Dossier zur Nutzenbewertung gemäß § 35a SGB V

Selpercatinib (Retsevmo®)

Lilly Deutschland GmbH

Modul 4A – Anhang 4-M1

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

Fortgeschrittenes NSCLC mit RET-Fusion nach vorheriger Therapie

Stand: 12.03.2021

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Merkmal	Selpercatinib Subpopulation A1 – NSCLC 2L (N=85)	Selpercatinib Subpopulation A2 – NSCLC 3L (N=173)
Demographische Charakteristika und Baseline Charakteristika		
Geschlecht, n (%)		
Männer	38 (44,7)	76 (43,9)
Frauen	47 (55,3)	97 (56,1)
Ethnische Zugehörigkeit, n (%)		
Weiß	42 (49,4)	75 (43,4)
Schwarz oder Afroamerikaner	7 (8,2)	5 (2,9)
Asiaten	33 (38,8)	87 (50,3)
Amerikanische Indianer oder Ureinwohner Alaskas	0 (0,0)	1 (0,6)
Ureinwohner Hawaiis oder andere pazifische Inselbewohner	0 (0,0)	0 (0,0)
Andere	2 (2,4)	4 (2,3)
Fehlend	1 (1,2)	1 (0,6)
Geografische Region, n (%)		
Nordamerika	44 (51,8)	74 (42,8)
Europa	10 (11,8)	23 (13,3)
Rest der Welt	31 (36,5)	76 (43,9)
Altersgruppen, n (%)		
18 bis < 45 Jahre	9 (10,6)	22 (12,7)
45 bis < 65 Jahre	50 (58,8)	85 (49,1)
65 bis < 75 Jahre	19 (22,4)	56 (32,4)
≥ 75 Jahre	7 (8,2)	10 (5,8)
Alter in Jahren		
Anzahl der Patienten	85	173
Mittelwert (SD)	59,7 (10,98)	58,9 (11,57)
Median (min–max)	61,0 (35-80)	61,0 (23-81)
ECOG Performance Status, n (%)		
0	32 (37,6)	59 (34,1)
1	51 (60,0)	108 (62,4)
2	2 (2,4)	6 (3,5)
Raucherhistorie, n (%)		
Nieraucher	58 (68,2)	118 (68,2)
Früherer Raucher	26 (30,6)	52 (30,1)
Raucher	1 (1,2)	3 (1,7)
Fehlend	0 (0,0)	0 (0,0)
Erkrankungshistorie		
Primäre Diagnose, n (%)		
Adenokarzinom	73 (85,9)	157 (90,8)
Großzelliges neuroendokrines Karzinom	3 (3,5)	0 (0,0)
Plattenepithelkarzinom	0 (0,0)	1 (0,6)

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/T001_bc_nsclc.rtf

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

Merkmal	Selpercatinib Subpopulation A1 – NSCLC 2L (N=85)	Selpercatinib Subpopulation A2 – NSCLC 3L (N=173)
Andere	1 (1,2)	0 (0,0)
Unbekannt	8 (9,4)	15 (8,7)
Krankheitsstadium bei der Erstdiagnose, n (%)		
I	1 (1,2)	2 (1,2)
II	0 (0,0)	3 (1,7)
III	2 (2,4)	12 (6,9)
IV	82 (96,5)	156 (90,2)
Zeit seit der Erstdiagnose in Monaten		
Anzahl der Patienten	85	173
Mittelwert (SD)	16,4 (20,51)	42,1 (34,96)
Median (min–max)	8,8 (2-128)	32,0 (3-194)
Metastasierte Erkrankung bei Baseline, n (%)		
Ja	84 (98,8)	167 (96,5)
Nein	1 (1,2)	6 (3,5)
Metastasen im zentralen Nervensystem (ZNS) bei Baselinea[a], n (%)		
Ja	31 (36,5)	55 (31,8)
Nein	54 (63,5)	118 (68,2)
Vortherapien		
Vorherige systemische Therapie, n (%)		
Ja	85 (100,0)	173 (100,0)
Nein	0 (0,0)	0 (0,0)
Art der vorherigen systemischen Therapie[b], n (%)		
Multikinase-Inhibitoren (MKI)	4 (4,7)	76 (43,9)
- Cabozantinib	1 (1,2)	27 (15,6)
- Vandetanib	1 (1,2)	12 (6,9)
- Sorafenib	0 (0,0)	0 (0,0)
- Lenvatinib	0 (0,0)	9 (5,2)
- Andere MKI	2 (2,4)	50 (28,9)
Chemotherapie	71 (83,5)	169 (97,7)
- Platinhaltige Chemotherapie	71 (83,5)	168 (97,1)
- Taxanhaltige Chemotherapie	4 (4,7)	80 (46,2)
- Andere Chemotherapien	0 (0,0)	0 (0,0)
PD1/PD-L1 Inhibitoren	38 (44,7)	113 (65,3)
Selektive RET Inhibitoren	0 (0,0)	2 (1,2)
Andere systemische Therapie	19 (22,4)	90 (52,0)
Anzahl der vorherigen systemischen Therapien, n (%)		
0	0 (0,0)	0 (0,0)
1-2	85 (100,0)	64 (37,0)
3 oder mehr	0 (0,0)	109 (63,0)

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/T001_bc_nsclc.rtf

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

Merkmal	Selpercatinib Subpopulation A1 – NSCLC 2L (N=85)	Selpercatinib Subpopulation A2 – NSCLC 3L (N=173)
Anzahl der vorherigen systemischen Therapien		
Anzahl der Patienten	85	173
Mittelwert (SD)	1,0 (0,00)	3,5 (1,93)
Median (min–max)	1,0 (1-1)	3,0 (2-15)
Vorherige Strahlentherapie, n (%)		
Ja	39 (45,9)	96 (55,5)
Nein	46 (54,1)	77 (44,5)
Vorherige Krebsbedingte Operation, n (%)		
Ja	33 (38,8)	80 (46,2)
Nein	52 (61,2)	93 (53,8)
RET-Alterationsstatus		
Art der RET-Alteration, n (%)		
Fusion	85 (100,0)	173 (100,0)
- KIF5B	58 (68,2)	103 (59,5)
- CCDC6	19 (22,4)	36 (20,8)
- NCOA4	1 (1,2)	5 (2,9)
- Andere	3 (3,5)	13 (7,5)
- Unbekannt	4 (4,7)	16 (9,2)
Mutation	0 (0,0)	0 (0,0)
- M918T	0 (0,0)	0 (0,0)
- V804 M/L	0 (0,0)	0 (0,0)
- Extrazelluläre Cystein Mutation	0 (0,0)	0 (0,0)
- Andere	0 (0,0)	0 (0,0)
Andere	0 (0,0)	0 (0,0)
Methode zur Identifizierung der vorliegenden RET-Alteration, n (%)		
Next-Generation-Sequencing (NGS) mit Tumormaterial	70 (82,4)	149 (86,1)
Next-Generation-Sequencing (NGS) mit Blut oder Plasma	10 (11,8)	13 (7,5)
PCR	1 (1,2)	4 (2,3)
FISH	3 (3,5)	7 (4,0)
Andere	1 (1,2)	0 (0,0)
Krankheitscharakteristika zu Baseline		
Messbare Erkrankung[c], n (%)		
Ja	85 (100,0)	172 (99,4)
Nein	0 (0,0)	1 (0,6)
Tumorlast in mm[d]		
Anzahl der Patienten	85	172
Mittelwert (SD)	60,0 (49,72)	72,3 (52,00)

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/T001_bc_nsclc.rtf

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

Merkmal	Selpercatinib Subpopulation A1 – NSCLC 2L (N=85)	Selpercatinib Subpopulation A2 – NSCLC 3L (N=173)
Median (min–max)	44,0 (10-250)	58,9 (10-297)

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; 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; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NCOA4: Nuclear Receptor Coactivator 4; NGS: Next-Generation-Sequencing; NSCLC: nicht-kleinzelliges Lungenkarzinom; PCR: Polymerase-Kettenreaktion; PD1: Programmed Cell Death Protein 1; PD-L1: Programmed Cell Death Ligand 1; RET: Rearranged during Transfection; SD: Standardabweichung; T: Threonin; USA: United States of America; 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 Prüfärzten 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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Tabelle 001: Charakterisierung der Studienpopulation – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Merkmal	Selpercatinib Subpopulation A1 – NSCLC 2L (N=78)	Selpercatinib Subpopulation A2 – NSCLC 3L (N=158)
Demographische Charakteristika und Baseline Charakteristika		
Geschlecht, n (%)		
Männer	35 (44,9)	70 (44,3)
Frauen	43 (55,1)	88 (55,7)
Ethnische Zugehörigkeit, n (%)		
Weiß	39 (50,0)	73 (46,2)
Schwarz oder Afroamerikaner	7 (9,0)	5 (3,2)
Asiaten	29 (37,2)	74 (46,8)
Amerikanische Indianer oder Ureinwohner Alaskas	0 (0,0)	1 (0,6)
Ureinwohner Hawaiis oder andere pazifische Inselbewohner	0 (0,0)	0 (0,0)
Andere	2 (2,6)	4 (2,5)
Fehlend	1 (1,3)	1 (0,6)
Geografische Region, n (%)		
Nordamerika	43 (55,1)	72 (45,6)
Europa	8 (10,3)	22 (13,9)
Rest der Welt	27 (34,6)	64 (40,5)
Altersgruppen, n (%)		
18 bis < 45 Jahre	9 (11,5)	21 (13,3)
45 bis < 65 Jahre	46 (59,0)	76 (48,1)
65 bis < 75 Jahre	16 (20,5)	51 (32,3)
≥ 75 Jahre	7 (9,0)	10 (6,3)
Alter in Jahren		
Anzahl der Patienten	78	158
Mittelwert (SD)	59,5 (11,24)	59,0 (11,64)
Median (min–max)	60,5 (35-80)	61,0 (23-81)
ECOG Performance Status, n (%)		
0	29 (37,2)	55 (34,8)
1	47 (60,3)	99 (62,7)
2	2 (2,6)	4 (2,5)
Raucherhistorie, n (%)		
Nieraucher	53 (67,9)	110 (69,6)
Früherer Raucher	24 (30,8)	45 (28,5)
Raucher	1 (1,3)	3 (1,9)
Fehlend	0 (0,0)	0 (0,0)
Erkrankungshistorie		
Primäre Diagnose, n (%)		
Adenokarzinom	66 (84,6)	144 (91,1)
Großzelliges neuroendokrines Karzinom	3 (3,8)	0 (0,0)
Plattenepithelkarzinom	0 (0,0)	1 (0,6)

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/T001_bc_nsclc.rtf

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

Merkmal	Selpercatinib Subpopulation A1 – NSCLC 2L (N=78)	Selpercatinib Subpopulation A2 – NSCLC 3L (N=158)
Andere	1 (1,3)	0 (0,0)
Unbekannt	8 (10,3)	13 (8,2)
Krankheitsstadium bei der Erstdiagnose, n (%)		
I	1 (1,3)	2 (1,3)
II	0 (0,0)	3 (1,9)
III	2 (2,6)	8 (5,1)
IV	75 (96,2)	145 (91,8)
Zeit seit der Erstdiagnose in Monaten		
Anzahl der Patienten	78	158
Mittelwert (SD)	16,3 (20,21)	41,9 (33,36)
Median (min–max)	8,8 (2-128)	32,2 (3-165)
Metastasierte Erkrankung bei Baseline, n (%)		
Ja	78 (100,0)	153 (96,8)
Nein	0 (0,0)	5 (3,2)
Metastasen im zentralen Nervensystem (ZNS) bei Baselinea[a], n (%)		
Ja	30 (38,5)	52 (32,9)
Nein	48 (61,5)	106 (67,1)
Vortherapien		
Vorherige systemische Therapie, n (%)		
Ja	78 (100,0)	158 (100,0)
Nein	0 (0,0)	0 (0,0)
Art der vorherigen systemischen Therapie[b], n (%)		
Multikinase-Inhibitoren (MKI)	4 (5,1)	74 (46,8)
- Cabozantinib	1 (1,3)	26 (16,5)
- Vandetanib	1 (1,3)	12 (7,6)
- Sorafenib	0 (0,0)	0 (0,0)
- Lenvatinib	0 (0,0)	9 (5,7)
- Andere MKI	2 (2,6)	48 (30,4)
Chemotherapie	65 (83,3)	154 (97,5)
- Platinhaltige Chemotherapie	65 (83,3)	153 (96,8)
- Taxanhaltige Chemotherapie	3 (3,8)	71 (44,9)
- Andere Chemotherapien	0 (0,0)	0 (0,0)
PD1/PD-L1 Inhibitoren	32 (41,0)	99 (62,7)
Selektive RET Inhibitoren	0 (0,0)	1 (0,6)
Andere systemische Therapie	18 (23,1)	84 (53,2)
Anzahl der vorherigen systemischen Therapien, n (%)		
0	0 (0,0)	0 (0,0)
1-2	78 (100,0)	61 (38,6)
3 oder mehr	0 (0,0)	97 (61,4)

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/T001_bc_nsclc.rtf

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

Merkmal	Selpercatinib Subpopulation A1 – NSCLC 2L (N=78)	Selpercatinib Subpopulation A2 – NSCLC 3L (N=158)
Anzahl der vorherigen systemischen Therapien		
Anzahl der Patienten	78	158
Mittelwert (SD)	1,0 (0,00)	3,5 (1,87)
Median (min–max)	1,0 (1-1)	3,0 (2-15)
Vorherige Strahlentherapie, n (%)		
Ja	37 (47,4)	90 (57,0)
Nein	41 (52,6)	68 (43,0)
Vorherige Krebsbedingte Operation, n (%)		
Ja	30 (38,5)	77 (48,7)
Nein	48 (61,5)	81 (51,3)
RET-Alterationsstatus		
Art der RET-Alteration, n (%)		
Fusion	78 (100,0)	158 (100,0)
- KIF5B	53 (67,9)	94 (59,5)
- CCDC6	18 (23,1)	34 (21,5)
- NCOA4	1 (1,3)	5 (3,2)
- Andere	3 (3,8)	12 (7,6)
- Unbekannt	3 (3,8)	13 (8,2)
Mutation	0 (0,0)	0 (0,0)
- M918T	0 (0,0)	0 (0,0)
- V804 M/L	0 (0,0)	0 (0,0)
- Extrazelluläre Cystein Mutation	0 (0,0)	0 (0,0)
- Andere	0 (0,0)	0 (0,0)
Andere	0 (0,0)	0 (0,0)
Methode zur Identifizierung der vorliegenden RET-Alteration, n (%)		
Next-Generation-Sequencing (NGS) mit Tumormaterial	64 (82,1)	135 (85,4)
Next-Generation-Sequencing (NGS) mit Blut oder Plasma	9 (11,5)	13 (8,2)
PCR	1 (1,3)	4 (2,5)
FISH	3 (3,8)	6 (3,8)
Andere	1 (1,3)	0 (0,0)
Krankheitscharakteristika zu Baseline		
Messbare Erkrankung[c], n (%)		
Ja	78 (100,0)	157 (99,4)
Nein	0 (0,0)	1 (0,6)
Tumorlast in mm[d]		
Anzahl der Patienten	78	157
Mittelwert (SD)	61,4 (50,42)	71,8 (53,19)

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/T001_bc_nsclc.rtf

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

Merkmal	Selpercatinib	
	Subpopulation A1 – NSCLC 2L (N=78)	**Subpopulation A2 – NSCLC 3L (N=158)**
Median (min–max)	44,0 (10-250)	58,8 (10-297)

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; 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; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NCOA4: Nuclear Receptor Coactivator 4; NGS: Next-Generation-Sequencing; NSCLC: nicht-kleinzelliges Lungenkarzinom; PCR: Polymerase-Kettenreaktion; PD1: Programmed Cell Death Protein 1; PD-L1: Programmed Cell Death Ligand 1; RET: Rearranged during Transfection; SD: Standardabweichung; T: Threonin; USA: United States of America; 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 Prüfärzten 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/T001_bc_nsclc.rtf

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Protocol Number: LOXO-RET-17001 03:41 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

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
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.1.2.1_sf.rtf

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
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.1.2.1_sf.rtf

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.
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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.
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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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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.1.2.1_eff.rtf

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.
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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)
LIOTHYRONINE SODIUM	1 (1.2)	1 (0.6)	8 (5.2)	1 (4.8)
LIOTHYRONINE	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).
Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spcm2.sas
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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)
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)

Percentage is calculated based on the number of patients in the column heading as the denominator.
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Reported medication terms were coded using WHO Drug Dictionary (version September 2015).
Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
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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)
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)

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 Safety Analysis Set.
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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/T14.1.5_sf.rtf

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)
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)

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 Safety Analysis Set.
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.1.5_sf.rtf

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)
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)

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 Safety Analysis Set.
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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)
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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Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spcm2.sas
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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)
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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Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
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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)
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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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)
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/SENNA	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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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)
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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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)
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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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)
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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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)
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)
BENZYDAMINE 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/DIPHENHYDRAMI	0 (0.0)	0 (0.0)	1 (0.7)	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)
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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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)
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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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)
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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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)
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)
PAPAVER 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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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)
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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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)
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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Safety Analysis Set
by Subpopulation

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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Concomitant Medications
Safety Analysis Set
by Subpopulation

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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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Concomitant Medications
Safety Analysis Set
by Subpopulation

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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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)
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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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)
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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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)
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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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)
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)
DESLORATADINE	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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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)
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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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)
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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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)
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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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)
CORTICOSTEROIDS, POTENT (GROUP III)	13 (15.3)	25 (14.5)	7 (4.6)	2 (9.5)
FLUOCINOLONE 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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Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spcm2.sas
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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)
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)
PRAZOSIN	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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Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spcm2.sas
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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)
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)
CEFTRIAXONE	4 (4.7)	6 (3.5)	2 (1.3)	1 (4.8)
CEFTRIAXONE 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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Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spcm2.sas
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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)
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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Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spcm2.sas
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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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)
XANTOFYL	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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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)
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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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)
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)
CAMPHOR 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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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)
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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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)
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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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)
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)
RESPAIRE-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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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)
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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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)
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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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)
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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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)
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-STEROIDS 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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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
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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)
ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS 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)
DEXKETOPROFEN	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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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)
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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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)
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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Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
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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)
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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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)
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/CYANOCOBA	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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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)
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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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)
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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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)
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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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)
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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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)
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)
SALIVEHT	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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Concomitant Medications
Safety Analysis Set
by Subpopulation

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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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Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
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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)
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)
CEFACLOR	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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Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spcm2.sas
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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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 Safety Analysis Set.
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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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)
GLYCYRRHIZIC 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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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)
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/UBIDECAREN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Concomitant Medications
Safety Analysis Set
by Subpopulation

Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
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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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)
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)
BENZOTHIAZEPINE 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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Concomitant Medications
Safety Analysis Set
by Subpopulation

Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
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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Safety Analysis Set
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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Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spcm2.sas
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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)
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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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)
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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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)
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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Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
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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)
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)
ANTIHISTAMINES 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)
ANTIVERTIGO 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)
ACETYLLEUCINE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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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)
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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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)
ANTIINFLAMMATORY AGENTS, NON-STEROIDS	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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Concomitant Medications
Safety Analysis Set
by Subpopulation

Therapeutic Class Preferred Term	A1 (N=85)	A2 (N=173)	B (N=153)	C (N=21)
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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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)
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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Concomitant Medications
Safety Analysis Set
by Subpopulation

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)
XAMIOL	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)
ARIPIPRAZOLE	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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Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
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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)
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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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)
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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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)
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 IN	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)
TENOFOVIR 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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Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
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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)
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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Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
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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)
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. BUPIVACAIN	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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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)
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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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)
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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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)
LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
DYAZIDE	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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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)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR V	0 (0.0)	2 (1.2)	1 (0.7)	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)
ANTICHOLINESTERASES	0 (0.0)	1 (0.6)	1 (0.7)	1 (4.8)
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 (4.8)
ASCORBIC ACID (VITAMIN C), COMBINATIONS	1 (1.2)	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 (1.2)	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 (4.8)
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 (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)
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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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)
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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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)
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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Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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_sf.rtf

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)
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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Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
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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)
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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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)
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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Reported medication terms were coded using WHO Drug Dictionary (version September 2015).
Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spcm2.sas
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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)
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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Reported medication terms were coded using WHO Drug Dictionary (version September 2015).
Medications are sorted in decreasing order of frequency based on Overall Safety Analysis Set.
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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)
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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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)
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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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)
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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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)
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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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)
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 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
CAPZASIN QUICK RELIEF	1 (1.2)	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)
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)
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)

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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)
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 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
DRUGS FOR BILE THERAPY AND LIPOTROPICS IN COM	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
DRUGS USED IN ALCOHOL DEPENDENCE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
NALTREXONE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
ECTOPARASITICIDES, INCL. SCABICIDES	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
SODIUM CHLORIDE	1 (1.2)	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)

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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)
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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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)
IRON IN COMBINATION WITH FOLIC ACID	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
HIERROQUICK	1 (1.2)	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)
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)
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)
METHYLDOPA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
METHYLDOPA	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
MORPHINAN DERIVATIVES	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
NALBUPHINE	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)

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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)
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 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
MODIFIED CITRUSPECTIN	1 (1.2)	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)
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)

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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)
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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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)
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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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)
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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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)
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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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)
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)
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)

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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)
BETA BLOCKING AGENTS, SELECTIVE, AND OTHER DIURETI	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TENORETIC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BISPHOSPHONATES, COMBINATIONS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FOSAVANCE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CENTRALLY ACTING ANTIOBESITY 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)
DRUGS FOR CONSTIPATION	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DRUGS FOR CONSTIPATION	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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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)
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
Concomitant Medications
Safety Analysis Set
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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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)
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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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 Safety 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_sf.rtf

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)
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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Patients are counted once within each preferred term.
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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
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.1.5_eff.rtf

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)
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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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
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.1.5_eff.rtf

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)
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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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

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)
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)

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
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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)
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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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
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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)
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)

Percentage is calculated based on the number of patients in the column heading as the denominator.
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Medications are sorted in decreasing order of frequency based on Overall Efficacy Analysis Set.
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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)
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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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.
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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)
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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Medications are sorted in decreasing order of frequency based on Overall Efficacy Analysis Set.
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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)
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/SENNA	1 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)

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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
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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)
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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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)
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)
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)
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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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)
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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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)
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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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)
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/DIPHENHYDRAMI	0 (0.0)	0 (0.0)	1 (0.7)	1 (5.6)

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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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)
DESLORATADINE	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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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)
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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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)
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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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)
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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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)
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)
PRAZOSIN	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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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Concomitant Medications
Efficacy Analysis Set
by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
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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Concomitant Medications
Efficacy Analysis Set
by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
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)
CAMPHOR 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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Concomitant Medications
Efficacy Analysis Set
by Subpopulation

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)
RESPAIRE-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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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/CYANOCOBA	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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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)
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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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)
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/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)
ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS 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)
DEXKETOPROFEN	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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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)
FLUOROMETHOLONE	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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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)
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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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)
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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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)
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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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)
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)
BENZACLIN 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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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)
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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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)
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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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)
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)
CEFACLOR	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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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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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)
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)
GLYCYRRHIZIC ACID, AMMONIUM SALT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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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)
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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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)
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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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)
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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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)
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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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)
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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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)
BENZOTHIAZEPINE 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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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)
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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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)
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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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)
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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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)
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)
ANTIHISTAMINES 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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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)
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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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)
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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Concomitant Medications
Efficacy Analysis Set
by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
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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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)
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/UBIDECAREN	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)

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
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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)
ANTIVERTIGO PREPARATIONS	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)
ACETYLLEUCINE	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)

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
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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)
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)
ARIPIPRAZOLE	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)

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

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)
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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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
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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)
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)

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
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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)
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)

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
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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)
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. BUPIVACAIN	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)
XAMIOL	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)

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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
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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)
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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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
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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)
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)
TENOFOVIR 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)

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
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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)
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)
NAPHCON-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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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)
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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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)
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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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)
LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
DYAZIDE	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 DISEAS	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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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)
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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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)
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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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)
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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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)
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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Concomitant Medications
Efficacy Analysis Set
by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
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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Concomitant Medications
Efficacy Analysis Set
by Subpopulation

Therapeutic Class Preferred Term	A1 (N=78)	A2 (N=158)	B (N=143)	C (N=18)
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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Concomitant Medications
Efficacy Analysis Set
by Subpopulation

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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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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.1.5_eff.rtf

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)
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)

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

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)
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)

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

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)
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)

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
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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)
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)

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
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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)
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)

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
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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)
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)

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
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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)
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)

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
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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)
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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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.
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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)
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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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.
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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)
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)
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 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
AFLIBERCEPT	1 (1.3)	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)
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)
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)

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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.
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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)
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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Medications are sorted in decreasing order of frequency based on Overall Efficacy Analysis Set.
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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)
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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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)
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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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)
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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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)
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)

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.
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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)
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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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.
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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)
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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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.
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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)
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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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)
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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Medications are sorted in decreasing order of frequency based on Overall Efficacy Analysis Set.
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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)
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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Reported medication terms were coded using WHO Drug Dictionary (version September 2015).
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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)
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 ANTIOBESITY 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)

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Medications are sorted in decreasing order of frequency based on Overall Efficacy Analysis Set.
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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

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 - A1

Weight / Start Dose	160 mg BID	120 mg BID	Other	Total
< 50 kg	6 (7,1%)	0 (0,0%)	0 (0,0%)	6 (7,1%)
≥ 50 kg	68 (80,0%)	5 (5,9%)	6 (7,1%)	79 (92,9%)
Total	74 (87,1%)	5 (5,9%)	6 (7,1%)	85 (100,0%)

Efficacy Population - A1

Weight / Start Dose	160 mg BID	120 mg BID	Other	Total
< 50 kg	6 (7,7%)	0 (0,0%)	0 (0,0%)	6 (7,7%)
≥ 50 kg	61 (78,2%)	5 (6,4%)	6 (7,7%)	72 (92,3%)
Total	67 (85,9%)	5 (6,4%)	6 (7,7%)	78 (100,0%)

Safety Population - A2

Weight / Start Dose	160 mg BID	120 mg BID	Other	Total
< 50 kg	22 (12,7%)	1 (0,6%)	2 (1,2%)	25 (14,5%)
≥ 50 kg	119 (68,8%)	7 (4,0%)	21 (12,1%)	147 (85,0%)
Missing	1 (0,6%)	0 (0,0%)	0 (0,0%)	1 (0,6%)
Total	142 (82,1%)	8 (4,6%)	23 (13,3%)	173 (100,0%)

Efficacy Population - A2

Weight / Start Dose	160 mg BID	120 mg BID	Other	Total
< 50 kg	20 (12,7%)	1 (0,6%)	2 (1,3%)	23 (14,6%)
≥ 50 kg	106 (67,1%)	7 (4,4%)	21 (13,3%)	134 (84,8%)
Missing	1 (0,6%)	0 (0,0%)	0 (0,0%)	1 (0,6%)
Total	127 (80,4%)	8 (5,1%)	23 (14,6%)	158 (100,0%)

Tabelle 004: Behandlungsdauer – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

	Selpercatinib	
	Subpopulation A1 – NSCLC 2L (N=78)	**Subpopulation A2 – NSCLC 3L (N=158)**
Behandlungsdauer in Monaten		
Anzahl der Patienten	78	158
Mittelwert (SD)	11,5 (6,11)	13,0 (7,66)
Median (min–max)	11,30 (0,53-29,14)	12,21 (0,10-34,50)

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; max: Maximum; min: Minimum; NSCLC: nicht-kleinzelliges Lungenkarzinom; 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/T004_tte_nsclc.rtf

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

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=78)	Selpercatinib Subpopulation A2 – NSCLC 3L (N=158)
Gesamtüberleben		
Überlebensstatus[a], n (%)		
Tot	13 (16,7)	34 (21,5)
Lebend	65 (83,3)	124 (78,5)
Medianes Gesamtüberleben (Monate) [95%-KI][b,c]	28,88 [28,9; NE]	NE [25,7; NE]
Überlebensrate (≥ 12 Monate), % [95%-KI][b,d]	87,0 [76,1; 93,1]	86,5 [79,6; 91,2]
Mediane Beobachtungsdauer (Monate)[b]	12,7	15,8

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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.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/T007_os_nsclc_eff.rtf

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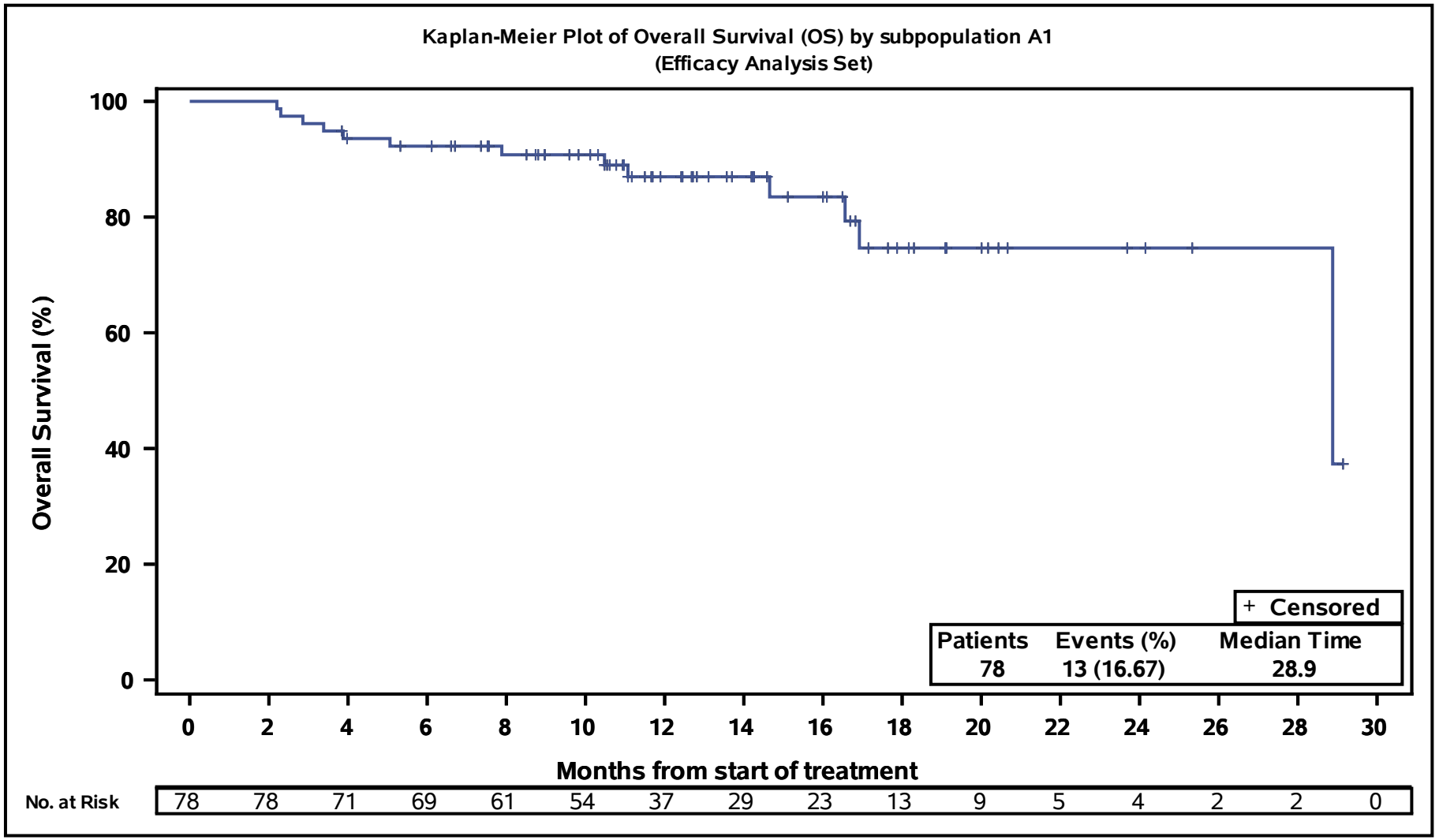

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Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F001_1_os_a1_nsclc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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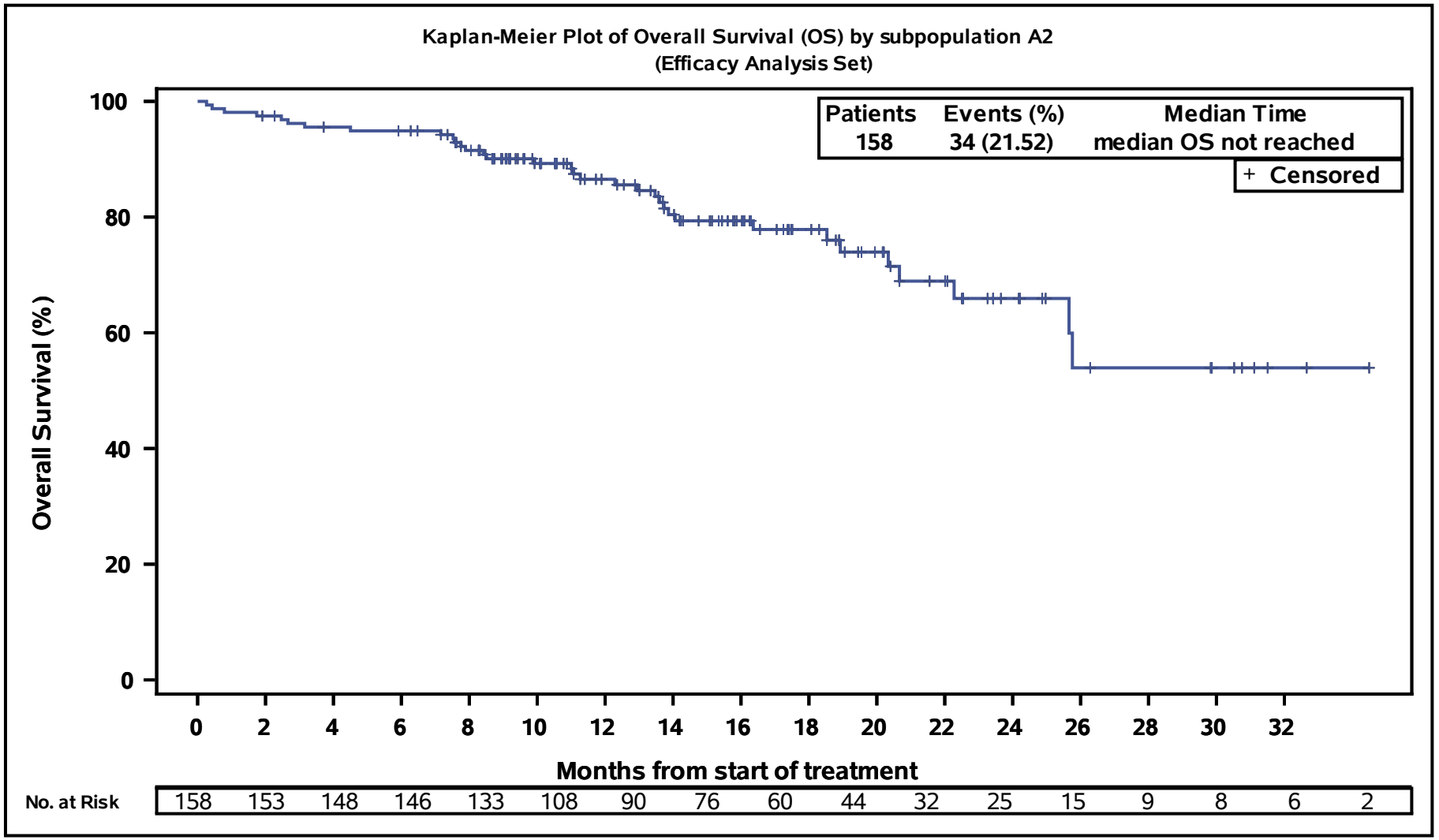

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Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F001_2_os_a2_nsclc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=78)	Selpercatinib Subpopulation A2 – NSCLC 3L (N=158)
Progressionsfreies Überleben		
Progressionsstatus[a,c], n (%)		
Progression	20 (25,6)	45 (28,5)
Tod (ohne vorherigen Progress)	4 (5,1)	11 (7,0)
Zensiert	54 (69,2)	102 (64,6)
Grund für Zensierung, n (%)		
Am Leben ohne Progress[b]	47 (60,3)	87 (55,1)
Anschl. Krebstherapie oder krebsbedingte Operation ohne Progress[b]	4 (5,1)	11 (7,0)
Abbruch der Studie ohne Progress[b]	3 (3,8)	4 (2,5)
Medianes progressionsfreies Überleben (Monate) [95%-KI][d,e]	19,32 [13,6; NE]	19,25 [13,9; NE]
Dauer des progressionsfreien Überlebens nach Kategorie, n (%)		
< 6 Monate	20 (25,6)	41 (25,9)
≥ 6 bis < 12 Monate	37 (47,4)	56 (35,4)
≥ 12 bis < 18 Monate	15 (19,2)	39 (24,7)
≥ 18 bis < 24 Monate	5 (6,4)	17 (10,8)
≥ 24 Monate	1 (1,3)	5 (3,2)
Progressionsfreie Überlebensrate[d,f], % [95%-KI]		
≥ 6 Monate	83,9 [73,3; 90,5]	83,1 [76,0; 88,2]
≥ 12 Monate	69,3 [56,0; 79,3]	69,8 [61,1; 76,9]

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_pfs_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/T008_pfs_nsclc_eff.rtf

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

	Selpercatinib	
Endpunkt	**Subpopulation A1 – NSCLC 2L (N=78)**	**Subpopulation A2 – NSCLC 3L (N=158)**
Mediane Beobachtungsdauer (Monate)[d]	11,1	13,7

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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.

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.

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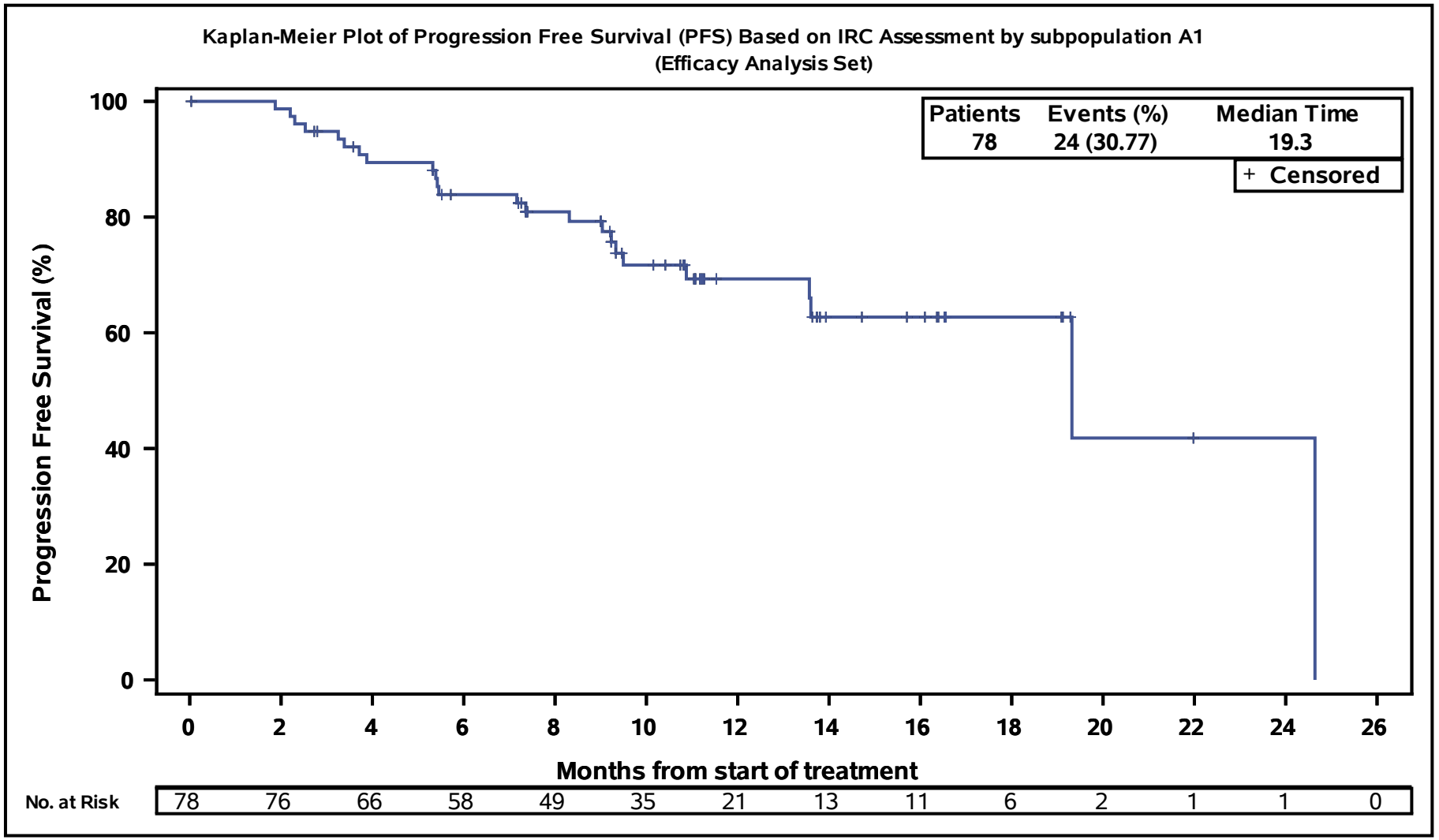
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T008_pfs_nsclc_eff.rtf

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



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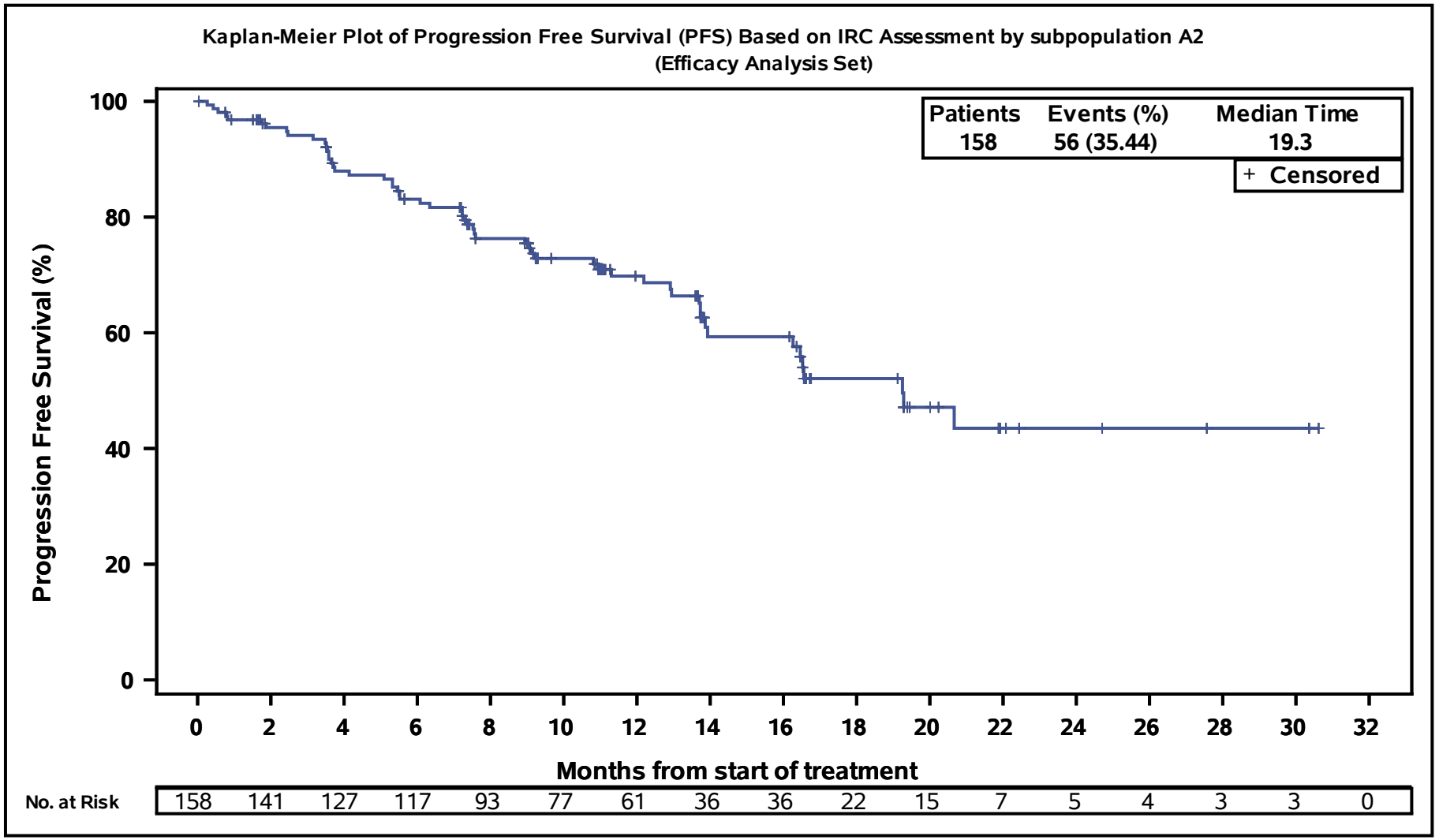
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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

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LOXO-RET-17001
Clinical Study Report (Visit Cutoff 20-MAR-2020)
Efficacy Analysis Set
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 Überlebensrated (≥ 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
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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: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=78)	Selpercatinib Subpopulation A2 – NSCLC 3L (N=158)
Objektive Ansprechrate (CR+PR), n (%)		
Objektive Ansprechrate [95%-KI][a,b]	46 (59,0) [47,3; 70,0]	86 (54,4) [46,3; 62,4]

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; CR: komplettes Ansprechen; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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 Ansprechrate (%) ist definiert als der Anteil an Patienten mit bestätigtem kompletten 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.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/T012_orr_nsclc_eff.rtf

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

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=78)	Selpercatinib Subpopulation A2 – NSCLC 3L (N=158)
Bestes Gesamtansprechen, n (%)		
Komplettes Ansprechen (CR)	3 (3,8)	6 (3,8)
Partielles Ansprechen (PR)	43 (55,1)	80 (50,6)
Stabile Erkrankung (SD)	30 (38,5)	60 (38,0)
SD*	22 (28,2)	43 (27,2)
Progressive Erkrankung (PD)	1 (1,3)	5 (3,2)
Nicht auswertbar	1 (1,3)	7 (4,4)
Krankheitskontrollrate, n (%)[a]		
Krankheitskontrollrate [95%-KI][a,b]	68 (87,2) [77,7; 93,7]	129 (81,6) [74,7; 87,3]

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; CR: komplettes Ansprechen; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; PD: progressive Erkrankung; PR: partielles Ansprechen; RET: Rearranged during Transfection; SD: stabile Erkrankung. SD*: stabile Erkrankung über mindestens 16 Wochen.

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 kompletten 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.sas
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T014_borcbr_nsclc_eff.rtf

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

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=78)	Selpercatinib Subpopulation A2 – NSCLC 3L (N=158)
Patienten mit Ansprechen, n[a,e]	46	86
Status des Ansprechens, n (%)[b,c]		
Progression	15 (32,6)	20 (23,3)
Tod (ohne vorherigen Progress)	0 (0,0)	4 (4,7)
Zensiert	31 (67,4)	62 (72,1)
Grund für Zensierung, n (%)		
Am Leben ohne Progress[d]	30 (65,2)	59 (68,6)
Anschl. Krebstherapie oder krebsbedingte Operation ohne Progress[d]	1 (2,2)	3 (3,5)
Abbruch der Studie ohne Progress[d]	0 (0,0)	0 (0,0)
Dauer des Ansprechens		
Dauer des Ansprechens (Monate), Median [95% KI][a,c,f,g,]	17,51 [11,0; NE]	NE [12,5; NE]
Dauer des Ansprechens nach Kategorie, n (%)[a,c]		
< 6 Monate	15 (32,6)	22 (25,6)
≥ 6 bis < 12 Monate	22 (47,8)	33 (38,4)
≥ 12 bis < 18 Monate	9 (19,6)	23 (26,7)
≥ 18 bis < 24 Monate	0 (0,0)	5 (5,8)

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_dor_ge.sas
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T009_dor_nsclc_eff.rtf

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

	Selpercatinib	
Endpunkt	**Subpopulation A1 – NSCLC 2L (N=78)**	**Subpopulation A2 – NSCLC 3L (N=158)**
≥ 24 Monate	0 (0,0)	3 (3,5)

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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.sas
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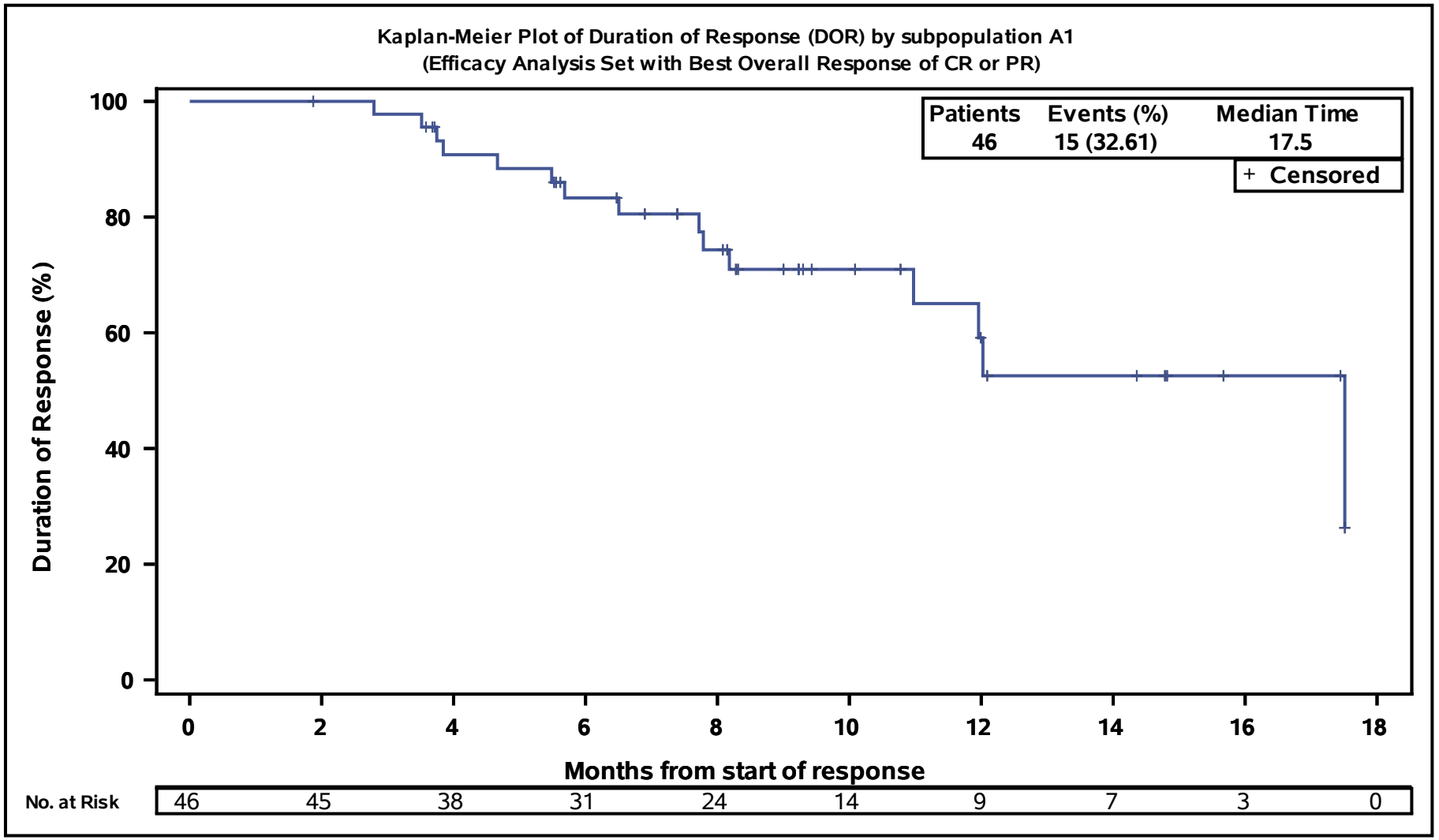
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T009_dor_nsclc_eff.rtf

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



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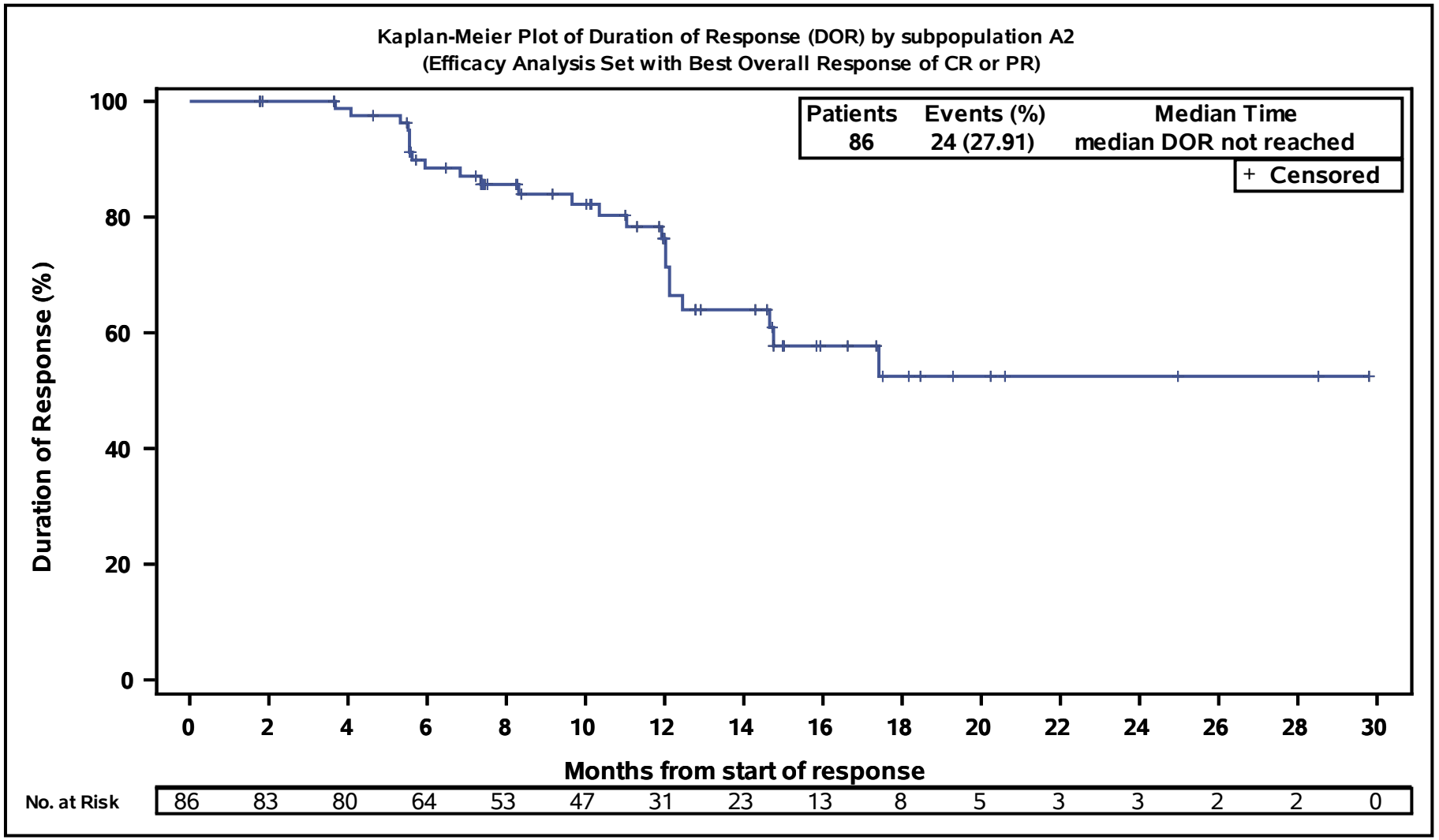
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



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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: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=78)	Selpercatinib Subpopulation A2 – NSCLC 3L (N=158)
Patienten mit Ansprechen, n[a,c]	46	86
Zeit bis zum Ansprechen		
Zeit bis zum Ansprechen (Monate), Median [95%-KI][b]	1,84 [1,7; 2,0]	1,87 [1,8; 1,9]
Zeit bis zum Ansprechen nach Kategorie, n (%)[b]		
< 2 Monate	30 (65,2)	54 (62,8)
≥ 2 und < 4 Monate	8 (17,4)	15 (17,4)
≥ 4 und < 6 Monate	5 (10,9)	8 (9,3)
≥ 6 und < 9 Monate	1 (2,2)	5 (5,8)
≥ 9 Monate	2 (4,3)	4 (4,7)

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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 Ansprechens (CR) oder partiellen Ansprechens (PR) als bestes Ansprechen.
b: Analyse basierend auf Daten von Patienten mit bestätigtem kompletten 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.

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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T011_ttr_nsclc_eff.rtf

Tabelle 013: Ergebnisse für den Endpunkt Objektive Ansprechrate – ZNS aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=78)	Selpercatinib Subpopulation A2 – NSCLC 3L (N=158)
Objektive Ansprechrate - ZNS, Patienten mit messbaren ZNS-Metastasen (CR+PR), n (%)		
N'	6	13
Objektive Ansprechrate [95%-KI][a,b]	4 (66,7) [22,3; 95,7]	13 (100,0) [75,3; 100,0]
Objektive Ansprechrate - ZNS, Patienten mit messbaren und nicht-messbaren ZNS-Metastasen (CR+PR), n (%)		
N'	30	52
Objektive Ansprechrate [95%-KI][a,b]	13 (43,3) [25,5; 62,6]	25 (48,1) [34,0; 62,4]

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; CR: komplettes Ansprechen; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); N': Anzahl der auswertbaren Patienten in der Analyse; NSCLC: nicht-kleinzelliges Lungenkarzinom; PR: partielles Ansprechen; RET: Rearranged during Transfection; ZNS: zentrales Nervensystem.

Der Prozentsatz wird basierend auf der Anzahl an Patienten mit messbaren ZNS Metastasen / messbaren und nicht messbaren ZNS Metastasen und mit bestätigtem kompletten Ansprechen (CR) oder partiellen Ansprechen (PR) als bestes Gesamtansprechen als Nenner berechnet.
a: Die objektive Ansprechrate (%) ist definiert als der Anteil an Patienten mit bestätigtem kompletten 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.
Auswertbare Patienten mussten bei Baseline vom Prüfarzt bewertete ZNS-Metastasen aufweisen.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_cnsorr_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/T013_cnsorr_nsclc_eff.rtf

Tabelle 010: Ergebnisse für den Endpunkt Dauer des Ansprechens - ZNS aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	Selpercatinib	
	Subpopulation A1 – NSCLC 2L (N=78)	**Subpopulation A2 – NSCLC 3L (N=158)**
Patienten mit messbaren ZNS-Metastasen		
N'	6	13
Patienten mit Ansprechen, n[a,e]	4	13
Status des Ansprechens, n (%)[b,c]		
Progression	2 (50,0)	9 (69,2)
Tod (ohne vorherigen Progress)	0 (0,0)	1 (7,7)
Zensiert	2 (50,0)	3 (23,1)
Grund für Zensierung, n (%)		
Am Leben ohne Progress[d]	1 (25,0)	2 (15,4)
Anschl. Krebstherapie oder krebsbedingte Operation ohne Progress[d]	1 (25,0)	1 (7,7)
Dauer des Ansprechens		
Dauer des Ansprechens (Monate), Median [95% KI][a,c,f,g,]	NE [3,7; NE]	9,36 [6,7; 12,1]
Dauer des Ansprechens nach Kategorie, n (%)[a,c]		
< 6 Monate	1 (25,0)	3 (23,1)
≥ 6 bis < 12 Monate	1 (25,0)	8 (61,5)
≥ 12 bis < 18 Monate	1 (25,0)	1 (7,7)
≥ 18 bis < 24 Monate	1 (25,0)	1 (7,7)
Patienten mit messbaren und nicht-messbaren ZNS-Metastasen		
N'	30	52
Patienten mit Ansprechen, n[a,e]	13	25
Status des Ansprechens, n (%)[b,c]		
Progression	2 (15,4)	9 (36,0)
Tod (ohne vorherigen Progress)	0 (0,0)	3 (12,0)
Zensiert	11 (84,6)	13 (52,0)
Grund für Zensierung, n (%)		
Am Leben ohne Progress[d]	9 (69,2)	10 (40,0)
Anschl. Krebstherapie oder krebsbedingte Operation ohne Progress[d]	2 (15,4)	2 (8,0)
Abbruch der Studie ohne Progress[d]	0 (0,0)	1 (4,0)
Dauer des Ansprechens		
Dauer des Ansprechens (Monate), Median [95% KI][a,c,f,g,]	NE [8,3; NE]	10,09 [7,4; NE]
Dauer des Ansprechens nach Kategorie, n (%)[a,c]		

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_cnsdor_ge.sas
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T010_cnsdor_nsclc_eff.rtf

Tabelle 010: Ergebnisse für den Endpunkt Dauer des Ansprechens - ZNS aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=78)	Selpercatinib Subpopulation A2 – NSCLC 3L (N=158)
< 6 Monate	6 (46,2)	7 (28,0)
≥ 6 bis < 12 Monate	3 (23,1)	10 (40,0)
≥ 12 bis < 18 Monate	3 (23,1)	5 (20,0)
≥ 18 bis < 24 Monate	1 (7,7)	3 (12,0)

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; RET: Rearranged during Transfection.

Der Prozentsatz wird basierend auf der Anzahl an Patienten mit messbaren ZNS Metastasen / messbaren und nicht messbaren ZNS Metastasen und 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.
Auswertbare Patienten mussten bei Baseline vom Prüfarzt bewertete ZNS-Metastasen aufweisen.
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_cnsdor_ge.sas
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T010_cnsdor_nsclc_eff.rtf

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

	Selpercatinib	
Endpunkt	**Subpopulation A1 - NSCLC 2L (N'=51) (N=78)**	**Subpopulation A2 - NSCLC 3L (N'=76) (N=158)**
Gesamtrate[a] über alle Zeitpunkte	273/319 (85,6)	397/450 (88,2)
Compliance-Rate[b] pro geplante Visite		
Baseline	51/78 (65,4)	76/158 (48,1)
Zyklus 3, Tag 1	42/78 (53,8)	68/158 (43,0)
Zyklus 5, Tag 1	39/78 (50,0)	61/158 (38,6)
Zyklus 7, Tag 1	39/78 (50,0)	60/158 (38,0)
Zyklus 9, Tag 1	32/78 (41,0)	49/158 (31,0)
Zyklus 11, Tag 1	27/78 (34,6)	35/158 (22,2)
Zyklus 13, Tag 1	21/78 (26,9)	22/158 (13,9)
Zyklus 16, Tag 1	9/78 (11,5)	15/158 (9,5)
Zyklus 19, Tag 1	5/78 (6,4)	1/158 (0,6)
Zyklus 22, Tag 1	2/78 (2,6)	0/158 (0,0)
Visite bei Ende der Behandlung	6/78 (7,7)	10/158 (6,3)

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; EORTC: European Organisation for Research and Treatment of Cancer; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); N': Anzahl der behandelten Patienten mit einem Baseline- und mindestens einem Post-Baseline-Wert; NSCLC: nicht-kleinzelliges Lungenkarzinom; 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.

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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: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

	Selpercatinib	
Endpunkt	**Subpopulation A1 - NSCLC 2L (N'=78) (N=78)**	**Subpopulation A2 - NSCLC 3L (N'=158) (N=158)**
EORTC QLQ-C30 – Symptomskalen		
Fatigue	51	76
Patienten mit Ereignis		
Verbesserung, n (%)	30 (58,8)	50 (65,8)
Zensierte Patienten, n (%)	21 (41,2)	26 (34,2)
Verschlechterung, n (%)	26 (51,0)	41 (53,9)
Zensierte Patienten, n (%)	25 (49,0)	35 (46,1)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	3,7 [2,10; NE]	3,7 [1,94; 5,62]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	8,3 [2,00; NE]	7,4 [3,71;11,30]
Schmerzen	51	76
Patienten mit Ereignis		
Verbesserung, n (%)	26 (51,0)	40 (52,6)
Zensierte Patienten, n (%)	25 (49,0)	36 (47,4)
Verschlechterung, n (%)	24 (47,1)	31 (40,8)
Zensierte Patienten, n (%)	27 (52,9)	45 (59,2)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	5,7 [1,94; NE]	3,9 [1,94; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	10,0 [7,39; NE]	11,0 [7,33; NE]
Übelkeit und Erbrechen	51	76
Patienten mit Ereignis		
Verbesserung, n (%)	13 (25,5)	23 (30,3)
Zensierte Patienten, n (%)	38 (74,5)	53 (69,7)
Verschlechterung, n (%)	13 (25,5)	26 (34,2)
Zensierte Patienten, n (%)	38 (74,5)	50 (65,8)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	NE [11,20; NE]	NE [11,07; NE]
Dyspnoe	51	76
Patienten mit Ereignis		
Verbesserung, n (%)	21 (41,2)	38 (50,0)
Zensierte Patienten, n (%)	30 (58,8)	38 (50,0)
Verschlechterung, n (%)	12 (23,5)	15 (19,7)
Zensierte Patienten, n (%)	39 (76,5)	61 (80,3)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [3,94; NE]	4,6 [2,10; NE]

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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: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

	Selpercatinib	
Endpunkt	**Subpopulation A1 - NSCLC 2L (N'=78) (N=78)**	**Subpopulation A2 - NSCLC 3L (N'=158) (N=158)**
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [14,23; NE]
Schlaflosigkeit	51	76
Patienten mit Ereignis		
Verbesserung, n (%)	18 (35,3)	31 (40,8)
Zensierte Patienten, n (%)	33 (64,7)	45 (59,2)
Verschlechterung, n (%)	16 (31,4)	30 (39,5)
Zensierte Patienten, n (%)	35 (68,6)	46 (60,5)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	13,8 [5,52; NE]	NE [6,74; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	NE [9,30; NE]	NE [5,49; NE]
Appetitverlust	51	76
Patienten mit Ereignis		
Verbesserung, n (%)	27 (52,9)	31 (40,8)
Zensierte Patienten, n (%)	24 (47,1)	45 (59,2)
Verschlechterung, n (%)	14 (27,5)	32 (42,1)
Zensierte Patienten, n (%)	37 (72,5)	44 (57,9)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	3,8 [2,00; NE]	13,9 [3,94; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	NE [13,77; NE]	NE [6,74; NE]
Verstopfung	51	76
Patienten mit Ereignis		
Verbesserung, n (%)	18 (35,3)	25 (32,9)
Zensierte Patienten, n (%)	33 (64,7)	51 (67,1)
Verschlechterung, n (%)	23 (45,1)	34 (44,7)
Zensierte Patienten, n (%)	28 (54,9)	42 (55,3)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [5,72; NE]	16,2 [16,16; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	11,5 [5,59; NE]	9,5 [5,55; NE]
Diarrhoe	51	76
Patienten mit Ereignis		
Verbesserung, n (%)	11 (21,6)	16 (21,1)
Zensierte Patienten, n (%)	40 (78,4)	60 (78,9)
Verschlechterung, n (%)	26 (51,0)	41 (53,9)
Zensierte Patienten, n (%)	25 (49,0)	35 (46,1)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]

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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: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

	Selpercatinib	
Endpunkt	**Subpopulation A1 - NSCLC 2L (N'=78) (N=78)**	**Subpopulation A2 - NSCLC 3L (N'=158) (N=158)**
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	8,3 [5,49; NE]	7,4 [3,75;11,07]

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; 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; NSCLC: nicht-kleinzelliges Lungenkarzinom; 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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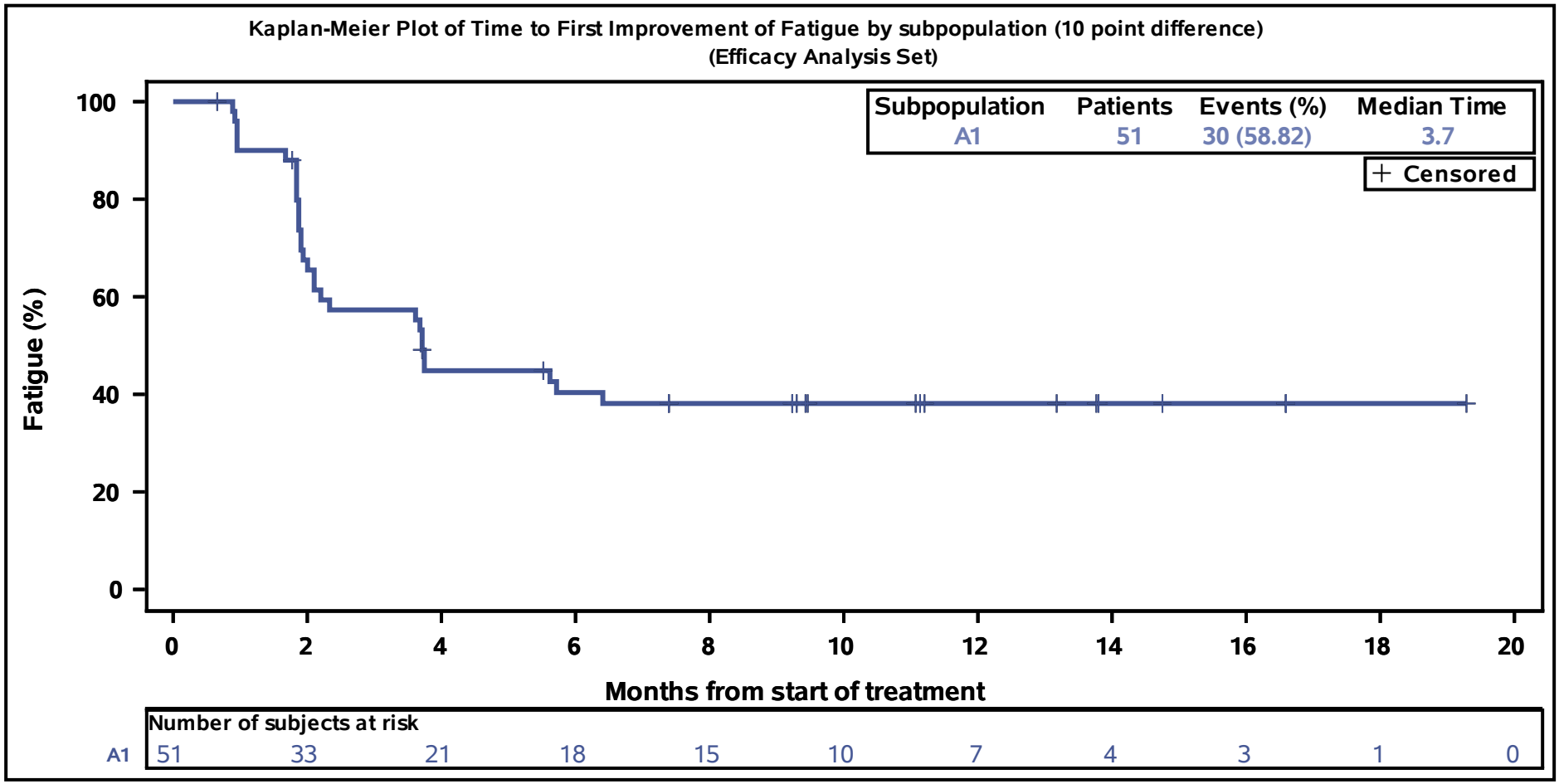
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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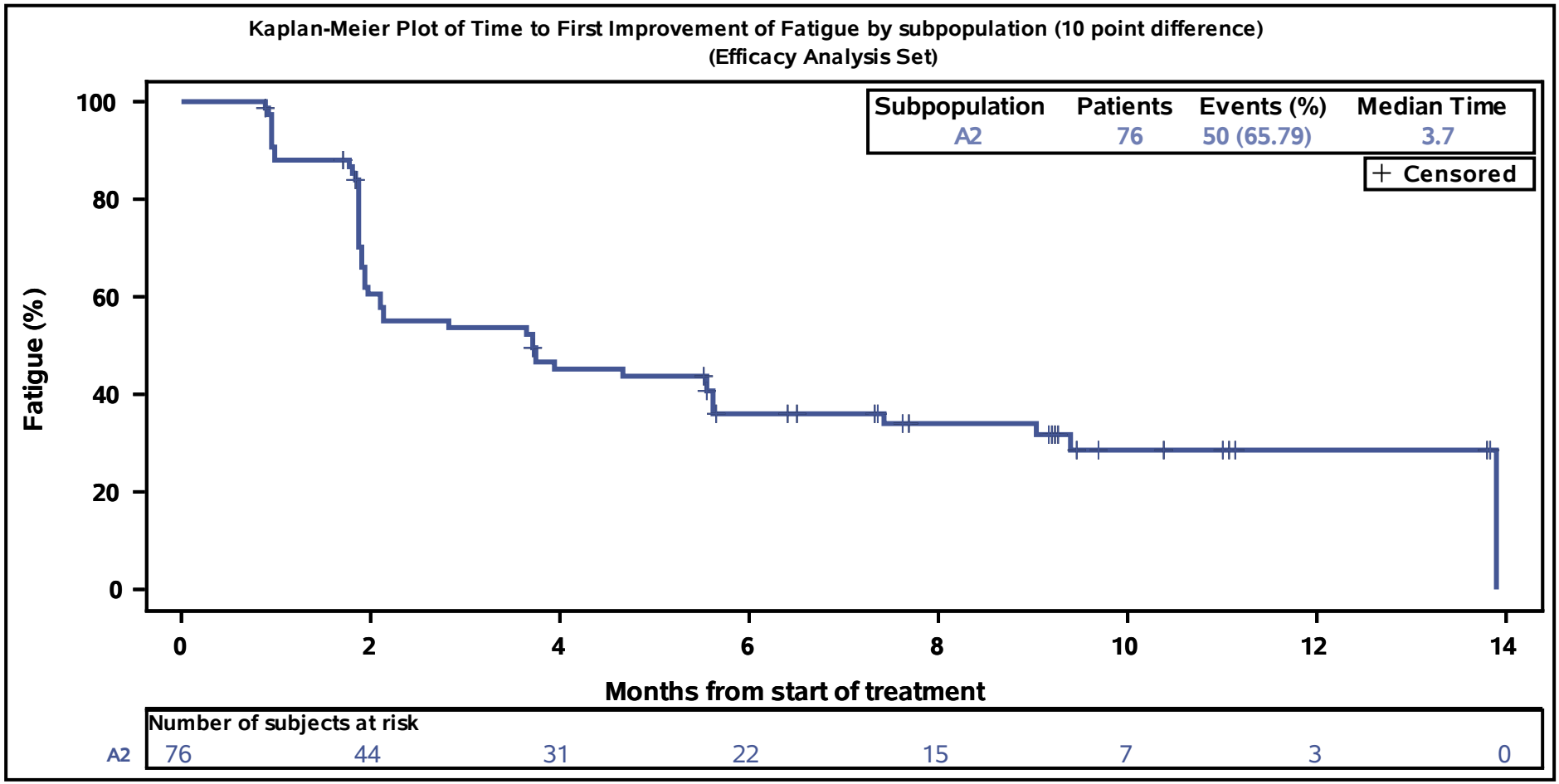
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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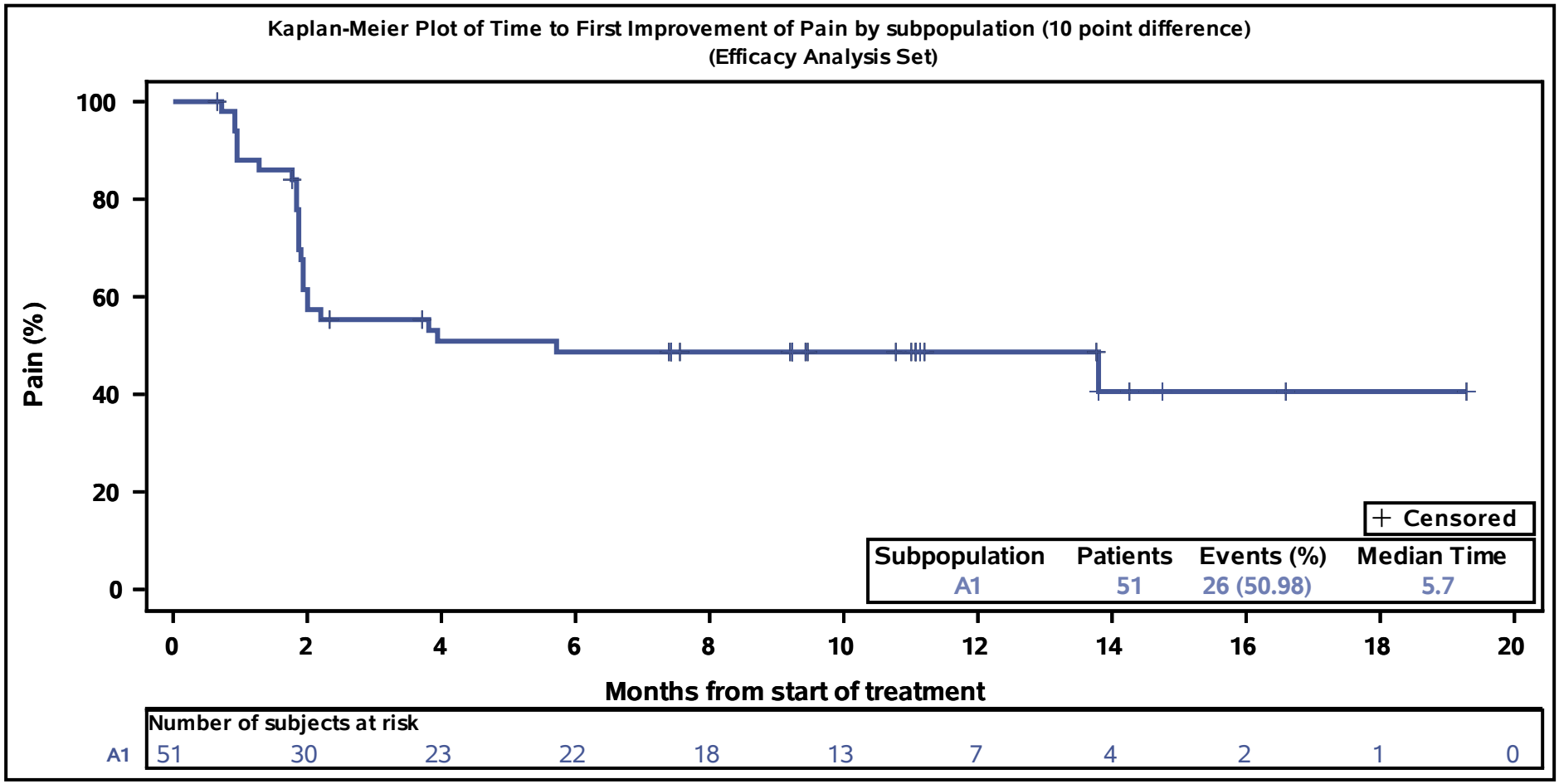
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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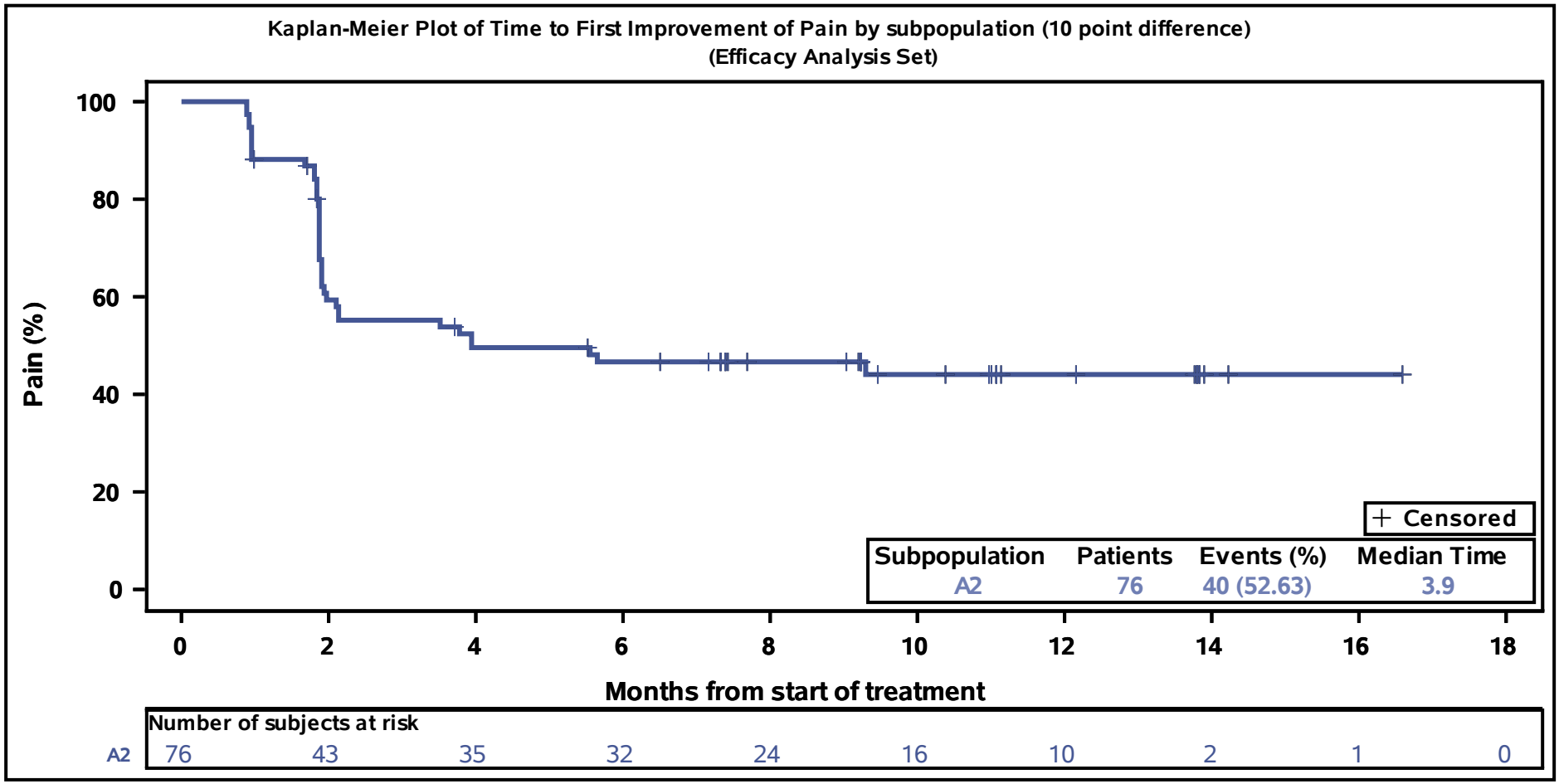
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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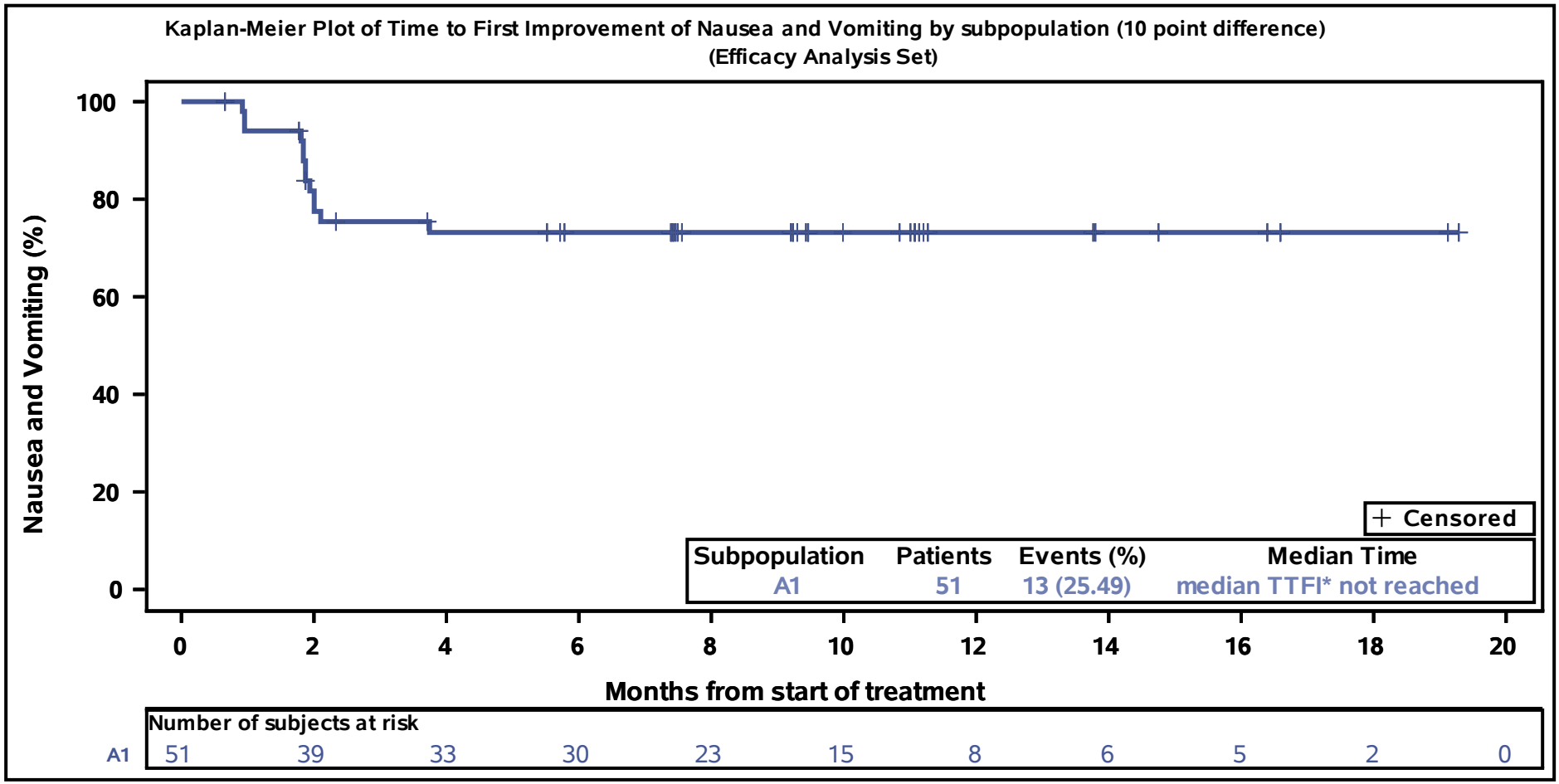

* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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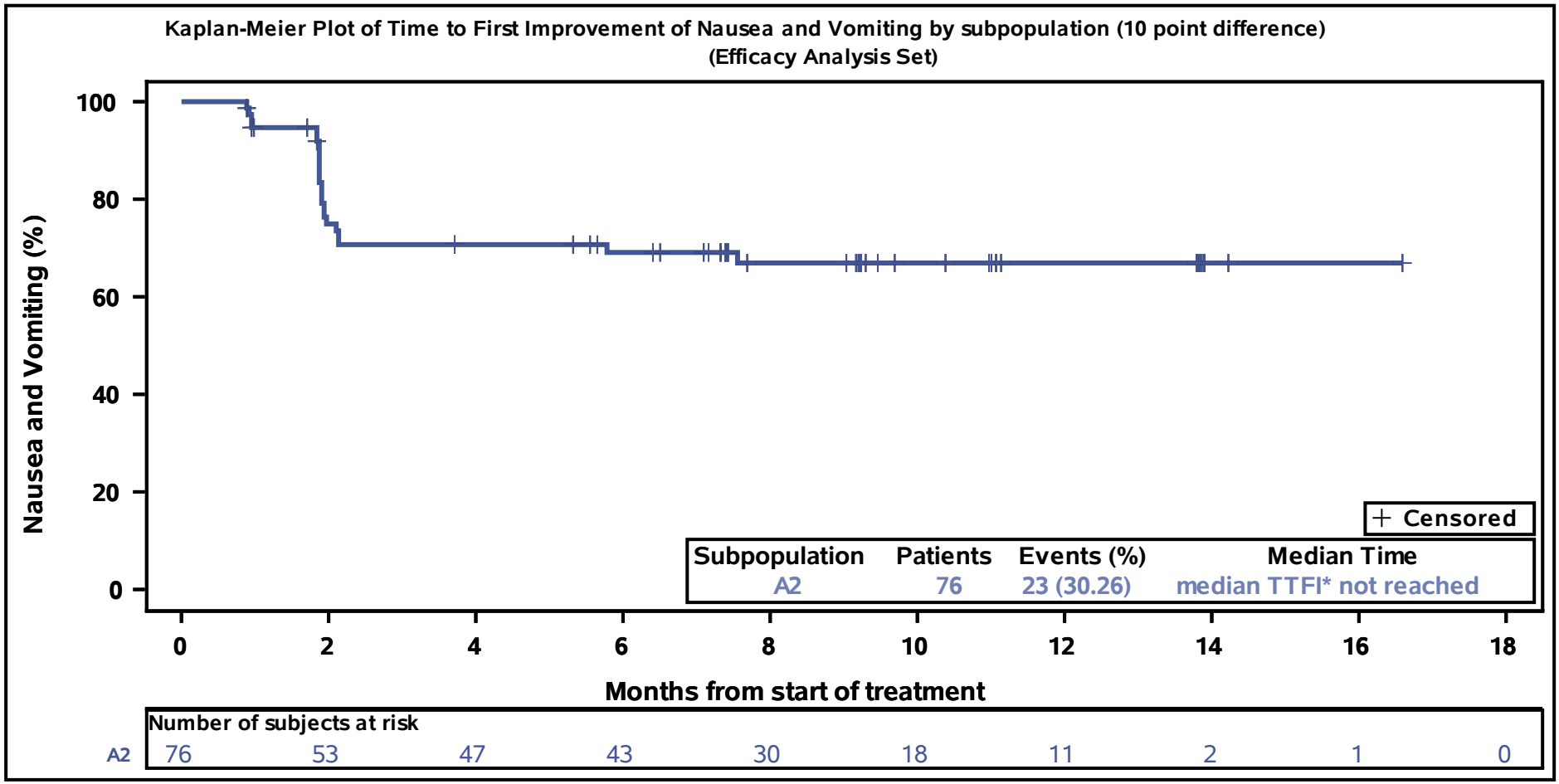

* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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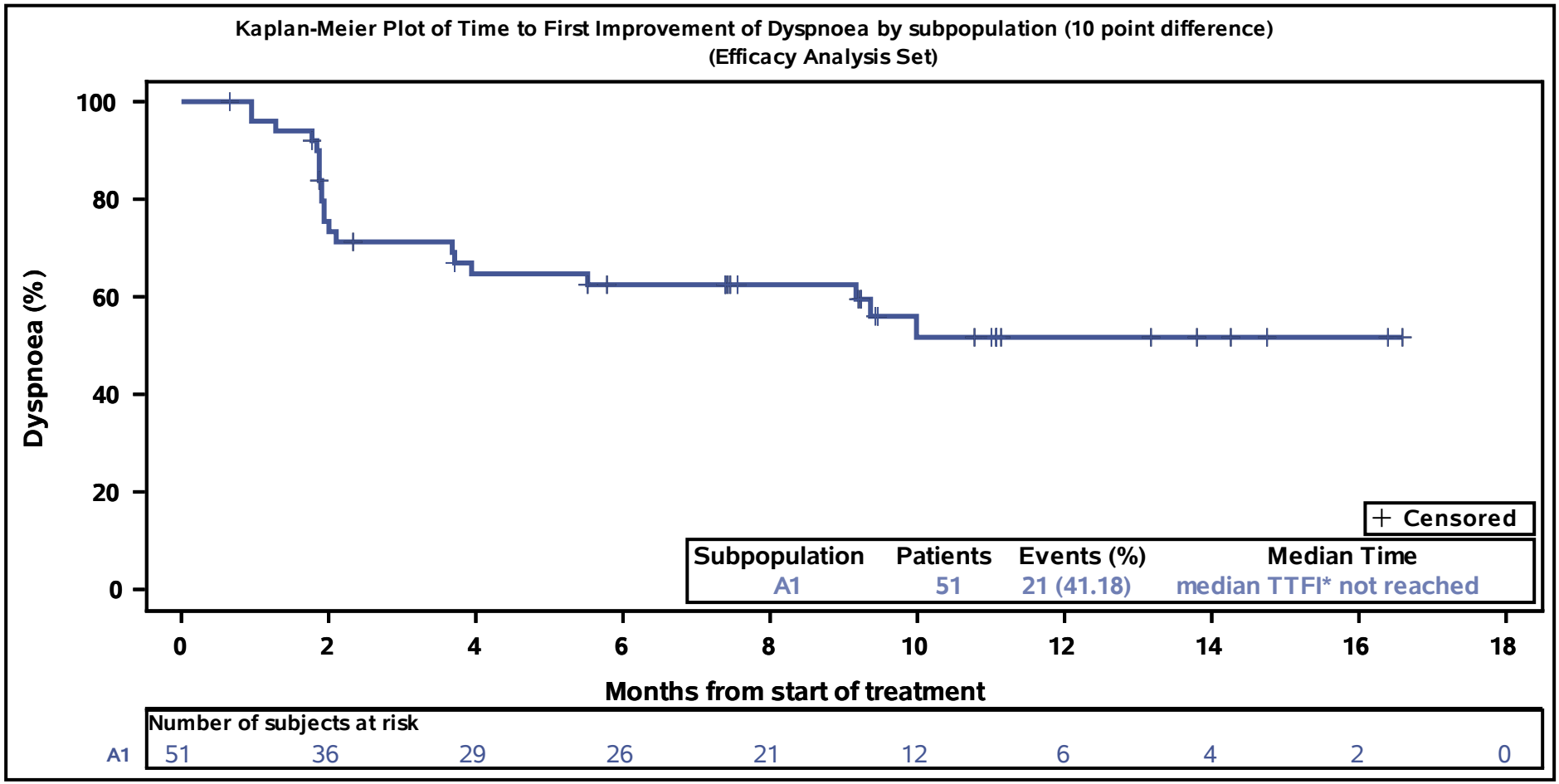
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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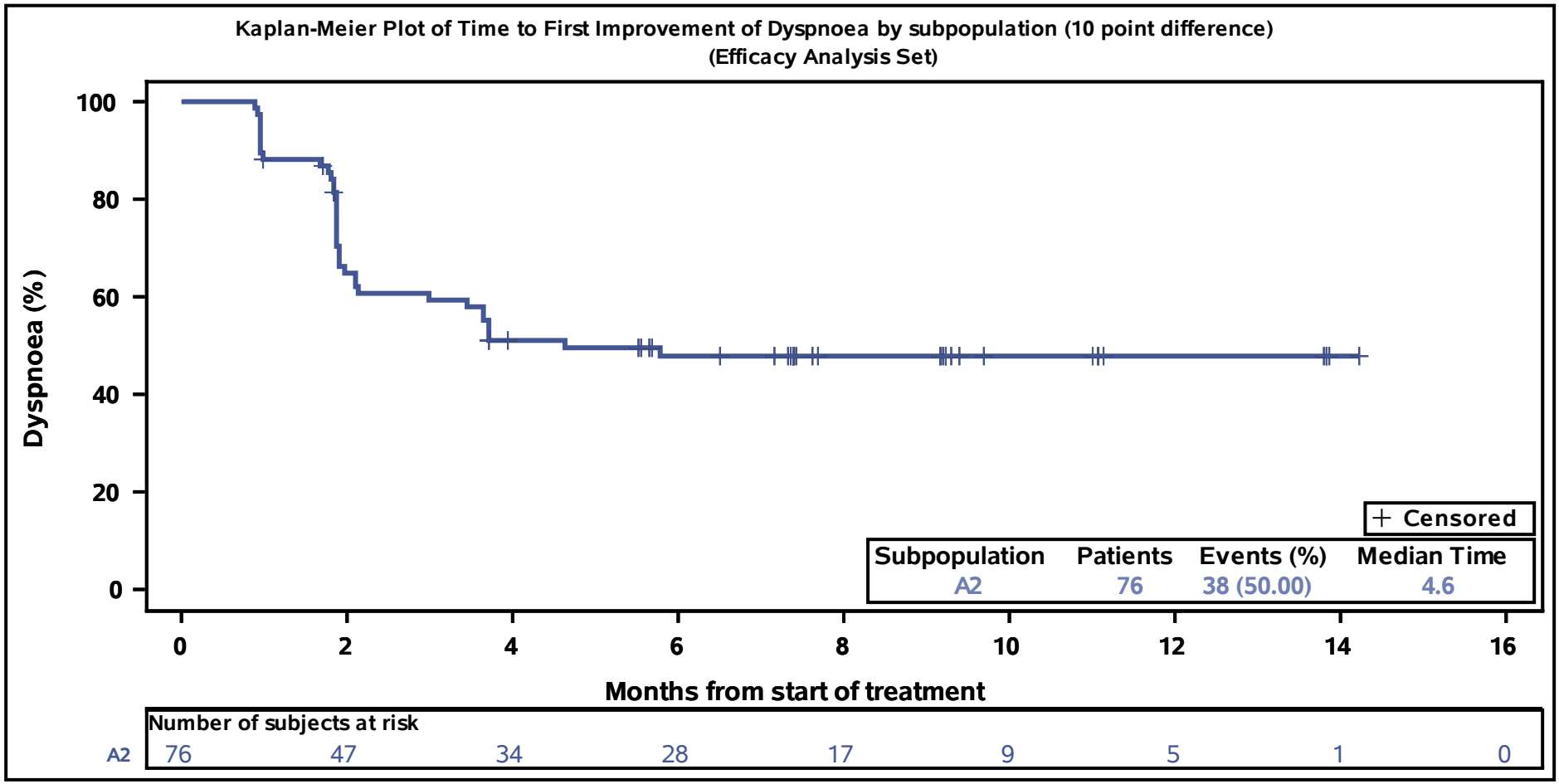
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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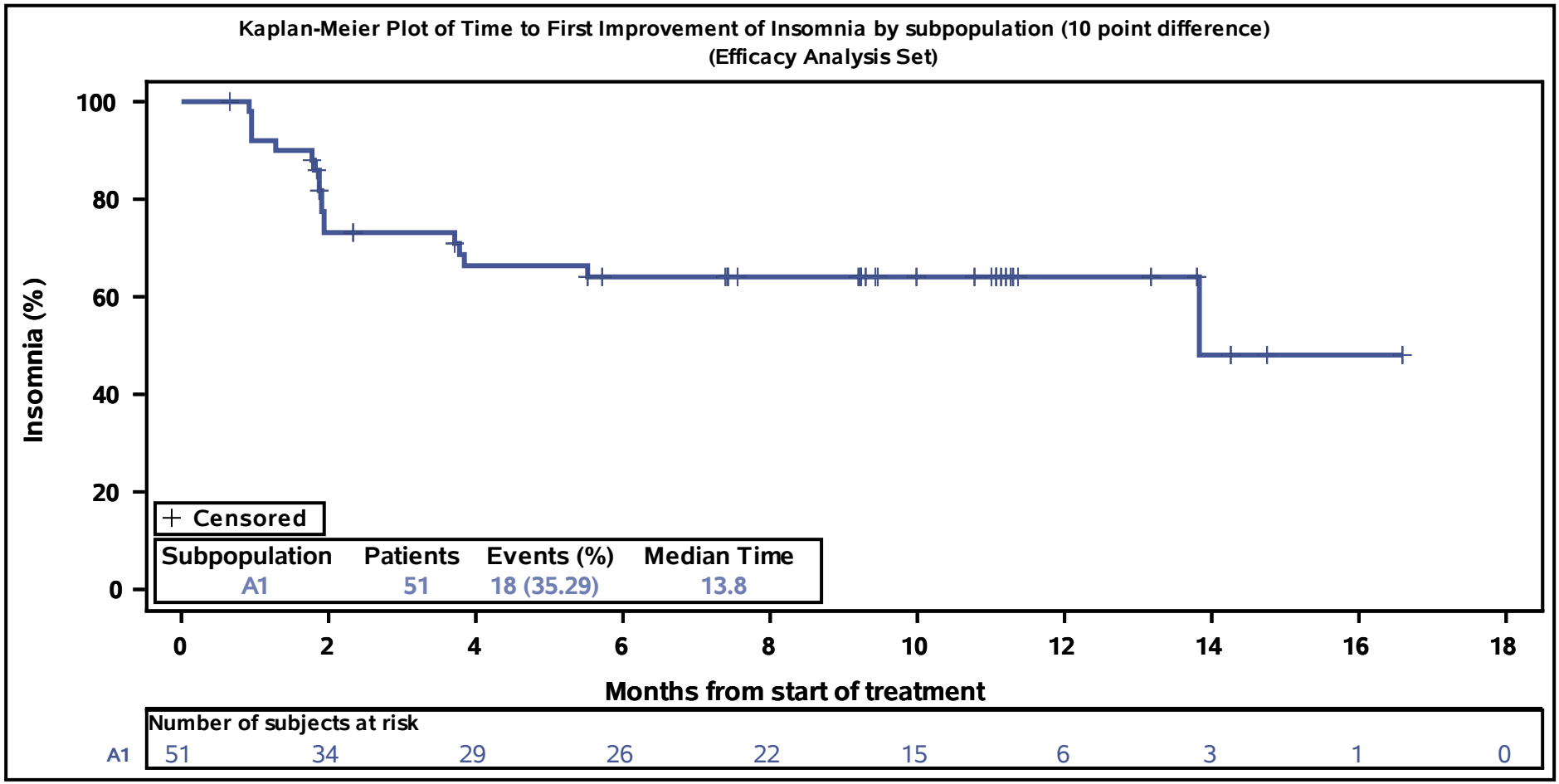
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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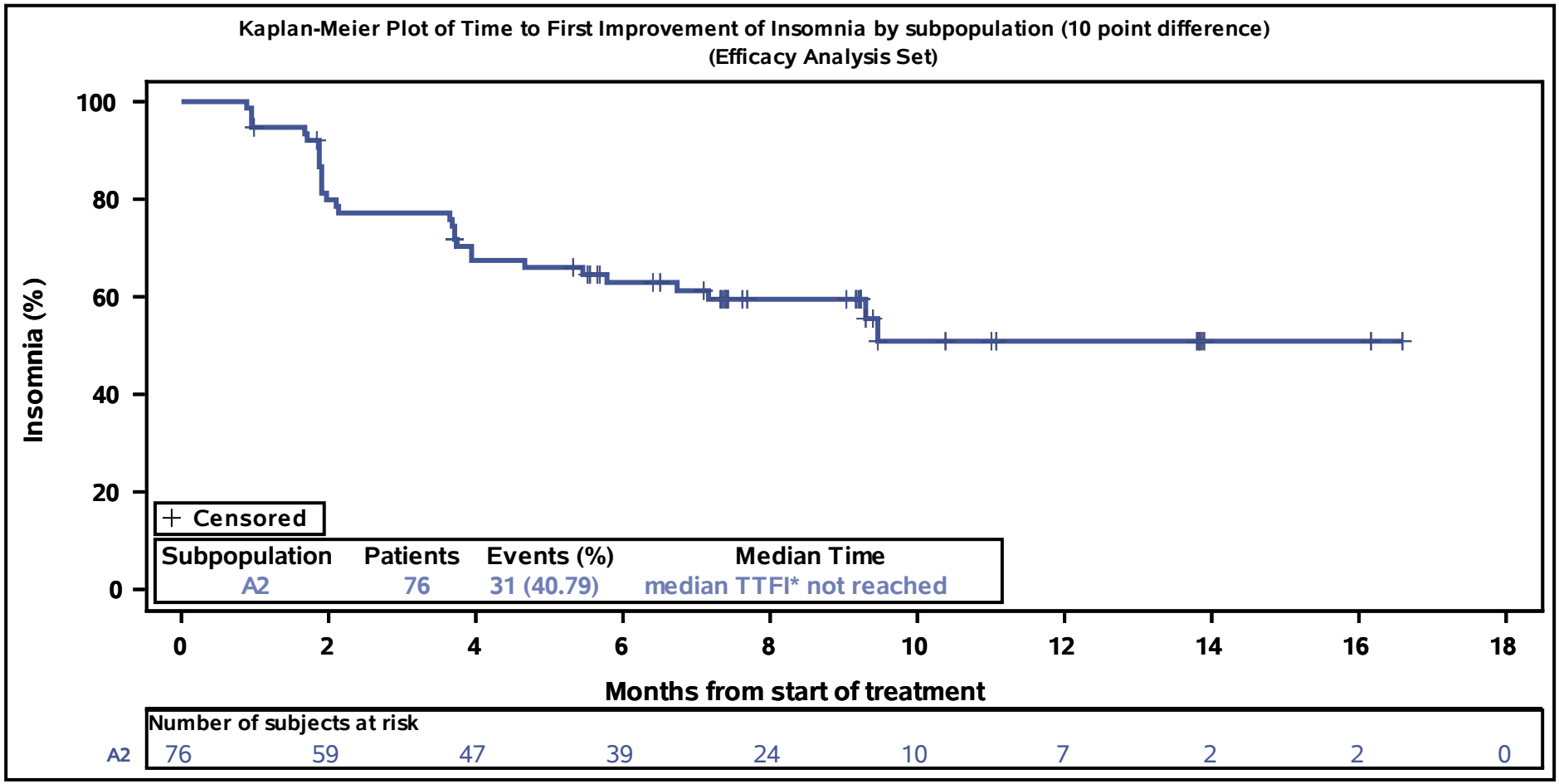
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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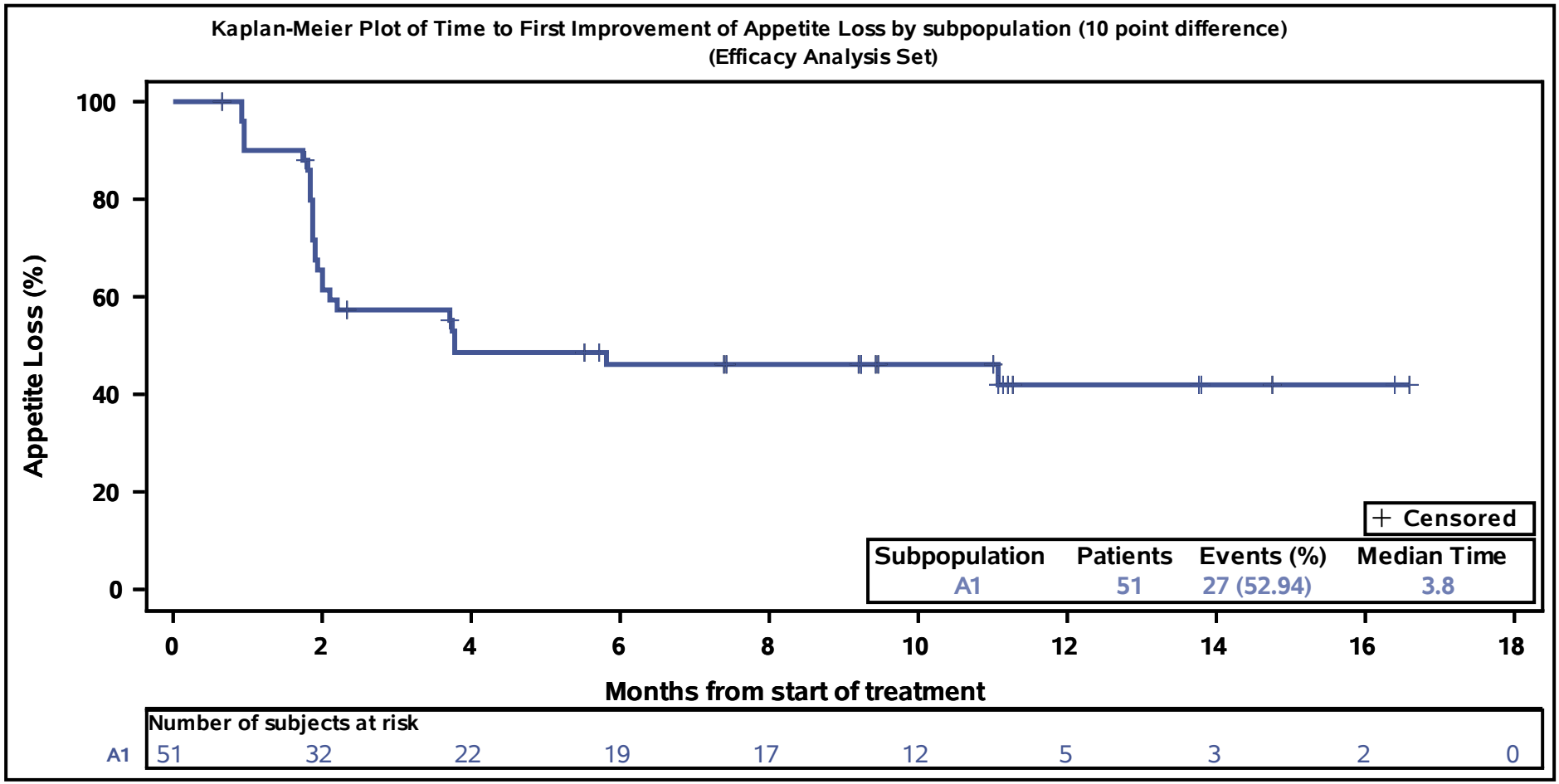
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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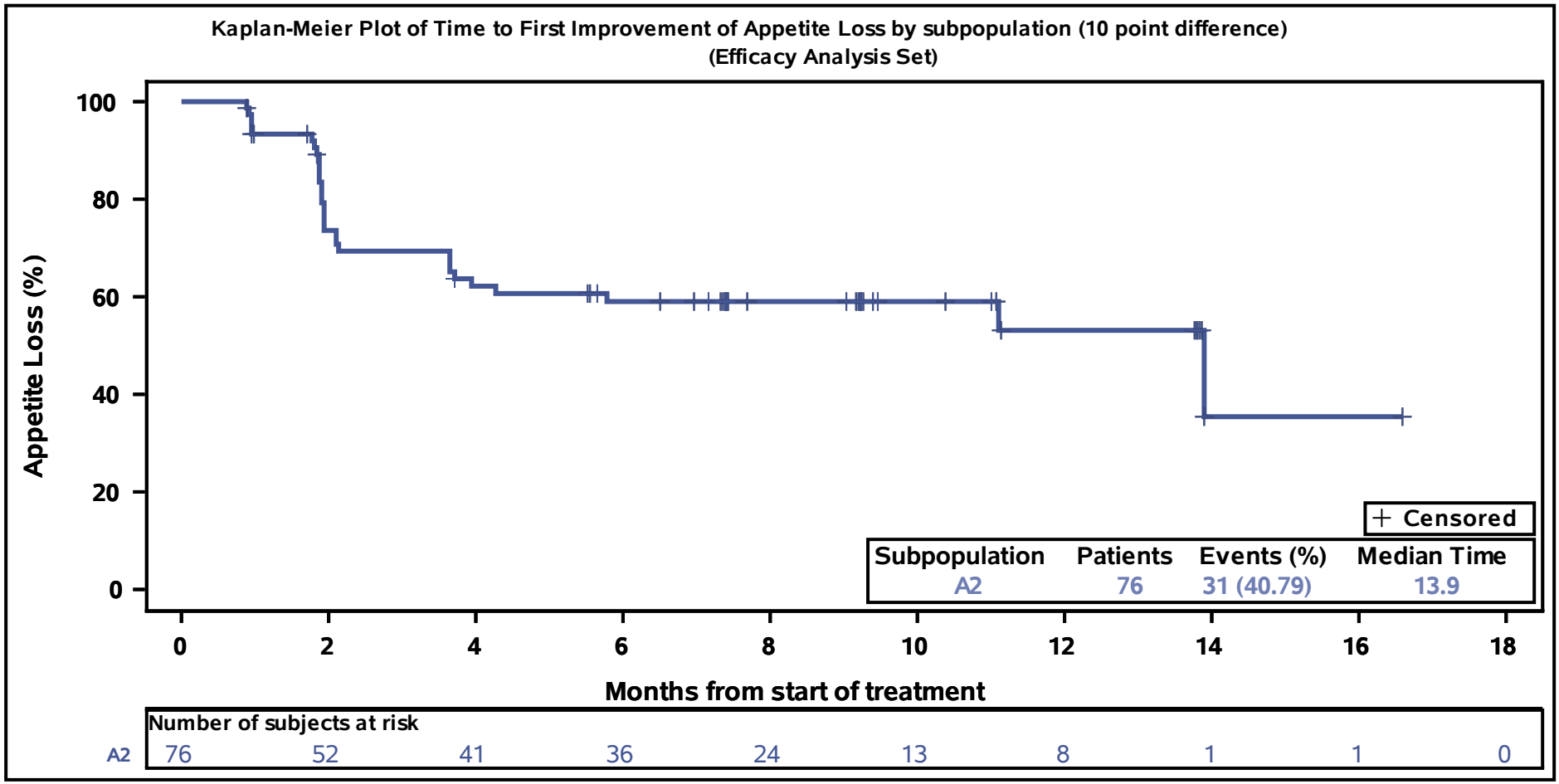

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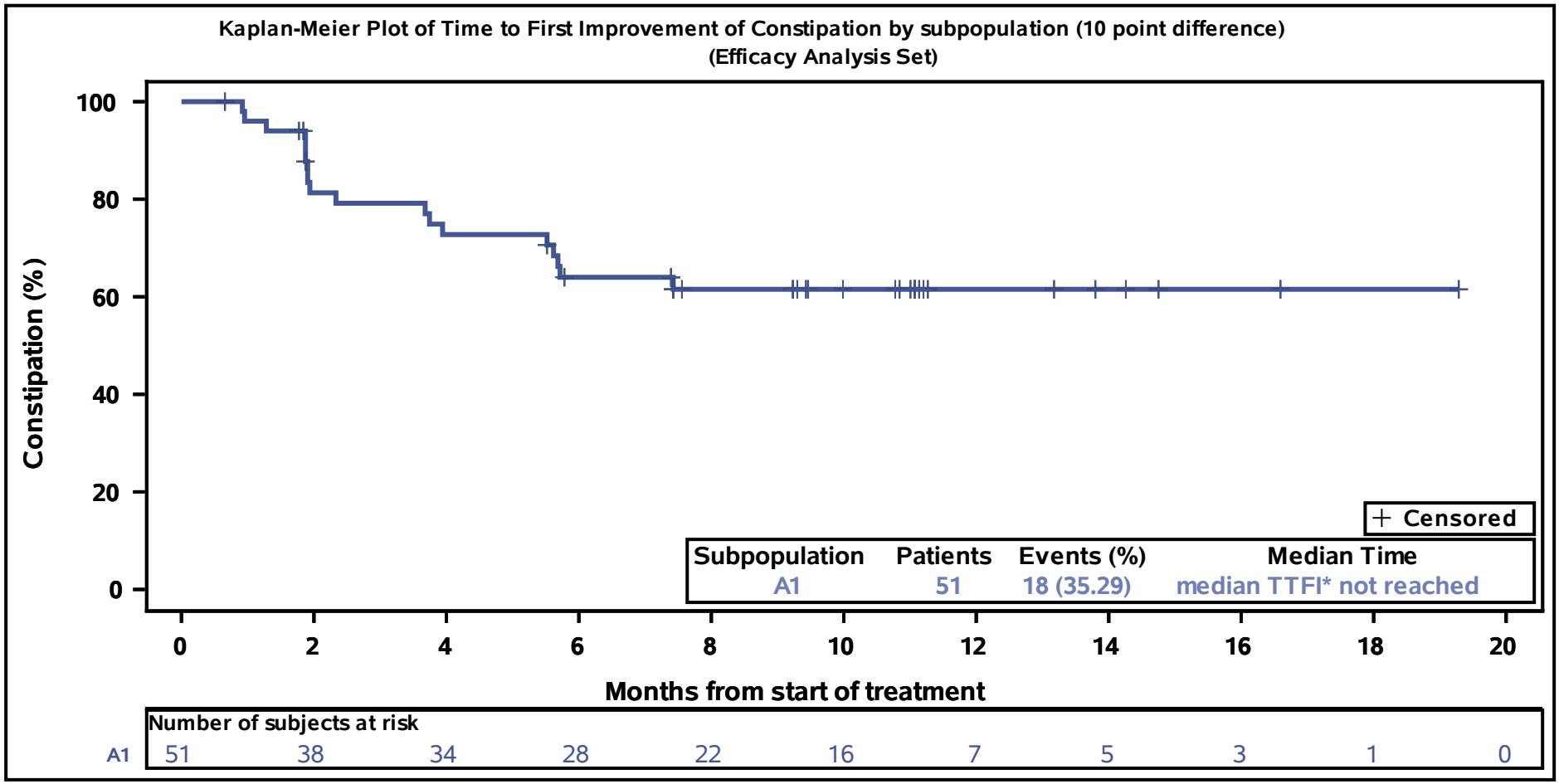

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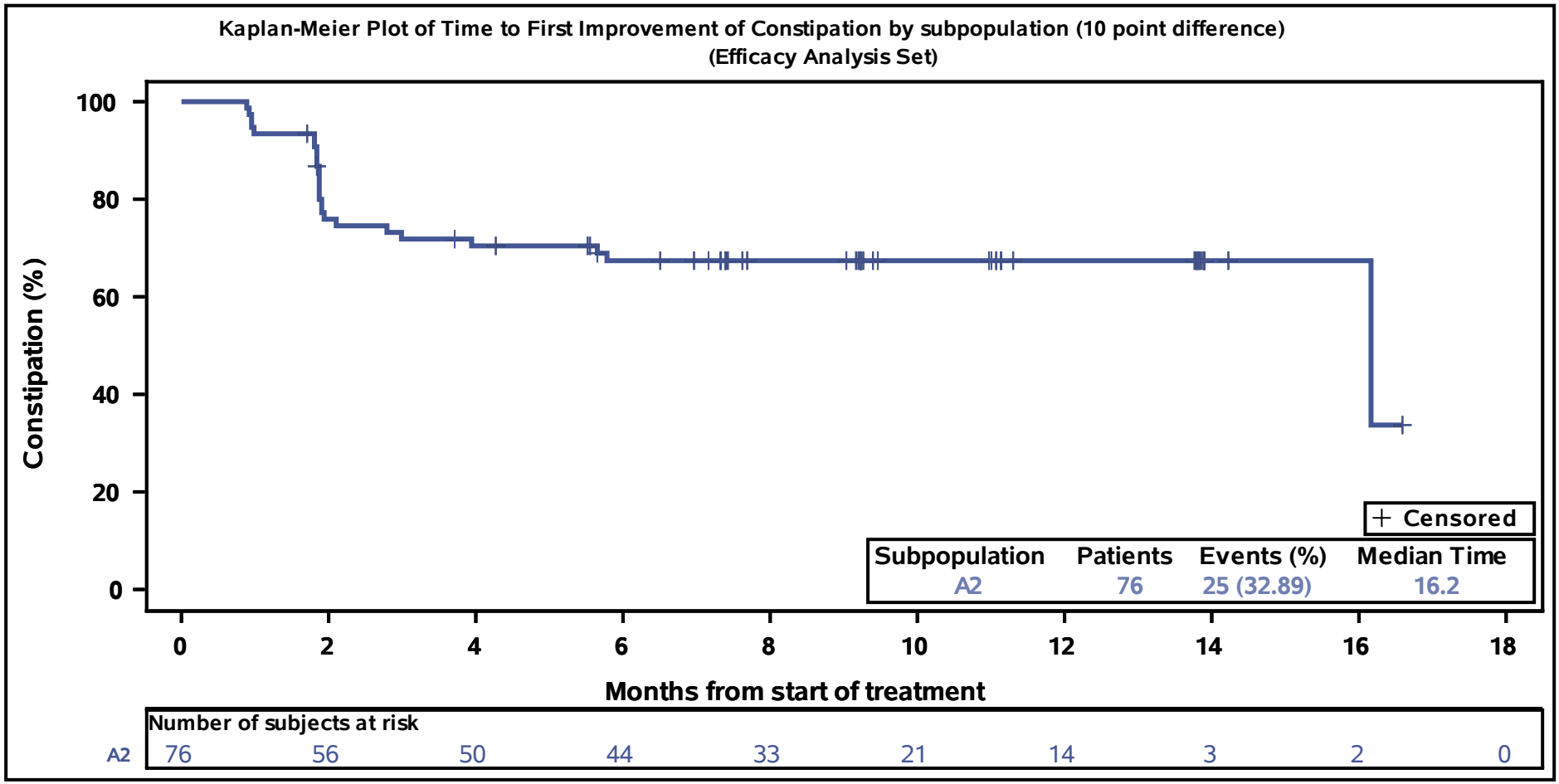

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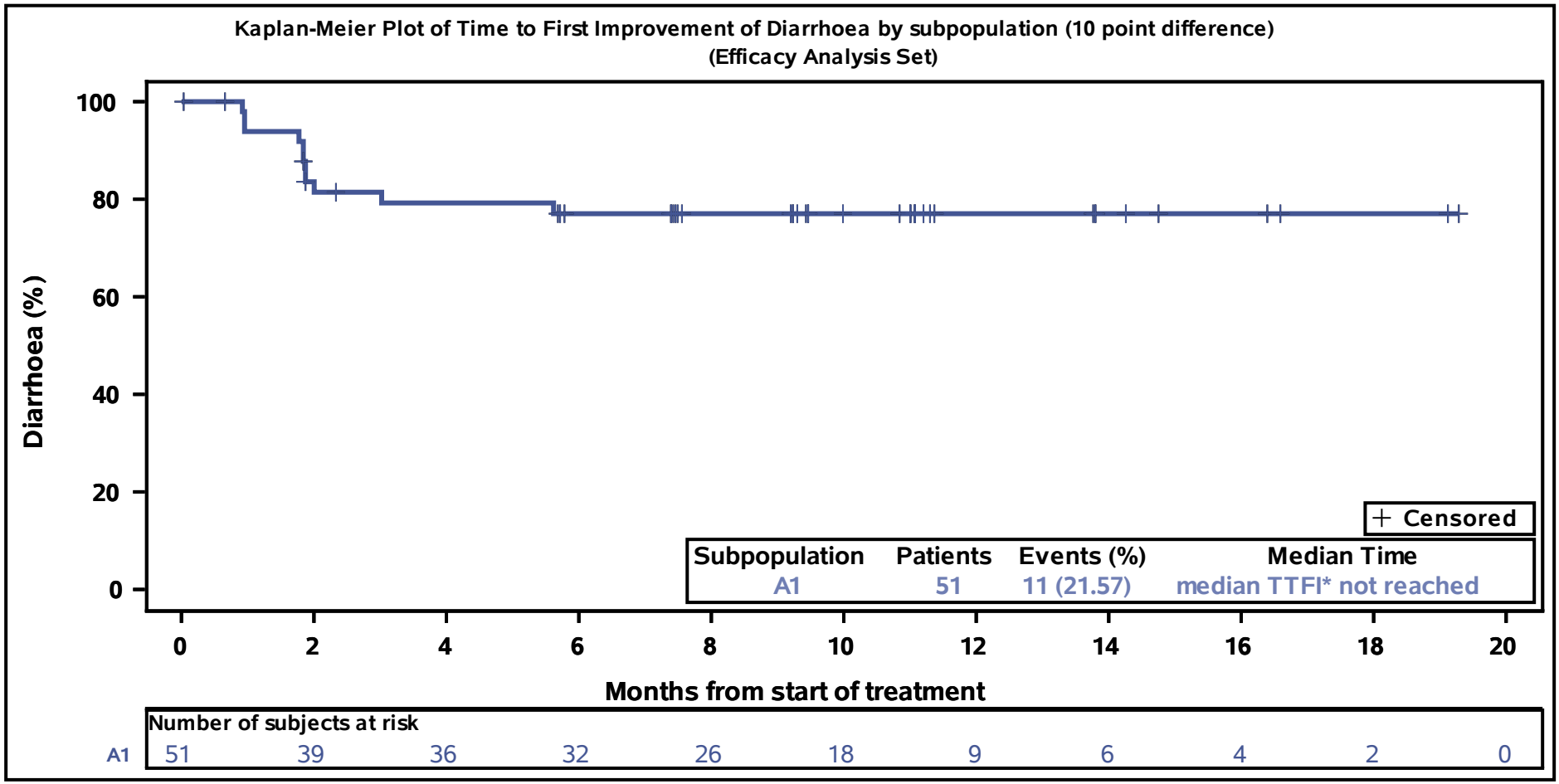

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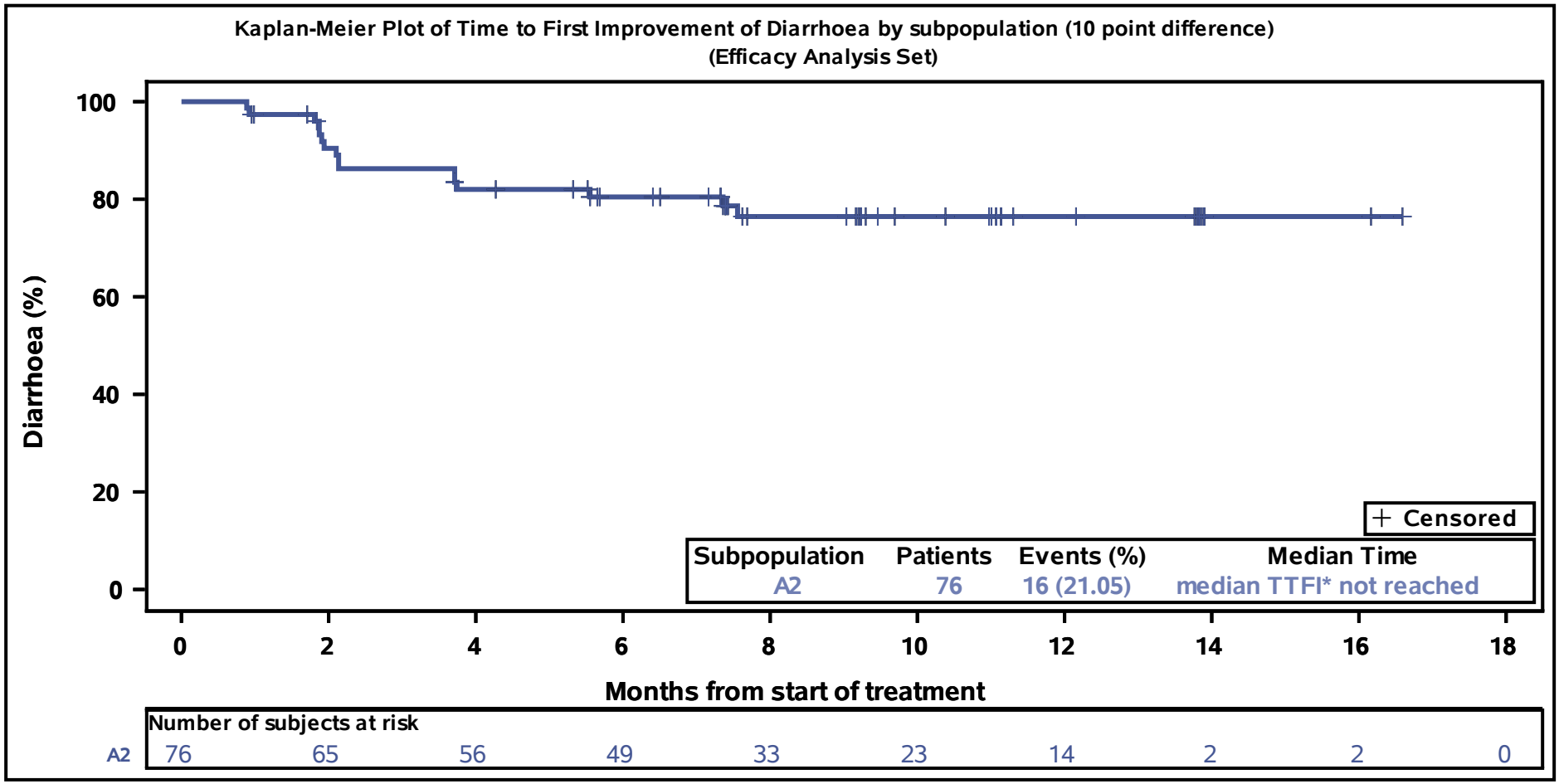

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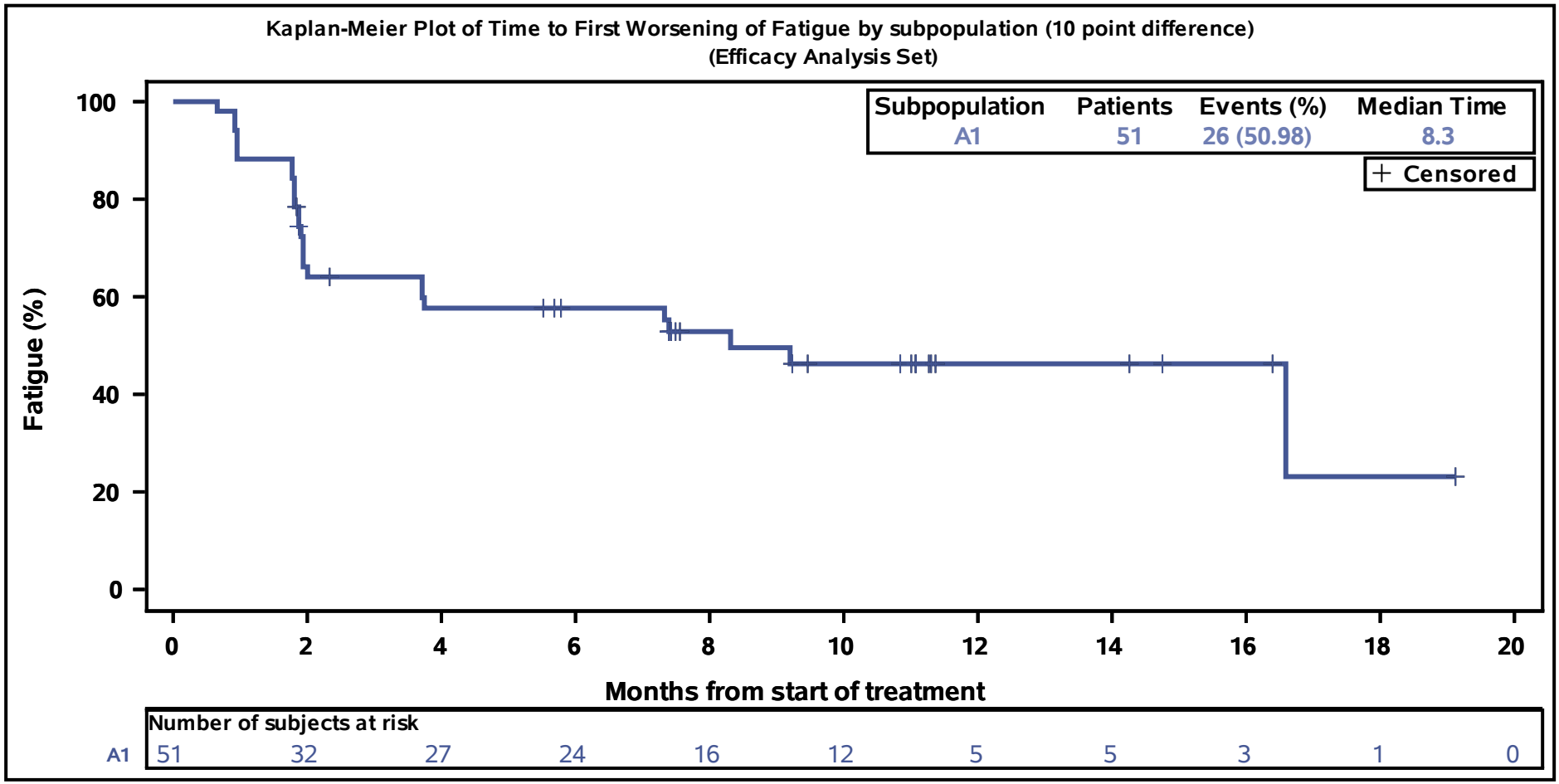

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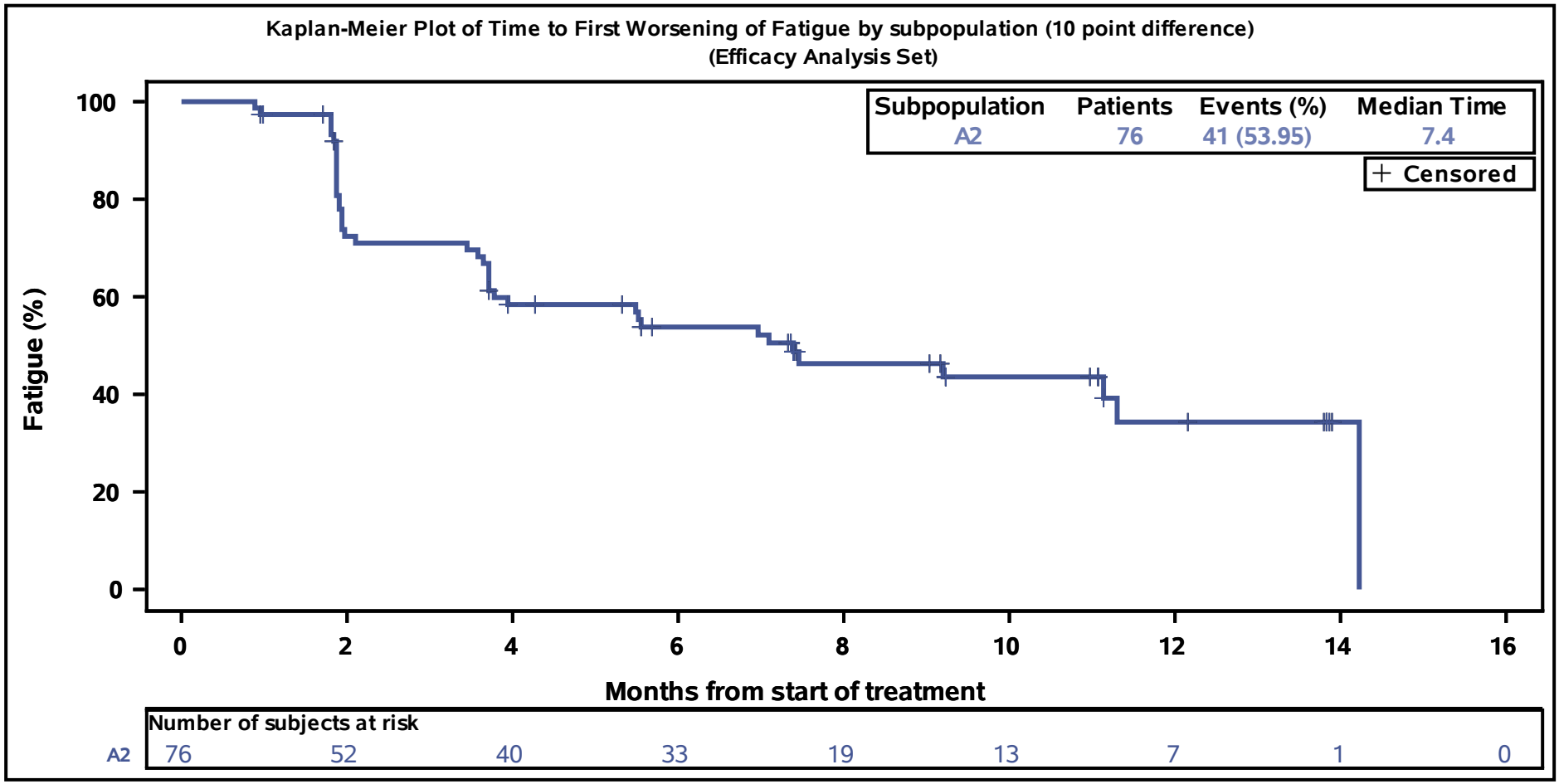

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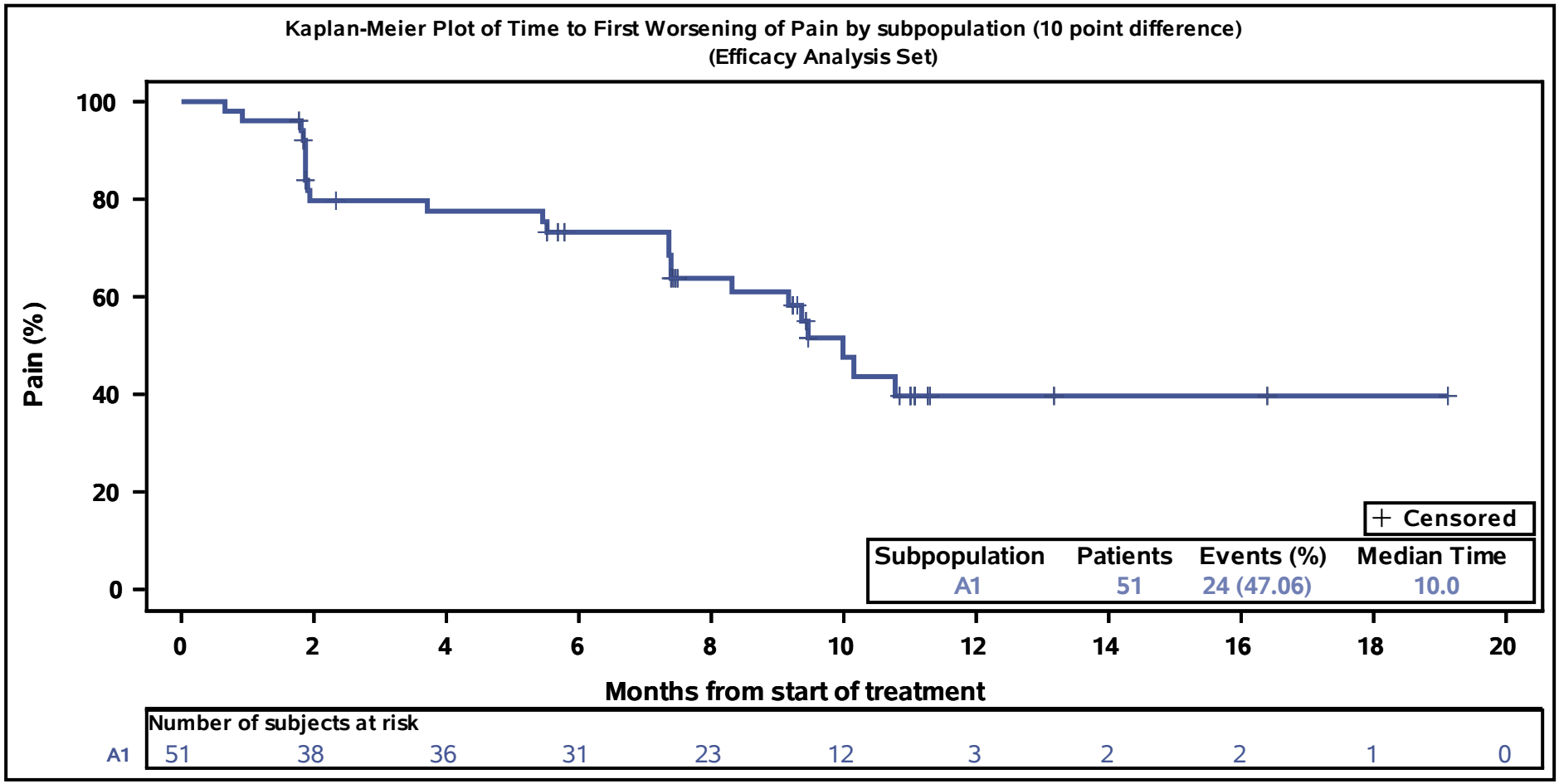

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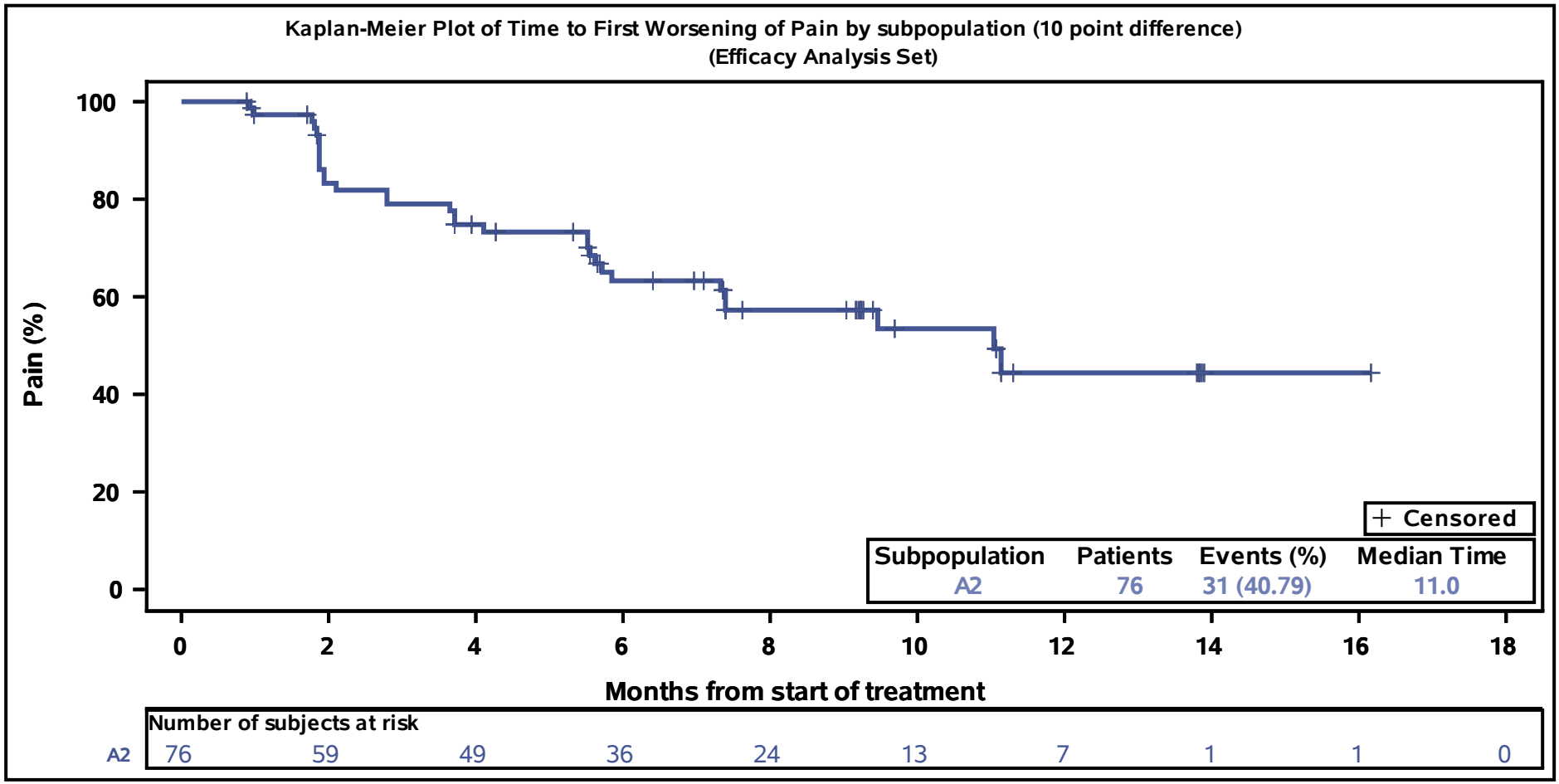

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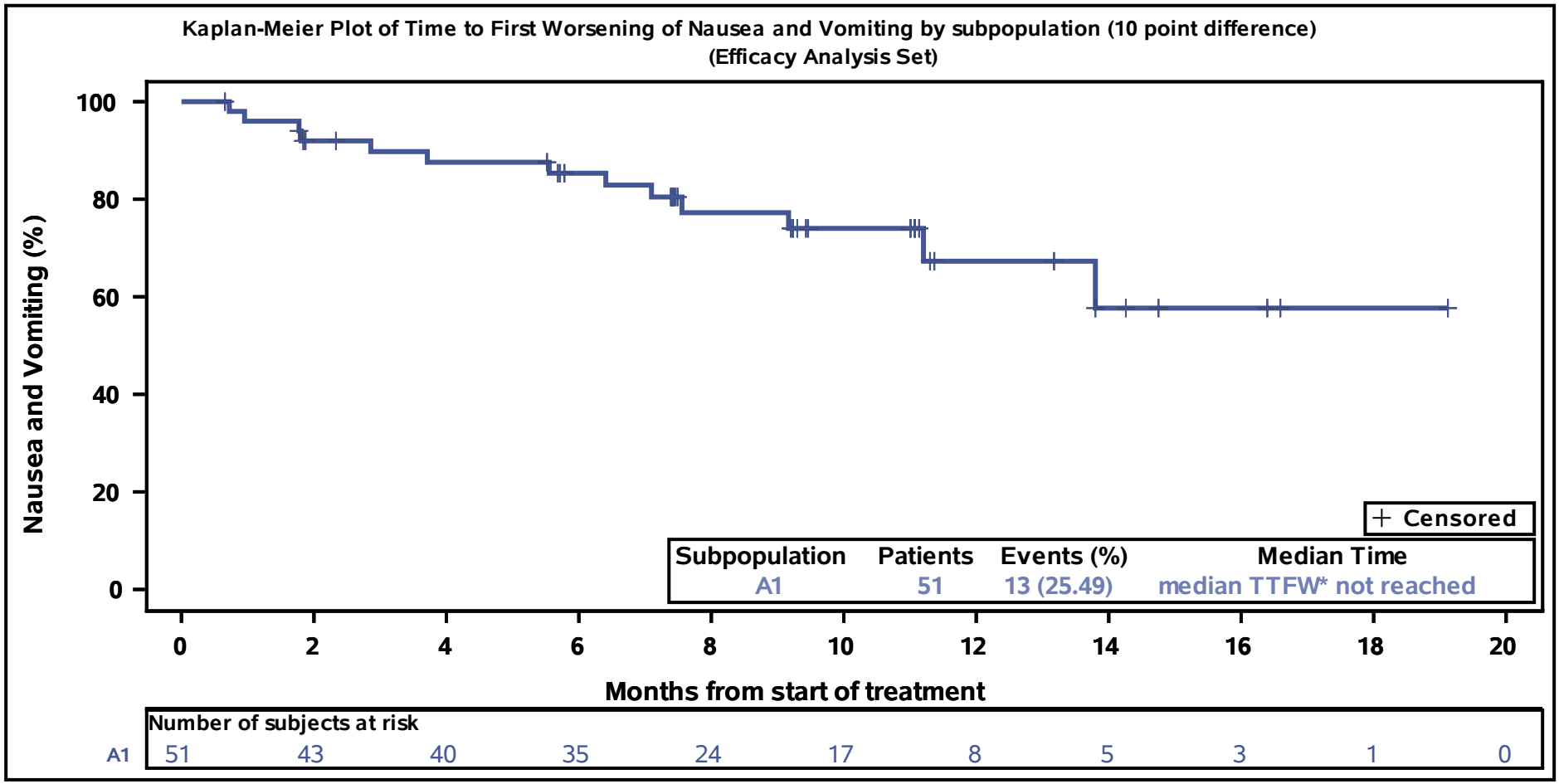

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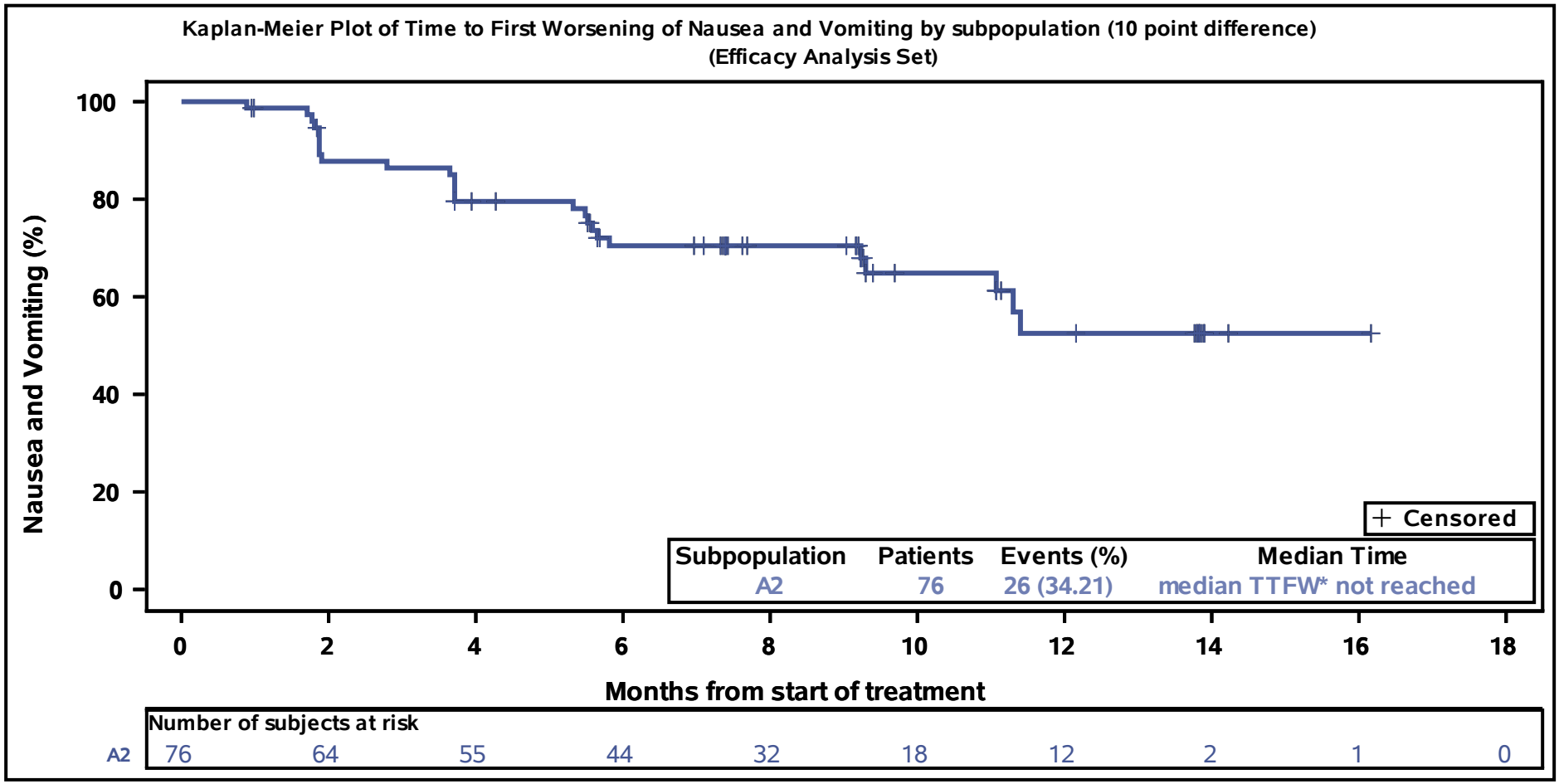

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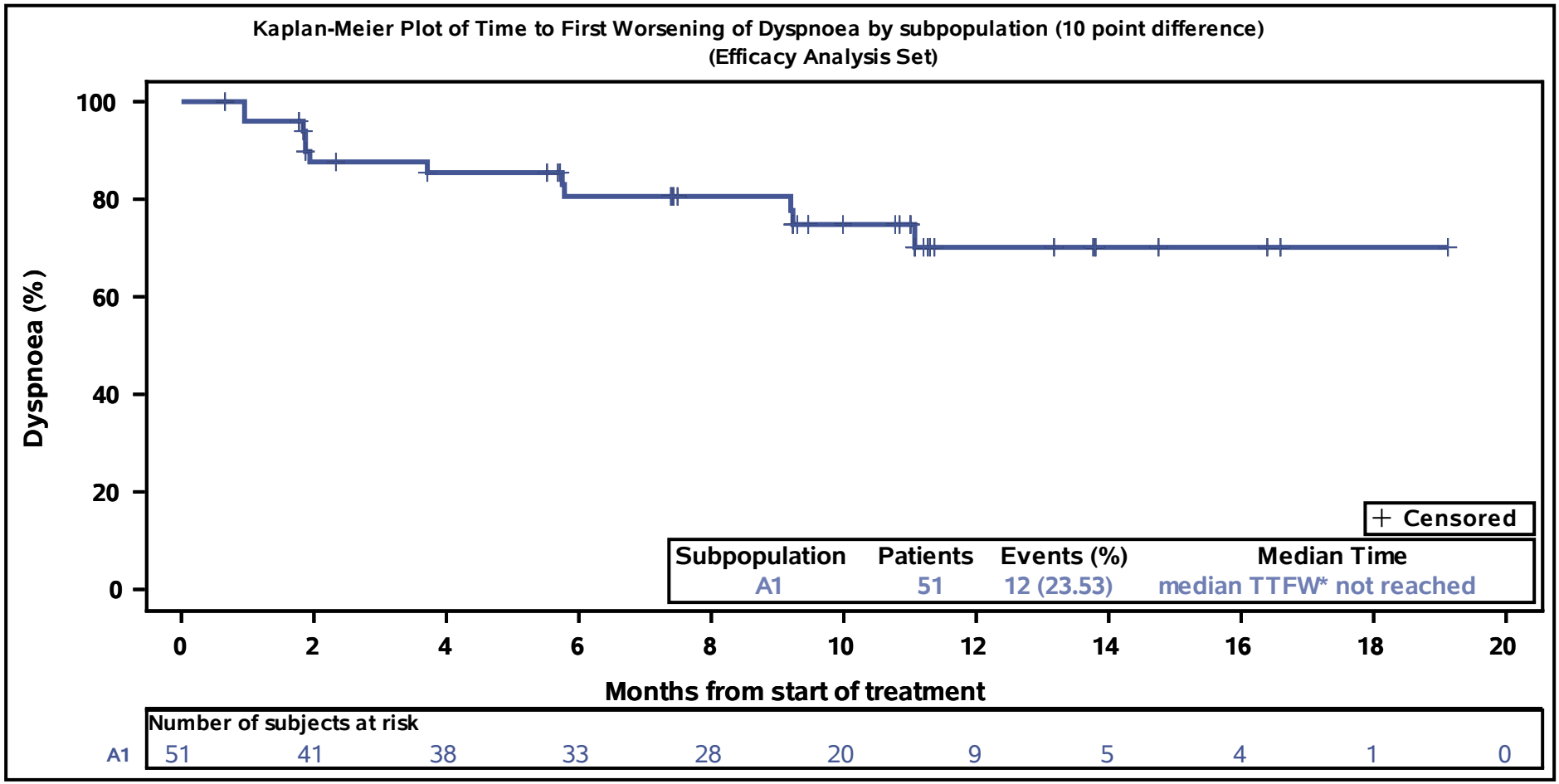

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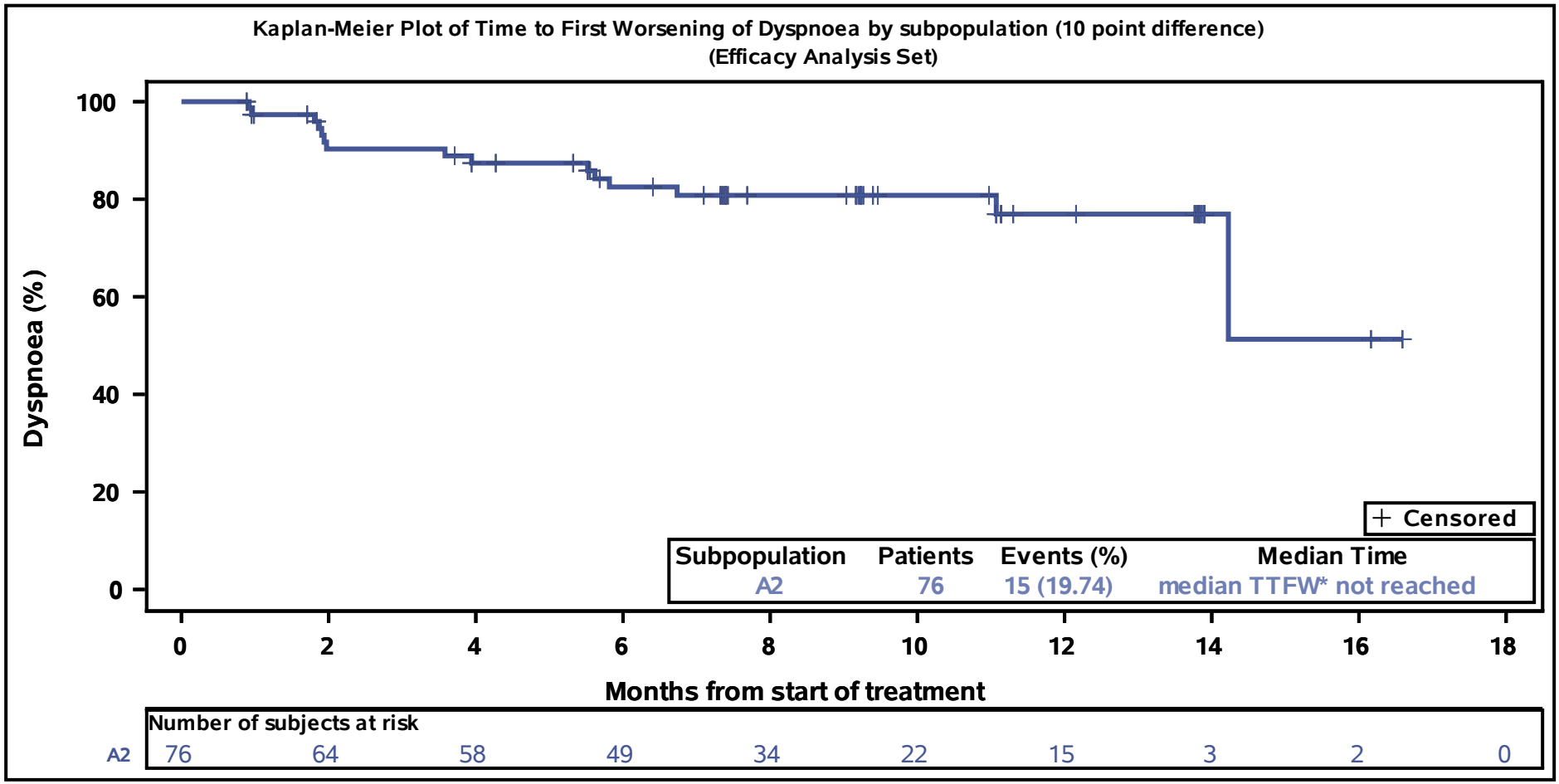

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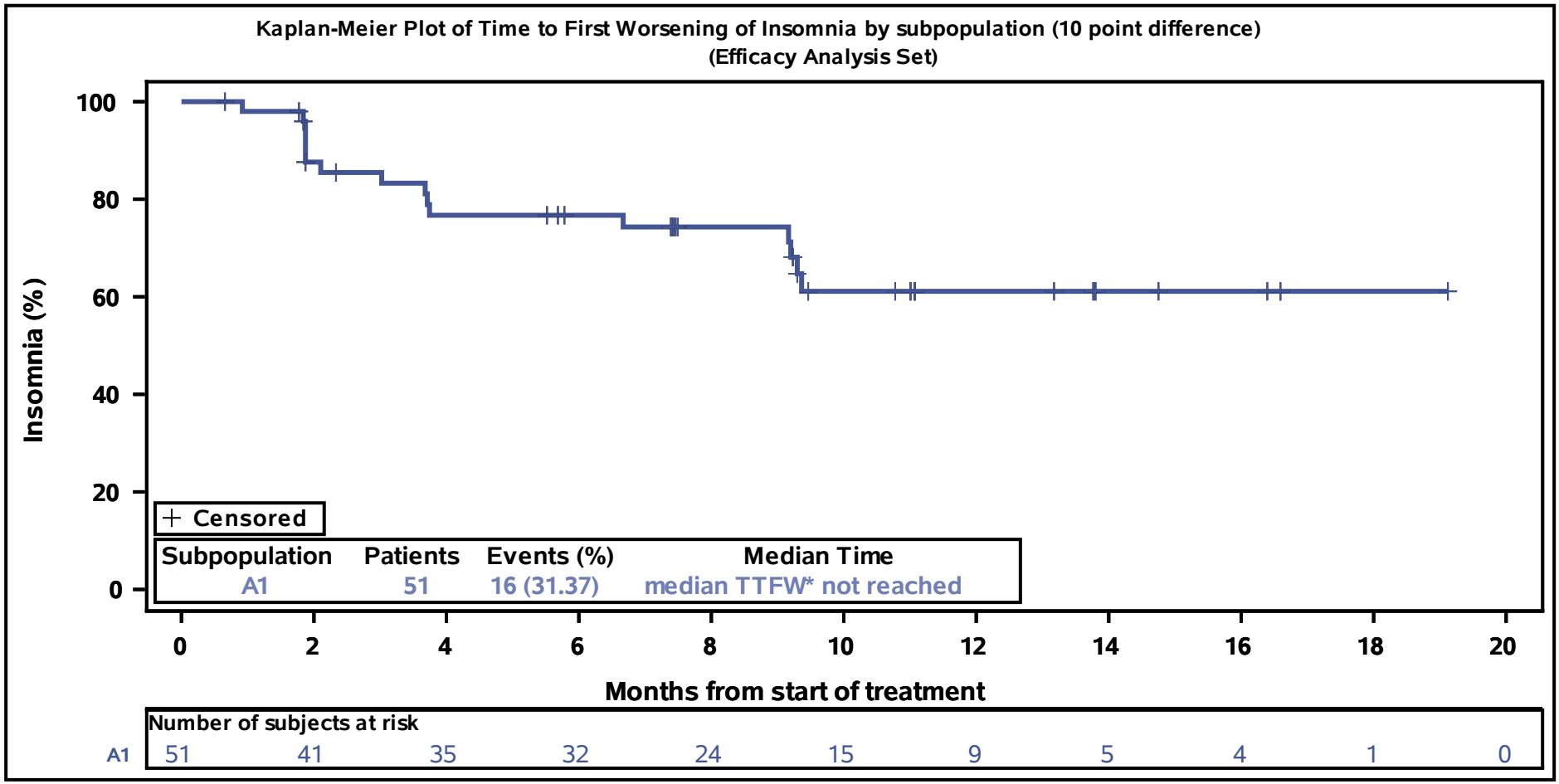

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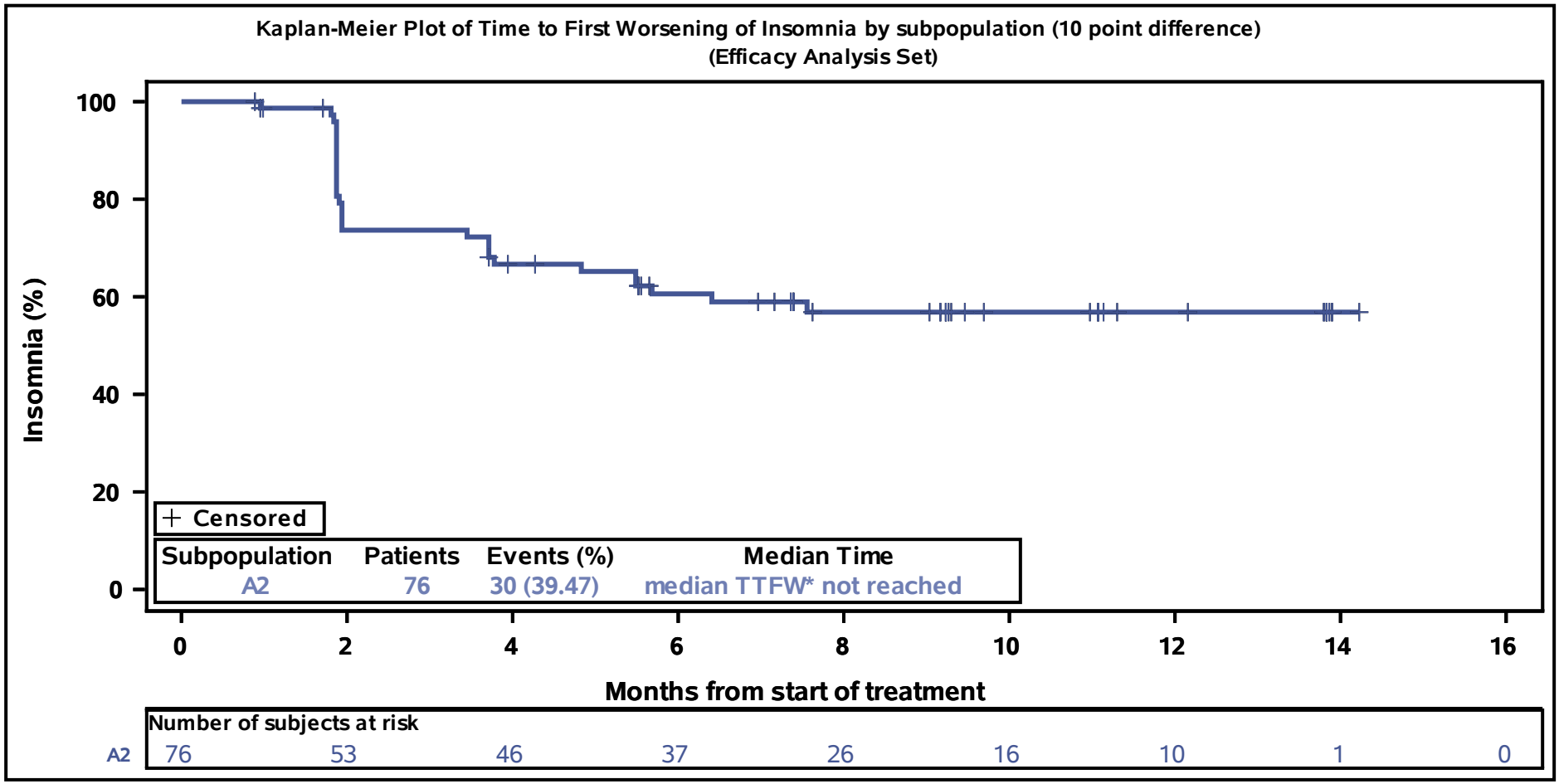

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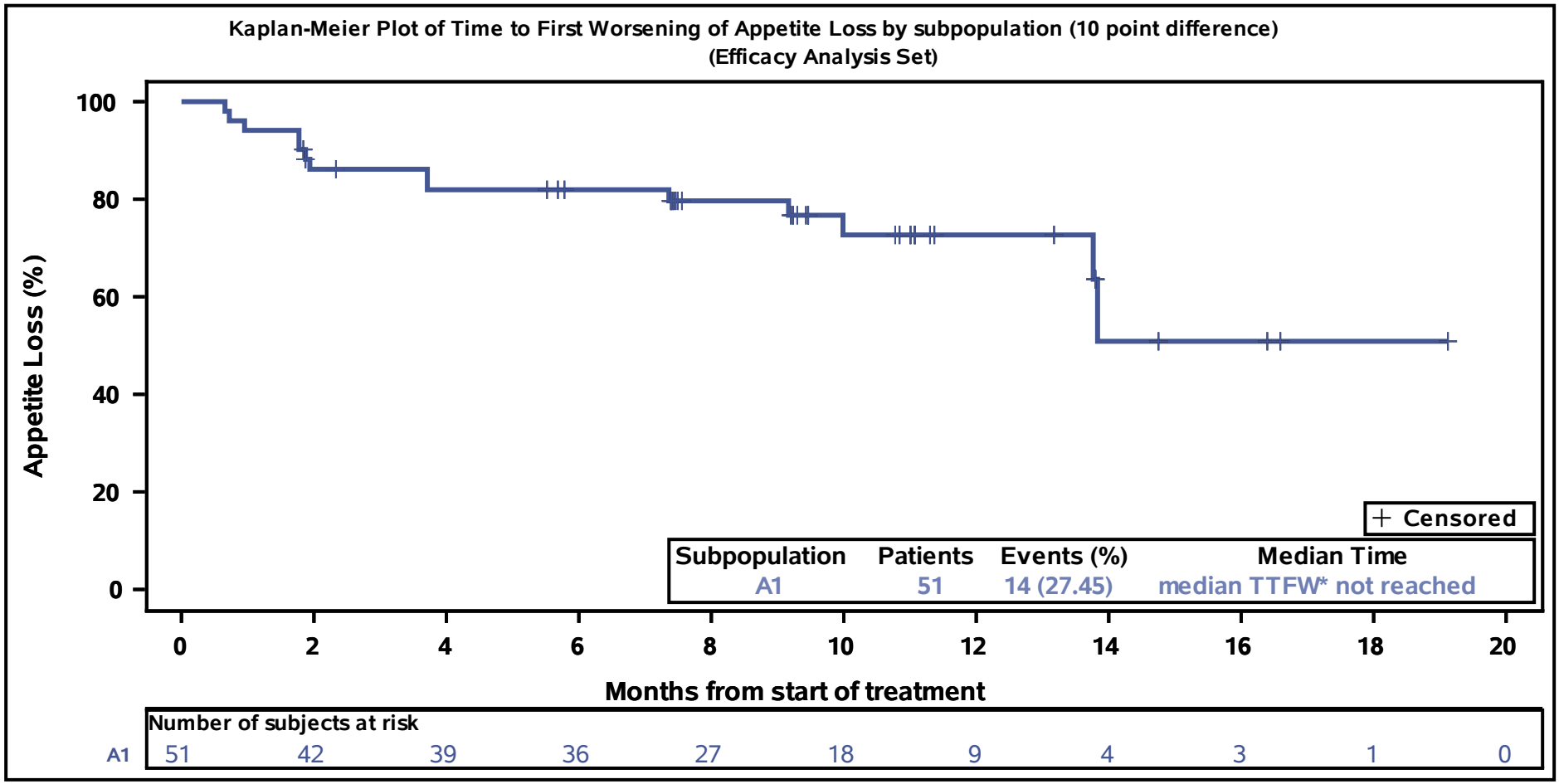

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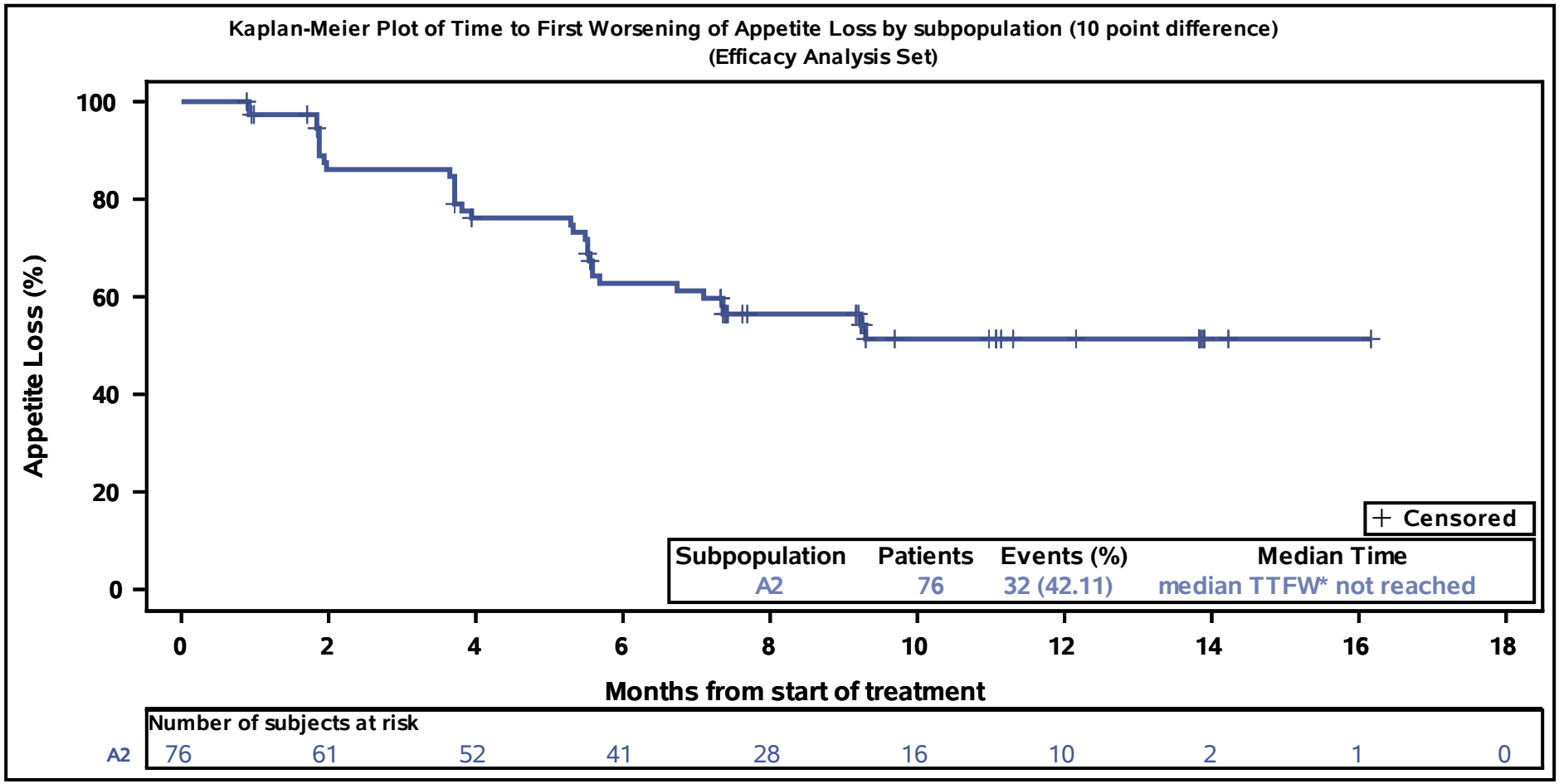

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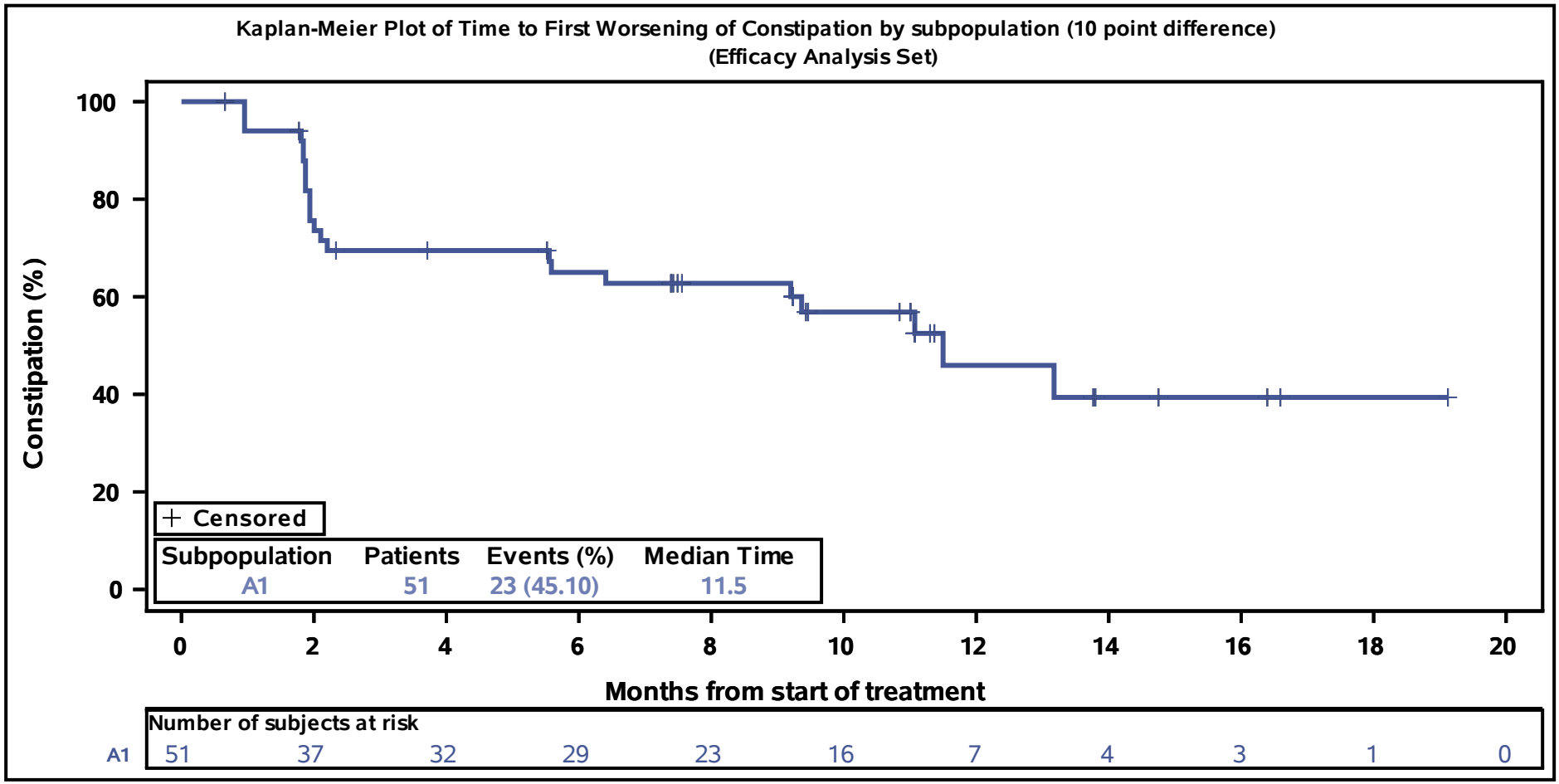

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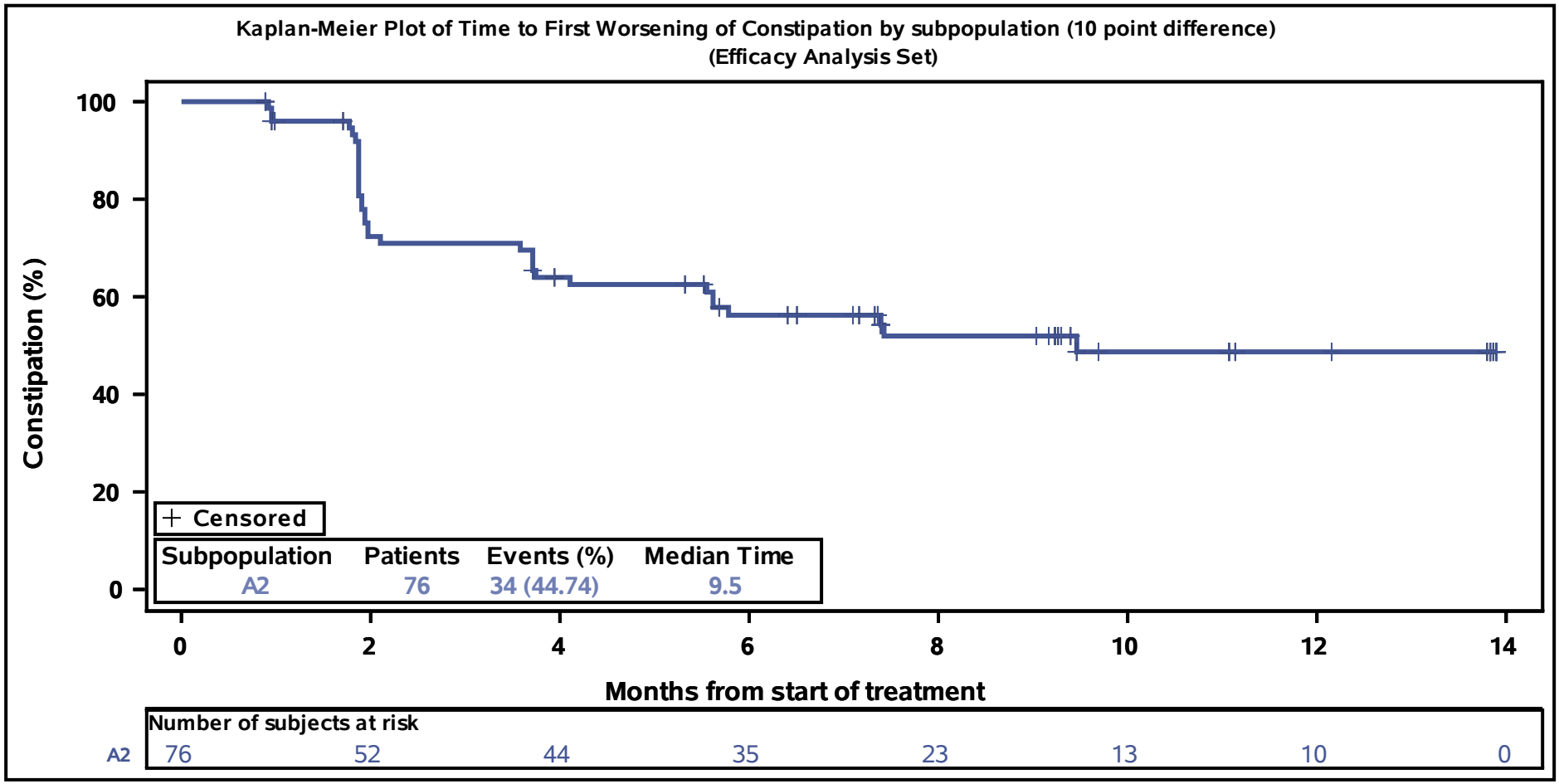

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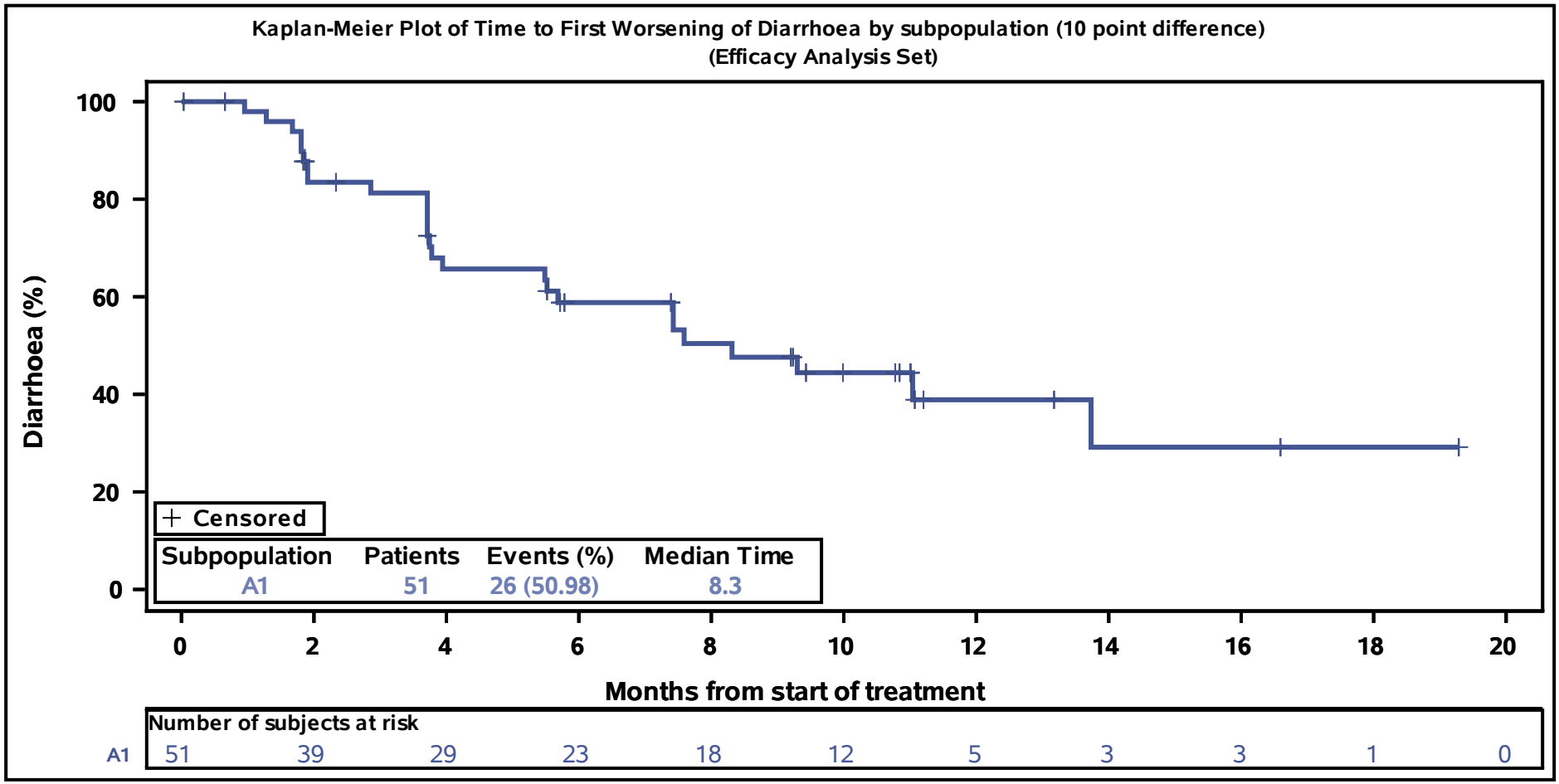
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



