0.0)
DESLOMATADINE	1 (1.3)	2 (1.3)	1 (0.7)	0 (0.0)
HYDROXYZINE HYDROCHLORIDE	3 (3.8)	1 (0.6)	0 (0.0)	0 (0.0)
BILASTINE	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)
FEXOFENADINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
EBASTINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
EPINASTINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HYDROXYZINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OLOPATADINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
KETOTIFEN FUMARATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	6 (7.7)	21 (13.3)	17 (11.9)	3 (16.7)
ACETYLSALICYLIC ACID	5 (6.4)	20 (12.7)	12 (8.4)	3 (16.7)
ACETYLSALICYLATE LYSINE	0 (0.0)	1 (0.6)	5 (3.5)	0 (0.0)
CLOPIDOGREL BISULFATE	0 (0.0)	2 (1.3)	2 (1.4)	0 (0.0)
CLOPIDOGREL	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
TICAGRELOR	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	6 (7.7)	21 (13.3)	17 (11.9)	3 (16.7)
ILOPROST TROMETAMOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	8 (10.3)	11 (7.0)	18 (12.6)	2 (11.1)
SERTRALINE	3 (3.8)	1 (0.6)	1 (0.7)	1 (5.6)
SERTRALINE HYDROCHLORIDE	0 (0.0)	2 (1.3)	3 (2.1)	0 (0.0)
ESCITALOPRAM	2 (2.6)	1 (0.6)	2 (1.4)	0 (0.0)
ESCITALOPRAM OXALATE	0 (0.0)	1 (0.6)	3 (2.1)	0 (0.0)
PAROXETINE	1 (1.3)	3 (1.9)	1 (0.7)	1 (5.6)
CITALOPRAM	0 (0.0)	0 (0.0)	5 (3.5)	0 (0.0)
CITALOPRAM HYDROBROMIDE	1 (1.3)	1 (0.6)	3 (2.1)	0 (0.0)
FLUOXETINE	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
FLUOXETINE HYDROCHLORIDE	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
PAROXETINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
DIRECT FACTOR XA INHIBITORS	15 (19.2)	21 (13.3)	12 (8.4)	1 (5.6)
RIVAROXABAN	10 (12.8)	10 (6.3)	6 (4.2)	1 (5.6)
APIXABAN	5 (6.4)	7 (4.4)	6 (4.2)	0 (0.0)
EDOXABAN TOSILATE	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	8 (10.3)	18 (11.4)	15 (10.5)	0 (0.0)
TRIAMCINOLONE ACETONIDE	3 (3.8)	4 (2.5)	5 (3.5)	0 (0.0)
TRIAMCINOLONE	3 (3.8)	4 (2.5)	6 (4.2)	0 (0.0)
ALCLOMETASONE DIPROPIONATE	0 (0.0)	5 (3.2)	0 (0.0)	0 (0.0)
DESONIDE	0 (0.0)	2 (1.3)	2 (1.4)	0 (0.0)
ALCLOMETASONE	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
HYDROCORTISONE BUTYRATE	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
CLOBETASONE BUTYRATE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
DEXAMETHASONE DIPROPIONATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DEXAMETHASONE VALERATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLUMETASONE PIVALATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
INFLUENZA VACCINES	9 (11.5)	21 (13.3)	12 (8.4)	2 (11.1)
INFLUENZA VACCINE	9 (11.5)	21 (13.3)	12 (8.4)	2 (11.1)
BENZODIAZEPINE RELATED DRUGS	10 (12.8)	15 (9.5)	16 (11.2)	1 (5.6)
ZOLPIDEM	4 (5.1)	9 (5.7)	8 (5.6)	1 (5.6)
ZOLPIDEM TARTRATE	6 (7.7)	4 (2.5)	4 (2.8)	0 (0.0)
ZOPICLONE	3 (3.8)	3 (1.9)	3 (2.1)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
BENZODIAZEPINE RELATED DRUGS	10 (12.8)	15 (9.5)	16 (11.2)	1 (5.6)
ESZOPICLONE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
ZALEPLON	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS, POTENT (GROUP III)	13 (16.7)	23 (14.6)	7 (4.9)	1 (5.6)
BETAMETHASONE VALERATE	6 (7.7)	3 (1.9)	0 (0.0)	0 (0.0)
BETAMETHASONE DIPROPIONATE	2 (2.6)	1 (0.6)	2 (1.4)	1 (5.6)
BETAMETHASONE BUTYRATE PROPIONATE	2 (2.6)	6 (3.8)	0 (0.0)	0 (0.0)
FLUOCINONIDE	1 (1.3)	3 (1.9)	2 (1.4)	0 (0.0)
DIFLUPREDNATE	2 (2.6)	4 (2.5)	0 (0.0)	0 (0.0)
MOMETASONE FUROATE	1 (1.3)	0 (0.0)	2 (1.4)	0 (0.0)
FLUOCINOLONE ACETONIDE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
DESOXIMETASONE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
MOMETASONE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
METHYLPREDNISOLONE ACEPONATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PREDNICARBATE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
DIFLORASONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLUDROXYCORTIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
DIFLUCORTOLONE VALERATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
ALPHA-ADRENORECEPTOR ANTAGONISTS	9 (11.5)	15 (9.5)	19 (13.3)	1 (5.6)
TAMSULOSIN HYDROCHLORIDE	5 (6.4)	4 (2.5)	9 (6.3)	0 (0.0)
TAMSULOSIN	4 (5.1)	6 (3.8)	3 (2.1)	1 (5.6)
ALFUZOSIN HYDROCHLORIDE	2 (2.6)	0 (0.0)	1 (0.7)	0 (0.0)
DOXAZOSIN MESILATE	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
SILODOSIN	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
ALFUZOSIN	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
DOXAZOSIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DUTAS-T	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
PAZOSIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
URAPIDIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TERAZOSIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
THIRD-GENERATION CEPHALOSPORINS	6 (7.7)	20 (12.7)	13 (9.1)	3 (16.7)
CEFTRIAXONE	4 (5.1)	6 (3.8)	2 (1.4)	1 (5.6)
CEFTRIAXONE SODIUM	0 (0.0)	6 (3.8)	5 (3.5)	0 (0.0)
CEFDINIR	0 (0.0)	3 (1.9)	4 (2.8)	1 (5.6)
CEFPODOXIME PROXETIL	2 (2.6)	3 (1.9)	0 (0.0)	1 (5.6)
CEFCAPENE PIVOXIL HYDROCHLORIDE	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)

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THIRD-GENERATION CEPHALOSPORINS	6 (7.7)	20 (12.7)	13 (9.1)	3 (16.7)
CEFIXIME	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
CEFPODOXIME	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CEFDITOREN PIVOXIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CEFOTAXIME	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CEFTAZIDIME	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZ	11 (14.1)	19 (12.0)	9 (6.3)	2 (11.1)
DENOSUMAB	11 (14.1)	19 (12.0)	9 (6.3)	2 (11.1)
PIPERAZINE DERIVATIVES	10 (12.8)	15 (9.5)	12 (8.4)	2 (11.1)
CETIRIZINE HYDROCHLORIDE	6 (7.7)	4 (2.5)	7 (4.9)	0 (0.0)
CETIRIZINE	3 (3.8)	4 (2.5)	3 (2.1)	2 (11.1)
LEVOCETIRIZINE DIHYDROCHLORIDE	0 (0.0)	5 (3.2)	1 (0.7)	0 (0.0)
MECLOZINE	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
LEVOCETIRIZINE	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
CYCLIZINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPIUM ALKALOIDS AND DERIVATIVES	13 (16.7)	23 (14.6)	5 (3.5)	0 (0.0)
CODEINE	6 (7.7)	5 (3.2)	0 (0.0)	0 (0.0)
HYDROCODONE COMPOUND	3 (3.8)	3 (1.9)	1 (0.7)	0 (0.0)
PROMETHAZINE W/CODEINE	3 (3.8)	2 (1.3)	0 (0.0)	0 (0.0)
DEXTROMETHORPHAN HYDROBROMIDE	0 (0.0)	4 (2.5)	1 (0.7)	0 (0.0)
TUSSIONEX PENNKINETIC	1 (1.3)	3 (1.9)	0 (0.0)	0 (0.0)
CODEINE PHOSPHATE	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
BROMPHENIRAMINE W/DEXTROMETHORPHAN/PSEUDOEPHE	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
CODIPRONT	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
DEXTROMETHORPHAN	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
PHOLCODINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ACTIFED COMPOUND LINCTUS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CODENA-S	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DIMEMORFAN PHOSPHATE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
DIMETANE DX	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HUSCODE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NOTUSS NX	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CODEINE SULFATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DEXTROMETHORPHAN W/PROMETHAZINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PENICILLINS WITH EXTENDED SPECTRUM	6 (7.7)	13 (8.2)	15 (10.5)	3 (16.7)
AMOXICILLIN	4 (5.1)	9 (5.7)	13 (9.1)	3 (16.7)
AMPICILLIN	1 (1.3)	1 (0.6)	2 (1.4)	0 (0.0)
AMOXICILLIN TRIHYDRATE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
PIVMECILLINAM	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
AMPICILLIN SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMOXICILLIN SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TETRACYCLINES	8 (10.3)	12 (7.6)	16 (11.2)	2 (11.1)
DOXYCYCLINE	4 (5.1)	7 (4.4)	9 (6.3)	2 (11.1)
DOXYCYCLINE HYCLATE	4 (5.1)	4 (2.5)	4 (2.8)	0 (0.0)
DOXYCYCLINE MONOHYDRATE	2 (2.6)	0 (0.0)	2 (1.4)	0 (0.0)
MINOCYCLINE HYDROCHLORIDE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
MINOCYCLINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
TIGECYCLINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ANTIDIARRHEAL MICROORGANISMS	5 (6.4)	14 (8.9)	10 (7.0)	2 (11.1)
PROBIOTICS NOS	3 (3.8)	6 (3.8)	4 (2.8)	1 (5.6)
LACTOBACILLUS ACIDOPHILUS	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)

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ANTIDIARRHEAL MICROORGANISMS	5 (6.4)	14 (8.9)	10 (7.0)	2 (11.1)
LACTINEX	0 (0.0)	1 (0.6)	1 (0.7)	1 (5.6)
ANTIBIOTICS-RESISTANT LACTIC ACID BACTERIAE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
BACILLUS COAGULANS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BIFIDOBACTERIUM LACTIS	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
BIFIDOBACTERIUM NOS	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
BIO-THREE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
LACTOBACILLUS RHAMNOSUS	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
BIFIDOBACTERIUM INFANTIS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BACTERIA NOS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LACTIBIANE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
NATURES WAY PRIMADOPHILUS ORIGINAL	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
SACCHAROMYCES BOULARDII	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
VSL#3	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIDIARRHEAL MICROORGANISMS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ENTEROCOCCUS FAECALIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ENTEROCOCCUS FAECIUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
INNER HEALTH PLUS DAIRY FREE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
KYO-DOPHILUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
FIRST-GENERATION CEPHALOSPORINS	7 (9.0)	16 (10.1)	11 (7.7)	2 (11.1)
CEFALEXIN	3 (3.8)	8 (5.1)	8 (5.6)	0 (0.0)
CEFAZOLIN	3 (3.8)	7 (4.4)	3 (2.1)	0 (0.0)
CEFADROXIL	1 (1.3)	3 (1.9)	1 (0.7)	1 (5.6)
CEFAZOLIN SODIUM	1 (1.3)	2 (1.3)	1 (0.7)	0 (0.0)
CEFAZOLIN W/DEXTROSE	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
CEFALEXIN MONOHYDRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FOLIC ACID AND DERIVATIVES	15 (19.2)	15 (9.5)	6 (4.2)	0 (0.0)
FOLIC ACID	15 (19.2)	15 (9.5)	6 (4.2)	0 (0.0)
PROTON PUMP INHIBITORS	7 (9.0)	22 (13.9)	8 (5.6)	1 (5.6)
PANTOPRAZOLE	4 (5.1)	8 (5.1)	3 (2.1)	1 (5.6)
PANTOPRAZOLE SODIUM SESQUIHYDRATE	0 (0.0)	7 (4.4)	3 (2.1)	0 (0.0)
OMEPRazole	2 (2.6)	3 (1.9)	2 (1.4)	1 (5.6)
LANSOPRAZOLE	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
ESOMEPRazole MAGNESIUM	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
DEXLANSOPRAZOLE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ESOMEPRazole SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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PROTON PUMP INHIBITORS	7 (9.0)	22 (13.9)	8 (5.6)	1 (5.6)
RABEPRAZOLE SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VONOPRAZAN FUMARATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INC	8 (10.3)	11 (7.0)	13 (9.1)	2 (11.1)
BACTRIM	8 (10.3)	11 (7.0)	13 (9.1)	2 (11.1)
MACROLIDES	8 (10.3)	11 (7.0)	12 (8.4)	3 (16.7)
AZITHROMYCIN	8 (10.3)	10 (6.3)	12 (8.4)	3 (16.7)
ROXITHROMYCIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	4 (5.1)	14 (8.9)	14 (9.8)	2 (11.1)
CYANOCOBALAMIN	3 (3.8)	13 (8.2)	13 (9.1)	1 (5.6)
MECOBALAMIN	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
FOLGAMMA	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
HEPAGRISEVIT FORTE-N	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREA	4 (5.1)	22 (13.9)	6 (4.2)	2 (11.1)
NYSTATIN	3 (3.8)	8 (5.1)	2 (1.4)	2 (11.1)
CHLORHEXIDINE GLUCONATE	0 (0.0)	6 (3.8)	2 (1.4)	0 (0.0)

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ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREA	4 (5.1)	22 (13.9)	6 (4.2)	2 (11.1)
CHLORHEXIDINE	1 (1.3)	2 (1.3)	3 (2.1)	0 (0.0)
AMPHOTERICIN B	0 (0.0)	3 (1.9)	1 (0.7)	0 (0.0)
CLOTRIMAZOLE	1 (1.3)	3 (1.9)	0 (0.0)	0 (0.0)
HYDROGEN PEROXIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
THYMOL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMINOALKYL ETHERS	6 (7.7)	13 (8.2)	10 (7.0)	4 (22.2)
DIPHENHYDRAMINE HYDROCHLORIDE	5 (6.4)	9 (5.7)	8 (5.6)	3 (16.7)
DIPHENHYDRAMINE	1 (1.3)	5 (3.2)	2 (1.4)	1 (5.6)
DIMENHYDRINATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS	4 (5.1)	9 (5.7)	14 (9.8)	1 (5.6)
FLUTICASONE PROPIONATE	2 (2.6)	1 (0.6)	8 (5.6)	0 (0.0)
FLUTICASONE	1 (1.3)	5 (3.2)	3 (2.1)	1 (5.6)
MOMETASONE FUROATE	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
BECLOMETASONE DIPROPIONATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BUDESONIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HYDROCORTISONE ACETATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
POSTERISAN F	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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CORTICOSTEROIDS	4 (5.1)	9 (5.7)	14 (9.8)	1 (5.6)
TRIAMCINOLONE ACETONIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
ULTRAPROCT	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DUONASE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FLUOCINOLONE ACETONIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYDROCORTISONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MOMETASONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROCTOSEDYL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS, WEAK (GROUP I)	12 (15.4)	10 (6.3)	8 (5.6)	2 (11.1)
HYDROCORTISONE	12 (15.4)	8 (5.1)	6 (4.2)	2 (11.1)
HYDROCORTISONE ACETATE	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
PREDNISOLONE VALEROACETATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER OPHTHALMOLOGICALS	7 (9.0)	17 (10.8)	8 (5.6)	1 (5.6)
SYSTANE LUBRICANT	3 (3.8)	0 (0.0)	2 (1.4)	0 (0.0)
ARTIFICIAL TEARS	1 (1.3)	3 (1.9)	0 (0.0)	0 (0.0)
HYPROMELLOSE	1 (1.3)	0 (0.0)	3 (2.1)	0 (0.0)
CICLOSPORIN	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)
TEARS PLUS	0 (0.0)	2 (1.3)	2 (1.4)	0 (0.0)

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OTHER OPHTHALMOLOGICALS	7 (9.0)	17 (10.8)	8 (5.6)	1 (5.6)
HYALURONATE SODIUM	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
DIQUAFOSOL TETRASODIUM	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
OTHER OPHTHALMOLOGICALS	0 (0.0)	1 (0.6)	0 (0.0)	1 (5.6)
CARMELLOSE SODIUM	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
CARBOMER	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
CYANOCOBALAMIN	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
MYTEAR	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
HYALURONIC ACID	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MUCOFADIN	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
PIRENOXINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VISINE ADVANCED RELIEF	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
XANTOFYL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SOOTHE XP	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TEARS NATURAL II	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TEARS NATURALE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEA	5 (6.4)	18 (11.4)	9 (6.3)	2 (11.1)
SUCRALFATE	2 (2.6)	6 (3.8)	7 (4.9)	2 (11.1)
REBAMIPIDE	3 (3.8)	7 (4.4)	0 (0.0)	0 (0.0)

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OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEA	5 (6.4)	18 (11.4)	9 (6.3)	2 (11.1)
PEPTAC	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
SODIUM ALGINATE	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
ECABET MONOSODIUM	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOP	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
POLAPREZINC	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ALGITAB	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PHENYLPIPERIDINE DERIVATIVES	8 (10.3)	17 (10.8)	6 (4.2)	2 (11.1)
FENTANYL	7 (9.0)	16 (10.1)	5 (3.5)	2 (11.1)
FENTANYL CITRATE	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
PETHIDINE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
PETHIDINE HYDROCHLORIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
BIGUANIDES	5 (6.4)	12 (7.6)	9 (6.3)	2 (11.1)
METFORMIN	2 (2.6)	8 (5.1)	5 (3.5)	2 (11.1)
METFORMIN HYDROCHLORIDE	3 (3.8)	4 (2.5)	4 (2.8)	0 (0.0)

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MUCOLYTICS	8 (10.3)	19 (12.0)	3 (2.1)	1 (5.6)
ACETYLCYSTEINE	4 (5.1)	9 (5.7)	1 (0.7)	1 (5.6)
SODIUM CHLORIDE	1 (1.3)	2 (1.3)	2 (1.4)	0 (0.0)
AMBROXOL	2 (2.6)	3 (1.9)	0 (0.0)	0 (0.0)
ERDOSTEINE	2 (2.6)	2 (1.3)	0 (0.0)	0 (0.0)
BROMHEXINE HYDROCHLORIDE	1 (1.3)	3 (1.9)	0 (0.0)	0 (0.0)
CARBOCISTEINE	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)
AMBROXOL ACEFYLLINATE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
BROMHEXINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMBROXOL HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DORNASE ALFA	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DRUGS USED IN ERECTILE DYSFUNCTION	2 (2.6)	8 (5.1)	12 (8.4)	0 (0.0)
SILDENAFIL CITRATE	0 (0.0)	5 (3.2)	6 (4.2)	0 (0.0)
TADALAFIL	1 (1.3)	2 (1.3)	3 (2.1)	0 (0.0)
SILDENAFIL	1 (1.3)	2 (1.3)	4 (2.8)	0 (0.0)
TRIMIX	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VARDENAFIL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OTHER EMOLLIENTS AND PROTECTIVES	9 (11.5)	18 (11.4)	5 (3.5)	0 (0.0)
HEPARINOID	6 (7.7)	14 (8.9)	0 (0.0)	0 (0.0)
DEXERYL	0 (0.0)	1 (0.6)	5 (3.5)	0 (0.0)
PARAFFIN SOFT	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CETAPHIL	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
AMMONIUM LACTATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CAMPBOR W/MENTHOL	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
TOCOPHEROL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER COUGH SUPPRESSANTS	8 (10.3)	12 (7.6)	7 (4.9)	1 (5.6)
BENZONATATE	8 (10.3)	8 (5.1)	7 (4.9)	1 (5.6)
LEVODROPROPIZINE	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
BENPROPERINE PHOSPHATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER COUGH SUPPRESSANTS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORD	7 (9.0)	10 (6.3)	10 (7.0)	2 (11.1)
SIMETICONE	7 (9.0)	9 (5.7)	8 (5.6)	2 (11.1)
DIMETICONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SPASFON	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORD	7 (9.0)	10 (6.3)	10 (7.0)	2 (11.1)
PHLOROGLUCINOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
EXPECTORANTS	5 (6.4)	11 (7.0)	10 (7.0)	1 (5.6)
GUAIFENESIN	4 (5.1)	10 (6.3)	10 (7.0)	1 (5.6)
AMMONIUM BICARBONATE W/CEPHAELIS SP	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
OPHAN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
RESPIRE-SR-120	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PREPARATIONS INHIBITING URIC ACID PRODUCTION	3 (3.8)	11 (7.0)	11 (7.7)	1 (5.6)
ALLOPURINOL	1 (1.3)	8 (5.1)	10 (7.0)	1 (5.6)
FEBUXOSTAT	2 (2.6)	3 (1.9)	1 (0.7)	0 (0.0)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	5 (6.4)	15 (9.5)	6 (4.2)	3 (16.7)
NORMOSOL	3 (3.8)	7 (4.4)	0 (0.0)	1 (5.6)
RINGER-LACTATE	2 (2.6)	3 (1.9)	3 (2.1)	2 (11.1)
DEXTROSE AND SODIUM CHLORIDE INJECTION	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
OSMOTAN	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
EL-4	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
LACTEC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	5 (6.4)	15 (9.5)	6 (4.2)	3 (16.7)
POTACOL R	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DEXTROSE W/POTASSIUM CHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
JONOSTERIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
RINGOLACT D	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	7 (9.0)	12 (7.6)	8 (5.6)	2 (11.1)
KETOROLAC	3 (3.8)	4 (2.5)	3 (2.1)	1 (5.6)
KETOROLAC TROMETHAMINE	2 (2.6)	2 (1.3)	4 (2.8)	0 (0.0)
DICLOFENAC	2 (2.6)	2 (1.3)	2 (1.4)	0 (0.0)
DICLOFENAC SODIUM	1 (1.3)	2 (1.3)	0 (0.0)	1 (5.6)
ACECLOFENAC	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
INDOMETACIN	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
ETODOLAC	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
SULINDAC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ASCORBIC ACID (VITAMIN C), PLAIN	5 (6.4)	9 (5.7)	10 (7.0)	3 (16.7)
ASCORBIC ACID	5 (6.4)	9 (5.7)	9 (6.3)	2 (11.1)
CALCIUM ASCORBATE	0 (0.0)	0 (0.0)	1 (0.7)	1 (5.6)

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CALCIUM COMPOUNDS	3 (3.8)	7 (4.4)	11 (7.7)	0 (0.0)
CALCIUM CARBONATE	3 (3.8)	7 (4.4)	11 (7.7)	0 (0.0)
MELATONIN RECEPTOR AGONISTS	5 (6.4)	5 (3.2)	13 (9.1)	1 (5.6)
MELATONIN	4 (5.1)	5 (3.2)	13 (9.1)	1 (5.6)
RAMELTEON	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
BISPHOSPHONATES	3 (3.8)	8 (5.1)	10 (7.0)	3 (16.7)
ZOLEDRONIC ACID	2 (2.6)	3 (1.9)	8 (5.6)	2 (11.1)
ALENDRONATE SODIUM	1 (1.3)	3 (1.9)	0 (0.0)	0 (0.0)
PAMIDRONATE DISODIUM	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
RISEDRONATE SODIUM	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
IBANDRONATE SODIUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
RISEDRONIC ACID	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
THIAZIDES, PLAIN	4 (5.1)	9 (5.7)	8 (5.6)	1 (5.6)
HYDROCHLOROTHIAZIDE	4 (5.1)	7 (4.4)	8 (5.6)	1 (5.6)
TRICHLORMETHIAZIDE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)

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GLYCOPEPTIDE ANTIBACTERIALS	4 (5.1)	12 (7.6)	10 (7.0)	2 (11.1)
VANCOMYCIN	3 (3.8)	9 (5.7)	8 (5.6)	2 (11.1)
VANCOMYCIN HYDROCHLORIDE	1 (1.3)	3 (1.9)	1 (0.7)	1 (5.6)
DALBAVANCIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CORTICOSTEROIDS, VERY POTENT (GROUP IV)	4 (5.1)	10 (6.3)	9 (6.3)	0 (0.0)
CLOBETASOL PROPIONATE	2 (2.6)	7 (4.4)	4 (2.8)	0 (0.0)
CLOBETASOL	2 (2.6)	3 (1.9)	5 (3.5)	0 (0.0)
CORTICOSTEROIDS FOR LOCAL ORAL TREATMENT	7 (9.0)	12 (7.6)	2 (1.4)	2 (11.1)
DEXAMETHASONE	3 (3.8)	7 (4.4)	2 (1.4)	1 (5.6)
TRIAMCINOLONE ACETONIDE	3 (3.8)	3 (1.9)	0 (0.0)	1 (5.6)
TRIAMCINOLONE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
ORAL AID	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
PREDNISOLONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NITROFURAN DERIVATIVES	5 (6.4)	8 (5.1)	9 (6.3)	3 (16.7)
NITROFURANTOIN	5 (6.4)	8 (5.1)	9 (6.3)	3 (16.7)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER CENTRALLY ACTING AGENTS	5 (6.4)	9 (5.7)	8 (5.6)	1 (5.6)
CYCLOBENZAPRINE	1 (1.3)	2 (1.3)	4 (2.8)	0 (0.0)
CYCLOBENZAPRINE HYDROCHLORIDE	2 (2.6)	2 (1.3)	3 (2.1)	0 (0.0)
BACLOFEN	1 (1.3)	0 (0.0)	2 (1.4)	1 (5.6)
TIZANIDINE	0 (0.0)	2 (1.3)	0 (0.0)	1 (5.6)
EPERISONE HYDROCHLORIDE	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
EPERISONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER ANTIBIOTICS FOR TOPICAL USE	3 (3.8)	11 (7.0)	8 (5.6)	1 (5.6)
MUPIROCIN	0 (0.0)	7 (4.4)	5 (3.5)	1 (5.6)
BACITRACIN	1 (1.3)	2 (1.3)	1 (0.7)	0 (0.0)
NEOTRACIN	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
FUSIDATE SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FUSIDIC ACID	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GENTAMICIN SULFATE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
NEOSPORIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CHLORAMPHENICOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES	3 (3.8)	10 (6.3)	8 (5.6)	3 (16.7)
OLANZAPINE	2 (2.6)	9 (5.7)	8 (5.6)	3 (16.7)
QUETIAPINE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
QUETIAPINE FUMARATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SOFT PARAFFIN AND FAT PRODUCTS	7 (9.0)	11 (7.0)	1 (0.7)	1 (5.6)
WHITE SOFT PARAFFIN	4 (5.1)	5 (3.2)	0 (0.0)	0 (0.0)
SOFT PARAFFIN AND FAT PRODUCTS	3 (3.8)	3 (1.9)	0 (0.0)	0 (0.0)
EUCERIN	0 (0.0)	2 (1.3)	0 (0.0)	1 (5.6)
AQUAPHOR	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
AQUEOUS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LIPIKAR	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AKWA TEARS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DIPROBASE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PARAFFIN, LIQUID	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
PETROLATUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
ANTICHOLINERGICS	4 (5.1)	14 (8.9)	2 (1.4)	3 (16.7)
IPRATROPIUM BROMIDE	2 (2.6)	7 (4.4)	1 (0.7)	2 (11.1)
IPRATROPIUM	1 (1.3)	4 (2.5)	0 (0.0)	3 (16.7)
TIOTROPIUM BROMIDE	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
MYDRIN P	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
UMECLIDINIUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ATROPINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TIOTROPIUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TIOTROPIUM BROMIDE MONOHYDRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTIEPILEPTICS	7 (9.0)	9 (5.7)	4 (2.8)	2 (11.1)
LEVETIRACETAM	5 (6.4)	5 (3.2)	2 (1.4)	2 (11.1)
LACOSAMIDE	1 (1.3)	2 (1.3)	0 (0.0)	1 (5.6)
LAMOTRIGINE	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
GABAPENTIN	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
PREGABALIN	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER LIPID MODIFYING AGENTS	4 (5.1)	11 (7.0)	4 (2.8)	0 (0.0)
FISH OIL	0 (0.0)	5 (3.2)	0 (0.0)	0 (0.0)
WILD SALMON	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
OMEGA-3 FATTY ACIDS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
EZETIMIBE	2 (2.6)	0 (0.0)	1 (0.7)	0 (0.0)
OMEGA-3 FATTY ACIDS W/TOCOPHEROL	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
DOCOSAHEXAENOIC ACID	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
EPACAPS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
COLECALCIFEROL W/DOCOSAHEXAENOIC AC	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
EICOSAPENTAENOIC ACID	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
COXIBS	5 (6.4)	11 (7.0)	3 (2.1)	1 (5.6)
CELECOXIB	2 (2.6)	5 (3.2)	3 (2.1)	1 (5.6)
ETORICOXIB	3 (3.8)	6 (3.8)	0 (0.0)	0 (0.0)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR	1 (1.3)	12 (7.6)	5 (3.5)	2 (11.1)
BUDESONIDE W/FORMOTEROL FUMARATE	1 (1.3)	10 (6.3)	1 (0.7)	0 (0.0)
SERETIDE	1 (1.3)	1 (0.6)	1 (0.7)	1 (5.6)
BREO ELLIPTA	0 (0.0)	3 (1.9)	1 (0.7)	0 (0.0)

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ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR	1 (1.3)	12 (7.6)	5 (3.5)	2 (11.1)
BUDESONIDE W/FORMOTEROL	0 (0.0)	1 (0.6)	0 (0.0)	1 (5.6)
FLUTICASONE FUROATE W/VILANTEROL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DULERA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLUTICASONE W/SALMETEROL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
APPETITE STIMULANTS	4 (5.1)	14 (8.9)	5 (3.5)	0 (0.0)
MEGESTROL ACETATE	2 (2.6)	7 (4.4)	5 (3.5)	0 (0.0)
MEGESTROL	2 (2.6)	7 (4.4)	0 (0.0)	0 (0.0)
CARNITINE HYDROCHLORIDE W/CYANOCOPA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CYPROHEPTADINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
IMIDAZOLE DERIVATIVES	3 (3.8)	8 (5.1)	8 (5.6)	0 (0.0)
METRONIDAZOLE	3 (3.8)	7 (4.4)	5 (3.5)	0 (0.0)
ECONAZOLE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ORNIDAZOLE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
TINIDAZOLE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
TIOCONAZOLE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MICONAZOLE NITRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OPIOID ANESTHETICS	8 (10.3)	9 (5.7)	4 (2.8)	1 (5.6)
FENTANYL	6 (7.7)	9 (5.7)	2 (1.4)	1 (5.6)
FENTANYL CITRATE	2 (2.6)	0 (0.0)	1 (0.7)	0 (0.0)
BUPIVACAINE W/FENTANYL	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRI	5 (6.4)	6 (3.8)	6 (4.2)	0 (0.0)
VALACICLOVIR HYDROCHLORIDE	3 (3.8)	3 (1.9)	1 (0.7)	0 (0.0)
ACICLOVIR	1 (1.3)	0 (0.0)	3 (2.1)	0 (0.0)
VALACICLOVIR	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
FAMCICLOVIR	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
ALDOSTERONE ANTAGONISTS	2 (2.6)	9 (5.7)	6 (4.2)	2 (11.1)
SPIRONOLACTONE	2 (2.6)	8 (5.1)	6 (4.2)	2 (11.1)
EPLERENONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
POTASSIUM CANRENOATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MULTIVITAMINS WITH MINERALS	4 (5.1)	5 (3.2)	7 (4.9)	0 (0.0)
MULTIVITAMINS WITH MINERALS	2 (2.6)	1 (0.6)	2 (1.4)	0 (0.0)
MINERALS NOS W/VITAMINS NOS	1 (1.3)	2 (1.3)	1 (0.7)	0 (0.0)

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MULTIVITAMINS WITH MINERALS	4 (5.1)	5 (3.2)	7 (4.9)	0 (0.0)
CENTRUM SILVER	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
ALVITYL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
AQUADEKS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CENTRUM SILVER ADULTS 50+	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
FOLIC ACID W/IRON/MINERALS NOS/VITAMINS NOS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
ASCORBIC ACID W/CHROMIUM/COPPER/CYANOCOBALAM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FOLIC ACID W/MINERALS NOS/VITAMINS NOS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIINFLAMMATORY PREPARATIONS, NON-STERIODS FOR TO	5 (6.4)	10 (6.3)	4 (2.8)	0 (0.0)
DICLOFENAC SODIUM	1 (1.3)	2 (1.3)	2 (1.4)	0 (0.0)
KETOPROFEN	1 (1.3)	3 (1.9)	1 (0.7)	0 (0.0)
LOXOPROFEN SODIUM	1 (1.3)	3 (1.9)	0 (0.0)	0 (0.0)
INDOMETACIN	2 (2.6)	1 (0.6)	0 (0.0)	0 (0.0)
DICLOFENAC	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
PIROXICAM	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
DEKXETOPROFEN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DICLOFENAC EPOLAMINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ETOFENAMATE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
IBUPROFEN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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DRUGS FOR TREATMENT OF HYPERKALEMIA AND HYPERPHOSP	1 (1.3)	7 (4.4)	8 (5.6)	0 (0.0)
SODIUM POLYSTYRENE SULFONATE	1 (1.3)	4 (2.5)	2 (1.4)	0 (0.0)
SEVELAMER HYDROCHLORIDE	1 (1.3)	2 (1.3)	2 (1.4)	0 (0.0)
SEVELAMER	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
SEVELAMER CARBONATE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
CALCIUM POLYSTYRENE SULFONATE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
LANTHANUM CARBONATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OTHER PLAIN VITAMIN PREPARATIONS	2 (2.6)	7 (4.4)	3 (2.1)	3 (16.7)
BIOTIN	1 (1.3)	3 (1.9)	0 (0.0)	2 (11.1)
TOCOPHEROL	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
PYRIDOXINE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
NICOTINAMIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CALCIUM PANTOTHENATE	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
OTHER PLAIN VITAMIN PREPARATIONS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PYRIDOXINE HYDROCHLORIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
TOCOPHERYL ACETATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DL-ALPHA TOCOPHERYL ACETATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
RIBOFLAVIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPIUM DERIVATIVES AND EXPECTORANTS	5 (6.4)	6 (3.8)	5 (3.5)	1 (5.6)
CHERACOL	3 (3.8)	3 (1.9)	3 (2.1)	0 (0.0)
TUSSIN DM	1 (1.3)	2 (1.3)	1 (0.7)	1 (5.6)
DEX-CO	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
MEIJI SEKIDOME	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NEO CODION	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
RESYL PLUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIBIOTICS	3 (3.8)	6 (3.8)	6 (4.2)	1 (5.6)
VANCOMYCIN	1 (1.3)	2 (1.3)	2 (1.4)	0 (0.0)
NYSTATIN	2 (2.6)	1 (0.6)	0 (0.0)	0 (0.0)
CHLORAMPHENICOL	1 (1.3)	0 (0.0)	2 (1.4)	0 (0.0)
POLYTRIM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
TOBRAMYCIN	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.6)
ERYTHROMYCIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMPHOTERICIN B	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BACITRACIN	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
CEFMENOXIME HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
RIFAXIMIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
ANTIBIOTICS	3 (3.8)	6 (3.8)	6 (4.2)	1 (5.6)
AZITHROMYCIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
POLYMYXIN B	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BILE ACID PREPARATIONS	4 (5.1)	14 (8.9)	0 (0.0)	0 (0.0)
URSODEOXYCHOLIC ACID	4 (5.1)	14 (8.9)	0 (0.0)	0 (0.0)
IRON BIVALENT, ORAL PREPARATIONS	0 (0.0)	6 (3.8)	7 (4.9)	2 (11.1)
FERROUS SULFATE	0 (0.0)	5 (3.2)	7 (4.9)	1 (5.6)
FERROUS SODIUM CITRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FERROUS SULFATE EXSICCATED	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
FERROUS BISGLYCINATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ADRENERGIC AND DOPAMINERGIC AGENTS	4 (5.1)	7 (4.4)	7 (4.9)	1 (5.6)
EPINEPHRINE	2 (2.6)	2 (1.3)	3 (2.1)	0 (0.0)
NOREPINEPHRINE	1 (1.3)	3 (1.9)	0 (0.0)	0 (0.0)
PHENYLEPHRINE	1 (1.3)	1 (0.6)	1 (0.7)	1 (5.6)
MIDODRINE	1 (1.3)	0 (0.0)	2 (1.4)	0 (0.0)
EPHEDRINE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
EPHEDRINE SULFATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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ADRENERGIC AND DOPAMINERGIC AGENTS	4 (5.1)	7 (4.4)	7 (4.9)	1 (5.6)
NOREPINEPHRINE BITARTRATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PHENYLEPHRINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ALPHA AND BETA BLOCKING AGENTS	2 (2.6)	6 (3.8)	5 (3.5)	0 (0.0)
CARVEDILOL	1 (1.3)	4 (2.5)	4 (2.8)	0 (0.0)
LABETALOL	1 (1.3)	1 (0.6)	2 (1.4)	0 (0.0)
LABETALOL HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CENTRALLY ACTING SYMPATHOMIMETICS	2 (2.6)	6 (3.8)	4 (2.8)	2 (11.1)
METHYLPHENIDATE	1 (1.3)	4 (2.5)	0 (0.0)	1 (5.6)
METHYLPHENIDATE HYDROCHLORIDE	1 (1.3)	1 (0.6)	2 (1.4)	0 (0.0)
OBETROL	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
AMFETAMINE	0 (0.0)	1 (0.6)	0 (0.0)	1 (5.6)
MODAFINIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ATOMOXETINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DUROPHET	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER NASAL PREPARATIONS	1 (1.3)	9 (5.7)	3 (2.1)	3 (16.7)
SODIUM CHLORIDE	1 (1.3)	5 (3.2)	3 (2.1)	1 (5.6)
MUPIROCIN	0 (0.0)	3 (1.9)	0 (0.0)	1 (5.6)
IPRATROPIUM BROMIDE	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
FLO POST OPERATIVE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NISITA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER NASAL PREPARATIONS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CARIES PROPHYLACTIC AGENTS	0 (0.0)	7 (4.4)	3 (2.1)	3 (16.7)
XYLITOL	0 (0.0)	5 (3.2)	0 (0.0)	2 (11.1)
SODIUM FLUORIDE	0 (0.0)	2 (1.3)	3 (2.1)	1 (5.6)
SENSODYNE PROTECCION TOTAL	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
LEUKOTRIENE RECEPTOR ANTAGONISTS	0 (0.0)	8 (5.1)	6 (4.2)	2 (11.1)
MONTELUKAST	0 (0.0)	4 (2.5)	2 (1.4)	2 (11.1)
MONTELUKAST SODIUM	0 (0.0)	3 (1.9)	4 (2.8)	0 (0.0)
PRANLUKAST	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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IMIDAZOLE AND TRIAZOLE DERIVATIVES	2 (2.6)	3 (1.9)	8 (5.6)	0 (0.0)
KETOCONAZOLE	2 (2.6)	1 (0.6)	3 (2.1)	0 (0.0)
CLOTRIMAZOLE	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
MICONAZOLE	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
ECONAZOLE NITRATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DAKTOZIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
LANOCONAZOLE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LOTRISONE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CANESTEN-HC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ECONAZOLE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER CARDIAC PREPARATIONS	2 (2.6)	7 (4.4)	5 (3.5)	0 (0.0)
UBIDECARENONE	2 (2.6)	7 (4.4)	4 (2.8)	0 (0.0)
OTHER CARDIAC PREPARATIONS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ADENOSINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
UBIQUINOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER RESPIRATORY SYSTEM PRODUCTS	2 (2.6)	6 (3.8)	5 (3.5)	2 (11.1)
OXYGEN	2 (2.6)	6 (3.8)	5 (3.5)	2 (11.1)
PYRAZOLONES	2 (2.6)	8 (5.1)	5 (3.5)	0 (0.0)
METAMIZOLE SODIUM	2 (2.6)	5 (3.2)	4 (2.8)	0 (0.0)
METAMIZOLE	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
METAMIZOLE SODIUM MONOHYDRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FOURTH-GENERATION CEPHALOSPORINS	2 (2.6)	4 (2.5)	8 (5.6)	2 (11.1)
CEFEPIME	2 (2.6)	2 (1.3)	5 (3.5)	2 (11.1)
CEFEPIME HYDROCHLORIDE	0 (0.0)	2 (1.3)	3 (2.1)	0 (0.0)
ADRENERGICS IN COMBINATION WITH ANTICHOLINERGICS	0 (0.0)	10 (6.3)	4 (2.8)	0 (0.0)
COMBIVENT	0 (0.0)	7 (4.4)	3 (2.1)	0 (0.0)
OLODATEROL HYDROCHLORIDE W/TIOTROPIUM BROMIDE	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
UMECLIDINIUM BROMIDE W/VILANTEROL TRIFENATATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
ANTIDOTES	6 (7.7)	9 (5.7)	0 (0.0)	0 (0.0)
GLYCYRON	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)
NALOXONE HYDROCHLORIDE	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
ACETYLCYSTEINE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
FLUMAZENIL	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
GLUTATHIONE	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
NALOXONE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
SUGAMMADEX	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS, PLAIN	3 (3.8)	8 (5.1)	3 (2.1)	0 (0.0)
PREDNISOLONE ACETATE	1 (1.3)	3 (1.9)	0 (0.0)	0 (0.0)
FLUROMETHOLONE	0 (0.0)	3 (1.9)	1 (0.7)	0 (0.0)
LOTEPREDNOL ETABONATE	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
PREDNISOLONE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DEXAMETHASONE SODIUM PHOSPHATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DIFLUPREDNATE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
LOTEPREDNOL	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
TRIAMCINOLONE ACETONIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DEXAMETHASONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
ENZYME PREPARATIONS	3 (3.8)	5 (3.2)	3 (2.1)	0 (0.0)
PANCRELIPASE	1 (1.3)	0 (0.0)	2 (1.4)	0 (0.0)
TILACTASE	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
PANCREATIN	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
BESZYME	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BIODIASTASE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
METEOZYM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NORTASE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SOLUTIONS FOR PARENTERAL NUTRITION	1 (1.3)	11 (7.0)	0 (0.0)	2 (11.1)
GLUCOSE	0 (0.0)	5 (3.2)	0 (0.0)	2 (11.1)
AMINO ACIDS NOS W/GLUCOSE/LIPIDS NOS	1 (1.3)	4 (2.5)	0 (0.0)	0 (0.0)
AMINO ACIDS NOS W/ELECTROLYTES NOS/GLUCOSE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
CLINIMIX N14G30E	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
FREAMINE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
AMINIC	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MG TNA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMINO ACIDS NOS W/ELECTROLYTES NOS/GLUCOSE/VI	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SOLUTIONS FOR PARENTERAL NUTRITION	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS	4 (5.1)	2 (1.3)	5 (3.5)	1 (5.6)
FINASTERIDE	3 (3.8)	2 (1.3)	4 (2.8)	1 (5.6)
DUTASTERIDE	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
EMOLLIENTS AND PROTECTIVES	1 (1.3)	6 (3.8)	3 (2.1)	0 (0.0)
EMOLLIENTS AND PROTECTIVES	1 (1.3)	5 (3.2)	3 (2.1)	0 (0.0)
TOPIALYSE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	1 (1.3)	6 (3.8)	3 (2.1)	1 (5.6)
INSULIN ASPART	0 (0.0)	3 (1.9)	3 (2.1)	1 (5.6)
INSULIN LISPRO	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)
INSULIN	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER MINERAL PRODUCTS	1 (1.3)	5 (3.2)	5 (3.5)	0 (0.0)
K-PHOS NEUTRAL	1 (1.3)	2 (1.3)	3 (2.1)	0 (0.0)
POTASSIUM PHOSPHATE MONOBASIC W/SOD	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
PHOSPHONEUROL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MINERALS NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
NEUTRA-PHOS-K	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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OTHER MINERAL PRODUCTS	1 (1.3)	5 (3.2)	5 (3.5)	0 (0.0)
COPPER	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
STOMATOLOGICAL PREPARATIONS	1 (1.3)	8 (5.1)	4 (2.8)	0 (0.0)
SODIUM BICARBONATE	1 (1.3)	7 (4.4)	3 (2.1)	0 (0.0)
GELCLAIR	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GLANDOMED	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
VITAMIN B-COMPLEX, PLAIN	4 (5.1)	2 (1.3)	4 (2.8)	1 (5.6)
VITAMIN B COMPLEX	4 (5.1)	2 (1.3)	4 (2.8)	1 (5.6)
ZINC	5 (6.4)	2 (1.3)	4 (2.8)	3 (16.7)
ZINC SULFATE	3 (3.8)	1 (0.6)	1 (0.7)	2 (11.1)
ZINC	1 (1.3)	1 (0.6)	3 (2.1)	1 (5.6)
ZINC GLUCONATE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
ALL OTHER NON-THERAPEUTIC PRODUCTS	1 (1.3)	6 (3.8)	5 (3.5)	1 (5.6)
ALL OTHER NON-THERAPEUTIC PRODUCTS	1 (1.3)	6 (3.8)	5 (3.5)	1 (5.6)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER INTESTINAL ADSORBENTS	1 (1.3)	9 (5.7)	4 (2.8)	0 (0.0)
DIOSMECTITE	1 (1.3)	8 (5.1)	4 (2.8)	0 (0.0)
EUPATILIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANTIINFECTIVES FOR TREATMENT OF ACNE	1 (1.3)	3 (1.9)	6 (4.2)	0 (0.0)
CLINDAMYCIN	0 (0.0)	1 (0.6)	5 (3.5)	0 (0.0)
CLINDAMYCIN PHOSPHATE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
NADIFLOXACIN	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
BENZAFLIN TOPICAL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS	1 (1.3)	7 (4.4)	3 (2.1)	1 (5.6)
AMITRIPTYLINE HYDROCHLORIDE	0 (0.0)	4 (2.5)	2 (1.4)	0 (0.0)
AMITRIPTYLINE	1 (1.3)	1 (0.6)	1 (0.7)	1 (5.6)
DOXEPIN HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
IMIPRAMINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NORTRIPTYLINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, N	0 (0.0)	6 (3.8)	3 (2.1)	1 (5.6)
GLUCOSAMINE	0 (0.0)	2 (1.3)	2 (1.4)	0 (0.0)
CURCUMIN	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
CHONDROITIN W/GLUCOSAMINE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
BIOGLAN JOINT MOBILITY	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HYDROXYCHLOROQUINE	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
MOVE FREE JOINT STRENGTHENER	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
GLUCOSAMINE SULFATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYDROXYCHLOROQUINE SULFATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NABUMETONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANGIOTENSIN II ANTAGONISTS AND DIURETICS	1 (1.3)	3 (1.9)	2 (1.4)	1 (5.6)
HYZAAR	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
KARVEA HCT	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
PRITORPLUS	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
BENICAR HCT	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
BLOPRESS PLUS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CO-DIOVAN	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
HYDROCHLOROTHIAZIDE W/OLMESARTAN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS	4 (5.1)	9 (5.7)	0 (0.0)	0 (0.0)
ALBUMIN HUMAN	2 (2.6)	7 (4.4)	0 (0.0)	0 (0.0)
CALCIUM CHLORIDE W/GLUCONATE SODIUM/MAGNESIUM	2 (2.6)	4 (2.5)	0 (0.0)	0 (0.0)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	0 (0.0)	3 (1.9)	6 (4.2)	0 (0.0)
OXYBUTYNIN	0 (0.0)	0 (0.0)	3 (2.1)	0 (0.0)
MIRABEGRON	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OXYBUTYNIN HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
SOLIFENACIN	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
FESOTERODINE FUMARATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PROPIVERINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SOLIFENACIN SUCCINATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
TOLTERODINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TOLTERODINE L-TARTRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTACIDS WITH SODIUM BICARBONATE	3 (3.8)	7 (4.4)	2 (1.4)	0 (0.0)
SODIUM BICARBONATE	2 (2.6)	4 (2.5)	0 (0.0)	0 (0.0)
GAVISCON	0 (0.0)	2 (1.3)	2 (1.4)	0 (0.0)
MIST. MAG. TRISIL. CO.	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)

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ANTACIDS WITH SODIUM BICARBONATE	3 (3.8)	7 (4.4)	2 (1.4)	0 (0.0)
CARMINATIVE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GASTRON	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SECOND-GENERATION CEPHALOSPORINS	1 (1.3)	7 (4.4)	1 (0.7)	1 (5.6)
CEFUROXIME	1 (1.3)	2 (1.3)	0 (0.0)	1 (5.6)
CEFUROXIME AXETIL	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
CEFACLOX	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
CEFOTETAN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLOMOXEF SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TRIAZOLE DERIVATIVES	3 (3.8)	5 (3.2)	2 (1.4)	1 (5.6)
FLUCONAZOLE	3 (3.8)	5 (3.2)	2 (1.4)	1 (5.6)
PROSTAGLANDIN ANALOGUES	3 (3.8)	3 (1.9)	3 (2.1)	1 (5.6)
LATANOPROST	3 (3.8)	3 (1.9)	2 (1.4)	0 (0.0)
BIMATOPROST	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
TRAVOPROST	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER UROLOGICALS	2 (2.6)	3 (1.9)	3 (2.1)	1 (5.6)
PHENAZOPYRIDINE HYDROCHLORIDE	0 (0.0)	3 (1.9)	1 (0.7)	1 (5.6)
PHENAZOPYRIDINE	2 (2.6)	0 (0.0)	1 (0.7)	0 (0.0)
METHENAMINE W/SALICYLATE SODIUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MIST. POT. CIT.	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
URAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SODIUM	3 (3.8)	2 (1.3)	1 (0.7)	3 (16.7)
SODIUM CHLORIDE	3 (3.8)	2 (1.3)	1 (0.7)	3 (16.7)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	0 (0.0)	4 (2.5)	4 (2.8)	1 (5.6)
INSULIN GLARGINE	0 (0.0)	4 (2.5)	2 (1.4)	1 (5.6)
INSULIN DEGLUDEC	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
INSULIN DETEMIR	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MINERALOCORTICOIDS	0 (0.0)	0 (0.0)	8 (5.6)	0 (0.0)
FLUDROCORTISONE	0 (0.0)	0 (0.0)	5 (3.5)	0 (0.0)
FLUDROCORTISONE ACETATE	0 (0.0)	0 (0.0)	3 (2.1)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
SALICYLIC ACID AND DERIVATIVES	0 (0.0)	5 (3.2)	2 (1.4)	0 (0.0)
ACETYLSALICYLIC ACID	0 (0.0)	2 (1.3)	2 (1.4)	0 (0.0)
ACETYLSALICYLATE LYSINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ALKA-SELTZER	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BUFFERIN A	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NEURAMINIDASE INHIBITORS	4 (5.1)	4 (2.5)	0 (0.0)	0 (0.0)
OSELTAMIVIR PHOSPHATE	4 (5.1)	3 (1.9)	0 (0.0)	0 (0.0)
PERAMIVIR	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OSELTAMIVIR	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER BLOOD PRODUCTS	3 (3.8)	6 (3.8)	0 (0.0)	0 (0.0)
RED BLOOD CELLS, CONCENTRATED	2 (2.6)	1 (0.6)	0 (0.0)	0 (0.0)
PLATELETS, CONCENTRATED	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
PLATELETS	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
PLASMA	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
RED BLOOD CELLS	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
RED BLOOD CELLS, LEUCOCYTE DEPLETED	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)

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SELECTIVE SEROTONIN (5HT1) AGONISTS	1 (1.3)	1 (0.6)	3 (2.1)	2 (11.1)
SUMATRIPTAN	0 (0.0)	0 (0.0)	1 (0.7)	2 (11.1)
ELETRIPTAN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ELETRIPTAN HYDROBROMIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
RIZATRIPTAN	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
RIZATRIPTAN BENZOATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ZOLMITRIPTAN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
NARATRIPTAN HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SUMATRIPTAN SUCCINATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTISEPTICS	2 (2.6)	6 (3.8)	0 (0.0)	0 (0.0)
DEQUALINIUM CHLORIDE	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)
POVIDONE-IODINE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
BENZETHONIUM CHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
IODINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PHENOL	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
SODIUM GUALENATE HYDRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DIFFLAM MOUTH	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
STREPSILS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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ANTISEPTICS	2 (2.6)	6 (3.8)	0 (0.0)	0 (0.0)
STREPSILS SORE THROAT & BLOCKED NOSE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CARBAMIDE PRODUCTS	0 (0.0)	3 (1.9)	5 (3.5)	0 (0.0)
UREA	0 (0.0)	2 (1.3)	5 (3.5)	0 (0.0)
OPTIDERM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TOPICREM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DIPHENYLPROPYLAMINE DERIVATIVES	1 (1.3)	2 (1.3)	4 (2.8)	2 (11.1)
METHADONE	1 (1.3)	2 (1.3)	3 (2.1)	2 (11.1)
METHADONE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OTHER DRUGS FOR CONSTIPATION	0 (0.0)	6 (3.8)	3 (2.1)	1 (5.6)
LINACLOTIDE	0 (0.0)	1 (0.6)	3 (2.1)	1 (5.6)
GLYCEROL	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
PRUCALOPRIDE SUCCINATE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
LUBIPROSTONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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OTHER HYPNOTICS AND SEDATIVES	1 (1.3)	2 (1.3)	4 (2.8)	0 (0.0)
DIPHENHYDRAMINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
DIPHENHYDRAMINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DOXYLAMINE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
DOXYLAMINE SUCCINATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DEXMEDETOMIDINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
SUVOREXANT	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SUBSTITUTED ALKYLAMINES	2 (2.6)	7 (4.4)	0 (0.0)	0 (0.0)
CHLORPHENAMINE MALEATE	2 (2.6)	3 (1.9)	0 (0.0)	0 (0.0)
CHLORPHENAMINE	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
DEXCHLORPHENIRAMINE MALEATE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
ANTACIDS WITH ANTIFLATULENTS	1 (1.3)	1 (0.6)	3 (2.1)	1 (5.6)
SIMECO	1 (1.3)	1 (0.6)	2 (1.4)	1 (5.6)
MAALOX MAX	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
BELLADONNA ALKALOIDS, SEMISYNTHETIC, QUATERNARY AM	2 (2.6)	3 (1.9)	3 (2.1)	0 (0.0)
HYOSCINE BUTYLBROMIDE	0 (0.0)	2 (1.3)	3 (2.1)	0 (0.0)
HYOSCINE METHOBROMIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
CIMETROPIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
METHYLSCOPOLAMINE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS ACTING LOCALLY	0 (0.0)	4 (2.5)	3 (2.1)	1 (5.6)
BUDESONIDE	0 (0.0)	4 (2.5)	3 (2.1)	1 (5.6)
PREDNISOLONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	2 (2.6)	3 (1.9)	2 (1.4)	1 (5.6)
SITAGLIPTIN PHOSPHATE	1 (1.3)	2 (1.3)	1 (0.7)	0 (0.0)
LINAGLIPTIN	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
SITAGLIPTIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
SAXAGLIPTIN	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
SITAGLIPTIN PHOSPHATE MONOHYDRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VILDAGLIPTIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
HYDRAZINOPHTHALAZINE DERIVATIVES	1 (1.3)	3 (1.9)	4 (2.8)	0 (0.0)
HYDRALAZINE	1 (1.3)	2 (1.3)	3 (2.1)	0 (0.0)
HYDRALAZINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	0 (0.0)	2 (1.3)	1 (0.7)	1 (5.6)
ESTRADIOL	0 (0.0)	1 (0.6)	1 (0.7)	1 (5.6)
ESTROGENS CONJUGATED	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ESTRIOL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BETA BLOCKING AGENTS, NON-SELECTIVE	2 (2.6)	2 (1.3)	4 (2.8)	0 (0.0)
PROPRANOLOL	1 (1.3)	2 (1.3)	1 (0.7)	0 (0.0)
SOTALOL	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
NADOLOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PROPRANOLOL HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM A	1 (1.3)	4 (2.5)	2 (1.4)	0 (0.0)
ALUDROX	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
GAVISCON	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MAGALDRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM A	1 (1.3)	4 (2.5)	2 (1.4)	0 (0.0)
NOVALUCOL NOVUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANTACIDA FNA	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
MOXYDAR	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
LINCOSAMIDES	1 (1.3)	4 (2.5)	3 (2.1)	0 (0.0)
CLINDAMYCIN	1 (1.3)	3 (1.9)	2 (1.4)	0 (0.0)
CLINDAMYCIN HYDROCHLORIDE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
PNEUMOCOCCAL VACCINES	2 (2.6)	4 (2.5)	2 (1.4)	0 (0.0)
PNEUMOCOCCAL VACCINE	2 (2.6)	4 (2.5)	2 (1.4)	0 (0.0)
WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONT	2 (2.6)	2 (1.3)	2 (1.4)	2 (11.1)
IOHEXOL	2 (2.6)	1 (0.6)	2 (1.4)	2 (11.1)
IOPAMIDOL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LIVER THERAPY	4 (5.1)	4 (2.5)	0 (0.0)	0 (0.0)
GODEX	2 (2.6)	3 (1.9)	0 (0.0)	0 (0.0)
MINOFIT	2 (2.6)	1 (0.6)	0 (0.0)	0 (0.0)
GLICYRRHIZIC ACID, AMMONIUM SALT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	3 (3.8)	4 (2.5)	0 (0.0)	0 (0.0)
CLOSTRIDIUM BUTYRICUM	2 (2.6)	2 (1.3)	0 (0.0)	0 (0.0)
ARTISIAL	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
RESVERATROL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER PARASYMPATHOMIMETICS	1 (1.3)	5 (3.2)	1 (0.7)	0 (0.0)
PILOCARPINE HYDROCHLORIDE	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
PILOCARPINE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
CHOLINE ALFOSCERATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER PARASYMPATHOMIMETICS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OXICAMS	0 (0.0)	1 (0.6)	3 (2.1)	0 (0.0)
MELOXICAM	0 (0.0)	1 (0.6)	3 (2.1)	0 (0.0)
PIROXICAM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY A	0 (0.0)	4 (2.5)	3 (2.1)	0 (0.0)
DICYCLOVERINE HYDROCHLORIDE	0 (0.0)	3 (1.9)	2 (1.4)	0 (0.0)
DICYCLOVERINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TRIMEBUTINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
VITAMIN K ANTAGONISTS	2 (2.6)	2 (1.3)	4 (2.8)	0 (0.0)
WARFARIN	1 (1.3)	0 (0.0)	2 (1.4)	0 (0.0)
WARFARIN SODIUM	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
FLUINDIONE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
ANESTHETICS, LOCAL	2 (2.6)	5 (3.2)	0 (0.0)	0 (0.0)
LIDOCAINE	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)
LARYTON	2 (2.6)	1 (0.6)	0 (0.0)	0 (0.0)
LIDOCAINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER ANTIDIARRHEALS	0 (0.0)	5 (3.2)	3 (2.1)	0 (0.0)
RACECADOTRIL	0 (0.0)	4 (2.5)	3 (2.1)	0 (0.0)
ALBUMIN TANNATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER COMBINATIONS OF NUTRIENTS	1 (1.3)	3 (1.9)	4 (2.8)	0 (0.0)
OTHER COMBINATIONS OF NUTRIENTS	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
BETA GLUCAN	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
CARBOHYDRATES NOS W/FATS NOS/FIBRE,	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CARBOHYDRATES NOS W/PROTEINS NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER COMBINATIONS OF NUTRIENTS	1 (1.3)	3 (1.9)	4 (2.8)	0 (0.0)
MINERALS NOS W/PROTEINS NOS/VITAMINS NOS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
THERMOTABS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER GENERAL ANESTHETICS	1 (1.3)	3 (1.9)	2 (1.4)	1 (5.6)
PROPOFOL	0 (0.0)	3 (1.9)	2 (1.4)	1 (5.6)
ETOMIDATE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
KETAMINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS	1 (1.3)	1 (0.6)	3 (2.1)	1 (5.6)
MARVELON	0 (0.0)	0 (0.0)	1 (0.7)	1 (5.6)
OVIDON	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
NORLESTRIN FE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
EUGYNON	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ZUMESTON	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
NORMENSAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
AMINOSALICYLIC ACID AND SIMILAR AGENTS	0 (0.0)	2 (1.3)	4 (2.8)	1 (5.6)
MESALAZINE	0 (0.0)	2 (1.3)	3 (2.1)	0 (0.0)
SULFASALAZINE	0 (0.0)	0 (0.0)	1 (0.7)	1 (5.6)

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ENEMAS	1 (1.3)	3 (1.9)	2 (1.4)	1 (5.6)
FLEET	0 (0.0)	1 (0.6)	1 (0.7)	1 (5.6)
ENEMAS	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
GLYCEROL	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
MICROKLIST	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER DERMATOLOGICALS	0 (0.0)	5 (3.2)	1 (0.7)	0 (0.0)
GUAIAZULENE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
FINASTERIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MINOXIDIL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
POLYURETHANE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
RETINOL W/VITAMIN D NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
TRI-LUMA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SULFONYLUREAS	2 (2.6)	1 (0.6)	2 (1.4)	1 (5.6)
GLIMEPIRIDE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
GLIPIZIDE	0 (0.0)	0 (0.0)	1 (0.7)	1 (5.6)
GLICLAZIDE	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
SYMPATHOMIMETICS	0 (0.0)	3 (1.9)	2 (1.4)	0 (0.0)
NARINE	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
PSEUDOEPHEDRINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CIRRUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PHENYLEPHRINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
LORATADINE W/PSEUDOEPHEDRINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PSEUDOEPHEDRINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ACE INHIBITORS AND DIURETICS	2 (2.6)	2 (1.3)	3 (2.1)	0 (0.0)
ZESTORETIC	1 (1.3)	1 (0.6)	2 (1.4)	0 (0.0)
PRETERAX ARGININE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
INDAPAMIDE W/PERINDOPRIL	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
AMINO ACIDS	3 (3.8)	4 (2.5)	0 (0.0)	0 (0.0)
TRANEXAMIC ACID	3 (3.8)	4 (2.5)	0 (0.0)	0 (0.0)
ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS	0 (0.0)	2 (1.3)	2 (1.4)	0 (0.0)
AZELASTINE	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
AZELASTINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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BENZOTHAZEPINE DERIVATIVES	1 (1.3)	3 (1.9)	1 (0.7)	1 (5.6)
DILTIAZEM	0 (0.0)	2 (1.3)	1 (0.7)	1 (5.6)
DILTIAZEM HYDROCHLORIDE	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
CARBAPENEMS	1 (1.3)	3 (1.9)	2 (1.4)	0 (0.0)
MEROPENEM	1 (1.3)	2 (1.3)	1 (0.7)	0 (0.0)
ERTAPENEM	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
MEROPENEM TRIHYDRATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
COUGH AND COLD PREPARATIONS	2 (2.6)	2 (1.3)	2 (1.4)	0 (0.0)
COUGH AND COLD PREPARATIONS	2 (2.6)	1 (0.6)	1 (0.7)	0 (0.0)
GLYCEROL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ZINC	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
IMIDAZOLINE RECEPTOR AGONISTS	1 (1.3)	0 (0.0)	4 (2.8)	0 (0.0)
CLONIDINE	0 (0.0)	0 (0.0)	3 (2.1)	0 (0.0)
CLONIDINE HYDROCHLORIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
MOXONIDINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER ANTIALLERGICS	2 (2.6)	2 (1.3)	2 (1.4)	0 (0.0)
EPINASTINE HYDROCHLORIDE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
OLOPATADINE HYDROCHLORIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
AZELASTINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ISOSPAGLUMIC ACID SODIUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OLOPATADINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LEVOCABASTINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTIFUNGALS FOR TOPICAL USE	0 (0.0)	4 (2.5)	2 (1.4)	0 (0.0)
CICLOPIROX	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
CICLOPIROX OLAMINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LULICONAZOLE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TERBINAFINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TERBINAFINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION	1 (1.3)	3 (1.9)	1 (0.7)	1 (5.6)
BETNESOL-N	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
FRAMOPTIC-D	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NETILDEX	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION	1 (1.3)	3 (1.9)	1 (0.7)	1 (5.6)
OTOSPORIN	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
TOBRADEX	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
CIPRODAC-DM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS, POTENT, COMBINATIONS WITH ANTIBIO	1 (1.3)	5 (3.2)	0 (0.0)	0 (0.0)
VALISONE-G	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)
FUCICORT	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
TRIDERM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FAT/CARBOHYDRATES/PROTEINS/MINERALS/VITAMINS, COMB	0 (0.0)	4 (2.5)	1 (0.7)	1 (5.6)
ASCORBIC ACID W/BIOTIN/CALCIUM/CARB	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
CARBOHYDRATES NOS W/FATTY ACIDS NOS/MINERALS	0 (0.0)	1 (0.6)	0 (0.0)	1 (5.6)
CARBOHYDRATES NOS W/ELECTROLYTES NOS/FATTY AC	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
COLOSTRUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
FAT/CARBOHYDRATES/PROTEINS/MINERALS/VITAMINS,	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FATS NOS W/PROTEINS NOS/VITAMINS NOS	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)

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IRON, PARENTERAL PREPARATIONS	1 (1.3)	2 (1.3)	2 (1.4)	0 (0.0)
FERRIC CARBOXYMALTOSE	1 (1.3)	1 (0.6)	2 (1.4)	0 (0.0)
FERRIC SODIUM GLUCONATE COMPLEX	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ORGANIC NITRATES	0 (0.0)	3 (1.9)	1 (0.7)	0 (0.0)
GLYCERYL TRINITRATE	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
ISOSORBIDE DINITRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ISOSORBIDE MONONITRATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OTHER ANTIBACTERIALS	2 (2.6)	1 (0.6)	2 (1.4)	0 (0.0)
FOSFOMYCIN	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
LINEZOLID	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BACITRACIN	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLIS	0 (0.0)	2 (1.3)	3 (2.1)	0 (0.0)
COLCHICINE	0 (0.0)	2 (1.3)	3 (2.1)	0 (0.0)

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3-OXOANDROSTEN (4) DERIVATIVES	1 (1.3)	1 (0.6)	4 (2.8)	0 (0.0)
TESTOSTERONE	1 (1.3)	1 (0.6)	3 (2.1)	0 (0.0)
TESTOSTERONE CIPIONATE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
TESTOSTERONE ENANTHATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
AGENTS FOR DERMATITIS, EXCLUDING CORTICOSTEROIDS	1 (1.3)	2 (1.3)	2 (1.4)	0 (0.0)
TACROLIMUS	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
PIMECROLIMUS	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
ANTI-HISTAMINES FOR TOPICAL USE	2 (2.6)	1 (0.6)	1 (0.7)	1 (5.6)
DIPHENHYDRAMINE HYDROCHLORIDE	2 (2.6)	0 (0.0)	1 (0.7)	1 (5.6)
DIPHENHYDRAMINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DIPHENHYDRAMINE W/ZINC ACETATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DOXEPIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DOXEPIN HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DIGITALIS GLYCOSIDES	0 (0.0)	5 (3.2)	0 (0.0)	0 (0.0)
DIGOXIN	0 (0.0)	5 (3.2)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	3 (3.8)	1 (0.6)	1 (0.7)	0 (0.0)
THIOCTIC ACID	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
ZINC ACETATE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
PHOSPHORUS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
NATURES WAY RESTORE DAILY PROBIOTIC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VITAMIN B1, PLAIN	2 (2.6)	2 (1.3)	1 (0.7)	0 (0.0)
THIAMINE	2 (2.6)	2 (1.3)	1 (0.7)	0 (0.0)
VITAMINS	1 (1.3)	5 (3.2)	0 (0.0)	0 (0.0)
VITAMINS NOS	1 (1.3)	5 (3.2)	0 (0.0)	0 (0.0)
ANGIOTENSIN II ANTAGONISTS AND CALCIUM CHANNEL BLO	0 (0.0)	2 (1.3)	3 (2.1)	0 (0.0)
DIOVAN AMLO	0 (0.0)	0 (0.0)	3 (2.1)	0 (0.0)
AMLODIPINE W/VALSARTAN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AZOR	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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ANTIINFLAMMATORY AGENTS, NON-STEROIDS	0 (0.0)	4 (2.5)	1 (0.7)	0 (0.0)
BROMFENAC SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
KETOROLAC	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
KETOROLAC TROMETHAMINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NEPAFENAC	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PRANOPROFEN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DICLOFENAC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BETA BLOCKING AGENTS	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
TIMOLOL MALEATE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
GANFORT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CARTEOLOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
COSOPT	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
COMBIGAN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CARBAMIC ACID ESTERS	0 (0.0)	2 (1.3)	2 (1.4)	0 (0.0)
CARISOPRODOL	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
METHOCARBAMOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFL	1 (1.3)	4 (2.5)	0 (0.0)	0 (0.0)
TEPRENONE	1 (1.3)	4 (2.5)	0 (0.0)	0 (0.0)
GENERAL NUTRIENTS	1 (1.3)	2 (1.3)	1 (0.7)	0 (0.0)
GENERAL NUTRIENTS	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
WHEY PROTEIN	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
NUTRIENTS NOS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER CICATRIZANTS	0 (0.0)	2 (1.3)	3 (2.1)	0 (0.0)
DEXPANTHENOL	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
OTHER CICATRIZANTS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BUCLADESINE SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PURILON	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PROTEIN SUPPLEMENTS	1 (1.3)	2 (1.3)	2 (1.4)	0 (0.0)
PROTEINS NOS	1 (1.3)	2 (1.3)	2 (1.4)	0 (0.0)

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VITAMINS, OTHER COMBINATIONS	0 (0.0)	1 (0.6)	3 (2.1)	0 (0.0)
VITAMINS, OTHER COMBINATIONS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
ASCORBIC ACID W/BIOTIN/CALCIUM PANT	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OCUVITE ADULT 50+	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
EAGLE TRESOS B PLUSE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HERBAL NOS W/LECITHIN/MINERALS NOS/UBIDEACAREN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OCUVITE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ZINC PRODUCTS	0 (0.0)	2 (1.3)	1 (0.7)	1 (5.6)
ZINC OXIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ZINC PRODUCTS	0 (0.0)	1 (0.6)	0 (0.0)	1 (5.6)
GOLD BOND	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SUDOCREM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
AYRTONS ANTISEPTIC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIVERTIGO PREPARATIONS	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)
CINNARIZINE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
BETAHISTINE MESILATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DIMENHYDRINATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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ANTIVERTIGO PREPARATIONS	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)
ACETYLLLEUCINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BULK-FORMING LAXATIVES	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
POLYCARBOPHIL CALCIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FIBRE, DIETARY	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BULK-FORMING LAXATIVES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
METHYLCELLULOSE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ENZYMES	3 (3.8)	0 (0.0)	2 (1.4)	0 (0.0)
ALTEPLASE	2 (2.6)	0 (0.0)	2 (1.4)	0 (0.0)
BROEN-C	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
FATTY ACID DERIVATIVES	2 (2.6)	2 (1.3)	1 (0.7)	0 (0.0)
VALPROATE SODIUM	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
GAMMA-AMINOBUTYRIC ACID	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
VALPROATE SEMISODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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ORIPAVINE DERIVATIVES	1 (1.3)	1 (0.6)	2 (1.4)	0 (0.0)
BUPRENORPHINE	1 (1.3)	1 (0.6)	2 (1.4)	0 (0.0)
OTHER ANTIPSYCHOTICS	1 (1.3)	0 (0.0)	3 (2.1)	0 (0.0)
ARIPIRAZOLE	1 (1.3)	0 (0.0)	2 (1.4)	0 (0.0)
RISPERIDONE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OTHER BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	0 (0.0)	3 (1.9)	1 (0.7)	0 (0.0)
EMPAGLIFLOZIN	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
CANAGLIFLOZIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
REPAGLINIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LIRAGLUTIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SULFONAMIDES	0 (0.0)	1 (0.6)	3 (2.1)	0 (0.0)
SULFADIAZINE SILVER	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
SULFACETAMIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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ANALGESICS	0 (0.0)	2 (1.3)	2 (1.4)	0 (0.0)
DULOXETINE	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
DULOXETINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
RISTFOR	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
ALOGLIPTIN BENZOATE W/PIOGLITAZONE HYDROCHLOR	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
METFORMIN HYDROCHLORIDE W/SITAGLIPTIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
METFORMIN W/SAXAGLIPTIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
I.V. SOLUTIONS	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
I.V. SOLUTIONS	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
PHYSIO 140	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PERIPHERAL OPIOID RECEPTOR ANTAGONISTS	1 (1.3)	1 (0.6)	0 (0.0)	1 (5.6)
NALOXEGOL OXALATE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
METHYLNALTREXONE	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
NALDEMEDINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
METHYLNALTREXONE BROMIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PERIPHERAL OPIOID RECEPTOR ANTAGONISTS	1 (1.3)	1 (0.6)	0 (0.0)	1 (5.6)
NALOXEGOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROGESTOGENS AND ESTROGENS, SEQUENTIAL PREPARATION	1 (1.3)	1 (0.6)	2 (1.4)	0 (0.0)
CILEST	1 (1.3)	0 (0.0)	2 (1.4)	0 (0.0)
ANOVLAR	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SYMPATHOMIMETICS IN GLAUCOMA THERAPY	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
BRIMONIDINE	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
BRIMONIDINE TARTRATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SIMBRINZA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SYMPATHOMIMETICS, PLAIN	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
OXYMETAZOLINE HYDROCHLORIDE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
OXYMETAZOLINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMINO ACIDS, INCL. COMBINATIONS WITH POLYPEPTIDES	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
LYSINE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
AMINO ACIDS NOS W/ELECTROLYTES NOS/GLUCOSE/TH	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ARGININE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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ANTIARRHYTHMICS, CLASS III	2 (2.6)	0 (0.0)	2 (1.4)	0 (0.0)
AMIODARONE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
AMIODARONE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DRONEDARONE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
DRONEDARONE HYDROCHLORIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIBACTERIALS FOR SYSTEMIC USE	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
ANTIBIOTICS	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
BILE ACID SEQUESTRANTS	1 (1.3)	0 (0.0)	2 (1.4)	0 (0.0)
COLESTYRAMINE	1 (1.3)	0 (0.0)	2 (1.4)	0 (0.0)
COLESEVELAM HYDROCHLORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
COLESTIPOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BISMUTH PREPARATIONS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
BISMUTH SUBSALICYLATE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)

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CORTICOSTEROIDS FOR SYSTEMIC USE, COMBINATIONS	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS FOR SYSTEMIC USE, COMBINATION	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
STELAMIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SOLOMET C. BUPIVACAINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FIBRATES	1 (1.3)	1 (0.6)	2 (1.4)	0 (0.0)
FENOFIBRATE	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
GEMFIBROZIL	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
INTRAUTERINE CONTRACEPTIVES	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
LEVONORGESTREL	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
OTHER ANTIPSORIATICS FOR TOPICAL USE	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
CALCIPOTRIOL	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
CRISABOROLE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
XAMIOLOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER CHEMOTHERAPEUTICS	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
METRONIDAZOLE	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
OTHER COLD PREPARATIONS	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
MENTHOL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER COLD PREPARATIONS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
CEDOVIX	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HALL'S MENTHO-LYPTUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VITAMINS WITH MINERALS	2 (2.6)	1 (0.6)	0 (0.0)	0 (0.0)
ARONAMIN C PLUS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BORON W/CALCIUM/COPPER/MAGNESIUM/MANGANESE/PY	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
MACULA SUPPORT	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
CHROMIC CHLORIDE W/MAGNESIUM AMINO ACID CHELA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VITAMINS WITH MINERALS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
COVERAM	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
COROVAL B	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
AMLODIPINE W/BENAZEPRIL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HEPARINS OR HEPARINOIDS FOR TOPICAL USE	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE IN	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
ENTECAVIR	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
TENOFVIR ALAFENAMIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OPHTHALMOLOGICALS	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
OPHTHALMOLOGICALS	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
OTHER AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOA	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
ATOVAQUONE	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
PHENOTHIAZINE DERIVATIVES	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
PROMETHAZINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MEQUITAZINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OXOMEMAZINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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PREPARATIONS WITH SALICYLIC ACID DERIVATIVES	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
DUYUNGSON	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
MEDIPLASTER	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
METHYL SALICYLATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TROLAMINE SALICYLATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
RETINOIDS FOR TOPICAL USE IN ACNE	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
TRETINOIN	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
SYMPATHOMIMETICS USED AS DECONGESTANTS	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
NAPHAZOLINE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
NAPHCN-A	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
ADVANCED EYE RELIEF REDNESS INSTANT RELIEF	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ALL OTHER THERAPEUTIC PRODUCTS	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
ALL OTHER THERAPEUTIC PRODUCTS	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)

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ANTICHOLINESTERASES	0 (0.0)	1 (0.6)	1 (0.7)	1 (5.6)
AMBENONIUM CHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DONEPEZIL HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
NEOSTIGMINE	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
ASCORBIC ACID (VITAMIN C), COMBINATIONS	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
ASCORBIC ACID (VITAMIN C), COMBINATIONS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CINAL	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
PROANTHENOLS 100	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SCHIFF VITAMIN C WITH ROSE HIPS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
AZASPIRODECANEDIONE DERIVATIVES	0 (0.0)	1 (0.6)	0 (0.0)	1 (5.6)
BUSPIRONE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BUSPIRONE	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
CARBONIC ANHYDRASE INHIBITORS	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)
ACETAZOLAMIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DORZOLAMIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DORZOLAMIDE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
DOPA AND DOPA DERIVATIVES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SINEMET	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DOPAMINE AGONISTS	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
ROPINIROLE	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
PRAMIPEXOLE DIHYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DRUGS USED IN NICOTINE DEPENDENCE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
NICOTINE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
BUPROPION	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
VARENICLINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HMG COA REDUCTASE INHIBITORS IN COMBINATION WITH O	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
INEGY	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
ROSUVAST EZ	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
IODINE PRODUCTS	1 (1.3)	1 (0.6)	0 (0.0)	1 (5.6)
POVIDONE-IODINE	1 (1.3)	1 (0.6)	0 (0.0)	1 (5.6)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
DIAZIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
NICOTINIC ACID AND DERIVATIVES	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
NICOTINIC ACID	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TOCOPHERYL NICOTINATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OTHER ANTI-DEMENTIA DRUGS	2 (2.6)	1 (0.6)	0 (0.0)	0 (0.0)
MEMANTINE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
MEMANTINE HYDROCHLORIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS	0 (0.0)	1 (0.6)	1 (0.7)	1 (5.6)
BOTULINUM TOXIN TYPE A	0 (0.0)	1 (0.6)	1 (0.7)	1 (5.6)
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
OMALIZUMAB	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
ZILEUTON	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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PEROXIDES	0 (0.0)	0 (0.0)	3 (2.1)	0 (0.0)
BENZOYL PEROXIDE	0 (0.0)	0 (0.0)	3 (2.1)	0 (0.0)
PHENYLALKYLAMINE DERIVATIVES	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
VERAPAMIL	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
VERAPAMIL HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PYRIMIDINE ANALOGUES	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
FLUOROURACIL	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)
STREPTOGRAMINS	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
PRISTINAMYCIN	0 (0.0)	2 (1.3)	1 (0.7)	0 (0.0)
VASOPRESSIN AND ANALOGUES	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
VASOPRESSIN	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
DESMOPRESSIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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VITAMIN K	1 (1.3)	2 (1.3)	0 (0.0)	0 (0.0)
PHYTOMENADIONE	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
VITAMIN K NOS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ACTH	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
TETRACOSACTIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TETRACOSACTIDE ACETATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANTIVIRALS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ACICLOVIR	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GANCICLOVIR	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TRIFLURIDINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BIOFLAVONOIDS	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
QUERCETIN	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
CAPIVEN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
COLONY STIMULATING FACTORS	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.6)
FILGRASTIM	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.6)
PEGFILGRASTIM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MONOBACTAMS	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
AZTREONAM	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
HYALURONATE SODIUM	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
HYALURONIC ACID	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HYLAN G-F 20	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER NUTRIENTS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
OTHER NUTRIENTS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
LINOLEIC ACID	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER PSYCHOSTIMULANTS AND NOOTROPICS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
GINKGO BILOBA W/VINPOCETINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OXIRACETAM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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OTHER PSYCHOSTIMULANTS AND NOOTROPICS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
OTHER PSYCHOSTIMULANTS AND NOOTROPICS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TETRACYCLINE AND DERIVATIVES	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
TETRACYCLINE HYDROCHLORIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
OXYTETRACYCLINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
THROAT PREPARATIONS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
THROAT PREPARATIONS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
VARICELLA ZOSTER VACCINES	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
VARICELLA ZOSTER VACCINE	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR V	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
VITAMEDIN INTRAVENOUS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VITAMINES-B-LABAZ	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
NEUROBION	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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ANTACIDS	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
ANTACIDS	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
ANTIINFECTIVES	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
CIPROFLOXACIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
OFLOXACIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BARIUM SULFATE CONTAINING X-RAY CONTRAST MEDIA	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
BARIUM SULFATE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
BELLADONNA ALKALOIDS, TERTIARY AMINES	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
HYOSCYAMINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
HYOSCYAMINE SULFATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BETA BLOCKING AGENTS, SELECTIVE, AND THIAZIDES	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
BISELECT	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NEBICARD-H	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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BETA-LACTAMASE RESISTANT PENICILLINS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
DICLOXACILLIN SODIUM MONOHYDRATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
FLUCLOXACILLIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BETA-LACTAMASE SENSITIVE PENICILLINS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PHENOXYMETHYLPENICILLIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PHENOXYMETHYLPENICILLIN POTASSIUM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BLOOD AND RELATED PRODUCTS	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
BLOOD AND RELATED PRODUCTS	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
CARBOHYDRATES NOS W/POTASSIUM CHLORIDE/SODIUM	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
SOLACET F	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CALCITONIN PREPARATIONS	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
CALCITONIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ELCATONIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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CARBOHYDRATES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GLUCOSE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DEXTRIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CARBOXAMIDE DERIVATIVES	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.6)
CARBAMAZEPINE	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.6)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
CORTICOSTEROID NOS	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
DIPHENYLMETHANE DERIVATIVES	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
HYDROXYZINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
HYDROXYZINE EMBONATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ETHERS, CHEMICALLY CLOSE TO ANTIHISTAMINES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NORGESIC	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ORPHENADRINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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IRON PREPARATIONS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
IRON	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LOCAL ANESTHETICS	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
PROXYMETACAINE	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
LIDOCAINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TETRACAINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MAGNESIUM COMPOUNDS	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
MAGNESIUM CARBONATE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
MAGNESIUM HYDROXIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MINERAL SUPPLEMENTS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
MINERAL SUPPLEMENTS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
POTASSIUM W/SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MULTIVITAMINS, OTHER COMBINATIONS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MULTIVITAMINS, OTHER COMBINATIONS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER AMINOGLYCOSIDES	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
GENTAMICIN	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
OTHER ANTITHROMBOTIC AGENTS	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
FONDAPARINUX	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
FONDAPARINUX SODIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER QUATERNARY AMMONIUM COMPOUNDS	0 (0.0)	1 (0.6)	0 (0.0)	1 (5.6)
ROCURONIUM	0 (0.0)	1 (0.6)	0 (0.0)	1 (5.6)
PARAMAGNETIC CONTRAST MEDIA	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
GADOBUTROL	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
MEGLUMINE GADOTERATE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
PARATHYROID HORMONES AND ANALOGUES	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
PARATHYROID HORMONE	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
TERIPARATIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
U-PASTA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PROSTAGLANDINS	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
ALPROSTADIL ALFADEX	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MISOPROSTOL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PURINE DERIVATIVES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
PENTOXIFYLLINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SALT SOLUTIONS	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
SODIUM CHLORIDE	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
SELENIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SELENIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
SOLUTIONS PRODUCING OSMOTIC DIURESIS	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
MANNITOL	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
SYNTHETIC ANTICHOLINERGICS, QUATERNARY AMMONIUM CO	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.6)
GLYCOPYRRONIUM	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.6)
VITAMIN A, PLAIN	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
RETINOL	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
XANTHINES	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)
AMINOPHYLLINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
THEOPHYLLINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMINO ACIDS AND DERIVATIVES	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BETAINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
LEVOCARNITINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
ANGIOTENSIN II ANTAGONISTS, OTHER COMBINATIONS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TRIBENZOR	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANGIOTENSIN II ANTAGONISTS, OTHER COMBINATION	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIARRHYTHMICS, CLASS IC	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
FLECAINIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
FLECAINIDE ACETATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIFUNGALS FOR SYSTEMIC USE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TERBINAFINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BETA-LACTAMASE INHIBITORS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CLAVULANATE POTASSIUM	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BIGUANIDES AND AMIDINES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CHLORHEXIDINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CHLORHEXIDINE GLUCONATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
CORTICOSTEROIDS FOR SYSTEMIC USE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CORTICOSTEROID NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DIRECT THROMBIN INHIBITORS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DABIGATRAN ETEXILATE MESILATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
DIURETICS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ACETAZOLAMIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
HEPATITIS VACCINES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HEPATITIS A VACCINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HYPNOTICS AND SEDATIVES	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
HYPNOTICS AND SEDATIVES	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
PROMETHAZINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
IRON IN OTHER COMBINATIONS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
ASCORBIC ACID W/FOLIC ACID/IRON/VIT	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
IRON PLUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
ORAL REHYDRATION SALT FORMULATIONS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ORAL REHYDRATION SALT FORMULATIONS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ELECTROLYTES NOS W/GLUCOSE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTIANEMIC PREPARATIONS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
LIVALAVIN	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
EPOETIN ALFA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTIVIRALS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
LYSOZYME CHLORIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
OXAZOL, THIAZINE, AND TRIAZINE DERIVATIVES	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
METAXALONE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PHENOTHIAZINES WITH ALIPHATIC SIDE-CHAIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CHLORPROMAZINE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CYAMEMAZINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
SELECTIVE ESTROGEN RECEPTOR MODULATORS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
BAZEDOXIFENE ACETATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
RALOXIFENE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SENSITIZERS USED IN PHOTODYNAMIC/RADIATION THERAPY	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AMINOLEVULINIC ACID	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SOMATOSTATIN AND ANALOGUES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LANREOTIDE ACETATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OCTREOTIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OCTREOTIDE ACETATE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TETANUS VACCINES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DITEMER	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TONICS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CITRULLINE MALATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ARMAFORCE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
ACE INHIBITORS, COMBINATIONS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ACE INHIBITORS, COMBINATIONS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSU	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ALUMINIUM COMPOUNDS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
ALUMINIUM SILICATE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
ANESTHETICS FOR TOPICAL USE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
PRAMOCAINE HYDROCHLORIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
ANTACIDS, OTHER COMBINATIONS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ANTACIDS, OTHER COMBINATIONS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ANTHRACYCLINES AND RELATED SUBSTANCES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
EPIRUBICIN HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
ANTIARRHYTHMICS, CLASS IB LIDOCAINE	0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS SHARK CARTILAGE	0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
ANTINEOVASCULARISATION AGENTS AFLIBERCEPT	1 (1.3) 1 (1.3)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
ANTISPASMODICS, PSYCHOLEPTICS AND ANALGESICS IN CO SPASMALGIN	0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBIN EMTRICITABINE W/TENOFOVIR	0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
BENZAMIDES AMISULPRIDE	0 (0.0) 0 (0.0)	1 (0.6) 1 (0.6)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)

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BETA-LACTAM ANTIBACTERIALS, PENICILLINS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PENICILLIN NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
BUTYROPHENONE DERIVATIVES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HALOPERIDOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CALCINEURIN INHIBITORS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CICLOSPORIN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CALCIUM CHANNEL BLOCKERS AND DIURETICS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
AMLODAC D	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
CAPSAICIN AND SIMILAR AGENTS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
CAPZASIN QUICK RELIEF	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
CHARCOAL PREPARATIONS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CHARCOAL, ACTIVATED	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
COMBINATIONS OF ADRENERGICS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
COMBINATIONS OF ADRENERGICS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
COMBINATIONS OF VITAMINS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
COMBINATIONS OF VITAMINS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VITAMINS NOS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS, WEAK, COMBINATIONS WITH ANTIBIOTI	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CHLOMY-P	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS, WEAK, COMBINATIONS WITH ANTISEPTI	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VIOFORM+HYDROCORTISONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
DRUGS FOR BILE THERAPY AND LIPOTROPICS IN COMBINAT	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
DRUGS FOR BILE THERAPY AND LIPOTROPICS IN COM	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
DRUGS USED IN ALCOHOL DEPENDENCE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
NALTREXONE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
ECTOPARASITICIDES, INCL. SCABICIDES	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
SODIUM CHLORIDE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
EMERGENCY CONTRACEPTIVES	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
LEVONORGESTREL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
GLYCOGENOLYTIC HORMONES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
GLUCAGON	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
ORAL CONTRACEPTIVE NOS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
HYDANTOIN DERIVATIVES	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
FOSPHENYTOIN	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
PHENYTOIN	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
IMMUNOGLOBULINS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
IMMUNOGLOBULINS NOS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)

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INDOLE DERIVATIVES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LURASIDONE HYDROCHLORIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
INSULIN HUMAN INJECTION, ISOPHANE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
IRON IN COMBINATION WITH FOLIC ACID	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
HIERROQUICK	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
LITHIUM	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LITHIUM CARBONATE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LIVER THERAPY, LIPOTROPICS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
NEUPHAGEN	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
LOCAL HEMOSTATICS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
EPINEPHRINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
MEDICATED DRESSINGS WITH ANTIINFECTIVES	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
POVIDONE-IODINE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MORPHINAN DERIVATIVES	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
NALBUPHINE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PREPARATION H	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TUCKS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTI-PARATHYROID AGENTS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
CINACALCET	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER ANTINEOPLASTIC AGENTS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
MODIFIED CITRUSPECTIN	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTIPRURITICS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CALAMINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTIPRURITICS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER ANTISEPTICS AND DISINFECTANTS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ETHANOL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER DRUGS FOR BILE THERAPY	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
ANETHOLE TRITHIONE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTRO	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER LOCAL ANESTHETICS	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
CAPSAICIN	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
OTHER PERIPHERAL VASODILATORS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PHENOXYBENZAMINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER SPECIFIC ANTIRHEUMATIC AGENTS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
METHOTREXATE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
OTHER THROAT PREPARATIONS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
AZ	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
OTHER TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
MENTHOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PERTUSSIS VACCINES	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
VACCIN IPAD D.T.C.	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
PHENOL AND DERIVATIVES	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
HEXACHLOROPHENE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PHENOTHIAZINES WITH PIPERAZINE STRUCTURE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
PROCHLORPERAZINE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
PROTEOLYTIC ENZYMES	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
COLLAGENASE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
PYRETHRINES, INCL. SYNTHETIC COMPOUNDS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
MARIE ROSE	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
QUININE AND DERIVATIVES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
HEXAQUINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SELECTIVE IMMUNOSUPPRESSANTS	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
APREMILAST	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
THIAMAZOLE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SYNTHETIC ANTISPASMODICS, AMIDES WITH TERTIARY AMI	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TIROPRAMIDE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
THIAZIDES AND POTASSIUM IN COMBINATION	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SALURES-K	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
THIAZOLIDINEDIONES	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
PIOGLITAZONE HYDROCHLORIDE	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
TRIMETHOPRIM AND DERIVATIVES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TRIMETHOPRIM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TYPHOID VACCINES	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
TYPHOID VACCINE	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VITAMIN A AND D IN COMBINATION	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
COD-LIVER OIL	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
VITAMIN B-COMPLEX WITH VITAMIN C	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
ASCORBIC ACID W/VITAMIN B NOS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
WART AND ANTI-CORN PREPARATIONS	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
SALICYLIC ACID	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
ANESTHETICS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANESTHETICS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTI-GONADOTROPIN-RELEASING HORMONES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CETRORELIX	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIARRHYTHMICS, CLASS I AND III	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ATROPINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIBIOTICS FOR TOPICAL USE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIBIOTICS FOR TOPICAL USE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS,	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHET	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTISEPTICS AND DISINFECTANTS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANTISEPTICS AND DISINFECTANTS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
BARBITURATES AND DERIVATIVES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PRIMIDONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CENTRALLY ACTING ANTIIOBESITY PRODUCTS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LORCASERIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CORTICOSTEROIDS, MODERATELY POTENT, COMBINATIONS W	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MYCOLOG	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DETOXIFYING AGENTS FOR ANTINEOPLASTIC TREATMENT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
RASBURICASE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
GENITO URINARY SYSTEM AND SEX HORMONES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ARGININE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
INTRAVAGINAL CONTRACEPTIVES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NUVARING	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Percentage is calculated based on the number of patients in the column heading as the denominator.
 Patients are counted once within each preferred term.
 Reported medication terms were coded using WHO Drug Dictionary (version September 2015).
 Medications are sorted in decreasing order of frequency based on Overall Efficacy Analysis Set.
 Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spcm2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.1.5_eff.rtf

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Table 14.1.5
 Concomitant Medications
 Efficacy Analysis Set
 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
MENINGOCOCCAL VACCINES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MENINGOCOCCAL VACCINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTIMIGRAINE PREPARATIONS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANTIMIGRAINE PREPARATIONS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER ANXIOLYTICS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PREGABALIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTHER INTESTINAL ANTIINFECTIVES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NIFUROXAZIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PARASYMPATHOMIMETICS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PILOCARPINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PREGNEN (4) DERIVATIVES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROGESTERONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Percentage is calculated based on the number of patients in the column heading as the denominator.
 Patients are counted once within each preferred term.
 Reported medication terms were coded using WHO Drug Dictionary (version September 2015).
 Medications are sorted in decreasing order of frequency based on Overall Efficacy Analysis Set.
 Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spcm2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.1.5_eff.rtf

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Table 14.1.5
 Concomitant Medications
 Efficacy Analysis Set
 by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
PROGESTOGENS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MEDROXYPROGESTERONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROLACTINE INHIBITORS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CABERGOLINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROTECTIVES AGAINST UV-RADIATION FOR TOPICAL USE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROTECTIVES AGAINST UV-RADIATION FOR TOPICAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TUBERCULOSIS DIAGNOSTICS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TUBERCULIN PPD	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ULTRASOUND CONTRAST MEDIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SULFUR HEXAFLUORIDE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Percentage is calculated based on the number of patients in the column heading as the denominator.
 Patients are counted once within each preferred term.
 Reported medication terms were coded using WHO Drug Dictionary (version September 2015).
 Medications are sorted in decreasing order of frequency based on Overall Efficacy Analysis Set.
 Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spcm2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.1.5_eff.rtf

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Table 14.1.6
 Summary of Subsequent Anti-Cancer Therapy
 Safety Analysis Set
 by Subpopulation

Category Subcategory	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
Any Subsequent Anti-Cancer Therapy	9 (10.6)	24 (13.9)	16 (10.5)	1 (4.8)
Type of Subsequent Anti-Cancer Therapy [1]				
Chemotherapy	2 (2.4)	14 (8.1)	5 (3.3)	0 (0.0)
Targeted Therapy	8 (9.4)	9 (5.2)	10 (6.5)	1 (4.8)
Radiation	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Other	1 (1.2)	6 (3.5)	4 (2.6)	0 (0.0)

Percentage is calculated based on the number of patients in the column heading as the denominator.

[1] Subjects may be counted in more than one type of therapy but are counted at most once within a therapy type.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spanticancer.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.1.6_sf.rtf

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Table 14.1.6
 Summary of Subsequent Anti-Cancer Therapy
 Efficacy Analysis Set
 by Subpopulation

Category Subcategory	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
Any Subsequent Anti-Cancer Therapy	9 (11.5)	24 (15.2)	16 (11.2)	1 (5.6)
Type of Subsequent Anti-Cancer Therapy [1]				
Chemotherapy	2 (2.6)	14 (8.9)	5 (3.5)	0 (0.0)
Targeted Therapy	8 (10.3)	9 (5.7)	10 (7.0)	1 (5.6)
Radiation	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Other	1 (1.3)	6 (3.8)	4 (2.8)	0 (0.0)

Percentage is calculated based on the number of patients in the column heading as the denominator.

[1] Subjects may be counted in more than one type of therapy but are counted at most once within a therapy type.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spanticancer.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.1.6_eff.rtf

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Table 14.1.7.2
 Study Drug Dosage Modifications
 Safety Analysis Set
 by Subpopulation

Status	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
Any Dose Reduction	41 (48.2)	65 (37.6)	39 (25.5)	9 (42.9)
Adverse Event	38 (44.7)	62 (35.8)	34 (22.2)	8 (38.1)
Other Reasons	3 (3.5)	9 (5.2)	7 (4.6)	1 (4.8)
Any Dose Interruption	59 (69.4)	118 (68.2)	91 (59.5)	15 (71.4)
Adverse Event	53 (62.4)	101 (58.4)	80 (52.3)	13 (61.9)
Other Reasons	16 (18.8)	37 (21.4)	30 (19.6)	5 (23.8)
Any Dose Increase	21 (24.7)	50 (28.9)	32 (20.9)	6 (28.6)
Intra-Patient Dose Escalation	4 (4.7)	25 (14.5)	17 (11.1)	6 (28.6)
Dose Re-Escalation	13 (15.3)	21 (12.1)	10 (6.5)	0 (0.0)
Other Reasons	6 (7.1)	8 (4.6)	7 (4.6)	0 (0.0)
The dose to which the initial dose was reduced to				
20 mg/dose	1 (1.2)	3 (1.7)	1 (0.7)	0 (0.0)
30 mg/dose	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
40 mg/dose	14 (16.5)	15 (8.7)	7 (4.6)	0 (0.0)
60 mg/dose	2 (2.4)	12 (6.9)	3 (2.0)	2 (9.5)
80 mg/dose	10 (11.8)	11 (6.4)	9 (5.9)	4 (19.0)
120 mg/dose	13 (15.3)	20 (11.6)	14 (9.2)	3 (14.3)
160 mg/dose	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
200 mg/dose	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

Percentage is calculated using the number of patients in the column heading as the denominator.
 Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spex.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.1.7.2_sf.rtf

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Table 14.1.7.2
 Study Drug Dosage Modifications
 Efficacy Analysis Set
 by Subpopulation

Status	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
Any Dose Reduction	37 (47.4)	60 (38.0)	37 (25.9)	7 (38.9)
Adverse Event	34 (43.6)	57 (36.1)	32 (22.4)	6 (33.3)
Other Reasons	3 (3.8)	8 (5.1)	7 (4.9)	1 (5.6)
Any Dose Interruption	53 (67.9)	110 (69.6)	89 (62.2)	13 (72.2)
Adverse Event	47 (60.3)	93 (58.9)	78 (54.5)	11 (61.1)
Other Reasons	16 (20.5)	37 (23.4)	30 (21.0)	5 (27.8)
Any Dose Increase	19 (24.4)	45 (28.5)	32 (22.4)	6 (33.3)
Intra-Patient Dose Escalation	4 (5.1)	25 (15.8)	17 (11.9)	6 (33.3)
Dose Re-Escalation	11 (14.1)	16 (10.1)	10 (7.0)	0 (0.0)
Other Reasons	6 (7.7)	7 (4.4)	7 (4.9)	0 (0.0)
The dose to which the initial dose was reduced to				
20 mg/dose	1 (1.3)	1 (0.6)	1 (0.7)	0 (0.0)
30 mg/dose	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
40 mg/dose	10 (12.8)	13 (8.2)	7 (4.9)	0 (0.0)
60 mg/dose	2 (2.6)	12 (7.6)	3 (2.1)	2 (11.1)
80 mg/dose	10 (12.8)	10 (6.3)	9 (6.3)	2 (11.1)
120 mg/dose	13 (16.7)	20 (12.7)	13 (9.1)	3 (16.7)
160 mg/dose	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)
200 mg/dose	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

Percentage is calculated using the number of patients in the column heading as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spex.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.1.7.2_eff.rtf

Safety Population - B

Weight / Start Dose	160 mg BID	120 mg BID	Other	Total
< 50 kg	16 (10,5%)	1 (0,7%)	2 (1,3%)	19 (12,4%)
≥ 50 kg	112 (73,2%)	1 (0,7%)	21 (13,7%)	134 (87,6%)
Total	128 (83,7%)	2 (1,3%)	23 (15,0%)	153 (100,0%)

Efficacy Population - B

Weight / Start Dose	160 mg BID	120 mg BID	Other	Total
< 50 kg	15 (10,5%)	1 (0,7%)	2 (1,4%)	18 (12,6%)
≥ 50 kg	103 (72,0%)	1 (0,7%)	21 (14,7%)	125 (87,4%)
Total	118 (82,5%)	2 (1,4%)	23 (16,1%)	143 (100,0%)

Tabelle 005: Behandlungsdauer – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel
(Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

	Selpercatinib Subpopulation B – MTC (N=143)
Behandlungsdauer in Monaten	
Anzahl der Patienten	143
Mittelwert (SD)	14,0 (7,69)
Median (min–max)	13,34 (0,20-33,31)
max: Maximum; min: Minimum; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; RET: Rearranged during Transfection; SD: Standardabweichung.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sptte_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T005_tte_mtc.rtf

Tabelle 007: Ergebnisse für den Endpunkt Gesamtüberleben aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	Selpercatinib
	Subpopulation B – MTC (N=143)
Gesamtüberleben	
Überlebensstatus ^a , n (%)	
Tot	26 (18,2)
Lebend	117 (81,8)
Medianes Gesamtüberleben (Monate) [95%-KI] ^{b,c}	33,25 [33,2; NE]
Überlebensrate (≥ 12 Monate), % [95%-KI] ^{b,d}	86,9 [79,7; 91,6]
Mediane Beobachtungsdauer (Monate) ^b	15,7
KI: Konfidenzintervall; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); RET: Rearranged during Transfection. Der Prozentsatz wird basierend auf der Anzahl an Patienten in der Spaltenüberschrift als Nenner berechnet. a: Status des letzten Kontaktes am oder vor dem Datenschnitt des 30. März 2020. b: Die Schätzung basiert auf der Kaplan-Meier Methode. NE = nicht schätzbar. c: Das 95%-KI wurde mittels Brookmeyer und Crowley Methode berechnet. d: Das 95%-KI wurde mittels Greenwood Formel berechnet. Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben.	

Anmerkung:

In Datensätzen mit unreifen Daten sind die meisten Beobachtungen zensiert, und typischerweise ist der Median (basierend auf der Kaplan-Meier Kurve) in solchen Fällen nicht schätzbar (d. h., "der Median ist nicht erreicht"). Wenn es sich jedoch bei der spätesten Beobachtung eines Datensatzes zufällig um eine Ereigniszeit handelt, dann ist der Kaplan-Meier Schätzer des Ereignisses/Überlebens jenseits dieses Zeitpunkts Null, selbst wenn die meisten anderen Beobachtungen zensiert sind. In solchen Fällen zeigt die Kaplan-Meier Kurve am Punkt der längsten Ereigniszeit normalerweise einen abrupten Abfall, auch wenn die Ereignis-/Überlebenswahrscheinlichkeit kurz vor diesem Zeitpunkt recht hoch war. Wenn die Kaplan-Meier Kurve wie beschrieben abfällt, ist es zwar möglich, einen Median zu berechnen; dieser Wert kann jedoch nicht sinnvoll interpretiert werden und stellt höchstwahrscheinlich eine deutliche Unterschätzung des wahren Medians dar.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_os_ge_2.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

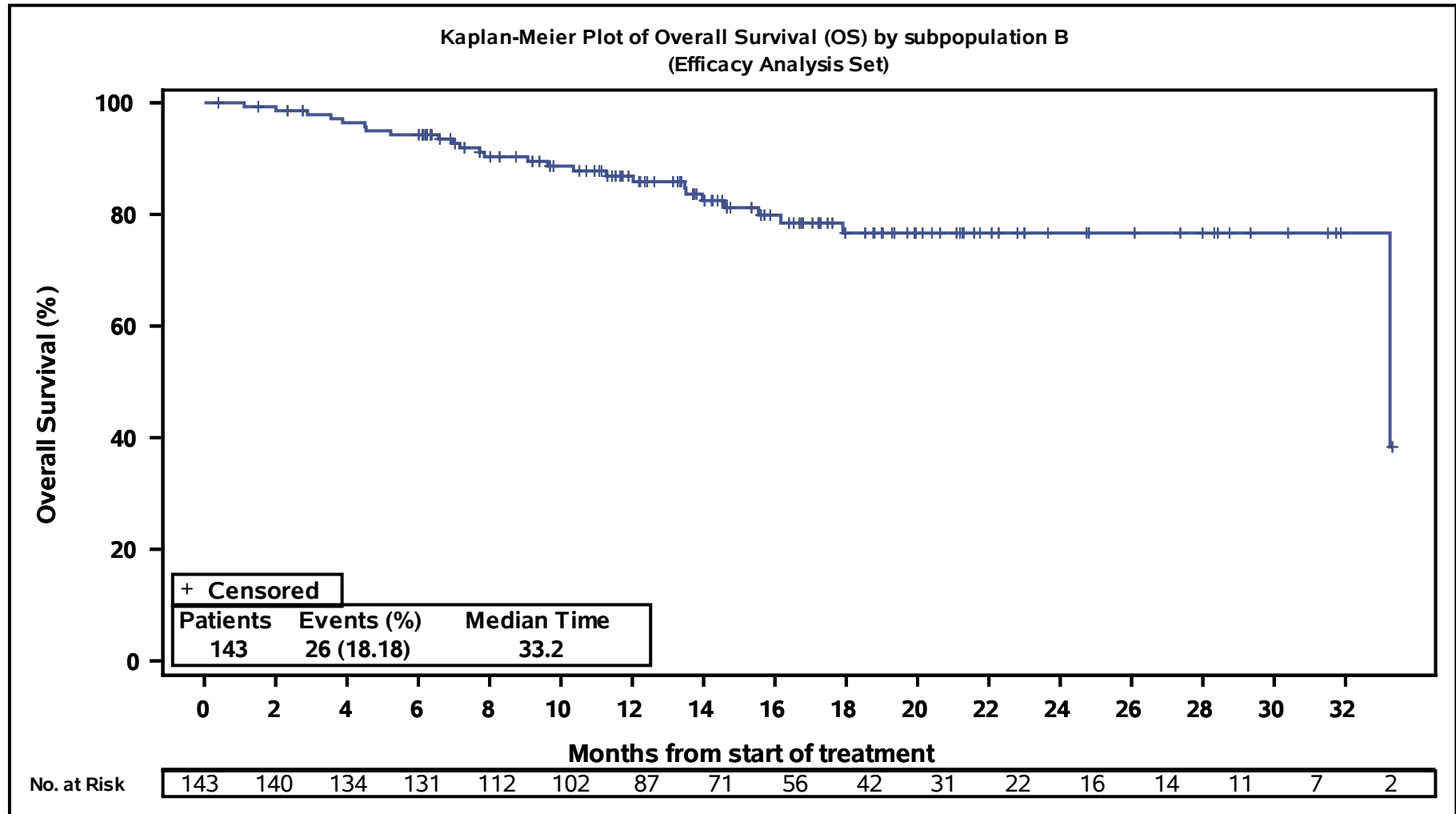
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T007_os_mtc_eff_modified_for_PDF.rtf

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Program Location: //lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10.sas
 Output Location: //lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F001_1_os_b_mtc_eff.rtf
 Data Location: //lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: //lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Tabelle 008: Ergebnisse für den Endpunkt progressionsfreies Überleben aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	Selpercatinib Subpopulation B – MTC (N=143)
Progressionsfreies Überleben	
Progressionsstatus ^{a,c} , n (%)	
Progression	27 (18,9)
Tod (ohne vorherigen Progress)	9 (6,3)
Zensiert	107 (74,8)
Grund für Zensierung, n (%)	
Am Leben ohne Progress ^b	91 (63,6)
Anschl. Krebstherapie oder krebsbedingte Operation ohne Progress ^b	9 (6,3)
Abbruch der Studie ohne Progress ^b	7 (4,9)
Medianes progressionsfreies Überleben (Monate) [95%-KI] ^{d,e}	NE [20,0; NE]
Dauer des progressionsfreien Überlebens nach Kategorie, n (%)	
< 6 Monate	37 (25,9)
≥ 6 bis < 12 Monate	45 (31,5)
≥ 12 bis < 18 Monate	29 (20,3)
≥ 18 bis < 24 Monate	19 (13,3)
≥ 24 Monate	13 (9,1)
Progressionsfreie Überlebensrate ^{d,f} , % [95%-KI]	
≥ 6 Monate	89,5 [82,9; 93,7]
≥ 12 Monate	76,9 [67,9; 83,7]
Mediane Beobachtungsdauer (Monate) ^d	13,9
KI: Konfidenzintervall; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); RET: Rearranged during Transfection. Der Prozentsatz wird basierend auf der Anzahl an Patienten in der Spaltenüberschrift als Nenner berechnet. a: Status basiert auf der letzten Krankheitsbewertung des Patienten am oder vor dem Datenschnitt des 30. März 2020. b: Ohne dokumentierte Krankheitsprogression. c: Beurteilung erfolgte durch ein unabhängiges Expertenkomitee (Independent Review Committee [IRC]) anhand der RECIST Kriterien (Version 1.1). d: Die Schätzung basiert auf der Kaplan-Meier Methode. NE = nicht schätzbar. e: Das 95%-KI wurde mittels Brookmeyer und Crowley Methode berechnet. f: Das 95%-KI wurde mittels Greenwood Formel berechnet. Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_pfs_ge_2.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

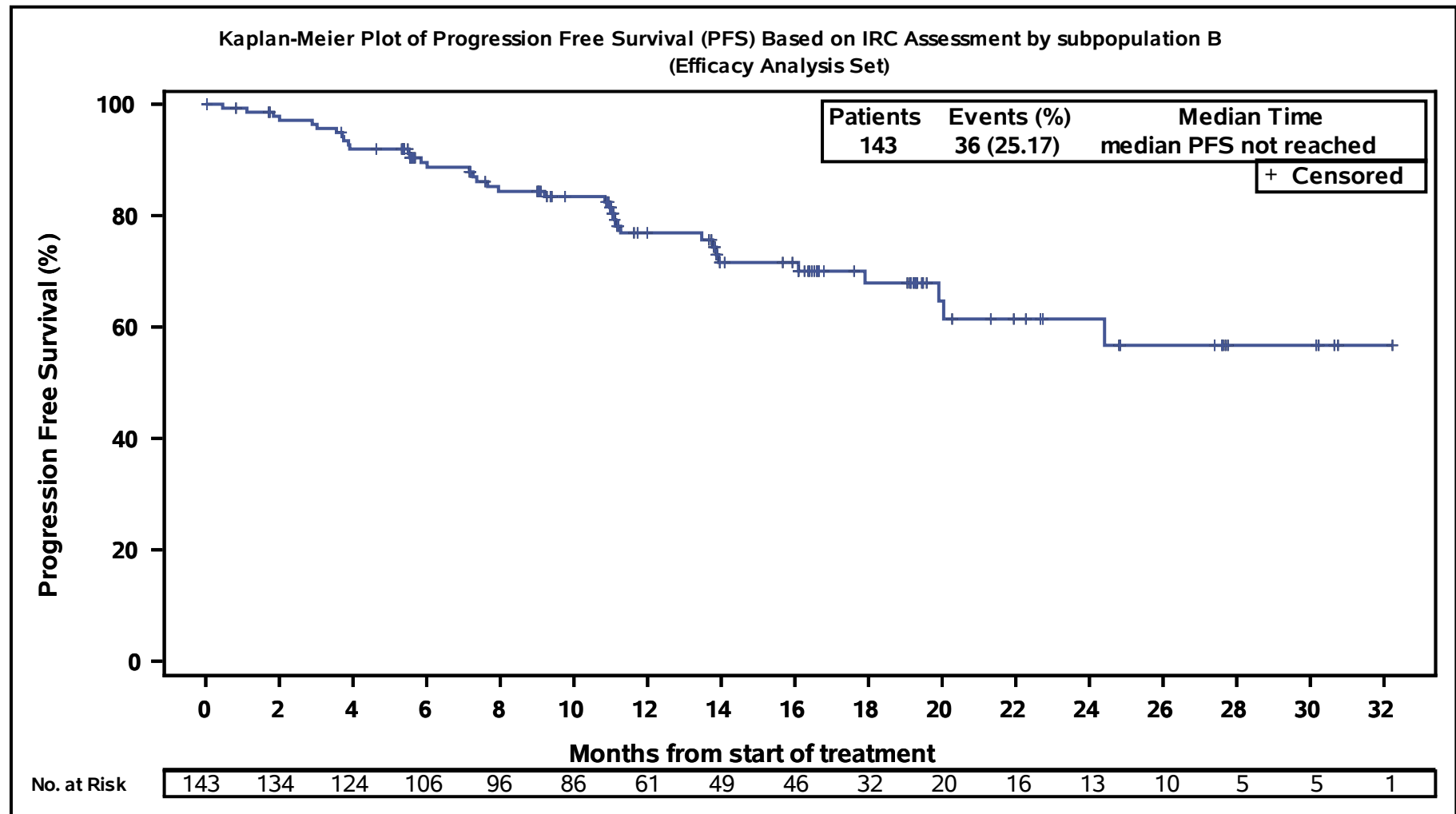
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T008_pfs_mtc_eff_modified_for_PDF.rtf

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Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10.sas
 Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F002_1_pfs_b_mtc_eff.rtf
 Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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Adhoc Table 1 - 24 month OS/PFS rates by subpopulation

term	A1	A2	B	C
Überlebensrate (≥ 24 Monate), % [95%-KI]	74.6 [56.2; 86.2]	65.9 [52.7; 76.3]	76.7 [66.8; 84.0]	74.9 [38.8; 91.5]
Progressionsfreie Überlebensrate (≥ 24 Monate), % [95%-KI]	41.8 [10.5; 71.4]	43.5 [30.6; 55.7]	61.4 [48.0; 72.4]	35.3 [6.9; 66.8]

Program location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/adhoc1.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/OS_PFS_24mth.xls

Tabelle 012: Ergebnisse für den Endpunkt Zeit bis zum Ansprechen aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	Selpercatinib Subpopulation B – MTC (N=143)
Objektive Ansprechrates (CR+PR), n (%)	
Objektive Ansprechrates [95%-KI] ^{a,b}	99 (69,2) [61,0; 76,7]
CR: komplettes Ansprechen; KI: Konfidenzintervall; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); PR: partielles Ansprechen; RET: Rearranged during Transfection. Der Prozentsatz wird basierend auf der Anzahl an Patienten in der Spaltenüberschrift als Nenner berechnet. a: Die objektive Ansprechrates (%) ist definiert als der Anteil an Patienten mit bestätigtem komplettem Ansprechen (CR) oder partiellen Ansprechen (PR) als bestes Gesamtansprechen. Das Ansprechen wurde durch eine erneute Untersuchung nach mindestens 28 Tagen bestätigt. b: Das 95% Konfidenzintervall wurde mittels Clopper-Pearson Methode bestimmt. Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_orr_ge_2.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T012_orr_mtc_eff_modified_for_PDF.rtf

Tabelle 014: Ergebnisse für die Endpunkte Bestes Gesamtansprechen und Krankheitskontrollrate aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	Selpercatinib
	Subpopulation B – MTC (N=143)
Bestes Gesamtansprechen, n (%)	
Komplettes Ansprechen (CR)	6 (4,2)
Partielles Ansprechen (PR)	93 (65,0)
Stabile Erkrankung (SD)	35 (24,5)
SD*	31 (21,7)
Progressive Erkrankung (PD)	2 (1,4)
Nicht auswertbar	7 (4,9)
Krankheitskontrollrate, n (%)^a	
Krankheitskontrollrate [95%-KI] ^{a,b}	130 (90,9) [85,0; 95,1]
CR: komplettes Ansprechen; KI: Konfidenzintervall; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); PD: progressive Erkrankung; PR: partielles Ansprechen; RET: Rearranged during Transfection; SD: stabile Erkrankung. Der Prozentsatz wird basierend auf der Anzahl an Patienten in der Spaltenüberschrift als Nenner berechnet. a: Die Krankheitskontrollrate [%] ist definiert als Anteil an Patienten mit bestätigtem komplettem Ansprechen (CR), partiellen Ansprechen (PR) oder stabiler Erkrankung über mindestens 16 Wochen (SD*) als bestes Gesamtansprechen. b: Das 95% Konfidenzintervall wurde mittels Clopper-Pearson Methode bestimmt. Der Prozentsatz wird basierend auf der Anzahl an Patienten in der Spaltenüberschrift als Nenner berechnet. Stabile Erkrankung wurde gemessen vom Zeitpunkt der ersten Gabe der Prüfmedikation bis zum ersten Auftreten einer Krankheitsprogression. Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_borcbr_ge_2.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T014_borcbr_mtc_eff_modified_for_PDF.rtf

Tabelle 009: Ergebnisse für den Endpunkt Dauer des Ansprechens aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

	Selpercatinib
Endpunkt	Subpopulation B – MTC (N=143)
Patienten mit Ansprechen, n ^{a,c}	99
Status des Ansprechens, n (%) ^{b,c}	
Progression	17 (17,2)
Tod (ohne vorherigen Progress)	1 (1,0)
Zensiert	81 (81,8)
Grund für Zensierung, n (%)	
Am Leben ohne Progress ^d	75 (75,8)
Anschl. Krebstherapie oder krebsbedingte Operation ohne Progress ^d	5 (5,1)
Abbruch der Studie ohne Progress ^d	1 (1,0)
Dauer des Ansprechens	
Dauer des Ansprechens (Monate), Median [95% KI] ^{a,c,f,g}	NE [19,1; NE]
Dauer des Ansprechens nach Kategorie, n (%) ^{a,c}	
< 6 Monate	32 (32,3)
≥ 6 bis < 12 Monate	31 (31,3)
≥ 12 bis < 18 Monate	24 (24,2)
≥ 18 bis < 24 Monate	8 (8,1)

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_dor_ge_2.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T009_dor_mtc_eff_modified_for_PDF.rtf

Tabelle 009: Ergebnisse für den Endpunkt Dauer des Ansprechens aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	Selpercatinib Subpopulation B – MTC (N=143)
≥ 24 Monate	4 (4,0)
KI: Konfidenzintervall; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); RET: Rearranged during Transfection. Der Prozentsatz wird basierend auf der Anzahl an Patienten mit bestätigtem kompletten Ansprechen (CR) oder partiellen Ansprechen (PR) als bestes Gesamtansprechen als Nenner berechnet. a: Ansprechen ist definiert als Erreichen eines bestätigten kompletten (CR) oder partiellen Ansprechens (PR) als bestes Ansprechen. b: Status des Ansprechens basiert auf der letzten Krankheitsbewertung des Patienten vor oder am Tag des Datenschnitts (30. März 2020). c: Bezogen auf Patienten mit bestätigtem kompletten (CR) oder partiellen Ansprechen (PR) als bestes Ansprechen. d: Ohne dokumentierte Krankheitsprogression. e: Beurteilung erfolgte durch ein unabhängiges Expertenkomitee (Independent Review Committee [IRC]) anhand der RECIST Kriterien (Version 1.1). f: Die Schätzung basiert auf der Kaplan-Meier Methode. NE = nicht schätzbar. g: Das 95%-KI wurde mittels Brookmeyer und Crowley Methode berechnet. Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben. Dauer des Ansprechens ist definiert als die Anzahl der Monate von Beginn des bestätigten kompletten Ansprechens (CR) oder partiellen Ansprechens (PR) (je nachdem, was früher auftrat) bis zum Datum der dokumentierten Progression.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_dor_ge_2.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

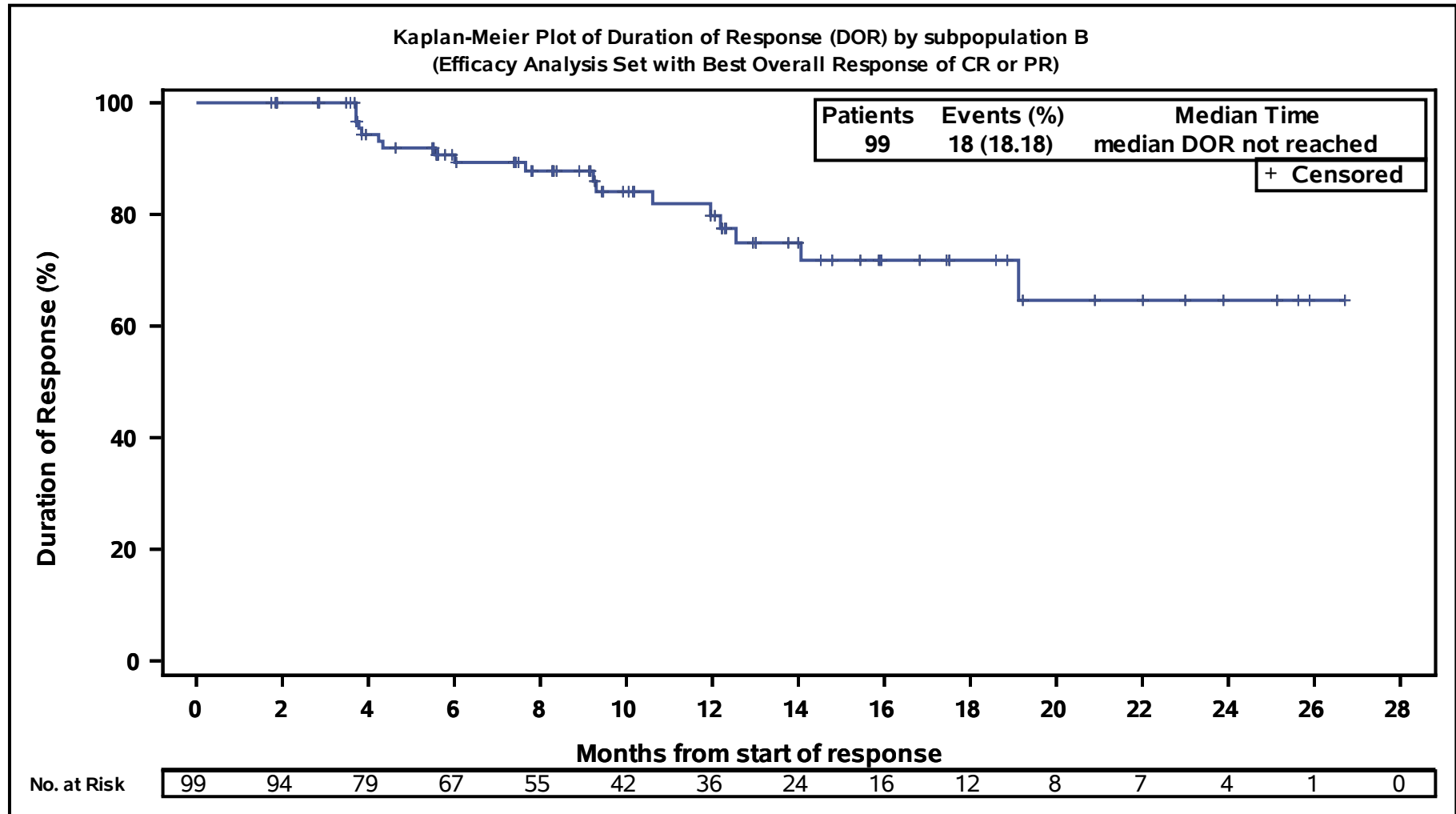
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T009_dor_mtc_eff_modified_for_PDF.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10.sas
 Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F003_1_dor_b_mtc_eff.rtf
 Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Tabelle 011: Ergebnisse für den Endpunkt Zeit bis zum Ansprechen aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	Selpercatinib
	Subpopulation B – MTC (N=143)
Patienten mit Ansprechen, n ^{a,c}	99
Zeit bis zum Ansprechen	
Zeit bis zum Ansprechen (Monate), Median [95%-KI] ^b	3,48 [2,0; 3,7]
Zeit bis zum Ansprechen nach Kategorie, n (%) ^b	
< 2 Monate	39 (39,4)
≥ 2 und < 4 Monate	31 (31,3)
≥ 4 und < 6 Monate	15 (15,2)
≥ 6 und < 9 Monate	6 (6,1)
≥ 9 Monate	8 (8,1)
KI: Konfidenzintervall; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); RET: Rearranged during Transfection. Der Prozentsatz wird basierend auf der Anzahl an Patienten mit bestätigtem komplettem Ansprechen (CR) oder partiellen Ansprechen (PR) als bestes Gesamtansprechen als Nenner berechnet. a: Ansprechen ist definiert als Erreichen eines bestätigten kompletten Ansprechens (CR) oder partiellen Ansprechens (PR) als bestes Ansprechen. b: Analyse basierend auf Daten von Patienten mit bestätigtem komplettem Ansprechen (CR) oder partiellen Ansprechen (PR) als bestes Ansprechen. c: Beurteilung erfolgte durch ein unabhängiges Expertenkomitee (Independent Review Committee [IRC]) anhand der RECIST Kriterien (Version 1.1). Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben. Zeit bis zum Ansprechen ist definiert als Anzahl der Monate zwischen der ersten Dosis der Prüfmedikation und der ersten Dokumentation eines objektiven Ansprechens (komplettes Ansprechen (CR) oder partielles Ansprechen (PR), je nachdem, welches früher auftrat) mit anschließender Bestätigung.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_ttr_ge_2.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T011_ttr_mtc_eff_modified_for_PDF.rtf

Tabelle 030: Compliance-Rate für den Fragebogen EORTC QLQ-C30 in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020)
- Efficacy Analysis Set

	Selpercatinib
	Subpopulation B - MTC
Endpunkt	(N'=84) (N=143)
Gesamtrate^a über alle Zeitpunkte	516/563 (91,7)
Compliance-Rate^b pro geplante Visite	
Baseline	84/143 (58,7)
Zyklus 3, Tag 1	78/143 (54,5)
Zyklus 5, Tag 1	77/143 (53,8)
Zyklus 7, Tag 1	72/143 (50,3)
Zyklus 9, Tag 1	62/143 (43,4)
Zyklus 11, Tag 1	56/143 (39,2)
Zyklus 13, Tag 1	43/143 (30,1)
Zyklus 16, Tag 1	24/143 (16,8)
Zyklus 19, Tag 1	10/143 (7,0)
Zyklus 22, Tag 1	2/143 (1,4)
Visite bei Ende der Behandlung	8/143 (5,6)
EORTC: European Organisation for Research and Treatment of Cancer; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); N': Anzahl der behandelten Patienten mit einem Baseline- und mindestens einem Post-Baseline-Wert; QLQ-C30: Core Quality of Life Questionnaire C30; RET: Rearranged during Transfection. a: Die Gesamtrate wird berechnet, in dem die Gesamtzahl an Patienten, für die der EORTC QLQ-C30 bei jeder Visite erhoben wurde, durch die Gesamtzahl an Patienten, die bei jeder Visite unter Behandlung waren, geteilt wird. b: Die Compliance-Rate ist definiert als der prozentuale Anteil der Patienten, für die der EORTC QLQ-C30 bei der entsprechenden Visite erhoben wurde, an den Patienten, die bei dieser Visite unter Behandlung waren. Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqcomp_mtc_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T030_sp_qlqcomp_mtc_eff_mod_for_PDF.rtf

Tabelle 031: Ergebnisse für die Zeit bis zur ersten Verbesserung bzw. Verschlechterung der Symptome gemessen anhand des EORTC QLQ-C30 in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020)
- Efficacy Analysis Set

Endpunkt	Selpercatinib
	Subpopulation B - MTC (N') (N=143)
EORTC QLQ-C30 – Symptomskalen	
Fatigue	84
Patienten mit Ereignis	
Verbesserung, n (%)	66 (78,6)
Zensierte Patienten, n (%)	18 (21,4)
Verschlechterung, n (%)	34 (40,5)
Zensierte Patienten, n (%)	50 (59,5)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] ^{a,b}	2,0 [1,91; 3,71]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] ^{a,b}	13,9 [11,04; NE]
Schmerzen	84
Patienten mit Ereignis	
Verbesserung, n (%)	51 (60,7)
Zensierte Patienten, n (%)	33 (39,3)
Verschlechterung, n (%)	38 (45,2)
Zensierte Patienten, n (%)	46 (54,8)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] ^{a,b}	2,8 [1,97; 12,45]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] ^{a,b}	13,8 [7,39; NE]
Übelkeit und Erbrechen	84
Patienten mit Ereignis	
Verbesserung, n (%)	24 (28,6)
Zensierte Patienten, n (%)	60 (71,4)
Verschlechterung, n (%)	28 (33,3)
Zensierte Patienten, n (%)	56 (66,7)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [11,17; NE]
Dyspnoe	84
Patienten mit Ereignis	
Verbesserung, n (%)	33 (39,3)
Zensierte Patienten, n (%)	51 (60,7)
Verschlechterung, n (%)	31 (36,9)
Zensierte Patienten, n (%)	53 (63,1)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] ^{a,b}	NE [6,21; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [9,69; NE]
Schlaflosigkeit	84
Patienten mit Ereignis	
Verbesserung, n (%)	48 (57,1)
Zensierte Patienten, n (%)	36 (42,9)
Verschlechterung, n (%)	29 (34,5)
Zensierte Patienten, n (%)	55 (65,5)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] ^{a,b}	5,7 [3,61; NE]

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_tte_mtc_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T031_sp_qlqc30_tte_mtc_eff_mod_for_PDF.rtf

Tabelle 031: Ergebnisse für die Zeit bis zur ersten Verbesserung bzw. Verschlechterung der Symptome gemessen anhand des EORTC QLQ-C30 in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020)
- Efficacy Analysis Set

Endpunkt	Selpercatinib
	Subpopulation B - MTC (N') (N=143)
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [11,07; NE]
Appetitverlust	84
Patienten mit Ereignis	
Verbesserung, n (%)	40 (47,6)
Zensierte Patienten, n (%)	44 (52,4)
Verschlechterung, n (%)	23 (27,4)
Zensierte Patienten, n (%)	61 (72,6)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] ^{a,b}	NE [2,96; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [16,13; NE]
Verstopfung	84
Patienten mit Ereignis	
Verbesserung, n (%)	15 (17,9)
Zensierte Patienten, n (%)	69 (82,1)
Verschlechterung, n (%)	34 (40,5)
Zensierte Patienten, n (%)	50 (59,5)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] ^{a,b}	13,8 [8,34; NE]
Diarrhoe	84
Patienten mit Ereignis	
Verbesserung, n (%)	49 (58,3)
Zensierte Patienten, n (%)	35 (41,7)
Verschlechterung, n (%)	25 (29,8)
Zensierte Patienten, n (%)	59 (70,2)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] ^{a,b}	3,6 [1,91; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [13,90; NE]
EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); N': Anzahl der behandelten Patienten mit einem Baseline- und mindestens einem Post-Baseline-Wert; QLQ-C30: Core Quality of Life Questionnaire C30; RET: Rearranged during Transfection. a: Die Schätzung basiert auf der Kaplan-Meier Methode. NE = nicht schätzbar. b: Das 95%-KI wurde mittels Brookmeyer und Crowley Methode berechnet. Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben. Verbesserung ist definiert als Anstieg im jeweiligen EORTC QLQ-C30 Score um ≥ 10 Punkte gegenüber Baseline. Verschlechterung ist definiert als Reduktion im jeweiligen EORTC QLQ-C30 Score um ≥ 10 Punkte gegenüber Baseline. Zeit bis zur ersten Verbesserung bzw. Verschlechterung ist definiert als Anzahl der Monate zwischen der ersten Dosis der Prüfmedikation und dem ersten Auftreten einer Verbesserung bzw. Verschlechterung in den jeweiligen Symptomskalen.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_tte_mtc_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T031_sp_qlqc30_tte_mtc_eff_mod_for_PDF.rtf

Tabelle 031: Ergebnisse für die Zeit bis zur ersten Verbesserung bzw. Verschlechterung der Symptome gemessen anhand des EORTC QLQ-C30 in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020)
- Efficacy Analysis Set

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_tte_mtc_ge.sas
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location:
/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T031_sp_qlqc30_tte_mtc_eff_mod_for_PDF.rtf

Tabelle 032: Ergebnisse für die Zeit bis zur ersten Verbesserung bzw. Verschlechterung der gesundheitsbezogenen Lebensqualität gemessen anhand des EORTC QLQ-C30 in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020)
- Efficacy Analysis Set

Endpunkt	Selpercatinib
	Subpopulation B - MTC (N') (N=143)
EORTC QLQ-C30 - Globaler Gesundheitsstatus	84
Patienten mit Ereignis	
Verbesserung, n (%)	54 (64,3)
Zensierte Patienten, n (%)	30 (35,7)
Verschlechterung, n (%)	28 (33,3)
Zensierte Patienten, n (%)	56 (66,7)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] ^{a,b}	3,7 [2,00; 7,36]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [11,79; NE]
EORTC QLQ-C30 – Funktionsskalen	
Physische Funktion	84
Patienten mit Ereignis	
Verbesserung, n (%)	38 (45,2)
Zensierte Patienten, n (%)	46 (54,8)
Verschlechterung, n (%)	27 (32,1)
Zensierte Patienten, n (%)	57 (67,9)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] ^{a,b}	NE [3,71; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] ^{a,b}	16,8 [11,79; NE]
Emotionale Funktion	84
Patienten mit Ereignis	
Verbesserung, n (%)	40 (47,6)
Zensierte Patienten, n (%)	44 (52,4)
Verschlechterung, n (%)	24 (28,6)
Zensierte Patienten, n (%)	60 (71,4)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] ^{a,b}	NE [3,71; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [11,79; NE]
Rollenfunktion	84
Patienten mit Ereignis	
Verbesserung, n (%)	50 (59,5)
Zensierte Patienten, n (%)	34 (40,5)
Verschlechterung, n (%)	28 (33,3)
Zensierte Patienten, n (%)	56 (66,7)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] ^{a,b}	3,7 [1,97; 9,23]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [13,86; NE]
Kognitive Funktion	84
Patienten mit Ereignis	
Verbesserung, n (%)	35 (41,7)
Zensierte Patienten, n (%)	49 (58,3)
Verschlechterung, n (%)	39 (46,4)
Zensierte Patienten, n (%)	45 (53,6)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] ^{a,b}	NE [5,85; NE]

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_tte_mtc_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

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Tabelle 032: Ergebnisse für die Zeit bis zur ersten Verbesserung bzw. Verschlechterung der gesundheitsbezogenen Lebensqualität gemessen anhand des EORTC QLQ-C30 in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020)
- Efficacy Analysis Set

Endpunkt	Selpercatinib
	Subpopulation B - MTC (N') (N=143)
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] ^{a,b}	11,8 [7,43; NE]
Soziale Funktion	84
Patienten mit Ereignis	
Verbesserung, n (%)	52 (61,9)
Zensierte Patienten, n (%)	32 (38,1)
Verschlechterung, n (%)	25 (29,8)
Zensierte Patienten, n (%)	59 (70,2)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] ^{a,b}	3,7 [1,94; 5,78]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); N': Anzahl der behandelten Patienten mit einem Baseline- und mindestens einem Post-Baseline-Wert; QLQ-C30: Core Quality of Life Questionnaire C30; RET: Rearranged during Transfection. a: Die Schätzung basiert auf der Kaplan-Meier Methode. NE = nicht schätzbar. b: Das 95%-KI wurde mittels Brookmeyer und Crowley Methode berechnet. Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben. Verbesserung ist definiert als Anstieg im jeweiligen EORTC QLQ-C30 Score um ≥ 10 Punkte gegenüber Baseline. Verschlechterung ist definiert als Reduktion im jeweiligen EORTC QLQ-C30 Score um ≥ 10 Punkte gegenüber Baseline. Zeit bis zur ersten Verbesserung bzw. Verschlechterung ist definiert als Anzahl der Monate zwischen der ersten Dosis der Prüfmedikation und dem ersten Auftreten einer Verbesserung bzw. Verschlechterung in den jeweiligen Symptomskalen.	