* 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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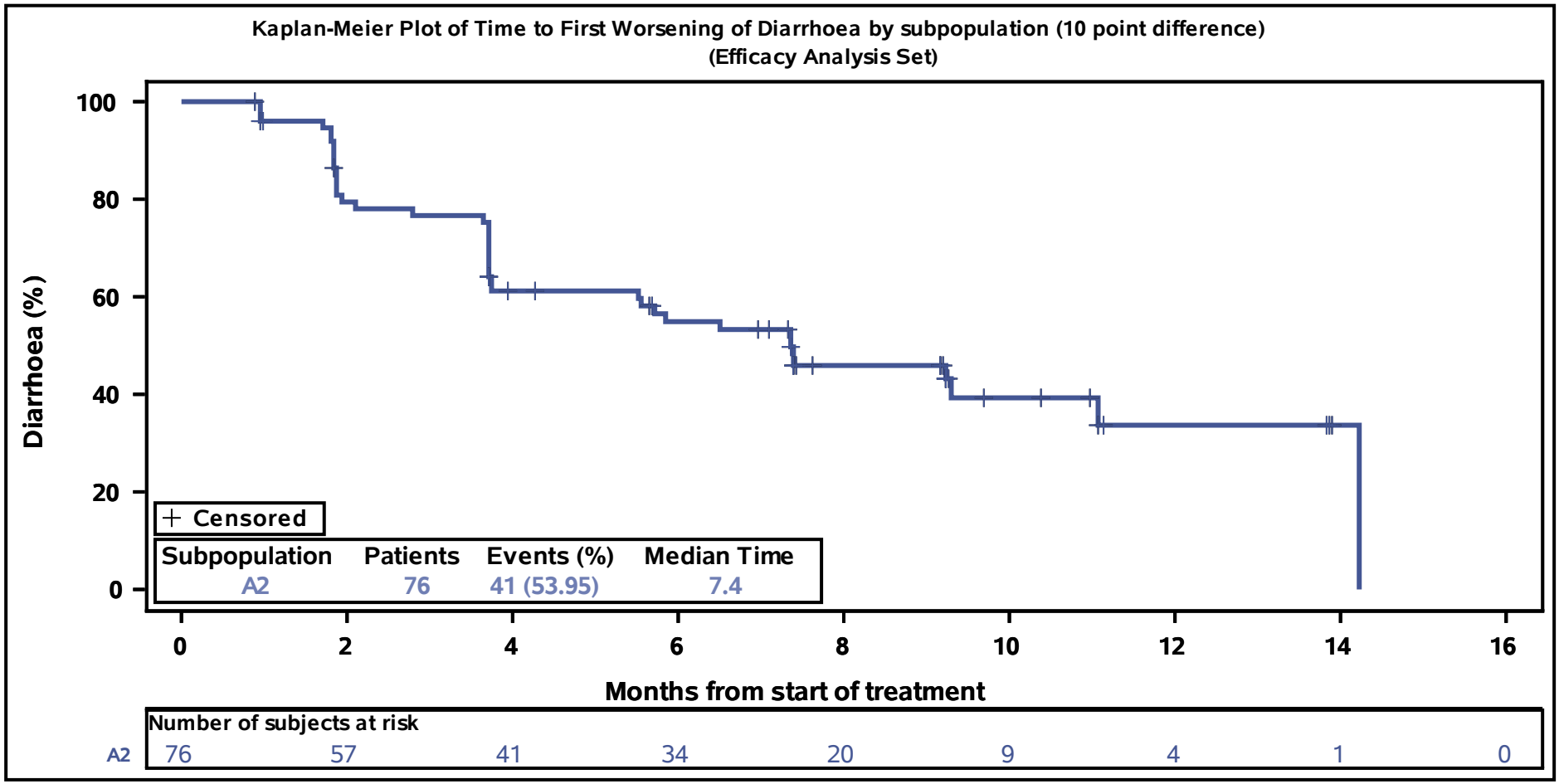

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Tabelle 032: Ergebnisse für die Zeit bis zur ersten Verbesserung bzw. Verschlechterung der gesundheitsbezogenen Lebensqualität gemessen anhand des EORTC QLQ-C30 in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion;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

	Selpercatinib	
Endpunkt	**Subpopulation A1 - NSCLC 2L (N'=78) (N=78)**	**Subpopulation A2 - NSCLC 3L (N'=158) (N=158)**
EORTC QLQ-C30 - Globaler Gesundheitsstatus	51	76
Patienten mit Ereignis		
Verbesserung, n (%)	32 (62,7)	46 (60,5)
Zensierte Patienten, n (%)	19 (37,3)	30 (39,5)
Verschlechterung, n (%)	23 (45,1)	30 (39,5)
Zensierte Patienten, n (%)	28 (54,9)	46 (60,5)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	3,7 [1,91; 5,72]	3,7 [1,94; 7,62]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	11,3 [5,78; NE]	14,2 [7,36; NE]
EORTC QLQ-C30 – Funktionsskalen		
Physische Funktion	51	76
Patienten mit Ereignis		
Verbesserung, n (%)	20 (39,2)	36 (47,4)
Zensierte Patienten, n (%)	31 (60,8)	40 (52,6)
Verschlechterung, n (%)	14 (27,5)	34 (44,7)
Zensierte Patienten, n (%)	37 (72,5)	42 (55,3)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [3,75; NE]	13,8 [3,75; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	16,6 [11,30; NE]	11,1 [6,97; NE]
Emotionale Funktion	51	76
Patienten mit Ereignis		
Verbesserung, n (%)	18 (35,3)	29 (38,2)
Zensierte Patienten, n (%)	33 (64,7)	47 (61,8)
Verschlechterung, n (%)	20 (39,2)	24 (31,6)
Zensierte Patienten, n (%)	31 (60,8)	52 (68,4)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [3,94; NE]	13,8 [9,23; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	11,3 [7,49; NE]	14,2 [9,30; NE]
Rollenfunktion	51	76
Patienten mit Ereignis		
Verbesserung, n (%)	23 (45,1)	42 (55,3)
Zensierte Patienten, n (%)	28 (54,9)	34 (44,7)
Verschlechterung, n (%)	24 (47,1)	40 (52,6)
Zensierte Patienten, n (%)	27 (52,9)	36 (47,4)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [2,10; NE]	5,6 [2,14; NE]

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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: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

	Selpercatinib	
Endpunkt	**Subpopulation A1 - NSCLC 2L (N'=78) (N=78)**	**Subpopulation A2 - NSCLC 3L (N'=158) (N=158)**
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	11,3 [5,55; NE]	7,4 [5,49; NE]
Kognitive Funktion	51	76
Patienten mit Ereignis		
Verbesserung, n (%)	21 (41,2)	22 (28,9)
Zensierte Patienten, n (%)	30 (58,8)	54 (71,1)
Verschlechterung, n (%)	29 (56,9)	42 (55,3)
Zensierte Patienten, n (%)	22 (43,1)	34 (44,7)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	13,8 [3,78; NE]	NE [NE; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	8,3 [3,71;13,83]	7,4 [4,11;11,14]
Soziale Funktion	51	76
Patienten mit Ereignis		
Verbesserung, n (%)	29 (56,9)	36 (47,4)
Zensierte Patienten, n (%)	22 (43,1)	40 (52,6)
Verschlechterung, n (%)	18 (35,3)	39 (51,3)
Zensierte Patienten, n (%)	33 (64,7)	37 (48,7)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	3,7 [2,10; NE]	9,2 [3,68; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	NE [8,31; NE]	7,4 [5,55; NE]

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; 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; NSCLC: nicht-kleinzelliges Lungenkarzinom; 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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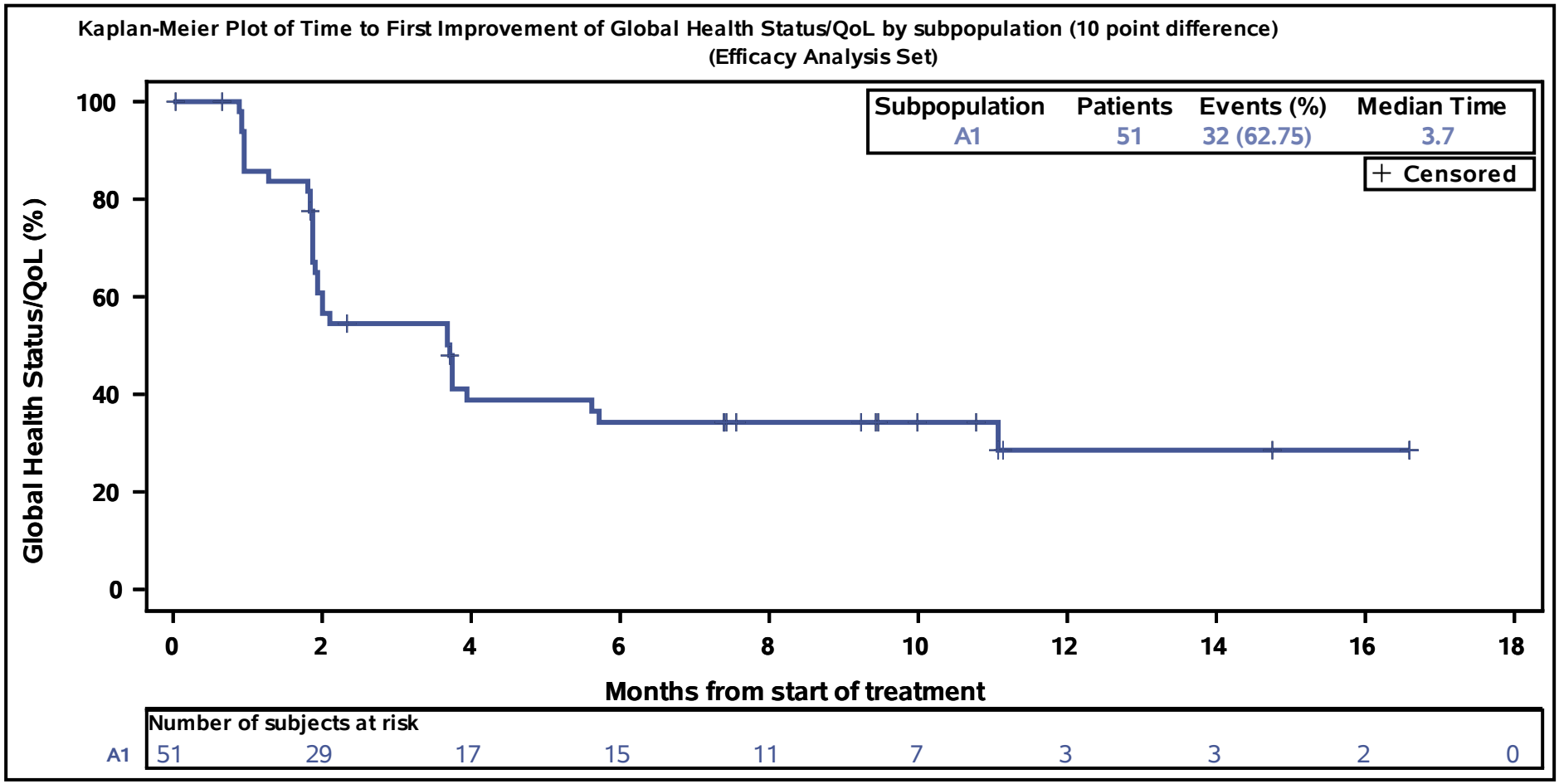
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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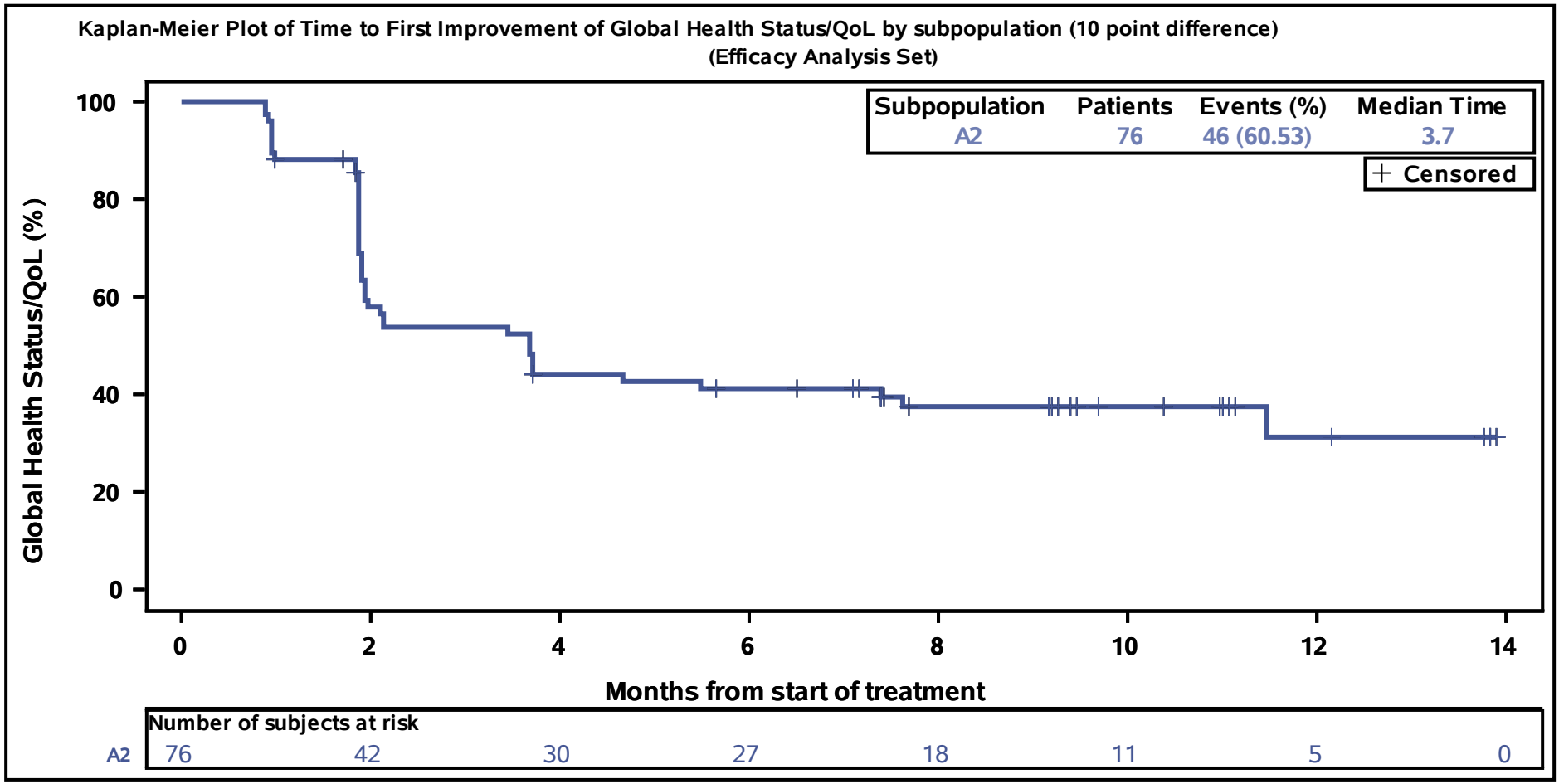

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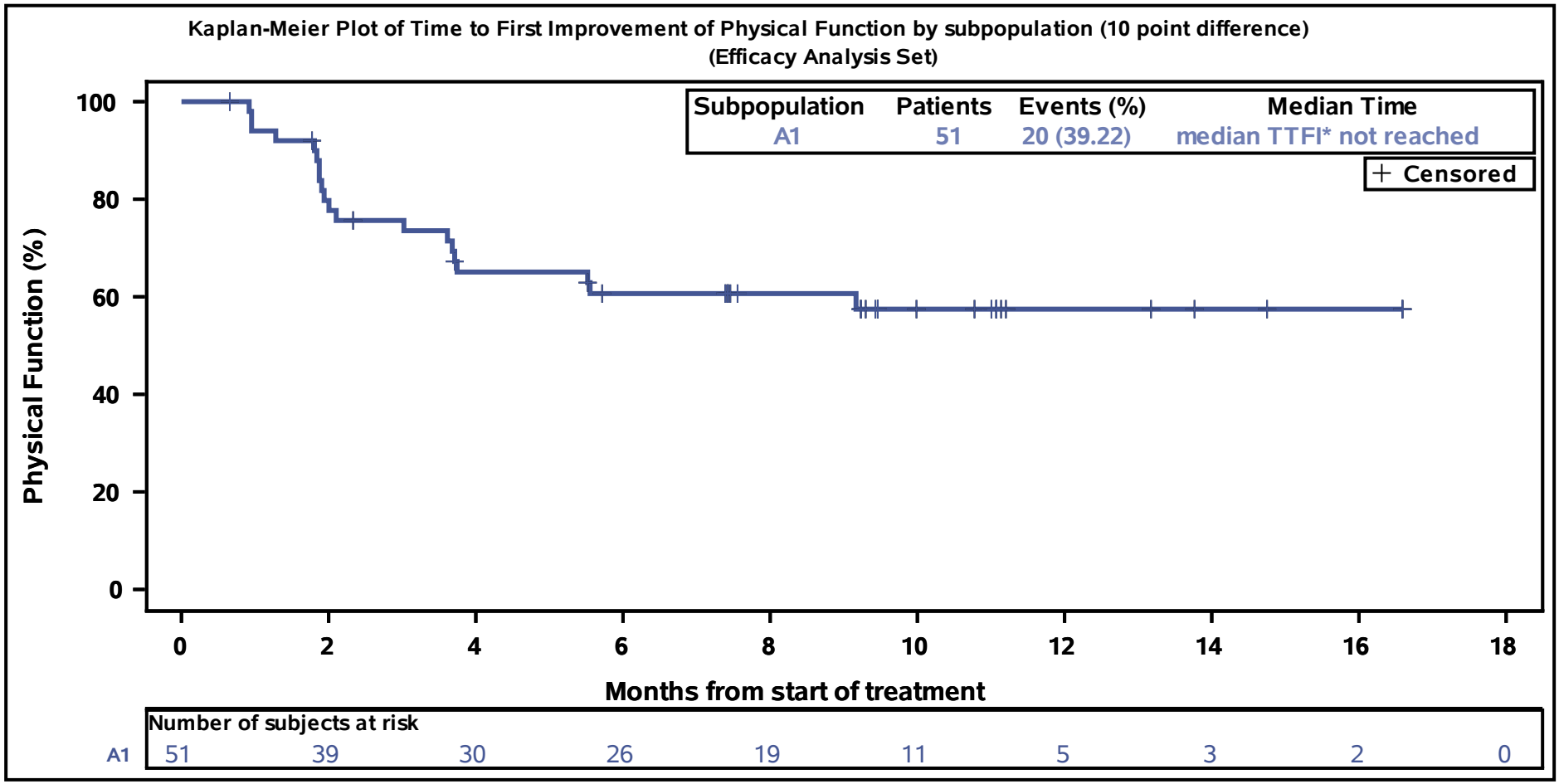

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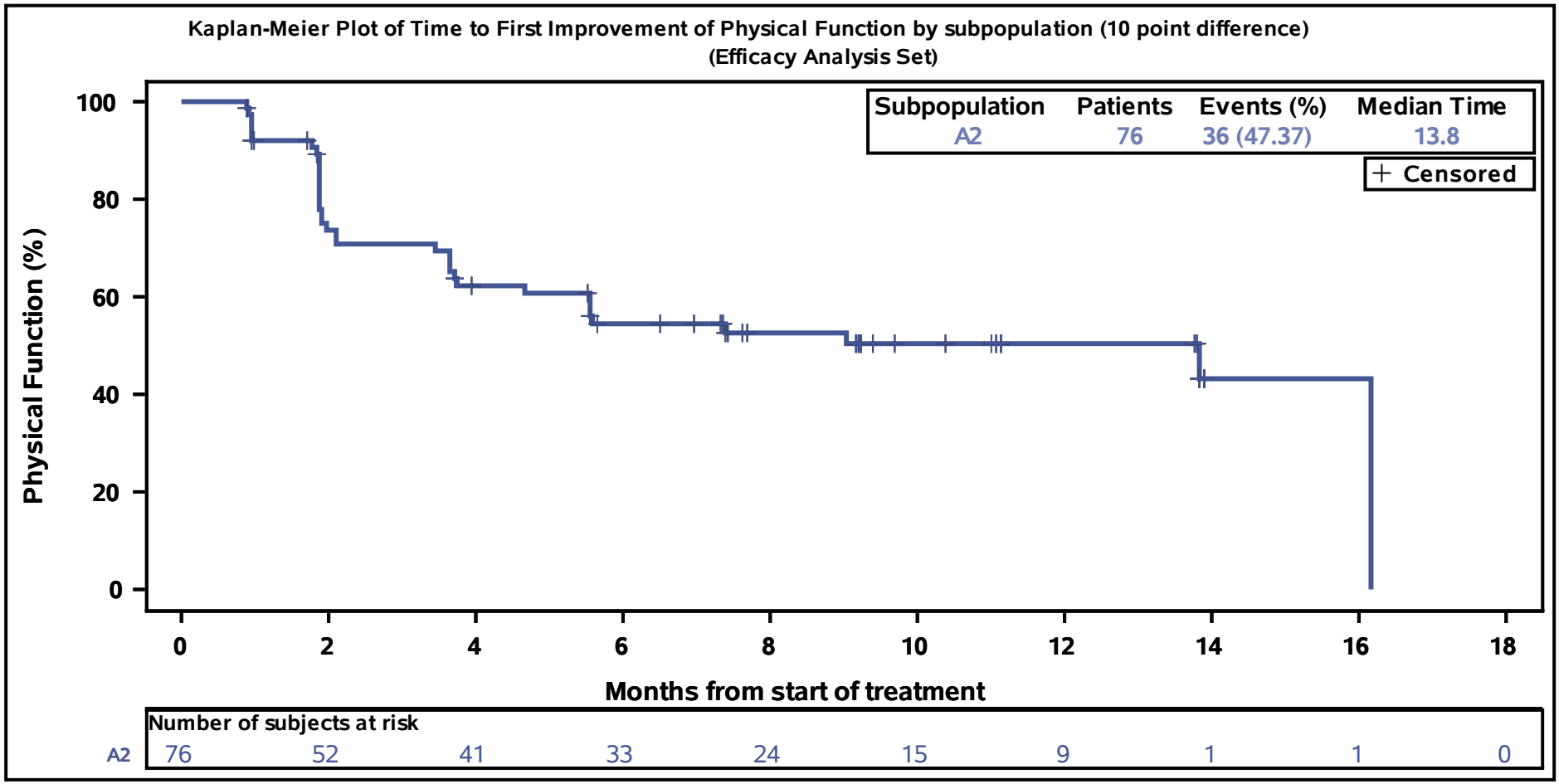

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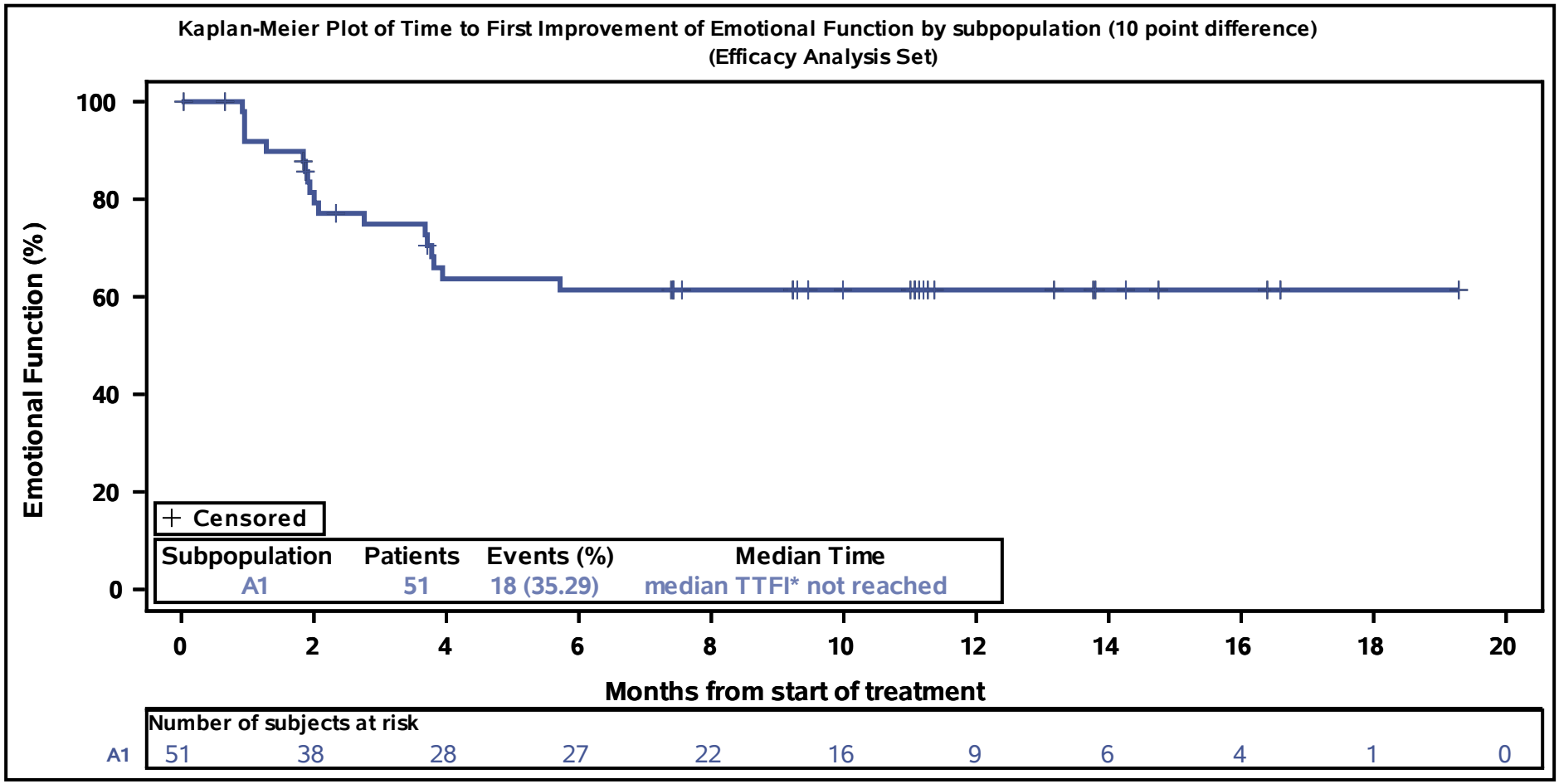

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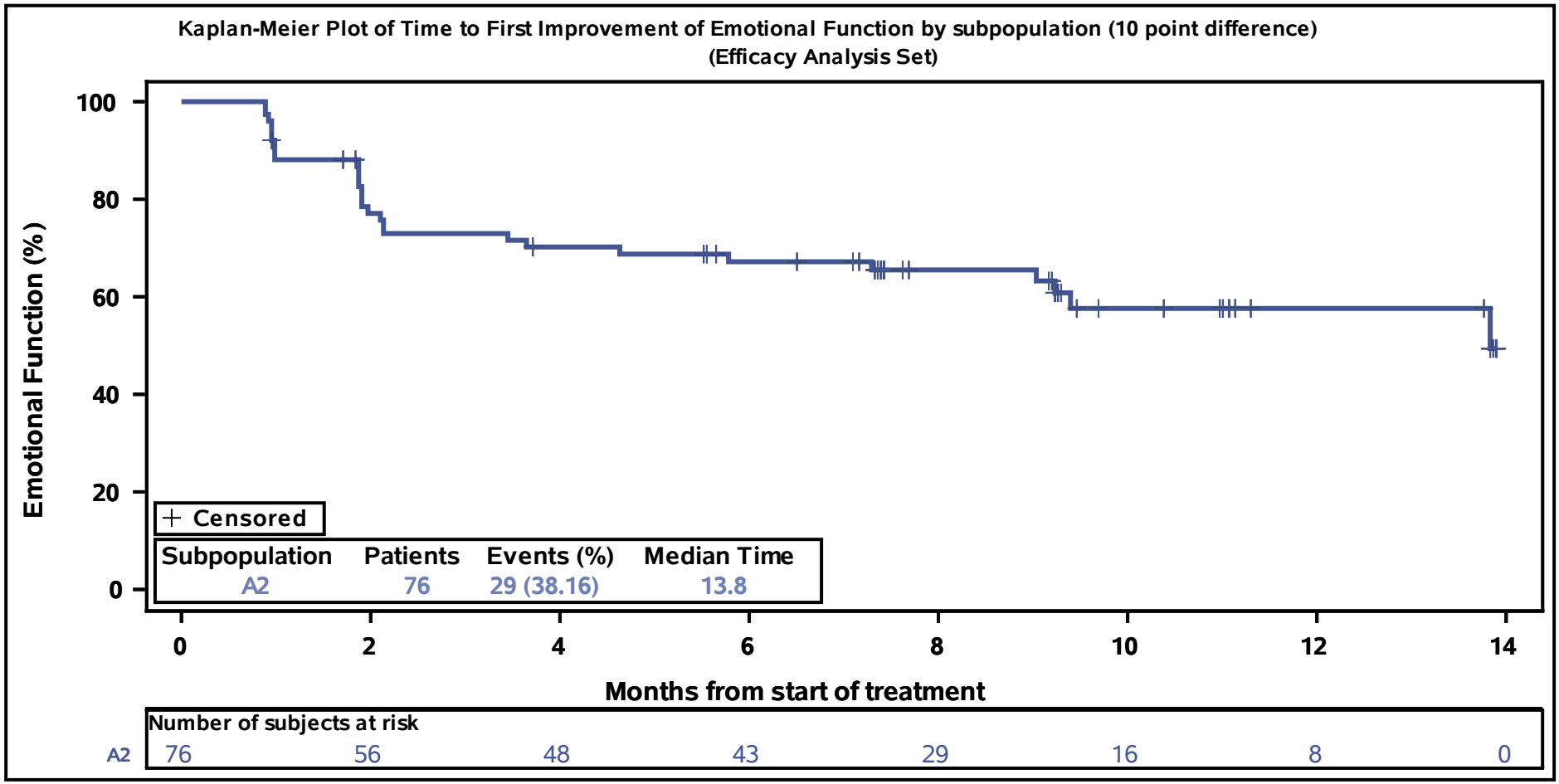

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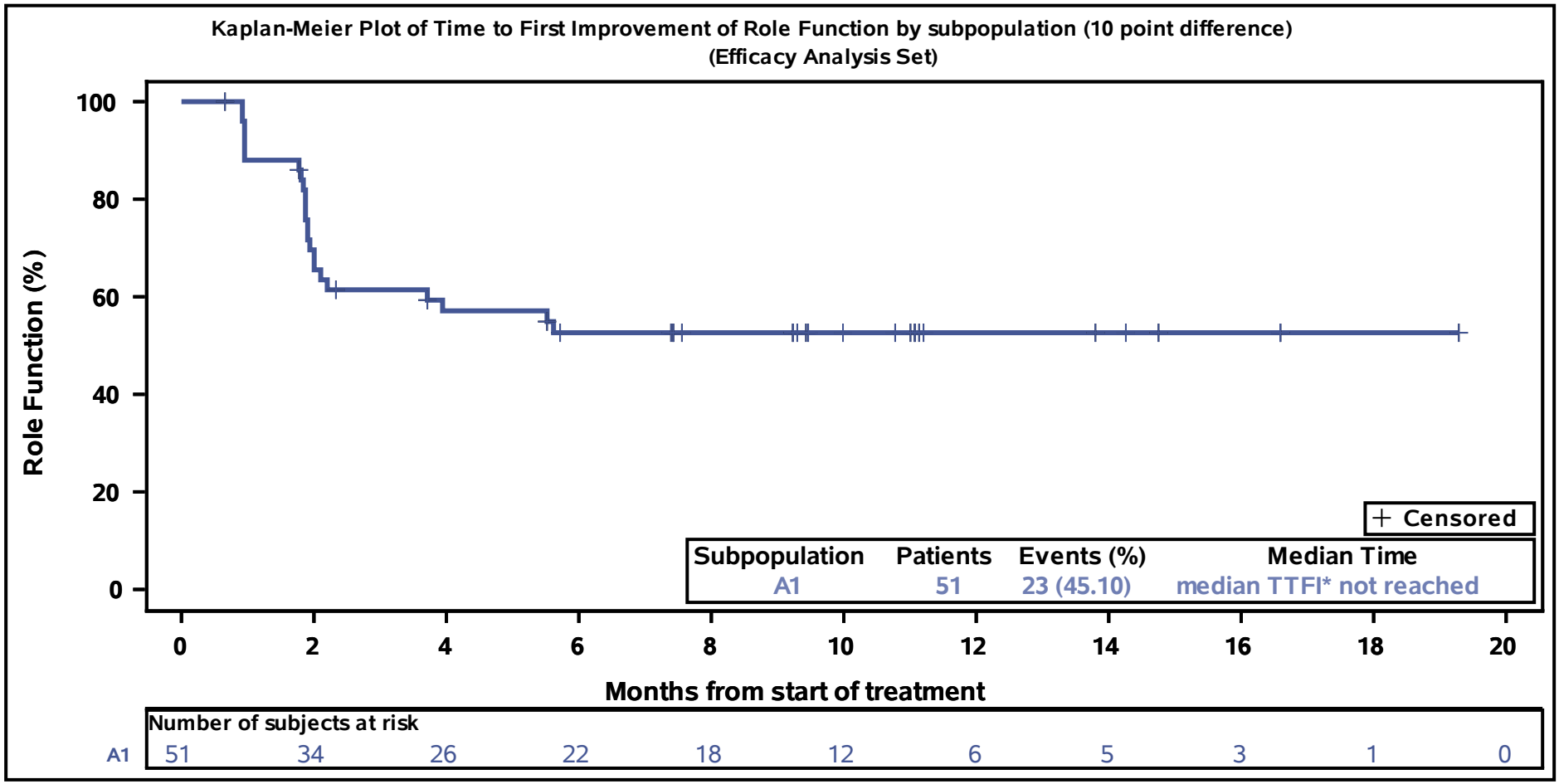

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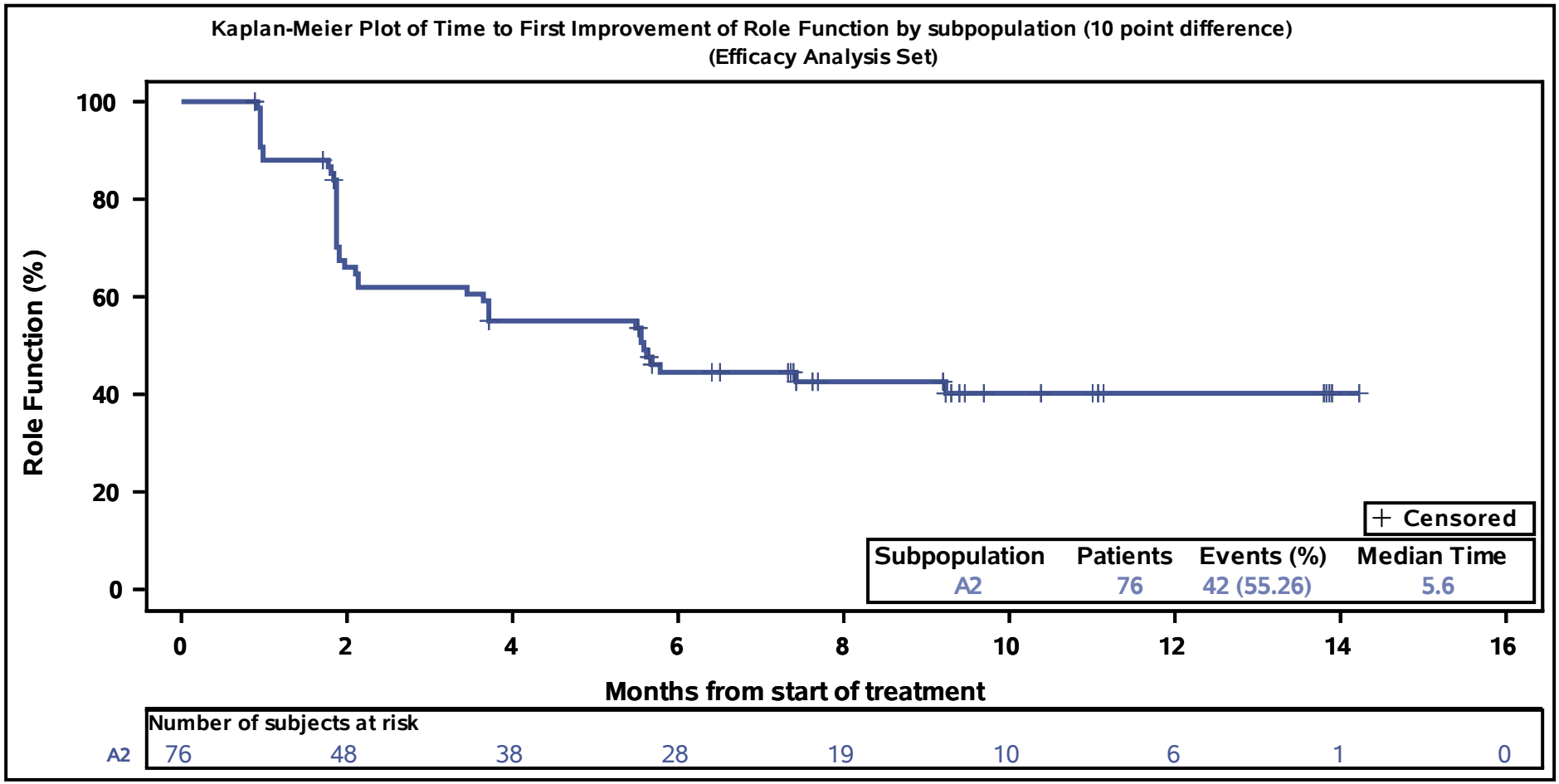

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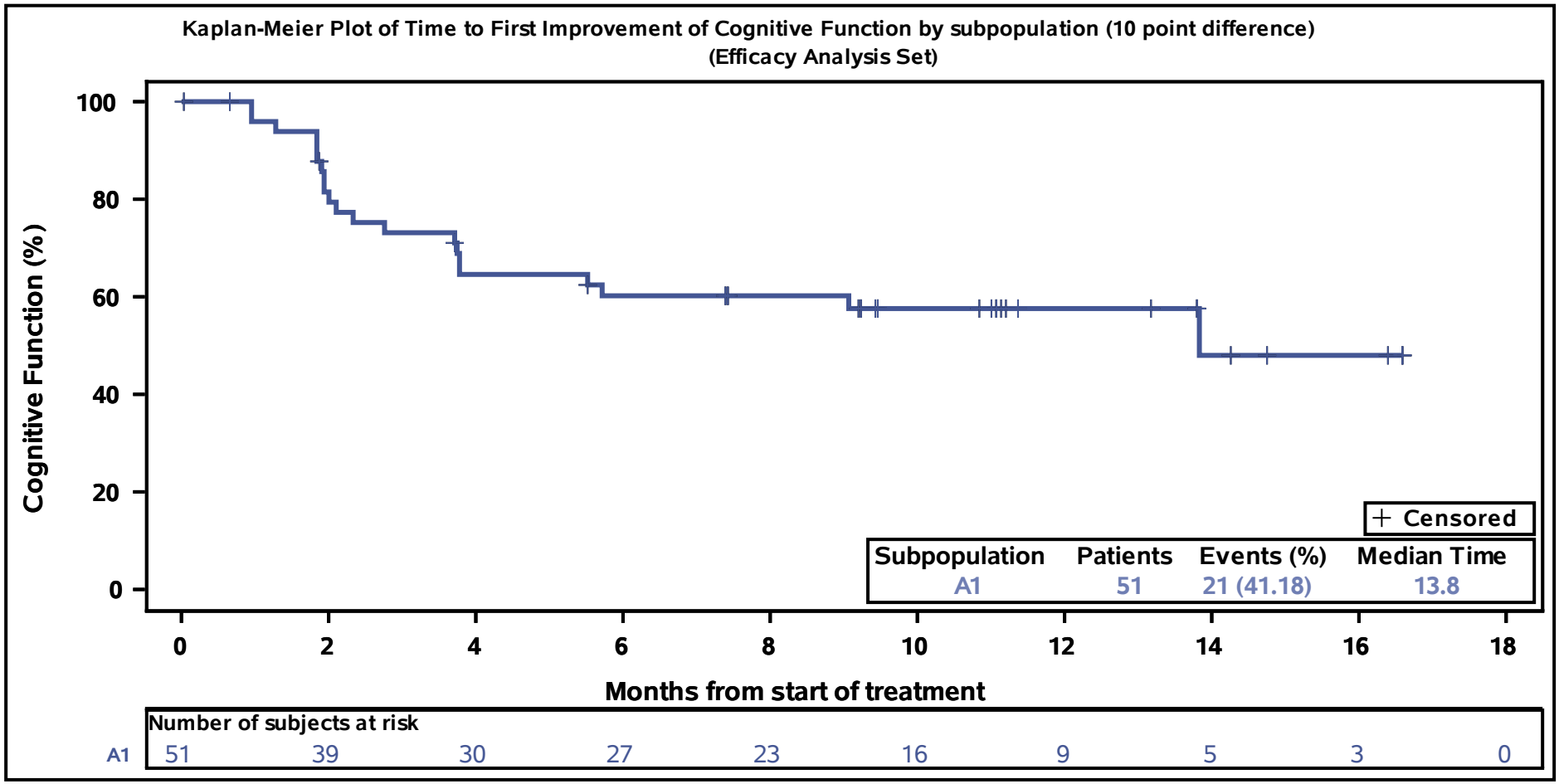

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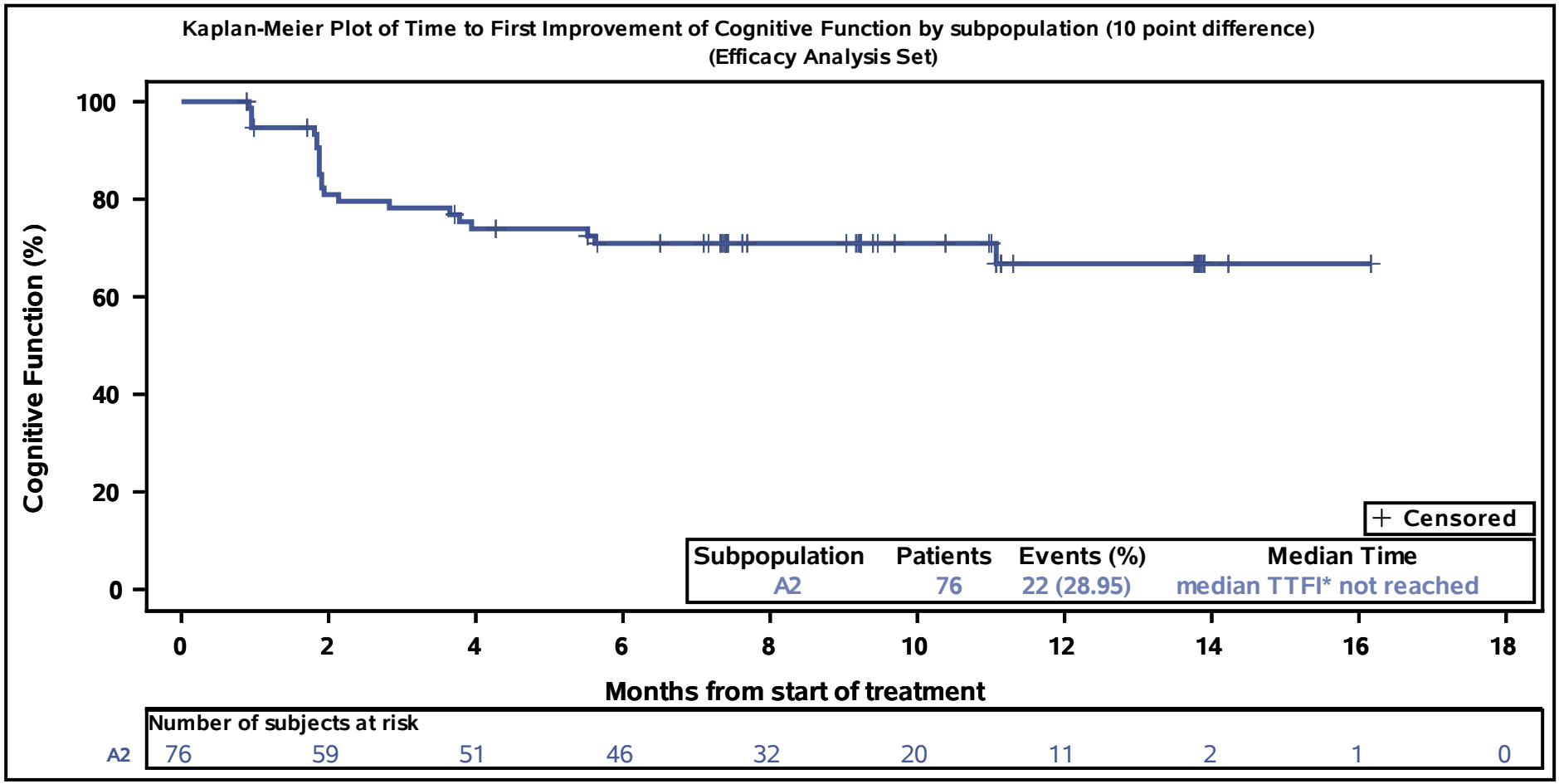

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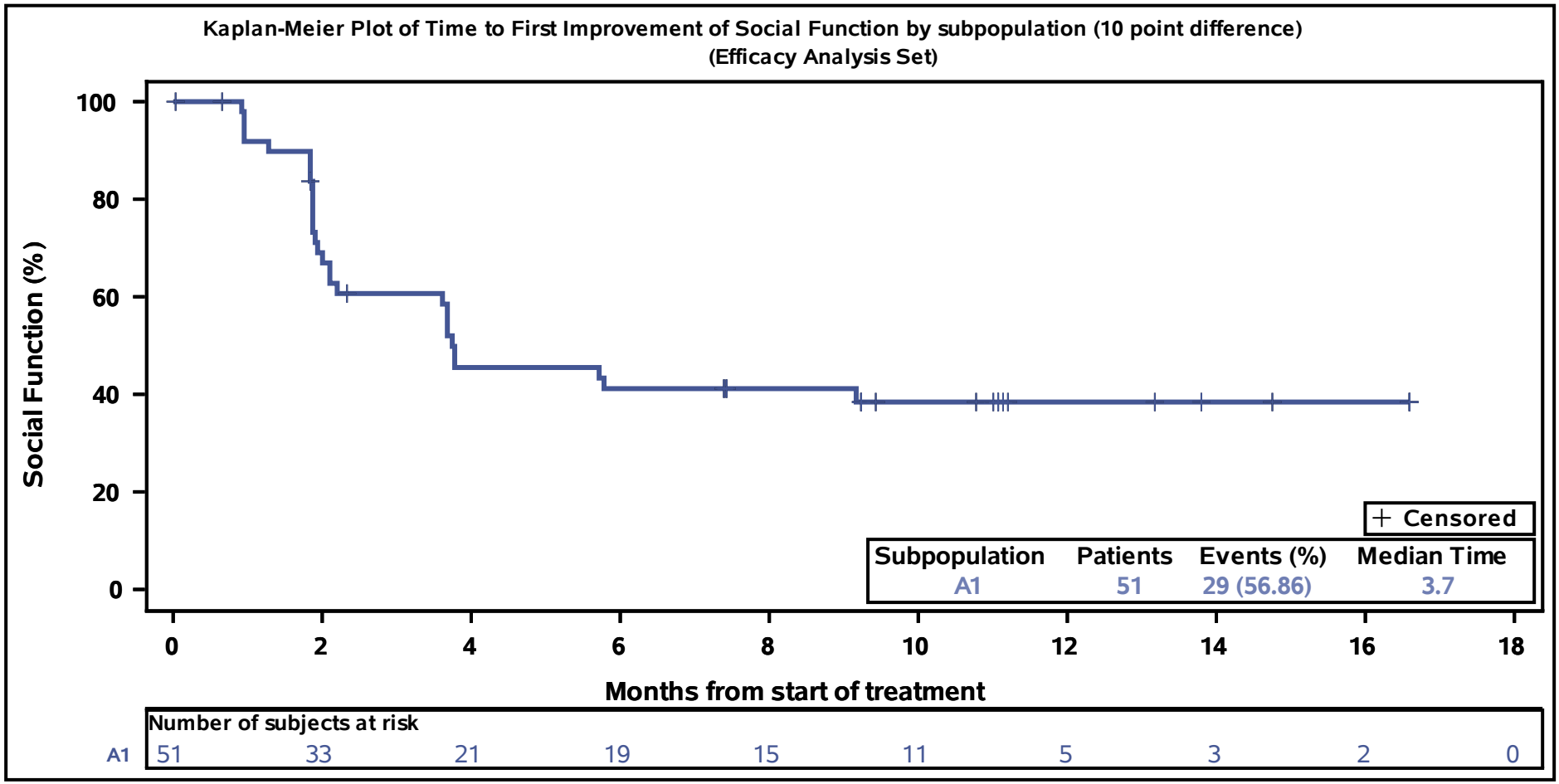

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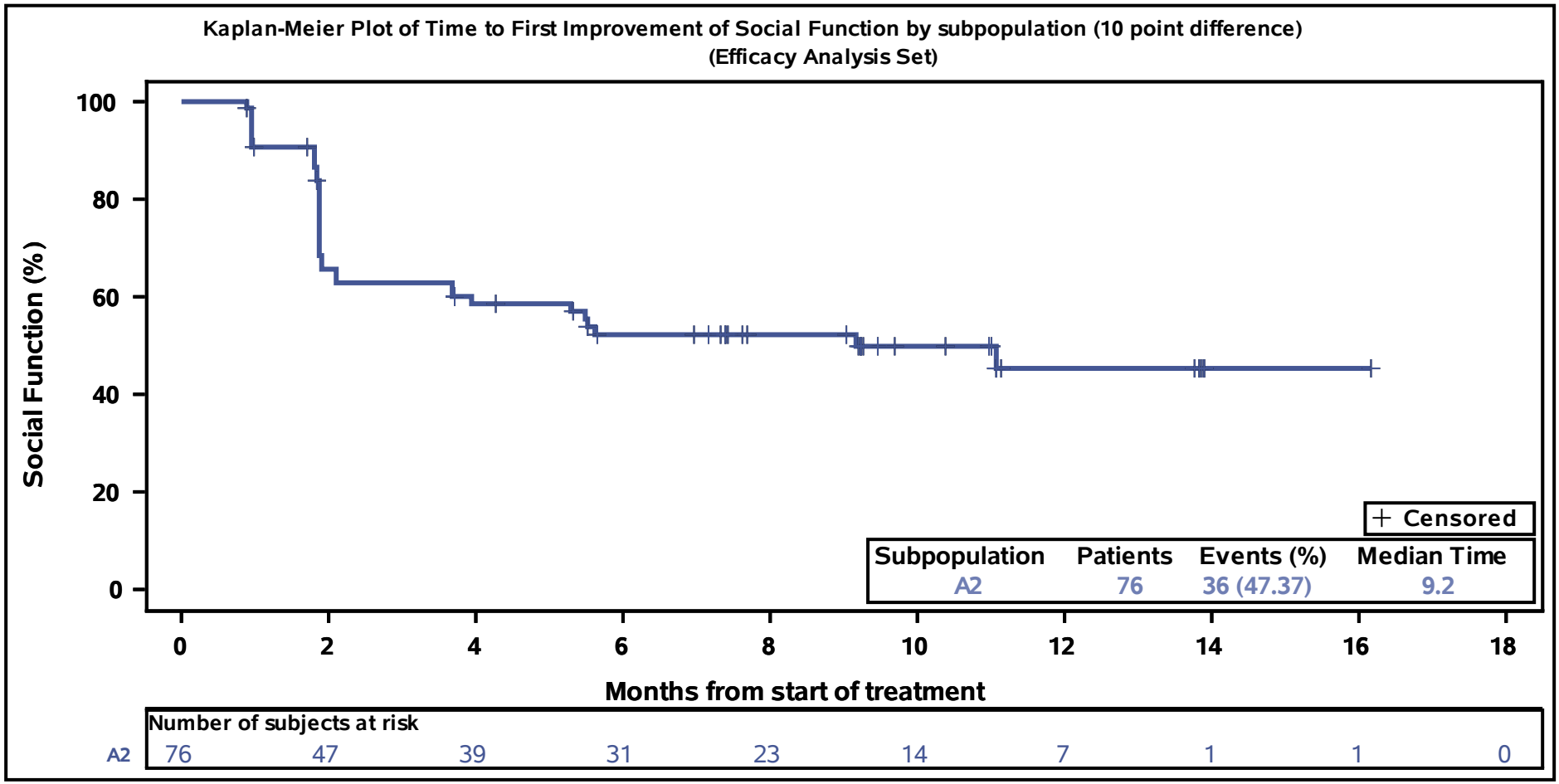

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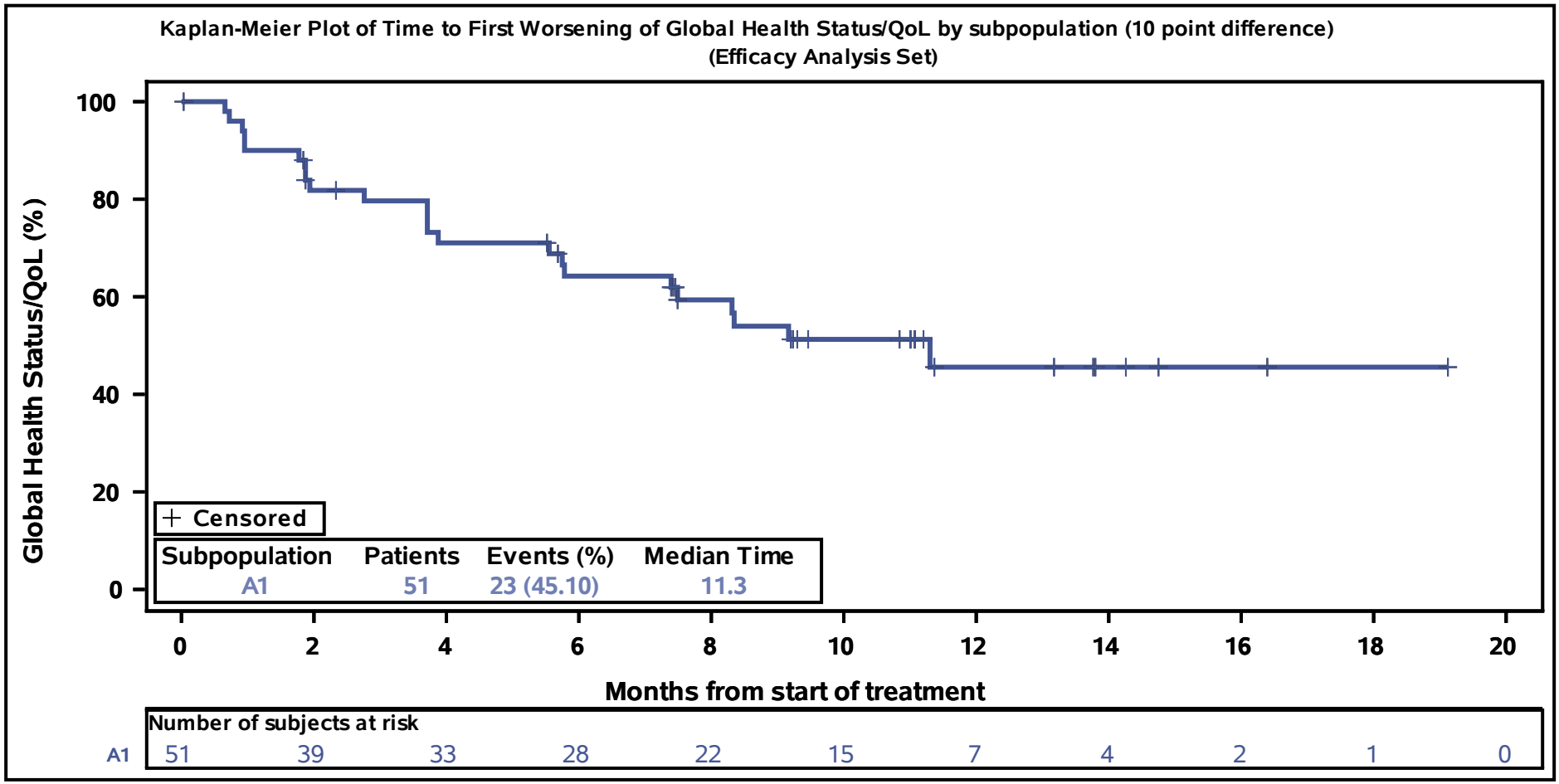

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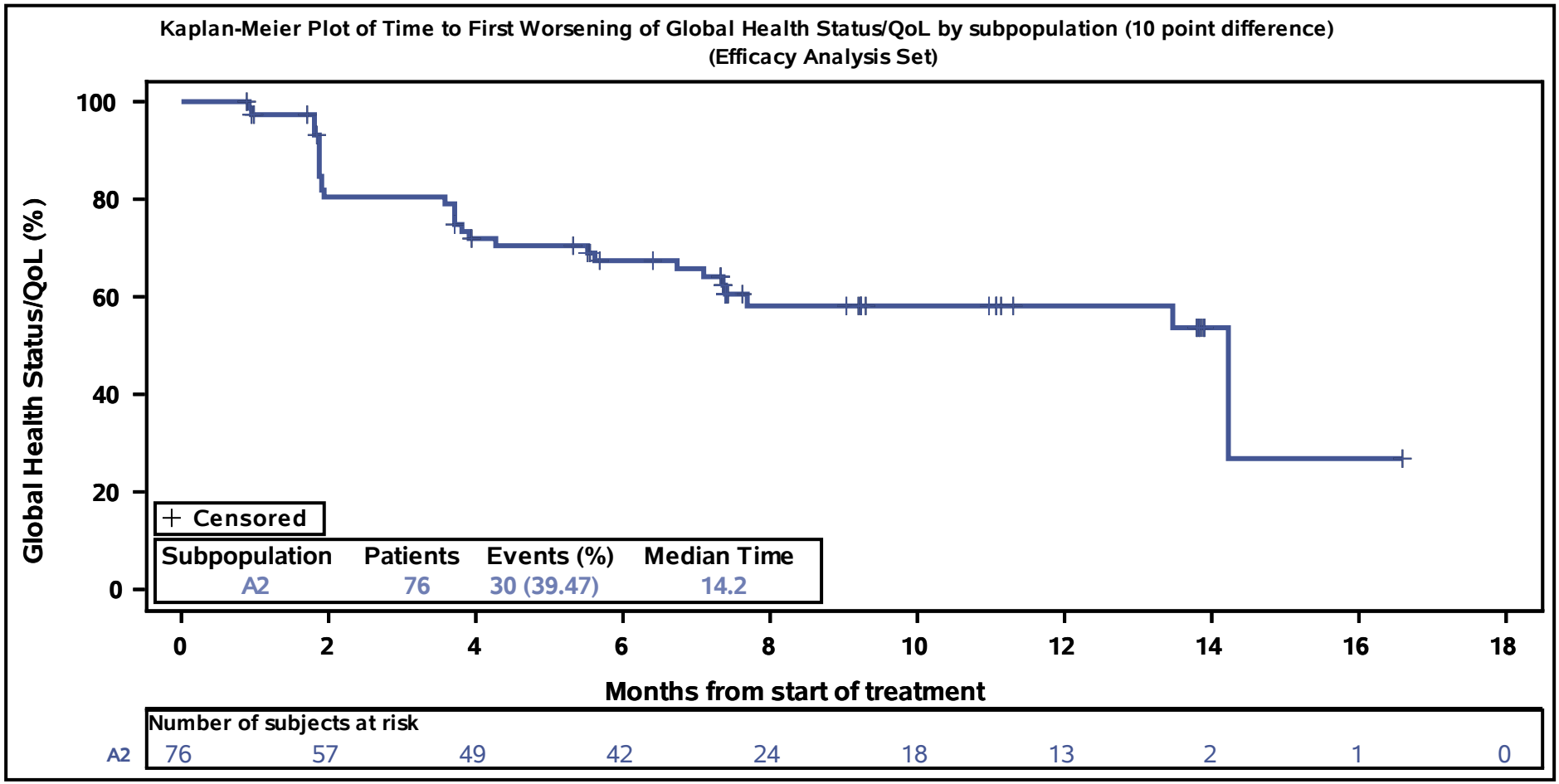

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Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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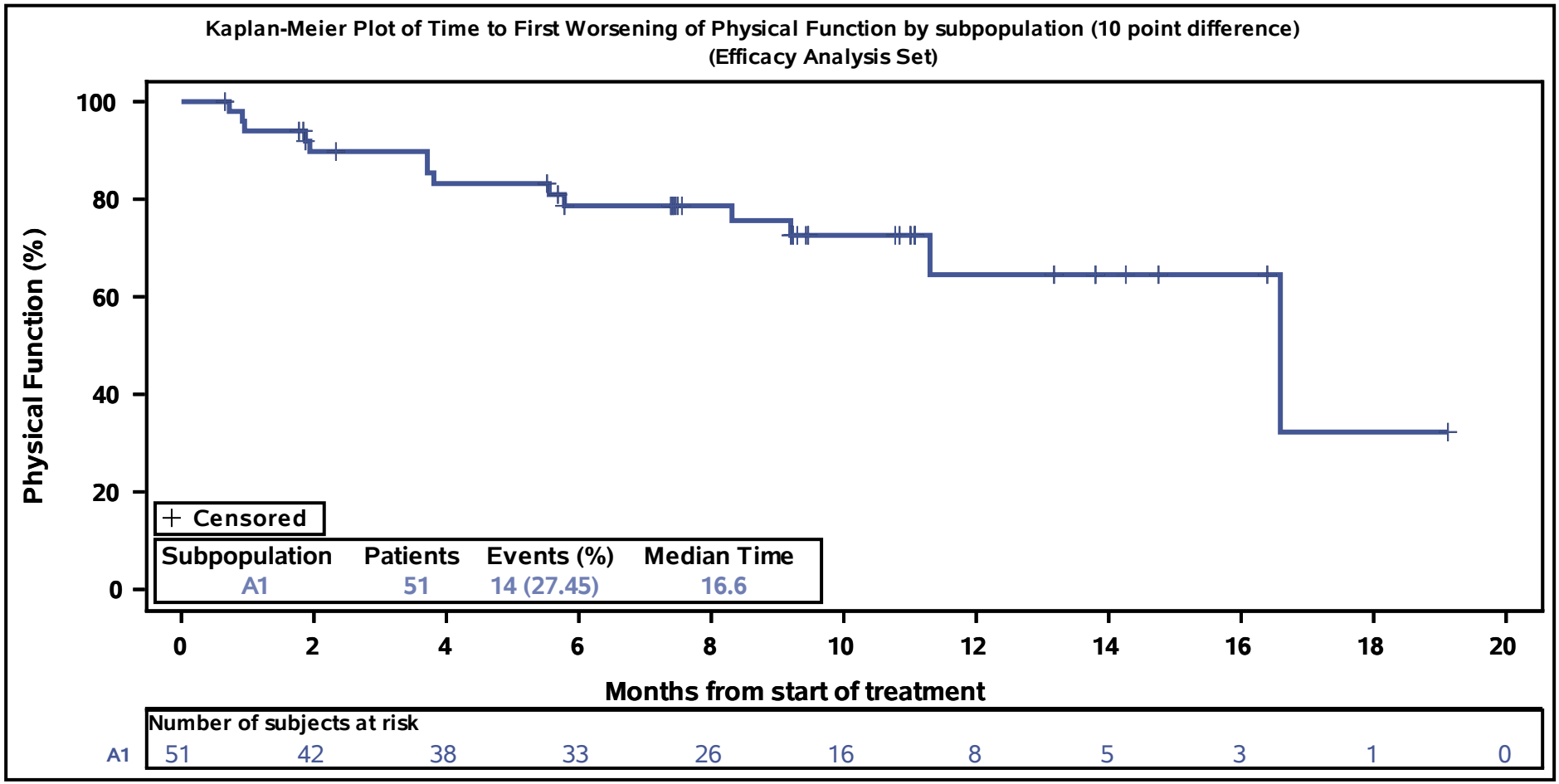
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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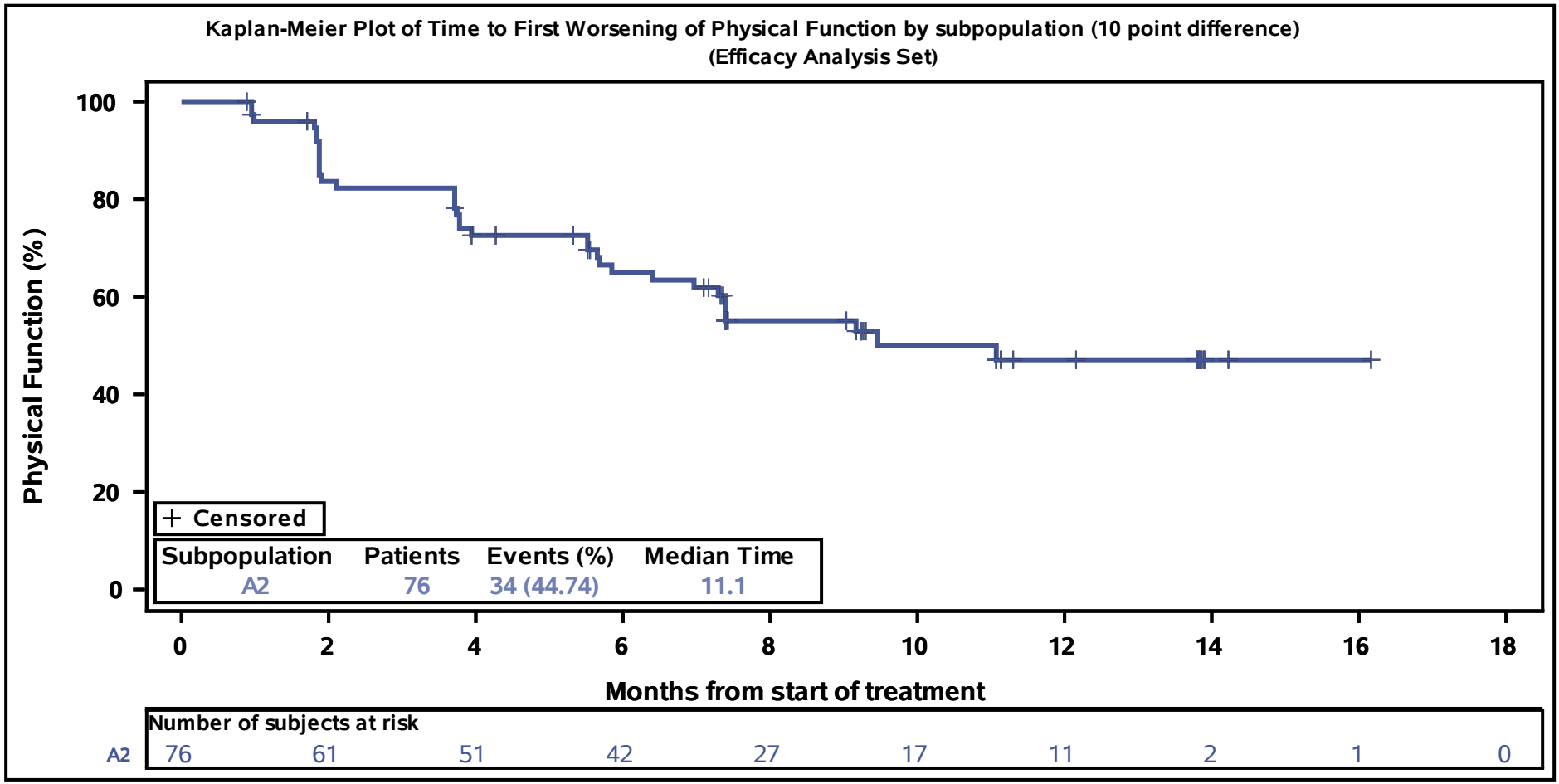

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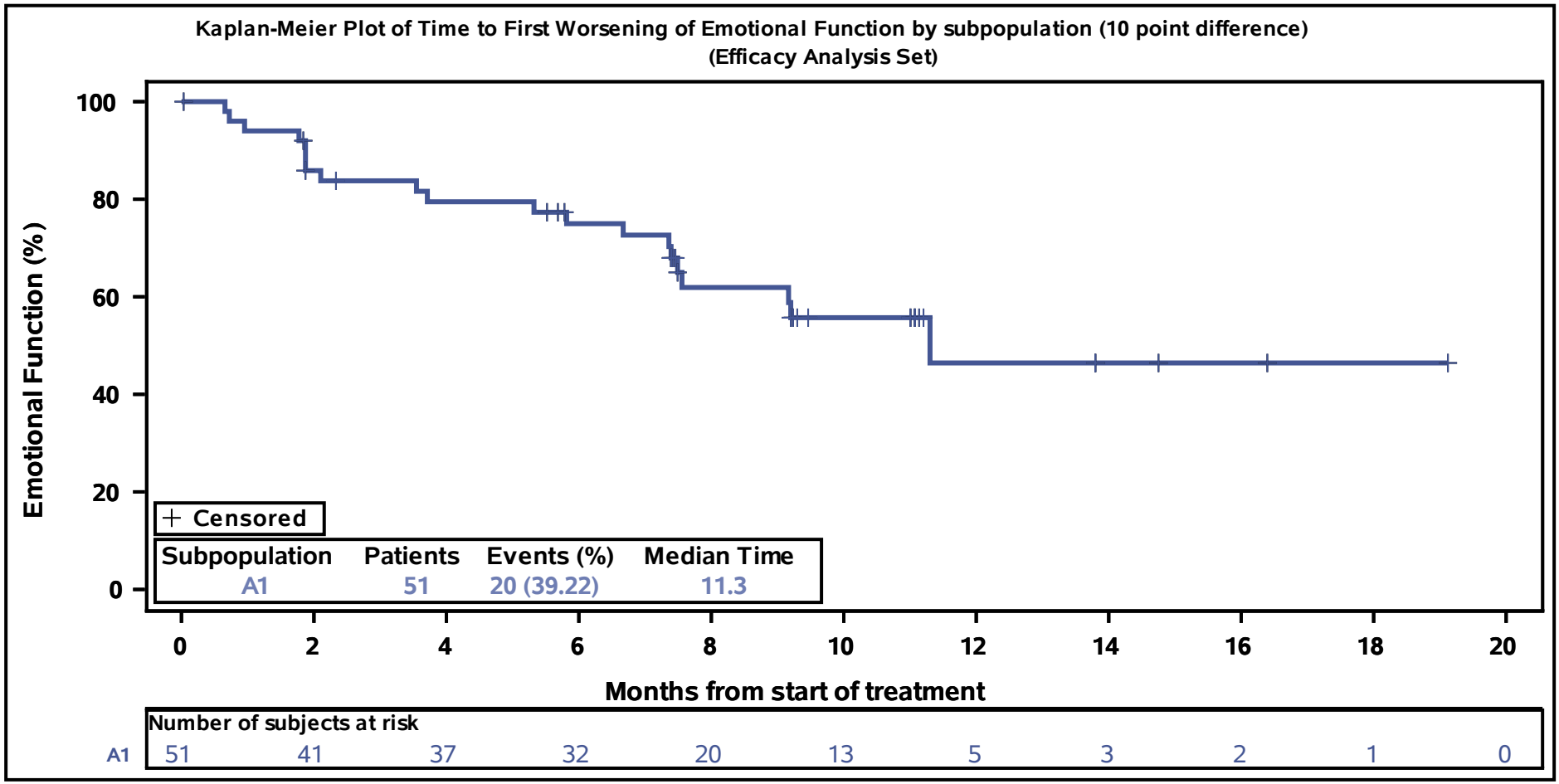

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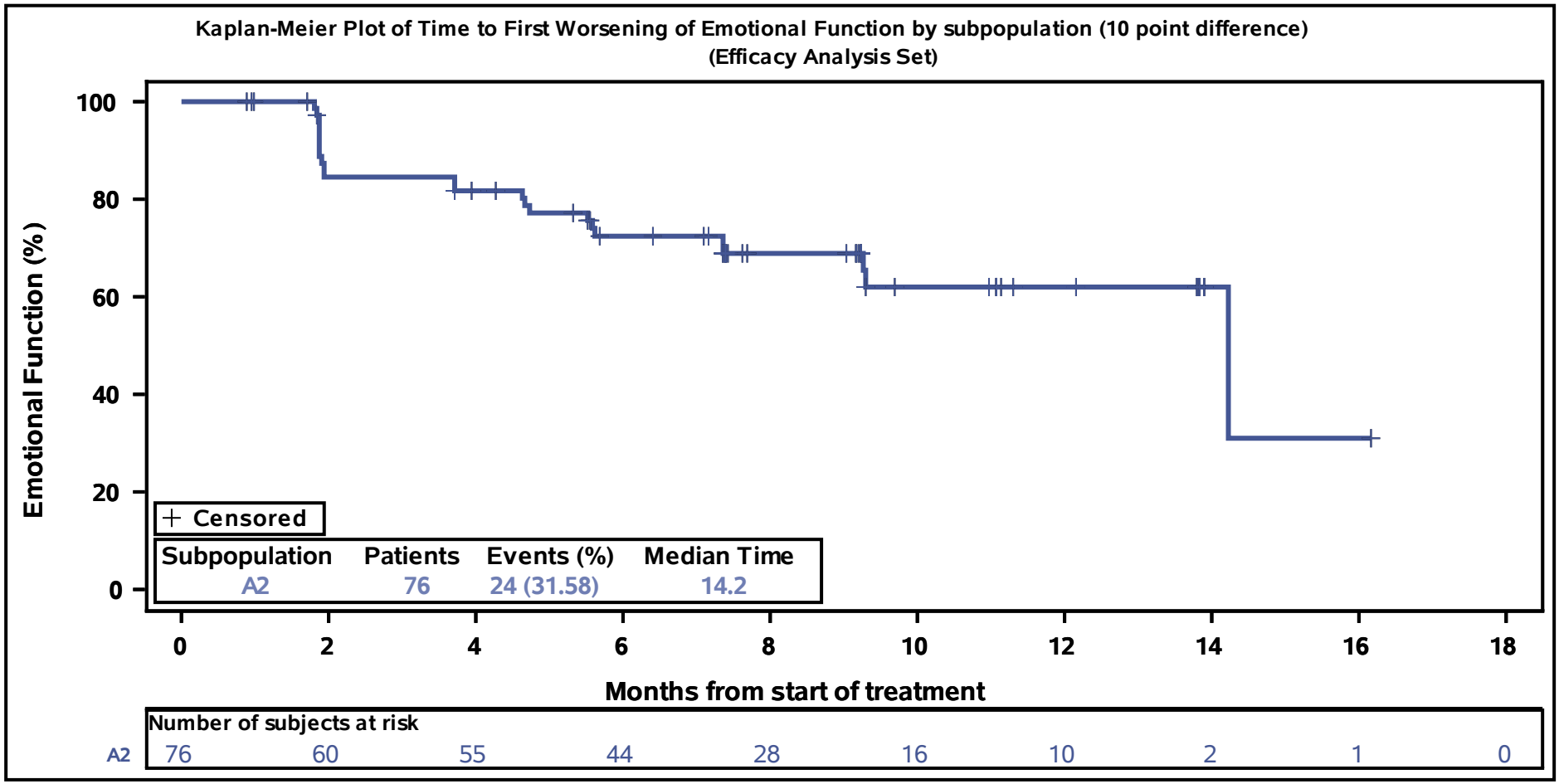

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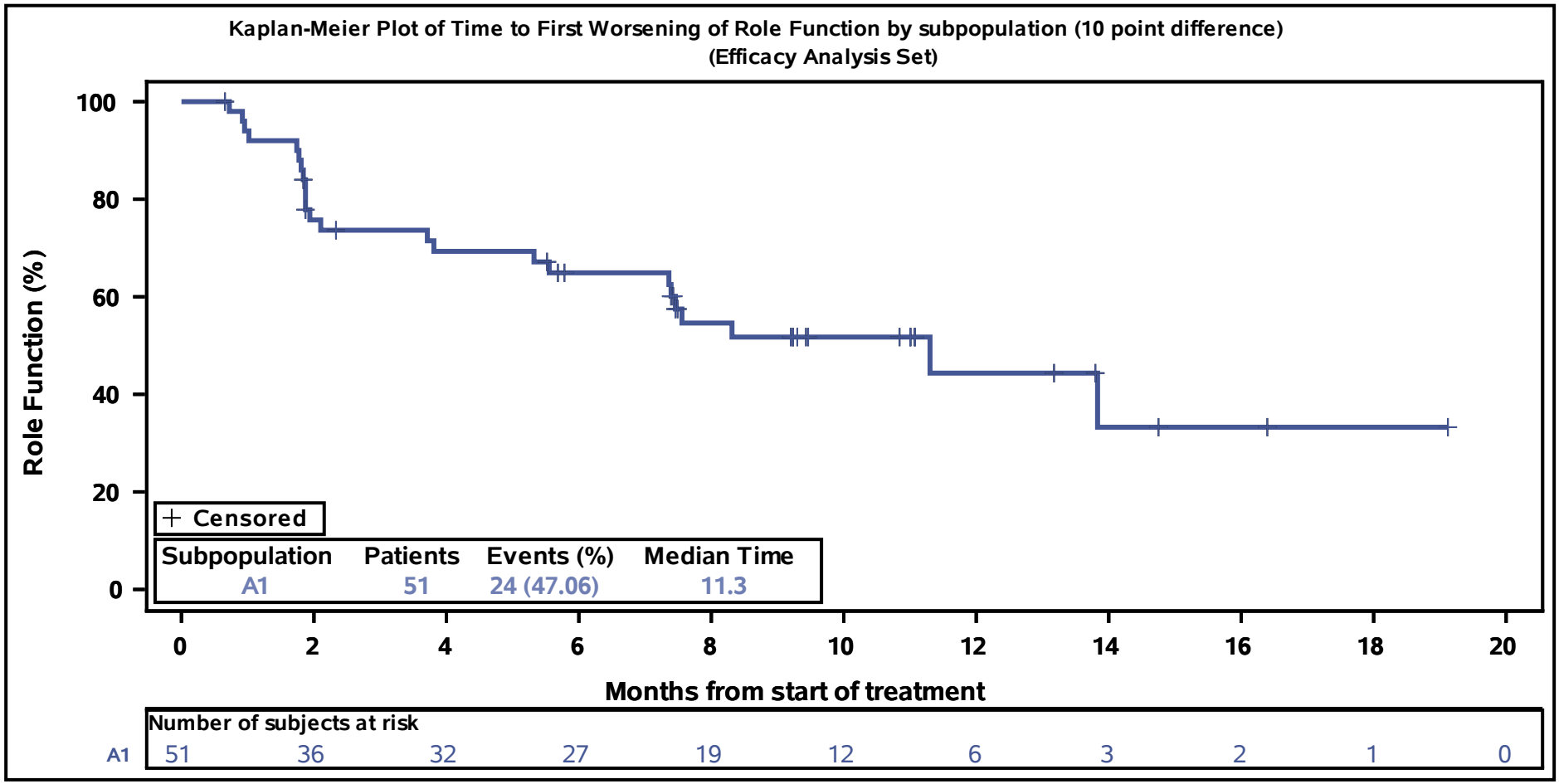

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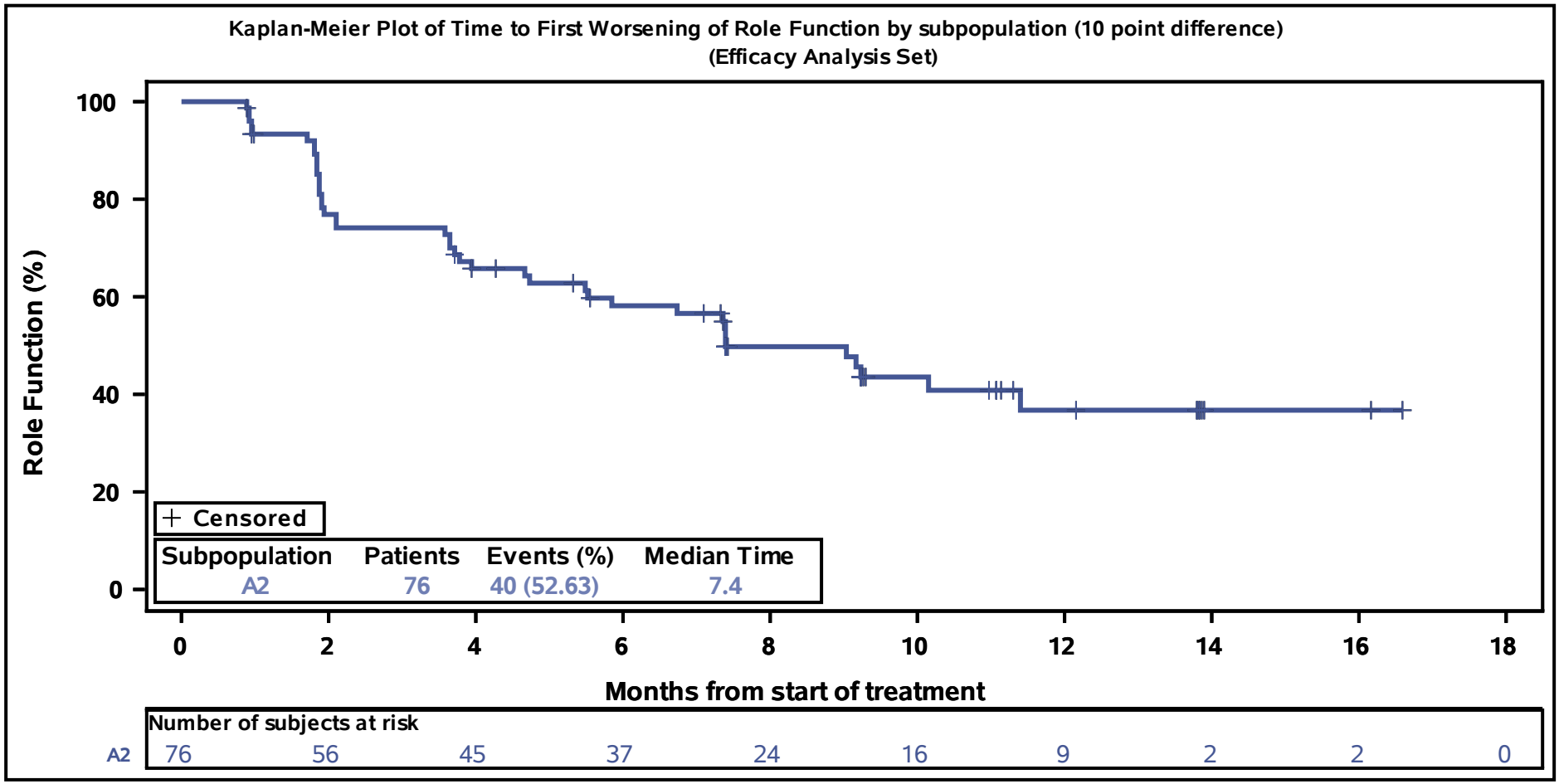

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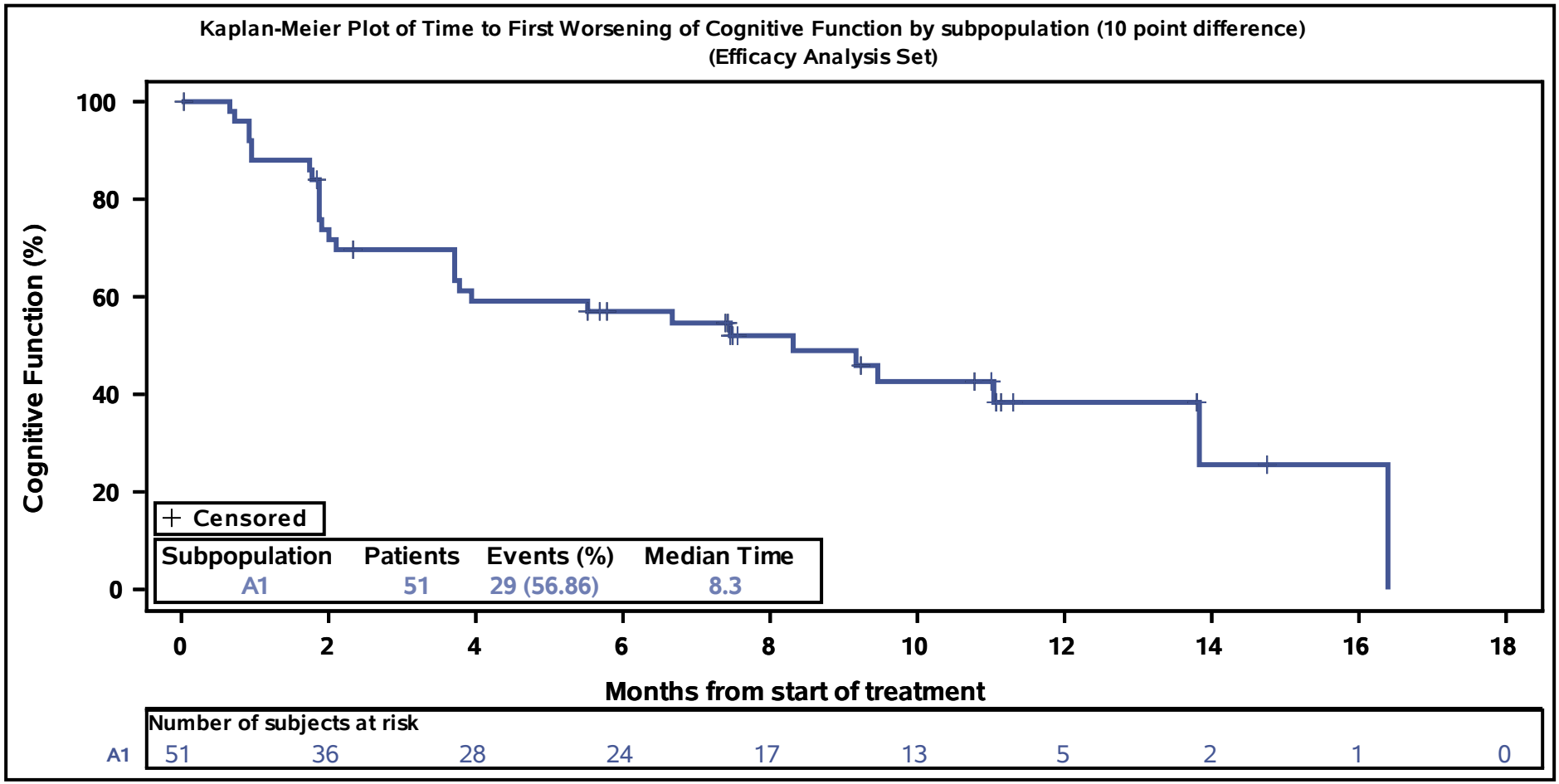

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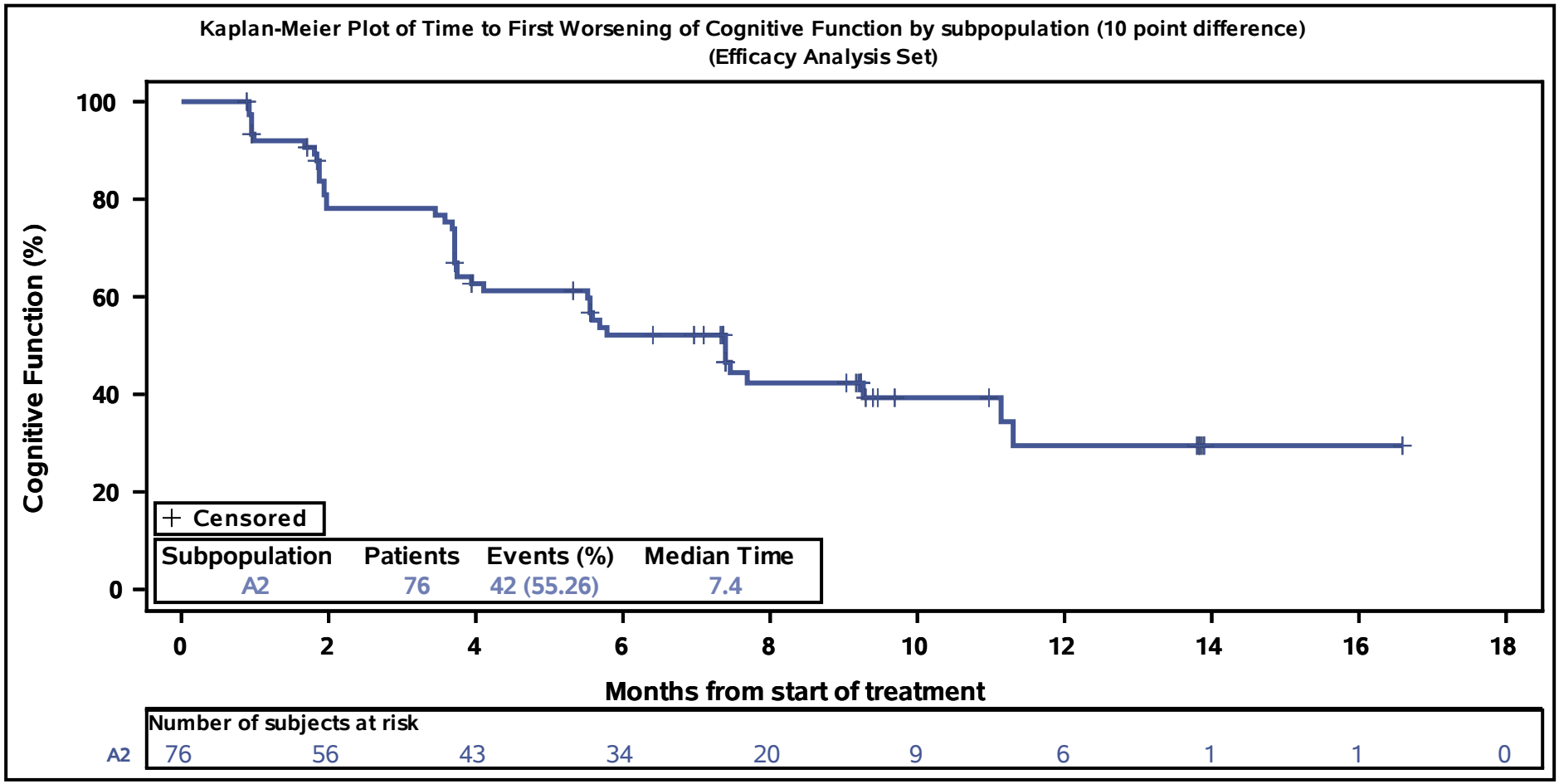