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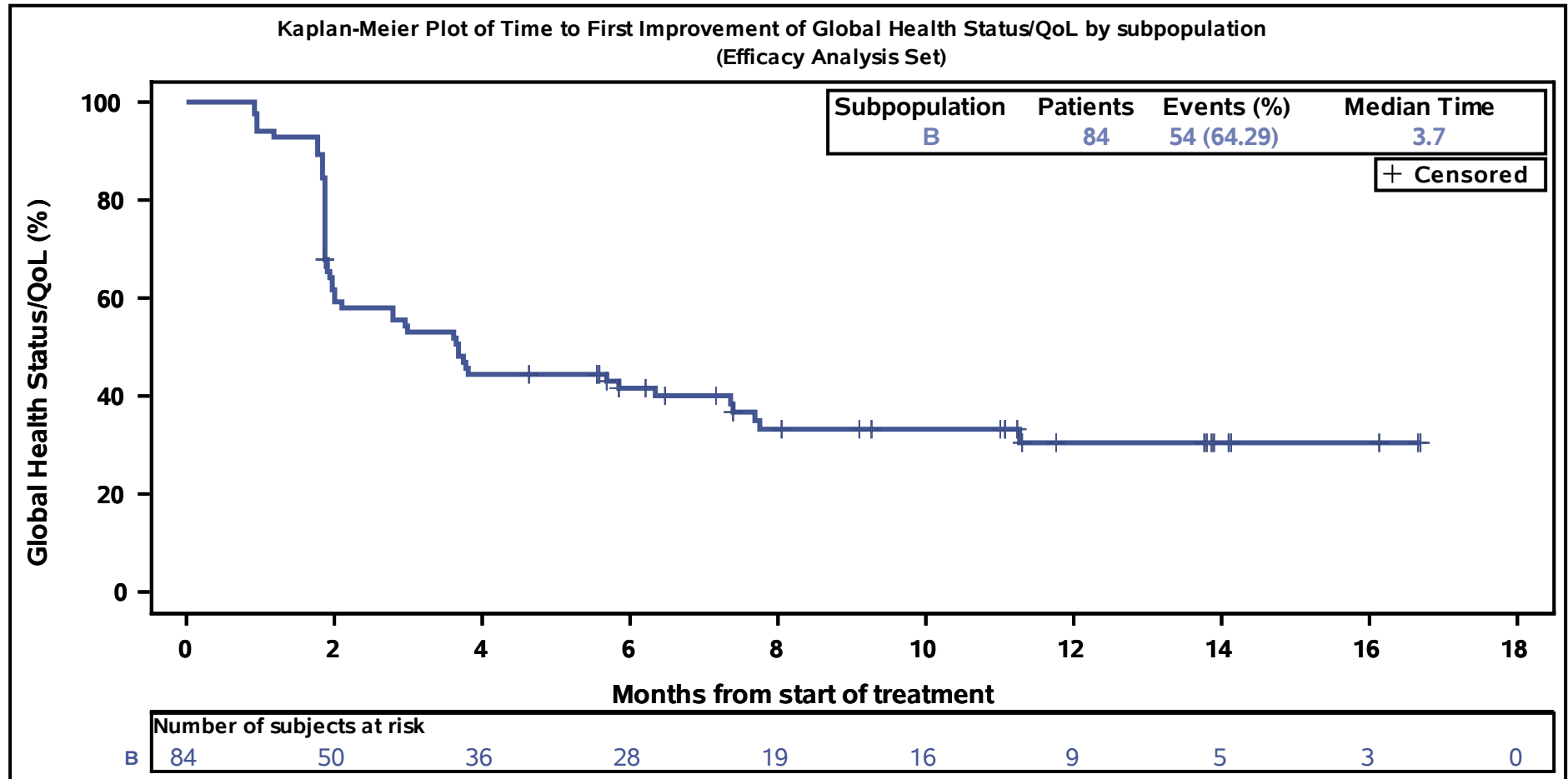
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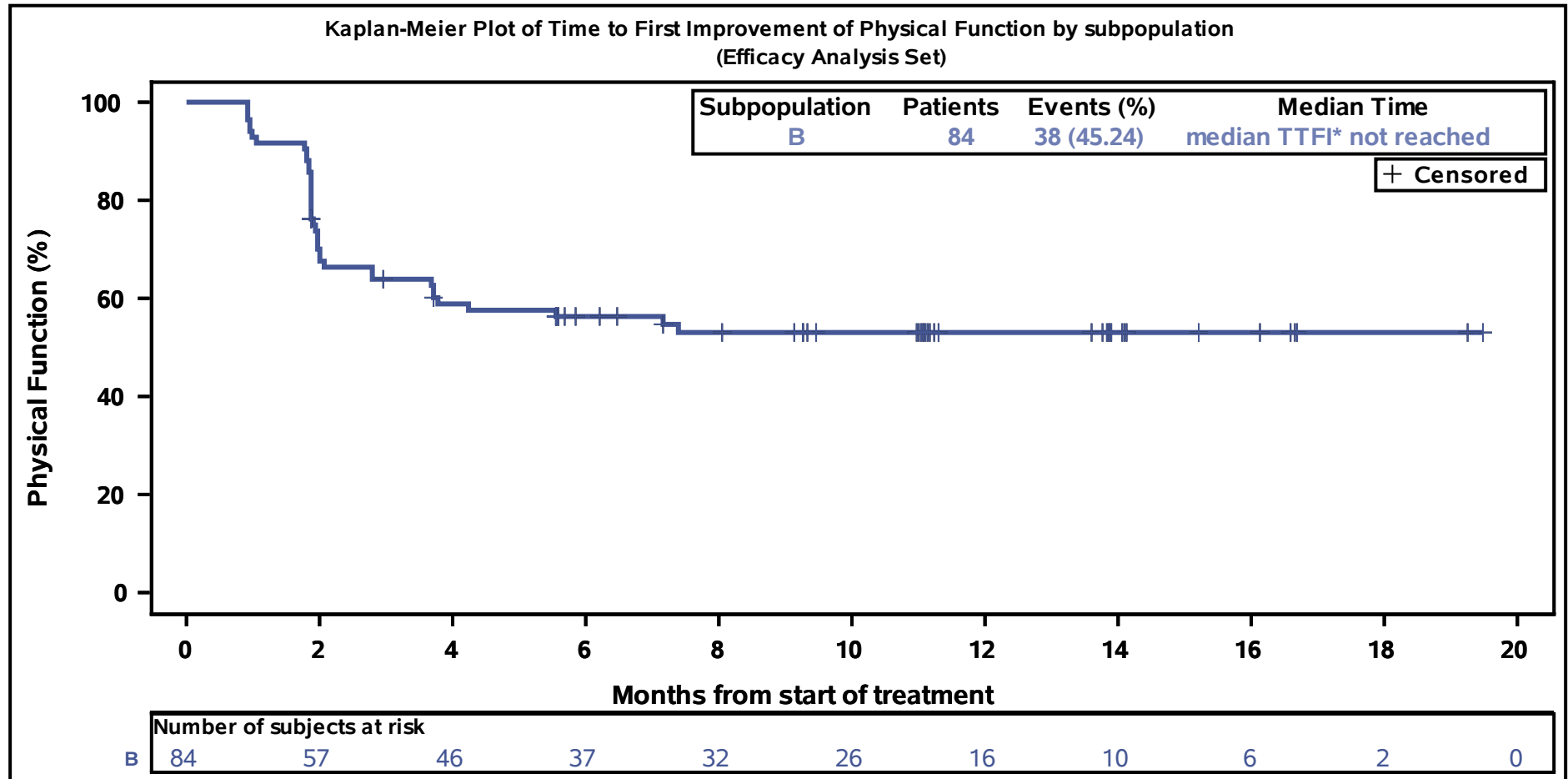
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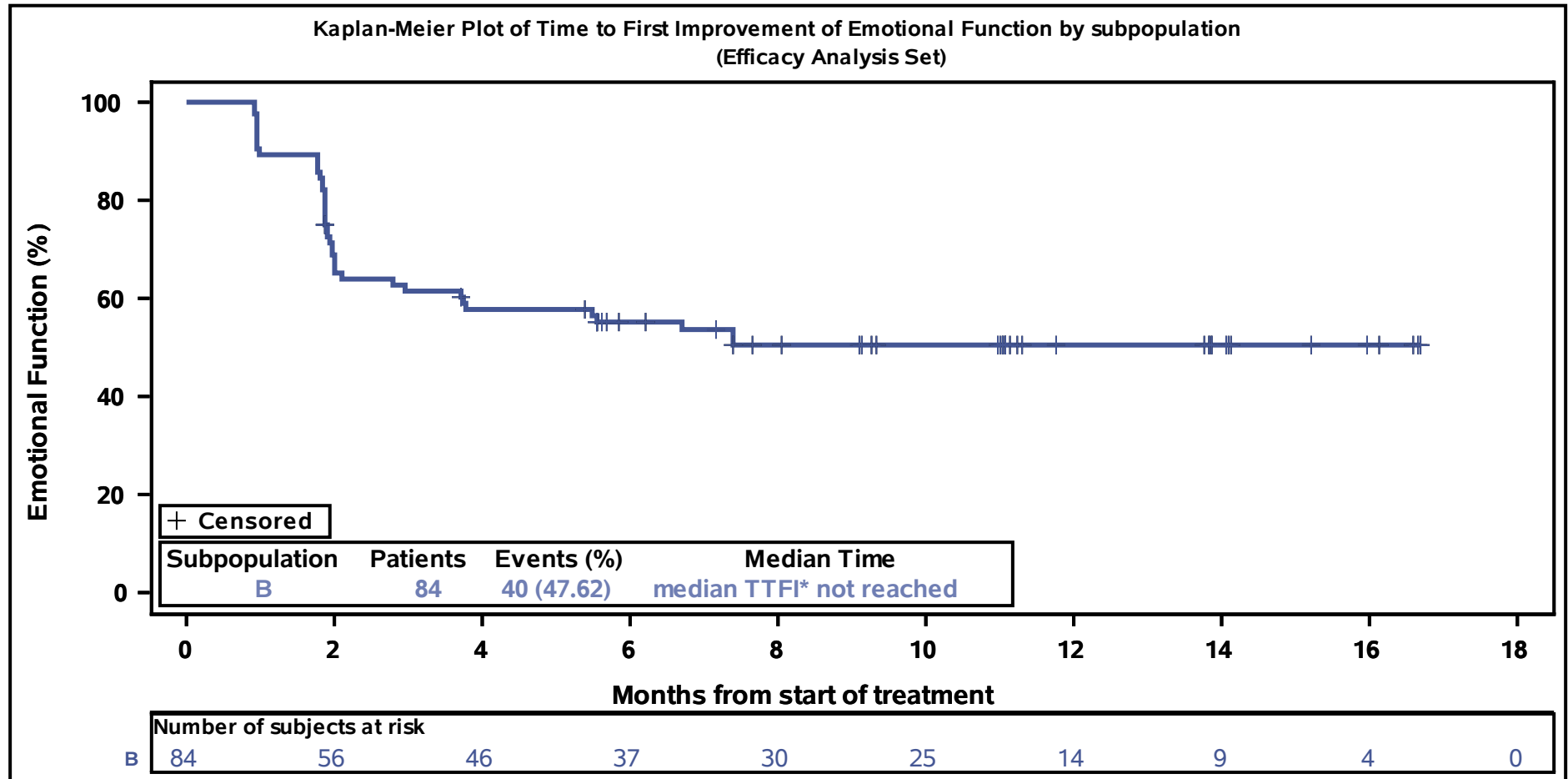
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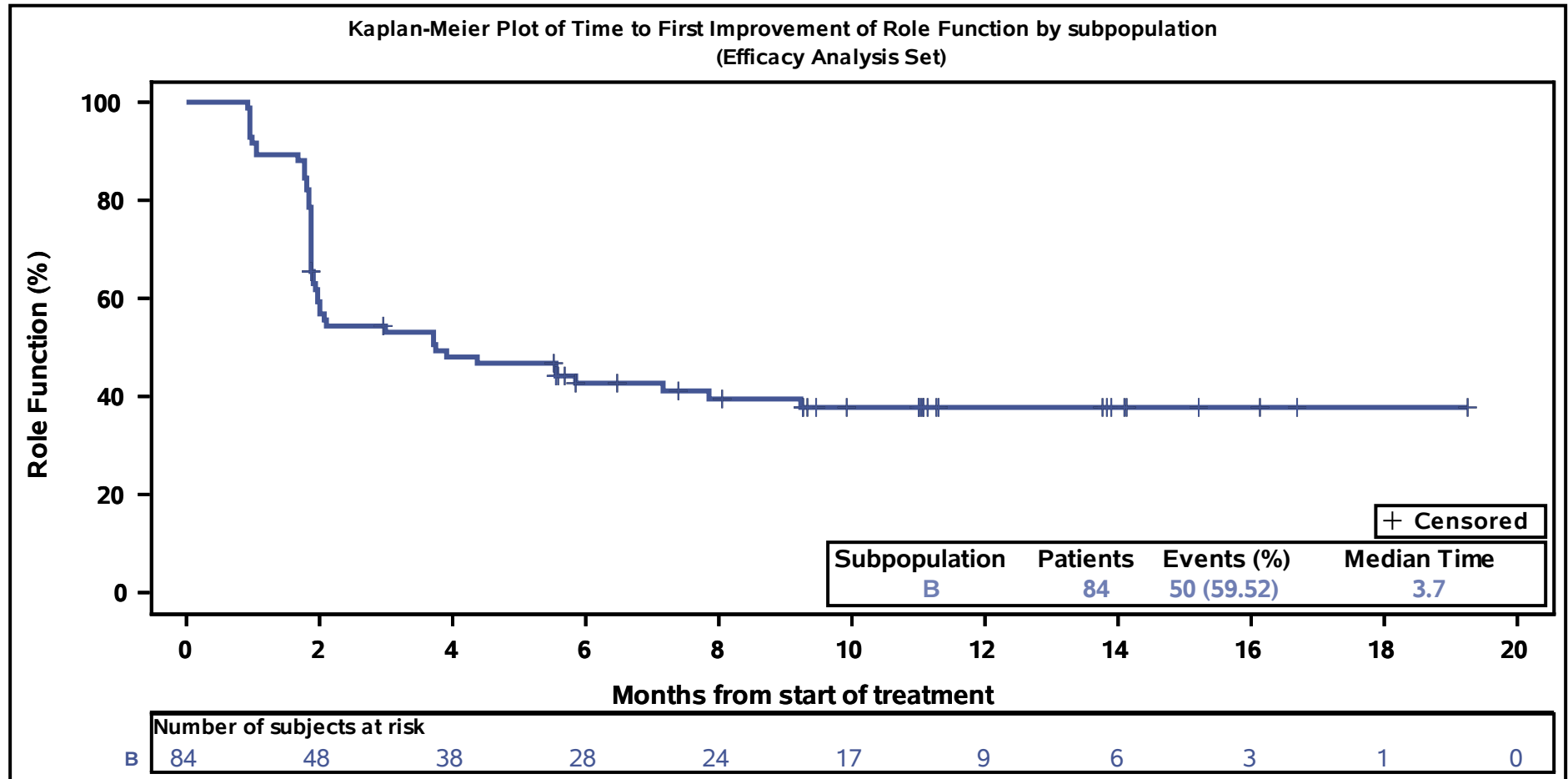
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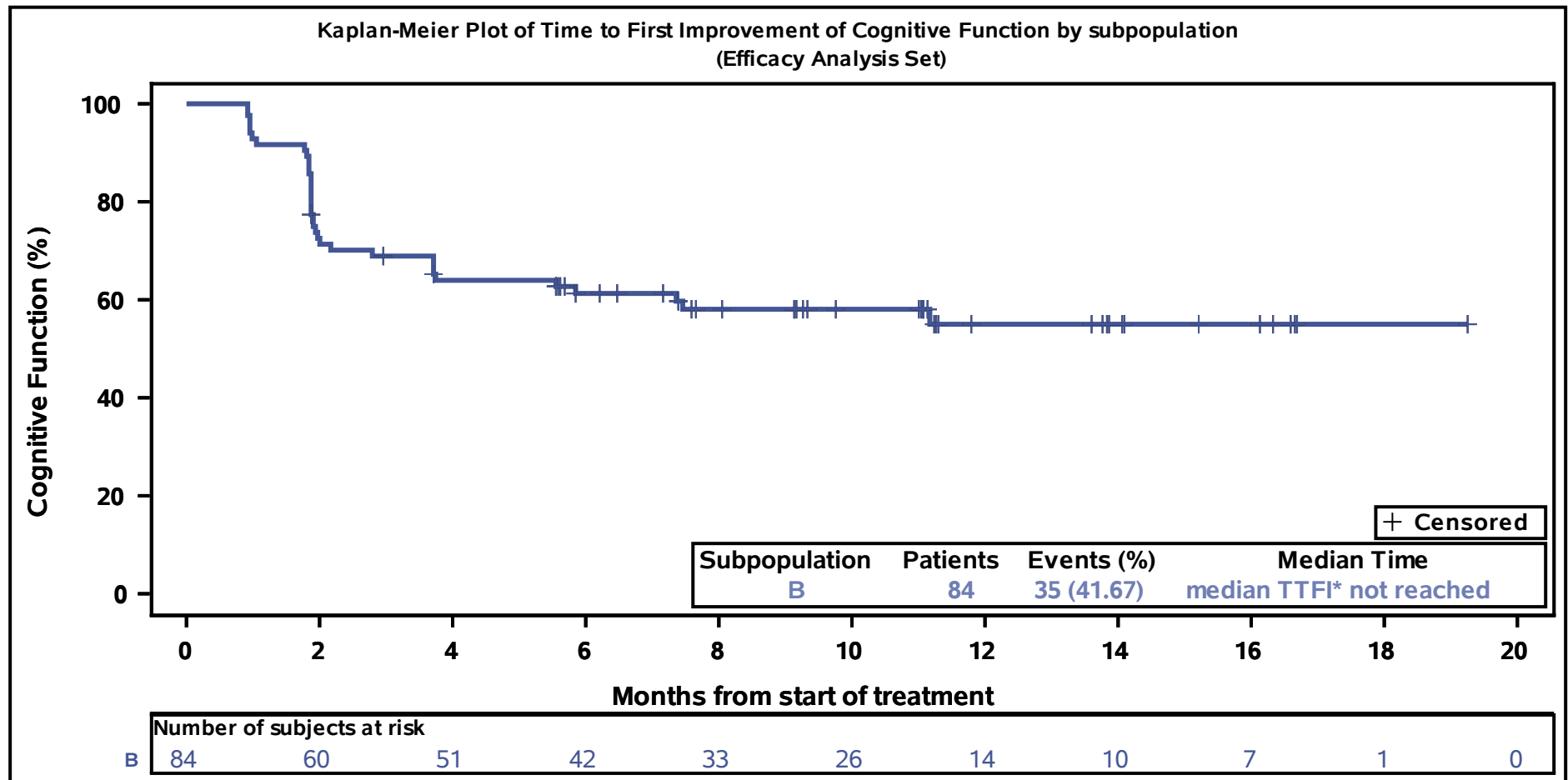
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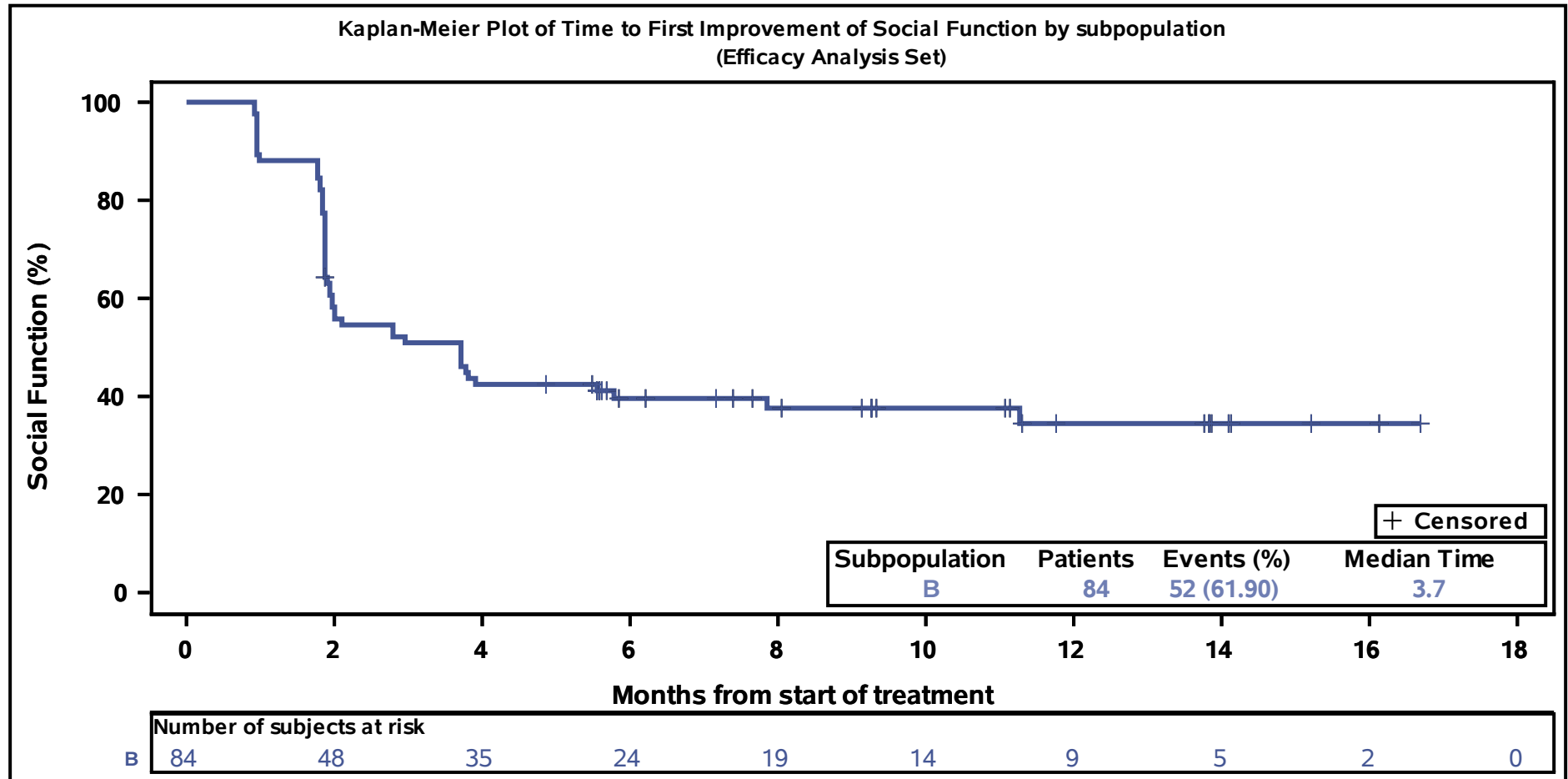
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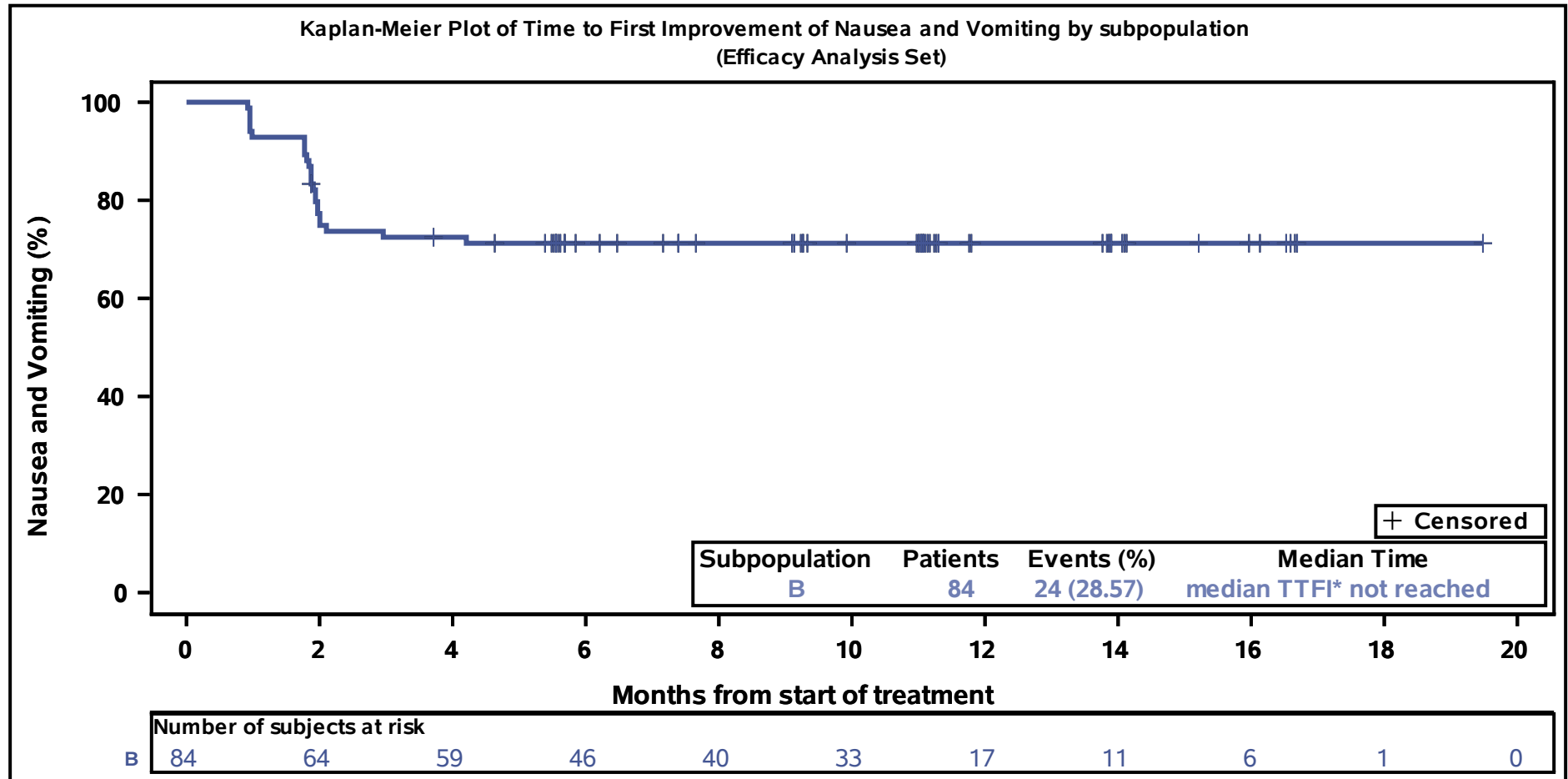
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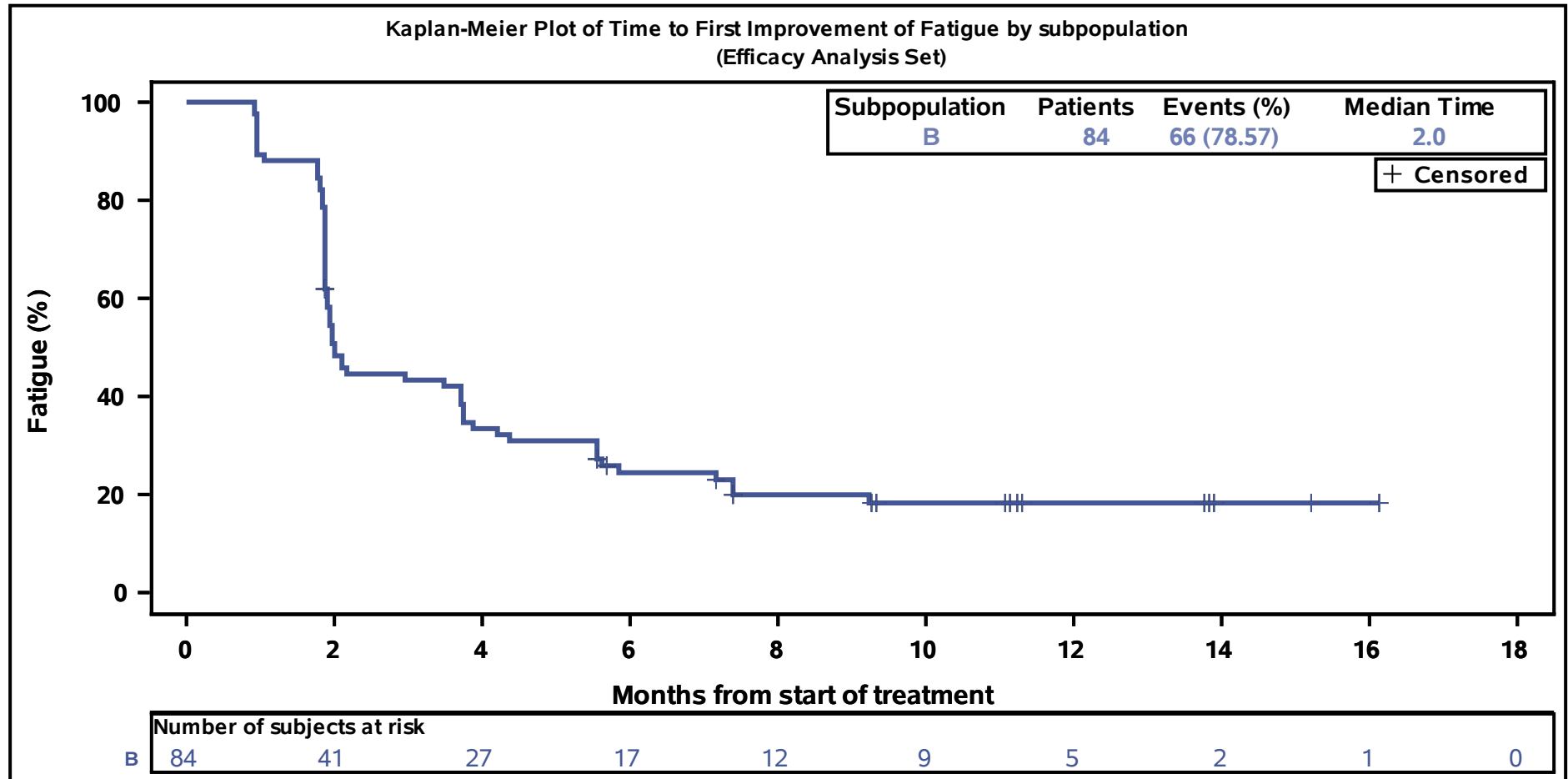
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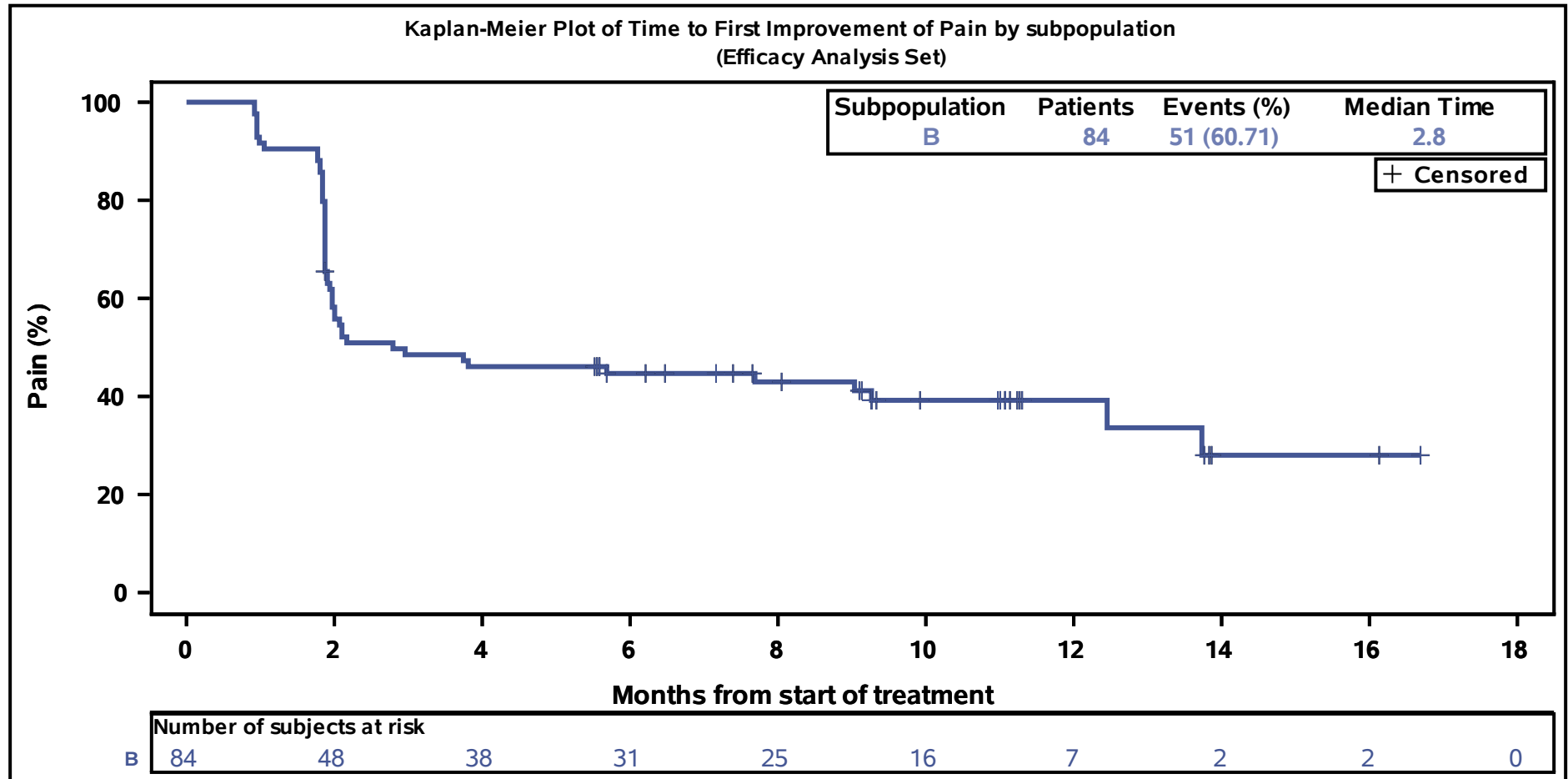
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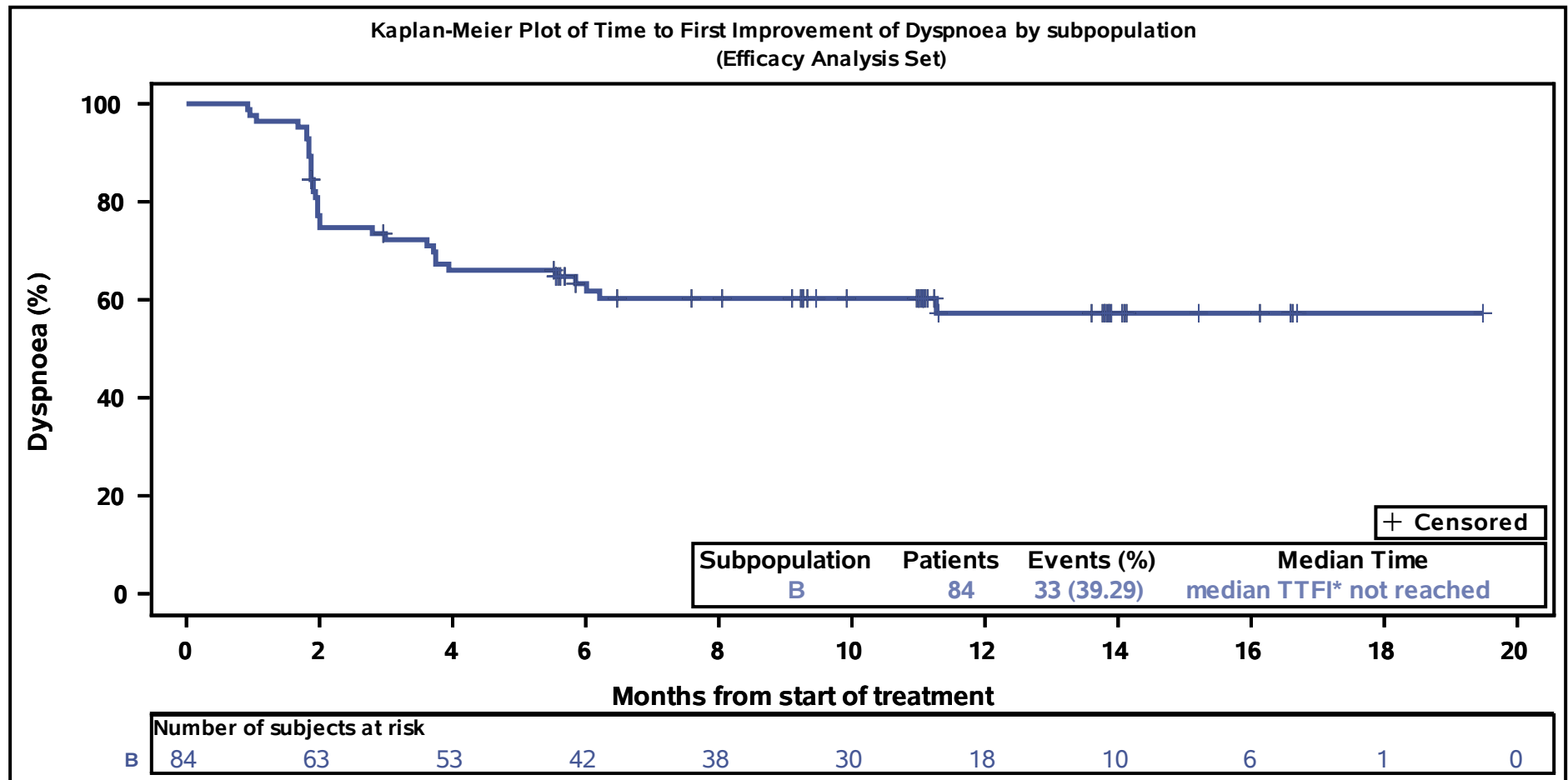
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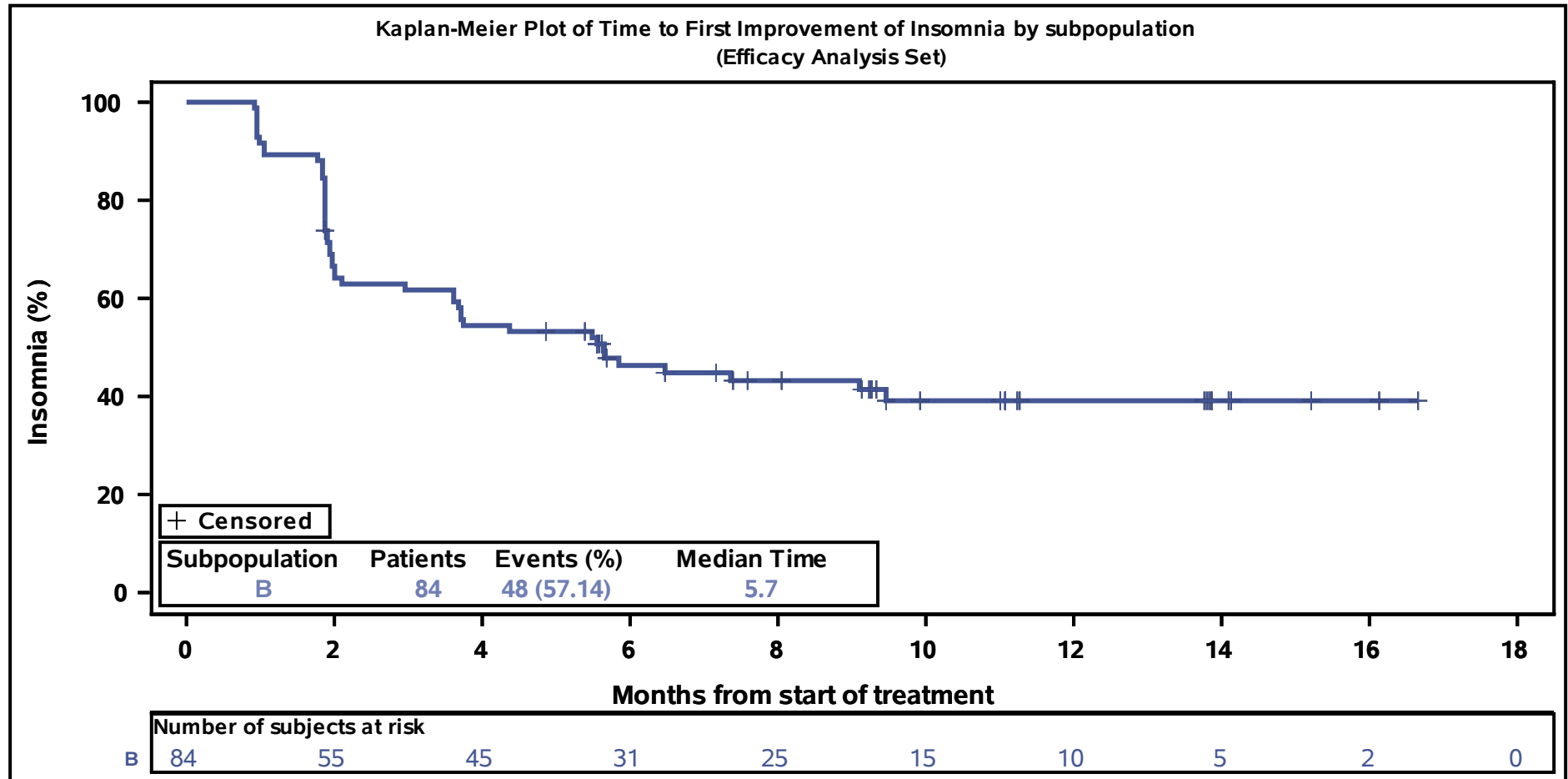
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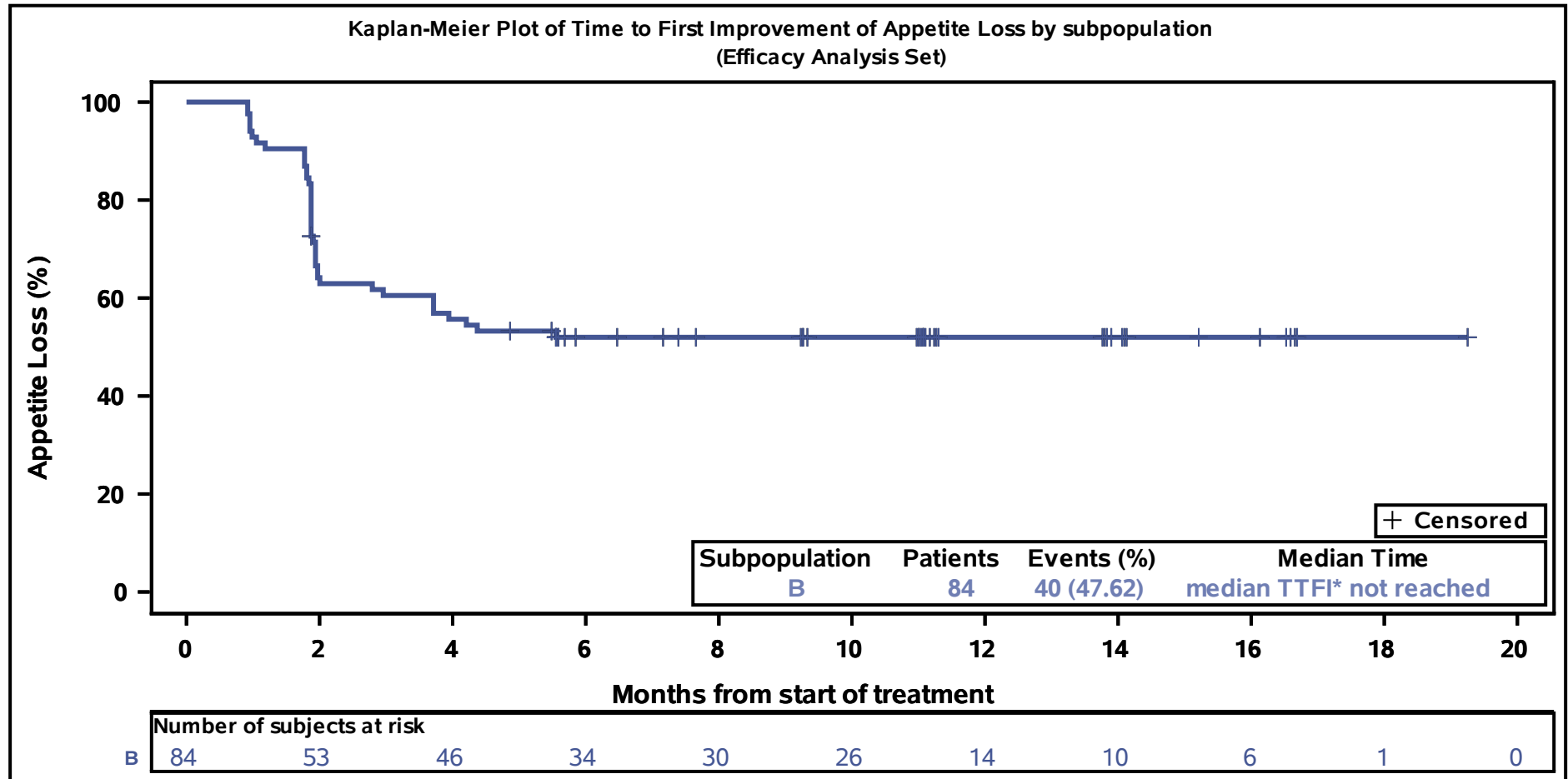
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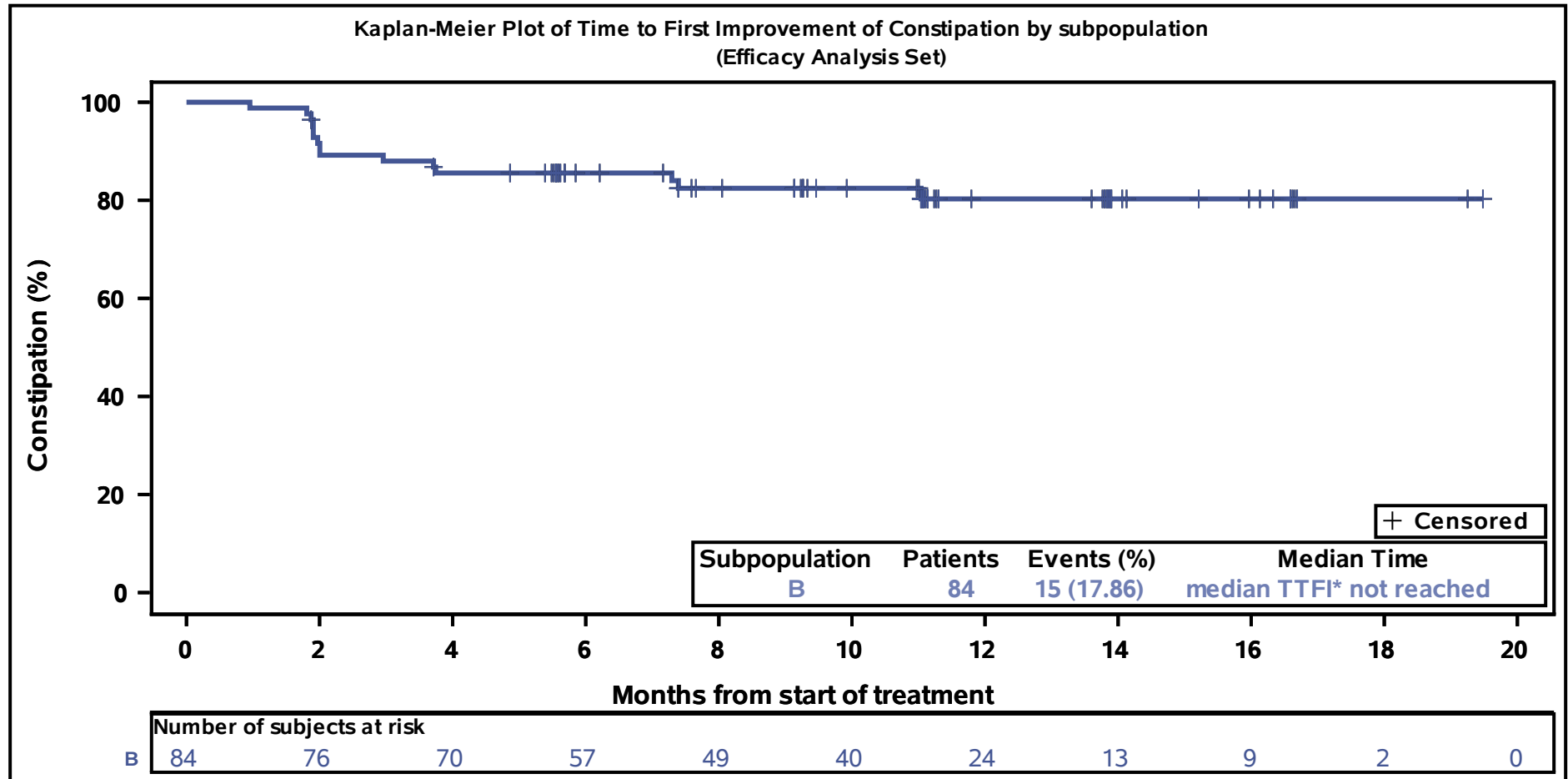
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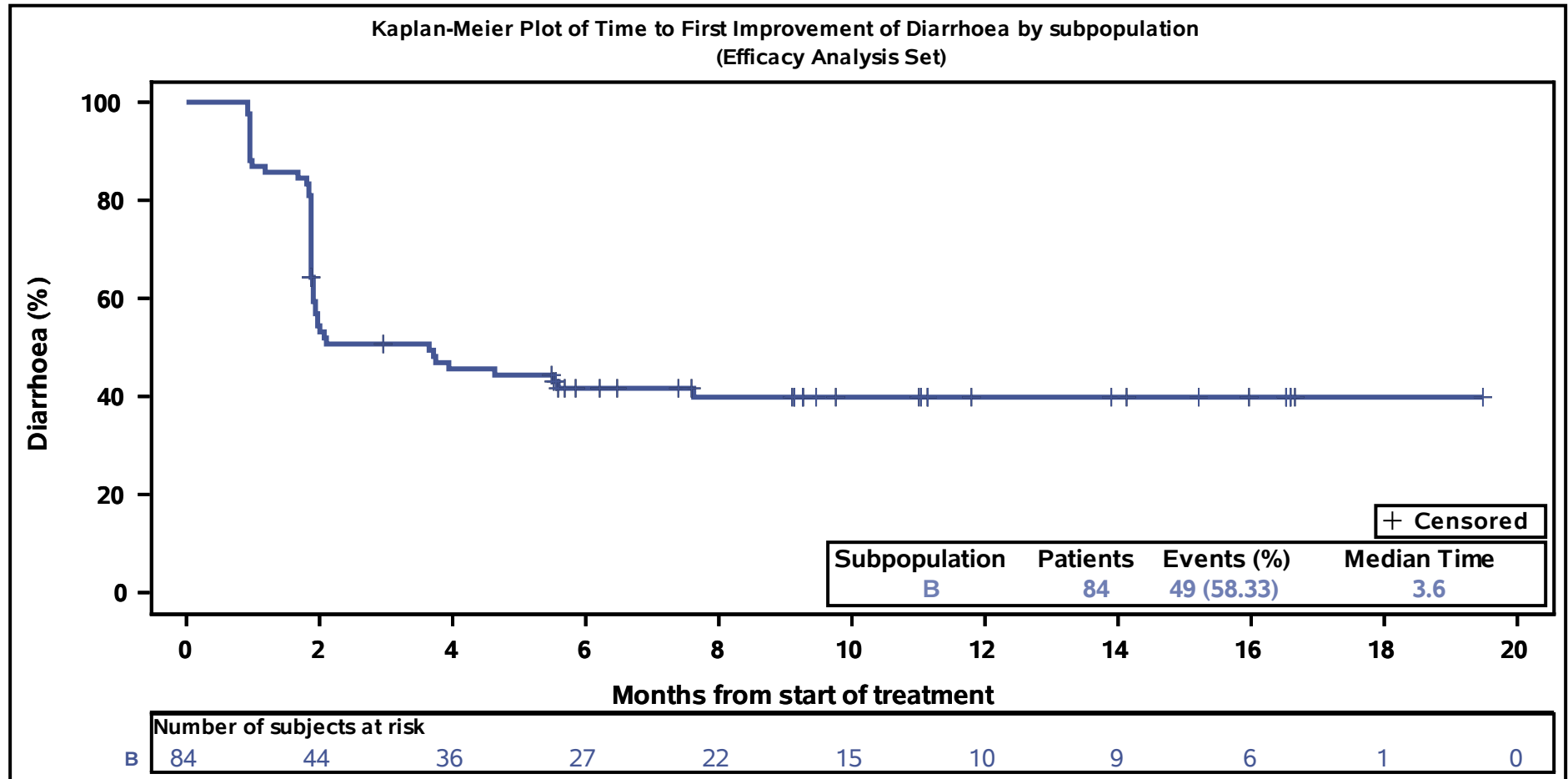
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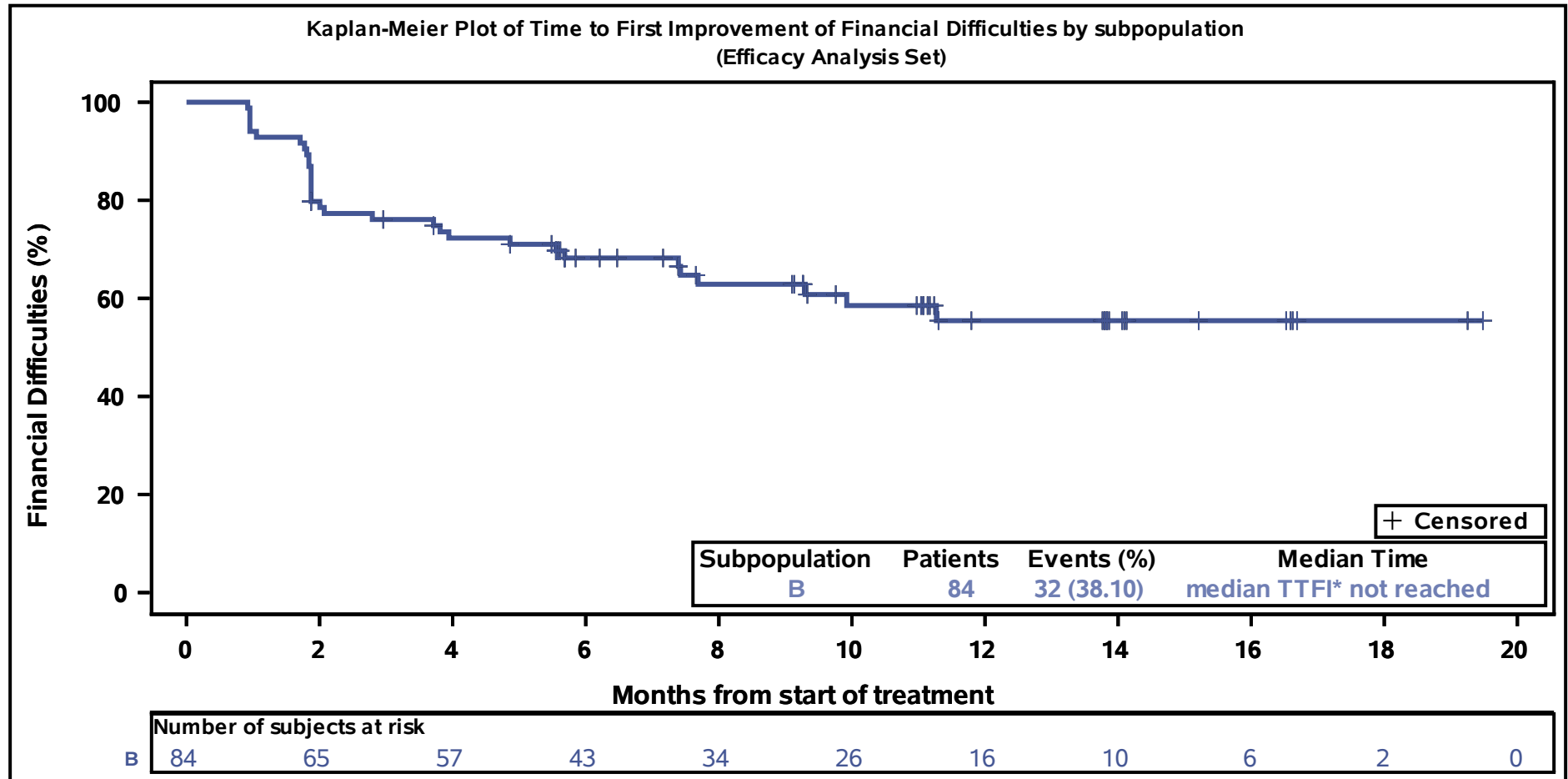
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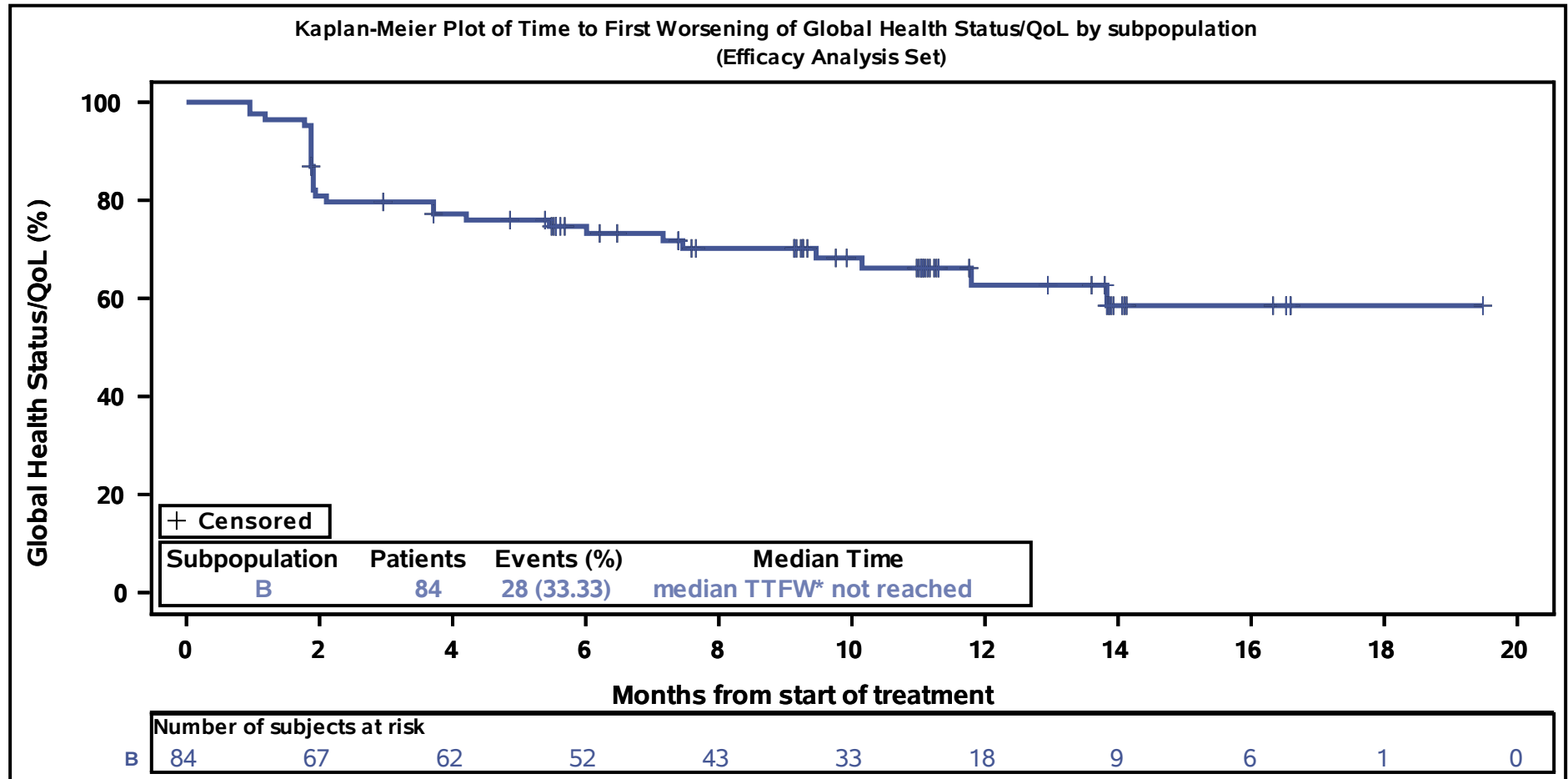
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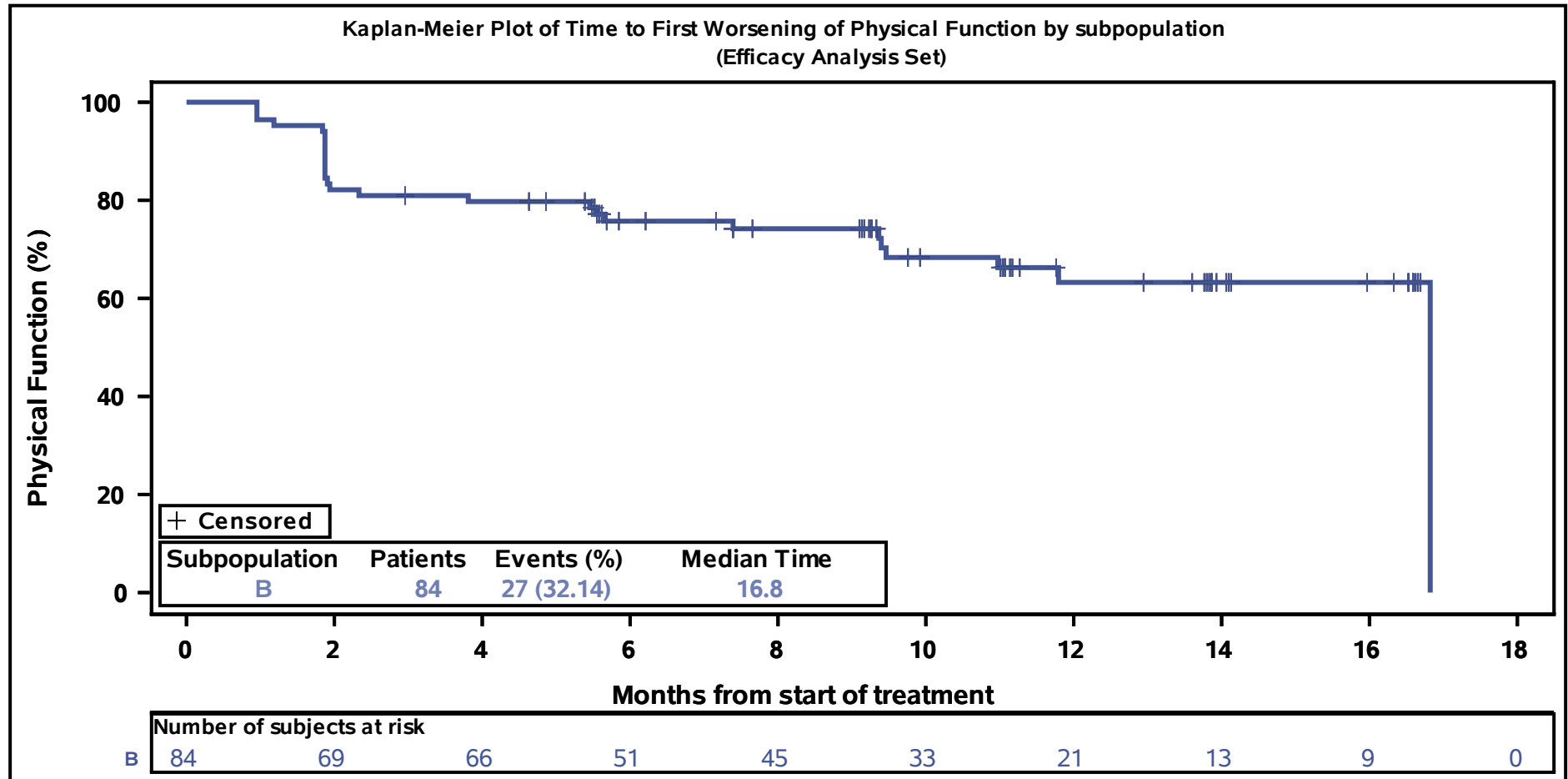
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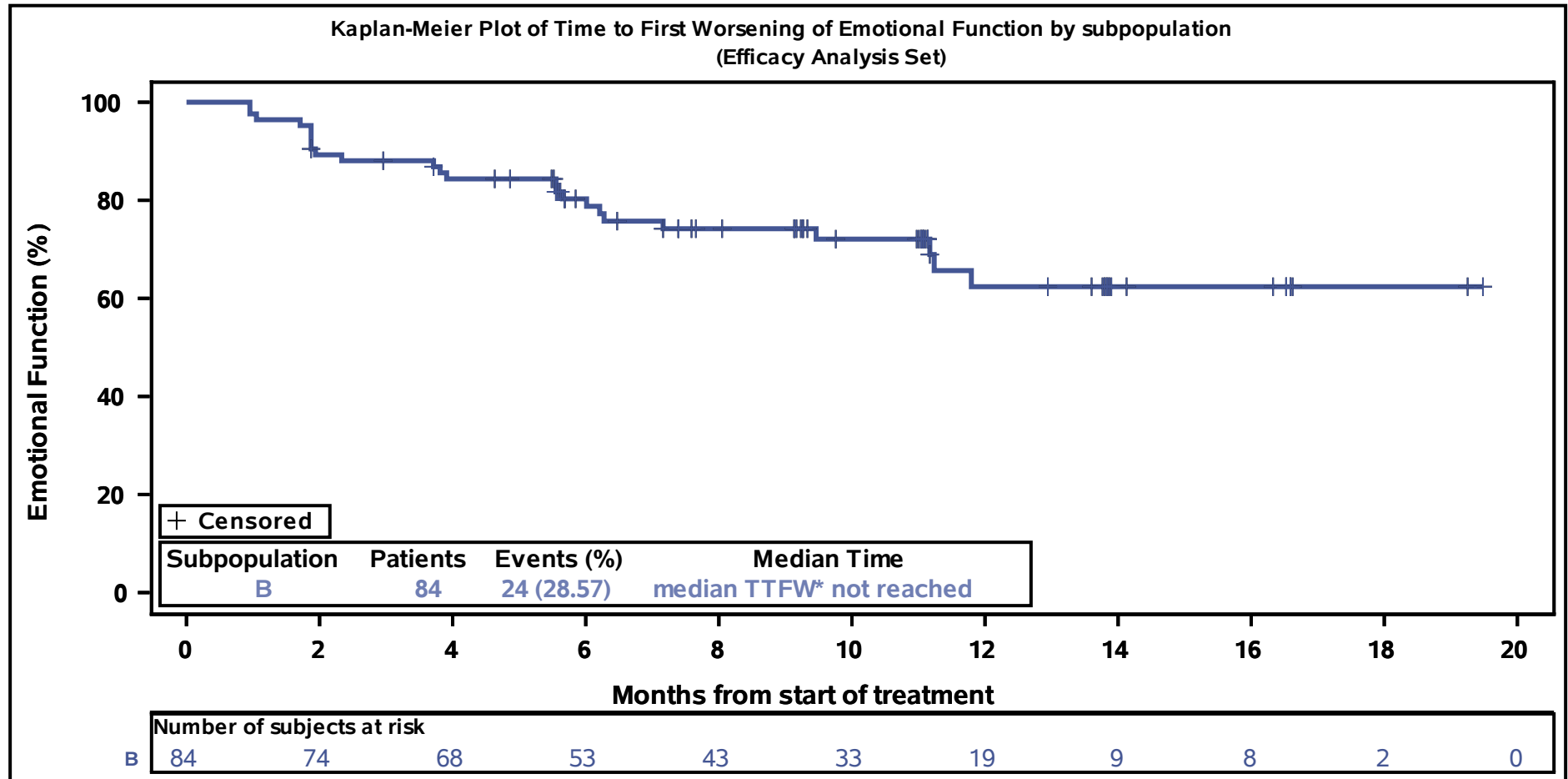
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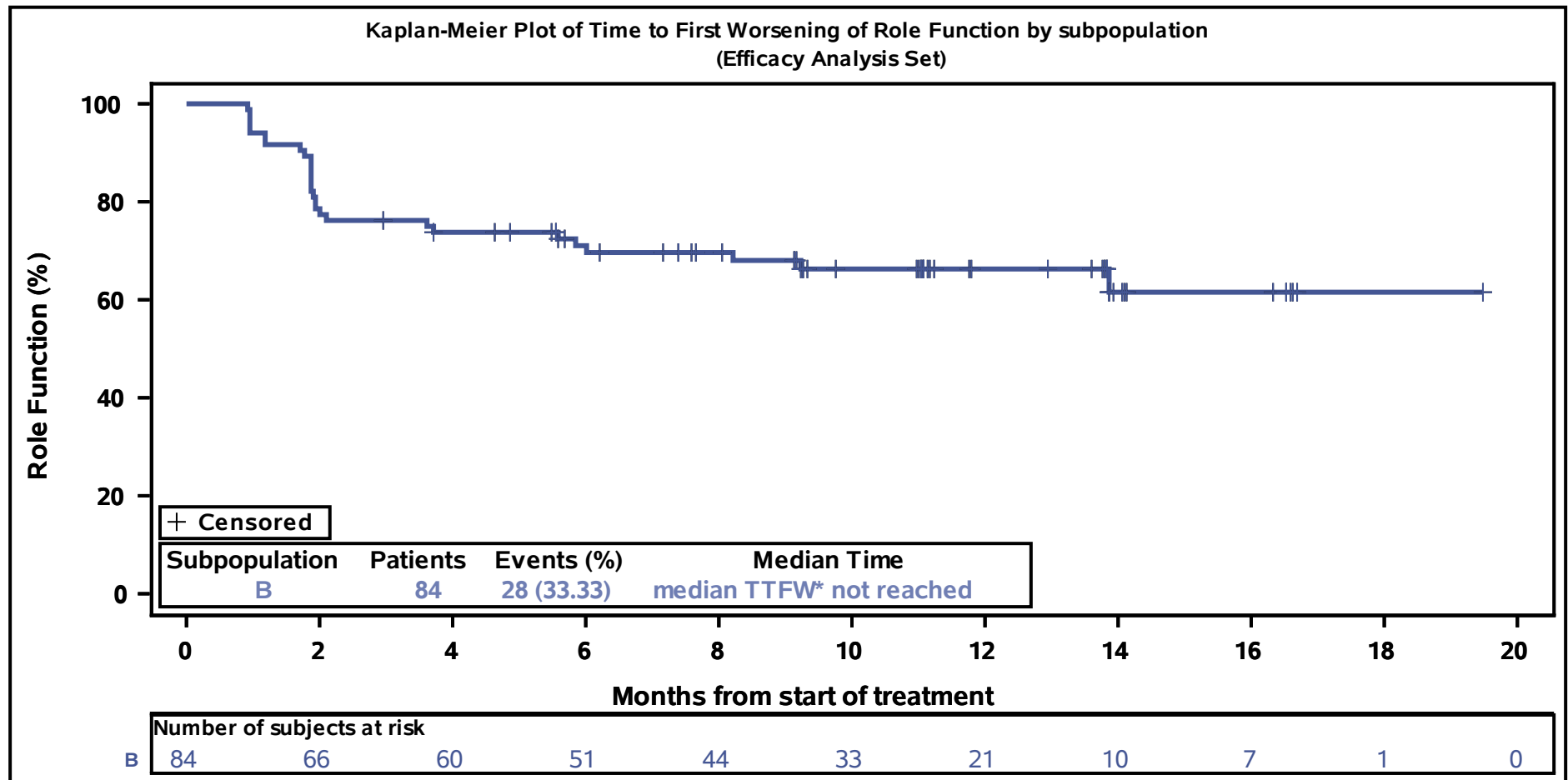
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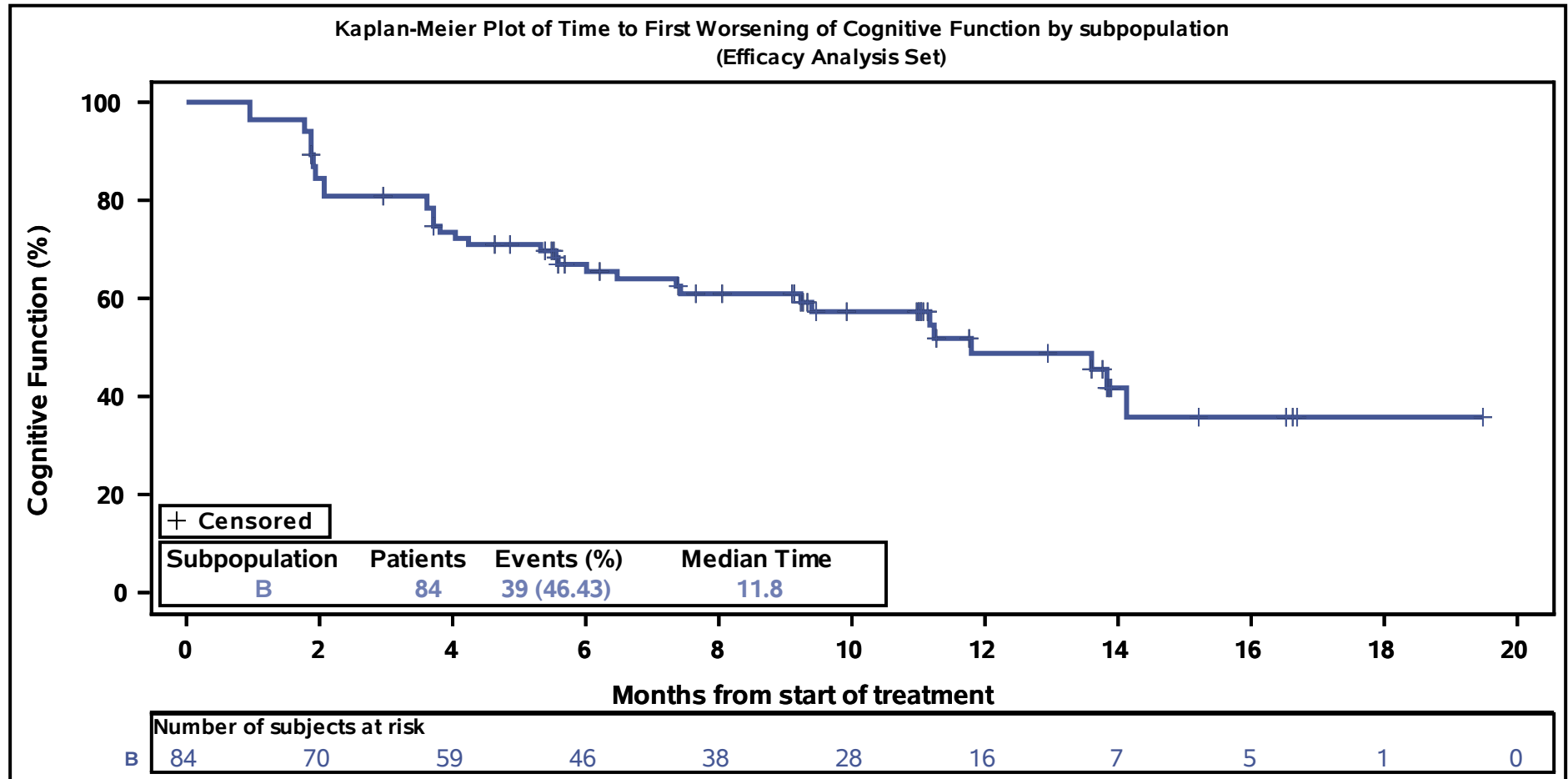
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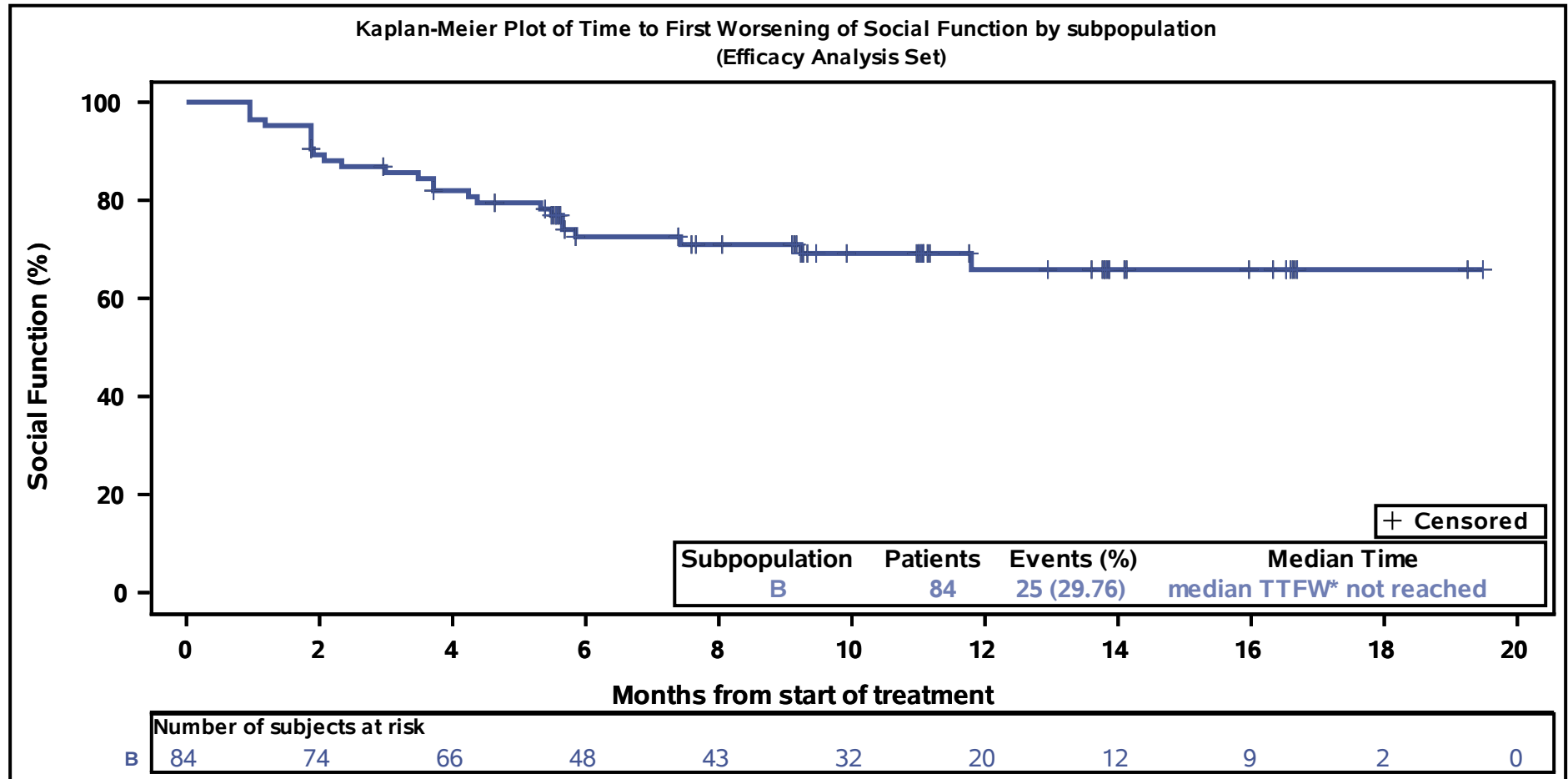
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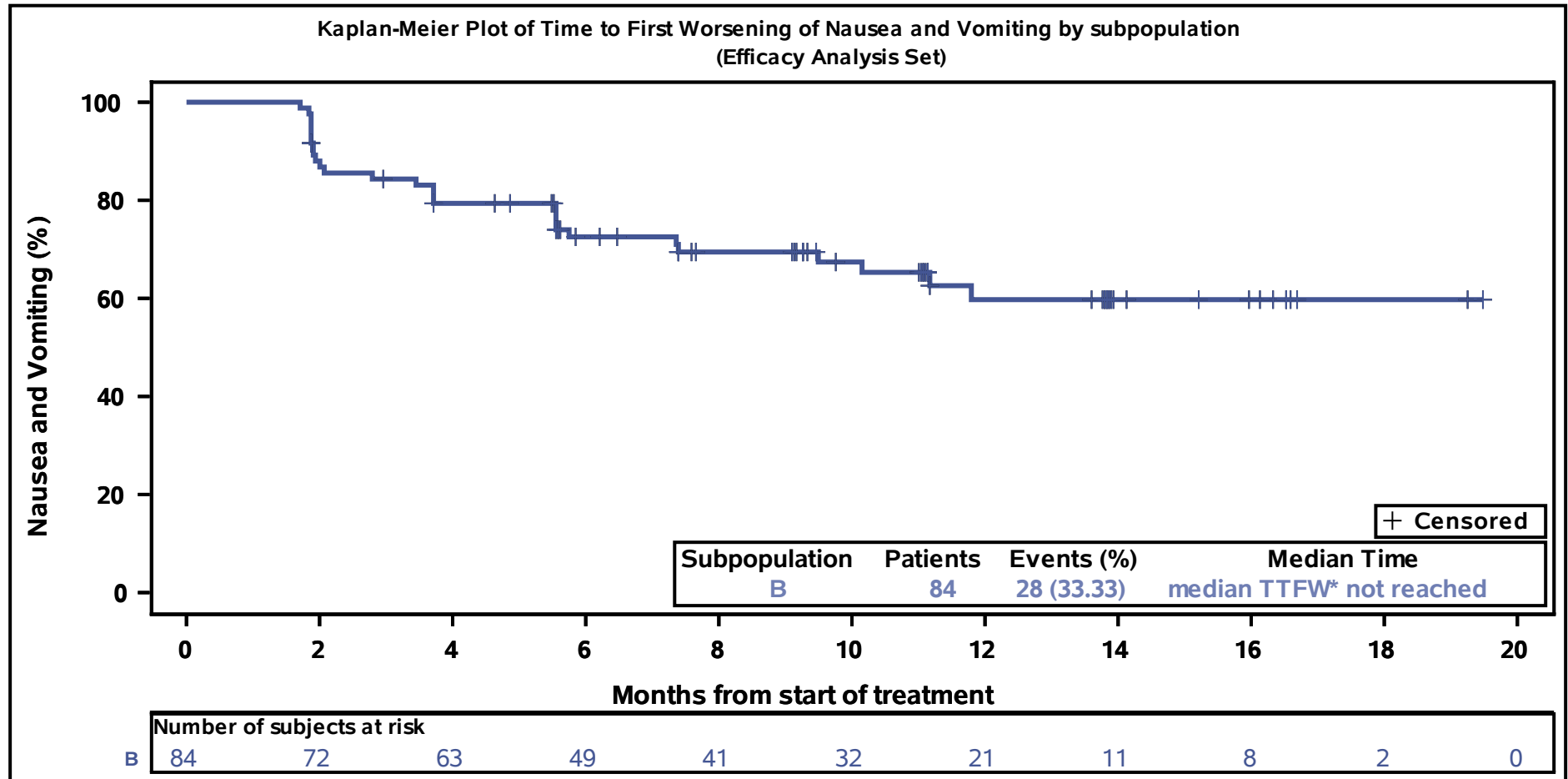
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* TTFW = Time-to-First Worsening

Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included

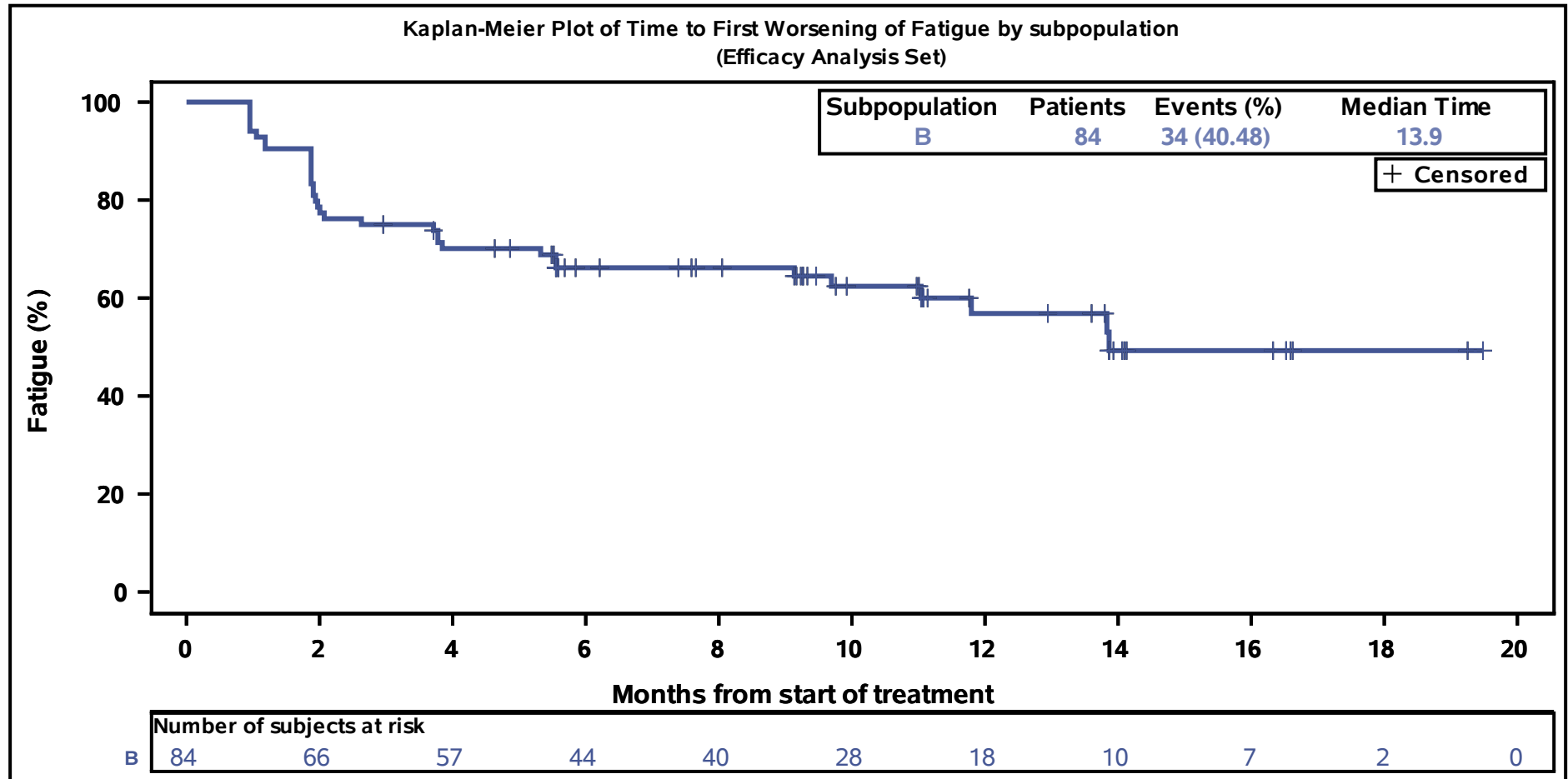
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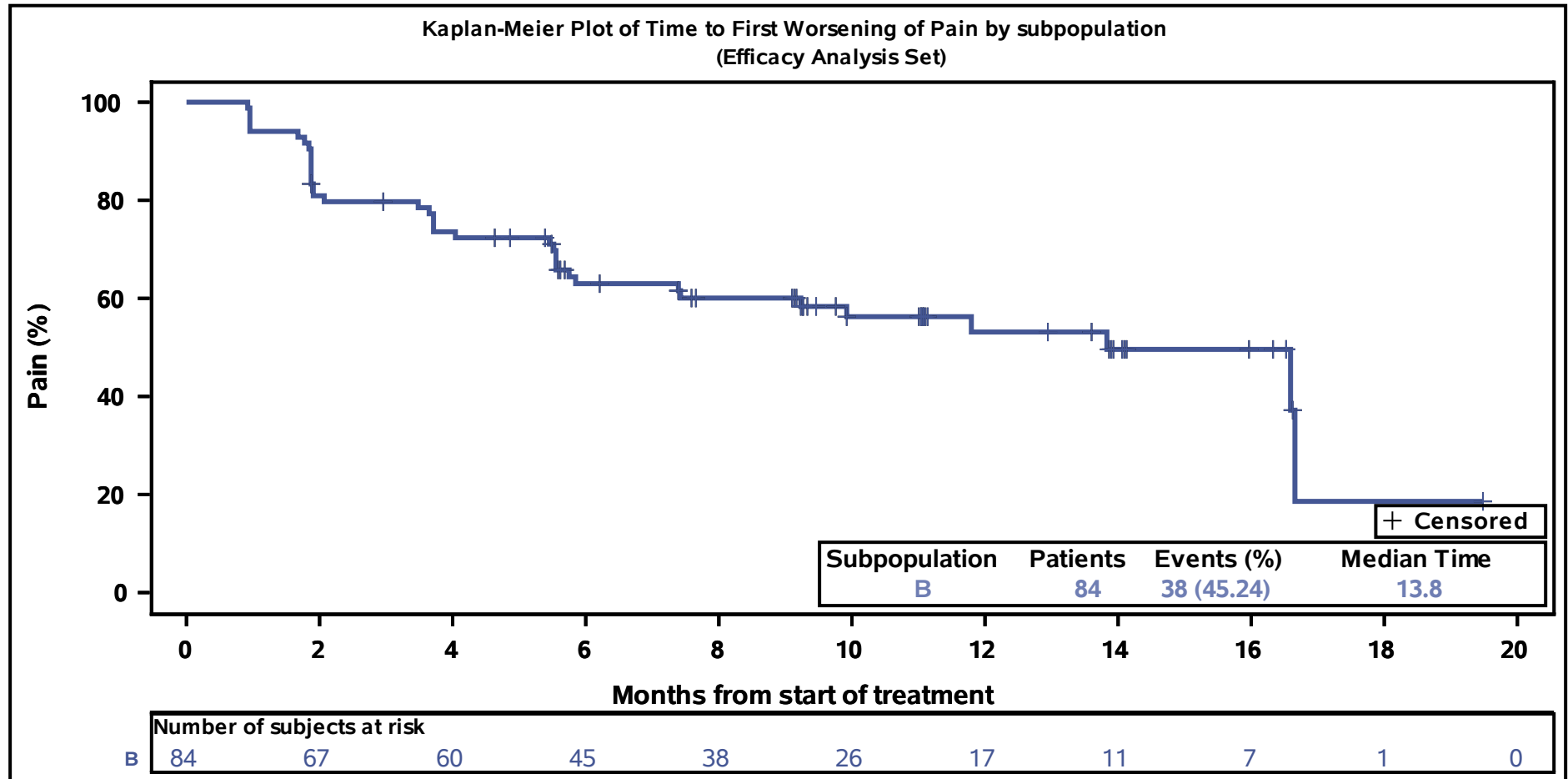
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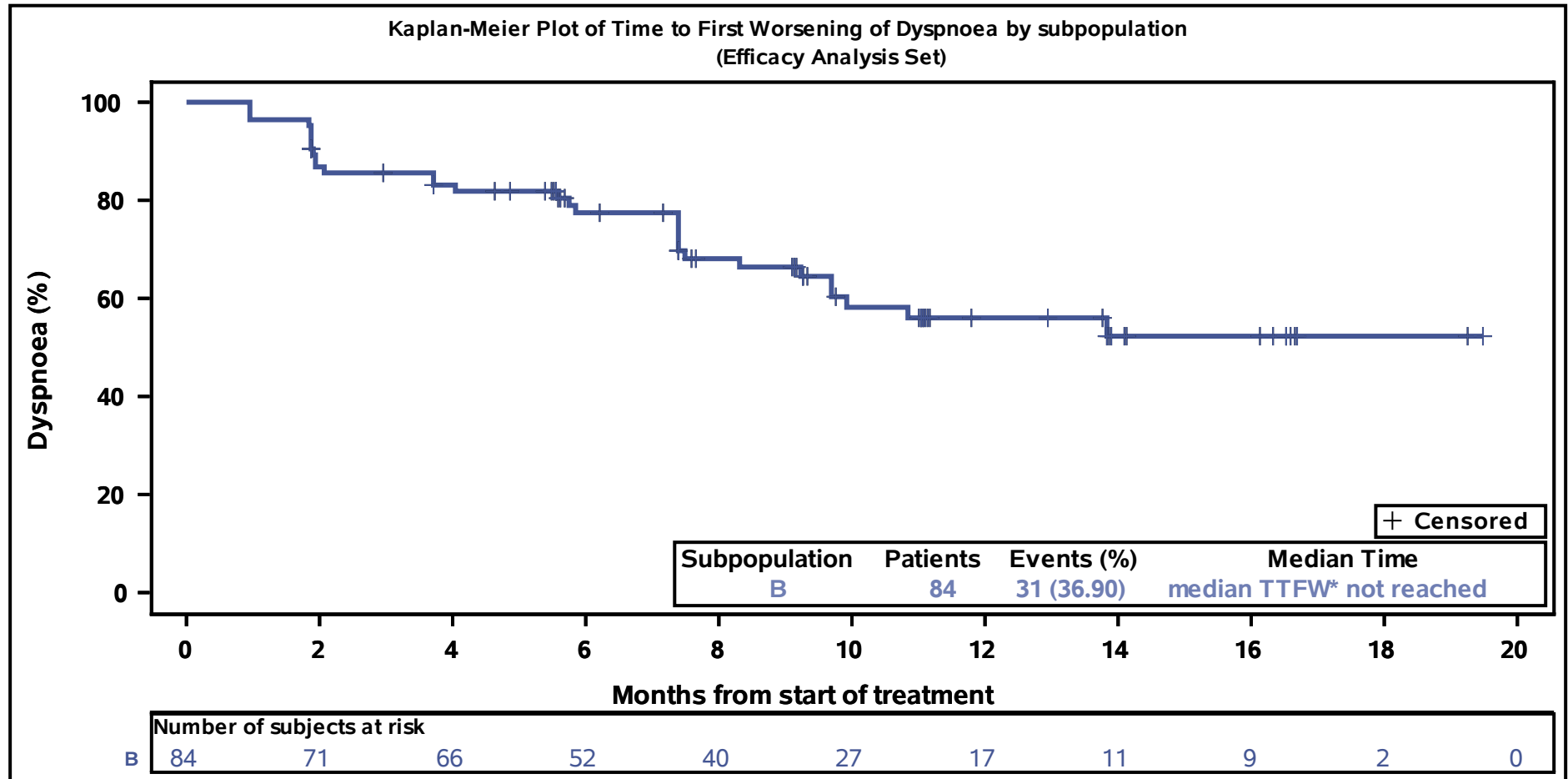
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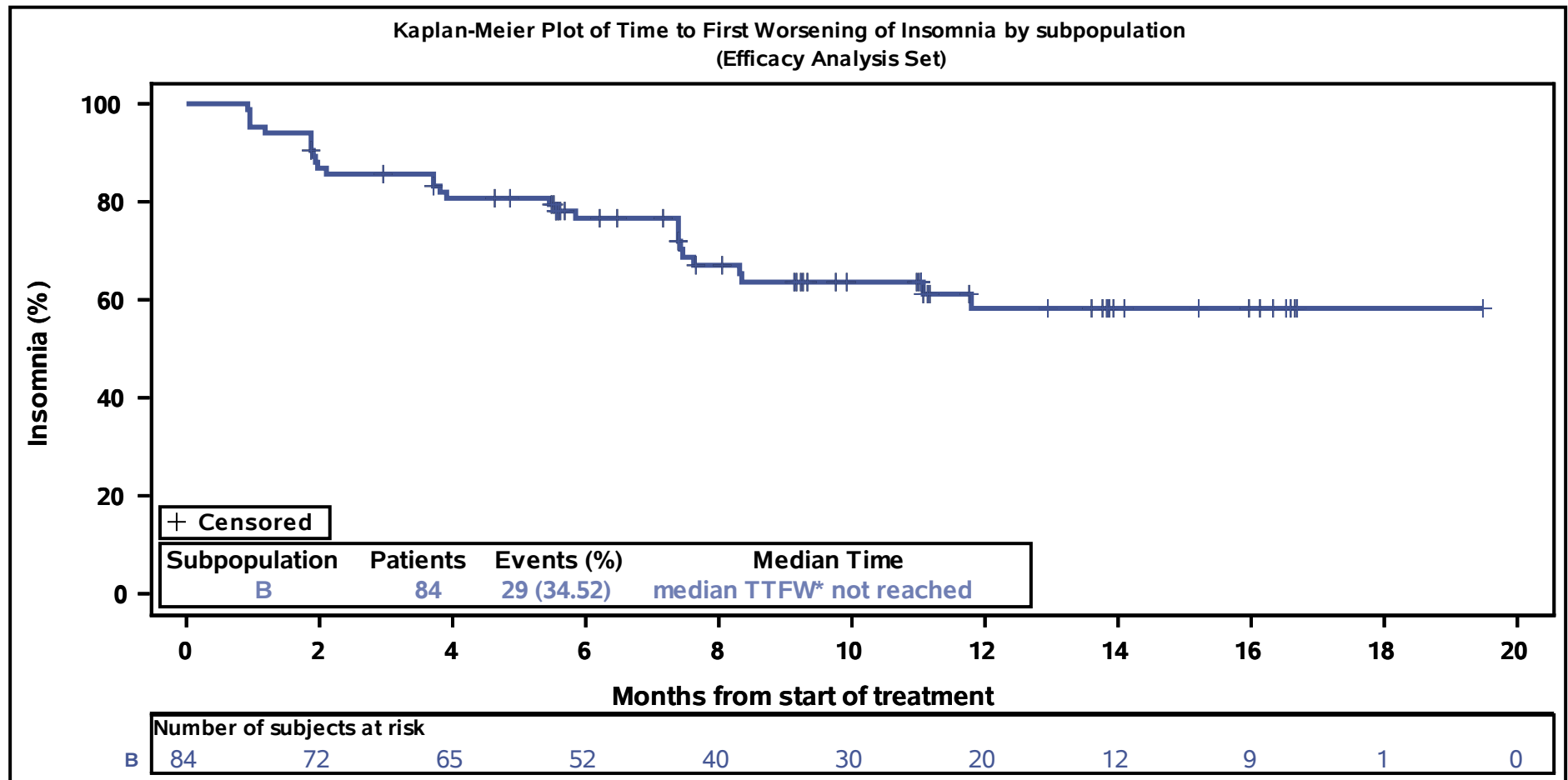
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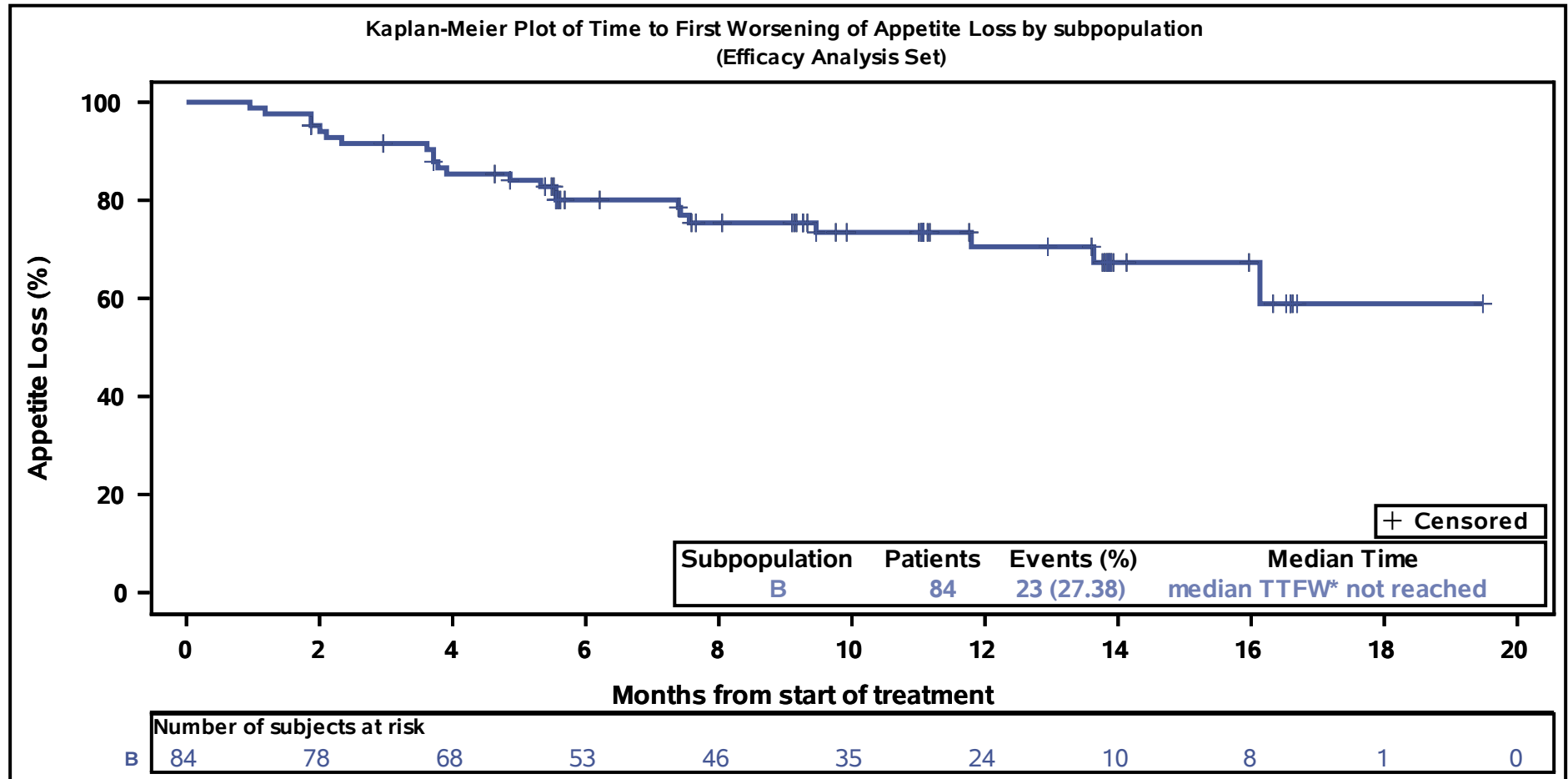
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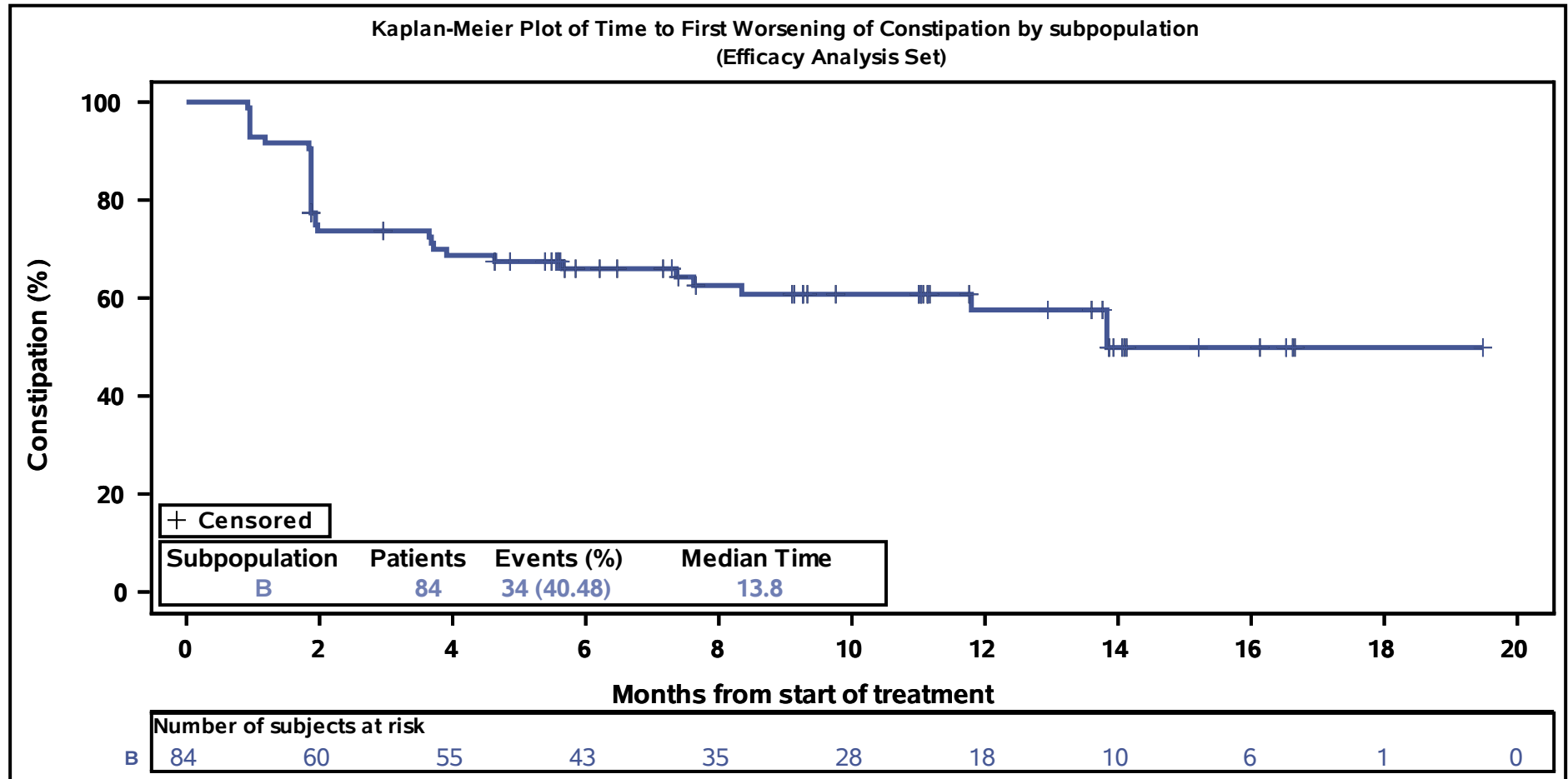
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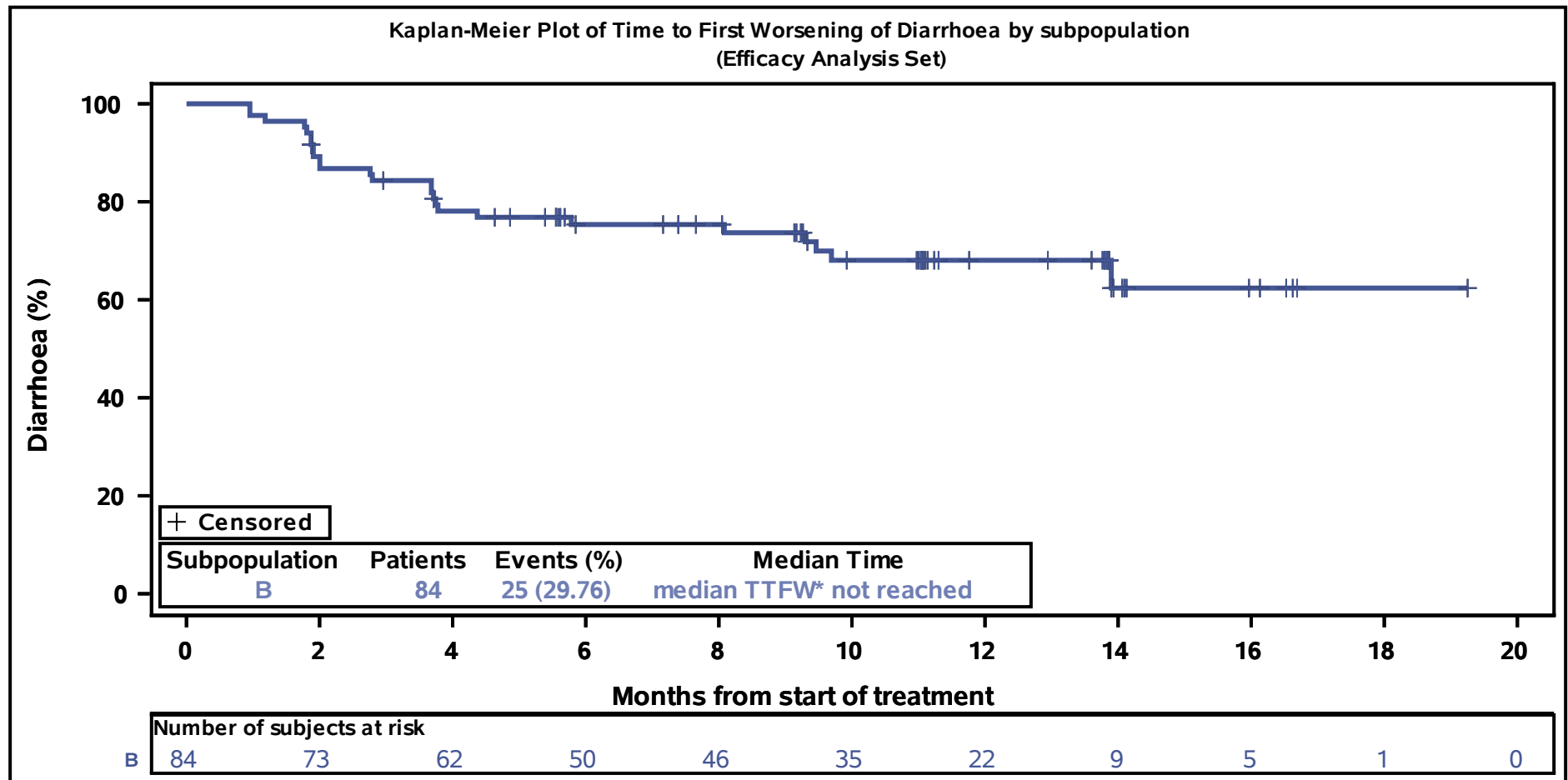
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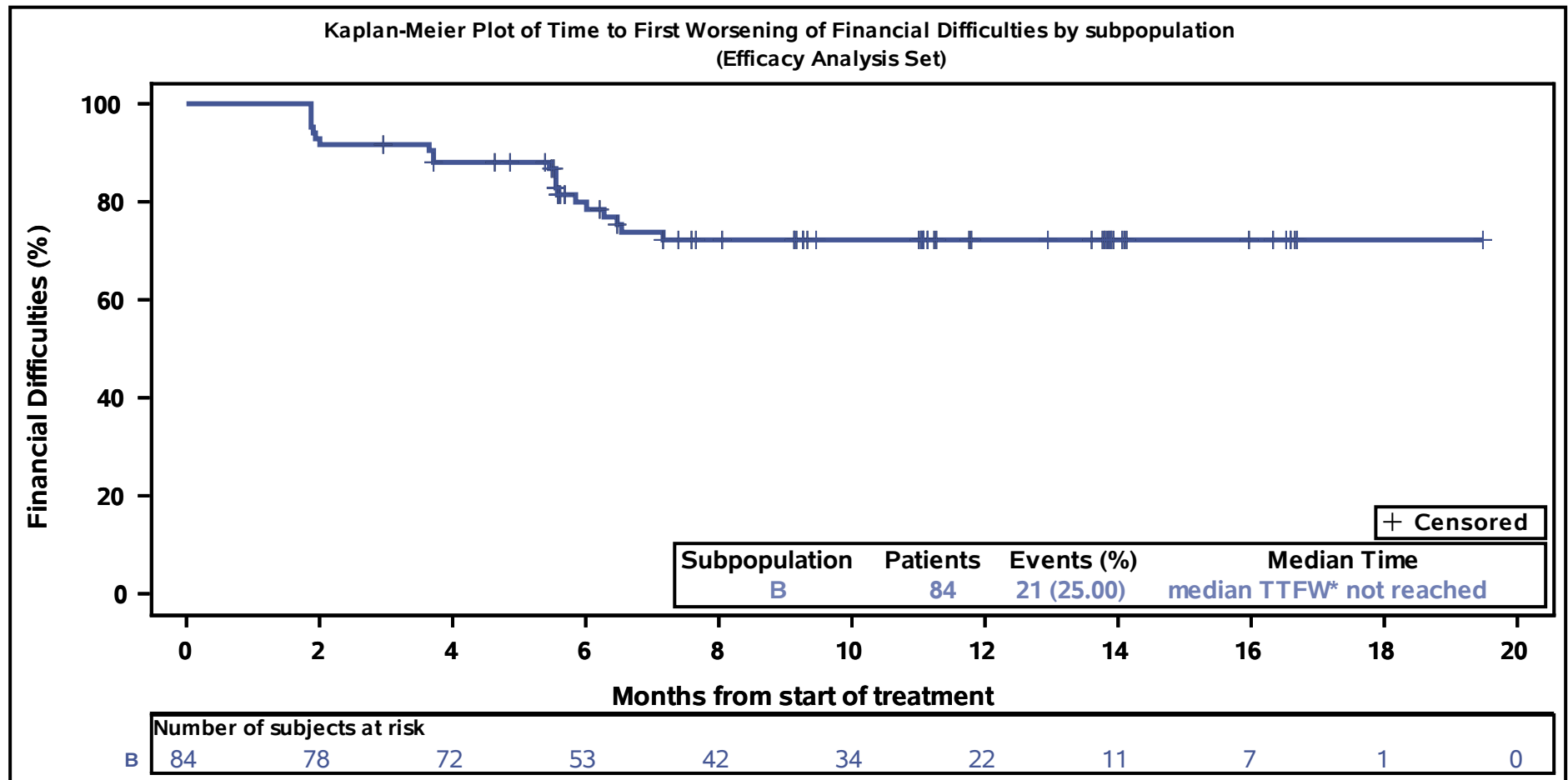
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Tabelle 033: Ergebnisse für die Zeit bis zur anhaltenden Verbesserung bzw. Verschlechterung der Symptome gemessen anhand des EORTC QLQ-C30 in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020)
- Efficacy Analysis Set

Endpunkt	Selpercatinib
	Subpopulation B - MTC (N') (N=143)
EORTC QLQ-C30 – Symptomskalen	
Fatigue	84
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	34 (40,5)
Zensierte Patienten, n (%)	50 (59,5)
Anhaltende Verschlechterung, n (%)	13 (15,5)
Zensierte Patienten, n (%)	71 (84,5)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] ^{a,b}	NE [5,55; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Schmerzen	84
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	27 (32,1)
Zensierte Patienten, n (%)	57 (67,9)
Anhaltende Verschlechterung, n (%)	10 (11,9)
Zensierte Patienten, n (%)	74 (88,1)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [16,59; NE]
Übelkeit und Erbrechen	84
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	12 (14,3)
Zensierte Patienten, n (%)	72 (85,7)
Anhaltende Verschlechterung, n (%)	3 (3,6)
Zensierte Patienten, n (%)	81 (96,4)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Dyspnoe	84
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	20 (23,8)
Zensierte Patienten, n (%)	64 (76,2)
Anhaltende Verschlechterung, n (%)	4 (4,8)
Zensierte Patienten, n (%)	80 (95,2)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Schlaflosigkeit	84
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	24 (28,6)
Zensierte Patienten, n (%)	60 (71,4)

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Tabelle 033: Ergebnisse für die Zeit bis zur anhaltenden Verbesserung bzw. Verschlechterung der Symptome gemessen anhand des EORTC QLQ-C30 in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020)
- Efficacy Analysis Set

Endpunkt	Selpercatinib
	Subpopulation B - MTC (N') (N=143)
Anhaltende Verschlechterung, n (%)	5 (6,0)
Zensierte Patienten, n (%)	79 (94,0)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Appetitverlust	84
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	24 (28,6)
Zensierte Patienten, n (%)	60 (71,4)
Anhaltende Verschlechterung, n (%)	6 (7,1)
Zensierte Patienten, n (%)	78 (92,9)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Verstopfung	84
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	9 (10,7)
Zensierte Patienten, n (%)	75 (89,3)
Anhaltende Verschlechterung, n (%)	8 (9,5)
Zensierte Patienten, n (%)	76 (90,5)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Diarrhoe	84
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	40 (47,6)
Zensierte Patienten, n (%)	44 (52,4)
Anhaltende Verschlechterung, n (%)	6 (7,1)
Zensierte Patienten, n (%)	78 (92,9)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] ^{a,b}	NE [1,97; NE]

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_tte_mtc_ge.sas

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- Efficacy Analysis Set

Endpunkt	Selpercatinib
	Subpopulation B - MTC (N') (N=143)
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); N': Anzahl der behandelten Patienten mit einem Baseline- und mindestens einem Post-Baseline-Wert; QLQ-C30: Core Quality of Life Questionnaire C30; RET: Rearranged during Transfection. a: Die Schätzung basiert auf der Kaplan-Meier Methode. NE = nicht schätzbar. b: Das 95%-KI wurde mittels Brookmeyer und Crowley Methode berechnet. Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben. Anhaltende Verbesserung ist definiert als Anstieg im jeweiligen EORTC QLQ-C30 Score um ≥ 10 Punkte gegenüber Baseline ohne folgende Verschlechterung des Scores um ≥ 10 Punkte. Anhaltende Verschlechterung ist definiert als Reduktion im jeweiligen EORTC QLQ-C30 Score um ≥ 10 Punkte gegenüber Baseline ohne folgende Verbesserung des Scores um ≥ 10 Punkte. Zeit bis zur anhaltenden Verbesserung bzw. Verschlechterung ist definiert als Anzahl der Monate zwischen der ersten Dosis der Prüfmedikation und dem ersten Auftreten einer anhaltenden Verbesserung bzw. Verschlechterung in den jeweiligen Symptomskalen.	

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Tabelle 034: Ergebnisse für die Zeit bis zur anhaltenden Verbesserung bzw. Verschlechterung der gesundheitsbezogenen Lebensqualität gemessen anhand des EORTC QLQ-C30 in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020)
- Efficacy Analysis Set

Endpunkt	Selpercatinib
	Subpopulation B - MTC (N') (N=143)
EORTC QLQ-C30 - Globaler Gesundheitsstatus	84
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	22 (26,2)
Zensierte Patienten, n (%)	62 (73,8)
Anhaltende Verschlechterung, n (%)	7 (8,3)
Zensierte Patienten, n (%)	77 (91,7)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
EORTC QLQ-C30 – Funktionsskalen	
Physische Funktion	84
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	19 (22,6)
Zensierte Patienten, n (%)	65 (77,4)
Anhaltende Verschlechterung, n (%)	6 (7,1)
Zensierte Patienten, n (%)	78 (92,9)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] ^{a,b}	16,8 [16,82; NE]
Emotionale Funktion	84
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	16 (19,0)
Zensierte Patienten, n (%)	68 (81,0)
Anhaltende Verschlechterung, n (%)	4 (4,8)
Zensierte Patienten, n (%)	80 (95,2)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Rollenfunktion	84
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	26 (31,0)
Zensierte Patienten, n (%)	58 (69,0)
Anhaltende Verschlechterung, n (%)	7 (8,3)
Zensierte Patienten, n (%)	77 (91,7)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Kognitive Funktion	84
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	11 (13,1)
Zensierte Patienten, n (%)	73 (86,9)

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- Efficacy Analysis Set

Endpunkt	Selpercatinib
	Subpopulation B - MTC (N') (N=143)
Anhaltende Verschlechterung, n (%)	15 (17,9)
Zensierte Patienten, n (%)	69 (82,1)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Soziale Funktion	84
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	28 (33,3)
Zensierte Patienten, n (%)	56 (66,7)
Anhaltende Verschlechterung, n (%)	7 (8,3)
Zensierte Patienten, n (%)	77 (91,7)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] ^{a,b}	NE [NE; NE]
EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); N': Anzahl der behandelten Patienten mit einem Baseline- und mindestens einem Post-Baseline-Wert; QLQ-C30: Core Quality of Life Questionnaire C30; RET: Rearranged during Transfection. a: Die Schätzung basiert auf der Kaplan-Meier Methode. NE = nicht schätzbar. b: Das 95%-KI wurde mittels Brookmeyer und Crowley Methode berechnet. Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben. Anhaltende Verbesserung ist definiert als Anstieg im jeweiligen EORTC QLQ-C30 Score um ≥ 10 Punkte gegenüber Baseline ohne folgende Verschlechterung des Scores um ≥ 10 Punkte. Anhaltende Verschlechterung ist definiert als Reduktion im jeweiligen EORTC QLQ-C30 Score um ≥ 10 Punkte gegenüber Baseline ohne folgende Verbesserung des Scores um ≥ 10 Punkte. Zeit bis zur anhaltenden Verbesserung bzw. Verschlechterung ist definiert als Anzahl der Monate zwischen der ersten Dosis der Prüfmedikation und dem ersten Auftreten einer anhaltenden Verbesserung bzw. Verschlechterung in den jeweiligen Symptomskalen.	