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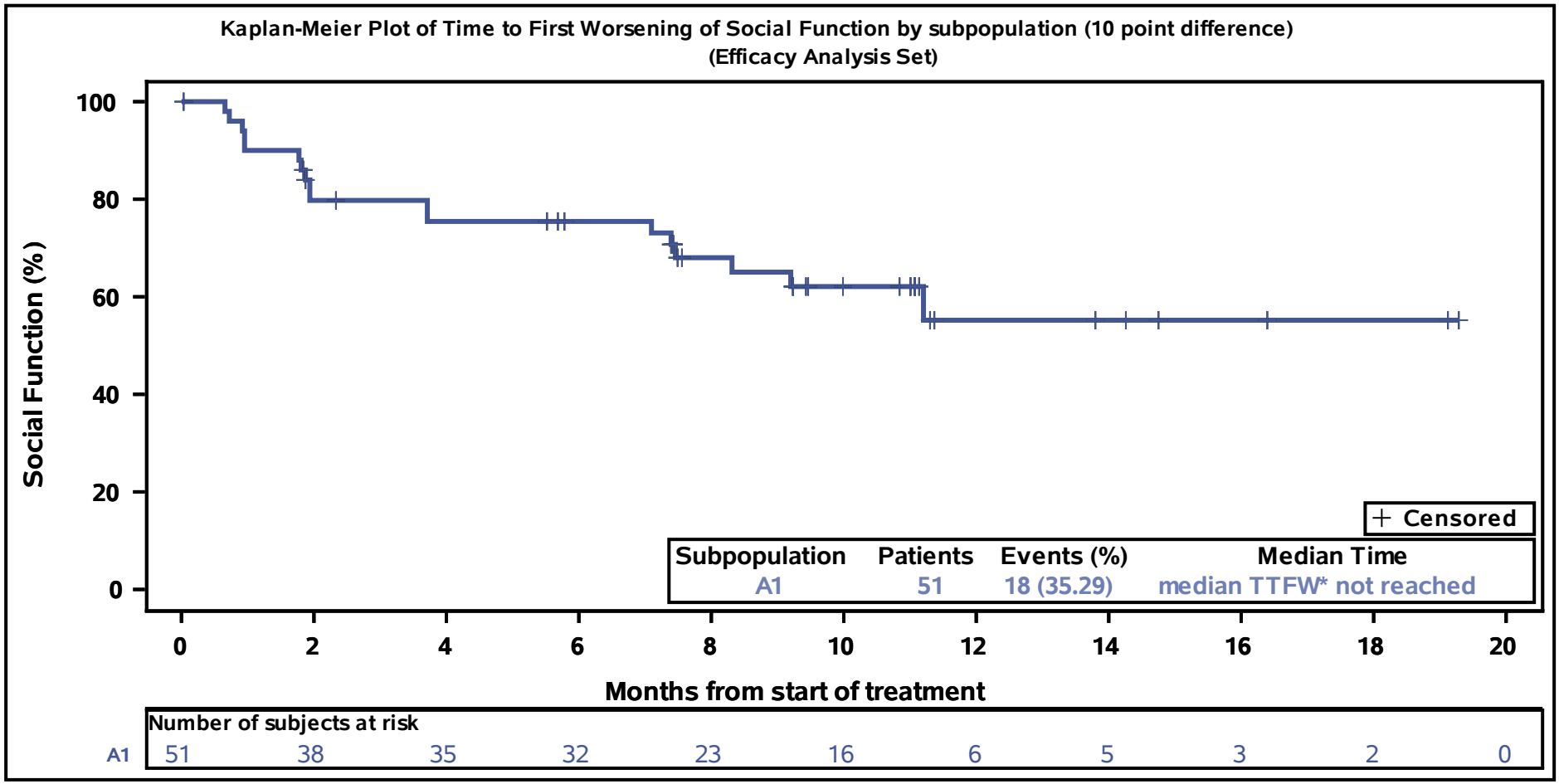

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Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)

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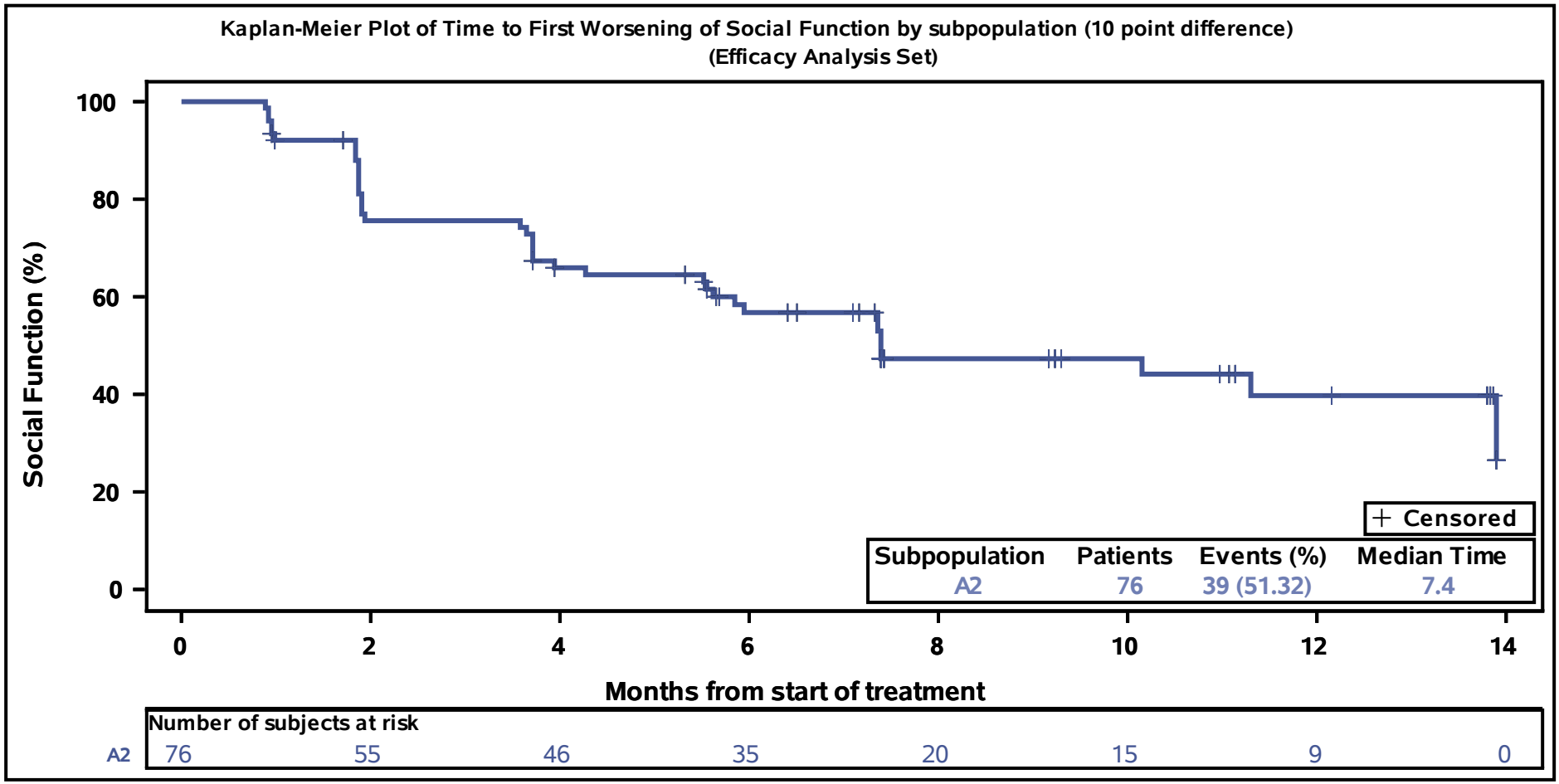

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Tabelle 033: Ergebnisse für die Zeit bis zur anhaltenden Verbesserung bzw. Verschlechterung der Symptome gemessen anhand des EORTC QLQ-C30 in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30.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

	Selpercatinib	
Endpunkt	**Subpopulation A1 - NSCLC 2L (N'=78) (N=78)**	**Subpopulation A2 - NSCLC 3L (N'=158) (N=158)**
EORTC QLQ-C30 – Symptomskalen		
Fatigue	51	76
Patienten mit Ereignis		
Anhaltende Verbesserung, n (%)	16 (31,4)	21 (27,6)
Zensierte Patienten, n (%)	35 (68,6)	55 (72,4)
Anhaltende Verschlechterung, n (%)	8 (15,7)	15 (19,7)
Zensierte Patienten, n (%)	43 (84,3)	61 (80,3)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [13,90; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [16,59; NE]	14,2 [14,23; NE]
Schmerzen	51	76
Patienten mit Ereignis		
Anhaltende Verbesserung, n (%)	19 (37,3)	22 (28,9)
Zensierte Patienten, n (%)	32 (62,7)	54 (71,1)
Anhaltende Verschlechterung, n (%)	8 (15,7)	14 (18,4)
Zensierte Patienten, n (%)	43 (84,3)	62 (81,6)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [5,72; NE]	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]
Übelkeit und Erbrechen	51	76
Patienten mit Ereignis		
Anhaltende Verbesserung, n (%)	9 (17,6)	15 (19,7)
Zensierte Patienten, n (%)	42 (82,4)	61 (80,3)
Anhaltende Verschlechterung, n (%)	5 (9,8)	9 (11,8)
Zensierte Patienten, n (%)	46 (90,2)	67 (88,2)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [13,80; NE]	NE [NE; NE]
Dyspnoe	51	76
Patienten mit Ereignis		
Anhaltende Verbesserung, n (%)	11 (21,6)	19 (25,0)
Zensierte Patienten, n (%)	40 (78,4)	57 (75,0)
Anhaltende Verschlechterung, n (%)	2 (3,9)	5 (6,6)
Zensierte Patienten, n (%)	49 (96,1)	71 (93,4)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]

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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: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

	Selpercatinib	
Endpunkt	**Subpopulation A1 - NSCLC 2L (N'=78) (N=78)**	**Subpopulation A2 - NSCLC 3L (N'=158) (N=158)**
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [14,23; NE]
Schlaflosigkeit	51	76
Patienten mit Ereignis		
Anhaltende Verbesserung, n (%)	5 (9,8)	17 (22,4)
Zensierte Patienten, n (%)	46 (90,2)	59 (77,6)
Anhaltende Verschlechterung, n (%)	5 (9,8)	11 (14,5)
Zensierte Patienten, n (%)	46 (90,2)	65 (85,5)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]
Appetitverlust	51	76
Patienten mit Ereignis		
Anhaltende Verbesserung, n (%)	15 (29,4)	14 (18,4)
Zensierte Patienten, n (%)	36 (70,6)	62 (81,6)
Anhaltende Verschlechterung, n (%)	6 (11,8)	12 (15,8)
Zensierte Patienten, n (%)	45 (88,2)	64 (84,2)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [11,07; NE]	NE [13,90; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]
Verstopfung	51	76
Patienten mit Ereignis		
Anhaltende Verbesserung, n (%)	12 (23,5)	16 (21,1)
Zensierte Patienten, n (%)	39 (76,5)	60 (78,9)
Anhaltende Verschlechterung, n (%)	5 (9,8)	10 (13,2)
Zensierte Patienten, n (%)	46 (90,2)	66 (86,8)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]	16,2 [16,16; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]
Diarrhoe	51	76
Patienten mit Ereignis		
Anhaltende Verbesserung, n (%)	2 (3,9)	7 (9,2)
Zensierte Patienten, n (%)	49 (96,1)	69 (90,8)
Anhaltende Verschlechterung, n (%)	9 (17,6)	18 (23,7)
Zensierte Patienten, n (%)	42 (82,4)	58 (76,3)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]

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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: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

	Selpercatinib	
Endpunkt	**Subpopulation A1 - NSCLC 2L (N'=78) (N=78)**	**Subpopulation A2 - NSCLC 3L (N'=158) (N=158)**
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [13,73; NE]	14,2 [14,23; NE]

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; 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; NSCLC: nicht-kleinzelliges Lungenkarzinom; 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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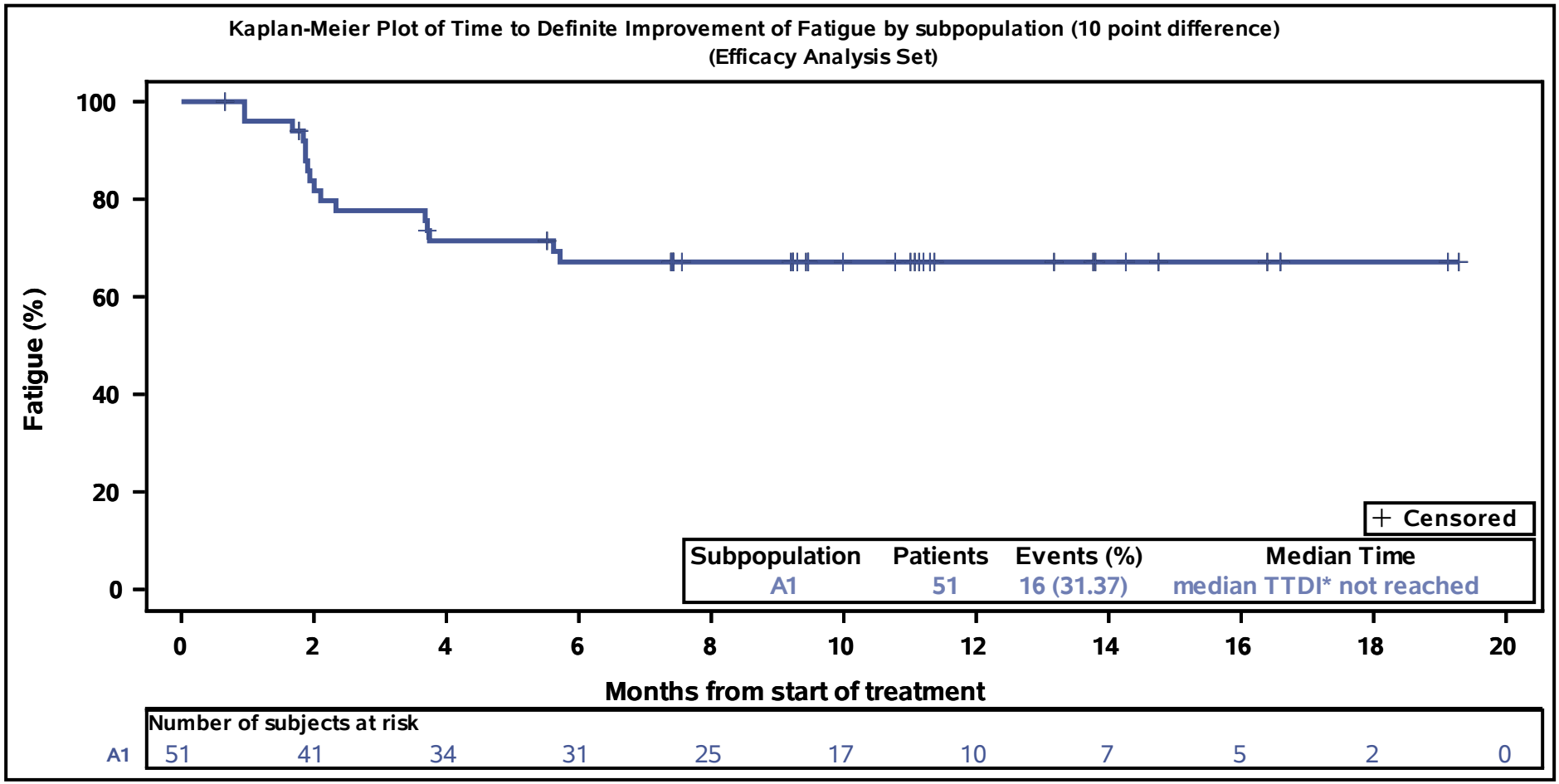

* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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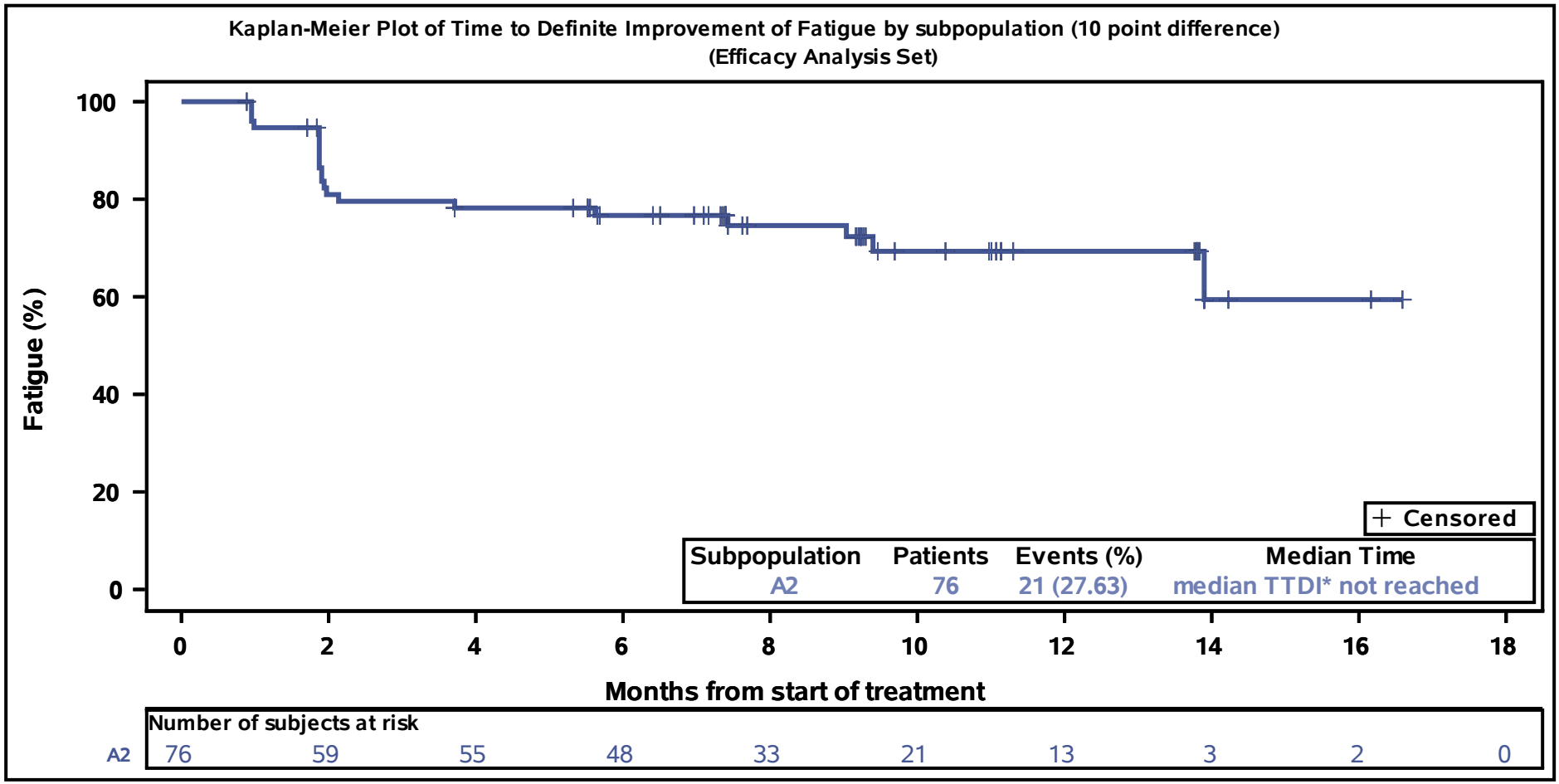

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Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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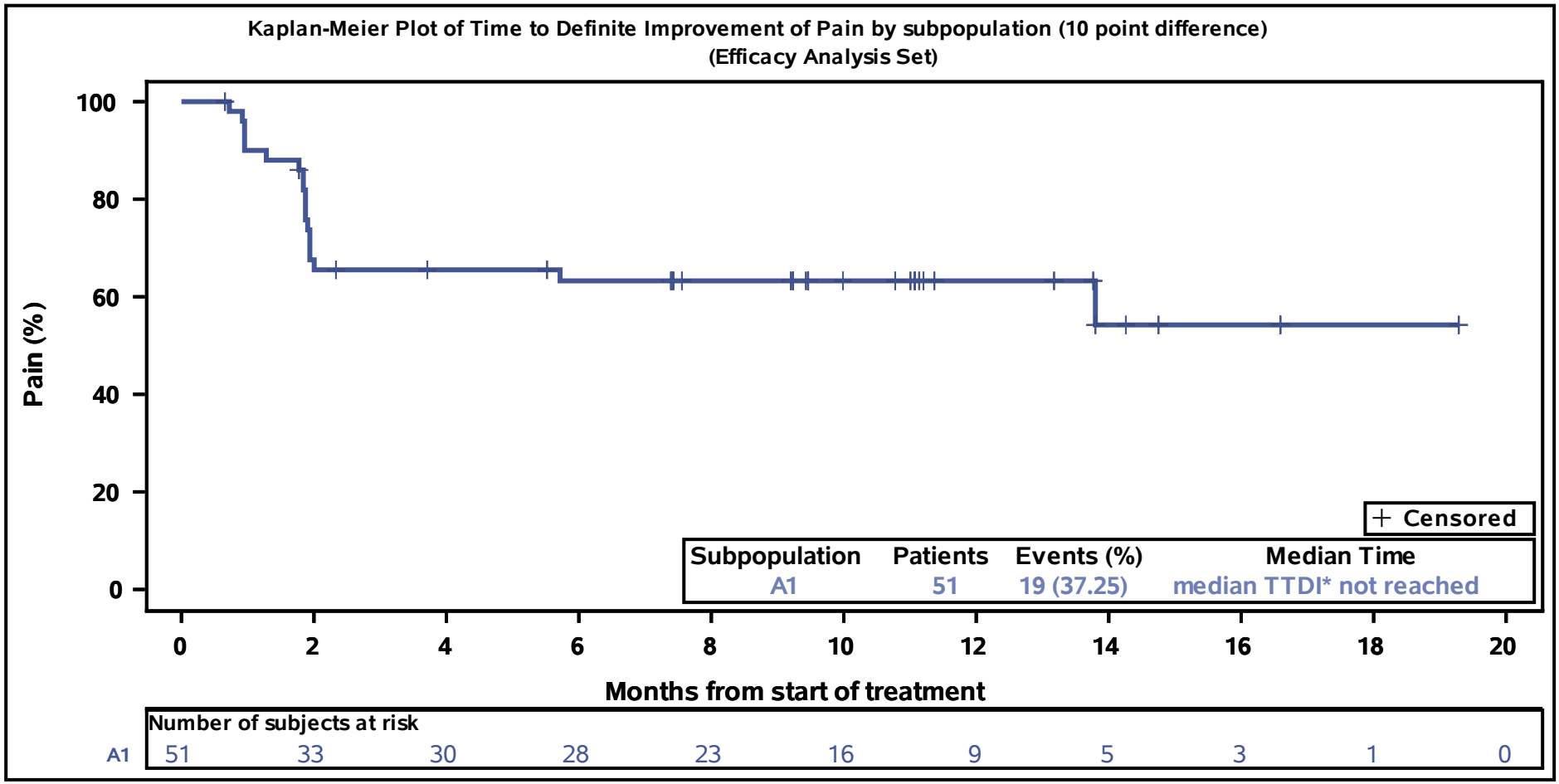

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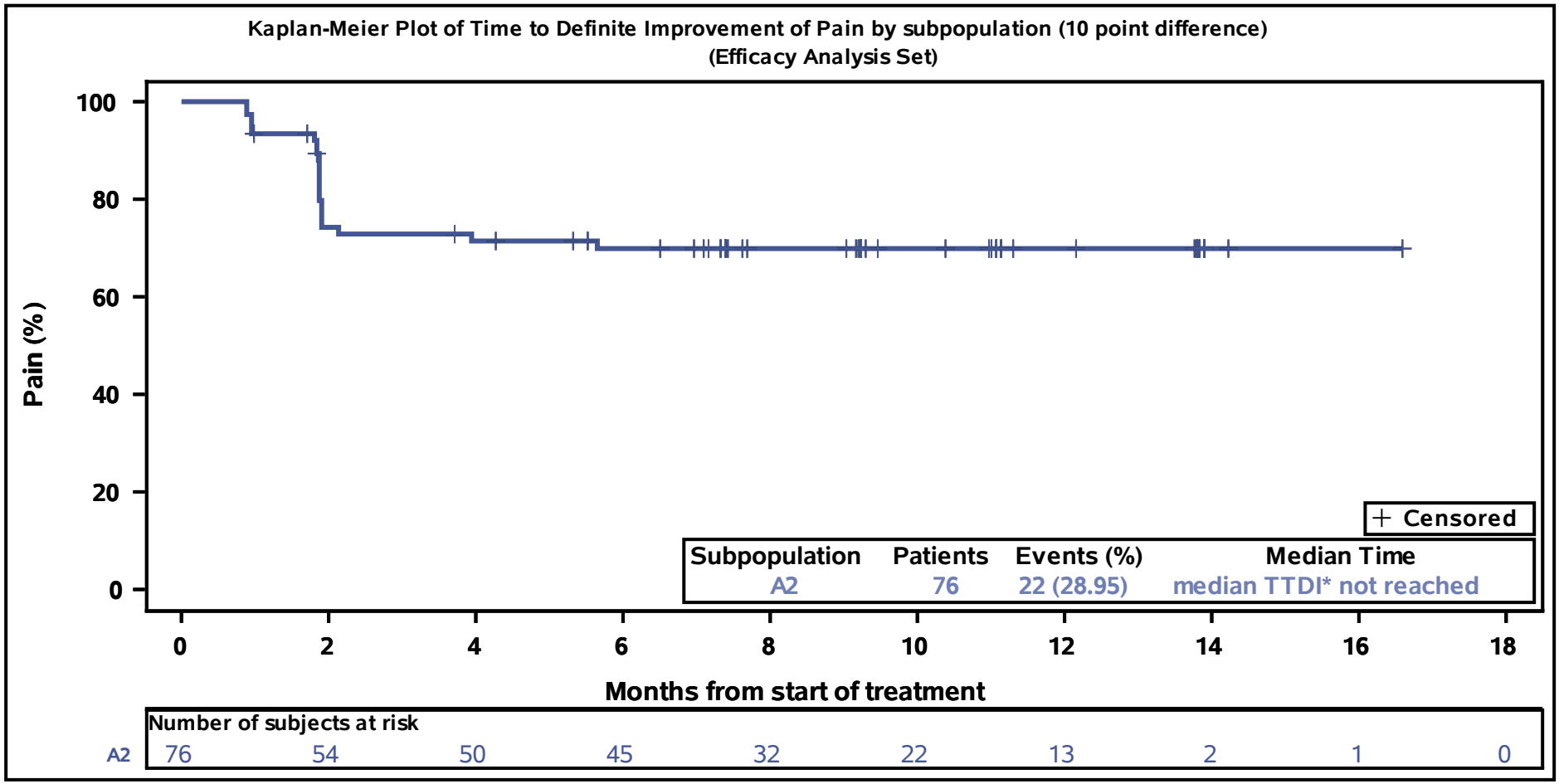

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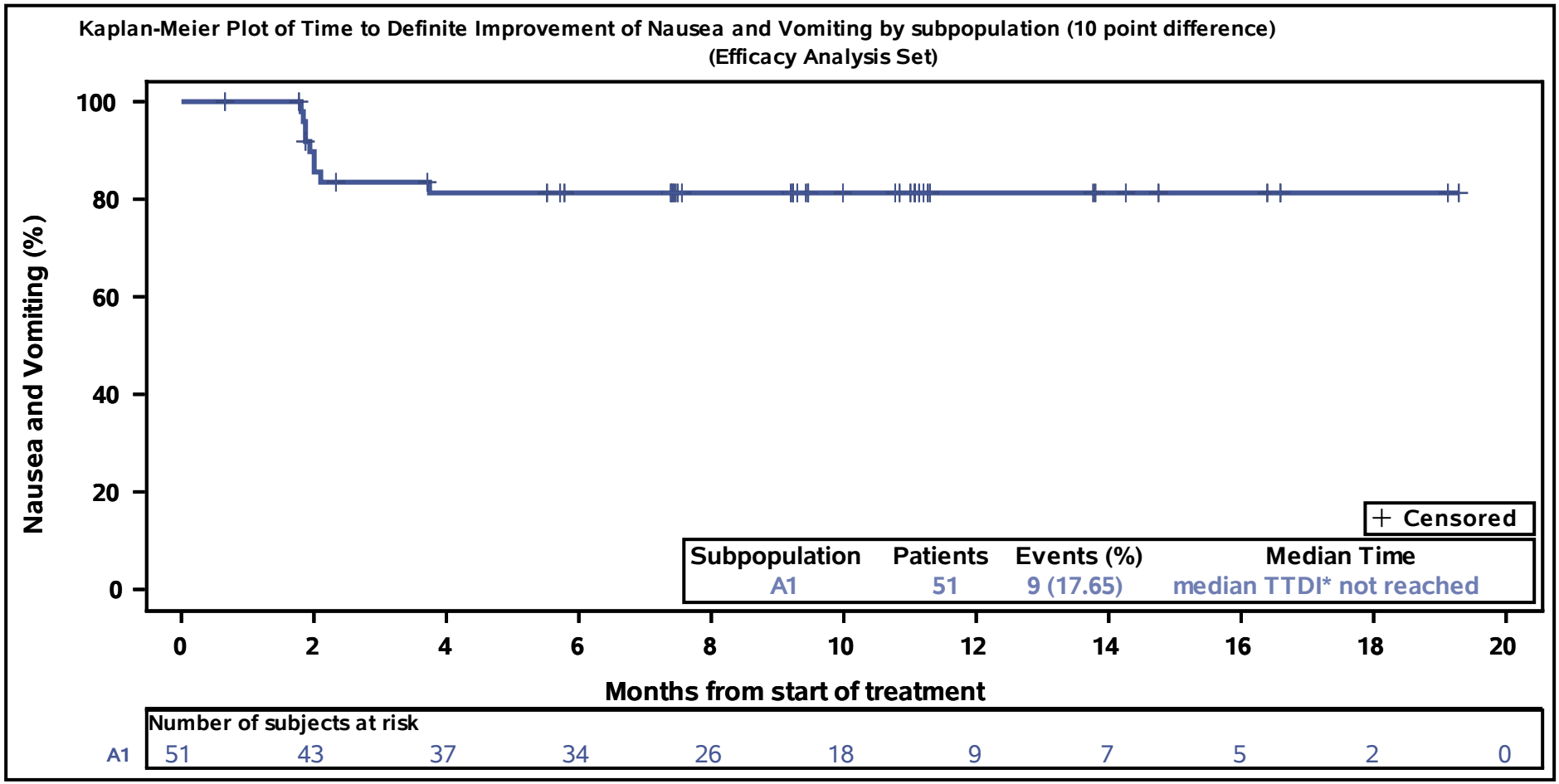
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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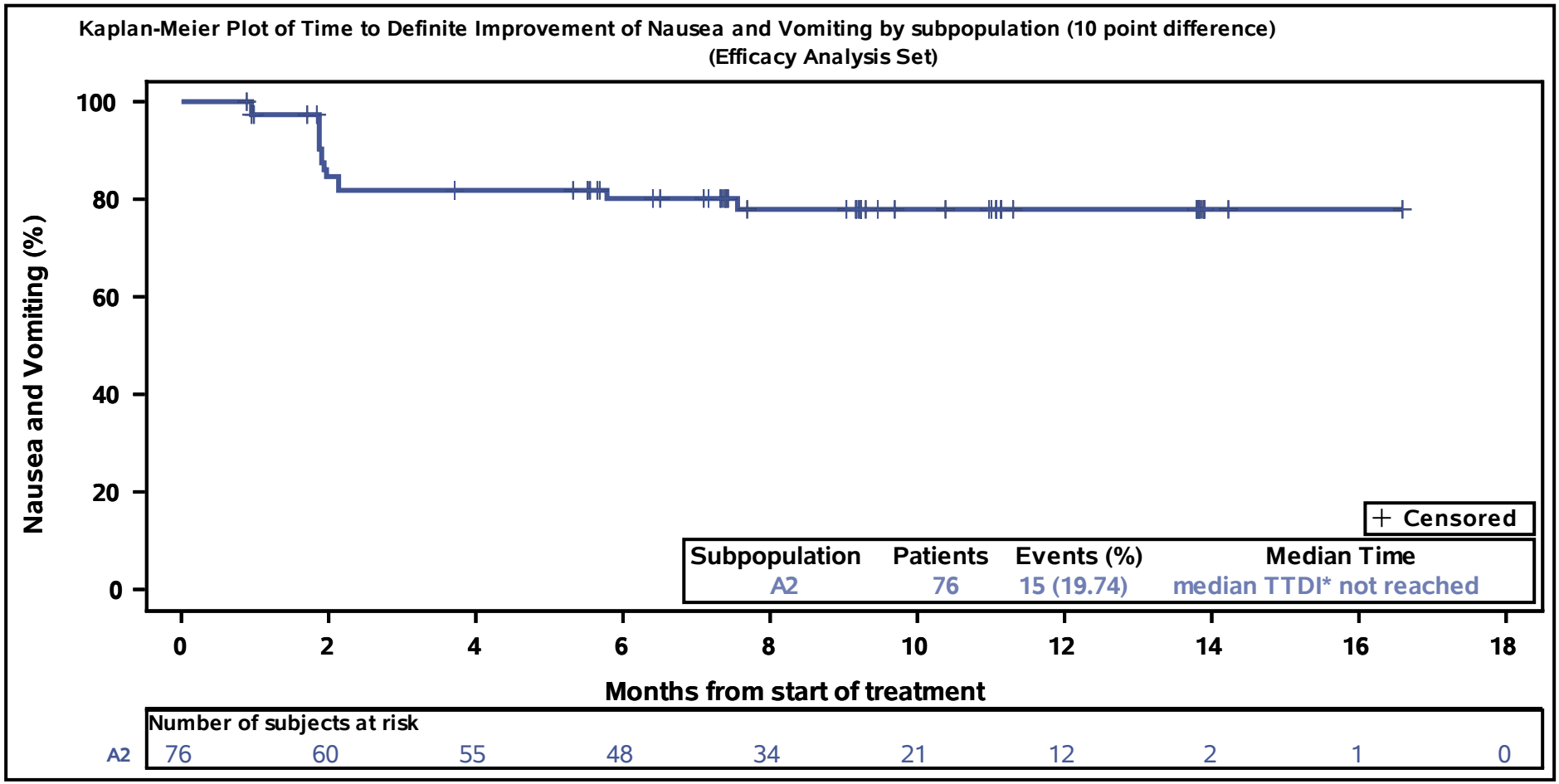

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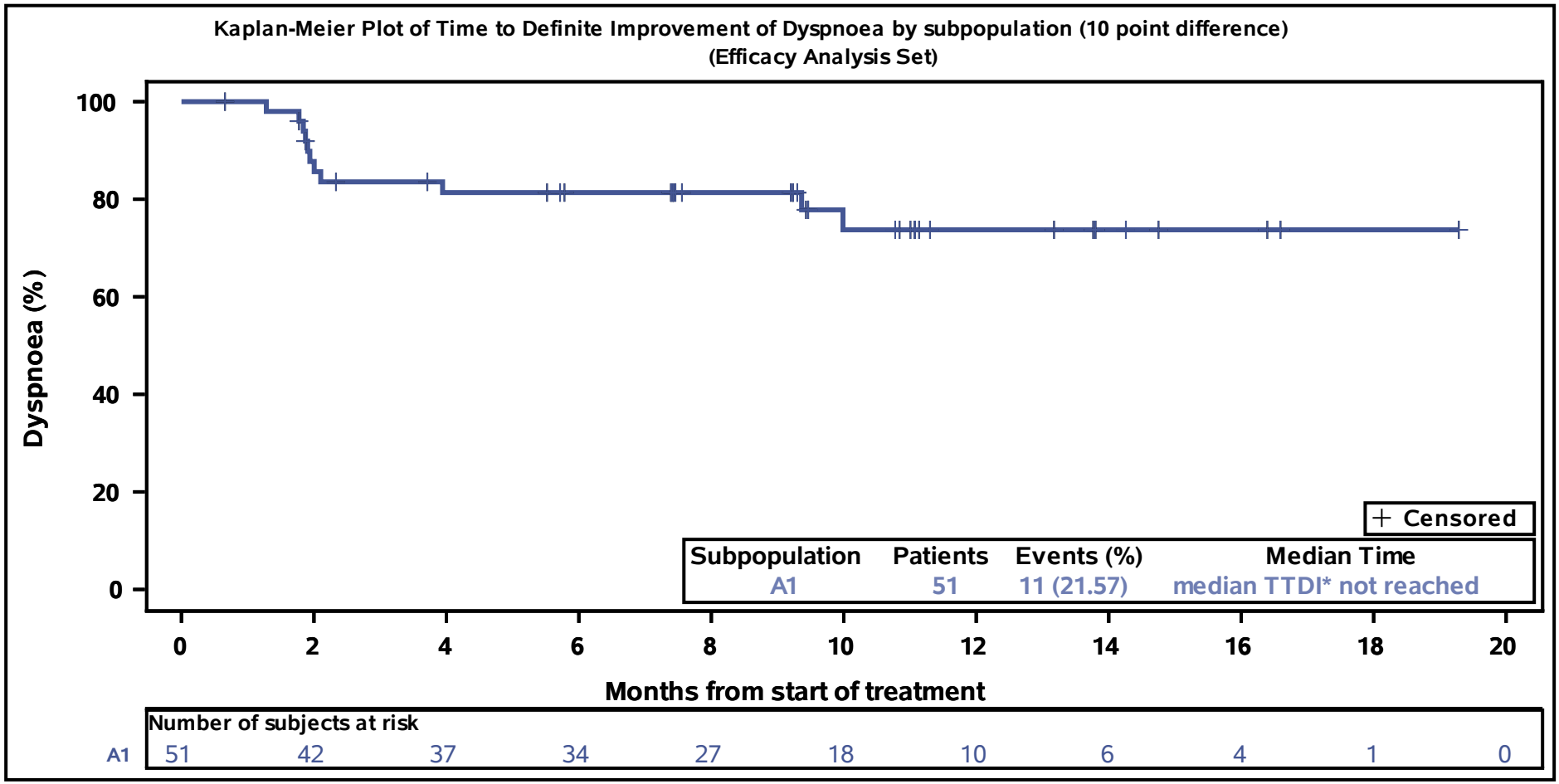

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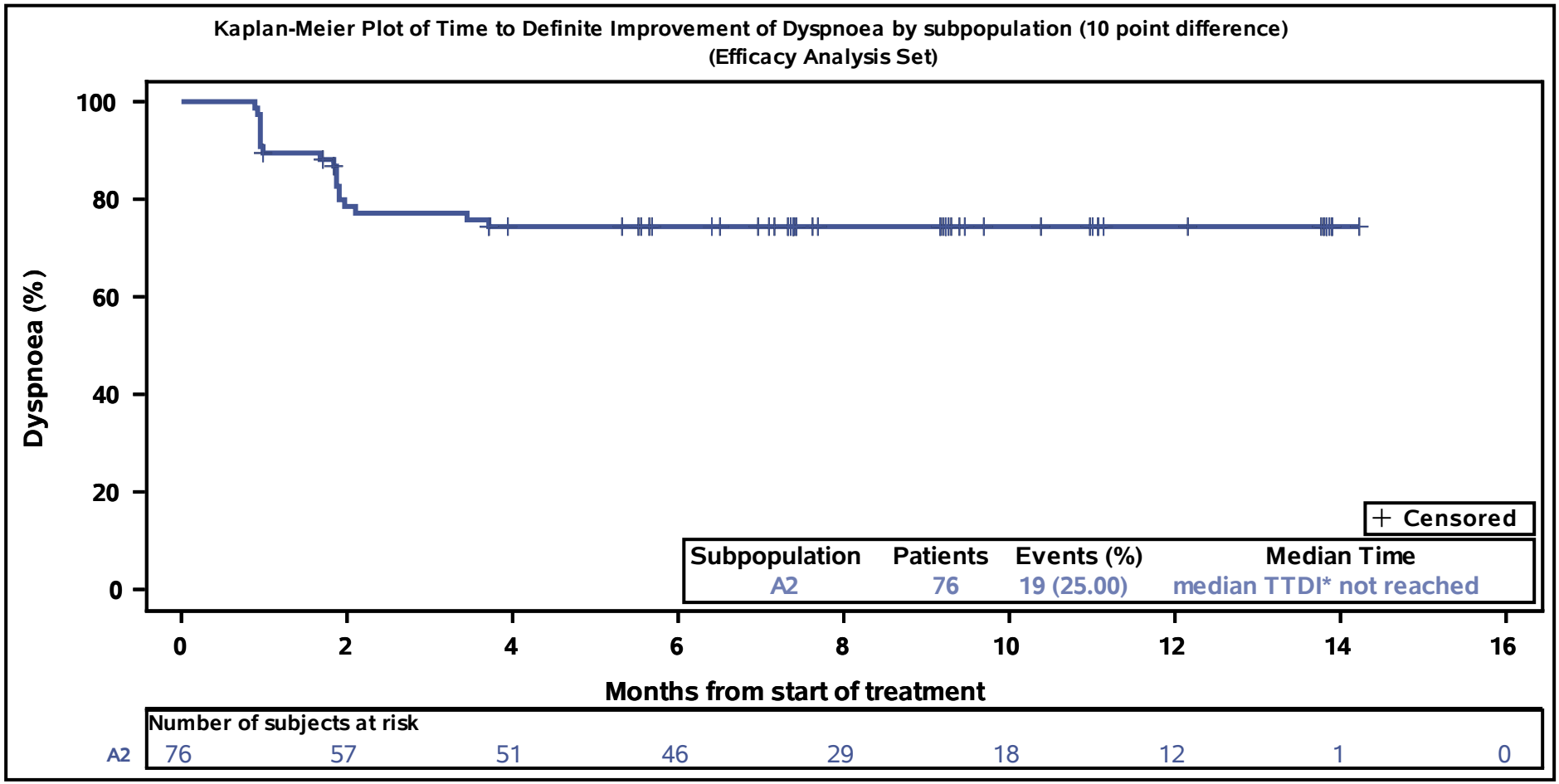

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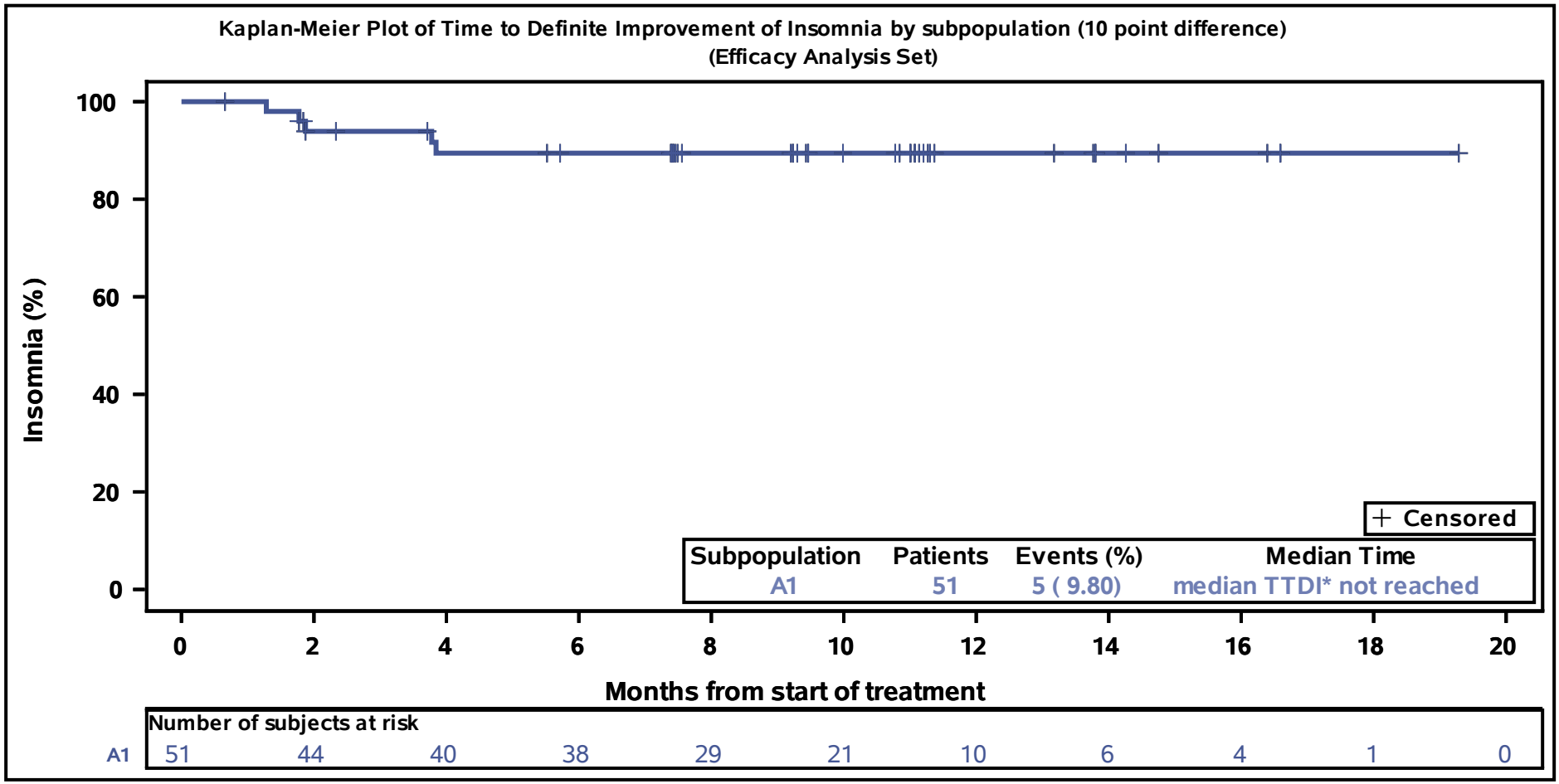

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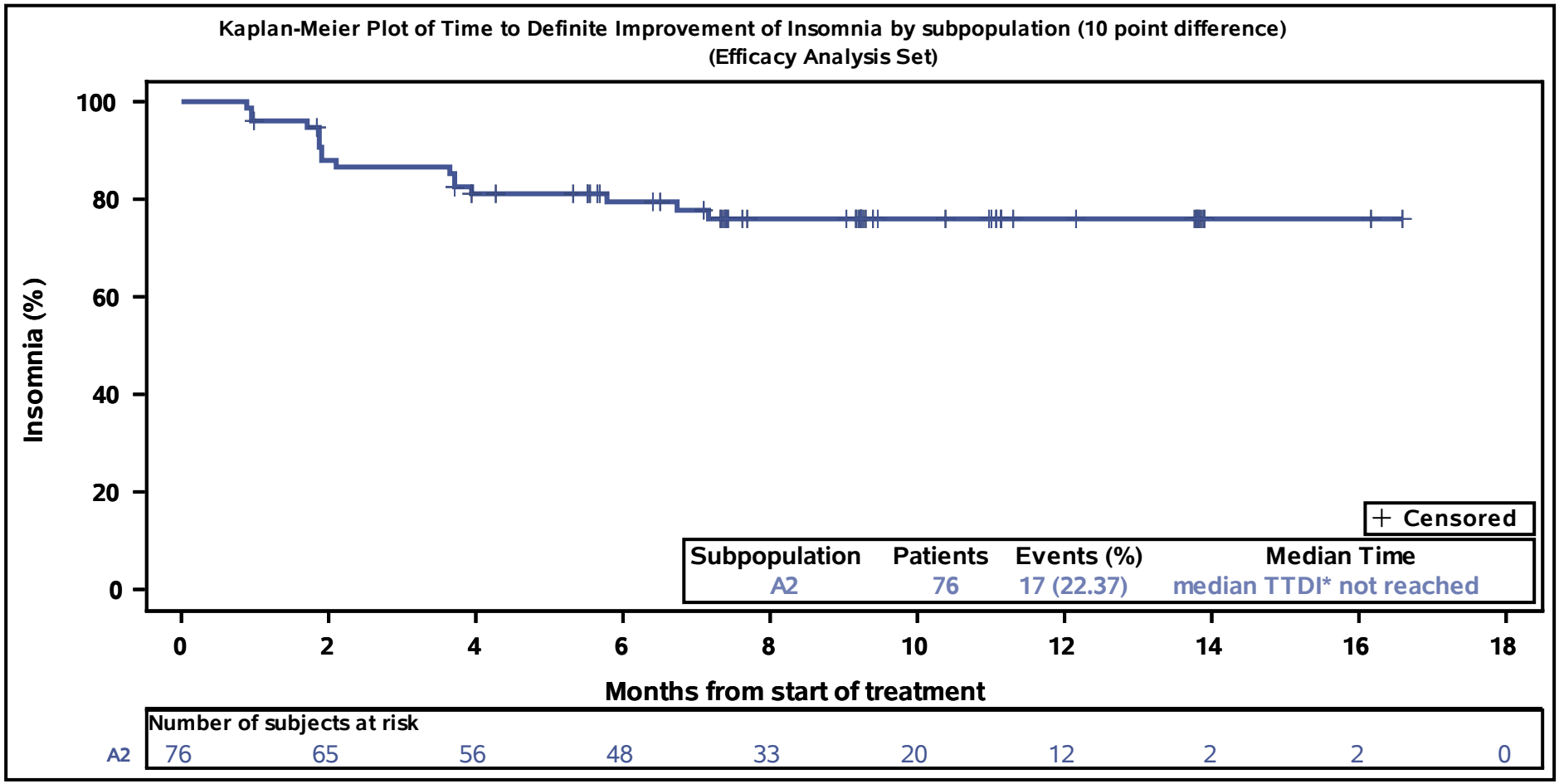

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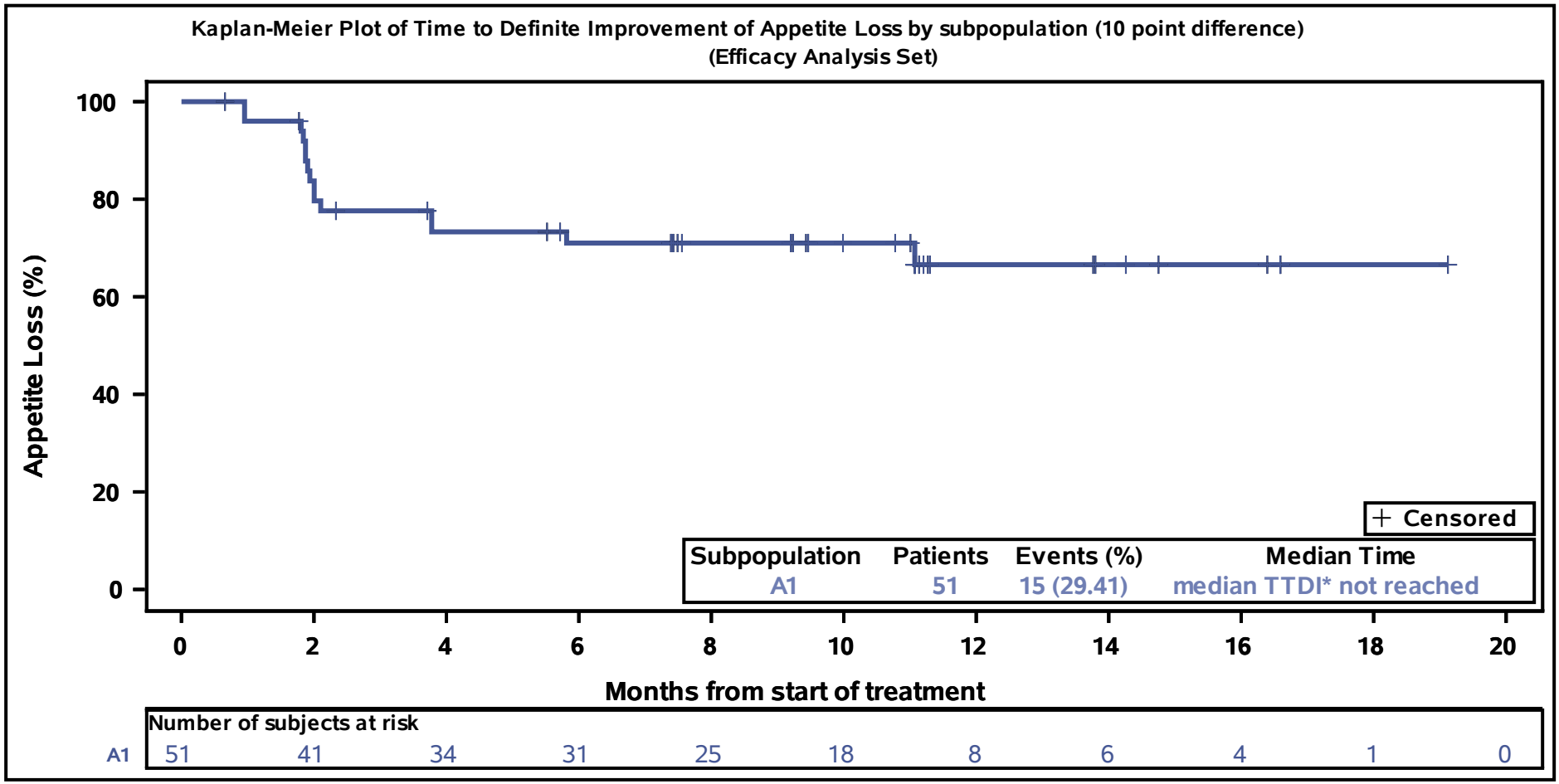

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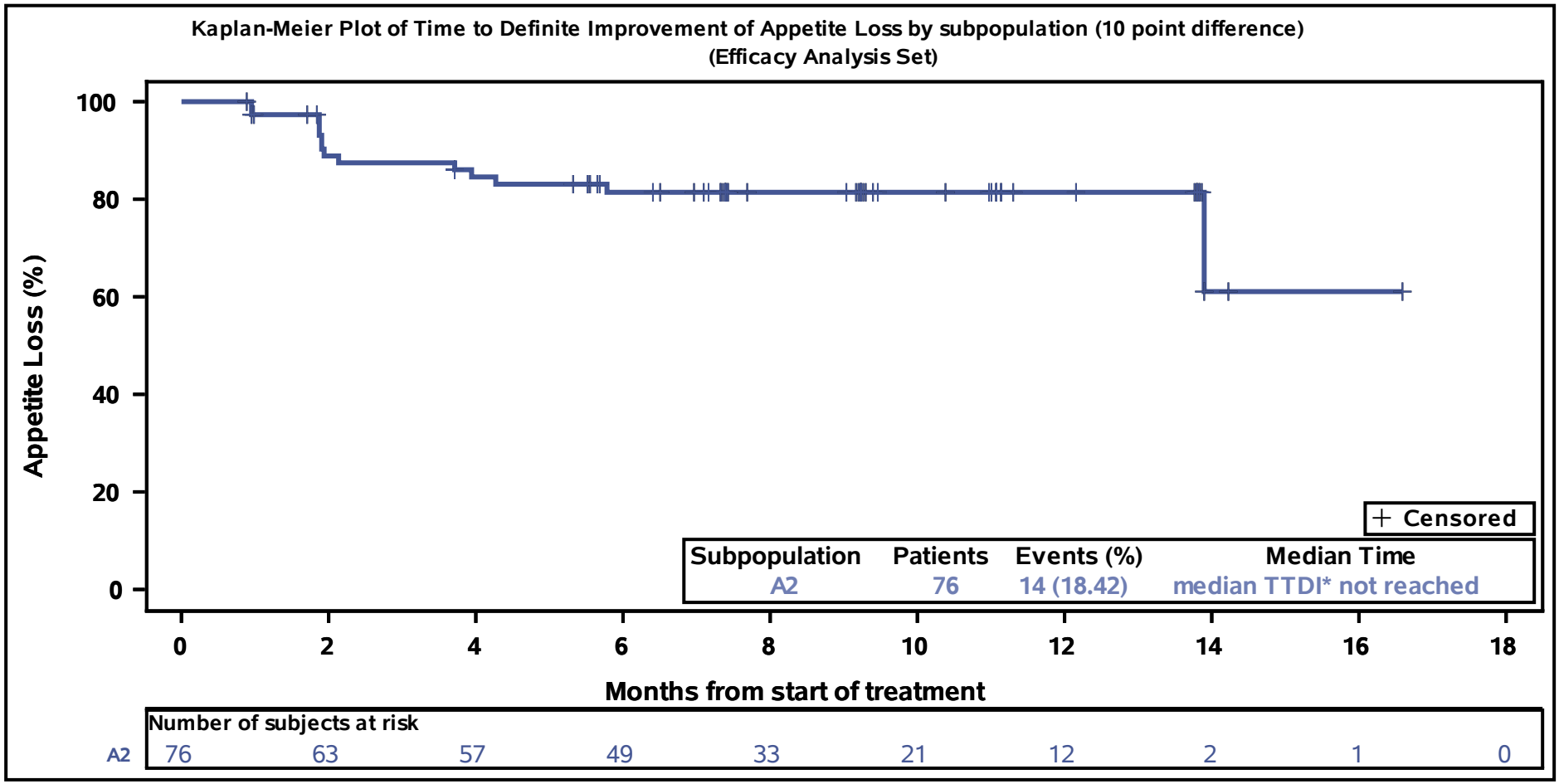

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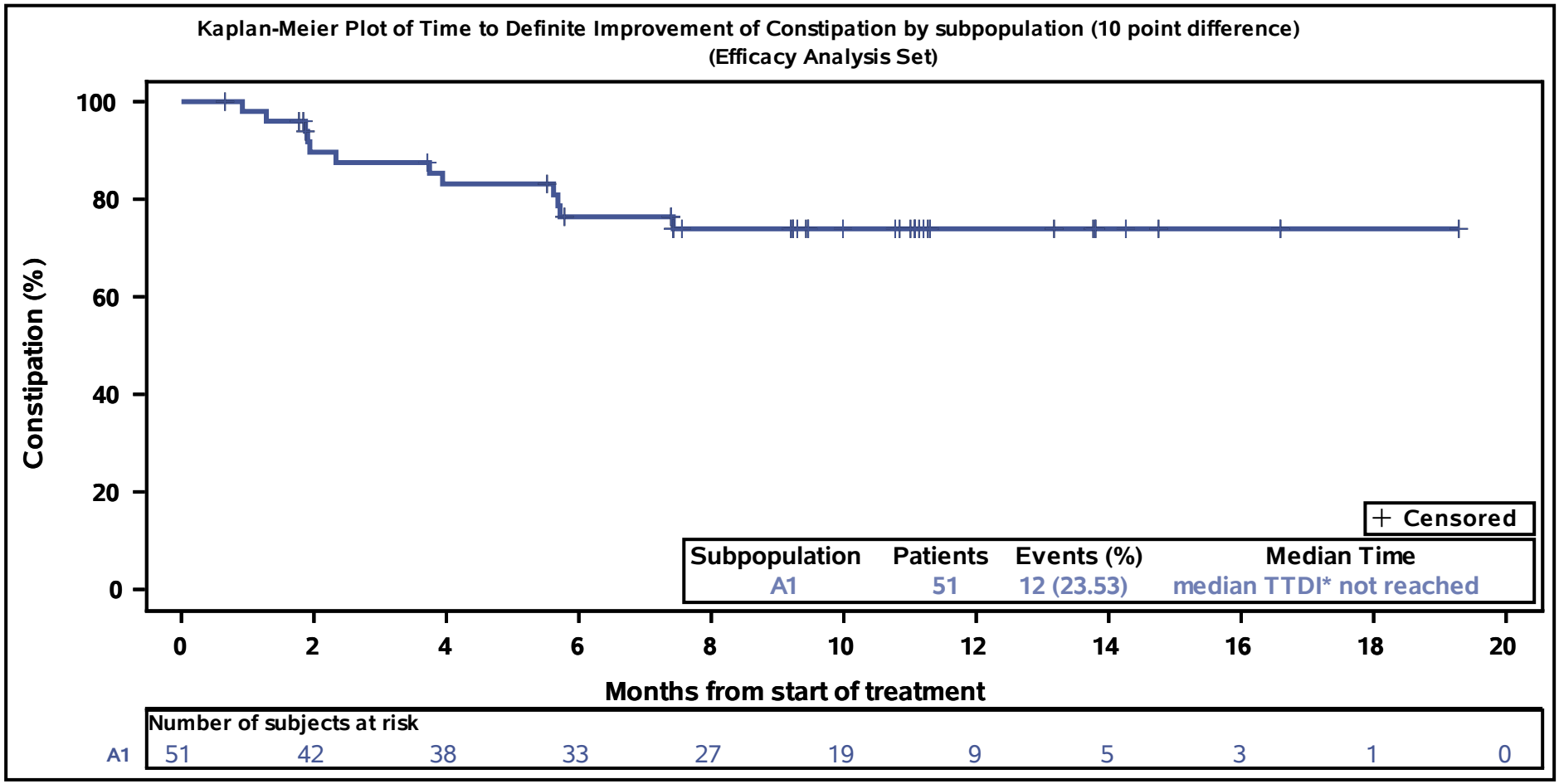

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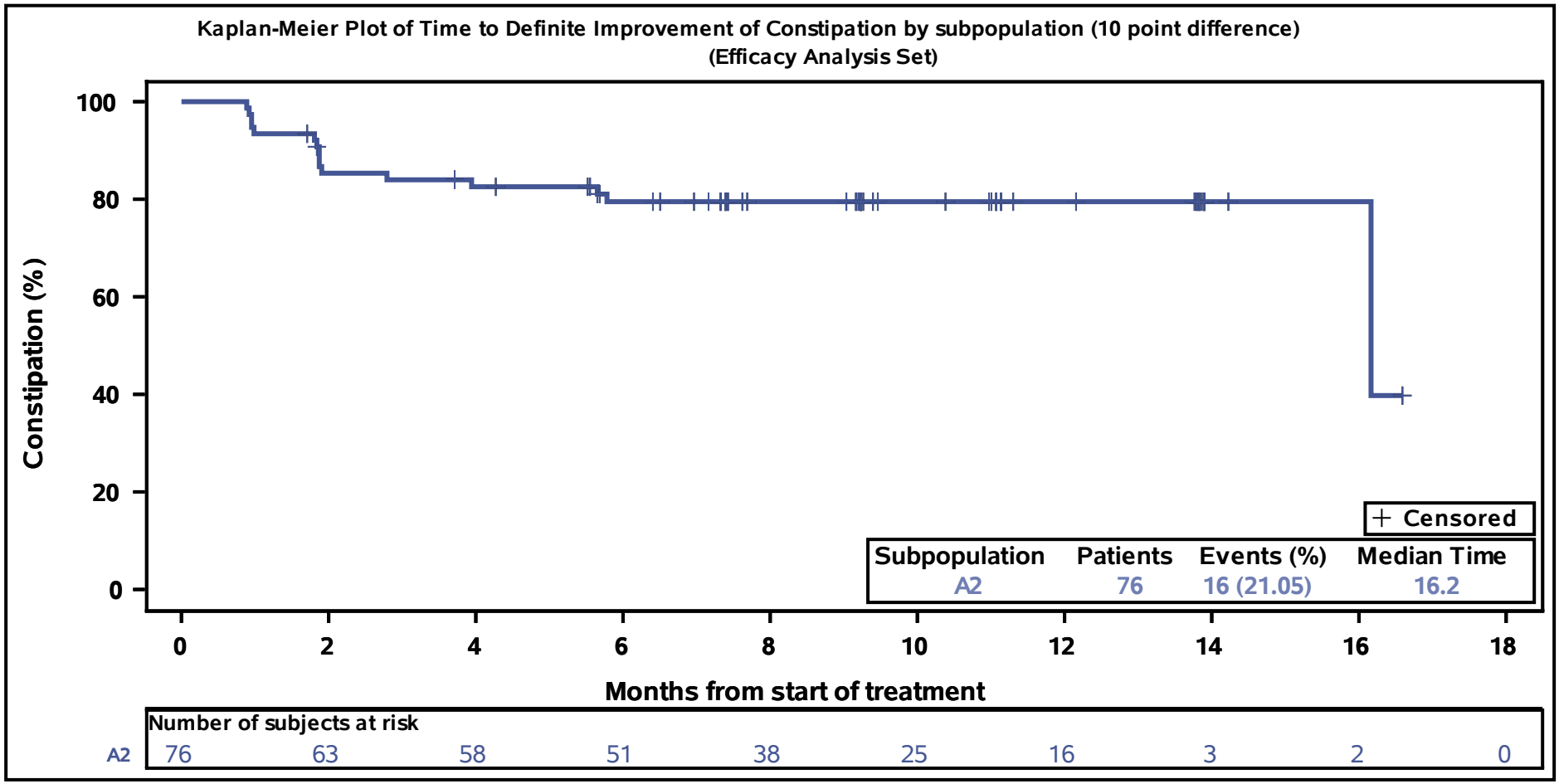

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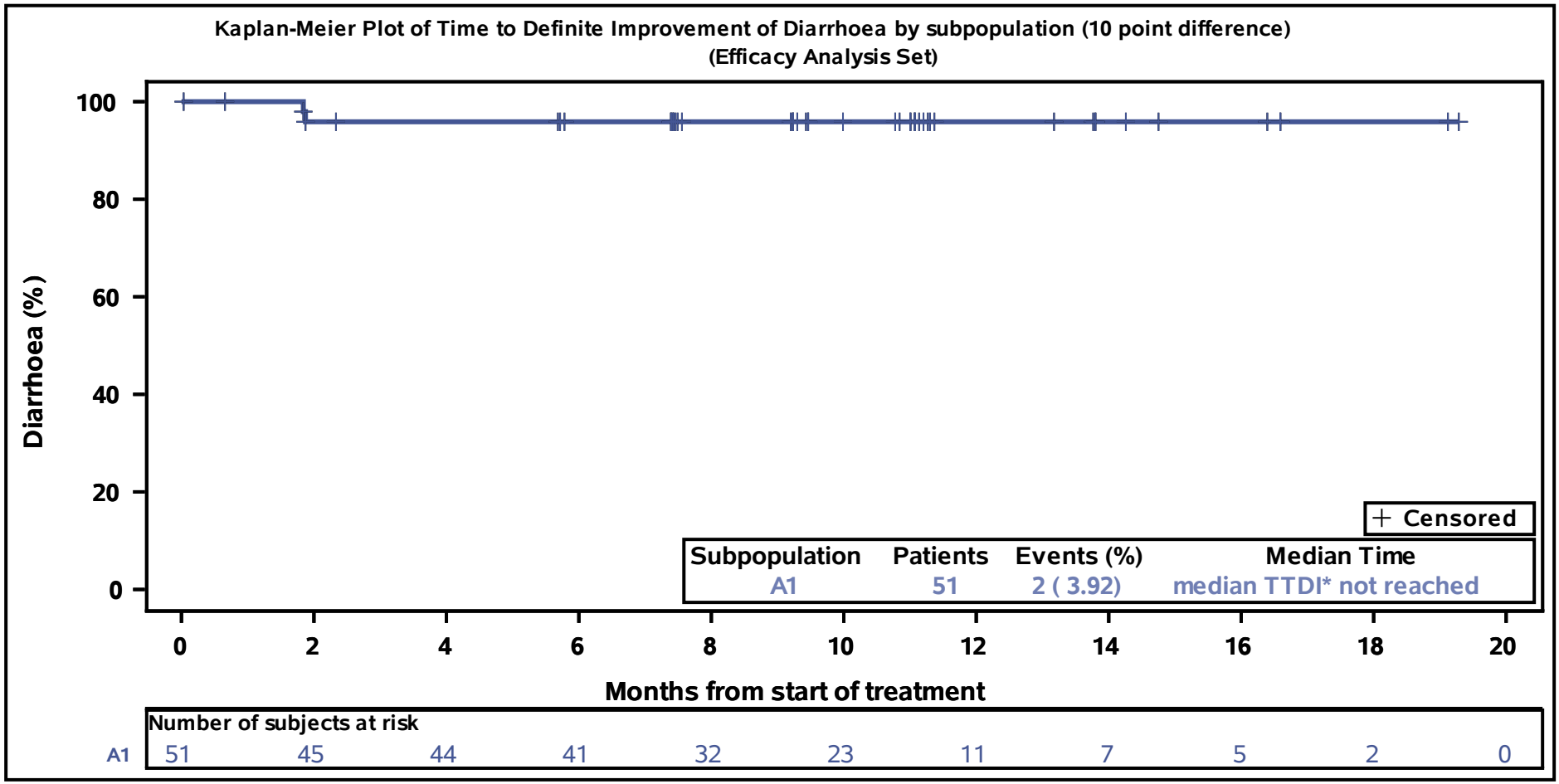

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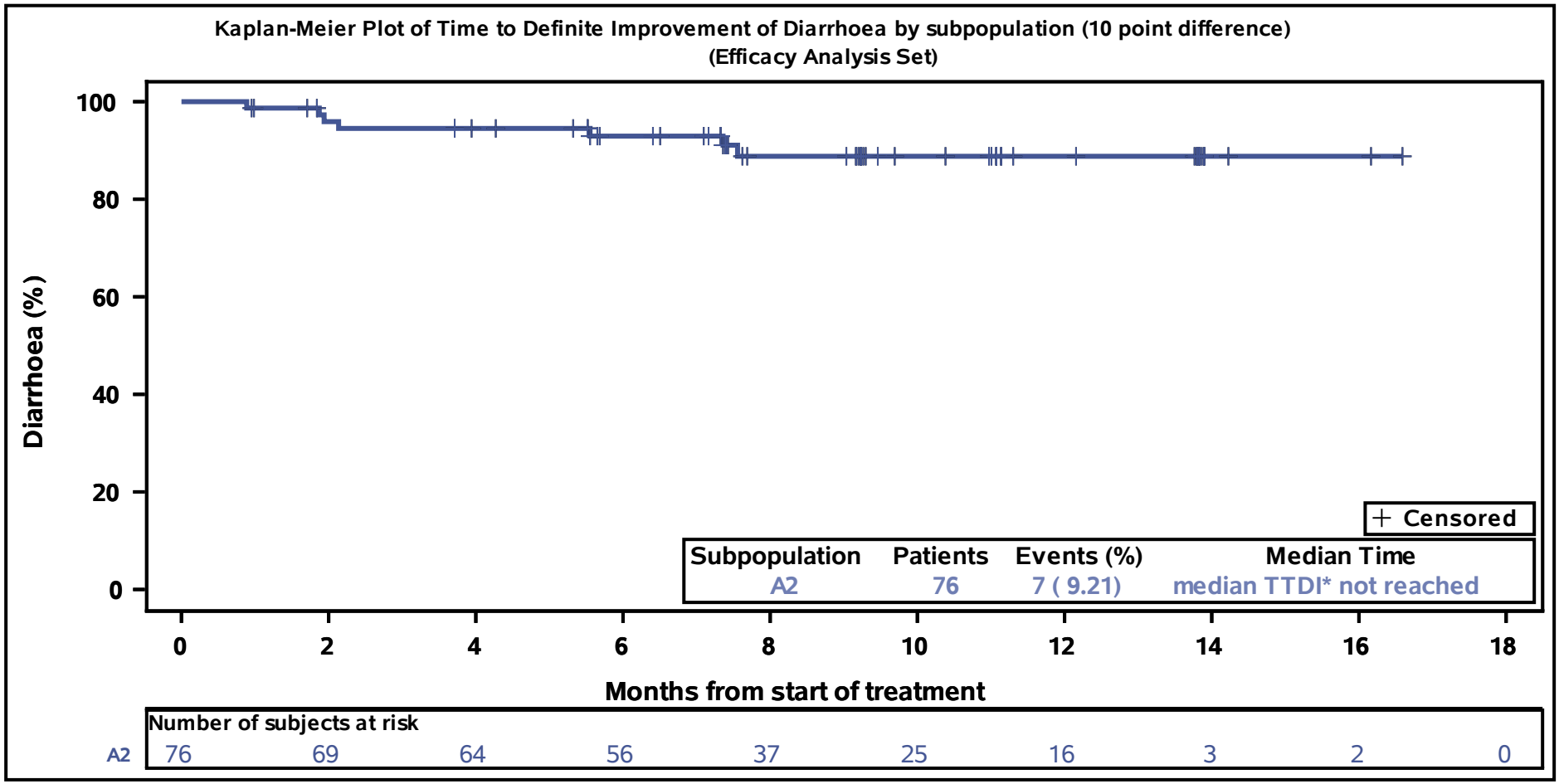

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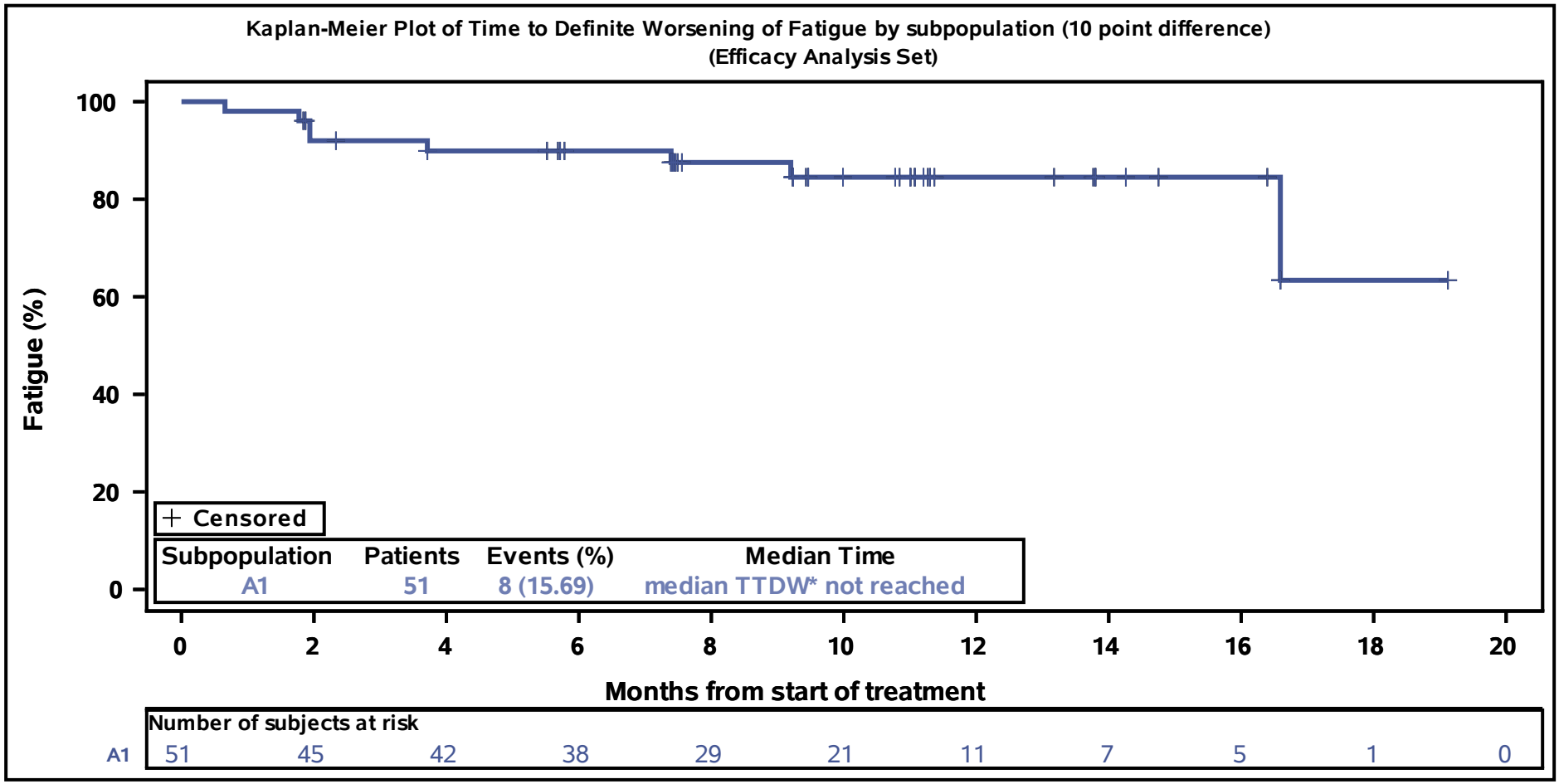

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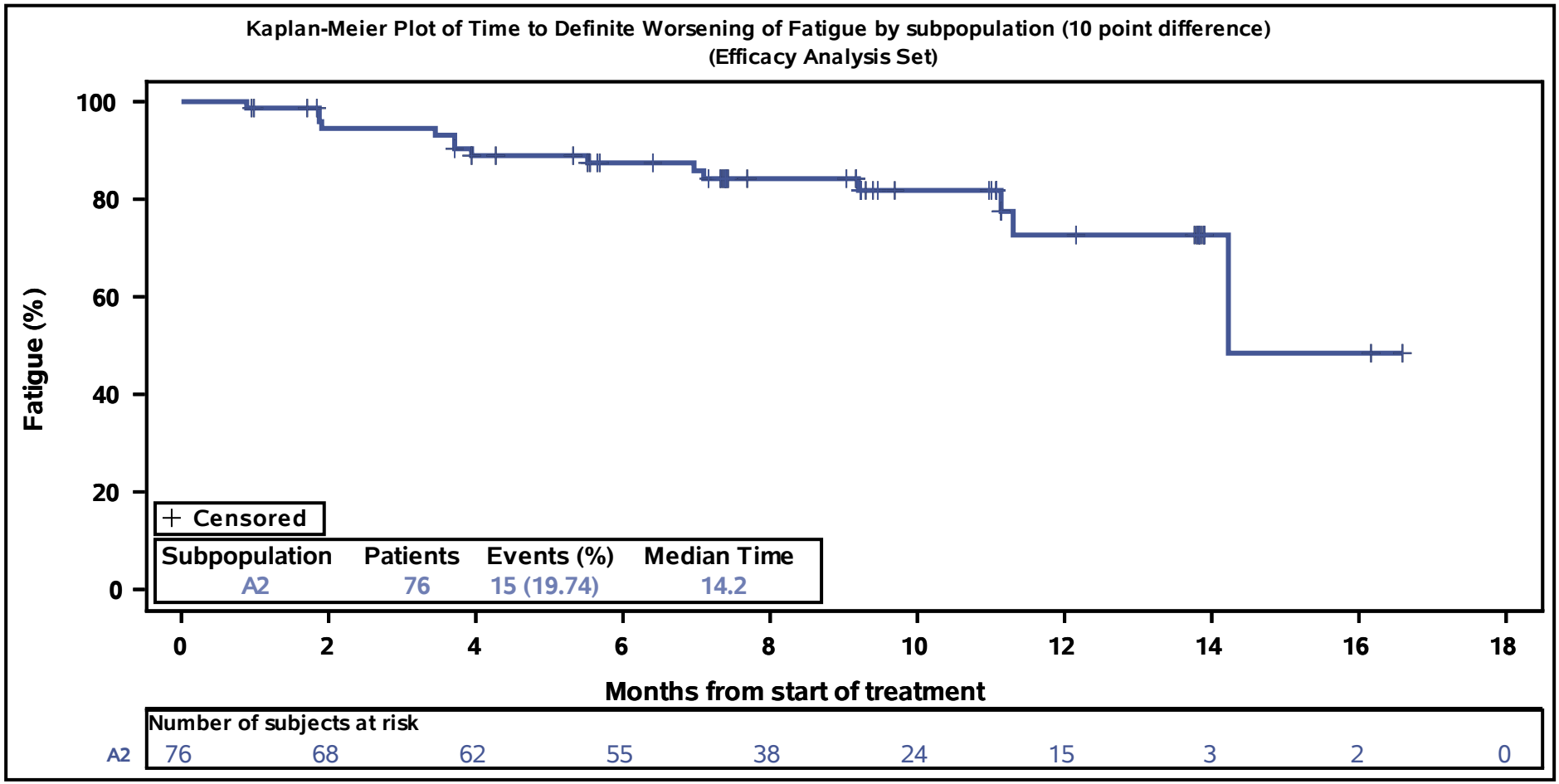

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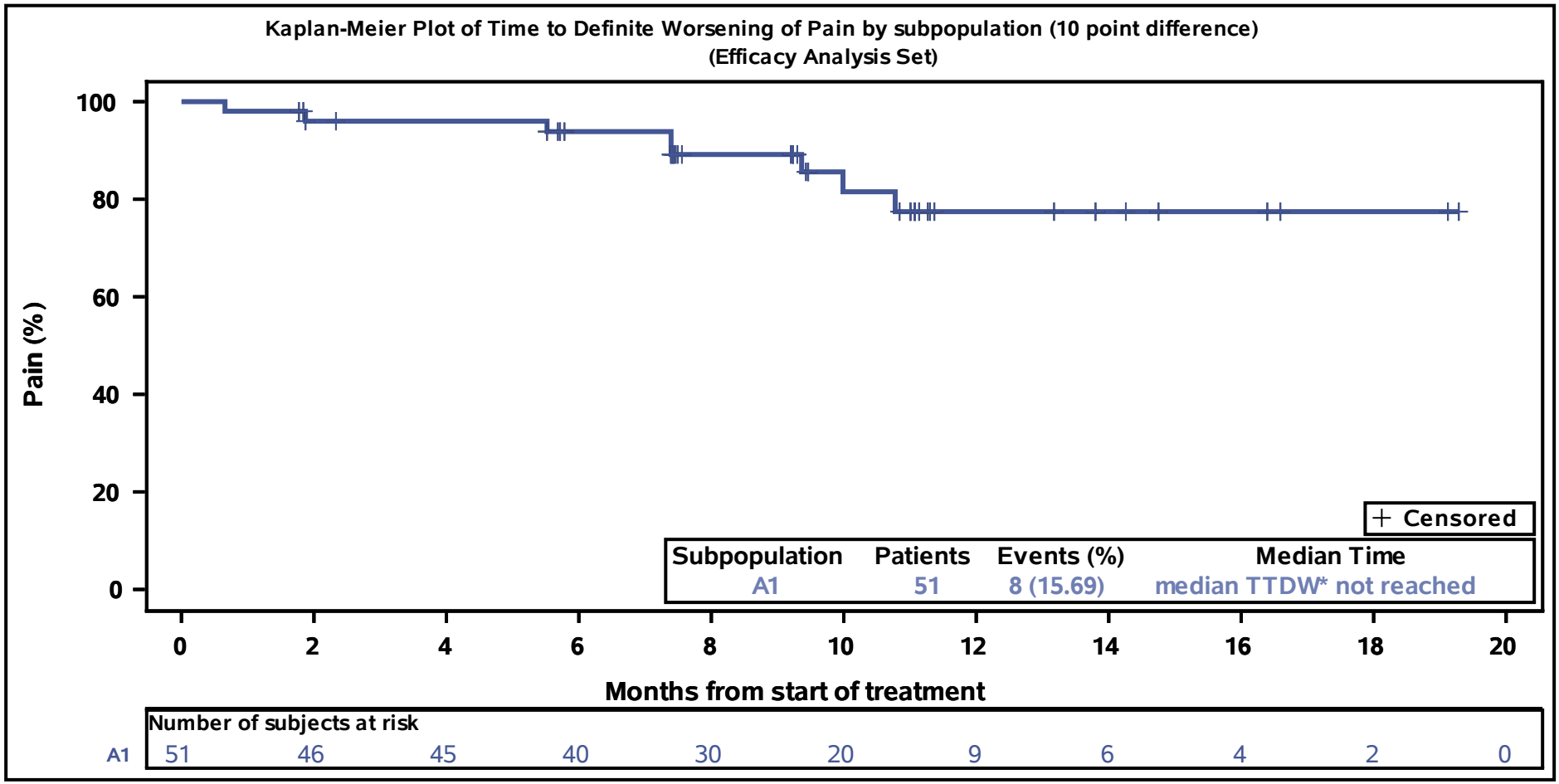

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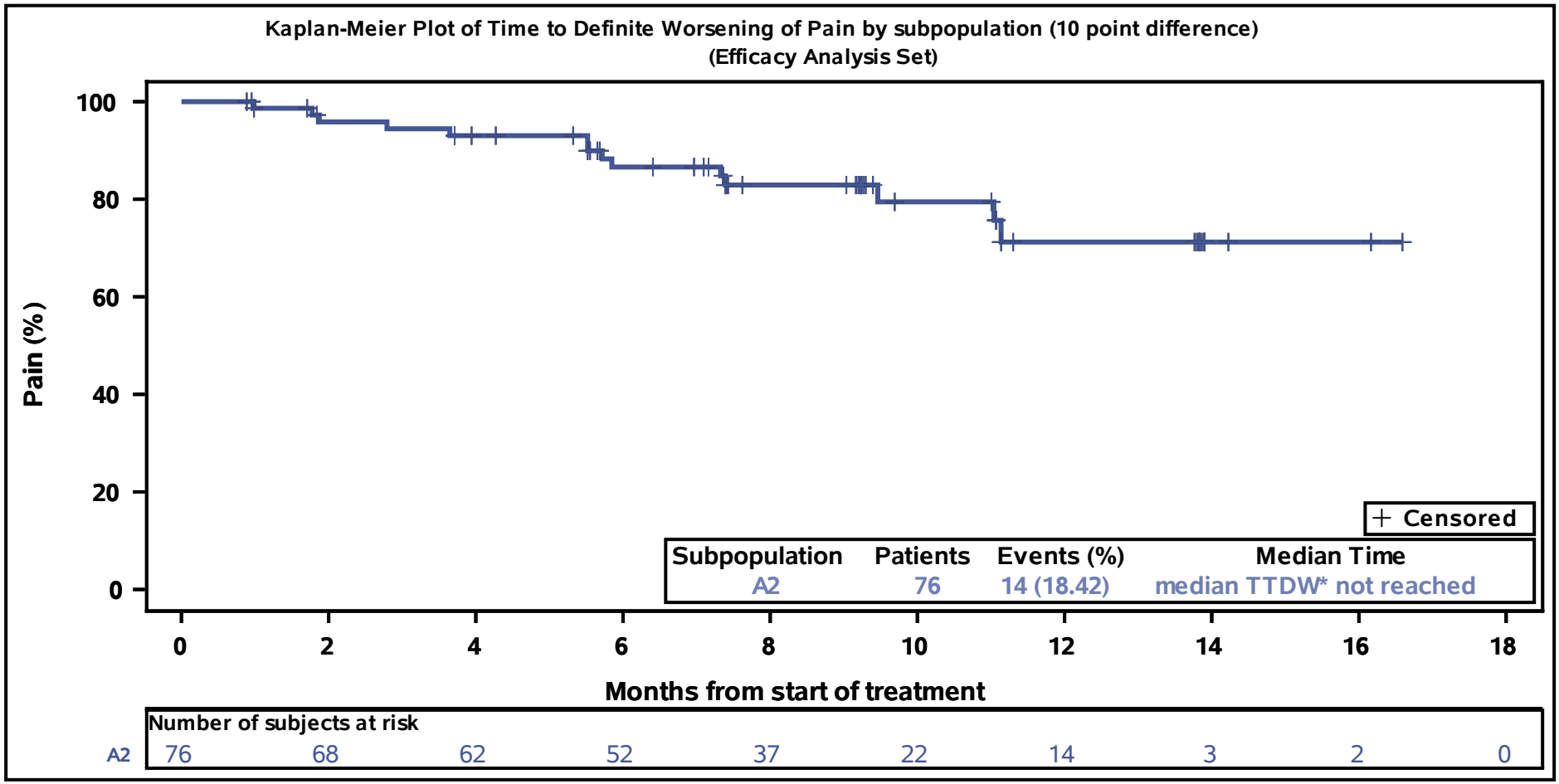

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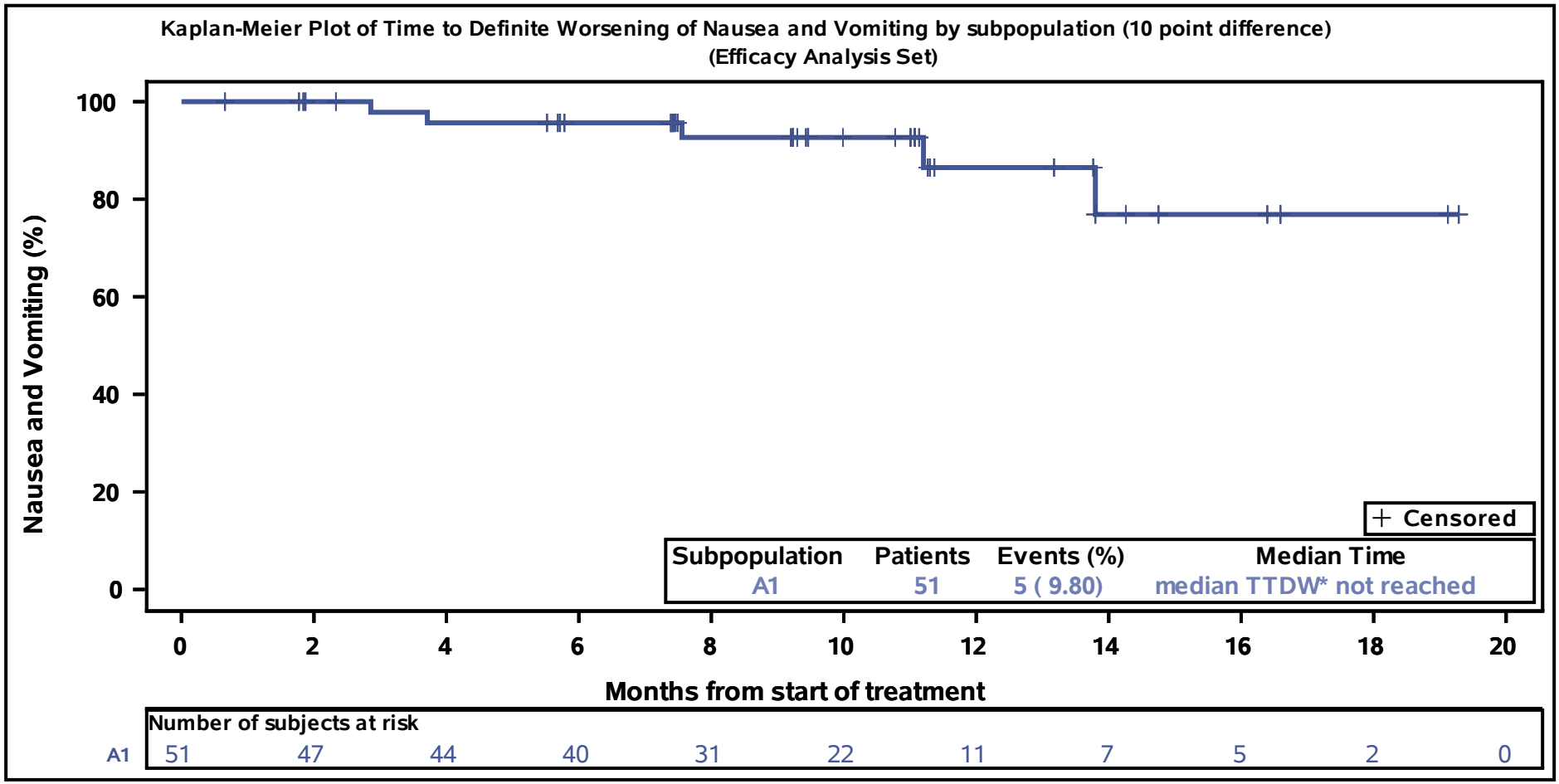

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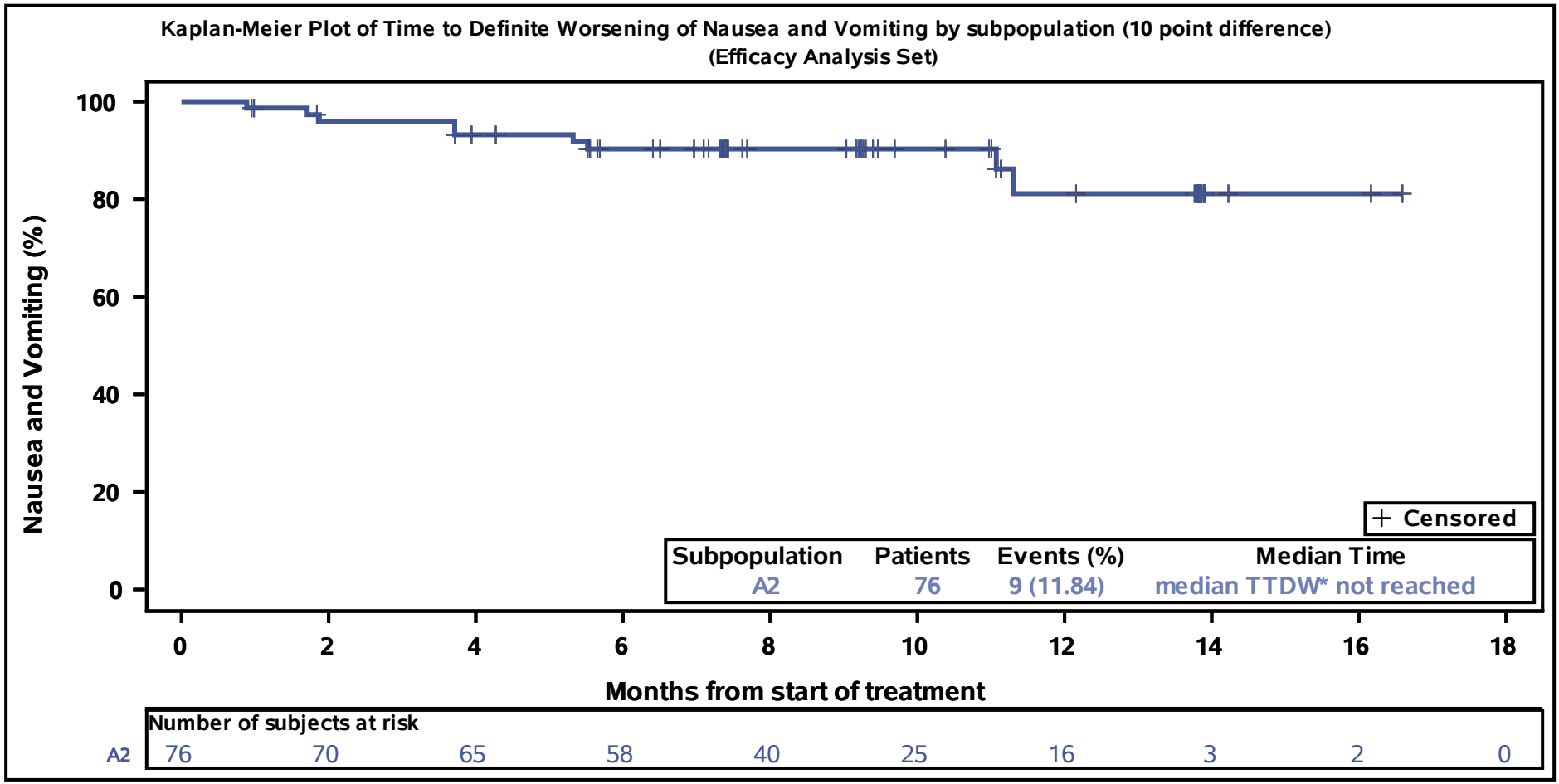

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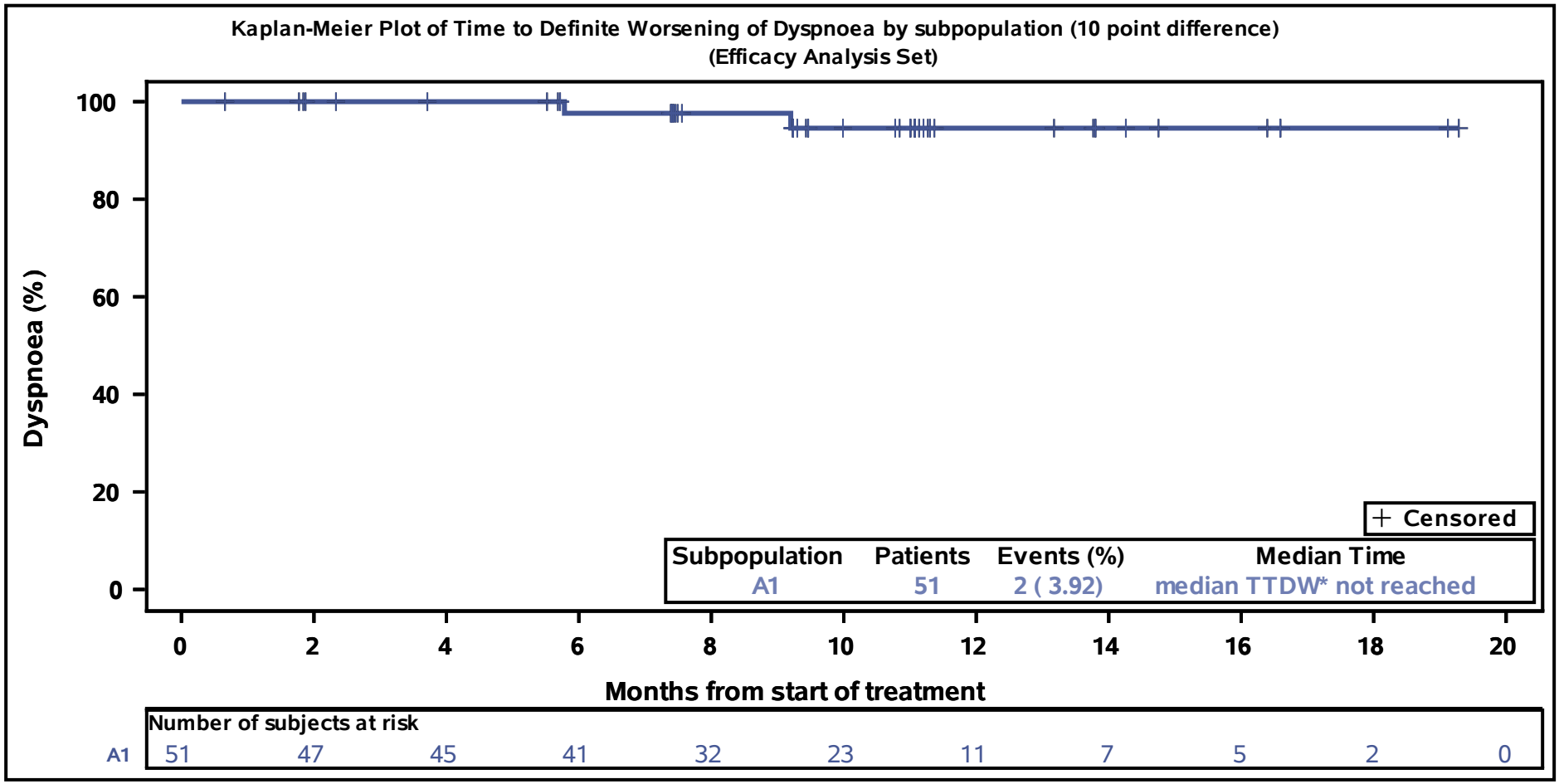

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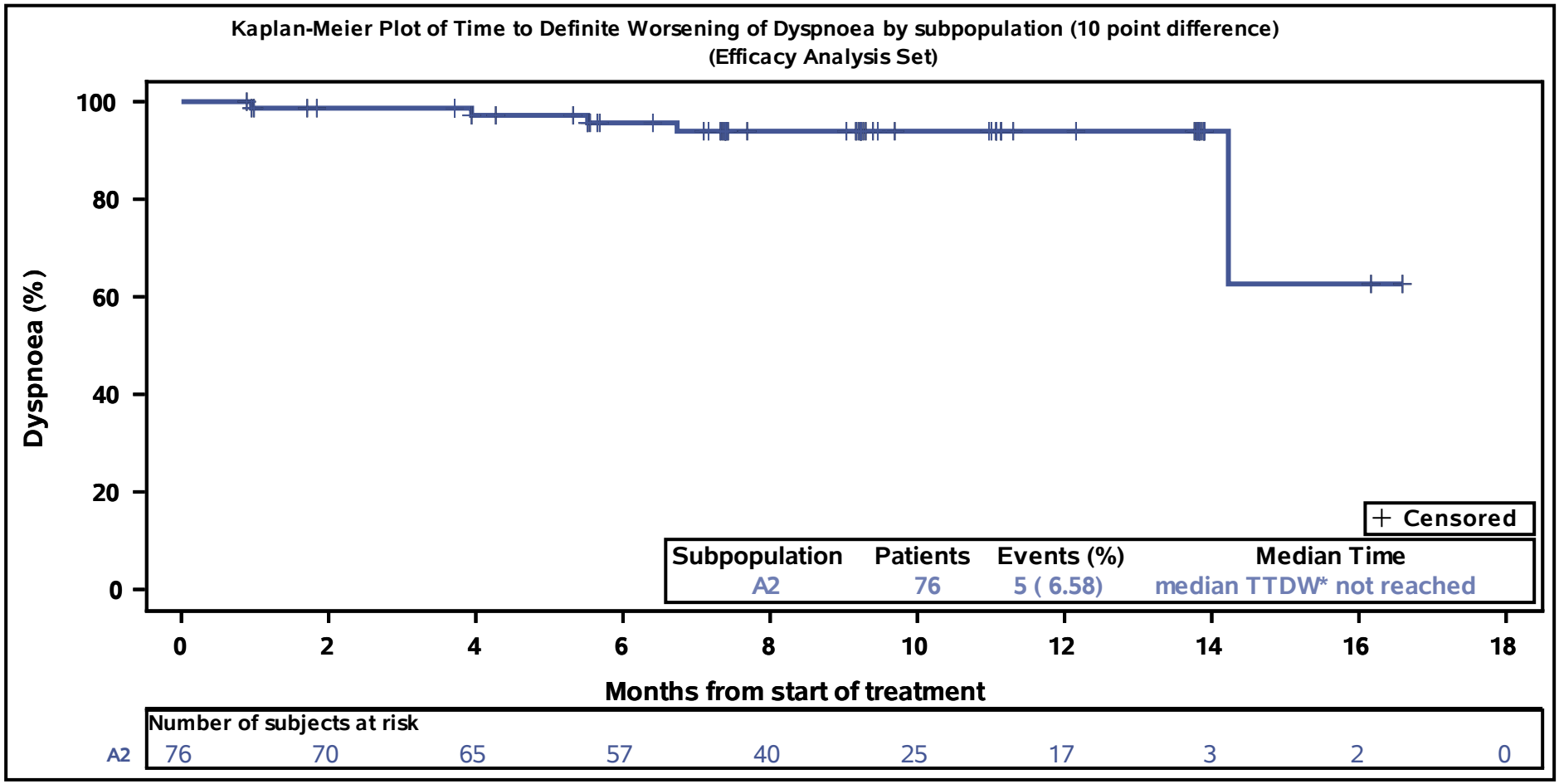

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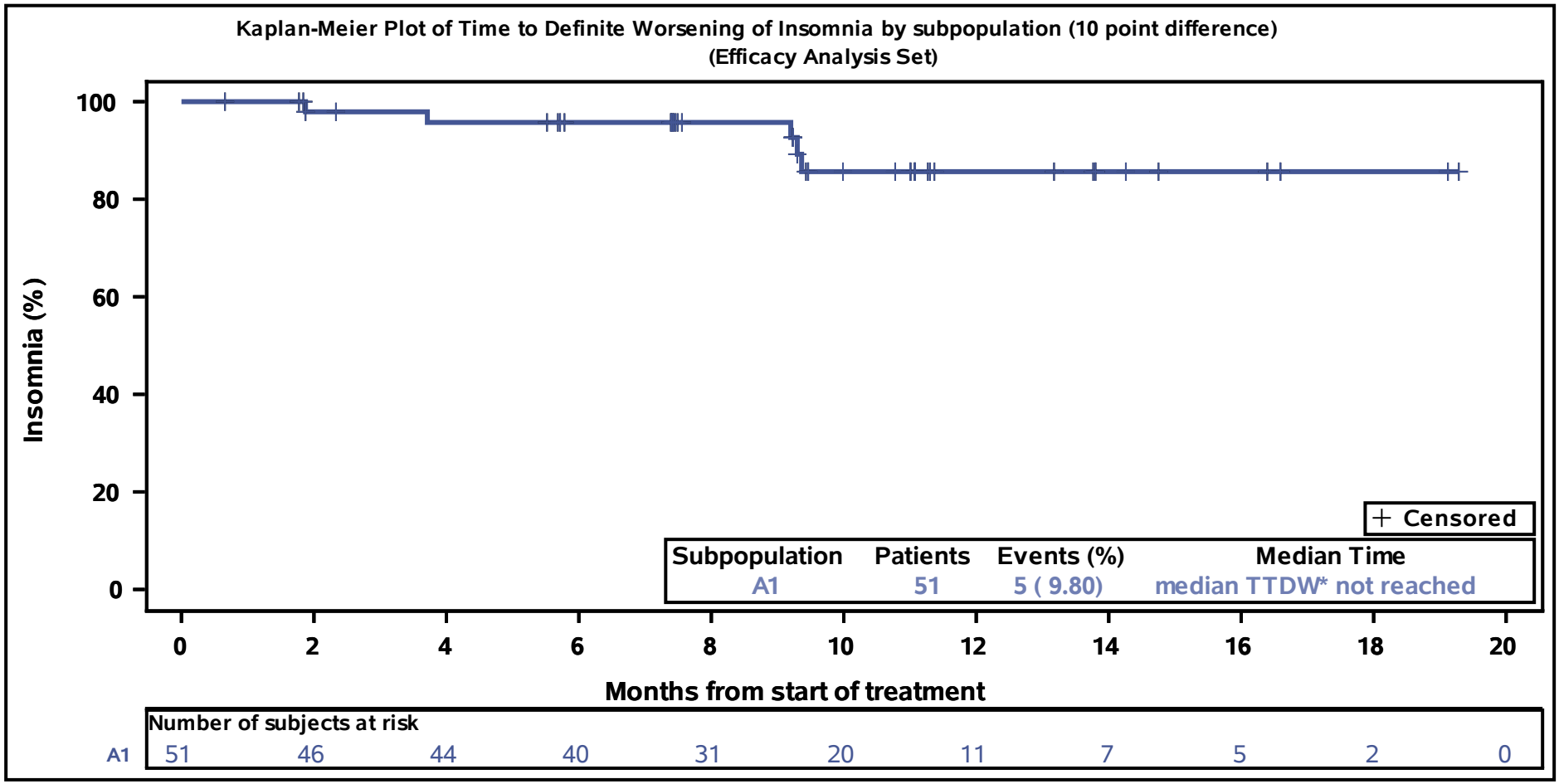

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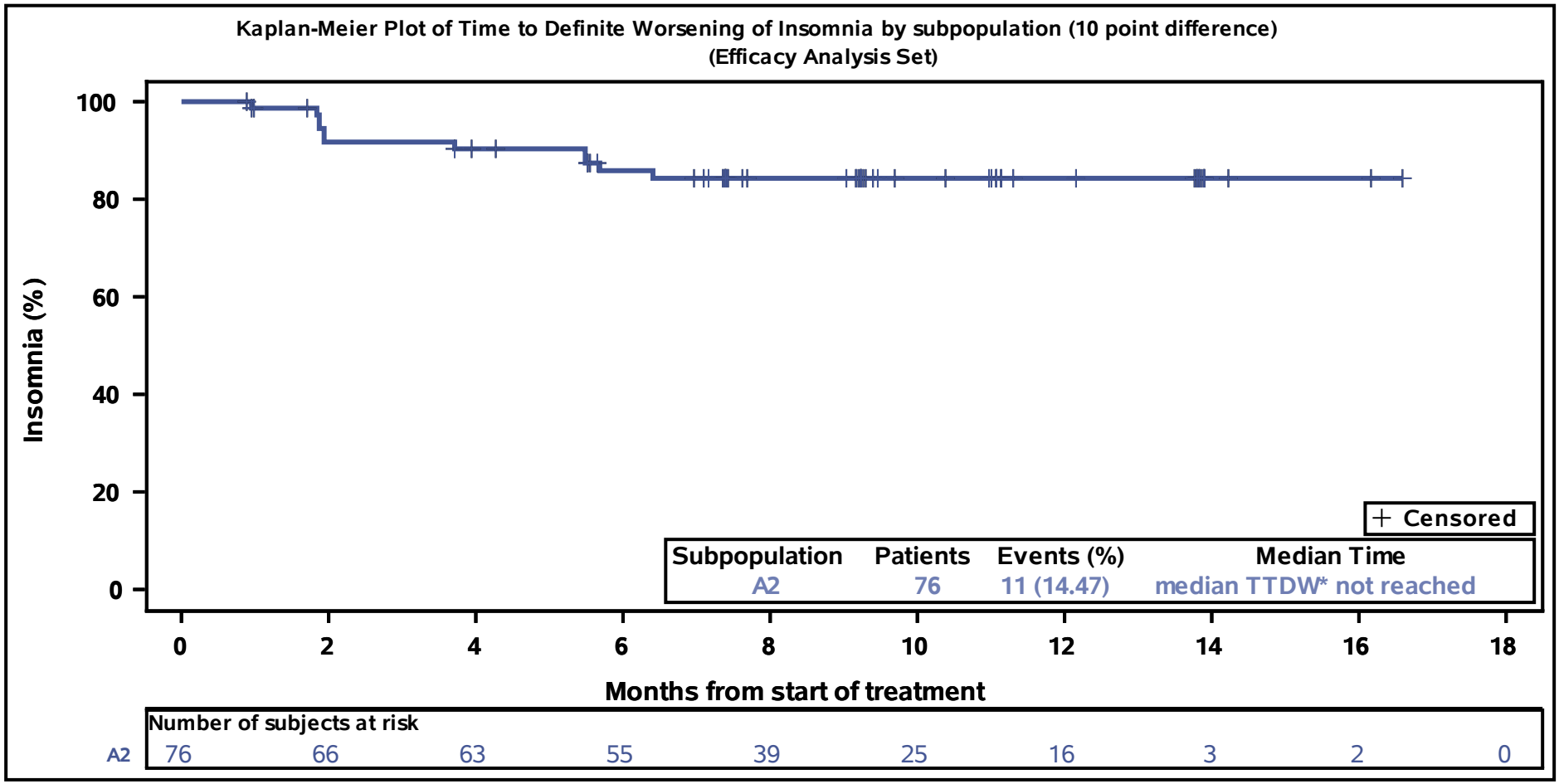
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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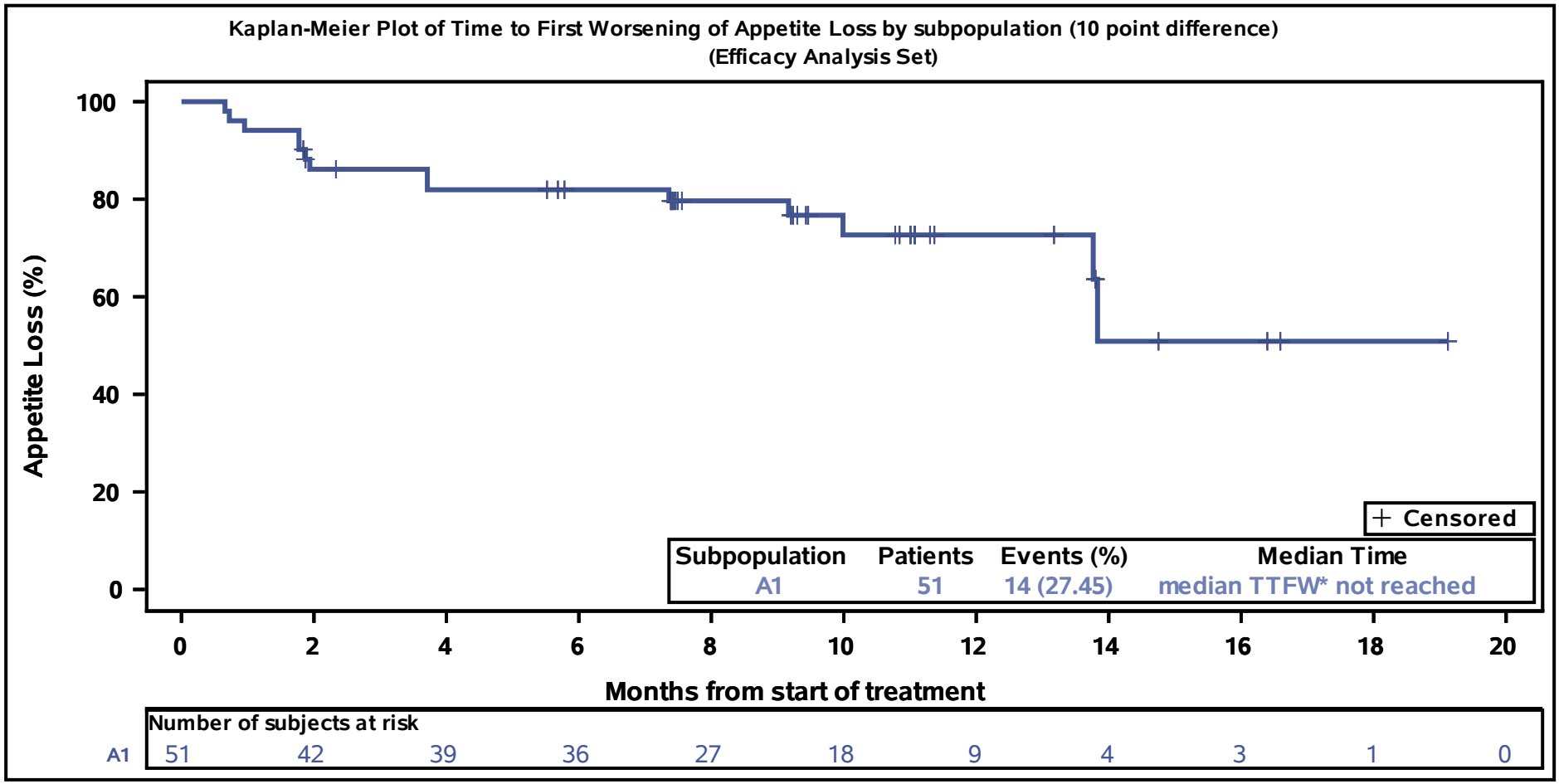

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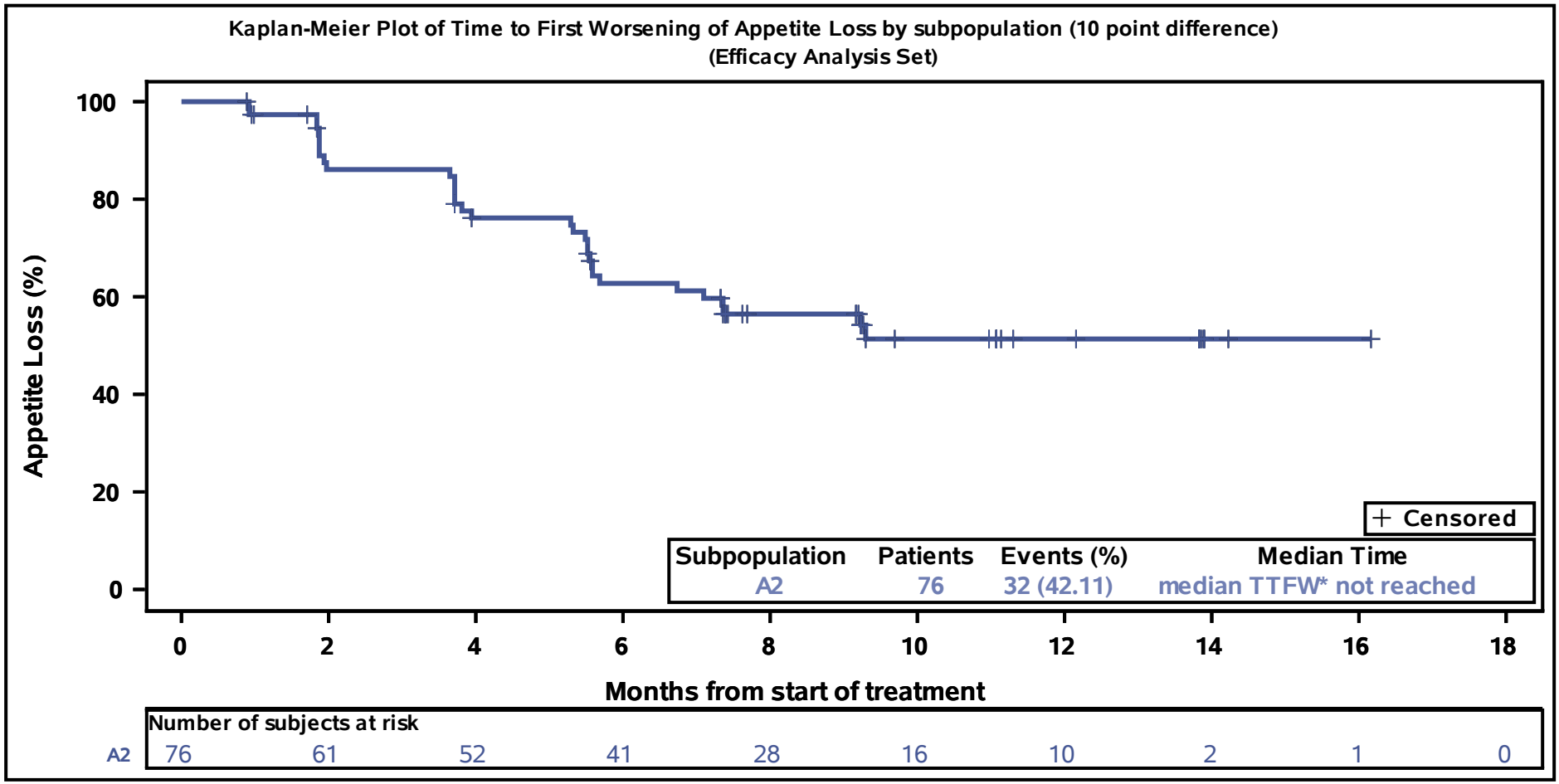
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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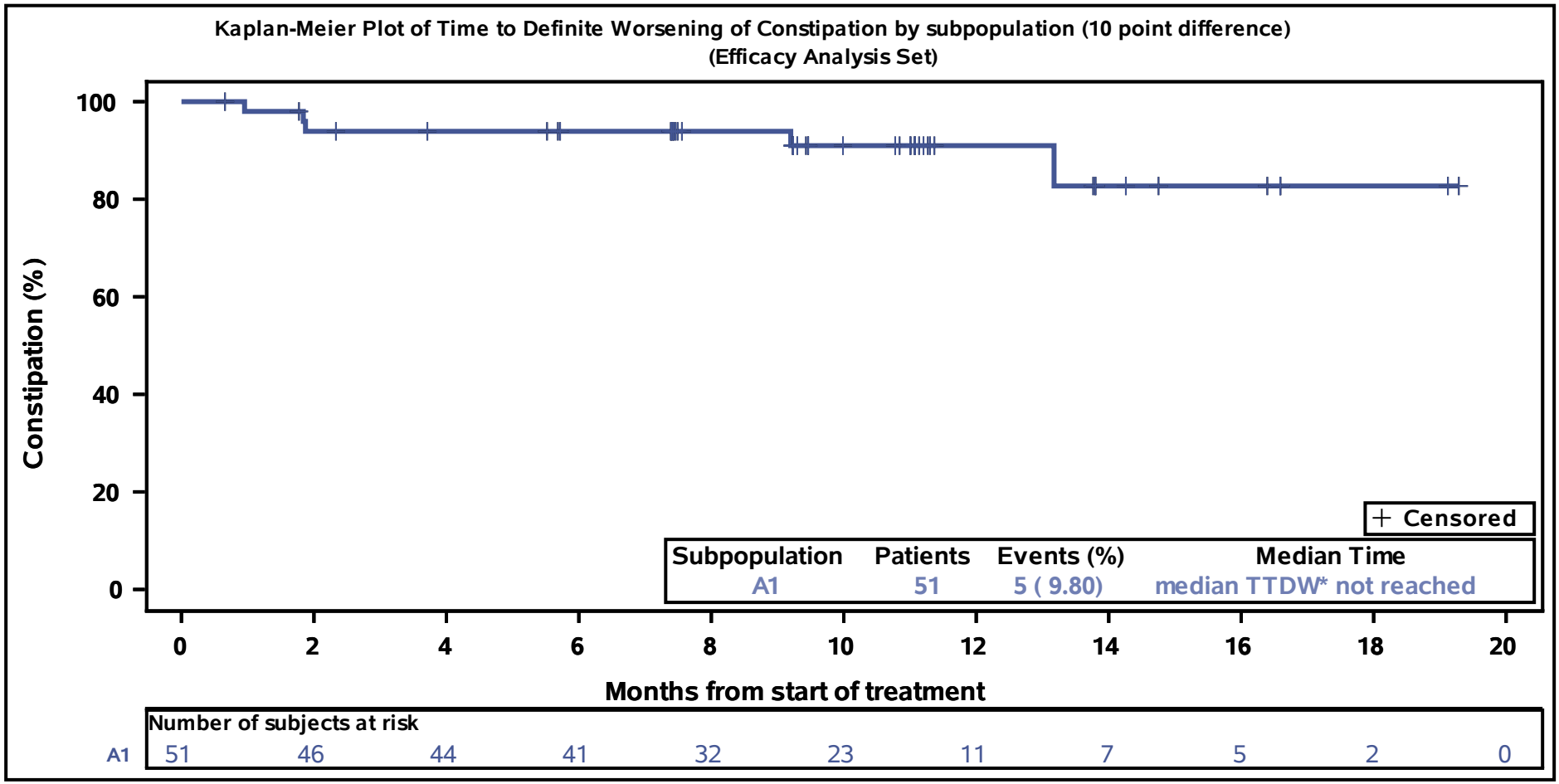

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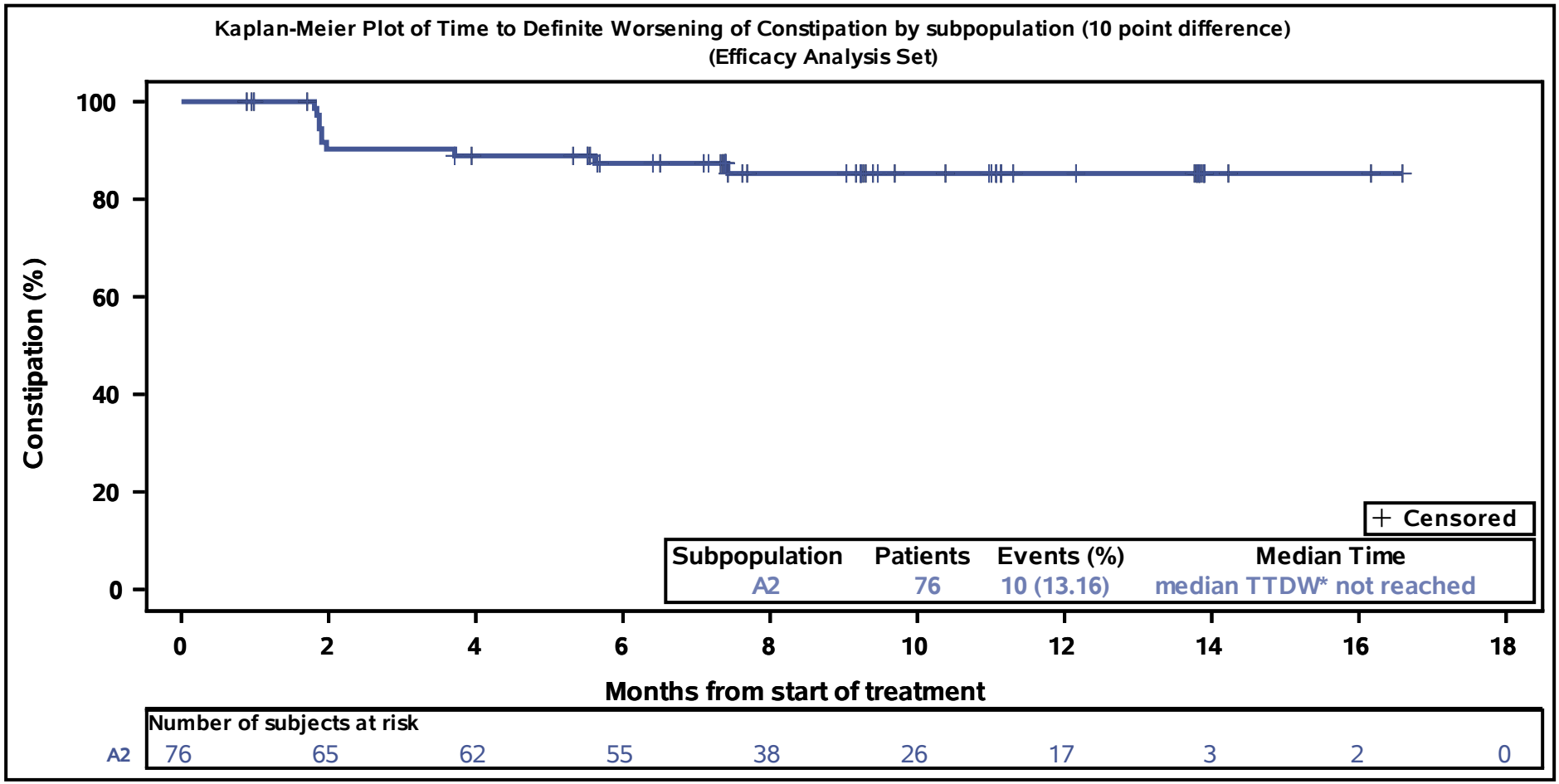

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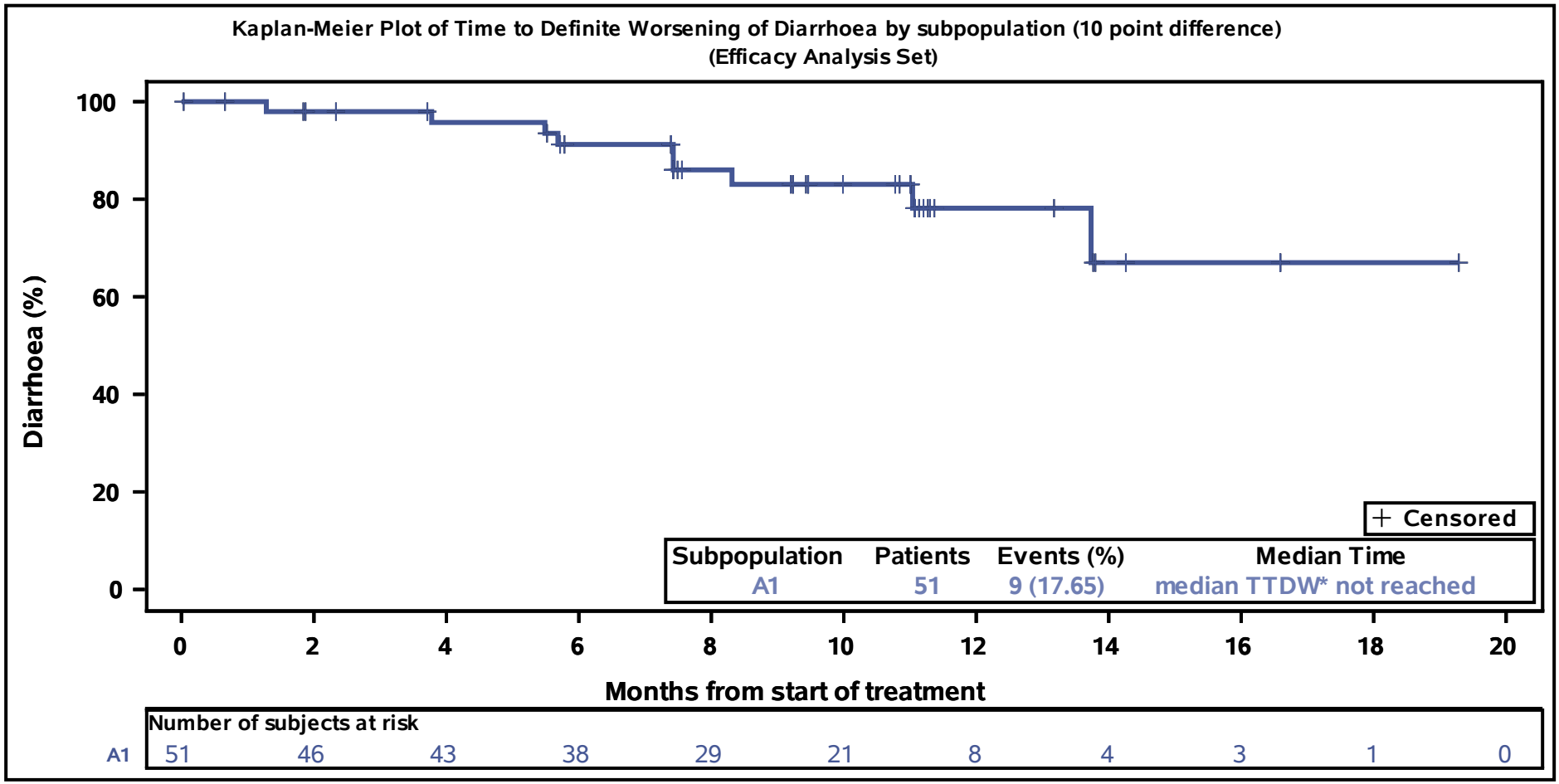

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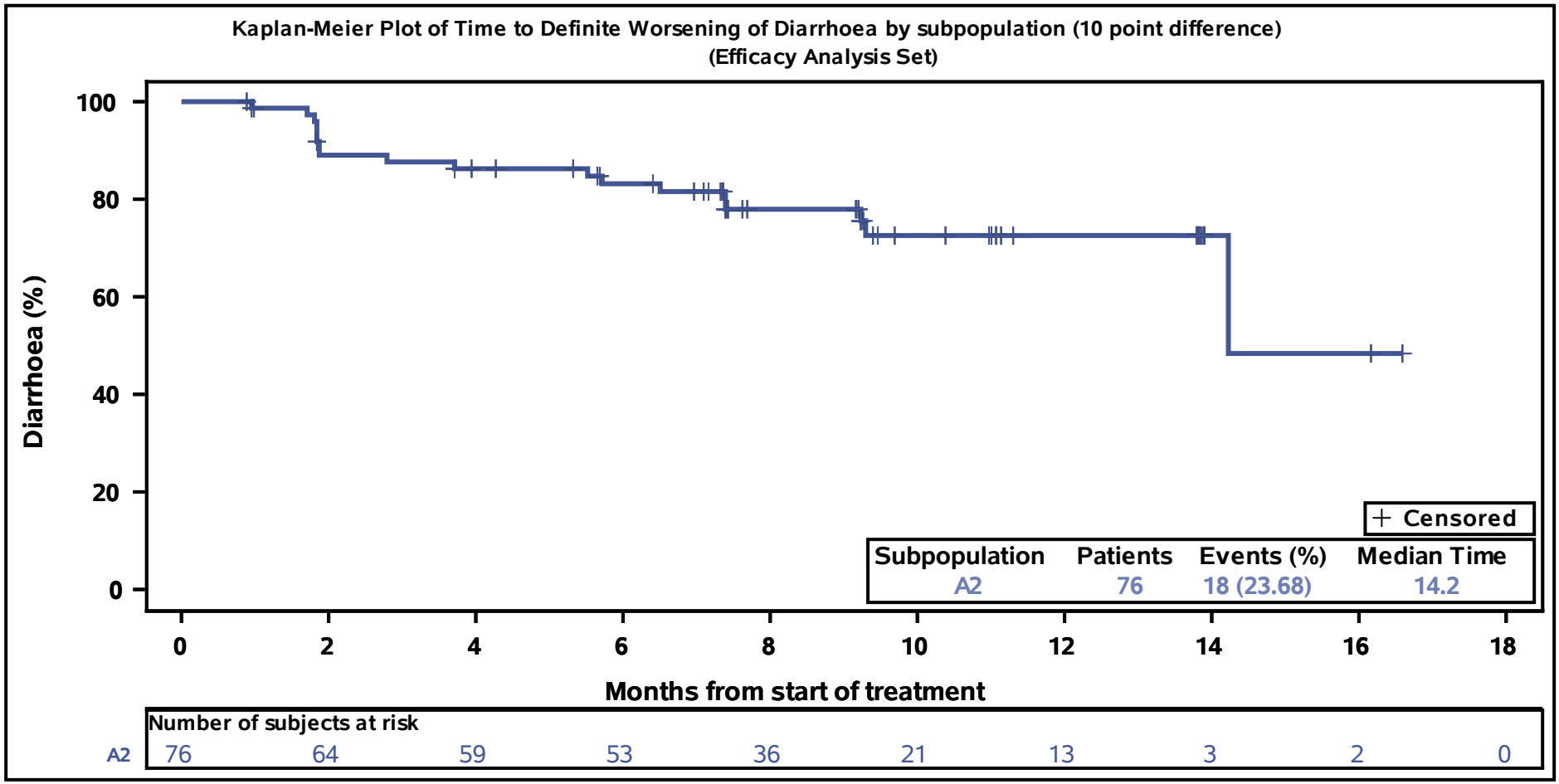

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Tabelle 034: Ergebnisse für die Zeit bis zur anhaltenden Verbesserung bzw. Verschlechterung der gesundheitsbezogenen Lebensqualität gemessen anhand des EORTC QLQ-C30 in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit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

	Selpercatinib	
Endpunkt	**Subpopulation A1 - NSCLC 2L (N'=78) (N=78)**	**Subpopulation A2 - NSCLC 3L (N'=158) (N=158)**
EORTC QLQ-C30 - Globaler Gesundheitsstatus	51	76
Patienten mit Ereignis		
Anhaltende Verbesserung, n (%)	15 (29,4)	26 (34,2)
Zensierte Patienten, n (%)	36 (70,6)	50 (65,8)
Anhaltende Verschlechterung, n (%)	9 (17,6)	12 (15,8)
Zensierte Patienten, n (%)	42 (82,4)	64 (84,2)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [14,23; NE]
EORTC QLQ-C30 – Funktionsskalen		
Physische Funktion	51	76
Patienten mit Ereignis		
Anhaltende Verbesserung, n (%)	12 (23,5)	15 (19,7)
Zensierte Patienten, n (%)	39 (76,5)	61 (80,3)
Anhaltende Verschlechterung, n (%)	3 (5,9)	17 (22,4)
Zensierte Patienten, n (%)	48 (94,1)	59 (77,6)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]	16,2 [16,16; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]
Emotionale Funktion	51	76
Patienten mit Ereignis		
Anhaltende Verbesserung, n (%)	5 (9,8)	12 (15,8)
Zensierte Patienten, n (%)	46 (90,2)	64 (84,2)
Anhaltende Verschlechterung, n (%)	5 (9,8)	8 (10,5)
Zensierte Patienten, n (%)	46 (90,2)	68 (89,5)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [14,23; NE]
Rollenfunktion	51	76
Patienten mit Ereignis		
Anhaltende Verbesserung, n (%)	13 (25,5)	23 (30,3)
Zensierte Patienten, n (%)	38 (74,5)	53 (69,7)
Anhaltende Verschlechterung, n (%)	9 (17,6)	15 (19,7)
Zensierte Patienten, n (%)	42 (82,4)	61 (80,3)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]

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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: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

	Selpercatinib	
Endpunkt	**Subpopulation A1 - NSCLC 2L (N'=78) (N=78)**	**Subpopulation A2 - NSCLC 3L (N'=158) (N=158)**
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]
Kognitive Funktion	51	76
Patienten mit Ereignis		
Anhaltende Verbesserung, n (%)	12 (23,5)	9 (11,8)
Zensierte Patienten, n (%)	39 (76,5)	67 (88,2)
Anhaltende Verschlechterung, n (%)	8 (15,7)	14 (18,4)
Zensierte Patienten, n (%)	43 (84,3)	62 (81,6)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [16,39; NE]	NE [NE; NE]
Soziale Funktion	51	76
Patienten mit Ereignis		
Anhaltende Verbesserung, n (%)	17 (33,3)	22 (28,9)
Zensierte Patienten, n (%)	34 (66,7)	54 (71,1)
Anhaltende Verschlechterung, n (%)	5 (9,8)	13 (17,1)
Zensierte Patienten, n (%)	46 (90,2)	63 (82,9)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [9,17; NE]	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [NE; NE]	NE [13,90; NE]

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; 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; NSCLC: nicht-kleinzelliges Lungenkarzinom; 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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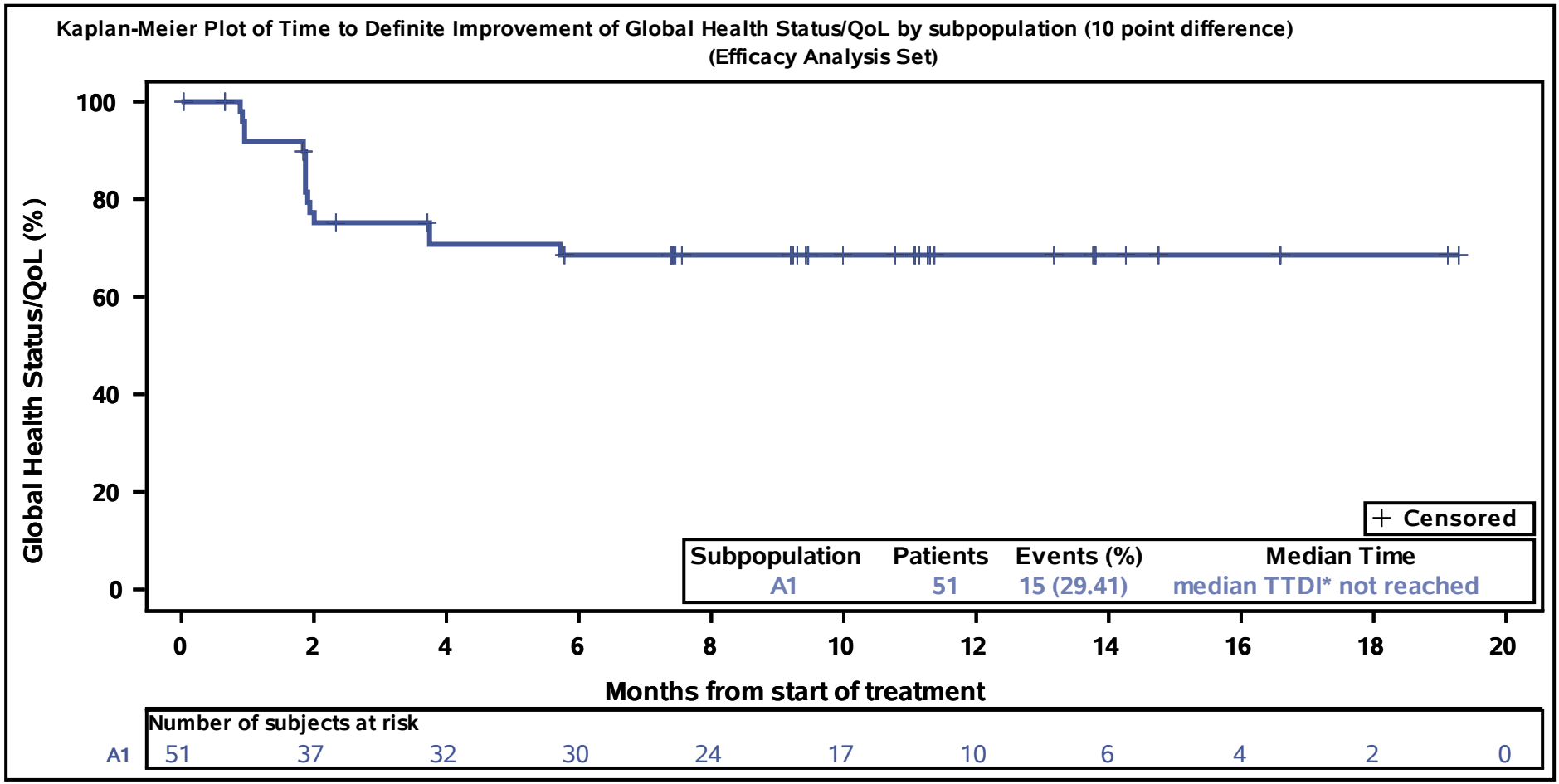
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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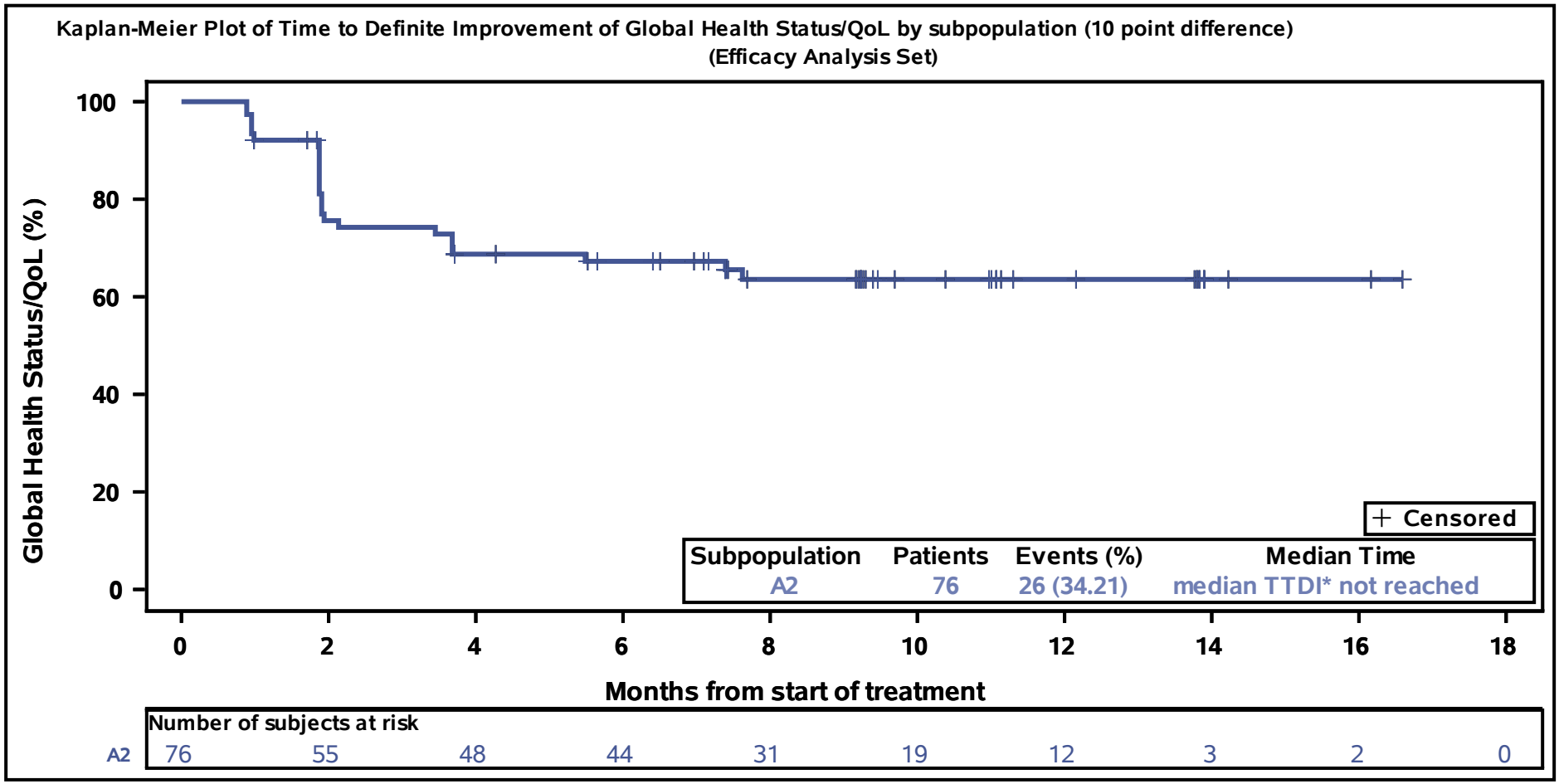

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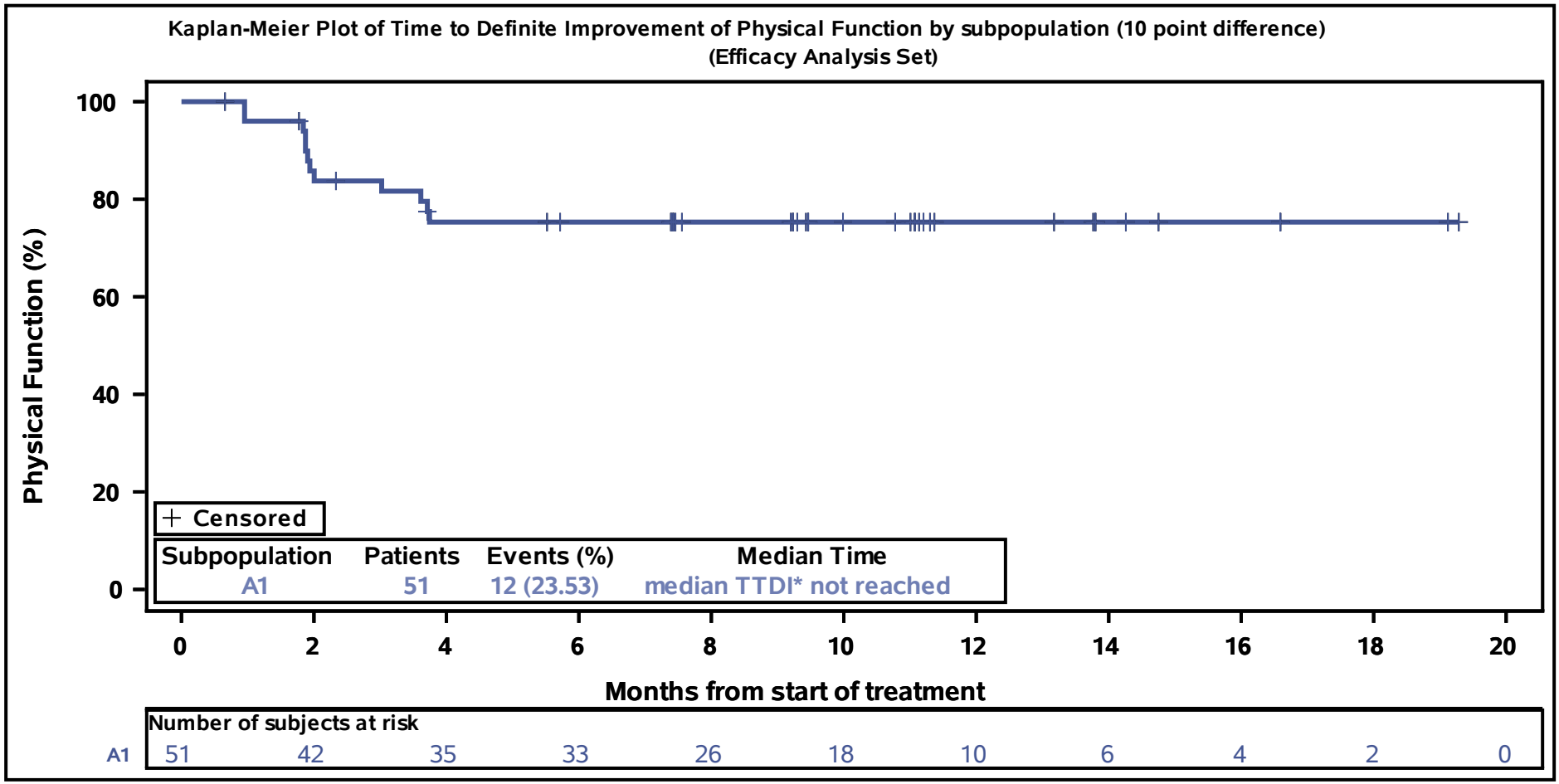

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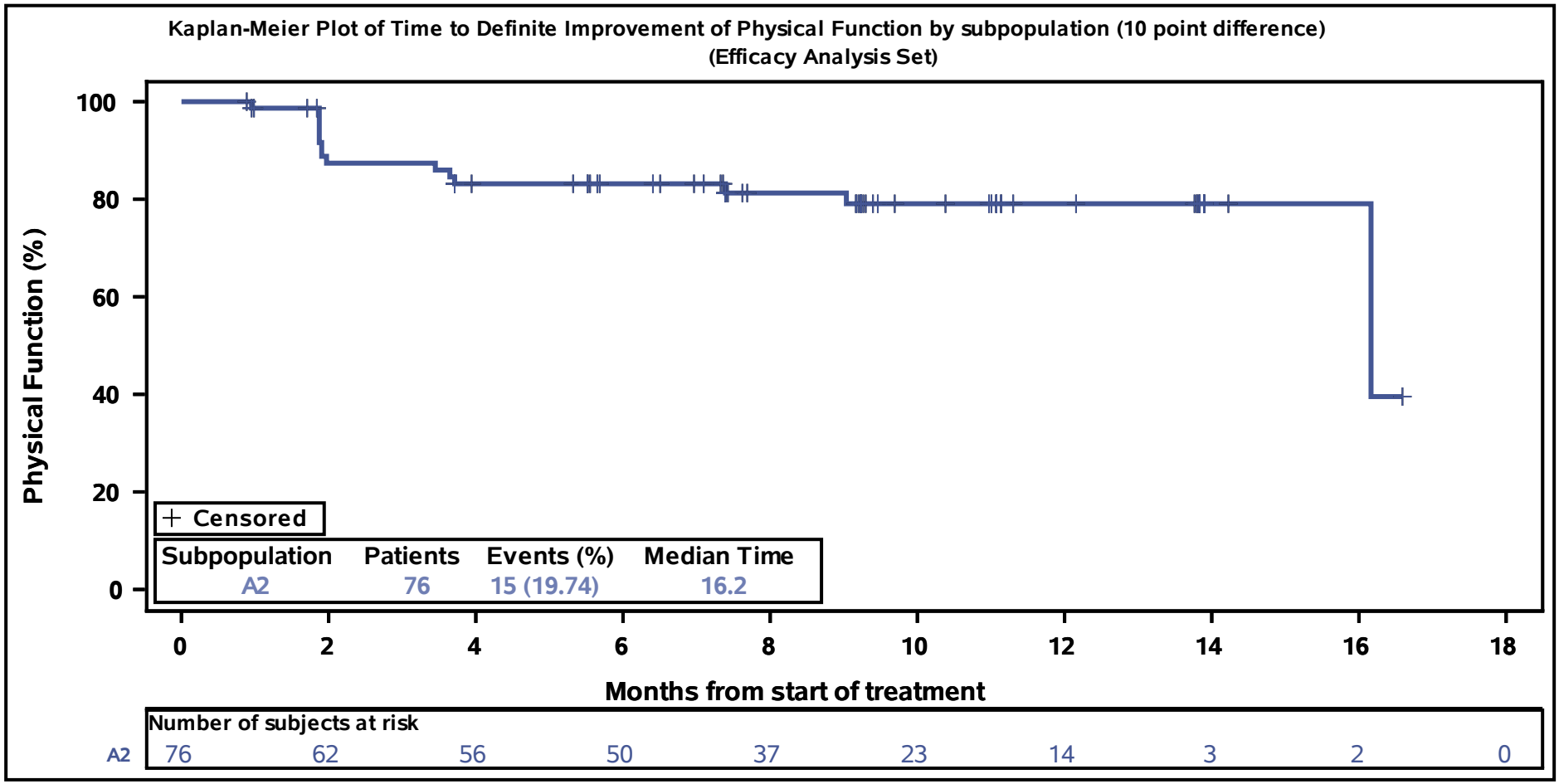

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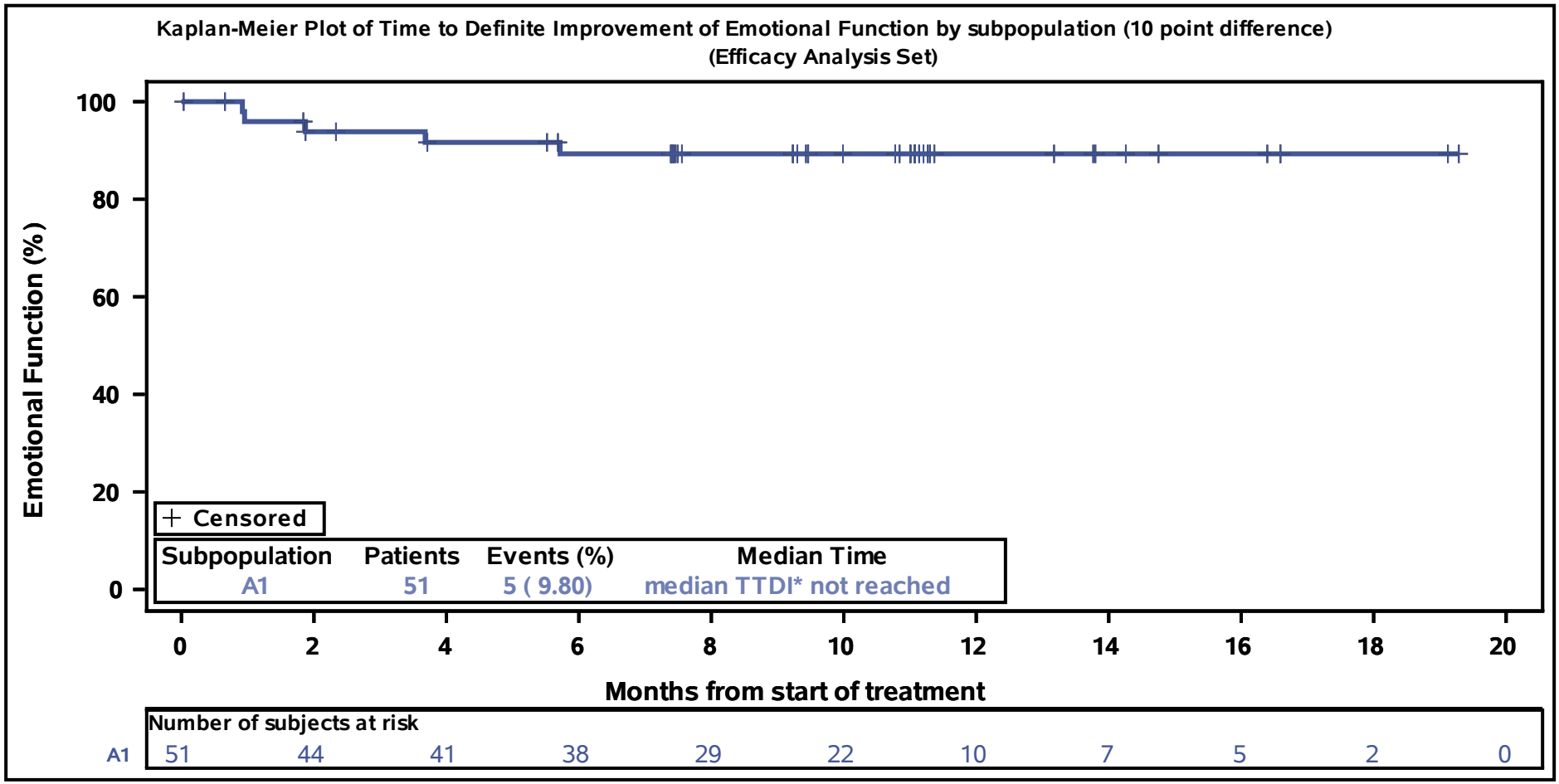

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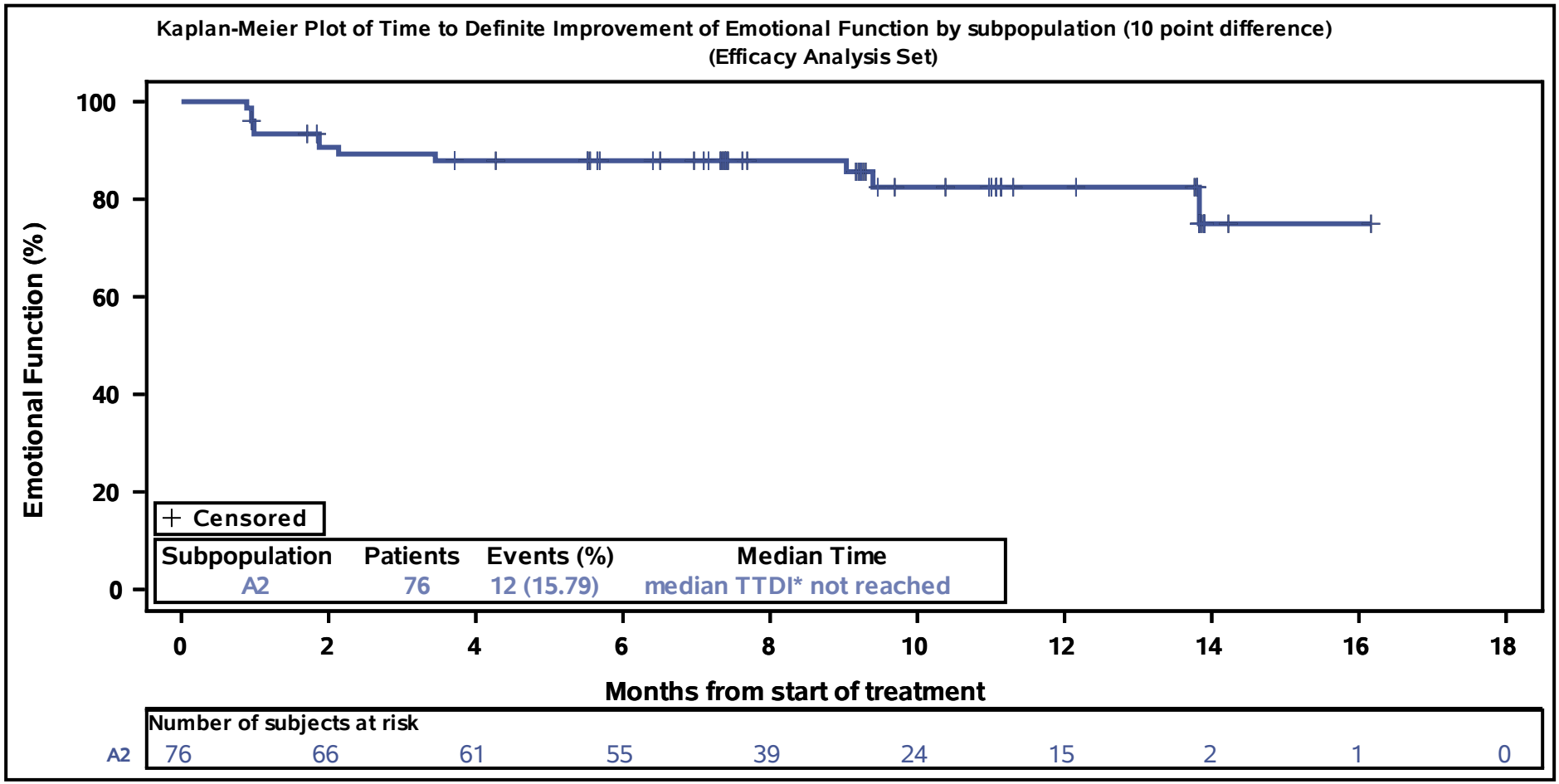

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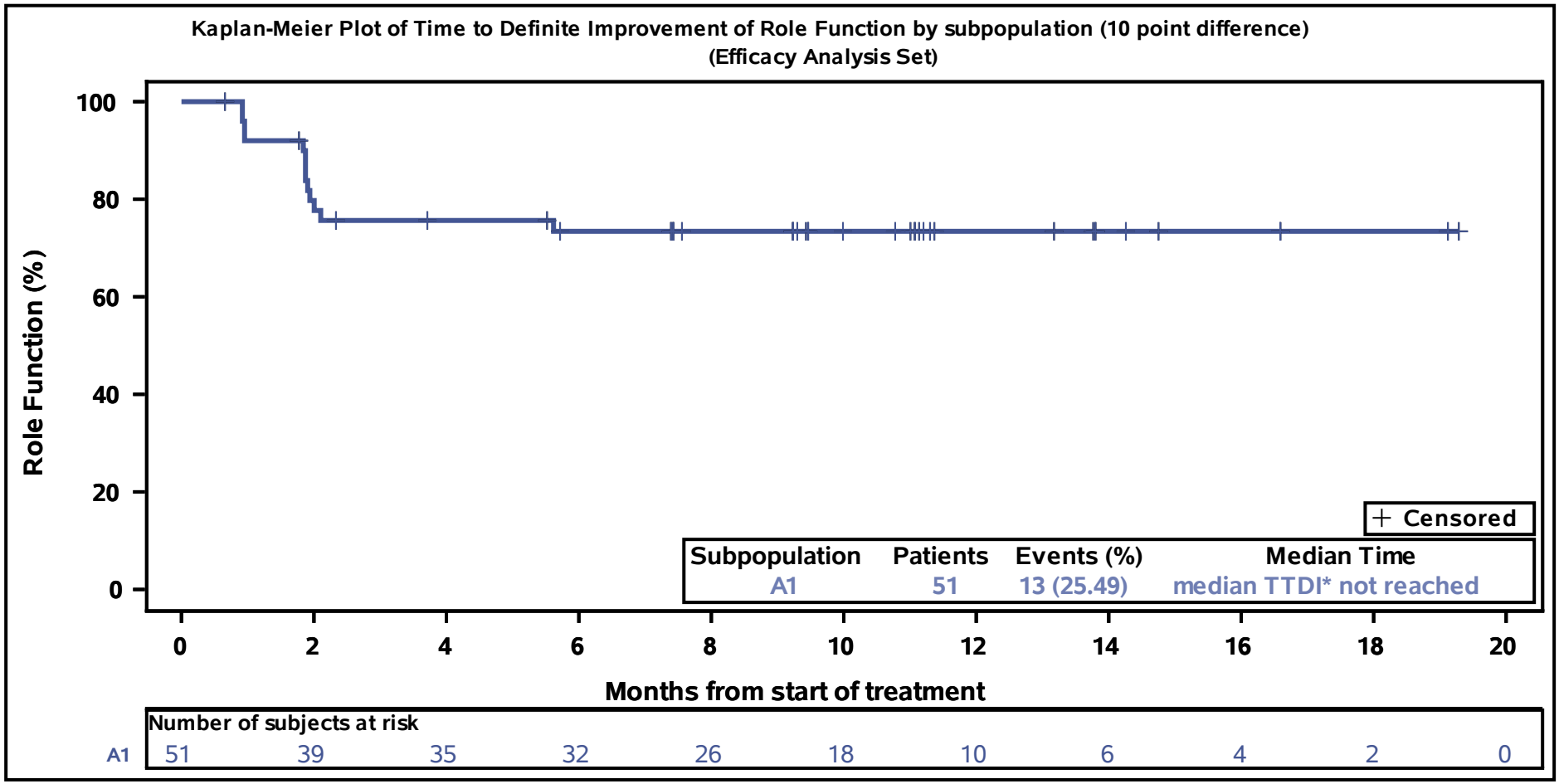

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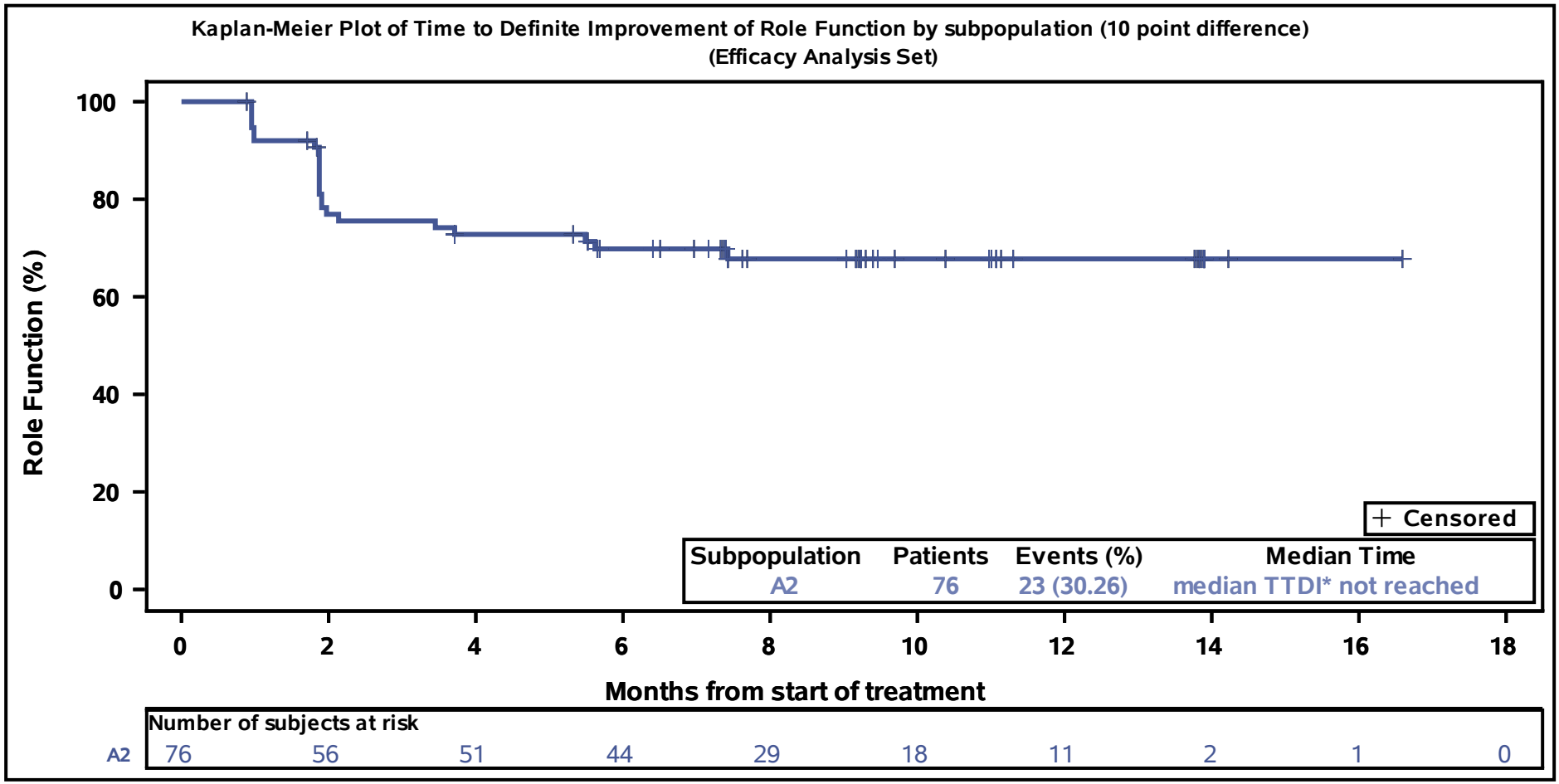

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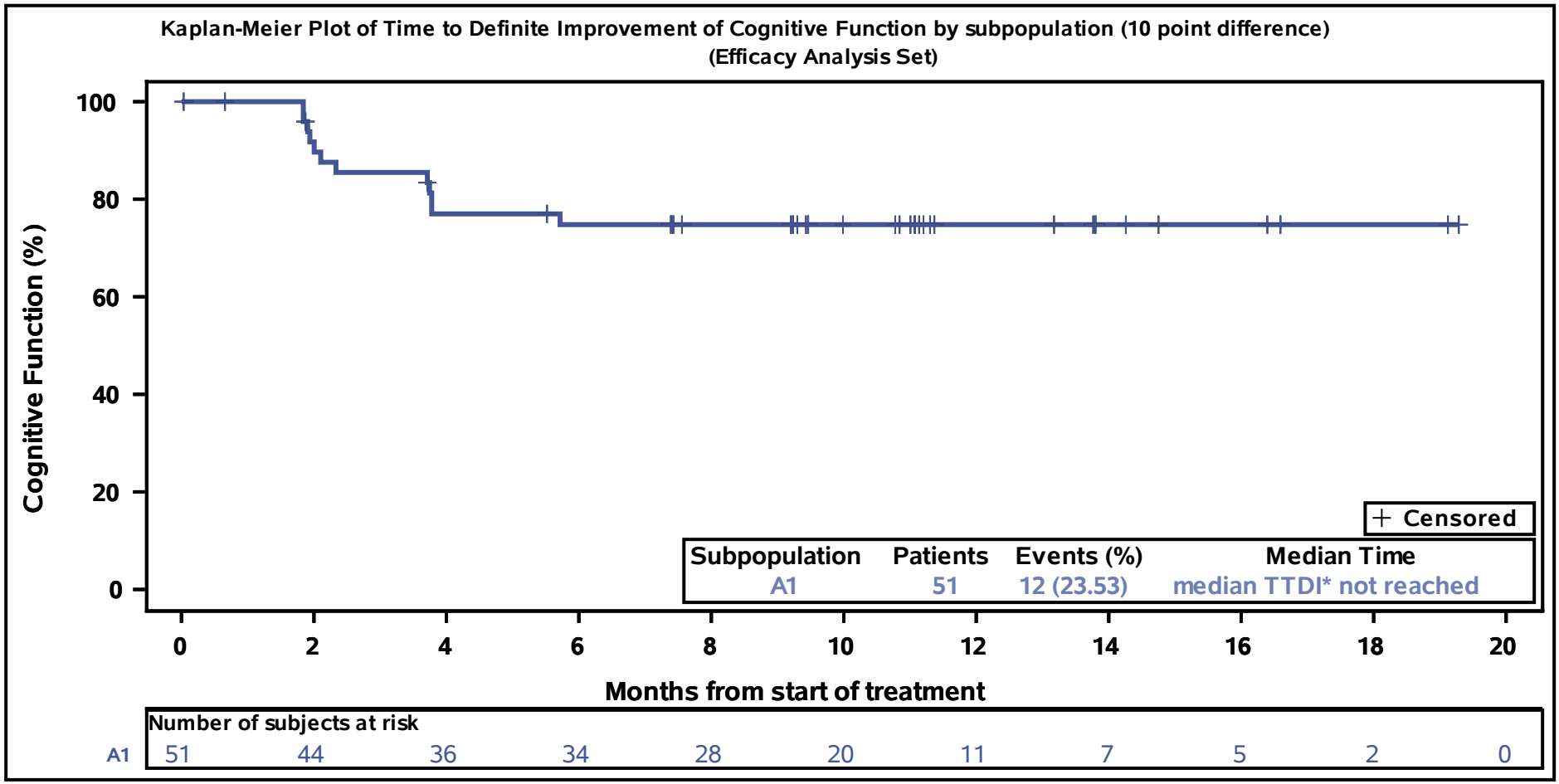
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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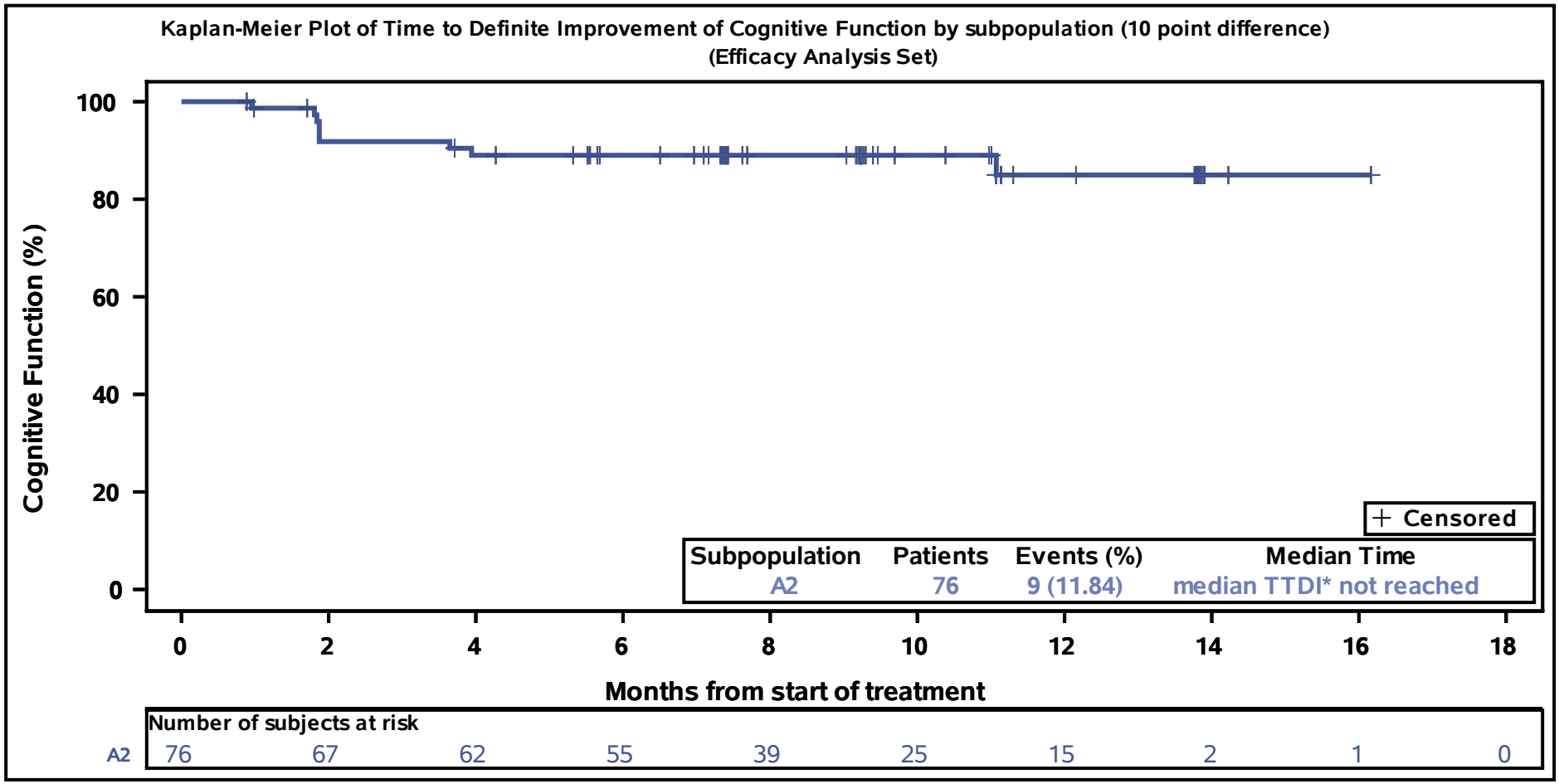
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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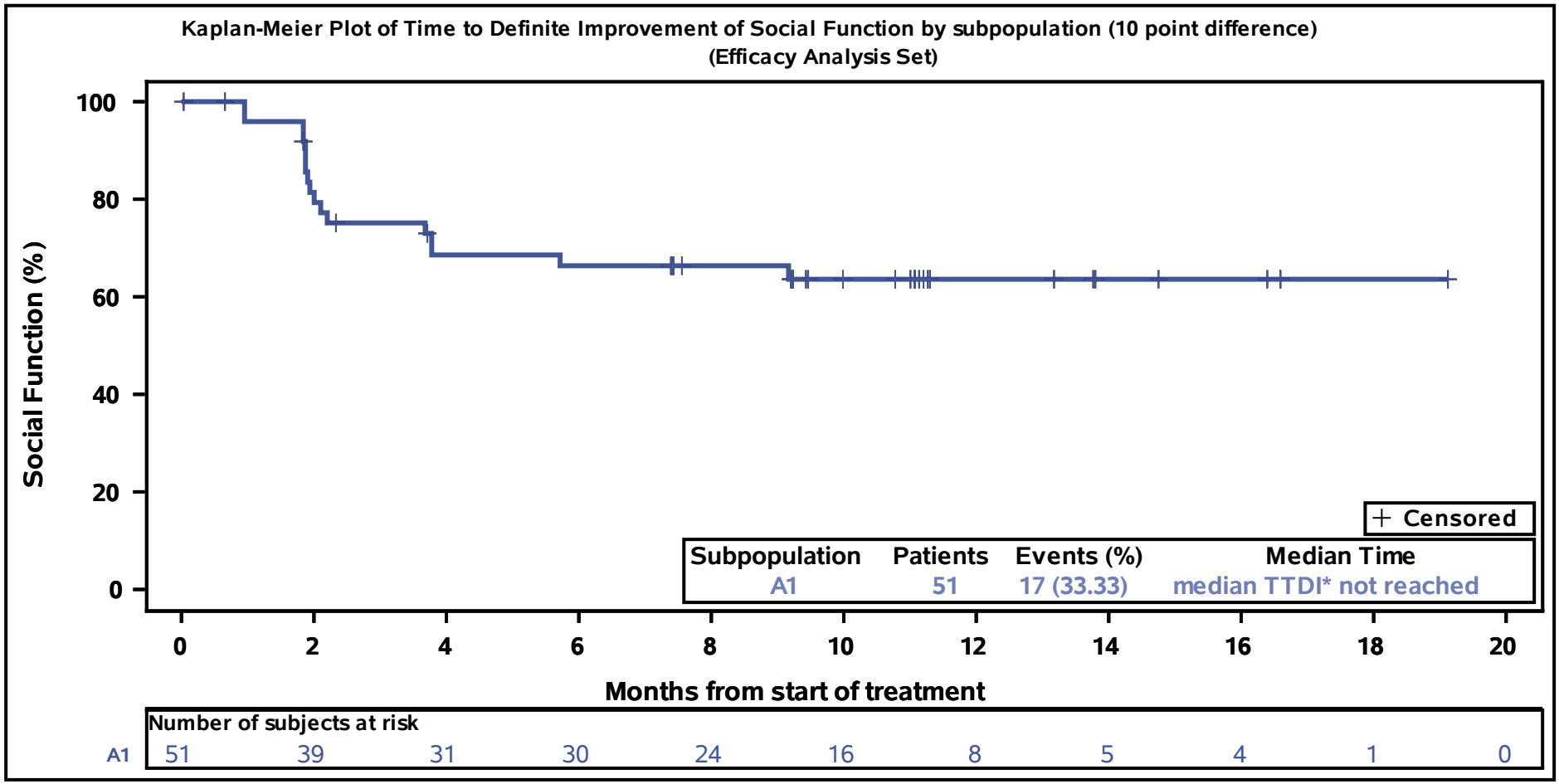
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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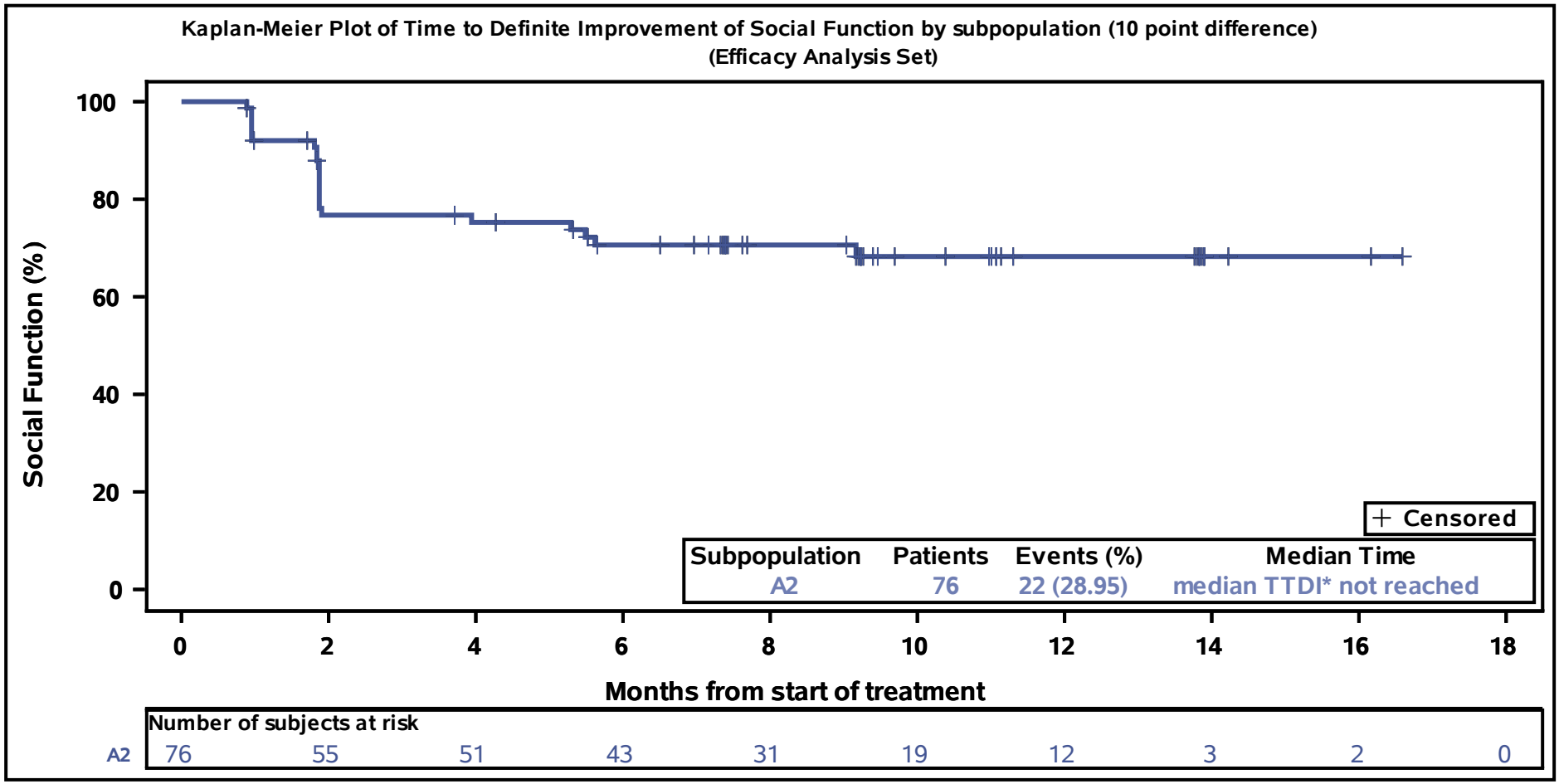
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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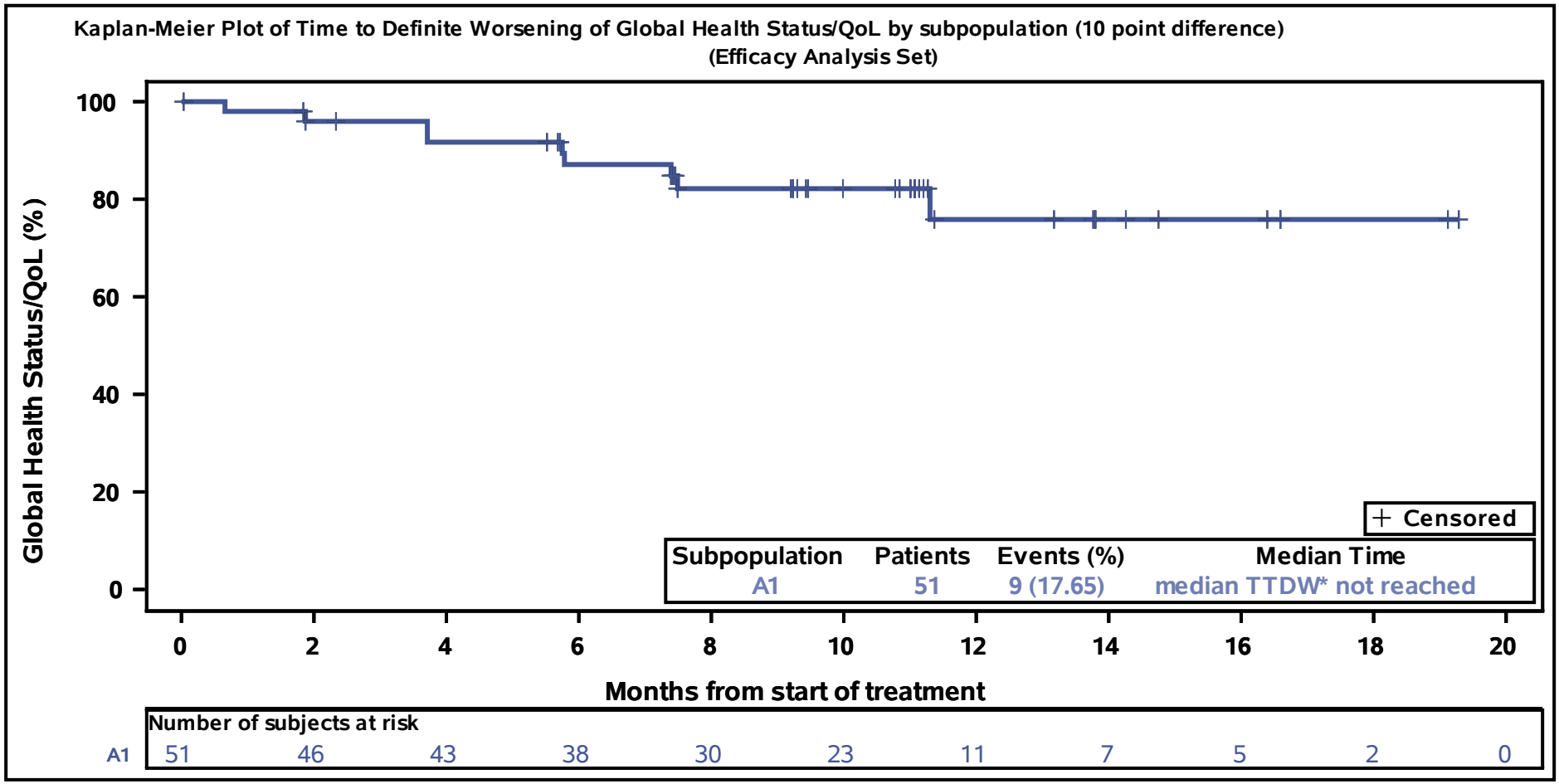
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