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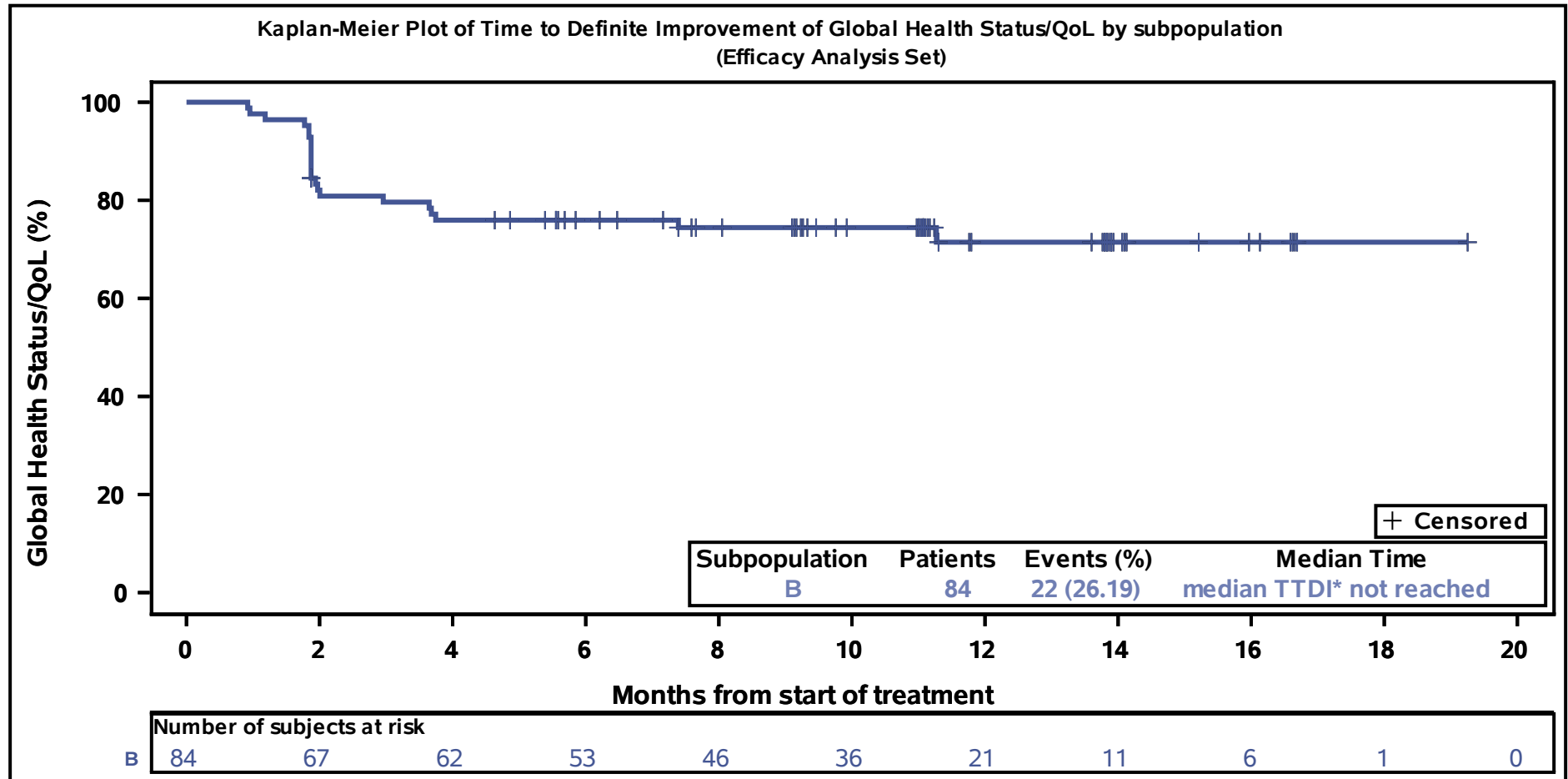
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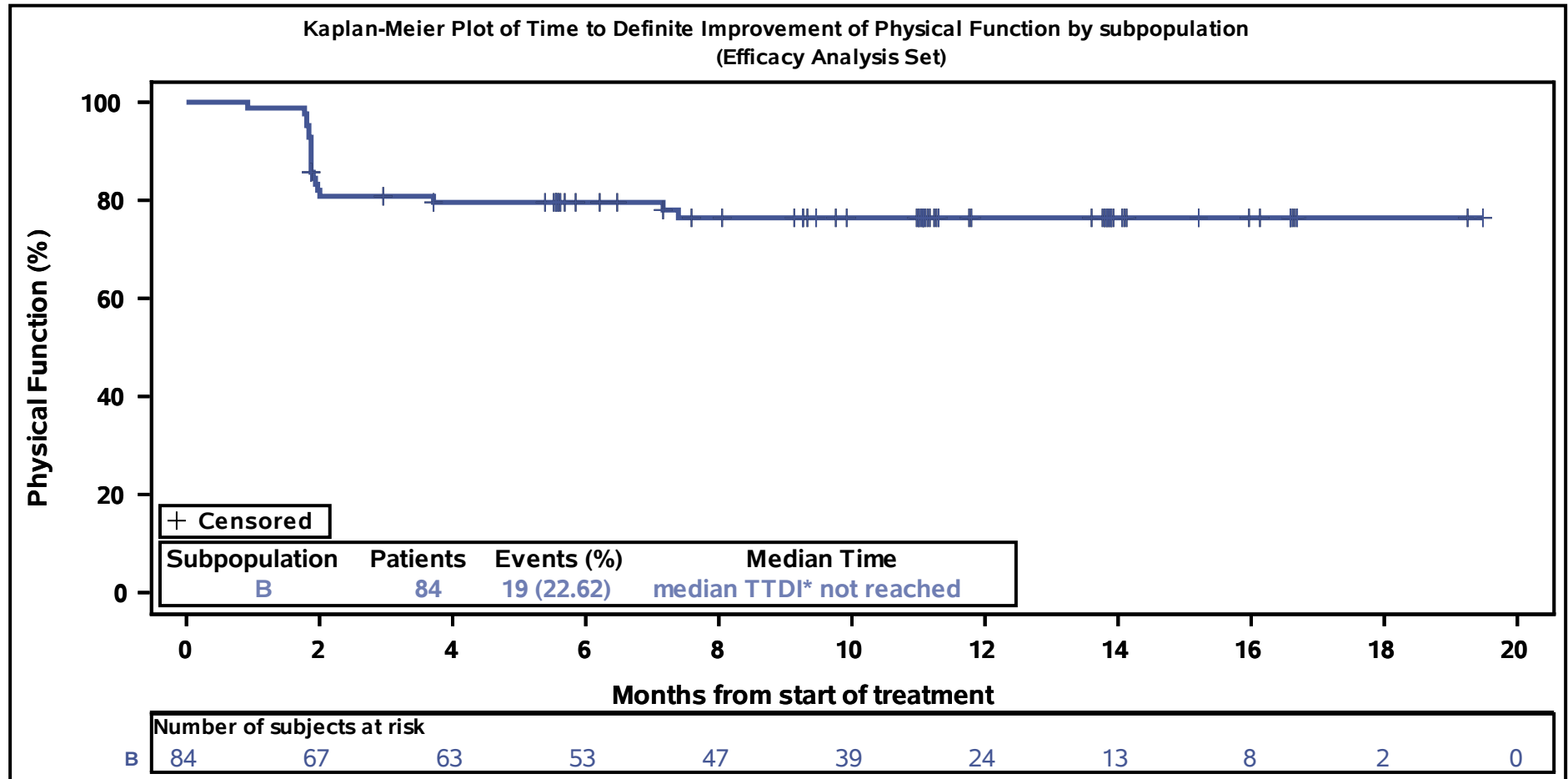
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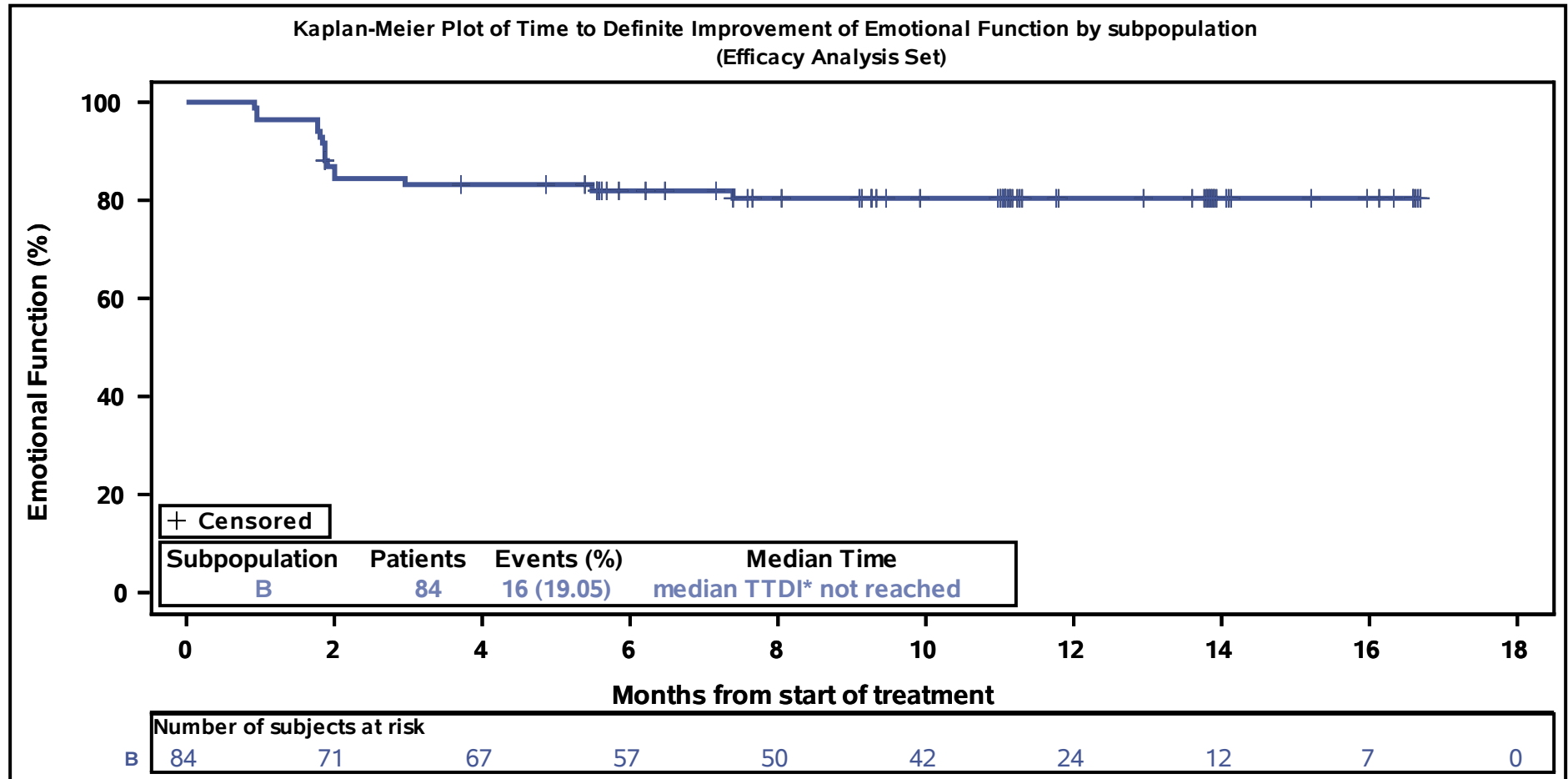
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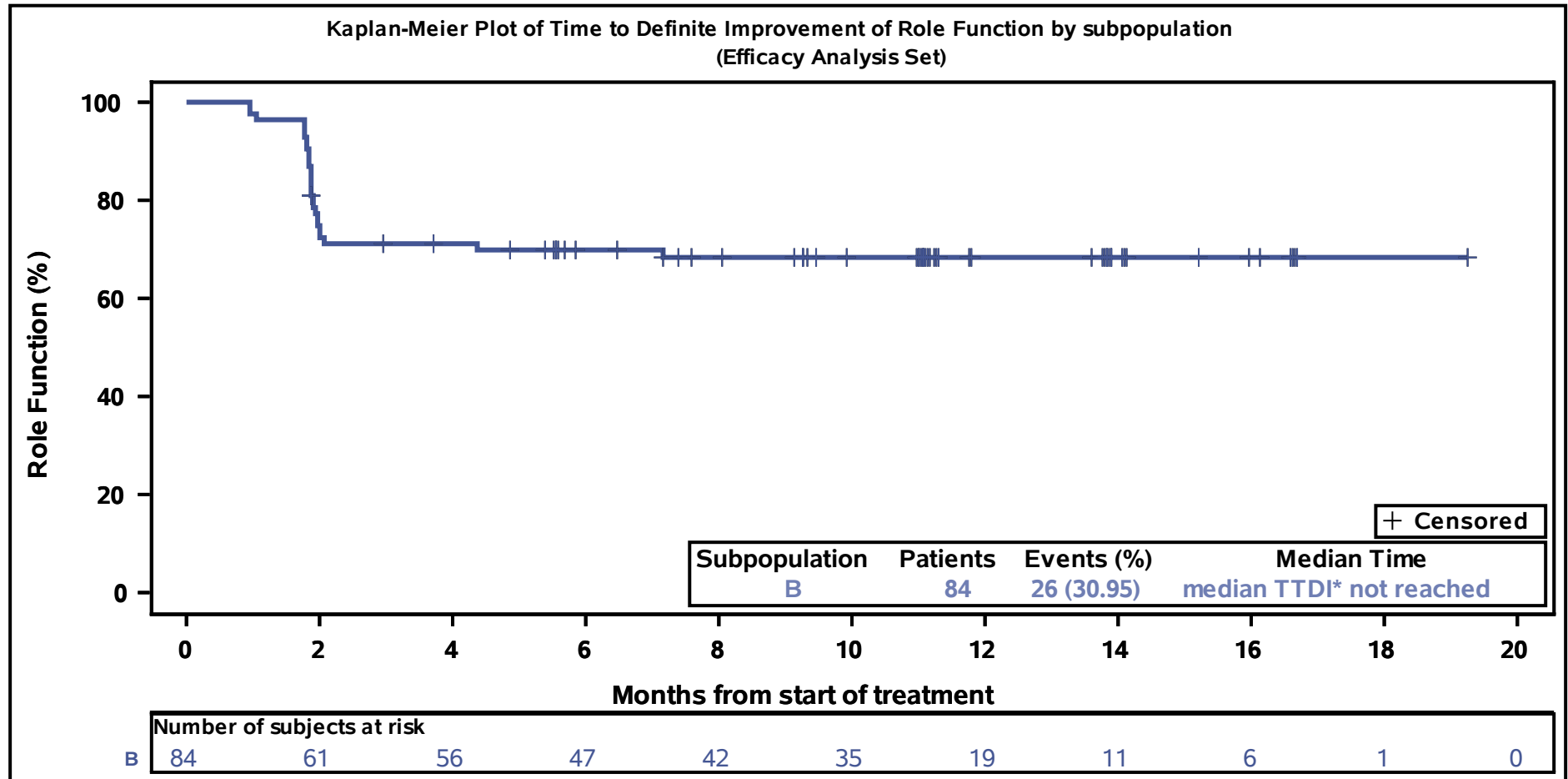
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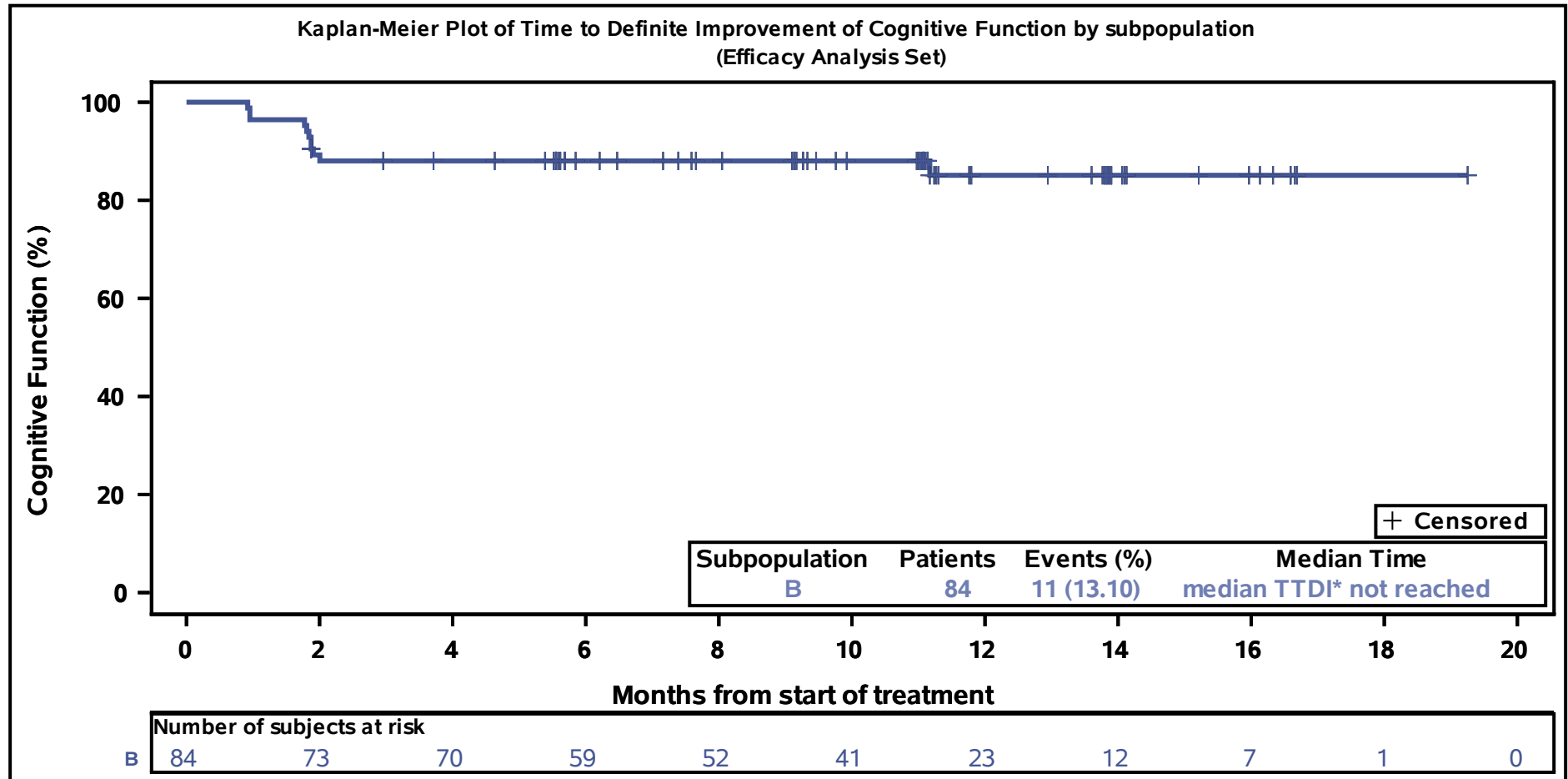
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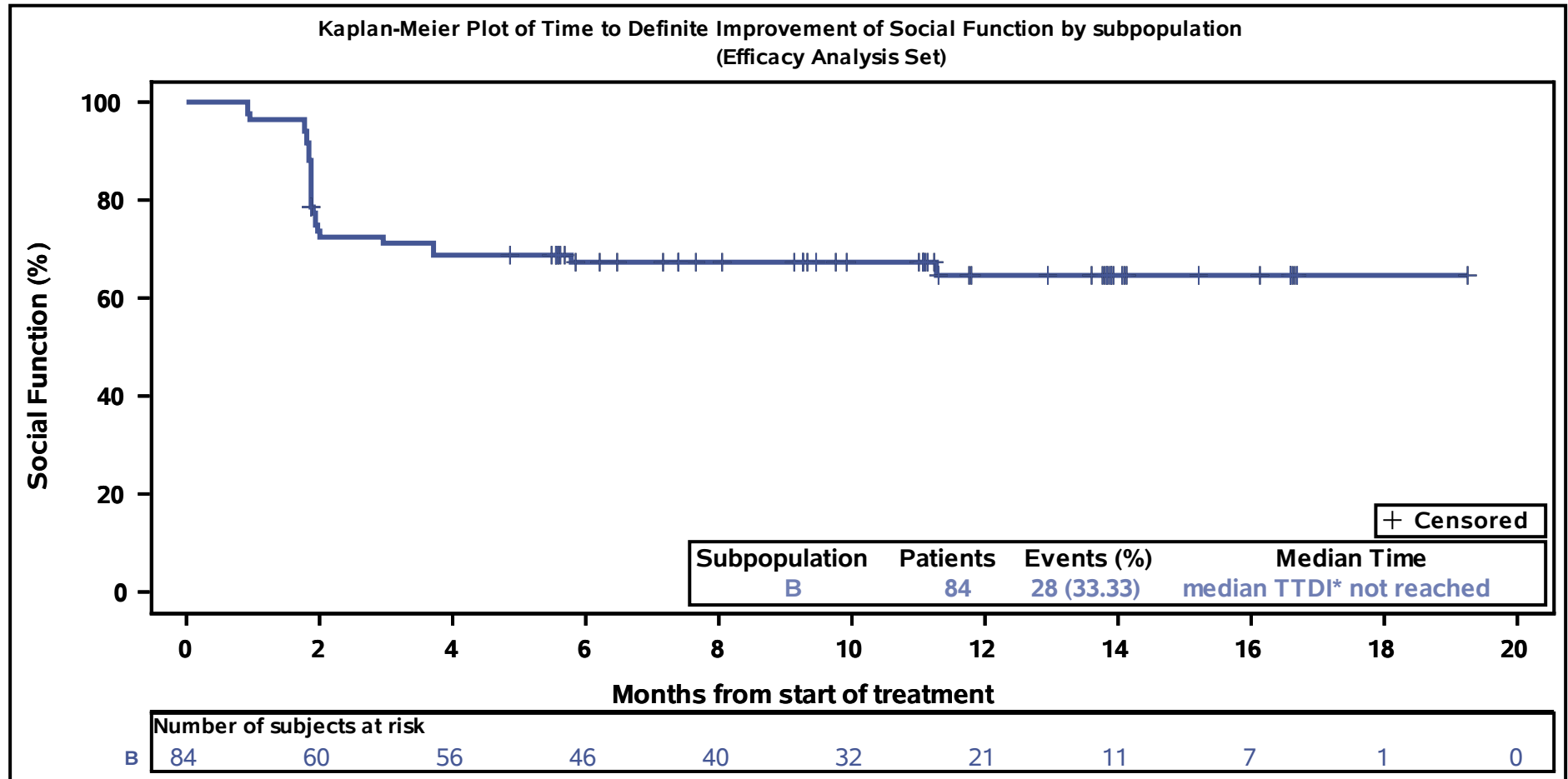
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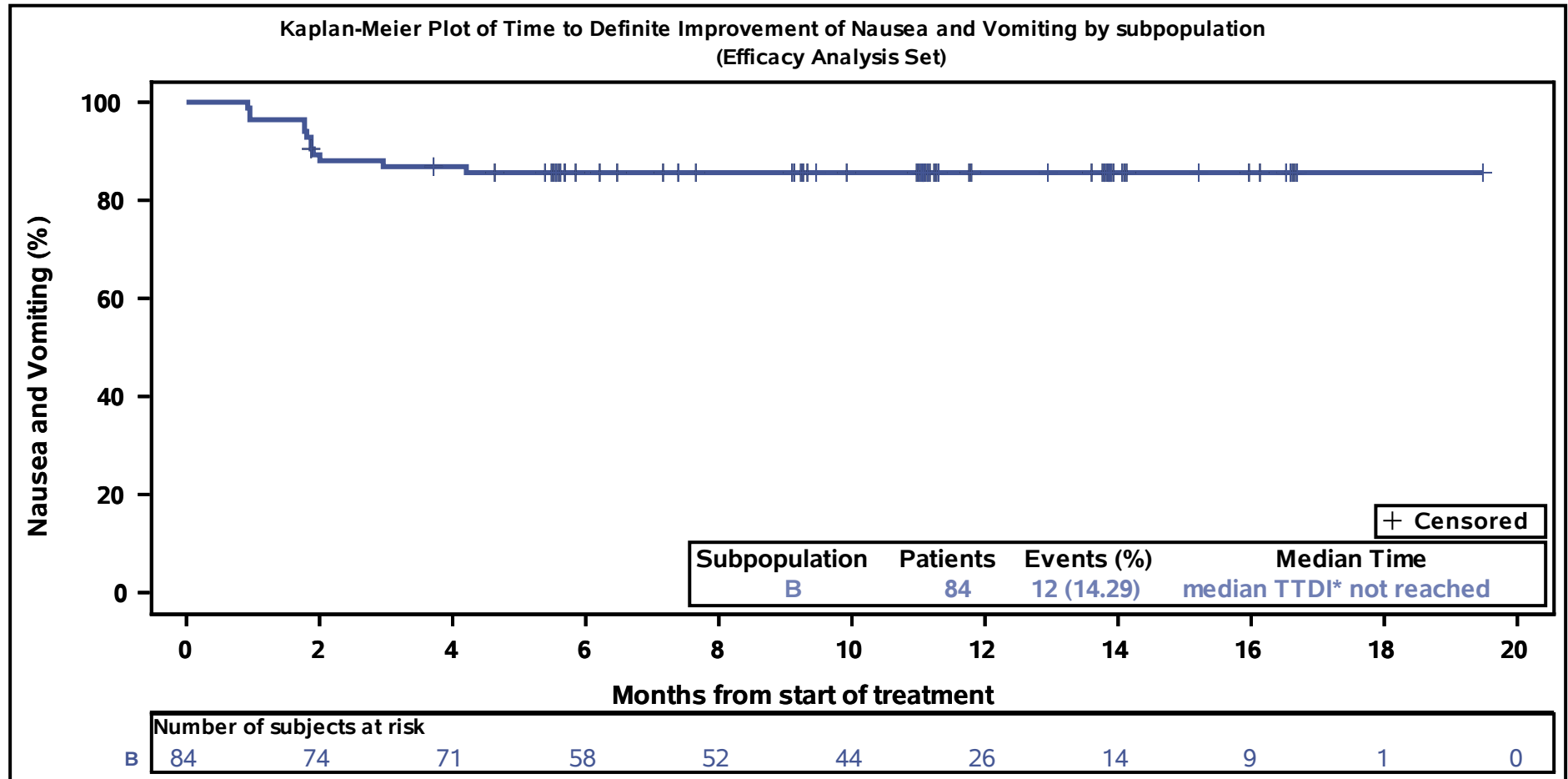
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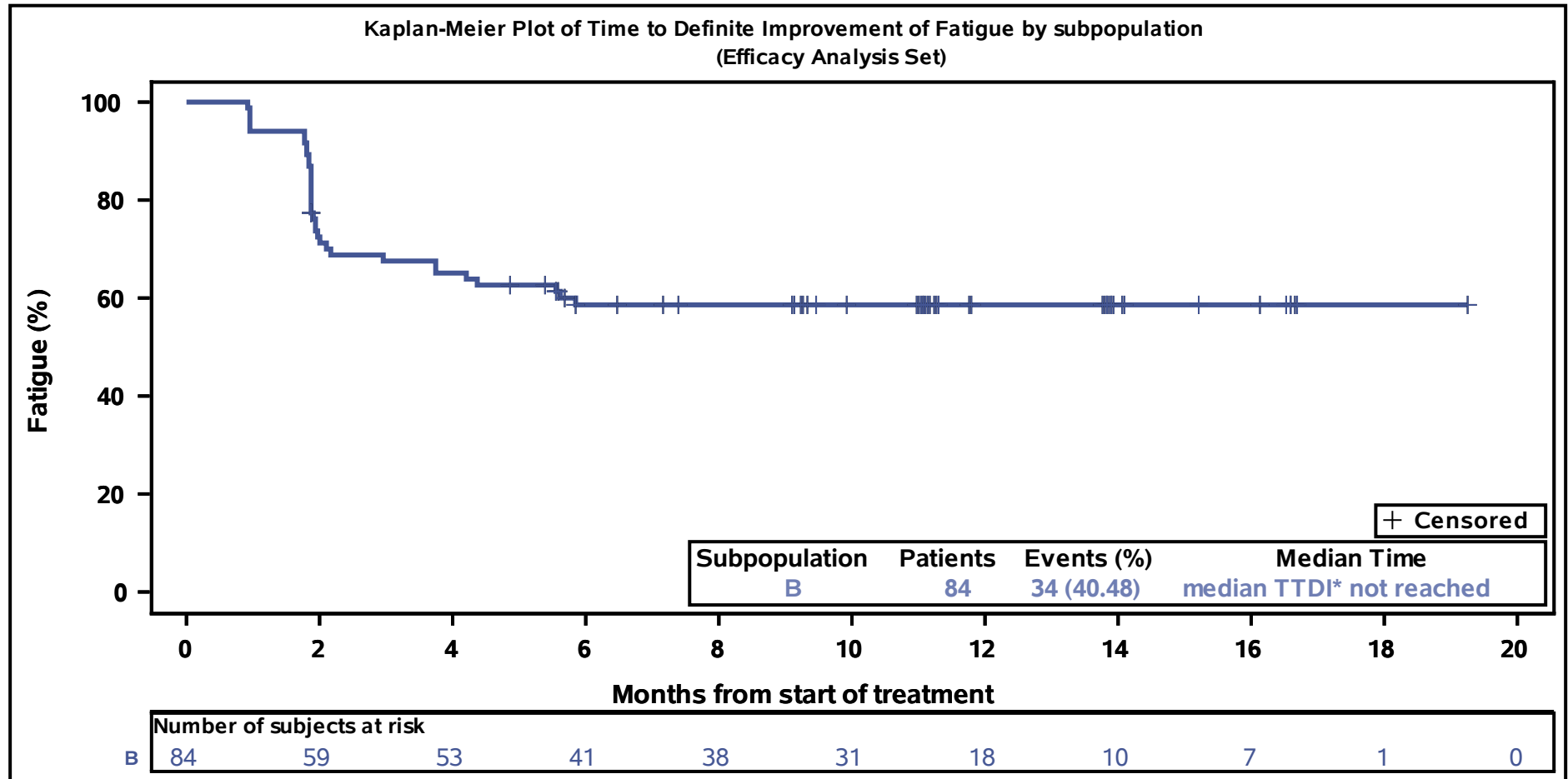
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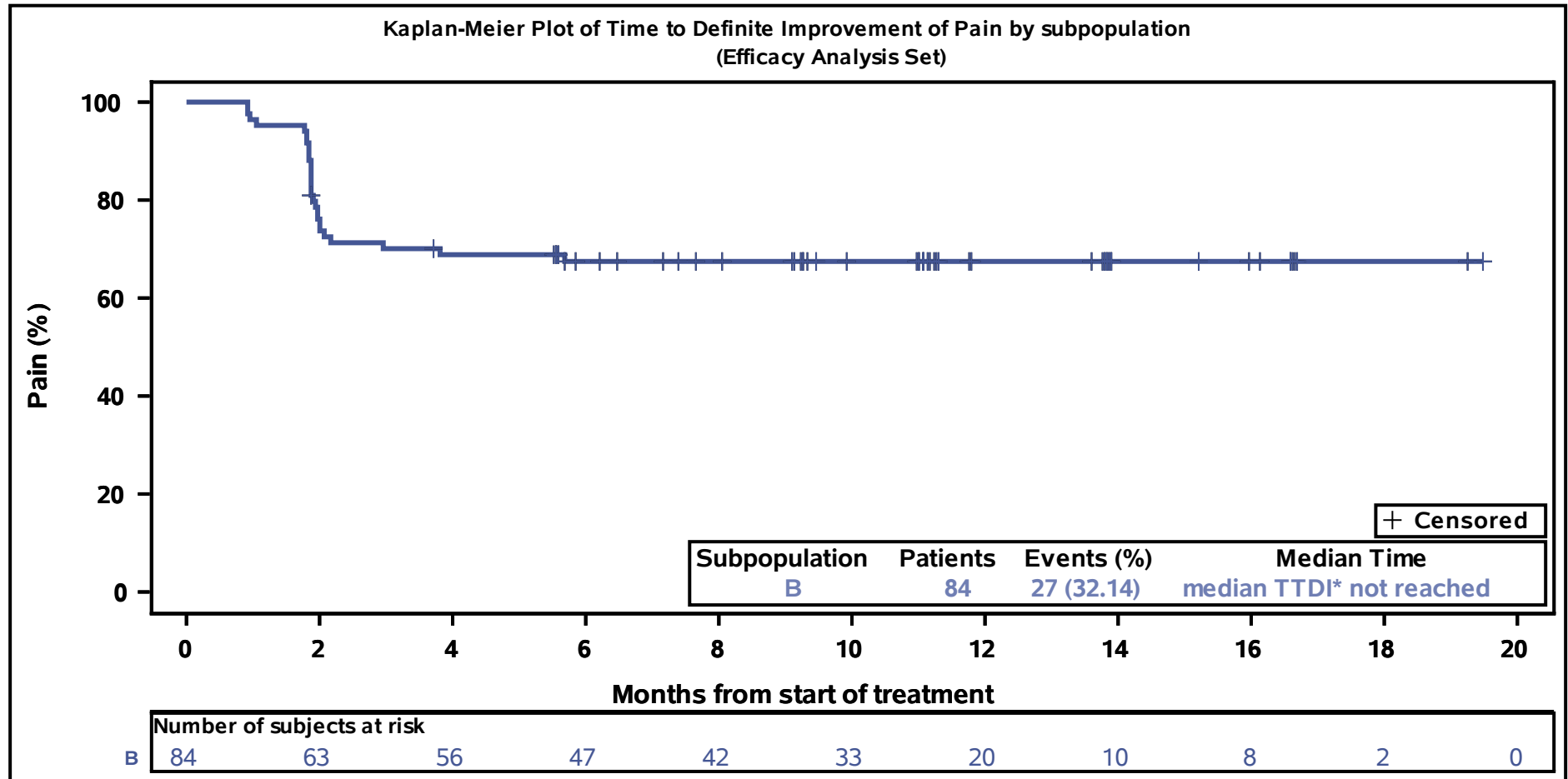
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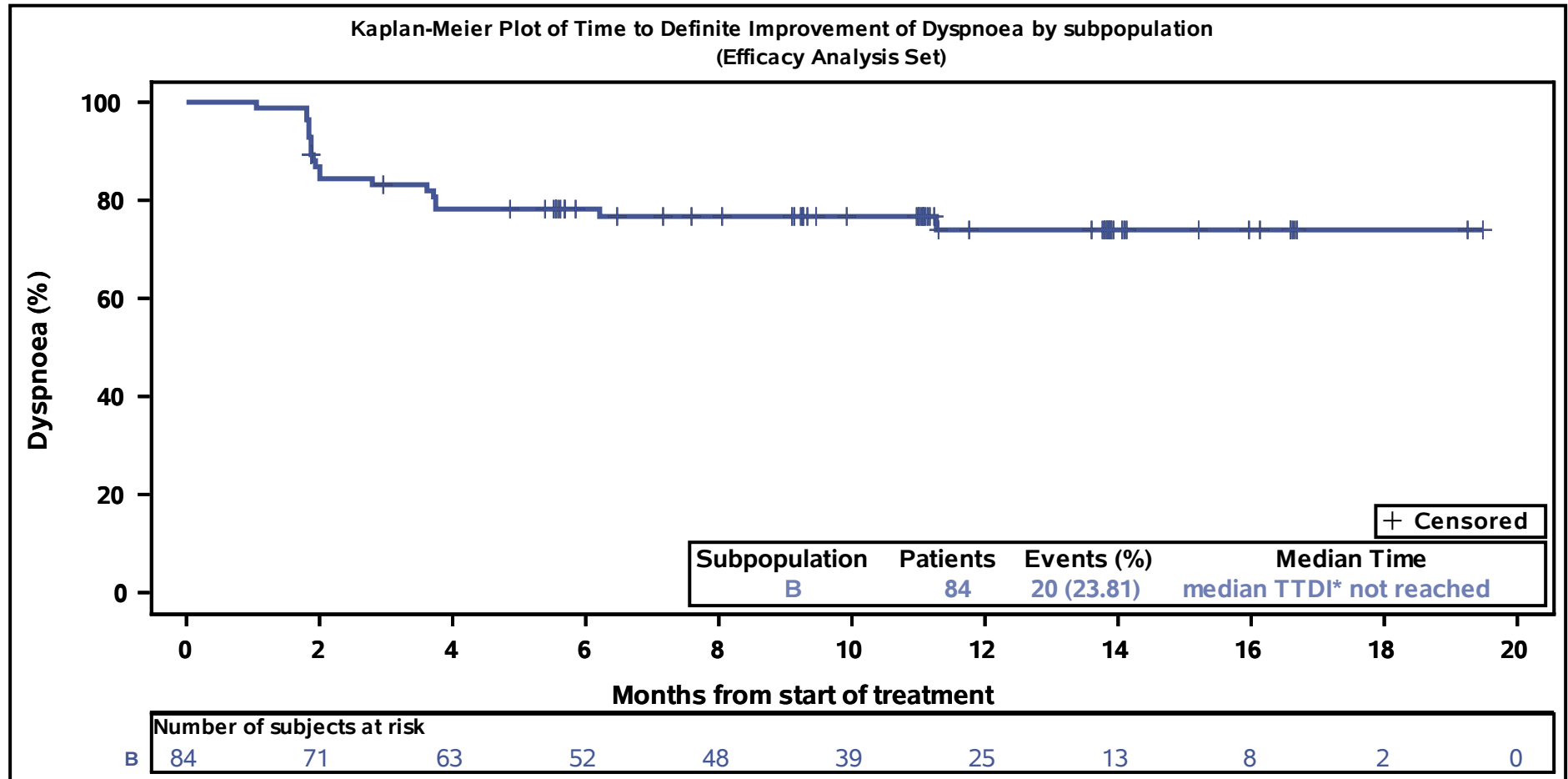
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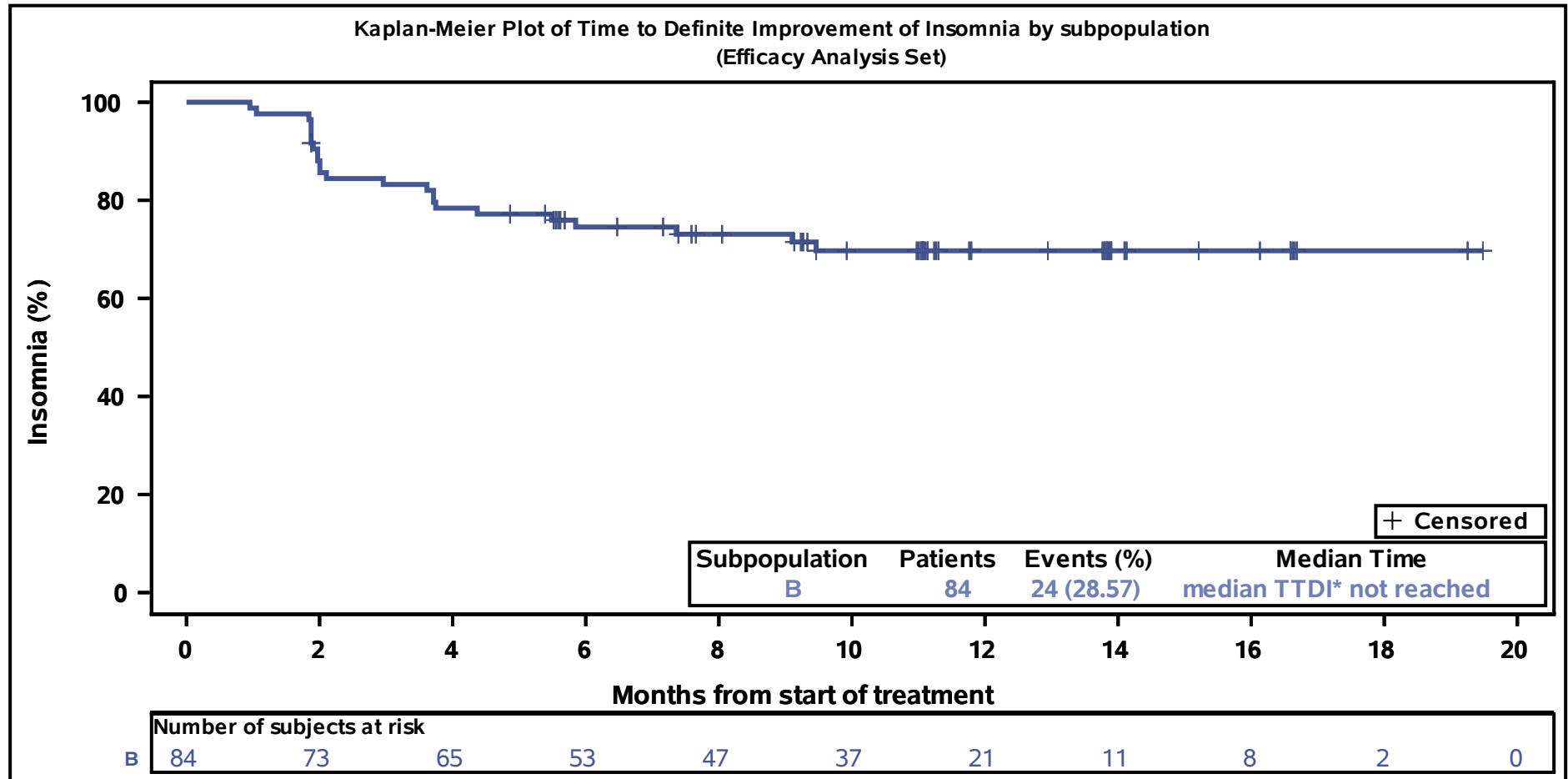
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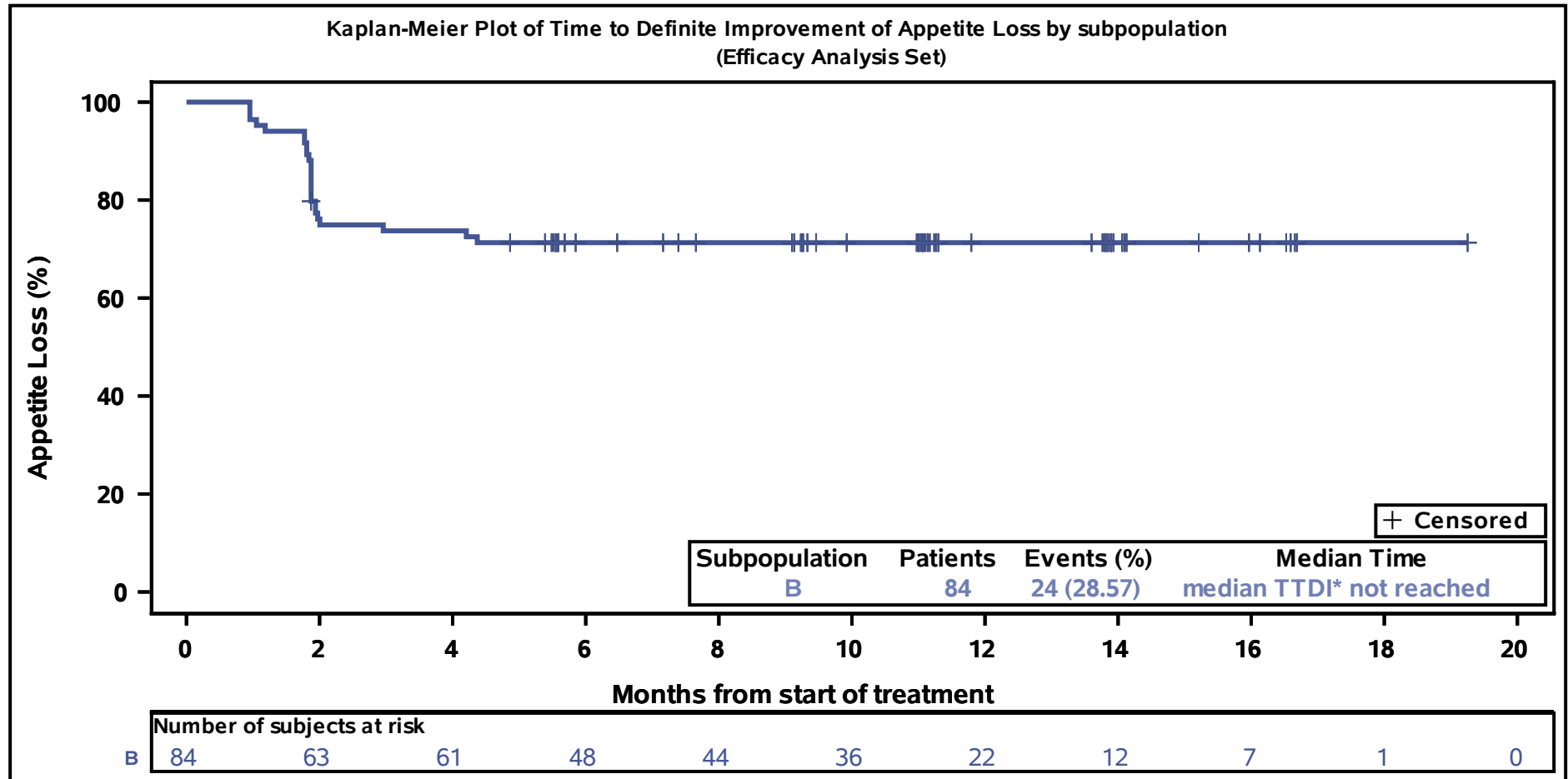
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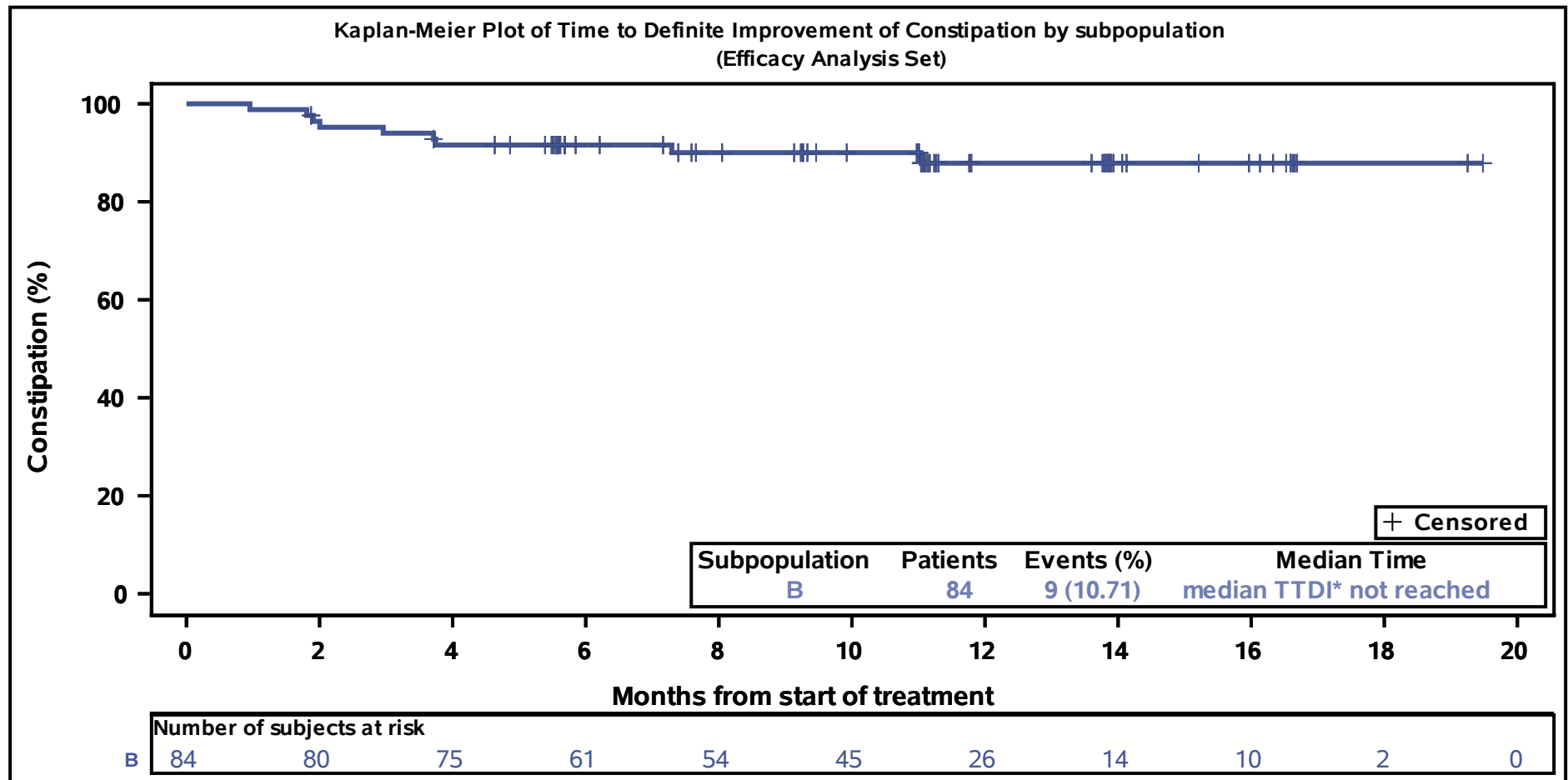
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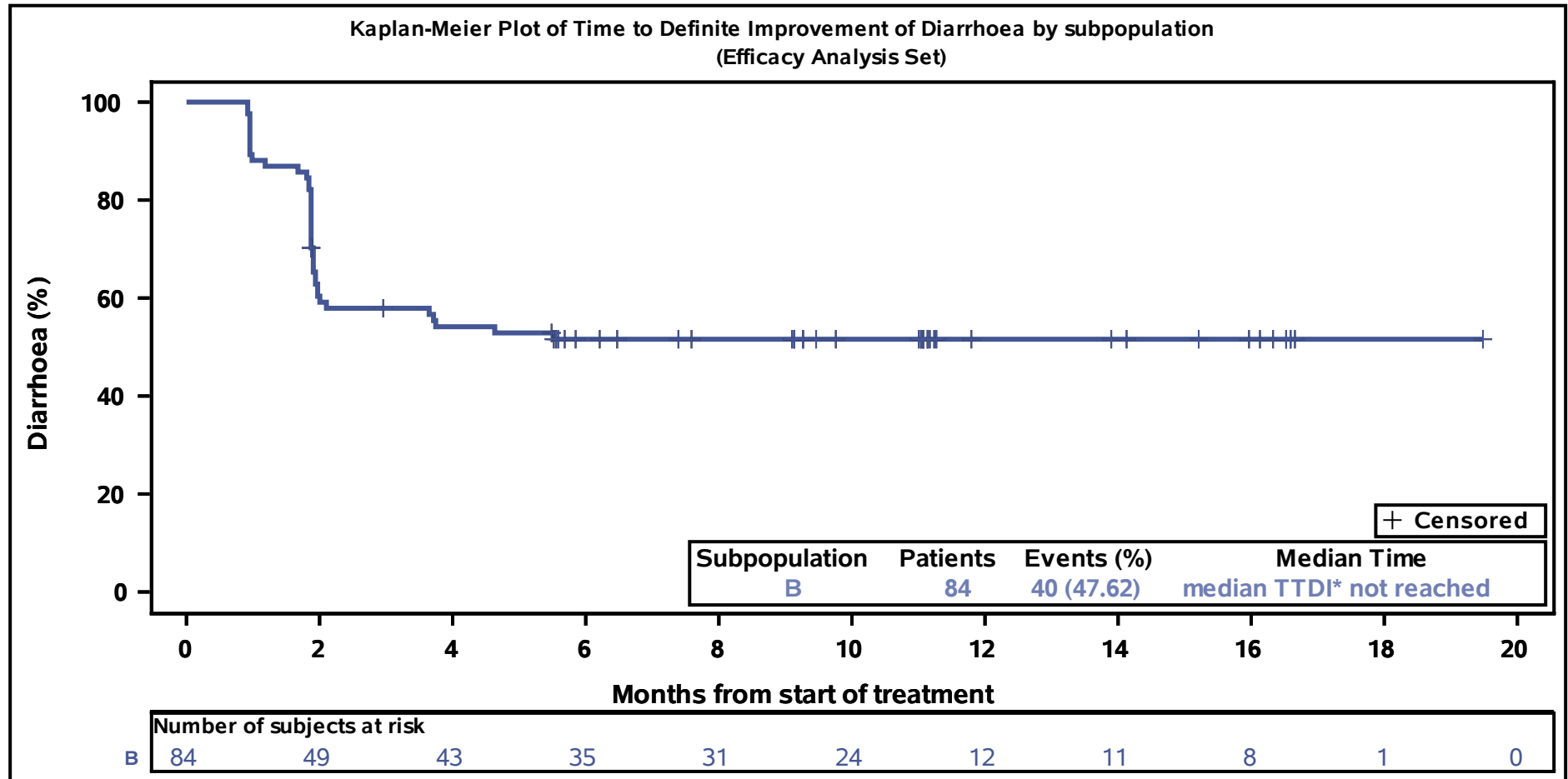
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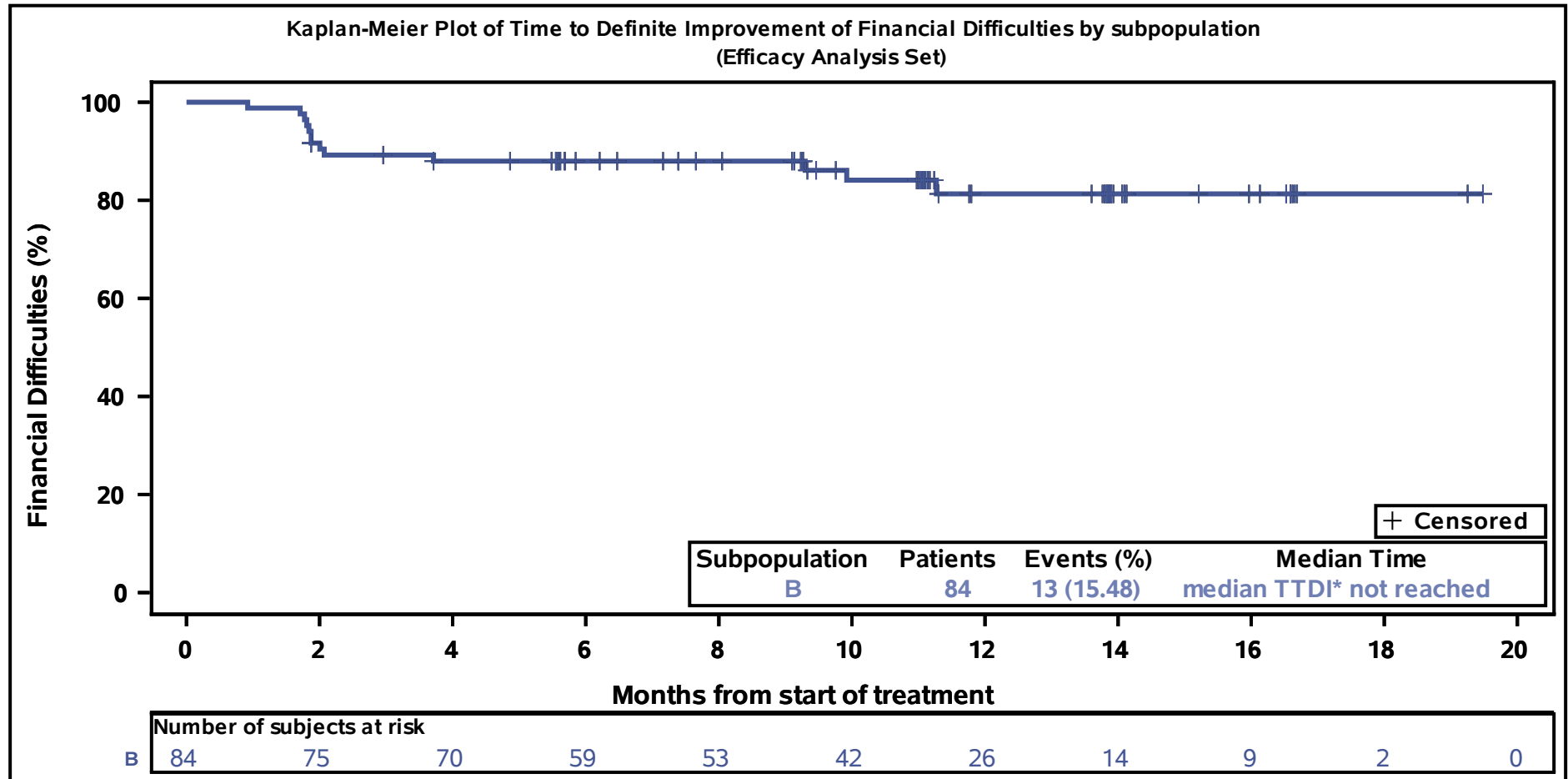
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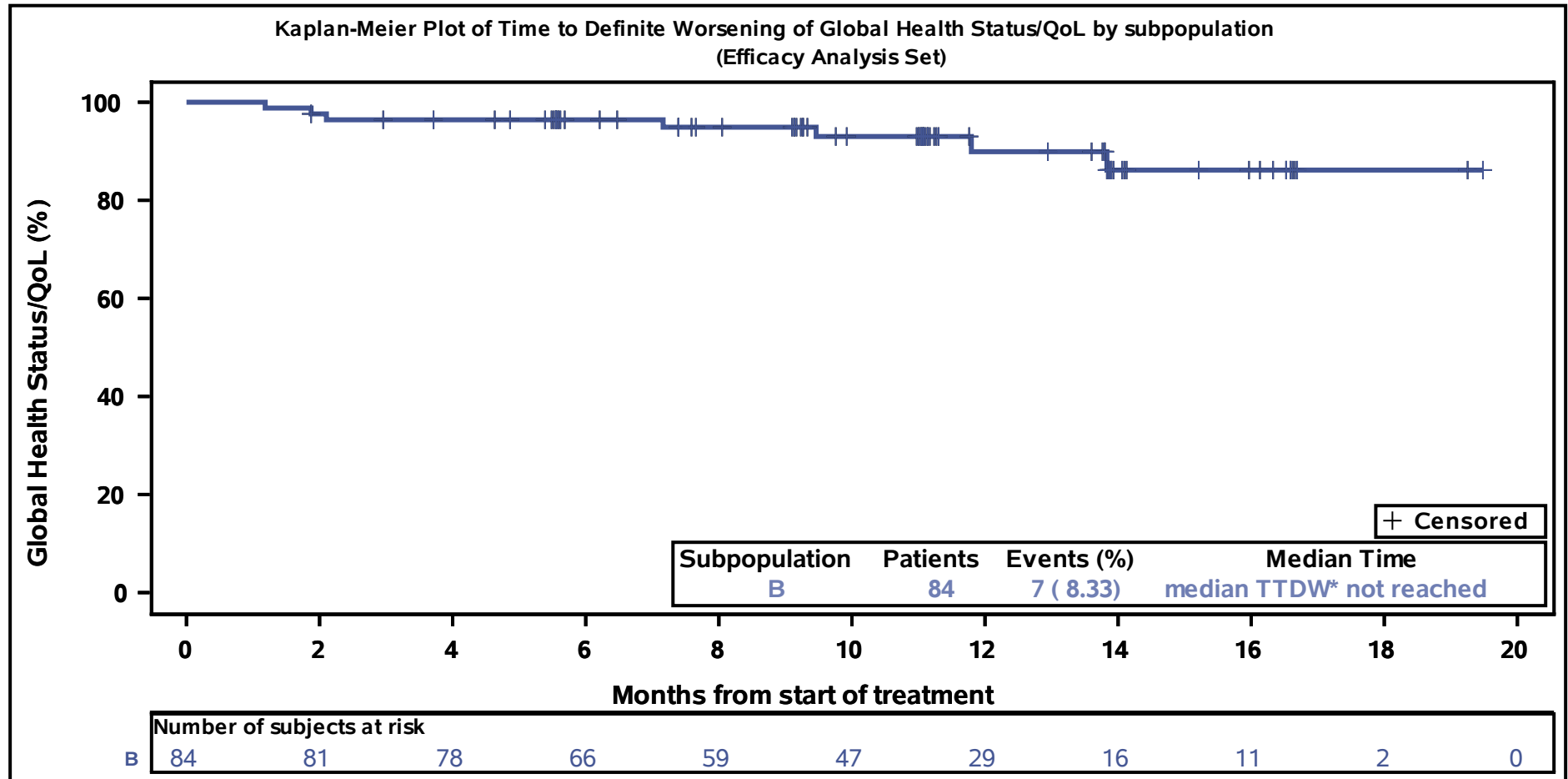
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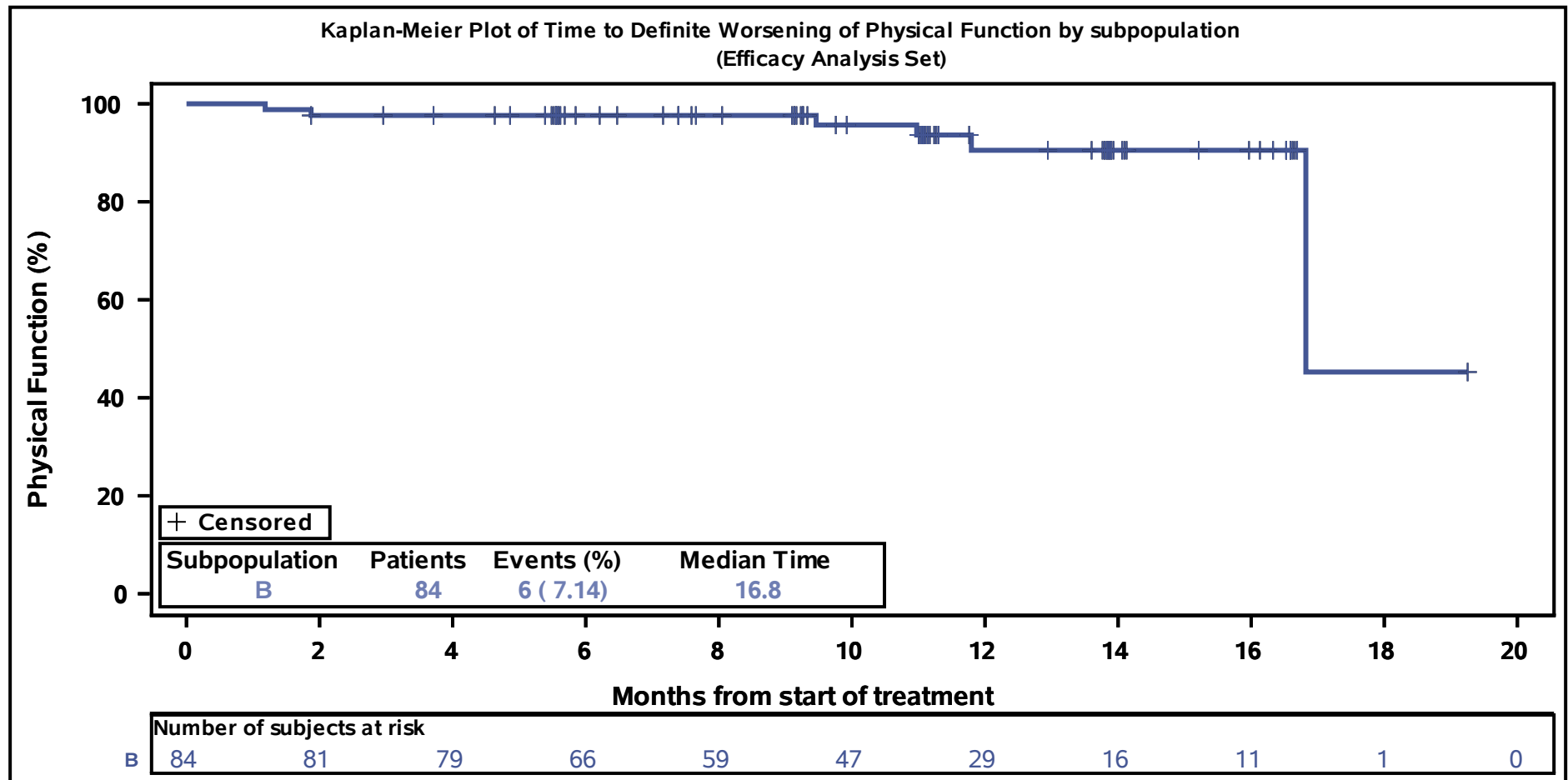
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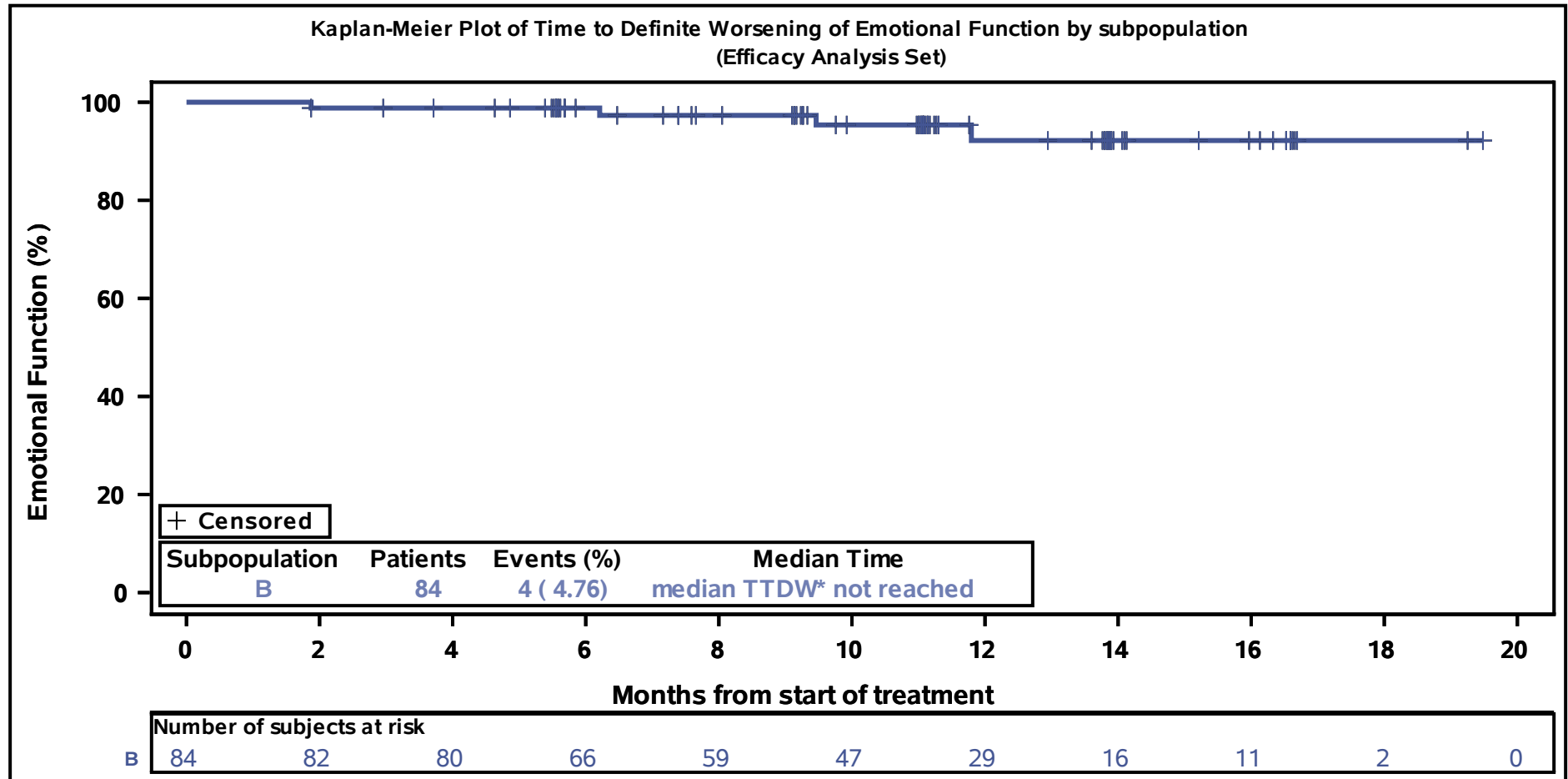
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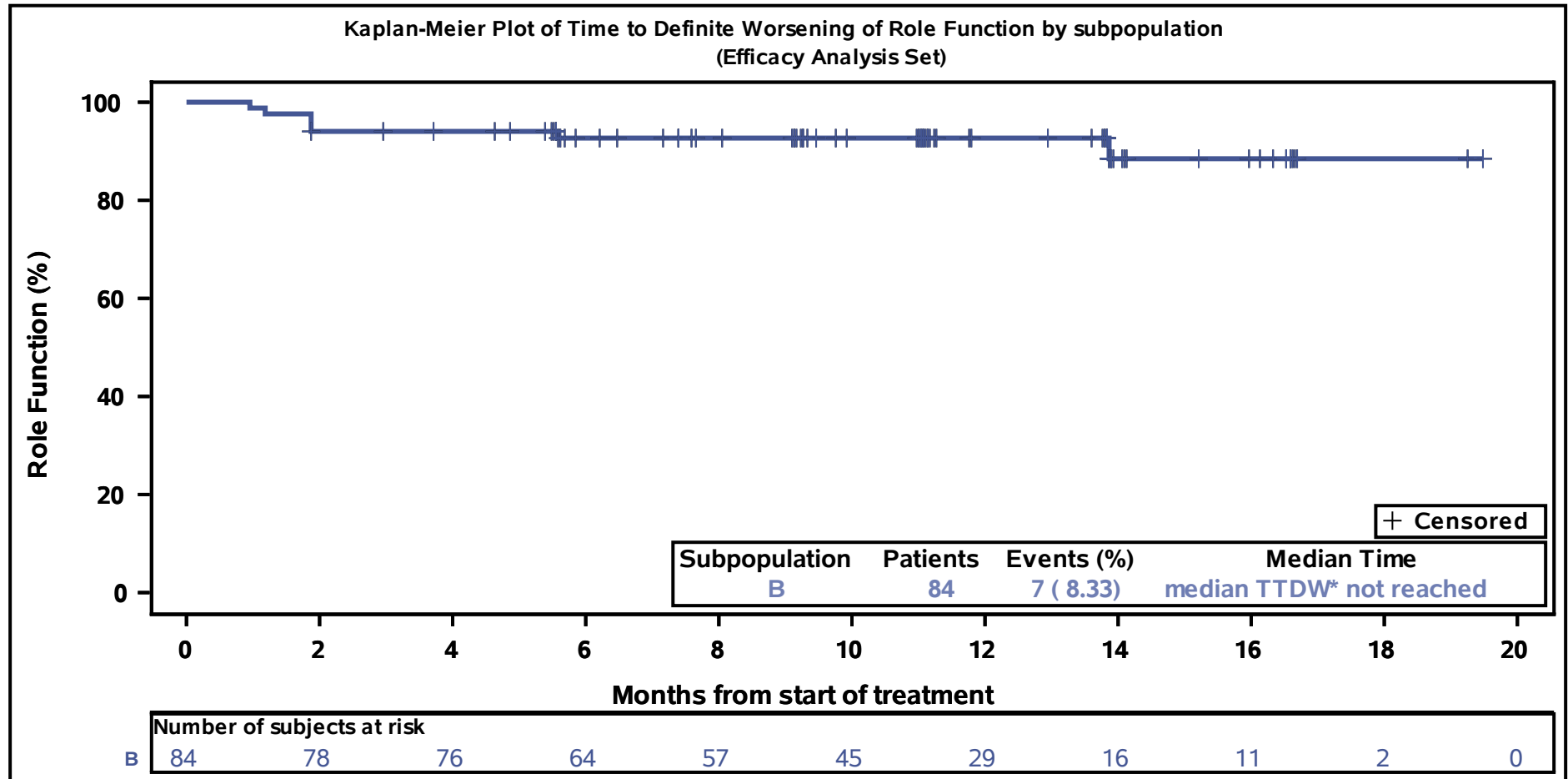
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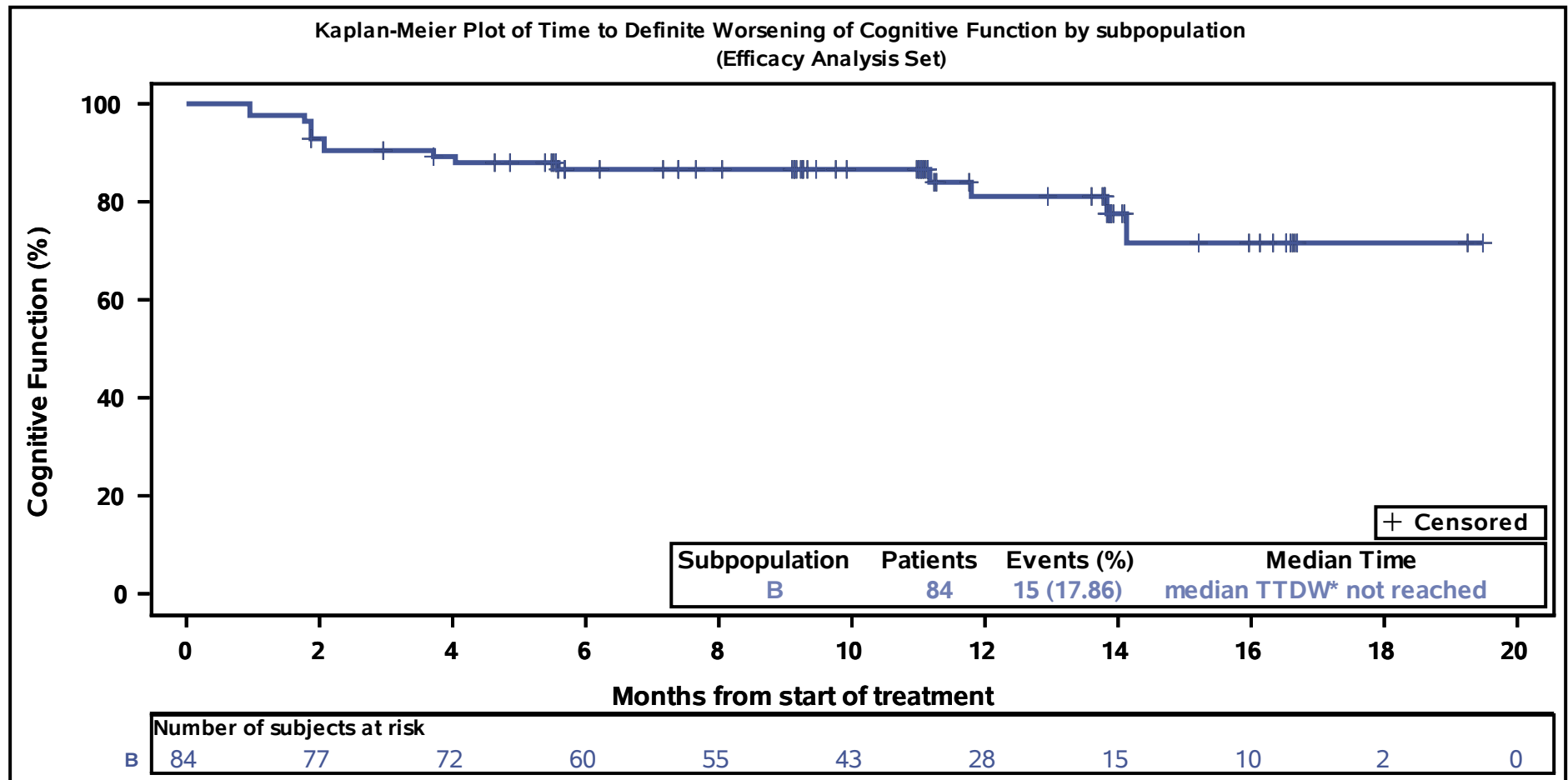
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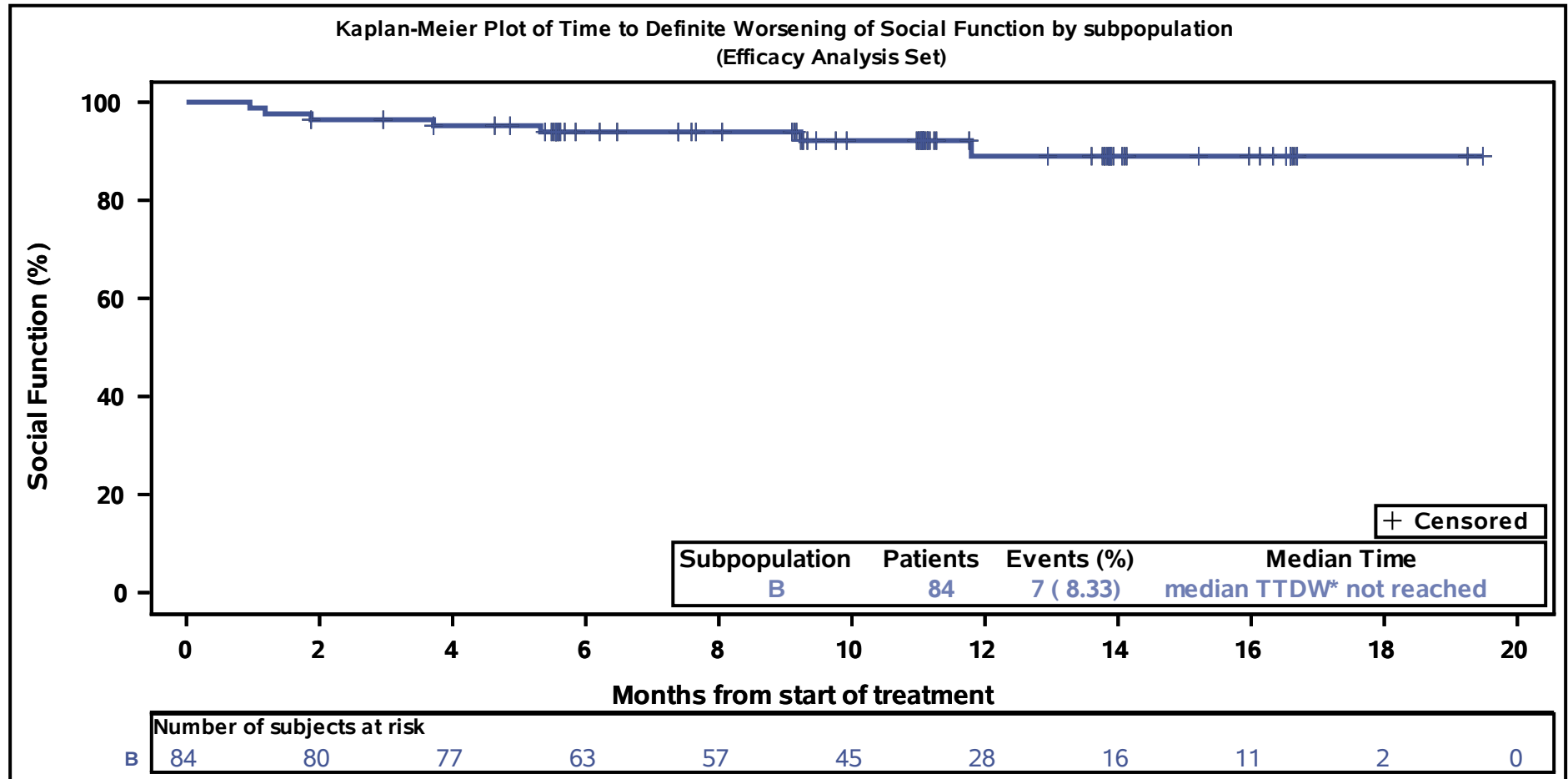
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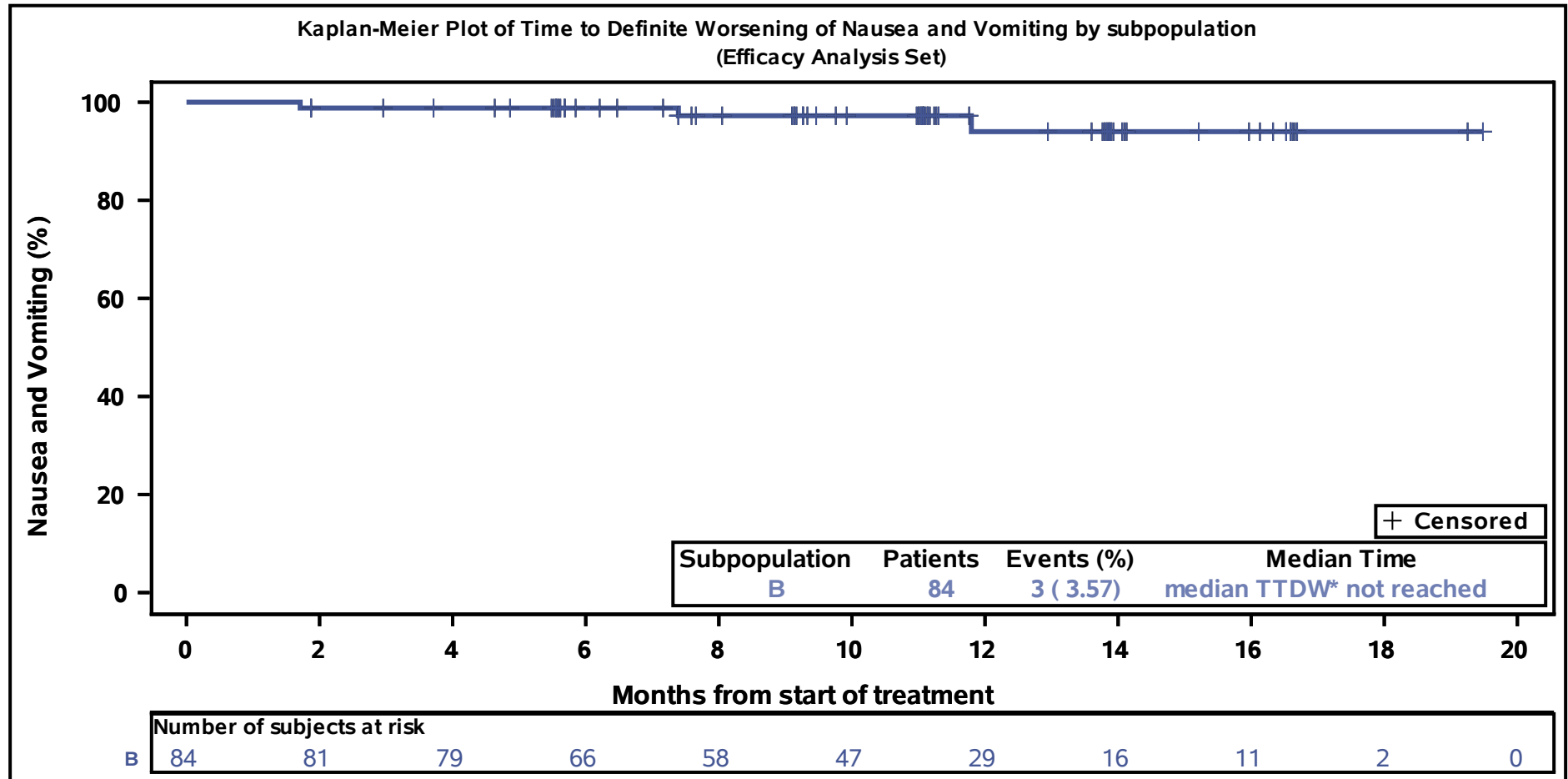
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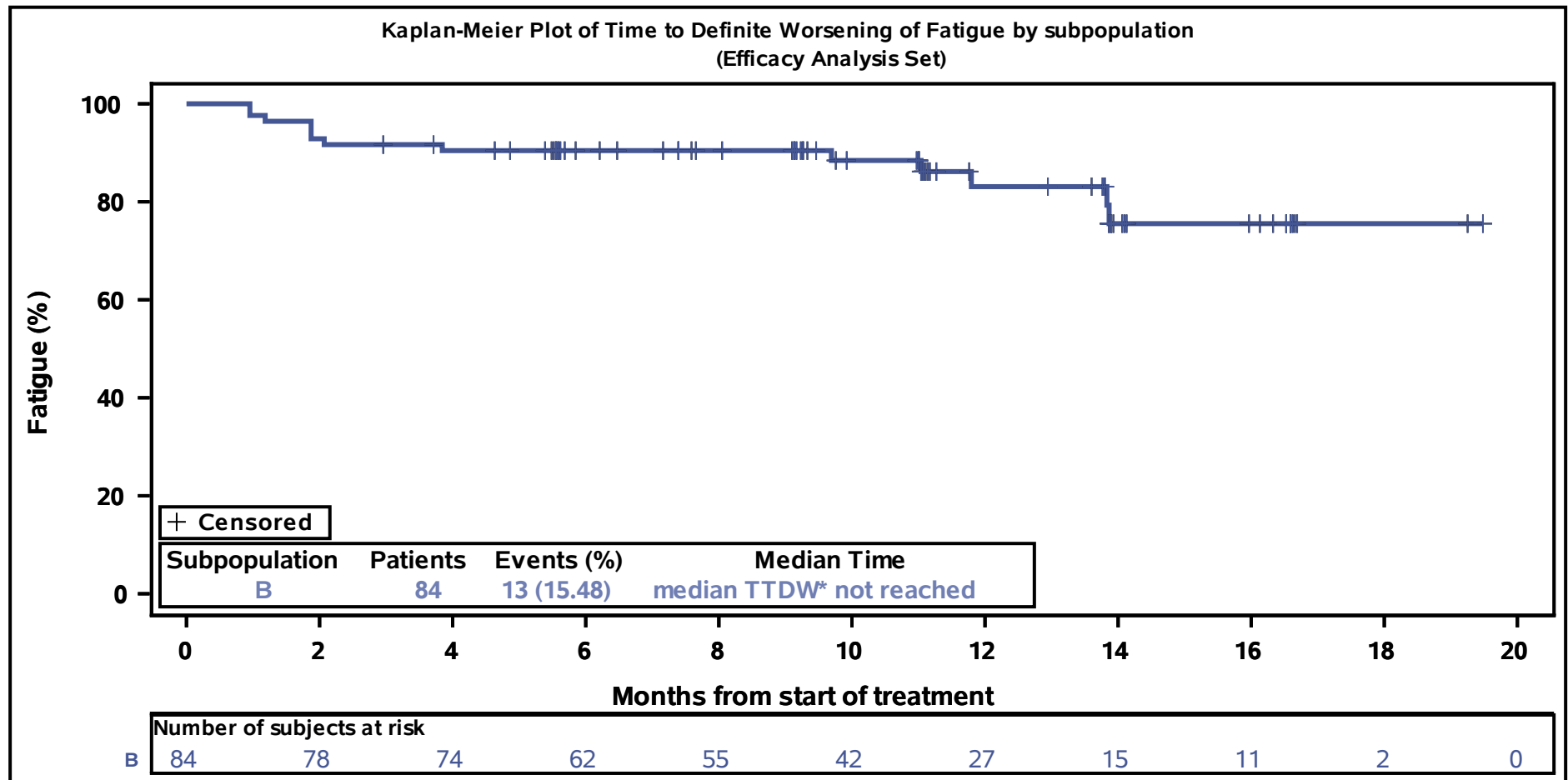
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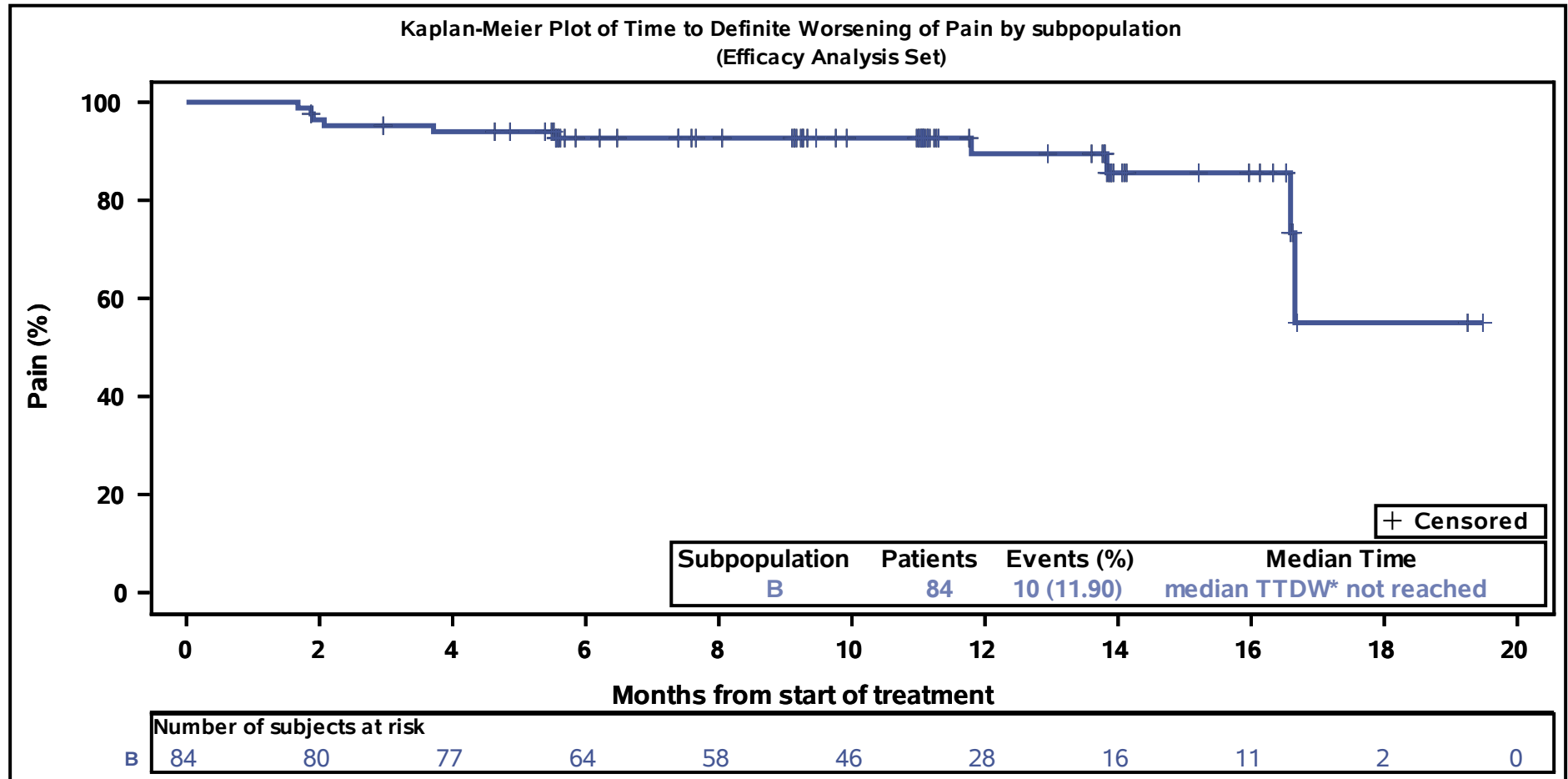
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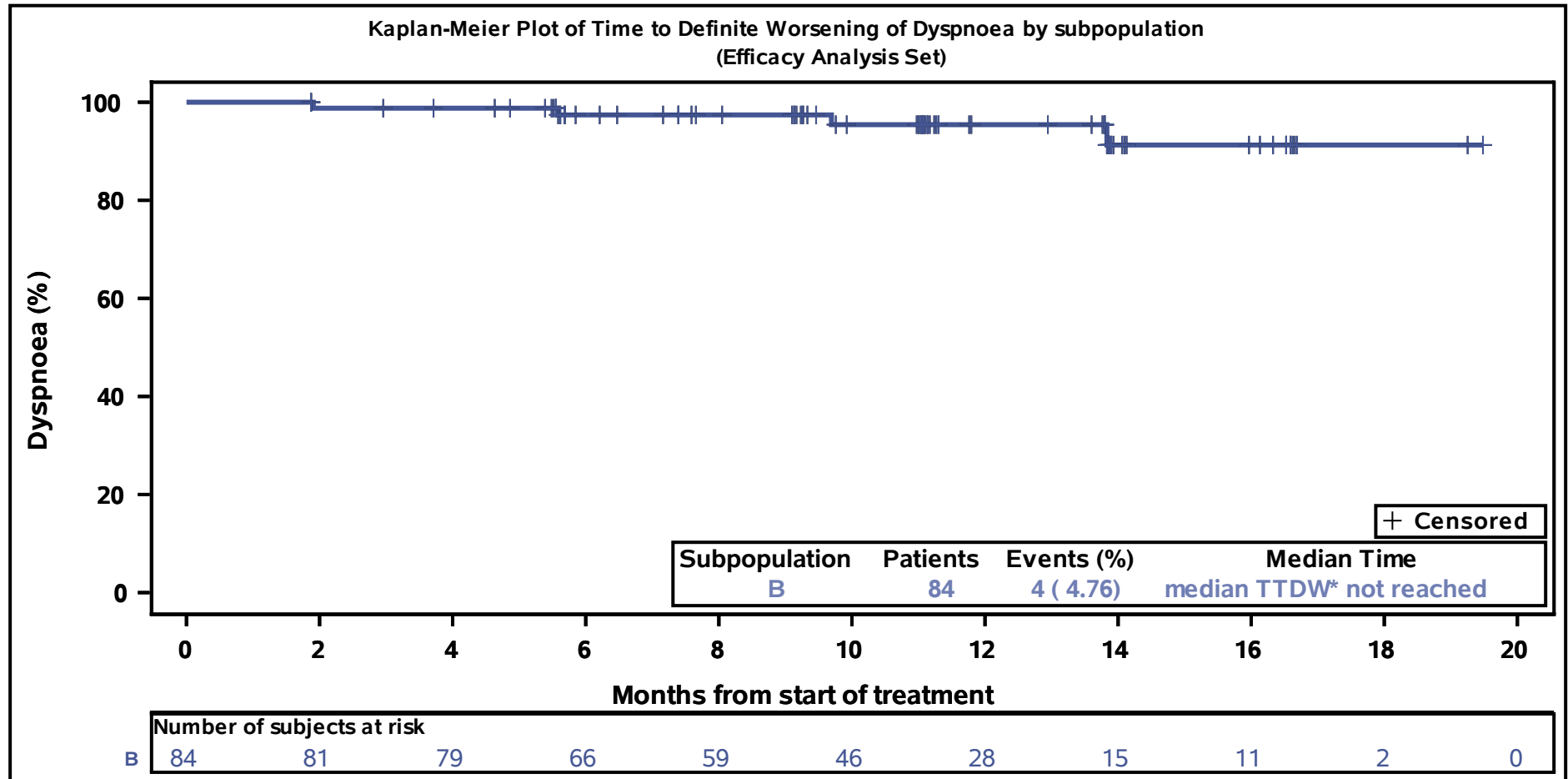
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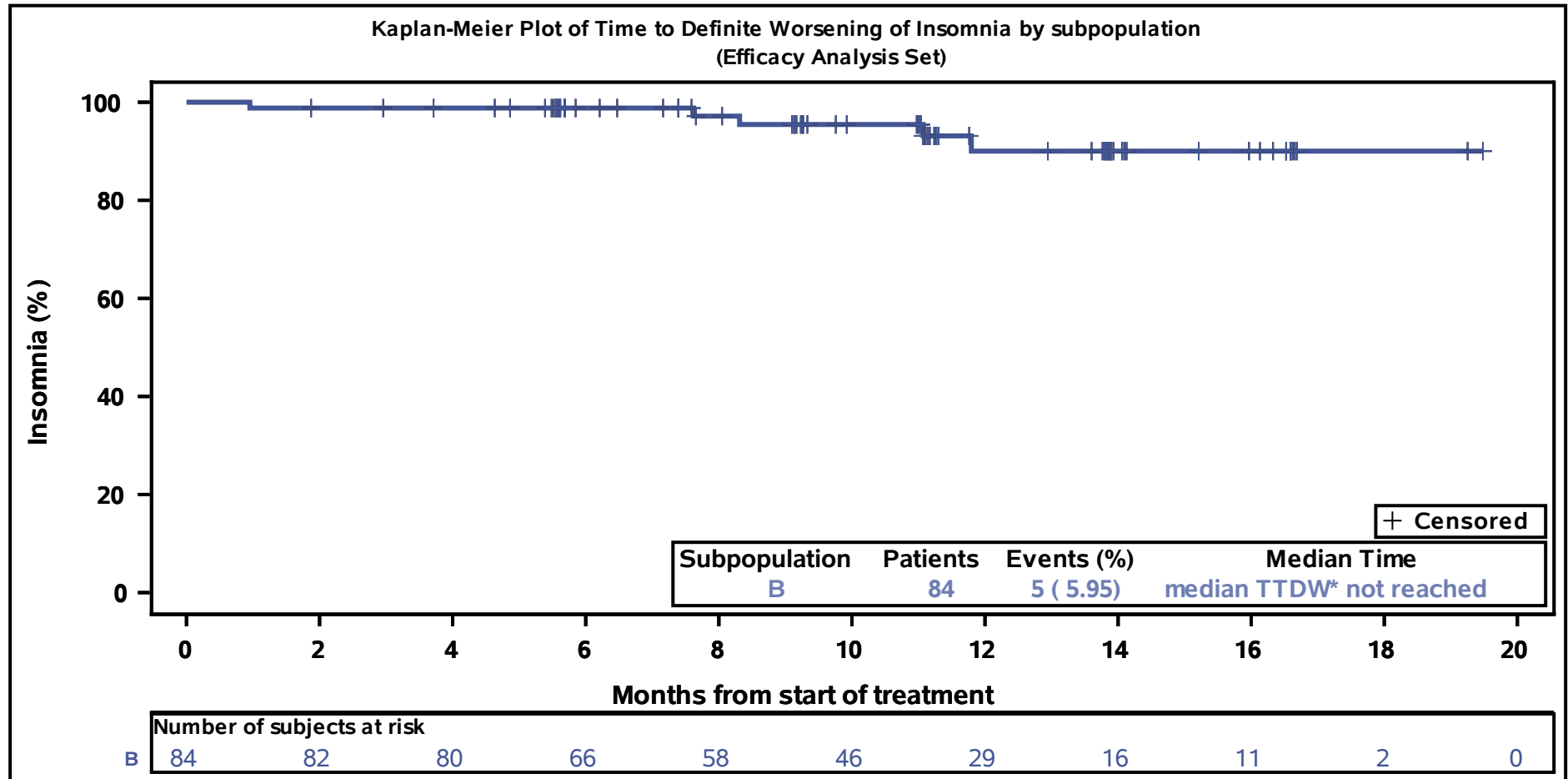
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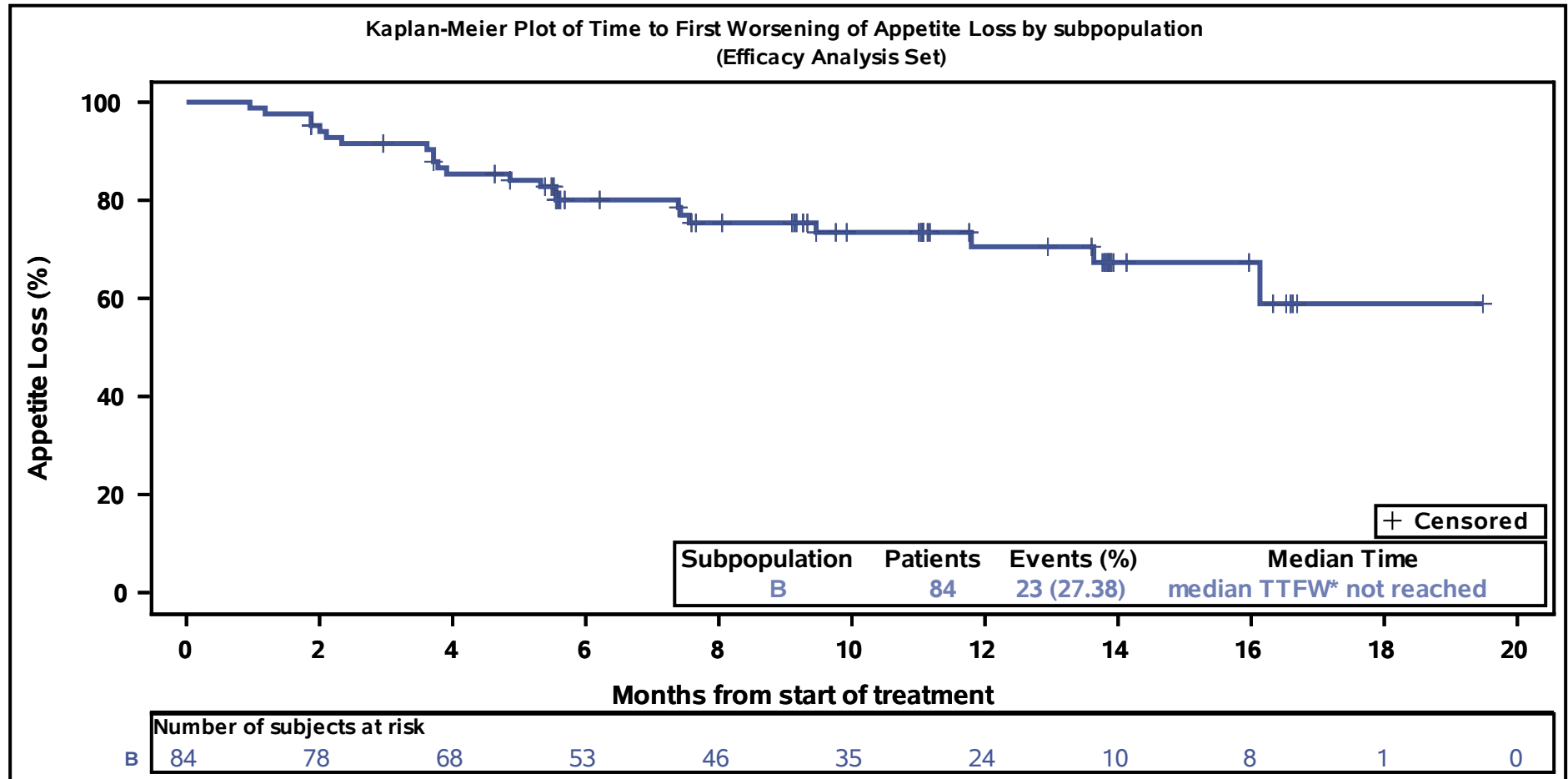
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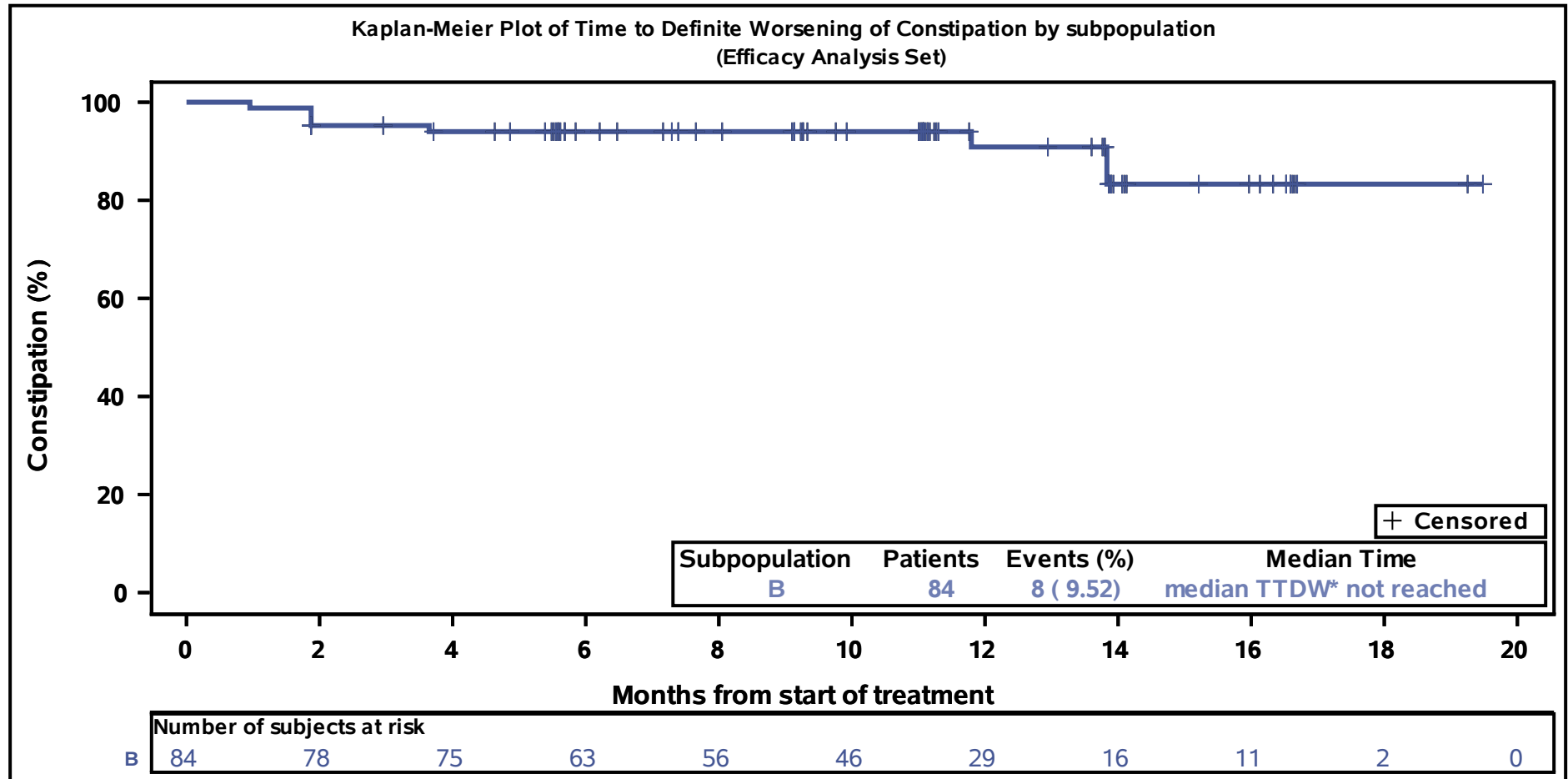
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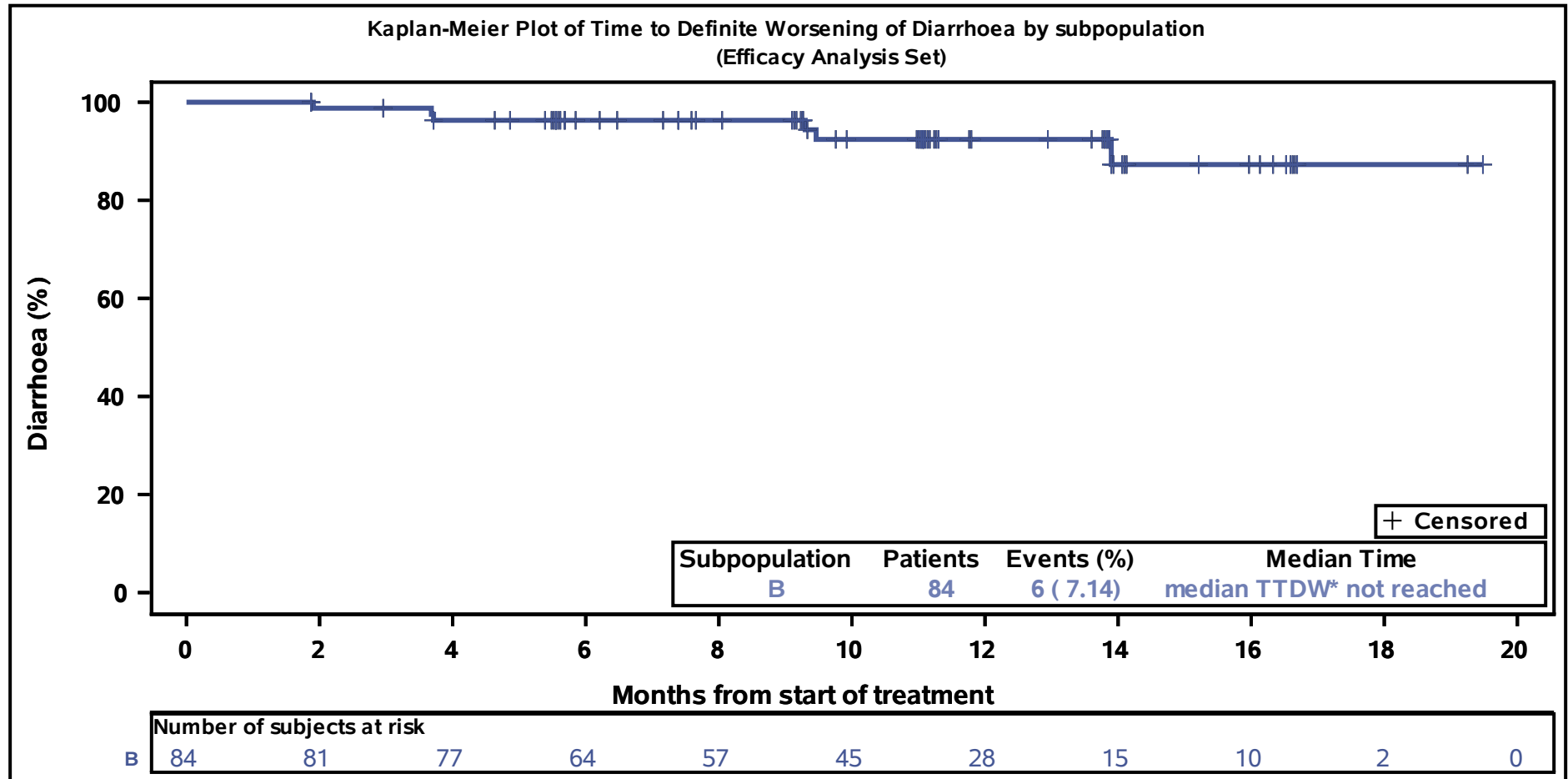
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Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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* TTDW = Time-to Definite Worsening

Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included

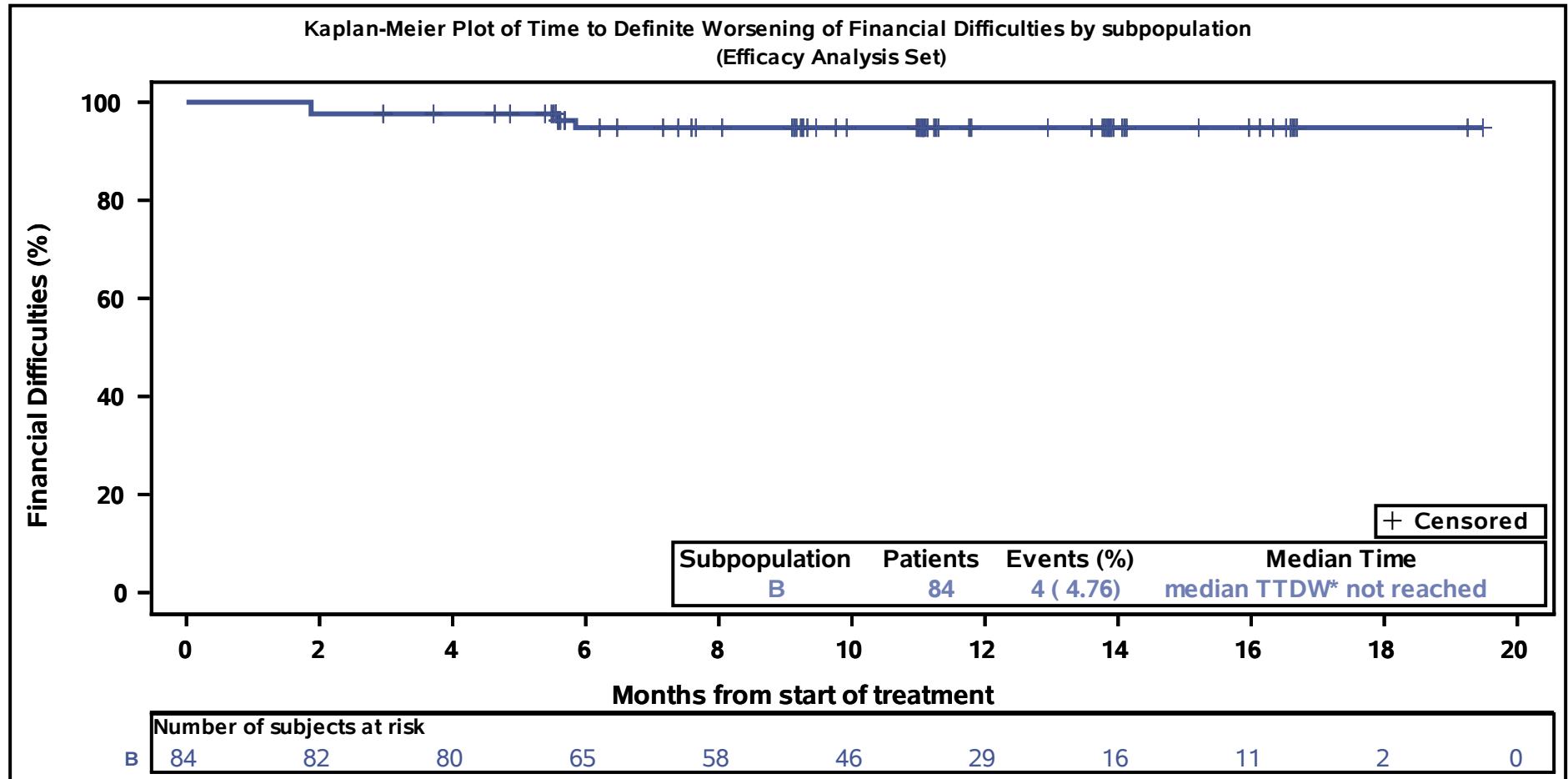
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Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F033_1_ttw_10pt_mtc_b_eff.rtf

Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
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* TTDW = Time-to Definite Worsening

Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included

Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas

Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F034_1_ttw_10pt_mtc_b_eff.rtf

Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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T14.2.6.1.1_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)
Baseline [1]	
n [2]	83
Mean	60.94
Standard Deviation	23.387
Median	66.67
Q1, Q3	41.7, 83.3
Min, Max	16.7, 100.0

- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.1_mtc_eff.rtf

Loxo Oncology Inc.
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T14.2.6.1.1_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 3 Day 1	
n [2]	77
Mean	68.72
Standard Deviation	23.692
Median	66.67
Q1, Q3	50.0, 91.7
Min, Max	0.0, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	77
Mean	8.01
Standard Deviation	26.882
Median	8.33
Q1, Q3	-8.3, 25.0
Min, Max	-66.7, 75.0
Status [3]	
Improved	32 (41.6)
Stable	30 (39.0)
Worsened	15 (19.5)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.1_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
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T14.2.6.1.1_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 5 Day 1	
n [2]	76
Mean	70.29
Standard Deviation	19.405
Median	66.67
Q1, Q3	58.3, 83.3
Min, Max	16.7, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	76
Mean	9.87
Standard Deviation	19.565
Median	8.33
Q1, Q3	0.0, 16.7
Min, Max	-50.0, 58.3
Status [3]	
Improved	33 (43.4)
Stable	37 (48.7)
Worsened	6 (7.9)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.1_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
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T14.2.6.1.1_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 7 Day 1	
n [2]	71
Mean	71.13
Standard Deviation	19.962
Median	75.00
Q1, Q3	58.3, 83.3
Min, Max	16.7, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	71
Mean	8.80
Standard Deviation	21.817
Median	8.33
Q1, Q3	0.0, 25.0
Min, Max	-58.3, 58.3
Status [3]	
Improved	33 (46.5)
Stable	29 (40.8)
Worsened	9 (12.7)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.1_mtc_eff.rtf

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T14.2.6.1.1_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)

Cycle 9 Day 1	
n [2]	62
Mean	71.77
Standard Deviation	20.264
Median	75.00
Q1, Q3	58.3, 83.3
Min, Max	16.7, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	62
Mean	11.02
Standard Deviation	19.603
Median	8.33
Q1, Q3	0.0, 16.7
Min, Max	-50.0, 58.3
Status [3]	
Improved	28 (45.2)
Stable	29 (46.8)
Worsened	5 (8.1)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
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 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.1_mtc_eff.rtf

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T14.2.6.1.1_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 11 Day 1	
n [2]	56
Mean	70.54
Standard Deviation	19.067
Median	75.00
Q1, Q3	58.3, 83.3
Min, Max	33.3, 100.0
Change from Baseline to Cycle 11 Day 1	
n [2]	56
Mean	9.52
Standard Deviation	21.108
Median	4.17
Q1, Q3	-8.3, 20.8
Min, Max	-33.3, 58.3
Status [3]	
Improved	23 (41.1)
Stable	27 (48.2)
Worsened	6 (10.7)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
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 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.1_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)

Cycle 13 Day 1	
n [2]	43
Mean	71.71
Standard Deviation	15.230
Median	66.67
Q1, Q3	66.7, 83.3
Min, Max	41.7, 100.0
Change from Baseline to Cycle 13 Day 1	
n [2]	43
Mean	10.66
Standard Deviation	17.567
Median	8.33
Q1, Q3	0.0, 25.0
Min, Max	-16.7, 50.0
Status [3]	
Improved	19 (44.2)
Stable	22 (51.2)
Worsened	2 (4.7)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.1_mtc_eff.rtf

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 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.1_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)

Cycle 16 Day 1	
n [2]	24
Mean	68.75
Standard Deviation	20.596
Median	66.67
Q1, Q3	58.3, 83.3
Min, Max	16.7, 100.0
Change from Baseline to Cycle 16 Day 1	
n [2]	24
Mean	10.07
Standard Deviation	26.004
Median	8.33
Q1, Q3	0.0, 25.0
Min, Max	-66.7, 50.0
Status [3]	
Improved	11 (45.8)
Stable	9 (37.5)
Worsened	4 (16.7)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.1_mtc_eff.rtf

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 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.1_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 19 Day 1	
n [2]	10
Mean	66.67
Standard Deviation	16.667
Median	75.00
Q1, Q3	50.0, 75.0
Min, Max	33.3, 83.3
Change from Baseline to Cycle 19 Day 1	
n [2]	10
Mean	15.83
Standard Deviation	22.720
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	-16.7, 41.7
Status [3]	
Improved	5 (50.0)
Stable	4 (40.0)
Worsened	1 (10.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.1_mtc_eff.rtf

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T14.2.6.1.1_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 22 Day 1	
n [2]	2
Mean	70.83
Standard Deviation	5.893
Median	70.83
Q1, Q3	66.7, 75.0
Min, Max	66.7, 75.0
Change from Baseline to Cycle 22 Day 1	
n [2]	2
Mean	16.67
Standard Deviation	35.355
Median	16.67
Q1, Q3	-8.3, 41.7
Min, Max	-8.3, 41.7
Status [3]	
Improved	1 (50.0)
Stable	1 (50.0)
Worsened	0 (0.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.1_mtc_eff.rtf

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T14.2.6.1.1_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

End of Treatment	
n [2]	7
Mean	60.71
Standard Deviation	24.867
Median	58.33
Q1, Q3	33.3, 83.3
Min, Max	33.3, 100.0
Change from Baseline to End of Treatment	
n [2]	7
Mean	5.95
Standard Deviation	22.420
Median	0.00
Q1, Q3	-8.3, 16.7
Min, Max	-16.7, 50.0
Status [3]	
Improved	2 (28.6)
Stable	4 (57.1)
Worsened	1 (14.3)

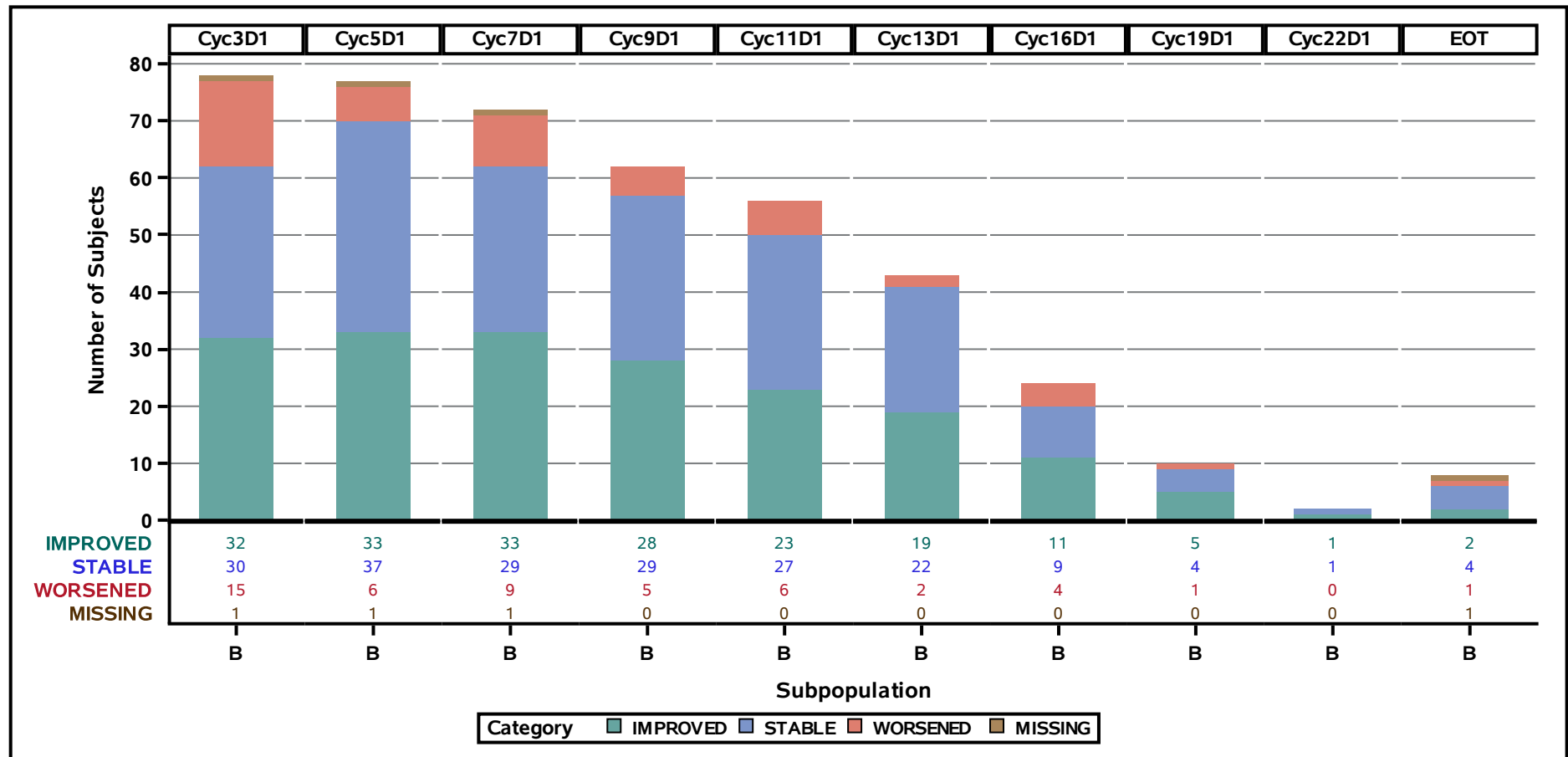
-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.1_mtc_eff.rtf

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 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Changes from baseline in QLQ-C30 scores by Global Health Status/QoL
 (Efficacy Analysis Set)
 by Subpopulation



Program Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
 Output Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F040_ql2_10pt_mtc_eff.rtf
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
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T14.2.6.1.31
 EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	83 60.94 (23.39)	77 8.11 (4.15, 12.08)
CYCLE 5 DAY 1		76 9.80 (5.81, 13.79)
CYCLE 7 DAY 1		71 9.83 (5.70, 13.97)
CYCLE 9 DAY 1		62 11.15 (6.73, 15.57)
CYCLE 11 DAY 1		56 9.80 (5.15, 14.45)
CYCLE 13 DAY 1		43 10.95 (5.65, 16.26)
CYCLE 16 DAY 1		24 9.00 (1.90, 16.11)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.31.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
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T14.2.6.1.31
 EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1		10 10.25 (-0.78, 21.28)
CYCLE 22 DAY 1		2 13.00 (-11.62, 37.62)
END OF TREATMENT		7 2.63 (-10.53, 15.79)

 N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
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 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.31.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.2_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)
Baseline [1]	
n [2]	84
Mean	75.48
Standard Deviation	21.712
Median	73.33
Q1, Q3	60.0, 96.7
Min, Max	20.0, 100.0

- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.2_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
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T14.2.6.1.2_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 3 Day 1	
n [2]	78
Mean	80.09
Standard Deviation	20.541
Median	86.67
Q1, Q3	60.0, 100.0
Min, Max	26.7, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	78
Mean	4.27
Standard Deviation	19.279
Median	0.00
Q1, Q3	0.0, 13.3
Min, Max	-66.7, 66.7
Status [3]	
Improved	23 (29.5)
Stable	43 (55.1)
Worsened	12 (15.4)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.2_mtc_eff.rtf

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T14.2.6.1.2_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 5 Day 1	
n [2]	77
Mean	84.09
Standard Deviation	17.627
Median	86.67
Q1, Q3	73.3, 100.0
Min, Max	13.3, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	77
Mean	8.07
Standard Deviation	15.818
Median	0.00
Q1, Q3	0.0, 20.0
Min, Max	-20.0, 46.7
Status [3]	
Improved	25 (32.5)
Stable	47 (61.0)
Worsened	5 (6.5)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.2_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
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T14.2.6.1.2_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 7 Day 1	
n [2]	72
Mean	83.84
Standard Deviation	19.337
Median	93.33
Q1, Q3	73.3, 100.0
Min, Max	20.0, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	72
Mean	5.97
Standard Deviation	16.941
Median	0.00
Q1, Q3	0.0, 15.0
Min, Max	-33.3, 46.7
Status [3]	
Improved	23 (31.9)
Stable	41 (56.9)
Worsened	8 (11.1)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.2_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
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T14.2.6.1.2_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 9 Day 1	
n [2]	62
Mean	82.37
Standard Deviation	19.356
Median	86.67
Q1, Q3	66.7, 100.0
Min, Max	13.3, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	62
Mean	6.02
Standard Deviation	17.314
Median	0.00
Q1, Q3	0.0, 13.3
Min, Max	-33.3, 46.7
Status [3]	
Improved	19 (30.6)
Stable	36 (58.1)
Worsened	7 (11.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.2_mtc_eff.rtf

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T14.2.6.1.2_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 11 Day 1	
n [2]	56
Mean	83.93
Standard Deviation	16.565
Median	86.67
Q1, Q3	80.0, 100.0
Min, Max	6.7, 100.0
Change from Baseline to Cycle 11 Day 1	
n [2]	56
Mean	8.10
Standard Deviation	19.057
Median	0.00
Q1, Q3	0.0, 20.0
Min, Max	-20.0, 60.0
Status [3]	
Improved	21 (37.5)
Stable	27 (48.2)
Worsened	8 (14.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.2_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.2_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 13 Day 1	
n [2]	43
Mean	82.17
Standard Deviation	20.248
Median	86.67
Q1, Q3	73.3, 100.0
Min, Max	20.0, 100.0
Change from Baseline to Cycle 13 Day 1	
n [2]	43
Mean	3.57
Standard Deviation	15.143
Median	0.00
Q1, Q3	0.0, 13.3
Min, Max	-26.7, 46.7
Status [3]	
Improved	11 (25.6)
Stable	25 (58.1)
Worsened	7 (16.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.2_mtc_eff.rtf

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 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.2_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 16 Day 1	
n [2]	24
Mean	81.39
Standard Deviation	17.581
Median	86.67
Q1, Q3	66.7, 100.0
Min, Max	40.0, 100.0
Change from Baseline to Cycle 16 Day 1	
n [2]	24
Mean	3.89
Standard Deviation	17.574
Median	0.00
Q1, Q3	-6.7, 13.3
Min, Max	-20.0, 46.7
Status [3]	
Improved	7 (29.2)
Stable	13 (54.2)
Worsened	4 (16.7)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.2_mtc_eff.rtf

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 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.2_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 19 Day 1	
n [2]	10
Mean	78.00
Standard Deviation	19.386
Median	76.67
Q1, Q3	66.7, 93.3
Min, Max	40.0, 100.0
Change from Baseline to Cycle 19 Day 1	
n [2]	10
Mean	8.67
Standard Deviation	25.925
Median	0.00
Q1, Q3	-6.7, 33.3
Min, Max	-33.3, 53.3
Status [3]	
Improved	3 (30.0)
Stable	6 (60.0)
Worsened	1 (10.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.2_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.2_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 22 Day 1	
n [2]	2
Mean	60.00
Standard Deviation	9.428
Median	60.00
Q1, Q3	53.3, 66.7
Min, Max	53.3, 66.7
Change from Baseline to Cycle 22 Day 1	
n [2]	2
Mean	-23.33
Standard Deviation	23.570
Median	-23.33
Q1, Q3	-40.0, -6.7
Min, Max	-40.0, -6.7
Status [3]	
Improved	0 (0.0)
Stable	1 (50.0)
Worsened	1 (50.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.2_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.2_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

End of Treatment	
n [2]	8
Mean	82.50
Standard Deviation	21.063
Median	86.67
Q1, Q3	83.3, 93.3
Min, Max	33.3, 100.0
Change from Baseline to End of Treatment	
n [2]	8
Mean	15.00
Standard Deviation	25.635
Median	16.67
Q1, Q3	0.0, 26.7
Min, Max	-26.7, 60.0
Status [3]	
Improved	5 (62.5)
Stable	2 (25.0)
Worsened	1 (12.5)

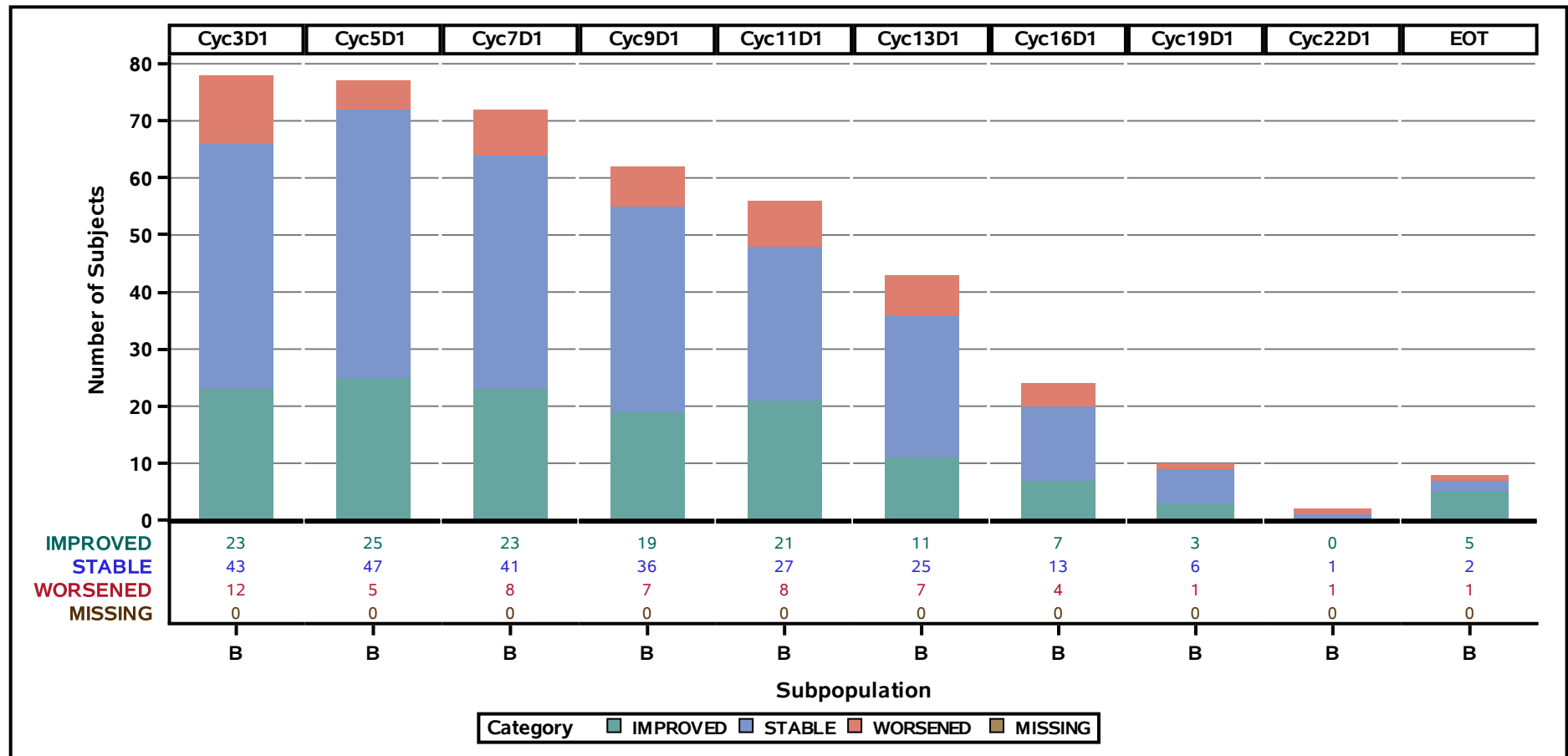
-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.2_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Changes from baseline in QLQ-C30 scores by Physical Function
 (Efficacy Analysis Set)
 by Subpopulation



Program Location: //lilly/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
 Output Location: //lilly/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F041_pf2_10pt_mtc_eff.rtf
 Data Location: //lilly/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: //lilly/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.32
 EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	84 75.48 (21.71)	78 4.02 (0.70, 7.33)
CYCLE 5 DAY 1		77 7.91 (4.58, 11.25)
CYCLE 7 DAY 1		72 6.66 (3.20, 10.11)
CYCLE 9 DAY 1		62 6.01 (2.29, 9.73)
CYCLE 11 DAY 1		56 7.85 (3.94, 11.76)
CYCLE 13 DAY 1		43 4.58 (0.12, 9.05)
CYCLE 16 DAY 1		24 4.40 (-1.57, 10.38)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.32.rtf

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 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.32
 EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1		10 5.46 (-3.81, 14.72)
CYCLE 22 DAY 1		2 -20.16 (-40.86, 0.54)
END OF TREATMENT		8 10.95 (0.59, 21.32)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.32.rtf

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 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.3_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)
Baseline [1]	
n [2]	83
Mean	75.67
Standard Deviation	23.304
Median	83.33
Q1, Q3	58.3, 100.0
Min, Max	8.3, 100.0

- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
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 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.3_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.3_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 3 Day 1	
n [2]	77
Mean	82.68
Standard Deviation	20.491
Median	91.67
Q1, Q3	75.0, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	77
Mean	8.12
Standard Deviation	19.495
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	-33.3, 83.3
Status [3]	
Improved	27 (35.1)
Stable	42 (54.5)
Worsened	8 (10.4)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.3_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.3_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 5 Day 1	
n [2]	76
Mean	82.24
Standard Deviation	21.574
Median	91.67
Q1, Q3	66.7, 100.0
Min, Max	16.7, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	76
Mean	6.62
Standard Deviation	20.326
Median	5.56
Q1, Q3	0.0, 16.7
Min, Max	-41.7, 75.0
Status [3]	
Improved	22 (28.9)
Stable	45 (59.2)
Worsened	9 (11.8)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.3_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
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T14.2.6.1.3_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 7 Day 1	
n [2]	71
Mean	83.33
Standard Deviation	18.740
Median	91.67
Q1, Q3	66.7, 100.0
Min, Max	33.3, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	71
Mean	6.92
Standard Deviation	17.705
Median	8.33
Q1, Q3	0.0, 16.7
Min, Max	-25.0, 50.0
Status [3]	
Improved	23 (32.4)
Stable	38 (53.5)
Worsened	10 (14.1)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.3_mtc_eff.rtf

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T14.2.6.1.3_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)

Cycle 9 Day 1	
n [2]	62
Mean	83.33
Standard Deviation	20.524
Median	91.67
Q1, Q3	75.0, 100.0
Min, Max	8.3, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	62
Mean	8.06
Standard Deviation	22.277
Median	8.33
Q1, Q3	0.0, 16.7
Min, Max	-50.0, 83.3
Status [3]	
Improved	22 (35.5)
Stable	32 (51.6)
Worsened	8 (12.9)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.3_mtc_eff.rtf

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T14.2.6.1.3_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 11 Day 1	
n [2]	56
Mean	86.76
Standard Deviation	14.718
Median	91.67
Q1, Q3	75.0, 100.0
Min, Max	41.7, 100.0
Change from Baseline to Cycle 11 Day 1	
n [2]	56
Mean	11.01
Standard Deviation	22.591
Median	0.00
Q1, Q3	0.0, 25.0
Min, Max	-25.0, 91.7
Status [3]	
Improved	21 (37.5)
Stable	31 (55.4)
Worsened	4 (7.1)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.3_mtc_eff.rtf

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T14.2.6.1.3_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 13 Day 1	
n [2]	43
Mean	82.56
Standard Deviation	18.969
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	16.7, 100.0
Change from Baseline to Cycle 13 Day 1	
n [2]	43
Mean	6.01
Standard Deviation	19.101
Median	0.00
Q1, Q3	-8.3, 16.7
Min, Max	-25.0, 58.3
Status [3]	
Improved	15 (34.9)
Stable	21 (48.8)
Worsened	7 (16.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.3_mtc_eff.rtf

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T14.2.6.1.3_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 16 Day 1	
n [2]	24
Mean	83.33
Standard Deviation	17.549
Median	87.50
Q1, Q3	66.7, 100.0
Min, Max	50.0, 100.0
Change from Baseline to Cycle 16 Day 1	
n [2]	24
Mean	13.54
Standard Deviation	21.816
Median	8.33
Q1, Q3	0.0, 16.7
Min, Max	-25.0, 75.0
Status [3]	
Improved	11 (45.8)
Stable	12 (50.0)
Worsened	1 (4.2)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.3_mtc_eff.rtf

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T14.2.6.1.3_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)

Cycle 19 Day 1	
n [2]	10
Mean	87.50
Standard Deviation	12.577
Median	87.50
Q1, Q3	75.0, 100.0
Min, Max	66.7, 100.0
Change from Baseline to Cycle 19 Day 1	
n [2]	10
Mean	23.33
Standard Deviation	31.131
Median	16.67
Q1, Q3	0.0, 50.0
Min, Max	-25.0, 75.0
Status [3]	
Improved	7 (70.0)
Stable	2 (20.0)
Worsened	1 (10.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.3_mtc_eff.rtf

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T14.2.6.1.3_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 22 Day 1	
n [2]	2
Mean	100.00
Standard Deviation	0.000
Median	100.00
Q1, Q3	100.0, 100.0
Min, Max	100.0, 100.0
Change from Baseline to Cycle 22 Day 1	
n [2]	2
Mean	16.67
Standard Deviation	0.000
Median	16.67
Q1, Q3	16.7, 16.7
Min, Max	16.7, 16.7
Status [3]	
Improved	2 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.3_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.3_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

End of Treatment	
n [2]	7
Mean	78.57
Standard Deviation	24.934
Median	91.67
Q1, Q3	58.3, 100.0
Min, Max	33.3, 100.0
Change from Baseline to End of Treatment	
n [2]	7
Mean	-3.57
Standard Deviation	23.002
Median	0.00
Q1, Q3	-8.3, 8.3
Min, Max	-50.0, 25.0
Status [3]	
Improved	1 (14.3)
Stable	5 (71.4)
Worsened	1 (14.3)

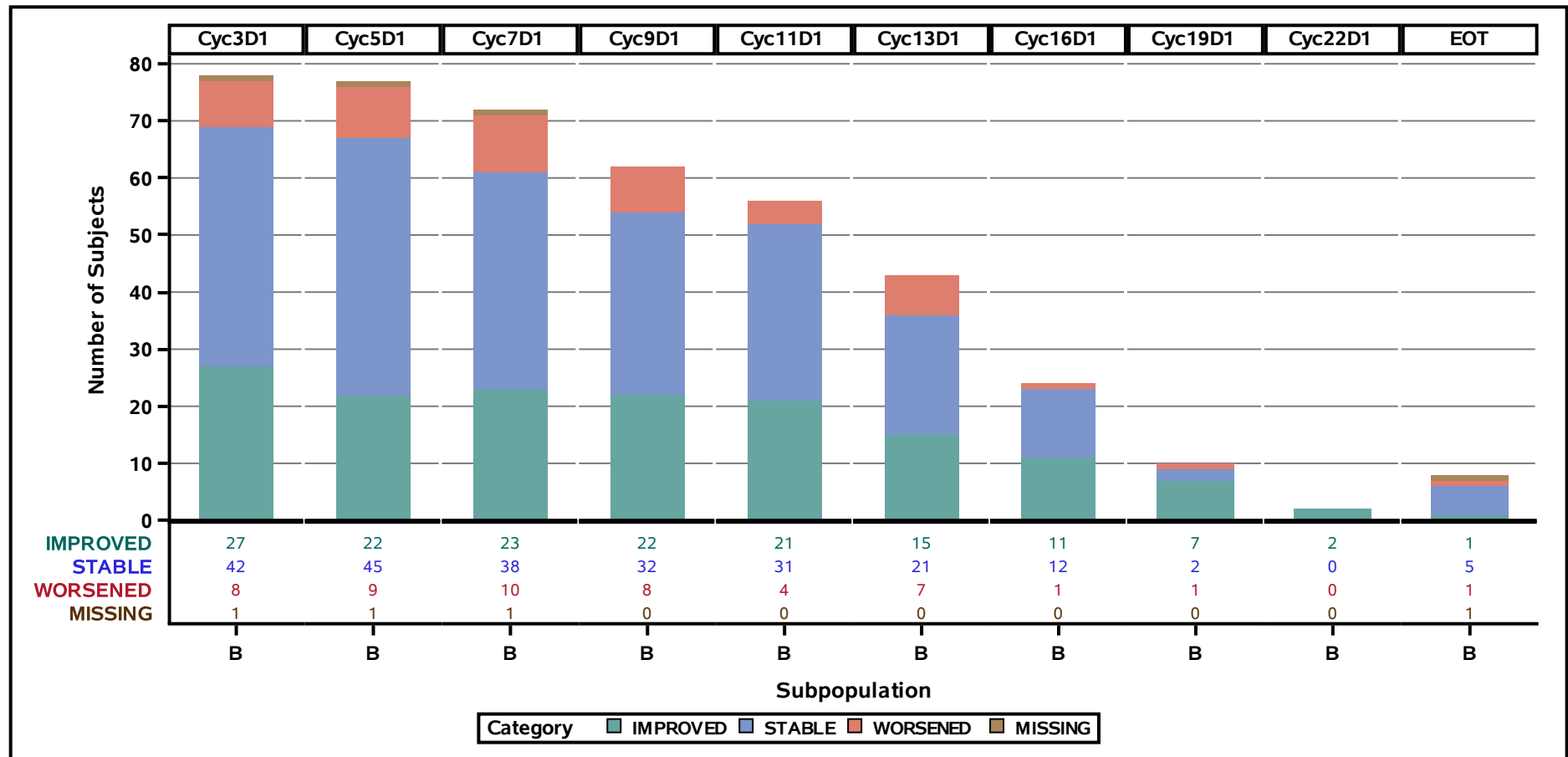
-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.3_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Changes from baseline in QLQ-C30 scores by Emotional functioning
 (Efficacy Analysis Set)
 by Subpopulation



Program Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
 Output Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F042_ef_10pt_mtc_eff.rtf
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.33
 EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	83 75.67 (23.30)	77 7.79 (4.18, 11.40)
CYCLE 5 DAY 1		76 6.86 (3.23, 10.49)
CYCLE 7 DAY 1		71 7.60 (3.85, 11.36)
CYCLE 9 DAY 1		62 8.12 (4.10, 12.14)
CYCLE 11 DAY 1		56 11.33 (7.10, 15.56)
CYCLE 13 DAY 1		43 6.76 (1.94, 11.59)
CYCLE 16 DAY 1		24 10.60 (4.13, 17.07)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.33.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.33
 EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1		10 17.32 (7.28, 27.35)
CYCLE 22 DAY 1		2 21.13 (-1.26, 43.52)
END OF TREATMENT		7 0.24 (-11.73, 12.21)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.33.rtf

Loxo Oncology Inc.
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 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.4_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)
Baseline [1]	
n [2]	84
Mean	66.27
Standard Deviation	30.827
Median	66.67
Q1, Q3	41.7, 100.0
Min, Max	0.0, 100.0

- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.4_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.4_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 3 Day 1	
n [2]	78
Mean	73.93
Standard Deviation	28.119
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	78
Mean	7.91
Standard Deviation	31.178
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	-100.0, 83.3
Status [3]	
Improved	37 (47.4)
Stable	25 (32.1)
Worsened	16 (20.5)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.4_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.4_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 5 Day 1	
n [2]	77
Mean	80.30
Standard Deviation	24.591
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	16.7, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	77
Mean	14.72
Standard Deviation	26.898
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	-33.3, 100.0
Status [3]	
Improved	35 (45.5)
Stable	32 (41.6)
Worsened	10 (13.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.4_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.4_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 7 Day 1	
n [2]	72
Mean	80.32
Standard Deviation	25.381
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	72
Mean	12.27
Standard Deviation	32.740
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	-66.7, 100.0
Status [3]	
Improved	34 (47.2)
Stable	22 (30.6)
Worsened	16 (22.2)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.4_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.4_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 9 Day 1	
n [2]	62
Mean	79.57
Standard Deviation	22.868
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	62
Mean	14.52
Standard Deviation	28.227
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	-33.3, 100.0
Status [3]	
Improved	30 (48.4)
Stable	25 (40.3)
Worsened	7 (11.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.4_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
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T14.2.6.1.4_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 11 Day 1	
n [2]	56
Mean	80.06
Standard Deviation	22.115
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 11 Day 1	
n [2]	56
Mean	14.58
Standard Deviation	31.150
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	-33.3, 100.0
Status [3]	
Improved	24 (42.9)
Stable	24 (42.9)
Worsened	8 (14.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.4_mtc_eff.rtf

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T14.2.6.1.4_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 13 Day 1	
n [2]	43
Mean	78.29
Standard Deviation	25.338
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 13 Day 1	
n [2]	43
Mean	11.24
Standard Deviation	27.632
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	-33.3, 100.0
Status [3]	
Improved	16 (37.2)
Stable	21 (48.8)
Worsened	6 (14.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.4_mtc_eff.rtf

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T14.2.6.1.4_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 16 Day 1	
n [2]	24
Mean	76.39
Standard Deviation	26.882
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 16 Day 1	
n [2]	24
Mean	14.58
Standard Deviation	35.885
Median	0.00
Q1, Q3	0.0, 41.7
Min, Max	-100.0, 83.3
Status [3]	
Improved	11 (45.8)
Stable	11 (45.8)
Worsened	2 (8.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.4_mtc_eff.rtf

Loxo Oncology Inc.
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T14.2.6.1.4_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 19 Day 1	
n [2]	10
Mean	78.33
Standard Deviation	17.656
Median	75.00
Q1, Q3	66.7, 100.0
Min, Max	50.0, 100.0
Change from Baseline to Cycle 19 Day 1	
n [2]	10
Mean	21.67
Standard Deviation	33.380
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	-16.7, 100.0
Status [3]	
Improved	6 (60.0)
Stable	3 (30.0)
Worsened	1 (10.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.4_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.4_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 22 Day 1	
n [2]	2
Mean	83.33
Standard Deviation	23.570
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	66.7, 100.0
Change from Baseline to Cycle 22 Day 1	
n [2]	2
Mean	-8.33
Standard Deviation	35.355
Median	-8.33
Q1, Q3	-33.3, 16.7
Min, Max	-33.3, 16.7
Status [3]	
Improved	1 (50.0)
Stable	0 (0.0)
Worsened	1 (50.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.4_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.4_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

End of Treatment	
n [2]	8
Mean	72.92
Standard Deviation	33.259
Median	75.00
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to End of Treatment	
n [2]	8
Mean	16.67
Standard Deviation	26.726
Median	25.00
Q1, Q3	0.0, 33.3
Min, Max	-33.3, 50.0
Status [3]	
Improved	5 (62.5)
Stable	2 (25.0)
Worsened	1 (12.5)

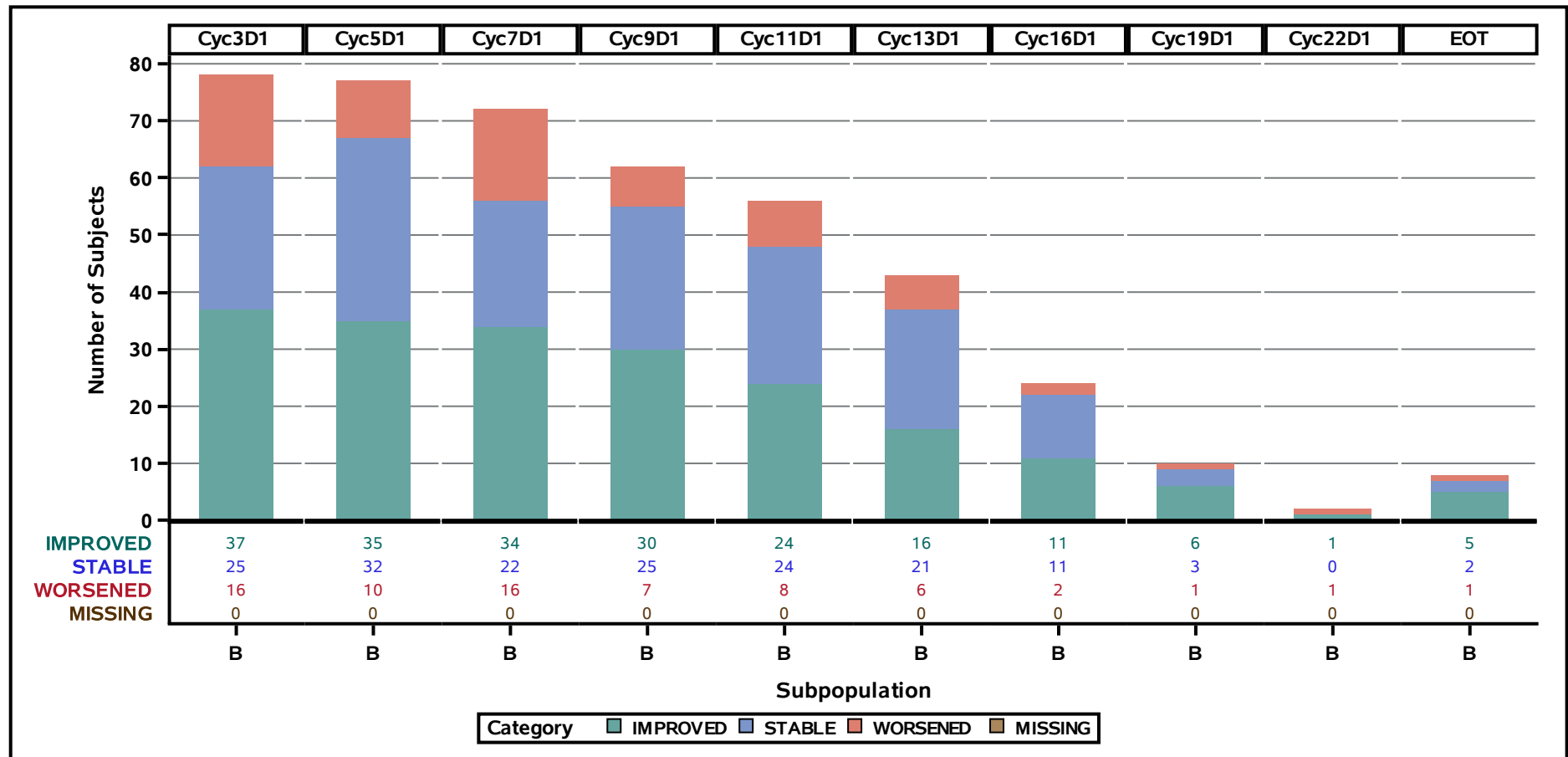
-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.4_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Changes from baseline in QLQ-C30 scores by Role functioning
 (Efficacy Analysis Set)
 by Subpopulation



Program Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
 Output Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F043_rf2_10pt_mtc_eff.rtf
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.34
 EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	84 66.27 (30.83)	78 8.14 (3.15, 13.12)
CYCLE 5 DAY 1		77 14.67 (9.65, 19.68)
CYCLE 7 DAY 1		72 13.80 (8.61, 18.99)
CYCLE 9 DAY 1		62 14.13 (8.54, 19.72)
CYCLE 11 DAY 1		56 14.46 (8.58, 20.35)
CYCLE 13 DAY 1		43 12.13 (5.42, 18.84)
CYCLE 16 DAY 1		24 12.11 (3.12, 21.10)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.34.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.34
 EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1		10 15.91 (1.97, 29.84)
CYCLE 22 DAY 1		2 8.32 (-22.86, 39.49)
END OF TREATMENT		8 10.64 (-4.94, 26.21)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.34.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
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T14.2.6.1.5_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)
Baseline [1]	
n [2]	83
Mean	79.72
Standard Deviation	24.837
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0

- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.5_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.5_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 3 Day 1	
n [2]	77
Mean	79.44
Standard Deviation	23.709
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	77
Mean	1.08
Standard Deviation	20.651
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	-83.3, 66.7
Status [3]	
Improved	21 (27.3)
Stable	40 (51.9)
Worsened	16 (20.8)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.5_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
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T14.2.6.1.5_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 5 Day 1	
n [2]	76
Mean	81.14
Standard Deviation	22.335
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	76
Mean	1.10
Standard Deviation	19.877
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	-50.0, 50.0
Status [3]	
Improved	22 (28.9)
Stable	36 (47.4)
Worsened	18 (23.7)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.5_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.5_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 7 Day 1	
n [2]	71
Mean	80.05
Standard Deviation	23.166
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	16.7, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	71
Mean	-1.64
Standard Deviation	20.345
Median	0.00
Q1, Q3	-16.7, 16.7
Min, Max	-66.7, 50.0
Status [3]	
Improved	18 (25.4)
Stable	32 (45.1)
Worsened	21 (29.6)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.5_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.5_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)

Cycle 9 Day 1	
n [2]	62
Mean	80.91
Standard Deviation	26.283
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	62
Mean	1.88
Standard Deviation	24.905
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	-83.3, 66.7
Status [3]	
Improved	16 (25.8)
Stable	34 (54.8)
Worsened	12 (19.4)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.5_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.5_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)

Cycle 11 Day 1	
n [2]	56
Mean	81.25
Standard Deviation	20.612
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	33.3, 100.0
Change from Baseline to Cycle 11 Day 1	
n [2]	56
Mean	2.68
Standard Deviation	21.267
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	-66.7, 66.7
Status [3]	
Improved	15 (26.8)
Stable	29 (51.8)
Worsened	12 (21.4)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.5_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.5_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 13 Day 1	
n [2]	43
Mean	82.56
Standard Deviation	19.905
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	33.3, 100.0
Change from Baseline to Cycle 13 Day 1	
n [2]	43
Mean	3.88
Standard Deviation	19.189
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	-33.3, 50.0
Status [3]	
Improved	15 (34.9)
Stable	21 (48.8)
Worsened	7 (16.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.5_mtc_eff.rtf

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T14.2.6.1.5_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 16 Day 1	
n [2]	24
Mean	76.39
Standard Deviation	22.477
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	33.3, 100.0
Change from Baseline to Cycle 16 Day 1	
n [2]	24
Mean	4.17
Standard Deviation	22.656
Median	0.00
Q1, Q3	-8.3, 16.7
Min, Max	-50.0, 50.0
Status [3]	
Improved	8 (33.3)
Stable	10 (41.7)
Worsened	6 (25.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.5_mtc_eff.rtf

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T14.2.6.1.5_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 19 Day 1	
n [2]	10
Mean	85.00
Standard Deviation	12.298
Median	83.33
Q1, Q3	83.3, 100.0
Min, Max	66.7, 100.0
Change from Baseline to Cycle 19 Day 1	
n [2]	10
Mean	8.33
Standard Deviation	31.672
Median	0.00
Q1, Q3	-16.7, 50.0
Min, Max	-33.3, 50.0
Status [3]	
Improved	4 (40.0)
Stable	2 (20.0)
Worsened	4 (40.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.5_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
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T14.2.6.1.5_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 22 Day 1	
n [2]	2
Mean	91.67
Standard Deviation	11.785
Median	91.67
Q1, Q3	83.3, 100.0
Min, Max	83.3, 100.0
Change from Baseline to Cycle 22 Day 1	
n [2]	2
Mean	8.33
Standard Deviation	11.785
Median	8.33
Q1, Q3	0.0, 16.7
Min, Max	0.0, 16.7
Status [3]	
Improved	1 (50.0)
Stable	1 (50.0)
Worsened	0 (0.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.5_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.5_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

End of Treatment	
n [2]	7
Mean	78.57
Standard Deviation	23.002
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	33.3, 100.0
Change from Baseline to End of Treatment	
n [2]	7
Mean	0.00
Standard Deviation	9.623
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-16.7, 16.7
Status [3]	
Improved	1 (14.3)
Stable	5 (71.4)
Worsened	1 (14.3)

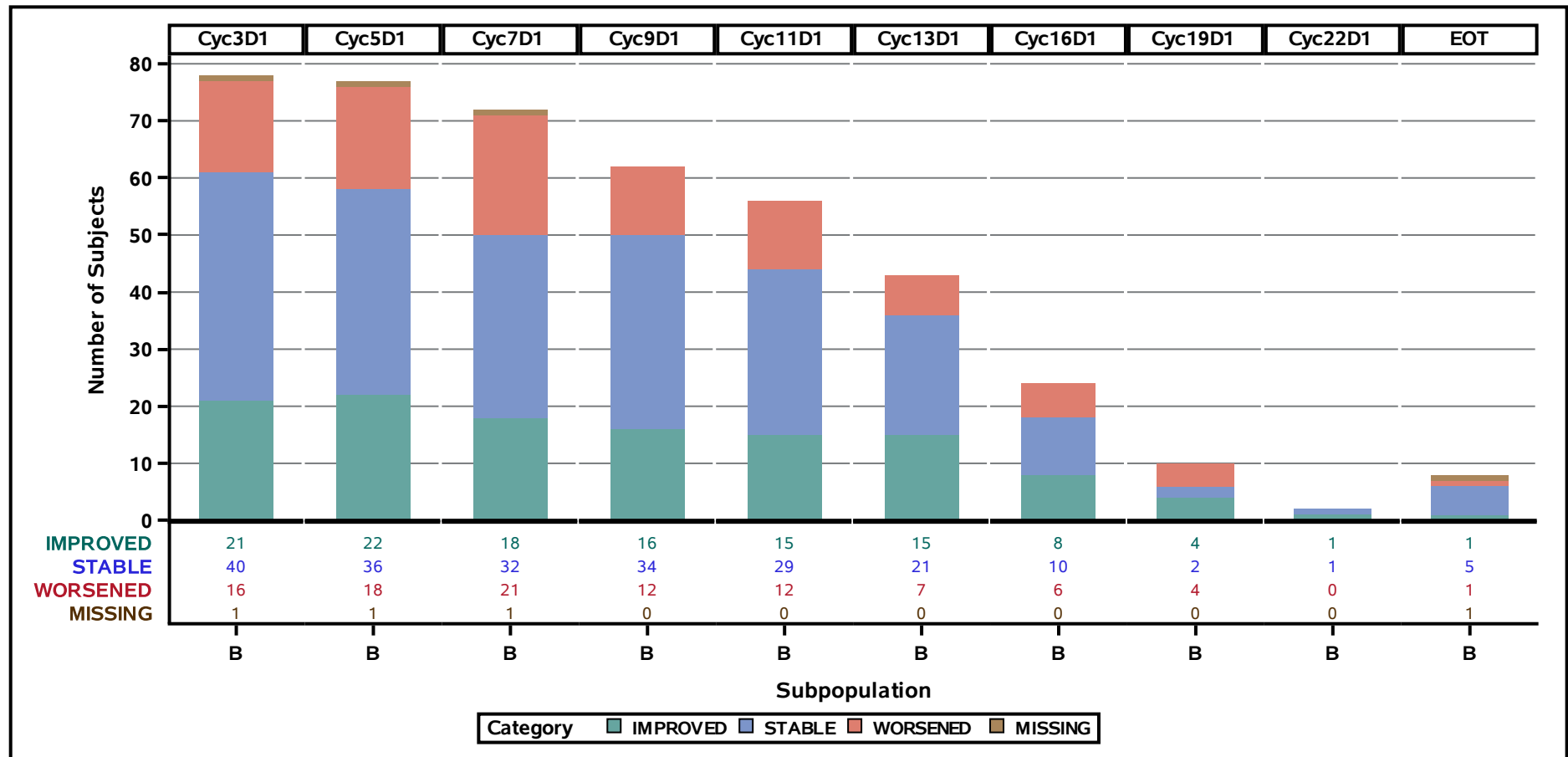
-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.5_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Changes from baseline in QLQ-C30 scores by Cognitive functioning
 (Efficacy Analysis Set)
 by Subpopulation



Program Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
 Output Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F044_cf_10pt_mtc_eff.rtf
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.35
 EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	83 79.72 (24.84)	77 0.79 (-3.27, 4.84)
CYCLE 5 DAY 1		76 1.56 (-2.52, 5.65)
CYCLE 7 DAY 1		71 -0.43 (-4.66, 3.80)
CYCLE 9 DAY 1		62 1.89 (-2.63, 6.41)
CYCLE 11 DAY 1		56 2.48 (-2.28, 7.24)
CYCLE 13 DAY 1		43 3.73 (-1.70, 9.16)
CYCLE 16 DAY 1		24 1.10 (-6.18, 8.38)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.35.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.35
 EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1		10 7.27 (-3.99, 18.53)
CYCLE 22 DAY 1		2 10.29 (-14.89, 35.46)
END OF TREATMENT		7 -0.20 (-13.65, 13.26)

 N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.35.rtf

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 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.6_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)
Baseline [1]	
n [2]	83
Mean	69.28
Standard Deviation	28.689
Median	66.67
Q1, Q3	50.0, 100.0
Min, Max	0.0, 100.0

- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.6_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.6_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 3 Day 1	
n [2]	77
Mean	79.00
Standard Deviation	26.956
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	77
Mean	10.82
Standard Deviation	28.067
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	-83.3, 83.3
Status [3]	
Improved	37 (48.1)
Stable	29 (37.7)
Worsened	11 (14.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.6_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
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T14.2.6.1.6_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 5 Day 1	
n [2]	76
Mean	85.31
Standard Deviation	21.076
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	76
Mean	16.45
Standard Deviation	23.959
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	-16.7, 83.3
Status [3]	
Improved	40 (52.6)
Stable	29 (38.2)
Worsened	7 (9.2)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.6_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.6_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 7 Day 1	
n [2]	71
Mean	82.39
Standard Deviation	26.858
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	71
Mean	11.50
Standard Deviation	29.357
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	-66.7, 83.3
Status [3]	
Improved	31 (43.7)
Stable	27 (38.0)
Worsened	13 (18.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.6_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.6_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 9 Day 1	
n [2]	62
Mean	84.95
Standard Deviation	21.701
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	62
Mean	16.67
Standard Deviation	23.954
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	-33.3, 83.3
Status [3]	
Improved	34 (54.8)
Stable	22 (35.5)
Worsened	6 (9.7)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.6_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.6_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 11 Day 1	
n [2]	56
Mean	85.71
Standard Deviation	16.946
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	50.0, 100.0
Change from Baseline to Cycle 11 Day 1	
n [2]	56
Mean	17.26
Standard Deviation	27.333
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	-33.3, 83.3
Status [3]	
Improved	31 (55.4)
Stable	20 (35.7)
Worsened	5 (8.9)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.6_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.6_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 13 Day 1	
n [2]	43
Mean	84.50
Standard Deviation	21.330
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 13 Day 1	
n [2]	43
Mean	15.89
Standard Deviation	26.715
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	-33.3, 83.3
Status [3]	
Improved	24 (55.8)
Stable	12 (27.9)
Worsened	7 (16.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.6_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.6_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 16 Day 1	
n [2]	24
Mean	82.64
Standard Deviation	28.859
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 16 Day 1	
n [2]	24
Mean	13.19
Standard Deviation	37.423
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	-83.3, 83.3
Status [3]	
Improved	11 (45.8)
Stable	9 (37.5)
Worsened	4 (16.7)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.6_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.6_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 19 Day 1	
n [2]	10
Mean	83.33
Standard Deviation	17.568
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	66.7, 100.0
Change from Baseline to Cycle 19 Day 1	
n [2]	10
Mean	26.67
Standard Deviation	30.631
Median	16.67
Q1, Q3	0.0, 50.0
Min, Max	0.0, 83.3
Status [3]	
Improved	6 (60.0)
Stable	4 (40.0)
Worsened	0 (0.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.6_mtc_eff.rtf

Loxo Oncology Inc.
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T14.2.6.1.6_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 22 Day 1		
n [2]	2	
Mean	100.00	
Standard Deviation	0.000	
Median	100.00	
Q1, Q3	100.0, 100.0	
Min, Max	100.0, 100.0	
Change from Baseline to Cycle 22 Day 1		
n [2]	2	
Mean	25.00	
Standard Deviation	11.785	
Median	25.00	
Q1, Q3	16.7, 33.3	
Min, Max	16.7, 33.3	
Status [3]		
Improved	2	(100.0)
Stable	0	(0.0)
Worsened	0	(0.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.6_mtc_eff.rtf

Loxo Oncology Inc.
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T14.2.6.1.6_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

End of Treatment	
n [2]	7
Mean	73.81
Standard Deviation	23.288
Median	66.67
Q1, Q3	66.7, 100.0
Min, Max	33.3, 100.0
Change from Baseline to End of Treatment	
n [2]	7
Mean	4.76
Standard Deviation	24.934
Median	0.00
Q1, Q3	-16.7, 33.3
Min, Max	-33.3, 33.3
Status [3]	
Improved	3 (42.9)
Stable	2 (28.6)
Worsened	2 (28.6)