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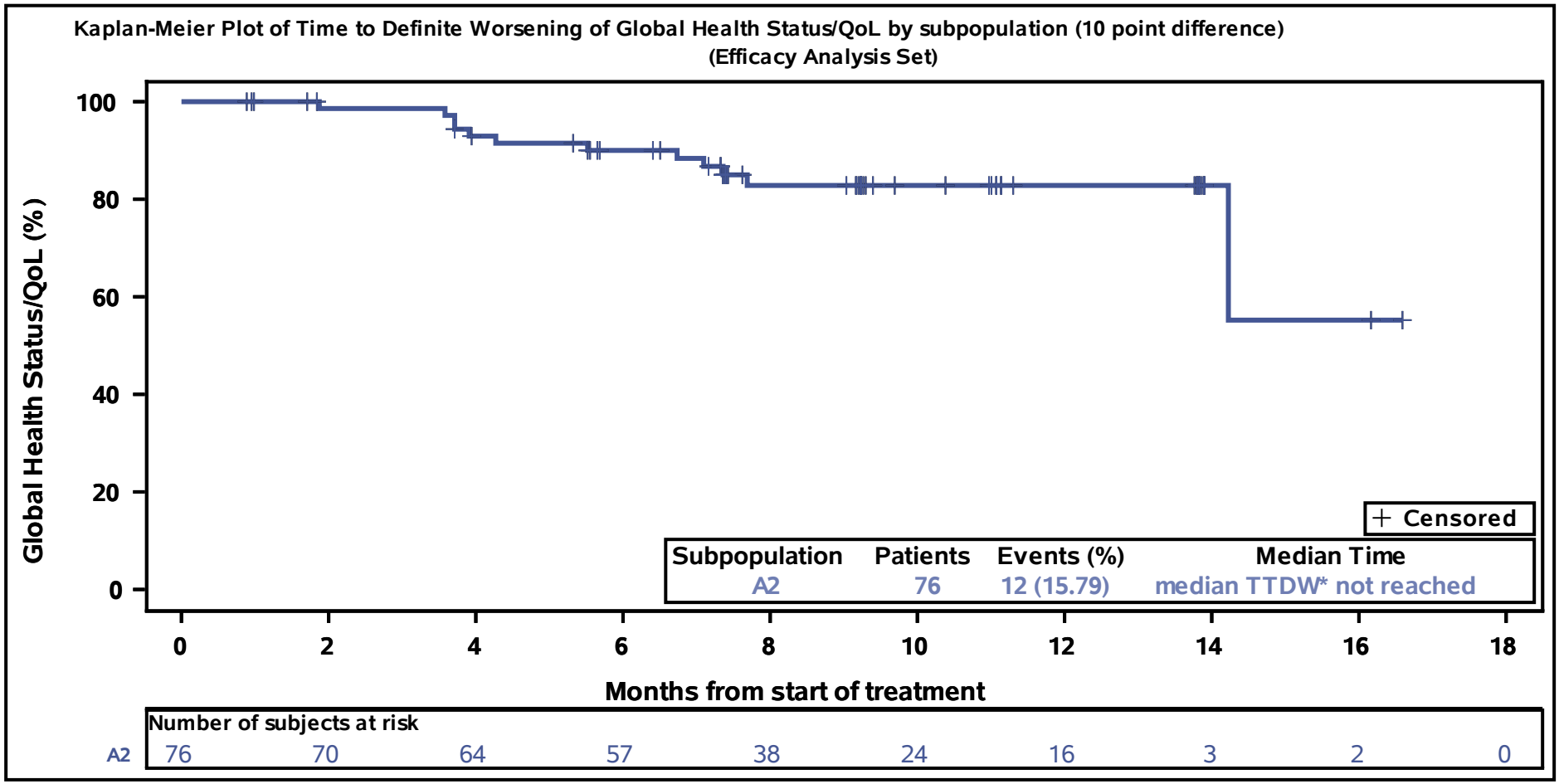
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
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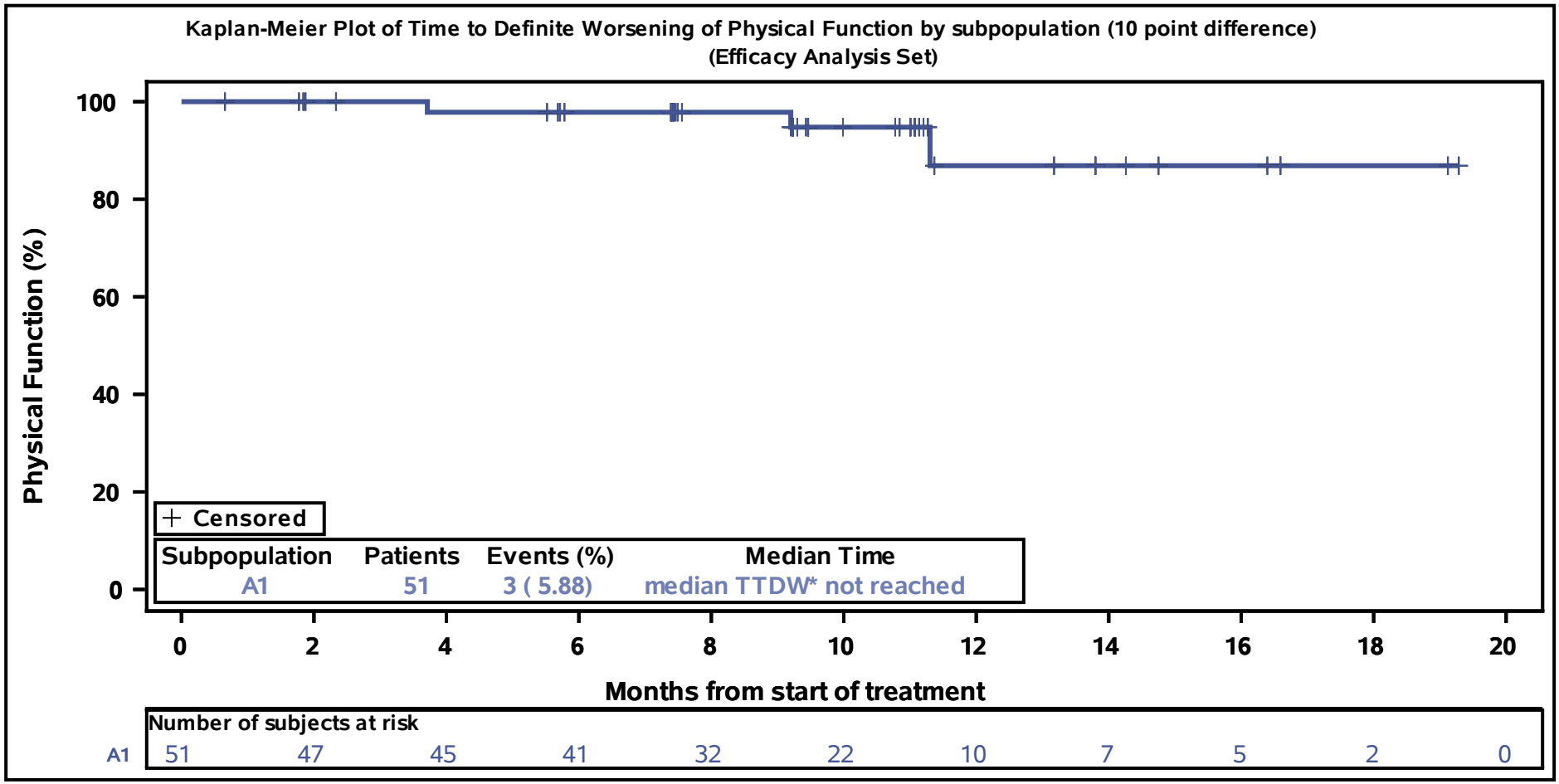
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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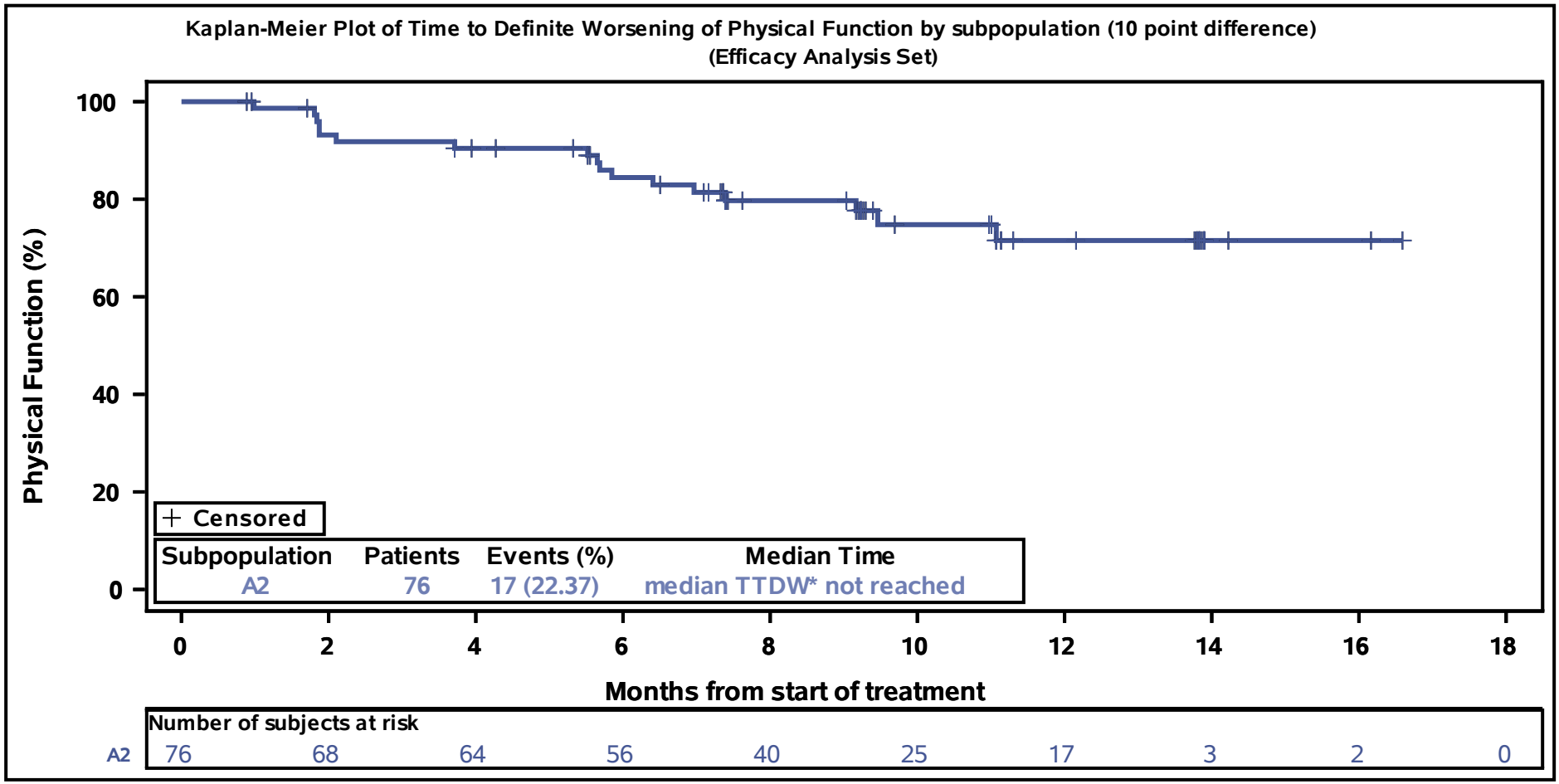
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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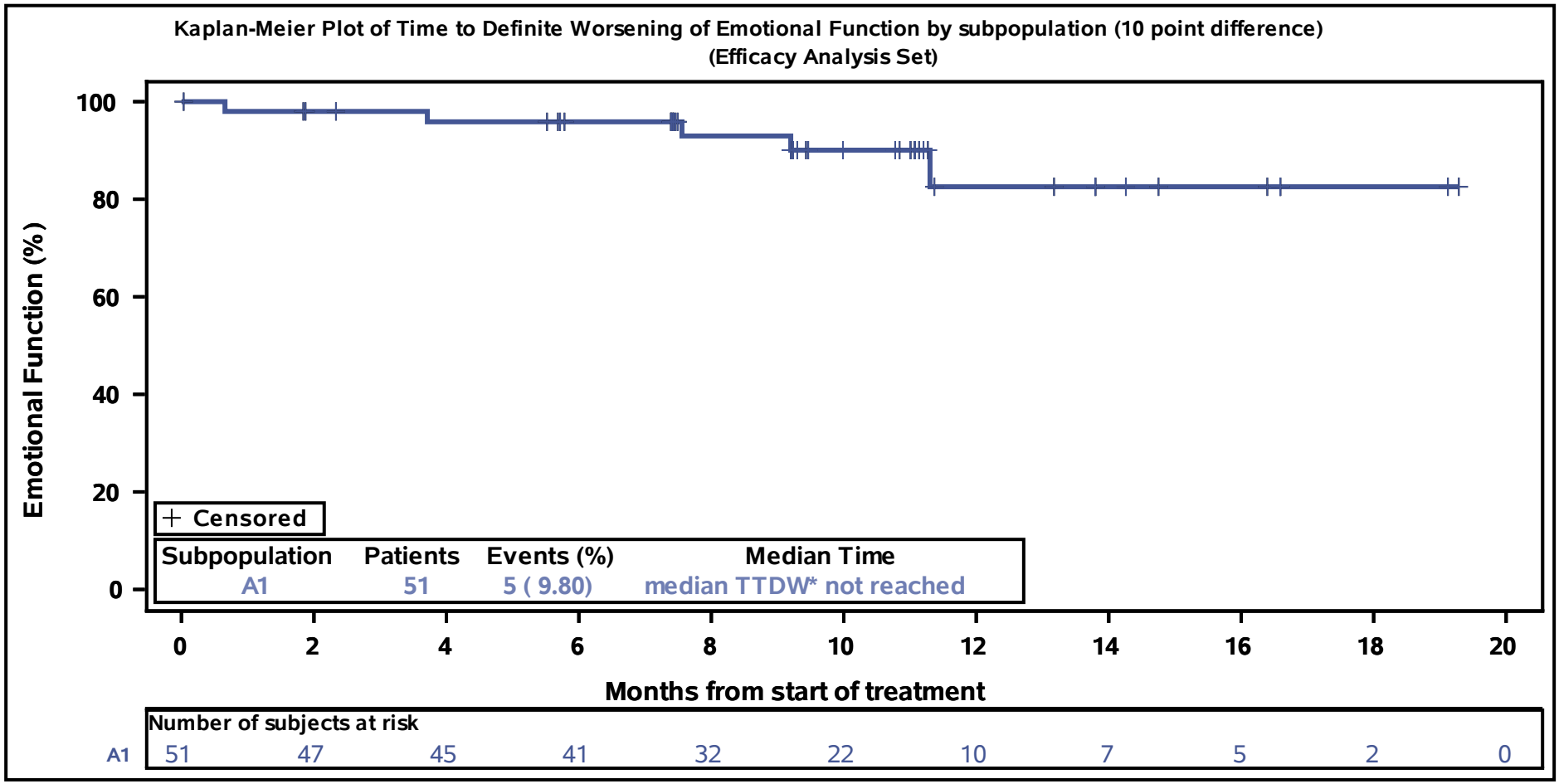
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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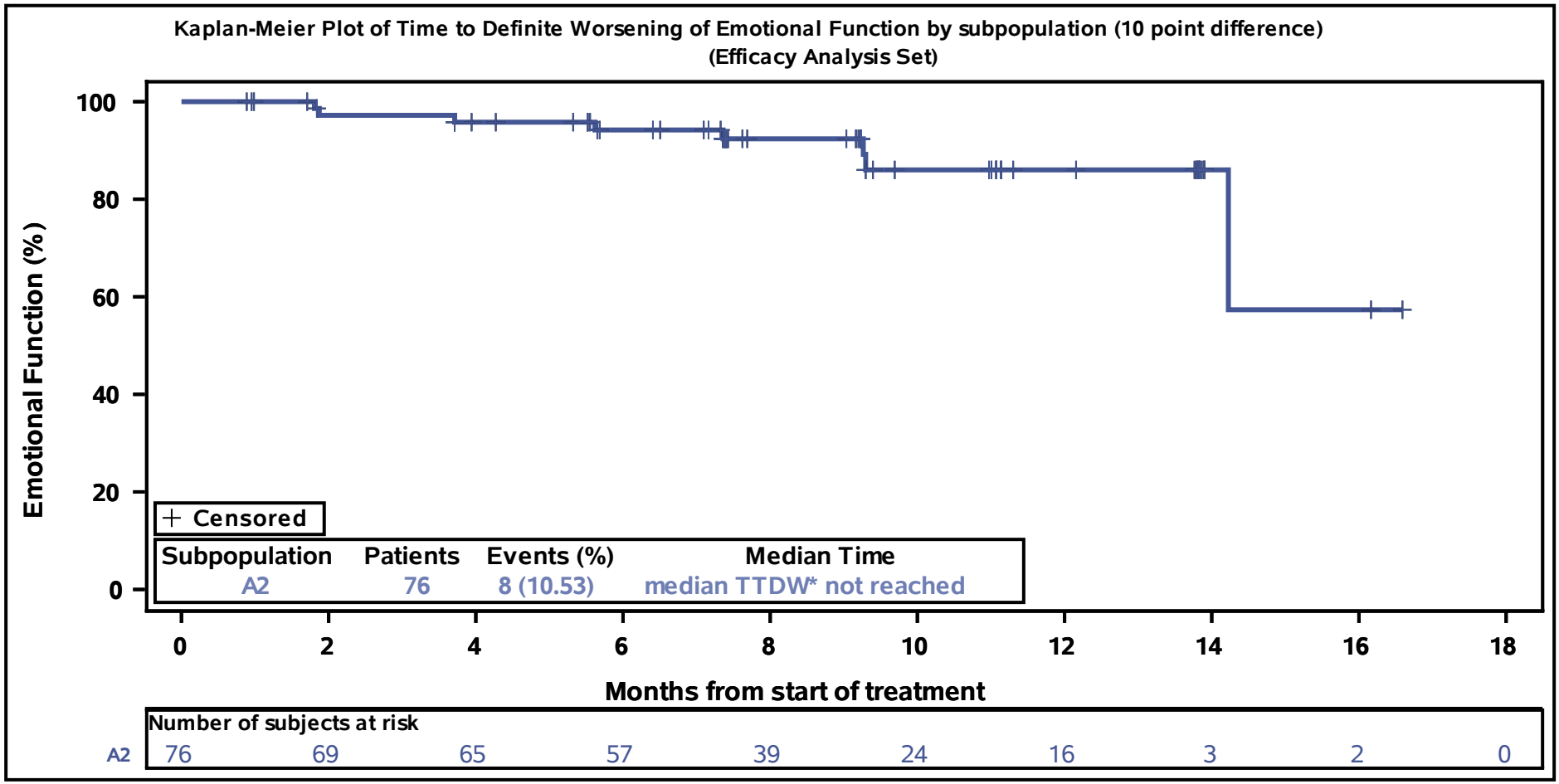
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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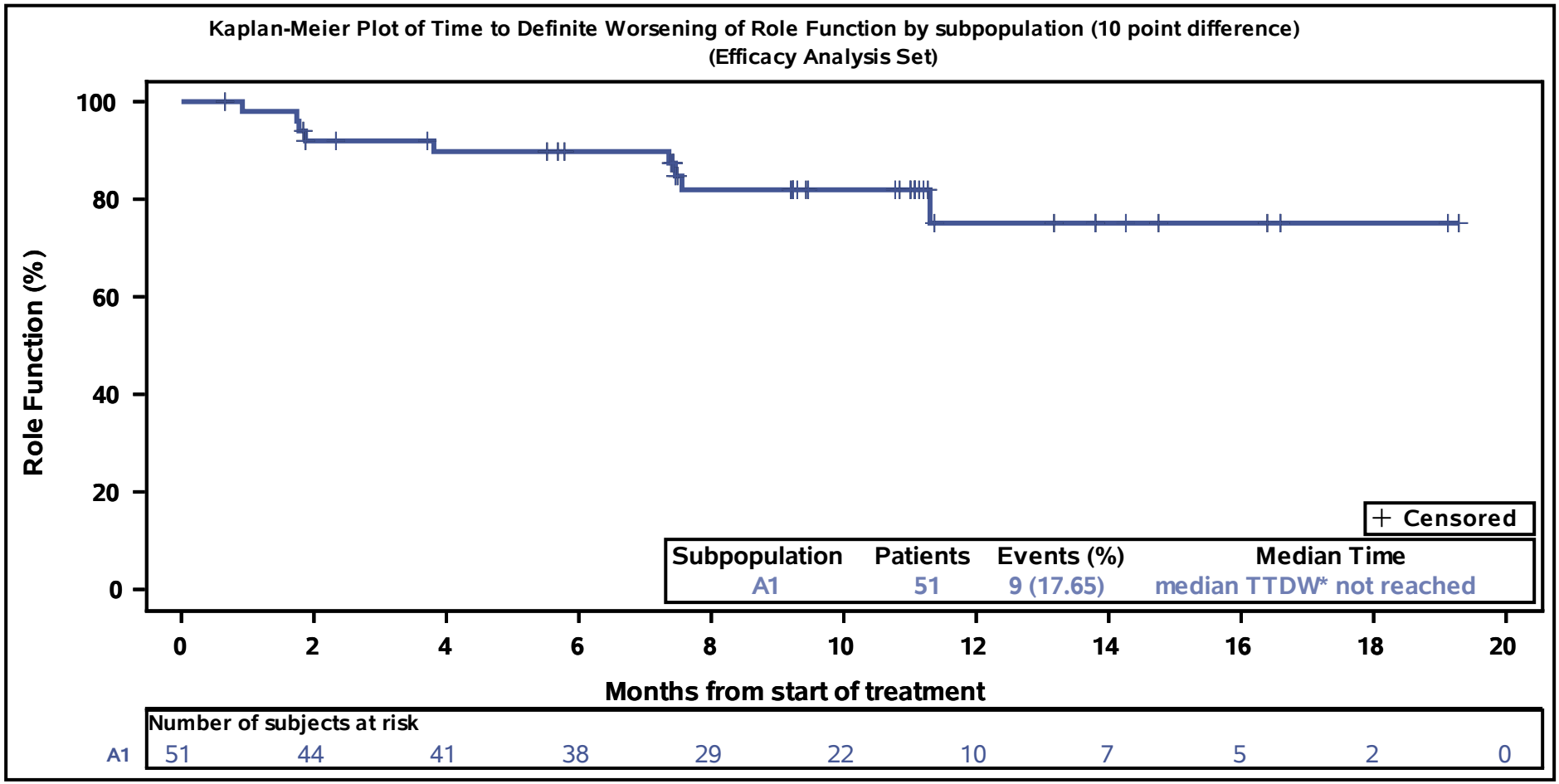
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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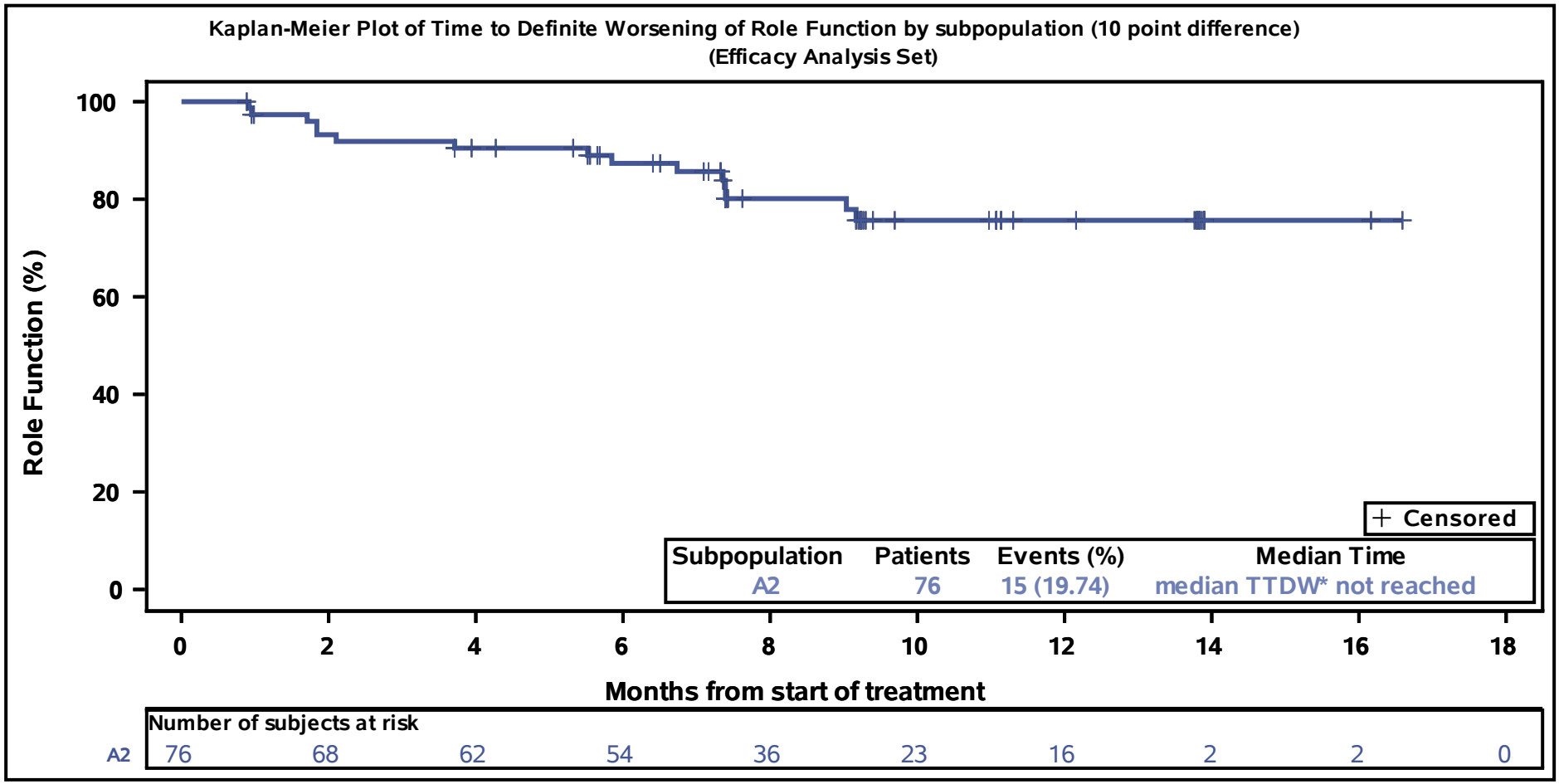
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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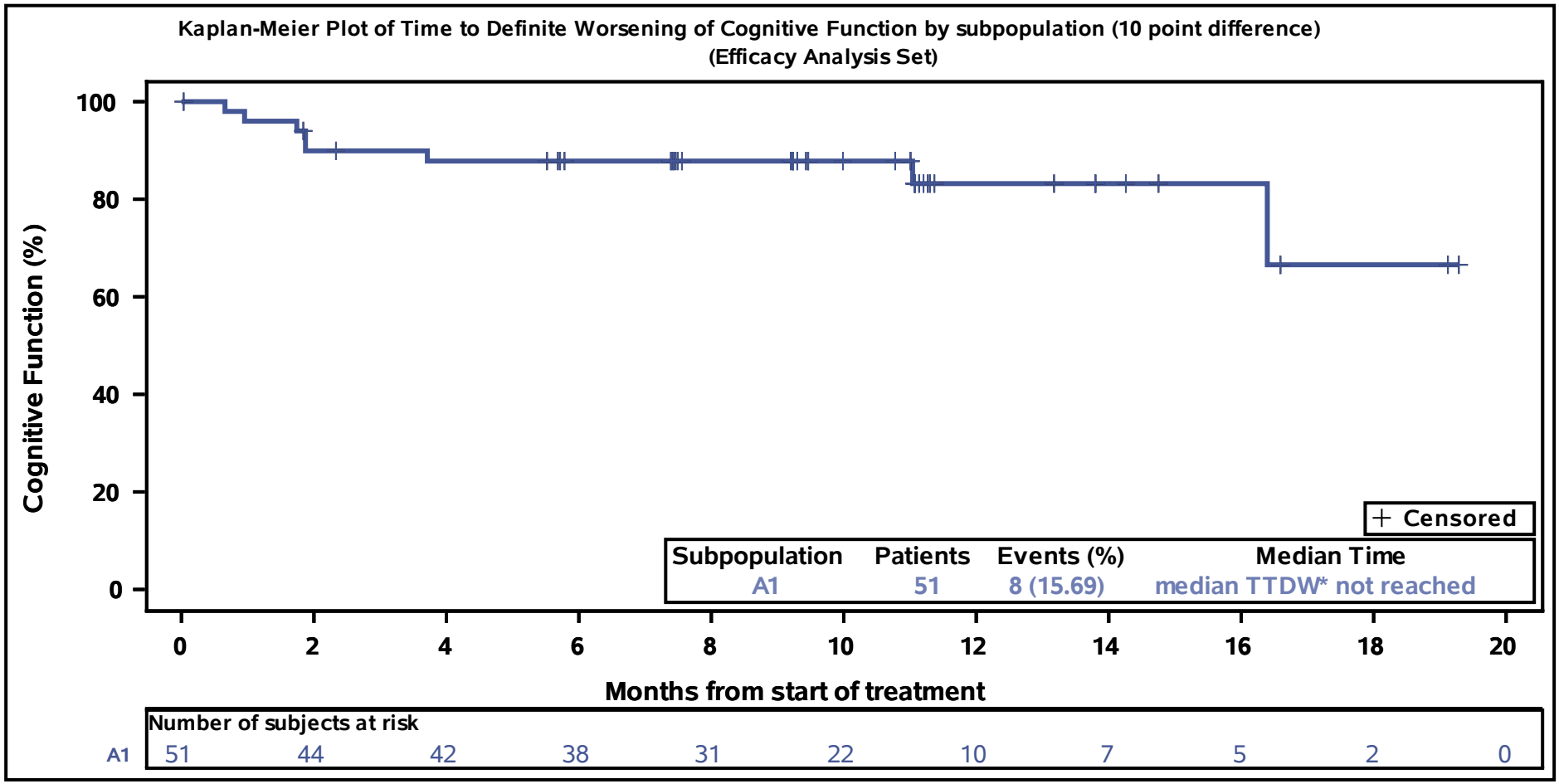
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
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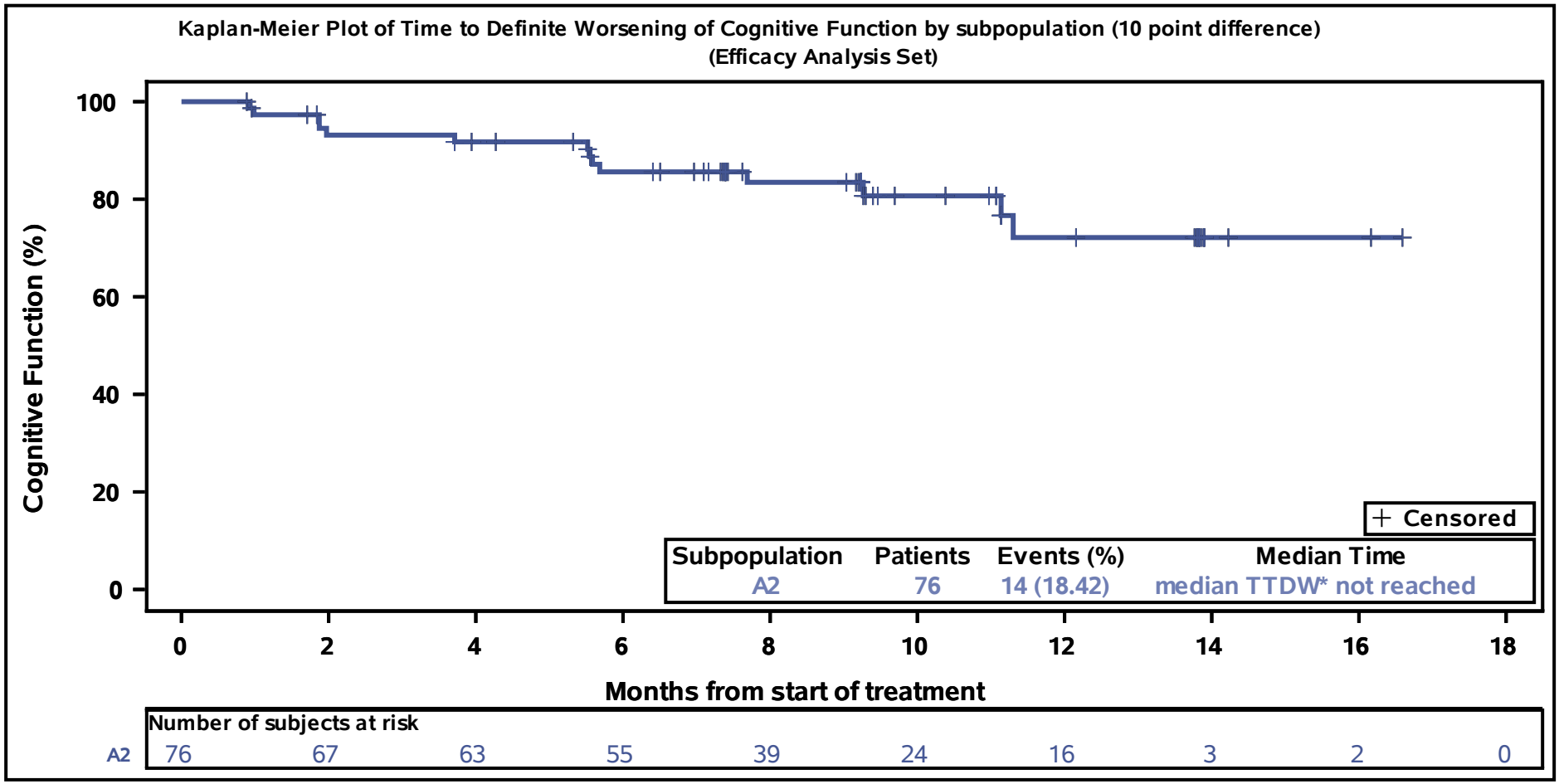
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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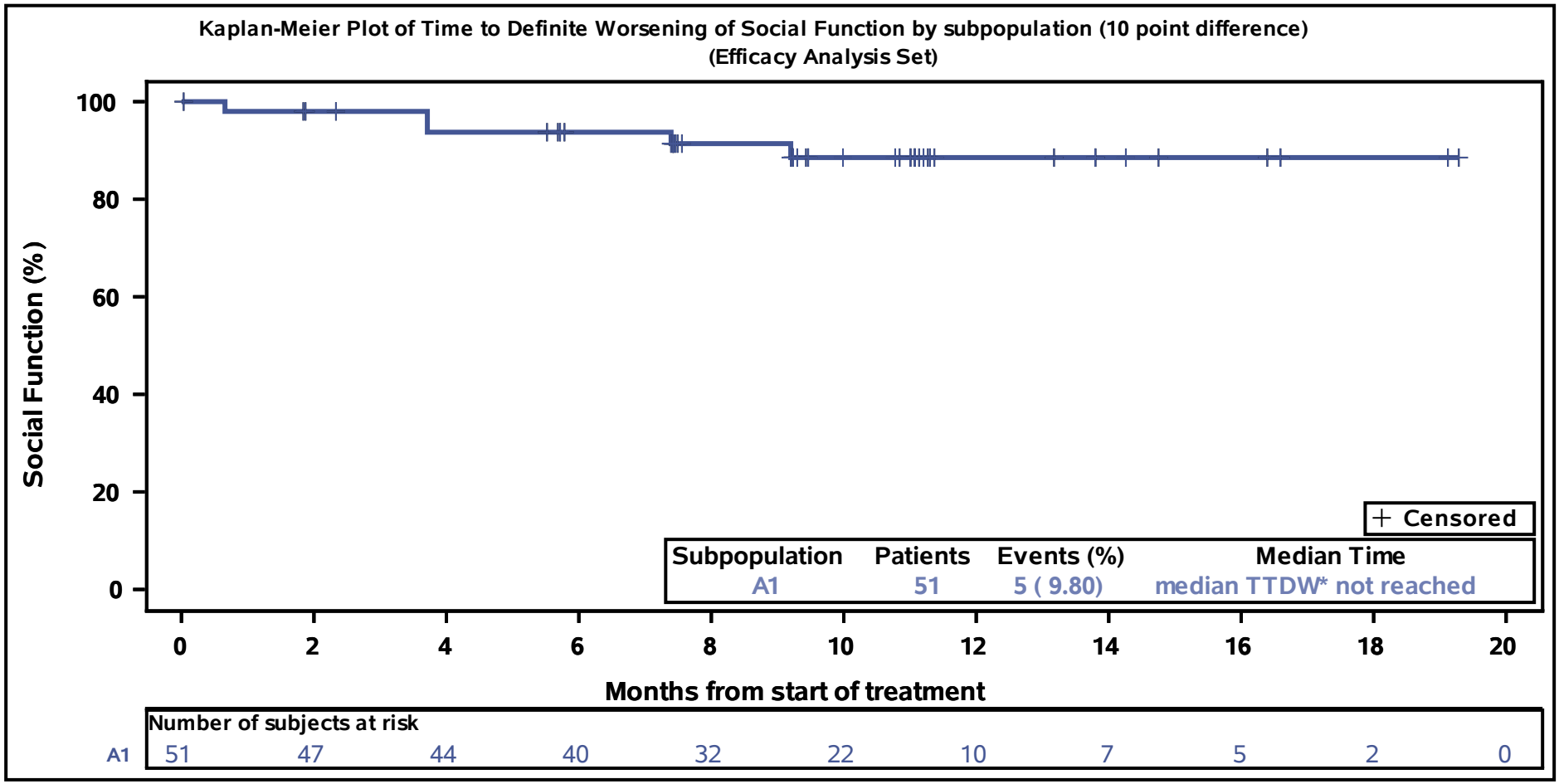
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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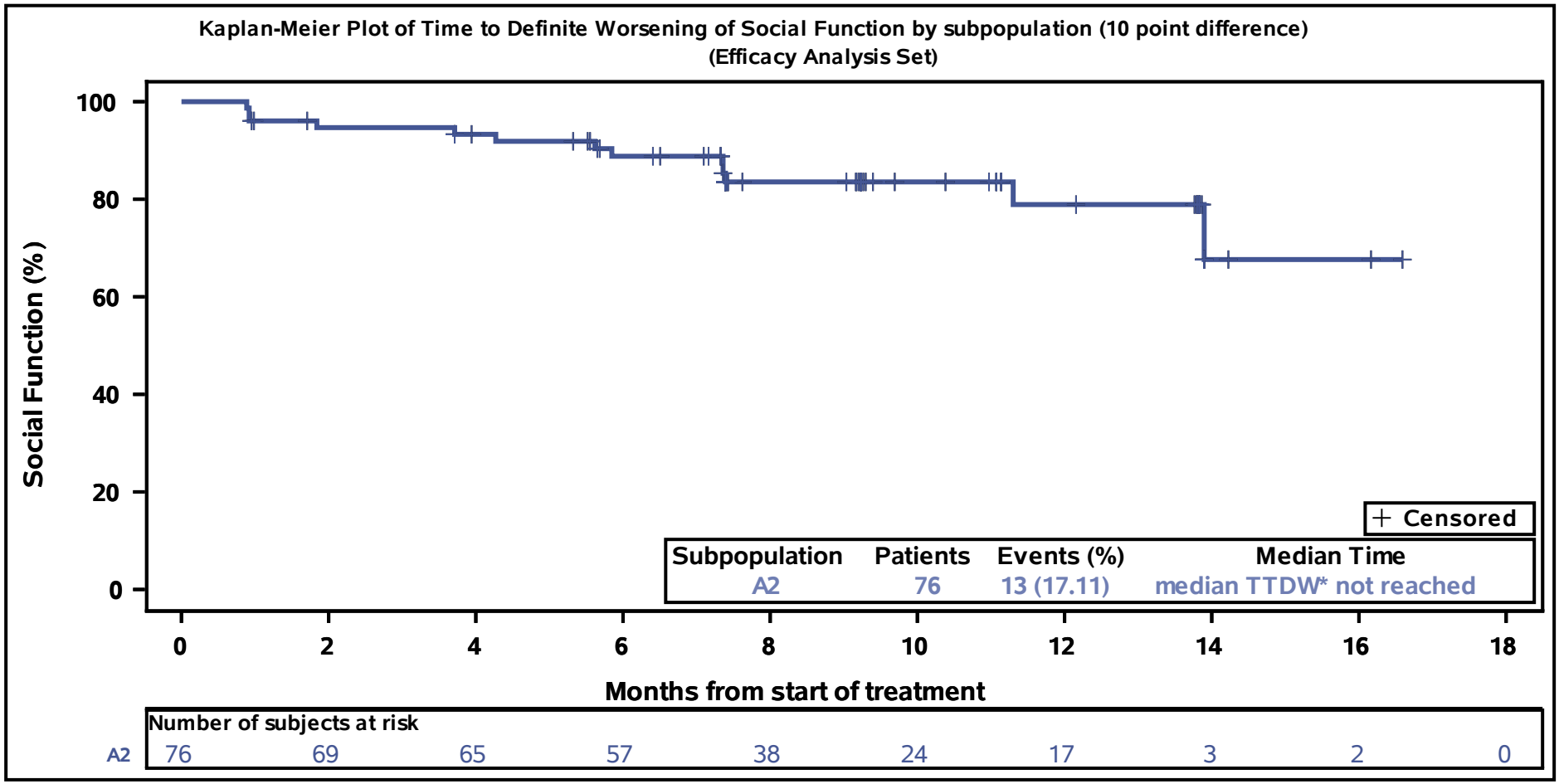
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - NSCLC (Visit Cutoff 30-MAR-2020)



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

Loxo Oncology Inc. Page 1 of 11
Protocol Number: LOXO-RET-17001 15:25 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Baseline [1]		
n [2]	51	75
Mean	62.42	60.00
Standard Deviation	24.174	22.924
Median	66.67	66.67
Q1, Q3	41.7, 83.3	41.7, 83.3
Min, Max	8.3, 100.0	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
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.1_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 3 Day 1		
n [2]	41	67
Mean	71.75	66.04
Standard Deviation	17.764	18.987
Median	75.00	66.67
Q1, Q3	58.3, 83.3	50.0, 75.0
Min, Max	33.3, 100.0	16.7, 100.0
Change from Baseline to Cycle 3 Day 1		
n [2]	41	67
Mean	10.98	6.47
Standard Deviation	20.534	23.784
Median	8.33	8.33
Q1, Q3	0.0, 16.7	-8.3, 25.0
Min, Max	-25.0, 58.3	-66.7, 50.0
Status [3]		
Improved	19 (46.3)	30 (44.8)
Stable	17 (41.5)	26 (38.8)
Worsened	5 (12.2)	11 (16.4)

[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
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.1_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 5 Day 1		
n [2]	39	60
Mean	77.14	70.42
Standard Deviation	19.091	16.837
Median	83.33	66.67
Q1, Q3	66.7, 83.3	58.3, 83.3
Min, Max	16.7, 100.0	33.3, 100.0
Change from Baseline to Cycle 5 Day 1		
n [2]	39	60
Mean	16.88	11.25
Standard Deviation	22.335	20.915
Median	16.67	12.50
Q1, Q3	0.0, 33.3	0.0, 25.0
Min, Max	-25.0, 58.3	-50.0, 58.3
Status [3]		
Improved	25 (64.1)	30 (50.0)
Stable	8 (20.5)	22 (36.7)
Worsened	6 (15.4)	8 (13.3)

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 7 Day 1		
n [2]	39	59
Mean	73.93	67.23
Standard Deviation	20.518	20.580
Median	83.33	66.67
Q1, Q3	66.7, 83.3	50.0, 83.3
Min, Max	16.7, 100.0	16.7, 100.0
Change from Baseline to Cycle 7 Day 1		
n [2]	39	59
Mean	12.61	8.62
Standard Deviation	27.163	25.331
Median	16.67	8.33
Q1, Q3	0.0, 33.3	-8.3, 25.0
Min, Max	-66.7, 58.3	-66.7, 58.3
Status [3]		
Improved	22 (56.4)	28 (47.5)
Stable	10 (25.6)	19 (32.2)
Worsened	7 (17.9)	12 (20.3)

[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/T14.2.6.1.1_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 9 Day 1		
n [2]	31	48
Mean	76.08	68.23
Standard Deviation	21.163	19.948
Median	75.00	70.83
Q1, Q3	66.7, 100.0	58.3, 83.3
Min, Max	16.7, 100.0	0.0, 100.0
Change from Baseline to Cycle 9 Day 1		
n [2]	31	48
Mean	12.10	8.68
Standard Deviation	25.625	27.232
Median	16.67	8.33
Q1, Q3	0.0, 33.3	0.0, 25.0
Min, Max	-41.7, 50.0	-91.7, 50.0
Status [3]		
Improved	16 (51.6)	22 (45.8)
Stable	9 (29.0)	18 (37.5)
Worsened	6 (19.4)	8 (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/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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 11 Day 1		
n [2]	27	34
Mean	75.00	75.49
Standard Deviation	21.309	12.637
Median	83.33	75.00
Q1, Q3	66.7, 91.7	66.7, 83.3
Min, Max	33.3, 100.0	50.0, 100.0
Change from Baseline to Cycle 11 Day 1		
n [2]	27	34
Mean	9.26	13.97
Standard Deviation	22.209	21.094
Median	8.33	16.67
Q1, Q3	-8.3, 33.3	0.0, 25.0
Min, Max	-33.3, 50.0	-33.3, 50.0
Status [3]		
Improved	12 (44.4)	19 (55.9)
Stable	10 (37.0)	12 (35.3)
Worsened	5 (18.5)	3 (8.8)

[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/T14.2.6.1.1_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 13 Day 1		
n [2]	21	21
Mean	76.59	71.83
Standard Deviation	21.184	19.978
Median	75.00	83.33
Q1, Q3	66.7, 100.0	66.7, 83.3
Min, Max	16.7, 100.0	8.3, 91.7
Change from Baseline to Cycle 13 Day 1		
n [2]	21	21
Mean	11.90	12.70
Standard Deviation	23.210	20.517
Median	16.67	16.67
Q1, Q3	0.0, 33.3	0.0, 25.0
Min, Max	-33.3, 50.0	-16.7, 50.0
Status [3]		
Improved	11 (52.4)	12 (57.1)
Stable	6 (28.6)	6 (28.6)
Worsened	4 (19.0)	3 (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/T14.2.6.1.1_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 16 Day 1		
n [2]	9	15
Mean	81.48	71.11
Standard Deviation	18.056	16.627
Median	83.33	75.00
Q1, Q3	75.0, 100.0	58.3, 83.3
Min, Max	50.0, 100.0	33.3, 91.7
Change from Baseline to Cycle 16 Day 1		
n [2]	9	15
Mean	12.04	11.11
Standard Deviation	19.593	22.640
Median	8.33	8.33
Q1, Q3	0.0, 33.3	-8.3, 33.3
Min, Max	-25.0, 33.3	-25.0, 50.0
Status [3]		
Improved	4 (44.4)	6 (40.0)
Stable	4 (44.4)	7 (46.7)
Worsened	1 (11.1)	2 (13.3)

[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/T14.2.6.1.1_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 19 Day 1		
n [2]	5	1
Mean	71.67	66.67
Standard Deviation	20.069	
Median	66.67	66.67
Q1, Q3	58.3, 83.3	66.7, 66.7
Min, Max	50.0, 100.0	66.7, 66.7
Change from Baseline to Cycle 19 Day 1		
n [2]	5	1
Mean	-1.67	8.33
Standard Deviation	19.003	
Median	0.00	8.33
Q1, Q3	-16.7, 16.7	8.3, 8.3
Min, Max	-25.0, 16.7	8.3, 8.3
Status [3]		
Improved	2 (40.0)	0 (0.0)
Stable	1 (20.0)	1 (100.0)
Worsened	2 (40.0)	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/T14.2.6.1.1_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 22 Day 1		
n [2]	2	0
Mean	83.33	
Standard Deviation	11.785	
Median	83.33	
Q1, Q3	75.0, 91.7	
Min, Max	75.0, 91.7	
Change from Baseline to Cycle 22 Day 1		
n [2]	2	0
Mean	16.67	
Standard Deviation	11.785	
Median	16.67	
Q1, Q3	8.3, 25.0	
Min, Max	8.3, 25.0	
Status [3]		
Improved	1 (50.0)	0 (0.0)
Stable	1 (50.0)	0 (0.0)
Worsened	0 (0.0)	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/T14.2.6.1.1_nsclc_eff.rtf

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

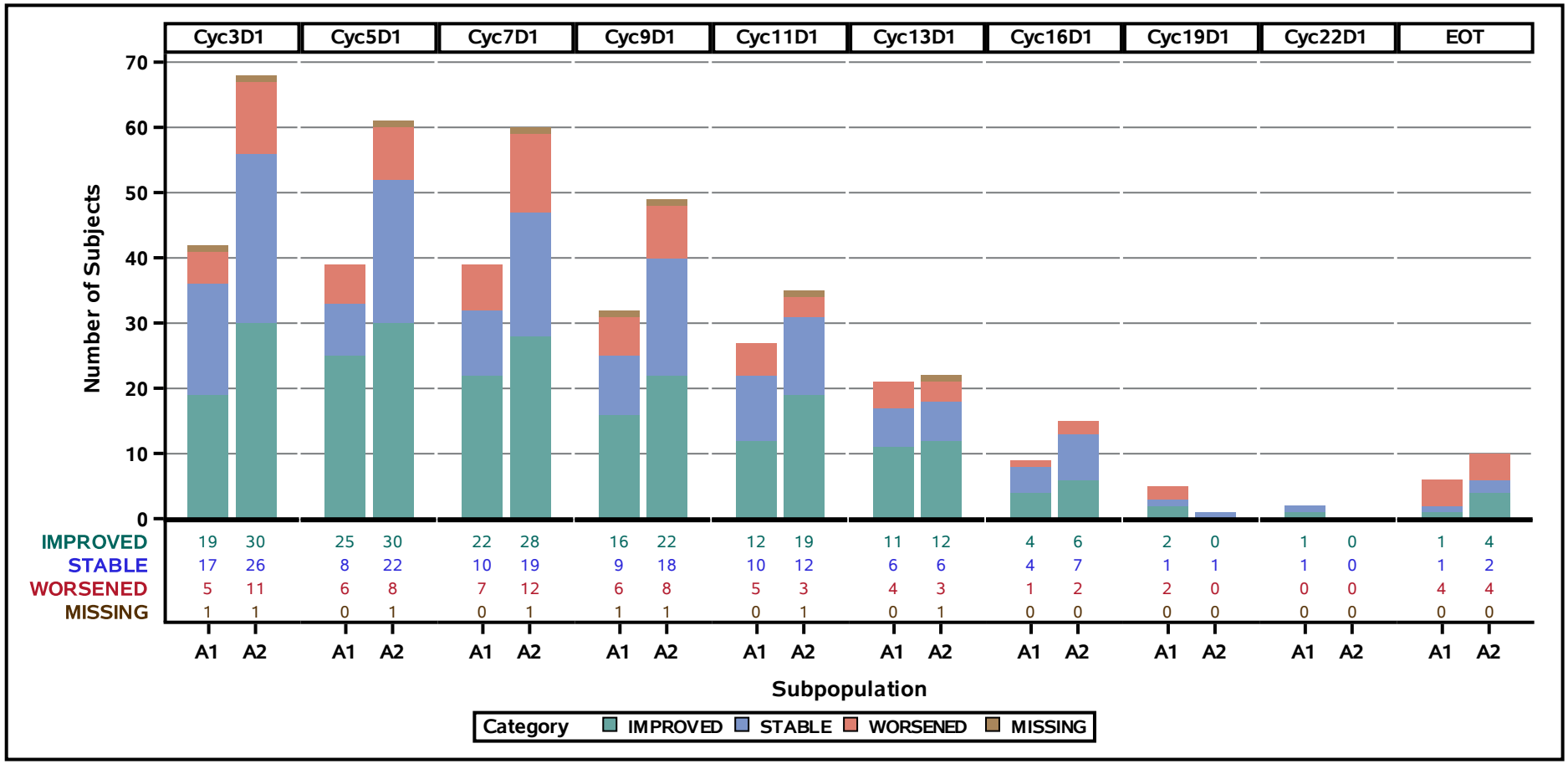
Visit Statistics	A1 (N= 51)	A2 (N= 76)
End of Treatment		
n [2]	6	10
Mean	55.56	56.67
Standard Deviation	20.861	21.802
Median	50.00	54.17
Q1, Q3	41.7, 66.7	41.7, 66.7
Min, Max	33.3, 91.7	33.3, 100.0
Change from Baseline to End of Treatment		
n [2]	6	10
Mean	-16.67	-3.33
Standard Deviation	23.570	20.488
Median	-16.67	-8.33
Q1, Q3	-33.3, 0.0	-16.7, 16.7
Min, Max	-50.0, 16.7	-33.3, 25.0
Status [3]		
Improved	1 (16.7)	4 (40.0)
Stable	1 (16.7)	2 (20.0)
Worsened	4 (66.7)	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/T14.2.6.1.1_nsclc_eff.rtf

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

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



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F040_ql2_10pt_nsclc_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

Loxo Oncology Inc. Page 1 of 2
Protocol Number: LOXO-RET-17001 03:41 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

T14.2.6.1.16
EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	51 62.42 (24.17)	41 9.44 (3.94, 14.94)	75 60.00 (22.92)	67 6.51 (2.32, 10.69)
CYCLE 5 DAY 1		39 15.02 (9.37, 20.66)		60 11.00 (6.57, 15.42)
CYCLE 7 DAY 1		39 11.42 (5.78, 17.05)		59 7.97 (3.51, 12.43)
CYCLE 9 DAY 1		31 12.57 (6.25, 18.89)		48 8.70 (3.75, 13.65)
CYCLE 11 DAY 1		27 10.84 (4.07, 17.62)		34 15.39 (9.51, 21.27)

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_mmrm.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/T14.2.6.1.16.rtf

T14.2.6.1.16
EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 13 DAY 1	21 12.82	21 12.42 (5.14, 20.51)		(4.94, 19.90)
CYCLE 16 DAY 1	9 15.95	15 11.45 (4.20, 27.70)		(2.60, 20.30)
CYCLE 19 DAY 1	5 4.69	1 7.49 (-11.08, 20.46)		(-26.79, 41.77)
CYCLE 22 DAY 1	2 18.83	0 N.E (-6.05, 43.72)		(N.E, N.E)
END OF TREATMENT	6 -11.01	10 -3.00 (-25.40, 3.39)		(-13.84, 7.84)

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_mmrm.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/T14.2.6.1.16.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Baseline [1]		
n [2]	51	76
Mean	77.65	76.40
Standard Deviation	23.658	19.366
Median	86.67	80.00
Q1, Q3	66.7, 100.0	63.3, 90.0
Min, Max	13.3, 100.0	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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 3 Day 1		
n [2]	42	68
Mean	82.70	79.61
Standard Deviation	19.145	18.208
Median	86.67	80.00
Q1, Q3	73.3, 100.0	73.3, 93.3
Min, Max	13.3, 100.0	6.7, 100.0
Change from Baseline to Cycle 3 Day 1		
n [2]	42	68
Mean	6.03	3.04
Standard Deviation	18.201	18.588
Median	0.00	0.00
Q1, Q3	-6.7, 13.3	-6.7, 13.3
Min, Max	-33.3, 53.3	-60.0, 53.3
Status [3]		
Improved	12 (28.6)	19 (27.9)
Stable	28 (66.7)	38 (55.9)
Worsened	2 (4.8)	11 (16.2)

[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
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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/T14.2.6.1.2_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 5 Day 1		
n [2]	39	61
Mean	84.10	79.70
Standard Deviation	18.007	15.455
Median	93.33	86.67
Q1, Q3	73.3, 100.0	66.7, 86.7
Min, Max	20.0, 100.0	40.0, 100.0
Change from Baseline to Cycle 5 Day 1		
n [2]	39	61
Mean	8.55	3.42
Standard Deviation	17.368	16.206
Median	6.67	0.00
Q1, Q3	0.0, 13.3	-6.7, 13.3
Min, Max	-20.0, 53.3	-26.7, 53.3
Status [3]		
Improved	14 (35.9)	16 (26.2)
Stable	22 (56.4)	35 (57.4)
Worsened	3 (7.7)	10 (16.4)

[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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 7 Day 1		
n [2]	39	60
Mean	85.47	80.89
Standard Deviation	18.153	17.117
Median	93.33	86.67
Q1, Q3	73.3, 100.0	73.3, 93.3
Min, Max	20.0, 100.0	26.7, 100.0
Change from Baseline to Cycle 7 Day 1		
n [2]	39	60
Mean	8.72	5.00
Standard Deviation	21.311	16.813
Median	0.00	0.00
Q1, Q3	0.0, 20.0	0.0, 13.3
Min, Max	-20.0, 60.0	-46.7, 40.0
Status [3]		
Improved	13 (33.3)	18 (30.0)
Stable	20 (51.3)	33 (55.0)
Worsened	6 (15.4)	9 (15.0)

[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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 9 Day 1		
n [2]	32	49
Mean	84.17	82.04
Standard Deviation	17.081	15.823
Median	86.67	86.67
Q1, Q3	76.7, 100.0	73.3, 93.3
Min, Max	20.0, 100.0	33.3, 100.0
Change from Baseline to Cycle 9 Day 1		
n [2]	32	49
Mean	5.42	5.99
Standard Deviation	18.194	17.387
Median	0.00	6.67
Q1, Q3	-6.7, 13.3	0.0, 13.3
Min, Max	-40.0, 60.0	-26.7, 53.3
Status [3]		
Improved	10 (31.3)	14 (28.6)
Stable	20 (62.5)	26 (53.1)
Worsened	2 (6.3)	9 (18.4)

[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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 11 Day 1		
n [2]	27	35
Mean	86.67	86.48
Standard Deviation	13.461	10.905
Median	86.67	86.67
Q1, Q3	80.0, 100.0	80.0, 93.3
Min, Max	46.7, 100.0	53.3, 100.0
Change from Baseline to Cycle 11 Day 1		
n [2]	27	35
Mean	7.16	7.24
Standard Deviation	17.631	12.459
Median	0.00	0.00
Q1, Q3	0.0, 13.3	0.0, 6.7
Min, Max	-13.3, 60.0	-6.7, 40.0
Status [3]		
Improved	9 (33.3)	8 (22.9)
Stable	15 (55.6)	27 (77.1)
Worsened	3 (11.1)	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/T14.2.6.1.2_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 13 Day 1		
n [2]	21	22
Mean	83.17	81.82
Standard Deviation	22.173	17.839
Median	86.67	86.67
Q1, Q3	80.0, 93.3	80.0, 93.3
Min, Max	6.7, 100.0	26.7, 100.0
Change from Baseline to Cycle 13 Day 1		
n [2]	21	22
Mean	6.35	4.85
Standard Deviation	24.356	15.421
Median	0.00	0.00
Q1, Q3	-6.7, 13.3	-6.7, 6.7
Min, Max	-46.7, 66.7	-20.0, 40.0
Status [3]		
Improved	9 (42.9)	4 (18.2)
Stable	8 (38.1)	16 (72.7)
Worsened	4 (19.0)	2 (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/T14.2.6.1.2_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 16 Day 1		
n [2]	9	15
Mean	88.15	84.89
Standard Deviation	18.791	16.029
Median	93.33	86.67
Q1, Q3	86.7, 100.0	73.3, 100.0
Min, Max	40.0, 100.0	53.3, 100.0
Change from Baseline to Cycle 16 Day 1		
n [2]	9	15
Mean	6.67	8.44
Standard Deviation	12.910	22.743
Median	13.33	0.00
Q1, Q3	0.0, 13.3	-6.7, 20.0
Min, Max	-20.0, 20.0	-26.7, 53.3
Status [3]		
Improved	6 (66.7)	6 (40.0)
Stable	2 (22.2)	7 (46.7)
Worsened	1 (11.1)	2 (13.3)

[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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 19 Day 1		
n [2]	5	1
Mean	86.67	86.67
Standard Deviation	14.142	
Median	86.67	86.67
Q1, Q3	80.0, 100.0	86.7, 86.7
Min, Max	66.7, 100.0	86.7, 86.7
Change from Baseline to Cycle 19 Day 1		
n [2]	5	1
Mean	-1.33	6.67
Standard Deviation	11.926	
Median	0.00	6.67
Q1, Q3	-13.3, 6.7	6.7, 6.7
Min, Max	-13.3, 13.3	6.7, 6.7
Status [3]		
Improved	1 (20.0)	0 (0.0)
Stable	2 (40.0)	1 (100.0)
Worsened	2 (40.0)	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/T14.2.6.1.2_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 22 Day 1		
n [2]	2	0
Mean	96.67	
Standard Deviation	4.714	
Median	96.67	
Q1, Q3	93.3, 100.0	
Min, Max	93.3, 100.0	
Change from Baseline to Cycle 22 Day 1		
n [2]	2	0
Mean	20.00	
Standard Deviation	0.000	
Median	20.00	
Q1, Q3	20.0, 20.0	
Min, Max	20.0, 20.0	
Status [3]		
Improved	2 (100.0)	0 (0.0)
Stable	0 (0.0)	0 (0.0)
Worsened	0 (0.0)	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/T14.2.6.1.2_nsclc_eff.rtf

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

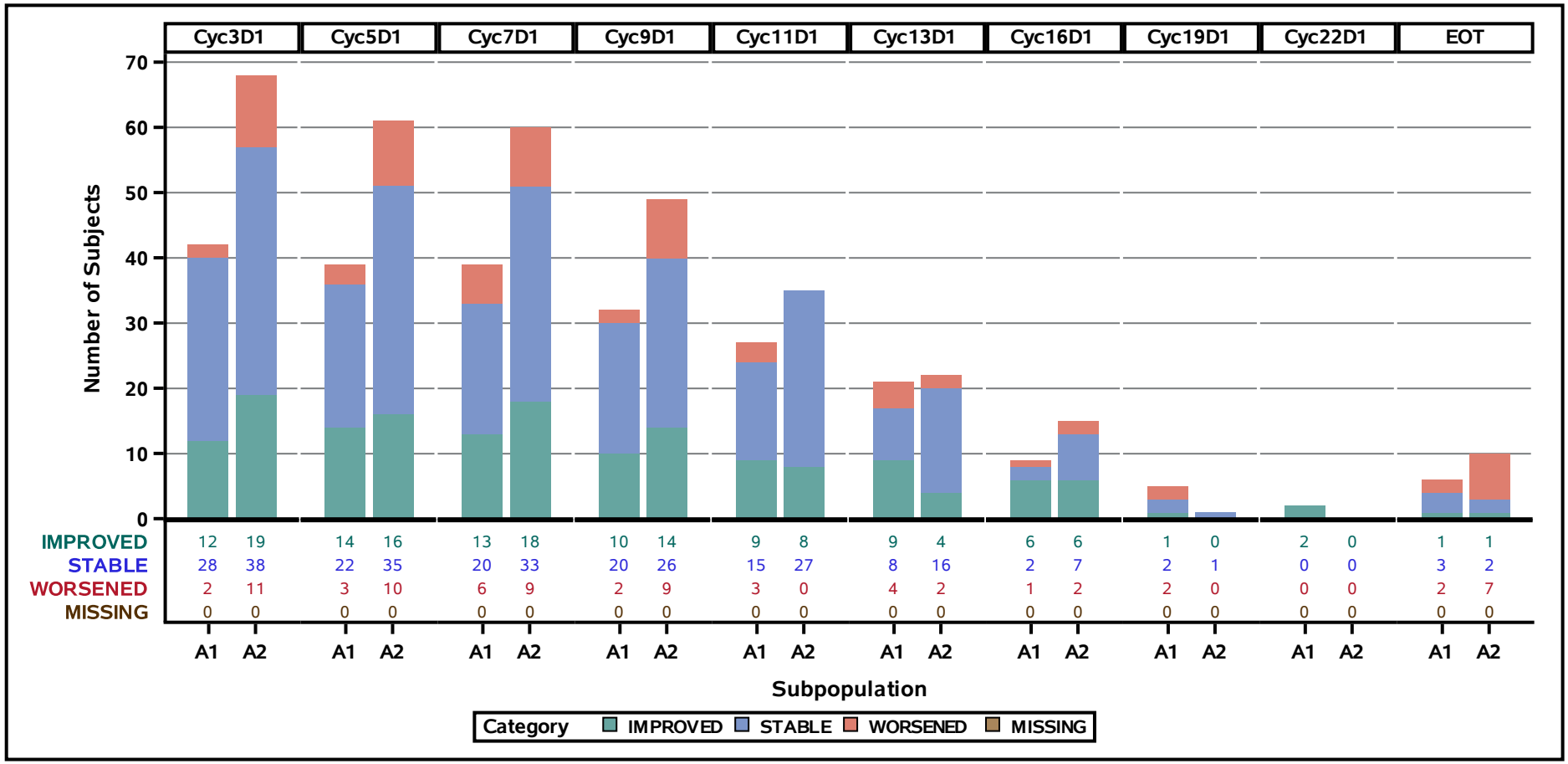
Visit Statistics	A1 (N= 51)	A2 (N= 76)
End of Treatment		
n [2]	6	10
Mean	80.00	72.00
Standard Deviation	29.212	17.441
Median	93.33	73.33
Q1, Q3	66.7, 100.0	53.3, 80.0
Min, Max	26.7, 100.0	46.7, 100.0
Change from Baseline to End of Treatment		
n [2]	6	10
Mean	-5.56	-10.00
Standard Deviation	36.616	10.062
Median	-3.33	-13.33
Q1, Q3	-20.0, 0.0	-13.3, -6.7
Min, Max	-60.0, 53.3	-20.0, 13.3
Status [3]		
Improved	1 (16.7)	1 (10.0)
Stable	3 (50.0)	2 (20.0)
Worsened	2 (33.3)	7 (70.0)

[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_nsclc_eff.rtf

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

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



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F041_pf2_10pt_nsclc_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

Loxo Oncology Inc. Page 1 of 2
Protocol Number: LOXO-RET-17001 03:41 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

T14.2.6.1.17
EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	51 77.65 (23.66)	42 5.40 (0.89, 9.91)	76 76.40 (19.37)	68 2.92 (-0.33, 6.16)
CYCLE 5 DAY 1		39 7.31 (2.63, 11.99)		61 3.14 (-0.28, 6.57)
CYCLE 7 DAY 1		39 8.13 (3.45, 12.81)		60 4.52 (1.07, 7.98)
CYCLE 9 DAY 1		32 5.91 (0.75, 11.07)		49 5.59 (1.77, 9.42)
CYCLE 11 DAY 1		27 8.06 (2.44, 13.68)		35 8.52 (3.99, 13.04)

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_mmrm.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/T14.2.6.1.17.rtf

T14.2.6.1.17
EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 13 DAY 1	21 5.80	21 5.80 (-0.57, 12.18)	22 4.94	22 4.94 (-0.77, 10.64)
CYCLE 16 DAY 1	9 8.64	9 8.64 (-1.10, 18.38)	15 8.26	15 8.26 (1.35, 15.17)
CYCLE 19 DAY 1	5 4.16	5 4.16 (-8.93, 17.25)	1 8.35	1 8.35 (-18.41, 35.10)
CYCLE 22 DAY 1	2 19.37	2 19.37 (-1.28, 40.02)	0 N.E	0 N.E (N.E, N.E)
END OF TREATMENT	6 -1.38	6 -1.38 (-13.32, 10.56)	10 -7.27	10 -7.27 (-15.74, 1.20)

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_mmrm.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/T14.2.6.1.17.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Baseline [1]		
n [2]	51	75
Mean	80.07	80.48
Standard Deviation	18.565	19.963
Median	83.33	83.33
Q1, Q3	66.7, 100.0	66.7, 100.0
Min, Max	25.0, 100.0	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
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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 3 Day 1		
n [2]	41	67
Mean	79.88	83.13
Standard Deviation	22.514	17.690
Median	83.33	91.67
Q1, Q3	75.0, 100.0	75.0, 100.0
Min, Max	8.3, 100.0	33.3, 100.0
Change from Baseline to Cycle 3 Day 1		
n [2]	41	67
Mean	2.24	2.24
Standard Deviation	13.947	17.530
Median	0.00	0.00
Q1, Q3	-8.3, 8.3	-8.3, 16.7
Min, Max	-33.3, 33.3	-41.7, 50.0
Status [3]		
Improved	8 (19.5)	17 (25.4)
Stable	29 (70.7)	39 (58.2)
Worsened	4 (9.8)	11 (16.4)

[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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 5 Day 1		
n [2]	39	60
Mean	83.33	86.39
Standard Deviation	18.732	16.522
Median	91.67	91.67
Q1, Q3	75.0, 100.0	83.3, 100.0
Min, Max	25.0, 100.0	33.3, 100.0
Change from Baseline to Cycle 5 Day 1		
n [2]	39	60
Mean	5.98	6.76
Standard Deviation	15.989	15.303
Median	0.00	0.00
Q1, Q3	0.0, 16.7	0.0, 12.5
Min, Max	-33.3, 58.3	-25.0, 58.3
Status [3]		
Improved	11 (28.2)	15 (25.0)
Stable	25 (64.1)	42 (70.0)
Worsened	3 (7.7)	3 (5.0)

[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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 7 Day 1		
n [2]	39	59
Mean	83.33	83.47
Standard Deviation	19.403	19.726
Median	91.67	91.67
Q1, Q3	75.0, 100.0	66.7, 100.0
Min, Max	33.3, 100.0	16.7, 100.0
Change from Baseline to Cycle 7 Day 1		
n [2]	39	59
Mean	4.91	2.92
Standard Deviation	13.344	17.953
Median	0.00	0.00
Q1, Q3	0.0, 8.3	-8.3, 8.3
Min, Max	-25.0, 33.3	-41.7, 50.0
Status [3]		
Improved	9 (23.1)	14 (23.7)
Stable	27 (69.2)	39 (66.1)
Worsened	3 (7.7)	6 (10.2)

[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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 9 Day 1		
n [2]	31	48
Mean	84.14	82.87
Standard Deviation	21.011	22.002
Median	91.67	91.67
Q1, Q3	83.3, 100.0	70.8, 100.0
Min, Max	16.7, 100.0	16.7, 100.0
Change from Baseline to Cycle 9 Day 1		
n [2]	31	48
Mean	1.88	0.87
Standard Deviation	15.621	22.850
Median	0.00	0.00
Q1, Q3	-8.3, 8.3	-8.3, 8.3
Min, Max	-25.0, 33.3	-83.3, 50.0
Status [3]		
Improved	7 (22.6)	11 (22.9)
Stable	19 (61.3)	31 (64.6)
Worsened	5 (16.1)	6 (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/T14.2.6.1.3_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 11 Day 1		
n [2]	27	34
Mean	86.11	85.29
Standard Deviation	17.450	17.171
Median	91.67	91.67
Q1, Q3	75.0, 100.0	75.0, 100.0
Min, Max	33.3, 100.0	33.3, 100.0
Change from Baseline to Cycle 11 Day 1		
n [2]	27	34
Mean	3.40	3.10
Standard Deviation	12.714	16.480
Median	0.00	0.00
Q1, Q3	0.0, 8.3	-8.3, 8.3
Min, Max	-25.0, 25.0	-33.3, 41.7
Status [3]		
Improved	6 (22.2)	8 (23.5)
Stable	18 (66.7)	21 (61.8)
Worsened	3 (11.1)	5 (14.7)

[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/T14.2.6.1.3_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 13 Day 1		
n [2]	21	21
Mean	82.94	83.33
Standard Deviation	21.486	20.750
Median	91.67	91.67
Q1, Q3	75.0, 100.0	75.0, 100.0
Min, Max	16.7, 100.0	16.7, 100.0
Change from Baseline to Cycle 13 Day 1		
n [2]	21	21
Mean	-0.40	1.59
Standard Deviation	16.557	16.376
Median	0.00	0.00
Q1, Q3	-8.3, 8.3	0.0, 8.3
Min, Max	-25.0, 33.3	-33.3, 33.3
Status [3]		
Improved	3 (14.3)	4 (19.0)
Stable	13 (61.9)	14 (66.7)
Worsened	5 (23.8)	3 (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/T14.2.6.1.3_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 16 Day 1		
n [2]	9	15
Mean	86.11	82.22
Standard Deviation	15.023	25.756
Median	91.67	91.67
Q1, Q3	75.0, 100.0	75.0, 100.0
Min, Max	66.7, 100.0	16.7, 100.0
Change from Baseline to Cycle 16 Day 1		
n [2]	9	15
Mean	-0.93	0.56
Standard Deviation	12.805	20.036
Median	0.00	0.00
Q1, Q3	0.0, 8.3	-8.3, 8.3
Min, Max	-25.0, 16.7	-33.3, 41.7
Status [3]		
Improved	1 (11.1)	3 (20.0)
Stable	6 (66.7)	9 (60.0)
Worsened	2 (22.2)	3 (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/T14.2.6.1.3_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 19 Day 1		
n [2]	5	1
Mean	76.11	83.33
Standard Deviation	30.907	
Median	83.33	83.33
Q1, Q3	83.3, 91.7	83.3, 83.3
Min, Max	22.2, 100.0	83.3, 83.3
Change from Baseline to Cycle 19 Day 1		
n [2]	5	1
Mean	-12.22	16.67
Standard Deviation	33.252	
Median	0.00	16.67
Q1, Q3	-8.3, 0.0	16.7, 16.7
Min, Max	-69.4, 16.7	16.7, 16.7
Status [3]		
Improved	1 (20.0)	1 (100.0)
Stable	3 (60.0)	0 (0.0)
Worsened	1 (20.0)	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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 22 Day 1		
n [2]	2	0
Mean	95.83	
Standard Deviation	5.893	
Median	95.83	
Q1, Q3	91.7, 100.0	
Min, Max	91.7, 100.0	
Change from Baseline to Cycle 22 Day 1		
n [2]	2	0
Mean	16.67	
Standard Deviation	11.785	
Median	16.67	
Q1, Q3	8.3, 25.0	
Min, Max	8.3, 25.0	
Status [3]		
Improved	1 (50.0)	0 (0.0)
Stable	1 (50.0)	0 (0.0)
Worsened	0 (0.0)	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_nsclc_eff.rtf

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

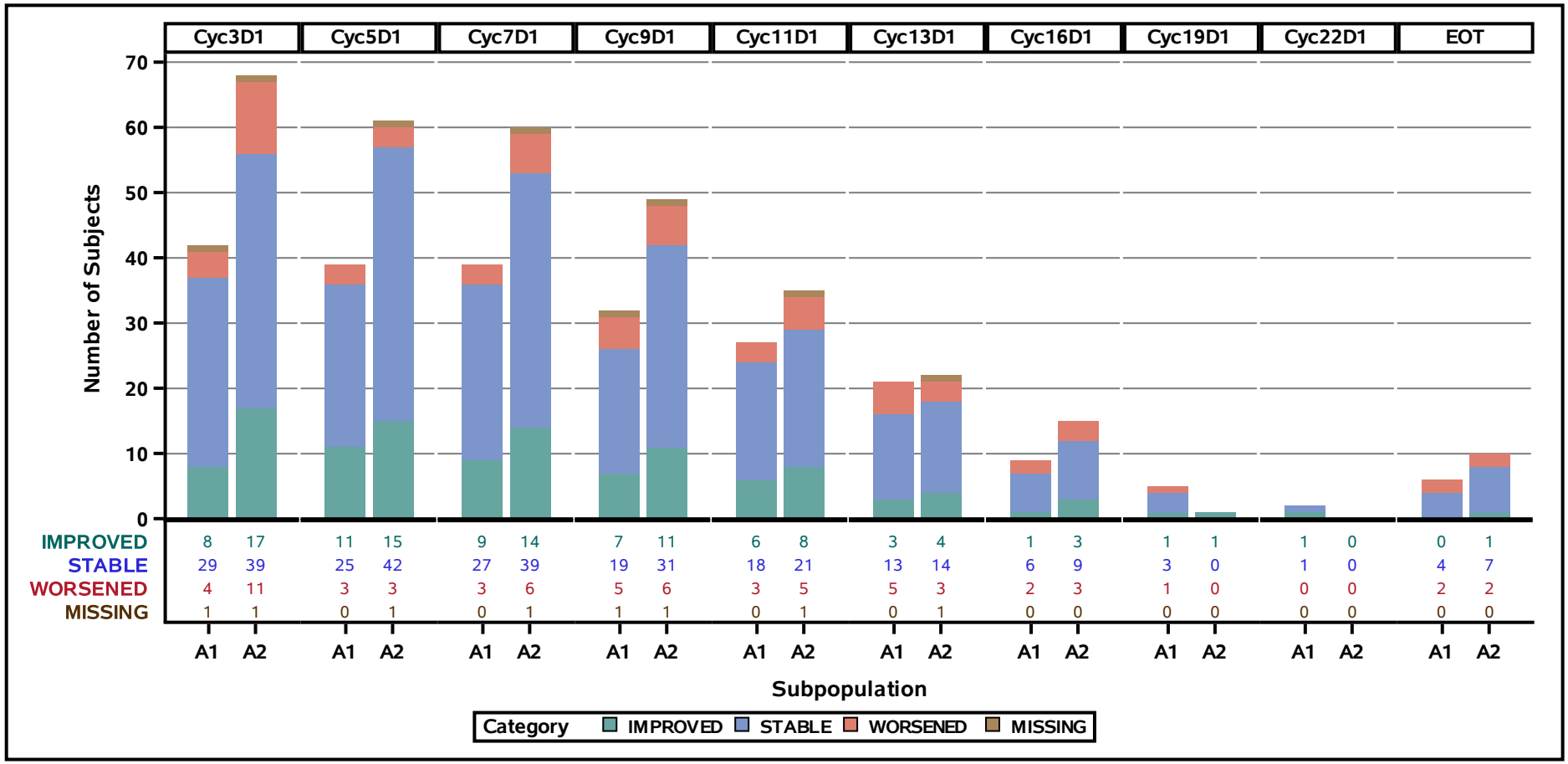
Visit Statistics	A1 (N= 51)	A2 (N= 76)
End of Treatment		
n [2]	6	10
Mean	75.00	80.83
Standard Deviation	12.910	30.944
Median	70.83	91.67
Q1, Q3	66.7, 75.0	75.0, 100.0
Min, Max	66.7, 100.0	0.0, 100.0
Change from Baseline to End of Treatment		
n [2]	6	10
Mean	-9.72	-5.83
Standard Deviation	19.305	22.240
Median	-4.17	0.00
Q1, Q3	-33.3, 8.3	-8.3, 0.0
Min, Max	-33.3, 8.3	-58.3, 25.0
Status [3]		
Improved	0 (0.0)	1 (10.0)
Stable	4 (66.7)	7 (70.0)
Worsened	2 (33.3)	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/T14.2.6.1.3_nsclc_eff.rtf

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

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



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F042_ef_10pt_nsclc_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

T14.2.6.1.18
EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	51 80.07 (18.57)	41 1.56 (-2.96, 6.09)	75 80.48 (19.96)	67 2.14 (-1.82, 6.09)
CYCLE 5 DAY 1		39 5.24 (0.60, 9.88)		60 6.13 (1.94, 10.31)
CYCLE 7 DAY 1		39 4.43 (-0.20, 9.06)		59 2.68 (-1.54, 6.89)
CYCLE 9 DAY 1		31 2.34 (-2.85, 7.54)		48 1.24 (-3.44, 5.91)
CYCLE 11 DAY 1		27 3.97 (-1.60, 9.54)		34 3.55 (-2.00, 9.11)

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/tfl/t_sp_qlqc30_mmrm.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/T14.2.6.1.18.rtf

T14.2.6.1.18
EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 13 DAY 1	21 0.33	21 1.85		
		(-5.98, 6.64)		(-5.22, 8.92)
CYCLE 16 DAY 1	9 0.71	15 0.78		
		(-8.95, 10.37)		(-7.58, 9.15)
CYCLE 19 DAY 1	5 -10.27	1 10.55		
		(-23.22, 2.69)		(-21.87, 42.96)
CYCLE 22 DAY 1	2 16.37	0 N.E		
		(-4.06, 36.80)		(N.E, N.E)
END OF TREATMENT	6 -8.65	10 -3.49		
		(-20.46, 3.15)		(-13.75, 6.77)

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_mmrm.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/T14.2.6.1.18.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Baseline [1]		
n [2]	51	76
Mean	74.51	69.08
Standard Deviation	30.433	29.276
Median	83.33	66.67
Q1, Q3	50.0, 100.0	50.0, 100.0
Min, Max	0.0, 100.0	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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 3 Day 1		
n [2]	42	68
Mean	80.95	75.25
Standard Deviation	22.861	24.686
Median	83.33	83.33
Q1, Q3	66.7, 100.0	66.7, 100.0
Min, Max	16.7, 100.0	0.0, 100.0
Change from Baseline to Cycle 3 Day 1		
n [2]	42	68
Mean	8.33	5.64
Standard Deviation	27.361	31.493
Median	0.00	0.00
Q1, Q3	-16.7, 16.7	0.0, 16.7
Min, Max	-33.3, 100.0	-83.3, 100.0
Status [3]		
Improved	15 (35.7)	26 (38.2)
Stable	16 (38.1)	27 (39.7)
Worsened	11 (26.2)	15 (22.1)

[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
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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/T14.2.6.1.4_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 5 Day 1		
n [2]	39	61
Mean	82.91	77.32
Standard Deviation	19.678	19.961
Median	83.33	66.67
Q1, Q3	66.7, 100.0	66.7, 100.0
Min, Max	16.7, 100.0	16.7, 100.0
Change from Baseline to Cycle 5 Day 1		
n [2]	39	61
Mean	8.97	7.38
Standard Deviation	25.606	27.643
Median	0.00	0.00
Q1, Q3	0.0, 16.7	0.0, 16.7
Min, Max	-33.3, 83.3	-50.0, 100.0
Status [3]		
Improved	12 (30.8)	22 (36.1)
Stable	20 (51.3)	24 (39.3)
Worsened	7 (17.9)	15 (24.6)

[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/T14.2.6.1.4_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 7 Day 1		
n [2]	39	60
Mean	83.76	76.67
Standard Deviation	20.046	26.433
Median	100.00	83.33
Q1, Q3	66.7, 100.0	66.7, 100.0
Min, Max	33.3, 100.0	0.0, 100.0
Change from Baseline to Cycle 7 Day 1		
n [2]	39	60
Mean	8.97	7.50
Standard Deviation	25.318	31.056
Median	0.00	0.00
Q1, Q3	0.0, 16.7	0.0, 16.7
Min, Max	-33.3, 66.7	-83.3, 100.0
Status [3]		
Improved	14 (35.9)	26 (43.3)
Stable	17 (43.6)	22 (36.7)
Worsened	8 (20.5)	12 (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/T14.2.6.1.4_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 9 Day 1		
n [2]	32	49
Mean	83.33	77.89
Standard Deviation	19.400	25.547
Median	83.33	83.33
Q1, Q3	66.7, 100.0	66.7, 100.0
Min, Max	33.3, 100.0	0.0, 100.0
Change from Baseline to Cycle 9 Day 1		
n [2]	32	49
Mean	6.25	8.84
Standard Deviation	29.558	33.524
Median	0.00	0.00
Q1, Q3	-8.3, 16.7	0.0, 33.3
Min, Max	-50.0, 83.3	-100.0, 83.3
Status [3]		
Improved	11 (34.4)	23 (46.9)
Stable	13 (40.6)	15 (30.6)
Worsened	8 (25.0)	11 (22.4)

[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/T14.2.6.1.4_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 11 Day 1		
n [2]	27	35
Mean	89.51	85.71
Standard Deviation	16.761	19.446
Median	100.00	100.00
Q1, Q3	83.3, 100.0	66.7, 100.0
Min, Max	33.3, 100.0	33.3, 100.0
Change from Baseline to Cycle 11 Day 1		
n [2]	27	35
Mean	10.49	14.76
Standard Deviation	27.792	31.252
Median	0.00	16.67
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	-33.3, 83.3	-33.3, 100.0
Status [3]		
Improved	9 (33.3)	18 (51.4)
Stable	14 (51.9)	9 (25.7)
Worsened	4 (14.8)	8 (22.9)

[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/T14.2.6.1.4_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 13 Day 1		
n [2]	21	22
Mean	76.19	79.55
Standard Deviation	25.588	22.963
Median	83.33	83.33
Q1, Q3	66.7, 100.0	66.7, 100.0
Min, Max	33.3, 100.0	16.7, 100.0
Change from Baseline to Cycle 13 Day 1		
n [2]	21	22
Mean	0.79	12.88
Standard Deviation	29.569	33.306
Median	0.00	0.00
Q1, Q3	-16.7, 16.7	0.0, 33.3
Min, Max	-66.7, 50.0	-33.3, 100.0
Status [3]		
Improved	6 (28.6)	8 (36.4)
Stable	9 (42.9)	10 (45.5)
Worsened	6 (28.6)	4 (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/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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 16 Day 1		
n [2]	9	15
Mean	83.33	84.44
Standard Deviation	22.048	19.382
Median	83.33	83.33
Q1, Q3	83.3, 100.0	66.7, 100.0
Min, Max	33.3, 100.0	33.3, 100.0
Change from Baseline to Cycle 16 Day 1		
n [2]	9	15
Mean	0.00	14.44
Standard Deviation	26.352	38.764
Median	0.00	0.00
Q1, Q3	-16.7, 16.7	0.0, 33.3
Min, Max	-33.3, 50.0	-66.7, 100.0
Status [3]		
Improved	3 (33.3)	7 (46.7)
Stable	3 (33.3)	5 (33.3)
Worsened	3 (33.3)	3 (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/T14.2.6.1.4_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 19 Day 1		
n [2]	5	1
Mean	86.67	66.67
Standard Deviation	13.944	
Median	83.33	66.67
Q1, Q3	83.3, 100.0	66.7, 66.7
Min, Max	66.7, 100.0	66.7, 66.7
Change from Baseline to Cycle 19 Day 1		
n [2]	5	1
Mean	6.67	33.33
Standard Deviation	25.276	
Median	0.00	33.33
Q1, Q3	0.0, 0.0	33.3, 33.3
Min, Max	-16.7, 50.0	33.3, 33.3
Status [3]		
Improved	1 (20.0)	1 (100.0)
Stable	3 (60.0)	0 (0.0)
Worsened	1 (20.0)	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/T14.2.6.1.4_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 22 Day 1		
n [2]	2	0
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	0
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)	0 (0.0)
Stable	1 (50.0)	0 (0.0)
Worsened	0 (0.0)	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/T14.2.6.1.4_nsclc_eff.rtf