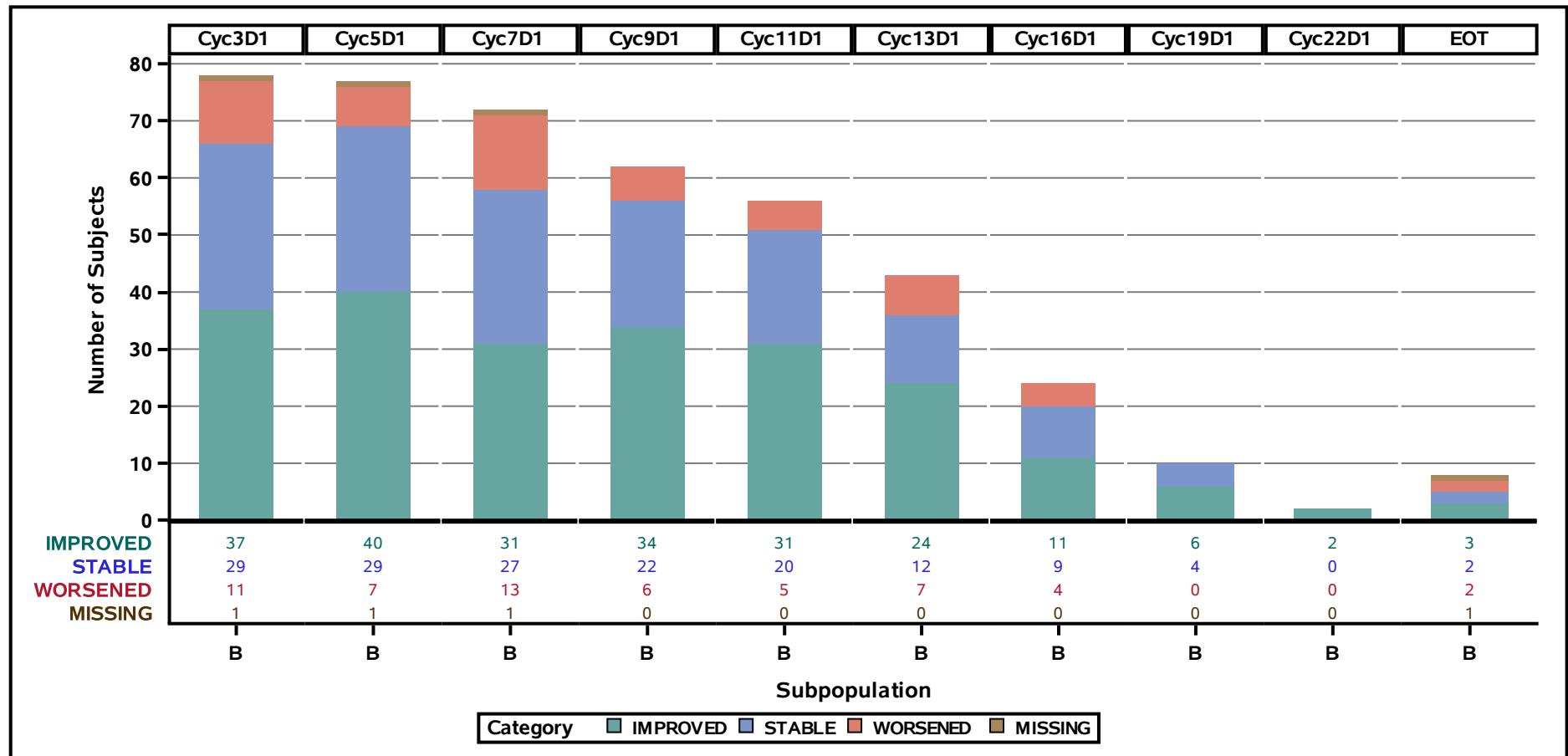
-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.6_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Changes from baseline in QLQ-C30 scores by Social Function
 (Efficacy Analysis Set)
 by Subpopulation



Program Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
 Output Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F045_sf_10pt_mtc_eff.rtf
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.36
 EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	83 69.28 (28.69)	77 10.50 (5.82, 15.18)
CYCLE 5 DAY 1		76 16.55 (11.84, 21.26)
CYCLE 7 DAY 1		71 12.89 (8.01, 17.76)
CYCLE 9 DAY 1		62 16.41 (11.19, 21.62)
CYCLE 11 DAY 1		56 17.11 (11.62, 22.60)
CYCLE 13 DAY 1		43 15.84 (9.57, 22.10)
CYCLE 16 DAY 1		24 13.67 (5.28, 22.05)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.36.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
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T14.2.6.1.36
 EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1		10 19.11 (6.09, 32.12)
CYCLE 22 DAY 1		2 28.97 (-0.08, 58.01)
END OF TREATMENT		7 4.99 (-10.54, 20.51)

 N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.36.rtf

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 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.7_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)
Baseline [1]	
n [2]	84
Mean	8.93
Standard Deviation	16.656
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	0.0, 83.3

[1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.7_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)	

Cycle 3 Day 1		
n [2]	78	
Mean	4.91	
Standard Deviation	11.742	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	0.0,	50.0
Change from Baseline to Cycle 3 Day 1		
n [2]	78	
Mean	-3.42	
Standard Deviation	18.289	
Median	0.00	
Q1, Q3	-16.7,	0.0
Min, Max	-50.0,	50.0
Status [3]		
Improved	21	(26.9)
Stable	46	(59.0)
Worsened	11	(14.1)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.7_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 5 Day 1		
n [2]	77	
Mean	4.11	
Standard Deviation	9.030	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	0.0,	33.3
Change from Baseline to Cycle 5 Day 1		
n [2]	77	
Mean	-4.11	
Standard Deviation	14.089	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	-50.0,	33.3
Status [3]		
Improved	19	(24.7)
Stable	52	(67.5)
Worsened	6	(7.8)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.7_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 7 Day 1		
n [2]	72	
Mean	5.09	
Standard Deviation	12.708	
Median	0.00	
Q1, Q3	0.0, 0.0	
Min, Max	0.0, 83.3	
Change from Baseline to Cycle 7 Day 1		
n [2]	72	
Mean	-2.78	
Standard Deviation	18.555	
Median	0.00	
Q1, Q3	0.0, 0.0	
Min, Max	-50.0, 83.3	
Status [3]		
Improved	17 (23.6)	
Stable	46 (63.9)	
Worsened	9 (12.5)	

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_mtc_eff.rtf

Loxo Oncology Inc.
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T14.2.6.1.7_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)	

Cycle 9 Day 1		
n [2]	62	
Mean	2.42	
Standard Deviation	8.454	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	0.0,	50.0
Change from Baseline to Cycle 9 Day 1		
n [2]	62	
Mean	-6.99	
Standard Deviation	17.993	
Median	0.00	
Q1, Q3	-16.7,	0.0
Min, Max	-50.0,	33.3
Status [3]		
Improved	18	(29.0)
Stable	39	(62.9)
Worsened	5	(8.1)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.7_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 11 Day 1	
n [2]	56
Mean	7.74
Standard Deviation	14.895
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	0.0, 83.3
Change from Baseline to Cycle 11 Day 1	
n [2]	56
Mean	-0.89
Standard Deviation	19.700
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-50.0, 83.3
Status [3]	
Improved	11 (19.6)
Stable	37 (66.1)
Worsened	8 (14.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.7_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 13 Day 1		
n [2]	43	
Mean	5.81	
Standard Deviation	11.999	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	0.0,	50.0
Change from Baseline to Cycle 13 Day 1		
n [2]	43	
Mean	-2.33	
Standard Deviation	14.810	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	-50.0,	33.3
Status [3]		
Improved	9	(20.9)
Stable	29	(67.4)
Worsened	5	(11.6)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.7_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 16 Day 1		
n [2]	24	
Mean	4.86	
Standard Deviation	9.167	
Median	0.00	
Q1, Q3	0.0, 8.3	
Min, Max	0.0, 33.3	
Change from Baseline to Cycle 16 Day 1		
n [2]	24	
Mean	-6.25	
Standard Deviation	16.161	
Median	0.00	
Q1, Q3	-16.7, 0.0	
Min, Max	-50.0, 33.3	
Status [3]		
Improved	9 (37.5)	
Stable	13 (54.2)	
Worsened	2 (8.3)	

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_mtc_eff.rtf

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T14.2.6.1.7_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 19 Day 1		
n [2]	10	
Mean	6.67	
Standard Deviation	11.653	
Median	0.00	
Q1, Q3	0.0, 16.7	
Min, Max	0.0, 33.3	
Change from Baseline to Cycle 19 Day 1		
n [2]	10	
Mean	-8.33	
Standard Deviation	16.197	
Median	0.00	
Q1, Q3	-16.7, 0.0	
Min, Max	-50.0, 0.0	
Status [3]		
Improved	3 (30.0)	
Stable	7 (70.0)	
Worsened	0 (0.0)	

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.7_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 22 Day 1		
n [2]	2	
Mean	0.00	
Standard Deviation	0.000	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	0.0,	0.0
Change from Baseline to Cycle 22 Day 1		
n [2]	2	
Mean	-8.33	
Standard Deviation	11.785	
Median	-8.33	
Q1, Q3	-16.7,	0.0
Min, Max	-16.7,	0.0
Status [3]		
Improved	1	(50.0)
Stable	1	(50.0)
Worsened	0	(0.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.7_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

End of Treatment	
n [2]	8
Mean	6.25
Standard Deviation	8.626
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	0.0, 16.7
Change from Baseline to End of Treatment	
n [2]	8
Mean	4.17
Standard Deviation	7.715
Median	0.00
Q1, Q3	0.0, 8.3
Min, Max	0.0, 16.7
Status [3]	
Improved	0 (0.0)
Stable	6 (75.0)
Worsened	2 (25.0)

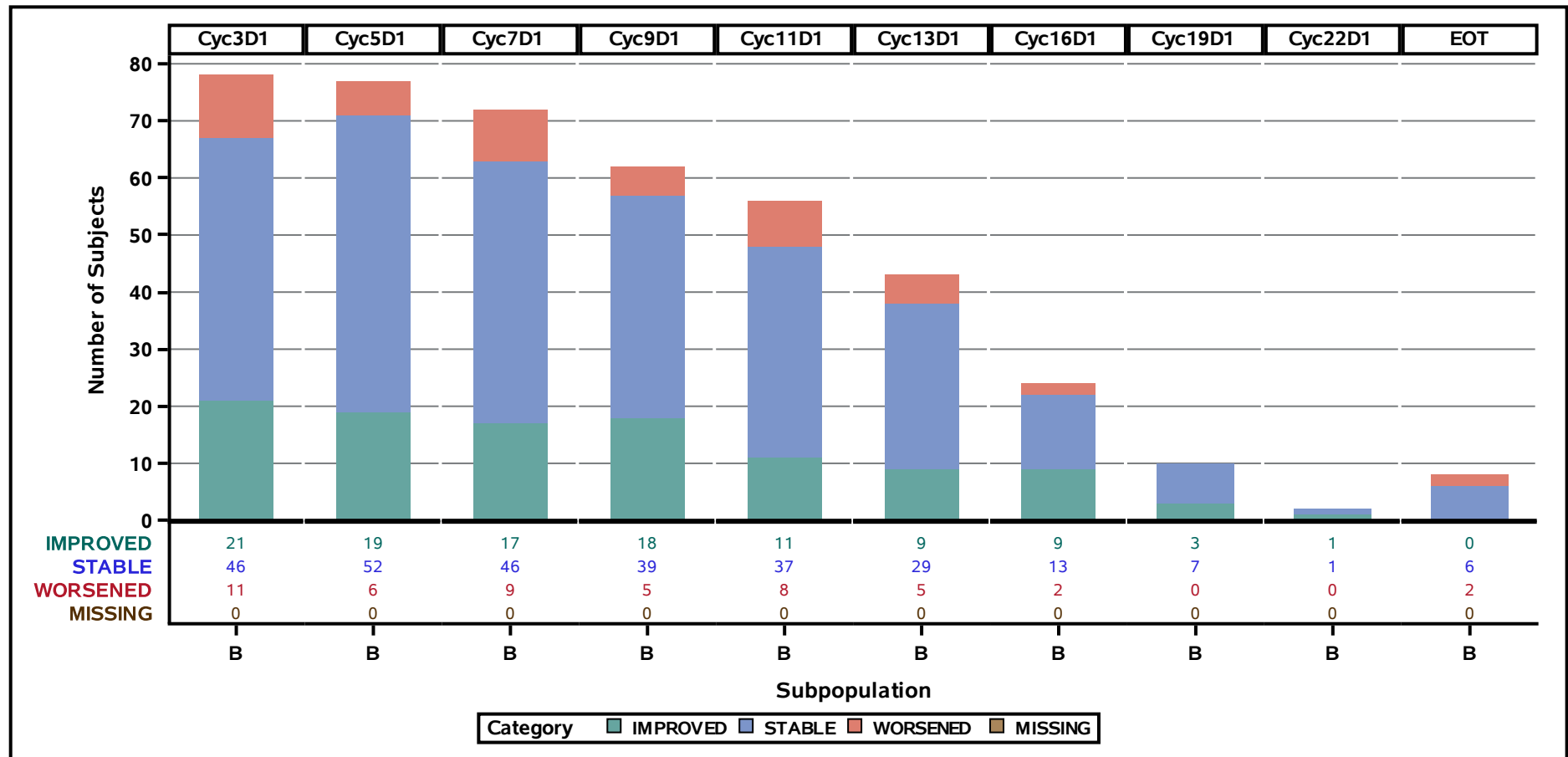
-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Changes from baseline in QLQ-C30 scores by Nausea and vomiting
 (Efficacy Analysis Set)
 by Subpopulation



Program Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
 Output Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F046_nv_10pt_mtc_eff.rtf
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.37
 EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	84 8.93 (16.66)	78 -3.65 (-6.14, -1.16)
CYCLE 5 DAY 1		77 -4.44 (-6.94, -1.93)
CYCLE 7 DAY 1		72 -3.40 (-5.99, -0.82)
CYCLE 9 DAY 1		62 -6.30 (-9.09, -3.51)
CYCLE 11 DAY 1		56 -0.87 (-3.80, 2.07)
CYCLE 13 DAY 1		43 -2.72 (-6.07, 0.63)
CYCLE 16 DAY 1		24 -4.10 (-8.59, 0.38)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.37.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.37
 EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1		10 -2.86 (-9.82, 4.10)
CYCLE 22 DAY 1		2 -8.56 (-24.10, 6.97)
END OF TREATMENT		8 -1.41 (-9.19, 6.37)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.37.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.8_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)
Baseline [1]	
n [2]	84
Mean	42.13
Standard Deviation	27.369
Median	33.33
Q1, Q3	22.2, 66.7
Min, Max	0.0, 100.0

- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.8_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 3 Day 1	
n [2]	78
Mean	33.76
Standard Deviation	27.535
Median	27.78
Q1, Q3	11.1, 55.6
Min, Max	0.0, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	78
Mean	-8.69
Standard Deviation	29.131
Median	-11.11
Q1, Q3	-22.2, 0.0
Min, Max	-77.8, 77.8
Status [3]	
Improved	46 (59.0)
Stable	15 (19.2)
Worsened	17 (21.8)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
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 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.8_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 5 Day 1	
n [2]	77
Mean	29.44
Standard Deviation	23.346
Median	33.33
Q1, Q3	11.1, 44.4
Min, Max	0.0, 88.9
Change from Baseline to Cycle 5 Day 1	
n [2]	77
Mean	-12.55
Standard Deviation	20.261
Median	-11.11
Q1, Q3	-22.2, 0.0
Min, Max	-77.8, 33.3
Status [3]	
Improved	43 (55.8)
Stable	25 (32.5)
Worsened	9 (11.7)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.8_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)

Cycle 7 Day 1	
n [2]	72
Mean	30.25
Standard Deviation	26.189
Median	27.78
Q1, Q3	11.1, 44.4
Min, Max	0.0, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	72
Mean	-8.64
Standard Deviation	24.756
Median	-11.11
Q1, Q3	-22.2, 0.0
Min, Max	-66.7, 66.7
Status [3]	
Improved	41 (56.9)
Stable	15 (20.8)
Worsened	16 (22.2)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_mtc_eff.rtf

Loxo Oncology Inc.
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T14.2.6.1.8_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 9 Day 1	
n [2]	62
Mean	29.57
Standard Deviation	24.054
Median	33.33
Q1, Q3	11.1, 44.4
Min, Max	0.0, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	62
Mean	-12.37
Standard Deviation	25.616
Median	-11.11
Q1, Q3	-33.3, 0.0
Min, Max	-88.9, 44.4
Status [3]	
Improved	35 (56.5)
Stable	17 (27.4)
Worsened	10 (16.1)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.8_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 11 Day 1	
n [2]	56
Mean	27.38
Standard Deviation	21.604
Median	33.33
Q1, Q3	5.6, 38.9
Min, Max	0.0, 88.9
Change from Baseline to Cycle 11 Day 1	
n [2]	56
Mean	-13.89
Standard Deviation	26.230
Median	-5.56
Q1, Q3	-33.3, 0.0
Min, Max	-88.9, 33.3
Status [3]	
Improved	28 (50.0)
Stable	18 (32.1)
Worsened	10 (17.9)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.8_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 13 Day 1	
n [2]	43
Mean	30.23
Standard Deviation	23.044
Median	22.22
Q1, Q3	11.1, 44.4
Min, Max	0.0, 88.9
Change from Baseline to Cycle 13 Day 1	
n [2]	43
Mean	-11.11
Standard Deviation	25.314
Median	-11.11
Q1, Q3	-33.3, 11.1
Min, Max	-77.8, 33.3
Status [3]	
Improved	22 (51.2)
Stable	9 (20.9)
Worsened	12 (27.9)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.8_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 16 Day 1	
n [2]	24
Mean	34.72
Standard Deviation	25.020
Median	33.33
Q1, Q3	11.1, 55.6
Min, Max	0.0, 100.0
Change from Baseline to Cycle 16 Day 1	
n [2]	24
Mean	-11.11
Standard Deviation	32.270
Median	-11.11
Q1, Q3	-33.3, 11.1
Min, Max	-77.8, 77.8
Status [3]	
Improved	14 (58.3)
Stable	3 (12.5)
Worsened	7 (29.2)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.8_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 19 Day 1		
n [2]	10	
Mean	41.11	
Standard Deviation	27.242	
Median	33.33	
Q1, Q3	22.2,	66.7
Min, Max	0.0,	88.9
Change from Baseline to Cycle 19 Day 1		
n [2]	10	
Mean	-12.22	
Standard Deviation	36.080	
Median	0.00	
Q1, Q3	-33.3,	11.1
Min, Max	-88.9,	33.3
Status [3]		
Improved	4	(40.0)
Stable	3	(30.0)
Worsened	3	(30.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
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 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
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T14.2.6.1.8_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 22 Day 1		
n [2]	2	
Mean	22.22	
Standard Deviation	0.000	
Median	22.22	
Q1, Q3	22.2, 22.2	
Min, Max	22.2, 22.2	
Change from Baseline to Cycle 22 Day 1		
n [2]	2	
Mean	-11.11	
Standard Deviation	15.713	
Median	-11.11	
Q1, Q3	-22.2, 0.0	
Min, Max	-22.2, 0.0	
Status [3]		
Improved	1 (50.0)	
Stable	1 (50.0)	
Worsened	0 (0.0)	

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.8_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

End of Treatment	
n [2]	8
Mean	33.33
Standard Deviation	31.427
Median	33.33
Q1, Q3	5.6, 50.0
Min, Max	0.0, 88.9
Change from Baseline to End of Treatment	
n [2]	8
Mean	-5.56
Standard Deviation	27.217
Median	-5.56
Q1, Q3	-22.2, 5.6
Min, Max	-44.4, 44.4
Status [3]	
Improved	4 (50.0)
Stable	2 (25.0)
Worsened	2 (25.0)

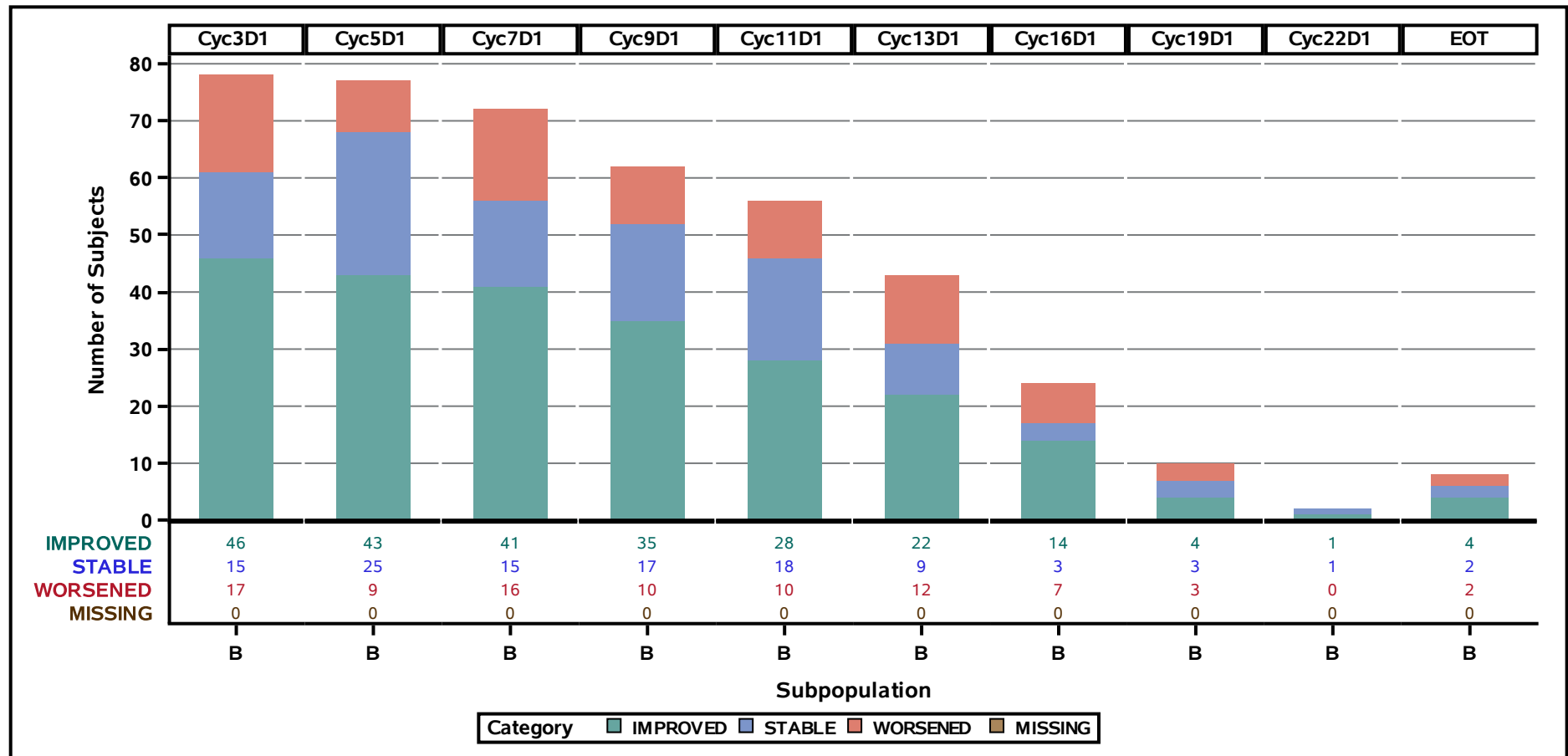
-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Changes from baseline in QLQ-C30 scores by Fatigue
 (Efficacy Analysis Set)
 by Subpopulation



Program Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
 Output Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F047_fa_10pt_mtc_eff.rtf
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.38
 EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	84 42.13 (27.37)	78 -8.32 (-13.07, -3.57)
CYCLE 5 DAY 1		77 -12.43 (-17.22, -7.65)
CYCLE 7 DAY 1		72 -10.20 (-15.15, -5.25)
CYCLE 9 DAY 1		62 -12.28 (-17.60, -6.95)
CYCLE 11 DAY 1		56 -14.16 (-19.77, -8.55)
CYCLE 13 DAY 1		43 -11.34 (-17.74, -4.94)
CYCLE 16 DAY 1		24 -8.91 (-17.48, -0.34)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.38.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.38
 EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1		10 -5.97 (-19.27, 7.32)
CYCLE 22 DAY 1		2 -15.67 (-45.35, 14.00)
END OF TREATMENT		8 -7.11 (-21.95, 7.72)

 N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
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 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.38.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.9_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)
Baseline [1]	
n [2]	84
Mean	31.55
Standard Deviation	30.832
Median	16.67
Q1, Q3	0.0, 50.0
Min, Max	0.0, 100.0

- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
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T14.2.6.1.9_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 3 Day 1	
n [2]	78
Mean	20.73
Standard Deviation	25.081
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	78
Mean	-11.11
Standard Deviation	25.577
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-66.7, 50.0
Status [3]	
Improved	37 (47.4)
Stable	26 (33.3)
Worsened	15 (19.2)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
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T14.2.6.1.9_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 5 Day 1	
n [2]	77
Mean	20.35
Standard Deviation	24.724
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	0.0, 83.3
Change from Baseline to Cycle 5 Day 1	
n [2]	77
Mean	-11.04
Standard Deviation	25.307
Median	0.00
Q1, Q3	-16.7, 0.0
Min, Max	-66.7, 50.0
Status [3]	
Improved	35 (45.5)
Stable	28 (36.4)
Worsened	14 (18.2)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_mtc_eff.rtf

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T14.2.6.1.9_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 7 Day 1	
n [2]	72
Mean	23.15
Standard Deviation	28.466
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	72
Mean	-7.41
Standard Deviation	29.589
Median	0.00
Q1, Q3	-16.7, 0.0
Min, Max	-100.0, 83.3
Status [3]	
Improved	27 (37.5)
Stable	29 (40.3)
Worsened	16 (22.2)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_mtc_eff.rtf

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T14.2.6.1.9_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 9 Day 1	
n [2]	62
Mean	22.31
Standard Deviation	26.472
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	62
Mean	-10.48
Standard Deviation	27.698
Median	0.00
Q1, Q3	-16.7, 0.0
Min, Max	-100.0, 50.0
Status [3]	
Improved	27 (43.5)
Stable	24 (38.7)
Worsened	11 (17.7)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_mtc_eff.rtf

Loxo Oncology Inc.
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T14.2.6.1.9_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 11 Day 1	
n [2]	56
Mean	20.54
Standard Deviation	25.424
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 83.3
Change from Baseline to Cycle 11 Day 1	
n [2]	56
Mean	-13.69
Standard Deviation	26.800
Median	0.00
Q1, Q3	-16.7, 0.0
Min, Max	-100.0, 66.7
Status [3]	
Improved	26 (46.4)
Stable	25 (44.6)
Worsened	5 (8.9)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_mtc_eff.rtf

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T14.2.6.1.9_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 13 Day 1	
n [2]	43
Mean	22.09
Standard Deviation	26.408
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 13 Day 1	
n [2]	43
Mean	-12.02
Standard Deviation	27.537
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 50.0
Status [3]	
Improved	19 (44.2)
Stable	17 (39.5)
Worsened	7 (16.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_mtc_eff.rtf

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T14.2.6.1.9_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 16 Day 1	
n [2]	24
Mean	20.14
Standard Deviation	23.041
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to Cycle 16 Day 1	
n [2]	24
Mean	-18.75
Standard Deviation	33.446
Median	-16.67
Q1, Q3	-41.7, 0.0
Min, Max	-100.0, 50.0
Status [3]	
Improved	14 (58.3)
Stable	7 (29.2)
Worsened	3 (12.5)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_mtc_eff.rtf

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T14.2.6.1.9_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 19 Day 1	
n [2]	10
Mean	30.00
Standard Deviation	24.595
Median	25.00
Q1, Q3	16.7, 50.0
Min, Max	0.0, 66.7
Change from Baseline to Cycle 19 Day 1	
n [2]	10
Mean	-15.00
Standard Deviation	37.226
Median	0.00
Q1, Q3	-33.3, 16.7
Min, Max	-100.0, 16.7
Status [3]	
Improved	4 (40.0)
Stable	3 (30.0)
Worsened	3 (30.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.9_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 22 Day 1	
n [2]	2
Mean	41.67
Standard Deviation	11.785
Median	41.67
Q1, Q3	33.3, 50.0
Min, Max	33.3, 50.0
Change from Baseline to Cycle 22 Day 1	
n [2]	2
Mean	-8.33
Standard Deviation	11.785
Median	-8.33
Q1, Q3	-16.7, 0.0
Min, Max	-16.7, 0.0
Status [3]	
Improved	1 (50.0)
Stable	1 (50.0)
Worsened	0 (0.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_mtc_eff.rtf

Loxo Oncology Inc.
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T14.2.6.1.9_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

End of Treatment	
n [2]	8
Mean	27.08
Standard Deviation	29.463
Median	25.00
Q1, Q3	0.0, 41.7
Min, Max	0.0, 83.3
Change from Baseline to End of Treatment	
n [2]	8
Mean	-14.58
Standard Deviation	22.603
Median	-25.00
Q1, Q3	-33.3, 8.3
Min, Max	-33.3, 16.7
Status [3]	
Improved	5 (62.5)
Stable	1 (12.5)
Worsened	2 (25.0)

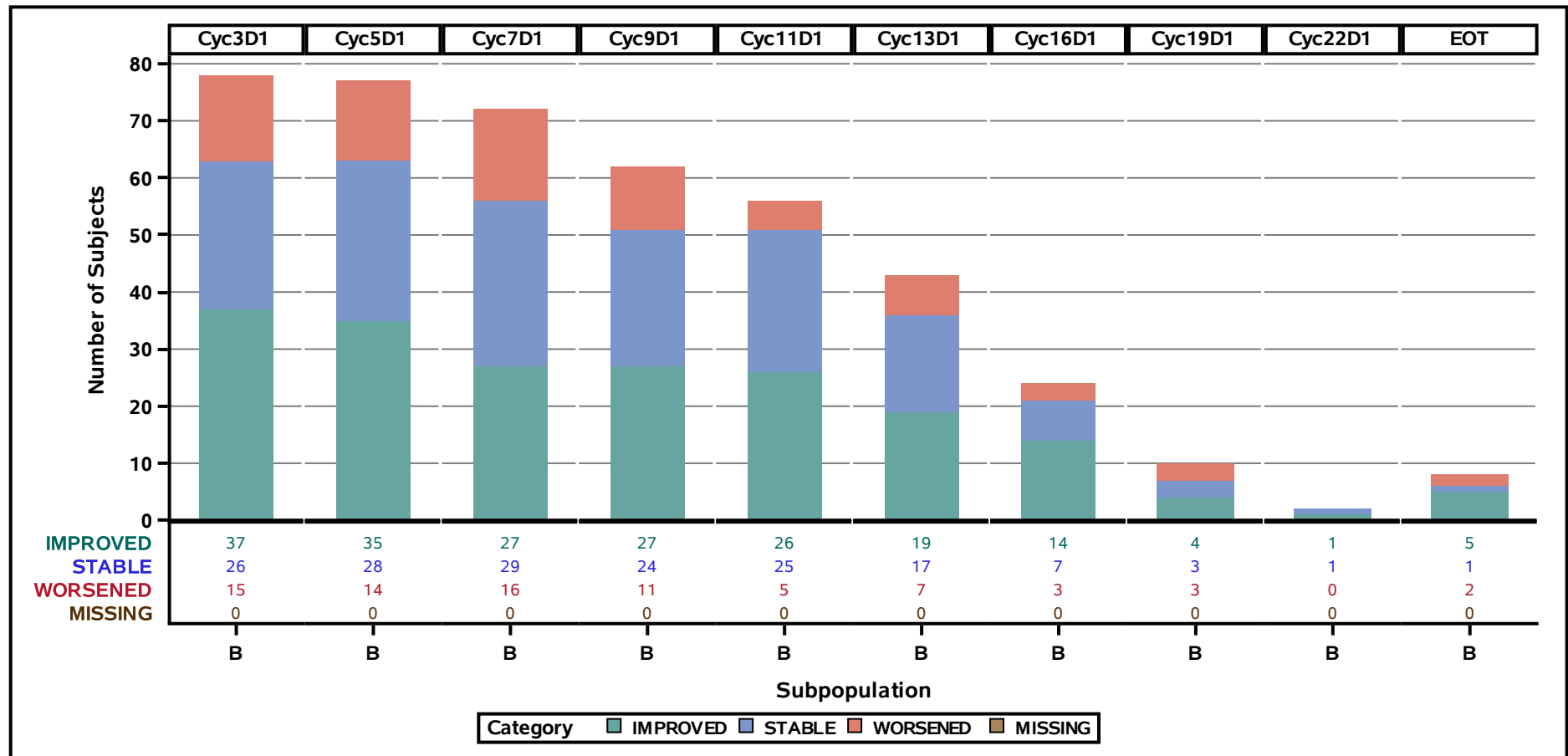
-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Changes from baseline in QLQ-C30 scores by Pain
 (Efficacy Analysis Set)
 by Subpopulation



Program Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
 Output Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F048_pa_10pt_mtc_eff.rtf
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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T14.2.6.1.39
 EORTC QLQ-C30 (v3.0): Summary of Pain by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	84 31.55 (30.83)	78 -11.84 (-16.67, -7.02)
CYCLE 5 DAY 1		77 -12.02 (-16.87, -7.16)
CYCLE 7 DAY 1		72 -8.84 (-13.86, -3.81)
CYCLE 9 DAY 1		62 -10.69 (-16.10, -5.28)
CYCLE 11 DAY 1		56 -13.12 (-18.81, -7.43)
CYCLE 13 DAY 1		43 -11.51 (-18.01, -5.01)
CYCLE 16 DAY 1		24 -15.64 (-24.34, -6.93)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.39.rtf

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T14.2.6.1.39
 EORTC QLQ-C30 (v3.0): Summary of Pain by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1		10 -8.56 (-22.06, 4.94)
CYCLE 22 DAY 1		2 0.83 (-29.32, 30.98)
END OF TREATMENT		8 -9.96 (-25.03, 5.12)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.39.rtf

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T14.2.6.1.10_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)
Baseline [1]	
n [2]	84
Mean	28.57
Standard Deviation	30.235
Median	33.33
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0

- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_mtc_eff.rtf

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T14.2.6.1.10_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 3 Day 1	
n [2]	78
Mean	21.37
Standard Deviation	26.304
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	78
Mean	-7.26
Standard Deviation	28.754
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 66.7
Status [3]	
Improved	20 (25.6)
Stable	48 (61.5)
Worsened	10 (12.8)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_mtc_eff.rtf

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T14.2.6.1.10_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)

Cycle 5 Day 1	
n [2]	77
Mean	18.18
Standard Deviation	25.099
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	77
Mean	-10.39
Standard Deviation	31.185
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 100.0
Status [3]	
Improved	24 (31.2)
Stable	45 (58.4)
Worsened	8 (10.4)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_mtc_eff.rtf

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T14.2.6.1.10_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)	

Cycle 7 Day 1		
n [2]	71	
Mean	16.90	
Standard Deviation	23.144	
Median	0.00	
Q1, Q3	0.0, 33.3	
Min, Max	0.0, 66.7	
Change from Baseline to Cycle 7 Day 1		
n [2]	71	
Mean	-8.45	
Standard Deviation	29.664	
Median	0.00	
Q1, Q3	-33.3, 0.0	
Min, Max	-100.0, 33.3	
Status [3]		
Improved	21 (29.6)	
Stable	39 (54.9)	
Worsened	11 (15.5)	

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_mtc_eff.rtf

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T14.2.6.1.10_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)

Cycle 9 Day 1	
n [2]	62
Mean	16.67
Standard Deviation	25.429
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	62
Mean	-9.68
Standard Deviation	30.411
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 33.3
Status [3]	
Improved	20 (32.3)
Stable	32 (51.6)
Worsened	10 (16.1)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_mtc_eff.rtf

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T14.2.6.1.10_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 11 Day 1	
n [2]	56
Mean	16.67
Standard Deviation	25.426
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 11 Day 1	
n [2]	56
Mean	-8.33
Standard Deviation	34.378
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 66.7
Status [3]	
Improved	15 (26.8)
Stable	31 (55.4)
Worsened	10 (17.9)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.10_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)

Cycle 13 Day 1	
n [2]	42
Mean	19.05
Standard Deviation	25.654
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 13 Day 1	
n [2]	42
Mean	-4.76
Standard Deviation	23.937
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-66.7, 33.3
Status [3]	
Improved	10 (23.8)
Stable	26 (61.9)
Worsened	6 (14.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
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T14.2.6.1.10_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)

Cycle 16 Day 1	
n [2]	24
Mean	29.17
Standard Deviation	29.996
Median	33.33
Q1, Q3	0.0, 50.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 16 Day 1	
n [2]	24
Mean	2.78
Standard Deviation	32.477
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-66.7, 100.0
Status [3]	
Improved	3 (12.5)
Stable	16 (66.7)
Worsened	5 (20.8)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_mtc_eff.rtf

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T14.2.6.1.10_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 19 Day 1		
n [2]	10	
Mean	20.00	
Standard Deviation	23.307	
Median	16.67	
Q1, Q3	0.0, 33.3	
Min, Max	0.0, 66.7	
Change from Baseline to Cycle 19 Day 1		
n [2]	10	
Mean	-20.00	
Standard Deviation	35.832	
Median	0.00	
Q1, Q3	-33.3, 0.0	
Min, Max	-100.0, 0.0	
Status [3]		
Improved	3 (30.0)	
Stable	7 (70.0)	
Worsened	0 (0.0)	

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
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T14.2.6.1.10_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)

Cycle 22 Day 1	
n [2]	2
Mean	16.67
Standard Deviation	23.570
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Change from Baseline to Cycle 22 Day 1	
n [2]	2
Mean	0.00
Standard Deviation	0.000
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Status [3]	
Improved	0 (0.0)
Stable	2 (100.0)
Worsened	0 (0.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_mtc_eff.rtf

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T14.2.6.1.10_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

End of Treatment	
n [2]	8
Mean	12.50
Standard Deviation	17.252
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Change from Baseline to End of Treatment	
n [2]	8
Mean	-25.00
Standard Deviation	29.547
Median	-33.33
Q1, Q3	-33.3, -16.7
Min, Max	-66.7, 33.3
Status [3]	
Improved	6 (75.0)
Stable	1 (12.5)
Worsened	1 (12.5)

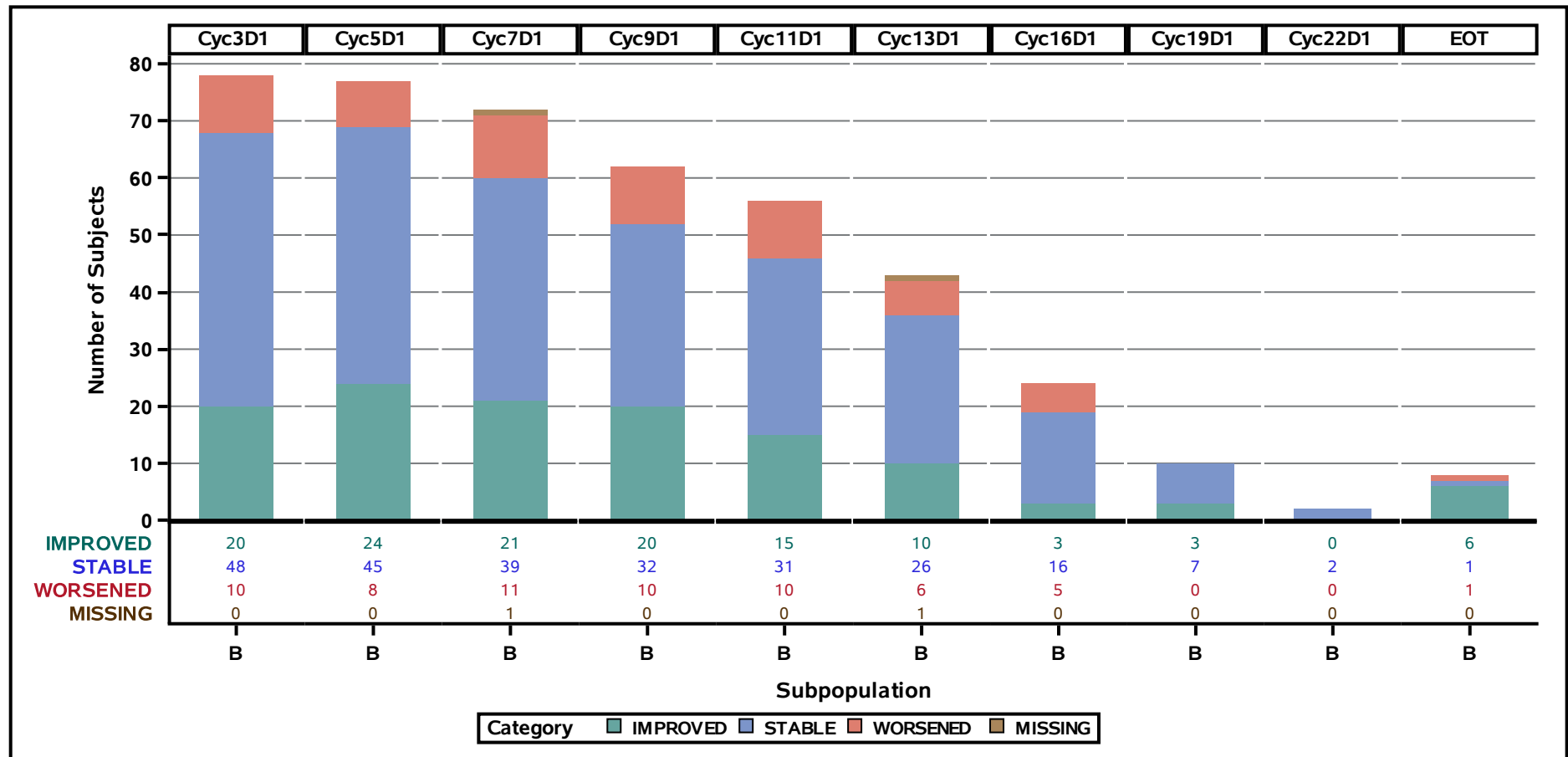
-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_mtc_eff.rtf

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 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Changes from baseline in QLQ-C30 scores by Dyspnoea
 (Efficacy Analysis Set)
 by Subpopulation



Program Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
 Output Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F049_dy_10pt_mtc_eff.rtf
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.40
 EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	84 28.57 (30.23)	78 -6.24 (-11.36, -1.12)
CYCLE 5 DAY 1		77 -9.40 (-14.56, -4.25)
CYCLE 7 DAY 1		71 -9.56 (-14.93, -4.19)
CYCLE 9 DAY 1		62 -10.14 (-15.88, -4.40)
CYCLE 11 DAY 1		56 -9.67 (-15.71, -3.63)
CYCLE 13 DAY 1		42 -6.87 (-13.85, 0.11)
CYCLE 16 DAY 1		24 2.34 (-6.88, 11.57)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.40.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.40
 EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1		10 -11.58 (-25.91, 2.75)
CYCLE 22 DAY 1		2 -6.76 (-38.74, 25.22)
END OF TREATMENT		8 -18.20 (-34.21, -2.20)

 N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.40.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.11_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)
Baseline [1]	
n [2]	84
Mean	38.10
Standard Deviation	31.535
Median	33.33
Q1, Q3	0.0, 66.7
Min, Max	0.0, 100.0

- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_mtc_eff.rtf

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T14.2.6.1.11_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 3 Day 1	
n [2]	78
Mean	28.21
Standard Deviation	31.817
Median	33.33
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	78
Mean	-10.68
Standard Deviation	29.666
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-66.7, 66.7
Status [3]	
Improved	27 (34.6)
Stable	42 (53.8)
Worsened	9 (11.5)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_mtc_eff.rtf

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T14.2.6.1.11_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 5 Day 1	
n [2]	77
Mean	23.38
Standard Deviation	30.139
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	77
Mean	-14.29
Standard Deviation	31.728
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 66.7
Status [3]	
Improved	30 (39.0)
Stable	40 (51.9)
Worsened	7 (9.1)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_mtc_eff.rtf

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 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.11_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 7 Day 1	
n [2]	72
Mean	24.07
Standard Deviation	30.243
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	72
Mean	-12.04
Standard Deviation	33.242
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 66.7
Status [3]	
Improved	25 (34.7)
Stable	39 (54.2)
Worsened	8 (11.1)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_mtc_eff.rtf

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T14.2.6.1.11_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)

Cycle 9 Day 1	
n [2]	62
Mean	24.73
Standard Deviation	29.529
Median	33.33
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	62
Mean	-10.75
Standard Deviation	30.042
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-66.7, 33.3
Status [3]	
Improved	22 (35.5)
Stable	30 (48.4)
Worsened	10 (16.1)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_mtc_eff.rtf

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T14.2.6.1.11_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 11 Day 1	
n [2]	56
Mean	16.07
Standard Deviation	23.776
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 11 Day 1	
n [2]	56
Mean	-19.05
Standard Deviation	27.603
Median	-33.33
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 33.3
Status [3]	
Improved	29 (51.8)
Stable	23 (41.1)
Worsened	4 (7.1)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_mtc_eff.rtf

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T14.2.6.1.11_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 13 Day 1	
n [2]	43
Mean	22.48
Standard Deviation	28.841
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 13 Day 1	
n [2]	43
Mean	-14.73
Standard Deviation	30.257
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-66.7, 66.7
Status [3]	
Improved	20 (46.5)
Stable	18 (41.9)
Worsened	5 (11.6)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_mtc_eff.rtf

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 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.11_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 16 Day 1	
n [2]	24
Mean	22.22
Standard Deviation	30.561
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 16 Day 1	
n [2]	24
Mean	-19.44
Standard Deviation	32.477
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 33.3
Status [3]	
Improved	11 (45.8)
Stable	11 (45.8)
Worsened	2 (8.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.11_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 19 Day 1	
n [2]	10
Mean	20.00
Standard Deviation	28.109
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to Cycle 19 Day 1	
n [2]	10
Mean	-26.67
Standard Deviation	26.294
Median	-33.33
Q1, Q3	-33.3, 0.0
Min, Max	-66.7, 0.0
Status [3]	
Improved	6 (60.0)
Stable	4 (40.0)
Worsened	0 (0.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_mtc_eff.rtf

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T14.2.6.1.11_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 22 Day 1	
n [2]	2
Mean	16.67
Standard Deviation	23.570
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Change from Baseline to Cycle 22 Day 1	
n [2]	2
Mean	-16.67
Standard Deviation	23.570
Median	-16.67
Q1, Q3	-33.3, 0.0
Min, Max	-33.3, 0.0
Status [3]	
Improved	1 (50.0)
Stable	1 (50.0)
Worsened	0 (0.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.11_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

End of Treatment	
n [2]	8
Mean	29.17
Standard Deviation	33.034
Median	33.33
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to End of Treatment	
n [2]	8
Mean	-12.50
Standard Deviation	30.538
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-66.7, 33.3
Status [3]	
Improved	3 (37.5)
Stable	4 (50.0)
Worsened	1 (12.5)

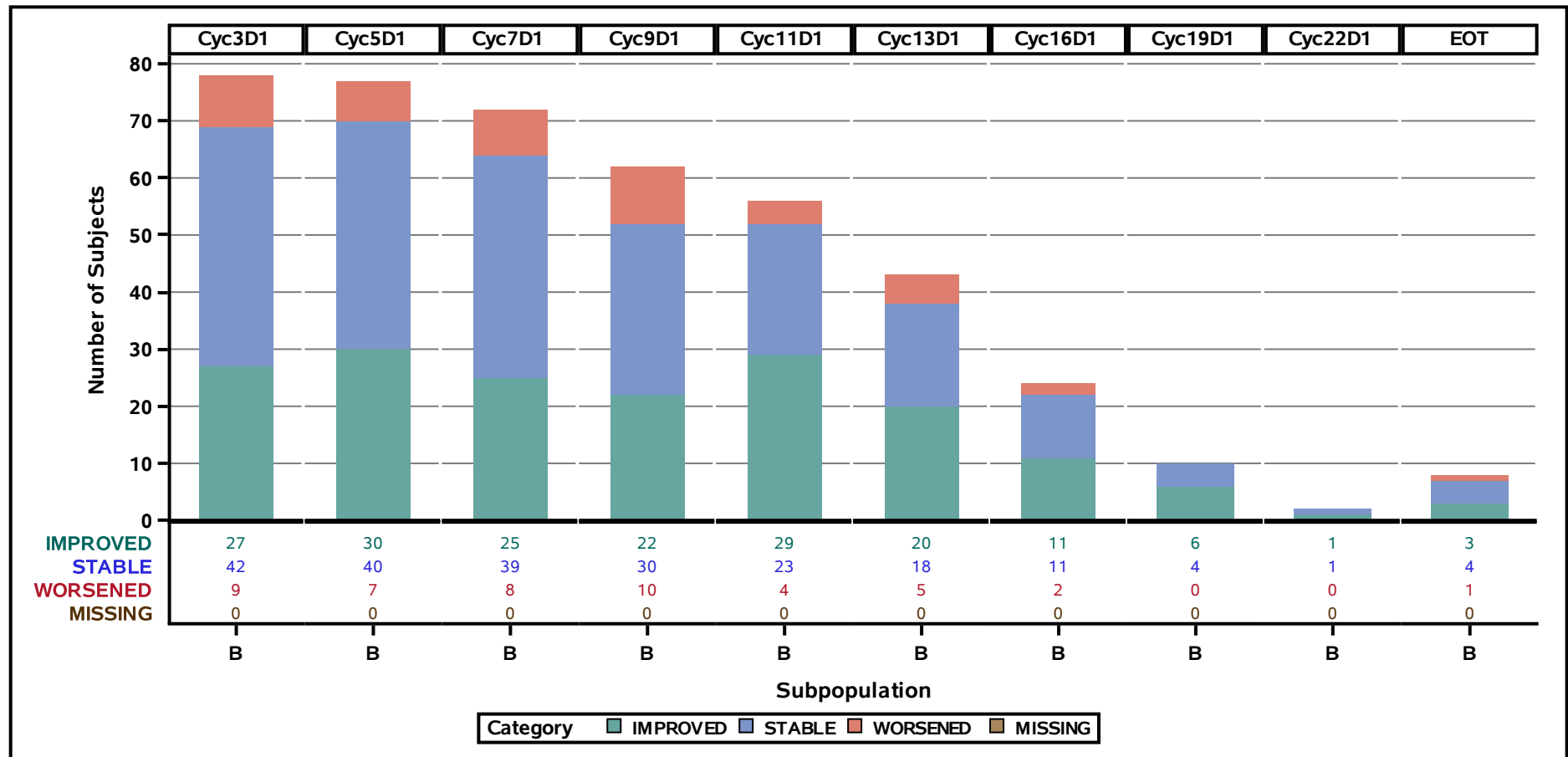
-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Changes from baseline in QLQ-C30 scores by Insomnia
 (Efficacy Analysis Set)
 by Subpopulation



Program Location: //lilly/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
 Output Location: //lilly/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F050_sl_10pt_mtc_eff.rtf
 Data Location: //lilly/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: //lilly/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.41
 EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	84 38.10 (31.53)	78 -9.90 (-15.65, -4.15)
CYCLE 5 DAY 1		77 -14.16 (-19.95, -8.37)
CYCLE 7 DAY 1		72 -12.74 (-18.72, -6.75)
CYCLE 9 DAY 1		62 -11.79 (-18.24, -5.34)
CYCLE 11 DAY 1		56 -20.28 (-27.07, -13.49)
CYCLE 13 DAY 1		43 -14.84 (-22.59, -7.10)
CYCLE 16 DAY 1		24 -17.18 (-27.55, -6.80)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.41.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.41
 EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1		10 -21.73 (-37.80, -5.65)
CYCLE 22 DAY 1		2 -18.85 (-54.76, 17.06)
END OF TREATMENT		8 -10.23 (-28.19, 7.73)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.41.rtf

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 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.12_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)
Baseline [1]	
n [2]	84
Mean	26.59
Standard Deviation	31.380
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0

- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.12_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 3 Day 1	
n [2]	78
Mean	10.68
Standard Deviation	20.452
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	78
Mean	-15.38
Standard Deviation	30.243
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 66.7
Status [3]	
Improved	32 (41.0)
Stable	40 (51.3)
Worsened	6 (7.7)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
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T14.2.6.1.12_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 5 Day 1	
n [2]	77
Mean	10.39
Standard Deviation	21.804
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	77
Mean	-15.58
Standard Deviation	31.800
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 66.7
Status [3]	
Improved	31 (40.3)
Stable	39 (50.6)
Worsened	7 (9.1)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_mtc_eff.rtf

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T14.2.6.1.12_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)

Cycle 7 Day 1	
n [2]	72
Mean	12.04
Standard Deviation	23.273
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	0.0, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	72
Mean	-12.50
Standard Deviation	37.711
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 100.0
Status [3]	
Improved	26 (36.1)
Stable	35 (48.6)
Worsened	11 (15.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_mtc_eff.rtf

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T14.2.6.1.12_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 9 Day 1	
n [2]	62
Mean	12.37
Standard Deviation	22.771
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	62
Mean	-13.98
Standard Deviation	34.959
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 100.0
Status [3]	
Improved	27 (43.5)
Stable	26 (41.9)
Worsened	9 (14.5)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_mtc_eff.rtf

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T14.2.6.1.12_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)

Cycle 11 Day 1	
n [2]	56
Mean	13.10
Standard Deviation	26.726
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	0.0, 100.0
Change from Baseline to Cycle 11 Day 1	
n [2]	56
Mean	-13.10
Standard Deviation	41.526
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 100.0
Status [3]	
Improved	22 (39.3)
Stable	26 (46.4)
Worsened	8 (14.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_mtc_eff.rtf

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T14.2.6.1.12_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 13 Day 1		
n [2]	43	
Mean	10.08	
Standard Deviation	19.967	
Median	0.00	
Q1, Q3	0.0, 0.0	
Min, Max	0.0, 66.7	
Change from Baseline to Cycle 13 Day 1		
n [2]	43	
Mean	-12.40	
Standard Deviation	30.881	
Median	0.00	
Q1, Q3	-33.3, 0.0	
Min, Max	-100.0, 33.3	
Status [3]		
Improved	15 (34.9)	
Stable	23 (53.5)	
Worsened	5 (11.6)	

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_mtc_eff.rtf

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T14.2.6.1.12_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 16 Day 1	
n [2]	24
Mean	12.50
Standard Deviation	23.698
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 16 Day 1	
n [2]	24
Mean	-18.06
Standard Deviation	36.751
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 33.3
Status [3]	
Improved	8 (33.3)
Stable	14 (58.3)
Worsened	2 (8.3)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
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T14.2.6.1.12_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 19 Day 1		
n [2]	10	
Mean	6.67	
Standard Deviation	14.055	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	0.0,	33.3
Change from Baseline to Cycle 19 Day 1		
n [2]	10	
Mean	-26.67	
Standard Deviation	46.614	
Median	0.00	
Q1, Q3	-66.7,	0.0
Min, Max	-100.0,	33.3
Status [3]		
Improved	4	(40.0)
Stable	5	(50.0)
Worsened	1	(10.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_mtc_eff.rtf

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T14.2.6.1.12_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 22 Day 1		
n [2]	2	
Mean	0.00	
Standard Deviation	0.000	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	0.0,	0.0
Change from Baseline to Cycle 22 Day 1		
n [2]	2	
Mean	-16.67	
Standard Deviation	23.570	
Median	-16.67	
Q1, Q3	-33.3,	0.0
Min, Max	-33.3,	0.0
Status [3]		
Improved	1	(50.0)
Stable	1	(50.0)
Worsened	0	(0.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.12_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

End of Treatment	
n [2]	8
Mean	16.67
Standard Deviation	25.198
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to End of Treatment	
n [2]	8
Mean	-12.50
Standard Deviation	39.591
Median	0.00
Q1, Q3	-50.0, 16.7
Min, Max	-66.7, 33.3
Status [3]	
Improved	3 (37.5)
Stable	3 (37.5)
Worsened	2 (25.0)

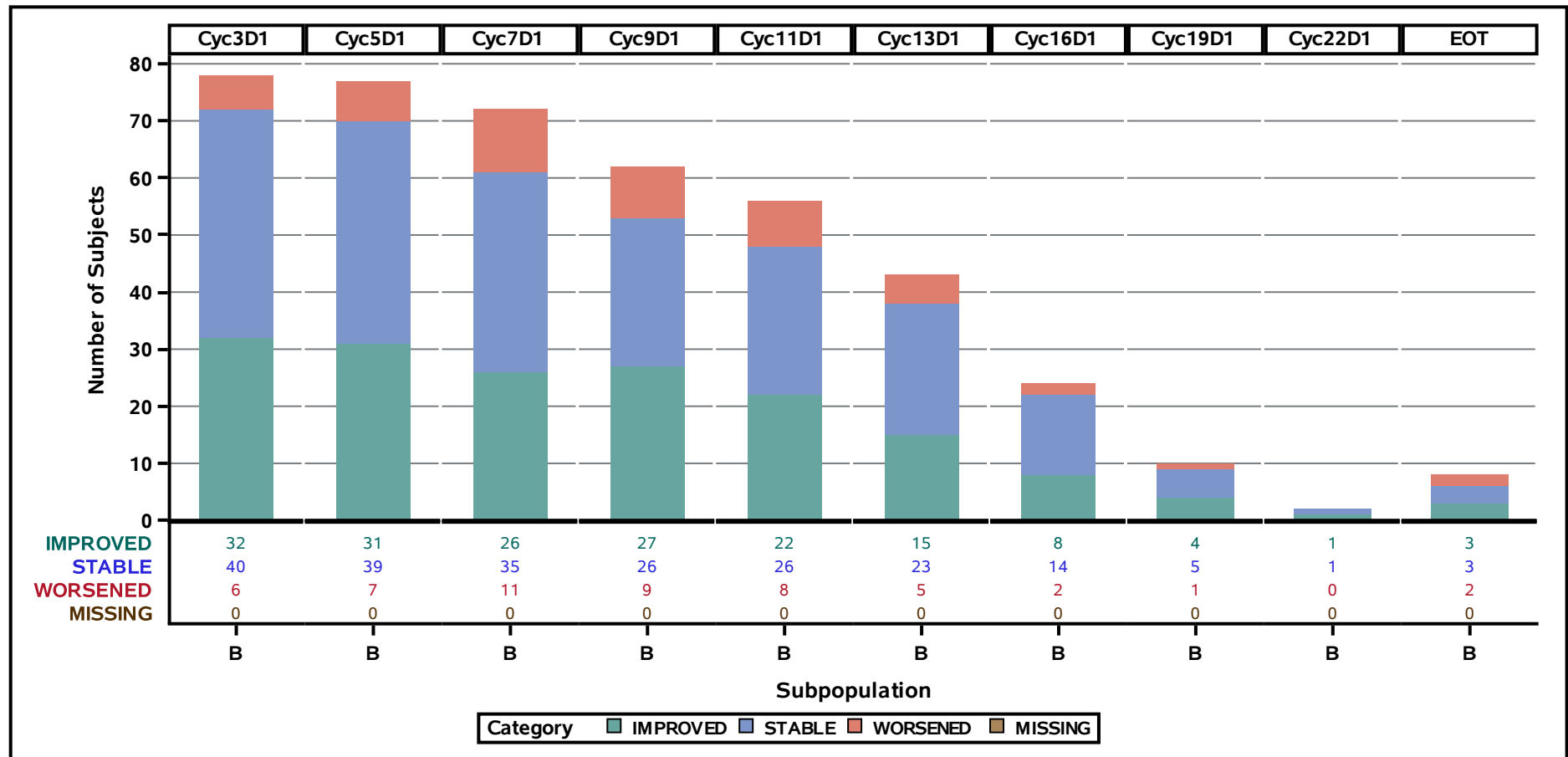
-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Changes from baseline in QLQ-C30 scores by Appetite loss
 (Efficacy Analysis Set)
 by Subpopulation



Program Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
 Output Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F051_ap_10pt_mtc_eff.rtf
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.42
 EORTC QLQ-C30 (v3.0): Summary of Appetite Loss by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	84 26.59 (31.38)	78 -15.26 (-20.17, -10.36)
CYCLE 5 DAY 1		77 -15.54 (-20.48, -10.61)
CYCLE 7 DAY 1		72 -13.68 (-18.79, -8.58)
CYCLE 9 DAY 1		62 -13.62 (-19.12, -8.12)
CYCLE 11 DAY 1		56 -12.87 (-18.66, -7.08)
CYCLE 13 DAY 1		43 -15.34 (-21.95, -8.73)
CYCLE 16 DAY 1		24 -14.11 (-22.96, -5.26)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.42.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.42
 EORTC QLQ-C30 (v3.0): Summary of Appetite Loss by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1		10 -20.35 (-34.06, -6.65)
CYCLE 22 DAY 1		2 -24.56 (-55.19, 6.07)
END OF TREATMENT		8 -9.74 (-25.05, 5.58)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.42.rtf

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T14.2.6.1.13_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)
Baseline [1]	
n [2]	84
Mean	9.52
Standard Deviation	22.891
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 100.0

- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.13_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 3 Day 1	
n [2]	78
Mean	14.96
Standard Deviation	21.919
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to Cycle 3 Day 1	
n [2]	78
Mean	5.56
Standard Deviation	27.611
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	-100.0, 66.7
Status [3]	
Improved	9 (11.5)
Stable	49 (62.8)
Worsened	20 (25.6)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.13_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 5 Day 1	
n [2]	77
Mean	16.02
Standard Deviation	26.825
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	77
Mean	7.36
Standard Deviation	31.355
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-100.0, 100.0
Status [3]	
Improved	8 (10.4)
Stable	50 (64.9)
Worsened	19 (24.7)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
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T14.2.6.1.13_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)

Cycle 7 Day 1	
n [2]	72
Mean	12.04
Standard Deviation	22.591
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	72
Mean	4.63
Standard Deviation	26.422
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-100.0, 100.0
Status [3]	
Improved	6 (8.3)
Stable	51 (70.8)
Worsened	15 (20.8)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
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T14.2.6.1.13_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 9 Day 1	
n [2]	62
Mean	12.90
Standard Deviation	22.057
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	62
Mean	3.76
Standard Deviation	27.728
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-100.0, 66.7
Status [3]	
Improved	8 (12.9)
Stable	39 (62.9)
Worsened	15 (24.2)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_mtc_eff.rtf

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T14.2.6.1.13_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 11 Day 1		
n [2]	55	
Mean	7.88	
Standard Deviation	15.666	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	0.0,	66.7
Change from Baseline to Cycle 11 Day 1		
n [2]	55	
Mean	-1.82	
Standard Deviation	25.993	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	-100.0,	66.7
Status [3]		
Improved	8	(14.5)
Stable	39	(70.9)
Worsened	8	(14.5)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_mtc_eff.rtf

Loxo Oncology Inc.
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T14.2.6.1.13_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)

Cycle 13 Day 1	
n [2]	43
Mean	12.40
Standard Deviation	24.150
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 13 Day 1	
n [2]	43
Mean	3.10
Standard Deviation	33.973
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-100.0, 100.0
Status [3]	
Improved	5 (11.6)
Stable	30 (69.8)
Worsened	8 (18.6)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_mtc_eff.rtf

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T14.2.6.1.13_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 16 Day 1		
n [2]	24	
Mean	6.94	
Standard Deviation	13.828	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	0.0,	33.3
Change from Baseline to Cycle 16 Day 1		
n [2]	24	
Mean	-5.56	
Standard Deviation	30.561	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	-100.0,	33.3
Status [3]		
Improved	3	(12.5)
Stable	18	(75.0)
Worsened	3	(12.5)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_mtc_eff.rtf

Loxo Oncology Inc.
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T14.2.6.1.13_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 19 Day 1		
n [2]	10	
Mean	3.33	
Standard Deviation	10.541	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	0.0,	33.3
Change from Baseline to Cycle 19 Day 1		
n [2]	10	
Mean	-10.00	
Standard Deviation	35.312	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	-100.0,	33.3
Status [3]		
Improved	2	(20.0)
Stable	7	(70.0)
Worsened	1	(10.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_mtc_eff.rtf

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T14.2.6.1.13_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 22 Day 1		
n [2]	2	
Mean	0.00	
Standard Deviation	0.000	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	0.0,	0.0
Change from Baseline to Cycle 22 Day 1		
n [2]	2	
Mean	0.00	
Standard Deviation	0.000	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	0.0,	0.0
Status [3]		
Improved	0	(0.0)
Stable	2	(100.0)
Worsened	0	(0.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.13_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

End of Treatment	
n [2]	8
Mean	16.67
Standard Deviation	30.861
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to End of Treatment	
n [2]	8
Mean	4.17
Standard Deviation	27.817
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-33.3, 66.7
Status [3]	
Improved	1 (12.5)
Stable	6 (75.0)
Worsened	1 (12.5)

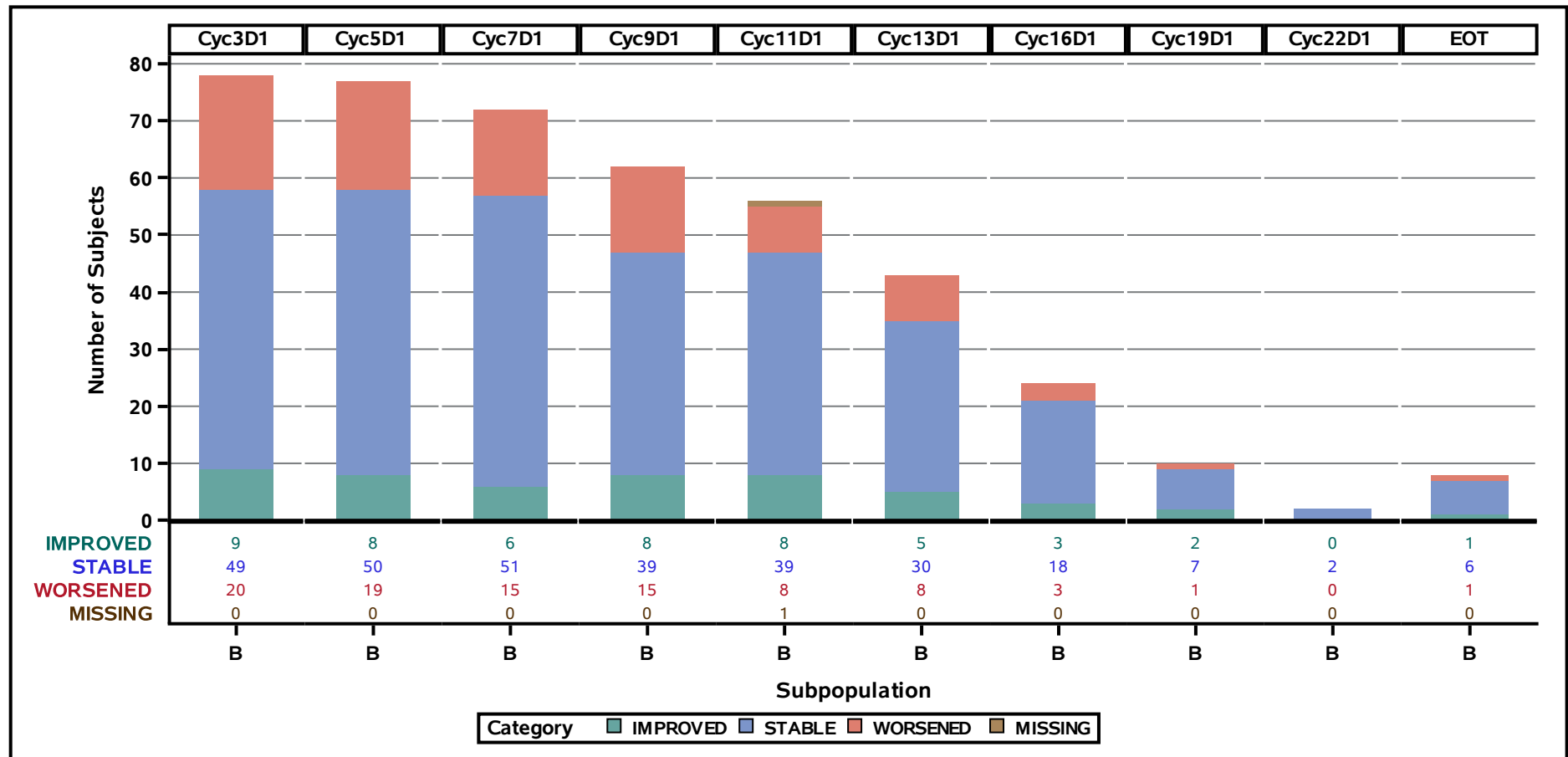
-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Changes from baseline in QLQ-C30 scores by Constipation
 (Efficacy Analysis Set)
 by Subpopulation



Program Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
 Output Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F052_co_10pt_mtc_eff.rtf
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.43
 EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	84 9.52 (22.89)	78 5.72 (0.86, 10.57)
CYCLE 5 DAY 1		77 6.91 (2.03, 11.80)
CYCLE 7 DAY 1		72 3.16 (-1.89, 8.22)
CYCLE 9 DAY 1		62 3.71 (-1.73, 9.16)
CYCLE 11 DAY 1		55 -1.42 (-7.20, 4.37)
CYCLE 13 DAY 1		43 3.18 (-3.36, 9.72)
CYCLE 16 DAY 1		24 -2.87 (-11.62, 5.89)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.43.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.43
 EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1		10 -6.63 (-20.20, 6.94)
CYCLE 22 DAY 1		2 -7.51 (-37.84, 22.82)
END OF TREATMENT		8 6.86 (-8.31, 22.02)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.43.rtf

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 Protocol Number: LOXO-RET-17001
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T14.2.6.1.14_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)
Baseline [1]	
n [2]	83
Mean	39.76
Standard Deviation	37.343
Median	33.33
Q1, Q3	0.0, 66.7
Min, Max	0.0, 100.0

- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.14_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 3 Day 1	
n [2]	77
Mean	15.58
Standard Deviation	23.311
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	77
Mean	-24.24
Standard Deviation	41.758
Median	-33.33
Q1, Q3	-66.7, 0.0
Min, Max	-100.0, 66.7
Status [3]	
Improved	39 (50.6)
Stable	28 (36.4)
Worsened	10 (13.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.14_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 5 Day 1	
n [2]	76
Mean	15.35
Standard Deviation	19.956
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to Cycle 5 Day 1	
n [2]	76
Mean	-26.32
Standard Deviation	39.746
Median	-33.33
Q1, Q3	-66.7, 0.0
Min, Max	-100.0, 33.3
Status [3]	
Improved	42 (55.3)
Stable	22 (28.9)
Worsened	12 (15.8)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.14_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 7 Day 1	
n [2]	71
Mean	11.74
Standard Deviation	18.771
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to Cycle 7 Day 1	
n [2]	71
Mean	-27.70
Standard Deviation	37.368
Median	-33.33
Q1, Q3	-66.7, 0.0
Min, Max	-100.0, 33.3
Status [3]	
Improved	39 (54.9)
Stable	25 (35.2)
Worsened	7 (9.9)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.14_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 9 Day 1	
n [2]	62
Mean	11.83
Standard Deviation	20.106
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to Cycle 9 Day 1	
n [2]	62
Mean	-30.11
Standard Deviation	38.510
Median	-33.33
Q1, Q3	-66.7, 0.0
Min, Max	-100.0, 66.7
Status [3]	
Improved	38 (61.3)
Stable	19 (30.6)
Worsened	5 (8.1)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_mtc_eff.rtf

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 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.14_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 11 Day 1	
n [2]	56
Mean	15.48
Standard Deviation	23.753
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 11 Day 1	
n [2]	56
Mean	-24.40
Standard Deviation	42.872
Median	-33.33
Q1, Q3	-66.7, 0.0
Min, Max	-100.0, 100.0
Status [3]	
Improved	32 (57.1)
Stable	15 (26.8)
Worsened	9 (16.1)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_mtc_eff.rtf

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T14.2.6.1.14_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)