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

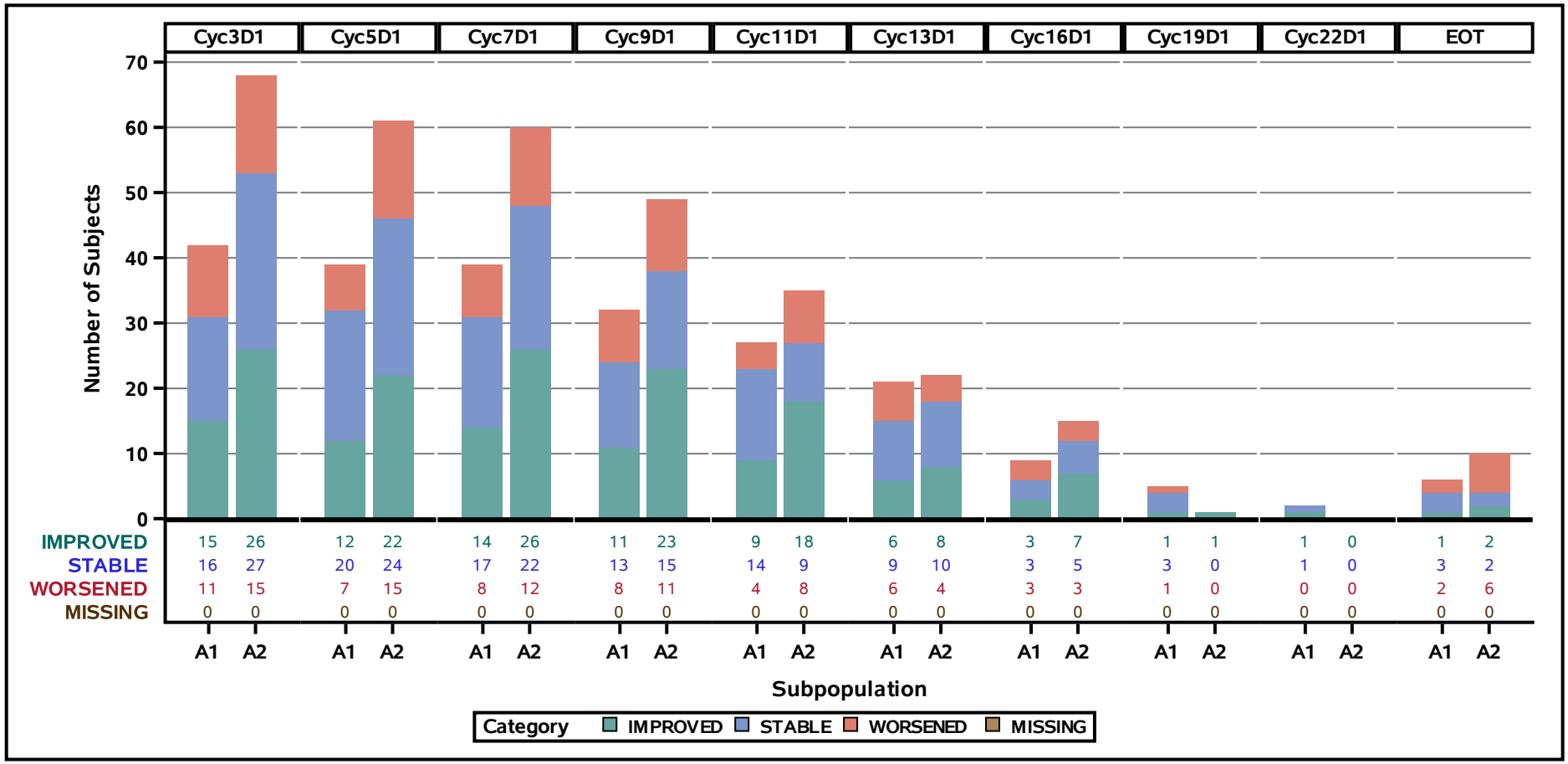
Visit Statistics	A1 (N= 51)	A2 (N= 76)
End of Treatment		
n [2]	6	10
Mean	77.78	68.33
Standard Deviation	27.217	16.574
Median	83.33	66.67
Q1, Q3	66.7, 100.0	66.7, 66.7
Min, Max	33.3, 100.0	33.3, 100.0
Change from Baseline to End of Treatment		
n [2]	6	10
Mean	-8.33	-8.33
Standard Deviation	22.973	31.672
Median	0.00	-16.67
Q1, Q3	-16.7, 0.0	-33.3, 0.0
Min, Max	-50.0, 16.7	-33.3, 66.7
Status [3]		
Improved	1 (16.7)	2 (20.0)
Stable	3 (50.0)	2 (20.0)
Worsened	2 (33.3)	6 (60.0)

[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_nsclc_eff.rtf

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

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



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F043_rf2_10pt_nsclc_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

Loxo Oncology Inc. Page 1 of 2
Protocol Number: LOXO-RET-17001 03:41 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

T14.2.6.1.19
EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	51 74.51 (30.43)	42 6.09 (0.49, 11.69)	76 69.08 (29.28)	68 5.66 (0.39, 10.93)
CYCLE 5 DAY 1		39 7.61 (1.80, 13.42)		61 7.66 (2.09, 13.22)
CYCLE 7 DAY 1		39 8.18 (2.37, 13.99)		60 7.19 (1.58, 12.81)
CYCLE 9 DAY 1		32 6.99 (0.58, 13.40)		49 8.45 (2.24, 14.66)
CYCLE 11 DAY 1		27 12.52 (5.54, 19.51)		35 15.80 (8.45, 23.15)

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_mmrm.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/T14.2.6.1.19.rtf

T14.2.6.1.19
EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 13 DAY 1	21 0.41	21 0.41 (-7.51, 8.32)	22 10.70	22 10.70 (1.42, 19.97)
CYCLE 16 DAY 1	9 4.91	9 4.91 (-7.19, 17.02)	15 14.76	15 14.76 (3.54, 25.99)
CYCLE 19 DAY 1	5 9.35	5 9.35 (-6.87, 25.58)	1 6.13	1 6.13 (-37.45, 49.70)
CYCLE 22 DAY 1	2 13.25	2 13.25 (-12.40, 38.90)	0 N.E	0 N.E (N.E, N.E)
END OF TREATMENT	6 -1.56	6 -1.56 (-16.39, 13.27)	10 -3.01	10 -3.01 (-16.77, 10.75)

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_mmrm.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/T14.2.6.1.19.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Baseline [1]		
n [2]	51	75
Mean	84.64	86.44
Standard Deviation	16.945	17.903
Median	83.33	100.00
Q1, Q3	66.7, 100.0	83.3, 100.0
Min, Max	33.3, 100.0	33.3, 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
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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 3 Day 1		
n [2]	41	67
Mean	83.74	85.57
Standard Deviation	20.578	18.554
Median	83.33	83.33
Q1, Q3	66.7, 100.0	83.3, 100.0
Min, Max	33.3, 100.0	16.7, 100.0
Change from Baseline to Cycle 3 Day 1		
n [2]	41	67
Mean	-0.41	-0.50
Standard Deviation	19.180	13.286
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-66.7, 33.3	-50.0, 33.3
Status [3]		
Improved	10 (24.4)	13 (19.4)
Stable	21 (51.2)	42 (62.7)
Worsened	10 (24.4)	12 (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
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.5_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 5 Day 1		
n [2]	39	60
Mean	84.62	85.28
Standard Deviation	19.640	17.110
Median	100.00	83.33
Q1, Q3	66.7, 100.0	66.7, 100.0
Min, Max	33.3, 100.0	33.3, 100.0
Change from Baseline to Cycle 5 Day 1		
n [2]	39	60
Mean	2.14	-2.22
Standard Deviation	19.564	13.539
Median	0.00	0.00
Q1, Q3	0.0, 16.7	-16.7, 0.0
Min, Max	-66.7, 33.3	-33.3, 33.3
Status [3]		
Improved	12 (30.8)	9 (15.0)
Stable	19 (48.7)	35 (58.3)
Worsened	8 (20.5)	16 (26.7)

[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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 7 Day 1		
n [2]	39	59
Mean	86.32	85.88
Standard Deviation	16.610	16.899
Median	83.33	83.33
Q1, Q3	83.3, 100.0	83.3, 100.0
Min, Max	33.3, 100.0	33.3, 100.0
Change from Baseline to Cycle 7 Day 1		
n [2]	39	59
Mean	3.85	-1.69
Standard Deviation	15.513	12.646
Median	0.00	0.00
Q1, Q3	0.0, 16.7	0.0, 0.0
Min, Max	-33.3, 33.3	-50.0, 16.7
Status [3]		
Improved	14 (35.9)	10 (16.9)
Stable	19 (48.7)	36 (61.0)
Worsened	6 (15.4)	13 (22.0)

[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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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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 9 Day 1		
n [2]	31	48
Mean	82.26	82.64
Standard Deviation	22.334	22.003
Median	83.33	83.33
Q1, Q3	66.7, 100.0	66.7, 100.0
Min, Max	33.3, 100.0	16.7, 100.0
Change from Baseline to Cycle 9 Day 1		
n [2]	31	48
Mean	-4.84	-6.25
Standard Deviation	16.212	16.353
Median	0.00	0.00
Q1, Q3	-16.7, 0.0	-16.7, 0.0
Min, Max	-50.0, 16.7	-66.7, 16.7
Status [3]		
Improved	4 (12.9)	5 (10.4)
Stable	19 (61.3)	28 (58.3)
Worsened	8 (25.8)	15 (31.3)

[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
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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/T14.2.6.1.5_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 11 Day 1		
n [2]	27	34
Mean	86.42	89.22
Standard Deviation	17.319	13.535
Median	100.00	100.00
Q1, Q3	83.3, 100.0	83.3, 100.0
Min, Max	50.0, 100.0	66.7, 100.0
Change from Baseline to Cycle 11 Day 1		
n [2]	27	34
Mean	-1.85	-1.47
Standard Deviation	17.501	11.137
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-50.0, 33.3	-33.3, 33.3
Status [3]		
Improved	4 (14.8)	3 (8.8)
Stable	18 (66.7)	25 (73.5)
Worsened	5 (18.5)	6 (17.6)

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 13 Day 1		
n [2]	21	21
Mean	84.92	83.33
Standard Deviation	18.933	21.731
Median	83.33	100.00
Q1, Q3	83.3, 100.0	66.7, 100.0
Min, Max	33.3, 100.0	33.3, 100.0
Change from Baseline to Cycle 13 Day 1		
n [2]	21	21
Mean	-1.59	-7.14
Standard Deviation	21.019	19.416
Median	0.00	0.00
Q1, Q3	0.0, 0.0	-16.7, 0.0
Min, Max	-66.7, 33.3	-66.7, 16.7
Status [3]		
Improved	3 (14.3)	3 (14.3)
Stable	13 (61.9)	11 (52.4)
Worsened	5 (23.8)	7 (33.3)

[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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 16 Day 1		
n [2]	9	15
Mean	87.04	85.56
Standard Deviation	26.058	28.078
Median	100.00	100.00
Q1, Q3	100.0, 100.0	83.3, 100.0
Min, Max	33.3, 100.0	0.0, 100.0
Change from Baseline to Cycle 16 Day 1		
n [2]	9	15
Mean	-3.70	-2.22
Standard Deviation	13.889	17.668
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-33.3, 16.7	-50.0, 33.3
Status [3]		
Improved	1 (11.1)	2 (13.3)
Stable	6 (66.7)	10 (66.7)
Worsened	2 (22.2)	3 (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/T14.2.6.1.5_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 19 Day 1		
n [2]	5	1
Mean	83.33	83.33
Standard Deviation	20.412	
Median	83.33	83.33
Q1, Q3	83.3, 100.0	83.3, 83.3
Min, Max	50.0, 100.0	83.3, 83.3
Change from Baseline to Cycle 19 Day 1		
n [2]	5	1
Mean	-6.67	16.67
Standard Deviation	14.907	
Median	-16.67	16.67
Q1, Q3	-16.7, 0.0	16.7, 16.7
Min, Max	-16.7, 16.7	16.7, 16.7
Status [3]		
Improved	1 (20.0)	1 (100.0)
Stable	1 (20.0)	0 (0.0)
Worsened	3 (60.0)	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/T14.2.6.1.5_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 22 Day 1		
n [2]	2	0
Mean	58.33	
Standard Deviation	11.785	
Median	58.33	
Q1, Q3	50.0, 66.7	
Min, Max	50.0, 66.7	
Change from Baseline to Cycle 22 Day 1		
n [2]	2	0
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	0 (0.0)	0 (0.0)
Stable	1 (50.0)	0 (0.0)
Worsened	1 (50.0)	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/T14.2.6.1.5_nsclc_eff.rtf

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

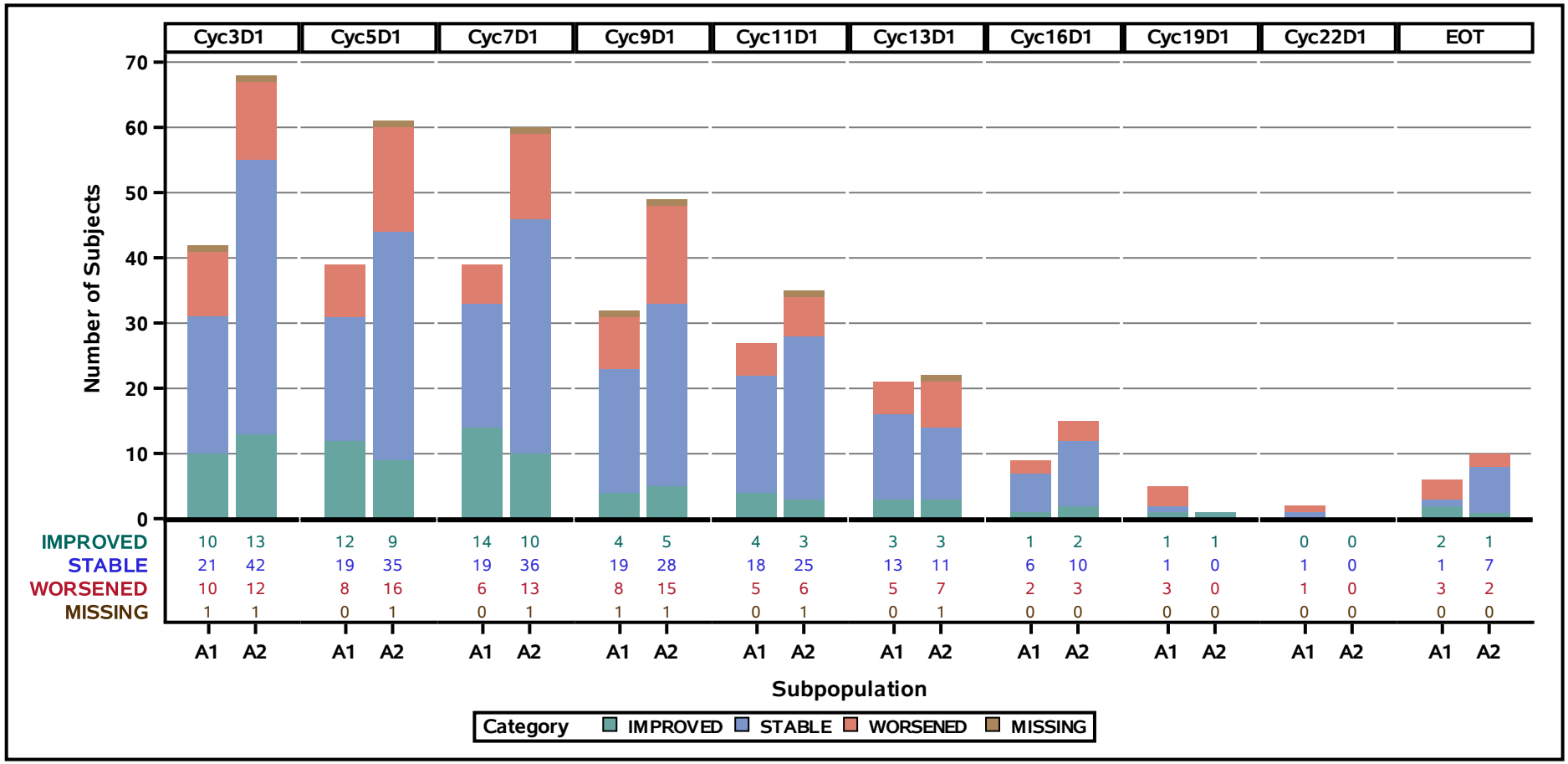
Visit Statistics	A1 (N= 51)	A2 (N= 76)
End of Treatment		
n [2]	6	10
Mean	72.22	81.67
Standard Deviation	22.771	26.586
Median	75.00	100.00
Q1, Q3	66.7, 83.3	50.0, 100.0
Min, Max	33.3, 100.0	33.3, 100.0
Change from Baseline to End of Treatment		
n [2]	6	10
Mean	-8.33	-3.33
Standard Deviation	22.973	13.147
Median	-8.33	0.00
Q1, Q3	-33.3, 16.7	0.0, 0.0
Min, Max	-33.3, 16.7	-33.3, 16.7
Status [3]		
Improved	2 (33.3)	1 (10.0)
Stable	1 (16.7)	7 (70.0)
Worsened	3 (50.0)	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/T14.2.6.1.5_nsclc_eff.rtf

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

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



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F044_cf_10pt_nsclc_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

T14.2.6.1.20
EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	51 84.64 (16.95)	41 -0.72 (-5.82, 4.38)	75 86.44 (17.90)	67 -0.87 (-4.19, 2.45)
CYCLE 5 DAY 1		39 1.14 (-4.09, 6.38)		60 -2.29 (-5.80, 1.21)
CYCLE 7 DAY 1		39 2.85 (-2.38, 8.09)		59 -1.75 (-5.29, 1.79)
CYCLE 9 DAY 1		31 -3.96 (-9.82, 1.91)		48 -6.03 (-9.95, -2.10)
CYCLE 11 DAY 1		27 -0.49 (-6.79, 5.81)		34 -0.87 (-5.53, 3.80)

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/tfl/t_sp_qlqc30_mmrm.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/T14.2.6.1.20.rtf

T14.2.6.1.20
EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 13 DAY 1	21	21		
	-0.94	-6.58		
	(-8.07, 6.18)	(-12.52, -0.65)		
CYCLE 16 DAY 1	9	15		
	-1.34	-2.23		
	(-12.24, 9.57)	(-9.25, 4.78)		
CYCLE 19 DAY 1	5	1		
	-4.60	12.20		
	(-19.22, 10.01)	(-15.03, 39.43)		
CYCLE 22 DAY 1	2	0		
	-20.70	N.E		
	(-43.82, 2.42)	(N.E, N.E)		
END OF TREATMENT	6	10		
	-10.11	-3.93		
	(-23.45, 3.23)	(-12.52, 4.66)		

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_mmrm.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/T14.2.6.1.20.rtf

Loxo Oncology Inc. Page 1 of 11
Protocol Number: LOXO-RET-17001 15:25 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Baseline [1]		
n [2]	51	75
Mean	70.59	72.89
Standard Deviation	28.980	26.105
Median	66.67	66.67
Q1, Q3	50.0, 100.0	50.0, 100.0
Min, Max	0.0, 100.0	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
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.6_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 3 Day 1		
n [2]	41	67
Mean	82.11	76.37
Standard Deviation	23.685	24.814
Median	100.00	83.33
Q1, Q3	66.7, 100.0	66.7, 100.0
Min, Max	16.7, 100.0	0.0, 100.0
Change from Baseline to Cycle 3 Day 1		
n [2]	41	67
Mean	14.23	3.73
Standard Deviation	27.779	27.649
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 16.7
Min, Max	-33.3, 100.0	-83.3, 83.3
Status [3]		
Improved	16 (39.0)	25 (37.3)
Stable	21 (51.2)	27 (40.3)
Worsened	4 (9.8)	15 (22.4)

[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.

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 5 Day 1		
n [2]	39	60
Mean	87.18	80.00
Standard Deviation	17.713	21.436
Median	100.00	83.33
Q1, Q3	83.3, 100.0	66.7, 100.0
Min, Max	33.3, 100.0	16.7, 100.0
Change from Baseline to Cycle 5 Day 1		
n [2]	39	60
Mean	18.38	7.22
Standard Deviation	25.875	29.170
Median	16.67	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	-16.7, 100.0	-50.0, 83.3
Status [3]		
Improved	22 (56.4)	26 (43.3)
Stable	14 (35.9)	20 (33.3)
Worsened	3 (7.7)	14 (23.3)

[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.

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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/T14.2.6.1.6_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 7 Day 1		
n [2]	39	59
Mean	88.46	76.27
Standard Deviation	16.291	24.799
Median	100.00	83.33
Q1, Q3	83.3, 100.0	66.7, 100.0
Min, Max	33.3, 100.0	0.0, 100.0
Change from Baseline to Cycle 7 Day 1		
n [2]	39	59
Mean	18.80	3.67
Standard Deviation	24.833	28.712
Median	16.67	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	-16.7, 100.0	-100.0, 50.0
Status [3]		
Improved	20 (51.3)	23 (39.0)
Stable	18 (46.2)	24 (40.7)
Worsened	1 (2.6)	12 (20.3)

[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/T14.2.6.1.6_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 9 Day 1		
n [2]	31	48
Mean	86.56	75.00
Standard Deviation	20.376	27.071
Median	100.00	83.33
Q1, Q3	66.7, 100.0	66.7, 100.0
Min, Max	33.3, 100.0	0.0, 100.0
Change from Baseline to Cycle 9 Day 1		
n [2]	31	48
Mean	12.90	0.00
Standard Deviation	27.457	32.068
Median	0.00	0.00
Q1, Q3	0.0, 33.3	-16.7, 33.3
Min, Max	-33.3, 100.0	-100.0, 50.0
Status [3]		
Improved	13 (41.9)	18 (37.5)
Stable	14 (45.2)	12 (25.0)
Worsened	4 (12.9)	18 (37.5)

[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
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.6_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 11 Day 1		
n [2]	27	34
Mean	88.27	89.22
Standard Deviation	17.792	17.351
Median	100.00	100.00
Q1, Q3	66.7, 100.0	66.7, 100.0
Min, Max	50.0, 100.0	33.3, 100.0
Change from Baseline to Cycle 11 Day 1		
n [2]	27	34
Mean	12.96	10.29
Standard Deviation	27.085	20.927
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	-33.3, 66.7	-33.3, 50.0
Status [3]		
Improved	10 (37.0)	14 (41.2)
Stable	14 (51.9)	15 (44.1)
Worsened	3 (11.1)	5 (14.7)

[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
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.6_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 13 Day 1		
n [2]	21	21
Mean	86.51	81.75
Standard Deviation	16.346	27.338
Median	100.00	100.00
Q1, Q3	66.7, 100.0	66.7, 100.0
Min, Max	50.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 13 Day 1		
n [2]	21	21
Mean	15.08	5.56
Standard Deviation	30.233	28.545
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 16.7
Min, Max	-33.3, 83.3	-66.7, 50.0
Status [3]		
Improved	9 (42.9)	9 (42.9)
Stable	8 (38.1)	8 (38.1)
Worsened	4 (19.0)	4 (19.0)

[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_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 16 Day 1		
n [2]	9	15
Mean	85.19	77.78
Standard Deviation	29.397	29.322
Median	100.00	83.33
Q1, Q3	100.0, 100.0	66.7, 100.0
Min, Max	33.3, 100.0	0.0, 100.0
Change from Baseline to Cycle 16 Day 1		
n [2]	9	15
Mean	11.11	1.11
Standard Deviation	44.876	30.516
Median	33.33	0.00
Q1, Q3	0.0, 33.3	-33.3, 16.7
Min, Max	-66.7, 66.7	-50.0, 50.0
Status [3]		
Improved	5 (55.6)	6 (40.0)
Stable	2 (22.2)	4 (26.7)
Worsened	2 (22.2)	5 (33.3)

[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/T14.2.6.1.6_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 19 Day 1		
n [2]	5	1
Mean	83.33	66.67
Standard Deviation	16.667	
Median	83.33	66.67
Q1, Q3	66.7, 100.0	66.7, 66.7
Min, Max	66.7, 100.0	66.7, 66.7
Change from Baseline to Cycle 19 Day 1		
n [2]	5	1
Mean	10.00	0.00
Standard Deviation	32.489	
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-16.7, 66.7	0.0, 0.0
Status [3]		
Improved	1 (20.0)	0 (0.0)
Stable	3 (60.0)	1 (100.0)
Worsened	1 (20.0)	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/T14.2.6.1.6_nsclc_eff.rtf

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

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 22 Day 1		
n [2]	2	0
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	0
Mean	41.67	
Standard Deviation	11.785	
Median	41.67	
Q1, Q3	33.3, 50.0	
Min, Max	33.3, 50.0	
Status [3]		
Improved	2 (100.0)	0 (0.0)
Stable	0 (0.0)	0 (0.0)
Worsened	0 (0.0)	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/T14.2.6.1.6_nsclc_eff.rtf

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

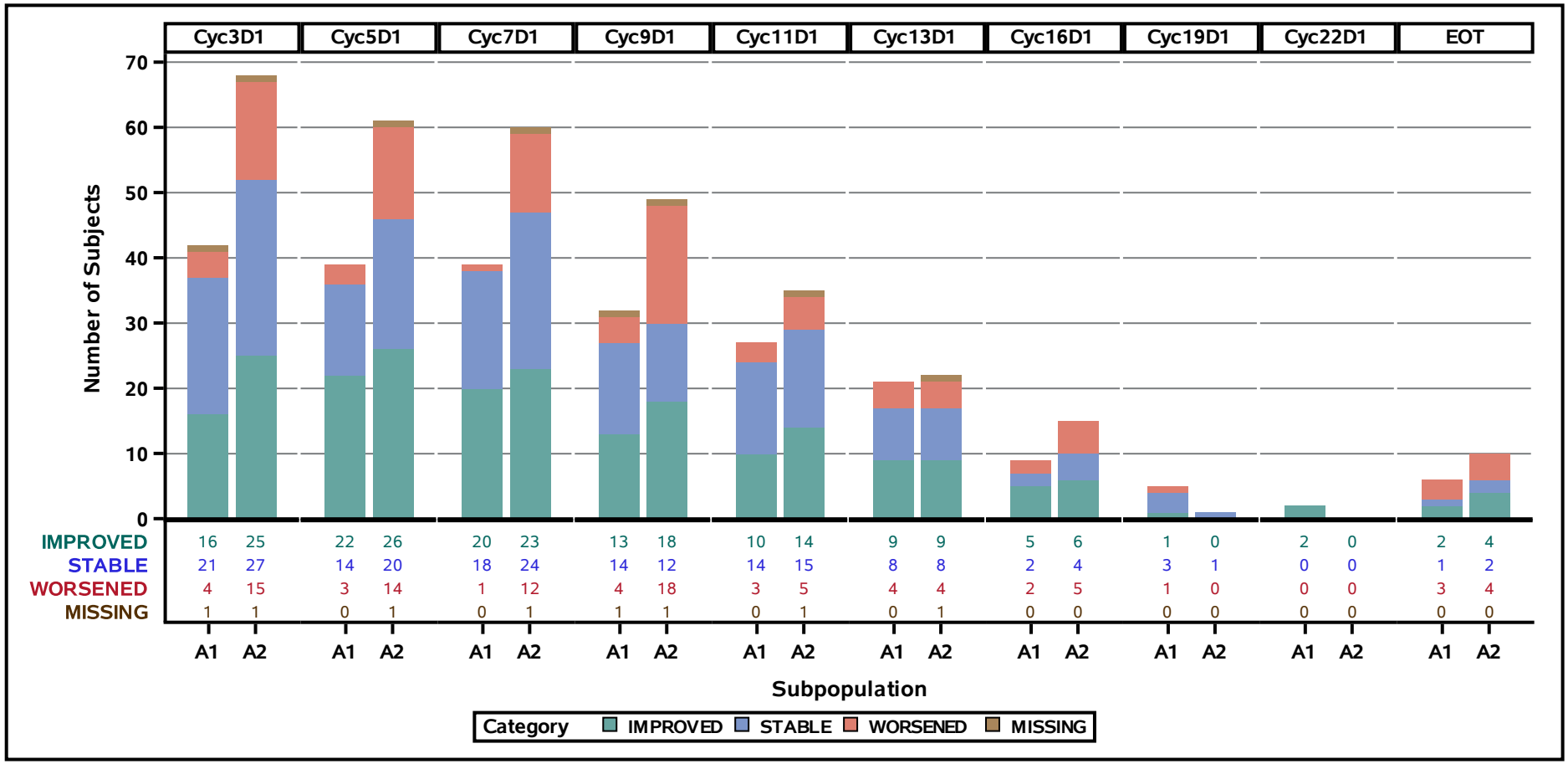
Visit Statistics	A1 (N= 51)	A2 (N= 76)
End of Treatment		
n [2]	6	10
Mean	72.22	65.00
Standard Deviation	25.092	31.866
Median	66.67	66.67
Q1, Q3	66.7, 100.0	50.0, 100.0
Min, Max	33.3, 100.0	0.0, 100.0
Change from Baseline to End of Treatment		
n [2]	6	10
Mean	-8.33	-5.00
Standard Deviation	40.483	29.450
Median	-8.33	0.00
Q1, Q3	-33.3, 16.7	-16.7, 16.7
Min, Max	-66.7, 50.0	-66.7, 33.3
Status [3]		
Improved	2 (33.3)	4 (40.0)
Stable	1 (16.7)	2 (20.0)
Worsened	3 (50.0)	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/T14.2.6.1.6_nsclc_eff.rtf

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

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



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F045_sf_10pt_nsclc_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

Loxo Oncology Inc. Page 1 of 2
Protocol Number: LOXO-RET-17001 03:41 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

T14.2.6.1.21
EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	51 70.59 (28.98)	41 11.99 (6.46, 17.51)	75 72.89 (26.11)	67 2.81 (-2.73, 8.35)
CYCLE 5 DAY 1		39 16.80 (11.14, 22.46)		60 6.40 (0.54, 12.25)
CYCLE 7 DAY 1		39 17.84 (12.18, 23.50)		59 2.73 (-3.18, 8.63)
CYCLE 9 DAY 1		31 14.84 (8.48, 21.19)		48 0.65 (-5.90, 7.20)
CYCLE 11 DAY 1		27 16.09 (9.28, 22.90)		34 13.55 (5.75, 21.34)

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/tfl/t_sp_qlqc30_mmrm.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/T14.2.6.1.21.rtf

T14.2.6.1.21
EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 13 DAY 1	21 15.40	21 6.99		
		(7.69, 23.11)		(-2.90, 16.89)
CYCLE 16 DAY 1	9 13.35	15 2.87		
		(1.56, 25.13)		(-8.84, 14.58)
CYCLE 19 DAY 1	5 11.70	1 -4.88		
		(-4.11, 27.51)		(-50.23, 40.47)
CYCLE 22 DAY 1	2 26.49	0 N.E		
		(1.44, 51.54)		(N.E, N.E)
END OF TREATMENT	6 -1.41	10 -7.67		
		(-15.86, 13.04)		(-22.01, 6.68)

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_mmrm.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/T14.2.6.1.21.rtf

T14.2.6.1.7_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Baseline [1]		
n [2]	51	76
Mean	10.13	8.99
Standard Deviation	22.131	15.016
Median	0.00	0.00
Q1, Q3	0.0, 16.7	0.0, 16.7
Min, Max	0.0, 100.0	0.0, 66.7

[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
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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/T14.2.6.1.7_nsclc_eff.rtf

T14.2.6.1.7_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 3 Day 1		
n [2]	42	68
Mean	4.37	4.17
Standard Deviation	16.487	10.531
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	0.0, 83.3	0.0, 50.0
Change from Baseline to Cycle 3 Day 1		
n [2]	42	68
Mean	-6.35	-5.64
Standard Deviation	23.557	16.941
Median	0.00	0.00
Q1, Q3	0.0, 0.0	-16.7, 0.0
Min, Max	-83.3, 83.3	-66.7, 33.3
Status [3]		
Improved	10 (23.8)	21 (30.9)
Stable	31 (73.8)	40 (58.8)
Worsened	1 (2.4)	7 (10.3)

[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
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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/T14.2.6.1.7_nsclc_eff.rtf

T14.2.6.1.7_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 5 Day 1		
n [2]	39	61
Mean	6.84	5.46
Standard Deviation	18.225	12.810
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	0.0, 66.7	0.0, 66.7
Change from Baseline to Cycle 5 Day 1		
n [2]	39	61
Mean	-4.70	-4.92
Standard Deviation	17.913	19.087
Median	0.00	0.00
Q1, Q3	0.0, 0.0	-16.7, 0.0
Min, Max	-50.0, 66.7	-66.7, 50.0
Status [3]		
Improved	9 (23.1)	18 (29.5)
Stable	29 (74.4)	36 (59.0)
Worsened	1 (2.6)	7 (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/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/T14.2.6.1.7_nsclc_eff.rtf

T14.2.6.1.7_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 7 Day 1		
n [2]	39	60
Mean	3.85	7.50
Standard Deviation	11.122	18.004
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	0.0, 50.0	0.0, 83.3
Change from Baseline to Cycle 7 Day 1		
n [2]	39	60
Mean	-8.55	-1.67
Standard Deviation	22.901	23.106
Median	0.00	0.00
Q1, Q3	-16.7, 0.0	-8.3, 0.0
Min, Max	-83.3, 33.3	-66.7, 83.3
Status [3]		
Improved	10 (25.6)	15 (25.0)
Stable	27 (69.2)	37 (61.7)
Worsened	2 (5.1)	8 (13.3)

[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
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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/T14.2.6.1.7_nsclc_eff.rtf

T14.2.6.1.7_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 9 Day 1		
n [2]	32	49
Mean	4.69	8.50
Standard Deviation	10.570	23.105
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	0.0, 33.3	0.0, 100.0
Change from Baseline to Cycle 9 Day 1		
n [2]	32	49
Mean	-6.77	-1.02
Standard Deviation	21.527	27.932
Median	0.00	0.00
Q1, Q3	0.0, 0.0	-16.7, 0.0
Min, Max	-66.7, 33.3	-66.7, 100.0
Status [3]		
Improved	7 (21.9)	14 (28.6)
Stable	22 (68.8)	30 (61.2)
Worsened	3 (9.4)	5 (10.2)

[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
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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/T14.2.6.1.7_nsclc_eff.rtf

T14.2.6.1.7_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 11 Day 1		
n [2]	27	35
Mean	9.26	5.24
Standard Deviation	21.350	12.636
Median	0.00	0.00
Q1, Q3	0.0, 16.7	0.0, 0.0
Min, Max	0.0, 100.0	0.0, 50.0
Change from Baseline to Cycle 11 Day 1		
n [2]	27	35
Mean	-0.62	-3.33
Standard Deviation	27.144	15.551
Median	0.00	0.00
Q1, Q3	0.0, 0.0	-16.7, 0.0
Min, Max	-83.3, 100.0	-50.0, 33.3
Status [3]		
Improved	5 (18.5)	9 (25.7)
Stable	20 (74.1)	21 (60.0)
Worsened	2 (7.4)	5 (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
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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/T14.2.6.1.7_nsclc_eff.rtf

T14.2.6.1.7_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 13 Day 1		
n [2]	21	22
Mean	7.14	7.58
Standard Deviation	14.502	14.298
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 16.7
Min, Max	0.0, 50.0	0.0, 50.0
Change from Baseline to Cycle 13 Day 1		
n [2]	21	22
Mean	-5.56	-0.76
Standard Deviation	25.459	14.976
Median	0.00	0.00
Q1, Q3	-16.7, 0.0	0.0, 0.0
Min, Max	-83.3, 50.0	-33.3, 33.3
Status [3]		
Improved	7 (33.3)	4 (18.2)
Stable	10 (47.6)	14 (63.6)
Worsened	4 (19.0)	4 (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/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/T14.2.6.1.7_nsclc_eff.rtf

T14.2.6.1.7_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 16 Day 1		
n [2]	9	15
Mean	9.26	6.67
Standard Deviation	12.108	12.280
Median	0.00	0.00
Q1, Q3	0.0, 16.7	0.0, 16.7
Min, Max	0.0, 33.3	0.0, 33.3
Change from Baseline to Cycle 16 Day 1		
n [2]	9	15
Mean	5.56	-2.22
Standard Deviation	14.434	15.258
Median	0.00	0.00
Q1, Q3	0.0, 16.7	0.0, 0.0
Min, Max	-16.7, 33.3	-33.3, 16.7
Status [3]		
Improved	1 (11.1)	3 (20.0)
Stable	5 (55.6)	9 (60.0)
Worsened	3 (33.3)	3 (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/T14.2.6.1.7_nsclc_eff.rtf

T14.2.6.1.7_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 19 Day 1		
n [2]	5	1
Mean	6.67	16.67
Standard Deviation	14.907	
Median	0.00	16.67
Q1, Q3	0.0, 0.0	16.7, 16.7
Min, Max	0.0, 33.3	16.7, 16.7
Change from Baseline to Cycle 19 Day 1		
n [2]	5	1
Mean	6.67	16.67
Standard Deviation	14.907	
Median	0.00	16.67
Q1, Q3	0.0, 0.0	16.7, 16.7
Min, Max	0.0, 33.3	16.7, 16.7
Status [3]		
Improved	0 (0.0)	0 (0.0)
Stable	4 (80.0)	0 (0.0)
Worsened	1 (20.0)	1 (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/T14.2.6.1.7_nsclc_eff.rtf

T14.2.6.1.7_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 22 Day 1		
n [2]	2	0
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	0
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)	0 (0.0)
Stable	2 (100.0)	0 (0.0)
Worsened	0 (0.0)	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_nsclc_eff.rtf

T14.2.6.1.7_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits
Efficacy Analysis Set
by Subpopulation

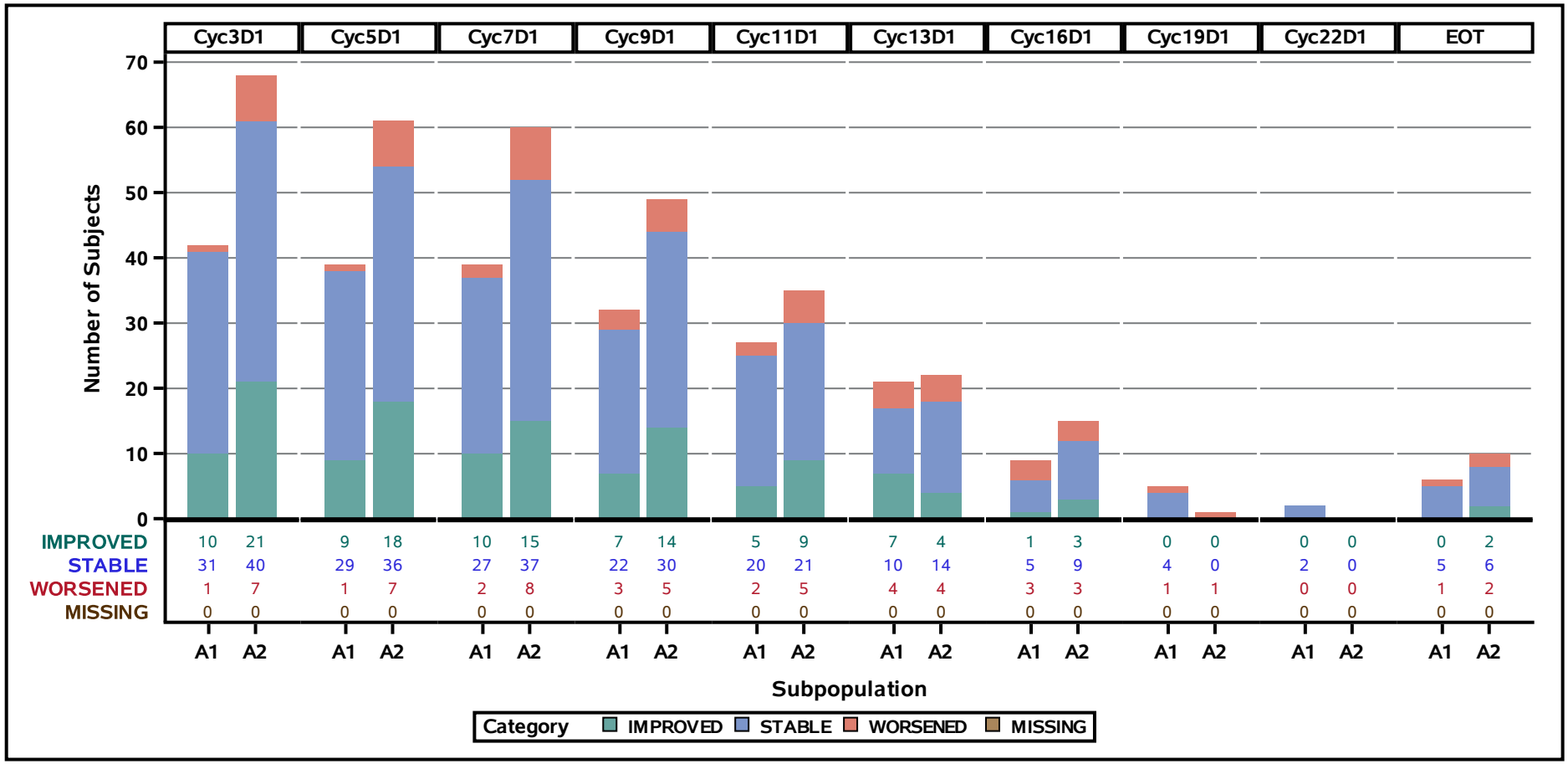
Visit Statistics	A1 (N= 51)	A2 (N= 76)
End of Treatment		
n [2]	6	10
Mean	8.33	6.67
Standard Deviation	13.944	11.653
Median	0.00	0.00
Q1, Q3	0.0, 16.7	0.0, 16.7
Min, Max	0.0, 33.3	0.0, 33.3
Change from Baseline to End of Treatment		
n [2]	6	10
Mean	5.56	0.00
Standard Deviation	13.608	17.568
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	0.0, 33.3	-33.3, 33.3
Status [3]		
Improved	0 (0.0)	2 (20.0)
Stable	5 (83.3)	6 (60.0)
Worsened	1 (16.7)	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/T14.2.6.1.7_nsclc_eff.rtf

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

Changes from baseline in QLQ-C30 scores by Nausea and vomiting (Efficacy Analysis Set) by Subpopulation



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F046_nv_10pt_nsclc_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

Loxo Oncology Inc. Page 1 of 2
Protocol Number: LOXO-RET-17001 03:41 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

T14.2.6.1.22
EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	51 10.13 (22.13)	42 -6.20 (-10.62, -1.77)	76 8.99 (15.02)	68 -5.23 (-8.92, -1.53)
CYCLE 5 DAY 1		39 -3.93 (-8.52, 0.67)		61 -3.99 (-7.89, -0.09)
CYCLE 7 DAY 1		39 -7.13 (-11.73, -2.53)		60 -1.83 (-5.76, 2.11)
CYCLE 9 DAY 1		32 -6.06 (-11.13, -0.99)		49 -0.86 (-5.21, 3.49)
CYCLE 11 DAY 1		27 -1.09 (-6.62, 4.43)		35 -4.03 (-9.18, 1.12)

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/tfl/t_sp_qlqc30_mmrm.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/T14.2.6.1.22.rtf

T14.2.6.1.22
EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 13 DAY 1	21 -3.91 (-10.17, 2.35)		22 -1.67 (-8.16, 4.83)	
CYCLE 16 DAY 1	9 0.43 (-9.15, 10.01)		15 -2.63 (-10.50, 5.23)	
CYCLE 19 DAY 1	5 -1.25 (-14.11, 11.62)		1 8.28 (-22.20, 38.76)	
CYCLE 22 DAY 1	2 -7.91 (-28.22, 12.39)		0 N.E (N.E, N.E)	
END OF TREATMENT	6 -0.27 (-12.00, 11.46)		10 -2.41 (-12.04, 7.23)	

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_mmrm.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/T14.2.6.1.22.rtf

Loxo Oncology Inc. Page 1 of 11
Protocol Number: LOXO-RET-17001 15:25 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

T14.2.6.1.8_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Baseline [1]		
n [2]	51	76
Mean	36.17	37.43
Standard Deviation	29.635	23.923
Median	33.33	33.33
Q1, Q3	22.2, 55.6	22.2, 55.6
Min, Max	0.0, 100.0	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_nsclc_eff.rtf

T14.2.6.1.8_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 3 Day 1		
n [2]	42	68
Mean	29.76	30.23
Standard Deviation	25.791	21.103
Median	22.22	33.33
Q1, Q3	11.1, 44.4	11.1, 44.4
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 3 Day 1		
n [2]	42	68
Mean	-7.80	-8.17
Standard Deviation	23.826	25.222
Median	0.00	0.00
Q1, Q3	-22.2, 11.1	-16.7, 5.6
Min, Max	-77.8, 44.4	-100.0, 44.4
Status [3]		
Improved	18 (42.9)	30 (44.1)
Stable	13 (31.0)	21 (30.9)
Worsened	11 (26.2)	17 (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/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_nsclc_eff.rtf

T14.2.6.1.8_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 5 Day 1		
n [2]	39	61
Mean	27.92	29.87
Standard Deviation	20.845	19.725
Median	22.22	33.33
Q1, Q3	11.1, 33.3	22.2, 33.3
Min, Max	0.0, 88.9	0.0, 88.9
Change from Baseline to Cycle 5 Day 1		
n [2]	39	61
Mean	-10.26	-8.01
Standard Deviation	25.155	22.510
Median	0.00	0.00
Q1, Q3	-22.2, 0.0	-22.2, 0.0
Min, Max	-77.8, 33.3	-88.9, 33.3
Status [3]		
Improved	18 (46.2)	28 (45.9)
Stable	13 (33.3)	19 (31.1)
Worsened	8 (20.5)	14 (23.0)

[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_nsclc_eff.rtf

T14.2.6.1.8_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 7 Day 1		
n [2]	39	60
Mean	23.65	29.63
Standard Deviation	16.158	23.024
Median	22.22	33.33
Q1, Q3	11.1, 33.3	11.1, 33.3
Min, Max	0.0, 88.9	0.0, 100.0
Change from Baseline to Cycle 7 Day 1		
n [2]	39	60
Mean	-13.11	-8.15
Standard Deviation	26.228	23.492
Median	0.00	0.00
Q1, Q3	-22.2, 0.0	-22.2, 0.0
Min, Max	-77.8, 33.3	-88.9, 44.4
Status [3]		
Improved	18 (46.2)	29 (48.3)
Stable	14 (35.9)	20 (33.3)
Worsened	7 (17.9)	11 (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/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_nsclc_eff.rtf

T14.2.6.1.8_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 9 Day 1		
n [2]	32	49
Mean	28.99	32.43
Standard Deviation	22.610	21.256
Median	22.22	33.33
Q1, Q3	11.1, 33.3	22.2, 44.4
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 9 Day 1		
n [2]	32	49
Mean	-5.38	-6.35
Standard Deviation	25.614	24.741
Median	0.00	0.00
Q1, Q3	-13.9, 11.1	-22.2, 0.0
Min, Max	-77.8, 44.4	-88.9, 66.7
Status [3]		
Improved	12 (37.5)	23 (46.9)
Stable	7 (21.9)	15 (30.6)
Worsened	13 (40.6)	11 (22.4)

[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/T14.2.6.1.8_nsclc_eff.rtf

T14.2.6.1.8_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 11 Day 1		
n [2]	27	35
Mean	23.46	29.84
Standard Deviation	19.327	19.202
Median	22.22	33.33
Q1, Q3	11.1, 33.3	22.2, 33.3
Min, Max	0.0, 66.7	0.0, 77.8
Change from Baseline to Cycle 11 Day 1		
n [2]	27	35
Mean	-7.00	-8.89
Standard Deviation	24.873	24.224
Median	0.00	0.00
Q1, Q3	-22.2, 11.1	-11.1, 0.0
Min, Max	-77.8, 22.2	-100.0, 33.3
Status [3]		
Improved	10 (37.0)	16 (45.7)
Stable	8 (29.6)	13 (37.1)
Worsened	9 (33.3)	6 (17.1)

[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_nsclc_eff.rtf

T14.2.6.1.8_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 13 Day 1		
n [2]	21	22
Mean	30.16	30.81
Standard Deviation	24.881	28.675
Median	22.22	27.78
Q1, Q3	22.2, 33.3	11.1, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 13 Day 1		
n [2]	21	22
Mean	-4.23	-10.61
Standard Deviation	29.706	27.746
Median	0.00	0.00
Q1, Q3	-11.1, 11.1	-22.2, 0.0
Min, Max	-66.7, 55.6	-100.0, 33.3
Status [3]		
Improved	8 (38.1)	8 (36.4)
Stable	7 (33.3)	11 (50.0)
Worsened	6 (28.6)	3 (13.6)

[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/T14.2.6.1.8_nsclc_eff.rtf

T14.2.6.1.8_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 16 Day 1		
n [2]	9	15
Mean	25.93	32.59
Standard Deviation	26.058	25.706
Median	22.22	33.33
Q1, Q3	11.1, 33.3	22.2, 33.3
Min, Max	0.0, 77.8	0.0, 88.9
Change from Baseline to Cycle 16 Day 1		
n [2]	9	15
Mean	2.47	-8.89
Standard Deviation	24.074	33.121
Median	0.00	0.00
Q1, Q3	0.0, 0.0	-11.1, 11.1
Min, Max	-33.3, 44.4	-100.0, 33.3
Status [3]		
Improved	2 (22.2)	6 (40.0)
Stable	5 (55.6)	4 (26.7)
Worsened	2 (22.2)	5 (33.3)

[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/T14.2.6.1.8_nsclc_eff.rtf

T14.2.6.1.8_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 19 Day 1		
n [2]	5	1
Mean	28.89	33.33
Standard Deviation	21.660	
Median	22.22	33.33
Q1, Q3	22.2, 44.4	33.3, 33.3
Min, Max	0.0, 55.6	33.3, 33.3
Change from Baseline to Cycle 19 Day 1		
n [2]	5	1
Mean	8.89	0.00
Standard Deviation	18.257	
Median	0.00	0.00
Q1, Q3	0.0, 22.2	0.0, 0.0
Min, Max	-11.1, 33.3	0.0, 0.0
Status [3]		
Improved	1 (20.0)	0 (0.0)
Stable	2 (40.0)	1 (100.0)
Worsened	2 (40.0)	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/T14.2.6.1.8_nsclc_eff.rtf

T14.2.6.1.8_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 22 Day 1		
n [2]	2	0
Mean	33.33	
Standard Deviation	15.713	
Median	33.33	
Q1, Q3	22.2, 44.4	
Min, Max	22.2, 44.4	
Change from Baseline to Cycle 22 Day 1		
n [2]	2	0
Mean	5.56	
Standard Deviation	23.570	
Median	5.56	
Q1, Q3	-11.1, 22.2	
Min, Max	-11.1, 22.2	
Status [3]		
Improved	1 (50.0)	0 (0.0)
Stable	0 (0.0)	0 (0.0)
Worsened	1 (50.0)	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/T14.2.6.1.8_nsclc_eff.rtf

T14.2.6.1.8_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits
Efficacy Analysis Set
by Subpopulation

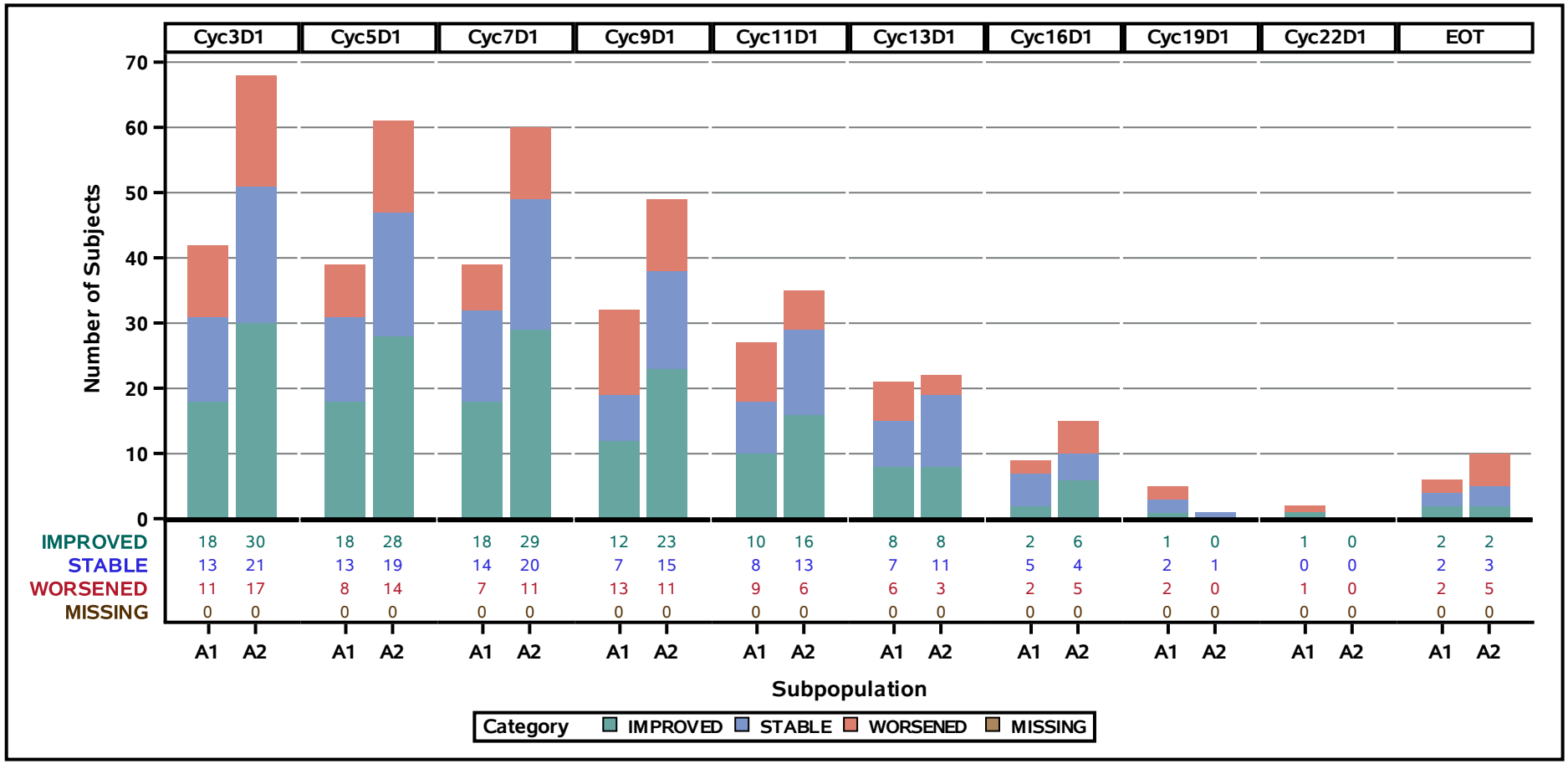
Visit Statistics	A1 (N= 51)	A2 (N= 76)
End of Treatment		
n [2]	6	10
Mean	31.48	37.78
Standard Deviation	25.740	24.679
Median	27.78	33.33
Q1, Q3	22.2, 33.3	22.2, 55.6
Min, Max	0.0, 77.8	0.0, 88.9
Change from Baseline to End of Treatment		
n [2]	6	10
Mean	3.70	3.33
Standard Deviation	20.688	16.605
Median	0.00	5.56
Q1, Q3	-11.1, 22.2	0.0, 11.1
Min, Max	-22.2, 33.3	-33.3, 22.2
Status [3]		
Improved	2 (33.3)	2 (20.0)
Stable	2 (33.3)	3 (30.0)
Worsened	2 (33.3)	5 (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/T14.2.6.1.8_nsclc_eff.rtf

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

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



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F047_fa_10pt_nsclc_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

T14.2.6.1.23
EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	51 36.17 (29.64)	42 -6.04 (-11.67, -0.41)	76 37.43 (23.92)	68 -8.23 (-12.91, -3.54)
CYCLE 5 DAY 1		39 -8.13 (-13.98, -2.29)		61 -8.38 (-13.33, -3.43)
CYCLE 7 DAY 1		39 -11.82 (-17.66, -5.98)		60 -8.58 (-13.57, -3.58)
CYCLE 9 DAY 1		32 -5.51 (-11.95, 0.94)		49 -6.18 (-11.70, -0.65)
CYCLE 11 DAY 1		27 -9.44 (-16.47, -2.42)		35 -8.75 (-15.28, -2.21)

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_mmrm.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/T14.2.6.1.23.rtf

T14.2.6.1.23
EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 13 DAY 1	21 -4.35	(-12.30, 3.61)	22 -8.85	(-17.10, -0.61)
CYCLE 16 DAY 1	9 -4.12	(-16.30, 8.07)	15 -7.10	(-17.08, 2.89)
CYCLE 19 DAY 1	5 0.26	(-16.09, 16.61)	1 -3.09	(-41.76, 35.58)
CYCLE 22 DAY 1	2 1.53	(-24.26, 27.31)	0 N.E	(N.E, N.E)
END OF TREATMENT	6 -0.32	(-15.22, 14.57)	10 0.91	(-11.32, 13.14)

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_mmrm.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/T14.2.6.1.23.rtf

T14.2.6.1.9_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Baseline [1]		
n [2]	51	76
Mean	27.78	27.19
Standard Deviation	31.564	26.783
Median	16.67	16.67
Q1, Q3	0.0, 50.0	0.0, 50.0
Min, Max	0.0, 100.0	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
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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/T14.2.6.1.9_nsclc_eff.rtf

T14.2.6.1.9_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 3 Day 1		
n [2]	42	68
Mean	19.05	21.08
Standard Deviation	24.575	28.158
Median	16.67	16.67
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 3 Day 1		
n [2]	42	68
Mean	-10.32	-7.11
Standard Deviation	28.263	31.056
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-16.7, 0.0
Min, Max	-66.7, 33.3	-83.3, 100.0
Status [3]		
Improved	17 (40.5)	29 (42.6)
Stable	16 (38.1)	27 (39.7)
Worsened	9 (21.4)	12 (17.6)

[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
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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/T14.2.6.1.9_nsclc_eff.rtf

T14.2.6.1.9_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 5 Day 1		
n [2]	39	61
Mean	14.53	19.40
Standard Deviation	21.690	23.210
Median	0.00	16.67
Q1, Q3	0.0, 16.7	0.0, 33.3
Min, Max	0.0, 83.3	0.0, 100.0
Change from Baseline to Cycle 5 Day 1		
n [2]	39	61
Mean	-13.68	-9.02
Standard Deviation	21.245	24.828
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-16.7, 0.0
Min, Max	-66.7, 16.7	-83.3, 66.7
Status [3]		
Improved	18 (46.2)	26 (42.6)
Stable	18 (46.2)	25 (41.0)
Worsened	3 (7.7)	10 (16.4)

[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/T14.2.6.1.9_nsclc_eff.rtf

T14.2.6.1.9_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 7 Day 1		
n [2]	39	60
Mean	12.82	17.22
Standard Deviation	16.429	26.391
Median	0.00	0.00
Q1, Q3	0.0, 16.7	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 7 Day 1		
n [2]	39	60
Mean	-14.96	-9.44
Standard Deviation	26.434	26.640
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-16.7, 0.0
Min, Max	-66.7, 50.0	-83.3, 33.3
Status [3]		
Improved	17 (43.6)	27 (45.0)
Stable	19 (48.7)	22 (36.7)
Worsened	3 (7.7)	11 (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/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_nsclc_eff.rtf

T14.2.6.1.9_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 9 Day 1		
n [2]	32	49
Mean	16.67	17.69
Standard Deviation	21.586	24.863
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 9 Day 1		
n [2]	32	49
Mean	-8.33	-5.78
Standard Deviation	28.081	26.254
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-16.7, 0.0
Min, Max	-66.7, 50.0	-83.3, 50.0
Status [3]		
Improved	11 (34.4)	17 (34.7)
Stable	16 (50.0)	23 (46.9)
Worsened	5 (15.6)	9 (18.4)

[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
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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/T14.2.6.1.9_nsclc_eff.rtf

T14.2.6.1.9_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 11 Day 1		
n [2]	27	35
Mean	21.60	18.10
Standard Deviation	26.073	27.526
Median	16.67	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 11 Day 1		
n [2]	27	35
Mean	-1.23	-5.24
Standard Deviation	36.376	23.836
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-16.7, 0.0
Min, Max	-50.0, 100.0	-66.7, 50.0
Status [3]		
Improved	8 (29.6)	12 (34.3)
Stable	13 (48.1)	17 (48.6)
Worsened	6 (22.2)	6 (17.1)

[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
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_nsclc_eff.rtf

T14.2.6.1.9_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 13 Day 1		
n [2]	21	22
Mean	23.81	25.00
Standard Deviation	22.713	28.982
Median	16.67	16.67
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 83.3	0.0, 100.0
Change from Baseline to Cycle 13 Day 1		
n [2]	21	22
Mean	-3.97	0.76
Standard Deviation	30.689	22.700
Median	0.00	0.00
Q1, Q3	-33.3, 16.7	0.0, 16.7
Min, Max	-66.7, 66.7	-66.7, 33.3
Status [3]		
Improved	8 (38.1)	5 (22.7)
Stable	5 (23.8)	10 (45.5)
Worsened	8 (38.1)	7 (31.8)

[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/T14.2.6.1.9_nsclc_eff.rtf

T14.2.6.1.9_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 16 Day 1		
n [2]	9	15
Mean	24.07	26.67
Standard Deviation	27.778	33.214
Median	16.67	16.67
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 83.3	0.0, 100.0
Change from Baseline to Cycle 16 Day 1		
n [2]	9	15
Mean	3.70	1.11
Standard Deviation	42.310	27.070
Median	0.00	0.00
Q1, Q3	-16.7, 33.3	0.0, 16.7
Min, Max	-50.0, 83.3	-66.7, 50.0
Status [3]		
Improved	3 (33.3)	3 (20.0)
Stable	3 (33.3)	7 (46.7)
Worsened	3 (33.3)	5 (33.3)

[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/T14.2.6.1.9_nsclc_eff.rtf

T14.2.6.1.9_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 19 Day 1		
n [2]	5	1
Mean	26.67	33.33
Standard Deviation	43.461	
Median	0.00	33.33
Q1, Q3	0.0, 33.3	33.3, 33.3
Min, Max	0.0, 100.0	33.3, 33.3
Change from Baseline to Cycle 19 Day 1		
n [2]	5	1
Mean	0.00	33.33
Standard Deviation	51.370	
Median	0.00	33.33
Q1, Q3	-33.3, 0.0	33.3, 33.3
Min, Max	-50.0, 83.3	33.3, 33.3
Status [3]		
Improved	2 (40.0)	0 (0.0)
Stable	2 (40.0)	0 (0.0)
Worsened	1 (20.0)	1 (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_nsclc_eff.rtf

T14.2.6.1.9_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 22 Day 1		
n [2]	2	0
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	0
Mean	-25.00	
Standard Deviation	35.355	
Median	-25.00	
Q1, Q3	-50.0, 0.0	
Min, Max	-50.0, 0.0	
Status [3]		
Improved	1 (50.0)	0 (0.0)
Stable	1 (50.0)	0 (0.0)
Worsened	0 (0.0)	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/T14.2.6.1.9_nsclc_eff.rtf

T14.2.6.1.9_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Pain by Visits
Efficacy Analysis Set
by Subpopulation

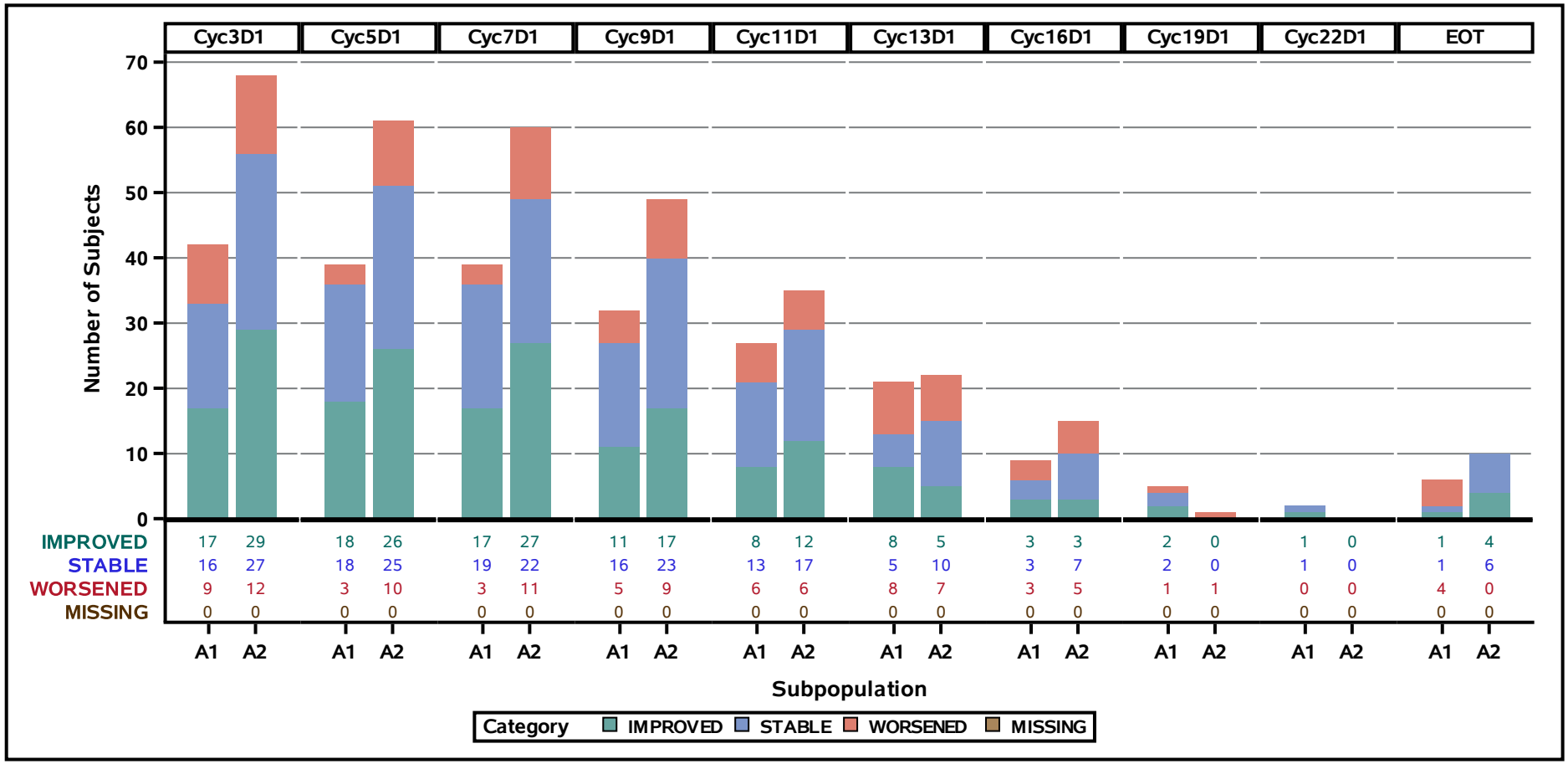
Visit Statistics	A1 (N= 51)	A2 (N= 76)
End of Treatment		
n [2]	6	10
Mean	33.33	16.67
Standard Deviation	23.570	15.713
Median	33.33	16.67
Q1, Q3	16.7, 50.0	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 33.3
Change from Baseline to End of Treatment		
n [2]	6	10
Mean	11.11	-15.00
Standard Deviation	25.092	19.954
Median	16.67	0.00
Q1, Q3	0.0, 33.3	-33.3, 0.0
Min, Max	-33.3, 33.3	-50.0, 0.0
Status [3]		
Improved	1 (16.7)	4 (40.0)
Stable	1 (16.7)	6 (60.0)
Worsened	4 (66.7)	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/T14.2.6.1.9_nsclc_eff.rtf

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

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



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F048_pa_10pt_nsclc_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

T14.2.6.1.24
EORTC QLQ-C30 (v3.0): Summary of Pain by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	51 27.78 (31.56)	42 -8.48 (-14.80, -2.17)	76 27.19 (26.78)	68 -6.16 (-11.63, -0.69)
CYCLE 5 DAY 1		39 -12.63 (-19.17, -6.08)		61 -7.96 (-13.73, -2.18)
CYCLE 7 DAY 1		39 -14.20 (-20.75, -7.65)		60 -9.27 (-15.09, -3.45)
CYCLE 9 DAY 1		32 -9.45 (-16.68, -2.22)		49 -7.23 (-13.68, -0.78)
CYCLE 11 DAY 1		27 -3.81 (-11.69, 4.07)		35 -6.76 (-14.38, 0.87)

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_mmrm.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/T14.2.6.1.24.rtf

T14.2.6.1.24
EORTC QLQ-C30 (v3.0): Summary of Pain by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 13 DAY 1	21	21	22	22
	-3.21	-3.21	-0.30	-0.30
	(-12.13, 5.72)	(-12.13, 5.72)	(-9.91, 9.32)	(-9.91, 9.32)
CYCLE 16 DAY 1	9	9	15	15
	-0.54	-0.54	0.72	0.72
	(-14.19, 13.10)	(-14.19, 13.10)	(-10.92, 12.36)	(-10.92, 12.36)
CYCLE 19 DAY 1	5	5	1	1
	0.01	0.01	19.98	19.98
	(-18.28, 18.30)	(-18.28, 18.30)	(-25.18, 65.13)	(-25.18, 65.13)
CYCLE 22 DAY 1	2	2	0	0
	-26.12	-26.12	N.E	N.E
	(-55.03, 2.80)	(-55.03, 2.80)	(N.E, N.E)	(N.E, N.E)
END OF TREATMENT	6	6	10	10
	8.12	8.12	-12.29	-12.29
	(-8.58, 24.82)	(-8.58, 24.82)	(-26.56, 1.98)	(-26.56, 1.98)

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_mmrm.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/T14.2.6.1.24.rtf

T14.2.6.1.10_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Baseline [1]		
n [2]	51	75
Mean	26.80	33.33
Standard Deviation	29.074	28.997
Median	33.33	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	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_nsclc_eff.rtf

T14.2.6.1.10_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 3 Day 1		
n [2]	41	68
Mean	20.33	19.61
Standard Deviation	23.426	22.479
Median	33.33	16.67
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 3 Day 1		
n [2]	41	68
Mean	-6.50	-14.22
Standard Deviation	23.828	27.206
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-33.3, 0.0
Min, Max	-66.7, 33.3	-100.0, 33.3
Status [3]		
Improved	11 (26.8)	26 (38.2)
Stable	25 (61.0)	37 (54.4)
Worsened	5 (12.2)	5 (7.4)

[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/T14.2.6.1.10_nsclc_eff.rtf

T14.2.6.1.10_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 5 Day 1		
n [2]	39	60
Mean	17.95	18.33
Standard Deviation	22.745	20.744
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 66.7
Change from Baseline to Cycle 5 Day 1		
n [2]	39	60
Mean	-10.26	-16.67
Standard Deviation	26.660	25.674
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-33.3, 0.0
Min, Max	-100.0, 33.3	-100.0, 33.3
Status [3]		
Improved	13 (33.3)	27 (45.0)
Stable	22 (56.4)	30 (50.0)
Worsened	4 (10.3)	3 (5.0)

[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_nsclc_eff.rtf

T14.2.6.1.10_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 7 Day 1		
n [2]	39	60
Mean	18.80	20.00
Standard Deviation	22.679	22.297
Median	0.00	16.67
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 66.7
Change from Baseline to Cycle 7 Day 1		
n [2]	39	60
Mean	-9.40	-15.00
Standard Deviation	30.540	28.407
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-33.3, 0.0
Min, Max	-66.7, 66.7	-100.0, 66.7
Status [3]		
Improved	10 (25.6)	25 (41.7)
Stable	25 (64.1)	31 (51.7)
Worsened	4 (10.3)	4 (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/T14.2.6.1.10_nsclc_eff.rtf

T14.2.6.1.10_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 9 Day 1		
n [2]	32	49
Mean	14.58	17.01
Standard Deviation	18.813	21.648
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 66.7
Change from Baseline to Cycle 9 Day 1		
n [2]	32	49
Mean	-10.42	-18.37
Standard Deviation	23.090	28.105
Median	0.00	0.00
Q1, Q3	-16.7, 0.0	-33.3, 0.0
Min, Max	-66.7, 33.3	-100.0, 33.3
Status [3]		
Improved	8 (25.0)	21 (42.9)
Stable	23 (71.9)	26 (53.1)
Worsened	1 (3.1)	2 (4.1)

[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/T14.2.6.1.10_nsclc_eff.rtf

T14.2.6.1.10_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 11 Day 1		
n [2]	27	35
Mean	16.05	20.95
Standard Deviation	19.327	24.369
Median	0.00	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 11 Day 1		
n [2]	27	35
Mean	-7.41	-18.10
Standard Deviation	32.467	26.000
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-33.3, 0.0
Min, Max	-100.0, 33.3	-100.0, 33.3
Status [3]		
Improved	7 (25.9)	16 (45.7)
Stable	15 (55.6)	18 (51.4)
Worsened	5 (18.5)	1 (2.9)

[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/T14.2.6.1.10_nsclc_eff.rtf

T14.2.6.1.10_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 13 Day 1		
n [2]	21	22
Mean	14.29	21.21
Standard Deviation	24.881	19.370
Median	0.00	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 66.7
Change from Baseline to Cycle 13 Day 1		
n [2]	21	22
Mean	-14.29	-18.18
Standard Deviation	29.005	32.083
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-33.3, 0.0
Min, Max	-66.7, 33.3	-100.0, 33.3
Status [3]		
Improved	8 (38.1)	10 (45.5)
Stable	11 (52.4)	10 (45.5)
Worsened	2 (9.5)	2 (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
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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/T14.2.6.1.10_nsclc_eff.rtf

T14.2.6.1.10_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 16 Day 1		
n [2]	9	15
Mean	14.81	20.00
Standard Deviation	17.568	21.082
Median	0.00	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 33.3	0.0, 66.7
Change from Baseline to Cycle 16 Day 1		
n [2]	9	15
Mean	-11.11	-15.56
Standard Deviation	28.868	27.794
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-33.3, 0.0
Min, Max	-66.7, 33.3	-66.7, 33.3
Status [3]		
Improved	3 (33.3)	6 (40.0)
Stable	5 (55.6)	8 (53.3)
Worsened	1 (11.1)	1 (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/T14.2.6.1.10_nsclc_eff.rtf

T14.2.6.1.10_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 19 Day 1		
n [2]	5	1
Mean	13.33	33.33
Standard Deviation	29.814	
Median	0.00	33.33
Q1, Q3	0.0, 0.0	33.3, 33.3
Min, Max	0.0, 66.7	33.3, 33.3
Change from Baseline to Cycle 19 Day 1		
n [2]	5	1
Mean	-20.00	-33.33
Standard Deviation	29.814	
Median	0.00	-33.33
Q1, Q3	-33.3, 0.0	-33.3, -33.3
Min, Max	-66.7, 0.0	-33.3, -33.3
Status [3]		
Improved	2 (40.0)	1 (100.0)
Stable	3 (60.0)	0 (0.0)
Worsened	0 (0.0)	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_nsclc_eff.rtf

T14.2.6.1.10_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 22 Day 1		
n [2]	2	0
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	0
Mean	-66.67	
Standard Deviation	0.000	
Median	-66.67	
Q1, Q3	-66.7, -66.7	
Min, Max	-66.7, -66.7	
Status [3]		
Improved	2 (100.0)	0 (0.0)
Stable	0 (0.0)	0 (0.0)
Worsened	0 (0.0)	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_nsclc_eff.rtf

T14.2.6.1.10_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits
Efficacy Analysis Set
by Subpopulation

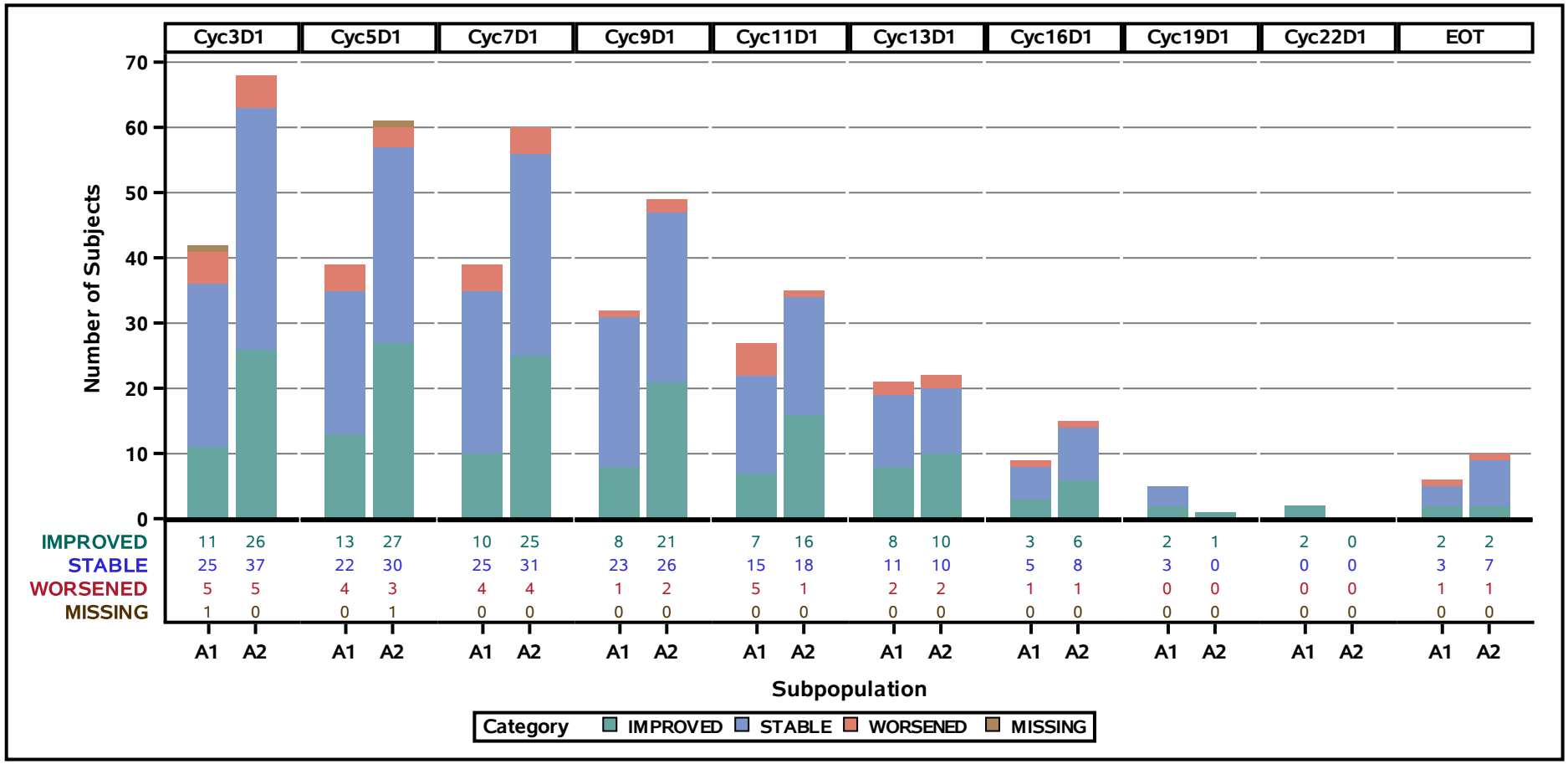
Visit Statistics	A1 (N= 51)	A2 (N= 76)
End of Treatment		
n [2]	6	10
Mean	11.11	26.67
Standard Deviation	17.213	30.631
Median	0.00	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 33.3	0.0, 100.0
Change from Baseline to End of Treatment		
n [2]	6	10
Mean	-5.56	-3.33
Standard Deviation	25.092	18.922
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	0.0, 0.0
Min, Max	-33.3, 33.3	-33.3, 33.3
Status [3]		
Improved	2 (33.3)	2 (20.0)
Stable	3 (50.0)	7 (70.0)
Worsened	1 (16.7)	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/T14.2.6.1.10_nsclc_eff.rtf

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

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



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F049_dy_10pt_nsclc_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

T14.2.6.1.25
EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	51 26.80 (29.07)	41 -6.62 (-12.63, -0.60)	75 33.33 (29.00)	68 -15.31 (-20.02, -10.61)
CYCLE 5 DAY 1		39 -9.46 (-15.64, -3.29)		60 -17.00 (-22.01, -11.99)
CYCLE 7 DAY 1		39 -8.61 (-14.78, -2.44)		60 -15.34 (-20.35, -10.33)
CYCLE 9 DAY 1		32 -11.73 (-18.54, -4.91)		49 -18.46 (-24.01, -12.92)
CYCLE 11 DAY 1		27 -9.73 (-17.15, -2.31)		35 -15.81 (-22.38, -9.25)

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_mmrm.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/T14.2.6.1.25.rtf

T14.2.6.1.25
EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 13 DAY 1	21	21	22	22
	-13.25	-13.25	-15.68	-15.68
	(-21.66, -4.84)	(-21.66, -4.84)	(-23.96, -7.40)	(-23.96, -7.40)
CYCLE 16 DAY 1	9	9	15	15
	-11.81	-11.81	-15.53	-15.53
	(-24.66, 1.03)	(-24.66, 1.03)	(-25.55, -5.51)	(-25.55, -5.51)
CYCLE 19 DAY 1	5	5	1	1
	-15.84	-15.84	-13.19	-13.19
	(-33.08, 1.40)	(-33.08, 1.40)	(-52.07, 25.69)	(-52.07, 25.69)
CYCLE 22 DAY 1	2	2	0	0
	-40.64	-40.64	N.E	N.E
	(-68.11, -13.16)	(-68.11, -13.16)	(N.E, N.E)	(N.E, N.E)
END OF TREATMENT	6	6	10	10
	-12.34	-12.34	-6.90	-6.90
	(-28.09, 3.42)	(-28.09, 3.42)	(-19.18, 5.38)	(-19.18, 5.38)

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/tfl/t_sp_qlqc30_mmrm.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/T14.2.6.1.25.rtf

T14.2.6.1.11_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Baseline [1]		
n [2]	51	75
Mean	27.45	26.22
Standard Deviation	31.767	31.141
Median	33.33	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	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_nsclc_eff.rtf

T14.2.6.1.11_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 3 Day 1		
n [2]	42	68
Mean	23.02	25.00
Standard Deviation	30.787	26.626
Median	0.00	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 3 Day 1		
n [2]	42	68
Mean	-2.38	-0.49
Standard Deviation	23.734	33.824
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 33.3
Min, Max	-66.7, 33.3	-100.0, 66.7
Status [3]		
Improved	10 (23.8)	14 (20.6)
Stable	24 (57.1)	35 (51.5)
Worsened	8 (19.0)	19 (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/T14.2.6.1.11_nsclc_eff.rtf

T14.2.6.1.11_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 5 Day 1		
n [2]	39	61
Mean	18.80	19.67
Standard Deviation	27.354	25.369
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 5 Day 1		
n [2]	39	61
Mean	-3.42	-7.10
Standard Deviation	26.263	31.100
Median	0.00	0.00
Q1, Q3	0.0, 0.0	-33.3, 0.0
Min, Max	-66.7, 66.7	-100.0, 66.7
Status [3]		
Improved	9 (23.1)	17 (27.9)
Stable	24 (61.5)	34 (55.7)
Worsened	6 (15.4)	10 (16.4)

[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/T14.2.6.1.11_nsclc_eff.rtf

T14.2.6.1.11_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 7 Day 1		
n [2]	39	60
Mean	15.38	21.67
Standard Deviation	21.421	23.630
Median	0.00	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 7 Day 1		
n [2]	39	60
Mean	-8.55	-4.44
Standard Deviation	27.272	29.090
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-33.3, 0.0
Min, Max	-66.7, 33.3	-66.7, 66.7
Status [3]		
Improved	11 (28.2)	16 (26.7)
Stable	23 (59.0)	32 (53.3)
Worsened	5 (12.8)	12 (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/T14.2.6.1.11_nsclc_eff.rtf

T14.2.6.1.11_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 9 Day 1		
n [2]	32	49
Mean	20.83	22.45
Standard Deviation	23.570	27.544
Median	16.67	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 9 Day 1		
n [2]	32	49
Mean	-2.08	-5.44
Standard Deviation	25.312	36.226
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-66.7, 66.7	-100.0, 100.0
Status [3]		
Improved	5 (15.6)	12 (24.5)
Stable	23 (71.9)	28 (57.1)
Worsened	4 (12.5)	9 (18.4)

[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/T14.2.6.1.11_nsclc_eff.rtf

T14.2.6.1.11_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 11 Day 1		
n [2]	27	35
Mean	23.46	22.86
Standard Deviation	28.963	30.002
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 11 Day 1		
n [2]	27	35
Mean	0.00	-11.43
Standard Deviation	27.735	36.103
Median	0.00	0.00
Q1, Q3	0.0, 0.0	-33.3, 0.0
Min, Max	-66.7, 66.7	-100.0, 66.7
Status [3]		
Improved	6 (22.2)	13 (37.1)
Stable	15 (55.6)	17 (48.6)
Worsened	6 (22.2)	5 (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
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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/T14.2.6.1.11_nsclc_eff.rtf

T14.2.6.1.11_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 13 Day 1		
n [2]	21	22
Mean	28.57	27.27
Standard Deviation	35.411	30.231
Median	33.33	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 13 Day 1		
n [2]	21	22
Mean	1.59	-15.15
Standard Deviation	30.689	36.699
Median	0.00	0.00
Q1, Q3	0.0, 33.3	-66.7, 0.0
Min, Max	-66.7, 66.7	-66.7, 66.7
Status [3]		
Improved	5 (23.8)	7 (31.8)
Stable	10 (47.6)	13 (59.1)
Worsened	6 (28.6)	2 (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
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Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
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T14.2.6.1.11_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 16 Day 1		
n [2]	9	15
Mean	18.52	26.67
Standard Deviation	29.397	28.730
Median	0.00	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 16 Day 1		
n [2]	9	15
Mean	-18.52	-20.00
Standard Deviation	29.397	43.278
Median	-33.33	0.00
Q1, Q3	-33.3, 0.0	-66.7, 0.0
Min, Max	-66.7, 33.3	-100.0, 66.7
Status [3]		
Improved	5 (55.6)	7 (46.7)
Stable	3 (33.3)	6 (40.0)
Worsened	1 (11.1)	2 (13.3)

[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/T14.2.6.1.11_nsclc_eff.rtf

T14.2.6.1.11_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 19 Day 1		
n [2]	5	1
Mean	33.33	0.00
Standard Deviation	33.333	
Median	33.33	0.00
Q1, Q3	0.0, 66.7	0.0, 0.0
Min, Max	0.0, 66.7	0.0, 0.0
Change from Baseline to Cycle 19 Day 1		
n [2]	5	1
Mean	-13.33	0.00
Standard Deviation	18.257	
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	0.0, 0.0
Min, Max	-33.3, 0.0	0.0, 0.0
Status [3]		
Improved	2 (40.0)	0 (0.0)
Stable	3 (60.0)	1 (100.0)
Worsened	0 (0.0)	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
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T14.2.6.1.11_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 22 Day 1		
n [2]	2	0
Mean	33.33	
Standard Deviation	47.140	
Median	33.33	
Q1, Q3	0.0, 66.7	
Min, Max	0.0, 66.7	
Change from Baseline to Cycle 22 Day 1		
n [2]	2	0
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)	0 (0.0)
Stable	1 (50.0)	0 (0.0)
Worsened	0 (0.0)	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/T14.2.6.1.11_nsclc_eff.rtf

T14.2.6.1.11_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits
Efficacy Analysis Set
by Subpopulation

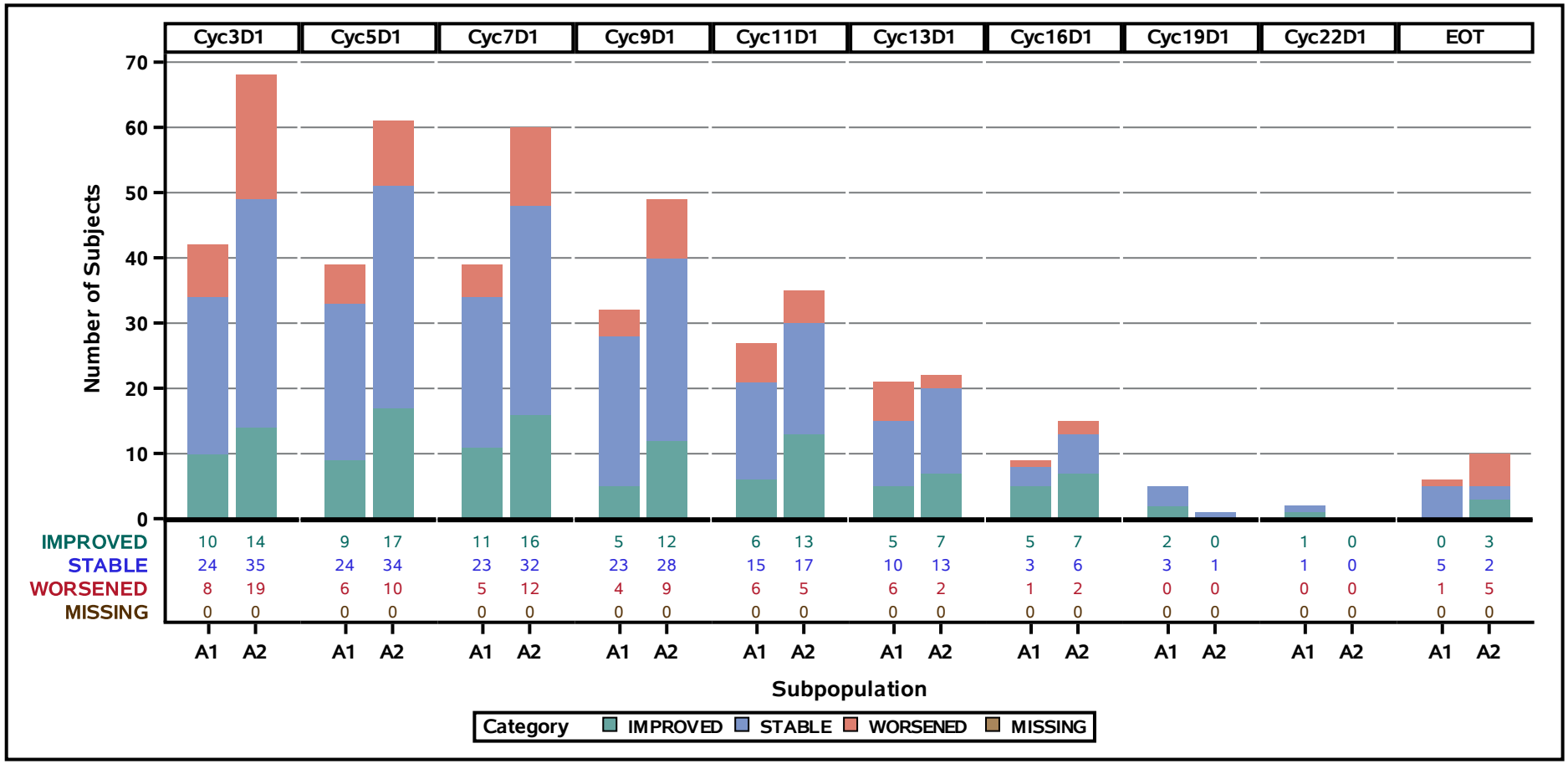
Visit Statistics	A1 (N= 51)	A2 (N= 76)
End of Treatment		
n [2]	6	10
Mean	27.78	26.67
Standard Deviation	25.092	26.294
Median	33.33	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 66.7
Change from Baseline to End of Treatment		
n [2]	6	10
Mean	5.56	10.00
Standard Deviation	13.608	35.312
Median	0.00	16.67
Q1, Q3	0.0, 0.0	-33.3, 33.3
Min, Max	0.0, 33.3	-33.3, 66.7
Status [3]		
Improved	0 (0.0)	3 (30.0)
Stable	5 (83.3)	2 (20.0)
Worsened	1 (16.7)	5 (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/T14.2.6.1.11_nsclc_eff.rtf

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

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



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F050_sl_10pt_nsclc_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

Loxo Oncology Inc. Page 1 of 2
Protocol Number: LOXO-RET-17001 03:41 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

T14.2.6.1.26
EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	51 27.45 (31.77)	42 -2.30 (-9.15, 4.54)	75 26.22 (31.14)	68 -2.90 (-8.80, 3.01)
CYCLE 5 DAY 1		39 -4.77 (-11.88, 2.34)		61 -8.62 (-14.85, -2.39)
CYCLE 7 DAY 1		39 -9.13 (-16.23, -2.03)		60 -6.42 (-12.71, -0.14)
CYCLE 9 DAY 1		32 -3.12 (-10.97, 4.72)		49 -6.19 (-13.14, 0.76)
CYCLE 11 DAY 1		27 -0.80 (-9.33, 7.74)		35 -7.75 (-15.99, 0.48)

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_mmrm.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/T14.2.6.1.26.rtf

T14.2.6.1.26
EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 13 DAY 1	21 2.38	21 2.38 (-7.30, 12.06)	22 -5.85	22 -5.85 (-16.28, 4.58)
CYCLE 16 DAY 1	9 -13.20	9 -13.20 (-28.04, 1.63)	15 -7.76	15 -7.76 (-20.41, 4.88)
CYCLE 19 DAY 1	5 -3.69	5 -3.69 (-23.64, 16.26)	1 -20.04	1 -20.04 (-68.73, 28.66)
CYCLE 22 DAY 1	2 -5.52	2 -5.52 (-36.98, 25.94)	0 N.E	0 N.E (N.E, N.E)
END OF TREATMENT	6 4.20	6 4.20 (-13.91, 22.31)	10 1.49	10 1.49 (-13.92, 16.90)

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_mmrm.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/T14.2.6.1.26.rtf