Cycle 13 Day 1	
n [2]	43
Mean	16.28
Standard Deviation	22.268
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to Cycle 13 Day 1	
n [2]	43
Mean	-30.23
Standard Deviation	37.666
Median	-33.33
Q1, Q3	-66.7, 0.0
Min, Max	-100.0, 66.7
Status [3]	
Improved	24 (55.8)
Stable	17 (39.5)
Worsened	2 (4.7)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_mtc_eff.rtf

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T14.2.6.1.14_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 16 Day 1	
n [2]	24
Mean	18.06
Standard Deviation	25.968
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 16 Day 1	
n [2]	24
Mean	-31.94
Standard Deviation	45.555
Median	-33.33
Q1, Q3	-66.7, 0.0
Min, Max	-100.0, 33.3
Status [3]	
Improved	15 (62.5)
Stable	4 (16.7)
Worsened	5 (20.8)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_mtc_eff.rtf

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T14.2.6.1.14_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 19 Day 1	
n [2]	10
Mean	30.00
Standard Deviation	29.187
Median	33.33
Q1, Q3	0.0, 66.7
Min, Max	0.0, 66.7
Change from Baseline to Cycle 19 Day 1	
n [2]	10
Mean	0.00
Standard Deviation	38.490
Median	0.00
Q1, Q3	-33.3, 33.3
Min, Max	-66.7, 66.7
Status [3]	
Improved	3 (30.0)
Stable	4 (40.0)
Worsened	3 (30.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_mtc_eff.rtf

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T14.2.6.1.14_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 22 Day 1		
n [2]	2	
Mean	0.00	
Standard Deviation	0.000	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	0.0,	0.0
Change from Baseline to Cycle 22 Day 1		
n [2]	2	
Mean	-33.33	
Standard Deviation	47.140	
Median	-33.33	
Q1, Q3	-66.7,	0.0
Min, Max	-66.7,	0.0
Status [3]		
Improved	1	(50.0)
Stable	1	(50.0)
Worsened	0	(0.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.14_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

End of Treatment	
n [2]	7
Mean	19.05
Standard Deviation	26.227
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to End of Treatment	
n [2]	7
Mean	-14.29
Standard Deviation	26.227
Median	-33.33
Q1, Q3	-33.3, 0.0
Min, Max	-33.3, 33.3
Status [3]	
Improved	4 (57.1)
Stable	2 (28.6)
Worsened	1 (14.3)

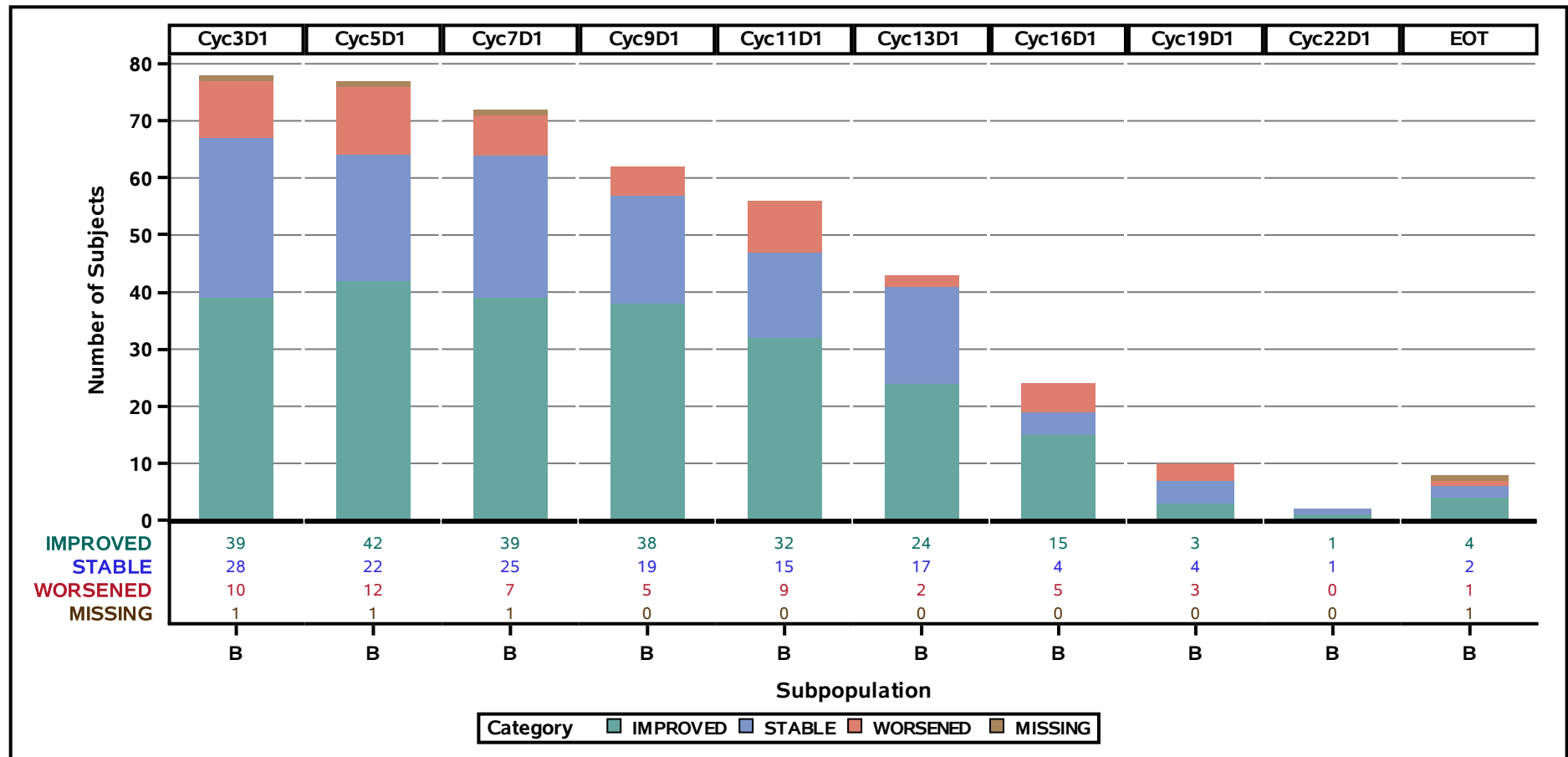
-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Changes from baseline in QLQ-C30 scores by Diarrhoea
 (Efficacy Analysis Set)
 by Subpopulation



Program Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
 Output Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F053_di_10pt_mtc_eff.rtf
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.44
 EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	83 39.76 (37.34)	77 -25.58 (-30.44, -20.72)
CYCLE 5 DAY 1		76 -25.96 (-30.85, -21.06)
CYCLE 7 DAY 1		71 -29.40 (-34.46, -24.33)
CYCLE 9 DAY 1		62 -29.50 (-34.92, -24.08)
CYCLE 11 DAY 1		56 -25.69 (-31.40, -19.99)
CYCLE 13 DAY 1		43 -25.41 (-31.92, -18.89)
CYCLE 16 DAY 1		24 -23.90 (-32.63, -15.18)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.44.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.44
 EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1		10 -10.40 (-23.91, 3.11)
CYCLE 22 DAY 1		2 -40.66 (-70.84, -10.48)
END OF TREATMENT		7 -21.61 (-37.74, -5.47)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.44.rtf

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 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.15_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)
Baseline [1]	
n [2]	83
Mean	24.10
Standard Deviation	30.935
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0

- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.15_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 3 Day 1	
n [2]	76
Mean	19.74
Standard Deviation	30.877
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	76
Mean	-4.82
Standard Deviation	24.162
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-100.0, 100.0
Status [3]	
Improved	16 (21.1)
Stable	54 (71.1)
Worsened	6 (7.9)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_mtc_eff.rtf

Loxo Oncology Inc.
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T14.2.6.1.15_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 5 Day 1	
n [2]	75
Mean	20.00
Standard Deviation	28.997
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	75
Mean	-6.67
Standard Deviation	19.758
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-66.7, 33.3
Status [3]	
Improved	18 (24.0)
Stable	52 (69.3)
Worsened	5 (6.7)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.15_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B
	(N= 84)

Cycle 7 Day 1	
n [2]	71
Mean	21.60
Standard Deviation	31.922
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	71
Mean	-1.88
Standard Deviation	20.227
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-33.3, 33.3
Status [3]	
Improved	15 (21.1)
Stable	45 (63.4)
Worsened	11 (15.5)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.15_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)

Cycle 9 Day 1	
n [2]	62
Mean	20.43
Standard Deviation	27.892
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	62
Mean	-8.06
Standard Deviation	23.904
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-100.0, 33.3
Status [3]	
Improved	18 (29.0)
Stable	38 (61.3)
Worsened	6 (9.7)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.15_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)

Cycle 11 Day 1	
n [2]	56
Mean	20.83
Standard Deviation	30.193
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 11 Day 1	
n [2]	56
Mean	-7.14
Standard Deviation	21.756
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-66.7, 33.3
Status [3]	
Improved	15 (26.8)
Stable	36 (64.3)
Worsened	5 (8.9)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_mtc_eff.rtf

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 Protocol Number: LOXO-RET-17001
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T14.2.6.1.15_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)

Cycle 13 Day 1	
n [2]	42
Mean	20.63
Standard Deviation	28.468
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 13 Day 1	
n [2]	42
Mean	-6.35
Standard Deviation	21.131
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-66.7, 66.7
Status [3]	
Improved	10 (23.8)
Stable	30 (71.4)
Worsened	2 (4.8)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_mtc_eff.rtf

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T14.2.6.1.15_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)

Cycle 16 Day 1	
n [2]	24
Mean	18.06
Standard Deviation	27.766
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 16 Day 1	
n [2]	24
Mean	-6.94
Standard Deviation	25.968
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-66.7, 66.7
Status [3]	
Improved	5 (20.8)
Stable	18 (75.0)
Worsened	1 (4.2)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_mtc_eff.rtf

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T14.2.6.1.15_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	
Statistics	B (N= 84)

Cycle 19 Day 1	
n [2]	10
Mean	23.33
Standard Deviation	22.498
Median	33.33
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to Cycle 19 Day 1	
n [2]	10
Mean	0.00
Standard Deviation	22.222
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-33.3, 33.3
Status [3]	
Improved	2 (20.0)
Stable	6 (60.0)
Worsened	2 (20.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_mtc_eff.rtf

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T14.2.6.1.15_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit	B	
Statistics	(N= 84)	

Cycle 22 Day 1		
n [2]	2	
Mean	0.00	
Standard Deviation	0.000	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	0.0,	0.0
Change from Baseline to Cycle 22 Day 1		
n [2]	2	
Mean	0.00	
Standard Deviation	0.000	
Median	0.00	
Q1, Q3	0.0,	0.0
Min, Max	0.0,	0.0
Status [3]		
Improved	0	(0.0)
Stable	2	(100.0)
Worsened	0	(0.0)

-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
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T14.2.6.1.15_mtc_eff
 EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
 Efficacy Analysis Set
 by Subpopulation

Visit Statistics	B (N= 84)	

End of Treatment		
n [2]	7	
Mean	23.81	
Standard Deviation	16.265	
Median	33.33	
Q1, Q3	0.0, 33.3	
Min, Max	0.0, 33.3	
Change from Baseline to End of Treatment		
n [2]	7	
Mean	-14.29	
Standard Deviation	17.817	
Median	0.00	
Q1, Q3	-33.3, 0.0	
Min, Max	-33.3, 0.0	
Status [3]		
Improved	3	(42.9)
Stable	4	(57.1)
Worsened	0	(0.0)

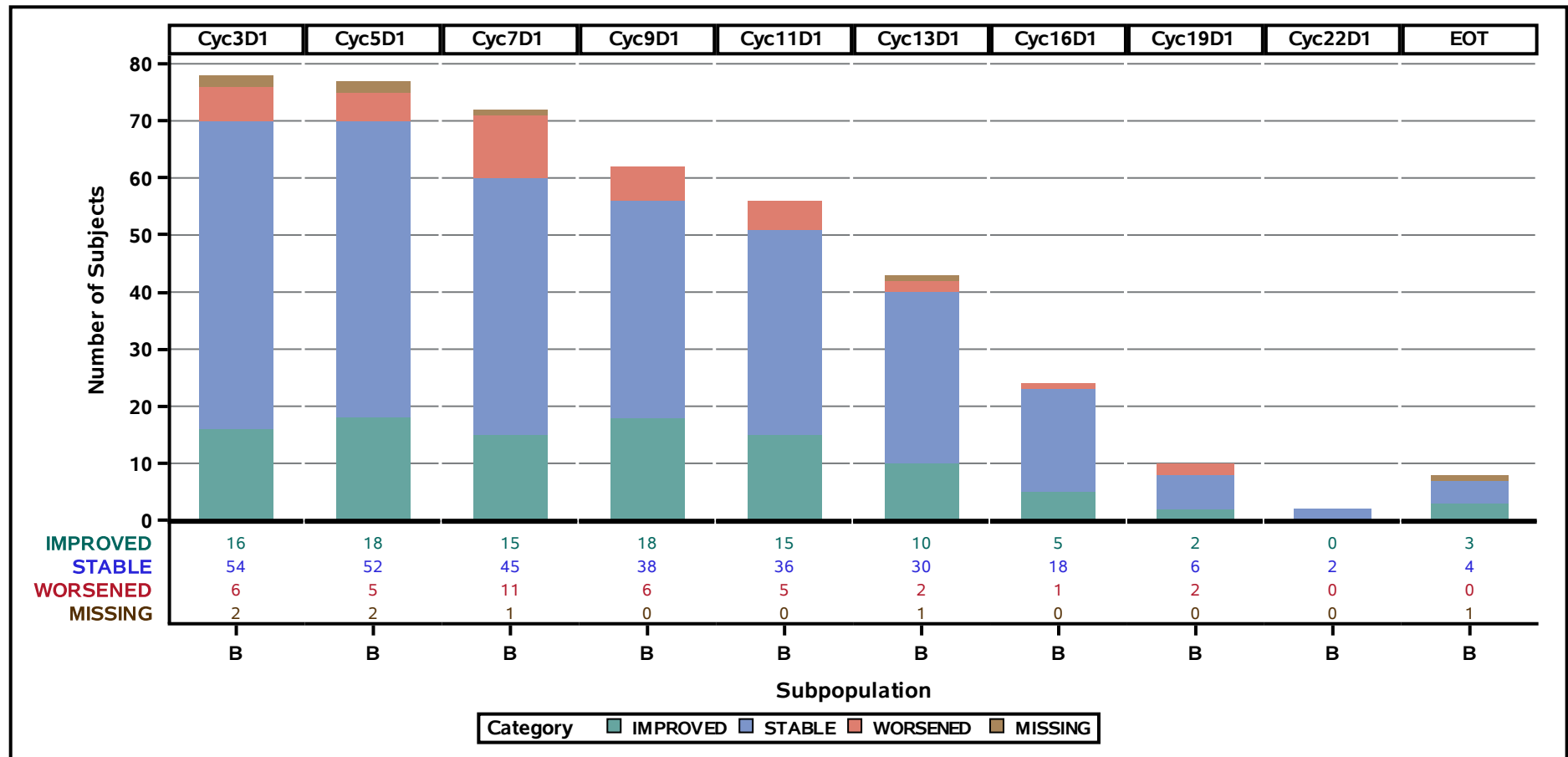
-
- [1] Baseline is defined as the last measurement available prior to the first dose of LOXO-292.
 [2] n is the number of subjects with both baseline and corresponding post-baseline assessment.
 [3] Percentage is calculated using the number of patients with both baseline and corresponding post-baseline assessment (n) as the denominator.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_sum.sas
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
 Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_mtc_eff.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Summary of Clinical Efficacy - MTC (Visit Cutoff 30-MAR-2020)

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Changes from baseline in QLQ-C30 scores by Financial difficulties
 (Efficacy Analysis Set)
 by Subpopulation



Program Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
 Output Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F054_fi_10pt_mtc_eff.rtf
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data Location: /lilly/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.45
 EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	83 24.10 (30.94)	76 -5.31 (-9.77, -0.84)
CYCLE 5 DAY 1		75 -6.50 (-10.99, -2.00)
CYCLE 7 DAY 1		71 -2.70 (-7.32, 1.92)
CYCLE 9 DAY 1		62 -7.33 (-12.27, -2.38)
CYCLE 11 DAY 1		56 -6.56 (-11.77, -1.36)
CYCLE 13 DAY 1		42 -6.08 (-12.09, -0.07)
CYCLE 16 DAY 1		24 -7.29 (-15.24, 0.65)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.45.rtf

Loxo Oncology Inc.
 Protocol Number: LOXO-RET-17001
 Clinical Study Report (Visit Cutoff 30-MAR-2020)

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T14.2.6.1.45
 EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits (MMRM)
 Efficacy Analysis Set
 by Subpopulation

----- B -----		
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1		10 -0.87 (-13.18, 11.44)
CYCLE 22 DAY 1		2 -8.12 (-35.69, 19.45)
END OF TREATMENT		7 -10.56 (-25.29, 4.17)

N is the number of subjects with both baseline and corresponding post-baseline assessment.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_sp_qlqc30_mmr2.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.2.6.1.45.rtf

Tabelle 30.1: Compliance-Rate für den Fragebogen Bowel Diary Questinnaire in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020)
- Efficacy Analysis Set

	Selpercatinib
	Subpopulation B - MTC
Endpunkt	(N'=50) (N=143)
Gesamtrate^a über alle Zeitpunkte	711/815 (87,2)
Compliance-Rate^b pro geplante Visite	
Baseline	50/50 (100,0)
Zyklus 1, Tag 8	43/50 (86,0)
Zyklus 1, Tag 15	41/47 (87,2)
Zyklus 1, Tag 22	29/49 (59,2)
Zyklus 2, Tag 1	46/49 (93,9)
Zyklus 3, Tag 1	44/48 (91,7)
Zyklus 4, Tag 1	47/48 (97,9)
Zyklus 5, Tag 1	43/48 (89,6)
Zyklus 6, Tag 1	44/48 (91,7)
Zyklus 7, Tag 1	43/47 (91,5)
Zyklus 8, Tag 1	37/44 (84,1)
Zyklus 9, Tag 1	39/40 (97,5)
Zyklus 10, Tag 1	35/39 (89,7)
Zyklus 11, Tag 1	33/37 (89,2)
Zyklus 12, Tag 1	31/35 (88,6)
Zyklus 13, Tag 1	29/32 (90,6)
Zyklus 14, Tag 1	19/26 (73,1)
Zyklus 15, Tag 1	17/22 (77,3)
Zyklus 16, Tag 1	14/17 (82,4)
Zyklus 17, Tag 1	8/11 (72,7)
Zyklus 18, Tag 1	5/6 (83,3)
Zyklus 19, Tag 1	5/6 (83,3)
Zyklus 20, Tag 1	2/3 (66,7)
Zyklus 21, Tag 1	2/3 (66,7)
Visite bei Ende der Behandlung	5/10 (50,0)
MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); N': Anzahl der behandelten Patienten mit einem Baseline- und mindestens einem Post-Baseline-Wert; RET: Rearranged during Transfection. a: Die Gesamtrate wird berechnet, in dem die Gesamtzahl an Patienten, für die der Bowel Diary Questionnaire bei jeder Visite erhoben wurde, durch die Gesamtzahl an Patienten, die bei jeder Visite unter Behandlung waren, geteilt wird. b: Die Compliance-Rate ist definiert als der prozentuale Anteil der Patienten, für die der Bowel Diary Questionnaire bei der entsprechenden Visite erhoben wurde, an den Patienten, die bei dieser Visite unter Behandlung waren. Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_bdcomp_mtc_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T030_1_sp_bdcomp_mtc_eff_mod_for_PDF.rtf

Tabelle 30.2: Compliance-Rate für den Fragebogen Bowel Diary Questinnaire in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020)
- Efficacy Analysis Set - MTC Patienten mit Diarrhoe bei Baseline

	Selpercatinib
	Subpopulation B - MTC
Endpunkt	(N'=35) (N=143)
Gesamtrate^a über alle Zeitpunkte	526/602 (87,4)
Compliance-Rate^b pro geplante Visite	
Baseline	35/35 (100,0)
Zyklus 1, Tag 8	30/35 (85,7)
Zyklus 1, Tag 15	31/33 (93,9)
Zyklus 1, Tag 22	22/35 (62,9)
Zyklus 2, Tag 1	33/35 (94,3)
Zyklus 3, Tag 1	32/35 (91,4)
Zyklus 4, Tag 1	34/35 (97,1)
Zyklus 5, Tag 1	31/35 (88,6)
Zyklus 6, Tag 1	31/35 (88,6)
Zyklus 7, Tag 1	31/34 (91,2)
Zyklus 8, Tag 1	27/33 (81,8)
Zyklus 9, Tag 1	30/30 (100,0)
Zyklus 10, Tag 1	26/29 (89,7)
Zyklus 11, Tag 1	25/27 (92,6)
Zyklus 12, Tag 1	23/27 (85,2)
Zyklus 13, Tag 1	23/26 (88,5)
Zyklus 14, Tag 1	15/21 (71,4)
Zyklus 15, Tag 1	14/19 (73,7)
Zyklus 16, Tag 1	12/14 (85,7)
Zyklus 17, Tag 1	7/8 (87,5)
Zyklus 18, Tag 1	4/5 (80,0)
Zyklus 19, Tag 1	4/5 (80,0)
Zyklus 20, Tag 1	1/2 (50,0)
Zyklus 21, Tag 1	1/2 (50,0)
Visite bei Ende der Behandlung	4/7 (57,1)
MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); N': Anzahl der behandelten Patienten mit einem Baseline- und mindestens einem Post-Baseline-Wert - Patienten mit Diarrhoe bei Baseline; RET: Rearranged during Transfection. a: Die Gesamtrate wird berechnet, in dem die Gesamtzahl an Patienten, für die der Bowel Diary Questionnaire bei jeder Visite erhoben wurde, durch die Gesamtzahl an Patienten, die bei jeder Visite unter Behandlung waren, geteilt wird. b: Die Compliance-Rate ist definiert als der prozentuale Anteil der Patienten, für die der Bowel Diary Questionnaire bei der entsprechenden Visite erhoben wurde, an den Patienten, die bei dieser Visite unter Behandlung waren. Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_bdcomp_mtc_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T030_2_sp_bdcomp_mtc_eff_mod_for_PDF.rtf

Tabelle 30.3: Compliance-Rate für den Fragebogen Bowel Diary Questinnaire in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020)
- Efficacy Analysis Set - MTC Patienten ohne Diarrhoe bei Baseline

	Selpercatinib
	Subpopulation B - MTC
Endpunkt	(N'=15) (N=143)
Gesamtrate^a über alle Zeitpunkte	185/213 (86,9)
Compliance-Rate^b pro geplante Visite	
Baseline	15/15 (100,0)
Zyklus 1, Tag 8	13/15 (86,7)
Zyklus 1, Tag 15	10/14 (71,4)
Zyklus 1, Tag 22	7/14 (50,0)
Zyklus 2, Tag 1	13/14 (92,9)
Zyklus 3, Tag 1	12/13 (92,3)
Zyklus 4, Tag 1	13/13 (100,0)
Zyklus 5, Tag 1	12/13 (92,3)
Zyklus 6, Tag 1	13/13 (100,0)
Zyklus 7, Tag 1	12/13 (92,3)
Zyklus 8, Tag 1	10/11 (90,9)
Zyklus 9, Tag 1	9/10 (90,0)
Zyklus 10, Tag 1	9/10 (90,0)
Zyklus 11, Tag 1	8/10 (80,0)
Zyklus 12, Tag 1	8/8 (100,0)
Zyklus 13, Tag 1	6/6 (100,0)
Zyklus 14, Tag 1	4/5 (80,0)
Zyklus 15, Tag 1	3/3 (100,0)
Zyklus 16, Tag 1	2/3 (66,7)
Zyklus 17, Tag 1	1/3 (33,3)
Zyklus 18, Tag 1	1/1 (100,0)
Zyklus 19, Tag 1	1/1 (100,0)
Zyklus 20, Tag 1	1/1 (100,0)
Zyklus 21, Tag 1	1/1 (100,0)
Visite bei Ende der Behandlung	1/3 (33,3)
MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); N': Anzahl der behandelten Patienten mit einem Baseline- und mindestens einem Post-Baseline-Wert - Patienten ohne Diarrhoe bei Baseline; RET: Rearranged during Transfection. a: Die Gesamtrate wird berechnet, in dem die Gesamtzahl an Patienten, für die der Bowel Diary Questionnaire bei jeder Visite erhoben wurde, durch die Gesamtzahl an Patienten, die bei jeder Visite unter Behandlung waren, geteilt wird. b: Die Compliance-Rate ist definiert als der prozentuale Anteil der Patienten, für die der Bowel Diary Questionnaire bei der entsprechenden Visite erhoben wurde, an den Patienten, die bei dieser Visite unter Behandlung waren. Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_bdcomp_mtc_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T030_3_sp_bdcomp_mtc_eff_mod_for_PDF.rtf

Tabelle 035: Ergebnisse für die Zeit bis zur ersten Verbesserung bzw. Verschlechterung der Diarrhoe und für die Dauer der Verbesserung der Diarrhoe gemessen anhand des Bowel Diary Questionnaires aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

		Selpercatinib	
		Subpopulation B - MTC	
Endpunkt		(N'=50)	(N=143)
Anzahl der Patienten mit Diarrhoe bei Baseline		35	
Patienten mit Ereignis			
Verbesserung der Diarrhoe, n (%) ^{a,b}		31 (62,0)	
Zensierte Patienten, n (%)		19 (38,0)	
Verschlechterung der Diarrhoe, n (%) ^{a,c}		12 (24,0)	
Zensierte Patienten, n (%)		38 (76,0)	
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] ^{d,e}		1,9 [0,46; 6,47]	
Mediane Dauer der Verbesserung (Monate) [95%-KI] ^{e,f}		NE [6,01; NE]	
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] ^{e,g}		NE [NE; NE]	
KI: Konfidenzintervall; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); N': Anzahl der behandelten Patienten mit einem Baseline- und mindestens einem Post-Baseline-Wert; NE: nicht schätzbar; RET: Rearranged during Transfection. a: Der prozentuale Anteil basiert auf der Anzahl an behandelten Patienten mit einem Baseline- und mindestens einem Post-Baseline-Wert. b: Verbesserung der Diarrhoe ist definiert als jede schrittweise Verbesserung (z.B. leichte zu keine Diarrhoe, mittelschwere zu leichte oder keine Diarrhoe, schwere zu mittelschwere, leichte oder keine Diarrhoe). c: Verschlechterung der Diarrhoe ist definiert als jede schrittweise Verschlechterung (z.B. keine zu leichte, mittelschwere oder schwere Diarrhoe, leichte zu mittelschwere oder schwere Diarrhoe, mittelschwere zu schwere Diarrhoe). d: Die Zeit bis zur ersten Verbesserung ist definiert als Anzahl der Monate zwischen der ersten Dosis der Prüfmedikation und dem ersten Auftreten einer Verbesserung der Diarrhoe. e: Die Schätzung basiert auf der Kaplan-Meier Methode. Das 95%-KI wurde mittels Brookmeyer und Crowley Methode berechnet. f: Die Dauer der Verbesserung ist definiert als Anzahl der Monate zwischen dem ersten Auftreten einer Verbesserung bis zu jeglicher schrittweiser Verschlechterung der Diarrhoe. g: Die Zeit bis zur ersten Verschlechterung ist definiert als Anzahl der Monate zwischen der ersten Dosis der Prüfmedikation und dem ersten Auftreten einer Verschlechterung der Diarrhoe. Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben.			

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_bd_tte_mtc_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

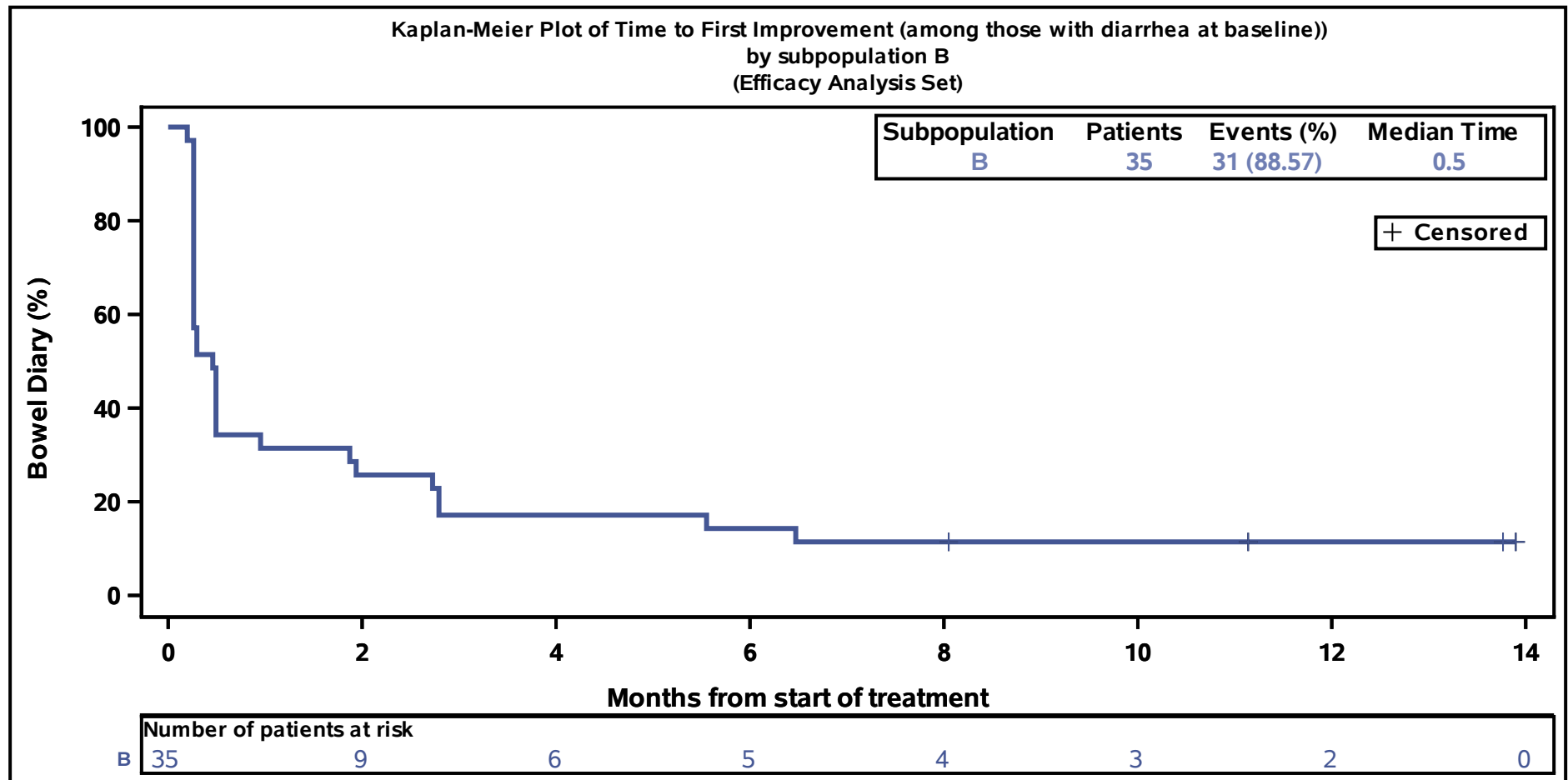
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Output location:

/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T035_sp_bd_tte_mtc_eff_mod_for_PDF.rtf

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* TTFI = Time-to-First Improvement

Only patients who had diarrhoea at Baseline have been included.

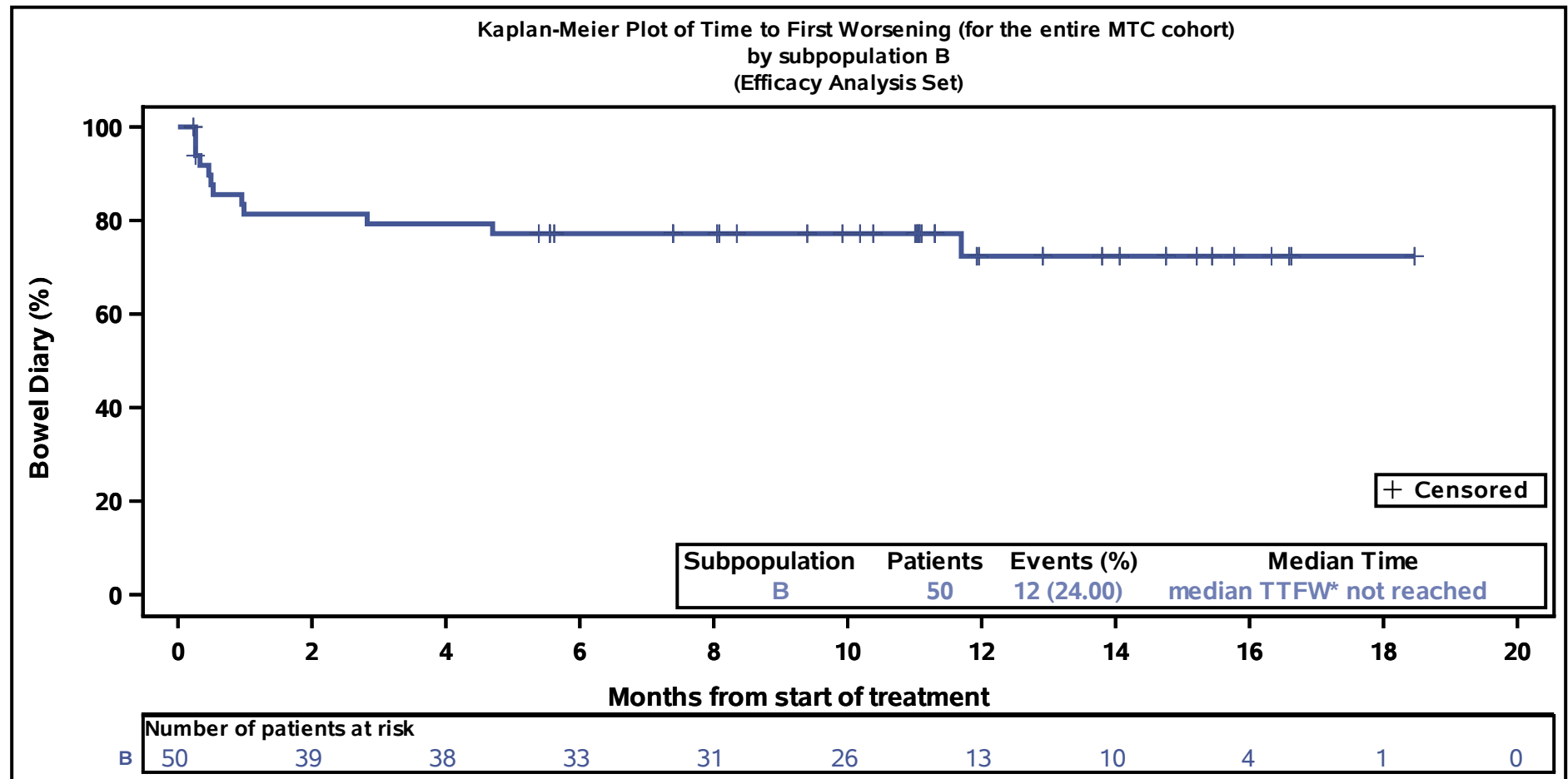
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Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F90_tti_mtc_eff.rtf

Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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* TTFW = Time-to-First Worsening

All patients included because patients without diarrhoea at Baseline can develop diarrhoea at a later visit.

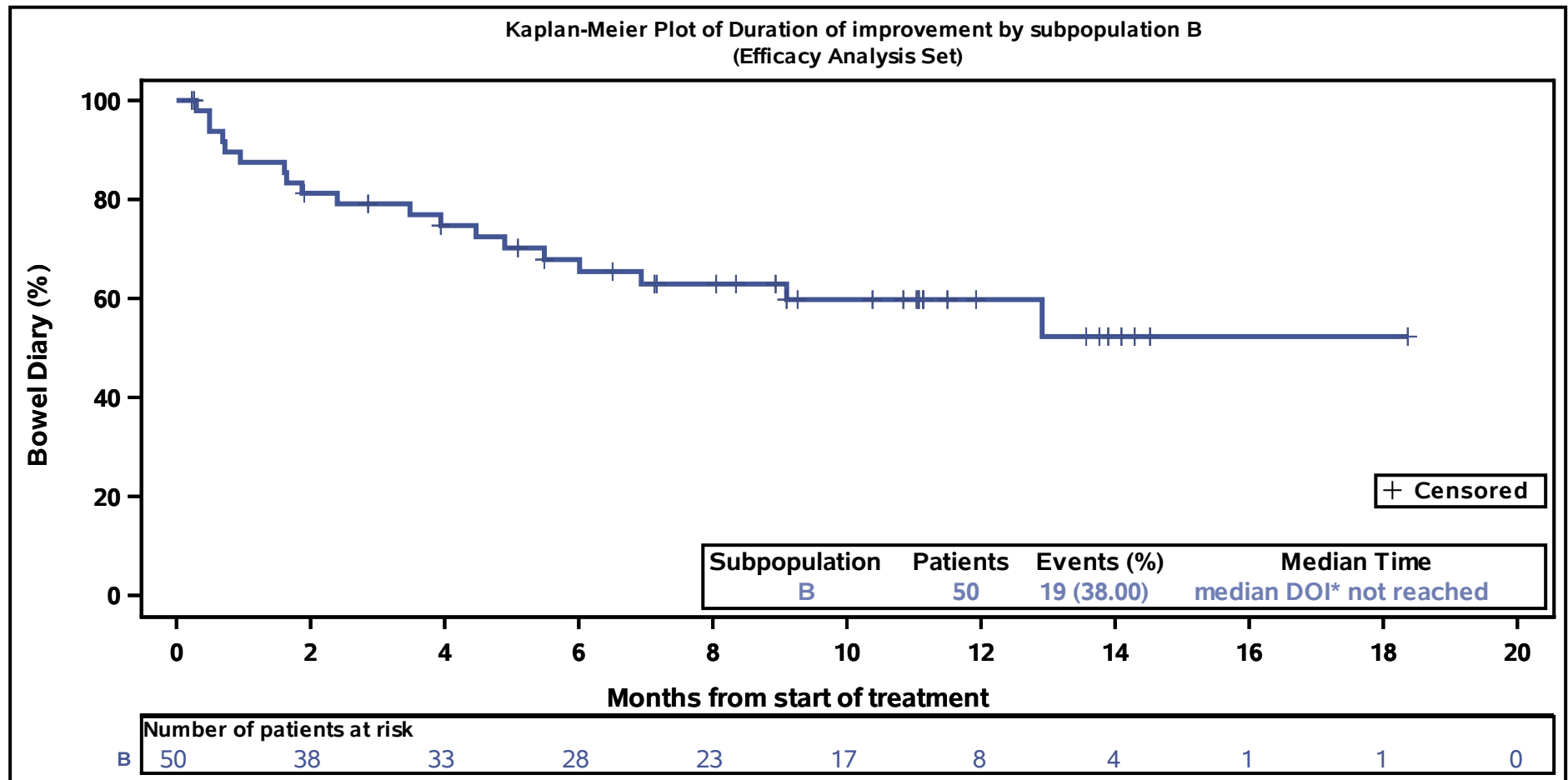
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Output Location: //lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F91_ttw_mtc_eff.rtf

Data Location: //lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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* DOI = Duration of Improvement

Only patients who had diarrhoea at Baseline have been included.

Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_bd_km_b16.sas

Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F92_doi_mtc_eff.rtf

Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Tabelle 005: Behandlungsdauer – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel
(Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Safety Analysis Set

	Selpercatinib Subpopulation B – MTC (N=153)
Behandlungsdauer in Monaten	
Anzahl der Patienten	153
Mittelwert (SD)	13,3 (7,84)
Median (min–max)	12,42 (0,20-33,31)
max: Maximum; min: Minimum; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; RET: Rearranged during Transfection; SD: Standardabweichung.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sptte_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T005_tte_mtc.rtf

Tabelle 021: Ergebnisse für den Endpunkt jegliche unerwünschte Ereignisse aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mutation; Datenschnitt: 30. März 2020) - Safety Population

Endpunkt	Selpercatinib
	Subpopulation B - MTC (N=153)
Jegliche unerwünschte Ereignisse, n (%)	
Jegliche unerwünschte Ereignisse	
Jeglicher Schweregrad	153 (100)
CTCAE-Grad < 3	55 (35,9)
CTCAE-Grad $\geq$ 3	98 (64,1)
CTCAE-Grad 3	78 (51,0)
CTCAE-Grad 4	13 (8,5)
CTCAE-Grad 5	7 (4,6)
Therapiebezogene ^a unerwünschte Ereignisse	139 (90,8)
Therapiebezogene ^a unerwünschte Ereignisse vom CTCAE-Grad $\geq$ 3	37 (24,2)
Schwerwiegende unerwünschte Ereignisse	57 (37,3)
Therapiebezogene ^a schwerwiegende unerwünschte Ereignisse	10 (6,5)
Behandlungsabbruch aufgrund unerwünschter Ereignisse	10 (6,5)
CTCAE: Common Terminology Criteria for Adverse Events; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Safety Analysis Set); RET: Rearranged during Transfection. a: In potenziellem Zusammenhang mit der Prüfmedikation stehende unerwünschte Ereignisse; die Einstufung erfolgte durch den Prüfarzt.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_anyae_mtc_ge.sas

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared

Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

/lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T021_sp_anyae_sf_modified_for_PDF.rtf

Tabelle 021.10: Ergebnisse für den Endpunkt unerwünschte Ereignisse von besonderem Interesse aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: MTC mit RET-Mitigation; Datenschnitt: 30. März 2020) - Safety Population

Endpunkt	Selpercatinib
	Subpopulation B - MTC (N=153)
Unerwünschte Ereignisse von besonderem Interesse, n (%)	
Erhöhung von AST und ALT	
Jeglicher Schweregrad	41 (26,8)
CTCAE-Grad < 3	34 (22,2)
CTCAE-Grad $\geq$ 3	7 (4,6)
Schwerwiegend	1 (0,7)
Behandlungsabbruch	1 (0,7)
Überempfindlichkeit	
Jeglicher Schweregrad	1 (0,7)
CTCAE-Grad < 3	0
CTCAE-Grad $\geq$ 3	1 (0,7)
Schwerwiegend	0
Behandlungsabbruch	0
Hypertonie	
Jeglicher Schweregrad	57 (37,3)
CTCAE-Grad < 3	29 (19,0)
CTCAE-Grad $\geq$ 3	28 (18,3)
Schwerwiegend	3 (2,0)
Behandlungsabbruch	1 (0,7)
Thrombozytopenie	
Jeglicher Schweregrad	10 (6,5)
CTCAE-Grad < 3	10 (6,5)
CTCAE-Grad $\geq$ 3	0
Schwerwiegend	0
Behandlungsabbruch	0
Verlängerung der QT-Zeit	
Jeglicher Schweregrad	32 (20,9)
CTCAE-Grad < 3	27 (17,6)
CTCAE-Grad $\geq$ 3	5 (3,3)
Schwerwiegend	0
Behandlungsabbruch	0
ALT: Alanin-Aminotransferase; AST: Aspartat-Aminotransferase; CTCAE: Common Terminology Criteria for Adverse Events; MKI: Multikinase-Inhibitor; MTC: medulläres Schilddrüsenkarzinom; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Safety Analysis Set); RET: Rearranged during Transfection.	

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_aes_i_mtc_ge.sas

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Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Output location:

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Table 14.4.2.5
 Proportions of patients with AE by SOC (cut-off: $\geq 10\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

System Organ Class	B
	(N=153) n (%)
Patients with TEAEs	153 (100)
Gastrointestinal disorders	127 (83.0)
Investigations	112 (73.2)
General disorders and administration site conditions	107 (69.9)
Metabolism and nutrition disorders	97 (63.4)
Nervous system disorders	92 (60.1)
Infections and infestations	85 (55.6)
Respiratory, thoracic and mediastinal disorders	84 (54.9)
Skin and subcutaneous tissue disorders	84 (54.9)
Musculoskeletal and connective tissue disorders	81 (52.9)
Vascular disorders	69 (45.1)
Blood and lymphatic system disorders	49 (32.0)
Renal and urinary disorders	49 (32.0)
Psychiatric disorders	42 (27.5)
Eye disorders	38 (24.8)
Injury, poisoning and procedural complications	32 (20.9)
Reproductive system and breast disorders	27 (17.6)
Cardiac disorders	25 (16.3)
Endocrine disorders	20 (13.1)

Percentage is calculated using the number of patients in the column heading as the denominator.
 Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
 Reported adverse event terms were coded using MedDRA (version 21.0).
 Adverse events are sorted in descending frequency.
 Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_aespt_en.sas
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Table 14.4.2.11
 Proportions of patients with AE by PT (cut-off: $\geq 10\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

Preferred Term	B (N=153)	
	n	(%)
Patients with TEAEs	153	(100)
Hypertension	55	(35.9)
Diarrhoea	53	(34.6)
Oedema peripheral	49	(32.0)
Constipation	47	(30.7)
Fatigue	46	(30.1)
Dry mouth	44	(28.8)
Abdominal pain	43	(28.1)
Nausea	43	(28.1)
Headache	39	(25.5)
Aspartate aminotransferase increased	36	(23.5)
Alanine aminotransferase increased	33	(21.6)
Blood creatinine increased	33	(21.6)
Electrocardiogram QT prolonged	32	(20.9)
Dyspnoea	30	(19.6)
Arthralgia	28	(18.3)
Vomiting	28	(18.3)
Hypocalcaemia	27	(17.6)
Hyperphosphataemia	26	(17.0)
Weight increased	24	(15.7)
Cough	23	(15.0)
Decreased appetite	23	(15.0)

Percentage is calculated using the number of patients in the column heading as the denominator.
 Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
 Reported adverse event terms were coded using MedDRA (version 21.0).
 Adverse events are sorted in descending frequency.
 Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aespt_en.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.11_sf.rtf

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Table 14.4.2.11
 Proportions of patients with AE by PT (cut-off: $\geq 10\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

Preferred Term	B (N=153)	
	n	(%)
Urinary tract infection	23	(15.0)
Back pain	21	(13.7)
Lymphopenia	21	(13.7)
Rash	21	(13.7)
Hyperkalaemia	19	(12.4)
Abdominal distension	18	(11.8)
Blood alkaline phosphatase increased	18	(11.8)
Dry skin	18	(11.8)
Gastrooesophageal reflux disease	18	(11.8)
Hypoalbuminaemia	18	(11.8)
Weight decreased	18	(11.8)
Hypomagnesaemia	17	(11.1)
Upper respiratory tract infection	17	(11.1)
Dizziness	16	(10.5)
Dysphagia	16	(10.5)
Insomnia	16	(10.5)
Neck pain	16	(10.5)

Percentage is calculated using the number of patients in the column heading as the denominator.
 Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
 Reported adverse event terms were coded using MedDRA (version 21.0).
 Adverse events are sorted in descending frequency.
 Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aespt_en.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
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Table 14.4.2.17
 Proportions of patients with severe AE by SOC (cut-off: $\geq 5\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

Analysis Set System Organ Class	-----Maximum Severity (n, %)-----			
	Grade 3	Grade 4	Grade 5	Total

Overall Safety (N=153)				
Any SOC	78 (51.0)	13 (8.5)	7 (4.6)	98 (64.1)
Vascular disorders	30 (19.6)	1 (0.7)	0 (0.0)	31 (20.3)
Metabolism and nutrition disorders	26 (17.0)	3 (2.0)	0 (0.0)	29 (19.0)
Investigations	21 (13.7)	5 (3.3)	0 (0.0)	26 (17.0)
Infections and infestations	17 (11.1)	2 (1.3)	1 (0.7)	20 (13.1)
Gastrointestinal disorders	14 (9.2)	0 (0.0)	0 (0.0)	14 (9.2)
Respiratory, thoracic and mediastinal disorders	7 (4.6)	4 (2.6)	1 (0.7)	12 (7.8)
Nervous system disorders	10 (6.5)	0 (0.0)	0 (0.0)	10 (6.5)
Blood and lymphatic system disorders	7 (4.6)	2 (1.3)	0 (0.0)	9 (5.9)

Percentage is calculated based on the number of patients in the corresponding analysis set (N) as the denominator.
 Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
 Patients with multiple severity ratings for a given AE are counted once under the maximum severity.
 Reported adverse event terms were coded using MedDRA (version 21.0).
 Severity grade assignment based on CTCAE (v4.03): Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), Grade 4 (life-threatening/debilitating), Grade 5 (fatal). Adverse events are sorted in descending frequency overall.
 Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aespt_grd_en.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
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 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.17_sf.rtf

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Table 14.4.2.23
 Proportions of patients with severe AE by PT (cut-off: $\geq 5\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

Analysis Set Preferred Term	-----Maximum Severity (n, %)-----			
	Grade 3	Grade 4	Grade 5	Total

Overall Safety (N=153)				
Any PT	78 (51.0)	13 (8.5)	7 (4.6)	98 (64.1)
Hypertension	26 (17.0)	1 (0.7)	0 (0.0)	27 (17.6)
Lymphopenia	6 (3.9)	2 (1.3)	0 (0.0)	8 (5.2)
Weight increased	8 (5.2)	0 (0.0)	0 (0.0)	8 (5.2)

Percentage is calculated based on the number of patients in the corresponding analysis set (N) as the denominator.
 Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
 Patients with multiple severity ratings for a given AE are counted once under the maximum severity.
 Reported adverse event terms were coded using MedDRA (version 21.0).
 Severity grade assignment based on CTCAE (v4.03): Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), Grade 4 (life-threatening/debilitating), Grade 5 (fatal). Adverse events are sorted in descending frequency overall.
 Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aespt_grd_en.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
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Table 14.4.2.29
 Proportions of patients with serious AE by SOC (cut-off: $\geq 5\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

System Organ Class	B
	(N=153) n (%)
Patients with TEAEs	57 (37.3)
Infections and infestations	18 (11.8)
Gastrointestinal disorders	12 (7.8)
Metabolism and nutrition disorders	9 (5.9)
Respiratory, thoracic and mediastinal disorders	9 (5.9)

Percentage is calculated using the number of patients in the column heading as the denominator.
 Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
 Reported adverse event terms were coded using MedDRA (version 21.0).
 Adverse events are sorted in descending frequency.
 Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aespt_en.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.29_sf.rtf

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Table 14.4.2.35
 Proportions of patients with AE by SOC (cut-off: ≥ 10 patients and $\geq 1\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

System Organ Class	B
	(N=153) n (%)
Patients with TEAEs	153 (100)
Gastrointestinal disorders	127 (83.0)
Investigations	112 (73.2)
General disorders and administration site conditions	107 (69.9)
Metabolism and nutrition disorders	97 (63.4)
Nervous system disorders	92 (60.1)
Infections and infestations	85 (55.6)
Respiratory, thoracic and mediastinal disorders	84 (54.9)
Skin and subcutaneous tissue disorders	84 (54.9)
Musculoskeletal and connective tissue disorders	81 (52.9)
Vascular disorders	69 (45.1)
Blood and lymphatic system disorders	49 (32.0)
Renal and urinary disorders	49 (32.0)
Psychiatric disorders	42 (27.5)
Eye disorders	38 (24.8)
Injury, poisoning and procedural complications	32 (20.9)
Reproductive system and breast disorders	27 (17.6)
Cardiac disorders	25 (16.3)
Endocrine disorders	20 (13.1)

Percentage is calculated using the number of patients in the column heading as the denominator.
 Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
 Reported adverse event terms were coded using MedDRA (version 21.0).
 Adverse events are sorted in descending frequency.
 Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_aespt_en.sas
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
 Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
 Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.35_sf.rtf

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Table 14.4.2.37
 Proportions of patients with AE by SOC leading to treatment discontinuation
 Safety Analysis Set
 by Subpopulation

System Organ Class	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
	n (%)	n (%)	n (%)	n (%)
Patients with TEAEs	6 (7.1)	13 (7.5)	10 (6.5)	2 (9.5)
Blood and lymphatic system disorders	0 (0.0)	1 (0.6)	0 (0.0)	1 (4.8)
Cardiac disorders	1 (1.2)	2 (1.2)	1 (0.7)	0 (0.0)
Gastrointestinal disorders	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
General disorders and administration site conditions	0 (0.0)	5 (2.9)	0 (0.0)	0 (0.0)
Immune system disorders	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
Infections and infestations	2 (2.4)	1 (0.6)	3 (2.0)	1 (4.8)
Investigations	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Nervous system disorders	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
Renal and urinary disorders	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	2 (2.4)	1 (0.6)	0 (0.0)	0 (0.0)
Skin and subcutaneous tissue disorders	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
Vascular disorders	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

Percentage is calculated using the number of patients in the column heading as the denominator.
 Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
 Reported adverse event terms were coded using MedDRA (version 21.0).
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Table 14.4.2.38
 Proportions of patients with AE by PT leading to treatment discontinuation
 Safety Analysis Set
 by Subpopulation

Preferred Term	A1 (N=85) n (%)	A2 (N=173) n (%)	B (N=153) n (%)	C (N=21) n (%)
Patients with TEAEs	6 (7.1)	13 (7.5)	10 (6.5)	2 (9.5)
Abdominal pain	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Alanine aminotransferase increased	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
Aspartate aminotransferase increased	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Bacteraemia	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
Blood bilirubin increased	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Cardiac failure	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Cardio-respiratory arrest	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Cerebral haemorrhage	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
Cerebral infarction	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Drug eruption	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
Drug hypersensitivity	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Erythema	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Fatigue	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
Febrile neutropenia	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
Gait disturbance	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Hypersensitivity	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Hypoxia	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Meningitis bacterial	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
Multiple organ dysfunction syndrome	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Pericardial effusion	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
Pleurocutaneous fistula	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)

Percentage is calculated using the number of patients in the column heading as the denominator.

Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.

Reported adverse event terms were coded using MedDRA (version21.0).

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Table 14.4.2.38
 Proportions of patients with AE by PT leading to treatment discontinuation
 Safety Analysis Set
 by Subpopulation

Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
	n (%)	n (%)	n (%)	n (%)
Pneumotosis intestinalis	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Pneumonia	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Proteinuria	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Pulmonary embolism	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
Sensation of foreign body	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Sepsis	0 (0.0)	1 (0.6)	1 (0.7)	1 (4.8)
Septic shock	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Skin ulcer	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Squamous cell carcinoma	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Tachycardia	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Thrombocytopenia	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Transient ischaemic attack	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Urinary retention	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

Percentage is calculated using the number of patients in the column heading as the denominator.
 Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
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Table 14.4.2.43
 Proportions of patients with serious AE by PT (cut-off: $\geq 5\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

Preferred Term	B
	(N=153) n (%)
Patients with TEAEs	57 (37.3)

Percentage is calculated using the number of patients in the column heading as the denominator.
 Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
 Reported adverse event terms were coded using MedDRA (version 21.0).
 Adverse events are sorted in descending frequency.
 Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aespt_en.sas
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Table 14.4.2.49
 Proportions of patients with AE by PT (cut-off: ≥ 10 patients and $\geq 1\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

Preferred Term	B (N=153)	
	n	(%)
Patients with TEAEs	153	(100)
Hypertension	55	(35.9)
Diarrhoea	53	(34.6)
Oedema peripheral	49	(32.0)
Constipation	47	(30.7)
Fatigue	46	(30.1)
Dry mouth	44	(28.8)
Abdominal pain	43	(28.1)
Nausea	43	(28.1)
Headache	39	(25.5)
Aspartate aminotransferase increased	36	(23.5)
Alanine aminotransferase increased	33	(21.6)
Blood creatinine increased	33	(21.6)
Electrocardiogram QT prolonged	32	(20.9)
Dyspnoea	30	(19.6)
Arthralgia	28	(18.3)
Vomiting	28	(18.3)
Hypocalcaemia	27	(17.6)
Hyperphosphataemia	26	(17.0)
Weight increased	24	(15.7)
Cough	23	(15.0)
Decreased appetite	23	(15.0)

Percentage is calculated using the number of patients in the column heading as the denominator.
 Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
 Reported adverse event terms were coded using MedDRA (version 21.0).
 Adverse events are sorted in descending frequency.
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Table 14.4.2.49
 Proportions of patients with AE by PT (cut-off: ≥ 10 patients and $\geq 1\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

Preferred Term	B	
	n	(%)
Urinary tract infection	23	(15.0)
Back pain	21	(13.7)
Lymphopenia	21	(13.7)
Rash	21	(13.7)
Hyperkalaemia	19	(12.4)
Abdominal distension	18	(11.8)
Blood alkaline phosphatase increased	18	(11.8)
Dry skin	18	(11.8)
Gastrooesophageal reflux disease	18	(11.8)
Hypoalbuminaemia	18	(11.8)
Weight decreased	18	(11.8)
Hypomagnesaemia	17	(11.1)
Upper respiratory tract infection	17	(11.1)
Dizziness	16	(10.5)
Dysphagia	16	(10.5)
Insomnia	16	(10.5)
Neck pain	16	(10.5)
Hyponatraemia	15	(9.8)
Myalgia	15	(9.8)
Paraesthesia	15	(9.8)
Anxiety	14	(9.2)
Asthenia	14	(9.2)
Rash maculo-papular	14	(9.2)

Percentage is calculated using the number of patients in the column heading as the denominator.

Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.

Reported adverse event terms were coded using MedDRA (version 21.0).

Adverse events are sorted in descending frequency.

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Table 14.4.2.49
 Proportions of patients with AE by PT (cut-off: ≥ 10 patients and $\geq 1\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

Preferred Term	B (N=153)	
	n	(%)
Acute kidney injury	13	(8.5)
Anaemia	13	(8.5)
Blood bilirubin increased	13	(8.5)
Erectile dysfunction	13	(8.5)
Leukopenia	13	(8.5)
Pyrexia	13	(8.5)
Dyspepsia	12	(7.8)
Dysphonia	12	(7.8)
Hypokalaemia	12	(7.8)
Hypothyroidism	12	(7.8)
Neuropathy peripheral	11	(7.2)
Oropharyngeal pain	11	(7.2)
Proteinuria	11	(7.2)
Face oedema	10	(6.5)
Fall	10	(6.5)
Hyperglycaemia	10	(6.5)
Nasal congestion	10	(6.5)
Thrombocytopenia	10	(6.5)

Percentage is calculated using the number of patients in the column heading as the denominator.

Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.

Reported adverse event terms were coded using MedDRA (version 21.0).

Adverse events are sorted in descending frequency.

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Table 14.4.2.54
 Proportions of patients with AE by SOC and PT (cut-off: $\geq 10\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

System Organ Class Preferred Term	B (N=153)	
	n	(%)
Patients with TEAEs	153	(100)
Gastrointestinal disorders	127	(83.0)
Diarrhoea	53	(34.6)
Constipation	47	(30.7)
Dry mouth	44	(28.8)
Abdominal pain	43	(28.1)
Nausea	43	(28.1)
Vomiting	28	(18.3)
Abdominal distension	18	(11.8)
Gastroesophageal reflux disease	18	(11.8)
Dysphagia	16	(10.5)
Investigations	112	(73.2)
Aspartate aminotransferase increased	36	(23.5)
Alanine aminotransferase increased	33	(21.6)
Blood creatinine increased	33	(21.6)
Electrocardiogram QT prolonged	32	(20.9)
Weight increased	24	(15.7)
Blood alkaline phosphatase increased	18	(11.8)
Weight decreased	18	(11.8)
General disorders and administration site conditions	107	(69.9)
Oedema peripheral	49	(32.0)
Fatigue	46	(30.1)

Percentage is calculated using the number of patients in the column heading as the denominator.
 Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
 Reported adverse event terms were coded using MedDRA (version 21.0).
 Adverse events are sorted in descending frequency.
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Table 14.4.2.54
 Proportions of patients with AE by SOC and PT (cut-off: $\geq 10\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

System Organ Class Preferred Term	B (N=153)
	n (%)
Metabolism and nutrition disorders	97 (63.4)
Hypocalcaemia	27 (17.6)
Hyperphosphataemia	26 (17.0)
Decreased appetite	23 (15.0)
Hyperkalaemia	19 (12.4)
Hypoalbuminaemia	18 (11.8)
Hypomagnesaemia	17 (11.1)
Nervous system disorders	92 (60.1)
Headache	39 (25.5)
Dizziness	16 (10.5)
Infections and infestations	85 (55.6)
Urinary tract infection	23 (15.0)
Upper respiratory tract infection	17 (11.1)
Respiratory, thoracic and mediastinal disorders	84 (54.9)
Dyspnoea	30 (19.6)
Cough	23 (15.0)
Skin and subcutaneous tissue disorders	84 (54.9)
Rash	21 (13.7)
Dry skin	18 (11.8)
Musculoskeletal and connective tissue disorders	81 (52.9)
Arthralgia	28 (18.3)
Back pain	21 (13.7)
Neck pain	16 (10.5)

Percentage is calculated using the number of patients in the column heading as the denominator.

Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.

Reported adverse event terms were coded using MedDRA (version 21.0).

Adverse events are sorted in descending frequency.

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Table 14.4.2.54
 Proportions of patients with AE by SOC and PT (cut-off: $\geq 10\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

System Organ Class Preferred Term	B (N=153)	
	n	(%)
Vascular disorders	69	(45.1)
Hypertension	55	(35.9)
Blood and lymphatic system disorders	49	(32.0)
Lymphopenia	21	(13.7)
Renal and urinary disorders	49	(32.0)
Psychiatric disorders	42	(27.5)
Insomnia	16	(10.5)
Eye disorders	38	(24.8)
Injury, poisoning and procedural complications	32	(20.9)
Reproductive system and breast disorders	27	(17.6)
Cardiac disorders	25	(16.3)
Endocrine disorders	20	(13.1)

Percentage is calculated using the number of patients in the column heading as the denominator.
 Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
 Reported adverse event terms were coded using MedDRA (version 21.0).
 Adverse events are sorted in descending frequency.
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Table 14.4.2.60
 Proportions of patients with Severe AE (CTCAE grade $\geq$ 3) by SOC and PT (cut-off: $\geq$ 5% of patients)
 Safety Analysis Set
 by Subpopulation B

System Organ Class Preferred Term	B (N=153)	
	n	(%)
Patients with TEAEs	98	(64.1)
Vascular disorders	31	(20.3)
Hypertension	27	(17.6)
Metabolism and nutrition disorders	29	(19.0)
Investigations	26	(17.0)
Weight increased	8	(5.2)
Infections and infestations	20	(13.1)
Gastrointestinal disorders	14	(9.2)
Respiratory, thoracic and mediastinal disorders	12	(7.8)
Nervous system disorders	10	(6.5)
Blood and lymphatic system disorders	9	(5.9)
Lymphopenia	8	(5.2)

Percentage is calculated using the number of patients in the column heading as the denominator.
 Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
 Reported adverse event terms were coded using MedDRA (version21.0).
 Adverse events are sorted in descending frequency.
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Table 14.4.2.66
 Proportions of patients with Serious AE by SOC and PT (cut-off: $\geq 5\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

System Organ Class Preferred Term	B (N=153)	
	n	(%)
Patients with TEAEs	57	(37.3)
Infections and infestations	18	(11.8)
Gastrointestinal disorders	12	(7.8)
Metabolism and nutrition disorders	9	(5.9)
Respiratory, thoracic and mediastinal disorders	9	(5.9)

Percentage is calculated using the number of patients in the column heading as the denominator.
 Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
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Table 14.4.2.72
 Proportions of patients with AE by SOC and PT (cut-off: ≥ 10 patients and $\geq 1\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

System Organ Class Preferred Term	B (N=153)	
	n	(%)
Patients with TEAEs	153	(100)
Gastrointestinal disorders	127	(83.0)
Diarrhoea	53	(34.6)
Constipation	47	(30.7)
Dry mouth	44	(28.8)
Abdominal pain	43	(28.1)
Nausea	43	(28.1)
Vomiting	28	(18.3)
Abdominal distension	18	(11.8)
Gastroesophageal reflux disease	18	(11.8)
Dysphagia	16	(10.5)
Dyspepsia	12	(7.8)
Investigations	112	(73.2)
Aspartate aminotransferase increased	36	(23.5)
Alanine aminotransferase increased	33	(21.6)
Blood creatinine increased	33	(21.6)
Electrocardiogram QT prolonged	32	(20.9)
Weight increased	24	(15.7)
Blood alkaline phosphatase increased	18	(11.8)
Weight decreased	18	(11.8)
Blood bilirubin increased	13	(8.5)
General disorders and administration site conditions	107	(69.9)

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 Reported adverse event terms were coded using MedDRA (version21.0).
 Adverse events are sorted in descending frequency.
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Table 14.4.2.72
 Proportions of patients with AE by SOC and PT (cut-off: ≥ 10 patients and $\geq 1\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

System Organ Class Preferred Term	B (N=153)	
	n	(%)
Oedema peripheral	49	(32.0)
Fatigue	46	(30.1)
Asthenia	14	(9.2)
Pyrexia	13	(8.5)
Face oedema	10	(6.5)
Metabolism and nutrition disorders	97	(63.4)
Hypocalcaemia	27	(17.6)
Hyperphosphataemia	26	(17.0)
Decreased appetite	23	(15.0)
Hyperkalaemia	19	(12.4)
Hypoalbuminaemia	18	(11.8)
Hypomagnesaemia	17	(11.1)
Hyponatraemia	15	(9.8)
Hypokalaemia	12	(7.8)
Hyperglycaemia	10	(6.5)
Nervous system disorders	92	(60.1)
Headache	39	(25.5)
Dizziness	16	(10.5)
Paraesthesia	15	(9.8)
Neuropathy peripheral	11	(7.2)
Infections and infestations	85	(55.6)
Urinary tract infection	23	(15.0)
Upper respiratory tract infection	17	(11.1)

Percentage is calculated using the number of patients in the column heading as the denominator.

Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.

Reported adverse event terms were coded using MedDRA (version21.0).

Adverse events are sorted in descending frequency.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tf1/t_aesocpt_en.sas

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Table 14.4.2.72
 Proportions of patients with AE by SOC and PT (cut-off: ≥ 10 patients and $\geq 1\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

System Organ Class Preferred Term	B (N=153)	
	n	(%)
Respiratory, thoracic and mediastinal disorders	84	(54.9)
Dyspnoea	30	(19.6)
Cough	23	(15.0)
Dysphonia	12	(7.8)
Oropharyngeal pain	11	(7.2)
Nasal congestion	10	(6.5)
Skin and subcutaneous tissue disorders	84	(54.9)
Rash	21	(13.7)
Dry skin	18	(11.8)
Rash maculo-papular	14	(9.2)
Musculoskeletal and connective tissue disorders	81	(52.9)
Arthralgia	28	(18.3)
Back pain	21	(13.7)
Neck pain	16	(10.5)
Myalgia	15	(9.8)
Vascular disorders	69	(45.1)
Hypertension	55	(35.9)
Blood and lymphatic system disorders	49	(32.0)
Lymphopenia	21	(13.7)
Anaemia	13	(8.5)
Leukopenia	13	(8.5)
Thrombocytopenia	10	(6.5)
Renal and urinary disorders	49	(32.0)

Percentage is calculated using the number of patients in the column heading as the denominator.

Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.

Reported adverse event terms were coded using MedDRA (version 21.0).

Adverse events are sorted in descending frequency.

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Table 14.4.2.72
 Proportions of patients with AE by SOC and PT (cut-off: ≥ 10 patients and $\geq 1\%$ of patients)
 Safety Analysis Set
 by Subpopulation B

System Organ Class Preferred Term	B (N=153)	
	n	(%)
Acute kidney injury	13	(8.5)
Proteinuria	11	(7.2)
Psychiatric disorders	42	(27.5)
Insomnia	16	(10.5)
Anxiety	14	(9.2)
Eye disorders	38	(24.8)
Injury, poisoning and procedural complications	32	(20.9)
Fall	10	(6.5)
Reproductive system and breast disorders	27	(17.6)
Erectile dysfunction	13	(8.5)
Cardiac disorders	25	(16.3)
Endocrine disorders	20	(13.1)
Hypothyroidism	12	(7.8)

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Table 14.4.2.74
 Proportions of patients with AE leading to treatment discontinuation by SOC and PT
 Safety Analysis Set
 by Subpopulation

System Organ Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
	n (%)	n (%)	n (%)	n (%)
Patients with TEAEs	6 (7.1)	13 (7.5)	10 (6.5)	2 (9.5)
Blood and lymphatic system disorders	0 (0.0)	1 (0.6)	0 (0.0)	1 (4.8)
Febrile neutropenia	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
Thrombocytopenia	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Cardiac disorders	1 (1.2)	2 (1.2)	1 (0.7)	0 (0.0)
Cardiac failure	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Cardio-respiratory arrest	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Pericardial effusion	1 (1.2)	1 (0.6)	0 (0.0)	0 (0.0)
Tachycardia	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Gastrointestinal disorders	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)
Abdominal pain	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Pneumatosis intestinalis	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
General disorders and administration site conditions	0 (0.0)	5 (2.9)	0 (0.0)	0 (0.0)
Fatigue	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
Gait disturbance	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Multiple organ dysfunction syndrome	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Sensation of foreign body	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Immune system disorders	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
Drug hypersensitivity	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Hypersensitivity	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Infections and infestations	2 (2.4)	1 (0.6)	3 (2.0)	1 (4.8)
Bacteraemia	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
Meningitis bacterial	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)

Percentage is calculated using the number of patients in the column heading as the denominator.

Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.

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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.74_sf.rtf

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Table 14.4.2.74
 Proportions of patients with AE leading to treatment discontinuation by SOC and PT
 Safety Analysis Set
 by Subpopulation

System Organ Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
	n (%)	n (%)	n (%)	n (%)
Pneumonia	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Sepsis	0 (0.0)	1 (0.6)	1 (0.7)	1 (4.8)
Septic shock	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Investigations	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
Alanine aminotransferase increased	0 (0.0)	1 (0.6)	1 (0.7)	0 (0.0)
Aspartate aminotransferase increased	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Blood bilirubin increased	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Squamous cell carcinoma	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Nervous system disorders	1 (1.2)	2 (1.2)	0 (0.0)	0 (0.0)
Cerebral haemorrhage	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
Cerebral infarction	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Transient ischaemic attack	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Renal and urinary disorders	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
Proteinuria	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Urinary retention	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	2 (2.4)	1 (0.6)	0 (0.0)	0 (0.0)
Hypoxia	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Pleurocutaneous fistula	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
Pulmonary embolism	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
Skin and subcutaneous tissue disorders	1 (1.2)	1 (0.6)	1 (0.7)	0 (0.0)
Drug eruption	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
Erythema	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Skin ulcer	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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 Proportions of patients with AE leading to treatment discontinuation by SOC and PT
 Safety Analysis Set
 by Subpopulation

System Organ Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
	n (%)	n (%)	n (%)	n (%)
Vascular disorders	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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