Loxo Oncology Inc. Page 1 of 11
Protocol Number: LOXO-RET-17001 15:25 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

T14.2.6.1.12_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Baseline [1]		
n [2]	51	76
Mean	27.45	23.25
Standard Deviation	33.137	28.813
Median	33.33	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	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_nsclc_eff.rtf

T14.2.6.1.12_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 3 Day 1		
n [2]	42	68
Mean	8.73	16.18
Standard Deviation	16.560	27.313
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 3 Day 1		
n [2]	42	68
Mean	-17.46	-7.84
Standard Deviation	31.441	37.376
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-33.3, 0.0
Min, Max	-100.0, 33.3	-100.0, 100.0
Status [3]		
Improved	18 (42.9)	22 (32.4)
Stable	21 (50.0)	36 (52.9)
Worsened	3 (7.1)	10 (14.7)

[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/T14.2.6.1.12_nsclc_eff.rtf

T14.2.6.1.12_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 5 Day 1		
n [2]	39	61
Mean	7.69	16.39
Standard Deviation	19.439	26.263
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 5 Day 1		
n [2]	39	61
Mean	-20.51	-9.29
Standard Deviation	35.554	35.554
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-33.3, 0.0
Min, Max	-100.0, 33.3	-100.0, 66.7
Status [3]		
Improved	17 (43.6)	23 (37.7)
Stable	19 (48.7)	29 (47.5)
Worsened	3 (7.7)	9 (14.8)

[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/T14.2.6.1.12_nsclc_eff.rtf

T14.2.6.1.12_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 7 Day 1		
n [2]	39	59
Mean	5.98	20.34
Standard Deviation	18.531	26.274
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 7 Day 1		
n [2]	39	59
Mean	-23.08	-3.95
Standard Deviation	31.673	34.511
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-33.3, 0.0
Min, Max	-100.0, 33.3	-100.0, 100.0
Status [3]		
Improved	19 (48.7)	18 (30.5)
Stable	19 (48.7)	27 (45.8)
Worsened	1 (2.6)	14 (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/T14.2.6.1.12_nsclc_eff.rtf

T14.2.6.1.12_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 9 Day 1		
n [2]	32	49
Mean	10.42	18.37
Standard Deviation	26.010	30.476
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 9 Day 1		
n [2]	32	49
Mean	-20.83	-6.12
Standard Deviation	30.232	38.293
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-33.3, 0.0
Min, Max	-100.0, 33.3	-66.7, 100.0
Status [3]		
Improved	15 (46.9)	16 (32.7)
Stable	16 (50.0)	26 (53.1)
Worsened	1 (3.1)	7 (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/T14.2.6.1.12_nsclc_eff.rtf

T14.2.6.1.12_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 11 Day 1		
n [2]	27	35
Mean	13.58	15.24
Standard Deviation	24.909	21.907
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 66.7
Change from Baseline to Cycle 11 Day 1		
n [2]	27	35
Mean	-14.81	-11.43
Standard Deviation	33.758	32.280
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-33.3, 0.0
Min, Max	-100.0, 33.3	-100.0, 66.7
Status [3]		
Improved	9 (33.3)	12 (34.3)
Stable	15 (55.6)	19 (54.3)
Worsened	3 (11.1)	4 (11.4)

[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/T14.2.6.1.12_nsclc_eff.rtf

T14.2.6.1.12_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 13 Day 1		
n [2]	21	22
Mean	14.29	18.18
Standard Deviation	22.537	28.595
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 13 Day 1		
n [2]	21	22
Mean	-20.63	-12.12
Standard Deviation	30.689	33.405
Median	-33.33	0.00
Q1, Q3	-33.3, 0.0	-33.3, 0.0
Min, Max	-66.7, 33.3	-100.0, 66.7
Status [3]		
Improved	11 (52.4)	8 (36.4)
Stable	8 (38.1)	12 (54.5)
Worsened	2 (9.5)	2 (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_nsclc_eff.rtf

T14.2.6.1.12_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 16 Day 1		
n [2]	9	15
Mean	14.81	22.22
Standard Deviation	17.568	24.125
Median	0.00	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 33.3	0.0, 66.7
Change from Baseline to Cycle 16 Day 1		
n [2]	9	15
Mean	-14.81	-4.44
Standard Deviation	44.444	43.400
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-33.3, 33.3
Min, Max	-100.0, 33.3	-100.0, 66.7
Status [3]		
Improved	3 (33.3)	5 (33.3)
Stable	4 (44.4)	5 (33.3)
Worsened	2 (22.2)	5 (33.3)

[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/T14.2.6.1.12_nsclc_eff.rtf

T14.2.6.1.12_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 19 Day 1		
n [2]	5	1
Mean	33.33	66.67
Standard Deviation	40.825	
Median	33.33	66.67
Q1, Q3	0.0, 33.3	66.7, 66.7
Min, Max	0.0, 100.0	66.7, 66.7
Change from Baseline to Cycle 19 Day 1		
n [2]	5	1
Mean	0.00	66.67
Standard Deviation	23.570	
Median	0.00	66.67
Q1, Q3	0.0, 0.0	66.7, 66.7
Min, Max	-33.3, 33.3	66.7, 66.7
Status [3]		
Improved	1 (20.0)	0 (0.0)
Stable	3 (60.0)	0 (0.0)
Worsened	1 (20.0)	1 (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
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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/T14.2.6.1.12_nsclc_eff.rtf

T14.2.6.1.12_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 22 Day 1		
n [2]	2	0
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	0
Mean	-33.33	
Standard Deviation	0.000	
Median	-33.33	
Q1, Q3	-33.3, -33.3	
Min, Max	-33.3, -33.3	
Status [3]		
Improved	2 (100.0)	0 (0.0)
Stable	0 (0.0)	0 (0.0)
Worsened	0 (0.0)	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_nsclc_eff.rtf

T14.2.6.1.12_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Appetite by Visits
Efficacy Analysis Set
by Subpopulation

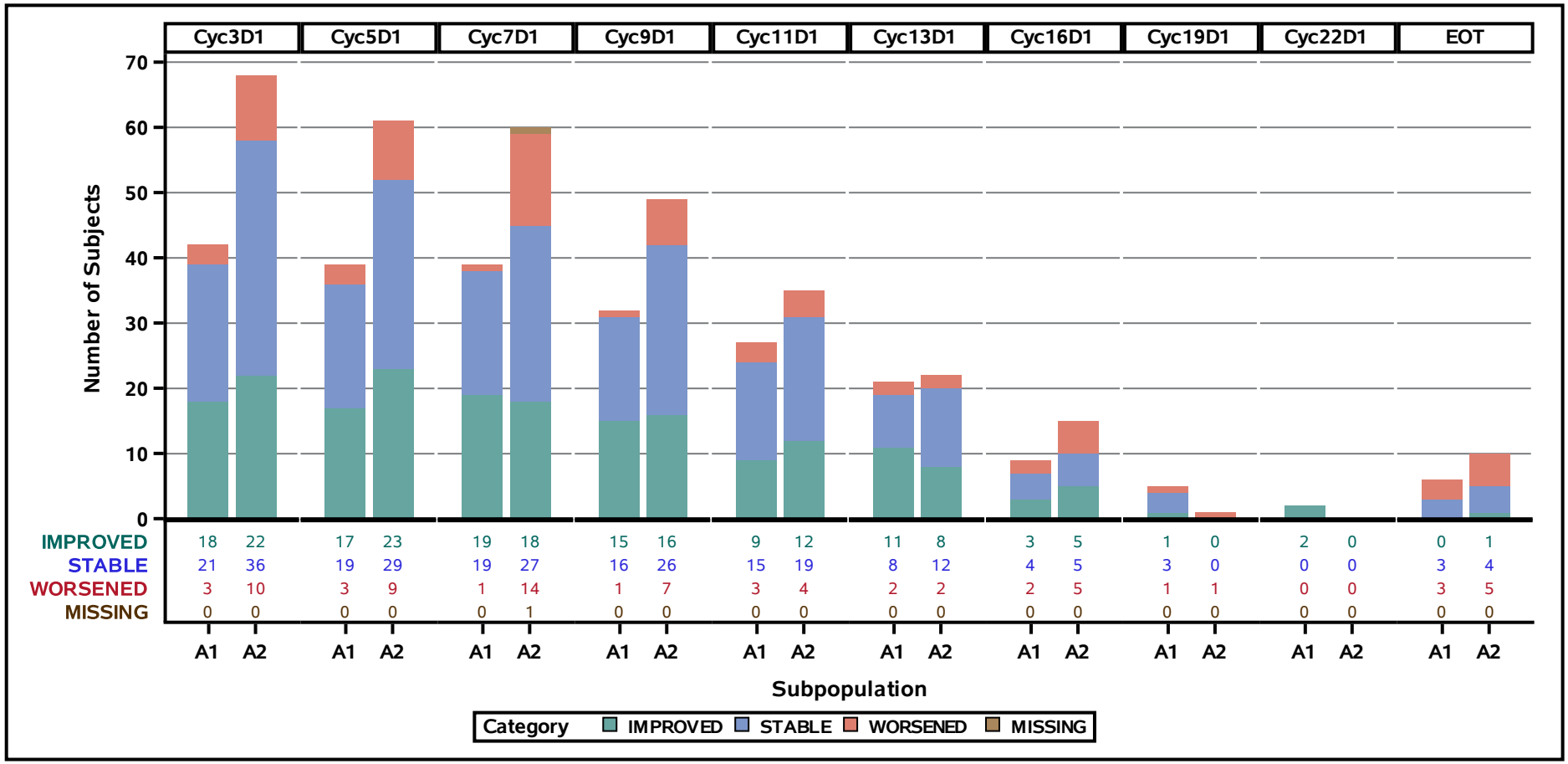
Visit Statistics	A1 (N= 51)	A2 (N= 76)
End of Treatment		
n [2]	6	10
Mean	33.33	33.33
Standard Deviation	29.814	35.136
Median	33.33	33.33
Q1, Q3	0.0, 66.7	0.0, 66.7
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline to End of Treatment		
n [2]	6	10
Mean	22.22	16.67
Standard Deviation	27.217	28.328
Median	16.67	16.67
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	-33.3, 66.7
Status [3]		
Improved	0 (0.0)	1 (10.0)
Stable	3 (50.0)	4 (40.0)
Worsened	3 (50.0)	5 (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/T14.2.6.1.12_nsclc_eff.rtf

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

Changes from baseline in QLQ-C30 scores by Appetite loss (Efficacy Analysis Set) by Subpopulation



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F051_ap_10pt_nsclc_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

Loxo Oncology Inc. Page 1 of 2
Protocol Number: LOXO-RET-17001 03:41 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

T14.2.6.1.27
EORTC QLQ-C30 (v3.0): Summary of Appetite Loss by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	51 27.45 (33.14)	42 -19.44 (-25.53, -13.36)	76 23.25 (28.81)	68 -8.61 (-14.90, -2.32)
CYCLE 5 DAY 1		39 -20.98 (-27.29, -14.67)		61 -8.75 (-15.39, -2.11)
CYCLE 7 DAY 1		39 -22.90 (-29.21, -16.59)		59 -4.51 (-11.26, 2.24)
CYCLE 9 DAY 1		32 -19.01 (-25.98, -12.04)		49 -6.52 (-13.93, 0.88)
CYCLE 11 DAY 1		27 -15.14 (-22.73, -7.56)		35 -10.12 (-18.89, -1.35)

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_mmrm.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/T14.2.6.1.27.rtf

T14.2.6.1.27
EORTC QLQ-C30 (v3.0): Summary of Appetite Loss by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 13 DAY 1	21 -16.06	21 -16.06 (-24.67, -7.44)	22 -7.96	22 -7.96 (-19.02, 3.11)
CYCLE 16 DAY 1	9 -14.21	9 -14.21 (-27.35, -1.08)	15 -3.14	15 -3.14 (-16.53, 10.26)
CYCLE 19 DAY 1	5 3.39	5 3.39 (-14.24, 21.01)	1 47.03	1 47.03 (-4.88, 98.94)
CYCLE 22 DAY 1	2 -29.95	2 -29.95 (-57.82, -2.08)	0 N.E	0 N.E (N.E, N.E)
END OF TREATMENT	6 8.91	6 8.91 (-7.24, 25.06)	10 10.12	10 10.12 (-6.30, 26.54)

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_mmrm.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/T14.2.6.1.27.rtf

T14.2.6.1.13_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Baseline [1]		
n [2]	51	76
Mean	17.65	18.42
Standard Deviation	24.361	24.582
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	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_nsclc_eff.rtf

T14.2.6.1.13_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 3 Day 1		
n [2]	42	68
Mean	23.02	17.65
Standard Deviation	28.973	22.652
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 3 Day 1		
n [2]	42	68
Mean	5.56	0.98
Standard Deviation	26.459	30.998
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	-33.3, 66.7	-66.7, 66.7
Status [3]		
Improved	8 (19.0)	16 (23.5)
Stable	21 (50.0)	31 (45.6)
Worsened	13 (31.0)	21 (30.9)

[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/T14.2.6.1.13_nsclc_eff.rtf

T14.2.6.1.13_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 5 Day 1		
n [2]	39	61
Mean	12.82	15.30
Standard Deviation	21.103	20.704
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 66.7
Change from Baseline to Cycle 5 Day 1		
n [2]	39	61
Mean	-6.84	-1.09
Standard Deviation	24.399	29.794
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	0.0, 33.3
Min, Max	-100.0, 33.3	-100.0, 66.7
Status [3]		
Improved	10 (25.6)	15 (24.6)
Stable	25 (64.1)	30 (49.2)
Worsened	4 (10.3)	16 (26.2)

[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/T14.2.6.1.13_nsclc_eff.rtf

T14.2.6.1.13_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 7 Day 1		
n [2]	39	59
Mean	13.68	15.82
Standard Deviation	26.177	22.621
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 66.7
Change from Baseline to Cycle 7 Day 1		
n [2]	39	59
Mean	-5.98	0.56
Standard Deviation	24.027	28.020
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	0.0, 0.0
Min, Max	-33.3, 66.7	-66.7, 66.7
Status [3]		
Improved	13 (33.3)	13 (22.0)
Stable	21 (53.8)	33 (55.9)
Worsened	5 (12.8)	13 (22.0)

[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_nsclc_eff.rtf

T14.2.6.1.13_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 9 Day 1		
n [2]	32	49
Mean	13.54	19.05
Standard Deviation	27.901	25.459
Median	0.00	0.00
Q1, Q3	0.0, 16.7	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 9 Day 1		
n [2]	32	49
Mean	-5.21	6.12
Standard Deviation	19.138	31.677
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 33.3
Min, Max	-33.3, 66.7	-66.7, 100.0
Status [3]		
Improved	7 (21.9)	7 (14.3)
Stable	24 (75.0)	27 (55.1)
Worsened	1 (3.1)	15 (30.6)

[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_nsclc_eff.rtf

T14.2.6.1.13_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 11 Day 1		
n [2]	27	35
Mean	12.35	12.38
Standard Deviation	29.451	18.232
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 66.7
Change from Baseline to Cycle 11 Day 1		
n [2]	27	35
Mean	-6.17	2.86
Standard Deviation	20.749	20.407
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-66.7, 33.3	-66.7, 33.3
Status [3]		
Improved	6 (22.2)	3 (8.6)
Stable	19 (70.4)	25 (71.4)
Worsened	2 (7.4)	7 (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/T14.2.6.1.13_nsclc_eff.rtf

T14.2.6.1.13_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 13 Day 1		
n [2]	21	22
Mean	14.29	15.15
Standard Deviation	27.021	26.681
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 13 Day 1		
n [2]	21	22
Mean	-6.35	6.06
Standard Deviation	32.692	24.422
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	0.0, 0.0
Min, Max	-100.0, 66.7	-33.3, 100.0
Status [3]		
Improved	6 (28.6)	1 (4.5)
Stable	12 (57.1)	18 (81.8)
Worsened	3 (14.3)	3 (13.6)

[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_nsclc_eff.rtf

T14.2.6.1.13_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 16 Day 1		
n [2]	9	15
Mean	14.81	13.33
Standard Deviation	24.216	24.560
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 66.7
Change from Baseline to Cycle 16 Day 1		
n [2]	9	15
Mean	0.00	2.22
Standard Deviation	28.868	15.258
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-33.3, 66.7	-33.3, 33.3
Status [3]		
Improved	2 (22.2)	1 (6.7)
Stable	6 (66.7)	12 (80.0)
Worsened	1 (11.1)	2 (13.3)

[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/T14.2.6.1.13_nsclc_eff.rtf

T14.2.6.1.13_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 19 Day 1		
n [2]	5	1
Mean	0.00	33.33
Standard Deviation	0.000	
Median	0.00	33.33
Q1, Q3	0.0, 0.0	33.3, 33.3
Min, Max	0.0, 0.0	33.3, 33.3
Change from Baseline to Cycle 19 Day 1		
n [2]	5	1
Mean	-13.33	33.33
Standard Deviation	18.257	
Median	0.00	33.33
Q1, Q3	-33.3, 0.0	33.3, 33.3
Min, Max	-33.3, 0.0	33.3, 33.3
Status [3]		
Improved	2 (40.0)	0 (0.0)
Stable	3 (60.0)	0 (0.0)
Worsened	0 (0.0)	1 (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_nsclc_eff.rtf

T14.2.6.1.13_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 22 Day 1		
n [2]	2	0
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	0
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)	0 (0.0)
Stable	1 (50.0)	0 (0.0)
Worsened	0 (0.0)	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/T14.2.6.1.13_nsclc_eff.rtf

T14.2.6.1.13_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits
Efficacy Analysis Set
by Subpopulation

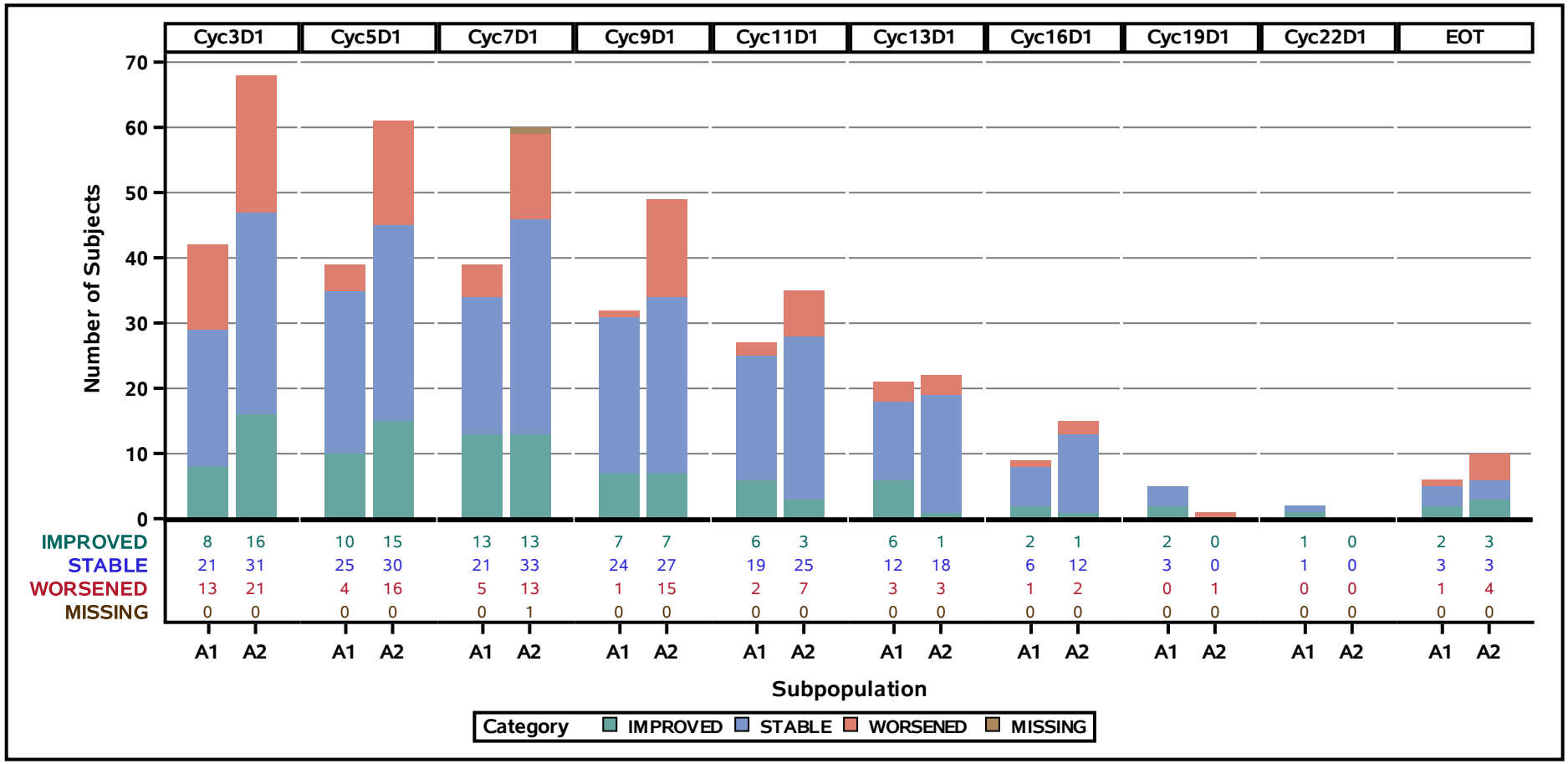
Visit Statistics	A1 (N= 51)	A2 (N= 76)
End of Treatment		
n [2]	6	10
Mean	16.67	26.67
Standard Deviation	27.889	30.631
Median	0.00	16.67
Q1, Q3	0.0, 33.3	0.0, 66.7
Min, Max	0.0, 66.7	0.0, 66.7
Change from Baseline to End of Treatment		
n [2]	6	10
Mean	0.00	3.33
Standard Deviation	36.515	29.187
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	-33.3, 33.3
Min, Max	-33.3, 66.7	-33.3, 33.3
Status [3]		
Improved	2 (33.3)	3 (30.0)
Stable	3 (50.0)	3 (30.0)
Worsened	1 (16.7)	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/T14.2.6.1.13_nsclc_eff.rtf

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

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



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F052_co_10pt_nsclc_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

T14.2.6.1.28
EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	51 17.65 (24.36)	42 5.03 (-1.69, 11.76)	76 18.42 (24.58)	68 2.82 (-2.59, 8.24)
CYCLE 5 DAY 1		39 -6.37 (-13.35, 0.61)		61 0.53 (-5.18, 6.24)
CYCLE 7 DAY 1		39 -5.52 (-12.49, 1.46)		59 1.27 (-4.53, 7.08)
CYCLE 9 DAY 1		32 -5.15 (-12.85, 2.55)		49 4.96 (-1.41, 11.33)
CYCLE 11 DAY 1		27 -6.22 (-14.60, 2.17)		35 -1.05 (-8.60, 6.51)

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_mmrm.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/T14.2.6.1.28.rtf

T14.2.6.1.28
EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 13 DAY 1	21 -5.44 (-14.95, 4.07)		22 1.81 (-7.71, 11.33)	
CYCLE 16 DAY 1	9 -1.71 (-16.24, 12.82)		15 -0.40 (-11.92, 11.11)	
CYCLE 19 DAY 1	5 -15.71 (-35.20, 3.78)		1 21.77 (-22.84, 66.37)	
CYCLE 22 DAY 1	2 -17.54 (-48.35, 13.26)		0 N.E (N.E, N.E)	
END OF TREATMENT	6 -0.88 (-18.67, 16.91)		10 10.54 (-3.59, 24.68)	

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_mmrm.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/T14.2.6.1.28.rtf

Loxo Oncology Inc. Page 1 of 11
Protocol Number: LOXO-RET-17001 15:25 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

T14.2.6.1.14_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Baseline [1]		
n [2]	51	75
Mean	8.50	9.33
Standard Deviation	17.440	16.944
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 66.7

[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/T14.2.6.1.14_nsclc_eff.rtf

T14.2.6.1.14_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 3 Day 1		
n [2]	41	67
Mean	10.57	15.42
Standard Deviation	18.914	26.162
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 3 Day 1		
n [2]	41	67
Mean	2.44	5.47
Standard Deviation	22.840	29.357
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-33.3, 66.7	-66.7, 100.0
Status [3]		
Improved	6 (14.6)	9 (13.4)
Stable	28 (68.3)	44 (65.7)
Worsened	7 (17.1)	14 (20.9)

[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/T14.2.6.1.14_nsclc_eff.rtf

T14.2.6.1.14_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 5 Day 1		
n [2]	39	60
Mean	15.38	25.00
Standard Deviation	21.421	32.835
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 5 Day 1		
n [2]	39	60
Mean	7.69	15.00
Standard Deviation	17.871	34.947
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	-33.3, 33.3	-33.3, 100.0
Status [3]		
Improved	2 (5.1)	9 (15.0)
Stable	26 (66.7)	27 (45.0)
Worsened	11 (28.2)	24 (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/T14.2.6.1.14_nsclc_eff.rtf

T14.2.6.1.14_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 7 Day 1		
n [2]	39	59
Mean	14.53	23.16
Standard Deviation	25.125	31.106
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 7 Day 1		
n [2]	39	59
Mean	6.84	12.43
Standard Deviation	27.762	32.103
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 33.3
Min, Max	-33.3, 100.0	-66.7, 100.0
Status [3]		
Improved	5 (12.8)	6 (10.2)
Stable	25 (64.1)	34 (57.6)
Worsened	9 (23.1)	19 (32.2)

[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/T14.2.6.1.14_nsclc_eff.rtf

T14.2.6.1.14_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 9 Day 1		
n [2]	31	48
Mean	9.68	21.53
Standard Deviation	23.084	31.125
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 9 Day 1		
n [2]	31	48
Mean	2.15	11.81
Standard Deviation	17.074	33.326
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 33.3
Min, Max	-33.3, 33.3	-33.3, 100.0
Status [3]		
Improved	3 (9.7)	6 (12.5)
Stable	23 (74.2)	28 (58.3)
Worsened	5 (16.1)	14 (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/T14.2.6.1.14_nsclc_eff.rtf

T14.2.6.1.14_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 11 Day 1		
n [2]	27	34
Mean	13.58	28.43
Standard Deviation	21.202	30.849
Median	0.00	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 11 Day 1		
n [2]	27	34
Mean	7.41	16.67
Standard Deviation	21.350	36.004
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	-33.3, 66.7	-33.3, 100.0
Status [3]		
Improved	2 (7.4)	6 (17.6)
Stable	18 (66.7)	13 (38.2)
Worsened	7 (25.9)	15 (44.1)

[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/T14.2.6.1.14_nsclc_eff.rtf

T14.2.6.1.14_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 13 Day 1		
n [2]	21	21
Mean	9.52	22.22
Standard Deviation	15.430	26.527
Median	0.00	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 33.3	0.0, 100.0
Change from Baseline to Cycle 13 Day 1		
n [2]	21	21
Mean	1.59	14.29
Standard Deviation	19.653	27.021
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 33.3
Min, Max	-33.3, 33.3	-33.3, 100.0
Status [3]		
Improved	3 (14.3)	1 (4.8)
Stable	14 (66.7)	12 (57.1)
Worsened	4 (19.0)	8 (38.1)

[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/T14.2.6.1.14_nsclc_eff.rtf

T14.2.6.1.14_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 16 Day 1		
n [2]	9	15
Mean	25.93	22.22
Standard Deviation	22.222	20.574
Median	33.33	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 66.7
Change from Baseline to Cycle 16 Day 1		
n [2]	9	15
Mean	18.52	11.11
Standard Deviation	17.568	24.125
Median	33.33	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 33.3	-33.3, 33.3
Status [3]		
Improved	0 (0.0)	2 (13.3)
Stable	4 (44.4)	6 (40.0)
Worsened	5 (55.6)	7 (46.7)

[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/T14.2.6.1.14_nsclc_eff.rtf

T14.2.6.1.14_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 19 Day 1		
n [2]	5	1
Mean	20.00	33.33
Standard Deviation	18.257	
Median	33.33	33.33
Q1, Q3	0.0, 33.3	33.3, 33.3
Min, Max	0.0, 33.3	33.3, 33.3
Change from Baseline to Cycle 19 Day 1		
n [2]	5	1
Mean	6.67	33.33
Standard Deviation	27.889	
Median	0.00	33.33
Q1, Q3	0.0, 33.3	33.3, 33.3
Min, Max	-33.3, 33.3	33.3, 33.3
Status [3]		
Improved	1 (20.0)	0 (0.0)
Stable	2 (40.0)	0 (0.0)
Worsened	2 (40.0)	1 (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_nsclc_eff.rtf

T14.2.6.1.14_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 22 Day 1		
n [2]	2	0
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	0
Mean	16.67	
Standard Deviation	23.570	
Median	16.67	
Q1, Q3	0.0, 33.3	
Min, Max	0.0, 33.3	
Status [3]		
Improved	0 (0.0)	0 (0.0)
Stable	1 (50.0)	0 (0.0)
Worsened	1 (50.0)	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_nsclc_eff.rtf

T14.2.6.1.14_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits
Efficacy Analysis Set
by Subpopulation

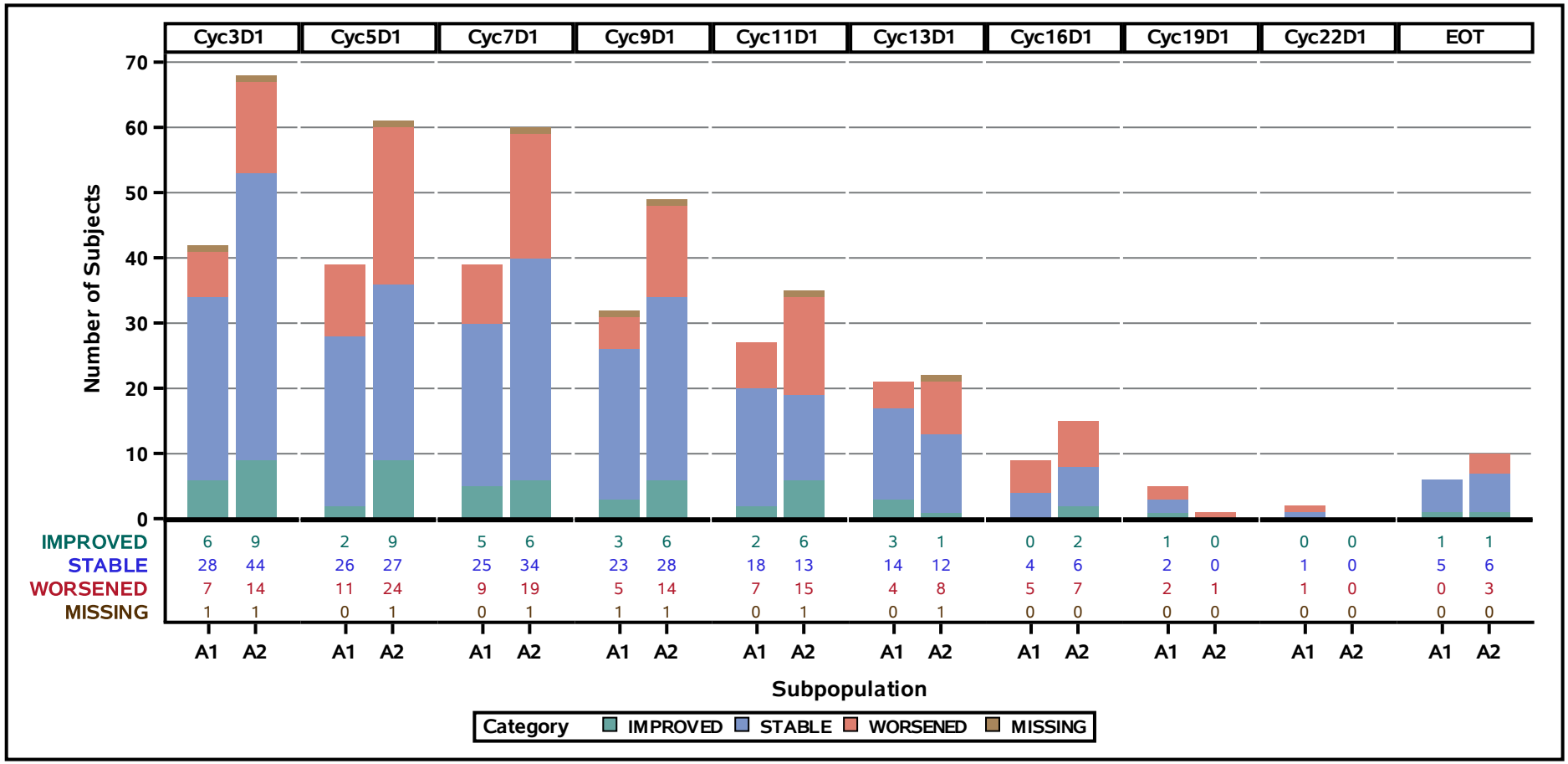
Visit Statistics	A1 (N= 51)	A2 (N= 76)
End of Treatment		
n [2]	6	10
Mean	5.56	13.33
Standard Deviation	13.608	17.213
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 33.3
Min, Max	0.0, 33.3	0.0, 33.3
Change from Baseline to End of Treatment		
n [2]	6	10
Mean	-5.56	3.33
Standard Deviation	13.608	29.187
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 33.3
Min, Max	-33.3, 0.0	-66.7, 33.3
Status [3]		
Improved	1 (16.7)	1 (10.0)
Stable	5 (83.3)	6 (60.0)
Worsened	0 (0.0)	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
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_nsclc_eff.rtf

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

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



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
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Loxo Oncology Inc. Page 1 of 2
Protocol Number: LOXO-RET-17001 03:41 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

T14.2.6.1.29
EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	51 8.50 (17.44)	41 2.65 (-3.40, 8.70)	75 9.33 (16.94)	67 5.31 (-1.71, 12.33)
CYCLE 5 DAY 1		39 7.67 (1.47, 13.88)		60 14.88 (7.46, 22.30)
CYCLE 7 DAY 1		39 6.82 (0.61, 13.03)		59 12.87 (5.39, 20.36)
CYCLE 9 DAY 1		31 2.05 (-4.91, 9.01)		48 11.47 (3.17, 19.77)
CYCLE 11 DAY 1		27 6.60 (-0.87, 14.06)		34 17.90 (8.04, 27.77)

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_mmrm.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/T14.2.6.1.29.rtf

T14.2.6.1.29
EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 13 DAY 1	21 1.70	21 12.57		
		(-6.76, 10.15)		(0.02, 25.12)
CYCLE 16 DAY 1	9 18.35	15 11.85		
		(5.43, 31.27)		(-3.00, 26.69)
CYCLE 19 DAY 1	5 9.59	1 25.50		
		(-7.76, 26.95)		(-32.01, 83.02)
CYCLE 22 DAY 1	2 12.64	0 N.E		
		(-14.80, 40.07)		(N.E, N.E)
END OF TREATMENT	6 -3.79	10 3.21		
		(-19.62, 12.04)		(-14.97, 21.39)

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_mmrm.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/T14.2.6.1.29.rtf

T14.2.6.1.15_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Baseline [1]		
n [2]	51	75
Mean	21.57	21.33
Standard Deviation	28.924	28.284
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	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
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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/T14.2.6.1.15_nsclc_eff.rtf

T14.2.6.1.15_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 3 Day 1		
n [2]	41	67
Mean	15.45	17.91
Standard Deviation	22.482	26.798
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 3 Day 1		
n [2]	41	67
Mean	-7.32	-2.99
Standard Deviation	20.429	22.271
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-66.7, 33.3	-66.7, 66.7
Status [3]		
Improved	9 (22.0)	13 (19.4)
Stable	30 (73.2)	46 (68.7)
Worsened	2 (4.9)	8 (11.9)

[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_nsclc_eff.rtf

T14.2.6.1.15_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 5 Day 1		
n [2]	39	60
Mean	18.80	16.11
Standard Deviation	28.403	24.923
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 5 Day 1		
n [2]	39	60
Mean	-2.56	-4.44
Standard Deviation	25.802	22.522
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-66.7, 66.7	-66.7, 66.7
Status [3]		
Improved	7 (17.9)	11 (18.3)
Stable	28 (71.8)	44 (73.3)
Worsened	4 (10.3)	5 (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/T14.2.6.1.15_nsclc_eff.rtf

T14.2.6.1.15_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 7 Day 1		
n [2]	39	59
Mean	12.82	16.95
Standard Deviation	21.103	27.244
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 100.0
Change from Baseline to Cycle 7 Day 1		
n [2]	39	59
Mean	-8.55	-3.39
Standard Deviation	21.245	24.522
Median	0.00	0.00
Q1, Q3	-33.3, 0.0	0.0, 0.0
Min, Max	-66.7, 33.3	-66.7, 100.0
Status [3]		
Improved	10 (25.6)	13 (22.0)
Stable	27 (69.2)	41 (69.5)
Worsened	2 (5.1)	5 (8.5)

[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/T14.2.6.1.15_nsclc_eff.rtf

T14.2.6.1.15_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 9 Day 1		
n [2]	31	48
Mean	15.05	19.44
Standard Deviation	18.932	29.038
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 100.0
Change from Baseline to Cycle 9 Day 1		
n [2]	31	48
Mean	-5.38	0.00
Standard Deviation	19.430	23.820
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-66.7, 33.3	-66.7, 66.7
Status [3]		
Improved	6 (19.4)	9 (18.8)
Stable	23 (74.2)	30 (62.5)
Worsened	2 (6.5)	9 (18.8)

[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/T14.2.6.1.15_nsclc_eff.rtf

T14.2.6.1.15_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 11 Day 1		
n [2]	27	34
Mean	11.11	10.78
Standard Deviation	18.490	19.627
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 66.7	0.0, 66.7
Change from Baseline to Cycle 11 Day 1		
n [2]	27	34
Mean	-3.70	-6.86
Standard Deviation	25.036	24.315
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-100.0, 66.7	-66.7, 66.7
Status [3]		
Improved	3 (11.1)	8 (23.5)
Stable	23 (85.2)	24 (70.6)
Worsened	1 (3.7)	2 (5.9)

[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
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_nsclc_eff.rtf

T14.2.6.1.15_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 13 Day 1		
n [2]	21	21
Mean	17.46	12.70
Standard Deviation	29.096	19.653
Median	0.00	0.00
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 66.7
Change from Baseline to Cycle 13 Day 1		
n [2]	21	21
Mean	1.59	-3.17
Standard Deviation	16.587	25.614
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-33.3, 66.7	-66.7, 66.7
Status [3]		
Improved	1 (4.8)	4 (19.0)
Stable	19 (90.5)	15 (71.4)
Worsened	1 (4.8)	2 (9.5)

[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
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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/T14.2.6.1.15_nsclc_eff.rtf

T14.2.6.1.15_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 16 Day 1		
n [2]	9	15
Mean	14.81	11.11
Standard Deviation	33.793	20.574
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 66.7
Change from Baseline to Cycle 16 Day 1		
n [2]	9	15
Mean	7.41	-6.67
Standard Deviation	36.430	22.537
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	-33.3, 100.0	-66.7, 33.3
Status [3]		
Improved	1 (11.1)	3 (20.0)
Stable	7 (77.8)	11 (73.3)
Worsened	1 (11.1)	1 (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_nsclc_eff.rtf

T14.2.6.1.15_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 19 Day 1		
n [2]	5	1
Mean	13.33	33.33
Standard Deviation	18.257	
Median	0.00	33.33
Q1, Q3	0.0, 33.3	33.3, 33.3
Min, Max	0.0, 33.3	33.3, 33.3
Change from Baseline to Cycle 19 Day 1		
n [2]	5	1
Mean	13.33	-33.33
Standard Deviation	18.257	
Median	0.00	-33.33
Q1, Q3	0.0, 33.3	-33.3, -33.3
Min, Max	0.0, 33.3	-33.3, -33.3
Status [3]		
Improved	0 (0.0)	1 (100.0)
Stable	3 (60.0)	0 (0.0)
Worsened	2 (40.0)	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_nsclc_eff.rtf

T14.2.6.1.15_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
Cycle 22 Day 1		
n [2]	2	0
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	0
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)	0 (0.0)
Stable	2 (100.0)	0 (0.0)
Worsened	0 (0.0)	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_nsclc_eff.rtf

T14.2.6.1.15_nsclc_eff
EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits
Efficacy Analysis Set
by Subpopulation

Visit Statistics	A1 (N= 51)	A2 (N= 76)
End of Treatment		
n [2]	6	10
Mean	22.22	26.67
Standard Deviation	40.369	26.294
Median	0.00	33.33
Q1, Q3	0.0, 33.3	0.0, 33.3
Min, Max	0.0, 100.0	0.0, 66.7
Change from Baseline to End of Treatment		
n [2]	6	10
Mean	5.56	10.00
Standard Deviation	13.608	22.498
Median	0.00	0.00
Q1, Q3	0.0, 0.0	0.0, 0.0
Min, Max	0.0, 33.3	0.0, 66.7
Status [3]		
Improved	0 (0.0)	0 (0.0)
Stable	5 (83.3)	8 (80.0)
Worsened	1 (16.7)	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.

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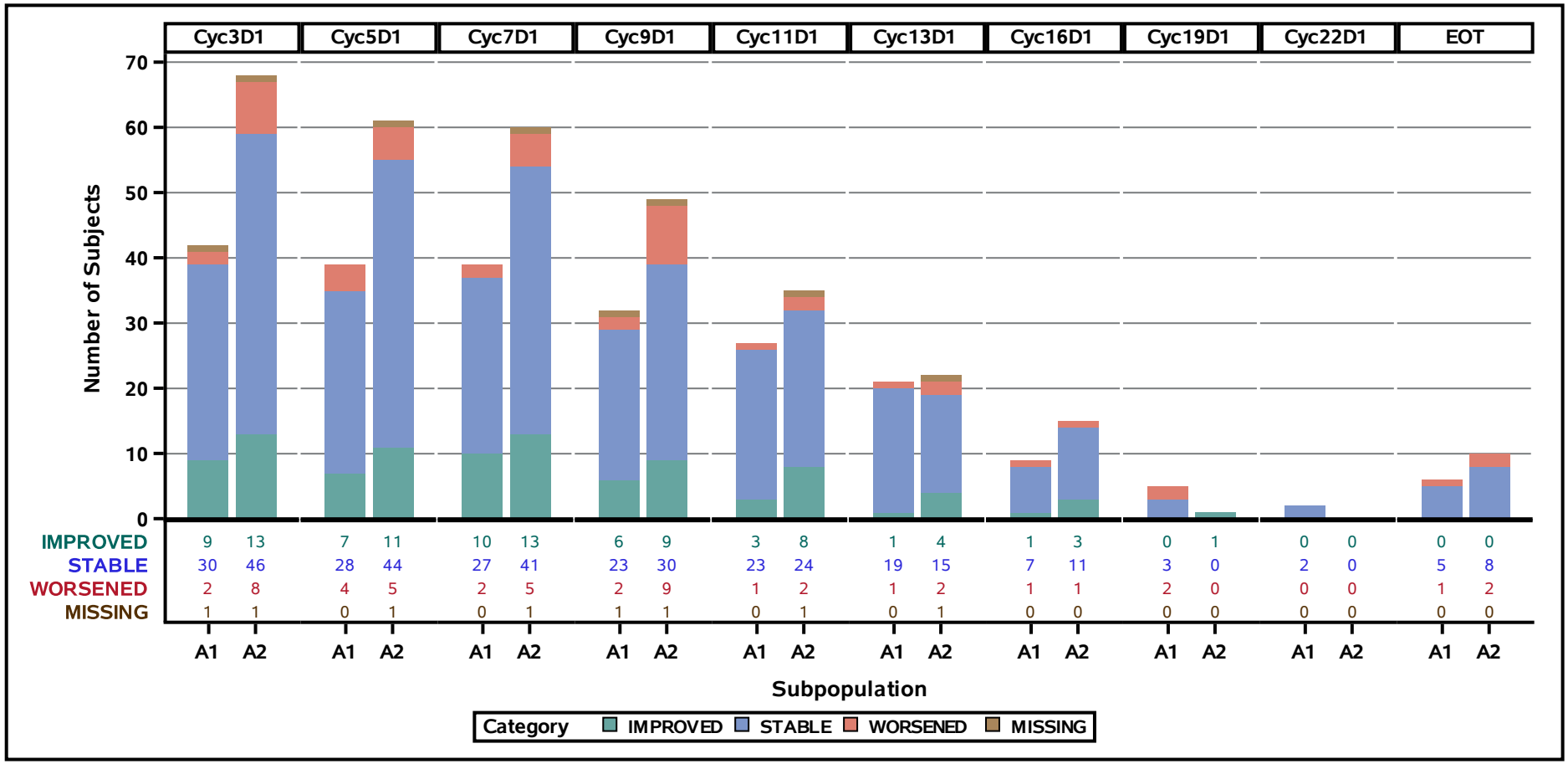
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_nsclc_eff.rtf

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

Changes from baseline in QLQ-C30 scores by Financial difficulties (Efficacy Analysis Set) by Subpopulation



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_bc_b7.sas
Output Location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F054_fi_10pt_nsclc_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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T14.2.6.1.30
EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	51 21.57 (28.92)	41 -5.53 (-11.21, 0.14)	75 21.33 (28.28)	67 -2.46 (-7.30, 2.39)
CYCLE 5 DAY 1		39 -1.41 (-7.22, 4.40)		60 -4.06 (-9.18, 1.06)
CYCLE 7 DAY 1		39 -7.39 (-13.20, -1.58)		59 -3.10 (-8.27, 2.06)
CYCLE 9 DAY 1		31 -4.64 (-11.16, 1.88)		48 -0.10 (-5.83, 5.62)
CYCLE 11 DAY 1		27 -5.48 (-12.47, 1.50)		34 -7.75 (-14.55, -0.95)

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_mmrm.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/T14.2.6.1.30.rtf

T14.2.6.1.30
EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	A1		A2	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 13 DAY 1	21	0.28	21	-4.83
		(-7.64, 8.20)		(-13.49, 3.83)
CYCLE 16 DAY 1	9	2.31	15	-7.50
		(-9.83, 14.44)		(-17.74, 2.75)
CYCLE 19 DAY 1	5	4.91	1	-12.89
		(-11.39, 21.22)		(-52.73, 26.95)
CYCLE 22 DAY 1	2	-8.42	0	N.E
		(-34.12, 17.28)		(N.E, N.E)
END OF TREATMENT	6	4.60	10	8.69
		(-10.20, 19.41)		(-3.86, 21.23)

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_mmrm.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/T14.2.6.1.30.rtf

Tabelle 004: Behandlungsdauer – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Safety Analysis Set

	Selpercatinib	
	Subpopulation A1 – NSCLC 2L (N=85)	**Subpopulation A2 – NSCLC 3L (N=173)**
Behandlungsdauer in Monaten		
Anzahl der Patienten	85	173
Mittelwert (SD)	10,8 (6,31)	12,2 (7,82)
Median (min–max)	10,78 (0,46-29,14)	11,10 (0,10-34,50)

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; max: Maximum; min: Minimum; NSCLC: nicht-kleinzelliges Lungenkarzinom; 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/T004_tte_nsclc.rtf

Tabelle 020.10: Ergebnisse für den Endpunkt unerwünschte Ereignisse von besonderem Interesse aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Safety Population

Endpunkt	Selpercatinib Subpopulation A1 - NSCLC 2L (N=85)	Selpercatinib Subpopulation A2 - NSCLC 3L (N=173)
Unerwünschte Ereignisse von besonderem Interesse, n (%)		
Erhöhung von AST und ALT		
Jeglicher Schweregrad	42 (49,4)	68 (39,3)
CTCAE-Grad < 3	26 (30,6)	45 (26,0)
CTCAE-Grad ≥ 3	16 (18,8)	23 (13,3)
Schwerwiegend	4 (4,7)	3 (1,7)
Behandlungsabbruch	0	1 (0,6)
Überempfindlichkeit		
Jeglicher Schweregrad	9 (10,6)	15 (8,7)
CTCAE-Grad < 3	7 (8,2)	9 (5,2)
CTCAE-Grad ≥ 3	2 (2,4)	6 (3,5)
Schwerwiegend	3 (3,5)	7 (4,0)
Behandlungsabbruch	0	2 (1,2)
Hypertonie		
Jeglicher Schweregrad	31 (36,5)	55 (31,8)
CTCAE-Grad < 3	15 (17,6)	25 (14,5)
CTCAE-Grad ≥ 3	16 (18,8)	30 (17,3)
Schwerwiegend	1 (1,2)	2 (1,2)
Behandlungsabbruch	0	0

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; ALT: Alanin-Aminotransferase; AST: Aspartat-Aminotransferase; CTCAE: Common Terminology Criteria for Adverse Events;
n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Safety Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; RET: Rearranged during Transfection.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_aesi_ge.sas (created original output - T020_10_sp_aesi_sf.pdf)
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/T020_10_sp_aesi_sf_mod_for_pdf.rtf

Tabelle 020: Ergebnisse für den Endpunkt jegliche unerwünschte Ereignisse aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Safety Population

Endpunkt	Selpercatinib Subpopulation A1 - NSCLC 2L (N=85)	Selpercatinib Subpopulation A2 - NSCLC 3L (N=173)
Jegliche unerwünschte Ereignisse, n (%)		
Jegliche unerwünschte Ereignisse		
Jeglicher Schweregrad	85 (100)	173 (100)
CTCAE-Grad < 3	31 (36,5)	60 (34,7)
CTCAE-Grad ≥ 3	54 (63,5)	113 (65,3)
CTCAE-Grad 3	42 (49,4)	88 (50,9)
CTCAE-Grad 4	10 (11,8)	17 (9,8)
CTCAE-Grad 5	2 (2,4)	8 (4,6)
Therapiebezogene [a] unerwünschte Ereignisse	81 (95,3)	159 (91,9)
Therapiebezogene [a] unerwünschte Ereignisse vom CTCAE-Grad ≥ 3	31 (36,5)	51 (29,5)
Schwerwiegende unerwünschte Ereignisse	32 (37,6)	77 (44,5)
Therapiebezogene [a] schwerwiegende unerwünschte Ereignisse	11 (12,9)	19 (11,0)
Behandlungsabbruch aufgrund unerwünschter Ereignisse	6 (7,1)	13 (7,5)

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; CTCAE: Common Terminology Criteria for Adverse Events; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Safety Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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_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/T020_sp_anyae_sf.rtf

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Table 14.4.2.13
Proportions of patients with severe AE by SOC (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation A1

Analysis Set / System Organ Class	Maximum Severity (n, %) Grade 3	Grade 4	Grade 5	Total
Overall Safety (N=85)				
Any SOC	42 (49.4)	10 (11.8)	2 (2.4)	54 (63.5)
Investigations	16 (18.8)	4 (4.7)	0 (0.0)	20 (23.5)
Vascular disorders	18 (21.2)	0 (0.0)	0 (0.0)	18 (21.2)
Infections and infestations	10 (11.8)	1 (1.2)	0 (0.0)	11 (12.9)
Respiratory, thoracic and mediastinal disorders	8 (9.4)	2 (2.4)	1 (1.2)	11 (12.9)
Blood and lymphatic system disorders	8 (9.4)	2 (2.4)	0 (0.0)	10 (11.8)
Metabolism and nutrition disorders	7 (8.2)	1 (1.2)	0 (0.0)	8 (9.4)
Gastrointestinal disorders	7 (8.2)	0 (0.0)	0 (0.0)	7 (8.2)

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
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.13_sf.rtf

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Table 14.4.2.14
Proportions of patients with severe AE by SOC (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation A2

Analysis Set / System Organ Class	Maximum Severity (n, %) Grade 3	Grade 4	Grade 5	Total
Overall Safety (N=173)				
Any SOC	88 (50.9)	17 (9.8)	8 (4.6)	113 (65.3)
Investigations	36 (20.8)	7 (4.0)	0 (0.0)	43 (24.9)
Blood and lymphatic system disorders	26 (15.0)	6 (3.5)	0 (0.0)	32 (18.5)
Vascular disorders	31 (17.9)	0 (0.0)	0 (0.0)	31 (17.9)
Metabolism and nutrition disorders	21 (12.1)	4 (2.3)	0 (0.0)	25 (14.5)
Infections and infestations	18 (10.4)	1 (0.6)	3 (1.7)	22 (12.7)
Gastrointestinal disorders	18 (10.4)	0 (0.0)	0 (0.0)	18 (10.4)
Respiratory, thoracic and mediastinal disorders	12 (6.9)	1 (0.6)	1 (0.6)	14 (8.1)
Nervous system disorders	10 (5.8)	1 (0.6)	1 (0.6)	12 (6.9)
General disorders and administration site conditions	9 (5.2)	0 (0.0)	1 (0.6)	10 (5.8)

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
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.14_sf.rtf

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Table 14.4.2.19
Proportions of patients with severe AE by PT (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation A1

Analysis Set / Preferred Term	Maximum Severity (n, %) Grade 3	Grade 4	Grade 5	Total
Overall Safety (N=85)				
Any PT	42 (49.4)	10 (11.8)	2 (2.4)	54 (63.5)
Hypertension	16 (18.8)	0 (0.0)	0 (0.0)	16 (18.8)
Alanine aminotransferase increased	12 (14.1)	3 (3.5)	0 (0.0)	15 (17.6)
Aspartate aminotransferase increased	8 (9.4)	3 (3.5)	0 (0.0)	11 (12.9)
Hyponatraemia	4 (4.7)	1 (1.2)	0 (0.0)	5 (5.9)
Pleural effusion	5 (5.9)	0 (0.0)	0 (0.0)	5 (5.9)
Thrombocytopenia	3 (3.5)	2 (2.4)	0 (0.0)	5 (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
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.19_sf.rtf

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Table 14.4.2.1
Proportions of patients with AE by SOC (cut-off: >=10% of patients)
Safety Analysis Set
by Subpopulation A1

System Organ Class	A1 (N=85) n (%)
Patients with TEAEs	85 (100)
Gastrointestinal disorders	73 (85.9)
General disorders and administration site conditions	64 (75.3)
Investigations	64 (75.3)
Respiratory, thoracic and mediastinal disorders	54 (63.5)
Skin and subcutaneous tissue disorders	53 (62.4)
Musculoskeletal and connective tissue disorders	52 (61.2)
Infections and infestations	47 (55.3)
Nervous system disorders	44 (51.8)
Metabolism and nutrition disorders	42 (49.4)
Vascular disorders	37 (43.5)
Blood and lymphatic system disorders	33 (38.8)
Psychiatric disorders	24 (28.2)
Renal and urinary disorders	19 (22.4)
Injury, poisoning and procedural complications	14 (16.5)
Eye disorders	13 (15.3)
Cardiac disorders	11 (12.9)
Endocrine disorders	10 (11.8)
Immune system disorders	10 (11.8)
Hepatobiliary disorders	9 (10.6)
Reproductive system and breast disorders	9 (10.6)

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/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/T14.4.2.1_sf.rtf

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Table 14.4.2.20
Proportions of patients with severe AE by PT (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation A2

Analysis Set / Preferred Term	Maximum Severity (n, %) Grade 3	Grade 4	Grade 5	Total
Overall Safety (N=173)				
Any PT	88 (50.9)	17 (9.8)	8 (4.6)	113 (65.3)
Hypertension	30 (17.3)	0 (0.0)	0 (0.0)	30 (17.3)
Alanine aminotransferase increased	17 (9.8)	2 (1.2)	0 (0.0)	19 (11.0)
Aspartate aminotransferase increased	15 (8.7)	2 (1.2)	0 (0.0)	17 (9.8)
Electrocardiogram QT prolonged	12 (6.9)	0 (0.0)	0 (0.0)	12 (6.9)
Lymphopenia	9 (5.2)	2 (1.2)	0 (0.0)	11 (6.4)
Anaemia	9 (5.2)	0 (0.0)	0 (0.0)	9 (5.2)
Hyponatraemia	7 (4.0)	2 (1.2)	0 (0.0)	9 (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
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.20_sf.rtf

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Table 14.4.2.25
Proportions of patients with serious AE by SOC (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation A1

System Organ Class	A1 (N=85) n (%)
Patients with TEAEs	32 (37.6)
Respiratory, thoracic and mediastinal disorders	9 (10.6)
Infections and infestations	7 (8.2)
Investigations	5 (5.9)
Nervous system disorders	5 (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 (version21.0).
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/T14.4.2.25_sf.rtf

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Table 14.4.2.26
Proportions of patients with serious AE by SOC (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation A2

System Organ Class	A2 (N=173) n (%)
Patients with TEAEs	77 (44.5)
Infections and infestations	22 (12.7)
Nervous system disorders	15 (8.7)
Gastrointestinal disorders	13 (7.5)
General disorders and administration site conditions	13 (7.5)
Respiratory, thoracic and mediastinal disorders	13 (7.5)
Metabolism and nutrition disorders	9 (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.
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/T14.4.2.26_sf.rtf

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Table 14.4.2.2
Proportions of patients with AE by SOC (cut-off: >=10% of patients)
Safety Analysis Set
by Subpopulation A2

System Organ Class	A2 (N=173) n (%)
Patients with TEAEs	173 (100)
Gastrointestinal disorders	141 (81.5)
General disorders and administration site conditions	121 (69.9)
Investigations	113 (65.3)
Skin and subcutaneous tissue disorders	96 (55.5)
Infections and infestations	94 (54.3)
Respiratory, thoracic and mediastinal disorders	86 (49.7)
Metabolism and nutrition disorders	83 (48.0)
Nervous system disorders	79 (45.7)
Blood and lymphatic system disorders	76 (43.9)
Musculoskeletal and connective tissue disorders	74 (42.8)
Vascular disorders	66 (38.2)
Renal and urinary disorders	41 (23.7)
Eye disorders	39 (22.5)
Injury, poisoning and procedural complications	32 (18.5)
Psychiatric disorders	31 (17.9)
Cardiac disorders	26 (15.0)
Endocrine disorders	21 (12.1)

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/tfl/t_aespt_en.sas
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.2_sf.rtf

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Table 14.4.2.32
Proportions of patients with AE by SOC (cut-off: >=10 patients and >=1% of patients)
Safety Analysis Set
by Subpopulation A2

System Organ Class	A2 (N=173) n (%)
Patients with TEAEs	173 (100)
Gastrointestinal disorders	141 (81.5)
General disorders and administration site conditions	121 (69.9)
Investigations	113 (65.3)
Skin and subcutaneous tissue disorders	96 (55.5)
Infections and infestations	94 (54.3)
Respiratory, thoracic and mediastinal disorders	86 (49.7)
Metabolism and nutrition disorders	83 (48.0)
Nervous system disorders	79 (45.7)
Blood and lymphatic system disorders	76 (43.9)
Musculoskeletal and connective tissue disorders	74 (42.8)
Vascular disorders	66 (38.2)
Renal and urinary disorders	41 (23.7)
Eye disorders	39 (22.5)
Injury, poisoning and procedural complications	32 (18.5)
Psychiatric disorders	31 (17.9)
Cardiac disorders	26 (15.0)
Endocrine disorders	21 (12.1)
Immune system disorders	17 (9.8)
Reproductive system and breast disorders	15 (8.7)
Ear and labyrinth disorders	12 (6.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	12 (6.9)

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 (version21.0).
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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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.32_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) 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)
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 (version21.0).
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aespt_tdisc_en.sas
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.37_sf.rtf

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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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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.38_sf.rtf

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 (%)
Pneumatosis 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.
Reported adverse event terms were coded using MedDRA (version21.0).
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aespt_tdisc_en.sas
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.38_sf.rtf

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Table 14.4.2.39
Proportions of patients with serious AE by PT (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation A1

Preferred Term	A1 (N=85) n (%)
Patients with TEAEs	32 (37.6)

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/tfl/t_aespt_en.sas
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.39_sf.rtf

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Table 14.4.2.40
Proportions of patients with serious AE by PT (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation A2

Preferred Term	A2 (N=173) n (%)
Patients with TEAEs	77 (44.5)
Pneumonia	10 (5.8)

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/tfl/t_aespt_en.sas
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Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
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Table 14.4.2.46
Proportions of patients with AE by PT (cut-off: >=10 patients and >=1% of patients)
Safety Analysis Set
by Subpopulation A2

Preferred Term	A2 (N=173) n (%)
Patients with TEAEs	173 (100)
Diarrhoea	78 (45.1)
Dry mouth	67 (38.7)
Alanine aminotransferase increased	63 (36.4)
Aspartate aminotransferase increased	59 (34.1)
Hypertension	55 (31.8)
Oedema peripheral	49 (28.3)
Fatigue	43 (24.9)
Constipation	39 (22.5)
Headache	39 (22.5)
Nausea	37 (21.4)
Thrombocytopenia	35 (20.2)
Electrocardiogram QT prolonged	34 (19.7)
Pyrexia	34 (19.7)
Rash	32 (18.5)
Dyspnoea	29 (16.8)
Blood creatinine increased	28 (16.2)
Leukopenia	27 (15.6)
Urinary tract infection	26 (15.0)
Vomiting	25 (14.5)
Decreased appetite	24 (13.9)
Dry skin	24 (13.9)

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 (version21.0).
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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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.46_sf.rtf

Table 14.4.2.46
Proportions of patients with AE by PT (cut-off: >=10 patients and >=1% of patients)
Safety Analysis Set
by Subpopulation A2

Preferred Term	A2 (N=173) n (%)
Dizziness	23 (13.3)
Anaemia	22 (12.7)
Hypomagnesaemia	22 (12.7)
Neutropenia	22 (12.7)
Abdominal pain	21 (12.1)
Blood bilirubin increased	21 (12.1)
Blood alkaline phosphatase increased	20 (11.6)
Lymphopenia	20 (11.6)
Cough	19 (11.0)
Face oedema	19 (11.0)
Hypoalbuminaemia	19 (11.0)
Arthralgia	18 (10.4)
Hyponatraemia	18 (10.4)
Back pain	17 (9.8)
Dysgeusia	17 (9.8)
Myalgia	16 (9.2)
Pneumonia	16 (9.2)
Hypothyroidism	15 (8.7)
Insomnia	15 (8.7)
Oropharyngeal pain	15 (8.7)
Stomatitis	15 (8.7)
Upper respiratory tract infection	15 (8.7)
Asthenia	14 (8.1)

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/tfl/t_aespt_en.sas
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.46_sf.rtf

Table 14.4.2.46
Proportions of patients with AE by PT (cut-off: >=10 patients and >=1% of patients)
Safety Analysis Set
by Subpopulation A2

Preferred Term	A2 (N=173) n (%)
Rash maculo-papular	14 (8.1)
Hypokalaemia	13 (7.5)
Pleural effusion	13 (7.5)
Abdominal distension	12 (6.9)
Alopecia	12 (6.9)
Drug hypersensitivity	12 (6.9)
Fall	12 (6.9)
Proteinuria	12 (6.9)
Pruritus	12 (6.9)
Weight decreased	12 (6.9)
Ascites	11 (6.4)
Dysphonia	11 (6.4)
Hypophosphataemia	11 (6.4)
Pain in extremity	11 (6.4)
Productive cough	11 (6.4)
Abdominal pain upper	10 (5.8)
Dry eye	10 (5.8)
Hyperkalaemia	10 (5.8)
Vision blurred	10 (5.8)

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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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.46_sf.rtf

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Table 14.4.2.51
Proportions of patients with AE by SOC and PT (cut-off: >=10% of patients)
Safety Analysis Set
by Subpopulation A2

System Organ Class Preferred Term	A2 (N=173) n (%)
Patients with TEAEs	173 (100)
Gastrointestinal disorders	141 (81.5)
Diarrhoea	78 (45.1)
Dry mouth	67 (38.7)
Constipation	39 (22.5)
Nausea	37 (21.4)
Vomiting	25 (14.5)
Abdominal pain	21 (12.1)
General disorders and administration site conditions	121 (69.9)
Oedema peripheral	49 (28.3)
Fatigue	43 (24.9)
Pyrexia	34 (19.7)
Face oedema	19 (11.0)
Investigations	113 (65.3)
Alanine aminotransferase increased	63 (36.4)
Aspartate aminotransferase increased	59 (34.1)
Electrocardiogram QT prolonged	34 (19.7)
Blood creatinine increased	28 (16.2)
Blood bilirubin increased	21 (12.1)
Blood alkaline phosphatase increased	20 (11.6)
Skin and subcutaneous tissue disorders	96 (55.5)
Rash	32 (18.5)

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 (version21.0).
Adverse events are sorted in descending frequency.
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.51_sf.rtf

Table 14.4.2.51
Proportions of patients with AE by SOC and PT (cut-off: >=10% of patients)
Safety Analysis Set
by Subpopulation A2

System Organ Class Preferred Term	A2 (N=173) n (%)
Dry skin	24 (13.9)
Infections and infestations	94 (54.3)
Urinary tract infection	26 (15.0)
Respiratory, thoracic and mediastinal disorders	86 (49.7)
Dyspnoea	29 (16.8)
Cough	19 (11.0)
Metabolism and nutrition disorders	83 (48.0)
Decreased appetite	24 (13.9)
Hypomagnesaemia	22 (12.7)
Hypoalbuminaemia	19 (11.0)
Hyponatraemia	18 (10.4)
Nervous system disorders	79 (45.7)
Headache	39 (22.5)
Dizziness	23 (13.3)
Blood and lymphatic system disorders	76 (43.9)
Thrombocytopenia	35 (20.2)
Leukopenia	27 (15.6)
Anaemia	22 (12.7)
Neutropenia	22 (12.7)
Lymphopenia	20 (11.6)
Musculoskeletal and connective tissue disorders	74 (42.8)
Arthralgia	18 (10.4)
Vascular disorders	66 (38.2)

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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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.51_sf.rtf

Table 14.4.2.51
Proportions of patients with AE by SOC and PT (cut-off: >=10% of patients)
Safety Analysis Set
by Subpopulation A2

System Organ Class Preferred Term	A2 (N=173) n (%)
Hypertension	55 (31.8)
Renal and urinary disorders	41 (23.7)
Eye disorders	39 (22.5)
Injury, poisoning and procedural complications	32 (18.5)
Psychiatric disorders	31 (17.9)
Cardiac disorders	26 (15.0)
Endocrine disorders	21 (12.1)

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.
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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/T14.4.2.51_sf.rtf

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Table 14.4.2.56
Proportions of patients with Severe AE (CTCAE grade>=3) by SOC and PT (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation A1

System Organ Class Preferred Term	A1 (N=85) n (%)
Patients with TEAEs	54 (63.5)
Investigations	20 (23.5)
Alanine aminotransferase increased	15 (17.6)
Aspartate aminotransferase increased	11 (12.9)
Vascular disorders	18 (21.2)
Hypertension	16 (18.8)
Infections and infestations	11 (12.9)
Respiratory, thoracic and mediastinal disorders	11 (12.9)
Pleural effusion	5 (5.9)
Blood and lymphatic system disorders	10 (11.8)
Thrombocytopenia	5 (5.9)
Metabolism and nutrition disorders	8 (9.4)
Hyponatraemia	5 (5.9)
Gastrointestinal disorders	7 (8.2)

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 14.4.2.57
Proportions of patients with Severe AE (CTCAE grade>=3) by SOC and PT (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation A2

System Organ Class Preferred Term	A2 (N=173) n (%)
Patients with TEAEs	113 (65.3)
Investigations	43 (24.9)
Alanine aminotransferase increased	19 (11.0)
Aspartate aminotransferase increased	17 (9.8)
Electrocardiogram QT prolonged	12 (6.9)
Blood and lymphatic system disorders	32 (18.5)
Lymphopenia	11 (6.4)
Anaemia	9 (5.2)
Vascular disorders	31 (17.9)
Hypertension	30 (17.3)
Metabolism and nutrition disorders	25 (14.5)
Hyponatraemia	9 (5.2)
Infections and infestations	22 (12.7)
Gastrointestinal disorders	18 (10.4)
Respiratory, thoracic and mediastinal disorders	14 (8.1)
Nervous system disorders	12 (6.9)
General disorders and administration site conditions	10 (5.8)

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/tfl/t_aesocpt_en.sas
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Table 14.4.2.62
Proportions of patients with Serious AE by SOC and PT (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation A1

System Organ Class Preferred Term	A1 (N=85) n (%)
Patients with TEAEs	32 (37.6)
Respiratory, thoracic and mediastinal disorders	9 (10.6)
Infections and infestations	7 (8.2)
Investigations	5 (5.9)
Nervous system disorders	5 (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 (version21.0).
Adverse events are sorted in descending frequency.
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aesocpt_en.sas
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Table 14.4.2.63
Proportions of patients with Serious AE by SOC and PT (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation A2

System Organ Class Preferred Term	A2 (N=173) n (%)
Patients with TEAEs	77 (44.5)
Infections and infestations	22 (12.7)
Pneumonia	10 (5.8)
Nervous system disorders	15 (8.7)
Gastrointestinal disorders	13 (7.5)
General disorders and administration site conditions	13 (7.5)
Respiratory, thoracic and mediastinal disorders	13 (7.5)
Metabolism and nutrition disorders	9 (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.
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aesocpt_en.sas
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Table 14.4.2.68
Proportions of patients with AE by SOC and PT (cut-off: >=10 patients and >=1% of patients)
Safety Analysis Set
by Subpopulation A1

System Organ Class Preferred Term	A1 (N=85) n (%)
Patients with TEAEs	85 (100)
Gastrointestinal disorders	73 (85.9)
Dry mouth	42 (49.4)
Diarrhoea	39 (45.9)
Nausea	19 (22.4)
Abdominal pain	17 (20.0)
Constipation	16 (18.8)
Vomiting	15 (17.6)
Stomatitis	12 (14.1)
General disorders and administration site conditions	64 (75.3)
Fatigue	29 (34.1)
Oedema peripheral	24 (28.2)
Pyrexia	24 (28.2)
Face oedema	12 (14.1)
Investigations	64 (75.3)
Aspartate aminotransferase increased	40 (47.1)
Alanine aminotransferase increased	38 (44.7)
Blood creatinine increased	21 (24.7)
Blood alkaline phosphatase increased	13 (15.3)
Electrocardiogram QT prolonged	13 (15.3)
Respiratory, thoracic and mediastinal disorders	54 (63.5)
Cough	15 (17.6)

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/tfl/t_aesocpt_en.sas
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.68_sf.rtf

Table 14.4.2.68
Proportions of patients with AE by SOC and PT (cut-off: >=10 patients and >=1% of patients)
Safety Analysis Set
by Subpopulation A1

System Organ Class Preferred Term	A1 (N=85) n (%)
Dyspnoea	14 (16.5)
Pleural effusion	12 (14.1)
Skin and subcutaneous tissue disorders	53 (62.4)
Rash	20 (23.5)
Rash maculo-papular	12 (14.1)
Musculoskeletal and connective tissue disorders	52 (61.2)
Back pain	15 (17.6)
Arthralgia	10 (11.8)
Infections and infestations	47 (55.3)
Urinary tract infection	14 (16.5)
Nervous system disorders	44 (51.8)
Headache	18 (21.2)
Metabolism and nutrition disorders	42 (49.4)
Decreased appetite	16 (18.8)
Hypomagnesaemia	10 (11.8)
Vascular disorders	37 (43.5)
Hypertension	30 (35.3)
Blood and lymphatic system disorders	33 (38.8)
Thrombocytopenia	17 (20.0)
Neutropenia	12 (14.1)
Leukopenia	10 (11.8)
Psychiatric disorders	24 (28.2)
Insomnia	11 (12.9)

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 (version21.0).
Adverse events are sorted in descending frequency.
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aesocpt_en.sas
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.68_sf.rtf

Table 14.4.2.68
Proportions of patients with AE by SOC and PT (cut-off: >=10 patients and >=1% of patients)
Safety Analysis Set
by Subpopulation A1

System Organ Class Preferred Term	A1 (N=85) n (%)
Renal and urinary disorders	19 (22.4)
Injury, poisoning and procedural complications	14 (16.5)
Eye disorders	13 (15.3)
Cardiac disorders	11 (12.9)
Endocrine disorders	10 (11.8)
Immune system disorders	10 (11.8)

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/tfl/t_aesocpt_en.sas
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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) 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)
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.
Reported adverse event terms were coded using MedDRA (version21.0).
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.74_sf.rtf

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) n (%)	A2 (N=173) n (%)	B (N=153) n (%)	C (N=21) 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)

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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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.74_sf.rtf

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) n (%)	A2 (N=173) n (%)	B (N=153) n (%)	C (N=21) 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)

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).
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aesocpt_tdisc_en.sas
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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 14.4.2.7
Proportions of patients with AE by PT (cut-off: >=10% of patients)
Safety Analysis Set
by Subpopulation A1

Preferred Term	A1 (N=85) n (%)
Patients with TEAEs	85 (100)
Dry mouth	42 (49.4)
Aspartate aminotransferase increased	40 (47.1)
Diarrhoea	39 (45.9)
Alanine aminotransferase increased	38 (44.7)
Hypertension	30 (35.3)
Fatigue	29 (34.1)
Oedema peripheral	24 (28.2)
Pyrexia	24 (28.2)
Blood creatinine increased	21 (24.7)
Rash	20 (23.5)
Nausea	19 (22.4)
Headache	18 (21.2)
Abdominal pain	17 (20.0)
Thrombocytopenia	17 (20.0)
Constipation	16 (18.8)
Decreased appetite	16 (18.8)
Back pain	15 (17.6)
Cough	15 (17.6)
Vomiting	15 (17.6)
Dyspnoea	14 (16.5)
Urinary tract infection	14 (16.5)

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 (version21.0).
Adverse events are sorted in descending frequency.
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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.7_sf.rtf

Table 14.4.2.7
Proportions of patients with AE by PT (cut-off: >=10% of patients)
Safety Analysis Set
by Subpopulation A1

Preferred Term	A1 (N=85) n (%)
Blood alkaline phosphatase increased	13 (15.3)
Electrocardiogram QT prolonged	13 (15.3)
Face oedema	12 (14.1)
Neutropenia	12 (14.1)
Pleural effusion	12 (14.1)
Rash maculo-papular	12 (14.1)
Stomatitis	12 (14.1)
Insomnia	11 (12.9)
Arthralgia	10 (11.8)
Hypomagnesaemia	10 (11.8)
Leukopenia	10 (11.8)
Anaemia	9 (10.6)
Peripheral sensory neuropathy	9 (10.6)

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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Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T14.4.2.7_sf.rtf

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Table 14.4.2.8
Proportions of patients with AE by PT (cut-off: >=10% of patients)
Safety Analysis Set
by Subpopulation A2

Preferred Term	A2 (N=173) n (%)
Patients with TEAEs	173 (100)
Diarrhoea	78 (45.1)
Dry mouth	67 (38.7)
Alanine aminotransferase increased	63 (36.4)
Aspartate aminotransferase increased	59 (34.1)
Hypertension	55 (31.8)
Oedema peripheral	49 (28.3)
Fatigue	43 (24.9)
Constipation	39 (22.5)
Headache	39 (22.5)
Nausea	37 (21.4)
Thrombocytopenia	35 (20.2)
Electrocardiogram QT prolonged	34 (19.7)
Pyrexia	34 (19.7)
Rash	32 (18.5)
Dyspnoea	29 (16.8)
Blood creatinine increased	28 (16.2)
Leukopenia	27 (15.6)
Urinary tract infection	26 (15.0)
Vomiting	25 (14.5)
Decreased appetite	24 (13.9)
Dry skin	24 (13.9)

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 (version21.0).
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/T14.4.2.8_sf.rtf

Table 14.4.2.8
Proportions of patients with AE by PT (cut-off: >=10% of patients)
Safety Analysis Set
by Subpopulation A2

Preferred Term	A2 (N=173) n (%)
Dizziness	23 (13.3)
Anaemia	22 (12.7)
Hypomagnesaemia	22 (12.7)
Neutropenia	22 (12.7)
Abdominal pain	21 (12.1)
Blood bilirubin increased	21 (12.1)
Blood alkaline phosphatase increased	20 (11.6)
Lymphopenia	20 (11.6)
Cough	19 (11.0)
Face oedema	19 (11.0)
Hypoalbuminaemia	19 (11.0)
Arthralgia	18 (10.4)
Hyponatraemia	18 (10.4)

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/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/T14.4.2.8_sf.rtf

Tabelle 007.10: Ergebnisse für den Endpunkt Gesamtüberleben aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set - nach Vorherige systemische Therapie: Nur PD1

Endpunkt	**Selpercatinib** **Subpopulation A1 – NSCLC 2L (N=9)**
Gesamtüberleben	
Überlebensstatus[a], n (%)	
Tot	3 (33,3)
Lebend	6 (66,7)
Medianes Gesamtüberleben (Monate) [95%-KI][b,c]	28,88 [2,3; NE]
Überlebensrate (≥ 12 Monate), % [95%-KI][b,d]	77,8 [36,5; 93,9]
Mediane Beobachtungsdauer (Monate)[b]	17,1

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_os_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/T007_10_os_nsclc_eff.rtf

Tabelle 007.11: Ergebnisse für den Endpunkt Gesamtüberleben aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set - nach Vorherige systemische Therapie: PD1+PLT

Endpunkt	**Selpercatinib** **Subpopulation A1 – NSCLC 2L (N=23)**
Gesamtüberleben	
Überlebensstatus[a], n (%)	
Tot	3 (13,0)
Lebend	20 (87,0)
Medianes Gesamtüberleben (Monate) [95%-KI][b,c]	NE [NE; NE]
Überlebensrate (≥ 12 Monate), % [95%-KI][b,d]	84,8 [58,9; 95,0]
Mediane Beobachtungsdauer (Monate)[b]	12,4

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_os_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/T007_11_os_nsclc_eff.rtf

Tabelle 007.12: Ergebnisse für den Endpunkt Gesamtüberleben aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set - nach Vorherige systemische Therapie: Chemotherapie

Endpunkt	**Selpercatinib** **Subpopulation A1 – NSCLC 2L (N=34)**
Gesamtüberleben	
Überlebensstatus[a], n (%)	
Tot	6 (17,6)
Lebend	28 (82,4)
Medianes Gesamtüberleben (Monate) [95%-KI][b,c]	NE [16,6; NE]
Überlebensrate (≥ 12 Monate), % [95%-KI][b,d]	90,4 [72,7; 96,8]
Mediane Beobachtungsdauer (Monate)[b]	14,2

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_os_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/T007_12_os_nsclc_eff.rtf

Tabelle 007.13: Ergebnisse für den Endpunkt Gesamtüberleben aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set - nach Vorherige systemische Therapie: Andere

Endpunkt	**Selpercatinib** **Subpopulation A1 – NSCLC 2L (N=12)**
Gesamtüberleben	
Überlebensstatus[a], n (%)	
Tot	1 (8,3)
Lebend	11 (91,7)
Medianes Gesamtüberleben (Monate) [95%-KI][b,c]	NE [NE; NE]
Überlebensrate (≥ 12 Monate), % [95%-KI][b,d]	91,7 [53,9; 98,8]
Mediane Beobachtungsdauer (Monate)[b]	8,7

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_os_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/T007_13_os_nsclc_eff.rtf

Tabelle 008.10: Ergebnisse für den Endpunkt progressionsfreies Überleben aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set - nach Vorherige systemische Therapie: Nur PD1

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=9)
Progressionsfreies Überleben	
Progressionsstatus[a,c], n (%)	
Progression	1 (11,1)
Tod (ohne vorherigen Progress)	2 (22,2)
Zensiert	6 (66,7)
Grund für Zensierung, n (%)	
Am Leben ohne Progress[b]	4 (44,4)
Anschl. Krebstherapie oder krebsbedingte Operation ohne Progress[b]	2 (22,2)
Abbruch der Studie ohne Progress[b]	0 (0,0)
Medianes progressionsfreies Überleben (Monate) [95%-KI][d,e]	NE [2,3; NE]
Dauer des progressionsfreien Überlebens nach Kategorie, n (%)	
< 6 Monate	4 (44,4)
≥ 6 bis < 12 Monate	2 (22,2)
≥ 12 bis < 18 Monate	3 (33,3)
≥ 18 bis < 24 Monate	0 (0,0)
≥ 24 Monate	0 (0,0)
Progressionsfreie Überlebensrate[d,f], % [95%-KI]	
≥ 6 Monate	77,8 [36,5; 93,9]
≥ 12 Monate	77,8 [36,5; 93,9]
Mediane Beobachtungsdauer (Monate)[d]	11,5

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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.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_10_pfs_nsclc_eff.rtf

Tabelle 008.11: Ergebnisse für den Endpunkt progressionsfreies Überleben aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set - nach Vorherige systemische Therapie: PD1+PLT

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=23)
Progressionsfreies Überleben	
Progressionsstatus[a,c], n (%)	
Progression	5 (21,7)
Tod (ohne vorherigen Progress)	2 (8,7)
Zensiert	16 (69,6)
Grund für Zensierung, n (%)	
Am Leben ohne Progress[b]	13 (56,5)
Anschl. Krebstherapie oder krebsbedingte Operation ohne Progress[b]	0 (0,0)
Abbruch der Studie ohne Progress[b]	3 (13,0)
Medianes progressionsfreies Überleben (Monate) [95%-KI][d,e]	NE [9,0; NE]
Dauer des progressionsfreien Überlebens nach Kategorie, n (%)	
< 6 Monate	7 (30,4)
≥ 6 bis < 12 Monate	11 (47,8)
≥ 12 bis < 18 Monate	4 (17,4)
≥ 18 bis < 24 Monate	1 (4,3)
≥ 24 Monate	0 (0,0)
Progressionsfreie Überlebensrate[d,f], % [95%-KI]	
≥ 6 Monate	85,8 [62,1; 95,2]
≥ 12 Monate	57,9 [29,2; 78,4]
Mediane Beobachtungsdauer (Monate)[d]	10,8

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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.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_11_pfs_nsclc_eff.rtf

Tabelle 008.12: Ergebnisse für den Endpunkt progressionsfreies Überleben aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set - nach Vorherige systemische Therapie: Chemotherapie

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=34)
Progressionsfreies Überleben	
Progressionsstatus[a,c], n (%)	
Progression	11 (32,4)
Tod (ohne vorherigen Progress)	0 (0,0)
Zensiert	23 (67,6)
Grund für Zensierung, n (%)	
Am Leben ohne Progress[b]	22 (64,7)
Anschl. Krebstherapie oder krebsbedingte Operation ohne Progress[b]	1 (2,9)
Abbruch der Studie ohne Progress[b]	0 (0,0)
Medianes progressionsfreies Überleben (Monate) [95%-KI][d,e]	19,32 [13,6; NE]
Dauer des progressionsfreien Überlebens nach Kategorie, n (%)	
< 6 Monate	4 (11,8)
≥ 6 bis < 12 Monate	18 (52,9)
≥ 12 bis < 18 Monate	8 (23,5)
≥ 18 bis < 24 Monate	3 (8,8)
≥ 24 Monate	1 (2,9)
Progressionsfreie Überlebensrate[d,f], % [95%-KI]	
≥ 6 Monate	88,2 [71,6; 95,4]
≥ 12 Monate	75,0 [56,0; 86,7]
Mediane Beobachtungsdauer (Monate)[d]	11,3

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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.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_12_pfs_nsclc_eff.rtf

Tabelle 008.13: Ergebnisse für den Endpunkt progressionsfreies Überleben aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set - nach Vorherige systemische Therapie: Andere

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=12)
Progressionsfreies Überleben	
Progressionsstatus[a,c], n (%)	
Progression	3 (25,0)
Tod (ohne vorherigen Progress)	0 (0,0)
Zensiert	9 (75,0)
Grund für Zensierung, n (%)	
Am Leben ohne Progress[b]	8 (66,7)
Anschl. Krebstherapie oder krebsbedingte Operation ohne Progress[b]	1 (8,3)
Abbruch der Studie ohne Progress[b]	0 (0,0)
Medianes progressionsfreies Überleben (Monate) [95%-KI][d,e]	NE [3,3; NE]
Dauer des progressionsfreien Überlebens nach Kategorie, n (%)	
< 6 Monate	5 (41,7)
≥ 6 bis < 12 Monate	6 (50,0)
≥ 12 bis < 18 Monate	0 (0,0)
≥ 18 bis < 24 Monate	1 (8,3)
≥ 24 Monate	0 (0,0)
Progressionsfreie Überlebensrate[d,f], % [95%-KI]	
≥ 6 Monate	72,7 [37,1; 90,3]
≥ 12 Monate	72,7 [37,1; 90,3]
Mediane Beobachtungsdauer (Monate)[d]	7,4

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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.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_13_pfs_nsclc_eff.rtf

Tabelle 012.10: Ergebnisse für den Endpunkt Zeit bis zum Ansprechen aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set - nach Vorherige systemische Therapie: Nur PD1

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=9)
Objektive Ansprechrate (CR+PR), n (%)	
Objektive Ansprechrate [95%-KI][a,b]	6 (66,7) [29,9; 92,5]

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; CR: komplettes Ansprechen; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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 Ansprechrate (%) ist definiert als der Anteil an Patienten mit bestätigtem kompletten 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.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_10_orr_nsclc_eff.rtf

Tabelle 012.11: Ergebnisse für den Endpunkt Zeit bis zum Ansprechen aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set - nach Vorherige systemische Therapie: PD1+PLT

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=23)
Objektive Ansprechrate (CR+PR), n (%)	
Objektive Ansprechrate [95%-KI][a,b]	16 (69,6) [47,1; 86,8]

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; CR: komplettes Ansprechen; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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 Ansprechrate (%) ist definiert als der Anteil an Patienten mit bestätigtem kompletten 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.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_11_orr_nsclc_eff.rtf

Tabelle 012.12: Ergebnisse für den Endpunkt Zeit bis zum Ansprechen aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Efficacy Analysis Set - nach Vorherige systemische Therapie: Chemotherapie

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=34)
Objektive Ansprechrate (CR+PR), n (%)	
Objektive Ansprechrate [95%-KI][a,b]	21 (61,8) [43,6; 77,8]

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; CR: komplettes Ansprechen; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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 Ansprechrate (%) ist definiert als der Anteil an Patienten mit bestätigtem kompletten 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.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_12_orr_nsclc_eff.rtf

Tabelle 012.13: Ergebnisse für den Endpunkt Zeit bis zum Ansprechen aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 16. Dezember 2019) - Efficacy Analysis Set - nach Vorherige systemische Therapie: Andere

Endpunkt	Selpercatinib Subpopulation A1 – NSCLC 2L (N=12)
Objektive Ansprechrate (CR+PR), n (%)	
Objektive Ansprechrate [95%-KI][a,b]	3 (25,0) [5,5; 57,2]

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; CR: komplettes Ansprechen; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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 Ansprechrate (%) ist definiert als der Anteil an Patienten mit bestätigtem kompletten 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.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_13_orr_nsclc_eff.rtf

Tabelle 020.10: Ergebnisse für den Endpunkt jegliche unerwünschte Ereignisse aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Safety Population - nach Vorherige systemische Therapie: Nur PD1

Endpunkt	Selpercatinib Subpopulation A1 - NSCLC 2L (N=10)
Jegliche unerwünschte Ereignisse, n (%)	
Jegliche unerwünschte Ereignisse	
Jeglicher Schweregrad	10 (100)
CTCAE-Grad < 3	3 (30,0)
CTCAE-Grad ≥ 3	7 (70,0)
CTCAE-Grad 3	6 (60,0)
CTCAE-Grad 4	1 (10,0)
CTCAE-Grad 5	0
Therapiebezogene [a] unerwünschte Ereignisse	10 (100)
Therapiebezogene [a] unerwünschte Ereignisse vom CTCAE-Grad ≥ 3	7 (70,0)
Schwerwiegende unerwünschte Ereignisse	7 (70,0)
Therapiebezogene [a] schwerwiegende unerwünschte Ereignisse	2 (20,0)
Behandlungsabbruch aufgrund unerwünschter Ereignisse	0

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; CTCAE: Common Terminology Criteria for Adverse Events; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Safety Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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_ge_a1.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/T020_10_sp_anyae_sf.rtf

Tabelle 020.11: Ergebnisse für den Endpunkt jegliche unerwünschte Ereignisse aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Safety Population - nach Vorherige systemische Therapie: PD1+PLT

Endpunkt	Selpercatinib Subpopulation A1 - NSCLC 2L (N=28)
Jegliche unerwünschte Ereignisse, n (%)	
Jegliche unerwünschte Ereignisse	
Jeglicher Schweregrad	28 (100)
CTCAE-Grad < 3	6 (21,4)
CTCAE-Grad ≥ 3	22 (78,6)
CTCAE-Grad 3	16 (57,1)
CTCAE-Grad 4	5 (17,9)
CTCAE-Grad 5	1 (3,6)
Therapiebezogene [a] unerwünschte Ereignisse	25 (89,3)
Therapiebezogene [a] unerwünschte Ereignisse vom CTCAE-Grad ≥ 3	19 (67,9)
Schwerwiegende unerwünschte Ereignisse	15 (53,6)
Therapiebezogene [a] schwerwiegende unerwünschte Ereignisse	6 (21,4)
Behandlungsabbruch aufgrund unerwünschter Ereignisse	4 (14,3)

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; CTCAE: Common Terminology Criteria for Adverse Events; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Safety Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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_ge_a1.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/T020_11_sp_anyae_sf.rtf

Tabelle 020.12: Ergebnisse für den Endpunkt jegliche unerwünschte Ereignisse aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Safety Population - nach Vorherige systemische Therapie: Chemotherapie

Endpunkt	Selpercatinib Subpopulation A1 - NSCLC 2L (N=34)
Jegliche unerwünschte Ereignisse, n (%)	
Jegliche unerwünschte Ereignisse	
Jeglicher Schweregrad	34 (100)
CTCAE-Grad < 3	16 (47,1)
CTCAE-Grad ≥ 3	18 (52,9)
CTCAE-Grad 3	15 (44,1)
CTCAE-Grad 4	3 (8,8)
CTCAE-Grad 5	0
Therapiebezogene [a] unerwünschte Ereignisse	33 (97,1)
Therapiebezogene [a] unerwünschte Ereignisse vom CTCAE-Grad ≥ 3	12 (35,3)
Schwerwiegende unerwünschte Ereignisse	7 (20,6)
Therapiebezogene [a] schwerwiegende unerwünschte Ereignisse	3 (8,8)
Behandlungsabbruch aufgrund unerwünschter Ereignisse	2 (5,9)

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; CTCAE: Common Terminology Criteria for Adverse Events; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Safety Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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_ge_a1.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/T020_12_sp_anyae_sf.rtf

Tabelle 020.13: Ergebnisse für den Endpunkt jegliche unerwünschte Ereignisse aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: NSCLC mit RET-Fusion; Datenschnitt: 30. März 2020) - Safety Population - nach Vorherige systemische Therapie: Andere

Endpunkt	Selpercatinib Subpopulation A1 - NSCLC 2L (N=13)
Jegliche unerwünschte Ereignisse, n (%)	
Jegliche unerwünschte Ereignisse	
Jeglicher Schweregrad	13 (100)
CTCAE-Grad < 3	6 (46,2)
CTCAE-Grad ≥ 3	7 (53,8)
CTCAE-Grad 3	5 (38,5)
CTCAE-Grad 4	1 (7,7)
CTCAE-Grad 5	1 (7,7)
Therapiebezogene [a] unerwünschte Ereignisse	13 (100)
Therapiebezogene [a] unerwünschte Ereignisse vom CTCAE-Grad ≥ 3	7 (53,8)
Schwerwiegende unerwünschte Ereignisse	3 (23,1)
Therapiebezogene [a] schwerwiegende unerwünschte Ereignisse	0
Behandlungsabbruch aufgrund unerwünschter Ereignisse	0

1L: Erstlinie; 2L: Zweitlinie; 3L: Drittlinie; CTCAE: Common Terminology Criteria for Adverse Events; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Safety Analysis Set); NSCLC: nicht-kleinzelliges Lungenkarzinom; 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_ge_a1.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/T020_13_sp_anyae_sf.rtf